MyoSure® Hysteroscopic Tissue Removal System

MyoSure® XL Tissue Removal Device

Instructions for Use

HOLOGIC®

PLEASE READ ALL INFORMATION CAREFULLY.

℞ ONLY

Description

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

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

The sterile, disposable, 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 tissue removal device by turning the motor in the control unit on and off.

Indications for Use

The MyoSure Tissue Removal System is intended for hysteroscopic intrauterine procedures by trained gynecologists to resect and remove tissue including submucous myomas and endometrial polyps.

Contraindications

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 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 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 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 MyoSure XL Tissue Removal 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 MyoSure XL Tissue Removal Device's outflow tube to prevent a loss of uterine distension;
  - disconnect the MyoSure XL Tissue Removal Device's drive cable from the control box;
  - grasp the end of the 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 MyoSure XL Tissue Removal Device into the hysteroscope to detach the 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

℞ U.S. 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. Do not lubricate tissue removal device. Discard tissue removal device assembly after use.
- Use of a reprocessed, single-use tissue removal device may permanently damage, impede performance, or cause failure of the MyoSure Hysteroscopic Tissue Removal 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 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 insure 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.

Tissue Removal Device: 50-501XL

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

Figure 1. 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 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.

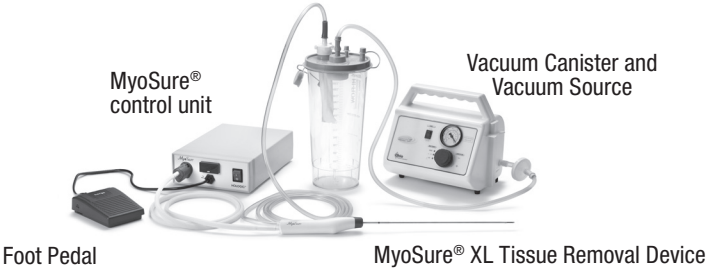

Figure 2. System Configuration

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 Tissue Removal Device to the Control Unit

1. Remove the 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 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.

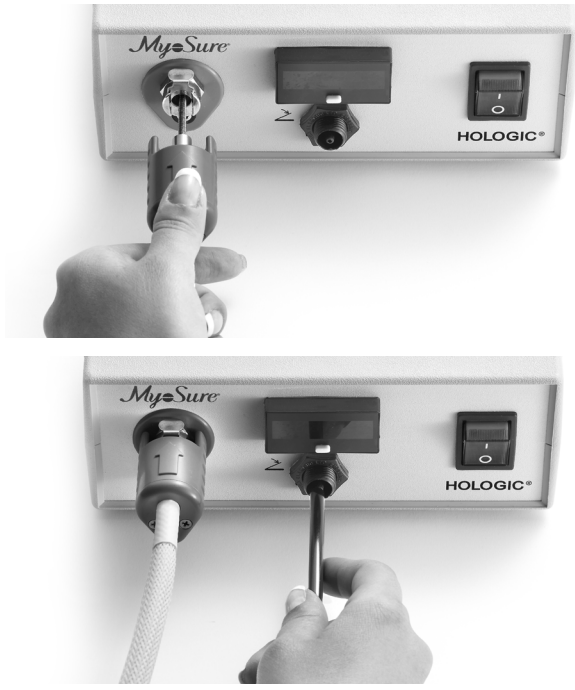

Figure 3. Insert Drive Cable and Foot Pedal into Control Unit

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 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.

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

Figure 4. Attach Vacuum Tube to Collection Canister

Operation

1. Push the power switch to the ON (I) 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 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 5.

Figure 5. Closed Tissue Removal Device Cutting Window on Left

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.

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 vacuum flow thereby drawing tissue into the cutting window.
8. Cutting takes place when the tissue removal device cutting edge rotates and translates across the 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 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.

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 control unit. 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

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 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

To Reorder : 50-501XL 3 Pack: 50-503XL

Sterile, single use device

Length: 25.25" / 64.14 cm

OD: 4 mm

Weight: 17 oz. / 482 g

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 60601-1:1988-1995 (e.g., for USA, UL 60601-1:2003; for Europe, EN 60601-1:1990-1996; for Canada, CSA C22.2 No. 601.1:1998, etc)

Vacuum Canister & Tissue Trap

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

WARRANTY, SERVICE, AND REPAIR

WARRANTY INFORMATION

Hologic warrants to the original purchaser of the MyoSure® Hysteroscopic Tissue Removal System that it shall be free of defects in material and workmanship when used as intended under normal surgical conditions and in conformance with its instructions for use and maintenance instructions. The obligation of Hologic under this warranty shall be limited to the repair or replacement, each at no charge, at the option of Hologic within one year from the date of purchase, if examination shall disclose to the satisfaction of Hologic that the product does not meet this warranty.

THIS WARRANTY IS MADE IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE AND ALL OTHER OBLIGATIONS AND LIABILITIES ON THE PART OF HOLOGIC. HOLOGIC NEITHER ASSUMES NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT ANY OTHER LIABILITY IN CONNECTION WITH THE SALE OF A MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM. THIS WARRANTY SHALL NOT APPLY TO A MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM OR ANY OTHER PART THEREOF WHICH HAS BEEN SUBJECT TO ACCIDENT, NEGLIGENCE, ALTERATION, ABUSE, OR MISUSE, NOR TO ANY MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM THAT HAS BEEN REPAIRED OR ALTERED BY ANYONE OTHER THAN AN AUTHORIZED HOLOGIC SERVICE PERSON. HOLOGIC MAKES NO WARRANTY WHATSOEVER WITH REGARD TO ACCESSORIES OR PARTS USED IN CONJUNCTION WITH THE MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM AND NOT SUPPLIED AND MANUFACTURED BY HOLOGIC. THE TERM “ORIGINAL PURCHASER”, AS USED IN THE WARRANTY, SHALL BE DEEMED TO MEAN THAT PERSON OR ORGANIZATION AND ITS EMPLOYEES, IF APPLICABLE, TO WHOM THE MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM WAS SOLD BY HOLOGIC. THIS WARRANTY MAY NOT BE ASSIGNED OR TRANSFERRED IN ANY MANNER.

TECHNICAL SUPPORT AND PRODUCT RETURN INFORMATION

Contact Hologic Technical Support if the MyoSure Hysteroscopic Tissue Removal System 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 Hysteroscopic Tissue Removal System 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.

Hologic Technical Support

United States
Hologic, Inc., 250 Campus Drive, Marlborough, MA 01752 USA
Phone: 1.800.442.9892 (toll-free) or 1.508.263.2900
Fax: 1.508.229.2795

EC REP European Representative
Hologic UK, Ltd.
Link 10 Napier Way, Crawley, West Sussex RH10 9 RA UK
Phone: +44 (0) 1293 522 080

Symbols Used on Labeling

Authorized Representative in the European Community	EC REP
Batch code, Lot code	LOT
Catalogue number, Part number, or reorder number	REF
Consult instructions for use	
Contents	
Do not re-use	
Do not use if package is damaged	
Follow instructions for use	
Use by	
Manufacturer	
ON Main electrical power on.	
OFF Main electrical power off.	
Patient contact parts do not contain phthalates	
Sterilized using ethylene oxide	STERILE EO
Do not resterilize	
U.S. federal law restricts this device to sale by or on the order of a physician	R_x

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