MyoSure® Hysteroscopic Tissue Removal System

Operating Manual

HOLOGIC®

Preface

This manual provides the information you need to operate and maintain the Hologic MyoSure Hysteroscopic Tissue Removal System. It is essential that you read and understand all the information in this manual before using or maintaining the system.

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Symbols Used On Labeling

Atmospheric Pressure Limitation	
Authorized Representative in the European Community	
Batch code Lot number	
Catalogue number Part number or reorder number	
Consult instructions for use	
Contents	
Earth ground	
Equipotential terminal	
Equipment classification Type BF equipment	
European Community Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/EC	
Follow instructions for use	
Foot pedal Foot pedal control	
Fuse	
Humidity Limitation	
Manufacturer	
Non-sterile	
OFF Main electrical power off.	
ON Main electrical power on.	
Patient contact parts do not contain phthalate	
Radio-frequency (RF) energy (non-ionizing radiation)	
Serial number	
Sterilized using irradiation	
Temperature Limitation	
U.S. federal law restricts this device to sale by or on the order of a physician	
Use by	
Watertight Equipment per IEC 529	IPX1

Symbols Used On Labeling

Symbols used only on Tissue Removal Device	
Do not re-use	
Do not use if package is damaged	
Do not resterilize	
Sterilized using ethylene oxide	
INMETRO Mark	

Introduction, Indications for Use, Contraindications

Introduction

Read these instructions completely prior to using the MyoSure Hysteroscopic Tissue Removal System.

The MyoSure Hysteroscopic Tissue Removal System is designed to meet the requirements of intrauterine tissue removal. The system consists of the following procedural components:

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

A sterile, disposable, hand-held tissue removal device is used for tissue removal. 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 off and on.

The MyoSure Hysteroscopic Tissue Removal System features many performance and ease-of-use advantages, including:

- A simple user interface with only a power switch and
- A display that shows the time spent cutting and removing tissue.

The MyoSure Hysteroscopic Tissue Removal System is designed to be used in operating room, ambulatory surgical center, and physician's office environments. The gynecologist should be trained in diagnostic and therapeutic hysteroscopy, resection, and removal of gynecological tissue.

Indications for Use

The MyoSure Hysteroscopic 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 Hysteroscopic 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, while the recommended maintenance procedures will ensure optimal performance over years of reliable use. Of course, as with any surgical instrument, there are important health and safety considerations. These are listed below and highlighted within the text.

Warnings

- Before using the MyoSure Tissue Removal System for the first time, please review all available product information.

- Before using the MyoSure 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 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 the 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 Tissue Removal Device to resect tissue that is adjacent to an implant. When resecting tissue in patients that have implants, assure that:
  - the MyoSure Tissue Removal Device's cutting window is facing away (i.e., 180° opposite) the implant;
  - the visual field is clear;
  - the MyoSure 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 Tissue Removal Device's outflow tube to prevent a loss of uterine distension;
  - disconnect the MyoSure Tissue Removal Device's drive cable from the control box;
  - grasp the end of the MyoSure 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;
  - gently pull the MyoSure Tissue Removal Device into the hysteroscope to detach the MyoSure 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, and any equipment used with the MyoSure Tissue Removal System should be Type BF.
- 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.
- The 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 MyoSure 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 MyoSure Control Unit to overheat and stop. During a procedure, a minimum distance of 5 feet (1.5 meters) should be maintained between the MyoSure Control Unit and the MyoSure 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 MyoSure Tissue Removal Device's cutter blade has stopped rotating during a procedure, check to ensure that all connections to the MyoSure Tissue Removal Device and the MyoSure Control Unit (both mechanical and electrical) are secure and that the drive cable has not wrapped up 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 MyoSure 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 Hysteroscopic 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 this 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 will pose a safety risk to the patient or operator of this equipment.
- **Note: If the MyoSure Hysteroscopic 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 this manual.
- The MyoSure Hysteroscopic 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 Hysteroscopic 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 this manual.

System Components

MyoSure Control Unit (REF 10-500)

Control Unit—Front Panel

The MyoSure Control Unit front panel includes power switch, tissue removal system timer display, foot pedal, and tissue removal device connectors (Figure 1).



FIGURE 1. MYOSURE CONTROL UNIT—FRONT PANEL

Power Switch

The power switch is the power ON / OFF switch for the entire system and must be activated prior to use.

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

Timer Display Window

The MyoSure Control Unit displays the elapsed operating time for the tissue removal device in MIN:SEC format.

MyoSure Foot Pedal and Tissue Removal Device Connectors

The foot pedal and tissue removal device connectors are located on the front panel.

MyoSure Control Unit—Rear Panel

There is one connector and equipotential compensator terminal on the rear panel (Figure 2).



FIGURE 2. MYOSURE CONTROL UNIT—REAR PANEL (*=EQUIPOTENTIAL COMPENSATOR TERMINAL)

The 3-pronged electrical connector allows any 100–120/200–240 VAC, 50/60 Hz, ISO VA source using the power cord supplied with the system. The MyoSure Control Unit power supply automatically detects the local power standard and adapts the tissue removal device to that standard. The equipotential compensator terminal permits connection of the MyoSure Control Unit to an external earthing system (not shown).

WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

MyoSure Tissue Removal Device

The MyoSure Tissue Removal Device is shown in Figure 3. It is a hand-held unit which is connected to the MyoSure 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 MyoSure Tissue Removal Device is a single-use device designed to hysteroscopically remove intrauterine tissue.

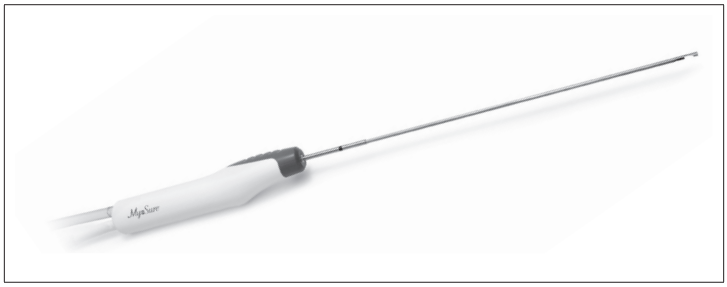


FIGURE 3. MYOSURE TISSUE REMOVAL DEVICE

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.

MyoSure Foot Pedal (REF 10-903)

The tissue removal system foot pedal (Figure 4) controls tissue removal device operation. The foot pedal plugs into the connector on the front of the MyoSure Control Unit panel. It has a single pedal and is pneumatically operated.



FIGURE 4. FOOT PEDAL

Set-up

Setting up the Hologic MyoSure Hysteroscopic Tissue Removal System

WARNING: Before using the MyoSure Tissue Removal System for the first time, you should review all available product information. You should be experienced in hysteroscopic surgery with powered instruments. Healthly uterine tissue can be injured by improper use of the tissue removal device. Use every available means to avoid such injury.

The MyoSure Tissue Removal Device is EtO sterilized. Verify that the tissue removal device is sterile prior to use. Do not use if package is opened or damaged. Discard all opened, unused devices. Do not use after expiration date.

CAUTION: The MyoSure Tissue Removal Device is intended for single use only. DO NOT RE-STERILIZE. DO NOT REUSE. Do not lubricate MyoSure Tissue Removal Device. Discard MyoSure Tissue Removal Device after use. Dispose of the MyoSure 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 5 for set-up outline.

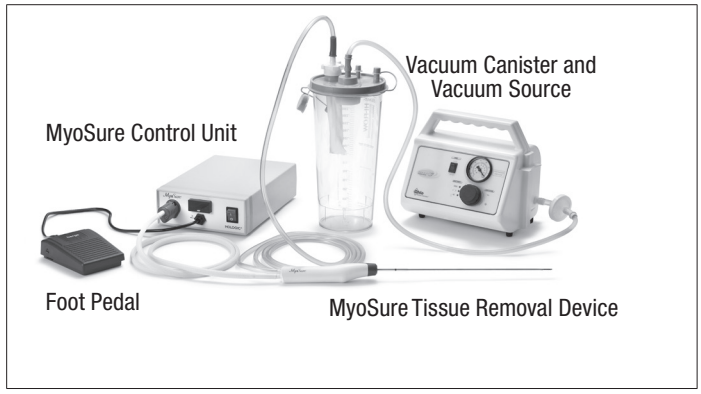


FIGURE 5. SYSTEM CONFIGURATION

2. Place the MyoSure Control Unit on top of a cart or other stable work surface. Plug the MyoSure 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 MyoSure Control Unit panel.

Connecting a MyoSure Tissue Removal Device to the Control Unit

1. Remove the tissue removal device 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 MyoSure Control Unit as shown in Figure 6.
4. The tissue removal device flexible drive cable has a keyed feature that serves to align the handpiece cable to the MyoSure Control Unit connector. The metal tab on the connector is pushed down, the flexible cable inserted and then the tab is released.

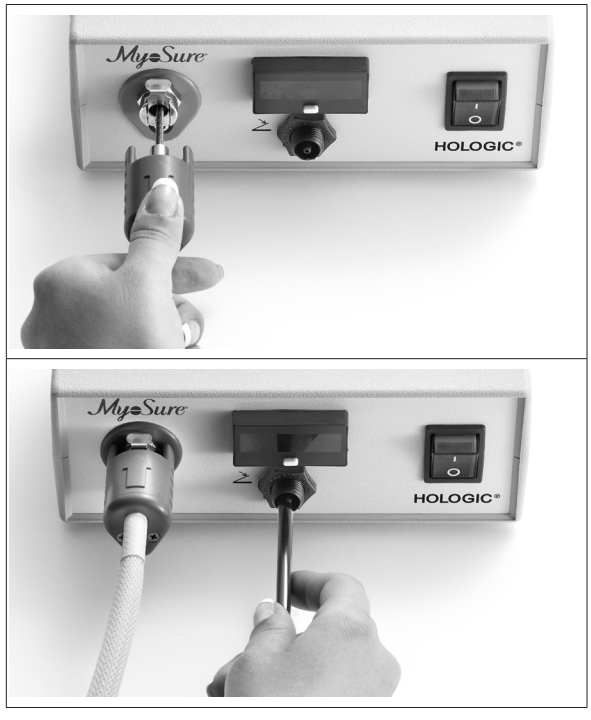


FIGURE 6. INSERT DRIVE CABLE AND FOOT PEDAL INTO MYOSURE CONTROL UNIT

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 MyoSure Control Unit to overheat and stop. During a procedure, a minimum distance of 5 feet (1.5 meters) should be maintained between the MyoSure Control Unit and the MyoSure 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 7.



FIGURE 7. ATTACH VACUUM TUBE TO COLLECTION CANISTER

6. The patient should be placed in dorsal lithotomy position, as the MyoSure Tissue Removal System is performed as a hysteroscopic procedure.

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 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 8.

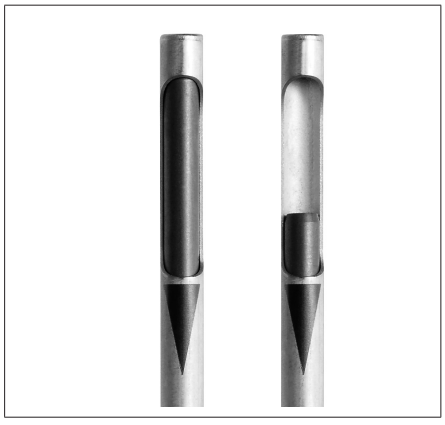


FIGURE 8. CLOSED TISSUE REMOVAL DEVICE CUTTING WINDOW ON LEFT

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 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.

CAUTION: If it appears that the blade has stopped rotating during a procedure, check to ensure that all connections to the MyoSure Tissue Removal Device and the MyoSure Control Unit (both mechanical and electrical) are secure and that the drive cable has not wrapped up into a loop.

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

CAUTION: Do not operate the tissue removal device in open air for an extended period, as the lack of irrigation may cause the tissue removal device to overheat and seize.

Cleaning

MyoSure Control Unit and Foot Pedal Cleaning

Follow this procedure after each operation to clean the MyoSure Control Unit and the foot pedal:

1. Disconnect the tissue removal device from the MyoSure Control Unit and dispose.
2. Disconnect the MyoSure Control Unit from the electrical source.
3. Wipe the MyoSure Control Unit with a clean damp cloth and mild germicide or isopropyl alcohol.

CAUTION: Do not sterilize or immerse the MyoSure Control Unit in disinfecant.

4. Wipe the foot pedal and the foot pedal connecting tube with a clean damp cloth.

The foot pedal (REF 10-903) has no electrical connections and is watertight per IPX8.

Maintenance and Service

Maintenance

Electrical Interference

CAUTION: 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.**

Environmental Protection

CAUTION: The control unit and tissue removal device contain 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.

CAUTION: Tissue removal device (single-use, disposable) may represent biohazard. Treat and dispose of only in accordance with any applicable national or institutional related policy.

Preventive Maintenance

Recommended Annual Performance Checks

Hologic recommends that Dielectric Strength, Earth Leakage Current, and Protective Earth Testing be performed annually to assure continued compliance with applicable safety requirements. These tests should be conducted in accordance with specifications UL 2601-1/IEC 60601-1.

CAUTION: Electrical safety testing should be performed by a biomedical engineer or other qualified person.

Service

The following are replacement parts for the Hologic MyoSure Hysteroscopic Tissue Removal System:

REF	Description
10-903	MyoSure Foot Pedal

Service Philosophy

There are no user serviceable components inside the MyoSure Hysteroscopic Tissue Removal System Control Unit. Repairs and adjustments are to be performed only by Hologic authorized service centers.

WARNING: No modification of this equipment is allowed.

If service becomes necessary, refer to the Technical Support Product Return Information in these instructions for use.

MyoSure Control Unit Fuses

The MyoSure Control Unit is protected by two 1.5 amp/250 V fuses mounted on the rear panel below the three-pronged electrical connector.

If the MyoSure Control Unit fails to power up when properly connected to a 100–120/200–240 VAC, 50/60Hz, 150 VA, AC power source, check the fuses in the rear panel.

To change the rear panel fuse:

1. Disconnect the unit from the power source.
2. Locate the fuse tray just above the power cord socket and just below the fuse label (refer to Figure 2 rear panel view).
3. Use a slotted screwdriver to press the tabs on either side of the fuse holder in, toward the center of the tray.
4. Slide the fuse tray out.
5. Replace the fuse with 1.5 amp/250 V Slow Acting fuses.
6. Insert the tray into the holder until the tabs click into place.
7. Reapply power to the unit.

NOTE: Blown fuses usually indicate a short circuit or a failed component. Make sure components are properly interconnected. If the problem persists, contact Hologic Technical Support for troubleshooting assistance.

CAUTION: Electrical safety testing should be performed by a biomedical engineer or other qualified person.

Troubleshooting

1. The MyoSure Hysteroscopic 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:
2. Unit is plugged into wall outlet.
3. Wall outlet has power.
4. Power cord is attached to back of MyoSure Control Unit.
5. Foot Pedal has been connected to front panel.
6. Vacuum pressure is available.
7. Vacuum tubing is connected.

If excess force or bend is applied to the MyoSure 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

MyoSure Control Unit (REF 10-500)

Dimensions 7.5” W x 11” L x 3” H
19 cm W x 28 cm L x 7.6 cm H

Weight 5.4 lbs / 2460 g

Power 100–240 VAC, 50/60 Hz, 1.5 A

Equipment Classification

Protection against electrical shock class 1 with BF type applied part.
Protection against harmful ingress of water, IPX1.
Not suitable for use in the presence of flammable anesthetics with mixture of air, oxygen, or nitrous oxide. (Not suitable)

Mode of Operation Continuous operation

Environmental Conditions

Transportation and Storage

Temperature Range:	-15°C to 40°C (5° F to 104° F)
Relative Humidity:	10 to 93% RH non-condensing
Air Pressure:	500 to 1060 hPa(15 to 31 in Hg)

Operation

Temperature Range:	10°C to 40°C (50° F to 104° F)
Relative Humidity:	30 to 75% RH
Air Pressure:	700 to 1060 hPa (21 to 31 in Hg)

Front Panel

Power ON/OFF Push button switch

Time Display Window

6-character by one-line numeric display which indicates elapsed time Min:Sec

Connectors

Flexible drive cable connector for tissue removal device.
Foot Pedal cable connector for foot control.

Rear Panel

Cooling None required

AC Power

Detachable power cord with a three-pin hospital-grade connector. Power input circuit automatically detects AC power standard.

NOTE: Removal of the detachable power supply cord from the control unit isolates unit from supply mains.

Ground Terminal Equipotential Compensator Terminal

Fuses Two 1.5 amp/250 V Slow Acting fuses

MyoSure Tissue Removal Device

	MyoSure Tissue Removal Device	MyoSure LITE Tissue Removal Device	MyoSure XL Tissue Removal Device
Length:	25.25" / 64.14 cm	25.25" / 64.14 cm	25.25" / 64.14 cm
OD:	3 mm	3 mm	4 mm
Weight:	17 oz. / 482 g	17 oz. / 482 g	17 oz. / 482 g

MyoSure Foot Pedal (REF 10-903)

Dimensions: 4" x 6" x 2" / 10 cm x 15 cm x 5 cm

Weight: 10 oz. / 284 g

Equipped with 12-foot (3.6-meter) cord. The foot pedal (REF 10-903) has no electrical connections.

MyoSure 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:

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.

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 and its distributors and customers in the European Community are required to comply with the Waste Electrical and Electronic Equipment (WEEE) Directive (2002/96/EC). Hologic is dedicated to meeting country specific requirements related to the environmentally sound treatment of its products. Hologic's objective is to reduce the waste resulting from the disposal of its electrical and electronic equipment. Hologic realizes the benefits of subjecting such WEEE to potential reuse, treatment, recycling, or recovery to minimize the amount of hazardous substances entering the environment. Hologic customers in the European Community are responsible for ensuring that medical devices marked with the following symbol, indicating that the WEEE Directive applies, are not placed into a municipal waste system unless authorized to do so by local authorities.



Contact Hologic Technical Support to arrange for proper disposal of the control unit in accordance with the WEEE Directive.

For More Information:

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



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250 Campus Drive
Marlborough, MA 01752 US
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Electromagnetic Safety Guidance

The following tables provide information on the electromagnetic environment that the MyoSure Hysteroscopic Tissue Removal System is capable of operating in safely. Use of this equipement in an enviroment that exceeds these limits may cause the device to stop working, change cutting speed, or produce other unknown behavior. It is the responsibility of the person installing the Hologic MyoSure Hysteroscopic Tissue Removal System to insure the electromagnetic environment does not exceed the specification set forth below in Tables 1–4.

Table 1 – Guidance and manufacturer's declaration – electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The MyoSure Hysteroscopic Tissue Removal System is intended for use in the electromagnetic environment specified below. The customer or the user of the MyoSure Hysteroscopic Tissue Removal System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The MyoSure Hysteroscopic Tissue Removal System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The MyoSure Hysteroscopic Tissue Removal System is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2 – Guidance and manufacturer's declaration – electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The MyoSure Hysteroscopic Tissue Removal System is intended for use in the electromagnetic environment specified below. The customer or the user of the MyoSure Hysteroscopic Tissue Removal 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 transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output 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 differential mode ±2 kV common mode	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 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip inU_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MyoSure Hysteroscopic Tissue Removal System requires continued operation during power mains interruptions, it is recommended that the MyoSure Hysteroscopic Tissue Removal System be powered from an uninterruptible power supply.
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 typical for commercial or hospital environments.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 3 – Guidance and manufacturer's declaration – electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The MyoSure Hysteroscopic Tissue Removal System is intended for use in the electromagnetic environment specified below. The customer or the user of the MyoSure Hysteroscopic Tissue Removal System should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the MyoSure Hysteroscopic Tissue Removal System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance (in meters)**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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 metres (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 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 from 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 MyoSure Hysteroscopic Tissue Removal System is used exceeds the applicable RF compliance level above, the MyoSure Hysteroscopic Tissue Removal 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 MyoSure Hysteroscopic Tissue Removal System.

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

Table 4 – Recommended separation distances between portable and mobile RF communications equipment and the MyoSure Hysteroscopic Tissue Removal System

Recommended separation distances between portable and mobile RF communications equipment and the MyoSure Hysteroscopic Tissue Removal System			
The MyoSure Hysteroscopic Tissue Removal System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MyoSure Hysteroscopic Tissue Removal System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MyoSure Hysteroscopic Tissue Removal System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** in meters		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 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 metres (m) can be estimated 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.

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