Reprocessed by

stryker®

Sustainability Solutions

Instructions for Use
Reprocessed MyoSure XL Tissue Removal Device

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 Ethylene Oxide (EO) gas

Explanation of Symbols

Symbol	Standard	Registration Number	Symbol Title	Description
STERILE EO	ISO 15223-1:2016	2501	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide
	ISO 15223-1:2016	2497	Date of manufacture	Indicates the date when the medical device was manufactured.
	ISO 15223-1:2016	2607	Use-by date	Indicates the date after which the medical device is not to be used.
REF	ISO 15223-1:2016	2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT	ISO 15223-1:2016	2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1:2016	1641	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
2	ISO 15223-1:2016	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.
2 STERILIZE	ISO 15223-1:2016	2608	Do not resterilize	Indicates medical device that is not to be resterilized.
	ISO 15223-1:2016	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.
PHT NON-DEHP DEHP	BS EN 15986:2011	N/A	Does not contain or presence of phthalate DEHP	Indicates product that does not contain or have presence of the phthalate bis (2-ethylhexyl) phthalate (DEHP).

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Reprocessed MyoSure XL Tissue Removal Device Description

The MyoSure Tissue Removal System consists of the following procedural components:

- Control Unit
- Reprocessed Tissue Removal Device (Reprocessed Single Use Device)
- Foot Pedal

The sterile, reprocessed hand-held tissue removal device is used to hysteroscopically remove intrauterine tissue. It is connected via a flexible drive shaft to a motorized control unit. A foot pedal allows the user to control the reprocessed tissue removal device by turning the motor in the control unit on and off.

Indications for Use

The Reprocessed MyoSure XL Tissue Removal Device is intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: Submucous myomas, endometrial polyps and retained products of conception.

Contraindications for Use

The MyoSure Tissue Removal System should not be used with pregnant patients or patients exhibiting pelvic infection, cervical malignancies, or previously diagnosed endometrial cancer.

Warnings and Precautions

The brief operating instructions in this guide will make the system easier to use. As with any surgical instrument, there are important health and safety considerations. These are as follows:

- Before using the MyoSure Tissue Removal System for the first time, please review all available product information.
- Before using the MyoSure Tissue Removal System, you should be experienced in hysteroscopic surgery with powered instruments. Healthy uterine tissue can be injured by improper use of the tissue removal device. Use every available means to avoid such injury.
- Use only the MyoSure Control Unit to connect to the Reprocessed MyoSure XL Tissue Removal Device. Use of any other drive mechanism may result in failure of the device to operate or lead to patient or physician injury.
- If visualization is lost at any point during a procedure, stop cutting immediately.
- Periodic irrigation of the tissue removal device tip is recommended to provide adequate cooling and to prevent accumulation of excised materials in the surgical site.
- Ensure that vacuum pressure >200 mm Hg is available before commencing surgery.
- **DANGER:** Risk of explosion if used in the presence of flammable anesthetics.
- **WARNING - Exercise extreme caution when resecting tissue in patients who have implants that extend into the uterine cavity.**
- Do not use the Reprocessed MyoSure XL Tissue Removal Device to resect tissue that is adjacent to an implant. When resecting tissue in patients that have implants, assure that:
    - The Reprocessed MyoSure XL Tissue Removal Device's cutting window is facing away from (i.e. 180° opposite) the implant;
    - the visual field is clear; and
    - the Reprocessed MyoSure XL Tissue Removal Device's cutting window is engaged in tissue and is moved away from the implant as tissue resection proceeds.
- **Warning: Please consider pre-operative imaging prior to the procedure to assess the patient for evidence of placental invasion of the myometrium. In the immediate postpartum phase, removal of retained products of conception (RPOC) in the setting of known or suspected placenta acreta, placenta increta or placenta percreta poses a risk of significant and potentially life threatening bleeding.**
- In the event an implant becomes entangled with a MyoSure cutter, the following steps are recommended:
    - cease cutting immediately:
    - kink the Reprocessed MyoSure XL Tissue Removal Device's outflow tube to prevent a loss of uterine distension;
    - disconnect the Reprocessed MyoSure XL Tissue Removal Device's drive cable from the control box;
    - grasp the end of the Reprocessed MyoSure XL Tissue Removal Device drive cable with a hemostat or other clamping device;
    - hold the drive cable hub and tissue removal device to prevent twisting;
    - open the tissue removal device's cutting window by manually twisting the hemostat counterclockwise; and
    - gently pull the Reprocessed MyoSure XL Tissue Removal Device into the hysteroscope to detach the Reprocessed MyoSure XL device from the implant.
- If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1.
- If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 2601-1/IEC 60601-1 approved isolation transformer and retest the system.

- The use of accessory equipment in the patient vicinity not complying with the equivalent medical safety requirements of this equipment may lead to a reduced level of safety of the resulting system. The use of accessory equipment outside the patient vicinity not complying with medical or otherwise appropriate safety requirements may lead to a reduced level of safety of the resulting system.
- Use of an accessory, transducer, or cable, other than those specified by Hologic may result in increased emissions or decreased immunity of the MyoSure Hysteroscopic Tissue Removal System.

Precautions

- The tissue removal device should be stored at room temperature, away from moisture and direct heat.
- Do not use after expiration date.
- Do not use the device if the sterile package is open or appears compromised. Do not use the device if damage is observed.
- To assure optimal performance, replace the tissue removal device after 2 hours of cutting time.
- The reprocessed tissue removal device is intended for single use only. Do not re-sterilize. Do not lubricate tissue removal device. Discard tissue removal device assembly after use.
- DO NOT attempt to sharply bend the flexible drive cable in a diameter of less than 8 inches (20 centimeters). A sharply bent or kinked drive cable may cause the control unit to overheat and stop. During a procedure, a minimum distance of 5 feet (1.5 meters) should be maintained between the control unit and the tissue removal device to allow the drive cable to hang in a large arc with no bends, loops, or kinks.
- DO NOT rotate the tissue removal device >180° if the tissue removal device is not running. The cutting window may open up which will lead to inability to maintain distension. If such situation occurs, just tap the foot pedal once or twice to run the tissue removal device; the cutting window will then close automatically.
- If it appears that the tissue removal device's cutter blade has stopped rotating during a procedure, check to ensure that all connections to the tissue removal device and the control unit (both mechanical and electrical) are secure and that the drive cable has not wrapped into a loop.
- Exercise care when inserting or removing the device. Insertion and removal of the device should be performed under direct visualization at all times.
- To avoid perforation, keep the device tip under direct visualization and exercise care at all times when maneuvering it or cutting tissue close to uterine wall. Never use the device tip as a probe or dissecting tool.
- Exercise care when inserting or removing the device. Excessive bending of the device distal tip can cause the tissue removal device's cutter to come out of the cutting window. If such damage occurs, replace the device immediately.
- Do not allow the rotating portion of the tissue removal device to touch any metallic object such as a hysteroscope or sheath. Damage to both instruments is likely. Damage to the tissue removal device can range from a slight distortion or dulling of the cutting edge to actual fracture of the tip in vivo. If such contact does occur, inspect the tip. If you find cracks, fractures, or dulling, or if you have any other reason to suspect a tissue removal device is damaged, replace it immediately.
- Do not operate the tissue removal device in the open air for an extended period, as the lack of irrigation may cause the tissue removal device to overheat and seize.
- Excessive leverage on the tissue removal device does not improve cutting performance and, in extreme cases, may result in wear, degradation, and seizing of the inner assembly.
- Do not sterilize or immerse the control unit in disinfectant.
- Do not cool the tissue removal device by immersing it in cold water.
- Electrical safety testing should be performed by a biomedical engineer or other qualified person.
- This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

Electromagnetic Safety

- The MyoSure Tissue Removal System needs special precautions regarding electromagnetic safety and needs to be installed and put into service according to the electromagnetic safety information provided in the system's Operating Manual.
- This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:
    - Reorient or relocate this equipment, the other equipment, or both.
    - Increase the separation between the pieces of equipment.
    - Connect the pieces of equipment into different outlets or circuits.
    - Consult a biomedical engineer.
- All equipment performance is considered safety-related performance. That is, the failure or degradation of the performance specified in this manual may pose a safety risk to the patient or operator of this equipment.
- **Note: If the MyoSure Tissue Removal System is put into service in accordance to the safety instruction in this manual, the product should remain safe and provide the performance listed above. If the product fails to provide**

this level of performance, the procedure should be aborted and the biomedical staff alerted to the observed problem. The problem needs to be corrected before continuing or starting a new procedure.

- Portable and mobile RF communications equipment, including cellular telephones and other wireless devices can affect medical electrical equipment. To ensure safe operation of the MyoSure Hysteroscopic Tissue Removal System, do not operate communications equipment or cellular telephones at a distance closer than specified in Table 4 of the Operating Manual.
- The MyoSure Tissue Removal System is not designed to work with or in the vicinity of electrical surgical equipment. If electrical surgical equipment must be used in the same area as the MyoSure Hysteroscopic Tissue Removal System, the MyoSure Tissue Removal System should be observed for proper operation before performing a procedure. This includes operating the electrical surgical equipment in its active mode at a power level suitable for the procedure.
- For more information regarding the electromagnetic safety of this product, please see Tables 1–4 in the back of the Operating Manual.

Reprocessed MyoSure Tissue Removal Device: 50-501XL

The Reprocessed MyoSure XL Tissue Removal Device is shown in Figure 1. It is a hand-held unit which is connected to the control unit via a 6-foot (1.8-meter) flexible drive cable and to a collection canister via a 10-foot (3-meter) vacuum tube. Cutting action is activated by a foot pedal. The tissue removal device is a reprocessed single-use device designed to hysteroscopically remove intrauterine tissue.

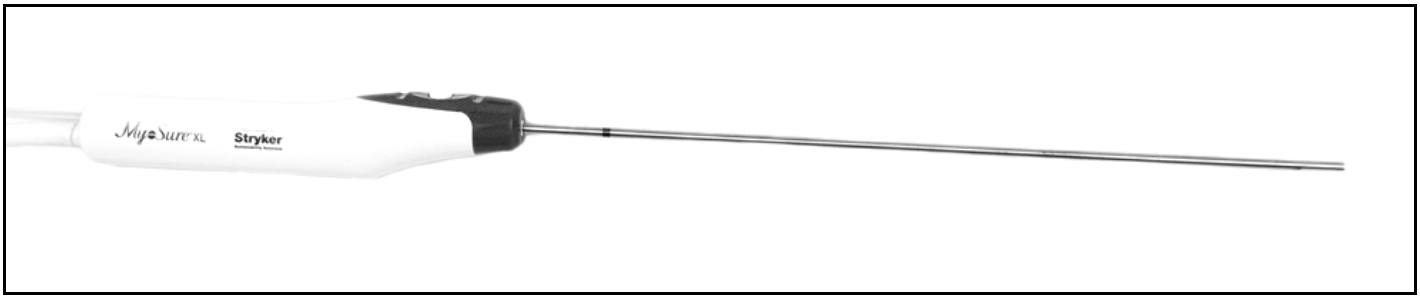

FIGURE 1: REPROCESSED MYOSURE XL TISSUE REMOVAL DEVICE

The flexible drive cable is inserted into the drive cable connection on the front panel of the MyoSure Control Unit.
The proximal end of the vacuum tubing is connected to a collection canister. The vacuum pressure draws fluid and resected tissue through the tissue removal device's cutting window.

Set-up

The tissue removal device is EtO sterilized. Verify that the tissue removal device is sterile prior to use. Do not use if the package is opened or damaged. Discard all opened, unused devices.

CAUTION: The reprocessed tissue removal device is intended for single use only. DO NOT RE-STERILIZE. DO NOT REUSE. Do not lubricate tissue removal device. Discard tissue removal device after use. Dispose of the tissue removal device and packaging according to your facility's policies and procedures concerning biohazardous materials and sharps waste.

WARNING-DANGER: Risk of explosion if used in the presence of flammable anesthetics.

1. Review the System Configuration Diagram in Figure 2 for set-up outline.

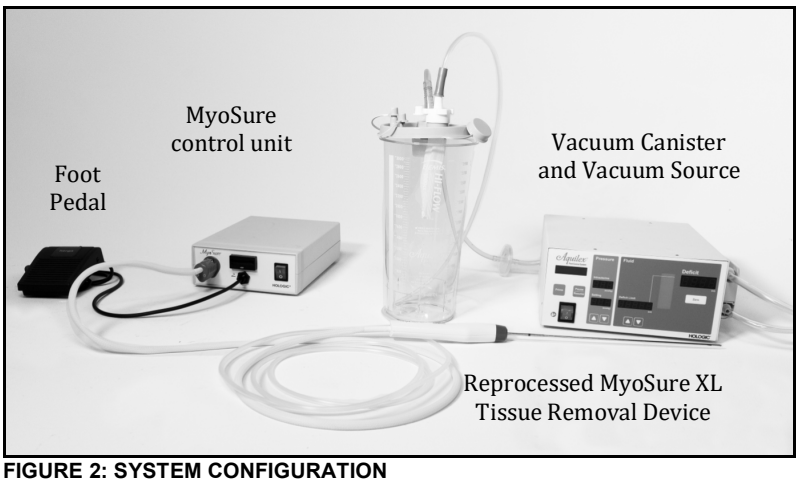

FIGURE 2: SYSTEM CONFIGURATION

2. Place the control unit on top of a cart or other stable work surface. Plug the control unit power cord into the rear panel connector and a grounded AC power source.
3. Connect the foot pedal tube to the connector on the front of the control unit panel.

Connecting Reprocessed Tissue Removal device to the Control Unit

1. Remove the reprocessed tissue removal device (REF 50-501XL) from the sterile package.
2. Sterile person hands the flexible drive cable and vacuum tubing to the non-sterile person.
3. Non-sterile person inserts the flexible cable into the corresponding connection on the control unit as shown in Figure 3.
4. The reprocessed tissue removal device flexible drive cable has a keyed feature that serves to align the handpiece cable to the control unit connector. The metal tab on the connector is pushed down, the flexible cable inserted and then the tab is released.

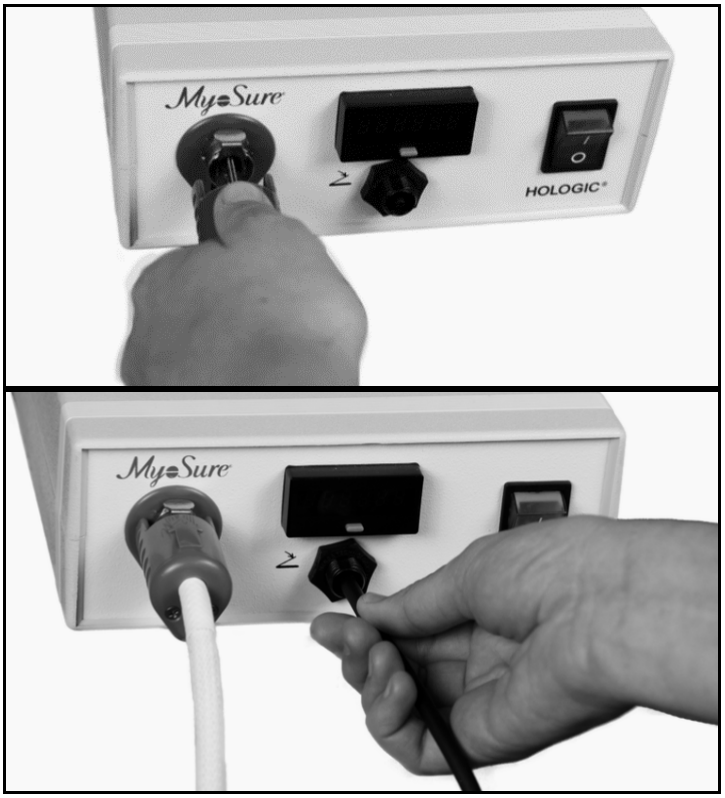

FIGURE 3: INSERT DRIVE CABLE AND FOOT PEDAL INTO CONTROL UNIT

CAUTION: DO NOT attempt to sharply bend the flexible drive cable in a diameter of less than 8 inches (20 centimeters). A sharply bent or inked drive cable may cause the control unit to overheat and stop. During a procedure, a minimum distance of 5 feet (1.5 meters) should be maintained between the control unit and the tissue removal device to allow the drive cable to hang in a large arc with no bends, loops, or kinks.

5. Non-sterile person attached the tissue removal device vacuum tubing to the corresponding connection on the tissue trap of the collection canister as shown in Figure 4.

FIGURE 4: ATTACH VACUUM TUBE TO COLLECTION CANISTER

Operation

1. Push the power switch to the ON (|) position.
2. The foot pedal activates tissue removal device operation. The foot pedal turns the motor ON and OFF. Once the foot pedal is depressed, the reprocessed tissue removal device accelerates and rotates to the set speed and continues until the foot pedal is released.
3. Press the foot pedal and observe the reprocessed tissue removal device action to verify that the motor runs and that the cutting window is closed as shown in Figure 5.

FIGURE 5: CLOSED TISSUE REMOVAL DEVICE CUTTING WINDOW ON LEFT

WARNING: Periodic irrigation of the reprocessed tissue removal device tip is recommended to provide adequate cooling and to prevent accumulation of excised materials in the surgical site.

4. Introduce the reprocessed tissue removal device through the straight 4 mm working channel of a hysteroscope.
5. Under direct hysteroscopic visualization, position the reprocessed tissue removal device's side facing cutting window against target pathology.

CAUTION: Excessive leverage on the reprocessed tissue removal device does not improve cutting performance and, in extreme cases, may result in wear, degradation, and seizing of the cutter assembly.

6. Press the foot pedal to activate the reprocessed tissue removal device's cutting blade.

7. The reprocessed tissue removal device's reciprocating action alternately opens and closes the device's cutting window to the vacuum flow thereby drawing tissue into the cutting window.
8. Cutting takes place when the reprocessed tissue removal device cutting edge rotates and translates across the reprocessed tissue removal device's cutting window.

Clearing the Field of View

1. If visualization is lost, stop cutting immediately.
2. Press the aspiration button located on the thumb rest (figure 6) to momentarily increase suction to facilitate clearing the field of view.
3. Periodically press the aspiration button to clear the field of view as needed.

FIGURE 6: ASPIRATION BUTTON TO CLEAR THE FIELD OF VIEW

CAUTION: If it appears that the blade has stopped rotating during a procedure, check to ensure that all connections to the reprocessed tissue removal device and the control unit (both mechanical and electrical) are secure and that the drive cable has not wrapped into a loop.

NOTE: If system is turned off for any reason, wait at least 15 seconds before turning power back on.

Disposal

Disconnect the reprocessed tissue removal device from the control unit. Dispose of the reprocessed tissue removal device and packaging according to your facility's policies and procedures concerning biohazardous materials and sharps waste.

CAUTION: The reprocessed tissue removal device contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

Troubleshooting

The MyoSure Tissue Removal System is very simple to operate. The control unit is switched ON using the front panel power switch. If the unit does not operate, check the following:

1. Unit is plugged into wall outlet.
2. Wall outlet has power.
3. Power cord is attached to back of control unit.
4. Foot pedal has been connected to front panel.
5. Vacuum pressure is available.
6. Vacuum tubing is connected.

If excess force or bend is applied to the reprocessed tissue removal device, the control unit will shut off the timer display to protect the system. In this event, switch the main power switch located in the front panel of the control unit to OFF, wait for 15 seconds and then switch the main power switch to ON to resume operation of the MyoSure Tissue Removal System.

NOTE: If the system is turned off for any reason, wait at least 15 seconds before turning the power back on.

Technical Specifications

Reprocessed Tissue Removal Device: 50-501XL
Sterile, reprocessed single use device

Working Length: 12.6" / 32.0 cm
OD: 4 mm

Tissue Removal Device Accessories

Vacuum Source – 200-650 mm Hg
Aquilex™ Fluid Control System or equivalent in compliance with national version of safety standard, IEC 60601-1 (e.g., for USA, UL 60601-1; for Canada, CSA C22.2 No 601.1, etc.)

Vacuum Canister & Tissue Trap
Bemis 3000 cc Hi-Flow Canister Model 3002 055 or equivalent
Bemis Specimen Collection Adapter 533810 or equivalent

Storage and Handling
The reprocessed MyoSure Tissue Removal Device should be stored at room temperature, away from moisture and direct heat. Do not use after expiration date.

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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