



The MyoSure[®] System Startup Guide

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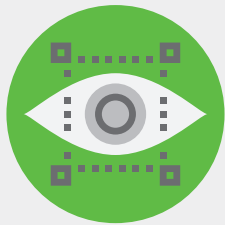
PRODUCT INFORMATION

PRODUCT INFORMATION

About the MyoSure[®] LITE device

In-office procedures just got enLITEd.

Remove small polyps up to 3 cm and also use the resected tissue for histologic assessment. With the 6 mm diameter of the MyoSure hysteroscope, only 6 mm cervical dilation is required during a MyoSure LITE procedure.



VISUALIZE

the uterine cavity throughout the entire procedure



COMPLETE

the procedure efficiently in one simple step



TRUST

that the quality and quantity of your collection will allow for histologic assessment

Offer patients the in-office benefits of the MyoSure LITE device.

Indications

The MyoSure[®] tissue removal system is intended for intrauterine use by trained gynecologists to hysteroscopically resect and remove tissue such as: submucous myomas, endometrial polyps, and retained products of conception.

Contraindications

The MyoSure[®] tissue removal system should not be used with patients who are or may be pregnant, or are exhibiting pelvic infection, cervical malignancies, or previously diagnosed endometrial cancer.

REIMBURSEMENT

REIMBURSEMENT RATES

Announcing improved reimbursement rate for polypectomy procedures in the office setting

[237% INCREASE] in reimbursement rate for in-office hysteroscopic biopsy and polypectomy

On January 1, 2017, the Medicare Physician Fee Schedule increased the relative value unit (RVU) for in-office hysteroscopy with biopsy/polypectomy (CPT code 58558). Based on the 2017 RVU and 2017 Medicare conversion factor, the average Medicare payment rate increased from \$410 to \$1,382.*

What does this mean for your practice?

If your practice has a contract based on a:

Percentage of Medicare

You may potentially receive higher reimbursement for CPT code 58558 in-office

Negotiated fee schedule

You will not automatically receive an increase in reimbursement, but you may have the opportunity to renegotiate your rate when your contract is up for renewal or during your contract period

CPT code 58558

Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D&C

YEAR	Facility (Professional)		Office/Freestanding (Global)	
	RVU	Rate	RVU	Rate
2016	7.56	\$270.68	11.44	\$409.60
2017	6.72	\$241.17	38.51	\$1,382

*The 2016 and 2017 physician RVUs are from the 2016 and 2017 RVU files available on the Center for Medicare and Medicaid Services website at www.cms.gov.

The information contained on this page is provided for informational purposes only and represents no guarantee by Hologic concerning levels of reimbursement or payment. While we have made an effort to provide information that is current, the information may not be as current or comprehensive when you view it. We recommend that you consult your reimbursement advisor or payor organization with regard to reimbursement policies. Providers are responsible for determining insurance coverage, as well as, determining the appropriate billing and coding submissions.

REIMBURSEMENT GUIDE

As you know, there is a CPT code for a polyp removal procedure (58558) that includes procedures performed with the MyoSure® device (system). There are offices throughout the country that have been successful with a carve-out for this procedure with commercial payers.

Below are a few things your office can do to gain a better understanding of how to approach payers through our reimbursement hotline.

- 1. PPR form:** Fill out Private Payer Research form and fax to Pinnacle with top 5 payers.
 - a. Make sure to request that Pinnacle looks up physician reimbursement in both the office and hospital for the following CPT code: 58558.
- 2. Current contractual agreements:**
 - a. What is the current fee schedule based upon?
 - i. Percentage of Medicare fee schedule? If so, which year?
 - ii. Percentage of billed charges? If so, what is the maximum allowable rate?
 - b. When does the current fee schedule expire?
 - c. When is the contract typically updated/renegotiated with insurance providers?

- 3. Data collection:** How many polypectomies and myomectomies have been performed with MyoSure in the last 12 months?
 - a. Data should be listed by payer, for example:

	58558 (polyp)
BCBS	15
United	9
Aetna	13
Cigna	32

*Sample numbers are reflected in the chart above for a 12-month volume by payer, by CPT code.

- 4. EOB collection:** EOBs from the cases should be collected.
- 5. Complete packet of information for payer with collected data.**
 - a. Physician request letter, including clinical data
 - b. Practice Administrator/Office Manager request, including economic data and cost effectiveness research

Calculating Expenses

- 1. Supply costs:** Determine actual cost per procedure.
 - a. Device cost
 - b. Hysteroscopic disposable seal sets
 - c. Sterile supplies (kit)
 - d. Tubing (inflow and outflow)
 - e. Saline (3 L bag)
 - f. Collection canisters and tissue trap
 - g. Labor
 - h. Professional reimbursement
- 2. Capital costs:** Determine cost of capital equipment.
 - a. MyoSure control unit w/foot pedal
 - b. MyoSure operative hysteroscope
 - c. Hysteroscopic fluid pump
 - d. Regulated vacuum source and tubing
 - e. Collection canisters (reusable)
 - f. Camera, light source, video monitor

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REIMBURSEMENT SUPPORT

In partnership with the Pinnacle Health Group staff, Hologic provides reimbursement and coding support for our partner providers. The Pinnacle Health Group staff of professional certified coders addresses questions regarding:

- **CODING**
- **INSURANCE COVERAGE**
- **MANAGED CARE CONTRACTED RATE VERIFICATION**
- **PATIENT BENEFIT VERIFICATION**
- **PATIENT PRE-AUTHORIZATION/PRE-CERTIFICATION**
- **CLAIMS APPEALS & DENIALS**
- **LOW CLAIMS PAYMENT**
- **HIPAA COMPLIANCE SUPPORT**

Contact Pinnacle Health Group

Tel: (866) 369-9290

Email: Hologic@thepinnaclehealthgroup.com

Available: Mon - Fri 8:30 am - 6:00 pm EST

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PROCEDURE

SUPPLIES & EQUIPMENT: INVENTORY CHECKLIST TO GET YOU STARTED

IN-OFFICE PROCEDURE DUE DILIGENCE

- Contracts with insurance companies _____
- Processes for reimbursement _____
- Office procedure management _____
- Personnel training to manage emergencies _____

SAFETY EQUIPMENT

- Blood pressure and pulse monitor _____
- Oxygen with end tidal carbon dioxide monitor _____
- Pulse oximeter _____
- Source of oxygen _____
- Source of suction _____

PROTOCOLS

- Controlled substances storage and administration _____
- Testing and inspection of equipment _____
- Treatment of emergencies such as cardiopulmonary events or malignant hyperthermia _____
- Emergency transport and admission to a predetermined acute care facility _____

ANESTHESIA

It is important to review the applicable federal, state, and local laws for outpatient surgery to ensure that you are safely and effectively setting up your office. These guidelines vary from state to state, so you should consult with your local and state medical regulatory boards that govern office-based procedures to learn which regulations apply to your practice.

SUPPLIES

- MyoSure instrument tray _____
- MyoSure controller _____
- MyoSure device _____
- Hysteroscope _____
- Aquilex fluid management system _____
- ≥ 1000 mL bag of saline _____
- Pole to hang the bag _____
- Cysto tubing _____
- Buttocks drape _____
- Enzymatic cleaner for the scope after the procedure _____
- 20 cc syringe to clean scope _____
- Cidex (high-level disinfectant) OPA (gallon jug) to soak (or state required in-office policies) _____
- Endoscope tray to soak or autoclave _____

List not exhaustive, each account must determine the necessary supplies, protocols, and equipment based on the requirements of their jurisdiction and individual needs of their practice and patients.

MAINTENANCE & STERILIZATION: INSTRUMENT TRAY

The solution to properly store and reprocess the MySure® Rod Lens Hysteroscope.

Compatible with the following sterilization systems:

- Steam pre-vacuum sterilization (pre-vacuum autoclave): 270°F (132°C) for 4 minutes
- Steam gravity displacement sterilization (gravity autoclave): 270°F (132°C) for 15 minutes
- STERRAD® 100S™ system



Lightweight tray for easy transportation

Custom posts and graphics for simplified disassembly of hysteroscope, outflow channel, and accessories



Clear lid for easy identification of components

Locking lid for ease in transporting, handling, and storing

MySure Instrument Tray Ordering Information

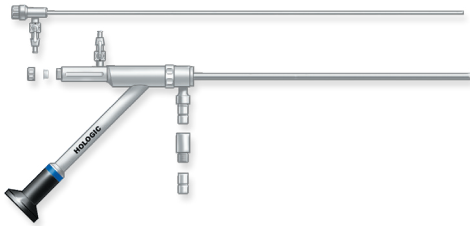
DESCRIPTION	PART NUMBER
MySure Rod Lens Hysteroscope Instrument Tray	40-903

To place an order, contact Hologic Customer Service at (800) 442-9892

MAINTENANCE & STERILIZATION: HYSTEROSCOPE REPROCESSING

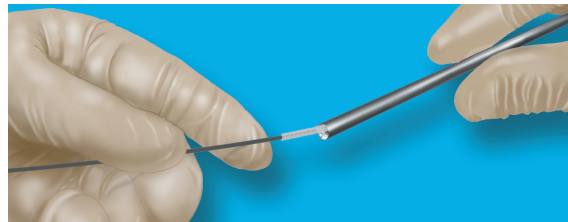
GENERAL CLEANING

Proper cleaning should be performed prior to sterilization



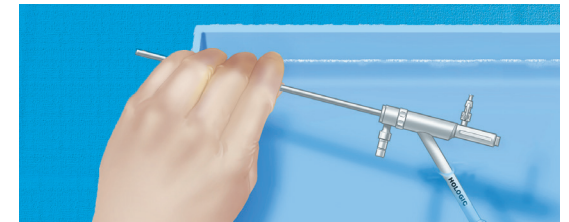
Disassembly:

- Remove light post adapters
- Remove single-use seals from hysteroscope and outflow channel
- Open stopcocks on hysteroscope and removable outflow channel



Cleaning:

- Scrub all crevices using a cleaning brush to remove any visible debris (do not scratch any optical surface)
- Scrub each lumen and flush with an enzymatic, neutral pH cleaner a minimum of 3 times to ensure no air remains within the lumen



Soaking and Rinsing:

- Soak hysteroscope and accessories in an enzymatic, neutral pH cleaner for 5 minutes
- Thoroughly rinse the scope and accessory components to completely remove the cleaning solution

STERILIZATION

Sterilization of hysteroscope and outflow channel is achieved with the following validated systems:

Ethylene Oxide (100% EtO – wrapped)

Follow standard hospital procedure maintaining the following parameters:

- Temperature: 131° ±5°F (55°C)
- Relative Humidity: 35-70%
- Gas Concentration: ~736 mg/l
- Exposure Time: 60 minutes
- Aeration Time: 11 hours

Sterrad®

- Devices meet guidelines for Sterrad 100S, NX, and 100NX systems and require the use of a Sterrad-compatible tray or container system. Refer to manufacturer's Instructions for Use for more information.

Steam Autoclave Wrapped

Follow standard hospital procedures:

- Pre-vacuum method: 270-275°F (132-135°C) for 3 minutes
- Gravity method: 270-275°F (132-135°C) for 15 minutes

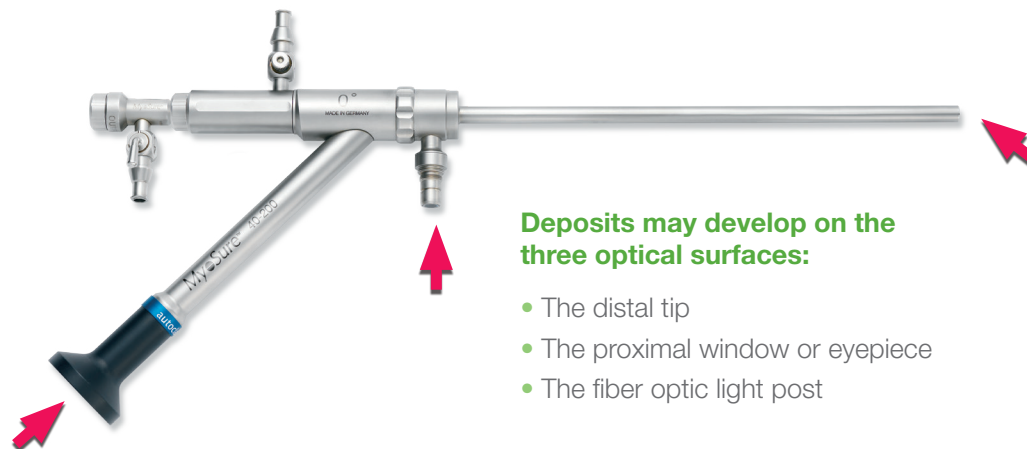
MAINTENANCE & STERILIZATION: HYSTEROSCOPE REPROCESSING

MAINTENANCE

- Always check the distal and proximal lenses of the hysteroscope for cracked or scratched lenses
- Check the surface cleanliness of the distal and proximal lenses
 - A foggy or cloudy image can be the result of moisture entering the optical system or lack of cleanliness of exterior surfaces

Polishing of Optical Surfaces

Polishing should only be performed when the image, as viewed through the scope, is cloudy and not as part of your routine cleaning procedures.



Please refer to the following steps to ensure scope is producing the best possible image:

Polishing of distal tip, eyepiece, and fiber optic light post:

- 1 Dab some polishing paste onto a clean cotton swab and apply to optical surface in a light circular motion.



- 2 Take a clean cotton swab and use a little more force to clean any deposits on the optical surface.



- 3 When surface is clean, take another cotton swab and remove any leftover polishing paste. If you have acetone or alcohol, use to clean off any extra polishing paste.

- 4 Check surfaces with an eye loupe to see if all deposits are removed and/or look through the scope to confirm clear image.



ANESTHESIA & PAIN MANAGEMENT: OVERVIEW OF OPTIONS

Overview of Options for In-office Procedures

1. PARA/INTRACERVICAL BLOCK

- Effective in a randomized, comparative trial
- Well-tolerated by patients: low pain scores reported
- For example of pain management, please request the following clinical summary in the Resources section
 - “Randomized Comparative Trial of Cervical Block Protocols for Pain Management During Hysteroscopic Removal of Polyps and Myomas” by Lukes A, et al

2. INTRACERVICAL BLOCK

- Effective in a randomized, comparative trial
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3. MOBILE ANESTHESIA

- Consult your local mobile anesthesia group (available in certain markets)



IN-OFFICE & PATIENT SUPPORT

AVAILABLE SERVICES

Support services available from Hologic

Take advantage of these training, support, and outreach programs from the makers of the NovaSure® and MyoSure® systems to help you succeed.

Education and Training



Accredited educational offerings including e-learning, peer-to-peer education, and hands-on training

Visit: Hologic.com/training

Patient Outreach



Online portal featuring patient education and customizable outreach material

Visit: GYNMarketing.com

Reimbursement Support



Coding guides with Medicare national average reimbursement, payer tools, and a reimbursement hotline

Call: 866-369-9290

Customer Support



Expert sales representatives and clinical specialists

Call: 800-442-9892

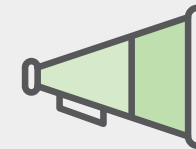
Product Support



Unlimited telephone support and expedited replacements to avoid costly downtime

Call: 800-442-9892

Patient Advocacy



Hologic raises awareness about women's health through consumer sites, blogs, and partnerships with non-profits

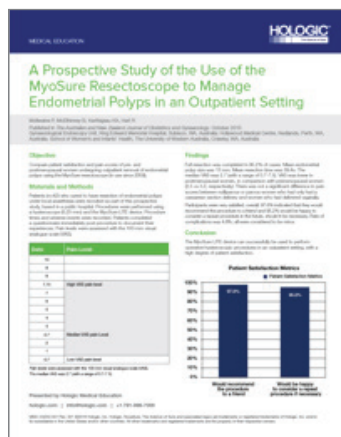
Visit: ChangeTheCycle.com

RESOURCES

RESOURCES: CLINICAL SUMMARIES ON PAIN MANAGEMENT & PROVEN OUTCOMES

Please contact your sales representative to obtain copies of the following resources:

MCLLWAINE P, ET AL



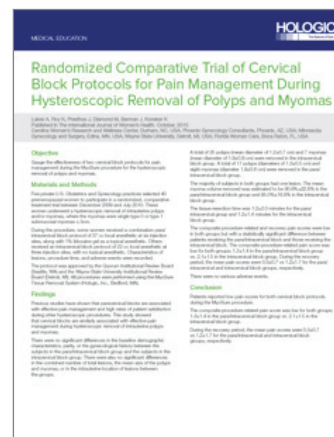
Title

“A Prospective Study of the Use of the MyoSure Resectoscope to Manage Endometrial Polyps in an Outpatient Setting”

Objective

Compare patient satisfaction and pain scores of pre- and postmenopausal women undergoing outpatient removal of endometrial polyps using the MyoSure resectoscope (in use since 2009).

LUKES A, ET AL



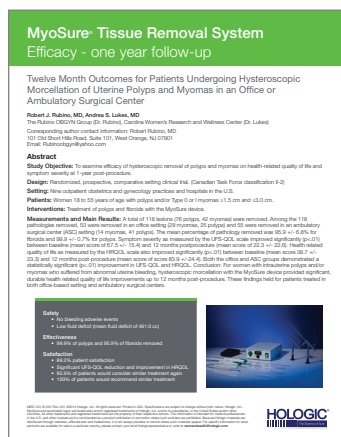
Title

“Randomized Comparative Trial of Cervical Block Protocols for Pain Management During Hysteroscopic Removal of Polyps and Myomas”

Objective

Gauge the effectiveness of two cervical block protocols for pain management during the MyoSure procedure for the hysteroscopic removal of polyps and myomas.

RUBINO RJ, ET AL



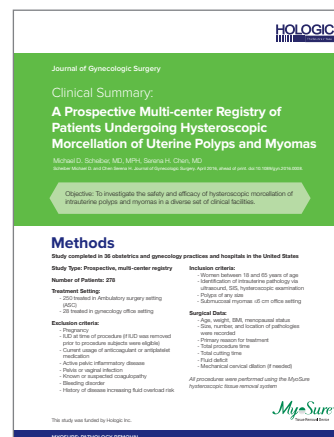
Title

“Twelve Month Outcomes for Patients Undergoing Hysteroscopic Morcellation of Uterine Polyps and Myomas in an Office or Ambulatory Surgical Center”

Objective

Examine efficacy of hysteroscopic removal of polyps and myomas on health-related quality of life and symptom severity at 1-year post-procedure.

SCHEIBER MD, ET AL



Title

“Clinical Summary: A Prospective Multi-center Registry of Patients Undergoing Hysteroscopic Morcellation of Uterine Polyps and Myomas”

Objective

Investigate the safety and efficacy of hysteroscopic morcellation of intrauterine polyps and myomas in a diverse set of clinical facilities.

RESOURCES: ADDITIONAL RESOURCES

Please contact your sales representative to obtain copies of the following resources:

MYOSURE® SYSTEM SETUP GUIDE



Simplifies the setup process with easy-to-follow instructions for everything from inventory to implementation.

AQUILEX® FLUID CONTROL SYSTEM SETUP & TROUBLESHOOTING GUIDE



Provides comprehensive support for Aquilex setup, settings, user tips, error codes, configuration images, and troubleshooting.

TREATMENT OPTIONS FOR ABNORMAL UTERINE BLEEDING (AUB)

The table lists various treatment options for AUB, including medical and surgical treatments, with columns for treatment name, efficacy, advantages, and disadvantages.

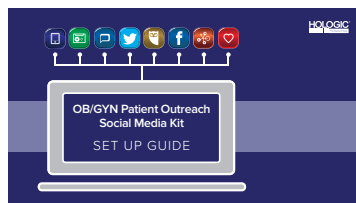
Outlines and describes the available AUB treatments, as well as efficacy rates, advantages, and disadvantages.

2017 CODING GUIDE

The table lists various gynecological procedures with their corresponding CPT codes and Medicare RVU rates.

Reference the gynecologic procedures coding guide to access 2017 Medicare RVUs and rates.

SOCIAL MEDIA KIT



Share non-branded, patient-focused marketing content on your practice's social media channels.



Important Safety Information

The MyoSure[®] tissue removal system is intended for hysteroscopic intrauterine procedures by trained gynecologists to resect and remove tissue including submucous myomas, endometrial polyps, and retained products of conception. It is not appropriate for patients who are or may be pregnant, or are exhibiting pelvic infection, cervical malignancies, or previously diagnosed endometrial cancer.