

Reprocessed by



Instructions for Use Reprocessed Ultrasonic WAVE™ Coagulating Shears


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 Ultrasonic WAVE™ Coagulating Shears

Device Description

The reprocessed Ultrasonic WAVE™ Coagulating Shears (hereinafter Ultrasonic Coagulating Shears) with Scissor Handle and Hand Control is an instrument consisting of a scissor handle housing assembly with hand control buttons (MIN for minimum power level and MAX for maximum power level). The handle housing has an audible/tactile mechanism for indicating full closure. The device has a straight blade and clamp arm and is designed to function through an incision without the use of a trocar. The device is 18 cm long with a shaft diameter of 8.5mm and an active blade length of 18mm.

The Ultrasonic Coagulating Shears allow for the cutting and coagulation of vessels up to and including 5mm in diameter.

The Ultrasonic Coagulating Shears are designed for use exclusively with the Harmonic™ Generator 300 (GEN04) and Hand Piece (HP054). Before using this device, refer to the Harmonic™ Generator 300 Operators Manual.

The Ultrasonic Coagulating Shears are to be used with only the green single-use torque wrench (TWGREEN) or equivalent torque wrench. The torque wrench should not be discarded until the completion of a surgical case. In the event the torque wrench falls out of sterile field, replace with a sterile torque wrench (TWGREEN). Do not attempt to sterilize the single-use torque wrench.

Note: Use of torque wrenches other than TWGREEN or equivalent may result in damage to the device.

Indications for Use

The Reprocessed Ultrasonic Coagulating Shears with Scissor Handle and Hand Control are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The shears can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures and other open procedures.

Contraindications for Use

- The instrument is not indicated for incising bone.
- The instrument is not intended for contraceptive tubal occlusion.

Warnings and Precautions

- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive procedures. Review medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may differ in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together, verify compatibility prior to initiation of the procedure.
- A comprehensive understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Make certain that electrical insulation or grounding is not compromised. Do not submerge instruments in liquid unless the instruments are designed and labeled to be immersed.
- Confirm compatibility with generators. Ultrasonic WAVE™ instruments are compatible only with the Harmonic™ Generator 300 (GEN04). They are not compatible with the UltraCision Generator (GEN01/GEN32).
- Ensure the availability of the appropriate back up equipment relevant to the specific procedure, in case of system failure.
- Audible high-pitched tones, resonating from the blade or hand piece, is an indicator that the blade or hand piece is not operating properly. The tones may be an indicator that the hand piece is beyond its useful life or that the blade has not been attached properly, which may result in abnormally high shaft temperatures and user or patient injury.
- Blood and tissue buildup between the blade and shaft may cause high temperatures at the distal end of the shaft. Remove any visible tissue buildup at the distal end of the shaft, to prevent burn injury.
- With all energy sources (Electrosurgery, Laser, or Ultrasound), there are concerns about the carcinogenic and infectious potential of the by-products, such as tissue smoke plume and aerosols. Appropriate measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- Do not bend, sharpen or otherwise alter the shape of the blade. Altering the device may cause blade failure and user or patient injury.
- While not in use, to avoid user or patient injury in the event that accidental activation occurs, the instrument blade, clamp arm, and distal end of the shaft should not be in contact with the patient, drapes, or flammable materials. During

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prolonged activation in tissue, the blade, clamp arm, and distal 7cm of the shaft may become hot. Avoid contact with tissue, drapes, surgical gowns, or other unintended sites at all times.

- Incidental and prolonged activation next to solid surfaces, such as bone, may result in blade heating and subsequent blade failure, and should be avoided.
- When the device is activated, avoid contact with any and all metal or plastic instruments or objects. While the device is activated, contact with staples, clips, or other instruments may result in cracked or broken blades, which may be identified by generator solid tone or instrument error.
- Care should be taken not to apply pressure between the device and tissue pad without having tissue between them. This can result in potential damage to the device as well as increase the temperature of the distal 7 cm of the shaft. Both conditions may cause a system failure signaled by a continuous beep when either of the foot pedals or hand controls buttons are depressed.
- To avoid damage to the tissue pad, keep the clamp arm open while the blade is active without tissue between the blade and tissue pad.
- The entire exposed blade tip is active and will cut/coagulate tissue when the device blade is activated. Be careful to avoid inadvertent contact between all exposed blade surfaces and surrounding tissue when using the Ultrasonic Coagulating Shears.
- Use only the Harmonic™ Foot Switch, Hand Piece, Instruments, and power cord to ensure that they are compatible with the Generator.
- Adjust MIN power to level 2 or lower for optimal hemostasis on vessels greater than 3mm. After removing the device, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- When using instruments on solid organs, use caution. Due to the limited ability of the device to grasp large portions of solid organs and occlude vascular structures of this nature, hemostasis may not be predictable and may require adjunct measures for coagulation.
- Devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- **This device is packaged and sterilized for single use only.**

Adverse Reactions

None.

Directions for Use

The package label is detachable and may be affixed to the medical record of the patient.

Verify compatibility of all instruments and accessories prior to using the instrument (refer to **Warning and Precautions**).

1. Remove the instrument from the package using sterile technique. To avoid damage, do not flip the instrument into the sterile field.

Assembly

2. Attach the hand piece to the device by rotating the device onto the hand piece in a clock wise rotation as viewed from the distal end of the device (finger tight only).
3. Use the torque wrench to tighten the blade onto the hand piece. Slide the torque wrench up the shaft, rotating as necessary to engage ribs on the internal knob of the shaft, Turn the torque wrench clockwise while holding only the silver hand piece until it snaps twice indicative that sufficient torque has been applied to secure the blade.

Note: Do not use any other means than the torque wrench to attach or detach the device from the hand piece.

Note: Do not torque the device by hand or damage may occur to the hand piece.

Note: Hold only the silver hand piece and not the shears handle while applying the torque wrench.

4. Remove the tip protector and discard, Remove the torque wrench by sliding it off the shaft. Do not dispose of the torque wrench until completion of the procedure as it is used for removal of the instrument from the hand piece following the procedure. Dispose of the torque wrench only after completing the procedure.

Note: Take care to avoid damage to the blade and clamp arm by closing the trigger while sliding the torque wrench onto or off the shaft.

Note: Take care to avoid injury from the blade tip while sliding the torque wrench onto or off of the shaft.

Operation

See the Harmonic™ Generator 300 Operator's Manual (GEN04) for hand piece attachment and system operations instructions.

1. Connect the assembled hand piece and device to the generator and turn the generator power on. **Note: Do not turn the generation power on before the hand piece and device are connected to the generator.**

2. Select the desired MIN power level using the INCREASE and DECREASE buttons on the generator.

Note: MIN power is defaulted at power level 3.

Caution: Adjust MIN power to level 2 or lower for optimal hemostasis on vessels greater than 3mm.

For greater tissue cutting speed use a higher generator power level, and for greater coagulation use a lower generator power level. The amount of energy delivered to the tissue and resultant tissue effects are a function of many factors, including the power level, blade characteristics, grip force, tissue tension, tissue type, pathology, and surgical technique.

3. For hand control function, select the hand activation button on the generator. The hand activation button on the generator must be illuminated for the Ultrasonic WAVE™ hand control buttons to be active. Refer to the Harmonic™ Generator 300 (GEN054) Operator's Manual for setup and operation instructions.

4. Remove the generator from stand-by by depressing the stand-by button on the generator.

5. System check and activation: Each time the generator is activated after exiting Standby, hold the device in air with clamp arm open and depress the MIN and MAX power level on the foot switch or hand control button. "TEST IN PROGRESS" will appear on the graphic display and a rapid two-pulse will sound while the test is occurring. During this five-second period, a system check is being performed.

Note: Failure to have the jaws open during activation may result in a false message from the generator.

6. For optimal performance and to avoid tissue sticking, clean the device blade, clamp arm, and distal end of the shaft throughout the procedure by activating the instrument tip in sterile saline.

Note: Do not touch the device to metal while activated.

Note: Do not clean the blade tip with abrasives. Wipe the blade tip with a sterile moist gauze sponge to remove tissue, if necessary.

If tissue is still visible in the clamp arm, use hemostats to remove residue with the generator in standby mode.

7. The blade is ultrasonically energized when either the foot switch pedal is depressed or one of the hand control buttons is depressed. Pressing the left foot pedal of the footswitch or the proximal hand control button (MIN) on the Ultrasonic Coagulating Shears activates the selected minimum power level. Pressing the right foot pedal of the footswitch or distal hand control button (MAX) on the Ultrasonic Coagulating Shears activates the maximum power level.

8. **Note: Scratches on the blade may lead to premature blade failure.**

- Avoid contact with other devices during use.

- Do not use any other means than the torque wrench to attach or detach the device or the hand piece.

9. Close the clamp arm by closing the trigger and finger ring together and insert the shaft through the incision.

Note: Optimum instrument performance is achieved with full trigger closure. An audible/tactile click indicates full trigger closure. A second click is heard and/or felt when full trigger closure is lost due to a decreased grip force. If full trigger closure is released prior to or during activation on tissue, increase grip force until full trigger closure is achieved.

10. The Ultrasonic Coagulating Shears can be used for dissection, grasping, coagulation, and cutting between the blade and clamp arm.

Note: Refer to Warnings and Precautions section for proper use.

Disassembly

1. Turn the generator OFF at the power switch or use Standby mode.

2. Close up the clamp arm and slide the torque wrench over the distal end and up the shaft until the wrench aligns with the ribs in the internal knob.

Note: To avoid injury from the blade tip, take care while sliding the torque wrench onto or off of the shaft.

3. Loosen the device by turning the wrench counterclockwise. Continue to loosen by turning the device manually to completely remove the instrument from the hand piece.

4. Remove the torque wrench by pulling it straight back over the device blade.

Note: Hold only the silver hand piece and not the Ultrasonic Coagulating Shears handle while using the torque wrench.

Note: Take care to avoid damage to the device blade and clamp arm by closing the trigger while sliding the torque wrench onto or off of the shaft.

5. Place the device and the torque wrench in an appropriate used device collection container.

How Supplied

The Ultrasonic Coagulating Shears with Scissor Handle and Hand Control is supplied sterile for single patient use. Each device is shipped with one sterile, single patient use, torque wrench.

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Storage and Handling

- Store at room temperature.
- Avoid prolonged exposure to elevated temperatures.

The user facility is responsible for providing personal protective equipment (PPE) for all service personnel. Such equipment should comply with OSHA regulations, and can include protective gloves, liquid-resistant clothing, face shields, and surgical face masks. PPE should be worn whenever an individual might be exposed to infectious agents..

Additionally, personnel who might be exposed to infectious agents should receive training on how to recognize potentially unsafe conditions, when and how to use safety equipment, and how to decontaminate surfaces when this is practical. As an additional safety measure, the user facility should offer hepatitis B vaccinations to their service staff. Any questions regarding these instructions should be forwarded to the Ascent Healthcare Solutions Account Service Representative or the Ascent Healthcare Solutions corporate office at 1.888.888.3433.

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.

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