

Reprocessed by



Instructions for Use Reprocessed Ultrasonic Scalpels

(LCS-C5L, LCS-C5, LCS-C1, LCS-K5,
LCS-B5, LCS-C5HA, LCS-C1HA, ACE14S, ACE23S, ACE36S, ACE36P, ACE23P, ACE23E,
ACE36E, CS-23C, CS-14C)


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 Ultrasonic Scalpels

Ultrasonic Scalpel Description

The following Instructions for Use refers to the following device models:

Foot Controlled Device Models	Generator
LCS-C5L	Generator 300 (GEN04) *Not compatible with ULTRACISION Generator (GEN01/GEN32)
LCS-C5	Generator 300 (GEN04) ULTRACISION Generator (GEN01/GEN32)
LCS-C1	Generator 300 (GEN04) ULTRACISION Generator (GEN01/GEN32)
LCS-K5	Generator 300 (GEN04) ULTRACISION Generator (GEN01/GEN32)
LCS-B5	Generator 300 (GEN04) ULTRACISION Generator (GEN01/GEN32)
CS-23C	ULTRACISION Generator (GEN01/GEN32)
CS-14C	ULTRACISION Generator (GEN01/GEN32)

Hand Controlled Device Models	Generator
LCS-C5HA	Generator 300 (GEN04) *Not compatible with ULTRACISION Generator (GEN01/GEN32)
LCS-C1HA	Generator 300 (GEN04) *Not compatible with ULTRACISION Generator (GEN01/GEN32)
ACE 14S	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)

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 obtain 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 and ACE36E 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.

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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, 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 when either of the foot pedals is depressed.
- Verify hemostasis after withdrawing instrument. If bleeding is still observed, employ appropriate techniques to achieve hemostasis.
- Use with caution on solid organs. Due to the device's limited ability to grasp large portions of solid organs and occlude large vascular/biliary bundles, hemostasis may not be predictable and may require adjunct measure for coagulation.
- 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 only the ULTRACISION HARMONIC® SCALPEL 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 ULTRACISION HARMONIC® 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.

Reprocessed Ultrasonic Scalpels

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 Ascent Healthcare 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 Ascent Healthcare 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 blade 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 signals that the blade is secure. **Note:** Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.
 - Slide the blade wrench straight back along the blade and remove. **Do not dispose of the reusable blade wrench.** After the surgical procedure, the wrench can be used to remove the blade. **Note:** Take care to avoid injury from the blade tip while sliding the blade 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.**
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.
 - Do not clean blade tip with abrasives. Instead, wipe with a moist gauze sponge to remove tissue.
 - Always use the blade wrench to attach and detach the blade.
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. Turn the knob on the grip handle to rotate the instrument shaft as desired.
10. Follow a suitable surgery protocol.
11. To disassemble the blade and hand piece:
 - First turn the generator **OFF** or enter **STANDBY** mode.
 - Close the blade arm and slide the 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 blade wrench on or off of the shaft.
 - Pull the wrench straight back over the blade and **save the blade wrench for future use.**
 - Remove the blade and reattach the protective cap.
12. At the completion of each procedure, single-use devices to be reprocessed by Ascent 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 Ascent Healthcare 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 Ascent Healthcare 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.

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- Screw blade manually onto hand piece by turning it clockwise with fingers. Tighten blade further with blade 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 signals that the blade is secure. **Note:** Inspect the blade wrench hub for cracks or wear before use. If damage is seen, replace the blade wrench. Before use after autoclaving, cool the blade wrench at room temperature for at least 45 minutes or soak it in room temperature sterile water for 5 minutes.
 - Slide the blade wrench straight back along the blade and remove. **Do not dispose of the reusable blade wrench.** After the surgical procedure, the wrench can be used to remove the blade.
Note: Take care to avoid injury from the blade tip while sliding the blade wrench onto or off of the shaft.
6. Refer to the HARMONIC® SCALPEL 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.**
 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 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.
 12. 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, arm, and distal end of shaft throughout procedure to achieve optimal performance by activating the device 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.

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.

Storage and Handling

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

Reprocessed Ultrasonic Scalpels

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.

ACE[®] and Harmonic[®] are registered trademarks of Ethicon Endo-Surgery, Inc.
Sporicidin[®] is a registered trademark of Contec, Inc.
SurgiSoak[®] is a registered trademark of Geddis, Inc.