Reprocessed by

stryker

Instructions for use

Reprocessed HARMONIC® 1100 Shears

Reprocessed device for single use

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

- STERILE

Explanation of 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 5.1.3	2497	Date of manufacture	Indicates the date when the medical device was manufactured.
	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 5.1.6	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.

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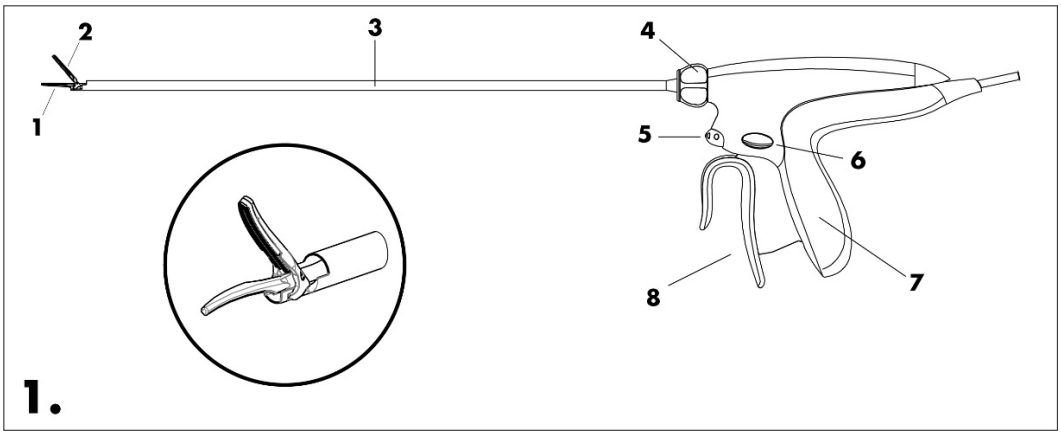
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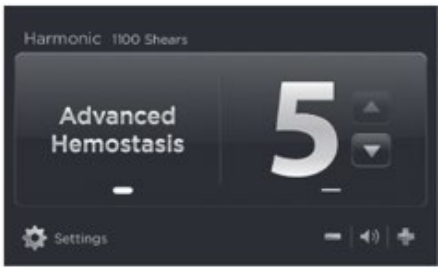
Harmonic 1100 Shears
Advanced Hemostasis
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Settings

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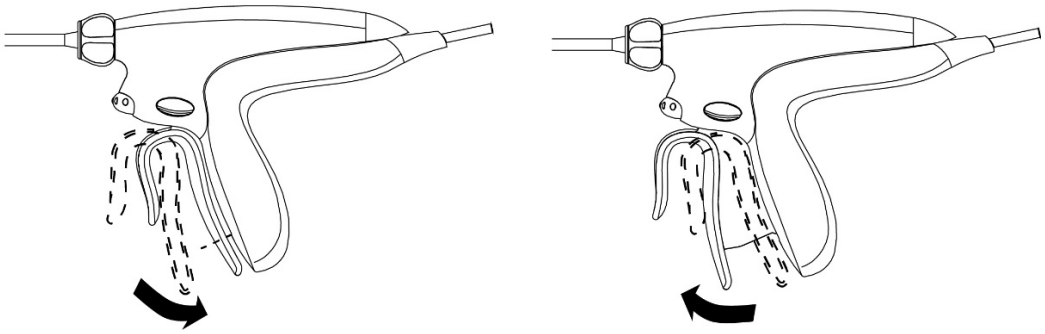

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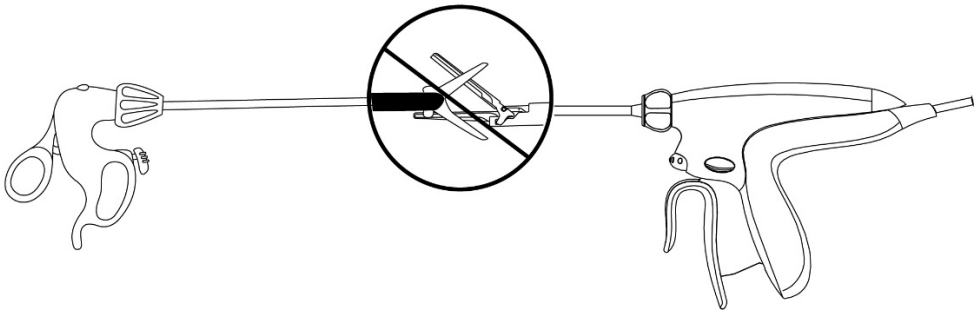

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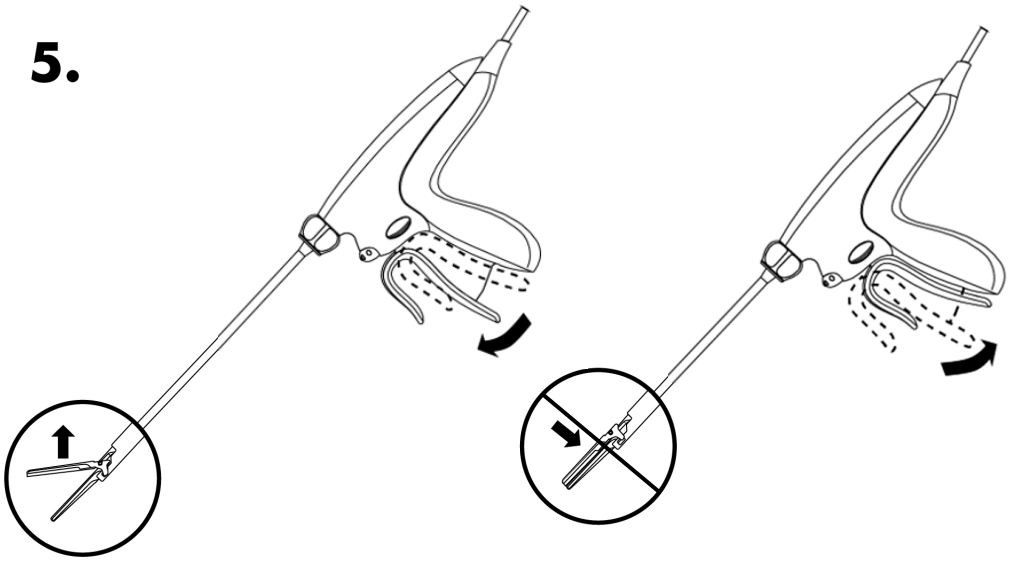

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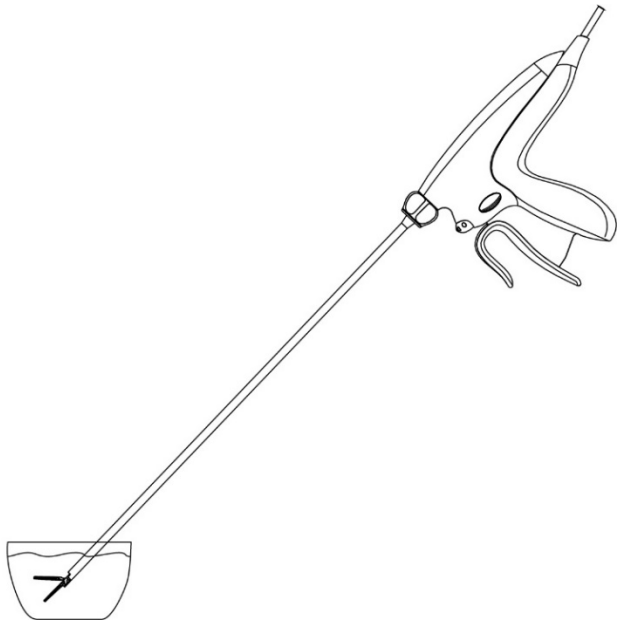

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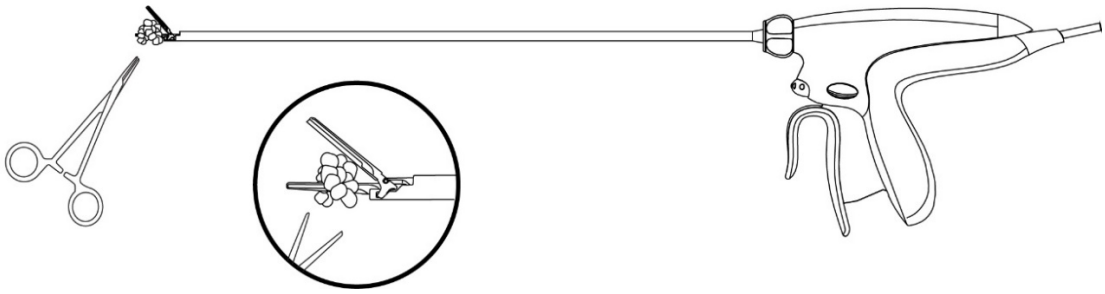

Illustration and Nomenclature (Illustration 1)

1. Coated Blade
2. Clamp Arm and Tissue Pad
3. Shaft
4. Rotation Knob
5. Energy Button
6. Energy Button with Advanced Hemostasis
7. Handle
8. Trigger

Reprocessed HARMONIC® 1100 Shears description

The Reprocessed HARMONIC 1100 Shears instrument is a sterile, single patient use instrument used for dissection, grasping, coagulation, and cutting between the blade and clamp arm. It consists of an ergonomic handle with an integrated hand piece and two energy delivery buttons:

1) Energy button  - user can adjust power levels from 1-5.

2) Energy button with Advanced Hemostasis  - for large vessel sealing; user cannot adjust.

The instrument is available in two shaft lengths -- 20 cm and 36 cm.

An integrated audible and tactile mechanism in the handle indicates full trigger closure. The instrument has 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 shaft can be rotated continuously to facilitate visualization and access to targeted tissue. The two dashes on the instrument are intended to represent relative vessel size. The Energy button is indicated for vessels up to 5 mm in diameter. When the Energy button is used, cutting speed is the fastest. The Energy button with Advanced Hemostasis is designed for larger vessels and is indicated for vessels up to 7mm in diameter. When the Energy button with Advanced Hemostasis is used, cutting speed is reduced and hemostasis is maximized. The instrument utilizes Adaptive Tissue Technology that is specific to the Reprocesssed HARMONIC 1100 Shears. 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.

The Reprocessed HARMONIC® 1100 Shears instrument is designed for use exclusively with the Generator G11 (GEN11) software version 2018-1 or later. Software revision can be found under “System Information” in the Generator G11 (GEN11) “Settings” menu. Refer to the Generator G11 (GEN11) Operator’s Manual before using this instrument.

Indications for use

The Reprocessed HARMONIC® 1100 Shears instrument is 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, 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 Energy button with Advanced Hemostasis.

Contraindications for use

Reprocessed HARMONIC® 1100 Shears are contraindicated for:

- 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.

Output specifications

- 300 VAC RMS maximum
- 60 watts continuous

Warning and caution statements

- 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.
- A Caution statement alerts the user of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.

Precautions

Warnings and Precautions

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- 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 2018-1 or later. 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.
- 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 scratches on the blade, cracked or broken blades and premature blade failure.
- Do not use the Energy button with Advanced Hemostasis when energy application is desired prior to full closure of the jaws. Energy is not delivered using the Energy button with Advanced Hemostasis until the jaws are completely closed. Using the Energy button with Advanced Hemostasis without full trigger closure may result in lack of hemostasis.
- If activation is unintentionally stopped while sealing, maintain jaw closure and reactivate. Releasing the trigger while sealing may result in lack of hemostasis.
- 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.
- 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.
- 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 instrument. Do not touch the instrument to the hemostats while activated. Scratches on the blade may lead to cracked or broken blades and premature blade failure.
- In case of system failure, ensure the availability of the appropriate back up equipment relevant to the specific procedure.
- Audible high-pitched ringing, resonating from the blade, is an abnormal condition and an indicator that the blade is not operating properly. This 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 Energy button with Advanced Hemostasis. 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 eye wear, 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.
- 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.
- 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, 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 to transect 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.
- Products manufactured or distributed by companies not authorized by Ethicon Endo-Surgery may not be compatible with the HARMONIC system. Use of such products may lead to unanticipated results and possible injury to the user or patient.
- 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.
- Instruments or devices which come into 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.
- Dispose of all opened instruments whether used or unused. This device is packaged and sterilized for single use only.
- Reuse and improper reprocessing or resterilization of single use devices may compromise the structural integrity of the device and/or lead to device failure that in turn may result in patient injury, illness, or death.
- Reuse and improper reprocessing or resterilization of single use devices may create a risk of contamination and/or cause infection or cross-infection, including, but not limited to, the transmission of infectious diseases. Contamination may lead to injury, illness, or death.

- Tissue pad damage may occur if device is activated without tissue in the closed jaws. Activation without tissue between the jaws will cause tissue pad degradation.
- Avoid contact with any and all metal or plastic instruments or objects such as graspers, uterine manipulators.
- Prolonged blade activation with the clamp arm closed (with or without tissue between the blade and tissue pad) may cause tissue pad damage.

Adverse reactions

- None

Directions for use

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

1. Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
2. Connect the instrument to the generator and turn the generator power on.
3. Select the desired power level using the INCREASE and DECREASE buttons on the generator touchscreen. Only the power level for the Energy button can be adjusted (1-5). The system defaults to power level 5. (Illustration 2) For greater tissue cutting speed use a higher generator power level, and for greater coagulation use a lower generator power level. For thicker tissue types, such as liver parenchyma, the recommended generator power setting is power level 3 when activating HARMONIC 1100 while gradually closing the jaws. 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. Close the clamp arm by closing the trigger, and insert the shaft through a trocar or incision (Illustration 3).
5. Position the tissue within the jaws at the desired location. The instrument's shaft can be rotated continuously using the rotation knob to facilitate visualization and access to target tissue.
6. Squeeze the trigger until it stops against the plastic handle (and a click is heard) to clamp targeted tissue between the jaws.
   - 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). Grip force needs to be maintained throughout the transection to keep trigger closed.
7. To activate the instrument blade, press one of the foot pedal switches or one of the energy buttons on the instrument.
   - Pressing the left foot pedal of the footswitch or the Energy button with Advanced Hemostasis on the instrument activates Advanced Hemostasis. When using the Energy button with Advanced Hemostasis, energy is not delivered unless the jaws are completely closed. This button activates an algorithm in the generator that, in conjunction with full trigger closure, allows for sealing larger vessels (up to 7 mm in diameter).
   - Pressing the right foot pedal of the footswitch or Energy button on the instrument activates the selected power level (1-5). The Energy button allows for sealing vessels up to 5 mm in diameter with full trigger closure and can enable other soft tissue applications (backcutting, scoring, drilling/otomy creation, etc.), where full trigger closure is not needed.

Foot Pedal	Button
Right	Energy Button
Left	Energy Button with Advanced Hemostasis

- The generator emits one of the audible tones listed in the table below to indicate when the instrument blade is first activated.

Tone	Button	Action
Repeating single tone	Energy Button	Generator On: Device is active
3 repeating, ascending tones	Energy Button with Advanced Hemostasis	Generator On: Device is active and in Advanced Hemostasis mode

- The generator changes to a second audible 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 audible tone change is not a substitute for surgical experience.

Tone	Button	Action
High pitched, repeating single tone	Applies to both buttons	Adaptive Tissue Technology is active

WARNING: Avoid contact with any and all metal or plastic instruments or objects when the instrument is activated (Illustration 4). Contact with staples, clips or other instruments while the instrument is activated may result in scratches on the blade, cracked or broken blades and premature blade failure.
Caution: Avoid contact with any and all metal or plastic instruments or objects such as graspers or uterine manipulators.
WARNING: Do not use the Energy button with Advanced Hemostasis when energy application is desired prior to full closure of the jaws. Energy is not delivered using the Energy button with Advanced Hemostasis until the jaws are completely closed. Using the Energy button with Advanced Hemostasis without full trigger closure may result in lack of hemostasis.
WARNING: If activation is unintentionally stopped while sealing, maintain jaw closure and reactivate. Releasing the trigger while sealing may result in lack of hemostasis.
Caution: 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 (Illustration 5).
Caution: Tissue pad damage may occur if device is activated without tissue in the closed jaws. Activation without tissue between the jaws will cause tissue pad degradation.

Caution: Prolonged blade activation with the clamp arm closed (with or without tissue between the blade and tissue pad) may cause tissue pad damage.
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.
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 6)
WARNING: 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 instrument (Illustration 7). Do not touch the instrument to the hemostats while activated. Scratches on the blade may lead to cracked or broken blades and premature blade failure.

8. Close the clamp arm by closing the trigger and remove the shaft from the trocar or incision.
9. Unplug the instrument from the generator.
10. Turn the generator OFF at the power switch.
11. Dispose of the instrument and cable in an appropriate container. No disassembly is required.

Disposal

- Some internal components of the Reprocessed HARMONIC 1100 Shears instrument contain Lead (PZT Lead-Zirconate-Titanate). Disposal should be performed according to local requirements and regulations.

Storage and handling

- Temperature: -20 - +60°C
- Relative Humidity: 15% - 90%

Storage and transportation conditions

- Keep Dry
- Keep Away from Heat

How supplied

- The Reprocessed HARMONIC® 1100 Shears are supplied sterile for single patient use.

Compatibility

- The Reprocessed HARMONIC® 1100 Shears instrument is designed for use exclusively with the Generator G11 (GEN11) software version 2018-1 or later. 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.

Standards and IEC classifications

- The Reprocessed HARMONIC® 1100 Shears meets all pertinent clauses of IEC 60601-1 Edition 3+A1;C1, IEC 60601-1-2, and IEC 60601-2-2 Edition 6.0. If the Reprocessed HARMONIC® 1100 Shears experience loss or degradation of the essential performance described in these instructions as a result of EMC disturbances, there would be no effect to intended use.
- The medical device is suitable to be used in the Professional Healthcare Facility Environment.

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.

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