

Reprocessed by



## Instructions for Use Reprocessed Ultrasonic Focus™ Curved 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

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 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

**REF** Ascent Product Code

 Do Not Reuse

 See Instructions For Use

## Reprocessed Ultrasonic Focus™ Curved Shears

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### Device Description

The reprocessed Ultrasonic FOCUS™ Curved Shears (hereinafter Ultrasonic Curved Shears) 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 instrument has a working length of 9cm, an active blade length of 16mm, and utilizes a curved blade and clamp arm. The Ultrasonic Curved Shears device allows for the cutting and coagulation of vessels up to and including 5mm in diameter.

The Reprocessed Ultrasonic Curved Shears with torque wrench and grip assist are compatible with the Harmonic™ Generator 300 (GEN04) and Harmonic™ Blue Hand Piece (HPBLUE), packaged separately. Refer to the Harmonic™ Generator 300 Operator's Manual before using this instrument and the Instructions for Use of the Harmonic™ Blue Hand Piece and Test Tip (TTBLUE).

Use only the Blue Torque Wrench (TWBLUE) or equivalent torque wrench and Blue Grip Assist (GABBLUE) or equivalent grip assist.

The Blue Torque Wrench and Blue Grip Assist should not be discarded until the completion of a surgical case. In the event the Blue Torque Wrench falls out of sterile field, replace with a sterile Blue Torque Wrench (TWBLUE). Do not attempt to sterilize the Blue Torque Wrench. Replace the Blue Grip Assist (GABBLUE) if it happens to fall out of the sterile field with a sterile Blue Grip Assist.

### Indications for Use

The Reprocessed Ultrasonic Curved Shears is indicated for soft tissue incisions when bleeding control and minimal thermal injury is desired. The device 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

Reprocessed Ultrasonic Curved Shears are contraindicated for the following uses:

- Incising bone
- Contraceptive tubal occlusion

### Warnings and Precautions

- These instruments are only intended for use by individuals with adequate training and familiarity with techniques associated with the surgical procedure employed. For further information about techniques, complications and hazards, consult the medical literature.
- Prior to the initiation of the procedure, verify compatibility of minimally invasive instruments and accessories when they will be used together since there may be variations from manufacturer to manufacturer.
- The use of these instruments requires a thorough understanding of the techniques and principles of laser, electrosurgical, and ultrasonic procedures. Inappropriate use may result in shock and burn hazards to both patient and medical personnel or damage to the device or other medical instruments. Check and ensure electrical insulation or grounding is not compromised. Do not immerse instruments in liquid unless it is designed and stated.
- The Reprocessed Ultrasonic Curved Shears are only compatible with the Harmonic™ Generator 300 (GEN04)
- Use the Harmonic™ foot switch, Blue Hand Piece, and the Blue Grip Assist to ensure compatibility with the generator.
- In case of system failure, arrange for the availability of appropriate back up equipment relevant to the specific procedure.
- Audible high-pitched tones, resonating from the blade or hand piece, are an abnormal condition and 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, and may result in abnormally high shaft temperatures and user or patient injury.
- High temperatures at the distal end of the shaft can occur due to blood and tissue buildup between the blade and shaft. Remove any visible tissue to prevent burn injury.
- Measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures to address the concerns with the carcinogenic and infectious potential of the by-products (tissue smoke plume and aerosols) of electrosurgery, laser and ultrasound energy sources.
- Do not sharpen, bend, or alter the shape of the blade as it can result in blade failure and user or patient injury.
- While not in use, the instrument's blade should be kept out of contact with the patient, drapes, or flammable materials in the case that accidental activation occurs.
- During prolonged activation, the blade, the clamp arm, and the distal end of the shaft may become hot. At all times

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- avoid unintended contact with tissue, drapes, surgical gowns, or other unintended sites.
- Avoid contact with any and all metal or plastic instruments or objects during instrument activation. Contact with staples, clips, or other instruments during instrument activation may result in premature blade failure, resulting in generator solid tone or instrument error.
  - Avoid incidental and prolonged activation against solid surfaces (such as bone), which may result in blade heating and/or blade failure.
  - Take care to avoid application of pressure between the blade and tissue pad without tissue in between them as this can result in damage to the instrument. Both conditions may cause a system failure signaled by a continuous beep when either of the foot pedals or hand controls buttons are depressed.
  - When the instrument blade is activated the blade tip is active and will cut and coagulate tissue. Care must be taken to avoid unintentional contact between the blade surfaces and surrounding tissues.
  - The instruments Minimum starting power level defaults to power level 3.
  - Verify hemostasis after withdrawing instrument. If bleeding is still observed, employ appropriate techniques to achieve hemostasis.
  - When using the Reprocessed Ultrasonic Curved Shears on solid organs, use caution. Due to the limited ability of the shears to grasp large portions of solid organs and occlude vascular structures of this nature, hemostasis may not be predictable and may require additional measures for coagulation.
  - Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination. Special disposal handling techniques may be needed to prevent biological contamination if instruments or devices come into contact with bodily fluids.

### Directions for Use

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

### Assembly

1. Inspect the instrument and package before opening. The contents of the package are sterile if the packaging has not been compromised. If the package is damaged or if it was opened and the instrument was not used, return the instrument and package to Ascent Healthcare Solutions.
2. Remove the instrument from the package and place it in a sterile work area using aseptic technique.
3. 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.
4. Attach the Blue Grip Assist on the Hand Piece to the instrument by rotating the instrument onto the Hand Piece in a clock wise rotation as viewed from the distal end of the instrument (finger tight only).
5. The Blue Torque wrench is used to tighten the instrument onto the Hand Piece. Use the Grip Assist to hold the Hand Piece and not the instrument handle when applying the Blue Torque Wrench. Turn the Blue Torque Wrench clockwise while holding the Hand Piece with the Grip Assist until it snaps twice indicative that sufficient torque has been applied to secure the instrument.  
**Note:** Do not use any other means than the Torque Wrench and Grip Assist to attach or detach the device from the Hand Piece.  
**Note:** Do not hand torque, damage to the Hand Piece may occur.
6. Carefully remove the Blue Torque Wrench and Blue Grip Assist from the Hand Piece. Do not dispose of the Blue Torque Wrench and Grip Assist until completion of the procedure as it is used for removal of the instrument from the Hand Piece following the procedure.
7. **Note:** Take care to avoid damage to the blade while sliding the Blue Torque Wrench onto or off the shaft.
8. **Note:** Take care to avoid injury from the blade tip while sliding the Blue Torque Wrench onto or off of the shaft.

### Operation

Refer to the Harmonic™ Generator 300 Operator's Manual (GEN04) for Hand Piece attachment and system operations instructions.

1. Before beginning the procedure, verify compatibility of all instruments and accessories.
2. The generator power may be turned ON after the assembled Hand Piece and Instrument have been connected to the generator.
  - a. **Note:** Ensure the Hand Piece and instrument are connected to the generator before turning on the power.
3. Select the desired MIN power level using the INCREASE and DECREASE buttons on the generator.
  - a. **Note:** MIN power is defaulted at power level 3.
4. Higher generator power level is warranted for greater tissue cutting speed 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

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many factors, including the selected power level, blade characteristics, grip force, tissue tension, tissue type, pathology, and surgical technique.

5. The instrument operates with either the foot switch or hand control. To operate using hand control, select the hand activation button on the generator. The hand activation button will be illuminated on the generator for the hand control buttons to be active. For further detailed and operation instruction, refer to the Generator 300 (GEN04) Operator's Manual.
6. The stand-by button on the generator should be depressed to remove the generator from stand-by.
7. Clean the instrument blade and clamp arm throughout the procedure by activating the tip in a sterile saline solution for optimum performance.
  - a. **Note:** Take care not to touch the activated instrument to metal.
  - b. **Note:** The instrument may be wiped with a sterile moist gauze sponge to remove tissue but do not clean the instrument with abrasives.
8. Place the generator in Standby mode to remove visible tissue in the clamp arm, use hemostats to remove the tissue. Depress the standby button on the generator to return the instrument into use.
9. Depress one of the foot pedals or one of the hand control buttons to ultrasonically energize the instrument blade.
10. The selected minimum power level is activated by pressing the left foot pedal of the footswitch or the proximal hand control button (MIN). The selected maximum power level is activated by pressing the right foot pedal of the footswitch or distal hand control button (MAX).
11. **Note:** Premature blade failure could occur from scratches on the blade.
  - a. When instrument is in use, avoid accidental contact with other instruments.
  - b. Use only the Torque Wrench to attach or detach the instrument from the hand piece.
12. Close the clamp arm by closing the finger rings together and insert the shaft through the incision.
13. The Reprocessed Ultrasonic Curved Shears can be used for dissection, grasping, coagulation, and cutting between the blade and clamp arm.
14. For backcutting, use the top of the blade.
  - a. **Note:** When backcutting, or while the blade is active without tissue between the blade and tissue pad, keep the clamp arm open to avoid damage to the tissue pad.

### Disassembly

1. At the power switch turn the generator OFF or enter the Standby mode.
  - a. Close the clamp arm and place the Torque Wrench over the distal end of the shears.
  - b. **Note:** Take care to avoid injury from the blade tip while placing the Torque Wrench onto or off of the shears.
2. Attach the Blue Grip Assist on the Hand Piece and loosen the instrument by turning the Torque Wrench counterclockwise. Continue to loosen by turning the instrument manually to completely remove the instrument from the Hand Piece.
3. Remove the Torque Wrench.
4. Dispose of the Torque Wrench, Grip Assist and the instrument in an appropriate container.

### Storage and Handling

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

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### 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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