Reprocessed by

Sustainability Solutions

Instructions for Use
Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology

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

STERILE EO	Sterilized by Ethylene Oxide Gas
	Date of Reprocessing
	Use by Date
REF	Product Code
	Do Not Reuse
	See Instructions For Use

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Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology

HARMONIC ACE® Shears without Adaptive Tissue Technology Description
Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology (HAR23, HAR36) are sterile, single patient use instruments consisting of an ergonomic grip housing assembly with hand control buttons (MIN for minimum power level and MAX for maximum power level).

An integrated audible and tactile mechanism in the grip housing indicates full trigger closure. The instruments have a clamp arm and coated curved blade that are designed to work through a 5 mm trocar, through a 5 mm reducer cap in a larger diameter trocar, or through an incision without the use of a trocar. The instrument shafts can be rotated 360° to facilitate visualization and access to targeted tissue. The instruments allow for the coagulation of vessels up to and including 5mm in diameter.

Each instrument is shipped with one sterile, single-use, disposable torque wrench. Use only the gray torque wrench provided with the instrument. The torque wrench should not be discarded until the completion of the surgical case. Do not attempt to sterilize the disposable torque wrench.

Note: Adaptive Tissue Technology features have been disabled on this device. Upon connection of the device to Ethicon Endo-Surgery Generator G11, the generator will display a notification stating “Adaptive Tissue Technology features are not available in this device”. This notification will continue to be displayed at the top of the generator screen during clinical use of the device.

Note: Use of HARMONIC torque wrenches other than the one provided may result in damage to the device.

The HARMONIC ACE® Shears without Adaptive Tissue Technology are designed for use exclusively with Ethicon Endo-Surgery Generator G11 (GEN11) software version X or later. Refer to the Ethicon Endo-Surgery Generator G11 (GEN11) Operator's Manual to confirm software version.

Mechanism of Action
The harmonic instruments vibrate longitudinally at 55.5 kilohertz. This ultrasonic vibration at the blade enhances its cutting ability, while the vibrating instrument edge coagulates blood as tissues are incised. Hemostasis occurs when tissue couples with the instrument. This coupling causes collagen molecules within the tissue to vibrate and become denatured, forming a coagulum.

Indications for Use
Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instruments 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 (such as spine and joint space) and other open and endoscopic procedures.

Contraindications for Use
Reprocessed HARMONIC ACE® Shears without Adaptive Tissue Technology are contraindicated for the following uses:
- Incising bone
- Contraceptive tubal occlusion

Warnings and Precautions
- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough 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. Ensure that electrical insulation or grounding is not compromised. Do not immerse instruments in liquid unless the instruments are designed and labeled to be immersed.
- Verify compatibility with generators. Use device only with Ethicon Endo-Surgery Generator G11 (GEN11) software version X or later. Refer to the Generator G11 (GEN11) Operator's Manual to confirm software version.
- In case of system failure, ensure the availability of the appropriate back up equipment relevant to the specific procedure.

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- Audible high-pitched ringing, 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 ringing 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.
- The instruments allow for the coagulation of vessels up to and including 5 mm in diameter. Do not attempt to seal vessels in excess of 5 mm in diameter.
- Blood and tissue buildup between the blade and shaft may result in abnormally high temperatures at the distal end of the shaft. To prevent burn injury, remove any visible tissue buildup at the distal end of the shaft.
- As 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 attempt to bend, sharpen, or otherwise alter the shape of the blade. Doing so may cause blade failure and user or patient injury.
- 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 while not in use.
- During and following activation in tissue, the instrument blade, clamp arm, and distal 7 cm of the shaft may be hot. Avoid unintended contact with tissue, drapes, surgical gowns, at all times.
- Avoid contact with any and all metal or plastic instruments or objects when the instrument is activated. Contact with staples, clips or other instruments while the instrument is activated may result in cracked or broken blades.
- Do not introduce or withdraw the instrument with the jaws open through a trocar sleeve as this may damage the instrument.
- Care should be taken not to apply pressure between the instrument blade and tissue pad without having tissue between them. Clamping the tissue pad against the active blade without tissue on the full length of the blade will result in higher blade, clamp arm and distal shaft temperatures and can result in possible damage to the instrument. If this occurs, there may be an instrument failure, and the generator touchscreen displays a troubleshooting message.
- To avoid user or patient injury, do not activate an electrosurgical device in close proximity to the HARMONIC instruments. The aerosols created by the activation of the HARMONIC instruments in fatty tissue are potentially flammable.
- Keep the clamp arm open when backcutting or while the blade is active without tissue between the blade and tissue pad to avoid damage to the tissue pad and increased blade, clamp arm and distal shaft temperatures.
- The entire exposed blade tip and any exposed blade shaft are active and will cut/coagulate tissue when the instrument blade is activated. Be careful to avoid inadvertent contact between all exposed blade surfaces and surrounding tissue when using the instrument.
- Use only the appropriate Foot Switch (FSW11), Hand Piece (HP054), Connector (HGA11), and power cord (supplied with Generator GEN11) to ensure that they are compatible with the generator.
- After removing the instrument, examine the tissue for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Successful hemostasis may require adjunct measures when HARMONIC instruments are used on solid organs. Due to the difficulty of visualizing internal structures, proceed slowly and do not attempt to transect large masses of tissue in one activation. Avoid the division of large vascular/biliary bundles when using the instrument under these conditions.
- Instruments or devices that come in contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Incidental and prolonged activation against solid surfaces, such as bone, may result in blade heating and subsequent blade failure, and should be avoided.
- This device is packaged and sterilized for single use only. Multiple patient use may compromise the device integrity or create a risk of contamination that, in turn, may result in patient injury or illness.

Adverse Reactions

- None

Directions for Use

Verify compatibility of all instruments and accessories prior to using this instrument (refer to Warnings and Precautions).

The Hand Piece is shipped non-sterile (not supplied by Stryker Sustainability Solutions). It must be sterilized prior to each use according to the instructions for use supplied with the Hand Piece.

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Assembly

1 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 the package to Stryker.

2 Do not attempt to resterilize. Stryker will not accept instruments for reprocessing that have been reprocessed and sterilized by other facilities.

3 Remove the instrument from the package and place it in a sterile work area using aseptic technique. To avoid damage, do not flip the instrument into the sterile field.

4 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 Stryker if it is not in acceptable condition for the procedure.

5 Attach the Hand Piece to the instrument by rotating the instrument onto the Hand Piece in a clockwise rotation as viewed from the distal end of the instrument (finger tight only).

6 Use the torque wrench (already mounted to the shaft) to tighten the blade onto the Hand Piece. Turn the torque wrench clockwise while holding only the gray Hand Piece until it clicks twice indicating 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 instrument from the Hand Piece.
Note: Do not torque the instrument by hand without the torque wrench or damage may occur to the Hand Piece.
Note: Hold only the gray Hand Piece and not the instrument handle while applying the torque wrench.

7 Close the trigger. Remove the torque wrench by sliding it off of the shaft. Do not dispose of the torque wrench until the procedure is completed. The torque wrench is used to remove 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 of the shaft
Note: Take care to avoid injury from the blade tip while sliding the torque wrench onto or off of the shaft.

Operation

1 Connect the assembled Hand Piece and instrument to the generator and turn the generator power on. **Note: MAX power is set at power level 5 and cannot be adjusted.**

2 Once the generator has identified the device and completed the system start up sequence, a notification will be displayed on the generator screen stating the “Adaptive Tissue Technology features are not available in this device”. Press the OK button in the lower right corner of the generator screen to continue with the activation test. After completion of the activation test, “Adaptive Tissue Technology features are not available” will be displayed at the top of the generator screen during clinical use of this device.

3 Select the desired minimum power level using the INCREASE and DECREASE buttons on the generator touchscreen.
Note: The recommended minimum starting power level is Level 3. 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 selected, blade characteristics, grip force, tissue tension, tissue type, pathology, and surgical technique.

4 For optimal performance and to avoid tissue sticking, clean the instrument blade, clamp arm, and distal end of the shaft throughout the procedure by activating the instrument tip in saline.
Note: Do not touch the instrument to metal while activated.
Note: Do not clean the blade tip with abrasives. It can be wiped with a moist gauze sponge to remove tissue, if necessary.
If tissue is still visible in the clamp arm, use hemostats to remove residue, taking care not to actuate the Hand Piece. If desired, the instrument may be unplugged.

5 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 Foot Switch or the lower hand control button (MIN) on the instrument activates the selected minimum power level. Pressing the right foot pedal of the Foot Switch or upper hand control button (MAX) on the instrument activates the maximum power level.
Note: The generator provides an audible tone to indicate when the instrument blade is active.
Note: Scratches on the blade may lead to premature blade failure.
- Avoid accidental contact with other instruments during use.
- Do not use any means other than the torque wrench to attach or detach the instrument from the Hand Piece.

6 Close the clamp arm by closing the trigger, and insert the shaft through a trocar or incision.

7 The instrument can be used for dissection, grasping, coagulation, and cutting between the blade and clamp arm.
Note: Optimum instrument performance is achieved with full trigger closure. An audible and tactile "click" indicates full trigger closure. To achieve full closure of the jaws of the device, squeeze the plastic trigger until you feel it stop

against the plastic handle (plastic to plastic). If full trigger closure is released prior to or during activation on tissue, an audible and tactile "click" is evident. Increase grip force until full trigger closure is achieved.
Note: Keep clamp arm open when using the inside bottom of the blade for backcutting.

8 Close the clamp arm by closing the trigger and remove the shaft from the trocar or incision.

9 At the completion of each procedure, single-use devices to be reprocessed by Stryker Sustainability should be physically segregated from other devices.

Shaft Rotation
The instrument's shaft can be rotated 360° by turning the rotation knob, located on the proximal end of the shaft, in either direction to facilitate visualization and access to target tissue when dissecting, grasping, coagulating, and cutting.

Disassembly

1 Turn the generator **OFF** at the power switch.

2 Close the clamp arm and slide the torque wrench over the distal end and up the shaft until the wrench aligns with the flats on the shaft. Hold by the Hand Piece only, not the instrument handle, and loosen the instrument by turning the wrench counterclockwise. Continue to loosen by turning the rotation knob manually to completely unscrew the instrument. Do not untorque the instrument by hand without the torque wrench or damage may occur to the Hand Piece.
Note: Do not use any other means than the torque wrench to detach the instrument from the Hand Piece.
Note: Take care to avoid injury from the blade tip while sliding the torque wrench onto or off of the shaft.

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

Storage and Handling

- **Temperature:** -18°C to 60°C
- **Relative Humidity:** 10 to 80%

Compatibility
The HARMONIC ACE® Shears without Adaptive Tissue Technology are designed for use exclusively with the Ethicon Endo-Surgery Generator G11 (GEN 11) software version X or later. Refer to the Ethicon Endo-Surgery Generator G11 (GEN 11) Operator's Manual to confirm software version.

Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE

OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

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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