

Reprocessed by









Instructions for Use Reprocessed Electrosurgical Laparoscopic/Endoscopic Instruments

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
	Ascent Product Code
	Do Not Reuse
	See Instructions For Use

Reprocessed Electrosurgical Laparoscopic/Endoscopic Instruments

Reprocessed Electrosurgical Laparoscopic/Endoscopic Instruments Description

Electrosurgical laparoscopic/endoscopic instruments are electrosurgical instruments consisting of a rigid plastic handpiece with loop handles connected to the distal end scissors or jaws by an elongated, narrow-diameter insulated barrel or 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. An on/off ratchet handle is available for grasper instruments to lock instrument handles in the closed position.

The blades or jaws of electrosurgical laparoscopic/endoscopic instruments can deliver a cauterizing current that enters the instrument through the unipolar cautery connector on the handpiece, runs down the insulated shaft and through the tissue in the blades or jaws. Monopolar electrocautery is possible only with instruments equipped with a cautery pin in conjunction with a compatible electrosurgical unit and patient grounding pad.

Indications for Use

Reprocessed unipolar laparoscopic/endoscopic instruments, including scissors, dissectors and graspers, are to be used for patients requiring minimally invasive surgical procedures to manipulate and manage internal soft tissue by grasping, cutting, dissecting, cauterizing or coagulating tissue.

Contraindications for Use

Reprocessed electrosurgical laparoscopic/endoscopic instruments are contraindicated for:

- Contraceptive coagulation of fallopian tissue.
- Other conditions contraindicated for minimally invasive techniques.

Warnings

- Package is provided sterile by method of ethylene oxide gas and is for single patient use only. Do not use if there is any evidence of damage to the package.
- These instruments are only intended for use by individuals with adequate training and familiarity with minimally invasive surgical techniques. For further information about techniques, complications and hazards, consult the medical literature.
- The use of these instruments requires a thorough understanding of the techniques and principles of electrosurgical procedures. Inappropriate use may result in shock and burn hazards to both patient and physician or damage to medical equipment.
- Accidental burns to the operator can be prevented by wearing protective gloves during electrocautery. To avoid patient injury or equipment damage, the electrosurgical unit should be switched OFF while inserting, removing or positioning the instrument.
- Damage to the instrument or the insulation can lead to shock and burn injuries. Always inspect instrument carefully before use for overall instrument integrity and for integrity of the insulation and grounding.
- Electrosurgical generators with a high frequency voltage as high as 3000 volts may be used with these instruments. The electrosurgical generator's specifications must be consulted for indications and instructions and to verify compatibility. Follow all safety instructions provided by the electrosurgical generator's manufacturer.
- The higher the voltage, the higher the risk of capacitive coupling and inadvertent burning. Set the voltage (power) at the lowest possible setting that provides the desired surgical effect.
- Activating an electrosurgical device when it is not in contact with target tissue may cause capacitive coupling and inadvertent burning.
- If, during surgery, there is a drop in the power level without any change being made to the settings of the generator, the electrical circuit should be checked for faults, paying close attention to the ground plate, before the power setting is raised.
- Do not directly apply electrosurgical current to staples or clips.
- 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.
- Electrosurgery should not be employed in high-oxygen concentration environments or in the presence of flammable gases or other flammable materials.
- Electrocautery can disrupt a pacemaker or other medical equipment, such as electrocardiograph, pulse oximeter, endoscopy photo exposure circuit.

Reprocessed Electrosurgical Laparoscopic/Endoscopic Instruments

Precautions

- If using instruments from different manufacturers, verify compatibility of instruments before use to avoid complications during surgery.
- To avoid damage to the patient, operator or instrument, become familiar with specific instruments and their clamping or cutting mechanism prior to employing in surgical procedures.
- To ensure all safety precautions are followed, refer to appropriate electrosurgical system manual.
- 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.
- If the instrument is used through a trocar sleeve, do not introduce or withdraw with open blades or jaws.
- Never submerge electrosurgical instruments in liquid. The resulting damage to the instrument can lead to malfunction and injury.
- Instruments are designed for monopolar cautery. Do not attempt to use as bipolar cautery instruments.
- To avoid compromising the insulation, do not bend or strain instrument shaft.
- Do not attempt to attach bipolar cables in the place of monopolar cables.
- Do not use these, or any electrosurgical instruments, with a cable that does not make good, secure contact with the electrosurgical adapter of the instrument or the electrosurgical generator.
- Do not coil or loop electrosurgical cables or hang a looped cable on a metal object such as the operating room table or IV pole.

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 packaging 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 package 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 the insulation has been compromised or 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 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 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 and 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 switch is in the ON position.
12. 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.
13. Verify that the electrosurgical generator is switched OFF or is in standby mode. Connect the instrument to an appropriate electrosurgical generator (refer to generator manual) with compatible cables intended for unipolar cautery. Turn the generator ON and set the power output to the lowest possible setting that provides the desired surgical effect.
14. Follow a suitable endoscopic surgery protocol.
15. Deactivate instrument and close blades or jaws before attempting to withdraw instrument through the cannula. View the distal tip of the instrument fully to avoid trapping tissue between the jaws of the instrument and causing inadvertent damage. Pull the instrument straight out through the cannula and avoid lateral pressure that may damage the working tip.

Storage and Handling

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

Reprocessed Electrosurgical Laparoscopic/Endoscopic Instruments

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.