



Instructions for Use
Reprocessed Endoscopic Trocars and Cannulas (Sleeves) – Rev 7-6-2020

- a) This device has been reprocessed by Green OR
- b) This device is a reprocessed device designed for an additional Single Use.
- c) This device has been sterilized using Ethylene Oxide Gas. Do not use this device if the packaging has been prematurely opened or damaged.
- d) Federal law restricts this device to sale by or on the order of a licensed physician.
- e) To ensure the safe and effective use of this device, read the Instructions for Use in its entirety prior to using this device.
- f) For further information regarding this device, contact Green OR at 1-866-783-6006.

Device 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 this device within a clinical setting, Green OR received this device and subsequently performed a complete reprocessing of the device including identification, decontamination, cleaning, refurbishing, testing, inspection, packaging, labeling and sterilization with ethylene oxide.

Indications for Use:

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) Original Equipment Manufacturers (OEMs) provide Instructions for Use (IFUs) with the original device. When a health facility reprocesses that original device through a third-party FDA registered reprocessing company, the health facility needs to keep the original OEM IFU as this original OEM IFU, and any materials associated with it, supersede all other instructions.
- b) These instructions apply to Green OR's 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.
- c) 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.

- d) 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.
- e) 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.
- f) Do not use this device for any other purpose other than those indicated in these instructions.
- g) 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.
- h) 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.
- i) 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.
- j) To avoid damage to the trocar and/or cannula, never insert the trocar in to the cannula at an angle.
- k) 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.
- l) To prevent the premature dislodging of the cannula, use care when removing instruments.
- m) 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

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 Green OR 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 Green OR. Green OR 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 Green 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 Green OR for evaluation.
- c) Prior to the 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.

- e) Injury to internal vessels
- f) Hematoma
- g) Infection
- 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 Green OR in the collection containers provided to your facility.

Note: The names of other companies and products which may have been mentioned herein may be trademarks of their respective companies

Note: Green OR is not liable for any damages caused by any defect in material, design or workmanship by the OEM or by any act of omission by the OEM.

Packaging Symbols:

	Production batch number
	Green OR, LLC's part number
	Quantity of devices in package
	Manufacturer
	Date of manufacture
	Date of expiry
	Sterilized using ethylene oxide
	Caution, consult accompanying documents
	Do not reuse
	Do not re-sterilize