

HOLOGIC®

MyoSure® MANUAL Tissue Removal Device Instructions for Use

REF 20-401ML / 20-403ML

MyoSure MANUAL
Tissue Removal Device



Figure 1

Please read all information carefully.

Description

The sterile, non-powered, hand-actuated MyoSure MANUAL Tissue Removal Device is a MyoSure® Hysteroscope, Omni® Hysteroscope, and AcuVu™ HTx60s Hysteroscope compatible device that collects uterine tissue. The device is intended to be used in the office setting.

Indications for Use

The MyoSure MANUAL Tissue Removal Device is intended for intrauterine use by a trained gynecologist to hysteroscopically resect and remove tissue, including focal lesions such as endometrial polyps and retained products of conception.

Patient Target Group

The MyoSure MANUAL Tissue Removal Device is intended for use on women with focal lesions such as endometrial polyps and retained products of conception. The MyoSure MANUAL Tissue Removal Device 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 tissue, including focal lesions such as endometrial polyps, and retained products of conception.

Intended User

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

Contraindications

The MyoSure MANUAL Tissue Removal Device should not be used with pregnant patients or patients exhibiting pelvic infection, cervical malignancies, or previously diagnosed uterine cancer.

Warnings and Precautions

Warnings

The brief operating instructions in this guide will make the Device easier to use. As with any surgical instrument, there are important health and safety considerations. These are as follows:

- Please consider pre-operative imaging prior to the procedure to assess the patient for evidence of placental invasion of the myometrium. In the immediate postpartum phase, removal of retained products of conception (RPOC) in the setting of known or suspected placenta accreta, placenta increta or placenta percreta poses a risk of significant and potentially life threatening bleeding.
- Before using the MyoSure MANUAL Tissue Removal Device for the first time, please review all available product information.
- Before using the MyoSure MANUAL Tissue Removal Device, you should be experienced in hysteroscopic surgery. Healthy uterine tissue can be injured by improper use of the tissue removal device. Use every available means to avoid such injury.
- If visualization is lost at any point during a procedure, stop cutting immediately.

WARNING: Exercise extreme caution when resecting tissue in patients who have implants that extend into the uterine cavity.

- Do not use the MyoSure MANUAL Tissue Removal Device to resect tissue that is adjacent to a tubal implant or intrauterine device.
- However when resecting tissue in patients that have implants, assure that:
 - The MyoSure MANUAL Tissue Removal Device's cutting window is facing away from (i.e., 180°opposite) the implant;
 - The visual field is clear.
 - The MyoSure MANUAL Tissue Removal Device's cutting window is engaged with tissue and is moved away from the implant as tissue resection proceeds.
- In the event that an implant becomes entangled with a MyoSure cutter, the following steps are recommended:
 1. Cease cutting immediately.
 2. Make sure the window is open. If not, push the Trigger forward to the full open position.
 3. Dislodge by rotating the Adjustment Knob in either direction.
 4. Gently pull the MyoSure MANUAL Tissue Removal Device into the hysteroscope to detach the MyoSure device from the implant.

Precautions

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

- The MyoSure MANUAL 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.
- The MyoSure MANUAL Tissue Removal Device is intended for single use only. Do not re-sterilize. Do not lubricate Tissue Removal Device. Discard Tissue Removal Device after use.
- Use of a reprocessed, single-use tissue removal device may permanently damage, impede performance, or cause failure of the MyoSure MANUAL Tissue Removal Device. Use of such products may render any warranties null and void.
- 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 MyoSure MANUAL Tissue Removal Device’s cutter to come out of the cutting window. If such damage occurs, replace the device immediately.
- Do not allow the cutting window 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 MyoSure MANUAL 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.
- Excessive leverage on the MyoSure MANUAL Tissue Removal Device does not improve cutting performance and, in extreme cases, may result in wear, degradation, and seizing of the inner assembly.
- Use of the device has not been evaluated for fibroids and should not be used for myomectomy.

Tissue Removal Device: 20-401ML/20-403ML

The hand-held MyoSure MANUAL Tissue Removal Device is shown in Figure 2.

The MyoSure MANUAL Tissue Removal Device parts are defined below.

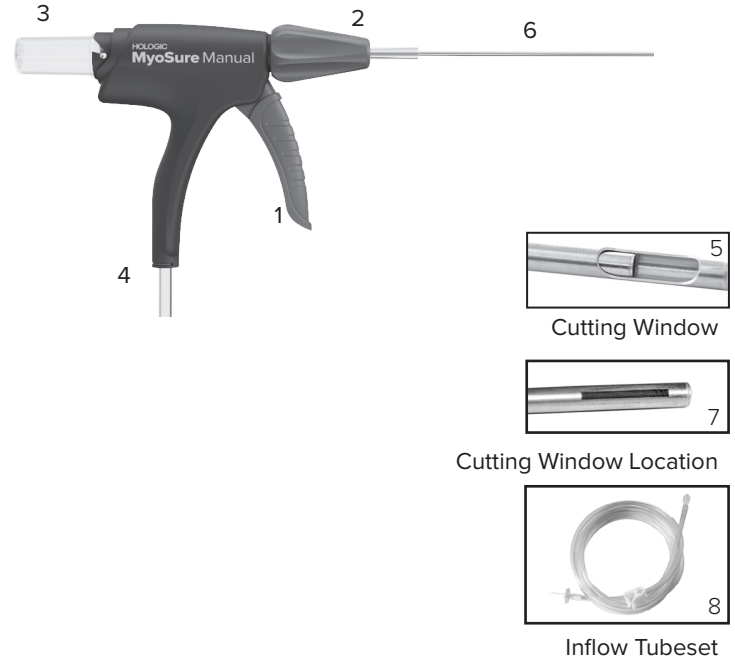


Figure 2. MyoSure MANUAL Tissue Removal Device

1.	Trigger	Squeezing actuates cutting and suction action.
2.	Adjustment Knob	Turning adjusts the orientation of the cutting window.
3.	Tissue Trap and Cover	Captures removed intrauterine tissue.
4.	Outflow Tube	Removes waste fluid from the MyoSure MANUAL Tissue Removal Device and Hysteroscope Outflow Channel through the Tissue Trap.
5.	Cutting window	Side cutting window located at distal tip
6.	Distal tip locator	Indicates depth relative to hysteroscope.
7.	Cutting window locator	Indicates orientation of cutting window
8.	Inflow Tube Set	1/4" inside diameter tubing

COMPONENTS NOT INCLUDED WITH THE MYOSURE MANUAL TISSUE REMOVAL DEVICE

The following components are not included with the MyoSure MANUAL Tissue Removal Device.

- Under Buttocks drape or fluid collection system
- IV Pole or Fluid Management System
- Fluid Bag
- MyoSure Hysteroscope, Omni Hysteroscope, or AcuVu HTx60s Hysteroscope.

Note: The MyoSure MANUAL Tissue Removal Device works only with the MyoSure, Omni, or AcuVu HTx60s Hysteroscope.

Set-up

The MyoSure MANUAL Tissue Removal Device is EO sterilized. Verify that the MyoSure MANUAL Tissue Removal Device is sterile prior to use. Do not use if the product is damaged or if the package is opened or damaged.

CAUTION: The MyoSure MANUAL Tissue Removal Device is intended for single use only. DO NOT RE-STERILIZE. DO NOT REUSE.

1. Hang a 1L bag using gravity to establish uterine distention.
 - a. Open the packaging and connect supplied inflow tubing to fluid bag and the hysteroscope.
 - b. The fluid bag should be minimally 40" above patient.
 - c. Place an Under Buttocks drape or similar fluid collection system.
2. If using a fluid management system to provide uterine distention and suction, or gravity distention and wall suction, be aware that excessive fluid usage may occur due to the device being normally opened.
 - a. To minimize excessive fluid, close the window by squeezing and holding the Trigger.

Operation

After set up is complete, the physician may remove tissue with the MyoSure MANUAL Tissue Removal Device.

1. Actuate the MyoSure MANUAL trigger prior to introducing into the working channel of the hysteroscope.
2. Place outflow tubing into the under buttocks drape or other appropriate fluid collection mechanism.
3. Introduce the Tissue Removal Device through the working channel of the hysteroscope.
4. Use the Adjustment Knob to orient the side-facing cutting window against the target pathology.
5. Actuate the Trigger to activate the cutting blade.
 - Excised tissue is collected in the Tissue Trap.

Ending the Procedure

When the physician has determined sufficient tissue has been removed, perform the following steps.

1. Retract the MyoSure MANUAL Tissue Removal Device into the hysteroscope until the window is within the hysteroscope working channel.
2. Actuate the Trigger three times to ensure that all tissue is transferred into the Tissue Trap.
3. Remove the MyoSure MANUAL Tissue Removal Device from the hysteroscope.
4. To access excised tissue, do the following:
 - a. Orient the MyoSure MANUAL Tissue Removal Device with the distal tip of the device pointing upwards.
 - b. Rotate the Tissue Trap cover counterclockwise to remove.
 - c. Ensure Tissue Trap remains within the Tissue Trap cover. (Figure 3.)



Figure 3. Tissue Trap

- d. Remove the Tissue Trap from the Tissue Trap cover.
- e. If needed, tissue trap can be removed, emptied and reattached for additional tissue collection.
- f. Transport and process tissue samples according to your facility's protocol.

Sterility

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

Storage

The tissue removal device should be stored at room temperature, away from moisture and direct heat.

Disposal

Dispose of the MyoSure MANUAL Tissue Removal Device according to your facility's policies and procedures for biohazardous materials and sharps waste.

Technical Specifications

TISSUE REMOVAL DEVICE: 20-401ML/20-403ML

Sterile, single use device

Working Length: 12.6" / 32 cm

OD: 0.120" / 3.0 mm

TISSUE REMOVAL DEVICE ACCESSORIES:

MyoSure Hysteroscope, Omni Hysteroscope, or AcuVu HTx60s Hysteroscope.

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 MANUAL Tissue Removal Device 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 MANUAL Tissue Removal Device 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

 Hologic BV
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1930 Zaventem
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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
	EN ISO 15223-1, 5.1.2	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
	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.
	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.
	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.

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
	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.
	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.
	FDA 21 CFR 801	Prescription use only	Caution: Federal law restricts this device to sale by or on the order of a physician.
	EN ISO 15223-1, 5.1.7 ISO 7000, 2498	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	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.
	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.
	EN ISO 15223-1, 5.3.7 ISO 7000, 0632	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
	ISO 7000, 0623 ISO 780, 0623 IATA 2004	This side up	To indicate correct upright position of the transport package.
	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.

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