HOLOGIC®

MyoSure® Tissue Removal System

Instructions for Use

REF 10-401FC / 10-403FC

Myosure REACH
Tissue Removal Device

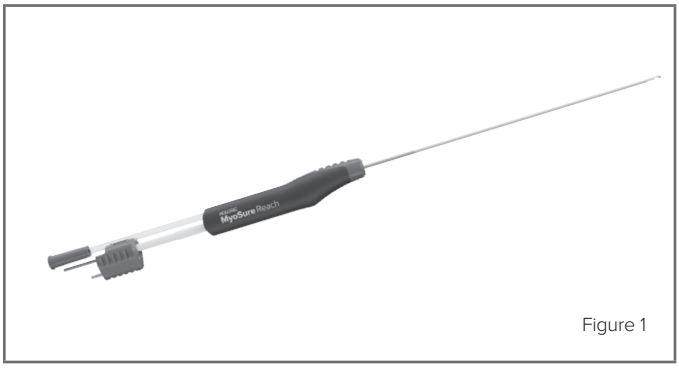

Figure 1

REF 30-401LITE / 30-403 LITE

Myosure LITE
Tissue Removal Device

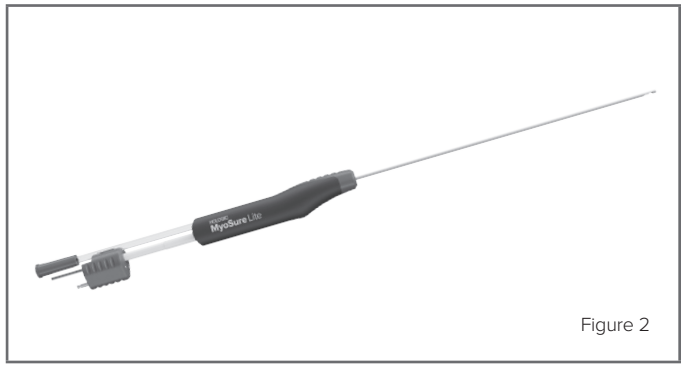

Figure 2

REF 50-501XL / 50-503XL

Myosure XL
Tissue Removal Device

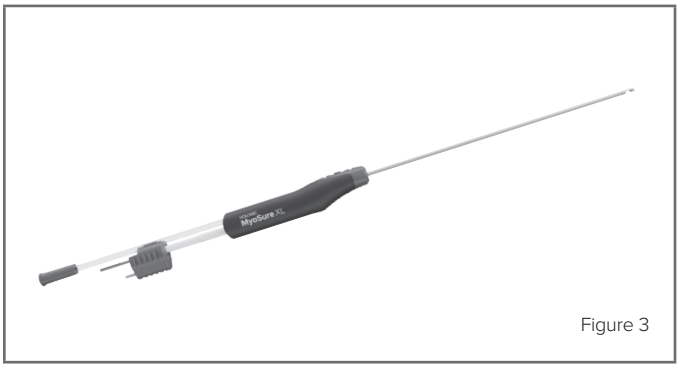

Figure 3

REF 50-601XL / 50-603XL

Myosure XL
Tissue Removal Device For Fluent

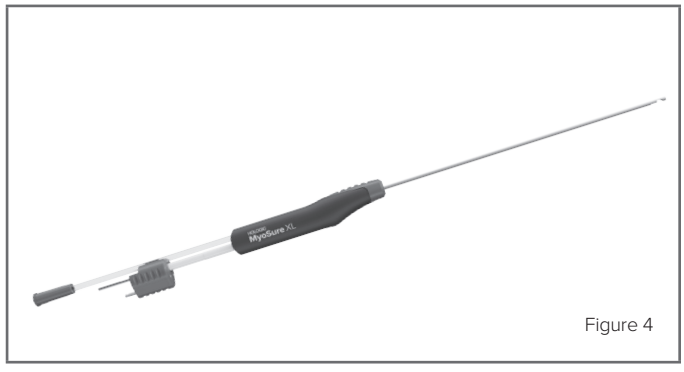

Figure 4

Please read all information carefully.

Description

The MyoSure Tissue Removal Device is a sterile, disposable, hand-held tissue removal device used to hysteroscopically remove intrauterine tissue. It is connected via flexible drive cable to the Controller. A foot pedal allows the user to control the tissue removal device by turning the motor in the Controller on and off.

Refer to the following Table for the compatibility of the MyoSure Tissue Removal Devices with the MyoSure Controllers: The MyoSure Control Unit (10-500/10-550) and the Fluent Fluid Management System (FLT-100):

Table 1

MyoSure Tissue Removal Device	Compatible Controller(s)
LITE: 30-401LITE/30-403LITE	Control Unit (10-500/10-550) or Fluent Fluid Management System (FLT-100)
REACH: 10-401FC/10-403FC	Control Unit (10-550) or Fluent Fluid Management System (FLT-100)
XL for Fluent: 50-601XL/50-603XL	Fluent Fluid Management System (FLT-100)
XL: 50-501XL/50-503XL	Control Unit (10-500/10-550)

Indications for Use

The MyoSure Tissue Removal System are intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: Submucous myomas, Endometrial Polyps and Retained products of conception.

Patient Target Group

The MyoSure Tissue Removal System is intended for use on women with submucosal fibroids, polyps and retained products of conception. The MyoSure Tissue Removal System is not appropriate for patients who are or may be pregnant, or are exhibiting pelvic infection, cervical malignancies or previously diagnosed with uterine cancer.

Intended Clinical Benefits to Patient

To hysteroscopically resect and remove submucosal fibroids, endometrial polyps, and retained products of conception.

Intended User

The MyoSure Tissue Removal System is intended to be used under control and guidance of an OB/GYN physician or GYN physician or surgeon.

Contraindications

The MyoSure Tissue Removal System 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 acreta, placenta increta or placenta percreta poses a risk of significant and potentially life threatening bleeding.
- 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.
- The use of other drive mechanism different than the Control Unit (10-500/10-550) or Fluent Fluid Management System (FLT-100) may result in a failure of the device to operate or lead to patient or physician injury. Refer to Table 1 for MyoSure Tissue Removal Devices compatibility with the controllers.
- 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.
- For procedures performed using the Control Unit (10-500/10-550) and a vacuum source, ensure that the vacuum pressure is >200 mmHg 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 from (i.e., 180° opposite) the implant;
  - the visual field is clear; and
  - 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;
  - 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; and
  - gently pull the MyoSure Tissue Removal Device into the hysteroscope to detach the MyoSure device from the implant.
- 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 Tissue Removal System.

Precautions

- 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 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 controller to overheat and stop. During a procedure, a minimum distance of 5 feet (1.5 meters) should be maintained between the controller 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.
- For MyoSure REACH Tissue Removal Device 10-401FC /10-403FC only use with 10-550 controller. Using the device with the 10-500 controller may result in an open cutting window which could lead to the inability to maintain distension. If such a 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 all connections to the tissue removal device and the controller (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 from the 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.

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.
- 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.
- 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.

MyoSure Tissue Removal Device

The MyoSure Tissue Removal Device is a single-use device designed to hysteroscopically remove intrauterine tissue. It is a hand-held unit which is connected to the front panel of the controller (Control Unit or the Fluent Fluid Management System) via a 6-foot (1.8-meter) flexible drive cable and to the collection canister or Out-FloPak, via a 10 foot (3-meter) suction tube. Cutting action is activated by a foot pedal. The suction pressure draws fluid and resected tissue through the tissue removal device cutting window. Refer to Table 1 for controller compatibility with the different MyoSure Tissue Removal Devices.

Set-up: Control Unit

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 5. for set-up outline.

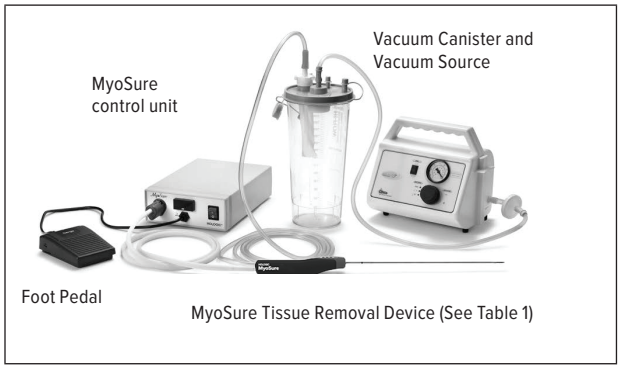

Figure 5. System Configuration

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 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 6.
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.

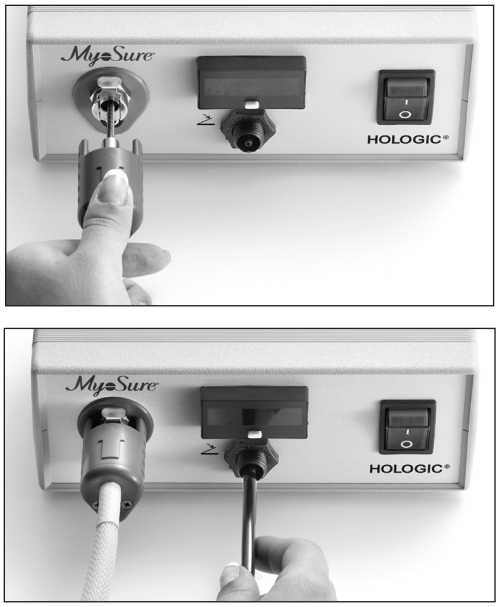

Figure 6. Insert Drive Cable and Foot Pedal into Control Unit

⚠ **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 7.

Figure 7. Attach Vacuum Tube to Collection Canister

Set-up: Fluent Fluid Management System

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 8. for set-up outline.

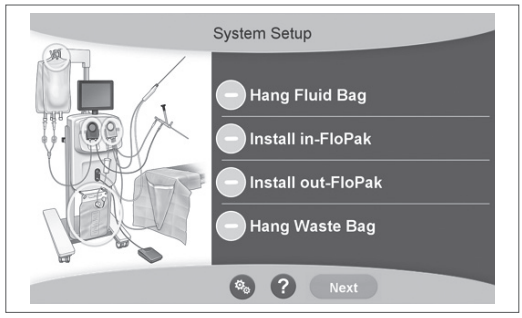

Figure 8. System Configuration for Fluent Fluid Management System (See Table 1)

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.

CONNECTING THE TISSUE REMOVAL DEVICE TO THE FLUENT FLUID MANAGEMENT SYSTEM

1. Remove the tissue removal device 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 9.

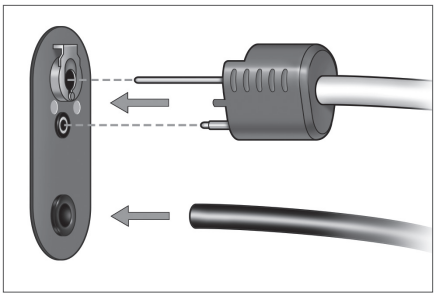

Figure 9. Insert drive cable and foot pedal into the Fluent Fluid Management System.

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.

   ⚠ **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. Push the power switch to the ON (|) position, to ensure controller power is on.
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 10.

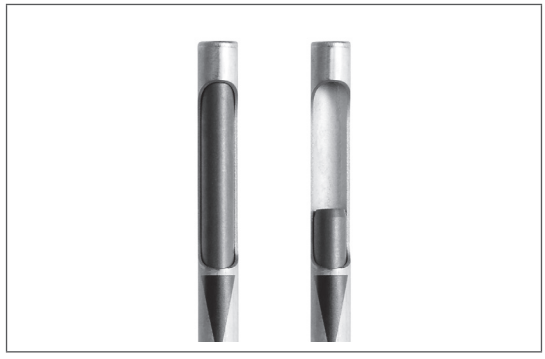

Figure 10. Closed Tissue Removal Device Cutting Window on Left

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 tissue removal device and the controller (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.

CLEARING THE FIELD OF VIEW FOR MYOSURE XL (50-501XL/50-503XL)

1. If visualization is lost, stop cutting immediately.
2. Press the aspiration button located on the thumb rest (figure 11) 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 11. 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 controller (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.

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 controller. 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 controller unit is switched ON using the power switch. If the unit does not operate, check the following:

1. The controller is plugged into wall outlet.
2. Wall outlet has power.
3. Power cord is attached to back of the controller.
4. Foot pedal has been connected to the front panel of the controller.
5. Vacuum pressure is available for the controller.
6. Suction 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. The control unit powers down unexpectedly, leave it off for 15 seconds, restart the system and follow on-screen prompts.

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

Technical Specifications

TISSUE REMOVAL DEVICE:

10-401FC / 10-403FC

Sterile, single use device

Working Length: 12.6" / 32 cm

OD: 3 mm

30-401LITE / 403LITE

Sterile, single use device

Working Length: 12.6" / 32 cm

OD: 3 mm

50-501XL / 50-503XL

Sterile, single use device

Working Length: 12.6" / 32 cm

OD: 4 mm

50-601XL / 50-603XL

Sterile, single use device

Working Length: 12.6" / 32 cm

OD: 4 mm

The MyoSure Tissue Removal Device can be used with a vacuum source (200-650 mm Hg). Examples include. Aquilex™ Fluid Control or Olympus Vacuum pump model kv-5 System or equivalent in compliance with national version of safety standard, IEC 60601-1 (e.g., for USA UL 60601-1, for Europe EN 60601-1, for Canada CSA C22.2 No. 601.1, etc.).

VACUUM CANISTER & TISSUE TRAP

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

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 Return Information

Contact Hologic Technical Support if the MyoSure 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 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.

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: 800-442-9892
www.hologic.com

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

EC REP Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium
Phone: +32 2 711 46 80

Report any complaints or problems in the quality, reliability, safety, or performance of this product to Hologic. If the device has caused or added to patient injury, immediately report the incident to Hologic Authorized Representative and Competent authority of the respective member state or country. The Competent Authorities, for medical devices, are usually the individual Member States' Ministry of Health, or an agency within the Ministry of Health.

Symbols Glossary

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
EC REP	EN ISO 15223-1, 5.1.2	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
LOT	EN ISO 15223-1, 5.1.5 ISO 7000, 2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	EN ISO 15223-1, 5.1.6 ISO 7000, 2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	EN ISO 15223-1, 5.4.4 ISO 7000, 0434A IEC 60601-1, Table D.1, 10	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
CE 2797	European Medical Directive 93/42/EEC, Article 17 and Annex XII European Medical Device Regulation 2017/745, Annex V	CE marking of conformity with notified body identification number	Indicates the medical device conforms to European Medical Directive 93/42/EEC and meets applicable health, safety, and environmental requirements. If the mark is accompanied by a number, conformity is verified by the indicated notified body.
	EN ISO 15223-1, 5.4.3 ISO 7000, 1641 IEC 60601-1, Table D.1, 11	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO/DIS 15223-1, 5.7.11 ISO 7000, 6049	Country of manufacture	To identify the country of manufacture of products.
	EN ISO 15223-1, 5.1.3 ISO 7000, 2497	Date of manufacture	Indicates the date when the medical device was manufactured.
	BS EN 15986 Annex B	Does not contain the presence phthalates	Indicates patient contact parts do not contain the presence phthalates.
	EN ISO 15223-1, 5.2.6 ISO 7000, 2608	Do not resterilize	Indicates a medical device that is not to be resterilized.
	EN ISO 15223-1, 5.4.2 ISO 7000, 1051 IEC 60601-1, Table D.1, 28	Do not re-use	Indicates a medical device that is intended for one single use only.
	EN ISO 15223-1, 5.2.8 ISO 7000, 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 and that the user should consult the instructions for use for additional information.
	EN ISO 15223-1, 5.3.2 ISO 7000, 0624 ISO 780	Keep away from heat	Indicates a medical device that needs protection from heat sources.
	EN ISO 15223-1, 5.3.4 ISO 7000, 0626 ISO 780	Keep dry	Indicates a medical device that needs to be protected from moisture.
	EN ISO 15223-1, 5.1.1 ISO 7000, 3082	Manufacturer	Indicates the medical device manufacturer.
MD	ISO/DIS 15223-1, 5.7.7	Medical device	Indicates the item is a medical device
	ISO 7000, 2794	Packaging unit	To indicate the number of pieces in the package.
℞ ONLY	FDA 21 CFR 801	Prescription use only	Caution: Federal law restricts this device to sale by or on the order of a physician.
	ISO/DIS 15223-1, 5.7.11 ISO 7000, 3707	Single sterile barrier system	Indicates a single sterile barrier system.
	ISO/DIS 15223-1, 5.7.14 ISO 7000, 3709	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside.

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
STERILE EO	EN ISO 15223-1, 5.2.3 ISO 7000, 2501	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
UDI	ISO/DIS 15223-1, 5.7.10	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information
	EN ISO 15223-1, 5.1.4 ISO 7000, 2607	Use-by date	Indicates the date after which the medical device is not to be used.

CE 2797

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