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Dear Teffany,

This is another request for interactive review of your submission. Please address the following concern:

(b)(4)

Please respond by COB Friday, July 29, to facilitate timely review of your device.

Regards,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
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Section 9 Declarations of Conformity

9.1 Declaration of Conformity to Recognized Standards

Recognized Consensus Standards Declaration of Conformity

CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH/VHR AND VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 AND CYF TYPE V2R complies with recognized consensus standards for medical electrical endoscopic equipment, medical endoscopes, and endotherapy devices (see **Table 9-1**). The verification reports are included in **Section 17 – Electrical Safety and Electromagnetic Compatibility** and **Section 18 – Performance Testing – Bench**. The labeling information is included in **Section 14 – Proposed Labeling**.

Table 9-1: Declaration of Conformity to FDA Recognized Consensus Standards.

Recognition Number	Number	Title	Date of Recognition
9-114	IEC 60601-2-18: Edition 3.0 2009-08	Medical Electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	06-07-2018
9-130	ISO 8600-6 Second edition 2020-09	Endoscopes – Medical endoscopes and endotherapy devices – Part 6: Vocabulary	12-21-2020

For the voluntary standards listed in **Table 9-1**, Olympus certifies that the results from the requisite testing performed meet specified acceptance criteria and CYF-VH/VHR AND CYF-V2/V2R conform to applicable and relevant portions of each respective standard.

Sterilization Declaration of Conformity

CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH/VHR AND VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 AND CYF TYPE V2R complies with recognized consensus standards for sterilization (see **Table 9-2**). The sterilization, reprocessing validation reports are detailed in **Section 14 – Sterilization and Shelf Life**.

Table 9-2: Sterilization Declaration of Conformity to FDA Recognized Consensus Standards.

Recognition Number	Number	Title	Date of Recognition
14-529	ANSI AAMI ISO 11135: 2014	Sterilization of health care products – Ethylene Oxide – requirements for development, validation and routine control of a sterilization process for medical devices	07-15-2019
2-191	ANSI AAMI ISO 10993-12: 2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	07-26-2016

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Recognition Number	Number	Title	Date of Recognition
2-237	ISO 10993-17 First edition 2002-12-01	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances	07-26-2016
2-276	ISO 10993-18 Second edition 2020-01	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process	07-06-2020
2-275	ISO 10993-7 Second edition 2008-10-15	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)]	07-06-2020

For the voluntary standards listed in **Table 9-2**, Olympus certifies that the results from the requisite testing performed meet specified acceptance criteria and CYF-VH/VHR AND CYF-V2/V2R conform to applicable and relevant portions of each respective standard.

Biocompatibility Declaration of Conformity

CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH/VHR AND VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 AND CYF TYPE V2R complies with recognized consensus standards for biocompatibility (see **Table 9-3**). The biocompatibility reports are detailed in **Section 15 – Biocompatibility**.

Table 9-3: Biocompatibility Declaration of Conformity to FDA Recognized Consensus Standards.

Recognition Number	Number	Title	Date of Recognition
2-191	ANSI AAMI ISO 10993-12: 2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	07-26-2016
2-174	ISO 10993-10 Third edition 2010-08-01	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	07-26-2016
2-245	ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	12-23-2016
2-258	ISO 10993-1: 2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	01-14-2019
2-222	ISO 10993-2 Second edition 2006-07-15	Biological evaluation of medical devices – Part 2: Animal welfare requirements	07-26-2016

For the voluntary standards listed in **Table 9-3**, Olympus certifies that the results from the requisite testing performed meet specified acceptance criteria and CYF-VH/VHR AND CYF-V2/V2R conform to applicable and relevant portions of each respective standard.

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Electrical Safety and Electromagnetic Compatibility (EMC) Declaration of Conformity

CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH/VHR AND VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 AND CYF TYPE V2R complies with recognized consensus standards for electrical safety and electromagnetic compatibility (see **Table 9-4**). The electrical safety and essential performance reports are detailed in **Section 17 – Electrical Safety and Electromagnetic Compatibility**.

Table 9-4: Electrical Safety & EMC Declaration of Conformity to FDA Recognized Consensus Standards.

Recognition Number	Number	Title	Date of Recognition
19-4	ANSI AAMI ES 60601-1:2005 /(R)2012L and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	07-09-2014
19-8	ANSI AAMI IEC 60601-1-2:2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests	09-17-2018
9-114	IEC 60601-2-18: Edition 3.0 2009-08	Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	06-07-2018
5-89	IEC 60601-1-6 Edition 3.1 2013-10	Medical electrical equipment – Part 6: General requirements for basic safety and essential performance – Collateral standard: Usability	06-27-2016

For the voluntary standards listed **Table 9-4**, Olympus certifies that the results from the requisite testing performed meet specified acceptance criteria and CYF-VH/VHR AND CYF-V2/V2R conform to applicable and relevant portions of each respective standard.

Photobiological Safety Declaration of Conformity

CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH/VHR AND VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 AND CYF TYPE V2R complies with recognized consensus standards for photobiological safety and international standards for photography noise measurement (see **Table 9-5**). The noise and dynamic range and photobiological safety performance reports are detailed in **Section 18 – Performance Testing - Bench**.

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Table 9-5: Photobiological Safety Declaration of Conformity to FDA Recognized Consensus Standards.

Recognition Number	Number	Title	Date of Recognition
12-249	IEC 62471 First edition 2006-07	Photobiological safety of lamps and lamp systems	08-20-2012
Not Recognized	ISO 15739: 2017	Photography – Electronic still-picture imaging – Noise measurements	Not Applicable

For the voluntary standards listed in **Table 9-5**, Olympus certifies that the results from the requisite testing performed meet specified acceptance criteria and CYF-VH/VHR AND CYF-V2/V2R conform to applicable and relevant portions of each respective standard.

Risk Management Declaration of Conformity

CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH/VHR AND VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 AND CYF TYPE V2R complies with recognized consensus standards for Risk Management (see **Table 9-6**). The risk management reports are detailed in **Section 21 – Risk Management**.

Table 9-6: Risk Management Declaration of Conformity to FDA Recognized Consensus Standards.

Recognition Number	Number	Title	Date of Recognition
5-40	ANSI AAMI ISO 14971:2007	Medical Devices – Application of risk management to medical devices	06-27-2016

For the voluntary standards listed in **Table 9-6**, Olympus certifies that the results from the requisite testing performed meet specified acceptance criteria and CYF-VH/VHR AND CYF-V2/V2R conform to applicable and relevant portions of each respective standard.

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DATE	22 April 2022
AUTHOR	(b)(4)
SUBJECT	CYF-V2 Testing Root Cause analysis and Conclusion

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Low Level Positive Extraction Efficiency Validation for CYF-5, MAJ-2092, and MAJ-1413 GLP Report

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Cleaning Validation for CYF-VH (FlexClean) GLP Report

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U.S. FOOD & DRUG ADMINISTRATION

January 20, 2023

Olympus Medical Systems Corporation
% Teffany Hutto
Regulatory Affairs Consultant
Olympus Corporation of the Americas
3500 Corporate Parkway
P.O. Box 610
Center Valley, PA 18034

Re: K221683
Trade/Device Name: VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE V2R
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH, CYF-VHR
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: December 22, 2022
Received: December 22, 2022

Dear Teffany Hutto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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GLP PROTOCOL

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

ISO Acute Systemic Toxicity Study in Mice

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MAJOR DEFICIENCY

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EMC Testing of the

Olympus Medical Systems Corp.
CYF- VH
In accordance with AIM 7351731:2021

(b)(4)

Prepared for: Olympus Medical Systems Corp.
2951 Ishikawa-cho, Hachioji-shi
Tokyo, Japan 192-8507

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OLYMPUS

REPROCESSING MANUAL

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-V2
OLYMPUS CYF-V2R

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Accessories:

- ETO cap (MB-156)
- Single use combination cleaning brush (BW-411B)
- Sterilization tray (WA05991A*1, sold separately)

*1 This product may not be available in some areas.

MB-156

WA05991A

BW-411B

Refer to the endoscope's companion manual, the "OPERATION MANUAL" with your endoscope model listed on the cover, for operation information.

USA: CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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Chapter 1 General Policy

1.1 Instructions

- This manual contains the reprocessing methods recommended by Olympus for the endoscopes and accessories listed on the front cover.
- This instruction manual contains essential information on reprocessing endoscopes and accessories safely and effectively.
- Before reprocessing, thoroughly review this manual and the manuals of the reprocessing equipment and chemicals that will be used for reprocessing. Reprocess all the devices as instructed.
- Note that the complete instruction manual set for the endoscope and accessories consists of this manual and the "OPERATION MANUAL" with your endoscope model listed on the cover. Both manuals accompanied the endoscope at shipment.
- Keep this manual and all related manuals in a safe and accessible location (e.g., in the reprocessing area).
- If you have any questions or comments about any information in this manual, or if a problem that cannot be solved occurs while reprocessing, contact Olympus.

❍ Terms used in this manual

AER/WD:

AER and WD are abbreviations for Automated Endoscope Reprocessor and Washer-Disinfector, which are used for reprocessing the endoscopes and accessories.

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1.2 Importance of reprocessing

The medical literature reports incidents of cross-contamination resulting from improper reprocessing. It is strongly recommended that all individuals engaged in reprocessing closely observe all instructions given in this manual and the manuals of all ancillary equipment, and have a thorough understanding of the following items:

- Professional health and safety policies of your hospital
- Instruction manuals for the endoscope, accessories, and all the other reprocessing equipment
- Structure and handling of the endoscope and accessories
- Handling of pertinent chemicals

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization according to Section 4.3, “Workflow for manually cleaning and sterilizing endoscopes and accessories”.

1.3 Signal words

The following signal words are used throughout this manual:

WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.
NOTE	Indicates additional helpful information.

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1.4 Precautions

WARNING

- An insufficiently reprocessed endoscope and/or accessory may pose an infection control risk to the patients and/or operators who contact them.
- The endoscope reprocessor, video system center, light source, and/or front panels of equipment may cause an infection control risk. Perform proper cleaning and disinfection as described in their respective instruction manuals. A tap or basin that medical personnel come in contact with may cause an infection control risk as well. Perform proper replacement, cleaning, and disinfection.
- All disinfection methods (whether performed manually or by an AER/WD) and all sterilization methods (whether performed by ethylene oxide gas, hydrogen peroxide or steam) require thorough prior cleaning of the instruments being reprocessed. If the instruments are not adequately cleaned prior to disinfection/sterilization, these processes will be ineffective. Immediately after each patient procedure and before disinfection/sterilization, thoroughly clean the endoscope and the accessories used with the endoscope.
- The channel of the endoscope and all accessories used with the endoscope during the patient procedure must be cleaned and disinfected/sterilized after each patient procedure, even if the channel or accessories were not used during the patient procedure. Insufficient cleaning and disinfection/sterilization of these components may pose an infection control risk to patients and/or operators.
- Residual disinfectant solution and detergent solution may cause adverse reactions in patients. Therefore, rinse all external surfaces and the channel of the endoscope and accessories thoroughly with water to remove residual disinfectant solution and detergent solution after cleaning and disinfection.
- The results of sterilization depend on various factors. These factors include how the equipment was packaged and the placing and loading of the package in the sterilization device. Verify the sterilization process using biological and/or chemical indicators. Follow the guidelines for sterilization issued by national authorities, professional organizations and infection control professionals, including the frequency of the above verification, as well as the instruction manual for the sterilization device.
- Establish an internal system of identifying contaminated versus reprocessed endoscopes and accessories to prevent both mix-ups and cross-contamination. Some national or professional guidelines recommend separating dirty (contaminated) area, clean area, and storage area. Touching a reprocessed endoscope and/or accessories with contaminated gloves or placing them on a contaminated hanger or surface, including letting them touch the floor, will recontaminate them.

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WARNING

- Prior to each patient procedure, confirm that the endoscope and accessories have been properly reprocessed and stored. If there are any doubts or questions, reprocess them again before the patient procedure, following the instructions given in this manual.
- Perform a leakage test on the endoscope after each precleaning procedure. Do not use the endoscope if a leak is detected. Use of an endoscope with a leak may cause a sudden loss of the endoscopic image, damage to the bending mechanism, or other malfunctions. Use of a leaking endoscope may also pose an infection control risk.

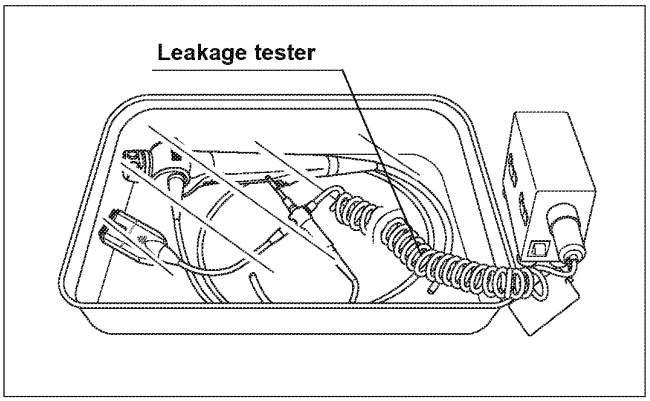

Figure 1.1

- Store alcohol in an airtight container. Alcohol stored in an open container may cause a fire hazard and may result in a loss of efficacy due to evaporation.
- The accessories listed on the front cover of this manual cannot be refurbished or repaired and are intended to be replaced once they show any signs of wear and tear. Should any irregularity be observed, use a replacement accessory instead. Using defective accessories may cause equipment malfunction, reduce the efficacy of reprocessing, present a risk to patients and/or operators, or damage the endoscope and/or accessories.
- Single-use brush, such as the single use combination cleaning brush (BW-411B) is designed for cleaning only one endoscope and its related accessories. Dispose of the single-use brush immediately after use. Using a single-use brush to clean multiple endoscopes and/or accessories may reduce its cleaning efficacy and may damage the brush leading to brush breakage or the endoscope and/or accessory damage.
- Patient debris and used reprocessing chemicals pose infection control risks. To guard against contact with dangerous chemicals and potentially infectious material, wear appropriate personal protective equipment during reprocessing. Such protective equipment should include appropriate eyewear, face mask, cap, moisture-resistant clothing, shoe covers, and chemical-resistant gloves that fit properly and are long enough to prevent skin exposure.

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WARNING

- The reprocessing room must be adequately ventilated to minimize the risks from chemical vapors.
- Always remove contaminated personal protective equipment before leaving the reprocessing area to prevent contamination from spreading.
- Only Olympus-recommended or Olympus-endorsed AERs/WDs have been validated by Olympus. When using an AER/WD that is not recommended by Olympus, the manufacturer of the AER/WD is responsible for validating compatibility of the AER/WD with each Olympus endoscope and accessory.
- Before using an AER/WD, confirm that it is capable of reprocessing the endoscope including the channel and accessories. Be sure to attach all required connectors/adaptors. Otherwise, insufficient reprocessing may pose an infection control risk. If you are uncertain as to the ability of your AER/WD to reprocess the endoscope including the channel and accessories, contact the manufacturer of the AER/WD for specific instructions and information on compatibility and required connectors/adaptors.
- The instructions provided in this manual are not valid for Olympus devices repaired by a non-Olympus facility. The Olympus recommended reprocessing procedures have not been validated for reprocessing devices repaired by a non-Olympus facility. In the event that your device has been repaired by a non-Olympus facility, please contact the repair facility for instructions regarding reprocessing.
- Prions, which are the pathogenic agents of the Creutzfeldt-Jakob disease (CJD) cannot be destroyed or inactivated by the reprocessing methods stated in this instruction manual. When using the endoscope and accessories on patients with CJD or variant Creutzfeldt-Jakob disease (vCJD), be sure to use them for such patients only, or immediately dispose of them after use in an appropriate manner to prevent the usage of exposed devices on other patients. For methods to handle CJD, please follow the respective guidelines in your country.
- The endoscope and accessories may be damaged by published methods for destroying or inactivating prions. For information on the durability of Olympus equipment against a particular reprocessing method, please contact Olympus. In general, Olympus cannot guarantee the effectiveness, safety, and durability of reprocessing methods not described in this reprocessing manual. If you choose to use a reprocessing method not recommended in this manual, the local institution and/or physicians must assume responsibility for its safety and efficacy. Make sure to carefully inspect each piece of endoscopic equipment for irregularities (damage) prior to each patient procedure. Do not use the equipment if any irregularity is observed.
- Good quality control practices typically require appropriate documentation. Items such as local SOPs (Standard Operating Procedures), confirmation of operator training, routine testing of the disinfectant's MEC (Minimal Effective Concentration), confirmation of the disinfectant's use-life, etc. should be documented as performed.

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WARNING

- In case of performing any microbial test or other test using extraction fluid on the reprocessed endoscope, the reprocessing process has to be performed again according to the “REPROCESSING MANUAL” before patient procedure.

CAUTION

- Before immersing the endoscope in reprocessing fluids, confirm that the ETO cap (MB-156) is not attached to the endoscope. If the ETO cap is attached, the reprocessing fluids will be able to penetrate the inside of the endoscope, and it can be damaged.
- When aerating or irrigating the endoscope channel, the air or water pressure must not exceed 0.3 MPa (3 kgf/cm^2, 43 psig). Higher pressures may cause damage to the endoscope.
- Store spare accessories in their original packaging to prevent damage.
- To prevent damage, do not apply excessive force to the endoscope and accessories during reprocessing.
- Vapors from disinfectant solution and alcohol may damage electronic devices such as computers. Properly manage the quality and durability of the devices used in reprocessing rooms and the ventilation performance of the rooms.

1.5 Reprocessing before the first use

New endoscopes, repaired endoscopes, accessories, and the carrying case for endoscopes are not reprocessed prior to shipping from Olympus, regardless of whether those instruments are for new purchase, demo or loaner purposes. Reprocess all such endoscopes and accessories received from Olympus according to the instructions given in this manual before storage and before using them in a patient procedure.

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization according to Section 4.3, “Workflow for manually cleaning and sterilizing endoscopes and accessories”.

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1.6 Reprocessing and storage after use

WARNING

- Do not reuse detergent solution.
- Do not reuse rinse water.
- Disinfectant and detergent solutions are only effective when used according to the disinfectant and detergent manufacturer's instructions. Follow the manufacturer's instructions regarding activation (if required), concentration, temperature, contact time and use life required to achieve successful cleaning and disinfection.
- If the disinfectant solution is reused, check its efficacy by proper methods, such as using a test strip, according to the disinfectant manufacturer's recommendations prior to use.
- Do not reuse alcohol.
- Alcohol is not a sterilant or high-level disinfectant.
- To maintain sterility of equipment following sterilization, use sterile packaging and wraps according to national guidelines.
- Store the endoscope and accessories in a proper storage cabinet, following the policies at your institution, applicable national laws and standards, and professional society guidelines and recommended practices.
- Improper storage practices, such as not thoroughly drying external and internal surfaces (lumens) prior to storage, will lead to an infection control risk.

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Ch.1

1.7 Reprocessing before patient procedure

WARNING

- Improper handling, such as touching a reprocessed endoscope and/or accessories with contaminated gloves, placing a reprocessed device on a contaminated hanger or surface, allowing devices to touch the floor, etc. will recontaminate the device.
- For nephroscopy procedures, cystoscope should be cleaned followed by sterilization according to Section 4.3, “Workflow for manually cleaning and sterilizing endoscopes and accessories”.

NOTE

Some national or professional guidelines recommend reprocessing endoscopes prior to their first use of the day, when the certain time passes after disinfecting/sterilizing, or in case the storage time recommended by the national authorities is exceeded.

Confirm that the endoscope and accessories have undergone proper reprocessing following their last use and that they have been stored properly. Check the storage period of reprocessed endoscopes, and check for surface contamination (e.g., dust). Check the expiration date marked on all items and check for tears or breaches in the sterile packaging. If there are any doubts or questions concerning whether a device is contaminated, reprocess it again following the instructions given in this manual.

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Chapter 2 Function and Inspection of the Accessories for Reprocessing

Certain accessories are required for reprocessing the endoscope. This chapter describes the function of these accessories. It also describes how to inspect these accessories before using them to reprocess the endoscope.

2.1 ETO cap (MB-156)

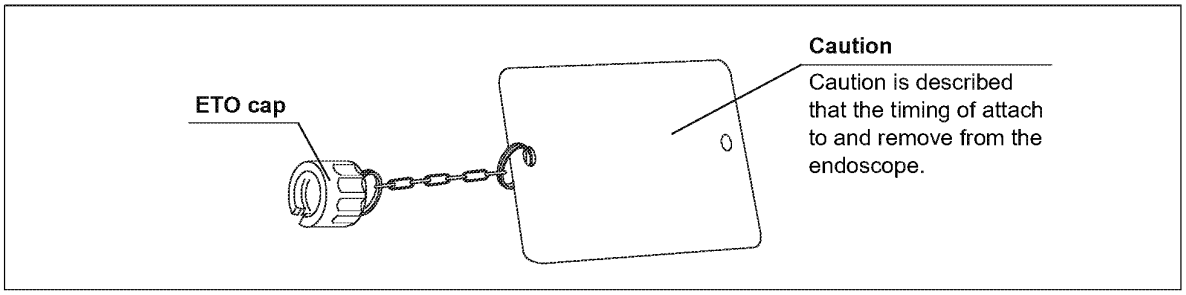

Figure 2.1

CAUTION

A miss attaching/removing may cause a breakage of the endoscope.

Function

When performing gas sterilization (e.g., ethylene oxide gas sterilization, hydrogen peroxide low temperature plasma), the ETO cap must be attached to the venting connector on the light guide connector.

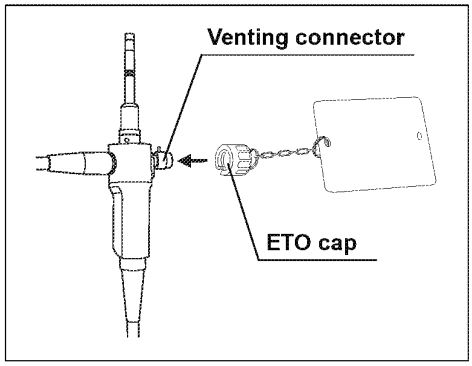

Figure 2.2

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Inspection

Confirm that the ETO cap is free from scratches, flaws, and debris.

2.2 Sterilization tray (WA05991A, sold separately)

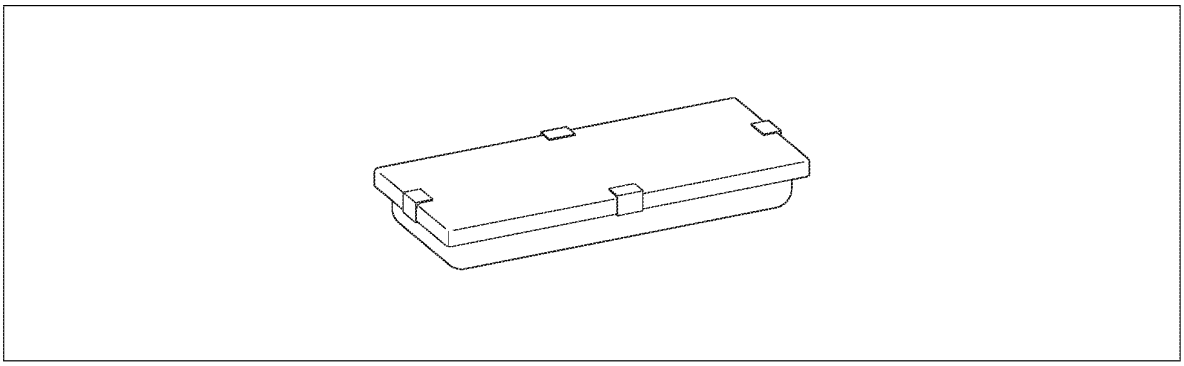

Figure 2.3

Function

This sterilization tray is used to transport and sterilize the endoscope and accessories.

Inspection

Check every part of the sterilization tray for damage.

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2.3 Single use combination cleaning brush (BW-411B)

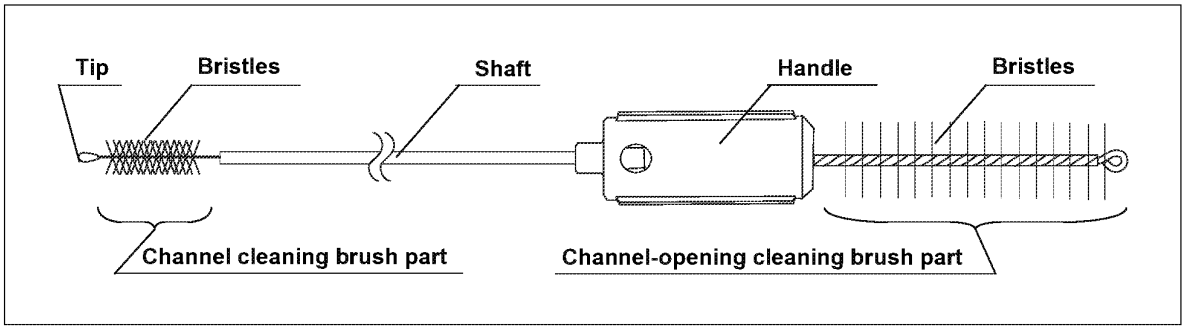

Figure 2.4

Function

The channel cleaning brush part of the single use combination cleaning brush is used to brush the instrument channel of the endoscope.

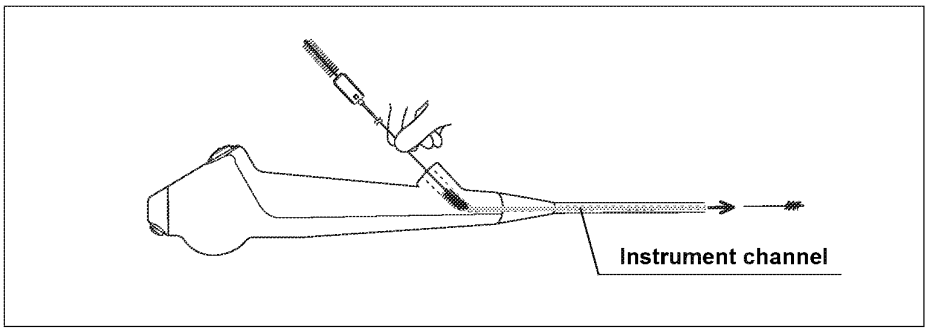

Figure 2.5

The channel-opening cleaning brush part of the single use combination cleaning brush is used to brush the instrument channel port of the endoscope.

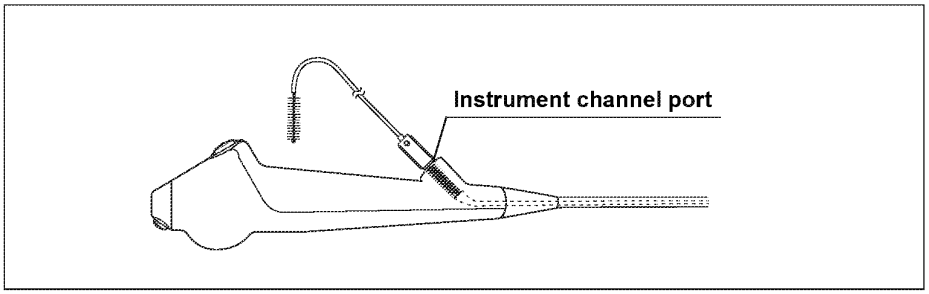

Figure 2.6

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Inspection

CAUTION

Do not reprocess the single use channel cleaning brush prior to use. The brush may be damaged.

1. Remove the brush from its packaging just prior to use.
2. Confirm that the channel cleaning brush part and tip at the distal end are securely attached.
3. Check the channel cleaning brush and channel-opening cleaning brush parts for loose or missing bristles.
4. Check the bristles of the channel cleaning brush and the channel-opening cleaning brush parts for any damage.
5. If the bristles are crushed, gently straighten them with your gloved fingertips.
6. Check for bends, scratches, and other damage to the shaft.

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Chapter 3 Compatible Reprocessing Methods and Chemical Agents

3.1 Compatibility summary

The endoscope and accessories are compatible with several methods of reprocessing. However, not all reprocessing methods are compatible with all endoscopes and all accessories. Reprocessing with incompatible methods can cause equipment damage even if the number of reprocessing cycles is small. For appropriate reprocessing methods, see Table 3.1.
Follow the policies at your local institution when choosing which methods listed in Table 3.1 to employ.

CAUTION

- The methods listed as “compatible” in Table 3.1 are compatible for routine use only when used according to manufacturer’s instructions. Repeated use and reprocessing of endoscopes and accessories leads to gradual wear and tear. Furthermore, reprocessing methods that employ higher temperatures and more caustic/corrosive materials may lead to faster deterioration. In general, sterilization processes are harsher on equipment than disinfection processes. Before each patient procedure, inspect the endoscope and accessories for damage, according to the instructions described in this manual and its companion “OPERATION MANUAL”.
- The instructions provided in this manual regarding compatible reprocessing methods and chemical agents are not valid for Olympus devices repaired by a non-Olympus facility. Olympus repairs devices to manufacturer’s specifications using original equipment manufacturer’s (OEM) materials. The use of non-OEM materials to repair an Olympus device may affect the material compatibility and reprocessing efficacy of the device with certain reprocessing chemicals or methods. In the event that your device has been repaired by a non-Olympus facility, please contact the repair facility for instructions regarding compatible reprocessing methods and chemical agents.

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3.2 List of the compatible methods

Reprocessing methods listed in Table 3.1 have been validated with this endoscope and accessories. For details on the chemicals and devices that can be used, refer to Section 3.4 and subsequent sections.

			Endoscope	ETO cap (MB-156)
Ultrasonic cleaning			*1	
Manual cleaning	Detergent solution			
Disinfection	2 – 3.5% glutaraldehyde			
	ACECIDE disinfectant solution*2			
Drying	Alcohol			
Sterilization	Hydrogen peroxide	V-PRO® maX (Flexibile cycle)		*6, *7
		STERRAD® NX® (Advanced cycle)*3		*6
		STERRAD® 100S (Long cycle)*4	*5	*6, *7
		STERRAD® 100NX® (Duo cycle)		*7
	Steam (autoclaving)			
	Ethylene oxide gas			*6
	Low Temperature steam and formaldehyde (LTSF)			

compatible not compatible

Table 3.1 List of compatible methods

*1 The endoscope is only compatible with ultrasonic cleaning as performed in an Olympus-recommended endoscope reprocessor, such as OER-AW, OER-Pro, OER-Mini, and OER-Elite(OER-AW is available in some areas other than the USA. OER-Mini is only available in the USA. OER-Pro and OER-Elite are available in the USA and some areas.). When using an AER/WD that is recommended by Olympus other than listed above, please contact Olympus.

*2 ACECIDE disinfectant solution is exclusively for an Olympus recommended endoscope reprocessor, such as OER-AW, OER-Pro, OER-Mini, and OER-Elite (ACECIDE is available in the USA and some areas).

*3 Olympus products can be processed with or without ALLClear· Technology. For further details, contact ASP.

*4 For countries other than the USA.

*5 Attaching a booster is necessary. Refer to Section 3.9, “Hydrogen peroxide sterilization”.

*6 If sterilized alone, use appropriate packaging that is legally marketed in the USA and sterilize under the appropriate parameters following the policies at your facility.

*7 The accessory alone is not compatible with STERRAD® 100NX® (DUO cycle). This product can be used to sterilize when combined with the endoscope which is compatible with the sterilization shown on the left.

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3.3 Water (for reprocessing)

Water is used for leakage testing and manual cleaning of the endoscope and accessories. For these purposes, use either fresh, potable water or water that has been processed (e.g., filtered, deionized or purified) to improve its chemical and/or microbiological quality. Consult with your hospital's infection control committee.

When rinsing the endoscope and accessories following disinfection, use the water as described in Section 3.6, "Rinse water".

3.4 Detergent solution

WARNING

- Excessive foaming prevents detergent solution from properly contacting the surfaces and channel walls of the endoscope and accessories, and may impair effective cleaning.
- Do not reuse detergent solution.

Use a medical-grade, low-foaming, neutral pH detergent that is labeled for use on medical device, which may or may not contain enzymes. Follow the instructions provided by the detergent manufacturer regarding concentration, temperature, contact time, and expiration date. Contact Olympus for the names of specific brands of detergent solution that have been tested for compatibility with endoscopes and accessories.

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3.5 Disinfectant solution

Use a disinfectant cleared/approved by your national regulatory agency for use in reprocessing flexible endoscopes. If national or professional guidelines applicable to your institution define “high-level disinfection” and require using a high-level disinfectant for the flexible endoscopes, follow the requirement. Follow the disinfectant manufacturer's instructions regarding activation (if required), concentration, temperature, contact time, and expiration date.

For further information regarding the compatibility of glutaraldehyde-based or non glutaraldehyde-based disinfectant solution, contact Olympus.

WARNING

- As per Advanced Sterilization Products® Safety Alert, dated January 3, 2005, entitled “Labeling Change to Cidex® OPA Solution Instructions for Use” – “In rare instances Cidex OPA Solution has been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies. Therefore, ASP is contraindicating the use of Cidex OPA Solution for the reprocessing of any urological instruments to be used on patients with a history of bladder cancer.”.
- If the disinfectant solution is reused, check its efficacy by proper methods, such as using a test strip, according to the disinfectant manufacturer's recommendations prior to use.
- For nephroscopy procedures, cystoscope should be cleaned followed by sterilization. Refer to Section 3.8, “Ethylene oxide gas sterilization”, and Section 3.9, “Hydrogen peroxide sterilization”.
- For cystoscopy procedures, cystoscopes should be cleaned followed by either high-level disinfection or sterilization.

NOTE

Sterilization can be selected for the endoscope as a preferable reprocessing method instead of high-level disinfection if sterilization is recommended based on decision by medical professionals.

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3.6 Rinse water

CAUTION

Do not reuse rinse water.

Rinsing after disinfection

Olympus recommends using sterile water, fresh potable water or water that has been processed (e.g., filtered, deionized, or purified) to improve its chemical and/or microbiological quality. Some national or professional guideline recommend using sterile water for rinsing endoscopes, accessories, and medical instruments. Consult with your institution's infection control committee regarding local policies on water quality.

3.7 Alcohol

WARNING

- Do not reuse alcohol.
- Alcohol is not a sterilant or high-level disinfectant.

Use medical-grade 70% ethyl or 70% isopropyl alcohol.

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3.8 Ethylene oxide gas sterilization

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization.

CAUTION

- When performing ethylene oxide gas sterilization, the ETO cap (MB-156) must be attached to the venting connector.

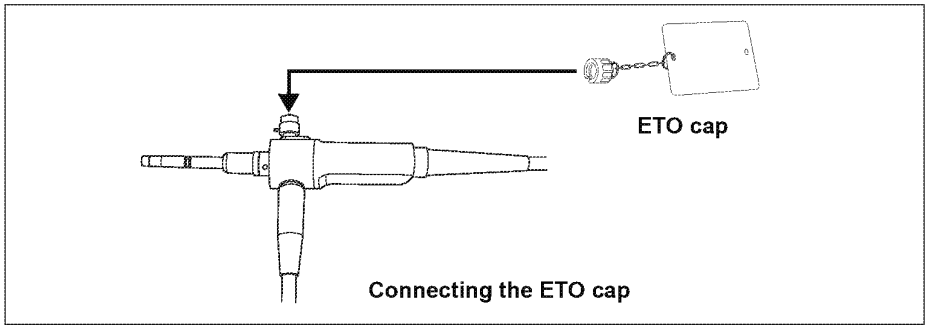

Figure 3.1

- Exceeding the recommended parameters may cause equipment damage.

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Parameters for 100% ethylene oxide gas sterilization cycles, for the USA and some countries

The endoscope and accessories listed as compatible with ethylene oxide gas sterilization in Table 3.1 can be sterilized by 3M™ Steri-Vac™ 5XL or STERIS Amsco® Eagle® 3017 ethylene oxide gas sterilizers with the "55°C cycle" given in Table 3.2, and aerated with 12 hours or more at 55°C (130°F). When performing ethylene oxide gas sterilization, follow all national, professional, and institutional reprocessing protocols as well as the instructions provided by the manufacturer of your sterilization equipment.

Process phase	Parameter	Value
Sterilization	**Temperature**	55°C (130°F)
	Relative humidity	50 – 80%
	Ethylene oxide gas concentration	0.735 – 0.740 mg/cm^3 (735 – 740 mg/L)
	Exposure time	60 minutes
Aeration	**Minimum aeration parameters**	12 hours in an aeration chamber at 55°C (130°F)

Table 3.2

Parameters for 20% ethylene oxide gas/80% CO_2 gas sterilization cycles for countries other than the USA

The endoscope and accessories listed as compatible with ethylene oxide gas sterilization in Table 3.1 can be sterilized by ethylene oxide gas and aerated within the parameters given in Table 3.3. When performing ethylene oxide gas sterilization, follow all national, professional, and institutional reprocessing protocols as well as the instructions provided by the manufacturer of your sterilization equipment.

Process phase	Parameter	Value
Sterilization	**Temperature**	55°C (130°F)
	Relative pressure	0.1 – 0.17 MPa
	Relative humidity	35 – 85%
	Ethylene oxide gas concentration	0.6 – 0.7 mg/cm^3 (600 – 700 mg/L)
	Exposure time	2 – 4 hours
Aeration	**Minimum aeration parameters**	12 hours in an aeration chamber at 50 – 57°C (122 – 135°F) or 7 days at room temperature

Table 3.3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.9 Hydrogen peroxide sterilization

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization.

❍ STERRAD® 100S*/NX®

* For countries other than the USA.

WARNING

When sterilizing a flexible endoscope that has an instrument channel with the STERRAD® 100S Sterilization System, depending on the inner diameter/length of channel and the model of sterilizer, it is necessary to attach the booster (REF15400) that is provided by ASP (Advanced Sterilization Products) to the endoscope. Do not attach the booster to the distal end of the insertion section. For further details, refer to the ASP instruction manual or contact ASP directly.

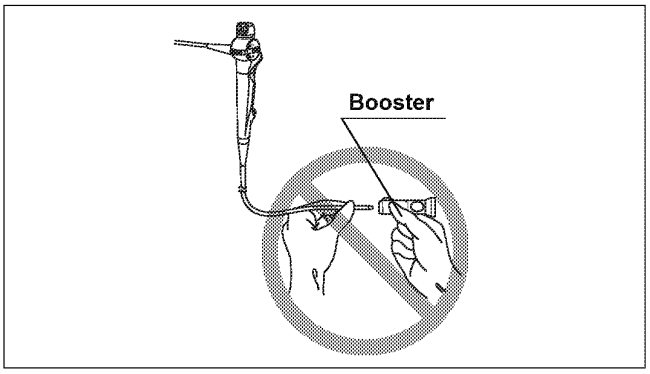

Figure 3.2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CAUTION

- When performing STERRAD® 100S/NX® (with/without ALL Clear Technology) sterilization, the ETO cap (MB-156) must be attached to the venting connector in order to avoid rupture of the bending section.

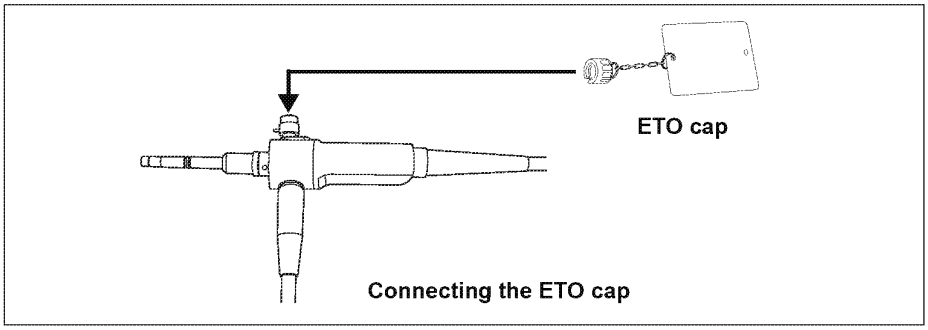

Figure 3.3

- Do not use cycles not listed Table 3.1. If used, severe damage may be caused or efficacy of sterilization may not be achieved.

NOTE

Use sterilization wraps and packaging compliant with ISO 11607-1: 2006+A1, ISO 11607-2: 2006+A1.

As for the sterilizer, contact ASP. Also, refer to the "STERRAD® 100S/NX® (with/without ALL Clear Technology) instruction manual.

3.10 Signs of degradation from reprocessing and its number of times

When reprocessed devices with chemicals, AER and sterilizer as described above, you will eventually start to see signs of deterioration.

CAUTION

Improper reprocessing shown below may significantly reduce the life time of a medical device.

- Reprocessing without observing the instructions of the manufacturer
- Application of multiple sterilization methods
- Immersion in a chemical for an excessive amount of time

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Endoscope

- Cleaning, disinfection, and sterilization may cause the following degradations. If any of these signs of degradation happens, contact Olympus.
  - Pitted, cracked, peeled or discolored adhesives at either end of the bending section shown as Figure 3.4.
  - Abnormal bulges or swelling, scratches and holes in the bending section
  - Swelling or peeling of the insertion tube
- Olympus has verified no degradation when the listed number of sterilization cycle is performed. If this endoscope has been sterilized the following times (see below), the degradation shown in Figure 3.4 may occur. If such degradation happens, maintenance is required. For more details, contact Olympus.

STERRAD 100S/NX	100 times
Ethylene oxide gas	60 times

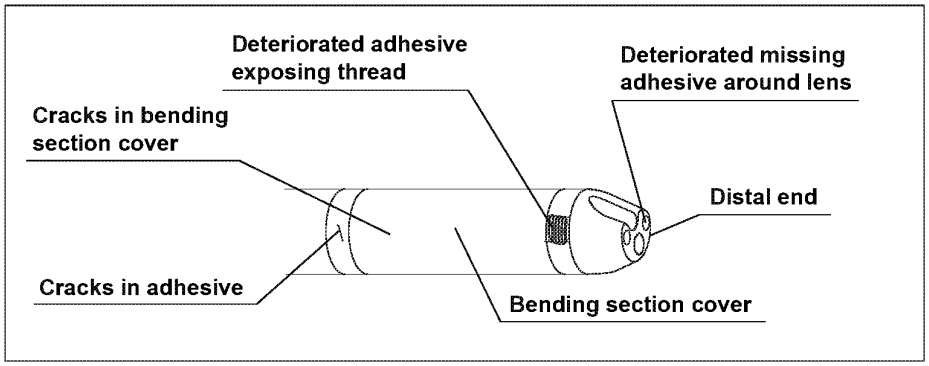

Figure 3.4

Accessory (MB-156)

Cleaning, disinfection, and sterilization may cause the above accessories to be pitted, cracked and discoloration. If any of these signs of degradation happens, discard and replace this accessory.

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Chapter 4 Reprocessing Workflow for Endoscopes and Accessories

4.1 Summary of reprocessing workflow

This chapter describes the workflow for reprocessing the endoscope and accessories.

WARNING

Deviation from the recommended workflow may pose an infection control risk.

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4.2 Workflow for manually cleaning and manually or automated disinfecting endoscopes and accessories

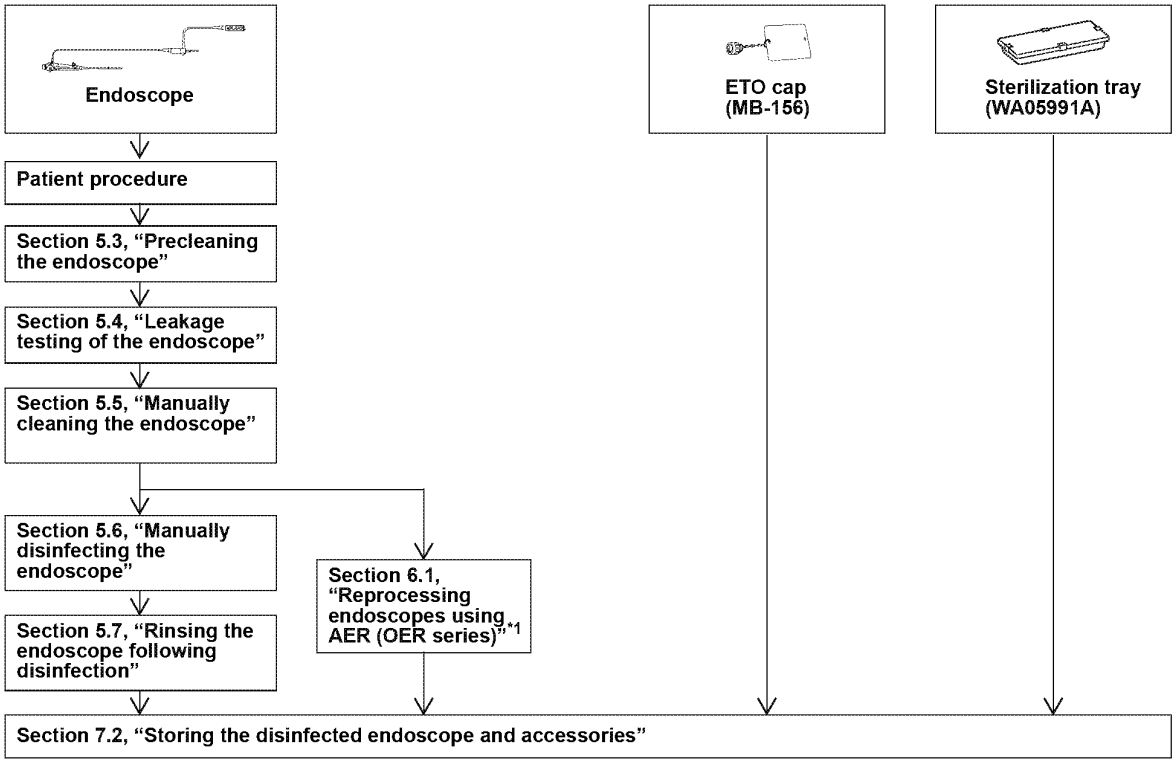
The endoscope and accessories used for cystoscopy should be reprocessed according to the workflow in this section.

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization. Refer to Section 4.3, “Workflow for manually cleaning and sterilizing endoscopes and accessories”.

NOTE

- Automated disinfection means disinfection using OER series.
- Sterilization can be selected for the endoscope as a preferable reprocessing method instead of high-level disinfection if sterilization is recommended based on decision by medical professionals.



*1 Depending upon the model of the OER series, you may be able to simplify Section 5.3, “Precleaning the endoscope” and Section 5.5, “Manually cleaning the endoscope”. Refer to the instruction manual for the OER series you have.

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4.3 Workflow for manually cleaning and sterilizing endoscopes and accessories

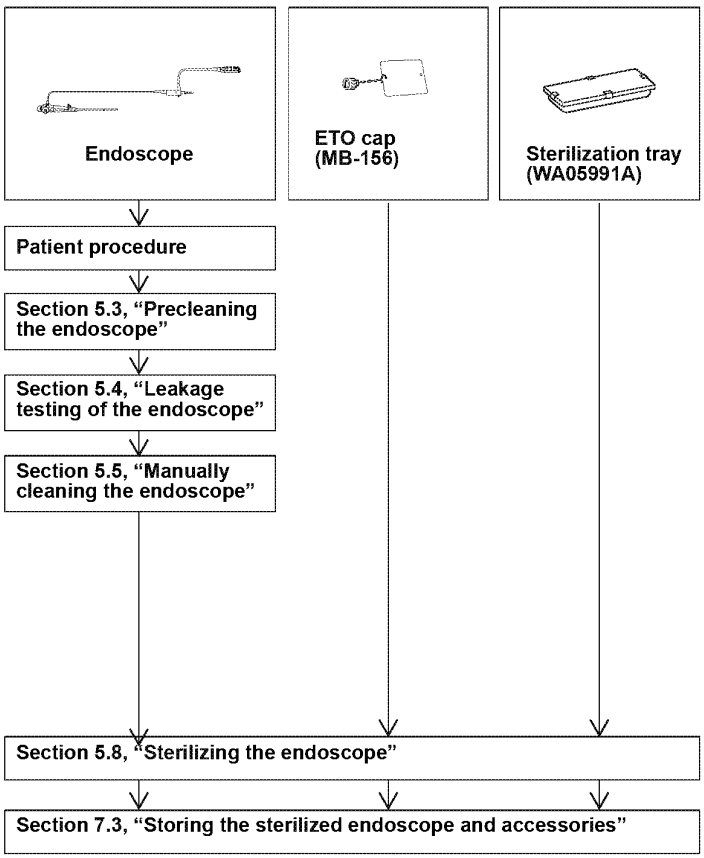
The endoscope and accessories used for nephroscopy should be reprocessed according to the workflow in this section.

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization according to Section 4.3, "Workflow for manually cleaning and sterilizing endoscopes and accessories".

NOTE

- If required by your facility's local policy, manually or automated disinfection may be performed between manual cleaning and sterilization.
- Automated disinfection means disinfection using OER series.



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4.3 Workflow for manually cleaning and sterilizing endoscopes and accessories

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Chapter 5 Reprocessing the Endoscope

5.1 Summary of reprocessing the endoscope

Certain accessories are required to manually reprocess the endoscope. The steps for reprocessing the endoscope are explained in this chapter.

The reprocessing workflow of all accessories is outlined in Chapter 4, “Reprocessing Workflow for Endoscopes and Accessories”.

CAUTION

- The insertion section of the endoscope is composed of the insertion tube, the bending section, and the distal end. The bending section is covered by a thin, easily damaged elastic covering. Do not allow reprocessing equipment to forcefully contact the bending section. Do not allow any sharp edges, such as the distal ends of EndoTherapy accessories (needles, forceps, snares, etc. used in the instrument channel of the endoscope) to contact the bending section. Such improper handling may damage the covering and cause the endoscope to leak.

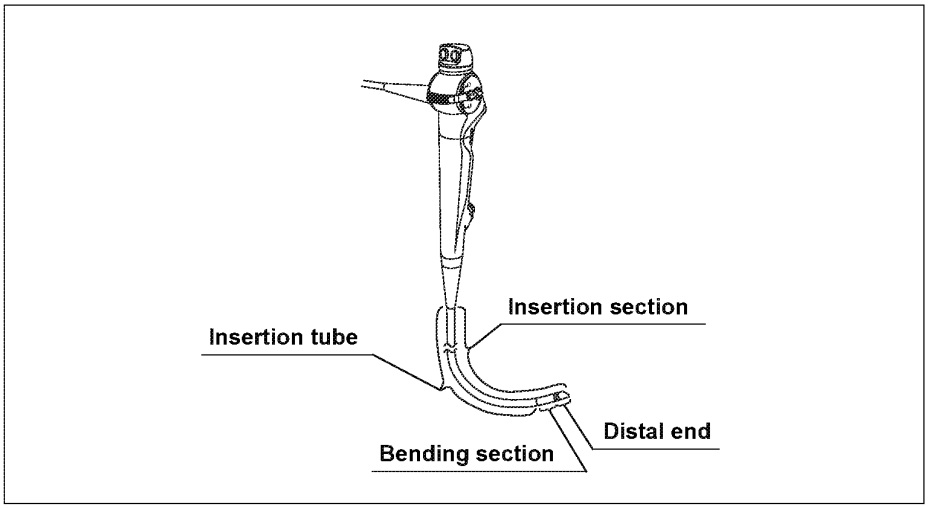

Figure 5.1

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CAUTION

- Handle the insertion section carefully. Tightly gripping or sharply bending the insertion tube or the bending section can stretch or severely damage the insertion tube and/or the covering of the bending section.
- To prevent damage to the endoscope, do not immerse the endoscope with objects other than the equipment used for reprocessing the endoscope.
- To prevent damage, do not coil the insertion tube or the universal cord of the endoscope with a diameter less than 10 cm.

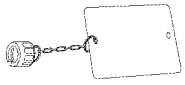
5.2 Preparing the equipment for reprocessing

Equipment needed

The following equipment is prepared to perform the reprocessing steps described in this chapter.

Accessories for reprocessing

Single use combination cleaning brush (BW-411B)



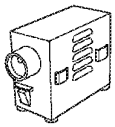
ETO cap (MB-156)

Sterilization tray (WA05991A) (Sold separately. See its instruction manual.)

Accessories and equipment for leakage test

Leakage tester (MB-155) (Sold separately. Refer to its instruction manual.)

+



Maintenance unit (MU-1) (Sold separately. Refer to its instruction manual.)

or

Leakage tester (WA23080A) (Sold separately. Refer to its instruction manual.)

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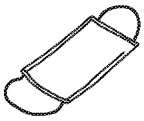
Personal protective equipment (e.g.)

Eyewear



Face mask

Moisture-resistant clothing

Chemical-resistant gloves*1

Other

- Clean lint-free cloths*2
- Clean sponges
- Clean 30 ml (30 cc) syringes
- Clean 500 ml containers
- Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)
- Sterile, large basins*3 (size: 40 (W) × 40 (H) × 25 (D) cm or more)
- Sterilization wraps*4
- Water (for reprocessing) (Refer to Section 3.3, "Water (for reprocessing)")
- Disinfectant solution (Refer to Section 3.5, "Disinfectant solution")
- 70% ethyl or 70% isopropyl alcohol (Refer to Section 3.7, "Alcohol")
- Sterile lint-free cloths*2, *3
- Sterile cotton swabs*3
- Sterile 30 ml (30 cc) syringes*3
- Small basins
- Clean, large basins with tight-fitting lids (size: 40 (W) × 40 (H) × 25 (D) cm or more)
- Sterilization pouches*4
- Instrument tray*4
- Detergent solution (Refer to Section 3.4, "Detergent solution")
- Rinse water (Refer to Section 3.6, "Rinse water")

*1 Gloves are recommended to be long enough so that your skin is not exposed.

*2 All cloths used in reprocessing are recommended to be lint-free. Lint or cloth fibers shed into reprocessing fluids may be injected into the endoscope channel. There is the potential for lint or cloth fibers to lodge in channel. If gauze is used to reprocess the endoscope, ensure that fibers do not get caught on or remain trapped by protruding components.

*3 Following disinfection, it is very important not to recontaminate the endoscope and accessories with potentially infectious microorganisms. When rinsing and drying the endoscope and accessories following disinfection, the use of sterile equipment (basins, cloths, syringes, etc.) is recommended. If sterile equipment is not available, use clean equipment that does not recontaminate the endoscope and accessories with potentially infectious microorganisms. Consult with your hospital's infection control committee regarding local policies or requirements regarding reprocessing equipment.

*4 For the USA
Use sterilization wraps, instrument tray, and sterilization pouches that are legally marketed in the USA.

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5.3 Precleaning the endoscope

WARNING

If the endoscope and accessories used in the patient procedure are not immediately cleaned after each patient procedure, residual organic debris will begin to dry and solidify, hindering effective removal and reprocessing efficacy. Preclean the endoscope and the accessories at the bedside immediately after each patient procedure.

NOTE

Some national or professional guidelines recommend using a detergent solution for precleaning. Consult with your hospital's infection control committee regarding use of the detergent solution.

Equipment needed

Prepare the following equipment.

• **Clean lint-free cloths**	• **Clean sponges**
• **Clean 30 ml (30 cc) syringes**	• **Water (for reprocessing) (See Section 3.3, "Water (for reprocessing)")**
• **Clean 500 ml containers**	• **Small basins**

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Preparation

Immediately after the patient procedure, with the endoscope still connected to the equipment used in the patient procedure (i.e., the light source, video system center), perform the following precleaning steps at the patient bed side.

1. Turn the video system center and the light source OFF.
2. Prepare a clean 500 ml container of the water as described in Section 3.3, “Water (for reprocessing)”.

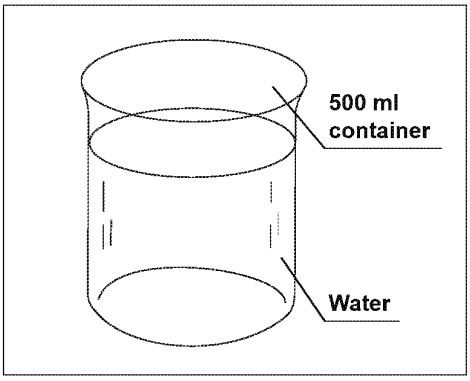

Figure 5.2

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■ *Wipe the insertion section*

CAUTION

Handle the insertion section carefully. Tightly gripping or sharply bending the insertion tube or bending section can stretch or severely damage the insertion tube and the covering of the bending section.

NOTE

If it is difficult to clean the endoscope while connecting it to the equipment, such as the light source and video system center, disconnect the endoscope from the equipment before wiping the external surface of the insertion section. For disconnecting the endoscope, refer to "■ Detach the endoscope from the video system center" and "■ Detach the endoscope from the light source" on page 34.

1. Dip clean lint-free cloths or sponges in the water.
2. With the lint-free cloths or sponges, wipe the entire insertion section of the endoscope from the boot at the control section toward the distal end.

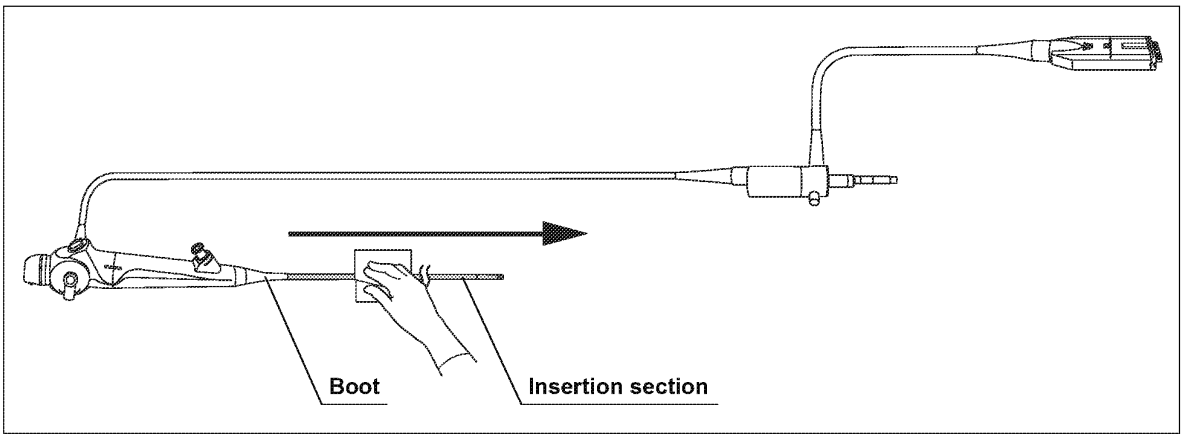

Figure 5.3

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Flush the instrument channel with water

1 Loosen the locking ring, detach a forceps/irrigation plug from the endoscope.

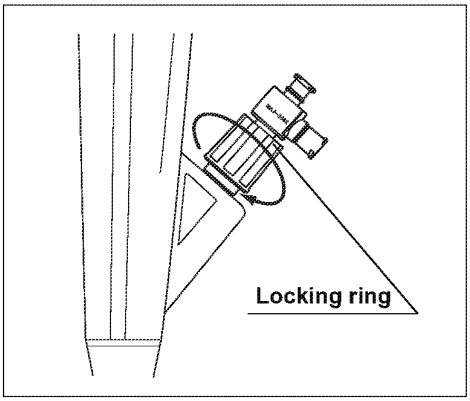

Figure 5.4

2 Fill a clean 30 ml syringe with the water.

3 Attach the syringe to the instrument channel port.

4 Flush the channel with 30 mL of the water into the small basin.

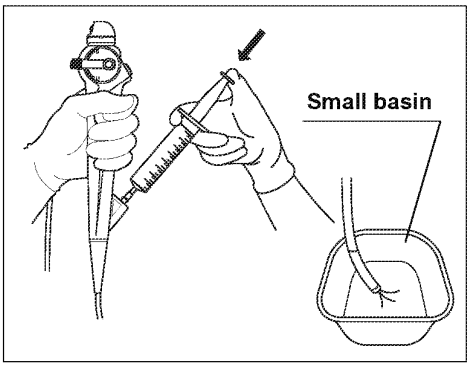

Figure 5.5

5 Detach the syringe from the endoscope.

6 Repeat Step 2 through 5 two additional times.

7 Fill a clean 30 ml syringe with air.

8 Attach the syringe to the instrument channel port.

9 Flush the channel with 30 ml of air.

10 Detach the syringe from the endoscope.

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Detach the endoscope from the video system center

Detach the video connector from the video system center while holding the video system center with a hand so that it does not move and pushing the locking lever down.

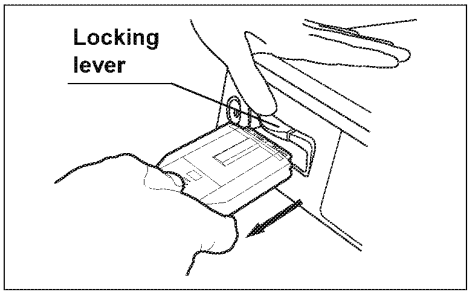

Figure 5.6

Detach the endoscope from the light source

WARNING

Do not touch the light guide of the light guide connector immediately after detaching it from the light source because it is extremely hot. Injury may result.

Detach the light guide connector of the endoscope from the output socket of the light source while holding the light source with a hand so that it does not move.

Transport the endoscope and accessories

NOTE

Refer to each instrument's instructions for reprocessing accessories.

Transport the endoscope to the reprocessing area. Use a covered container to avoid environmental contamination if required by local policy.

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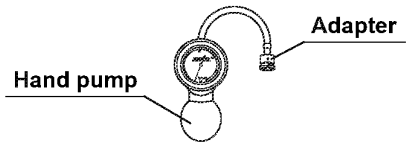
5.4 Leakage testing of the endoscope

Equipment needed

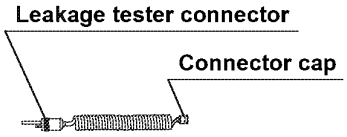
When performing a leakage test using WA23080A, prepare the following equipment.



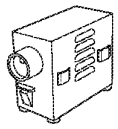
Leakage tester (WA23080A)
(Sold separately. See its instruction manual.)

- **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Water (for reprocessing) (See Section 3.3, "Water (for reprocessing)")**
- **Clean lint-free cloths**

When performing a leakage test using MB-155, prepare the following equipment.



Leakage tester (MB-155)
(Sold separately. See its instruction manual.)



Maintenance unit (MU-1)
(Sold separately. See its instruction manual.)

- **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Water (for reprocessing) (See Section 3.3, "Water (for reprocessing)")**
- **Clean lint-free cloths**

NOTE

Leakage testing can be also performed with the automated endoscope leak tester (ALT-Pro*1). Refer to the instruction manual for the automated endoscope leak tester.

*1 This product is available in the USA and some areas.

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Perform the leakage test

CAUTION

- When attaching the connector cap of the leakage tester to the venting connector of the endoscope, make sure that both the connector cap and the venting connector are thoroughly dry. Water on the surface of either component may enter the endoscope and could cause endoscope damage.
- When attaching the connector cap of the leakage tester to the venting connector of the endoscope, push on and rotate the connector cap clockwise fully until it stops. If it is not fully and properly attached, the interior of the endoscope will not be properly pressurized and accurate leakage testing will be impossible.
- Do not attach/detach the leakage tester while immersed. Attaching/detaching under water could allow the water to enter the endoscope, resulting in endoscope damage.
- If you identify a leak during leakage testing, remove the endoscope from the water with both the venting connector and the leakage tester (WA23080A or MB-155) still attached. Contact Olympus regarding instructions for reprocessing a leaking endoscope in preparation for returning the endoscope to Olympus for repair.
- Detach the leakage tester (MB-155) from the maintenance unit (MU-1) before detaching the leakage tester from the venting connector on the endoscope. If the leakage tester is detached from the venting connector before detaching the leakage tester from the maintenance unit, the air pressure inside the endoscope will not vent properly. This may damage the endoscope.

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Leakage testing with leakage tester (hand pump) (WA23080A)

CAUTION

- The leakage test pressure must not exceed 27 kPa (i.e., the pointer should remain within the “green area” on the pressure display). If the pressure increases so that the pointer moves into the red area on the display, the endoscope may be damaged. Press the pressure release lever to let the air escape.

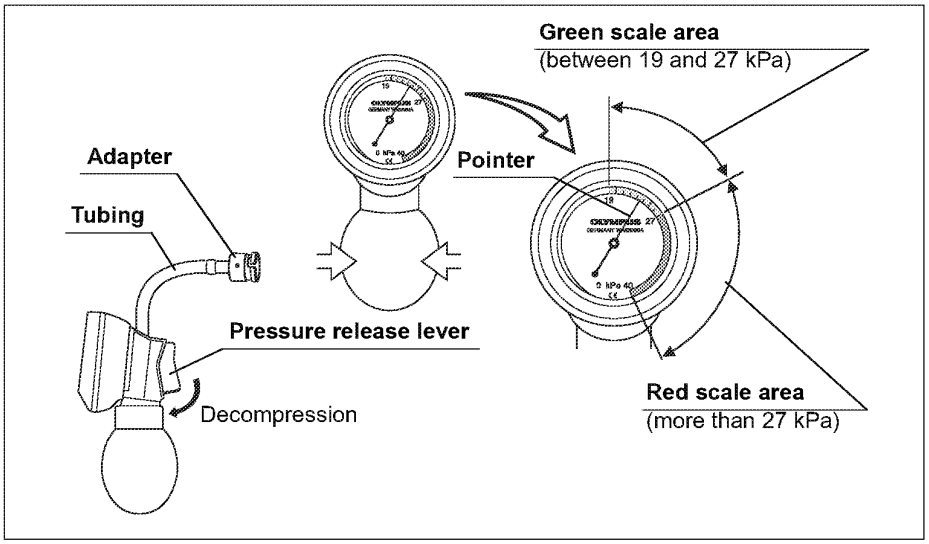

Figure 5.7

- Only the tubing and adapter of the leakage tester should be immersed. Other parts of the leakage tester could be damaged if immersed.
- Before detaching the adapter of the leakage tester from the venting connector, press the pressure release lever. Allow air to escape from the endoscope until 0 kPa is indicated on the display. Otherwise, the endoscope may be damaged.

1 Fill a clean, large basin with the water as described in Section 3.3, “Water (for reprocessing)”.

2 Confirm that both the inside of the adapter is dry. If not, dry it with clean lint-free cloths.

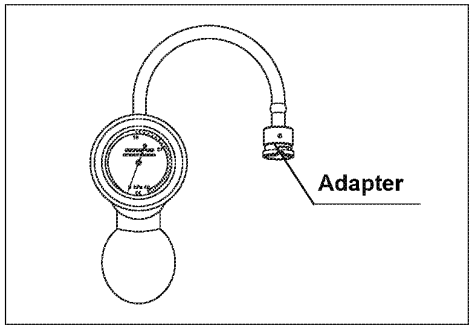

Figure 5.8

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3 Confirm that the venting connector on the endoscope's light guide connector is dry. If not, dry it by wiping with clean lint-free cloths.

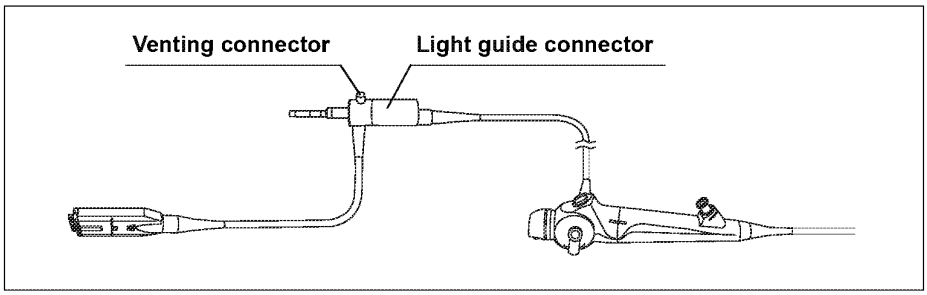

Figure 5.9

4 Attach the adapter of the leakage tester to the venting connector on the light guide connector as follows:

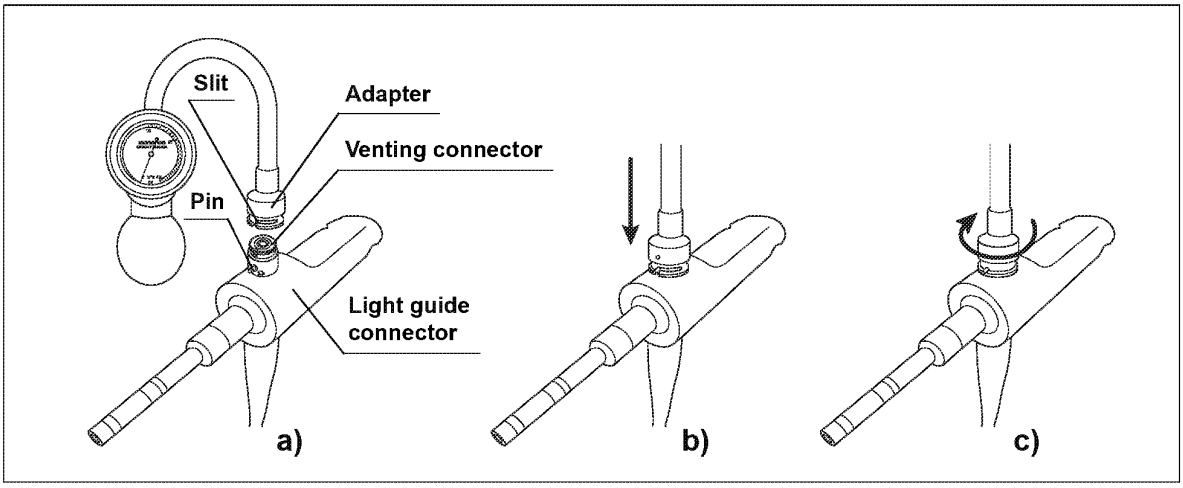

Figure 5.10

a) Align the pin on the venting connector with the slit on the adapter;
b) Push the adapter towards the light guide connector of the endoscope until it stops;
c) Rotate the adapter clockwise (approximately 90°) until it stops.

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5 Grasp the hand pump until the pointer is in the green scale area (between 19 and 27 kPa) on the pressure display.

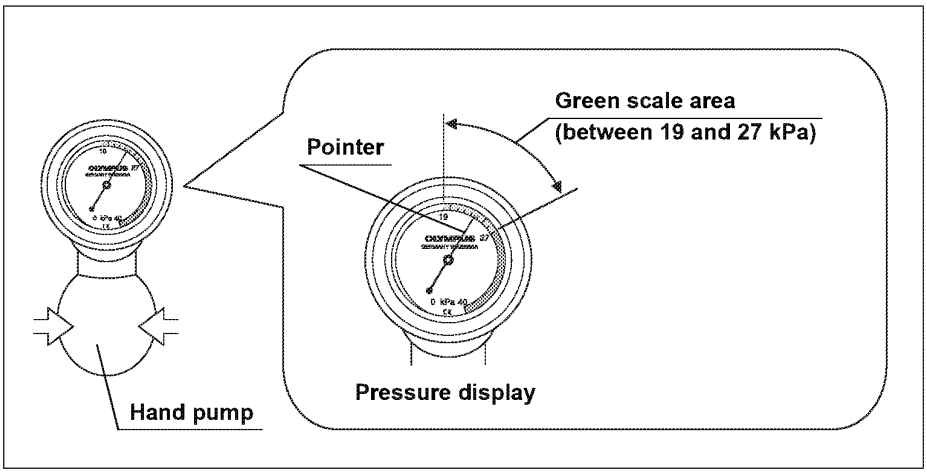

Figure 5.11

NOTE

To detect a slight water leakage, pressurize to near 27 kPa.

6 After several seconds, confirm that the pointer remains stable, and pressure is maintained.

CAUTION

If the pointer continues to fall towards 0 kPa, the endoscope might have a serious water leakage, or the leakage tester may be damaged. Stop the leakage test immediately. Water may enter the endoscope with no pressure inside if it is still immersed in water. As a result, severe damage may occur.

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7 With the leakage tester attached, completely immerse all sections of the endoscope and the adapter of the leakage tester in the water. Keep the pressure display and the hand pump of the leakage tester out of the water.

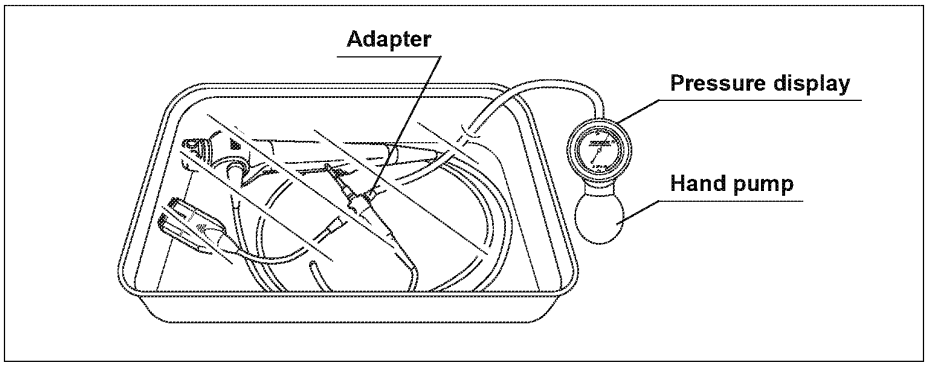

Figure 5.12

CAUTION

If continuous or intermittent air bubbles emerge from the adapter during leakage testing, the adapter might be damaged. For further details, contact Olympus.

8 While keeping all sections of the endoscope under the water for approximately 30 seconds, confirm that air bubbles do not emerge continuously or intermittently from any location on the endoscope.

9 While deflecting the bending section of the endoscope by moving the endoscope's UP/DOWN angulation control lever in the water, confirm that air bubbles do not emerge continuously or intermittently from any location on the endoscope.

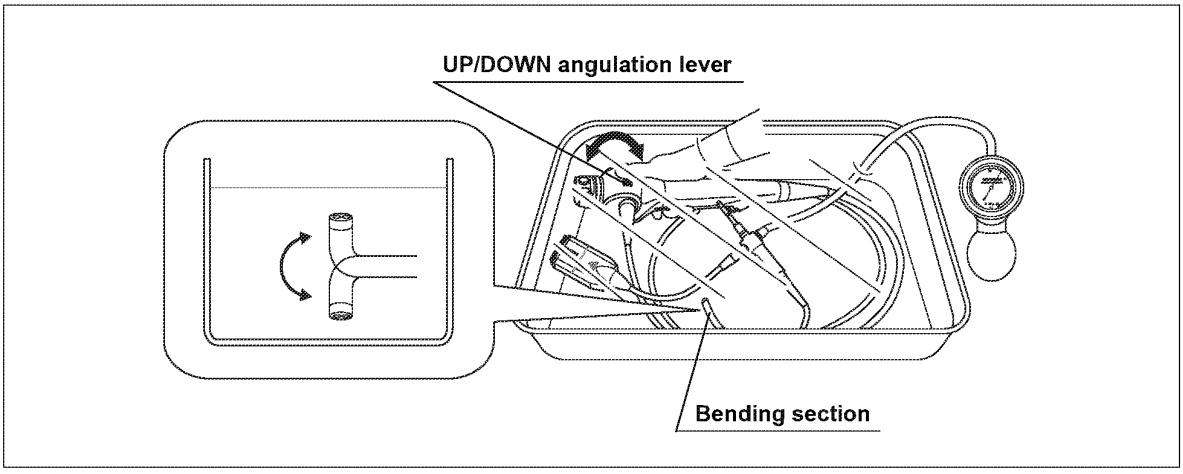

Figure 5.13

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NOTE

- Air bubbles emerging continuously or intermittently from any location on the endoscope indicate a leak at that location. If there is a leak in the instrument channel of the endoscope, air bubbles will emerge continuously or intermittently from one or more channel openings (e.g., distal end, instrument channel port) on the immersed endoscope.

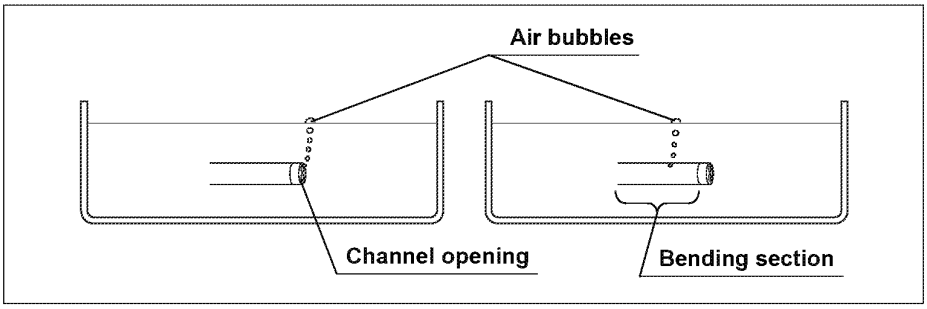

Figure 5.14

- During the leakage test, the covering of the bending section will expand as the air pressure inside the endoscope increases. This is normal.

10 Remove the endoscope attached with the leakage tester from the water.

11 Reconfirm that the pointer remains in the green scale area (between 19 and 27 kPa) on the pressure display. If not, repeat Step 5 through 11.

NOTE

If the pointer is not in the green scale area, the pressure release lever may have been pressed unintentionally.

12 Press the pressure release lever until 0 kPa is indicated on the display to let the air escape from the endoscope.

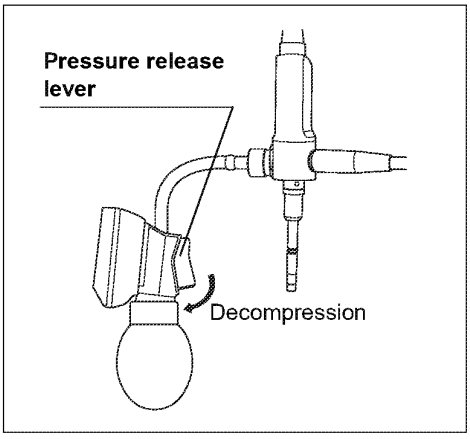

Figure 5.15

13 Detach the leakage tester from the venting connector of the endoscope by turning the adapter counterclockwise.

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14 Thoroughly dry the leakage tester using clean lint-free cloths.

❍ Leakage testing with leakage tester (MB-155)

1 Fill a clean, large basin with the water as described in Section 3.3, “Water (for reprocessing)”.

2 Attach the leakage tester connector of the leakage tester (MB-155) to the output socket of the maintenance unit (MU-1).

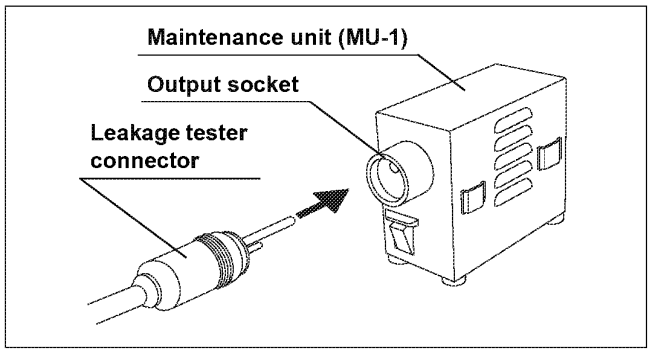

Figure 5.16

3 Turn the maintenance unit ON.

4 Depress the pin located inside the connector cap of the leakage tester and confirm that air is emitted from the connector cap with a whoosh sound.

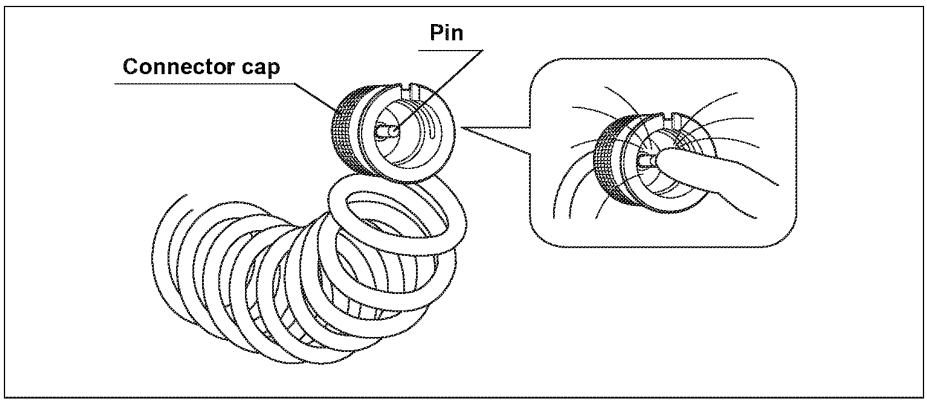

Figure 5.17

5 Confirm that the inside of the connector cap of the leakage tester is dry. If not, dry it by wiping with clean lint-free cloths.

6 Confirm that the venting connector on the endoscope’s light guide connector is dry. If not, dry it by wiping with clean lint-free cloths.

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7 Attach the connector cap of the leakage tester to the venting connector on the light guide connector as follows:

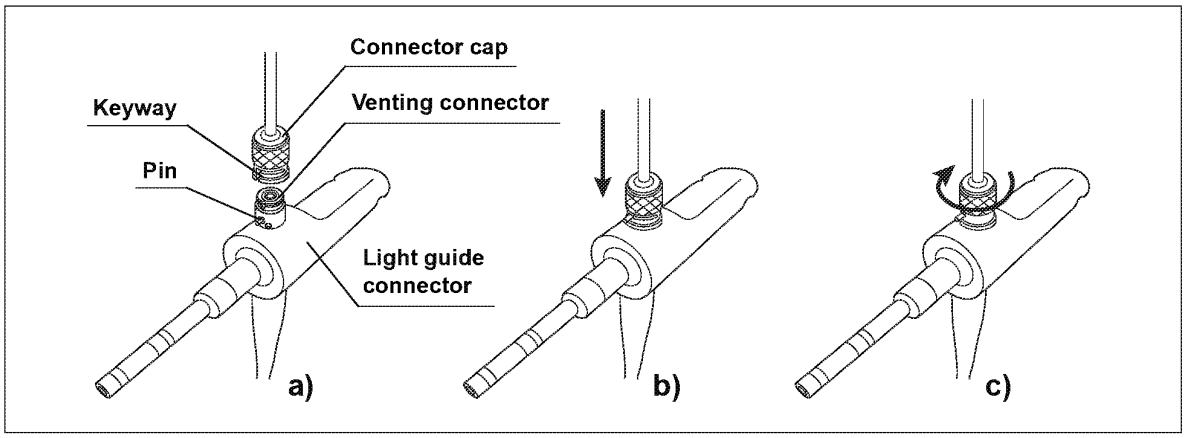

Figure 5.18

a) Align the pin on the venting connector with the keyway on the connector cap;

b) Push the connector cap towards the light guide connector of the endoscope until it stops;

c) Rotate the connector cap clockwise (approximately 90°) until it stops.

8 With the leakage tester attached, completely immerse all sections of the endoscope and the connector cap of the leakage tester in the water.

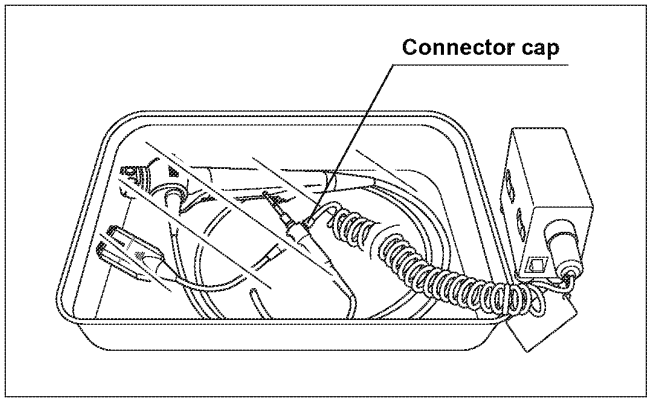

Figure 5.19

CAUTION

If continuous or intermittent air bubbles emerge from the adapter during leakage testing, the connector cap might be damaged. For further details, contact Olympus.

9 While keeping all sections of the endoscope under the water for approximately 30 seconds, confirm that air bubbles do not emerge continuously or intermittently from any location on the endoscope.

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10 While deflecting the bending section of the endoscope by moving the endoscope's UP/DOWN angulation control lever in the water, confirm that air bubbles do not emerge continuously or intermittently from any location on the endoscope.

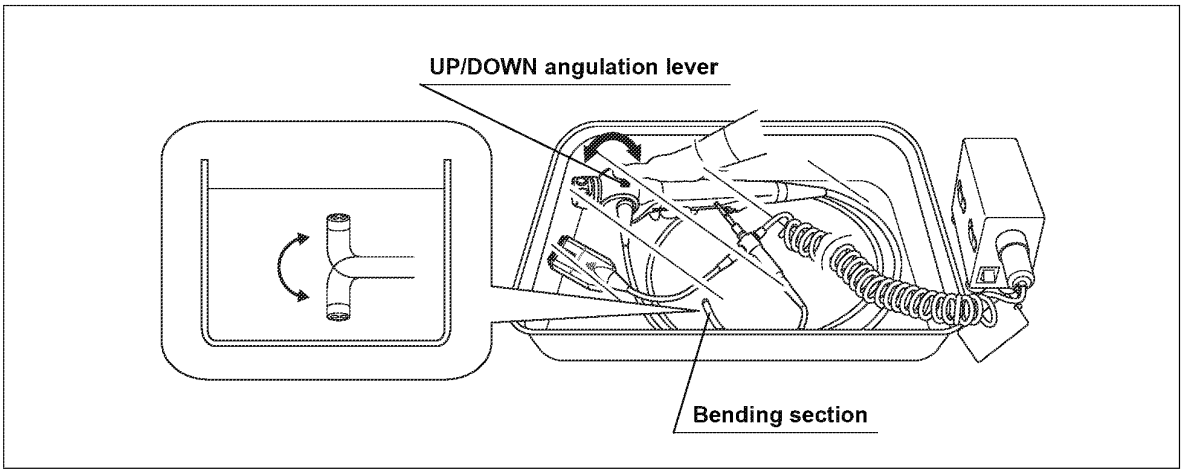

Figure 5.20

NOTE

- Air bubbles emerging continuously or intermittently from any location on the endoscope indicate a leak at that location. If there is a leak in the instrument channel of the endoscope, air bubbles will emerge continuously or intermittently from one or more channel openings (e.g., distal end, instrument channel port) on the immersed endoscope.

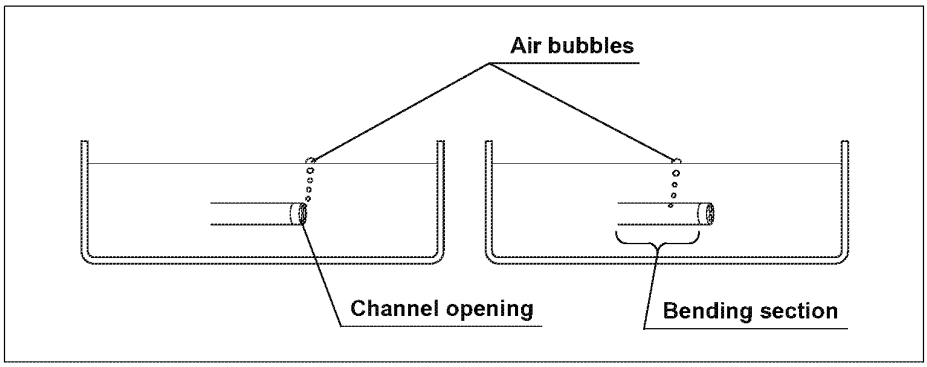

Figure 5.21

- During the leakage test, the covering of the bending section will expand as the air pressure inside the endoscope increases. This is normal.

11 Remove the endoscope attached with the leakage tester from the water.

12 Turn the maintenance unit OFF.

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13 Detach the leakage tester connector from the maintenance unit.

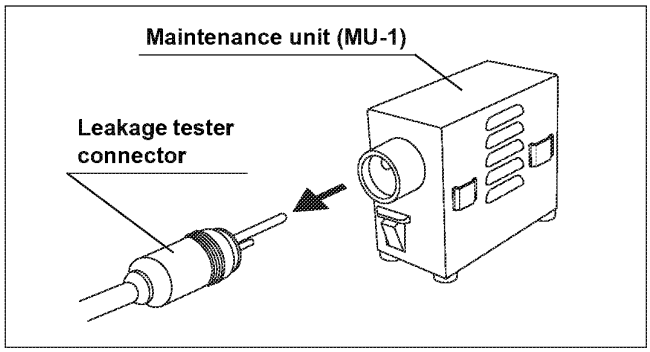

Figure 5.22

14 Wait 30 seconds or until the covering of the bending section contracts to its pre-expansion size.

15 Detach the leakage tester from the venting connector of the endoscope by turning the connector cap counterclockwise.

16 Thoroughly dry the leakage tester using clean lint-free cloths.

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5.5 Manually cleaning the endoscope

If manual cleaning could not be performed within 1 hour after the patient procedure or if you are not sure whether manual cleaning could be performed within 1 hour, presoak the endoscope in the detergent solution to loosen debris that has dried and hardened as described in Section 5.9, "Presoaking the endoscope" before manually cleaning the endoscope.

CAUTION

Handle the insertion section carefully. Tightly gripping or sharply bending the insertion tube or bending section can stretch or severely damage the insertion tube and the covering of the bending section.

Equipment needed

Prepare the following equipment.

Single use combination cleaning brush (BW-411B)

• **Clean lint-free cloths**	• **Sterile lint-free cloths**[*1]
• **Clean 30 ml (30 cc) syringes**	• **Sterile 30 ml (30 cc) syringes**[*1]
• **Clean sponges**	• **Sterile cotton swabs**[*1]
• **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**	• **Water (for reprocessing) (Refer to Section 3.3, "Water (for reprocessing)")**
• **Detergent solution (Refer to Section 3.4, "Detergent solution")**	• **70% ethyl or 70% isopropyl alcohol (Refer to Section 3.7, "Alcohol")**

*1 Following disinfection, it is very important not to recontaminate the endoscope and accessories with potentially infectious microorganisms. When rinsing and drying the endoscope and accessories following disinfection, the use of sterile equipment (basins, cloths, syringes, etc.) is recommended. If sterile equipment is not available, use clean equipment that does not recontaminate the endoscope and accessories with potentially infectious microorganisms. Consult with your hospital's infection control committee regarding local policies or requirements regarding reprocessing equipment.

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■ *Clean the external surfaces*

❍ Preparation

1 Fill a clean, large basin with the detergent solution at the temperature and concentration recommended by the detergent manufacturer.

2 Completely immerse the entire endoscope in the detergent solution.

❍ Clean the external surfaces of the video connector, the video cable, the light guide connector, and the universal cord

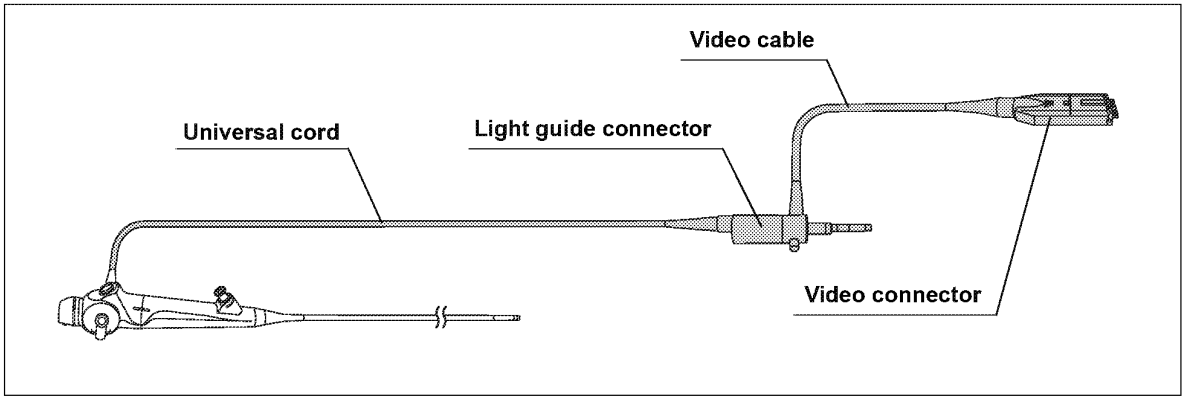

Figure 5.23

1 While immersing the entire endoscope completely in the detergent solution, thoroughly wipe or brush all external surfaces of the video connector, the video cable, the light guide connector, and the universal cord, using clean lint-free cloths, sponges or brushes.

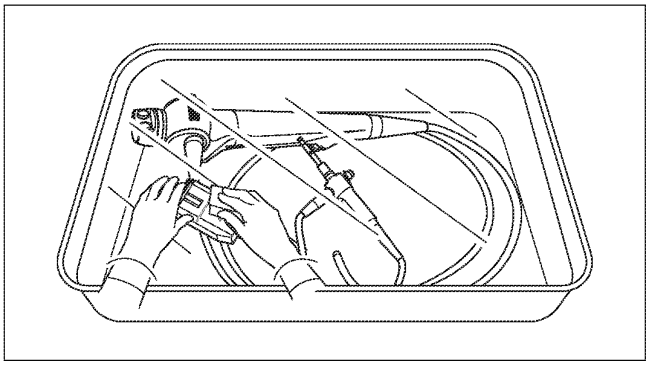

Figure 5.24

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2 Take the video connector, the video cable, the light guide connector, and the universal cord out of the detergent solution.

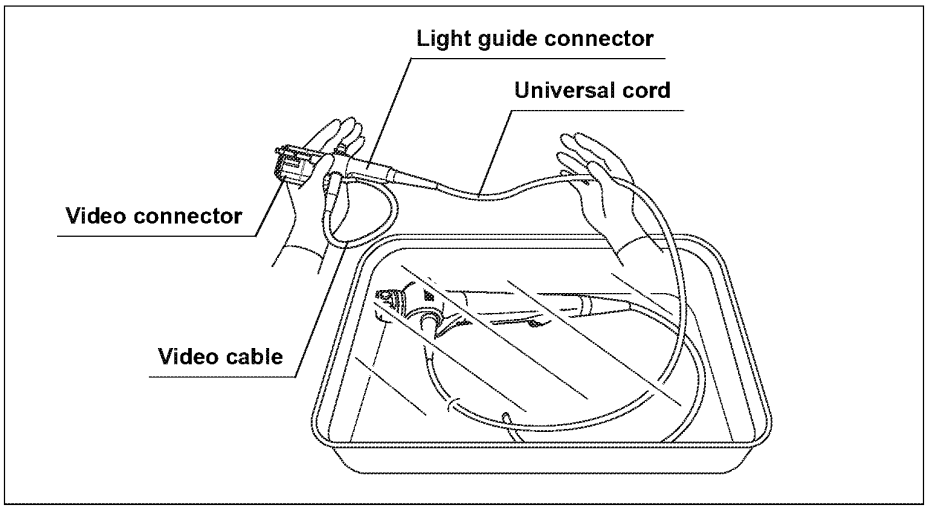

Figure 5.25

3 Confirm that no debris remains on all their external surfaces.

4 If any debris remains, repeat Step 1 through 3 until no debris is observed.

5 When all debris is removed, put back the video connector, the video cable, the light guide connector, and the universal cord in the detergent solution.

❍ Clean the external surfaces of the control section and its surrounding parts

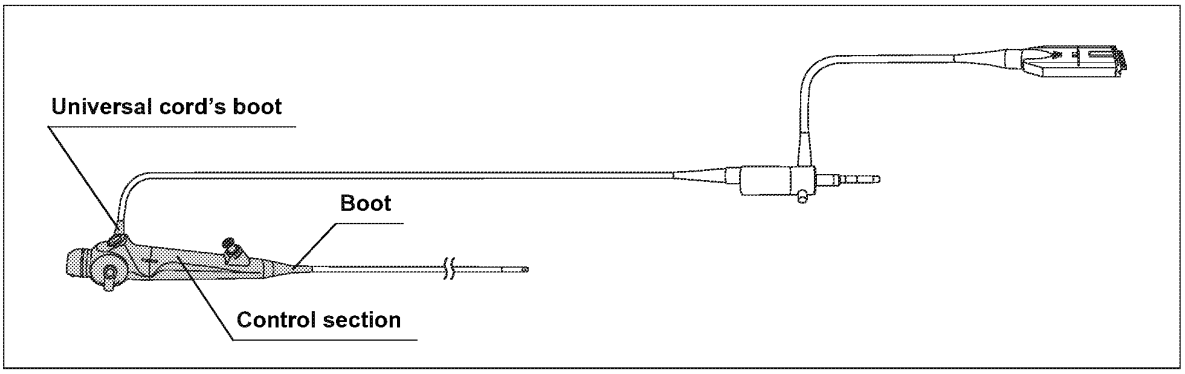

Figure 5.26

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1 While immersing the entire endoscope completely in the detergent solution, thoroughly wipe or brush all external surfaces of the universal cord's boot, the control section, and the boot, using clean lint-free cloths, sponges or brushes.

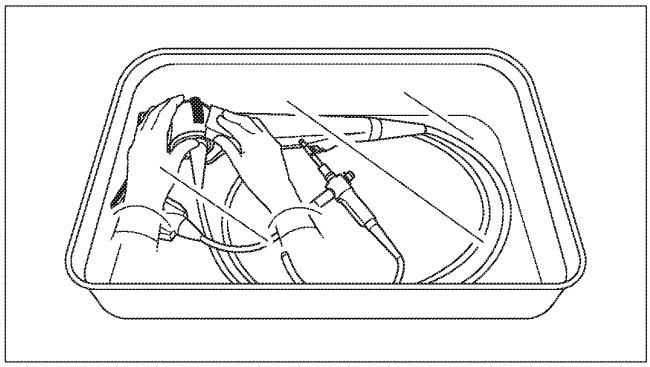

Figure 5.27

2 Take the universal cord's boot, the control section, and the boot out of the detergent solution.

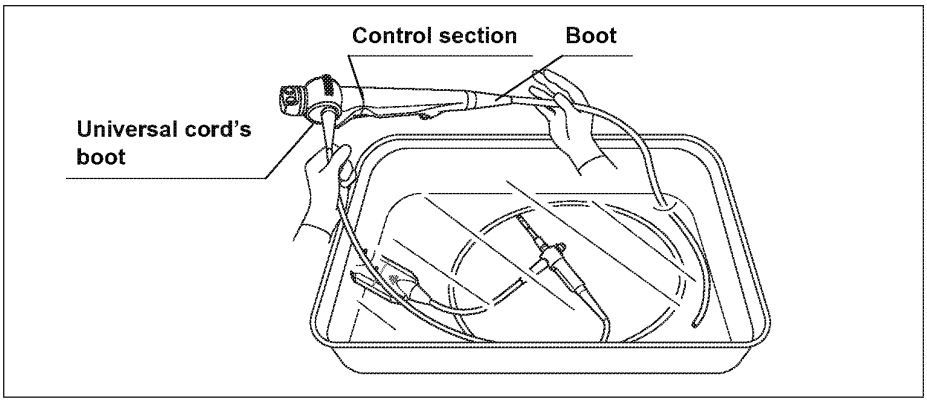

Figure 5.28

3 Confirm that no debris remains on all their external surfaces.

4 If any debris remains, repeat Step 1 through 3 until no debris is observed.

5 When all debris is removed, put back the universal cord's boot, the control section, and the boot in the detergent solution.

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Clean the external surfaces of the insertion section

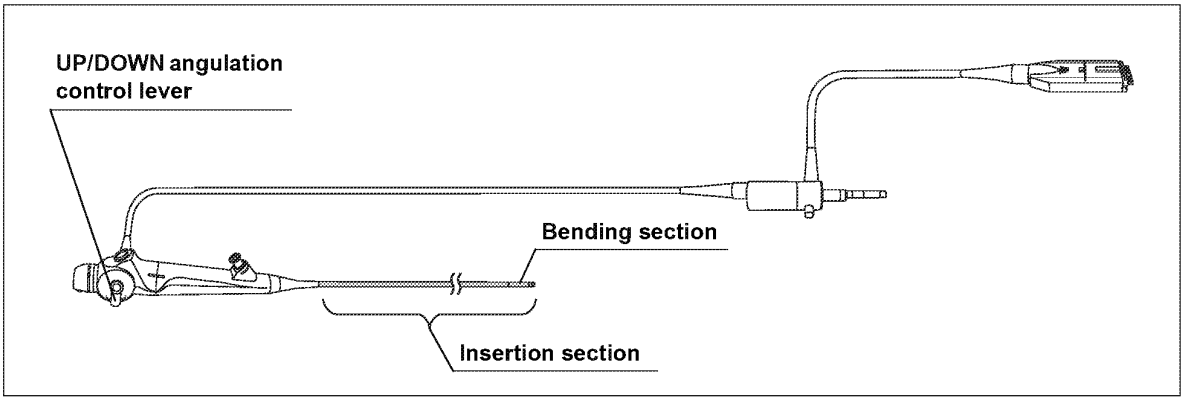

Figure 5.29

1. Straighten the bending section by use of endoscope's UP/DOWN angulation control lever.
2. While immersing the entire endoscope completely in the detergent solution, thoroughly wipe or brush all external surfaces of the insertion section, using clean lint-free cloths, sponges or brushes.

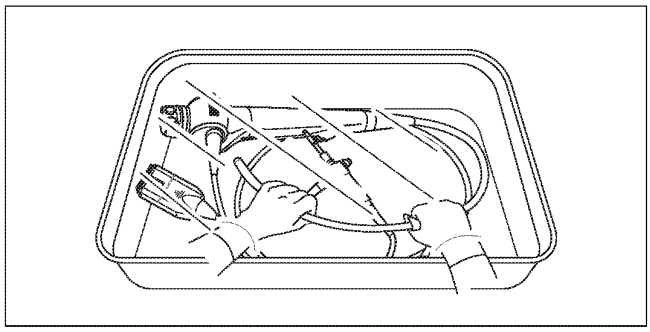

Figure 5.30

3. Take the insertion section out of the detergent solution.

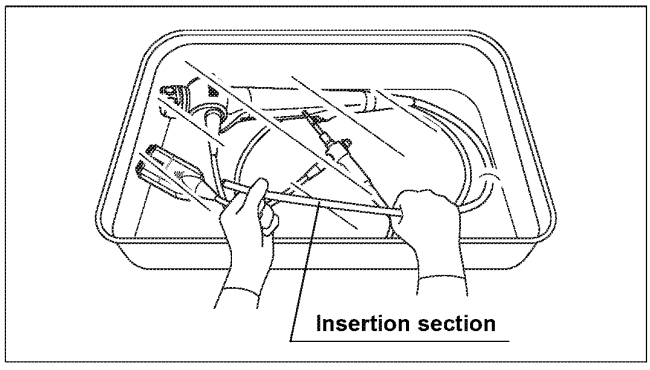

Figure 5.31

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4 Confirm that no debris remains on all its external surfaces, particularly the objective lens on the distal end.

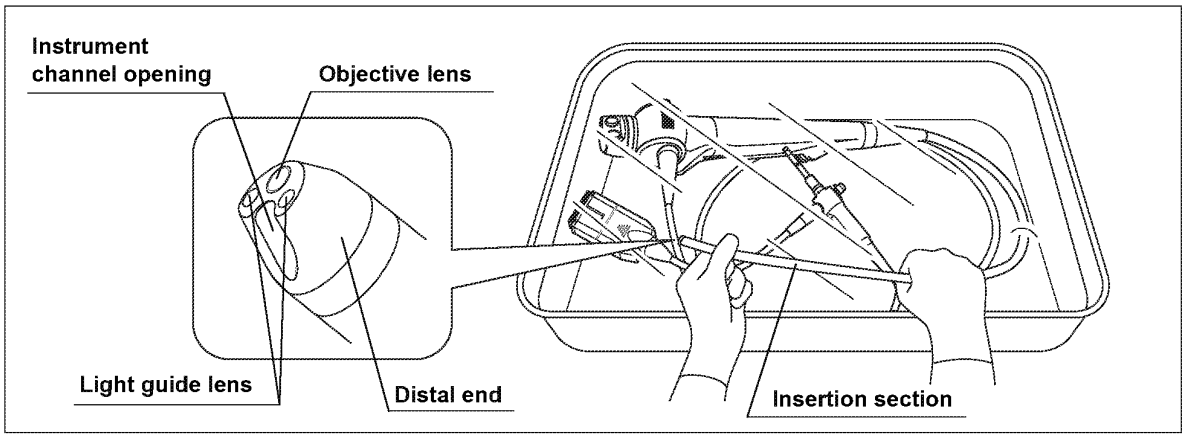

Figure 5.32

5 If any debris remains, repeat Step 2 through 4 until no debris is observed.

6 When all debris is removed, put back the insertion section in the detergent solution.

■ *Brush the channel*

WARNING

- Be sure to thoroughly brush the inside of the instrument channel, the instrument channel junction and the instrument channel port of the endoscope. Insufficient brushing may pose an infection control risk.

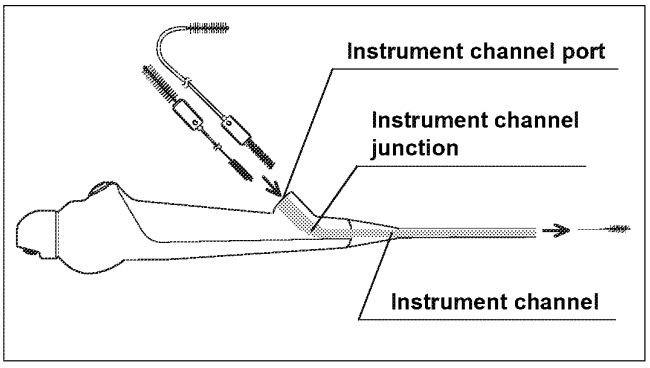

Figure 5.33

- To avoid splashing the detergent solution when the brush is pulled out from the endoscope, keep the endoscope completely immersed in the detergent solution.

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WARNING

- The single use combination cleaning brush (BW-411B) are for single use. Repeated usage of the brush may cause the brush head to become bent or kinked, which could cause it to come off during use. Before and after use, confirm that the brush is free from any damage or other irregularities. If a piece of the brush comes off inside the endoscope channel, immediately retrieve it. Confirm that no parts remain inside the instrument channel of the endoscope by carefully passing a new brush through the channel. Any part left in the channel can drop into the patient during a subsequent patient procedure. Depending on the location of the missing part, the part may not be retrievable by passing a new brush. In this case, contact Olympus.

CAUTION

- Do not attempt to pass the single use combination cleaning brush backwards – i.e. by inserting the brush directly into the instrument channel outlet at the distal end of the endoscope's insertion section. It may get caught, making retrieval impossible.

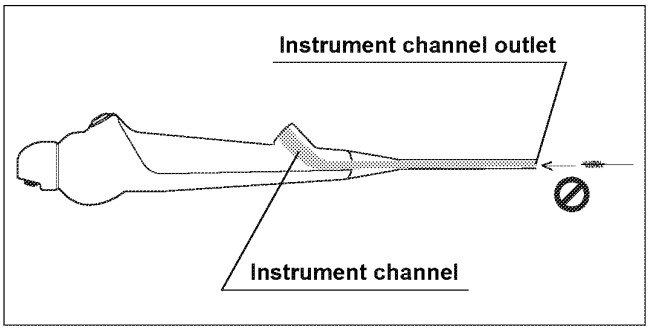

Figure 5.34

- Do not coil the insertion section of the endoscope with a diameter of less than 40 cm. If the diameter is less than 40 cm, it may be difficult to pass the brush completely through the channel.

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Brush the instrument channel

1 Straighten the bending section by use of endoscope's UP/DOWN angulation control lever.

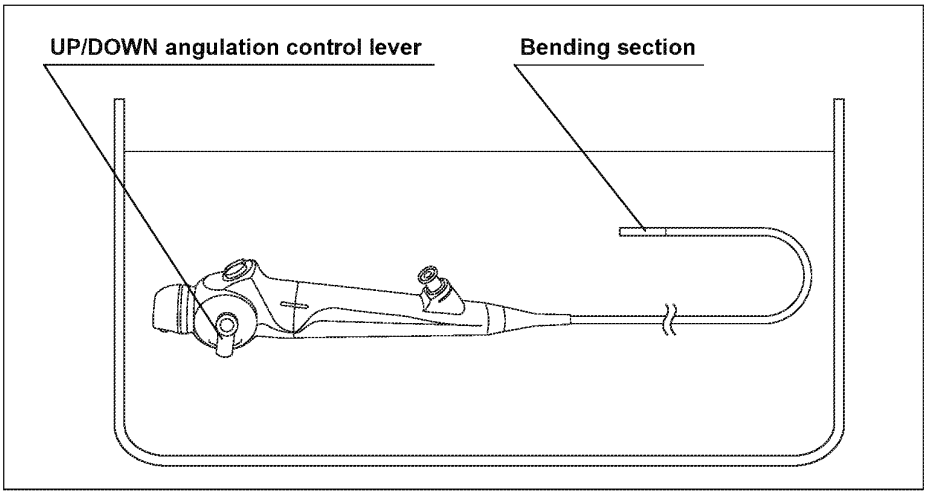

Figure 5.35

2 Grip the shaft of the single use combination cleaning brush (BW-411B) at a point 3 cm from the bristles of the channel cleaning brush part.

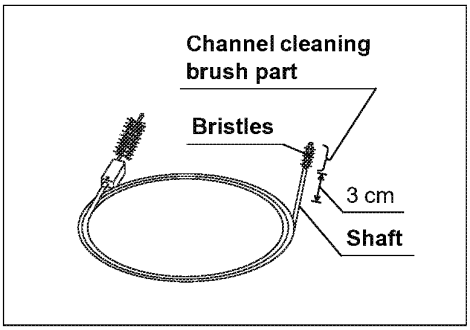

Figure 5.36

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3 While immersing the entire endoscope completely in the detergent solution, insert the brush straight into the opening of the instrument channel port. Using short strokes, feed the brush through the instrument channel until it emerges from the distal end of the endoscope.

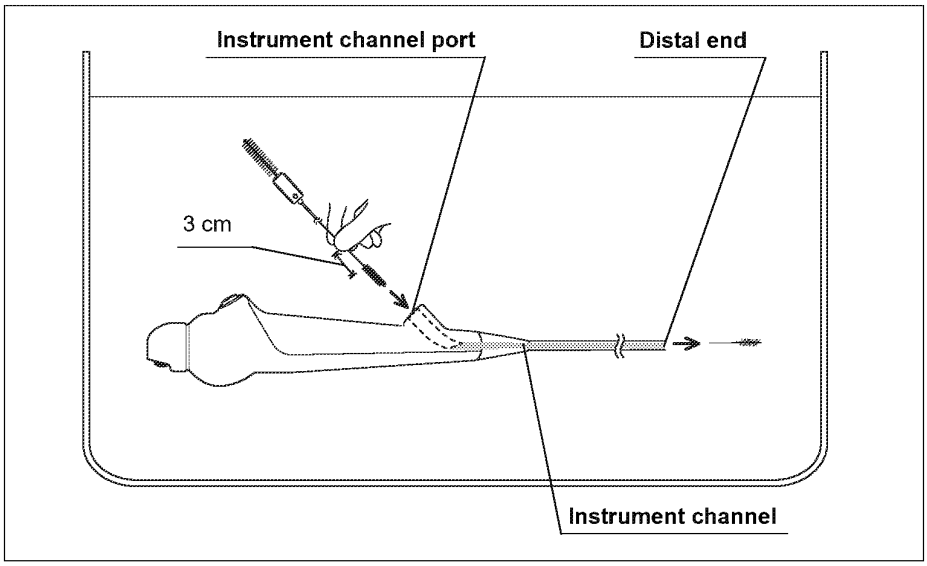

Figure 5.37

4 Inspect whether there is debris on the bristles when the brush emerges from the distal end of the endoscope.

5 Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.

6 While immersing the entire endoscope completely in the detergent solution, carefully pull the brush through the instrument channel and out of the instrument channel port.

7 Inspect whether there is debris on the bristles when the brush emerges from the instrument channel port.

8 Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.

9 Repeat Step 2 through 8 two additional times.

10 If any debris remains, repeat Step 2 through 8 until no debris is observed upon inspection of the brush.

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Brush the instrument channel port

1 Grip the handle of the single use combination cleaning brush (BW-411B).

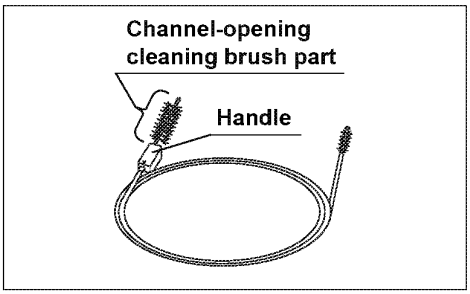

Figure 5.38

2 While immersing the entire endoscope completely in the detergent solution, insert the channel-opening cleaning brush part of the single use combination cleaning brush into the instrument channel port until the brush handle touches the channel opening.

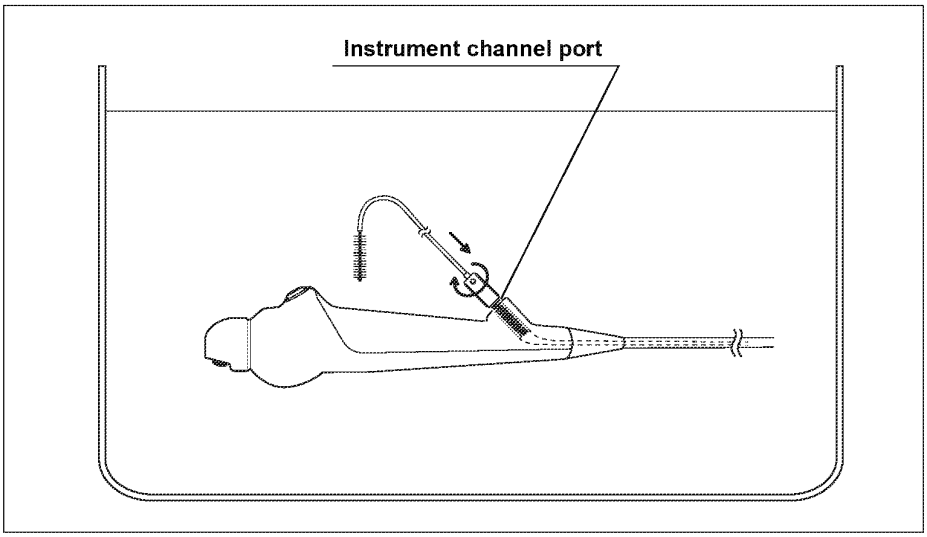

Figure 5.39

3 While immersing the entire endoscope completely in the detergent solution, rotate the inserted brush one full revolution.

4 While immersing the entire endoscope completely in the detergent solution, pull the brush out of the instrument channel port.

5 Inspect whether there is debris on the bristles when the brush emerges from the instrument channel port.

6 Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.

7 Repeat Step 1 through 6 two additional times.

8 If any debris remains, repeat Step 1 through 6 until no debris is observed upon inspection of the brush.

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9 Dispose of the single use combination cleaning brush as described in Section 7.4, “Disposal”.

Flush the instrument channel with detergent solution

1 Completely immerse the entire endoscope in the detergent solution.

2 Fill a clean 30 ml syringe with the detergent solution.

3 While immersing the entire endoscope completely in the detergent solution, attach the syringe to the instrument channel port.

4 While immersing the entire endoscope completely in the detergent solution, flush the channel with 30 ml of the detergent solution.

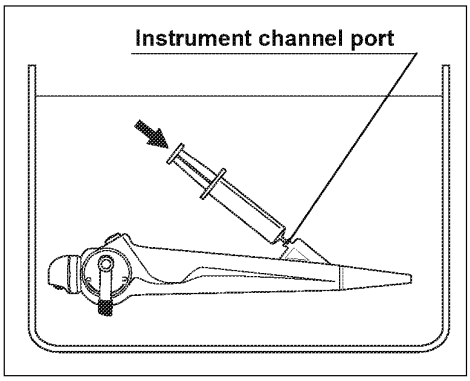

Figure 5.40

5 While immersing the entire endoscope completely in the detergent solution, detach the syringe from the endoscope.

6 Repeat Step 2 through 5 two additional times.

Immerse the endoscope in detergent solution

1 While immersing the entire endoscope completely in the detergent solution, wipe or brush all external surfaces of the endoscope to remove debris, using clean lint-free cloths, sponges or brushes.

2 Leave the endoscope completely immersed in the detergent solution during the recommended contact time according to the instructions of the detergent manufacturer.

3 Remove the endoscope from the detergent solution.

4 Place the endoscope in a clean, large basin.

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Remove detergent solution from the channel

1. Fill a clean, large basin with the water as described in Section 3.3, “Water (for reprocessing)”.
2. Completely immerse the entire endoscope in the water.
3. Gently sway the endoscope to thoroughly rinse it.
4. Fill a clean 30 ml syringe with the water.
5. Attach the syringe to the instrument channel port.
6. Flush the channel with 30 ml of the water.
7. Detach the syringe from the endoscope.
8. Repeat Step 4 through 7 two additional times.
9. Remove the endoscope from the water.
10. Place the endoscope in a clean, large basin.
11. Fill a clean 30 ml syringe with air.
12. Attach the syringe to the instrument channel port.
13. Cover the distal end of the endoscope with clean lint-free cloths to prevent splashing from the channel opening.

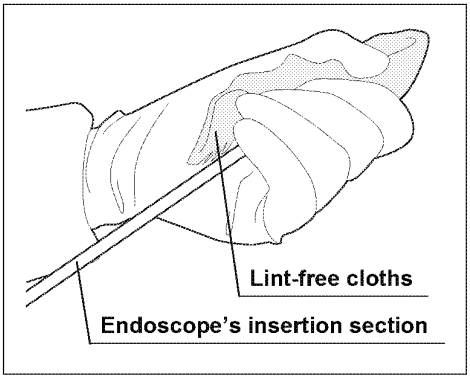

Figure 5.41

14. Flush the channel with 30 ml of air.
15. Detach the syringe from the endoscope.
16. Repeat Step 11 through 15 two additional times.
17. Remove the cloths from the endoscope.

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(Optional) Alcohol flush

WARNING

To reduce the risk of residual alcohol by contacting patient's mucosa and by electrosurgical procedures, remove residual alcohol from the endoscope channel by inspecting the irrigation function before each patient procedure, according to the procedures described in the operation manual of the endoscope.

If the endoscope is disinfected (with manually) after cleaning, this step may be skipped.

1. Fill a sterile 30 ml syringe with the alcohol as described in Section 3.7, "Alcohol".
2. Attach the syringe to the instrument channel port.
3. Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing alcohol from the channel opening.

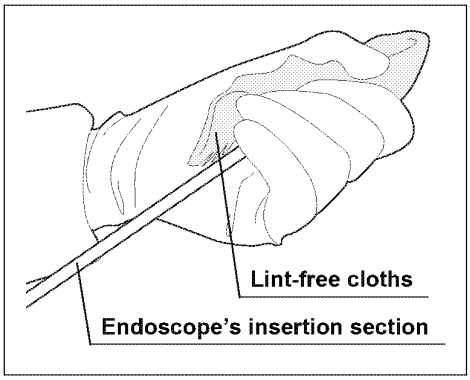

Figure 5.42

4. Flush the channel with 30 ml of the alcohol.
5. Detach the syringe from the endoscope.
6. Remove the cloths from the endoscope.
7. Fill a sterile 30 ml syringe with air.
8. Attach the syringe to the instrument channel port.
9. Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing alcohol from the channel opening.
10. Flush the channel with 30 ml of air to expel all alcohol.
11. Detach the syringe from the endoscope.
12. Remove the cloths from the endoscope.

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Dry the endoscope

If the endoscope is disinfected (with manually) after cleaning, this step may be skipped.

NOTE

Some national or professional guidelines recommend drying endoscope channel with compressed filtered air.

When using a syringe

1 Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing from the channel opening.

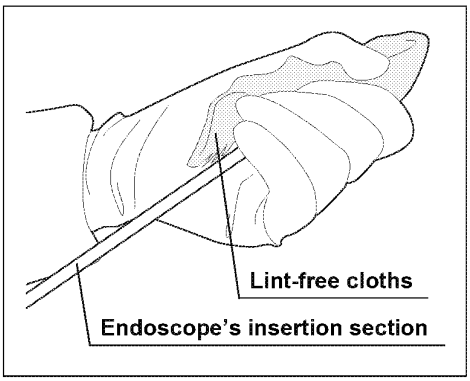

Figure 5.43

2 Fill a sterile 30 ml syringe with air.

3 Attach the syringe to the instrument channel port.

4 Flush 30 ml of the air to the channel.

5 Detach the syringe from the instrument channel port.

6 Repeat Step 2 through 5 two additional times.

7 Confirm that no water or alcohol exits from the channel opening.

8 If water or alcohol still exit, repeat Step 2 through 5 until no water or alcohol exits from the channel opening.

9 Remove the cloths from the endoscope.

10 Thoroughly dry the inside of the instrument channel port of the endoscope, using sterile cotton swabs.

11 Thoroughly dry the external surfaces of the endoscope by wiping with sterile lint-free cloths.

12 Inspect all items for residual debris. If any debris remains, return to the beginning of Section 5.5, "Manually cleaning the endoscope" and repeat the entire cleaning procedure until all debris is removed.

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When using copmressed air

CAUTION

When aerating the endoscope channels, the air pressure should be set 0.2 MPa or more but less than 0.3 MPa (≥2 and <3 kgf/cm^2, ≥29 and <43 psig). High pressure may cause damage to the endoscope.

1 Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing from the channel opening.

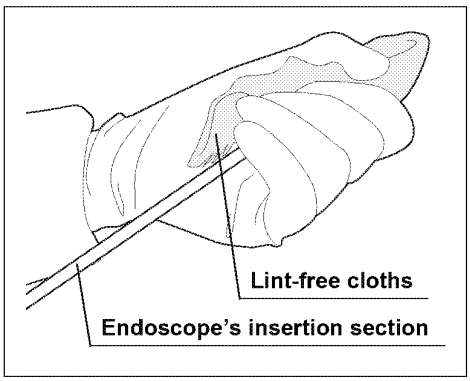

Figure 5.44

2 Feed instrument channel port with compressed filtered air of 0.2 – 0.3 MPa for 30 seconds.

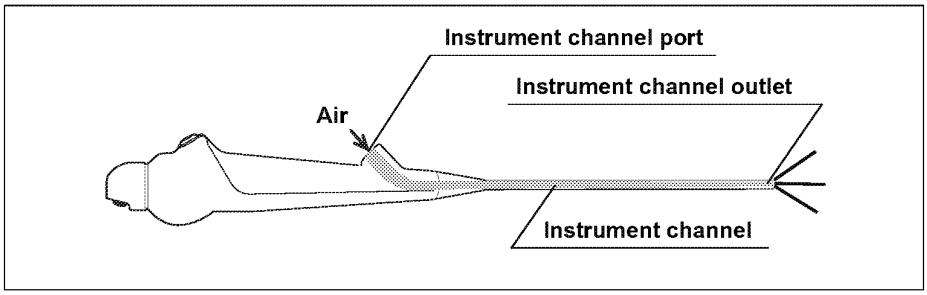

Figure 5.45

3 With new sterile lint-free cloths, cover the distal end of the endoscope to prevent splashing from the channel opening.

4 Feed compressed filtered air again and confirm that no water or alcohol exits from the channel opening.

5 If water or alcohol still exits, repeat Step 2 through 4 until no water or alcohol exits from the channel opening.

6 Remove the cloths from the endoscope.

7 Thoroughly dry the external surfaces of the endoscope by wiping with sterile lint-free cloths.

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8 Thoroughly dry the inside of the instrument channel port of the endoscope, using sterile cotton swabs.

9 Inspect all items for residual debris. If any debris remains, repeat the entire cleaning procedure until all debris is removed.

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5.6 Manually disinfecting the endoscope

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization. Refer to Section 5.8, “Sterilizing the endoscope”.

NOTE

Sterilization can be selected for the endoscope as a preferable reprocessing method instead of high-level disinfection if sterilization is recommended based on decision by medical professionals.

Use sterile equipment, such as sterile syringes and cloths, for all reprocessing steps occurring after immersion of the endoscope in disinfectant solution.

Equipment needed

Prepare the following equipment.

- **Clean lint-free cloths**
- **Clean 30 ml (30 cc)syringes**
- **Clean, large basins with tight-fitting lids (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Disinfectant solution (Refer to Section 3.5, “Disinfectant solution”)**
- **Sterile lint-free cloths**[*1]
- **Sterile 30 ml (30 cc) syringes**[*1]
- **Sterile, large basins**[*1] **(size: 40 (W) × 40 (H) × 25 (D) cm or more)**

*1 Following disinfection, it is very important not to recontaminate the endoscope and accessories with potentially infectious microorganisms. When rinsing and drying the endoscope and accessories following disinfection, the use of sterile equipment (basins, cloths, syringes, etc.) is recommended. If sterile equipment is not available, use clean equipment that does not recontaminate the endoscope and accessories with potentially infectious microorganisms. Consult with your hospital’s infection control committee regarding local policies or requirements regarding reprocessing equipment.

Preparation

Fill a clean, large basin with the disinfectant solution. Check the concentration of the disinfectant solution according to the manufacturer’s instructions to verify that the concentration is above the recommended minimum.

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Flush the channel with disinfectant solution

WARNING

Make sure that the disinfectant solution contacts all internal channel surfaces of the endoscope by completely removing all air bubbles from the channel. Air bubbles may inhibit disinfection of the channel's surfaces. When filling the channel with the disinfectant solution, flush until no more air bubbles exit from the channel openings.

CAUTION

Do not immerse the endoscope in the disinfectant solution for a longer contact time, at a higher temperature, or at a greater concentration than recommended by the disinfectant manufacturer. Such immersion may cause damage to the endoscope.

NOTE

Removal of air bubbles can be facilitated by forcefully flushing the disinfectant solution through the channel.

1. Completely immerse the entire endoscope in the disinfectant solution.
2. Fill a clean 30 ml syringe with the disinfectant solution.
3. While immersing the entire endoscope completely in the disinfectant solution, attach the syringe to the instrument channel port.
4. While immersing the entire endoscope completely in the disinfectant solution, flush the instrument channel with 30 ml of the disinfectant solution.

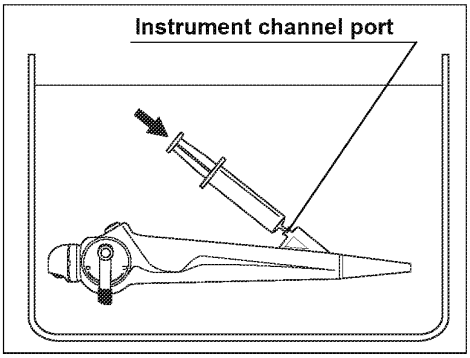

Figure 5.46

5. While immersing the entire endoscope completely in the disinfectant solution, detach the syringe from the endoscope.
6. Repeat Step 2 through 5 two additional times.
7. Confirm that no air bubbles exit the distal end of the endoscope during the flush.
8. If air bubbles still exit during the flush, repeat Step 2 through 5 until no air bubbles exit.

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Immerse the endoscope in disinfectant solution

WARNING

- During disinfection, keep the syringe detached from the endoscope. If the syringe remains attached to the endoscope during disinfection, the disinfectant solution cannot adequately contact the mated surfaces between the endoscope and the syringe.
- In addition, completely immerse the endoscope below the surface of the disinfectant solution so that all external surfaces of the endoscope contact the disinfectant solution. If the endoscope is not completely immersed, any protruding sections of this device will not be adequately disinfected.

CAUTION

Do not immerse the endoscope in the disinfectant solution for a longer contact time, at a higher temperature, or at a greater concentration than recommended by the disinfectant manufacturer. Such immersion may cause damage to the endoscope.

1. Confirm that the entire endoscope is completely immersed in the disinfectant solution.
2. Immerse clean lint-free cloths and then wring them out by hand until all trapped air bubbles are expelled in the disinfectant solution.
3. While completely immersing the entire endoscope in the disinfectant solution, wipe all external surfaces of the endoscope to remove air bubbles, using clean lint-free cloths.
4. While completely immersing the entire endoscope in the disinfectant solution, confirm that there are no air bubbles on all external surfaces of the endoscope.
5. If air bubbles adhere to the surfaces of the endoscope, wipe them away using your gloved fingertips or clean lint-free cloths.
6. Cover the basin of the disinfectant solution with a tight-fitting lid to minimize the diffusion of disinfectant vapors.
7. Leave the endoscope immersed in the disinfectant solution according to the instructions of the disinfectant manufacturer. Confirm the recommended contact time, temperature, and concentration. Use a clock or timer to accurately measure the disinfection contact time.
8. Remove the endoscope from the disinfectant solution.
9. Place the endoscope in a sterile, large basin.

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Remove disinfectant solution from the channel

1. Fill a sterile 30 ml syringe with air.
2. Attach the syringe to the instrument channel port.
3. Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing from the channel opening.

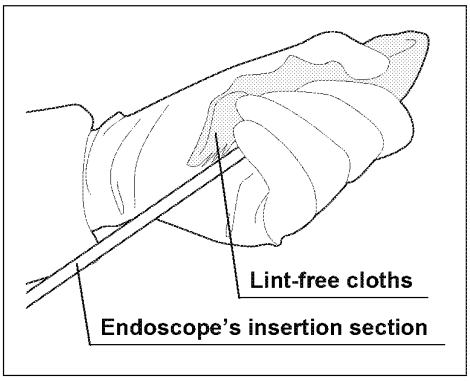

Figure 5.47

4. Flush the channel with 30 ml of air.
5. Detach the syringe from the endoscope.
6. Repeat Step 1 through 5 two additional times.
7. Remove the cloths from the endoscope.

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5.7 Rinsing the endoscope following disinfection

This instruction manual describes procedures for rinsing the endoscope and flushing it with alcohol following disinfection.

WARNING

After rinsing, thoroughly dry the instrument channel of the endoscope. Otherwise, bacteria may proliferate in the instrument channel and pose an infection control risk.

CAUTION

Carefully dry the electrical contacts of the video connector after performing the procedure described in this section. Otherwise, equipment damage can result.

NOTE

Olympus recommends using sterile water, fresh potable water or water that has been processed (e.g., filtered, deionized, or purified) to improve its chemical and/or microbiological quality. Some national or professional guideline recommend using sterile water for rinsing endoscopes, accessories, and medical instruments. Consult with your institution's infection control committee regarding local policies on water quality.

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Equipment needed

Prepare the following equipment.

• **Sterile lint-free cloths**[*1]	• **Sterile cotton swabs**[*1]
• **Sterile 30 ml (30 cc) syringes**[*1]	• **Sterile, large basins**[*1] **(size: 40 (W) × 40 (H) × 25 (D) cm or more)**
• **Rinse water (See Section 3.6, "Rinse water")**	• **70% ethyl or 70% isopropyl alcohol (See Section 3.7, "Alcohol")**

*1 Following disinfection, it is very important not to recontaminate the endoscope and accessories with potentially infectious microorganisms. When rinsing and drying the endoscope and accessories following disinfection, the use of sterile equipment (e.g., basins, cloths, syringes, etc.) is recommended. If sterile equipment is not available, use clean equipment that does not recontaminate the endoscope and accessories with potentially infectious microorganisms. Consult with your hospital's infection control committee regarding local policies or requirements regarding reprocessing equipment.

Rinse the endoscope

Use appropriate rinse water as instructed in Section 3.6, "Rinse water".

1. Fill a sterile, large basin with the rinse water as described in Section 3.6, "Rinse water".
2. Completely immerse the entire endoscope in the rinse water.
3. While immersing the entire endoscope completely in the rinse water, wipe all external surfaces of the endoscope, using sterile lint-free cloths.
4. Fill a sterile 30 ml syringe with the rinse water.
5. While immersing the entire endoscope completely in the rinse water, attach the syringe to the instrument channel port.
6. While immersing the entire endoscope completely in the rinse water, flush the channel with 30 ml of the rinse water.
7. While immersing the entire endoscope completely in the rinse water, detach the syringe from the endoscope.
8. Repeat Step 4 through 7 two additional times.
9. Remove the endoscope from the rinse water and place them in a sterile basin.
10. Fill a sterile 30 ml syringe with air.
11. Attach the syringe to the instrument channel port.
12. Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing from the channel opening.

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13 Flush the channel with 30 ml of air.

14 Detach the syringe from the endoscope.

15 Repeat Step 10 through 14 two additional times.

16 Remove the cloths from the endoscope.

17 Repeat Step 1 through 16 above for the necessary number of times described in the disinfectant manufacturer's instruction.

■ (Optional) Alcohol flush

Refer to "■ (Optional) Alcohol flush" on page 58 as the procedure is same.

■ Dry the endoscope

Refer to "■ Dry the endoscope" on page 59 as the procedure is same.

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5.8 Sterilizing the endoscope

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization.

Equipment needed

Prepare the following equipment.

ETO cap (MB-156)	Sterilization tray (WA05991A) (Sold separately. See its instruction manual.)
• **Sterilization wraps**[*1]	• **Sterilization pouches**[*1]
• **Instrument tray**[*1]	• **Sterile lint-free cloths**

*1 For the USA
Use sterilization wraps, instrument tray, and sterilization pouches that are legally marketed in the USA.

Ethylene oxide gas sterilization of the endoscope

WARNING

- Thoroughly dry the endoscope and accessories before sterilization.
- All instruments must be properly aerated following ethylene oxide gas sterilization to remove toxic ethylene oxide residuals.
- All accessories must be removed from the endoscope prior to sterilization (except the ETO cap (MB-156)).
- Only use the sterilization tray (WA05991A). When using other sterilization trays, the endoscope may impair effective sterilizing and/or the endoscope may be damaged.
- Use only ethylene oxide gas sterilization compatible sterilization wraps and sterilization pouches.

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CAUTION

- Exceeding the recommended sterilization parameters may cause damage to the endoscope and accessories.
- Attach the ETO cap to the venting connector on the light guide connector prior to ethylene oxide gas sterilization. If the ETO cap is not attached to the venting connector during the ethylene oxide gas sterilization, the air inside the endoscope will expand and could rupture the bending section cover and/or damage the angulation mechanism.

1 Confirm that all external surfaces of the endoscope are thoroughly dry. If not, dry them as described in "■ Dry the endoscope" on page 59.

Ch.5

2 Dry the external surfaces of the ETO cap by wiping with sterile lint-free cloths.

3 Attach the ETO cap to the venting connector on the light guide connector as follows:

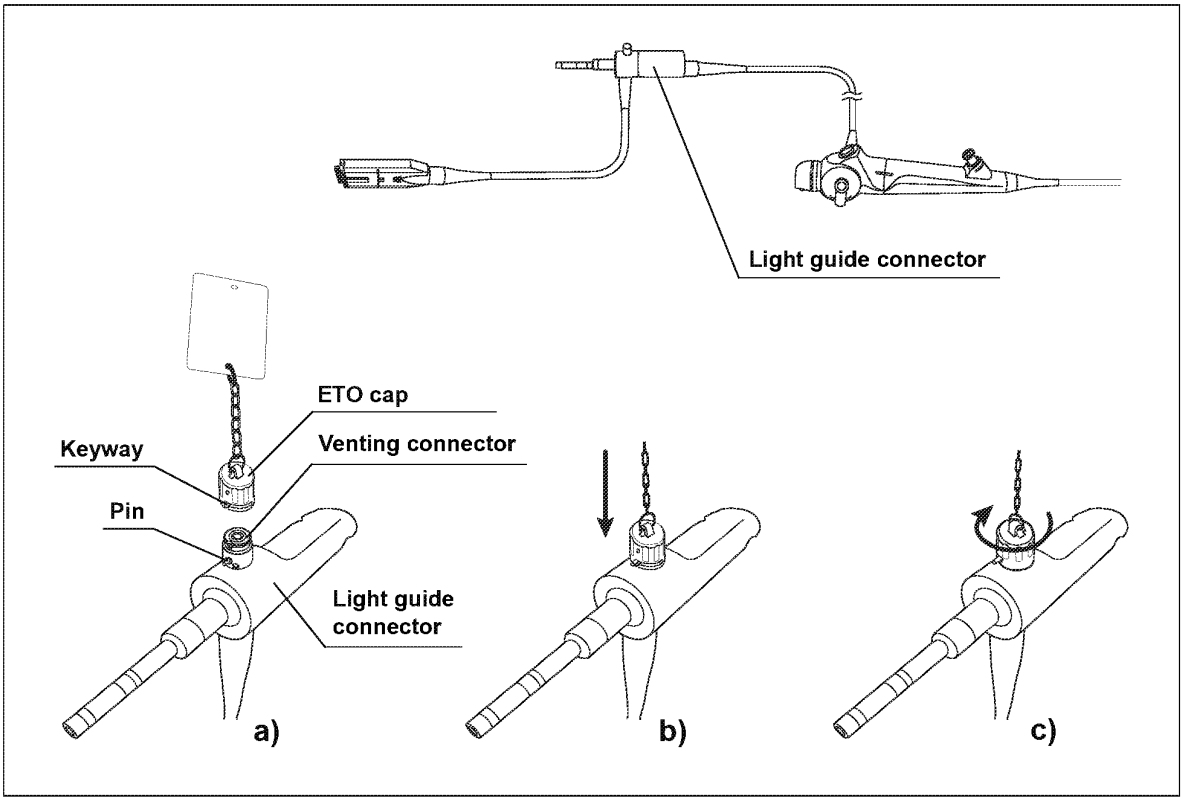

Figure 5.48

a) Align the pin on the venting connector with the keyway on the ETO cap;

b) Push the ETO cap towards the light guide connector of the endoscope until it stops;

c) Rotate the ETO cap clockwise (approximately 90°) until it stops.

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4 Place the endoscope on the sterilization tray as follows (a through m);

a) Open the lid of the sterilization tray according to the instruction manual for the sterilization tray.

b) Place the control section of the endoscope on the No.1 area of the sterilization tray.

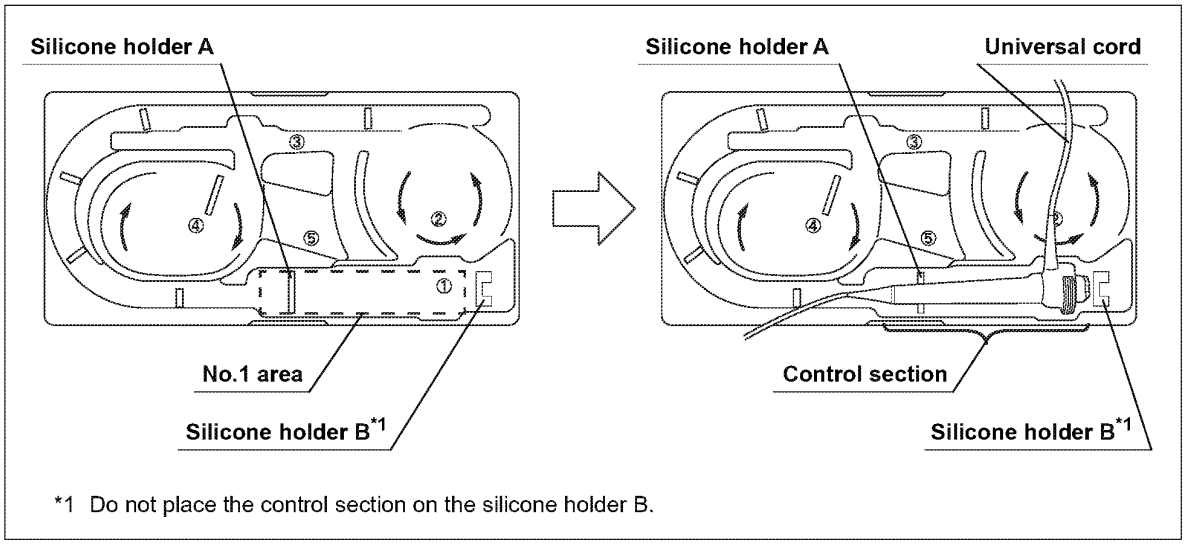

Figure 5.49

c) Push the control section of the endoscope into the silicone holder A.

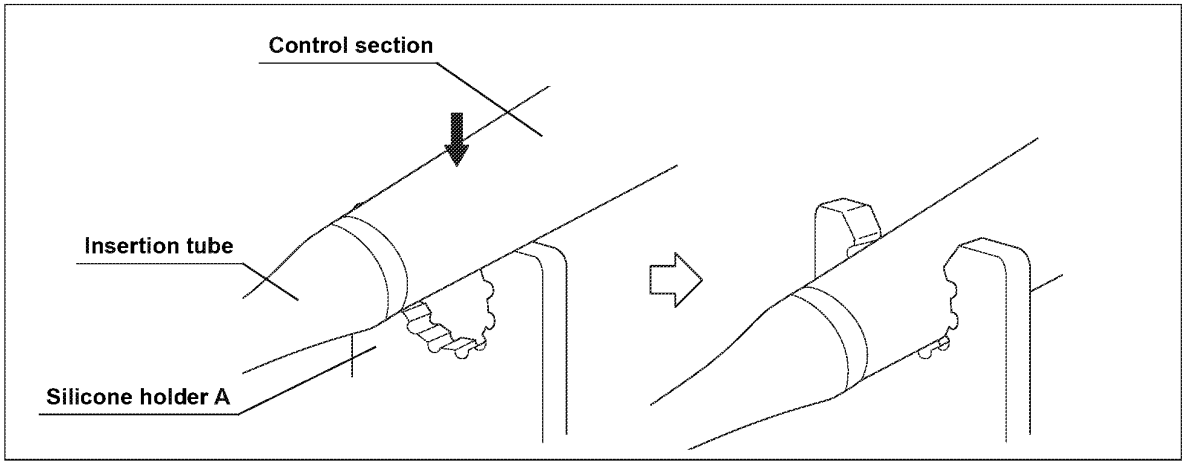

Figure 5.50

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d) Push the insertion tube of the endoscope into the silicone holder C, D, and E.

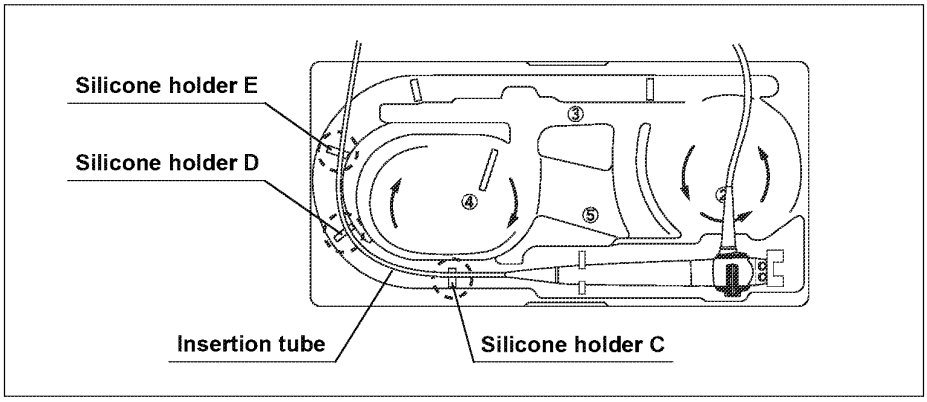

Figure 5.51

e) Loop the universal cord of the endoscope counterclockwise, creating four loops and place it in the No.2 area of the sterilization tray.

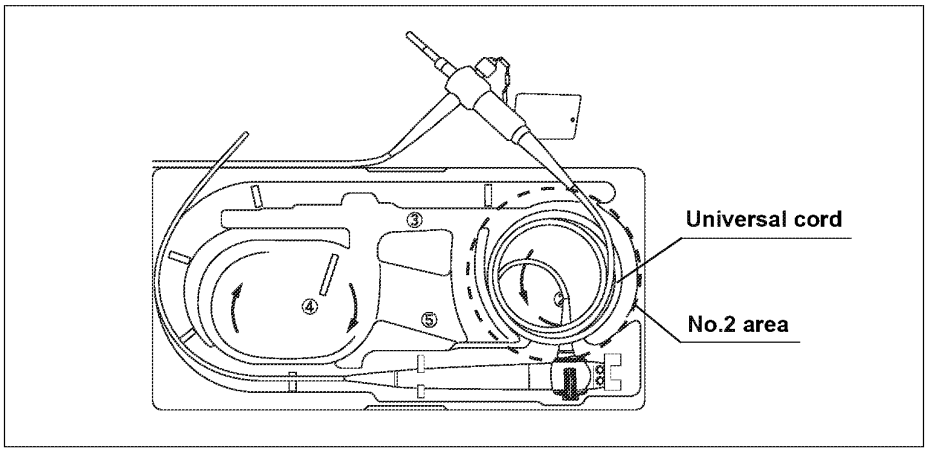

Figure 5.52

f) Place the light guide connector of the endoscope on the No.3 area of the sterilization tray.

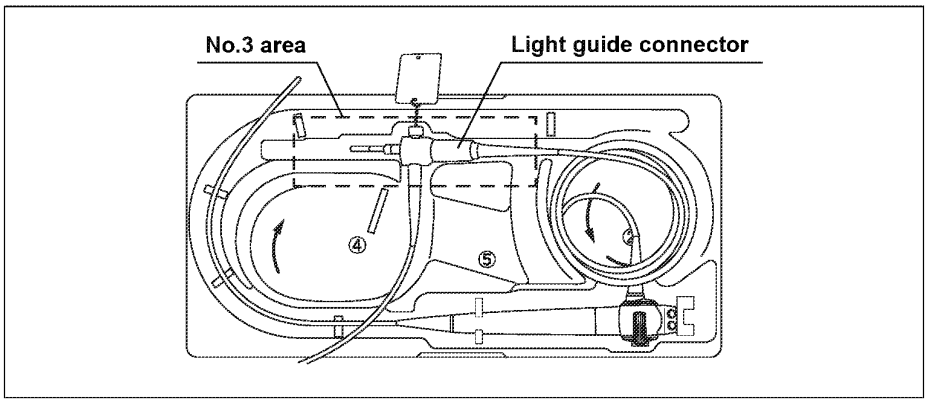

Figure 5.53

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g) Place the plate of the ETO cap on the light guide connector of the endoscope.

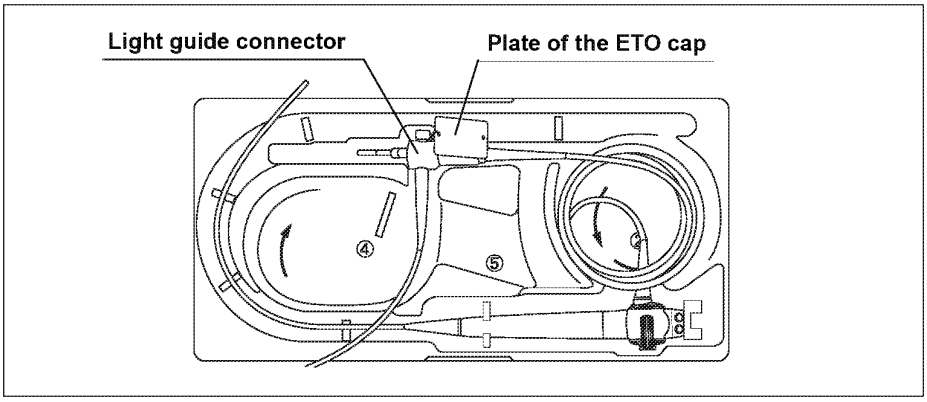

Figure 5.54

h) Loop the video cable of the endoscope clockwise, creating two loops and place it in the No.4 area of the sterilization tray.

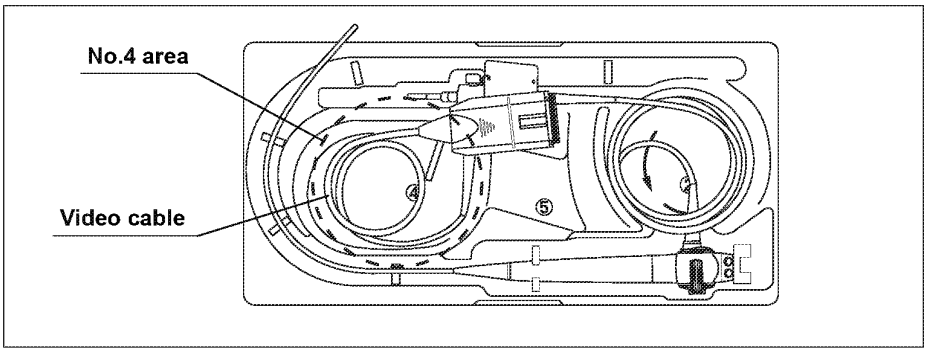

Figure 5.55

i) Place the video connector of the endoscope on the No.5 area of the sterilization tray.

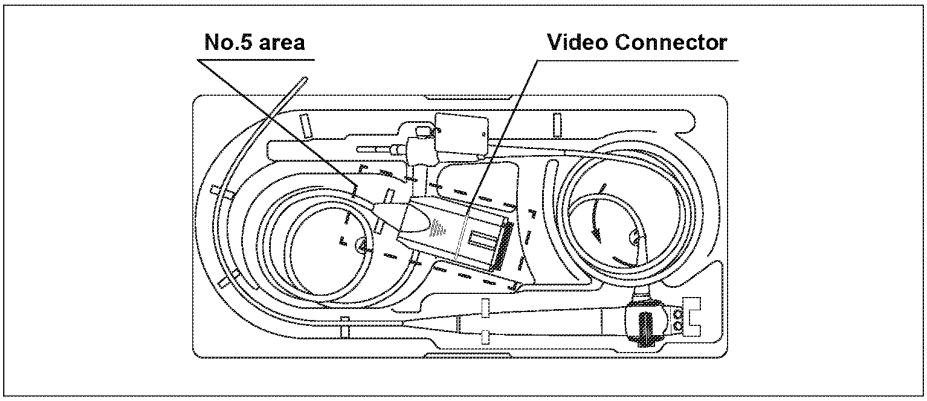

Figure 5.56

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j) Push the video connector of the endoscope into the silicone holder G.

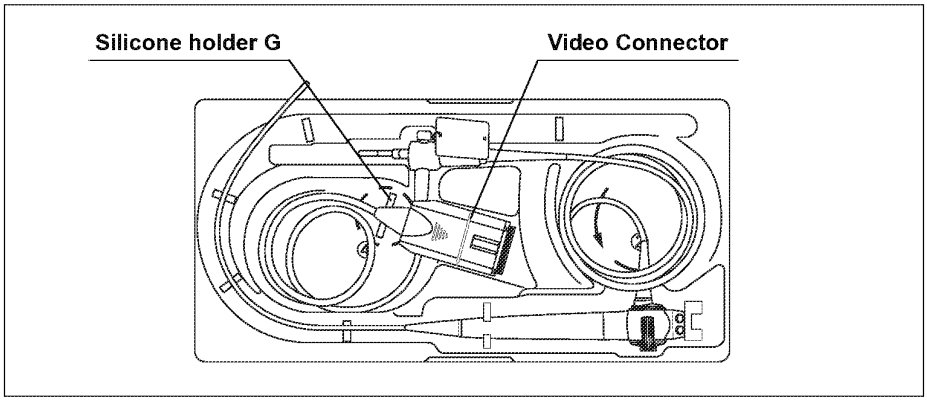

Figure 5.57

k) Insert the insertion section of the endoscope into the notch of the silicone holder F.

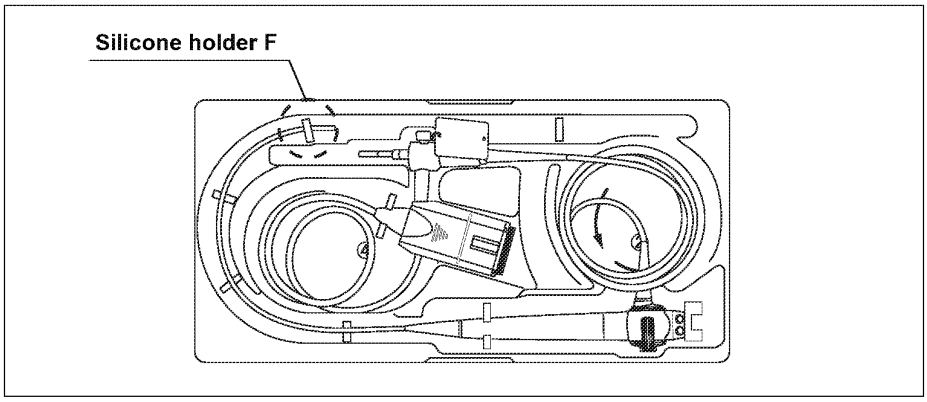

Figure 5.58

l) Confirm that all sections of the endoscope are contained completely in the groove formed on the sterilization tray.

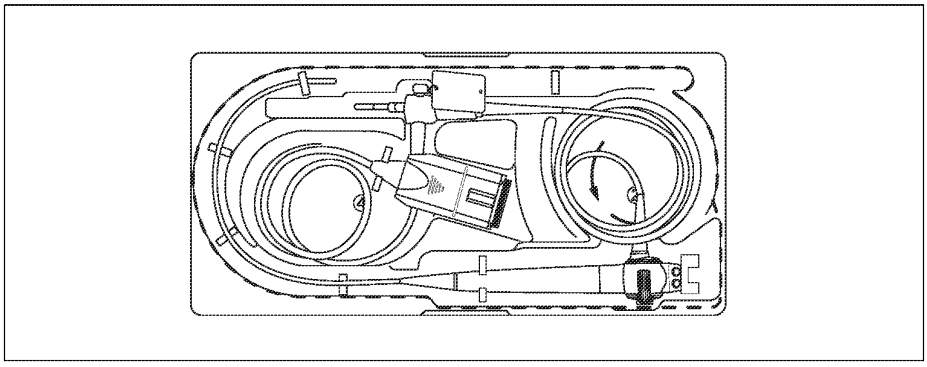

Figure 5.59

m) Close the lid of the sterilization tray according to the instruction manual for the sterilization tray.

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5 Double wrap the sterilization tray containing the endoscope with sterilization wraps for ethylene oxide gas sterilization, according to your institution's protocol.

6 Sterilize and aerate the packaged endoscope, according to the parameters described in Section 3.8, "Ethylene oxide gas sterilization". In addition, always follow the instructions of the sterilizer manufacturer.

■ *STERRAD® 100S*/NX® sterilization of the endoscope*

* For countries other than the USA.

WARNING

- Thoroughly dry the endoscope and accessories before sterilization.
- All accessories must be removed from the endoscope prior to sterilization (except the ETO cap (MB-156)).
- Use only STERRAD® compatible instrument trays and sterilization wraps.

CAUTION

Attach the ETO cap to the venting connector on the light guide connector prior to STERRAD® 100S/NX® sterilization. If the ETO cap is not attached to the venting connector during sterilization, the air inside the endoscope will expand and could rupture the bending section cover and/or damage the angulation mechanism.

1 Confirm that all external surfaces of the endoscope are thoroughly dry. If not, dry them as described in "■ Dry the endoscope" on page 59.

2 Dry the external surfaces of the ETO cap by wiping with sterile lint-free cloths.

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3 Attach the ETO cap to the venting connector on the light guide connector as follows:

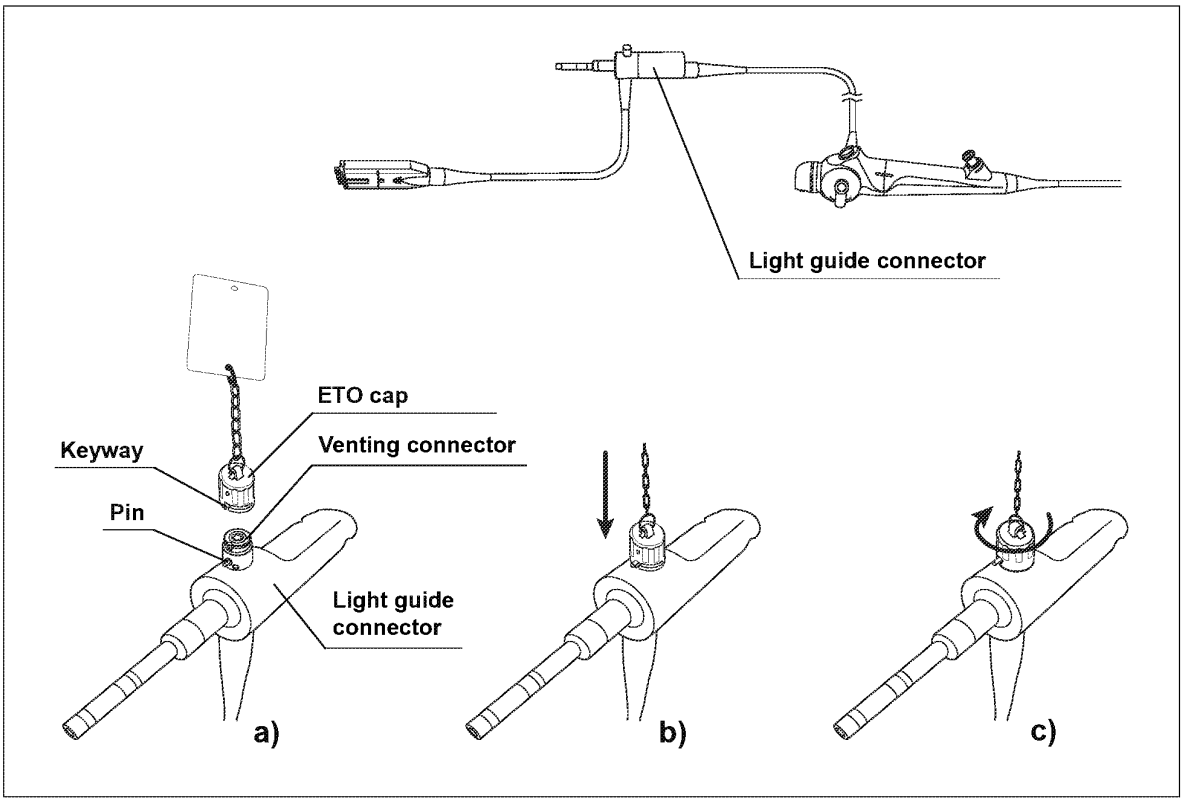

Figure 5.60

a) Align the pin on the venting connector with the keyway on the ETO cap;
b) Push the ETO cap towards the light guide connector of the endoscope until it stops;
c) Rotate the ETO cap clockwise (approximately 90°) until it stops.

4 When sterilizing with the STERRAD® 100S Sterilization System, depending on the inner diameter/length of channel, it is necessary to attach the booster (REF15400) to instrument channel of the endoscope according to the instructions of the sterilizer manufacturer.

5 Place the endoscope upon an instrument tray and double wrap the tray with sterilization wraps. Use a STERRAD® compatible instrument tray and sterilization wraps.

6 Sterilize the packaged endoscope, according to the instructions of the sterilizer manufacturer.

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5.9 Presoaking the endoscope

If manual cleaning could not be performed within 1 hour after the patient procedure or if you are not sure whether manual cleaning could be performed within 1 hour, presoaking the endoscope in detergent solution before manually cleaning the endoscope may be required to wet and loosen debris that has dried and hardened onto the endoscope's surfaces. Follow the procedure described below.

WARNING

- If manual cleaning could not be performed within 24 hours after the patient procedure or if you are not sure whether manual cleaning could be performed within 24 hours, dried debris may not be removed and reprocessing of the endoscope may not be performed effectively.
- Do not reuse the detergent solution used for presoak. If performing manual cleaning with the detergent solution used for presoak, reprocessing of the endoscope may not be performed effectively.

CAUTION

Presoak the endoscope only if manual cleaning of the endoscope was delayed for more than 1 hour or if you are not sure whether manual cleaning could be performed within 1 hour. Unnecessary long-term immersions should be avoided. Consecutive reprocessing sessions using extended immersion may damage the endoscope.

Equipment needed

Prepare the following equipment.

- **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Detergent solution containing enzymes (Refer to Section 3.4, "Detergent solution")**
- **Clean 30 ml (30 cc) syringes**

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Presoak the endoscope

1. If a leakage test has not been performed, perform a leakage test according to Section 5.4, “Leakage testing of the endoscope”.
2. Fill a clean, large basin with the detergent solution containing enzymes at the temperature and concentration recommended by the detergent manufacturer.
3. Completely immerse the entire endoscope in the detergent solution.
4. Fill a clean 30 ml syringe with the detergent solution.
5. While immersing the entire endoscope completely in the detergent solution, attach the syringe to the instrument channel port.
6. While immersing the entire endoscope completely in the detergent solution, flush the channel with 30 ml of the detergent solution. Confirm that air bubbles exit from the distal end of the endoscope during the flush to make sure that the instrument channel is not clogged.
7. When air bubbles did not exit from the distal end of the endoscope in Step 6, immerse the endoscope in the detergent solution for 30 minutes. And then repeat Step 4 through 6 to perform additional flushes of the instrument channel port.
8. While immersing the entire endoscope completely in the detergent solution, detach the syringe from the endoscope.
9. Allow the endoscope to soak completely in the detergent solution for 0.5 to 1 hour. Do not immerse the endoscope for more than 1 hour. Use a clock or timer to accurately measure the immersion time.
10. Remove the endoscope from the detergent solution.
11. Return to Section 5.5, “Manually cleaning the endoscope” and reprocess according to the procedure. Use the detergent solution containing enzymes in manual cleaning. Even when AER, perform all procedures according to Section 5.5 after presoaking.

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Chapter 6 Reprocessing Endoscopes and Accessories Using an AER

6.1 Reprocessing endoscopes using AER (OER series)

Follow the workflow described in Section 4.2, "Workflow for manually cleaning and manually or automated disinfecting endoscopes and accessories" when reprocessing endoscopes with OER series. Be sure to attach all required connectors to the endoscope. For details concerning appropriate connectors, refer to the instructions of the each OER model.

CAUTION

After reprocessing the endoscope using an OER series, dry the electrical contacts of the endoscope connector not by air-drying but by wiping with sterile lint-free cloths. Otherwise, hard water residue may be deposited on the electrical contacts, which may cause an abnormal endoscopic image when the endoscope is used.

When setting the endoscope in the OER series, Refer to the instruction manual of each OER model.

NOTE

- When cleaning and disinfecting the endoscope in the OER series, use connectors that are compatible with the endoscope model. The compatible connectors for the endoscope model are listed in the "List of Compatible Endoscopes/Connecting Tubes" and the instruction manual for the each OER model, or Table 6.1.

	Connecting tube for instrument channel	Leak test air tube
OER-AW*1 OER-Pro*2 OER-Mini*3	MAJ-1515	MAJ-821
OER-Elite*2	MAJ-2117	MAJ-2127

Table 6.1

*1 OER-AW is available in some areas other than the USA.

*2 OER-Pro and OER-Elite are available in the USA and some areas.

*3 OER-Mini is only available in the USA.

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NOTE

- When the endoscope is cleaned and disinfected simultaneously in combination with an endoscope of the same or another model using the each OER model, see the group number of the endoscopes shown in the "List of Compatible Endoscopes/Connecting Tubes" and the instruction manual for each OER model to confirm the combination. The group numbers of the endoscope model are listed in Table 6.2.

	OER-AW	OER-Pro	OER-Mini	OER-Elite
CYF-V2/V2R	Group 2	Group 2	Group 1	Group 2

Table 6.2

■ *Dry the endoscope*

Refer to "■ Dry the endoscope" on page 59 for the endoscope as the procedures are same.

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Chapter 7 Storage and Disposal

7.1 Precaution of storage and disposal

WARNING

- After reprocessing, maintain appropriate transportation and storage procedures to keep reprocessed endoscopes and accessories away from contaminated equipment. If the reprocessed endoscope or accessories become contaminated before subsequent patient procedures, they could pose an infection control risk to patients and/or operators who touch them.
- Establish a local policy regarding the method and frequency of cleaning and disinfecting the endoscope storage cabinet, which staff members can access the cabinet, which items can be stored in the cabinet, etc.
- Improper storage practices, such as not thoroughly drying external and internal surfaces (lumens) prior to storage, will lead to an infection control risk.

CAUTION

- Store the endoscope and accessories in an endoscope storage cabinet which also protects the equipment from physical damage.
- To prevent damage, do not store the endoscope and/or accessories in direct sunlight, at high temperatures, in high humidity, or exposed to X-rays, ultraviolet rays, or ozone.
- To prevent damage, do not store the endoscope and/or accessories with chemicals or in a gas-generating area.
- Do not coil the endoscope's insertion tube or universal cord with a diameter of less than 10 cm. Such improper storage may damage the endoscope.

NOTE

Some national or professional guidelines recommend checking the quality of the final drying and if necessary, drying endoscopes manually with compressed filtered air before storage.

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7.2 Storing the disinfected endoscope and accessories

WARNING

- Proper storage procedures are as important as proper reprocessing procedures in maintaining good infection control practices. Be sure that the endoscope storage cabinet is properly maintained, clean, dry, and well ventilated. All equipment must be thoroughly dried prior to storage. Microorganisms proliferate in wet/moist environments. Keep the cabinet doors closed to protect the equipment from environmental contaminants and accidental contact. Limit access to stored equipment by unauthorized personnel.
- Store only adequately reprocessed endoscopes and accessories in the endoscope storage cabinet.
- Do not store the endoscope and/or accessories in the endoscope's carrying case. The carrying case does not provide a proper storage environment for patient-ready endoscopes. Storing patient-ready endoscopes in the carrying case may pose an infection control risk. Use the carrying case only for shipping the endoscope and/or accessories. Any endoscope or accessory removed from a carrying case must be reprocessed prior to patient use or storage in an endoscope storage cabinet.
- Never put a dirty endoscope into the carrying case, as it will contaminate the carrying case. It is not possible to adequately decontaminate a contaminated carrying case for further use as a shipping case.

NOTE

- Some national or professional guidelines recommend checking the quality of the final drying and if necessary, drying endoscopes manually with compressed filtered air before storage.
- Some professional guidelines as well as Olympus recommend storing endoscopes in an endoscope storage cabinet with the insertion tube and the universal cord hanging vertically.

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1 Confirm that "■ Dry the endoscope" on page 59 was performed. If not, dry the endoscope according to the procedure.

2 Place the endoscope's angulation lock in the "F▼" (or free) position.

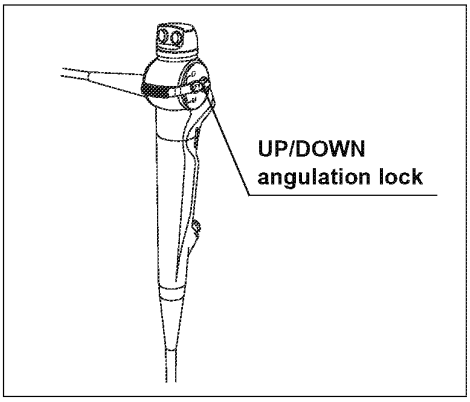

Figure 7.1

3 Store the disinfected endoscope and accessories properly.

7.3 Storing the sterilized endoscope and accessories

CAUTION

Do not damage the sterile packaging.

Store the sterilized endoscope and accessories in a proper storage cabinet, following your institutional guidelines.

NOTE

Sterile endoscopes may be stored flat in their sterile packaging.

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7.4 Disposal

When disposing of the endoscope, accessories, packaging, and reprocessing supplies (such as gloves, cloths, and the liquids used for reprocessing), handle these items in a manner that will prevent the spread of contamination from the reprocessing area, and follow all applicable national and local laws regarding disposal.

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CONFIDENTIAL

STUDY TITLE

ISO Intracutaneous Irritation Study

TEST ARTICLE NAME

VISERA CYSTO-NEPHRO VIDEOSCOPE
OLYMPUS CYF TYPE V2 and Luer-Split MAJ-2092

TEST ARTICLE IDENTIFICATION

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(b)(4)

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CONFIDENTIAL

STUDY TITLE

ISO Intracutaneous Irritation Study

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STUDY TITLE

ISO Intracutaneous Irritation Study - Extract

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Test Report

Title

High Level Disinfection test Using OER-Mini with Acecide-C of CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH

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Dear Ms. Kaplan,

Thank you for agreeing to speak with us yesterday. The additional information that you provided was helpful in determining our response for Question #1. The additional information that you have requested is provided below.

Again, if you need any other information, please let me know.

Best regards,

Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>

Sent: Monday, July 25, 2022 9:48 AM

To: Teffany Hutto <teffany.hutto@olympus.com>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov

Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Dear Teffany,

Thank you for your response. I have a few clarifying questions:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Please respond by tomorrow, July 26, to facilitate a timely review of your submission.

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: 301-796-1863

esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

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[cid:image013.jpg@01D8A0C7.B233E0B0]<https://www.facebook.com/FDA>
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[cid:image016.jpg@01D8A0C7.B233E0B0] <http://secure-web.cisco.com/1jI0okb0DGz6d8a94DkWFRVvuKoey4ZHOE5bSBseKuKJxsPwblZxzajV5TpKB3_CH4Xxoi6tGcZhbV4EAHokuQ6sPhdJqya7mdCaIvnnCjsOYMh373GDXRzlZlZK8A4jN-cnorEfpE2tnkUmdGgxFd_baI9c2_tXXerAB-s8EPwzOiSyMiPiuyXF_YBnGVAa_Pzgl4CCUN5VTCaiRyRMuIw/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image017.jpg@01D8A0C7.B233E0B0]
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From: Teffany Hutto <teffany.hutto@olympus.com<mailto:teffany.hutto@olympus.com>>

Sent: Monday, July 25, 2022 8:21 AM

To: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov<mailto:Esther.Kaplan@fda.hhs.gov>>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov<mailto:Reginald.Avery@fda.hhs.gov>>; K221683@docs.fda.gov<mailto:K221683@docs.fda.gov>

Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Kaplan,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

The requested information has been provided below. If you have any other questions, please let me know.

Best regards,

Teffany Hutto

Consultant for Olympus Medical.

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov<mailto:Esther.Kaplan@fda.hhs.gov>>

Sent: Wednesday, July 20, 2022 8:43 AM

To: Teffany Hutto <teffany.hutto@olympus.com<mailto:teffany.hutto@olympus.com>>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov<mailto:Reginald.Avery@fda.hhs.gov>>; K221683@docs.fda.gov<mailto:K221683@docs.fda.gov>

Subject: [EXTERNAL] K221683 Interactive Review Request #1

You don't often get email from esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>. Learn why this is important<https://secure-web.cisco.com/1HSCqHZMspigePNJuLaL0upTTlPEIr-D2ycnwSXR5Lq4q8r68NxW55joD8UnJj9g_D3Xfac1FIKokY9EFsuDuNzTtFsKtDHJsIGWjNrnGARWtNE0vuPzU1hQ7g9HuzelTm5lgQOzNExBZry_U1d7OwKzOEybRKWXD_NGoKmusbEXAibr2cJonr3mpP9D5baDiyZAkctVj9bSvx9CTIEbXSQ/https%3A%2F%2Faka.ms%2FLearnAboutSenderIdentification>

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Dear Ms. Hutto,

I am the lead reviewer for your submission for the Cysto-Nephro Videoscopes Olympus CYF Type V2/V2R and VH/VHR. This email is a request for information to facilitate interactive review of the device. As the review of your device continues I may send out additional requests for information the review team needs to make a determination on the substantial equivalence of your device to the selected predicate.

Please address the following:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please reply via email by COB July 25, to facilitate timely review of your submission. Be sure to copy the file folder address K221683@docs.fda.gov<mailto:K221683@docs.fda.gov> on your reply to help maintain the record of our communication.

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: 301-796-1863

esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

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[cid:image016.jpg@01D8A0C7.B233E0B0] <http://secure-web.cisco.com/1WfnODOIry9z9Bl5jHKufqaahDz4aK5Ny6W1PNy9roy5PYufIK2hBQ5WTjT6mE0tqBOsMgqnzL_9wlp_PwpnMfC64WS2p3-Y1VnsgVj7IylmlL_de_OGuxrVub1bYFx5SliKO34xrKlN-zGLM365wh-T5fX8AAW6P6umysF6ynfuYQEDsFyAyQxZsSEyIOHligq9YevUZWb8ulDe8l5yMEQ/http%3A%2F%2Fwww.flickr.com%2Fphotos%2Ffdaphotos%2F> [cid:image017.jpg@01D8A0C7.B233E0B0] <http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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Identification information : (b)(4)

OLYMPUS

Test Report

Title
Cleaning test Using OER-Pro with EndoQuick of OES
CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5

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Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Title	[Report] Implementation of biological safety testing preconditioning (CYF-V2 and MAJ-2092)

(b)(4)

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Section 18.4

Color Performance

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Document Released under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Section 18.4
Color Performance

1. Test performed

(b)(4)

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FDA/CDRH/DCC
JUN 14 2022
RECEIVED

June 13, 2022

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue,
Silver Spring, Maryland 20993-0002

K221683

Re: Traditional Premarket [510(k)] Notification- CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH/VHR and VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and CYF TYPE V2R – REPLACEMENT COPY – K221683

Dear Sir or Madam;

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, Olympus Medical Systems Corporation is notifying the Food and Drug Administration of its intent to market the CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH and CYF-VHR, VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and CYF TYPE V2R. As a result of the retrospective review on the regulatory history of the subject devices, Olympus has concluded that the attached "Catch-up" 510(k) would be necessary for the subject devices, which were previously introduced via letter-to-file before. The FDA requested Olympus to submit via premarket submission 510(k) notification pathway as remediation.

Olympus Corporation of the Americas is submitting this premarket notification on behalf of Olympus Medical Systems Corporation.

The accompanying information is submitted as demonstration of the device's substantial equivalence to the legally marketed (predicate) devices. An electronic copy of this submission is being submitted per the instructions accessed at "eCopy Program for Medical Device Submissions."

Olympus Medical Systems Corporation considers our intent to market this device as confidential commercial information and requests that it is treated as such by the FDA. The existence of this submission, the data, and other information that it contains are confidential, and the protection afforded to such confidential information under 21 CFR 807.95(b).

Thank you in advance for your consideration of our submission. If you have any questions or require additional information, please contact me at teffany.hutto@olympus.com or by phone at (512) 508-6550

Sincerely,

(b)(6)

Teffany Hutto
Regulatory Consultant for Olympus Corporation of the Americas

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

FDA/CDRH/DCC
JUN 13 2022
RECEIVED

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K221683

June 10, 2022

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue,
Silver Spring, Maryland 20993-0002

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S3

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K221683

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FDA/CDRH/DCC
JUN 10 2022
RECEIVED

June 9, 2022

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue,
Silver Spring, Maryland 20993-0002

Re: Traditional Premarket [510(k)] Notification- CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH/VHR and VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and CYF TYPE V2R

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Section 18
Performance Testing – Bench

(b)(4)

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Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Report for residual toxicity evaluation (rinsing validation) after OER-Elite/ Pro(Acecid-C)/Mini disinfection for CYF-V2/V2R and MAJ-2092

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Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Step-by-Step Comparison of Automated HLD (OER-Pro/Aldahol 1.8 and Acecide-C)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Report for residual toxicity evaluation (rinsing validation) after manual disinfection for CYF-VH/VHR and MAJ-2092

(b)(4)

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Document Released Under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Section 17.1.7

Test Condition for EMC Test

(b)(4)

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Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Dear Ms. Kaplan,

Please see the information provided below to address your question for Interactive Review Request #2.

Best regards,
Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Thursday, July 28, 2022 9:56 AM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: [EXTERNAL] K221683 - Interactive Review Request #2

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Dear Teffany,

This is another request for interactive review of your submission. Please address the following concern:

(b)(4)

Please respond by COB Friday, July 29, to facilitate timely review of your device.

Regards,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
esther.kaplan@fda.hhs.gov

Excellent customer service is important to us! Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=1523&S=E

Dear Ms. Kaplan,

Thank you for reviewing our response so quickly. I will work to make sure the requested information is received by tomorrow.

Have a good day,
Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Monday, July 25, 2022 9:48 AM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Dear Teffany,

Thank you for your response. I have a few clarifying questions:

(b)(4)

Please respond by tomorrow, July 26, to facilitate a timely review of your submission.

Thank you,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
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esther.kaplan@fda.hhs.gov

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From: Teffany Hutto <teffany.hutto@olympus.com>
Sent: Monday, July 25, 2022 8:21 AM
To: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Kaplan,

The requested information has been provided below. If you have any other questions, please let me know.

Best regards,
Teffany Hutto
Consultant for Olympus Medical.

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Wednesday, July 20, 2022 8:43 AM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Subject: [EXTERNAL] K221683 Interactive Review Request #1

You don't often get email from esther.kaplan@fda.hhs.gov. Learn why this is important

Dear Ms. Hutto,

I am the lead reviewer for your submission for the Cysto-Nephro Videoscopes Olympus CYF Type V2/V2R and VH/VHR. This email is a request for information to facilitate interactive review of the device. As the review of your device continues I may send out additional requests for information the review team needs to make a determination on the substantial equivalence of your device to the selected predicate.

Please address the following:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

(b)(4)

Please reply via email by COB July 25, to facilitate timely review of your submission. Be sure to copy the file folder address K221683@docs.fda.gov on your reply to help maintain the record of our communication.

Thank you,

Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
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Tel: 301-796-1863
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OLYMPUS

June 9, 2022

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue,
Silver Spring, Maryland 20993-0002

Re: Traditional Premarket [510(k)] Notification- CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH/VHR and VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and CYF TYPE V2R

Dear Sir or Madam;

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, Olympus Medical Systems Corporation is notifying the Food and Drug Administration of its intent to market the CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH and CYF-VHR, VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and CYF TYPE V2R. As a result of the retrospective review on the regulatory history of the subject devices, Olympus has concluded that the attached "Catch-up" 510(k) would be necessary for the subject devices, which were previously introduced via letter-to-file before. The FDA requested Olympus to submit via premarket submission 510(k) notification pathway as remediation.

Olympus Corporation of the Americas is submitting this premarket notification on behalf of Olympus Medical Systems Corporation.

The accompanying information is submitted as demonstration of the device's substantial equivalence to the legally marketed (predicate) devices. An electronic copy of this submission is being submitted per the instructions accessed at "eCopy Program for Medical Device Submissions."

Olympus Medical Systems Corporation considers our intent to market this device as confidential commercial information and requests that it is treated as such by the FDA. The existence of this submission, the data, and other information that it contains are confidential, and the protection afforded to such confidential information under 21 CFR 807.95(b).

Thank you in advance for your consideration of our submission. If you have any questions or require additional information, please contact me at teffany.hutto@olympus.com or by phone at (512) 508-6550

Sincerely,

(b)(6)

Teffany Hutto
Regulatory Consultant for Olympus Corporation of the Americas

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

GLP REPORT

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

CONFIDENTIAL

STUDY TITLE

USP Rabbit Pyrogen Study, Material Mediated

TEST ARTICLE NAME

CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH
and Luer-Split MAJ-2092

TEST ARTICLE IDENTIFICATION

(b)(4)

(b)(4)

Questions? Contact FDA at CDRH-PRODUCTDISTATUS@fda.hhs.gov or 301-796-8118

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GLP PROTOCOL

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

USP Rabbit Pyrogen Study, Material Mediated

(b)(4)

Questions? Contact FDA/CDRH/OSE/DIDSR CDRH-FOISTAFF-US@fda.hhs.gov or 301-796-8118

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Identification information : (b)(4)

OLYMPUS

Test Report

Title
Cleaning test Using OER-Mini with EndoQuick of
OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5

(b)(4)

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Dear Ms. Kaplan,

Thank you very much for this additional information. I will make sure it gets communicated to Olympus.

Best regards,

Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>

Sent: Tuesday, August 23, 2022 11:32 AM

To: Teffany Hutto <teffany.hutto@olympus.com>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov

Subject: [EXTERNAL] K221683 Teleconference Follow-up - EMC testing

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Hello Teffany,

(b)(4)

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: 301-796-1863

esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

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2951 Ishikawa-machi
Hachioji-shi, Tokyo, 192-8507
JAPAN

Delayed Cleaning Validation (EndozimeAW) for CYF-5 GLP Report

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Report for residual toxicity evaluation (rinsing validation) after manual disinfection for CYF-V2/V2R and MAJ-2092

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(b)(4)

(b)(4)

TEST REPORT

Report number	: (b)(4)
Applicant	: OLYMPUS MEDICAL SYSTEMS CORP.
Equipment under test (EUT)	: VISERA CYSTO-NEPHRO VIDEOSCOPE
Model number	: OLYMPUS CYF TYPE V2
Testing standard	: IEC60601-1-2 : 2014

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Sponsor:
(b)(4)
Olympus Medical Systems Corp.
2951 Ishikawa-machi
Hachioji-shi, Tokyo, 192-8507
JAPAN

Simulated Use Cycles GLP Report

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Form Approved: OMB No. 0910-0511 Expiration Date: August 31, 2022. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

OLYMPUS SURGICAL TECHNOLOGIES AMERICA
800 West Park Drive
Westboro
MA 01581
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****9904

2. CONTACT NAME
Angela Caputo

2.1 E-MAIL ADDRESS
angela.caputo@olympus-osta.com

2.2 TELEPHONE NUMBER (include Area code)
508-8042667

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice
[ ] De Novo Request

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)

[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES
[X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Page 1 of 1 Processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 14-Mar-2022

Form FDA 3601 (08/19)

"Close Window" Print Cover sheet

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Section 8

Financial Certification or Disclosure Statement

This section does not apply. No clinical study was performed.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)
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(b)(4) File No. (b)(4)

TEST REPORT

APPLICANT	OLYMPUS MEDICAL SYSTEMS CORP.
ADDRESS	2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan
PRODUCTS	CYSTO-NEPHRO VIDEOSCOPE
MODEL NO.	OLYMPUS CYF-VH, OLYMPUS CYF-VHR
SERIAL NO.	7143588
TEST STANDARD	IEC 60601-2-18: 2009
ADDITIONAL INFORMATION	-

(b)(4)

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Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ **Traditional** ☐ **Abbreviated** ☐ **Special**

(Should be completed within 15 days of DCC receipt)
The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K221683 Date Received by DCC: Jun 14, 2022

Lead Reviewer: Esther Kaplan

Center: CDRH Office: OHT 3 Division: DHT3B

Decision:

◉ Accept. If Accept, notify submitter.

○ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ◉ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	Yes	No	N/A
1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* ~~If the product does not appear to be a device or such a combination product, mark "No."~~	☒	☐	
Comments:			
2 Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in section 503(g)(5)(C)(ii)-(v) of the FD&C Act? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.*	☐	☐	☒
Comments:			
5 Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., class III type and PMA required, or class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6 Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☐	☒
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action. Note that, for a device which is clearly ineligible for a 510(k) submission (such as a device type which is class III requiring PMA or class I/II and 510(k) exempt), this may be considered a basis for a refusal to accept the submission. A 510(k) submitted for a class I/II, 510(k)-exempt device that trips the limitations of the exemption would not be refused on this basis.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

Records processed under FOIA Request 2024-3254, Released by CDRH on 08-29-2024

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	001 pa
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	
3) All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	003 pa
Comments:			

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Records processed under FOIA Request 2024-3284, Released by CDRH on 08-29-2024

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				☐	
a) Device trade/proprietary name	☒	☐			S3 p2
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			S3 p3
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). *See recommended format (*https://www.fda.gov/media/86323/download*).*	☒	☐		☐	S4
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	S5
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(i) *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☒	☐		☐	S6
6) Submission is a class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☐		☒	☐	
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	S3
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☒	☐	☐		Att 3.1
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☐	
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		S1
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			S9

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission cites non-FDA-recognized voluntary consensus standard(s).	☒		☐		S9 p4
i) The basis of use is included along with the underlying information or data that supports how the standard was used.	☒	☐			S18
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☐		☒	☐	
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
14) The submission includes descriptive information for the device, including the following:				☐	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐	☐		S11 p19
c) A list and description of each device for which clearance is requested.	☒	☐	☐		S11 p1
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			S11 p14
15) Device is intended to be marketed with accessories and/or as part of a system.	☒		☐	☐	
a) Submission includes a list of all accessories to be marketed with the subject device.	☒	☐			S11 p21
b) Submission includes a description (as detailed in item 14(a), 14(b) and 14(d) above) of each accessory.	☒	☐	☐		
c) A 510(k) number is provided for each accessory that received a prior 510(k) clearance. **AND** A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☒	☐			
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐			S12 p1
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☐	
a) Indications for Use	☒	☐			S12 p2
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			S12 p6
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☒	S13
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐			
Comments:					
19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		☐	S13 p9
20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling).	☒	☐	☐	☐	S13 p9

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.	☐		☒		
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	☐	☐	☒	☐	
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
☐ Provided sterile, intended to be single-use					
☒ Requires processing during its use-life					
☐ Non-sterile when used (and no processing required)					
☐ Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*					
23) Assessment of the need for cleaning and subsequent disinfection or sterilization information				☐	
a) Identification of device and/or accessories, if applicable, that are provided sterile.	☐	☐	☒		
b) Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected.	☒	☐	☐		
c) Identification of device, and/or accessories, if applicable, that are reusable.	☒	☐	☐		
24) If the device and/or accessories, if applicable, are provided sterile:			☒	☐	
25) If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected:			☐	☐	
a) Cleaning method is provided in labeling for each device and/or accessory, if applicable.	☒	☐	☐		Att 13.4
b) Disinfection method is provided in labeling for each device and/or accessory, if applicable.	☒	☐	☐		Att 13.4
c) Sterilization method is provided in labeling for each device and/or accessory, if applicable.	☒	☐	☐		Att 13.4

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
d) Device types in this submission are listed in the Federal Register (FR) Notice entitled "Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice, available at https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable).	☒		☐		
i) If device types in this submission are included in the Reprocessing FR Notice, the submission includes protocols and test reports for validating the reprocessing instructions.	☒	☐	☐		S14
26) The device has a device-specific guidance document, special controls, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.	☐		☒	☐	
F. Shelf Life					
27) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐	☐	☐	S14 p2
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	☐	☐	☒	☐	
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐		☐	S14 p2
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
Submission states that there: (one of the below must be checked)		☐		☐	
☒ Are direct or indirect tissue-contacting components.					
☐ Are no direct or indirect tissue-contacting components.					
☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐ Tissue contact information not needed for this device (e.g., software-only device)					
☐ Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
30) Submission includes a list identifying each of tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		☐	S15 p1
31) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter).	☒	☐		☐	S15 p2

Questions? Contact CAVD/PMO CE Lead at CDRH-FOIAPUBLIC@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
32) For a biocompatibility assessment of tissue-contacting components, submission includes: – Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☒	☐		☐	S15 p3
H. Software					
Submission states that the device: (one of the below must be checked)		☐		☐	
☒ Does contain software/firmware					
☐ Does not contain software/firmware					
☐ Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Software/firmware information not needed for this device (e.g., surgical suture, condom)					
☐ Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
33) Submission includes a statement of software level of concern and rationale for the software level of concern.	☒	☐		☐	S16 p2
34) All applicable software documentation provided based on level of concern identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒	☐		☐	S16
I. Cybersecurity					
Submission states that the device: *(one of the below must be checked)*		☐		☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
☒ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)					
☐ Does not contain external interfaces as described above					
☐ Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom)					
☐ Cybersecurity information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
35) All applicable documentation identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0. **OR** Submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒	☐		☐	16 p22
J. Electrical Safety and EMC					
Electrical Safety Submission states that the device: *(one of the below must be checked)*		☐		☐	S17
☒ Does require electrical safety evaluation					
☐ Does not require electrical safety evaluation					
☐ Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Electrical safety information not needed for this device (e.g., surgical suture, condom)					
☐ Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
36) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard), **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		☐	S17
EMC Submission states that the device: (one of the below must be checked)		☐		☐	S17
☒ Does require EMC evaluation					
☐ Does not require EMC evaluation					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
☐ Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ EMC information not needed for this device (e.g., surgical suture, condom)					
☐ EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
37) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		☐	S17
K. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐		
38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.	☒	☐	☐	☐	S18
a) Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☒	☐			
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	☐		☒	☐	
40) If literature is referenced in the submission, submission includes:			☐	X	
a) Legible reprints or a summary of each article.	☒	☐			S18
b) Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☐	☒			
Comments:	(b)(4)				
41) For each completed animal study, the submission provides the following:			☒	☐	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
L. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)			☐		
☐ is an in vitro diagnostic device.					
☒ is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

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Digital Signature Concurrence Table

Reviewer Sign-Off	Esther L. Kaplan -S 2022.06.23 09:27:51 -04'00'
Management Sign-Off (digital signature optional)*	

* Management review of checklist and concurrence with with decision required.

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Section 12.2

Attachment

— Depth of Field —

This section describes how to define DOF (depth of field).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. How to define DOF

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

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(b)(4)

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(b)(4)

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(b)(4)

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Section 16-1

Software and Cybersecurity for CYF-V2/V2R

This document describes the software of videoscopes, CYF-V2/V2R, and presents an overview of Olympus' compliance to the FDA guidance document titled *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued on May 11, 2005.

(b)(4)

The structure of this document is as follows:

Contents

1.0 Level of Concern
2.0 Software Description
3.0 Device Hazard Analysis
4.0 Software Requirements Specification
5.0 Architecture Design Chart
6.0 Software Design Specification
7.0 Traceability Analysis
8.0 Software Development Environment Description
9.0 Verification and Validation Documentation
10.0 Revision Level History
11.0 Unresolved Anomalies (Bugs or Defects)
12.0 Cybersecurity Documentation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1.0 Level of Concern

(b)(4)

Level of Concern was determined by answering questions in "Guidance for the content of Premarket Submissions for Software Contained in Medical Devices" as shown in **Table 1-1** and **Table 1-2**.

Table 1-1. (b)(4) Level of Concern

(b)(4)		Yes/ No	Reason
1.	Does the Software Device qualify as Blood Establishment Computer Software? (Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.)	(b)(4)	
2.	Is the Software Device intended to be used in combination with a drug or biologic?		
3.	Is the Software Device an accessory to a medical device that has a Major Level of Concern?		
4.	Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:		
a.	Does the Software Device control a life supporting or life sustaining function?		
b.	Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?		
c.	Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?		
d.	Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)	Yes/ No	Reason
e. Does the Software Device provide vital signs monitoring and alarms for potentially life-threatening situations in which medical intervention is necessary?	(b)(4)	

Table 1-2. (b)(4) Level of Concern

(b)(4)	Yes/ No	Reason
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	(b)(4)	
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?		
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?		

2.0 Software Description

This is a software function that transmits the data for each videoscope to the video system center in the combination of the corresponding video system center and videoscope.

2.1 Device Features

Device features of video scope are shown in Section 4.1 INFORMATION ABOUT THE PRODUCT of this document.

2.2 Intended Operational Environments

Table 2-1: Intended Operational Environment

Programming Language	See **Section 4.2.1.2.2**
Hardware Platform	
Operating System	
Use of Off-The-Shelf (OTS) Software	(b)(4)

3.0 Device Hazard Analysis

The tabular description of identified hardware and software hazards can be found in **Attachment 21-A**. Software related hazards are detailed in **Table 3-1**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4.0 Software Requirements Specification

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4.1 INFORMATION ABOUT THE PRODUCT

4.1.1 Nomenclature and Functions

Refer to **Section 11 - Device Description** of this 510(k) submission for the instrument nomenclature and functions of the videoscope.

4.1.2 Functions Controlled by Software

4.1.2.1 Product Functions

The function of this product is to acquire image data entering from the tip of the scope by Charge Coupled Device (CCD), and send the analog signal to the video system center.

Table 4-1: Functions Controlled by Software

Function	Description
Software controls the following functions	(b)(4)

4.2 System Requirement

4.2.1 Product Functions

4.2.1.1 Quality Requirements

4.2.1.1.1 Internal Software Tests and Checks Requirements

For details of the internal software tests and checks requirements, refer to Section 9 Verification and Validation Documentation of this document.

4.2.1.1.2 Error and Interrupt Handling Requirements

Table 4-2: Error and Interrupt Handling Requirements

Item	Functional requirement
Command reception interrupt from external devices	(b)(4)
Communication timer function	
Exception handling	
Power on reset	

(b)(4)

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8.0 Software Development Environment Description

8.1 Development Steps

To develop software the following requirements must be observed.

8.1.1 Outline of Development Steps

Software development works explained in Section 8.1.2 of this document are based on the V-model as described in **Figure 8-1**.

(b)(4)

(b)(4), the software in the software system is not subject to requirements of **Section 8.1.2**. (b)(4) (b)(4) the software system contained in such a subsystem is not subject to requirements of **Section 8.1.2**.

(b)(4)

Figure 8-1: V-model

8.1.2 Software System Development Steps and Details of Work

8.1.2.1 Software requirement specification analysis/definition

Software requirement specification must be defined and reviewed. As appropriate, the software requirement specification (b)(4)

8.1.2.2 Software development plan

- (b)(4)

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8.1.2.3 Software Basic Design

- Basic software design must be established on the basis of the software requirement specification to prepare a software basic design specification.
- (b)(4)

8.1.2.4 Software Detailed Design

- Detailed software design must be established on the basis of the software basic design specification to prepare a software detailed design specification.
- (b)(4)

8.1.2.5 Software Implementation

- (b)(4)

8.1.2.6 Software Unit Test

- (b)(4)

8.1.2.7 Software Integration/Integration Test

- (b)(4)

8.1.2.8 Software System Test

- (b)(4)

(b)(4)

8.1.2.9 Software Maintenance

(1) Software Maintenance Plan

- Software maintenance plan must be established and documented.

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- (b)(4)

(2) Perform of Software Maintenance

- (b)(4)

(3) Availability of Update Software

- (b)(4)

8.2 Development Support Activities

The requirements specified in Sections 8.2.1 through 8.2.5 below must be observed when the software development work defined in Section 8.1 is performed.

(b)(4)

8.2.1 Risk Management

Risk management must be implemented on the basis of the risk management plan.

8.2.1.1 Classifying the Level of Concern for the Software System

If medical equipment is subject to 510(k) clearance to be marketed in the US, the level of concern must be assigned to the software.

8.2.2 Traceability Analysis

Traceability analysis must be analyzed to ensure that the deliverables from work depicted in **Figure 8-1** can be linked to Risk Management Table.

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Traceability analysis is also required between the deliverables from work shown in **Figure 8-1** and the risk management table. (b)(4)

(b)(4)

(b)(4)

8.2.3 Review

(1) Format of Review

- (b)(4)
-

(2) Timing of Review

- (b)(4)

(3) Review Results

- Review results must be kept as a (b)(4).

8.2.4 Configuration Management

(1) Schedule of Configuration Management

Configuration management must be performed and documented in accordance with the development plan. (b)(4)

(b)(4)

(2) Configuration Identification and Configuration Management

As for configuration management, configuration items and their versions are identified on the basis of the schedule of configuration management.

(b)(4)

(3) Change Control

(b)(4)

(4) Record of Configuration

Record the history of managed configuration items including system configuration.

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8.2.5 Preparation and management of Drawings and Documents

(b)(4)

- Documents
  a.
  b. (b)(4)

8.2.6 Outsourcing Process

(b)(4)

8.2.6.1 Selection of a supplier

(b)(4)

8.2.6.2 Order

(b)(4)

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(b)(4)

8.2.6.3 Acceptance Inspection

(b)(4)

8.2.7 Problem Resolution Process

8.2.7.1 Software Problem Resolution Process

(b)(4)

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The work items specified in **Figure 8-2** "Software problem resolution process" below must be done.

The following section (A) to (F) describes details of each work item:

(b)(4)

Figure 8-2: Software Problem Resolution Process

(b)(4)

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(b)(4)

8.3 OTS software

There is no OTS software.

8.3.1 Risk Management of OTS Software

Not Applicable.

8.3.2 Agreement with OTS providers

Not Applicable.

8.3.3 Order and acceptance test of OTS software

Not Applicable.

8.3.4 Evaluation and verification of OTS software

Not Applicable.

8.3.5 Maintenance of OTS software

Not Applicable.

9.0 Verification and Validation Documentation

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Section 18.13

Resolution

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Section 18.13
Resolution

(b)(4)

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From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 12/22/2022 6:19:14 PM
To: teffany.hutto@olympus.com
CC: DCCLetters@fda.hhs.gov
Subject: K221683/S001 Acknowledgement Letter
Attachments: K221683-S001-Acknowledgement Letter.pdf

December 22, 2022

Thank you for your submission. We have attached your acknowledgement letter for your records. If you have any questions about your acknowledgement letter, please contact us at DCCmailroom@fda.hhs.gov. Please do not reply to this email.

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Acknowledgement Letter

12/22/2022

Teffany Hutto, Regulatory Affairs Consultant
Olympus Corporation of the Americas
3500 Corporate Parkway P.O. BOX 610
Center Valley, PA 18034
UNITED STATES

Dear Teffany Hutto:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov .

Submision Number: K221683/S001
Received: 12/22/2022
Applicant: Olympus Medical Systems Corporation
Device: CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2R), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VH) and CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VHR)

We will notify you when the review of this submission document has been completed or if any additional information is required.If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm .

Sincerely yours,

Center for Devices and Radiological Health

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Section 14.1.2

Step-by-Step Comparison of Cleaning Steps (Manual)

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Step-by-Step Comparison of the Cleaning Steps (Manual)

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June 23, 2022</br></br>

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your submission K221683, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review.

The lead reviewer assigned to your submission is me, Esther Kaplan. The file is being reviewed in Office of Health Technology 3, Division of Health Technology 3 B. The first line supervisor is the Assistant Director, Urological Devices. You may contact me at any point during the review if you have questions or concerns. You can provide valuable support for CDRH to continue to improve our programs by raising to the attention of management relevant issues that arise during the course of this review. If you feel there is an unresolved issue or a matter that requires additional attention, you should contact the Assistant Director. If your concern or issue is not addressed by the Assistant Director, you should contact the Division Director or OHT Director. The contact information for each management level can be found in the CDRH Management Directory.

We will contact you should we require any additional information during the course of the substantive review. FDA aims to apply the least burdensome principles when requesting additional information.

If you have general questions about the review process for your submission, you should contact OPEQSubmissionSupport@fda.hhs.gov.

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Section 18.10

Image Intensity Uniformity

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Section 18.10
Image Intensity Uniformity

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GLP PROTOCOL

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

USP Rabbit Pyrogen Study, Material Mediated

(b)(4)

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(b)(4)

Project Number: (b)(4)

Technical Memorandum
CONFIDENTIAL

Date: 12-APR-2022

To: Olympus Medical Systems Corporation
(b)(4)
2951 Ishikawa-cho
Hachioji-shi, Tokyo, 192-8507
Japan

From: (b)(4)

Subject: CYF-VH Particulate Observation Following Extraction

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-202

(b)(4)

Final Report

Test Description: **Extractables of CYF-V2**

Sponsor:

Olympus Surgical Technologies
9600 Louisiana Avenue
Brooklyn Park, MN 55445
US

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Teffany,

In addition to the interactive review request I sent earlier today, please also address the following:

(b)(4)

Please respond by COB Monday, August 1, to facilitate a timely review of your submission.

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: 301-796-1863

esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

[cid:image001.png@01D8A29B.80A7F0B0]<http://www.fda.gov/>

[cid:image002.jpg@01D8A29B.80A7F0B0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D8A29B.80A7F0B0] <https://twitter.com/US_FDA>
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Report Number: (b)(4) Report Revision: (b)(4)

Report Title: Safety Profile and Margin of Exposure Analysis for Metal and Organic Compounds Identified in Extracts from Cysto-nephro videoscope (CYF-VH-VHR)

Protocol Number: (b)(4) Protocol Revision: (b)(4)

(b)(4)

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OLYMPUS

Test Report

Title

High Level Disinfection test Using OER-Pro with Aldahol 1.8 of OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5

(b)(4)

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Section 17.2.4

Selection of Representative Video system center for Electrical Safety Test

(b)(4)

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Section 16-2

Software and Cybersecurity for CYF-VH/VHR

This document describes the software of videoscopes, CYF-VH/VHR, and presents an overview of Olympus' compliance to the FDA guidance document titled *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued on May 11, 2005.

(b)(4)

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Section 6
Truthful and Accuracy Statement

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required By 21 CFR 807.87(k))

[Subject Device]

VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2R
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VHR

I certify that, in my capacity as Manager of OLYMPUS MEDICAL SYSTEMS CORP., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)
[Signature]

Shinichiro Kawachi
[Typed Name]

Manager
Product Registration
Quality Assurance and Regulatory Affairs
[Title]

June 9, 2022
[Date]

[Premarket Notification 510(k) Number]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Document Released Under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Section 18.3
Composite durability test for CYF-V2/V2R and CYF-VH/VHR

(b)(4)

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Identification information (b)(4)

OLYMPUS

Test Report

Title

High Level Disinfection test Using OER-Pro with Acecide-C of CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH

(b)(4)

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Hello Teffany,

Thank you for your previous response. (b)(4)

(b)(4)

Please reply by end of day today, January 19 as the review cycle is coming to a close. Let me know if you will be unable to respond in that time.

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: 301-796-1863

esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

[cid:image001.png@01D92BE7.F7D261E0]<http://www.fda.gov/>

[cid:image002.jpg@01D92BE7.F7D261E0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D92BE7.F7D261E0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D92BE7.F7D261E0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D92BE7.F7D261E0] <http://www.flickr.com/photos/fdaphotos/>
[cid:image006.jpg@01D92BE7.F7D261E0]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Sumpter, Melanie * [Melanie.Sumpter@fda.hhs.gov]
Sent: 6/13/2022 8:31:45 PM
To: teffany.hutto@olympus.com
Subject: K221683 eCopy Hold Notification
Attachments: K221683 Letter.pdf; K221683 Attachment.pdf

Sincerely,
Melanie N. Sumpter
Technical Information Specialist - 510(k) Staff
CDRH Document Control Center
Melanie.Sumpter@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

eCopy Hold Letter

6/13/2022

Teffany Hutto, Regulatory Affairs Consultant
Olympus Corporation of the Americas
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610
UNITED STATES

Dear Teffany Hutto:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

Submission Number: K221690
Received: 06/10/2022
Applicant: Olympus Medical Systems Corp.
Device: OES CYSTONEPHRO FIBERSCOPE (OLYMPUS CYF-5), OES CYSTONEPHRO FIBERSCOPE (OLYMPUS CYF-5R), LIGHT GUIDE ADAPTER (MAJ-1413)

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. **You have received this letter because you have either not provided an eCopy or you provided an eCopy that failed the loading process because it did not meet the technical standards.** If you provided an eCopy that failed the loading process, then please see the attached document that identifies all reasons for the failure that need to be addressed. To understand the reasons for your eCopy failure, please refer to the eCopy guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf.

To verify your eCopy meets the technical standards prior to submitting to FDA, you may use the eCopy Validation Module (a voluntary tool that verifies the format of an eCopy you have already developed on your local drive) available on the eCopy Program webpage at https://www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-program-medical-device-submissions.

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Please write the specific submission number identified above AND "Replacement eCopy" directly on the CD (or other media) and send that with a paper copy of your cover letter (revised if applicable) to the CDRH Document Control Center (DCC) at the address below.

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

You should provide the complete content for the document, not just the corrected files or folders, in your replacement eCopy. **When your Replacement eCopy has been received and been verified as a valid eCopy, review of this submission will start as of that date.**

If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,

Center for Devices and Radiological Health

Attachment

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Attachment

Attachment for Submission Number(s):

K221683

The list below identifies the reason(s) why your eCopy failed FDA's eCopy validation process. All of these items need to be addressed or your eCopy will not pass the validation process.

1. **The PDF files were not sequentially numbered starting with 001, with no two PDF files having the same number.**

   There is a gap in the file sequence number found before 039_Section 15.6_(b)(4) CYF-VH_VHR Toxicological Risk Assessment.pdf

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REPORT

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

CONFIDENTIAL

STUDY TITLE

Subcontracted Testing – Identification by SEM-EDS and Microscopic FTIR

TEST ARTICLE NAME

(b)(4)

TEST ARTICLE IDENTIFICATION

N/A

TEST ARTICLE PHYSICAL DESCRIPTION

(b)(4)

TEST ARTICLE RECEIVED

January 17, 2022

(b)(4)

Questions? Contact [illegible] CDRH/OSE/DSD at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

ISO 9001:2015 CERTIFIED

(b)(4)

Test Report

Analysis of orange particulates in (b)(4) Induction 2 Saline

(b)(4)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Dear Ms. Kaplan,

Olympus has asked me to see if you're available for a quick phone call later today so that they can get clarification on what information they need to provide to address question #1. We can make ourselves available for any time that works for you.

Best regards,
Teffany

From: Teffany Hutto
Sent: Monday, July 25, 2022 9:54 AM
To: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

Dear Ms. Kaplan,

Thank you for reviewing our response so quickly. I will work to make sure the requested information is received by tomorrow.

Have a good day,
Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Monday, July 25, 2022 9:48 AM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Dear Teffany,

Thank you for your response. I have a few clarifying questions:

(b)(4)

Please respond by tomorrow, July 26, to facilitate a timely review of your submission.

Thank you,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
esther.kaplan@fda.hhs.gov

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From: Teffany Hutto <teffany.hutto@olympus.com>
Sent: Monday, July 25, 2022 8:21 AM
To: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Kaplan,

The requested information has been provided below. If you have any other questions, please let me know.

Best regards,
Teffany Hutto
Consultant for Olympus Medical.

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Wednesday, July 20, 2022 8:43 AM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: [EXTERNAL] K221683 Interactive Review Request #1

You don't often get email from esther.kaplan@fda.hhs.gov. Learn why this is important

Dear Ms. Hutto,

I am the lead reviewer for your submission for the Cysto-Nephro Videoscopes Olympus CYF Type V2/V2R and VH/VHR. This email is a request for information to facilitate interactive review of the device. As the review of your device continues I may send out additional requests for information the review team needs to make a determination on the substantial equivalence of your device to the selected predicate.

Please address the following:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Please reply via email by COB July 25, to facilitate timely review of your submission. Be sure to copy the file folder address K221683@docs.fda.gov on your reply to help maintain the record of our communication.

Thank you,

Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
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GLP REPORT AMENDMENT 1

TEST FACILITY

(b)(4)

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OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho
Hachioji-shi, Tokyo, 192-8507
Japan

CONFIDENTIAL

STUDY TITLE

Cytotoxicity Study Using the ISO Elution Method

TEST ARTICLE NAME

VISERA CYSTO-NEPHRO VIDEOSCOPE
OLYMPUS CYF TYPE V2 and Luer-Split MAJ-2092

TEST ARTICLE IDENTIFICATION

(b)(4)

(b)(4)

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GLP REPORT

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

CONFIDENTIAL

STUDY TITLE

Cytotoxicity Study Using the ISO Elution Method

TEST ARTICLE NAME

VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and Luer-Split MAJ-2092

TEST ARTICLE IDENTIFICATION

(b)(4)

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GLP PROTOCOL

TEST FACILITY

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SPONSOR

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OLYMPUS

REPROCESSING MANUAL

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-VH
OLYMPUS CYF-VHR

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Step-by-Step Comparison of Automated HLD (OER-mini/Acecide-C)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Step-by-Step Comparison of the Automated HLD (OER-mini/Acecide-C) Steps

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 3.3
Market survey results

(b)(4)

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Dear Ms. Kaplan,

Please see the information provided below to address your question for Interactive Review Request #2.

Best regards,

Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>

Sent: Thursday, July 28, 2022 9:56 AM

To: Teffany Hutto <teffany.hutto@olympus.com>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov

Subject: [EXTERNAL] K221683 - Interactive Review Request #2

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Dear Teffany,

This is another request for interactive review of your submission. Please address the following concern:

(b)(4)

Please respond by COB Friday, July 29, to facilitate timely review of your device.

Regards,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Tel: 301-796-1863

esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

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<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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Section 13

Proposed Labeling

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 13.1
Proposed Instruction Labeling

Proposed Instruction Manuals and its contents are listed in the following section.

13.1.1 Operation Manual for CYF-V2/V2R (**Attachment 13.2**)
"Operation Manual for CYF-V2/V2R" describes the preparation, operation and maintenance of the CYF-V2 and CYF-V2R.

It also includes the important information about the intended use, applicability of use, user qualifications, names and address of the manufacturer, detailed operating or use instructions, pre-cleaning instruction, troubleshooting guide, warnings and cautions, information regarding operating environment, and routine maintenance and inspections.

13.1.2 Reprocessing Manual for CYF-V2/V2R (**Attachment 13.3**)
"Reprocessing Manual for CYF-V2/V2R" describes how to reprocess the CYF-V2 and CYF-V2R. It includes all the reprocessing methods applicable to CYF-V2 and CYF-V2R.

13.1.3 Operation Manual for CYF-VH/VHR (**Attachment 13.4**)
"Operation Manual for CYF-VH/VHR" describes the preparation, operation and maintenance of the CYF-VH and CYF-VHR.

It also includes the important information about the intended use, applicability of use, user qualifications, names and address of the manufacturer, detailed operating or use instructions, pre-cleaning instruction, troubleshooting guide, warnings and cautions, information regarding operating environment, and routine maintenance and inspections.

13.1.4 Reprocessing Manual for CYF-VH/VHR (**Attachment 13.5**)
"Reprocessing Manual for CYF-VH/VHR" describes how to reprocess the CYF-VH and CYF-VHR. It includes all the reprocessing methods applicable to CYF-VH and CYF-VHR.

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Section 13.2
Proposed Product Labeling

13.2.1. CYF-V2/V2R

(a) Product Labeling

The product labeling for CYF-V2/V2R is shown in Fig.13-1.

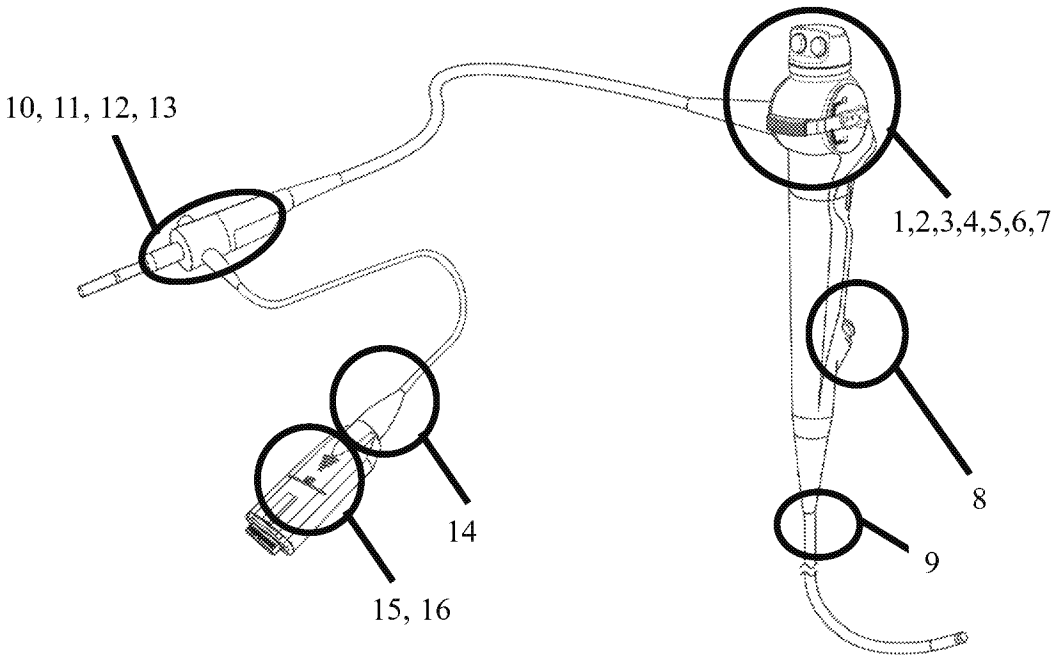
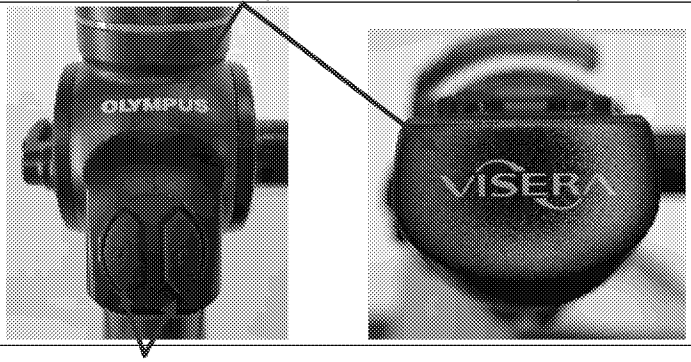


Fig.13-1. Product Labeling (CYF-V2/V2R)

1	Trade mark (CYF-V2, V2R common)
	
2	Switch 1 and Switch 4 (CYF-V2, CYF-V2R common)

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<table>
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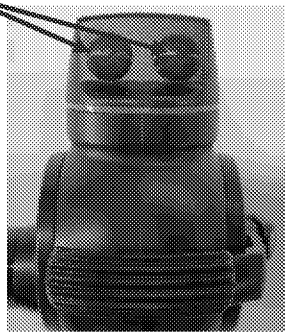
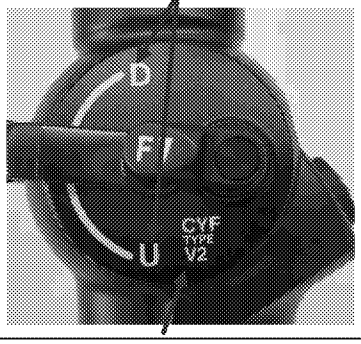
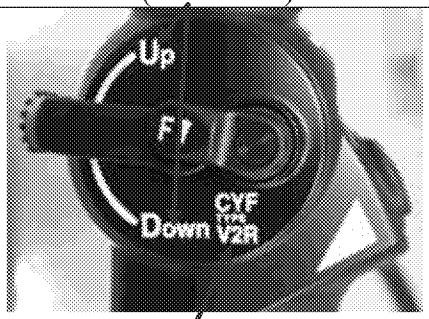
  </td></tr>
<tr><td rowspan="3">4</td><td>Indication of angulation
(CYF-V2)</td><td>Indication of angulation
(CYF-V2R)</td></tr>
<tr><td> 
</td><td> 
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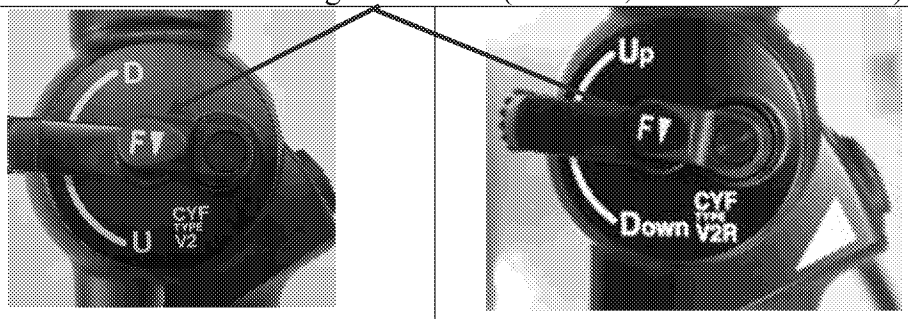
<tr><td>6</td><td colspan="2">Indication of UP/DOWN angulation lock (CYF-V2, CYF-V2R common)
 
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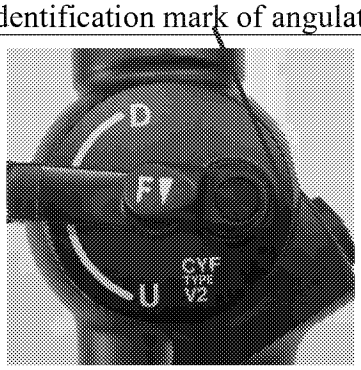
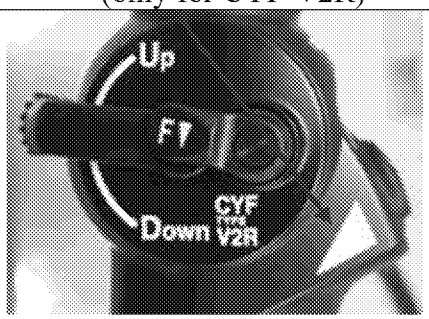
(only for CYF-V2R)</td></tr>
<tr><td></td><td> 
</td><td> 
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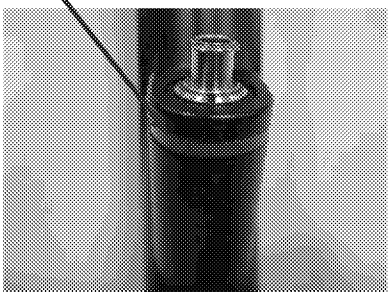
(CYF-V2, CYF-V2R common)</td></tr>
<tr><td></td><td colspan="2">  </td></tr>
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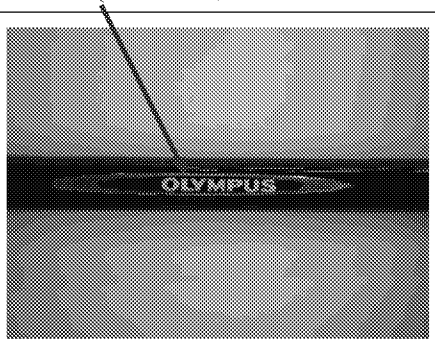
<tr><td></td><td colspan="2"> 
</td></tr>
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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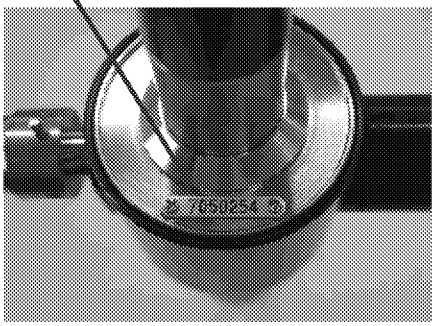
10	Serial number (CYF-V2, CYF-V2R common)
	
11	Manufacture name (CYF-V2, CYF-V2R common)
12	STERILIZATION CAP Label (CYF-V2, CYF-V2R common)
13	Manufacture country (CYF-V2, CYF-V2R common)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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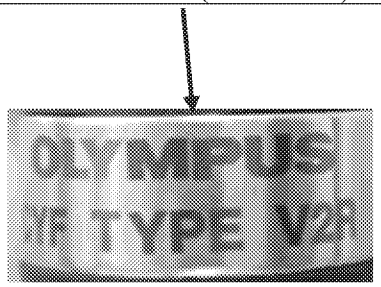
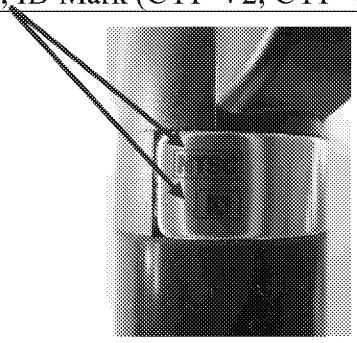
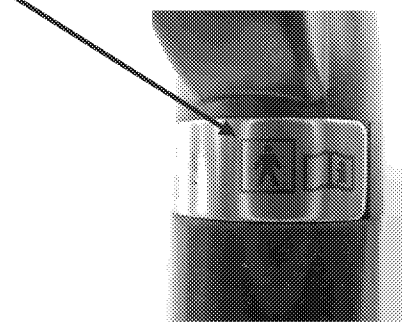
14	Model name (CYF-V2)	Model name (CYF-V2R)
		
15	NTSC, ID Mark (CYF-V2, CYF-V2R common)	
		
16	TYPE BF applied part (CYF-V2, CYF-V2R common)	
		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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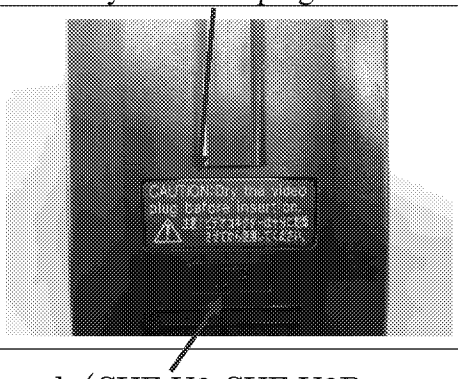
17	Caution (CYF-V2, CYF-V2R common) "CAUTION: Dry the video plug before insertion."
	
18	UP mark (CYF-V2,CYF-V2R common)

(b) Package Labeling

The package labeling for OLYMPUS CYF-V2/V2R is shown in Fig.13-2, Fig.13-3 and Fig13-4.

CYF TYPE V2 CYF TYPE V2R

Fig.13-2. Package Labeling 1 (CYF-V2/V2R)

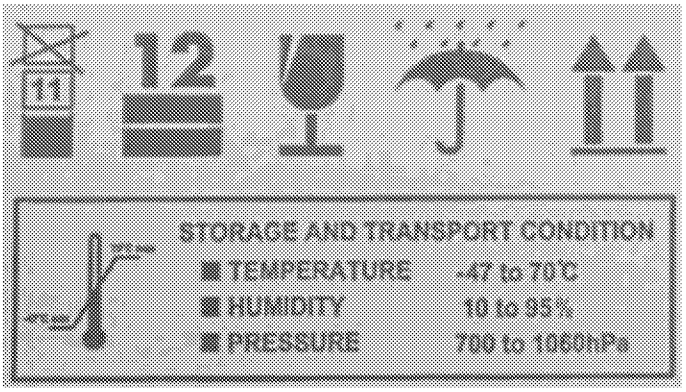


Fig.13-3. Package Labeling 2 (CYF-V2/V2R common)
(Pictorial marking for handling of goods and
Storage and transport condition)

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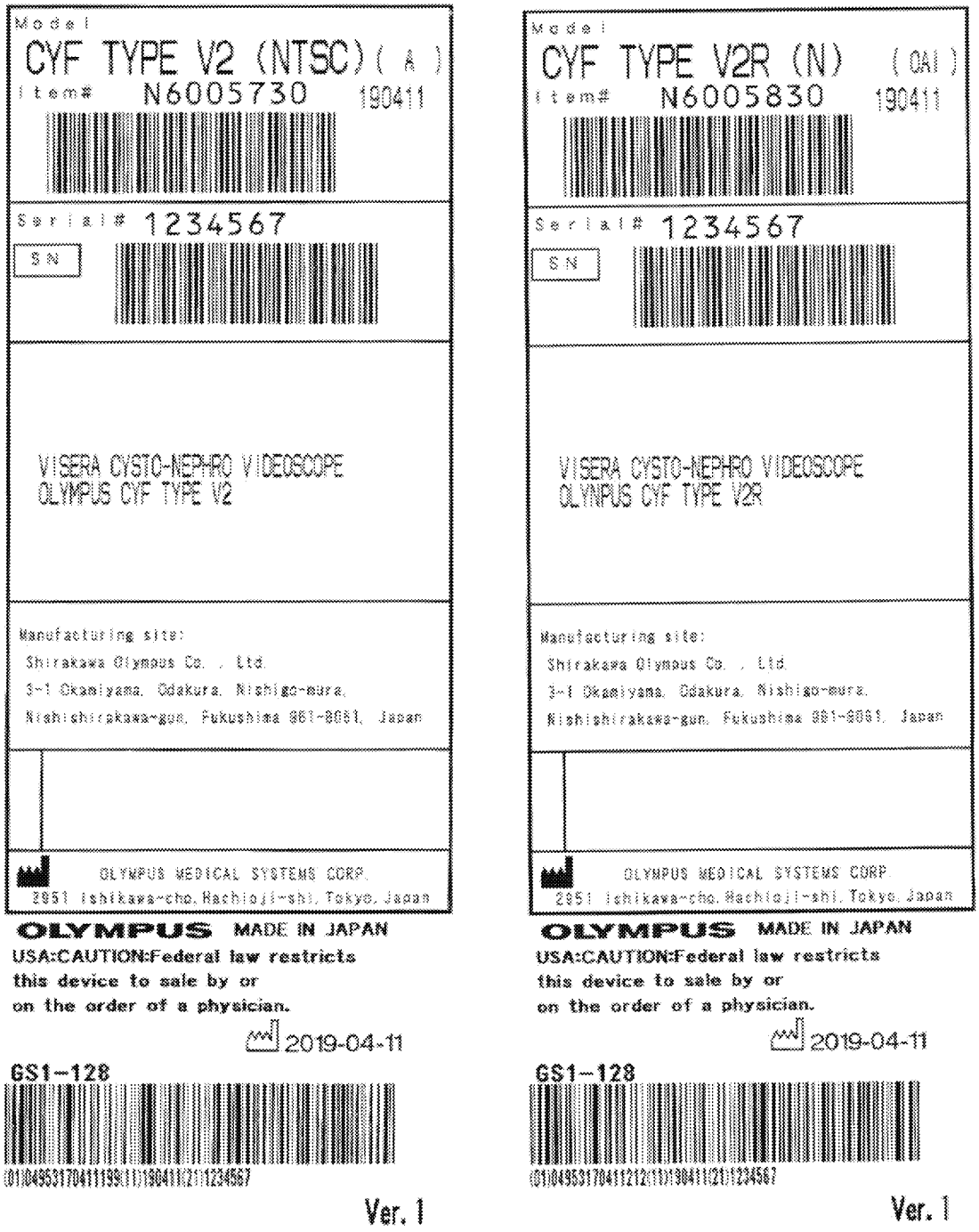

Fig.13-4. Package Labeling 3 (CYF-V2/V2R)

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The devices (CYF-V2/V2R) will be delivered by carry case. Please refer to Fig.13-5, Fig.13-6 and Fig.13-7 for the image of carry case (packaging) and the location of the package labeling.

Packaging label 1

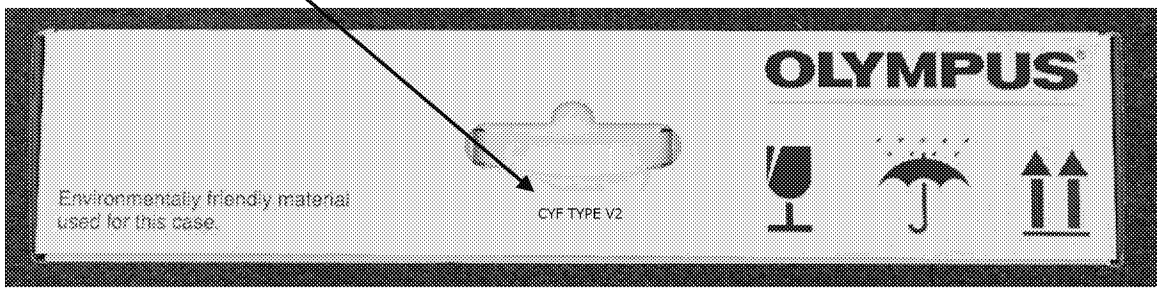

Fig.13-5. Top side of carry case A*1

Packaging label 3 Packaging label 2

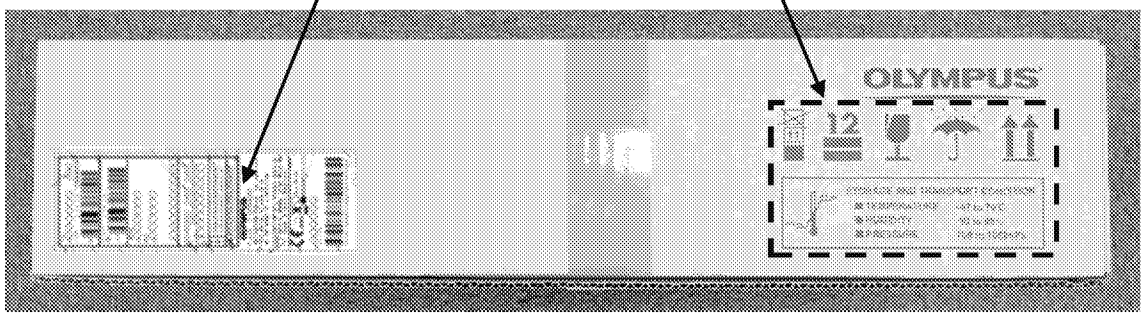

Fig.13-6. Top side of carry case B *1

Packaging label 2 Packaging label 3

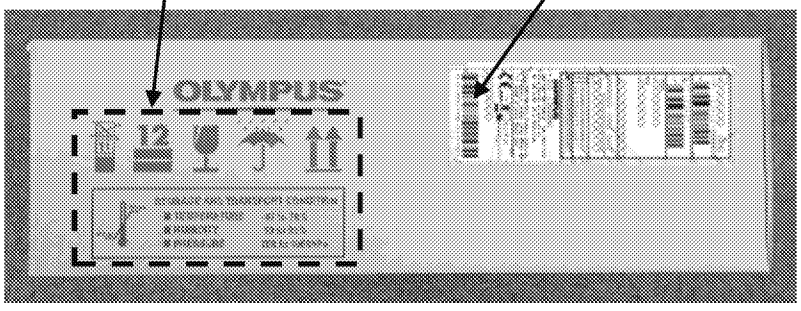

Fig.13-7. Right side of carry case B *1

*1 The Carry case A (inner case) is enclosed in the carry case B (outermost case).

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13.2.2. CYF-VH/VHR

(a) Product Labeling

The product labeling for CYF-VH/VHR is shown in Fig.13-8.

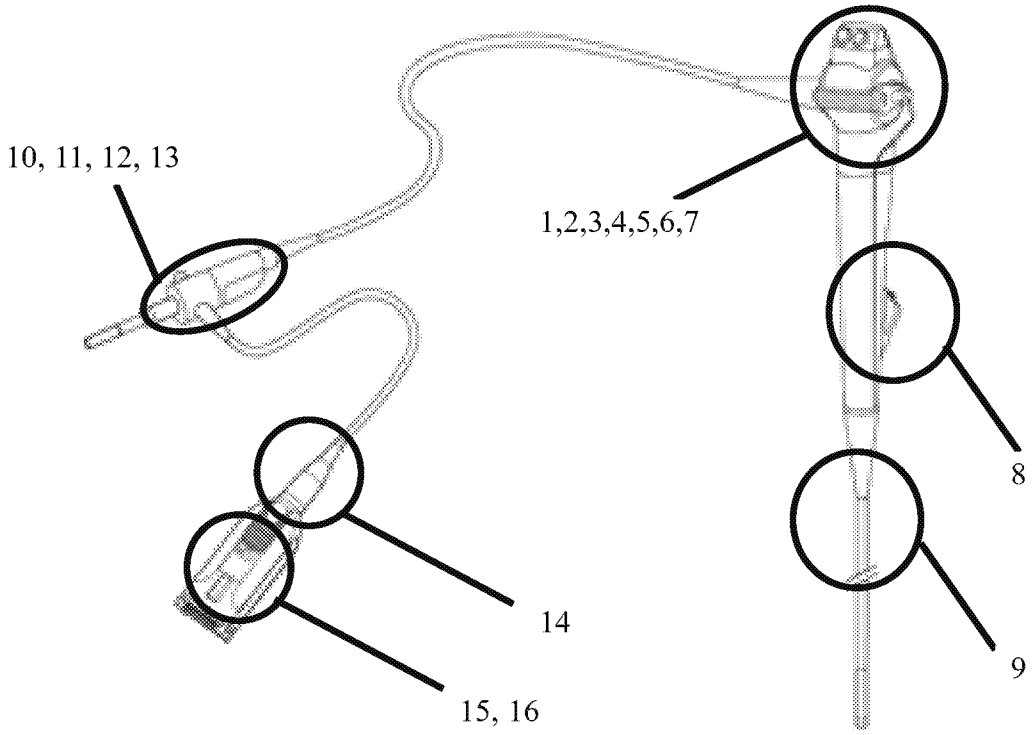
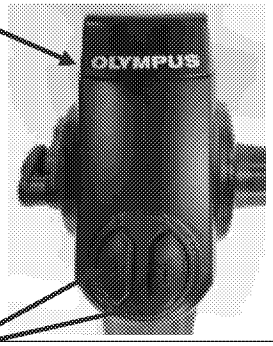


Fig.13-8. Product Labeling (CYF-VH/VHR)

1	Trade mark (CYF-VH, VHR common)
	
2	Switch 1 and Switch 4 (CYF-VH, CYF-VHR common)

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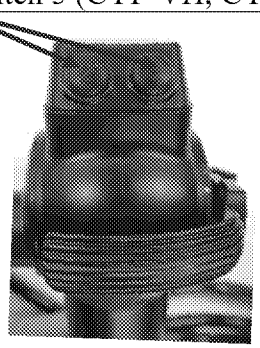
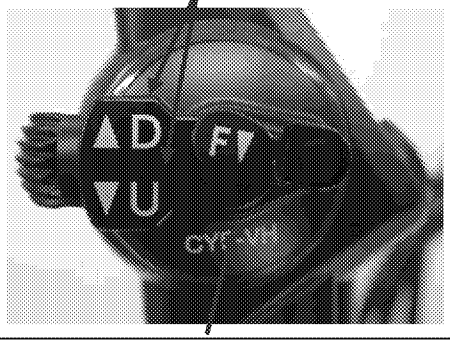
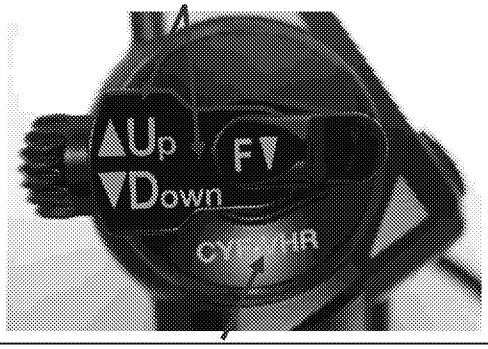
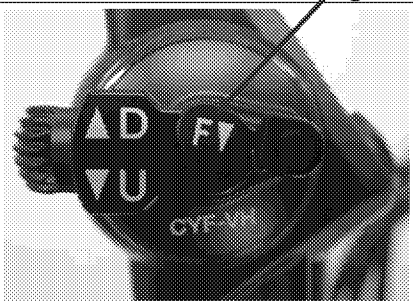
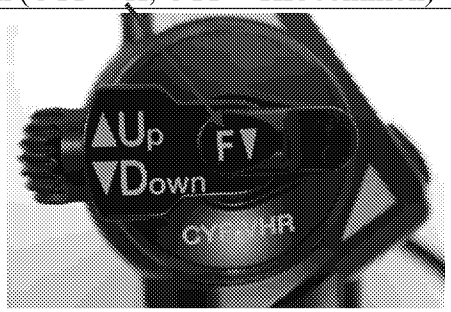
<table>
<tr><td>3</td><td colspan="2">Switch 2 and Switch 3 (CYF-VH, CYF-VHR common)</td></tr>
<tr><td></td><td colspan="2">  </td></tr>
<tr><td>4</td><td>Indication of angulation
(CYF-VH)</td><td>Indication of angulation
(CYF-VHR)</td></tr>
<tr><td></td><td> 
</td><td> 
</td></tr>
<tr><td>5</td><td>Model name (CYF-VH)</td><td>Model name (CYF-VHR)</td></tr>
<tr><td>6</td><td colspan="2">Indication of UP/DOWN angulation lock (CYF-VH, CYF-VHR common)</td></tr>
<tr><td></td><td> 
</td><td> 
</td></tr>
</table>

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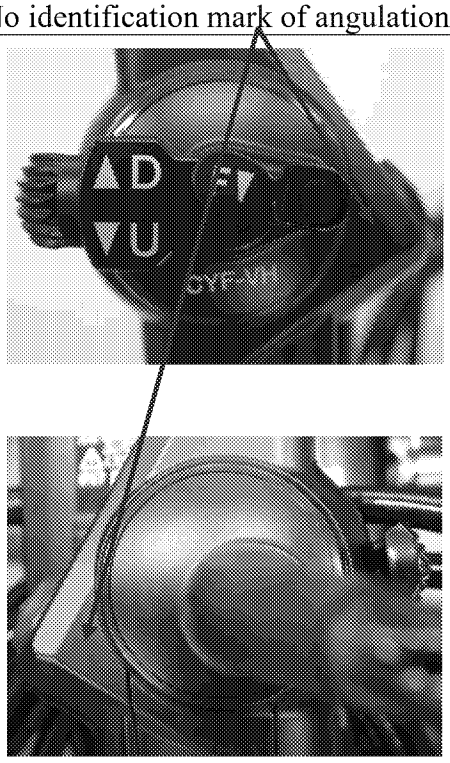
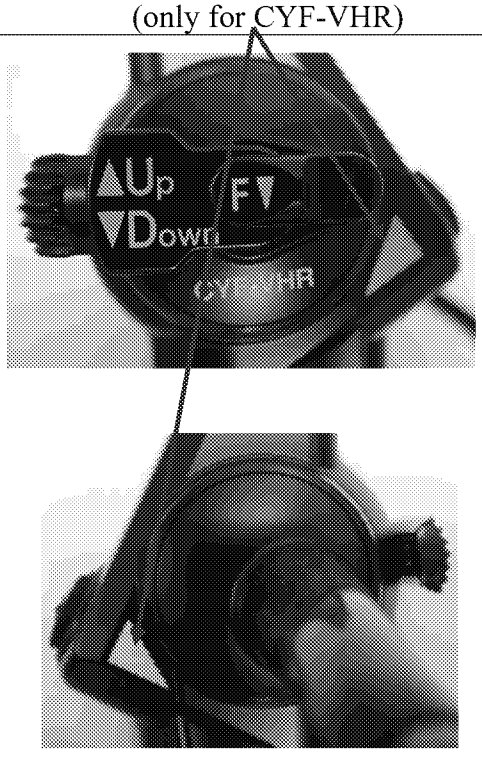
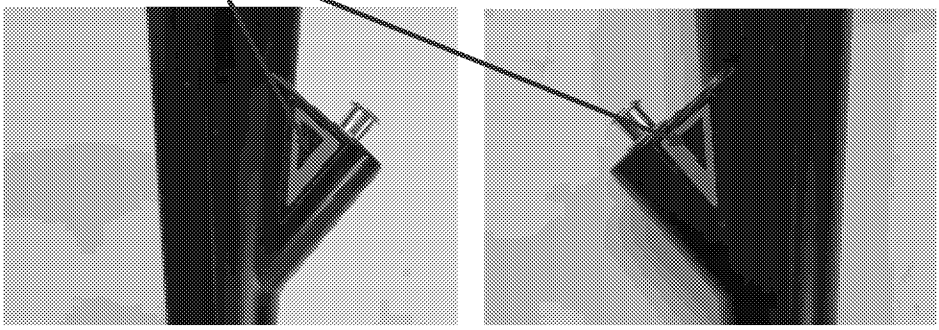
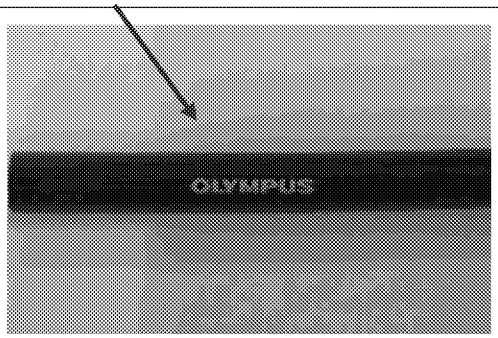
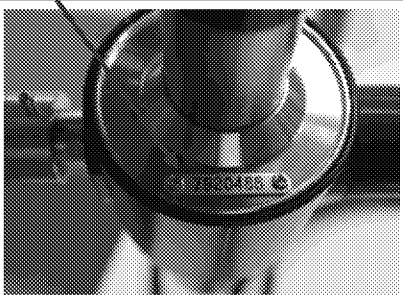
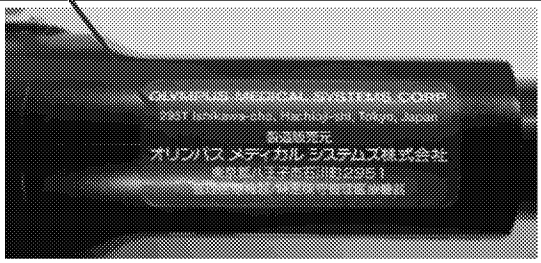
7	Reference: CYF-VH (No identification mark of angulation)	Identification mark of angulation (only for CYF-VHR)
		
8	Identification of endo-therapy accessories compatibility (CYF-VH, CYF-VHR common)	
		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

9	Trade mark (CYF-VH, CYF-VHR common)
	
10	Serial number (CYF-VH, CYF-VHR common)
	
11	Manufacture name (CYF-VH, CYF-VHR common)
	
12	STERILIZATION CAP Label (CYF-VH, CYF-VHR common)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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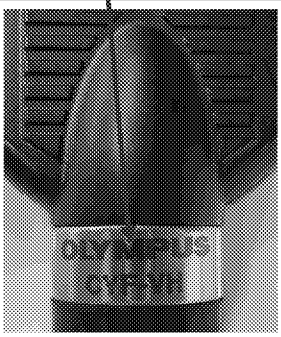
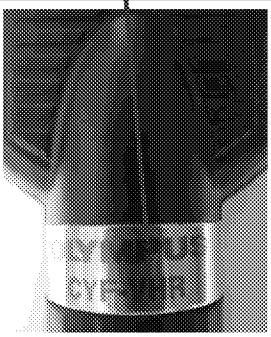
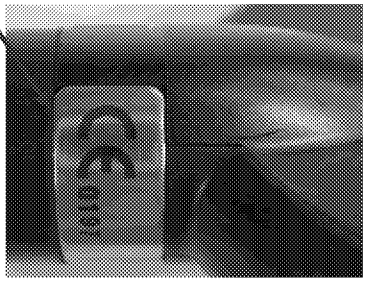
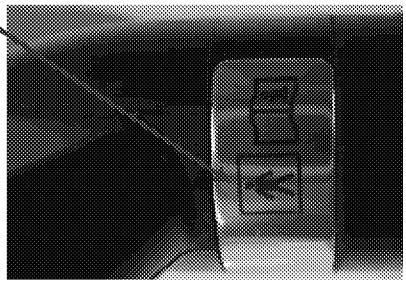
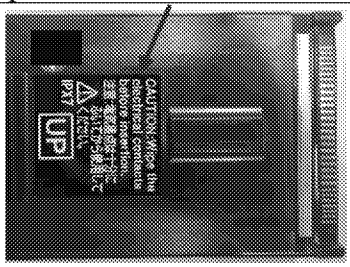
13	Manufacture country (CYF-VH, CYF-VHR common)	
14	Model name (CYF-VH)	Model name (CYF-VHR)
		
15	CE Mark (CYF-VH, CYF-VHR common)	
		
16	TYPE BF applied part (CYF-VH, CYF-VHR common)	
		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

17	Caution (CYF-VH, CYF-VHR common) "CAUTION: Wipe the electrical contacts before insertion."
	

(b) Package Labeling

The package labeling for OLYMPUS CYF-VH/VHR is shown in Fig.13-9, Fig13-10 and Fig13-11.

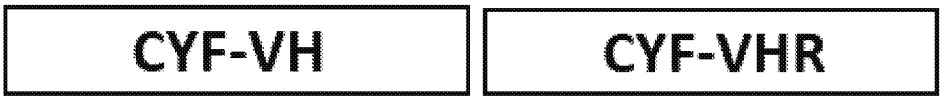


Fig.13-9. Package Labeling 1 (CYF-VH/VHR)

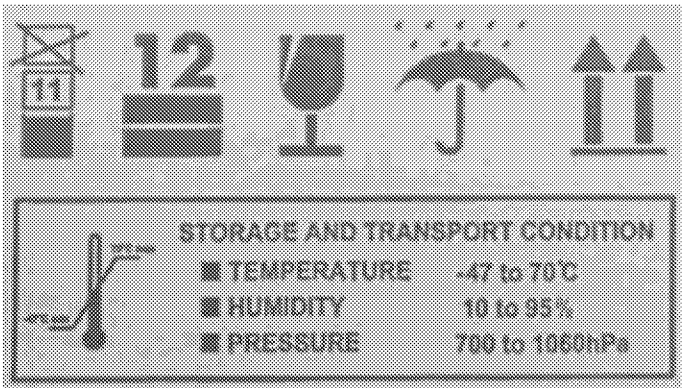


Fig.13-10. Package Labeling 2 (CYF-VH/VHR common)
(Pictorial marking for handling of goods and
Storage and transport condition)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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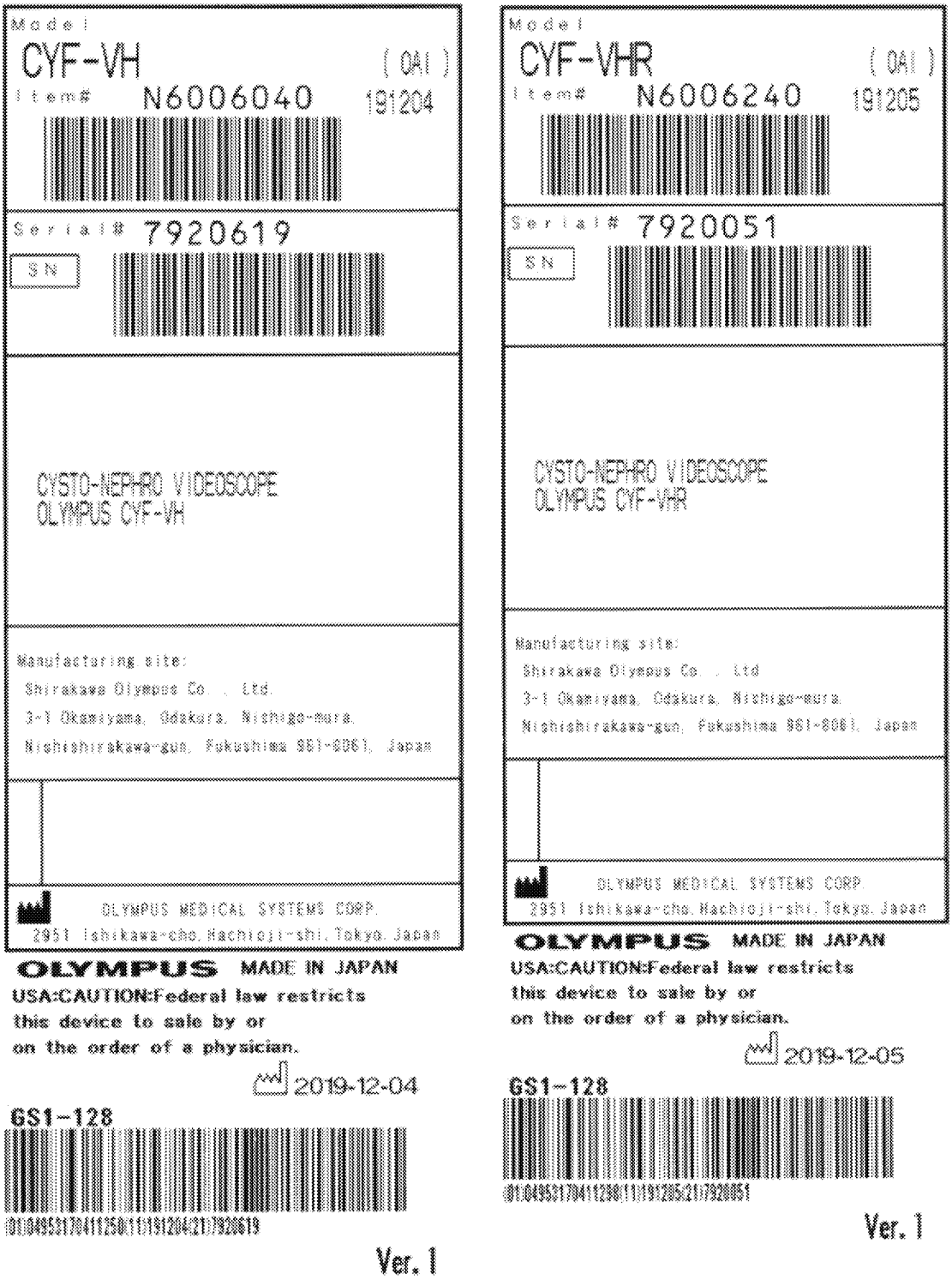

Fig.13-11. Package Labeling 3 (CYF-VH/VHR)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The devices (CYF-VH/VHR) will be delivered by carry case. Please refer to Fig.13-12, Fig.13-13 and Fig.13-14 for the image of carry case (packaging) and the location of the package labeling.

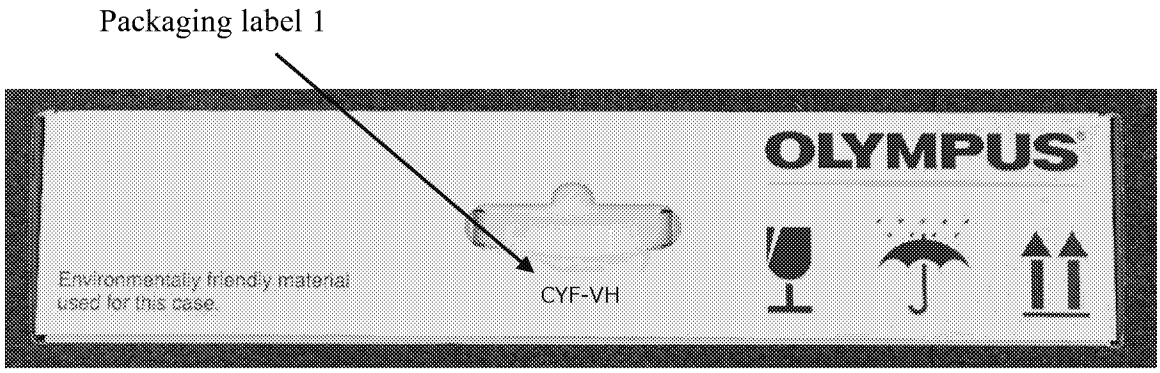

Fig.13-12. Top side of carry case A*1

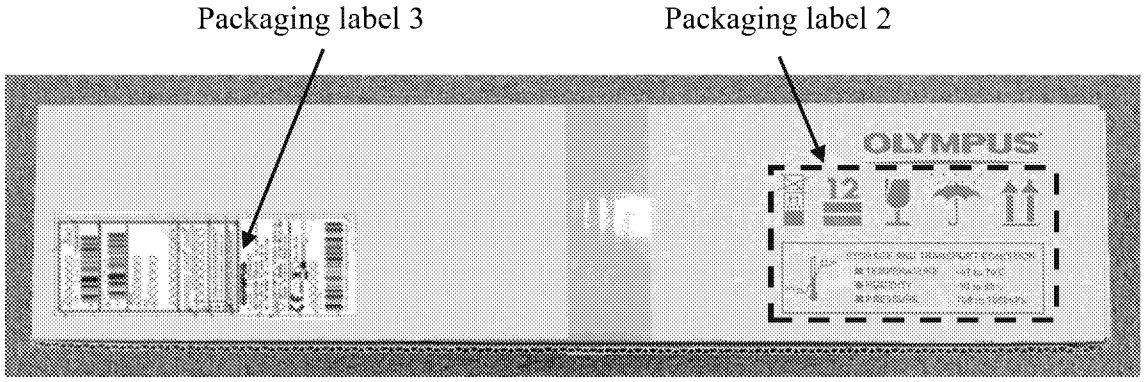

Fig.13-13. Top side of carry case B *1

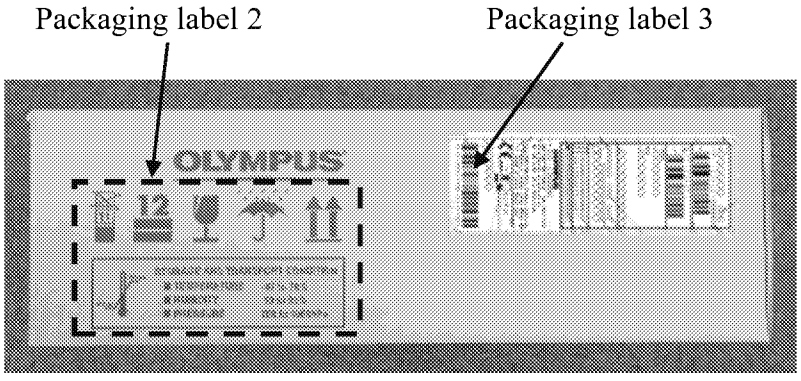

Fig.13-14. Right side of carry case B *1

*1 The Carry case A (inner case) is enclosed in the carry case B (outermost case).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTIII/DHTIIIB
AWL RMONR
Global Work Location
Silver Spring, MD 20705
301-796-1863

Premarket Notification 510(k) Review

Date: January 12, 2023

Reviewer: Esther Kaplan

510(k)# K221683/S001 Subject: Traditional

Applicant: Olympus Medical Systems Corporation	**Device Trade Name:** CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2R), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VH) and CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VHR)
Contact Name: Teffany Hutto	**Contact Title:** Regulatory Affairs Consultant
Correspondent Firm: Olympus Corporation of the Americas	**Phone:** (512) 508-6550 **Email:** teffany.hutto@olympus.com
Received Date: December 22, 2022	**Due Date:** January 22, 2023
Pro Code(s): FAJ **Class:** II **Reg #:** 876.1500	**Reg Name:** Endoscope And Accessories

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K133538	NWB, FAJ	Visera Cysto-nephro Videoscope Olympus Cyf Type V2, Visera Cysto-nephro Videoscope Olympus Cyf Type Va2, Visera Cysto-ne	Olympus Corporation Of The Americas

Recommendation

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

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(b)(5)

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(b)(5)

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(b)(5)

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(b)(5)

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(b)(5)

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Digital Signature Concurrence Table (Doc ID: 04500.14.06)	
This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.	
Reviewer Sign-Off	Esther L. Kaplan -S

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
06/09/2022	(b)(4)	

SECTION A — TYPE OF SUBMISSION

PMA & PDP
- ☐ Original
- ☐ Modular Submission
- ☐ Amendment
- ☐ Report (annual or PAS)
- ☐ Report Amendment
- ☐ Other:
  - ☐ Premarket Report (reprocessed SUD)
  - ☐ Licensing Agreement

PMA/PDP Supplement
- ☐ 180 day - PAS protocol or labeling change, location change, trade name change
- ☐ 180 day - Design or labeling change
- ☐ Special CBE
- ☐ Panel Track
- ☐ 30-day Notice
- ☐ Real-time Review
- ☐ Amendment to PMA/PDP Supplement

510(k)
- ☒ Original Submission:
  - ☒ Traditional
  - ☐ Special
  - ☐ Abbreviated
  - ☐ 3rd Party Traditional
  - ☐ 3rd Party Special
  - ☐ 3rd Party Abbreviated
  - ☐ Dual Track (Dual 510(k) and CLIA Waiver by Application)
- ☐ Amendment
- ☐ Supplement

CLIA

CLIA Categorization Record (CR)
- ☐ Original
- ☐ Amendment

CLIA Waiver by Application (CW)
- ☐ Original
- ☐ Amendment
- ☐ Supplement

Q-Submission
- ☐ Pre-Submission
- ☐ Informational Meeting
- ☐ Submission Issue Meeting
- ☐ Day 100 Meeting
- ☐ Agreement Meeting
- ☐ Determination Meeting
- ☐ Study Risk Determination
- ☐ Other *(Specify below)*

IDE
- ☐ Original IDE:
  - ☐ Amendment to Original IDE
- ☐ Supplement:
  - ☐ Amendment to Supplement
- ☐ Report:
  - ☐ Amendment to Report

HDE
- ☐ Original Submission
- ☐ Amendment to Original
- ☐ Report
- ☐ Report Amendment
- ☐ HDE Supplement:
  - ☐ 75-day Supplement
  - ☐ 30-day Notice
  - ☐ Special CBE
  - ☐ Amendment to Supplement

Class II Exemption Petition
- ☐ Original Submission
- ☐ Additional Information

Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment
- ☐ Report

De Novo
- ☐ Original:
  - ☐ Direct
  - ☐ Post-NSE
- ☐ Amendment
- ☐ Supplement

Pre-Emergency Use Authorization
- ☐ Original
- ☐ Supplement
- ☐ Amendment

Other Submission
- ☐ 513(g)
- ☐ Appeal
- ☐ Other *(Briefly describe submission below)*

Expanded Access to Devices
- ☐ Compassionate Use Request **NOT associated with an IDE**
- ☐ Follow-up Report for Compassionate Use **NOT associated with an IDE**
- ☐ Emergency Use Follow-up Report **NOT associated with an IDE**

SECTION B — APPLICANT / SPONSOR

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
OLYMPUS MEDICAL SYSTEMS CORP.		8010047
Street Address		**City**
2951 Ishikawa-cho		Hachioji-Shi
State/Province	**ZIP/Postal Code**	**Country**
Tokyo	192-8507	Japan

Contact Name	Contact Title
Shinichiro Kawachi	Manager
Division Name *(if applicable)*	**Phone Number *(including area code)***
Product Registration Department	(+81)42-642-2694
Fax Number *(including area code)*	**Contact Email Address**
(+81)42-642-2307	shinichiro.kawachi@olympus.com

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SECTION C OFFICIAL CORRESPONDENT (e.g., may be a consultant and/or 510(k) Third Party) (if different from Section B)

Company/Institution Name Olympus Corporation of the Americas		Establishment Registration Number/FEI *(if known)*
Street Address 3500 Corporate Parkway PO Box 610		City Center Valley
State/Province Pennsylvania	ZIP/Postal Code 18034-0610	Country USA

Contact 1 Name Teffany Hutto	Contact 1 Title Regulatory Affairs Consultant
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)* (512) 508-6550
Contact 1 Fax Number *(including area code)* (484) 896-7128	Contact 1 Email Address teffany.hutto@olympus.com
Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address
Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

To add another set of Section C items, please click on the button to the right. May be repeated as needed. Add Section C

SECTION D INTENDED USE POPULATION

Check all that apply.

- ☐ Adults Only (greater than 21 years of age)
- ☐ Adults and Pediatrics
- ☐ Neonate/Newborn (birth through 28 days)
- ☐ Infant (from 29 days to 2 years of age)
- ☐ Child (from 2 years to 12 years of age)
- ☐ Adolescent (from 12 years to 18 years of age)
- ☐ Transitional Adolescent A (18 through 21 years of age)
- ☐ Transitional Adolescent B (18 through 21 years of age)
- ☐ Other *(Specify below)*

SECTION E PRODUCT INFORMATION – APPLICABLE TO ALL SUBMISSIONS

	Trade Name
1	CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2)
2	CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2R)
3	CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VH)
4	CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VHR)
5	
	Common/Generic Name *(Include if no Trade Name)*

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SECTION F PRIOR RELATED SUBMISSIONS FOR THIS DEVICE OR STUDY

FDA document numbers of all prior related submissions *(regardless of outcome)* or state no prior submission in box 1.

1 (b)(4)	2	3
4	5	6
7	8	9
10	11	12

SECTION G PRODUCT CLASSIFICATION – APPLICABLE TO ALL SUBMISSIONS

Product Code(s) *(when applicable) (If more than one, please separate with commas.)*

FAJ

C.F.R. Section *(If applicable)*	Classification Panel/Medical Specialty
876.1500	Gastroenterology/Urology

Device Class

☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

SECTION H1 REASON FOR APPLICATION – PMA, PDP, OR HDE

☐ New Device
☐ STED

☐ Post-approval Study Protocol

☐ HDE Request for Annual Distribution Number (ADN)

☐ Change in Design, Component, or Specification:
- ☐ Software/Hardware
- ☐ Color Additive
- ☐ Material
- ☐ Specifications
- ☐ Other *(Specify below)*

☐ Location Change:
- ☐ Manufacturer
- ☐ Sterilizer
- ☐ Packager

☐ Report Submission:
- ☐ Annual or Periodic
- ☐ Post-approval Study

☐ Process Change:
- ☐ Manufacturing
- ☐ Packaging
- ☐ Sterilization
- ☐ Vendor/Supplier Change
- ☐ Other *(Specify below)*

☐ Labeling Change:
- ☐ Indications
- ☐ Instructions
- ☐ PAS update
- ☐ Performance Characteristics
- ☐ Shelf Life
- ☐ Trade Name
- ☐ Other *(Specify below)*

☐ Amendment:
- ☐ Withdrawal
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Address
- ☐ Request for Extension
- ☐ Response to FDA Correspondence
- ☐ Other *(Specify below)*

☐ Bundle Submission -- *If this is selected, list in the spaces below any PMAs in the Bundle.*

1	2	3
4	5	6
7	8	9

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SECTION H2 REASON FOR APPLICATION – IDE

☐ Original IDE

☐ Supplement:
- ☐ New Study/New Protocol
- ☐ Change in Correspondent
- ☐ Change in Manufacturer
- ☐ Change in Sponsor
- ☐ Change in Design
- ☐ Change in Informed Consent
- ☐ Change in Manufacturing
- ☐ Change in Protocol
- ☐ 5-Day Notice – Device or Manufacturing
- ☐ 5-Day Notice – Protocol
- ☐ Compassionate Use Request (under an IDE)
- ☐ Live Case Request
- ☐ Request Deviation from Protocol
- ☐ Expansion of Study (Study/Sites)
- ☐ Extension of Time to Submit Annual Report or Respond to FDA Letter

Supplement *(Continued)*
- ☐ Request for Waiver
- ☐ IRB Certification
- ☐ Request for CMS Recategorization
- ☐ Study Resumed
- ☐ Study Suspension
- ☐ Other *(Specify below)*

☐ Report:
- ☐ Adverse Effect
- ☐ Final, Study Completed
- ☐ Annual Progress
- ☐ Interim Progress
- ☐ Semiannual Investigator List
- ☐ Failure to Obtain Informed Consent
- ☐ Compassionate Use Follow-up
- ☐ Emergency Use
- ☐ Live Case Follow-up
- ☐ Completion of Patient Enrollment
- ☐ Completion of Patient Follow-up
- ☐ Other *(Specify below)*

☐ Amendment to Original IDE:
- ☐ Amendment Before Final Decision
- ☐ Response to Refuse to Accept
- ☐ Response to Disapproval
- ☐ Response to Approval with Conditions
- ☐ Withdrawal
- ☐ Other *(Specify below)*

☐ Amendment to Supplement:
- ☐ Response to Disapproval
- ☐ Response to Approval with Conditions
- ☐ Withdrawal
- ☐ Amendment Before Final Decision (additional Information)
- ☐ Other *(Specify below)*

☐ Amendment to Report:
- ☐ Response to Deficiency Letter
- ☐ Withdrawal
- ☐ Amendment Before Final Decision (additional Information)
- ☐ Other *(Specify below)*

SECTION H3 REASON FOR SUBMISSION – Q-SUBMISSION

☐ Pre-Submission:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Request Email Response
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-con

☐ Submission Issue Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Request Email Response
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-con

☐ Additional Information

☐ Change in Legal Entity:
- ☐ Change in Correspondent
- ☐ Change in Sponsors
- ☐ Change in Manufacturer
- ☐ Other *(Specify below)*

☐ Agreement Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference

☐ Determination Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference

☐ Informational Meeting:
- ☐ Request Face-to-Face Meeting
- ☐ Request Teleconference
- ☐ Submit Meeting Minutes
- ☐ Request Meeting Minutes Disagreement T-Con

☐ Other *(Specify)*:

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SECTION H4 REASON FOR SUBMISSION – 510(k)

- ☒ Original
- ☐ Withdrawal of Original
- ☐ Amendment Before Final Decision:
  - ☐ Change in Ownership
  - ☐ Change in Correspondent
  - ☐ Withdrawal
- ☐ Amendment After Final Decision
- ☐ Supplement:
  - ☐ Response to Refuse to Accept (RTA)
  - ☐ Response to Additional Information Request
  - ☐ Withdrawal
- ☐ Reprocessed SUD
- ☐ Corrective Action
- ☐ STED
- ☐ Third Party *(Complete Section C)*
- ☐ Other Reason *(Specify)*:

Information on devices to which substantial equivalence is claimed *(If known)*

	510(k) Number	*Trade Name*	*Submitter*	*Product Code*
Primary Predicate (A)	K133538	VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF V2, CYF VA2, CYR V2R	OLYMPUS MEDICAL SYSTEMS CORP.	FAJ
Predicate or Reference Device (B)				

To add another Predicate or Reference Device (B) entry row, please click on the button to the right. May be repeated as needed. Add Device Information

SECTION H5 DE NOVO SUBMISSIONS

- ☐ Post NSE De Novo: Number of the 510(k) that was NSE'd in the past 30 days:
- ☐ Withdrawal

SECTION H6 REASON FOR APPLICATION – CLIA

Includes CLIA Parent Document number, CR number, or CW number.

- ☐ **CLIA Categorization Record (CR):**
  - ☐ CLIA Categorization of marketed device (include marketing submission number)
  - ☐ CLIA Categorization of device exempt from premarket review
  - ☐ Additional information regarding an open CR (include CR number)
- ☐ **CLIA Waiver by Application (CW):**
  - ☐ Request for CLIA Waiver by Application for marketed device (include marketing submission number)
  - ☐ Request for Dual 510(k) Clearance and CLIA Waiver by Application (include Pre-submission number)
  - ☐ Response to FDA correspondence
  - ☐ Additional information regarding an open CW (include CW number)
- ☐ **Other Reason** *(Specify)*

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SECTION I MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

Applicable only to IDEs

Note: Submission of this information does not affect Registration and Listing.	FDA Document Number *(if known)*

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager/Relabeler

Company/Institution Name		Establishment Registration Number/FEI *(if known)*
Street Address		City
State/Province	ZIP/Postal Code	Country

Contact 1 Name	Contact 1 Title
Contact 1 Division Name *(if applicable)*	Contact 1 Phone Number *(including area code)*
Contact 1 Fax Number *(including area code)*	Contact 1 Email Address
Contact 2 Name	Contact 2 Title
Contact 2 Division Name *(if applicable)*	Contact 2 Phone Number *(including area code)*
Contact 2 Fax Number *(including area code)*	Contact 2 Email Address
Contact 3 Name	Contact 3 Title
Contact 3 Division Name *(if applicable)*	Contact 3 Phone Number *(including area code)*
Contact 3 Fax Number *(including area code)*	Contact 3 Email Address

To add another set of Section I items, please click on the button to the right. May be repeated as needed. Add Section I

SECTION J UTILIZATION OF STANDARDS

Note: Please see guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" for details on the Declaration of Conformity.

How to fill out this section:

Recognition Number: State the FDA recognition number. If the standard is not recognized, write **NR**.

Declaration of Conformity or General Use: Select 'Declaration of Conformity' if including a "Declaration of Conformity to a Recognized Standard" statement. For all other uses, select 'General Use' and indicate if you have made deviations from the Recognized/Non-recognized standard.

Standard: State the Standards Development Organization (SDO), the Designation Number (including year), and the Title.

Location: State the section and/or the page number(s) in the submission where the standard is applied.

Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	8-185	Declaration of Conformity	*If General Use,* Deviation?	ASTM F451-08, standard specification for acrylic bone cement.	Section 3, p. 15
2 X	3-44	General Use	*If General Use,* Deviation? Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4, p. 32

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Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	9-114	Declaration of Conformity	*If General Use,* Deviation?	IEC 60601-2-18: Edition 3.0 2009-08 Medical Electrical equipment – Part 2-18: Particular requirements for the basic safety and essential	Sec. 14, 17, 18
2 X	9-130	Declaration of Conformity	*If General Use,* Deviation?	ISO 8600-6 Second edition 2020-09 Endoscopes – Medical endoscopes and endotherapy devices – Part 6: Vocabulary	Sec. 14, 17, 18
3 X	14-529	Declaration of Conformity	*If General Use,* Deviation?	ANSI AAMI ISO 11135: 2014 Sterilization of health care products – Ethylene Oxide – requirements for development, validation and routi	Sec. 14
4 X	2-191	Declaration of Conformity	*If General Use,* Deviation?	ANSI AAMI ISO 10993-12: 2012 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	Sec. 14
5 X	2-237	Declaration of Conformity	*If General Use,* Deviation?	ISO 10993-18 Second edition 2020-01 Biological evaluation of medical devices – Part 18: Chemical characterization of medical devi	Sec. 14
6 X	2-276	Declaration of Conformity	*If General Use,* Deviation?	ISO 10993-18 Second edition 2020-01 Biological evaluation of medical devices – Part 18: Chemical characterization of medical devi	Sec. 14
7 X	2-275	Declaration of Conformity	*If General Use,* Deviation?	ISO 10993-7 Second edition 2008-10-15 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals [Inclu	Sec. 14
8 X	2-191	Declaration of Conformity	*If General Use,* Deviation?	ANSI AAMI ISO 10993-12: 2012 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials	Sec. 15
9 X	2-174	Declaration of Conformity	*If General Use,* Deviation?	ISO 10993-10 Third edition 2010-08-01 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	Sec. 15
10 X	2-245	Declaration of Conformity	*If General Use,* Deviation?	ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	Sec. 15
11 X	2-258	Declaration of Conformity	*If General Use,* Deviation?	ISO 10993-1: 2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	Sec. 15
12 X	2-222	Declaration of Conformity	*If General Use,* Deviation?	ISO 10993-2 Second edition 2006-07-15 Biological evaluation of medical devices – Part 2: Animal welfare requirements	Sec. 15
13 X	19-4	Declaration of Conformity	*If General Use,* Deviation?	ANSI AAMI ES 60601-1:2005 /(R)2012L and A1:2012, C1:2009/ (R)2012 and A2:2010/(R)2012 Medical electrical equipment – Part	Sec. 17
14 X	19-8	Declaration of Conformity	*If General Use,* Deviation?	ANSI AAMI IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential perform	Sec. 17
15 X	9-114	Declaration of Conformity	*If General Use,* Deviation?	IEC 60601-2-18: Edition 3.0 2009-08 Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential p	Sec. 17
16 X	5-89	Declaration of Conformity	*If General Use,* Deviation?	IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment – Part 6: General requirements for basic safety and essential performan	Sec. 17
17 X	12-249	Declaration of Conformity	*If General Use,* Deviation?	IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems	Sec. 18
18 X		Declaration of Conformity	*If General Use,* Deviation?	ISO 15739: 2017 Photography – Electronic still-picture imaging – Noise measurements	Sec. 18
19 X	5-40	Declaration of Conformity	*If General Use,* Deviation?	ANSI AAMI ISO 14971:2007 Medical Devices – Application of risk management to medical devices	Sec. 21

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

SECTION K UTILIZATION OF CDRH GUIDANCE DOCUMENTS

Questions? Contact FDA/CDRH/OCE/DID at CDRH-IDESTATUS@fda.hhs.gov or 301-796-8118

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How to fill out this section:

Title: Enter the title of the guidance documents used in the preparation of your premarket submission. CDRH guidance documents can be found at ***http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm***.

Entries for Utilization of CDRH Guidance Documents	
	Title of Guidance Document
1 X	

To add another row for Section K, please click on the button to the right. May be repeated as needed.
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Add Row/Document

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Department of Health and Human Services
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Office of Chief Information Officer
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U.S. FOOD & DRUG ADMINISTRATION

eConsult Cover Sheet

Consult Number: CON2214470

Document Number: K221683

Applicant: Olympus Medical Systems Corporation

Trade Name: CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2R), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VH) and CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VHR)

Consult Type: Optical Diagnostics and Therapeutics

Requestor: Esther Kaplan [ESTHER.KAPLAN]

esther.kaplan@fda.hhs.gov

Requestor Home: CDRH\ OHT3\ DHT3B\ THT3B3

Requested Consultant: Andrea Kim [ANDREA.KIM]

andrea.kim@fda.hhs.gov ; 703-399-5815

Gatekeeper / Consultant: Andrea Kim [ANDREA.KIM]

andrea.kim@fda.hhs.gov ; 703-399-5815

Consultant Home: CDRH\ OSEL\ DIDSR

Date Requested: June 24, 2022

Due Date: July 26, 2022

Instructions: (b)(5)

RECOMMENDATIONS

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Andrea S. Kim -S

Digitally signed by Andrea S. Kim -S
Date: 2022.07.27 01:18:06 -04'00'

Andrea S. Kim, M.S.

Division of Imaging, Diagnostics, and Software Reliability

OSEL / CDRH / FDA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Date Prepared: 01/19/2023

510(k) Summary

1. GENERAL INFORMATION

■ 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

■ Contact Person: Teffany Hutto
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 512-508-6550
Fax: 484-896-7128
Email: teffany.hutto@olympus.com

■ Manufacturing site: Shirakawa Olympus Co., Ltd.
3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun,
Fukushima 961-8061, Japan

Aizu Olympus Co., Ltd.,
3-1-1 Niiderakita, Aizuwakamatsu-shi, Fukushima 965-8520, Japan

2. DEVICE IDENTIFICATION

■ Trade/Device Name: VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE V2R
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH, CYF-VHR

■ Model Name: OLYMPUS CYF-V2, CYF-V2R, CYF-VH, CYF-VHR

■ Common Name: CYSTO-NEPHRO VIDEOSCOPE

■ Regulation Number: 876.1500

■ Regulation Name: Endoscope and accessories

■ Regulatory Class: Class II

■ Product Code: FAJ (Cystoscope and Accessories, Flexible/Rigid)

■ Classification Panel: Gastroenterology/Urology

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

3. PREDICATE DEVICE

■ **Predicate device**

Device name	510(k) Submitter	510(k) No.
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R	OLYMPUS MEDICAL SYSTEMS CORP.	K133538

4. DEVICE DESCRIPTION

■ **General Description of the subject device**

The subject device has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

■ **Principle of Operation**

The subject devices consist of three parts: the control section, the insertion section, and the connector section. The basic principle including user interface and operation for the procedure of the subject device are identical to that of the predicate device.

■ **List of device components**

The VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-V2/V2R will be packed and offered together with the devices listed in the table below. They can be used with commercially available Olympus devices as described within the Instruction Manual.

Model No.	Device Name
BW-411B	Single Use Combination Cleaning Brush
MB-156	ETO Cap

The CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH and CYF-VHR will be packed and offered together with the devices listed in the table below. They can be used with commercially available Olympus devices as described within the Instruction Manual.

Model No.	Device Name
BW-411B	Single Use Combination Cleaning Brush
MAJ-1538	Sterilization Cap

5. INDICATIONS FOR USE

VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHR have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device has the same technological characteristics and design as the predicate device except for the following features:

- Optical performance
- Shape of the distal end

Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

A side-by-side comparison of the subject device and the predicate device is provided below.

Item	Subject Device	Predicate Device
	OLYMPUS CYF-V2, CYF-V2R	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Indications for Use	VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2 and CYF TYPE V2R have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.	This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter, and kidney.
Regulation Number	21CFR 876.1500	21CFR 876.1500
Regulation Name	Endoscope and accessories	Endoscope and accessories
Regulatory Class	Class II	Class II

Item	Subject Device	Predicate Device
	OLYMPUS CYF-V2, CYF-V2R	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Product Code	FAJ	FAJ
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology
Use Environment	Healthcare facility/hospital	Healthcare facility/hospital
Reprocessing	[Cleaning] AER and manual [Disinfection] AER and manual [Sterilization] - Ethylene oxide gas - STERRAD NX	[Cleaning] AER and manual [Disinfection] AER and manual [Sterilization] - Ethylene oxide gas - STERRAD NX
Single-Use/Reuse	Reusable	Reusable
Duration and type of contact	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours).	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours).
Depth of Field	3-50mm	3-50mm
Direction of View	0°(Forward viewing)	0°(Forward viewing)
Field of View	120°	120°
Type of CCD	Color CCD	Color CCD
Number of CCD Chip	1	1
Outer Diameter of Distal End	ø 4.8mm (bullet shape)	ø 4.8mm (bullet shape)
Diameter of Insertion Tube	ø 5.4mm	ø 5.4mm
Bending Section Angulation	Up 210° / Down 120°	Up 210° / Down 120°
Working Length	380mm	380mm
Instrument Channel inner diameter	ø 2.2 mm	ø 2.2 mm
Observation mode	WLI, NBI	WLI, NBI

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Item	Subject Device	Predicate Device
	OLYMPUS CYF-V2, CYF-V2R	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Patient contacting material	Insertion tube: Forced dry-hard type of fluorine resin coat Bending section: Fluoro Rubber Glue: Epoxy glue Distal End: Polyphenylsulfone Objective lens/ Light guide lens: Glass Solder: AuSn Solder Instrument channel pipe/ Instrument channel joint/ Junction/ Instrument channel port: Stainless Steel Instrument Channel: Polytetrafluoroethylene Rubber seal: Silicone	Insertion tube: Forced dry-hard type of fluorine resin coat Bending section: Fluoro Rubber Glue: Epoxy glue Distal End: Polyphenylsulfone Objective lens/ Light guide lens: Glass Solder: AuSn Solder Instrument channel pipe/ Instrument channel joint/ Junction/ Instrument channel port: Stainless Steel Instrument Channel: Polytetrafluoroethylene Rubber seal: Silicone

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Item	Subject Device	Predicate Device
	OLYMPUS CYF-VH, CYF-VHR	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Indications for Use	CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHRhave been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra and kidney.	This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter, and kidney.
Regulation Number	21CFR 876.1500	21CFR 876.1500
Regulation Name	Endoscope and accessories	Endoscope and accessories
Regulatory Class	Class II	Class II
Product Code	FAJ	FAJ
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology
Use Environment	Healthcare facility/hospital	Healthcare facility/hospital
Reprocessing	[Cleaning] AER and manual [Disinfection] AER and manual [Sterilization] - Ethylene oxide gas - STERRAD NX	[Cleaning] AER and manual [Disinfection] AER and manual [Sterilization] - Ethylene oxide gas - STERRAD NX
Single-Use/Reuse	Reusable	Reusable
Duration and type of contact	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours).	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours).
Depth of Field	3-50mm	3-50mm
Direction of View	0°(Forward viewing)	0°(Forward viewing)
Field of View	120°	120°
Type of CCD	Color CCD	Color CCD
Number of CCD Chip	1	1
Outer Diameter of Distal End	ø 2.7mm (bullet shape)	ø 4.8mm (bullet shape)
Diameter of Insertion Tube	ø 5.5mm	ø 5.4mm
Bending Section Angulation	Up 220° / Down 130°	Up 210° / Down 120°
Working Length	380mm	380mm

Item	Subject Device	Predicate Device
	OLYMPUS CYF-VH, CYF-VHR	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Instrument Channel inner diameter	ø 2.2 mm	ø 2.2 mm
Observation mode	WLI, NBI	WLI, NBI
Patient contacting material	Insertion tube: Forced dry-hard type of fluorine resin coat Bending section: Fluoro Rubber Glue: Epoxy glue Distal End/ Light guide lens: Polysulfone Objective lens: Glass Solder: AuSn Solder Instrument channel pipe/ Instrument channel joint/ Junction/ Instrument channel port: Stainless Steel Instrument Channel: Polytetrafluoroethylene Rubber seal: Silicone	Insertion tube: Forced dry-hard type of fluorine resin coat Bending section: Fluoro Rubber Glue: Epoxy glue Distal End: Polyphenylsulfone Objective lens/ Light guide lens: Glass Solder: AuSn Solder Instrument channel pipe/ Instrument channel joint/ Junction/ Instrument channel port: Stainless Steel Instrument Channel: Polytetrafluoroethylene Rubber seal: Silicone

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

1) Reprocessing validation testing

Reprocessing instruction and reprocessing method validation testing were conducted and documentations were provided as recommended by Guidance for Industry and Food and Drug Administration Staff, "Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling".

2) Biocompatibility testing

Biocompatibility testing were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

- Cytotoxicity Study Using the ISO Elution Method
- ISO Intracutaneous Study in Rabbits
- ISO Guinea Pig Maximization Sensitization Test
- ISO Intracutaneous Study in Rabbits
- USP Rabbit Pyrogen Study
- ISO Acute Systemic Toxicity Study in Mice

3) Software verification and validation testing

Software verification and validation testing were conducted, and documentations were provided as

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recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

4) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted in accordance with the ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18:2009 standards for safety and the IEC 60601-1-2:2014 standards for EMC.

5) Performance testing - Bench

Bench testing as listed below were conducted to ensure that the subject device performs as intended and meet design specifications.

- Thermal Safety
- Composite Durability
- Color Performance
- Photobiological Safety
- Noise and Dynamic Range
- Image Intensity Uniformity
- Field of View and Direction of View
- Resolution
- Effectiveness NBI

6) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

7) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

8) Risk management

Risk management was performed in accordance with ISO 14971:2007. The design verification tests and their acceptance criteria were performed and identified as a result of this risk management.

8. CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate device, VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYF TYPE V2R, CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHR raise no new issue of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, effectiveness and performance.

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April 30, 2024

Olympus Medical Systems Corporation
% Teffany Hutto
Regulatory Affairs Consultant
Olympus Corporation of the Americas
3500 Corporate Parkway
P.O. Box 610
Center Valley, PA 18034

Re: K221683
Trade/Device Name: VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE V2R
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH, CYF-VHR
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: December 22, 2022
Received: December 22, 2022

Dear Teffany Hutto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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U.S. FOOD & DRUG ADMINISTRATION

K221683
Olympus Medical Systems Corporation
Trade/Device Name: Cysto-Nephro Videoscope (Olympus CYF-V2), Cysto-Nephro Videoscope (Olympus CYF-V2R), Cysto-Nephro Videoscope (Olympus CYF-VH) and Cysto-Nephro Videoscope (Olympus CYF-VHR)
Contact Name: Teffany Hutto

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K221683 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K221683 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at https://www.fda.gov/media/83522/download for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued

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on September 29, 2017 (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

MAJOR DEFICIENCY LIST

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FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. Please note that if the specific clarification questions are not received at least 48 hours before the teleconference, the review team might not be able to provide feedback. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least

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burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.

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TEST REPORT

APPLICANT	OLYMPUS MEDICAL SYSTEMS CORP.
ADDRESS	2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan
PRODUCTS	VISERA CYSTO-NEPHRO VIDEOSCOPE
MODEL NO.	OLYMPUS CYF TYPE V2, OLYMPUS CYF TYPE V2R
SERIAL NO.	(b)(4)
TEST STANDARD	IEC 60601-1: 2005+AMD1: 2012, IEC 60601-1-6: 2010+AMD1: 2013
ADDITIONAL INFORMATION	-

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Test Report issued under the responsibility of:

(b)(4)

TEST REPORT
IEC 60601-1-6
Medical electrical equipment - Part 1-6:
General requirements for basic safety and essential performance - Collateral standard: Usability

Report Number. ..... :	370-210055-1, Attachment No.1
Date of issue..... :	2021-12-20
Total number of pages ..... :	11 pages

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Protocol Revision:

Protocol Title: Biological Safety Risk Assessment Visera Cyto-Nephro Videoscope (CYF-V2)

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U.S. FOOD & DRUG ADMINISTRATION

Memorandum

To: Esther Kaplan, Lead Reviewer (OHT3/DHT3B/THT3B3)

From: Andrew Fales, General Engineer (OHT3/DHT3B/THT3B2)

Date: January 10, 2023

Subject: Optical Performance Review
K221683/S001
Olympus Medical Systems Corp.
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE V2R
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH, CYF-VHR

Summary

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(b)(5)

Andrew M. Fales -S

Digitally signed by Andrew M. Fales -S
Date: 2023.01.10 07:08:13 -05'00'

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OLYMPUS

OPERATION MANUAL

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-VH
OLYMPUS CYF-VHR

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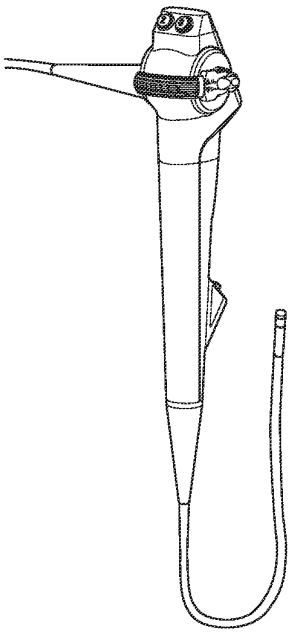

Refer to the endoscope's companion manual, the "REPROCESSING manual" with your endoscope model listed on the cover, for reprocessing information.

USA: CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Symbols

The meaning(s) of the symbol(s) shown on the component packaging, the instruction manual, and/or the instrument are as follows:

Symbol	Description	Symbol	Description
	Consult instructions for use or consult electronic instructions for use		Endoscope
	TYPE BF applied part		Caution
	Do not re-use		Batch code
	Serial number		Keep away from sunlight
	Keep dry		Not Made with Natural Rubber Latex
	Manufacturer		Authorized representative in the European Community
	Importer (into European Union)		Date of Manufacture
IPX7	Ingress protection rating is 7.		Optical radiation
	Non-ionizing electromagnetic radiation		

For US Customers only

For a Symbols Glossary, visit us:
http://www.olympus-global.com/en/common/pdf/symbolsglossary.pdf

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Important Information — Please Read Before Use

Intended use

CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHR have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

Do not use CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHR for any purpose other than its intended use.
Select the endoscope to be used according to the objective of the intended procedure based on the full understanding of the endoscope's specifications and functionality as described in this instruction manual.

Contraindication

Contraindications for this device are those specific to urinary tract endoscopy.
Diagnostic or therapeutic ureteroscopy is contraindicated in people with an untreated urinary tract infection.

Applicability of endoscopy and endoscopic treatment

If there are official standards on the applicability of endoscopy and endoscopic treatment that are defined by the hospital's administrations or other official institutions, such as academic societies on endoscopy, follow those standards. Before starting endoscopy and endoscopic treatment, thoroughly evaluate their properties, purposes, effects, and possible risks (their nature, extent and probability). Perform endoscopy and endoscopic treatment only when their potential benefits are greater than their risks.

Fully explain to the patient the potential benefits and risks of the endoscopy and endoscopic treatment as well as any examination/treatment methods that can be performed in its place, and perform the endoscopy and endoscopic treatment only after obtaining the consent of the patient.

Even after starting the endoscopy and endoscopic treatment, continue to evaluate the potential benefits and risks, and immediately stop the endoscopy/treatment and take proper measures if the risks to the patient become greater than the potential benefits.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Instruction manual

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment that will be used during the procedure and use the equipment as instructed.
Note that the complete instruction manual set for this endoscope consists of this manual and the "REPROCESSING MANUAL" with your endoscope model listed on the cover. It also accompanied the endoscope at shipment.
Keep this and all related instruction manuals in a safe, accessible location.
If you have any questions or comments about any information in this manual, please contact Olympus.

Terms used in this manual

NBI (Narrow Band Imaging) observation:

This is optical-digital observation using narrowband light.

Normal light observation (or WLI (White Light Imaging) observation):

This is observation using white light.

Image sensor:

The image sensor is a device that converts light into electrical signals.

User qualifications

If there are official standards for user qualifications to perform endoscopy and endoscopic treatment that are defined by the hospital's medical administrators or other official institutions, such as academic societies on endoscopy, follow those standards. If there are no official qualification standards, the operator of this instrument must be a physician approved by the medical safety manager of the hospital or person in charge of the department (department of urology, etc.).

The physician should be capable of safely performing the planned endoscopy and endoscopic treatment following guidelines set by the academic societies on endoscopy, etc., and considering the difficulty of endoscopy and endoscopic treatment.This manual does not explain or discuss endoscopic procedures.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Instrument compatibility

Refer to the “Combination equipment” on page 65 to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient or operator injury and/or equipment damage.

This instrument complies with the EMC standard for medical electrical equipment, edition 4 (IEC 60601-1-2: 2014).
When connecting to an instrument that complies with a previous edition of the EMC standard for medical electrical equipment edition, the EMC characteristics could be vulnerable.

Reprocessing before the first use/reprocessing and storage after use

This instrument was not reprocessed before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in the endoscope's companion “REPROCESSING MANUAL” with your endoscope model listed on the cover.
After using this instrument, reprocess and store it according to the instructions given in the endoscope's companion reprocessing manual. Improper and/or incomplete reprocessing or storage can pose an infection control risk, cause equipment damage, or reduce performance.

Spare equipment

Be sure to prepare another endoscope to avoid interruption of the examination due to equipment failure or malfunction.

Maintenance management

The probability of failure of the endoscope and ancillary equipment increases as the number of procedures performed and/or the total operating hours increase. In addition to the inspection before each procedure, the person in charge of medical equipment maintenance in each hospital should inspect the items specified in this manual periodically following regulations, guidelines, etc. required of you. An endoscope with an observed irregularity should not be used, but should be inspected by following Section 5.2, “Troubleshooting guide”. If the irregularity is still observed after inspection, contact Olympus.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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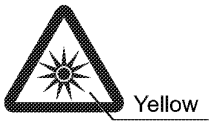
Prohibition of improper repair and modification

This instrument does not contain any user-serviceable parts. Do not disassemble, modify, or attempt to repair it; patient or operator injury and/or equipment damage may result.
Equipment that has been disassembled, repaired, altered, changed, or modified by persons other than Olympus' own authorized service personnel is excluded from Olympus' limited warranty and is not warranted by Olympus in any manner.

Classification of safety optical radiation

The endoscope is Risk Group 2 product (IEC 62471: 2006).

Risk Group 2	
CAUTION  	• UV emitted from this device. Skin irritation may result. Do not keep the distal end of the endoscope in contact with skin for over four seconds. • The light emitted may be harmful to the eyes. Do not stare directly into the distal end of the endoscope while the examination light is ON.

Signal words

The following signal words are used throughout this manual:

WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.
NOTE	Indicates additional helpful information.

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Precautions

Follow the warnings and cautions given below when handling this endoscope. This information is to be supplemented by the warnings and cautions given in each chapter.

WARNING

- Do not use this instrument for any purpose other than its indications for use. Select the endoscope to be used according to the objective of the intended procedure based on the full understanding of the endoscope's specifications and functionality as described in this instruction manual.
- After using this endoscope, reprocess and store it according to the instructions given in the endoscope's companion "REPROCESSING MANUAL" with your endoscope model listed on the cover. Using improperly or incompletely reprocessed or stored instruments may cause patient cross-contamination and/or infection.
- Do not strike, hit, or drop the endoscope's distal end, insertion tube, bending section, control section, universal cord, video connector, or light guide connector. Also, do not bend, pull, or twist the endoscope's distal end, insertion tube, bending section, control section, universal cord, video connector, or light guide connector with excessive force. The endoscope may be damaged and could cause patient injury, burns, bleeding, and/or perforations. It could also cause parts of the endoscope to fall off inside the patient.
- Never perform angulation control forcibly or abruptly. Never forcefully pull, twist, or rotate the angulated bending section. Patient injury, bleeding, and/or perforation may result. It may also become impossible to straighten the bending section during an examination.
- Never insert or withdraw the endoscope's insertion section while the bending section is locked. When using an endoscope with the UP/DOWN angulation lock, never insert or withdraw the endoscope while the angulation lock is moved in the opposite direction of the "F▼" mark. Patient injury, bleeding, and/or perforation may result.
- Never operate the bending section, insert or withdraw the endoscope's insertion section, or use EndoTherapy accessories without viewing the endoscopic image. Patient injury, bleeding, and/or perforation may result.
- Never use EndoTherapy accessories, insert or withdraw the insertion section, or perform angulation control while the image is frozen. Patient injury, bleeding, and/or perforation may result.
- If it is difficult to insert the endoscope, do not forcibly insert the endoscope; stop the endoscopy. Forcible insertion can result in patient injury, bleeding, and/or perforation.
- Never insert or withdraw the insertion section abruptly or with excessive force. Patient injury, bleeding, and/or perforation may result.

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WARNING

- Do not touch the light guide on the light guide connector immediately after removing it from the light source because it is extremely hot. Operator or patient burns can result.
- Although the illumination light emitted from the endoscope's distal end is required for endoscopic observation, it may also cause alteration of living tissues such as protein denaturation of living tissue and perforation of the tissue by inappropriate using. Observe the following warnings for illumination.
  - Always set the minimum required brightness. The brightness of the image on a monitor may differ from the actual brightness at the distal end of the endoscope. Pay special attention to the brightness level setting of the light source, particularly when operating the electrical shutter function of a video system center. When both a light source and a video system center have the automatic brightness control function, use the function on the light source. This function can better maintain the illumination level. Refer to the instruction manual for the light source and the video system center for further details.
  - Always maintain a suitable distance necessary for adequate viewing while using the minimum level of illumination for the minimum amount of time. Do not use close stationary viewing or leave the distal end of the endoscope close to the mucous membrane for a long time without necessity.
  - When the endoscope will not be used for a long period, be sure to turn OFF the light source or activate the light shield function (standby mode, etc.) so that the endoscope is not illuminated unnecessarily.
- Push the video connector into the video system center until it clicks, then confirm that the video connector is securely attached by pulling it gently. Improper connection will damage the image sensor. The damaged image sensor will display no image and make the distal end hot, which could cause operator and/or patient burns.
- Do not insert the video connector while the electrical contacts are wet and/or dirty. This may result in an electric shock, causing severe damage to the endoscope and compromising patient and/or operator safety.
- If the endoscopic image becomes dimmer during the procedure, it may indicate that blood or mucus is adhering to the light guide lens on the distal end of the endoscope. Carefully withdraw the endoscope from the patient and remove blood or mucus to restore optimum illumination and to ensure the safety of the examination. If you continue to use the endoscope with its obstructed light guide lens, the temperature at the distal end may rise and cause mucosal burns to the patient. It may also cause patient and/or operator injury.
- When the endoscopic image does not appear on the monitor, the image sensor may have been damaged. Turn the video system center OFF immediately. Continued power supply in such a case will cause the distal end to become hot and could cause operator and/or patient burns.

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WARNING

- Do not rely on the NBI observation mode alone for primary detection of lesions or to make a decision regarding any potential diagnostic or therapeutic intervention.

CAUTION

- Do not pull the universal cord and video cable during an examination. The light guide connector will be pulled out from the output socket of the light source and the endoscopic image will not be visible.
- Do not coil the insertion tube, universal cord, or video cable with a diameter of less than 10 cm. Equipment damage may result.
- Do not attempt to bend or twist the endoscope's insertion section with excessive force. The insertion section may be damaged.
- Do not apply shock to the distal end of the insertion section, particularly the objective lens surface at the distal end. Visual abnormalities may result.
- If the endoscope is dropped or the distal end of the endoscope receives a hard impact, the endoscope may be damaged even if no visible damage of the lens on the distal end can be found. In this case, stop using the endoscope, and contact Olympus.
- Do not twist or bend the bending section with your hands. Equipment damage may result.
- Do not squeeze the bending section forcefully. The covering of the bending section may stretch or break and cause water leaks.
- Do not put or press the video connector and light guide connector on the insertion section when transporting or reprocessing. The insertion section may be damaged.
- Turn the video system center ON only when the video connector is connected to the video system center. In particular, confirm that the video system center is OFF before connecting or disconnecting the video connector. Failure to do so can result in equipment damage, including destruction of the image sensor.
- The endoscope's remote switches cannot be removed from the control section. Pressing, pulling, or twisting them with excessive force can break the switches and/or cause water leaks.
- Do not hit or bend the electrical contacts on the video connector. The connection to the video system center may be impaired and faulty contact can result.
- Do not pull the video cable during an examination. The endoscopic image may not be visible.

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CAUTION

- Electromagnetic interference may occur on this endoscope near equipment marked with the following symbol or other portable and mobile RF (Radio Frequency) communications equipment, such as cellular phones, or other RF emitter devices such as electrocautery, RFID, or diathermy. If electromagnetic interference occurs, mitigation measures may be necessary, such as reorienting or relocating this endoscope, or shielding the location.

- Be sure that this endoscope is not used adjacent to or stacked with other equipment (other than the components of this endoscope or system) to avoid electromagnetic interference.
- To check the electromagnetic interference from other equipment (any equipment other than this endoscope or the components that constitute this system), the system should be observed to verify its normal operation in the configuration in which it will be used.

NOTE

- This endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center OTV-S190.
- When the endoscope gets strong static electricity, noise may be observed in the endoscopic image. This does not indicate a malfunction.

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Precaution for disappeared or frozen endoscopic image

WARNING

- If the endoscopic image disappears unexpectedly or the frozen image cannot be restored during an examination, immediately stop using the endoscope and withdraw it from the patient as described in Section 5.3, "Withdrawal of the endoscope with an irregularity". Continued use of the endoscope under this condition could result in patient injury, bleeding, and/or perforation.
- Follow the precautions given below. Otherwise, the endoscopic image may disappear unexpectedly or the frozen image may not be restored during the examination.
  - Connect the video connector to the video system center completely by pushing the video connector until it clicks. Otherwise, faulty contact can result.
  - Do not bend, hit, pull, or twist the insertion section, bending section, control section, universal cord, video cable, video connector, and light guide connector. The endoscope may be damaged, and water leaks and/or breakage of internal parts like the image sensor cable can result.
  - Make sure that the video connector and its electrical contacts are completely dry before connecting the video connector to the video system center. Wet contacts could cause the equipment to malfunction.
  - If air bubbles emerge from the endoscope continuously during the leakage test, do not use the endoscope. Water may enter the endoscope and cause a short circuit. This may result in image sensor damage.

CAUTION

- Turn the video system center ON only when the video connector is connected to the video system center. In particular, confirm that the video system center is OFF before connecting or disconnecting the video connector. Failure to do so can result in equipment damage, including destruction of the image sensor.
- Do not hit or bend the electrical contacts on the video connector. The connection to the video system center may be impaired and faulty contact can result.

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Examples of inappropriate handling

Details on clinical endoscopic technique are the responsibility of trained specialists. Patient safety in endoscopic examinations and endoscopic treatment can be ensured through appropriate handling by the physician and the medical facility. Examples of inappropriate handling are described below.

- Inserting, withdrawing, and using EndoTherapy accessories without a clear endoscopic image may cause patient injury, burns, bleeding, and/or perforation.
- Inserting or withdrawing the endoscope, or operating the bending section without a clear endoscopic image may cause patient injury, bleeding, and/or perforation.
- For reasons described below, do not rely on the NBI*1 observation mode alone for primary detection of lesions to make a decision regarding any potential diagnostic or therapeutic intervention.
  - NBI has not been demonstrated to increase the yield or sensitivity of finding any specific mucosal lesion.
  - NBI has not been demonstrated to aid in differentiating and establishing the presence or absence of dysplasia or neoplastic changes within mucosa or mucosal lesions.

*1 Narrow Band Imaging. For more details, refer to the instruction manual for the video system center.

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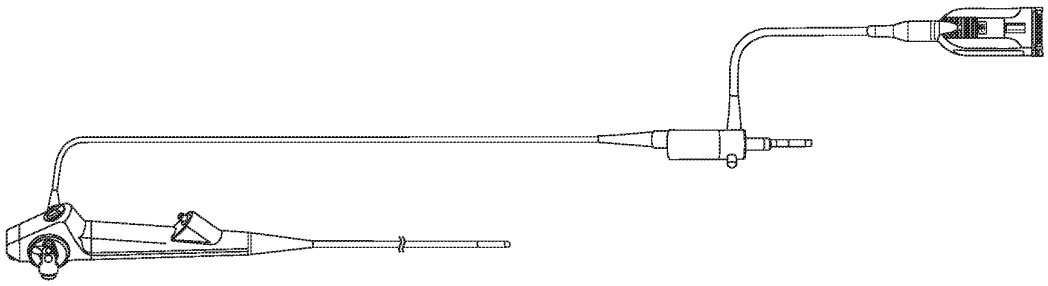
Chapter 1 Checking the Package Contents

1.1 Checking the package contents

Match all items in the package with the components shown below. Inspect each item for damage. If the endoscope is damaged, a component is missing, or you have any questions, do not use the items; immediately contact Olympus.

Endoscope



CYF-VH/VHR

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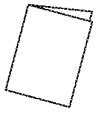
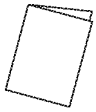
Accessories

Single use combination cleaning brush (BW-411B)

Sterilization cap (MAJ-1538)



Operation manual



Reprocessing manual

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Chapter 2 Instrument Nomenclature and Specifications

The instrument nomenclature, functions, and specifications are described in this chapter.

2.1 Nomenclature and functions

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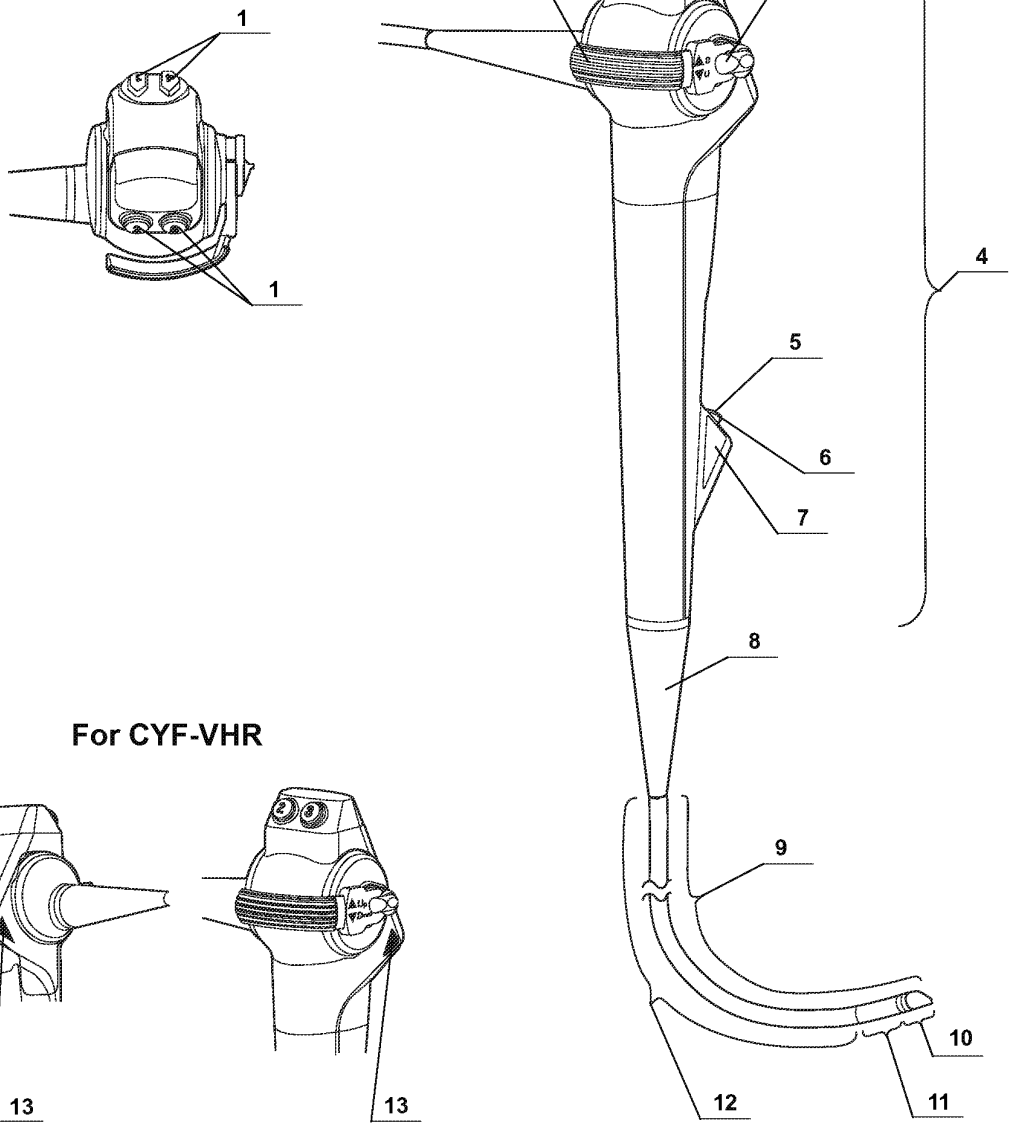
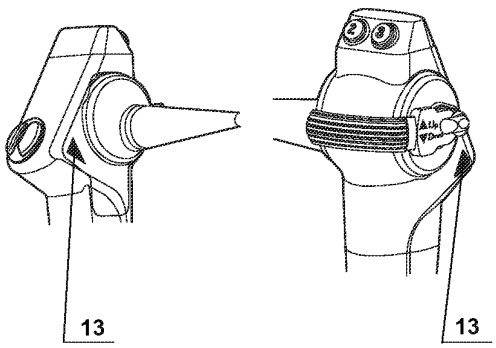
Control section, insertion section

Endoscope model: CYF-VH, CYF-VHR



For CYF-VHR



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No.	Nomenclature	Description	Endoscope model
1	Remote switches 1 to 4	The functions of the remote switches 1 to 4 can be selected on the video system center. Refer to the instruction manual for the video system center when setting these functions.	
2	UP/DOWN angulation control lever	When this lever is turned in the “U” direction (for CYF-VHR: “Up”), the bending section moves UP; when the lever is turned in the “D” direction (for CYF-VHR: “Down”), the bending section moves DOWN.	
3	UP/DOWN angulation lock	Moving this lever in the “F▼” direction frees angulation. Moving the lever in the opposite direction locks the bending section at any desired position.	
4	Control section	Operates the endoscope, such as controlling angulation.	
5	Instrument channel	An EndoTherapy accessory can be inserted to this channel. The instrument channel is connected to the distal end of the endoscope. The instrument channel functions are: • Channel for the insertion of EndoTherapy accessories • Fluid feed channel	
6	Instrument channel port	Attach the Forceps/irrigation plug to this port.	
7	Color code	The color code is used to quickly determine the compatibility of EndoTherapy accessories. The endoscope can be used with EndoTherapy accessories that have the same color code. For more information on combining the endoscope with particular EndoTherapy accessories, refer to the “■ Compatible EndoTherapy accessories” on page 68 and the instruction manuals for the compatible accessories. • Blue: CYF-VH, CYF-VHR	
8	Boot	Avoids the junction between the insertion tube and control section from bending.	
9	Insertion section	This section is inserted into the patient body cavity.	
10	Distal end	The objective lens and light guide lens are on this distal end.	
11	Bending section	The bending section moves the distal end of the endoscope when the UP/DOWN angulation control lever is operated.	
12	Insertion tube	Connects the control section and bending section.	
13	Identification marking for opposite bending direction	This marking indicates that the bending section of the CYF-VHR moves in the direction opposite to the conventional endoscopes, such as the CYF-VH.	CYF-VHR

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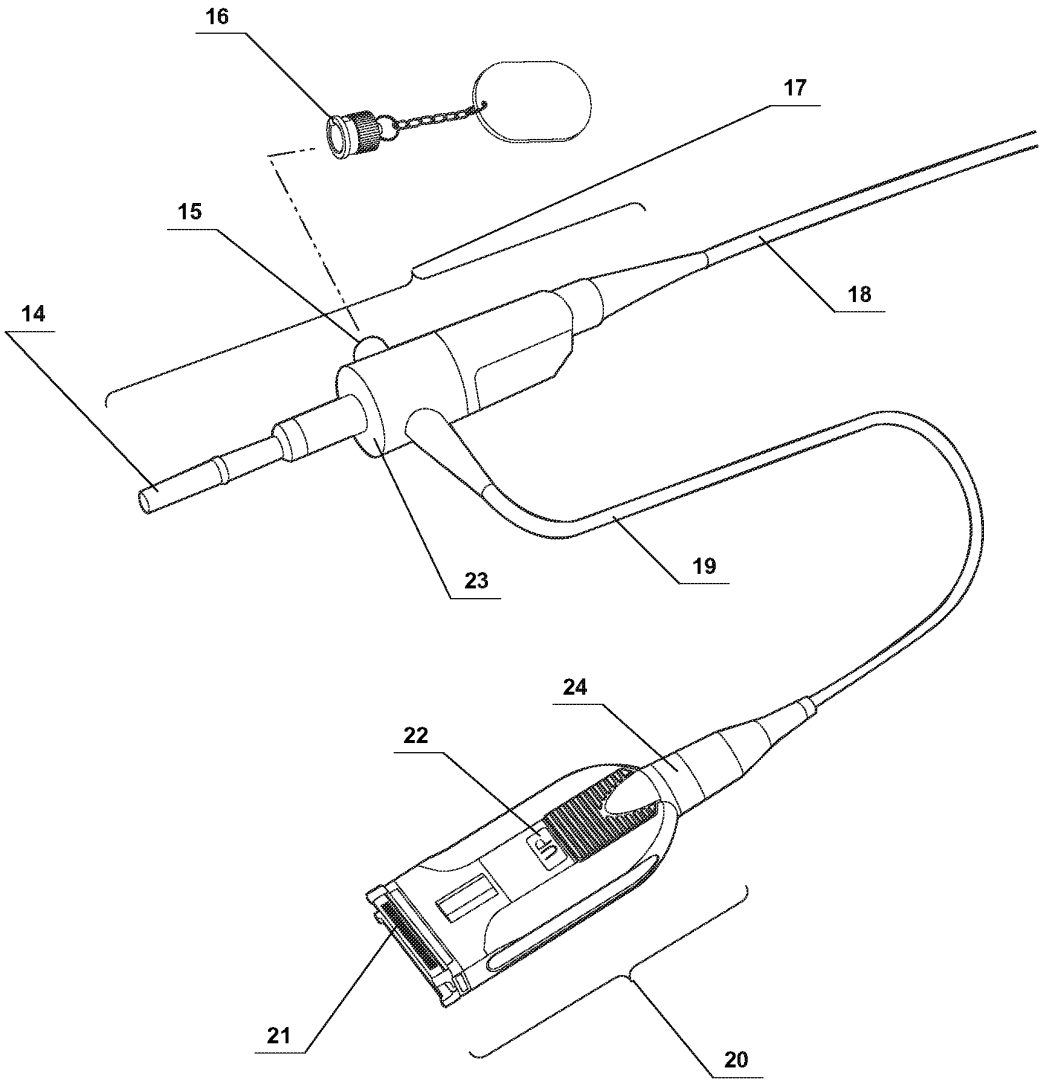
Light guide connector, video connector



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No.	Nomenclature	Description
14	Light guide	Connects the endoscope to the light source and transmits light to the distal end of the endoscope.
15	Venting connector	Attach the sterilization cap or leakage tester here.
16	Sterilization cap (MAJ-1538)	The sterilization cap equalizes the outer and inner pressure of the endoscope. The cap must be attached prior to gas sterilization (ethylene oxide gas, STERRAD® etc.) and aeration and removed prior to immersion or clinical examination. The cap must also be attached when the endoscope is transported outside the hospital (shipment, return for repairs, etc.).
17	Light guide connector	The light guide connector connects the endoscope to the output socket of the light source and transmits light from the light source to the distal end of the endoscope.
18	Universal cord	Connects the light guide connector and the control section.
19	Video cable	Connects the light guide connector and the video connector.
20	Video connector	The video connector connects the endoscope to the video connector socket of the video system center so that the endoscopic image becomes visible. The endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center. For more details, refer to the instruction manual for the video system center.
21	Electrical contacts	Connects the video system center and the endoscope electrically.
22	UP mark	When the video connector is connected to the video system center, this mark is facing upward.
23	Serial number	The serial number is marked here.
24	Product ID plate	UDI indication and the product name (model) are marked here.

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2.2 Specifications

Environment

Operating environment	**Ambient temperature**	10 – 40°C (50 – 104°F)
	Relative humidity	30 – 85%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)
Standard storage environment (e.g. within the hospital)	**Ambient temperature**	5 – 40°C (41 – 104°F)
	Relative humidity	10 – 95%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)
Transportation environment (conditions during transportation and short-term storage)	**Ambient temperature**	–47 to +70°C (–52.6 to +158°F)
	Relative humidity	10 – 95%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)

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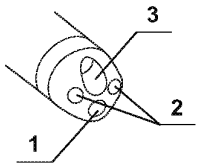
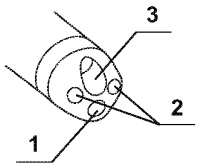
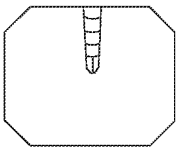
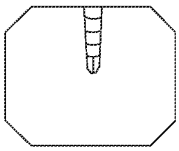
Specifications

Endoscope function

Model		CYF-VH	CYF-VHR
Optical system	**Field of view**	120°	120°
	Direction of view	0° (Forward viewing)	0° (Forward viewing)
	Depth of field	3 – 50 mm	3 – 50 mm
Insertion section	**Distal end outer diameter**	ø 2.7 mm (Bullet shape)	ø 2.7 mm (Bullet shape)
	Distal end enlarged 1 Objective lens 2 Light guide lens 3 Instrument channel outlet		
	Insertion tube outer diameter	ø 5.5 mm (16.5 Fr)	ø 5.5 mm (16.5 Fr)
	Insertion section working length	380 mm	380 mm
Instrument channel	**Channel inner diameter**	ø 2.2 mm (6.6 Fr)	ø 2.2 mm (6.6 Fr)
	Minimum visible distance[*1]	2.5 mm	2.5 mm
	Direction from which EndoTherapy accessories enter and exit the endoscopic image		
Bending section	**Angulation range**	UP 220° DOWN 130°	UP 220° DOWN 130°
Total length		660 mm	660 mm
NBI observation mode[*2]		Available	Available
Records of endoscope's information[*2]		Available	Available
Electronic shutter function[*2]		Available	Available
Electronic zoom function[*2]		Available	Available
High-frequency treatment		Compatible	Compatible
Laser treatment		Not compatible	Not compatible

*1 Distance from the distal end of the endoscope.

*2 For more details, refer to the instruction manual for the video system center.

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Common specifications

EMC	**Applied standard**	IEC 60601-1-2: 2014 IEC 60601-2-18: 1996 IEC 60601-2-18: 2009 • This instrument complies with the EMC standard for medical electrical equipment, edition 4 (IEC 60601-1-2: 2014). When connecting to an instrument that complies with a previous edition of the EMC standard for medical electrical equipment edition, the EMC characteristics could be vulnerable. • CISPR 11 of emission: Group 1, Class B
Degree of protection against electric shock		TYPE BF applied part (the entire endoscope)
Classification of safety of optical radiation		Risk Group 2 (IEC 62471: 2006)
Ingress protection rating		IPX7
UDI Indication		 The UDI Indication is required by some countries' regulations regarding the identification of medical device also known as Unique Device Identification (UDI). The following information is being coded in the 2-dimensional barcode (GS1 Data Matrix): • (01) 14-digit GS1 Global Trade Item Number; • (11) 6-digit date of manufacture; • (21) 7-digit serial number.

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Chapter 3 Preparation and Inspection

The equipment prepared before using this endoscope and procedures for the inspection of the endoscope and equipment are described in this chapter.

3.1 The workflow of preparation and inspection

The workflow of preparation and inspection is shown below.

Before each case, prepare and inspect this endoscope as instructed below. Inspect other equipment to be used with this endoscope as instructed in their respective instruction manuals. Should any irregularity be observed after inspection, follow the instructions as described in Chapter 5, “Troubleshooting”. If this endoscope malfunctions, do not use it. Return it to Olympus for repair as described in Section 5.4, “Returning the endoscope for repair”.

WARNING

- Using an endoscope that is not functioning properly may compromise patient or operator safety and may result in more severe equipment damage.
- This endoscope was not reprocessed before shipment. Before using this endoscope for the first time, reprocess it according to the instructions as described in the endoscope's companion “REPROCESSING MANUAL” with your endoscope model listed on the cover.

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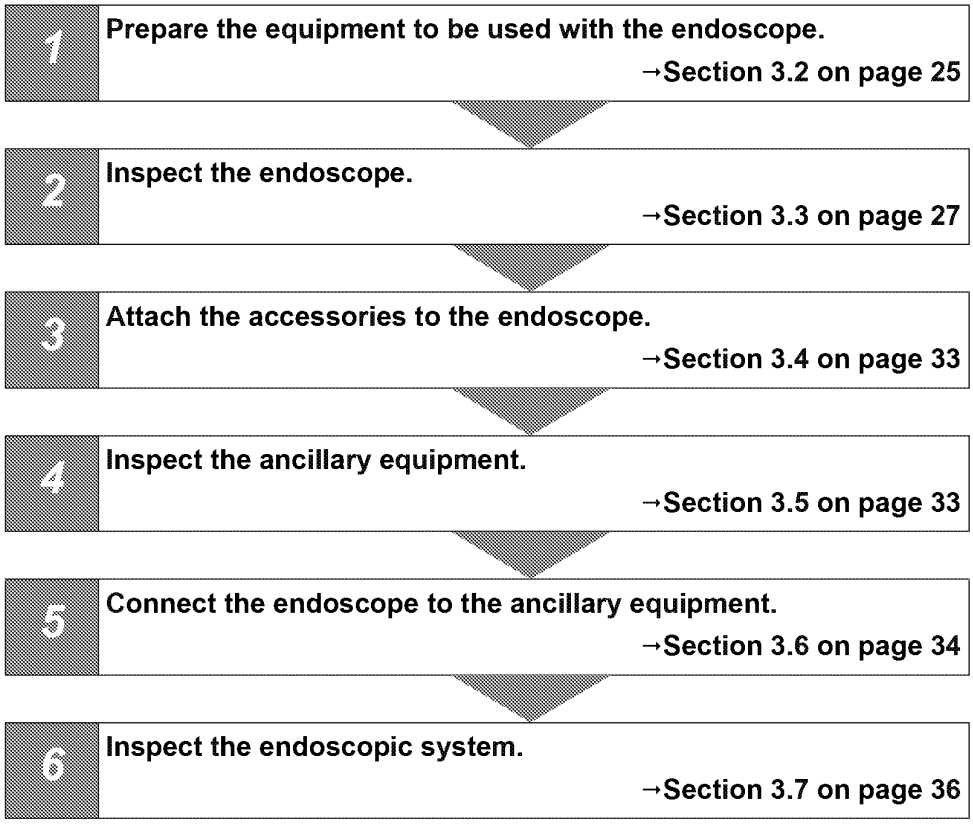
3.1 The workflow of preparation and inspection



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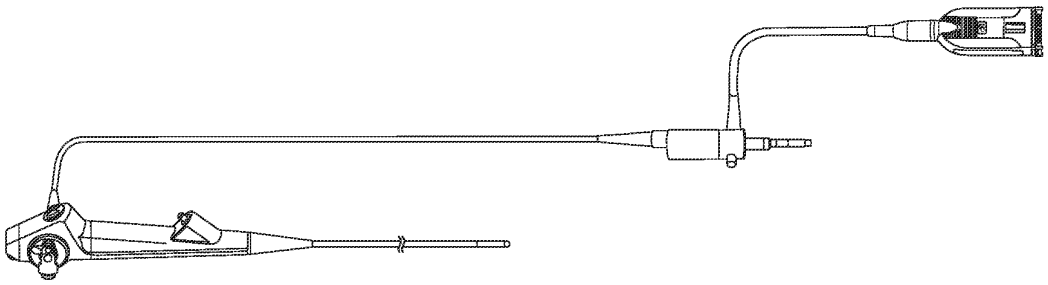
3.2 Preparation of the equipment

WARNING

- For cystoscopy procedures, prepare the endoscope and accessories that has been cleaned and then high-level disinfected or sterilized.
- For nephroscopy procedures, prepare the endoscope and accessories that has been cleaned and then sterilized.

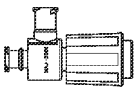
Prepare this endoscope, the accessories, equipment, and all personal protective equipment shown in Figure 3.1. Prepare the equipment in “Combination equipment” on page 65 in accordance with the intended use.
Also, refer to the respective instruction manuals for each piece of equipment before use.

Endoscope



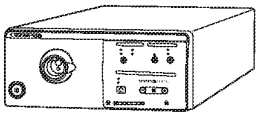
Endoscope*1

Accessories and ancillary equipment



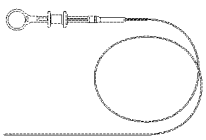
Forceps/irrigation plug

Video system center

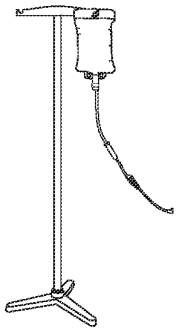


Light source

Monitor



EndoTherapy accessories



Irrigation system

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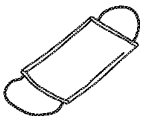
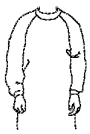
❍ Personal protective equipment (e.g.)

Eyewear



Face mask



Moisture-resistant clothing

Chemical-resistant gloves

❍ Other

- **Lint-free cloths**
- **Container for sterile water**
- **Sterile water**

Figure 3.1

*1 Prepare the endoscope that has been reprocessed as described in the “REPROCESSING MANUAL” with your endoscope model listed on the cover.

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3.3 Inspection of the endoscope

CAUTION

Detach the sterilization cap (MAJ-1538) from the venting connector if it is attached, especially after gas sterilization (e.g., ethylene oxide gas sterilization, hydrogen peroxide low temperature plasma). Otherwise, the remote switches may not work normally due to a difference between internal and external pressures of the endoscope.

Inspection of the endoscope

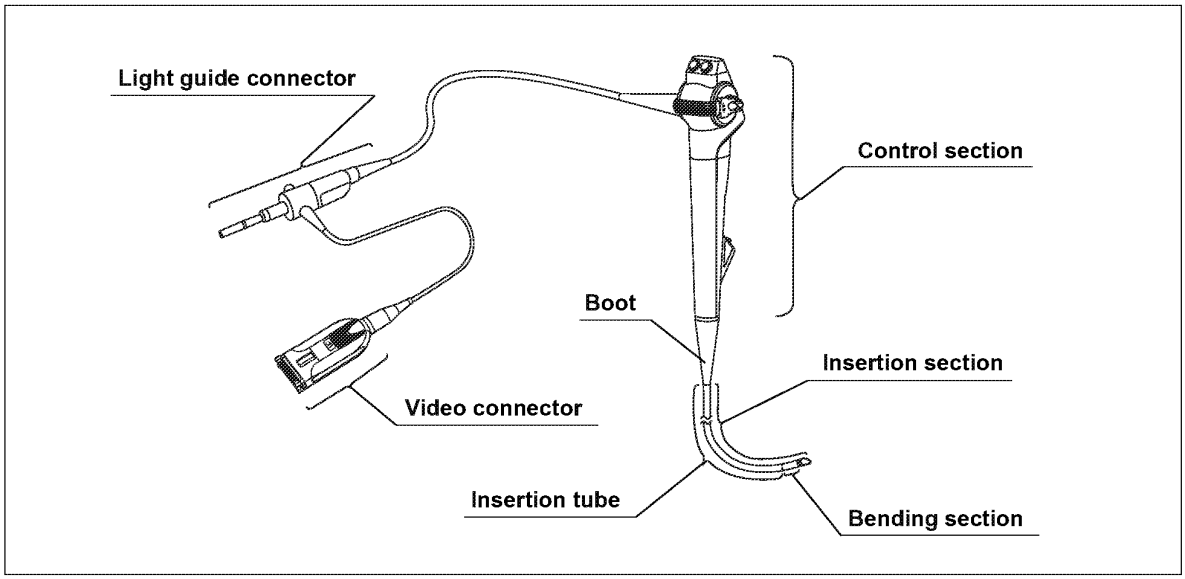

Figure 3.2

1. Inspect the control section, video connector, and light guide connector for excessive scratching, deformation, loose parts, or other irregularities.
2. Inspect the electrical contacts on the video connector for corrosion.
3. Inspect the boot and the insertion section near the boot for bends, twists, or other irregularities.
4. Inspect the external surface of the entire insertion section, including the bending section and the distal end for dents, bulges, swelling, scratches, peeling of coating, holes, sagging, transformation, bends, adhesion of foreign bodies, missing parts, protruding objects, or other irregularities.

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5 Holding the control section with one hand, carefully run your other hand back and forth over the entire length of the insertion section. Confirm that no objects or metallic wire protrude from the insertion section. Also, confirm that the insertion tube is not abnormally rigid.

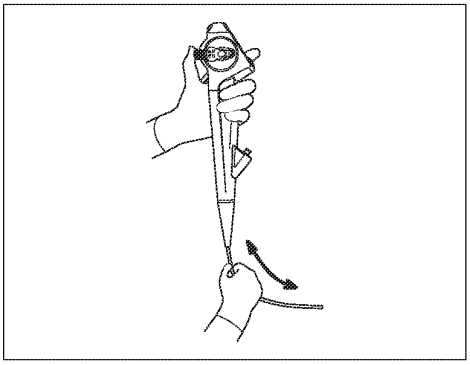

Figure 3.3

6 Using both hands, bend the insertion tube of the endoscope into a semicircle. Then, moving your hands as shown by the arrows in Figure 3.4, confirm that the entire insertion tube can be smoothly bent to form a semicircle and that the insertion tube is pliable.

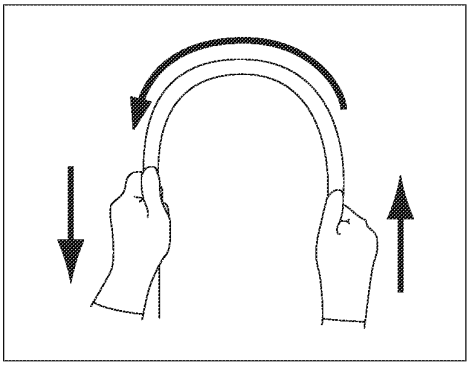

Figure 3.4

7 Gently hold the vicinity of the distal end and a point 10 cm from the distal end. Push and pull gently to confirm that the junction between the bending section and the insertion tube is not loose.

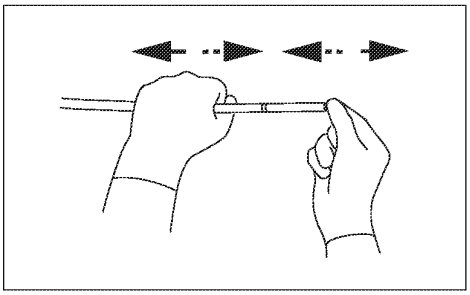

Figure 3.5

8 Inspect the lens at the distal end of the endoscope's insertion section for scratches, cracks, stains, gaps around the lens, or other irregularities. Also, inspect the entire distal end of the endoscope for chips or cracks.

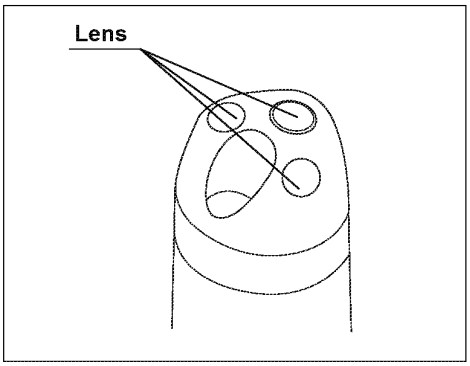

Figure 3.6

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9 Inspect the adhesives attaching the bending section cover to the insertion section for deterioration, pitting or cracking.

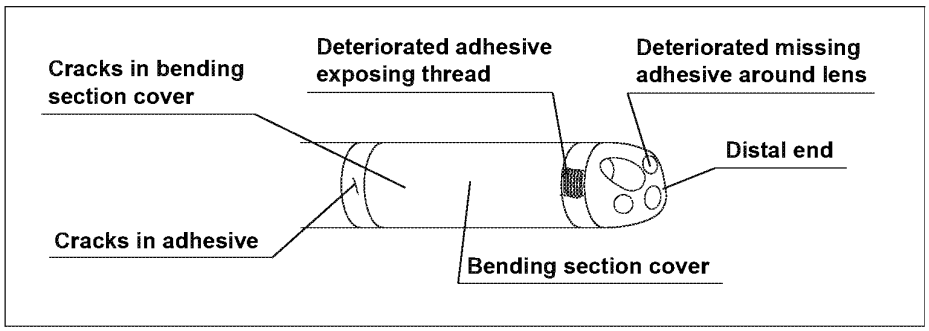

Figure 3.7

CAUTION

Insertion section should be free of rough surfaces, sharp edges or protrusions which may cause harm.

NOTE

The covering on both ends of the bending section is wound with thread. The adhesives cover them so that they are fixed. Therefore, the thread is exposed if the adhesives become chipped.

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Inspection of the bending mechanism

Perform the following inspections while the bending section is straight.

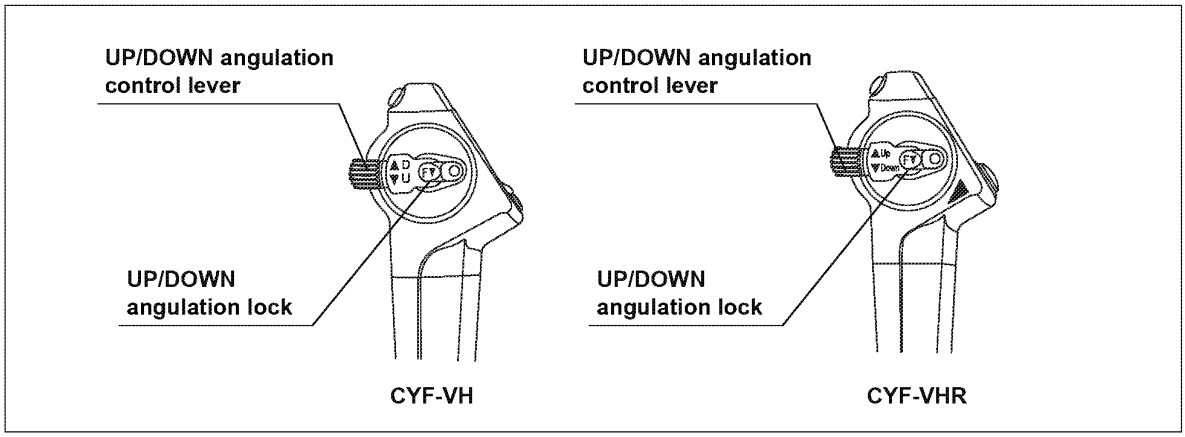

Figure 3.8

WARNING

- If the movement of the UP/DOWN angulation lock and the angulation control lever is loose and/or not smooth, or the bending section does not angulate smoothly, the bending mechanism may be abnormal. In this case, do not use the endoscope because it may be impossible to straighten the bending section during an examination, and patient injury, bleeding, and/or perforation may result.
- The UP/DOWN angulation control of the CYF-VHR is the opposite of the CYF-VH. Inspect the bending mechanism before the procedure. The bending section may bend in a different direction from the intended direction, and may cause patient injury, bleeding, and/or perforation.

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Inspection for smooth operation

1 Straighten the bending section.

2 Confirm that the UP/DOWN angulation lock is placed in the free “F▼” position.

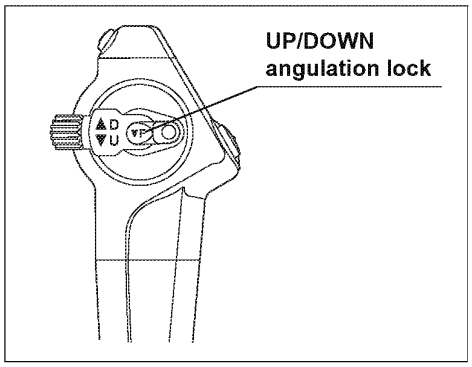

Figure 3.9

3 Operate the UP/DOWN angulation control lever slowly in each direction until it stops. Confirm that the bending section angulates smoothly and correctly, and that maximum angulation can be achieved.

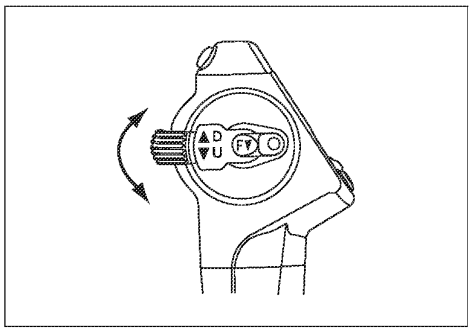

Figure 3.10

4 Operate the UP/DOWN angulation control lever slowly to its straight (neutral) position. Confirm that the bending section returns smoothly to an approximately straight position.

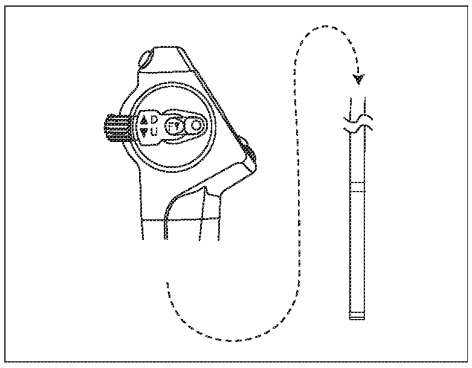

Figure 3.11

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Inspection of the angulation mechanism

1 Move the UP/DOWN angulation lock in the opposite direction of the "F▼" mark into the locked position.

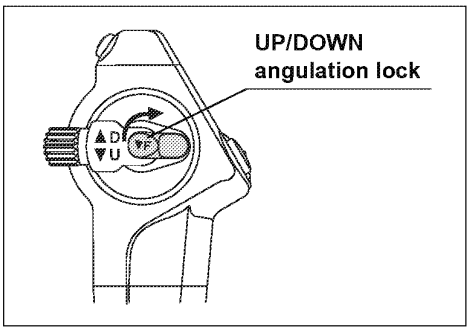

Figure 3.12

2 Move the UP/DOWN angulation control lever in the "U" or "D" direction (for CYF-VHR: "Up" or "Down") until it stops.

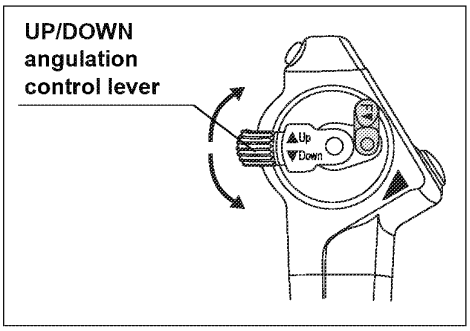

Figure 3.13

3 Confirm that the angle of the bending section is roughly stabilized when the UP/DOWN angulation control lever is released.

4 Confirm that the bending section returns to its straight (neutral) position when the UP/DOWN angulation lock is placed in the free position and the UP/DOWN angulation control lever is released.

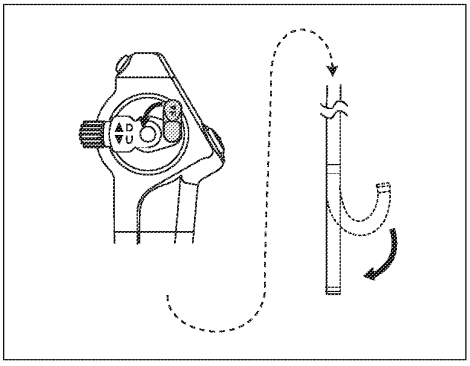

Figure 3.14

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3.4 Attaching accessories to the endoscope

■ Attaching a forceps/irrigation plug

Attach a forceps/irrigation plug to the instrument channel port.

3.5 Inspection of ancillary equipment

1 Inspect the following equipment as described in their respective instruction manuals.

- Light source
- Video system center
- Monitor
- EndoTherapy accessories

2 Inspect the irrigation system to be used.

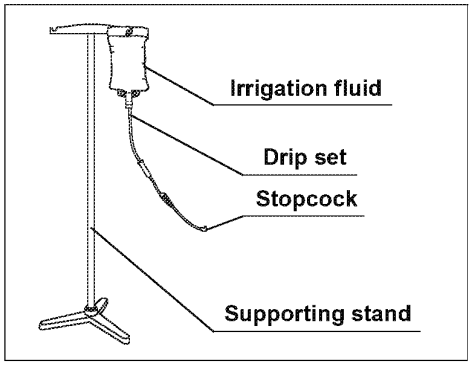

Figure 3.15

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3.6 Connection of the endoscope and ancillary equipment

Connect the ancillary equipment to the endoscope as described below.

Connection to the light source and video system center

WARNING

If the video connector and video system center are not connected properly, the endoscopic image may flicker or may not be displayed. Continuous use of such an endoscope may cause patient injury, bleeding, and/or perforation.

CAUTION

Before connecting the video connector to the video system center, confirm that the electrical contacts are not wet. If the electrical contacts are wet, the endoscope and video system center may malfunction.

NOTE

Connect the endoscope's light guide connector to the light source, then connect the video connector to the video system center. This can prevent a twisting of the video cable, and the video connector can be connected smoothly.

1. If any ancillary equipment is ON, turn it OFF.
2. While holding the video connector with one hand, insert the light guide connector completely into the output socket of the light source.

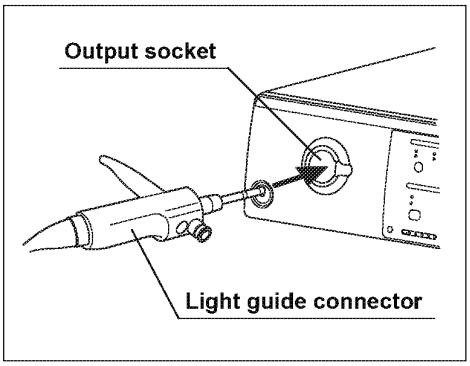

Figure 3.16

3. Make sure that the UP mark on the video connector is facing up. (See Figure 3.17)

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4 Hold the video system center stationary with one hand. With the other hand, push the video connector into the video connector socket until it clicks.

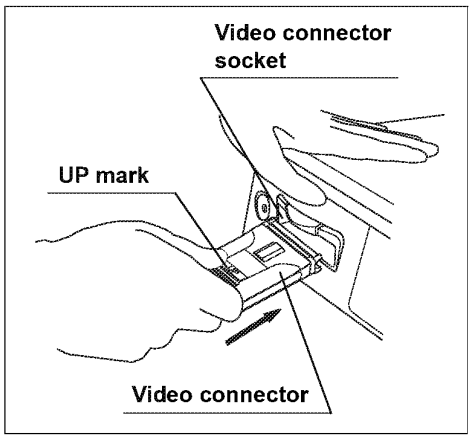

Figure 3.17

5 Confirm that the video connector is securely attached by pulling it gently.

Connection of irrigation system

Connect the irrigation tube from the irrigation system to the irrigation port on a forceps/irrigation plug.

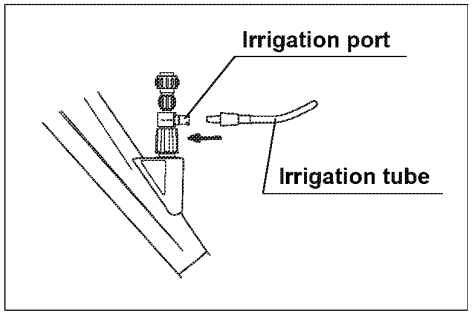

Figure 3.18

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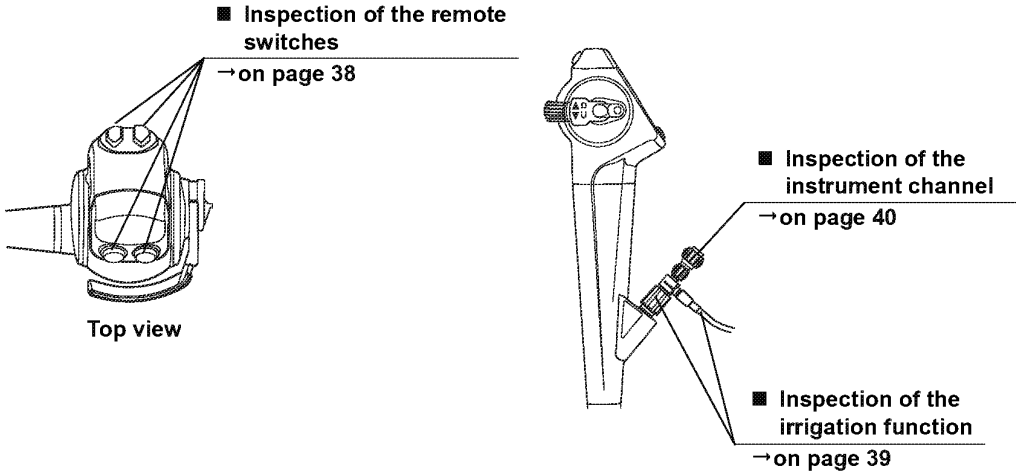
3.7 Inspection of the endoscopic system

■ Inspection summary



■ Inspection of the ancillary equipment

Turn ON the video system center, light source, and monitor. Inspect them as described in their respective instruction manuals.

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Inspection of the endoscopic image

Confirm that the WLI and NBI endoscopic images are normal.

WARNING

Do not stare directly into the distal end of the endoscope while the examination light is ON. Eye injury may result.

NOTE

Confirm that the endoscope provides a live image and has the correct image orientation.

1. Before inspection, wipe the objective lens with clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.
2. Observe the palm of your hand in the WLI and NBI endoscopic images.

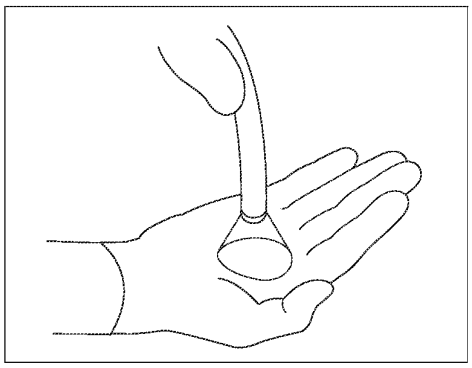

Figure 3.19

3. Confirm that light is output from the endoscope's distal end. (See Figure 3.19)
4. Adjust the brightness level as appropriate.
5. Confirm that the WLI and NBI endoscopic images are free from noise, blur, fog, or other irregularities.
6. Turn the UP/DOWN angulation control lever slowly in each direction until it stops.

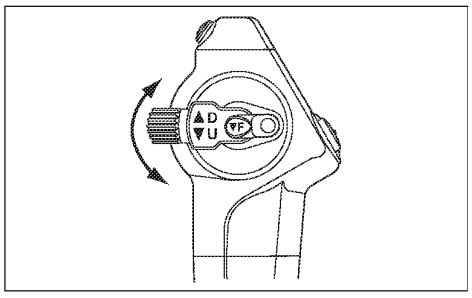

Figure 3.20

7. Confirm that the WLI and NBI endoscopic images do not momentarily disappear or display any other irregularities.

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Inspection of the remote switches

WARNING

All remote switches should be checked to work normally even if they are not expected to be used. The endoscopic image may freeze, or other irregularities may occur during examination and may cause patient injury, bleeding, and/or perforation.

CAUTION

Detach the sterilization cap from the venting connector after gas sterilization (e.g., ethylene oxide gas sterilization, hydrogen peroxide low temperature plasma). Otherwise, the remote switches may not work normally due to a difference between internal and external pressures of the endoscope.

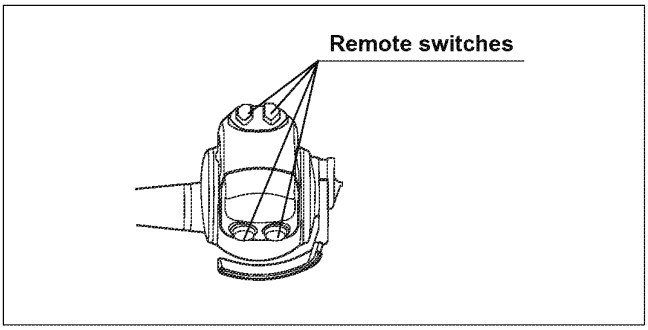

Figure 3.21

1. Depress every remote switch.
2. Confirm that the specified functions work normally.

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Inspection of the irrigation function

1. Inject irrigation fluid through the irrigation tube.
2. Confirm that fluid is emitted from the instrument channel outlet at the distal end of the endoscope.
3. Confirm that no water leaks from a forceps/irrigation plug and irrigation tube.

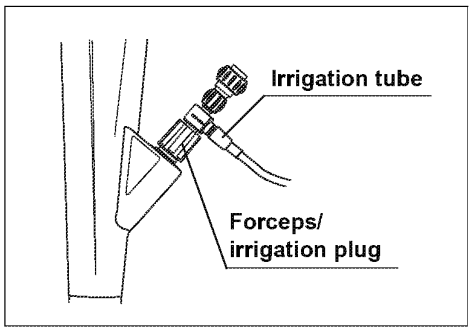

Figure 3.22

NOTE

The amount of irrigation fluid will be reduced when an EndoTherapy accessory is inserted in the instrument channel. Confirm the amount of irrigation fluid under these conditions in advance.

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Inspection of the instrument channel

WARNING

Keep your eyes away from the distal end when inserting EndoTherapy accessories. Extending the EndoTherapy accessory from the distal end could cause an eye injury.

CAUTION

- Use EndoTherapy accessories with the same color code (ø 2.0 mm channel or less). The endoscope and/or the EndoTherapy accessory may be damaged.
- If significant resistance is encountered and insertion becomes very difficult, straighten the bending section as much as possible without losing the endoscopic image. Inserting EndoTherapy accessories with excessive force may damage the endoscope and/or the EndoTherapy accessories.
- Confirm that the tip of the EndoTherapy accessory is closed or retracted into its sheath and slowly insert the EndoTherapy accessory into the forceps port of the sealing accessories. Do not open the tip of the EndoTherapy accessory or extend the tip of the EndoTherapy accessory from its sheath while inserting it into the channel. The endoscope and/or the EndoTherapy accessory may be damaged.
- Hold the EndoTherapy accessory close to the forceps port of the sealing accessories and insert it straight into the sealing accessories using slow, short strokes. The sheath of the EndoTherapy accessory could bend or break.

1. Straighten the insertion section of the endoscope.
2. Insert the EndoTherapy accessory straight into the forceps port of the sealing accessories while closing its distal end and retracting it into the sheath.
3. Confirm that the EndoTherapy accessory extends smoothly from the instrument channel outlet at the distal end of the endoscope. Also make sure that no foreign objects come out of the distal end.
4. Confirm that the EndoTherapy accessory is withdrawn smoothly from the sealing accessories.

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Chapter 4 Operation

This manual does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this endoscope. Therefore, the operator of this endoscope must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique.

4.1 Precautions

WARNING

- To guard against dangerous chemicals and potentially infectious material during the procedure, wear personal protective equipment, such as eyewear, face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.
- The temperature of the distal end of the endoscope may exceed 41°C (106°F) and reach 50°C (122°F) due to intense endoscopic illumination. Surface temperatures over 41°C (106°F) may cause mucosal burns. Always maintain a suitable distance necessary for adequate viewing while using the minimum level of illumination for the minimum amount of time. Do not use close stationary viewing or leave the distal end of the endoscope close to the mucous membrane for a long time without necessity.
- Whenever possible, do not leave the endoscope illuminated before and/or after an examination. Continued illumination will cause the distal end of the endoscope to become hot and could cause operator and/or patient burns.
- Never insert or withdraw the endoscope under any of the following conditions. Patient injury, bleeding, and/or perforation can result.
  - While the EndoTherapy accessory extends from the distal end of the endoscope.
  - While the bending section is locked in position.
  - Insertion or withdrawal with excessive force.

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WARNING

- If any of the following conditions occur during an examination, immediately stop the examination and withdraw the endoscope from the patient as described in Section 5.3, "Withdrawal of the endoscope with an irregularity".
  - If any irregularity is observed with the functionality of the endoscope.
  - If the endoscopic image on the monitor disappears or freezes unexpectedly.
  - If noise, blur or fog appear on the endoscopic image.
  - If the angulation control lever does not move.
  - If the angulation control mechanism is not functioning properly.

  Continued use of the endoscope under these conditions could result in patient injury, bleeding, and/or perforation.
- If an abnormal endoscopic image appears or an abnormal function occurs but quickly corrects itself, the endoscope may have malfunctioned. In this case, stop using the endoscope because the irregularity can occur again and the endoscope may not return to its normal condition. Stop the examination immediately and slowly withdraw the endoscope while viewing the endoscopic image. Otherwise, patient injury, bleeding, and/or perforation can result.
- The endoscopic image may be disturbed while switching between WLI observation mode and NBI observation mode. Therefore, do not perform any endoscopic operation or treatment while switching between WLI observation mode and NBI observation mode. Injury in the body cavity may result.
- When a part of the endoscopic image, normal colors, or a whole image is not displayed, the image sensor may be damaged. Using the damaged image sensor continuously for a long time makes the distal end of the endoscope extremely hot. Immediately turn OFF the video system center and light source. Otherwise, operator or patient burns may result.
- If the endoscopic image on the monitor should unexpectedly disappear or freeze during an examination and cannot be restored, turn the video system center OFF and then ON again. If the image still does not appear, stop the examination immediately, turn the video system center OFF, place the UP/DOWN angulation lock in the free "F▼" position, then, without touching the angulation control lever, slowly withdraw the endoscope from the patient.
- If the angulation control mechanism or any other part of the system is not functioning properly, stop the procedure immediately and place the UP/DOWN angulation lock in the free "F▼" position. Then carefully withdraw the endoscope while observing the endoscopic image. If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope carefully. If the endoscope cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope may cause patient injury, bleeding, and/or perforation. If any irregularities with the endoscope are observed, contact Olympus.

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WARNING

- Turn the video system center ON to operate the light source's automatic brightness function. When the video system center is OFF, it cannot operate the light source's automatic brightness function, and the light intensity may be set to the maximum level. In this case, the distal end of the endoscope can become hot and could cause operator and/or patient burns.
- When performing high-frequency cauterization, do not get the external surface of the control section and its surroundings wet. Electric current may flow, and operator and patient injury can result.
- The endoscope must be always sterilized before using for percutaneous nephroscopic diagnosis.

CAUTION

- Set the brightness of the light source to the minimum level necessary to perform the procedure safely.
- The surface temperatures of the endoscope may become maximum 50°C (122°F) by the operating environment. If the operator and/or patient touches there for a long time, it may cause the operator and/or patient burns.
- If the endoscope is dropped or the distal end of the endoscope receives hard impact, the endoscope may be damaged even if a crack or chip of the lens on the distal end can not be found. Stop using the endoscope and contact Olympus.
- The observation of X-ray image may interfere with the endoscopic image. This is normal and does not indicate a malfunction.

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4.2 Insertion

Holding and manipulating the endoscope

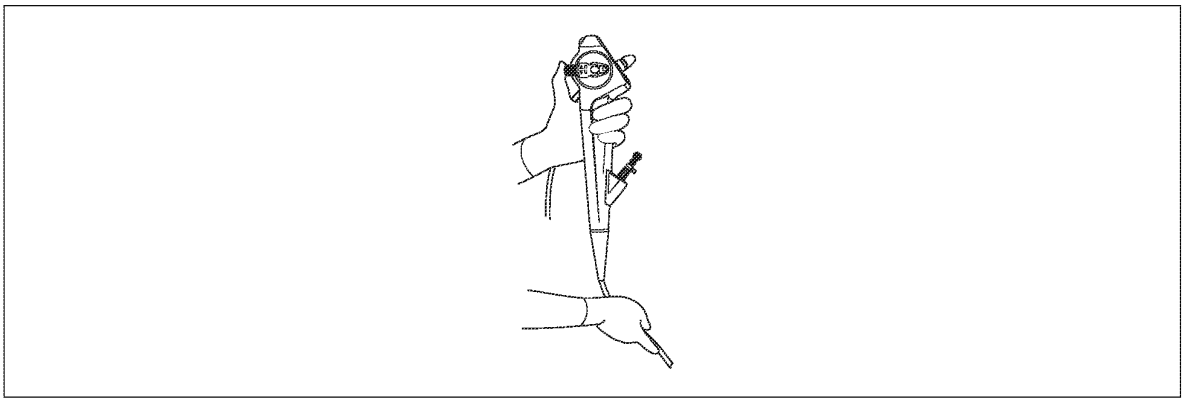

Figure 4.1

1. Hold the control section of the endoscope using your left hand.
2. Operate remote switches 1 and 4 using the left index finger.
3. Operate the UP/DOWN angulation control lever using the left thumb.
4. Maintain the insertion section using the right hand.

Irrigation

Feed the irrigation fluid through the irrigation tube.

NOTE

If it doesn't keep the view clear enough because of the amount of irrigation fluid while passing an EndoTherapy accessory through the channel, stop the examination. Then withdraw the EndoTherapy accessory and irrigation.

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Insertion of the endoscope

CAUTION

- Do not apply olive oil or products containing petroleum-based lubricants (e.g., Vaseline®) to the endoscope. These products may cause stretching and deterioration of the bending section's covering.
- Do not allow the insertion section to be bent within a distance of 10 cm or less from the junction of the boot. Insertion section damage can occur.

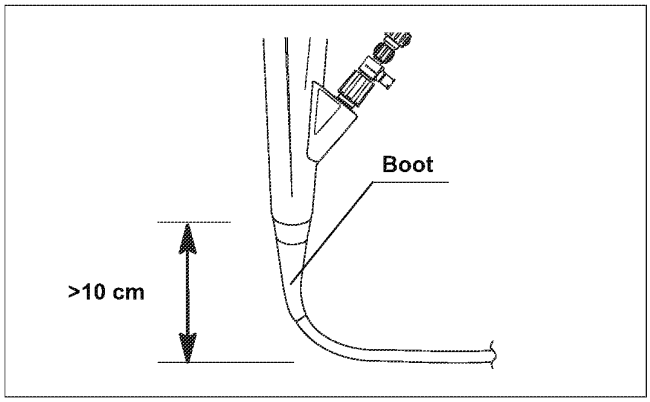

Figure 4.2

1 If necessary, apply a medical-grade, water-soluble lubricant to the insertion section.

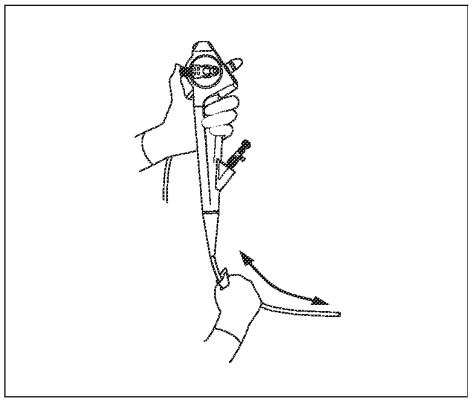

Figure 4.3

2 Insert the distal end of the endoscope into the body cavity while viewing the endoscopic image.

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Angulation of the distal end

WARNING

- If the angulation control mechanism or any other part of the system is not functioning properly, stop the examination immediately and place the UP/DOWN angulation lock in the free "F▼" position. Then carefully withdraw the endoscope while observing the endoscopic image. If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope carefully. If the endoscope cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope may cause patient injury, bleeding, and/or perforation. If any irregularities with the endoscope are observed, contact Olympus.
- Operate the UP/DOWN angulation control lever slowly while observing the endoscopic image. Otherwise, patient injury, bleeding, and/or perforation can result.

NOTE

- The endoscope's UP/DOWN angulation lock is used to hold the angulated distal end in position. When passing an EndoTherapy accessory through the channel while the angulation is locked, the angulation control lever should be held in place to help maintain the angle of the distal end. When it is necessary to keep the angulation stationary, hold the angulation control lever in place.
- When operating the UP/DOWN angulation lock, hold the UP/DOWN angulation control lever stationary with your fingers. The angulation will change.

Operate the UP/DOWN angulation control lever slowly to guide the distal end for insertion and observation.

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Observation of the endoscopic image

WARNING

- Do not rely on the NBI observation mode alone for primary detection of lesions to make a decision regarding any potential diagnostic or therapeutic intervention.
- If the endoscopic image seems to be dark in the NBI observation mode, change to the normal observation mode. Otherwise, the examination might not be done properly.

NOTE

The color tone and brightness of the NBI observation mode is different from the WLI observation mode. Use the NBI observation mode only after fully understanding its features.

Refer to the light source's instruction manual for instructions on how to adjust the brightness.

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4.3 Using EndoTherapy accessories

For more information on combining the endoscope with particular EndoTherapy accessories, refer to the "■ Compatible EndoTherapy accessories" on page 68 and the instruction manuals for the accessories. Also, refer to their respective instruction manuals for operating the accessories.

WARNING

- When using EndoTherapy accessories, keep the distance between the distal end of the endoscope and the mucous membrane greater than the endoscope's minimum visible distance so that the EndoTherapy accessory remains visible in the endoscopic image. If the distal end of the endoscope is placed closer than its minimum visible distance, the position of the accessory cannot be seen in the endoscopic image. This could cause serious patient injury and/or equipment damage. The minimum visible distance depends on the type of endoscope being used. Refer to Section 2.2, "Specifications".
- When inserting or withdrawing an EndoTherapy accessory, confirm that its distal end is closed or completely retracted into the sheath. Insert or withdraw the EndoTherapy accessory slowly and straight into or from the forceps port of the forceps/ irrigation plug. The biopsy valve may be damaged and pieces of it could fall off.
- If insertion or withdrawal of EndoTherapy accessories is difficult, straighten the bending section as much as possible without losing the endoscopic image. Inserting or withdrawing EndoTherapy accessories with excessive force may damage the instrument channel or EndoTherapy accessories and could cause some parts to fall off and/or cause patient injury.
- If the distal end of an EndoTherapy accessory is not visible in the endoscopic image, do not open the distal end of the EndoTherapy accessory. This could cause patient injury, bleeding, perforation, and/or equipment damage.
- If the EndoTherapy accessory cannot be withdrawn from the endoscope, close the tip of the EndoTherapy accessory or retract the tip of the EndoTherapy accessory into its sheath. Then carefully withdraw both the endoscope and the EndoTherapy accessory together while observing the endoscopic image. Inserting or withdrawing EndoTherapy accessories with excessive force may damage the instrument channel or EndoTherapy accessories and/or cause patient injury.
- Do not use the channel cleaning brush for cytologic tissue sampling or other diagnostic or therapeutic purposes. Patient injury, cross-contamination, and/or equipment damage may occur.

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CAUTION

Select the EndoTherapy accessories compatible with the endoscope by referring to "Channel inner diameter" in "■ Specifications" on page 21.

NOTE

When using EndoTherapy accessories, the image might become dark. In that case, adjust the brightness of the light source.

■ *Insertion of EndoTherapy accessories into the endoscope*

WARNING

Do not insert EndoTherapy accessories forcibly or abruptly. The EndoTherapy accessory may extend from the distal end of the endoscope abruptly, which could cause patient injury, bleeding, and/or perforation.

CAUTION

- When the bending section of the endoscope angulates significantly and insertion of an EndoTherapy accessory becomes very difficult, straighten the bending section as much as possible. Inserting the EndoTherapy accessory with excessive force may damage the instrument channel and/or the EndoTherapy accessory.
- Hold the EndoTherapy accessory close to the forceps port of the sealing accessories and insert it straight into the forceps port of the sealing accessories using slow short strokes. Otherwise, the EndoTherapy accessory could bend or break.

1 Select EndoTherapy accessories compatible with the endoscope from the "■ Compatible EndoTherapy accessories" on page 68 and the accessories' instruction manuals for operating instructions.

2 Hold the UP/DOWN angulation control lever stationary so that the bending section is straight.

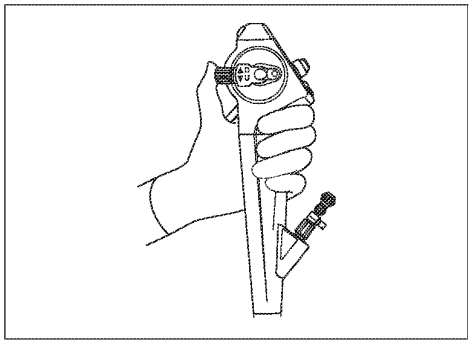

Figure 4.4

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3 Confirm that the tip of the EndoTherapy accessory is closed or retracted into its sheath.

4 Insert the EndoTherapy accessory slowly and straight into the forceps port of the sealing accessories.

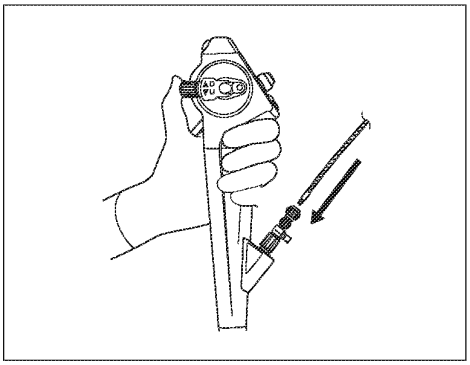

Figure 4.5

5 Hold the EndoTherapy accessory at a point approximately 4 cm from the sealing accessories and advance it slowly and straight into the sealing accessories using short strokes while observing the endoscopic image.

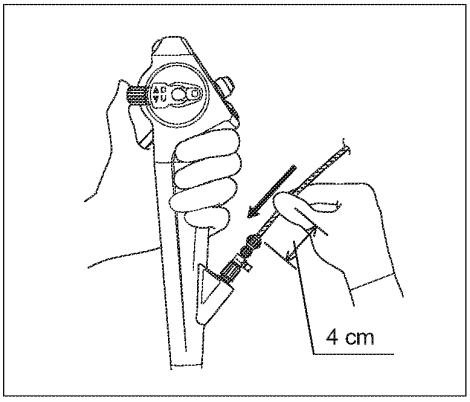

Figure 4.6

NOTE

When the tip of the EndoTherapy accessory extends approximately 2.5 mm from the distal end of the endoscope, the accessory will appear in the endoscopic image.

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Operation of EndoTherapy accessories

Operate the EndoTherapy accessory according to the directions given in its instruction manual.

Withdrawal of EndoTherapy accessories

WARNING

- Fluid might spray when the EndoTherapy accessories are withdrawn from the sealing accessories. To prevent this, hold a piece of gauze around the accessory and the sealing accessories during withdrawal.
- Withdraw the EndoTherapy accessory slowly and straight out of the sealing accessories. Otherwise, the biopsy valve could be damaged. This may leak or spray fluid, posing an infection control risk.
- If the EndoTherapy accessory cannot be withdrawn from the endoscope, close the EndoTherapy accessory and/or retract it into its sheath. Then carefully withdraw both the endoscope and the EndoTherapy accessory together under endoscopic observation. Take care not to cause tissue trauma.

Withdraw the EndoTherapy accessory slowly while the tip of the EndoTherapy accessory is closed and/or retracted into its sheath.

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High-frequency cauterization

WARNING

- When performing high-frequency cauterization, use only an isolated-type of a forceps/irrigation plug. If a non-isolated type is used, operator injury can result.
- Always confirm that the tissue is an appropriate distance away from the distal end of the endoscope. If high-frequency cauterization is performed when the distal end of the endoscope contacts the tissue, patient injury, burns, bleeding, perforation, and equipment damage may occur.
- Use non-electrolytic solution for irrigation. Once urine and/or blood is mixed into the solution, the non-electrolytic solution will be diluted, and electrosurgical faculty may be degraded. In this case, do not raise the power of the electrosurgical unit. Instead, replace the diluted solution with new solution. If the power setting is raised, patient injury can result.

- Do not perform high-frequency cauterization while supplying oxygen. This may result in combustion during cauterization.
- Always confirm that the electrode section of the electrosurgical accessory is at an appropriate distance from the distal end of the endoscope. Confirm that the entire green marking (in case of WLI observation mode) at the distal tip of the electrosurgical accessory can be observed on the endoscopic image. If the electrode is used when it is too close to the distal end of the endoscope, the endoscope and/or ancillary equipment may be damaged. Patient injury, burns, bleeding, perforation, and/or equipment damage may result.

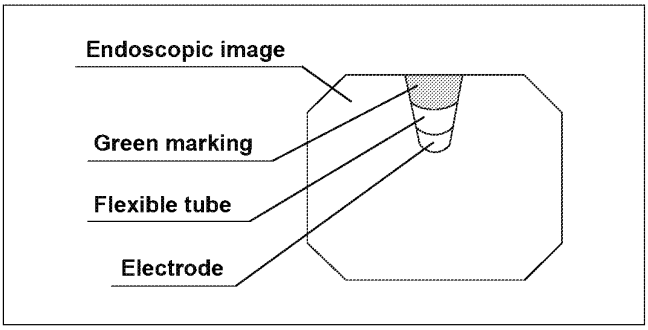

Figure 4.7

- Be sure to contact the electrode section of the EndoTherapy accessory with tissue when performing high-frequency cauterization treatment to prevent equipment damage and operator and/or patient burns.
- Improper connection between the patient plate and patient's skin surface may cause burns. For further details on the patient plate, refer to the patient plate's instruction manual.

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WARNING

- Do not perform high-frequency cauterization without gloves. Operator injury can result.
- Before performing high-frequency cauterization, inspect the surface of the endoscope for any dents, bulges, or other irregularities. Otherwise, patient injury, burns, bleeding, perforation, and/or equipment damage may result.
- When performing high-frequency cauterization, do not use the electrosurgical unit's SPRAY coagulation mode. The endoscope may be damaged and it cause patient and/or operator burns.
- Set the electrosurgical unit to the minimum necessary output level. If the output level is too high, the endoscope's and/or accessory's insulation may be damaged and cause operator and/or patient burns.
- Prolonged excessive flow rates and/or irrigation fluid/gas pressures may result in excessive absorption into the vascular system (e.g., through an open vessel) or gas embolism.

NOTE

The application of high-frequency current may interfere with the endoscopic image. This does not indicate a malfunction.

Prepare, inspect, and connect the electrosurgical unit and electrosurgical accessories as described in their instruction manuals.

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4.4 Withdrawal of the endoscope

WARNING

- If the endoscope or EndoTherapy accessory cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope carefully. If the endoscope cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope or EndoTherapy accessory may cause patient injury, bleeding, and/or perforation. If any irregularities with the endoscope are observed, contact Olympus.
- Avoid patient fluids adhering to the withdrawn endoscope from coming in contact with the bed or floor. The patient fluids may pose an infection control risk to the patient and/or medical personnel.

1 Turn the UP/DOWN angulation lock to the free "F▼" position.

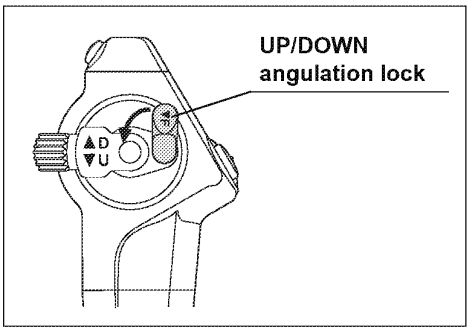

Figure 4.8

2 Carefully withdraw the endoscope while observing the endoscopic image.

3 Reprocess the endoscope and accessories after the procedure as described in the "REPROCESSING MANUAL" with your endoscope model listed on the cover.

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4.5 Transportation of the endoscope

Transporting within the hospital

When carrying the endoscope by hand, loop the universal cord, hold the light guide connector with the control section in one hand and hold the distal end of the insertion tube securely, but gently without squeezing, with the video connector in the other hand.

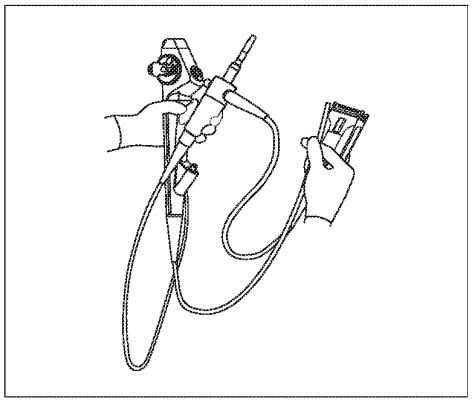

Figure 4.9

Transporting outside the hospital

WARNING

Always reprocess the endoscope after removing it from the carrying case. If the endoscope is not reprocessed, it could pose an infection control risk.

CAUTION

- The carrying case cannot be reprocessed. Reprocess the endoscope before placing it in the carrying case.
- Attach the sterilization cap (MAJ-1538) when transporting the endoscope. Otherwise, the endoscope may be damaged by changes in air pressure.

Transport the endoscope in the carrying case.

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4.5 Transportation of the endoscope

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Chapter 5 Troubleshooting

The countermeasures against troubles are described in this chapter.

5.1 Troubleshooting

If any irregularity is observed during the inspection described in Chapter 3, “Preparation and Inspection”, do not use the endoscope and solve the problem as described in Section 5.2, “Troubleshooting guide”.

If the problem still cannot be resolved, send the endoscope to Olympus for repair as described in Section 5.4, “Returning the endoscope for repair”.

Also, should any irregularity be observed while using the endoscope, stop using it immediately and withdraw the endoscope from the patient as described Section 5.3, “Withdrawal of the endoscope with an irregularity”.

WARNING

- Never use the endoscope on a patient if an irregularity is observed. Damage or an irregularity in the endoscope may compromise patient or user safety and may result in more severe equipment damage.
- If any parts of the endoscope fall off inside the patient body due to equipment damage or failure, stop using the endoscope immediately and retrieve the parts in an appropriate way.

The accessories are consumables. Olympus does not repair accessory parts. If an accessory part becomes damaged, contact Olympus to purchase a replacement.

5.2 Troubleshooting guide

The following table shows the possible causes of and countermeasures against troubles that may occur due to equipment setting errors or deterioration of consumables.
Troubles or failures due to other causes than those listed below should be serviced. As repair performed by persons who are not qualified by Olympus could cause patient or user injury and/or equipment damage, be sure to contact Olympus for repair following the instructions given in Section 5.4, “Returning the endoscope for repair”.

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Image quality or brightness

Irregularity description	Possible cause	Solution
There is no video image.	Not all equipment is ON.	Turn ON all equipment.
	The video connector is not connected securely.	Insert the video connector with its UP mark facing upwards into the output socket of the video system center securely until it stops and clicks.
An image is not clear.	The objective lens is dirty.	Wipe the objective lens with a cotton swab moistened with 70% ethyl or 70% isopropyl alcohol.
An image is excessively dark or bright.	The light source is not set properly.	Adjust the light source's setting as described in its instruction manual.
	The light guide lens at the distal end of the endoscope is dirty.	Wipe the light guide lens with a cotton swab moistened with 70% ethyl or 70% isopropyl alcohol.
	The glass at the light guide connector end is dirty.	Wipe the glass with a cotton swab moistened with 70% ethyl or 70% isopropyl alcohol.

Irrigation fluid feeding

Irregularity description	Possible cause	Solution
No irrigation fluid feeding.	The instrument channel is obstructed.	Clean the channel with a channel cleaning brush as described in the "REPROCESSING MANUAL" with your endoscope model listed on the cover.
	The sealing accessory is worn out.	Replace it with a new one.
Irrigation fluid leaks.	The instrument channel is obstructed.	Clean the channel with a channel cleaning brush as described in the "REPROCESSING MANUAL" with your endoscope model listed on the cover.
	The sealing accessory is worn out.	Replace it with a new one.

Angulation

Irregularity description	Possible cause	Solution
Resistance is encountered when rotating the UP/DOWN angulation control lever.	The UP/DOWN angulation lock is engaged.	Rotate the UP/DOWN angulation lock in the "F▼" direction.

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■ EndoTherapy accessories

Irregularity description	Possible cause	Solution
EndoTherapy accessory does not pass through the instrument channel smoothly.	An incompatible EndoTherapy accessory is being used.	Refer to the "■ Compatible EndoTherapy accessories" on page 68 and select a compatible EndoTherapy accessory. Confirm that the color code on the EndoTherapy accessory matches that on the endoscope.
	The forceps/irrigation plug is incorrectly assembled.	Reassemble it correctly as described in its instruction manual.
	The bending section angulates sharply.	Straighten it as much as possible.
	The tightening ring on the forceps/irrigation plug is turned too tightly.	Turn the tightening ring so that the ends of the biopsy valve and tightening ring are aligned.

■ Other

Irregularity description	Possible cause	Solution
The remote switch does not work.	The wrong remote switch is operated.	Operate the correct remote switch.
	The remote switch function has been set incorrectly.	Set the remote switch function correctly as described in the video system center's instruction manual.
	The remote switch is left depressed due to a difference between internal and external pressures of the endoscope that is made in the pressure reduction process of gas sterilization.	If the sterilization cap is attached to the venting connector, detach it. If not, attach the sterilization cap to the venting connector once and then detach it.

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5.3 Withdrawal of the endoscope with an irregularity

If an irregularity occurs while the endoscope is in use, take proper measures as described in either "■ Withdrawal when the WLI and NBI endoscopic images appear on the monitor", "■ Withdrawal when either the WLI or the NBI endoscopic image does not appear on the monitor", or "■ Withdrawal when all endoscopic images do not appear on the monitor or a frozen image cannot be restored" below. After withdrawal, return the endoscope for repair as described in Section 5.4, "Returning the endoscope for repair".

WARNING

If the endoscope or EndoTherapy accessory cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope or EndoTherapy accessory carefully. If the endoscope or EndoTherapy accessory cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope or EndoTherapy accessory may cause patient injury, bleeding, and/or perforation. If any irregularities with the endoscope or EndoTherapy accessory are observed, contact Olympus.

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■ *Withdrawal when the WLI and NBI endoscopic images appear on the monitor*

1. Turn all equipment OFF except the video system center, light source, and monitor.
2. When the NBI endoscopic image is displayed, switch to the WLI endoscopic image by operating the video system center and light source.
3. When using the image magnification function of the video system center, release the function.
4. When using an EndoTherapy accessory, close the tip of the EndoTherapy accessory and/or retract it into its sheath. Then withdraw the EndoTherapy accessory slowly.
5. Turn the UP/DOWN angulation lock to the free "F▼" position.

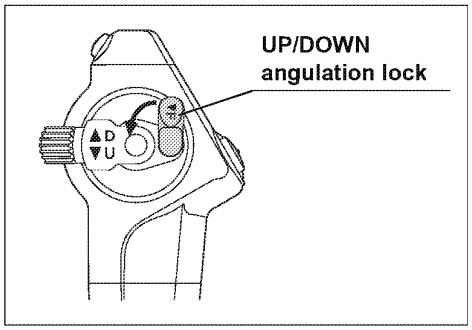

Figure 5.1

6. Carefully withdraw the endoscope while observing the endoscopic image.

■ *Withdrawal when either the WLI or the NBI endoscopic image does not appear on the monitor*

1. Turn all equipment OFF except the video system center, light source, and monitor.
2. Operate the video system center and the light source to switch to the endoscopic image that is still displayed.
3. Follow the procedure of Step 3 above in "■ Withdrawal when the WLI and NBI endoscopic images appear on the monitor". Carefully withdraw the endoscope under the visible observation mode when the WLI endoscopic image is not displayed.

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■ *Withdrawal when all endoscopic images do not appear on the monitor or a frozen image cannot be restored*

1 Turn all equipment OFF except the video system center, light source, and monitor.

2 Turn the video system center and light source OFF and then ON again. If the WLI or NBI endoscopic image appears or the frozen image is restored, follow the procedure given in "■ Withdrawal when either the WLI or the NBI endoscopic image does not appear on the monitor", beginning from Step 2.
If all endoscopic images still do not appear or the frozen image cannot be restored, perform the following steps.

3 Turn the video system center, light source, and monitor OFF.

4 When using an EndoTherapy accessory, close the tip of the EndoTherapy accessory and/or retract it into its sheath. Then withdraw the EndoTherapy accessory slowly.

5 Turn the UP/DOWN angulation lock to the free "F▼" position.

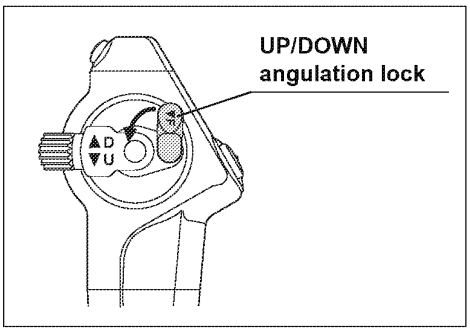

Figure 5.2

6 Turn the UP/DOWN angulation control lever to its neutral position and release the angulation control lever.

7 Withdraw the endoscope from the patient carefully.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5.4 Returning the endoscope for repair

WARNING

Thoroughly reprocess the endoscope before returning it for repair. Improperly reprocessed equipment poses an infection control risk to each person who handles the endoscope within the hospital and at Olympus.

CAUTION

Olympus is not liable for any injury or damage that occurs as a result of repairs attempted by non-Olympus personnel.

Before returning the endoscope for repair, contact Olympus. With the endoscope, include a description of the malfunction or damage and the name and telephone number of the individual at your location who is most familiar with the problem. Also include a repair purchase order. When returning the endoscope for repair, follow the instructions given in "■ Transporting outside the hospital" on page 55.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5.4 Returning the endoscope for repair

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Appendix

The equipment compatible with this endoscope and the EMC information are described in this Appendix.

Combination equipment

■ System chart

The recommended combination of equipment and accessories that can be used with this endoscope are listed below. Some items may not be available in some areas. New products released after the introduction of the endoscope may also be compatible for use in combination with the endoscope. For further details, contact Olympus.

WARNING

Be sure to use the equipment in one of the recommended combinations.
If combinations of equipment other than those shown below are used, the full responsibility is assumed by the medical treatment facility.

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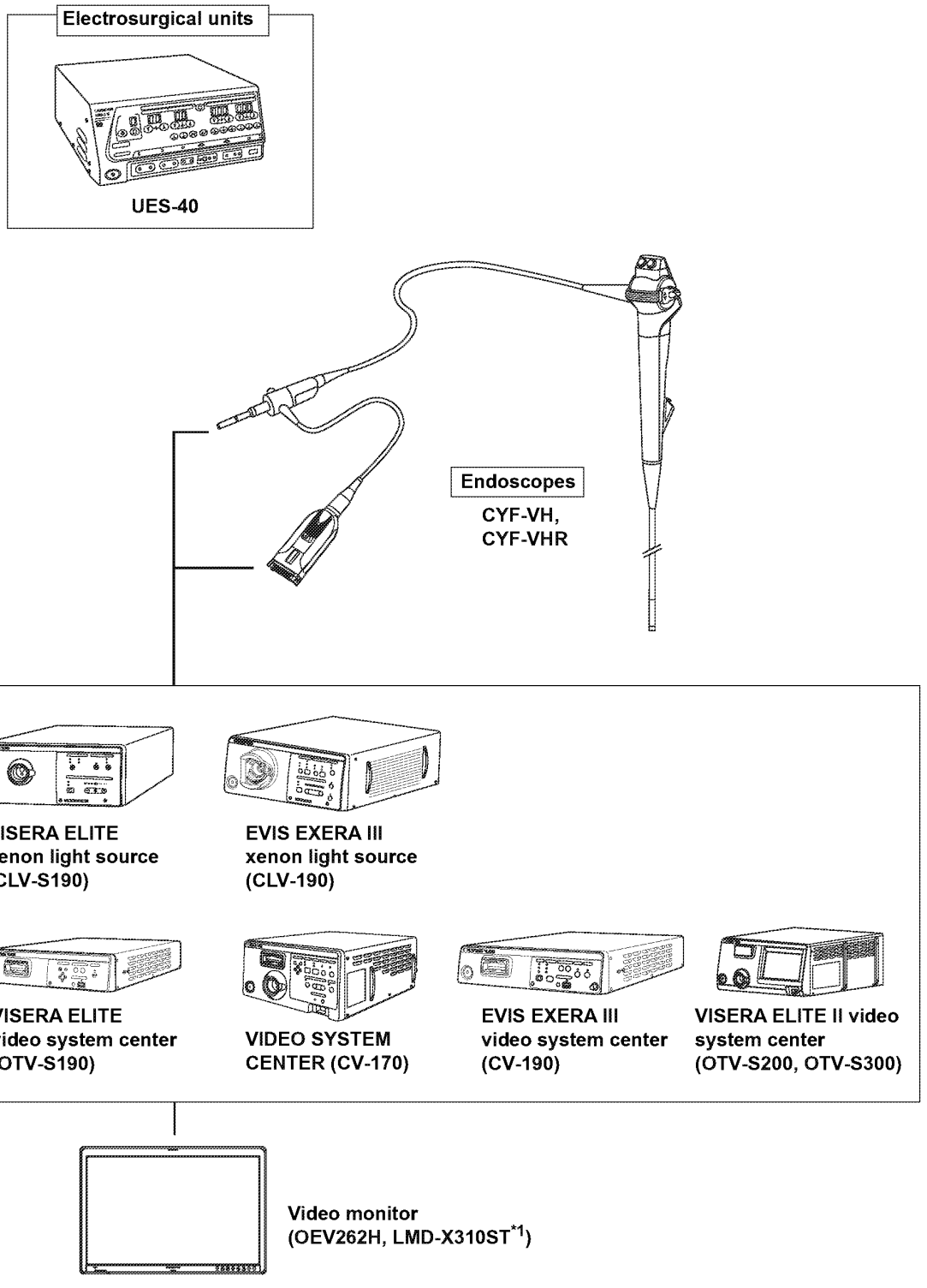

App.

*1 This can be combined with only OTV-S300.

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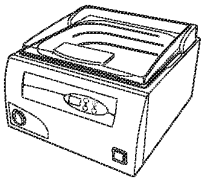
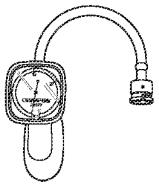
Reprocessing equipment

Single use combination cleaning brush (BW-411B)

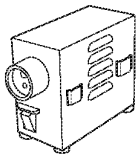


Ultrasonic cleaner (KS-2/ENDOSONIC)



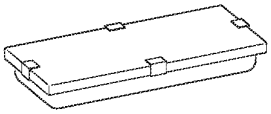
Leakage tester (WA23080A)

Leakage tester (MB-155)

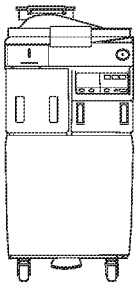


Maintenance unit (MU-1)

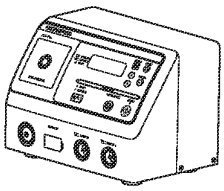
Sterilization cap (MAJ-1538)



Sterilization tray (WA05991A)[*1]



Endoscope reprocessor (OER-AW[*2], OER-Pro[*1], OER-Mini[*3], OER-Elite[*1])



Automated endoscope leak tester (ALT-Pro[*1])

App.

*1 These products are available in the USA and some areas.

*2 This product is available in some areas other than the USA.

*3 This product is only available in the USA.

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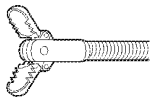
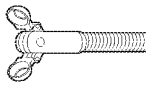
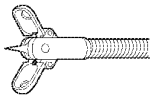
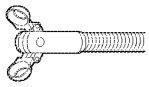
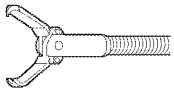
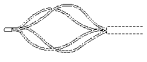
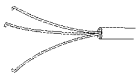
■ *Compatible EndoTherapy accessories*

❍ EndoTherapy accessories

Please note that some of the accessories may not be available in some areas.

	Biopsy forceps	Biopsy forceps (fenestrated)		Rotatable biopsy forceps (fenestrated)
	Alligator jaws type	Standard type	Standard type (with needle)	Standard type
Endoscope				
CYF-VH CYF-VHR	FB-15C-1	FB-19SX-1 FB-21-SX-1	FB-34C-1	FB-19CR-1

	Grasping forceps	Grasping forceps
	Sharp tooth type	Basket type
Endoscope		
CYF-VH CYF-VHR	FG-38SX-1 FG-53SX-1	FG-24SX-1

	Disposable grasping forceps			
	Spiral basket type		Parallel basket type	Three nail type
Endoscope				
CYF-VH CYF-VHR	FG-51D	FG-52D	FG-55D	FG-54D

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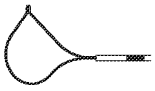
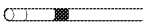
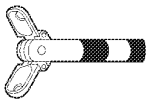
Electrosurgical accessories

Please note that some of the accessories may not be available in some areas.

	Electrosurgical snare Crescent type	Coagulation electrode	Hot biopsy forceps
Endoscope			
CYF-VH CYF-VHR	SD-7C-1 SD-18C-1	CD-6C-1	FD-7C-1

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EMC information

NOTE

The ME system including the CYSTO-NEPHRO VIDEOSCOPE has the performance for providing a live endoscopic image that can be used for identifying observed objects. If the performance is lost or degraded, the ME system may not be able to provide an endoscopic image for diagnosis or treatment under endoscopic surgery (ex. if noise is superimposed on the endoscopic image, the observation target object may not be identified. Under the influence of electromagnetic waves, it is possible that the endoscopic live images of different directions from the upper and lower left and right directions of the endoscope tip intended by the operator may be displayed.). Refer to the Section 3.7, "Inspection of the endoscopic system" for using the ME system safely and for the purposes for which it is intended.

Guidance and manufacturer's declaration — Electromagnetic emissions

App.

This model is intended for use by medical personnel in hospital environments and for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — Guidance
RF emissions CISPR 11	Group 1	This instrument uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emissions CISPR 11	Class B	This instrument's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Main terminal conducted emissions CISPR 11		
Harmonic emissions IEC 61000-3-2	Class A	This instrument's harmonic emissions are low and are not likely to cause any problem in the typical commercial power supply connected to this instrument.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	This instrument stabilizes its own radio variability and has no effect such as flicker in lighting apparatus.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Guidance and manufacturer's declaration — Electromagnetic immunity

This model is intended for use by medical personnel in hospital environments and for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.
This instrument can be used with the high-frequency electrosurgical equipment that designated by Olympus.

Immunity test	IEC 60601-1-2 (2014) test level	Compliance level	Electromagnetic environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±2, ±4, ±8, ±15 kV	Same as left	Floors should be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Same as left	Mains power quality should be that of a typical commercial (original condition feeding the facilities) or hospital environment.
Surge IEC 61000-4-5	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV for signal input/ output lines: ±2 kV	Same as left	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle/ 1 cycle	Same as left	Mains power quality should be that of a typical commercial or hospital environment. If the user of this instrument requires continued operation during power mains interruptions, it is recommended that this instrument be powered from an uninterruptible power supply or a battery.
	70% U_T (30% dip in U_T) for 25 cycle (50 Hz)/ 30 cycle (60 Hz) Phase angle causing voltage dips: 0°		
	0% U_T (100% dip in U_T) for 250 cycle (50 Hz)/ 300 cycle (60 Hz)		
	U_T is the a.c. mains voltage prior to application of the test level.		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 Hz, 60 Hz)	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.

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Immunity test	IEC 60601-1-2 (2014) test level	Compliance level	Electromagnetic environment — Guidance
Conducted RF IEC 61000-4-6	3V (150 kHz – 80 MHz)	Same as left	–
	6V (ISM band of 150 kHz – 80 MHz)	Same as left	
	ISM (industry, science, and medical care) band of 6.765 MHz – 6.795 MHz, 13.553 MHz – 13.567 MHz, 26.957 MHz – 27.283 MHz, and 40.66 MHz – 40.70 MHz between 0.15 MHz and 80 MHz		
Radiated RF IEC 61000-4-3	3V/m (80 MHz – 2.7 GHz)	Same as left	–
Proximity magnetic field from RF communication equipment IEC 61000-4-3	Refer to the table of the next page.	Same as left	

NOTE

- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- Electromagnetic interference may occur in the vicinity of high-frequency electrosurgical equipment and/or other equipment marked with the following symbol:

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NOTE

- Field strength from fixed RF transmitters as determined by an electromagnetic site survey[a)] should be less than the compliance level in each frequency range[b)].

  a) Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this model is used exceeds the applicable RF compliance level above, this model should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this model.

  b) Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

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Test frequency [MHz]	Band [MHz]	Modulation*1	Maximum power [W]	Immunity test level [V/m]
385	380 – 390	Pulse modulation*1 18 Hz	1.8	27
450	430 – 470	FM ±5 kHz deviation 1 kHz sine	2	28
710	704 – 787	Pulse modulation*1 217 Hz	0.2	9
745				
780				
810	800 – 960	Pulse modulation*1 18 Hz	2	28
870				
930				
1720	1700 – 1990	Pulse modulation*1 217 Hz	2	28
1845				
1970				
2450	2400 – 2570	Pulse modulation*1 217 Hz	2	28
5240	5100 – 5800	Pulse modulation*1 217 Hz	0.2	9
5500				
5785				

*1 The carrier shall be modulated using a 50% duty cycle square wave signal.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the video system center, including cables specified by Olympus. Otherwise, degradation of the performance of this equipment could result.

Guidance and manufacturer's declaration — Cables used for EMC compliance testing

Refer to the instruction manuals for each piece of equipment.

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTIII/DHTIIIB
AWL RMONR
Global Work Location
Silver Spring, MD 20705
301-796-1863

Premarket Notification 510(k) Review

Date: August 12, 2022

Reviewer: Esther Kaplan

510(k)# K221683 Subject: Traditional

Applicant: Olympus Medical Systems Corporation	**Device Trade Name:** CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2R), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VH) and CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VHR)
Contact Name: Teffany Hutto	**Contact Title:** Regulatory Affairs Consultant
Correspondent Firm: Olympus Corporation of the Americas	**Phone:** (512) 508-6550 **Email:** teffany.hutto@olympus.com
Received Date: June 10, 2022	**Due Date:** September 12, 2022
Pro Code(s): FAJ **Class:** II **Reg #:** 876.1500	**Reg Name:** Endoscope And Accessories

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K133538	NWB, FAJ	Visera Cysto-nephro Videoscope Olympus Cyf Type V2, Visera Cysto-nephro Videoscope Olympus Cyf Type Va2, Visera Cysto-ne	Olympus Corporation Of The Americas

Recommendation

(b)(5)

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(b)(5)

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This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.	
Reviewer Sign-Off	Esther L. Kaplan -S 2022.08.12 10:10:20 -04'00'

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Dear Ms. Kaplan,

Please find attached an (b)(4) If I can provide you with anything else, please let me know.

Best regards,

Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>

Sent: Thursday, January 19, 2023 8:30 AM

To: Teffany Hutto <teffany.hutto@olympus.com>

Cc: K221683@docs.fda.gov

Subject: [EXTERNAL] K221683/S001 Interactive Review Request

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Hello Teffany,

Thank you for your previous response. (b)(4)

(b)(4)

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: 301-796-1863

esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

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OLYMPUS

REPROCESSING MANUAL

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-V2
OLYMPUS CYF-V2R

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From: Teffany Hutto <teffany.hutto@olympus.com>

Sent: Tuesday, August 23, 2022 5:01 PM

To: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>; Jenkins, Klara <Klara.Jenkins@fda.hhs.gov>

Subject: [EXTERNAL] Teleconference Meeting Minutes

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Kaplan and Ms. Jenkins,

Thank you to you and your team for meeting with us yesterday.

Attached are minutes from the meeting. If you have any questions, please let me know.

Best regards,

Teffany Hutto

Consultant for Olympus Medical

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K221683 Cysto-Nephro Videoscopes OLYMPUS CYF-V2 and CYF-V2R and CYF-VH and CYF-VHR
Olympus Medical Systems Corporation
Reprocessing Consult

Date: August 9, 2022

From: Ángel A. Soler-García, Ph.D.
Lead Microbiologist
CDRH/OPEQ/OHT3/DHT3B/THT3B4

To: Esther Kaplan
Mechanical Engineer
CDRH/OPEQ/OHT3/DHT3B/THT3B3

Subject: K221683

VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2/V2R

CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH/VHR

Olympus Medical Systems Corporation

Scope: Reprocessing validation and labeling.

Recommendation: (b)(5)

(b)(5)

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Ángel A. Soler-García, Ph.D.
Lead Microbiologist
CDRH/OPEQ/OHT3/DHT3B/THT3B4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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GLP REPORT

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

CONFIDENTIAL

STUDY TITLE

ISO Acute Systemic Toxicity Study in Mice

TEST ARTICLE NAME

CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH
and Luer-Split MAJ-2092

TEST ARTICLE IDENTIFICATION

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OSE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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GLP PROTOCOL

TEST FACILITY

(b)(4)

SPONSOR

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OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

ISO Acute Systemic Toxicity Study in Mice

(b)(4)

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Table 17-8. Individual Immunity Test Essential Performance Acceptance Criteria

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Hello Teffany,

Thank you for providing your response to our August 12, 2022 request for additional information. (b)(4)

(b)(4)

Please reply via email by end of day January 18, as the review cycle is coming to a close.

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: 301-796-1863

esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

[cid:image001.png@01D92A56.0D47BEA0]<http://www.fda.gov/>

[cid:image002.jpg@01D92A56.0D47BEA0]<https://www.facebook.com/FDA>
[cid:image003.jpg@01D92A56.0D47BEA0] <https://twitter.com/US_FDA>
[cid:image004.jpg@01D92A56.0D47BEA0] <http://www.youtube.com/user/USFoodandDrugAdmin>
[cid:image005.jpg@01D92A56.0D47BEA0] <http://www.flickr.com/photos/fdaphotos/>
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<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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K221683
Olympus Medical Systems Corporation
Trade/Device Name: Cysto-Nephro Videoscope (Olympus CYF-V2), Cysto-Nephro Videoscope (Olympus CYF-V2R), Cysto-Nephro Videoscope (Olympus CYF-VH) and Cysto-Nephro Videoscope (Olympus CYF-VHR)
Contact Name: Teffany Hutto

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K221683 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K221683 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at https://www.fda.gov/media/83522/download for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued

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on September 29, 2017 (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

MAJOR DEFICIENCY LIST

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MINOR DEFICIENCY LIST

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FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. Please note that if the specific clarification questions are not received at least 48 hours before the teleconference, the review team might not be able to provide feedback. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.

Least Burdensome (LB) Flag

The LB flag is an approach to allow submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least

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burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact OPEQSubmissionSupport@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistant Director. You should also copy OPEQSubmissionSupport@fda.hhs.gov on your LB flag email request. Within two business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact OPEQSubmissionSupport@fda.hhs.gov.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 10
Executive Summary

10.1 DEVICE DESCRIPTION

1) General Description of the subject device

The subject devices VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYF TYPE V2R, and CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHR (hereinafter referred to as CYF-V2/V2R and CYF-VH/VHR) have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter and kidney.

The subject devices VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYF TYPE V2R will be packed and offered together per the Table below. They can be used with commercially available Olympus devices as described within the Instruction Manual.

Model No.	Device Name	510(k) No.
BW-411B	Single Use Combination Cleaning Brush	510(k) Exempt
MB-156	ETO Cap	K181240

The subject devices CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHR will be packed and offered together per the Table below. They can be used with commercially available Olympus devices as described within the Instruction Manual.

Model No.	Device Name	510(k) No.
BW-411B	Single Use Combination Cleaning Brush	510(k) Exempt
MAJ-1538	Sterilization Cap	K172726

2) Principle of Operation

The subject devices consists of three parts: the control section, the insertion section, and the connector section. The basic principle including user interface and operation for the procedure of the subject devices are identical to that of the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1. The control section

The UP/DOWN angulation control lever on the control section is connected to the tip of the bending section by bundles of wires. By operating the UP/DOWN angulation control lever, the bending section at the distal end bends to guide the distal end for insertion and observation into the urethra and bladder. Therapeutic instruments can pass through the instrument channel for treatment. It can also be perfused through the instrument channel.

2. The insertion section

The insertion section consists of the CCD, light guides that bring light from the light source through the endoscope, and instrument channel where therapeutic accessories can be inserted and withdrawn.

3. The connector section

The connector section connects the endoscope with video system center and light source.

10.2 COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEIVCE

The subject devices have the same technological characteristics and design as the predicate device except for the following features:

- Optical performance
- Shape of the distal end

10.3 DEVICE COMPARISON TABLE – V2/V2R

(b)(4)

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10.5 PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

1) **Reprocessing validation testing**
   Reprocessing instruction and reprocessing method validation testing were conducted and documentations were provided as recommended by Guidance for Industry and Food and Drug Administration Staff, "Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling".

2) **Biocompatibility testing**
   Biocompatibility testing were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

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3) Software verification and validation testing

Software verification and validation testing were conducted and documentations were provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

4) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted in accordance with the ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18:2009 standards for safety and the IEC 60601-1-2:2014 standards for EMC.

5) Performance testing - Bench

Bench testing as listed below were conducted to ensure that the subject device performs as intended and meet design specifications.

- Thermal Safety
- Composite Durability
- Color Performance
- Photobiological Safety
- Noise and Dynamic Range
- Image Intensity Uniformity
- Field of View and Direction of View
- Resolution
- Effectiveness NBI

6) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

7) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

8) Risk management

Risk management was performed in accordance with ISO 14971:2007. The design verification tests and their acceptance criteria were performed and identified as a result of this risk management.

10.6 CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the subject devices CYF-V2/V2R and CYF-VH/VHR raise no new issue of safety and effectiveness and are substantially equivalent to the predicate devices in terms of safety, efficacy and performance.

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Section 5

510(k) Summary

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Sponsor:
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OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-machi
Hachioji-shi, Tokyo, 192-8507
JAPAN

Manual Cleaning Validation (FlexClean 895) for CYF-5, MAJ-2092, and MAJ-1413 GLP Report

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Sponsor:
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Olympus Medical Systems Corp.
2951 Ishikawa-machi
Hachioji-shi, Tokyo, 192-8507
JAPAN

High Level Disinfection Validation for CYF-5, MAJ-2092, and MAJ-1413 GLP Report

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Sponsor:
(b)(4)
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-machi
Hachioji-shi, Tokyo, 192-8507
JAPAN

Retest for Manual Delayed Cleaning Validation for CYF-5 (Endozime AW) GLP Report

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REPORT

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

CONFIDENTIAL

STUDY TITLE

Subcontracted Testing – Identification by SEM-EDS and Microscopic FTIR

TEST ARTICLE NAME

(b)(4)

TEST ARTICLE IDENTIFICATION

N/A

TEST ARTICLE PHYSICAL DESCRIPTION

(b)(4)

TEST ARTICLE RECEIVED

February 10, 2022

(b)(4)

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(b)(4)

ISO 9001:2015 CERTIFIED

(b)(4)

Test Report
Identification of Orange Particle in (b)(4)

(b)(4)

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Identification information (b)(4)

OLYMPUS

Test Report

Title
Simulated use conditioning test of
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH

(b)(4)

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2951 Ishikawa-machi
Hachioji-shi, Tokyo, 192-8507
JAPAN

High Level Disinfection Validation for CYF-VH GLP Report

(b)(4)

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TEST REPORT

Report number	(b)(4)
Applicant	: OLYMPUS MEDICAL SYSTEMS CORP.
Equipment under test (EUT)	: CYSTO-NEPHRO VIDEOSCOPE
Model number	: OLYMPUS CYF-VH
Testing standard	: IEC60601-1-2 : 2014

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Sponsor:
(b)(4)
Olympus Medical Systems Corp.
2951 Ishikawa-machi
Hachioji-shi, Tokyo, 192-8507
JAPAN

Ethylene Oxide (EO) Sterilization Validation GLP Report

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Negative Device Control Replicate Justification for Cleaning Validations

(b)(4)
OLYMPUS MEDICAL SYSTEMS CORP
Planning 2, Infection Prevention Engineering Strategy
Add.
2951 Ishikawa-machi, Hachioji-shi, Tokyo 192-8507, Japan
E-mail: masanao_abe@ot.olympus.co.jp

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Good morning Ms. Kaplan,

The requested information for the instrument channel is provided below.

As always, please let me know if you have any additional questions.

Best regards,
Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Thursday, July 28, 2022 3:06 PM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: [EXTERNAL] K221683 - Interactive Review Request #3

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Dear Teffany,

In addition to the interactive review request I sent earlier today, please also address the following:

(b)(4)

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(b)(4)

Please respond by COB Monday, August 1, to facilitate a timely review of your submission.

Thank you,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
esther.kaplan@fda.hhs.gov

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OLYMPUS

OPERATION MANUAL

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-VH
OLYMPUS CYF-VHR

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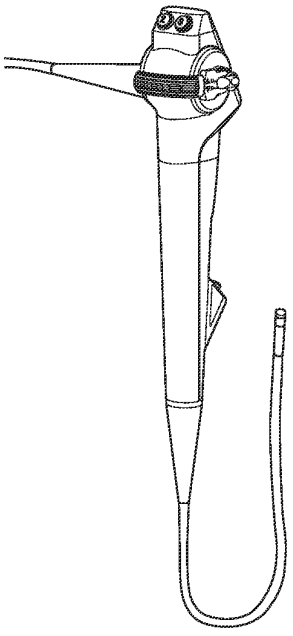
Chapter 2 Instrument Nomenclature and Specifications 15

Chapter 3 Preparation and Inspection 23

Chapter 4 Operation 41

Chapter 5 Troubleshooting 57

Appendix 65



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Section 17.1.5

Selection of Representative Video system center for EMC Test

(b)(4)

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Department of Health & Human Services
Food and Drug Administration

Biocompatibility Memorandum

Date: July 27, 2022

From: Matthew Cho, Toxicologist
OHT3/DHT3B/THT3B3

Subject: K221683
CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2R), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VH) and CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VHR)
Olympus Medical Systems Corporation

To: Esther Kaplan, Project Leader
OHT3/DHT3B/THT3B3

Recommendation: (b)(5)

(b)(5)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(5)

Taehyeon M. Cho -S

Digitally signed by Taehyeon M. Cho -S
Date: 2022.07.27 16:37:24 -04'00'

T. Matthew Cho, Ph.D.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 17.1.6

Test Condition for Electrical Safety Test

(b)(4)

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Section 15
Biocompatibility

This submission has no device-specific guidance documents, or any declaration of conformity top recognized standards specified by the device regulation. No specific performance standards have been established under Section 514 of the Food, Drug, and Cosmetic Act. However, certain voluntary standards and guidance have been used in the design and testing of the device.

VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYF TYPE V2R, CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHR (CYF-V2/V2R and CYF-VH/VHR) have been designed to be used with an Olympus light source, documentation equipment, display monitor, EndoTherapy accessories and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra and kidney.

Identification of Device Biocompatibility
The CYF-V2/V2R and CYF-VH/VHR have the same direct patient contacting parts, which are similar to the predicate devices, CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R, respectively (See **Section 12 – Substantial Equivalence Discussion, Table 12-10**).

Table 15-1 lists the direct patient-contacting materials of CYF-V2/V2R are required to demonstrate biocompatibility in compliance with ISO 10993-1, *Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process*.

Table 15-1 Direct Patient Contact Materials for CYF-V2

Part Name	Material Name
Insertion Tube	Forced dry-hard type of fluorine resin coat (b)(4)
Bending Section	Fluoro Rubber (b)(4)
Glue Bending Section	Epoxy Glue (b)(4) (b)(4)
Distal End	PolyPhenylSulfone (b)(4)
Objective Lens	Glass (b)(4)
Light Guide Lens	Glass (b)(4)
Glue on Distal End	Epoxy Glue (b)(4) (b)(4)

(b)(4)

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Table 15-2 lists the direct patient-contacting materials of CYF-VH/VHR are required to demonstrate biocompatibility in compliance with ISO 10993-1, *Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process*.

Table 15-2 Direct Patient Contact Materials for CYF-VH

Part Name	Material Name
Insertion Tube	Forced dry-hard type of fluorine resin coat (b)(4)
Bending Section	Fluoro Rubber (b)(4)
Glue Bending Section	Epoxy Glue (b)(4) (b)(4)
Distal End	Polysulfone (b)(4) (b)(4)
Objective Lens	Glass (b)(4)
Light Guide Lens	Polysulfone (b)(4)
Solder	AuSn-Solder

(b)(4)

15.1Biocompatibility Categorization

The CYF-V2/V2R and CYF-VH/VHR is considered a surface-contacting device in contact with mucosal membranes with limited exposure (i.e., contact is up to 24 hours). These devices have materials that are identical and unchanged to the predicate devices as shown in **Table 15-3**. Refer to **Sections 12** of this 510(k) submission for the detailed substantial equivalence discussion.

Table 15-3 Comparison of Patient Contact (Direct) Material for CYF-V2/V2R and CYF-VH/VHR to the predicate devices.

Part	Subject Device (SD) Material	Predicate Device (PD) Material	SE Discussion
	CYF-V2/V2R and CYF-VH/VHR	CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R	
Insertion Tube	Forced dry-hard type of fluorine resin coat (b)(4)	Forced dry-hard type of fluorine resin coat (b)(4)	The device materials that are different than the predicate have been evaluated for biocompatibility as part of this Section.
Bending Section	CYF-V2: Fluoro Rubber (b)(4) CYF-VH: Fluoro Rubber (b)(4)	Fluoro Rubber (b)(4)	
Glue Bending Section	Epoxy Glue (b)(4)	Epoxy Glue (b)(4)	

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Part	Subject Device (SD) Material CYF-V2/V2R and CYF-VH/VHR	Predicate Device (PD) Material CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R	SE Discussion
Distal End	CYF-V2: PolyPhenylSulfone (b)(4) CYF-VH: Polysulfone (b)(4)	PolyPhenylSulfone (b)(4)	
Objective Lens	Glass (b)(4)	Glass Sapphire	
Light Guide Lens	CYF-V2: Glass (b)(4) (b)(4) CYF-VH: Polysulfone (b)(4)	Glass (b)(4)	
Glue on Distal End	CYF-V2: ES-19SC CYF-VH: none	-	

15.2 Biocompatibility Evaluation and Risk Assessment

The biological safety of the CYF-V2/V2R and CYF-VH/VHR subject devices was evaluated in accordance with ISO 10993-1 and the guidance document Blue Book Memorandum G95-1 *Use of International Standard ISO 10993, and Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing.*

Olympus has performed risk assessment for biocompatibility for the subject devices in accordance with the guidance, Use of International Standard ISO 10993-1, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. Olympus has performed biocompatibility tests in final finished form in accordance with ISO 10993-1.

Olympus completed an evaluation of changes from ISO 10993-1 Fifth Edition 2018-08 and determined that changes do not raise new questions regarding safety and effectiveness. No new risks were identified; thus, Olympus has determined that the completed biological safety testing meets industry and state of the art expectations for safety and effectiveness.

Evaluation tests (**Table 15-4 and 15-5**) are identified in ISO 10993-1 and have been selected based on the medical device categorization (**Section 15.1**).

Table 15-4 Biocompatibility Test Information – CYF-V2/V2R

Test Type	ISO 10993 Standard	Test Report	Test Protocol
N/A	Biocompatibility Summary Report	Section 15.1	N/A
Cytotoxicity	ISO 10993-5: Cytotoxicity Study Using the ISO Elution Method	15.1 Attachment 2	15.3 Attachment 2.1
Sensitization	ISO 10993-10: Guinea Pig Maximization Sensitization Test	15.1 Attachment 3	15.3 Attachment 2.2
Irritation	ISO 10993-10: Intracutaneous Irritation Study	15.1 Attachment 4	15.3 Attachment 2.3
Pyrogenicity	ISO 10993-11: Rabbit Pyrogen Study	15.1 Attachment 5	15.3 Attachment 2.4
Toxicity	ISO 10993-11: Acute Systemic Toxicity Study in Mice	15.1 Attachment 6	15.3 Attachment 2.5
Cytotoxicity	ISO 10993-5: Cytotoxicity Study Using the ISO Elution Method (Dilution)	15.1 Attachment 7	

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Test Type	ISO 10993 Standard	Test Report	Test Protocol
Sensitization	Identification by SEM-EDS and Microscopic FTIR (Identification of Particulates)	15.1 Attachment 8	
Sensitization	Identification by SEM-EDS and Microscopic FTIR (Identification of Particulates)	15.1 Attachment 9	
Pyrogencity	Identification by SEM-EDS and Microscopic FTIR (Identification of Particulates)	15.1 Attachment 10	
N/A	CYF-V2 Testing Root Cause Analysis and Conclusion	15.1 Attachment 11	
Pre-Conditioning	Implementation of Biological Safety Testing Preconditioning (CYF-V2)	15.1 Attachment 12	
Particulates	CYF-V2 Results of Particulate Analysis	15.1 Attachment 13	
Cytotoxicity	ISO 10993-5: Cytotoxicity Study for blank scope Using the ISO Elution Method	15.1 Attachment 14	

Table 15-5 Biocompatibility Test Information – CYF-VH/VHR

Test Type	ISO 10993 Standard	Test Report	Test Protocol
N/A	Biocompatibility Summary Report	Section 15.1	N/A
Cytotoxicity	ISO 10993-5: Cytotoxicity Study Using the ISO Elution Method	15.2 Attachment 2	15.4 Attachment 2.1
Sensitization	ISO 10993-10: Guinea Pig Maximization Sensitization Test	15.2 Attachment 3	15.4 Attachment 2.2
Irritation	ISO 10993-10: Intracutaneous Irritation Study	15.2 Attachment 4	15.4 Attachment 2.3
Pyrogenicity	ISO 10993-11: Rabbit Pyrogen Study	15.2 Attachment 5	15.4 Attachment 2.4
Toxicity	ISO 10993-11: Acute Systemic Toxicity Study in Mice	15.3 Attachment 6	15.4 Attachment 2.5
Pyrogenicity	Identification by SEM-EDS and Microscopic FTIR (Analysis of Orange Particulates)	15.2 Attachment 7	
Particulates	CYF-VH Particulate Observation Following Extraction	15.2 Attachment 8	
Pre-Conditioning	Implementation of Biological Safety Testing Preconditioning (CYF-VH)	15.2 Attachment 9	

15.3Biological Testing

Biocompatibility testing was performed using CYF-V2 and CYF-VH as the representative devices for CYF-V2/V2R and CYF-VH/VHR based on the comparison evaluation in **Section 15.2**.

Each of the biocompatibility tests were carried out in accordance with the following guidelines or standards:

- Cytotoxicity Study Using the ISO Elution Method: ISO 10993-5
- ISO Intracutaneous Study in Rabbits: ISO 10993-10
- ISO Guinea Pig Maximization Sensitization Test: ISO 10993-10
- USP Rabbit Pyrogen Study: ISO 10993-11
- ISO Acute Systemic Toxicity Study in Mice: ISO 10993-11

15.4 Samples for Biocompatibility

All biological safety testing was completed with CYF-V2 and CYF-VH as the representative device for the CYF-V2/V2R and CYF-VH/VHR subject devices based on the following comparison evaluation.

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To support the selection of CYF-V2 and CYF-VH as the representative devices for the biocompatibility testing, the differences between the two subject devices are shown in **Tables 15-6 and 15-7**, Olympus has determined to select CYF-V2 and CYF-VH as a representative test device.

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There are no differences between the material and surface area of the patient contacting parts of CYF-V2 and CYF-V2R. Therefore, the biocompatibility testing for CYF-V2 is appliable for demonstration of biological safety of CYF-V2R.

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Identification information (b)(4)

OLYMPUS

Test Report

Title

High Level Disinfection test Using OER-Mini with Acecide-C of
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH

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Section 18.9

Noise and Dynamic range

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Protocol Number: (b)(4)

Protocol Revision:

Protocol Title: Biological Safety Risk Assessment Cysto-Nephro Videoscope (CYF-VH-VHR)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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August 12, 2022</br></br> We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Esther Kaplan.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Sumpter, Melanie * [Melanie.Sumpter@fda.hhs.gov]
Sent: 6/13/2022 9:02:46 PM
To: teffany.hutto@olympus.com
Subject: Corrected K221683 eCopy Hold Notification
Attachments: K221683 Letter.pdf; K221683 Attachment.pdf

Sincerely,
Melanie N. Sumpter
Technical Information Specialist - 510(k) Staff
CDRH Document Control Center
Melanie.Sumpter@fda.hhs.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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eCopy Hold Letter

6/13/2022

Teffany Hutto, Regulatory Affairs Consultant
Olympus Corporation of the Americas
3500 Corporate Parkway
P.O. BOX 610
Center Valley, PA 18034
UNITED STATES

Dear Teffany Hutto:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

Submission Number: K221683
Received: 06/10/2022
Applicant: Olympus Medical Systems Corporation
Device: CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2R), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VH) and CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VHR)

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. **You have received this letter because you have either not provided an eCopy or you provided an eCopy that failed the loading process because it did not meet the technical standards.** If you provided an eCopy that failed the loading process, then please see the attached document that identifies all reasons for the failure that need to be addressed. To understand the reasons for your eCopy failure, please refer to the eCopy guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf.

To verify your eCopy meets the technical standards prior to submitting to FDA, you may use the eCopy Validation Module (a voluntary tool that verifies the format of an eCopy you have already developed on your local drive) available on the eCopy Program webpage at https://www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-program-

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medical-device-submissions.

Please write the specific submission number identified above AND "Replacement eCopy" directly on the CD (or other media) and send that with a paper copy of your cover letter (revised if applicable) to the CDRH Document Control Center (DCC) at the address below.

Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

You should provide the complete content for the document, not just the corrected files or folders, in your replacement eCopy. **When your Replacement eCopy has been received and been verified as a valid eCopy, review of this submission will start as of that date.**

If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,

Center for Devices and Radiological Health

Attachment

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

From: Teffany Hutto <teffany.hutto@olympus.com>
Sent: Tuesday, August 23, 2022 5:01 PM
To: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>; Jenkins, Klara <Klara.Jenkins@fda.hhs.gov>
Subject: [EXTERNAL] Teleconference Meeting Minutes

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Ms. Kaplan and Ms. Jenkins,

Thank you to you and your team for meeting with us yesterday.

Attached are minutes from the meeting. If you have any questions, please let me know.

Best regards,

Teffany Hutto
Consultant for Olympus Medical

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 3.2
Letter to File History

Letters to file were completed for changes to the CYF-V2/V2R (under K133538). A summary of each change is provided in **Tables 3.2-1 and 3.2-2.**

Table 3.2-1 – Letter to File History for CYF-V2

(b)(4)

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U.S. FOOD & DRUG ADMINISTRATION

January 20, 2023

Olympus Medical Systems Corporation
% Teffany Hutto
Regulatory Affairs Consultant
Olympus Corporation of the Americas
3500 Corporate Parkway
P.O. Box 610
Center Valley, PA 18034

Re: K221683
Trade/Device Name: VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE V2R
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH, CYF-VHR
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ
Dated: December 22, 2022
Received: December 22, 2022

Dear Teffany Hutto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark J. Antonino -S

Mark J. Antonino, M.S.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221683

Device Name
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE V2R

Indications for Use *(Describe)*
VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYF TYPE V2R have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221683

Device Name
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH, CYF-VHR

Indications for Use *(Describe)*
CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF VH, and CYF VHR have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Date Prepared: 01/19/2023

510(k) Summary

1. GENERAL INFORMATION

■ 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

■ Contact Person: Teffany Hutto
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 512-508-6550
Fax: 484-896-7128
Email: teffany.hutto@olympus.com

■ Manufacturing site: Shirakawa Olympus Co., Ltd.
3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun,
Fukushima 961-8061, Japan

Aizu Olympus Co., Ltd.,
3-1-1 Niiderakita, Aizuwakamatsu-shi, Fukushima 965-8520, Japan

2. DEVICE IDENTIFICATION

■ Trade/Device Name: VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE V2R
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH, CYF-VHR

■ Model Name: OLYMPUS CYF-V2, CYF-V2R, CYF-VH, CYF-VHR

■ Common Name: CYSTO-NEPHRO VIDEOSCOPE

■ Regulation Number: 876.1500

■ Regulation Name: Endoscope and accessories

■ Regulatory Class: Class II

■ Product Code: FAJ (Cystoscope and Accessories, Flexible/Rigid)

■ Classification Panel: Gastroenterology/Urology

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

3. PREDICATE DEVICE

■ **Predicate device**

Device name	510(k) Submitter	510(k) No.
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R	OLYMPUS MEDICAL SYSTEMS CORP.	K133538

4. DEVICE DESCRIPTION

■ **General Description of the subject device**

The subject device has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

■ **Principle of Operation**

The subject devices consist of three parts: the control section, the insertion section, and the connector section. The basic principle including user interface and operation for the procedure of the subject device are identical to that of the predicate device.

■ **List of device components**

The VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-V2/V2R will be packed and offered together with the devices listed in the table below. They can be used with commercially available Olympus devices as described within the Instruction Manual.

Model No.	Device Name
BW-411B	Single Use Combination Cleaning Brush
MB-156	ETO Cap

The CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH and CYF-VHR will be packed and offered together with the devices listed in the table below. They can be used with commercially available Olympus devices as described within the Instruction Manual.

Model No.	Device Name
BW-411B	Single Use Combination Cleaning Brush
MAJ-1538	Sterilization Cap

5. INDICATIONS FOR USE

VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHR have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device has the same technological characteristics and design as the predicate device except for the following features:

- Optical performance
- Shape of the distal end

Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

A side-by-side comparison of the subject device and the predicate device is provided below.

Item	Subject Device	Predicate Device
	OLYMPUS CYF-V2, CYF-V2R	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Indications for Use	VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2 and CYF TYPE V2R have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.	This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter, and kidney.
Regulation Number	21CFR 876.1500	21CFR 876.1500
Regulation Name	Endoscope and accessories	Endoscope and accessories
Regulatory Class	Class II	Class II

Item	Subject Device	Predicate Device
	OLYMPUS CYF-V2, CYF-V2R	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Product Code	FAJ	FAJ
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology
Use Environment	Healthcare facility/hospital	Healthcare facility/hospital
Reprocessing	[Cleaning] AER and manual [Disinfection] AER and manual [Sterilization] - Ethylene oxide gas - STERRAD NX	[Cleaning] AER and manual [Disinfection] AER and manual [Sterilization] - Ethylene oxide gas - STERRAD NX
Single-Use/Reuse	Reusable	Reusable
Duration and type of contact	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours).	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours).
Depth of Field	3-50mm	3-50mm
Direction of View	0°(Forward viewing)	0°(Forward viewing)
Field of View	120°	120°
Type of CCD	Color CCD	Color CCD
Number of CCD Chip	1	1
Outer Diameter of Distal End	ø 4.8mm (bullet shape)	ø 4.8mm (bullet shape)
Diameter of Insertion Tube	ø 5.4mm	ø 5.4mm
Bending Section Angulation	Up 210° / Down 120°	Up 210° / Down 120°
Working Length	380mm	380mm
Instrument Channel inner diameter	ø 2.2 mm	ø 2.2 mm
Observation mode	WLI, NBI	WLI, NBI

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Item	Subject Device	Predicate Device
	OLYMPUS CYF-V2, CYF-V2R	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Patient contacting material	Insertion tube: Forced dry-hard type of fluorine resin coat Bending section: Fluoro Rubber Glue: Epoxy glue Distal End: Polyphenylsulfone Objective lens/ Light guide lens: Glass Solder: AuSn Solder Instrument channel pipe/ Instrument channel joint/ Junction/ Instrument channel port: Stainless Steel Instrument Channel: Polytetrafluoroethylene Rubber seal: Silicone	Insertion tube: Forced dry-hard type of fluorine resin coat Bending section: Fluoro Rubber Glue: Epoxy glue Distal End: Polyphenylsulfone Objective lens/ Light guide lens: Glass Solder: AuSn Solder Instrument channel pipe/ Instrument channel joint/ Junction/ Instrument channel port: Stainless Steel Instrument Channel: Polytetrafluoroethylene Rubber seal: Silicone

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Item	Subject Device	Predicate Device
	OLYMPUS CYF-VH, CYF-VHR	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Indications for Use	CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHRhave been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra and kidney.	This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter, and kidney.
Regulation Number	21CFR 876.1500	21CFR 876.1500
Regulation Name	Endoscope and accessories	Endoscope and accessories
Regulatory Class	Class II	Class II
Product Code	FAJ	FAJ
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology
Use Environment	Healthcare facility/hospital	Healthcare facility/hospital
Reprocessing	[Cleaning] AER and manual [Disinfection] AER and manual [Sterilization] - Ethylene oxide gas - STERRAD NX	[Cleaning] AER and manual [Disinfection] AER and manual [Sterilization] - Ethylene oxide gas - STERRAD NX
Single-Use/Reuse	Reusable	Reusable
Duration and type of contact	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours).	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours).
Depth of Field	3-50mm	3-50mm
Direction of View	0°(Forward viewing)	0°(Forward viewing)
Field of View	120°	120°
Type of CCD	Color CCD	Color CCD
Number of CCD Chip	1	1
Outer Diameter of Distal End	ø 2.7mm (bullet shape)	ø 4.8mm (bullet shape)
Diameter of Insertion Tube	ø 5.5mm	ø 5.4mm
Bending Section Angulation	Up 220° / Down 130°	Up 210° / Down 120°
Working Length	380mm	380mm

Item	Subject Device	Predicate Device
	OLYMPUS CYF-VH, CYF-VHR	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Instrument Channel inner diameter	ø 2.2 mm	ø 2.2 mm
Observation mode	WLI, NBI	WLI, NBI
Patient contacting material	Insertion tube: Forced dry-hard type of fluorine resin coat Bending section: Fluoro Rubber Glue: Epoxy glue Distal End/ Light guide lens: Polysulfone Objective lens: Glass Solder: AuSn Solder Instrument channel pipe/ Instrument channel joint/ Junction/ Instrument channel port: Stainless Steel Instrument Channel: Polytetrafluoroethylene Rubber seal: Silicone	Insertion tube: Forced dry-hard type of fluorine resin coat Bending section: Fluoro Rubber Glue: Epoxy glue Distal End: Polyphenylsulfone Objective lens/ Light guide lens: Glass Solder: AuSn Solder Instrument channel pipe/ Instrument channel joint/ Junction/ Instrument channel port: Stainless Steel Instrument Channel: Polytetrafluoroethylene Rubber seal: Silicone

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

1) Reprocessing validation testing

Reprocessing instruction and reprocessing method validation testing were conducted and documentations were provided as recommended by Guidance for Industry and Food and Drug Administration Staff, "Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling".

2) Biocompatibility testing

Biocompatibility testing were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

- Cytotoxicity Study Using the ISO Elution Method
- ISO Intracutaneous Study in Rabbits
- ISO Guinea Pig Maximization Sensitization Test
- ISO Intracutaneous Study in Rabbits
- USP Rabbit Pyrogen Study
- ISO Acute Systemic Toxicity Study in Mice

3) Software verification and validation testing

Software verification and validation testing were conducted, and documentations were provided as

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recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

4) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted in accordance with the ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18:2009 standards for safety and the IEC 60601-1-2:2014 standards for EMC.

5) Performance testing - Bench

Bench testing as listed below were conducted to ensure that the subject device performs as intended and meet design specifications.

- Thermal Safety
- Composite Durability
- Color Performance
- Photobiological Safety
- Noise and Dynamic Range
- Image Intensity Uniformity
- Field of View and Direction of View
- Resolution
- Effectiveness NBI

6) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

7) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

8) Risk management

Risk management was performed in accordance with ISO 14971:2007. The design verification tests and their acceptance criteria were performed and identified as a result of this risk management.

8. CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate device, VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYF TYPE V2R, CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHR raise no new issue of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, effectiveness and performance.

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Step-by-Step Comparison of Rinsing validation steps(Manual HLD)

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Step-by-step comparison of rinsing validation (Manual HLD) steps for CYF-V2 and CYF-V2R

(b)(4)

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Dear Ms. Kaplan,

Just wanted to let you know that I've received both requests from today and I will continue to work with Olympus to ensure that the requested information is received by the timeframe requested.

Have a nice afternoon,
Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Thursday, July 28, 2022 3:06 PM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: [EXTERNAL] K221683 - Interactive Review Request #3

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Dear Teffany,

In addition to the interactive review request I sent earlier today, please also address the following:

(b)(4)

Please respond by COB Monday, August 1, to facilitate a timely review of your submission.

Thank you,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
esther.kaplan@fda.hhs.gov

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Identification information : (b)(4)

OLYMPUS

Test Report

Title

High Level Disinfection test Using OER-Pro with Acecide-C of CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH

(b)(4)

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Section 7

Class III Summary and Certification

This section does not apply. The subject device is not a class III device.

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Attachment 12.1

— Depth of Field —

This section describes how to define DOF (depth of field).

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OLYMPUS

OPERATION MANUAL

INSTRUCTIONS

VISERA CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF TYPE V2
OLYMPUS CYF TYPE V2R

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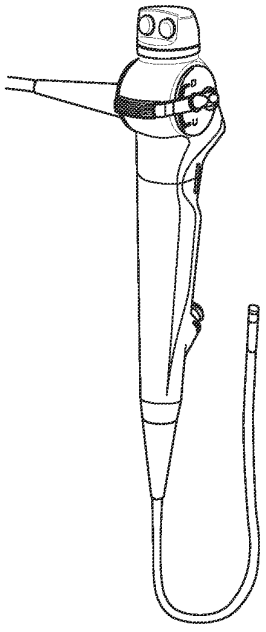
Appendix 65



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GLP REPORT

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

CONFIDENTIAL

STUDY TITLE

Cytotoxicity Study Using the ISO Elution Method

TEST ARTICLE NAME

CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH
and Luer-Split MAJ-2092

TEST ARTICLE IDENTIFICATION

(b)(4)

(b)(4)

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GLP PROTOCOL

TEST FACILITY

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SPONSOR

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OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

Cytotoxicity Study Using the ISO Elution Method

(b)(4)

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Dear Ms. Kaplan,

Thank you very much for this additional information. I will make sure it gets communicated to Olympus.

Best regards,
Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Tuesday, August 23, 2022 11:32 AM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: [EXTERNAL] K221683 Teleconference Follow-up - (b)(4)

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Hello Teffany,

(b)(4)

Thank you,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
esther.kaplan@fda.hhs.gov

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Section 17.1.4

Selection of Representative Video system center for Electrical Safety Test

(b)(4)

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Section 18.2

Thermal Safety Test Report

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Step-by-Step Comparison of Automated Cleaning (OER-mini)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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OLYMPUS CONFIDENTIAL

Cytotoxicity (Non-preconditioning test article)			Test Article	CYF-(b)(4)
Department		Name	Number	Date
Prepare	Biological Evaluation Technology 2	(b)(4)		3/ 29/ 2022
Review	Biological Evaluation Technology 2			3/ 29/ 2022
Approve	Biological Evaluation Technology 2			3/ 29/ 2022

Final Report for Cytotoxicity Study Using the ISO Elution Method

OLYMPUS

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OLYMPUS
CONFIDENTIAL

STUDY TITLE

Cytotoxicity Study Using the Elution Method

TEST ARTICLE NAME

VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and Luer-Split MAJ-2092

(b)(4)

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OLYMPUS

REPROCESSING MANUAL

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-VH
OLYMPUS CYF-VHR

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Chapter 7 Storage and Disposal 83

Accessories:

- Sterilization cap (MAJ-1538)
- Single use combination cleaning brush (BW-411B)

*1 This product may not be available in some areas.

- Sterilization tray (WA05991A*1, sold separately)

MAJ-1538

WA05991A

BW-411B

Refer to the endoscope's companion manual, the "OPERATION MANUAL" with your endoscope model listed on the cover, for operation information.

USA: CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Chapter 1 General Policy

1.1 Instructions

- This manual contains the reprocessing methods recommended by Olympus for the endoscopes and accessories listed on the front cover.
- This instruction manual contains essential information on reprocessing endoscopes and accessories safely and effectively.
- Before reprocessing, thoroughly review this manual and the manuals of the reprocessing equipment and chemicals that will be used for reprocessing. Reprocess all the devices as instructed.
- Note that the complete instruction manual set for the endoscope and accessories consists of this manual and the "OPERATION MANUAL" with your endoscope model listed on the cover. Both manuals accompanied the endoscope at shipment.
- Keep this manual and all related manuals in a safe and accessible location (e.g., in the reprocessing area).
- If you have any questions or comments about any information in this manual, or if a problem that cannot be solved occurs while reprocessing, contact Olympus.

❍ Terms used in this manual

AER/WD:

AER and WD are abbreviations for Automated Endoscope Reprocessor and Washer-Disinfector, which are used for reprocessing the endoscopes and accessories.

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1.2 Importance of reprocessing

The medical literature reports incidents of cross-contamination resulting from improper reprocessing. It is strongly recommended that all individuals engaged in reprocessing closely observe all instructions given in this manual and the manuals of all ancillary equipment, and have a thorough understanding of the following items:

- Professional health and safety policies of your hospital
- Instruction manuals for the endoscope, accessories, and all the other reprocessing equipment
- Structure and handling of the endoscope and accessories
- Handling of pertinent chemicals

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization according to Section 4.3, “Workflow for manually cleaning and sterilizing endoscopes and accessories”.

1.3 Signal words

The following signal words are used throughout this manual:

WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.
NOTE	Indicates additional helpful information.

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1.4 Precautions

WARNING

- An insufficiently reprocessed endoscope and/or accessory may pose an infection control risk to the patients and/or operators who contact them.
- The endoscope reprocessor, video system center, light source, and/or front panels of equipment may cause an infection control risk. Perform proper cleaning and disinfection as described in their respective instruction manuals. A tap or basin that medical personnel come in contact with may cause an infection control risk as well. Perform proper replacement, cleaning, and disinfection.
- All disinfection methods (whether performed manually or by an AER/WD) and all sterilization methods (whether performed by ethylene oxide gas, hydrogen peroxide or steam) require thorough prior cleaning of the instruments being reprocessed. If the instruments are not adequately cleaned prior to disinfection/sterilization, these processes will be ineffective. Immediately after each patient procedure and before disinfection/sterilization, thoroughly clean the endoscope and the accessories used with the endoscope.
- The channel of the endoscope and all accessories used with the endoscope during the patient procedure must be cleaned and disinfected/sterilized after each patient procedure, even if the channel or accessories were not used during the patient procedure. Insufficient cleaning and disinfection/sterilization of these components may pose an infection control risk to patients and/or operators.
- Residual disinfectant solution and detergent solution may cause adverse reactions in patients. Therefore, rinse all external surfaces and the channel of the endoscope and accessories thoroughly with water to remove residual disinfectant solution and detergent solution after cleaning and disinfection.
- The results of sterilization depend on various factors. These factors include how the equipment was packaged and the placing and loading of the package in the sterilization device. Verify the sterilization process using biological and/or chemical indicators. Follow the guidelines for sterilization issued by national authorities, professional organizations and infection control professionals, including the frequency of the above verification, as well as the instruction manual for the sterilization device.
- Establish an internal system of identifying contaminated versus reprocessed endoscopes and accessories to prevent both mix-ups and cross-contamination. Some national or professional guidelines recommend separating dirty (contaminated) area, clean area, and storage area. Touching a reprocessed endoscope and/or accessories with contaminated gloves or placing them on a contaminated hanger or surface, including letting them touch the floor, will recontaminate them.

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WARNING

- Prior to each patient procedure, confirm that the endoscope and accessories have been properly reprocessed and stored. If there are any doubts or questions, reprocess them again before the patient procedure, following the instructions given in this manual.
- Perform a leakage test on the endoscope after each precleaning procedure. Do not use the endoscope if a leak is detected. Use of an endoscope with a leak may cause a sudden loss of the endoscopic image, damage to the bending mechanism, or other malfunctions. Use of a leaking endoscope may also pose an infection control risk.

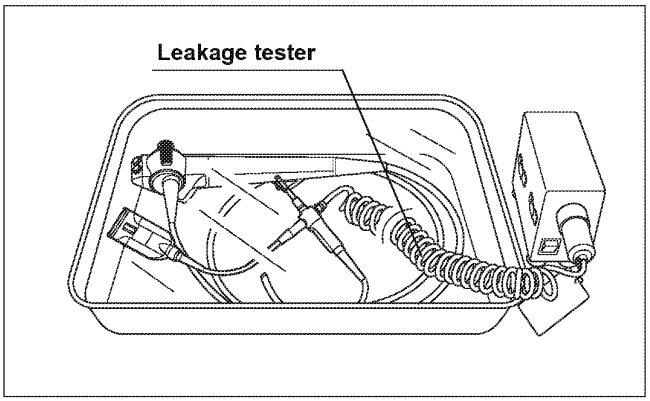

Figure 1.1

- Store alcohol in an airtight container. Alcohol stored in an open container may cause a fire hazard and may result in a loss of efficacy due to evaporation.
- The accessories listed on the front cover of this manual cannot be refurbished or repaired and are intended to be replaced once they show any signs of wear and tear. Should any irregularity be observed, use a replacement accessory instead. Using defective accessories may cause equipment malfunction, reduce the efficacy of reprocessing, present a risk to patients and/or operators, or damage the endoscope and/or accessories.
- Single-use brush, such as the single use combination cleaning brush (BW-411B) is designed for cleaning only one endoscope and its related accessories. Dispose of the single-use brush immediately after use. Using a single-use brush to clean multiple endoscopes and/or accessories may reduce its cleaning efficacy and may damage the brush leading to brush breakage or the endoscope and/or accessory damage.
- Patient debris and used reprocessing chemicals pose infection control risks. To guard against contact with dangerous chemicals and potentially infectious material, wear appropriate personal protective equipment during reprocessing. Such protective equipment should include appropriate eyewear, face mask, cap, moisture-resistant clothing, shoe covers, and chemical-resistant gloves that fit properly and are long enough to prevent skin exposure.

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WARNING

- The reprocessing room must be adequately ventilated to minimize the risks from chemical vapors.
- Always remove contaminated personal protective equipment before leaving the reprocessing area to prevent contamination from spreading.
- Only Olympus-recommended or Olympus-endorsed AERs/WDs have been validated by Olympus. When using an AER/WD that is not recommended by Olympus, the manufacturer of the AER/WD is responsible for validating compatibility of the AER/WD with each Olympus endoscope and accessory.
- Before using an AER/WD, confirm that it is capable of reprocessing the endoscope including the channel and accessories. Be sure to attach all required connectors/adaptors. Otherwise, insufficient reprocessing may pose an infection control risk. If you are uncertain as to the ability of your AER/WD to reprocess the endoscope including the channel and accessories, contact the manufacturer of the AER/WD for specific instructions and information on compatibility and required connectors/adaptors.
- The instructions provided in this manual are not valid for Olympus devices repaired by a non-Olympus facility. The Olympus recommended reprocessing procedures have not been validated for reprocessing devices repaired by a non-Olympus facility. In the event that your device has been repaired by a non-Olympus facility, please contact the repair facility for instructions regarding reprocessing.
- Prions, which are the pathogenic agents of the Creutzfeldt-Jakob disease (CJD) cannot be destroyed or inactivated by the reprocessing methods stated in this instruction manual. When using the endoscope and accessories on patients with CJD or variant Creutzfeldt-Jakob disease (vCJD), be sure to use them for such patients only, or immediately dispose of them after use in an appropriate manner to prevent the usage of exposed devices on other patients. For methods to handle CJD, please follow the respective guidelines in your country.
- The endoscope and accessories may be damaged by published methods for destroying or inactivating prions. For information on the durability of Olympus equipment against a particular reprocessing method, please contact Olympus. In general, Olympus cannot guarantee the effectiveness, safety, and durability of reprocessing methods not described in this reprocessing manual. If you choose to use a reprocessing method not recommended in this manual, the local institution and/or physicians must assume responsibility for its safety and efficacy. Make sure to carefully inspect each piece of endoscopic equipment for irregularities (damage) prior to each patient procedure. Do not use the equipment if any irregularity is observed.
- Good quality control practices typically require appropriate documentation. Items such as local SOPs (Standard Operating Procedures), confirmation of operator training, routine testing of the disinfectant's MEC (Minimal Effective Concentration), confirmation of the disinfectant's use-life, etc. should be documented as performed.

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WARNING

- In case of performing any microbial test or other test using extraction fluid on the reprocessed endoscope, the reprocessing process has to be performed again according to the “REPROCESSING MANUAL” before patient procedure.

CAUTION

- Before immersing the endoscope in reprocessing fluids, confirm that the sterilization cap (MAJ-1538) is not attached to the endoscope. If the sterilization cap is attached, the reprocessing fluids will be able to penetrate the inside of the endoscope, and it can be damaged.
- When aerating or irrigating the endoscope channel, the air or water pressure must not exceed 0.3 MPa (3 kgf/cm^2, 43 psig). Higher pressures may cause damage to the endoscope.
- Store spare accessories in their original packaging to prevent damage.
- To prevent damage, do not apply excessive force to the endoscope and accessories during reprocessing.
- Vapors from disinfectant solution and alcohol may damage electronic devices such as computers. Properly manage the quality and durability of the devices used in reprocessing rooms and the ventilation performance of the rooms.

1.5 Reprocessing before the first use

New endoscopes, repaired endoscopes, accessories, and the carrying case for endoscopes are not reprocessed prior to shipping from Olympus, regardless of whether those instruments are for new purchase, demo or loaner purposes. Reprocess all such endoscopes and accessories received from Olympus according to the instructions given in this manual before storage and before using them in a patient procedure.

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization according to Section 4.3, “Workflow for manually cleaning and sterilizing endoscopes and accessories”.

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1.6 Reprocessing and storage after use

WARNING

- Do not reuse detergent solution.
- Do not reuse rinse water.
- Disinfectant and detergent solutions are only effective when used according to the disinfectant and detergent manufacturer's instructions. Follow the manufacturer's instructions regarding activation (if required), concentration, temperature, contact time and use life required to achieve successful cleaning and disinfection.
- If the disinfectant solution is reused, check its efficacy by proper methods, such as using a test strip, according to the disinfectant manufacturer's recommendations prior to use.
- Do not reuse alcohol.
- Alcohol is not a sterilant or high-level disinfectant.
- To maintain sterility of equipment following sterilization, use sterile packaging and wraps according to national guidelines.
- Store the endoscope and accessories in a proper storage cabinet, following the policies at your institution, applicable national laws and standards, and professional society guidelines and recommended practices.
- Improper storage practices, such as not thoroughly drying external and internal surfaces (lumens) prior to storage, will lead to an infection control risk.

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Ch.1

1.7 Reprocessing before patient procedure

WARNING

- Improper handling, such as touching a reprocessed endoscope and/or accessories with contaminated gloves, placing a reprocessed device on a contaminated hanger or surface, allowing devices to touch the floor, etc. will recontaminate the device.
- For nephroscopy procedures, cystoscope should be cleaned followed by sterilization according to Section 4.3, “Workflow for manually cleaning and sterilizing endoscopes and accessories”.

NOTE

Some national or professional guidelines recommend reprocessing endoscopes prior to their first use of the day, when the certain time passes after disinfecting/sterilizing, or in case the storage time recommended by the national authorities is exceeded.

Confirm that the endoscope and accessories have undergone proper reprocessing following their last use and that they have been stored properly. Check the storage period of reprocessed endoscopes, and check for surface contamination (e.g., dust). Check the expiration date marked on all items and check for tears or breaches in the sterile packaging. If there are any doubts or questions concerning whether a device is contaminated, reprocess it again following the instructions given in this manual.

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Chapter 2 Function and Inspection of the Accessories for Reprocessing

Certain accessories are required for reprocessing the endoscope. This chapter describes the function of these accessories. It also describes how to inspect these accessories before using them to reprocess the endoscope.

2.1 Sterilization cap (MAJ-1538)

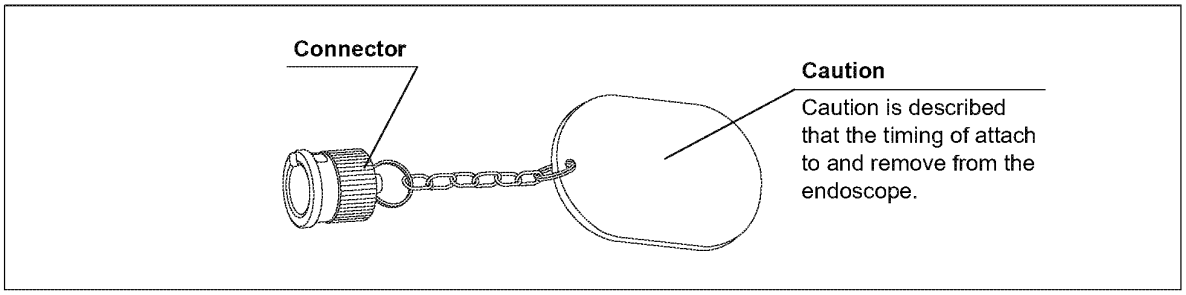

Figure 2.1

CAUTION

A miss attaching/removing may cause a breakage of the endoscope.

Function

When performing gas sterilization (e.g., ethylene oxide gas sterilization, hydrogen peroxide low temperature plasma), the sterilization cap must be attached to the venting connector on the light guide connector.

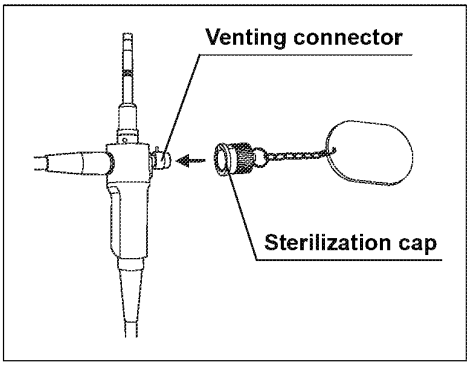

Figure 2.2

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Inspection

Confirm that the sterilization cap is free from scratches, flaws, and debris.

2.2 Sterilization tray (WA05991A, sold separately)

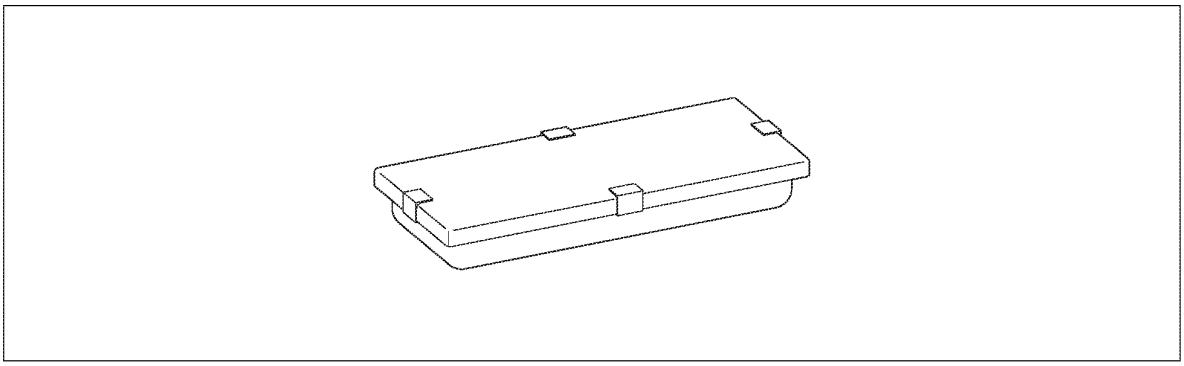

Figure 2.3

Function

This sterilization tray is used to transport and sterilize the endoscope and accessories.

Inspection

Check every part of the sterilization tray for damage.

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2.3 Single use combination cleaning brush (BW-411B)

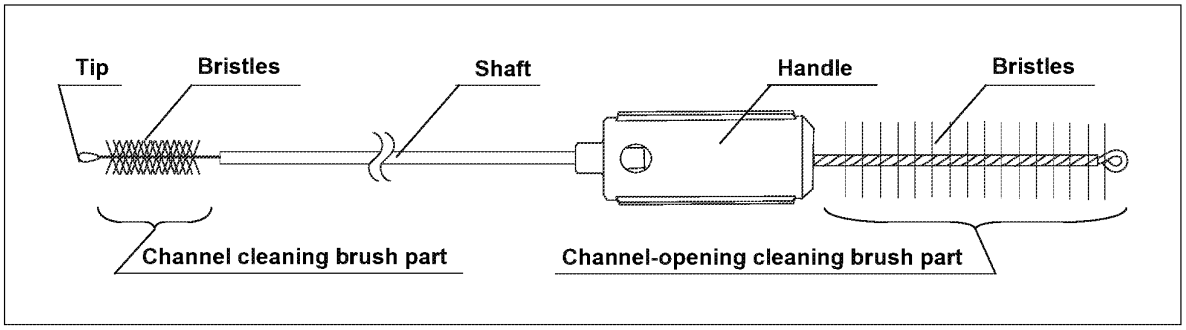

Figure 2.4

Function

The channel cleaning brush part of the single use combination cleaning brush is used to brush the instrument channel of the endoscope.

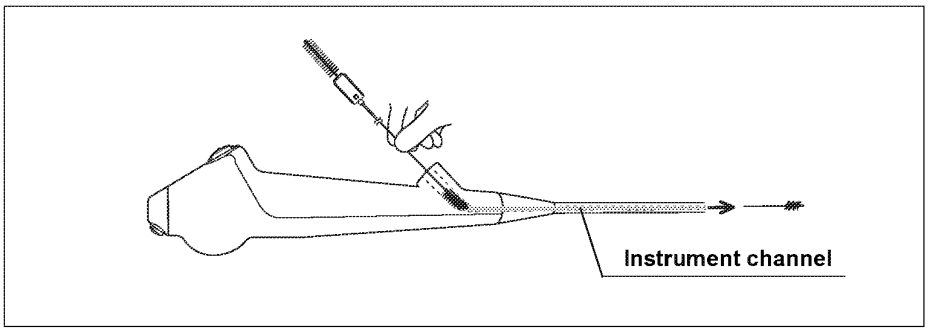

Figure 2.5

The channel-opening cleaning brush part of the single use combination cleaning brush is used to brush the instrument channel port of the endoscope.

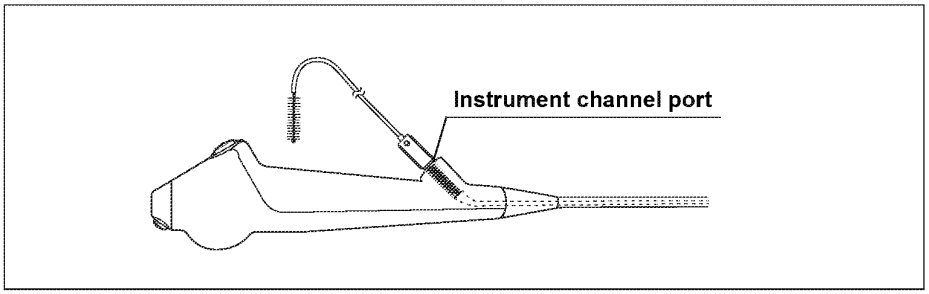

Figure 2.6

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Inspection

CAUTION

Do not reprocess the single use channel cleaning brush prior to use. The brush may be damaged.

1. Remove the brush from its packaging just prior to use.
2. Confirm that the channel cleaning brush part and tip at the distal end are securely attached.
3. Check the channel cleaning brush and channel-opening cleaning brush parts for loose or missing bristles.
4. Check the bristles of the channel cleaning brush and the channel-opening cleaning brush parts for any damage.
5. If the bristles are crushed, gently straighten them with your gloved fingertips.
6. Check for bends, scratches, and other damage to the shaft.

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Chapter 3 Compatible Reprocessing Methods and Chemical Agents

3.1 Compatibility summary

The endoscope and accessories are compatible with several methods of reprocessing. However, not all reprocessing methods are compatible with all endoscopes and all accessories. Reprocessing with incompatible methods can cause equipment damage even if the number of reprocessing cycles is small. For appropriate reprocessing methods, see Table 3.1.
Follow the policies at your local institution when choosing which methods listed in Table 3.1 to employ.

CAUTION

- The methods listed as “compatible” in Table 3.1 are compatible for routine use only when used according to manufacturer’s instructions. Repeated use and reprocessing of endoscopes and accessories leads to gradual wear and tear. Furthermore, reprocessing methods that employ higher temperatures and more caustic/corrosive materials may lead to faster deterioration. In general, sterilization processes are harsher on equipment than disinfection processes. Before each patient procedure, inspect the endoscope and accessories for damage, according to the instructions described in this manual and its companion “OPERATION MANUAL”.
- The instructions provided in this manual regarding compatible reprocessing methods and chemical agents are not valid for Olympus devices repaired by a non-Olympus facility. Olympus repairs devices to manufacturer’s specifications using original equipment manufacturer’s (OEM) materials. The use of non-OEM materials to repair an Olympus device may affect the material compatibility and reprocessing efficacy of the device with certain reprocessing chemicals or methods. In the event that your device has been repaired by a non-Olympus facility, please contact the repair facility for instructions regarding compatible reprocessing methods and chemical agents.

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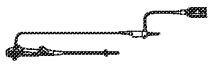
3.2 List of the compatible methods

Reprocessing methods listed in Table 3.1 have been validated with this endoscope and accessories. For details on the chemicals and devices that can be used, refer to Section 3.4 and subsequent sections.

			Endoscope 	Sterilization cap (MAJ-1538)
Ultrasonic cleaning			*1	
Manual cleaning	Detergent solution			
Disinfection	2 – 3.5% glutaraldehyde			
	ACECIDE disinfectant solution*2			
Drying	Alcohol			
Sterilization	Hydrogen peroxide	V-PRO® maX (Flexibile cycle)		*6, *7
		STERRAD® NX® (Advanced cycle)*3		*6
		STERRAD® 100S (Long cycle)*4	*5	*6, *7
		STERRAD® 100NX® (Duo cycle)		*7
	Steam (autoclaving)			*6, *7
	Ethylene oxide gas			*6
	Low Temperature steam and formaldehyde (LTSF)			

compatible not compatible

Table 3.1 List of compatible methods

*1 The endoscope is only compatible with ultrasonic cleaning as performed in an Olympus-recommended endoscope reprocessor, such as OER-AW, OER-Pro, OER-Mini, and OER-Elite (OER-AW is available in some areas other than the USA. OER-Mini is only available in the USA. OER-Pro and OER-Elite are available in the USA and some areas.)

. When using an AER/WD that is recommended by Olympus other than listed above, please contact Olympus.

*2 ACECIDE disinfectant solution is exclusively for an Olympus recommended endoscope reprocessor, such as OER-AW, OER-Pro, OER-Mini, and OER-Elite (ACECIDE is available in the USA and some areas).

*3 Olympus products can be processed with or without ALLClear· Technology. For further details, contact ASP.

*4 For countries other than the USA.

*5 Attaching a booster is necessary. Refer to Section 3.10, “Hydrogen peroxide sterilization”.

*6 If sterilized alone, use appropriate packaging that is legally marketed in the USA and sterilize under the appropriate parameters following the policies at your facility.

*7 The accessory alone is not compatible with STERRAD® 100NX® (DUO cycle). This product can be used to sterilize when combined with the endoscope which is compatible with the sterilization shown on the left.

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3.3 Water (for reprocessing)

Water is used for leakage testing and manual cleaning of the endoscope and accessories. For these purposes, use either fresh, potable water or water that has been processed (e.g., filtered, deionized or purified) to improve its chemical and/or microbiological quality. Consult with your hospital's infection control committee.

When rinsing the endoscope and accessories following disinfection, use the water as described in Section 3.6, "Rinse water".

3.4 Detergent solution

WARNING

- Excessive foaming prevents detergent solution from properly contacting the surfaces and channel walls of the endoscope and accessories, and may impair effective cleaning.
- Do not reuse detergent solution.

Use a medical-grade, low-foaming, neutral pH detergent that is labeled for use on medical device, which may or may not contain enzymes. Follow the instructions provided by the detergent manufacturer regarding concentration, temperature, contact time, and expiration date. Contact Olympus for the names of specific brands of detergent solution that have been tested for compatibility with endoscopes and accessories.

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3.5 Disinfectant solution

Use a disinfectant cleared/approved by your national regulatory agency for use in reprocessing flexible endoscopes. If national or professional guidelines applicable to your institution define "high-level disinfection" and require using a high-level disinfectant for the flexible endoscopes, follow the requirement. Follow the disinfectant manufacturer's instructions regarding activation (if required), concentration, temperature, contact time, and expiration date.

For further information regarding the compatibility of glutaraldehyde-based or non glutaraldehyde-based disinfectant solution, contact Olympus.

WARNING

- As per Advanced Sterilization Products® Safety Alert, dated January 3, 2005, entitled "Labeling Change to Cidex® OPA Solution Instructions for Use" – "In rare instances Cidex OPA Solution has been associated with anaphylaxis-like reactions in bladder cancer patients undergoing repeated cystoscopies. Therefore, ASP is contraindicating the use of Cidex OPA Solution for the reprocessing of any urological instruments to be used on patients with a history of bladder cancer.".
- If the disinfectant solution is reused, check its efficacy by proper methods, such as using a test strip, according to the disinfectant manufacturer's recommendations prior to use.
- For nephroscopy procedures, cystoscope should be cleaned followed by sterilization. Refer to Section 3.8, "Ethylene oxide gas sterilization", Section 3.9, "Steam sterilization (autoclaving)" and Section 3.10, "Hydrogen peroxide sterilization".
- For cystoscopy procedures, cystoscopes should be cleaned followed by either high-level disinfection or sterilization.

NOTE

Sterilization can be selected for the endoscope as a preferable reprocessing method instead of high-level disinfection if sterilization is recommended based on decision by medical professionals.

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3.6 Rinse water

CAUTION

Do not reuse rinse water.

Rinsing after disinfection

Olympus recommends using sterile water, fresh potable water or water that has been processed (e.g., filtered, deionized, or purified) to improve its chemical and/or microbiological quality. Some national or professional guideline recommend using sterile water for rinsing endoscopes, accessories, and medical instruments. Consult with your institution's infection control committee regarding local policies on water quality.

3.7 Alcohol

WARNING

- Do not reuse alcohol.
- Alcohol is not a sterilant or high-level disinfectant.

Use medical-grade 70% ethyl or 70% isopropyl alcohol.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.8 Ethylene oxide gas sterilization

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization.

CAUTION

- When performing ethylene oxide gas sterilization, the sterilization cap (MAJ-1538) must be attached to the venting connector.

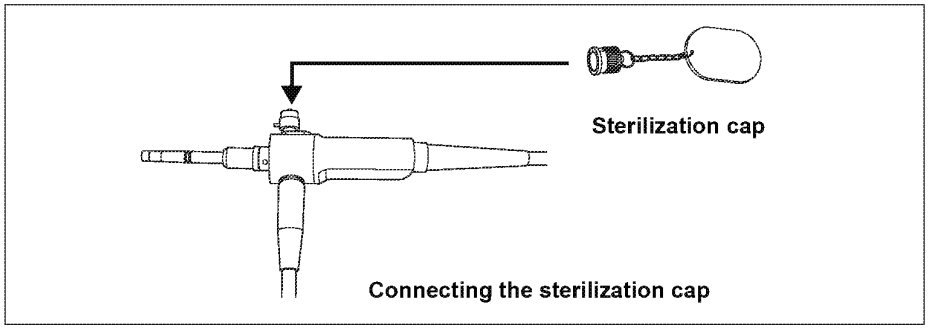

Figure 3.1

- Exceeding the recommended parameters may cause equipment damage.

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Parameters for 100% ethylene oxide gas sterilization cycles, for the USA and some countries

The endoscope and accessories listed as compatible with ethylene oxide gas sterilization in Table 3.1 can be sterilized by 3M™ Steri-Vac™ 5XL or STERIS Amsco® Eagle® 3017 ethylene oxide gas sterilizers with the "55°C cycle" given in Table 3.2, and aerated with 12 hours or more at 55°C (130°F). When performing ethylene oxide gas sterilization, follow all national, professional, and institutional reprocessing protocols as well as the instructions provided by the manufacturer of your sterilization equipment.

Process phase	Parameter	Value
Sterilization	**Temperature**	55°C (130°F)
	Relative humidity	50 – 80%
	Ethylene oxide gas concentration	0.735 – 0.740 mg/cm^3 (735 – 740 mg/L)
	Exposure time	60 minutes
Aeration	**Minimum aeration parameters**	12 hours in an aeration chamber at 55°C (130°F)

Table 3.2

Parameters for 20% ethylene oxide gas/80% CO_2 gas sterilization cycles for countries other than the USA

The endoscope and accessories listed as compatible with ethylene oxide gas sterilization in Table 3.1 can be sterilized by ethylene oxide gas and aerated within the parameters given in Table 3.3. When performing ethylene oxide gas sterilization, follow all national, professional, and institutional reprocessing protocols as well as the instructions provided by the manufacturer of your sterilization equipment.

Process phase	Parameter	Value
Sterilization	**Temperature**	55°C (130°F)
	Relative pressure	0.1 – 0.17 MPa
	Relative humidity	35 – 85%
	Ethylene oxide gas concentration	0.6 – 0.7 mg/cm^3 (600 – 700 mg/L)
	Exposure time	2 – 4 hours
Aeration	**Minimum aeration parameters**	12 hours in an aeration chamber at 50 – 57°C (122 – 135°F) or 7 days at room temperature

Table 3.3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.9 Steam sterilization (autoclaving)

The accessories listed as compatible with steam sterilization in Table 3.1 can be sterilized by steam within the parameters given in Table 3.4. When steam sterilizing, follow all national, professional, and institutional reprocessing protocols as well as the instructions provided by the manufacturer of your sterilization equipment.

CAUTION

- Do not steam sterilize the endoscope. Steam sterilization will cause severe damage.
- Exceeding the recommended parameters may damage the accessories.

Process phase	Parameter	Value	
		For the USA	For countries other than the USA
Prevacuum steam sterilization cycle	Setting temperature	132°C (270°F)	134°C (274°F)
	Setting exposure time	4 minutes	3 minutes
Drying	Setting drying time	A minimum of 30 minutes	
	• If the sterilization packaging of accessory taken out of the sterilizer is wet, sterilization effect may not be maintained. Reconsider conditions such as drying time and sterilize again. • Drying time depends on various factors including kinds of sterilizer, type of sterilization pouch and volume of loading. Confirm the appropriate drying time beforehand.		

Table 3.4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.10 Hydrogen peroxide sterilization

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization.

STERRAD® 100S*/NX®

* For countries other than the USA.

WARNING

When sterilizing a flexible endoscope that has an instrument channel with the STERRAD® 100S Sterilization System, depending on the inner diameter/length of channel and the model of sterilizer, it is necessary to attach the booster (REF15400) that is provided by ASP (Advanced Sterilization Products) to the endoscope. Do not attach the booster to the distal end of the insertion section. For further details, refer to the ASP instruction manual or contact ASP directly.

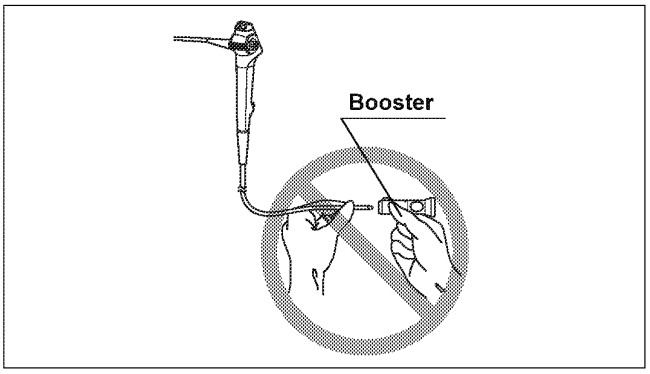

Figure 3.2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CAUTION

- When performing STERRAD® 100S/NX® (with/without ALL Clear Technology) sterilization, the sterilization cap (MAJ-1538) must be attached to the venting connector in order to avoid rupture of the bending section.

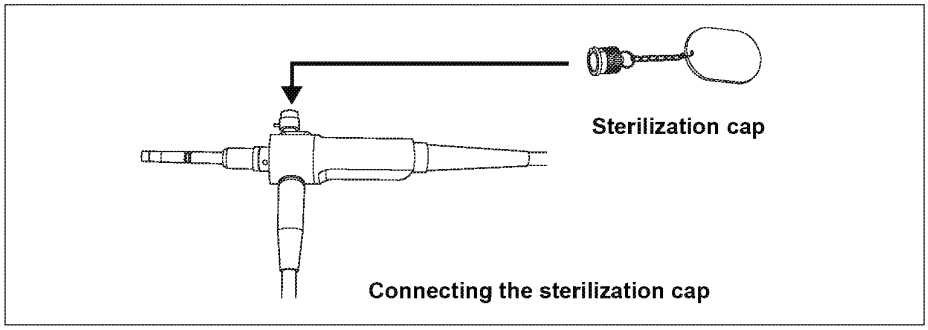

Figure 3.3

- Do not use cycles not listed Table 3.1. If used, severe damage may be caused or efficacy of sterilization may not be achieved.

NOTE

Use sterilization wraps and packaging compliant with ISO 11607-1: 2006+A1, ISO 11607-2: 2006+A1.

As for the sterilizer, contact ASP. Also, refer to the “STERRAD® 100S/NX® (with/without ALL Clear Technology) instruction manual.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.11 Signs of degradation from reprocessing and its number of times

When reprocessed devices with chemicals, AER and sterilizer as described above, you will eventually start to see signs of deterioration.

CAUTION

Improper reprocessing shown below may significantly reduce the life time of a medical device.

- Reprocessing without observing the instructions of the manufacturer
- Application of multiple sterilization methods
- Immersion in a chemical for an excessive amount of time

Endoscope

- Cleaning, disinfection, and sterilization may cause the following degradations. If any of these signs of degradation happens, contact Olympus.
  - Pitted, cracked, peeled or discolored adhesives at either end of the bending section shown as Figure 3.4.
  - Abnormal bulges or swelling, scratches and holes in the bending section
  - Swelling or peeling of the insertion tube
- Olympus has verified no degradation when the listed number of sterilization cycle is performed. If this endoscope has been sterilized the following times (see below), the degradation shown in Figure 3.4 may occur. If such degradation happens, maintenance is required. For more details, contact Olympus.

STERRAD 100S/NX	100 times
Ethylene oxide gas	60 times

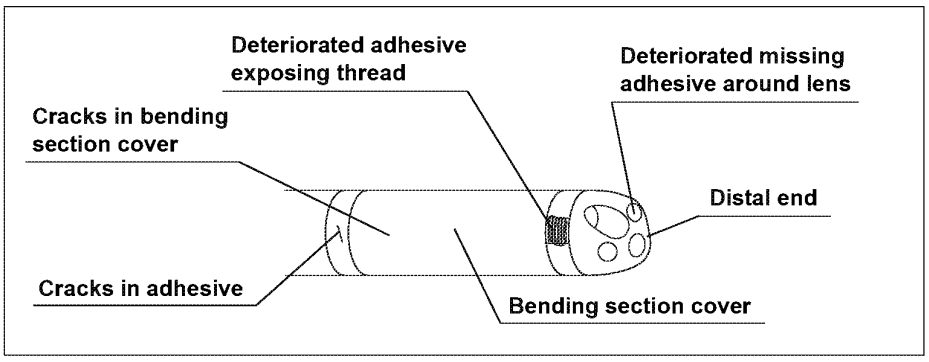

Figure 3.4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Accessory (MAJ-1538)

Cleaning, disinfection, and sterilization may cause the above accessories to be pitted, cracked and discoloration. If any of these signs of degradation happens, discard and replace this accessory.

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Chapter 4 Reprocessing Workflow for Endoscopes and Accessories

4.1 Summary of reprocessing workflow

This chapter describes the workflow for reprocessing the endoscope and accessories.

WARNING

Deviation from the recommended workflow may pose an infection control risk.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4.2 Workflow for manually cleaning and manually or automated disinfecting endoscopes and accessories

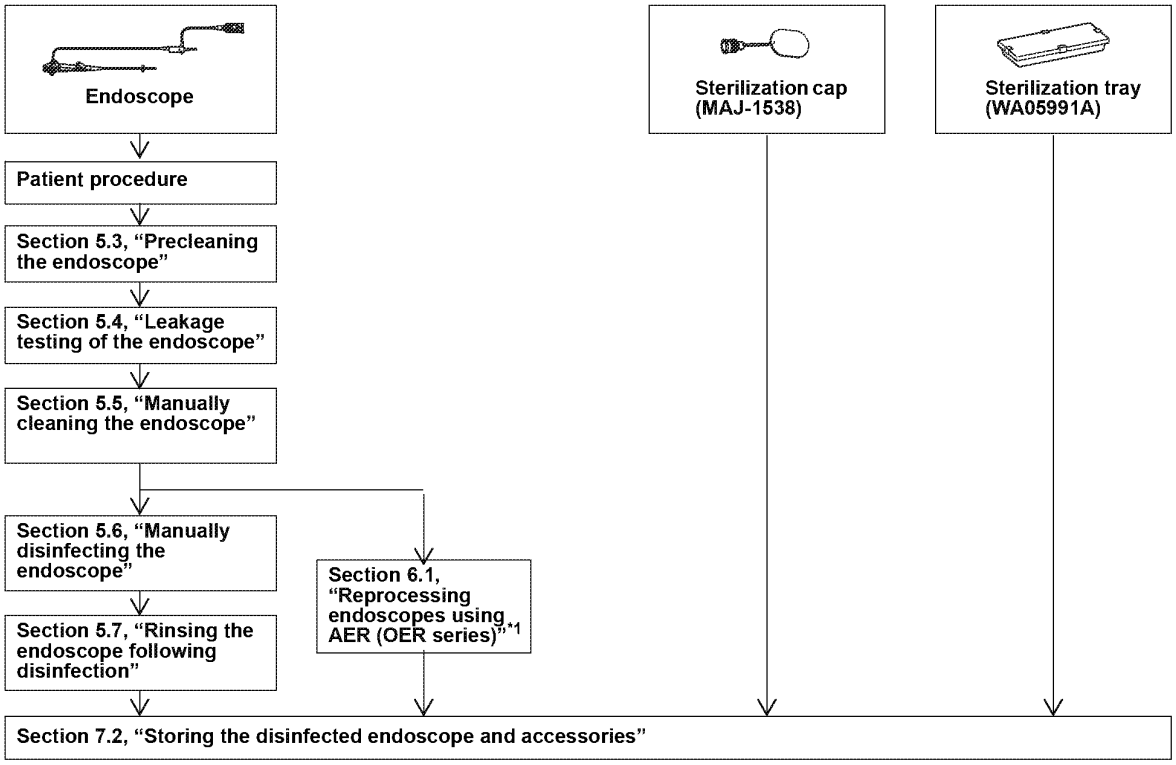
The endoscope and accessories used for cystoscopy should be reprocessed according to the workflow in this section.

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization. Refer to Section 4.3, “Workflow for manually cleaning and sterilizing endoscopes and accessories”.

NOTE

- Automated disinfection means disinfection using OER series.
- Sterilization can be selected for the endoscope as a preferable reprocessing method instead of high-level disinfection if sterilization is recommended based on decision by medical professionals.



*1 Depending upon the model of the OER series, you may be able to simplify Section 5.3, “Precleaning the endoscope” and Section 5.5, “Manually cleaning the endoscope”. Refer to the instruction manual for the OER series you have.

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4.3 Workflow for manually cleaning and sterilizing endoscopes and accessories

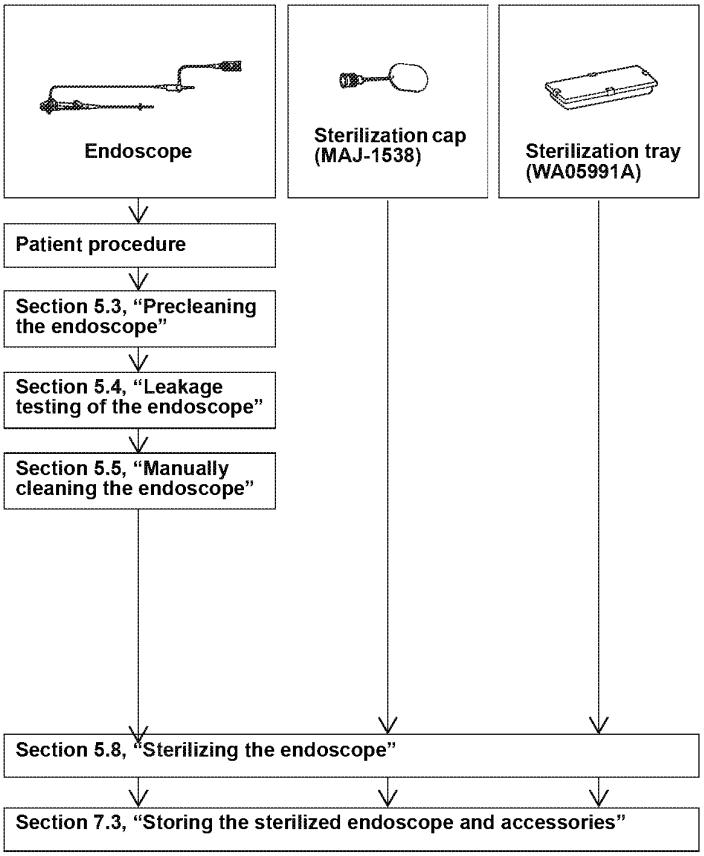
The endoscope and accessories used for nephroscopy should be reprocessed according to the workflow in this section.

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization according to Section 4.3, "Workflow for manually cleaning and sterilizing endoscopes and accessories".

NOTE

- If required by your facility's local policy, manually or automated disinfection may be performed between manual cleaning and sterilization.
- Automated disinfection means disinfection using OER series.



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4.3 Workflow for manually cleaning and sterilizing endoscopes and accessories

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Chapter 5 Reprocessing the Endoscope

5.1 Summary of reprocessing the endoscope

Certain accessories are required to manually reprocess the endoscope. The steps for reprocessing the endoscope are explained in this chapter.

The reprocessing workflow of all accessories is outlined in Chapter 4, “Reprocessing Workflow for Endoscopes and Accessories”.

CAUTION

- The insertion section of the endoscope is composed of the insertion tube, the bending section, and the distal end. The bending section is covered by a thin, easily damaged elastic covering. Do not allow reprocessing equipment to forcefully contact the bending section. Do not allow any sharp edges, such as the distal ends of EndoTherapy accessories (needles, forceps, snares, etc. used in the instrument channel of the endoscope) to contact the bending section. Such improper handling may damage the covering and cause the endoscope to leak.

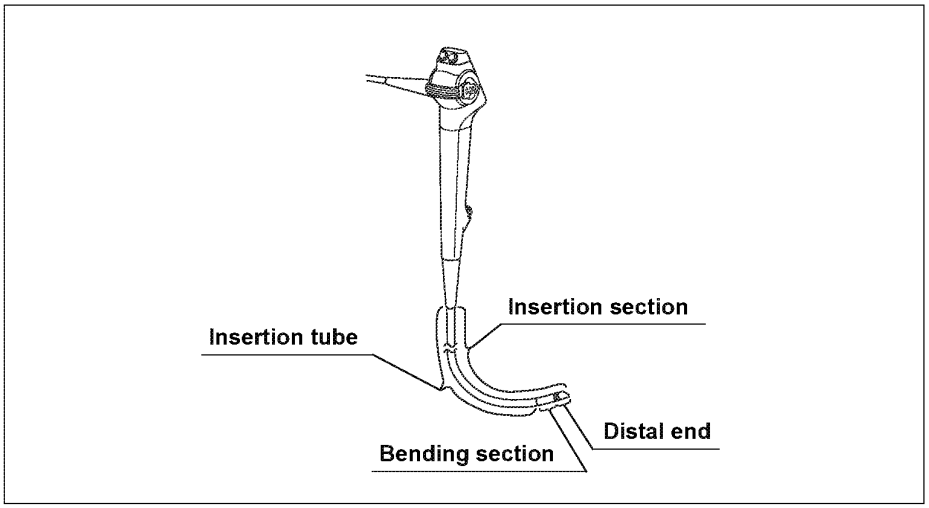

Figure 5.1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CAUTION

- Handle the insertion section carefully. Tightly gripping or sharply bending the insertion tube or the bending section can stretch or severely damage the insertion tube and/or the covering of the bending section.
- To prevent damage to the endoscope, do not immerse the endoscope with objects other than the equipment used for reprocessing the endoscope.
- To prevent damage, do not coil the insertion tube or the universal cord of the endoscope with a diameter less than 10 cm.

5.2 Preparing the equipment for reprocessing

Equipment needed

The following equipment is prepared to perform the reprocessing steps described in this chapter.

Accessories for reprocessing

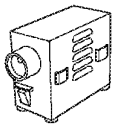
Single use combination cleaning brush (BW-411B)

Sterilization cap (MAJ-1538)

Sterilization tray (WA05991A) (Sold separately. See its instruction manual.)

Accessories and equipment for leakage test

Leakage tester (MB-155) (Sold separately. Refer to its instruction manual.)



Maintenance unit (MU-1) (Sold separately. Refer to its instruction manual.)

or

Leakage tester (WA23080A) (Sold separately. Refer to its instruction manual.)

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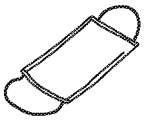
Personal protective equipment (e.g.)

Eyewear



Face mask

Moisture-resistant clothing

Chemical-resistant gloves*1

Other

- Clean lint-free cloths*2
- Clean sponges
- Clean 30 ml (30 cc) syringes
- Clean 500 ml containers
- Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)
- Sterile, large basins*3 (size: 40 (W) × 40 (H) × 25 (D) cm or more)
- Sterilization wraps*4
- Water (for reprocessing) (Refer to Section 3.3, "Water (for reprocessing)")
- Disnfectant solution (Refer to Section 3.5, "Disinfectant solution")
- 70% ethyl or 70% isopropyl alcohol (Refer to Section 3.7, "Alcohol")
- Sterile lint-free cloths*2, *3
- Sterile cotton swabs*3
- Sterile 30 ml (30 cc) syringes*3
- Small basins
- Clean, large basins with tight-fitting lids (size: 40 (W) × 40 (H) × 25 (D) cm or more)
- Sterilization pouches*4
- Instrument tray*4
- Detergent solution (Refer to Section 3.4, "Detergent solution")
- Rinse water (Refer to Section 3.6, "Rinse water")

*1 Gloves are recommended to be long enough so that your skin is not exposed.

*2 All cloths used in reprocessing are recommended to be lint-free. Lint or cloth fibers shed into reprocessing fluids may be injected into the endoscope channel. There is the potential for lint or cloth fibers to lodge in channel. If gauze is used to reprocess the endoscope, ensure that fibers do not get caught on or remain trapped by protruding components.

*3 Following disinfection, it is very important not to recontaminate the endoscope and accessories with potentially infectious microorganisms. When rinsing and drying the endoscope and accessories following disinfection, the use of sterile equipment (basins, cloths, syringes, etc.) is recommended. If sterile equipment is not available, use clean equipment that does not recontaminate the endoscope and accessories with potentially infectious microorganisms. Consult with your hospital's infection control committee regarding local policies or requirements regarding reprocessing equipment.

*4 For the USA
Use sterilization wraps, instrument tray, and sterilization pouches that are legally marketed in the USA.

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5.3 Precleaning the endoscope

WARNING

If the endoscope and accessories used in the patient procedure are not immediately cleaned after each patient procedure, residual organic debris will begin to dry and solidify, hindering effective removal and reprocessing efficacy. Preclean the endoscope and the accessories at the bedside immediately after each patient procedure.

NOTE

Some national or professional guidelines recommend using a detergent solution for precleaning. Consult with your hospital's infection control committee regarding use of the detergent solution.

Equipment needed

Prepare the following equipment.

• **Clean lint-free cloths**	• **Clean sponges**
• **Clean 30 ml (30 cc) syringes**	• **Water (for reprocessing) (See Section 3.3, "Water (for reprocessing)")**
• **Clean 500 ml containers**	• **Small basins**

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Preparation

Immediately after the patient procedure, with the endoscope still connected to the equipment used in the patient procedure (i.e., the light source, video system center), perform the following precleaning steps at the patient bed side.

1. Turn the video system center and the light source OFF.
2. Prepare a clean 500 ml container of the water as described in Section 3.3, “Water (for reprocessing)”.

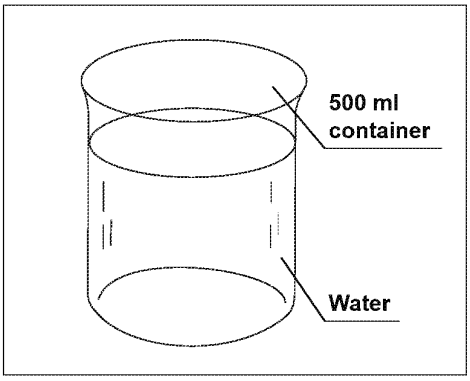

Figure 5.2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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■ *Wipe the insertion section*

CAUTION

Handle the insertion section carefully. Tightly gripping or sharply bending the insertion tube or bending section can stretch or severely damage the insertion tube and the covering of the bending section.

NOTE

If it is difficult to clean the endoscope while connecting it to the equipment, such as the light source and video system center, disconnect the endoscope from the equipment before wiping the external surface of the insertion section. For disconnecting the endoscope, refer to "■ Detach the endoscope from the video system center" and "■ Detach the endoscope from the light source" on page 36.

1. Dip clean lint-free cloths or sponges in the water.
2. With the lint-free cloths or sponges, wipe the entire insertion section of the endoscope from the boot at the control section toward the distal end.

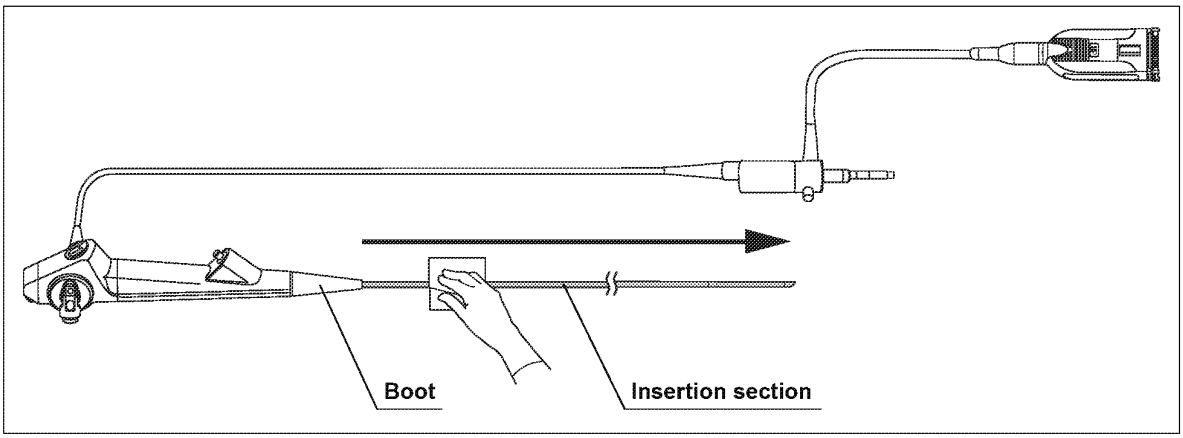

Figure 5.3

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Flush the instrument channel with water

1 Loosen the locking ring, detach a forceps/irrigation plug from the endoscope.

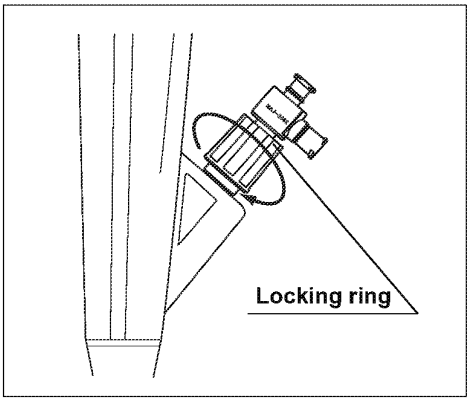

Figure 5.4

2 Fill a clean 30 ml syringe with the water.

3 Attach the syringe to the instrument channel port.

4 Flush the channel with 30 mL of the water into the small basin.

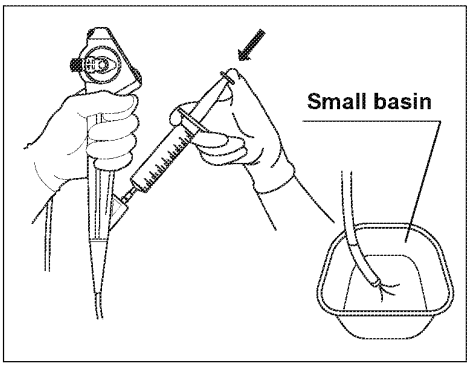

Figure 5.5

5 Detach the syringe from the endoscope.

6 Repeat Step 2 through 5 two additional times.

7 Fill a clean 30 ml syringe with air.

8 Attach the syringe to the instrument channel port.

9 Flush the channel with 30 ml of air.

10 Detach the syringe from the endoscope.

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Detach the endoscope from the video system center

Detach the video connector from the video system center while holding the video system center with a hand so that it does not move and pushing the locking lever down.

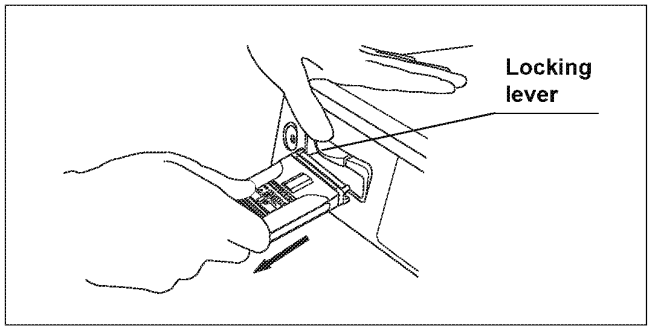

Figure 5.6

Detach the endoscope from the light source

WARNING

Do not touch the light guide of the light guide connector immediately after detaching it from the light source because it is extremely hot. Injury may result.

Detach the light guide connector of the endoscope from the output socket of the light source while holding the light source with a hand so that it does not move.

Transport the endoscope and accessories

NOTE

Refer to each instrument's instructions for reprocessing accessories.

Transport the endoscope to the reprocessing area. Use a covered container to avoid environmental contamination if required by local policy.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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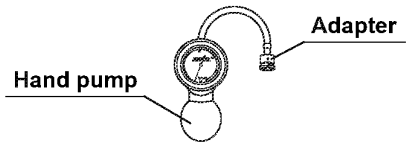
5.4 Leakage testing of the endoscope

Equipment needed

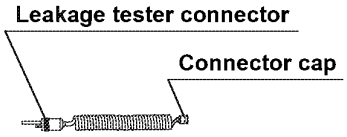
When performing a leakage test using WA23080A, prepare the following equipment.



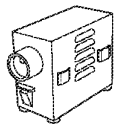
Leakage tester (WA23080A)
(Sold separately. See its instruction manual.)

- **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Water (for reprocessing) (See Section 3.3, "Water (for reprocessing)")**
- **Clean lint-free cloths**

When performing a leakage test using MB-155, prepare the following equipment.



Leakage tester (MB-155)
(Sold separately. See its instruction manual.)



Maintenance unit (MU-1)
(Sold separately. See its instruction manual.)

- **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Water (for reprocessing) (See Section 3.3, "Water (for reprocessing)")**
- **Clean lint-free cloths**

NOTE

Leakage testing can be also performed with the automated endoscope leak tester (ALT-Pro*1). Refer to the instruction manual for the automated endoscope leak tester.

*1 This product is available in the USA and some areas.

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Perform the leakage test

CAUTION

- When attaching the connector cap of the leakage tester to the venting connector of the endoscope, make sure that both the connector cap and the venting connector are thoroughly dry. Water on the surface of either component may enter the endoscope and could cause endoscope damage.
- When attaching the connector cap of the leakage tester to the venting connector of the endoscope, push on and rotate the connector cap clockwise fully until it stops. If it is not fully and properly attached, the interior of the endoscope will not be properly pressurized and accurate leakage testing will be impossible.
- Do not attach/detach the leakage tester while immersed. Attaching/detaching under water could allow the water to enter the endoscope, resulting in endoscope damage.
- If you identify a leak during leakage testing, remove the endoscope from the water with both the venting connector and the leakage tester (WA23080A or MB-155) still attached. Contact Olympus regarding instructions for reprocessing a leaking endoscope in preparation for returning the endoscope to Olympus for repair.
- Detach the leakage tester (MB-155) from the maintenance unit (MU-1) before detaching the leakage tester from the venting connector on the endoscope. If the leakage tester is detached from the venting connector before detaching the leakage tester from the maintenance unit, the air pressure inside the endoscope will not vent properly. This may damage the endoscope.

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Leakage testing with leakage tester (hand pump) (WA23080A)

CAUTION

- The leakage test pressure must not exceed 27 kPa (i.e., the pointer should remain within the “green area” on the pressure display). If the pressure increases so that the pointer moves into the red area on the display, the endoscope may be damaged. Press the pressure release lever to let the air escape.

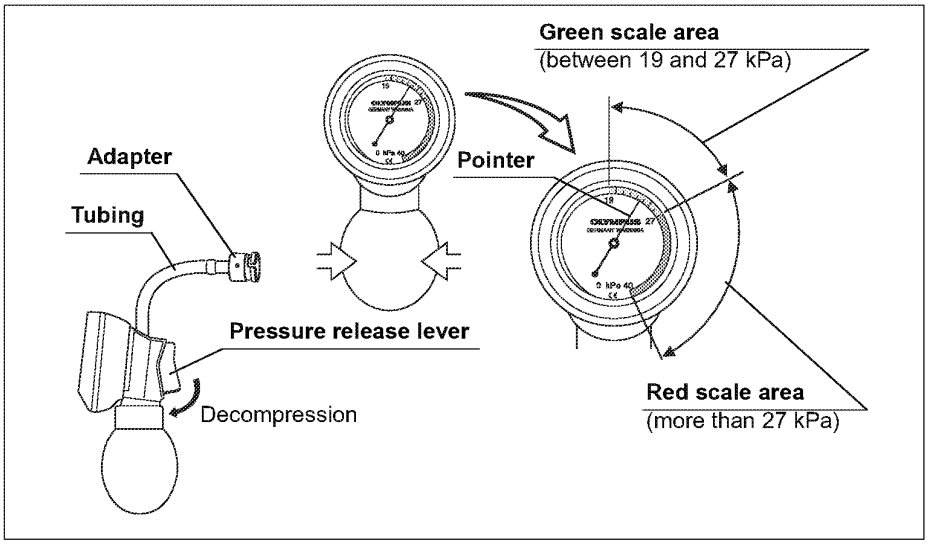

Figure 5.7

- Only the tubing and adapter of the leakage tester should be immersed. Other parts of the leakage tester could be damaged if immersed.
- Before detaching the adapter of the leakage tester from the venting connector, press the pressure release lever. Allow air to escape from the endoscope until 0 kPa is indicated on the display. Otherwise, the endoscope may be damaged.

1 Fill a clean, large basin with the water as described in Section 3.3, “Water (for reprocessing)”.

2 Confirm that both the inside of the adapter is dry. If not, dry it with clean lint-free cloths.

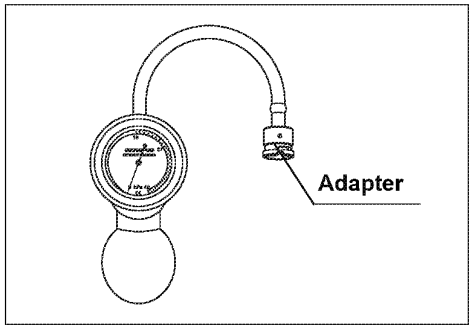

Figure 5.8

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3 Confirm that the venting connector on the endoscope's light guide connector is dry. If not, dry it by wiping with clean lint-free cloths.

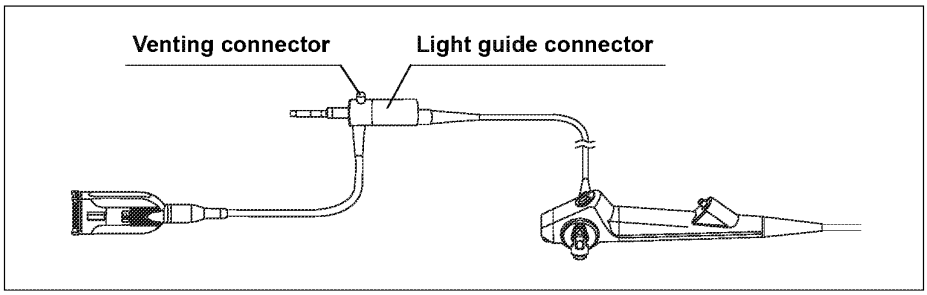

Figure 5.9

4 Attach the adapter of the leakage tester to the venting connector on the light guide connector as follows:

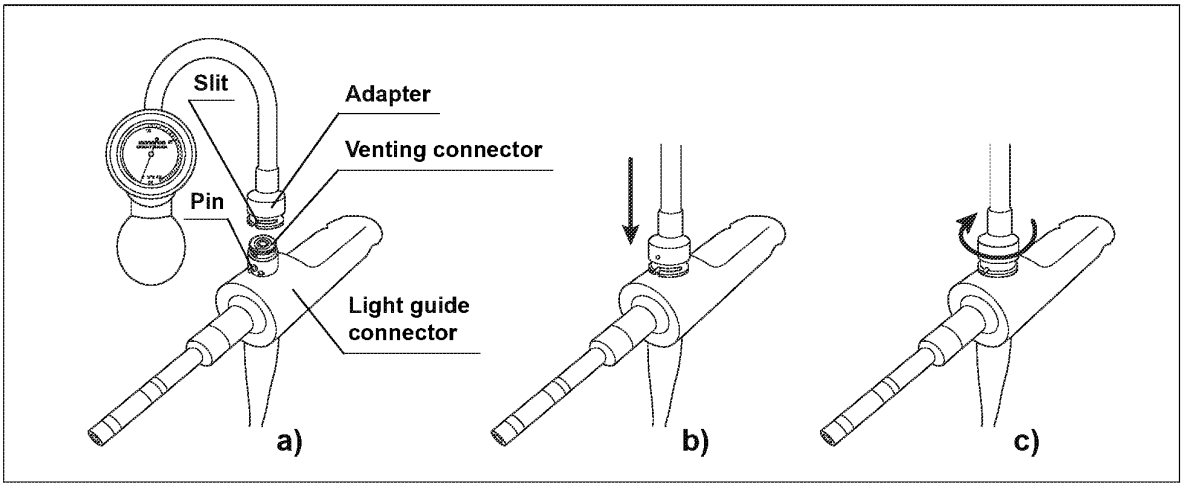

Figure 5.10

a) Align the pin on the venting connector with the slit on the adapter;
b) Push the adapter towards the light guide connector of the endoscope until it stops;
c) Rotate the adapter clockwise (approximately 90°) until it stops.

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5 Grasp the hand pump until the pointer is in the green scale area (between 19 and 27 kPa) on the pressure display.

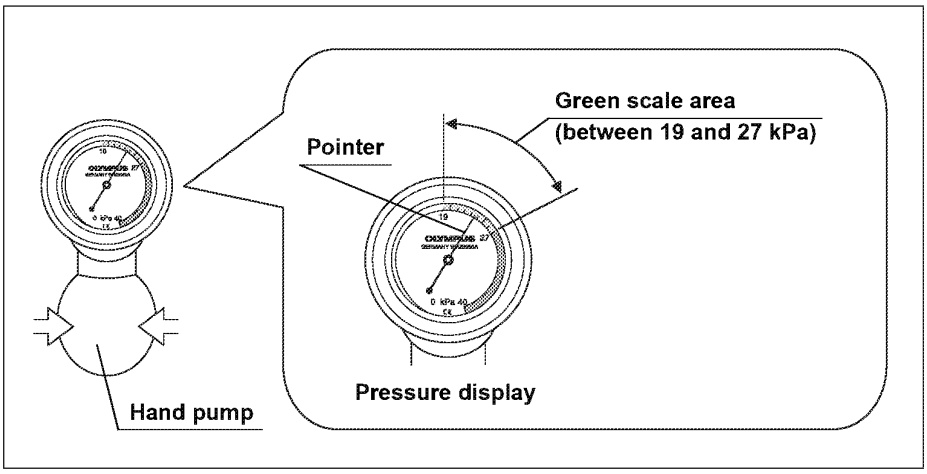

Figure 5.11

NOTE

To detect a slight water leakage, pressurize to near 27 kPa.

6 After several seconds, confirm that the pointer remains stable, and pressure is maintained.

CAUTION

If the pointer continues to fall towards 0 kPa, the endoscope might have a serious water leakage, or the leakage tester may be damaged. Stop the leakage test immediately. Water may enter the endoscope with no pressure inside if it is still immersed in water. As a result, severe damage may occur.

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7 With the leakage tester attached, completely immerse all sections of the endoscope and the adapter of the leakage tester in the water. Keep the pressure display and the hand pump of the leakage tester out of the water.

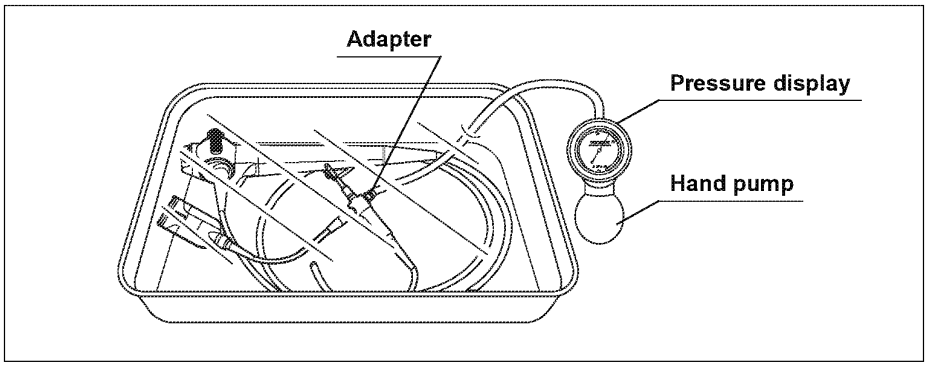

Figure 5.12

CAUTION

If continuous or intermittent air bubbles emerge from the adapter during leakage testing, the adapter might be damaged. For further details, contact Olympus.

8 While keeping all sections of the endoscope under the water for approximately 30 seconds, confirm that air bubbles do not emerge continuously or intermittently from any location on the endoscope.

9 While deflecting the bending section of the endoscope by moving the endoscope's UP/DOWN angulation control lever in the water, confirm that air bubbles do not emerge continuously or intermittently from any location on the endoscope.

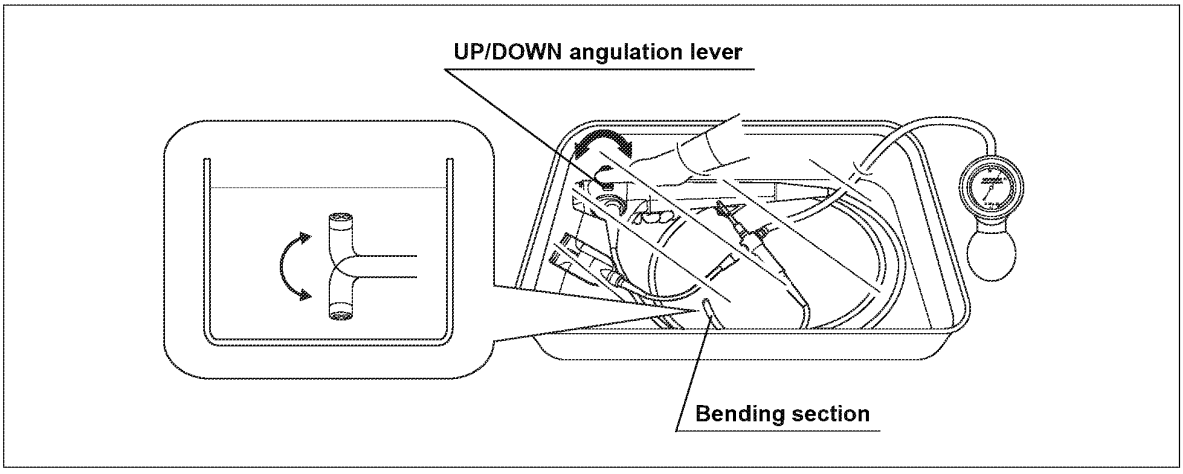

Figure 5.13

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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NOTE

- Air bubbles emerging continuously or intermittently from any location on the endoscope indicate a leak at that location. If there is a leak in the instrument channel of the endoscope, air bubbles will emerge continuously or intermittently from one or more channel openings (e.g., distal end, instrument channel port) on the immersed endoscope.

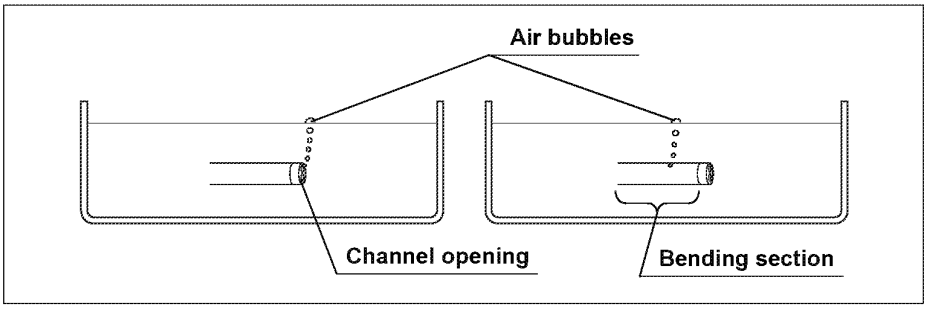

Figure 5.14

- During the leakage test, the covering of the bending section will expand as the air pressure inside the endoscope increases. This is normal.

10 Remove the endoscope attached with the leakage tester from the water.

11 Reconfirm that the pointer remains in the green scale area (between 19 and 27 kPa) on the pressure display. If not, repeat Step 5 through 11.

NOTE

If the pointer is not in the green scale area, the pressure release lever may have been pressed unintentionally.

12 Press the pressure release lever until 0 kPa is indicated on the display to let the air escape from the endoscope.

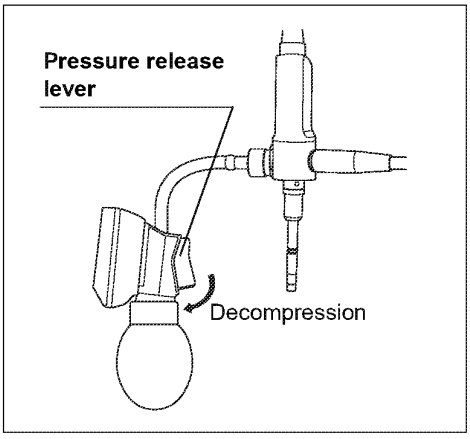

Figure 5.15

13 Detach the leakage tester from the venting connector of the endoscope by turning the adapter counterclockwise.

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14 Thoroughly dry the leakage tester using clean lint-free cloths.

Leakage testing with leakage tester (MB-155)

1 Fill a clean, large basin with the water as described in Section 3.3, “Water (for reprocessing)”.

2 Attach the leakage tester connector of the leakage tester (MB-155) to the output socket of the maintenance unit (MU-1).

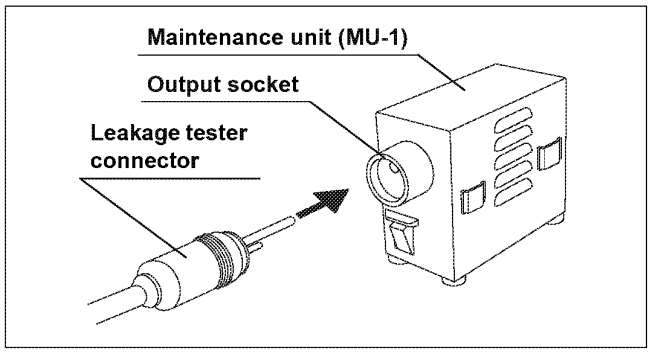

Figure 5.16

3 Turn the maintenance unit ON.

4 Depress the pin located inside the connector cap of the leakage tester and confirm that air is emitted from the connector cap with a whoosh sound.

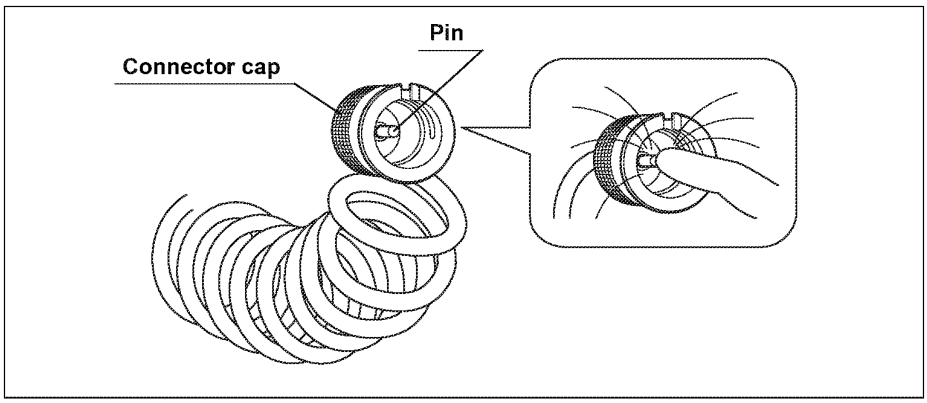

Figure 5.17

5 Confirm that the inside of the connector cap of the leakage tester is dry. If not, dry it by wiping with clean lint-free cloths.

6 Confirm that the venting connector on the endoscope’s light guide connector is dry. If not, dry it by wiping with clean lint-free cloths.

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7 Attach the connector cap of the leakage tester to the venting connector on the light guide connector as follows:

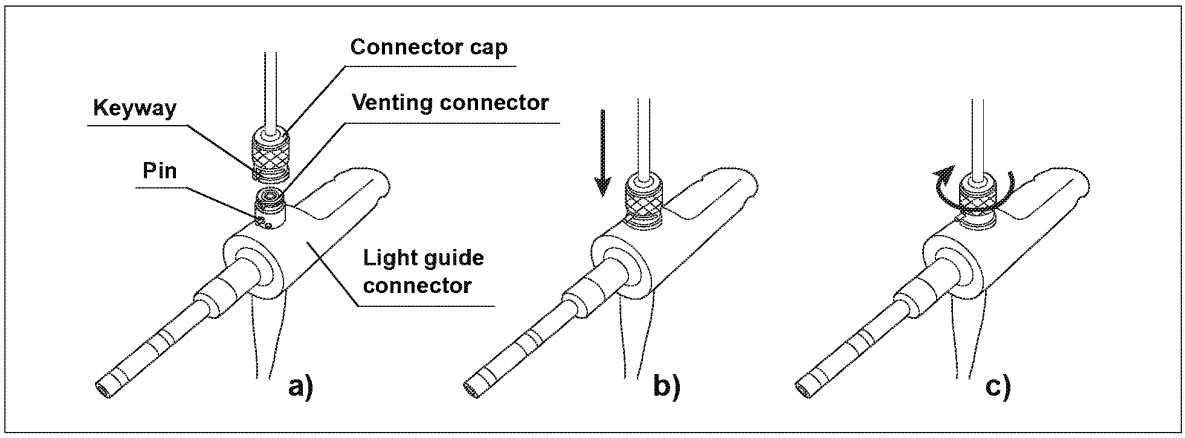

Figure 5.18

a) Align the pin on the venting connector with the keyway on the connector cap;

b) Push the connector cap towards the light guide connector of the endoscope until it stops;

c) Rotate the connector cap clockwise (approximately 90°) until it stops.

8 With the leakage tester attached, completely immerse all sections of the endoscope and the connector cap of the leakage tester in the water.

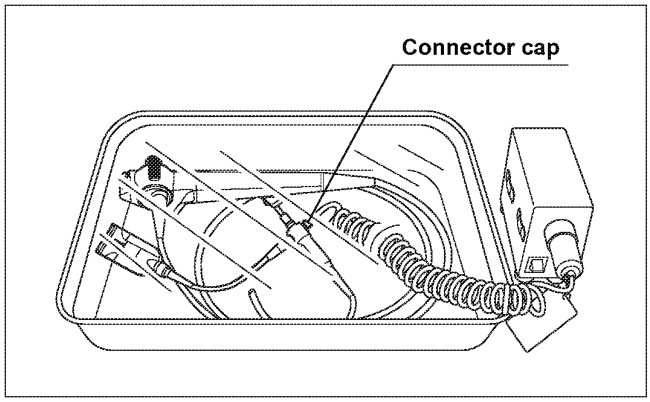

Figure 5.19

CAUTION

If continuous or intermittent air bubbles emerge from the adapter during leakage testing, the connector cap might be damaged. For further details, contact Olympus.

9 While keeping all sections of the endoscope under the water for approximately 30 seconds, confirm that air bubbles do not emerge continuously or intermittently from any location on the endoscope.

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10 While deflecting the bending section of the endoscope by moving the endoscope's UP/DOWN angulation control lever in the water, confirm that air bubbles do not emerge continuously or intermittently from any location on the endoscope.

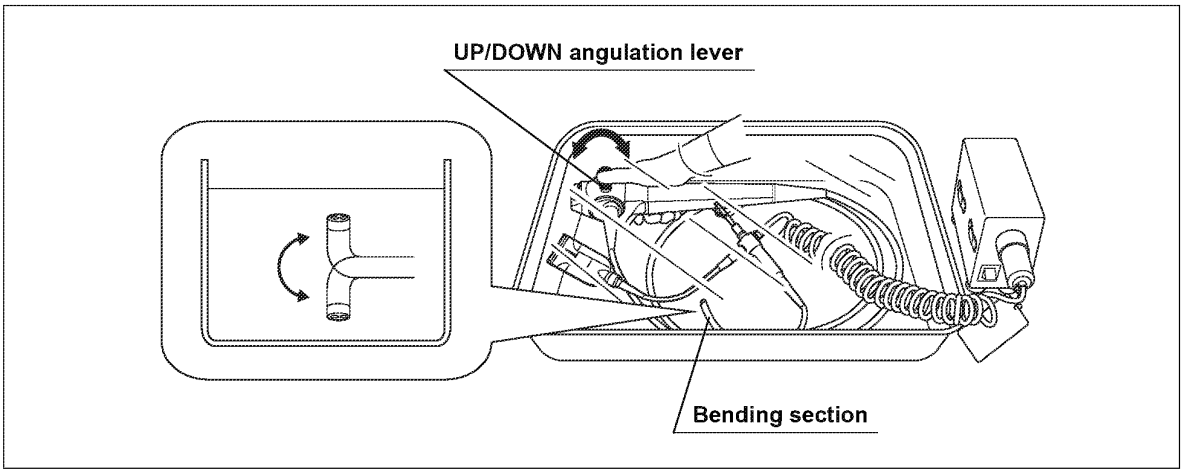

Figure 5.20

NOTE

- Air bubbles emerging continuously or intermittently from any location on the endoscope indicate a leak at that location. If there is a leak in the instrument channel of the endoscope, air bubbles will emerge continuously or intermittently from one or more channel openings (e.g., distal end, instrument channel port) on the immersed endoscope.

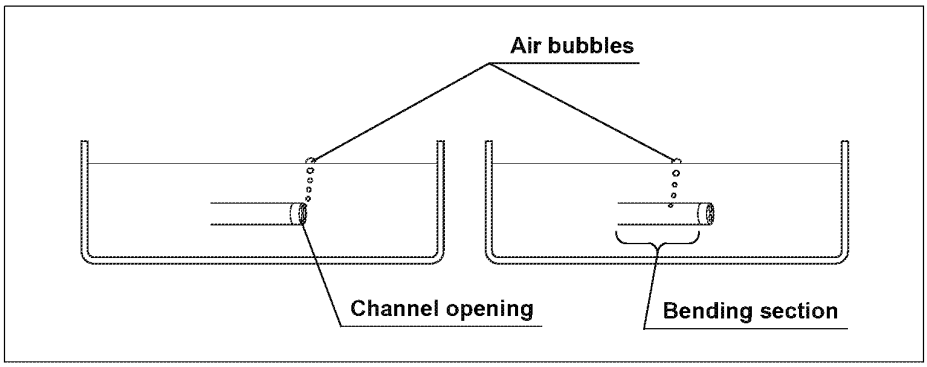

Figure 5.21

- During the leakage test, the covering of the bending section will expand as the air pressure inside the endoscope increases. This is normal.

11 Remove the endoscope attached with the leakage tester from the water.

12 Turn the maintenance unit OFF.

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13 Detach the leakage tester connector from the maintenance unit.

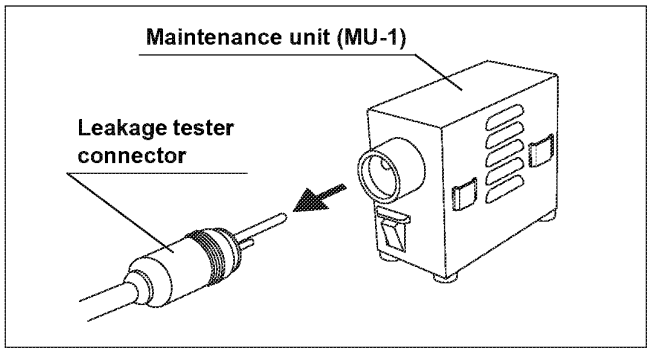

Figure 5.22

14 Wait 30 seconds or until the covering of the bending section contracts to its pre-expansion size.

15 Detach the leakage tester from the venting connector of the endoscope by turning the connector cap counterclockwise.

16 Thoroughly dry the leakage tester using clean lint-free cloths.

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5.5 Manually cleaning the endoscope

If manual cleaning could not be performed within 1 hour after the patient procedure or if you are not sure whether manual cleaning could be performed within 1 hour, presoak the endoscope in the detergent solution to loosen debris that has dried and hardened as described in Section 5.9, "Presoaking the endoscope" before manually cleaning the endoscope.

CAUTION

Handle the insertion section carefully. Tightly gripping or sharply bending the insertion tube or bending section can stretch or severely damage the insertion tube and the covering of the bending section.

Equipment needed

Prepare the following equipment.

Single use combination cleaning brush (BW-411B)

• **Clean lint-free cloths**	• **Sterile lint-free cloths**[*1]
• **Clean 30 ml (30 cc) syringes**	• **Sterile 30 ml (30 cc) syringes**[*1]
• **Clean sponges**	• **Sterile cotton swabs**[*1]
• **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**	• **Water (for reprocessing) (Refer to Section 3.3, "Water (for reprocessing)")**
• **Detergent solution (Refer to Section 3.4, "Detergent solution")**	• **70% ethyl or 70% isopropyl alcohol (Refer to Section 3.7, "Alcohol")**

*1 Following disinfection, it is very important not to recontaminate the endoscope and accessories with potentially infectious microorganisms. When rinsing and drying the endoscope and accessories following disinfection, the use of sterile equipment (basins, cloths, syringes, etc.) is recommended. If sterile equipment is not available, use clean equipment that does not recontaminate the endoscope and accessories with potentially infectious microorganisms. Consult with your hospital's infection control committee regarding local policies or requirements regarding reprocessing equipment.

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■ *Clean the external surfaces*

❍ Preparation

1 Fill a clean, large basin with the detergent solution at the temperature and concentration recommended by the detergent manufacturer.

2 Completely immerse the entire endoscope in the detergent solution.

❍ Clean the external surfaces of the video connector, the video cable, the light guide connector, and the universal cord

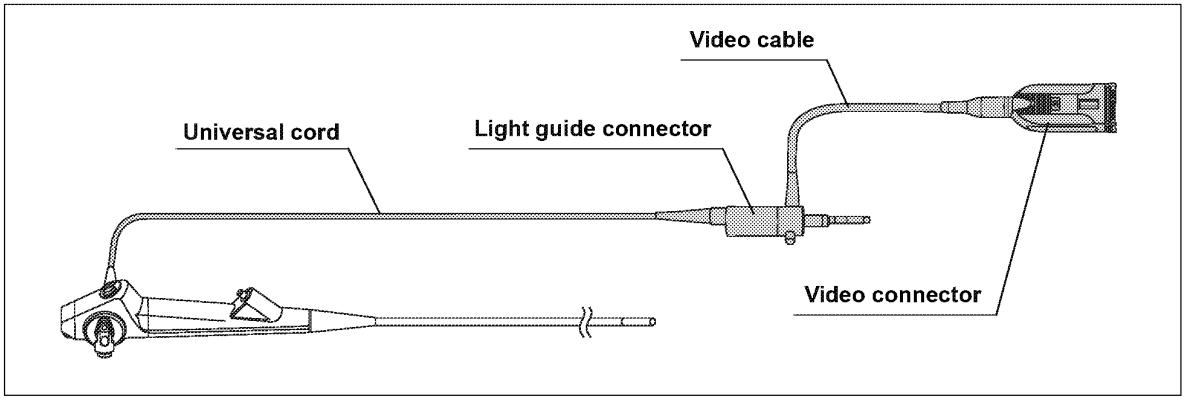

Figure 5.23

1 While immersing the entire endoscope completely in the detergent solution, thoroughly wipe or brush all external surfaces of the video connector, the video cable, the light guide connector, and the universal cord, using clean lint-free cloths, sponges or brushes.

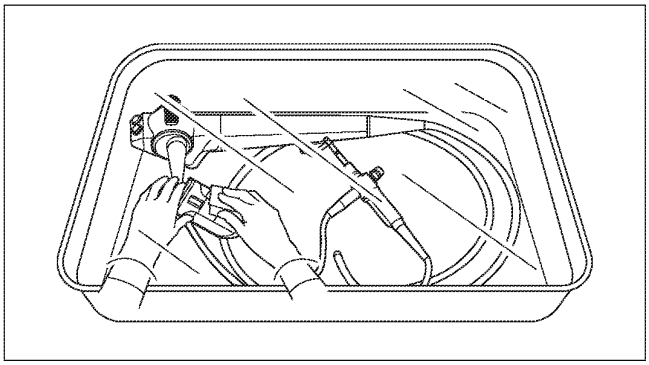

Figure 5.24

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2 Take the video connector, the video cable, the light guide connector, and the universal cord out of the detergent solution.

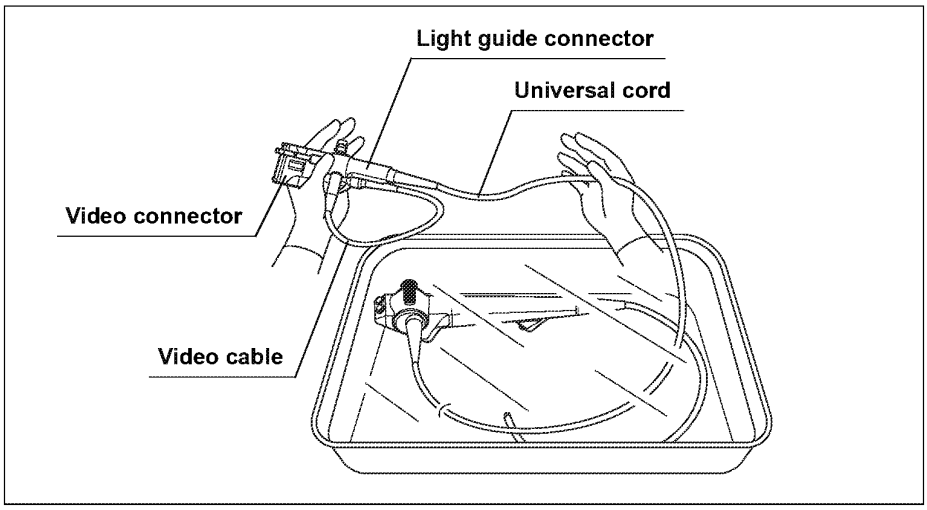

Figure 5.25

3 Confirm that no debris remains on all their external surfaces.

4 If any debris remains, repeat Step 1 through 3 until no debris is observed.

5 When all debris is removed, put back the video connector, the video cable, the light guide connector, and the universal cord in the detergent solution.

❍ Clean the external surfaces of the control section and its surrounding parts

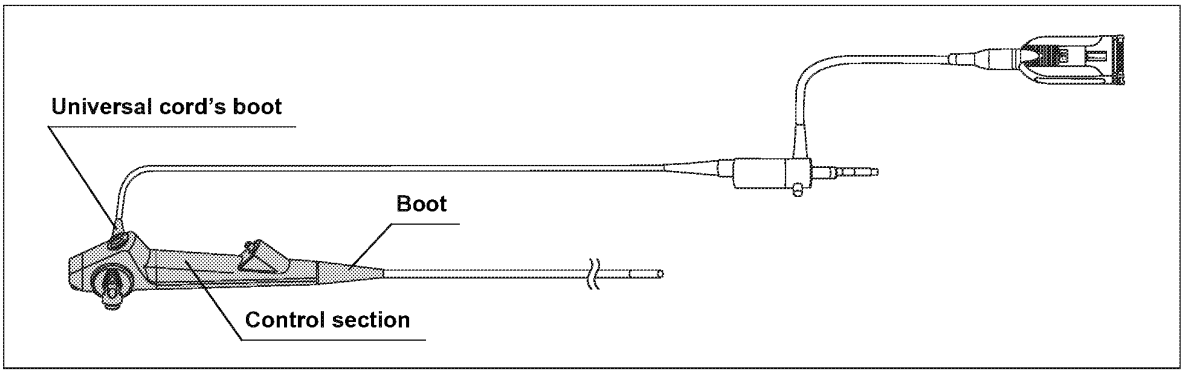

Figure 5.26

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1 While immersing the entire endoscope completely in the detergent solution, thoroughly wipe or brush all external surfaces of the universal cord's boot, the control section, and the boot, using clean lint-free cloths, sponges or brushes.

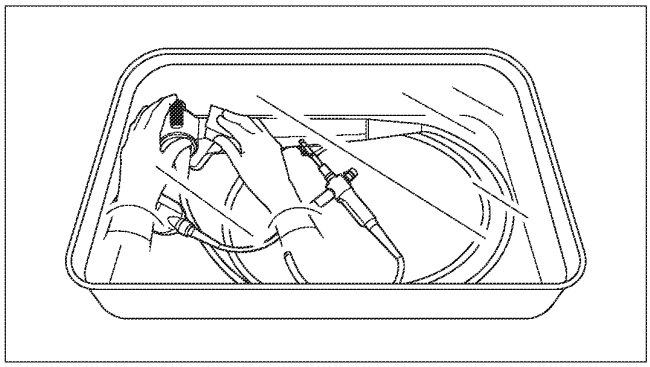

Figure 5.27

2 Take the universal cord's boot, the control section, and the boot out of the detergent solution.

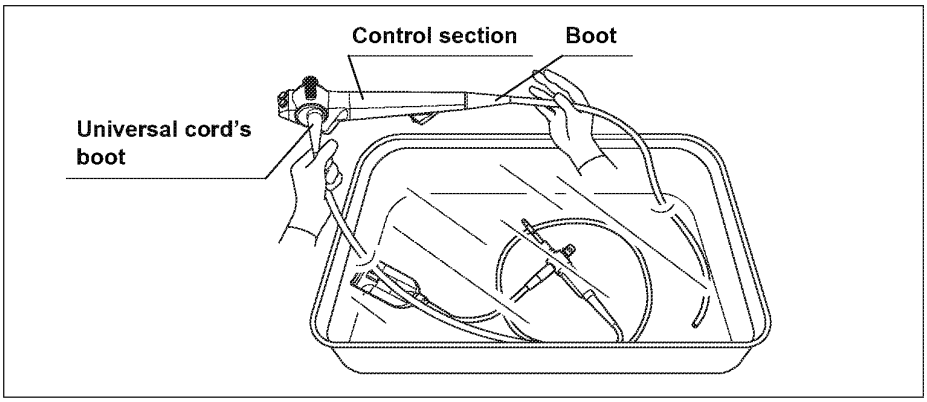

Figure 5.28

3 Confirm that no debris remains on all their external surfaces.

4 If any debris remains, repeat Step 1 through 3 until no debris is observed.

5 When all debris is removed, put back the universal cord's boot, the control section, and the boot in the detergent solution.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Clean the external surfaces of the insertion section

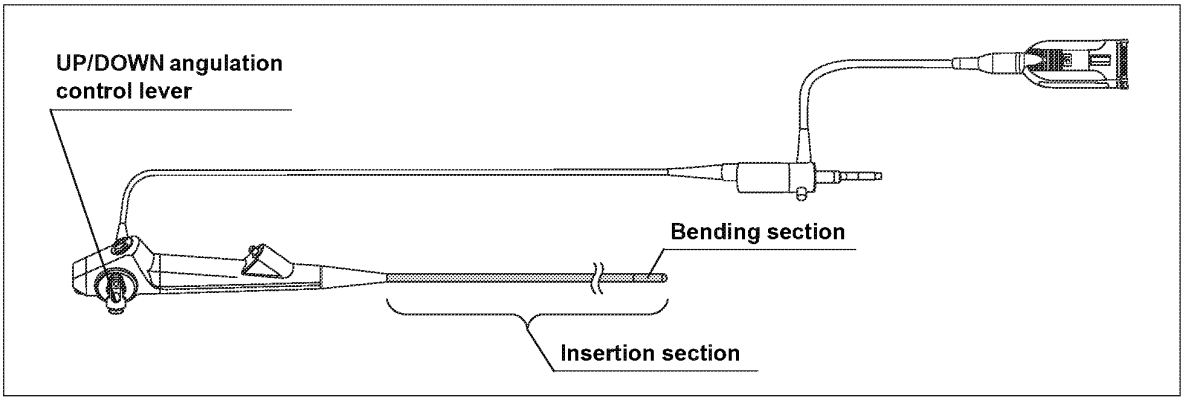

Figure 5.29

1. Straighten the bending section by use of endoscope's UP/DOWN angulation control lever.
2. While immersing the entire endoscope completely in the detergent solution, thoroughly wipe or brush all external surfaces of the insertion section, using clean lint-free cloths, sponges or brushes.

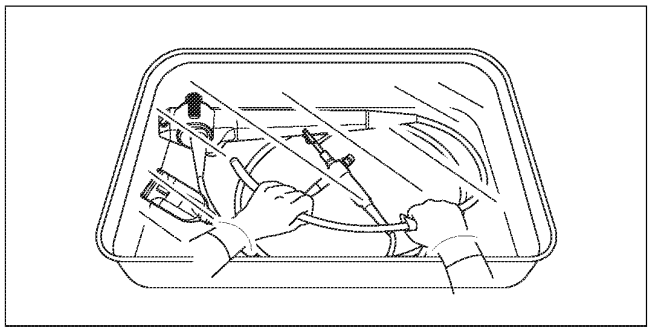

Figure 5.30

3. Take the insertion section out of the detergent solution.

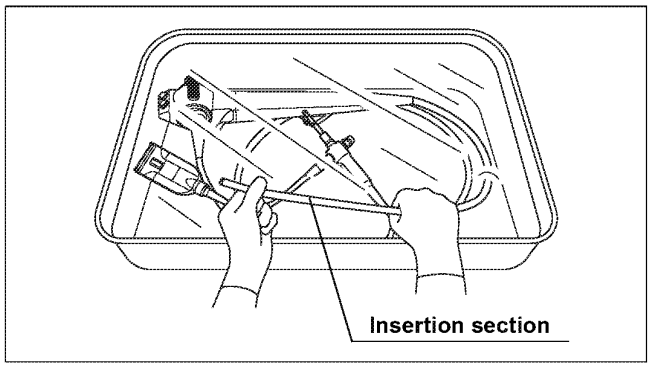

Figure 5.31

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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4 Confirm that no debris remains on all its external surfaces, particularly the objective lens on the distal end.

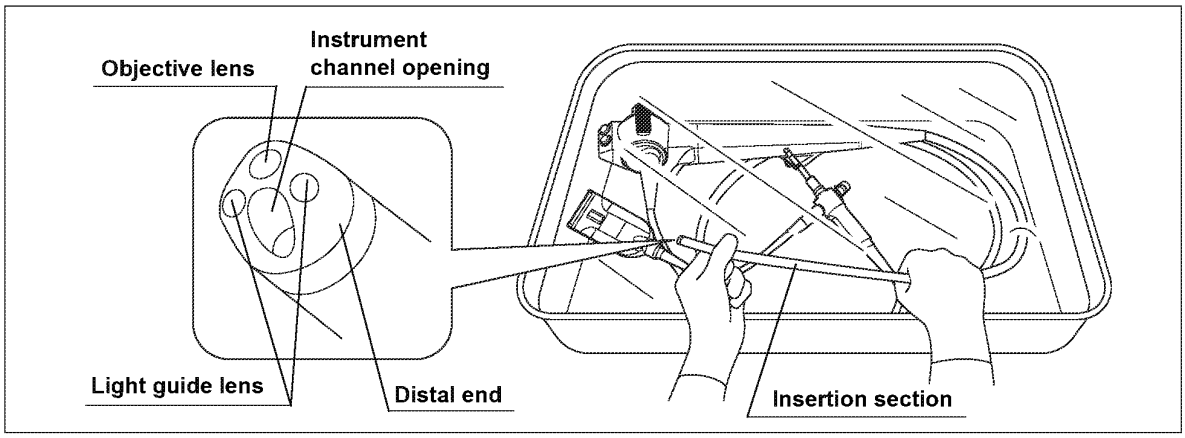

Figure 5.32

5 If any debris remains, repeat Step 2 through 4 until no debris is observed.

6 When all debris is removed, put back the insertion section in the detergent solution.

■ *Brush the channel*

WARNING

- Be sure to thoroughly brush the inside of the instrument channel, the instrument channel junction and the instrument channel port of the endoscope. Insufficient brushing may pose an infection control risk.

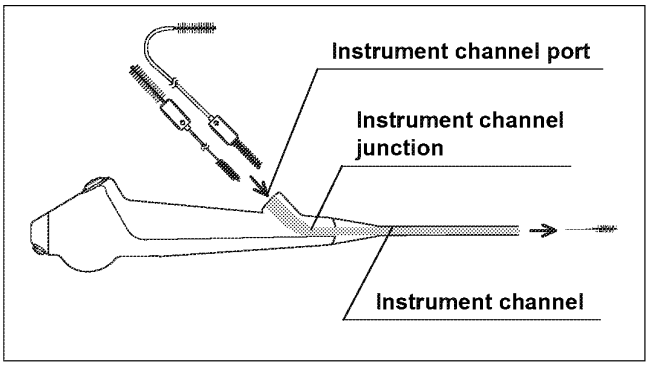

Figure 5.33

- To avoid splashing the detergent solution when the brush is pulled out from the endoscope, keep the endoscope completely immersed in the detergent solution.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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WARNING

- The single use combination cleaning brush (BW-411B) are for single use. Repeated usage of the brush may cause the brush head to become bent or kinked, which could cause it to come off during use. Before and after use, confirm that the brush is free from any damage or other irregularities. If a piece of the brush comes off inside the endoscope channel, immediately retrieve it. Confirm that no parts remain inside the instrument channel of the endoscope by carefully passing a new brush through the channel. Any part left in the channel can drop into the patient during a subsequent patient procedure. Depending on the location of the missing part, the part may not be retrievable by passing a new brush. In this case, contact Olympus.

CAUTION

- Do not attempt to pass the single use combination cleaning brush backwards – i.e. by inserting the brush directly into the instrument channel outlet at the distal end of the endoscope's insertion section. It may get caught, making retrieval impossible.

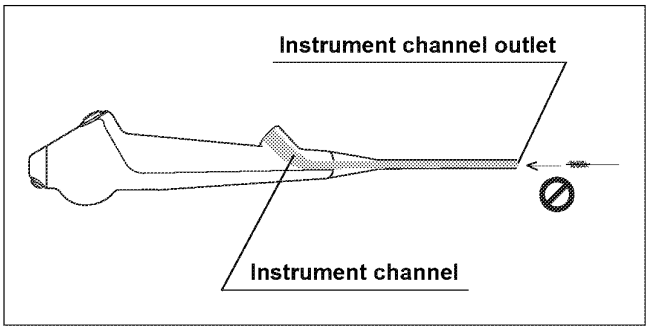

Figure 5.34

- Do not coil the insertion section of the endoscope with a diameter of less than 40 cm. If the diameter is less than 40 cm, it may be difficult to pass the brush completely through the channel.

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Brush the instrument channel

1 Straighten the bending section by use of endoscope's UP/DOWN angulation control lever.

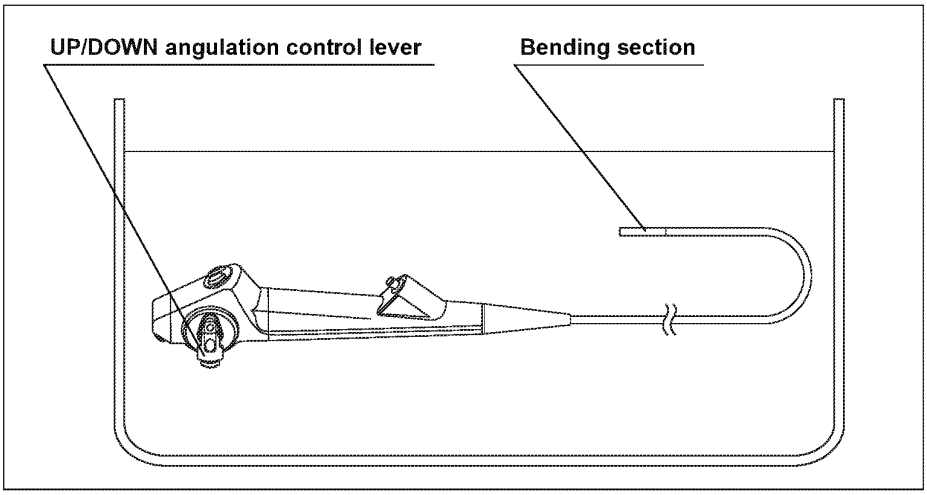

Figure 5.35

2 Grip the shaft of the single use combination cleaning brush (BW-411B) at a point 3 cm from the bristles of the channel cleaning brush part.

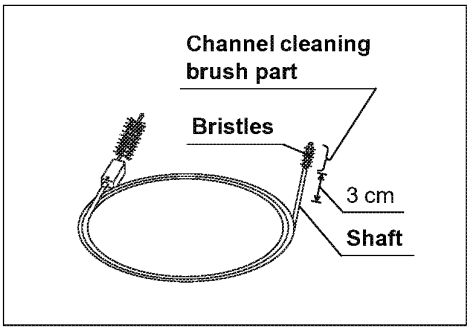

Figure 5.36

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3 While immersing the entire endoscope completely in the detergent solution, insert the brush straight into the opening of the instrument channel port. Using short strokes, feed the brush through the instrument channel until it emerges from the distal end of the endoscope.

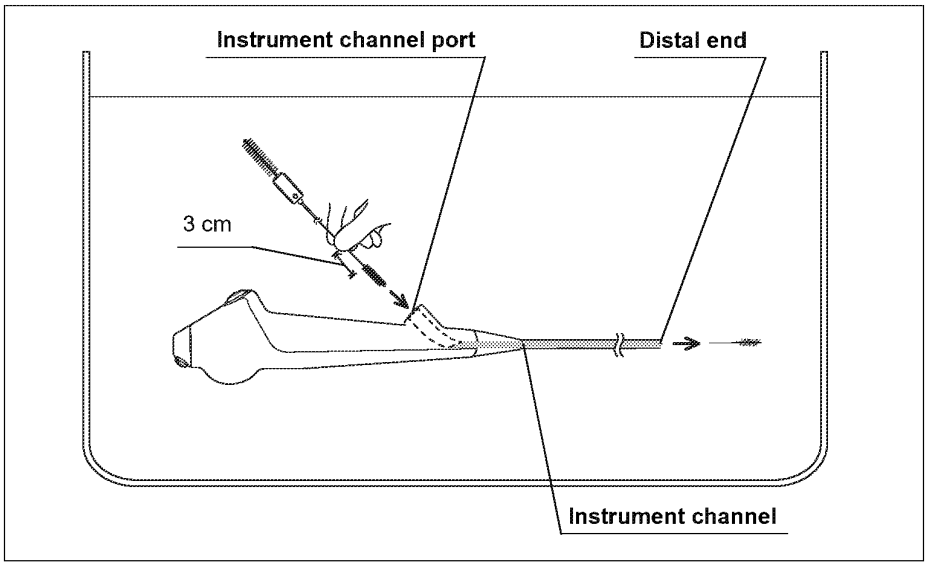

Figure 5.37

4 Inspect whether there is debris on the bristles when the brush emerges from the distal end of the endoscope.

5 Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.

6 While immersing the entire endoscope completely in the detergent solution, carefully pull the brush through the instrument channel and out of the instrument channel port.

7 Inspect whether there is debris on the bristles when the brush emerges from the instrument channel port.

8 Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.

9 Repeat Step 2 through 8 two additional times.

10 If any debris remains, repeat Step 2 through 8 until no debris is observed upon inspection of the brush.

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Brush the instrument channel port

1 Grip the handle of the single use combination cleaning brush (BW-411B).

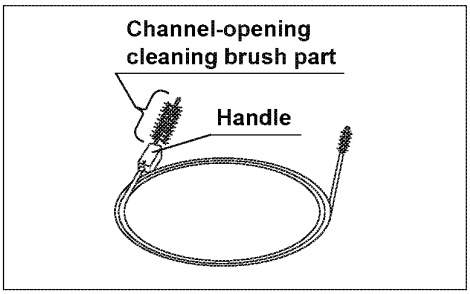

Figure 5.38

2 While immersing the entire endoscope completely in the detergent solution, insert the channel-opening cleaning brush part of the single use combination cleaning brush into the instrument channel port until the brush handle touches the channel opening.

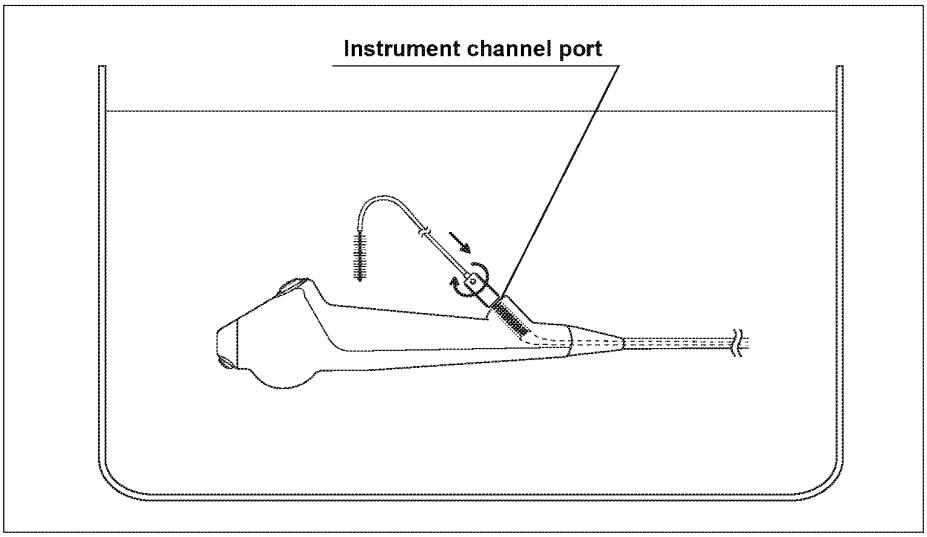

Figure 5.39

3 While immersing the entire endoscope completely in the detergent solution, rotate the inserted brush one full revolution.

4 While immersing the entire endoscope completely in the detergent solution, pull the brush out of the instrument channel port.

5 Inspect whether there is debris on the bristles when the brush emerges from the instrument channel port.

6 Clean the bristles in the detergent solution using your gloved fingertips to remove any debris.

7 Repeat Step 1 through 6 two additional times.

8 If any debris remains, repeat Step 1 through 6 until no debris is observed upon inspection of the brush.

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9 Dispose of the single use combination cleaning brush as described in Section 7.4, “Disposal”.

Flush the instrument channel with detergent solution

1 Completely immerse the entire endoscope in the detergent solution.

2 Fill a clean 30 ml syringe with the detergent solution.

3 While immersing the entire endoscope completely in the detergent solution, attach the syringe to the instrument channel port.

4 While immersing the entire endoscope completely in the detergent solution, flush the channel with 30 ml of the detergent solution.

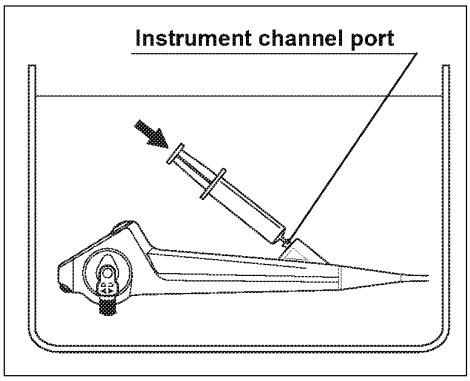

Figure 5.40

5 While immersing the entire endoscope completely in the detergent solution, detach the syringe from the endoscope.

6 Repeat Step 2 through 5 two additional times.

Immerse the endoscope in detergent solution

1 While immersing the entire endoscope completely in the detergent solution, wipe or brush all external surfaces of the endoscope to remove debris, using clean lint-free cloths, sponges or brushes.

2 Leave the endoscope completely immersed in the detergent solution during the recommended contact time according to the instructions of the detergent manufacturer.

3 Remove the endoscope from the detergent solution.

4 Place the endoscope in a clean, large basin.

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Remove detergent solution from the channel

1. Fill a clean, large basin with the water as described in Section 3.3, “Water (for reprocessing)”.
2. Completely immerse the entire endoscope in the water.
3. Gently sway the endoscope to thoroughly rinse it.
4. Fill a clean 30 ml syringe with the water.
5. Attach the syringe to the instrument channel port.
6. Flush the channel with 30 ml of the water.
7. Detach the syringe from the endoscope.
8. Repeat Step 4 through 7 two additional times.
9. Remove the endoscope from the water.
10. Place the endoscope in a clean, large basin.
11. Fill a clean 30 ml syringe with air.
12. Attach the syringe to the instrument channel port.
13. Cover the distal end of the endoscope with clean lint-free cloths to prevent splashing from the channel opening.

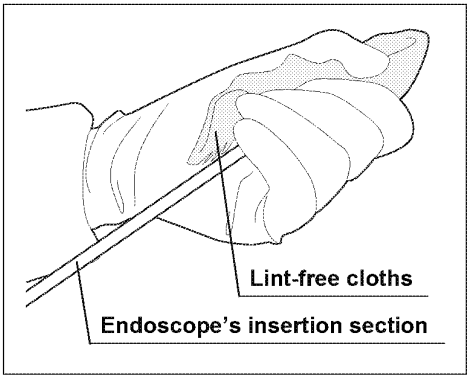

Figure 5.41

14. Flush the channel with 30 ml of air.
15. Detach the syringe from the endoscope.
16. Repeat Step 11 through 15 two additional times.
17. Remove the cloths from the endoscope.

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(Optional) Alcohol flush

WARNING

To reduce the risk of residual alcohol by contacting patient's mucosa and by electrosurgical procedures, remove residual alcohol from the endoscope channel by inspecting the irrigation function before each patient procedure, according to the procedures described in the operation manual of the endoscope.

If the endoscope is disinfected (with manually) after cleaning, this step may be skipped.

1. Fill a sterile 30 ml syringe with the alcohol as described in Section 3.7, "Alcohol".
2. Attach the syringe to the instrument channel port.
3. Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing alcohol from the channel opening.

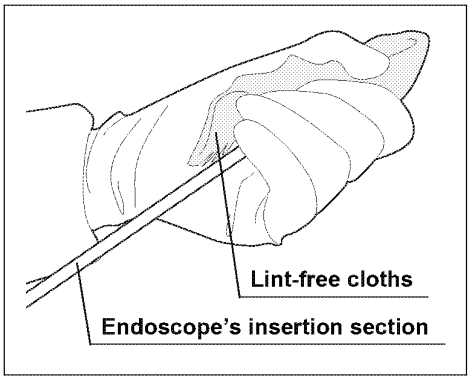

Figure 5.42

4. Flush the channel with 30 ml of the alcohol.
5. Detach the syringe from the endoscope.
6. Remove the cloths from the endoscope.
7. Fill a sterile 30 ml syringe with air.
8. Attach the syringe to the instrument channel port.
9. Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing alcohol from the channel opening.
10. Flush the channel with 30 ml of air to expel all alcohol.
11. Detach the syringe from the endoscope.
12. Remove the cloths from the endoscope.

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Dry the endoscope

If the endoscope is disinfected (with manually) after cleaning, this step may be skipped.

NOTE

Some national or professional guidelines recommend drying endoscope channel with compressed filtered air.

When using a syringe

1 Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing from the channel opening.

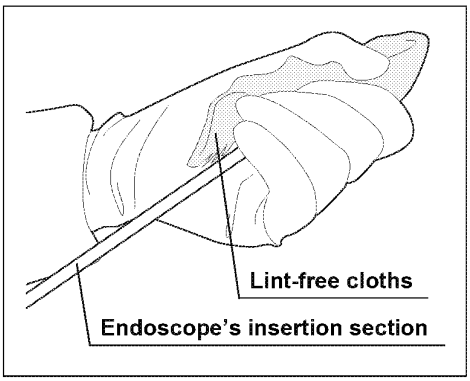

Figure 5.43

2 Fill a sterile 30 ml syringe with air.

3 Attach the syringe to the instrument channel port.

4 Flush 30 ml of the air to the channel.

5 Detach the syringe from the instrument channel port.

6 Repeat Step 2 through 5 two additional times.

7 Confirm that no water or alcohol exits from the channel opening.

8 If water or alcohol still exit, repeat Step 2 through 5 until no water or alcohol exits from the channel opening.

9 Remove the cloths from the endoscope.

10 Thoroughly dry the inside of the instrument channel port of the endoscope, using sterile cotton swabs.

11 Thoroughly dry the external surfaces of the endoscope by wiping with sterile lint-free cloths.

12 Inspect all items for residual debris. If any debris remains, return to the beginning of Section 5.5, "Manually cleaning the endoscope" and repeat the entire cleaning procedure until all debris is removed.

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When using copmressed air

CAUTION

When aerating the endoscope channels, the air pressure should be set 0.2 MPa or more but less than 0.3 MPa (≥2 and <3 kgf/cm^2, ≥29 and <43 psig). High pressure may cause damage to the endoscope.

1 Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing from the channel opening.

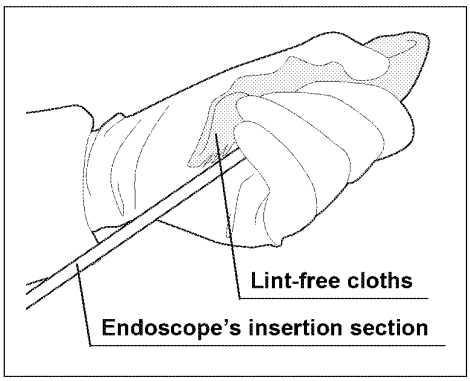

Figure 5.44

2 Feed instrument channel port with compressed filtered air of 0.2 – 0.3 MPa for 30 seconds.

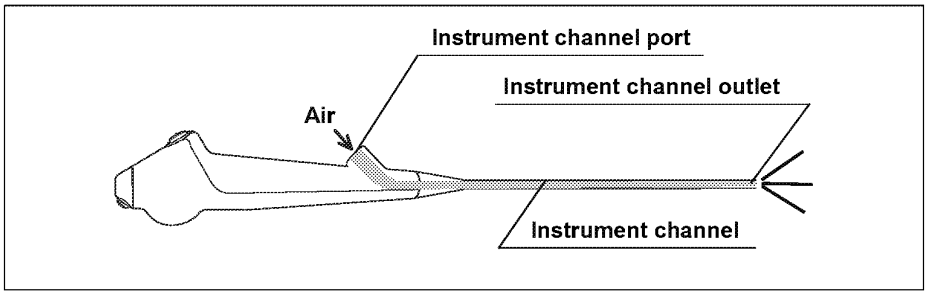

Figure 5.45

3 With new sterile lint-free cloths, cover the distal end of the endoscope to prevent splashing from the channel opening.

4 Feed compressed filtered air again and confirm that no water or alcohol exits from the channel opening.

5 If water or alcohol still exits, repeat Step 2 through 4 until no water or alcohol exits from the channel opening.

6 Remove the cloths from the endoscope.

7 Thoroughly dry the external surfaces of the endoscope by wiping with sterile lint-free cloths.

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8 Thoroughly dry the inside of the instrument channel port of the endoscope, using sterile cotton swabs.

9 Inspect all items for residual debris. If any debris remains, return to the beginning of Section 5.5, “Manually cleaning the endoscope” and repeat the entire procedure until all debris is removed.

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5.6 Manually disinfecting the endoscope

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization. Refer to Section 5.8, “Sterilizing the endoscope”.

NOTE

Sterilization can be selected for the endoscope as a preferable reprocessing method instead of high-level disinfection if sterilization is recommended based on decision by medical professionals.

Use sterile equipment, such as sterile syringes and cloths, for all reprocessing steps occurring after immersion of the endoscope in disinfectant solution.

Equipment needed

Prepare the following equipment.

- **Clean lint-free cloths**
- **Clean 30 ml (30 cc)syringes**
- **Clean, large basins with tight-fitting lids (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Disinfectant solution (Refer to Section 3.5, “Disinfectant solution”)**
- **Sterile lint-free cloths**[*1]
- **Sterile 30 ml (30 cc)syringes**[*1]
- **Sterile, large basins**[*1] **(size: 40 (W) × 40 (H) × 25 (D) cm or more)**

*1 Following disinfection, it is very important not to recontaminate the endoscope and accessories with potentially infectious microorganisms. When rinsing and drying the endoscope and accessories following disinfection, the use of sterile equipment (basins, cloths, syringes, etc.) is recommended. If sterile equipment is not available, use clean equipment that does not recontaminate the endoscope and accessories with potentially infectious microorganisms. Consult with your hospital’s infection control committee regarding local policies or requirements regarding reprocessing equipment.

Preparation

Fill a clean, large basin with the disinfectant solution. Check the concentration of the disinfectant solution according to the manufacturer’s instructions to verify that the concentration is above the recommended minimum.

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Flush the channel with disinfectant solution

WARNING

Make sure that the disinfectant solution contacts all internal channel surfaces of the endoscope by completely removing all air bubbles from the channel. Air bubbles may inhibit disinfection of the channel's surfaces. When filling the channel with the disinfectant solution, flush until no more air bubbles exit from the channel opening.

CAUTION

Do not immerse the endoscope in the disinfectant solution for a longer contact time, at a higher temperature, or at a greater concentration than recommended by the disinfectant manufacturer. Such immersion may cause damage to the endoscope.

NOTE

Removal of air bubbles can be facilitated by forcefully flushing the disinfectant solution through the channel.

1. Completely immerse the entire endoscope in the disinfectant solution.
2. Fill a clean 30 ml syringe with the disinfectant solution.
3. While immersing the entire endoscope completely in the disinfectant solution, attach the syringe to the instrument channel port.
4. While immersing the entire endoscope completely in the disinfectant solution, flush the instrument channel with 30 ml of the disinfectant solution.

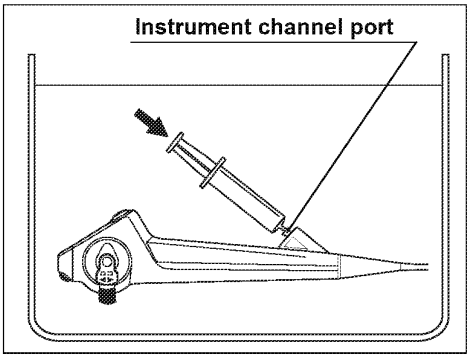

Figure 5.46

5. While immersing the entire endoscope completely in the disinfectant solution, detach the syringe from the endoscope.
6. Repeat Step 2 through 5 two additional times.
7. Confirm that no air bubbles exit the distal end of the endoscope during the flush.
8. If air bubbles still exit during the flush, repeat Step 2 through 5 until no air bubbles exit.

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Immerse the endoscope in disinfectant solution

WARNING

- During disinfection, keep the syringe detached from the endoscope. If the syringe remains attached to the endoscope during disinfection, the disinfectant solution cannot adequately contact the mated surfaces between the endoscope and the syringe.
- In addition, completely immerse the endoscope below the surface of the disinfectant solution so that all external surfaces of the endoscope contact the disinfectant solution. If the endoscope is not completely immersed, any protruding sections of this device will not be adequately disinfected.

CAUTION

Do not immerse the endoscope in the disinfectant solution for a longer contact time, at a higher temperature, or at a greater concentration than recommended by the disinfectant manufacturer. Such immersion may cause damage to the endoscope.

1. Confirm that the entire endoscope is completely immersed in the disinfectant solution.
2. Immerse clean lint-free cloths and then wring them out by hand until all trapped air bubbles are expelled in the disinfectant solution.
3. While completely immersing the entire endoscope in the disinfectant solution, wipe all external surfaces of the endoscope to remove air bubbles, using clean lint-free cloths.
4. While completely immersing the entire endoscope in the disinfectant solution, confirm that there are no air bubbles on all external surfaces of the endoscope.
5. If air bubbles adhere to the surfaces of the endoscope, wipe them away using your gloved fingertips or clean lint-free cloths.
6. Cover the basin of the disinfectant solution with a tight-fitting lid to minimize the diffusion of disinfectant vapors.
7. Leave the endoscope immersed in the disinfectant solution according to the instructions of the disinfectant manufacturer. Confirm the recommended contact time, temperature, and concentration. Use a clock or timer to accurately measure the disinfection contact time.
8. Remove the endoscope from the disinfectant solution.
9. Place the endoscope in a sterile, large basin.

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Remove disinfectant solution from the channel

1. Fill a sterile 30 ml syringe with air.
2. Attach the syringe to the instrument channel port.
3. Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing from the channel opening.

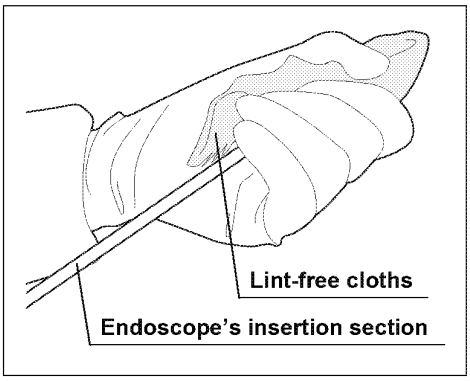

Figure 5.47

4. Flush the channel with 30 ml of air.
5. Detach the syringe from the endoscope.
6. Repeat Step 1 through 5 two additional times.
7. Remove the cloths from the endoscope.

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5.7 Rinsing the endoscope following disinfection

This instruction manual describes procedures for rinsing the endoscope and flushing it with alcohol following disinfection.

WARNING

After rinsing, thoroughly dry the instrument channel of the endoscope. Otherwise, bacteria may proliferate in the instrument channel and pose an infection control risk.

CAUTION

Carefully dry the electrical contacts of the video connector after performing the procedure described in this section. Otherwise, equipment damage can result.

NOTE

Olympus recommends using sterile water, fresh potable water or water that has been processed (e.g., filtered, deionized, or purified) to improve its chemical and/or microbiological quality. Some national or professional guideline recommend using sterile water for rinsing endoscopes, accessories, and medical instruments. Consult with your institution's infection control committee regarding local policies on water quality.

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Equipment needed

Prepare the following equipment.

• **Sterile lint-free cloths**[*1]	• **Sterile cotton swabs**[*1]
• **Sterile 30 ml (30 cc) syringes**[*1]	• **Sterile, large basins**[*1] **(size: 40 (W) × 40 (H) × 25 (D) cm or more)**
• **Rinse water (See Section 3.6, "Rinse water")**	• **70% ethyl or 70% isopropyl alcohol (See Section 3.7, "Alcohol")**

*1 Following disinfection, it is very important not to recontaminate the endoscope and accessories with potentially infectious microorganisms. When rinsing and drying the endoscope and accessories following disinfection, the use of sterile equipment (e.g., basins, cloths, syringes, etc.) is recommended. If sterile equipment is not available, use clean equipment that does not recontaminate the endoscope and accessories with potentially infectious microorganisms. Consult with your hospital's infection control committee regarding local policies or requirements regarding reprocessing equipment.

Rinse the endoscope

Use appropriate rinse water as instructed in Section 3.6, "Rinse water".

1. Fill a sterile, large basin with the rinse water as described in Section 3.6, "Rinse water".
2. Completely immerse the entire endoscope in the rinse water.
3. While immersing the entire endoscope completely in the rinse water, wipe all external surfaces of the endoscope, using sterile lint-free cloths.
4. Fill a sterile 30 ml syringe with the rinse water.
5. While immersing the entire endoscope completely in the rinse water, attach the syringe to the instrument channel port.
6. While immersing the entire endoscope completely in the rinse water, flush the channel with 30 ml of the rinse water.
7. While immersing the entire endoscope completely in the rinse water, detach the syringe from the endoscope.
8. Repeat Step 4 through 7 two additional times.
9. Remove the endoscope from the rinse water and place them in a sterile basin.
10. Fill a sterile 30 ml syringe with air.
11. Attach the syringe to the instrument channel port.
12. Cover the distal end of the endoscope with sterile lint-free cloths to prevent splashing from the channel opening.

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13 Flush the channel with 30 ml of air.

14 Detach the syringe from the endoscope.

15 Repeat Step 10 through 14 two additional times.

16 Remove the cloths from the endoscope.

17 Repeat Step 1 through 16 above for the necessary number of times described in the disinfectant manufacturer's instruction.

■ (Optional) Alcohol flush

Refer to "■ (Optional) Alcohol flush" on page 60 as the procedure is same.

■ Dry the endoscope

Refer to "■ Dry the endoscope" on page 61 as the procedure is same.

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5.8 Sterilizing the endoscope

WARNING

For nephroscopy procedures, cystoscope should be cleaned followed by sterilization.

Equipment needed

Prepare the following equipment.

Sterilization cap (MAJ-1538)	Sterilization tray (WA05991A) (Sold separately. See its instruction manual.)
• **Sterilization wraps**[*1]	• **Sterilization pouches**[*1]
• **Instrument tray**[*1]	• **Sterile lint-free cloths**

*1 For the USA
Use sterilization wraps, instrument tray, and sterilization pouches that are legally marketed in the USA.

Ethylene oxide gas sterilization of the endoscope

WARNING

- Thoroughly dry the endoscope and accessories before sterilization.
- All instruments must be properly aerated following ethylene oxide gas sterilization to remove toxic ethylene oxide residuals.
- All accessories must be removed from the endoscope prior to sterilization (except the sterilization cap (MAJ-1538)).
- Only use the sterilization tray (WA05991A). When using other sterilization trays, the endoscope may impair effective sterilizing and/or the endoscope may be damaged.
- Use only ethylene oxide gas sterilization compatible sterilization wraps and sterilization pouches.

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CAUTION

- Exceeding the recommended sterilization parameters may cause damage to the endoscope and accessories.
- Attach the sterilization cap to the venting connector on the light guide connector prior to ethylene oxide gas sterilization. If the sterilization cap is not attached to the venting connector during the ethylene oxide gas sterilization, the air inside the endoscope will expand and could rupture the bending section cover and/or damage the angulation mechanism.

1 Confirm that all external surfaces of the endoscope are thoroughly dry. If not, dry them as described in "■ Dry the endoscope" on page 61.

2 Dry the external surfaces of the sterilization cap by wiping with sterile lint-free cloths.

3 Attach the sterilization cap to the venting connector on the light guide connector as follows:

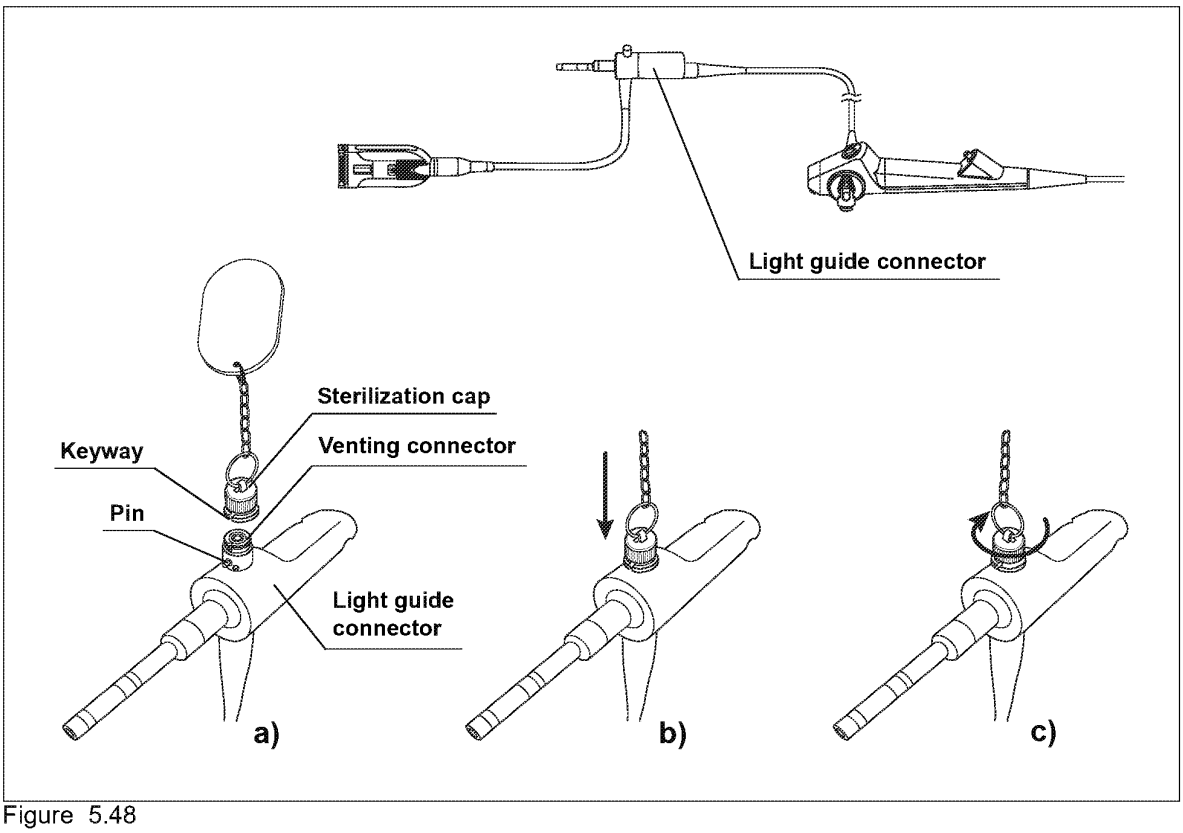

Figure 5.48

a) Align the pin on the venting connector with the keyway on the sterilization cap;

b) Push the sterilization cap towards the light guide connector of the endoscope until it stops;

c) Rotate the sterilization cap clockwise (approximately 90°) until it stops.

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4 Place the endoscope on the sterilization tray as follows (a through m);

a) Open the lid of the sterilization tray according to the instruction manual for the sterilization tray.

b) Place the control section of the endoscope on the No.1 area of the sterilization tray.

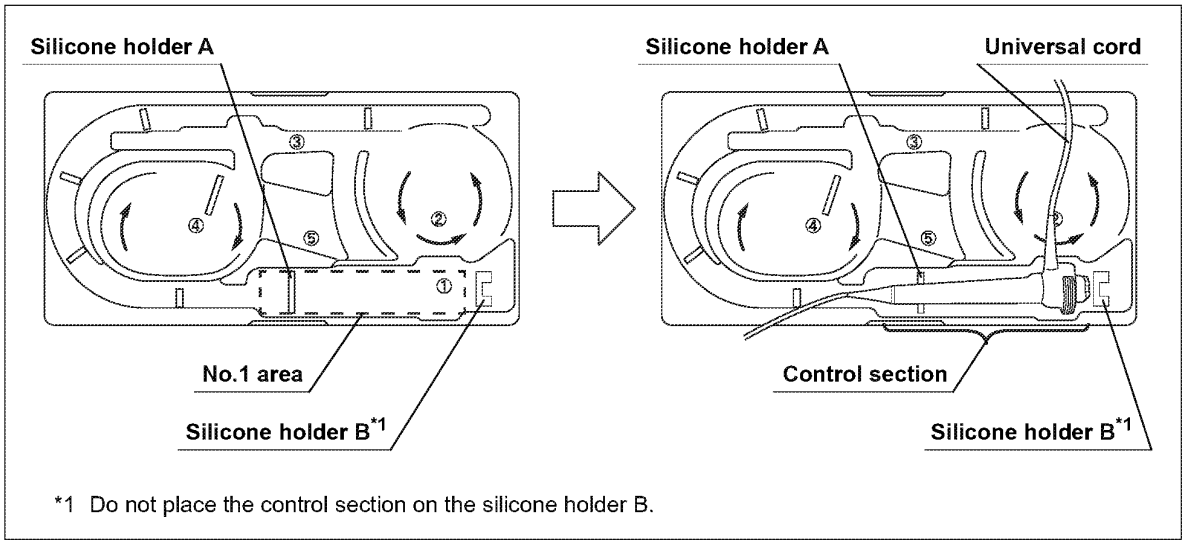

Figure 5.49

c) Push the control section of the endoscope into the silicone holder A.

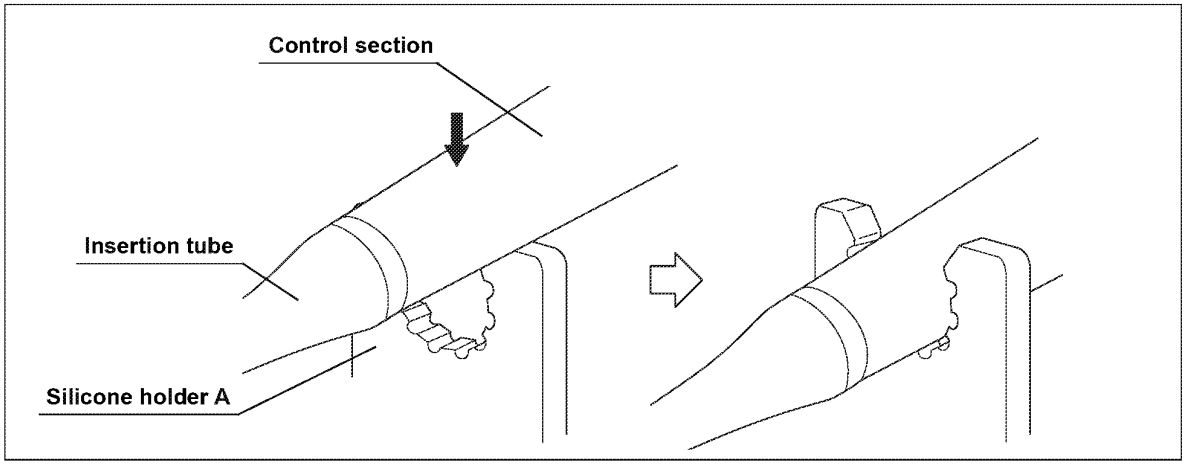

Figure 5.50

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d) Push the insertion tube of the endoscope into the silicone holder C, D, and E.

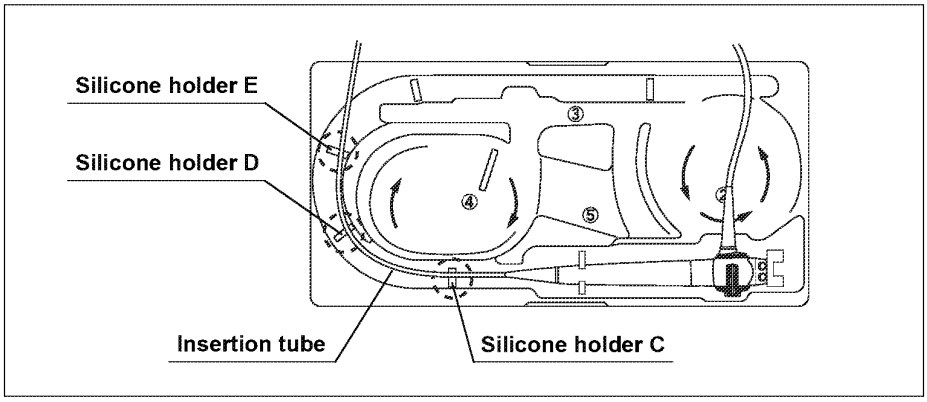

Figure 5.51

e) Loop the universal cord of the endoscope counterclockwise, creating four loops and place it in the No.2 area of the sterilization tray.

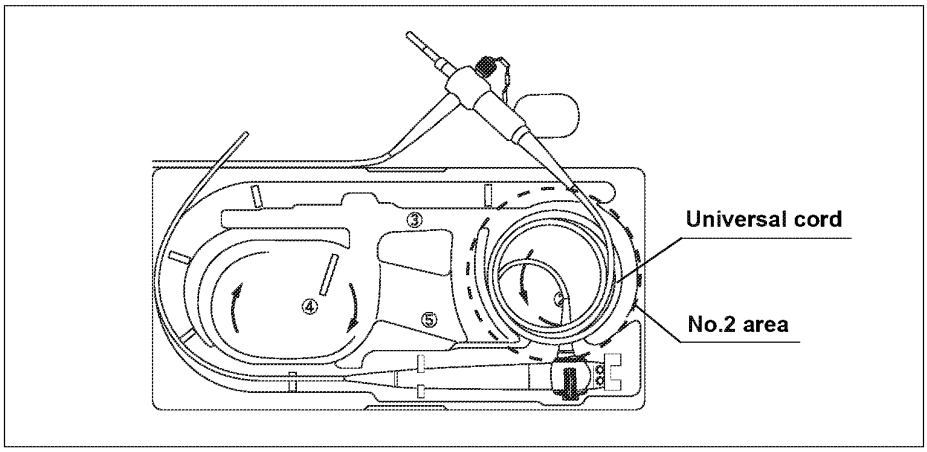

Figure 5.52

f) Place the light guide connector of the endoscope on the No.3 area of the sterilization tray.

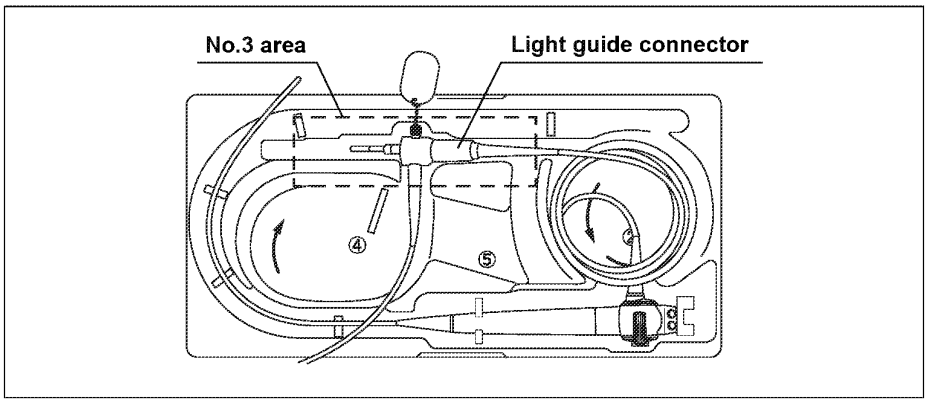

Figure 5.53

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g) Place the plate of the sterilization cap on the light guide connector of the endoscope.

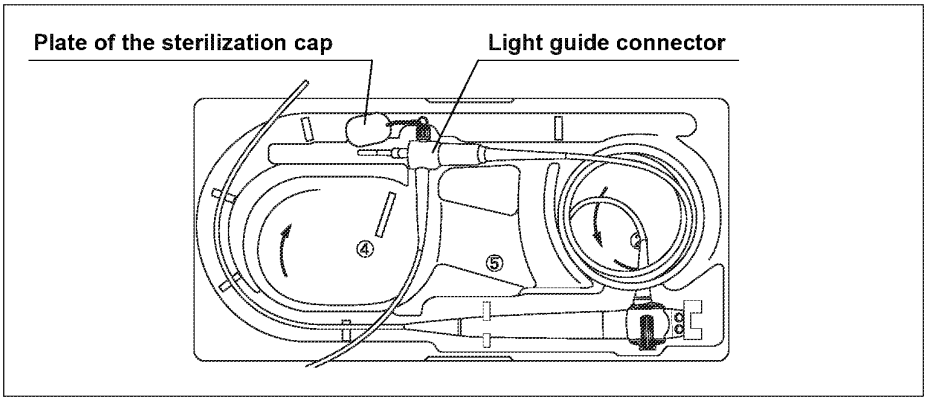

Figure 5.54

h) Loop the video cable of the endoscope clockwise, creating two loops and place it in the No.4 area of the sterilization tray.

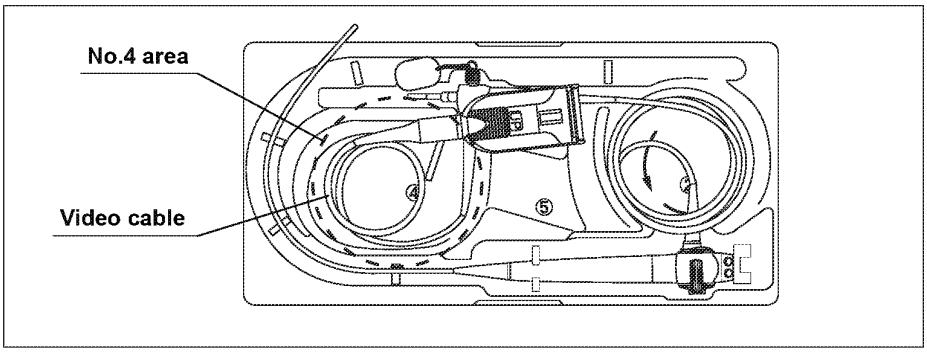

Figure 5.55

i) Place the video connector of the endoscope on the No.5 area of the sterilization tray.

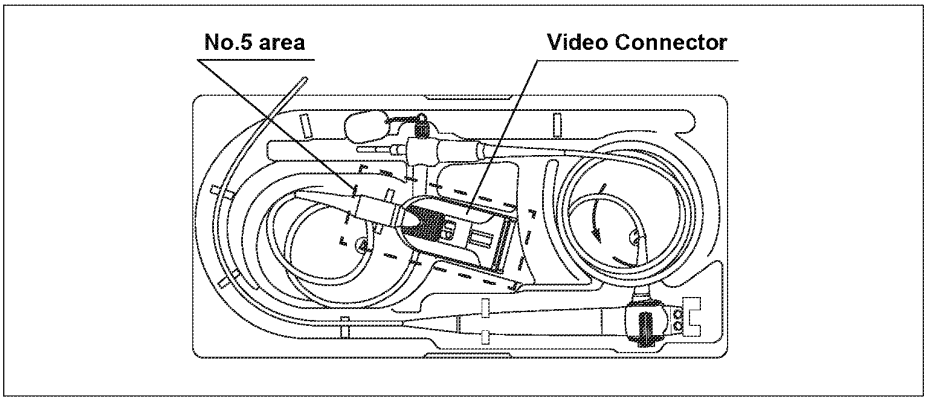

Figure 5.56

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j) Push the video connector of the endoscope into the silicone holder G.

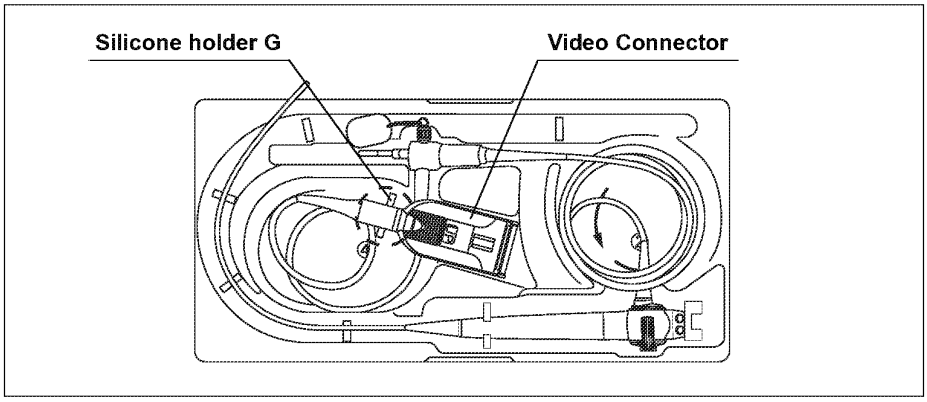

Figure 5.57

k) Insert the insertion section of the endoscope into the notch of the silicone holder F.

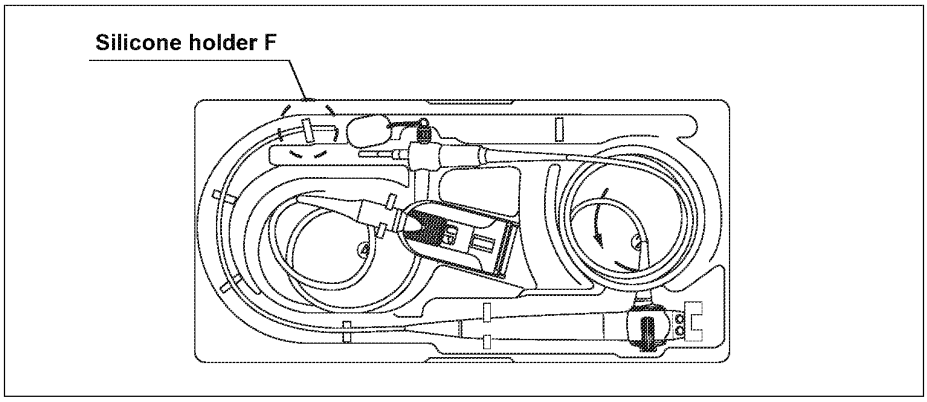

Figure 5.58

l) Confirm that all sections of the endoscope are contained completely in the groove formed on the sterilization tray.

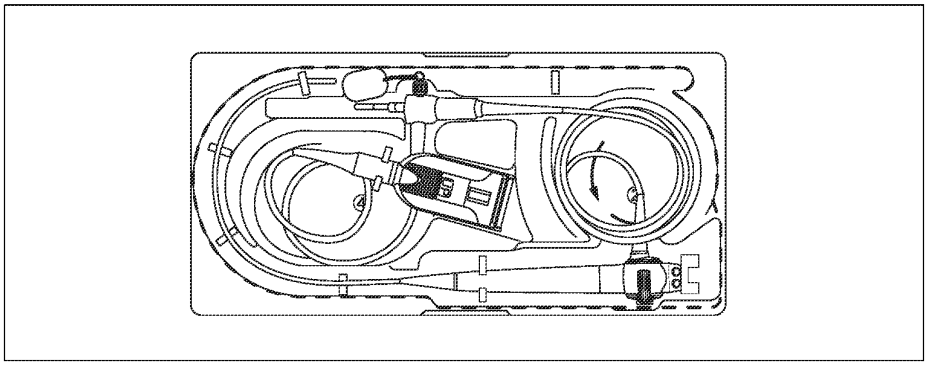

Figure 5.59

m) Close the lid of the sterilization tray according to the instruction manual for the sterilization tray.

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5 Double wrap the sterilization tray containing the endoscope with sterilization wraps for ethylene oxide gas sterilization, according to your institution's protocol.

6 Sterilize and aerate the packaged endoscope, according to the parameters described in Section 3.8, "Ethylene oxide gas sterilization". In addition, always follow the instructions of the sterilizer manufacturer.

■ *STERRAD® 100S*/NX® sterilization of the endoscope*

* For countries other than the USA.

WARNING

- Thoroughly dry the endoscope and accessories before sterilization.
- All accessories must be removed from the endoscope prior to sterilization (except the sterilization cap (MAJ-1538)).
- Use only STERRAD® compatible instrument trays and sterilization wraps.

CAUTION

Attach the sterilization cap to the venting connector on the light guide connector prior to STERRAD® 100S/NX® sterilization. If the sterilization cap is not attached to the venting connector during sterilization, the air inside the endoscope will expand and could rupture the bending section cover and/or damage the angulation mechanism.

1 Confirm that all external surfaces of the endoscope are thoroughly dry. If not, dry them as described in "■ Dry the endoscope" on page 61.

2 Dry the external surfaces of the sterilization cap by wiping with sterile lint-free cloths.

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3 Attach the sterilization cap to the venting connector on the light guide connector as follows:

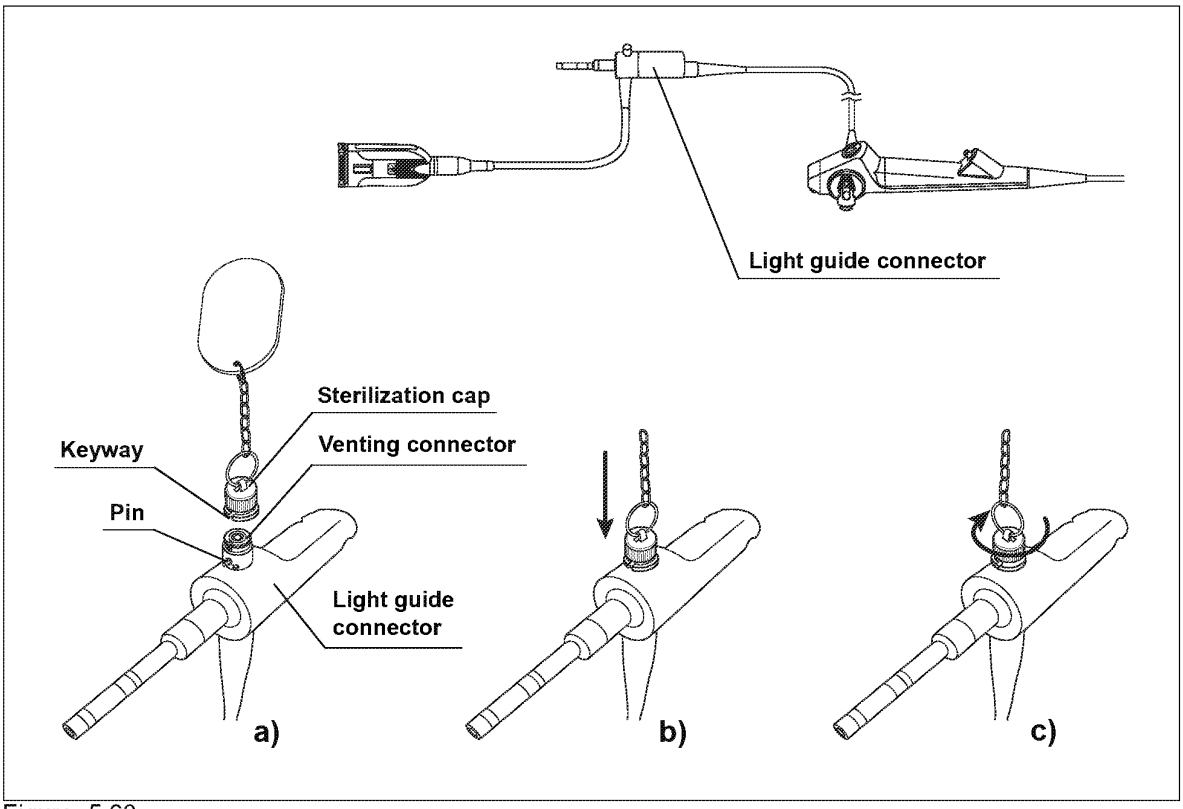

Figure 5.60

a) Align the pin on the venting connector with the keyway on the sterilization cap;

b) Push the sterilization cap towards the light guide connector of the endoscope until it stops;

c) Rotate the sterilization cap clockwise (approximately 90°) until it stops.

4 When sterilizing with the STERRAD® 100S Sterilization System, depending on the inner diameter/length of channel, it is necessary to attach the booster (REF15400) to instrument channel of the endoscope according to the instructions of the sterilizer manufacturer.

5 Place the endoscope upon an instrument tray and double wrap the tray with sterilization wraps. Use a STERRAD® compatible instrument tray and sterilization wraps.

6 Sterilize the packaged endoscope, according to the instructions of the sterilizer manufacturer.

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5.9 Presoaking the endoscope

If manual cleaning could not be performed within 1 hour after the patient procedure or if you are not sure whether manual cleaning could be performed within 1 hour, presoaking the endoscope in detergent solution before manually cleaning the endoscope may be required to wet and loosen debris that has dried and hardened onto the endoscope's surfaces. Follow the procedure described below.

WARNING

- If manual cleaning could not be performed within 24 hours after the patient procedure or if you are not sure whether manual cleaning could be performed within 24 hours, dried debris may not be removed and reprocessing of the endoscope may not be performed effectively.
- Do not reuse the detergent solution used for presoak. If performing manual cleaning with the detergent solution used for presoak, reprocessing of the endoscope may not be performed effectively.

CAUTION

Presoak the endoscope only if manual cleaning of the endoscope was delayed for more than 1 hour or if you are not sure whether manual cleaning could be performed within 1 hour. Unnecessary long-term immersions should be avoided. Consecutive reprocessing sessions using extended immersion may damage the endoscope.

Equipment needed

Prepare the following equipment.

- **Clean, large basins (size: 40 (W) × 40 (H) × 25 (D) cm or more)**
- **Detergent solution containing enzymes (Refer to Section 3.4, "Detergent solution")**
- **Clean 30 ml (30 cc) syringes**

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Presoak the endoscope

1. If a leakage test has not been performed, perform a leakage test according to Section 5.4, “Leakage testing of the endoscope”.
2. Fill a clean, large basin with the detergent solution containing enzymes at the temperature and concentration recommended by the detergent manufacturer.
3. Completely immerse the entire endoscope in the detergent solution.
4. Fill a clean 30 ml syringe with the detergent solution.
5. While immersing the entire endoscope completely in the detergent solution, attach the syringe to the instrument channel port.
6. While immersing the entire endoscope completely in the detergent solution, flush the channel with 30 ml of the detergent solution. Confirm that air bubbles exit from the distal end of the endoscope during the flush to make sure that the instrument channel is not clogged.
7. When air bubbles did not exit from the distal end of the endoscope in Step 6, immerse the endoscope in the detergent solution for 30 minutes. And then repeat Step 4 through 6 to perform additional flushes of the instrument channel port.
8. While immersing the entire endoscope completely in the detergent solution, detach the syringe from the endoscope.
9. Allow the endoscope to soak completely in the detergent solution for 0.5 to 1 hour. Do not immerse the endoscope for more than 1 hour. Use a clock or timer to accurately measure the immersion time.
10. Remove the endoscope from the detergent solution.
11. Return to Section 5.5, “Manually cleaning the endoscope” and reprocess according to the procedure. Use the detergent solution containing enzymes in manual cleaning. Even when AER, perform all procedures according to Section 5.5 after presoaking.

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Chapter 6 Reprocessing Endoscopes and Accessories Using an AER

6.1 Reprocessing endoscopes using AER (OER series)

Follow the workflow described in Section 4.2, "Workflow for manually cleaning and manually or automated disinfecting endoscopes and accessories" when reprocessing endoscopes with OER series. Be sure to attach all required connectors to the endoscope. For details concerning appropriate connectors, refer to the instructions of the each OER model.

CAUTION

After reprocessing the endoscope using an OER series, dry the electrical contacts of the endoscope connector not by air-drying but by wiping with sterile lint-free cloths. Otherwise, hard water residue may be deposited on the electrical contacts, which may cause an abnormal endoscopic image when the endoscope is used.

When setting the endoscope in the OER series, Refer to the instruction manual of each OER model.

NOTE

- When cleaning and disinfecting the endoscope in the OER series, use connectors that are compatible with the endoscope model. The compatible connectors for the endoscope model are listed in the "List of Compatible Endoscopes/Connecting Tubes" and the instruction manual for the each OER model, or Table 6.1.

	Connecting tube for instrument channel	Leak test air tube
OER-AW*1 OER-Pro*2 OER-Mini*3	MAJ-1515	MAJ-821
OER-Elite*2	MAJ-2117	MAJ-2127

Table 6.1

*1 OER-AW is available in some areas other than the USA.

*2 OER-Pro and OER-Elite are available in the USA and some areas.

*3 OER-Mini is only available in the USA.

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NOTE

- When the endoscope is cleaned and disinfected simultaneously in combination with an endoscope of the same or another model using the each OER model, see the group number of the endoscopes shown in the "List of Compatible Endoscopes/Connecting Tubes" and the instruction manual for each OER model to confirm the combination. The group numbers of the endoscope model are listed in Table 6.2.

	OER-AW	OER-Pro	OER-Mini	OER-Elite
CYF-VH/VHR	Group 2	Group 2	Group 1	Group 2

Table 6.2

■ *Dry the endoscope*

Ch.6

Refer to "■ Dry the endoscope" on page 61 for the endoscope as the procedures are same.

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Chapter 7 Storage and Disposal

7.1 Precaution of storage and disposal

WARNING

- After reprocessing, maintain appropriate transportation and storage procedures to keep reprocessed endoscopes and accessories away from contaminated equipment. If the reprocessed endoscope or accessories become contaminated before subsequent patient procedures, they could pose an infection control risk to patients and/or operators who touch them.
- Establish a local policy regarding the method and frequency of cleaning and disinfecting the endoscope storage cabinet, which staff members can access the cabinet, which items can be stored in the cabinet, etc.
- Improper storage practices, such as not thoroughly drying external and internal surfaces (lumens) prior to storage, will lead to an infection control risk.

CAUTION

- Store the endoscope and accessories in an endoscope storage cabinet which also protects the equipment from physical damage.
- To prevent damage, do not store the endoscope and/or accessories in direct sunlight, at high temperatures, in high humidity, or exposed to X-rays, ultraviolet rays, or ozone.
- To prevent damage, do not store the endoscope and/or accessories with chemicals or in a gas-generating area.
- Do not coil the endoscope's insertion tube or universal cord with a diameter of less than 10 cm. Such improper storage may damage the endoscope.

NOTE

Some national or professional guidelines recommend checking the quality of the final drying and if necessary, drying endoscopes manually with compressed filtered air before storage.

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7.2 Storing the disinfected endoscope and accessories

WARNING

- Proper storage procedures are as important as proper reprocessing procedures in maintaining good infection control practices. Be sure that the endoscope storage cabinet is properly maintained, clean, dry, and well ventilated. All equipment must be thoroughly dried prior to storage. Microorganisms proliferate in wet/moist environments. Keep the cabinet doors closed to protect the equipment from environmental contaminants and accidental contact. Limit access to stored equipment by unauthorized personnel.
- Store only adequately reprocessed endoscopes and accessories in the endoscope storage cabinet.
- Do not store the endoscope and/or accessories in the endoscope's carrying case. The carrying case does not provide a proper storage environment for patient-ready endoscopes. Storing patient-ready endoscopes in the carrying case may pose an infection control risk. Use the carrying case only for shipping the endoscope and/or accessories. Any endoscope or accessory removed from a carrying case must be reprocessed prior to patient use or storage in an endoscope storage cabinet.
- Never put a dirty endoscope into the carrying case, as it will contaminate the carrying case. It is not possible to adequately decontaminate a contaminated carrying case for further use as a shipping case.

NOTE

- Some national or professional guidelines recommend checking the quality of the final drying and if necessary, drying endoscopes manually with compressed filtered air before storage.
- Some professional guidelines as well as Olympus recommend storing endoscopes in an endoscope storage cabinet with the insertion tube and the universal cord hanging vertically.

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1 Confirm that "■ Dry the endoscope" on page 61 was performed. If not, dry the endoscope according to the procedure.

2 Place the endoscope's angulation lock in the "F▼" (or free) position.

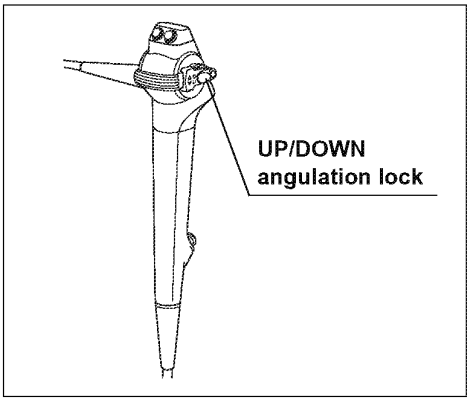

Figure 7.1

3 Store the disinfected endoscope and accessories properly.

7.3 Storing the sterilized endoscope and accessories

CAUTION

Do not damage the sterile packaging.

Store the sterilized endoscope and accessories in a proper storage cabinet, following your institutional guidelines.

NOTE

Sterile endoscopes may be stored flat in their sterile packaging.

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7.4 Disposal

When disposing of the endoscope, accessories, packaging, and reprocessing supplies (such as gloves, cloths, and the liquids used for reprocessing), handle these items in a manner that will prevent the spread of contamination from the reprocessing area, and follow all applicable national and local laws regarding disposal.

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Test Report

Title

Cleaning test Using OER-Mini with EndoQuick of CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH

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(b)(4)

Low Level Positive Control Justification

Prepared For: Olympus Corporation

10 Oct 2022

Acceptance Criteria Justification for low level positive controls

Company:

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
Planning 2, Infection Prevention Engineering Strategy
Add.
2951 Ishikawa-machi, Hachioji-shi,
Tokyo 192-8507, Japan

(b)(4)

(b)(4)

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K221683-S001 Cysto-Nephro Videoscopes OLYMPUS CYF-V2 and CYF-V2R and CYF-VH and CYF-VHR
Olympus Medical Systems Corporation
Reprocessing Consult

Date: January 11, 2022

From: Ángel A. Soler-García, Ph.D.
Lead Microbiologist
CDRH/OPEQ/OHT3/DHT3B/THT3B4

To: Esther Kaplan
Mechanical Engineer
CDRH/OPEQ/OHT3/DHT3B/THT3B3

Subject: K221683 – S001

VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2/V2R

CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH/VHR

Olympus Medical Systems Corporation

Scope: Responses to the deficiencies issues in the K221683 Additional Information Request (AI) Letter sent August 12, 2022.

Recommendation: (b)(5)

(b)(5)

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STERILIZATION REPORT

SPONSOR:	OLYMPUS CORPORATION
TEST ARTICLE AND ACCESSORY:	CYSTO-NEPHRO VIDEOSCOPE (P/N: CYF-VH) LUER-SPLIT (P/N: MAJ-2092)
TITLE:	STERILIZATION TESTING OF CYSTO-NEPHRO VIDEOSCOPE (P/N: CYF-VH) FROM OLYMPUS CORPORATION IN THE STERRAD NX® ADVANCED CYCLE
NUMBER:	(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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APPENDIX 1

Protocol Training Signature Sheet

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APPENDIX 2

(b)(4) Sterilization Testing of CYSTO-NEPHRO VIDEOSCOPE (P/N: CYF-VH) from OLYMPUS CORPORATION in the STERRAD NX® ADVANCED Cycle

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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STERILIZATION PROTOCOL

SPONSOR:	OLYMPUS CORPORATION
TEST ARTICLE AND ACCESSORY:	CYSTO-NEPHRO VIDEOSCOPE (P/N: CYF-VH) LUER-SPLIT (P/N: MAJ-2092)
TITLE:	STERILIZATION TESTING OF CYSTO-NEPHRO VIDEOSCOPE (P/N: CYF-VH) FROM OLYMPUS CORPORATION IN THE STERRAD NX® ADVANCED CYCLE
NUMBER:	(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 12
Substantial Equivalence Discussion

12.1 PREDICATE DEVICE

The CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH and CYF-VHR and VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and CYF TYPE V2R (hereinafter referred to as CYF-V2/V2R and CYF-VH/VHR) is substantially equivalent to the legally marketed predicate devices listed in Table 12-1.

Table 12-1. Predicate device

Device name	510(k) Submitter	510(k) No.
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R	OLYMPUS MEDICAL SYSTEMS CORP.	K133538

12.2 DIFFERENCE BETWEEN SUBJECT DEVICE AND PREDICATE DEVICE

Olympus bases the claim of substantial equivalence on similarities in indications for use, technological features, and materials. A side-by-side comparison of the similarities and differences between the proposed device and the predicate device are described in the following section.

1) Indications for use

The indication for use of the subject devices are equivalent to the predicate device as shown in Table 12-2.

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Table 12-2. Comparison of Indications for Use

Indications for Use		
CYF-V2/V2R	**CYF-VH/VHR**	**CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R**(K133538)
VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYF TYPE V2R have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.	CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE VH, and CYF TYPE VHR have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.	These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter, and kidney

2) Technological Characteristics

In terms of the technological features of the subject device, the major differences from the primary predicate device are as follows:

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3. Insertion Section

The diameter of the CYF-VH/VHR distal end of the insertion tube is smaller than the predicate device and is larger for the outer diameter as shown in Table 12-5. These same diameters are exactly the same as the predicate device for CYF-V2/V2R.

Table 12-5. Insertion Section

	CYF-VH/VHR	CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R
Insertion Tube Diameter	Distal end size: ø 2.7mm (bullet shape) Flexible tube outer Diameter: ø 5.5mm (16.5 Fr)	Distal end size: ø 4.8mm (bullet shape) Flexible tube outer Diameter: ø 5.4mm (16.2 Fr)

<Comments on the difference>

This change in dimensional specification of the distal end and the insertion tube is minor enough and is not expected to affect the insertion of the endoscope into the patient body.

4. Bending Section

The angulation range of the CYF-VH/VHR is different than the predicate device and is larger for the outer diameter as shown in Table 12-6. The angulation range for CYF-V2/V2R is exactly the same as the predicate device.

Table 12-6. Angulation Range

	CYF-VH/VHR	CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R
Angulation range	Up 220° / Down 130°	Up 210° / Down 120°

<Comments on the difference>

The angulation range of subject device can cover that of predicate device, so it can keep the

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performance as effective as predicate device. No new issues of safety and effectiveness have been identified.

5. Materials

The materials are changed for CYF-VH/VHR from the predicate device as shown in Table 12-7. Biocompatibility test has been performed with a final finished product to show that the subject device can be safely used in terms of biocompatibility. The materials for CYF-V2/V2R is exactly the same as the predicate device. Please refer to **Section 15** for complete biocompatibility data.

Table 12-7 Difference of Materials

Parts	CYF-VH/VHR	CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R
Bending rubber	Fluoro Rubber (b)(4)	Fluoro Rubber (b)(4)
Distal end	Polysulfone (b)(4)	PolyPhenylSulfone (b)(4)
Light guide lens	Polysulfone	Glass (b)(4)
Rubber seal	Polysulfone Silicone Rubber (b)(4)	Polysulfone Silicone Rubber (b)(4)

<Comments on the difference>

Biocompatibility test, reprocessing test, and performance test (Thermal safety test, Mechanical Durability test, and Photobiological safety test) have been performed with a final finished product including the modified material. Please refer to **Section 15** for complete biocompatibility test result, **Section 14** for reprocessing test result, and **Section 18** for performance test result. As a result of the above validation testing, no issues of safety or effectiveness were raised from the subject device.

6. Compatible Processor, Light Source, and Monitor

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Table 12-9 Compatible Processors, Light Sources, and Monitors

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A comparison of Olympus **CYF-V2/V2R** device characteristics to the proposed predicate devices is provided below in **Table 12-10**

Table 12-10: CYF-V2/V2R Device and Predicate Devices Comparison Table

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A comparison of Olympus **CYF-VH/VHR** device characteristics to the proposed predicate devices is provided below in **Table 12-11**.

Table 12-11: CYF-VH/VHR Device and Predicate Devices Comparison Table

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12.6 CONCLUSION

In terms of the indications for use, technological features and materials, Olympus believes the CYF-VH/VHR and CYF-V2/V2R are substantially equivalent to the cited predicate device. The differences between the devices are minor and do not raise any new issues of safety or effectiveness in comparison to the predicate.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sponsor:
(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-machi
Hachioji-shi, Tokyo, 192-8507
JAPAN

Low Level Positive Extraction Efficiency Validation for CYF-VH GLP Report

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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OLYMPUS

OPERATION MANUAL

INSTRUCTIONS

VISERA CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF TYPE V2
OLYMPUS CYF TYPE V2R

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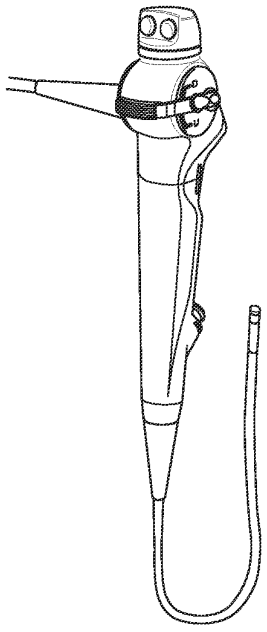

Refer to the endoscope's companion manual, the "REPROCESSING manual" with your endoscope model listed on the cover, for reprocessing information.

USA: CAUTION: Federal law restricts this device to sale by or on the order of a physician.

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Symbols

The meaning(s) of the symbol(s) shown on the component packaging, the instruction manual, and/or the instrument are as follows:

Symbol	Description	Symbol	Description
	Consult instructions for use or consult electronic instructions for use		Endoscope
	TYPE BF applied part		Caution
	Do not re-use		Batch code
	Serial number		Keep away from sunlight
	Keep dry		Not Made with Natural Rubber Latex
	Manufacturer		Authorized representative in the European Community
	Importer (into European Union)		Date of Manufacture
	Optical radiation		Non-ionizing electromagnetic radiation

For US Customers only

For a Symbols Glossary, visit us:
http://www.olympus-global.com/en/common/pdf/symbolsglossary.pdf

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Important Information — Please Read Before Use

Intended use

VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2 and CYF TYPE V2R have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

Do not use VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2 and CYF TYPE V2R for any purpose other than its intended use.
Select the endoscope to be used according to the objective of the intended procedure based on the full understanding of the endoscope's specifications and functionality as described in this instruction manual.

Contraindication

Contraindications for this device are those specific to urinary tract endoscopy.
Diagnostic or therapeutic ureteroscopy is contraindicated in people with an untreated urinary tract infection.

Applicability of endoscopy and endoscopic treatment

If there are official standards on the applicability of endoscopy and endoscopic treatment that are defined by the hospital's administrations or other official institutions, such as academic societies on endoscopy, follow those standards. Before starting endoscopy and endoscopic treatment, thoroughly evaluate their properties, purposes, effects, and possible risks (their nature, extent and probability). Perform endoscopy and endoscopic treatment only when their potential benefits are greater than their risks.

Fully explain to the patient the potential benefits and risks of the endoscopy and endoscopic treatment as well as any examination/treatment methods that can be performed in its place, and perform the endoscopy and endoscopic treatment only after obtaining the consent of the patient.

Even after starting the endoscopy and endoscopic treatment, continue to evaluate the potential benefits and risks, and immediately stop the endoscopy/treatment and take proper measures if the risks to the patient become greater than the potential benefits.

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Instruction manual

This instruction manual contains essential information on using this instrument safely and effectively. Before use, thoroughly review this manual and the manuals of all equipment that will be used during the procedure and use the equipment as instructed.
Note that the complete instruction manual set for this endoscope consists of this manual and the "REPROCESSING MANUAL" with your endoscope model listed on the cover. It also accompanied the endoscope at shipment.
Keep this and all related instruction manuals in a safe, accessible location.
If you have any questions or comments about any information in this manual, please contact Olympus.

Terms used in this manual

NBI (Narrow Band Imaging) observation:

This is optical-digital observation using narrowband light.

Normal light observation (or WLI (White Light Imaging) observation):

This is observation using white light.

Image sensor:

The image sensor is a device that converts light into electrical signals.

User qualifications

If there are official standards for user qualifications to perform endoscopy and endoscopic treatment that are defined by the hospital's medical administrators or other official institutions, such as academic societies on endoscopy, follow those standards. If there are no official qualification standards, the operator of this instrument must be a physician approved by the medical safety manager of the hospital or person in charge of the department (department of urology, etc.).

The physician should be capable of safely performing the planned endoscopy and endoscopic treatment following guidelines set by the academic societies on endoscopy, etc., and considering the difficulty of endoscopy and endoscopic treatment.This manual does not explain or discuss endoscopic procedures.

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Instrument compatibility

Refer to the “Combination equipment” on page 65 to confirm that this instrument is compatible with the ancillary equipment being used. Using incompatible equipment can result in patient or operator injury and/or equipment damage.

This instrument complies with the EMC standard for medical electrical equipment, edition 4 (IEC 60601-1-2: 2014).
When connecting to an instrument that complies with a previous edition of the EMC standard for medical electrical equipment edition, the EMC characteristics could be vulnerable.

Reprocessing before the first use/reprocessing and storage after use

This instrument was not reprocessed before shipment. Before using this instrument for the first time, reprocess it according to the instructions given in the endoscope's companion “REPROCESSING MANUAL” with your endoscope model listed on the cover.
After using this instrument, reprocess and store it according to the instructions given in the endoscope's companion reprocessing manual. Improper and/or incomplete reprocessing or storage can pose an infection control risk, cause equipment damage, or reduce performance.

Spare equipment

Be sure to prepare another endoscope to avoid interruption of the examination due to equipment failure or malfunction.

Maintenance management

The probability of failure of the endoscope and ancillary equipment increases as the number of procedures performed and/or the total operating hours increase. In addition to the inspection before each procedure, the person in charge of medical equipment maintenance in each hospital should inspect the items specified in this manual periodically following regulations, guidelines, etc. required of you. An endoscope with an observed irregularity should not be used, but should be inspected by following Section 5.2, “Troubleshooting guide”. If the irregularity is still observed after inspection, contact Olympus.

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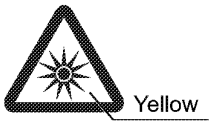
Prohibition of improper repair and modification

This instrument does not contain any user-serviceable parts. Do not disassemble, modify, or attempt to repair it; patient or operator injury and/or equipment damage may result.
Equipment that has been disassembled, repaired, altered, changed, or modified by persons other than Olympus' own authorized service personnel is excluded from Olympus' limited warranty and is not warranted by Olympus in any manner.

Classification of safety optical radiation

The endoscope is Risk Group 2 product (IEC 62471: 2006).

Risk Group 2	
CAUTION  	• UV emitted from this device. Skin irritation may result. Do not keep the distal end of the endoscope in contact with skin for over four seconds. • The light emitted may be harmful to the eyes. Do not stare directly into the distal end of the endoscope while the examination light is ON.

Signal words

The following signal words are used throughout this manual:

WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices or potential equipment damage.
NOTE	Indicates additional helpful information.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Precautions

Follow the warnings and cautions given below when handling this endoscope. This information is to be supplemented by the warnings and cautions given in each chapter.

WARNING

- Do not use this instrument for any purpose other than its indications for use. Select the endoscope to be used according to the objective of the intended procedure based on the full understanding of the endoscope's specifications and functionality as described in this instruction manual.
- After using this endoscope, reprocess and store it according to the instructions given in the endoscope's companion "REPROCESSING MANUAL" with your endoscope model listed on the cover. Using improperly or incompletely reprocessed or stored instruments may cause patient cross-contamination and/or infection.
- Do not strike, hit, or drop the endoscope's distal end, insertion tube, bending section, control section, universal cord, video connector, or light guide connector. Also, do not bend, pull, or twist the endoscope's distal end, insertion tube, bending section, control section, universal cord, video connector, or light guide connector with excessive force. The endoscope may be damaged and could cause patient injury, burns, bleeding, and/or perforations. It could also cause parts of the endoscope to fall off inside the patient.
- Never perform angulation control forcibly or abruptly. Never forcefully pull, twist, or rotate the angulated bending section. Patient injury, bleeding, and/or perforation may result. It may also become impossible to straighten the bending section during an examination.
- Never insert or withdraw the endoscope's insertion section while the bending section is locked. When using an endoscope with the UP/DOWN angulation lock, never insert or withdraw the endoscope while the angulation lock is moved in the opposite direction of the "F▼" mark. Patient injury, bleeding, and/or perforation may result.
- Never operate the bending section, insert or withdraw the endoscope's insertion section, or use EndoTherapy accessories without viewing the endoscopic image. Patient injury, bleeding, and/or perforation may result.
- Never use EndoTherapy accessories, insert or withdraw the insertion section, or perform angulation control while the image is frozen. Patient injury, bleeding, and/or perforation may result.
- If it is difficult to insert the endoscope, do not forcibly insert the endoscope; stop the endoscopy. Forcible insertion can result in patient injury, bleeding, and/or perforation.

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WARNING

- Never insert or withdraw the insertion section abruptly or with excessive force. Patient injury, bleeding, and/or perforation may result.
- Do not touch the light guide on the light guide connector immediately after removing it from the light source because it is extremely hot. Operator or patient burns can result.
- Although the illumination light emitted from the endoscope's distal end is required for endoscopic observation, it may also cause alteration of living tissues such as protein denaturation of living tissue and perforation of the tissue by inappropriate using. Observe the following warnings for illumination.
  - Always set the minimum required brightness. The brightness of the image on a monitor may differ from the actual brightness at the distal end of the endoscope. Pay special attention to the brightness level setting of the light source, particularly when operating the electrical shutter function of a video system center. When both a light source and a video system center have the automatic brightness control function, use the function on the light source. This function can better maintain the illumination level. Refer to the instruction manual for the light source and the video system center for further details.
  - Always maintain a suitable distance necessary for adequate viewing while using the minimum level of illumination for the minimum amount of time. Do not use close stationary viewing or leave the distal end of the endoscope close to the mucous membrane for a long time without necessity.
  - When the endoscope will not be used for a long period, be sure to turn OFF the light source or activate the light shield function (standby mode, etc.) so that the endoscope is not illuminated unnecessarily.
- Push the video connector into the video system center until it clicks, then confirm that the video connector is securely attached by pulling it gently. Improper connection will damage the image sensor. The damaged image sensor will display no image and make the distal end hot, which could cause operator and/or patient burns.
- Do not insert the video connector while the electrical contacts are wet and/or dirty. This may result in an electric shock, causing severe damage to the endoscope and compromising patient and/or operator safety.
- If the endoscopic image becomes dimmer during the procedure, it may indicate that blood or mucus is adhering to the light guide lens on the distal end of the endoscope. Carefully withdraw the endoscope from the patient and remove blood or mucus to restore optimum illumination and to ensure the safety of the examination. If you continue to use the endoscope with its obstructed light guide lens, the temperature at the distal end may rise and cause mucosal burns to the patient. It may also cause patient and/or operator injury.

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WARNING

- When the endoscopic image does not appear on the monitor, the image sensor may have been damaged. Turn the video system center OFF immediately. Continued power supply in such a case will cause the distal end to become hot and could cause operator and/or patient burns.
- Do not rely on the NBI observation mode alone for primary detection of lesions or to make a decision regarding any potential diagnostic or therapeutic intervention.

CAUTION

- Do not pull the universal cord and video cable during an examination. The light guide connector will be pulled out from the output socket of the light source and the endoscopic image will not be visible.
- Do not coil the insertion tube, universal cord, or video cable with a diameter of less than 10 cm. Equipment damage may result.
- Do not attempt to bend or twist the endoscope's insertion section with excessive force. The insertion section may be damaged.
- Do not apply shock to the distal end of the insertion section, particularly the objective lens surface at the distal end. Visual abnormalities may result.
- If the endoscope is dropped or the distal end of the endoscope receives a hard impact, the endoscope may be damaged even if no visible damage of the lens on the distal end can be found. In this case, stop using the endoscope, and contact Olympus.
- Do not twist or bend the bending section with your hands. Equipment damage may result.
- Do not squeeze the bending section forcefully. The covering of the bending section may stretch or break and cause water leaks.
- Do not put or press the video connector and light guide connector on the insertion section when transporting or reprocessing. The insertion section may be damaged.
- Turn the video system center ON only when the video connector is connected to the video system center. In particular, confirm that the video system center is OFF before connecting or disconnecting the video connector. Failure to do so can result in equipment damage, including destruction of the image sensor.
- The endoscope's remote switches cannot be removed from the control section. Pressing, pulling, or twisting them with excessive force can break the switches and/or cause water leaks.
- Do not hit or bend the electrical contacts on the video connector. The connection to the video system center may be impaired and faulty contact can result.

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CAUTION

- Do not pull the video cable during an examination. The endoscopic image may not be visible.
- Electromagnetic interference may occur on this endoscope near equipment marked with the following symbol or other portable and mobile RF (Radio Frequency) communications equipment, such as cellular phones, or other RF emitter devices such as electrocautery, RFID, or diathermy. If electromagnetic interference occurs, mitigation measures may be necessary, such as reorienting or relocating this endoscope, or shielding the location.

- Be sure that this endoscope is not used adjacent to or stacked with other equipment (other than the components of this endoscope or system) to avoid electromagnetic interference.
- To check the electromagnetic interference from other equipment (any equipment other than this endoscope or the components that constitute this system), the system should be observed to verify its normal operation in the configuration in which it will be used.

NOTE

- This endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center.
- When the endoscope gets strong static electricity, noise may be observed in the endoscopic image. This does not indicate a malfunction.

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Precaution for disappeared or frozen endoscopic image

WARNING

- If the endoscopic image disappears unexpectedly or the frozen image cannot be restored during an examination, immediately stop using the endoscope and withdraw it from the patient as described in Section 5.3, "Withdrawal of the endoscope with an irregularity". Continued use of the endoscope under this condition could result in patient injury, bleeding, and/or perforation.
- Follow the precautions given below. Otherwise, the endoscopic image may disappear unexpectedly or the frozen image may not be restored during the examination.
  - Connect the video connector to the video system center completely by pushing the video connector until it clicks. Otherwise, faulty contact can result.
  - Do not bend, hit, pull, or twist the insertion section, bending section, control section, universal cord, video cable, video connector, and light guide connector. The endoscope may be damaged, and water leaks and/or breakage of internal parts like the image sensor cable can result.
  - Make sure that the video connector and its electrical contacts are completely dry before connecting the video connector to the video system center. Wet contacts could cause the equipment to malfunction.
  - If air bubbles emerge from the endoscope continuously during the leakage test, do not use the endoscope. Water may enter the endoscope and cause a short circuit. This may result in image sensor damage.

CAUTION

- Turn the video system center ON only when the video connector is connected to the video system center. In particular, confirm that the video system center is OFF before connecting or disconnecting the video connector. Failure to do so can result in equipment damage, including destruction of the image sensor.
- Do not hit or bend the electrical contacts on the video connector. The connection to the video system center may be impaired and faulty contact can result.

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Examples of inappropriate handling

Details on clinical endoscopic technique are the responsibility of trained specialists. Patient safety in endoscopic examinations and endoscopic treatment can be ensured through appropriate handling by the physician and the medical facility. Examples of inappropriate handling are described below.

- Inserting, withdrawing, and using EndoTherapy accessories without a clear endoscopic image may cause patient injury, burns, bleeding, and/or perforation.
- Inserting or withdrawing the endoscope, or operating the bending section without a clear endoscopic image may cause patient injury, bleeding, and/or perforation.
- For reasons described below, do not rely on the NBI*1 observation mode alone for primary detection of lesions to make a decision regarding any potential diagnostic or therapeutic intervention.
  - NBI has not been demonstrated to increase the yield or sensitivity of finding any specific mucosal lesion.
  - NBI has not been demonstrated to aid in differentiating and establishing the presence or absence of dysplasia or neoplastic changes within mucosa or mucosal lesions.

*1 Narrow Band Imaging. For more details, refer to the instruction manual for the video system center.

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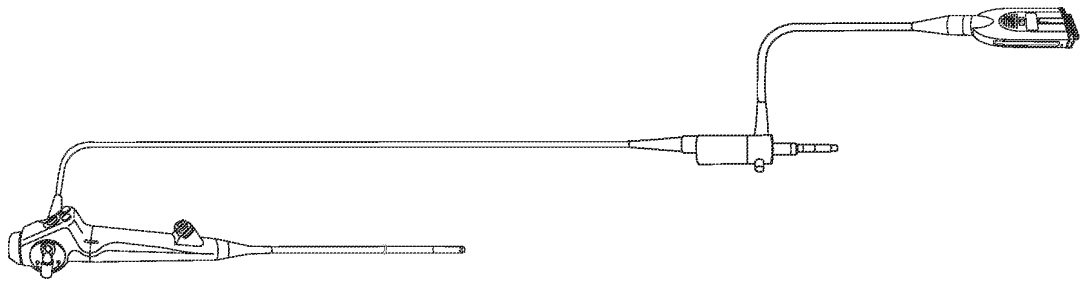
Chapter 1 Checking the Package Contents

1.1 Checking the package contents

Match all items in the package with the components shown below. Inspect each item for damage. If the endoscope is damaged, a component is missing, or you have any questions, do not use the items; immediately contact Olympus.

Endoscope



CYF-V2/V2R

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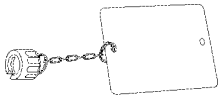
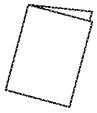
Accessories

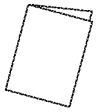
Single use combination cleaning brush (BW-411B)



ETO cap (MB-156)



Operation manual



Reprocessing manual

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Chapter 2 Instrument Nomenclature and Specifications

The instrument nomenclature, functions, and specifications are described in this chapter.

2.1 Nomenclature and functions

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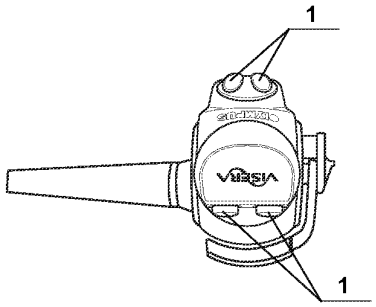
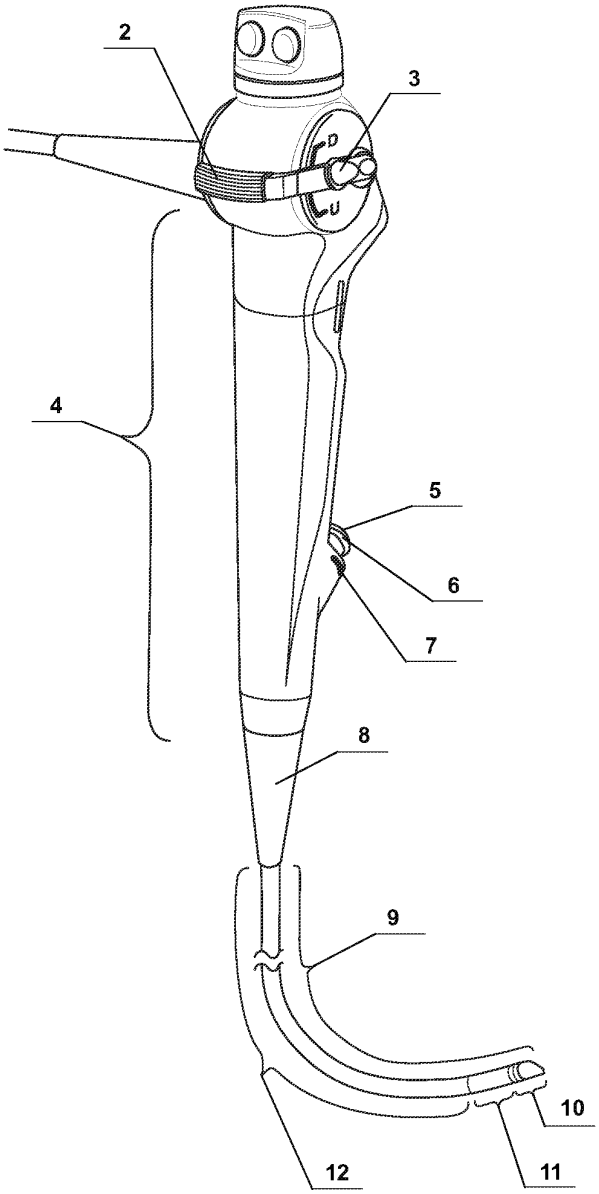
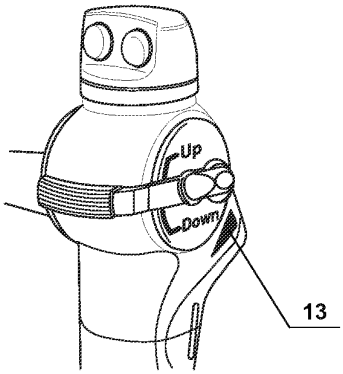
Control section, insertion section

Endoscope model: CYF-V2, CYF-V2R





For CYF-V2R



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No.	Nomenclature	Description	Endoscope model
1	Remote switches 1 to 4	The functions of the remote switches 1 to 4 can be selected on the video system center. Refer to the instruction manual for the video system center when setting these functions.	
2	UP/DOWN angulation control lever	When this lever is turned in the “U” direction (for CYF-V2R: “Up”), the bending section moves UP; when the lever is turned in the “D” direction (for CYF-V2R: “Down”), the bending section moves DOWN.	
3	UP/DOWN angulation lock	Moving this lever in the “F▼” direction frees angulation. Moving the lever in the opposite direction locks the bending section at any desired position.	
4	Control section	Operates the endoscope, such as controlling angulation.	
5	Instrument channel	An EndoTherapy accessory can be inserted to this channel. The instrument channel is connected to the distal end of the endoscope. The instrument channel functions are: • Channel for the insertion of EndoTherapy accessories • Fluid feed channel	
6	Instrument channel port	Attach the Forceps/irrigation plug to this port.	
7	Color code	The color code is used to quickly determine the compatibility of EndoTherapy accessories. The endoscope can be used with EndoTherapy accessories that have the same color code. For more information on combining the endoscope with particular EndoTherapy accessories, refer to the “■ Compatible EndoTherapy accessories” on page 68 and the instruction manuals for the compatible accessories. • Blue: CYF-V2, CYF-V2R	
8	Boot	Avoids the junction between the insertion tube and control section from bending.	
9	Insertion section	This section is inserted into the patient body cavity.	
10	Distal end	The objective lens and light guide lens are on this distal end.	
11	Bending section	The bending section moves the distal end of the endoscope when the UP/DOWN angulation control lever is operated.	
12	Insertion tube	Connects the control section and bending section.	
13	Identification marking for opposite bending direction	This marking indicates that the bending section of the CYF-V2R moves in the direction opposite to the conventional endoscopes, such as the CYF-V2.	CYF-V2R

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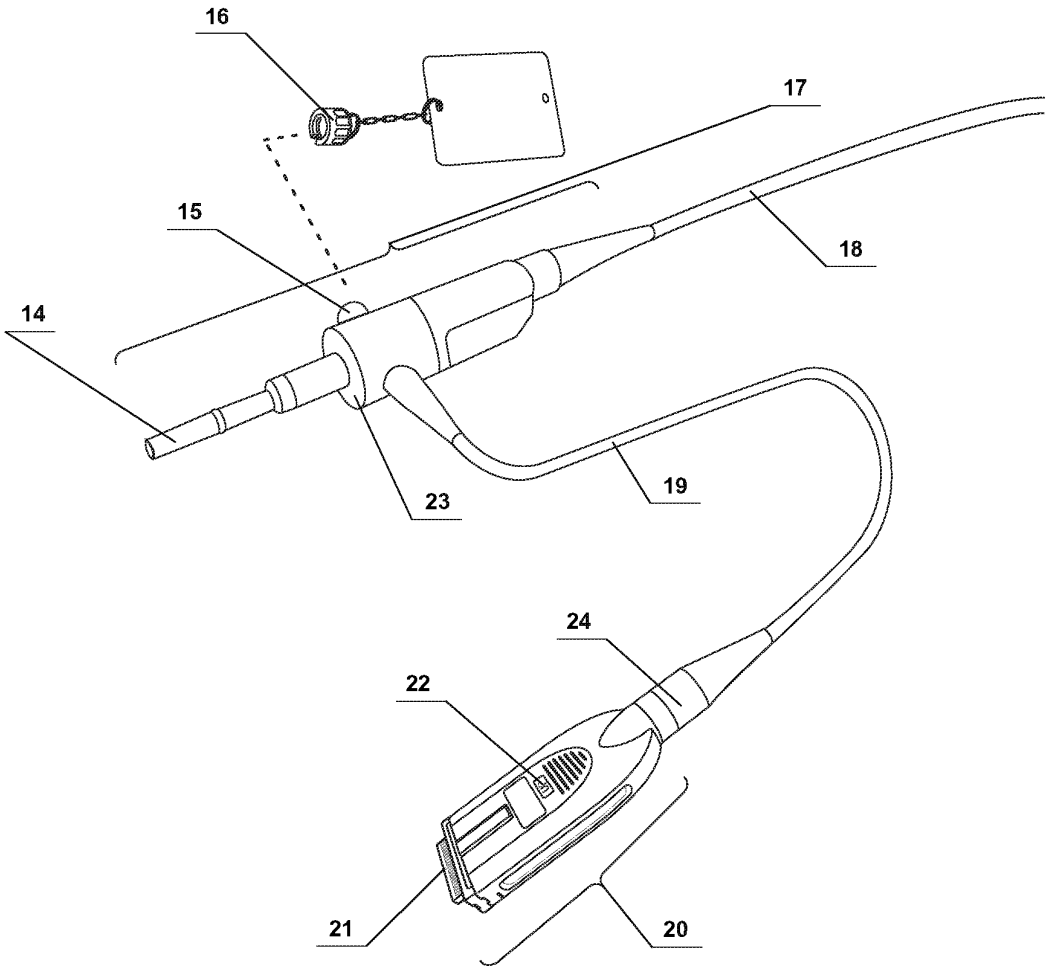
Light guide connector, video connector



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No.	Nomenclature	Description
14	Light guide	Connects the endoscope to the light source and transmits light to the distal end of the endoscope.
15	Venting connector	Attach the sterilization cap or leakage tester here.
16	ETO cap (MB-156)	The ETO cap equalizes the outer and inner pressure of the endoscope. The cap must be attached prior to gas sterilization (ethylene oxide gas, STERRAD® etc.) and aeration and removed prior to immersion or clinical examination. The cap must also be attached when the endoscope is transported outside the hospital (shipment, return for repairs, etc.).
17	Light guide connector	The light guide connector connects the endoscope to the output socket of the light source and transmits light from the light source to the distal end of the endoscope.
18	Universal cord	Connects the light guide connector and the control section.
19	Video cable	Connects the light guide connector and the video connector.
20	Video connector	The video connector connects the endoscope to the video connector socket of the video system center so that the endoscopic image becomes visible. The endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center. For more details, refer to the instruction manual for the video system center.
21	Electrical contacts	Connects the video system center and the endoscope electrically.
22	UP mark	When the video connector is connected to the video system center, this mark is facing upward.
23	Serial number	The serial number is marked here.
24	Product ID plate	UDI indication, the product name (model) and NTSC/PAL label are marked here.

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2.2 Specifications

Environment

Operating environment	**Ambient temperature**	10 – 40°C (50 – 104°F)
	Relative humidity	30 – 85%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)
Standard storage environment (e.g. within the hospital)	**Ambient temperature**	5 – 40°C (41 – 104°F)
	Relative humidity	10 – 95%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)
Transportation environment (conditions during transportation and short-term storage)	**Ambient temperature**	–47 to +70°C (–52.6 to +158°F)
	Relative humidity	10 – 95%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)

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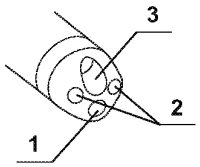
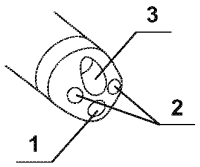
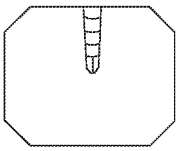
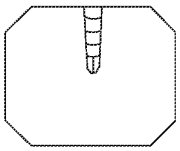
Specifications

Endoscope function

Model		CYF-V2	CYF-V2R
Optical system	Field of view	120°	120°
	Direction of view	0° (Forward viewing)	0° (Forward viewing)
	Depth of field	3 – 50 mm	3 – 50 mm
Insertion section	Distal end outer diameter	ø 4.8 mm (Bullet shape)	ø 4.8 mm (Bullet shape)
	Distal end enlarged 1 Objective lens 2 Light guide lens 3 Instrument channel outlet		
	Insertion tube outer diameter	ø 5.4 mm (16.2 Fr)	ø 5.4 mm (16.2 Fr)
	Insertion section working length	380 mm	380 mm
Instrument channel	Channel inner diameter	ø 2.2 mm (6.6 Fr)	ø 2.2 mm (6.6 Fr)
	Minimum visible distance*1	2 mm	2 mm
	Direction from which EndoTherapy accessories enter and exit the endoscopic image		
Bending section	Angulation range	UP 210° DOWN 120°	UP 210° DOWN 120°
Total length		660 mm	660 mm
NBI observation mode*2		Available	Available
High-frequency treatment		Compatible	Compatible
Laser treatment		Not compatible	Not compatible

*1 Distance from the distal end of the endoscope.

*2 For more details, refer to the instruction manual for the video system center.

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Common specifications

EMC	**Applied standard**	IEC 60601-1-2: 2014 IEC 60601-2-18: 1996 IEC 60601-2-18: 2009 • This instrument complies with the EMC standard for medical electrical equipment, edition 4 (IEC 60601-1-2: 2014). When connecting to an instrument that complies with a previous edition of the EMC standard for medical electrical equipment edition, the EMC characteristics could be vulnerable. • CISPR 11 of emission: Group 1, Class B
Degree of protection against electric shock		TYPE BF applied part (the entire endoscope)
Classification of safety of optical radiation		Risk Group 2 (IEC 62471: 2006)
UDI Indication		 The UDI Indication is required by some countries' regulations regarding the identification of medical device also known as Unique Device Identification (UDI). The following information is being coded in the 2-dimensional barcode (GS1 Data Matrix): • (01) 14-digit GS1 Global Trade Item Number; • (11) 6-digit date of manufacture; • (21) 7-digit serial number.

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Chapter 3 Preparation and Inspection

The equipment prepared before using this endoscope and procedures for the inspection of the endoscope and equipment are described in this chapter.

3.1 The workflow of preparation and inspection

The workflow of preparation and inspection is shown below.

Before each case, prepare and inspect this endoscope as instructed below. Inspect other equipment to be used with this endoscope as instructed in their respective instruction manuals. Should any irregularity be observed after inspection, follow the instructions as described in Chapter 5, “Troubleshooting”. If this endoscope malfunctions, do not use it. Return it to Olympus for repair as described in Section 5.4, “Returning the endoscope for repair”.

WARNING

- Using an endoscope that is not functioning properly may compromise patient or operator safety and may result in more severe equipment damage.
- This endoscope was not reprocessed before shipment. Before using this endoscope for the first time, reprocess it according to the instructions as described in the endoscope's companion “REPROCESSING MANUAL” with your endoscope model listed on the cover.

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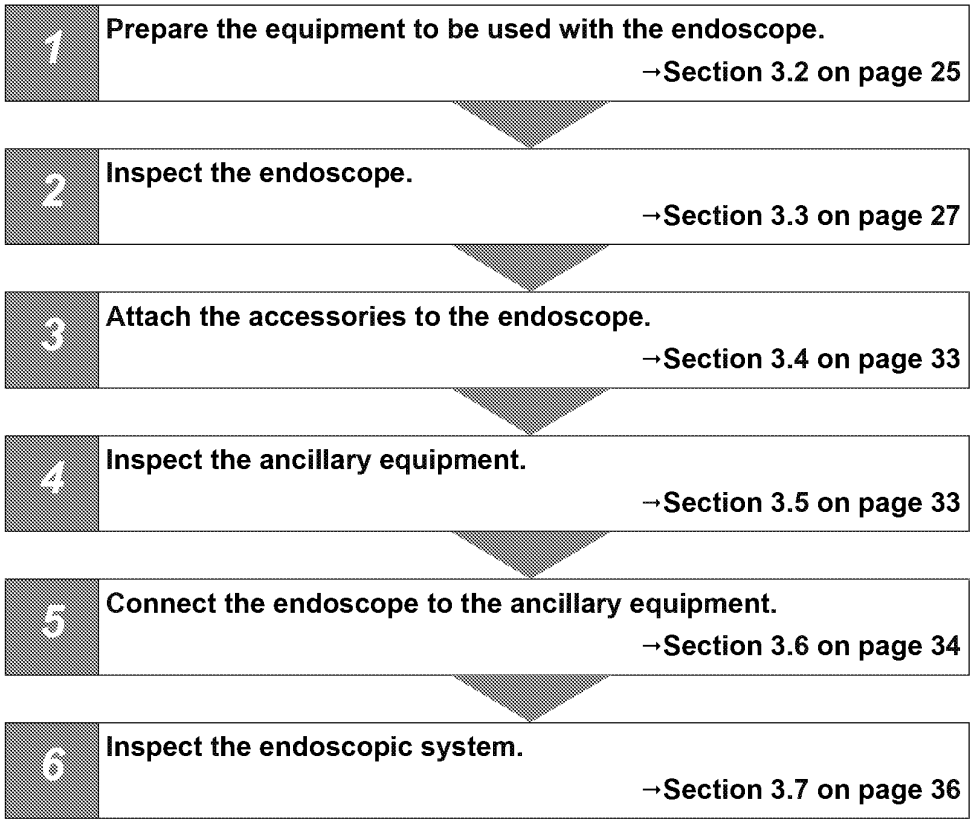
3.1 The workflow of preparation and inspection



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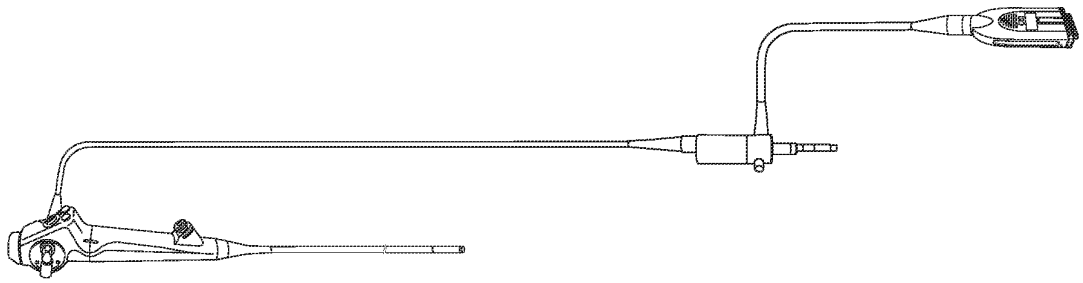
3.2 Preparation of the equipment

WARNING

- For cystoscopy procedures, prepare the endoscope and accessories that has been cleaned and then high-level disinfected or sterilized.
- For nephroscopy procedures, prepare the endoscope and accessories that has been cleaned and then sterilized.

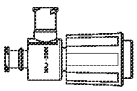
Prepare this endoscope, the accessories, equipment, and all personal protective equipment shown in Figure 3.1. Prepare the equipment in “Combination equipment” on page 65 in accordance with the intended use.
Also, refer to the respective instruction manuals for each piece of equipment before use.

Endoscope



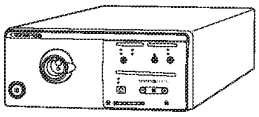
Endoscope*1

Accessories and ancillary equipment



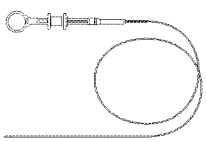
Forceps/irrigation plug

Video system center

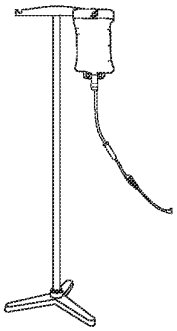


Light source

Monitor



EndoTherapy accessories



Irrigation system

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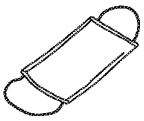
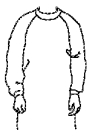
❍ Personal protective equipment (e.g.)

Eyewear



Face mask



Moisture-resistant clothing

Chemical-resistant gloves

❍ Other

- **Lint-free cloths**
- **Container for sterile water**
- **Sterile water**

Figure 3.1

*1 Prepare the endoscope that has been reprocessed as described in the “REPROCESSING MANUAL” with your endoscope model listed on the cover.

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3.3 Inspection of the endoscope

CAUTION

Detach the ETO cap (MB-156) from the venting connector if it is attached, especially after gas sterilization (e.g., ethylene oxide gas sterilization, hydrogen peroxide low temperature plasma). Otherwise, the remote switches may not work normally due to a difference between internal and external pressures of the endoscope.

Inspection of the endoscope

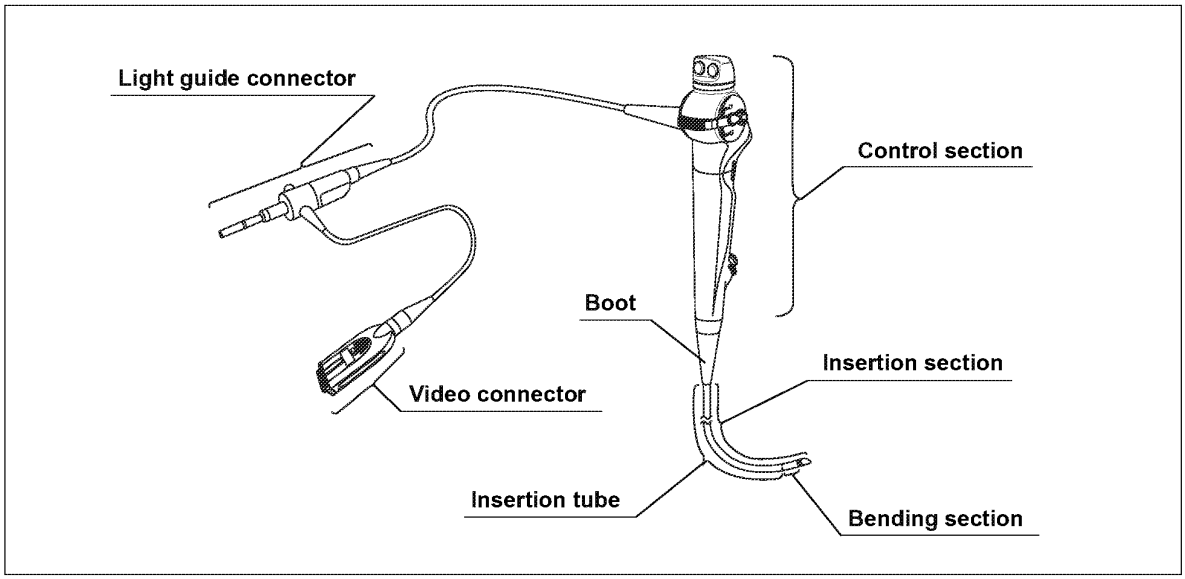

Figure 3.2

1. Inspect the control section, video connector, and light guide connector for excessive scratching, deformation, loose parts, or other irregularities.
2. Inspect the electrical contacts on the video connector for corrosion.
3. Inspect the boot and the insertion section near the boot for bends, twists, or other irregularities.
4. Inspect the external surface of the entire insertion section, including the bending section and the distal end for dents, bulges, swelling, scratches, peeling of coating, holes, sagging, transformation, bends, adhesion of foreign bodies, missing parts, protruding objects, or other irregularities.

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5 Holding the control section with one hand, carefully run your other hand back and forth over the entire length of the insertion section. Confirm that no objects or metallic wire protrude from the insertion section. Also, confirm that the insertion tube is not abnormally rigid.

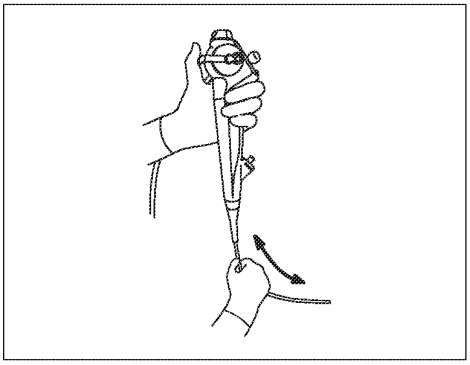

Figure 3.3

6 Using both hands, bend the insertion tube of the endoscope into a semicircle. Then, moving your hands as shown by the arrows in Figure 3.4, confirm that the entire insertion tube can be smoothly bent to form a semicircle and that the insertion tube is pliable.

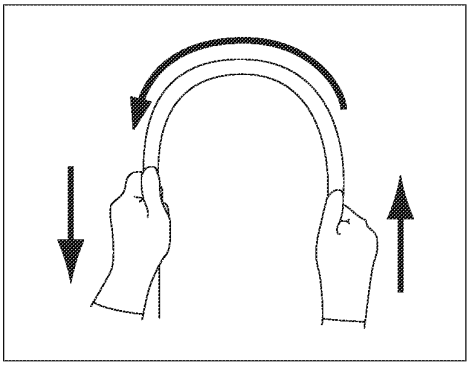

Figure 3.4

7 Gently hold the vicinity of the distal end and a point 10 cm from the distal end. Push and pull gently to confirm that the junction between the bending section and the insertion tube is not loose.

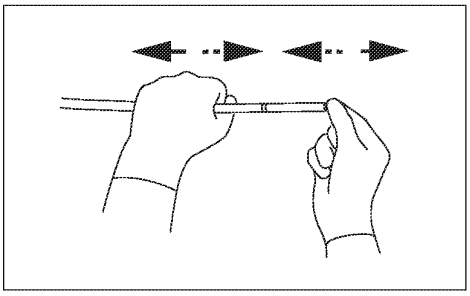

Figure 3.5

8 Inspect the lens at the distal end of the endoscope's insertion section for scratches, cracks, stains, gaps around the lens, or other irregularities. Also, inspect the entire distal end of the endoscope for chips or cracks.

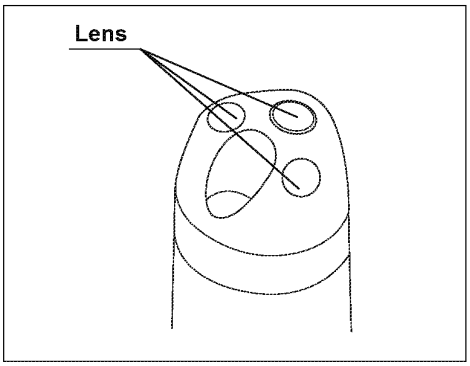

Figure 3.6

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9 Inspect the adhesives attaching the bending section cover to the insertion section for deterioration, pitting or cracking.

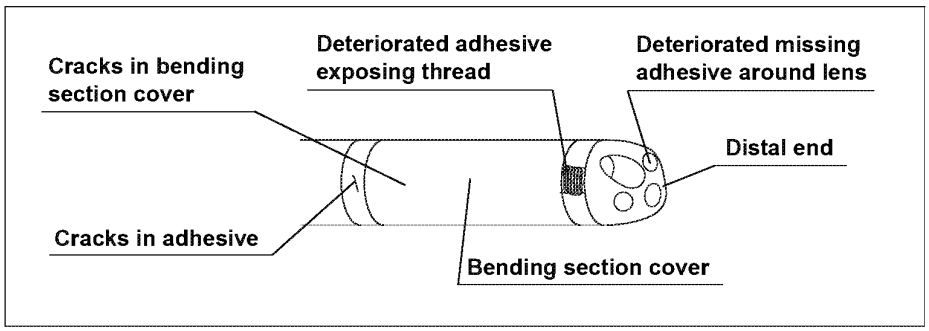

Figure 3.7

CAUTION

Insertion section should be free of rough surfaces, sharp edges or protrusions which may cause harm.

NOTE

The covering on both ends of the bending section is wound with thread. The adhesives cover them so that they are fixed. Therefore, the thread is exposed if the adhesives become chipped.

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Inspection of the bending mechanism

Perform the following inspections while the bending section is straight.

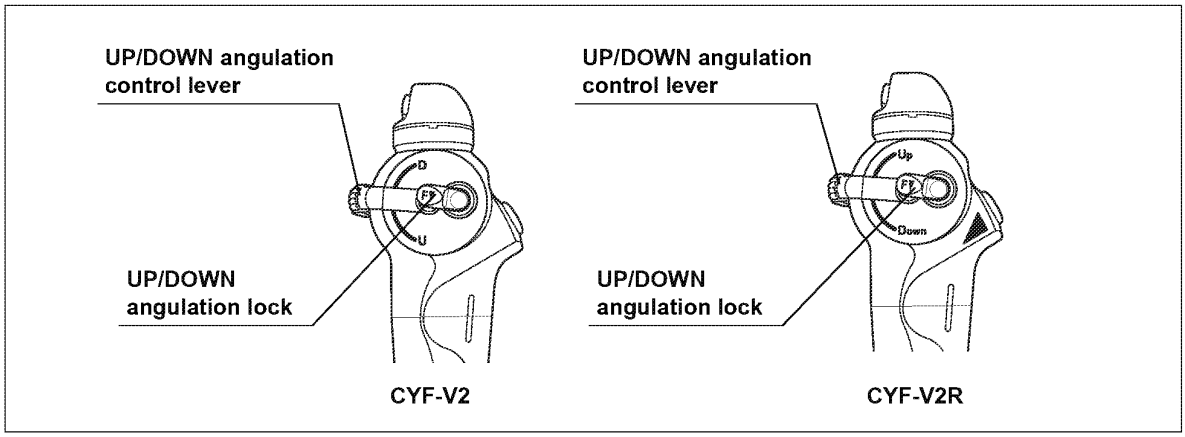

Figure 3.8

WARNING

- If the movement of the UP/DOWN angulation lock and the angulation control lever is loose and/or not smooth, or the bending section does not angulate smoothly, the bending mechanism may be abnormal. In this case, do not use the endoscope because it may be impossible to straighten the bending section during an examination, and patient injury, bleeding, and/or perforation may result.
- The UP/DOWN angulation control of the CYF-V2R is the opposite of the CYF-V2. Inspect the bending mechanism before the procedure. The bending section may bend in a different direction from the intended direction, and may cause patient injury, bleeding, and/or perforation.

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Inspection for smooth operation

1 Straighten the bending section.

2 Confirm that the UP/DOWN angulation lock is placed in the free “F▼” position.

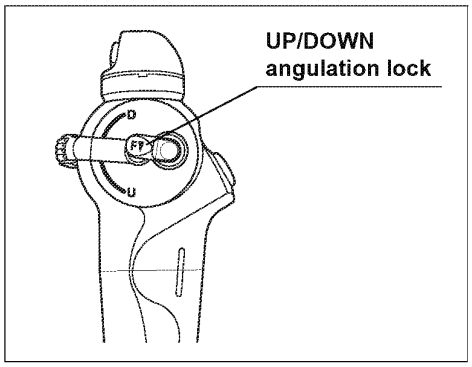

Figure 3.9

3 Operate the UP/DOWN angulation control lever slowly in each direction until it stops. Confirm that the bending section angulates smoothly and correctly, and that maximum angulation can be achieved.

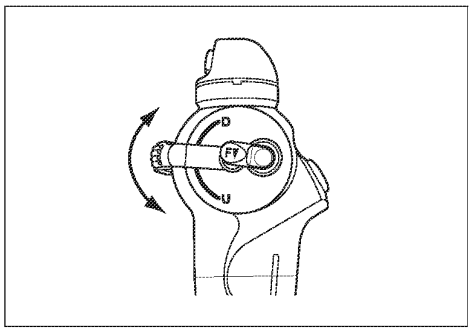

Figure 3.10

4 Operate the UP/DOWN angulation control lever slowly to its straight (neutral) position. Confirm that the bending section returns smoothly to an approximately straight position.

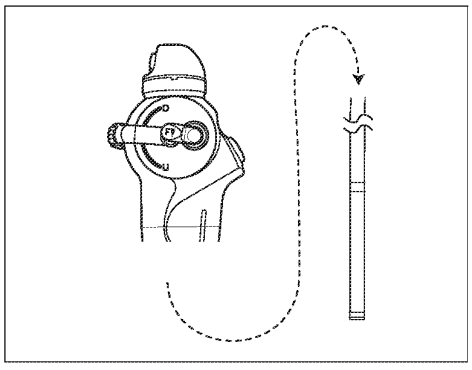

Figure 3.11

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Inspection of the angulation mechanism

1 Move the UP/DOWN angulation lock in the opposite direction of the “F▼” mark into the locked position.

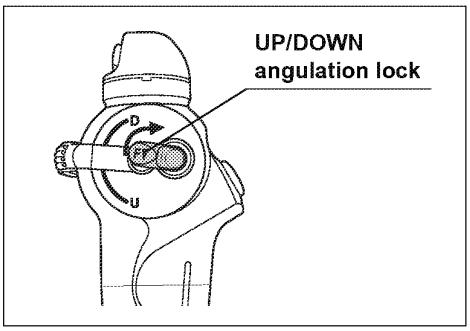

Figure 3.12

2 Move the UP/DOWN angulation control lever in the “U” or “D” direction (for CYF-V2R: “Up” or “Down”) until it stops.

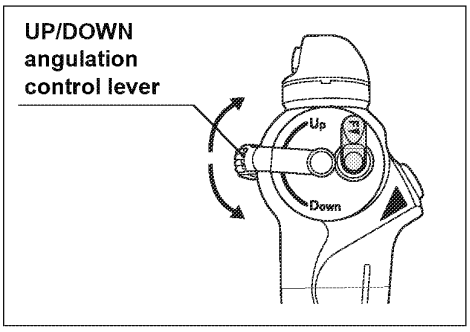

Figure 3.13

3 Confirm that the angle of the bending section is roughly stabilized when the UP/DOWN angulation control lever is released.

4 Confirm that the bending section returns to its straight (neutral) position when the UP/DOWN angulation lock is placed in the free position and the UP/DOWN angulation control lever is released.

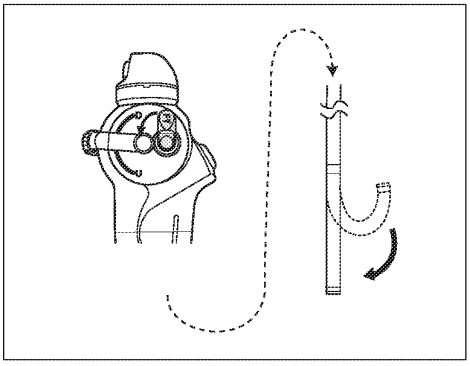

Figure 3.14

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3.4 Attaching accessories to the endoscope

■ Attaching a forceps/irrigation plug

Attach a forceps/irrigation plug to the instrument channel port.

3.5 Inspection of ancillary equipment

1 Inspect the following equipment as described in their respective instruction manuals.

- Light source
- Video system center
- Monitor
- EndoTherapy accessories

2 Inspect the irrigation system to be used.

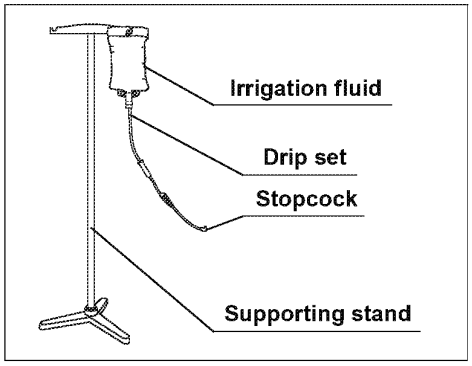

Figure 3.15

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3.6 Connection of the endoscope and ancillary equipment

Connect the ancillary equipment to the endoscope as described below.

Connection to the light source and video system center

WARNING

If the video connector and video system center are not connected properly, the endoscopic image may flicker or may not be displayed. Continuous use of such an endoscope may cause patient injury, bleeding, and/or perforation.

CAUTION

Before connecting the video connector to the video system center, confirm that the electrical contacts are not wet. If the electrical contacts are wet, the endoscope and video system center may malfunction.

NOTE

Connect the endoscope's light guide connector to the light source, then connect the video connector to the video system center. This can prevent a twisting of the video cable, and the video connector can be connected smoothly.

1. If any ancillary equipment is ON, turn it OFF.
2. While holding the video connector with one hand, insert the light guide connector completely into the output socket of the light source.

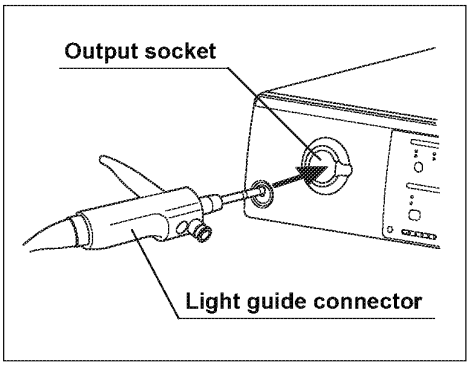

Figure 3.16

3. Make sure that the UP mark on the video connector is facing up. (See Figure 3.17)

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4 Hold the video system center stationary with one hand. With the other hand, push the video connector into the video connector socket until it clicks.

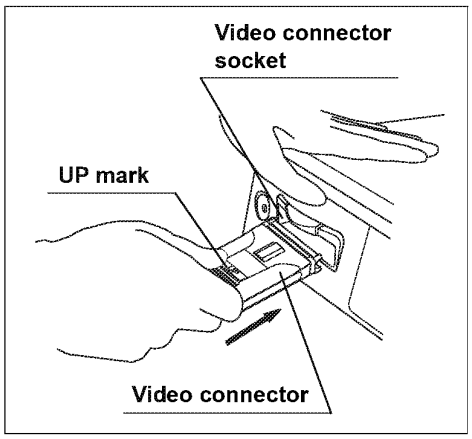

Figure 3.17

5 Confirm that the video connector is securely attached by pulling it gently.

Connection of irrigation system

Connect the irrigation tube from the irrigation system to the irrigation port on a forceps/irrigation plug.

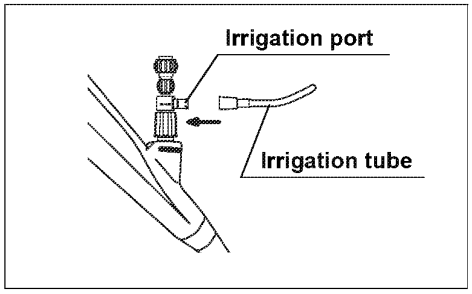

Figure 3.18

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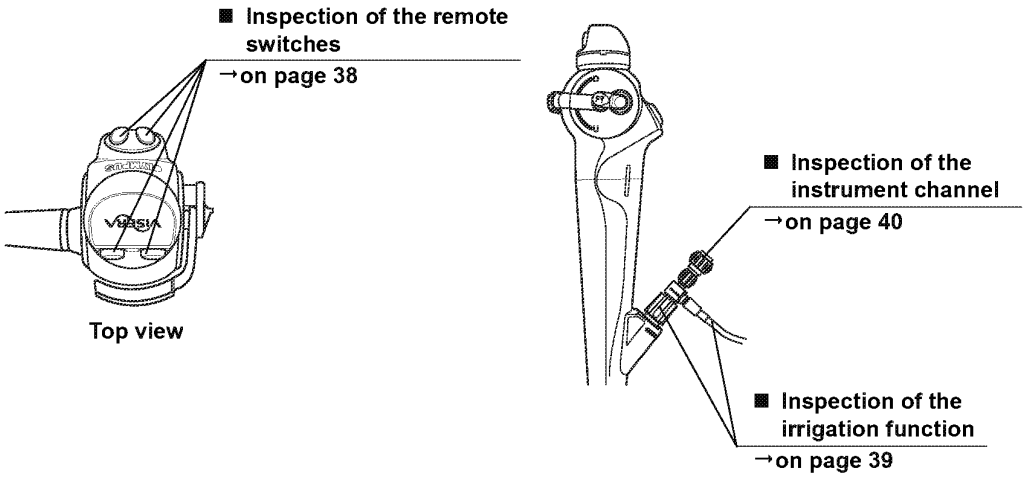
3.7 Inspection of the endoscopic system

■ Inspection summary



■ Inspection of the ancillary equipment

Turn ON the video system center, light source, and monitor. Inspect them as described in their respective instruction manuals.

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Inspection of the endoscopic image

Confirm that the WLI and NBI endoscopic images are normal.

WARNING

Do not stare directly into the distal end of the endoscope while the examination light is ON. Eye injury may result.

NOTE

Confirm that the endoscope provides a live image and has the correct image orientation.

1. Before inspection, wipe the objective lens with clean lint-free cloths moistened with 70% ethyl or 70% isopropyl alcohol.
2. Observe the palm of your hand in the WLI and NBI endoscopic images.

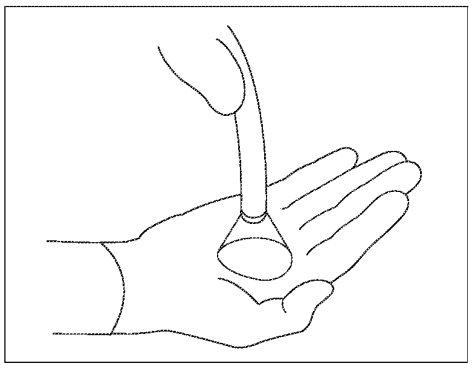

Figure 3.19

3. Confirm that light is output from the endoscope's distal end. (See Figure 3.19)
4. Adjust the brightness level as appropriate.
5. Confirm that the WLI and NBI endoscopic images are free from noise, blur, fog, or other irregularities.
6. Turn the UP/DOWN angulation control lever slowly in each direction until it stops.

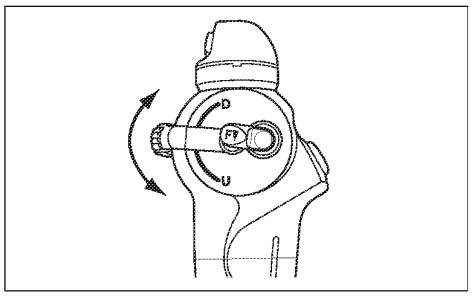

Figure 3.20

7. Confirm that the WLI and NBI endoscopic images do not momentarily disappear or display any other irregularities.

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Inspection of the remote switches

WARNING

All remote switches should be checked to work normally even if they are not expected to be used. The endoscopic image may freeze, or other irregularities may occur during examination and may cause patient injury, bleeding, and/or perforation.

CAUTION

Detach the sterilization cap from the venting connector after gas sterilization (e.g., ethylene oxide gas sterilization, hydrogen peroxide low temperature plasma). Otherwise, the remote switches may not work normally due to a difference between internal and external pressures of the endoscope.

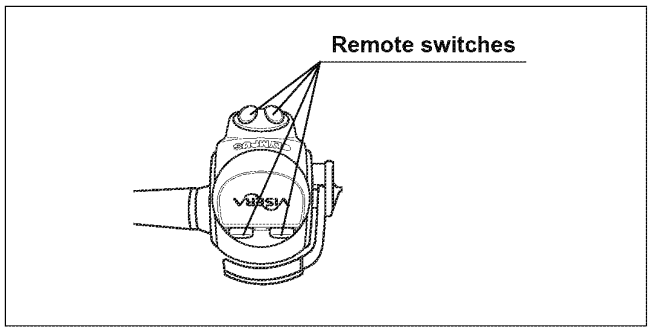

Figure 3.21

1. Depress every remote switch.
2. Confirm that the specified functions work normally.

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Inspection of the irrigation function

1. Inject irrigation fluid through the irrigation tube.
2. Confirm that fluid is emitted from the instrument channel outlet at the distal end of the endoscope.
3. Confirm that no water leaks from a forceps/irrigation plug and irrigation tube.

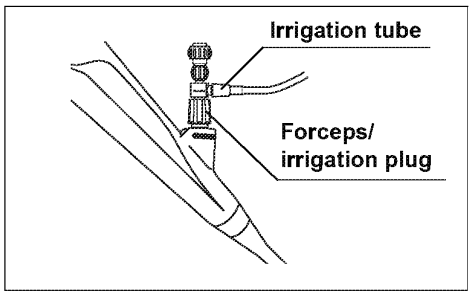

Figure 3.22

NOTE

The amount of irrigation fluid will be reduced when an EndoTherapy accessory is inserted in the instrument channel. Confirm the amount of irrigation fluid under these conditions in advance.

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Inspection of the instrument channel

WARNING

Keep your eyes away from the distal end when inserting EndoTherapy accessories. Extending the EndoTherapy accessory from the distal end could cause an eye injury.

CAUTION

- Use EndoTherapy accessories with the same color code (ø 2.0 mm channel or less). The endoscope and/or the EndoTherapy accessory may be damaged.
- If significant resistance is encountered and insertion becomes very difficult, straighten the bending section as much as possible without losing the endoscopic image. Inserting EndoTherapy accessories with excessive force may damage the endoscope and/or the EndoTherapy accessories.
- Confirm that the tip of the EndoTherapy accessory is closed or retracted into its sheath and slowly insert the EndoTherapy accessory into the forceps port of the sealing accessories. Do not open the tip of the EndoTherapy accessory or extend the tip of the EndoTherapy accessory from its sheath while inserting it into the channel. The endoscope and/or the EndoTherapy accessory may be damaged.
- Hold the EndoTherapy accessory close to the forceps port of the sealing accessories and insert it straight into the sealing accessories using slow, short strokes. The sheath of the EndoTherapy accessory could bend or break.

1. Straighten the insertion section of the endoscope.
2. Insert the EndoTherapy accessory straight into the forceps port of the sealing accessories while closing its distal end and retracting it into the sheath.
3. Confirm that the EndoTherapy accessory extends smoothly from the instrument channel outlet at the distal end of the endoscope. Also make sure that no foreign objects come out of the distal end.
4. Confirm that the EndoTherapy accessory is withdrawn smoothly from the sealing accessories.

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Chapter 4 Operation

This manual does not explain or discuss clinical endoscopic procedures. It only describes basic operation and precautions related to the operation of this endoscope. Therefore, the operator of this endoscope must be a physician or medical personnel under the supervision of a physician and must have received sufficient training in clinical endoscopic technique.

4.1 Precautions

WARNING

- To guard against dangerous chemicals and potentially infectious material during the procedure, wear personal protective equipment, such as eyewear, face mask, moisture-resistant clothing, and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed.
- Anytime you observe an irregularity in an endoscope function, stop the examination immediately and slowly remove the endoscope while viewing the endoscopic image if possible. Using an endoscope that is not functioning properly may cause patient injury.
- The temperature of the distal end of the endoscope may exceed 41°C (106°F) and reach 50°C (122°F) due to intense endoscopic illumination. Surface temperatures over 41°C (106°F) may cause mucosal burns. Always maintain a suitable distance necessary for adequate viewing while using the minimum level of illumination for the minimum amount of time. Do not use close stationary viewing or leave the distal end of the endoscope close to the mucous membrane for a long time without necessity.
- Whenever possible, do not leave the endoscope illuminated before and/or after an examination. Continued illumination will cause the distal end of the endoscope to become hot and could cause operator and/or patient burns.
- Never insert or withdraw the endoscope under any of the following conditions. Patient injury, bleeding, and/or perforation can result.
  - While the EndoTherapy accessory extends from the distal end of the endoscope.
  - While the bending section is locked in position.
  - Insertion or withdrawal with excessive force.

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WARNING

- If any of the following conditions occur during an examination, immediately stop the examination and withdraw the endoscope from the patient as described in Section 5.3, "Withdrawal of the endoscope with an irregularity".
  - If any irregularity is observed with the functionality of the endoscope.
  - If the endoscopic image on the monitor disappears or freezes unexpectedly.
  - If noise, blur or fog appear on the endoscopic image.
  - If the angulation control lever does not move.
  - If the angulation control mechanism is not functioning properly.

  Continued use of the endoscope under these conditions could result in patient injury, bleeding, and/or perforation.
- If an abnormal endoscopic image appears or an abnormal function occurs but quickly corrects itself, the endoscope may have malfunctioned. In this case, stop using the endoscope because the irregularity can occur again and the endoscope may not return to its normal condition. Stop the examination immediately and slowly withdraw the endoscope while viewing the endoscopic image. Otherwise, patient injury, bleeding, and/or perforation can result.
- The endoscopic image may be disturbed while switching between WLI observation mode and NBI observation mode. Therefore, do not perform any endoscopic operation or treatment while switching between WLI observation mode and NBI observation mode. Injury in the body cavity may result.
- When a part of the endoscopic image, normal colors, or a whole image is not displayed, the image sensor may be damaged. Using the damaged image sensor continuously for a long time makes the distal end of the endoscope extremely hot. Immediately turn OFF the video system center and light source. Otherwise, operator or patient burns may result.
- If the endoscopic image on the monitor should unexpectedly disappear or freeze during an examination and cannot be restored, turn the video system center OFF and then ON again. If the image still does not appear, stop the examination immediately, turn the video system center OFF, place the UP/DOWN angulation lock in the free "F▼" position, then, without touching the angulation control lever, slowly withdraw the endoscope from the patient.
- If the angulation control mechanism or any other part of the system is not functioning properly, stop the procedure immediately and place the UP/DOWN angulation lock in the free "F▼" position. Then carefully withdraw the endoscope while observing the endoscopic image. If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope carefully. If the endoscope cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope may cause patient injury, bleeding, and/or perforation. If any irregularities with the endoscope are observed, contact Olympus.

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WARNING

- Turn the video system center ON to operate the light source's automatic brightness function. When the video system center is OFF, it cannot operate the light source's automatic brightness function, and the light intensity may be set to the maximum level. In this case, the distal end of the endoscope can become hot and could cause operator and/or patient burns.
- When performing high-frequency cauterization, do not get the external surface of the control section and its surroundings wet. Electric current may flow, and operator and patient injury can result.
- The endoscope must be always sterilized before using for percutaneous nephroscopic diagnosis.
- Adjust the white balance of the endoscope before the procedure to display the correct color on the monitor.
- Detach the ETO cap before the operation, as liquid may enter inside of the endoscope.

CAUTION

- Set the brightness of the light source to the minimum level necessary to perform the procedure safely.
- The surface temperatures of the endoscope may become maximum 50°C (122°F) by the operating environment. If the operator and/or patient touches there for a long time, it may cause the operator and/or patient burns.
- If the endoscope is dropped or the distal end of the endoscope receives hard impact, the endoscope may be damaged even if a crack or chip of the lens on the distal end can not be found. Stop using the endoscope and contact Olympus.
- The observation of X-ray image may interfere with the endoscopic image. This is normal and does not indicate a malfunction.

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4.2 Insertion

Holding and manipulating the endoscope

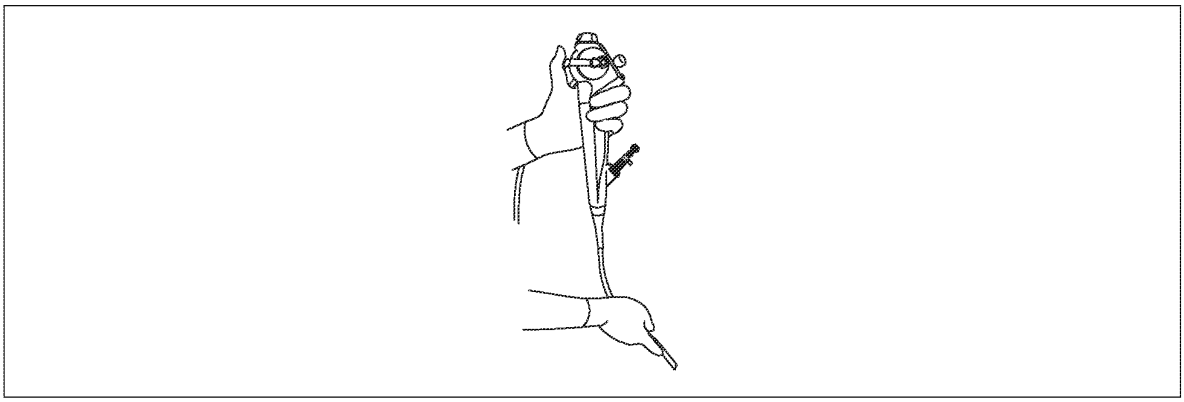

Figure 4.1

1. Hold the control section of the endoscope using your left hand.
2. Operate remote switches 1 and 4 using the left index finger.
3. Operate the UP/DOWN angulation control lever using the left thumb.
4. Maintain the insertion section using the right hand.

Irrigation

Feed the irrigation fluid through the irrigation tube.

NOTE

If it doesn't keep the view clear enough because of the amount of irrigation fluid while passing an EndoTherapy accessory through the channel, stop the examination. Then withdraw the EndoTherapy accessory and irrigation.

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Insertion of the endoscope

CAUTION

- Do not apply olive oil or products containing petroleum-based lubricants (e.g., Vaseline®) to the endoscope. These products may cause stretching and deterioration of the bending section's covering.
- Do not allow the insertion section to be bent within a distance of 10 cm or less from the junction of the boot. Insertion section damage can occur.

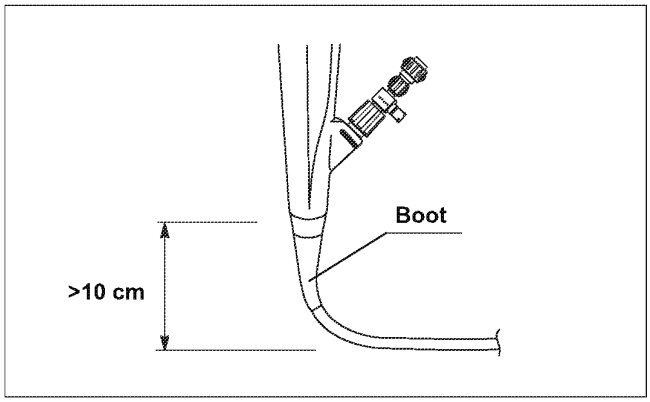

Figure 4.2

1 If necessary, apply a medical-grade, water-soluble lubricant to the insertion section.

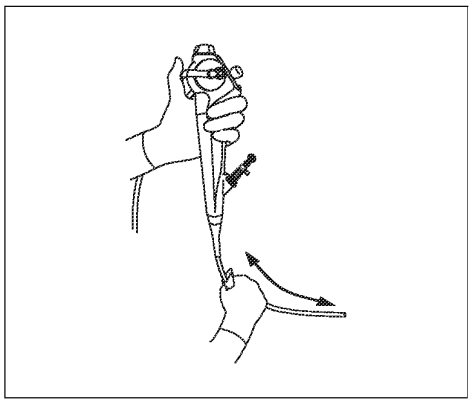

Figure 4.3

2 Insert the distal end of the endoscope into the body cavity while viewing the endoscopic image.

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Angulation of the distal end

WARNING

- If the angulation control mechanism or any other part of the system is not functioning properly, stop the examination immediately and place the UP/DOWN angulation lock in the free "F▼" position. Then carefully withdraw the endoscope while observing the endoscopic image. If the endoscope cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope carefully. If the endoscope cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope may cause patient injury, bleeding, and/or perforation. If any irregularities with the endoscope are observed, contact Olympus.
- Operate the UP/DOWN angulation control lever slowly while observing the endoscopic image. Otherwise, patient injury, bleeding, and/or perforation can result.

NOTE

- The endoscope's UP/DOWN angulation lock is used to hold the angulated distal end in position. When passing an EndoTherapy accessory through the channel while the angulation is locked, the angulation control lever should be held in place to help maintain the angle of the distal end. When it is necessary to keep the angulation stationary, hold the angulation control lever in place.
- When operating the UP/DOWN angulation lock, hold the UP/DOWN angulation control lever stationary with your fingers. The angulation will change.

Operate the UP/DOWN angulation control lever slowly to guide the distal end for insertion and observation.

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Observation of the endoscopic image

WARNING

- Do not rely on the NBI observation mode alone for primary detection of lesions to make a decision regarding any potential diagnostic or therapeutic intervention.
- If the endoscopic image seems to be dark in the NBI observation mode, change to the normal observation mode. Otherwise, the examination might not be done properly.

NOTE

The color tone and brightness of the NBI observation mode is different from the WLI observation mode. Use the NBI observation mode only after fully understanding its features.

Refer to the light source's instruction manual for instructions on how to adjust the brightness.

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4.3 Using EndoTherapy accessories

For more information on combining the endoscope with particular EndoTherapy accessories, refer to the "■ Compatible EndoTherapy accessories" on page 68 and the instruction manuals for the accessories. Also, refer to their respective instruction manuals for operating the accessories.

WARNING

- When using EndoTherapy accessories, keep the distance between the distal end of the endoscope and the mucous membrane greater than the endoscope's minimum visible distance so that the EndoTherapy accessory remains visible in the endoscopic image. If the distal end of the endoscope is placed closer than its minimum visible distance, the position of the accessory cannot be seen in the endoscopic image. This could cause serious patient injury and/or equipment damage. The minimum visible distance depends on the type of endoscope being used. Refer to Section 2.2, "Specifications".
- When inserting or withdrawing an EndoTherapy accessory, confirm that its distal end is closed or completely retracted into the sheath. Insert or withdraw the EndoTherapy accessory slowly and straight into or from the forceps port of the forceps/ irrigation plug. The biopsy valve may be damaged and pieces of it could fall off.
- If insertion or withdrawal of EndoTherapy accessories is difficult, straighten the bending section as much as possible without losing the endoscopic image. Inserting or withdrawing EndoTherapy accessories with excessive force may damage the instrument channel or EndoTherapy accessories and could cause some parts to fall off and/or cause patient injury.
- If the distal end of an EndoTherapy accessory is not visible in the endoscopic image, do not open the distal end of the EndoTherapy accessory. This could cause patient injury, bleeding, perforation, and/or equipment damage.
- If the EndoTherapy accessory cannot be withdrawn from the endoscope, close the tip of the EndoTherapy accessory or retract the tip of the EndoTherapy accessory into its sheath. Then carefully withdraw both the endoscope and the EndoTherapy accessory together while observing the endoscopic image. Inserting or withdrawing EndoTherapy accessories with excessive force may damage the instrument channel or EndoTherapy accessories and/or cause patient injury.
- Do not use the channel cleaning brush for cytologic tissue sampling or other diagnostic or therapeutic purposes. Patient injury, cross-contamination, and/or equipment damage may occur.

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CAUTION

Select the EndoTherapy accessories compatible with the endoscope by referring to "Channel inner diameter" in "■ Specifications" on page 21.

NOTE

When using EndoTherapy accessories, the image might become dark. In that case, adjust the brightness of the light source.

■ *Insertion of EndoTherapy accessories into the endoscope*

WARNING

Do not insert EndoTherapy accessories forcibly or abruptly. The EndoTherapy accessory may extend from the distal end of the endoscope abruptly, which could cause patient injury, bleeding, and/or perforation.

CAUTION

- When the bending section of the endoscope angulates significantly and insertion of an EndoTherapy accessory becomes very difficult, straighten the bending section as much as possible. Inserting the EndoTherapy accessory with excessive force may damage the instrument channel and/or the EndoTherapy accessory.
- Confirm that the tip of the EndoTherapy accessory is closed or retracted into its sheath. Slowly insert the EndoTherapy accessory into the forceps/irrigation plug. Do not open the tip of the EndoTherapy accessory or extend the tip of the EndoTherapy accessory from its sheath while inserting the EndoTherapy accessory into the instrument channel. The instrument channel and/or the EndoTherapy accessory may be damaged.
- Hold the EndoTherapy accessory close to the forceps port of the sealing accessories and insert it straight into the forceps port of the sealing accessories using slow short strokes. Otherwise, the EndoTherapy accessory could bend or break.

1 Select EndoTherapy accessories compatible with the endoscope from the "■ Compatible EndoTherapy accessories" on page 68 and the accessories' instruction manuals for operating instructions.

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2 Hold the UP/DOWN angulation control lever stationary so that the bending section is straight.

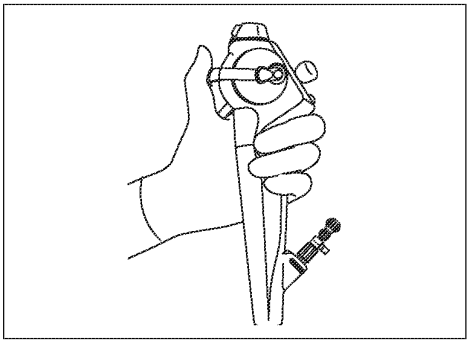

Figure 4.4

3 Confirm that the tip of the EndoTherapy accessory is closed or retracted into its sheath.

4 Insert the EndoTherapy accessory slowly and straight into the forceps port of the sealing accessories.

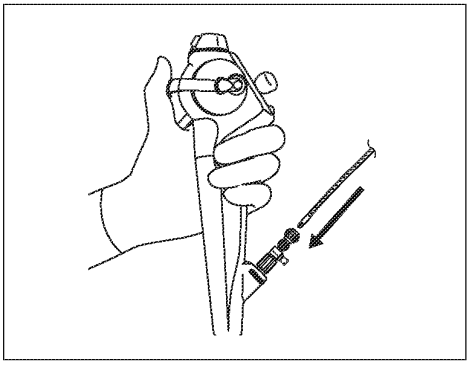

Figure 4.5

5 Hold the EndoTherapy accessory at a point approximately 4 cm from the sealing accessories and advance it slowly and straight into the sealing accessories using short strokes while observing the endoscopic image.

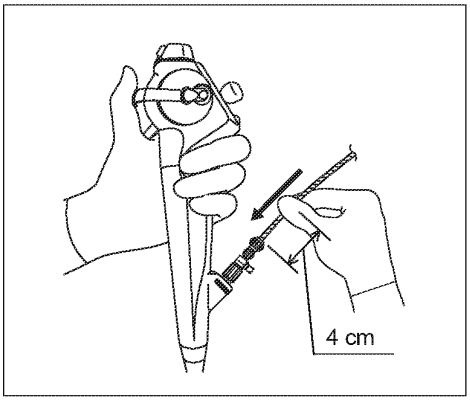

Figure 4.6

NOTE

When the tip of the EndoTherapy accessory extends approximately 2 mm from the distal end of the endoscope, the accessory will appear in the endoscopic image.

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Operation of EndoTherapy accessories

Operate the EndoTherapy accessory according to the directions given in its instruction manual.

Withdrawal of EndoTherapy accessories

WARNING

- Fluid might spray when the EndoTherapy accessories are withdrawn from the sealing accessories. To prevent this, hold a piece of gauze around the accessory and the sealing accessories during withdrawal.
- Do not withdraw the EndoTherapy accessory if the tip is open or extended from its sheath; patient injury and/or instrument damage may occur.
- Withdraw the EndoTherapy accessory slowly and straight out of the sealing accessories. Otherwise, the biopsy valve could be damaged. This may leak or spray fluid, posing an infection control risk.
- If the EndoTherapy accessory cannot be withdrawn from the endoscope, close the EndoTherapy accessory and/or retract it into its sheath. Then carefully withdraw both the endoscope and the EndoTherapy accessory together under endoscopic observation. Take care not to cause tissue trauma.

Withdraw the EndoTherapy accessory slowly while the tip of the EndoTherapy accessory is closed and/or retracted into its sheath.

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High-frequency cauterization

WARNING

- When performing high-frequency cauterization, use only an isolated-type of a forceps/irrigation plug. If a non-isolated type is used, operator injury can result.
- Always confirm that the tissue is an appropriate distance away from the distal end of the endoscope. If high-frequency cauterization is performed when the distal end of the endoscope contacts the tissue, patient injury, burns, bleeding, perforation, and equipment damage may occur.
- Use non-electrolytic solution for irrigation. Once urine and/or blood is mixed into the solution, the non-electrolytic solution will be diluted, and electrosurgical faculty may be degraded. In this case, do not raise the power of the electrosurgical unit. Instead, replace the diluted solution with new solution. If the power setting is raised, patient injury can result.

- Do not perform high-frequency cauterization while supplying oxygen. This may result in combustion during cauterization.
- Always confirm that the electrode section of the electrosurgical accessory is at an appropriate distance from the distal end of the endoscope. Confirm that the entire green marking (in case of WLI observation mode) at the distal tip of the electrosurgical accessory can be observed on the endoscopic image. If the electrode is used when it is too close to the distal end of the endoscope, the endoscope and/or ancillary equipment may be damaged. Patient injury, burns, bleeding, perforation, and/or equipment damage may result.

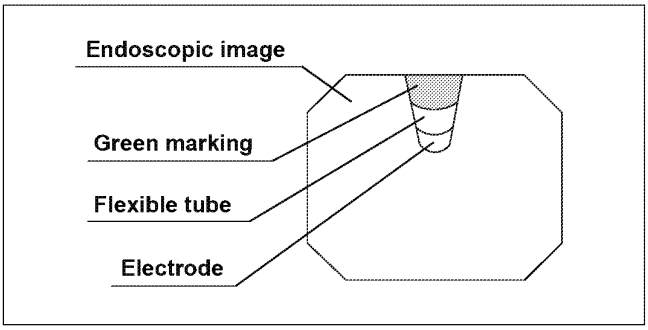

Figure 4.7

- Be sure to contact the electrode section of the EndoTherapy accessory with tissue when performing high-frequency cauterization treatment to prevent equipment damage and operator and/or patient burns.
- Improper connection between the patient plate and patient's skin surface may cause burns. For further details on the patient plate, refer to the patient plate's instruction manual.

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WARNING

- Do not perform high-frequency cauterization without gloves. Operator injury can result.
- Before performing high-frequency cauterization, inspect the surface of the endoscope for any dents, bulges, or other irregularities. Otherwise, patient injury, burns, bleeding, perforation, and/or equipment damage may result.
- When performing high-frequency cauterization, do not use the electrosurgical unit's SPRAY coagulation mode. The endoscope may be damaged and it cause patient and/or operator burns.
- Set the electrosurgical unit to the minimum necessary output level. If the output level is too high, the endoscope's and/or accessory's insulation may be damaged and cause operator and/or patient burns.
- Prolonged excessive flow rates and/or irrigation fluid/gas pressures may result in excessive absorption into the vascular system (e.g., through an open vessel) or gas embolism.

NOTE

The application of high-frequency current may interfere with the endoscopic image. This does not indicate a malfunction.

Prepare, inspect, and connect the electrosurgical unit and electrosurgical accessories as described in their instruction manuals.

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4.4 Withdrawal of the endoscope

WARNING

- If the endoscope or EndoTherapy accessory cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope carefully. If the endoscope cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope or EndoTherapy accessory may cause patient injury, bleeding, and/or perforation. If any irregularities with the endoscope are observed, contact Olympus.
- Avoid patient fluids adhering to the withdrawn endoscope from coming in contact with the bed or floor. The patient fluids may pose an infection control risk to the patient and/or medical personnel.

1 Turn the UP/DOWN angulation lock to the free "F▼" position.

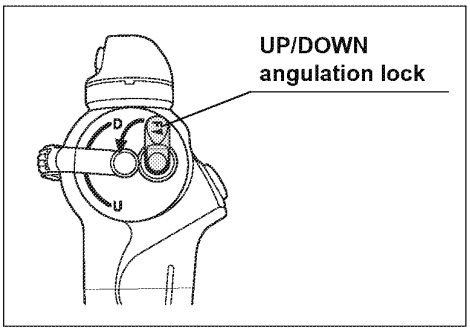

Figure 4.8

2 Carefully withdraw the endoscope while observing the endoscopic image.

3 Reprocess the endoscope and accessories after the procedure as described in the "REPROCESSING MANUAL" with your endoscope model listed on the cover.

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4.5 Transportation of the endoscope

Transporting within the hospital

When carrying the endoscope by hand, loop the universal cord, hold the light guide connector with the control section in one hand and hold the distal end of the insertion tube securely, but gently without squeezing, with the video connector in the other hand.

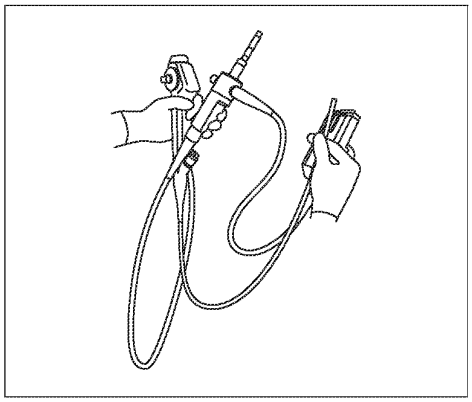

Figure 4.9

Transporting outside the hospital

WARNING

Always reprocess the endoscope after removing it from the carrying case. If the endoscope is not reprocessed, it could pose an infection control risk.

CAUTION

- The carrying case cannot be reprocessed. Reprocess the endoscope before placing it in the carrying case.
- Attach the ETO cap (MB-156) when transporting the endoscope. Otherwise, the endoscope may be damaged by changes in air pressure.

Transport the endoscope in the carrying case.

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4.5 Transportation of the endoscope

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Chapter 5 Troubleshooting

The countermeasures against troubles are described in this chapter.

5.1 Troubleshooting

If any irregularity is observed during the inspection described in Chapter 3, “Preparation and Inspection”, do not use the endoscope and solve the problem as described in Section 5.2, “Troubleshooting guide”.

If the problem still cannot be resolved, send the endoscope to Olympus for repair as described in Section 5.4, “Returning the endoscope for repair”.

Also, should any irregularity be observed while using the endoscope, stop using it immediately and withdraw the endoscope from the patient as described Section 5.3, “Withdrawal of the endoscope with an irregularity”.

WARNING

- Never use the endoscope on a patient if an irregularity is observed. Damage or an irregularity in the endoscope may compromise patient or user safety and may result in more severe equipment damage.
- If any parts of the endoscope fall off inside the patient body due to equipment damage or failure, stop using the endoscope immediately and retrieve the parts in an appropriate way.

The accessories are consumables. Olympus does not repair accessory parts. If an accessory part becomes damaged, contact Olympus to purchase a replacement.

5.2 Troubleshooting guide

The following table shows the possible causes of and countermeasures against troubles that may occur due to equipment setting errors or deterioration of consumables.
Troubles or failures due to other causes than those listed below should be serviced. As repair performed by persons who are not qualified by Olympus could cause patient or user injury and/or equipment damage, be sure to contact Olympus for repair following the instructions given in Section 5.4, “Returning the endoscope for repair”.

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Image quality or brightness

Irregularity description	Possible cause	Solution
There is no video image.	Not all equipment is ON.	Turn ON all equipment.
	The video connector is not connected securely.	Insert the video connector with its UP mark facing upwards into the output socket of the video system center securely until it stops and clicks.
An image is not clear.	The objective lens is dirty.	Wipe the objective lens with a cotton swab moistened with 70% ethyl or 70% isopropyl alcohol.
An image is excessively dark or bright.	The light source is not set properly.	Adjust the light source's setting as described in its instruction manual.
	The light guide lens at the distal end of the endoscope is dirty.	Wipe the light guide lens with a cotton swab moistened with 70% ethyl or 70% isopropyl alcohol.
	The glass at the light guide connector end is dirty.	Wipe the glass with a cotton swab moistened with 70% ethyl or 70% isopropyl alcohol.

Irrigation fluid feeding

Irregularity description	Possible cause	Solution
No irrigation fluid feeding.	The instrument channel is obstructed.	Clean the channel with a channel cleaning brush as described in the "REPROCESSING MANUAL" with your endoscope model listed on the cover.
	The sealing accessory is worn out.	Replace it with a new one.
Irrigation fluid leaks.	The instrument channel is obstructed.	Clean the channel with a channel cleaning brush as described in the "REPROCESSING MANUAL" with your endoscope model listed on the cover.
	The sealing accessory is worn out.	Replace it with a new one.

Angulation

Irregularity description	Possible cause	Solution
Resistance is encountered when rotating the UP/DOWN angulation control lever.	The UP/DOWN angulation lock is engaged.	Rotate the UP/DOWN angulation lock in the "F▼" direction.

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■ EndoTherapy accessories

Irregularity description	Possible cause	Solution
EndoTherapy accessory does not pass through the instrument channel smoothly.	An incompatible EndoTherapy accessory is being used.	Refer to the "■ Compatible EndoTherapy accessories" on page 68 and select a compatible EndoTherapy accessory. Confirm that the color code on the EndoTherapy accessory matches that on the endoscope.
	The forceps/irrigation plug is incorrectly assembled.	Reassemble it correctly as described in its instruction manual.
	The bending section angulates sharply.	Straighten it as much as possible.
	The tightening ring on the forceps/irrigation plug is turned too tightly.	Turn the tightening ring so that the ends of the biopsy valve and tightening ring are aligned.

■ Other

Irregularity description	Possible cause	Solution
The remote switch does not work.	The wrong remote switch is operated.	Operate the correct remote switch.
	The remote switch function has been set incorrectly.	Set the remote switch function correctly as described in the video system center's instruction manual.

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5.3 Withdrawal of the endoscope with an irregularity

If an irregularity occurs while the endoscope is in use, take proper measures as described in either "■ Withdrawal when the WLI and NBI endoscopic images appear on the monitor", "■ Withdrawal when either the WLI or the NBI endoscopic image does not appear on the monitor", or "■ Withdrawal when all endoscopic images do not appear on the monitor or a frozen image cannot be restored" below. After withdrawal, return the endoscope for repair as described in Section 5.4, "Returning the endoscope for repair".

WARNING

If the endoscope or EndoTherapy accessory cannot be withdrawn from the patient smoothly, do not attempt to forcibly withdraw it. Rather, withdraw the endoscope or EndoTherapy accessory carefully. If the endoscope or EndoTherapy accessory cannot be withdrawn from the patient, consider removing it through open surgery and take proper measures. Forcibly withdrawing the endoscope or EndoTherapy accessory may cause patient injury, bleeding, and/or perforation. If any irregularities with the endoscope or EndoTherapy accessory are observed, contact Olympus.

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■ *Withdrawal when the WLI and NBI endoscopic images appear on the monitor*

1. Turn all equipment OFF except the video system center, light source, and monitor.
2. When the NBI endoscopic image is displayed, switch to the WLI endoscopic image by operating the video system center and light source.
3. When using the image magnification function of the video system center, release the function.
4. When using an EndoTherapy accessory, close the tip of the EndoTherapy accessory and/or retract it into its sheath. Then withdraw the EndoTherapy accessory slowly.
5. Turn the UP/DOWN angulation lock to the free "F▼" position.

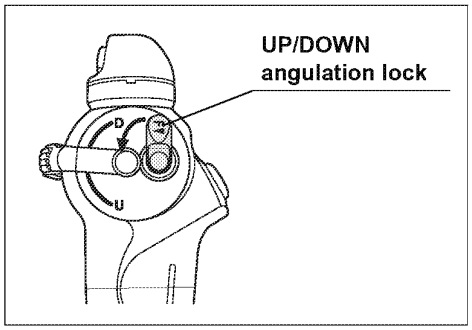

Figure 5.1

6. Carefully withdraw the endoscope while observing the endoscopic image.

■ *Withdrawal when either the WLI or the NBI endoscopic image does not appear on the monitor*

1. Turn all equipment OFF except the video system center, light source, and monitor.
2. Operate the video system center and the light source to switch to the endoscopic image that is still displayed.
3. Follow the procedure of Step 3 above in "■ Withdrawal when the WLI and NBI endoscopic images appear on the monitor". Carefully withdraw the endoscope under the visible observation mode when the WLI endoscopic image is not displayed.

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■ *Withdrawal when all endoscopic images do not appear on the monitor or a frozen image cannot be restored*

1. Turn all equipment OFF except the video system center, light source, and monitor.
2. Turn the video system center and light source OFF and then ON again. If the WLI or NBI endoscopic image appears or the frozen image is restored, follow the procedure given in "■ Withdrawal when either the WLI or the NBI endoscopic image does not appear on the monitor", beginning from Step 2.
   If all endoscopic images still do not appear or the frozen image cannot be restored, perform the following steps.
3. Turn the video system center, light source, and monitor OFF.
4. When using an EndoTherapy accessory, close the tip of the EndoTherapy accessory and/or retract it into its sheath. Then withdraw the EndoTherapy accessory slowly.
5. Turn the UP/DOWN angulation lock to the free "F▼" position.

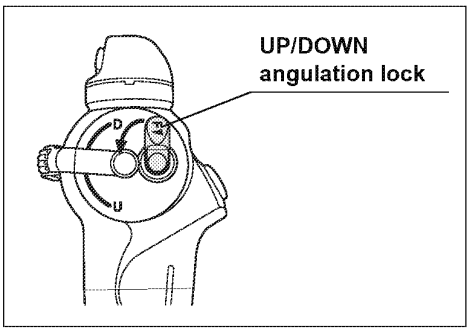

Figure 5.2

6. Turn the UP/DOWN angulation control lever to its neutral position and release the angulation control lever.
7. Withdraw the endoscope from the patient carefully.

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5.4 Returning the endoscope for repair

WARNING

Thoroughly reprocess the endoscope before returning it for repair. Improperly reprocessed equipment poses an infection control risk to each person who handles the endoscope within the hospital and at Olympus.

CAUTION

Olympus is not liable for any injury or damage that occurs as a result of repairs attempted by non-Olympus personnel.

Before returning the endoscope for repair, contact Olympus. With the endoscope, include a description of the malfunction or damage and the name and telephone number of the individual at your location who is most familiar with the problem. Also include a repair purchase order. When returning the endoscope for repair, follow the instructions given in "■ Transporting outside the hospital" on page 55.

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5.4 Returning the endoscope for repair

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Appendix

The equipment compatible with this endoscope and the EMC information are described in this Appendix.

Combination equipment

■ System chart

The recommended combination of equipment and accessories that can be used with this endoscope are listed below. Some items may not be available in some areas. New products released after the introduction of the endoscope may also be compatible for use in combination with the endoscope. For further details, contact Olympus.

WARNING

Be sure to use the equipment in one of the recommended combinations.
If combinations of equipment other than those shown below are used, the full responsibility is assumed by the medical treatment facility.

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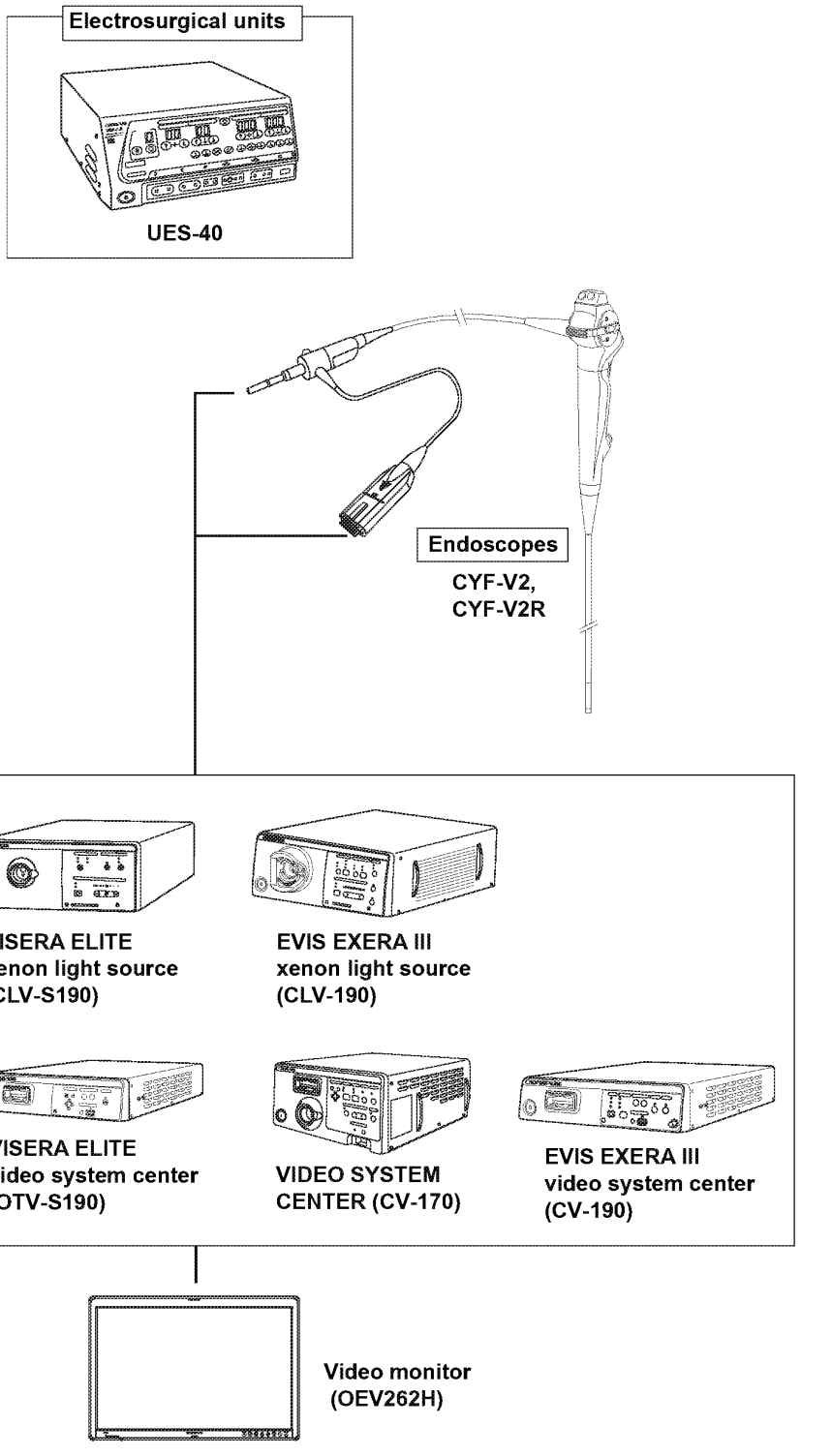

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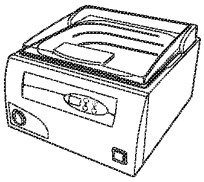
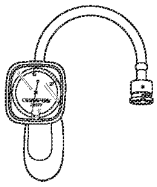
Reprocessing equipment

Single use combination cleaning brush (BW-411B)

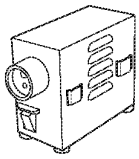


Ultrasonic cleaner (KS-2/ENDOSONIC)



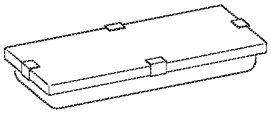
Leakage tester (WA23080A)

Leakage tester (MB-155)

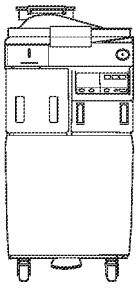


Maintenance unit (MU-1)

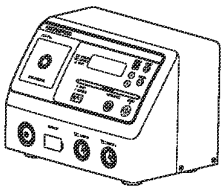
ETO cap (MB-156)



Sterilization tray (WA05991A[*1])



Endoscope reprocessor (OER-AW[*2], OER-Pro[*1], OER-Mini[*3], OER-Elite[*1])



Automated endoscope leak tester (ALT-Pro[*1])

*1 These products are available in the USA and some areas.

*2 This product is available in some areas other than the USA.

*3 This product is only available in the USA.

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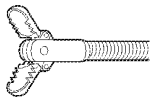
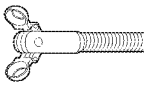
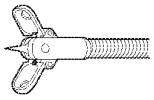
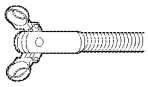
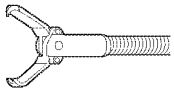
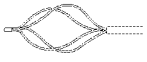
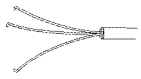
■ *Compatible EndoTherapy accessories*

❍ EndoTherapy accessories

Please note that some of the accessories may not be available in some areas.

	Biopsy forceps	Biopsy forceps (fenestrated)		Rotatable biopsy forceps (fenestrated)
	Alligator jaws type	Standard type	Standard type (with needle)	Standard type
Endoscope				
CYF-V2 CYF-V2R	FB-15C-1	FB-19SX-1 FB-21-SX-1	FB-34C-1	FB-19CR-1

	Grasping forceps	Grasping forceps
	Sharp tooth type	Basket type
Endoscope		
CYF-V2 CYF-V2R	FG-38SX-1 FG-53SX-1	FG-24SX-1

	Disposable grasping forceps			
	Spiral basket type		Parallel basket type	Three nail type
Endoscope				
CYF-V2 CYF-V2R	FG-51D	FG-52D	FG-55D	FG-54D

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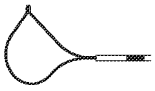
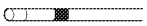
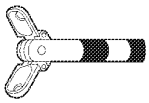
Electrosurgical accessories

Please note that some of the accessories may not be available in some areas.

	Electrosurgical snare Crescent type	Coagulation electrode	Hot biopsy forceps
Endoscope			
CYF-V2 CYF-V2R	SD-7C-1 SD-18C-1	CD-6C-1	FD-7C-1

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EMC information

NOTE

The ME system including the CYSTO-NEPHRO VIDEOSCOPE has the performance for providing a live endoscopic image that can be used for identifying observed objects. If the performance is lost or degraded, the ME system may not be able to provide an endoscopic image for diagnosis or treatment under endoscopic surgery (ex. if noise is superimposed on the endoscopic image, the observation target object may not be identified. Under the influence of electromagnetic waves, it is possible that the endoscopic live images of different directions from the upper and lower left and right directions of the endoscope tip intended by the operator may be displayed.). Refer to the Section 3.7, "Inspection of the endoscopic system" for using the ME system safely and for the purposes for which it is intended.

Guidance and manufacturer's declaration — Electromagnetic emissions

App.

This model is intended for use by medical personnel in hospital environments and for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment — Guidance
RF emissions CISPR 11	Group 1	This instrument uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emissions CISPR 11	Class B	This instrument's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Main terminal conducted emissions CISPR 11		
Harmonic emissions IEC 61000-3-2	Class A	This instrument's harmonic emissions are low and are not likely to cause any problem in the typical commercial power supply connected to this instrument.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	This instrument stabilizes its own radio variability and has no effect such as flicker in lighting apparatus.

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Guidance and manufacturer's declaration — Electromagnetic immunity

This model is intended for use by medical personnel in hospital environments and for use in the electromagnetic environment specified below. The customer or the user of this model should assure that it is used in such an environment.
This instrument can be used with the high-frequency electrosurgical equipment that designated by Olympus.

Immunity test	IEC 60601-1-2 (2014) test level	Compliance level	Electromagnetic environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	Contact: ±8 kV Air: ±2, ±4, ±8, ±15 kV	Same as left	Floors should be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to produce static, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Same as left	Mains power quality should be that of a typical commercial (original condition feeding the facilities) or hospital environment.
Surge IEC 61000-4-5	Differential mode: ±0.5, ±1 kV Common mode: ±0.5, ±1, ±2 kV for signal input/ output lines: ±2 kV	Same as left	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle/ 1 cycle	Same as left	Mains power quality should be that of a typical commercial or hospital environment. If the user of this instrument requires continued operation during power mains interruptions, it is recommended that this instrument be powered from an uninterruptible power supply or a battery.
	70% U_T (30% dip in U_T) for 25 cycle (50 Hz)/ 30 cycle (60 Hz) Phase angle causing voltage dips: 0°		
	0% U_T (100% dip in U_T) for 250 cycle (50 Hz)/ 300 cycle (60 Hz)		
	U_T is the a.c. mains voltage prior to application of the test level.		
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 Hz, 60 Hz)	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.

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Immunity test	IEC 60601-1-2 (2014) test level	Compliance level	Electromagnetic environment — Guidance
Conducted RF IEC 61000-4-6	3V (150 kHz – 80 MHz)	Same as left	–
	6V (ISM band of 150 kHz – 80 MHz)	Same as left	
	ISM (industry, science, and medical care) band of 6.765 MHz – 6.795 MHz, 13.553 MHz – 13.567 MHz, 26.957 MHz – 27.283 MHz, and 40.66 MHz – 40.70 MHz between 0.15 MHz and 80 MHz		
Radiated RF IEC 61000-4-3	3V/m (80 MHz – 2.7 GHz)	Same as left	–
Proximity magnetic field from RF communication equipment IEC 61000-4-3	Refer to the table of the next page.	Same as left	

NOTE

- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
- Electromagnetic interference may occur in the vicinity of high-frequency electrosurgical equipment and/or other equipment marked with the following symbol:

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NOTE

- Field strength from fixed RF transmitters as determined by an electromagnetic site survey[a)] should be less than the compliance level in each frequency range[b)].

  a) Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this model is used exceeds the applicable RF compliance level above, this model should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating this model.

  b) Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

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Test frequency [MHz]	Band [MHz]	Modulation*1	Maximum power [W]	Immunity test level [V/m]
385	380 – 390	Pulse modulation*1 18 Hz	1.8	27
450	430 – 470	FM ±5 kHz deviation 1 kHz sine	2	28
710	704 – 787	Pulse modulation*1 217 Hz	0.2	9
745				
780				
810	800 – 960	Pulse modulation*1 18 Hz	2	28
870				
930				
1720	1700 – 1990	Pulse modulation*1 217 Hz	2	28
1845				
1970				
2450	2400 – 2570	Pulse modulation*1 217 Hz	2	28
5240	5100 – 5800	Pulse modulation*1 217 Hz	0.2	9
5500				
5785				

*1 The carrier shall be modulated using a 50% duty cycle square wave signal.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the video system center, including cables specified by Olympus. Otherwise, degradation of the performance of this equipment could result.

Guidance and manufacturer's declaration — Cables used for EMC compliance testing

Refer to the instruction manuals for each piece of equipment.

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Section 13

Proposed Labeling

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Section 13.1
Proposed Instruction Labeling

Proposed Instruction Manuals and its contents are listed in the following section.

13.1.1 Operation Manual for CYF-V2/V2R (**Attachment 13.2**)
"Operation Manual for CYF-V2/V2R" describes the preparation, operation and maintenance of the CYF-V2 and CYF-V2R.

It also includes the important information about the intended use, applicability of use, user qualifications, names and address of the manufacturer, detailed operating or use instructions, pre-cleaning instruction, troubleshooting guide, warnings and cautions, information regarding operating environment, and routine maintenance and inspections.

13.1.2 Reprocessing Manual for CYF-V2/V2R (**Attachment 13.3**)
"Reprocessing Manual for CYF-V2/V2R" describes how to reprocess the CYF-V2 and CYF-V2R. It includes all the reprocessing methods applicable to CYF-V2 and CYF-V2R.

13.1.3 Operation Manual for CYF-VH/VHR (**Attachment 13.4**)
"Operation Manual for CYF-VH/VHR" describes the preparation, operation and maintenance of the CYF-VH and CYF-VHR.

It also includes the important information about the intended use, applicability of use, user qualifications, names and address of the manufacturer, detailed operating or use instructions, pre-cleaning instruction, troubleshooting guide, warnings and cautions, information regarding operating environment, and routine maintenance and inspections.

13.1.4 Reprocessing Manual for CYF-VH/VHR (**Attachment 13.5**)
"Reprocessing Manual for CYF-VH/VHR" describes how to reprocess the CYF-VH and CYF-VHR. It includes all the reprocessing methods applicable to CYF-VH and CYF-VHR.

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Section 13.2
Proposed Product Labeling

13.2.1. CYF-V2/V2R

(a) Product Labeling

The product labeling for CYF-V2/V2R is shown in Fig.13-1.

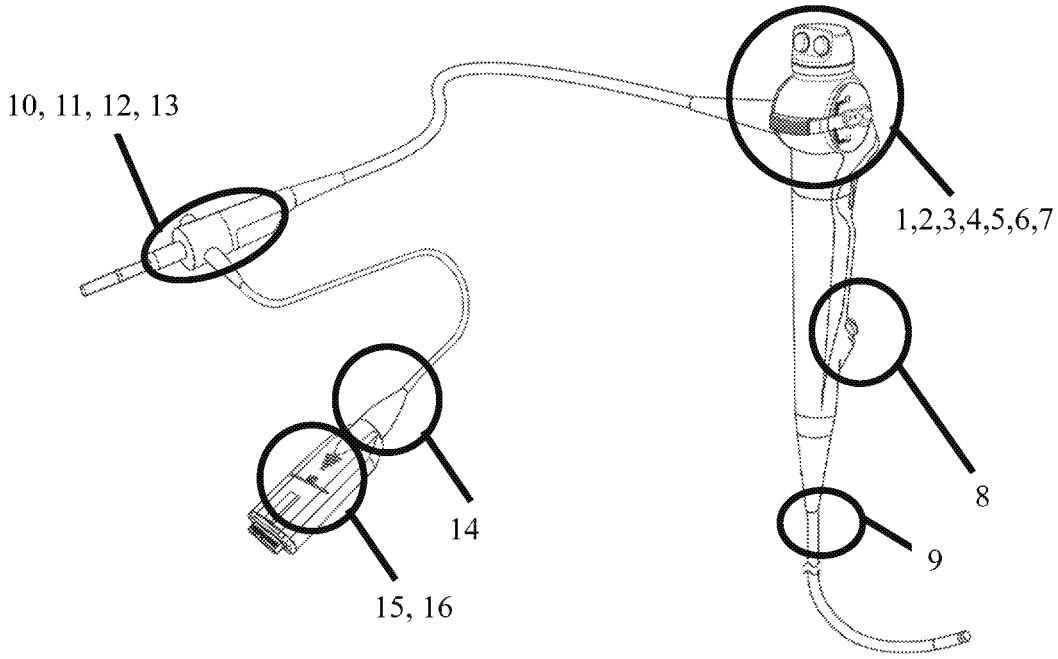
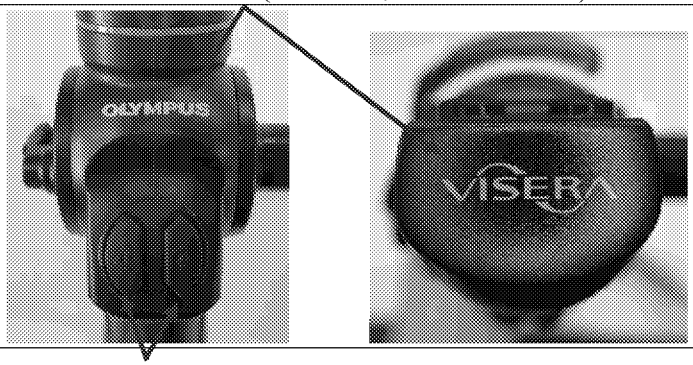


Fig.13-1. Product Labeling (CYF-V2/V2R)

1	Trade mark (CYF-V2, V2R common)
	
2	Switch 1 and Switch 4 (CYF-V2, CYF-V2R common)

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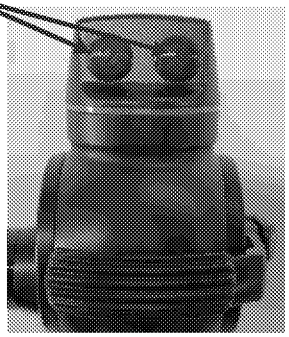
<tr><td></td><td colspan="2">  </td></tr>
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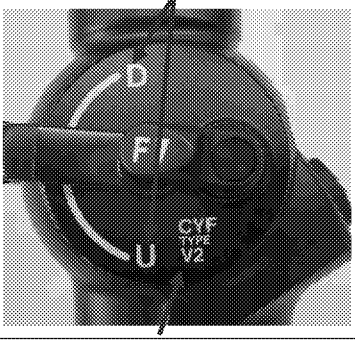
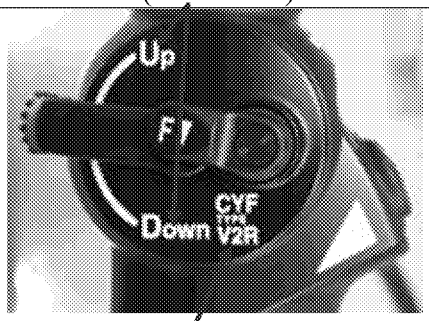
(CYF-V2)</td><td>Indication of angulation
(CYF-V2R)</td></tr>
<tr><td></td><td> 
</td><td> 
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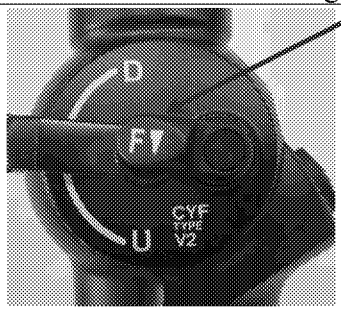
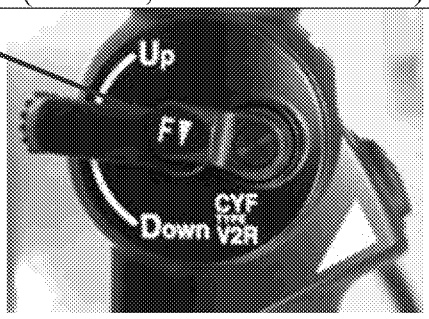
<tr><td>5</td><td>Model name (CYF-V2)</td><td>Model name (CYF-V2R)</td></tr>
<tr><td>6</td><td colspan="2">Indication of UP/DOWN angulation lock (CYF-V2, CYF-V2R common)</td></tr>
<tr><td></td><td> 
</td><td> 
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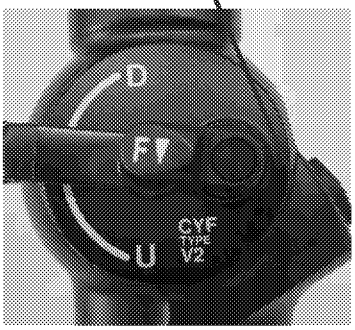
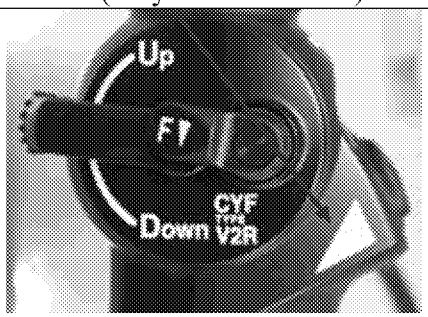
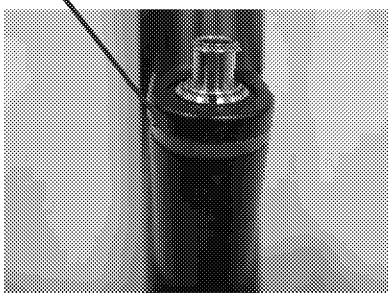
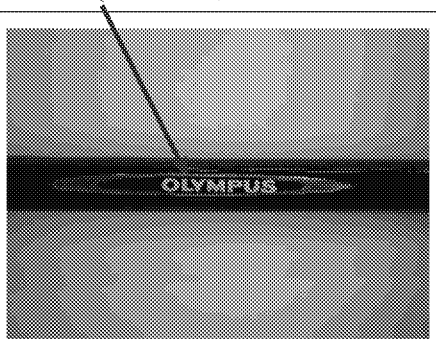
7	Reference: CYF-V2 (No identification mark of angulation)	Identification mark of angulation (only for CYF-V2R)
		
8	Identification of endo-therapy accessories compatibility (CYF-V2, CYF-V2R common)	
		
9	Trade mark (CYF-V2, CYF-V2R common)	
		

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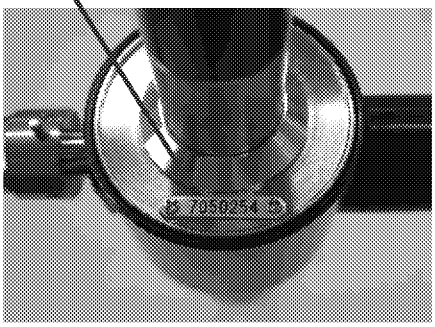
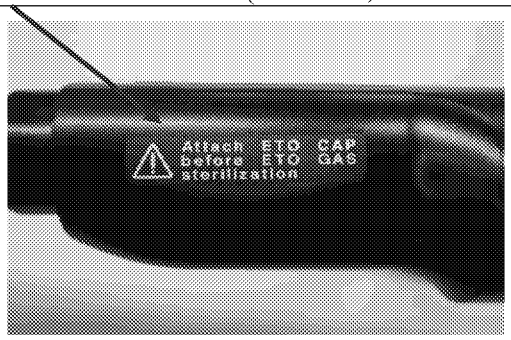
10	Serial number (CYF-V2, CYF-V2R common)
	
11	Manufacture name (CYF-V2, CYF-V2R common)
12	STERILIZATION CAP Label (CYF-V2, CYF-V2R common)
	
13	Manufacture country (CYF-V2, CYF-V2R common)

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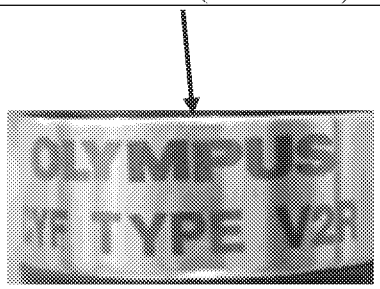
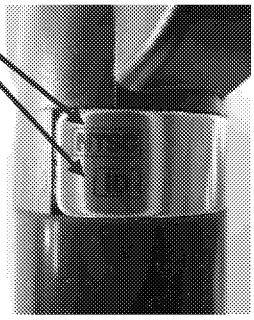
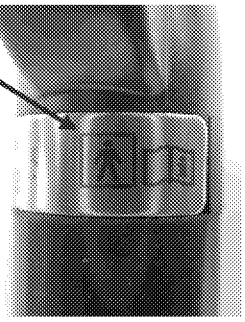
14	Model name (CYF-V2)	Model name (CYF-V2R)
		
15	NTSC, ID Mark (CYF-V2, CYF-V2R common)	
		
16	TYPE BF applied part (CYF-V2, CYF-V2R common)	
		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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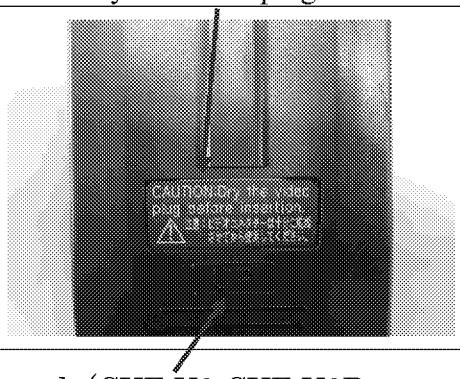
17	Caution (CYF-V2, CYF-V2R common) "CAUTION: Dry the video plug before insertion."
	
18	UP mark (CYF-V2,CYF-V2R common)

(b) Package Labeling

The package labeling for OLYMPUS CYF-V2/V2R is shown in Fig.13-2, Fig.13-3 and Fig13-4.

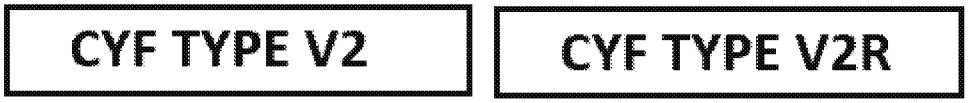


Fig.13-2. Package Labeling 1 (CYF-V2/V2R)

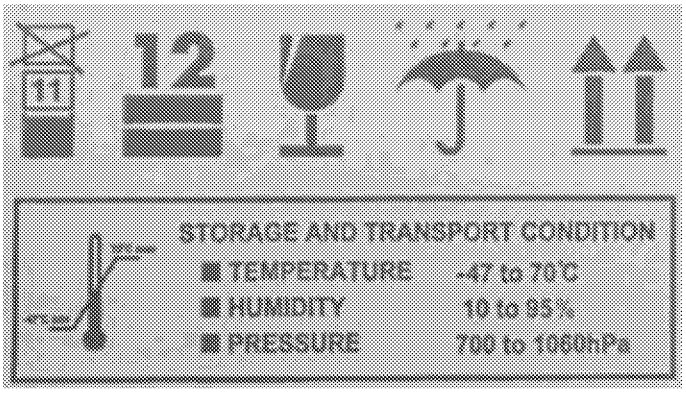


Fig.13-3. Package Labeling 2 (CYF-V2/V2R common)
(Pictorial marking for handling of goods and
Storage and transport condition)

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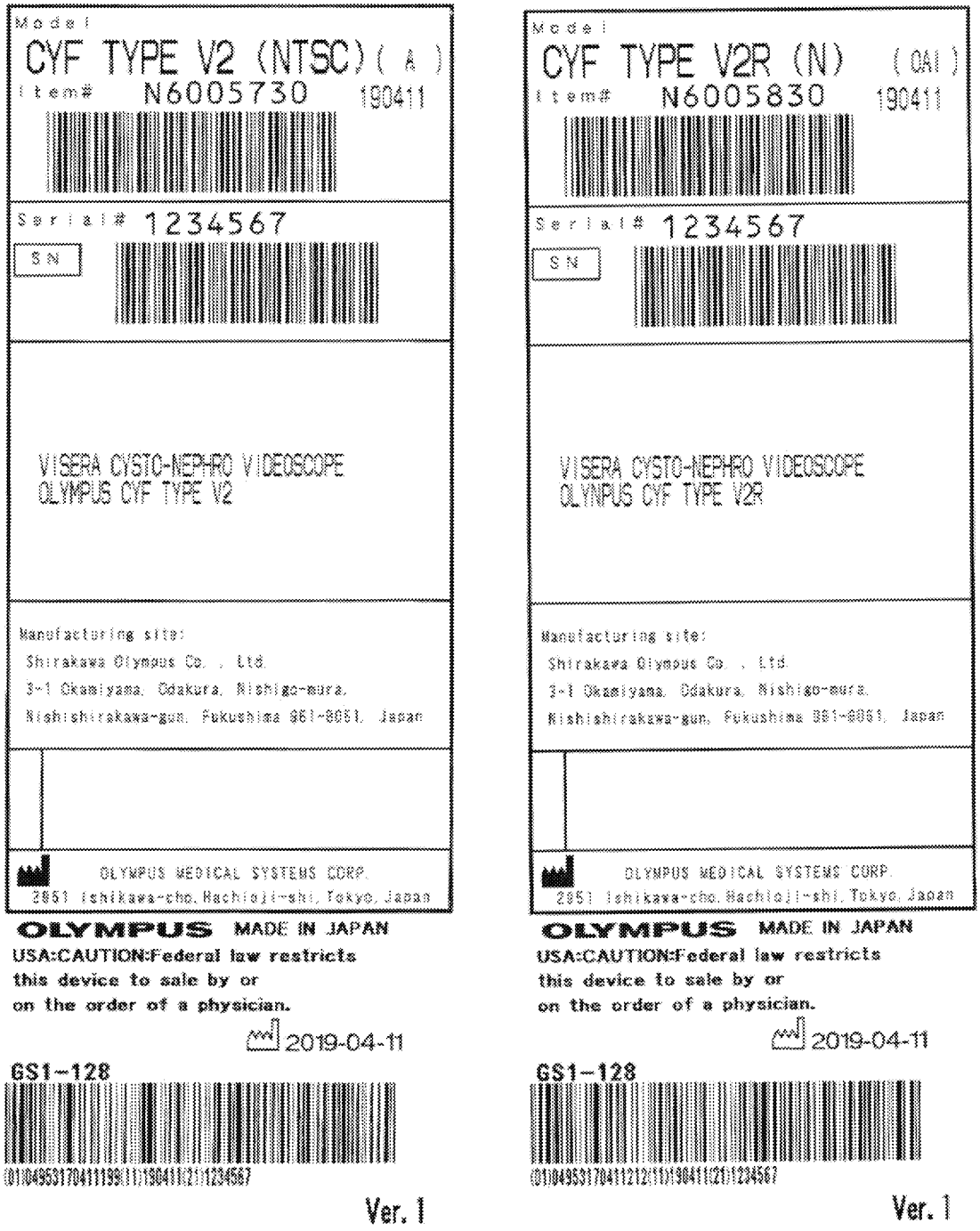

Fig.13-4. Package Labeling 3 (CYF-V2/V2R)

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The devices (CYF-V2/V2R) will be delivered by carry case. Please refer to Fig.13-5, Fig.13-6 and Fig.13-7 for the image of carry case (packaging) and the location of the package labeling.

Packaging label 1

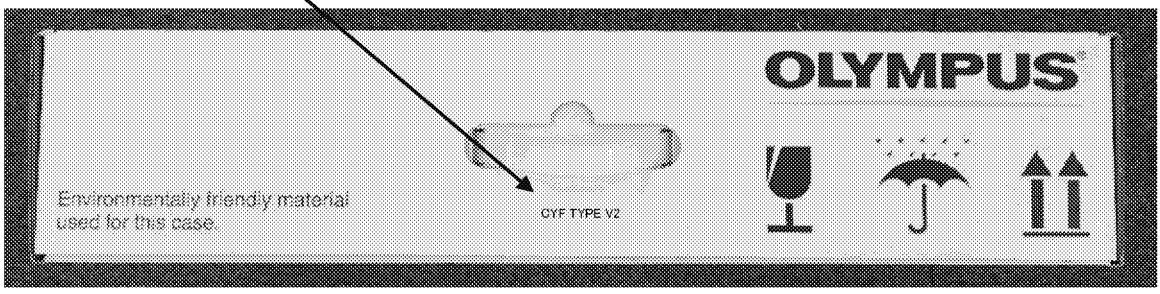

Fig.13-5. Top side of carry case A*1

Packaging label 3 Packaging label 2

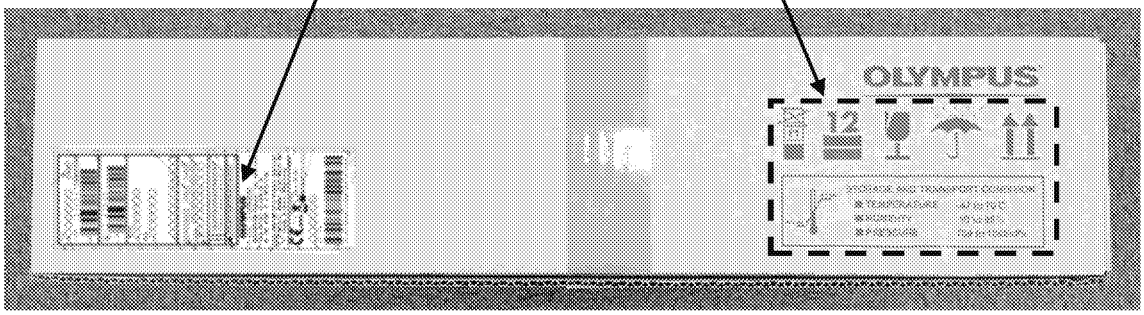

Fig.13-6. Top side of carry case B *1

Packaging label 2 Packaging label 3

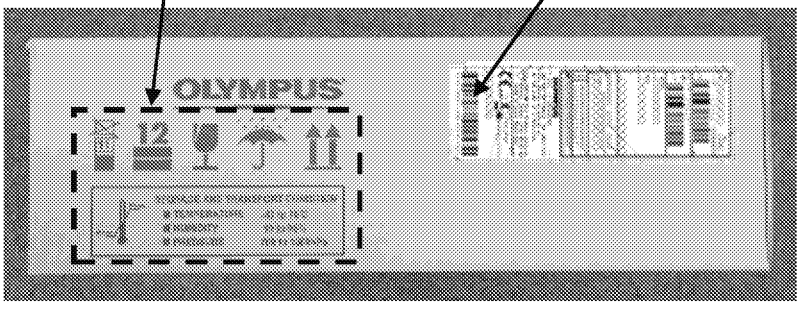

Fig.13-7. Right side of carry case B *1

*1 The Carry case A (inner case) is enclosed in the carry case B (outermost case).

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13.2.2. CYF-VH/VHR

(a) Product Labeling

The product labeling for CYF-VH/VHR is shown in Fig.13-8.

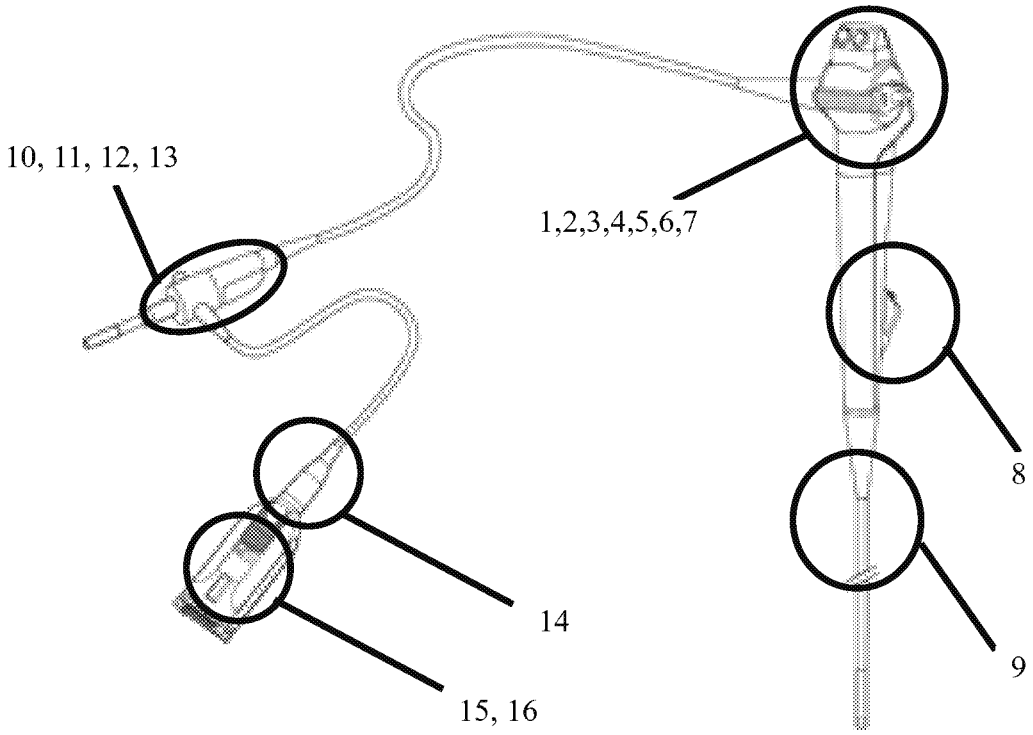
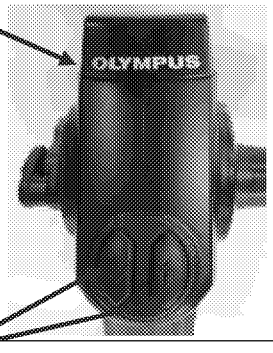


Fig.13-8. Product Labeling (CYF-VH/VHR)

1	Trade mark (CYF-VH, VHR common)
	
2	Switch 1 and Switch 4 (CYF-VH, CYF-VHR common)

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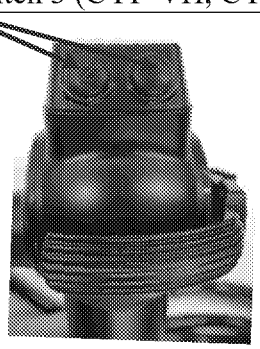
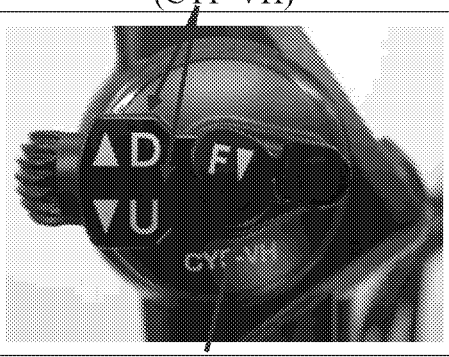
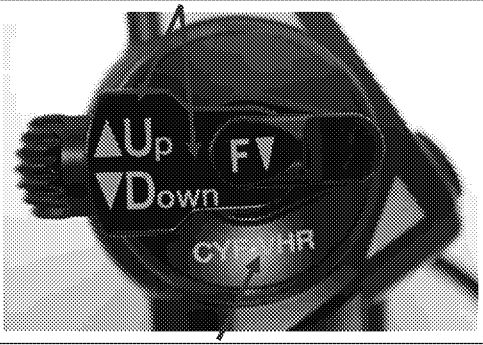
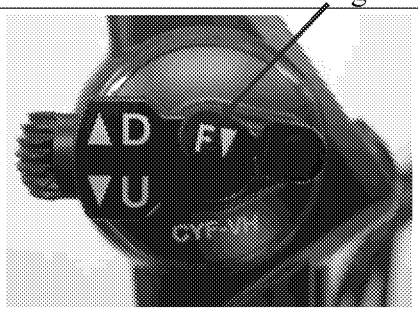
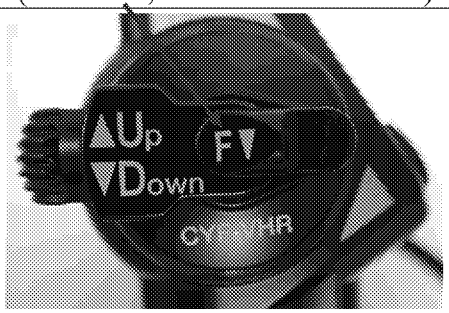
<table>
<tr><td>3</td><td colspan="2">Switch 2 and Switch 3 (CYF-VH, CYF-VHR common)</td></tr>
<tr><td></td><td colspan="2">  </td></tr>
<tr><td>4</td><td>Indication of angulation
(CYF-VH)</td><td>Indication of angulation
(CYF-VHR)</td></tr>
<tr><td></td><td> 
</td><td> 
</td></tr>
<tr><td>5</td><td>Model name (CYF-VH)</td><td>Model name (CYF-VHR)</td></tr>
<tr><td>6</td><td colspan="2">Indication of UP/DOWN angulation lock (CYF-VH, CYF-VHR common)</td></tr>
<tr><td></td><td> 
</td><td> 
</td></tr>
</table>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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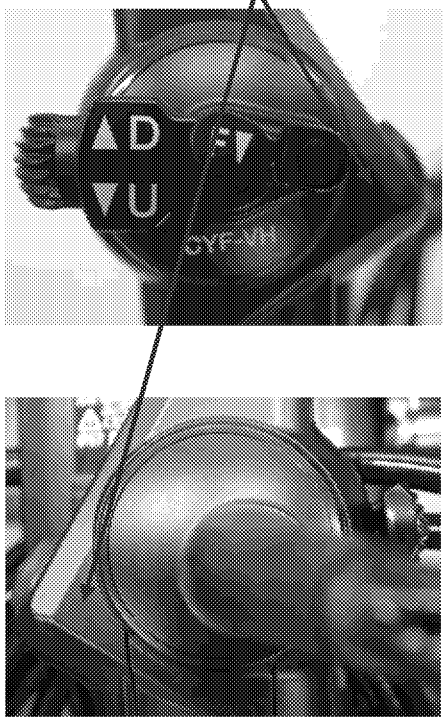
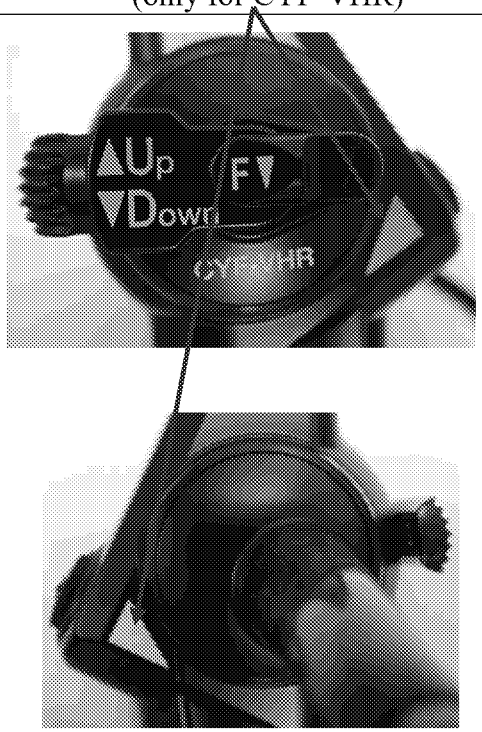
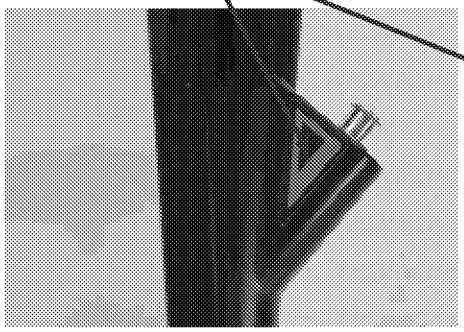
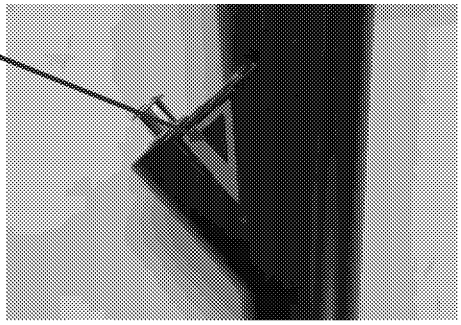
7	Reference: CYF-VH (No identification mark of angulation)	Identification mark of angulation (only for CYF-VHR)
		
8	Identification of endo-therapy accessories compatibility (CYF-VH, CYF-VHR common)	
	 	

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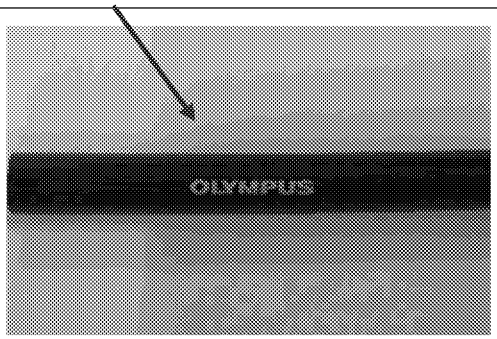
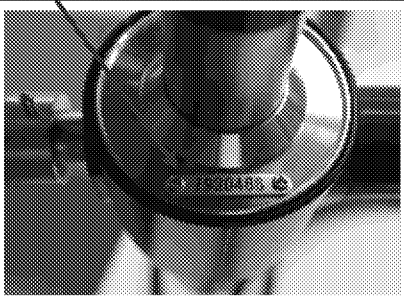
9	Trade mark (CYF-VH, CYF-VHR common)
	
10	Serial number (CYF-VH, CYF-VHR common)
	
11	Manufacture name (CYF-VH, CYF-VHR common)
12	STERILIZATION CAP Label (CYF-VH, CYF-VHR common)

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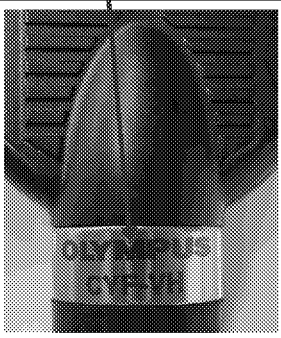
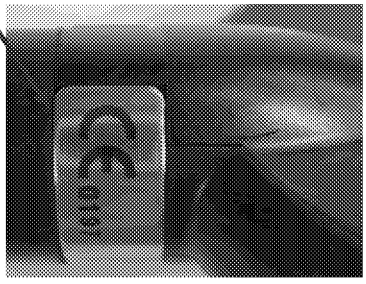
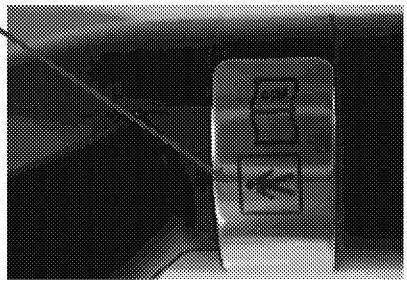
13	Manufacture country (CYF-VH, CYF-VHR common)	
14	Model name (CYF-VH)	Model name (CYF-VHR)
		
15	CE Mark (CYF-VH, CYF-VHR common)	
		
16	TYPE BF applied part (CYF-VH, CYF-VHR common)	
		

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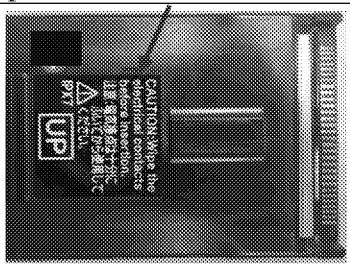
17	Caution (CYF-VH, CYF-VHR common) "CAUTION: Wipe the electrical contacts before insertion."
	

(b) Package Labeling

The package labeling for OLYMPUS CYF-VH/VHR is shown in Fig.13-9, Fig13-10 and Fig13-11.

Fig.13-9. Package Labeling 1 (CYF-VH/VHR)

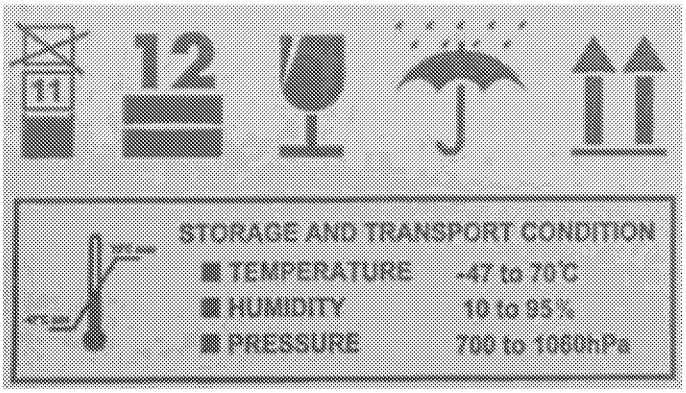


Fig.13-10. Package Labeling 2 (CYF-VH/VHR common)
(Pictorial marking for handling of goods and
Storage and transport condition)

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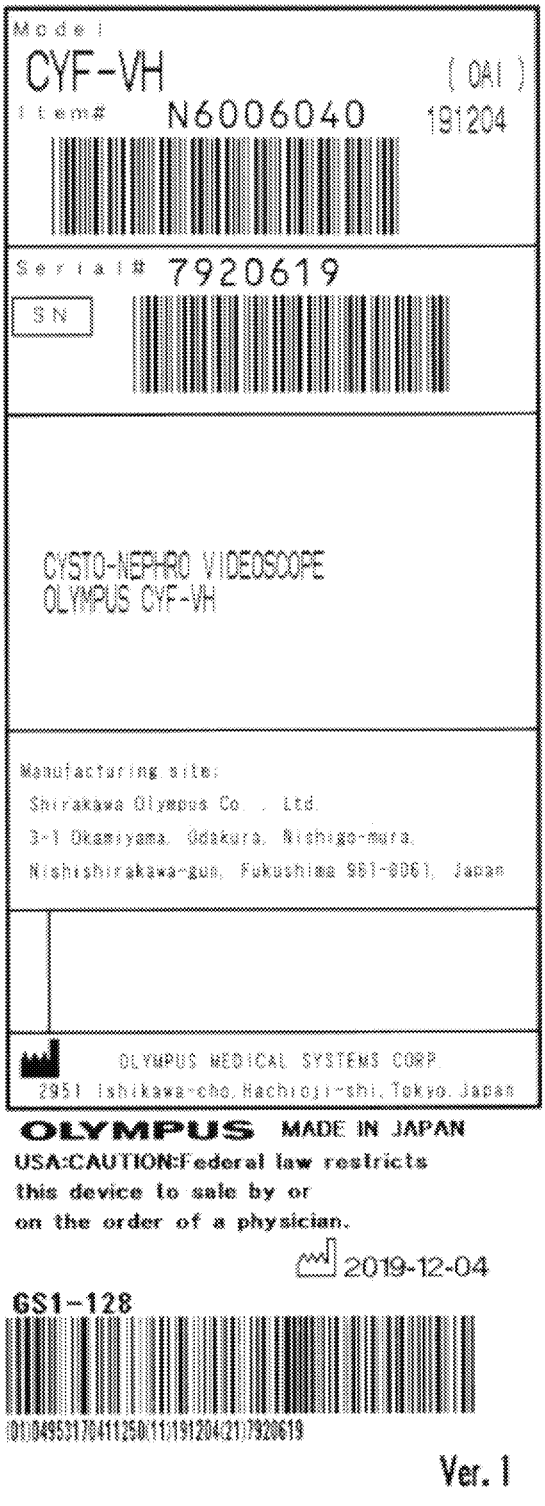

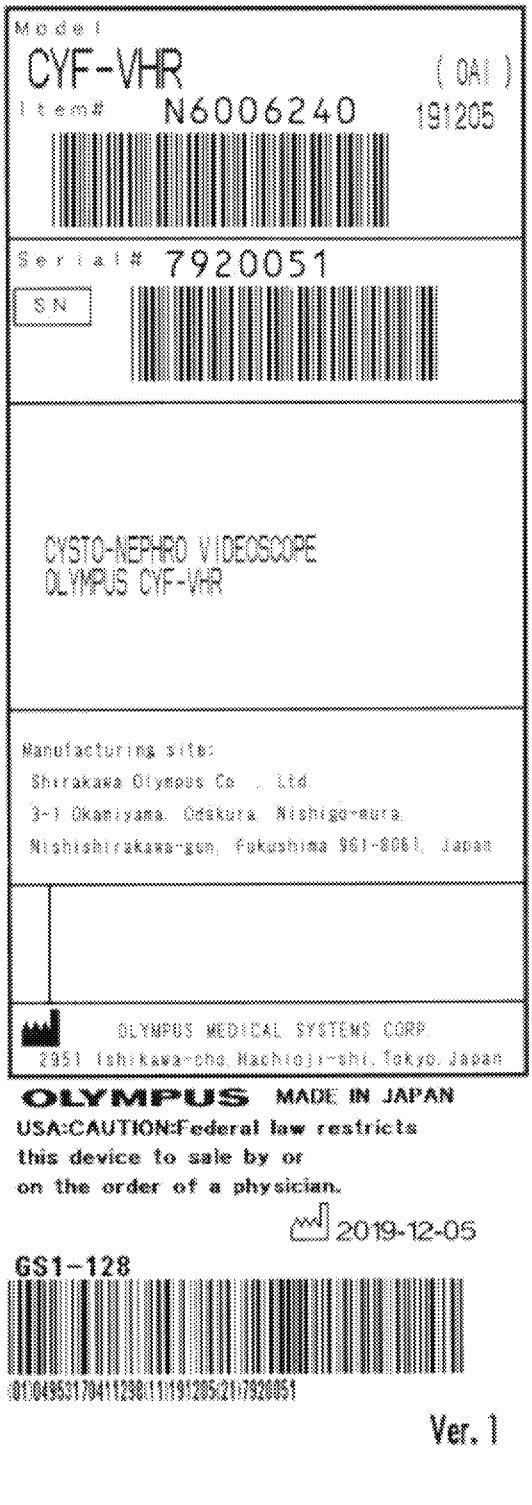

Fig.13-11. Package Labeling 3 (CYF-VH/VHR)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The devices (CYF-VH/VHR) will be delivered by carry case. Please refer to Fig.13-12, Fig.13-13 and Fig.13-14 for the image of carry case (packaging) and the location of the package labeling.

Packaging label 1

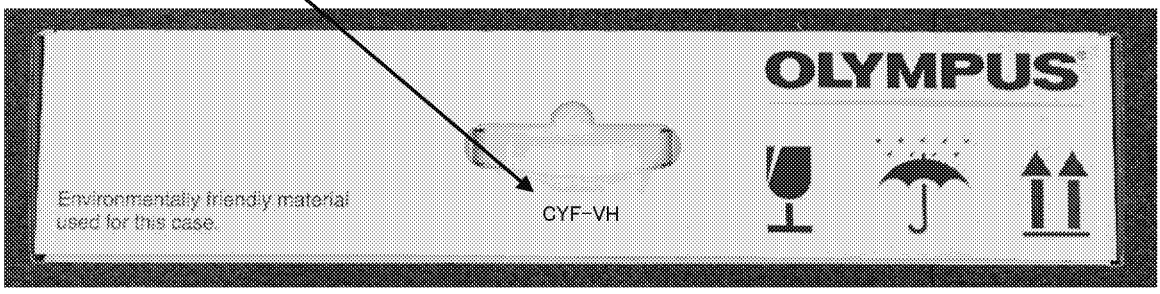

Fig.13-12. Top side of carry case A*1

Packaging label 3 Packaging label 2

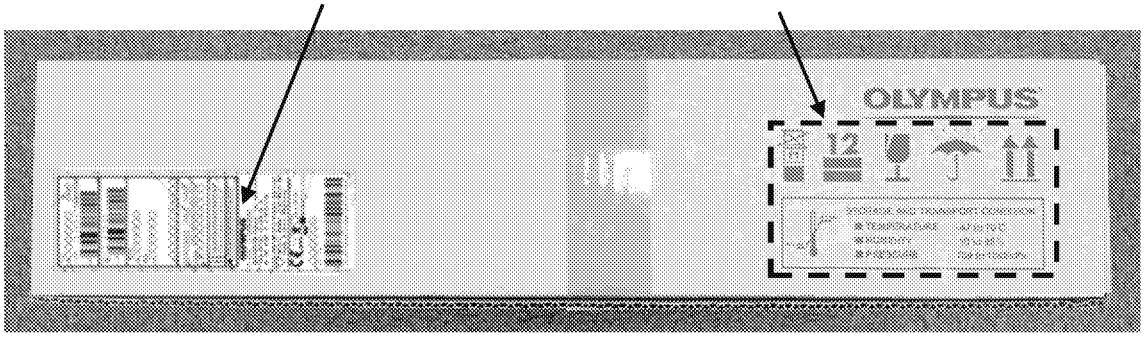

Fig.13-13. Top side of carry case B *1

Packaging label 2 Packaging label 3

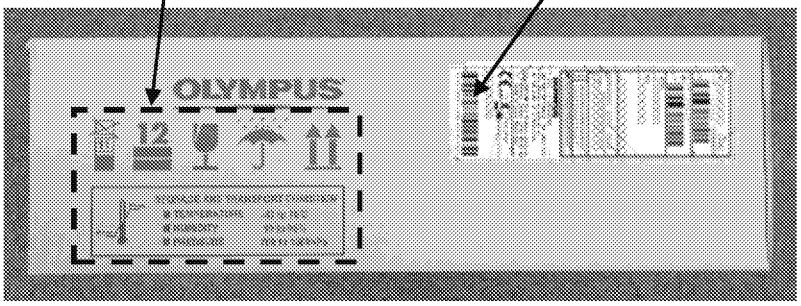

Fig.13-14. Right side of carry case B *1

*1 The Carry case A (inner case) is enclosed in the carry case B (outermost case).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Title	[Report] Implementation of biological safety testing preconditioning (CYF-VH and MAJ-2092)

(b)(4)

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(b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-28-2024

Section 17.2.6

Test Condition for Electrical Safety Test

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Identification information: 202112061325

OLYMPUS

Test Report

Title

High Level Disinfection test Using OER-Pro with Aldahol 1.8 of CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18.12

FOV and DOV

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18.12
FOV and DOV

(b)(4)

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(b)(4)

Project Number: (b)(4)

Technical Memorandum

Date: 10-MAY-2022

To: Olympus Medical Systems Corporation
(b)(4)
2951 Ishikawa-cho
Hachioji-shi, Tokyo, 192-8507
Japan

From: (b)(4)

Subject: CYF-V2 Results of Particulate Analysis

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Ms. Kaplan,

Thank you for your email. Attached please find an (b)(4)

Please let me know if you need anything else.

Best regards,
Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Tuesday, January 17, 2023 8:35 AM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: K221683@docs.fda.gov
Subject: [EXTERNAL] K221683/S001 Interactive Review Request

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Hello Teffany,

Thank you for providing your response to our August 12, 2022 request for additional information. (b)(4)

(b)(4)

Please reply via email by end of day January 18, as the review cycle is coming to a close.

Thank you,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
esther.kaplan@fda.hhs.gov

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Section 5

510(k) Summary

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Section 18.15

Effectiveness of NBI function

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Section 18.15

Effectiveness of NBI function

(b)(4)

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Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Identification information : (b)(4)

OLYMPUS

Test Report

Title
Cleaning test Using OER-Pro with EndoQuick of
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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GLP REPORT

TEST FACILITY

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SPONSOR

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

CONFIDENTIAL

STUDY TITLE

ISO Intracutaneous Irritation Study

TEST ARTICLE NAME

CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH
and Luer-Split MAJ-2092

TEST ARTICLE IDENTIFICATION

(b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OSE/DIDSI at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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GLP PROTOCOL

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

ISO Intracutaneous Irritation Study - Extract

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

ISO Intracutaneous Irritation Study - Extract

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(b)(4)

Sponsor:
(b)(6)
Olympus Medical Systems Corp.
2951 Ishikawa-machi
Hachioji-shi, Tokyo, 192-8507
JAPAN

20 Jan 2022

Dear (b)(4)

Justification regarding the extraction efficiency for the Insertion Section test site of the CYF-VH delayed cleaning validation (Lab Number (b)(4) Protocol Number (b)(4)

Company:
(b)(6)
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-machi
Hacioji-shi, 192-8507
JAPAN

(b)(4)

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GLP PROTOCOL

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

Olympus Medical Systems Corp.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

ISO Acute Systemic Toxicity Study in Mice

(b)(4)

Questions? Contact FDA/CDRH/OCE/DCI at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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REVISED REPORT

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

CONFIDENTIAL

STUDY TITLE

Subcontracted Testing – Identification by SEM-EDS and Microscopic FTIR

(b)(4)

Questions? Contact FDA/CDRH/OSE/DI at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

ISO 9001:2015 CERTIFIED

(b)(4)

Test Report

Identification of Particles in (b)(4) Saline Solution

(b)(4)

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Dear Ms. Kaplan,

The requested information has been provided below. If you have any other questions, please let me know.

Best regards,

Teffany Hutto

Consultant for Olympus Medical.

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>

Sent: Wednesday, July 20, 2022 8:43 AM

To: Teffany Hutto <teffany.hutto@olympus.com>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov

Subject: [EXTERNAL] K221683 Interactive Review Request #1

You don't often get email from esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>. Learn why this is important<https://secure-web.cisco.com/1ctkBQMefns8rIq9pKwyzAd4Jxuuj76t7aayuSerQxTHbzABwUQJ4p4yMrQp-1G5owj-NIjaXov5Hgv1acTigt3nn-f7FAksHpnvMkOOkeosJ2HursLUCqassccV6Y7TMbU_QgDRbwroWJJCWvEdzumrVwBoO85yaonzaTZBeR0FIsP5rpPxCyKBujccsYQ-3R-b0UjAzEIMZKb8ze7Fnqg/https%3A%2F%2Faka.ms%2FLearnAboutSenderIdentification>

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Dear Ms. Hutto,

I am the lead reviewer for your submission for the Cysto-Nephro Videoscopes Olympus CYF Type V2/V2R and VH/VHR. This email is a request for information to facilitate interactive review of the device. As the review of your device continues I may send out additional requests for information the review team needs to make a determination on the substantial equivalence of your device to the selected predicate.

Please address the following:

(b)(4)

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Please reply via email by COB July 25, to facilitate timely review of your submission. Be sure to copy the file folder address K221683@docs.fda.gov<mailto:K221683@docs.fda.gov> on your reply to help maintain the record of our communication.

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: 301-796-1863

esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

[cid:image008.png@01D89FF5.FBF8CC60]<http://www.fda.gov/>

[cid:image009.jpg@01D89FF5.FBF8CC60]<https://www.facebook.com/FDA>
[cid:image010.jpg@01D89FF5.FBF8CC60] <https://twitter.com/US_FDA>
[cid:image011.jpg@01D89FF5.FBF8CC60] <http://www.youtube.com/user/USFoodandDrugAdmin>
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[cid:image013.jpg@01D89FF5.FBF8CC60]
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTIII/DHTIIIB
AWL RMONR
Global Work Location
Silver Spring, MD 20705
301-796-1863

Premarket Notification 510(k) Review

Date: August 12, 2022

Reviewer: Esther Kaplan

510(k)# K221683 Subject: Traditional

Applicant: Olympus Medical Systems Corporation	**Device Trade Name:** CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2R), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VH) and CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VHR)
Contact Name: Teffany Hutto	**Contact Title:** Regulatory Affairs Consultant
Correspondent Firm: Olympus Corporation of the Americas	**Phone:** (512) 508-6550 **Email:** teffany.hutto@olympus.com
Received Date: June 10, 2022	**Due Date:** September 12, 2022
Pro Code(s): FAJ **Class:** II **Reg #:** 876.1500	**Reg Name:** Endoscope And Accessories

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K133538	NWB, FAJ	Visera Cysto-nephro Videoscope Olympus Cyf Type V2, Visera Cysto-nephro Videoscope Olympus Cyf Type Va2, Visera Cysto-ne	Olympus Corporation Of The Americas

Recommendation

(b)(5)

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(b)(4)

TEST REPORT

APPLICANT	OLYMPUS MEDICAL SYSTEMS CORP.
ADDRESS	2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan
PRODUCTS	CYSTO-NEPHRO VIDEOSCOPE
MODEL NO.	OLYMPUS CYF-VH, OLYMPUS CYF-VHR
SERIAL NO.	(b)(4)
TEST STANDARD	IEC 60601-1: 2005+AMD1: 2012, IEC 60601-1-6: 2010+AMD1: 2013
ADDITIONAL INFORMATION	-
TESTING LOCATION	(b)(4)
TEST RESULTS	
DATE OF TEST	

(b)(4)

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Section 18.14

Resolution

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18.14

Resolution

(b)(4)

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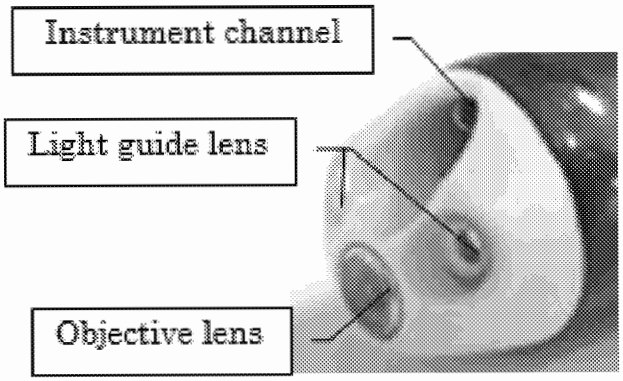

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Step-by-Step Comparison of Automated Cleaning (OER-Pro)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Step-by-Step Comparison of the Automated Cleaning (OER-Pro) Steps

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Ms. Hutto,

I am the lead reviewer for your submission for the Cysto-Nephro Videoscopes Olympus CYF Type V2/V2R and VH/VHR. This email is a request for information to facilitate interactive review of the device. As the review of your device continues I may send out additional requests for information the review team needs to make a determination on the substantial equivalence of your device to the selected predicate.

Please address the following:

(b)(4)

Please reply via email by COB July 25, to facilitate timely review of your submission. Be sure to copy the file folder address K221683@docs.fda.gov on your reply to help maintain the record of our communication.

Thank you,

Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
esther.kaplan@fda.hhs.gov

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Record processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

(b)(4)

Sponsor:
(b)(4)
Olympus Medical Systems Corp.
2951 Ishikawa-machi
Hachioji-shi, Tokyo, 192-8507
JAPAN

05 Jan 2022

Dear (b)(4)

Justification regarding the extraction efficiency for the Insertion Section test site of the CYF-VH high level disinfection validation (Lab Number: (b)(4) Protocol Number: (b)(4)

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Ms. Kaplan,

Just wanted to let you know that I've received both requests from today and I will continue to work with Olympus to ensure that the requested information is received by the timeframe requested.

Have a nice afternoon,

Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>

Sent: Thursday, July 28, 2022 3:06 PM

To: Teffany Hutto <teffany.hutto@olympus.com>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov

Subject: [EXTERNAL] K221683 - Interactive Review Request #3

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Dear Teffany,

In addition to the interactive review request I sent earlier today, please also address the following:

(b)(4)

Please respond by COB Monday, August 1, to facilitate a timely review of your submission.

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CDRH | Food and Drug Administration

Tel: 301-796-1863

esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

[cid:image001.png@01D8A294.1039C2B0]<http://www.fda.gov/>

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<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Dear Teffany,

Thank you for your response. I have a few clarifying questions:

(b)(4)

Please respond by tomorrow, July 26, to facilitate a timely review of your submission.

Thank you,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
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From: Teffany Hutto <teffany.hutto@olympus.com>
Sent: Monday, July 25, 2022 8:21 AM
To: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

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Dear Ms. Kaplan,

The requested information has been provided below. If you have any other questions, please let me know.

Best regards,
Teffany Hutto
Consultant for Olympus Medical.

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Wednesday, July 20, 2022 8:43 AM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: [EXTERNAL] K221683 Interactive Review Request #1

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Dear Ms. Hutto,

I am the lead reviewer for your submission for the Cysto-Nephro Videoscopes Olympus CYF Type V2/V2R and VH/VHR. This email is a request for information to facilitate interactive review of the device. As the review of your device continues I may send out additional requests for information the review team needs to make a determination on the substantial equivalence of your device to the selected predicate.

Please address the following:

(b)(4)

Questions? Contact FDA/CDRH OC [illegible] at CDRH-FOIA-STATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Please reply via email by COB July 25, to facilitate timely review of your submission. Be sure to copy the file folder address K221683@docs.fda.gov on your reply to help maintain the record of our communication.

Thank you,

Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
esther.kaplan@fda.hhs.gov

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GLP PROTOCOL

TEST FACILITY

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SPONSOR

(b)(4)

Olympus Medical Systems Corp.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

ISO Guinea Pig Maximization Sensitization Test

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Dear Ms. Kaplan,

Thank you for reviewing our response so quickly. I will work to make sure the requested information is received by tomorrow.

Have a good day,

Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>

Sent: Monday, July 25, 2022 9:48 AM

To: Teffany Hutto <teffany.hutto@olympus.com>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov

Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

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Dear Teffany,

Thank you for your response. I have a few clarifying questions:

(b)(4)

Please respond by tomorrow, July 26, to facilitate a timely review of your submission.

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: 301-796-1863

esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

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From: Teffany Hutto <teffany.hutto@olympus.com<mailto:teffany.hutto@olympus.com>>

Sent: Monday, July 25, 2022 8:21 AM

To: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov<mailto:Esther.Kaplan@fda.hhs.gov>>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov<mailto:Reginald.Avery@fda.hhs.gov>>; K221683@docs.fda.gov<mailto:K221683@docs.fda.gov>

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Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov<mailto:Reginald.Avery@fda.hhs.gov>>; K221683@docs.fda.gov<mailto:K221683@docs.fda.gov>

Subject: [EXTERNAL] K221683 Interactive Review Request #1

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Thank you,

Esther Kaplan

Mechanical Engineer

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Section 18.8

Noise and Dynamic range

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Date Prepared: 01/19/2023

510(k) Summary

1. GENERAL INFORMATION

■ 510(k) Submitter: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

■ Contact Person: Teffany Hutto
Olympus Corporation of the Americas
3500 Corporate Parkway PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 512-508-6550
Fax: 484-896-7128
Email: teffany.hutto@olympus.com

■ Manufacturing site: Shirakawa Olympus Co., Ltd.
3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun,
Fukushima 961-8061, Japan

Aizu Olympus Co., Ltd.,
3-1-1 Niiderakita, Aizuwakamatsu-shi, Fukushima 965-8520, Japan

2. DEVICE IDENTIFICATION

■ Trade/Device Name: VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE V2R
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH, CYF-VHR

■ Model Name: OLYMPUS CYF-V2, CYF-V2R, CYF-VH, CYF-VHR

■ Common Name: CYSTO-NEPHRO VIDEOSCOPE

■ Regulation Number: 876.1500

■ Regulation Name: Endoscope and accessories

■ Regulatory Class: Class II

■ Product Code: FAJ (Cystoscope and Accessories, Flexible/Rigid)

■ Classification Panel: Gastroenterology/Urology

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

3. PREDICATE DEVICE

■ **Predicate device**

Device name	510(k) Submitter	510(k) No.
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R	OLYMPUS MEDICAL SYSTEMS CORP.	K133538

4. DEVICE DESCRIPTION

■ **General Description of the subject device**

The subject device has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

■ **Principle of Operation**

The subject devices consist of three parts: the control section, the insertion section, and the connector section. The basic principle including user interface and operation for the procedure of the subject device are identical to that of the predicate device.

■ **List of device components**

The VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-V2/V2R will be packed and offered together with the devices listed in the table below. They can be used with commercially available Olympus devices as described within the Instruction Manual.

Model No.	Device Name
BW-411B	Single Use Combination Cleaning Brush
MB-156	ETO Cap

The CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH and CYF-VHR will be packed and offered together with the devices listed in the table below. They can be used with commercially available Olympus devices as described within the Instruction Manual.

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Model No.	Device Name
BW-411B	Single Use Combination Cleaning Brush
MAJ-1538	Sterilization Cap

5. INDICATIONS FOR USE

VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHR have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

6. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device has the same technological characteristics and design as the predicate device except for the following features:

- Optical performance
- Shape of the distal end

Validation from non-clinical testing demonstrated that these technological features do not raise any new issues of safety or effectiveness of the subject device.

A side-by-side comparison of the subject device and the predicate device is provided below.

Item	Subject Device	Predicate Device
	OLYMPUS CYF-V2, CYF-V2R	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Indications for Use	VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2 and CYF TYPE V2R have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.	This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter, and kidney.
Regulation Number	21CFR 876.1500	21CFR 876.1500
Regulation Name	Endoscope and accessories	Endoscope and accessories
Regulatory Class	Class II	Class II

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Item	Subject Device	Predicate Device
	OLYMPUS CYF-V2, CYF-V2R	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Product Code	FAJ	FAJ
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology
Use Environment	Healthcare facility/hospital	Healthcare facility/hospital
Reprocessing	[Cleaning] AER and manual [Disinfection] AER and manual [Sterilization] - Ethylene oxide gas - STERRAD NX	[Cleaning] AER and manual [Disinfection] AER and manual [Sterilization] - Ethylene oxide gas - STERRAD NX
Single-Use/Reuse	Reusable	Reusable
Duration and type of contact	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours).	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours).
Depth of Field	3-50mm	3-50mm
Direction of View	0°(Forward viewing)	0°(Forward viewing)
Field of View	120°	120°
Type of CCD	Color CCD	Color CCD
Number of CCD Chip	1	1
Outer Diameter of Distal End	ø 4.8mm (bullet shape)	ø 4.8mm (bullet shape)
Diameter of Insertion Tube	ø 5.4mm	ø 5.4mm
Bending Section Angulation	Up 210° / Down 120°	Up 210° / Down 120°
Working Length	380mm	380mm
Instrument Channel inner diameter	ø 2.2 mm	ø 2.2 mm
Observation mode	WLI, NBI	WLI, NBI

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Item	Subject Device	Predicate Device
	OLYMPUS CYF-V2, CYF-V2R	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Patient contacting material	Insertion tube: Forced dry-hard type of fluorine resin coat Bending section: Fluoro Rubber Glue: Epoxy glue Distal End: Polyphenylsulfone Objective lens/ Light guide lens: Glass Solder: AuSn Solder Instrument channel pipe/ Instrument channel joint/ Junction/ Instrument channel port: Stainless Steel Instrument Channel: Polytetrafluoroethylene Rubber seal: Silicone	Insertion tube: Forced dry-hard type of fluorine resin coat Bending section: Fluoro Rubber Glue: Epoxy glue Distal End: Polyphenylsulfone Objective lens/ Light guide lens: Glass Solder: AuSn Solder Instrument channel pipe/ Instrument channel joint/ Junction/ Instrument channel port: Stainless Steel Instrument Channel: Polytetrafluoroethylene Rubber seal: Silicone

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATLIS@fda.hhs.gov or 301-796-8118

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Item	Subject Device	Predicate Device
	OLYMPUS CYF-VH, CYF-VHR	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Indications for Use	CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHRhave been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra and kidney.	This instrument has been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter, and kidney.
Regulation Number	21CFR 876.1500	21CFR 876.1500
Regulation Name	Endoscope and accessories	Endoscope and accessories
Regulatory Class	Class II	Class II
Product Code	FAJ	FAJ
Classification Panel	Gastroenterology/Urology	Gastroenterology/Urology
Use Environment	Healthcare facility/hospital	Healthcare facility/hospital
Reprocessing	[Cleaning] AER and manual [Disinfection] AER and manual [Sterilization] - Ethylene oxide gas - STERRAD NX	[Cleaning] AER and manual [Disinfection] AER and manual [Sterilization] - Ethylene oxide gas - STERRAD NX
Single-Use/Reuse	Reusable	Reusable
Duration and type of contact	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours).	Surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (<24 hours).
Depth of Field	3-50mm	3-50mm
Direction of View	0°(Forward viewing)	0°(Forward viewing)
Field of View	120°	120°
Type of CCD	Color CCD	Color CCD
Number of CCD Chip	1	1
Outer Diameter of Distal End	ø 2.7mm (bullet shape)	ø 4.8mm (bullet shape)
Diameter of Insertion Tube	ø 5.5mm	ø 5.4mm
Bending Section Angulation	Up 220° / Down 130°	Up 210° / Down 120°
Working Length	380mm	380mm

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Item	Subject Device	Predicate Device
	OLYMPUS CYF-VH, CYF-VHR	OLYMPUS CYF TYPE V2, VA2, V2R (K133538)
Instrument Channel inner diameter	ø 2.2 mm	ø 2.2 mm
Observation mode	WLI, NBI	WLI, NBI
Patient contacting material	Insertion tube: Forced dry-hard type of fluorine resin coat Bending section: Fluoro Rubber Glue: Epoxy glue Distal End/ Light guide lens: Polysulfone Objective lens: Glass Solder: AuSn Solder Instrument channel pipe/ Instrument channel joint/ Junction/ Instrument channel port: Stainless Steel Instrument Channel: Polytetrafluoroethylene Rubber seal: Silicone	Insertion tube: Forced dry-hard type of fluorine resin coat Bending section: Fluoro Rubber Glue: Epoxy glue Distal End: Polyphenylsulfone Objective lens/ Light guide lens: Glass Solder: AuSn Solder Instrument channel pipe/ Instrument channel joint/ Junction/ Instrument channel port: Stainless Steel Instrument Channel: Polytetrafluoroethylene Rubber seal: Silicone

7. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

1) Reprocessing validation testing

Reprocessing instruction and reprocessing method validation testing were conducted and documentations were provided as recommended by Guidance for Industry and Food and Drug Administration Staff, "Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling".

2) Biocompatibility testing

Biocompatibility testing were conducted in accordance with the FDA's Guidance for Industry and Food and Drug Administration Staff, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The biocompatibility testing included the following tests:

- Cytotoxicity Study Using the ISO Elution Method
- ISO Intracutaneous Study in Rabbits
- ISO Guinea Pig Maximization Sensitization Test
- ISO Intracutaneous Study in Rabbits
- USP Rabbit Pyrogen Study
- ISO Acute Systemic Toxicity Study in Mice

3) Software verification and validation testing

Software verification and validation testing were conducted, and documentations were provided as

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recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".

4) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted in accordance with the ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-2-18:2009 standards for safety and the IEC 60601-1-2:2014 standards for EMC.

5) Performance testing - Bench

Bench testing as listed below were conducted to ensure that the subject device performs as intended and meet design specifications.

- Thermal Safety
- Composite Durability
- Color Performance
- Photobiological Safety
- Noise and Dynamic Range
- Image Intensity Uniformity
- Field of View and Direction of View
- Resolution
- Effectiveness NBI

6) Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

7) Performance testing - Clinical

No clinical study was performed to demonstrate substantial equivalence.

8) Risk management

Risk management was performed in accordance with ISO 14971:2007. The design verification tests and their acceptance criteria were performed and identified as a result of this risk management.

8. CONCLUSIONS

Based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate device, VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYF TYPE V2R, CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHR raise no new issue of safety and effectiveness and are substantially equivalent to the predicate device in terms of safety, effectiveness and performance.

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Section 14

Sterilization and Shelf Life

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14.1 Sterilization

CYF-V2, CYF-V2R, CYF-VH, and CYF-VHR and their reusable accessories are not sterilized before shipment. Before using these instruments for the first time and after using the endoscope, the devices are reprocessed according to the instructions given in the subject endoscope's companion Reprocessing Manual as described in **Section 13**.

All cleaning, disinfection, and sterilization methods instructed in the "REPROCESSING MANUAL" were validated pursuant to *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff*, issued March 17, 2015. Since the device type of the subject devices are listed in Appendix E of the above-mentioned FDA Guidance, full test reports for each reprocessing validation are provided in this premarket submission. The summary of the reprocessing validation is provided in **Section 14.3**.

14.2 Shelf Life

The shelf-life is not applicable for CYF-V2, CYF-V2R, CYF-VH, and CYF-VHR because of the low likelihood of time-dependent product degradation.

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EMC Testing of the

Olympus Medical Systems Corp.
CYF TYPE V2
In accordance with AIM 7351731:2021

(b)(4)

Prepared for: Olympus Medical Systems Corp.
2951 Ishikawa-cho, Hachioji-shi
Tokyo, Japan 192-8507

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Section 11

Device Description

11.1 Device Identification

Device Name	*VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE V2R* *CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH, CYF-VHR*
Common Name	CYSTO-NEPHRO VIDEOSCOPE
Regulation Number	876.1500
Regulation Name	Endoscope and accessories
Regulatory Class	Class II
Product Code	FAJ
Classification Panel	Gastroenterology/Urology
Predicate Device	VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R (K133538)

11.2 General Description

VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYF TYPE V2R, CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHR have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

For the components and compatible devices of the subject devices (OLYMPUS CYF-V2/VR and OLYMPUS CYF-VH/VHR), refer to the Section 11.8 below.

The system chart is shown in **Figure 11-1**. The **CYF-V2/V2R** components that are part of this submission are outlined below in blue. Differences between these devices and the device cleared via K133538 is outlined in **Section 12**.

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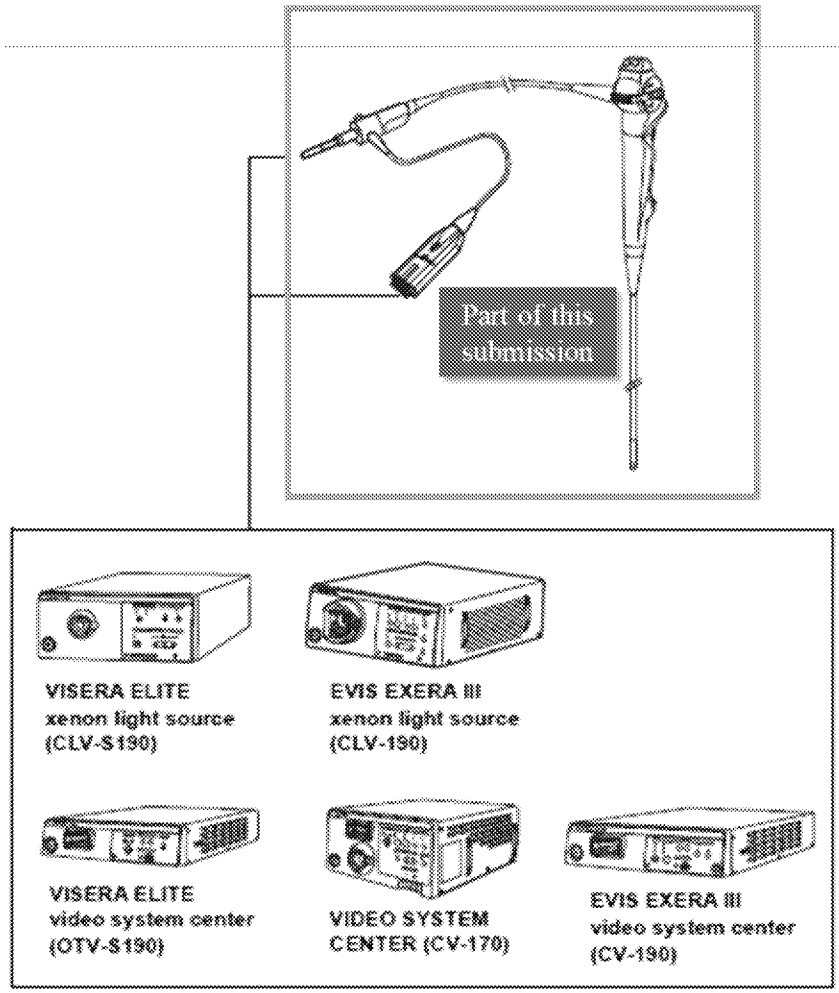

Figure 11-1: Interfacing System Components (CYF-V2/V2R Component Highlighted)

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The system chart is shown in **Figure 11-2**. The **CYF VH/VHR** components that are part of this submission are outlined in blue.

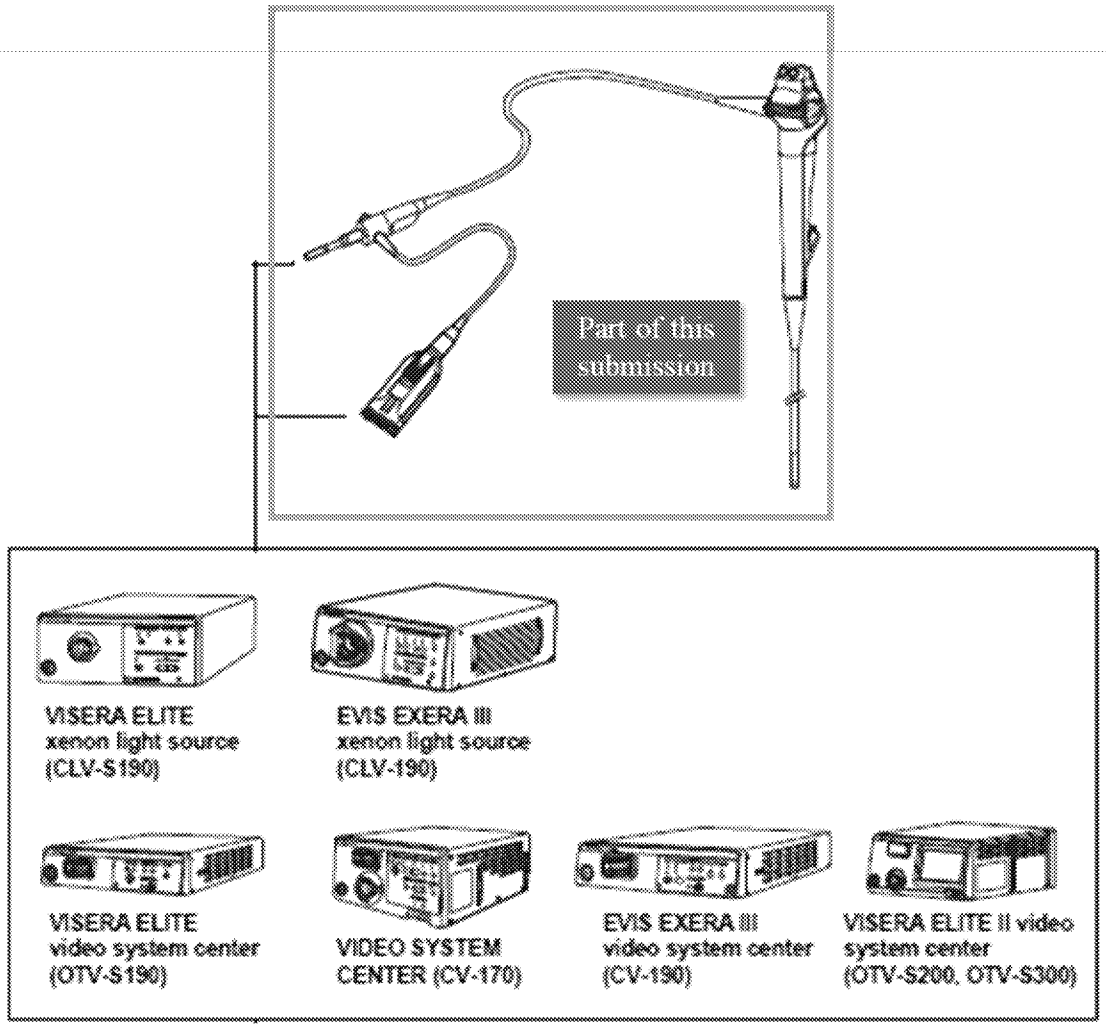

Figure 11-2: Interfacing System Components (CYF-VH/VHR Component Highlighted)

11.3 Principles of Operation

Both CYF-V2/V2R and CYF-VH/VR consist of three parts: the control section, the insertion section, and the connector section.

The basic principle including user interface and operation for the procedure of the CYF-V2/V2R and VH/VHR are identical to that of the predicate CYF-V2.

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The Control Section

The UP/DOWN angulation control lever on the control section is connected to the tip of the bending section by bundles of wires. By operating the UP/DOWN angulation control lever, the bending section at the distal end bends to guide the distal end for insertion and observation into the urethra and bladder. Therapeutic instruments can pass through the instrument channel for treatment. It can also be perfused through the instrument channel.

The Insertion Section

The insertion section consists of the CCD, light guides that bring light from the light source through the endoscope, an instrument channel where therapeutic accessories can be inserted and withdrawn.

The Connector Section

The connector section connects the endoscope with video system center and light source.

11.4 Technological Characteristics

Difference between CYF V2/V2R and VH/VHR

The difference between CYF V2/VH and CYF-V2R/VHR is angle operation direction. Refer **Tables 11-1 and 11- 2** and **Figures 11-3 through 11-5** below for details.

Table 11-1: Angle operation direction

	CYF-V2	CYF-V2R
Angle operation direction	When the angulation control lever is moved upward (toward symbol "D"), the bending section moves down. When the angulation control lever is moved downward (toward symbol "U"), the bending section moves up.	When the Angulation control lever is moved upward (toward symbol "Up"), the bending section moves up. When the Angulation control lever is moved downward (toward symbol "Down"), the bending section moves down.

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Table 11-2: Angle operation direction

	CYF-VH	CYF-VHR
Angle operation direction	When the angulation control lever is moved upward (toward symbol "D"), the bending section moves down. When the angulation control lever is moved downward (toward symbol "U"), the bending section moves up.	When the Angulation control lever is moved upward (toward symbol "Up"), the bending section moves up. When the Angulation control lever is moved downward (toward symbol "Down"), the bending section moves down.

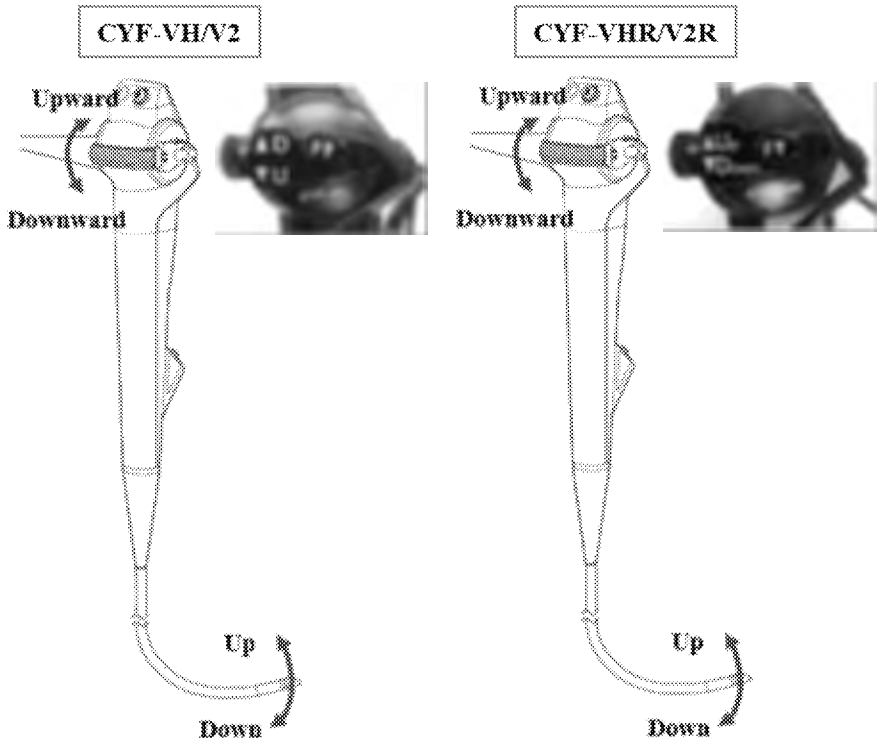

Figure 11-3: Angle operation direction

Reference – Structure which changes the Angle operation direction

There are upward and downward bending wires and the wire ends are fixed to the tip of the bending section and the angulation control lever, respectively. Therefore, when the lever is pulled, the bending section bends to each direction. If

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the wire ends connected to the angulation control lever are crossed, the bending direction is reversed.

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(b)(4)

11.5 Descriptions of Individual Device Components

Figure 11-7 provides an illustration with numbered components of the CYF-V2/V2R device.

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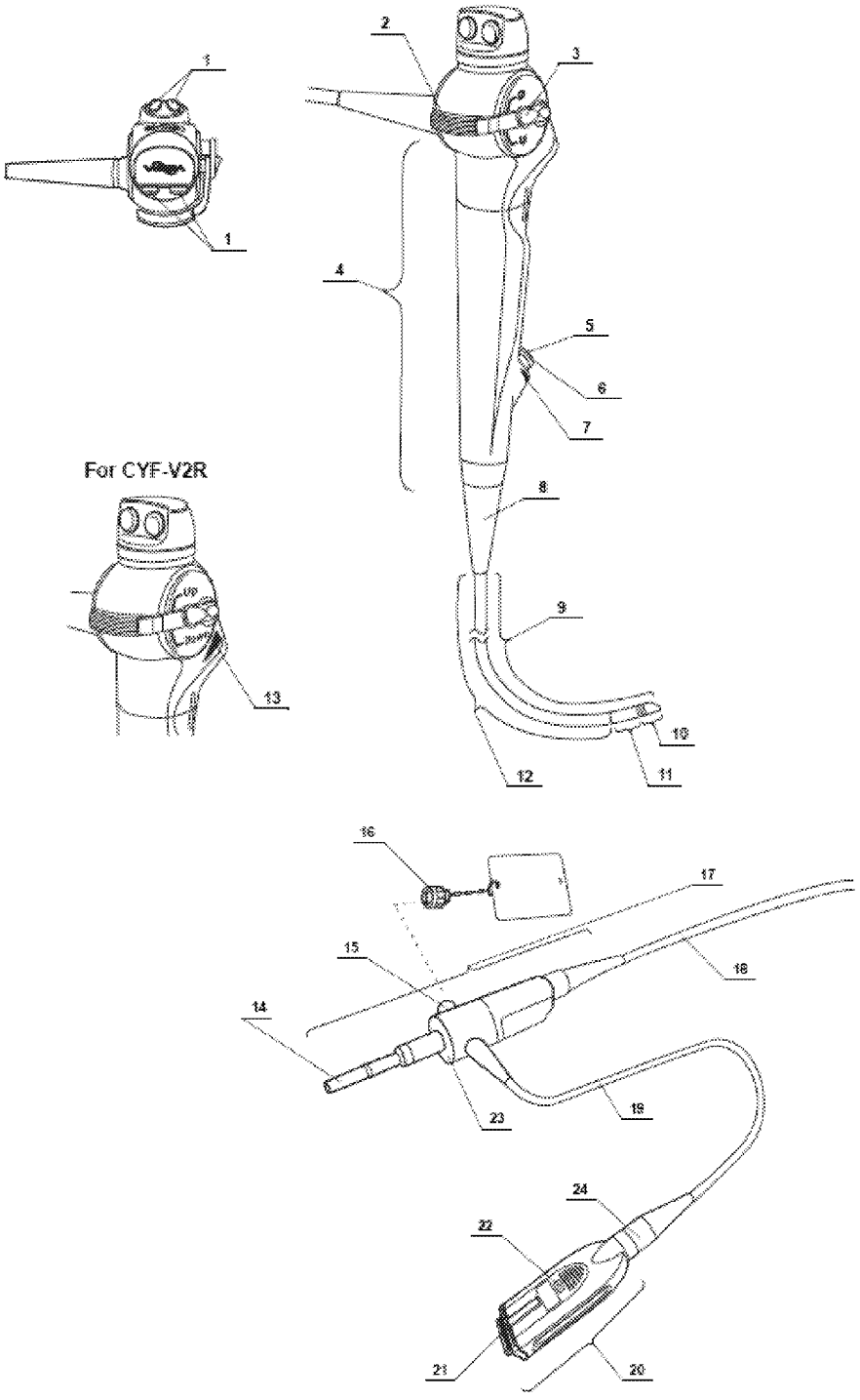

Figure 11-7: CYF-V2/V2R Device Components

Descriptions of each CYF-V2/V2R numbered component in **Figure 11-7** are provided in **Table 11-4.**

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Table 11-4: CYF-V2/V2R – Nomenclature and Descriptions of each Numbered Component

No	Nomenclature	Description
1	Remote switches 1 to 4	The functions of remote switches 1 to 4 can be selected on the video system center. When selecting the functions, refer to the instruction manual for the video system center.
2	UP/DOWN angulation control lever	When turned in the "U" direction (CYF-V2R: "Up"), the bending section moves UP; when turned in the "D" direction (CYF-V2R: "Down"), the bending section moves DOWN.
3	UP/DOWN angulation lock	Pushing this lever in the "F▼" direction frees the angulation. Pushing the lever in the opposite direction locks the bending section at any desired position.
4	Control section	Operates the endoscope, such as controlling angulation.
5	Instrument channel	An EndoTherapy accessory can be inserted to this channel. The instrument channel is connected to the distal end of the endoscope. The instrument channel functions are: • Channel for the insertion of EndoTherapy accessories • Fluid feed channel
6	Instrument channel port	Attach the Forceps/irrigation plug to this port.
7	Color code	The color code is used to quickly determine the compatibility of EndoTherapy accessories. The endoscope can be used with EndoTherapy accessories that have the same color code. • Blue: CYF-V2, CYF-V2R
8	Boot	Avoids the junction between the insertion tube and control section from bending.
9	Insertion section	This section is inserted into the patient body cavity.
10	Distal end	The objective lens and light guide lens are on this distal end.
11	Insertion tube	Connects the control section and bending section.
12	Bending section	The bending section moves the distal end of the endoscope when the UP/DOWN angulation control lever is operated.

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No	Nomenclature	Description
13	Identification marking for opposite bending direction	This marking indicates that the bending section of the CYF-V2R moves in the direction opposite to the conventional endoscopes, such as the CYF-V2.
14	Light guide	Connects the endoscope to the light source and transmits light to the distal end of the endoscope.
15	Venting connector	Attach the sterilization cap or leakage tetser here.
16	ETO cap (MB-156)	The ETO cap equalizes the outer and inner pressure of the endoscope. The cap must be attached prior to gas sterilization (ethylene oxide gas, STERRAD® etc.) and aeration and removed prior to immersion or clinical examination. The cap must also be attached when the endoscope is transported outside the hospital (shipment, return for repairs, etc.).
17	Light guide connector	The light guide connector connects the endoscope to the output socket of the light source and transmits light from the light source to the distal end of the endoscope.
18	Universal cord	Connects the light guide connector and the control section.
19	Video cable	Connects the light guide connector and the control section.
20	Video connector	The video connector connects the endoscope to the video connector socket of the video system center so that the endoscopic image becomes visible. The endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center.
21	Electrical contacts	Connects the video system center and the endoscope electrically.
22	UP mark	When the video connector is connected to the video system center, this mark is facing upward.
23	Serial number	The serial number is marked here.
24	Product ID plate	UDI indication, the product name (model) and TSC/PAL label are marked here.

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Figure 11-8 provides an illustration with numbered components of the CYF-VH/VHR device.

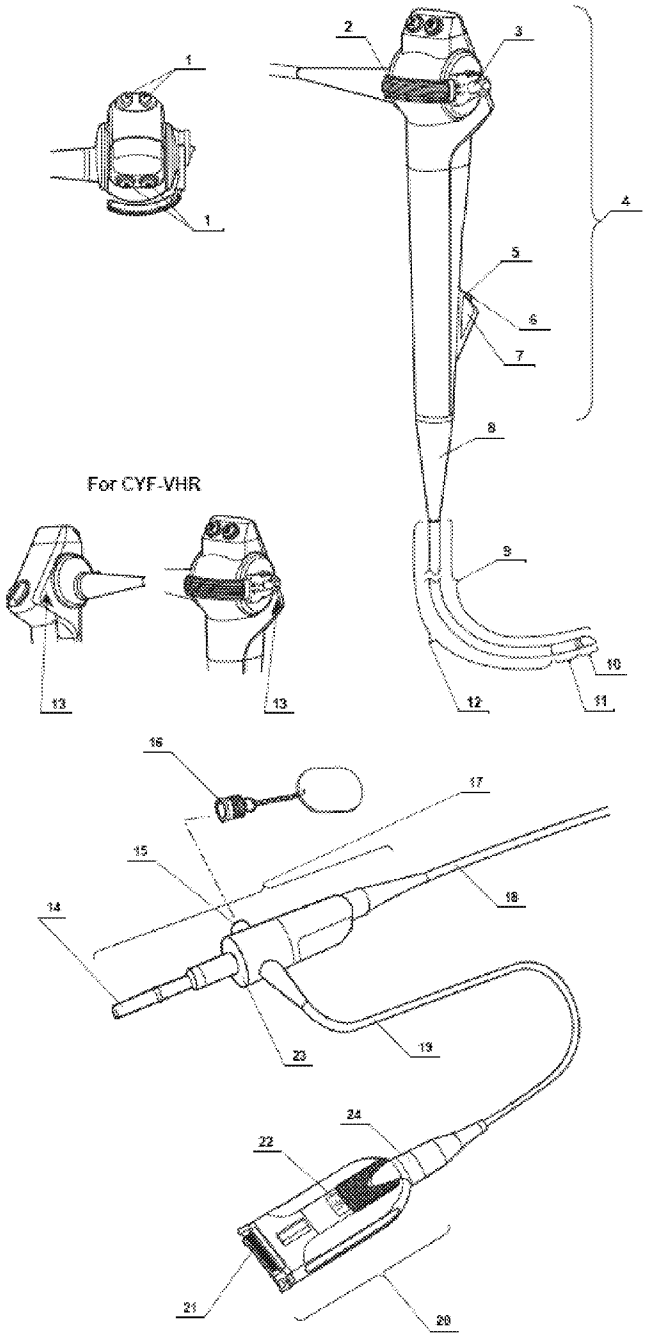

Figure 11-8: CYF-VH/VHR Device Components

Descriptions of each CYF-VH/VHR numbered component in **Figure 11-8** are provided in **Table 11-5.**.

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Table 11-5: CYF-VH/VHR – Nomenclature and Descriptions of each Numbered Component

No	Nomenclature	Description
1	Remote switches 1 to 4	The functions of the remote switches 1 to 4 can be selected on the video system center. Refer to the instruction manual for the video system center when setting these functions.
2	UP/DOWN angulation control lever	When this lever is turned in the "U" direction (for CYF-VHR: "Up"), the bending section moves UP; when the lever is turned in the "D" direction (for CYF-VHR: "Down"), the bending section moves DOWN.
3	UP/DOWN angulation lock	Moving this lever in the "F▼" direction frees angulation. Moving the lever in the opposite direction locks the bending section at any desired position.
4	Control section	Operates the endoscope, such as controlling angulation.
5	Instrument channel	An EndoTherapy accessory can be inserted to this channel. The instrument channel is connected to the distal end of the endoscope. The instrument channel functions are: • Channel for the insertion of EndoTherapy accessories • Fluid feed channel
6	Instrument channel port	Attach the Forceps/irrigation plug to this port.
7	Color code	The color code is used to quickly determine the compatibility of EndoTherapy accessories. The endoscope can be used with EndoTherapy accessories that have the same color code. • Blue: CYF-VH, CYF-VHR
8	Boot	Avoids the junction between the insertion tube and control section from bending.
9	Insertion section	This section is inserted into the patient body cavity.
10	Distal end	The objective lens and light guide lens are on this distal end.
11	Bending section	The bending section moves the distal end of the endoscope when the UP/DOWN angulation control lever is operated.

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No	Nomenclature	Description
12	Insertion tube	Connects the control section and bending section.
13	Identification marking for opposite bending direction	This marking indicates that the bending section of the CYF-VHR moves in the direction opposite to the conventional endoscopes, such as the CYF-VH.
14	Light guide	Connects the endoscope to the light source and transmits light to the distal end of the endoscope.
15	Venting connector	Attach the sterilization cap or leakage tester here.
16	Sterilization cap (MAJ-1538)	The sterilization cap equalizes the outer and inner pressure of the endoscope. The cap must be attached prior to gas sterilization (ethylene oxide gas, STERRAD® etc.) and aeration and removed prior to immersion or clinical examination. The cap must also be attached when the endoscope is transported outside the hospital (shipment, return for repairs, etc.).
17	Light guide connector	The light guide connector connects the endoscope to the output socket of the light source and transmits light from the light source to the distal end of the endoscope.
18	Universal cord	Connects the light guide connector and the control section.
19	Video cable	Connects the light guide connector and the video connector.
20	Video connector	The video connector connects the endoscope to the video connector socket of the video system center so that the endoscopic image becomes visible. The endoscope contains a memory chip that stores information about the endoscope and communicates this information to the video system center.
21	Electrical contacts	Connects the video system center and the endoscope electrically.
22	UP mark	When the video connector is connected to the video system center, this mark is facing upward.
23	Serial number	The serial number is marked here.
24	Product ID plate	UDI indication and the product name (model) are marked here.

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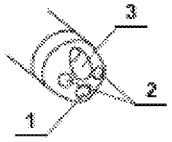
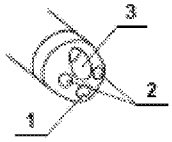
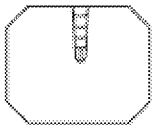
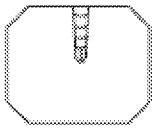
11.6 Device Specifications and Dimensions

Table 11-6 lists the various CYF-V2/V2R device specifications and dimensions.

Table 11-6: CYF-V2/V2R Device Specifications and Dimensions

Model		CYF-V2	CYF-V2R
Optical system	Field of view	120°	120°
	Direction of view	0° (Forward viewing)	0° (Forward viewing)
	Depth of field	3 – 50 mm	3 – 50 mm
Insertion section	Distal end outer diameter	ø 4.8 mm (Bullet shape)	ø 4.8 mm (Bullet shape)
	Distal end enlarged 1 Objective lens 2 Light guide lens 3 Instrument channel outlet		
	Insertion tube outer diameter	ø 5.4 mm (16.2 Fr)	ø 5.4 mm (16.2 Fr)
	Insertion section working length	380 mm	380 mm
Instrument channel	Channel inner diameter	ø 2.2 mm (6.6 Fr)	ø 2.2 mm (6.6 Fr)
	Minimum visible distance*1	2 mm	2 mm
	Direction from which EndoTherapy accessories enter and exit the endoscopic image		
Bending section	Angulation range	UP 210° DOWN 120°	UP 210° DOWN 120°
Total length		660 mm	660 mm
NBI observation mode*2		Available	Available
High-frequency treatment		Compatible	Compatible
Laser treatment		Not compatible	Not compatible

*1 Distance from the distal end of the endoscope.

*2 For more details, refer to the instruction manual for the video system center.

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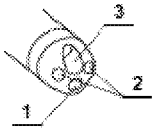
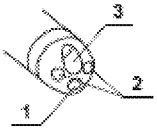
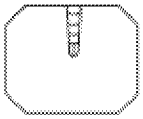
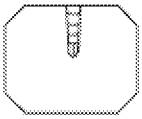
Table 11-7 lists the various CYF-VH/VHR device specifications and dimensions.

Table 11-7: CYF-VH/VHR Device Specifications and Dimensions

Model		CYF-VH	CYF-VHR
Optical system	Field of view	120°	120°
	Direction of view	0° (Forward viewing)	0° (Forward viewing)
	Depth of field	3 – 50 mm	3 – 50 mm
Insertion section	Distal end outer diameter	ø 2.7 mm (Bullet shape)	ø 2.7 mm (Bullet shape)
	Distal end enlarged 1 Objective lens 2 Light guide lens 3 Instrument channel outlet		
	Insertion tube outer diameter	ø 5.5 mm (16.5 Fr)	ø 5.5 mm (16.5 Fr)
	Insertion section working length	380 mm	380 mm
Instrument channel	Channel inner diameter	ø 2.2 mm (6.6 Fr)	ø 2.2 mm (6.6 Fr)
	Minimum visible distance*1	2.5 mm	2.5 mm
	Direction from which EndoTherapy accessories enter and exit the endoscopic image		
Bending section	Angulation range	UP 220° DOWN 130°	UP 220° DOWN 130°
Total length		660 mm	660 mm
NBI observation mode*2		Available	Available
Records of endoscope's information*2		Available	Available
Electronic shutter function*2		Available	Available
Electronic zoom function*2		Available	Available
High-frequency treatment		Compatible	Compatible
Laser treatment		Not compatible	Not compatible

*1 Distance from the distal end of the endoscope.
*2 For more details, refer to the instruction manual for the video system center.

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11.7 Conditions of Use

■ Operating environment

Table 11-8: **Operating Environment Specifications**

Operating environment	Ambient temperature	10 – 40°C (50 – 104°F)
	Relative humidity	30 – 85%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)
Standard storage environment (e.g. within the hospital)	Ambient temperature	5 – 40°C (41 – 104°F)
	Relative humidity	10 – 95%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)
Transportation environment (conditions during transportation and short-term storage)	Ambient temperature	–47 to +70°C (–52.6 to +158°F)
	Relative humidity	10 – 95%
	Atmospheric pressure	700 – 1060 hPa (0.7 – 1.1 kgf/cm^2) (10.2 – 15.4 psia)

■ Operation procedure

Insertion:

1) Holding and manipulating the endoscope
   (1) Hold the control section of the endoscope using your left hand.
   (2) Operate the remote switches 1 and 4 using the left index finger.
   (3) Operate the UP/DOWN angulation control lever using the left thumb.
   (4) Maintain the insertion section using the right hand.
2) Irrigation
   (1) Feed the irrigation fluid through the irrigation tube.
3) Insertion of the endoscope
   (1) If necessary, apply a medical-grade, water-soluble lubricant to the insertion section.
   (2) Insert the distal end of the endoscope into the body cavity while

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viewing the endoscopic image.

4) Angulation of the distal end
   (1) Operate the UP/DOWN angulation control lever slowly to guide the distal end for insertion and observation.
5) Observation of the endoscopic image
   (1) Refer to the light source's instruction manual for instructions on how to adjust the brightness.

Using EndoTherapy accessories:

1) Insertion of EndoTherapy accessories into the endoscope
   (1) Hold the UP/DOWN angulation control lever stationary so that the bending section is straight.
   (2) Confirm that the tip of the EndoTherapy accessory is closed or retracted into its sheath.
   (3) Insert the EndoTherapy accessory slowly and straight into the forceps port of the sealing accessories.
   (4) Hold the EndoTherapy accessory at a point approximately 4 cm from the sealing accessories and advance it slowly and straight into the sealing accessories using short strokes while observing the endoscopic image.
2) Operation of EndoTherapy accessories
   (1) Operate the EndoTherapy accessory according to the directions given in its instruction manual.
3) Withdrawal of EndoTherapy accessories
   (1) Withdraw the EndoTherapy accessory slowly while the tip of the EndoTherapy accessory is closed and/or retracted into its sheath.
4) High-frequency cauterization
   (1) Prepare, inspect, and connect the electrosurgical unit and electrosurgical accessories as described in their instruction manuals.

Withdrawal of the endoscope:

(1) Turn the UP/DOWN angulation lock to the free "F▼ " position.
(2) Carefully withdraw the endoscope while observing the endoscopic image.
(3) Reprocess the endoscope and accessories after the procedure as described in the "REPROCESSING MANUAL" with your endoscope model listed on the cover.

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Transportation of the endoscope:

1) Transporting within the hospital
   (1) When carrying the endoscope by hand, loop the universal cord, hold the light guide connector with the control section in one hand and hold the distal end of the insertion tube securely, but gently without squeezing, with the video connector in the other hand.
2) Transporting outside the hospital
   (1) Transport the endoscope in the carrying case.

11.8 List of Each Device for Which Clearance is Requested

The CYF-V2/V2R will be packed and offered together as provided in **Table 11-9** below. They can be used with commercially available Olympus devices as described within the Instruction Manual.

Table 11-9: Devices Packaged with CYF-V2/V2R

Model No.	Device Name	510(k) No.
BW-411B	Single Use Combination Cleaning Brush	510(k) Exempt
MB-156	ETO Cap	K181240

The CYF-VH/VHR will be packed and offered together as provided in **Table 11-10** below. They can be used with commercially available Olympus devices as described within the Instruction Manual.

Table 11-10: Devices Packaged with CYF-VH and CYF-VHR

Model No.	Device Name	510(k) No.
BW-411B	Single Use Combination Cleaning Brush	510(k) Exempt
MAJ-1538	Sterilization Cap	K172726

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A list of recommended combination devices for CYF-V2/V2R are provided in **Table 1111-11**. All compatible devices are currently in commercial distribution.

Table 11-11: Recommended combinations list of the CYF-V2/V2R

(b)(4)

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A list of recommended combination devices for CYF-VH/VHR are provided in **Table 1111-12**. All compatible devices are currently in commercial distribution.

Table 11-12: Recommended combinations list of the CYF-VH/VHR

(b)(4)

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11.9 Sterilization & Reprocessing

The CYF-V2/V2R and CYF-VH/VHR and their reusable accessories are not sterilized prior to shipment. Before using these instruments for the first time, it must be reprocessed according to the instructions provided in the endoscope's companion "REPROCESSING MANUAL" with the subject devices listed. After using the subject device, the device must be reprocessed and stored according to the instructions provided of the endoscope's companion "REPROCESSING MANUAL".

All cleaning, disinfection, and sterilization methods instructed in the "REPROCESSING MANUAL" will be validated pursuant to *"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff"*, issued March 17, 2015. Since the device type of the subject devices are listed in Appendix E of the above-mentioned FDA Guidance, full testing for each reprocessing validation will be completed. The CYF-V2/V2R and CYF-VH/VHR reprocessing validation is provided in **Section 14.**

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11.10 Patient-Contacting Materials

The **CYF-V2/V2R** has patient-contacting materials which are listed in **Table 11-13** below.

Table 11-13: List of Patient-Contacting Materials for CYF-V2/V2R

Parts	Material name	Chemical Name
Insertion tube	Forced dry-hard type of fluorine resin coat	(b)(4)
Bending section	Fluoro rubber	
Glue	Epoxy glue	
Distal End	Polyphenylsulfone	
Objective lens	Glass	
Light guide lens	Glass	
Solder	AuSn-Solder	
Instrument channel pipe	Stainless Steel	
Glue	Epoxy glue	
InstrumentChannel	Polytetrafluoroethylene	
Instrument channel joint	Stainless Steel	
Junction	Stainless Steel	
Rubber seal	Silicone	
Instrument channel port	Stainless Steel	

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The **CYF-VH/VHR** has patient-contacting materials which are listed in **Table 11-14** below.

Table 11-14: List of Patient-Contacting Materials for CYF-VH/VHR

Parts	Material Name	Chemical Name
Insertion tube	Forced dry-hard type of fluorine resin coat	(b)(4)
Bending section	Fluoro rubber	
Glue	Epoxy glue	
Distal end	Polysulfone	
Objective lens	Glass	
Light guide lens	Polysulfone	
Solder	AuSn-Solder	
Instrument channel pipe	Stainless Steel	
Glue	Epoxy glue	
Instrument channel	Polytetrafluoroethylene	
Instrument channel joint	Stainless Steel	
Junction	Stainless Steel	
Rubber seal	Silicone	
Instrument channel port	Stainless Steel	

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH, CYF-VHR

Indications for Use *(Describe)*
CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF VH, and CYF VHR have been designed to be used with an Olympus video system center, light source, documentation equipment,
monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Dear Teffany,

In addition to the interactive review request I sent earlier today, please also address the following:

(b)(4)

Please respond by COB Monday, August 1, to facilitate a timely review of your submission.

Thank you,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
esther.kaplan@fda.hhs.gov

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Olympus Medical Systems Corporation
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

CONFIDENTIAL

STUDY TITLE

ISO Acute Systemic Toxicity Study in Mice

TEST ARTICLE NAME

VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and Luer-Split MAJ-2092

TEST ARTICLE IDENTIFICATION

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OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

ISO Acute Systemic Toxicity Study in Mice

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Japan

CONFIDENTIAL

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Cytotoxicity Study Using the ISO Elution Method

TEST ARTICLE NAME

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TEST ARTICLE IDENTIFICATION

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Japan

STUDY TITLE

Cytotoxicity Study Using the ISO Elution Method

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Olympus Medical Systems Corp.
2951 Ishikawa-cho,
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Japan

STUDY TITLE

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Dear Ms. Kaplan,

The requested information has been provided below. If you have any other questions, please let me know.

Best regards,
Teffany Hutto
Consultant for Olympus Medical.

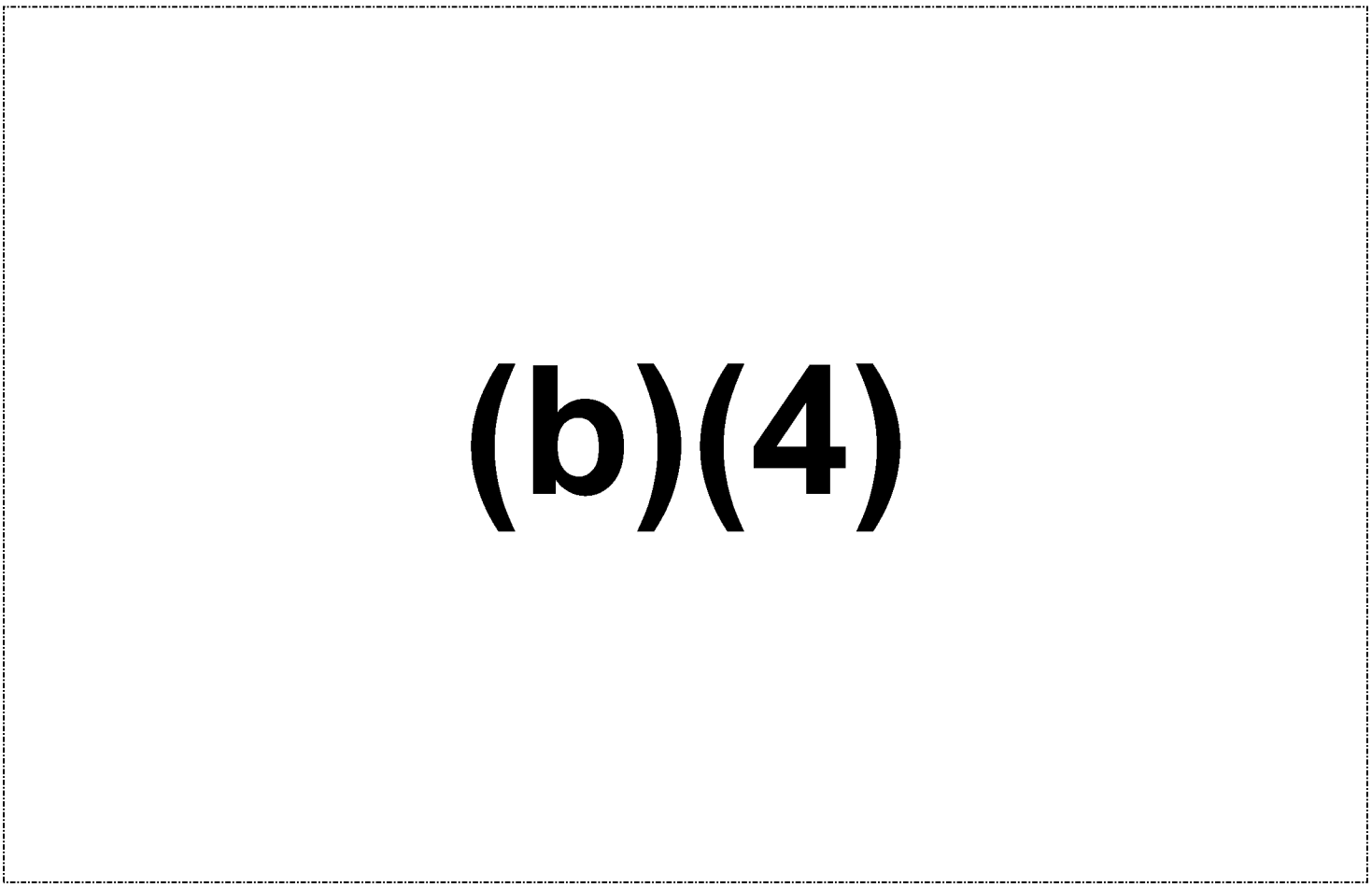
From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Wednesday, July 20, 2022 8:43 AM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: [EXTERNAL] K221683 Interactive Review Request #1

You don't often get email from esther.kaplan@fda.hhs.gov. Learn why this is important

Dear Ms. Hutto,

I am the lead reviewer for your submission for the Cysto-Nephro Videoscopes Olympus CYF Type V2/V2R and VH/VHR. This email is a request for information to facilitate interactive review of the device. As the review of your device continues I may send out additional requests for information the review team needs to make a determination on the substantial equivalence of your device to the selected predicate.

Please address the following:



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(b)(4)

Please reply via email by COB July 25, to facilitate timely review of your submission. Be sure to copy the file folder address K221683@docs.fda.gov on your reply to help maintain the record of our communication.

Thank you,

Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
esther.kaplan@fda.hhs.gov

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Section 14.1.2

Step-by-Step Comparison of Cleaning Steps (Manual)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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1.Step-by-Step Comparison of the Cleaning Steps (Manual) for CYF-VH/VHR

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GLP PROTOCOL

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

USP Rabbit Pyrogen Study, Material Mediated

(b)(4)

Questions? Contact FDA/CDRH/OC/DIDSI CDRH-FOISTAFFUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024
Identification information: (b)(4)

OLYMPUS

Test Report

Title

Recovery Test for Low Number of Organisms of
OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5
and Luer-Split MAJ-2092

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Good morning Ms. Kaplan,

The requested information for the instrument channel is provided below.

As always, please let me know if you have any additional questions.

Best regards,

Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>

Sent: Thursday, July 28, 2022 3:06 PM

To: Teffany Hutto <teffany.hutto@olympus.com>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov

Subject: [EXTERNAL] K221683 - Interactive Review Request #3

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Dear Teffany,

In addition to the interactive review request I sent earlier today, please also address the following:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Please respond by COB Monday, August 1, to facilitate a timely review of your submission.

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: 301-796-1863

esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

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<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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Step-by-Step Comparison of Rinsing validation steps(Manual HLD)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Step-by-step comparison of rinsing validation (Manual HLD) steps for CYF-VH and CYF-VHR

(b)(4)

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Appendix A. Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the application.

510(k)#: **Date Received by DCC:**

510(k) Lead Reviewer:

Center: **Office:** **Division:**

Decision: **Accept_____Refuse to Accept_____**

If Accept, notify the submitter.

If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: Yes No

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

Preliminary Questions			
Answers in the shaded blocks indicate consultation with an identified Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)	**Yes**	**No**	**N/A**
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.*	☒	☐	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

If the product does not appear to be a device or such a combination product, mark "No."			
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **(a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **(b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4. Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in section 503(g)(5)(C)(ii)-(v) of the FD&C Act? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.*	☐	☒	☐
Comments:			

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5. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., class III type and PMA required, or class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6. Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☐	☒
Comments:			

- **If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.**
- **If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.**
- **If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.**
- **If the answer to 5 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action. Note that, for a device which is clearly ineligible for a 510(k) submission (such as a device type which is class III requiring PMA or**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

class I/II and 510(k) exempt), this may be considered a basis for a refusal to accept the submission. A 510(k) submitted for a class I/II, 510(k)-exempt device that trips the limitations of the exemption would not be refused on this basis.

- **If the answer to 6 is "Yes," then stop review of the 510(k), contact CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.**
- **If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.**

Organizational Elements Failure to include these items should not result in an RTA designation.				
***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	***Page #**
1.	Submission contains a Table of Contents.	☒	☐	Vol. 001
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☒	☐	
3.	All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	Vol. 003 Cover Letter
Comments:				

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed.
• Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review. • Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
A.	**Administrative**						
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).		☒	☐		
		Comments:					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):					
		a.	Device trade/proprietary name	☒	☐		Vol. 011 Pg. 1
		b.	Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐		Vol. 011 Pg. 1
		Comments:					
	3.	Submission contains an Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). *See recommended format (https://www.fda.gov/media/86323/download).*		☒	☐		Vol. 004
		Comments:					
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*		☒	☐		Vol. 005
		Comments:					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(*l*). *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*		☒	☐		Vol. 006
		Comments:					
	6.	Submission is a class III 510(k) Device. *Select "N/A" only if submission is not a class III 510(k).*		☐		☒	
		a.	Contains class III Summary and Certification per 21 CFR 807.87(k). *See recommended content (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-class-iii-certification-and-summary). Select "N/A" only if submission is not a class III 510(k).*	☐	☐	☒	
		Comments:					
	7.	Submission contains clinical data. *Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a, b, and c below are omitted from the checklist.*		☐		☒	
		a.	Submission includes completed Financial Certification (FDA Form 3454, available at https://www.fda.gov/media/70465/download) or Disclosure (FDA Form 3455, available at https://www.fda.gov/media/69872/download) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the guidance entitled "Financial Disclosures by Clinical Investigators," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/financial-disclosure-clinical-investigators.*	☐	☐	☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (see FDA Form 3674 which can be obtained at https://www.fda.gov/about-fda/reports-manuals-forms/forms) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j).*	☐	☐	☐	
		c.	Statements of Compliance for Clinical Investigations *Select "N/A" if the submission does not contain any clinical data from investigations (as defined in 21 CFR 812.3(h)) to demonstrate substantial equivalence.* *For multicenter clinical investigations involving both United States (US) and outside United States (OUS) sites, part (i) should be addressed for the US sites and part (ii) should be addressed for the OUS sites. 21 CFR 812.28 applies to all OUS clinical investigations that enroll the first subject on or after February 21, 2019.* *Please refer to the guidance document entitled "Acceptance of Clinical Data to Support Medical Device Applications and Submissions - Frequently Asked Questions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acceptance-clinical-data-support-medical-device-applications-and-submissions-frequently-asked for more information.*	☐		☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
			i.	For each clinical investigation conducted in the US, the submission includes a statement that the investigation was conducted in compliance with 21 CFR parts 50, 56, and 812 (or, with respect to part 56, that it was not subject to the regulations under 21 CFR 56.104 or 56.105). **OR** The submission includes a brief statement of the reason for noncompliance with 21 CFR parts 50, 56, and/or 812. *Select "N/A" if the clinical investigations were conducted solely OUS.*	☐	☐	☐	
			ii.	For each clinical investigation conducted OUS, the submission includes a statement that the clinical investigations were conducted in accordance with good clinical practice (GCP) as described in 21 CFR 812.28(a)(1). **OR** The submission includes a waiver request in accordance with 21 CFR 812.28(c). **OR** The submission includes a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected. *Select "N/A" if the clinical investigations were conducted solely inside the US.*	☐	☐	☐	
			Comments:					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	8.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download). This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).*			☒	☐		Vol. 003 -Sec. 3. -Att. 3.1 -Att. 3.2
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*	☒	☐	☐	Vol. 003 -Sec. 3 -Att. 3.1
			Comments:				
	9.	The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards. Select "N/A" if the submission does not utilize voluntary consensus standards.*		☒		☐	Vol. 009
		a.	The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐	Vol. 009

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
			i.	The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐		Vol. 009
		b.	The submission cites non-FDA-recognized voluntary consensus standard(s).		☒		☐	Vol. 009 pg. 4
			i.	The basis of use is included along with the underlying information or data that supports how the standard was used.	☒	☐		Vol. 018 Att. 18.6 Att. 18.7
		Comments:						
	Combination Product Provisions – Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.						☒	
	10.	Submission identifies the product as a combination product.			☐	☐		
	11.	The combination product contains as a constituent part an approved drug as defined in section 503(g)(5)(B) of the FD&C Act. Select "N/A" if the combination product does not contain as a constituent part an approved drug. Please also select "N/A" if a right of reference or use for the drug constituent part(s) is included with the submission. If "N/A" is selected, part a below is omitted from the checklist.			☐		☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a.	The submission includes appropriate patent statement or certification and a statement that the submitter will give notice, as applicable. See section 503(g)(5)(A)&(C) of the FD&C Act.	☐	☐		
			Comments:				
B.	**Device Description**						
	12.	The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☒	
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
			Comments:				
	13.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		☒	☐		Vol. 011 Vol. 013
		Comments:					
	14.	The submission includes descriptive information for the device, including the following:					
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐		Vol. 011 pg. 3
		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐		Vol. 011 pgs. 19-20
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*	☒	☐	☐	Vol. 011 pg. 21

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). *In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.*	☒	☐		Vol. 011 pgs. 11 and 14
			Comments:				
	15.	Device is intended to be marketed with accessories and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with accessories and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.*		☒		☐	
		a.	Submission includes a list of all accessories to be marketed with the subject device.	☒	☐		Vol. 011 pg. 21
		b.	Submission includes a description (as detailed in item 14a., 14b., and 14d. above) of each accessory. *Select "N/A" if the accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*	☒	☐	☐	Vol. 011 pg. 21
		c.	A 510(k) number is provided for each accessory that received a prior 510(k) clearance. **AND** A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☒	☐		Vol. 011 pg. 21
			Comments:				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
C.	**Substantial Equivalence Discussion**						
	16.	Submitter has identified a predicate device(s), including the following information:					
		a.	Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐		Vol. 012 pg. 1
		b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☒	☐		Vol. 005 Vol. 012
			Comments:				
	17.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)]. *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	☒	☐		Vol. 012
		b.	Technology, including technical specifications, features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.*	☒	☐		Vol. 012
			Comments:				
D.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**						
	18.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		☒	☐		Vol. 013
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐		Vol. 004 Vol. 005 Vol. 013
		b.	Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐		Vol. 013

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			Comments:				
	19.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).		☒	☐		Vol. 013
		Comments:					
	20.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's final rule, "Use of Symbols in Labeling" (81 FR 38911), available at https://www.federalregister.gov/documents/2016/06/15/2016-13989/use-of-symbols-in-labeling). *Select "N/A" if not indicated for prescription use.*		☒	☐	☐	Vol. 013 Att. 13.1 -pg. 17
		Comments:					
	21.	The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☒	
		a.	The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	

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		b.	The submission includes labeling information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
			Comments:				
	22.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. *Select "N/A" if not an in vitro diagnostic device.*		☐	☐	☒	
		Comment:					
E.	**Sterilization** *If an in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*					☐	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	Submission states that the device and/or accessories, if applicable, are: (*one of the below must be checked*) ☐ Provided sterile, intended to be single-use ☒ Requires processing during its use-life ☐ Non-sterile when used (and no processing required) ☐ Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) ☐ Sterility status not needed for this device (e.g., software-only device) ☐ Sterility status needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist.* *If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."* *The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:* • *Supplied sterile and requires reprocessing prior to subsequent patient use* • *Supplied non-sterile and requires user to process the device for initial use, as well as to reprocess the device after each use* • *Reusable medical device (single-user) reprocessed between each use* • *Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use* *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*			☐		Vol. 014 pg. 2
	Comments:					
	23.	Assessment of the need for cleaning and subsequent disinfection or sterilization information.				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a.	Identification of device and/or accessories, if applicable, that are provided sterile. *Select "N/A" if no part of the device or accessories are provided sterile.*	☐	☐	☒	
		b.	Identification of device and/or accessories, if applicable, that are end user sterilized or disinfected. *Select "N/A" if no part of the device are accessories are end user sterilized or disinfected.*	☒	☐	☐	Vol. 014 pg. 2
		c.	Identification of device and/or accessories, if applicable, that are reusable. *Select "N/A" if no part of the device or accessories, are reusable.*	☒	☐	☐	Vol. 014 pg. 2
			Comments:				
	24.	If the device and/or accessories, if applicable, are provided sterile: *Select "N/A" if no part of the device or accessories are provided sterile, otherwise complete a-f below.*				☒	
		a.	Sterilization method is stated for each device (including dose for radiation sterilization)	☐	☐		
		b.	A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date). *Note: the sterilization validation report is not required.*	☐	☐		
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*	☐	☐	☐	
		d.	Sterility Assurance Level (SAL) stated	☐	☐		
		e.	Submission includes description of packaging	☐	☐		

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]). *Select "N/A" if not labeled "non-pyrogenic."*	☐	☐	☐	
			Comments:				
	25.	If the device and/or accessory, if applicable, is reusable or end user sterilized or disinfected: *Select "N/A" if no part of the device or accessories are reusable or end user sterilized or disinfected, otherwise complete a-d below.*				☐	
		a.	Cleaning method is provided in labeling for each device and/or accessory, if applicable. *Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization.*	☒	☐	☐	Vol. 013 Att. 13.4 Att. 13.5
		b.	Disinfection method is provided in labeling for each device and/or accessory, if applicable. *Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use.*	☒	☐	☐	Vol. 013 Att. 13.4 Att. 13.5
		c.	Sterilization method is provided in labeling for each device and/or accessory, if applicable. *Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use.*	☒	☐	☐	Vol. 013 Att. 13.4 Att. 13.5

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**					**Yes**	**No**	**N/A**	***Page #**
		d.	Device types in this submission are listed in the Federal Register (FR) Notice entitled "Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications" (Reprocessing FR Notice, available at https://www.federalregister.gov/documents/2017/06/09/2017-12007/medical-devices-validated-instructions-for-use-and-validation-data-requirements-for-certain-reusable). *Device types identified in the Reprocessing FR Notice represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in the Reprocessing FR Notice.*		☒	☐	☐	
			i.	If device types in this submission are included in the Reprocessing FR Notice, the submission includes protocols and test reports for validating the reprocessing instructions. *Select "N/A" if the device type in the submission is not included in the Reprocessing FR Notice.*	☒	☐	☐	Vol. 014
			Comments:					
	26.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding sterility and/or reprocessing that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*			☒	☐	☐	Vol. 014 pg. 2

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☒	☐	☐	Vol. 014
		b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☒	☐	☐	Vol. 014
			Comments:				
F.	**Shelf-Life**						
	27.		Proposed shelf life/ expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation.	☒	☐		Vol. 014 pg. 2

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
		Comments:				
	28.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. *Select "N/A" if the device is not provided sterile.*	☐	☐	☒	
		Comments:				
	29.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐	☐	Vol. 014 pg. 2
		Comments:				
G.	**Biocompatibility** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				☐	

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	Submission states that there: (*one of the below must be checked*) ☒ Are direct or indirect tissue-contacting components ☐ Are no direct or indirect tissue-contacting components ☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below) ☐ Tissue contact information not needed for this device (e.g., software-only device) ☐ Tissue contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are no" or "not provided and not needed" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information on the tissue-contact status is not provided, and contact information is needed or its contact status is unclear, select "No."* *An example of a direct tissue-contacting device would be an implant that has direct contact with tissues during use. An example of an indirect tissue-contacting device would be fluid entering the body following passing through device/device components not in direct contact with the tissue.*			☐		Vol. 015
	Comments:					
	30.	Submission includes a list identifying each tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		Vol. 015 pgs. 1 and 2
		Comments:				
	31.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter).	☒	☐		Vol. 015 pg. 2
		Comments:				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	32.	For a biocompatibility assessment of tissue-contacting components, submission includes: • Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. • For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☒	☐		Vol. 015
		Comments:				
H.	**Software**					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	Submission states that the device: (*one of the below must be checked*) ☒ Does contain software/firmware ☐ Does not contain software/firmware ☐ Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) ☐ Software/firmware information not needed for this device (e.g., surgical suture, condom) ☐ Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No."*			☐		Vol. 016
	Comments:					
	33.	Submission includes a statement of software level of concern and rationale for the software level of concern	☒	☐		Vol. 016 Sec. 16-1 pg. 2 16-2 pg. 2
		Comments:				
	34.	All applicable software documentation provided based on level of concern identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). *Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.*	☒	☐		Vol. 016

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
		Comments:				
I.	**Cybersecurity**					
	Submission states that the device: (*one of the below must be checked*) ☒ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.) ☐ Does not contain external interfaces as described above ☐ Information on whether device has external interfaces is not provided (if this box is checked, please also check one of the two boxes below) ☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom) ☐ Cybersecurity information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the cybersecurity criteria below are omitted from the checklist. If information on cybersecurity is not provided, and this information is needed or the need is unclear, select "No."*			☐		Vol. 016 Sec.16-1 pg. 21 Sec. 16-2 pg. 27
	35.	All applicable documentation identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0. **OR** Submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒	☐		Vol. 016 Sec. 16-1 pg. 21 Sec. 16-2 pg. 27
		Comments:				
J.	**Electrical Safety and EMC**					

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	Electrical Safety: Submission states that the device: (*one of the below must be checked*) ☒ Does require electrical safety evaluation ☐ Does not require electrical safety evaluation ☐ Information on whether device requires electrical safety evaluation is not provided (if this box checked, please also check one of the two boxes below) ☐ Electrical safety information not needed for this device (e.g., surgical suture, condom) ☐ Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No."*			☐		Vol. 017
	36.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		Vol. 017
		Comments:				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**			**Yes**	**No**	**N/A**	***Page #**
	EMC: Submission states that the device: (*one of the below must be checked*) ☒ Does require EMC evaluation ☐ Does not require EMC evaluation ☐ Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No."*			☐		Vol. 017
	Comments:					
	37.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, a device-specific standard). **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		Vol. 017
		Comments:				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
K.	**Performance Data General** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section L.*					☐	
	Comments:						
	38.	Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. *Select "N/A" if the submission appropriately does not include performance data or there are no completed tests without a Declaration of Conformity.*		☒	☐	☐	Vol. 018
		a.	Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.). *Select "N/A" if the submission does not include performance data.*	☒	☐	☐	Vol. 018
			Comments:				

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Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	39.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding performance data that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐		☒	
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
			Comments:				

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	40.		If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. If "N/A" is selected, parts a and b below are omitted from the checklist.* *Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*			☐	
		a.	Legible reprints or a summary of each article.	☒	☐		Vol. 020
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	☒	☐		Vol. 020
			Comments:				
	41.		For each completed animal study, the submission provides the following: *Select "N/A" if no animal study was conducted. If "N/A" is selected, parts a-c below are omitted from the checklist. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist.*			☒	
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120	☐	☐		
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185	☐	☐		
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), OR, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	☐	☐		
			Comments:				

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L.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**						
	Submission indicates that device: (*one of the below must be checked*) ☐ Is an in vitro diagnostic device ☐ Is not an in vitro diagnostic device *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*						
	42.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:					
		a.	Precision/reproducibility	☐	☐	☐	
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff).	☐	☐	☐	
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).	☐	☐	☐	
		d.	Analytical specificity	☐	☐	☐	
			Comments:				
	43.	The device has a device-specific guidance document, special controls, and/or requirement in a device-specific classification regulation regarding performance data that is applicable to the subject device. *If "N/A" is selected, parts a and b below are omitted from the checklist.*		☐	☐	☐	

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		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	☐	☐	☐	
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there are no applicable special controls or device-specific classification regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*	☐	☐	☐	
			Comments:				

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Digital Signature Concurrence Table	
Reviewer Sign-Off	
Management Sign-Off (digital signature optional)*	

*Management review of checklist and concurrence with decision required.

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Hello Teffany,

Thank you for providing your response to our August 12, 2022 request for additional information. (b)(4)

(b)(4)

Thank you,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
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Dear Ms. Kaplan,

Please find attached an (b)(4). If I can provide you with anything else, please let me know.

Best regards,
Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Thursday, January 19, 2023 8:30 AM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: K221683@docs.fda.gov
Subject: [EXTERNAL] K221683/S001 Interactive Review Request

PLEASE NOTE: Please use caution when opening links and attachments in this message.

Hello Teffany,

Thank you for your previous response. (b)(4)

(b)(4)

Please reply by end of day today, January 19 as the review cycle is coming to a close. Let me know if you will be unable to respond in that time.

Thank you,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
esther.kaplan@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221683

Device Name
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE V2R

Indications for Use *(Describe)*
VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYF TYPE V2R have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221683

Device Name
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH, CYF-VHR

Indications for Use *(Describe)*
CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF VH, and CYF VHR have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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GLP PROTOCOL

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

Cytotoxicity Study Using the ISO Elution Method

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Section 17.2.7

Test Condition for EMC Test

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Identification information (b)(4)

OLYMPUS

Test Report

Title

Recovery Test for Low Number of Organisms of

CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH

(b)(4)

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Step-by-Step Comparison of Manual HLD Steps

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Step-by-Step Comparison of the Manual HLD steps

(b)(4)

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Identification information: (b)(4)

OLYMPUS

Test Report

Title

Simulated use conditioning test of OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5 and Luer-Split MAJ-2092

(b)(4)

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Dear Teffany,

This is another request for interactive review of your submission. Please address the following concern:

(b)(4)

Please respond by COB Friday, July 29, to facilitate timely review of your device.

Regards,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

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OLYMPUS

OPERATION MANUAL

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-VH
OLYMPUS CYF-VHR

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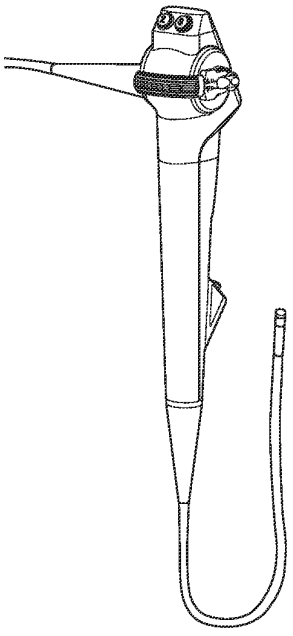

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For important information regarding the BCG shortage see MS-11. Also see the AUA BCG Shortage Notice.

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Section 18.11

Image Intensity Uniformity

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18.11

Image Intensity Uniformity

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Dear Ms. Kaplan,

Olympus has asked me to see if you're available for a quick phone call later today so that they can get clarification on what information they need to provide to address question #1. We can make ourselves available for any time that works for you.

Best regards,

Teffany

From: Teffany Hutto

Sent: Monday, July 25, 2022 9:54 AM

To: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov

Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

Dear Ms. Kaplan,

Thank you for reviewing our response so quickly. I will work to make sure the requested information is received by tomorrow.

Have a good day,

Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov<mailto:Esther.Kaplan@fda.hhs.gov>>

Sent: Monday, July 25, 2022 9:48 AM

To: Teffany Hutto <teffany.hutto@olympus.com<mailto:teffany.hutto@olympus.com>>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov<mailto:Reginald.Avery@fda.hhs.gov>>; K221683@docs.fda.gov<mailto:K221683@docs.fda.gov>

Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

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Dear Teffany,

Thank you for your response. I have a few clarifying questions:

(b)(4)

Please respond by tomorrow, July 26, to facilitate a timely review of your submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: 301-796-1863

esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

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From: Teffany Hutto <teffany.hutto@olympus.com<mailto:teffany.hutto@olympus.com>>

Sent: Monday, July 25, 2022 8:21 AM

To: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov<mailto:Esther.Kaplan@fda.hhs.gov>>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov<mailto:Reginald.Avery@fda.hhs.gov>>; K221683@docs.fda.gov<mailto:K221683@docs.fda.gov>

Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

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Dear Ms. Kaplan,

The requested information has been provided below. If you have any other questions, please let me know.

Best regards,

Teffany Hutto

Consultant for Olympus Medical.

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov<mailto:Esther.Kaplan@fda.hhs.gov>>

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Sent: Wednesday, July 20, 2022 8:43 AM

To: Teffany Hutto <teffany.hutto@olympus.com<mailto:teffany.hutto@olympus.com>>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov<mailto:Reginald.Avery@fda.hhs.gov>>; K221683@docs.fda.gov<mailto:K221683@docs.fda.gov>

Subject: [EXTERNAL] K221683 Interactive Review Request #1

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Dear Ms. Hutto,

I am the lead reviewer for your submission for the Cysto-Nephro Videoscopes Olympus CYF Type V2/V2R and VH/VHR. This email is a request for information to facilitate interactive review of the device. As the review of your device continues I may send out additional requests for information the review team needs to make a determination on the substantial equivalence of your device to the selected predicate.

Please address the following:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

(b)(4)

Please reply via email by COB July 25, to facilitate timely review of your submission. Be sure to copy the file folder address K221683@docs.fda.gov<mailto:K221683@docs.fda.gov> on your reply to help maintain the record of our communication.

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

Tel: 301-796-1863

esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

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Section 18.7
Photobiological Safety

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Report for residual toxicity evaluation (rinsing validation) after OER-Elite/ Pro(Acecid-C)/Mini disinfection for CYF-VH/VHR and MAJ-2092

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OLYMPUS

REPROCESSING MANUAL

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-V2
OLYMPUS CYF-V2R

Chapter 1 General Policy 1

Chapter 2 Function and Inspection of the Accessories for Reprocessing 9

Chapter 3 Compatible Reprocessing Methods and Chemical Agents 13

Chapter 4 Reprocessing Workflow for Endoscopes and Accessories 23

Chapter 5 Reprocessing the Endoscope 27

Chapter 6 Reprocessing Endoscopes and Accessories Using an AER 79

Chapter 7 Storage and Disposal 81

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Dear Ms. Kaplan,

I have received your questions and will work with Olympus to ensure that the information is provided to you by the deadline.

Have a good day,
Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Wednesday, July 20, 2022 8:43 AM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: [EXTERNAL] K221683 Interactive Review Request #1

You don't often get email from esther.kaplan@fda.hhs.gov. Learn why this is important

Dear Ms. Hutto,

I am the lead reviewer for your submission for the Cysto-Nephro Videoscopes Olympus CYF Type V2/V2R and VH/VHR. This email is a request for information to facilitate interactive review of the device. As the review of your device continues I may send out additional requests for information the review team needs to make a determination on the substantial equivalence of your device to the selected predicate.

Please address the following:

(b)(4)

Please reply via email by COB July 25, to facilitate timely review of your submission. Be sure to copy the file folder address K221683@docs.fda.gov on your reply to help maintain the record of our communication.

Thank you,

Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
esther.kaplan@fda.hhs.gov

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Section 21-2
Risk Management

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January 20, 2023</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Esther Kaplan.

 *** This is a system-generated email notification ***

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 20

Performance Testing - Clinical

This section is not applicable as there has been no clinical testing performed on the subject device.

Additionally, no Clinical Study was performed for the subject devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Hello Teffany,

(b)(4)

Thank you,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
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Section 18.5

Color Performance

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Section 18.5
Color Performance

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Identification information : (b)(4)

OLYMPUS

Test Report

Title

High Level Disinfection test Using OER-Pro with Acecide-C of OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5 and Luer-Split MAJ-2092

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Japan

STUDY TITLE

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Questions? Contact FDA/CDRH/OCE/DCI at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

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Dear Ms. Kaplan,

Thank you for agreeing to speak with us yesterday. The additional information that you provided was helpful in determining our response for Question #1. Th additional information that you have requested is provided below.

Again, if you need any other information, please let me know.

Best regards,
Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Monday, July 25, 2022 9:48 AM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

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Dear Teffany,

Thank you for your response. I have a few clarifying questions:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

Please respond by tomorrow, July 26, to facilitate a timely review of your submission.

Thank you,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
esther.kaplan@fda.hhs.gov

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From: Teffany Hutto <teffany.hutto@olympus.com>
Sent: Monday, July 25, 2022 8:21 AM
To: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

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Dear Ms. Kaplan,

The requested information has been provided below. If you have any other questions, please let me know.

Best regards,
Teffany Hutto
Consultant for Olympus Medical.

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>
Sent: Wednesday, July 20, 2022 8:43 AM
To: Teffany Hutto <teffany.hutto@olympus.com>
Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov
Subject: [EXTERNAL] K221683 Interactive Review Request #1

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Dear Ms. Hutto,

I am the lead reviewer for your submission for the Cysto-Nephro Videoscopes Olympus CYF Type V2/V2R and VH/VHR. This email is a request for information to facilitate interactive review of the device. As the review of your device continues I may send out additional requests for information the review team needs to make a determination on the substantial equivalence of your device to the selected predicate.

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Please reply via email by COB July 25, to facilitate timely review of your submission. Be sure to copy the file folder address K221683@docs.fda.gov on your reply to help maintain the record of our communication.

Thank you,

Esther Kaplan
Mechanical Engineer

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Report for residual toxicity evaluation (rinsing validation) after OER-Pro(Aldahol) disinfection for CYF-V2/V2R and MAJ-2092

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Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Report Number: (b)(4) Report Revision: (b)(4)

Report Title: Safety Profile and Margin of Exposure Analysis for Metal and Organic Compounds Identified in Extracts from Visera Cysto-Nephro Videoscope (CYF-V2)

Protocol Number: (b)(4) Protocol Revision: (b)(4)

(b)(4)

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Dear Teffany,

Thank you for your response. I have a few clarifying questions:

(b)(4)

Please respond by tomorrow, July 26, to facilitate a timely review of your submission.

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

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Office of Product Evaluation and Quality

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Tel: 301-796-1863

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From: Teffany Hutto <teffany.hutto@olympus.com>

Sent: Monday, July 25, 2022 8:21 AM

To: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Subject: RE: [EXTERNAL] K221683 Interactive Review Request #1

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Dear Ms. Kaplan,

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Best regards,

Teffany Hutto

Consultant for Olympus Medical.

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov<mailto:Esther.Kaplan@fda.hhs.gov>>

Sent: Wednesday, July 20, 2022 8:43 AM

To: Teffany Hutto <teffany.hutto@olympus.com<mailto:teffany.hutto@olympus.com>>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov<mailto:Reginald.Avery@fda.hhs.gov>>; K221683@docs.fda.gov<mailto:K221683@docs.fda.gov>

Subject: [EXTERNAL] K221683 Interactive Review Request #1

You don't often get email from esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>. Learn why this is important<https://secure-web.cisco.com/1HSCqHZMspigePNJuLaL0upTTlPEIr-D2ycnwSXR5Lq4q8r68NxW55joD8UnJj9g_D3Xfac1FIKokY9EFsuDuNzTtFsKtDHJsIGWjNrnGARWtNE0vuPzU1hQ7g9HuzelTm5lgQOzNExBZry_U1d7OwKzOEybRKWXD_NGoKmusbEXAibr2cJonr3mpP9D5baDiyZAkctVj9bSvx9CTIEbXSQ/https%3A%2F%2Faka.ms%2FLearnAboutSenderIdentification>

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Mechanical Engineer

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OLYMPUS

December 22, 2022

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

RE: K221683– CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH and CYF-VHR VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and CYF TYPE V2R

Dear Sir or Madam,

In response to a request dated August 12, 2022 related to the review of K221683– CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH and CYF-VHR VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and CYF TYPE V2R, please find the enclosed eCopy which addresses each question raised by the Agency.

The eCopy of this pre-submission will be submitted through the Customer Collaboration Portal in accordance with FDA's Guidance Document *eCopy Program for Medical Device Submissions* (April 27, 2020).

Please do not hesitate to contact me if you have any questions or require additional information. You can reach me by phone at (512) 508-6550 or by email at teffany.hutto@olympus.com.

Sincerely,

(b)(6)

Teffany Hutto
Regulatory Affairs Consultant for Olympus Corporation of the Americas

\enclosure (as stated)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Hello Teffany,

(b)(4)

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

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From: Venable, Latasha * [Latasha.Venable@fda.hhs.gov]
Sent: 6/10/2022 5:29:33 PM
To: teffany.hutto@olympus.com
Subject: K221683 eCopy Hold Notification with Attachment
Attachments: K221683.pdf; K221683 -eCopy Fail.pdf

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eCopy Hold Letter

6/10/2022

Teffany Hutto, Regulatory Affairs Consultant
Olympus Corporation of the Americas
3500 Corporate Parkway
P.O. BOX 610
Center Valley, PA 18034
UNITED STATES

Dear Teffany Hutto:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. Failure to reference this assigned number in future correspondence may result in processing delays.

Submission Number: K221683
Received: 06/10/2022
Applicant: Olympus Medical Systems Corporation
Device: CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2R), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VH) and CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VHR)

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to require an electronic copy (eCopy) for certain types of submissions. **You have received this letter because you have either not provided an eCopy or you provided an eCopy that failed the loading process because it did not meet the technical standards.** If you provided an eCopy that failed the loading process, then please see the attached document that identifies all reasons for the failure that need to be addressed. To understand the reasons for your eCopy failure, please refer to the eCopy guidance document, "eCopy Program for Medical Device Submissions" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf.

To verify your eCopy meets the technical standards prior to submitting to FDA, you may use the eCopy Validation Module (a voluntary tool that verifies the format of an eCopy you have already developed on your local drive) available on the eCopy Program webpage at https://www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-program-

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Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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If you have any questions concerning this letter, please contact the eCopy Program Coordinators at (240) 402-3717 or at CDRH-eCopyinfo@fda.hhs.gov.

Sincerely yours,

Center for Devices and Radiological Health

Attachment

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Attachment

Attachment for Submission Number(s):

K221683

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   001_Section 21-1_Risk Management_CYF-V2□V2R_220421.pdf

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Food and Drug Administration
CDRH/OPEQ/OHTIII/DHTIIIB
AWL RMONR
Global Work Location
Silver Spring, MD 20705
301-796-1863

Premarket Notification 510(k) Review

Date: January 12, 2023

Reviewer: Esther Kaplan

510(k)# K221683/S001 Subject: Traditional

Applicant: Olympus Medical Systems Corporation	**Device Trade Name:** CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2R), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VH) and CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VHR)
Contact Name: Teffany Hutto	**Contact Title:** Regulatory Affairs Consultant
Correspondent Firm: Olympus Corporation of the Americas	**Phone:** (512) 508-6550 **Email:** teffany.hutto@olympus.com
Received Date: December 22, 2022	**Due Date:** January 22, 2023
Pro Code(s): FAJ **Class:** II **Reg #:** 876.1500	**Reg Name:** Endoscope And Accessories

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K133538	NWB, FAJ	Visera Cysto-nephro Videoscope Olympus Cyf Type V2, Visera Cysto-nephro Videoscope Olympus Cyf Type Va2, Visera Cysto-ne	Olympus Corporation Of The Americas

Recommendation

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Sponsor:
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Olympus Medical Systems Corp.
2951 Ishikawa-machi
Hachioji-shi, Tokyo, 192-8507
JAPAN

Simulated Use Cycles GLP Report

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Hello Teffany,

Thank you for your previous response: (b)(4)

(b)(4)

Please reply by end of day today, January 19 as the review cycle is coming to a close. Let me know if you will be unable to respond in that time.

Thank you,
Esther Kaplan
Mechanical Engineer

Urological Devices Team (THT3B3)
Division of Reproductive, Gynecological, and Urological Devices (DHT3B)
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
Tel: 301-796-1863
esther.kaplan@fda.hhs.gov

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Section 18.1

Thermal Safety Test Report

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Records processed under FOIA Request 2023-3[illegible] Released by CDRH on 08-29-2024

OLYMPUS

K221683/S001

December 22, 2022

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

FDA/CDRH/DCC
DEC 22 2022
RECEIVED

RE: K221683– CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH and CYF-VHR VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and CYF TYPE V2R

Dear Sir or Madam,

In response to a request dated August 12, 2022 related to the review of K221683– CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH and CYF-VHR VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and CYF TYPE V2R, please find the enclosed eCopy which addresses each question raised by the Agency.

The eCopy of this pre-submission will be submitted through the Customer Collaboration Portal in accordance with FDA's Guidance Document *eCopy Program for Medical Device Submissions* (April 27, 2020).

Please do not hesitate to contact me if you have any questions or require additional information. You can reach me by phone at (512) 508-6550 or by email at teffany.hutto@olympus.com.

Sincerely,

(b)(6)

Teffany Hutto
Regulatory Affairs Consultant for Olympus Corporation of the Americas

\enclosure (as stated)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

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(b)(4)

TEST REPORT

APPLICANT	OLYMPUS MEDICAL SYSTEMS CORP.
ADDRESS	2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan
PRODUCTS	VISERA CYSTO-NEPHRO VIDEOSCOPE
MODEL NO.	OLYMPUS CYF TYPE V2, OLYMPUS CYF TYPE V2R
SERIAL NO.	(b)(4)
TEST STANDARD	IEC 60601-2-18: 2009
ADDITIONAL INFORMATION	-
TESTING LOCATION	(b)(4)
TEST RESULTS	Refer to the attached TEST REPORT
DATE OF TEST	From 2021-10-07 to 2021-12-20

Issued Date: 2021-12-20

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Test Report issued under the responsibility of:

(b)(4)

TEST REPORT
IEC 60601-2-18
Medical electrical equipment
Part 2: Particular requirements for the basic safety and essential performance of endoscopic equipment

(b)(4)

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GLP REPORT

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

CONFIDENTIAL

STUDY TITLE

USP Rabbit Pyrogen Study, Material Mediated

TEST ARTICLE NAME

VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and Luer-Split MAJ-2092

TEST ARTICLE IDENTIFICATION

(b)(4)

(b)(4)

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GLP PROTOCOL

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

USP Rabbit Pyrogen Study, Material Mediated

(b)(4)

Questions? Contact FDA/CDRH/OCE/DI at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

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Section 17

Electrical Safety and Electromagnetic Compatibility

This section is prepared based on *Electromagnetic Compatibility (EMC) of Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff*, issued on November 17, 2020.

A. Electrical Safety and EMC Related Device Characteristics and Intended Use Environments

VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2 and CYF TYPE V2R, have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

Device Overview

The Visera Cysto-Nephro Videoscope System is shown in **Figure 17-1**. CYF-V2/CYF-V2R, the subject of this submission, is outlined. See **Table 17-1** for cleared compatible devices intended for use with CYF-V2/CYF-V2R.

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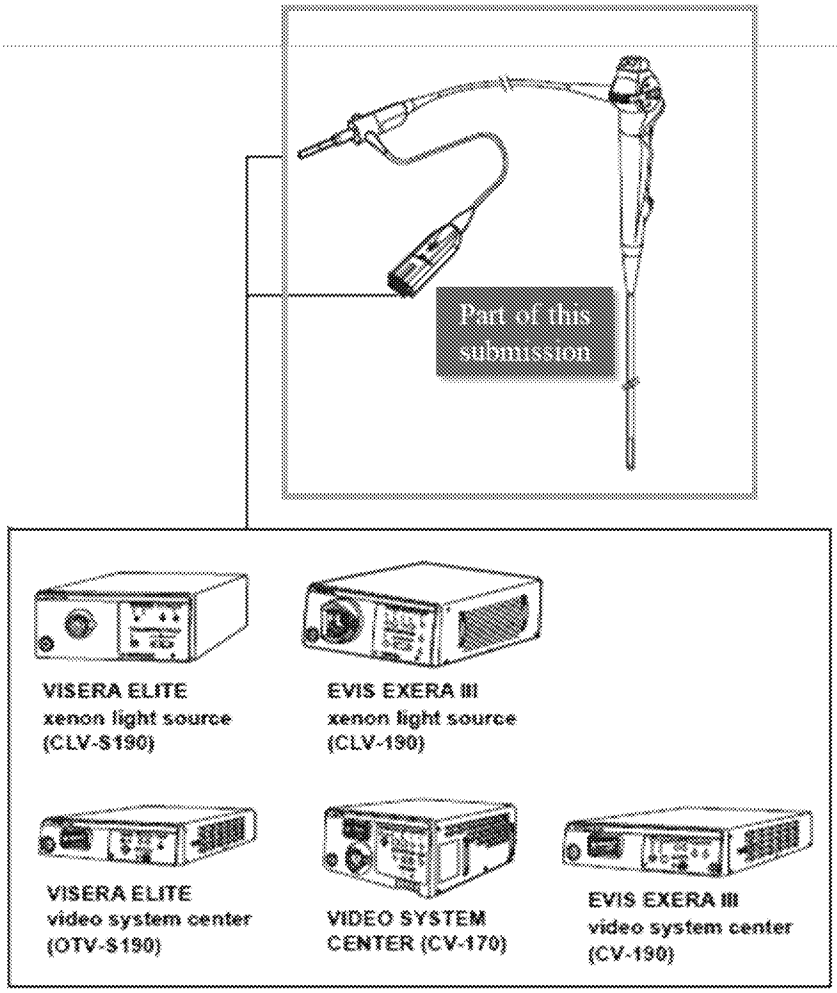

Figure 17-1 VISERA CYSTO-NEPHRO Videoscope System Components with CYF-V2/CYF-V2R Endoscope

Table 17-1 Compatible Devices Intended for use with CYF-V2/CYF-V2R

Model No.	Device Name/Description	510(k) Number
Video system center		
OTV-S190	VISERA ELITE video system center	K111425
CV-190	EVIS EXERA III video system center	K131780
CV-170	VIDEO SYSTEM CENTER (This device also has light source function)	K122831
Light source		
CLV-S190	VISERA ELITE xenon light source	K111425
CLV-190	EVIS EXERA III xenon light source	K131780
CV-170	VIDEO SYSTEM CENTER	K122831

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Monitor		
OEV262H	HIGH DEFINITION LCD MONITOR	K102379
Leakage Tester		
MB-155	Leakage tester	K051886
WA23080A	Leakage tester	510(k) Exempt
Instrument Tray		
WA05991A	Instrument tray	K110748
ENDOSCOPE REPROCESSOR		
OER-Pro	ENDOSCOPE REPROCESSOR	K103264
OER-Mini	ENDOSCOPE REPROCESSOR	K120357
OER-Elite	ENDOSCOPE REPROCESSOR	K201920

CYF-V2/ CYF-V2R consists of four functional parts: the video connection section, light guide connector section, control section, and insertion section (numbered parts below correspond to **Figure 17-2**).

1. **Video Connector Section:** Includes a video connector and video cable that connects the endoscope to the video system center for displaying images on compatible video monitors.
2. **Light Guide Connector Section:** The connection that links the endoscope with the light source and transmits light to the distal end of the endoscope.
3. **Control Section:** The UP/DOWN angulation control lever on the control section is connected to the tip of the bending section by bundles of wires. By operating the UP/DOWN angulation control lever, the bending section at the distal end bends to guide the distal end for insertion and observation into the urethra and bladder. Therapeutic instruments can pass through the instrument channel for treatment. It can also be perfused through the instrument channel.
4. **Insertion Section:** The insertion section consists of the CCD, light guides that bring light from the light source through the endoscope, an instrument channel where therapeutic accessories can be inserted and withdrawn.

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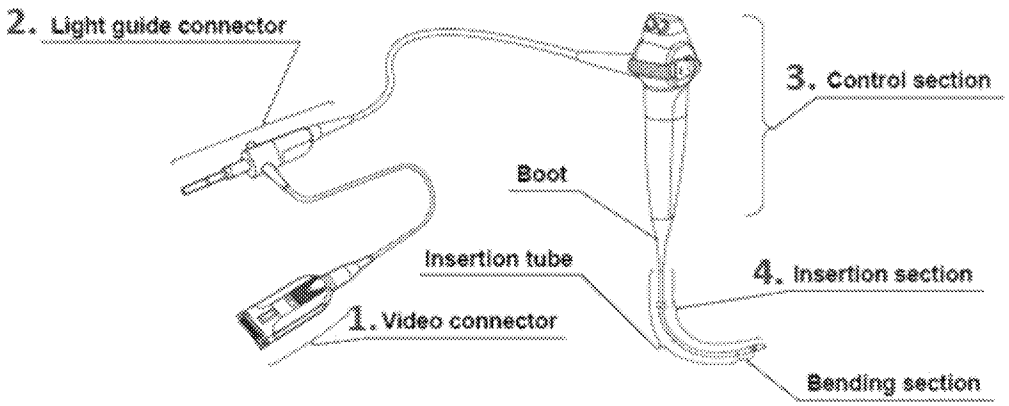

Figure 17-2 Functional Parts of the CYF-V2 / CYF-V2R

Power Supply Description

The Visera Cysto-Nephro Videoscope system (**Figure 17-2**), is powered by mains. The video system center, powered by mains, is couples directly to CYF-V2/V2R by the following connections:

A. CYF-V2/V2R is connected to the video connector socket of the compatible video system center via video connector (**Figure 17-2**, #1).
B. CYF-V2/V2R is connected to output socket of one of the compatible light sources via the light guide connector (**Figure 17-2**, #2).
C. The compatible monitor is connected to the video system center.

Intended Use Environment

CYF-V2/V2R are intended to be used in professional healthcare facility environments.

Wireless Technology

There is no wireless technology in CYF-V2/V2R.

RF Emitters in the Medical Device

CYF-V2/V2R uses RF (Radio Frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

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Final Report

Test Description: **Extractables of G1F-TH190**

Sponsor:

Olympus Surgical Technologies
9600 Louisiana Avenue
Brooklyn Park, MN 55445
US

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE V2R

Indications for Use *(Describe)*
VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYF TYPE V2R have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH, CYF-VHR

Indications for Use *(Describe)*
CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF VH, and CYF VHR have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Section 3

Prior Submissions

The CYF-V2/V2R and CYF-VH/VHR (b)(4) (b)(4) Feedback from the Agency was reviewed and addressed as part of this 510(k) application. A summary of how the feedback was addressed is provided in **Attachment 3.1 – Q-Submission Feedback**.

Since the CYF-V2/V2R is currently on the market under K133538, a summary of the letters to file completed for these devices is provided in **Attachment 3.2 – Letter to File History**.

A market survey was performed that included CYF-V2/V2R and CYF-VH/VHR to confirm the worst cycle number used before failure in the US market. This information is provided in **Attachment 3.3 – Market Survey Results**

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Step-by-Step Comparison of Rinsing validation Steps (Automated HLD for OER-Elite/OER-Pro/OER-Mini with Acecide-C)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Step-by-Step Comparison of the Automated HLD steps (Automated HLD for OER-Elite/OER-Pro/OER-Mini with Acecide-C)

(b)(4)

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Date Prepared: 11/14/2022

510(k) Summary

(b)(4)

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OLYMPUS

Identification information:
(b)(4)

Justification of Recovery Test for Low number of Organisms Criteria

(b)(4)

2. Test report title

Recovery Test for Low Number of Organisms of CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH

(b)(4)

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Section 18.4. Color performance : Attachment : XYZ measured (All devices)

(b)(4)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE V2R

Indications for Use *(Describe)*
VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYF TYPE V2R have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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REVISED REPORT

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

CONFIDENTIAL

STUDY TITLE

Subcontracted Testing – Identification by SEM-EDS and Microscopic FTIR

TEST ARTICLE NAME

(b)(4)

TEST ARTICLE IDENTIFICATION

N/A

TEST ARTICLE PHYSICAL DESCRIPTION

(b)(4)

TEST ARTICLE RECEIVED

January 17, 2022

(b)(4)

Questions? Contact FDA/CDRH/OPE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4)

ISO 9001:2015 CERTIFIED

(b)(4)

Test Report
Identification of Particles in (b)(4)

(b)(4)

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GLP REPORT

TEST FACILITY

(b)(4)

SPONSOR

(b)(4)

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

CONFIDENTIAL

STUDY TITLE

ISO Guinea Pig Maximization Sensitization Test

TEST ARTICLE NAME

VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and Luer-Split MAJ-2092

TEST ARTICLE IDENTIFICATION

(b)(4)

(b)(4)

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SPONSOR

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OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

ISO Guinea Pig Maximization Sensitization Test

(b)(4)

Questions? Contact FDA/CDRH/OCE/DIDSI at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SPONSOR

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Olympus Medical Systems Corp.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

ISO Intracutaneous Irritation Study - Extract

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SPONSOR

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OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

CONFIDENTIAL

STUDY TITLE

ISO Guinea Pig Maximization Sensitization Test

TEST ARTICLE NAME

CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH
and Luer-Split MAJ-2092

TEST ARTICLE IDENTIFICATION

(b)(4)

(b)(4)

Questions? Contact FOI@CDRH/OCE/DID at CDRH-DISTAFOIUS@fda.hhs.gov or 301-796-8118

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OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo, 192-8507
Japan

STUDY TITLE

ISO Guinea Pig Maximization Sensitization Test

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Attachment 3.2
Letter to File History

Letters to file were completed for changes to the CYF-V2/V2R (under K133538). A summary of each change is provided in **Tables 3.2-1 and 3.2-2.**

Table 3.2-1 – Letter to File History for CYF-V2

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From: DCCLetters@fda.hhs.gov [DCCLetters@fda.hhs.gov]
Sent: 6/14/2022 7:39:39 PM
To: teffany.hutto@olympus.com
CC: DCCLetters@fda.hhs.gov
Subject: K221683 Acknowledgement Letter
Attachments: K221683-Acknowlegement Letter.pdf

June 14, 2022

Thank you for your submission. We have attached your acknowledgement letter for your records. If you have any questions about your acknowledgement letter, please contact us at DCCmailroom@fda.hhs.gov. Please do not reply to this email.

*** This is a system-generated email notification ***

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U.S. FOOD & DRUG ADMINISTRATION

Acknowlegement Letter

06/14/2022

Teffany Hutto, Regulatory Affairs Consultant
Olympus Corporation of the Americas
3500 Corporate Parkway P.O. BOX 610
Center Valley, PA 18034
UNITED STATES

Dear Teffany Hutto:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the address listed below. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact the Office of Product Evaluation and Quality (OPEQ) submission support at (301) 796-5640 or OPEQSubmissionSupport@fda.hhs.gov .

Submision Number: K221683
Received: 06/10/2022
Applicant: Olympus Medical Systems Corporation
Device: CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2R), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VH) and CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VHR)

We will notify you when the review of this submission document has been completed or if any additional information is required.If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm .

Sincerely yours,

Center for Devices and Radiological Health

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Identification information (b)(4)

OLYMPUS

Test Report

Title

High Level Disinfection test Using OER-Pro with Aldahol 1.8 of CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH

(b)(4)

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Section 21-1
Risk Management

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Section 17.2.5

Selection of Representative Video system center for EMC Test

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MEMO OF

SOFTWARE and CYBERSECURITY REVIEW

(b)(5)

510(k): K221683

DATE: 8/1/22

FROM:	Pramodh Kariyawasam, MS	OHT3/DHT3A/THT3A2	Bldg 66 G615	301-348-1911
TO:	Esther Kaplan	OHT3/DHT3B/THT3B3	Bldg 66	301-796-1863

SUBJECT: Software review of the CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-V2R), CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VH) and CYSTO-NEPHRO VIDEOSCOPE (OLYMPUS CYF-VHR).
Olympus Medical Systems Corporation.
3500 Corporate Parkway P.O. BOX 610, Center Valley, PA 18034
US. Correspondent Contact: Teffany Hutto, Regulatory Affairs Consultant, (512) 508-6550

Consult #: CON2214588 and CON2214589

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Digital Signature Concurrence Table	
Consult Sign-Off	FDA Digitally signed by Pramodh Kariyawasam -S Date: 2022.08.01 22:56:49 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section 17

Electrical Safety and Electromagnetic Compatibility

This section is prepared based on *Electromagnetic Compatibility (EMC) of Medical Devices, Draft Guidance for Industry and Food and Drug Administration Staff*, issued on November 17, 2020.

A. Electrical Safety and EMC Related Device Characteristics and Intended Use Environments

CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF-VH and CYF-VHR, have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.

Device Overview

The CYSTO-NEPHRO Videoscope System is shown in **Figure 17-1**. CYF-VH/CYF-VHR, the subject of this submission, is outlined. See **Table 17-1** for cleared compatible devices intended for use with CYF-VH/CYF-VHR.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

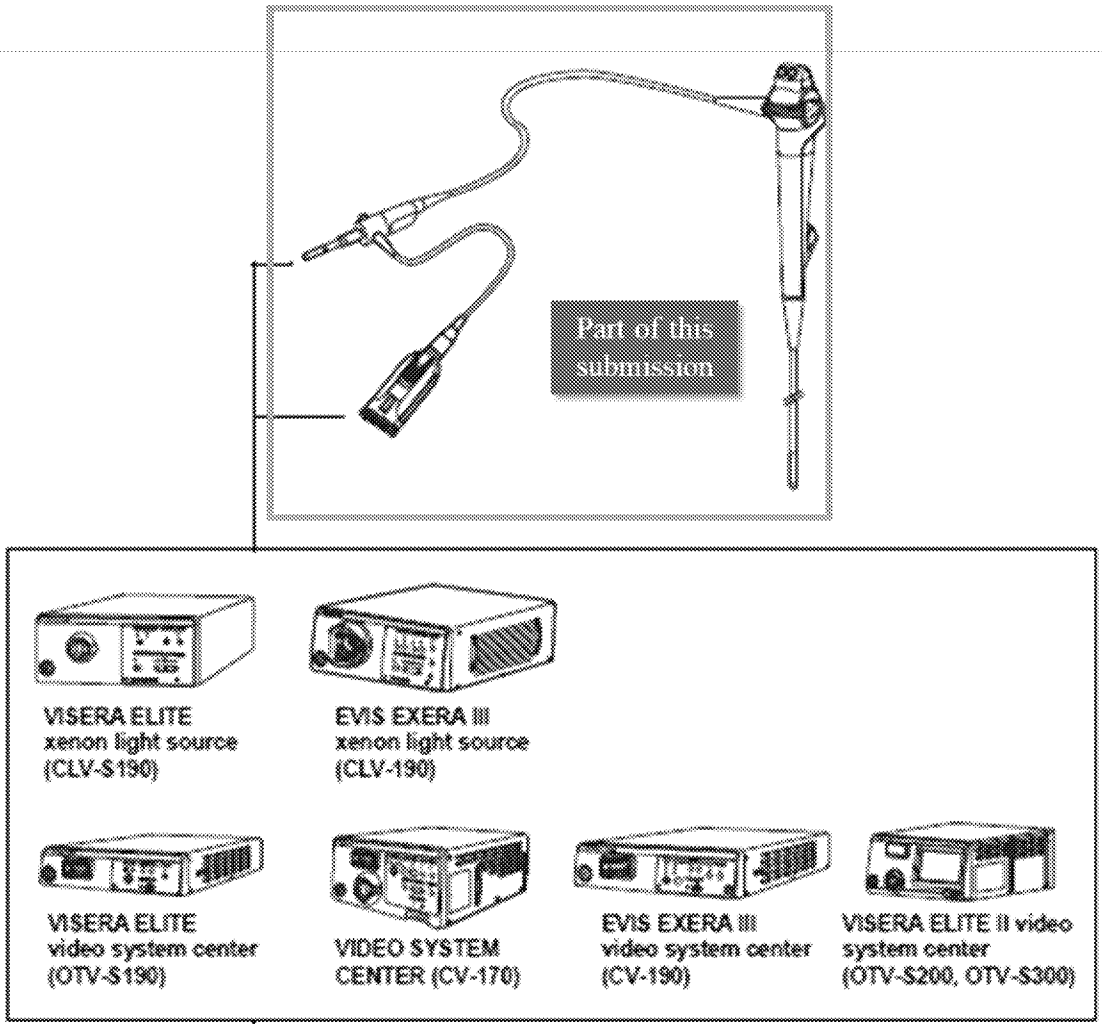

Figure 17-1 CYSTO-NEPHRO Videoscope System Components with CYF-VH/CYF-VHR Endoscope

Table 17-1 Compatible Devices Intended for use with CYF-VH/CYF-VHR

Model No.	Device Name/Description	510(k) Number
Video system center		
OTV-S300	VISERA ELITE II VIDEO SYSTEM CENTER (This device also has light source function)	K202646
OTV-S200	VISERA ELITE II video system center (This device also has light source function)	K190449
OTV-S190	VISERA ELITE video system center	K111425
CV-190	EVIS EXERA III video system center	K131780

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Model No.	Device Name/Description	510(k) Number
CV-170	VIDEO SYSTEM CENTER (This device also has light source function)	K122831
Light source		
OTV-S300	VISERA ELITE II VIDEO SYSTEM CENTER	K202646
OTV-S200	VISERA ELITE II video system center	K190449
CLV-S190	VISERA ELITE xenon light source	K111425
CLV-190	EVIS EXERA III xenon light source	K131780
CV-170	VIDEO SYSTEM CENTER	K122831
Monitor		
OEV262H	HIGH DEFINITION LCD MONITOR	K102379
LMD-X310ST	Sony LMD-X310ST LCD Monitor	K150377
Reprocessor		
OER-Pro	ENDOSCOPE REPROCESSOR	K103264
OER-Elite	ENDOSCOPE REPROCESSOR	K201920
OER-Mini	ENDOSCOPE REPROCESSOR	K120357
Leak Tester		
MB-155	Leakage tester	K051645
WA23080A	Leakage tester	510(k) Exempt
ALT-Pro	AUTOMATED ENDOSCOPE LEAK TESTER	K123704
Others		
MU-1	MAINTENANCE UNIT	K051645
WA05991A	Instrument tray	K110748

CYF-VH/ CYF-VHR consists of four functional parts: the video connection section, light guide connector section, control section, and insertion section (numbered parts below correspond to **Figure 17-2**).

1. **Video Connector Section:** Includes a video connector and video cable that connects the endoscope to the video system center for displaying images on compatible video monitors.
2. **Light Guide Connector Section:** The connection that links the endoscope with the light source and transmits light to the distal end of the endoscope.
3. **Control Section:** The UP/DOWN angulation control lever on the control section is connected to the tip of the bending section by bundles of wires. By operating the UP/DOWN angulation control lever, the bending section at the distal end bends to

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guide the distal end for insertion and observation into the urethra and bladder. Therapeutic instruments can pass through the instrument channel for treatment. It can also be perfused through the instrument channel.

4. **Insertion Section:** The insertion section consists of the CCD, light guides that bring light from the light source through the endoscope, an instrument channel where therapeutic accessories can be inserted and withdrawn.

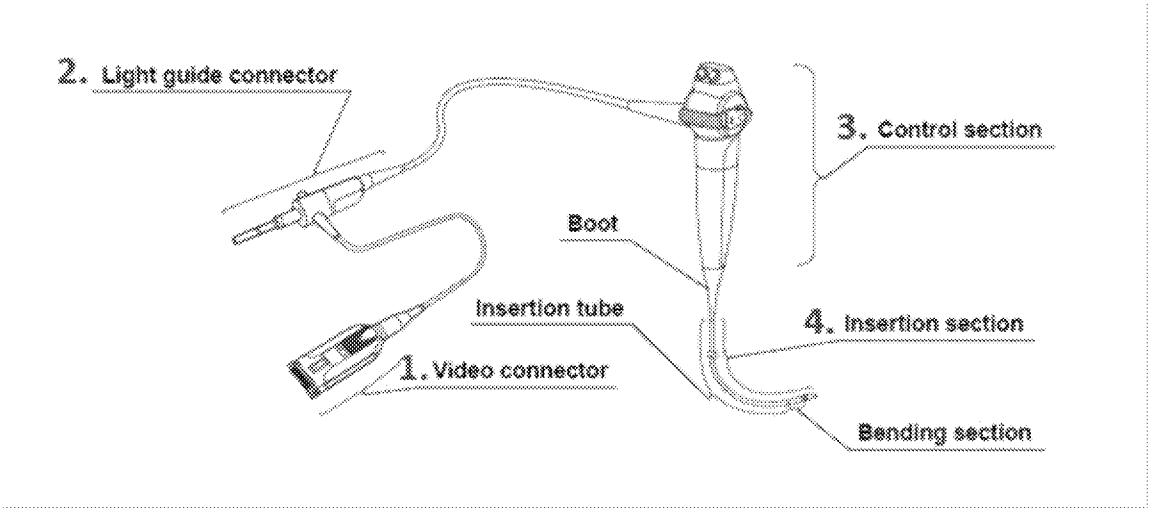

Figure 17-2 Functional Parts of the CYF-VH / CYF-VHR

Power Supply Description

The Cysto-Nephro Videoscope system (**Figure 17-2**), is powered by mains. The video system center, powered by mains, is couples directly to CYF-VH/VHR by the following connections:

A. CYF-VH/VHR is connected to the video connector socket of the compatible video system center via video connector (**Figure 17-2**, #1).
B. CYF-VH/VHR is connected to output socket of one of the compatible light sources via the light guide connector (**Figure 17-2**, #2).

Intended Use Environment

CYF-VH/VHR are intended to be used in Professional Healthcare Facility Environments.

Wireless Technology

There is no wireless technology in CYF-VH/VHR.

RF Emitters in the Medical Device

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OLYMPUS	Reference: (b)(4)	Type: Design Verification Report	PAGE 1 of 9

Report Number: (b)(4) Report Revision: (b)(4)

Report Title: Biological Safety and Biocompatibility Testing Summary Report

Protocol Number: (b)(4) Protocol Revision: AA

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Submission Number: (b)(4) and K221683
Submission Type: 510(k)
Product Name: (b)(4) and CYF-V2/V2R and CYF-VH/VHR
Submitter: Olympus Medical
Meeting Format: Teleconference
Date FDA Feedback was Sent: August 12, 2022

(b)(4)

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Dear Ms. Kaplan,

I have received your questions and will work with Olympus to ensure that the information is provided to you by the deadline.

Have a good day,

Teffany

From: Kaplan, Esther <Esther.Kaplan@fda.hhs.gov>

Sent: Wednesday, July 20, 2022 8:43 AM

To: Teffany Hutto <teffany.hutto@olympus.com>

Cc: Avery, Reginald <Reginald.Avery@fda.hhs.gov>; K221683@docs.fda.gov

Subject: [EXTERNAL] K221683 Interactive Review Request #1

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PLEASE NOTE: Please use caution when opening links and attachments in this message.

Dear Ms. Hutto,

I am the lead reviewer for your submission for the Cysto-Nephro Videoscopes Olympus CYF Type V2/V2R and VH/VHR. This email is a request for information to facilitate interactive review of the device. As the review of your device continues I may send out additional requests for information the review team needs to make a determination on the substantial equivalence of your device to the selected predicate.

Please address the following:

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Please reply via email by COB July 25, to facilitate timely review of your submission. Be sure to copy the file folder address K221683@docs.fda.gov<mailto:K221683@docs.fda.gov> on your reply to help maintain the record of our communication.

Thank you,

Esther Kaplan

Mechanical Engineer

Urological Devices Team (THT3B3)

Division of Reproductive, Gynecological, and Urological Devices (DHT3B)

OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

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esther.kaplan@fda.hhs.gov<mailto:esther.kaplan@fda.hhs.gov>

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JJCO Japanese Journal of Clinical Oncology

Japanese Journal of Clinical Oncology, 2016, 46(10) 964–967
doi: 10.1093/jjco/hyw111
Advance Access Publication Date: 10 August 2016
Short Communication

Short Communication

Clinical predictors for high-grade bladder cancer before first-time transurethral resection of the bladder tumor: a retrospective cohort study

Ken Wakai[1], Takanobu Utsumi[1,*], Ryo Oka[1], Takumi Endo[1], Masashi Yano[1], Shuichi Kamijima[1], Naoto Kamiya[1], Nobuyuki Hiruta[2], and Hiroyoshi Suzuki[1]

[1]Department of Urology, Toho University Sakura Medical Center, Sakura-shi, Chiba, Japan, and [2]Department of Surgical Pathology, Toho University Sakura Medical Center, Sakura-shi, Chiba, Japan

*For reprints and all correspondence: Takanobu Utsumi, Department of Urology, Toho University Sakura Medical Center, Shimoshizu 564-1, Sakura-shi, Chiba 285-8741, Japan. E-mail: takanobu.utsumi@med.toho-u.ac.jp

Received 25 April 2016; Accepted 14 July 2016

Abstract

The aim of this study was to identify the clinical predictors related to the risk of high-grade bladder cancer before first-time transurethral resection of the bladder tumor (TUR-Bt) and to externally validate the accuracy of Shapur's nomogram predicting the risk of high-grade bladder cancer in Japanese patients. As a result, episode of gross hematuria (odds ratio: 2.68, $P = 0.02$), larger tumor size (odds ratio: 1.89, $P < 0.01$) and positive urinary cytology (odds ratio: 8.34, $P < 0.01$) were found to be significant predictors for high-grade bladder cancer. Furthermore, the nomogram showed a high predictive accuracy in our Japanese population (area under the curve: 0.79). Clinicians will be able to predict high-grade bladder cancer using the common factors in Shapur's study and ours, such as tumor size and urinary cytology, and gross hematuria as the additional factor first identified here to decide priorities for the treatment of patients diagnosed with bladder cancer.

Key words: bladder cancer, high-grade, nomogram, transurethral resection of the bladder tumor, validation

Introduction

Bladder cancer is the seventh most common cancer in men and the 17th most common in women worldwide (1,2). In Japan, its actual annual incidence has increased in recent years to ~7.6 per 100 000 people (3). At initial diagnosis, more than 70% of patients have non-muscle invasive bladder cancer (NMIBC), which is generally treated with transurethral resection of the bladder tumor (TUR-Bt) with or without intravesical therapy (4). Recurrence rates for NMIBC range from 50% to 70% and ~10% to 15% of tumors progress to muscle invasive disease during a 5-year period (4–6). Bladder cancer is a highly diverse disease with both low-grade tumors that pose little threat to the patients and high-grade, potentially fatal tumors (7–9). Thus, high-grade is one of the most important factors for predicting a poor clinical outcome in NMIBC.

The histological grade of the bladder cancer is eventually determined by examining the resected tumor. The most widely used classification for grading of NMIBC (G1, G2 and G3) was the 1973 World Health Organization (WHO) classification (10). However, a revised grading system for urothelial carcinoma (UC) (low-grade and high-grade) was proposed and adopted by the WHO in 2004 to replace the 1973 WHO classification system (11). The 1973 WHO grade 1 carcinomas are reassigned, some to the PUNLMP category and some to the low-grade carcinoma category. Similarly, 1973 WHO grade 2 carcinomas are reassigned, some to the low-grade carcinoma category and others to the high-grade carcinoma category. All 1973 WHO grade 3 tumors are assigned to the high-grade carcinoma category (12).

Although there is no other way to decide whether the tumor is high or low-grade, most urologists have some clues such as

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'non-papillary tumors tend to be highly graded' or 'pedunculated tumors are somewhat better off'. However, these ideas remain experimental and obscure. If clinicians can predict high-grade bladder cancer and sift patients in advance, it would be a great help in clinical practice, because of the higher risk of recurrence and progression in high-grade bladder cancer.

Shapur et al. previously developed a nomogram predicting high-grade bladder cancer using non-invasive clinical data from 431 patients in Israel. The nomogram incorporated the following variables: age, tumor size, location of the tumor, presence of hydronephrosis and cytology (7). It was internally validated, and the area under the curve (AUC) value from the receiver operator characteristics (ROCs) was 0.85 (7). The predictive accuracy of this nomogram has not been externally validated, although the nomogram demonstrated high predictive accuracy on internal validation.

The aim of the present study was to identify the clinical predictors that influence the risk of high-grade bladder cancer before first-time TUR-Bt and to externally validate the predictive accuracy of Shapur's nomogram in Japanese patients with bladder cancer.

Patients and methods

Patient selection and clinical variables

This was a retrospective study approved by the institutional review board (No. 2015-101). A total of 332 patients who underwent first-time TUR-Bt for bladder cancer were seen at Toho University Sakura Medical Center between January 2012 and January 2016. A total of 143 patients were excluded from the present study because of missing or inappropriate values, a tumor from any other origin, bladder Tis lesion only and concurrent or recurrent bladder cancer with the upper urinary tract UC. Finally, the data of 189 patients were statistically analyzed in the present study. Preoperative evaluation of bladder cancer was performed using abdominal ultrasound (AUS), flexible or rigid cystoscopy, computed tomography (CT), magnetic resonance imaging (MRI) and urinary cytology.

Medical records were surveyed retrospectively, and the following data were collected from patients' charts: age, sex, episode of urinary symptoms, tumor size, number of tumors, location of the largest tumor (lateral walls, base, posterior wall, dome and anterior wall), tumor appearance (papillary or non-papillary, pedunculated or sessile), hydronephrosis presence and urinary cytology. Positive urinary cytology was defined as ≥ class IIIb (malignancy suspected) according to Papanicolaou's classification. Pathological evaluation was performed by two of three pathologists as a council system in Toho University Sakura Medical Center using the Tumor, Node, Metastasis classification system updated in 2009, and the new classification for grading non-invasive urothelial bladder carcinomas proposed by the WHO and the International Society of Urological Pathology in 2004 (11–13).

Statistical analysis

The results are presented as medians (range) or as means ± standard deviation, as appropriate. Continuous parametric variables were compared using *t*-tests. Non-parametric variables were compared using Mann–Whitney *U*-tests. Categorical variables were compared using χ^2 or Fisher's exact tests. First, univariate analyses were performed to evaluate the associations between high-grade bladder cancer and preoperative variables. After significant candidate variables were identified on univariate analyses, multivariate logistic regression analysis was used to identify clinical predictors associated with high-grade bladder cancer. Second, for a sub-analysis, high-grade G3 bladder cancer was compared to high- and low-grade bladder cancer without G3 components in the same manner as described above. Last, the predictive accuracy of Shapur's nomogram in our institutional data set was evaluated using the AUC value for external validation (14). Significance was defined at the level of $P < 0.05$. All statistical analyses were carried out using IBM SPSS Statistics 23.

Results

The baseline characteristics of 189 patients are shown in the Supplementary Table. The patients' mean age was 71.6 (± 0.98) years; 78.3% were male and 21.7% were female. An episode of gross hematuria and urinary frequency were reported in 71.4% and 14.8% of patients, respectively. The median tumor size was 1.8 (0.1–7.0) cm. A single tumor was confirmed in 48.1% of the patients, with multiple tumors in 51.9%. A papillary tumor was found in 90.5%, with a non-papillary tumor in 9.5%. A pedunculated tumor was confirmed in 41.8% of the main tumors, while a sessile tumor was seen in 58.2%. Positive urinary cytology was detected in 43.4% of the patients and high-grade bladder cancer was pathologically diagnosed in 74.6% of the patients.

Preoperative factors associated with the risk of high-grade bladder cancer on uni- and multivariate analyses are summarized in Table 1. On univariate analyses, episode of gross hematuria, larger tumor size, multiple tumors, tumor location involving lateral or posterior walls, non-papillary tumor and positive urinary cytology were significantly associated with high-grade bladder cancer ($P < 0.05$).

Table 1. Uni- and multivariate analyses of preoperative variables for high-grade bladder cancer

Variable		Univariate			Multivariate	
		High-grade ($n = 141$)	Low-grade ($n = 48$)	*P* value	Odds ratio (95% CI)	*P* value
Age (years)		71.5 (±0.79)	72.0 (±1.35)	0.73		
Male, *n* (%)		111 (78.7)	37 (77.1)	0.81		
Gross hematuria, *n* (%)		110 (78.0)	25 (52.1)	<0.01	2.68 (1.19–6.03)	0.02
Tumor size (cm)		2.0 (0.1–7.0)	1.1 (0.1–4.3)	<0.01	1.89 (1.20–2.99)	<0.01
Multiple tumors, *n* (%)		81 (57.4)	17 (35.4)	<0.01	–	0.44
Lateral or posterior main tumor, *n* (%)		80 (56.7)	19 (39.6)	0.04		
Appearance	Non-papillary, *n* (%)	18 (12.8)	0 (0.0)	<0.01	–	0.12
	Sessile, *n* (%)	87 (61.7)	23 (47.9)	0.09		
Hydronephrosis present, *n* (%)		12 (8.5)	2 (4.2)	0.26		
Positive urinary cytology, *n* (%)		77 (54.6)	5 (10.4)	<0.01	8.34 (2.97–23.41)	<0.01

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Table 2. Uni- and multivariate analyses of preoperative variables for high-grade bladder cancer with G3 components

Preoperative variable		Univariate			Multivariate	
		High-grade with G3 components (n = 81)	High-/low- grade without G3 components (n = 106)	P value	Odds ratio (95% CI)	P value
Age (years)		72.0 (±1.03)	71.3 (±0.93)	0.64		
Male, n (%)		63 (77.8)	83 (78.3)	0.93		
Gross hematuria, n (%)		65 (80.2)	69 (65.1)	0.02	-	0.11
Tumor size, (cm)		2.0 (0.1–7.0)	1.5 (0.1–4.3)	<0.01	1.43 (1.01–2.02)	0.04
Multiple tumors, n (%)		54 (66.7)	44 (41.5)	<0.01	-	0.05
Lateral or posterior main tumor, n (%)		54 (66.7)	44 (41.5)	<0.01	3.03 (1.49–7.34)	<0.01
Appearance	Non-papillary, n (%)	17 (21.0)	1 (0.9)	<0.01	26.92 (2.88–251.28)	<0.01
	Sessile, n (%)	57 (70.4)	51 (48.1)	<0.01	-	0.07
Hydronephrosis present, n (%)		9 (11.1)	5 (4.7)	0.10		
Positive urinary cytology, n (%)		61 (75.3)	20 (18.9)	<0.01	11.04 (4.99–24.43)	<0.01

On multivariate analysis, episode of gross hematuria (odds ratio: 2.68, $P = 0.02$), larger tumor size (odds ratio: 1.89, $P < 0.01$) and positive urinary cytology (odds ratio: 8.34, $P < 0.01$) were significant predictors for high-grade bladder cancer.

Preoperative factors associated with the risk of high-grade bladder cancer with G3 components on uni- and multivariate analyses are summarized in Table 2. On univariate analyses, episode of gross hematuria, larger tumor size, multiple tumors, tumor location involving lateral or posterior walls, non-papillary tumor, sessile tumor and positive urinary cytology were significant ($P < 0.05$). On multivariate analysis, larger tumor size (odds ratio: 1.43, $P = 0.04$), tumor location involving lateral or posterior walls (odds ratio: 3.30, $P < 0.01$), non-papillary tumor (odds ratio: 26.92, $P < 0.01$) and positive urinary cytology (odds ratio: 11.04, $P < 0.01$) were significant predictors for high-grade bladder cancer with G3 components.

The Supplementary Figure shows the ROC curves of Shapur's nomogram and each factor derived from the present data set. The AUC value was 0.79, which was slightly lower than in Shapur's internal validation. The AUC value of each factor is 0.47 (age), 0.63 (gross hematuria), 0.75 (tumor size), 0.59 (lateral/posterior tumors), 0.52 (hydronephrosis present) and 0.72 (positive urinary cytology).

Discussion

The natural history of bladder cancer is heterogeneous, ranging from a low-grade variant that does not recur after local resection to a high-grade subtype that recurs and progresses to metastatic, lethal disease (15,16). Although 80% of patients present with NMIBC (Ta, T1 and Tis) that may be managed by TUR-Bt, the recurrence rate reaches 61% at 1 year and 78% at 5 years (17,18). As a result of its high recurrence rate and the associated need for lifelong surveillance and repeat resections, the healthcare costs for bladder cancer are among the highest of all malignancies (17,19). The evaluation of high-grade bladder cancer was highlighted in the present study, because the outcome of NMIBC is largely dependent on tumor grading (20,21).

The present study showed that an episode of gross hematuria, larger tumor size and positive urinary cytology were significant predictors for high-grade bladder cancer on multivariate analysis. Based on multivariate analysis, Shapur et al. developed the nomogram with the following variables: age, tumor size, tumor location, hydronephrosis and positive urinary cytology. Tumor size and positive urinary cytology were common predictors between Shapur's and the present studies, which could reflect on the nature of high-grade bladder cancer, such as rapid growth and turn over. A high frequency of gross hematuria, which was first identified as a novel predictor in the present study, might reflect the stronger aggressiveness of high-grade bladder cancer compared to low-grade cancer. However, age and hydronephrosis were not significant predictors of high-grade bladder cancer in the present study. Moreover, tumor location in Shapur's study (dome or base) was different from the location in our study (posterior or lateral). Unfortunately, tumor location might not be a predictor, because it is strongly affected by the ratio of high-grade cancer in each study population.

Furthermore, the predictors for high-grade bladder cancer with G3 components were investigated in the present study. Non-papillary tumor was found to be a significant predictor for high-grade bladder cancer with G3 components, in addition to tumor size, tumor location and positive urinary cytology. These factors might become useful clinical variables predicting high-grade bladder cancer including G3 components, which has a higher risk of recurrence and progression.

Although all patients should be operated without delay, many surgeries are delayed, either due to administrative reasons (e.g. full operating room schedule) or due to a need for preoperative evaluations of background illnesses that are very common among bladder cancer patients (7). The present patients were also elderly (Supplementary Table) and frequently had multiple background diseases. Comprehensive geriatric assessment and correction of the more significant disabilities are often essential preoperatively (22,23). If clinicians in private practice or hospital can predict the patients with a higher risk of high-grade bladder cancer preoperatively using the predictors identified in Shapur's nomogram and our study, they will be able to cooperate each other in determining priorities for preoperative evaluation and scheduling surgery.

Certainly, these are some potential limitations of the present study. Tumor size was measured with various devices (AUS, cystoscopy, CT and MRI) in this study, although Shapur et al. originally used AUS alone. However, tumor size is simultaneously measured using multiple devices in our clinical practice. Moreover, central pathological review for TUR-Bt specimens was not performed in this study, although diagnosis by multiple pathologists is performed in daily clinical practice (24,25).

In conclusion, clinicians will be able to predict high-grade bladder cancer using the common factors in Shapur's study and ours,

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such as tumor size and urinary cytology, and gross hematuria as the additional factor first identified here to decide priorities for the treatment of patients diagnosed with bladder cancer.

Supplementary material

Supplementary data are available at http://www.jjco.oxfordjournals.org.

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None declared.

Conflict of interest statement

Hiroyoshi Suzuki has received paid consulting from Nihon Kayaku.

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Mechanical Engineer

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Thank you,

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Mechanical Engineer

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Section 18.6
Photobiological Safety

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(b)(4)

Sponsor:
(b)(4)
Olympus Medical Systems Corp.
2951 Ishikawa-machi
Hachioji-shi, Tokyo, 192-8507
JAPAN

Delayed Cleaning Validation for CYF-VH (Endozime) GLP Report

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U.S. FOOD & DRUG ADMINISTRATION

Memorandum

To: Esther Kaplan, Lead Reviewer (OHT3/DHT3B/THT3B3)

From: Andrew Fales, General Engineer (OHT3/DHT3B/THT3B2)

Date: July 20, 2022

Subject: Optical Performance Review
K221683
Olympus Medical Systems Corp.
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE V2R
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH, CYF-VHR

Summary

(b)(5)

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(b)(5)

Andrew M. Fales -S

Digitally signed by Andrew M. Fales -S
Date: 2022.07.20 07:54:35 -04'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 18.5. Color performance : Attachment : XYZ measured (All devices)

(b)(4)

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Step-by-Step Comparison of Rinsing validation Steps (Automated HLD for OER-Pro with Aldahol 1.8)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Step-by-Step Comparison of the Automated HLD steps (Automated HLD for OER-Pro with Aldahol 1.8)

(b)(4)

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Report for residual toxicity evaluation (rinsing validation) after OER-Pro(Aldahol) disinfection for CYF-VH/VHR and MAJ-2092

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024

Identification information (b)(4)

OLYMPUS

Test Report

Title

High Level Disinfection test Using OER-Mini with Acecide-C of OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5 and Luer-Split MAJ-2092

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 19

Performance Testing - Animal

This section is not applicable. No animal testing was performed for the subject devices.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2024-3284; Released by CDRH on 08-29-2024
Identification information : (b)(4)

OLYMPUS

Test Report

Title

High Level Disinfection test Using OER-Pro with Aldahol 1.8 of OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 12
Substantial Equivalence Discussion

12.1 PREDICATE DEVICE

The CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VH and CYF-VHR and VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2 and CYF TYPE V2R (hereinafter referred to as CYF-V2/V2R and CYF-VH/VHR) is substantially equivalent to the legally marketed predicate devices listed in Table 12-1.

Table 12-1. Predicate device

Device name	510(k) Submitter	510(k) No.
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R	OLYMPUS MEDICAL SYSTEMS CORP.	K133538

12.2 DIFFERENCE BETWEEN SUBJECT DEVICE AND PREDICATE DEVICE

Olympus bases the claim of substantial equivalence on similarities in indications for use, technological features, and materials. A side-by-side comparison of the similarities and differences between the proposed device and the predicate device are described in the following section.

1) Indications for use

The indication for use of the subject devices are equivalent to the predicate device as shown in Table 12-2.

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Table 12-2. Comparison of Indications for Use

Indications for Use		
CYF-V2/V2R	**CYF-VH/VHR**	**CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R**(K133538)
VISERA CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE V2, CYF TYPE V2R have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.	CYSTO-NEPHRO VIDEOSCOPEs OLYMPUS CYF TYPE VH, and CYF TYPE VHR have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, and kidney.	These instruments have been designed to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories, and other ancillary equipment for endoscopic diagnosis and treatment within the bladder, urethra, ureter, and kidney

2) Technological Characteristics

In terms of the technological features of the subject device, the major differences from the primary predicate device are as follows:

1. Optimum Working Distance

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2. Imaging System

(b)(4)

3. Insertion Section

The diameter of the CYF-VH/VHR distal end of the insertion tube is smaller than the predicate device and is larger for the outer diameter as shown in Table 12-5. These same diameters are exactly the same as the predicate device for CYF-V2/V2R.

Table 12-5. Insertion Section

	CYF-VH/VHR	CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R
Insertion Tube Diameter	Distal end size: ø 2.7mm (bullet shape) Flexible tube outer Diameter: ø 5.5mm (16.5 Fr)	Distal end size: ø 4.8mm (bullet shape) Flexible tube outer Diameter: ø 5.4mm (16.2 Fr)

<Comments on the difference>

This change in dimensional specification of the distal end and the insertion tube is minor enough and is not expected to affect the insertion of the endoscope into the patient body.

4. Bending Section

The angulation range of the CYF-VH/VHR is different than the predicate device and is larger for the outer diameter as shown in Table 12-6. The angulation range for CYF-V2/V2R is exactly the same as the predicate device.

Table 12-6. Angulation Range

	CYF-VH/VHR	CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R
Angulation range	Up 220° / Down 130°	Up 210° / Down 120°

<Comments on the difference>

The angulation range of subject device can cover that of predicate device, so it can keep the

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performance as effective as predicate device. No new issues of safety and effectiveness have been identified.

5. Materials

The materials are changed for CYF-VH/VHR from the predicate device as shown in Table 12-7. Biocompatibility test has been performed with a final finished product to show that the subject device can be safely used in terms of biocompatibility. The materials for CYF-V2/V2R is exactly the same as the predicate device. Please refer to **Section 15** for complete biocompatibility data.

Table 12-7 Difference of Materials

Parts	CYF-VH/VHR	CYF TYPE V2, CYF TYPE VA2, CYF TYPE V2R
Bending rubber	Fluoro Rubber (b)(4)	Fluoro Rubber (b)(4)
Distal end	Polysulfone (b)(4)	PolyPhenylSulfone (b)(4)
Light guide lens	Polysulfone (b)(4)	Glass (b)(4)
Rubber seal	Polysulfone Silicone Rubber (b)(4)	Polysulfone Silicone Rubber (b)(4)

<Comments on the difference>

Biocompatibility test, reprocessing test, and performance test (Thermal safety test, Mechanical Durability test, and Photobiological safety test) have been performed with a final finished product including the modified material. Please refer to **Section 15** for complete biocompatibility test result, **Section 14** for reprocessing test result, and **Section 18** for performance test result. As a result of the above validation testing, no issues of safety or effectiveness were raised from the subject device.

6. Compatible Processor, Light Source, and Monitor

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A comparison of Olympus **CYF-V2/V2R** device characteristics to the proposed predicate devices is provided below in **Table 12-10**

Table 12-10: CYF-V2/V2R Device and Predicate Devices Comparison Table

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12.6 CONCLUSION

In terms of the indications for use, technological features and materials, Olympus believes the CYF-VH/VHR and CYF-V2/V2R are substantially equivalent to the cited predicate device. The differences between the devices are minor and do not raise any new issues of safety or effectiveness in comparison to the predicate.

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OLYMPUS

REPROCESSING MANUAL

INSTRUCTIONS

CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF-VH
OLYMPUS CYF-VHR

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OLYMPUS

OPERATION MANUAL

INSTRUCTIONS

VISERA CYSTO-NEPHRO VIDEOSCOPE

OLYMPUS CYF TYPE V2
OLYMPUS CYF TYPE V2R

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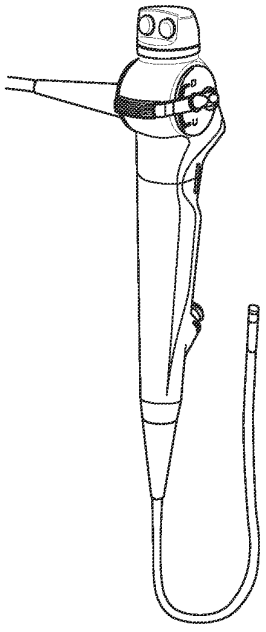

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Protocol Number: (b)(4)

Protocol Revision:

Protocol Title: Biological Safety/Biocompatibility Test Plan (BTPL) for CYF-VH

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