Reprocessed by

stryker

Instructions for use

Reprocessed HARMONIC 700, 5 mm Diameter Shears with Advanced Hemostasis

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
- EXPOSED to EO Gas

Please read all information carefully.

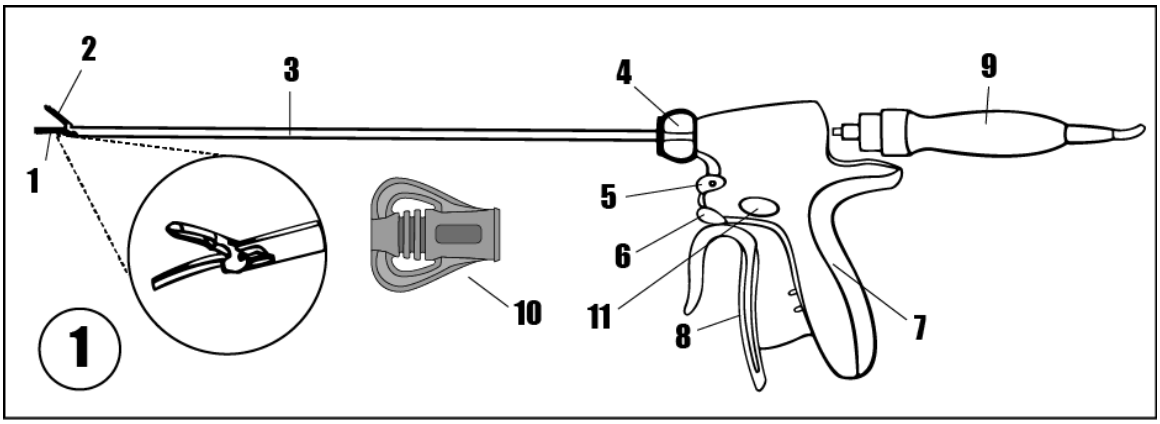
Failure to properly follow the instructions may lead to serious surgical consequences.

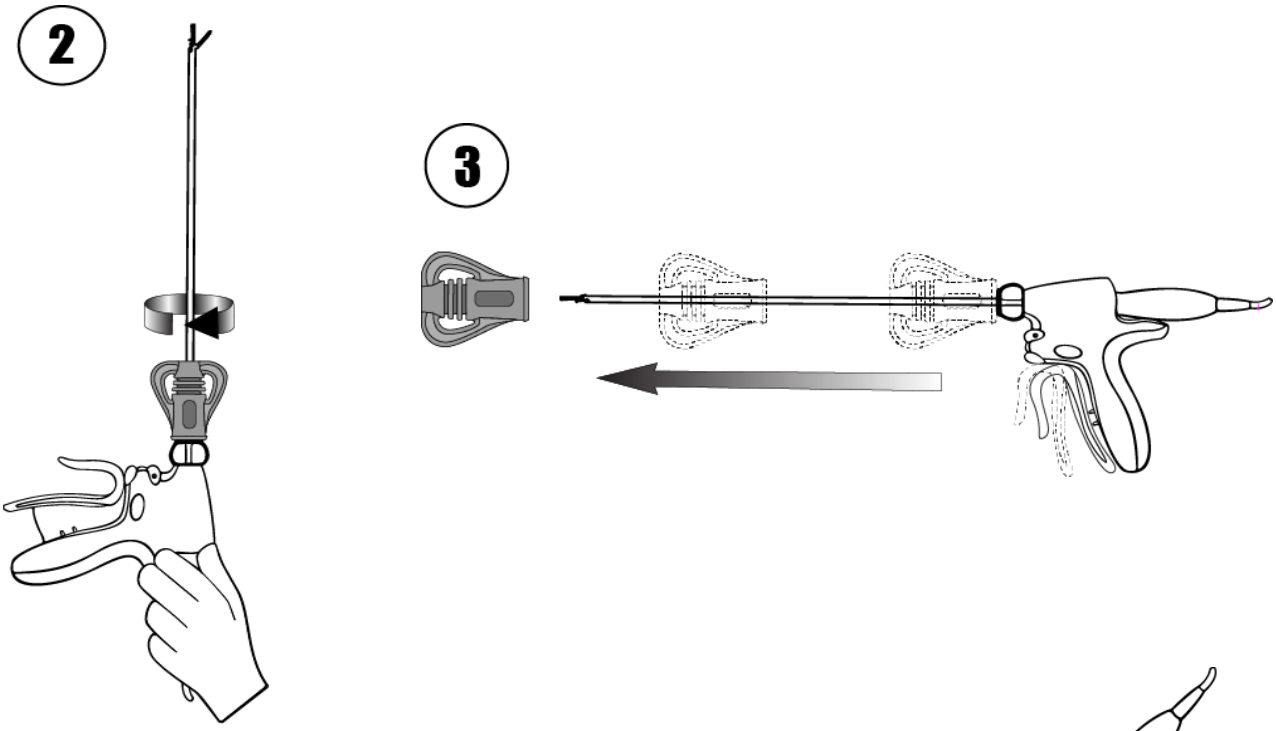
Important: This package insert is designed to provide instructions for use of the Reprocessed HARMONIC™ 700, 5 mm Diameter Shears with Advanced Hemostasis. It is not a reference to surgical techniques.

Explanation of symbols

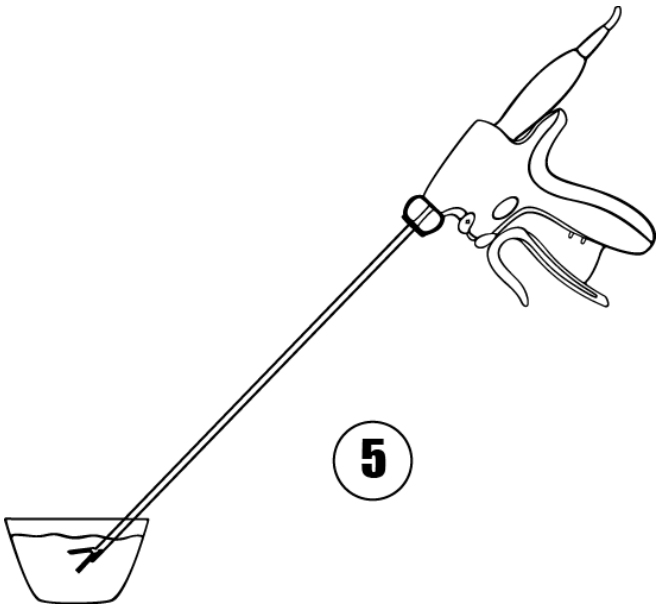
Symbol	Rules/ Standard Reference	ISO 7000 Registration Number	Symbol Title	Description
Rx Only	21CFR801	N/A	Prescription only	Indicates Federal (USA) law restricting device to sale by or on order of a physician.
	ISO 15223-1 Clause 5.1.1	3082	Manufacturer	Indicates the medical device manufacturer.
	ISO 15223-1 Clause 5.2.3	2501	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	ISO 15223-1 Clause 5.1.4	2607	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1 Clause 5.1.5	2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1 Clause 5.1.6	2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1 Clause 5.4.3	1641	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1 Clause 5.4.2	1051	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 15223-1 Clause 5.2.6	2608	Do not resterilize	Indicates a medical device that is not to be resterilized.
	ISO 15223-1 Clause 5.2.8	2606	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	ISO 15223-1 Clause 5.3.7	0632	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 15223-1 Clause 5.3.8	2620	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 15223-1 Clause 5.3.4	0626	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 7010	M002	Refer to Instruction Manual/Booklet	Indicates that the user should refer to the instruction manual/booklet

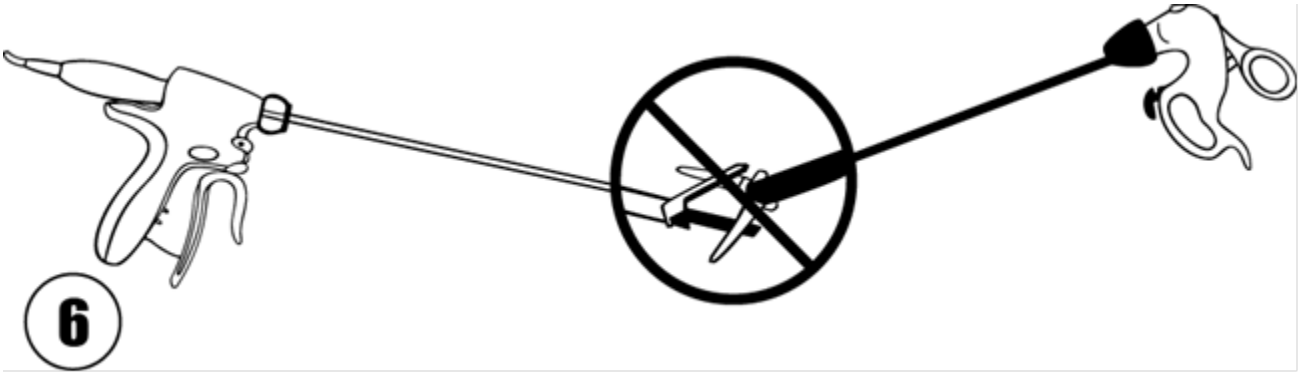
Stryker's Sustainability Solutions ©2025
1810 W Drake Dr.
Tempe AZ, 85283
stryker.com
888 888 3433

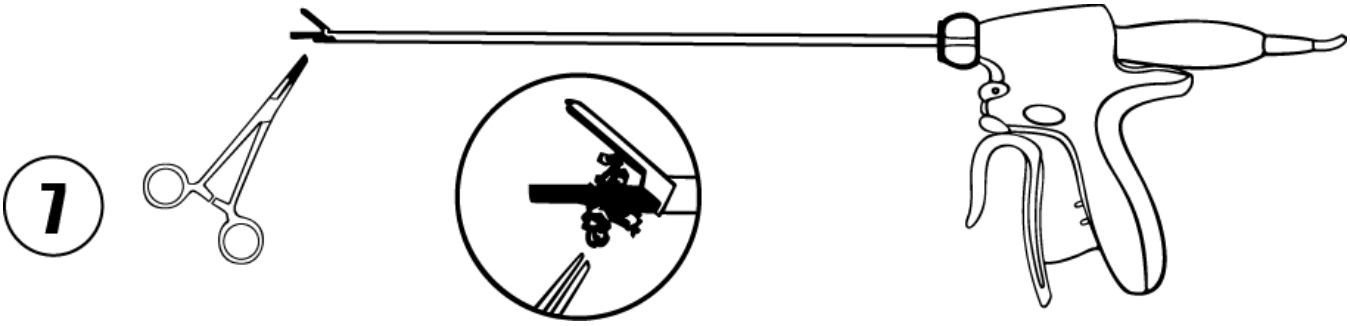

2
3
4
9
1
5
6
10
11
8
7
1

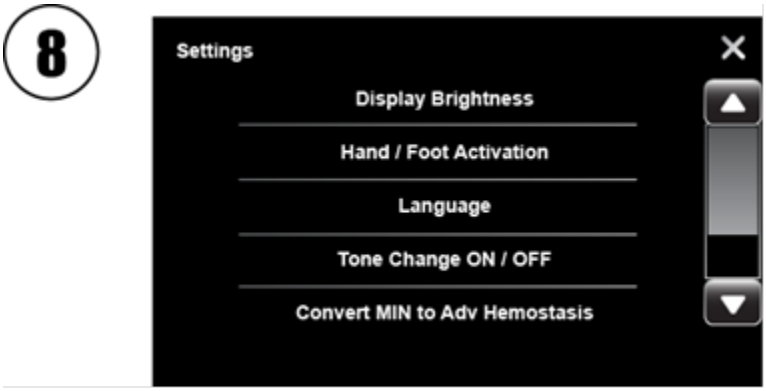

2
3

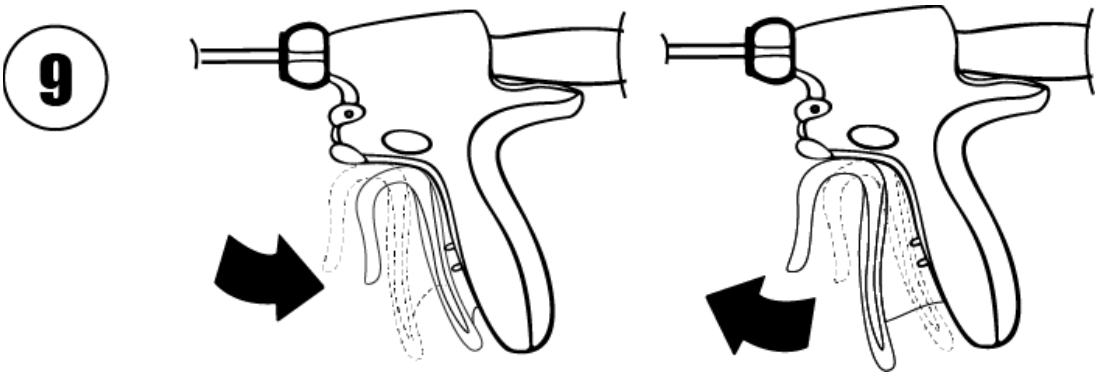

4
Harmonic 700 Shears
3
MIN
5
MAX
Settings


5


6


7


8
Settings
Display Brightness
Hand / Foot Activation
Language
Tone Change ON / OFF
Convert MIN to Adv Hemostasis


9

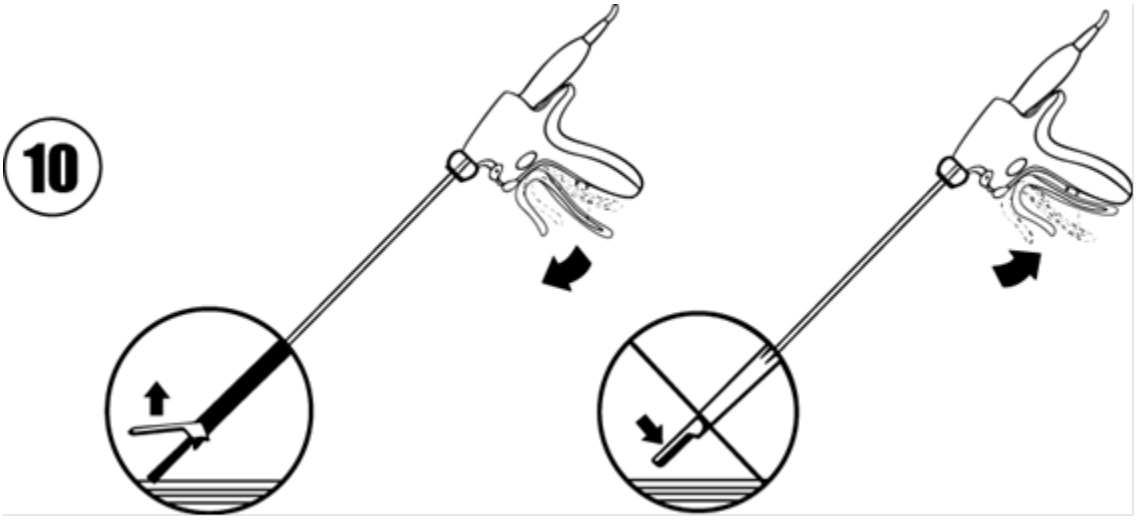


Illustration and Nomenclature (Illustration 1)

1. Coated Blade
2. Clamp Arm and Tissue Pad
3. Shaft
4. Rotation Knob
5. MAX Hand Control Button (both sides of instrument)
6. MIN Hand Control Button (both sides of instrument)
7. Grip Housing
8. Trigger
9. Hand Piece (not included)
10. Torque Wrench
11. Advanced Hemostasis Hand Control Button

Indications

The Reprocessed HARMONIC 700, 5 mm Diameter Shears with Advanced Hemostasis 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, pediatric, gynecologic, urologic, thoracic procedures, and sealing and transection of lymphatic vessels. The instruments allow for the coagulation of vessels up to and including 7 mm in diameter, using the Advanced Hemostasis hand control button.

Contraindications

- The instruments are not indicated for incising bone.
- The instruments are not intended for contraceptive tubal occlusion.

Undesirable Side Effects/Residual Risks

Undesirable side effects and risks associated with ultrasonic devices include the potential for bleeding, tissue injury via mechanical or thermal damage, introduction of non-sterile surfaces or pathogen transfer, inflammatory or unintended tissue reaction, electrical shock, foreign body or magnetic resonance incompatibility, and property or environmental damage. Also, unintended harm, extended surgery, or altered surgical approach may result from issues related to device

activation, damaged devices, electromagnetic interference, audible noise due to misassembly, misuse of the torque wrench, or an attempt to alter the device.

Device Description/Performance Characteristics

The Reprocessed HARMONIC 700, 5 mm Diameter Shears with Advanced Hemostasis are intended for soft tissue incisions when bleeding control and minimal thermal injury are desired.

The instruments are sterile, single-patient-use instruments consisting of an ergonomic grip housing assembly with hand control buttons (MIN for minimum power level, MAX for maximum power level, and Advanced Hemostasis for large vessel sealing).

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 three dashes on the instrument are intended to represent relative vessel size. The MAX button is typically used for smaller vessels where cutting speed is fastest. The MIN button is typically used in slightly larger vessels and has reduced cutting speed. It is indicated for vessels up to 5 mm in size. The Advanced Hemostasis button is designed for larger vessels and is indicated for vessels up to 7 mm in size. In this mode, cutting speed is further reduced and hemostasis is maximized. The instruments utilize Adaptive Tissue Technology. This provides the generator with the ability to identify and monitor the instrument during use, which enables the generator to modulate and adjust its power output as well as provide audible feedback to the user as appropriate.

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

The Reprocessed HARMONIC 700, 5 mm Diameter Shears with Advanced Hemostasis are designed for use exclusively with the Generator G11 (GEN11) software version 2018-1. Software revision can be found under “System Information” in the Generator G11 (GEN11) “Settings” menu. Refer to the Generator G11 (GEN11) Operator’s Manual for more information.

Procedures involving the use of the device should be performed only by healthcare professionals having adequate training and familiarity with open procedures and the use of ultrasonic devices.

One or more components of this device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight:		
 #	**Material Present**	**Residual Risk**
 1	Cobalt: CAS No. 7440-48-4 EC No. 231-158-0	Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.
The footnote adjacent to the above symbol on the packaging refers to the relevant Material Present		

Standard Conventions Used (Warnings and Caution Statement)

Information relative to the completion of a task in a safe and thorough manner will be supplied in the form of a Caution or a Warning statement. These statements are found throughout the documentation.

These statements should be read before continuing to the next step in a procedure.

- WARNING: A Warning statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in personal injury or loss of life.
- Caution: A Caution statement indicates an operating or maintenance procedure, practice, or condition that, if not strictly observed, could result in damage to or destruction of the equipment.

Instructions 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. It must be sterilized prior to each use according to the instructions for use supplied with the Hand Piece.

Assembly

1. Visually inspect all packaging for damage including a careful inspection of all sterile barrier systems for breaches in package integrity immediately prior to use.

   Caution: Do not use if the product sterile barrier system or its packaging is compromised.
2. Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
3. While holding the Hand Piece in a vertical orientation, 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).
4. 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. (Illustration 2).
5. 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. (Illustration 3) 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: MIN is the only mode that can be adjusted.
2. 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 (Illustration 4). 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.
3. 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.

   (Illustration 5)

   Note: Do not touch the instrument to metal while activated. (Illustration 6)

   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. (Illustration 7)
4. 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 lower hand control button (MIN) on the instrument activates the selected minimum power level. Pressing the right foot pedal of the footswitch or upper hand control button (MAX) on the instrument activates the maximum power level. Pressing the Advanced Hemostasis button on the instrument activates the Advanced Hemostasis. Under default settings, Advanced Hemostasis is hand-activated only.

   Note: The “MIN” button can be re-assigned to Advanced Hemostasis by selecting “Convert MIN to Advanced Hemostasis” on the GEN11 “Settings” screen. Refer to the Generator G11 Operator’s Manual “Settings” section. (Illustration 8) Once “Convert MIN to Advanced Hemostasis” is selected, the Advanced Hemostasis button is disabled.

   Note: Energy is not delivered in Advanced Hemostasis mode until the jaws are completely closed.

   Caution: If activation is unintentionally stopped while sealing, maintain jaw closure and reactivate.

   Note: The generator provides an audible tone to indicate when the instrument blade is active. The generator changes to a second activation tone as Adaptive Tissue Technology regulates the delivery of energy.

   - Thermal influences such as fluids or minimal to no tissue in the jaws may affect the presence or timing of the tone change.
   - The tone change does not provide confirmation of tissue effect. When the second tone is heard, the situation should be assessed and the intended surgical action completed, such as

gradual application of tension to facilitate transection.

- The secondary activation tone change is not a substitute for surgical experience.

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.

5. Close the clamp arm by closing the trigger and insert the shaft through a trocar or incision.
6. The instrument can be used for dissection, grasping, coagulation, and cutting between the blade and clamp arm.

Note: To achieve complete sealing, the trigger should be fully closed and the vessel fully contained between clamp arm and blade of device. 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) (Illustration 9). 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. (Illustration 10)

WARNING: Do not use Advanced Hemostasis mode for procedures where energy application is desired prior to full closure of the jaws (e.g. solid organs). Energy is not delivered in Advanced Hemostasis mode until the jaws are completely closed.

WARNING: During benchtop testing of vessels >5 mm, the strongest vessel seals were achieved by allowing the Advanced Hemostasis mode to completely transect the targeted vessel.

WARNING: Prolonged usage of Advanced Hemostasis Mode may cause tissue pad damage.

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

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.

4. Dispose of the instrument in an appropriate container.

Warnings and Precautions

- Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

- Minimally invasive procedures should be performed only by healthcare professionals 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 2018-1. Software revision can be found under “System Information” in the Generator G11 (GEN11) “Settings” menu. Refer to the Generator G11 (GEN11) Operator’s Manual for more information.
- In case of system failure, ensure the availability of the appropriate back up equipment relevant to the specific procedure.
- Do not use if the product sterile barrier system or its packaging is compromised.
- 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 7 mm in diameter, using the Advanced Hemostasis hand control button. Do not attempt to seal vessels in excess of 7 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, Hand Piece, instruments, and power cord 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.
- If activation is unintentionally stopped while sealing, maintain jaw closure and reactivate.
- Do not use Advanced Hemostasis mode for procedures where energy application is desired prior to full closure of the jaws (e.g. solid organs). Energy is not delivered in Advanced Hemostasis mode until the jaws are completely closed.
- During benchtop testing of vessels >5 mm, the strongest vessel seals were achieved by allowing the Advanced Hemostasis mode to completely transect the targeted vessel.
- Prolonged usage of Advanced Hemostasis Mode may cause tissue pad damage.
- If during use the generator displays “Advanced Features Are Not Available In This Device”, the following functions of Adaptive Tissue Technology are no longer available: Regulated Energy Delivery, Enhanced Audible Feedback and Advanced Hemostasis. As a consequence, the device vessel sealing indication does not exceed 5 mm.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination. Disposal of all medical device instruments and accessories should be performed according to local requirements and regulations.
- Incidental and prolonged activation against solid surfaces, such as bone, may result in blade heating and subsequent blade failure, and should be avoided.
- Dispose of all opened instruments whether used or unused. This device is packaged and sterilized for single use only.

- Reuse, non-validated reprocessing, or resterilization may compromise the structural integrity of the device or lead to device failure that in turn may result in patient injury, illness, or death.
- Reuse, non-validated reprocessing, or resterilization of single-use devices may create a risk of contamination or cause infection or cross-infection, including but not limited to, the transmission of infectious diseases. Contamination may lead to injury, illness, or death.
- Device has not been evaluated in main vessels of the central circulatory system and is not intended for use in the following named vessels: arteriae pulmonales, aorta ascendens, arcus aortae, aorta descendens to the bifurcatio aortae, arteriae coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae cerebrales, truncus brachiocephalicus, venae cordis, venae pulmonales, vena cava superior and vena cava inferior.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the local competent authority of the country in which the user and/or patient is established.

Storage and handling

Temperature: -20°C-50°C
Relative Humidity: 15%-90%

Storage and Transportation Conditions

Keep Dry
Keep away from heat

How Supplied

The Reprocessed HARMONIC 700, 5 mm Diameter Shears with Advanced Hemostasis are supplied sterile for single patient use. Each instrument is shipped with one sterile, single use, gray torque wrench. Place the instrument and torque wrench in the appropriate collections container after use.

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.

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.

EL10189, Rev. A 08/2025