

Reprocessed by



Instructions for Use
Reprocessed Laparoscope Accessories
(Scissors, Dissectors, Graspers)


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 Icons


 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

REF Ascent Product Code

 Do Not Reuse

 See Instructions For Use

Reprocessed Laparoscope Accessories

Laparoscope Accessory Description

Laparoscope accessory instruments consist of a rigid plastic handpiece with loop handles connected to the distal end effector jaw by an elongated, narrow-diameter insulated shaft. The devices are designed to be inserted through an appropriately sized trocar sleeve or cannula. The jaws are operated by the handpiece loop handles and may be shaped as scissors, dissectors or graspers. The jaws of some models may be rotated by manipulating controls on the handpiece. Grasper models may feature ratchet jaws to lock and hold tissue, again operated at the handpiece.

Indications for Use

Reprocessed Laparoscope Accessories are indicated for use during a variety of minimally invasive procedures including gynecologic, general, urologic, thoracic and endoscopic procedures to facilitate temporary grasping, clamping, mobilization, dissection, and transection of tissue.

Contraindications for Use

Reprocessed laparoscope accessories are contraindicated in the presence of the following conditions:

- Any other conditions contraindicated for minimally invasive techniques.

Warnings

- These instruments are only intended for use by individuals with adequate training and familiarity with minimally invasive techniques. For further information about techniques, complications and hazards, consult the medical literature.
- Damage to the instrument can lead to injuries. Always inspect instrument carefully before use for overall integrity.
- Employing instruments when the blades or jaws are not fully visible can result in unintended tissue damage.
- Verify hemostasis after withdrawing instrument. If bleeding is still observed, employ appropriate techniques to achieve hemostasis.
- Monitor patients closely for possible gas embolism when performing laparoscopic surgery.
- Avoid excessive clamping pressure that could cause damage to tissue.

Precautions

- If using instruments from different manufacturers, verify compatibility of instruments before use to avoid complications during surgery.
- To avoid damage to patient, to operator or to instrument, become familiar with a specific instrument and its clamping or cutting mechanism prior to employing it in a surgical procedure.
- Careful handling of instruments is necessary to avoid damage or breakage as a result of excessive force.
- Instruments were designed for cutting soft tissue. Attempting to cut staples or clips may damage the instrument.

Adverse Reactions

None.

Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Before beginning the procedure, verify compatibility of all instruments and accessories.
3. Inspect the package before opening. The contents of the package are sterile if the package has not been compromised. Do not use the instrument if the sterility has been compromised. If the package is damaged or if it was opened and the instrument not used, return the instrument and packaging to Ascent Healthcare Solutions.
4. Do not attempt to resterilize.
5. Remove the device from the packaging restraints using aseptic technique.
6. Remove the plastic tip protector that protects the scissor blades or dissector jaws.
7. Laparoscopic devices with ratchet switches are shipped in the 'locked' position. To release locking mechanism, press the grey ratchet switch located on the device handle. Do NOT rotate the ratchet switch.
8. Inspect the instrument for overall condition and physical integrity. Do not use the instrument if any damage is noted. Return the instrument and packaging to Ascent Healthcare Solutions if it is not in acceptable condition for surgery.
9. Using a standard endoscopic technique, insert the instrument through an appropriately sized cannula and direct the instrument to the desired site.
10. To rotate the blades or jaws of the instrument, turn the knob at the base of the shaft. For some models, the knob must be pushed forward to allow rotation.
11. For scissor instruments, cut along the distal two-thirds of the blade length.
12. For some clamping instruments, the jaws can be clamped or locked onto tissue using the ratchet ON/OFF switch on the handle. Manipulate the instrument so that the desired tissue is between the jaws or blades of the instrument and

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press the switch to the ON position. Do NOT rotate the ratchet switch. Compress the handles until the jaws are in the desired position. The jaws can be closed or tightened further by compressing the handles again, but the jaws cannot be opened or loosened while the ratchet switch is in the ON position.

13. Moving the ratchet switch to the OFF position will allow the tissue to be released from the jaws. For some instruments, the handles must be compressed to disengage the ratchet mechanism before the blades or jaws will open.
14. Follow a suitable surgery protocol.
15. Close blades or jaws before attempting to withdraw instrument through the cannula. Visualize fully to avoid trapping tissue between the jaws of the instrument and causing inadvertent damage. Pull the instrument straight out through the cannula, avoiding lateral pressure that may damage the working tip.

Storage and Handling

- Temperature: -22° C to 60° C
- Relative humidity: 0% to 80%

Warranty

Ascent Healthcare Solutions (**ASCENT**) will reprocess medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations and the ISO 13485:2003 standard for medical devices and the Canadian Medical Device Regulation designation.

ASCENT warrants the sterility of reprocessed medical instruments unless the packaging of the medical instrument has been opened or damaged, or the expiration date has been exceeded. ASCENT warrants the functionality of reprocessed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any reprocessed Medical Device, and the obligation to use the same, if at all, in accordance with such Device's instructions for use.

ASCENT shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY, PHYSICIANS AND CLINICIANS shall become legally obligated to pay as damages caused by bodily injury to patients as a result of ASCENT's negligent performance of services under this Agreement. This indemnity and hold harmless obligation shall not apply to damages arising out of misuse of medical instruments which are the subject of this Agreement. ASCENT shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of ASCENT and ASCENT makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

Ascent does not warrant reprocessed (in full or in part) Medical Devices that have been or will be resold, modified or treated by Medical Facility or any other party.

This Warranty is in lieu of and excludes all other warranties not expressly set forth herein.

Only Ascent Healthcare Solutions bears the responsibility for this device. 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.