Reprocessed by

Sustainability Solutions

Instructions for Use
Reprocessed Ultrasonic Scalpels

(LCSC5, LCSK5, LCSB5, CS23C, CS14C, LCSC5HA, ACE14S, ACE23S, ACE36S, ACE36P, ACE23P, ACE23E, ACE36E, ACE45E)

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

Stryker Sustainability Solutions, Inc.
1810 W. Drake Drive
Tempe, AZ 85283
sustainability.stryker.com
888.888.3433

Ultrasonic Scalpel Description
The following Instructions for Use refers to the following device models:

Foot Controlled Device Models	Generator
LCSC5	Generator 300 (GEN04) ULTRACISION Generator (GEN01/GEN32)
LCSK5	Generator 300 (GEN04) ULTRACISION Generator (GEN01/GEN32)
LCSB5	Generator 300 (GEN04) ULTRASONIC Generator (GEN01/GEN32)
CS23C	ULTRACISION Generator (GEN01/GEN32)
CS14C	ULTRACISION Generator (GEN01/GEN32)

Hand Controlled Device Models	Generator
LCSC5HA	Generator 300 (GEN04) *Not compatible with ULTRACISION Generator (GEN01/GEN32)
ACE14S	Generator 300 (GEN04)
ACE23S	Generator 300 (GEN04)
ACE36S	Generator 300 (GEN04)
ACE36P	Generator 300 (GEN04)
ACE23P	Generator 300 (GEN04)
ACE23E	Generator 300 (GEN04)
ACE36E	Generator 300 (GEN04)
ACE45E	Generator 300 (GEN04)

Reprocessed Ultrasonic Scalpels are hand-held instruments designed by the original equipment manufacturer to be used as part of an ultrasonic surgical system. These devices cut and coagulate tissue when attached to the ultrasonic hand piece and electrosurgical unit. These devices are composed of a pistol-grip handle, which includes housing for a removable adaptor and hand piece (containing a transducer) on the proximal end and a housing tube for a removable blade on the distal end. Hand controlled devices include additional activation buttons on the pistol-grip handle that can be used to obtained minimum and maximum power levels. The transducer converts electrical energy into longitudinal vibration of the blade. The blade is attached to the housing tube using an alignment pin and can be rotated to expose different shaped edges, enabling the user to vary the device's cutting and coagulating ability. At the distal tip, a tissue pad may be used to compress tissue against the vibrating blade.
Reprocessed ACE® Ultrasonic Scalpels allow for the coagulation of vessels up to and including 5mm in diameter.

Note: For ACE23E, ACE36E and ACE45E use of Harmonic® torque wrenches other than the TWGRAY or equivalent torque wrench may result in damage to the device and/or handpiece.

Indications for Use
Reprocessed Ultrasonic Scalpels are indicated in general and endoscopic surgery to cut and coagulate soft tissue when hemostasis is desired with a minimal risk of burns.

Contraindications for Use
Reprocessed Ultrasonic Scalpels 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.
- 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.
- 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. Ensure electrical insulation or grounding is not compromised. Do not immerse instruments in liquid unless it is designed and labeled to do so.
- 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 properly attached, which may result in abnormally high sheath temperatures and user or patient injury.
- 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, and ultrasound), there are concerns with the carcinogenic and infectious potential of the by-products, including tissue smoke plume and aerosols. Measures such as protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.
- 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 in tissue, the blade, the clamp arm, and the distal 7cm of the shaft may become hot. Avoid unintended contact with tissue, drapes, surgical gowns, or other unintended sites at all times.
- Avoid inadvertent contact with all exposed blade surfaces and surrounding tissue as the entire exposed blade tip will cut/coagulate tissue when activated.
- 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.
- Introducing or withdrawing the instrument with the jaws open through a trocar sleeve may damage the instrument.
- 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. This may cause a system failure signaled by a continuous beep or error code when either of the foot pedals or hand control buttons is depressed.
- Verify hemostasis after withdrawing instrument. If bleeding is still observed, employ appropriate techniques to achieve hemostasis.
- Use with caution on solid organs, successful hemostasis may require adjunct measures. Due to the difficulty of visualizing internal structures, proceed slowly and do not attempt to transect large masses of tissue in a single activation. When using the instrument under these conditions avoid the division of large vascular/biliary bundles.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Avoid incidental and prolonged activation against solid surfaces, such as bone, as this may result in blade heating and subsequent blade failure.
- Use the appropriate Foot Switch, Hand Piece, Instruments, and power cord to ensure that they are compatible with the generator. Products manufactured or distributed by other companies may not be compatible with the HARMONIC® or ULTRACISION SCALPEL system and may result in unanticipated results and user or patient injury.
- **Do Not Resterilize** this instrument as it may compromise the integrity of the product leading to unintended injury.

Adverse Reactions
None.

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

Ultrasonic Scalpel Foot Control Models
1. Before beginning the procedure, verify compatibility of all instruments and accessories.
2. 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 Stryker Sustainability Solutions.
3. Remove the instrument from the package and place it in a sterile work area using aseptic technique.
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 Sustainability Solutions if it is not in acceptable condition for surgery.
5. To attach the blade to the reusable hand piece and adaptor:
   - Remove the tip protector from the blade, taking care to avoid injury.
   - Screw blade manually onto hand piece by turning it clockwise with fingers. Tighten blade further with torque wrench. Slide wrench along blade until it stops. Turn the wrench and continue to push it gently until the wrench nose is adjacent to the hand piece. Turn the wrench clockwise. A snapping noise (or until it clicks twice) signals that the blade is secure.
     Note: Inspect the torque wrench hub for cracks or wear before use. If damage is seen, replace the torque wrench. Before use after autoclaving, cool the torque wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes. For ACE23E, ACE36E and ACE45E do not use any other means than the torque wrench to attach or detach the blade from the hand piece. Do not torque the blade by hand or damage may occur to the hand piece. Only hold the silver hand piece and not the handle while applying the torque wrench.
   - Close the trigger for ACE23E, ACE36E and ACE45E. Slide the torque wrench straight back along the blade and remove. **Do not dispose of the reusable torque wrench**. After the surgical procedure, the wrench can be used to remove the blade.
     Note: Take care to avoid injury from the blade and clamp arm by closing the trigger while sliding the torque wrench onto or off of the shaft. Avoid injury from the blade tip by taking special care while sliding the torque wrench onto or off of the shaft.
6. Connect the assembled hand piece and instrument to the generator and turn the power on. **Note: Do not turn the generator power on before the hand piece and instrument are connected to the generator. MAX power is defaulted at power level 5 and cannot be adjusted for Generator 300 (GEN04).**
7. Use the increase and decrease buttons on the generator to select the desired variable power level. Always use the lowest possible power setting needed to achieve the desired effect. Ultrasonically energize the blade by depressing either foot switch pedal. Note: Scratches on the blade may lead to premature blade failure.
   - Avoid accidental contact with other instruments during use.
   - Always use the torque wrench to attach and detach the blade from the hand piece.
8. Close the clamp arm and then insert the shaft through a trocar or incision. Direct the blade to the desired site, then press against tissue to dissect, grasp, cut, and coagulate.
   Note: Keep the clamp arm open when back cutting to avoid damage to the tissue pad.
   Note: The amount of energy delivered to the tissue pad and resultant tissue effects are a function of numerous factors including power level, blade characteristics, grip force, tissue tension, tissue type, pathology, and surgical technique.
9. Clean blade, clamp arm, and distal end of shaft throughout procedure to achieve optimal performance and to avoid tissue sticking by activating the instrument tip in saline.
   Note: Do not touch instrument to metal while activated.
   Note: Do not clean blade tip with abrasives. Instead, wipe with moist gauze sponge to remove tissue. If tissue is still visible, use hemostats to remove residue with generator in Standby mode.
10. Follow a suitable surgery protocol.
11. At the completion of each procedure, single-use devices to be reprocessed by Stryker Sustainability should be physically segregated from other devices.

Ultrasonic Scalpel Hand Control Models
1. Before beginning the procedure, verify compatibility of all instruments and accessories.
2. 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 Stryker Sustainability Solutions.
3. Remove the instrument from the package and place it in a sterile work area using aseptic technique.
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 Sustainability Solutions if it is not in acceptable condition for surgery.

5. To attach the blade to the reusable hand piece and adaptor:
   - Remove the tip protector from the blade, taking care to avoid injury.
   - Screw blade manually onto hand piece by turning it clockwise with fingers. Tighten blade further with torque wrench. Slide wrench along blade until it stops. Turn the wrench and continue to push it gently until the wrench nose is adjacent to the hand piece. Turn the wrench clockwise. A snapping noise (or until it clicks twice) signals that the blade is secure.
     Note: Inspect the torque wrench hub for cracks or wear before use. If damage is seen, replace the torque wrench. Before use after autoclaving, cool the torque wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes. For ACE23E, ACE36E and ACE45E do not use any other means than the torque wrench to attach or detach the blade from the hand piece. Do not torque the blade by hand or damage may occur to the hand piece. Only hold the silver hand piece and not the handle while applying the torque wrench.
   - Close the trigger for ACE23E, ACE36E and ACE45E. Slide the torque wrench straight back along the blade and remove. **Do not dispose of the reusable torque wrench**. After the surgical procedure, the wrench can be used to remove the blade.
     Note: Take care to avoid injury from the blade and clamp arm by closing the trigger while sliding the torque wrench onto or off of the shaft. Avoid injury from the blade tip by taking special care while sliding the torque wrench onto or off of the shaft.
6. Refer to the appropriate HARMONIC® or ULTRACISION Generator Manual for hand piece attachment and system operation instructions.
7. Connect the assembled hand piece and instrument to the generator and turn the power on. **Note: Do not turn the generator power on before the hand piece and instrument are connected to the generator**. **MAX power is defaulted at power level 5 and cannot be adjusted for Generator 300 (GEN04).**
8. Select the desired minimum power level using the INCREASE and DECREASE buttons on the generator. **Note:** The recommended minimum starting power level is Level 2 for LCSC5HA. For ACE® Harmonic Scalpels, it is recommended to start at power level 3 and increase the setting gradually.
9. Use a higher power level for greater tissue cutting speed and a lower power level for greater coagulation. The amount of energy delivered to the tissue pad and resultant tissue effects are a function of numerous factors including power level, blade characteristics, grip force, tissue tension, tissue type, pathology, and surgical technique.
10. For hand activation functions, select the hand activation button on the generator and ensure it illuminates. Refer to Generator Manual for further instructions.
11. When either the foot switch pedal is depressed or one of the hand control buttons is depressed, the blade is ultrasonically energized. To activate the selected minimum power level, press the left foot pedal of the footswitch or the lower hand control button (MIN) on the Curved Shears. To activate the selected maximum power level, press the right foot pedal of the footswitch or upper hand control button (MAX) on the Curved Shears. Note: Scratches on the blade may lead to premature blade failure.
    - Avoid accidental contact with other instruments during use.
    - Always use the torque wrench to attach and detach the blade from the hand piece.
12. Close the clamp arm and then insert the shaft through a trocar or incision. To attain full closure of the jaws, squeeze the plastic trigger until you feel it stop against the plastic handle (plastic to plastic). An audible and tactile “click” will be evident if full trigger closure is released prior to or during activation on tissue. Increase grip force until trigger is fully closed.
13. Clean blade, clamp arm, and distal end of shaft throughout procedure to achieve optimal performance and to avoid sticking by activating the device tip in saline.
    Note: Do not touch instrument to metal while activated.
    Note: Do not clean blade tip with abrasives. Instead, wipe with moist gauze sponge to remove tissue. If tissue is still visible, use hemostats to remove residue with generator in Standby mode.
14. For ACE23E, ACE36E and ACE45E use the inside bottom of the blade for backcutting with the clamp arm open. Close the clamp arm by closing the trigger and remove the shaft from the trocar or incision.
15. Follow a suitable surgery protocol.
16. 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 shaft of the instrument can be rotated 360° to facilitate visualization and allow easier access to target tissue when dissecting, grasping, coagulating, and cutting.

To move the shaft around to the desired position, turn the rotation knob. This can be achieved by using the index finger of the hand on the grip handle.

Disassembly

To disassemble the blade and hand piece:

- First turn the generator **OFF** or enter **STANDBY** mode.
- Close the blade arm and slide the torque wrench down the blade to the base of the hand piece. The flat surface on the wrench should be aligned with the flat surface of the blade.
- Turn the wrench counterclockwise to loosen the blade, continuing until it is completely unscrewed.
  Note: Take care to avoid injury from the blade tip while sliding the torque wrench on or off of the shaft.
- Pull the wrench straight back over the blade and **save the torque wrench for future use**.
- Remove the blade and reattach the protective cap.

Storage and Handling

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

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.

ULS Rev M 07-2013 RM702025