

Distributed by



Sustainability Solutions

Instructions for Use









**Reprocessed ENDOSCOPIC TROCARS AND CANNULAS
(SLEEVES)**

Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- STERILE

Explanation of Symbols

-  Federal (U.S.A.) law restricts this device to sale by or on the order of a physician
-  Sterilized by Ethylene Oxide Gas
-  Do not use if package is damaged
-  Catalog or model number
-  Lot Number
-  Use by Date
-  Do not Reuse
-  See Instructions for Use

Endoscopic Trocars and Cannulas Description

Endoscopic trocars and cannulas are designed to provide a port of entry for endoscopic instruments which are used during endoscopic surgical procedures.

Cannulas are available with smooth or threaded sleeves and are available in a selection of models with inner diameters between 5-18 mm and lengths of 70-150mm.

The Trocar/Obturator is available as either a bladed or non-bladed tip (bladeless). Bladed obturators are designed with or without a spring activated safety shield which exposes the blade during insertion and which then retracts the tip once the operative cavity has been penetrated and are available in both pyramidal and flat-edge configurations. Bladeless optical obturators are equipped with a clear tip and a video laparoscopy channel which allows the trocar to be inserted under direct visual guidance.

Following the use of the device within a clinical setting, the device is received and subsequently performed a complete reprocessing of the device including identification, decontamination, cleaning, testing, inspection, packaging, labeling and sterilization with ethylene oxide.

Indications for Use

Reprocessed Endoscopic trocars and cannulas are indicated for use in minimally invasive surgical procedures. These devices are indicated for use to establish a port of entry for endoscopic surgical instruments.

Contraindications for Use

Reprocessed trocars and cannulas are contraindicated in the following situation:

This device is contraindicated any time an endoscopic minimally invasive procedure is also contraindicated.

Warnings and Precautions

- a) These instructions apply to Stryker's distributed endoscopic trocars and cannulas only and are not to be used as instructions for use for any other device or techniques, nor are they intended to be used as instructions for use of the complementary components that may be used in this system. Read and follow the instructions for this device as well as those for the other instruments to be used in combination with this device prior to use.
- b) This device is intended for use by a licensed physician who has a thorough understanding of the techniques and principles of endoscopic procedures and who have received adequate training with endoscopic surgical procedures and, in particular, has received training on the use of trocars and cannulas.
- c) Inappropriate use of this device may result in injury to blood vessels and to the internal organs of the patient, may cause injury to the physician, and/or may cause damage to the medical equipment being used for this procedure. Use extreme caution when inserting this device in to the patient. If further information is required, consult medical literature regarding use, techniques, principle complications and hazards prior to the use of this device.
- d) Careful handling of this device is necessary to avoid damage or breakage. Always inspect the device prior to use to ensure device integrity and do not use the device if any damage is identified.
- e) Do not use this device for any other purpose other than those indicated in these instructions.
- f) Do not insert a second trocar in to the patient until the necessary pneumoperitoneum has been established (typically 12-18 mmHg). Note that failure to maintain pneumoperitoneum during the abdominal procedure may result in injury to internal structures.
- g) Since this device is used along with other devices, prior to use, ensure compatibility with all devices to be used during this surgical procedure. Devices that are smaller in diameter than the obturator may result in desufflation of the abdominal cavity which may result in injury to abdominal organs. In situations where this may exist, use a reducer cap or valve to seal the opening of the body cavity and allow the instruments through the cannula.
- h) To minimize the risk of damage to surrounding tissue, blood vessels and surrounding organs, use extreme caution when inserting the trocar. Use sufficient but not excessive force when inserting the trocar. For the best results, position the patient in such a way as to avoid damage to major blood vessels and other anatomic structures. Note that greater insertion force will be required if the incision is too small and if the incision is too large, the port may become unstable.
- i) To avoid damage to the trocar and/or cannula, never insert the trocar in to the cannula at an angle.
- j) When using bladed surgical instruments, use extreme care when inserting the instrument through this device so as not to damage the internal gaskets, the cannula valve and/or the seal as such may result in desufflation of the operative cavity.
- k) To prevent the premature dislodging of the cannula, use care when removing instruments.
- l) As standard operating procedure follow all precautions typically utilized during minimally invasive laparoscopic procedures.

Adverse Reactions

- a) Bleeding
- b) Peritonitis
- c) Superficial lesions
- d) Injury to the abdominal wall
- e) Injury to internal vessels
- f) Hematoma
- g) Infection

Directions for Use***General***

- a) Store endoscopic trocars and cannulas away from moisture and direct heat.
- b) Do not use expired devices. If the expiration date has passed, either return the device to Stryker for consideration to be reprocessed or discard the device.
- c) Select the device to be used based upon its internal diameter and length, bladed or non-bladed configuration, threaded or non-threaded cannula and function that will be the most appropriate for the patient and the procedure.

Packaging

- a) Inspect the packaging before opening. Since the contents of this package are intended to be sterile, if the package has been damaged or compromised in any way, do not use this device as sterility may be compromised. Return the device with this packaging to Stryker. Stryker will evaluate whether or not the device can be successfully reprocessed for another single use.
- b) If the packaging has been opened or compromised, but the device has not been used, do not attempt to re-sterilize the device and do not use this device on a subsequent procedure. Return the device with this packaging to Stryker. Stryker will evaluate whether or not the device can be successfully reprocessed for another single use.
- c) The packaging of this device contains removable labels which can be affixed to the patient's medical records file.

Device Inspection

- a) With the use of sterile technique, remove the device from the packaging.
- b) Inspect the device to ensure its physical integrity. If the device is damaged in a way that would make it unacceptable for surgery, do not use the device. Return the damaged device along with this packaging to Stryker for evaluation.
- c) Prior to utilizing the device, verify the overall compatibility of the device with its complimentary accessories.

Device Usage

- a) Prepare the patient pre-operatively according to standard procedures.
- b) Using sterile technique, remove the device from its packaging, place it in a sterile work area and use caution to avoid contact with the sharp edges of the trocar.
- c) Certain models may be packaged with a plastic tip protector. If this device contains a plastic tip protector, remove it prior to use.
- d) Follow suitable surgical protocol throughout this procedure.
- e) The trocar is designed with a stopcock. During insertion of the trocar into the patient, always turn the stopcock into the closed position to prevent desufflation.
- f) After creating an incision of appropriate size through which this device will enter the patient, use your finger to inspect the incision and ensure that the cavity can be entered.
- g) When introducing the trocar in to the patient, use continuous and controlled pressure. Do not use excessive force.
- h) Note that when using Ethicon Trocars, you must push down on the red switch on the obturator handle to disengage the shield.
- i) When using shielded trocars, note that when you apply downward pressure on the trocar, the shield should disengage and retract to expose the distal blade. Once the device has passed the abdominal or thoracic walls, the shield will once again engage and will lock to cover the blade.
- j) Once the trocar is positioned with the abdominal or thoracic cavity, remove the obturator and leave the cannula in place to serve as a port of entry for other surgical instruments.
- k) Establish the primary puncture site and if insufflation of the operative cavity is necessary, attach a gas line to the stopcock. Open the valve and adjust the flow of gas as needed.
- l) Do not reuse or re-sterilize this device. Return the used device to Stryker in the collection containers provided to your facility.

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:

Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.