Reprocessed by

stryker®

Sustainability Solutions

Instructions for Use
Reprocessed MyoSure® XL Tissue Removal Device for Fluent

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 for Fluent Description

The MyoSure XL Tissue Removal Device for Fluent is a sterile, reprocessed hand-held tissue removal device used to remove intrauterine tissue. It is connected via a flexible drive shaft to the Fluent Fluid Management System. A foot pedal allows the user to control the reprocessed tissue removal device by turning the motor in the Fluent Fluid Management System on and off.

Indications for Use

The Reprocessed MyoSure XL Tissue Removal Device for Fluent 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 XL Tissue Removal Device for Fluent 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:

- 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**.**
- Before using the MyoSure XL Tissue Removal Device for Fluent for the first time, please review all available product information.
- Before using the MyoSure XL Tissue Removal Device for Fluent, 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.
- The MyoSure XL Tissue Removal Device for Fluent is only compatible with the Fluent Fluid Management System. Use of any other motorized power source may fail to operate the device 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.
- **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 for Fluent to resect tissue that is adjacent to an implant. When resecting tissue in patients that have implants, assure that:
    - The device's cutting window is facing away from (i.e. 180° opposite) the implant;
    - the visual field is clear; and
    - the device's cutting window is engaged in tissue and is moved away from the implant as tissue resection proceeds.
- In the event an implant becomes entangled with a MyoSure cutter, the following steps are recommended:
    - cease cutting immediately:
    - kink the device's outflow tube to prevent a loss of uterine distension;
    - disconnect the device's drive cable from the Fluent Fluid Management System;
    - grasp the end of the 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 device into the hysteroscope to detach the Reprocessed MyoSure XL Tissue Removal Device for Fluent 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 Fluent Fluid Management System or the Reprocessed MyoSure XL Tissue Removal Device for Fluent.

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 Fluent Fluid Management System to overheat and stop. During a procedure, a minimum distance of 5 feet (1.5 meters) should be maintained between the Fluent Fluid Management System 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 the tissue removal device is properly connected to the Fluent Fluid Management System, all cables are secure, and the drive cable has not wrapped into a loop.
- Exercise care when inserting or removing the device from the MyoSure Hysteroscope. 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.
- 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 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 XL Tissue Removal Device for Fluent is only to be used with the Fluent Fluid Management System. The Fluent Fluid Management System needs special precautions regarding electromagnetic safety.

Impact of Mobile and Portable HF Communication Devices

The emission of high frequency energy by mobile communication devices may impact the function of the electrical medical device. Operating such devices (e.g., cell phones, GPS phones) in the proximity of the electrical medical device is prohibited.

Electrical Connections

Do not touch electrical connections identified with this warning label.
Do not establish a connection between these plugs and sockets without first implementing precautionary ESD (electrostatic discharge) measures.
The following are ESD precautionary measures:

- Apply potential equalization (PE), if available on your equipment, to all devices to be connected.
- Use only the listed equipment and accessories.

Employees have to be informed about and trained in ESP precautionary measures.

Guidelines and Manufacturer's Statement

The FLUENT FLUID MANAGEMENT SYSTEM is intended for use in the electromagnetic environment specified below. The customer or the user of the FLUENT FLUID MANAGEMENT SYSTEM should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The FLUENT FLUID MANAGEMENT SYSTEM uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment
RF emissions CISPR 11	Group 2	The FLUENT FLUID MANAGEMENT SYSTEM must emit electro-magnetic energy in order to perform its intended function. Nearby electronic equipment may be affected
RF emissions CISPR 11	Class A	The FLUENT FLUID MANAGEMENT SYSTEM is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations / flicker emissions IEC 6100-3-3	Complies	

Guidelines and Manufacturer's Declaration

Electromagnetic Immunity

The FLUENT FLUID MANAGEMENT SYSTEM is intended for use in the electromagnetic environment specified below. The customer or the user of the FLUENT FLUID MANAGEMENT SYSTEM should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients / bursts IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 6100-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 6100-4-11	< 5% UT* (> 95% dip in the UT) for ½ cycle 40% UT (60% dip in the UT) for 5 cycles 70% UT (30% dip in the UT) for 25 cycles. < 5% UT (> 95% dip in the UT) for 5 s	< 5% UT* (> 95% dip in the UT) for ½ cycle 40% UT (60% dip in the UT) for 5 cycles 70% UT (30% dip in the UT) for 25 cycles. < 5% UT (> 95% dip in the UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the /operator of FLUENT FLUID MANAGEMENT SYSTEM requires continued operation during power mains interruptions, it is recommended that the FLUENT FLUID MANAGEMENT SYSTEM be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Conducted RF IEC 61000-4-6 Radiated HF interference quantities according to IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment used no closer to any part of the FLUENT FLUID MANAGEMENT SYSTEM, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended safety distance: $d = 1.2\sqrt{P}$ for 150 KHz to 80 MHz

			d = 1.2√P for 80 MHz to 800 MHz d = 2.3√P for 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer, and d is the recommended separation distance in meters [m]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note *: UT is the AC mains voltage prior to application of the test level.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection of structures, objects, and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the FLUENT FLUID MANAGEMENT SYSTEM is used exceeds the applicable compliance level above, the FLUENT FLUID MANAGEMENT SYSTEM should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the changing orientation or the location of the FLUENT FLUID MANAGEMENT SYSTEM.

b) Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

The following lists the recommended separation distances between portable and mobile RF communications equipment and the FLUENT FLUID MANAGEMENT SYSTEM.

Recommended Separation Distances

The FLUENT FLUID MANAGEMENT SYSTEM is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FLUENT FLUID MANAGEMENT SYSTEM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FLUENT FLUID MANAGEMENT SYSTEM as recommended below, according to maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 GHz d = 2.3√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated by using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Reprocessed MyoSure XL Tissue Removal Device for Fluent: 50-601XL

The Reprocessed MyoSure XL Tissue Removal Device for Fluent is shown in Figure 1. It is a hand-held unit which is connected to the Fluent Fluid Management System via a 6-foot (1.8-meter) flexible drive cable and to the Out-FloPak via a 10-foot (3-meter) suction 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.

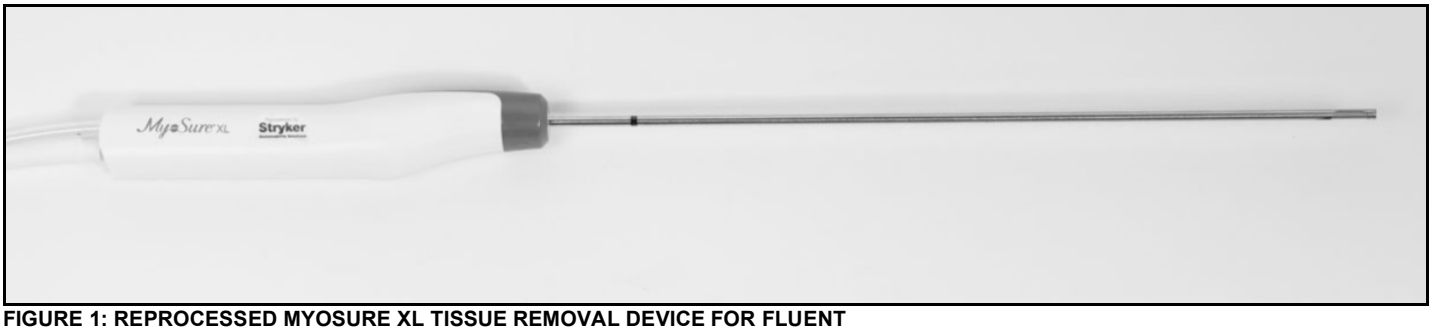

FIGURE 1: REPROCESSED MYOSURE XL TISSUE REMOVAL DEVICE FOR FLUENT

The flexible drive cable is inserted into the drive cable connection on the front panel of the Fluent Fluid Management System. The proximal end of the suction tube is connected to the Out-FloPak of the Fluent Fluid Management System. The suction pressure draws fluid and resected tissue through the tissue removal device's cutting window.

Set-up

The reprocessed tissue removal device is EtO sterilized. Verify that the reprocessed 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.

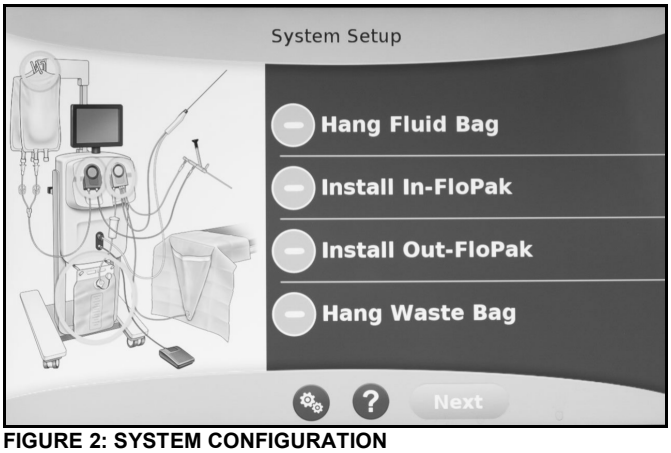

FIGURE 2: SYSTEM CONFIGURATION

2. Refer to the Fluent Fluid Management System Operator's Manual for instructions on how to set up the Fluent Fluid Management System.
3. Connect the foot pedal tube to the connector on the front of the Fluent Fluid Management System.

Connecting Reprocessed Tissue Removal device to the Control Unit

1. Remove the reprocessed tissue removal device (REF 50-601XL) 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 adapter on the Fluent Fluid Management System 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 Fluent Fluid Management System connector. The metal tab on the connector is pushed down, the flexible cable inserted and then the tab is released.

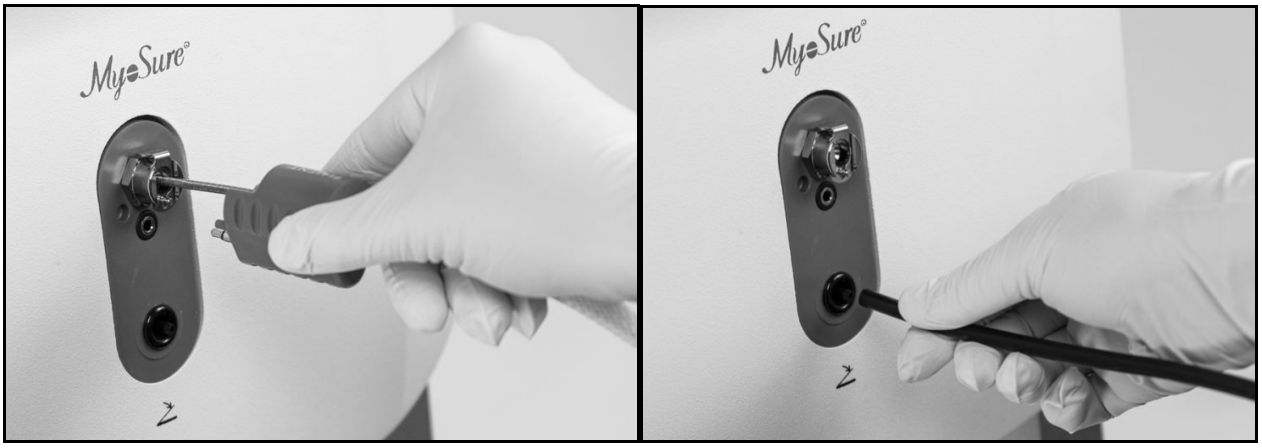

FIGURE 3: INSERT DRIVE CABLE AND FOOT PEDAL INTO FLUENT FLUID MANAGEMENT SYSTEM

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 Fluent Fluid Management System to overheat and stop. During a procedure, a minimum distance of 5 feet (1.5 meters) should be maintained between the Fluent Fluid Management System 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 suction tube to the corresponding fitting on the Out-FloPak.

Operation

1. Set up the Fluent Fluid Management System for a MyoSure tissue removal procedure per the instructions in the Fluent Fluid Management System Operating Manual.
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 4.

FIGURE 4: 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 outflow pump of the Fluent Fluid Management System thereby drawing tissue into the cutting window.
8. Cutting takes place when the reprocessed tissue removal device cutting edge rotates and translates through the reprocessed tissue removal device's cutting window.

CAUTION: If it appears that the blade has stopped rotating during a procedure, check to ensure that the tissue removal device is properly connected to the Fluent Fluid Management System, all cables to the Fluent Fluid Management System are secure, and that the drive cable has not wrapped into a loop.

NOTE: If the Fluent Fluid Management System powers down unexpectedly, leave it off for 15 seconds, restart the system and follow on-screen prompts.

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

If the device does not operate, check the following:

1. The Fluent Fluid Management System is plugged into a wall outlet.
2. The wall outlet has power.
3. The power cord is attached to the rear of the Fluent Fluid Management System.
4. The foot pedal is connected to the front of the Fluent Fluid Management System.
5. The suction tubing is connected.

If excess bending force is applied to the Reprocessed MyoSure CL Tissue Removal Device for Fluent, the system may temporarily stop to prevent further damage.

NOTE: If the Fluent Fluid Management System powers down unexpectedly, leave it off for 15 seconds, restart the system and follow on-screen prompts.

Technical Specifications

Reprocessed Tissue Removal Device: 50-601XL
Sterile, reprocessed single use device

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

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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