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MyoSure® XL Tissue Removal Device for Fluent

Instructions for Use

Please read all information carefully.



Description

The MyoSure XL Tissue Removal Device for Fluent is a sterile, 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 tissue removal device by turning the motor in the Fluent Fluid Management System on and off.

RX ONLY (U.S.) Federal law restricts this device to sale by or on the order of a physician pursuant to 21 CFR 801.109(b)(1).

RX ONLY

Indications for Use

The 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

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 uterine 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 accreta, 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 or fluid management system 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 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 cutting window by manually twisting the hemostat; and
 - gently pull the device into the hysteroscope to detach the 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 MyoSure XL Tissue Removal Device for Fluent.

Precautions

Federal law restricts this device to sale by or on the order of a physician.

- 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 tissue removal device is intended for single use only. Do not re-sterilize. Discard tissue removal device assembly after use.
- Do not lubricate tissue removal device.
- Use of a reprocessed, single-use tissue removal device may permanently damage, impede performance, or cause failure of the Fluent Fluid Management System. Use of such products may render any warranties null and void.
- 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 $>180^\circ$ if the tissue removal device is not running. The cutting window may open up which will lead to the inability to maintain distension. If this situation occurs, 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 that 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 the 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 ESD precautionary measures.

Guidelines and Manufacturer's Statement

Electromagnetic Emissions

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. NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance 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	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 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 61000-4-5	± 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.

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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
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

Tissue Removal Device for Fluent: 50-601XL/50-603XL

The 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 single-use device designed to hysteroscopically remove intrauterine tissue.

The flexible drive cable is inserted into the drive cable adapter 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.



Figure 1. MyoSure XL Tissue Removal Device for Fluent

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 tissue removal device is intended for single use only. DO NOT RE-STERILIZE. DO NOT REUSE. 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.
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 console.



Figure 2. System Configuration

Connecting the Tissue Removal Device to the Fluent Fluid Management System

1. Remove the tissue removal device (REF 50-601XL/50-603XL) from the sterile package.
2. Sterile person hands the flexible drive cable and suction tube 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 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.

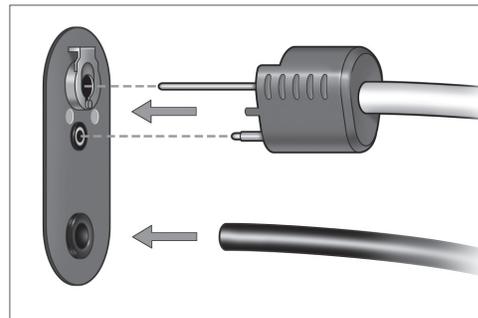


Figure 3. Insert drive cable and foot pedal into the Fluent Fluid Management System.

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 kinked drive cable may cause the Fluent Fluid Management System motor 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 attaches 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 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 tissue removal device action to verify that the motor runs and that the cutting window is closed as shown in Figure 4.

WARNING: 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.



Figure 4. Closed Tissue Removal Device cutting window on left

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

CAUTION: 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 cutter assembly.

6. Press the foot pedal to activate the tissue removal device's cutting blade.
7. The 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 tissue removal device cutting edge rotates and translates through the 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.

Storage

The tissue removal device should be stored at room temperature, away from moisture and direct heat. Do not use after expiration date.

Sterility

The tissue removal device is EtO sterilized. DO NOT RE-STERILIZE. DO NOT REUSE. Do not use if package is opened or damaged. Discard all opened, unused devices

Disposal

Disconnect the tissue removal device from the Fluent Fluid Management System. Dispose of the tissue removal device and packaging according to your facility's policies and procedures concerning biohazardous materials and sharps waste.

CAUTION: The 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 MyoSure XL 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

Tissue Removal Device: 50-601XL/50-603XL

Sterile, single use device

Working Length: 12.6" / 32.0 cm

OD: 4 mm

WARRANTY, SERVICE, AND REPAIR

Warranty

Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation ("Warranty Period"); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13-24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer's warranties shall extend to Hologic's customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products.

These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended Software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or "as-is" basis.

Technical Support and Product Information

Contact Hologic Technical Support if the MyoSure XL Tissue Removal Device for Fluent fails to operate as intended. If product is to be returned to Hologic for any reason, Technical Support will issue a Returned Materials Authorization (RMA) number and biohazard kit if applicable. Return the MyoSure XL Tissue Removal Device for Fluent according to the instructions provided by Technical Support. Be sure to clean and sterilize the product before returning it and include all accessories in the box with the returned unit.

Return used or opened product according to the instructions provided with the Hologic-supplied biohazard kit.

For More Information

For technical support or reorder information in the United States, please contact:

 Hologic, Inc., 250 Campus Drive
Marlborough, MA 01752 USA
Phone: 1.800.442.9892 (toll-free)
www.hologic.com

International customers, contact your distributor or local Hologic Sales Representative:

European Representative

 Hologic BVBA
Da Vincilaan 5
1930 Zaventem
Belgium
Phone: +32 2 711 46 80

Symbols	Definitions
	Authorized Representative in the European Community
	Batch code, Lot code
	Catalogue number, Part number, or reorder number
	Consult instructions for use
	Contents
	Do not re-use
	Follow instructions for use
	Use by
	Manufacturer
	ON Main electrical power on.

Symbols	Definitions
	OFF Main electrical power off.
	Patient contact parts not made with DEHP
	Serial number
	Sterilized using ethylene oxide
	U.S. federal law restricts this device to sale by or on the order of a physician
	Do not resterilize
	Do not use if package is damaged

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