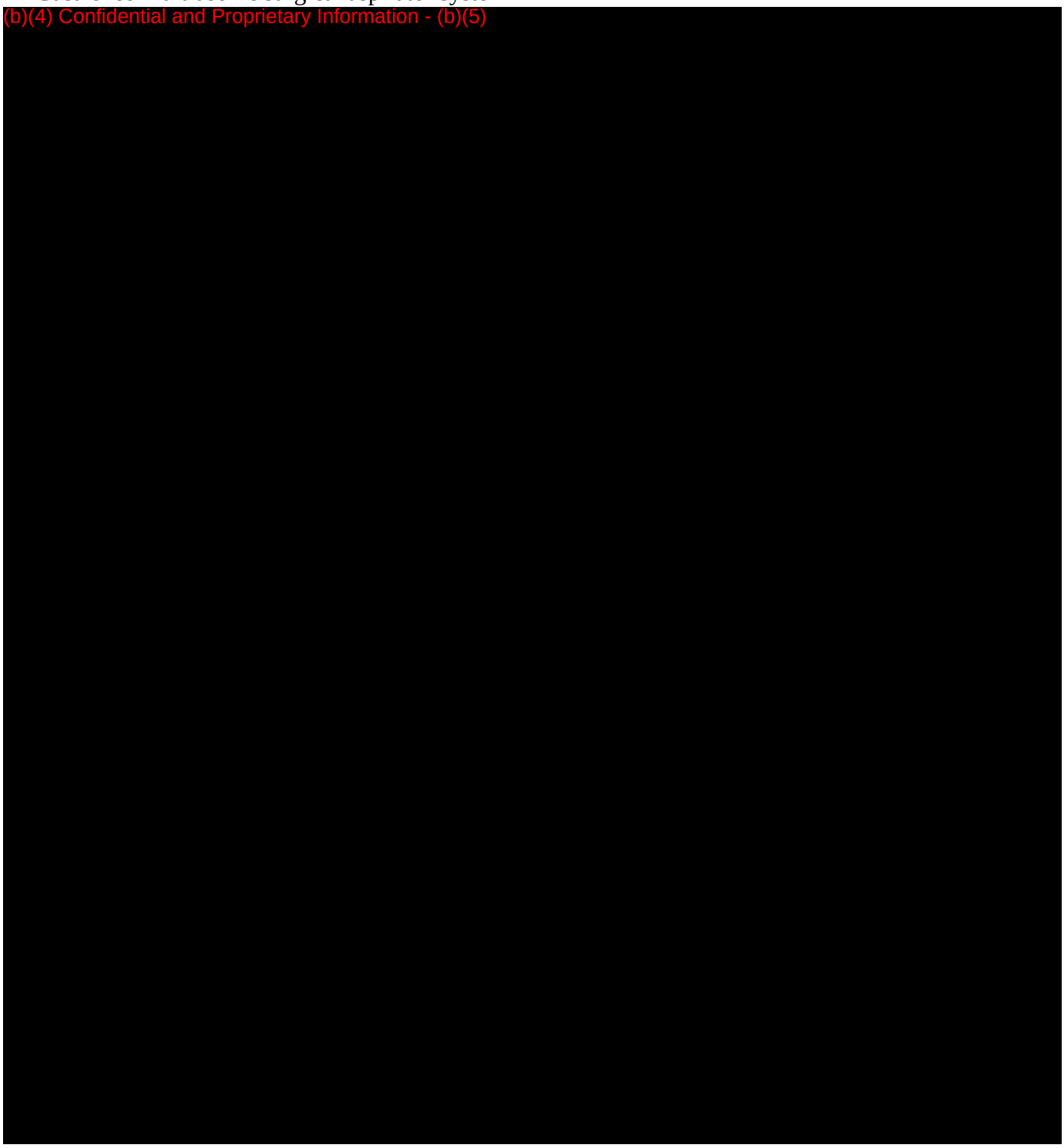
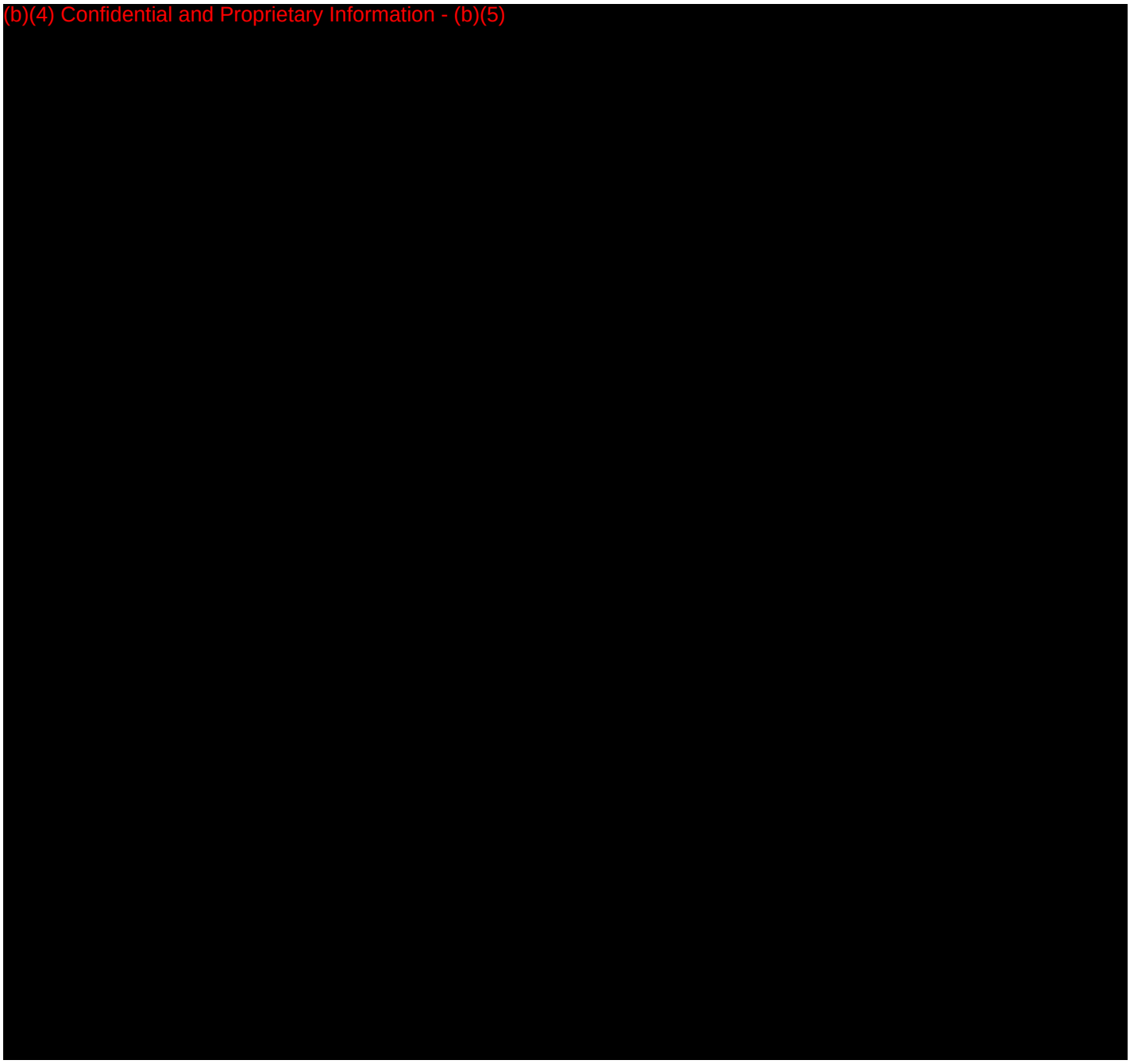
DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

K141668
Integra Lifesciences Corporation
Cusa excel+ ultrasonic surgical aspirator system

(b)(4) Confidential and Proprietary Information - (b)(5)





Indications for Use

510(k) Number (if known): K141668

Device Name:

CUSA® Excel+ Ultrasonic Surgical Aspirator System

Indications For Use:

The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. The CUSA Excel+ Ultrasonic Surgical Aspirator is indicated for use in:

Neurosurgery, Plastic and Reconstructive surgery, Orthopedic Surgery, Gynecological Surgery and Thoracic Surgery and the following specific uses:

Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy

Urological surgery- including removal of renal parenchyma during nephrectomy or partial nephrectomy

General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures

Laparoscopic Surgery - including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy

.

Prescription Use ___X___ **AND/OR** **Over-The Counter Use_____**

(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 6, 2014

Integra LifeSciences Corporation
Ms. Janet C. Kay
Director, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K141668
Trade/Device Name: CUSA® Excel+ Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL
Dated: October 8, 2014
Received: October 10, 2014

Dear Ms. Kay:

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. 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.

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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 6, 2014

Integra LifeSciences Corporation
Ms. Janet C. Kay
Director, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K141668
Trade/Device Name: CUSA® Excel+ Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL
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Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141668

Device Name:

CUSA® Excel+ Ultrasonic Surgical Aspirator System

Indications For Use:

The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. The CUSA Excel+ Ultrasonic Surgical Aspirator is indicated for use in:

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Urological surgery- including removal of renal parenchyma during nephrectomy or partial nephrectomy

General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures

Laparoscopic Surgery - including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy

.

Prescription Use ___X___ **AND/OR** **Over-The Counter Use_____**

(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

807.92(a)(1) – Submitter information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone Number	781-565-1347
Fax Number	781-238-0645
Establishment Registration Number	3003418325
Name of Contact Person	Janet C. Kay
Date Prepared	September 22, 2014
807.92(a)(2) – Name of device	
Trade or Propriety Name	CUSA® Excel+ Ultrasonic Surgical Aspirator System
Common or Usual Name	Ultrasonic Surgical Aspirator
Classification Name	Instrument, Ultrasonic Surgical
Classification Panel	General and Plastic Surgery
Regulation	Class II unclassified
Product Code(s)	LFL
807.92(a)(3) – Legally marketed device(s) to which equivalence is claimed	
CUSA Excel Ultrasonic Surgical Aspirator System K981262 CUSA Excel Ultrasonic Surgical Aspirator System with Bone Tip K051947	
807.92(a)(4) – Device description	

The CUSA Excel+ Ultrasonic Surgical Aspirator System (CUSA) is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. It allows the selective dissection of target tissue while preserving vessels, ducts and other delicate structures. The CUSA Excel+ System consists of a console which provides control and power functions, two surgical hand pieces which provide ultrasonic mechanical energy (23kHz and 36kHz), titanium hand piece tips (variety of models), flexible irrigation flue, and a suction/irrigation system (manifold tubing and cooling water canister). The CUSA Excel+ system accommodates most commercially available suction canisters. A two-pedal footswitch is provided with the console.

807.92(a)(5) – Intended use of the device

Indications for Use	The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. The CUSA Excel+ Ultrasonic Surgical Aspirator is indicated for use in: Neurosurgery, Plastic and Reconstructive surgery, Orthopedic Surgery, Gynecological Surgery and Thoracic Surgery and the following specific uses: Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy Urological surgery- including removal of renal parenchyma during nephrectomy or partial nephrectomy General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures Laparoscopic Surgery - including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial

	gastrectomy

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

The technological characteristic of the device are the same compared to the predicate device

807.92(b)(1-2) – Nonclinical and clinical tests submitted

No nonclinical testing was required as the device itself was not modified.

The clinical evidence used to support the change to the indications for use for Gastrointestinal (GI) and Affiliated Organ, Urologic, General, and Laparoscopic surgeries are peer reviewed journal articles:

Gastrointestinal and Affiliated Organ Surgery –
The largest body of data found was for GI and affiliated organ surgeries. Thirty-four articles reported on approximately 2,500 cases, including open hepatectomy and laparoscopic-assisted liver resection. Overall, the literature demonstrated that CUSA can be safely used in laparoscopic and open liver surgeries. The laparoscopic technique using CUSA has been shown to decrease morbidity, shorten hospital stay, improve cosmesis, and decrease blood loss. The literature showed CUSA to be safe and effective in liver surgery for pediatric, adult, and elderly patients and it has also been proven acceptable in both open and laparoscopic procedures.

Urologic Surgery –
Six articles report on the use of the CUSA system in renal surgical cases. These cases included resections performed for renal lithiasis and renal tumor removal and formation of a nipple valve during construction of a continent ileal urinary reservoir. A total of 8 urologic resection cases and 71 cases of nipple valve formation during construction of a continent ileal urinary reservoir were reported. No adverse events were reported with the use of the CUSA in these cases. The articles found that using CUSA for renal resection allows the surgeon to selectively aspirate certain tissues, including parenchyma, while leaving blood vessels and collecting systems intact. The literature reported that using CUSA resulted in increased visibility for the surgeons, reduced operating time, and a reduced volume of blood loss due to its selectivity.

General Surgery –
References are provided on the use of CUSA for the resection of carcinoma of the tongue in small numbers (10 patients) and treatment of using CUSA in papillary cystic and solid tumor of the pancreas (PCSTP) in children (5 cases). Although these case reports involve small numbers of patients no significant issues of safety or effectiveness are identified for the use of

CUSA device in these specific indications.

Laparoscopic Surgery –
Eight articles and two abstracts reveal that CUSA has been successfully used in laparoscopic appendectomies, laparoscopic colon resections, laparoscopic cholecystectomies, laparoscopic partial gastrectomies, laparoscopic transhiatal esophagectomy, laparoscopic ablation of endometriosis, and laparoscopic hepatectomies. One hundred thirty-one laparoscopic cholecystectomies, nine laparoscopic appendectomies, three laparoscopic colon resections, and two laparoscopic partial gastrectomies were performed using CUSA. The only complication observed in these cases was a thermal pinhole burn leading to bile leakage in one case of laparoscopic cholecystectomy. The articles for these cases reported that the advantage of using CUSA for these procedures included the ability of the system to dissect tissues while preserving the main structures. Six cases of laparoscopic esophagectomy were also completed using CUSA. The authors observed that using CUSA allowed for the isolation of vessels and periesophageal lymph nodes during the procedure and that transhiatal esophagectomies were performed successfully in all patients without massive bleeding. Over 150 laparoscopic hepatectomy procedures were performed using the CUSA system. Most of the articles presented concluded that use of CUSA led to successful surgical outcomes and reduced blood loss. The laparoscopic surgery articles presented in the literature review indicate that ultrasonic aspiration is a safe technology in a number of laparoscopic procedures. It may have advantages including less blood loss and preservation of main structures, including vessels and ducts.

807.92(b)(3) – Conclusions drawn from non-clinical and clinical data

The changes from general to specific indications for use are supported by the information provided including previously cleared 510ks and peer reviewed clinical literature.

INTEGRA
LIMIT UNCERTAINTY

November 6, 2014

Dwight Yen
Sr. Reviewer
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: K141668 CUSA Excel+ Expanded Indications – Agreement to withhold promotion for indications set forth in K141668

Dear Mr. Yen,

Please allow this letter to confirm that Integra LifeSciences Corporation agrees not to promote the CUSA Excel+ Ultrasonic Surgical Aspirator for the specific indications for use defined in K141668, until such time as the company includes a contraindication in the labeling for the CUSA Excel+ Surgical Aspirator and the CUSA Excel+ accessory Extended Life Laparoscopic Tip (C4604ELT). You have indicated that the FDA plans to release, in the near future, recommendations and requirements for power morcellator and power morcellator type devices, and the specific language of any contraindication will follow the receipt of this FDA guidance.

If you need any additional information, please do not hesitate to contact me at: Office, 609-936-2311; Cell, 732-310-7844; or email, judith.ogrady@integralife.com.

Sincerely,

Judith O'Grady, RN, MSN, RAC
Corporate Vice President, Global Regulatory Affairs

Integra LifeSciences Corporation

Integra • 311 Enterprise Drive, Plainsboro, NJ 08536
609-275-0500 • 800-654-2873 toll free • 609-750-4277 fax • integralife.com

Yen, Dwight

From: Krueger, Angela C
Sent: Wednesday, November 05, 2014 9:58 AM
To: Yen, Dwight; Yustein, Aron S
Cc: Ashar, Binita S; Nipper, Joshua; Shulman, Marjorie G.
Subject: RE: CUSA Device

Hi Dwight,
(b)(4) Confidential and Proprietary Information - (b)(5)
[redacted]

Thanks,
Angie

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?O=400&D=410&B=410&E=&S=E.

From: Yen, Dwight
Sent: Wednesday, November 05, 2014 9:52 AM
To: Krueger, Angela C; Yustein, Aron S
Cc: Ashar, Binita S; Nipper, Joshua; Shulman, Marjorie G.
Subject: CUSA Device

Hello Angie,
(b)(4) Confidential and Proprietary Information - (b)(5)
[redacted]

Best regards,

Dwight Yen
Sr. Reviewer
General Surgery Branch 2
Division of Surgical Devices
Office of Device Evaluation
CDRH/FDA/HHS
(301) 796-6401

Excellent customer service is important to us.

Yen, Dwight

From: Krause, David
Sent: Wednesday, November 05, 2014 3:57 PM
To: Yen, Dwight; Ashar, Binita S; Katzenmeyer-Pleuss, Kristy
Cc: Nipper, Joshua; Stevenson, Jennifer R
Subject: RE: K141668 and K141674 CUSA device SESE recommendation

Dwight,

This looks acceptable to me.

David

David Krause, PhD
Deputy Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

10903 New Hampshire Avenue
Bldg. 66, Room G412
Phone: 301.796.6970
Email: david.krause@fda.hhs.gov

From: Yen, Dwight
Sent: Wednesday, November 05, 2014 2:23 PM
To: Ashar, Binita S; Krause, David; Katzenmeyer-Pleuss, Kristy
Cc: Nipper, Joshua; Stevenson, Jennifer R
Subject: RE: K141668 and K141674 CUSA device SESE recommendation

Binita and David,

Attached please find the draft promissory note from the sponsor. The note states that the sponsor promises not to promote the device until a contraindication based on FDA's recommendation for power morcellator and similar devices is published.

The CDRH Morcellator working group expects the Immediate In-effect Guidance (IIG) to be published by the week of 11/24.

I believe this promissory note addresses our concerns. Please let me know if you have any additional comments or changes.

Thanks,
Dwight

From: Yen, Dwight
Sent: Wednesday, November 05, 2014 10:18 AM
To: Ashar, Binita S; Krause, David; Katzenmeyer, Kristy (Kristy.Katzenmeyer@fda.hhs.gov)
Cc: Nipper, Joshua
Subject: K141668 and K141674 CUSA device SESE recommendation

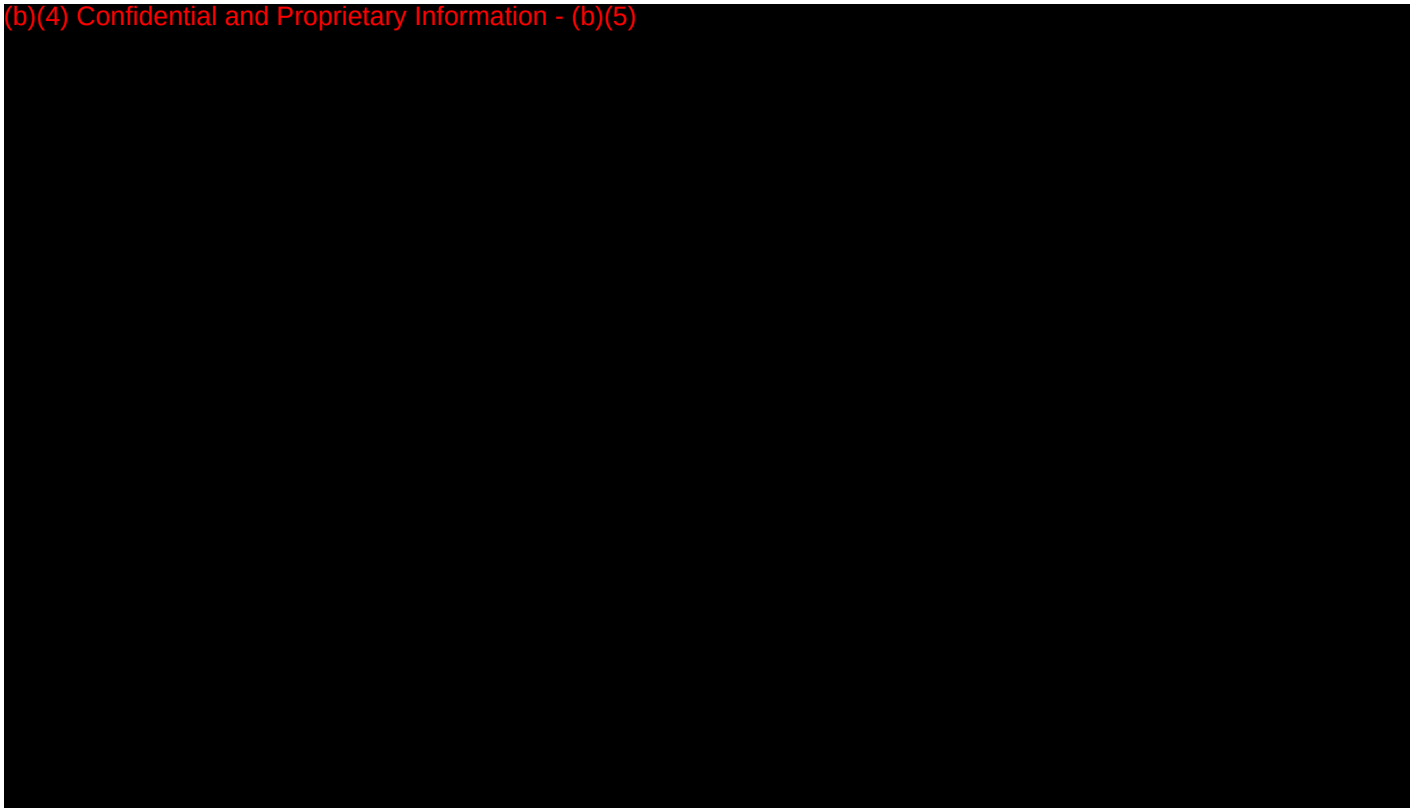
I just spoke with the sponsor and they have agreed to provide a written promissory note to the administrative record. The note will state the sponsor's commitment to address FDA's forth coming recommendation to provide labeling with specific safety statements for laparoscopic power morcellator.

I will circulate a draft of the promissory note as soon as I get it.

Dwight

From: Nipper, Joshua
Sent: Monday, November 03, 2014 5:03 PM
To: Katzenmeyer-Pleuss, Kristy; Stevenson, Jennifer R; Yen, Dwight; Ramirez, Edwin
Cc: Ashar, Binita S; Krause, David
Subject: Acting

(b)(4) Confidential and Proprietary Information - (b)(5)



Thanks again,

Joshua C. Nipper
Branch Chief, General Surgery Devices Branch II
HHS/FDA/CDRH/ODE/DSD/GSDB2

10903 New Hampshire Ave.
Building 66, Room G422
Silver Spring, MD 20993
Phone: (301)-796-6524
Fax: (301)-847-8112
Email: joshua.nipper@fda.hhs.gov

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November 5, 2014

Dwight Yen
Sr. Reviewer
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

(b)(4) Confidential and Proprietary Information - (b)(5)

[redacted]

Integra ▪ 311 Enterprise Drive, Plainsboro, NJ 08536

November 5, 2014

Dwight Yen
Sr. Reviewer
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Promissory Note – K141668 CUSA Excel+ Expanded Indications

Dear Mr. Yen,

The purpose of this note is to declare that Integra LifeSciences Corporation promises not to promote the CUSA Excel+ Ultrasonic Surgical Aspirator with the specific indications for use, as defined in K141668, until the company includes a contraindication in the CUSA Excel+ Surgical Aspirator labeling and the CUSA Excel+ accessory Extended Life Laparoscopic Tip (C4604ELT) labeling. The verbiage of a contraindication will follow the soon to be released FDA recommends/requirements for power morcellator and power morcellator type devices.

Sincerely,

Robert T. Davis, Jr
CVP, President, Specialty Surgical Solutions
Integra LifeSciences

Integra ▪ 311 Enterprise Drive, Plainsboro, NJ 08536
609-[illegible]

Yen, Dwight

From: Shulman, Marjorie G.
Sent: Wednesday, November 05, 2014 11:02 AM
To: Yen, Dwight; Krueger, Angela C; Yustein, Aron S
Cc: Ashar, Binita S; Nipper, Joshua
Subject: RE: CUSA Device

Thanks Dwight and Angie. I do agree with this plan since I didn't agree the file could go on hold awaiting the guidance. Hopefully this will alleviate some concerns. We just had to stay on a level playing field.

Marjie

Marjorie Shulman
Director, Premarket Notification [510(k)] Program
Program Operations Staff
ODE/CDRH/FDA, WO66-1536
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
(301) 796-6572
Marjorie.Shulman@FDA.HHS.GOV

From: Yen, Dwight
Sent: Wednesday, November 05, 2014 10:01 AM
To: Krueger, Angela C; Yustein, Aron S
Cc: Ashar, Binita S; Nipper, Joshua; Shulman, Marjorie G.
Subject: RE: CUSA Device

Hi Angie,

Understood. There will not be any timeframe required in the note.

Thanks,
Dwight

From: Krueger, Angela C
Sent: Wednesday, November 05, 2014 9:58 AM
To: Yen, Dwight; Yustein, Aron S
Cc: Ashar, Binita S; Nipper, Joshua; Shulman, Marjorie G.
Subject: RE: CUSA Device

Hi Dwight,

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Hello Angie,

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Best regards,

Dwight Yen
Sr. Reviewer
General Surgery Branch 2
Division of Surgical Devices
Office of Device Evaluation
CDRH/FDA/HHS
(301) 796-6401

CONSULT REVIEW

Date: August 21, 2014

From: Steven Nagel, MD FACS
CDRH/ODE/DSD/GSDB2

To: Dwight Yen, Lead Reviewer
CDRH/ODE/DSD/GSBD2

CC: Joshua Nipper, Branch Chief
CDRH/ODE/DSD/GSBD2

Submission Number: k141668

Submission Type: 510(k) Original

Applicant: Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536, USA

Trade Name: CUSA® Excel+ Ultrasonic Surgical Aspirator System

Predicate Devices:
CUSA Excel Ultrasonic Surgical Aspirator; K981262
CUSA Excel Ultrasonic Surgical Aspirator with Bone Tip; K051947

INTRODUCTION:

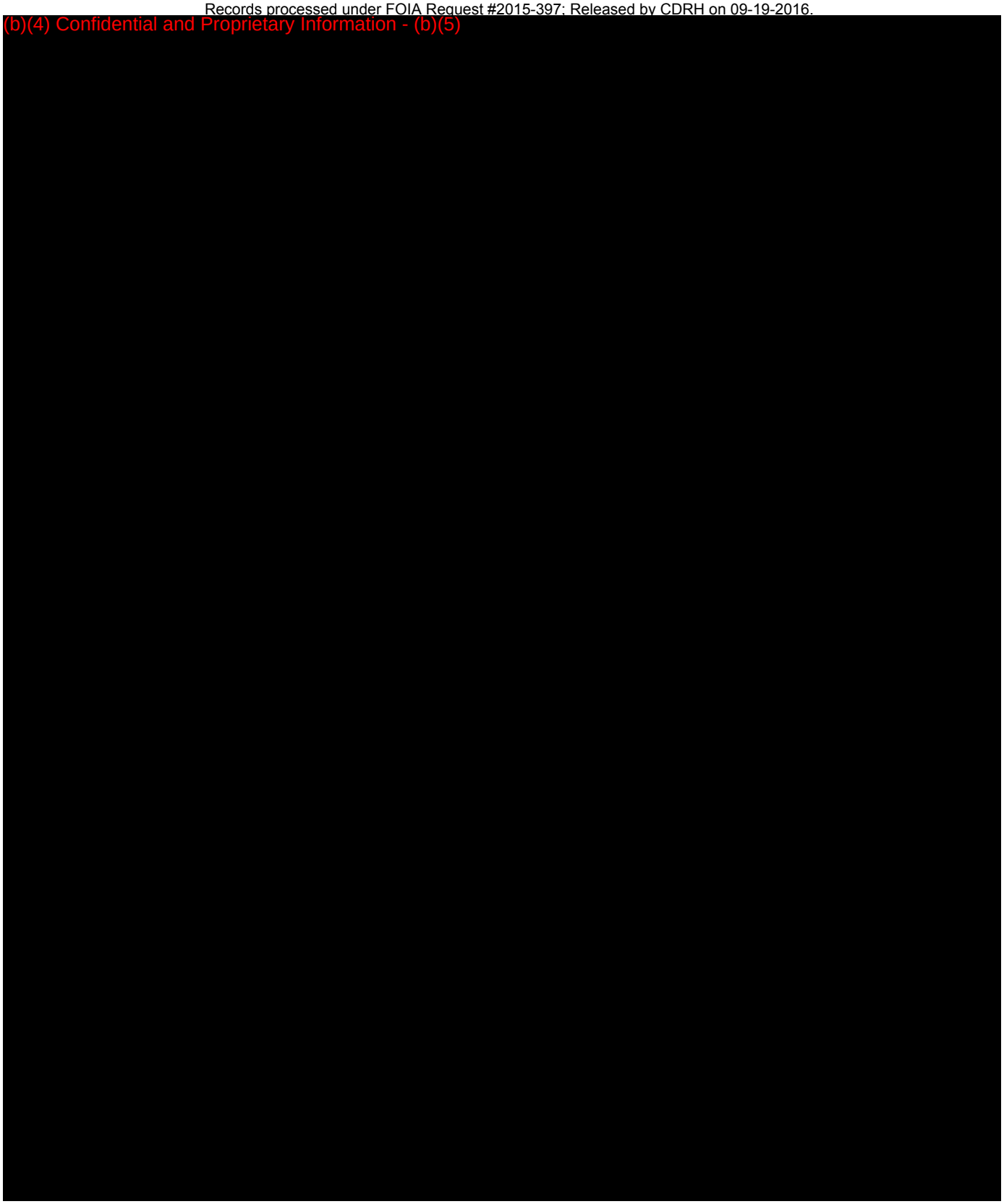
I have been asked by Dwight Yen, Lead Reviewer, to provide a clinical consult to support a decision for the CUSA (Cavitron Ultransonic Surgical Aspirator) system seeking modification of the general indication statement for use in areas of General Surgery, GI, Urology, Plastic and Reconstructive Surgery, and Thoracic surgery to include specific indications. The sponsor states that the specific indications for use are included within the general indications and are substantially equivalent to the predicate CUSA device.

The sponsor additionally submits that there have been no significant design changes or labeling changes made to the device since the original 510k clearance, which would impact safety or effectiveness of the device.

DEVICE IDENTIFICATION:

Trade or Propriety Name: CUSA® Excel+ Ultrasonic Surgical Aspirator System
Common or Usual Name: Ultrasonic Surgical Aspirator
Classification Name: Instrument, Ultrasonic Surgical
Classification Panel: General and Plastic Surgery
Regulation: Class II unclassified

(b)(4) Confidential and Proprietary Information - (b)(5)



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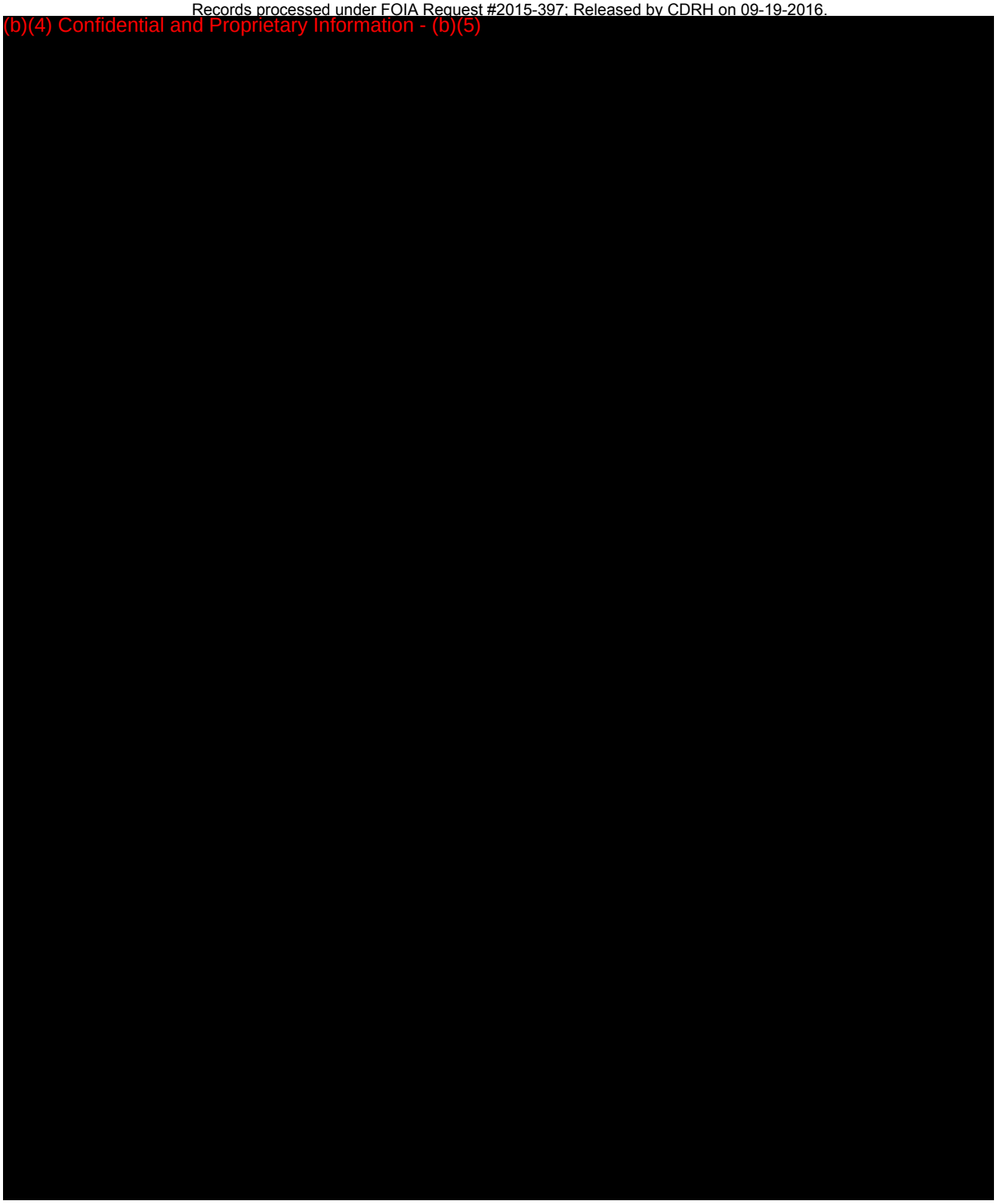
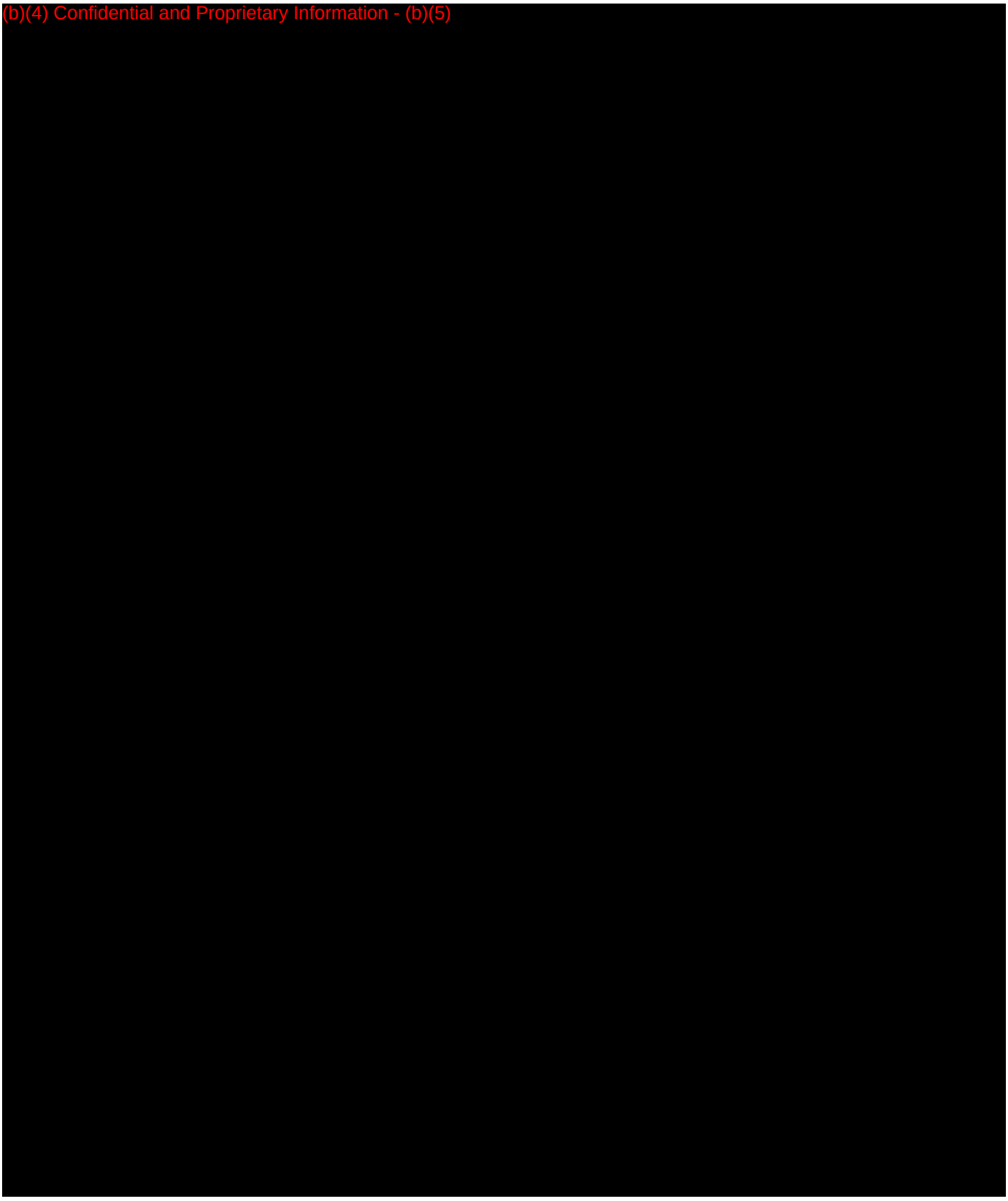


(b)(4) Confidential and Proprietary Information - (b)(5)



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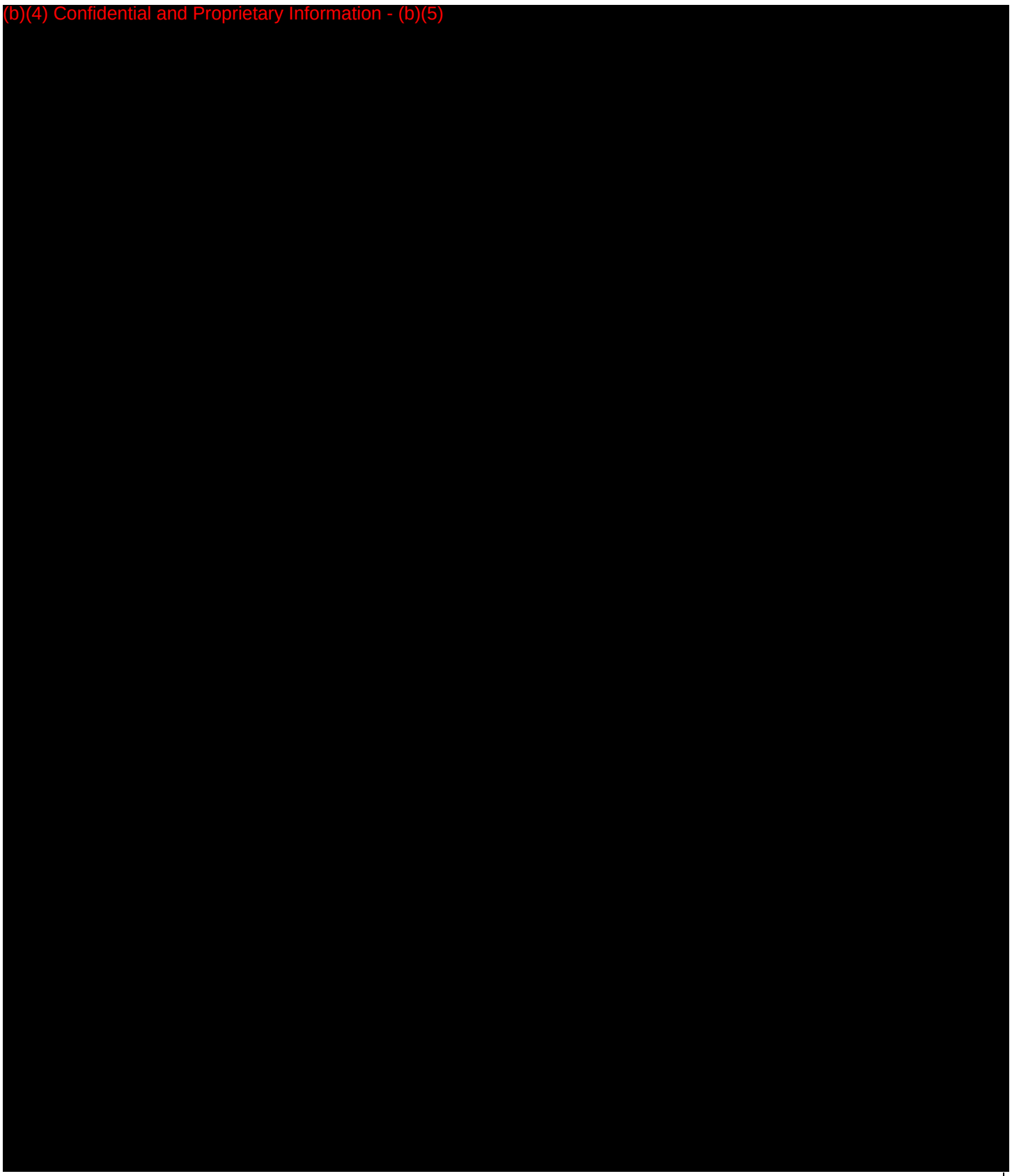

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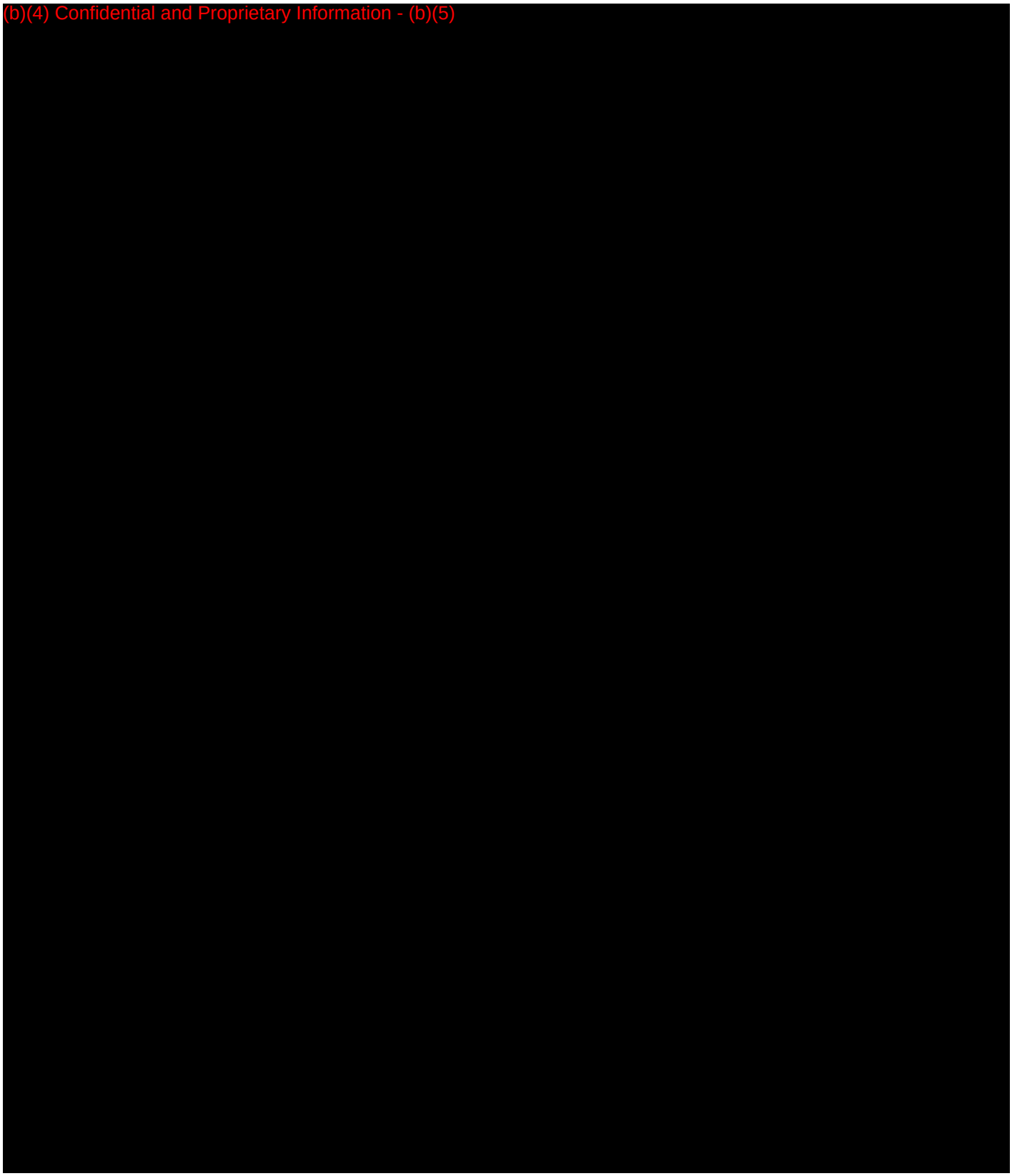

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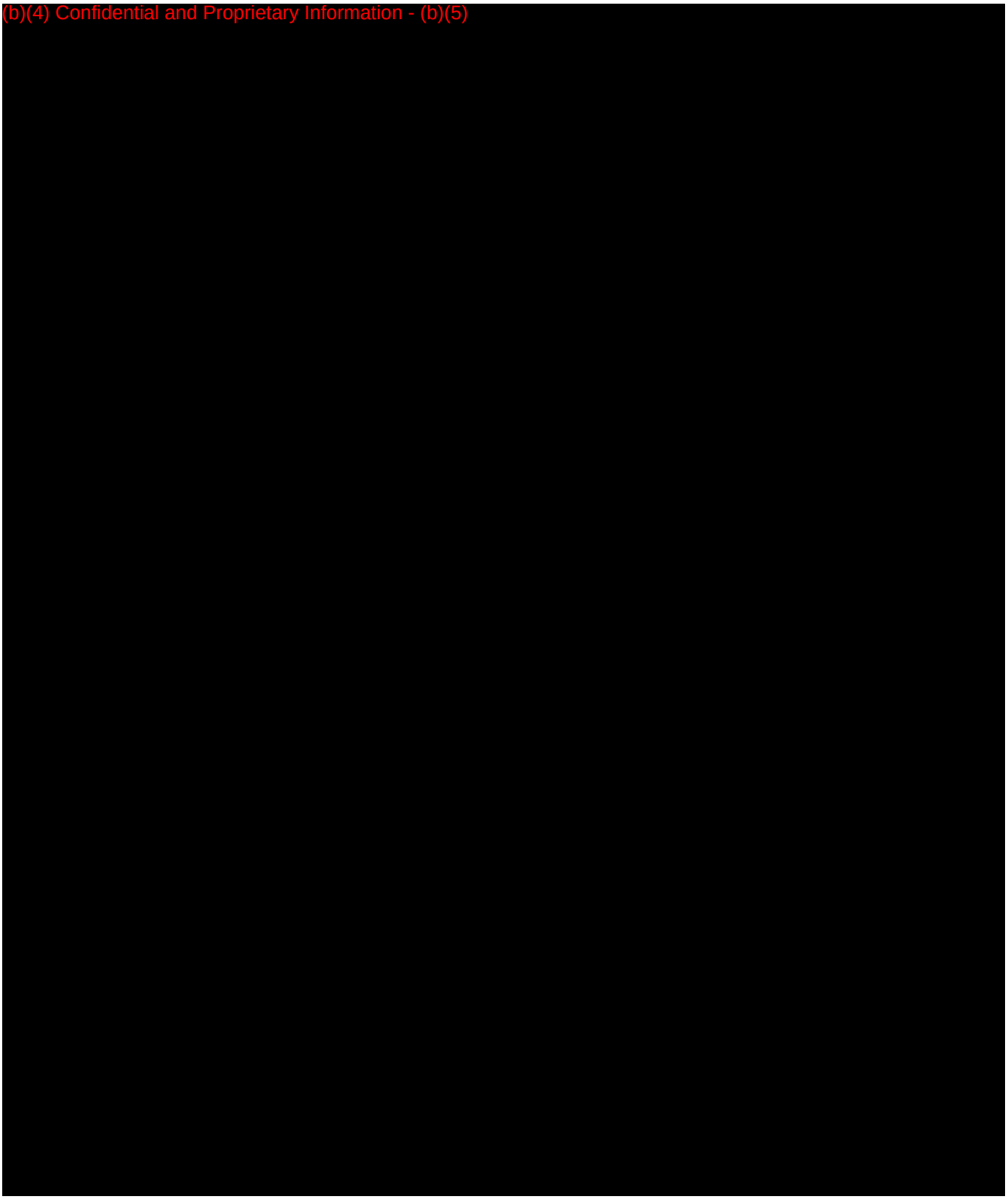

(b)(4) Confidential and Proprietary Information - (b)(5)

[redacted]

RECOMMENDATIONS: APPROVAL WITH CONDITIONS

Thank you for allowing me the privilege of consulting on this submission.

V/R,

Steven Nagel, MD, FACS
FDA/CDRH/ODE
Division of Surgical Devices
U.S. Food and Drug Administration
10903 New Hampshire Avenue, Bldg. 66/G454
Silver Spring, MD 20993-0002
Phone: 301-796-9448
Email: Steven.Nagel@fda.hhs.gov

Digital Signature Concurrence Table	
Reviewer Sign-Off Steven Nagel FDA/CDRH/DSD	
Lead Reviewer Sign Off Dwight Yen CDRH/ODE/DSD/GSBD2	
Branch Chief Sign-Off Joshua Nipper CDRH/ODE/DSD/GSBD2	
Division Sign-Off Binita Asher CDRH/ODE/DSD	

CONSULT REVIEW

Date: September 30. 2014

From: Steven Nagel, MD FACS
CDRH/ODE/DSD/GSDB2

To: Dwight Yen, Lead Reviewer
CDRH/ODE/DSD/GSBD2

CC: Joshua Nipper, Branch Chief
CDRH/ODE/DSD/GSBD2

Submission Number: k141668

Submission Type: 510(k) Original

Applicant: Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536, USA

Trade Name: CUSA® Excel+ Ultrasonic Surgical Aspirator System

Predicate Devices:
CUSA Excel Ultrasonic Surgical Aspirator; K981262
CUSA Excel Ultrasonic Surgical Aspirator with Bone Tip; K051947

INTRODUCTION:

I have been asked by Dwight Yen, Lead Reviewer, to provide a clinical consult to support a decision for the CUSA (Cavitron Ultransonic Surgical Aspirator) system seeking modification of the general indication statement for use in areas of General Surgery, GI, Urology, Plastic and Reconstructive Surgery, and Thoracic surgery to include specific indications. The sponsor states that the specific indications for use are included within the general indications and are substantially equivalent to the predicate CUSA device.

The sponsor additionally submits that there have been no significant design changes or labeling changes made to the device since the original 510k clearance, which would impact safety or effectiveness of the device.

DEVICE IDENTIFICATION:

Trade or Propriety Name: CUSA® Excel+ Ultrasonic Surgical Aspirator System
Common or Usual Name: Ultrasonic Surgical Aspirator
Classification Name: Instrument, Ultrasonic Surgical
Classification Panel: General and Plastic Surgery
Regulation: Class II unclassified

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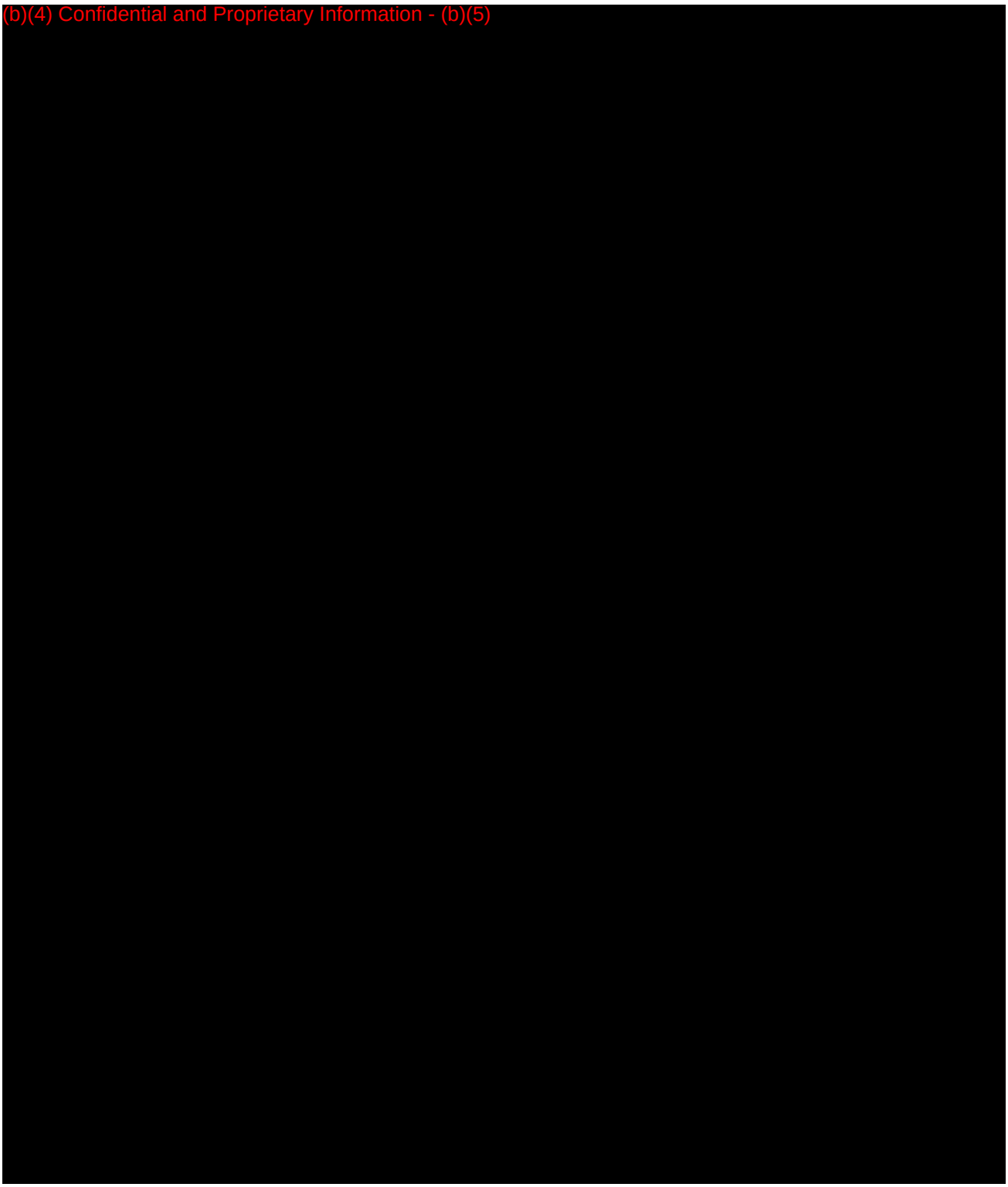

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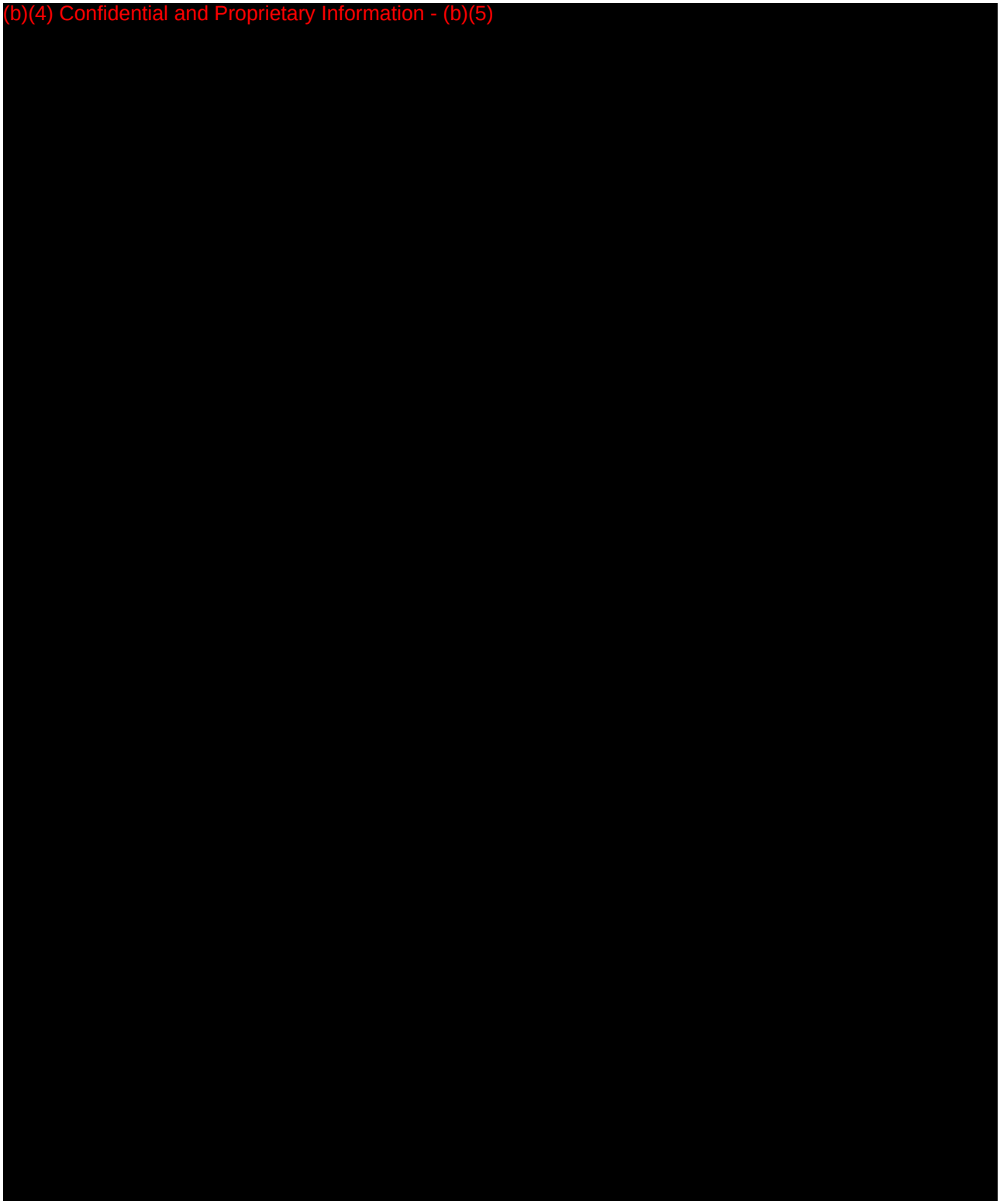

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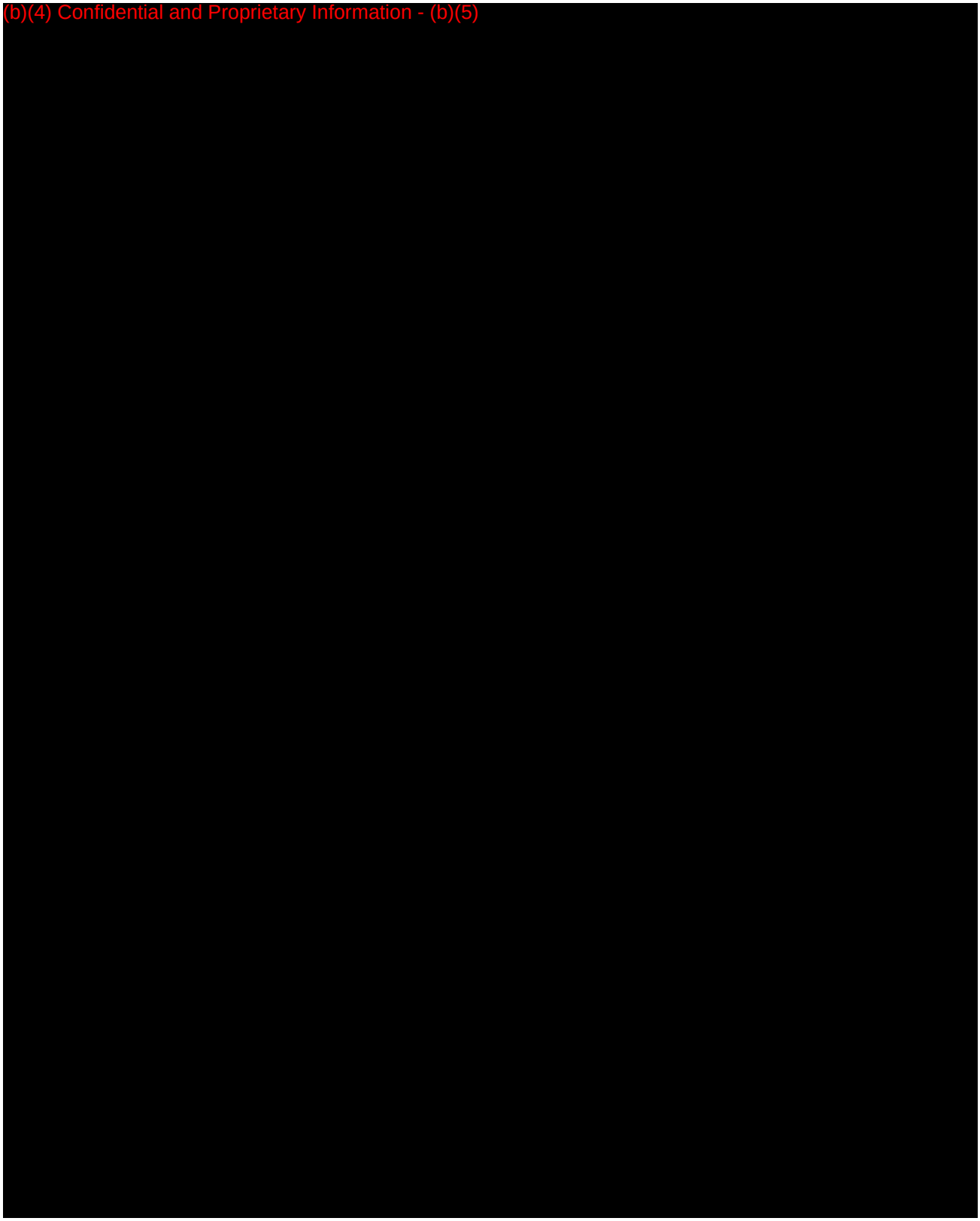

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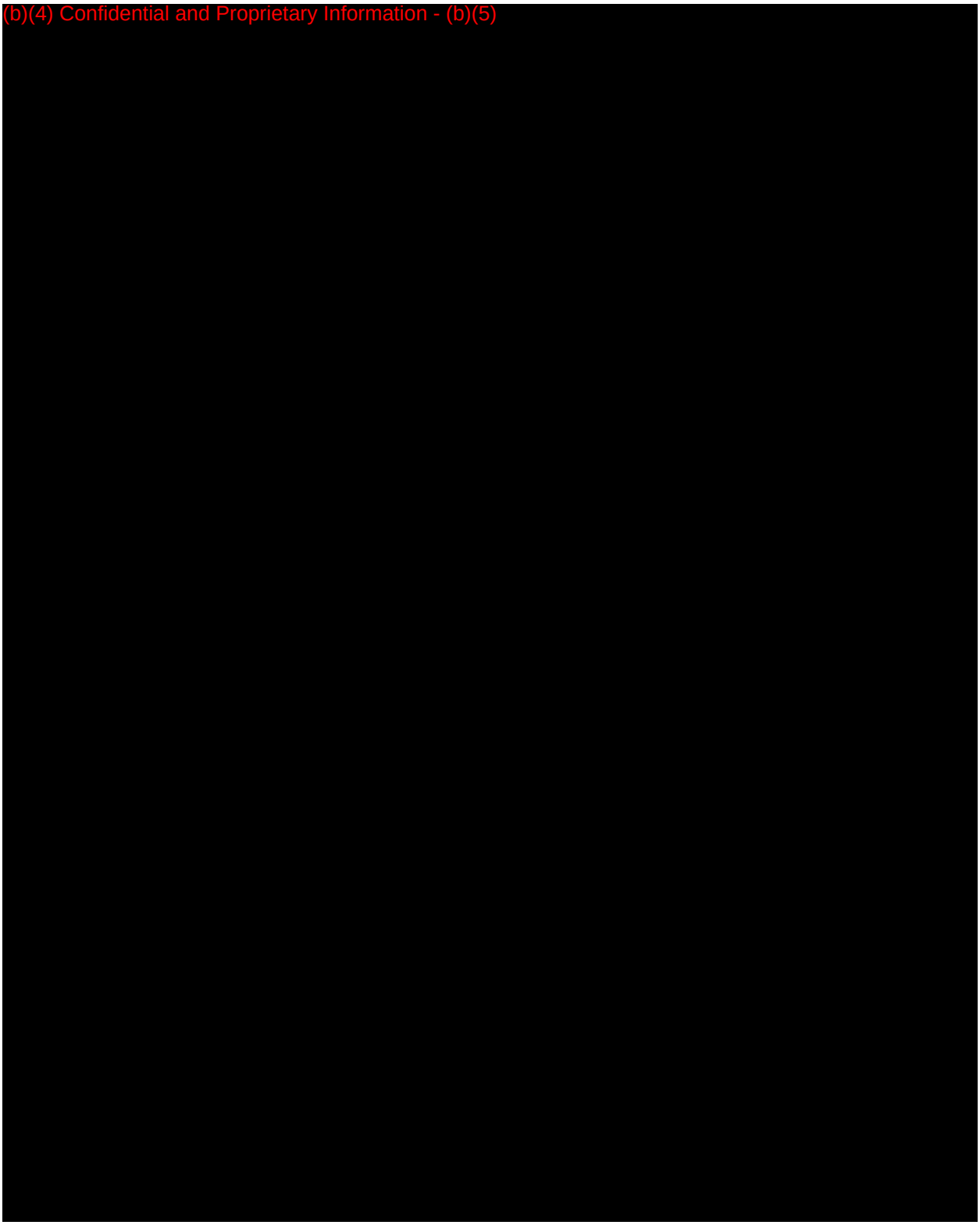

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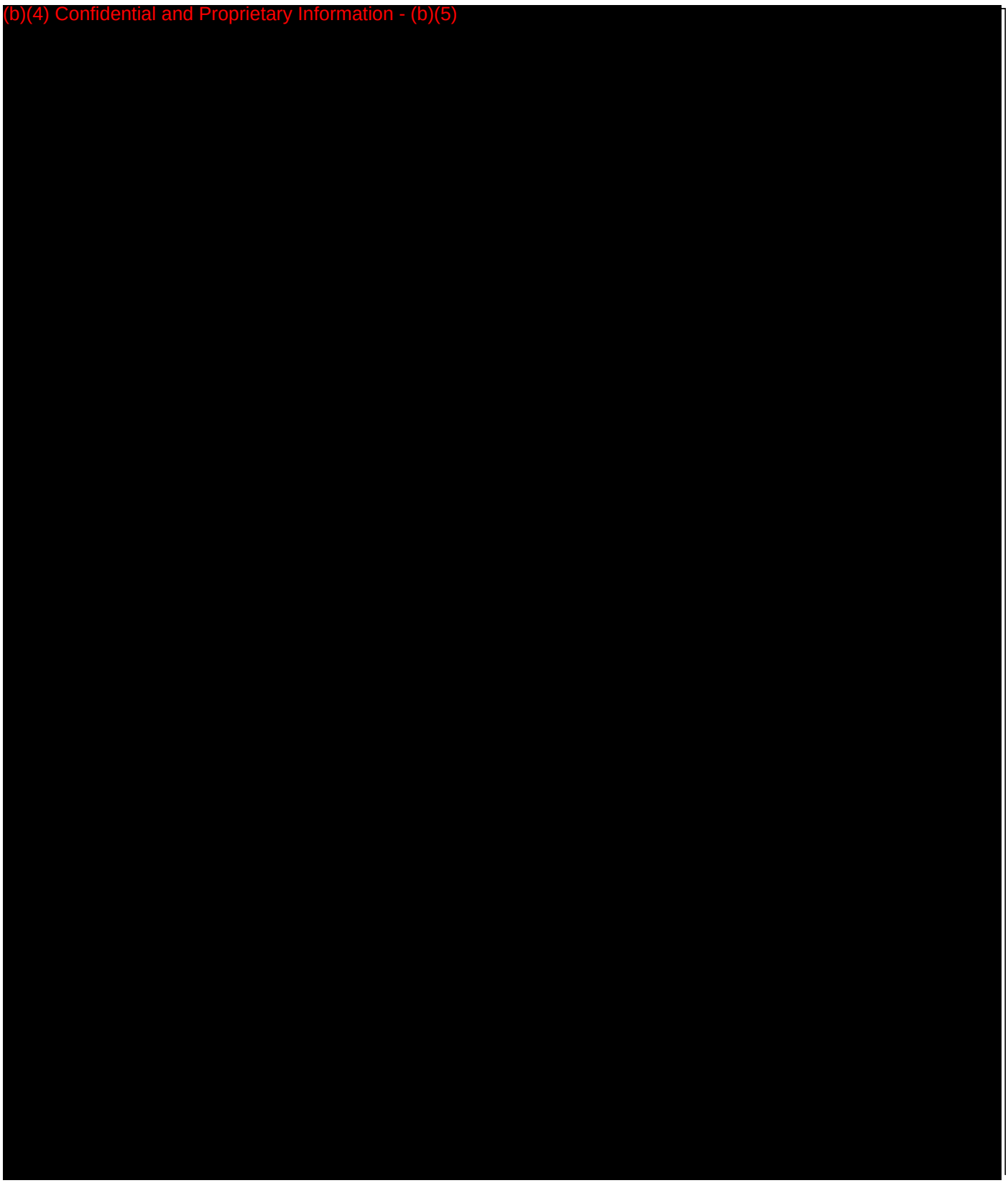

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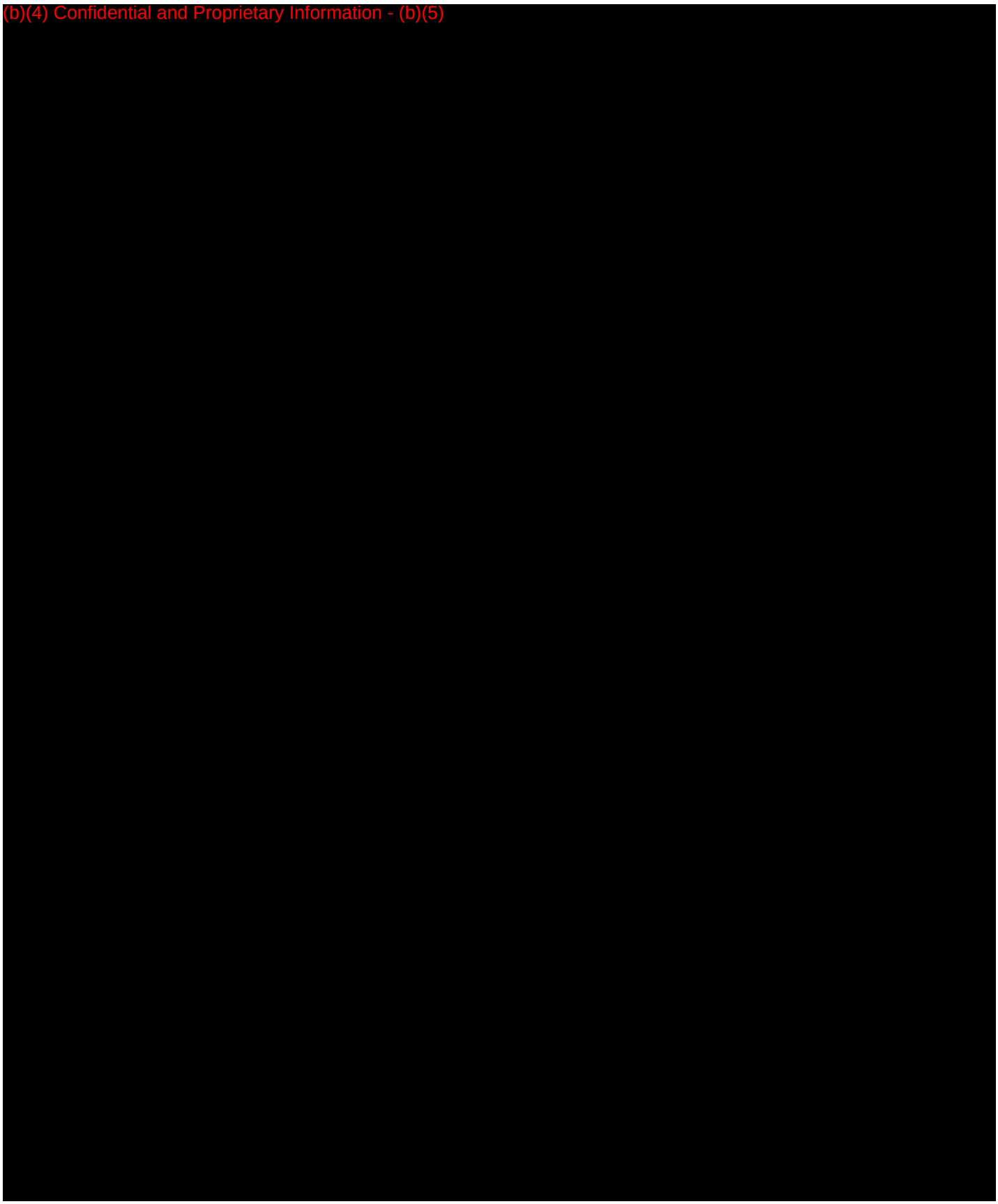

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RECOMMENDATIONS: APPROVAL WITH CONDITIONS

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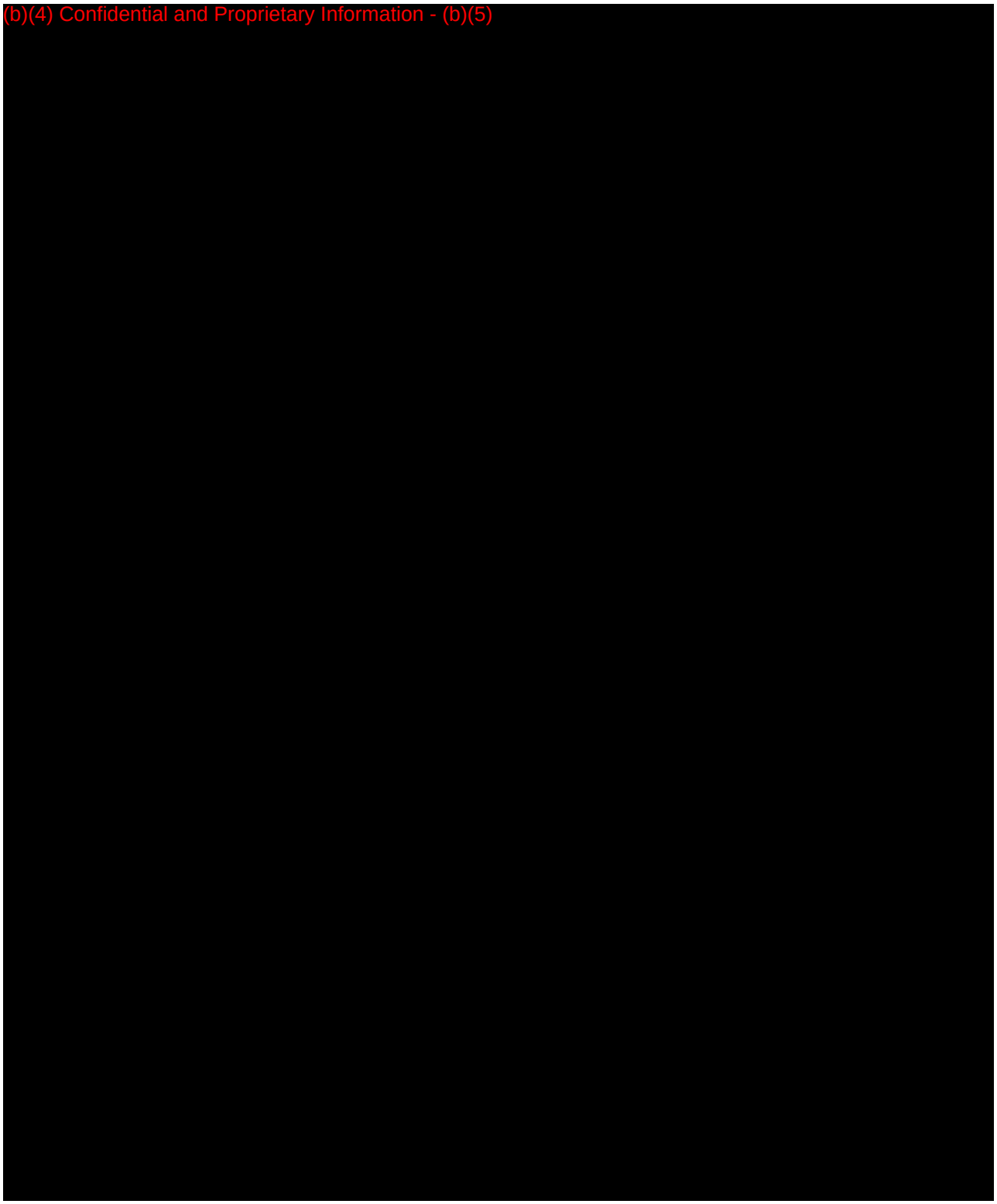

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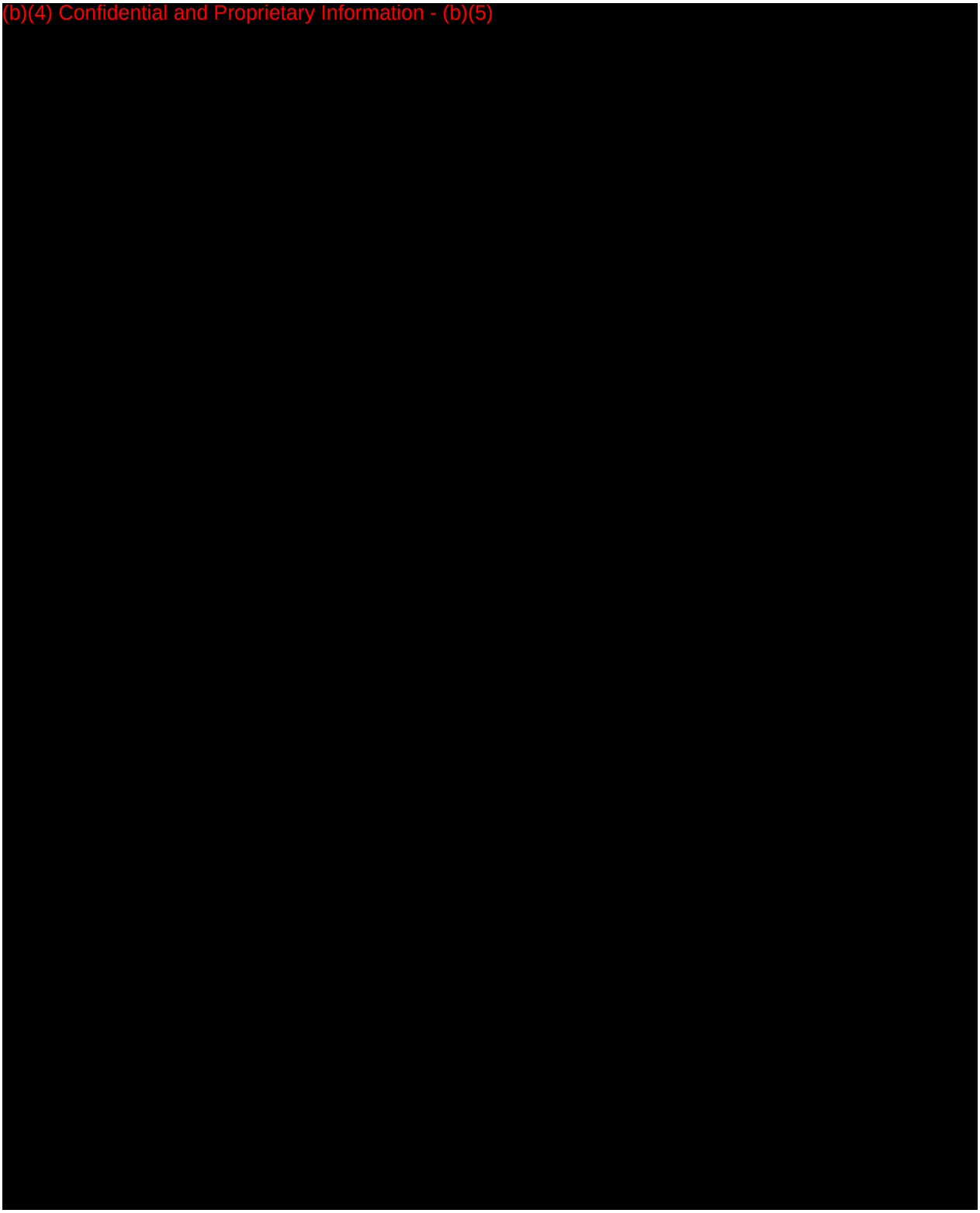

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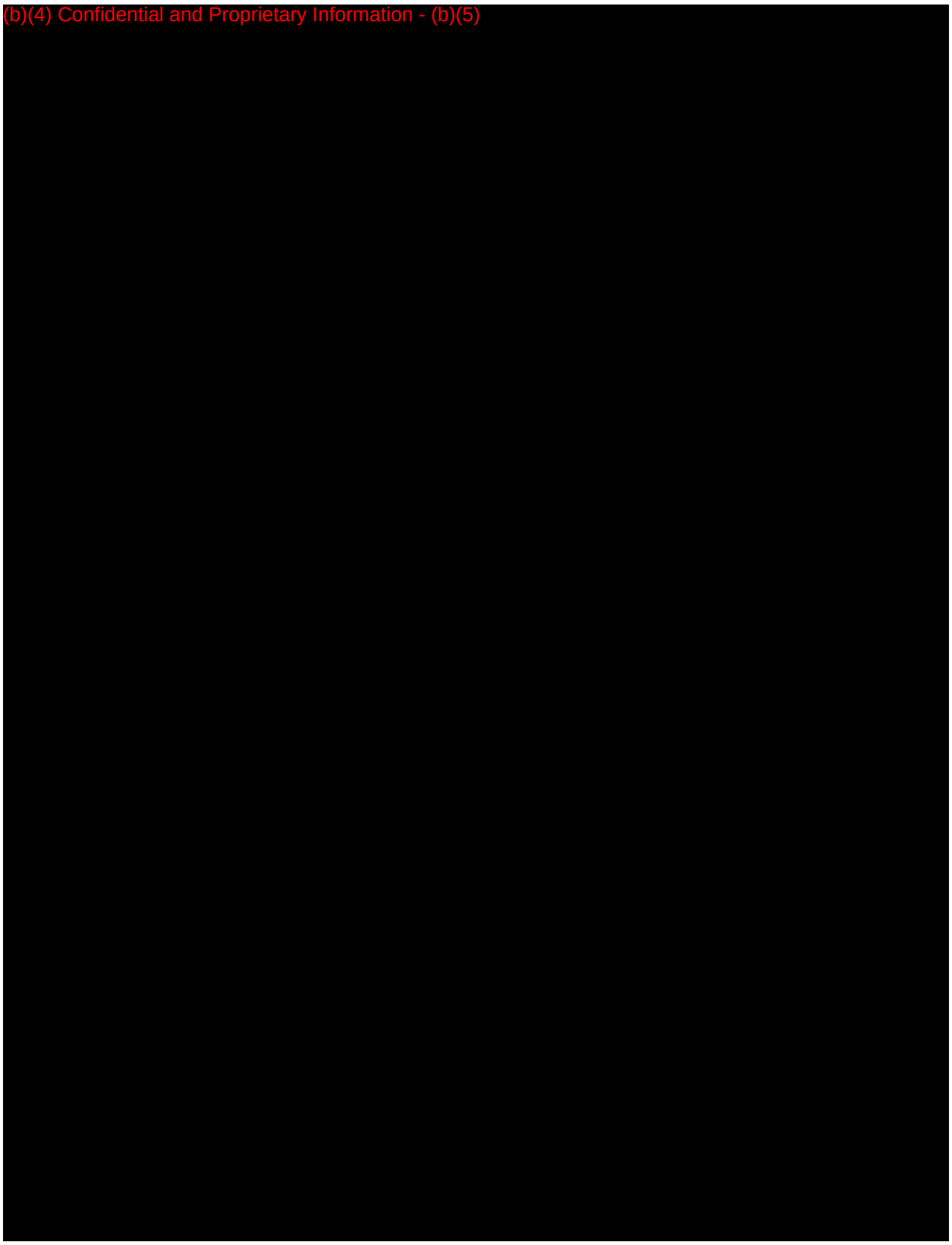

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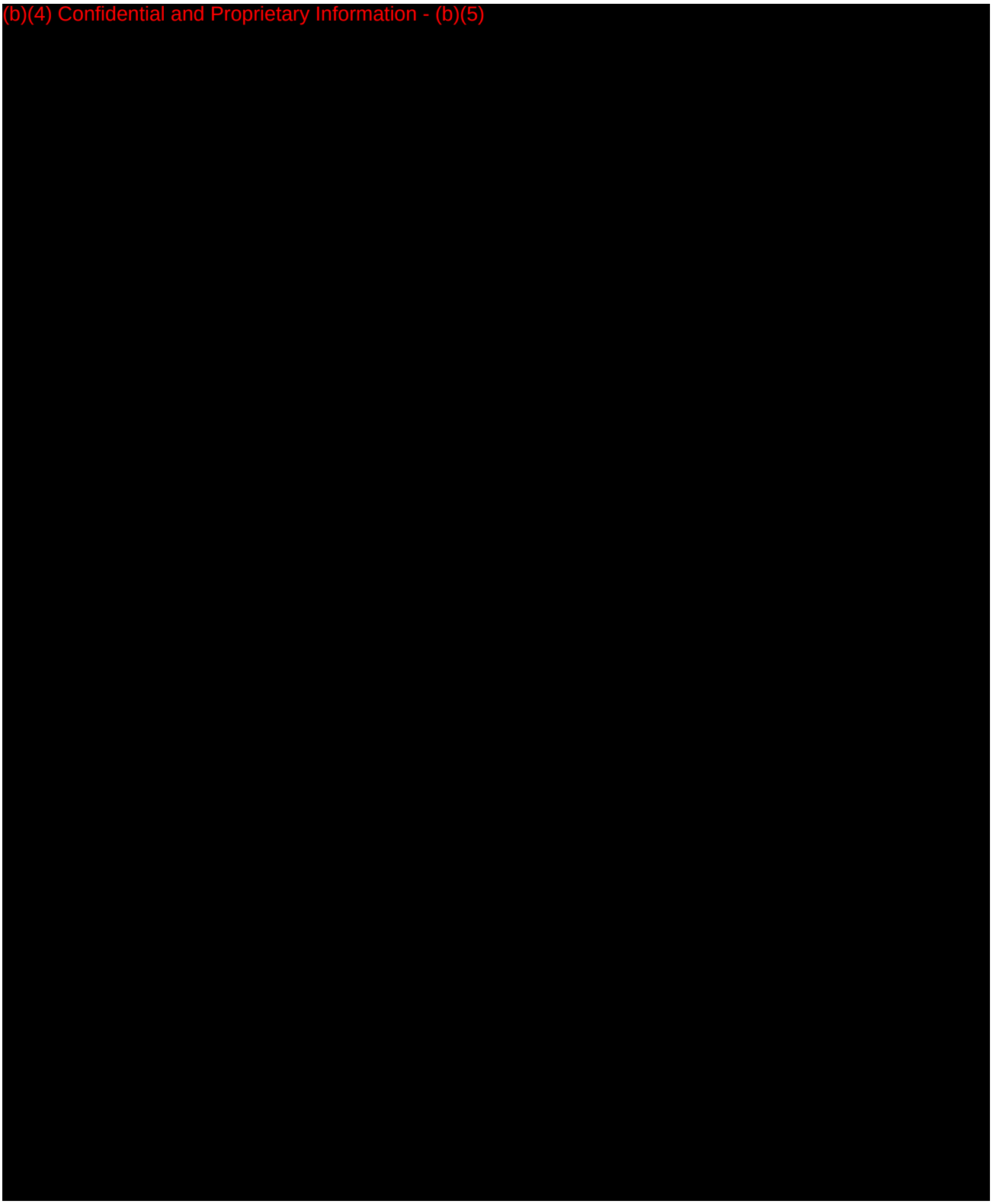

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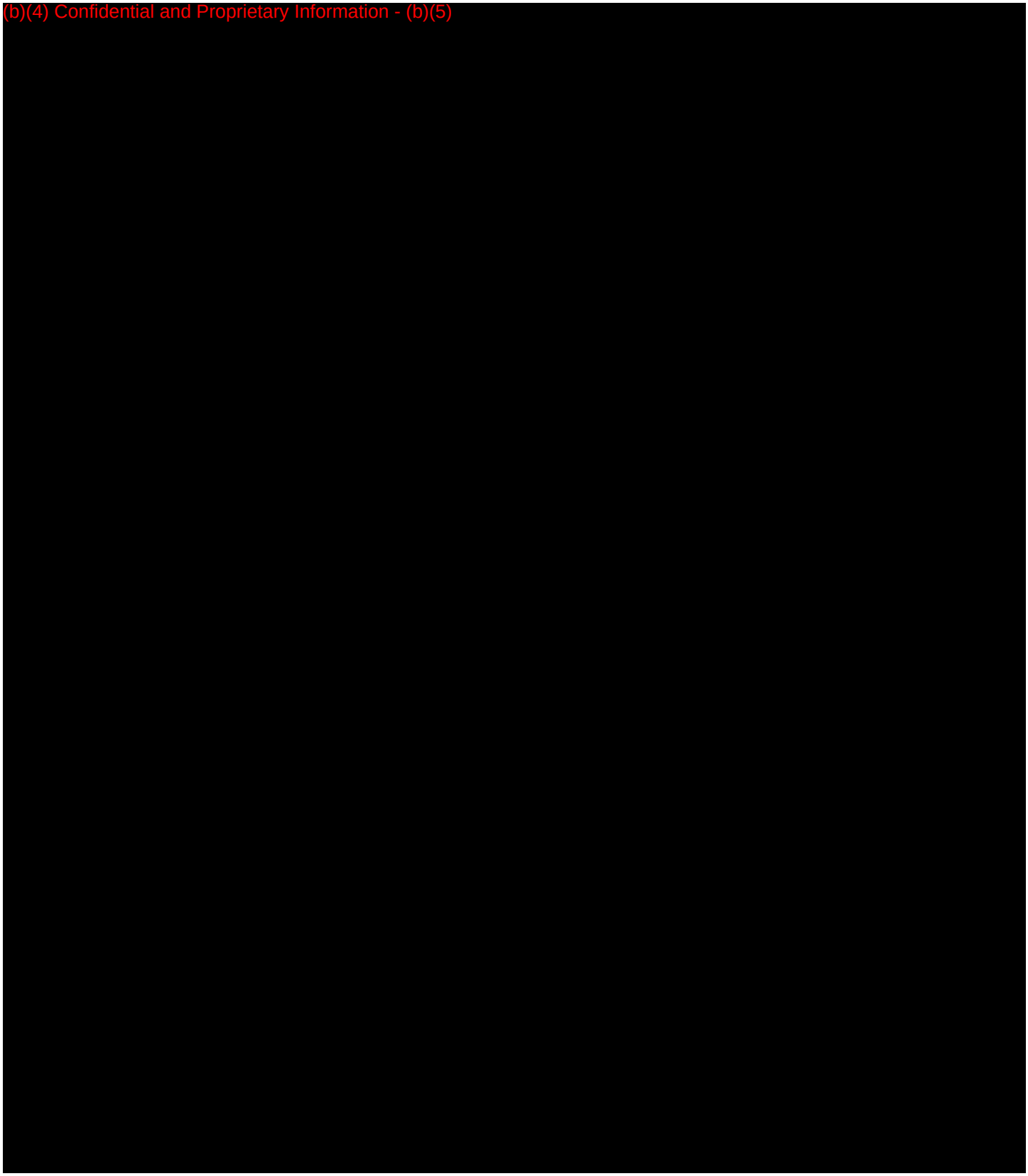

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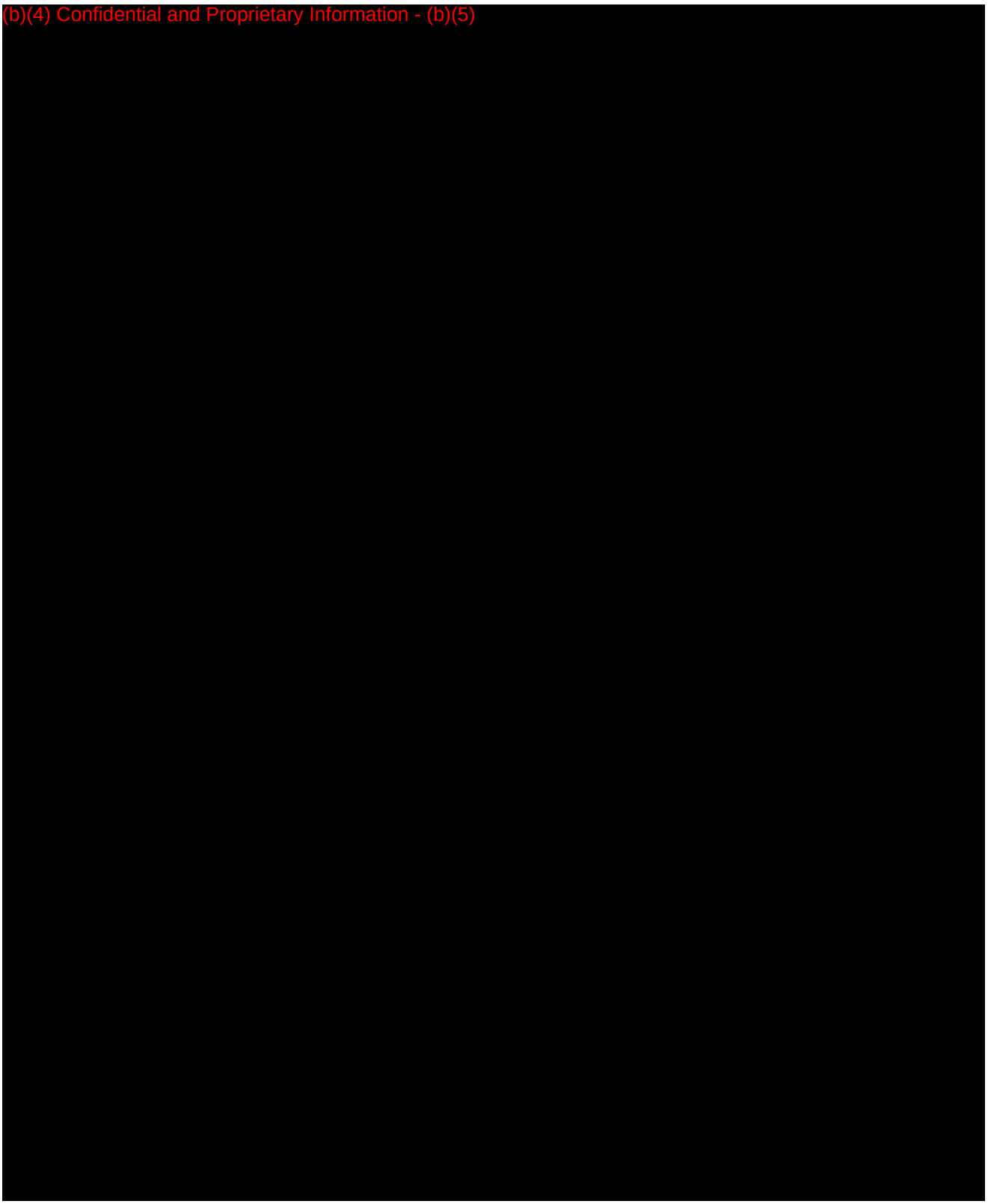

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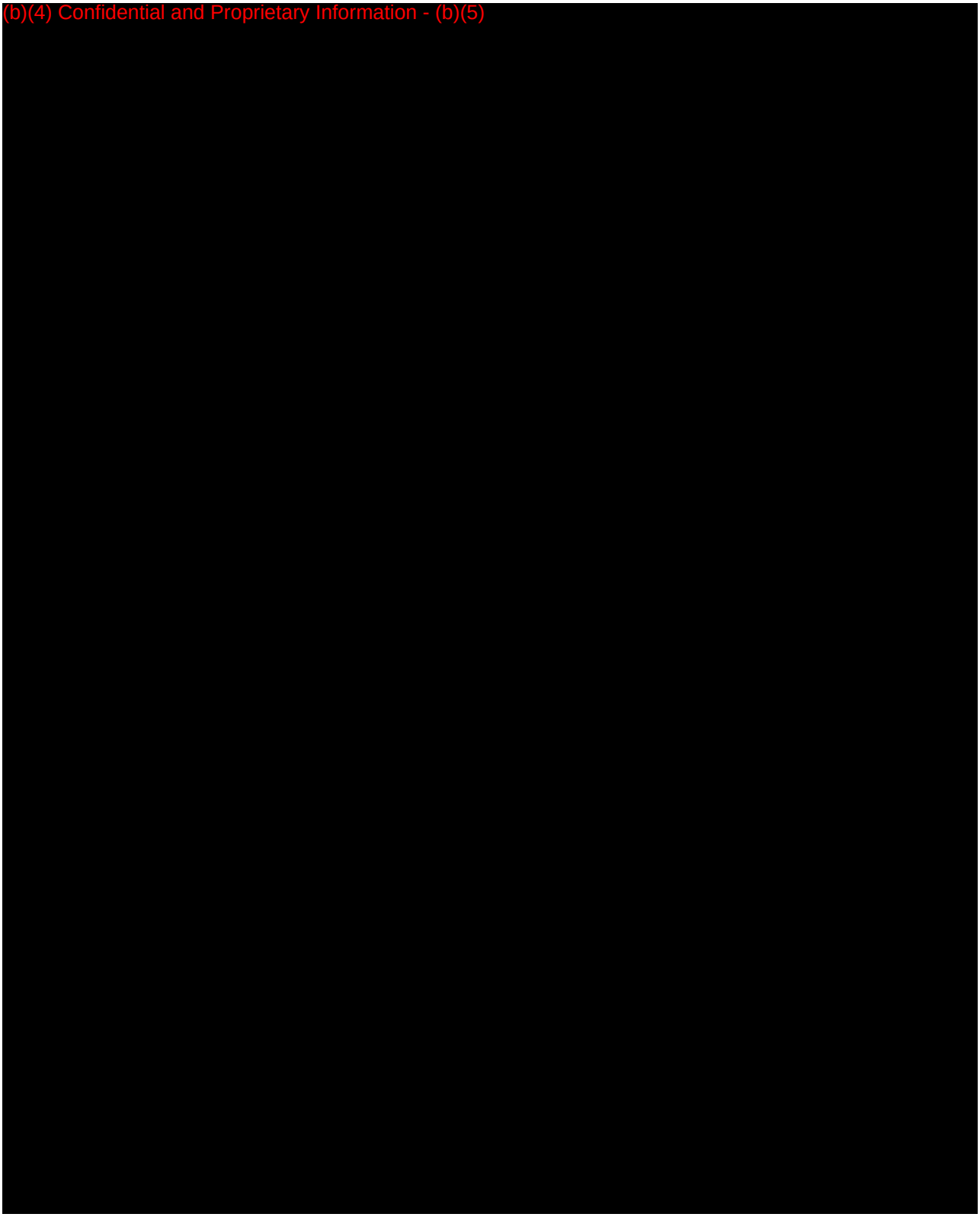

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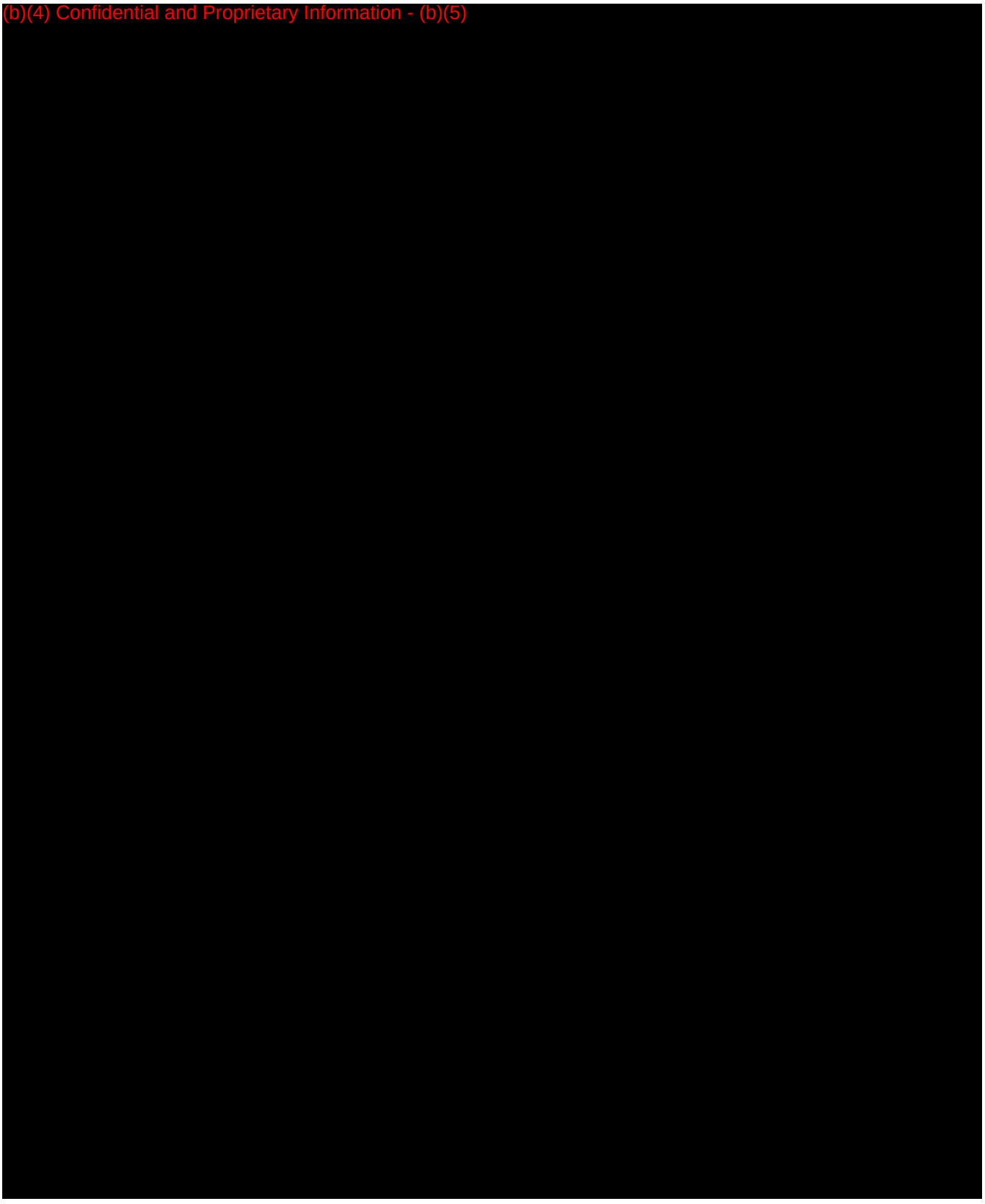

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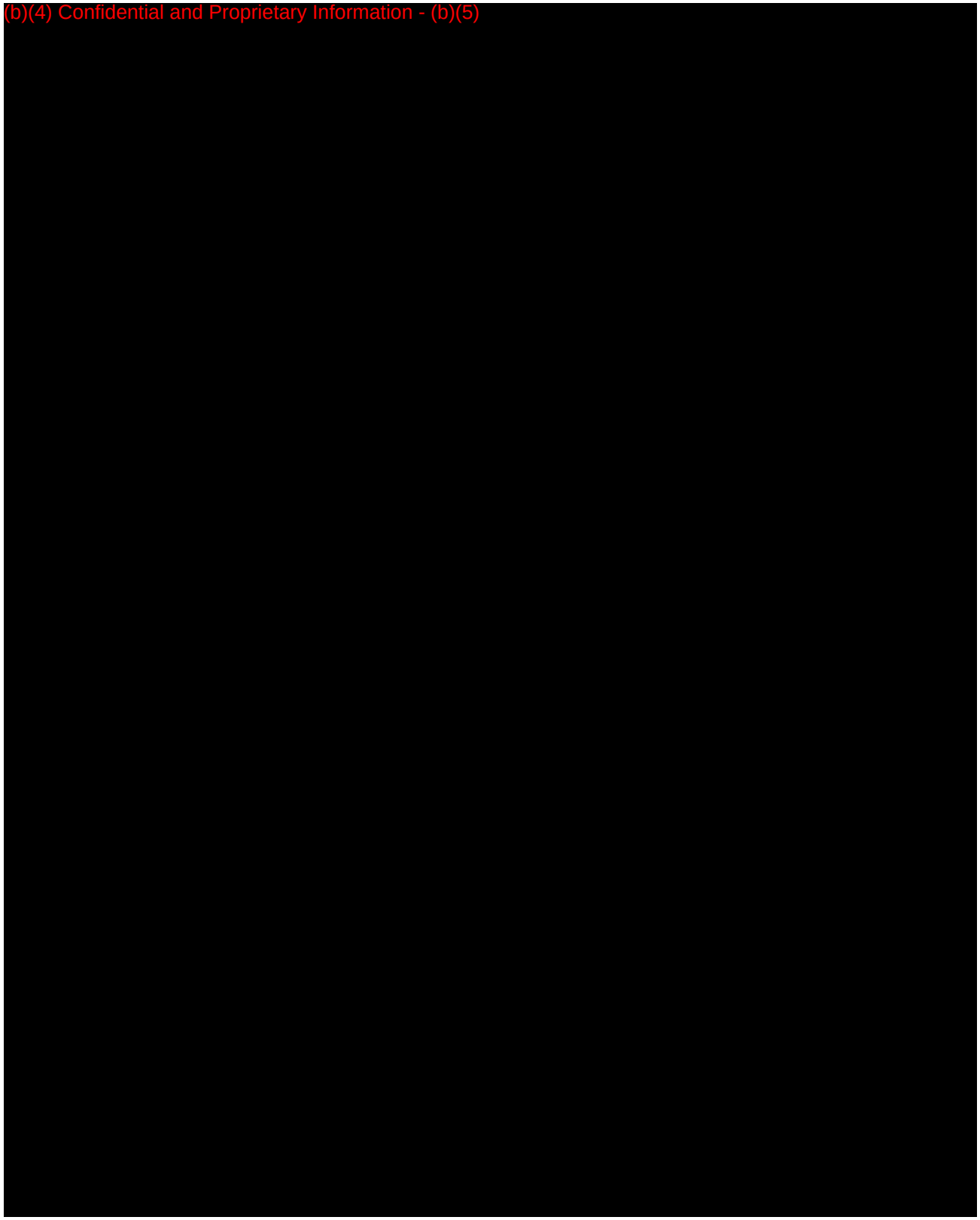
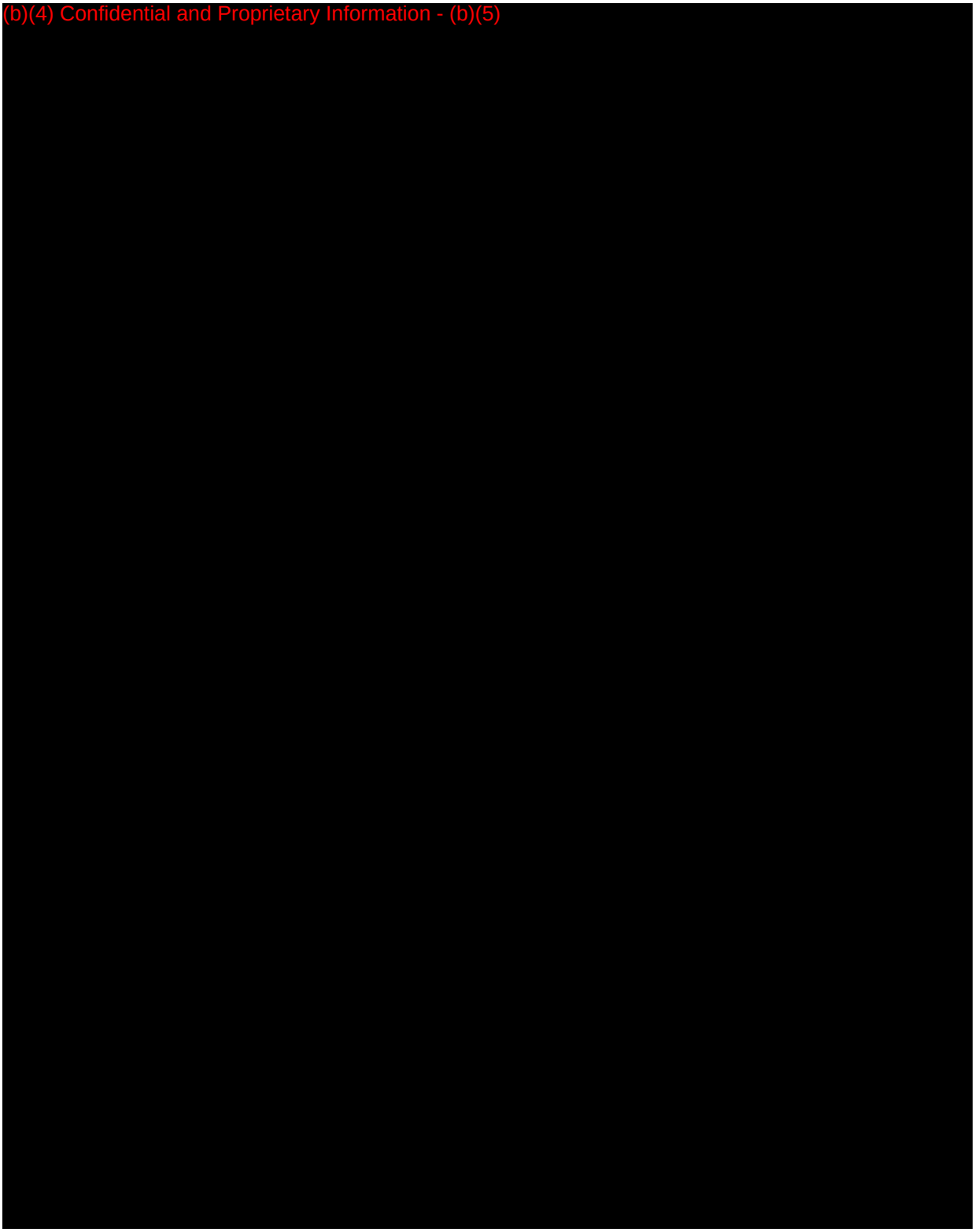


Thank you for allowing me the privilege of consulting on this submission.

V/R,

Steven Nagel, MD, FACS
U.S. Food and Drug Administration
Center for Devices and Radiological Health | Office of Device Evaluation | Division of Surgical Devices
U.S. Food and Drug Administration
10903 New Hampshire Avenue, Bldg. 66/G454
Silver Spring, MD 20993-0002
Phone: 301-796-9448
Email: Steven.Nagel@fda.hhs.gov

Digital Signature Concurrence Table	
Reviewer Sign-Off Steven Nagel FDA/CDRH/DSD	
Lead Reviewer Sign Off Dwight Yen CDRH/ODE/DSD/GSBD2	
Branch Chief Sign-Off Joshua Nipper CDRH/ODE/DSD/GSBD2	
Division Sign-Off Binita Asher CDRH/ODE/DSD	



510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

807.92(a)(1) – Submitter information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone Number	781-565-1347
Fax Number	781-238-0645
Establishment Registration Number	3003418325
Name of Contact Person	Janet C. Kay
Date Prepared	September 22, 2014
807.92(a)(2) – Name of device	
Trade or Propriety Name	CUSA® Excel+ Ultrasonic Surgical Aspirator System
Common or Usual Name	Ultrasonic Surgical Aspirator
Classification Name	Instrument, Ultrasonic Surgical
Classification Panel	General and Plastic Surgery
Regulation	Class II unclassified
Product Code(s)	LFL
807.92(a)(3) – Legally marketed device(s) to which equivalence is claimed	
CUSA Excel Ultrasonic Surgical Aspirator System K981262 CUSA Excel Ultrasonic Surgical Aspirator System with Bone Tip K051947	
807.92(a)(4) – Device description	

The CUSA Excel+ Ultrasonic Surgical Aspirator System (CUSA) is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. It allows the selective dissection of target tissue while preserving vessels, ducts and other delicate structures. The CUSA Excel+ System consists of a console which provides control and power functions, two surgical hand pieces which provide ultrasonic mechanical energy (23kHz and 36kHz), titanium hand piece tips (variety of models), flexible irrigation flue, and a suction/irrigation system (manifold tubing and cooling water canister). The CUSA Excel+ system accommodates most commercially available suction canisters. A two-pedal footswitch is provided with the console.

807.92(a)(5) – Intended use of the device

Indications for Use	The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. The CUSA Excel+ Ultrasonic Surgical Aspirator is indicated for use in: Neurosurgery, Plastic and Reconstructive surgery, Orthopedic Surgery, Gynecological Surgery and Thoracic Surgery and the following specific uses: Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy Urological surgery- including removal of renal parenchyma during nephrectomy or partial nephrectomy General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures Laparoscopic Surgery - including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial

	gastrectomy

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

The technological characteristic of the device are the same compared to the predicate device

807.92(b)(1-2) – Nonclinical and clinical tests submitted

No nonclinical testing was required as the device itself was not modified.

The clinical evidence used to support the change to the indications for use for Gastrointestinal (GI) and Affiliated Organ, Urologic, General, and Laparoscopic surgeries are peer reviewed journal articles:

Gastrointestinal and Affiliated Organ Surgery –
The largest body of data found was for GI and affiliated organ surgeries. Thirty-four articles reported on approximately 2,500 cases, including open hepatectomy and laparoscopic-assisted liver resection. Overall, the literature demonstrated that CUSA can be safely used in laparoscopic and open liver surgeries. The laparoscopic technique using CUSA has been shown to decrease morbidity, shorten hospital stay, improve cosmesis, and decrease blood loss. The literature showed CUSA to be safe and effective in liver surgery for pediatric, adult, and elderly patients and it has also been proven acceptable in both open and laparoscopic procedures.

Urologic Surgery –
Six articles report on the use of the CUSA system in renal surgical cases. These cases included resections performed for renal lithiasis and renal tumor removal and formation of a nipple valve during construction of a continent ileal urinary reservoir. A total of 8 urologic resection cases and 71 cases of nipple valve formation during construction of a continent ileal urinary reservoir were reported. No adverse events were reported with the use of the CUSA in these cases. The articles found that using CUSA for renal resection allows the surgeon to selectively aspirate certain tissues, including parenchyma, while leaving blood vessels and collecting systems intact. The literature reported that using CUSA resulted in increased visibility for the surgeons, reduced operating time, and a reduced volume of blood loss due to its selectivity.

General Surgery –
References are provided on the use of CUSA for the resection of carcinoma of the tongue in small numbers (10 patients) and treatment of using CUSA in papillary cystic and solid tumor of the pancreas (PCSTP) in children (5 cases). Although these case reports involve small numbers of patients no significant issues of safety or effectiveness are identified for the use of

CUSA device in these specific indications.

Laparoscopic Surgery –
Eight articles and two abstracts reveal that CUSA has been successfully used in laparoscopic appendectomies, laparoscopic colon resections, laparoscopic cholecystectomies, laparoscopic partial gastrectomies, laparoscopic transhiatal esophagectomy, laparoscopic ablation of endometriosis, and laparoscopic hepatectomies. One hundred thirty-one laparoscopic cholecystectomies, nine laparoscopic appendectomies, three laparoscopic colon resections, and two laparoscopic partial gastrectomies were performed using CUSA. The only complication observed in these cases was a thermal pinhole burn leading to bile leakage in one case of laparoscopic cholecystectomy. The articles for these cases reported that the advantage of using CUSA for these procedures included the ability of the system to dissect tissues while preserving the main structures. Six cases of laparoscopic esophagectomy were also completed using CUSA. The authors observed that using CUSA allowed for the isolation of vessels and periesophageal lymph nodes during the procedure and that transhiatal esophagectomies were performed successfully in all patients without massive bleeding. Over 150 laparoscopic hepatectomy procedures were performed using the CUSA system. Most of the articles presented concluded that use of CUSA led to successful surgical outcomes and reduced blood loss. The laparoscopic surgery articles presented in the literature review indicate that ultrasonic aspiration is a safe technology in a number of laparoscopic procedures. It may have advantages including less blood loss and preservation of main structures, including vessels and ducts.

807.92(b)(3) – Conclusions drawn from non-clinical and clinical data

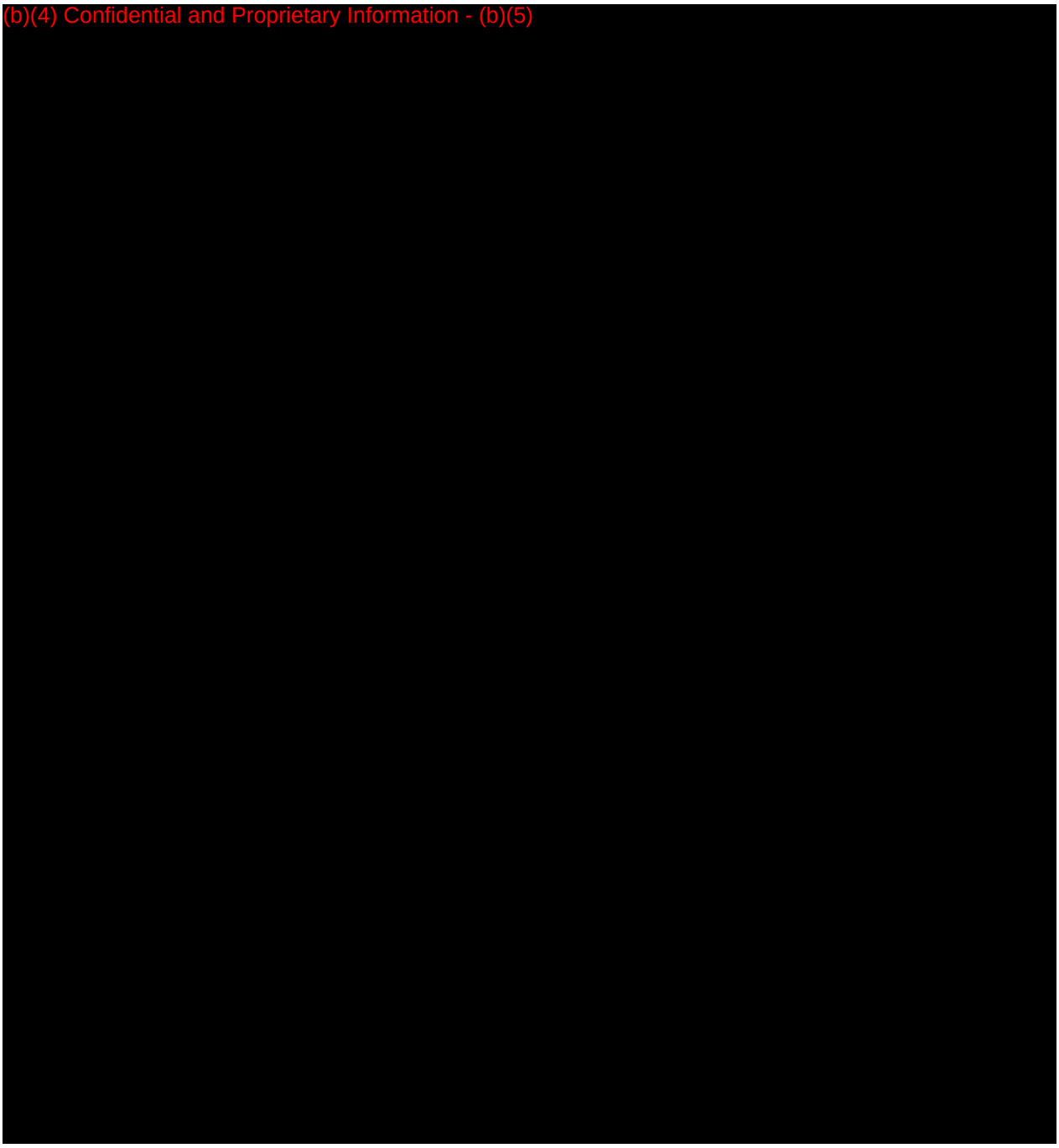
The changes from general to specific indications for use are supported by the information provided including previously cleared 510ks and peer reviewed clinical literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

K141668
Integra Lifesciences Corporation
Cusa excel+ ultrasonic surgical aspirator system

(b)(4) Confidential and Proprietary Information - (b)(5)



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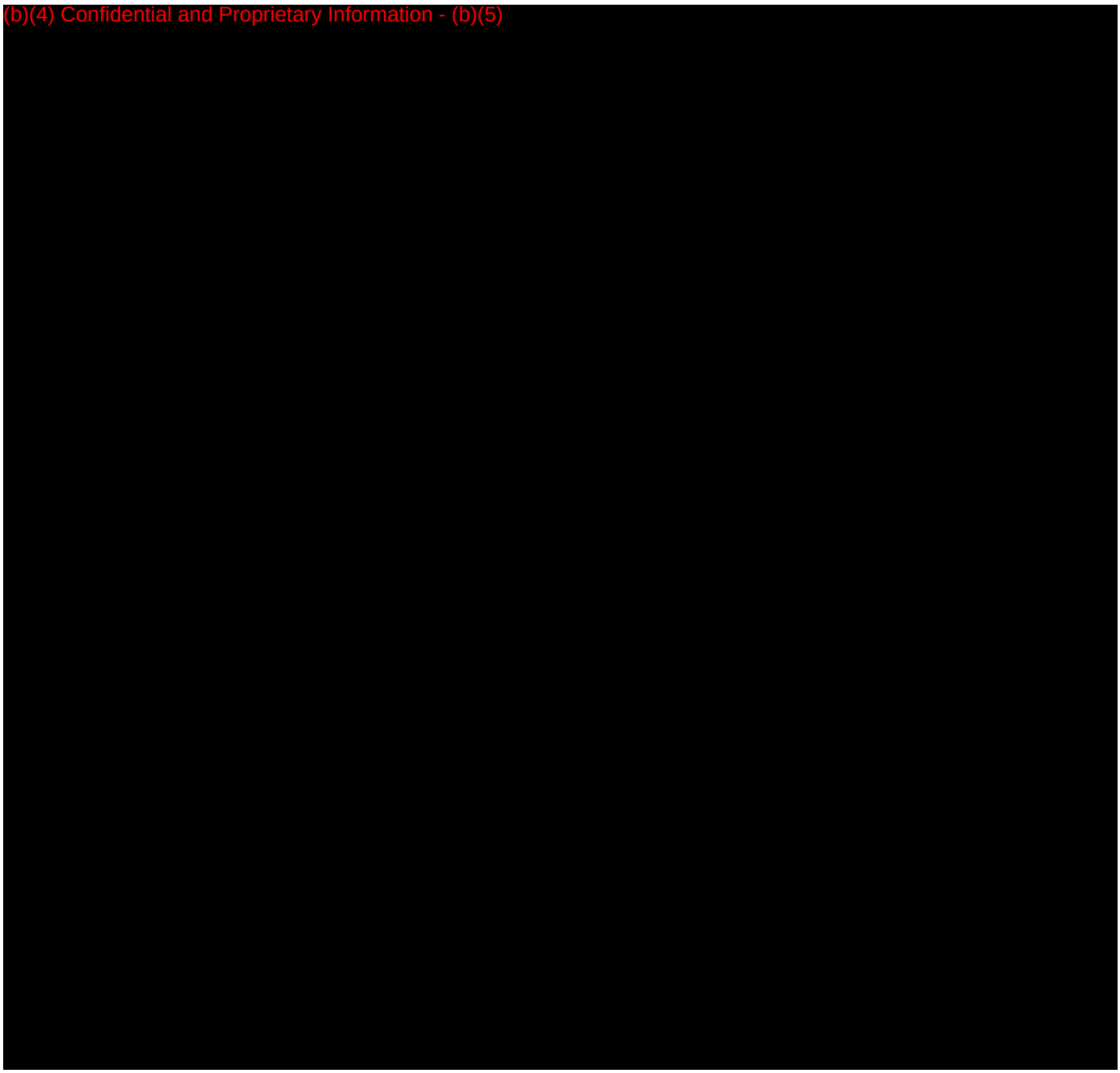


Indications for Use

510(k) Number (if known): K141668

Device Name:

CUSA® Excel+ Ultrasonic Surgical Aspirator System

Indications For Use:

The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. The CUSA Excel+ Ultrasonic Surgical Aspirator is indicated for use in:

Neurosurgery, Plastic and Reconstructive surgery, Orthopedic Surgery, Gynecological Surgery and Thoracic Surgery and the following specific uses:

Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy

Urological surgery- including removal of renal parenchyma during nephrectomy or partial nephrectomy

General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures

Laparoscopic Surgery - including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy

.

Prescription Use ___X___ **AND/OR** **Over-The Counter Use_____**

(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Food and Drug Administration
CDRH/ODE/DSD/GSDB2
WO66 RMG456 HFZ-410
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6401

Premarket Notification [510(k)] Review

Date: August 21, 2014
To: FILE
From: Dwight Yen
Subject: Traditional 510(k)# K141668

Applicant: Integra Lifesciences Corporation

Device Trade Name: Cusa excel+ ultrasonic surgical aspirator system

Correspondent: Janet Kay

Correspondent Title: Director, Regulatory Affairs

Consultant Firm (if Applicable): Enter consultant name here, or erase this if there is none

Phone: (609) 750-2864 **Email:** janet.kay@integralife.com

FDA Received Date: June 23, 2014

Due Date: September 21, 2014

Reg #: **Reg Name:** Pre-Amendment

Class: II **Product Code(s):** LFL

Predicate Devices:

510(k) #	Pro Code	Device Trade Name	Owner
K051947	LFL	Radionics cusa excel ultrasonic surgical aspirator system with bone	Radionics, A Division Of Tyco Healthcare Group Lp
K981262	LBK, LFL	Cusa excel ultrasonic surgical aspirator system	Valleylab, Inc.
K910696	LFL	Cusa(r) system 200c/200t/200m/200h ultra aspirator	Valleylab, Inc.
K921251	LFL	Cusa system 200c and 200t ultrasonic aspirator	Valleylab, Inc.

Review Summary

(b)(4) Confidential and Proprietary Information - (b)(5)

[redacted]

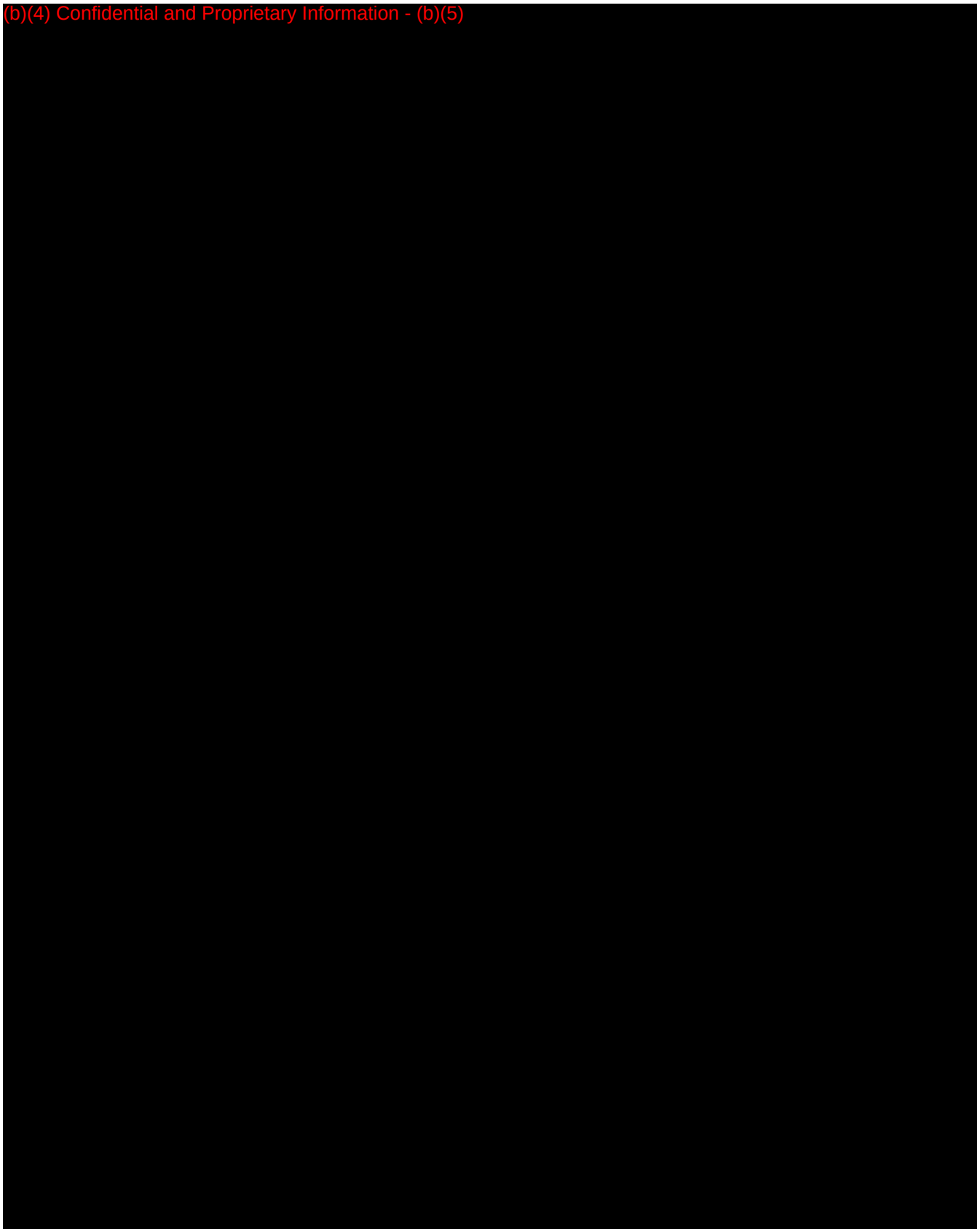
Recommendation

I recommend that the Cusa excel+ ultrasonic surgical aspirator system is/are in need of Additional Information (AI, AINN)

Review Team

Lead Reviewer	Dwight Yen (CDRH/ODE/DSD/GSDB2)
Clinical Reviewer	Steven Nagel, MD (CDRH/ODE/DSD/GSDB2)

(b)(4) Confidential and Proprietary Information - (b)(5)



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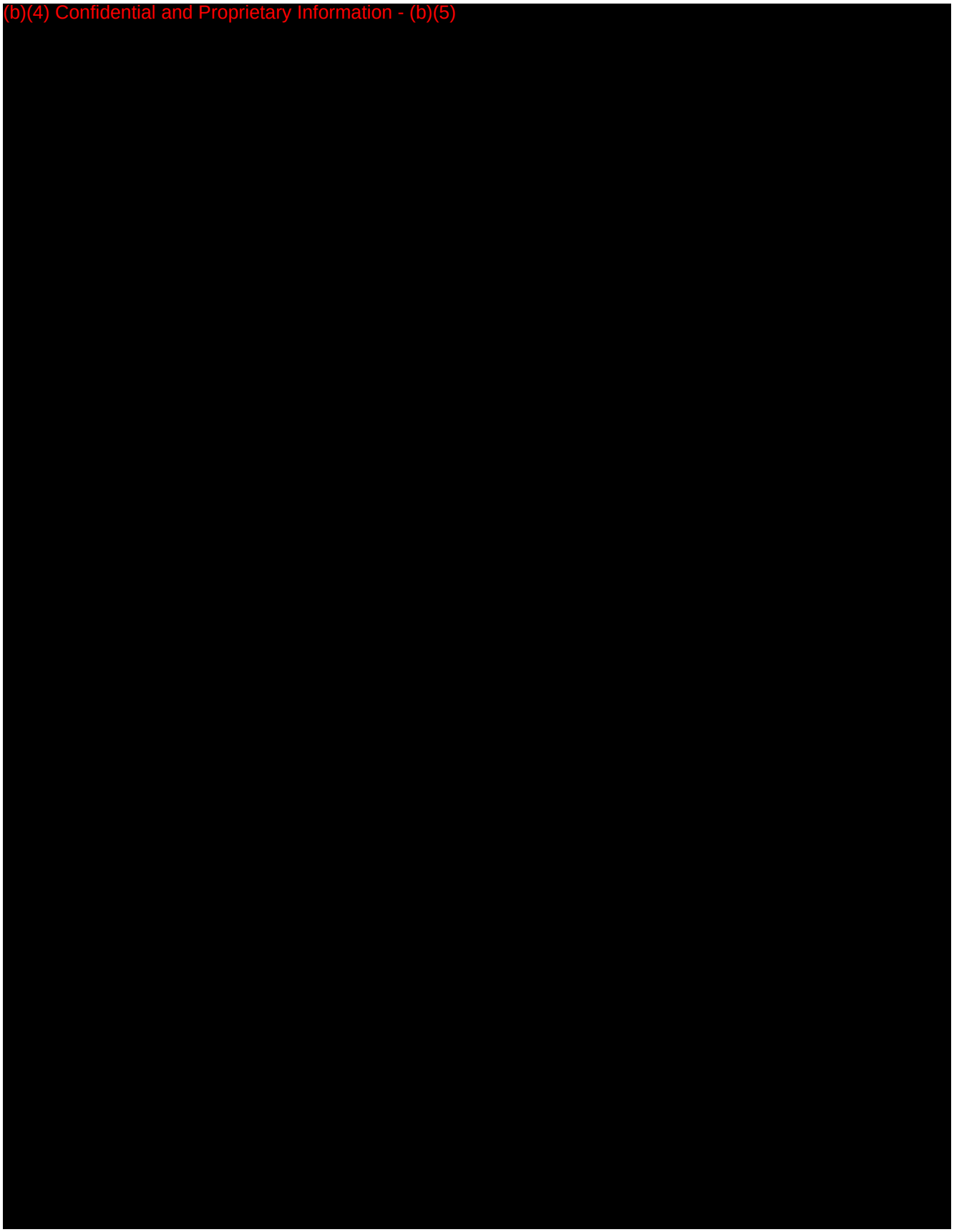

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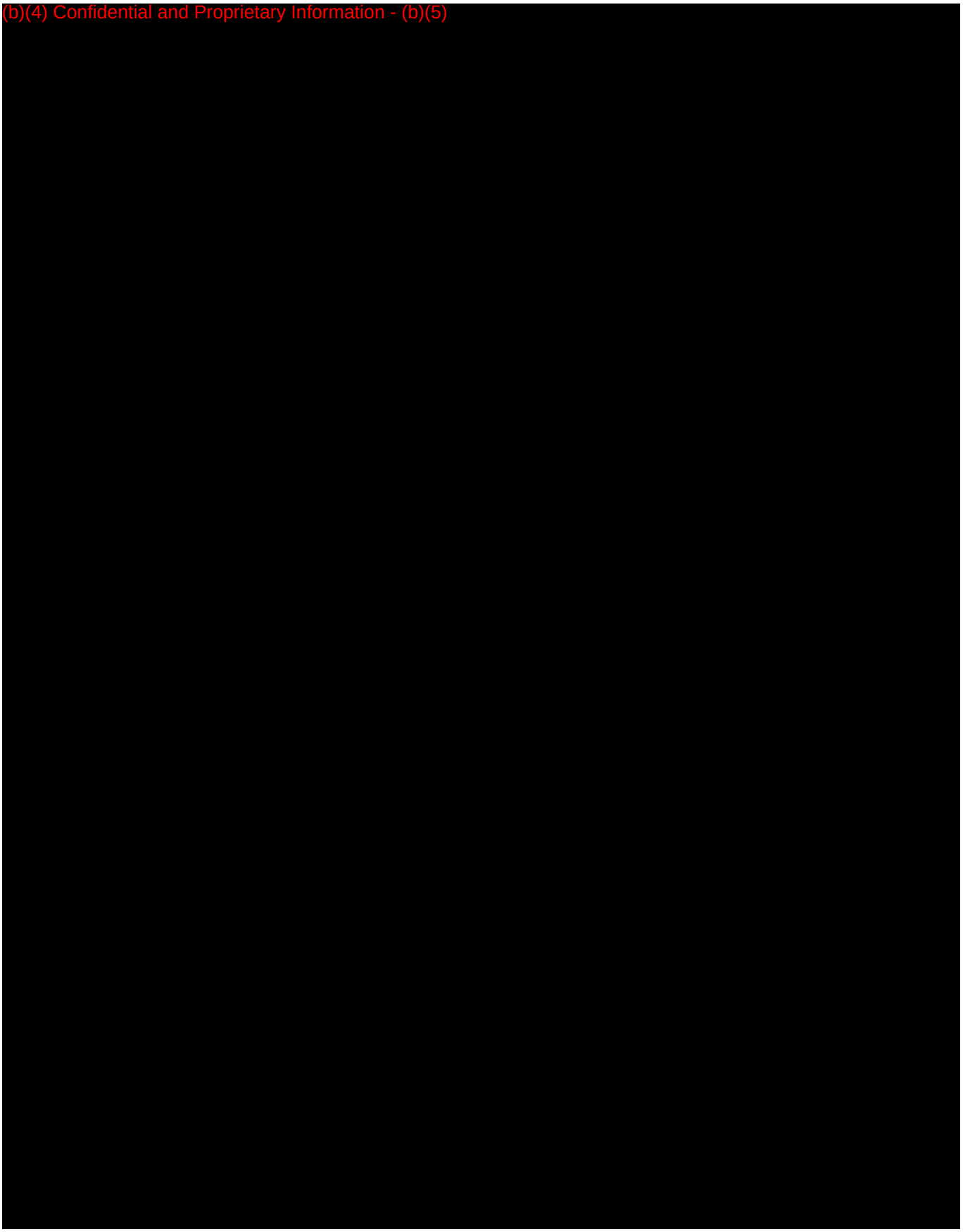

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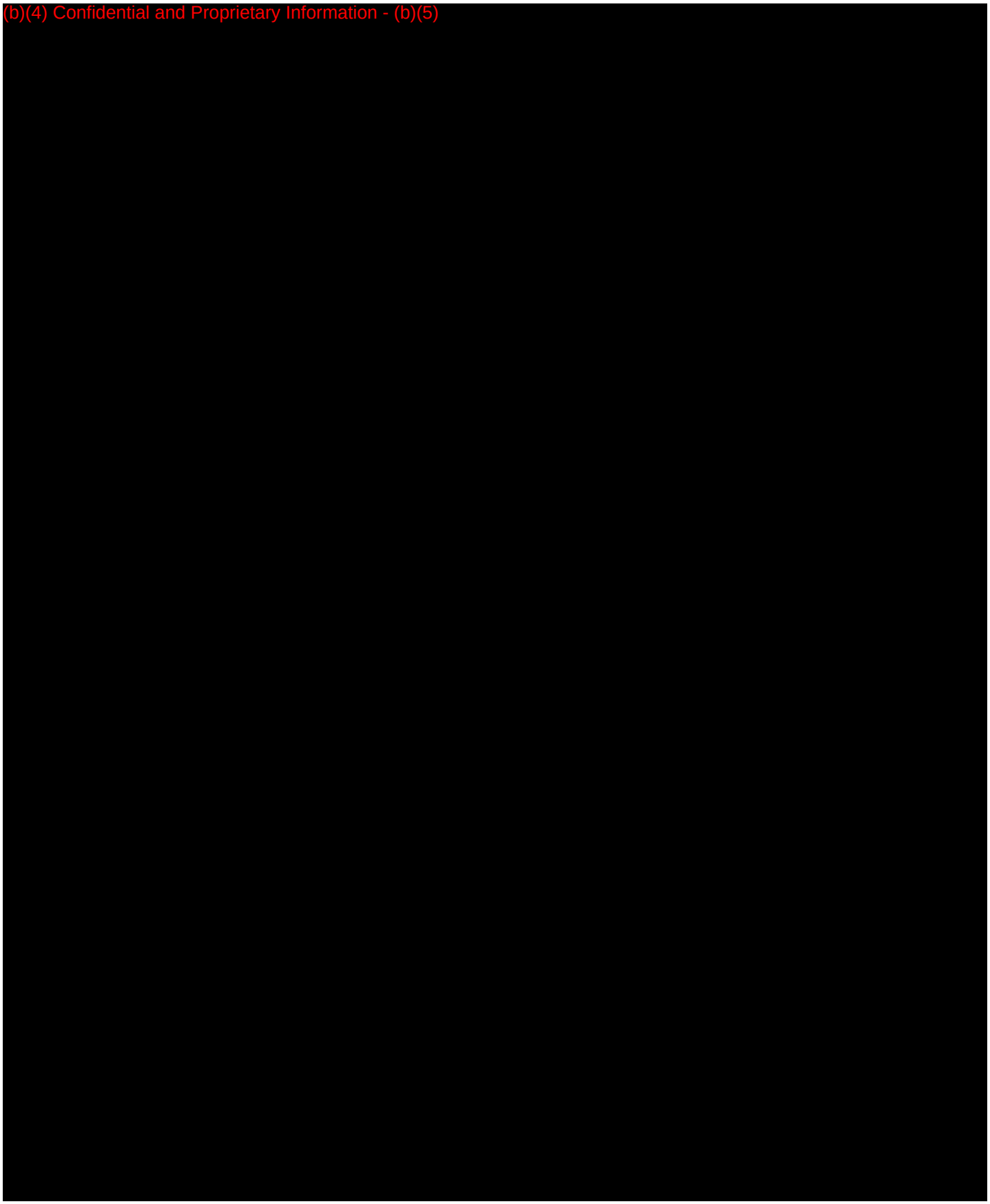
(b)(4) Confidential and Proprietary Information - (b)(5)

(b)(4) Confidential and Proprietary Information - (b)(5)



(b)(4) Confidential and Proprietary Information - (b)(5)

(b)(4) Confidential and Proprietary Information - (b)(5)

[redacted]

XVI. Contact History

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off	

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

November 6, 2014

Integra LifeSciences Corporation
Ms. Janet C. Kay
Director, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K141668
Trade/Device Name: CUSA® Excel+ Ultrasonic Surgical Aspirator System
Regulatory Class: Unclassified
Product Code: LFL
Dated: October 8, 2014
Received: October 10, 2014

Dear Ms. Kay:

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. 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.

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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Food and Drug Administration
CDRH/ODE/DSD/GSDB2
WO66 RMG456 HFZ-410
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6401

Premarket Notification [510(k)] Review

Date: November 6, 2014
To: FILE
From: Dwight Yen
Subject: Traditional 510(k)# K141668

Applicant: Integra Lifesciences Corporation

Device Trade Name: Cusa excel+ ultrasonic surgical aspirator system

Correspondent: Janet Kay

Correspondent Title: Director, Regulatory Affairs

Consultant Firm (if Applicable): Enter consultant name here, or erase this if there is none

Phone: (609) 750-2864 **Email:** janet.kay@integralife.com

FDA Received Date: June 23, 2014

Due Date: September 21, 2014

Reg #: **Reg Name:** Pre-Amendment

Class: II **Product Code(s):** LFL

Predicate Devices:

510(k) #	Pro Code	Device Trade Name	Owner
K051947	LFL	Radionics cusa excel ultrasonic surgical aspirator system with bone	Radionics, A Division Of Tyco Healthcare Group Lp
K981262	LBK, LFL	Cusa excel ultrasonic surgical aspirator system	Valleylab, Inc.
K910696	LFL	Cusa(r) system 200c/200t/200m/200h ultra aspirator	Valleylab, Inc.
K921251	LFL	Cusa system 200c and 200t ultrasonic aspirator	Valleylab, Inc.

(b)(4) Confidential and Proprietary Information - (b)(5)

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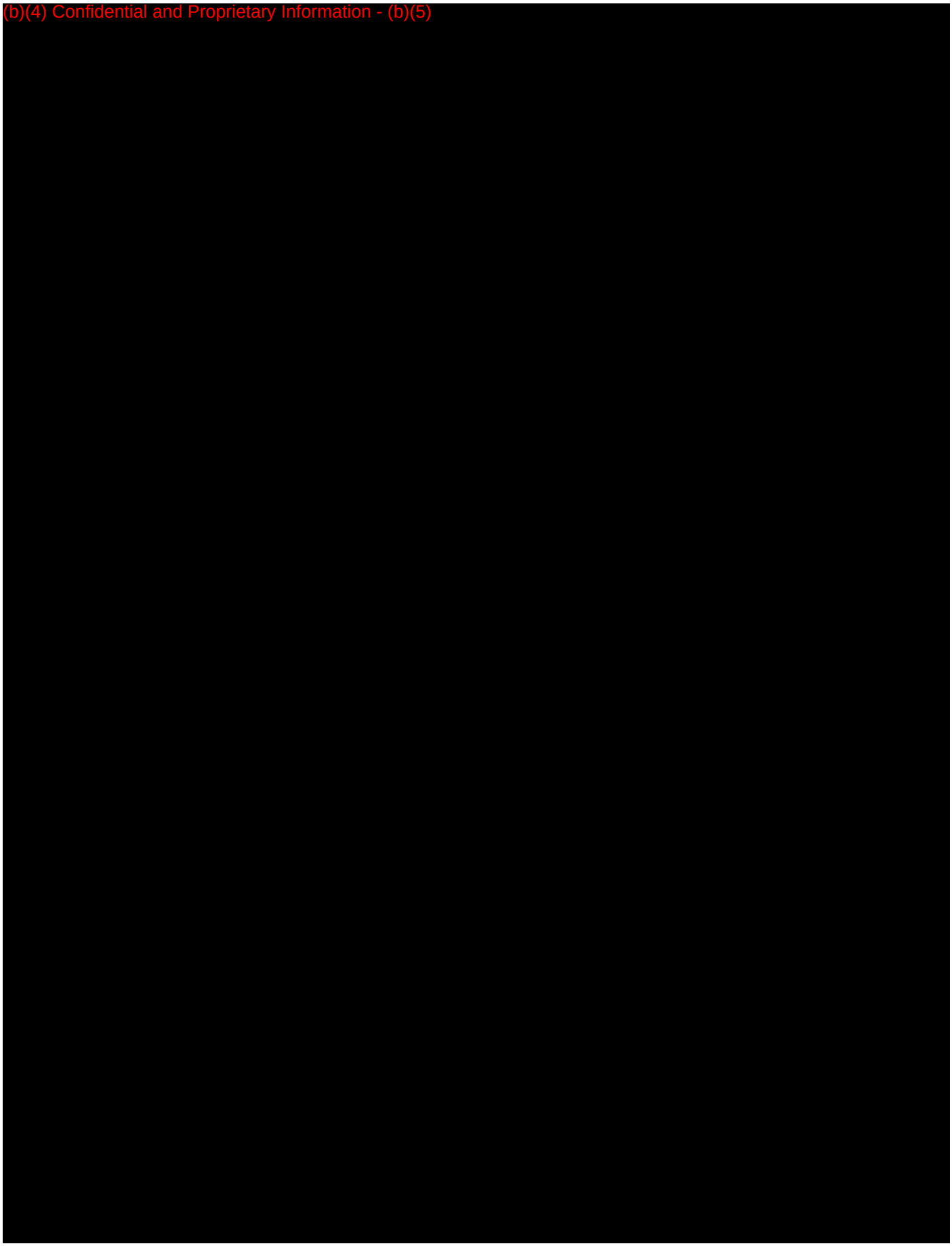

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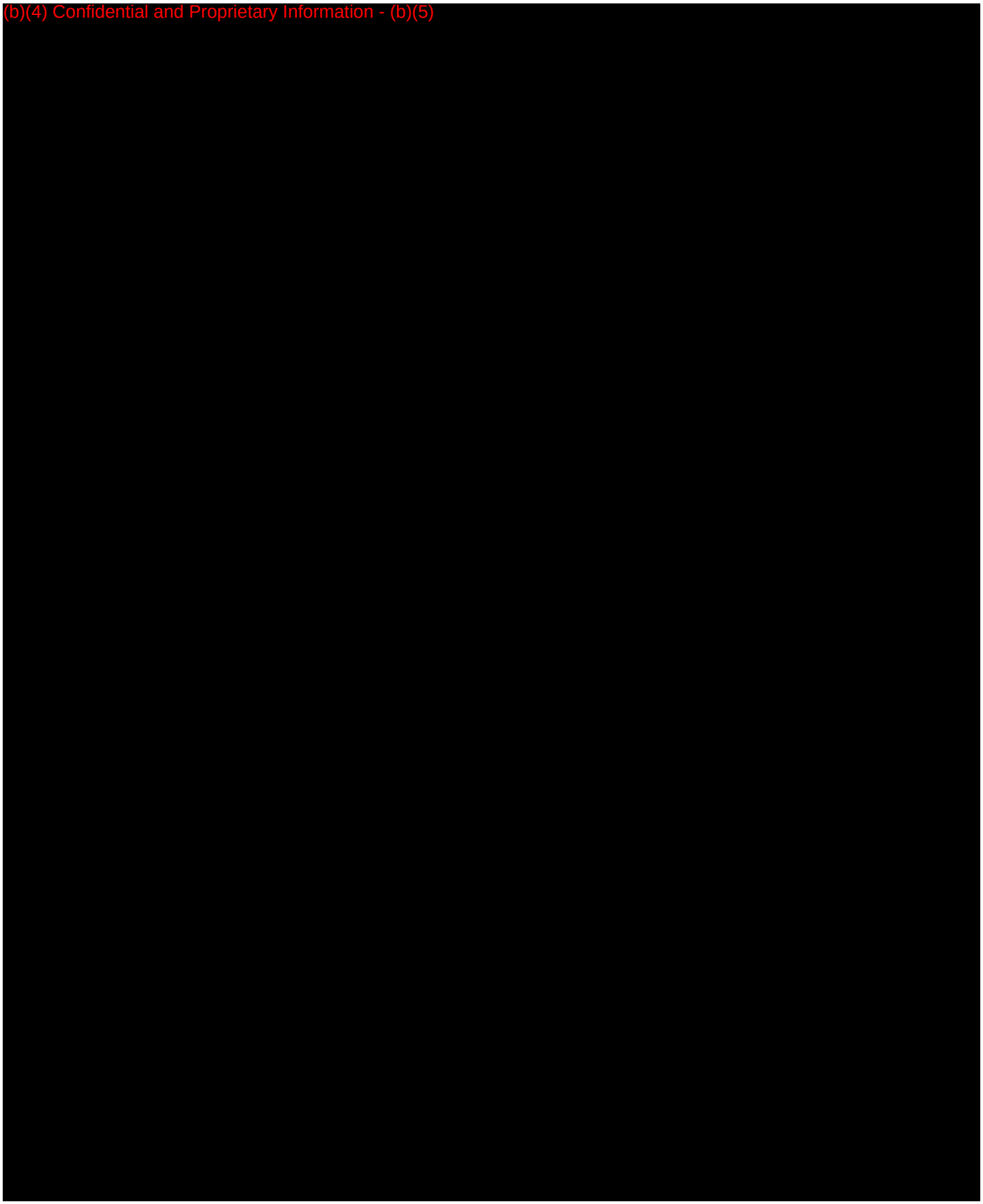

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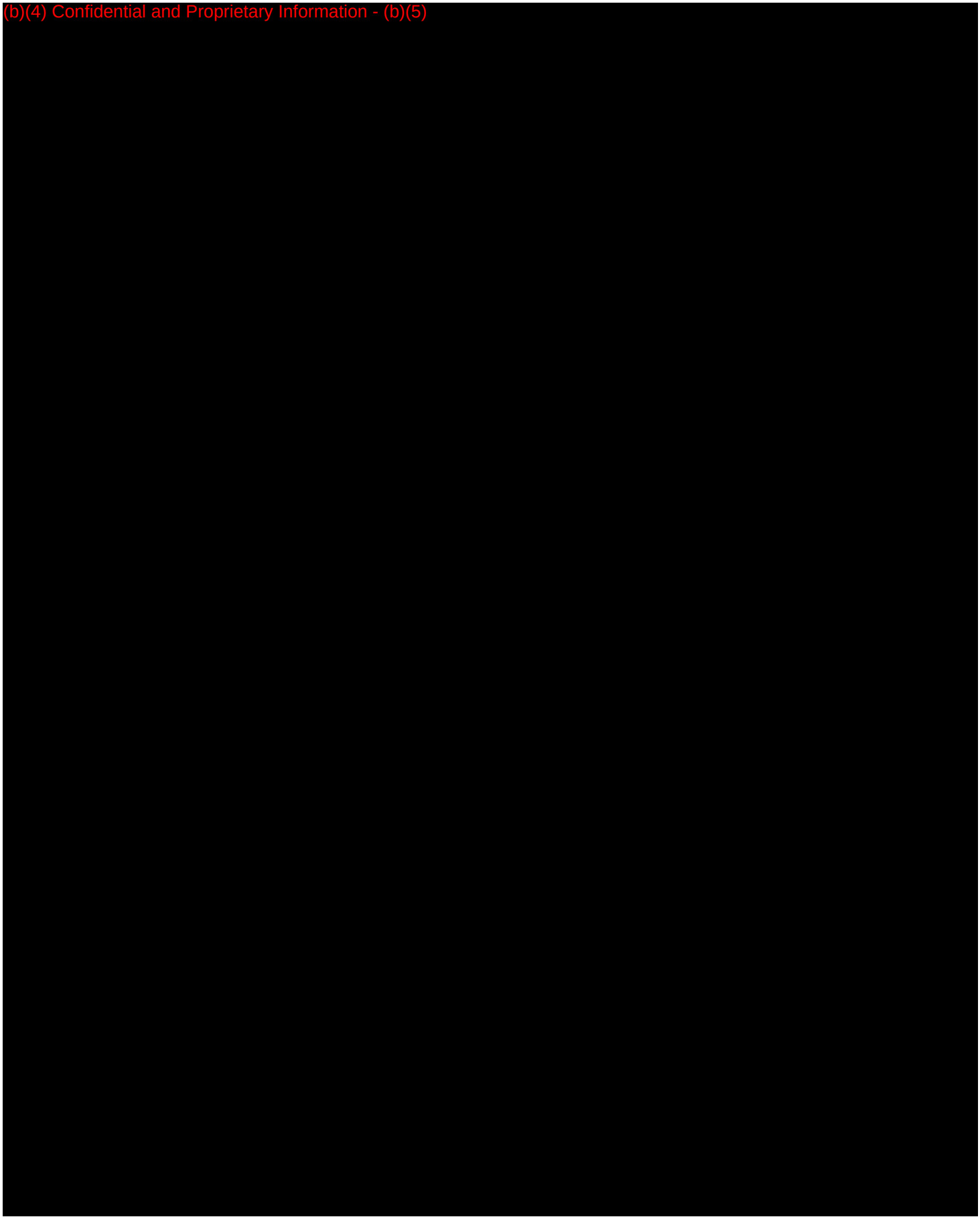

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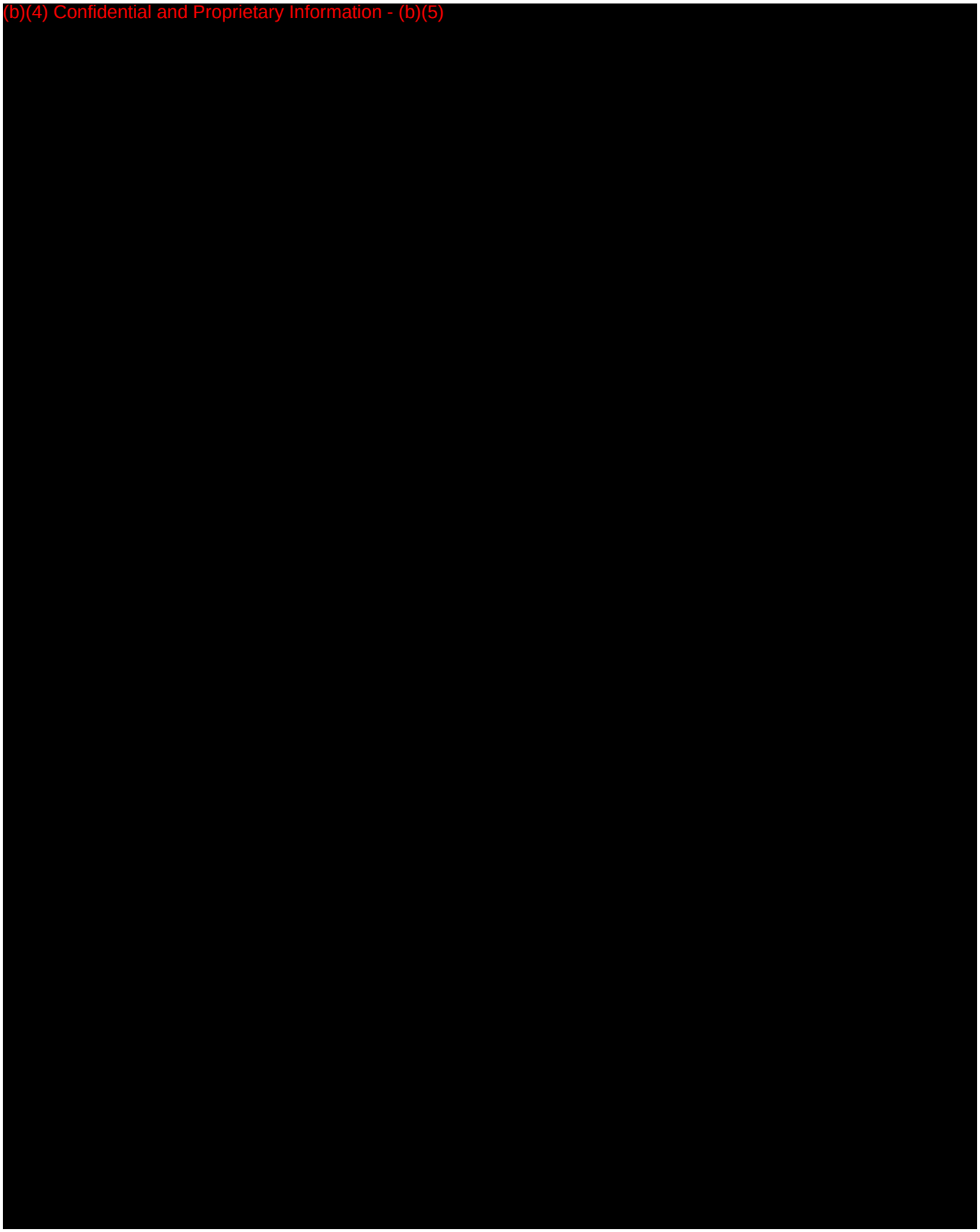
(b)(4) Confidential and Proprietary Information - (b)(5)



Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off	

Contains Nonbinding Recommendations

Print Form

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.

510(k) #: K141668 Date Received by DCC: Jun 23, 2014

Lead Reviewer: Dwight Yen

Branch: GSDB2 Division: DSD Center/Office: CDRH/ODE

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 RTA and the element will be assessed during the substantive review.

Preliminary Questions

Answers in the shaded blocks indicate consultations with Center advisor is needed	Yes	No
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, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments?		
2. Is the application 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 application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
Comments?		
3) If a Request for Designation 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 Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. Provide summary of Jurisdictional Officer's/Liaison's determination. If the answer to either question is no, mark "No." If there was no RFD, skip this question.		
Comments?		
4) 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), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments?		

5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments?		
6) 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 Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm		X
Comments?		

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
If the answer to 6 is "Yes," then contact CDRH/OC/DBM-BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements

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

	Yes	No
1) Submission contains a Table of Contents	X	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	
3) All pages of the submission are numbered.	X	
4) Type of 510(k) is identified (i.e., traditional, abbreviated, or special)	X	
Comments?		

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
A. Administrative				
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X			
2) Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):	X			
a) Device trade name or proprietary name	X			
b) Device common name	X			
c) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			
3) Submission contains Indications for Use Statement with Rx and/or OTC designation (see also 21 CFR 801.109).	X			
4) Submission contains 510(k) Summary or 510(k) Statement	X			
a) Summary contains all elements per 21 CFR 807.92 *(See also* 510(k) Summary Checklist*)*	X			
b) Statement contains all elements per 21 CFR 807.93			X	
5) Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended* format.	X			
6) Submission contains Class III Summary and Certification. *See recommended* content.			X	
7) Submission contains clinical data			X	
8) If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains Standards Data Report for 510(k)s (Form 3654) or includes detailed information about how and the extent to which the standard has been followed.			X	
9) The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device.	X			
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." Once finalized, this guidance will represent the Agency's current thinking on this topic.	X			
B. Device Description				
10)				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

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a) If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
11) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:				
a) A description of the principle of operation and mechanism of action for achieving the intended effect.	X			
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.	X			
c) A list and description of each device for which clearance is requested.			X	
12) Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions.	X			
13) If device is intended to be marketed with multiple components, accessories, and/or as part of a system			X	
C. Substantial Equivalence Discussion				
14) Submitter has identified a predicate device.	X			
a) Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online.*	X			
b) The identified predicate(s) is consistent throughout the submission (i.e., 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.	X			
15) Submission includes a comparison of the following for the predicate(s) and subject device				
a) Indications for Use	X			
b) Technology, including features, materials, and principles of operation	X			
16) Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f))	X			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

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- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
D. Proposed Labeling (see also 21 CFR part 801)				
If *in vitro* diagnostic (IVD) device, criteria 17 & 19 may be omitted.				
17) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use.	X			
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).	X			
b) Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) AND - includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X			
18) If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements]	X			
19) General labeling provisions				
a) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	X			
b) Labeling includes device common or usual name. (21 CFR 801.61)			X	
20)				
a) If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
21) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	
E. Sterilization				
If IVD device and sterilization is not applicable, select "N/A" and criteria below will be omitted from checklist.				X
Submission states that the device and/or accessories are: (one of the below must be checked)				

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
provided sterile				
provided non-sterile but sterilized by the end user				
non-sterile when used				
Information regarding the sterility status of the device is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
22) Assessment of the need for sterilization information				
a) Identification of device, and/or accessories, and/or components that are provided sterile.	X			
b) Identification of device, and/or accessories, and/or components that are end user sterilized.			X	
c) Identification of device, and/or accessories, and/or components that are reusable and cleaning /disinfection instructions are provided.			X	
23) If the device, and/or accessory, and/or a component is provided sterile:			X	
24) If the device, and/or accessory, and/or a component is end user sterilized:			X	
25)				
a) If there are requirements regarding sterility, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement.			X	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			X	
c) If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
F. Shelf Life				
26) Proposed shelf life/expiration date stated			X	
27) For sterile device, submission includes summary of methods used to establish that device will remain sterile through the proposed shelf life or a rationale for why testing to establish shelf life is not applicable.			X	

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
28) Submission includes summary of methods used to establish that device performance is not adversely affected by aging or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.		X		X

G. Biocompatibility

If IVD device, select "N/A" and the below criteria will be omitted from checklist.				X
Submission states that there: (one of the below must be checked)				
X	are direct or indirect (e.g., through fluid infusion) patient-contacting components.			
	are no direct or indirect (e.g., through fluid infusion) patient-contacting components.			
	Information regarding the patient contact status of the device is not provided.			
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				

29) Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present				
30) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration, etc.)				
31) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).				

H. Software

Submission states that the device: (one of the below must be checked)				
	does contain software/firmware.			
X	does not contain software/firmware.			
	Information regarding whether the device contains software is not provided.			
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				

I. EMC and Electrical Safety

				X

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
Submission states that the device: (one of the below must be checked)				
× does require EMC and Electrical Safety evaluation.				
does not require EMC and Electrical Safety evaluation.				
Information regarding whether the device requires EMC and Electrical Safety evaluation is not provided.				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.				
34) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the 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).				
35) 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).				
J. Performance Data - General If IVD device, select "N/A" and the below criteria will be omitted from checklist. Performance data criteria relating to IVD devices will be addressed in Section K.				
36) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence.			×	
37)				
a) If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement.			×	
b) If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach.			×	

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

Submission should be designated RTA if not addressed.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

- Any "No" answer will result in a "Refuse to Accept" decision. - Each element on the checklist should be addressed within the submission. An applicant may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criteria is considered Present (Yes). An assessment of the rationale will be considered during the review of the submission.	Yes	No	N/A	Comment
c) If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness.			X	
38) If literature is referenced in the submission, submission includes:				
a) Legible reprints or a summary of each article.	X			
b) Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	X			
39) For each completed nonclinical (i.e., animal) study conducted			X	

K. 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.
X	is not an in vitro diagnostic device.

Decision: (•) Accept ( ) Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off	Dwight Yen -S 2014.07.03 08:32:30 -04'00'
Branch Chief Sign-Off (digital signature optional)*	Digitally signed by Joshua C. Nipper -S Date: 2014.07.03 08:49:13 -04'00'
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.

INTEGRA
LIMIT UNCERTAINTY

November 6, 2014

Dwight Yen
Sr. Reviewer
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: K141668 CUSA Excel+ Expanded Indications – Agreement to withhold promotion for indications set forth in K141668

Dear Mr. Yen,

Please allow this letter to confirm that Integra LifeSciences Corporation agrees not to promote the CUSA Excel+ Ultrasonic Surgical Aspirator for the specific indications for use defined in K141668, until such time as the company includes a contraindication in the labeling for the CUSA Excel+ Surgical Aspirator and the CUSA Excel+ accessory Extended Life Laparoscopic Tip (C4604ELT). You have indicated that the FDA plans to release, in the near future, recommendations and requirements for power morcellator and power morcellator type devices, and the specific language of any contraindication will follow the receipt of this FDA guidance.

If you need any additional information, please do not hesitate to contact me at: Office, 609-936-2311; (b) (6) [redacted] or email, judith.ogrady@integralife.com.

Sincerely,

Judith O'Grady, RN, MSN, RAC
Corporate Vice President, Global Regulatory Affairs

Integra LifeSciences Corporation

Integra • 311 Enterprise Drive, Plainsboro, NJ 08536
609-275-0500 • 800-654-2873 toll free • 609-750-4277 fax • integralife.com

OFFICE OF DEVICE EVALUATION

Date: May 12, 2015

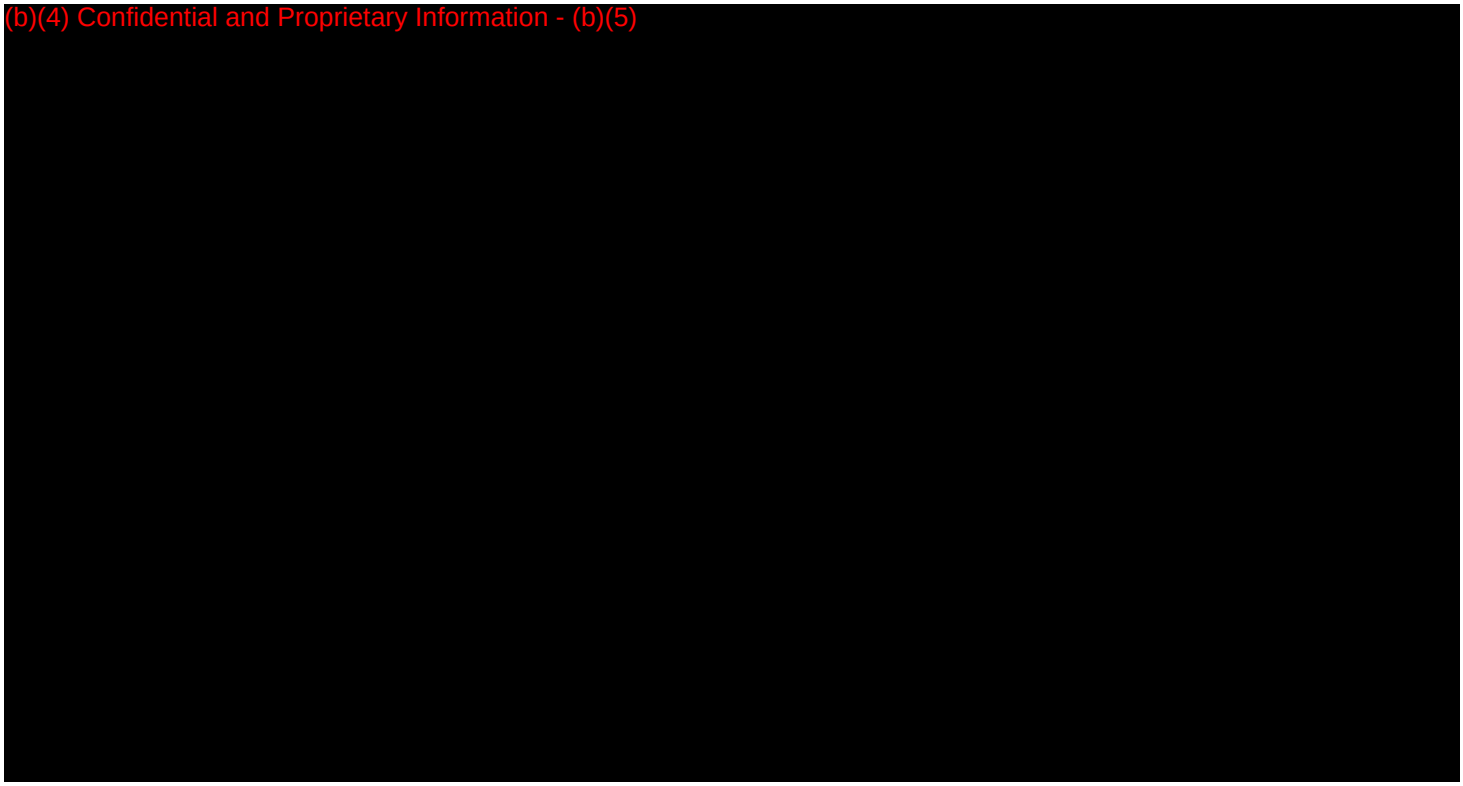
From: Steven Nagel
CDRH/ODE/DSD/GSBD2

To: Joshua Nipper
CDRH/ODE/DSD/GSBD2

Subject: Add to file draft letter for CUSA morcellator in response to IIG (K141668/A1)

As per our discussion I have reviewed the issues regarding the safety of the Cavitron US Surgical Aspirator use in surgical oncology.

(b)(4) Confidential and Proprietary Information - (b)(5)



(b)(4) Confidential and Proprietary Information - (b)(5)

[redacted]

Thank you for the privilege of allowing me to provide this consultation.

V/r,

Steven Nagel
CDRH/ODE/DSD/GSBD2

OFFICE OF DEVICE EVALUATION

Date: May 12, 2015

From: Steven Nagel
CDRH/ODE/DSD/GSBD2

To: Dwight Yen
CDRH/ODE/DSD/GSBD2

Cc: Joshua Nipper
CDRH/ODE/DSD/GSBD2

Subject: Add to file draft letter for CUSA morcellator in response to IIG (K141668/A1)

As per our discussion I have reviewed the issues regarding the safety of the Cavitron US Surgical Aspirator use in surgical oncology.

(b)(4) Confidential and Proprietary Information - (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information - (b)(5)

Thank you for the privilege of allowing me to provide this consultation.

V/r,

Steven Nagel
CDRH/ODE/DSD/GSBD2

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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

Integra LifeSciences Corporation
Ms. Janet C. Kay
Director, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K141668/A001 CUSA Excel+ Ultrasonic Surgical Aspirator System

Dear Ms. Kay,

(b)(4) Confidential and Proprietary Information

[redacted]

Therefore, the Agency recommends that you review our November 25, 2014 guidance and provide the recommended contraindications and warning in your CUSA Excel+ User Manual and in the CUSA Laparoscopic Tip package insert.

We request that your firm submit the revised labeling for the CUSA Excel+ and CUSA Laparoscopic Tip within 14 days of the date of this letter, or April XX, 2015. Failure to do so by this date may render these devices adulterated and/or misbranded under the Federal Food, Drug and Cosmetic Act.

Sincerely yours,

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

MEMORANDUM

Date: May 19, 2015

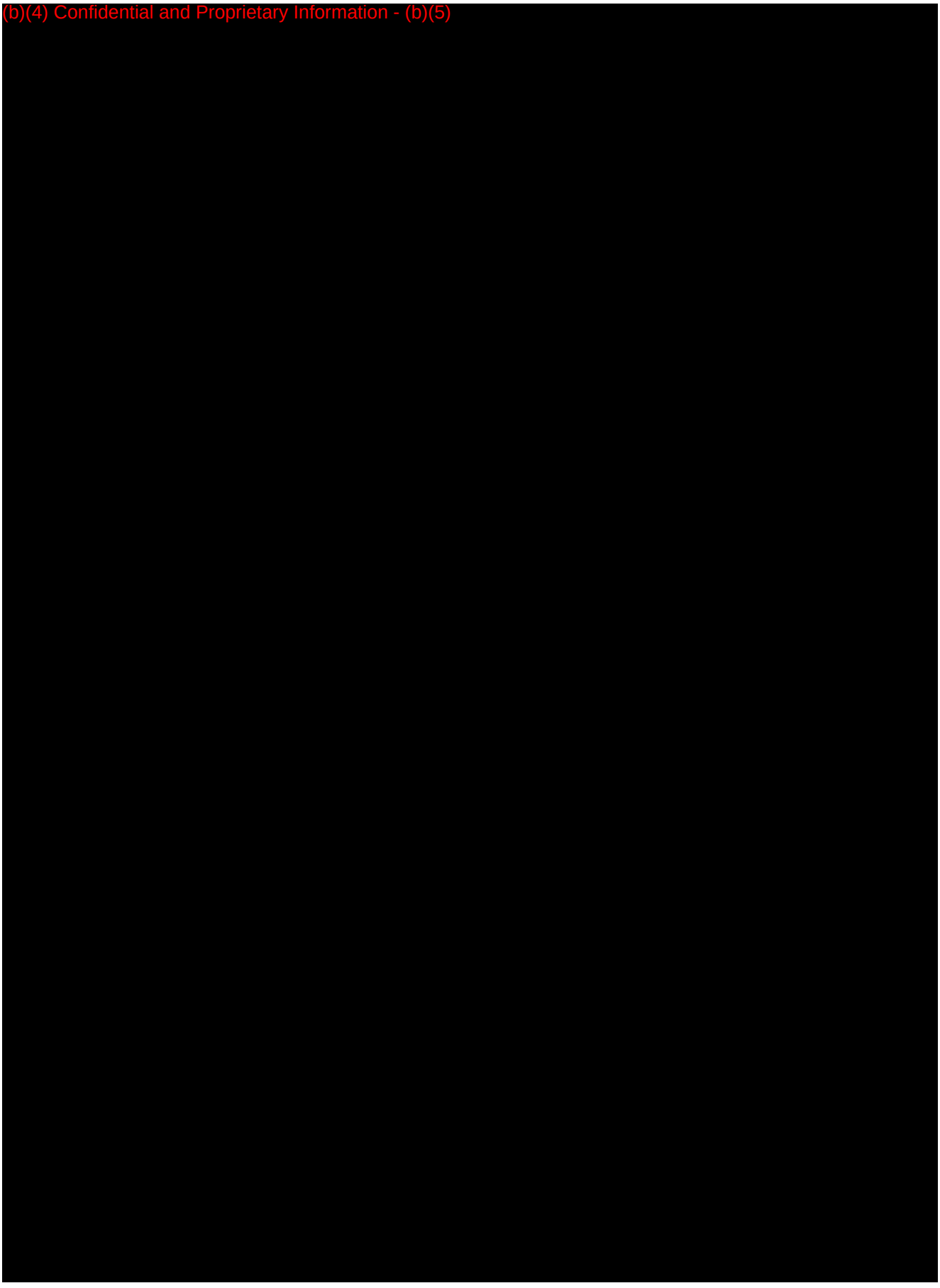
To: File
Fr: Dwight Yen
cc: Josh Nipper, Branch Chief

Re: CUSA Excel+ Ultrasonic Surgical Aspirator System (K141668/a1 and a2)

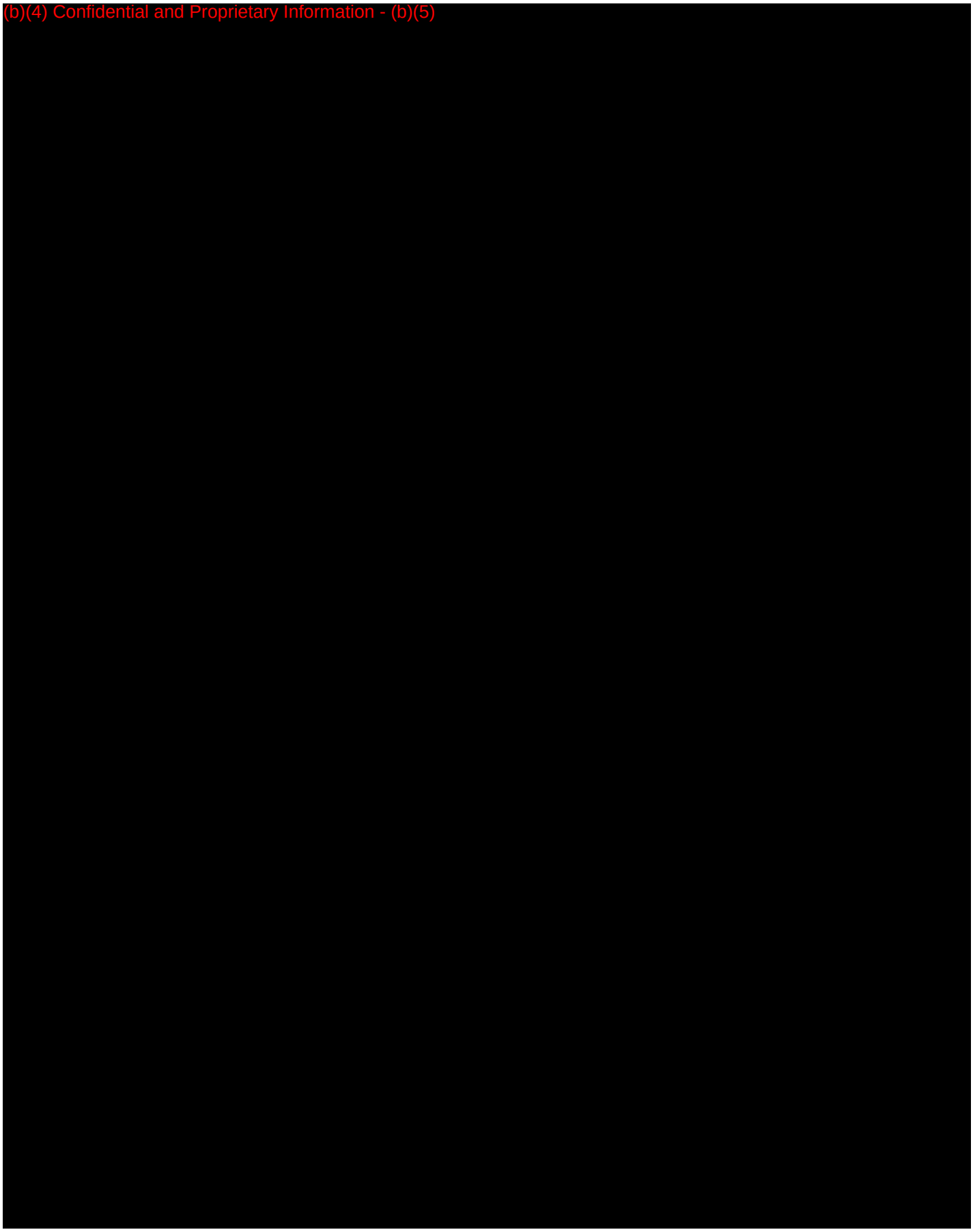
(b)(4) Confidential and Proprietary Information - (b)(5)

[redacted]

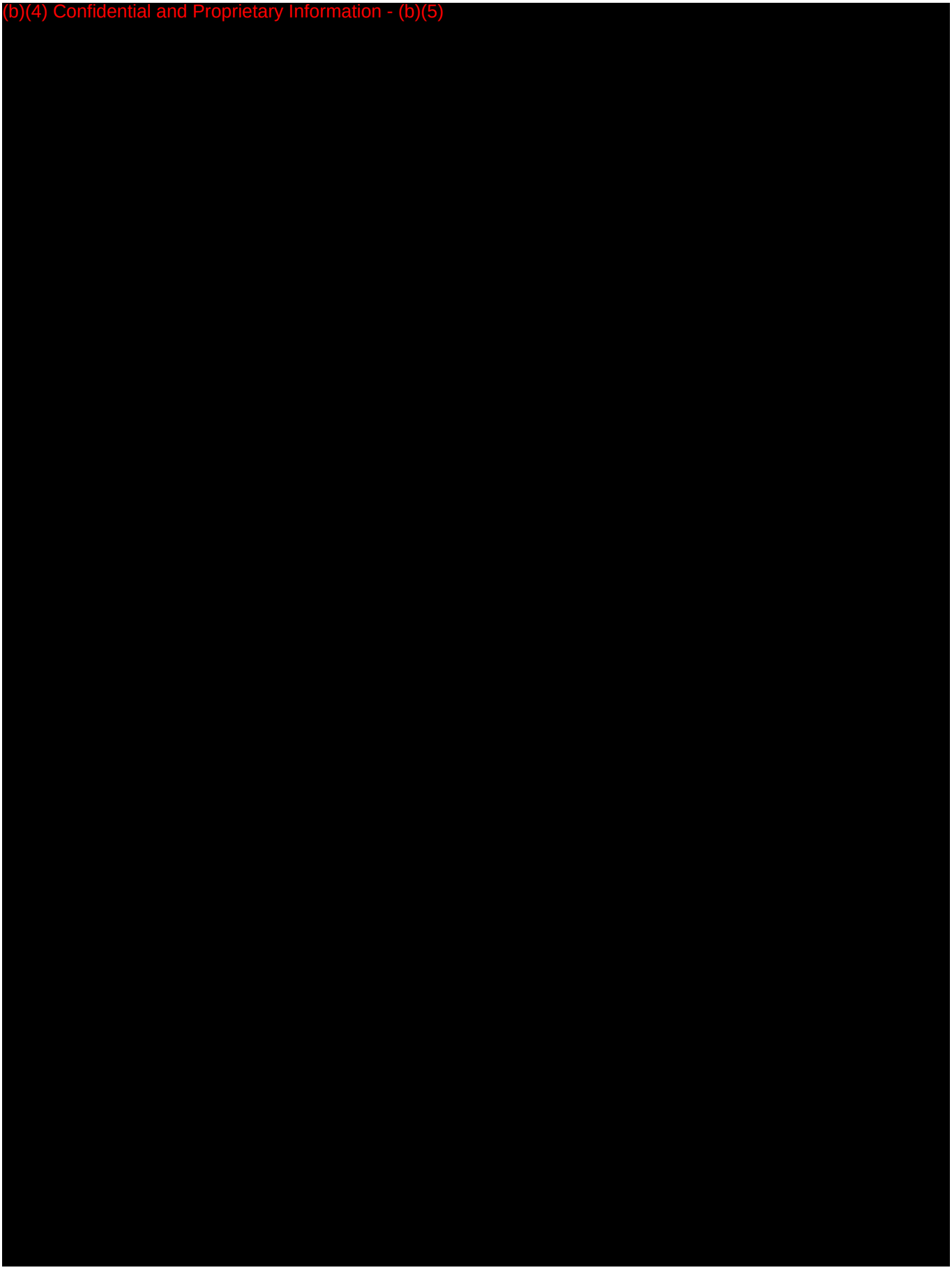
(b)(4) Confidential and Proprietary Information - (b)(5)

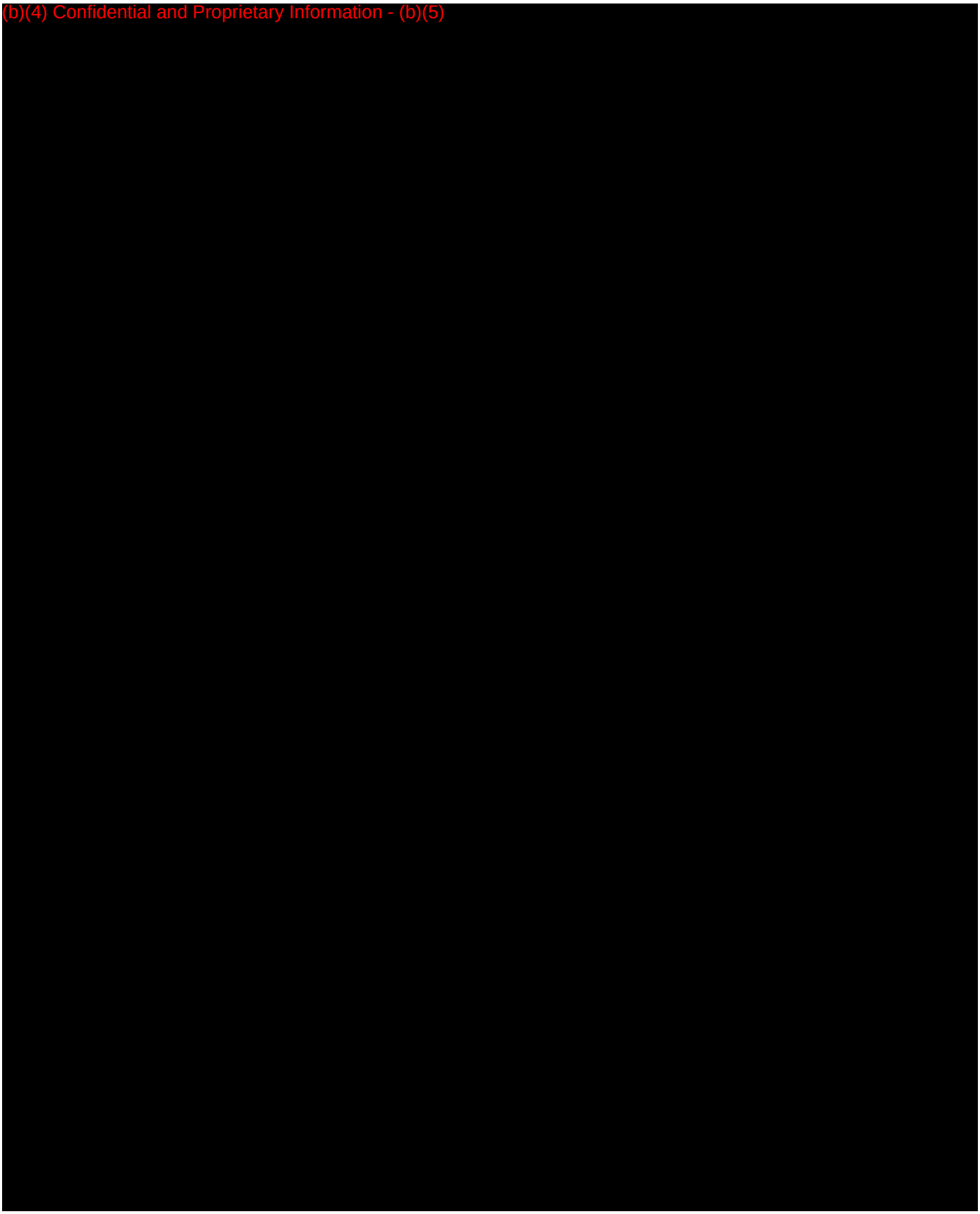


(b)(4) Confidential and Proprietary Information - (b)(5)



(b)(4) Confidential and Proprietary Information - (b)(5)





MEMORANDUM

Date: June 11, 2015

To: File
Fr: Dwight Yen
cc: Josh Nipper, Branch Chief

Re: CUSA Excel+ Ultrasonic Surgical Aspirator System (K141668/a1 and a2)

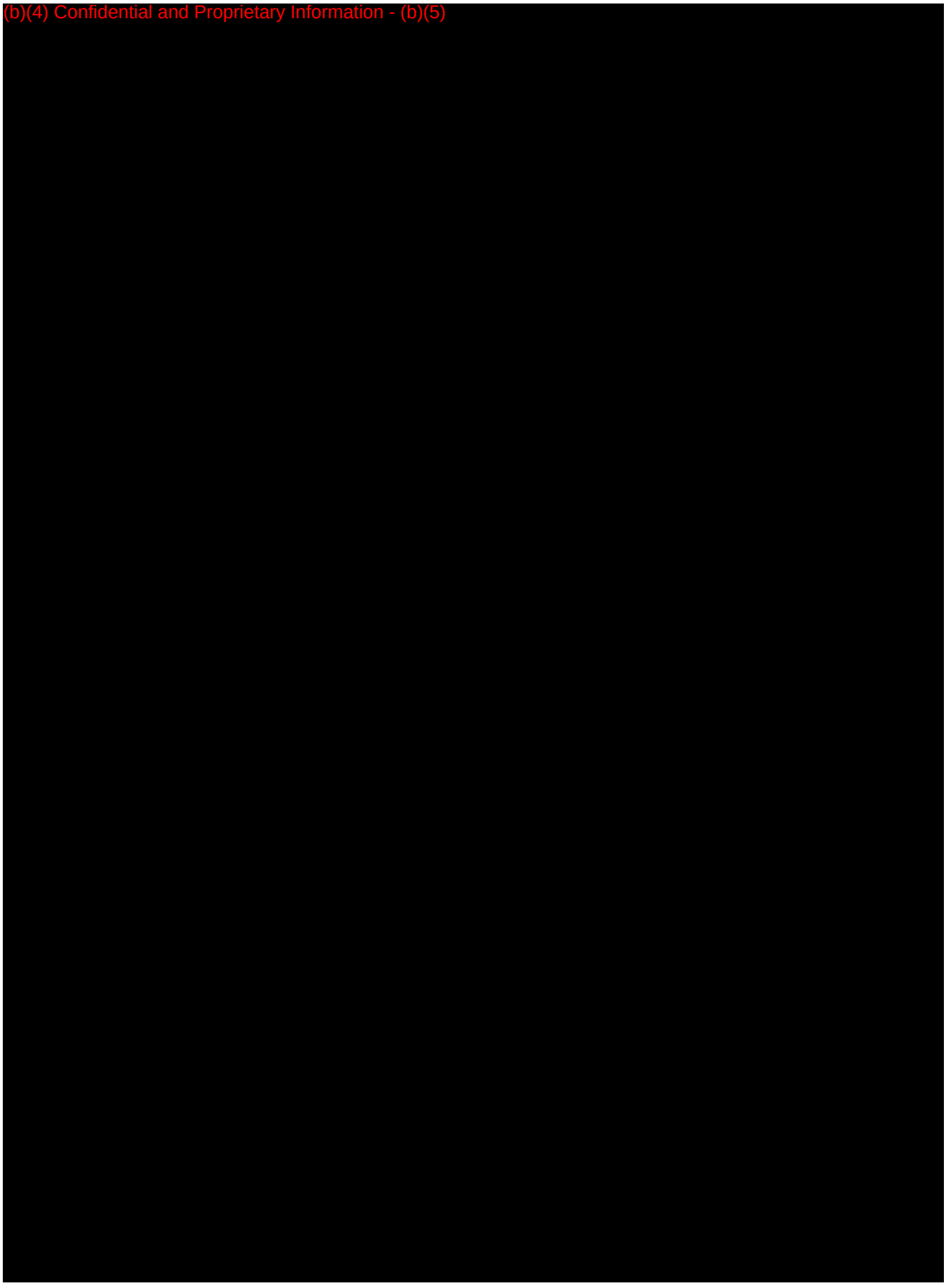
Purpose:

The purpose of this submission is to add a contraindication statement to the CUSA Excel+ User Manul and the CUSA Laparoscopic tip package insert. The addition of a contraindication statement to our product labeling is a result of recommendations made by FDA in their recently released FDA guidance document about power morcellator device[1] and part of an agreement between Integra LifeSciences Corp and the Agency[2].

(b)(4) Confidential and Proprietary Information - (b)(5)

[redacted]

(b)(4) Confidential and Proprietary Information - (b)(5)



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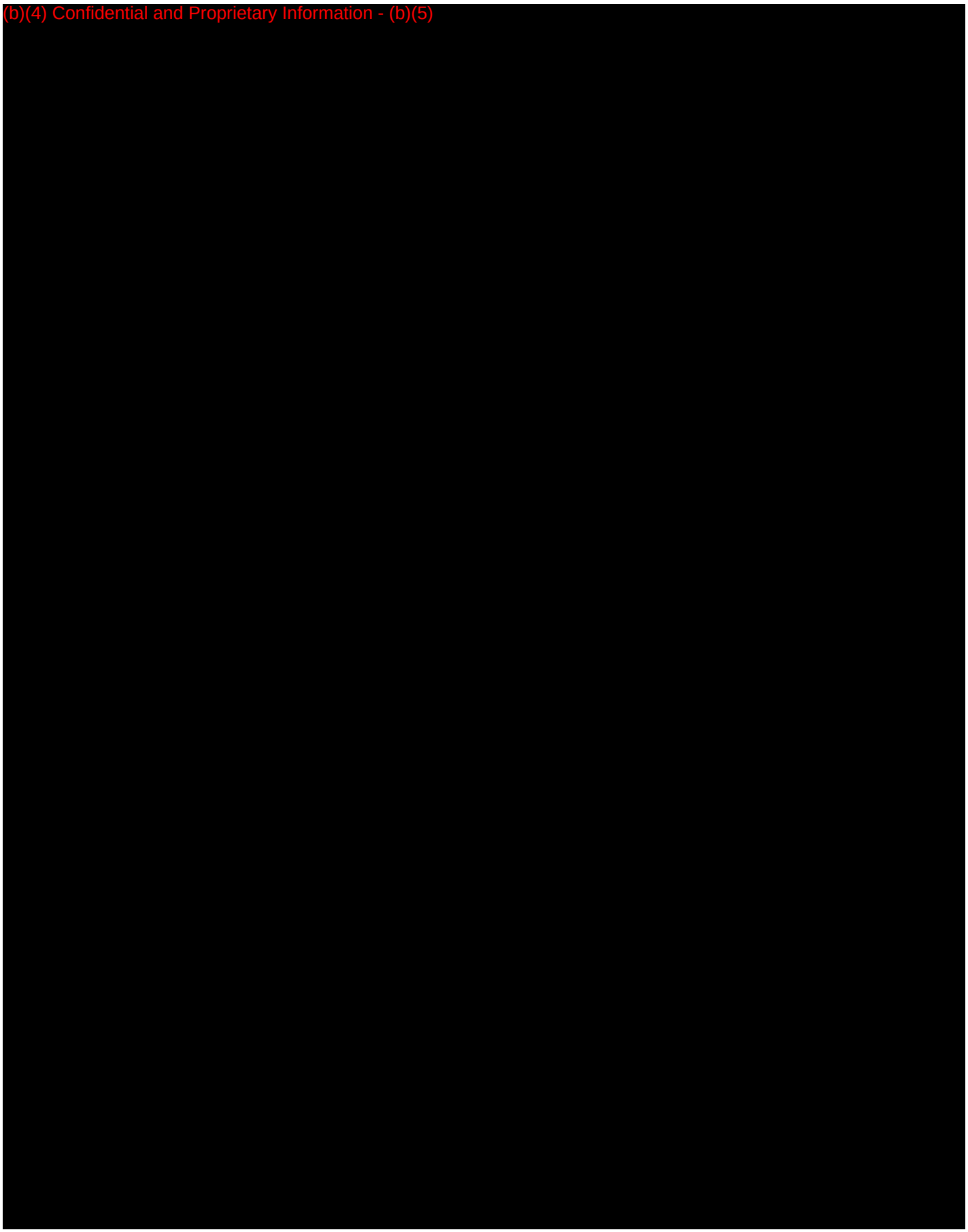
(b)(4) Confidential and Proprietary Information - (b)(5)



(b)(4) Confidential and Proprietary Information - (b)(5)

MEMORANDUM

Date: June 11, 2015/Revised July 3, 2015

To: File
Fr: Dwight Yen
cc: Josh Nipper, Branch Chief

Re: CUSA Excel+ Ultrasonic Surgical Aspirator System (K141668/a1 and a2)

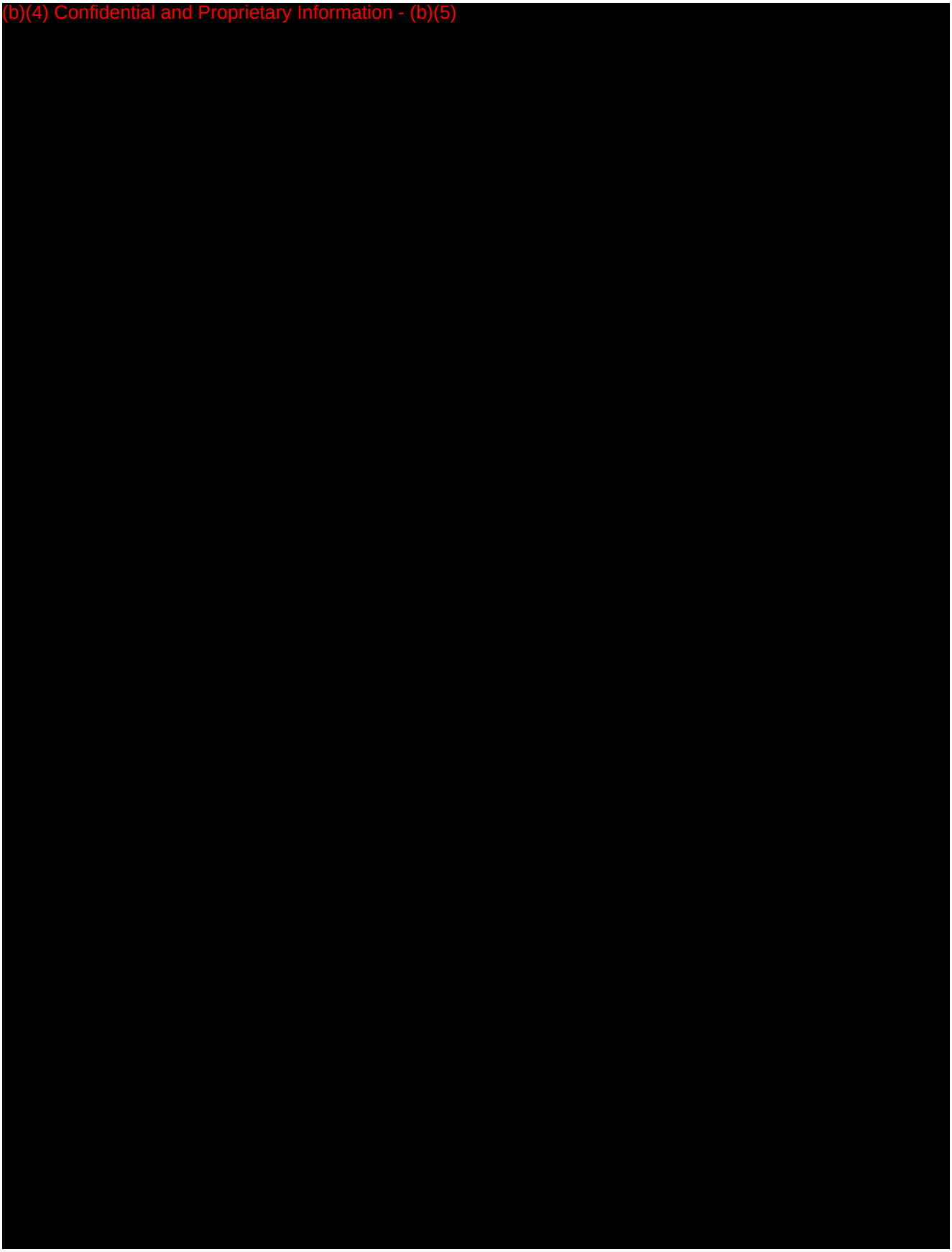
Purpose:

The purpose of this submission is to add a contraindication statement to the CUSA Excel+ User Manul and the CUSA Laparoscopic tip package insert. The addition of a contraindication statement to our product labeling is a result of recommendations made by FDA in their recently released FDA guidance document about power morcellator device[1] and part of an agreement between Integra LifeSciences Corp and the Agency[2].

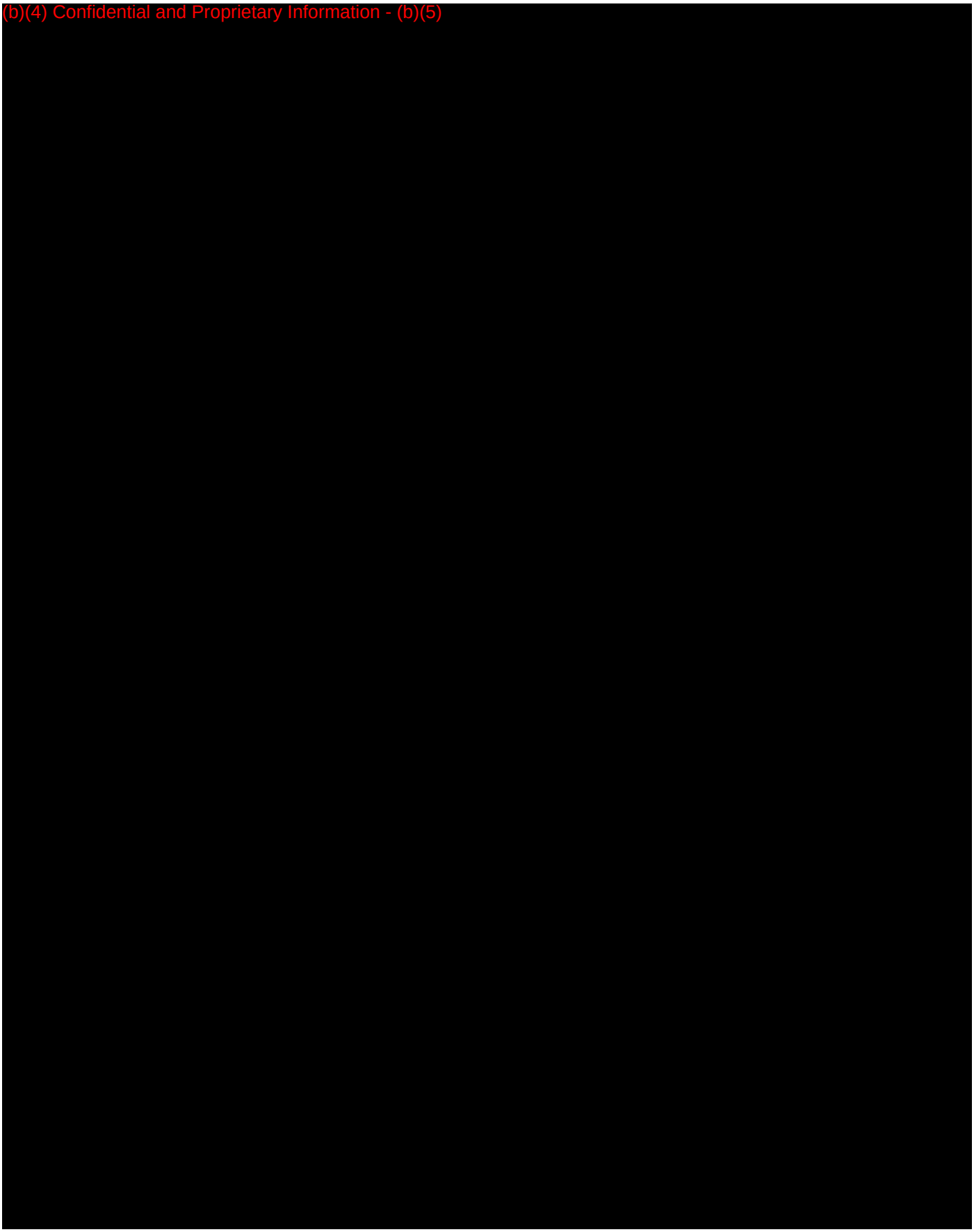
(b)(4) Confidential and Proprietary Information - (b)(5)

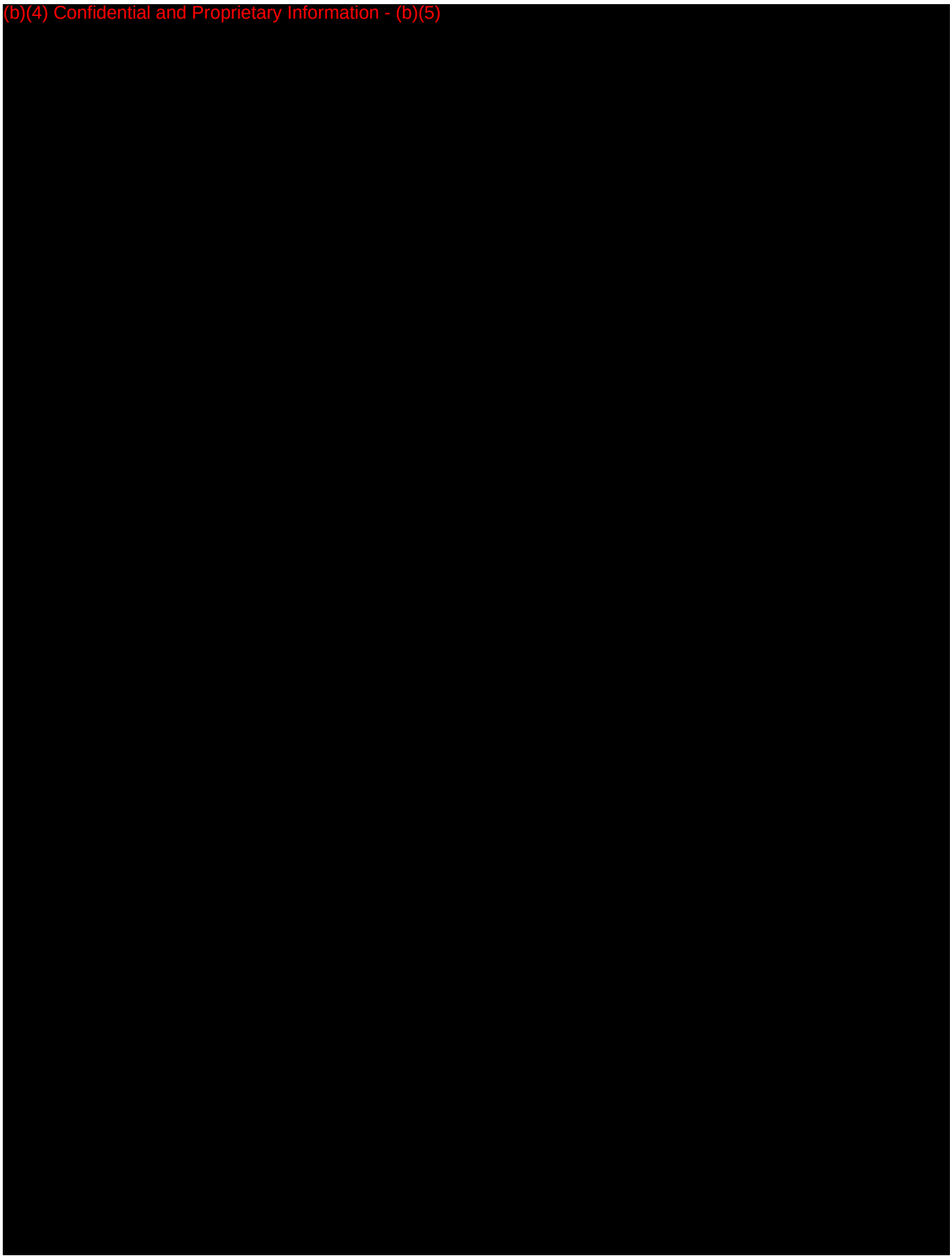
[redacted]

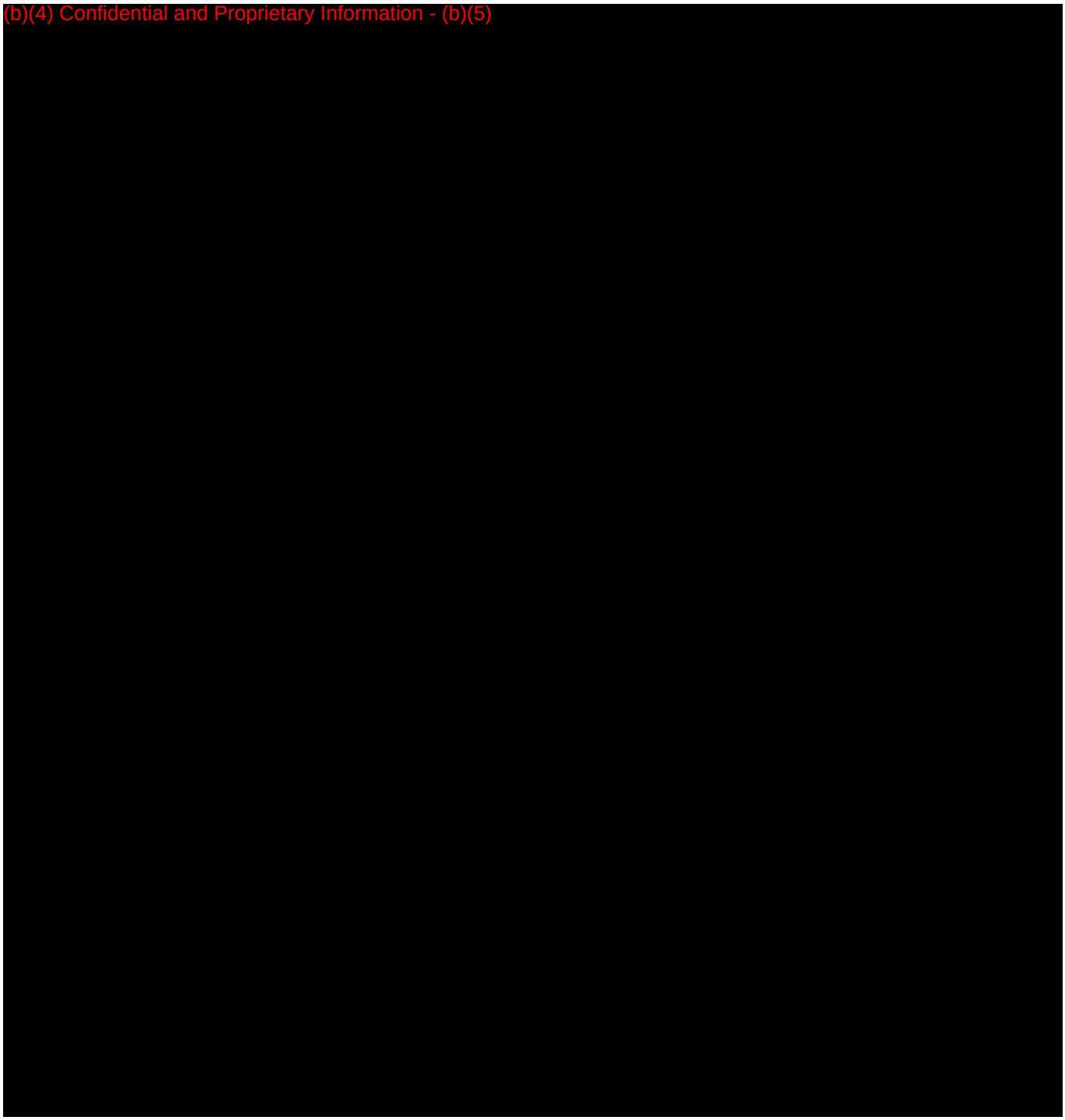
(b)(4) Confidential and Proprietary Information - (b)(5)



(b)(4) Confidential and Proprietary Information - (b)(5)







K141668/A001

January 20, 2015 **-Via Federal Express-**

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Add-To-File K141668
CUSA® Excel+ Ultrasonic Surgical Aspirator System

Dear Sir or Madam:

Integra LifeSciences Corporation hereby submits in duplicate this Add-To-File for its CUSA® Excel+ Ultrasonic Surgical Aspirator System (CUSA Excel+) K141668. The purpose of this submission is to add a contraindication statement to the CUSA Excel+ User Manual and the CUSA Laparoscopic tip package insert. The addition of a contraindication statement to our product labeling is a result of recommendations made by FDA in their recently released FDA guidance document about power morcellator[1] devices and part of an agreement between our company and the Agency[2].

Per the instructions accessed at http://www.fda.gov/cdrh/elecsub.html, an electronic copy is being provided with this submission. The eCopy is an exact duplicate of the paper submission.

1 FDA Guidance Document: Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators, released November 25th 2014

2 Agreement Letter dated November 6, 2014

Thank you in advance for your consideration of our application. If there are any questions, concerns or requests for additional information, please do not hesitate to contact me at 609-529-1247 or via e-mail at janet.kay@integralife.com.

Sincerely,

Janet C. Kay, RAC

Directory Regulatory Affairs

CONFIDENTIAL

January 20, 2015

-Via Federal Express-

K141668/A001

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Add-To-File K141668
CUSA® Excel+ Ultrasonic Surgical Aspirator System

Dear Sir or Madam:

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Thank you in advance for your consideration of our application. If there are any questions, concerns or requests for additional information, please do not hesitate to contact me at 609-529-1247 or via e-mail at janet.kay@integralife.com.

Sincerely,

Janet C. Kay, RAC

Directory Regulatory Affairs

510(k) Add-To-File

CUSA® Excel+ Ultrasonic Surgical Aspirator System
K141668

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536, USA

TABLE OF CONTENTS

LIST OF APPENDICES

SECTION 1 - CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
01/15/2015		K141668

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Integra LifeSciences Corporation	3003418325		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Specialty Surgical Solutions	609-750-2864		
Street Address	**FAX Number *(including area code)***		
311 Enterprise Dr.			
City	**State / Province**	**ZIP/Postal Code**	**Country**
Plainsboro	NJ	08535	USA
Contact Name			
Janet C. Kay			
Contact Title	**Contact E-mail Address**		
Director Regulatory Affairs	janet.kay@integralife.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☒ Other Reason *(specify)*:

Labeling Change - Addition of Contraindication Statement

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LFL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached
☐ 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K141668	1	CUSA Excel+ Ultrasonic Surgical Aspirator System	1	Integra LifeSciences Corporation
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Ultrasonic surgical aspirator

	Trade or Proprietary or Model Name for This Device		Model Number
1	CUSA Excel+ Ultrasonic Surgical Aspirator Systems	1	CUSAEXCEL2
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	K141668	2	K141674	3		4		5		6	
7		8		9		10		11		12	

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
LFL	unclassified	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

General and Plastic Surgery

Indications *(from labeling)*

The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. The CUSA Excel+ Ultrasonic Surgical Aspirator is indicated for use in:
Neurosurgery, Plastic and Reconstructive surgery, Orthopedic Surgery, Gynecological Surgery and Thoracic Surgery and the following specific uses: Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy.
Urological surgery- including removal of renal parenchyma during nephrectomy or partial nephrectomy. General Surgery – including removal of benign or malignant t

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)* K141668

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Integra LifeSciences (Ireland) Ltd.	3006697299
Division Name *(if applicable)*	**Phone Number *(including area code)***
IDA Business & Technology	609-750-2864
Street Address	**FAX Number *(including area code)***
Park, Siragh	

City	State / Province	ZIP Code	Country
Tullamore, Co Offaly	NJ		Ireland

Contact Name	Contact Title	Contact E-mail Address
Janet C. Kay	Director Regulatory Affairs	janet.kay@integralife.com

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	**Phone Number *(including area code)***
Street Address	**FAX Number *(including area code)***

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	**Phone Number *(including area code)***
Street Address	**FAX Number *(including area code)***

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

SECTION 2 - 510(K) COVER LETTER

January 20, 2015 **-Via Federal Express-**

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Add-To-File K141668
CUSA® Excel+ Ultrasonic Surgical Aspirator System

Dear Sir or Madam:

Integra LifeSciences Corporation hereby submits in duplicate this Add-To-File for its CUSA® Excel+ Ultrasonic Surgical Aspirator System (CUSA Excel+) K141668. The purpose of this submission is to add a contraindication statement to the CUSA Excel+ User Manual and the CUSA Laparoscopic tip package insert. The addition of a contraindication statement to our product labeling is a result of recommendations made by FDA in their recently released FDA guidance document about power morcellator[1]devices and part of an agreement between our company and the Agency[2].

Per the instructions accessed at http://www.fda.gov/cdrh/elecsub.html, an electronic copy is being provided with this submission. The eCopy is an exact duplicate of the paper submission.

1 FDA Guidance Document: Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators, released November 25th 2014

2 Agreement Letter dated November 6, 2014

Thank you in advance for your consideration of our application. If there are any questions, concerns or requests for additional information, please do not hesitate to contact me at 609-529-1247 or via e-mail at janet.kay@integralife.com.

Sincerely,

Directory Regulatory Affairs

SECTION 3 LABELING

The recently released FDA Guidance Document[3] for labeling of laparoscopic power morcellator (LPM) includes the ability of a manufacturer to propose an alternative approach as long as it meets the Agency's requirement. Our company agrees that accurate product labeling is important to make device users aware of potential risks in dissemination of malignant tissue and potential clinical outcome. However, our company is unaware of any incidents where dissemination of malignant tissues occurred as a result of using CUSA Excel or any like device (FDA product code LFL/LBK) or is the subject of the scientific information discussed in the guidance document. Since CUSA or like surgical aspirator devices are not classical power morcellator, our company believes the following contraindication statement in CUSA Excel+ User Manual and in the CUSA Laparoscopic Tip package insert is more appropriate.

> Laparoscopic procedures in women with known or suspected uterine sarcoma using devices that fragment tissue may spread cancerous tissue. Also, there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma. Therefore, devices that fragment tissue are contraindicated for use during laparoscopic hysterectomy or myomectomy for uterine fibroid removal.

Please see Appendix 1 for a copy of the revised User Manual. Please note the contraindication has been added to page iv.

Please see Appendix 2 for a copy of the revised Laparoscopic Tip package insert.

3 FDA Guidance Document: Immediately in Effect Guidance Document: Product Labeling for Laparoscopic Power Morcellators, released November 25th 2014

INTEGRA®

CUSA® Excel/CUSA® Excel+ Ultrasonic Surgical Aspirator System

User's Guide

CUSA® Excel/CUSA® Excel+ Ultrasonic Surgical Aspirator System User's Guide

This User's Guide and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. It is intended as a guide for using the CUSA® Excel and CUSA® Excel+ Ultrasonic Surgical Aspirator System only.

Equipment Covered in this Manual

The CUSA Excel refers to the following product models: CUSA Excel and CUSA Excel-8. Both product models utilize 23 kHz and 36 kHz handpieces.

The CUSA Excel+ refers to the product models: CUSA Excel 2 and CUSA Excel-9. The system incorporates graphic modifications of the logo design and color of the top cover of the system. The CUSA Excel+ System utilizes the same CUSA Excel family of handpieces.

Rx ONLY

Caution

Federal (USA) law restricts this device to sale by or on the order of a physician

Trademark Acknowledgements

Integra, the Integra logo, CUSA, CUSA Excel and Tissue Select are registered trademarks of Integra LifeSciences Corporation or its subsidiaries in the United States and/or other countries.

MacroTip, MicroTip, PrecisionTip, SaberTip, CEM and ShearTip are trademarks of Integra LifeSciences Corporation or its subsidiaries.

Ajax is a registered trademark of Colgate-Palmolive Company.

Comet is a registered trademark of the Spic and Span Company.

Klenzyme is a registered trademark of Steris Corporation.

Enzol is a registered trademark of Johnson & Johnson.

All other trademarks and trade names are the property of their respective owners.

Manufacturer:

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Distributed By:

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Patent Information

U.S. Patents 5,466,020; 6,214,017; 6,499,358; 6,602,227; 6,654,999; 7,204,825; 8,118,823; 8,142, 460; D438,952; additional patent(s) pending.

Preface

This User's Guide describes how to use the Integra® CUSA® Excel/CUSA® Excel+ Ultrasonic Surgical Aspirator System. It presents the Integra CUSA Excel/CUSA Excel+ as a system that includes a console, handpieces, and accessories. It describes:

- The System and its functions.
- The Console, its subsystems, and its components.
- The Handpiece and its components.
- How to setup and use the console.
- How to assemble and use the handpiece with the system.

Notice

A technical description of the CUSA Excel/CUSA Excel+ System is provided in the CUSA Excel/CUSA Excel+ System Ultrasonic Surgical Aspirator System Service Manual. The Service Manual is not supplied with the system as it is intended to be used only by Integra service personnel and/or their agents.

System Features

The CUSA Excel/CUSA Excel+ System includes several important features:

- 23 kHz (straight and angled) and 36 kHz (straight) handpieces
- A large variety of 23 kHz and 36 kHz surgical tips that attach to the handpieces:
  - Sterile, single-use tips
  - Nonsterile, extended-life tips
- Tissue Select® feature, which increases the selectivity of the surgical tip, allowing greater control and precision.

Organization

This User's Guide is organized into these sections:

- **Section 1:** *Patient and Operating Room Safety* presents the Warnings, Cautions and Notices that you need to read and understand to operate the CUSA Excel/CUSA Excel+ System with maximum safety.
- **Section 2:** *Introduction to the CUSA Excel/CUSA Excel+ System* gives an overview of the console and its functions, and an overview of handpieces and related accessories.
- **Section 3:** *Console Components* describes the console, its subsystems and its components.
- **Section 4:** *Control Panel Display and Functions* describes the control panel display, the signs and symbols on the control panel and the control panel behavior during system startup and operation.
- **Section 5:** *Setting Up the CUSA Excel/CUSA Excel+ System* explains how to prepare the console and its subsystems for use in surgery. It includes the handpiece assembly options; how to prepare the console for startup, connect and test the handpiece, connect the irrigation and suction systems; how to prime the system, adjust settings, and switch to the Run mode.

Location of Contraindication Statement. See next page for Indications

- **Section 6:** *Using CUSA Excel/CUSA Excel+ Console Controls* describes the control panel buttons and functions. It also includes guidelines on using the Tissue Select feature.
- **Section 7**: *Handpiece Components* presents the items that compose an assembled handpiece, their physical characteristics, and the function of each item. It also presents items that, although not a part of the handpiece itself, are essential in assembling a handpiece or preparing it for sterilization.
- **Section 8**: *Assembling the Handpiece in a Nonsterile Area* provides step-by-step instructions for assembling the handpiece and preparing it for sterilization.
- **Section 9**: *Sterilizing Handpieces and Accessories* provides the sterilization parameters you need to ensure that the handpiece is ready for use in the sterile field.
- **Section 10**: *Completing Handpiece Setup in the Sterile Field* describes how to complete the handpiece assembly in the sterile field.
- **Section 11**: *Assembling or Changing Tips in the Sterile Field* describes how to attach or change sterile tips in the sterile field.
- **Section 12**: *Shutting Down the CUSA Excel/CUSA Excel System* explains how to turn off the system; disconnect suction tubing, irrigation tubing, and the handpiece; and how to clean the console.
- **Section 13**: *Disassembling Handpieces* describes how to disassemble and clean the handpiece, and how to clean the tip torquing set.
- **Section 14**: *Troubleshooting the CUSA Excel/CUSA Excel+System* offers suggestions for problem solving before or during surgery.
- **Section 15**: *Maintaining the CUSA Excel/CUSA Excel+System* describes the maintenance tasks that help to keep the console and handpieces operating as intended.
- **Appendix A**: *Technical Specifications* provides detailed technical information.
- **Appendix B**: *Sterilization Validation* provides information on the sterilization validation procedure.
- **Appendix C**: *Warranty* provides warranty information.

Intended Uses

When you receive your CUSA Excel/CUSA Excel+ System, we recommend that you read and understand all of this User's Guide before using the system. Also, use the guide for:

- **Reference** - When you need specific information on a task. Once you are familiar with the system, use the "Quick Reference" cards (located behind the Control Panel).
- **Training** - When training new personnel to use the system.

To draw immediate attention to matters of importance, this guide presents Warnings, Cautions, Notices, and Important information.

Warning

Indicates a potentially hazardous situation that, if not avoided, could result in serious injury or death, or product damage.

Contraindication Statement for CUSA Excel Plus User Manual, Page iv.

Contraindication

Laparoscopic procedures in women with known or suspected uterine sarcoma using devices that fragment tissue may spread cancerous tissue. Also, there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma. Therefore devices that fragment tissue are contraindicated for use during laparoscopic hysterectomy or myomectomy for uterine fibroid removal.

Caution

Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury, or product damage.

Notice

Indicates a hazard that may result in product damage.

Table of Contents

List of Figures

SECTION 1

Patient and Operating Room Safety

In this section:

Indications for Use

The CUSA® Excel/CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in these surgical procedures where fragmentation, emulsification and aspiration of soft and hard tissue is desirable:

- Neurosurgery
- Gastrointestinal and affiliated organ surgery
- Urological surgery
- Plastic and reconstructive surgery
- General surgery
- Orthopedic surgery
- Gynecological surgery
- Thoracic surgery

obsolete indication Statement

* see next page for new indication statement

Indications for Use, CUSA Excel Plus User Manual Page 1-1

K141668: **(Specific indications cleared as part of K141668)**

The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. The CUSA Excel+ Ultrasonic Surgical Aspirator is indicated for use in:

Neurosurgery, Plastic and Reconstructive Surgery, Orthopedic Surgery, Gynecological Surgery and Thoracic Surgery and the following specific uses:

Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic hepatic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy.

Urological surgery- including removal of renal parenchyma during partial nephrectomy

General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures

Laparoscopic Surgery - including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy

- Laparoscopic surgery
- Thoracoscopic surgery

Warning

The CUSA Excel/CUSA Excel+ System cannot be used in an MRI (Magnetic Resonance Imaging) environment.

Warning

No modification of this equipment is allowed.

Notice

When you receive the CUSA Excel/CUSA Excel+ System and accessories, if any component is damaged, contact your Integra service representative for assistance. If the packaging for a sterile accessory is damaged, do not use the sterile accessory.

Intended Users

The intended users of this guide and the equipment it describes are qualified medical professionals who are trained in the particular surgical technique and surgical procedure to be performed, and trained in the use of this equipment. The CUSA Excel/CUSA Excel+ System should only be used in a surgical environment by qualified medical professionals.

Warning

It is the responsibility of the Healthcare Facility to ensure that intended users of CUSA Excel/CUSA Excel+ System are appropriately trained in the use of this equipment.

Safety Information

The safe and effective use of ultrasonic surgery depends to a large degree on factors solely under the control of the operator. Only medical professionals that are properly trained in the use of ultrasonic equipment should operate the CUSA Excel/CUSA Excel+ System. It is important that medical professionals read, understand, and follow the operating instructions supplied with this equipment.

Before starting any surgical procedure, medical professionals should be familiar with the medical literature, complications, and hazards of using ultrasonic surgery in that procedure.

Warnings, Cautions, and Notices

To promote the safe use of the CUSA Excel/CUSA Excel+ System, this section presents the warnings, cautions, and notices that appear throughout this User's Guide. To operate this equipment with maximum safety, it is important to read, understand, and follow the instructions in these warnings, cautions, and notices.

Patient and Operating Room Safety

Warning

The CUSA Excel/CUSA Excel+ System cannot be used in an MRI (Magnetic Resonance Imaging) environment.

No modification of this equipment is allowed.

It is the responsibility of the Healthcare Facility to ensure that intended users of CUSA Excel/CUSA Excel+ System are appropriately trained in the use of this equipment.

Notice

When you receive the CUSA Excel/CUSA Excel+ System and/or accessories, if any component is damaged, contact your Integra service representative for assistance.

Introduction to the System

Warning

Single Use devices are for single patient use only. Do not reprocess or re-use.

Devices (s) is (are) intended to be used for one procedure only. If reprocessed or re-used this may result in the infection of patient (or patient specimen) through cross-contamination, as well as would incur the risk of modifying the properties and performance of the device, and of increasing the likelihood of complications and/or undesirable effects. Once used, devices must be disposed of in accordance with hospital policies.

Only use Integra handpieces and accessories with the CUSA Excel/CUSA Excel+ System. Non-Integra handpieces and accessories are not supported.

Caution

Read the instructions, warnings, cautions, and notices provided with the CUSA Excel/CUSA Excel+ System before use. Otherwise injury to the patient or user or equipment damage may result.

Console Components

Warning

Ignoring alarms on the CUSA Excel/CUSA Excel+ System while continuing to use the system may result in injury to the patient and/or surgical personnel, or equipment damage.

To avoid injury to surgical personnel, keep fingers away from the suction pinch valve.

TO AVOID RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH.

The power cord on this product contains lead, a chemical known to the State of California, USA, to cause cancer, and birth defects or other reproductive harm. **Wash hands after handling.** The power cord complies with the DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast).

When you connect the handpiece to the console, the handpiece becomes a functional surgical device.

Setting Up the System

Warning

When the handpiece is connected to a CUSA Excel/CUSA Excel+ System that is powered on, but the handpiece is not in use, keep the handpiece away from the patient. Place the handpiece on a sterile, flat, dry, nonconductive, and highly visible surface.

Inadvertent contact between handpiece accessories and the patient may result in burns.

Do not use a damaged handpiece with the CUSA Excel/CUSA Excel+ System.This may result in injury to the patient or surgical personnel.

Ignoring alarms on the CUSA Excel/CUSA Excel+ System while continuing to use the system may result in injury to the patient and/or surgical personnel, or equipment damage.

To avoid injury to surgical personnel:

When closing the irrigation pump latch, keep fingers away from the area between the V-shaped tubing retainers.

If the pump latch is open, keep fingers away from the pump rollers.

To avoid injury to surgical personnel, keep fingers away from the suction pinch valve.

When you connect the handpiece to the console, the handpiece becomes a functional surgical device.

The handpiece and handpiece accessories must be sterile before surgical use.

Warning

Touching of the tip of the handpiece by the operator, while the handpiece is powered on, can result in personal injury.

When the handpiece is powered on, contact of the tip with a hard surface (e.g. a metal instrument, tray, staples, clips, instruments, etc) may damage the tip of the handpiece and require replacement before use.

CUSA Excel tips utilize silicone flues. Compressing the flue against the side of the vibrating surface along the length of the tip can cause excessive heating and potential hazard to adjacent tissue, such as burns.

Excessive loading of CUSA Excel tips at the surgical site can induce heating due to vibration and acoustic power transmissions. Thermal management of the surgical site with the aid of the appropriate irrigation and aspiration settings is essential.

Avoid excessive lateral loading of CUSA Excel tips.

Avoid contacting bone with the CUSA Excel tips (excluding SaberTip™).

Caution

When you test the handpiece, do not allow the handpiece tip to contact anyone or anything during tip activation. Contact may result in patient injury, user injury, or handpiece tip damage.

During surgery, under maximum loading conditions, the CUSA Excel/CUSA Excel+ console is suitable for ultrasonics activation times of 10 minutes on, 5 minutes off.

Sharp edge at the handpiece connection point.

Make sure that the irrigation tubing centers between the V-shaped tubing retainers before you close the pump latch. Otherwise, the pump latch will pinch the tubing, preventing the flow of irrigation fluid.

Before surgery, apply the brakes locks to all wheels on the console to stop the wheels from rolling.

Notice

To prevent fluid flowing into the vacuum line, only use a canister that has a non-return valve.

During surgery, do not allow the handpiece tip to touch metal objects such as staples, clips, instruments, etc. Handpiece tip damage will result.

Using the Console Controls

Warning

Ignoring alarms on the CUSA Excel/CUSA Excel+ System while continuing to use the system may result in injury to the patient and/or surgical personnel, or equipment damage.

Handpiece Components

Warning

Do not use the sterile wrench for more than one surgical procedure.

Assembling the Handpiece in a Nonsterile Area

Warning

Turning the torque wrench further clockwise will damage the handpiece.

Caution

Do not assemble the nonecone to the handpiece until you have sterilized the handpiece.

To avoid product damage, NEVER hold the handpiece in your hand while using the torque wrench to tighten or loosen the tip.

Notice

Do not sterilize the C5600 tip torquing base or the associated the torque wrench because it destroys the lubrication in the torquing mechanism, resulting in product damage.

Completing Handpiece Setup in the Sterile Field

Notice

Retaining a spare handpiece in the sterile field is highly recommended.

Assembling or Changing Tips in the Sterile Field

Warning

The handpiece and handpiece accessories must be sterile before surgical use.

Before use, sterilize the sterilizable torque base in the sterilizer tray with the handpiece.

Turning the torque wrench further clockwise will damage the handpiece.

Caution

To avoid product damage, NEVER hold the handpiece in your hand while using the torque wrench to tighten or loosen the tip.

Shutting Down, Disconnecting and Cleaning the System

Warning

Electric Shock Hazard – Always unplug the CUSA Excel/CUSA Excel+ System before cleaning it.

Sharp edge at the handpiece connection point.

Notice

Do not disconnect the handpiece until the control panel goes completely blank. Otherwise, product damage may result.

Do not rub, press, or touch any panels with solvents; caustic, corrosive, or abrasive cleaning or disinfectant compounds, or other materials that could scratch the panels. Do not use a betadine-based solution because it will cause discoloration.

Do not allow fluids to enter the console.

Disassembling Handpieces

Caution

To avoid product damage, NEVER hold the handpiece in your hand while using the torque wrench to tighten or loosen the tip.

Product damage will result if you do not follow these notices when cleaning the handpiece:

Do not immerse the handpiece cable electrical connector in liquid

Do not use ultrasonic or automated washers

Do not use chlorinated substances such as bleach solution

Do not clean the handpiece with abrasives such as Ajax®, Comet®, or steel wool

Product damage will result if you do not follow these notices when cleaning the Tip Torquing Set:

Do not use ultrasonic or automated washers

Do not autoclave

Do not use chlorinated substances such as bleach solution

Do not clean with abrasives such as Ajax, Comet, or steel wool

Maintaining the System

Notice

Do not clean the sterilizer case with abrasives. Product damage will result.

To avoid product damage, use proper packaging materials and packing procedures when preparing the console for shipment. Failure to return product in this manner may void the warranty and/or damage the product. Contact Integra for details.

Appendix A. Technical Specifications

Warning

Explosion Hazard – Do not use the CUSA Excel/CUSA Excel+ System in the presence of flammable anesthetics or any potentially explosive or flammable atmosphere.

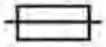
To avoid injury to surgical personnel, keep fingers away from the suction pinch valve while powering the unit on or off, activating vibration, or using fast flush.

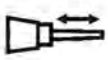
TO AVOID RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH.

The console must be earthed and therefore it MUST only be fitted with a 3-pin plug, or a 2-pin plug that has an integral earth grounding connection. Mains plug type and construction MUST comply with Legal requirements within country of installation. Only Integra Service personnel or Integra authorized representatives or agents can change the mains plug on the console.

Classification and Console Symbols

Symbol	Description
Console Symbols	
	Warning: When you connect the handpiece to the console, the handpiece becomes a functional surgical device.
	Warning: Dangerous Voltage To reduce the risk of electric shock, do not remove the cover. Refer servicing to qualified service personnel. Classified with respect to electrical shock, fire, mechanical, and other specified hazards only in accordance with UL60601-1 and CAN/CSA C22.2 No. 601.1.
	Follow Instructions for Use
	Cooling Reservoir: Do not fill the Cooling Reservoir with tap water or saline solution. Use distilled water only.
	Do not insert fingers. Pinch Point can cause injury. **Warning** To avoid injury to surgical personnel, keep fingers away from the suction pinch valve while powering the unit on or off, activating vibration, or using fast flush.
	Consult Instructions for Use
	Equipotentiality: Connect equipotential ground cable here.
	Protective earth (ground)

Symbol	Description
	Class I Equipment (IEC 601-1) Accessible conductive parts cannot become live in the event of a basic insulation failure because of the way in which they are connected to the protective earth conductor Type BF Applied Part Equipment (IEC 601-1) The CUSA Excel/CUSA Excel+ System console provides a high degree of protection against electric shock, particularly regarding allowable leakage currents. It is type BF isolated (floating) output. The handpiece, cord and tip are applied parts. IPX - 8 (IEC 529, UL60601) Footswitch IPX - 0 (IEC 529, UL60601) Console The CUSA Excel/CUSA Excel+ System **footswitch** includes protection against the effects of continuous immersion in water.
	ON (power) Applies power at the AC Main Switch and the System Power Switch.
	OFF (power)
	System Power Off / Standby When you turn off the System Power Switch, the system automatically drains water from the cooling water system and deactivates other system components. It also maintains power to the logic circuitry to monitor the System Power Switch position.
	Fuse Replacement Indicates the location of the fuse drawer on the rear panel.
	Volume Control
	Footswitch Connector
	Manufacturer

Symbol	Description
REF	Catalogue Number
SN	Serial Number
	Please dispose of in accordance with local regulations for the collection or disposal of waste electrical and electronic equipment.
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Temperature Limitation: Indicates upper and lower temperature limits
	Humidity Limitation: Indicates upper and lower humidity limits
	Recyclable material
Segurança 	UL Certification used in conjunction with the INMETRO Mark of the National Institute of Metrology, Standardization and Industrial Quality in Brazil.
 ИМО2	GOST R Russian mark of conformity
Footswitch Symbols	
	Activate vibration

Symbol	Description
	Activate fast flush (irrigation)
NOT FOR HUMAN USE	Accessories marked with the 'NOT FOR HUMAN USE' label are supplied for **demonstration purposes only**.
	Do not push, lean or rest against the control panel, or against the front or sides of the console. When moving the console, push the console using the handle only.

SECTION 2

Introduction to the System

In this section:

For Your Information

Caution

Read the instructions, warnings, cautions, and notices provided with the CUSA® Excel/CUSA® Excel+ System before use. Otherwise, injury to the patient or user or equipment damage may result.

This section presents general information about the CUSA Excel/CUSA Excel+ Ultrasonic Surgical Aspirator System: what it is, what it does, and how it works. It also describes the handpiece functions, configurations, and the sterilization requirements for the handpiece and accessories.

For complete instructions on handpieces and accessories, see Section 7 to Section 11.

About the CUSA® Excel/CUSA® Excel+ System

The CUSA Excel/CUSA Excel+ System is an ultrasonic surgical aspirator that allows a surgeon to remove tissue – selectively and with greater control. It performs three functions:

- Fragmentation
- Irrigation
- Aspiration (Suction)

All three functions may occur at the same time.

The system includes the following components:

- **Console**:
  - The Console Body houses electronics, pumps, and mechanical parts.
  - The Control Panel allows the user to control the functions of the system.
- **Handpiece**: a handheld surgical device with a tip that is applied to patient tissue.
- **Accessories**: manifold tubing, tips, tip torquing bases, torque wrenches, sterilizer cases and contamination guard.

You can also combine the CUSA Excel System with electrosurgery using the optional CUSA Electrosurgical Module (CEM™). Refer to the Instructions for Use for the CEM for details.

When you receive the CUSA Excel System, the shipment contains accessories that are marked with the label 'NOT FOR HUMAN USE'. Accessories marked with the 'NOT FOR HUMAN USE' label are supplied for **demonstration purposes only**.

Fragmentation

Electromechanical Operation

The console provides alternating current at 23 or 36 thousand cycles per second (kHz) to the handpiece (the frequency depends on which handpiece you connect to the console). In the handpiece, the current passes through a coil, which induces a magnetic field. The magnetic field excites a transducer of nickel alloy laminations, resulting in an oscillating motion in the transducer laminated structure – vibration – along its long axis (refer to the figure at left). The transducer vibrates at 23 or 36 kHz.

The transducer transmits vibrations through a metal connecting body to an attached surgical tip. The frequency of vibration remains the same at the tip (23 or 36 kHz), but the amount of motion (amplitude) at the tip varies: lower frequency, greater amplitude; higher frequency, smaller amplitude.

Amplitude also varies with the transducer/connecting body/tip configuration: handpiece angles reduce tip amplitude.

When the vibrating tip contacts tissue, it breaks cells apart (fragments them).

Cooling

The high frequency vibration generates heat. To reduce the heat, the system includes a closed, recirculating cooling water system. This system pumps water from a cooling water reservoir, through a tube in the handpiece cable, through the handpiece, and through a return tube in the handpiece cable to the cooling water reservoir. Cooling water flows at 35 to 50 ml/min.

As it passes through the handpiece, the water removes heat. Normal handpiece temperature, in sustained heavy use, remains at less than 40° C/104°F.

Use distilled water for the cooling water system. Do not use tap water because it contains impurities (natural minerals, chemical additives, or organic materials) that can cause problems within the cooling water system.

Irrigation

Sterile irrigation fluid flows from an IV set (bottle or bag and IV administration tubing) to a variable speed peristaltic pump. The pump:

- Moves fluid at 1 to 10 ml/min; default flow is 3 ml/min. Use the adjustment buttons (blue up/down arrows on black buttons at the bottom of the irrigation display column on the control panel) to increase or decrease the irrigation flow.
- Accelerates to a Fast Flush speed, pumping at greater than 25 ml/min. The Fast Flush pedal on the system footswitch activates the Fast Flush feature.

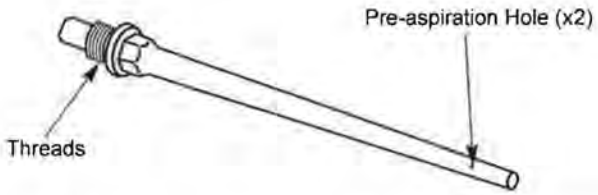
The accuracy of the irrigation flow is +/- 20% of setting or +/-1 ml/min, whichever is greater.

The pump pushes the fluid through the manifold irrigation tubing to a flue, a sleeve surrounding the vibrating tip. As the irrigation fluid passes through the flue, it cools the tip.

When the fluid reaches the distal end of the tip, as much as 99% of it passes through two pre-aspiration holes in the tip, eliminating fluid pooling in the sterile field and continually clearing the suction system. Fluid that does not pass through the pre-aspiration holes irrigates the surgical site and suspends fragmented tissue.

Aspiration (Suction)

A vacuum pump in the console body provides up to 660 mm/26 inches mercury maximum vacuum at sea level . Use the adjustment buttons (green up/down arrows on black buttons at the bottom of the aspiration display column on the control panel) to increase or decrease the suction from 10 to 100% in 10% increments.



The suction, which produces an air stream moving toward the vacuum pump, pulls irrigation fluid, fragmented tissue, and other materials through the distal end of the surgical tip. From the tip, the aspirated materials pass through the manifold suction tubing into the suction canister. From the suction canister, the air stream continues to flow through a contamination guard that filters any remaining particulate matter or moisture, preventing them from entering the vacuum pump.

The accuracy of the vacuum level between contamination guard and vacuum pump inlet is +/- 15% of scale setting or +/- 2.6 inches/66mm of mercury, whichever is greater.

A suction pinch valve on the front of the console opens when the system is on, and closes to stop suction when:

- Priming the irrigation system
- Pressing the Fast Flush pedal
- Releasing the Vibration pedal in Run Status (in this case, the pinch valve closes for approximately one second, then re-opens).
- Releasing the Vibration pedal in Lap Mode (this suction stoppage prevents depletion of the pneumoperitoneum).

When the System Power Switch is off, the suction pump remains off and the suction pinch valve remains closed. Use the button on the front of the suction pinch valve to open the valve manually.

About the Handpieces

Warning

Only use Integra® handpieces and accessories with the CUSA Excel/CUSA Excel+ System. Non-Integra handpieces and accessories are not supported.

A CUSA Excel/CUSA Excel+ handpiece is a handheld surgical device. It houses a transducer that vibrates at an ultrasonic frequency, transferring the vibrations to a hollow titanium tip. The figure (on left) shows the direction of vibration.

When applied to patient tissue, the vibrating tip provides the desired surgical effect – the fragmentation and removal of specific tissue.

The handpiece connects to the console by a handpiece cable and by manifold tubing:

- The cable consists of electric wires that power the transducer, and two water tubes. The circulating water removes heat from the vibrating transducer.
- The disposable manifold tubing consists of a tube for sterile irrigation fluid, which the console pumps to the handpiece, and a tube for suction. Clips on the manifold tubing fasten the tubing to the handpiece cable.

Handpiece Functions

Together, a handpiece and CUSA Excel/CUSA Excel+ console form an ultrasonic surgical aspirator system. This system has three functions:

- Fragmentation: As the vibrating tip contacts tissue, the vibrations break the tissue cells into fragments.
- Irrigation: Sterile irrigation fluid, pumped from the console through the manifold tubing, suspends the fragmented cells so that suction can easily remove them and prevent tip blocking. The irrigation fluid also cools the vibrating tip.
- Aspiration (Suction): Suction through the hollow tip removes the fragmented tissue and irrigation fluid from the surgical site.

All three functions can occur at the same time.

Handpiece Configurations

The CUSA Excel/CUSA Excel+ System includes three handpiece configurations:

- 36 kHz, straight (smaller handpiece, black body, blue connector)
- 23 kHz, straight (gray body, green connector)
- 23 kHz, angled (gray body, green connector).

Notice

The 36kHz handpiece operates within a frequency range and 36kHz is a representative value. Refer to the Technical Specification section for the frequency range.

Handpiece Tips

A variety of handpiece tips are available.Tips vary in inside diameter, length, and shape (straight or curved). For information on the tips available for each handpiece, contact your Integra representative.

About the Tissue Select Feature

Tissue Select allows the surgeon to maintain a high fragmentation rate while increasing selectivity and control at the surgical site.

Fragmentation occurs when the vibrating tip interacts with tissue. As the tip begins to move toward tissue, it accelerates, then impacts and penetrates the tissue. The acceleration, impact, and penetration produce a combination of direct mechanical forces and hydrodynamic pressures that burst cells.

Several variables affect the fragmentation rate. Most are functions of the CUSA Excel/CUSA Excel+ System:

- Stroke (tip excursion—the total distance the tip travels) – greater stroke results in greater fragmentation rate
- Suction
  - Suction has two functions:
    (1) It draws tissue toward the vibrating tip and creates a tip/tissue coupling effect.
    (2) It removes irrigation and fragmentation debris from the surgical site.
  - If there is no suction or low suction, coupling does not occur, resulting in minimal tissue fragmentation and increased tissue temperature.
- Tip acceleration – produces the peak forces and pressures that fragment tissue.
- Tip cross-sectional area at the tip-tissue contact site

These variables also affect tactile feedback—what the surgeon's hand feels when using the handpiece.

Inherent Tissue Selectivity

With all other variables remaining constant, the tip does not fragment all tissue types equally effectively. Another variable – tissue strength – affects fragmentation rate.

- "Low strength" soft tissues that are easiest to fragment include the brain and most organs. Older, partially dried tissues are also easy to fragment "High strength" strong tissues that are most difficult to fragment include vessel structures, tendons, ligaments, healthy skin, and organ capsules.

- Strength increases and fragmentation rate decreases with tissue containing greater collagen, elastin, or both (collagen type, quantity, and organization affect cell structural quality).

Tissue strength also affects tactile feedback. The surgeon can feel a difference between the tip contacting low strength tissue and the tip contacting high strength tissue. As the tip works through low strength tissue, the surgeon feels a smooth, rhythmic sensation from the handpiece. When the tip contacts high strength tissue, it feels like it is "bouncing off" the tissue. Also, the smooth, rhythmic sensation becomes rougher. To avoid fragmenting high strength tissue, the surgeon must apply less pressure to the tip or move the tip away from the tissue. To continue fragmenting high strength tissue, the surgeon must manually apply more pressure.

In Standard Mode, continued manual pressure could result in unintentional damage to critical structures. Using the Tissue Select feature, the CUSA Excel/CUSA Excel+ System can help the surgeon avoid these problems when dissecting near critical structures.

Increasing Tissue Selectivity

It is possible to increase the inherent selectivity resulting from variations in tissue strength while maintaining stroke amplitude, tip acceleration, and suction. This increase in selectivity results from reducing the reserve power that drives the tip. Remember: The ultrasonic generator delivers electrical power (which is directly related to the acoustic power present at the tip, which results in fragmentation) to the handpiece. Consider the power delivered to the handpiece in three terms:

- Initial power – the quantity of power necessary to drive the tip vibration in air; that is, no contact with tissue
- Reserve power – the power necessary to maintain tip vibration under load (in contact with tissue). When the tip encounters load, a feedback loop in the system senses the additional load and provides additional reserve power to maintain tip vibration.
- Maximum power – the greatest power output the console can provide. Maximum power is the sum of initial and reserve power.

A Common Misunderstanding of the Amplitude Setting

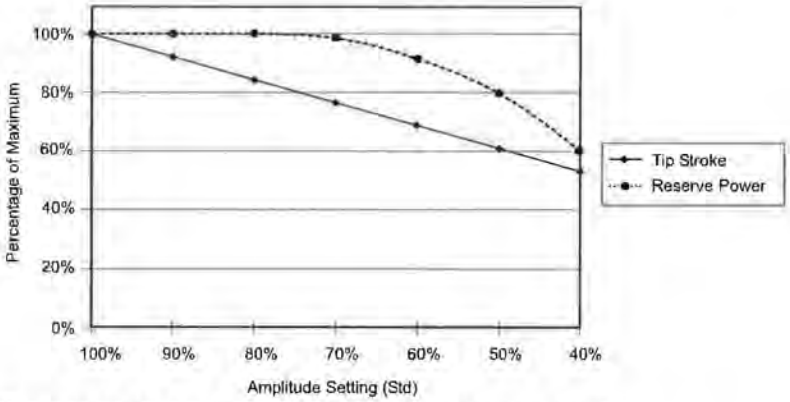
It has been common practice to decrease the amplitude setting when encountering critical structures. The reasoning behind this practice is that the lower amplitude setting results in slower fragmentation rate and greater selectivity, thus greater control to help avoid damage when dissecting near the critical structures. Consider this reasoning more carefully:

True: Decreasing the amplitude setting also decreases the fragmentation rate.

True: Because the fragmentation rate is slower, the surgeon has a little more time to move the tip away from a critical structure before damaging it; therefore, the surgeon *seems* to have greater selectivity and control.

False: The surgeon gains greater selectivity, thus greater control and precision, when dissecting near critical structures.

Why does the decrease in amplitude not give greater selectivity and control? Decreasing the amplitude does not greatly affect the reserve power.



Decreasing the amplitude leaves plenty of reserve power.

When the tip contacts critical structures, it still has more than enough power to fragment them if the surgeon applies pressure or prolongs the tip-tissue contact. Therefore, decreasing the amplitude setting gives the following results:

- Reduced fragmentation ability
- Reduced fragmentation rate
- Little increase in selectivity
- Little reduction in reserve power

Benefits of Tissue Select

The Tissue Select feature presents several benefits:

- Maintains fragmentation ability
- Reduces (automatically) fragmentation rate

- Provides maximum tissue selectivity
- Gives surgeon superior tactile feedback
- Gives surgeon greater control and precision when dissecting near delicate structures

For information on using the Tissue Select feature, see Using the Tissue Select Feature, page 6-4.

Sterilization of Handpieces and Accessories

You must sterilize the CUSA Excel/CUSA Excel+ handpiece with steam before use. Some of the CUSA Excel/CUSA Excel+ System accessories are sterile, single-use items. Other accessories are reusable. You must sterilize all reusable accessories with steam before use.

Table 2-1 describes the sterilization requirements for the handpiece and accessories. For information on the sterilization parameters and sterilization procedure for the handpieces and accessories, see Sterilization Parameters, page 9-2.

Table 2-1 *Handpiece and Accessory Sterilization*

Item	Supplied Sterile	Reusable /Requires Sterilization by the User	Permitted Number of Sterilizations	Sterilization Method
Handpieces (all configurations)	No	Yes	100 sterilization cycles **Note:** Refer to page 15-3: Handpiece Maintenance. Recalibrate the Handpiece after 100 Sterilization Cycles.	Steam
Standard nosecone	No	Yes	Unlimited	Steam

Item	Supplied Sterile	Reusable /Requires Sterilization by the User	Permitted Number of Sterilizations	Sterilization Method
Extended Life Tip (ELT)	No	Yes	Six	Steam
ELT Flue	No	Yes	One	
Standard Tip and Flue	Yes	No - Single patient use only	One* ***Note**: The sterile tips are for single patient use only. Each tip can be resterilized once before use but the tip cannot be reused or reprocessed.	Not applicable
Microtip™ and Flue	Yes	No - Single patient use only		Not applicable
Extended Length MicroTip Plus	Yes	No - Single patient use only		Not Applicable
Macrotip™ and Flue	Yes	No - Single patient use only		Not applicable
SaberTip™ and Flue	Yes	No - Single patient use only		Not applicable
ShearTip™ and Flue	Yes	No - Single patient use only		Not applicable
Manifold Tubing	Yes	No - Single patient use only	One* ***Note**: The manifold tubing is for single patient use only. It can be resterilized once before use but it cannot be reused or reprocessed.	Steam
Sterile Torque Wrench	Yes	No - Single patient use only	None	Not applicable

Item	Supplied Sterile	Reusable /Requires Sterilization by the User	Permitted Number of Sterilizations	Sterilization Method
Sterilizable Torque Base	No	Yes	Unlimited	Steam
Tip Torquing Set	No	Reusable only. The tip torquing set only used outside of the sterile field.	None	Not applicable

Warning

Single Use devices are for single patient use only. Do not reprocess or re-use. Devices (s) is (are) intended to be used for one procedure only. If reprocessed or re-used this may result in the infection of patient (or patient specimen) through cross-contamination, as well as would incur the risk of modifying the properties and performance of the device, and of increasing the likelihood of complications and/or undesirable effects. Once used, devices must be disposed of in accordance with hospital policies.

Notes

SECTION 3

Console Components

In this section:

For Your Information

This section presents the console for the CUSA® Excel/CUSA® Excel+ Ultrasonic Surgical Aspirator System. It provides an overview of the console, and a description of each major console subsystem and its components.

About the Console and Structural Features

Figure 3-1 presents the front view of the console; the components are described in Table 3-1.

Figure 3-1 *Console - Front View*

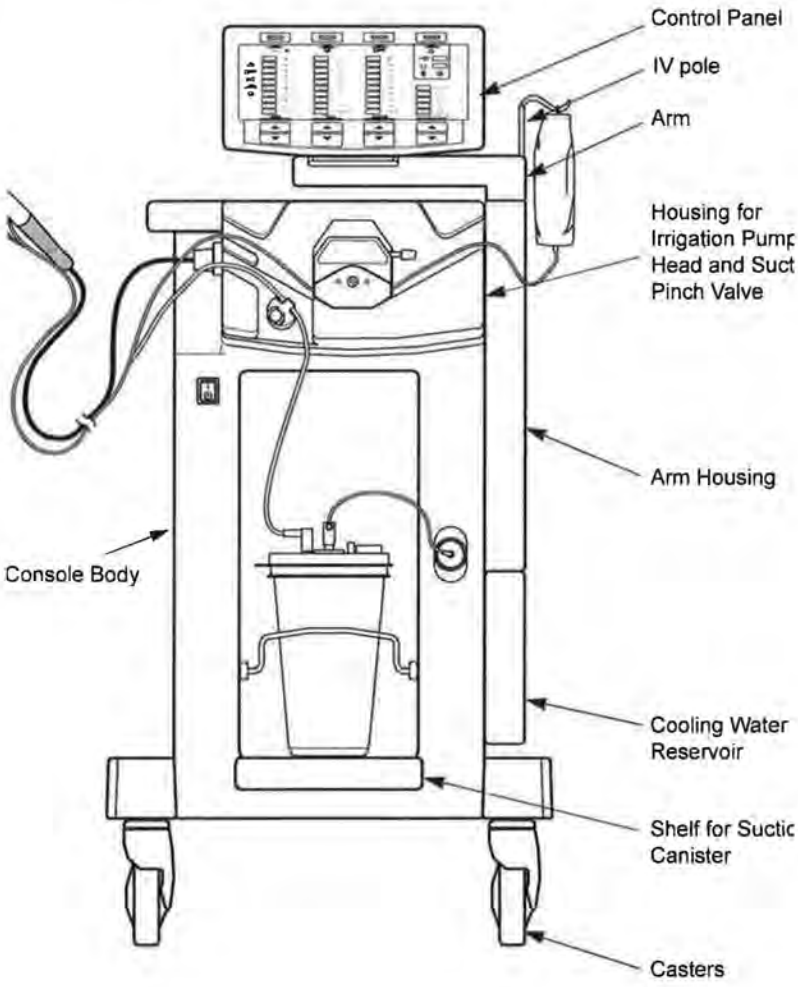


Table 3-1 *Description of Console Structural Features*

Component	Description
IV Pole	Supports the sterile irrigation fluid container. You can raise or lower the pole, and rotate it 90° in the lower position. The safe working load for the I.V. pole is 2 kilograms.
Control Panel	Allows the user to control all system functions. See Section 4: Control Panel Display and Functions.

Table 3-1 *Description of Console Structural Features*

Component	Description
Arm	• Supports the control panel • Pivots the control panel 135°, providing users with a view of the control panel from most of the operating room • Raises to two adjustable heights for ergonomic use
Arm Housing	Covers the arm attachment along the console body side panel.
Housing for Irrigation Pump Head and Suction Pinch Valve	Prominent black area at the top of the console body: • The irrigation pump head and irrigation tube pathway (marked with blue lines) • The suction pinch valve and suction tube pathway (marked with a light green line)
Console Body	Contains the electronics, pumps, and other working components.
Shelf for Suction Canister	Provides a place to put the hospital-provided suction canister.
Casters	Unlocked, both front and rear casters roll easily and rotate freely. When locked, each caster has a brake lock that stops the wheels from rolling.

Console Body – Front Panel

Figure 3-2 shows the front view of the console; the components are described in Table 3-2.

Figure 3-2 *Console Body - Front Panel*

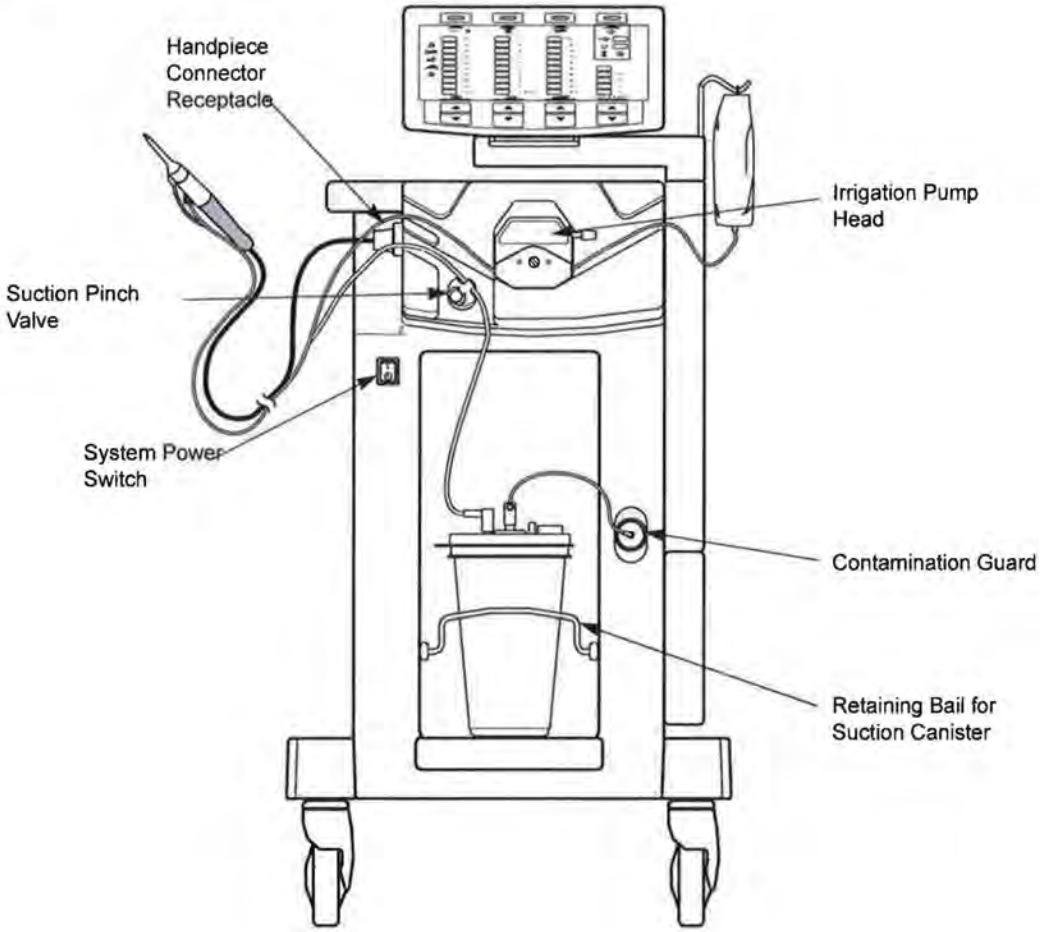


Table 3-2 *Description of Console Body Components - Front Panel*

Component	Description
Handpiece Connector Receptacle 	Connects the handpiece to the console. It is on the left side of the console (as you face the front panel). **Warning** When you connect the handpiece to the console, the handpiece becomes a functional surgical device.
Suction Pinch Valve 	Closed, the valve pinches off suction flow to the handpiece when: • Priming the handpiece with irrigation fluid • Pressing the Fast Flush pedal • Releasing the Vibration pedal (in LAP Mode) When the System Power Switch is off, the suction pump remains off and the suction pinch valve remains closed. Use the button on the front of the suction pinch valve to open the valve. **Warning** To avoid injury to surgical personnel, keep fingers away from the suction pinch valve.
System Power Switch	On (|): activates all system components and begins filling the handpiece with cooling water. Off (⏻) : activates the cooling water drain cycle. When the system has drained water from the cooling water system (about one minute), it automatically deactivates all system components.
Irrigation Pump Head	Rotate the latch from right to left to open the pump head, and from left to right to close. When open, insert irrigation tubing into the peristaltic pump. When closed, the pump head holds irrigation tubing against the peristaltic pump.
Contamination Guard	Protects the vacuum pump from particulate matter and moisture in the suction stream. It is necessary to replace the contamination guard every six months or when the color changes. ▶ ***Important*** *The guard is hydro-philic and becomes blocked when wet.*

Table 3-2 *Description of Console Body Components - Front Panel*

Component	Description
Retaining Bail for Suction Canister	Holds the suction canister in place on the shelf.

Console Body – Side Panel

Figure 3-3 shows the side view of the console; the components are described in Table 3-3.

Figure 3-3 *Console Body - Side Panel*

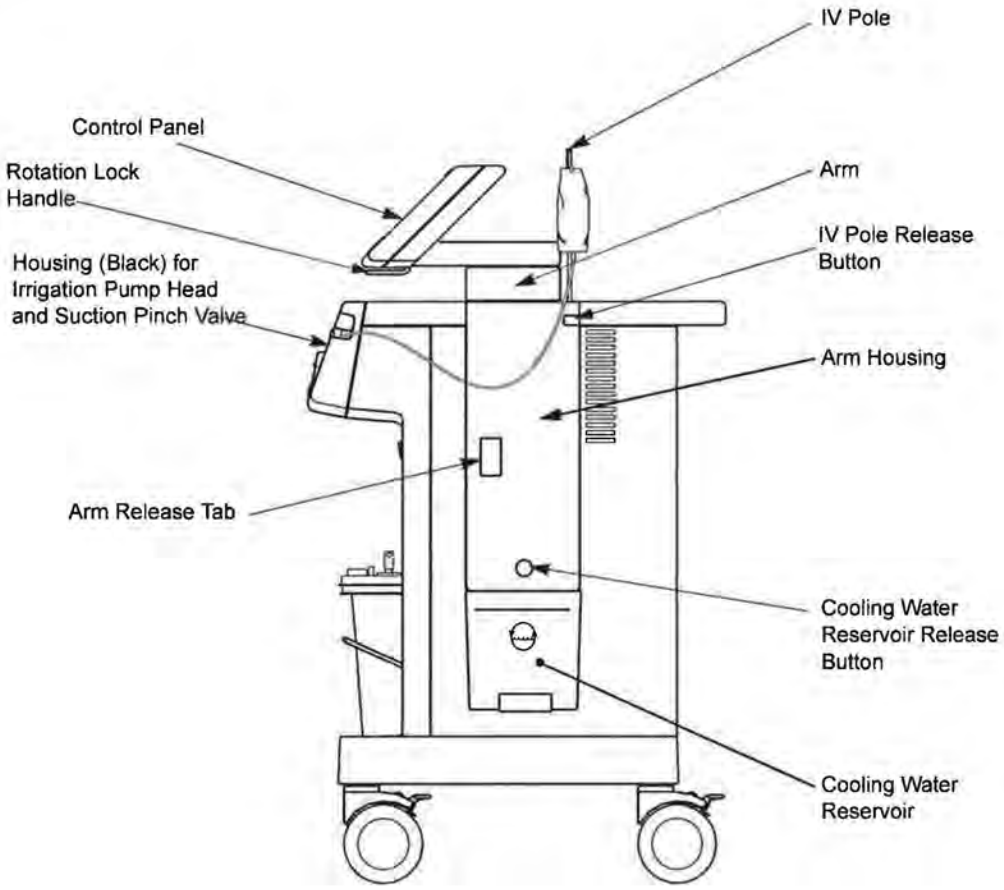


Table 3-3 *Description of Console Body Components - Side Panel*

Component	Description
Control Panel	See Section 4: Control Panel Display and Functions.

Table 3-3 *Description of Console Body Components - Side Panel*

Component	Description
Rotation Lock Handle	Releases the control panel, allowing it to swivel and lock into one of four positions: • Straight forward • 45 ° right • 45° left • 90° left
Housing for Irrigation Pump Head and Suction Pinch Valve	See Table 3-1.
IV Pole	
Arm and Arm Housing	
IV Pole Release Button	Releases the IV pole, to raise or lower it.
Arm Release Tab	Releases a lock that holds the arm in the vertical position.
Cooling Water Reservoir	Holds cooling water to be continuously circulated through the handpiece. The reservoir holds 1000 ml sterile or distilled water. A clear panel, which runs vertically up the side, shows the water level inside the reservoir. The reservoir also includes fittings that snap into receptacles inside the Arm Housing on the console side panel. The fittings and receptacles connect the reservoir to the cooling water system.

Console Body - Rear Panel

Figure 3-4 and Figure 3-5 show the rear view of the console; the components are described in Table 3-4.

Figure 3-4 *Console Body - Rear Panel*

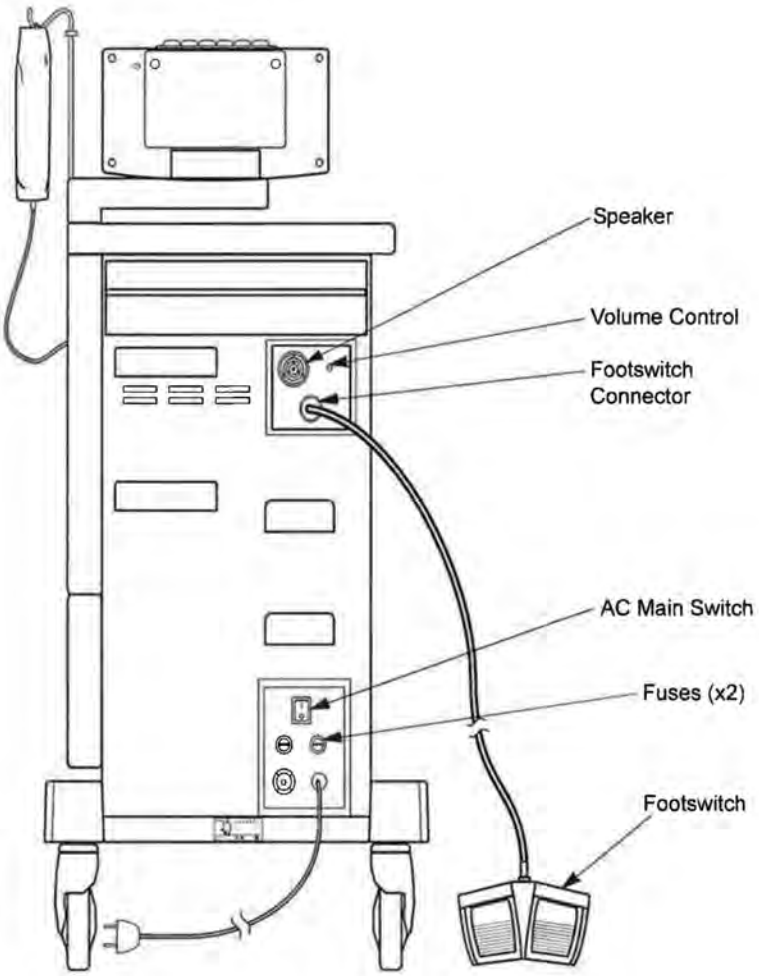


Figure 3-5 *Console Body - Rear Panel Continued*

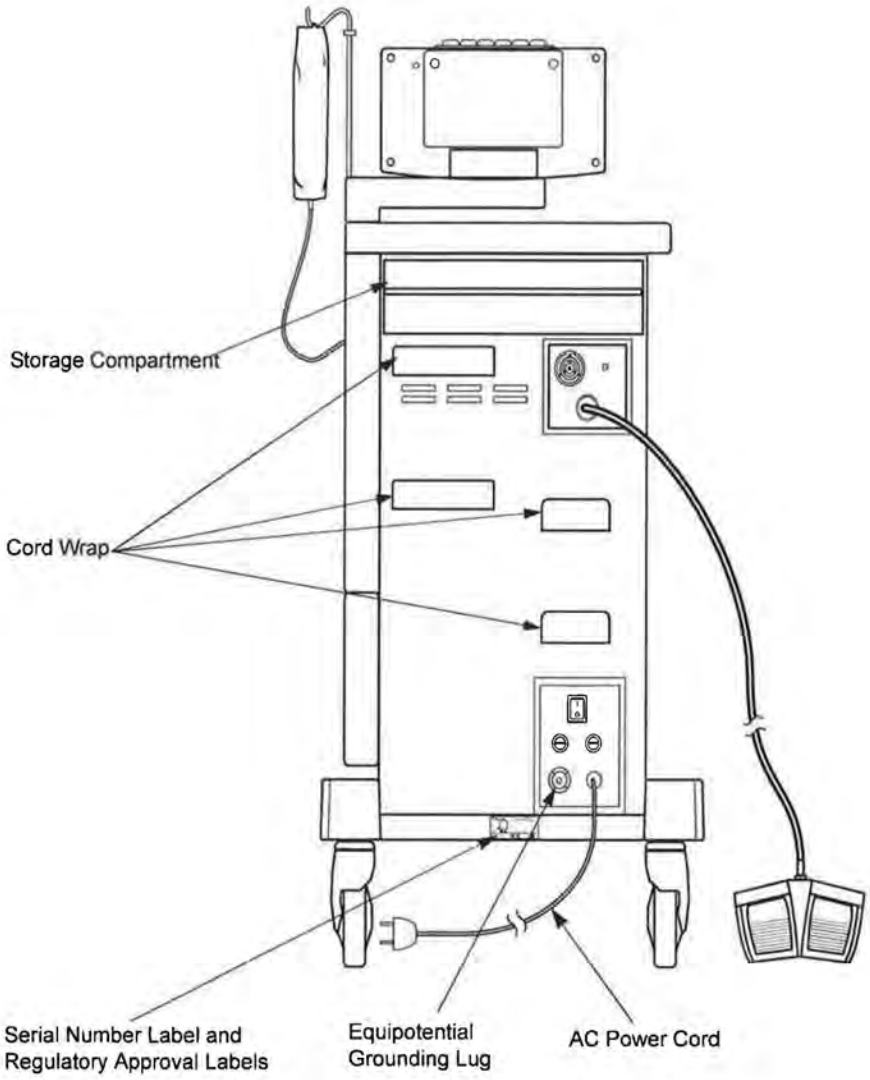


Table 3-4. Description of Console Body Components - Rear Panel

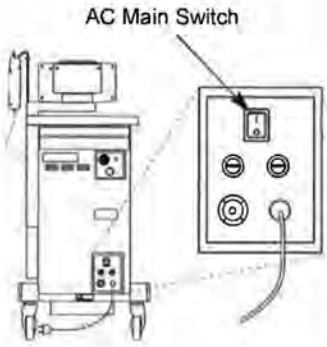
Component	Description
Speaker	Sounds an audible tone four times when an alarm condition exists, and sounds a constant tone when vibration is active.
Volume Control 	Adjusts the active vibration audible tone. You cannot adjust the alarm tone.
Footswitch Connector Receptacle 	Connects the footswitch to the console.
AC Main Switch	Controls AC power input to the system. See Section 3: About the Power Switches.
Fuses	Protect the system from electrical overloads.
Footswitch	Use the pedals on the footswitch to activate two functions: • Ultrasonics/vibration: Right pedal (orange), when pressed, activates vibration at the tip. When you release the pedal, vibration stops. • Fast Flush: Left pedal (blue), when pressed, increases the irrigation rate to greater than 25 ml/min. It also closes the Suction Pinch Valve, stopping suction. When you release the pedal, irrigation returns to the setpoint value and suction resumes.
AC Power Cord	Connects the system to the Mains power supply.
Equipotential Grounding Lug	Allows for the connection of a Potential Equalization Conductor that provides a connection between the equipment and the potential equalization busbar of the electrical installation (in accordance with the requirements of IEC 60601-1). This is a biomedical function.
Labels	Displays the console model number, serial number and regulatory approvals.
Cord Wrap	Use the four cord wraps to hang the cord on the back of the unit, keeping the cord safely out of the way.

Table 3-4. Description of Console Body Components - Rear Panel

Component	Description
Storage Compartment	Stores the footswitch and manual (includes one interior shelf)

About the Power Switches

The CUSA Excel/CUSA Excel+ console includes two power switches:

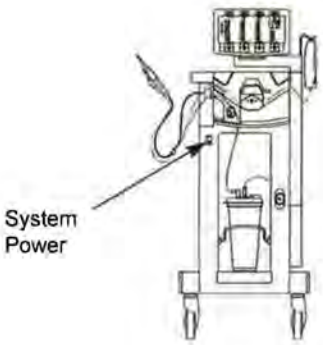


AC Main Switch

Located on the rear panel, this switch controls AC power input to the system. It does not activate the system; instead, it provides AC power to the System Power Switch (on the front panel) so that you can activate the system with the System Power Switch.

Once the AC Main Switch is on (|), you may leave it on, even when you unplug the console from the wall receptacle.

Note: To isolate the CUSA Excel/CUSA Excel+ from the AC power supply, you must unplug the console from the power source.



System Power Switch

Located on the front panel, this black switch activates system components, turning the CUSA Excel/CUSA Excel+ console on (|) or off/standby (⏻).

Warning

TO AVOID RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH.

Warning

The power cord on this product contains lead, a chemical known to the State of California, USA, to cause cancer, and birth defects or other reproductive harm. **Wash hands after handling.** The power cord complies with the DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast).

Notes

SECTION 4

Control Panel Display and Functions

In this section:

For Your Information

This section presents the control panel for the CUSA® Excel/CUSA® Excel+ Ultrasonic Surgical Aspirator System.

The control panel can contain icons only, or icons and text, depending on the product model. The control panel for the Excel8 and Excel9 product models contains icons only. The control panel for the Excel product model contains icons and text. This chapter describes the control panel display for the different models. It also describes the control panel behavior during system startup and operation.

About the Control Panel Display

The control panel display for the Excel8 and Excel9 models (Figure 4-1), and the Excel model (Figure 4-2), are illustrated in this section. Note: The control panel display is also printed on the quick reference cards (to be fitted in a slot at the rear of the control panel).

Figure 4-1 *Control Panel for Excel8 and Excel9 models*

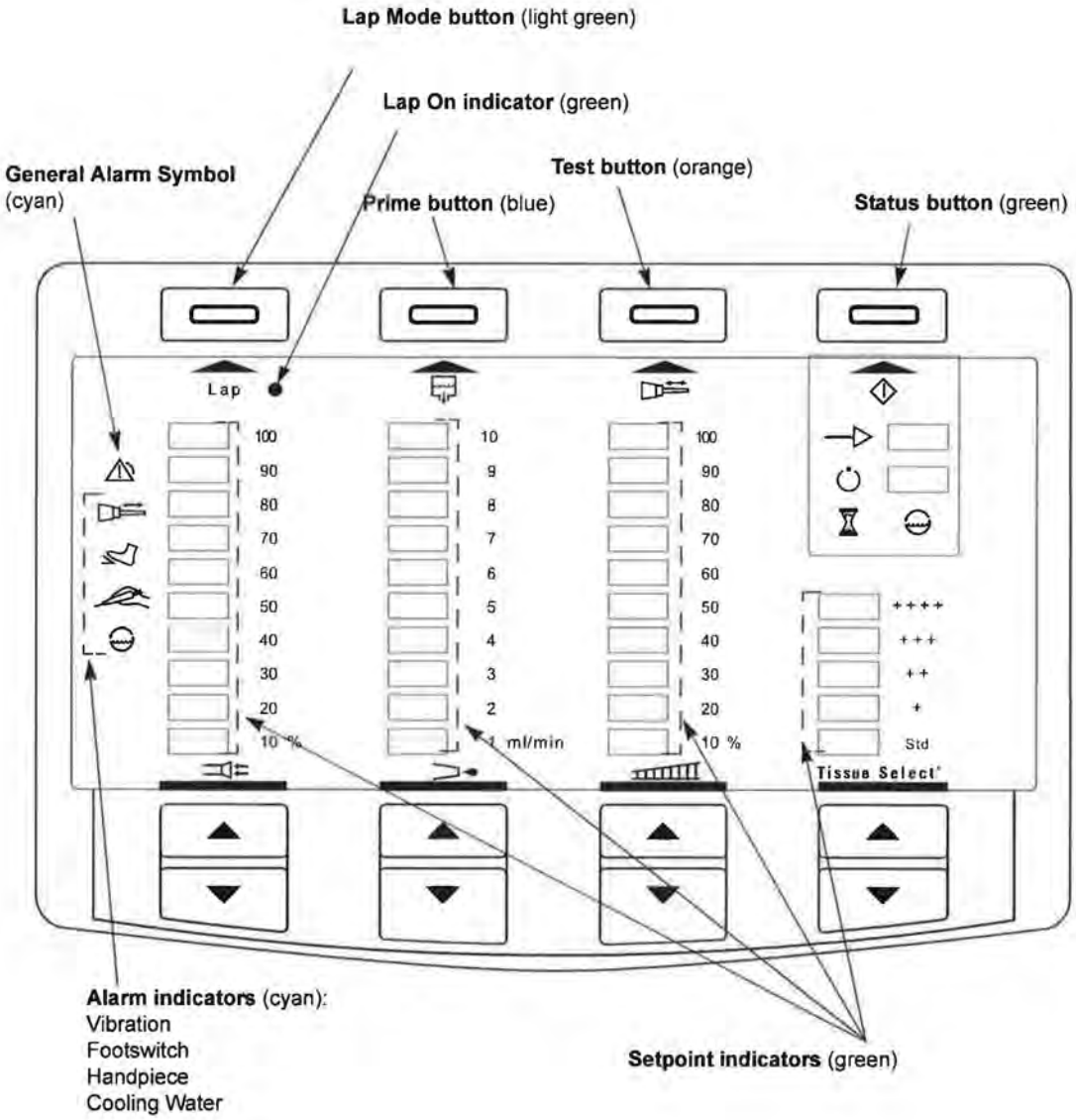
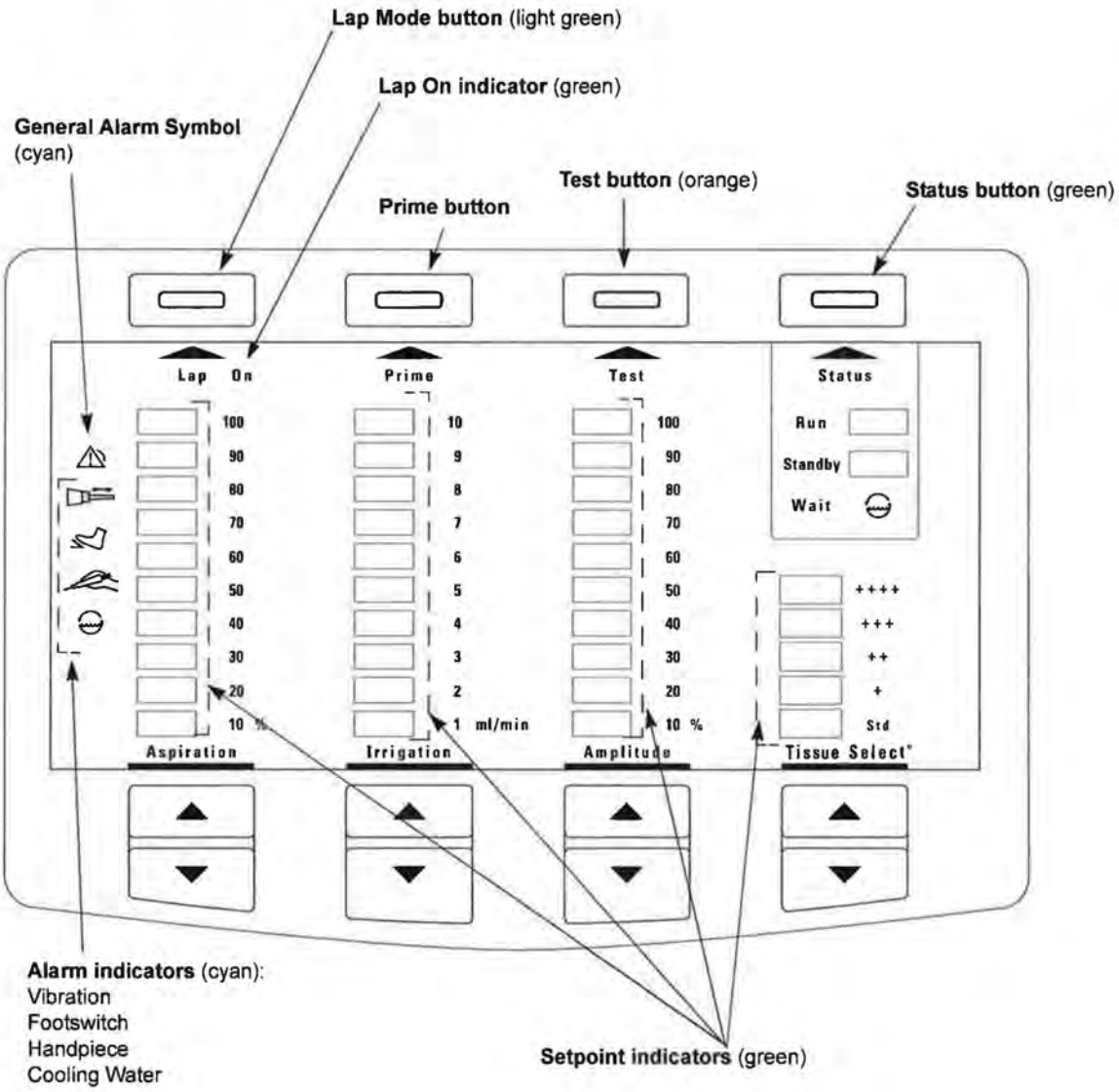


Figure 4-2 *Control Panel for Excel and Excel 2 model*



Alarm Indicators

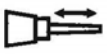
The CUSA Excel/CUSA Excel+ activates an alarm to indicate a technical problem with the system. All alarms on the CUSA Excel/CUSA Excel+ are technical, low-priority alarms, for example, mechanical or equipment-related. There are no physiological alarms on the CUSA Excel System.

When the CUSA Excel/CUSA Excel+ System activates an alarm, it:

- Illuminates the general alarm symbol in cyan on the control panel. This indicates that an alarm exists on the system
- Illuminates one or more alarm indicators in cyan on the control panel. This indicates the type of alarm(s) that exist
- Sounds the alarm tone four times

Table 4-1 describes each of the alarms on the CUSA Excel/CUSA Excel+ System. The general alarm symbol and alarm indicator(s) remain illuminated until you resolve the corresponding problem(s). For information on troubleshooting alarms, see Troubleshooting the System, page 14-1.

Table 4-1 *Description of Alarms*

Alarm Indicator	Alarm	Alarm Cause	Alarm Classification	Alarm Priority
	General	Triggered when an alarm condition exists	Technical	Low
	Handpiece	Triggered when system detects that there is no Handpiece connected.	Technical	Low
	Footswitch	Triggered when system detects that there is no Footswitch connected.	Technical	Low
	Vibration	Triggered when excessive vibration at tip is detected.	Technical	Low
	Cooling Water	Triggered when issue with the cooling system is detected.	Technical	Low

See Figure 4-1 and Figure 4-2 for the location of the alarm indicators on the control panel.

There is no method to silence alarms from the control panel, therefore, to manually turn off an alarm, you must turn off the console. If the system shuts down unexpectedly (for example a power failure) with an alarm illuminated on the control panel, the alarm remains illuminated when you power the system on again.The only method of turning off the alarm indicator on the control panel is to resolve the corresponding alarm.

Recommended: When you set up the CUSA Excel/CUSA Excel+ for surgery, make sure that the control panel is always clearly visible to the surgeon in the event of an alarm. Remove any obstructions that may block the surgeon's view of the control panel.

Lap Mode, Prime, Test, and Status Buttons

To activate Lap Mode, Prime, or Status, press the button once; to deactivate the function, press the button again. To activate Test, press the button once; it automatically deactivates when the test is complete.

Lap Mode: Selects the Laparoscopic mode of operation – the system provides no suction or irrigation to the handpiece until you activate the Vibration pedal.

When you activate the Lap Mode, the system illuminates the Lap Mode indicator.

Prime: Automatically increases irrigation rate to 25 to 30 ml/min to pump irrigation fluid to the tip. A timer turns Prime off after approximately one minute.

Test: Verifies the handpiece is working properly by automatically increasing tip amplitude to 100%, then decreasing it to 0% – all within 4 seconds.

Status: Toggles the status between Standby and Run.

See Figure 4-1 and Figure 4-2 for the location of the Lap Mode, Prime, Test, and Status buttons on the control panel.

Setpoint Indicators

Green setpoint indicators show user adjusted setpoints for Aspiration, Irrigation, and Amplitude:

- Not Activated: One setpoint indicator illuminates to show the setpoint value
- Activated: All setpoint indicators up to and including the setpoint value light up.

For Tissue Select®, "Std" (standard) is the first setpoint value; "++++" is the highest setpoint value and indicates increased selectivity.

See Figure 4-1 and Figure 4-2 for the location of the setpoint indicators on the control panel.

Figure 4-3 *Control Panel - Excel8 and Excel9 model (status indicators and setpoint adjustment)*

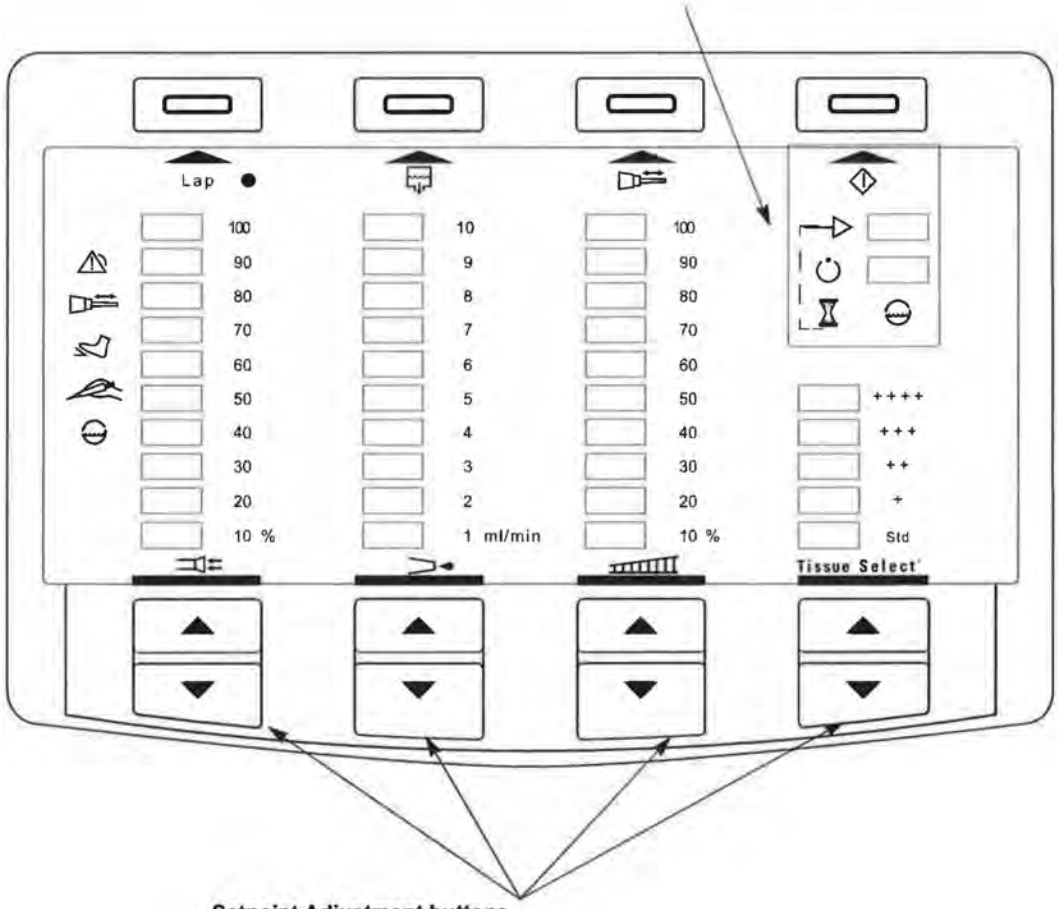
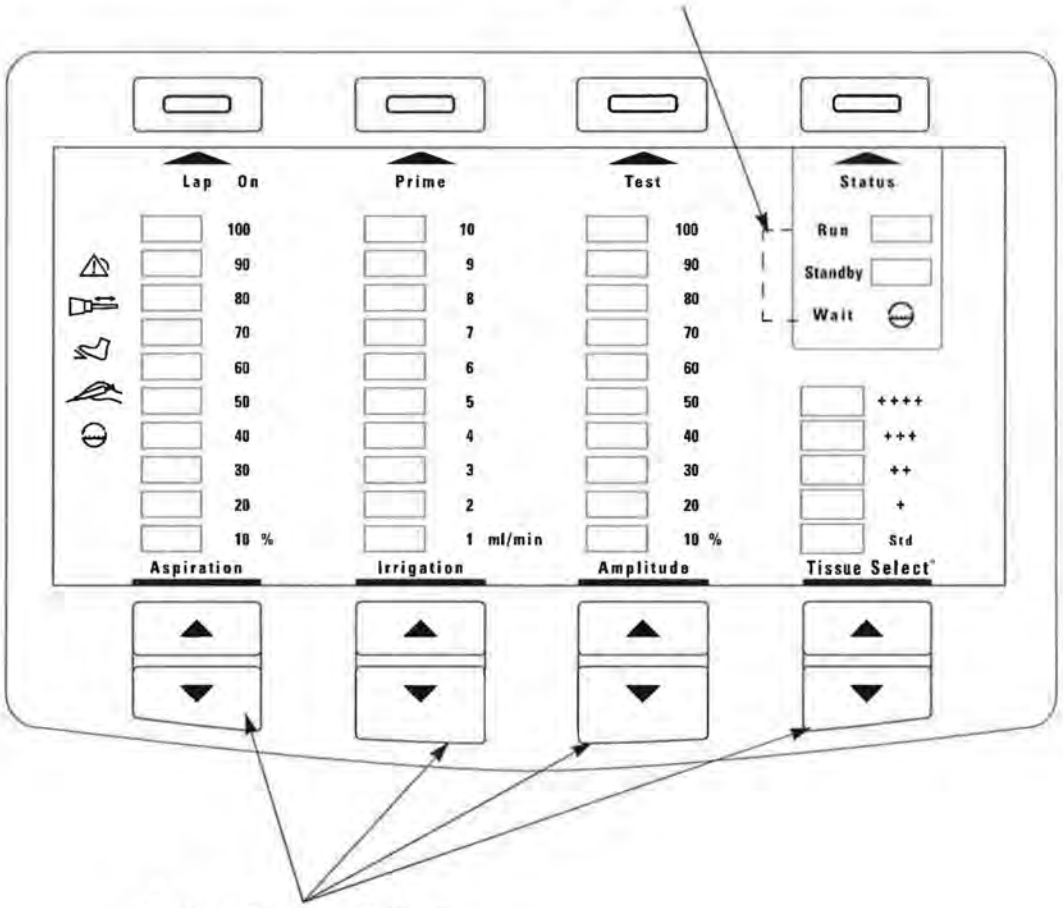


Figure 4-4 *Control Panel - Excel and Excel 2 model (status indicators and setpoint adjustment)*



Status Indicators

To change from Standby to Run, or from Run to Standby, press the Status button.

Run: A green status indicator illuminates to show when the system is in Run status. The CUSA Excel/CUSA Excel+ must remain in Run mode for a minimum of two minutes (continuous) before it is ready for use; once the two minutes elapses, the system is ready for use.

Standby: An orange status indicator illuminates when the system is in Standby.

Wait/Cooling Water: The Wait status indicator flashes and the Cooling Water status indicator illuminates in the following circumstances:

- Immediately after turning on (|) the System Power Switch, the system automatically fills the handpiece with cooling water.
- Immediately after turning off (⏻) the System Power Switch, the system automatically drains handpiece cooling water.

While the Wait/Cooling Water status indicators remain lit, you cannot use the control panel or footswitch.

See Figure 4-3 and Figure 4-4 for the location of the status indicators on the control panel.

Setpoint Adjustment Buttons

Marked with Up/Down arrows, use these buttons to adjust the setpoint values:

- **Aspiration (Suction)**: 10 increments; linear scale of 10 to 100%; default value is 100%.
- **Irrigation**: 10 increments; linear scale of 1 to 10 ml/min; default value is 3ml/min.
- **Amplitude**: 10 increments; linear scale of 10 to 100%; default value is 10%.
- **Tissue Select**: 5 increments from Std (standard operation) to ++++. Tissue Select interrupts continuous vibration for specified times:

Setting	On-Time	Off-Time
Std	continuous	0 ms*
+	40 ms	10 ms
++	30 ms	10 ms
+++	20 ms	10 ms
++++	10 ms	10 ms

**1 ms = 1 millisecond = 1 one-thousandth of a second*

Push a button once for a single change in setpoint value. Note: Holding down the button will only produce a single change in setpoint value.

See Figure 4-3 and Figure 4-4 for the location of the setpoint adjustment buttons on the control panel.

Signs and Symbols on the Excel8 and Excel9 Control Panel

Table 4-2 lists each symbol and its meaning. You can find this symbol list on the quick reference guide (to be fitted at the top of the control panel).

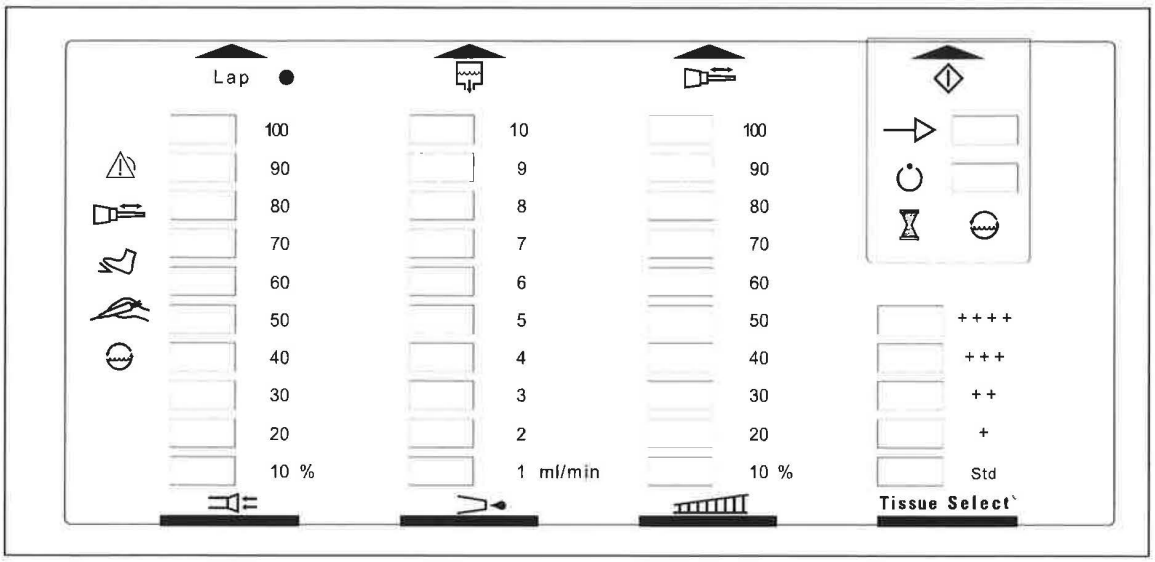


Table 4-2 *Signs and Symbols on the Excel8 and Excel9 Control Panel*

Symbol	Description
	General alarm symbol: Indicates that an alarm condition exists (cyan, left side of panel).
	Vibration alarm: Vibration failure/The handpiece is not working properly (cyan, left side of panel).
	Test (orange, top of amplitude display): System in Test mode.
	Footswitch alarm: Footswitch failure or footswitch connector not plugged into its receptacle on the console rear panel (cyan, left side of panel).
	Handpiece alarm: Handpiece failure or handpiece connector not plugged into its receptacle on the console (cyan, left side of panel).
	Cooling Water alarm: Cooling water problem in the system (cyan, left side of the control panel).
	Wait (orange, right side of the control panel): System is circulating cooling water through the handpiece or draining the handpiece

Table 4-2 Signs and Symbols on the Excel8 and Excel9 Control Panel

Symbol	Description
	Suction adjust
	Irrigation adjust
	Amplitude adjust
Std	Standard
	Standby
	Run
	Start action/change status
	Prime
Lap ●	Laparoscopic Mode is On/Selected (green, top left of control panel)

Signs and Symbols on the Excel and Excel 2 Control Panel

Table 4-3 lists each symbol and its meaning. You can find this symbol list on the quick reference guide (to be fitted at the top of the control panel).

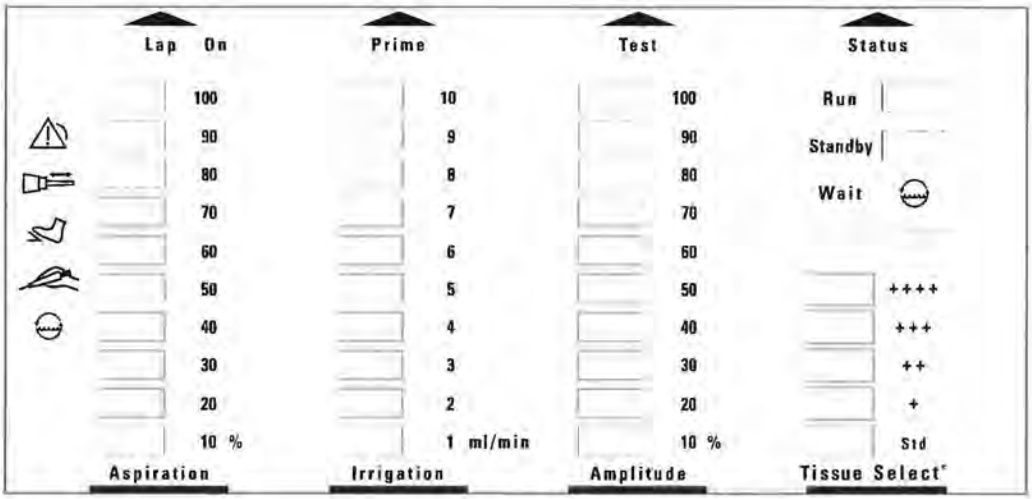


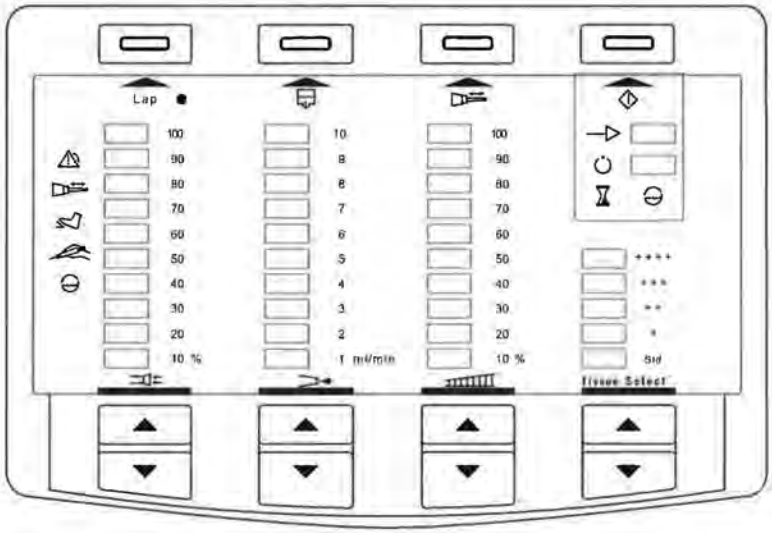
Table 4-3 *Signs and Symbols on the Excel and Excel 2 Control Panel*

Symbol	Description
	General alarm symbol: Indicates that an alarm condition exists (cyan, left side of panel).
	Vibration alarm: Vibration failure/The handpiece is not working properly (cyan, left side of panel).
	Footswitch alarm: Footswitch failure or footswitch connector not plugged into its receptacle on the console rear panel (cyan, left side of panel).
	Handpiece alarm: Handpiece failure or handpiece connector not plugged into its receptacle on the console (cyan, left side of panel).
	Cooling Water alarm: Cooling water problem in the system (cyan, left side of the control panel).
Lap On	Laparoscopic Mode is On/Selected (green, top left of control panel)

Understanding the Control Panel at System Startup

When you turn on (|) the System Power Switch, it activates the CUSA Excel/CUSA Excel+ System components. This section presents the control panel features in the order in which you will encounter them as you set up, test, and use the system.

Note: The Excel8 and Excel9 control panel illustration is shown for reference only.



When you turn on (|) the System Power Switch (on the front panel), the CUSA Excel/CUSA Excel+ System illuminates all indicators on the control panel, including the alarm indicators, for approximately four seconds; then it turns off all indicators.

The CUSA Excel/CUSA Excel+ System then checks for the footswitch and the handpiece connections. If the system detects the footswitch and handpiece, the Wait (flashing) and the Cooling Water (solid) status indicators turn on. After one minute, the Wait and Cooling Water status indicators turn off. The Test and Prime indicators then turn on. If the system cannot detect either the handpiece or footswitch connections, it activates the appropriate alarm.

Footswitch Alarm

When turned on (|), if the system does not find the footswitch connection, it illuminates the general alarm symbol and the Footswitch alarm indicator, and it sounds the alarm tone four times. Then it turns off the Wait status indicator. If this occurs, make sure the footswitch is connected to the console rear panel. If not, connect it. The Footswitch alarm will turn off and the Wait status indicator will turn on.

Handpiece Alarm

When turned on (|), if the system does not find the handpiece connection, it illuminates the general alarm symbol and the Handpiece alarm indicator, and it sounds the alarm tone four times. Then it turns off the Wait status indicator. If this occurs, make sure the handpiece is connected to the console. If not, connect it. The Handpiece alarm will turn off and the Wait status indicator will turn on.

Note: When turned off (⏻), the system automatically drains the cooling water from the handpiece and the cooling water system; the Wait status indicator and Cooling Water status indicator illuminate. Do not disconnect the handpiece while the system is draining cooling water. If you do, the system illuminates the Handpiece alarm and turns off the Wait status indicator. If this happens, reconnect the handpiece to the console. The system turns the Wait status indicator on and the alarm off, and resumes draining the cooling water. When the system completes draining the cooling water, the entire control panel turns off (goes blank). Then you can disconnect the handpiece.

System startup will not proceed until you clear a handpiece or footswitch alarm. If you connect the handpiece and footswitch and the corresponding alarm indicator remains on, call Integra for assistance.

Wait

Wait/Cooling Water

When the system detects that the handpiece and footswitch are connected, it automatically begins to circulate cooling water through the handpiece. This takes about one minute to complete. While the system performs this task, the orange Wait status indicator flashes and the orange Cooling Water status indicator (upper right on the control panel) illuminates.

When the Wait and Cooling Water status indicators are illuminated, you cannot use the control panel. When the system turns off the Wait and Cooling Water status indicators, it turns on the suction pump, the Test status indicator, and the Prime status indicator.

Cooling Water Alarm

If the system detects a cooling water problem, it illuminates the general alarm, symbol and the Cooling Water alarm indicator (left side of the control panel), and it sounds the alarm tone four times. Possible causes for this alarm are:

- No water in the cooling water reservoir
- Disconnected cooling water reservoir
- Damaged, misaligned, or missing o-rings in the handpiece connector
- Pinched or kinked handpiece cable
- Air leak in the cooling water system

To correct these conditions:

- Add water

- Connect the reservoir
- Remove the pinch or kink
- For an air leak in the handpiece tubing, or an o-ring problem in the handpiece connector, connect a new handpiece

While the Cooling Water alarm indicator remains illuminated, you cannot use the control panel or footswitch.

Warning

Ignoring alarms on the CUSA Excel/CUSA Excel+ System while continuing to use the system may result in injury to the patient and/or surgical personnel, or equipment damage.

Test 

Test

Use the Test button (orange box on a black button) at the top of the Amplitude display to test the handpiece function.

To test the handpiece, press the Test button. The system automatically activates the handpiece at 100% vibration for 4 seconds. During the test, green setpoint indicators in the amplitude display light up to 100% to show that the handpiece is working correctly.

If the setpoint indicators do not light up to 100%, a problem may exist. To troubleshoot:

- Push the Test button again
- Verify proper tip torquing
- If the problem persists, perform more complete troubleshooting (see Section 14: Troubleshooting the System)

Vibration Alarm

If the handpiece is not working properly, the system illuminates the general alarm symbol and the Vibration alarm (left side of the control panel), and it sounds the alarm tone four times. Possible causes for this alarm are:

- Damaged tip
- Loose tip (not properly attached to handpiece)

Prime 

Prime

To start Prime, press the Prime button (blue box on a black button at the top of the Irrigation display). You need to repeat Prime until you see irrigation fluid flow at the handpiece tip. If it doesn't, verify that all connections are tight, then press the Prime button again.

The Prime button automatically increases the rate of the irrigation pump to 25 to 30 milliliters per minute (ml/min). Prime allows the system to pump irrigation fluid through the manifold tubing, through the flue, and onto the tip as quickly as possible, reducing setup time. Watch for irrigation fluid

dripping from the handpiece tip. Priming takes about one minute. As the system primes, one setpoint indicator in the Irrigation display illuminates every 6 seconds to show its progress.

To stop Prime at any time, press the Prime button again.

You can repeat the Prime process at any time by pressing the Prime button once to start Prime, and pressing it again to stop Prime.

After priming, the system automatically proceeds to Standby status.

Standby 

Standby Status

When the system enters the Standby status, it illuminates the orange Standby status indicator (upper right on the panel). It automatically sets the following default values:

Aspiration	100%
Irrigation	3 ml/min
Amplitude	10%
Tissue Select	Std

Before using the CUSA Excel/CUSA Excel+ System at the surgical site, adjust setpoint values, then select Laparoscopic mode (if desired) and Run status.

SECTION 5

Setting Up the System

In this section:

For Your Information

This section describes how to set up the CUSA® Excel/CUSA® Excel+ Ultrasonic Surgical Aspirator Systemfor surgery, starting with the arrival of the sterilized handpiece and accessories to the operating room, and ending with the system in Run mode ready for the surgeon's use.

The CUSA Excel/CUSA Excel+ System requires a minimum of one hour exposure at its operating temperature range before you use it. Make sure that the system is located in the surgical room at least an hour before use.

Quick Reference – Setup

Use this list if you are a knowledgeable user who needs only a reminder of the steps to set up the CUSA Excel/CUSA Excel+ System.

Handpiece Assembly

1. Attach the tip to the handpiece.
2. Assemble the o-rings to the tip.
3. Attach the standard nosecone onto the handpiece.
4. Attach the flue.
5. Attach the sterile manifold tubing (if not attached before sterilization).
6. Attach the aspiration and irrigation tubing at the handpiece.

Console Assembly

1. Plug the power cord into a wall receptacle.
2. Confirm that the AC Main Switch located on the rear panel is on.
3. Confirm that the footswitch is plugged into its receptacle.
4. Spike an irrigation bag (Lactate Ringer's or normal saline) with large drip IV administration set, and hang it at the side of the console.
5. Fill the cooling water reservoir with distilled water, then slide it into place. Do not use tap water or saline solution.
6. Connect the suction canister to the console at the contamination guard.
7. Connect a sterile handpiece to the system.
8. Turn on (|) the System Power Switch located on the front panel.
9. Connect the suction manifold tubing to the console and the suction canister.
10. Connect the irrigation manifold tubing to the console and the IV administration set. Open the IV clamp.
11. Wait until the Wait (flashing) and Cooling Water status indicators go off.
12. Press the Test button to check the setup of the handpiece. If the cyan vibration alarm indicator does not illuminate, the handpiece is functioning properly.
13. Press the Prime button to prime the handpiece with sterile irrigation fluid.
14. Adjust settings for amplitude, suction, and irrigation.
15. Press the Status button to select the Run mode when the surgeon is ready to use the system.The CUSA Excel/CUSA Excel+ System must remain in Run mode for a minimum of two minutes (continuous) before it is ready for use; once the two minutes elapses, the system is ready for use.

Handpiece Assembly Options

If you want to:	Do this:
Assemble the tip to the handpiece in a nonsterile area before sterilization	Go to: • *Section 8: Assembling the Handpiece in a Nonsterile Area* • *Section 9: Sterilizing Handpieces and Accessoriess* • *Section 10: Completing Handpiece Setup in the Sterile Field*
Assemble the tip to the handpiece in the sterile field	Go to: • *Section 11: Assembling or Changing Tips in the Sterile Field.*

You also have the option of attaching manifold tubing to the handpiece cable before or after handpiece sterilization. If you chose to attach the manifold tubing after handpiece sterilization, you must attach it in the sterile field, see *Section 10: Completing Handpiece Setup in the Sterile Field.*

Preparing the System for Startup

At the Rear Panel

1. Plug the CUSA Excel/CUSA Excel+System power cord into a wall receptacle.
2. Confirm that the AC Main Switch on the rear panel is on (|).
3. Verify that the system footswitch is connected to the rear of the console.
4. Follow hospital policies and procedures regarding the placement of footswitches into plastic bags.

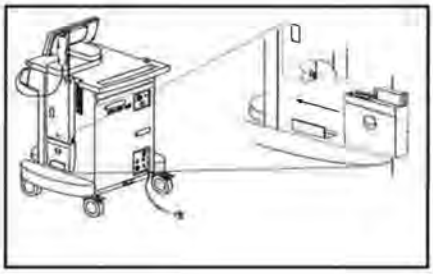
On the Side Panel: Filling the Cooling Water

1. Remove the cooling water reservoir from the console:
   a. Press the button (just above the reservoir) on the Arm Housing to release the latch inside the housing.
   b. Slide the reservoir toward the rear of the console, then remove it from its slot.
2. Gently open the black rubber lid on the reservoir top.
3. Fill the cooling water reservoir to the line with 1000 ml distilled water (sterile water is distilled).

Warning

Do not fill the Cooling Water reservoir with tap water or saline solution. Use distilled water only.

4. Gently close the black rubber lid.
5. Slide the cooling water reservoir into the slot on the console side panel until it snaps into place.

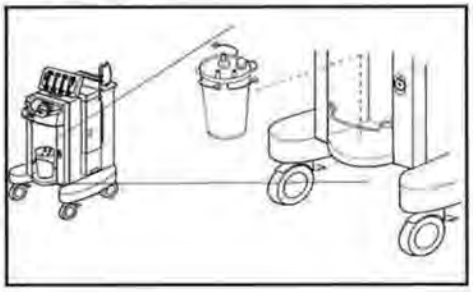


On the Front Panel: Suction

Notice

To prevent fluid flowing into the vacuum line, only use a suction canister that has a non-return valve.

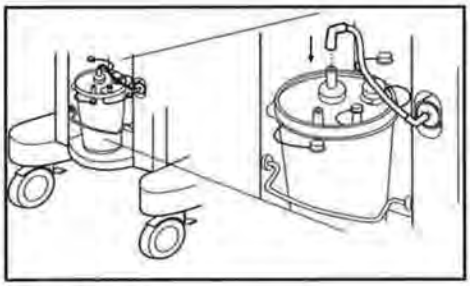
1. If used, install the specimen trap into the hospital-provided suction canister.
2. Put the suction canister on the shelf in the front of the console.



3. Verify that the contamination guard is in place in the console.

   Note: We recommend you retain a second contamination guard in the surgical environment in case the guard becomes blocked.

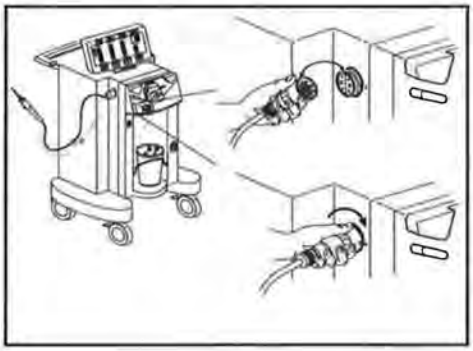
4. Attach the green L-shaped connector from the contamination guard to the VACUUM port on the suction canister lid.



5. Secure the canister with the retaining bail.

On the Front Panel: Handpiece

1. Connect the handpiece to the console.



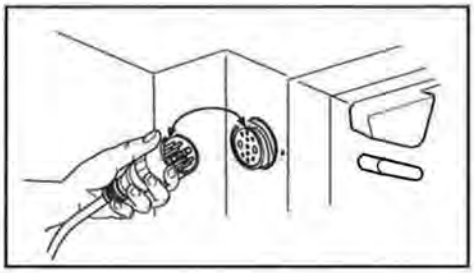
Warning

When you connect the handpiece to the console, the handpiece becomes a functional surgical device.

Caution

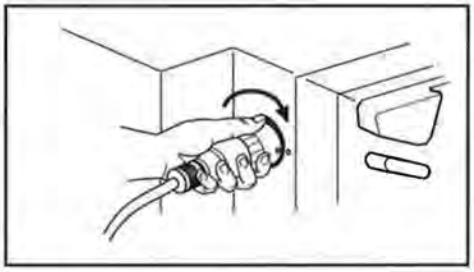
Sharp edge at the handpiece connection point.

a. Line up the notch on the handpiece connector to the key in the receptacle (at the 12 o'clock position).



b. Gently push the handpiece connector onto the console connector.

c. Turn the connecting ring in the clockwise direction until the yellow dot on the handpiece aligns with the yellow dot on the console.



Turning On the System

1. Turn on (|) the black System Power Switch (located on the front panel) to activate the system.
2. Verify that all indicators on the control panel (including the alarm indicators) illuminate for four seconds approximately, and then turn off again.

   Note: This step verifies that all indicators, including the alarm indicators, are functioning correctly.
3. Verify that the Wait (flashing) and the Cooling Water status indicators are on.

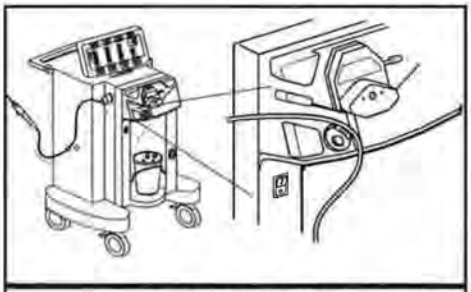
   When active, the system draws distilled water through the handpiece cooling system. This takes about one minute, during which time the Wait (flashing) and Cooling Water status indicators illuminate. When the system successfully fills the cooling system with water, it turns the Wait and Cooling Water status indicators off.
4. While you wait for the Wait and Cooling Water status indicators to go off, connect the manifold suction tubing to the console (next section).

Connecting the Suction Tubing

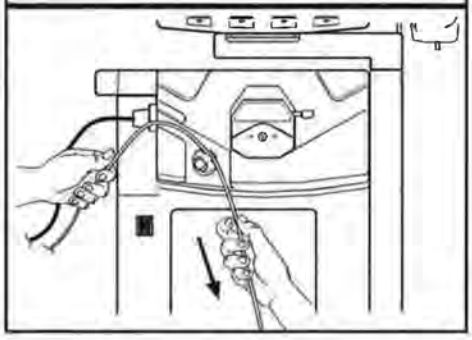
Warning

To avoid injury to surgical personnel, keep fingers away from the suction pinch valve.

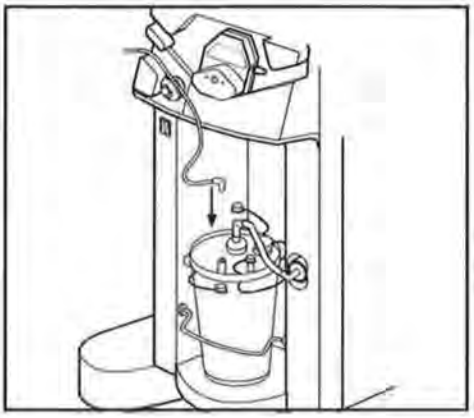
1. Align the green band on the manifold suction tubing with the green line on the front of the console.



2. Above the green band, hold the suction tubing with one hand; with the other hand, stretch the tubing into the suction pinch valve.

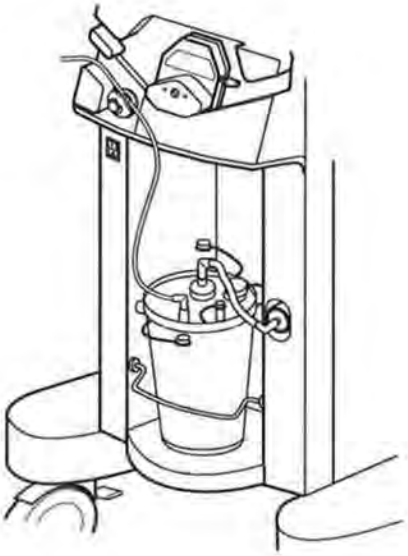


3. Connect the green L-shaped connector on the suction tube to the PATIENT port on the suction canister lid.
4. Make sure all unused ports on the suction canister lid are closed, and the canister lid is tightly sealed to the canister.



The following figure shows the suction system as it looks after successful setup.

Figure 5-1 *The assembled suction system*



Connecting the Irrigation Tubing

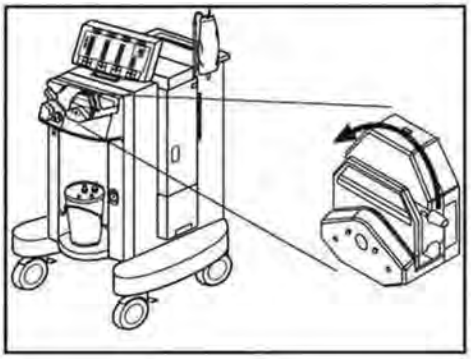
Warning

To avoid injury to surgical personnel:

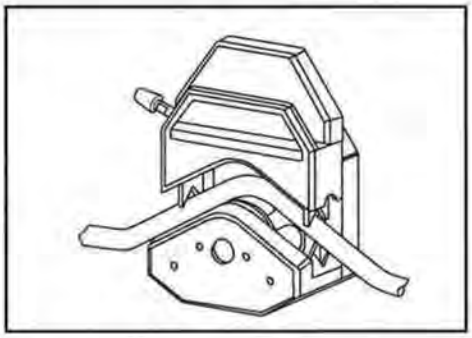
- When closing the irrigation pump latch, keep fingers away from the area between the V-shaped tubing retainers.
- If the pump latch is open, keep fingers away from the pump rollers.

1. Prepare a standard IV administration set and sterile irrigation solution, and put it on the IV pole located next to the adjustable arm.
2. Connect the irrigation tubing (from the handpiece) to the CUSA Excel/CUSA Excel+ System.

   a. To open the pump latch (if it is not already open), rotate the lever to the left.



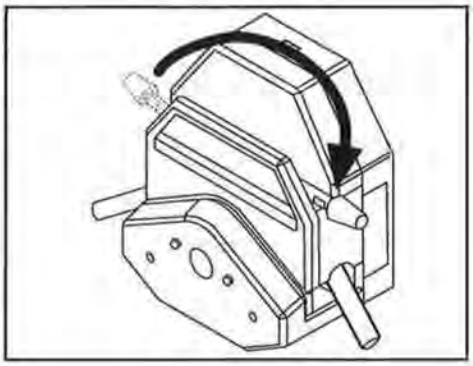
   b. Align the blue stripe on the irrigation tube with the blue line on the front of the console, then center the irrigation tubing inside the pump rollers, between the V-shaped tubing retainers.



Caution

Make sure that the irrigation tubing centers between the V-shaped tubing retainers before you close the pump latch. Otherwise, the pump latch will pinch the tubing, preventing the flow of irrigation fluid.

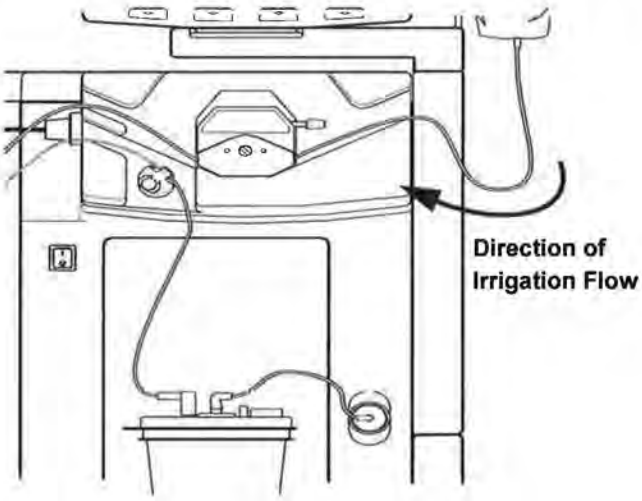
c. To close the pump latch, rotate the lever to the right.



3. Remove the cap from the irrigation tubing.
4. Connect the irrigation tubing to the IV administration set tubing.
5. Make sure that the person assembling the handpiece has connected the irrigation tubing to the handpiece flue.
6. Open the roller clamp on the IV tubing.

The following figure shows the irrigation system as it looks after successful setup.

Figure 5-2 *The assembled irrigation system*



Testing the Handpiece

Warning

Do not use a damaged handpiece with the CUSA Excel/CUSA Excel+ System. This may result in injury to the patient or surgical personnel.

Warning

When the handpiece is connected to a CUSA Excel/CUSA Excel+ System that is powered on, but the handpiece is not in use, keep the handpiece away from the patient. Place the handpiece on a sterile, flat, dry, nonconductive, and highly visible surface.

Warning

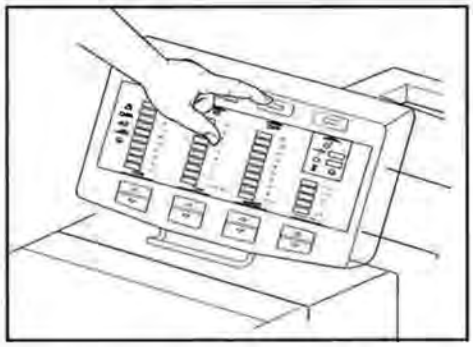
When you connect the handpiece to the console, the handpiece becomes a functional surgical device.

Caution

When you test the handpiece, do not allow the handpiece tip to contact anyone or anything during tip activation. Contact may result in patient injury, user injury, or handpiece tip damage.

When the handpiece cooling water system fills, the system automatically proceeds to the next step and illuminates the Test and Prime setpoint indicators.

1. Press the Test button (orange box on a black button at the top of the amplitude display column) on the control panel.



The system automatically activates the handpiece at 100% vibration for 4 seconds. During the test, green setpoint indicators in the amplitude display light up to 100% to show that the handpiece is working correctly.

2. Verify the following:
   - *The Vibration alarm (cyan) is off.*
   - *The setpoint indicators light up to 100%.*

   If no Vibration alarm illuminates, and if the setpoint indicators light up to 100%, the handpiece is working properly. Continue with the system setup.

If the Vibration alarm illuminates, or if the setpoint indicators do not light up to 100%, the handpiece is not working properly. This usually results from an improperly attached tip. To troubleshoot:

- *Verify proper tip torquing*
- *Push the Test button again*
- *If the problem persists, perform more complete troubleshooting (see Section 14: Troubleshooting the System)*

Testing the Alarm Tone

To verify the alarm tone functions correctly, you must intentionally trigger an alarm on the CUSA Excel/CUSA Excel+ System, for example, disconnect the footswitch from console:

1. Disconnect the footswitch from the console at the footswitch connector (rear panel).
2. The footswitch alarm triggers on the system.
3. Verify that the system sounds the alarm tone four times.

If the alarm tone doesn't sound, contact your Integra representative.

When the Surgeon Is Ready

Warning

Ignoring alarms on the CUSA Excel/CUSA Excel+ System while continuing to use the system may result in injury to the patient and/or surgical personnel, or equipment damage.

Warning

The handpiece and handpiece accessories must be sterile before surgical use.

Caution

During surgery, under maximum loading conditions, the CUSA Excel/CUSA Excel+ console is suitable for ultrasonics activation times of 10 minutes on, 5 minutes off.

1. Make sure the IV administration set roller clamp is open.
2. Prime the irrigation system:
   a. Press the Prime button.

      The CUSA Excel/CUSA Excel+ System automatically primes the irrigation system. Setpoint indicators move from 0 to 10 ml on the irrigation display column. This will take about 1 minute.

   b. Make sure irrigation fluid drips from the tip.

      If it doesn't, verify that all connections are tight, then press the Prime button again.

      If fluid appears at the top of the tip before priming is complete, stop the priming cycle by pressing the Prime button again.

When irrigation prime is complete, the system automatically goes to Standby mode; it illuminate the orange Standby status indicator and displays the default setpoint indicator levels for the Aspiration, Irrigation, Amplitude, and Tissue Select® settings

Aspiration	100%
Irrigation	3 ml/min
Amplitude	10%
Tissue Select	Std

For more information on these settings, see Section 6: Using the Console Controls

3. Adjust the Amplitude, Irrigation, Aspiration, and Tissue Select settings to the surgeon's requirements.
4. Press the Status button to put the system into the Run mode (green light).

The CUSA Excel/CUSA Excel+ System must remain in Run mode for a minimum of two minutes (continuous) before it is ready for use; once the two minutes elapse, the system is ready for use. Vibration will activate when the surgeon presses the Vibration pedal on the footswitch.

5. Position the footswitch where it is easily accessible to the surgeon.
6. Position the CUSA Excel/CUSA Excel+ System so that the control panel is clearly visible to the surgeon at all times. Remove any obstructions that may block the surgeon's view of the control panel.

   To move the console in the operating room, push it by the handle only. For guidelines on moving the console within your Healthcare Facility, see Handling and Transporting of the System, page 15-4.

Caution

Before surgery, apply the brakes locks to all wheels on the console to stop the wheels from rolling.

Notice

During surgery, do not allow the handpiece tip to touch metal objects such as staples, clips, instruments, etc. Handpiece tip damage will result.

Warnings Relating to Tip Usage During Surgery

Warning

Touching of the tip of the handpiece by the operator, while the handpiece is powered on, can result in personal injury.

Warning

When the handpiece is powered on, contact of the tip with a hard surface (e.g. a metal instrument, tray, staples, clips, instruments, etc) may damage the tip of the handpiece and require replacement before use.

Warning

CUSA Excel tips utilize silicone flues. Compressing the flue against the side of the vibrating surface along the length of the tip can cause excessive heating and potential hazard to adjacent tissue, such as burns.

Warning

Excessive loading of CUSA Excel tips at the surgical site can induce heating due to vibration and acoustic power transmissions. Thermal management of the surgical site with the aid of the appropriate irrigation and aspiration settings is essential.

Warning

Avoid excessive lateral loading of CUSA Excel tips.

Warning

Avoid contacting bone with the CUSA Excel tips (excluding SaberTip™).

Notes

SECTION 6

Using the Console Controls

In this section:

For Your Information

This section describes how to use the buttons and indicators on the control panel. It also describes how to use some of the mechanical features on the CUSA® Excel/CUSA® Excel+ Ultrasonic Surgical Aspirator System console.

Adjusting Setpoint Values

Press the up/down buttons at the bottom of the display to adjust the setpoint value. Green setpoint indicators illuminate to show the adjusted setpoint value indicating that the system is ready for use at that value. You can adjust setpoint values when the:

- System is in Standby status
- System is in Run status
- Surgeon presses the Vibration footswitch pedal

Aspiration 

Aspiration

The aspiration display includes 10 settings, ranging from 10 to 100% of available suction (up to 660 mm mercury at sea level). The default setting is 100%. Green up/down arrows mark the aspiration adjustment buttons.

Irrigation 

Irrigation

The irrigation display includes 10 settings. The irrigation rate ranges from 1 ml/min to 10 ml/min. The default setting is 3 ml/min. Blue up/down arrows mark the irrigation adjustment buttons.

Amplitude 

Amplitude

The amplitude display includes 10 settings, from 10 to 100% of the total amplitude (distance traveled by the tip as it vibrates) available for the handpiece.The default setting is 10%. Most surgical procedures require a higher setting. Orange up/down arrows mark the amplitude adjustment buttons.

The setpoint indicators in the amplitude display show real-time feedback from the system about the tip performance. The number of setpoint indicators lit shows the tip performance at any given time.

Tissue Select®

This display includes 5 settings, ranging from Std to ++++. These settings indicate the tissue selectivity at the handpiece tip. The highest setting (++++) makes the tip most selective. The default setting is Std (Standard). For more information on the Tissue Select feature and its settings, see Using the Tissue Select Feature, page 6-4. Yellow up/down arrows mark the Tissue Select adjustment buttons.

Changing Functions

When starting the CUSA Excel/CUSA Excel+ System, switch to Run status by pressing the green Status button.

Run → ▷ **Run Status**

To select the Run status, press the Status button. The system changes from Standby to Run, turning off the orange status indicator for Standby and turning on the green status indicator for Run.

The CUSA Excel/CUSA Excel+ System must remain in Run mode for a minimum of two minutes (continuous) before it is ready for use; once the two minutes elapse, the system is ready for use. Note that this is applicable each time the system changes from Standby to Run mode.

To activate the handpiece, press the Vibration (right) pedal on the footswitch. The tip vibrates.To stop vibration, release the pedal.

Lap On ● **Laparoscopic Mode**

In the laparoscopic (Lap) mode, the system provides suction and irrigation only when it provides vibration. When the surgeon activates vibration by stepping on the footswitch, the system opens the suction pinch valve. When the surgeon releases the footswitch, the system stops vibration, closes the suction pinch valve, and stops irrigation. This feature reduces the potential for evacuating the pneumoperitoneum.

To select the laparoscopic mode, press the Lap button. The system lights the Lap indicator (green status indicator below the Lap button).

To turn off the laparoscopic mode, press the Lap button again.

Fast Flush

Fast Flush increases irrigation rate from the setpoint value to greater than 25 ml/min to allow additional irrigation at the surgical site. When the surgeon activates Fast Flush, the system illuminates all setpoint indicators in the Irrigation display to show the higher rate. When the surgeon releases the pedal, the system returns the setpoint indicator display to the setpoint value.

To activate Fast Flush, press the Fast Flush (left) pedal on the footswitch.

To stop Fast Flush, release the pedal.

Quiet Function

When the surgeon has not pressed either footswitch pedal for at least four minutes, the system changes to a Quiet Function. In the Quiet Function, the irrigation and suction pumps run at reduced speed and the machine is quieter.

As soon as the surgeon presses either pedal, or the operator presses a control panel button, the system returns to normal operation.

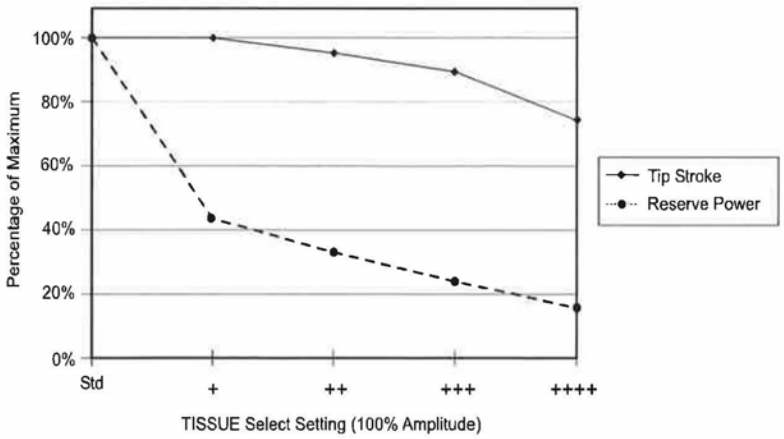
Using the Tissue Select Feature

The Tissue Select feature increases both the inherent selectivity and the tactile feedback of the vibrating tip by reducing the reserve power the ultrasonic generator provides to the handpiece.

One of the variables of power consumption is time: reduce time, reduce power consumed. To reduce power consumption, the ultrasonic generator reduces the time that it provides electrical power. Specifically, rather than providing power continuously, it provides power at measured on-off intervals:

Setting	Fragmentation Rate
Std	Maximum power
+	Slightly decreased tissue removal rate, increased tissue selectivity and tactile feedback
++ and +++	Further decreased tissue removal rate, increased tissue selectivity and tactile feedback
++++	slowest tissue removal rate, maximum selectivity and tactile feedback

Power decreases as on-time decreases.



At a 100% Amplitude setting, as Tissue Select settings increase, on-time and reserve power decrease.

The Tissue Select feature offers five settings from "std" (standard – least selective) to ++++ (most selective). The std setting selects continuous power, resulting in ample reserve power. The ++++ setting selects the least power.

Standard Operation

Power is continuous. The ultrasonic generator provides ample reserve power; more than is necessary to drive stroke amplitude under heavy load:

- The tip fragments "soft" tissue easily.
- The tip fragments "strong" tissue, but with more difficulty (slower, requires more surgeon pressure).

Tissue Select Operation

Power is interrupted. The ultrasonic generator provides less reserve power to the handpiece:

- The tip still fragments "soft" tissue easily.
- But, when it encounters "strong" tissue, the power the tip receives is no longer enough to fragment the tissue. The tip stalls.

At increased selectivity settings (+ to ++++), suction and the tip cross-sectional area remain the same, and stroke amplitude and tip acceleration decrease slightly:

Setting	Fragmentation Rate	On-Time	Off-Time
Std	Maximum tissue removal rate	Continuous	0 ms*
+ (Cavitation 1)	Slightly decreased tissue removal rate, increased tissue selectivity and tactile feedback	40 ms	10 ms
++ (Cavitation 2)	Further decreased tissue removal rate, increased tissue selectivity and tactile feedback	30 ms	10 ms
+++ (Cavitation 3)	Slow tissue removal rate, maximum selectivity and tactile feedback	20 ms	10 ms

Setting	Fragmentation Rate	On-Time	Off-Time
++++ (Cavitation 4)	Slowest tissue removal rate, maximum selectivity and tactile feedback	10 ms	10 ms

**1 ms = 1 millisecond = 1 one-thousandth of a second*

Note: The Tissue Select performance specifications are +/- 10% of setting.

Using Other Features

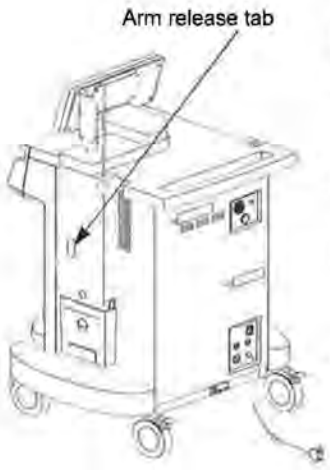
The CUSA Excel/CUSA Excel+ console offers other convenient features:

- Adjustable arm height
- Rotating control panel
- Adjustable audible tone (excluding the alarm tone)
- Adjustable IV pole

The next portion of this section describes how to use these features.

Raising/Lowering the Arm

It is possible to raise the arm that supports the control panel to improve ergonomics or to see the control panel more easily over obstacles. A locking mechanism holds the arm at one of three positions: normal (lowest position), 7.6 cm (2.992 in) above normal, and 15.2 cm (5.984 in) above normal.



To adjust the arm position:

1. With one hand, press the release tab (rectangular) on the arm housing to disengage the lock. Once you disengage the lock and begin to move the arm, it is not necessary to continue pressing the button.
2. With the other hand, grasp the arm and push gently up or down. A counterweight balances the arm, making it easy to raise or lower.
3. Continue to move the arm up or down until it reaches the next position at which the lock engages. You will feel and hear the arm click into place in the locked position.
4. To move the arm to another position, press the release tab again and continue to gently move the arm.

Rotating the Control Panel

The control panel rotates and locks into one of four positions:

- Straight forward
- 45° right
- 45° left
- 90° left

To rotate the control panel from one position to another:

1. Grasp the release handle located under the control panel, and pull the handle toward the front of the console.
2. While holding the handle in this position, rotate the control panel out of its previous position, then release the handle.
3. Continue to rotate the control panel. At its next locking position, it will automatically lock into place.

Adjusting the Tone Volume

The CUSA Excel/CUSA Excel+ System includes an audible tone that sounds in two circumstances:

- When you press the Ultrasonics pedal on the footswitch to activate tip vibration
- When an alarm activates

Ultrasonics Tone

This tone (constant) sounds when you press the Ultrasonics pedal on the footswitch. You can adjust its volume.

To adjust tone volume, rotate the stem on the volume control potentiometer located just above and to the right of the footswitch connector receptacle on the console rear panel:

- Volume up – clockwise
- Volume down – counter-clockwise

Note: At its lowest volume, the ultrasonics tone is barely audible. You cannot turn off the ultrasonics tone.

Alarm Tone

This tone (on/off) sounds when an alarm activates. You cannot adjust the volume of the alarm tones. The alarm tone is less than 80dB.

Adjusting the IV Pole

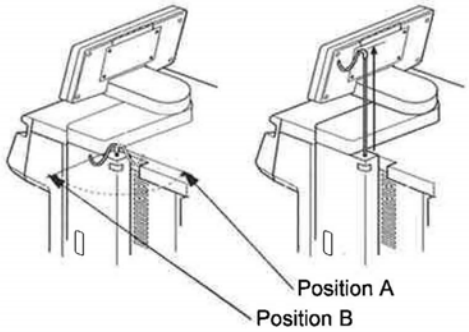
The IV pole, located at the top rear of the arm housing, adjusts to two locking positions: down or up. A spring-loaded locking pin slides into a recessed area on the pole to serve as a lock on the pole's up/down motion. A button, located just under the opening in which the pole rests in the arm housing, releases the locking pin.

When in the down position, the pole also rotates approximately 90° allowing two positions:

- Parallel to the console side (position A)
- At a right angle to the side (position B).

When in the up position, the pole does not rotate. It remains at position B. Notice that the IV bag does not hang over the console.

When the unit is shipped, the IV pole is in position A.



Raise the Pole

To raise the IV pole:

▶ ***Important***
Do not try to raise the pole from Position A. Do not try to rotate the pole when it is in the upper position.

1. Grasp the pole and rotate it to position B.
2. With one hand, hold the pole; with the other hand, press the button to release the locking pin.
3. Raise the pole. As the pole clears its lower locking position, release the button.
4. Continue to move the pole upward until it locks into position.

Lower the Pole

To lower the IV pole:

5. With one hand, hold the pole; with the other hand, press the button to release the locking pin.
6. Gently lower the pole. As the pole clears its upper locking position, release the button.
7. Continue to move the pole downward until it locks into position.
8. After the pole has locked into its lower position, you can rotate it to position A.

SECTION 7

Handpiece Components

In this section:

For Your Information

This section presents the items that compose an assembled handpiece for the CUSA® Excel/CUSA® Excel+ Ultrasonic Surgical Aspirator System, their physical characteristics, and functions.

This section also presents items that, although not a part of the handpiece itself, are essential in assembling a handpiece or preparing it for sterilization.

Components of Assembled Handpieces

The following figure shows the items that comprise a handpiece.

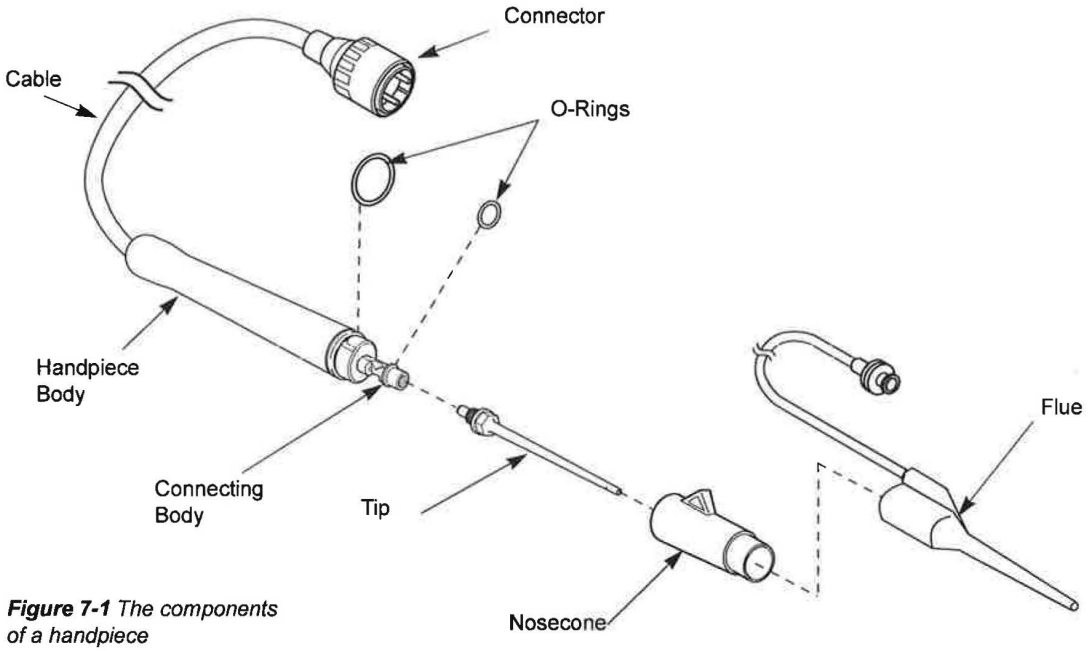


Figure 7-1 *The components of a handpiece*

Handpiece

The handpiece consists of a connector, a cable, a handpiece body, and a connecting body (see Figure 7-1). The connector attaches the cable to the CUSA Excel/CUSA Excel+ console. The cable contains:

- Cooling water tubes (deliver water from the console to cool the handpiece)
- Electric wires (deliver electric power from console to drive the handpiece)

The handpiece body contains these working items:

- An electric coil, which creates a magnetic field that excites the transducer
- A transducer, which converts electric energy to mechanical motion
- Cooling water tubes; the water removes the heat generated by the transducer in the energy conversion

The connecting body serves as the connecting point for the tip and transfers the vibrations from the transducer to the tip.

Remember:

- The 23 kHz handpieces are gray with green connectors

- The 36 kHz handpiece is black with a blue connector

O-Rings

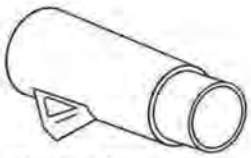
The o-rings fit onto the connecting body in two places:

- A large o-ring fits into a groove on the handpiece housing neck
- A smaller o-ring fits into a groove near the tip end of the connecting body

The o-rings provide stability for the nosecone and prevent fluid leaks into the connecting body.

Use different colored o-rings for different frequency handpieces:

	23 kHz	36 kHz
Large o-ring	black	white
Small o-ring	green	blue



Standard Nosecone

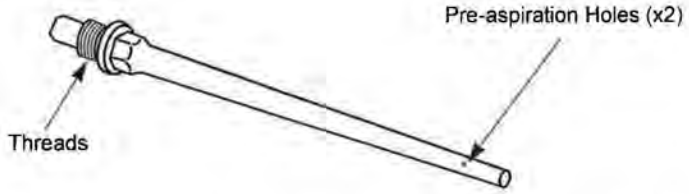
Nosecone

The nosecone attaches to the handpiece and covers the connecting body. The standard nosecone is nonsterile and reusable. It serves two purposes:

- Holds the flue in place
- Anchors the suction tube

Tip

The tip, a hollow titanium tube, touches patient tissue. When active, the tip vibrates at an ultrasonic frequency, causing it to fragment tissue.



The tip has two patented pre-aspiration holes, one on either side, which help to keep the tip clear and provide better visibility at the surgical site.

Threads on one end allow you to attach the tip to the connecting body on the handpiece.

For more information on various tip diameters and lengths, see Appendix A, *Technical Specifications*, in this guide.

Flue

The flue (see Figure 7-1), a translucent silicone tube tapered at one end, provides a sleeve over the tip. Irrigation fluid flows through an irrigation connection tube at one end of the flue and down the tip to the surgical site.

Each tip size requires a tip-specific flue; therefore, you will find the tip-specific flue packaged with the appropriate tip.

Manifold Tubing

The manifold tubing (silicone) consists of two tubes:

- Suction tubing – one end (with a light green fitting) connects to a suction canister on the console and passes through the suction pinch valve; the other end connects to the suction port on the handpiece nosecone.
- Irrigation tubing – one end connects to a standard IV set at the console and passes through the irrigation pump; the other end connects to the flue.

The manifold tubing set also includes clips (not shown) that attach the manifold tubing to the handpiece cable.

Manifold tubing is sterile, single patient use only. You can resterilize unused manifold tubing once. You have two options for attaching the tubing to the handpiece:

- Attach the manifold tubing before sterilization
- Attach the manifold tubing in the sterile field

Whether you attach the manifold tubing before or after sterilization, discard the tubing after one use.

Warning

Single Use devices are for single patient use only. Do not reprocess or re-use. Devices (s) is (are) intended to be used for one procedure only. If reprocessed or re-used may result in the infection of patient (or patient specimen) through cross-contamination, as well as would incur the risk of modifying the properties and performance of the device, and of increasing the likelihood of complications and/or undesirable effects. Once used, devices must be disposed of in accordance with hospital policies.

Additional Handpiece Components

This section presents components that are essential in assembling a handpiece or preparing it for sterilization.

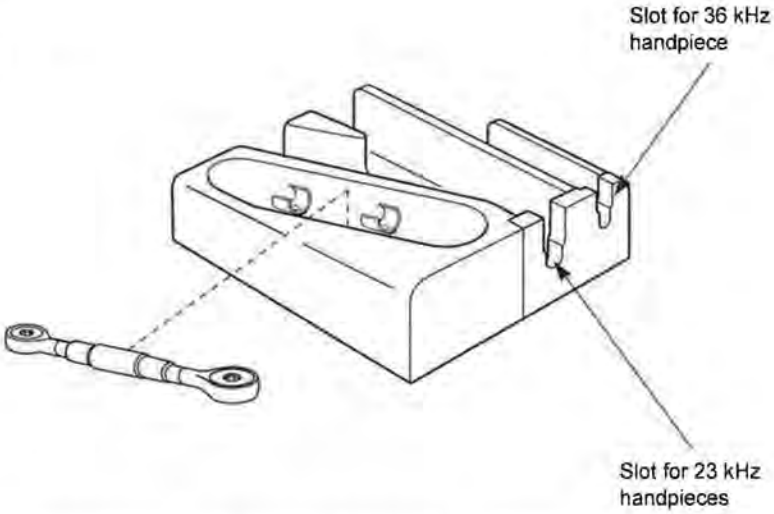
Nonsterile Tip Torquing Base and Torque Wrench

Use this set only if you are changing tips in the nonsterile field.

The tip torquing base holds the handpiece securely in place while you use the torque wrench to attach or remove a tip. The base contains a slot for each handpiece.

The double-headed wrench provides tip torquing and tip removal. The opening at one end fits 23 kHz tips; at the other end, 36 kHz tips.

Figure 7-2 *Tip torquing base and torque wrench for use when changing tips in the nonsterile field*



Color coding in the tip torquing base slots, on the ends of the torque wrench, and on each handpiece connector makes it easy to determine where to put the handpiece in the base and which end of the torque wrench to use when attaching a tip to a handpiece.

23 kHz	green
36 kHz	blue

Notice

Do not sterilize the tip torquing base or the torque wrench with steam. Steam destroys the lubrication in the torquing mechanism, resulting in product damage.

Sterilizable Torque Bases

Use sterilizable torque bases if you are changing tips in the sterile field.

The sterilizable torque bases hold the handpiece securely in place while you use a torque wrench to attach or remove a tip. Two bases are available:

- 23 kHz – This base contains two slots, one for the straight handpiece and one for the angled handpiece.
- 36 kHz - This base contains a single slot for the handpiece.

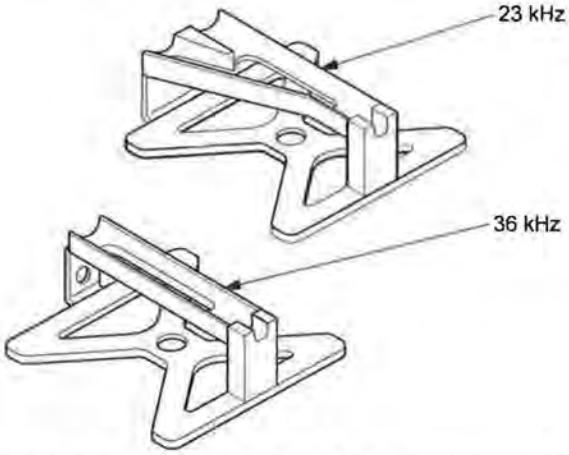


Figure 7-3 *The sterilizable torque bases for use when changing tips in the sterile field*

Sterilize the torque bases with steam. To hold the torque bases in position in the sterilizer case, install the restraining devices in the sterilizer case. These restraining devices comprise of pegs that snap into the tray and silicone straps that hold the bases to the pegs, and they are packaged with the torque bases.

Sterile Torque Wrenches

Use a sterile torque wrench if you are changing tips in the sterile field.

The sterile wrenches provide tip torquing and tip removal. You can use one sterile wrench to remove and re-install as many as five tips in one surgical procedure.

Warning

Do not use the sterile wrench for more than one surgical procedure.

Two sterile wrenches are available: 23 kHz and 36 kHz.

Figure 7-4 *The sterile torque wrench for use when changing tips in the sterile field*

Sterilizable torque bases and sterile wrenches bear the same color coding as other CUSA Excel/CUSA Excel+ System components:

23 kHz	green
36 kHz	blue

Sterilizer Cases

The sterilizer cases hold the handpiece and accessories during sterilization.

There are separate sterilizer cases for each handpiece:23 kHz (gray case) and 36 kHz (white case). The dimensions for both cases are:

- length – 54.6 cm (21.5 in.)
- width – 25.4 cm (10 in.)
- depth – 12.7 cm (5 in.)

The sterilizer case may be wrapped in hospital approved materials.

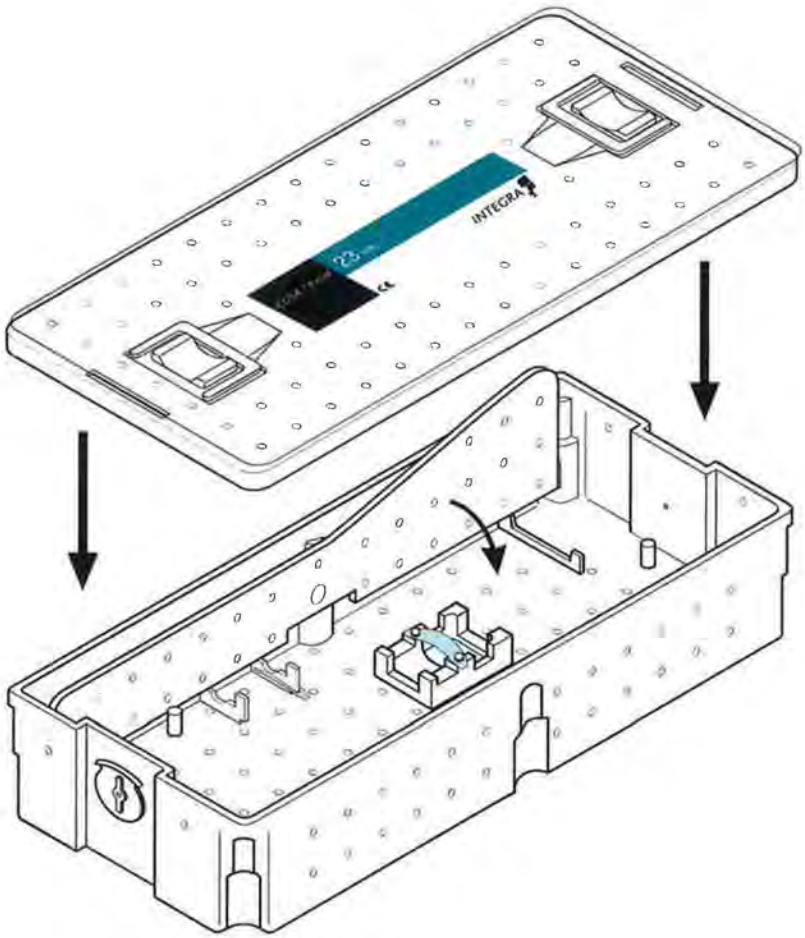


Figure 7-5 *The 23 kHz CUSA Excel/CUSA Excel+ handpiece sterilizer case*

SECTION 8

Assembling the Handpiece in a Nonsterile Area

In this section:

For Your Information

You have two options:

1. NOT Changing Tips in the Sterile Field – If assembling the tip to the handpiece in a nonsterile area before sterilization, see the following instructions in this User's Guide:
   - *Section 8: Assembling the Handpiece in a Nonsterile Area*
   - *Section 9: Sterilizing Handpieces and Accessoriess*
   - *Section 10: Completing Handpiece Setup in the Sterile Field*
2. Assembling or Changing Tips in the Sterile Field – For instructions on how to assemble and disassemble the handpiece as part of changing tips in the sterile field, refer to *Section 11: Assembling or Changing Tips in the Sterile Field*.

- Important notes: Use the same procedure to assemble the 23 kHz straight, 23 kHz angled, and 36 kHz straight handpieces.

- Handpiece cable connectors, tip pack packaging, manifold tubing packaging, nosecone packaging, slots in the tip torquing base, torque wrench heads, and sterilizer tray lids are color coded:

23 kHz	green
36 kHz	blue

- Recommended: When you assemble a handpiece, assemble at least one backup handpiece.

Items Needed for Handpiece Assembly

The following figures illustrate the items you need to assemble the handpiece. The tip, o-rings, and flue are part of tip packs.

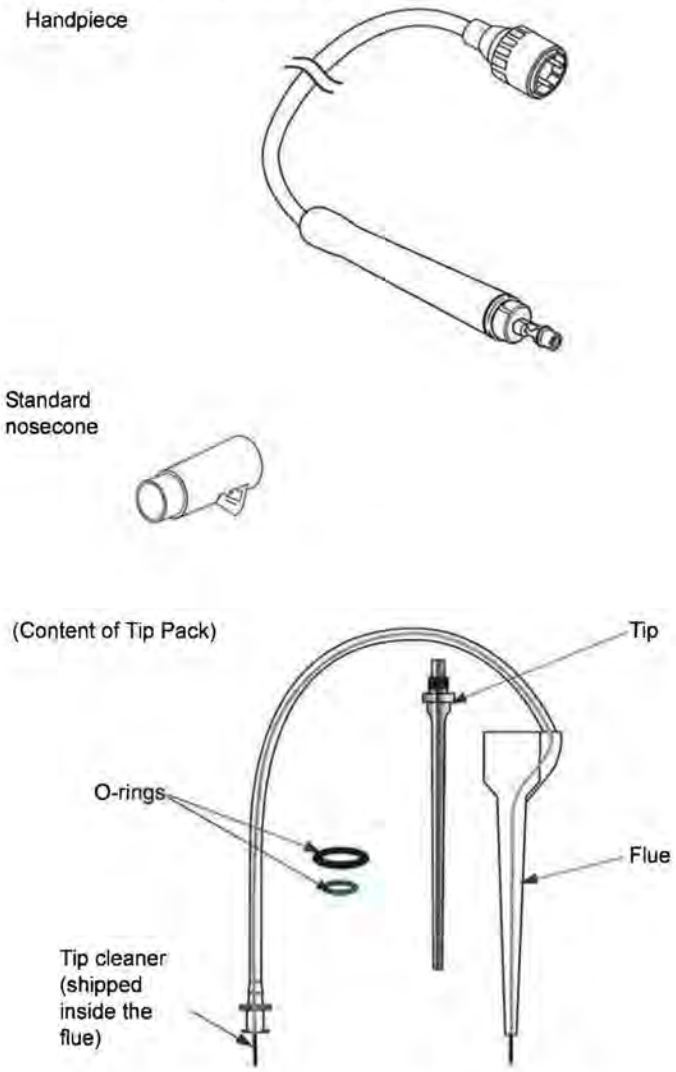
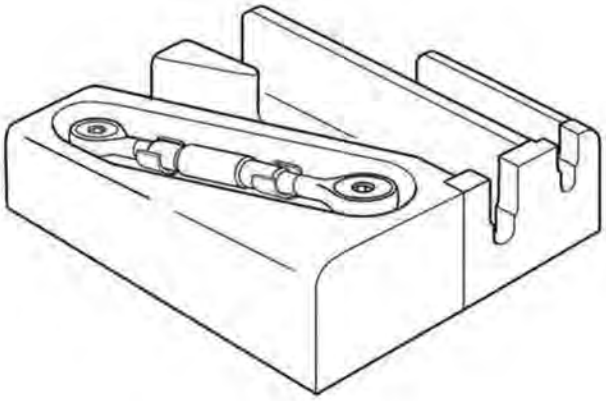


Figure 8-1 *The items you need to assemble a handpiece: handpiece, nosecone, and tip pack*

Figure 8-2 *Tip torquing base and torque wrench (for use in non-sterile field)*

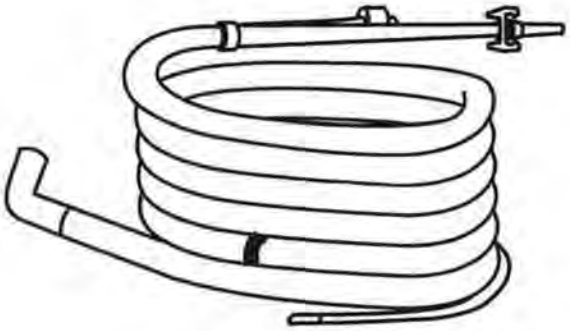


You also need a tip torquing base and torque wrench to assemble a handpiece.

Manifold tubing is sterile, single use only. Discard the manifold tubing after one use. You have two options for attaching the tubing to the handpiece:

- Attach the manifold tubing before sterilization
- Attach the manifold tubing in the sterile field

Figure 8-3 *Manifold tubing*

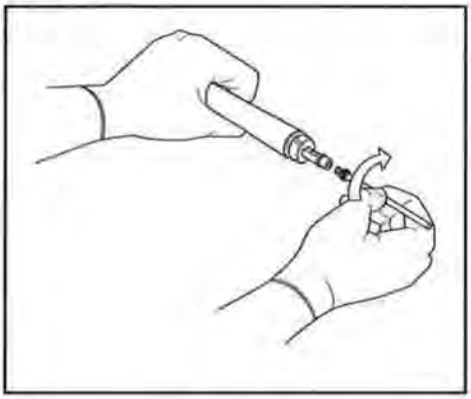


Warning

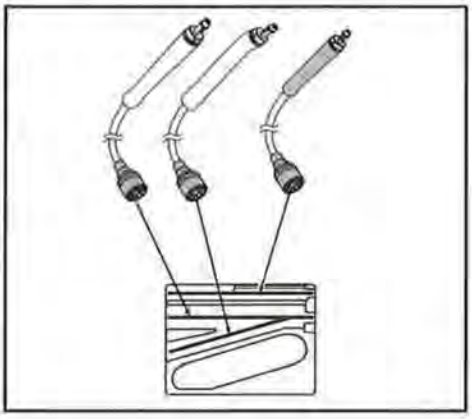
Single Use devices are for single patient use only. Do not reprocess or re-use. Devices (s) is (are) intended to be used for one procedure only. If reprocessed or re-used this may result in the infection of patient (or patient specimen) through cross-contamination, as well as would incur the risk of modifying the properties and performance of the device, and of increasing the likelihood of complications and/or undesirable effects. Once used, devices must be disposed of in accordance with hospital policies.

Attaching the Tip to the Connecting Body

1. Thread the tip of choice onto the handpiece connecting body. Turn the tip until it is finger tight.



2. Locate the slot in the tip torquing base that matches the color on the handpiece connector (23 kHz – green; 36 kHz – blue). Put the handpiece in the tip torquing base so that the metal connecting body fits snugly in the metal end of the slot.

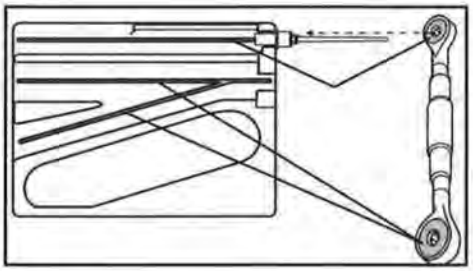


3. Hold the handpiece in place in the tip torquing base.

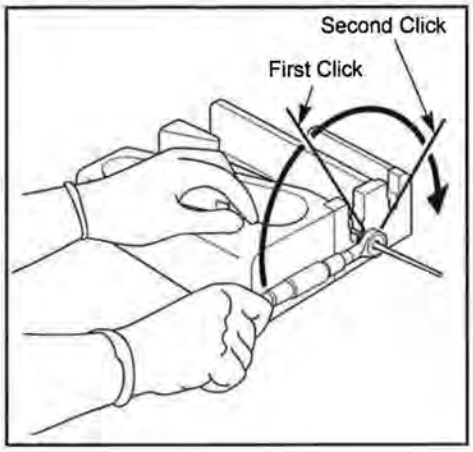
Caution

To avoid product damage, NEVER hold the handpiece in your hand while using the torque wrench to tighten or loosen the tip.

4. Match the colored end of the torque wrench with the handpiece color. Slide the color coded side of the wrench over the tip, being careful not to damage the tip, until the hex in the wrench engages the hex of the tip.



5. Rotate the wrench clockwise until you feel and hear a click. Rotate again until you feel and hear a second click.



Warning

Turning the torque wrench further clockwise will damage the handpiece.

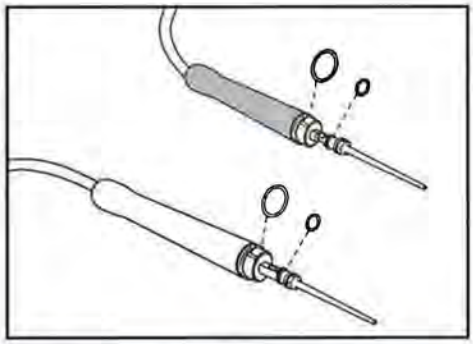
6. Remove the wrench from the tip.
7. Remove the handpiece from the tip torquing base.

Putting On the O-Rings

1. Locate the o-rings for the handpiece you are assembling:

	23 kHz	36 kHz
Large o-ring	black	white
Small o-ring	green	blue

2. Slide the larger o-ring over the connecting body and into the groove in the neck of the handpiece. Slide the smaller o-ring into the groove in the metal connecting body.



Caution

Do not assemble the nosecone to the handpiece until both the handpiece and nosecone are sterile.

Clipping the Manifold Tubing to the Handpiece Cable (Optional)

Manifold tubing is sterile, single patient use only. You can sterilize unused manifold tubing once. You have two options for attaching the tubing to the handpiece:

- Attach the manifold tubing before sterilization
- Attach the manifold tubing in the sterile field

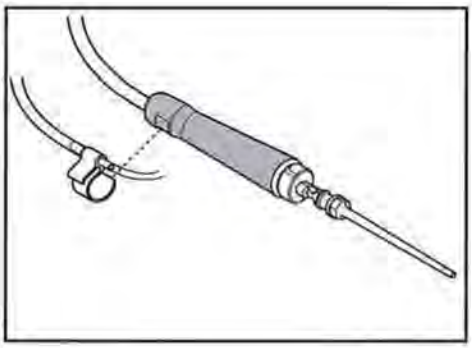
Whether you attach the tubing before or after sterilization, discard it after one use.

Warning

Single Use devices are for single patient use only. Do not reprocess or re-use. Devices (s) is (are) intended to be used for one procedure only. If reprocessed or re-used this may result in the infection of patient (or patient specimen) through cross-contamination, as well as would incur the risk of modifying the properties and performance of the device, and of increasing the likelihood of complications and/or undesirable effects. Once used, devices must be disposed of in accordance with hospital policies.

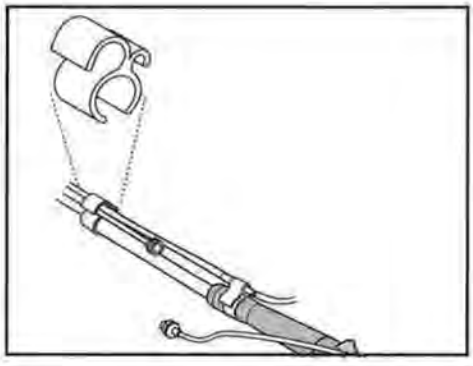
If you decide to clip the manifold tubing onto the handpiece cable before sterilization, follow this procedure:

1. Remove the manifold tubing with clips from the packaging. Uncoil the tubing.
2. Snap the handpiece clip in place on the handpiece housing.



3. Push one to three manifold tubing clips onto the handpiece cable.

   Note: It is only necessary to attach one to three clips, but you can attach all five clips in the package.



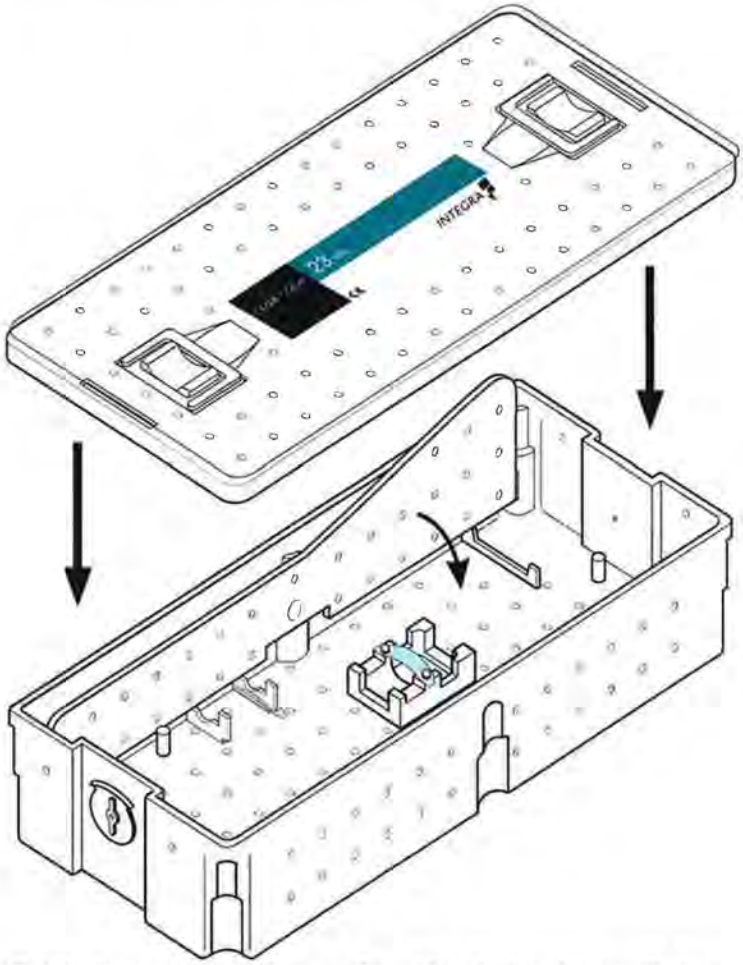
Packaging the Handpiece for Sterilization

After you have assembled the handpiece, prepare it for sterilization. Integra provides sterilizer cases for steam sterilization of the CUSA® Excel/CUSA® Excel+ System handpieces. These cases protect the handpieces during sterilization and during transfer to the sterile field. The case for the 23 kHz handpiece is gray; for the 36 kHz handpiece, white.

Items Needed

You will need the sterilizer case provided by Integra.

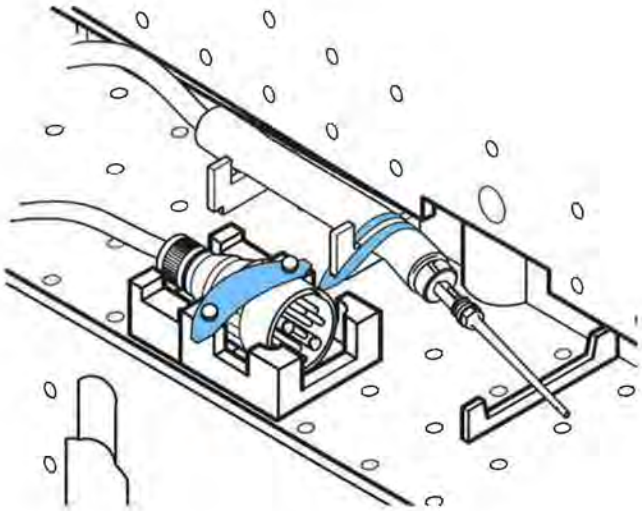
Figure 8-4 *The sterilizer case*



1. Put the handpiece into the case first. Align the handpiece with the outline on the case bottom. Secure the handpiece with the silicone strap.
2. Place the nosecone and flue with the tip cleaner in the handpiece compartment.
3. Close the protective cover over the handpiece.

4. Coil the cable and manifold tubing (if attached) around the inside of the case.
5. Put the handpiece connector in the center compartment and secure it in place.
6. Put on the lid. Close and latch the case.

Figure 8-5 *The handpiece and connector secured into the sterilizer tray*



SECTION 9

Sterilizing Handpieces and Accessories

In this section:

For Your Information

After preparing the handpiece, sterilize it using steam. This section describes the steam sterilization parameters.

Sterilization Parameters

Sterilize CUSA® Excel/CUSA® Excel+ handpieces and accessories with steam. Sterilizing manifold tubing with the handpiece increases the required sterilization times. For information on preparing the handpiece for sterilization, see Packaging the Handpiece for Sterilization, page 11-17.

The CUSA Excel family of tips, manifold tubing sets, reusable nosecones, sterilizer trays and sterilizable torque bases have been validated for steam sterilization under pre-vacuum at 132 °C (270 °F) for 3 minutes. This cycle validates sterility for all cycles that are at the same or higher temperatures, up to a maximum of 138 °C (280 °F), **and** at the same or longer exposure times.The following tables provide the minimum parameters:

Packaging

Wrapped: Sterilizer case double wrapped in hospital CSR material.

Flash: Sterilizer case unwrapped.

Handpieces without Manifold Tubing

Packaging	Temp	Type	Time	Dry Cycle
Wrapped	132°C or 270°F	Prevac	4 min	20 min
Flash (Unwrapped)	132°C or 270°F	Prevac	4 min	none

Handpieces with Manifold Tubing Attached

Packaging	Temp	Type	Time	Dry Cycle
Wrapped	132°C or 270°F	Prevac	4 min	20 min
Flash (Unwrapped)	132°C or 270°F	Prevac	4 min	none

For information on the validation procedure for the steam sterilization parameters defined here, see Validation of Steam Sterilization Parameters, page B-1.

Sterilizing the Handpiece with Steam

Sterilizing the handpiece with steam depends on the following factors:

- Temperature
- Exposure time
- Population and resistance of resident bioburden
- Method of air removal from the autoclave (high vacuum versus gravity displacement)

Use the validated steam sterilization cycle parameters in these instructions. If you deviate from this recommended method of sterilizing, it is your Health Care Facility's responsibility to validate the deviations.

For sterilizing the handpiece with steam, do not exceed 138° C (280°F).

After steam sterilization, the handpiece cable may appear collapsed. This is normal. The cable regains its shape in about one hour. This does not affect the handpiece performance or safety.

Notes

SECTION 10

Completing Handpiece Setup in the Sterile Field

In this section:

For Your Information

This section describes how to complete the handpiece setup in the sterile field. It begins with the arrival of the sterilized handpiece and accessories in the operating room. It ends with the handpiece ready to be connected to the console.

Notice

Retaining a spare handpiece in the sterile field is highly recommended.

Quick Reference – Setup

Use this list if you are a knowledgeable user who needs only a reminder of the steps to set up the CUSA® Excel/CUSA® Excel+ System.

Handpiece Assembly

1. Attach a standard nosecone onto the handpiece.
2. Attach the flue.
3. Attach the sterile manifold tubing (if not attached before sterilization).
4. Attach the aspiration and irrigation tubes at the handpiece.

Completing the Handpiece Assembly

You have the option of attaching manifold tubing to the handpiece cable before or after sterilization. If you chose to attach the tubing after sterilization, you must attach it in the sterile field.

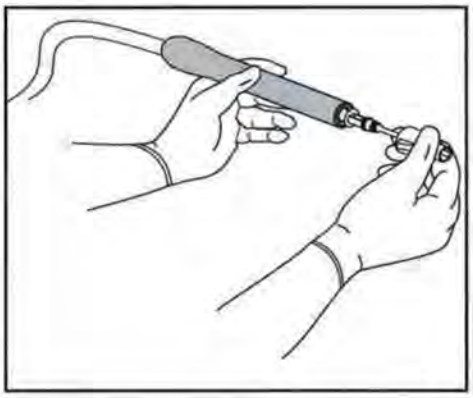
Items Needed

You need the following items to set up the handpiece for surgery:

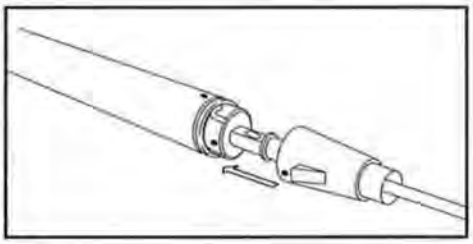
- Standard nosecone
- Flue
- Manifold tubing

Attach a Nosecone

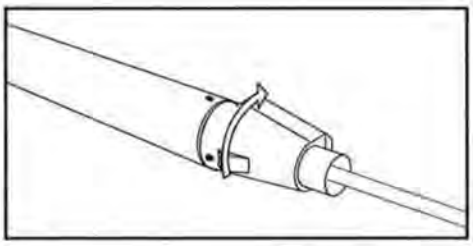
1. Attach a standard nosecone. Holding the handpiece, insert the tip into the nosecone.



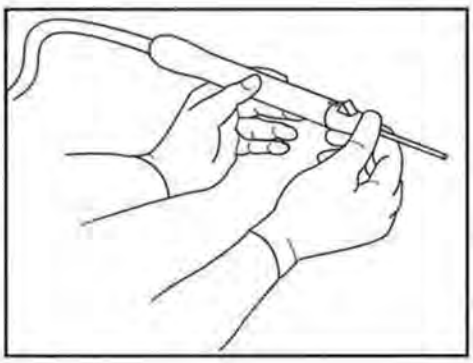
2. Align the dot on the nosecone with the dot on the neck of the handpiece.
3. Push the nosecone onto the handpiece so that the dots are on top of each other.



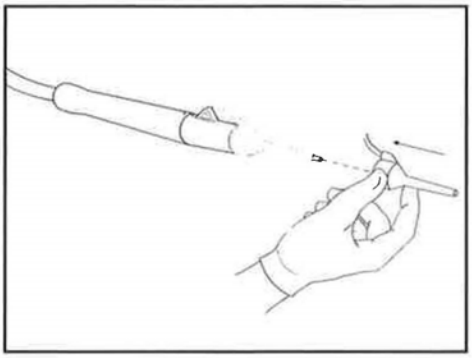
4. Twist the nosecone clockwise until it locks into place.



5. The dot on the nosecone must now align with the dot on the handpiece.



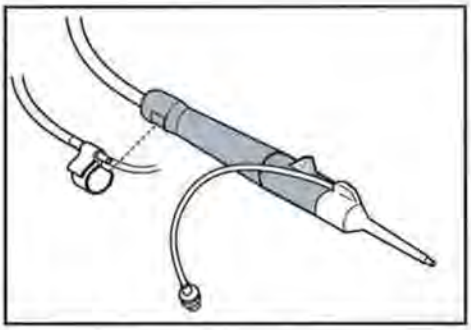
6. Remove the tip cleaner, and slide the flue that corresponds to the selected tip over the tip and onto the nosecone. Make sure to push the flue base completely over the nosecone base, and that the end of the flue lines up with the pre-aspiration holes.



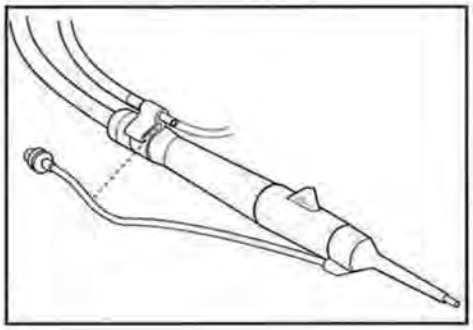
Clip the Manifold Tubing to the Handpiece Cable

If you receive the sterilized handpiece without the manifold tubing already clipped onto the handpiece cable, you must attach the manifold tubing now. Follow this procedure:

1. Remove the manifold tubing with clips from the packaging. Uncoil some of the tubing.
2. Snap the handpiece clip in place on the handpiece housing.



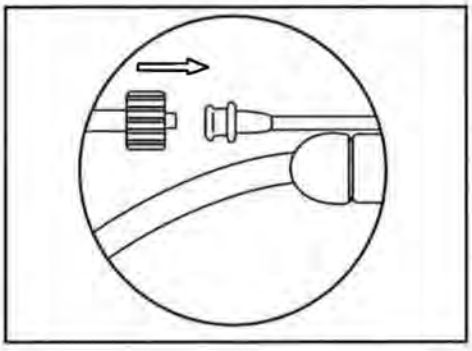
3. Insert the irrigation tube from the flue into the handpiece clip.



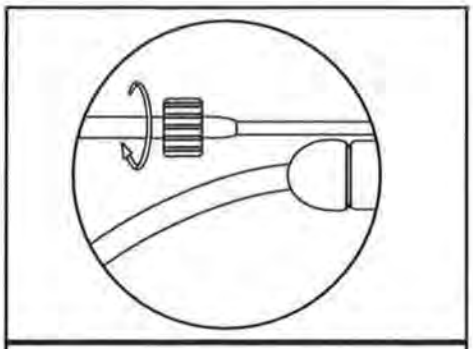
4. Connect the manifold irrigation tubing to the Luer fitting on the handpiece flue:

   (Viewed from rear)

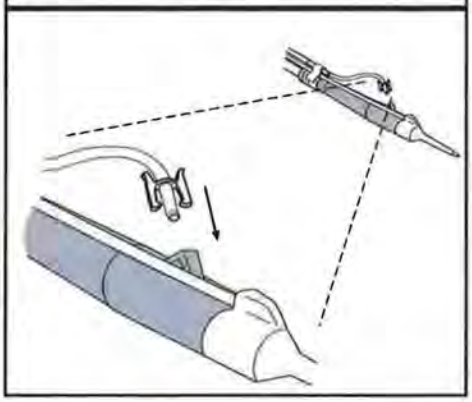
   a. Connect the Luer fitting.



b. Twist the knob clockwise to lock the fitting.

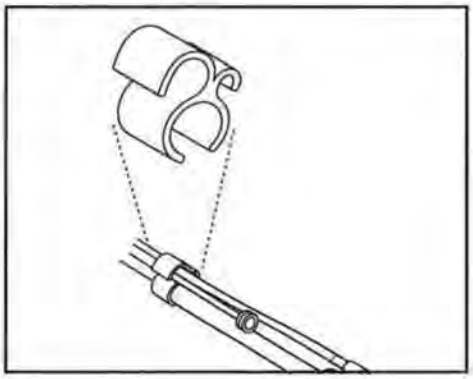


5. Connect the manifold suction tubing and clip to the suction port in the nosecone.



6. Push one to three manifold tubing clips onto the handpiece cable.

   Note: It is only necessary to attach one to three clips, but you can attach all five clips in the package.



7. Hand off the remaining manifold tubing, handpiece cable, and handpiece electrical connector to the circulator.

SECTION 11

Assembling or Changing Tips in the Sterile Field

In this section:

For Your Information

You have two options:

1. Assembling or Changing Tips in the Sterile Field – This section explains how to assemble and disassemble the handpiece as part of changing tips in the sterile field.
2. NOT Changing Tips in the Sterile Field – If assembling the tip to the handpiece in a nonsterile area before sterilization, see the following instructions:
   - *Section 8: Assembling the Handpiece in a Nonsterile Area*

- *Section 9: Sterilizing Handpieces and Accessoriess*
- *Section 10: Completing Handpiece Setup in the Sterile Field*

Important notes:

- Use the same procedure to assemble the 23kHz straight, 23kHz angled, and 36kHz handpieces
- Handpiece cable connectors, manifold tubing packaging, tip/flue packaging, nosecone packaging, slots in the tip torquing bases, and sterile torque wrenches are color coded:

23kHz	green
36kHz	blue

- Recommended: When you assemble a handpiece, assemble at least one backup handpiece.

Items Needed to Change Tip in Sterile Field

You need the following items to change tips in the sterile field:

- Sterilized handpiece(s)
- Sterilized standard nosecone
- Sterile tip/flue pack(s) or sterilized extended life tips and flues
- Sterilized tip torquing base
- Sterile torque wrench (23 kHz or 36 kHz)
- Sterile manifold tubing

The following figures illustrate these items.

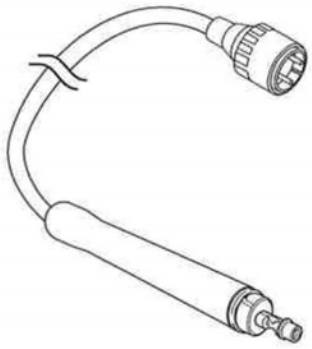


Figure 11-1 *The sterilized handpiece*

Figure 11-2 *The sterilized standard nosecone*

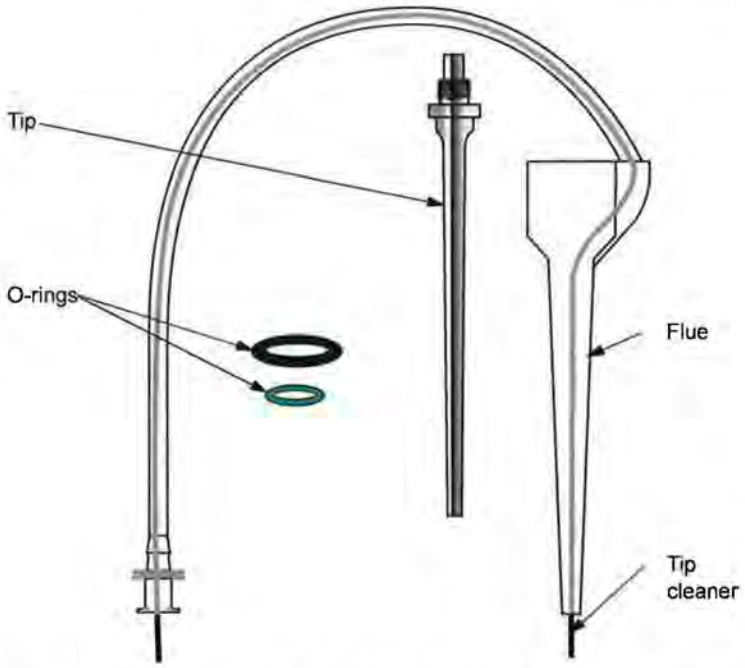
The contents of sterile tip/flue packs are sterile, single use only. You can resterilize unused tips and flues once.

The contents of extended life tip/flue packs are nonsterile. You can use them six times. If you use extended life tips and intend to attach the tip in the sterile field, ensure tips and flues are sterile before they are introduced to the sterile field.

You have two options for attaching tips to the handpiece:

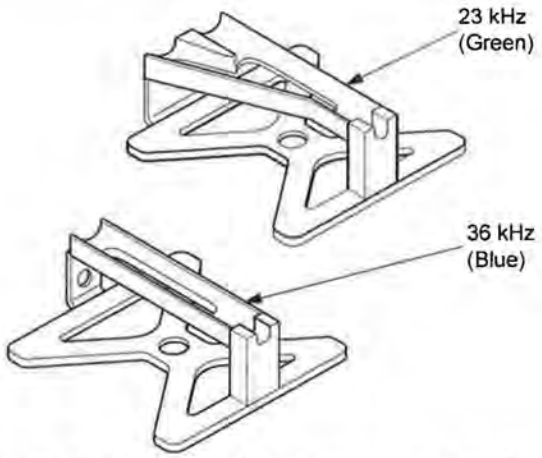
- Attach the tip in the sterile field
- Attach the tip before sterilizing the handpiece (If you use this option, do not change tips in the sterile field because the area under the tip threads will not be sterile)

Figure 11-3 *Sterile tip/flue pack contents. The tip cleaner is inside the flue.*



Steam sterilize the tip torquing base before each surgical procedure in which you change tips in the sterile field.

Figure 11-4 *Sterilizable tip torquing base*



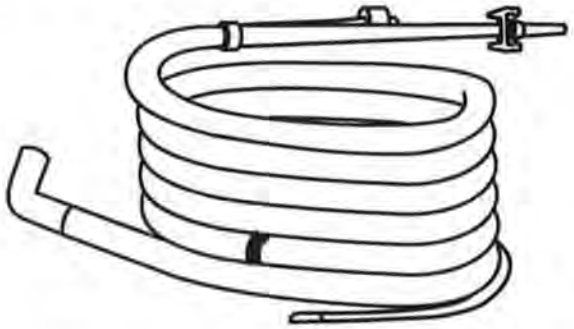
You can use the sterile torque wrench to change as many as five tips in one surgical procedure. Do not use the sterile torque wrench in more than one surgical procedure. Do not sterilize the sterile torque wrench; dispose of the used sterile torque wrench in accordance with your Healthcare Facility protocols.

Figure 11-5 *Sterile torque wrench (23 kHz or 36 kHz)*

Manifold tubing is sterile, single patient use only. You can resterilize unused manifold tubing once. You have two options for attaching the tubing to the handpiece:

- Attach the manifold tubing in the sterile field
- Attach the manifold tubing before sterilizing the handpiece

Figure 11-6 *Sterile manifold tubing*



Warning

Single Use devices are for single patient use only. Do not reprocess or re-use. Devices (s) is (are) intended to be used for one procedure only. If reprocessed or re-used this may result in the infection of patient (or patient specimen) through cross-contamination, as well as would incur the risk of modifying the properties and performance of the device, and of increasing the likelihood of complications and/or undesirable effects. Once used, devices must be disposed of in accordance with hospital policies.

Assembling the Tip

For this procedure, use the sterile, disposable torque wrench (C5601 for 23 kHz or C5602 for 36 kHz) and the sterilizable torque base (C5623 for 23 kHz or C5636 for 36 kHz).

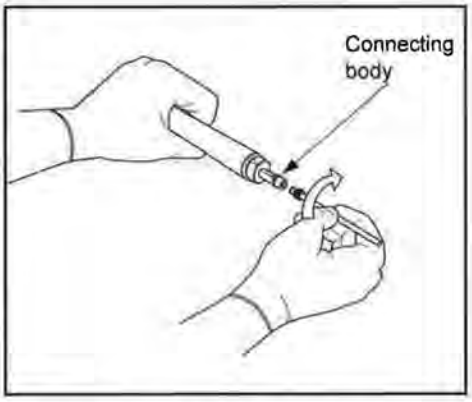
Warning

The handpiece and handpiece accessories must be sterile before surgical use.

Before use, sterilize the sterilizable torque base in the sterilizer tray with the handpiece.

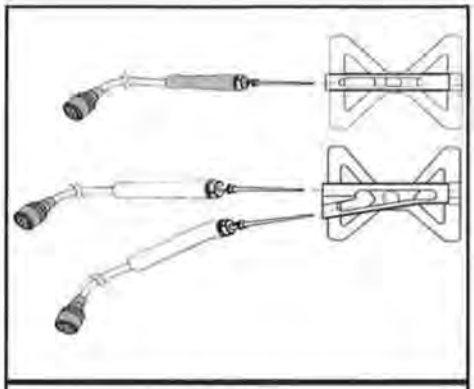
Attach the Tip and O-rings

1. Thread the tip of choice onto the handpiece connecting body. Turn the tip until it is finger tight.

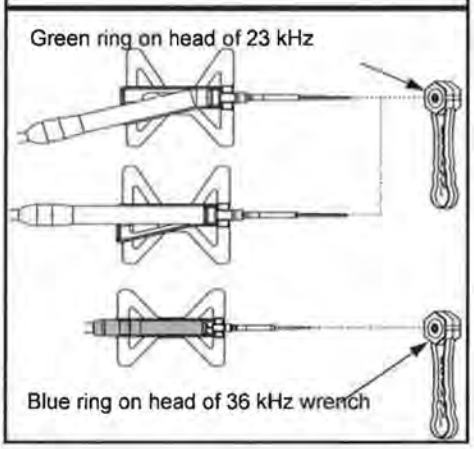


2. The sterilized torque base should be in the sterilizer tray. Verify that the handpiece support color on the torque base matches the color on the handpiece connector (23 kHz – green; 36 kHz – blue). Remove the sterilized torque base from the sterilizer tray.

3. Put the handpiece in the torque base so that the metal connecting body fits snugly in the metal slot at the end of the support.



4. Match the colored ring on the sterile torque wrench with the handpiece connector color or handpiece support color on the torque base. Slide the color coded side of the wrench over the tip, being careful not to damage the tip, until the hex in the wrench engages the hex of the tip.

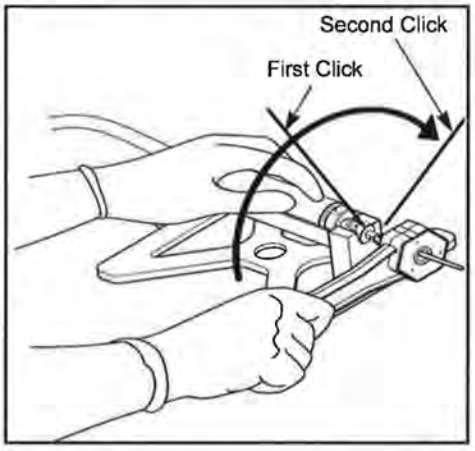


5. Hold the handpiece in place in the tip torquing base.

Caution

To avoid product damage, NEVER hold the handpiece in your hand while using the torque wrench to tighten or loosen the tip.

6. Rotate the wrench clockwise until you feel and hear one click. Rotate again until you feel and hear a second click.



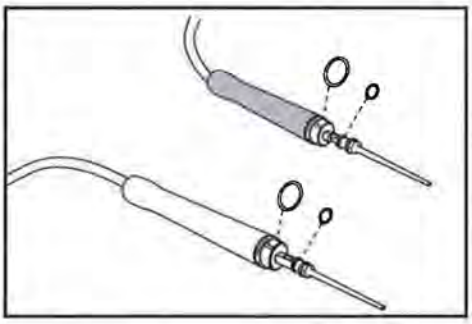
Warning

Turning the torque wrench further clockwise will damage the handpiece.

7. Carefully remove the sterile wrench from the tip.
8. Remove the handpiece from the tip torquing base.
9. Locate the o-rings for the handpiece you are assembling:

	23 kHz	36 kHz
Large o-ring	black	white
Small o-ring	green	blue

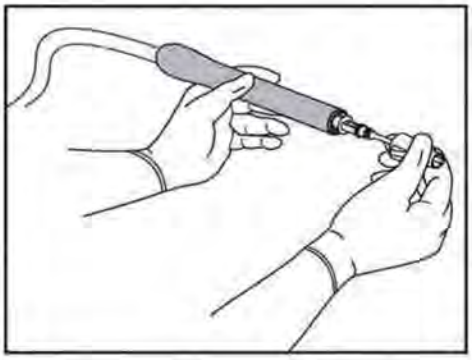
10. Slide the larger o-ring over the connecting body and into the groove in the neck of the handpiece. Slide the smaller o-ring into the groove in the metal connecting body.



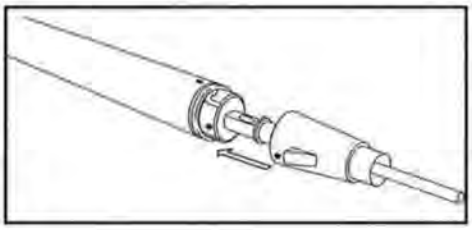
Attach a Nosecone and Flue

Attach a standard nosecone.

1. Holding the handpiece, insert the tip into the nosecone.

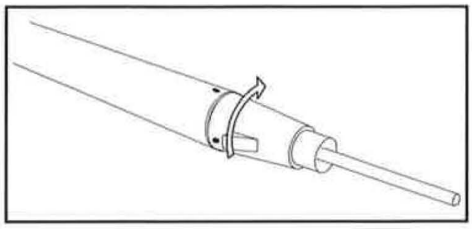


2. Align the dot on the nosecone with the dot on the neck of the handpiece.
3. Push the nosecone onto the handpiece so that the dots are on top of each other.



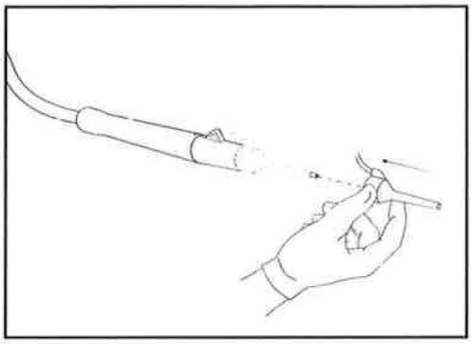
4. Twist the nosecone clockwise until it locks into place.

   The dot on the nosecone must now align with the dot on the handpiece.



5. Remove the tip cleaner from the flue and set it aside. You may need it during the surgical procedure to remove tissue blockage from the tip, the suction connection to the handpiece, or both.

6. Slide the flue that corresponds to the selected tip over the tip and onto the nosecone.



Markings on the flue indicate the tip the flue should cover:

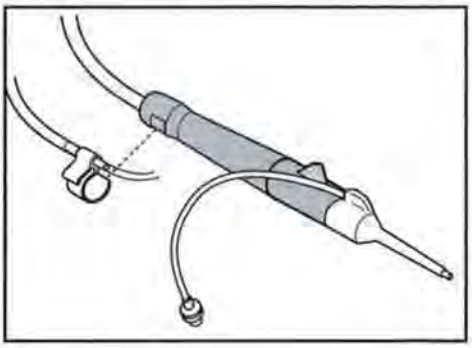
S	Standard Tip
Mi	MicroTip™, ShearTip™, SaberTip™
Mit	MicroTip™ Plus
P	PrecisionTip™
Ma	MacroTip™

Make sure to push the flue base completely over the nosecone base, and that the end of the flue lines up with the pre-aspiration holes.

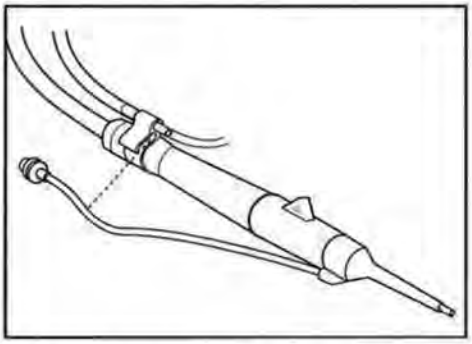
Attach the Manifold Tubing

If you receive the sterilized handpiece without the manifold tubing already clipped onto the handpiece cable, you must attach the manifold tubing now. Follow this procedure:

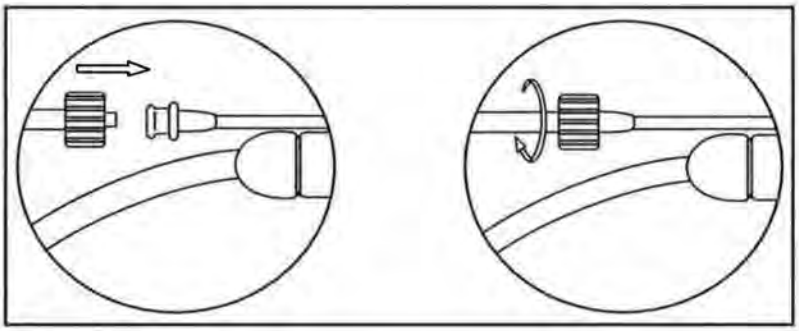
1. Remove the manifold tubing with clips from the packaging. Uncoil some of the tubing.
2. Snap the handpiece clip in place on the handpiece housing.



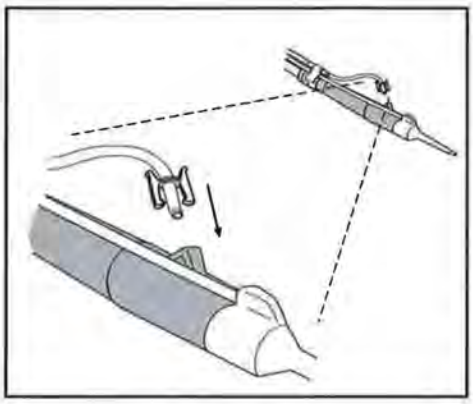
3. Insert the irrigation tube from the flue into the handpiece clip.



4. (Viewed from rear) Connect the manifold irrigation tubing to the Luer fitting on the handpiece flue.

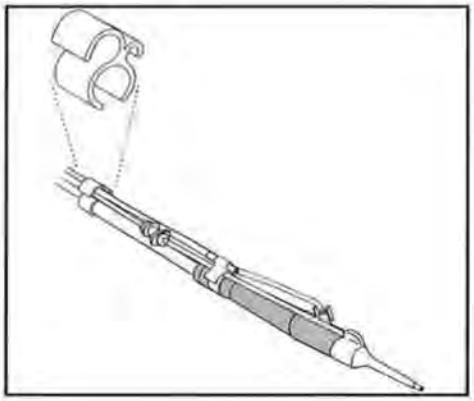


5. Connect the manifold suction tubing and clip to the suction port in the nosecone.



6. Push one to three manifold tubing clips onto the handpiece cable.

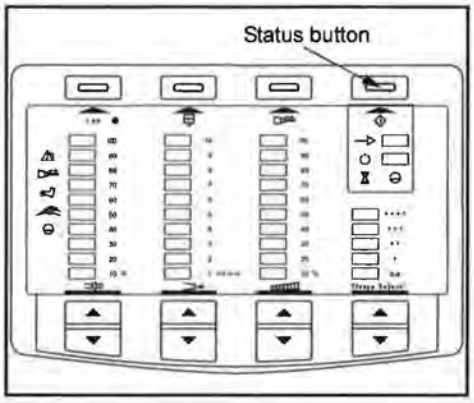
   Note: It is only necessary to attach one to three clips, but you can attach all five clips in the package.



Disassembling Handpiece to Change Tips in the Sterile Field

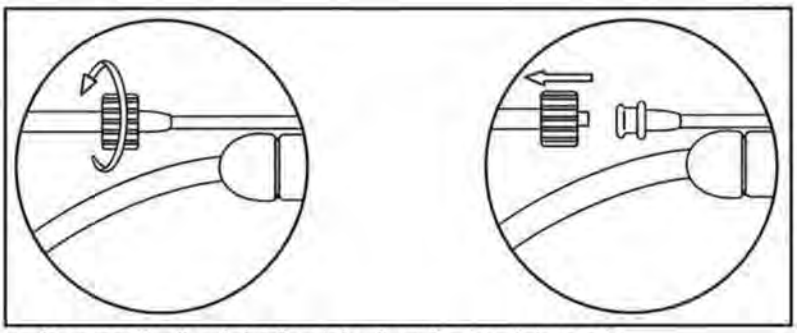
Use this procedure only if you are disassembling the handpiece as part of changing tips in the sterile field. To disassemble the handpiece at the end of the surgical procedure, see Section 13: Disassembling and Cleaning Handpieces.

1. Press the Status button to put the system in Standby.

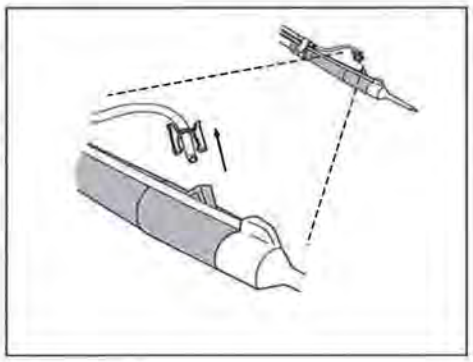


Disconnect the Manifold Tubing

1. (Viewed from rear) Disconnect the irrigation tubing from the handpiece flue.



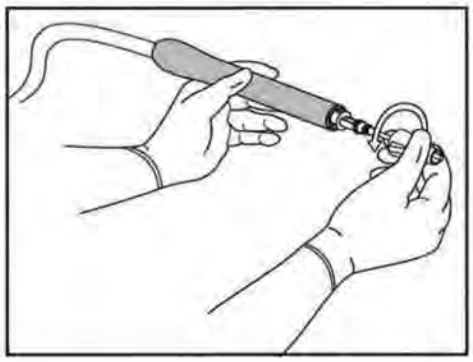
2. Remove the flue irrigation tube from the handpiece clip.
3. Remove the flue and set it aside.
4. Disconnect the manifold suction tubing and its clip from the handpiece and nosecone.



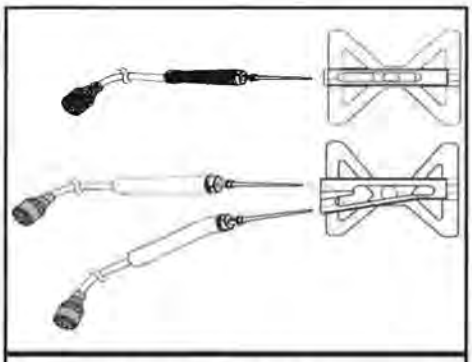
Remove the Nosecone, O-rings, and Tip

1. Remove the standard nosecone:
   a. Release the nosecone by twisting it counterclockwise.
   b. Pull the nosecone away from the handpiece and set it aside.

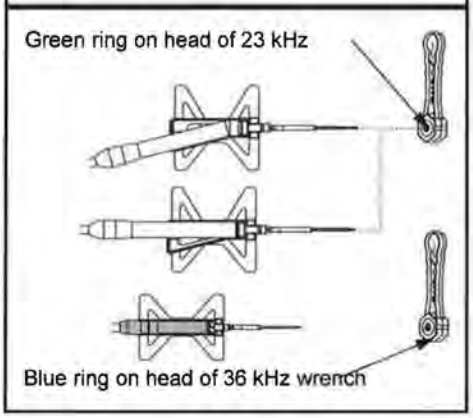
DO NOT DISCARD A STANDARD NOSECONE.



2. Locate the sterile torque base in which the handpiece support color matches the color on the handpiece connector (23 kHz – green; 36 kHz – blue).
3. Put the handpiece in the torque base so that the metal connecting body fits snugly in the metal slot at the end of the support.



4. Match the colored ring of the sterile torque wrench with the handpiece connector color or handpiece support color on the torque base. Slide the color coded side of the wrench over the tip until the hex in the wrench engages the hex of the tip.

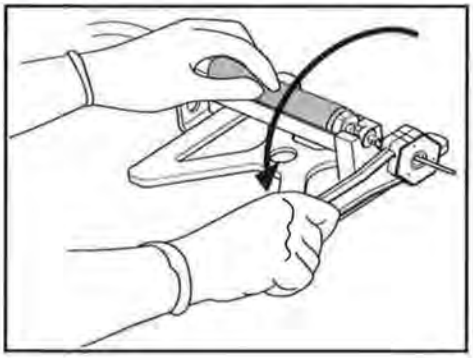


5. Hold the handpiece securely in place in the torque base.

Caution

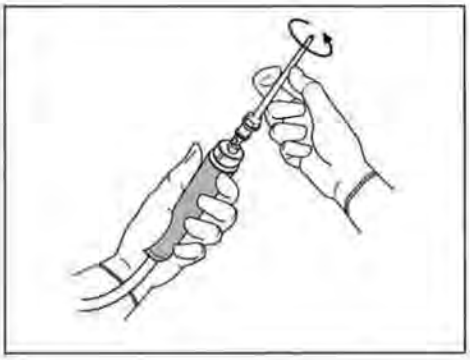
To avoid product damage, NEVER hold the handpiece in your hand while using the torque wrench to tighten or loosen the tip.

6. Rotate the wrench counterclockwise until the tip is loose.



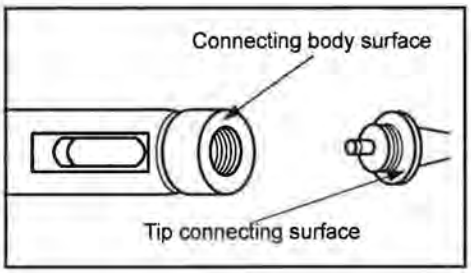
7. Carefully remove the sterile wrench from the tip.
8. Remove the handpiece from the tip torquing base.

9. Unscrew the used tip. Set the tip and flue aside for further use or disposal at the end of the surgical procedure.



10. Using a soft cloth, wipe the handpiece connecting body surface to remove gross contaminants.

    If reassembling a used tip to the handpiece, remove gross contaminants from the tip connecting surface by wiping with a soft cloth.



To reassemble the handpiece in the sterile field, refer to the *Assembly* earlier in this section.

Disassembling Handpiece After the Surgical Procedure

If you are disassembling the handpiece at the end of the surgical procedure, discard the following items in accordance with your Healthcare Facility's protocols:

- Flue(s)
- Manifold tubing
- Handpiece o-rings
- Tip(s) removed from the handpiece
- Sterile torque wrench
- Tip cleaner

Do not discard these items:

- Handpiece
- Standard nosecone
- Sterilizable torque base

Note: Do not discard the reusable tip at the end of the surgical procedure. Reusable tips can be reused six times.

See section Disassembling the Handpiece, page 13-2 for further information on disassembling handpieces.

When you have disassembled the tip from the handpiece, clean the handpiece and the sterilizable torque base, following the cleaning procedures described below.

Resterilizing the Handpiece

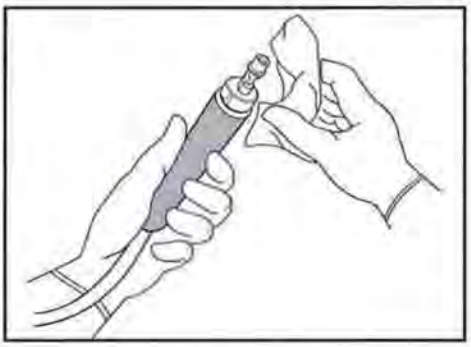
Notice

Product damage will result if you do not follow these notices when cleaning the handpiece:

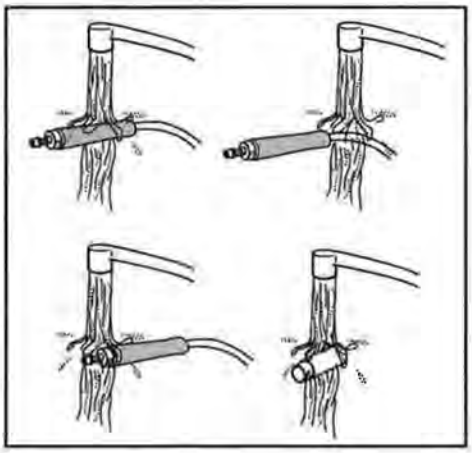
- Do not immerse the handpiece cable electrical connector in liquid.
- Do not use ultrasonic or automated washers.
- Do not use chlorinated substances such as bleach solution.
- Do not clean the handpiece with abrasives such as Ajax®, Comet®, or steel wool.

Clean the Handpiece

1. For general cleaning, using a soft cloth, manually clean the handpiece housing, connecting body, handpiece cable, handpiece electrical connector, and standard nosecone with a mild cleansing solution (neutral detergent) or blood dissolving detergent according to hospital policy.
2. Using a soft cloth, pipe cleaner, or cotton tipped applicator, manually clean the lumen, internal threads, and face of the connecting body.



3. Rinse the nosecone, connecting body, handpiece housing, and handpiece cable thoroughly with clean, running water.

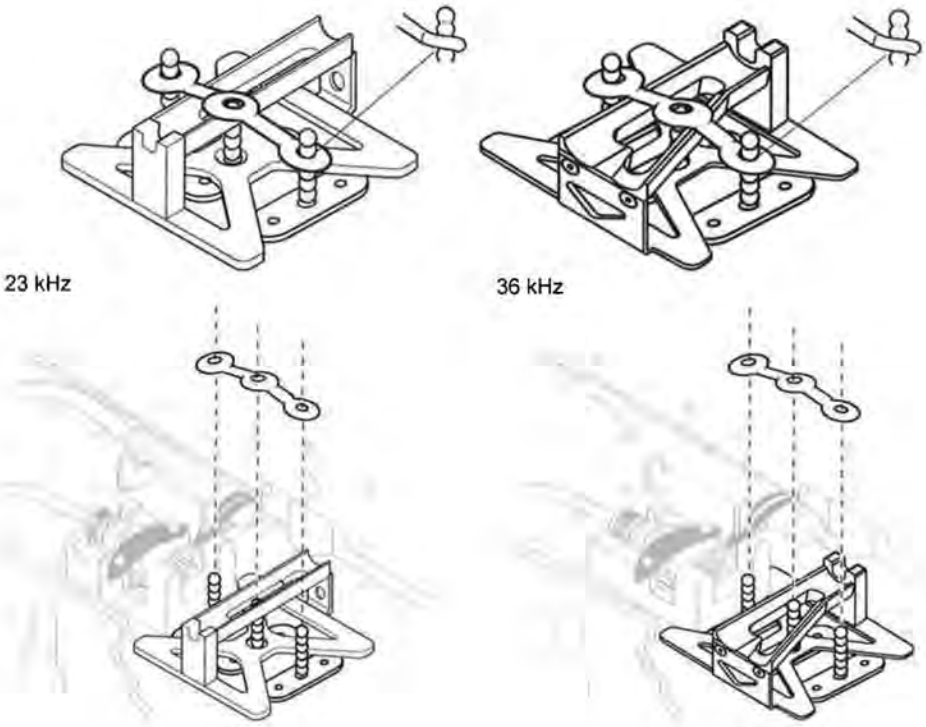


4. Manually wipe the handpiece electrical connector with a cloth moistened with water.

5. Using a soft cloth, dry the nosecone, connecting body, handpiece housing, handpiece cable, and handpiece electrical connector

Resterilizing the Sterilizable Torque Base

This procedure was developed in accordance with the professional recommendations of the Association for the Advancement of Medical Instrumentation (AAMI) and the Association of periOperative Registered Nurses (AORN).



Cleaning efficacy has been validated using enzymatic cleaning agents (for example, Klenzyme® and Enzol®) according to the manufacturer's instructions.

After disassembling the tip from the handpiece, clean, then sterilize, the sterilizable torque base. Refer to the cleaning instructions below.

Clean the Base

Notice

Product damage will result if you do not follow these notices when cleaning the handpiece:

- Do not use ultrasonic or automated washers
- Do not use chlorinated substances such as bleach solution
- Do not clean the handpiece with abrasives such as Ajax, Comet, or steel wool

1. Remove all gross matter (blood, mucous, and tissue):
   a. Dampen a soft cloth with a cleaning agent.
   b. Thoroughly wipe all surfaces of the base. Follow the procedures approved by your Healthcare Facility.
2. ***Soak at least two minutes*** in an enzymatic cleaning agent (for example, Klenzyme or Enzol) according to the manufacturer's instructions.
3. Scrub all surfaces with a small soft brush.
4. Rinse thoroughly with water.
5. Dry with a clean soft cloth.

Packaging the Handpiece for Sterilization

After you have cleaned the disassembled handpiece, prepare it for sterilization. Integra provides sterilizer cases for steam sterilization of the handpieces. They protect the handpieces during sterilization and during transfer to the sterile field. The case for the 23 kHz handpiece is gray; for the 36 kHz handpiece, white.

1. Put the disassembled handpiece into the case first. Align the handpiece with the outline on the case bottom. Secure the handpiece with the silicone strap.
2. Close the protective cover over the handpiece.
3. Place the nosecone into the opening in the protective cover.
4. Coil the cable and manifold tubing (if attached) around the inside of the case.
5. Put the handpiece connector in the center compartment and secure it in place.

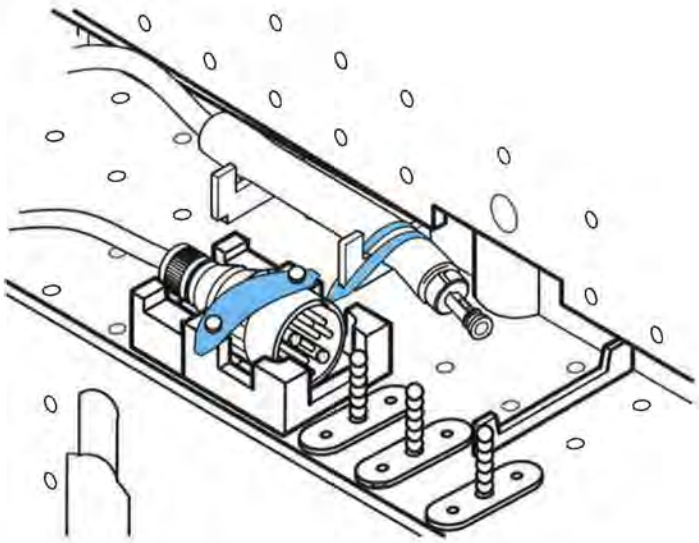
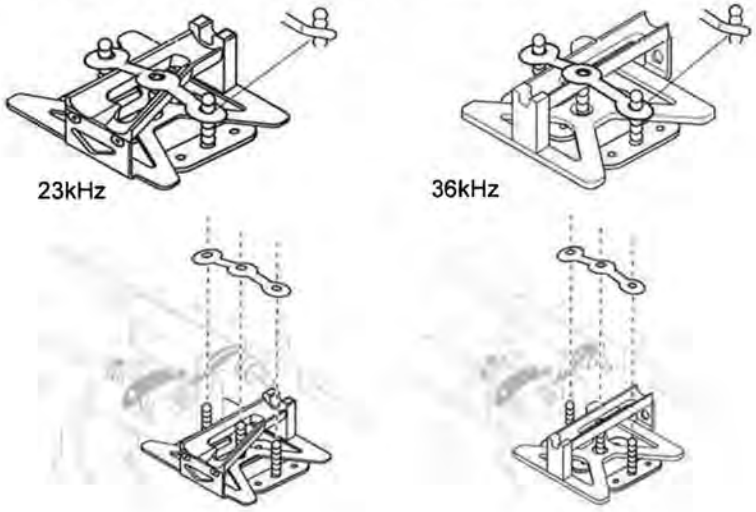


Figure 11-7 *The handpiece and connector secured into the sterilizer tray*

Do not close the sterilizer case until you clean and load the sterilizable torque base. Refer to the next page for instructions.

Packaging the Base for Sterilization

1. Load the sterilizable torque base into the CUSA® Excel/CUSA® Excel+ sterilizer tray and secure it with the silicone strap.
2. Put on the lid. Close and latch the sterilizer case



Sterilize the Handpiece and Base

Steam sterilize the handpiece and base using procedures approved by your Healthcare Facility.

For complete information on sterilization parameters, see Sterilizing Handpieces and Accessories, page 9-1.

Notes

SECTION 12

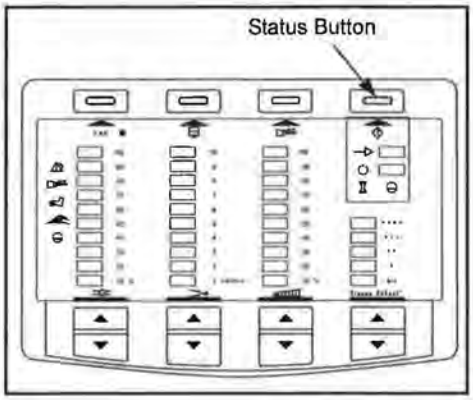
Shutting Down, Disconnecting and Cleaning the Console

In this section:

Shutting Down the System

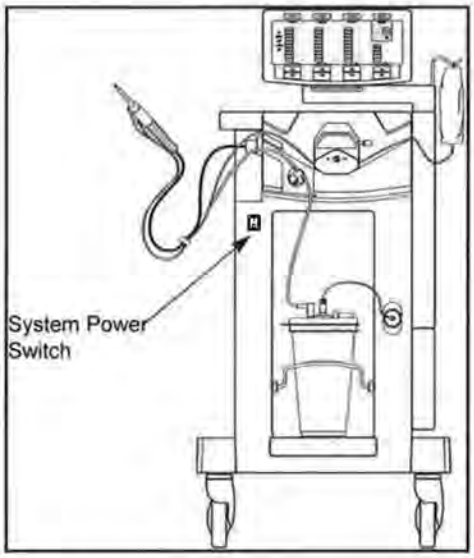
1. Press the Status button on the system control panel.

   This changes the system from Run mode to Standby mode.



2. Turn off (⏻) the System Power Switch.

   The system turns on the Wait and Cooling Water status indicators and automatically drains the handpiece cooling water. This takes about one minute. The Wait status indicator flashes.



3. While the system displays the flashing Wait status indicator and the Cooling Water status indicator, remove the green-banded suction tubing from the pinch valve.

When the flashing Wait status indicator goes off, the control panel goes blank and the system automatically powers down. When this occurs, the pinch valve automatically closes. If you haven't already removed the suction tubing before the pinch valve closes, use the valve override button on the front of the pinch valve to open the valve and remove the tubing. Manually opening the valve requires a strong push on the button.

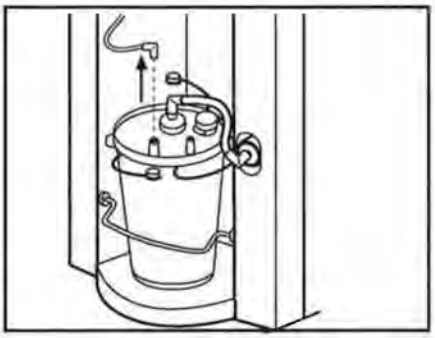
Disconnect the tubing and the handpiece, as described in the next procedure. Power down the system from the rear of the unit and unplug the system from the wall receptacle.

Notice

Do not disconnect the handpiece until the control panel goes completely blank. Otherwise, product damage may result.

Disconnecting Suction Tubing, Irrigation Tubing, and the Handpiece

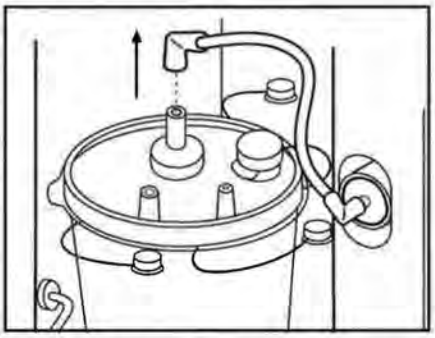
1. Disconnect the green L-shaped connector on the manifold suction tubing from the suction canister. Then put the cap (if available) on the canister lid.



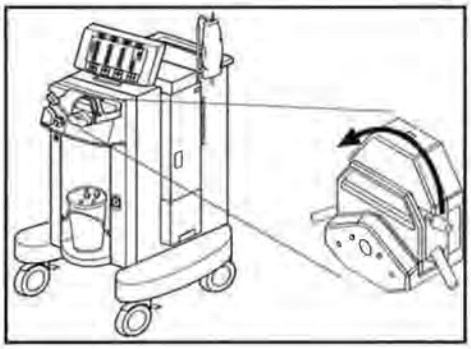
2. Disconnect the green L-shaped connector on the contamination guard tubing from the suction canister. Then put the cap (if available) on the canister lid.

   Do not discard the contamination guard or tubing.

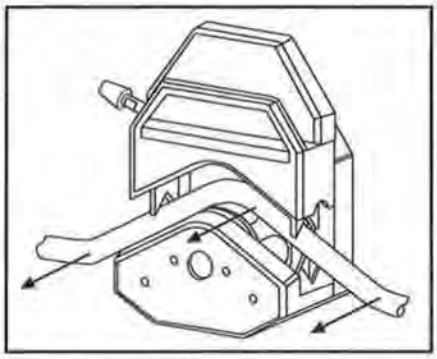
   After each surgical procedure, remove and dispose of the suction canister (as per hospital bio-hazard waste protocols).



3. Close the roller clamp on the IV tubing.
4. Disconnect the IV tubing from the irrigation tubing.
5. Open the irrigation pump latch.



6. Remove the blue-striped manifold irrigation tubing.



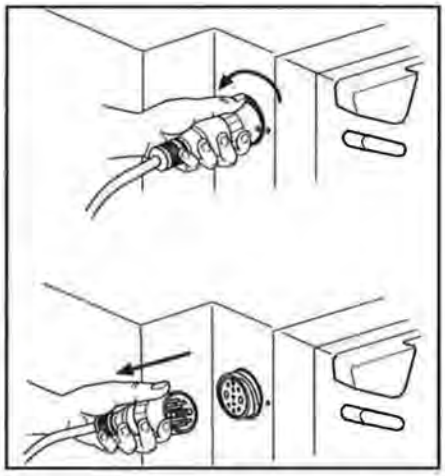
7. Close the irrigation pump latch.

Warning

To avoid injury to surgical personnel:

- When closing the irrigation pump latch, keep fingers away from the area between the V-shaped tubing retainers.
- If the pump latch is open, keep fingers away from the pump rollers.

8. After all indicators on the control panel are off, remove the handpiece:
   a. Turn the handpiece connector ring counter-clockwise.
   b. Remove the connector from the console.



Caution

Sharp edge at the handpiece connection point.

9. Remove and discard disposable components from the handpiece:
   - Disconnect the aspiration line from the nosecone.
   - Remove the flue from the tip.
   - Remove the tip from the handpiece.
   - Unclip the manifold tubing from the handpiece and handpiece cable.

▶ ***Important***

*A standard nosecone is **not** a disposable component. **Do not discard a standard nosecone.***

Discard all of these items in the patient's biohazard waste container. Do not discard a reusable tip. Reusable tips can be reused six times.

10. Empty cooling water from the cooling water reservoir:
    a. Press the button (just above the reservoir) on the Arm Housing to release the fittings inside the housing.
    b. Slide the reservoir toward the rear of the console, then remove it from its slot.
    c. Gently open the black rubber lid on the reservoir top and discard the distilled water.
    d. Gently close the black rubber lid.
    e. Slide the empty reservoir back into the slot at the base of the adjustable arm until it snaps into place.

DO NOT DISCARD THE COOLING WATER RESERVOIR.

Cleaning the Console

Clean the CUSA® Excel/CUSA® Excel+ System surfaces and power cord. Use a mild cleaning solution or disinfectant, and a soft cloth.

Warning

Electric Shock Hazard – Always unplug the CUSA Excel/CUSA Excel+ System before cleaning it.

Notice

Do not rub, press, or touch any panels with solvents; caustic, corrosive, or abrasive cleaning or disinfectant compounds, or other materials that could scratch the panels. Do not use a betadine-based solution because it will cause discoloration.Do not allow fluids to enter the chassis.

1. Unplug the unit power cord from the wall receptacle.
2. Using standard procedures for your facility, thoroughly wipe all surfaces, cords, and the footswitch with a cleaning solution or disinfectant.
3. To ensure sufficient conductivity, clean the four wheels at the base of the console. Make sure that the surface of the wheels are free from dirt and dust. Make sure that the surface is completely dry before using the system again.

Notes

SECTION 13

Disassembling and Cleaning Handpieces

In this section:

For Your Information

This section describes how to disassemble and clean the handpiece and tip torquing set.

Here is some information that may help as you disassemble the handpiece:

- Use the same disassembly procedure for all handpieces: 23 kHz straight, 23 kHz angled, and 36 kHz straight.
- Handpiece cable connectors, tip pack packaging, manifold tubing packaging, nosecone packaging, slots in the tip torquing base, torque wrench heads, and sterilizer tray lids are color coded:

23 kHz	green
36 kHz	blue

Disassembling the Handpiece

As you disassemble the handpiece, you keep some parts, and discard others. Table shows the parts to keep and to discard (in the order in which you remove them):

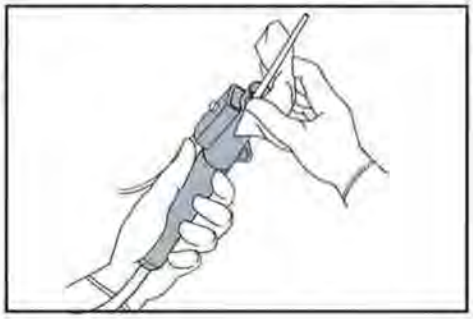
Table 13-1 *What to discard and what to keep*

What to Discard	What to Keep
manifold tubing with clips	handpiece
flue	standard nosecone
tip cleaner	
o-rings	
tip	

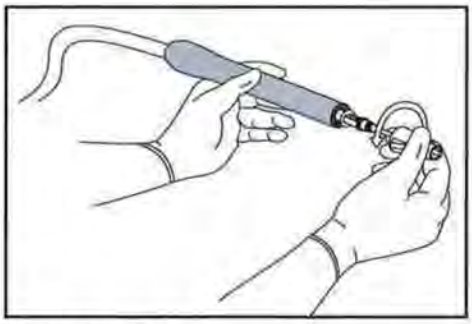
Note: Do not discard a reusable tip. Reusable tips can be reused six times.

When cleaning handpieces, wear protective clothing, gloves, and safety glasses in accordance with your hospital's cleaning policy.

1. Using a soft cloth moistened with a germicidal solution, wipe the handpiece to remove gross contaminants.

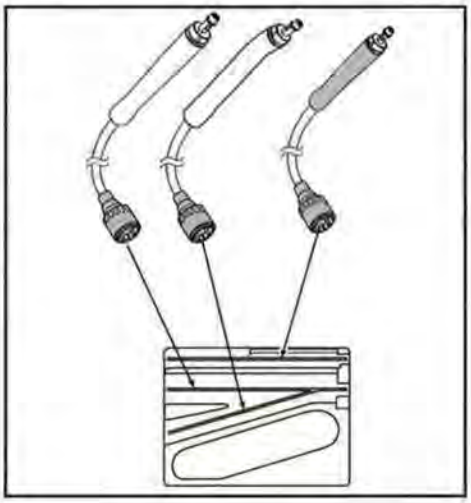


2. Remove the flue, if not already removed.
3. Remove the nosecone:
   a. Release the nosecone by twisting it counter clockwise.
   b. Pull the nosecone away from the handpiece.



DO NOT DISCARD A STANDARD NOSECONE.

4. Remove the o-rings and discard them.
5. Locate the slot in the tip torquing base that matches the color on the handpiece connector (23 kHz – green; 36 kHz – blue). Put the handpiece in the tip torquing base so that the metal connecting body rests snugly in the metal end of the slot.

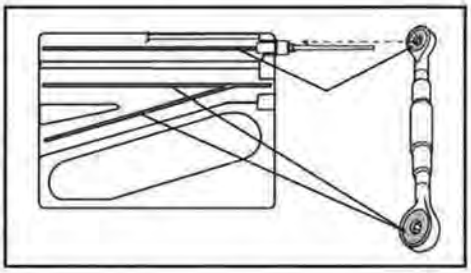


6. Hold the handpiece in place in the tip torquing base.

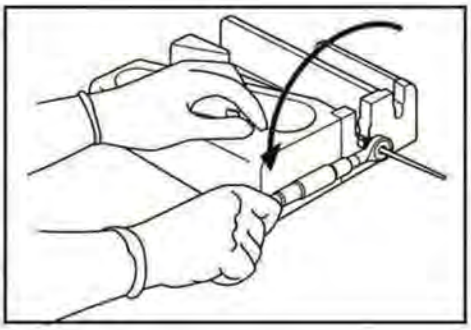
Caution

To avoid product damage, NEVER hold the handpiece in your hand while using the torque wrench to tighten or loosen the tip.

7. Match the colored end of the torque wrench with the handpiece color. Slide the color coded side of the wrench over the tip until the hex in the wrench engages the hex of the tip.

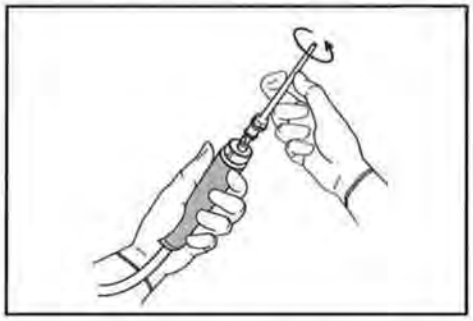


8. Rotate the wrench counter-clockwise until the tip is loose.



9. Remove the handpiece from the tip torquing base.

10. Unscrew the tip.



When you have disassembled the handpiece, clean the handpiece, the tip torquing base, and the torque wrench as described in the procedures below.

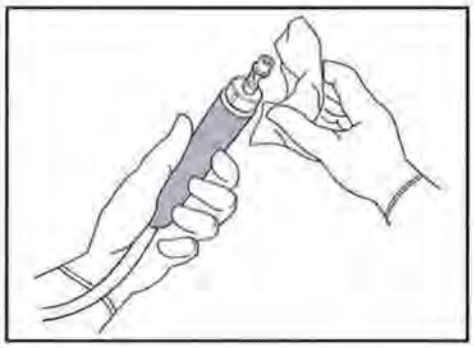
Cleaning the Handpiece

Notice

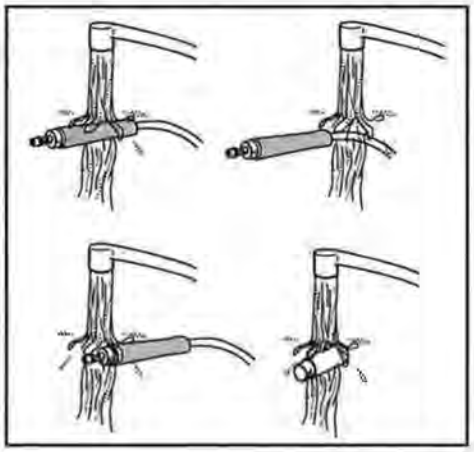
Product damage will result if you do not follow these notices when cleaning the handpiece:

- Do not immerse the handpiece cable electrical connector in liquid.
- Do not use ultrasonic or automated washers.
- Do not use chlorinated substances such as bleach solution.
- Do not clean the handpiece with abrasives such as Ajax®, Comet®, or steel wool.

1. For general cleaning, using a soft cloth, manually clean the handpiece, handpiece cable, handpiece electrical connector, and standard nosecone with a mild cleansing solution (neutral detergent) or blood dissolving detergent according to hospital policy.
2. Using a soft cloth, pipe cleaner, or cotton tipped applicator, manually clean the lumen, internal threads, and face of the connecting body.



Rinse the nosecone, connecting body, handpiece housing, and handpiece cable thoroughly with clean, running water.



3. Manually wipe the handpiece electrical connector with a cloth moistened with water.
4. Using a soft cloth, dry the nosecone, connecting body, handpiece housing, handpiece cable, and handpiece electrical connector.

Notice

For both the handpiece and the ELT tips, to clean threads and to polish connecting surfaces, you can use the Handpiece/Tip Maintenance Kits (Ref/Cat C0023 for 23 kHz and 36 kHz).

Cleaning the Tip Torquing Set

Notice

Product damage will result if you do not follow these notices when cleaning the Tip Torquing Set:.

- Do not use ultrasonic or automated washers
- Do not autoclave
- Do not use chlorinated substances such as bleach solution
- Do not clean with abrasives such as Ajax®, Comet®, or steel wool

1. Using a soft cloth and mild cleansing solution or blood dissolving detergent, manually clean the tip torquing base and the torque wrench.
2. Rinse the tip torquing base and torque wrench thoroughly with clean, running water.
3. Using a soft cloth, dry the tip torquing base and torque wrench.

SECTION 14

Troubleshooting the System

In this section:

For Your Information

This chapter describes troubleshooting procedures for the CUSA® Excel/CUSA® Excel+ Ultrasonic Surgical Aspirator System. It describes how to resolve an alarm on the system, and also general troubleshooting procedures

Note: To prevent tip blockage during surgery, try this. After using the tip, if you intend to set it aside for a while before using it again, flush it with saline solution. This removes debris before it can dry and block the tip while it is not in use.

Responding to Alarms

Alarm	Cause	Recommended Actions
Footswitch	Footswitch cable not properly connected to console	Connect the footswitch to the console (rear panel). Turn the connector until you feel it lock into place. If the alarm persists after you connect the footswitch to the console, call Integra for assistance.
Handpiece	Handpiece cable not properly connected to console	Connect the handpiece to the console. Twist the handpiece connector clockwise until it locks into place, then verify that the yellow dots align. If the alarm persists after you connect the handpiece to the console, call Integra for assistance.
Cooling Water	Not enough distilled water in the cooling water reservoir	Add distilled water to the cooling water reservoir up to the fill line.
	Cooling water reservoir not properly seated	Re-seat the cooling water reservoir in the console.
	A pinch or kink in the handpiece cable	Remove the pinch or kink in the cable.
	Handpiece cable not properly connected to console	Connect the handpiece to the console. Twist the handpiece connector clockwise until it locks into place, then verify that the yellow dots align.
	Damaged, misaligned, or missing o-rings in the handpiece connector	Connect a new sterilized handpiece to the system, and test it for proper function. If the alarm persists after you connect the new handpiece to the console, call Integra for assistance.
Cooling Water– On Intermittently	Possible air bubble in the handpiece cooling system	The CUSA Excel/CUSA Excel+ System corrects this condition. However, if the Cooling Water alarm remains lit, refer to the condition immediately before this one: *Cooling Water – continuously on*. Note: If the Cooling Water alarm persists (it continues to illuminate intermittently), call Integra for assistance.
	A pinch or kink in the handpiece cable	Remove the pinch or kink in the cable.

Alarm	Cause	Recommended Actions
Vibration–In Test mode only	Tip loose due to incorrect assembly	Testing before sterilization: 1. Use the tip torquing base and wrench to tighten the tip. 2. Test the tip by testing the handpiece. See Testing the Handpiece, page 5-11. 3. Sterilize the handpiece.
		Testing after sterilization when tip assembled in a nonsterile area: 1. Remove the handpiece from the sterile field. 2. Use the tip torquing base and wrench to tighten the tip. 3. Test the tip by testing the handpiece. See Testing the Handpiece, page 5-11. 4. Sterilize the handpiece.
		Testing after sterile tip assembled to handpiece in the sterile field: 1. Use the sterile torque base and a disposable sterile wrench to tighten the tip. (See Section 11:Assembling or Changing Tips in the Sterile Field) 2. Test the tip by testing the handpiece. See Testing the Handpiece, page 5-11.
	Tip contacting another object	Remove the contact with any other object.

Alarm	Cause	Recommended Actions
Vibration–In Test mode only	Blocked tip	1. Verify that the manifold suction tube connects properly to the nosecone by disconnecting, then reconnecting, the tubing and its clip. 2. Use the tip cleaner to dislodge the blockage in the tip. Continue to push the tip cleaner into the tip until the cleaner becomes visible in the tubing. 3. When you have cleared the blockage, verify again that the manifold suction tube connects properly to the nosecone. 4. If the tip remains blocked, disconnect the manifold suction tube connector from the nosecone. Use the tip cleaner to dislodge blockage from the tubing, then reconnect the tubing to the nosecone. 5. Immerse the handpiece tip in sterile irrigation fluid briefly. This may clear the suction tubing.
	Damaged or cracked tip	Testing before sterilization: 1. Use the tip torquing base and wrench to replace the tip. 2. Test the tip by testing the handpiece. See Testing the Handpiece, page 5-11. 3. Sterilize the handpiece. Testing after sterilization when tip assembled in a nonsterile area: 1. Remove the handpiece from the sterile field. 2. Use the tip torquing base and wrench to replace the tip. 3. Test the tip by testing the handpiece. See Testing the Handpiece, page 5-11. 4. Sterilize the handpiece. Testing after sterile tip assembled to handpiece in the sterile field: 1. Use the sterile torque base and a disposable sterile wrench to replace the tip. (See Section 11:Assembling or Changing Tips in the Sterile Field) 2. Test the tip by testing the handpiece.

Alarm	Cause	Recommended Actions
Vibration–In Test mode only	Damaged handpiece	1. Connect a new sterilized handpiece to the CUSA Excel/CUSA Excel+ System console and test it. 2. If the new handpiece corrects the problem: • Verify that the previous handpiece is correctly assembled, and • If it was correctly assembled, send it to Integra for repair. If the problem persists after you replace the handpiece, call Integra for assistance.

General Troubleshooting

Condition	Causes	Recommended Action
No power at the console	AC Main Switch (on the rear panel) off	Turn on the AC Main Switch (on the rear panel).
	System Power Switch (front of console) off	Turn on the System Power Switch (on the front of the console).
	Power cord not plugged in	Plug the power cord into the wall receptacle.
	Wall receptacle has no power available	Try another wall receptacle, or check the operating room circuit breakers.
	Fuse blown in plug	Change the fuse in the plug. This procedure should be performed by the hospital technician.
Power interruption to the console	Power cord becomes unplugged	1. Turn off the System Power Switch (on the front of the console). 2. Plug the power cord into the wall receptacle. 3. When power is restored, turn on the System Power Switch. 4. When the Wait status indicator (flashing) turns off, press the Prime button to make sure the irrigation system is ready to use. 5. Adjust the Aspiration, Irrigation, Amplitude, and Tissue Select® settings. 6. Push the Status button to change to Run mode.

Condition	Causes	Recommended Action
Power interruption in the operating room	Facility power loss	1. Turn off the System Power Switch (on the front of the console). 2. When power is restored, turn on the System Power Switch. 3. When the Wait status indicator (flashing) turns off, press the Prime button to make sure the irrigation system is ready to use. 4. Adjust the Aspiration, Irrigation, Amplitude, and Tissue Select settings. 5. Push the Status button to change to Run mode.
No irrigation flow from the handpiece flue; the handpiece tip gets hot	IV administration set roller clamp closed	Open the roller clamp.
	Irrigation tubing not routed properly through irrigation pump	Route the irrigation tubing properly through the irrigation pump.
	Manifold irrigation tubing not connected to the handpiece flue tubing	Connect the Luer fitting.
	Not enough time set at Prime to allow fluid to pass through the irrigation tubing	Press the Prime button, and wait until irrigation fluid drips from the tip.
	Irrigation tubing pinched or kinked	Remove the pinch or kink from the tubing.
	IV bag empty	Replace the IV bag. Note: For long periods of nonuse, switch the CUSA Excel/CUSA Excel+ System console to Standby mode to conserve irrigation solution.
	Irrigation pump not turning	Call Integra for assistance.

Condition	Causes	Recommended Action
Excessive misting at the handpiece tip	Flue not lined up with tip pre-aspiration holes	Adjust the flue position to line up with the pre-aspiration holes in the tip. See Attach a Nosecone and Flue, page 11-7.
	Too much irrigation	Reduce the irrigation rate.
	Low suction setting on the control panel	Increase the setting.
	Low or no suction due to suction tubing improperly connected to handpiece	Verify that the manifold suction tube connects properly to the nosecone by disconnecting, then reconnecting, the tubing and its clip.

Condition	Causes	Recommended Action
Excessive misting at the handpiece tip–continued	Blocked tip	1. Verify that the manifold suction tube connects properly to the nosecone by disconnecting, then reconnecting, the tubing and its clip. 2. Use the tip cleaner to dislodge the blockage in the tip. Continue to push the tip cleaner into the tip until the cleaner becomes visible in the tubing. 3. When you have cleared the blockage, verify again that the manifold suction tube connects properly to the nosecone. 4. If the suction remains low, disconnect the manifold suction tube connector from the nosecone. Use the tip cleaner to dislodge blockage from the tubing, then reconnect the tubing to the nosecone. 5. Immerse the handpiece tip in sterile irrigation fluid briefly. This may clear the blockage.
	Blockage in the suction tubing at the handpiece	1. Immerse the handpiece tip in sterile irrigation fluid briefly. This may clear the suction tubing. 2. Press the Status button to change to Standby mode. Use the sterile tip cleaner to clean out the tip, then put the tip in irrigating fluid to flush the tubing. 3. As necessary, disconnect, clean, and reconnect the suction tubing connector at the handpiece.
	A pinch or kink in the suction tubing	Straighten the tubing to remove a kink, or remove anything that might pinch the tube.
	A blockage in the suction tubing between the handpiece and the suction canister	1. Examine the suction tubing along its entire length for a blockage. 2. Squeeze the blocked area to loosen it. 3. Immerse the handpiece tip in sterile irrigation fluid briefly. This may clear the blockage.
	Suction canister full	Replace the suction canister.

Condition	Causes	Recommended Action
Excessive misting at the handpiece tip–continued	Suction connections at the suction canister not seated properly	1. Remove any unused suction canister "elbow" connectors. 2. Reseat all connections.
	Open port(s) on the suction canister	Close any open ports on the suction canister.
	Suction canister improperly connected	Refer to the canister manufacturer's instructions for connecting the canister.
	Inside of the contamination guard wet and blocked	1. Disconnect the contamination guard fitting from the suction canister tubing. If you feel no suction at the end of the contamination guard fitting, the guard is blocked. 2. Replace the contamination guard.
	Problem at the CUSA Excel/CUSA Excel+ System console suction port	Remove the contamination guard and put a finger in the suction system port. If you feel no suction, call Integra for assistance.
	Suction pinch valve not working properly	Check the Lap mode indicator. • If Lap mode is off, in Run mode the pinch valve should be open. • If Lap mode is on, in Run mode the pinch valve should be open ***only*** when you activate vibration. If these conditions do not exist, call Integra for assistance.
The Run mode status indicator does not illuminate when you activate vibration.	System in Standby mode	Press the Status button to switch the system to Run mode.

Condition	Causes	Recommended Action
Little or no vibration or fragmentation (Amplitude setpoint indicators may illuminate well below setpoint)	Excessive tip/tissue pressure (stalling tip)	1. Verify that console settings are at desired levels. 2. Remove the tip from contact with tissue, then reactivate vibration. Note: When first activating vibration, make sure that there is no tip/tissue pressure.
	Blocked tip	1. Verify that the manifold suction tube connects properly to the nosecone by disconnecting, then reconnecting, the tubing and its clip. 2. Use the tip cleaner to dislodge the blockage in the tip. Continue to push the tip cleaner into the tip until the cleaner becomes visible in the tubing. 3. When you have cleared the blockage, verify again that the manifold suction tube connects properly to the nosecone. 4. If the tip remains blocked, disconnect the manifold suction tube connector from the nosecone. Use the tip cleaner to dislodge blockage from the tubing, then reconnect the tubing to the nosecone. 5. Immerse the handpiece tip in sterile irrigation fluid briefly. This may clear the suction tubing.
	Incorrect flue installed	Install the correct flue.

Condition	Causes	Recommended Action
Little or no vibration or fragmentation (Amplitude setpoint indicators may illuminate well below setpoint)–continued	Tip loose due to improper assembly	1. Press the Status button to place the system in Standby mode. 2. Press the Test button to test the handpiece and tip. 3. If the Vibration alarm activates, do one of the following: If tip assembled in a nonsterile area: • Remove the handpiece from the sterile field. • Use the tip torquing base and wrench to tighten the tip. • Test the tip by testing the handpiece. • Sterilize the handpiece. If sterile tip assembled to handpiece in the sterile field: • Use the sterilizable torque base and a disposable sterile wrench to tighten the tip. (See Section 11:Assembling or Changing Tips in the Sterile Field)Test the tip by testing the handpiece.
	Console not left in Run mode for a minimum of two continuous minutes (36 kHz handpiece only).	1. Return to Standby mode. 2. Restart Run mode and wait for two minutes before using the system.

Condition	Causes	Recommended Action
Little or no vibration or fragmentation (Amplitude setpoint indicators may illuminate well below setpoint)–continued	Damaged or cracked tip	1. Press the Status button to place the system in Standby mode. 2. Press the Test button to test the handpiece and tip. 3. If the Vibration alarm activates, do one of the following: If tip assembled in a nonsterile area: • Remove the handpiece from the sterile field. • Use the tip torquing base and wrench to replace the tip. • Test the tip by testing the handpiece. • Sterilize the handpiece. If sterile tip assembled to handpiece in the sterile field: • Use the sterilizable torque base and a disposable sterile wrench to replace the tip. (See Section 11:Assembling or Changing Tips in the Sterile Field) • Test the tip by testing the handpiece.
	Damaged handpiece	1. Connect a new handpiece to the CUSA Excel/CUSA Excel+ console and test it. 2. If the new handpiece corrects the problem, • Verify that the previous handpiece is correctly assembled, and • If it was correctly assembled, send it to Integra for repair. If the problem persists after you replace the handpiece, call Integra for assistance.
Suction tube won't assemble correctly to handpiece nosecone	Nosecone not assembled to handpiece correctly	Align the dot on the nosecone with the dot on the handpiece.
	Transducer is twisted inside handpiece housing	Replace with a sterilized handpiece.

Condition	Causes	Recommended Action
Low suction at the handpiece tip	Low suction setting on the control panel	Increase the setting.
	System inadvertently in Lap mode	Turn off the Lap mode by pressing the Lap mode button.
	Suction tubing improperly connected to handpiece	Verify that the manifold suction tube connects properly to the nosecone by disconnecting, then reconnecting, the tubing and its clip.
	Blocked tip	1. Verify that the manifold suction tube connects properly to the nosecone by disconnecting, then reconnecting, the tubing and its clip. 2. Use the tip cleaner to dislodge the blockage in the tip. Continue to push the tip cleaner into the tip until the cleaner becomes visible in the tubing. 3. When you have cleared the blockage, verify that the manifold suction tube connects properly to the nosecone. 4. If the suction remains low, disconnect the manifold suction tube connector from the nosecone. Use the tip cleaner to dislodge blockage from the tubing, then reconnect the tubing to the nosecone. 5. Immerse the handpiece tip in sterile irrigation fluid briefly. This may clear the blockage.
	Blockage in the suction tubing at the handpiece	1. Immerse the handpiece tip in sterile irrigation fluid briefly. This may clear the suction tubing. 2. Press the Status button to change to Standby mode. Use the sterile tip cleaner to clean out the tip, then put the tip in irrigating fluid to flush the tubing. 3. As necessary, disconnect, clean, and reconnect the suction tubing connector at the handpiece.
	A pinch or kink in the suction tubing	Straighten the tubing to remove a kink, or remove anything that might pinch the tube.

Condition	Causes	Recommended Action
Low suction at the handpiece tip–continued	A blockage in the suction tubing between the handpiece and the suction canister	1. Examine the suction tubing along its entire length for a blockage. 2. Squeeze the blocked area to loosen it. 3. Immerse the handpiece tip in sterile irrigation fluid briefly. This may clear the blockage.
	Suction canister full	Replace the suction canister.
	Suction connections at the suction canister not seated properly	1. Remove any unused suction canister "elbow" connectors. 2. Reseat all connections.
	Open port(s) on the suction canister	Close any open ports on the suction canister.
	Suction canister improperly connected	Refer to the canister manufacturer's instructions for connecting the canister.
	Inside of the contamination guard wet, blocked, or both	1. Disconnect the contamination guard fitting from the suction canister tubing. If you feel no suction at the end of the contamination guard fitting, the guard is blocked. 2. Replace the contamination guard.
	Problem at the console suction port	Remove the contamination guard and put a finger in the suction system port. If you feel no suction, call Integra for assistance.
	Suction pinch valve working improperly	Check the Lap mode indicator. • If Lap mode is off, in Run mode the pinch valve should be open. • If Lap mode is on, in Run mode the pinch valve should be open ***only*** when you activate vibration. If these conditions do not exist, call Integra for assistance.

Condition	Causes	Recommended Action
The handpiece gets hot	Surgeon holding handpiece at tip and flue	Hold the handpiece at the nosecone.
	Handpiece damage due to tip torquing without the torque base	Replace with a sterilized handpiece.
	Loss of cooling water at the handpiece	Check the Cooling Water System. If problem persists, return handpiece for service.
The nosecone is loose	Large o-ring not installed correctly, or missing	Install the large o-ring in the proper position on the handpiece.
	Nosecone worn	Replace with a sterilized nosecone.

Notes

SECTION 15

Maintaining the System

In this section:

For Your Information

This chapter describes routine maintenance tasks for the system. Biomedical Engineering at your facility should perform these tasks.

It also describes handling and storage information for the system, and information on returning equipment to Integra for service.

Quick Reference

The following chart lists routine maintenance tasks, when you perform each task, and the equipment on which you perform them.

Table 15-1
Routine maintenance tasks for CUSA® Excel/CUSA® Excel+ System

When	Equipment	Task
Daily or when used	CUSA Excel/CUSA Excel+ console	Disinfect and wipe dry.
Daily or when used	Cooling Water Reservoir	Discard water from the reservoir.
Daily or when used	Footswitch	1. Discard the footswitch cover (if using). 2. Clean the footswitch.
Every 3 months, or every 12 to 15 procedures, whichever comes first	Console	Fill the cooling water reservoir with a solution consisting of 100 ml of 70% alcohol and 900 ml of water. Connect the handpiece, then turn on the system. Allow the system to run a few cooling cycles to clean the interior tubing. Turn off the system. Discard the alcohol solution, then fill the reservoir with distilled water. Turn on the system, and allow it to cycle the water to remove the alcohol solution from the tubing.
Every 6 months, or when filter changes color	Console	Replace the contamination guard. Write either the installation date or the expiration date on the guard.
Once a year	Console - Cooling Water Tubing	Contact a Integra service representative to replace the cooling water pump tubing.
Once a year	Console - Control Arm Gasket	Contact a Integra service representative to replace the control arm gasket.
After 50 hours of use, or 100 surgical procedures, whichever comes first	Handpiece	Return handpiece for service.
Every month or 80 hours of use	Handpiece	Apply a high viscosity lubricant to the handpiece connector o-rings.
Every 6 months or 500 hours of use	Handpiece	Replace the handpiece connector o-rings.

Handpiece Maintenance

Maintaining the handpiece involves lubricating the handpiece connector o-rings or replacing the handpiece connector o-rings.

Recalibrate the Handpiece

It is recommended that you return the handpiece for service after 50 hours of use, or 100 surgical procedures, whichever comes first.

It is recommended that you retain a spare handpiece in the sterile field. Contact Integra to arrange returning the handpiece for service. (Refer to *Return Equipment for Service*, later in this section.)

Lubricate the Handpiece Connector O-Rings

Keeping the o-rings lubricated prevents them from drying out and cracking, which may cause handpiece cooling problems.

Frequency: Every month or every 80 hours of use, whichever comes first.

Items needed: A high viscosity lubricant such as silicone grease.

Items to be lubricated: The four o-rings on the handpiece connector water prongs.

Replace the Handpiece Connector O-Rings

Regularly replacing the o-rings prevents excessive wear, which may result in handpiece cooling problems.

Frequency: Every six months or 500 hours of use, whichever comes first.

Items needed: O-Ring maintenance kit, which includes o-rings, an insertion tool, and instructions.

Items to be replaced: The four o-rings on the handpiece connector water prongs.

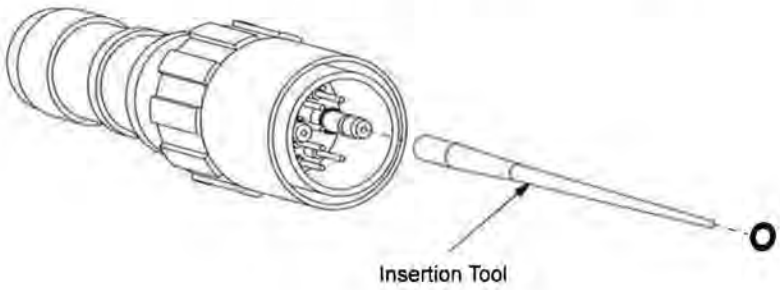


Figure 15-1 *Replacing o-ring on the handpiece connector water prongs*

Sterilizer Case Maintenance

Use a neutral detergent to clean the sterilizer case.

Notice

Do not clean the sterilizer case with abrasives. Product damage will result.

Handling and Transporting of the System

If you need to move/relocate the CUSA Excel/CUSA Excel+ System within the environment of the Healthcare Facility, note the guidelines below.

Before moving the console:

- Unplug the power cord from the wall receptacle and place the power cord in the storage compartment at the rear of the console.
- Disconnect the handpiece.
- Disconnect and remove the irrigation fluid.
- Retract the IV pole.
- Secure any loose objects. Make sure there are no loose objects placed on the top of the console.
- Secure the footswitch cord on cord wraps provided on the back of the console and place the footswitch in the storage compartment at the rear of the console.
- Adjust the control panel to its lowest height. Make sure the control panel is locked into position.

When moving the console:

- Push the console using the handle; don't pull it.
- Do not run whilst pushing the console.
- Use a lift to move the console between floors of a building. Never use a stairwell.
- Do not attempt to lift the console.

To move the console up or down a ramp, use two or more people.

The CUSA Excel/CUSA Excel+ System requires a minimum of one hour exposure at its operating temperature range before you use it; make sure that the system is located in the surgical room at least an hour before use.

Storage of the System and Accessories

Console

Drain all liquids. Make sure the system is clean. Store the system in a low traffic area that is free of dirt, blood, water, and other contaminants. Store the system at an ambient temperature between -34° C and 65° C.

Handpiece

Drain all liquids. Store the handpiece in the sterilizer case according to your facility's policy.

Store the handpiece at an ambient temperature between -34° C and 65° C.

Footswitch

You do not need to disconnect the footswitch from the console except for maintenance or service. When you are not using the CUSA Excel/CUSA Excel+ System, secure the footswitch cord on cord wraps provided on the back of the console and store the footswitch in the storage compartment in the rear of the console.

Disposal of the Equipment

The CUSA Excel family of consoles, handpieces and footswitches are considered electrical equipment and must be disposed of in accordance with regional regulations hospital protocols.

Return Equipment for Service

Before you return CUSA Excel/CUSA Excel+ equipment, call your Integra representative for help. If the representative tells you to send the equipment to Integra, first obtain a Return Authorization Number. Then clean the equipment and ship it to Integra for service.

Obtaining a Return Authorization Number

Call the Integra Service Center for your area (refer to *Integra Service Centers* in this section) to obtain a Return Authorization Number. Have the following information ready when you call:

- Hospital/clinic name/customer number
- Technician's name

- Telephone number
- Department/address, city, state, and zip or postal code
- Model number
- Serial number
- Description of the problem
- Type of repair to be done (if known)

Attach a tag with this same information to the equipment when you ship it for service.

Returning the Console

Notice

To avoid product damage, use proper packaging materials and packing procedures when preparing the console for shipment. Failure to return product in this manner may void your warranty.

For instructions on packing the console properly, contact your Integra representative.

Returning Handpieces

Clean, disinfect, and sterilize a handpiece before you package it for shipping.

Package a handpiece to protect the handpiece and handpiece cable connector from damage.

Package each handpiece in a separate packaging container.

Ordering Replacement Parts

The following replacement parts may be ordered from Integra:

- Cooling Water Reservoir (S202750115)
- O-Ring Maintenance Kit (S200700120)

When ordering replacement parts for equipment, include this information:

- Model number (located on the CUSA Excel/CUSA Excel+ System rear panel)
- Serial number (located on the CUSA Excel/CUSA Excel+ System rear panel)

Integra Service Centers

US Service Center

Integra Neurosciences
5965 Pacific Center Blvd,
Suite 702
San Diego, CA 92121
Tel: 858-455-1115 (X207 or X215)
Fax: 858-455-8298
E-mail: SanDiegoServiceCenter@Integralife.com

Europe, Middle East and Africa Service Center

Integra Neurosciences GmbH
Halskestrasse 25
Ratingen 40880
Germany
Tel: +49 2102 5535 6150
Fax: +49 2102 942 4872
E-mail: emea.techservice@integralife.com

Asia Pacific Service Center

Integra NeuroSciences Pty. Ltd.
Unit 3, 24-30 Winterton Road,
CLAYTON, VIC. 3168, Australia
Tel: +613 85400400
Fax: +613 95400004
E-mail: Service@integralife.com.au

Notes

APPENDIX A

Technical Specifications

Console Dimensions

CUSA® Excel/CUSA® Excel+ Console

Height	132 cm (52 in)
Width	55.88 cm (22 in)
Depth	71.12 cm (28 in)
Weight	93 kg (200 lbs)

Footswitch

Height	5.08 cm (2 in)
Width	30.48 cm(12 in)
Cable length	4.575 m (15 ft)

Console Subsystems

Ultrasonic

Frequency (23kHz)	23 kHz (nominal frequency)
Frequency (36kHz)	35.67 - 35.83 kHz (frequency range)
Maximum Tip Amplitude (23 kHz)	Up to 355 microns for straight handpiece Up to 183 microns for angled handpiece
Maximum Tip Amplitude (36 kHz)	Up to 210 microns

Fluidic System

Cooling System	Cooling water flow is 35 – 50 ml/min.
Irrigation Rate	The irrigation rate display shows digits 1 – 10 The irrigation rate is approximately 1 – 10 ml/min., normal; greater than 25 ml/min., Fast Flush
Suction System	Up to 660 mm (26 inches) mercury at the pump intake at sea level The suction level will be lower at higher altitudes.

Electrical Requirements

Input Power Source

Power Ratings	The CUSA Excel/CUSA Excel+ System operates on one of the following voltage ranges: 220–240 Volt 95–120 Volt 950-1200 VA (All 4 Models) The voltage range is specified on the serial number label on the console. Line fusing resides in fuse receptacles on the rear panel. The fuse values for 220–240 Volt operation are T5A; for 95–120 Volt operation, T10A.
Frequencies	50 Hz ± 2 Hz 60 Hz ± 2 Hz
Breaking Capacity	T5A: Low T10A: Low

Power Cords

Cord	Harmonized type three conductor cord or UL listed 3-conductor.
Connector	Integra provides a connector approved for the region in which your country is geographically located. Refer to the Plug IFU supplied in the console carton.

If a facility intends to use the CUSA Excel/CUSA Excel+ System in an operating room with another type of receptacle, the facility is responsible for replacing the connector on the power cord. The replacement connector must be properly grounded.

Warning

Explosion Hazard – Do not use the CUSA Excel/CUSA Excel+ System in the presence of flammable anesthetics or any potentially explosive or flammable atmosphere.

Warning

TO AVOID RISK OF ELECTRIC SHOCK, THIS EQUIPMENT MUST ONLY BE CONNECTED TO A SUPPLY MAINS WITH PROTECTIVE EARTH.

Warning

The console must be earthed, and therefore it MUST only be fitted with a 3-pin plug, or a 2-pin plug that has an integral earth grounding connection. Mains plug type and construction MUST comply with Legal requirements within country of installation. Only Integra Service personnel or Integra authorized representatives or agents can change the mains plug on the console.

Low Frequency Leakage

Touch current	<100µA
Patient leakage current	<100µA

Duty Cycle

Under maximum loading conditions, the CUSA Excel console is suitable for ultrasonics activation times of 10 minutes on, 5 minutes off.

Environment

Operating temperature range	10°C (50° F) to 35°C (95° F)
Operating humidity range	15 to 80%, relative humidity, non-condensing
Operating atmospheric pressure range	70 kPa to 106 kPa

Storage and shipping temperature	-34°C (-29° F) to 65°C (149° F)

Storage and shipping humidity	25 to 85% relative humidity, non-condensing

The system requires a minimum of one hour exposure at its operating temperature range before you use it.

See section EMC Compatibility on page A-5 for further information on environmental conditions.

Electromagnetic Interference

The CUSA Excel/CUSA Excel+ System console minimizes electromagnetic interference to other equipment used in the operating room. The system complies with the requirements of IEC 60601-1-2:2007.

Note that other devices in the operating room may generate electromagnetic interference. Use caution in locating equipment within the room to reduce the electromagnetic interference.

Voluntary Standards

The CUSA Excel/CUSA Excel+ System meets the following standards:

- **IEC 60601-1:2005** Medical electrical equipment: General requirements for basic safety and essential performance
- **cUL/CSA** Test requirements: (CSA 22.2, No. 601.1.8)
- **IEC 60601-1-6:2005** Medical electrical equipment: General requirements for basic safety and essential performance. Collateral Standard: Usability
- **IEC 60601-1-2:2005** Medical electrical equipment: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility - Requirements and tests
- **CISPR11** Electromagnetic compatibility for industrial-process measurement and control equipment: Emissions requirements
- **ISTA** Pre-Shipment Test Procedures

Statutory and Regulatory Classification

Class II (FDA) Medical Device (General Controls and Special Controls)

Class IIb (EU)

Class III (EU)

Class 4 (Canada)

EMC Compatibility

Notice

The CUSA Excel/CUSA Excel+ System should not be used adjacent to or stacked with equipment other than the equipment specified in the CUSA Excel/CUSA Excel+ System User Guide. If adjacent or stacked use is necessary, the CUSA Excel/CUSA Excel+ System should be observed to verify normal operation in the configuration in which it will be used.
The use of accessories, other than the accessories specified in the CUSA Excel/CUSA Excel+ System User Guide may result in increased emissions or decreased immunity of the CUSA Excel/CUSA Excel+ System.

Guidance and Manufacturer's Declarations

Guidance and manufacturer's declaration – electromagnetic emissions		
The CUSA Excel/CUSA Excel+ System is intended for use in the electromagnetic environment specified below. The customer or the user of the CUSA Excel/CUSA Excel+ System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - Guidance**
RF emissions CISPR 11	Group 1	The CUSA Excel/CUSA Excel+ System uses RF 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.
RF emissions CISPR 11	Class A	The CUSA Excel/CUSA Excel+ System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The CUSA Excel/CUSA Excel+ System is intended for use in the electromagnetic environment specified below. The customer or the user of the CUSA Excel/CUSA Excel+ System should assure that it is used in such an environment.			
IMMUNITY Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, 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	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	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	<5 % U_T (>95 % dip in U_T) for 0,5 cycle <40 % U_T (>60 % dip in U_T) for 5 cycles <70 % U_T (>30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle <40 % U_T (>60 % dip in U_T) for 5 cycles <70 % U_T (>30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CUSA Excel/CUSA Excel+ System requires continued operation during power mains interruptions, it is recommended that the CUSA Excel/CUSA Excel+ System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The CUSA Excel/CUSA Excel+ System is intended for use in the electromagnetic environment specified below. The customer or the user of the CUSA Excel/CUSA Excel+ System should assure that it is used in such an environment.			
IMMUNITY Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment -Guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CUSA Excel/CUSA Excel+ System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}4\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
[a] Field strengths 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 the CUSA Excel/CUSA Excel+ System is used exceeds the applicable RF compliance level above, the CUSA Excel/CUSA Excel+ System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the CUSA Excel/CUSA Excel+ System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the CUSA EXcel/CUSA Excel+ System

The CUSA Excel/CUSA Excel+ System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CUSA Excel/CUSA Excel+ System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CUSA Excel/CUSA Excel+ System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2{,}4\sqrt{P}$
0,01	0,12 m	0,12 m	0,24 m
0,1	0,38 m	0,38 m	0,76 m
1	1,2 m	1,2 m	2,4 m
10	3,8 m	3,8 m	7,6 m
100	12 m	12 m	24 m

For transmitters rated at maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Handpieces

Nominal Frequencies

23 kHz Straight	23 kHz
23 kHz Angled	23 kHz
36 kHz Straight	35.75 kHz

Dimensions

23 kHz Straight

Length	22.2 cm (8.74 in)
Diameter	2.08 cm (0.82 in)

23 kHz Angled

Length	22.2 cm (8.74 in)
Diameter	2.08 cm (0.82 in)

36 kHz Straight

Length	13.9 cm (5.47 in)
Diameter	1.64 cm (0.65 in)

Tip Specifications

The table on pages A-12 shows specifications for tips that attach to the 23 kHz handpiece.

The table on pages A-13 shows specifications for tips that attach to the 36 kHz handpiece.

Tip Specifications for 23 kHz Handpiece

Table A-1
Tip Specifications—23 kHz

Tip	Length (mm) [in]	ID (mm)[(in]	OD (mm) [in]	Amplitude (peak to peak) µm [in]	Weight (g)
Standard Tip	79.8 [3.140]	1.98 [0.078]	2.54 [0.100]	Straight Handpiece: 287 to 355 [0.0113 to 0.0140] Angled Handpiece: 112 to 163 [0.0044 to 0.0064]	3.54
MicroTip™	92.2 [3.630]	1.57 [0.062]	1.93 [0.076]	Straight Handpiece: 279 to 355 [0.0110 to 0.0140] Angled Handpiece: 127 to 183 [0.005 to 0.0072]	3.99
Straight Extended Standard Tip	183.8[7.238]	1.98 [0.078]	2.54 [0.100]	Straight Handpiece: 287 to 355 [0.0113 to 0.0140] Angled Handpiece: 112 to 163 [0.0044 to 0.0064]	16.15
Curved Extended Standard Tip	183.8 [7.238]	1.98 [0.078]	2.54 [0.100]	Straight Handpiece: 287 to 355 [0.0113 to 0.0140] Not compatible with angled handpiece	16.15
MacroTip™	79.5 [3.130]	2.64 [0.104]	3.18 [0.125]	Straight Handpiece: 254 to 307 [0.0100 to 0.0121] Angled Handpiece: 102 to 142 [0.0040 to 0.0056]	3.84
Laparoscopic Tip	301.4 [11.865]	1.98 [0.078]	2.54 [0.100]	Straight Handpiece: 178 to 229 [0.007 to 0.009] Not compatible with angled handpiece	32.13
Extended Life Standard Tip[a]	79.8 [3.140]	1.98 [0.078]	2.54 [0.100]	Straight Handpiece: 287 to 355 [0.0113 to 0.0140] Angled Handpiece: 112 to 163 [0.0044 to 0.0064]	3.54
Extended Life MacroTip[b]	79.5 [3.130]	2.64 [0.104]	3.18 [0.125]	Straight Handpiece: 254 to 307 [0.0100 to 0.0121] Angled Handpiece: 102 to 142 [0.0040 to 0.0056]	3.84

a. Not for sale within USA.
b. Not for sale within USA.

Tip Specifications for the 36 kHz Handpiece

Table A-2
Tip Specifications—36 kHz

Tip	Length (mm) [in]	ID (mm) [in]	OD (mm) [in]	Amplitude (peak to peak) µm [in]	Weight (g)
PrecisionTip™	56.4 [2.221]	1.14 [0.045]	1.45 [0.057]	191 to 210 [0.0075 to 0.0083]	1.37
Straight Extended PrecisionTip	125.1 [4.924]	1.14 [0.045]	1.45 [0.057]	191 to 210 [0.0075 to 0.0083]	7.86
Curved Extended PrecisionTip	125.1 [4.924]	1.14 [0.045]	1.45 [0.057]	191 to 210 [0.0075 to 0.0083]	7.86
MicroTip™	52.8 [2.080]	1.57 [0.062]	1.93 [0.076]	175 to 193 [0.0069 to 0.0076]	1.30
Straight Extended MicroTip	121.5 [4.783]	1.57 [0.062]	1.93 [0.076]	175 to 193 [0.0069 to 0.0076]	7.50
Curved Extended MicroTip	121.5 [4.783]	1.57 [0.062]	1.93 [0.076]	175 to 193 [0.0069 to 0.0076]	7.50
Exteneded MicroTip Plus	192.7 [7.588]	1.57 [0.062]	1.93 [0.076]	137 to 155 [0.0054 to 0.0061]	7.97
Standard Tip	45.7 [1.800]	1.98 [0.078]	2.54 [0.100]	137 to 155 [0.0054 to 0.0061]	1.31
Straight Extended Standard Tip	114.4 [4.504]	1.98 [0.078]	2.54 [0.100]	137 to 155 [0.0054 to 0.0061]	7.48
Curved Extended Standard Tip	114.4 [4.504]	1.98 [0.078]	2.54 [0.100]	137 to 155 [0.0054 to 0.0061]	7.48
CUSA SaberTip™	114.9 [4.525]	1.14 [0.45]	2.23 [0.088]	117 to 135 [0.0046 to 0.0053]	9.55
CUSA ShearTip™	117.9 [4.643]	1.57 [0.062]	2.33 [0.0919]	165 to 203 [0.0065 to 0.0080]	7.77
Extended Life Curved Extended PrecisionTip[a]	125.1 [4.924]	1.14 [0.45]	1.45 [0.057]	175 to 210 [0.0069 to 0.0083]	7.86
Extended Life Curved Extended MicroTip[b]	121.5 [4.783]	1.57 [0.062]	1.93 [0.076]	165 to 193 [0.0065 to 0.0076]	7.50
Extended Life Curved Extended Standard Tip[c]	114.4 [4.504]	1.98 [0.078]	2.54 [0.100]	137 to 155 [0.0054 to 0.0061]	7.48

a. Not for sale within USA.
b. Not for sale within USA.
c. Not for sale within USA.

APPENDIX B

Sterilization Validation

Validation of Steam Sterilization Parameters

A steam sterilization study was conducted according to AAMI TIR No. 12-2010– Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers.

Challenge

A minimum of 1 x 10^6 bacillus stearothermophilus on a spore strip/disk carrier and a braided nylon suture carrier. ($D_{121°C}$ = 1.5 and 1.6 minutes).

Placement of Biological Indicators (BIs)

CUSA 23 kHz Handpiece, Tip and Tubing:

Cycles contained four BIs (spore suture) placed in the following locations:

- Inside the tip, not assembled to the hand piece
- Wrapped around the handpiece cord
- Underneath the tip torquing base where it meets the bottom of the case
- Approximately half way inside the manifold tubing

CUSA 36 kHz Handpiece, Tip and Tubing:

Cycles contained four BIs (spore suture) placed in the following locations:

- Inside the tip when assembled to the handpiece
- Wrapped around the handpiece cord
- Underneath the tip torquing base where it meets the bottom of the case
- Approximately half way inside the manifold tubing

Acceptance Criteria

In order for the handpiece to be considered validated, none of the biological indicators demonstrated growth of the indicator organism. A 6-log reduction at the half cycle exposure time indicates that a full cycle (twice the half cycle exposure time) will produce sufficient lethality to effect at least a 12-log reduction and provide a 10^{-6} sterility assurance level (SAL).

APPENDIX C

Warranty

Integra Warranty for CUSA® Excel and CUSA® Excel+ Ultrasonic Surgical Aspirator Systems

1. Warranty.

INTEGRA LIFESCIENCES CORPORATION and its wholly owned subsidiaries ("Integra") warrant to Integra authorized distributors and the original purchaser only that each new Integra CUSA Excel and CUSA Excel+ Ultrasonic Surgical Aspirator (hereinafter the Equipment or the product) is free from manufacturing defects in material and workmanship under normal use and service for a period of one (1) year (except as otherwise expressly provided as to accessory items) from the date of invoice by Integra (or its authorized distributor) to the original purchaser, but in no event beyond the expiration date stated on any product labeling (hereinafter the Warranty Period). For purposes of products sold by Integra through an authorized distributor of Integra, "original purchaser" shall include the purchaser of Integra products to whom the distributor first sells the product. The original purchaser is hereinafter referred to as Customer.

1.1. *Coverage.* During the Warranty Period, Integra shall provide free-of-charge service and maintenance consistent with the provisions of Section 3 of this Warranty, so that the Equipment conforms to the specifications defined in the CUSA Excel and CUSA Excel+ Ultrasonic Surgical Aspirator Operator's Manuals, as such Operator's Manuals may be modified by Integra from time to time (the "Specifications").

1.2. *Exclusions.* The Warranty shall not apply in any manner to service or maintenance of the Equipment, or to replacement of its parts, with respect to:

(i) use of Equipment with any tips, flues, and manifold tubing sets and accessories other than those manufactured by Integra LifeSciences;

(ii) defects arising out of materials or parts provided, modified or designed by anyone other than an authorized Integra service agent (the Integra "Service Agent");

(iii) defects emanating from improper or negligent installation, storage or use of the Equipment or any component thereof, including but not limited to operating the Equipment not in accordance with instructions provided in the Operator's Manual;

(iv) defects arising from improper or negligent cleaning or sterilization methods or improper maintenance of the Equipment;

(v) defects resulting from repairs or service of the Equipment provided other than by Integra or its authorized representatives;

(vi) defects arising from accidental damage to the Equipment, acts of God, electrical power damage, equipment malfunction, unusual stress, unreasonable operating procedures or abnormal or extreme operating conditions; and

(vii) normal wear and tear.

2. Service, Repairs and Replacement.

2.1. *Service and Repairs.* All service and repairs covered by this Warranty may be referred to hereinafter as "in-warranty repairs," and all service and repairs not covered by this Warranty may be referred to as "out-of-warranty repairs." Integra's sole obligation for in-warranty repairs shall be to make all necessary adjustments and repairs in accordance with this Warranty. Integra shall charge Customer at Integra standard rates for any out-of-warranty repair performed by Integra.

2.2. *Equipment Replacement.* The defective Equipment or part thereof that is replaced in accordance with the Warranty shall be the property of Integra. Integra reserves the right to fill spare parts requests using refurbished sub-assemblies provided that such sub-assemblies are functionally equivalent to new sub-assemblies and carry the same warranty as the replaced sub-assemblies.

2.3. *Notification.* In order to avail itself of its rights under the Warranty, Customer or Integra authorized distributors, must immediately notify Integra of any defects and provide Integra every opportunity to inspect and remedy defects.

3. Repair Parts and Services.

3.1. Included under the Warranty are the following services:

3.1.1. *Consoles.* Integra or its distributor, when authorized for this purpose, shall, if possible, perform on-site repair of consoles and where not possible or otherwise decided at the sole discretion of Integra, Integra or its distributor shall arrange and pay to ship the affected Equipment to the designated repair facility. Integra or its distributor authorized for this purpose shall repair the affected Equipment or replace a console by a new or refurbished console (all of which at the discretion of Integra), that shall carry the same remaining warranty as the original equipment.

3.1.2. *Handpieces.* Integra shall repair or replace any defective handpieces covered by the Warranty by a new or refurbished handpiece (all of which at the discretion of Integra) that shall carry the same remaining warranty as the original equipment (an "Exchange Handpiece").

3.2. *Modifications to Covered Equipment.* From time to time, at its sole discretion, Integra may propose modifications to the covered Equipment and to the Specifications for the Equipment. Subject to Customer's approval and at its sole expense, the Customer may request Integra to make such modifications to the covered Equipment and to the Specifications. Integra shall make such modifications for the Customer, which modifications may include the installation of new parts in the Equipment, at a price equal to the then-current list price for such modifications, as such list price is established by Integra in its sole discretion.

4. Quality Control.

4.1. Customer shall maintain reasonable standards of quality control, operations, procedures, safety testing and inspection of Equipment to ensure that unnecessary service or maintenance is not required hereunder.

4.2. Customer shall provide a technical counterpart to Integra's Service Agent for assistance in Integra's telephonic diagnosis of the malfunction with the Equipment. Customer shall reasonably accept Integra's determination whether a repair or service is an in-warranty repair or an out-of-warranty repair.

5. Limitation of Liability.

5.1. INTEGRA's sole responsibility under the warranties described in Section 1 shall be repair or replacement, at INTEGRA's sole discretion at INTEGRA's expense, subject to the terms of this warranty and applicable agreements. THE WARRANTIES DESCRIBED IN SECTION 1 HEREOF ARE EXCLUSIVE AND ARE GIVEN AND ACCEPTED IN LIEU OF ALL OTHER WARRANTIES OF INTEGRA OR ITS SERVICE AGENTS WITH RESPECT TO THE QUALITY, PERFORMANCE AND OPERATION OF THE EQUIPMENT, WRITTEN OR ORAL, EXPRESS OR IMPLIED, AND WHETHER OR NOT ATTRIBUTABLE TO SERVICE PERFORMED PURSUANT TO THE WARRANTY. ALL OTHER REPRESENTATIONS OR WARRANTIES OF INTEGRA OR ITS REPRESENTATIVES, EXPRESS OR IMPLIED, WITH RESPECT TO THE EQUIPMENT OR THE SERVICES, DIAGNOSIS, ADVICE, ASSISTANCE OR PARTS TO BE TENDERED PURSUANT TO THE WARRANTY, INCLUDING, WITHOUT LIMITATION, THOSE OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE HEREBY EXPRESSLY DISCLAIMED. IN NO EVENT SHALL INTEGRA, ITS ASSIGNEES OR SERVICE AGENTS BE LIABLE FOR LOSS OF USE, REVENUE OR PROFIT OR ANY OTHER INDIRECT, INCIDENTAL, EXEMPLARY, CONSEQUENTIAL, SPECIAL OR OTHER DAMAGES, WHETHER ARISING IN CONTRACT OR IN TORT, BY VIRTUE OF THE WARRANTY OR ANY PERFORMANCE OR BREACH BY INTEGRA, ITS ASSIGNEES OR SERVICE AGENTS HEREUNDER OR PURSUANT HERETO.

5.2. Customer agrees that, notwithstanding the technical assistance provided pursuant to the Warranty by Integra or its representatives, Customer shall be fully and solely responsible for all treatments performed or attempted with the Equipment. INTEGRA MAKES NO REPRESENTATION OR WARRANTY AS TO THE EFFICACY OF THE EQUIPMENT OR OF THE TECHNICAL ASSISTANCE TO BE RENDERED BY INTEGRA, ITS ASSIGNEES OR SERVICE AGENTS, FOR PURPOSES OF THE PARTICULAR TREATMENT THAT CUSTOMER INTENDS TO PERFORM FOR THIRD PARTIES. Moreover, Integra disclaims any liability with respect to the efficacy of the Equipment or of said technical assistance or with respect to any claims by third parties related to any treatment performed by Customer.

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 CONFIDENTIAL

INTEGRA™ cusa excel®

CUSA EXcel® 23 kHz Extended Life Laparoscopic Tip

REF CAT. C4604ELT

Nonsterile, reusable

℞ ONLY

Read instructions before use

Latex Free

Não Estéril, reutilizável

Nicht steril, wiederverwendbar

No estéril, reutilizable

Non stérile, réutilisable

Non sterile, riutilizzabile

Niet steriel, herbruikbaar

Osteril, återanvandbart

Нестерильно, Многократного применения

未消毒、可再用

未滅菌、リユーザブル

BR CUSA EXcel® Ponta Laparoscópica de Vida Útil Prolongada de 23 kHz

DE CUSA EXcel®-Langzeit-Laparoskopiespitze, 23 kHz

ES Terminal laparascópico de duración prolongada CUSA EXcel® de 23 kHz

FR Aiguille coelioscopique longue durée 23 kHz CUSA EXcel®

IT Punta laparoscopica di durata maggiore CUSA EXcel® da 23 kHz

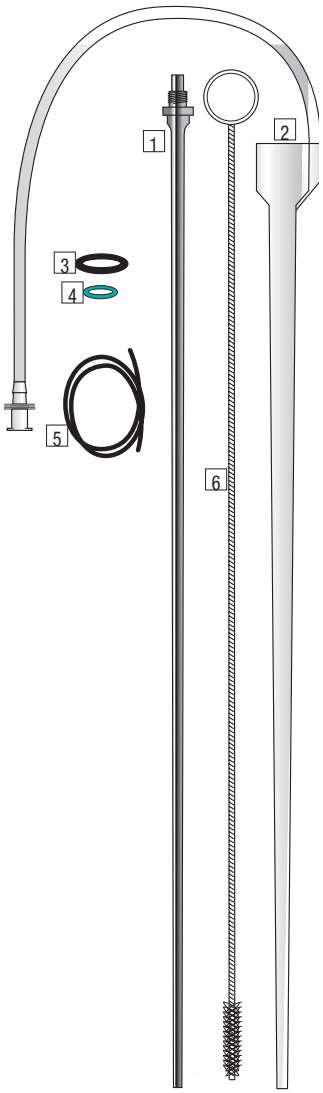
NL CUSA EXcel® 23 kHz Laparoscopische tip met extra lange levensduur

SE CUSA EXcel® 23 kHz laparoskopispetsar, flergångs

RU Лапароскопический наконечник CUSA EXcel® увеличенного срока использования на 23 Кгц

CN CUSA EXcel® 23 kHz 长寿命腹腔镜刀头

JP CUSA EXcel® 23 kHz エクステンドライフ・ラパロスコピック チップ



EN Contents

1. 1 Tip
2. 6 Flue assemblies
3. 6 Black o-rings
4. 6 Green o-rings
5. 6 Tip cleaners
6. 1 Reusable cleaning brush

BR Conteúdo

1. 1 Ponta
2. 6 Conjuntos de tubos coletores
3. 6 Anéis em O pretos
4. 6 Anéis em O verdes
5. 6 Limpadores de Ponta
6. 1 Uma escova para limpeza reutilizável

DE Inhalt

1. 1 Spitze
2. 6 Flue-Sätze
3. 6 schwarze O-Ringe
4. 6 grüne O-Ringe
5. 6 Spitzenreiniger
6. 1 wiederverwendbare Reinigungsbürste

ES Contenido

1. 1 Terminal
2. 6 conexiones de manguitos
3. 6 arandelas negras
4. 6 arandelas verdes
5. 6 limpiadores para el terminal
6. 1 cepillo de limpieza reutilizable

FR Contenu

1. 1 aiguille
2. 6 embouts d'irrigation
3. 6 joints noirs
4. 6 joints verts
5. 6 écouvillons de nettoyage
6. 1 brosse de nettoyage réutilisable

IT Contenuto

1. 1 punta
2. 6 gruppi di condotti
3. 6 o-ring neri
4. 6 o-ring verdi
5. 6 filtri della punta
6. 1 spazzola di pulizia riutilizzabile

NL Inhoud

1. 1 Tip
2. 6 Irrigatiehuls-sets
3. 6 Zwarte O-ringen
4. 6 Groene O-ringen
5. 6 Tipreinigers
6. 1 herbruikbare reinigingsborstel

SE Innehåller

1. 1 spets
2. 6 flödesskydd
3. 6 svarta O-ringar
4. 6 gröna O-ringar
5. 6 spetsrengörare
6. 1 rengöringsborste för flergångsbruk

RU Содержание

1. 1 наконечник
2. 6 ирригационных чехлов
3. 6 черных уплотнительных колец
4. 6 зеленых уплотнительных колец
5. 6 очистителей наконечника
6. 1 щетка для чистки наконечника многоразового использования

CN 所含物品

1. 1 个刀头
2. 6 套套管组件
3. 6 个黑色 O 形圈
4. 6 个绿色 O 形圈
5. 6 根刀头清洁丝
6. 1 把可重复使用的清洗刷

JP 内容物

1. チップ 1 本
2. フルーアセンブリ 6
3. O リング（黒）6 個
4. O リング（緑）6 個
5. チップクリーナー 6
6. リユーザブル クリーニングブラシ 1 本

Statement. See next page for language.

Location of Contamination *

EN

CUSA EXcel® 23 kHz Extended Life Laparoscopic Tip

The extended life laparoscopic tip (30.14 cm) is for use with the C2600 23 kHz straight handpiece:

REF CAT.	Description	Diameter
C4604ELT	Extended Life LaparoscopicTip	1.98 mm

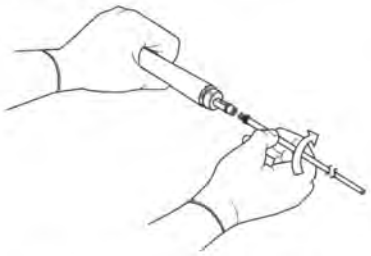
You can use the tip and cleaning brush in this pack six times (6X). All other items are for single use only. No items in this pack contain latex.

Refer to the CUSA EXcel® System User's Guide for complete assembly and sterilization instructions.

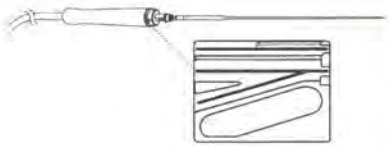
For Steam Sterilization Only. Nonsterile. Sterilize Before Use.

Assembly

1. Thread the tip onto the handpiece connecting body. Turn the tip until it is finger tight.



2. Locate the slot in the tip torquing base that matches the color on the handpiece connector (23 kHz – green). Put the handpiece in the tip torquing base so that the metal connecting body fits snugly in the metal end of the slot.

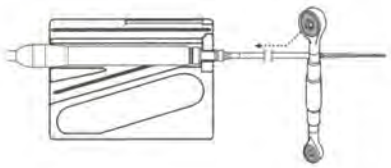


3. Hold the handpiece in place in the tip torquing base.

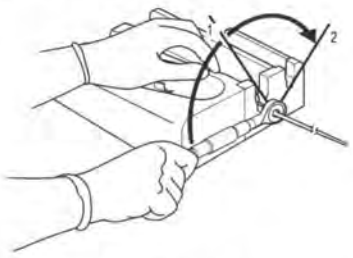
Notice

To avoid product damage, NEVER hold the handpiece in your hand while using the torque wrench to tighten or loosen the tip.

4. Match the colored end of the torque wrench with the handpiece connector color (23 kHz – green). Slide the color coded side of the wrench over the tip, being careful not to damage the tip, until the hex in the wrench engages the hex of the tip.



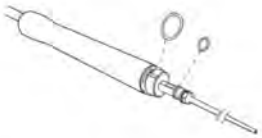
5. Rotate the wrench clockwise until you feel and hear a click. Rotate again until you feel and hear a second click.



6. Carefully remove the wrench from the tip.
7. Remove the handpiece from the tip torquing base.
8. Locate the o-rings for the handpiece you are assembling.

Large o-ring	black
Small o-ring	green

9. Slide the larger o-ring over the connecting body and into the groove in the neck of the handpiece. Slide the smaller o-ring into the groove in the metal connecting body.



10. Put the assembled handpiece, nosecone, and one flue, with tip cleaner into the sterilizer case.

Caution

Do not put a nosecone of any type onto the handpiece before sterilization. Surfaces covered by the nosecone may not be sterile.

Disassembly

When cleaning handpieces, be sure to wear protective clothing, gloves, and safety glasses according to your hospital's policy for the cleaning process.

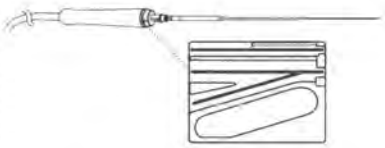
1. Using a soft cloth moistened with a germicidal solution, wipe the handpiece to remove the gross contaminants.

2. Remove the flue, if not already removed. Discard the flue.

3. Remove the nosecone:
   a. Release the nosecone by twisting it counterclockwise.
   b. Pull the nosecone away from the handpiece.

DO NOT DISCARD A STANDARD NOSECONE.

4. Remove the o-rings and discard them.
5. Locate the slot in the tip torquing base that matches the color on the handpiece connector (23 kHz – green). Put the handpiece in the tip torquing base so that the metal connecting body fits snugly in the metal end of the slot.

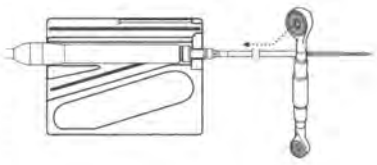


6. Hold the handpiece in place in the tip torquing base.

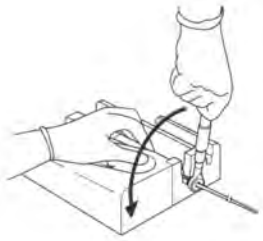
Notice

To avoid product damage, NEVER hold the handpiece in your hand while using the torque wrench to tighten or loosen the tip.

7. Match the colored end of the torque wrench with the handpiece connector color (23 kHz – green). Slide the color coded side of the wrench over the tip, being careful not to damage the tip, until the hex in the wrench engages the hex of the tip.



8. Rotate the wrench counterclockwise until the tip is loose.

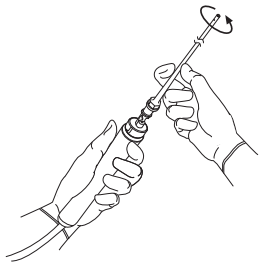


Contraindication for CUSA Excel 23 kHz Extended Life Laparoscopic Tip Package Insert

Contraindication

Laparoscopic procedures in women with known or suspected uterine sarcoma using devices that fragment tissue may spread cancerous tissue. Also, there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma. Therefore, devices that fragment tissue are contraindicated for use during laparoscopic hysterectomy or myomectomy for uterine fibroid removal.

9. Carefully remove the wrench from the tip.
10. Remove the handpiece from the tip torquing base.
11. Unscrew the tip.



Cleaning and Sterilizing

When you have disassembled the handpiece, you need to clean the handpiece, the tip torquing base, the torque wrench, and the tip. To clean threads and to polish connecting surfaces, for both the handpiece and the tip, you can use the CUSA® Handpiece/Tip Maintenance Kit (Ref/Cat C0023).

For complete instructions on cleaning and sterilization, refer to the CUSA EXcel® System User's Guide.

WARNING: Extended Life Tips (ELT) allow for 6 sterilisation cycles and are provided with 6 flues. Any tip used 6 times and flue used once must be disposed of. Tips used more than 6 times and flues used more than once increase the risk of modifying the properties and performance of the device, and of increasing the likelihood of complications and/or undesirable effects. Devices must be disposed of in accordance with hospital policies.

CUSA EXcel® Ponta Laparoscópica de Vida Útil Prolongada de 23 kHz.

A ponta laparoscópica de vida útil prolongada (30,14 cm) é para uso com peça de mão reta C2600 23 kHz:

REF. CAT.	Descrição	Diâmetro
C4604ELT	Ponta Laparoscópica de Vida Útil Prolongada	1,98 mm

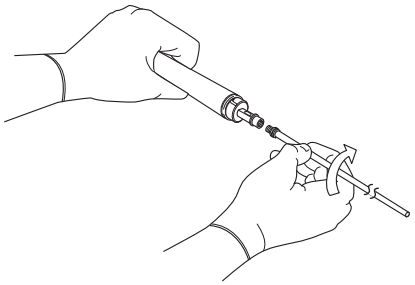
Você pode utilizar a ponta e a escova para limpeza contidas neste pacote seis vezes (6X). Todos os outros itens são uso único apenas. Nenhum dos itens deste pacote contêm látex.

Consulte o Guia do Usuário do Sistema CUSA EXcel® para obter instruções completas de montagem e esterilização.

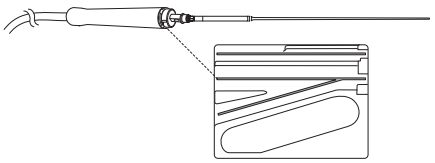
Apenas para Esterilização a Vapor. Não Estéril. Esterilize Antes de Usar.

Montagem

1. Parafuse a ponta no corpo conector da peça de mão. Gire a ponta até que fique bem firme.



2. Encontre o espaço na base de torque de ponta que combine com a cor no conector da peça de mão (23 kHz – verde). Coloque a peça de mão na base de torque de ponta de modo que o corpo conector de metal se ajuste bem na extremidade de metal do encaixe..

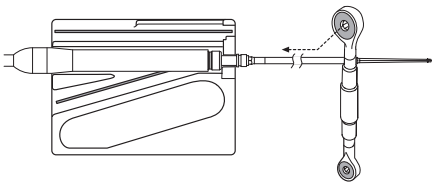


3. Segure a peça de mão mantendo-a na base de torque de ponta.

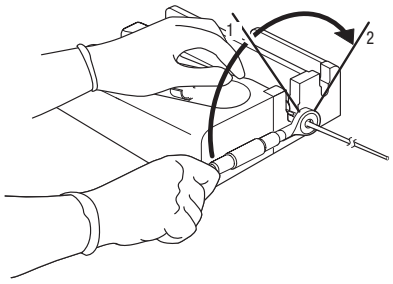
Aviso

Para evitar danos ao produto, NUNCA segure a peça de mão em sua mão enquanto estiver utilizando a chave de torque para apertar ou afrouxar a ponta.

4. Combine a extremidade colorida da chave de torque com a cor do conector da peça de mão (23 kHz – verde). Deslize o lado da cor do código de cores da chave sobre a ponta com cuidado para não danifica-la até que o hexágono da chave se encaixe no hexágono da ponta.



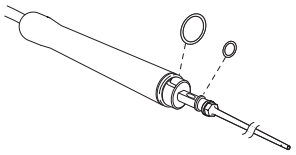
5. Gire a chave no sentido horário até sentir e ouvir um clique. Gire-a novamente até sentir e ouvir um segundo clique.



6. Remova a chave da ponta cuidadosamente.
7. Remova a peça de mão da base de torque de ponta.
8. Localize os anéis em O da peça de mão que você está montando:

Anel em O grande	preto
Anel em O pequeno	verde

9. Deslize o anel em O maior sobre o corpo de conexão e no encaixe localizado no fuste da peça de mão. Deslize o anel menor para dentro da ranhura no corpo conector de metal.



10. Coloque a peça de mão montada, o adaptador cônico e um tubo coletor com um limpador de ponta no estojo esterilizador.

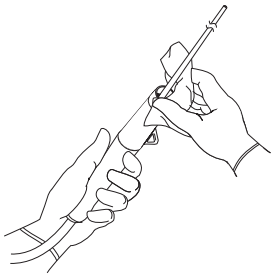
Cuidado

Não coloque um adaptador cônico, qualquer que seja o tipo, na peça de mão antes da esterilização. As superfícies cobertas pelo adaptador cônico podem não estar estéreis.

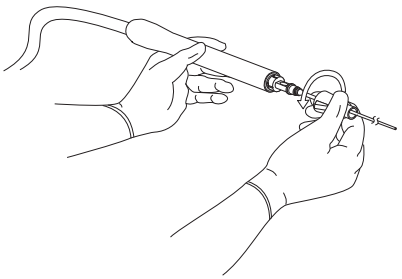
Desmonte

Quando estiver limpando as peças de mão, certifique-se do uso de roupa protetora, luvas e óculos de segurança de acordo com a política do hospital para o processo de limpeza.

1. Utilizando um pano macio umedecido em uma solução germicida, limpe a peça de mão para remoção dos contaminantes mais grosseiros.

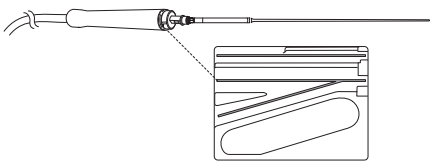


2. Remova o tubo, se ainda não tiver sido removido. Acople o tubo coletor
3. Remova o adaptador cônico.
   a. Libere o adaptador cônico girando-o no sentido anti-horário.
   b. Puxe o adaptador cônico para fora da peça de mão.



NÃO descarte um adaptador cônico PADRÃO.

4. Remova os anéis em O e descarte-os.
5. Encontre o espaço na base de torque de ponta que combine com a cor no conector da peça de mão (23 kHz – verde). Coloque a peça de mão na base de torque de ponta de modo que o corpo conector de metal se ajuste bem na extremidade de metal do encaixe.



6. Segure a peça de mão mantendo-a na base de torque de ponta.

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Para evitar danos ao produto, NUNCA segure a peça de mão em sua mão enquanto estiver utilizando a chave de torque para apertar ou afrouxar a ponta.

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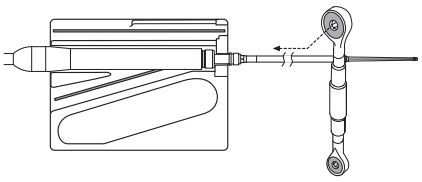
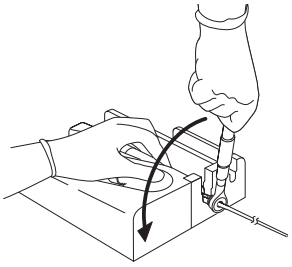


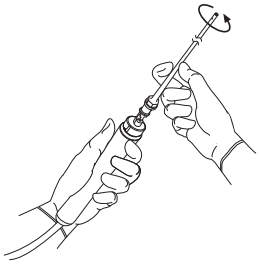
8. Gire a chave no sentido anti-horário até soltar a ponta.



9. Remova a chave da ponta cuidadosamente.

10.Remova a peça de mão da base de torque de ponta.

11.Desaparafuse a ponta.



Limpeza e Esterilização

Quando você tiver desmontado a peça de mão, será necessário limpá-la, assim como a pinta, a base de torque e o torquês. Tanto para a peça de mão quanto para a ponta, para limpar as roscas e polir as superfícies de contato, você poderá utilizar os estojos de manutenção CUSA® para Peça de Mão/Pontas(Ref. CAT C0023 para 23 kHz, e C0036 para 36 kHz).

Para instruç›es completas sobre limpeza e esterilização, consulte o Guia do Usuário do Sistema CUSA EXcel®.

AVISO: As Pontas Mais Resistentes (ELT) permitem até 6 ciclos de esterilização e são fornecidas com 6 tubos (flue). Qualquer ponta usada 6 vezes e cada tubo usado uma vez devem ser eliminados. As pontas usadas mais de 6 vezes e os tubos usados mais do que uma vez aumentam o risco de modificar as propriedades e o desempenho do dispositivo e de aumentar a possibilidade de complicações e/ou efeitos indesejáveis. Os dispositivos devem ser eliminados de acordo com as políticas hospitalares.

CUSA EXcel®-Langzeit-Laparoskopiespitze, 23 kHz

Die Langzeit-Laparoskopiespitze (30,14 cm) ist zur Verwendung mit dem geraden 23-kHz-Handstück C2600 vorgesehen.

REF CAT.	Beschreibung	Durchmesser
C4604ELT	Langzeit-Laparoskopiespitze	1,98 mm

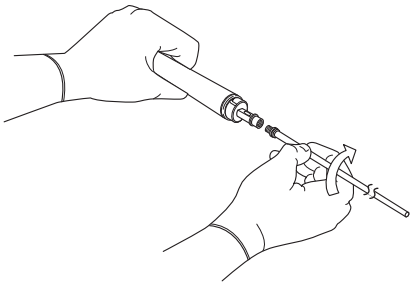
Die Spitze und die Reinigungsbürste in dieser Packung lassen sich sechs Mal (6 x) verwenden. Der übrige Inhalt ist nur zur einmaligen Verwendung vorgesehen. Der gesamte Inhalt dieser Packung ist latexfrei.

Hinweise zur kompletten Montage und zur Sterilisation sind der Bedienungsanleitung des CUSA EXcel®-Systems zu entnehmen.

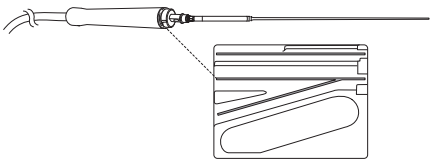
Nur zur Dampfsterilisierung. Nicht steril. Vor Verwendung sterilisieren.

Montage

1. Spitze auf das Verbindungsteil des Handstücks schrauben. Spitze mit den Fingern festdrehen.



2. Entsprechende Aufnahme des Montagesatzes wählen, die der Farbe des Handstückverbinders entspricht (23 kHz – grün). Handstück in den Montagesatz so einlegen, daß das metallene Verbindungsteil gut in das metallene Ende der Halterung paßt.

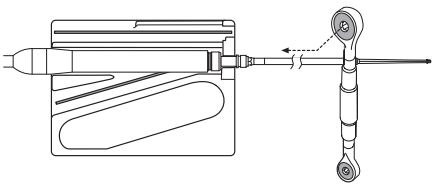


3. Handstück im Spitzen-Montagesatz festhalten.

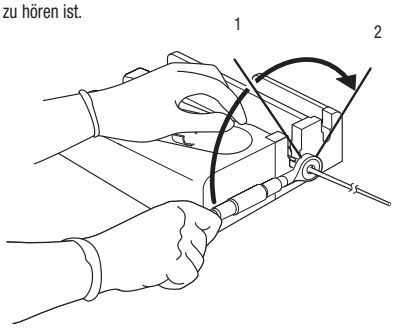
Hinweis

Zur Vermeidung einer Beschädigung des Produkts darf das Handstück beim Befestigen oder Lösen der Spitze mit dem Drehmomentschlüssel NIEMALS in der Hand gehalten werden.

4. Farbiges Ende des Drehmomentschlüssels in Übereinstimmung mit der Farbe des Handstückverbinders (23 kHz – grün) wählen. Die farbkodierte Seite des Schlüssels über die Spitze schieben, bis der Sechskant im Schlüssel und der Sechskant der Spitze ineinandergreifen. Dabei ist darauf zu achten, daß die Spitze nicht beschädigt wird.



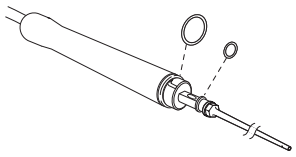
5. Schlüssel im Uhrzeigersinn drehen, bis ein Klicken zu spüren und zu hören ist. Weiterdrehen, bis ein zweites Klicken zu spüren und zu hören ist.



6. Schlüssel vorsichtig von der Spitze abnehmen.
7. Handstück aus dem Montagesatz nehmen.
8. O-Ringe für das zu montierende Handstück auswählen:

Großer O-Ring	schwarz
Kleiner O-Ring	grün

9. Größeren O-Ring über das Verbindungsteil auf die Nut im Ansatz des Handstücks schieben. Kleineren O-Ring auf die Nut im metallenen Verbindungsteil schieben.



10. Montiertes Handstück, Nosecone und einen Flue mit einen Spitzenreiniger in den Sterilisationsbehälter einlegen.

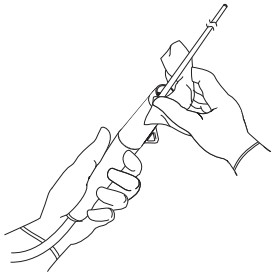
Achtung

Vor der Sterilisation ist kein Nosecone, gleich welcher Art, am Handstück zu befestigen. Die vom Nosecone bedeckten Flächen könnten nicht steril sein.

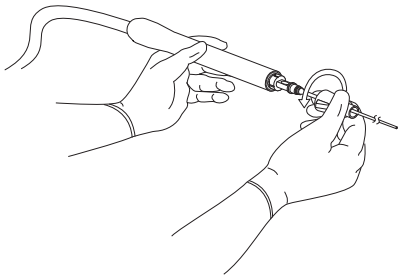
Demontage

Beim Reinigen der Handstücke sollten Schutzkleidung, Schutzhandschuhe und eine Schutzbrille entsprechend den Vorschriften Ihrer Gesundheitseinrichtung für den Reinigungsprozeß angelegt werden.

1. Weiches Tuch mit keimtötender Lösung anfeuchten und Handstück abwischen, um grobe Verunreinigungen zu beseitigen.

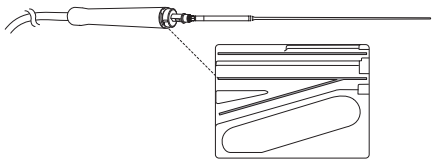


2. Flue abnehmen, sofern nicht bereits geschehen. Flue entsorgen.
3. Nosecone abnehmen:
   a. Nosecone durch Drehen entgegen dem Uhrzeigersinn lösen.
   b. Nosecone vom Handstück abziehen.



STANDARD-NOSECONE NICHT ENTSORGEN.

4. O-Ringe abnehmen und entsorgen.
5. Entsprechende Aufnahme des Montagesatzes wählen, die der Farbe des Handstückverbinders entspricht (23 kHz – grün). Handstück in den Montagesatz so einlegen, daß das metallene Verbindungsteil gut in das metallene Ende der Halterung paßt.

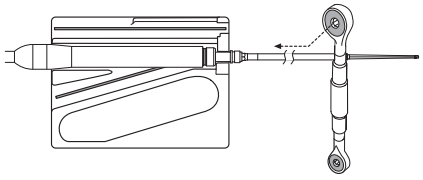


6. Handstück im Spitzen-Montagesatz festhalten.

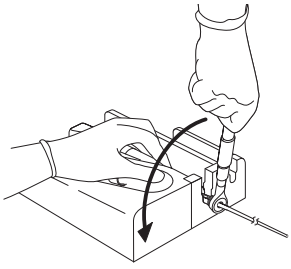
Hinweis

Zur Vermeidung einer Beschädigung des Produkts darf das Handstück beim Befestigen oder Lösen der Spitze mit dem Drehmomentschlüssel NIEMALS in der Hand gehalten werden.

7. Farbiges Ende des Drehmomentschlüssels in Übereinstimmung mit der Farbe des Handstückverbinders (23 kHz – grün) wählen. Die farbkodierte Seite des Schlüssels über die Spitze schieben, bis der Sechskant im Schlüssel und der Sechskant der Spitze ineinandergreifen. Dabei ist darauf zu achten, daß die Spitze nicht beschädigt wird.



8. Schlüssel entgegen dem Uhrzeigersinn drehen, bis die Spitze gelöst ist.

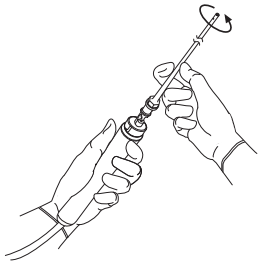


DE

9. Schlüssel vorsichtig von der Spitze abnehmen.

10. Handstück aus dem Montagesatz nehmen.

11. Spitze abschrauben.



Reinigung und Sterilisation

Sobald das Handstück demontiert ist, sind Handstück, Montagesatz, Drehmomentschlüssel und Spitze zu reinigen. Zur Reinigung der Gewinde und zum Polieren der Oberflächen von Handstück und Spitze kann das CUSA®-Handstück-/Spitzen-Wartungs-Kit (Ref/Cat C0023) verwendet werden.

Ausführliche Hinweise zur Reinigung und zur Sterilisation sind der Bedienungsanleitung des CUSA EXcel®-Systems zu entnehmen.

ACHTUNG! Spitzen der Art Extended Life Tips (ELT) können 6 Sterilisationszyklen unterzogen werden und werden mit 6 Flues bereitgestellt. Jede 6-mal verwendete Spitze und jeder einmal verwendete Flue muss entsorgt werden. Mehr als 6-mal verwendete Spitzen und mehr als einmal verwendete Flues erhöhen das Risiko einer Änderung der Eigenschaften und der Leistung der Vorrichtung sowie die Wahrscheinlichkeit von Komplikationen und/oder unerwünschten Wirkungen. Vorrichtungen sind entsprechend der Krankenausvorschriften zu entsorgen.

Terminal laparascópico de duración prolongada CUSA EXcel® de 23 kHz

El terminal laparoscópico de duración prolongada (30,14 cm) se utiliza con la pieza de mano recta C2600 de 23 kHz:

REF CAT.	Descripción	Diámetro
C4604ELT	Terminal laparoscópico de duración prolongada	1,98 mm

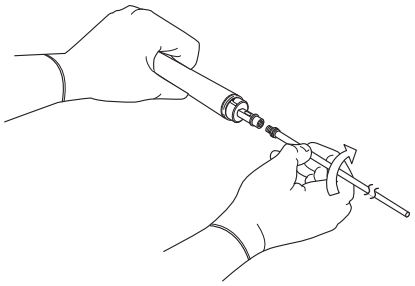
Puede utilizar el terminal y el cepillo de limpieza del paquete hasta seis veces (6X). Los otros elementos son para un solo uso. Los elementos de este paquete no contienen látex.

Consulte la Guía del usuario del sistema CUSA EXcel® si desea ver las instrucciones completas de montaje y esterilización.

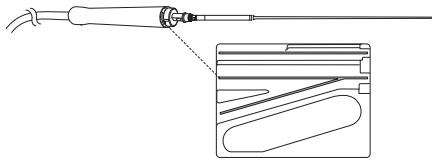
Sólo para esterilización a vapor. No estéril. Esterilizar antes de su uso.

Montaje

1. Enrosque el terminal en el cuerpo de conexión de la pieza de mano. Gire el terminal con la mano hasta que esté apretado.



2. En la base de roscado del terminal, localice la ranura que tenga el mismo color que el conector de la pieza de mano (23 kHz – verde). Coloque la pieza de mano en la base de roscado del terminal de manera tal que el cuerpo de conexión metálico encaje perfectamente en el extremo de metal de la ranura.

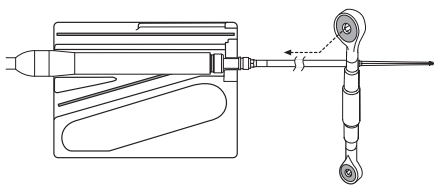


3. Mantenga fija la pieza de mano en la base de roscado del terminal.

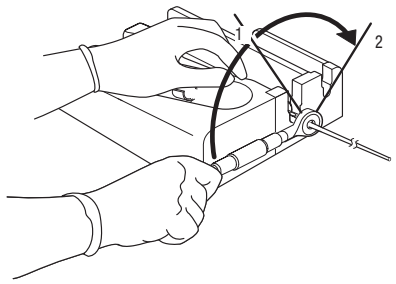
Aviso

Para evitar dañar el producto, NUNCA sostenga la pieza de mano mientras utiliza la llave de roscado para ajustar o aflojar el terminal.

4. Haga coincidir el extremo de color de la llave de roscado con el color del conector de la pieza de mano (23 kHz – verde). Con cuidado para no dañar el terminal, deslice el lado de color de la llave sobre el terminal hasta que el hexágono de la llave encaje en el hexágono del terminal.



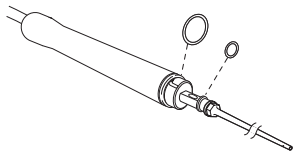
5. Gire la llave en sentido horario hasta que sienta y escuche un clic. Gire nuevamente hasta que sienta y oiga un segundo clic.



6. Extraiga cuidadosamente la llave del terminal.
7. Retire la pieza de mano de la base de roscado del terminal.
8. Coloque las arandelas correspondientes a la pieza de mano que está montando:

Arandela grande	negra
Arandela pequeña	verde

9. Deslice la arandela más grande sobre el cuerpo de conexión hasta alcanzar la ranura localizada en el cuello de la pieza de mano. Deslice la arandela más pequeña en la ranura del cuerpo de conexión metálico.



10. Coloque la pieza de mano montada, la funda cónica y el manguito con el limpiador del terminal en la caja de esterilización.

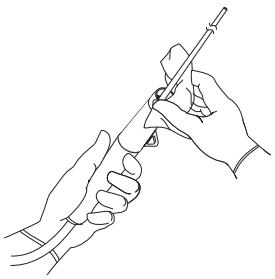
Precaución

No coloque ninguna funda cónica en la pieza de mano antes de esterilizar. Las superficies cubiertas con una funda cónica no pueden esterilizarse.

Desmontaje

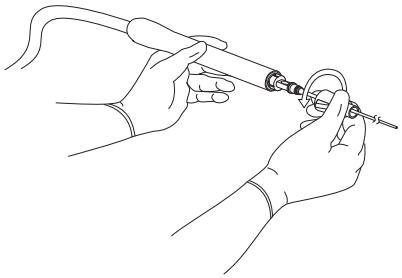
Cuando limpie las piezas de mano, utilice la correspondiente vestimenta protectora con guantes y gafas de seguridad, siguiendo la política de su hospital relativa a los procesos de limpieza.

1. Limpie la pieza de mano utilizando un paño suave humedecido en una solución germicida, para eliminar los contaminantes más visibles.



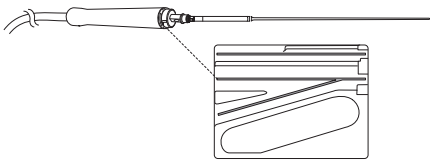
2. Retire el manguito, si aún no lo retiró. Deseche el manguito.

3. Retire la funda cónica:
   a. Libere la funda cónica haciéndola girar en sentido antihorario.
   b. Retire la funda cónica separándola de la pieza de mano.



NO DESECHE UNA FUNDA CÓNICA ESTÁNDAR.

4. Retire las arandelas y deséchelas.
5. En la base de roscado del terminal, localice la ranura que tenga el mismo color que el conector de la pieza de mano (23 kHz – verde). Coloque la pieza de mano en la base de roscado del terminal de manera tal que el cuerpo de conexión metálico encaje perfectamente en el extremo de metal de la ranura.

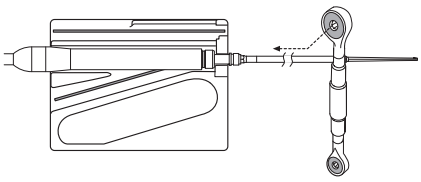


6. Mantenga fija la pieza de mano en la base de roscado del terminal.

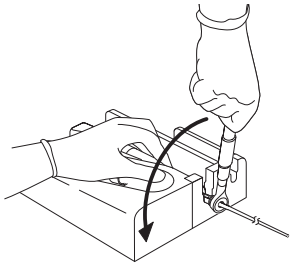
Aviso

Para evitar dañar el producto, NUNCA sostenga la pieza de mano mientras utiliza la llave de roscado para ajustar o aflojar el terminal.

7. Haga coincidir el extremo de color de la llave de roscado con el color del conector de la pieza de mano (23 kHz – verde). Con cuidado para no dañar el terminal, deslice el lado de color de la llave sobre el terminal hasta que el hexágono de la llave encaje en el hexágono del terminal.



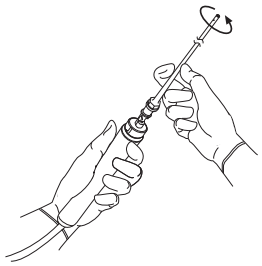
8. Gire la llave en sentido antihorario hasta aflojar el terminal.



9. Extraiga cuidadosamente la llave del terminal.

10. Retire la pieza de mano de la base de roscado del terminal.

11. Desenrosque el terminal.



Limpieza y esterilización

Cuando haya desmontado la pieza de mano, limpie la pieza de mano, la llave y la base de roscado del terminal y el terminal. Para limpiar las roscas y pulir las superficies de conexión, tanto para la pieza de mano como para el terminal, puede utilizar el Kit de mantenimiento para piezas de mano y terminales CUSA® (Ref/Cat C0023).

Para obtener más instrucciones sobre la limpieza y la esterilización, consulte la Guía del usuario del sistema CUSA EXcel®.

ADVERTENCIA: Las puntas de uso extendido (ELT, por sus siglas en inglés) permiten 6 ciclos de esterilización y se suministran con 6 conductos. Toda punta utilizada 6 veces y todo conducto utilizado una vez deben desecharse. Las puntas que se utilicen más de 6 veces y los conductos que se utilicen más de una vez aumentan el riesgo de modificar las propiedades y la funcionalidad del dispositivo, y de aumentar la probabilidad de complicaciones y/o efectos no deseados. Los dispositivos deben desecharse de acuerdo con la política del hospital.

Aiguille coelioscopique longue durée 23 kHz CUSA EXcel®

L'aiguille coelioscopique longue durée (30,14 cm) peut être utilisée avec les pièces à main droites 23 kHz C2600.

REF. CAT.	Description	Diamètre
C4604ELT	Longue durée Aiguille coelioscopique	1,98 mm

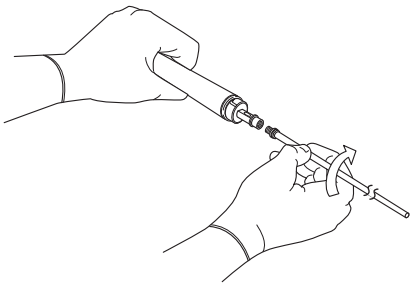
L'aiguille et la brosse de nettoyage contenues dans cette boîte peuvent être utilisées six fois (6 X). Tous les autres éléments sont exclusivement à usage unique. Ils ne contiennent pas de latex.

Se reporter au Guide de l'utilisateur du Système CUSA EXcel® pour les instructions complètes de montage et de stérilisation.

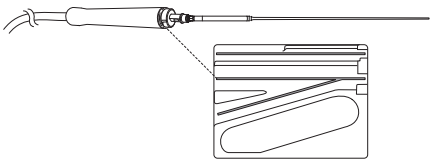
Stérilisation à la vapeur uniquement. Non stérile. Stériliser avant utilisation.

Montage

1. Visser l'aiguille sur le raccord de fixation de la pièce à main. Tourner l'aiguille jusqu'à ce qu'elle soit serrée.



2. Repérer l'emplacement du banc de montage d'aiguille dont la couleur correspond à celle du connecteur de la pièce à main (23 kHz - vert). Placer la pièce à main dans le banc de montage de l'aiguille de façon à ce que le raccord de fixation métallique soit bien installé dans l'extrémité métallique de l'emplacement.

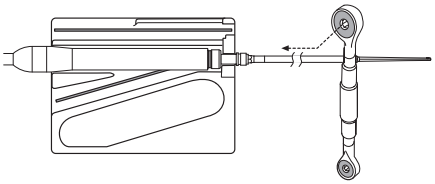


3. Maintenir la pièce à main en place dans le banc de montage de l'aiguille.

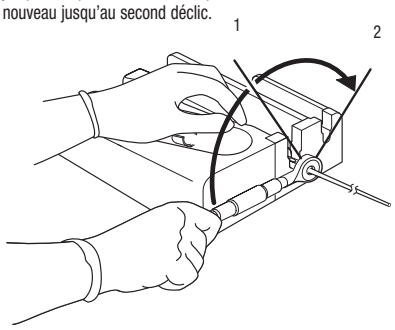
Remarque

Afin d'éviter d'endommager le produit, ne JAMAIS tenir dans la main la pièce à main, lorsque l'on utilise la clé dynamométrique pour serrer ou desserrer l'aiguille.

4. Faire correspondre le côté à code couleur de la clé dynamométrique avec la couleur du connecteur de la pièce à main (23 kHz - vert). Faire glisser le côté à code couleur de la clé sur l'aiguille, en prenant soin de ne pas heurter l'aiguille, jusqu'à ce que les six pans de la clé s'engagent sur les six pans de l'aiguille.



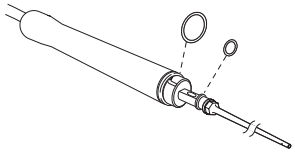
5. Faire tourner la clé dans le sens des aiguilles d'une montre jusqu'à ce que l'on entende un premier déclic. La faire tourner de nouveau jusqu'au second déclic.



6. Retirer soigneusement la clé de l'aiguille.
7. Dégager la pièce à main du banc de montage d'aiguille.
8. Repérer les joints de la pièce à main en cours de montage:

Grand joint	noir
Petit joint	vert

9. Faire glisser le plus grand des deux joints sur le raccord de fixation et dans la rainure du col de la pièce à main. Faire glisser le plus petit joint dans la rainure du raccord de fixation métallique.



10. Placer la pièce à main montée, la tête conique, un embout d'irrigation et un écouvillon de nettoyage dans la boîte de stérilisation.

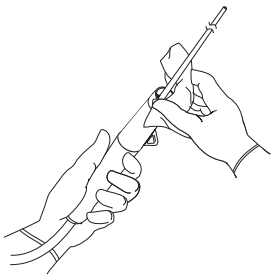
Mise en garde

Ne pas monter de tête conique sur la pièce à main avant la stérilisation. Les surfaces recouvertes par la tête conique pourraient ne pas être stériles.

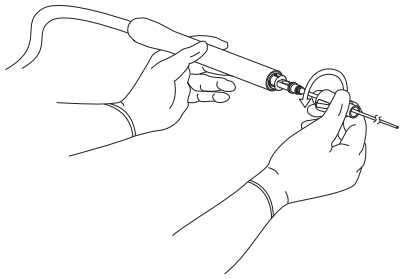
Démontage

Lors du nettoyage des pièces à main, porter des vêtements de protection, des gants et des lunettes de sécurité, conformément aux méthodes de nettoyage en vigueur dans l'Etablissement.

1. Utiliser un linge doux imbibé de solution germicide, essuyer la pièce à main, de façon à éliminer les agents contaminants visibles.

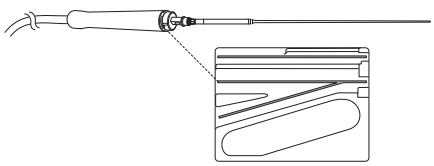


2. Enlever l'embout d'irrigation, s'il est encore présent. Jeter l'embout d'irrigation.
3. Enlever la tête conique:
   a. Détacher la tête conique en la faisant tourner dans le sens inverse des aiguilles d'une montre.
   b. Tirer sur la tête conique pour la désolidariser de la pièce à main.



NE PAS JETER UNE TÊTE CONIQUE STANDARD.

4. Enlever les joints et les éliminer.
5. Repérer l'emplacement du banc de montage d'aiguille dont la couleur correspond à celle du connecteur de la pièce à main (23 kHz - vert). Placer la pièce à main dans le banc de montage de l'aiguille de façon à ce que le raccord de fixation métallique soit bien installé dans l'extrémité métallique de l'emplacement.

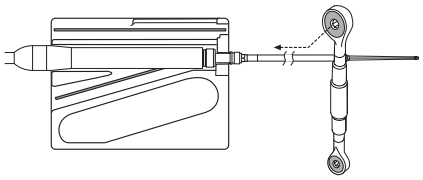


6. Maintenir la pièce à main en place dans le banc de montage de l'aiguille.

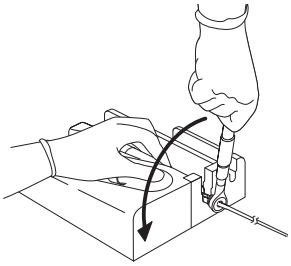
Remarque

Afin d'éviter d'endommager le produit, ne JAMAIS tenir dans la main la pièce à main, lorsque l'on utilise la clé dynamométrique pour serrer ou desserrer l'aiguille.

7. Faire correspondre le côté à code couleur de la clé dynamométrique avec la couleur du connecteur de la pièce à main (23 kHz - vert). Faire glisser le côté à code couleur de la clé sur l'aiguille, en prenant soin de ne pas heurter l'aiguille, jusqu'à ce que les six pans de la clé s'engagent sur les six pans de l'aiguille.



8. Faire tourner la clé dans le sens contraire des aiguilles d'une montre jusqu'à ce que l'aiguille se détache.

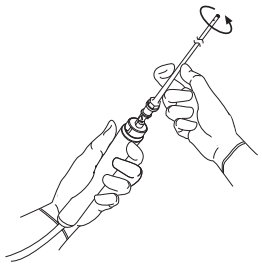


FR

9 Retirer soigneusement la clé de l'aiguille.

10.Dégager la pièce à main du banc de montage d'aiguille.

11.Dévisser l'aiguille.



Nettoyage et stérilisation

Une fois la pièce à main démontée, on doit la nettoyer, ainsi que le banc de montage, la clé dynamométrique et l'aiguille. Le nettoyage des filetages et le polissage des surfaces de connexion de la pièce à main et de l'aiguille peuvent être effectués à l'aide du Kit de maintenance de pièce à main et d'aiguille CUSA® (Réf/cat C0023).

Pour les instructions complètes de nettoyage et de stérilisation, se reporter au Guide de l'utilisateur du Système CUSA EXcel®

AVERTISSEMENT : Les embouts à durée prolongée (EDP) permettent d'effectuer 6 cycles de stérilisation et sont fournis avec 6 tuyaux. Un embout utilisé 6 fois et un tuyau utilisé une fois doivent être éliminés. Si un embout est utilisé plus de 6 fois ou un tuyau plus d'une fois, cela risque de modifier leurs caractéristiques et leurs performances ainsi que d'augmenter les risques de complications et/ou d'effets indésirables. Les dispositifs doivent être éliminés conformément aux procotoles hospitaliers.

Punta laparoscopica di durata maggiore CUSA EXcel® da 23 kHz

La punta laparoscopica di durata maggiore (30,14 cm) va utilizzata col manipolo diritto C2600 da 23 kHz:

REF. CAT.	Descrizione	Diametro
C4604ELT	Punta laparoscopica di durata maggiore	1,98 mm

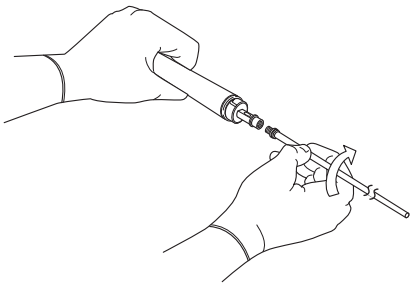
È possibile utilizzare la punta e la spazzola di pulizia contenute in questa confezione per sei volte (6X). Tutti gli altri articoli sono monouso. Nessuno degli articoli contenuti in questa confezione contiene lattice.

Consultare la Guida per l'utente del sistema CUSA EXcel® per istruzioni complete sul montaggio e la sterilizzazione.

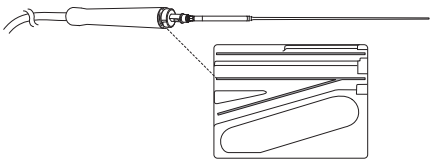
Solo per sterilizzazione a vapore. Non sterile. Sterilizzare prima dell'uso.

Montaggio

1. Infilare la punta sulla struttura di connessione del manipolo. Ruotare la punta fino a quando è ben stretta.



2. Localizzare la scanalatura, nella base di serraggio della punta, che corrisponda al colore sul connettore del manipolo (23 kHz: verde). Posizionare il manipolo sulla base di serraggio della punta in modo che la struttura di connessione in metallo si adatti perfettamente all'estremità metallica della scanalatura.

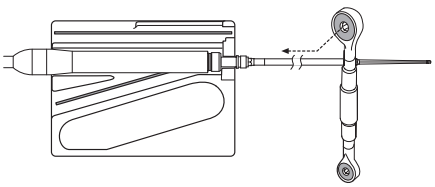


3. Tenere il manipolo fermo in posizione nella base di serraggio della punta.

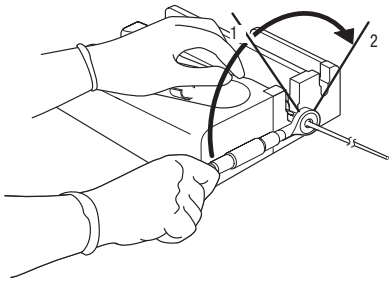
N.B.

Per evitare danni al prodotto, non tenere MAI il manipolo con le mani quando si usa la chiave di serraggio per serrare o allentare la punta.

4. Far corrispondere l'estremità colorata della chiave di serraggio al colore del connettore del manipolo (23 kHz: verde). Far scivolare il lato contrassegnato dal colore della chiave sulla punta, facendo attenzione a non danneggiarla, fino a quando la parte esagonale della chiave non si incastra nella parte esagonale della punta.



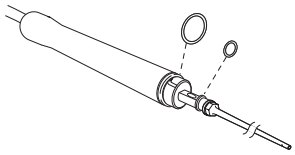
5. Ruotare la chiave in senso orario fino a quando non si percepisce e si sente uno scatto. Ruotare nuovamente fino a quando non si percepisce e si sente un secondo scatto.



6. Rimuovere con cura la chiave dalla punta.
7. Rimuovere il manipolo dalla base di serraggio della punta.
8. Individuare gli o-ring adatti al manipolo da montare:

O-ring grande	nero
O-ring piccolo	verde

9. Far scivolare l'o-ring grande sulla struttura di connessione e nella scanalatura del collo del manipolo. Spingere l'o-ring più piccolo nella scanalatura della struttura di connessione in metallo.



10. Collocare il manipolo montato, il cono terminale e un condotto con un filtro della punta nella custodia dello sterilizzatore.

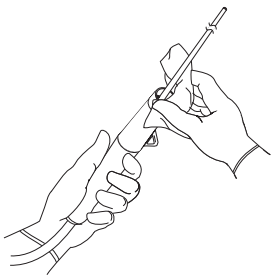
Attenzione

Non porre un cono terminale di alcun tipo sul manipolo prima della sterilizzazione. Le superfici coperte dal cono terminale potrebbero non essere sterili.

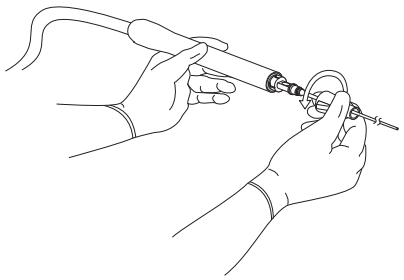
Smontaggio

Nella pulizia dei manipoli, indossare abbigliamento protettivo, guanti e occhiali di sicurezza secondo la politica ospedaliera per il processo di pulizia.

1. Utilizzando un panno morbido inumidito con una soluzione germicida, strofinare il manipolo per rimuovere gli agenti contaminanti più evidenti.

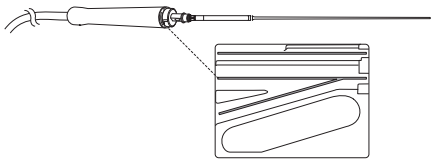


2. Rimuovere il condotto, se non fosse stato già rimosso. Scartare il condotto.
3. Rimuovere il cono terminale:
   a. Rilasciare il cono terminale ruotandolo in senso antiorario.
   b. Estrarre il cono terminale dal manipolo.



NON SCARTARE UN CONO TERMINALE STANDARD.

4. Rimuovere gli o-ring e scartarli.
5. Localizzare la scanalatura, nella base di serraggio della punta, che corrisponda al colore sul connettore del manipolo (23 kHz: verde). Posizionare il manipolo sulla base di serraggio della punta in modo che la struttura di connessione in metallo si adatti perfettamente all'estremità metallica della scanalatura.

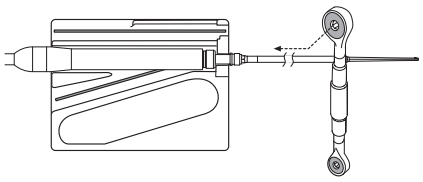


6. Tenere il manipolo fermo in posizione nella base di serraggio della punta.

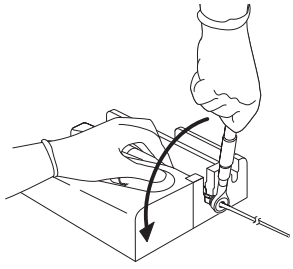
N.B.

Per evitare danni al prodotto, non tenere MAI il manipolo con le mani quando si usa la chiave di serraggio per serrare o allentare la punta.

7. Far corrispondere l'estremità colorata della chiave di serraggio al colore del connettore del manipolo (23 kHz: verde). Far scivolare il lato contrassegnato dal colore della chiave sulla punta, facendo attenzione a non danneggiarla, fino a quando la parte esagonale della chiave non si incastra nella parte esagonale della punta.



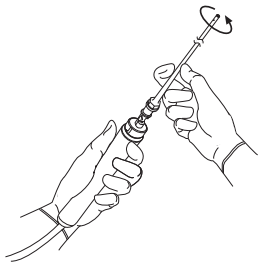
8. Ruotare la chiave in senso antiorario fino ad allentare la punta.



9. Rimuovere con cura la chiave dalla punta.

10. Rimuovere il manipolo dalla base di serraggio della punta.

11. Svitare la punta.



Pulizia e sterilizzazione

Una volta smontato il manipolo, è necessario pulire il manipolo, la base di serraggio della punta, la chiave di serraggio e la punta. Per la pulizia delle filettature e la lucidatura delle superfici di collegamento sia del manipolo sia della punta, è possibile utilizzare il kit di manutenzione del manipolo e della punta CUSA® (Rif/Cat C0023).

Per istruzioni complete sulla pulizia e la sterilizzazione, consultare la Guida per l'utente del sistema CUSA EXcel®.

AVVERTENZA: le punte a vita prolungata (ELT dall'Inglese Extended Life Tips) consentono 6 cicli di sterilizzazione e sono dotate di 6 canne. Gettare una punta usata 6 volte e una canna usata una volta. Se si usano le punte più di 6 volte e le canne più di una volta si aumenta il rischio di modificare le proprietà e il rendimento del dispositivo, ed aumentare la probabilità di complicazioni e/o effetti indesiderati. Gettare i dispositivi secondo la prassi dell'ospedale.

CUSA EXcel® 23 kHz Laparoscopische tip met extra lange levensduur

De laparoscopische tip met extra lange levensduur (30,14 cm) is voor gebruik met het C2600 23 kHz rechte handvat:

REF CAT.	Omschrijving	Doorsnede
C4604ELT	Laparoscopische tip met extra lange levensduur	1,98 mm

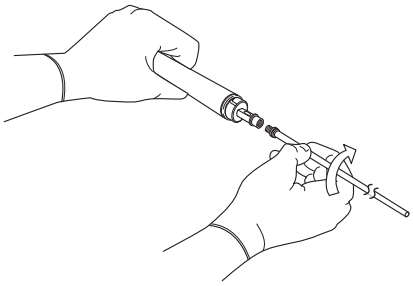
U kunt de tip en de reinigingsborstel in deze verpakking zes keer gebruiken (6x). Alle andere onderdelen zijn voor eenmalig gebruik. Geen van de onderdelen in deze verpakking bevat latex.

Zie de CUSA EXcel® Systeem gebruikersgids voor volledige instructies voor het in elkaar zetten en steriliseren.

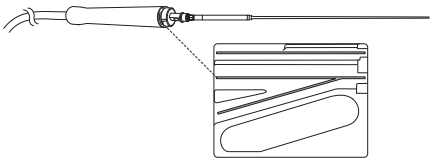
Uitsluitend voor stoomsterilisatie. Niet steriel. Steriliseren voor gebruik.

Montage

1. Schroef de tip op het verbindingsstuk van het handvat. Draai de tip met de vingers aan tot handvast.



2. Zoek de gleuf in de houder voor tipmontage waarvan de kleur overeenstemt met die van de connector van het handvat. (23 kHz – groen). Plaats het handvat in de houder voor de tipmontage zodat het metalen verbindingsstuk nauwkeurig past in het metalen uiteinde van de gleuf.

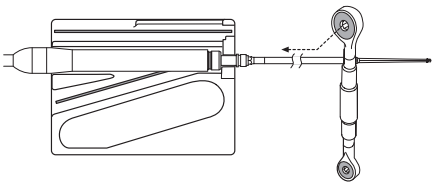


3. Houd het handvat op zijn plaats in de houder voor de tipmontage.

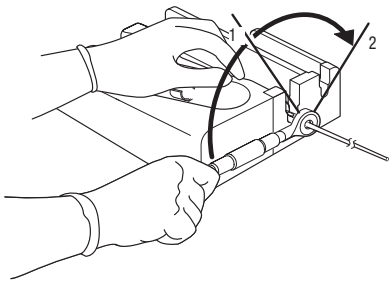
Opgelet

Om beschadiging van het product te voorkomen, het handvat NOOIT in de hand houden bij het gebruik van de momentsleutel om de tip vast of los te draaien.

4. Zorg dat het gekleurde uiteinde van de momentsleutel past bij de kleur van het verbindingsstuk van het handvat (23 kHz – groen). Schuif de kant met de kleurcodering van de sleutel over de tip, erop lettend de tip niet te beschadigen, tot de zeskantige uitsparing van de sleutel om het zeskantige deel van de tip past.



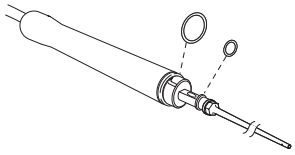
5. Draai de sleutel met de klok mee tot u een klik voelt en hoort. Draai nogmaals tot u een tweede klik voelt en hoort.



6. Verwijder voorzichtig de momentsleutel van de tip.
7. Verwijder het handvat uit de houder voor de tipmontage.
8. Neem de O-ringen voor het handvat dat u aan het monteren bent.

Grote O-ring	zwart
Kleine O-ring	groen

9. Schuif de grootste O-ring over het verbindingsstuk en in de groef in de hals van het handvat. Schuif de kleinere O-ring in de groef in het metalen verbindingsstuk.



10. Leg het gemonteerde handvat, de conus en één irrigatiehuls met een tipreiniger in de sterilisatiecassette.

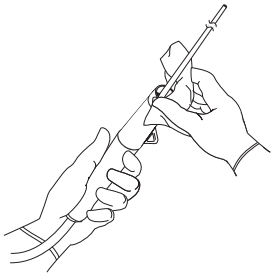
Opgepast

Geen conus van enig type op het handvat aanbrengen voor de sterilisatie. Oppervlakken die door de conus worden afgedekt zijn dan mogelijk niet steriel.

Uit elkaar nemen

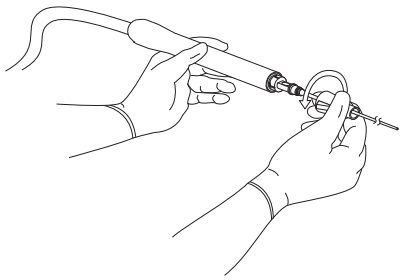
Let erop dat u bij het reinigen van handvatten beschermende kleding, handschoenen, en een veiligheidsbril draagt, volgens het schoonmaakprotocol in uw ziekenhuis.

1. Veeg met een zachte doek, bevochtigd met een ontsmettende vloeistof, het handvat af om macroscopisch zichtbaar vuil te verwijderen.



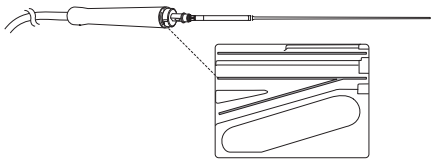
2. Verwijder de irrigatiehuls als dit niet al gedaan is. Werp de irrigatiehuls weg.

3. Verwijder de conus:
   a. Maak de conus los door hem tegen de klok in te draaien.
   b. Neem de conus van het handvat af.



EEN STANDAARD CONUS NIET WEGWERPEN.

4. Verwijder de O-ringen en werp ze weg.
5. Zoek de gleuf in de houder voor tipmontage waarvan de kleur overeenstemt met die van de connector van het handvat. (23 kHz – groen). Plaats het handvat in de houder voor de tipmontage zodat het metalen verbindingsstuk nauwkeurig past in het metalen uiteinde van de gleuf.

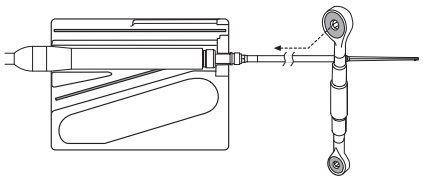


6. Houd het handvat op zijn plaats in de houder voor de tipmontage.

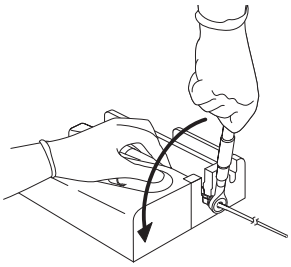
Opgelet

Om beschadiging van het product te voorkomen, het handvat NOOIT in de hand houden bij het gebruik van de momentsleutel om de tip vast of los te draaien.

7. Zorg dat het gekleurde uiteinde van de momentsleutel past bij de kleur van het handvat (23 kHz – groen). Schuif de kant met de kleurcodering van de sleutel over de tip, erop lettend de tip niet te beschadigen, tot de zeskantige uitsparing van de sleutel om het zeskantige deel van de tip past.



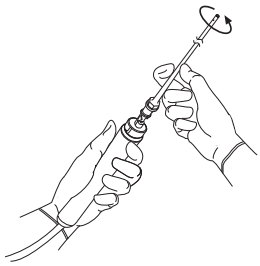
8. Draai de sleutel tegen de klok in tot de tip los is.



9. Verwijder voorzichtig de momentsleutel van de tip.

10. Verwijder het handvat uit de houder voor de tipmontage.

11. Schroef de tip eraf.



Reiniging en sterilisatie

Als u het handvat gedemonteerd heeft, moet u het handvat, de houder voor tipmontage, de momentsleutel, en de tip reinigen. Voor zowel het handvat als de tip kunt u om de schroefdraden te reinigen en de verbindingsoppervlakken te polijsten gebruik maken van de CUSA EXcel® handvat/tip onderhoudssets (Catalogusnr C0023).

Zie voor volledige instructies over het reinigen en steriliseren de CUSA EXcel® Systeem Gebruikersgids.

WAARSCHUWING: De Extended Life Tips (ELT-tips) kunnen 6 maal worden gesteriliseerd en worden geleverd met 6 rookbuisjes. Tips dienen na 6 maal gebruik en rookbuisjes dienen na eenmalig gebruik te worden weggeworpen. Als tips vaker dan 6 maal worden gebruikt of rookbuisjes meer dan eenmaal worden gebruikt, vergroot dat het risico van modificatie van de eigenschappen en prestatie van het hulpmiddel en de kans op complicaties en/of ongewenste gevolgen. De hulpmiddelen dienen te worden afgevoerd volgens het beleid van de instelling.

CUSA EXcel® 23 kHz laparoskopispetsar, flergångs

Laparoskopispetsarna för flergångsbruk (30,14 cm) är avsedda för användning med C2600 23 kHz raka handtag.

REF CAT.	Beskrivning	Diameter
C4604ELT	Laparoskopispets för flergångsbruk	1,98 mm

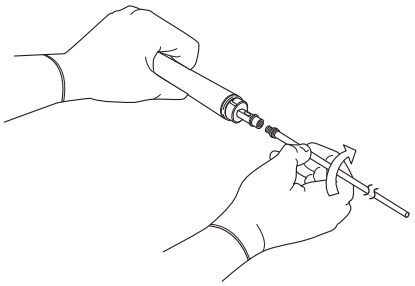
Spetsen och rengöringsborsten i denna förpackning kan användas sex gånger (6X). Alla andra artiklar är endast avsedda för engångsbruk. Inga artiklar i denna förpackning innehåller latex.

Se Användarhandboken för CUSA EXcel® System för fullständig information om montering och sterilisering.

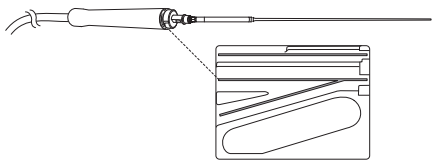
Endast ångsterilisering. Osteril. Sterilisera före användning.

Montering

1. Gänga på spetsen på handtagets anslutningsdel. Skruva fast den så hårt det går med fingrarna.



2. Skåran i monteringsverktyget ska ha samma färg som handtagets anslutning (23 kHz – grön). Placera handtaget i spetsfästet så att anslutningsdelen av metall passar in i skårans metalldel.

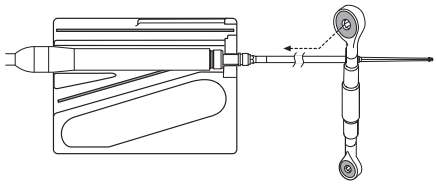


3. Håll handtaget på plats i spetsfästet.

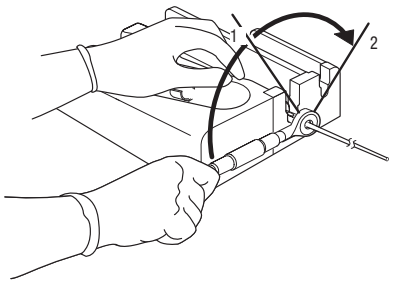
Notering

Undvik produktskada: Håll ALDRIG handtaget i handen när spetsen ska sättas fast eller lossas med momentnyckeln.

4. Kontrollera att färgmarkeringen på momentnyckeln stämmer överens med handtagsanslutningens färg (23 kHz – grön). Skjut in den färgmarkerade öppningen över spetsen, och var försiktig så att nyckeln inte kommer i beröring med själva spetsen, tills sexkantsfattningen låser om spetsen.



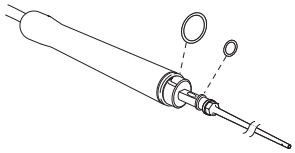
5. Vrid nyckeln medurs tills det känns och hörs ett klick. Fortsätt att vrida nyckeln tills det känns och hörs ännu ett klick.



6. Ta försiktigt bort momentnyckeln från spetsen.
7. Ta ut handtaget ur spetsfästet.
8. Plocka fram O-ringarna för det handtag som monteras:

Stor O-ring	svart
Liten O-ring	grön

9. Trä den större O-ringen över anslutningsdelen och in i skåran på handtaget. Trä in den mindre O-ringen över skåran i anslutningsdelen av metall.



10. Lägg det monterade handtaget med spets, noskon, ett flödesskydd med spetsrengörare i steriliseringslådan.

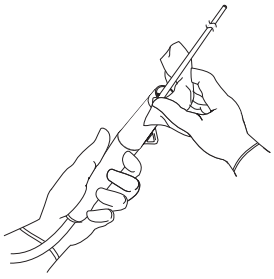
Försiktighet

Montera inte någon typ av noskon på handtaget före steriliseringen. Ytor som täcks av noskonen kanske inte blir sterila.

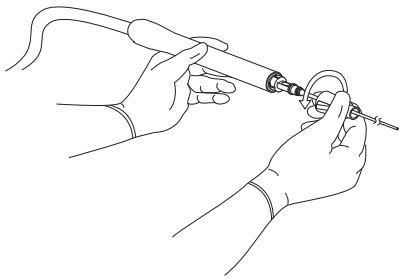
Demontering

Vid rengöring av handtagen, använd skyddskläder, handskar och skyddsglasögon enligt de lokala regler och föreskrifter som gäller för rengöring.

1. Använd en mjuk trasa, fuktad med en mild antiseptisk lösning och torka av handtaget för att få bort större föroreningar.

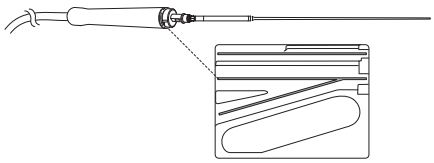


2. Ta bort flödesskyddet om det inte redan är gjort. Kasta flödesskyddet.
3. Ta bort noskonen:
   a. Lossa noskonen genom att vrida den moturs.
   b. Ta bort noskonen från handtaget.



KASTA INTE EN STANDARDNOSKON.

4. Ta bort O-ringarna och kasta dem.
5. Skåran i monteringsverktyget ska ha samma färg som handtagets anslutning (23 kHz – grön). Placera handtaget i spetsfästet så att anslutningsdelen av metall passar in i skårans metalldel.

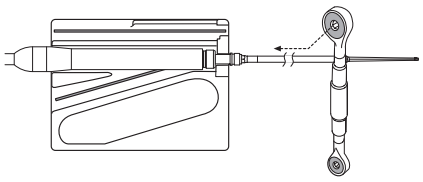


6. Håll handtaget på plats i spetsfästet.

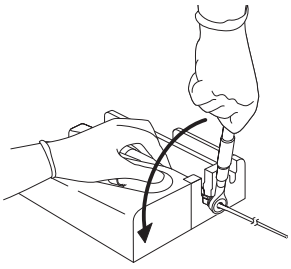
Notering

Undvik produktskada: Håll ALDRIG handtaget i handen när spetsen ska sättas fast eller lossas med momentnyckeln.

7. Kontrollera att färgmarkeringen på momentnyckeln stämmer överens med handtagsanslutningens färg (23 kHz – grön). Skjut in den färgmarkerade öppningen över spetsen, och var försiktig så att nyckeln inte kommer i beröring med själva spetsen, tills sexkantsfattningen låser om spetsen.



8. Vrid nyckeln moturs tills spetsen lossnar.

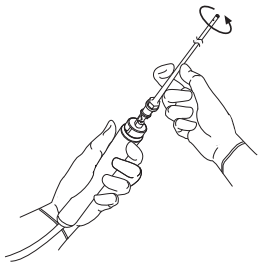


SE

9. Ta försiktigt bort momentnyckeln från spetsen.

10. Ta ut handtaget ur spetsfästet.

11. Skruva loss spetsen.



Rengöring och sterilisering

När handtaget har demonterats ska det rengöras, liksom spetsfästet, momentnyckeln och spetsen. Använd rengöringssetet för CUSA® handtag och spetsar (Ref/Cat C0023) för att rengöra gängor och anslutningsytor på både handtaget och spetsen.

Utförligare instruktioner för rengöring och sterilisering finns i Användarhandboken för CUSA EXcel® System.

VARNING! Spetsarna med förlängd livstid (ELT, "Extended Life Tips") kan steriliseras sex gånger och levereras med sex rör. Alla spetsar som använts sex gånger och alla rör som använts en gång måste kasseras. Spetsar som används mer än sex gånger och rör som används mer än en gång ökar risken för ändrade egenskaper och funktionssätt hos produkten samt för komplikationer och/eller oönskade effekter. Produkterna måste bortskaffas i enlighet med sjukhusets regler.

Лапароскопический наконечник увеличенного срока службы CUSA EXcel® на 23 Кгц

Лапароскопический наконечник увеличенного срока службы (30,14 см) предназначается для использования с прямым фрагментатором C2600 на 23 Кгц:

REF CAT.	Описание	Диаметр
C4604ELT	Лапароскопический наконечник увеличенного срока использования	1,98 мм

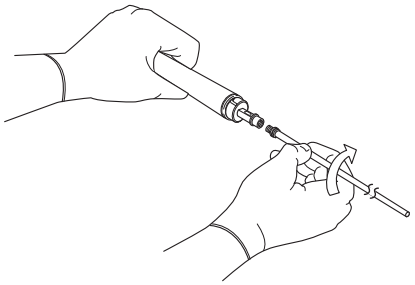
Вы можете использовать наконечник и щетку для очистки наконечника из этой упаковки шесть раз (6X). Все другие компоненты рассчитаны на одноразовое использование. Ни один из предметов, содержащихся в данной упаковке, не содержит латекса.

За подробными инструкциями по сборке и стерилизации обращайтесь к «Руководству по эксплуатации системы CUSA EXcel®».

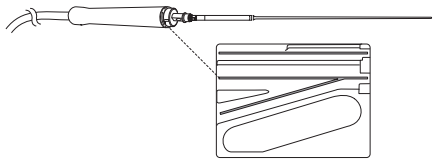
Только для паровой стерилизации. Не стерильно. Перед использованием простерилизуйте.

Сборка

1. Навинтите пальцами выбранный наконечник на соединительную деталь фрагментатора. Поворачивайте наконечник до тех пор, пока он не будет плотно навинчен.



2. Найдите отверстие в опорном основании комплекта для сборки наконечника, соответствующее по цвету разъему фрагментатора (23 Кгц - зеленый). Поместите фрагментатор в набор для сборки наконечника таким образом, чтобы металлическая соединительная деталь полностью вошла в металлическую сторону отверстия.

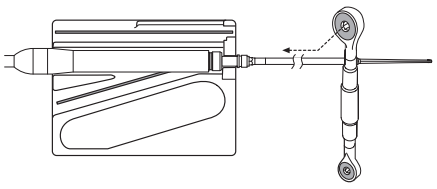


3. Придерживайте фрагментатор на месте в комплекте для сборки наконечника.

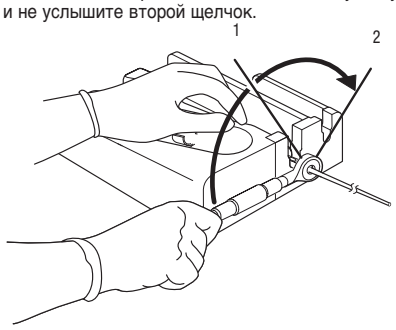
Уведомление

Для избежания повреждения изделия никогда не держите фрагментатор в руке, когда вы используете гаечный ключ для закрепления или ослабления наконечника.

4. Используйте ту сторону гаечного ключа, которая одинакова по цвету с разъемом фрагментатора (23 Кгц - зеленый). Продвигайте эту сторону гаечного ключа по наконечнику (будьте осторожны, не ударьте наконечник) до тех пор, пока грани гаечного ключа не войдут в зацепление с гранями наконечника.



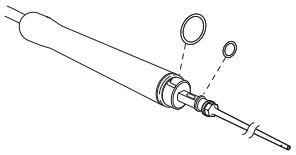
5. Вращайте наконечник по часовой стрелке до тех пор, пока вы не почувствуете и не услышите щелчок. Снова вращайте, пока вы не почувствуете и не услышите второй щелчок.



6. Осторожно снимите гаечный ключ с наконечника.
7. Снимите наконечник с комплекта для сборки наконечника.
8. Найдите уплотнительные кольца для фрагментатора, который вы собираете:

Большое уплотнительное кольцо	черное
Малое уплотнительное кольцо	зеленое

9. Продвиньте большее уплотнительное кольцо по соединительной детали в канавку на шейке фрагментатора. Продвиньте меньшее уплотнительное кольцо в канавку на металлической соединительной детали.



10. Положите собранный фрагментатор, стыковочный конус и один ирригационный чехол с очистителем наконечника в стерилизационную коробку.

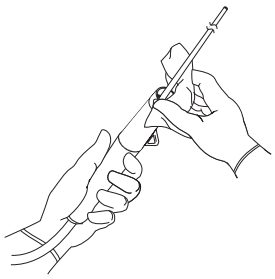
Предупреждение

Не насаживайте стыковочный конус какого-либо типа на фрагментатор до стерилизации. Поверхности, покрытые стыковочным конусом, могут быть не стерильными.

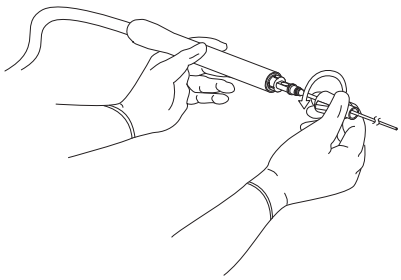
Разборка

При чистке фрагментаторов обязательно надевайте защитную одежду, перчатки и защитные очки в соответствии с нормами, установленными вашей больницей для процесса чистки.

1. Используя мягкую тряпку, смоченную в бактерицидном растворе, протрите фрагментатор для общего удаления загрязняющих веществ.

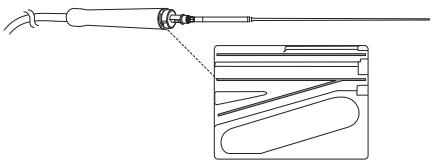


2. Снимите ирригационный чехол, если он еще не снят. Выбросьте его.
3. Снимите стыковочный конус:
   a. Освободите стыковочный конус, поворачивая его против часовой стрелки.
   b. Потяните стыковочный конус по направлению от фрагментатора.



НЕ ВЫБРАСЫВАЙТЕ СТАНДАРТНЫЙ СТЫКОВОЧНЫЙ КОНУС.

4. Снимите уплотнительные кольца и выбросите их.
5. Найдите отверстие в комплекте для сборки наконечника, соответствующее по цвету разъему фрагментатора (23 Кгц - зеленый). Поместите фрагментатор в набор для сборки наконечника таким образом, чтобы металлическая соединительная деталь полностью вошла в металлическую сторону отверстия.

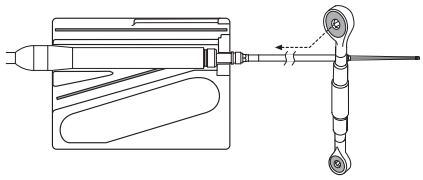


6. Придерживайте фрагментатор на месте в комплекте для сборки наконечника.

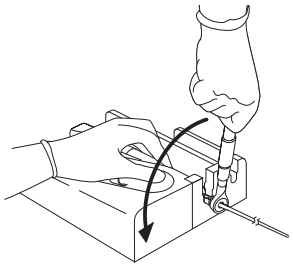
Уведомление

Для избежания повреждения изделия никогда не держите фрагментатор в руке, когда вы используете гаечный ключ для закрепления или ослабления наконечника.

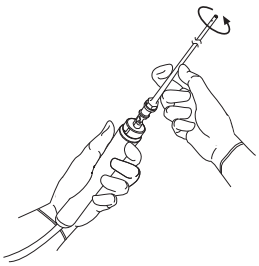
7. Используйте ту сторону гаечного ключа, которая одинакова по цвету с разъемом фрагментатора. Продвигайте эту сторону гаечного ключа по наконечнику (будьте осторожны, не ударьте наконечник) до тех пор, пока грани гаечного ключа не войдут в зацепление с гранями наконечника.



8. Поворачивайте гаечный ключ против часовой стрелки до тех пор, пока наконечник не ослабнет.



9. Осторожно снимите гаечный ключ с наконечника.
10. Снимите наконечник с комплекта для сборки наконечника.
11. Отвинтите наконечник.



Чистка и стерилизация

Когда фрагментатор разобран, нужно произвести чистку фрагментатора, комплекта для сборки наконечника и гаечного ключа. Для очистки резьбы и полировки соединительных поверхностей фрагментатора и наконечника вы можете использовать Набор для ухода за фрагментаторами и наконечниками CUSA® (Номер по каталогу C0023).

За подробными инструкциями по чистке и стерилизации обращайтесь к «Руководству по эксплуатации системы CUSA EXcel®».

ПРЕДУПРЕЖДЕНИЕ: Наконечники с увеличенным сроком службы (ELT) допускают 6 циклов стерилизации и снабжены 6 трубками. Любой наконечник, использованный 6 раз, и трубка, использованная один раз, подлежат утилизации. Наконечники, использованные более 6 раз, и трубки, использованные более одного раза, увеличивают риск изменения качеств и работы устройства, а также вероятность осложнений и/или нежелательных последствий. Устройства подлежат утилизации в соответствии с правилами больницы.

CUSA EXcel® 23 kHz 长寿命腹腔镜刀头

长寿命腹腔镜刀头（30.14 cm）适用于 C2600 23 kHz 直手柄：

REF CAT.	说明	直径
C4604ELT	长寿命腹腔镜刀头	1.98 mm

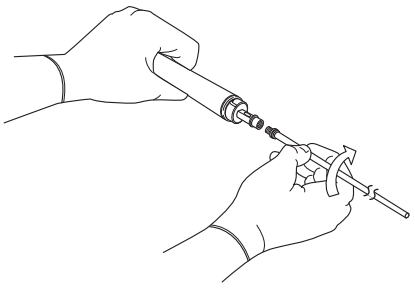
该包装内的刀头和清洗刷可使用六次（6X）。所有其它物品都只能一次性使用。该包装内的所有物品都不含乳胶。

有关装配和消毒处理的完整说明，请参阅 CUSA EXcel® 系统用户指南。

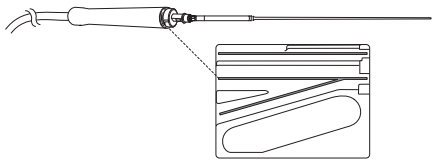
仅限用蒸汽消毒。未消毒。使用前要进行消毒处理。

装配

1. 将刀头拧到手柄的连接体上。用手指将其旋紧。



2. 在刀头转动基座上找到与手柄连接器的颜色相配的槽（23 kHz – 绿色）。将手柄放入刀头转动基座，使其金属连接体与槽的金属端紧密配合。

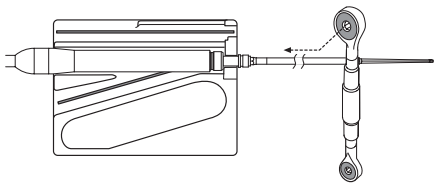


3. 将手柄固定在刀头转动基座内。

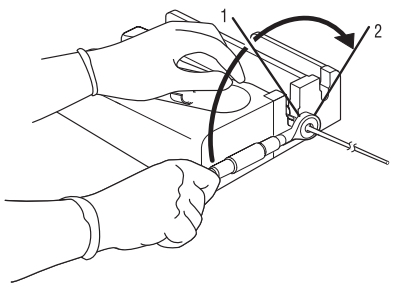
注意

为避免损坏产品，当用转动扳手紧固或松开刀头时**切勿**将手柄握在手中。

4. 使转动扳手端头的颜色与手柄连接器的颜色配上（23 kHz – 绿色）。将扳手带颜色的一侧轻轻套到刀头上，小心不要损坏刀头，直到扳手的六角口与刀头的六角体啮合。



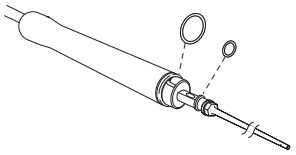
5. 顺时针旋转扳手，直至感到并听到“咔”的一声。接着旋转，直至感到并听到第二次“咔”的一声。



6. 从刀头上小心取下扳手。
7. 从刀头转动基座中取出手柄。
8. 找出正在装配的手柄所用的O形圈：

大 O 形圈	黑色
小 O 形圈	绿色

9. 将大O形圈从连接体上轻轻套过，放入手柄颈部的凹槽内。将小 O 形圈放入金属连接体的凹槽内。



10. 将已装配的手柄、电凝接口、及一套带刀头清洁丝的套管放入消毒盒内。

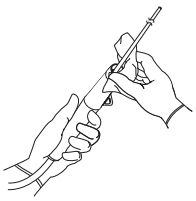
注意事项

进行消毒处理之前，不要将任何一种电凝接口装到手柄上。否则被电凝接口覆盖的表面可能未消毒。

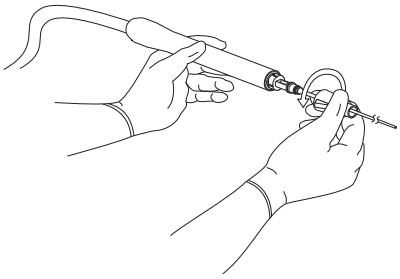
拆卸

清洗手柄时，一定要按照所在医院对清洗操作的规定穿戴防护服、手套及防护镜。

1. 用一块蘸有杀菌液的软布擦洗手柄，除去肉眼可见的污物。

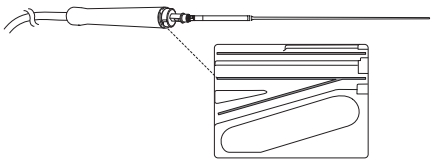


2. 若尚未取下套管，现在就将其取下。丢弃套管。
3. 取下电凝接口：
   a. 逆时针旋转电凝接口，使其松动。
   b. 从手柄中拔出电凝接口。



不要丢弃标准电凝接口。

4. 取下O形圈并将它们丢弃。
5. 在刀头转动基座上找到与手柄连接器的颜色相配的槽（23 kHz – 绿色）。将手柄放入刀头转动基座，使其金属连接体与槽的金属端紧密配合。

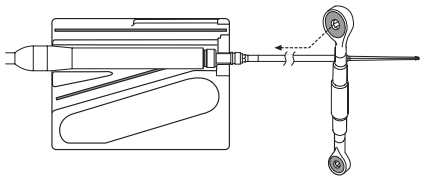


6. 将手柄固定在刀头转动基座内。

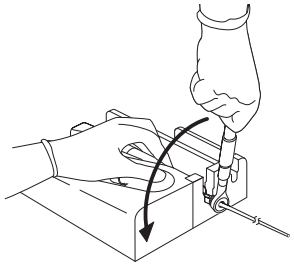
注意

为避免损坏产品，当用转动扳手紧固或松开刀头时**切勿**将手柄握在手中。

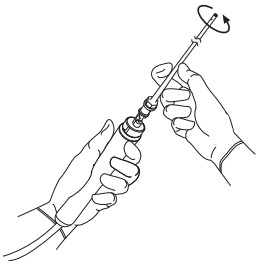
7. 使转动扳手端头的颜色与手柄连接器的颜色配上（23 kHz – 绿色）。将扳手带颜色的一侧轻轻套到刀头上，小心不要损坏刀头，直到扳手的六角口与刀头的六角体啮合。



8. 逆时针旋转扳手，直至刀头松动。



9. 从刀头上小心取下扳手。
10. 从刀头转动基座中取出手柄。
11. 拧下刀头。



清洗和消毒

手柄拆卸完毕后，要清洗手柄、刀头转动基座、转动扳手及刀头。手柄和刀头都可以用 CUSA®手柄/刀头保养工具包（Ref/Cat C0023）清洗螺纹及抛光连接表面。

有关清洗和消毒处理的完整说明，请参阅 CUSA EXcel® 系统用户指南。

警告：延寿激光头 (Extended Life Tips, ELT) 允许 6 个消毒周期，并配有 6 个套管。任何激光头使用 6 次 或套管使用一次后必须丢弃。激光头使用超过 6 次或套管使用一次以上都会增加本装置特性和功能改变的风险，并增加并发症和 / 或不良后果发生的可能性。本装置一经使用，即必须按照医院的规定进行处置。

JP

CUSA EXcel® 23 kHz エクステンドライフ・ラパロスコピック チップ

エクステンドライフ・ラパロスコピック チップ (30.14 cm) は C2600 23 kHz ストレートハンドピースと併用します。

REF CAT.	仕様	直径
C4604ELT	エクステンドライフ ラパロスコピック チップ	1.98 mm

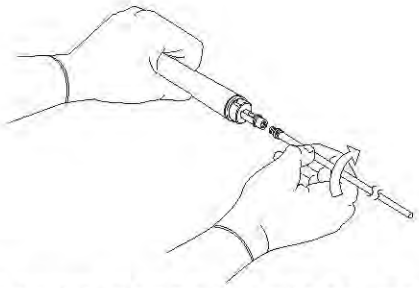
このパックに含まれるチップとクリーニング・ブラシは 6 回再可能です。ですその他のアイテムは使用一回限りです。このパックの中の全アイテムにラテックスは含まれておりません。

アセンブリー及び滅菌に関する完全な説明については、**CUSA EXcel® システム取扱説明書**を参照してください。

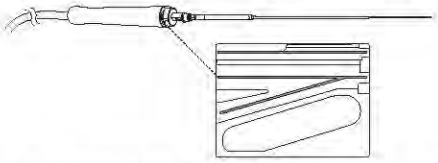
真圧蒸気滅菌のみ可能。未滅菌。使用前に滅菌してください。

組立

1. チップをハンドピースの接続体にネジを回して取り付けます。チップが動かなくなるまで手で回します。



2. ハンドピースのコネクターと同じ色のチップ締め台スロットを選択します（23 kHz - グリーン）。ハンドピースを金属の接続部とスロットの金属部分がきちんと合う様にチップ締め台に入れます。

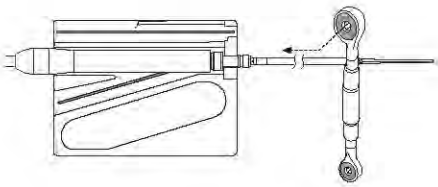


3. チップ締め台のスロットに収まったハンドピースを押さえます。

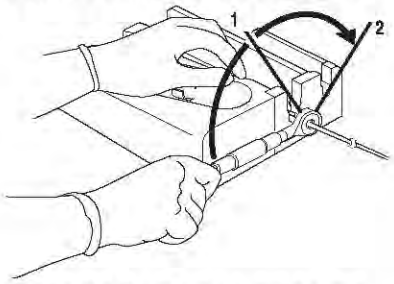
注意

製品への損傷を防ぐために、トルクレンチを使ってチップを締めたり、緩めたりしている時にはハンドピースを**絶対**手で押さえないでください。

4. トルクレンチの色付き部をハンドピース・コネクターの色（23 kHz - グリーン）と合わせます。レンチのカラーコードの付いている側を、チップを損傷しない様に注意しながらチップの上にスライドさせ、レンチの六角形とチップの六角形を合わせます。



5. カチッという音が聞こえ、感じるまでレンチを時計方向に回します。2 回目にカチッという音が聞こえ、感じるまでレンチをさらに回します。

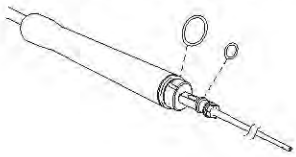


6. 注意しながらチップからレンチを外します。
7. チップ締め台からハンドピースを取り外します。
8. 組み立て中のハンドピース用の O リングを探します。

   O リング（大）　黒

   O リング（小）　緑

9. Oリング（大）を接続体にスライドさせ、ハンドピースの首にある溝に付けます。Oリング（小）を金属の接続体にある溝に取り付けます。



10. 組立てたハンドピース、ノーズコーン、フルー1本とチップクリーナーを滅菌ケースに入れます。

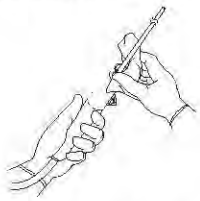
特別な注意

どのような種類のノーズコーンも、滅菌する前にハンドピースに取り付けないでください。ノーズコーンでカバーされている表面が滅菌されない可能性があります。

分解

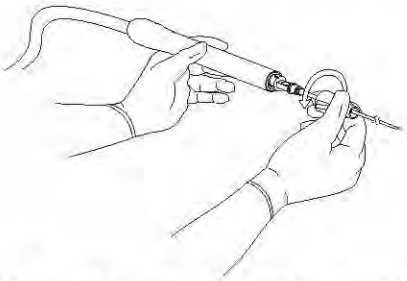
ハンドピースを洗浄する時、病院の洗浄作業時の方針に基づいて保護衣、手袋、安全めがねを必ず身につけて作業をしてください。

1. 殺菌溶剤で濡らした柔らかい布を使ってハンドピースから大まかな汚れを取り除きます。



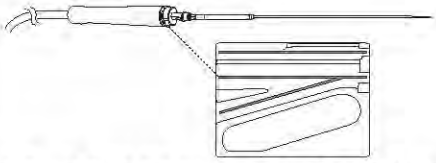
2. フルーがまだ取り外されていなければフルーを取り外してください。 フルーを廃棄してください。

3. ノーズコーンを取り外すには：
   a. ノーズコーンを反時計方向に回してゆるめます。
   b. ノーズコーンをハンドピースから取り外します。



スタンダードノーズコーンは廃棄しないでください。

4. O リングを取り外し廃棄します。
5. ハンドピースのコネクター（23 kHz - グリーン）と同じ色のチップ締め台スロットを選択します。ハンドピースを金属の接続部がきちんと合う様にチップの締め台に入れます。

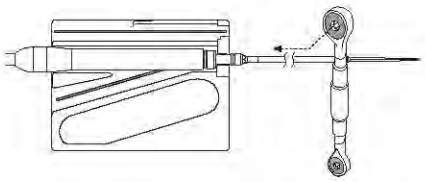


6. チップ締め台のスロットに収まったハンドピースを押さえます。

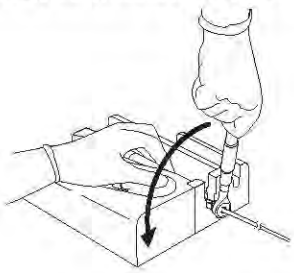
注意

製品への損傷を防ぐために、トルクレンチを使ってチップを締めたり、緩めたりしている時にはハンドピースを**絶対**手で押さえないでください。

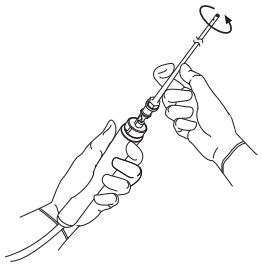
7. トルクレンチの色付き部をハンドピース・コネクターの色（23 kHz - グリーン）と合わせます。レンチのカラーコードの付いている側を、チップを損傷しない様に注意しながらチップの上にスライドさせ、レンチの六角形とチップの六角形を合わせます。



8. レンチを反時計方向に回し、チップをゆるめます。



9. 注意しながら、レンチをチップから取り外します。
10.チップ締め台からハンドピースを取り外します。
11.チップのネジをゆるめます。



洗浄と滅菌

ハンドピースの分解後、ハンドピース、チップ締め台、トルクレンチ、チップを洗浄する必要があります。ハンドピースおよびチップ共に、スレッドの洗浄および接触している表面を磨くのに、CUSA® ハンドピース/チップメンテナンスキット（Ref/Cat C0023）をご使用いただけます。

洗浄、滅菌の方法についての詳細は **CUSA EXcel® システム取扱説明書**を参照してください。

警告: Extended Life Tip（ELT）には6本のフル が提供されており、6回まで 菌できます。 6回使用したチップおよび一度使用したフル は、必ず してください。 6回使用したチップおよび一度使用したフル の再使用は、装置の特性および性能に 化を及ぼす恐れ、および合 症や望ましくない影 の可能性を す恐れがあります。装置は、必ず病院の方 にしたがって してください。

Integra LifeSciences (Ireland) Limited
IDA Business &Technology Park
Sragh
Tullamore
County Offaly
Ireland

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Integra LifeSciences Corporation
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Plainsboro, NJ 08536 USA

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UK/International
+44 (0) 1264 345 700
+44 (0) 1264 363 782 (Fax)

CE 0086

ИМО2

92901586 Rev. C

K141668

June 12, 2014

-Via Federal Express-

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional Premarket Notification 510(k)
CUSA® Excel+ Ultrasonic Surgical Aspirator System – Indication Expansion - General to Specific Indications for Use

Payment Identification Number: MD6074933-956733

Dear Sir or Madam:

Integra LifeSciences Corporation hereby submits in duplicate this Traditional 510(k) notification for its CUSA Excel+ Ultrasonic Surgical Aspirator System (CUSA). The general indication statement for Gastrointestinal and Affiliated Organ Surgery, Urological Surgery, Plastic and Reconstructive Surgery, General Surgery, Laparoscopic Surgery, and Thoracoscopic Surgery is being modified to include specific indications. The specific indications for use are included within the general indications and are substantially equivalent to the predicate CUSA device. The change to the indication statement has been made in accordance to the FDA guidance document "Guidance for Industry General/Specific Intended Use", issued November 4, 1998 and following the recommendations provided in the FDA email response dated January 17, 2014 to the company's Pre-Submission Application (Q130723).

(b)(4) Confidential and Proprietary Information

[redacted]

There have been no significant design changes or labeling changes made to the device since the original 510k clearance, which would impact safety or effectiveness of the device.

57

The submission contents are in accordance with the requirements outlined in 21 CFR 807 Subpart E and formatted in accordance with FDA Guidance for Industry and FDA Staff for Traditional and Abbreviated 510(k)s (issued on August 12, 2005).

In addition, this submission is complete per the FDA's guidance document Refuse to Accept Policy for 510(k)'s, published on December 31, 2012. Integra complies with this guidance document and has pre-filled the traditional 510(k) checklist (refer to **Appendix 1**).

The design and use of CUSA are presented in the table below.

Device and Use:

	CUSA Excel+ Ultrasonic Surgical Aspirator System	
Question	**Yes**	**No**
Is the device intended for prescription use?	X	
Is the device intended for over-the-counter use?		X
Does the device contain components from a tissue or biologic?		X
Is the device provided sterile?	X[1]	X
Is the device intended for single use?	X[1]	X
Is the device a reprocessed single use device?	X[2]	X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?	X	
Is the device implanted?		X

1 Some components sold separately are supplied sterile for single use only

2 Some components are reprocessed single use devices

The existence of this Premarket Notification and the data and information that it contains are Confidential, and the protection afforded to such confidential information by 21 CFR 807.95, and other applicable laws is hereby claimed.

Per the instructions accessed at http://www.fda.gov/cdrh/elecsub.html, an electronic copy is being provided with this submission. The eCopy is an exact duplicate of the paper submission.

Thank you in advance for your consideration of our application. If there are any questions, concerns or requests for additional information, please do not hesitate to contact me at 609-750-2864 or via e-mail at janet.kay@integralife.com. The designated alternate contact for this submission is Timothy Connors, 609-936-5531 or via email timothy.connors@integralife.com

Sincerely,

Janet C. Kay

Janet C. Kay, RAC

Director, Regulatory Affairs

510(k) PREMARKET NOTIFICATION

Traditional 510(k)

CUSA® Excel+ Ultrasonic Surgical Aspirator System

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536, USA

TABLE OF CONTENTS

LIST OF APPENDICES

Section 1 – Medical Device User Fee Cover Sheet (Form FDA 3601)

Site: null Page 1 of 1

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. 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: http://www.fda.gov/oc/mdufma/coversheet.html	
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) INTEGRA LIFESCIENCS CORP 22 Terry Avenue Burlington MA 01830 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****0030	2. CONTACT NAME Elizabeth McMeniman 2.1 E-MAIL ADDRESS elizabeth.mcmeniman@integralife.com 2.2 TELEPHONE NUMBER (include Area code) 781-5651347 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:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 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 our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; 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.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850

[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)

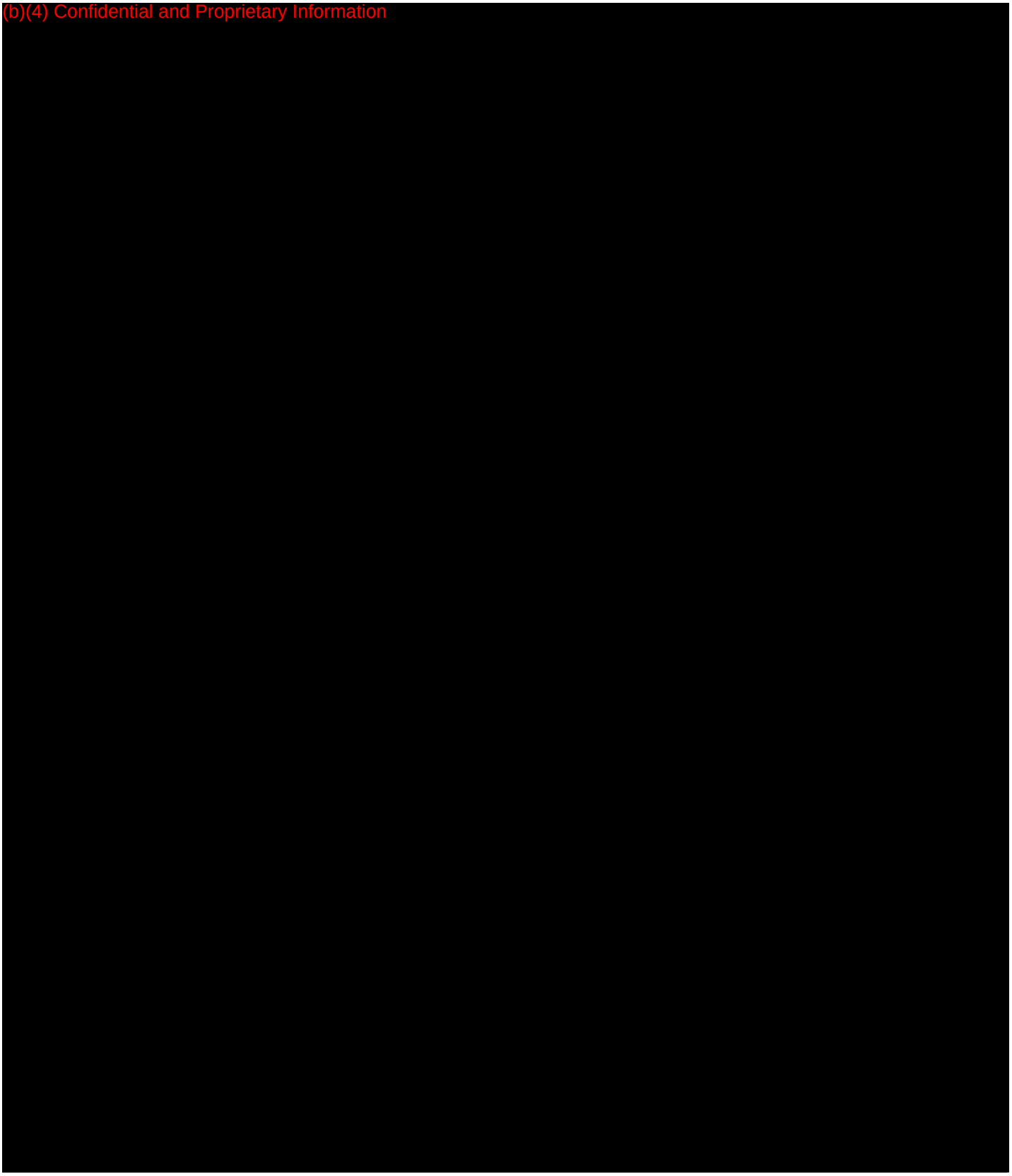
22-Apr-2014

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

https://userfees.fda.gov/OA_HTML/mdufmaCScdCfgItemsPopup.jsp?vcname=Elizabeth... 4/22/2014

(b)(4) Confidential and Proprietary Information



Section 2 - CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
06/06/2014	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Integra LifeSciences Corporation	1222895		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	609-750-2864		
Street Address	**FAX Number *(including area code)***		
311 Enterprise Drive	781-238-0645		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Plainsboro	New Jersey	08535	USA
Contact Name			
Janet C. Kay			
Contact Title	**Contact E-mail Address**		
Director, Regulatory Affairs	janet.kay@integralife.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

FORM FDA 3514 (1/13) Page 1 of 5 Pages

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software/Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☒ Additional or Expanded Indications
- ☐ Change in Technology
- ☐ Other Reason *(specify)*:

FORM FDA 3514 (1/13) Page 2 of 5 Pages

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LFL	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information
- ☒ 510 (k) summary attached
- ☐ 510 (k) statement

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K981262	1	CUSA Excel Ultrasonic Surgical Aspirator System	1	Integra LifeSciences Corporation
2	K051947	2	CUSA Excel Ultrasonic Surgical Aspirator System with Bone Tip	2	Integra LifeSciences Corporation
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Ultrasonic Surgical Aspirator

	Trade or Proprietary or Model Name for This Device		Model Number
1	CUSA® Excel+ Ultrasonic Surgical Aspirator System	1	CUSAEXCEL2
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

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

Data Included in Submission
- ☐ Laboratory Testing
- ☐ Animal Trials
- ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
LFL	Class II unclassified	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Neurology

Indications *(from labeling)*

See Submission

FORM FDA 3514 (1/13) Page 3 of 5 Pages

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.			FDA Document Number *(if known)*	
SECTION H	**MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**			
☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number		☒ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name: Integra Life Sciences (Ireland) Ltd			Establishment Registration Number: 3006697299	
Division Name *(if applicable)*: IDA Business & Technology			Phone Number *(including area code)*: 609-936-5447	
Street Address: Park, Sragh			FAX Number *(including area code)*	
City: Tullamore, Co Offaly		State / Province	ZIP Code	Country: Ireland
Contact Name: Janet C. Kay	Contact Title: Director, Regulatory Affairs		Contact E-mail Address: janet.kay@integralife.com	
☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number		☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number	
Division Name *(if applicable)*			Phone Number *(including area code)*	
Street Address			FAX Number *(including area code)*	
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	
☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number		☐ Manufacturer ☐ Contract Manufacturer ☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number	
Division Name *(if applicable)*			Phone Number *(including area code)*	
Street Address			FAX Number *(including area code)*	
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

FORM FDA 3514 (1/13) Add Continuation Page Page 4 of 5 Pages

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date
Please include any additional standards to be cited on a separate page.					

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

FORM FDA 3514 (1/13) Page 5 of 5 Pages

Section 3 - 510(k) Cover Letter

June 12, 2014 **-Via Federal Express-**

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional Premarket Notification 510(k)
CUSA® Excel+ Ultrasonic Surgical Aspirator System – Indication Expansion - General to Specific Indications for Use

Payment Identification Number: (b) (4) [redacted]

Dear Sir or Madam:

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(b)(4) Confidential and Proprietary Information [redacted]

There have been no significant design changes or labeling changes made to the device since the original 510k clearance, which would impact safety or effectiveness of the device.

The submission contents are in accordance with the requirements outlined in 21 CFR 807 Subpart E and formatted in accordance with FDA Guidance for Industry and FDA Staff for Traditional and Abbreviated 510(k)s (issued on August 12, 2005).

In addition, this submission is complete per the FDA's guidance document Refuse to Accept Policy for 510(k)'s, published on December 31, 2012. Integra complies with this guidance document and has pre-filled the traditional 510(k) checklist (refer to **Appendix 1**).

The design and use of CUSA are presented in the table below.

Device and Use:

	CUSA Excel+ Ultrasonic Surgical Aspirator System	
Question	**Yes**	**No**
Is the device intended for prescription use?	X	
Is the device intended for over-the-counter use?		X
Does the device contain components from a tissue or biologic?		X
Is the device provided sterile?	X[1]	X
Is the device intended for single use?	X[1]	X
Is the device a reprocessed single use device?	X[2]	X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?	X	
Is the device implanted?		X

1 Some components sold separately are supplied sterile for single use only

2 Some components are reprocessed single use devices

The existence of this Premarket Notification and the data and information that it contains are Confidential, and the protection afforded to such confidential information by 21 CFR 807.95, and other applicable laws is hereby claimed.

Per the instructions accessed at http://www.fda.gov/cdrh/elecsub.html, an electronic copy is being provided with this submission. The eCopy is an exact duplicate of the paper submission.

Thank you in advance for your consideration of our application. If there are any questions, concerns or requests for additional information, please do not hesitate to contact me at 609-750-2864 or via e-mail at janet.kay@integralife.com. The designated alternate contact for this submission is Timothy Connors, 609-936-5531 or via email timothy.connors@integralife.com

Sincerely,

Janet C. Kay, RAC

Director, Regulatory Affairs

ADMINISTRATIVE INFORMATION

Type of 510(k): Traditional 510(k)

Trade Name: CUSA® Excel+ Ultrasonic Surgical Aspirator System

Classification: Instrument, Ultrasonic Surgical

Device Class: Unclassified

Classification Panel: General and Plastic Surgery

Product Code: LFL

Predicate Devices: CUSA Excel Ultrasonic Surgical Aspirator; K981262

CUSA Excel Ultrasonic Surgical Aspirator with Bone Tip; K051947

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Owner:	Integra LifeSciences Corporation 311 Enterprise Drive Plainsboro, NJ 08536 USA Telephone: 609-936-5447 Facsimile: 609-275-9445 Establishment Registration Number: 3003418325
Manufacturing Sites:	Integra Life Sciences (Ireland) Ltd, IDA Business & Technology Park, Sragh, Tullamore, Co Offaly Establishment Registration Number: 3006697299

Section 4 - Indications for Use Statement

INTEGRA
LIMIT UNCERTAINTY

Indications for Use

510(k) Number (if known): _____

Device Name:

CUSA® Excel+ Ultrasonic Surgical Aspirator System

Indications For Use:

The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. The CUSA Excel+ Ultrasonic Surgical Aspirator is indicated for use in:

Neurosurgery, Orthopedic Surgery, Gynecological Surgery and the following specific uses:

Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy

Urological surgery- including removal of renal parenchyma during nephrectomy or partial nephrectomy

Plastic and reconstructive surgery – including removal of bone during rhinoplasty, dacryocystorhinostomy (DCR) procedure or orbital decompression

General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures

Laparoscopic Surgery - including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic excision of endometriosis or

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laparoscopic hysterectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy

Thoracoscopic Surgery – including removal of benign or malignant tissue in thoracoscopic pulmonary resection such as segmentectomies, nonanatomical subsegmentectomies and removal of metastatic lesions

.

Prescription Use ___X___ **AND/OR** **Over-The Counter Use_____**
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Section 5 – 510(k) Summary

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

807.92(a)(1) – Submitter information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone Number	781-565-1347
Fax Number	781-238-0645
Establishment Registration Number	3003418325
Name of Contact Person	Janet C. Kay
Date Prepared	June 12, 2014
807.92(a)(2) – Name of device	
Trade or Propriety Name	CUSA® Excel+ Ultrasonic Surgical Aspirator System
Common or Usual Name	Ultrasonic Surgical Aspirator
Classification Name	Instrument, Ultrasonic Surgical
Classification Panel	General and Plastic Surgery
Regulation	Class II unclassified
Product Code(s)	LFL
807.92(a)(3) – Legally marketed device(s) to which equivalence is claimed	
CUSA Excel Ultrasonic Surgical Aspirator System K981262 CUSA Excel Ultrasonic Surgical Aspirator System with Bone Tip K051947	
807.92(a)(4) – Device description	
The CUSA Excel+ Ultrasonic Surgical Aspirator System (CUSA) is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. It allows the selective dissection of target tissue while preserving vessels, ducts and other delicate structures. The CUSA Excel+ System consists of a console which provides control and power functions, two surgical hand pieces which provide ultrasonic mechanical energy (23kHz and 36kHz), titanium hand piece tips (variety of models), flexible irrigation flue, and a suction/irrigation system (manifold tubing and cooling water canister). The CUSA Excel+ system accommodates most commercially available suction canisters. A two-pedal footswitch is provided with the console.	
807.92(a)(5) – Intended use of the device	

Indications for Use	The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. The CUSA Excel+ Ultrasonic Surgical Aspirator is indicated for use in: Neurosurgery, Orthopedic Surgery, Gynecological Surgery and the following specific uses: Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy Urological surgery- including removal of renal parenchyma during nephrectomy or partial nephrectomy Plastic and reconstructive surgery – including removal of bone during rhinoplasty, dacryocystorhinostomy (DCR) procedure or orbital decompression General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures Laparoscopic Surgery - including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic excision of endometriosis or laparoscopic hysterectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy Thoracoscopic Surgery – including removal of benign or malignant tissue in thoracoscopic pulmonary resection such as segmentectomies, nonanatomical subsegmentectomies and removal of metastatic lesions

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate
The technological characteristic of the device are the same compared to the predicate device
807.92(b)(1-2) – Nonclinical and clinical tests submitted
No nonclinical testing was required as the device itself was not modified. The clinical evidence used to support the change to the indications for use is provided predominately from peer-reviewed clinical literature.
807.92(b)(3) – Conclusions drawn from non-clinical and clinical data
The changes from general to specific indications for use are supported by the information provided including previously cleared 510ks and peer reviewed clinical literature.

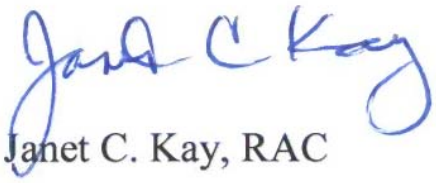
Section 6 – Truthful and Accurate Statement

Truthful and Accurate Statement

Premarket Notification 510(k) Submission

TRUTHFUL AND ACCURATE STATEMENT
[As Required by 21 CFR 807.87 (k)]

I certify that, in my capacity as Director of Regulatory Affairs at Integra LifeSciences Corporation, 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.



Janet C. Kay, RAC

Director, Regulatory Affairs Date: __6/12/2014____

Section 7 – Class III Summary and Certification

This Section Does Not Apply

Section 8 – Financial Certification or Disclosure Statement

This Section Does Not Apply

Section 9 – Declarations of Conformity and Summary Reports

This Section Does Not Apply

Section 10 – Executive Summary

EXECUTIVE SUMMARY

Integra LifeSciences is requesting the addition of specific indications to the general indications for use for the company's legally marketed CUSA Excel+ Ultrasonic Surgical Aspirator System (CUSA) (K981262, K051947). The company requests a change to the Indications for Use in order to better describe the specific surgical applications for which the device is commonly used.

The company and device users have identified the need for the product labeling to include specific applications for both training and reimbursement purposes. The need to describe specific indications reflects the evolution of CUSA's current use as a surgical tool in different anatomic locations and for different surgical applications. These specific indications are within the general intended use of the device and are not treatment or outcome claims.

This 510k submission focuses on the specific indications statements. The submission includes a system overview; however detailed information about the system, supporting documentation, test methods used for verification/validation testing can be found in the predicate devices submissions or can be provided by Integra LifeSciences upon request.

The CUSA is intended for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue and hard (e.g.: bone) is desirable. The specific indications for intended use include:

> Neurosurgery, Orthopedic Surgery, Gynecological Surgery and the following specific uses:
>
> Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy
>
> Urological surgery- including removal of renal parenchyma during nephrectomy or partial nephrectomy

Plastic and reconstructive surgery – including removal of bone during rhinoplasty, dacryocystorhinostomy (DCR) procedure or orbital decompression

General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures

Laparoscopic Surgery - including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic excision of endometriosis or laparoscopic hysterectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy

Thoracoscopic Surgery – including removal of benign or malignant tissue in thoracoscopic pulmonary resection such as segmentectomies, nonanatomical subsegmentectomies and removal of metastatic lesions

(b)(4) Confidential and Proprietary Information

There have been no significant design changes or labeling changes made to the device since the original 510k clearances which would impact the safety or effectiveness of the device.

The inclusions of the specific surgical indications does not alter the intended therapeutic effect of the fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue using ultrasonic cavitation and aspiration, nor its safety. These specific indications introduce no new risks other than those normally associated with the general intended use for CUSA.

These specific indications do not significantly change the target population. Although the population targeted by these more specific indications may be narrower, this narrower group of people is within the target population identified in the originally cleared general indications for use (K051947, K981261).

Using CUSA in these specific indications is well understood by the medical community and is

discussed in Section 20 of the submission. The specification of the indications does not change how the surgeon assesses the effectiveness of tissue ablation. Finally, there have been no design changes to the CUSA device or the fundamental operating principle of the device in order for the CUSA to be used in these specific indications.

The CUSA device is an effective aid in the removal of tumors. The company is requesting as part of the labeling change to include the removal of tumors (a surgical tool). The company will not promote outcome claims, but seeks to promote the use of CUSA to aid in the removal of tumors. FDA (Q130723) requested information about CUSA with respect to power morcellation. Specifically FDA stated "The CUSA device performs the same functions as a power morcellator and therefore presents the same type of risk to the patients. Please address how you intend to minimize this risk to the patients".

The company provides in the description section, a discussion about CUSA parametric controls that aid in minimizing misting and profusion of effluent and provides background on clinical considerations with references. Several particularly pertinent references from our existing database on CUSA papers are discussed. In one, Horowitz and Rader a retrospective study of treatment of tumors in gynecological procedures indicate a much lower incidence of recurrence with use of CUSA than alternative instruments.

Section 11 – Device Description

Device Description

11.1 System Overview

The CUSA Excel+ Ultrasonic Surgical Aspirator System (CUSA) is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. It allows the selective dissection of target tissue while preserving vessels, ducts and other delicate structures. The CUSA Excel+ System consists of a console which provides control and power functions, two surgical hand pieces which provide ultrasonic mechanical energy (23kHz and 36kHz), 18 titanium hand piece tips, flexible irrigation flue, and a suction/irrigation system (manifold tubing and cooling water canister). The CUSA Excel+ system accommodates most commercially available suction canisters, and specimen traps (optional). A two-pedal footswitch is provided with the console. The CUSA Excel+ System may also be used with an external CUSA Electrosurgical Module (CEM), which provides optional electrosurgical capability (K881687).

CUSA Excel+ Console

The mobile, free-standing console includes a base, a console body, and a control panel containing the controls and indicators for aspiration (suction), irrigation, amplitude (vibration) and TISSUE Select functions. The console is compact and easy to move. The *base* supports the console and provides mobility by means of four large conductive casters, providing a static ground for the system. Two of the four casters can be locked into a fixed position. The *console* provides aspiration (suction) and water cooling pumps, power supplies, and associated fuses. The console does not contain a microprocessor or memory. The irrigation and aspiration tubing are secured to the console in designated pathways in the irrigation pump head and suction pinch valve housings. The console body also supports the I.V. pole, and provides shelves for securing both the cooling water and vacuum canisters. All system controls and indicators are located on the *control panel* which has been designed for ease of use. The arm which supports the control panel allows the

panel to pivot 180 degrees, and can also be raised to allow the placement of a CUSA Electrosurgical Module (CEM) on top of the console body. The CUSA Excel+ console provides alternating current at 23 or 36 thousand cycles per second (kHz) to the handpiece.

CUSA Excel+ Handpieces

The CUSA Excel handpiece (23 kHz or 36 kHz) consists of a handpiece body, standard nosecone, and a cable with connector. The nosecone attaches to the handpiece and serves to hold the surgical tip flue in place and to anchor the suction tubing. The 15-foot cable contains an electric wire which powers the handpiece components, and two cooling water tubes. The alternating current provided by the CUSA Excel+ console passes through an electric coil in the handpiece body, which induces a magnetic field. The magnetic field excites a transducer of laminated nickel alloy which creates a mechanical oscillating motion (vibration) along its long axis. The transducer resonates at either 23 kHz or 36 kHz (specific to the CUSA Excel 23 kHz or 36 kHz handpiece). Fragmentation of the tissue occurs at the end of a hollow titanium surgical tip that vibrates longitudinally at either 23 kHz or 36 kHz to produce fragmentation.

The amount of motion (amplitude) at the tip varies, dependent upon the frequency of the handpiece (23 kHz or 36 kHz). Amplitude (tip stroke) is the longitudinal distance traveled by vibrating back and forth. Lower frequency (23 kHz) provides greater amplitude, and higher frequency (36 kHz) provides smaller amplitude. The greater the amplitude, the greater the force applied to the target which tissue, which results in a faster fragmentation rate. The handpiece provides simultaneous mechanical vibration, irrigation and aspiration.

The 36 kHz handpiece and associated surgical tips are smaller than the 23 kHz handpiece and surgical tips, and are designed for (but not limited to) applications which demand greater precision and user visibility. The 36 kHz handpiece is available in a straight configuration. The 23 kHz handpiece is available both in straight and angled configurations. All CUSA

handpieces are supplied non-sterile and are reusable.

CUSA Excel+ Accessories

Accessories include manifold tubing sets, tip and flue packs, CEM nosecones, tip torqueing set, wrenches, and sterilizer cases.

The *CUSA Excel Manifold Tubing* Set consists of suction and irrigation tubing, and is available in two configurations for use with the CUSA Excel 36 kHz handpiece and the 23k Hz handpiece when used with the Excel+ console. One end of the suction tubing connects to the suction canister located on the console and passes through the suction pinch valve; the other end connects to the suction port on the handpiece nosecone. One end of the irrigation tubing connects to the I.V. set attached to the console and passes through the irrigation pump; the other end connects to the surgical tip flue. The Manifold Tubing Set is supplied sterile, and may be re-sterilized one time using steam sterilization. Some surgeons prefer to connect the handpiece to the tubing set outside the sterile field then re-sterilize the handpiece and tubing set before use.

The *CUSA Excel Tip and Flue Pack* consist of a surgical titanium tip and a flexible rubber irrigation flue, and are available in a variety of tip configurations for the CUSA Excel+ handpiece (23 kHz or 36 kHz). The flue provides the outlet port for the irrigation solution. Two pre-aspiration holes at the distal end of the tip allow entry of irrigation fluid to facilitate the suction of aspirated tissue. The surgical tip protrudes from the flue and performs tissue fragmentation. Tips are available in various sizes. These were cleared as part of the original 510k K981262. The Tip and Flue Pack is supplied sterile for single use with the exception of the Extended Life Tip and Flue Packs which are Non-Sterile and reusable

A *CUSA Excel CEM Nosecone* is available for use with the CUSA Excel+ handpiece (23 kHz or 36 kHz). The CEM Nosecone for the 23 kHz handpiece includes buttons for the delivery of both electrosurgical cut and coagulation outputs, while the 36 kHz handpiece

has a single button for the delivery of coagulation output only. The CEM Nosecone is supplied sterile for single use.

The *CUSA Excel Handpiece Sterilizer Case* (23 kHz or 36 kHz) is used to hold the handpiece and any other items during sterilization. The *CUSA Excel Tip Torqueing* Set includes a tip torqueing base and a reusable torque wrench for the attachment or removal of handpiece surgical tips in a non-sterile field prior to sterilization. The Tip Torqueing Set cannot be re-sterilized and is for non-sterile use only. The torque wrench has an opening at one end which fits the 23 kHz handpiece, and an opening at the other which accommodates the 36 kHz handpiece. The *CUSA Excel Wrench* (23 kHz or 36 kHz) is a sterile, single use device which can be used to change tips in the sterile field. The *CUSA Sterilizable Torque Base* has the same function as the base in the Tip Torqueing Set, but it can be sterilized via steam by the user and is for use when torqueing is needed in the sterile field. It is sold non-sterile and is reusable.

The *CUSA Excel+ Footswitch* consists of two pedals in a base, and allows the activation of the vibration (right pedal) and Fast Flush (left pedal) functions. The footswitch is provided with the CUSA Excel+ console.

CUSA Excel+ Console

11.2 Principle of Operations - Ultrasonics

Ultrasonics use vibratory mechanical action or vibratory waves operating at frequencies that are beyond the upper limit of the human audible range, reported as being between 16,000 and 23,000 cycles per second. Ultrasonic vibration is the mechanical motion of an object about an equilibrium point at ultrasonic frequencies. Ultrasound is the radiant sound wave energy that is produced by objects that are vibrating at ultrasonic frequencies. The ultrasonic wave used for CUSA is between 20 kHz and 40 kHz which is far below the range traditionally used in imaging (1.5 MHz to 20.0 MHz)

CUSA Transducer

Ultrasonic energy is produced by a device known as a transducer. A transducer is a device that is activated by power from one system to supply power in a different form to a second system. In

the ultrasonic transducer, electrical energy is converted into ultrasonic mechanical energy or vibratory waves. A magnetostrictive transducer contained in the handpiece of the CUSA Excel models convert electrical energy into ultrasonic mechanical energy. (b)(4) Confidential and Proprietary Information

(b)(4) Confidential The resonant vibration of the transducer results from the contraction and expansion that the magnetostrictive core undergoes as the electrical current in the coil alternates at the appropriate frequency. The resonant vibration of the transducer is transferred into and is amplified by the cone shaped titanium tip to which it is physically coupled. (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information Applied alternating voltages of continuous waves are converted to stress and strain of the amplifying horns and surgical tips resulting in ultrasonic resonance and high amplitude vibration. The magnetostrictive and piezoelectric transducers produce the same net tissue fragmentation effect, given the same amplitude of vibration and frequency.

Ultrasonic Surgical Effect in Tissue

The mode of action of an ultrasonic surgical aspirator is to utilize a hollow titanium tip that vibrates longitudinally along its axis at ultrasonic frequencies to fragment and aspirate tissue in a controlled manner through direct contact between the end of the tip and the target tissue. When the ultrasonically vibrating tip is brought in direct contact with firm fleshy tissue, the high intensity, low frequency mechanical action of the tip causes the fluid in the tissue to cavitate and it is this effect which is responsible for the tissue fragmentation. Cavitation is defined as the

occurrence or formation of gas or, more specially, vapor filled vacuoles flowing in a liquid through dynamic generation of low pressure, usually on the order of the fluid's vapor pressure.

As the titanium tip vibrates at ultrasonic frequencies while in contact with high water content tissue, the transferred mechanical energy causes the pressure of the fluid in the tissue immediately next to the tip to be rapidly and repeatedly first reduced below, and then greatly elevated above the fluid's own vapor pressure. Under these conditions, the fluid forms microscopic vacuoles of vapor as small as 1 micron. These vacuoles alternately form and collapse as each cycle of pressure reduction and elevation takes place. Fluid dynamics dictates that the collapse of these vacuoles be accompanied by the production of extremely high pressure in the fluid immediately surrounding each vacuole. These pressures are typically on the order of one to ten million atmospheres when the frequency of vacuole formation and collapse is 23,000 times per second in water. These enormous pressures being created within the cells of the tissue cause the cell walls to rupture, thus producing fragmentation of the tissue.

Cavitation in water produced by an ultrasonically vibrating driver has long been used in research laboratories to rupture the cell walls of biological samples without destroying or altering the cell contents which are to be studied. The characteristics associated with cavitation are that (1) it requires the presence of a fluid, (2) can produce extremely high pressures, (3) does not involve the generation of macroscopic heat, and (4) requires a threshold of vibration intensity for production.

The fragmentation of tissue by the cavitational effect takes place only when and where the end of the ultrasonic tip actually comes in contact with the tissue. Since the tip is a round, hollow tube which presents an annular surface, tissue can be dissected to form tissue plugs (head on dissection), tissue slivers (angled dissection) and total tissue removal (overlapping dissection). With the tissue plugs and tissue slivers, the dissected tissue is structurally changed only along the dissection margin. The diameters of the tissue plugs and slivers dissected by the tip are equal to or less than the diameter of the tip. The interior portions of the aspirated segments are histologically intact and are suitable for pathological examination. Although a surgical tip

ultrasonically vibrating at high intensity and low frequency can heat up enough to cauterize small vessels, the continuous irrigation and aspiration of the CUSA system carries the heat away from the tip, thus minimizing the possibility of the tip imparting a thermal effect on the tissue.
Since ultrasonic dissection of tissue by cavitational effects is dependent on the fluid contained in the target tissue, its effect varies as a function of the tissue's water content. As a result, soft, fleshy, high water content tissues (such as parenchymal and adipose tissue) are readily dissected and hard, tough low water content tissues (such as intervertebral collagen, meniscus and large blood vessels) are not dissected. This phenomenon allows the rapid dissection of unwanted tissue while avoiding damage to structures which are not meant to be damaged or removed.

Ultrasonic Versus Ultrasound

An ultrasonic surgical device consists of a half wavelength transducer coupled to a wave-guide which is terminated with a working and surgical tip. Its working frequency is in a relatively low range of 19 - 40 kHz, and these devices are characterized by high intensity mechanical action (>5 W/cm²). The mechanical action of the tip is transferred, while in contact with high water content tissue, into cavitational effects which produce fragmentation of the target tissue. Although an ultrasonically vibrating surgical tip produces ultrasound as a by-product of its mechanical action, this ultrasound lacks the acoustical energy or focus for penetration beyond the irrigation fluid/target tissue plane and therefore, does not warrant consideration as a safety issue.
Ultrasound utilized in medical diagnostic and therapeutic devices is in the high frequency range between 0.5 to 20 MHz and is of relatively low intensity levels. The ultrasonic wave projected from most of these devices is focused within the patient's body at the desired depth and location. The radiant energy (ultrasound) is the ultrasonic energy that produces the desired effect within the patient's body.

The bio-effects observed with diagnostic ultrasound devices are predominantly thermal in nature, but there is evidence that unwanted cavitation may occur in the target tissue with extended exposure. The American Institute of Ultrasound in Medicine has concluded that, "In the low megahertz frequency range, there has been no independently confirmed significant biological effects in mammalian tissues exposed to intensities below 100 mW/cm²".

Power Morcellation

In a review of published literature, at least two groups address the spread of cancer cells in surgical ultrasonic aspiration: pathologists discussing potential hazards and surgeons discussing clear benefit of CUSA. Examples of papers discussing potential hazards specific to ultrasonic aspirators include the following:

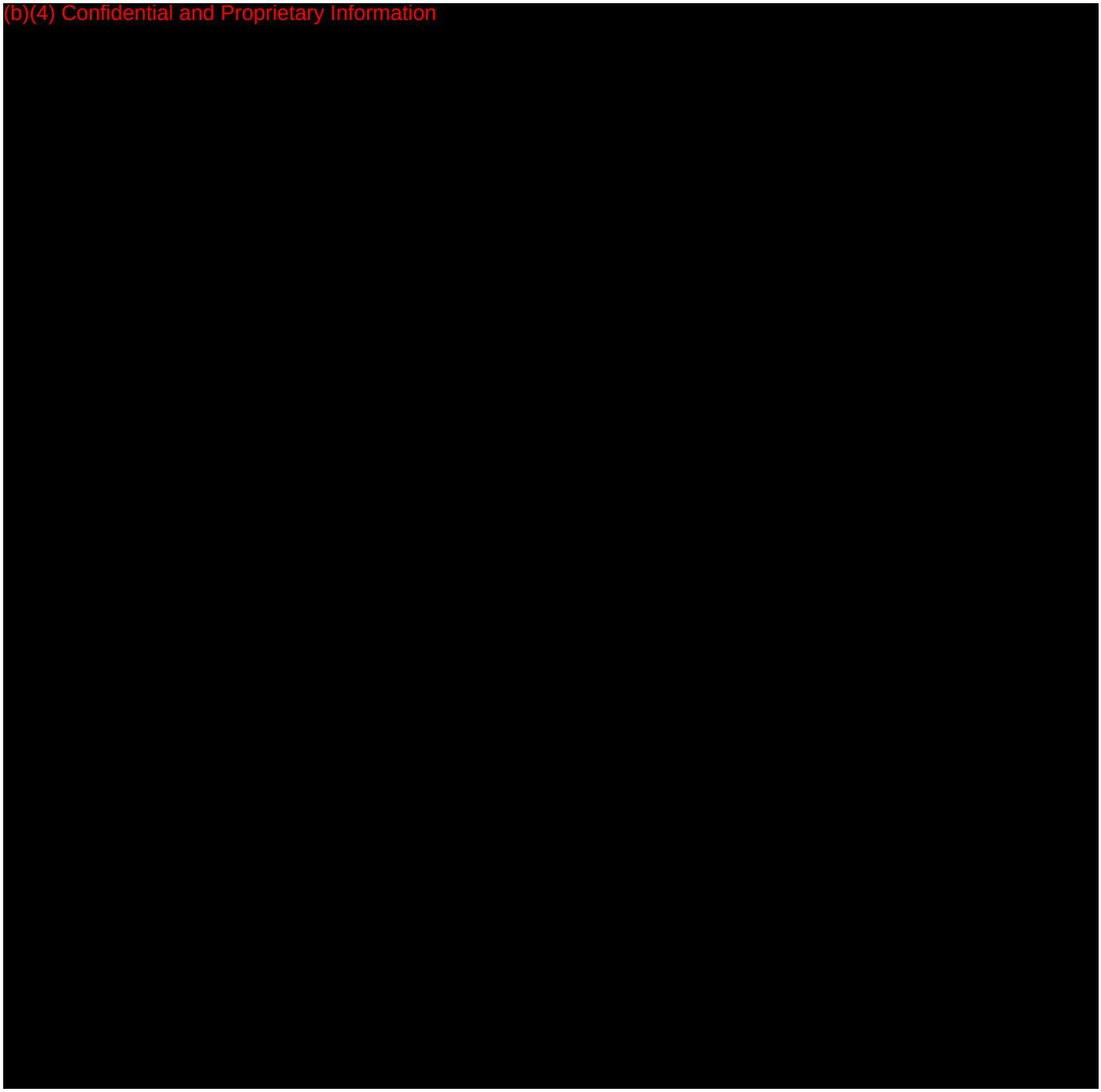
a) Tumor cell dispersion by the ultrasonic aspirator during brain tumor resection, J. K. Preston, et al.
b) Case Report, A potential hazard of the use of the Surgical Ultrasonic Aspirator in Tumor Reductive Surgery, W. A. Nahhas.
c) Case Report, Is there an increased risk for tumor dissemination using ultrasonic surgical aspiration in patients with vulvar carcinoma?, P.A. van Dam et al.
d) Risk for leptomeningeal seeding after resection for brain metastases: implication of tumor location with mode of resection, J.H. Ahn et al.

Examples of papers discussing the clinical benefit of CUSA, specifically for malignancy include the following:

e) Role of the ultrasonic surgical aspirator in gynecology, N. S. Horowitz and J. S. Rader.
f) Nerve-sparing radical hysterectomy: a pilot study, F. Raspagliesi, et al.
g) Dr. Kassam discussed employing the same principles as sharp dissection, entry to the capsular tumor with sharp dissection, debulking with CUSA and delivery of the capsule en bloc, as method to reduce spread of malignancy. We do not have a current reference to Dr. Kassam, as this was from his course notes at UPMC.

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information



Parametric Control of Misting and Profusion of Effluent (Cancer Cells)

CUSA provides a broad range of controls of amplitude, irrigation, and aspiration that can be adjusted by the surgeon in response to tissue fragmentation at the surgical site. As examples, the cavitation threshold of 23 kHz and 36 kHz conventional ultrasonic aspirating tips in saline irrigation liquid has been quantified with optical observations and cavitation spectrum signature

analysis. (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information The surgeon has control of reducing amplitude and increasing aspiration to minimize misting with nominal irrigations levels.

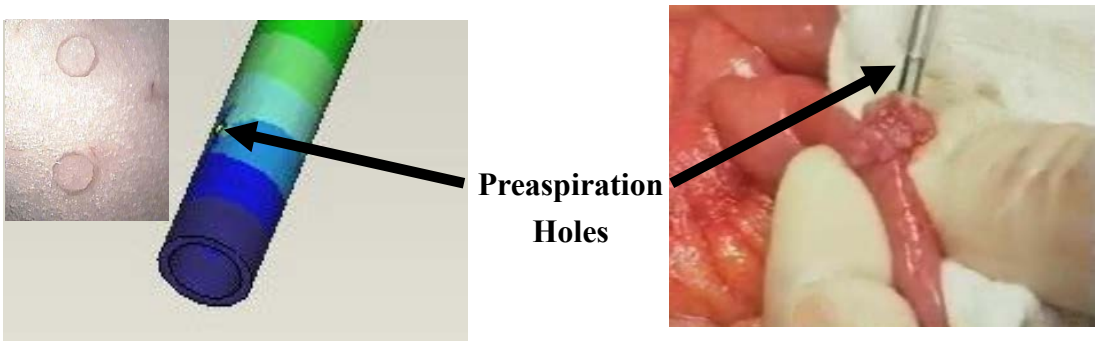
(b)(4) Confidential and Proprietary Information

Two (2) transducers (handpieces) with markedly different frequency at the surgical tips (horns) that have substantially different stroke, yield similar calculated pressures of about 1 ATM (101.3 kPa), based on the power transduced, area, and velocity of the horn or tip. Referencing Hodnett and Zeqiri, their measurements of peak negative pressure leading to inertial cavitation in a cavitation reference vessel yielded 101 kPa +/- 14%, consistent with theoretical modeling of threshold for inertial cavitation. Additional information on measurement techniques can be provided upon request.

Pre-aspiration holes of 0.38 mm (0.015 in) diameter, shown in Figure 1 below, are located proximal of the distal end of the surgical tip coincident with the flue supplying irrigation liquid. In this way, a large portion (90% or more) of saline is suctioned before it reaches the surgical site to cool the vibrating surgical tip, and wet suctioned tissue to prevent coagulation and clogging of the internal channel. A typical setting would be 3 -7 ml/min of irrigation with 0.3- 0.7 ml/min

reaching the open channel of the surgical tip interacting with the tissue.

Figure 1: Preaspiration Holes



It is often beneficial to the surgeon to control misting, tissue effluent and bleeding to ensure visualization of the surgical tip, as afforded by CUSA. This may be extended to control of misting and effluent in known or suspected malignancy.

Fundamentally, the ultrasonic aspirator is a suctioning system with the additional benefit of focused fragmentation available at the suction tube. The morcellation system discussed in the FDA safety alert dated FDA on 17th April 2014 is a tissue tearing instrument that does not necessarily have integrated aspiration. It is essentially a macroscopic tissue grinder, not unlike a sausage maker.

(b)(4) Confidential and Proprietary Information

[redacted]

Also with respect to "Power Morcellation", FDA appears to be working to stop use of any morcellator for laparoscopic uterine hysterectomy and myomectomy. Please see statement made by FDA on 17th April 2014:

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm393576.htm

Since the CUSA offers precise surgical removal through the use of a titanium tip where effluent is immediately aspirated, the company does not see the need for a broad warning about the spread of cells. However, the company agrees that the following warning could be useful to our customers if the FDA feels the warning is necessary:

> The CUSA Excel+ is not recommended for use in laparoscopic procedures in women with unsuspected uterine sarcoma. There may be a risk that the procedure will spread cancerous tissue within the abdomen and pelvis. For this reason, and because there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma, the CUSA Excel+ is not recommended for use in laparoscopic procedure during hysterectomy or myomectomy for uterine fibroids.

Biocompatibility

The biocompatibility of the CUSA components which are patient contacting have been assured through selection of materials which demonstrate biocompatibility. All materials used, including patient contacting materials, have been cleared in previous submissions.

Section 12 - Substantial Equivalence Discussion

12.1 Substantial Equivalence Discussion

The specific indications outlined below are included within the general indications and the use of the device is substantially equivalent to the predicate CUSA device (K051947, K981262). The change to the indication statement has been made in accordance to the FDA guidance document "Guidance for Industry General/Specific Intended Use", issued November 4, 1998. The inclusions of the specific General Surgery indications does not alter the intended therapeutic effect of the fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue using ultrasonic aspiration. The specific indications for use do not introduce new risks beyond those normally associated with the general indications stated above. These specific indications for use do not significantly change the target population. Although the target population may be more narrowly defined, it is within the target population identified in the originally cleared general indication for use. Using CUSA for these specific indications is well understood by the medical community and is discussed in Section 20 of the submission. The specification of the indications does not change how the surgeon assesses the effectiveness of tissue ablation. Finally, there have been no design changes to the CUSA device or the fundamental operating principle of the device in order for the CUSA to be used in these specific indications.

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Table 12.1: CUSA Excel+ Ultrasonic Surgical Aspirator Console Substantial Equivalence Chart

Characteristic	Modified Labeling	Predicate Device Label (K051947, K981262)	Comments
Intended Use/Indications for Use General Surgery	The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. The CUSA Excel+ Ultrasonic Surgical Aspirator is indicated for use in: Neurosurgery, Orthopedic Surgery, Gynecological Surgery and the following specific uses: Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy,	The CUSA Excel Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable, including Neurosurgery, Gastrointestinal and Affiliated Organ Surgery, Urological surgery, Plastic and reconstructive surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery and Thoracoscopic Surgery.	Different

Characteristic	Modified Labeling	Predicate Device Label (K051947, K981262)	Comments
	or removal of tissue during liver allotransplantation and donor hepatectomy Urological surgery- including removal of renal parenchyma during nephrectomy or partial nephrectomy Plastic and reconstructive surgery – including removal of bone during rhinoplasty, dacryocystorhinostomy (DCR) procedure or orbital decompression General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures Laparoscopic Surgery - including		

Characteristic	Modified Labeling	Predicate Device Label (K051947, K981262)	Comments
	removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic excision of endometriosis or laparoscopic hysterectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy Thoracoscopic Surgery – including removal of benign or malignant tissue in thoracoscopic pulmonary resection such as segmentectomies, nonanatomical subsegmentectomies and removal of metastatic lesions		

Characteristic	Modified Labeling	Predicate Device Label (K051947, K981262)	Comments
Product Classification	Class II	Class II	Same
Product Code	LFL	LFL	Same

Table 12.2: History of the General Surgery Indications previously cleared

The CUSA Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. This table lists previously cleared devices from the CUSA Excel+ lineage and notes the specific indications that were cleared with the devices.

510k #	Device Name	Applicant	Cleared Indication
K910696	CUSA200 C,T,M,H 23 kHz, 37kHz	Valley lab	Thoracoscopic Surgery - limited pulmonary resections such as segmentectomies, nonanatomical subsegmentectomies and metastatectomies
K921251	CUSA200 C,T,M,H 23 kHz, 37kHz	Valley lab	For use in laparoscopic surgical procedures where fragmentation, emulsification and aspiration of soft tissue combined with the availability (optional) of electrosurgery is desirable.

12.2 Substantial Equivalence Conclusion

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The changes from general to specific intended uses are supported by the information provided including previously cleared 510k and peer reviewed clinical literature.

(b)(4) Confidential and Proprietary Information

[redacted]

13 Proposed Draft Labeling

Draft Operators manual can be found in **Appendix 2.**

The proposed indication statement can be found in **Section 4 – Indications For Use Statement**.

Integra LifeSciences acknowledges the recent FDA Safety Communication issues April 17, 2014 discussing the use of power morcellators in certain gynecological procedures. The company has recently been in contact with several CUSA users, and the company is currently unaware of instances in which the CUSA would be used for laparoscopic hysterectomy or myomectomy for uterine fibroids, though it is impossible to claim with absolute certainty it would not be used with the procedures. Additionally, as described in Section 11 of this submission, the company does not believe the CUSA system is a power morcellator. Power morcellators are generally used for chunking large pieces of tissue. The CUSA system, however, is a precision device that fragments tissue that is then immediately aspirated away from the body.

Though the company does not believe the CUSA is used in the procedures cited in the FDA Safety Communication and is not a power morcellator, the company would be willing to include the following warning in the Operators Manual if deemed necessary upon FDA review:

> The CUSA Excel+ is not recommended for use in laparoscopic procedures in women with unsuspected uterine sarcoma. There may be a risk that the procedure will spread cancerous tissue within the abdomen and pelvis. For this reason, and because there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma, the CUSA Excel+ is not recommended for use in laparoscopic procedure during hysterectomy or myomectomy for uterine fibroids.

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

BIOCOMPATIBILITY

15.1 Biocompatibility

No new biocompatibility tests were required. Biocompatibility testing was cleared in the original 510k submissions K051947, K981262.

Section 16 - Software

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

Electromagnetic Compatibility and Electrical Safety

Electromagnetic compatibility and electrical safety was cleared as part of the original 510k submission K981262.

Minor labeling modifications were made to product labeling in order to obtain compliance to 60601-3rd ed. The modifications are discussed as part of CUSA Excel+ Ultrasonic Surgical Aspirator System pending 510k submission.

Section 18 - Performance Testing - Bench

This Section Does Not Apply

(b)(4) Confidential and Proprietary Information

[redacted]

(b)(4) Confidential and Proprietary Information

[redacted]

Clinical Testing

Specific Indications for Use

Using CUSA in the specific indications requested in this 510k is well understood by the medical community; the description of specific indications does not change how the surgeon assesses the effectiveness of tissue ablation. Although Integra did not perform any specific new clinical trials in support of this product labeling change, the submission contains an extensive review of articles from peer reviewed journals which support the use of CUSA in specific surgical applications. A summary of the results is presented below.

Gastrointestinal and Affiliated Organ Surgery

An analysis of peer-reviewed articles on the use of CUSA in gastrointestinal and affiliated organ surgery presents clinical evidence to support the specific indications for use. Thirty-four articles present CUSA or ultrasonic dissection in gastrointestinal surgical cases (approximately 2,500 cases), including open hepatectomy and laparoscopic-assisted liver resection. (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

[redacted]

Overall, the literature demonstrated that CUSA can be safely used in laparoscopic and open liver surgeries. The laparoscopic technique using CUSA has been shown to decrease morbidity, shorten hospital stay, improve cosmesis, and decrease blood loss. The literature showed CUSA to be safe and effective in liver surgery for pediatric, adult,

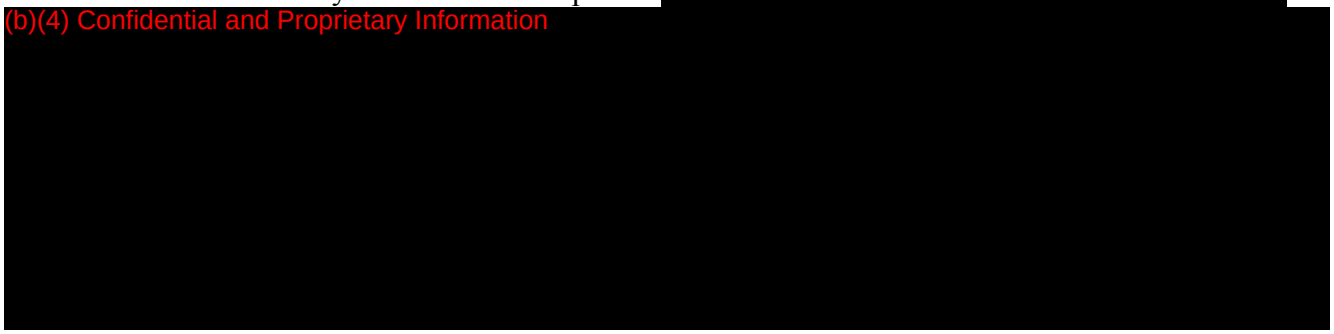
and elderly patients and it has also been proven acceptable in both open and laparoscopic procedures.

The literature review is provided in **Appendix 3**.

Urologic Surgery

Six articles report on the use of the CUSA system in renal surgical cases. These cases included resections performed for renal lithiasis and renal tumor removal and formation of a nipple valve during construction of a continent ileal urinary reservoir. A total of 8 urologic resection cases and 71 cases of nipple valve formation during construction of a continent ileal urinary reservoir were reported (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information



The literature review is located in **Appendix 4**.

Plastic Surgery

A search of peer-reviewed articles on the use of CUSA in plastic and reconstructive surgery was performed. Clinically relevant literature specific to CUSA was not available for review, however, literature was available for the Synergetics Sonopet. Because the Sonopet uses the same fundamental technology as the CUSA system, the review captures Sonopet articles which present clinical evidence that ultrasonic bone aspiration is safe and effective in plastic and reconstructive surgery.

The Sonopet system was used in 103 rhinoplasty cases, 5 lateral osteotomy cases, 64 dacyocystorhinostomy cases and 31 orbital decompression cases. No major complications were reported in any of the cases reviewed.

(b)(4) Confidential and Proprietary Information

The literature review is provided in **Appendix 5**

General Surgery

Four general surgery articles have been reviewed. One article discussed the successful treatment of osmidrosis by CUSA. The authors used the CUSA to aspirate and remove the apocrine glands that were causing the osmidrosis. (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

An article reported on the use of CUSA for the resection of carcinoma of the tongue in 10 patients. (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

Papillary cystic and solid tumor of the pancreas (PCSTP) is very rare in children. The authors reported on the successful treatment of five children using CUSA.

In a single patient case study, CUSA was used in a restorative proctocolectomy with mucosectomy for rectal mucosal stripping.In this case study, it was observed that some tissues ablated by the CUSA made some segments of the surgical specimen

uninterpretable by a pathologist. This could lead to a false "negative" pathology report. Based on their findings, the authors recommend regular pouch surveillance following mucosectomy.

The literature review is provided in **Appendix 6**

Laparoscopic Surgery

Eight articles and two abstracts reveal that CUSA has been successfully used in laparoscopic appendectomies, laparoscopic colon resections, laparoscopic cholecystectomies, laparoscopic partial gastrectomies, laparoscopic transhiatal esophagectomy, laparoscopic ablation of endometriosis, and laparoscopic hepatectomies. One hundred thirty-one laparoscopic cholecystectomies, nine laparoscopic appendectomies, three laparoscopic colon resections, and two laparoscopic partial gastrectomies were performed using CUSA. (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

Six cases of laparoscopic esophagectomy were also completed using CUSA. (b)(4) Confidential and Proprietary

(b)(4) Confidential and Proprietary Information

Over 150 laparoscopic hepatectomy procedures were performed using the CUSA system.

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

The literature review is provided in **Appendix 7**

Thoracoscopic Surgery

Two published articles present information on use of the CUSA system in thoracic surgical cases. The two types of procedures covered in the articles were segmental and subsegmental lung resections (27 patients) and laparoscopic transhiatal esophagectomies (6 patients). (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

The literature review is provided in **Appendix 8**.

20.4 Overall Conclusion

The literature reviews presented here cover GI and affiliated organ, Plastic, Urologic, General, Laparoscopic, and Thoracic surgeries. The largest body of data found was for GI and affiliated surgeries reporting on approximately 2,500 case. Articles on the other types of surgery report on approximately 400 cases. (b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

[redacted]

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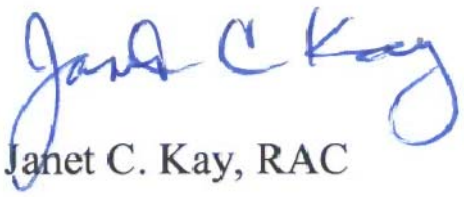
Section 21 – Other

21.1 Kit Certification

The CUSA Excel+ Ultrasonic Surgical Aspirator System does not include a convenience kit as described in the FDA "Convenience Kits Interim Regulatory Guidance."



Janet C. Kay, RAC

Director, Regulatory Affairs Date: 6/12/2014

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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.

510(k) Number: _____ **Date Received by DCC:** _____

Lead Reviewer Name: _____ **Branch:** _____ **Division:** _____ **Office:** _____

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 RTA and that element will be assessed during substantive review.

Preliminary Questions		
Answers in the shaded blocks indicate consultation with Center advisor is needed.	**Yes**	**No**
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, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Office Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	X	
Comments: Class II unclassified		
2. Is the application 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 application is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Office Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If application should not be reviewed by your Center mark "No."	X	
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 Jurisdictional Officer or appropriate CBER Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, skip this question.		
Comments: *Not Applicable*		
4. 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), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	X	
Comments: *Traditional 510(k)*		
5. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		X
Comments:		
6. 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 Compliance/Division of Bioresearch Monitoring (OC/DBM - BIMO) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm.		X

If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.
If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.

Acceptance Checklist for Traditional 510(k)

Contains Nonbinding Recommendations

If the answer to 6 is "Yes," then contact CDRH/OC/DBM – BIMO or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with the BIMO Staff, and indicate BIMO's recommendation/action.

Organizational Elements *Failure to include these items alone generally should not result in an RTA designation*		
	Yes	**No**
a. Submission contains Table of Contents	X	☐
b. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X	☐
c. 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…).*	X	
d. Type of 510(k) is identified– traditional, abbreviated, or special *If type of 510(k) is not designated, review as a traditional*	X	
Comments: *Traditional 510(k)*		

Elements of a Complete Submission (RTA Items) **(21 CFR 807.87 unless otherwise indicated)** Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
A.	**Administrative**					
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)		X		☐
		Comments:				
	2.	Submission identifies the following (such as in CDRH Premarket Review Submission Cover Sheet (Form 3514) or 510(k) cover letter):		X		☐
		a.	Device trade name or proprietary name	X		☐
		b.	Device common name	X		☐

Acceptance Checklist for Traditional 510(k)

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
		c.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X		
		Comments: *Section 5; 510(k) Summary*				
	3.	Submission contains Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109) *Submitter should use format appropriate for the reviewing Center/Office (CDRH/ODE, CDRH/OIVD, CBER/OBRR, CBER/OCTGT). If not provided in correct format, request the correct format during substantive review.*		X		
		Comments: *Section 4; Indications for Use*				
	4.	Submission contains 510(k) Summary or 510(k) Statement *Either a) or b) must be answered "Yes" to be considered complete. Identify any missing element(s) in Comments.*		X		
		a.	Summary contains all elements per 21 CFR 807.92 *See also 510(k) Summary Checklist*	X		
		b.	Statement contains all elements per 21 CFR 807.93		X	
		Comments: *Section 5; 510(k) Summary*				
	5.	Submission contains Truthful and Accuracy Statement per 21 CFR 807.87(k) *See recommended format. Select "Yes" if statement is present and includes the text in the recommended format, and is signed by a responsible person of the firm (not consultant).*		X		
		Comments: *Section 6; Truthful and Accuracy Statement*				

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
	6.	Submission contains Class III Summary and Certification *See recommended content. Form should be signed by a responsible person of the firm, not a consultant. Select "N/A" only if submission is not a Class III 510(k).*			X	
		Comments: *Section 7*				
	7.	Submission contains clinical data *Select "N/A" if the submission does not contain clinical data. If "N/A" is selected, parts a and b below are omitted from the checklist.*			X	
		a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) 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 for Industry-Financial Disclosures by Clinical Investigators*			
		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (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)*			
		Comments: *Section 20 – Performance Testing – Clinical-Literature*				
	8.	If submission references use of a national or international standard as part of demonstration of substantial equivalence, submission contains complete Standards Data Report for 510(k)s (FDA Form 3654) *There should be a completed form for each referenced national or international standard.* *Select "N/A" only if submission does not reference any standards.*			X	

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed					
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.		**Yes**	**N/A**	**No**
		Comments: Section 21-*Form 3654 and Standards Conformance Summary Reports*			
	9.	The submission identifies prior submissions for the same device for which FDA provided feedback related to the data or information needed to support substantial equivalence (e.g., submission numbers for Pre-Submission, IDE, prior not substantially equivalent (NSE) determination, prior 510(k) that was deleted or withdrawn) or states that there were no prior submissions for the subject device. *This information may 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). Alternatively, a list of submission numbers may be found in Section F (prior related submissions section) of the CDRH Coversheet form (Form 3514) to address this criterion. Please be advised that if this section of the form is left blank, it should not be considered a statement that there were no prior submissions.*	X		
		a. If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence outlined in prior communications are addressed. *To address this criterion, the submission may 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 the adequacy of how the feedback was addressed should be assessed during the substantive review.* For additional information regarding the Pre-Submission process, please refer to the Draft Guidance "Medical Devices: The Pre-Submission Program and Meetings with FDA Staff." (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm310375.htm). Once finalized, this guidance will represent the	X		

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
			Agency's current thinking on this topic. *Select "N/A" if the submitter states there were no prior submissions in criterion above.*			
		Comments:				
B.	**Device Description**					
	10.	a.	If there are requirements regarding the device description, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes device description information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*		X	
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes device description information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *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.*		X	
		Comments:				

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
	11.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling), including:		X		
		a.	A description of the principle of operation and mechanism of action for achieving the intended effect.	X		
		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.	X		
		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, or various sizes, etc.*		X	
		Comments: *Section 11 Device Description*				
	12.	Submission contains representative engineering drawing(s), schematics, illustrations and/or figures of the device that are clear, legible, labeled, and include dimensions. *In lieu of 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.* *Select "N/A" if the submitter provided a rationale for why the submission does not contain engineering drawings, schematics, etc. (e.g., device is a reagent and figures are not pertinent to describe the device).*		X		
		Comments: *Section 11 Device Description*				

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
	13.	If device is intended to be marketed with multiple components, accessories, and/or as part of a system, *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system.*			X	
		a.	Submission includes a list of all components and accessories to be marketed with the subject device.		X	
		b.	Submission includes a description (as detailed in item 11.a. and b. and 12 above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*		X	
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. *Select "N/A" if the submission states that the component(s)/ accessory(ies) does not have a prior 510(k) clearance or the component(s)/accessory(ies) is 510(k) exempt.*		X	
		Comments: *Section 11 Device Description*				
C.	**Substantial Equivalence Discussion**					
	14.	Submitter has identified a predicate(s) device		X		
		a.	Predicate's 510(k) number, trade name, and model number (if applicable) provided. For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidan*	X		

Contains Nonbinding Recommendations

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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.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
			ce/ComplianceActivities/ucm072746.htm).			
		b.	The identified predicate(s) is consistent throughout the submission (i.e., 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.	X		
		Comments: *Section 12 Substantial Equivalence Discussion*				
	15.	Submission includes a comparison of the following for the predicate(s) and subject device		X		
		a.	Indications for use	X		
		b.	Technology, including features, materials, and principles of operation	X		
		Comments: *Section 12 Substantial Equivalence Discussion*				
	16.	Submission includes an analysis of why any differences between the subject device and predicate(s) do not render the device NSE (e.g., does not constitute a new intended use; and any differences in technological characteristics are accompanied by information that demonstrates the device is as safe and effective as the predicate and do not raise different questions of safety and effectiveness than the predicate), affect safety or effectiveness, or raise different questions of safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)) *If there is no difference between the subject and predicate(s) with respect to indications for use or technology, this should be explicitly stated, in which case "N/A" should be selected. Select "No" only if the submission does not include an analysis of differences as described above or a statement that there are no differences. Note that the adequacy of the analysis should be assessed during the substantive review; only the presence of such an analysis is required for acceptance. In addition, note that due to potential differences in*		X		

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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.					
		· Any "No" answer will result in a "Refuse to Accept" decision. · 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.	**Yes**	**N/A**	**No**
		manufacturing that may not be known to the submitter, the fact that no differences are identified does not necessarily mean that no performance testing is needed.			
		Comments: *Section 12 Substantial Equivalence Discussion*			
D.	**Proposed Labeling (see also 21 CFR part 801)** *If in vitro diagnostic (IVD) device, criteria 17, 18, and 19 may be omitted. These criteria will be omitted from the checklist if "N/A" is selected. IVD labeling is addressed in section 21 below.*		X		
	17.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual) that include a description of the device, its intended use, and the directions for use	X		
		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)	X		
		b. Submission includes directions for use that - include statements of all conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes directions for layperson (see 21 CFR 801.5) OR submission states that device qualifies for exemption per 21 CFR 801 Subpart D	X		
		Comments: *Section 13; Proposed Draft Labeling*			
	18.	If indicated for prescription use, labeling includes the prescription use statement (see 21 CFR 801.109(b)(1)) or "Rx only" symbol [See also Alternative to Certain Prescription Device Labeling Requirements] *Select "N/A" if not indicated for prescription use.*	X		

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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.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
		Comments: *Section 13; Proposed Draft Labeling*				
	19.	General labeling provisions				
		a.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	X		
		b.	Labeling includes device common or usual name (21 CFR 801.61) *Select "N/A" if device is for prescription use only.*		X	
		Comments: *Section 13; Proposed Draft Labeling*				
	20.	a.	If there are requirements regarding labeling, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes labeling to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*		X	
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes labeling to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *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 have been addressed should be assessed during the substantive review.*		X	

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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.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
		c.	If there is a special controls document applicable to the device, the submission includes labeling to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document.* *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 mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*		X	
		Comments:				
	21.	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.*			X	
E.	**Sterilization** *If 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.*					
	Submission states that the device and/or accessories are: (*one of the below must be checked*) ☒ provided sterile ☒ provided non-sterile but sterilized by the end user ☒ non-sterile when used This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" is selected, the sterility-related criteria below are omitted from*					☐

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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.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
	the checklist. *If information regarding the sterility status of the device is not provided, select "No."*					
	Comments:					
	22.	Assessment of the need for sterilization information				
		a.	Identification of device, and/or accessories, and/or components that are provided sterile.	X		
		b.	Identification of device, and/or accessories, and/or components that are end user sterilized	X		
		c.	Identification of device, and/or accessories, and/or components that are reusable and cleaning/disinfection instructions are provided.	X		
		Comments: *Section 14; Sterilization & Shelf Life, submission references predicate devices*				
	23.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-e below.*		X		
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	X		
		b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation report is not required.*	X		
		c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum	X		

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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.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
			levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*			
		d.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X		
		e.	Sterility Assurance Level (SAL) stated	X		
		Comments: *Section 14; Sterilization & Shelf Life, references predicates*				
	24.	If the device, and/or accessory, and/or a component is end user sterilized: *Select "N/A" if no part of the device, accessories, or components are end user sterilized, otherwise complete a-d below.*		X		
		a.	Sterilization method is stated for each component (including parameters such as dry time for steam sterilization, radiation dose, etc.)	X		
		b.	A description of method to validate the sterilization parameters (e.g., half-cycle method and full citation of FDA-recognized standard, including date) is provided for each proposed sterilization method. *Note, the sterilization validation is not required.*	X		
		c.	Submission includes description of packaging and packaging contents (e.g., if multiple devices are included within the same package, Tyvek packaging, etc.)	X		
		d.	Submission includes sterilization instructions for end user	X		
		Comments: *Section 14; Sterilization & Shelf Life, references predicates*				
	25.	a.	If there are requirements regarding sterility, such as special		X	

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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.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
			controls, in a device-specific regulation that are applicable to the device, the submission includes sterility information to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*			
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes sterility information to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative approach. *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 have been addressed should be assessed during the substantive review.*		X	
		c.	If there is a special controls document applicable to the device, the submission includes sterility information to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. 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 mitigation measures in a*		X	

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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.					
		· Any "No" answer will result in a "Refuse to Accept" decision. · 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.	**Yes**	**N/A**	**No**
		special controls document have been addressed should be assessed during the substantive review.			
		Comments: references predicate device information			
F.	**Shelf Life**				
	26.	Proposed shelf life/ expiration date stated *Select "N/A" if the device is not provided sterile and the submitter states that storage conditions could not affect device safety or effectiveness.*	X		
		Comments: *Section 1; Sterilization & Shelf Life, references predicates*			
	27.	For sterile device, submission includes summary of methods used to establish that device sterility will remain substantially equivalent to that of the predicate through the proposed shelf life, or a rationale for why testing to establish shelf life is not applicable. *Select "N/A" if the device is not provided sterile.*	X		
		Comments: *Section 14; Sterilization & Shelf Life,*			
	28.	Submission includes summary of methods used to establish that device performance is not adversely affected by aging and therefore device performance will remain substantially equivalent to that of the predicate, or includes a rationale for why the storage conditions are not expected to affect device safety or effectiveness.	X		
		Comments: *Section 14; Sterilization & Shelf Life*			
G.	**Biocompatibility** *If in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*			X	
	Submission states that there: (*one of the below must be checked*) ☒ are				☐

Acceptance Checklist for Traditional 510(k)

Contains Nonbinding Recommendations

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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.					
		· Any "No" answer will result in a "Refuse to Accept" decision. · 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.	**Yes**	**N/A**	**No**
	☐ are not direct or indirect (e.g., through fluid infusion) patient-contacting components. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are not" is selected, the biocompatibility-related criteria below are omitted from the checklist. If information regarding whether the device is patient-contacting is not provided, select "No."*				
	Comments: *Section 15 device contacts patient, references predicates*				
	29.	Submission includes list of patient-contacting device components and associated materials of construction, including identification of color additives, if present		X	
		Comments: *Section 15 references predicates*			
	30.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration)		X	
		Comments: *Section 15 references predicates*			
	31.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test, OR a statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).		X	
		Comments: *Section 15 references predicates*			
H.	**Software**				

Contains Nonbinding Recommendations

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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.				
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.	**Yes**	**N/A**	**No**
	Submission states that the device: (*one of the below must be checked*) ☐ does ☒ does not contain software/firmware. This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the software-related criterion is omitted from the checklist. If information regarding whether the device contains software is not provided, select "No."*			☐
	Comments: *Section 16 Software*			
	32. Submission includes a statement of software level of concern and rationale for the software level of concern	X		
	Comments: Section 16 Software			
	33. 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, 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).	X		
	Comments: *Section 16 Software*			
I.	**EMC and Electrical Safety**			
	Submission states that the device: (*one of the below must be checked*) ☒ Does not require EMC and Electrical Safety 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.					
		· Any "No" answer will result in a "Refuse to Accept" decision. · 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.	**Yes**	**N/A**	**No**
	This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not" is selected, the EMC-related and Electrical Safety-related criteria below are omitted from the checklist. If information regarding whether the device requires EMC and Electrical Safety evaluation is not provided, select "No."*				
	Comments: *Section 17 - Electromagnetic Compatibility and Electrical Safety*				
	34.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, the 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).			
		Comments:			
	35.	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).			
		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.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
J.	**Performance Data – General** *If 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 will be addressed in Section K.*					
	Comments: *SECTION 18 - Performance Testing – Bench*					
	36.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre- defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test supports a finding of substantial equivalence. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*			X	
		Comments:				
	37.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*		X	
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the applicable statutory or regulatory criteria through an alternative		X	

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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.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
			approach. *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 have been addressed should be assessed during the substantive review.*			
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. 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 mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*		X	
		Comments:				
	38.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. 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.*		X		
		a.	Legible reprints or a summary of each article	X		
		b.	Discussion of how each article is applicable to support the	X		

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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.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
			substantial equivalence of the subject device to the predicate.			
		Comments:				
	39.	For each completed nonclinical (i.e., animal) study conducted, *Select "N/A" if no animal study was conducted. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist,*			X	
		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: *No nonclinical studies were conducted*				
K.	**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 ☒ is not an in vitro diagnostic device (IVD). *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*					
	Comments: *The Device is not an IVD*					

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	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
	40.	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:				
	41.	a.	If there are requirements regarding performance data, such as special controls, in a device-specific regulation that are applicable to the device, the submission includes performance data to establish that the submitter has followed the device-specific requirement. *Select "N/A" if there are no applicable requirements in a device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information. Note that the adequacy of how such requirements have been addressed should be assessed during the substantive review.*	☐	☐	☐
		b.	If there is a device-specific guidance, other than a special controls guidance document, applicable to the device, the submission includes performance data to establish that the submitter has addressed the recommendations or otherwise has met the	☐	☐	☐

Contains Nonbinding Recommendations

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated) Submission should be designated RTA if not addressed						
Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
	· Any "No" answer will result in a "Refuse to Accept" decision. · 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.			**Yes**	**N/A**	**No**
			applicable statutory or regulatory criteria through an alternative approach. *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 have been addressed should be assessed during the substantive review.*			
		c.	If there is a special controls document applicable to the device, the submission includes performance data to establish that the submitter has complied with the particular mitigation measures set forth in the special controls document or uses alternative mitigation measures but provides a rationale to demonstrate that those alternative measures identified by the firm will provide at least an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document. 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 mitigation measures in a special controls document have been addressed should be assessed during the substantive review.*	☐	☐	☐
		Comments:				

Contains Nonbinding Recommendations

Decision: Accept ___ Refuse to Accept ___

If Accept, notify applicant; if Refuse to Accept, notify applicant in writing and include a copy of this checklist.

Reviewer Signature: _____ Date: _____

Supervisory Signature: _____ Date: _____

SECTION 1

Patient and Operating Room Safety

In this section:

Indications for Use

The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. The CUSA Excel+ Ultrasonic Surgical Aspirator is indicated for use in:

Neurosurgery, Orthopedic Surgery, Gynecological and the following specific uses:

Gastrointestinal and Affiliated Organ Surgery - including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy.

Urological surgery - including removal of renal parenchyma during nephrectomy or partial nephrectomy.

Plastic and reconstructive surgery - including removal of bone during rhinoplasty, dacryocystorhinostomy (DCR) procedure or orbital decompression.

General Surgery - including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures.

Laparoscopic Surgery - including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic excision of endometriosis or laparoscopic hysterectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy.

Thoracoscopic Surgery - including removal of benign or malignant tissue in thoracoscopic pulmonary resection such as segmentectomies, nonanatomical subsegmentectomies and removal of metastatic lesions.

Warning

The CUSA Excel/CUSA Excel+ System cannot be used in an MRI (Magnetic Resonance Imaging) environment.

Warning

No modification of this equipment is allowed.

Notice

When you receive the CUSA Excel/CUSA Excel+ System and accessories, if any component is damaged, contact your Integra service representative for assistance. If the packaging for a sterile accessory is damaged, do not use the sterile accessory.

Intended Users

The intended users of this guide and the equipment it describes are qualified medical professionals who are trained in the particular surgical technique and surgical procedure to be performed, and trained in the use of this equipment. The CUSA Excel/CUSA Excel+ System should only be used in a surgical environment by qualified medical professionals.

Warning

It is the responsibility of the Healthcare Facility to ensure that intended users of CUSA Excel/CUSA Excel+ System are appropriately trained in the use of this equipment.

Safety Information

The safe and effective use of ultrasonic surgery depends to a large degree on factors solely under the control of the operator. Only medical professionals that are properly trained in the use of ultrasonic equipment should operate the CUSA Excel/CUSA Excel+ System. It is important that medical professionals read, understand, and follow the operating instructions supplied with this equipment.

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Clinical Literature on the Cavitron Ultrasonic Surgical Aspirator (CUSA): Gastrointestinal and Affiliated Organ Surgery

April 11, 2014

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1 Executive Summary – CUSA Use in Gastrointestinal and Affiliated Organ Surgery

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2 CUSA Use in Gastrointestinal and Affiliated Organ Surgery Literature Review

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2.1 Articles Reviewed

1. **Article:** Preliminary report on surgical technique in hepatic parenchymal transection for liver tumors in the elderly: a lesson learned from living-related liver transplantation.; *J Surg Oncol.* 2004 Dec 15;88(4):229-33.

Authors: Gruttadauria S, Doria C, Vitale CH, Cintorino D, Foglieni CS, Fung JJ, Marino IR.

Summary: Availability of hi-tech surgical devices has elaborated the technique of parenchymal transection during hepatectomy from classic crushing clamp technique to a combination of an ultrasonic dissection with special type of cautery. The authors developed a new technique to resect hepatic parenchyma using an ultrasonic surgical aspirator in association with a monopolar floating ball. This combination has been utilized in 42 liver resections. A retrospective analysis of perioperative mortality, length of hospitalization, and blood transfusion during surgery in two patient groups who underwent liver resection was carried out. The authors divided the patient population into Group A (42 patients), who underwent the new technique, and Group B (107 patients), who experienced the crushing clamp technique. A second analysis was performed, where the authors divided the same patient population group in Group 1 with age less than 65, and Group 2 including patients older than 65 years. It was found that the new technique reduced length of stay, procedure length, and use of perioperative blood. The authors determined that the two age groups performed similarly in comparison to length of hospitalization, length of procedure, blood use, and complications. This enforces the fact that the elderly can receive such surgical treatment without hesitation.

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2. **Article:** Application of dye-enhanced laser ablation for liver resection. Production of protein sealant on the cut surface of the liver by enhanced thermal energy of low power diode laser.; *Eur Surg Res.* 2005 May-Jun;37(3):153-8.

Authors: Noritomi T, Yamashita Y, Kodama T, Mikami K, Hashimoto T, Konno T, Maekawa T, Shirakusa T.

Summary: Dye-enhanced laser ablation (DLA) using a low-power diode laser for indocyanine green (ICG)-stained tissue has proven its effectiveness in dye-enhanced laser photocoagulation of retinal vessels or endoscopic surgical mucosectomy. The authors applied DLA in hepatectomy and described its histological distinction in comparison with the cavitron ultrasonic surgical aspirator (CUSA). A diode laser (UDL-60 Laser unit, Olympus, Tokyo, Japan) with 810 +/- 20 nm wavelength was employed for this study. The ICG dye (Diagnogreen, Daiichi Pharmaceutical, Tokyo, Japan) with a peak absorption wavelength at 800-810 nm was injected topically into the resection plane of the liver. The liver tissue was divided by touching the tip of the diode laser. Three different concentrations of ICG solution such as 2.0, 1.0 and 0.5 mg/ml were tested in the preliminary animal experiment. The use of a low-power diode laser at 10 W with an ICG concentration of 0.5 mg/ml was the appropriate combination for liver resection. In the clinical series, 27 hepatectomies were performed by DLA, and 10 with CUSA. DLA demonstrated smooth cutting and good hemostasis in liver resection. Among the hepatectomy cases given DLA, no postoperative hemorrhage or bile leakage was noted. The postoperative hospital stay was significantly shorter in the DLA than the CUSA group. The cut surface of the liver was sealed microscopically with a layer of protein coagulum. In conclusion, a layer of protein sealant on the cut surface of the liver contributes to the short postoperative hospital stay when using DLA.

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3. **Article:** Improvements in hepatic parenchymal transection for living related liver donor.; *Transplant Proc.* 2005 Jul-Aug;37(6):2589-91.

Authors: Gruttadauria S, Mandalà L, Vasta F, Cintorino D, Musumeci A, Marsh W, Marcos A, Gridelli B.

Summary: To eliminate mortality and morbidity risk in living related liver donors, the authors developed a new surgical technique to resect hepatic parenchyma using an ultrasonic surgical aspirator in association with a monopolar floating ball cautery. 17 right hepatectomis and 2 left hepatectomies were performed using the technique. The authors performed a retrospective analysis of perioperative mortality, length of hospitalization (LOS), blood transfused during surgery (IBT), intraoperative blood lost (IBL), biliary complications (BC), and aspartate aminotransferase (AST)/alanine aminotransferase (ALT) peak in the first postoperative week. This group of patients (Group A) was compared, using the analysis of variance (ANOVA) test ($P < .05$) with 2 different groups of 19 patients: Group B with liver neoplasms that had the same technique as Group A, and Group C wherein a crushing clamp technique was used. All of the analyzed variables showed significative statistical differences, especially between

Group A and Group C (IBL, P < .000; IBT, P < .006; LOS, P < .028; BC, P < .000; AST peak, P < .041; and ALT peak, P < .023). The association of these 2 techniques seems to reduce the LOS, and the need for intraoperative blood transfusions. Moreover, the surgical complications (biliary leaks) and the postoperative parenchymal cytonecrosis seem to be less using this technique.

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4. **Article:** Two-surgeon technique for hepatic parenchymal transection of the noncirrhotic liver using saline-linked cautery and ultrasonic dissection.; *Ann Surg.* 2005 Aug;242(2):172-7.

Authors: Aloia TA, Zorzi D, Abdalla EK, Vauthey JN.

Summary: The purpose of this study was to analyze our experience with saline-linked cautery in hepatic surgery. Safe and efficient hepatic parenchymal transection is predicated on the ability to simultaneously address 2 tasks: parenchymal dissection and hemostasis. To date, no single instrument has been designed that addresses both of these tasks. Saline-linked cautery is now widely used in liver surgery and is reported to decrease blood loss during liver transection, but data on its exact benefits are lacking. From a single institution, prospective liver surgery database, the authors identified 32 consecutive patients with noncirrhotic livers who underwent resection for primary or metastatic disease using a 2-surgeon technique with saline-linked cautery and ultrasonic dissection (SLC+UD) from December 2002 to January 2004. From the same database, the authors identified a contemporary and matched set of 32 patients who underwent liver resection with similar indications using ultrasonic dissection alone (UD alone). Operative and anesthetic variables were retrospectively analyzed to identify differences between the 2 groups. The 2 groups were equivalent in terms of age, gender, tumor histology, tumor number, and tumor size. The UD+SLC group had a decreased duration of inflow occlusion (20 minutes versus 30 minutes, P = 0.01), blood loss (150 mL versus 250 mL, P = 0.034), and operative time (187 minutes versus 211 minutes, P = 0.027). Postoperative liver function and complication rates were similar in each group. The 2-surgeon technique for liver parenchymal transection using SLC and UD in noncirrhotic livers is safe and may provide advantages over other techniques.

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5. **Article:** Hepatic resection by the Cavitron Ultrasonic Surgical Aspirator increases the incidence and severity of venous air embolism.; *Anesthesia & Analgesia*. 2005 Oct;101(4):966-70.

Authors: Koo BN, Kil HK, Choi JS, Kim JY, Chun DH, Hong YW.

Summary: The Cavitron Ultrasonic Surgical Aspirator (CUSA) is an innovative tool for resecting hepatic parenchyma, which reduces intraoperative blood loss and perioperative morbidity. We designed this study to compare the incidence and severity of venous air embolism (VAE) detected via transesophageal echocardiography (TEE) during hepatic resection by using either the clamp-crushing method or the CUSA method. Fifty patients scheduled for hepatic resection were randomly assigned to receive hepatic resection by the clamp-crushing method (CC group) or by CUSA (CUSA group). After the induction of anesthesia, the TEE probe was inserted into the patient's esophagus. An independent anesthesiologist graded VAE shown in the 4-chamber view of TEE. All patients in the CUSA group showed VAE during hepatic resection and 44% of the patients had air embolism filling more than half the right heart diameter. In CC group, 68% of the patients showed VAE, which filled less than half the right heart diameter. There were no significant differences in hemodynamics and end-tidal CO2 partial pressure between the two groups. In conclusion, hepatic resection by CUSA increases the incidence and severity of VAE.

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6. **Article:** How should transection of the liver be performed?: a prospective randomized study in 100 consecutive patients: comparing four different transection strategies.; *Ann Surg.* 2005 Dec;242(6):814-22.

Authors: Lesurtel M, Selzner M, Petrowsky H, McCormack L, Clavien PA.

Summary: The objective of this study was to identify the most efficient parenchyma transection technique for liver resection using a prospective randomized protocol. Liver resection can be performed by different transection devices with or without inflow occlusion (Pringle maneuver). Only limited data are currently available on the best transection technique. A randomized controlled trial was performed in noncirrhotic and noncholestatic patients undergoing liver resection comparing the clamp crushing technique with Pringle maneuver versus CUSA versus Hydrojet versus dissecting sealer without Pringle maneuver (25 patients each group). Primary endpoints were intraoperative blood loss, resection time, and postoperative liver injury. Secondary end points included the use of inflow occlusion, postoperative complications, and costs. The clamp crushing technique had the highest transection velocity (3.9 +/- 0.3 cm/min) and

lowest blood loss (1.5 +/- 0.3 mL/cm) compared with CUSA (2.3 +/- 0.2 cm/min and 4 +/- 0.7 mL/cm), Hydrojet (2.4 +/- 0.3 cm/min and 3.5 +/- 0.5 mL/cm), and dissecting sealer (2.5 +/- 0.3 cm/min and 3.4 +/- 0.4 mL/cm) (velocity: P = 0.001; blood loss: P = 0.003). Clamp crushing technique was associated with the lowest need for postoperative blood transfusions. The degree of postoperative reperfusion injury and complications were not significantly different among the groups. The clamp crushing technique proved to be most cost-efficient device and had a cost-saving potential of 600 to 2400 per case. In conclusion, the clamp crushing technique was the most efficient device in terms of resection time, blood loss, and blood transfusion frequency compared with CUSA, Hydrojet, and dissecting sealer, and proved to be also the most cost-efficient device.

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7. **Article:** Major hepatectomy in children: approaching blood transfusion-free.; *World J Surg.* 2006 Jun;30(6):1115-9.

Authors: Lin CC1, Chen CL, Cheng YF, Chiu KW, Jawan B, Hsaio CC.

Summary: Major hepatectomy complicated with massive blood loss requires blood transfusion, which may result in increased morbidity and mortality. Intraoperative techniques and postoperative management that achieves blood transfusion-free major hepatectomy in children are described. Fourteen children with a mean age of 3.1 years and mean body weight of 14 kg underwent major hepatectomy between May 1994 and September 2002. Demographic information, surgical techniques, and intraoperative management were analyzed. Hepatectomy included right trisegmentectomy in seven cases, extended right lobectomy in three, right lobectomy in two, and left lobectomy in two. Preoperative imaging, hemihepatic inflow control, intraoperative ultrasonography, and ultrasonic dissection were routinely applied. Fluid was restricted to target a low central venous pressure (5 cm H(2)O) during transection. Postoperative low hemoglobin (>6.3 g/dl) was tolerated in pediatric patients. There was no operative mortality or major complications and only two cases of pleural effusion. The mean blood loss was 68 ml (range 1.25-13.0 ml/kg), and no blood transfusions were required intraoperatively. Blood transfusion was given because of a liberal strategy for major operation in two patients and preoperative tumor bleeding in one. Despite being technically challenging, major hepatectomy can be performed with minimal blood loss and without blood transfusion in children to decrease postoperative complications.

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8. **Article:** Cardiac arrest by venous air embolism during hepatic resection using the Cavitron Ultrasonic Surgical Aspirator.; *Anasth Analg.* 2006 Aug;103(2)493-4.
Authors: Adachi YU, Doi M, Sato S.
Summary: Koo et al. recently demonstrated that patients undergoing resection of the liver using the Cavitron Ultrasonic Aspirator (CUSA®) have venous air embolism (VAE), a potentially fatal complication. The incidence of VAE using CUSA® had not been investigated. Within 6 mo of introducing the CUSA® device in the University Hospital, the authors had 3 cases of cardiac arrest during hepatic resection. The patients showed a sudden decrease of arterial blood pressure (systolic blood pressure 40 mm Hg) and end tidal carbon dioxide (less than 20 mm Hg) at the middle phase of resection. In two cases the authors could aspirate a small amount of air from the pulmonary catheter fortuitously placed at the beginning of anesthesia. All patients were resuscitated by rapid intravascular administration, IV administration of catecholamines, and trans-diaphragmatic cardiac massage. The surgeon reported palpating a completely collapsed heart immediately after the cardiac arrest. These episodes were diagnosed as VAE, and CUSA®-related air entrainment from liver was strongly suspected.

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9. **Article:** Current techniques of liver transection.; *HPB (Oxford).* 2007;9(3):166-73.
Authors: Poon RT.
Summary: The operative mortality rate of liver resection has decreased from 10% to 20% before the 1980s to <5% in most specialized hepatobiliary centers nowadays. The most important factor for better outcome is reduced blood loss due to improvement in surgical techniques. Liver transection is the most challenging part of liver resection, associated with a risk of massive hemorrhage. Understanding the segmental anatomy of the liver and delineation of the proper transection plane using intraoperative ultrasound are prerequisites to safe liver transection. Clamp crushing and ultrasonic dissection are the two most widely used transection techniques. In recent years, new instruments using different types of energy for coagulation or sealing of vessels have been developed for liver transection. These include radiofrequency devices, Harmonic Scalpel, Ligasure and TissueLink dissecting sealer. Whether these new instruments, used alone or in combination with clamp crushing or ultrasonic dissection, improve the safety of liver transection has not been clearly demonstrated. The use of the vascular stapler for transection of major intrahepatic vascular trunks is also gaining popularity. These new instruments are particularly useful in liver transection during laparoscopic liver resection. Adjunctive measures such as intermittent Pringle maneuver and low central venous pressure anesthesia are also useful measures to reduce the risk of hemorrhage. This article reviews the safety and efficacy of different techniques of liver transection, with particular attention to evidence from randomized controlled trials available in the literature.

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10. **Article:** Resection of colorectal liver metastases; is a resection margin of 3 mm enough? : a multicenter analysis of the GAST Study Group.; *World J Surg*. 2008 Sep;32(9):2047-56.

Authors: Konopke R, Kersting S, Makowiec F, Gassmann P, Kuhlisch E, Senninger N, Hopt U, Saeger HD.

Summary: A safety margin of > or =10 mm is generally accepted in surgery for colorectal metastases. It is reasonable that modern methods of liver parenchyma dissection may allow for a reduction in this distance. A total of 333 patients were included in a multicenter trial after resection of colorectal liver metastases. Dissection of the liver had been performed with a CUSA, UltraCision, or water-jet dissector. The size of the resection margin was correlated with recurrence risk and survival. The median hepatic recurrence-free survival reached 35 months for all patients; median recurrence-free survival was 24 months and overall survival was 41 months. Univariate analysis of different groups denoting the extent of resection margin (> or =10 mm, 6-9 mm, 3-5 mm, 1-2 mm, 0 mm (R1)) indicated that a margin of 1-2 mm leads to a significantly reduced median hepatic recurrence-free survival of 20 months (p = 0.004) and recurrence-free survival of 19 months (p = 0.011). Patients with R1 resection had the worst prognosis. Overall survival was not influenced by the size of the resection margin. Surgical margins were significantly reduced in simultaneous resections of four or more liver metastases and in cases in which metastatic infiltration of central liver segments was present. At multivariate analysis, resection margins of 1-2 mm and 0 mm were independent predictors of hepatic recurrence and overall recurrence. The indication for resection of metastases can be safely extended to cases in which tumors sit closer than 1 cm to nonresectable structures.

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11. **Article:** Influence of hepatic resection margin on recurrence and survival in intrahepatic cholangiocarcinoma.; *Ann Surg Oncol.* 2008 Oct;15(10):2787-94.

Authors: Tamandl D, Herberger B, Gruenberger B, Puhalla H, Klinger M, Gruenberger T.

Summary: Intrahepatic cholangiocarcinoma (ICC) is a rare disease in the Western world, hence little is known about its optimal surgical management. This study analyzed whether hepatic resection margin is a prognostic factor for local or distant recurrence and survival in patients resected with curative intent. Seventy-four patients underwent potentially curative surgery for ICC at the authors' institution from 1994 to 2007. Demographic, and tumor- and surgery-related details including hepatic resection margin were recorded, patients were followed up for recurrence and survival. All patients were resected using modern dissection devices (CUSA or Waterjet). Fifty-nine patients (80%) underwent R0 resection, 15 (20%) had a resection margin greater than 10 mm (wide margin, WM) and 38 (51%) between 1 and 10 mm (close margin, CM). In 14 patients (19%), hepatic resection margin was involved on histological examination; perioperative mortalities were excluded from analysis (n = 7). Forty-seven patients developed recurrence (WM, CM, and R1): hepatic recurrence was observed in 40%, 58%, and 50% of patients; extrahepatic spread occurred in 27, 16, and 14%; and 33, 26, and 36% had no recurrence of disease so far (P = 0.755). There was no difference between groups regarding local versus disseminated hepatic recurrence. Median recurrence free survival was 11.4 months (WM), 9.8 months (CM), and 9.9 months (R1), respectively (P = 0.880). Median overall survival was 27.2 months (WM), 29.7 months (CM), and not reached in the R1 group, (P = 0.350). In conclusion, hepatic resection margin seems to play a minor role in the prognosis of ICC as long as complete tumor clearance can be achieved with a modern liver dissection technique.

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12. **Article:** Techniques for liver parenchymal transection in liver resection.; *Cochrane Database Syst Rev.* 2009 Jan 21;(1):CD006880.
Authors: Gurusamy KS, Pamecha V, Sharma D, Davidson BR.
Summary: Blood loss during elective liver resection is one of the main factors affecting the surgical outcome. Different parenchymal transection techniques have been suggested to decrease blood loss. This study assessed the benefits and risks of the different techniques of parenchymal transection during liver resections. The authors searched the Cochrane Hepato-Biliary Group Controlled Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library, MEDLINE, EMBASE, and Science Citation Index Expanded (March 2008). They considered for inclusion all randomized clinical trials comparing different methods of parenchymal dissection irrespective of the method of vascular occlusion or any other measures used for lowering blood loss. Two authors identified the trials and extracted the data on the population characteristics, bias risk, mortality, morbidity, blood loss, transection speed, and hospital stay independently of each other. They calculated the odds ratio (OR), mean difference (MD), or standardized mean difference (SMD) with 95% confidence intervals

based on intention-to-treat analysis' or 'available case analysis' using RevMan 5. The authors included seven trials randomizing 556 patients. The comparisons include CUSA (cavitron ultrasound surgical aspirator) versus clamp-crush (two trials); radiofrequency dissecting sealer (RFDS) versus clamp-crush (two trials); sharp dissection versus clamp-crush technique (one trial); and hydrojet versus CUSA (one trial). One trial compared CUSA, RFDS, hydrojet, and clamp-crush technique. The infective complications and transection blood loss were greater in the RFDS than clamp-crush. There was no difference in the blood transfusion requirements, intensive therapy unit (ITU) stay, or hospital stay in this comparison. There was no significant differences in the mortality, morbidity, markers of liver parenchymal injury or liver dysfunction, ITU, or hospital stay in the other comparisons. The blood transfusion requirements were lower in the clamp-crush technique than CUSA and hydrojet. There was no difference in the transfusion requirements of clamp-crush technique and sharp dissection. Clamp-crush technique is quicker than CUSA, hydrojet, and RFDS. The transection speed of sharp dissection and clamp-crush technique was not compared. There was no clinically or statistically significant difference in the operating time between sharp dissection and clamp-crush techniques. Clamp-crush technique is two to six times cheaper than the other methods depending upon the number of surgeries performed each year. Clamp-crush technique is advocated as the method of choice in liver parenchymal transection because it avoids special equipment, whereas the newer methods do not seem to offer any benefit in decreasing the morbidity or transfusion requirement.

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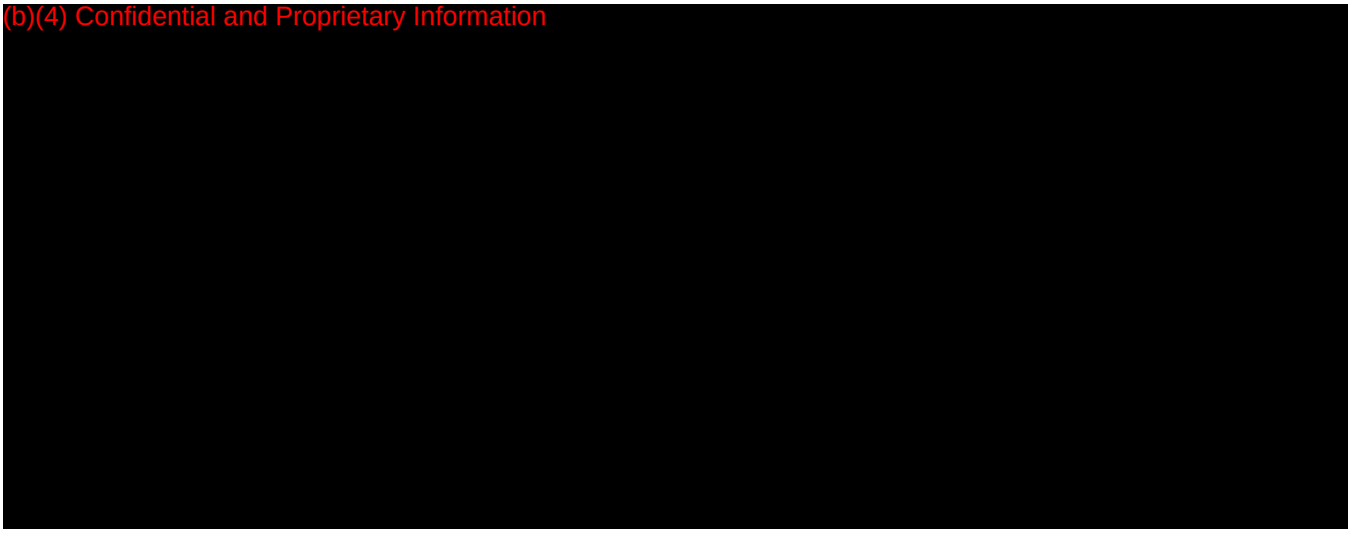

13. **Article:** Randomized clinical trial of efficacy and costs of three dissection devices in liver resection.; *BR J Surg.* 2009 Jun;96(6):593-601.

Authors: Richter S, Kollmar O, Schuld J, Moussavian MR, Igna D, Schilling MK; Chirurgische Arbeitsgemeinschaft OP-Technik und OP-Strukturen (CAOP) of the Deutsche Gesellschaft für Allgemein- und Viszeralchirurgie.

Summary: In recent decades a variety of instruments for liver dissection has become available. This randomized controlled trial analyzed the efficacy and costs of three different liver dissection devices. Ninety-six patients without cirrhosis undergoing liver resection were randomized to either ultrasonic dissection, waterjet dissection or dissecting sealer (32 in each group). Patients were unaware of the device used. The

primary endpoint was dissection speed. Secondary endpoints were intraoperative blood loss, morbidity and mortality, and costs of dissection devices, staplers and haemostatic agents. Dissection was slower with the dissecting sealer (P = 0.004 versus waterjet dissector). The difference was more pronounced for extended resections (mean(s.e.m.) 1.62(0.36) cm(2)/min versus 3.42(0.53) and 3.63(0.51) cm(2)/min for ultrasonic and water dissectors respectively; P = 0.037). Costs were significantly higher for the dissecting sealer when atypical or segmental resections were performed. Four patients died after extended resections; postoperative complications did not differ between groups. The dissecting sealer is slower than the ultrasonic dissector or water dissector. The three devices are equally safe in terms of blood loss, transfusions and postoperative complications. Ultrasonic and water dissectors might be more favorable economically than the dissecting sealer.

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14. **Article:** Feasibility of liver resection without the use of the routine Pringle manoeuver: an analysis of 248 consecutive cases.; *HPB (Oxford).* 2009 Jun;11(4):332-8.

Authors: Lee KF, Wong J, Ng W, Cheung YS, Lai P.

Summary: New instruments and techniques for hepatectomy have been shown to reduce blood loss during liver resection. The present study aims to evaluate the feasibility and result of our techniques of liver resection without routine inflow occlusion (the Pringle manoeuver). The cavitron ultrasonic surgical aspirator (CUSA) and saline-linked radio-frequency dissecting sealer (TissueLink) were used together for open hepatectomy, whereas a bipolar vessel sealing device (Ligasure) and TissueLink were used for laparoscopic hepatectomy. Between June 2003 and May 2007, 248 consecutive cases of liver resection were carried out using the above techniques without the routine Pringle manoeuver. The operative and clinical outcome data were prospectively collected and analyzed. During the study period, a total of 220 cases of open hepatectomy and 28 cases of laparoscopic hepatectomy were performed. The Pringle manoeuver was eventually applied in six patients (2.4%): two for portal vein tumour thrombus extraction and four as a result of heavy bleeding. Median blood loss was 300 ml (20-2700 ml) and the blood transfusion rate was 7.7%. In most of the cases, the liver function tests showed improvement on post-operative day 1 or 2, and the median post-operative hospital stay was 7 days. There were two post-operative deaths (0.8%). Complications occurred in 63 patients (25.4%) and most complications were minor.

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15. **Article:** Techniques for liver parenchymal transection: a meta-analysis of randomized controlled trials.; *HPB (Oxford).* 2009 Jun;11(4):275-81.
Authors: Pamecha V, Gurusamy KS, Sharma D, Davidson BR.
Summary: Different techniques of liver parenchymal transection have been described, including the finger fracture, sharp dissection, clamp-crush methods and, more recently, the Cavitron ultrasonic surgical aspirator (CUSA), the hydrojet and the radiofrequency dissection sealer (RFDS). This review assesses the benefits and risks associated with the various techniques. Randomized clinical trials were identified from the Cochrane Library Trials Register, MEDLINE, EMBASE, Science Citation Index Expanded and reference lists. Odds ratio (ORs), mean difference (MDs) and standardized mean differences (SMDs) were calculated with 95% confidence intervals based on intention-to-treat analysis or available-case analysis. The authors identified seven trials including a total of 556 patients. Blood transfusion requirements were lower with the clamp-crush technique than with the CUSA or hydrojet. The clamp-crush technique was quicker than the CUSA, hydrojet or RFDS. Infective complications and transection blood loss were greater with the RFDS than with the clamp-crush method. There was no significant difference between techniques in mortality, morbidity, liver dysfunction or intensive therapy unit and hospital stay. The clamp-crush technique is more rapid and is associated with lower rates of blood loss and otherwise similar outcomes when compared with other methods of parenchymal transection. It represents the reference standard against which new methods may be compared.

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16. **Article:** Fusion technique for liver transection with Kelly clysis and harmonic technology.; *World J Surg*. 2010 Jan;34(1):101-5.
Authors: Jagannath P, Chhabra DG, Sutariya KR, Shah RC.
Summary: Various devices are available for liver transection and comparative data on transection techniques are limited by the diversity of operative procedures. Clamp crushing (Kelly-clysis) with a Cavitron ultrasonic surgical aspirator (CUSA-Integra Radionics) is widely used for splitting the liver parenchyma. Hemostasis is achieved by bipolar coagulation, ligatures, or hemoclips. We introduce a fusion technique (Focus-clysis) for liver transection using a combination of Kelly-clysis and harmonic technology. A fusion technique (FT) was performed using FOCUS, a Kelly clamp like instrument attached to a Harmonic generator. Hepatic resections (nine major, nine minor) were performed with the fusion technique in 18 non-cirrhotic patients. Variables evaluated were blood loss, transection time, biliary leak, postoperative liver function, morbidity, and cost-effectiveness. The results were compared with 18 hepatic resections (nine major, nine minor) that were performed with our earlier technique, i.e., CUSA with bipolar

cautery, ligatures, and hemoclips. The mean blood loss was 416 ml in the FT group, compared to 833 ml in the CUSA group. Two patients in the FT group needed blood transfusion in the first 48 h, whereas eight patients in the CUSA group had transfusions. No major postoperative liver dysfunction was noted with the new technique, and postoperative morbidity was lower in the FT group. Liver transection with the fusion technique was faster.

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17. **Article:** Two-surgeon technique of parenchymal transection contributes to reduced transfusion rate in patients undergoing major hepatectomy: analysis of 1,557 consecutive liver resections.; *Surgery.* 2010 Jan;147(1):40-8.

Authors: Palavecino M, Kishi Y, Chun YS, Brown DL, Gottumukkala VN, Lichtiger B, Curley SA, Abdalla EK, Vauthey JN.

Summary: Blood transfusions are an independent risk factor for adverse outcomes after hepatectomy. In-hospital transfusions are still reported in one third of patients in major series. Data on factors affecting blood transfusions in large series of liver resection are limited. The aim of this study was to evaluate factors predictive of blood transfusion in hepatectomies performed at a tertiary referral center. Records of 1,477 patients who underwent 1,557 liver resections between 1998 and 2007 were reviewed. Multivariate analysis of risk factors for red cell transfusion was performed. Median intra-operative blood loss was 250 cc, and 30-day peri-operative red cell transfusion rate was 27%. On multivariate analysis, factors that significantly predicted increased red cell transfusion rates were female sex, pre-operative hematocrit<30%, platelet count<100,000/mm3, simultaneous resection of other organs, major hepatic resection, use of the Pringle maneuver, and tumors>10 cm. Parenchymal transection technique was an independent risk factor for perioperative red cell transfusion; the usage of the 2-surgeon technique (combined saline-linked cautery and ultrasonic dissection) was associated with a lower transfusion rate than other techniques, including ultrasonic dissection alone, finger fracture, and stapling (P<.001). Although most factors that affect the red cell transfusion rate for liver resection are patient- or tumor-related, the parenchymal transection technique is under the surgeon's control. The decrease in transfusion rate associated with the use of the 2-surgeon technique emphasizes the important role of the hepatobiliary surgeon in determining outcomes after liver resection.

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18. **Article:** Multiple cerebral infarction and paradoxical air embolism during hepatectomy using the Cavitron Ultrasonic Surgical Aspirator -A case report-.; *Korean J. Anesthesiol.* 2010 Dec;59 Suppl:S13306.

Authors: Lee JH, Kwon TD, Kim HJ, Kang B, Koo BN.

Summary: A venous air embolism and paradoxical air embolism (PAE) are serious complications in patients undergoing a hepatectomy. We report a case of PAE and cerebral infarctions in a patient undergoing a hepatic resection using a Cavitron Ultrasonic Surgical Aspirator (CUSA®). A 65-year-old woman underwent a left lobe hepatectomy. During the middle phase of the liver resection with CUSA®, there was a sudden decrease in arterial blood pressure, end-tidal carbon dioxide and SpO(2). With resuscitation, intraoperative ultrasonography revealed massive air emboli in both her left and right heart, which lasted for 40 min. The hepatectomy was completed after the disappearance of the air emboli from her heart. After surgery, her mental status was stuporous. The brain CT and MRI revealed multiple acute cerebral infarctions. Finally, she died from septic shock. This case highlights the need for anesthetists and surgeons to be aware of the potential for CUSA®-related massive PAE.

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19. **Article:** Hepatic veins as a site of clot formation following liver resection.; *World J Gastroenterol.* 2011 Jan 21;17(3):403-6.

Authors: Buc E, Dokmak S, Zappa M, Denninger MH, Valla DC, Belghiti J, Farges O.

Summary: Pulmonary embolism occurs more frequently after hepatectomy than previously thought but is infrequently associated with peripheral deep vein thrombosis. In this paper, the authors report 2 cases of postoperative hepatic vein thrombosis after liver resection. Both patients had undergone major hepatectomy of a non-cirrhotic liver largely exposing the middle hepatic vein. Clots were incidentally found in the middle hepatic vein 4 and 17 d after surgery despite routine systemic thrombo-prophylaxis with low molecular weight heparin. Coagulation of the transition plan in a context of mutation of the prothrombin gene and inflammation induced biloma were the likely predisposing conditions. Clots disappeared following curative anticoagulation. It is concluded that thrombosis of hepatic veins may occur after liver resection and is a potential source of pulmonary embolism.

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20. **Article:** Hemi-hepatectomy in pediatric patients using two-surgeon technique and a liver hanging maneuver.; *World J Gastroenterol.* 2011 Mar;17(10)1354-7.

Authors: Mochizuki K, Eguchi S, Hirose R, Kosaka T, Takatsuki M, Kanematsu T.

Summary: This study aimed to evaluate the efficacy of the two-surgeon technique with the liver hanging maneuver (LHM) for hepatectomies in pediatric patients with hepatoblastoma. Three pediatric patients with hepatoblastoma were enrolled in this study. Two underwent right hemi-hepatectomies and one underwent a left hemi-hepatectomy using the two-surgeon technique by means of saline-linked electric cautery (SLC) and the Cavitron Ultrasonic Surgical Aspirator (CUSA; Valleylab, Boulder, CO) and the LHM. The mean operative time during the parenchymal transections was 50 min and the mean blood loss was 235 g. There was no bile leakage from the cut surface after surgery. There were no intraoperative or postoperative complications and no macroscopic or

microscopic-positive margins were observed in the hepatic transections. All 3 patients could restart projected postoperative chemotherapy treatments from postoperative day 7, and all had complete remissions and no recurrences during the writing of this manuscript. In conclusion, the two-surgeon technique using SLC and CUSA with the LHM is applicable to even pediatric patients with hepatoblastoma.

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21. **Article:** How to Transect the Liver? A History Lasting More than a Century; *Digestive Surgery*. 2012 Mar;29(1):30-4.
Authors: Scalzone R, Lopez-Ben S, Figueras J.
Summary: There is a close relationship between blood loss during transection and unfavorable outcome. Many different methods have been used in order to cut the parenchyma, while leaving vital structures intact, coagulate small vessels and seal small biliary ducts. The first method described was the finger-fracture technique and, alternatively, the clamp-crushing method using a small forceps. With this technique, the liver is crushed between the 'jaws', and the vessels and bile ducts are successively ligated and divided. Technological research using different sources of energy developed the water jet dissectors and the ultrasonic dissectors. The CUSA® has been widely adopted for the fascinating way it could selectively destroy and aspirate parenchyma leaving vascular structures almost intact. Several studies have been addressed to clarify these critical points. However, in the majority of cases they are underpowered to demonstrate clear advantages of one method over the others. In conclusion, the evidence suggested no superiority of other techniques over clamp-crushing. But it must be taken into account that it requires strictly hepatic pedicle clamping. The devices available should be used within the limits of each instrument, as well as the surgical skills of the surgeon. Probably the best option should be a combined approach.

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22. **Article:** The efficacy of three transection techniques of the liver resection: a randomized clinical trial.; *Hepatogastroenterology.* 2012 Jul-Aug;59(117):1501-6.
Authors: Doklestic K, Karamarkovic A, Stefanovic B, Stefanovic B, Milic N, Gregoric P, Djukic V, Bajec D.
Summary: Liver resection is a demanding procedure due to the risk of massive blood loss. Different instruments for liver transection are available today. The aim of this randomized clinical trial was to analyze the efficacy of three different parenchyma transection techniques of liver resection. A total of 60 non-cirrhotic patients undergoing

hepatectomy were randomly selected for clamp crushing technique (CRUSH), ultrasonic dissection (CUSA) or bipolar device (LigaSure), n=20 in each group. All patients had liver resection under low central venous pressure anaesthesia (CVP), with ischemic preconditioning and intermittent inflow occlusion. Primary endpoints were surgery duration, transection duration, cumulative pedicle clamping time, intraoperative blood loss and blood transfusion. Secondary endpoints included the postoperative liver injury, postoperative morbidity and mortality. Overall surgery duration was 295 vs. 270 vs. 240min for LigaSure, CUSA and Clamp Crushing Technique, respectively. The transection duration was 85 vs. 52.5 vs. 40 minutes, respectively. These three different resection techniques of non-cirrhotic liver produced similar outcome in terms of intraoperative blood loss, blood transfusion, postoperative complications and mortality. The Clump Crushing Technique, CUSA and Liga Sure are equally safe for resection of non-cirrhotic liver. Liver resections can be performed safely if the entire concept is well designed and the choice of dissection device does not affect the outcome of hepatectomy.

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23. **Article:** A review of paediatric liver resections in Johannesburg: experiences and preferred technique.; *S Afr Med J.* 2012 Sep 10;102(11 Pt 2):881-3.

Authors: Loveland JA, Krog F, Beale P.

Summary: Liver resections are widely performed in paediatric surgery. Many techniques exist to achieve vascular control, minimise bleeding and complete the parenchymal division. The authors retrospectively reviewed all liver resections performed in the Department of Paediatric Surgery at the University of Witwatersrand between January 2005 and June 2012. Data pertaining to basic demographics, indications for surgery, parenchymal transection techniques, morbidity, mortality and histology were collated. Twenty-one resections were performed in children aged 6 weeks - 11 years; 18 for malignant liver disease (including 9 hepatoblastomas), and 3 for benign disease. The authors describe 1 peri-operative mortality secondary to torsion of the liver remnant, and no surgical morbidity. Three cases underwent total hepatic vascular exclusion with sharp parenchymal transection. The remaining patients underwent selective vascular inflow and outflow control using the Cavitron Ultra Sonic Aspirator and Harmonic Scalpel to divide the parenchyma. Care for these patients should be multidisciplinary. High-volume units and access to liver transplantation offer optimal results. No technique is proven superior to the 'clamp crush' technique of parenchymal transection. Knowledge of hepatic anatomy is key to minimizing morbidity, and surgeons should be familiar with and have the flexibility to use all techniques of vascular control.

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24. **Article:** Transection of the liver parenchyma with an ultrasound dissector or a stapler device: results of a randomized clinical study.; *World J Surg.* 2013 Apr;37(4): 799-805.
Authors: Savlid M, Strand AH, Jansson A, Agustsson T, Söderdahl G, Lundell L, Isaksson B.
Summary: Perioperative hemorrhage and postoperative bile leakage are severe complications of liver surgery. They may be related to the techniques used to divide the tissue. The authors designed a randomized clinical trial to compare the cavitron ultrasonic surgical aspirator (CUSA) and an endoscopic stapler device applied in routine clinical hepatic surgical practice. All consecutive patients admitted for elective hepatic resective surgery--at least bisegmentectomy of the liver--were assessed for enrollment in the study. A total of 100 patients were subsequently randomized. There was a good balance between the study groups concerning issues that may be of relevance for the perioperative and postoperative courses. The primary objective of the study was to achieve an approximately 25 % reduction in perioperative blood loss and postoperative bile leakage. Secondary outcome variables were operating time, general postoperative morbidity, length of hospital stay, and direct medical costs. The amount of perioperative or postoperative blood loss did not differ significantly between the two groups. We observed a trend toward shorter transection and operating time for patients in whom staplers were used, but the difference did not reach statistical significance. The postoperative courses were close to identical in the respective study arms with no difference in bile leakage rates or in the total morbidity profiles. The direct medical costs were nonsignificantly lower in the group where staplers were used for liver transection. The results show that the use of endoscopic vascular staplers in liver surgery is feasible and safe. It offers an attractive alternative for division of the liver parenchyma during routine hepatic surgery, being comparable to the use of CUSA without adding extra costs.

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25. **Article:** Technology-assisted versus clamp-crush liver resection: a systematic review and meta-analysis.; *Surg Innov.* 2013 Aug;20(4):414-28.
Authors: Alexiou VG, Tsitsias T, Mavros MN, Robertson GS, Pawlik TM.
Summary: The objective of this work was to review the published evidence on technology-assisted liver resection regarding operative time, intraoperative bleeding, mortality, hospital stay, postoperative bile leak, and other outcomes. A systematic review of clinical studies comparing liver resection using vessel sealing systems (VSSs LigaSure), Cavitron Ultrasonic Surgical Aspirator (CUSA), or radiofrequency dissecting sealer (RFDS) with the conventional clamp-crushing technique (CC) was performed. Data for each modality were synthesized and individually compared with CC with the methodology of meta-analysis. In all, 8 randomized controlled trials (RCTs) and 7

nonrandomized studies evaluating 1539 patients were included. Compared with CC, the VSS group (3 RCTs and 3 nonrandomized studies) had significantly lower blood loss by a mean of 109 mL (weighted mean difference [WMD] = -109; 95% confidence interval [CI] = -192, -26; data on 494 patients), lower risk for postoperative bile leak by 63% (odds ratio [OR] = 0.37; CI = 0.17, 0.78; 559 patients), and shorter total hospital stay by 2 days (WMD = -2.04; CI = -3.08, -1; 340 patients); no difference was noted for liver parenchyma transection time and mortality. No difference was noted between CUSA (4 RCTs and 1 nonrandomized study) or RFDS (3 RCTs and 3 nonrandomized studies) versus CC for any of the studied outcomes. Of the 3 modalities used in liver resection (VSS, CUSA, and RFDS), only VSS appeared to offer significant benefit over standard CC. However, the generalization of the findings is limited by the scarcity and clinical heterogeneity of the published studies. Large, well-designed and implemented RCTs are warranted to further investigate the usefulness of novel modalities used in liver resection.

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26. **Article:** A multicentre controlled study of the InLine radiofrequency ablation device for liver transection.; *HPB (Oxford).* 2007;9(4):267-71.

Authors: Yao P, Chu F, Daniel S, Gunasegaram A, Yan T, Lindemann W, Pistorius G, Schilling M, Machi J, Zuckerman R, Morris DL.

Summary: Surgical resection is the most effective therapy for liver cancer. Intraoperative blood loss during liver resection remains a major concern due to association with higher postoperative complications. The InLine radiofrequency ablation device (ILRFA) has achieved promising results in liver surgery with minimal blood loss and no increase of postoperative complications. In this multicentre controlled study, 108 patients undergoing liver resection were investigated. A total of 108 patients underwent liver resections in 4 medical centres; the prospective sequential cohort study consisted of 54 ILRFA and 54 ultrasonic surgical aspirator transections as the control group. The type of liver resection performed was very similar in both groups. The median number of RFA deployments was 3 (range 1-12) with a median coagulation time of 9 (range 3-36) min. Median blood loss was 165+/-20 ml (range 5-675) in the ILRFA and 654+/-83 ml (range 80-3600) in the control group ($p<0.001$). The median transection time was 27 (2-219) min in the ILRFA group and 35 (5-62) min in controls. This study indicates that ILRFA device for liver transection is effective in reducing blood loss and is safe. Precoagulation before parenchymal transection appears to be a valid concept in liver surgery. The avoidance of vascular inflow occlusion during parenchymal transection could also be of value.

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27. **Article:** Suprahilar vascular control and stapling device transsection of Glissonean Pedicle in Major and Minor hepatectomies.; *Hepatogastroenterology.* 2013 Oct 2;60(128).
Authors: Karamarkovic A, Natasa KD.
Summary: This study analyzed the authors' experience of Suprahilar - posterior intrahepatic Glissonean Pedicle approach using a endo-GIA Vascular Staplling device for the pedicle and hepatic vein division. 68 major and 102 minor liver resections were performed. The hilar extrahepatic structures remained intact, and during parenchyma dissection by CUSA, the whole right or left or the appropriate segmental pedicle was isolated intrahepatically and then transected using a Stapler device. The minor liver resections were associated with significantly shorter surgery duration (95.1+31.1 vs. 186.6± 56.5) and transection time (35.9±14.5 vs. 65.3±17.2) than major hepatectomies ($p<0.001$ for all). The mean blood loss was 255.6+129.9mL in minor resection and 385.7+200.1mL in major resection (p=0,003). The mean blood transfusion requirement was 300.8+99.5 ml for the patients with minor hepatectomy and 450.9+89.6 ml for those with major liver resection (p=0,067). There was no significant difference in morbidity and mortality between the groups (p=0,989; p=0,920). Major as well as minor liver resection were a superior oncologic operation with no significant difference in the 3-year overall survival rates. Therefore, liver transection using CUSA with suprahilar endo-GIA stapling of Glisson's pedicle, as well as major hepatic veins represents an effective and safe surgical procedure.

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28. **Article:** Liver resection using cavitron ultrasonic surgical aspirator (CUSA) versus harmonic scalpel: A retrospective cohort study.; *Int J Surg.* 2014 Feb 18. pii: S1743-9191(14)00044-2.
Authors: Bodzin AS, Leiby BE, Ramirez CG, Frank AM, Doria C.
Summary: The aim of this study was to evaluate the safety and efficacy of two device combinations used in parenchymal division during hepatic resections in non-cirrhotic patients and without inflow vascular occlusion. The authors retrospectively analyzed 47 patients who underwent liver resection at our Institution from 2004 to 2010 using the TissueLink with either the Cavitron Ultrasonic Surgical Aspirator (CUSA) or the Harmonic Scalpel. The TissueLink was used with the CUSA in 27 patients and with the Harmonic Scalpel in 20 patients. Median estimated blood loss (EBL) in the Harmonic Scalpel and CUSA groups was 250 and 1035 mL respectively ($p < 0.05$). Three patients were transfused banked blood perioperatively in the Harmonic Scalpel group and 11 in the CUSA group ($p < 0.05$). Median operative time in the Harmonic Scalpel and CUSA groups was 185 and 290 min respectively. Length of stay (LOS) was shorter in the Harmonic Scalpel group at 6 days compared to 7 days in the CUSA group ($p < 0.05$). Perioperative complications were documented in 20% and 26% in the Harmonic Scalpel and CUSA groups, respectively. Results show the Harmonic Scalpel with TissueLink to be a safe, effective method of parenchymal division with significantly less EBL and LOS when compared to CUSA with TissueLink.

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2.2 Abstracts Reviewed

1. **Article:** Hepatic resection through an anterior approach employing a modified liver hanging maneuver in patients with a massive liver tumor severely oppressing the inferior vena cava.; *Hepatogastroenterology.* 2004 Sep-Oct;51(59):1459-63.

Authors: Suzuki M, Unno M, Katayose Y, Takeuchi H, Rikiyama T, Onogawa T, Sato T, Mizuma M, Ohtuka H, Mastuno S.

Summary: For a large hepatic neoplasm existing in the right hepatic lobe, hepatic resection using an anterior approach is required. The authors have reported an operative procedure for hepatic transection using absorbable polyglycolic acid tape. In patients with suspected tumor invasion of the inferior vena cava, on the other hand, considering the range of the residual tumor while sparing the inferior vena cava as much as possible, combined resection and reconstruction of the inferior vena cava is conducted only if operative curativity is expected. A hepatic transection was conducted while maintaining the blood flow of the residual liver by applying the liver hanging maneuver method of Belghiti et al. and polyglycolic acid tape in patients with giant liver tumors of the right hepatic lobe compressing the hepatic inferior vena cava. Strong angled dissecting forceps were inserted into the ventral side of the inferior vena cava from the caudal side, and the tip was induced between hepatic veins. Two strips of polyglycolic acid tape were pinched with forceps and strongly ligated on the right and left sides of the cutoff line. Subsequently, hepatic transection was conducted using electrocautery spray coagulation and CUSA without blocking the inflow blood of the residual liver, and the right hepatic lobe was extirpated. This procedure has already been performed in 5 patients suspected of inferior vena cava invasion, and the inferior vena cava was able to be preserved in all the patients.

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2.3 Laparoscopic Procedures

1. **Article:** Laparoscopic liver resection for peripheral hepatocellular carcinoma in patients with chronic liver disease: midterm results and perspectives.; *Ann Surg.* 2006 Apr;243(4):499-506.

Authors: Cherqui D, Laurent A, Tayar C, Chang S, Van Nhieu JT, Loriau J, Karoui M, Duvoux C, Dhumeaux D, Fagniez PL.

Summary: The objective of this article was to report the midterm results of laparoscopic resection for hepatocellular in chronic liver disease (CLD). Surgical resection for hepatocellular carcinoma (HCC) in chronic liver disease (CLD) remains controversial because of high morbidity and recurrence rates. Laparoscopic resection of liver tumors has recently been developed and could reduce morbidity. From 1998 to 2003, patients with HCC and CLD were considered for laparoscopic liver resection. Inclusion criteria were chronic hepatitis or Child's A cirrhosis, solitary tumor < or =5 cm in size, and location in peripheral segments of the liver. Mortality, morbidity, recurrence rates, and survival were analyzed. A total of 27 patients were included. Liver resections included anatomic resection in 17 cases and non anatomic resection in 10. Seven conversions to laparotomy (26%) occurred for moderate hemorrhage in 5 cases and technical difficulties in 2 cases. Mortality and morbidity rates were 0% and 33%, respectively. Postoperative ascites and encephalopathy occurred in 2 patients (7%) who both had undergone conversion to laparotomy. Mean surgical margin was 11 mm (range, 1-47 mm). After a mean follow-up of 2 years (range, 1.1-4.7), 8 patients (30%) developed intrahepatic tumor recurrence of which one died. Treatment of recurrence was possible in 4 patients (50%), including orthotopic liver transplantation, right hepatectomy, radiofrequency ablation, and chemoembolization in 1 case each. There were no adhesions in the 2 reoperated patients. Overall and disease-free 3-year survival rates were 93% and 64%, respectively. Our study shows that laparoscopic liver resection for HCC in selected patients is a safe procedure with very good midterm results. This approach could have an impact on the therapeutic strategy of HCC complicating CLD as a treatment with curative intent or as a bridge to liver transplantation.

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2. **Article:** Laparoscopy-assisted right hepatic lobectomy using a wall-lifting procedure.; *Surg Endosc.* 2006 Aug;20(8):1326-8.

Authors: Eguchi D, Nishizaki T, Ohta M, Ishizaki Y, Hanaki N, Okita K, Ohga T, Takahashi I, Ojima Y, Wada H, Tsutsui S.

Summary: This article describes a new technique for performing a laparoscopy-assisted right hepatic lobectomy using a hanger wall-lifting procedure. The patient is placed in the left semi-lateral position. A cholecystectomy and hemi-hepatic vascular inflow control are then performed through a midline incision, through which the resected liver can be removed. Next, the right lower chest and right upper abdominal wall are lifted by two wires vertical to the abdominal wall. Two ports, a 5-mm port in right lateral abdomen for forceps and a 12-mm port just right of the umbilicus for the laparoscope, are inserted. The obtained view of the operative field in the right upper abdominal cavity is thus excellent. The laparoscopy-assisted mobilization of the right hepatic lobe is done with the assistance of a hand inserted through the midline incision, including a dissection of the hepato-renal ligament, the right triangular ligament, and the right coronary ligament. A parenchymal dissection is then performed using the Cavitron Ultrasonic Surgical

Aspirator (CUSA) and the resected specimen is passed through the midline incision without any morcellation of the liver. This procedure can minimize the length of the wound, while avoiding the lethal complications associated with pneumoperitoneum.

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3. **Article:** The use of water-jet dissection in open and laparoscopic liver resection.; *HPB (Oxford).* 2008;10(4):275-80.

Authors: Rau HG, Duessel AP, Wurzbacher S.

Summary: The objective of this article was to review the authors' experiences with the implementation of a new dissection technique in open and laparoscopic surgery. Their database comprises a total of 950 patients who underwent liver resection. Three hundred and fifty of them were performed exceptionally with the water-jet dissector. Forty-one laparoscopic partial liver resections were accomplished. Using the water-jet dissection technique it was possible to reduce the blood loss, the Pringle- and resection time in comparison to CUSA and blunt dissection. In the last five years the authors could reduce the Pringle-rate from 48 to 6% and the last 110 liver resections were performed without any Pringle's manoeuvre. At the same time, the transfusion-rate decreased from 1.86 to 0.46 EC/patient. In oncological resections, the used dissection technique had no influence on long-time survival. The water-jet dissection technique is fast, feasible, oncologically safe and can be used in open and in laparoscopic liver surgery.

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4. **Article:** Application of devices for safe laparoscopic hepatectomy.; *HPB (Oxford).* 2008;10(4):219-24.

Authors: Kaneko H, Otsuka Y, Tsuchiya M, Tamura A, Katagiri T, Yamazaki K.

Summary: The continuing evolution of a variety of laparoscopic instrument and devices has been gradually applied to the laparoscopic hepatectomy in many countries. Recent experience has persuaded the authors that there are great potential benefits derived from laparoscopic hepatectomy and that much has been learned about patient selection, the grade of surgical difficulty with respect to tumor location, and the required instrumentation. Among these efforts, various ways of hepatic parenchymal transection with mechanical devices have been attempted in order to perform safe laparoscopic hepatectomy. Important technologic developments and improved endoscopic procedures are equipment modifications in the process of being established. For safe laparoscopic hepatectomy, it is important to have all necessary equipment. The intraoperative laparoscopic ultrasonography, microwave coagulators, ultrasonic dissection, argon beam

coagulators, laparoscopic coagulation shears, endolinear staplers and TissueLink monopolar sealer are essential. This procedure requires experienced endoscopic and liver surgeons to collaborate in laparoscopic hepatectomy and that the indications are strictly followed based upon the location and size of tumors. Finally, a critical determinant for success and safe laparoscopic hepatectomy is familiarity with the relevant laparoscopic instruments and equipment. Laparoscopic hepatectomy is expected to develop further in the future as new surgical instruments, equipment, and methods arise, which improves patients' quality of life.

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5. **Article:** Totally laparoscopic hepatectomy exposing the major vessels.; *J Hepatobiliary Pancreat Sci.* 2013 Apr;20(4):435-40.

Authors: Honda G, Kurata M, Okuda Y, Kobayashi S, Tadano S, Yamaguchi T, Matsumoto H, Nakano D, Takahashi K.

Summary: Even during laparoscopic hepatectomy, a technique is often required to expose the major vessels, for example, in anatomical hepatectomy. The authors have standardized and performed such laparoscopic hepatectomy as successfully as open hepatectomy. They divide the liver parenchyma without pre-coagulation, exposing the major vessels using CUSA. To control the bleeding, they keep the central venous pressure low and often perform Pringle's maneuver. Over 49 months, totally laparoscopic hepatectomies in 41 patients were performed with the technique of exposing the major vessels. These included major hepatectomy in 7, sectorectomy in 17, segmentectomy in 14, and others in 3. The median operative time was 361 (range 176-605) minutes, with median blood loss of 216 (range 0-1600) g. The conversion rate was 4.9 %. Postoperative morbidity rate was 9.8 % (prolonged ascites in 1, port site infection in 1, peroneal palsy in 2). Mortality was zero. The median length of hospital stay after surgery was 8 (range 5-28) days. No local recurrence was found at the time of writing. By using the standardized procedure exposing the major vessels, the authors could raise the quality of laparoscopic hepatectomy toward the level of open hepatectomy significantly.

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3 Conclusions

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Clinical Literature on the Cavitron Ultrasonic Surgical Aspirator (CUSA): Urologic and Renal Surgery

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1 Executive Summary – CUSA Use in Urologic and Renal Surgery

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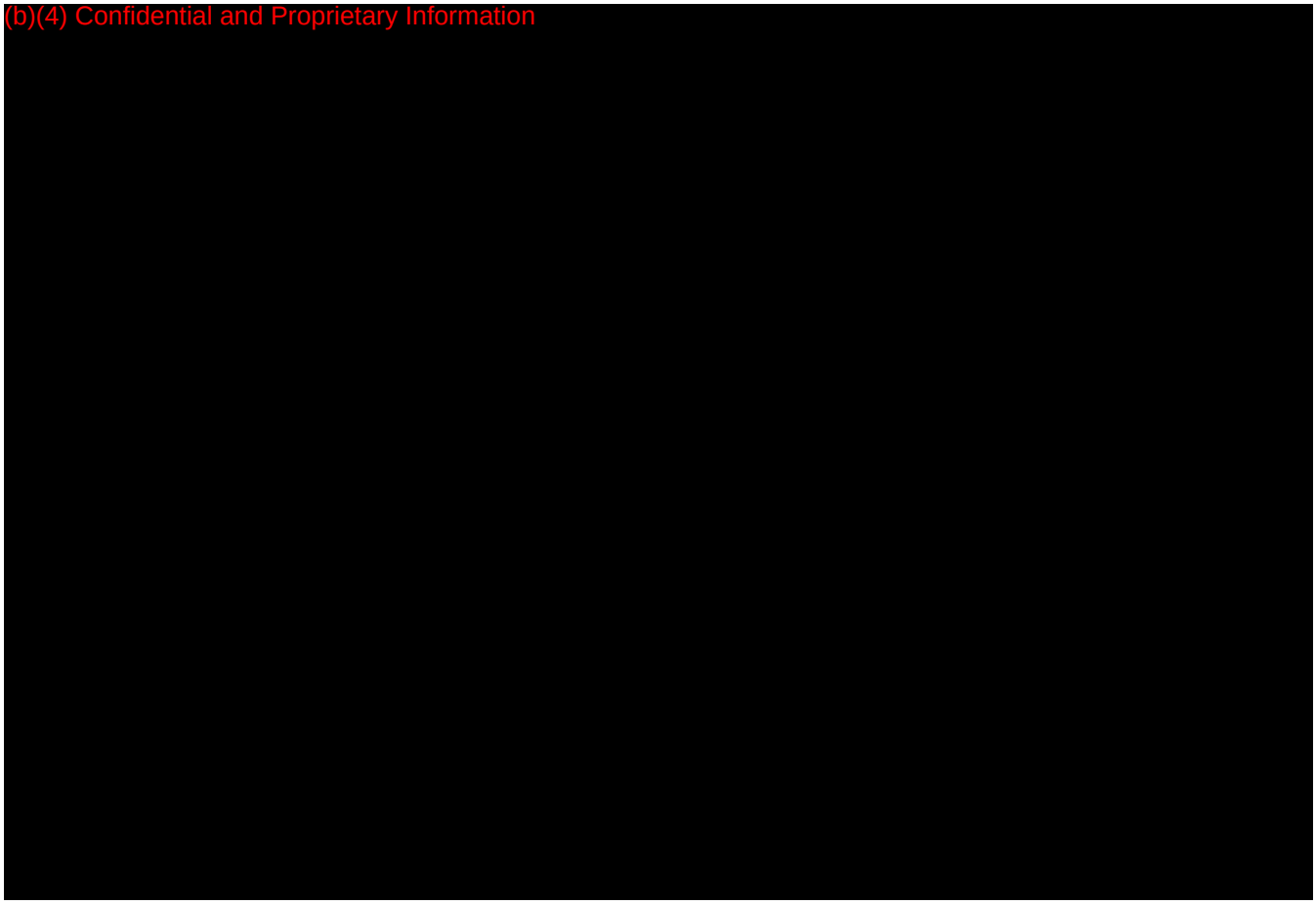

2 CUSA Use in Urologic Surgery Literature Review

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2.1 Articles Reviewed

Article: Use of Ultrasonic Surgical Aspirator in Renal Surgery. *Urology*. 1989 Aug;22(2):157-159. PubMed PMID: 6879888.
Authors: Chopp RT, Shah BB, Addonizio JC.
Summary: The Cavitron ultrasonic surgical aspirator (CUSA) was used to fragment and aspirate normal and pathologic renal tissue. The operative blood loss utilizing the CUSA was markedly reduced compared to electrocautery or the cold scalpel. This is due to the ability of the instrument selectively to fragment and aspirate tissue with high-water content, such as renal parenchyma, while sparing tissue with higher elastin and collagen content, such as collecting system or blood vessel. The surgeon can therefore skeletonize and secure the blood vessels before they are divided.

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Article: Giant renal angiomyolipoma with an uncommon growth pattern: a case report. Hinyokika Kiyo. 1990 Jul;36(7):837-40. PubMed PMID: 2239583.
Authors: Gohji K, Gotoh A, Kamidono S..
Summary: A case of a giant renal angiomyolipoma with uncommon growth pattern in a 66-year-old female is reported. The tumor originated from the upper pole of the left kidney and simultaneously grew posteriorly in a sheet-like fashion while a spheroid mass projected upwards. With magnetic resonance imaging (MRI), the relationship between the tumor and adjacent organs was clear. Tumorectomy employing cavitron ultrasonic surgical aspirator (CUSA) was performed, and proved to be a safe and simple procedure. There has been no recurrence of the growth 2 years post-operatively.

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2.2 Abstracts Reviewed

Article: Stable formation of the nipple valve in Kock pouch for diversion of the urinary tract. *Surg Gynecol Obstet*. 1989 Oct;169(4):315-8. Review. PubMed PMID: 2675358.
Authors: Okada Y, Arai Y, Oishi K, Takeuchi H, Yoshida O.
Summary: Construction of a continent ileal urinary reservoir is associated with a high incidence of late complications because of malfunction of the nipple valve. Three important modifications in the operative procedures for the construction of the nipple valve were developed with significant improvements in late complication rates and end results. First is the use of Dacron (polyester fiber) fabric as a collar instead of Marlex mesh (polypropylene), which frequently causes erosion. The second is treatment of the mesentery using a CUSA (Cavitron Ultrasonic Surgical Aspirator) (Cavitron Co. Ltd.) instead of making Deaver's windows, thus preserving the blood supply to the nipple valves. Third is anchoring of the nipple valves to the anterior wall of the reservoir, preventing prolapse, the most frequent malfunction of the nipple valve. The incidence of malfunction of the nipple valve and the end results of this innovative urinary diversion using an internal reservoir were analyzed in relation to these modifications of the operative technique among 71 patients. To date, with an established mode of operation, the success rate is more than 95 per cent.

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Article: Cavitrons in urologic surgery. *Urol Clin North Am*.1986 Aug;13(3):445-54. PubMed PMID: 3727199.
Authors: Addonizio JC, Choudhury MS.
Summary: The CUSA is a unique modality for precise removal of tissue. This ultrasonic scalpel represents a major technical advance in surgery by providing a small handpiece device that can selectively remove tissue in a controlled manner. The usefulness of this modality in removing parenchymal tissue while sparing vascular or ductal structures is outstanding. Laboratory and clinical experience have demonstrated that utilization of this scalpel, particularly in vascular organs and lesions, provides the surgeon with increased visibility, reduced bleeding, and shorter operating time. Our application of this instrument in the performance of renal surgery in dogs as well as in the clinical setting has been well documented. Its future application as a surgical tool in the armamentarium of the urologist is uncertain and awaits the outcome of future studies.

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Article: Cavitron ultrasonic surgical aspirator. Applications in urologic surgery. *Urology.* 1984 May;23(5):417-20. PubMed PMID: 6719660.
Authors: Addonizio JC, Choudhury MS, Sayegh N, Chopp RT.
Summary: The Cavitron Ultrasonic Surgical Aspirator is a unique modality for precise tissue removal which results in increased visibility, reduced bleeding, and shorter operating time when dealing with vascular lesions or organs. Herein, we present our experience in a dog laboratory as well as in a clinical setting with this new instrument. The mechanism of action, proper surgical technique required, and further application in urologic surgery are discussed.

(b)(4) Confidential and Proprietary Information

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3 Conclusions

(b)(4) Confidential and Proprietary Information

[redacted]

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4. Gohji K, Gotoh A, Kamidono S. Giant renal angiomyolipoma with an uncommon growth pattern: a case report. Hinyokika Kiyo. 1990 Jul;36(7):837-40.
5. Okada Y, Arai Y, Oishi K, Takeuchi H, Yoshida O. Stable formation of the nipple valve in Kock pouch for diversion of the urinary tract. *Surg Gynecol Obstet*. 1989 Oct;169(4):315-8. Review.

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Clinical Literature on the Cavitron Ultrasonic Surgical Aspirator (CUSA): Plastic Surgery

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1 Executive Summary – CUSA Use in Plastic and Reconstructive Surgery

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2 CUSA Use in Plastic and Reconstructive Surgery Literature Review

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2.1 Articles Reviewd

Article: Ultrasonic bone removal versus high-speed burring for lateral orbital decompression: comparison of surgical outcomes for the treatment of thyroid eye disease. Ophthal Plast Reconstr Surg. 2010 Mar-Apr;26(2):83-7. doi: 10.1097/IOP.0b013e3181b8e614. PubMed PMID: 20305505.
Authors: Cho RI, Choe CH, Elner VM.
Summary: The purpose of the study was to evaluate the efficacy of ultrasonic bone removal during lateral orbital decompression for thyroid eye disease. Retrospective, comparative, interventional case series of lateral orbital decompressions were performed by the senior author for thyroid eye disease between July 2005 and July 2008. Patients were excluded if they had other coexisting orbital conditions or concurrent decompression of other orbital walls. Primary outcome measures included visual acuity, proptosis, lagophthalmos, eyelid retraction, and exposure keratopathy. Thirty-six consecutive lateral orbital decompressions performed by the senior author were reviewed. The Sonopet Omni ultrasonic surgical aspirator was used to remove the lateral wall in 18 cases, and a high-speed drill with a cutting burr was used in the other 18 cases. There was no significant difference between the groups in postoperative visual acuity, proptosis reduction, lagophthalmos, eyelid retraction, exposure keratopathy, or surgical complications. The average reduction in proptosis was 3.9 mm (range, 1-6.5 mm) in the Sonopet group and 4.0 mm (range, 1-6 mm) in the drill group ($p = 0.86$). In our series, the average surgical case time was slightly shorter in the Sonopet group than in the drill group (104 vs. 118 minutes, $p = 0.032$). Ultrasonic bone removal is a safe and effective alternative to high-speed burring during lateral orbital decompression for thyroid eye disease.

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Article: Sonic rhinoplasty: histologic correlates and technical refinements using the ultrasonic bone aspirator..; *Arch Facial Plast Surg*. 2011 Sep-Oct;13(5):316-21.
Authors: Greywoode JD, Pribitkin EA.
Summary: This retrospective review of 103 consecutive patients undergoing cosmetic rhinoplasty at a tertiary care academic facial plastic surgery practice extends the applications for the ultrasonic bone aspirator to include reducing the nasal spine, glabellar deepening, sculpting of mobile bone fragments after osteotomy, smoothing of bony edges after medial osteotomy, and reducing the convexity of nasal bones. We performed histologic analysis of cartilage samples, and the patient and surgeon subjectively evaluated the aesthetic outcome of the procedure. All patients obtained satisfactory outcomes. Seven patients experienced minor complications. One patient had a visible dorsal irregularity, 2 had palpable but not visible dorsal irregularities, 2 had asymmetry of the dorsum, and 2 had underresection of the dorsum. No patients experienced skin or soft-tissue injury. The ultrasonic bone aspirator can be a useful adjunct for the cosmetic rhinoplasty surgeon. The ultrasonic bone aspirator permits precise, graded removal of bone without damage to surrounding soft tissue or mucosa. With multiple applications in nasal surgery, the ultrasonic bone aspirator permits refinement of subtle irregularities and asymmetry of the nasal bones. Complications associated with the device are rare.

(b)(4) Confidential and Proprietary Information

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Article: The ultrasonic bone aspirator in transnasal endoscopic dacryocystorhinostomy. Ophthal Plast Reconstr Surg. 2013 Jan-Feb;29(1):25-9. doi: 10.1097/IOP.0b013e318272d2d1. PubMed PMID: 23299805.
Authors: Murchison AP, Pribitkin EA, Rosen MR, Bilyk JR.
Summary: The purpose of this study was to evaluate the outcomes of endoscopic dacryocystorhinostomy (eDCR) with and without the use of ultrasonic bone aspirator (UBA; Sonopet). A retrospective, institutional review board approved chart review of all eDCRs over 49 months. Data included demographics, indication/etiologic factors of nasolacrimal duct obstruction, comorbidities, intraoperative findings, epiphora symptoms pre- and postoperatively, and complications. Patients were grouped in eDCR with or without UBA. One hundred and twenty-three primary eDCRs in 99 patients were included, 59 with UBA and 64 without UBA. Most patients were Caucasians (80.8%) and women (72.0%), with a mean age of 55.9 years (range, 9-89). There were no significant differences in the demographics of the 2 subgroups. Complete resolution of symptoms

was obtained in 81.3% of procedures without UBA and in 79.7% with UBA. Most patients (72.7%) were deemed idiopathic preoperatively. Lacrimal sac biopsy demonstrated significant pathologic factors in 9 (7.3%) cases, with 7 (5.7%) of these resulting in a new diagnosis for the patient. There were no cases of cerebrospinal fluid leakage, visual loss, diplopia, infection, or uncontrolled epistaxis in either group.Early results of eDCR with UBA appear to show reasonable efficacy. The overall success and failure rates of eDCR with and without UBA are similar. Neither group had any complications in this study, although any conclusion on the overall safety of the procedure is limited by the power of this study.

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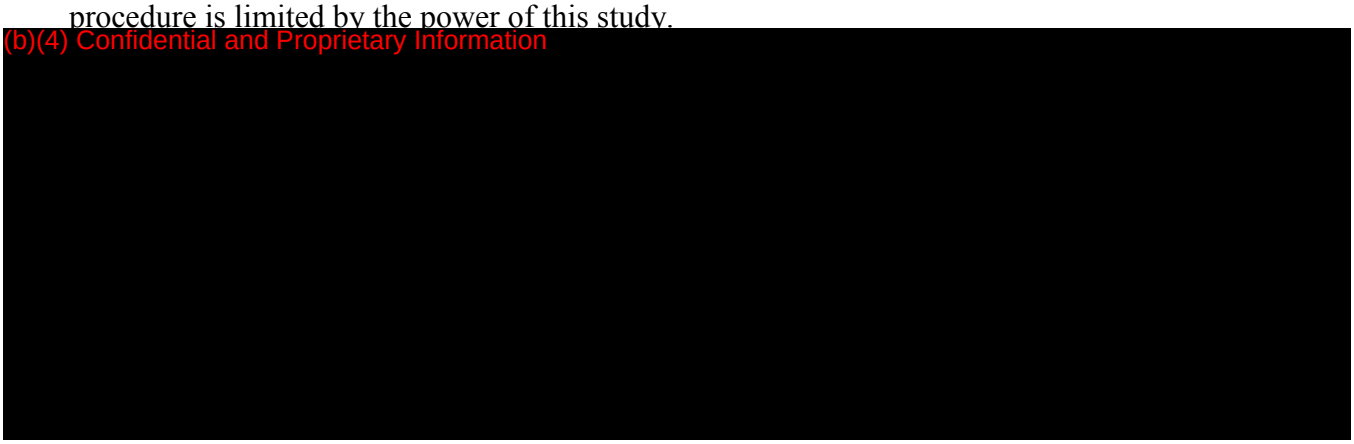

Article: Use of the ultrasonic bone aspirator for lateral osteotomies in rhinoplasty.; *Plast Reconstr Surg.* 2013 Dec;132(6):1430-3.
Authors: Cochran CS, Roostaeian J.
Summary: There remains considerable debate over the optimal method and approach to performing lateral osteotomies. Current methods rely on mechanical energy for performance of osteotomies, which can lead to soft-tissue injury and/or disruption of the bony or cartilaginous framework. The authors report the novel use of an ultrasonic bone aspirator device for performance of lateral osteotomies in rhinoplasty. The authors have found this technology to be safe and effective in a series of five consecutive patients. The main benefits of the device include avoidance of soft-tissue/mucosal injury, minimal bleeding/bruising, and the ability to avoid mechanical force to create bony cuts, which can destabilize the bony and/or cartilaginous construct of the nose. Being able to minimize tissue trauma with its associated morbidity while maintaining efficacy makes the ultrasonic bone aspirator an attractive option for lateral osteotomies in rhinoplasty that warrants further investigation.

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2.2 Abstract Reviewed

Article: Ultrasonic bone removal with the Sonopet Omni: a new instrument for orbital and lacrimal surgery. Arch Ophthalmol. 2005 Nov;123(11):1595-7. PubMed PMID: 16286624.
Authors: Sivak-Callcott JA, Linberg JV, Patel S.
Summary: We used a new instrument that ultrasonically removes bone (Sonopet Omni, model UST-2001 Ultrasonic Surgical Aspirator) in 13 orbital decompressions and 6 dacryocystorhinostomies. We noted no surgical complications of ocular or soft tissue damage, infection, inflammation, or visual loss. Visualization, manipulation, ease of use, and speed were far superior with the Sonopet ultrasonic bone curette compared with drills or rongeurs. The Sonopet Omni is an outstanding innovation in technology for bone removal in surgery.

(b)(4) Confidential and Proprietary Information

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3 Conclusions

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1. Cho RI, Choe CH, Elner VM. Ultrasonic bone removal versus high-speed burring for lateral orbital decompression: comparison of surgical outcomes for the treatment of thyroid eye disease. Ophthal Plast Reconstr Surg. 2010 Mar-Apr;26(2):83-7.

2. Cochran CS, Roostaeian J. Use of the ultrasonic bone aspirator for lateral osteotomies in rhinoplasty.; *Plast Reconstr Surg.* 2013 Dec;132(6):1430-3.

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4. Murchison AP, Pribitkin EA, Rosen MR, Bilyk JR. The ultrasonic bone aspirator in transnasal endoscopic dacryocystorhinostomy. Ophthal Plast Reconstr Surg. 2013 Jan-Feb;29(1):25-9.

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Clinical Literature on the Cavitron Ultrasonic Surgical Aspirator (CUSA): General Surgery

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1 Executive Summary – CUSA Use in General Surgery

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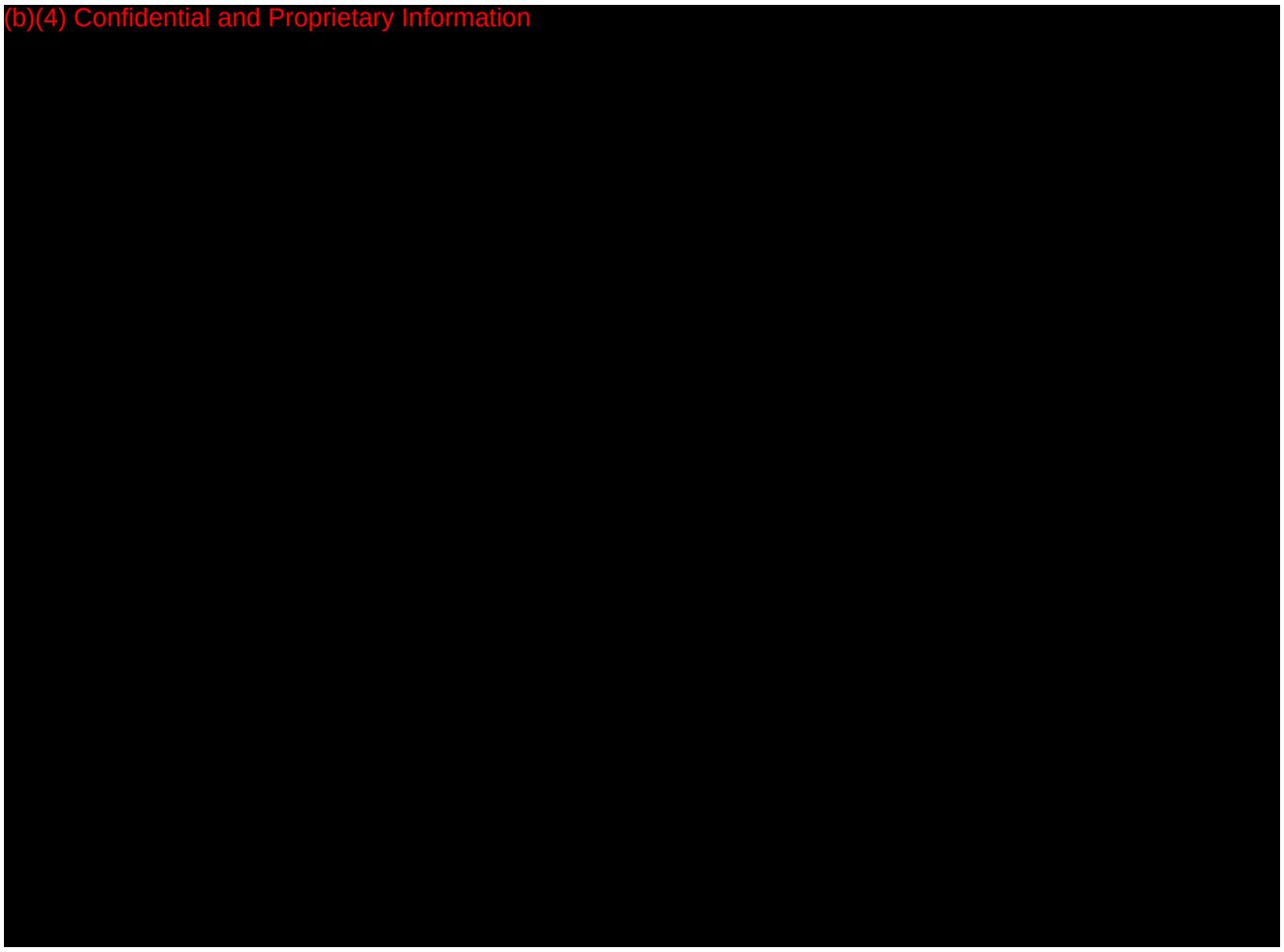

2 CUSA Use in General Surgery Literature Review

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2.1 Articles Reviewed

Article: Treatment of osmidrosis with the Cavitron ultrasonic surgical aspirator. Dermatol Surg. 2006 Oct;32(10):1251-5. PubMed PMID: 17034374.
Authors: Ozawa T, Nose K, Harada T, Muraoka M, Ishii M.
Summary: Axillary osmidrosis is an uncomfortable condition that can be a personal or social handicap. The objective was to present the treatment of osmidrosis with the Cavitron ultrasonic surgical aspirator (CUSA). Fifteen patients (3 males and 12 females) underwent surgery for bilateral axillary osmidrosis with the CUSA. The outcome of this operation with the CUSA was evaluated by the patients themselves according to the following criteria. Postoperative improvement was evaluated as good when the odor was decreased by >75%, fair when it was decreased by > or =50 and < or =75%, and poor when it was decreased by <50%. A total of 15 patients (3 males and 12 females) were evaluated. Eight patients (53.3%) had a good result, 6 patients (40%) had a fairly good result, and 1 patient (6.7%) had a poor result. None of the patients experienced any complications, such as skin necrosis, infection, or serous cyst. One dissatisfied patient underwent reoperation and achieved a good result after the second procedure. This treatment of osmidrosis with the CUSA achieves satisfactory therapeutic efficacy.

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Article: Adenocarcinoma complicating restorative protocolectomy for ulcerative colitis with mucosectomy performed by Cavitron Ultrasonic Surgical Aspirator. Colorectal Dis. 2009 May;11(4):428-9. doi: 10.1111/j.1463-1318.2008.01651.x. Epub 2008 Jul 25. PubMed PMID: 18662238.
Authors: Branco BC, Sachar DB, Heimann T, Sarpel U, Harpaz N, Greenstein AJ.
Summary: This is a report of adenocarcinoma arising in an ileal pouch after restorative proctocolectomy (RPC) with rectal mucosal stripping performed by Cavitron Ultrasonic Surgical Aspirator (CUSA) for ulcerative colitis. The CUSA was introduced to simplify and optimize ileal pouch-anal anastomosis with mucosectomy and has been shown to shorten the operative time and reduce blood loss. Its use however, may increase the number of pathology specimens made uninterpretable on account of tissue ablation. In the present case, even though preoperative colonoscopy had clearly shown dysplasia, the

surgical pathology report could not detect any neoplasia in the specimen; hence, the patient was not surveyed for pouch cancer. Six years later, the patient presented with intestinal obstruction caused by cancer. While protocols for universal pouch surveillance remain somewhat controversial, we conclude on the basis of this case and a review of the literature that in RPC with mucosectomy performed by CUSA, pouch cancer surveillance is particularly important because remnants of rectal epithelium may have been left behind and tissue ablation may have made the surgical pathology report uninterpretable.

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2.2 Abstracts Reviewed

Article: A bloodless technique for tongue surgery. Head Neck Surg. 1981 Jan-Feb;3(3):244-6. PubMed PMID: 7461983.
Authors: Weitz J, Hodgson WJ, Loscalzo LJ, McElhinney AJ..
Summary: The Cavitron Ultrasonic Surgical Aspirator (CUSA System) has been used at our institution in the resection of carcinoma of the tongue in 10 patients. This device is an ultrasonically powered aspirator that selectively fragments and aspirates tissue within a 1- to 2-mm radius of its tip. The technique used in our unit in tongue surgery was to incise the touch mucosal capsule of the tongue with electrocautery, and then to divide muscle and skeletonize blood vessels using the CUSA System. Smaller vessels, up to 2 mm in size, were cauterized directly by the friction created at the tip of the instrument. In this way, excellent control was available at all times and blood loss was consequently minimal. As our experience in the use of the CUSA System increased, blood loss was virtually eliminated, anatomic landmarks were more easily defined, and at no stage did any tongue necrosis occur in any of the patients of the series.

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Article:. Papillary cystic and solid tumor of the pancreas--surgical therapy with the use of CUSA, and a review of the pediatric literature. *Eur J Pediatr Surg*. 1999 Dec;9(6):416-9. PubMed PMID: 10661856.

Authors: Snajdauf J, Pýcha K, Rygl M, Kocmichová B, Kodet R, Koutecky J, Cumlivská E.
Summary: Papillary cystic and solid tumor of the pancreas (PCSTP), so-called Frantz tumor, is a very rare tumor in children. Only 62 cases, 57 girls and 5 boys, have been reported in children since 1959. The tumor presents usually as a slowly growing abdominal mass with or without abdominal pain. Surgical resection of the tumor is an adequate mode of treatment, and the prognosis is excellent. The authors present 4 girls and 1 boy with PCSTP and demonstrate that the Cavitron Ultrasonic Surgical Aspirator (CUSA, Valleylab) is successfully used in surgical therapy.

(b)(4) Confidential and Proprietary Information

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3 Conclusions

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1. Branco BC, Sachar DB, Heimann T, Sarpel U, Harpaz N, Greenstein AJ. Adenocarcinoma complicating restorative proctocolectomy for ulcerative colitis with mucosectomy performed by Cavitron Ultrasonic Surgical Aspirator. Colorectal Dis. 2009 May;11(4):428-9.

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of CUSA, and a review of the pediatric literature. *Eur J Pediatr Surg*. 1999 Dec;9(6):416-9.

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Clinical Literature on the Cavitron Ultrasonic Surgical Aspirator (CUSA): Laparoscopic Surgery

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1 Executive Summary – CUSA Use in Laparoscopic Surgery

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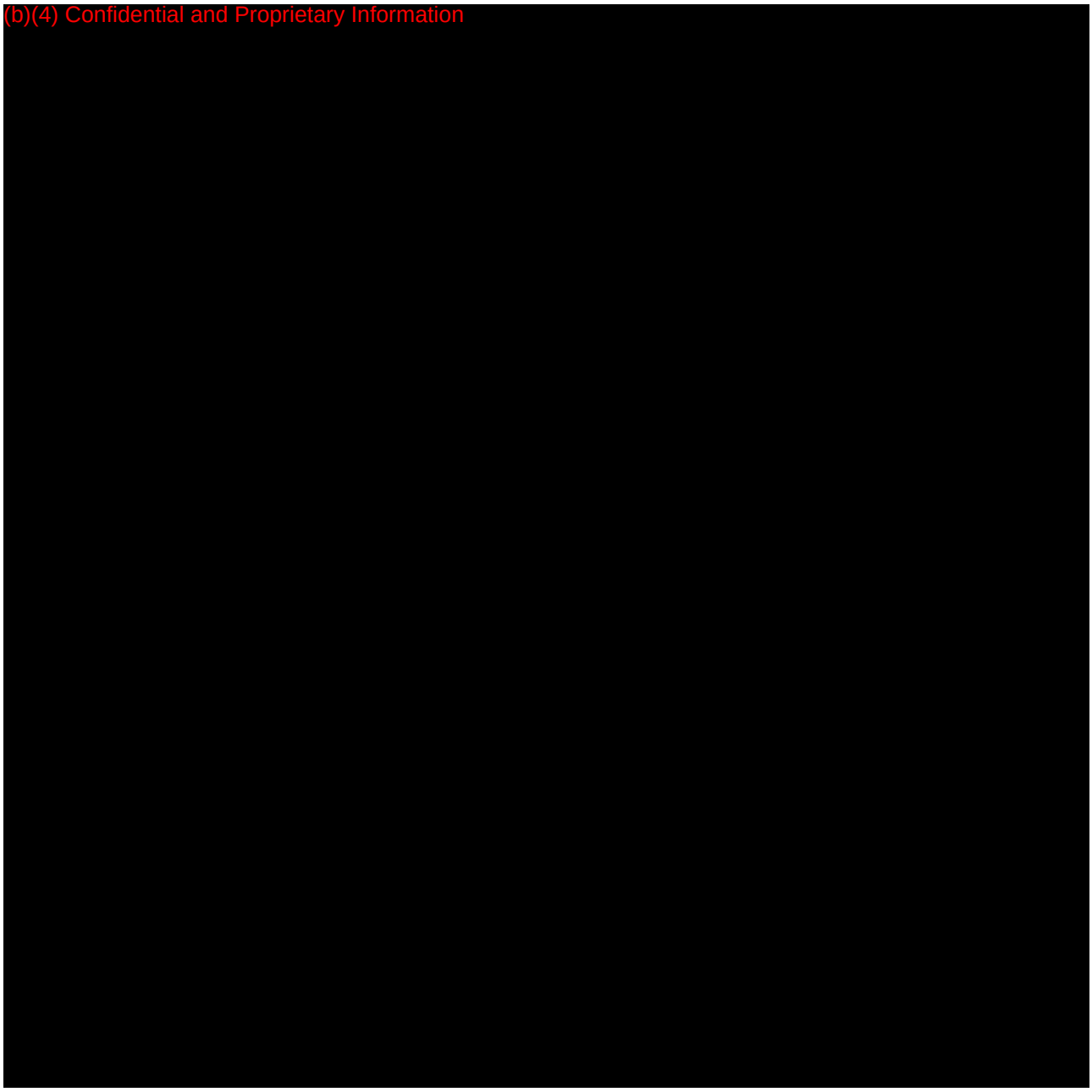

2 CUSA Use in Laparoscopic Surgery Literature Review

(b)(4) Confidential and Proprietary Information

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2.1 Articles Reviewed

Article: An Ultrasonically Powered Instrument for Laparoscopic Surgery: A Brief Technical Report of Preliminary Success. *J Laparoendosc Surg*. 1995 Feb;5(1):31-6. PubMed PMID:7766926.
Authors: Kato K, Matsuda M, Onodera K, Kasai S, Mito M, Saito T.
Summary: Reports the use of an ultrasonically powered instrument (CUSA) for laparoscopic surgery. A total of 105 patients underwent laparoscopic or laparoscopic assisted surgical procedures. Ninety-one laparoscopic cholecystectomies (LC), 9 laparoscopic appendectomies (LA), 3 laparoscopic colon resections (LCR), and 2 laparoscopic partial gastrectomies (LPG) were done using CUSA. In LC, CUSA separates the areolar connective tissue between gallbladder and liver bed without dividing any sizable vessels or injuring the liver. In LA, LCR, and LPG, CUSA makes mesenteric vessel identification and division rapid and safe.

(b)(4) Confidential and Proprietary Information

[redacted]

Article: Laparoscopic ablation of endometriosis using the cavitational ultrasonic surgical aspirator. *J Am Assoc Gynecol Laparosc*. 1993 Nov;1(1):36-42. PubMed PMID: 9050458.
Authors: Vasquez JM, Eisenberg E, Osteen KG, Hickerson D, Diamond MP.
Summary: Surgical modalities such as electrosurgery and lasers have been used for many years to treat endometriosis. They are relatively unselective with wide scatter, however, leading to the potential for significant tissue damage and injury. As an alternative, a technique for performing laparoscopic excision and adhesiolysis using a cavitational ultrasonic surgical aspirator (CUSA) was developed and studied in 15 patients. Endometriosis was removed using a prototype titanium probe developed for a 10-mm laparoscopic port. The ultrasonic laparoscopic probe consisted of an acoustic vibrator, a coupling device, a removable tip, and a protective flue. Vibrations from the acoustic vibrator (magnetostrictive device) were conveyed to the operating tip through a

coupling piece. The magnetostrictive device consisted of nickel alloy laminations 10.8 cm in length that transformed electrical energy into mechanical motion at the hollow titanium tip, vibrating at a frequency of 23 kHz. The excursion of the tip (amplitude setting) was arbitrarily set, with a fixed stroke of 200 microm in all cases to remove tissue with a 1- to 2-mm radius of the vibrating tip. The tip was tapered to obtain greater amplitude and ablation efficiency. When placed in contact with the endometriotic implants and adhesions, it destroyed and emulsified the cell membranes, which were irrigated and removed through a built-in suction tube. The resulting debris and irrigating fluid were removed through the hollow central portion of the probe. The vibrating tip was moved over the surgical site in a back-and-forth motion to allow continuous, controlled removal. Vessels larger than 0.5 mm in diameter, nerves, and fibrous tissue capsules rebounded with the ultrasonic vibration waves emitted by the CUSA, and thus were unimpaired by the procedure. The consistency of tissues was sensed accurately when the tip of the device was in contact with them. This tactile feedback was helpful in enabling the surgeon to differentiate target tissues. The future application of this instrument awaits the outcome of research.

(b)(4) Confidential and Proprietary Information

[redacted]

Article: Laparoscopic transhiatal esophagectomy for advanced thoracic esophageal cancer. *Surg Laparosc Endosc*. 1997 Feb;7(1):13-6. PubMed PMID: 9116939.
Authors: Yahata H, Sugino K, Takiguchi T, Yoshioka S, Tanji H, Shinozaki K, Uchida K, Okimoto T, Marubayashi S, Asahara T, Takeichi N, Fukuda Y, Dohi K.
Summary: The article reports transhiatal subtotal esophagectomy under laparoscopic guidance to reduce the invasiveness of subtotal esophagectomy while preserving dissectional accuracy. In six cases of advanced thoracic esophageal cancer with distant metastasis, a special type of handpiece of ultrasonic surgical aspirator (CUSA) was used for laparoscopic surgery to dissect the esophagus from surrounding tissues and to isolate vessels entering it while viewing with the video monitor. Hemostasis of isolated vessels was effected by clips or electrocoagulation. There was no massive bleeding from the mediastinum during the operation, nor was there postoperative bleeding or infection. All patients regained normal swallowing ability and were discharged. Transhiatal esophagectomy under laparoscopic guidance is considered a safe, less invasive operative treatment for patients who are suffering from advanced thoracic esophageal cancer.

(b)(4) Confidential and Proprietary Information

[redacted]

Article: Laparoscopic liver resection for subcapsular hepatocellular carcinoma complicating chronic liver disease.; *Arch Surg.* 2003 Jul;138(7):763-9; discussion 769.
Authors: Laurent A, Cherqui D, Lesurtel M, Brunetti F, Tayar C, Fagniez PL.
Summary: The authors hypothesized that laparoscopic liver resection for subcapsular hepatocellular carcinoma in patients with chronic liver disease is associated with lower morbidity than open resections. In a case-comparison study from December 1, 1998, to November 30, 2000, 13 patients with chronic liver disease who underwent laparoscopic resection of hepatocellular carcinoma formed the laparoscopic group (LG). Tumors were 5 cm or smaller, subcapsular, and located in anterolateral segments (segments II-VI). A control group was created by matching each laparoscopic case with patients identical for liver disease, tumor size, and location and type of hepatectomy who underwent open liver resection. Fourteen patients fulfilled the criteria and formed the open group (OG). The main outcome measures were postoperative mortality and morbidity. One segment or less was resected in 21 patients and 2 in 6 patients. Operative duration and cumulative portal triad clamping times were longer in the LG (267 +/- 79 minutes vs. 182 +/- 57 minutes, P =.006; 68 +/- 24 minutes vs. 25 +/- 19 minutes, P =.006, respectively). Mortality rates were 0% in the LG and 14% (2/14) in the OG (P =.2). Postoperative liver failure and ascites occurred in 8% (1/13) in the LG and 36% (5/14) in the OG (P =.15). Surgical margin was not different in the 2 groups. Three-year survival was significantly higher in the LG (89% vs. 55%; P =.04), but 3-year recurrence rates were similar (46% vs. 44%). The study suggests that, despite longer operative and clamping times without clinical consequences, the rate of decompensation of liver disease could be lower after laparoscopy.

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Article: Laparoscopic liver resection for peripheral hepatocellular carcinoma in patients with chronic liver disease: midterm results and perspectives.; *Ann Surg.* 2006 Apr;243(4):499-506.
Authors: Cherqui D, Laurent A, Tayar C, Chang S, Van Nhieu JT, Loriau J, Karoui M, Duvoux C, Dhumeaux D, Fagniez PL.
Summary: The objective of this article was to report the midterm results of laparoscopic resection for hepatocellular in chronic liver disease (CLD). Surgical resection for hepatocellular carcinoma (HCC) in chronic liver disease (CLD) remains controversial because of high morbidity and recurrence rates. Laparoscopic resection of liver tumors has recently been developed and could reduce morbidity. From 1998 to 2003, patients with HCC and CLD were considered for laparoscopic liver resection. Inclusion criteria

were chronic hepatitis or Child's A cirrhosis, solitary tumor < or =5 cm in size, and location in peripheral segments of the liver. Mortality, morbidity, recurrence rates, and survival were analyzed. A total of 27 patients were included. Liver resections included anatomic resection in 17 cases and non-anatomic resection in 10. Seven conversions to laparotomy (26%) occurred for moderate hemorrhage in 5 cases and technical difficulties in 2 cases. Mortality and morbidity rates were 0% and 33%, respectively. Postoperative ascites and encephalopathy occurred in 2 patients (7%) who both had undergone conversion to laparotomy. Mean surgical margin was 11 mm (range, 1-47 mm). After a mean follow-up of 2 years (range, 1.1-4.7), 8 patients (30%) developed intrahepatic tumor recurrence of which one died. Treatment of recurrence was possible in 4 patients (50%), including orthotropic liver transplantation, right hepatectomy, radiofrequency ablation, and chemoembolization in 1 case each. There were no adhesions in the 2 re-operated patients. Overall and disease-free 3-year survival rates were 93% and 64%, respectively. Our study shows that laparoscopic liver resection for HCC in selected patients is a safe procedure with very good midterm results. This approach could have an impact on the therapeutic strategy of HCC complicating CLD as a treatment with curative intent or as a bridge to liver transplantation.

(b)(4) Confidential and Proprietary Information

Article: Laparoscopy-assisted right hepatic lobectomy using a wall-lifting procedure.; *Surg Endosc.* 2006 Aug;20(8):1326-8.
Authors: Eguchi D, Nishizaki T, Ohta M, Ishizaki Y, Hanaki N, Okita K, Ohga T, Takahashi I, Ojima Y, Wada H, Tsutsui S.
Summary: This article describes a new technique for performing a laparoscopy-assisted right hepatic lobectomy using a hanger wall-lifting procedure. The patient is placed in the left semi-lateral position. A cholecystectomy and hemi-hepatic vascular inflow control are then performed through a midline incision, through which the resected liver can be removed. Next, the right lower chest and right upper abdominal wall are lifted by two wires vertical to the abdominal wall. Two ports, a 5-mm port in right lateral abdomen for forceps and a 12-mm port just right of the umbilicus for the laparoscope, are inserted. The obtained view of the operative field in the right upper abdominal cavity is thus excellent. The laparoscopy-assisted mobilization of the right hepatic lobe is done with the assistance of a hand inserted through the midline incision, including a dissection of the hepato-renal ligament, the right triangular ligament, and the right coronary ligament. A parenchymal dissection is then performed using the Cavitron Ultrasonic Surgical Aspirator (CUSA) and the resected specimen is passed through the midline incision without any morcellation of the liver. This procedure can minimize the length of the wound, while avoiding the lethal complications associated with pneumoperitoneum.

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information

[redacted]

Article: The use of water-jet dissection in open and laparoscopic liver resection.; *HPB (Oxford).* 2008;10(4):275-80.
Authors: Rau HG, Duessel AP, Wurzbacher S.
Summary: The objective of this article was to review the authors' experiences with the implementation of a new dissection technique in open and laparoscopic surgery. Their database comprises a total of 950 patients who underwent liver resection. Three hundred and fifty of them were performed exceptionally with the water-jet dissector. Forty-one laparoscopic partial liver resections were accomplished. Using the water-jet dissection technique it was possible to reduce the blood loss, the Pringle- and resection time in comparison to CUSA and blunt dissection. In the last five years the authors could reduce the Pringle-rate from 48 to 6% and the last 110 liver resections were performed without any Pringle's maneuver. At the same time, the transfusion-rate decreased from 1.86 to 0.46 EC/patient. In oncological resections, the used dissection technique had no influence on long-time survival. The water-jet dissection technique is fast, feasible, oncologically safe and can be used in open and in laparoscopic liver surgery.

(b)(4) Confidential and Proprietary Information

[redacted]

Article: Totally laparoscopic hepatectomy exposing the major vessels.; *J Hepatobiliary Pancreat Sci.* 2013 Apr;20(4):435-40.
Authors: Honda G, Kurata M, Okuda Y, Kobayashi S, Tadano S, Yamaguchi T, Matsumoto H, Nakano D, Takahashi K.
Summary: Even during laparoscopic hepatectomy, a technique is often required to expose the major vessels, for example, in anatomical hepatectomy. The authors have standardized and performed such laparoscopic hepatectomy as successfully as open hepatectomy. They divide the liver parenchyma without pre-coagulation, exposing the major vessels using CUSA. To control the bleeding, they keep the central venous pressure low and often perform Pringle's maneuver. Over 49 months, totally laparoscopic hepatectomies in 41 patients were performed with the technique of exposing the major vessels. These included major hepatectomy in 7, sectorectomy in 17, segmentectomy in 14, and others in 3. The median operative time was 361 (range 176-605) minutes, with median blood loss of 216 (range 0-1600) g. The conversion rate was 4.9 %. Postoperative morbidity rate was 9.8 % (prolonged ascites in 1, port site infection in 1, peroneal palsy in 2). Mortality was zero. The median length of hospital stay after surgery was 8 (range 5-28) days. No local recurrence was found at the time of writing. By using the standardized procedure exposing the major vessels, the authors could raise the quality of laparoscopic hepatectomy toward the level of open hepatectomy significantly.

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[redacted]

2.2 Abstracts Reviewed

Article: [Use of ultrasonic surgery in laparoscopic cholecystectomy]. *Minerva Chir*. 1994 Mar;49(3):195-7. Italian. PubMed PMID: 8028730.
Authors: Marino BM, Bigliani S, Drago GW, Kiss A, Rossi R, Vitale L.
Summary: Laparoscopic cholecystectomy now represents a valid alternative to traditional surgery in the treatment of gallstone diseases. For the past twenty years laparotomic cholecystectomy has represented the golden standard of gallstone treatment given its extremely low mortality rate (0.5%) and equally acceptable morbidity rate. Laparoscopic cholecystectomy now appears to have taken over the position of elective treatment. Sophisticated techniques, such as ultrasound scalpels make this form of surgery particularly safe. The authors report a series of 50 patients who underwent laparoscopic cholecystectomy in which ultrasound surgery was used in 40 cases using the CUSA system. The gallbladder hilus is prepared using ultrasound manipulation following the secure identification, respect and clipping of the cystic artery and duct. Laparoscopic cholecystectomy appears to be the ideal treatment for gallstone diseases. In the series reported here the use of the ultrasound scalpel allowed the gallbladder hilus to be reach skeletization, preserving the main structures and keeping the operating field clean and blood-free, without increasing operating times. The possibility of severe accidents, such as vascular lesions to the hepatic artery or vena portae, or damage to the common bile duct or other abdominal organs are reduced using this technique.

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[redacted]

Article: Laparoscopic partial hepatectomy and left lateral segmentectomy: technique and results of a clinical series.; *Surgery*. 1996 Sep;120(3):468-75.
Authors: Kaneko H, Takagi S, Shiba T.
Summary: Technical difficulties have impeded the development of laparoscopic hepatectomy. This article describes a new technique for performing partial hepatectomy and left lateral segmentectomy by means of laparoscopy, and the results in a series of 11 consecutive patients are reported. A microwave tissue coagulator is used in combination with an ultrasonic surgical aspirator to divide hepatic parenchyma without pneumoperitoneum. Branched vessels and ducts are clipped and transected. The largest vessels were suture ligated in some cases. The endoscopic linear stapler was used to transect the left hepatic vein for left lateral segmentectomy. The resected liver was maneuvered into a specimen bag and removed. The argon beam coagulator was used to secure hemostasis of the plane of transection. Eleven patients underwent laparoscopic hepatic resection. Indications included isolated metastatic lesion, hepatocellular carcinoma, hemangioma, Wilson's disease, and hemochromatosis. Three patients underwent left lateral segmentectomy, and eight underwent partial hepatectomy. Ten procedures were performed uneventfully; one patient required conversion to open hepatectomy because of excessive bleeding. Notable differences were seen in blood loss compared with open hepatectomy, and no operative complications occurred. Postoperative pain was minimal. The laparoscopic hepatectomy, especially partial or left lateral segmentectomy, appears to be a viable surgical alternative in selected cases.

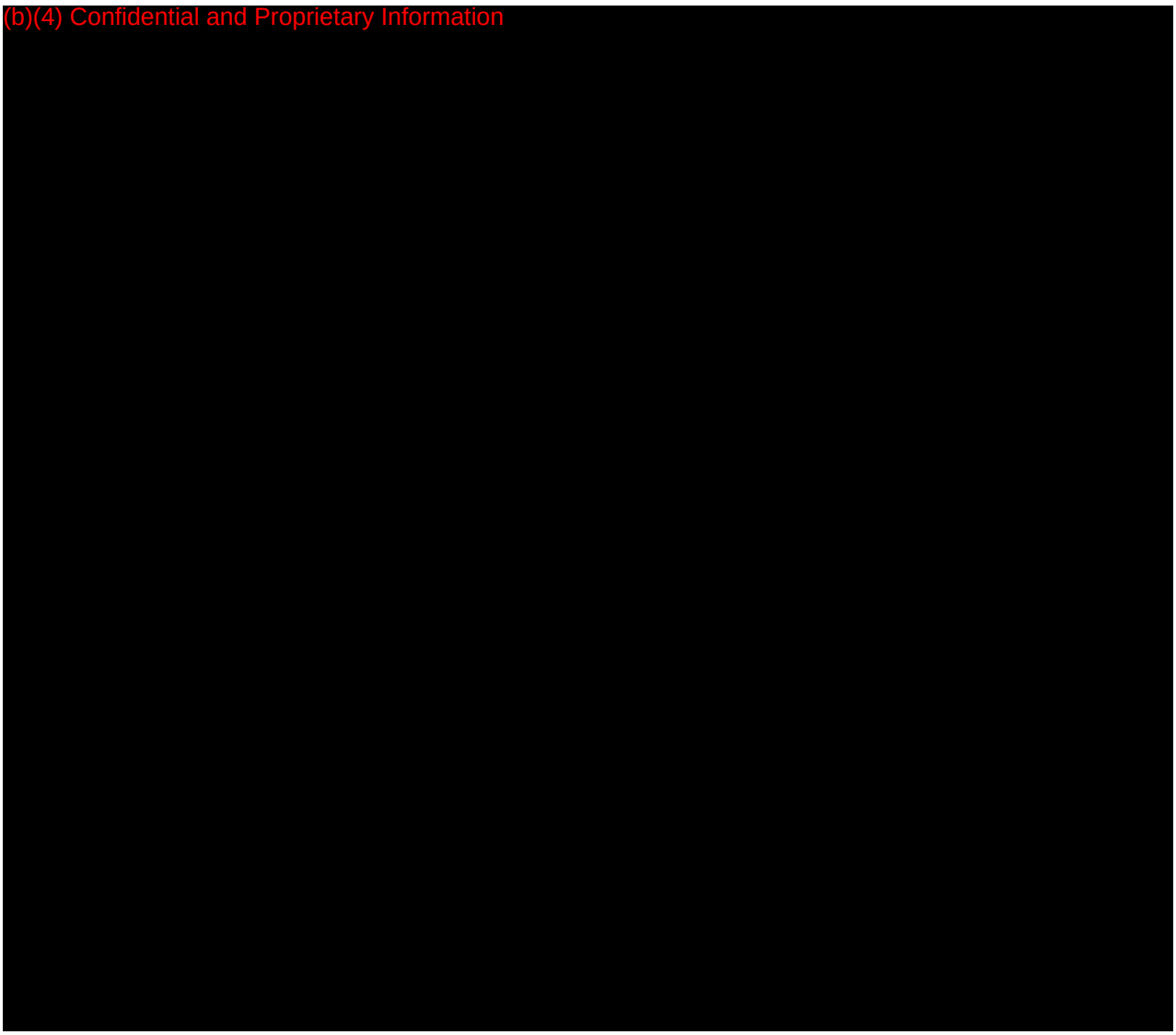
(b)(4) Confidential and Proprietary Information

[redacted]

3 Conclusions

(b)(4) Confidential and Proprietary Information

[redacted]



4 Bibliography

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4. Kaneko H, Takagi S, Shiba T. Laparoscopic partial hepatectomy and left lateral segmentectomy: technique and results of a clinical series.; *Surgery*. 1996 Sep;120(3):468-75.

5. Kato K, Matsuda M, Onodera K, Kasai S, Mito M, Saito T. An Ultrasonically Powered Instrument for Laparoscopic Surgery: A Brief Technical Report of Preliminary Success. *J Laparoendosc Surg*. 1995 Feb;5(1):31-6.

6. Laurent A, Cherqui D, Lesurtel M, Brunetti F, Tayar C, Fagniez PL. Laparoscopic liver resection for subcapsular hepatocellular carcinoma complicating chronic liver disease.; *Arch Surg.* 2003 Jul;138(7):763-9; discussion 769.

7. Marino BM, Bigliani S, Drago GW, Kiss A, Rossi R, Vitale L. [Use of ultrasonic surgery in laparoscopic cholecystectomy]. *Minerva Chir*. 1994 Mar;49(3):195-7. Italian. PubMed PMID: 8028730.

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Clinical Literature on the Cavitron Ultrasonic Surgical Aspirator (CUSA): Thoracic Surgery

11 April 2014

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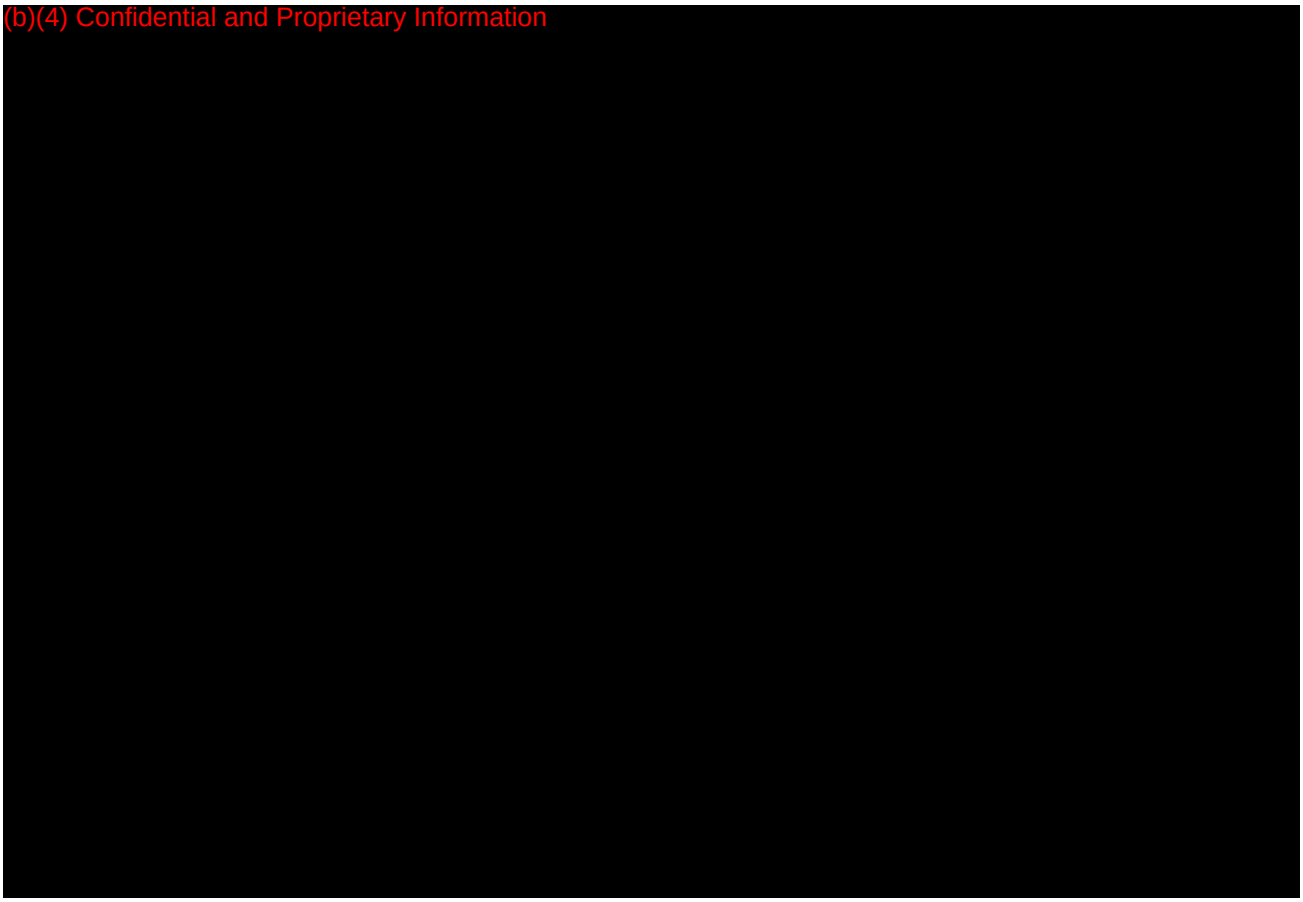
1 Executive Summary – CUSA Use in Thoracic Surgery

(b)(4) Confidential and Proprietary Information



2 CUSA Use in Thoracic Surgery Literature Review

(b)(4) Confidential and Proprietary Information

[redacted]

2.1 Articles Reviewed

Article: Ultrasonic surgical aspirator for lung resection. *Ann Thorac Surg*. 1991 Oct;52(4):787-90. PubMed PMID: 1929630.
Authors: Verazin GT, Regal AM, Antkowiak JG, Parvez Z, Takita H.
Summary: The ultrasonic surgical aspirator was originally developed for neurosurgical procedures and hepatic resections. Ultrasonic vibration at the tip of the instrument results in lysis of the parenchymal cells, leaving more resistant fibrous tissue such as blood vessels and bronchi intact and, thus, minimizing blood loss. We have studied the feasibility of applying the ultrasonic surgical aspirator for segmental and subsegmental lung resection for primary and metastatic neoplasms of the lung. Over the past 5 years, 27 patients underwent segmental or limited lung resection using the ultrasonic surgical aspirator. Except for prolonged air leak in 6 patients postoperatively, no other serious morbidity was noted. We observed several advantages: (1) the ultrasonic surgical aspirator dissects out the pulmonary vessels and bronchi, allowing the surgeon to perform segmental and subsegmental resections with minimal blood loss, (2) it permits lung-sparing operation for centrally located tumors that would otherwise have required lobectomy, and (3) it allows direct visualization of lung parenchyma during dissection, thus assuring grossly adequate margins.

(b)(4) Confidential and Proprietary Information

[redacted]

Article: Laparoscopic transhiatal esophagectomy for advanced thoracic esophageal cancer. *Surg Laparosc Endosc*. 1997 Feb;7(1):13-6. PubMed PMID: 9116939.
Authors: Yahata H, Sugino K, Takiguchi T, Yoshioka S, Tanji H, Shinozaki K, Uchida K, Okimoto T, Marubayashi S, Asahara T, Takeichi N, Fukuda Y, Dohi K.
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3 Conclusions

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[redacted]

4 Bibliography

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K141668/S001

October 8 2014

-Via Federal Express-

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: K141668 - Response FDA Inquiry dated August 22, 2014 CUSA Excel Indication Expansion

Dear Sir or Madam:

Integra LifeSciences Corporation hereby submits in duplicate our response to the Agency's inquiries dated August 22, 2014. The existence of this Premarket Notification, K141668 and the data and information that it contains are Confidential, and the protection afforded to such confidential information by 21 CFR 807.95, and other applicable laws is hereby claimed.

Per the instructions accessed at http://www.fda.gov/cdrh/elecsub.html, an electronic copy is being provided with this submission. The eCopy is an exact duplicate of the paper submission. Thank you in advance for your consideration of our application. If there are any questions, concerns or requests for additional information, please do not hesitate to contact me at 609-529-1247 or via e-mail at janet.kay@integralife.com. Alternatively please contact Timothy Connors 609-936-5531 or via email at timothy.connors@integralife.com

Sincerely,

Janet C. Kay, RAC

Director, Regulatory Affairs

October 8 2014 **-Via Federal Express-**

510(k) Document Mail Center (WO66-G609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: K141668 - Response FDA Inquiry dated August 22, 2014 CUSA Excel Indication Expansion

Dear Sir or Madam:

Integra LifeSciences Corporation hereby submits in duplicate our response to the Agency's inquiries dated August 22, 2014. The existence of this Premarket Notification, K141668 and the data and information that it contains are Confidential, and the protection afforded to such confidential information by 21 CFR 807.95, and other applicable laws is hereby claimed.

Per the instructions accessed at http://www.fda.gov/cdrh/elecsub.html, an electronic copy is being provided with this submission. The eCopy is an exact duplicate of the paper submission. Thank you in advance for your consideration of our application. If there are any questions, concerns or requests for additional information, please do not hesitate to contact me at 609-529-1247 or via e-mail at janet.kay@integralife.com. Alternatively please contact Timothy Connors 609-936-5531 or via email at timothy.connors@integralife.com

Sincerely,

Janet C. Kay, RAC

Director, Regulatory Affairs

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
10/08/14		K141668

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☐ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☒ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Integra LifeSciences Corporation	1222895		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Neurosurgery	609-750-2864		
Street Address	**FAX Number *(including area code)***		
22 Terry Avenue			
City	**State / Province**	**ZIP/Postal Code**	**Country**
Burlington	MA	01803	USA
Contact Name			
Janet C. Kay			
Contact Title	**Contact E-mail Address**		
Director Regulatory Affairs	janet.kay@integralife.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

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SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☒ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

SECTION E ADDITIONAL INFORMATION ON PRIOR(S) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1		2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached

☐ 510 (k) statement

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

	510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1			
2			
3			
4			
5			
6			

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Ultrasonic Surgical Aspirator

	Trade or Proprietary or Model Name for This Device	Model Number
1	CUSA Excel Ultrasonic Surgical Aspirator	Excel
2	CUSA Excel Ultrasonic Surgical Aspirator with Bone Tip	Excel
3		
4		
5		

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K981262	2 K051947	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
LFL	pre-amendment devices	☐ Class I ☒ Class II
Classification Panel		☐ Class III ☐ Unclassified
General and Plastic Surgery		

Indications *(from labeling)*

See Indications for Use Statement

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	Establishment Registration Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province: NJ	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I CONFORMITY STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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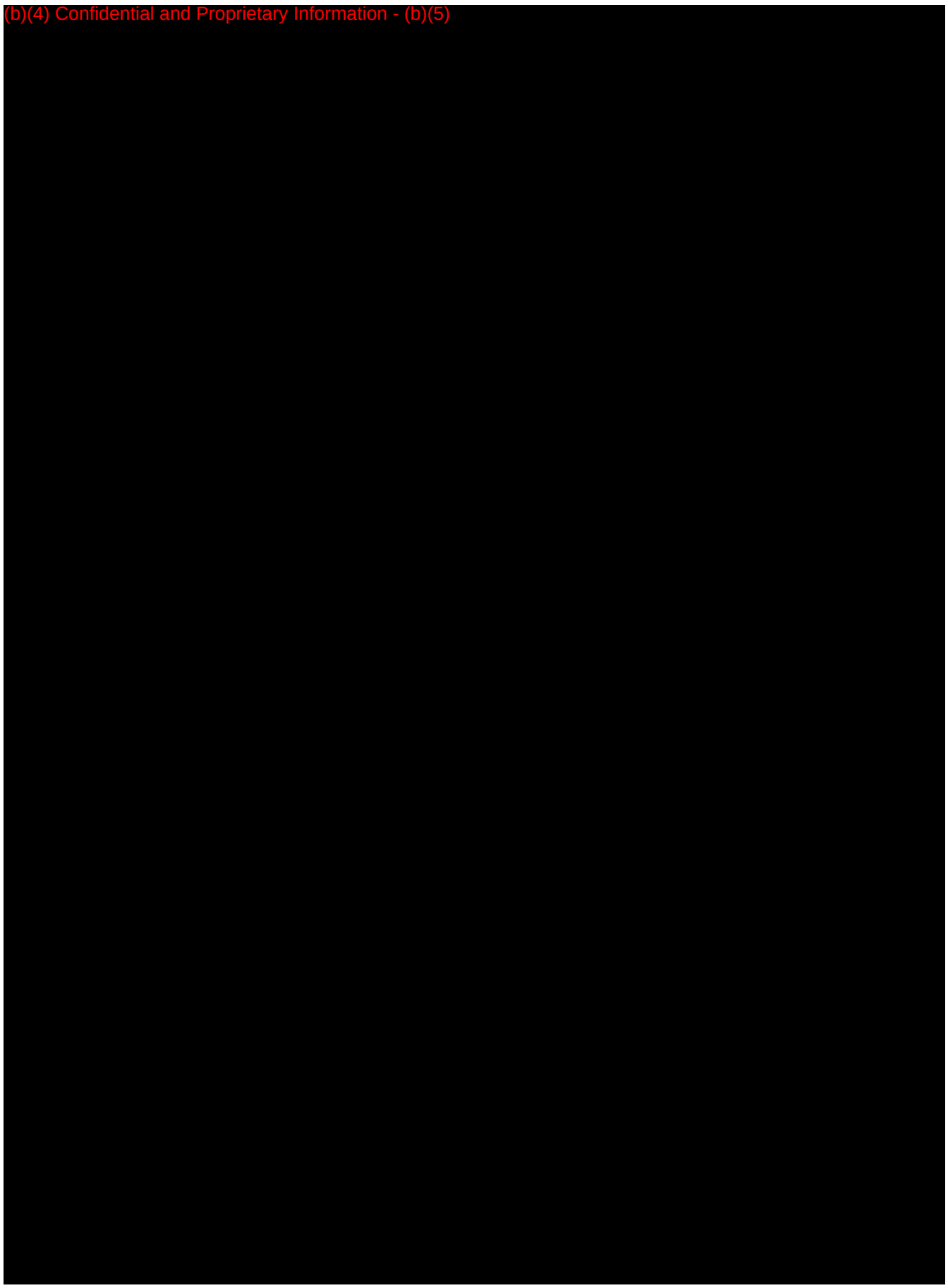

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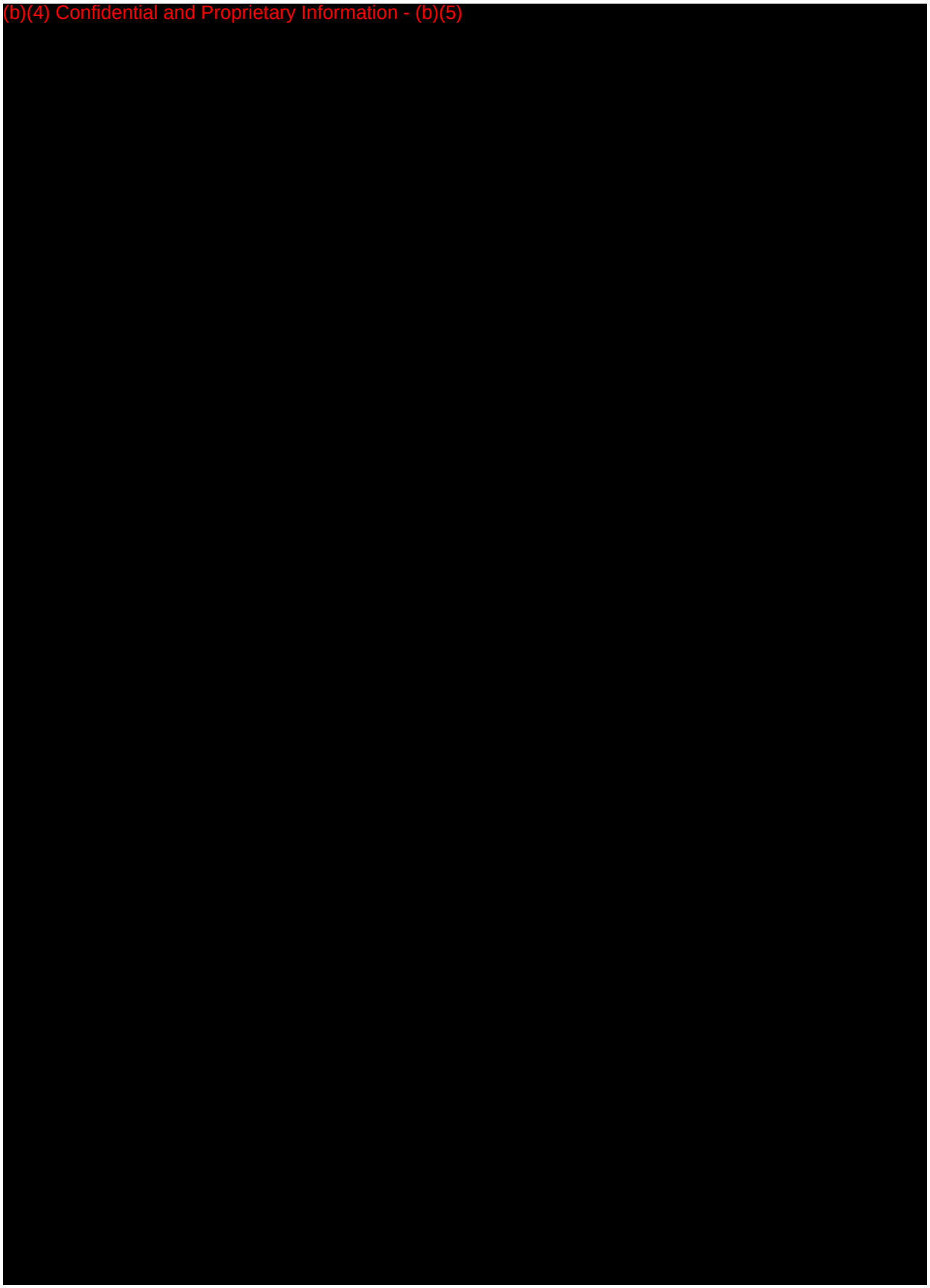

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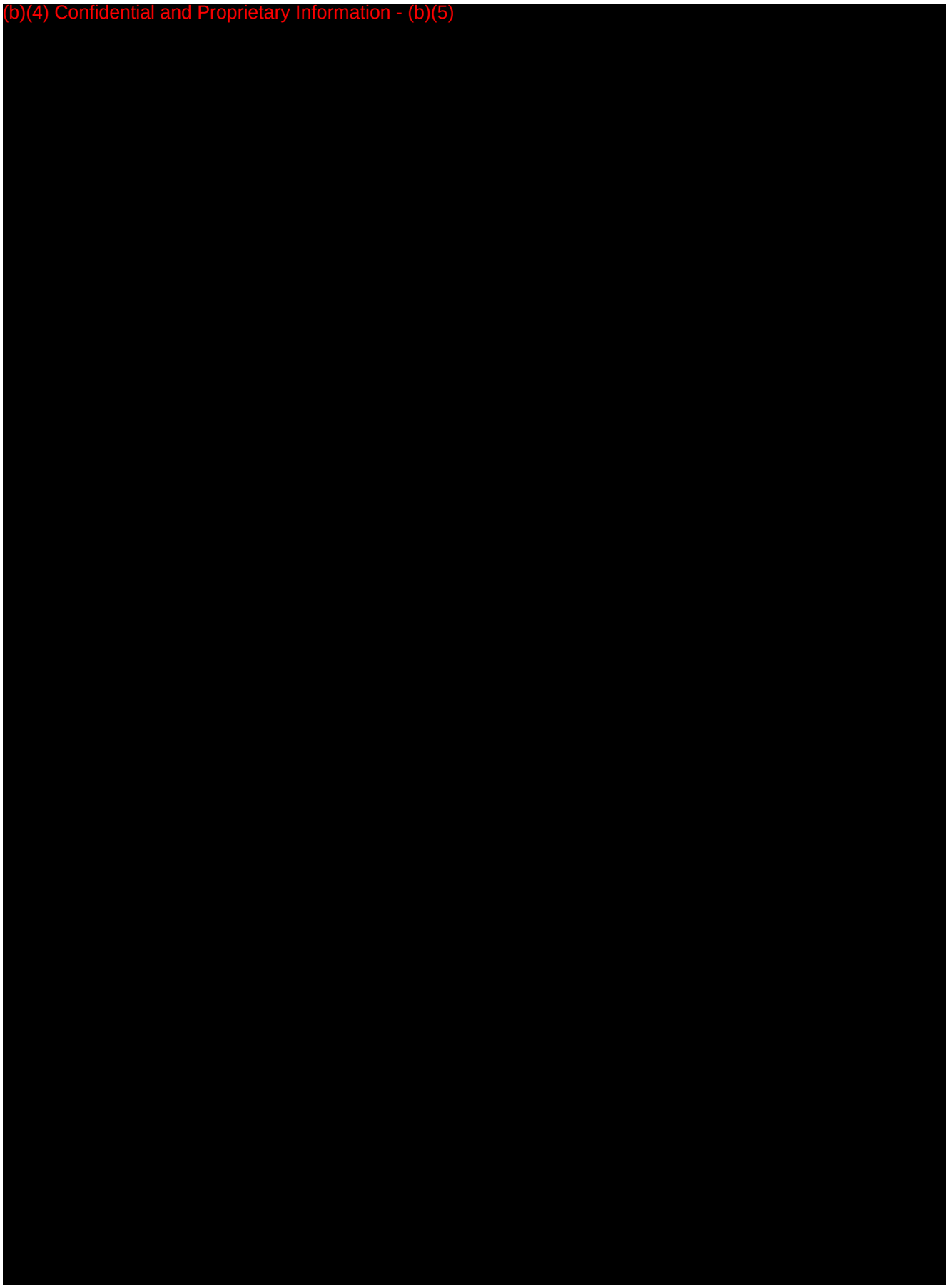

(b)(4) Confidential and Proprietary Information - (b)(5)

Appendix 1

Revised Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name:

CUSA® Excel+ Ultrasonic Surgical Aspirator System

Indications For Use:

The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. The CUSA Excel+ Ultrasonic Surgical Aspirator is indicated for use in:

Neurosurgery, Plastic and Reconstructive surgery, Orthopedic Surgery, Gynecological Surgery and Thoracic Surgery and the following specific uses:

Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy

Urological surgery- including removal of renal parenchyma during nephrectomy or partial nephrectomy

General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures

Laparoscopic Surgery - including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial gastrectomy

.

Prescription Use ___X___ **AND/OR** **Over-The Counter Use_____**

(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Appendix 2

Revised 510k Summary

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

807.92(a)(1) – Submitter information	
Name	Integra LifeSciences Corporation
Address	311 Enterprise Drive Plainsboro, NJ 08536 USA
Phone Number	781-565-1347
Fax Number	781-238-0645
Establishment Registration Number	3003418325
Name of Contact Person	Janet C. Kay
Date Prepared	September 22, 2014
807.92(a)(2) – Name of device	
Trade or Propriety Name	CUSA® Excel+ Ultrasonic Surgical Aspirator System
Common or Usual Name	Ultrasonic Surgical Aspirator
Classification Name	Instrument, Ultrasonic Surgical
Classification Panel	General and Plastic Surgery
Regulation	Class II unclassified
Product Code(s)	LFL
807.92(a)(3) – Legally marketed device(s) to which equivalence is claimed	
CUSA Excel Ultrasonic Surgical Aspirator System K981262 CUSA Excel Ultrasonic Surgical Aspirator System with Bone Tip K051947	
807.92(a)(4) – Device description	

The CUSA Excel+ Ultrasonic Surgical Aspirator System (CUSA) is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. It allows the selective dissection of target tissue while preserving vessels, ducts and other delicate structures. The CUSA Excel+ System consists of a console which provides control and power functions, two surgical hand pieces which provide ultrasonic mechanical energy (23kHz and 36kHz), titanium hand piece tips (variety of models), flexible irrigation flue, and a suction/irrigation system (manifold tubing and cooling water canister). The CUSA Excel+ system accommodates most commercially available suction canisters. A two-pedal footswitch is provided with the console.

807.92(a)(5) – Intended use of the device

Indications for Use	The CUSA® Excel+ Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable. The CUSA Excel+ Ultrasonic Surgical Aspirator is indicated for use in: Neurosurgery, Plastic and Reconstructive surgery, Orthopedic Surgery, Gynecological Surgery and Thoracic Surgery and the following specific uses: Gastrointestinal and Affiliated Organ Surgery – including removal of benign or malignant tumors or other unwanted tissue, including hepatic parenchyma, in open or laparoscopic procedures, hepatic resection, tumor resection, lobectomy or trisegmentectomy, or removal of tissue during liver allotransplantation and donor hepatectomy Urological surgery- including removal of renal parenchyma during nephrectomy or partial nephrectomy General Surgery – including removal of benign or malignant tumors or other unwanted soft or hard tissue in open or minimally invasive general surgical procedures Laparoscopic Surgery - including removal of hepatic parenchyma in laparoscopic hepatic resection, lobectomy or trisegmentectomy, in laparoscopic donor hepatectomy or laparoscopic cholecystectomy or laparoscopic pancreatic jejunostomy, or pancreatectomy, or laparoscopic appendectomy, laparoscopic colon resection or laparoscopic partial

	gastrectomy
807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate	
The technological characteristic of the device are the same compared to the predicate device	
807.92(b)(1-2) – Nonclinical and clinical tests submitted	
No nonclinical testing was required as the device itself was not modified. The clinical evidence used to support the change to the indications for use is provided predominately from peer-reviewed clinical literature.	
807.92(b)(3) – Conclusions drawn from non-clinical and clinical data	
The changes from general to specific indications for use are supported by the information provided including previously cleared 510ks and peer reviewed clinical literature.	

Appendix 3

The CUSA® Excel family of Ultrasonic Surgical Aspirator Systems

PRJ0022 CUSA Excel 60601 Medical Device Hazard Analysis (MDHA)

Rev 5.0

(b)(4) Confidential and Proprietary Information - Risk Analysis

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Appendix 4

INTEGRA®

CUSA® Excel

Instructions for Use

EN CEM™ Nosecone
for CUSA® Excel System
REF C6623
C6636

BR Nosecone CEM™
para Sistema CUSA® Excel
REF C6623
C6636

DE CEM™ Nosecone
Für CUSA® Excel System
REF C6623
C6636

ES Boquilla cónica CEM™
para instrumentos CUSA® Excel
REF C6623
C6636

FR Tête conique CEM™
pour Système CUSA® Excel
REF C6623
C6636

IT Punta conica CEM™
per il Sistema CUSA® Excel
REF C6623
C6636

NL CEM™ conus
voor CUSA® Excel Systeem
REF C6623
C6636

SE CEM™ Noskon
för CUSA® Excel System
REF C6623
C6636

RU Стыковочный конус «CEM™»
для системы «CUSA® Excel»
REF C6623
C6636

CN CEM™ 电凝接口
适用于 CUSA® Excel
REF C6623
C6636

JP CEM™ ノーズコーン
CUSA® Excel システムおよび
REF C6623
C6636

EN

Intended Use

The CUSA Electrosurgical Module (CEM™) provides Desiccate Coagulation waveform electrosurgical capability to CUSA® Excel handpieces.

The CEM nosecone is intended for use with the CUSA® Excel/ CUSA® Excel+ Ultrasonic Surgical Aspirator System, CUSA handpiece and the Covidien Force FX® Electrosurgical Generator.

The CUSA handpiece with the CEM nosecone works in conjunction with the Force FX Generator in surgical procedures where combined ultrasonic dissection and electrosurgical coagulation is desired, either simultaneously or independently.

Warning

The CEM nosecone must be used with the Force FX Electrosurgical Generator only.

Notice

The information in this guide supersedes any information relating to the CEM nosecone found in related user guides.

Intended Users

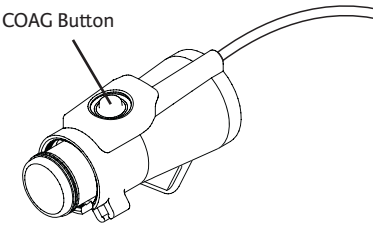
The intended users of this guide and the equipment it describes are qualified medical professionals who are trained in the particular surgical technique and surgical procedure to be performed, and trained in the use of this equipment.

Definition of Symbols

Symbol	Definition
	Mandatory Action: Read instructions before use.
	Mandatory Action: The CEM nosecone must be used with the Force Fx Electrosurgical Generator only.
	Do not reuse.
STERILE EO	Sterilized using ethylene oxide.
	Operating Temperature: +10°C to +35°C Transport & Storage Temperature: -34°C to +65°C
	Operating Humidity: +30% to +75 % Transport & Storage Humidity: +25% to +85%
	Keep Dry.
	Do not use if package is damaged.
	Manufacturer.
REF	Catalogue Number.
	Use By.
LOT	Batch Code.

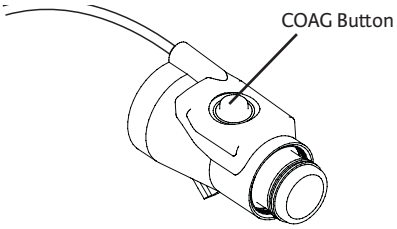
Types of CEM Nosecones

REF C6623 for 23kHz Handpiece



Nosecone	CUSA Handpiece
C6623	C2600 23kHz Straight
	C2601 23kHz Angled

REF C6636 for 36kHz Handpiece



Nosecone	CUSA Handpiece
C6636	C2602 36kHz Straight

When the CEM is assembled to the CUSA handpiece and connected to the Force FX generator, the blue COAG button on the CEM nosecone (shown above) activates the electrosurgical coagulation functionality.

Contents

Each package contains one CEM nosecone.

Sterilization Information

The CEM nosecone is provided sterile and it is single patient use only. You must assemble the CEM nosecone to the handpiece in the sterile field. **Do not re-sterilize the CEM nosecone.**

Warning

For single patient use only. Do not resterilize, reprocess or re-use. Device(s) is (are) intended to be used for one procedure only. It is not re-sterilisable and if reprocessed or re-used this may result in the infection of patient (or patient specimen) through cross-contamination, as well as would incur the risk of modifying the properties and performance of the device, and of increasing the likelihood of complications and/or undesirable effects. Once used, devices must be disposed of in accordance with hospital policies.

Power Limitations

When you connect the CUSA handpiece with the CEM nosecone to the Force FX Generator for ultrasonic surgery, the Force FX Generator automatically limits the monopolar output power to:

- Coagulation wave form only
- 70 watts maximum
- 3500 volts peak to peak maximum

To isolate the CEM nosecone from the mains power supply, unplug the CEM nosecone from the Force FX Generator.

Duty Cycle

The CEM nosecone is suitable for activation times of 10 seconds on, 30 seconds off.

Warnings Relating to CEM Nosecone

For safety information relating to the CUSA Excel System, refer to the CUSA Excel User's Guide. For safety information relating to the Force FX Generator, refer to the Force FX User's Guide.

Warning

It is the responsibility of the Healthcare Facility to ensure that intended users of CUSA Excel System are appropriately trained in the use of this equipment.

Warning

No modification of this equipment is allowed.

Warning

Only use Integra handpieces and accessories with the CUSA Excel System. Non-Integra handpieces and accessories are not supported.

Warning

If you resterilize the CEM nosecone, it becomes non-functional.

Warning

Do not plug the CEM nosecone into the generator when the CEM nosecone is not assembled to the handpiece.

Warning

Do not plug the CEM nosecone into the generator when the CEM nosecone is wet.

Warning

The handpiece and handpiece accessories must be sterile before surgical use.

Warning

Do not use the CEM nosecone with the CUSA® SaberTip™ (C4616S).

Warning

When not in use, keep active accessories away from the patient. Place the handpiece on a flat, clean, dry, nonconductive, and highly visible surface.

Warning

Do not activate the CEM nosecone while using the tip cleaner. Tip damage, user injury, electrical shock, or any combination of these effects may occur.

Warning

To avoid inadvertent activation of the CEM nosecone when not in use, place the assembled handpiece so that the weight of the handpiece does not rest on the nosecone activation button. Do not place other objects on the handpiece.

Warning

Inadvertent contact between handpiece accessories and the patient may result in burns. Store unused handpieces with the CEM nosecone attached in a location that is isolated from the patient.

Warning

Electric Shock Hazard – When simultaneously using an electrosurgical generator with a standard monopolar pencil and an activated ultrasonic handpiece, contact between the pencil blade and the vibrating tip creates sparking and possible tip fracture. The sparking and tip fracture result in product damage. The sparking and tip fracture can also result in injury to the patient, surgeon, or operating room staff. To avoid the effects of contact between the electrosurgical pencil blade and the ultrasonic tip:

- Ensure that the electrosurgical generator is at its lowest effective power setting.
- Do not allow the pencil blade to contact the exposed end of the ultrasonic tip or the pre-aspiration holes at any time.

For greater safety when both electrosurgery and ultrasonics are necessary, use the CEM system. The reduced voltage from CEM provides hemostasis without damage to the ultrasonic tip.

Warning

Explosion Hazard – Do not use the CEM nosecone and CUSA Excel System in the presence of flammable anesthetics or any potentially explosive or flammable atmosphere.

Warning

Ignoring alarms on the CUSA Excel System or the Force FX Generator, while continuing to use the system, may result in injury to the patient and/or surgical personnel, or equipment damage.

Warning

Ensure any pooled flammable cleaning or disinfecting agents have been moped up prior to high frequency coagulation/surgery.

Warning

There is a risk of ignition of cotton or gauze saturated with oxygen from sparks that may be produced by high frequency coagulation/surgery.

Warning

There is a risk of ignition of materials saturated with flammable agents or gases, from sparks that may be produced by high frequency coaglation/surgery.

Warning

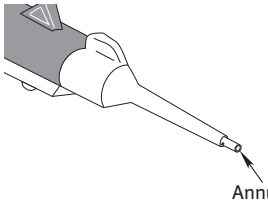
There is a risk of ignition of endogenous gases during high frequency surgery.

Warning

Inspect the CEM cable and nosecone for any signs of damage. Do not use if the CEM accessory is damaged.

Warning

Electric Shock Hazard – When using a CEM nosecone, be sure to dry all CEM surfaces before reassembling the nosecone to the handpiece. Wet surfaces may result in electric shock to the patient, the surgeon, or the operating room staff.



Warning

During CEM operation, contact between the side of the tip and the intended tissue can result in erosion of the tip leading to a tip breakage. When using the CEM nosecone, only the annulus of the tip should have contact with the intended tissue. (See diagram above)

Setting Up the CUSA Excel System

Set up the CUSA Excel System as described in the CUSA Excel System User's Guide.

Attaching the CEM Nosecone to the Sterilized Handpiece

Warning

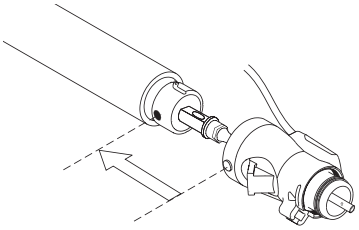
The handpiece and handpiece accessories must be sterile before surgical use. The CEM nosecone is supplied sterile, and it is assembled to the handpiece in the sterile field.

1. When using a CEM nosecone , put the standard nosecone into the sterilizer tray for safe storage.

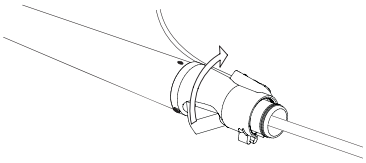
2. Holding the handpiece, attach the tip to the handpiece as described in the CUSA Excel System User's Guide.

3. Align the dot on the nosecone with the dot on the neck of the handpiece.

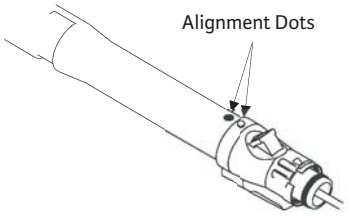
4. Push the nosecone onto the handpiece so that the dots are on top of each other. Be certain that the nosecone fits completely over the handpiece.



5. Twist the nosecone clockwise until it locks into place.

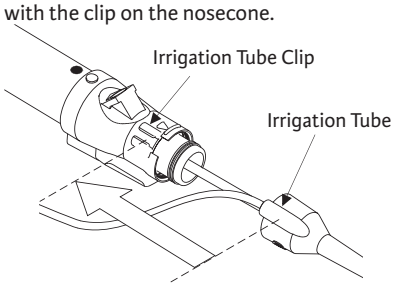


6. The dot on the nosecone must now align with the other dot on the handpiece body.



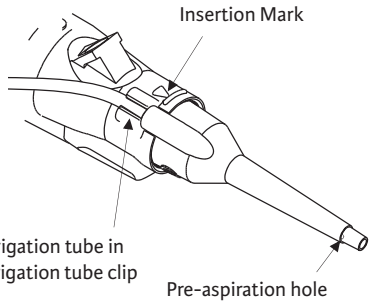
7. Remove the tip cleaner and slide the flue that corresponds to the selected tip in over the tip and onto the nosecone.

8. Align the irrigation tube on the flue with the clip on the nosecone.

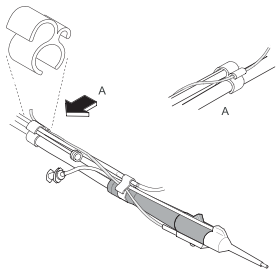


9. Push the flue completely under the nosecone up to the insertion mark. Verify that the end of the flue covers the pre-aspiration holes.

10. Snap the irrigation tube into the irrigation tube clip on the CEM nosecone.



11. Uncoil the CEM cable and insert it into the handpiece and manifold tubing clips.



Caution

When changing tips, completely dry the handpiece, nosecone, and flue fittings inside and outside to reduce the risk of unintended burns to the user or patient.

Testing the Handpiece

Once you have completed the CUSA Excel System setup, test the handpiece to ensure that you have assembled the tip correctly. Refer to the CUSA Excel System User's Guide for instructions on how to test the handpiece.

Priming the CUSA Excel System

Prime the irrigation system as described in the CUSA Excel System User's Guide. Repeat Prime until you see irrigation fluid at the handpiece tip.

The CUSA Excel System requires a minimum of one hour exposure at its operating temperature range before you use it.

EN

Setting Up and Testing the CEM Nosecone

1. Plug the Force FX Generator power cord into a wall receptacle.

2. Plug the CEM nosecone cable connector into the CEM accessory port on the Force FX Generator (Monopolar 1/ CEM).

3. Apply the patient return electrode to the patient and connect it to the Patient connection receptacle on the Force FX Generator. Refer to the Force FX User's Guide for safety information relating to this step.

4. Verify that you have set up the Force FX Generator properly, and that you have turned it on. Refer to the Force FX User's Guide for instructions.

5. To test the CEM nosecone:
- Set the COAG power level to the lowest setting on the Force FX Generator.
- Press the blue COAG button on the CEM nosecone for a maximum of five seconds.
- Verify that the blue COAG indicator on the Force FX Generator illuminates.
- If the blue COAG indicator on the Force FX Generator does not illuminate, do not use the CEM nosecone and handpiece for surgery. Replace the CEM noseone. If this does not resolve the issue, contact your Integra representative for assistance.

6. Adjust the COAG settings on the Force FX control panel to the surgeon's requirements.

7. Adjust the volume control on the Force FX Generator to above ambient level in the surgical area so that the surgeon can hear the activation tone.

8. Position the CUSA Excel and the Force FX Generator so that the control panels are clearly visible to the surgeon at all times. Remove any obstructions that may block the surgeon's view of the control panels.

Disassembly and Disposal

1. Disconnect the CEM nosecone from the electrosurgical generator.

2. Disassemble the CEM nosecone from the handpiece.

3. Discard the CEM nosecone in the patient's biohazard waste container following hospital protocols for biohazardous waste.

Refer to the CUSA Excel User Guide for information on shutting down, disassembling and cleaning the system, and information on disassembling and cleaning the handpiece.

Voluntary Standards

The CEM nosecone meets the following standards:

- IEC 60601-1:2005 - Medical electrical equipment: General requirements for safety.
- EN 60601-1-2:2006 - General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC 60601-2-2:2009 - Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.

<<Translations will be added from

approved baseline English>>

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