

OLYMPUS OES LAPARO-THORACO VIDEO SCOPE TYPE V

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Device Name: Olympus OES Laparo-Thoraco Videoscope Type V, its associated accessories and ancillary equipment

Common/Usual Name: Laparo-Thoraco Videoscope

Classification Name: Endoscope and Accessories
Mediastinoscope and Accessories
Gynecologic Laparoscope and Accessories

Predicate Devices: Olympus Flexible Tip Thoracoscope/ Laparoscope
K942338 & K942339

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Statement of Intended UseOES Laparo-Thoraco Videoscope Type V

The OES Laparo- Thoraco Videoscope Type V has been designed for endoscopic observation, diagnosis and treatment within the thoracic and abdominal cavity.

A4907 Lens Cleaning Sheath

The A4907 Lens Cleaning Sheath has been specifically designed to be used with an OES Laparo-Thoraco Videoscope Type V to clean the objective lens surface.

A4908 Valve

The A4908 Valve has been specifically designed for use in conjunction with the A4907 Cleaning Sheath to provide irrigation and aspiration of liquids when connected to the insertion tube of the Olympus videoscope.

Trocar Tube and Trocars

The trocar tubes are intended to provide a passageway for the endoscope or hand instruments, and permit the insufflation of CO₂ during the endoscopic procedure. The subject trocar tubes are specifically designed to use in conjunction with the OES Laparo-Thoraco Videoscope Type V.

The trocars are intended to pierce the abdominal wall tissue layer during the endoscopic procedure. The subject trocars are specifically designed to use in conjunction with the Laparo-Thoracoscope.

Device Description

OES Laparo-Thoraco Videoscope Type V

The OES Laparo-Thoraco Videoscope Type V is substantially equivalent in design to the predicate Olympus OES LTF Flexible Tip Thoracoscope/Laparoscope which was cleared in 510(k) # K915857. The predicate LTF Flexible Tip Thoracoscope/Laparoscope is a fiberscope. The only difference between these two endoscopes is that the predicate device which has a image guide (fiber bundle) to transmit an endoscopic image to the surgeon's eye or the CCD of of the video camera. The subject device is a videoscope that places the CCD at the distal end of the endoscope. The subject OES Laparo-Thoraco Videoscope Type V has an 11 mm distal tip, 10.6 mm diameter insertion tube, 70° forward viewing field of view, depth of field of 18mm ~100mm, and 90° angulation in all four (Up-Down-Left-Right) directions. It contains the color Charged Couple Devices (CCD) for image transmission to the video monitor.

When compared to the previously cleared predicate scope, the subject OES Laparo-Thoraco Videoscope Type V does not raises any new questions of safety or effectiveness.

A4907 Lens Cleaning Sheath

The A 4907 Lens Cleaning Sheath has been specifically designed for use in conjunction with the Olympus OES Laparo-Thoraco Videoscope Type V. It will be included in the standard set of Laparo-Thoraco Videoscope and will also be marketed separately.

When connected to the main body of videoscope, it offers lens cleaning, irrigation, and suction capabilities to the user during endoscopic procedures. It is substantially equivalent in design, intended use, and method of operation to the "Lens Cleaner" manufactured by Cook, "Optic Shaft" manufactured by Wiest, and "Lap Wash System" manufactured by DevMed Group Inc.

A4908 Valve

The A4908 Valve has been specifically designed for use in conjunction with the Olympus OES Laparo-Thoraco Videoscope Type V and A4907 lens cleaning sheath. It will be included in the standard set of the OES Laparo-Thoraco Videoscope Type V and will also be marketed separately.

The A4908 Valve is substantially equivalent in intended use, functions, and method of use to the T1020 Multiple Function Tube (Irrigation/Suction Probe) which was approved in 510(k) # K923982. Both devices have separate "plunger-like" valves that permit the operator to control when to activate the suction or irrigation function. The housing of design is such that tubing sets are easily connected to the irrigation/suction source.

Additionally, the A4908 Valve is also substantially equivalent in design, material intended use, functions, and method of use to the Olympus MH-325 Valve which was cleared in 510(k) # K915857 with the exception that the A4908 Valve controls the irrigation and suction of liquids. It has separate irrigation port and suction port connections. The irrigation and aspiration functions are controlled by separate buttons.

Trocar Tubes

The A5822 and A5824 trocar tubes have been specifically designed for use in conjunction with the Olympus OES Laparo-Thoraco Videoscope Type V. The 5 mm trocar tube is designed to deliver endoscopic accessories into the abdominal cavity

Model	Diameter	Description
A5820	5 mm	Trocar Tube
A5822	11 mm	Trocar Tube
A5824	13 mm	Trocar Tube

The A5822 and A5824 trocar tubes consist of a metal housing, a stopcock for insufflation of CO₂ gas, and a sealing valve. The A5820 trocar tubes does not have a stopcock for insufflation. The sealing valve is specifically designed to prevent damages to the insertion tube of the OES Laparo-Thoraco Videoscope Type V. It can also be purchased separately. These trocar tubes are substantially equivalent in intended use, functions, and method of use to the Olympus A5273 and A5276 Trocar Tubes with the exception that the predicate trocar tubes have a metal valve (flap or plunger type) while the subject trocar tubes have a medical grade silicone rubber valve. The predicate trocar tubes A5273 and A5276 were cleared in 510(k) # K923982.

Trocars

The following trocars have been specifically designed for use in conjunction with the trocar tubes listed above:

Model	Diameter	Description
A5821	5 mm	Trocar
A5823	11 mm	Trocar
A5825	13 mm	Trocar

General Safety

When compared to the predicate devices, Olympus OES Laparo-Thoraco Videoscope Type V, its associated accessories and ancillary equipment do not incorporate any significant change in intended use, method of operation, material, or design that could affect the safety or effectiveness. device.