U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(kml)
FOLDER:	K100559 - 204 pages
COMPANY:	INTERLACE MEDICAL INC. (INTEMEDI[)
PRODUCT:	HYSTEROSCOPE (AND ACCESSORIES) (HIH)
SUMMARY:	Product: MYOSURE HYSTEROSCOPIC TISSUE REMOVAL SYSTEM
DATE REQUESTED:	Oct 5, 2015
DATE PRINTED:	Oct 5, 2015
Note:	Printed

K100559
pg 1 of 3

5. 510(k) SUMMARY

MAR 30 2010

1. Submitter:

Interlace Medical Inc.
135 Newbury St
Framingham, MA 01701
Telephone: 508.875.1343, ext. 112

Contact: John J. Vozella, VP Clinical & Regulatory Affairs
Date Prepared: February 26, 2010

2. Device:

Trade Name: MyoSure™ Hysteroscopic Tissue Removal System
Common Name: Hysteroscope and accessories
Classification Name: Hysteroscope and accessories
Class: II

3. Predicate Device:

MyoSure™ Hysteroscopic Tissue Removal System (K091100)

4. Device Description:

The modified MyoSure Hysteroscopic Tissue Removal System consists of the following procedural components which are identical to those found in the predicate MyoSure System:

- MyoSure Control Unit
- MyoSure Tissue Removal Device
- MyoSure Foot Pedal

The MyoSure Control Unit contains an electric motor and software controller that drives the MyoSure Tissue Removal Device. The Control Unit motor is activated and deactivated by the MyoSure Foot Pedal. The MyoSURE Tissue Removal Device is a tissue morcellator that is connected to the Control Unit via a flexible drive cable. The MyoSure Tissue Removal Device features a rotating/reciprocating (2.5 mm OD) cutter blade encased in a (3 mm OD) outer tube (i.e. morcellator). The morcellator's cutter blade is controlled by a drive system that enables simultaneous rotation and reciprocation of the cutter. The cutter is also connected to a vacuum source which aspirates resected tissue through a side-facing cutting window in the device's outer tube. Distension fluid and resected tissue are transported from the MyoSure Tissue Removal Device to a tissue trap and vacuum canister via a tube protruding from the proximal end of the Tissue Removal Device. The MyoSure Hysteroscopic Tissue Removal System is compatible with commercially available fluid management systems and may be used with hysteroscopes that have a straight 3 mm working channel.

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5. Intended Use:

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

6. Comparison of Characteristics:

The modified MyoSure Hysteroscopic Tissue Removal System's intended use and indicated use are identical to that of the predicate MyoSure Hysteroscopic Tissue Removal System, K091100.

The principles of operation and primary functional specifications of the modified MyoSure Hysteroscopic Tissue Removal System are identical to those of the predicate MyoSure Hysteroscopic Tissue Removal System.

The primary functional components of the modified MyoSure Hysteroscopic Tissue Removal System are identical to those of the predicate MyoSure Hysteroscopic Tissue Removal System, i.e.:

- each system employs a sterile, single use, Tissue Removal Device (disposable straight surgical morcellator),
- a Foot Pedal controls activation and deactivation of a motor in the Control Unit which powers the morcellator in both systems,
- the modified MyoSure cutter rotates and reciprocates at a fixed rate that is identical to the predicate device, and
- the modified MyoSure cutter blade tip design is identical to that of the predicate device, and

The modified MyoSure Hysteroscopic Tissue Removal System is different from the predicate MyoSure Hysteroscopic Tissue Removal System as follows:

- The modified MyoSure Control Unit's motor control software has been changed to firmware and the controller component has been modified accordingly.
- The maximum running current limit and current limit has been decreased in the modified MyoSure device.
- The modified MyoSure Tissue Removal Device morcellator's cutting tube outer surface is now coated with a different material than was used in the predicate device.
- An O ring in the predicate device's fluid path has been changed to a different material in the modified MyoSure™ Hysteroscopic Tissue Removal System.

- The modified MyoSure™ Hysteroscopic Tissue Removal System utilizes a lubricant on the device's gear mechanism and O ring while the predicate MyoSure device had no gear lubrication.

7. **Performance Testing:**

The modified MyoSure Hysteroscopic Tissue Removal System meets electrical safety and EMC standards. New patient contact materials in the modified MyoSure device meet the biocompatibility requirements of ISO 10993-1 Biological Evaluation of Medical Devices. In addition, in-vitro testing demonstrated that the modified MyoSure device's performance is equivalent to the predicate MyoSure device.

8. **Conclusion:**

Based on the intended use, descriptive information and performance evaluation provided in this submission, the modified MyoSure Hysteroscopic Tissue Removal System has been shown to be equivalent in technology, method of operation, functional performance and intended use to the predicate MyoSure Hysteroscopic Tissue Removal System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. John Vozella
V.P. Clinical and Regulatory Affairs
Interlace Medical, Inc.
135 Newbury Street
FRAMINGHAM MA 01701

MAR 30 2010

Re: K100559
Trade Name: MyoSure Hysteroscopic Tissue Removal System
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: February 26, 2010
Received: March 1, 2010

Dear Mr. Vozella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100559

Device Name: MyoSURE™ Hysteroscopic Tissue Removal System

Indications For Use:

The MyoSURE™ Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K100559

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 1/20/2011

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K100559/A1

To: Division Director: OB/DRGUD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: _____

Date: _____

POS

3/9/11

K100559/A1

FDA CDRH DMC

JAN 19 2011

Interlace MEDICAL

January 17, 2011

Received

FDA CDRH

JAN 19 2011

Received

K74

Food and Drug Administration
Center for Devices and Radiological Health - Office of Device Evaluation
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Attention: Document Control Clerk
RE: Notification of Change in 510(k) Ownership

Dear Sir or Madam,

As announced in the below 1/7/2011 press release, Interlace Medical, Inc. has been acquired by Hologic, Inc.

Posted on: Friday, 7 January 2011, 06:00 CST

BEDFORD, Mass., Jan. 7, 2011 /PRNewswire/ -- Hologic, Inc. (Hologic or the Company) (Nasdaq: HOLX), a leading developer, manufacturer and supplier of premium diagnostics, medical imaging systems and surgical products dedicated to serving the healthcare needs of women, announced today it has acquired Interlace Medical, Inc. (Interlace), the developer and manufacturer of the MyoSure hysteroscopic tissue removal system (MyoSure). Interlace's operations will be integrated within Hologic's GYN Surgical Products division.

Attached, please find letters of notification for a change in ownership for the following pre-market notifications:

510(k) #:	Device Name:
K073690	Interlace Medical Hysteroscopic Morcellation System
K081070	Interlace Medical Operative Hysteroscopy System
K091100	MyoSure™ Hysteroscopic Tissue Removal System
K091465	MyoSure™ Rod Lens Hysteroscope
K100559	MyoSure™ Hysteroscopic Tissue Removal System
K102686	MyoSure™ Single Use Seals

Please place copies of the letters in the relevant 510(k) files and feel free to contact me directly at (508) 875-1343, extension 112 if questions arise concerning this notification.

Sincerely,

John J. Vozella

John J. Vozella
V.P. Clinical & Regulatory Affairs
Interlace Medical, Inc.
135 Newbury Street
Framingham, MA 01701

Interlace MEDICAL

January 17, 2011

FDA CDRH DMC

JAN 19 2011

Received

Food and Drug Administration
Center for Devices and Radiological Health - Office of Device Evaluation
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Attention: Document Control Clerk
RE: K100559 - 510(k) Supplement - Notification of Change in 510(k) Ownership

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Pursuant to this transaction, effective 1/7/2011, all assets of Interlace Medical are now owned by Hologic, Inc., and all right, title and interest in the following 510(k) has been transferred from Interlace Medical, Inc. to Hologic, Inc.:

510(k) #: K100559
Device Name: MyoSure™ Hysteroscopic Tissue Removal System

Please place a copy of this letter in the relevant 510(k) file and feel free to contact me directly at (508) 875-1343, extension 112 if questions arise concerning this notification.

Sincerely,

John Vozella

John J. Vozella
V.P. Clinical & Regulatory Affairs
Interlace Medical, Inc.

Interlace MEDICAL

January 17, 2011

Food and Drug Administration
Center for Devices and Radiological Health - Office of Device Evaluation
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

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Sincerely,

John Vozella

John J. Vozella
V.P. Clinical & Regulatory Affairs
Interlace Medical, Inc.

DJA 00001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. John Vozella
V.P. Clinical and Regulatory Affairs
Interlace Medical, Inc.
135 Newbury Street
FRAMINGHAM MA 01701

MAR 30 2010

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DJA 00002

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Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DJA 00003

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K100559

Device Name: MyoSURE™ Hysteroscopic Tissue Removal System

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Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K100559

DJA 00070

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 02, 2010

INTERLACE MEDICAL INC.
135 NEWBURY ST
FRAMINGHAM, MASSACHUSETTS 01701
UNITED STATES
ATTN: JOHN VOZELLA

510k Number: K100559
Received: 3/1/2010
Product: MYOSURE HYSTEROSCOPIC TISSUE R

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

DJA 00072

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

March 01, 2010

INTERLACE MEDICAL INC.
135 NEWBURY ST
FRAMINGHAM, MASSACHUSETTS 01701
UNITED STATES
ATTN: JOHN VOZELLA

510k Number: K100559
Received: 3/1/2010
User Fee ID Number: 6048135
Product: MYOSURE HYSTEROSCOPIC TI

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) and the FDA Amendments Act of 2007 (FDAAA) (Public Law 110-85), authorizes FDA to collect user fees for certain types of 510(k) submissions. The submission cannot be accepted for review until the fee is paid in full ; therefore, the file has been placed on hold. When your user fee payment has been received , review of the 510(k) will resume as of that date. Alternatively, you may request withdrawal of your submission. You now have the option to pay online by credit card. We recommend this form of payment. Credit card payments are directly linked to your user fee cover sheet and are processed the next business day. You may also pay by check. If you choose to mail a check, please send a check to one of the addresses listed below:

By Regular Mail
Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

By Private Courier(e.g.,Fed Ex, UPS, etc.)
U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301)847-8120 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/cdrh/mdufma/fy09userfee.html. In addition, the 510k Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements,

please visit our web site at
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (301)796-7100 or its toll-fee number (800)638-2041, or contact them at their Internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Diane Garcia at Diane.Garcia@fda.hhs.gov or directly at (301)796-6559. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

Diane Garcia
Public Affairs Specialist
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

DJA 00074

1624

TABLE OF CONTENTS

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ATTACHMENTS

Section 13: Labeling

Proposed Labeling

U - MyoSURE™ Control Unit Labeling
V - MyoSURE™ Tissue Removal Device Labeling
W - MyoSURE™ Foot Pedal Labeling

Predicate Labeling

Predicate Labeling
X - MyoSURE™ Control Unit Labeling
Y - MyoSURE™ Tissue Removal Device Labeling
Z - MyoSURE™ Foot Pedal Labeling

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SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

See Related Information

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

X Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	Section 3	
Table of Contents.	TOC-1 to TOC-3	
Truthful and Accurate Statement.	Section 6	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	Section 2, pg 2-3, 2-1	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	Section 2, pg 2-3	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	Section 13 Attach U, V & W	
Statement of Indications for Use that is on a separate page in the premarket submission.	Section 4	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	Section 12	
510(k) Summary or 510(k) Statement.	Section 5	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	Section 11	
Identification of legally marketed predicate device. *	Section 12, pg. 12-1	

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Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	Section 9	
Class III Certification and Summary. **	Section 7 N/A	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	Section 8 N/A	
510(k) Kit Certification ***	Section 21 N/A	

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	**Inadequate or Missing**
Name and 510(k) number of the submitter's own, unmodified predicate device.	Section 12, pg. 12-1	
A description of the modified device and a comparison to the sponsor's predicate device.	Section 11, pg. 11-2; Section 12, pg. 12-1 to 12-3	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	Section 12, pg. 12-1	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):	Section 22	
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	Section 22, pg 22-1	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	Section 22, pg 22-1	
c. A Declaration of Conformity with design controls that includes the following statements:	Section 22, pg 22-2	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated	Section 22, pg 22-2	

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individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	Section 22, pg 22-2	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.]**		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard		

and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	**Inadequate or Missing**
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:	Section 15	
b) Sterilization and expiration dating information:	Section 14	
i) sterilization process	Same	
ii) validation method of sterilization process	Same	
iii) SAL	Same	
iv) packaging	Same	
v) specify pyrogen free	Same	
vi) ETO residues	Same	
vii) radiation dose	N/A	
viii) Traditional Method or Non-Traditional Method	Section 14	
c) Software Documentation:	Section 16	

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the " Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No
Reviewer:_____
Concurrence by Review Branch:_____

Date:_____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the

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"A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

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Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: **MD6048135-956733**
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

INTERLACE MEDICAL
135 Newbury Street
Framingham MA 01748
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****4653

2. CONTACT NAME
John Vozella

2.1 E-MAIL ADDRESS
john@interlacemedical.com

2.2 TELEPHONE NUMBER (include Area code)
508-875-1343

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
508-370-8026

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD106085

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[ ] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
$2,004.00 26-Feb-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

1-1

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: May 31, 2007.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☑ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☑ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
Amendment	Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
Supplement	Supplement			
	Report			
	Report Amendment			

Have you used or cited Standards in your submission? ☑ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name: Interlace Medical, Inc.	Establishment Registration Number *(if known)*: 3006659293		
Division Name *(if applicable)*:	Phone Number *(including area code)*: (508) 875 – 1343		
Street Address: 135 Newbury Street	FAX Number *(including area code)*: (508) 370 – 8026		
City: Framingham	State / Province: Massachusetts	ZIP/Postal Code: 01701	Country: USA
Contact Name: John Vozella			
Contact Title: V.P. Clinical and Regulatory Affairs	Contact E-mail Address: john@interlacemedical.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name: same as above			
Division Name *(if applicable)*:	Phone Number *(including area code)*: ( )		
Street Address:	FAX Number *(including area code)*: ( )		
City:	State / Province:	ZIP/Postal Code:	Country:
Contact Name:			
Contact Title:	Contact E-mail Address:		

PSC Media Arts (301) 443-1090 EF

2-1

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

☐ Process change:
- Manufacturing
- Sterilization
- Packaging
- Other *(specify below)*

☐ Response to FDA correspondence:

☐ Change in design, component, or specification:
- Software / Hardware
- Color Additive
- Material
- Specifications
- Other *(specify below)*

☐ Labeling change:
- Indications
- Instructions
- Performance
- Shelf Life
- Trade Name
- Other *(specify below)*

☐ Location change:
- Manufacturer
- Sterilizer
- Packager

☐ Report Submission:
- Annual or Periodic
- Post-approval Study
- Adverse Reaction
- Device Defect
- Amendment

☐ Change in Ownership
☐ Change in Correspondent
☐ Change of Applicant Address

☐ Other Reason *(specify)*:

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

☐ Change in:
- Correspondent / Applicant
- Design / Device
- Informed Consent
- Manufacturer
- Manufacturing Process
- Protocol - Feasibility
- Protocol - Other
- Sponsor

☐ Report submission:
- Current Investigator
- Annual Progress Report
- Site Waiver Report
- Final

☐ Repose to FDA Letter Concerning:
- Conditional Approval
- Deemed Approved
- Deficient Final Report
- Deficient Progress Report
- Deficient Investigator Report
- Disapproval
- Request Extension of Time to Respond to FDA
- Request Meeting
- Request Hearing

☐ Other Reason *(specify)*:

SECTION D3 — REASON FOR SUBMISSION - 510(k)

☐ New Device

☐ Additional or Expanded Indications

☐ Change in Technology

☑ Other Reason *(specify)*:

modifications to predicate device: replaced software with firmware and changed motor control component, modified current limits, new patient contact materials

SECTION E — ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	HIH	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K091100	1	MyoSure Hysteroscopic Tissue Removal System	1	Interlace Medical, Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F — PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Hysteroscope and/or accessories

	Trade or Proprietary or Model Name for This Device		Model Number
1	MyoSURE™ Hysteroscopic Tissue Removal System	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1 K091100	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- [ ] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G — PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
HIH	21CFR884.1690	[ ] Class I [x] Class II [ ] Class III [ ] Unclassified

Classification Panel

Obstetrics / Gynecology

Indications *(from labeling)*

The MyoSURE™ Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☑ *Original* ☐ Add ☐ Delete	FDA Establishment Registration Number: 3006659293	☑ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name: Interlace Medical Inc.		Establishment Registration Number: 3006659293		
Division Name *(if applicable)*		Phone Number *(including area code)*: (508) 875-1343, ext. 112		
Street Address: 135 Newbury St		FAX Number *(including area code)*: (508) 370-8026		
City: Framingham		State / Province: MA	ZIP/Postal Code: 01701	Country: USA
Contact Name: John J. Vozella	Contact Title: VP Clinical & Regulatory Affairs		Contact E-mail Address: john@interlacemedical.com	

☐ Original ☑ Add ☐ Delete	FDA Establishment Registration Number: 1222313	☐ Manufacturer ☑ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name: Professional Contract Sterilization, Inc.		Establishment Registration Number: 1222313		
Division Name *(if applicable)*		Phone Number *(including area code)*: (508) 822-5524		
Street Address: 40 Myles Standish Blvd.		FAX Number *(including area code)*: (508) 880-6916		
City: Taunton		State / Province: MA	ZIP/Postal Code: 02780	Country: USA
Contact Name: Gary Cranston	Contact Title: President		Contact E-mail Address:	

☐ Original ☐ Add ☐ Delete	FDA Establishment Registration Number:	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name:		Establishment Registration Number:		
Division Name *(if applicable)*		Phone Number *(including area code)*: ( )		
Street Address:		FAX Number *(including area code)*: ( )		
City:		State / Province:	ZIP/Postal Code:	Country:
Contact Name:	Contact Title:		Contact E-mail Address:	

SECTION I UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC/EN	Medical Electrical Equipment - Part 1: General Requireme	2004	
2	60601-1-2	IEC/EN	Medical Electrical Equipment - Part 1: General Requireme	2001	
3	60601-2-18	IEC/EN	Medical Electrical Equipment - Part 2: Particular Requiren	1996	
4	11135-1	ANSI/AAMI/ISO	Sterilization of Health Care Products, Ethylene Oxide - Re	2007	
5	10993-1	AAMI/ISO	Biological Evaluation of Medical Devices	2003(E)	08/01/2003
6	10993-7	AAMI/ISO	Biological Evaluation of Medical Devices, Part 7: Ethylene	2007	
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

DJA 00089

Interlace™
MEDICAL

February 26, 2010

Food and Drug Administration
Center for Devices and Radiological Health - Office of Device Evaluation
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

FDA CDRH DMC

MAR - 1 2010

Received

Attention: Document Control Clerk
RE: 510(k) NOTIFICATION

Dear Sir or Madam,

This **special 510(k) submission** is being made to describe the following minor changes in the MyoSure™ Hysteroscopic Tissue Removal System:

- Change certain patient/fluid path contacting materials in the device, and
- Describe a minor modification to the software and motor control mechanism for the device.

The intended use(s) and indications of the modified MyoSure device, as described in its labeling are the same as the intended uses and indications for the unmodified predicate MyoSure device. In addition, none of the proposed changes affect the performance specifications of the MyoSure device.

Type of Submission: Special 510(k)

Device Type: Common Name: Hysteroscope and/or accessories

510(k) Submitter:
Interlace Medical Inc.
135 Newbury St
Framingham, MA 01701

Registration number: 3006659293

DJA 00090

Authorized Contact:
John J. Vozella
VP Clinical & Regulatory Affairs
Interlace Medical Inc.
135 Newbury St
Framingham, MA 01701

Phone: 508-875-1343, ext. 112
Email: john@interlacemedical.com

Confidentiality: In accordance with 21CFR807.95, Interlace Medical Inc. requests that the review status of this submission remain confidential.

Recommended Classification Regulation: 21CFR884.1690

Device Classification: Class II

Panel: Obstetrics / Gynecology

Product Code: HIH

Prior Correspondence: The MyoSure™ Hysteroscopic Tissue Removal System was cleared under **K091100**.

Basis for Submission: This submission is being made because the proposed changes to the MyoSure Hysteroscopic Tissue Removal System represent modifications to a legally marketed medical device that qualify for special 510(k) treatment. The proposed changes are supported by same types of bench testing presented in the initial 510(k) submission for the device as well as descriptive characteristics that demonstrate equivalence of the modified MyoSURE™ Hysteroscopic Tissue Removal System to the following predicate devices:

Tradename: MyoSure Hysteroscopic Tissue Removal System
Submitter / 510(k) Holder: Interlace Medical, Inc.
510(k) #'s: K091100

The details of the submission including: device descriptions, labeling, test summaries, certification statements and substantial equivalence information are presented in the attached document.

DJA 00091

Design and Use of the Device:

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?*	X	X
Is the device intended for single use?*	X	X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

* The MyoSure Hysteroscopic Tissue Removal System Single Use Device (SUD) is a sterile, single use component of the system; the MyoSure Hysteroscopic Tissue Removal System foot pedal and control unit are intended for reuse after appropriate cleaning and surface disinfection.

Conclusion: Interlace Medical believes that the information provided in this submission demonstrates the substantial equivalence of form, fit and function of the modified MyoSURE™ Hysteroscopic Tissue Removal System to its predicate MyoSure device.

Please feel free to contact me directly at (508) 875-1343, extension 112 if questions arise concerning this submission.

Sincerely,

John Vozella

John J. Vozella
V.P. Clinical & Regulatory Affairs
Interlace Medical, Inc.

DJA 00092

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: MyoSURE™ Hysteroscopic Tissue Removal System

Indications For Use:

The MyoSURE™ Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DJA 00093

5. 510(k) SUMMARY

1. Submitter:

Interlace Medical Inc.
135 Newbury St
Framingham, MA 01701
Telephone: 508.875.1343, ext. 112

Contact: John J. Vozella, VP Clinical & Regulatory Affairs
Date Prepared: February 26, 2010

2. Device:

Trade Name: MyoSure™ Hysteroscopic Tissue Removal System
Common Name: Hysteroscope and accessories
Classification Name: Hysteroscope and accessories
Class: II

3. Predicate Device:

MyoSure™ Hysteroscopic Tissue Removal System (K091100)

4. Device Description:

The modified MyoSure Hysteroscopic Tissue Removal System consists of the following procedural components which are identical to those found in the predicate MyoSure System:

- MyoSure Control Unit
- MyoSure Tissue Removal Device
- MyoSure Foot Pedal

The MyoSure Control Unit contains an electric motor and software controller that drives the MyoSure Tissue Removal Device. The Control Unit motor is activated and deactivated by the MyoSure Foot Pedal. The MyoSURE Tissue Removal Device is a tissue morcellator that is connected to the Control Unit via a flexible drive cable. The MyoSure Tissue Removal Device features a rotating/reciprocating (2.5 mm OD) cutter blade encased in a (3 mm OD) outer tube (i.e. morcellator). The morcellator's cutter blade is controlled by a drive system that enables simultaneous rotation and reciprocation of the cutter. The cutter is also connected to a vacuum source which aspirates resected tissue through a side-facing cutting window in the device's outer tube. Distension fluid and resected tissue are transported from the MyoSure Tissue Removal Device to a tissue trap and vacuum canister via a tube protruding from the proximal end of the Tissue Removal Device. The MyoSure Hysteroscopic Tissue Removal System is compatible with commercially available fluid management systems and may be used with hysteroscopes that have a straight 3 mm working channel.

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5. Intended Use:

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

6. Comparison of Characteristics:

The modified MyoSure Hysteroscopic Tissue Removal System's intended use and indicated use are identical to that of the predicate MyoSure Hysteroscopic Tissue Removal System, K091100.

The principles of operation and primary functional specifications of the modified MyoSure Hysteroscopic Tissue Removal System are identical to those of the predicate MyoSure Hysteroscopic Tissue Removal System.

The primary functional components of the modified MyoSure Hysteroscopic Tissue Removal System are identical to those of the predicate MyoSure Hysteroscopic Tissue Removal System, i.e.:

- each system employs a sterile, single use, Tissue Removal Device (disposable straight surgical morcellator),
- a Foot Pedal controls activation and deactivation of a motor in the Control Unit which powers the morcellator in both systems,
- the modified MyoSure cutter rotates and reciprocates at a fixed rate that is identical to the predicate device, and
- the modified MyoSure cutter blade tip design is identical to that of the predicate device, and

The modified MyoSure Hysteroscopic Tissue Removal System is different from the predicate MyoSure Hysteroscopic Tissue Removal System as follows:

- The modified MyoSure Control Unit's motor control software has been changed to firmware and the controller component has been modified accordingly.
- The maximum running current limit and current limit has been decreased in the modified MyoSure device.
- The modified MyoSure Tissue Removal Device morcellator's cutting tube outer surface is now coated with a different material than was used in the predicate device.
- An O ring in the predicate device's fluid path has been changed to a different material in the modified MyoSure™ Hysteroscopic Tissue Removal System.

DJA 00095

- The modified MyoSure™ Hysteroscopic Tissue Removal System utilizes a lubricant on the device's gear mechanism and O ring while the predicate MyoSure device had no gear lubrication.

7. Performance Testing:

The modified MyoSure Hysteroscopic Tissue Removal System meets electrical safety and EMC standards. New patient contact materials in the modified MyoSure device meet the biocompatibility requirements of ISO 10993-1 Biological Evaluation of Medical Devices. In addition, in-vitro testing demonstrated that the modified MyoSure device's performance is equivalent to the predicate MyoSure device.

8. Conclusion:

Based on the intended use, descriptive information and performance evaluation provided in this submission, the modified MyoSure Hysteroscopic Tissue Removal System has been shown to be equivalent in technology, method of operation, functional performance and intended use to the predicate MyoSure Hysteroscopic Tissue Removal System.

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6. TRUTHFUL AND ACCURACY STATEMENT

Pursuant to 21 CFR § 807.87(j), I certify that, in my capacity as the V.P. Clinical & Regulatory Affairs of Interlace Medical Inc., I believe to the best of my knowledge, that all data and information submitted in this premarket notification for the MyoSure™ Hysteroscopic Tissue Removal System are truthful and accurate and that no material fact has been omitted.

John J Vozella

(Signature) **February 26, 2010**
(Date)

John J. Vozella, V.P. Clinical & Regulatory Affairs
(Typed Name & Title)

Interlace Medical, Inc.
(Company)

DJA 00097

7. PREMARKET NOTIFICATION CLASS III CERTIFICATION AND SUMARY (As Required by 21 CFR 807.94)

Not applicable to this submission.

DJA 00098

8. FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS & STEPS TAKEN TO MINIMIZE BIAS OF CLINICAL STUDY RESULTS

Not Applicable to this Submission

DJA 00099

9. DECLARATIONS OF CONFORMITY AND SUMMARY REPORTS

- **IEC/EN 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety**
- **IEC/EN 60601-2-18 Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment**
- **IEC/EN 60601-1-2 Medical Electrical Equipment - Part 1: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility Requirements and Tests**
- **ANSI/AAMI/ISO 11135-1 Sterilization of Health Care Products, Ethylene Oxide - Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices**
- **AAMI/ISO 10993-1 Biological Evaluation of Medical Devices**
- **AAMI/ISO 10993-7 Biological Evaluation of Medical Devices, Part 7: Ethylene Oxide Residuals**

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]
Item # 5-4: Medical Electrical Equipment - Part 1: General Requirements for Safety, 60601-1 (1988); Amendment 1, 1991-11, Amendment 2, 1995

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 5-4	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: N/A

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics: (301) 443-1090 EF

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DJA 00101

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
"EM # 5-4: MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR SAFETY, 60601-1 (1988); AMENDMENT 1, .991-11, AMENDMENT 2, 1995

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Safety standard refers to Clauses. For all applicable clauses, see Attachment A	See Attachment A	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆
No deviations selected. Details are in Attachment A

DESCRIPTION
The MyoSure device will comply, before any shipments to customer, with all the applicable general safety requirements in IEC 60601-1:1988-1995. The compliance criteria will be that specified by the safety standard. See Attachment A for details.

JUSTIFICATION
At the time of this submission, safety test data is on file at Interlace Medical. Interlace Medical fully complies with the Safety requirements in IEC 60601-1 and all supplemental information requested by the FDA's extent of recognition.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

2/26/10 ☒ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

Item # 9-42: Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment 60601-2-18 (1996) Amendment 1 2000

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 9-42	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: N/A

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

'TEM #9-42: MEDICAL ELECTRICAL EQUIPMENT - PART 2: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ENDOSCOPIC EQUIPMENT 60601-2-18 (1996) AMENDMENT 1 2000

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Safety standard refers to Clauses. For all applicable clauses, see Attachment A	see Attachment A	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

No deviations selected. Details are in Attachment A

DESCRIPTION

The MyoSure device will comply, before any shipments to customer, *with all the* applicable particular safety requirements in IEC 60601-2-18:1996-2000. The compliance criteria will be that specified by the safety standard. See Attachment A for details.

JUSTIFICATION

At the time of this submission, safety test data is on file at Interlace Medical. Interlace Medical intends to fully comply with the safety requirements in IEC 60601-2-18 and all supplemental information requested by the FDA's extent of recognition.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
NA		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
NA		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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1350 Piccard Drive
Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

9N 2/26/10 ☒ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

Item 34: IEC 60601-1-2, Medical Electrical Equipment-Part 1-2:General Requirments for Safety-Collateral standard:Electromagnetic Compatibility-Requirments and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004).

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 013	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the *extent of conformance* of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics: (301) 443-1090 EF

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
TEM 34: IEC 60601-1-2, MEDICAL ELECTRICAL EQUIPMENT-PART 1-2:GENERAL REQUIRMENTS FOR SAFETY-COLLATERAL STANDARD:ELECTROMAGNETIC COMPATIBILITY-REQUIRMENTS AND TESTS (EDITION 2:2001 WITH AMENDMENT 1:2004; EDITION 2.1 (EDITION 2:2001 CONSOLIDATED WITH AMENDMENT 1:2004).

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
All	All	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆
No deviation from this standard is proposed.

DESCRIPTION
The MyoSure device will comply, before any shipments to customer, with all the EMC requirments in IEC 60601-1-2:2004. The compliance criteria to be applied to this device will be listed in Subclause 36.202.1 j of this standard. The essential performance referred to in this subclause will be the performance specified by the manufacturer for its intended use.

JUSTIFICATION
At the time of this submission, EMC test data is on file at Interlace Medical. Interlace Medical intends to fully comply with the EMC requirements in IEC 60601-1-2 and all supplemental information requested by the FDA's extent of recognition.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
NA		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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1350 Piccard Drive
Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

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TYPE OF 510(K) SUBMISSION
W 2/26/10 ☒ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]
ISO 11135-1:Sterilization of Health Care Products, Ethylene Oxide: Requiements for development, validation, and routine control of a sterilization process for medical devices: 2007.

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-228	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? *If no, complete a summary report table.*	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? *If no, include the results of testing in the 510(k).*	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics: (301) 443-1090 EF

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
SO 11135-1:STERILIZATION OF HEALTH CARE PRODUCTS, ETHYLENE OXIDE: REQUIEMENTS FOR DEVELOPMENT, VALIDATION, AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES: 2007.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆
Conformance with the standard is confirmed by PCS who is performing the sterelization validation. PCS is a registered FDA establishment-registration number 1222313. Full conformance to the standard using the half cycle method is being claimed prior to marketing of the device.

DESCRIPTION
SAL 10-6 will be confirmed.

JUSTIFICATION
See attached protocol

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Rockville, MD 20850

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

W 2/26/10 ☒ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]
ISO 10993-1 Biological Evaluation of Medical Devices, Part 1: EVALUATION & TESTING

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 2-98	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: N/A

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics: (301) 443-1090 EF

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
SO 10993-1:2003(E) BIOLOGICAL EVALUATION OF MEDICAL DEVICES; PART 1: EVALUATION & TESTING

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆
Conformance is confirmed by WuXi AppTec who performed the biocompatibility testing.

DESCRIPTION
Biocompatibility testing appropriate for an externally communicating device with limited tissue contact.

JUSTIFICATION
WuXi AppTec protocols for Cytotoxicity, Sensitization, Systemic Toxicity, Irritation/Intracutaneous Reactivity

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
NA		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
NA		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

4N 2/26/10 ☒ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]
ISO 10993-7 Biological Evaluation of Medical Devices, Part 7: Ethylene Oxide Sterilization Residuals

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-76	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: ____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:/www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics: (301) 443-1090 EF

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DJA 00114

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
SO 10993-7 BIOLOGICAL EVALUATION OF MEDICAL DEVICES, PART 7: ETHYLENE OXIDE STERILIZATION RESIDUALS

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

(b)(4) Trade Secret Process - Product Specification & Testing Data

[redacted]

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
NA		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

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DJA 00115

10. EXECUTIVE SUMMARY

10.1 Use: The MyoSure™ Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

10.2 Description of Device: The procedural components of the modified MyoSure Hysteroscopic Tissue Removal System are the same as those of the predicate MyoSure device, i.e.: the MyoSure Control Unit, MyoSure Tissue Removal Device and MyoSure Foot Pedal. The MyoSure Hysteroscopic Tissue Removal System remains unchanged with respect to its operating principles, functional performance, intended use and indicated use since the most recent clearance of the predicate MyoSure device (K091100), despite the following minor changes to the device's design and materials of construction:

(b)(4) Trade Secret Process - Product Specification

[redacted]

10.3 Device Comparison: The modified MyoSure Hysteroscopic Tissue Removal System is compared to the predicate MyoSure Hysteroscopic Tissue Removal System (K091100) below.

Table 10-1 – Device Comparison

Attribute	Predicate MyoSure™ Hysteroscopic Tissue Removal System (K091100)	Modified MyoSure™ Hysteroscopic Tissue Removal System	Status
Method of Use	Hysteroscopic surgical removal of intrauterine tissue including submucous myomas and endometrial polyps using an electro-mechanical device.	Hysteroscopic surgical removal of intrauterine tissue including submucous myomas and endometrial polyps using an electro-mechanical device.	Identical to predicate device
Indicated Use	The Interlace Medical Hysteroscopic Morcellation System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.	The MyoSure™ Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.	Identical to predicate device
Device Description	Electro-mechanical surgical device consisting of a reusable Control Unit & Foot Pedal and a Single Use Morcellator Device	Electro-mechanical surgical device consisting of a reusable Control Unit & Foot Pedal and a Single Use Morcellator Device	Identical to predicate device
Drive System	[redacted]	[redacted]	Similar to predicate device
Morcellator dimensions • OD • Cutting window • Max cutting depth	[redacted]	[redacted]	Identical to predicate device
Cutting Tip Configuration	[redacted]	[redacted]	Identical to predicate device
Material Composition	[redacted]	[redacted]	Similar to predicate device
Mechanism of Action	[redacted]	[redacted]	Identical to predicate device

(b)(4) Trade Secret Process - Product Specification

Attribute	Predicate MyoSure™ Hysteroscopic Tissue Removal System (K091100)	Modified MyoSure™ Hysteroscopic Tissue Removal System	Status
Mode of Operation	Vacuum is used to pull tissue into the side-facing cutting window where it is cut and aspirated thru the cutter and deposited into a collection canister.	Vacuum is used to pull tissue into the side-facing cutting window where it is cut and aspirated thru the cutter and deposited into a collection canister.	Identical to predicate device
Aspiration vacuum pressure	[redacted]	[redacted]	Identical to predicate device
Functional Spec. • Rotation Speed • Reciprocation Rate			Identical to predicate device
Tissue Volume Spec.			Identical to predicate device
Access to Targeted Tissue	The morcellator is inserted transcervically through a sheath or hysteroscope operating channel and it is visually guided to the target tissue.	The morcellator is inserted transcervically through a sheath or hysteroscope operating channel and it is visually guided to the target tissue.	Identical to predicate device
Visualization Techniques	Hysteroscope	Hysteroscope	Identical to predicate device
IFU & Operating Manual Device Description Indications for Use Contraindications Warnings Precautions Instructions for Use	As in K091100	As in K091100 w/ updated graphics and minor edits	Identical to predicate device

(b)(4) Trade Secret
Process - Product Specification

10.4 Equivalency Summary: The intended use and indicated use of the modified MyoSure™ Hysteroscopic Tissue Removal System are identical to those of the predicate MyoSure System (K091100).

The method of use, mechanism of action, mode of operation and functional performance of the modified MyoSure Hysteroscopic Tissue Removal System are identical to that of the predicate MyoSure System (K091100).

The form, fit, ergonomic design and hardware design of the modified MyoSure System are virtually identical to those of the predicate MyoSure System (K091100) in that:

- both devices are configured (b)(4) Trade Secret Process - Product Specification [redacted]
- both the (b)(4) Trade Secret Process - Product Specification [redacted]
- the firmware used (b)(4) Trade Secret Process - Product Specification [redacted]
- both devices use (b)(4) Trade Secret Process - Product Specification [redacted]

The modified MyoSure System's hand-held tissue morcellator is identical in design and materials of construction to the predicate MyoSure device in that:

- both devices (b)(4) Trade Secret Process - Product Specification [redacted]
- both devices (b)(4) Trade Secret Process - Product Specification [redacted]
- both devices utilize (b)(4) Trade Secret Process - Product Specification [redacted]

Product labeling for the modified MyoSure System is identical in terms of contraindications, precautions, potential complications and warnings to those present in labeling for the predicate MyoSure System.

DJA 00119

10.5 Biocompatibility Testing: Biocompatibility of patient contacting materials used in the modified MyoSure System meets AAMI/ISO 10993 requirements. Summarized biocompatibility profiles of MyoSure System patient contacting materials are presented in **Section 15** of this submission.

10.6 Performance Testing: [redacted] (b)(4) Trade Secret Process - Testi

10.6.1 Bench Testing:

(b)(4) Trade Secret Process - Testing [redacted]

10.6.2 Pre-Clinical Testing: (b)(4) Trade Secret Process - Testing [redacted]

10.6.3 Clinical Use: [redacted] (b)(4) Trade Secret [redacted]

DJA 00120

11. DEVICE DESCRIPTION

11.1 Performance Specification Summary: The MyoSure™ Hysteroscopic Tissue Removal System is used by trained gynecologists to resect and remove intrauterine tissue, including submucous myomas and endometrial polyps, under hysteroscopic visualization.

The performance specification for the modified MyoSure™ Hysteroscopic Tissue Removal System is identical to that of the predicate MyoSure™ Hysteroscopic Tissue Removal System, K091100.

Procedurally, a low profile hysteroscope with a 3mm straight working channel is inserted transcervically into the uterine cavity. The uterus is distended with physiologic distension media and the target pathology is visualized. The MyoSure Tissue Removal Device (i.e. TRD) is inserted into the hysteroscope's working channel and advanced until the TRD's distal tip is visible. The side-facing cutting window at the TRD's tip is positioned under direct hysteroscopic visualization directly adjacent to the target pathology within the distended uterus. The MyoSure Foot Pedal is depressed to activate the motor within the MyoSure Control Unit. The motor spins a flexible drive cable and correspondingly, the cutter blade within the TRD. Target pathology is suctioned into the TRD's cutting window where it is resected by the TRD's cutter blade. Distension fluid and resected tissue are aspirated through the TRD and collected in a tissue trap and vacuum canister. Resected tissue is then available for pathology examination.

11.2 Device Design Requirements: The MyoSure™ Hysteroscopic Tissue Removal System is designed for morcellation of intrauterine tissue.

The modified MyoSure System's principles of operation and functional performance are identical to those of the predicate MyoSure System (K091100).

The MyoSure™ Hysteroscopic Tissue Removal System features the following procedural components:

- MyoSure Control Unit
- MyoSure Foot Pedal
- MyoSure Tissue Removal Device

The disposable MyoSure Tissue Removal Device (surgical morcellator) is driven by a flexible drive cable which is coupled to an electric motor in the MyoSure Control Unit. The morcellator is inserted into the uterus via a hysteroscope or access sheath. A pneumatic Foot Pedal is used to control the morcellator by turning the Control Unit motor on and off. The morcellator consists of a rotating and reciprocating inner tube or cutter whose distal tip is sharpened. The cutter is totally contained within an outer tube and it has an integrated vacuum tube at its proximal end. The outer tube incorporates a side-facing "cutting window" into which targeted tissue is suctioned, cut, and aspirated through the inner tube to a collection canister.

DJA 00121

Procedural components of the modified MyoSure System differ from those of the predicate MyoSure System in the following minor ways:

(b)(4) Trade Secret Process - Product Specification

[redacted]

11.3 MyoSure™ Hysteroscopic Tissue Removal System Components: The following MyoSure™ Hysteroscopic Tissue Removal System procedural components are included in this submission:

- **MyoSure Control Unit**

(b)(4) Trade Secret Process - Product Specification

[redacted]

- **MyoSure Tissue Removal Device**

(b)(4) Trade Secret Process - Product Specification

[redacted]

DJA 00122

(b)(4) Trade Secret Process - Product Specification

[redacted]

- **MyoSure Foot Pedal**

The MyoSure Foot Pedal is a multi-use component of the MyoSure System. The Foot Pedal is pneumatically operated and features a single control switch. The Foot Pedal plugs into a connector on the MyoSure Control Unit's front panel. The Foot Pedal starts morcellator operation when it is pressed and stops morcellator operation when pressure on the pedal is removed. The Foot Pedal remains unchanged from that used in the predicate MyoSure System.

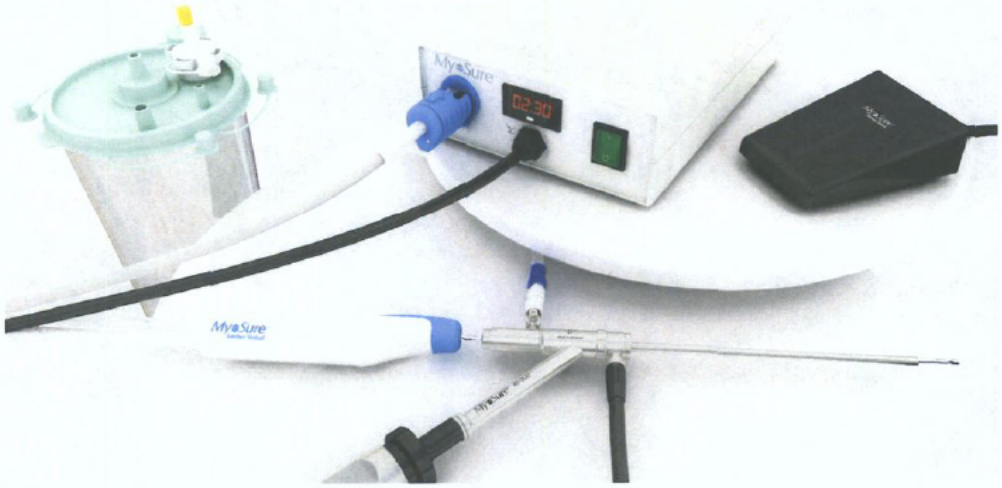


Figure 11-1. MyoSure System Configuration

11.4 Patient Contacting Components & Materials: The following MyoSure™ Hysteroscopic Tissue Removal System components described in this submission contact the patient and/or fluid path:

Table 11-1 – MyoSure™ System Patient Contact Materials

Name of Component	Material Composition	Type of Contact
Cutter blade	(b)(4) Trade Secret Process - Product Specification [redacted]	
Cutter tube		
Outer tube Heat shrink tubing		
Suction tube connector		
Suction tubing		
O-Ring		

The MyoSure™ System cutter blade, cutter tube, outer tube, suction tube connector, suction tubing and (b)(4) Trade Secret Process [redacted] are considered "externally communicating, limited exposure, tissue contacting" medical device components per ISO 10993-1:2003(E) because:

(b)(4) Trade Secret Process - Product Specification

[redacted]

DJA 00124

12. SUBSTANTIAL EQUIVALENCE DISCUSSION

12.1 Predicate Device: Interlace Medical, Inc. claims substantial equivalence to the following previously cleared devices:

Tradename: MyoSure™ Hysteroscopic Tissue Removal System
Model #'s: Tissue Removal Device 10-401, Control Unit 10-500, Foot Pedal 100-214
Submitter / 510(k) Holder: Interlace Medical, Inc.
510(k) #'s: K091100

12.2 Predicate Device Comparison

Intended and Indicated Use: The intended use and indicated use of the modified MyoSure™ Hysteroscopic Tissue Removal System are identical to those of the predicate **MyoSure™ Hysteroscopic Tissue Removal System (K091100)** in that both systems are used to resect and remove gynecologic tissue.

Table 12-1 – Device Comparison - Intended and Indicated Use

Attribute	Predicate MyoSure™ Hysteroscopic Tissue Removal System (K091100)	Modified MyoSure™ Hysteroscopic Tissue Removal System
Intended Use	Resection and removal of gynecologic tissue	Resection and removal of gynecologic tissue
Indicated Use	The MyoSure™ Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.	The MyoSure™ Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

Method of Operation: The method of use, mechanism of action and mode of operation of the predicate and modified MyoSure™ Hysteroscopic Tissue Removal Systems are identical in that both systems utilize an electro-mechanical instrument to hysteroscopically remove intrauterine tissue including submucous myomas and endometrial polyps. In both devices, the morcellator consists of a stationary outer sheath with a side-facing cutting window and a rotating and reciprocating inner cutter. Vacuum is used to pull tissue into the side-facing cutting window where it is cut and aspirated thru the cutter and deposited into a collection canister.

Table 12-2 – Device Comparison – Method of Operation

Attribute	Predicate MyoSure™ Hysteroscopic Tissue Removal System (K091100)	Modified MyoSure™ Hysteroscopic Tissue Removal System	Status
Method of Use	Hysteroscopic surgical removal of intrauterine tissue including submucous myomas and endometrial polyps using an electro-mechanical device.	No change	Identical to predicate
Mechanism of Action	The morcellator consists of a stationary outer sheath with a side-facing cutting window and a rotating and reciprocating inner cutter.	No change	Identical to predicate

DJA 00125

Mode of Operation	Vacuum is used to pull tissue into the side-facing cutting window where it is cut and aspirated thru the cutter and deposited into a collection canister.	No change	Identical to predicate

Technology: The underlying technology of the predicate and modifed MyoSure™ Hysteroscopic Tissue Removal Systems is identical in that both systems include a Control Unit, Foot Pedal and Single Use Tissue Removal Device (surgical morcellator) as procedural components. The predicate and modified MyoSure System's morcellator designs are identical in that both devices are comprised of stainless steel cutter blades encased in stainless steel outer sheaths which feature a side-facing cutting window. The cutter blade tip geometry is identical in both the predicate and modified MyoSure devices. The dimensions of morcellator components and cutting windows are identical in both devices. Tissue cutting performance of the predicate and modified MyoSure Systems is equivalent.

The modified MyoSure System includes several minor technology differences compared to the predicate MyoSure System as follows:

MyoSure Control Unit: (b)(4) Trade Secret Process - Product Specification [redacted]

MyoSure Tissue Removal Device: (b)(4) Trade Secret Process - Product Specification [redacted]

MyoSure Foot Pedal: (b)(4) Trade Secret Process - Product Specification [redacted].

DJA 00126

Table 12-3 – Device Comparison - Technology

Attribute	Predicate MyoSure™ Hysteroscopic Tissue Removal System (K091100)	Modified MyoSure™ Hysteroscopic Tissue Removal System	Status
Device Description	Electro-mechanical surgical device consisting of a reusable Control Unit & Foot Pedal and a Single Use Morcellator Device	No change	Identical to predicate
Drive System	Hand-piece connected via flexible cable to single motor in Motor Control Unit	No change	Identical to predicate
Morcellator dimensions • OD • Cutting window • Max cutting depth	(b)(4) Trade Secret Process - Product Specification [redacted]		
Cutting Tip Configuration			
Material Composition			
Aspiration vacuum pressure			
Functional Spec. • Rotation Speed • Reciprocation Rate			
Tissue Volume Specification			

Labeling: The labeling (Instructions for Use and Operator's Manual) for the modified MyoSure™ Hysteroscopic Tissue Removal System subject to this submission and the predicate MyoSure System (K091100) are identical with respect to the Precautions, Potential Complications, Warning and Procedure sections except that graphics have been updated and minor edits to the text have been made.

12.3 Conclusion: In summary, the modified MyoSure™ Hysteroscopic Tissue Removal System described in this submission has the following similarities to the predicate MyoSure device:

DJA 00127

- The same intended use and indications for use as the predicate MyoSure Hysteroscopic Tissue Removal System (K091100).
- The same method of use, mechanism of action, mode of operation and functional performance as that of the predicate MyoSure Hysteroscopic Tissue Removal System (K091100).
- The same technical performance characteristics as the predicate MyoSure Hysteroscopic Tissue Removal System (K091100).
- Similar patient contact materials as those found in the predicate MyoSure Hysteroscopic Tissue Removal System (K091100).
- Similar form, fit, ergonomic design and hardware design as those of the predicate MyoSure Hysteroscopic Tissue Removal System (K091100).
- The same labeling and instructions for use as those of the predicate MyoSure Hysteroscopic Tissue Removal System (K091100).

A summary of the substantial equivalence decision-making process for the modified MyoSure™ Hysteroscopic Tissue Removal System as detailed in the ODE Guidance Document #K86-31 and annotated in the "510(k) Substantial Equivalence Decision Making Process (Detailed) flowchart document is as follows:

Element #3: Does new device have the same indications statement?

(b)(4) Trade Secret Process - Product Specification

[redacted]

Element #5: Does new device have the same technological characteristics e.g. design, materials, etc.?

(b)(4) Trade Secret Process - Product Specification

[redacted]

Element #6: Could the new characteristics affect safety and effectiveness?

DJA 00128

(b)(4) Trade Secret Process - Product Specification

[redacted]

Element #8: Do the new characteristics raise new types of safety and effectiveness questions?

(b)(4) Trade Secret Process - Product Specification

[redacted]

Element #9: Do accepted scientific methods exist for assessing effects of the new characteristics?

(b)(4) Trade Secret Process - Product Specification

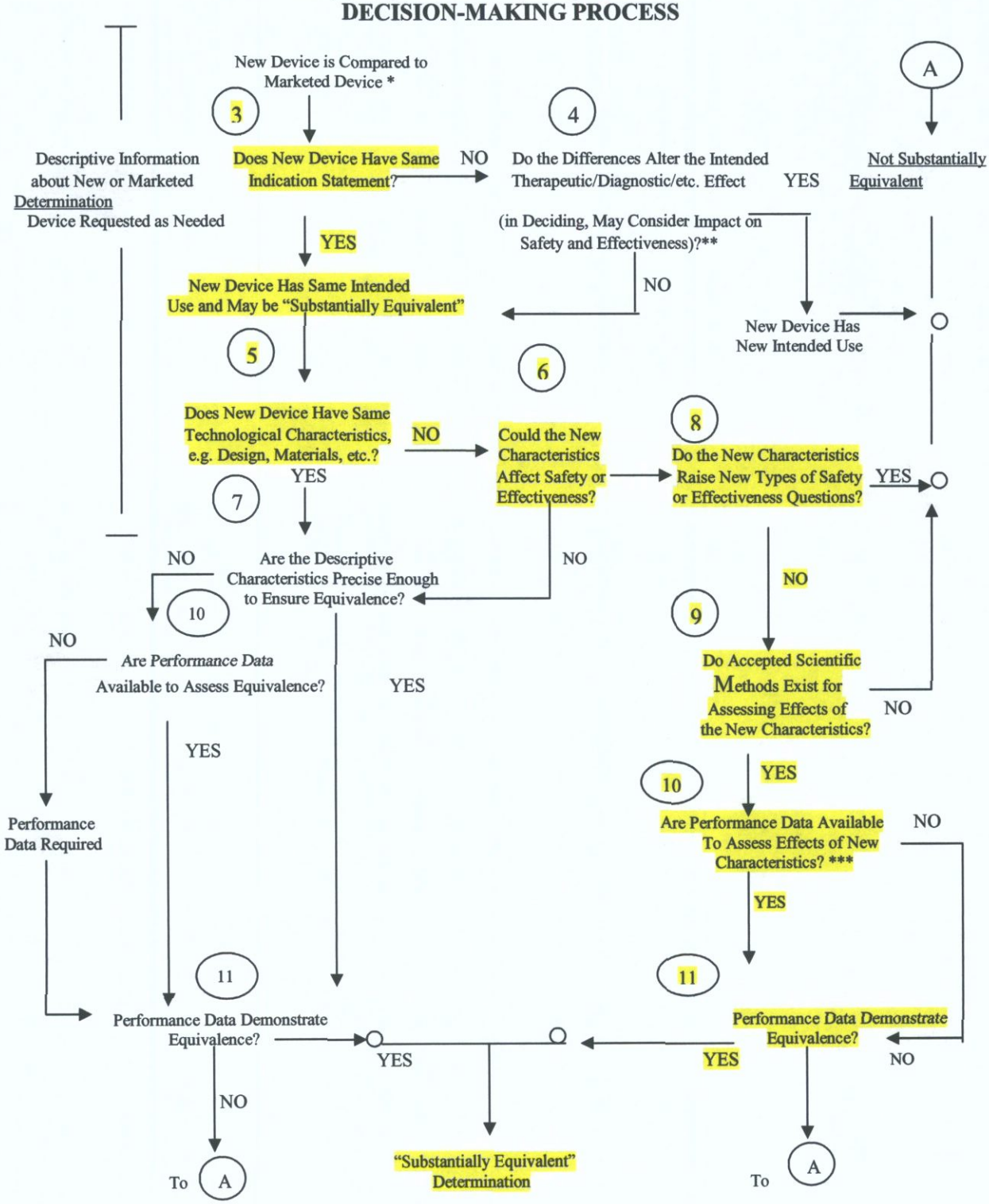
[redacted]

Element #'s 10 & 11: Yes, performance data summarized in this submission demonstrates that the modified MyoSure™ System's patient contact materials are biocompatible and that the device effectively resects submucosal fibroid tissue as follows:

(b)(4) Trade Secret Process - Product Specification

[redacted]

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DJA 00129

DJA 00130

13. LABELING

MODIFIED MYOSURE™ HYSTEROSCOPIC TISSUE REMOVAL SYSTEM LABELING: (SECTIONS U – W)

U – MYOSURE™ CONTROL UNIT
- **LABEL**
- **MYOSURE™ HYSTEROSCOPIC TISSUE REMOVAL SYSTEM OPERATING MANUAL**

V – MYOSURE™ TISSUE REMOVAL DEVICE
- **LABEL**
- **INSTRUCTIONS FOR USE**

W – MYOSURE™ FOOT PEDAL
- **LABEL**

PREDICATE MYOSURE™ HYSTEROSCOPIC TISSUE REMOVAL SYSTEM LABELING: (SECTIONS X – Z)

X – MYOSURE™ CONTROL UNIT
- **LABEL**
- **MYOSURE™ HYSTEROSCOPIC TISSUE REMOVAL SYSTEM OPERATING MANUAL**

Y – MYOSURE™ TISSUE REMOVAL DEVICE
- **LABEL**
- **INSTRUCTIONS FOR USE**

Z – MYOSURE™ FOOT PEDAL
- **LABEL**

Interlace™ MEDICAL

1 Contents: 1

REF 10-500

MyoSURE™ Control Unit

Read Instructions Prior to Use

Rx Caution: Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.

Manufactured By:
Interface Medical
135 Newbury Street
Framingham, MA 01701
(508) 875-1343

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SER 000000-00

CE 0120

EC REP

European Representative:
Emergo Group, Inc.
Molenstraat 15, 2513 BH
The Hague
The Netherlands

MADE IN USA

LAB-0010 Rev A

13-2

DJA 00132

MyoSure™ Hysteroscopic Tissue Removal System Operating Manual

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Preface / Contents / Glossary of Symbols

Preface

This manual provides the information you need to operate and maintain the Interlace Medical 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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I ON
Main electrical power on.

O OFF
Main electrical power off.

FOOTSWITCH
Foot pedal Control

Equipotential Terminal

CAUTION
See Instructions for Use.

REF CATALOG NUMBER
Part number or reorder number

EQUIPMENT CLASSIFICATION
Type BF Equipment

IPX1 Watertight Equipment
Per IEC 529

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Introductions, 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.

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 mmHg is available before commencing surgery.
- **DANGER**: Risk of explosion if used in the presence of flammable anesthetics.
- If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1.
- If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 2601-1/IEC 60601-1 approved isolation transformer and retest the system.
- The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include use of the accessory in the patient vicinity.
- The use of the accessory, transducer or cable, other than those specified by Interlace Medical may result in increased emissions or decreased immunity of the MyoSure™ Hysteroscopic Tissue Removal System.

Precautions

Rx only — U.S. Federal law restricts this device to sale by or on the order of a physician.

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- The MyoSure™ Tissue Removal Device should be stored at room temperature, away from moisture and direct heat. Do not use after expiration date.
- Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.
- 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 resterilize. 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.
- 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.
- 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

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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, Footswitch and Tissue Removal Device Connectors (Figure 1).

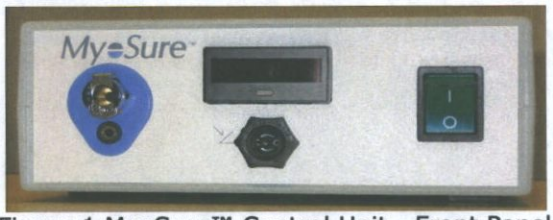

Figure 1 MyoSure™ Control Unit - Front Panel

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).

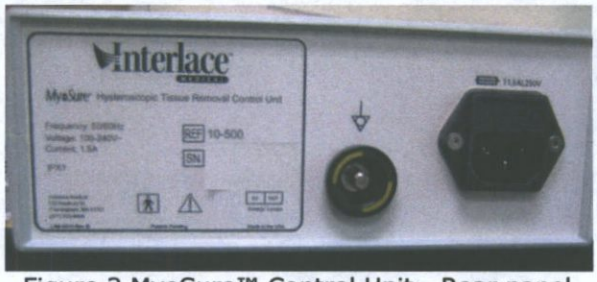

Figure 2 MyoSure™ Control Unit - Rear panel (*=Equipotential Compensator Terminal)

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).

Tissue Removal Device [REF 10-401]

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 flexible drive cable and to a collection canister via a 10-foot 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.

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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.

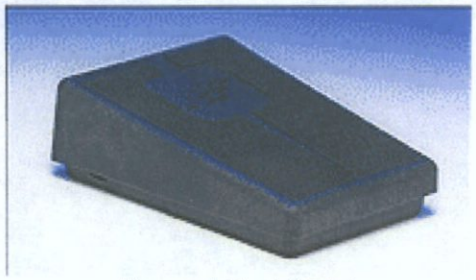

Figure 4 Foot Pedal

Setup

Setting up the Interlace Medical 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 RESTERILIZE. 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 setup outline.

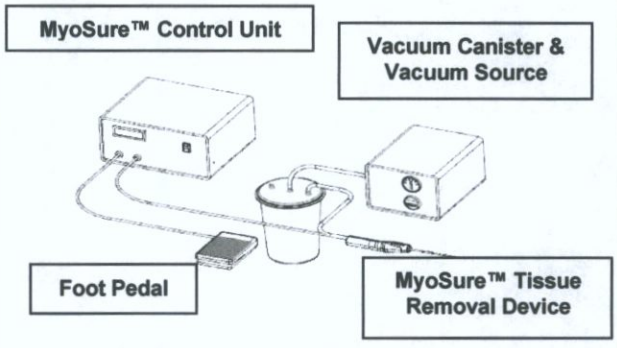

Figure 5. System Configuration

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 footpedal tube to the connector on the front of the MyoSure™ Control Unit panel.

Connecting Tissue Removal Device to the MyoSure™ Control Unit

1. Remove the Tissue Removal Device [REF 10-401] from the sterile package.
2. Sterile person hands the flexible drive cable and vacuum tubing to the non-sterile person.

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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.

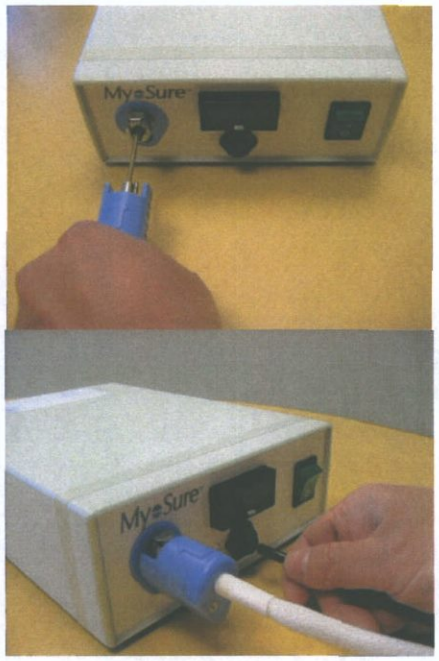

Figure 6. Insert Drive Cable and Foot Pedal into MyoSure™ Control Unit

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.

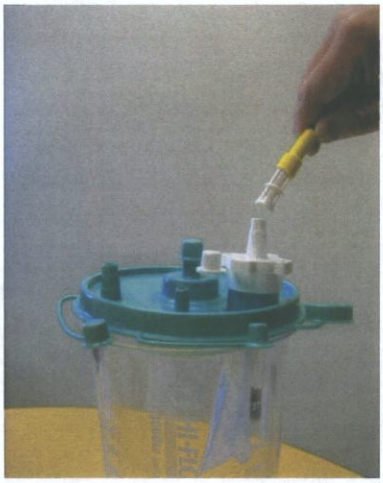

Figure 7. Attach Vacuum Tube to Collection Canister

Operation

1. Push the *power* switch to the ON (|) position.
2. The footpedal activates Tissue Removal Device operation. Since the Tissue Removal Device operates in only one direction and speed, the footpedal merely turns the motor ON and OFF. Once the footpedal is depressed, the Tissue Removal Device accelerates and rotates to the set speed and continues until the footpedal is released.
3. Press the footpedal 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.

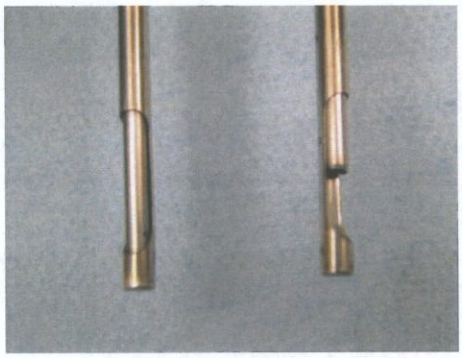

Figure 8. Closed Tissue Removal Device Cutting Window on Left

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.

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4. Introduce the Tissue Removal Device transvaginally through the straight 3mm working channel of a previously placed hysteroscope or introducer sheath.
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 footpedal 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 footpedal:

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 footpedal and the footpedal connecting tube with a clean damp cloth.

The footpedal [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 bio-hazard. Treat and dispose of only in accordance with any applicable national or institutional related policy.*

Preventative Maintenance

Recommended Annual Performance Checks

Interlace Medical 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.*

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Service

The following are replacement parts for the Interlace Medical MyoSure™ Hysteroscopic Tissue Removal System:

REF	Description
10-900	MyoSure™ Control Unit Power Cord
10-902	Rear Panel Fuse: Replace With 1.5 amp/250V Slow Acting
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 Interlace Medical authorized service centers.

If service becomes necessary, call your authorized Interlace Medical Customer Service representative prior to returning the device and request a Return Authorization (RA) number. Your representative can also explain the available Service Replacement and Repair Programs.

Service items should be carefully repackaged and returned post-paid to Interlace Medical. Your Interlace Medical customer service representative can provide additional instructions.

Note: Product returned that is found to have been serviced by an unauthorized third party repair facility and/or cleaned with a unapproved biocide other than one approved by Interlace Medical will incur additional costs, regardless of warranty status.

It is not necessary to include accessory items (i.e., power cords, etc.) when returning a device for service.

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/250V Slow Acting fuses [REF 10-902]
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 Interlace Medical Customer Service 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.

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Technical Specifications

MyoSure™ Control Unit [REF 10-500]

Dimensions

7.5"W x 11"L x 3"H

Weight

5.4 lbs / 2460 g

Power

100 – 120 / 200 -240 VAC, 50/60 Hz, 350 VA

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

Air Pressure: 500 to 1060 hPa(15 to 31 inHg)

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 inHg)

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.

Footswitch 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.

Ground Terminal

Equipotential Compensator Terminal

Fuses

Two 1.5 amp/250 V Slow Acting fuses [REF 10-902]

MyoSure™ Tissue Removal Device Handpiece [REF 10-401]

Length: 25.25"

OD: 3 mm

Weight: 17 oz.

MyoSure™ Foot Pedal [REF 10-903]

Dimensions: 4" x 6" x 2"

Weight: 10 oz.

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

MyoSure™ Tissue Removal Device Accessories

Vacuum Source – 200-650 mmHg

Olympus Vacuum Pump Model KV-5 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 3000cc Hi-Flow Canister Model 3002 055 or equivalent

Bemis Specimen Collection Adapter 533810 or equivalent

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NEW PRODUCT WARRANTY

Interlace Medical products are guaranteed to be free from defects in material and workmanship for one year beginning from date of invoice.

This limited warranty is restricted to repair or replacement by Interlace Medical, at its option, of any product found to be defective during the warranty period. Damage inflicted to a product by the user that causes it to be unsuitable for refurbishment may result in additional charges, regardless of warranty status. All warranties apply to the original buyer only. In no event shall Interlace Medical be liable for any anticipated profits, consequential damages or loss of time incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

SERVICE WARRANTY

Service Replacement Units

Warranty

The Interlace Medical MyoSure™ Hysteroscopic Tissue Removal System replacement unit is warranted to be free from defects in material and workmanship for 90 days from the date of original invoice unless otherwise provided by local law.

Service Replacement Program

Interlace Medical offers a 24-hour Service Replacement Program for its products to minimize downtime in your operating room. Our goal is to ship you a service replacement unit within 24 hours** of your call (during normal business hours). For a Return Authorization (RA) number or for additional information on this program, call Customer Service 1-877-222-8508 in the U.S., Address: 135 Newbury Street, Framingham, MA 01701 USA or contact your authorized representative.

**24-hour shipment is not offered in all countries

Repair Service Program

For devices no longer under warranty, repairs can be made by Interlace Medical or by an authorized agent. Non-warranty repairs will be made at the list price of replacement parts, plus labor. If requested, we will provide an estimate of repair cost and time required for the repair before any work is done. Repair items should be carefully repackaged, market with the Return Authorization (RA) number, and returned postpaid to the appropriate Interlace Medical Service Center. Interlace Medical Customer Service or your local authorized representative can provide shipping information.

EC	REP

European Representative
Emergo Group, Inc.
Molenstraat 15, 2513 BH
The Hague
The Netherlands

The Interlace Medical MyoSure™ Hysteroscopic Tissue Removal System and components are covered by one or more of the following U. S. Patent Numbers: patents pending.

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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 Interlace Medical 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	

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DJA 00144

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 in U_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.			

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DJA 00145

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**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	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)** $d = 1{,}2\sqrt{P}$
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.

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DJA 00146

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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MyoSure™
Tissue Removal Device

Contents - 1 MyoSure Tissue Removal Device

REF 10-401

SN 000000-000

0000-00

Do Not Use if Package is Damaged

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Interlace Medical
135 Newbury Street
Framingham, MA 01701
(877) 222-8508

0000-00

EC REP

European Representative:
Emergo Group, Inc.
Molenstraat 15, 2513 BH
The Hague
The Netherlands

MyoSure™
Tissue Removal Device

2

REF 10-401

STERILE EO

0000-00

LAB-0006 Rev E

Patents Pending

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Symbols Used On Labeling

ON
Main electrical power on.

OFF
Main electrical power off.

CAUTION

REF — CATALOG NUMBER
Part number or reorder number

Single Use Only

Do Not Use if Package is Damaged

Read Instructions Prior to Use

STERILE EO — Ethylene Oxide Sterilization

Prescription Use Only

Date of Manufacture

SN — Serial Number

Expiration Date

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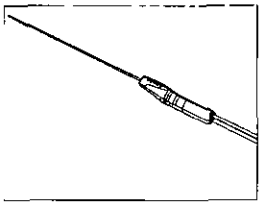
MyoSure™ Hysteroscopy Tissue Removal System Instructions for Use



Interlace™ MEDICAL

Please read all information carefully.

Rx only

Description

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

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

The sterile, disposable, hand held Tissue Removal Device is used to hysteroscopically removal intrauterine tissue. It is connected via a flexible drive shaft to a motorized Control Unit. A Foot Pedal allows the user to control the Tissue Removal Device by turning the motor in the Control Unit on and off.

Indications for Use

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

Contraindications

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

Warnings and Precautions

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

- Before using the MyoSure Tissue Removal System for the first time, please review all available product information.
- Before using the MyoSure Tissue Removal System, you should be experienced in hysteroscopic surgery with powered instruments. Healthy uterine tissue can be injured by improper use of the Tissue Removal Device. Use every available means to avoid such injury.
- Use only the MyoSure Control Unit to connect to the MyoSure Tissue Removal Device. Use of any other drive mechanism may result in failure of the device to operate or lead to patient or physician injury.
- If visualization is lost at any point during a procedure, stop cutting immediately.
- Periodic irrigation of the Tissue Removal Device tip is recommended to provide adequate cooling and to prevent accumulation of excised materials in the surgical site.

- Ensure t... vacuum pressure > 200 mmHg is available before commencing surgery.
- **DANGER**: Risk of explosion if used in the presence of flammable anesthetics.
- If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1.
- If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 2601-1/IEC 60601-1 approved isolation transformer and retest the system.
- The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include use of the accessory in the patient vicinity.
- The use of the accessory, transducer or cable, other than those specified by Interlace Medical may result in increased emissions or decreased immunity of the MyoSure Hysteroscopic Tissue Removal System.

Precautions

℞ U.S. Federal law restricts this device to sale by or on the order of a physician.

- The Tissue Removal Device should be stored at room temperature, away from moisture and direct heat. Do not use after expiration date.
- Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.
- 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 resterilize. Do not lubricate Tissue Removal Device. Discard Tissue Removal Device assembly after use.
- Use of a reprocessed, single-use Tissue Removal Device may permanently damage, impede performance, or cause failure of the MyoSure Hysteroscopic Tissue Removal System. Use of such products may render any warranties null and void.
- DO NOT attempt to sharply bend the flexible drive cable in a diameter of less than 8 inches (20 centimeters). A sharply bent or kinked drive cable may cause the Control Unit to overheat and stop. During a procedure, a minimum distance of 5 feet (1.5 meters) should be maintained between the Control Unit and the Tissue Removal Device to allow the drive cable to hang in a large arc with no bends, loops or kinks.
- If it appears that the Tissue Removal Device's cutter blade has stopped rotating during a procedure, check to ensure that all connections to the Tissue Removal Device and the Control Unit (both mechanical and electrical) are secure and that the drive cable has not wrapped 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.
- 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.

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Service Replacement Program

Interlace Medical offers a 24-hour Service Replacement Program for its products to minimize downtime in your operating room. Our goal is to ship you a service replacement unit within 24 hours** of your call (during normal business hours). For a Return Authorization (RA) number or for additional information on this program, call Customer Service 1-508-875-1343 in the U.S., Address: 135 Newbury Street, Framingham, MA 01701 USA or contact your authorized representative.

**24-hour shipment is not offered in all countries

EC	REP

European Representative
Emergo Group, Inc.
Molenstraat 15, 2513 BH
The Hague
The Netherlands

The Interlace Medical MyoSure Tissue Removal System and components are covered by one or more of the following U. S. Patent Numbers: patents pending.

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.

Storage

The Tissue Removal Device should be stored at room temperature, away from moisture and direct heat. Do not use after expiration date.

Sterility

The Tissue Removal Device is EtO sterilized. DO NOT RESTERILIZE. DO NOT REUSE. Do not use if package is opened or damaged. Discard all opened, unused devices.

Disposal

Disconnect the tissue removal device from the Control Unit. Dispose of the Tissue Removal Device and packaging according to your facility's policies and procedures concerning biohazardous materials and sharps waste.

Caution: *The Tissue Removal Device contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.*

Troubleshooting

The MyoSure Tissue Removal System is very simple to operate. The Control Unit is switched ON using the front panel power switch. If the unit does not operate, check the following:

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

If excess force or bend is applied to the Tissue Removal Device, the Control Unit will shut off the timer display to protect the system. In this event, switch the main power switch located in the front panel of the Control Unit to OFF, wait for 15 seconds and then switch the main power switch to ON to resume operation of the MyoSure Tissue Removal System.

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

Technical Specifications

Tissue Removal Device: 10-401

Sterile, single use device

Length: 25.25"

OD: 3 mm

Weight: 17 oz.

Tissue Removal Device Accessories

Vacuum Source - 200-650 mmHg

Olympus Vacuum Pump Model KV-5 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 3000cc Hi-Flow Canister Model 3002 055 or equivalent

Bemis Specimen Collection Adapter 533810 or equivalent

New Product Warranty

Interlace Medical products are guaranteed to be free from defects in material and workmanship for one year beginning from date of invoice. This limited warranty is restricted to repair or replacement by Interlace Medical, at its option, of any product found to be defective during the warranty period. Damage inflicted to a product by the user that causes it to be unsuitable for refurbishment may result in additional charges, regardless of warranty status. All warranties apply to the original buyer only. In no event shall Interlace Medical be liable for any anticipated profits, consequential damages or loss of time incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

- Do not sterilize or immerse the Control Unit in disinfectant.
- Do not cool the Tissue Removal Device by immersing it in cold water.
- Electrical safety testing should be performed by a biomedical engineer or other qualified person.
- This equipment contains electronic printed circuit assemblies. At the end of the useful life of the equipment it should be disposed of in accordance with any applicable national or institutional related policy relating to obsolete electronic equipment.

Electromagnetic Safety

- The MyoSure Tissue Removal System needs special precautions regarding Electromagnetic Safety and needs to be installed and put into service according to the Electromagnetic Safety information provided in the system's Operating Manual.
- This equipment is designed and tested to minimize interference with other electrical equipment. However, if interference occurs with other equipment it may be corrected by one or more of the following measures:
  - Reorient or relocate this equipment, the other equipment, or both.
  - Increase the separation between the pieces of equipment.
  - Connect the pieces of equipment into different outlets or circuits.
  - Consult a biomedical engineer.
- All equipment performance is considered safety related performance. That is, the failure or degradation of the performance specified in this manual may pose a safety risk to the patient or operator of this equipment.
- Note: If the MyoSure Tissue Removal System is put into service in accordance to the safety instruction in this manual, the product should remain safe and provide the performance listed above. If the product fails to provide this level of performance, the procedure should be aborted and the biomedical [illegible] alerted to the observed problem. The problem needs to be corrected before continuing or starting a new procedure.
- Portable and mobile RF communications equipment, including cellular telephones and other wireless devices can affect medical electrical equipment. To insure safe operation of the MyoSure Hysteroscopic Tissue Removal System, do not operate communications equipment or cellular telephones at a distance closer than specified in Table 4 of the Operating Manual.
- The MyoSure Tissue Removal System is not designed to work with or in the vicinity of Electrical Surgical Equipment. If Electrical Surgical Equipment must be used in the same area as the MyoSure Hysteroscopic Tissue Removal System, the MyoSure Tissue Removal System should be observed for proper operation before performing a procedure. This includes operating the Electrical Surgical Equipment in its active mode at a power level suitable for the procedure.
- For more information regarding the Electromagnetic Safety of this product, please see Tables 1-4 in the back of the Operating Manual.

Tissue Removal Device: 10-401

The MyoSure Tissue Removal Device is shown in Figure 1. It is a hand-held unit which is connected to the Control Unit via a 6-foot flexible drive cable and to a collection canister via a 10-foot vacuum tube. Cutting action is activated by a Foot Pedal. The Tissue Removal Device is a single use device designed to hysteroscopically remove intrauterine tissue.

Figure 1 MyoSure™ Tissue Removal Device

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The flexible d... 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.

Setup

The 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.

CAUTION: *The Tissue Removal Device is intended for single use only.* DO NOT RESTERILIZE. DO NOT REUSE. *Do not lubricate Tissue Removal Device. Discard Tissue Removal Device after use. Dispose of the Tissue Removal Device and packaging according to your facility's policies and procedures concerning biohazardous materials and sharps waste.*

WARNING-DANGER: Risk of explosion if used in the presence of flammable anesthetics

1. Review the System Configuration Diagram in Figure 2 for setup outline.

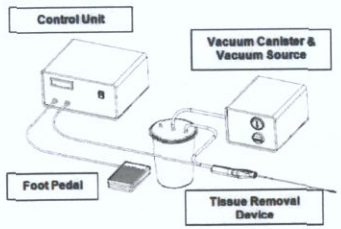

Figure 2. System Configuration

2. Place the Control Unit on top of a cart or other stable work surface. Plug the Control Unit power cord into the rear panel connector and a grounded AC power source.
3. Connect the Foot Pedal tube to the connector on the front of the Control Unit panel.

Connecting Tissue Removal Device to the Control Unit

1. Remove the Tissue Removal Device [REF 10-401] from the sterile package.
2. Sterile person hands the flexible drive cable and vacuum tubing to the non-sterile person.
3. Non-sterile person inserts the flexible cable into the corresponding connection on the Control Unit as shown in Figure 3.
4. The Tissue Removal Device flexible drive cable has a keyed feature that serves to align the handpiece cable to the Control Unit connector. The metal tab on the connector is pushed down, the flexible cable inserted and then the tab is released.

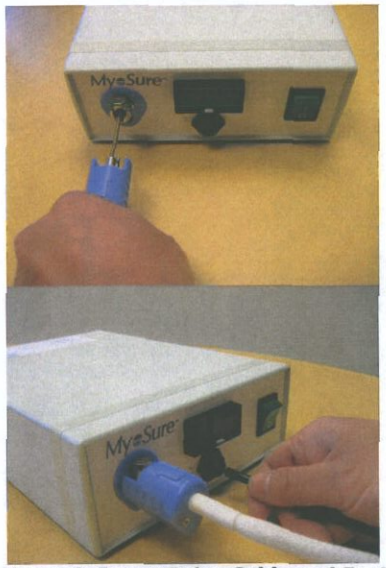

Figure 3. Insert Drive Cable and Foot Pedal into Control Unit

CAUTION: *DO NOT attempt to sharply bend the flexible drive cable in a diameter of less than 8 inches (20 centimeters). A sharply bent or kinked drive cable may cause the Control Unit to overheat and stop. During a procedure, a minimum distance of 5 feet (1.5 meters) should be maintained between the Control Unit and the Tissue Removal Device to allow the drive cable to hang in a large arc with no bends, loops or kinks.*

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

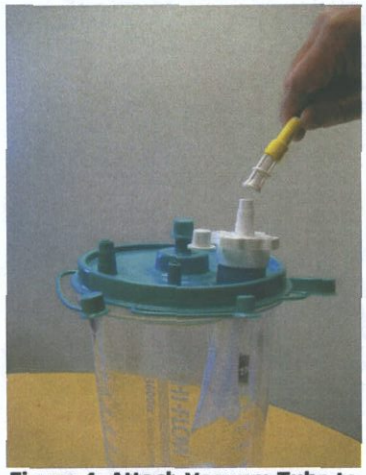

Figure 4. Attach Vacuum Tube to Collection Canister

Operation

1. Push the power switch to the ON ( ) position.
2. The Foot Pedal activates Tissue Removal Device operation. Since the Tissue Removal Device operates in only one direction and speed, the Foot Pedal merely turns the motor ON and OFF. Once the Foot Pedal is depressed, the Tissue Removal Device accelerates and rotates to the set speed and continues until the Foot Pedal is released.
3. Press the Foot Pedal and observe the Tissue Removal Device action to verify that the motor runs and that the cutting window is closed as shown in Figure 5.

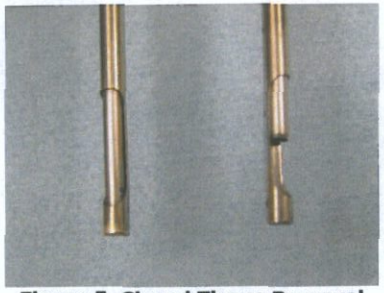

Figure 5. Closed Tissue Removal Device Cutting Window on Left

WARNING: Periodic irrigation of the Tissue Removal Device tip is recommended to provide adequate cooling and to prevent accumulation of excised materials in the surgical site.

4. Introduce the Tissue Removal Device transvaginally through the straight 3mm working channel of a previously placed hysteroscope or introducer sheath.
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 Control Unit (both mechanical and*

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Interlace™ MEDICAL

1 Contents: 1

REF 10-903

MyoSURE™ Foot Pedal

Read Instructions Prior to Use

Caution: Federal Law (U.S.A) restricts this device to sale by or on the order of a physician

Manufactured For:
Interlace Medical
135 Newbury Street
Framingham, MA 01701
(508) 875-1343

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EC REP

European Representative:
Emergo Group, Inc.
Molenstraat 15, 2513 BH
The Hague
The Netherlands

CE 0120

MADE IN USA

LAB-0011 Rev A

13-23

Interlace™ MEDICAL

Contents: 1

REF 10-500

MyoSURE™ Control Unit

Read Instructions Prior to Use

Rx *Caution:* Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.

Manufactured By:
Interlace Medical
135 Newbury Street
Framingham, MA 01701
(508) 875-1343

0000-00

SER 000000-00

CE 0120

EC REP

European Representative:
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Molenstraat 15, 2513 BH
The Hague
The Netherlands

MADE IN USA

LAB-0010 Rev A

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MyoSURE Hysteroscopic Tissue Removal System

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DJA 00155

Preface / Contents / Glossary of Symbols

eface

This manual provides the information you need to operate and maintain the Interlace Medical 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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I ON
Main electrical power on.

O OFF
Main electrical power off.

FOOTSWITCH
Foot pedal Control

CAUTION
See Instructions for Use.

EQUIPMENT CLASSIFICATION
Type BF Equipment

REF
CATALOG NUMBER
Part number or reorder number

IPX1
Watertight Equipment Per IEC 529

Equipotential Terminal

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DJA 00156

Introductions, 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 flexble 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.

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 mmHg is available before commencing surgery.
- **DANGER**: Risk of explosion if used in the presence of flammable anesthetics.
- If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1.
- If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 2601-1/IEC 60601-1 approved isolation transformer and retest the system.
- The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting

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system. Consideration relating to the choice shall includeuse of the accessory in the patient vicinity.

- The use of the accessory, transducer or cable, other than those specified by Interlace Medical may result in increased emissions or decreased immunity of the MyoSURE Hysteroscopic Tissue Removal System.

Precautions

Rx only

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

- Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.
- 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 resterilize. 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.
- 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.
- 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 and degradation 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

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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, Footswitch and Tissue Removal Device Connectors (Figure 1).

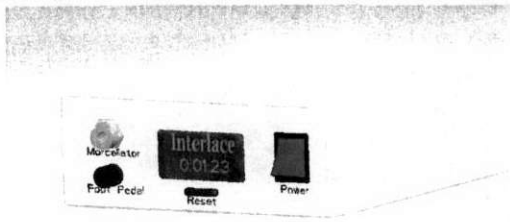

Figure 1 MyoSURE Control Unit - Front panel

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.

Foot Pedal and Tissue Removal Device Connectors

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The Footpedal 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).

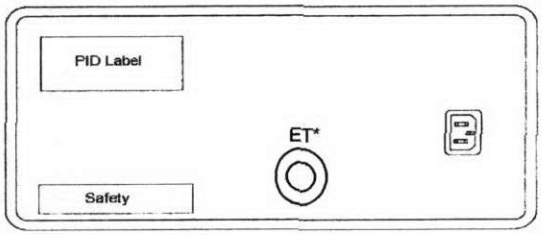

Figure 2 MyoSURE Control Unit - Rear panel (*=equipotential terminal)

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).

Tissue Removal Device

[REF 10-400]

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 flexible drive cable and to a collection canister via a 10-foot 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.

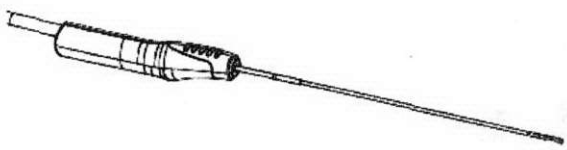

Figure 3 MyoSURE™ Tissue Removal Device

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.

Foot Pedal

[REF 10-903]

The tissue removal system foot pedal controls Tissue Removal Device operation (Figure 5). 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.

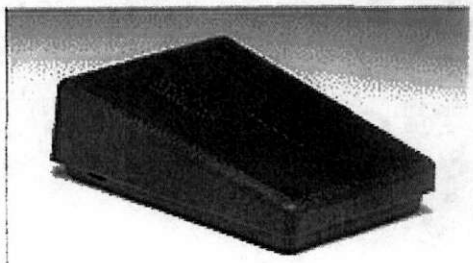

Figure 4 Foot Pedal

Setup

Setting up the Interlace Medical MyoSURE Hysteroscopic Tissue Removal System

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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 Tissue Removal Device is intended for single use only.* DO NOT RESTERILIZE. DO NOT REUSE. *Do not lubricate Tissue Removal Device. Discard 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 2 for setup outline.

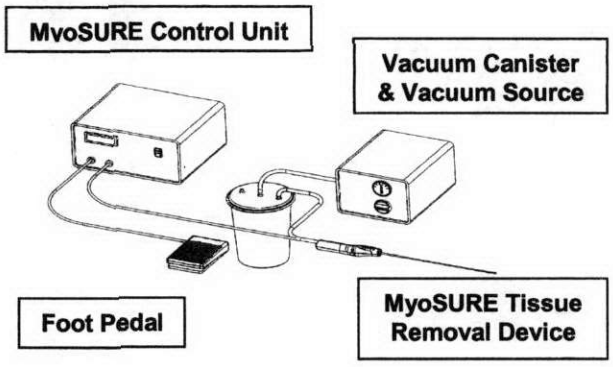

Figure 5. System Configuration

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 footpedal tube to the connector on the front of the MyoSURE Control Unit panel.

Connecting Tissue Removal Device to the MyoSURE Control Unit

4. Remove the Tissue Removal Device [REF 10-400] from the sterile package.
5. Sterile person hands the flexible drive cable and vacuum tubing to the non-sterile person.
6. Non-sterile person inserts the flexible cable into the corresponding connection on the MyoSURE Control Unit as shown in Figure 3.
7. 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 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.*

8. Non-sterile person attaches the Tissue Removal Device vacuum tubing to the

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corresponding connection on the tissue trap of the collecton canister as shown in Figure 4.

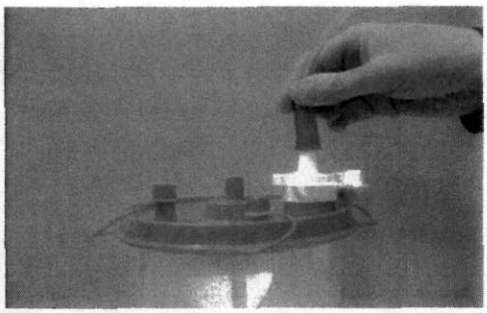

Figure 7. Attach Vacuum Tube to Collection Canister

Operation

1. Push the power switch to the ON (|) position.
2. The footpedal activates Tissue Removal Device operation. Since the Tissue Removal Device operates in only one direction and speed, the footpedal merely turns the motor ON and OFF. Once the footpedal is depressed, the Tissue Removal Device accelerates and rotates to the set speed and continues until the footpedal is released.
3. Press the footpedal and observe the Tissue Removal Device action to verify that the motor runs and that the cutting window is closed as shown in Figure 5.

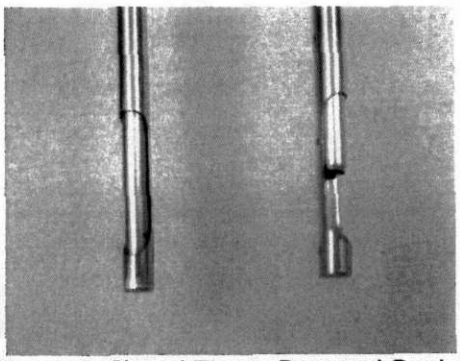

Figure 8. Closed Tissue Removal Device Cutting Window on Left

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 transvaginally through the straight 3mm working channel of a previously placed hysteroscope or introducer sheath.
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 and degradation of the cutter assembly.*

6. Press the footpedal 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

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MyoSURE Control Unit and Foot Pedal Cleaning

Follow this procedure after each operation to clean the MyoSURE Control Unit and the footpedal:

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 footpedal and the footpedal connecting tube with a clean damp cloth.

The footpedal [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 bio-hazard. Treat and dispose of only in accordance with any applicable national or institutional related policy.*

Preventative Maintenance

Recommended Annual Performance Checks

Interlace Medical 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.*

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Service

The following are replacement parts for the Interlace Medical MyoSURE™ Hysteroscopic Tissue Removal System:

REF	Description
10-900	MyoSURE Control Unit Power Cord
10-902	Rear Panel Fuse: Replace With 1.5 amp/250V Quick Acting
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 Interlace Medical authorized service centers.

If service becomes necessary, call your authorized Interlace Medical Customer Service representative prior to returning the device and request a Return Authorization (RA) number. Your representative can also explain the available Service Replacement and Repair Programs.

Service items should be carefully repackaged and returned post-paid to Interlace Medical. Your Interlace Medical customer service representative can provide additional instructions.

Note: Product returned that is found to have been serviced by an unauthorized third party repair facility and/or cleaned with a unapproved biocide other than one approved by Interlace Medical will incur additional costs, regardless of warranty status.

It is not necessary to include accessory items (i.e., power cords, etc.) when returning a device for service.

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/250V Quick Acting fuses [REF 10-902]
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 Interlace Medical Customer Service for troubleshooting assistance.

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

Troubleshooting

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:

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

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

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Technical Specifications

MyoSURE Control Unit [REF 10-500]

Dimensions

X" x X" x X"

Weight

X lbs

Power

100 - 120 / 200 -240 VAC, 50/60 Hz, 350 VA

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

Air Pressure: 500 to 1060 hPa(15 to 31 inHg)

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 inHg)

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.

Footswitch 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.

Ground Terminal

Equipotential Compensator Terminal

Fuses

Two 1.5 amp/250 V Quick Acting fuses [REF 10-902]

MyoSURE Tissue Removal Device [REF 10-400]

Length: 25.25"

OD: 3 mm

Weight: 4 oz.

MyoSURE Foot Pedal [REF 10-903]

Dimensions: 4" x 6" x 2"

Weight: 3.7 lbs

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

MyoSURE™ Tissue Removal Device Accessories

Vacuum Source - 200-650 mmHg

Olympus Vacuum Pump Model KV-5 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)

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Vacuum Canister & Tissue Trap

Bemis 3000cc Hi-Flow Canister Model 3002 055 or equivalent

Bemis Specimen Collection Adapter 533810 or equivalent

NEW PRODUCT WARRANTY

Interlace Medical products are guaranteed to be free from defects in material and workmanship for one year beginning from date of invoice.

This limited warranty is restricted to repair or replacement by Interlace Medical, at its option, of any product found to be defective during the warranty period. Damage inflicted to a product by the user that causes it to be unsuitable for refurbishment may result in additional charges, regardless of warranty status. All warranties apply to the original buyer only. In no event shall Interlace Medical be liable for any anticipated profits, consequential damages or loss of time incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

SERVICE WARRANTY

Service Replacement Units

Warranty

EC	REP

European Representative
Emergo Group, Inc.
Molenstraat 15, 2513 BH
The Hague
The Netherlands

The Interlace Medical MyoSURE Hysteroscopic Tissue Removal System replacement unit is warranted to be free from defects in material and workmanship for 90 days from the date of original invoice unless otherwise provided by local law.

Service Replacement Program

Interlace Medical offers a 24-hour Service Replacement Program for its products to minimize downtime in your operating room. Our goal is to ship you a service replacement unit within 24 hours** of your call (during normal business hours). For a Return Authorization (RA) number or for additional information on this program, call Customer Service 1-508-875-1343 in the U.S., Address: 135 Newbury Street, Framingham, MA 01701 USA or contact your authorized representative.

**24-hour shipment is not offered in all countries

Repair Service Program

For devices no longer under warranty, repairs can be made by Interlace Medical or by an authorized agent. Non-warranty repairs will be made at the list price of replacement parts, plus labor. If requested, we will provide an estimate of repair cost and time required for the repair before any work is done. Repair items should be carefully repackaged, market with the Return Authorization (RA) number, and returned postpaid to the appropriate Interlace Medical Service Center. Interlace Medical Customer Service or your local authorized representative can provide shipping information.

The Interlace Medical MyoSURE Hysteroscopic Tissue Removal System and components are covered by one or more of the following U. S. Patent Numbers: patents pending.

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 Interlace Medical 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	

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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 in U_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**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	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)** $d = 1{,}2\sqrt{P}$
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.

DJA 00169

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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Interlace™ MEDICAL

Contents: 1
Reorder Number
REF 10-400

MyoSURE™ Tissue Removal Device

Read Instructions Prior to Use

Single Use Only

STERILE | EO

Caution: Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.

Manufactured By:
Interlace Medical
135 Newbury Street
Framingham, MA 01701
(508) 875-1343

0000-00

LOT 000000-0

0000-00

CE 0120

EC REP

European Representative:
Emergo Group, Inc.
Molenstraat 15, 2513 BH
The Hague
The Netherlands

MADE IN USA US Patent Pending

LAB-0006 Rev B

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Interlace™ MEDICAL

3 Contents: 3
Reorder Number

REF 10-403

MyoSURE™ Tissue Removal Device

Read Instructions Prior to Use

Single Use Only

STERILE | EO

Caution: Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.

Manufactured By:
Interlace Medical
135 Newbury Street
Framingham, MA 01701
(508) 875-1343

0000-00

LOT 000000-0

0000-00

CE 0120

EC REP

European Representative:
Emergo Group, Inc.
Molenstraat 15, 2513 BH
The Hague
The Netherlands

MADE IN USA US Patent Pending

LAB-0009 Rev A

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Interlace MEDICAL

MyoSURE™ Hysteroscopic Tissue Removal System: Instructions For Use

Please read all information carefully.

℞ only

Description

The MyoSURE™ Hysteroscopic Tissue Removal System consists of the following procedural components:

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

The sterile, disposable, hand held Tissue Removal Device is used to hysteroscopically removal intrauterine tissue. It is connected via a flexble drive shaft to a motorized Control Unit. A Foot-Pedal allows the user to control the Tissue Removal Device by turning the motor in the Control Unit on and off.

Indications for Use

The MyoSURE 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. As with any surgical instrument, there are important health and safety considerations. These are as follows:

⚠ 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 a procedure, stop cutting immediately.
- Periodic irrigation of the Tissue Removal Device tip is recommended to provide adequate cooling and to prevent accumulation of excised materials in the surgical site.
- Ensure that vacuum pressure > 200 mmHg is available before commencing surgery.
- **DANGER**: Risk of explosion if used in the presence of flammable anesthetics.
- If this unit is configured as part of a system, the entire system should be tested for compliance with IEC 60601-1-1.
- If the leakage current of the configured system exceeds the limits of IEC 60601-1-1, install an appropriately rated UL 2601-1/IEC 60601-1 approved isolation transformer and retest the system.
- The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall includeuse of the accessory in the patient vicinity.

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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.
- Prior to use, examine the device(s) for possible damage to assure proper functioning. If damaged, do not use.
- The tissue removal device is intended for single use only. Do not resterilize. 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.
- 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.
- The side-facing cutting window should be completely closed during insertion and removal of the MyoSURE Tissue Removal Device. Exercise care when inserting or removing the device. Insertion and removal of the device should be performed under direct visualization at all times.
- 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 and degradation of the inner assembly.
- Do not cool the Tissue Removal Device by immersing it in cold water.
- 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 the sytem's Operating Manual.
- All equipment performance is considered safety related performance. That is, the

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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 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 the Operating Manual.

Tissue Removal Device: 10-400

The MyoSURE Tissue Removal Device is shown in Figure 1. It is a hand-held unit which is connected to the MyoSURE Control Unit via a 6-foot flexible drive cable and to a collection canister via a 10-foot 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 1. 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.

Setup

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.

CAUTION: *The Tissue Removal Device is intended for single use only.* DO NOT RESTERILIZE. DO NOT REUSE. *Do not lubricate Tissue Removal Device. Discard 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.*

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WARNING-DANGER: Risk of explosion if used in the presence of flammable anesthetics

1. Review the System Configuration Diagram in Figure 2 for setup outline.

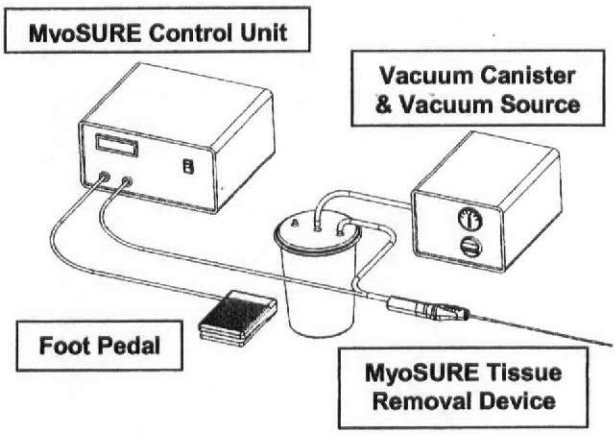

Figure 2. System Configuration

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 footpedal tube to the connector on the front of the MyoSURE Control Unit panel.

Connecting Tissue Removal Device to the MyoSURE Control Unit

4. Remove the Tissue Removal Device [REF 10-400] from the sterile package.
5. Sterile person hands the flexible drive cable and vacuum tubing to the non-sterile person.
6. Non-sterile person inserts the flexible cable into the corresponding connection on the MyoSURE Control Unit as shown in Figure 3.
7. 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.

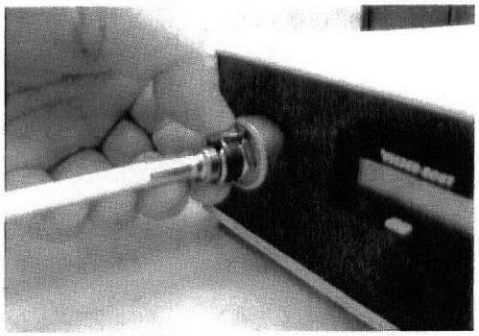

Figure 3. Insert Drive Cable into MyoSURE Control Unit

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.*

8. Non-sterile person attaches the Tissue Removal Device vacuum tubing to the corresponding connection on the tissue trap of the collecton canister as shown in Figure 4.

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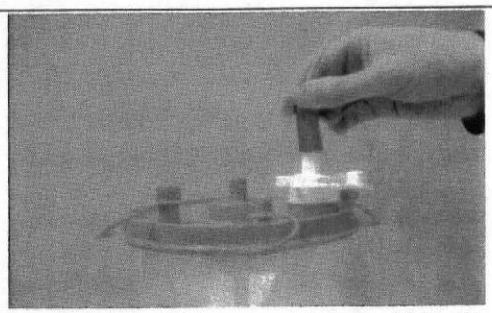

Figure 4. Attach Vacuum Tube to Collection Canister

Operation

1. Push the power switch to the ON (|) position.
2. The footpedal activates Tissue Removal Device operation. Since the Tissue Removal Device operates in only one direction and speed, the footpedal merely turns the motor ON and OFF. Once the footpedal is depressed, the Tissue Removal Device accelerates and rotates to the set speed and continues until the footpedal is released.
3. Press the footpedal and observe the Tissue Removal Device action to verify that the motor runs and that the cutting window is closed as shown in Figure 5.

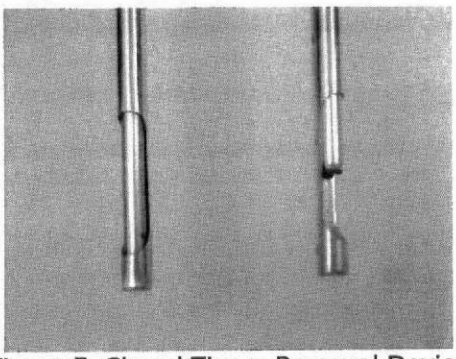

Figure 5. Closed Tissue Removal Device Cutting Window on Left

WARNING: Periodic irrigation of the Tissue Removal Device tip is recommended to provide adequate cooling and to prevent accumulation of excised materials in the surgical site.

4. Introduce the Tissue Removal Device transvaginally through the straight 3mm working channel of a previously placed hysteroscope or introducer sheath.
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 and degradation of the cutter assembly.*

6. Press the footpedal 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.

STORAGE

The MyoSURE Tissue Removal Device should be stored at room temperature, away from

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moisture and direct heat. Do not use after expiration date.

STERILITY

The MyoSURE Tissue Removal Device is EtO sterilized. DO NOT RESTERILIZE. 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 MyoSURE Control Unit. Dispose of the MyoSURE 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™ 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:

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

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

Technical Specifications

MyoSURE Tissue Removal Device: 10-400

Sterile, single use device

Length: 25.25"

OD: 3 mm

Weight: 4 oz.

MyoSURE™ Tissue Removal Device Accessories

Vacuum Source - 200-650 mmHg

Olympus Vacuum Pump Model KV-5 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 3000cc Hi-Flow Canister Model 3002 055 or equivalent

Bemis Specimen Collection Adapter 533810 or equivalent

New Product Warranty

Interlace Medical products are guaranteed to be free from defects in material and workmanship for one year beginning from date of invoice. This limited warranty is restricted to repair or replacement by Interlace Medical, at its option, of any product found to be defective during the warranty period. Damage inflicted to a product by the user that causes it to be unsuitable for refurbishment may result in additional charges, regardless of warranty status. All warranties apply to the original buyer only. In no event shall Interlace Medical be liable for any anticipated profits,

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consequential damages or loss of time incurred by the buyer with the purchase or use of any product.

NO OTHER WARRANTY, EXPRESSED OR IMPLIED, IS GIVEN.

Service Replacement Program

Interlace Medical offers a 24-hour Service Replacement Program for its products to minimize downtime in your operating room. Our goal is to ship you a service replacement unit within 24 hours** of your call (during normal business hours). For a Return Authorization (RA) number or for additional information on this program, call Customer Service 1-508-875-1343 in the U.S., Address: 135 Newbury Street, Framingham, MA 01701 USA or contact your authorized representative.

**24-hour shipment is not offered in all countries

EC	REP

European Representative
Emergo Group, Inc.
Molenstraat 15, 2513 BH
The Hague
The Netherlands

The Interlace Medical MyoSURE Hysteroscopic Tissue Removal System and components are covered by one or more of the following U. S. Patent Numbers: patents pending.

SYMBOLS USED ON LABELING

I ON
Main electrical power on.

O OFF
Main electrical power off.

CAUTION
See Instructions for Use.

REF CATALOG NUMBER
Part number or reorder number

Contents

Single Use Only

Read Instructions Prior to Use

STERILE EO Ethylene Oxide Sterilization

Rx Prescription Use Only

Date of Manufacture

13-14

LOT Lot Number

Expiration Date

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Interlace™ MEDICAL

1 Contents: 1

REF 10-903

MyoSURE™ Foot Pedal

Read Instructions Prior to Use

℞ Caution: Federal Law (U.S.A) restricts this device to sale by or on the order of a physician.

Manufactured For:
Interlace Medical
135 Newbury Street
Framingham, MA 01701
(508) 875-1343

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LOT 000000-0

CE 0120

EC REP

European Representative:
Emergo Group, Inc.
Molenstraat 15, 2513 BH
The Hague
The Netherlands

MADE IN USA

LAB-0011 Rev A

13-51

14 STERILIZATION

14.1 Sterilization Information - Sterilization information is unchanged from the predicate MyoSure™ Hysteroscopic Tissue Removal System (K091100).

14.1.1 The MyoSure™ Tissue Removal Device is the only sterile component of the MyoSure™ Hysteroscopic Tissue Removal System.

- **Sterilization Method**: Ethylene Oxide (traditional method)

- **Method Used to Validate the Sterilization Cycle:** ANSI/AAMI/ISO 11135-1994 *Medical Devices-Validation and Routine Control of Ethylene Oxide Sterilization.* The sterilization cycle validation protocol for the MyoSure device was previously submitted to FDA and cleared by the agency in K081070 (Interlace Medical Operative Hysteroscopy System).

- **SAL**: 10^{-6}

- **Packaging:** Packaging information is unchanged from the predicate MyoSure™ Hysteroscopic Tissue Removal System (K091100). The MyoSure Tissue Removal Device is secured to a solid bleached sulfate (SBS) paperboard mounting card and packaged in a standard Tyvek/Mylar pouch.

- **Pyrogenicity:** The product is **not** labeled pyrogen free.

- **ETO Residues:**

  Maximum residue levels for release purposes of Ethylene Oxide, Ethylene Chlorohydrin, and Ethylene Glycol are maintained in accordance with the proposed rules set forth in the June 23, 1978 Federal Register, Vol 43, No. 122, § 821.100.

Ethylene oxide:	**25 ppm**
Ethylene chlorohydrin:	**250 ppm**
Ethylene glycol:	**250 ppm**

  Maximum residue levels for release purposes of Ethylene Oxide and Ethylene Chlorohydrin are maintained in accordance with ISO 10993-7:1995.

Ethylene oxide:	**20 mg per device**
Ethylene chlorohydrin:	**12 mg per device**

DJA 00172

15 BIOCOMPATIBILITY

15.1 BIOCOMPATIBILITY SUMMARY

(b)(4) Trade Secret Process - Biocompatibility Specification

[redacted]

DJA 00173

Biocompatibility Test Results: (b)(4) Trade Secret Process - Biocompatibility Specification [redacted]

Table 15-2 – Summarized Biocompatibility Test Results - (b)(4) Trade Secret Process - Biocompatibility [redacted]

(b)(4) [redacted] Evaluation Test	Compliance System	Test Method	Results [Report No.]
(b)(4) Trade Secret Process - Biocompatibility Specification [redacted]			

DJA 00174

16. SOFTWARE

(b)(4) Trade Secret Process - Software Specification

[redacted]

DJA 00175

(b)(4) Trade Secret Process - Software Specification

[redacted]

DJA 00176

(b)(4) Trade Secret Process - Software Specification [redacted]

16.4 Risk/Hazard Analysis: (b)(4) Trade Secret Process - Software Specification [redacted]

16.5 Traceability Matrix: (b)(4) Trade Secret Process - Software Specification [redacted]

16.6 Software Revision Level History: (b)(4) Trade Secret Process - Software Specification [redacted]

16.7 Software Verification: (b)(4) Trade Secret Process - Software Specification [redacted]

DJA 00177

17. ELECTROMAGNETIC COMPATIBILITY / ELECTRICAL SAFETY

(b)(4) Trade Secret Process - Software Specification

[redacted]

DJA 00178

18. PERFORMANCE TESTING - BENCH

18.1 Performance Testing Summary: (b)(4) Trade Secret Process - Testing [redacted]

(b)(4) Trade Secret Process - Testing [redacted]

Test Report Reference – (b)(4) Trade Secret Process - Testing [redacted]

(b)(4) Trade Secret Process - Testing [redacted]

Test Report Reference – (b)(4) Trade Secret Process - Testing [redacted]

DJA 00179

(b)(4) Trade Secret Process - Testing

[redacted]

Test Report Reference – (b)(4) Trade Secret Process - Testing [redacted])

(b)(4) Trade Secret Process - Testing

[redacted]

DJA 00180

19. PERFORMANCE TESTING - ANIMAL

Not Applicable To This Submission

DJA 00181

20. PERFORMANCE TESTING - CLINICAL

Not Applicable To This Submission

DJA 00182

21. KIT CERTIFICATION

This device is not part of a kit. Not applicable to this submission.

DJA 00183

22. DESIGN CONTROL ACTIVITIES SUMMARY

22.1 Identification of Risk Analysis Methods:

(b)(4) Trade Secret Process - Risk Analysis

[redacted]

(b)(4) Trade Secret Process - Risk Analysis

[redacted]

22.2Identification of Verification & Validation Activities:

Modification	Hazard/Risk	Test Method	Acceptance Criteria

(b)(4) Trade Secret Process - Verification & Validation Report

[redacted]

DJA 00184

Modification	Hazard/Risk	Test Method	Acceptance Criteria

(b)(4) Trade Secret Process - Verification & Validation Report

[redacted]

22.3Declaration of Conformity with Design Controls:

I certify that, in my capacity as the V.P. of Research & Development of Interlace Medical Inc., I believe to the best of my knowledge, that as required by the previously referenced risk analysis, all verification activities were performed by qualified, designated individuals and the results of the activities demonstrated that the predetermined acceptance criteria were met.

February 26, 2010
(Signature) (Date)

Albert Chin, V.P. of Research & Development Interlace Medical, Inc.
(Typed Name & Title) (Company)

I certify that, in my capacity as the V.P. of Operations of Interlace Medical Inc., I believe to the best of my knowledge, that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

February 26, 2010
(Signature) (Date)

David Jacobs, V.P. of Operations Interlace Medical, Inc.
(Typed Name & Title) (Company)

DJA 00004

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Glenn Bell

Subject: 510(k) Number K100559

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		N/A
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category N, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			N/a
Is clinical data necessary to support the review of this 510(k)?			✓
Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing; different protocol procedures, etc.)			✓

DJA 00005

	yes	no
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		✓
Nanotechnology		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	✓

Regulation Number	Class*	Product Code
884.1690	II	HIH

(*If unclassified, see 510(k) Staff)

Additional Product Codes: none

Review Colin M Pollard (Branch Chief) OGDB (Branch Code) 3/29/10 (Date)

Final Review: (Division Director) 3/30/10 (Date)

SCREENING CHECKLIST FOR SPECIAL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K100559

Section 1: Required Elements for a SPECIAL 510(k) submission:

	Present or Adequate	Missing or Inadequate
Medical Device User Fee Cover Sheet www.fda.gov/oc/mdufma/coversheet.html	✓	
Cover Letter Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 http://www.fda.gov/cdrh/ode/guidance/1567.html	✓	
Table of Contents	✓	
Truthful and Accurate Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_9	✓	
Form FDA 3654 - Standards Data Report for 510(k)s – http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf 1: No standard used? = No Standards Form Required 2: Declaration of Conformity? = Yes Standards Form Required 3: Standard but no declaration? = Yes Standards Form Required	✓	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	✓	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	✓	
Proposed Labeling - Device Advice www.fda.gov/cdrh/devadvice/314312.html#link_10	✓	
Indications for Use Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_6	✓	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	✓	
510(k) Summary or 510(k) Statement Device Advice - www.fda.gov/cdrh/devadvice/314312.html#link_7	✓	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	✓	
Identification of legally marketed predicate device. *	✓	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	✓	
Class III Certification and Summary. **	N/A	

Class III Summary and Certification Form www.fda.gov/cdrh/manual/stmnciii.html	N/A	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3454.pdf FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators www.fda.gov/opacom/morechoices/fdaforms/FDA-3455.pdf Financial Disclosure by Clinical Investigators www.fda.gov/oc/guidance/financialdis.html.	N/A	
Kit Certification: Device Advice http://www.fda.gov/cdrh/ode/odecl874.html	N/A	

*- May not be applicable for Special 510(k)s.
**- Required for Class III devices, only.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present or Adequate	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	✓	
A description of the modified device and a comparison to the sponsor's predicate device.	✓	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	✓	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.	✓	
A Design Control Activities Summary that includes the following elements (a-c):	—	
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	✓	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	✓	
c. A Declaration of Conformity with design controls that includes the following statements:	—	
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met.? This statement is signed by the individual responsible for those particular activities.	✓	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	✓	

Items with checks in the Present or Adequate column do not require additional information from the sponsor. Items with checks in the Missing or Inadequate column must be submitted before substantive review of the document.

Passed Screening ✓ Yes ____ No - Reviewer: Glen B. Bell
Concurrence by Review Branch: CMP Date: 5/29/10

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving

DJA 00010

these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the A Suggested Approach to Resolving Least Burdensome Issues document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

SPECIAL 510(k): Device Modification
ODE Review Memorandum (Decision Making Document is Attached)

To: THE FILE **RE:** DOCUMENT NUMBER K100559

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II device requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

   MyoSure Hysteroscopic Tissue Removal System (K091100)

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

   The indications for use are unchanged.

   Indications for Use:

   The MyoSure Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedure by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

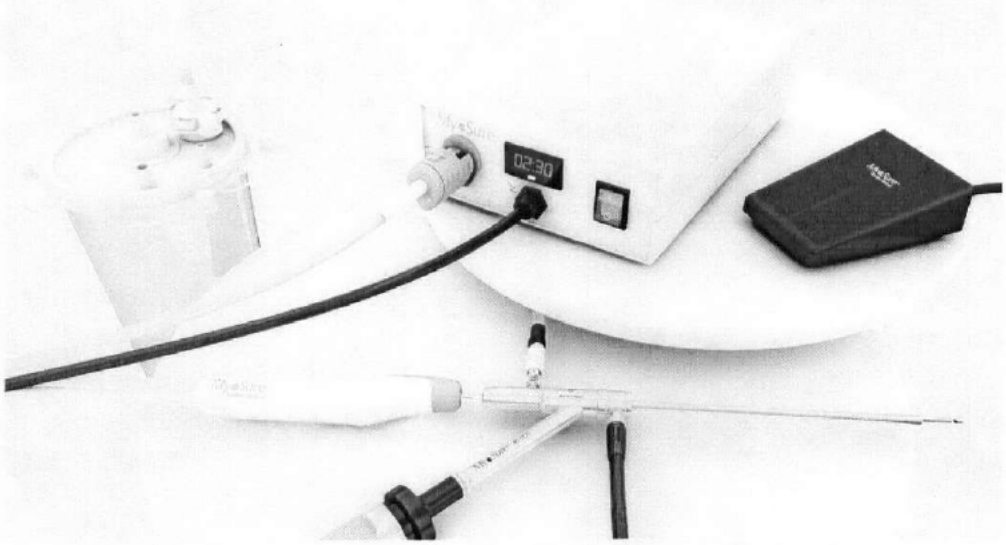
3. A description of the device (b)(4) Trade Secret Process - Product Specification [redacted]

   The device modifications are:

   - *Motor control software has been changed to firmware* - b(4)Trade Secret Process-Product Specs [redacted]
   - *Maximum running current and current limit have been decreased* - b(4)Trade Secret Process-Product Specs [redacted]
   - *Outer surface of cutting tube is coated with a different material* - b(4)Trade Secret Process-Product Specs [redacted]
   - *O ring changed to different material* - b(4)Trade Secret Process-Product Specs [redacted]

(b)(4) Trade Secret Process - Product Specification

[redacted]



MyoSure System

The fundamental scientific technology of the device has not changed.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics.

Similarities
The principles of operation of the modified MyoSure Hysteroscopic Tissue Removal System are identical to those of the predicate.

Device Comparison – Method of Operation

Attribute	Predicate MyoSure™ Hysteroscopic Tissue Removal System (K091100)	Modified MyoSure™ Hysteroscopic Tissue Removal System	Status
Method of Use	Hysteroscopic surgical removal of intrauterine tissue including submucous myomas and endometrial polyps using an electro-mechanical device.	No change	Identical to predicate
Mechanism of Action	The morcellator consists of a stationary outer sheath with a side-facing cutting window and a rotating and reciprocating inner cutter.	No change	Identical to predicate
Mode of Operation	Vacuum is used to pull tissue into the side-facing cutting window where it is cut and aspirated thru the cutter and deposited into a collection canister.	No change	Identical to predicate

DJA 00013

There are no changes to the labeling (i.e., Instructions for Use, component labels) or sterilization procedures.

Per the sponsor, the MyoSure Hysteroscopic Tissue Removal System is identical to the predicate device except for the differences listed below.

Differences

(b)(4) Trade Secret Process - Product Specification

[redacted]

5. A **Design Control Activities Summary** which includes:

(b)(4) Trade Secret Process - Product Specification

[redacted]

Biocompatibility Testing

(b)(4) Trade Secret Process - Testing

[redacted]

Corrosion Testing

(b)(4) Trade Secret Process - Testing

[redacted]

DJA 00014

(b)(4) Trade Secret Process - Testing

[redacted]

Performance and Thermal Testing

(b)(4) Trade Secret Process - Testing

[redacted]

Verification and Validation Testing

(b)(4) Trade Secret Process - Testing

[redacted]

Software Verification and Validation

(b)(4) Trade Secret Process - Testing

[redacted]

DJA 00015

6. A **Truthful and Accurate Statement**, a **510(k) Summary** and the **Indications for Use Enclosure**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modifications and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.

(Reviewer's Signature) (Date) 3/22/10

Comments

revised:8/1/03

DJA 00016

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	Yes	No	
1. Same Indication Statement?	x		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?		x	If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?	x		If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?			If **NO** = Go To 8
			If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?		x	If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?	x		If **NO** = Stop **NSE**
8. Performance Data Available?	x		If **NO** = Request Data
9. Data Demonstrate Equivalence?	x		Final Decision: SE

"Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

3. Same Technological Characteristics?
No. Several materials have been modified. Motor control software has been changed to firmware. Maximum running current and current limit have been decreased.

4. Could The New Characteristics Affect Safety Or Effectiveness?
Yes. The changes to materials could affect safety and changes to the software could affect safety or effectiveness.

6. New Types of Safety or Effectiveness Questions?
No. There are no new types of safety or effectiveness questions.

9. Data Demonstrate Equivalence?
Yes. The performance data show that the modified device is substantially equivalent to the predicate device.

510(k) SUMMARY REQUIREMENTS 21 CFR 807.92				
All 510(k) summaries shall contain the following information:		Y	N	N/A
1	The submitter's name, address, telephone number, a contact person, and the date the summary was prepared	✓		
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name	✓		
3	An identification of the legally marketed device to which the submitter claims equivalence.	✓		
4	A description of the device that is the subject of the premarket notification submission, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device (e.g., device design, material used, and physical properties)	✓		
5	A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. Or, if the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled	✓		
6	If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. Or, if the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section	✓		
510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information				
7	A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence	✓		
8	A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence			✓
9	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section	✓		

Public Health Service

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandums

Date: March 11, 2010

From: Michael T. Bailey, Ph.D.
Ob/Gyn Devices Branch, DRARD

To: Glenn Bell, Ph.D.
DRARD/OGDB

Subject: K100559 Interlace Medical, Inc. – MyoSure hysteroscopic tissue removal system -biocompatibility review.

Indication for Use
For hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

Scope of Review
The Interlace MyoSure device was previously submitted under K091100, and was found SE. The current submission is a Special 510(k) that was submitted due to various changes in the device (software, materials, etc.). The scope of this consulting review will be limited to modifications in device materials and supporting biocompatibility testing.

Device Description
The components of the MyoSure Hysteroscopic Tissue Removal System are as follows:

- MyoSure Control Unit
- MyoSure Tissue Removal Device
- MyoSure Foot Pedal

During a clinical procedure, a "thin profile commercial hysteroscope" is inserted transvaginally into the uterus, which is then distended with physiologic distension media. The MyoSure Tissue Removal Device (TRD) is attached to a vacuum source and inserted into the uterus via the working channel of the hysteroscope. The tip of the device is placed near the target tissue and the foot pedal is depressed to activate the vacuum and cutter blade. Resected tissue and distension fluid are then aspirated through the TRD and collected in a tissue trap/vacuum canister for pathology/disposal.

Device Materials

The updated device is composed of the following materials:

(b)(4) Trade Secret Process - Material & Biocompability Specifications

[redacted]

Biocompatibility

(b)(4) Trade Secret Process - Material & Biocompability Specifications

[redacted]

(b)(4) Trade Secret Process - Material & Biocompability Specifications

[redacted]

Biocompatibility testing acceptable

(b)(4) Trade Secret Process - Material & Biocompability Specifications

[redacted]

Recommendation

Biocompatibility testing acceptable – No further questions.

Michael T. Bailey, Ph.D. Dated: 3/11/10

Prepared: 3-11-10 MTB

Bell, Glenn

From: John Vozella [JVozella@interlacemedical.com]
Sent: Friday, March 05, 2010 10:19 AM
To: Bell, Glenn
Subject: RE: K100559 MyoSure Hysteroscopic Tissue Removal System (Interlace Medical)
Attachments: Section 15 - Biocompatability v2.doc; L929 MEM Cytotoxicity Test Report - WuXi 128734.pdf; Guinea Pig Sensitization Test Report - WuXi 128737.pdf

Glen,

(b)(4) Trade Secret Process - Product Specifications

[redacted]

Best Regards,

John J. Vozella, Esq.
V.P. of Clinical and Regulatory Affairs

Interlace Medical, Inc.
135 Newbury Street
Framingham, MA 01701

Tel: (508) 875-1343 ext. 112
Cell: (508) 243-3084
Fax: (508) 370-8026
Email: john@interlacemedical.com

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DJA 00022

From: Bell, Glenn [mailto:Glenn.Bell@fda.hhs.gov]
Sent: Thursday, March 04, 2010 4:39 PM
To: John Vozella
Subject: RE: K100559 MyoSure Hysteroscopic Tissue Removal System (Interlace Medical)

John,

The K100559 MyoSure Hysteroscopic Tissue Removal System (Interlace Medical) submission does not include complete test reports for the biocompatibility testing. Can you please provide copies of the complete test reports?

Sincerely,

Glenn

From: John Vozella [mailto:JVozella@interlacemedical.com]
Sent: Wednesday, March 03, 2010 2:02 PM
To: Bell, Glenn
Subject: RE: K100559 MyoSure Hysteroscopic Tissue Removal System (Interlace Medical)

Hi Glen,

Attached, please find the remaining relevant electronic sections for K100559:

- Section 14 – Sterilization & Packaging
- Section 15 – Biocompatibility
- Section 16 – Software
- Section 17 – EMC & Electrical Safety
- Section 18 – Performance Test Summary
- Section 21 – Kit Certification
- Section 22 – Design Control Activities Summary

Please confirm receipt via return email and let me know if I can be of further assistance.

Best Regards,

John

From: Bell, Glenn [mailto:Glenn.Bell@fda.hhs.gov]
Sent: Wednesday, March 03, 2010 11:58 AM
To: John Vozella
Subject: K100559 MyoSure Hysteroscopic Tissue Removal System (Interlace Medical)

John,

Can you please send me an electronic copy of your submission?

Sincerely,

Glenn

DJA 00023

Glenn B. Bell, Ph.D.
Biomedical Engineer
FDA/CDRH/DRARD/OGDB
10903 New Hampshire Avenue
Silver Spring, MD 20993
(301) 796-6531
FAX (301) 847-8111

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DJA 00024

15 BIOCOMPATIBILITY

(b)(4) Trade Secret Process - Biocompatiblity Specifications

[redacted]

Biocompatibility Test Results: [redacted] (b)(4) Trade Secret Process - Biocompatibility Specifications [redacted]

Table 15-2 – Summarized Biocompatibility Test Results - (b)(4) Trade Secret Process - Biocompatibility [redacted]

(b)(4) [redacted] Evaluation Test	Compliance System	Test Method	Results [Report No.]
(b)(4) Trade Secret Process - Biocompatiblity Specifications			
[redacted]			

(b)(4) Trade Secret Process - Testing

[redacted]

FINAL STUDY REPORT

STUDY TITLE

ISO MEM Elution Assay with L-929 Mouse Fibroblast Cells

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

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(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

DJA 00047

Bell, Glenn

From: John Vozella [JVozella@interlacemedical.com]
Sent: Friday, March 05, 2010 10:22 AM
To: Bell, Glenn
Subject: RE: K100559 MyoSure Hysteroscopic Tissue Removal System (Interlace Medical)
Attachments: Intracutaneous Reactivity Test Report - WuXi 128736.pdf; Acute Systemic Toxicity Test Report - WuXi 128735.pdf

Glen,

(b)(4) Trade Secret Process - Product Specification

[redacted]

Best Regards,

John J. Vozella, Esq.
V.P. of Clinical and Regulatory Affairs

Interlace Medical, Inc.
135 Newbury Street
Framingham, MA 01701

Tel: (508) 875-1343 ext. 112
Cell: (508) 243-3084
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Email: john@interlacemedical.com

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From: Bell, Glenn [mailto:Glenn.Bell@fda.hhs.gov]
Sent: Thursday, March 04, 2010 4:39 PM

DJA 00048

To: John Vozella
Subject: RE: K100559 MyoSure Hysteroscopic Tissue Removal System (Interlace Medical)

John,

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Sincerely,

Glenn

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- Section 22 – Design Control Activities Summary

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Sincerely,

Glenn

Glenn B. Bell, Ph.D.
Biomedical Engineer
FDA/CDRH/DRARD/OGDB

DJA 00049

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(b)(4) Trade Secret Process - Testing

[redacted]

FINAL STUDY REPORT

STUDY TITLE

ISO Intracutaneous Reactivity Test

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

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(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

[redacted]

FINAL STUDY REPORT

STUDY TITLE

ISO Acute Systemic Injection Test

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

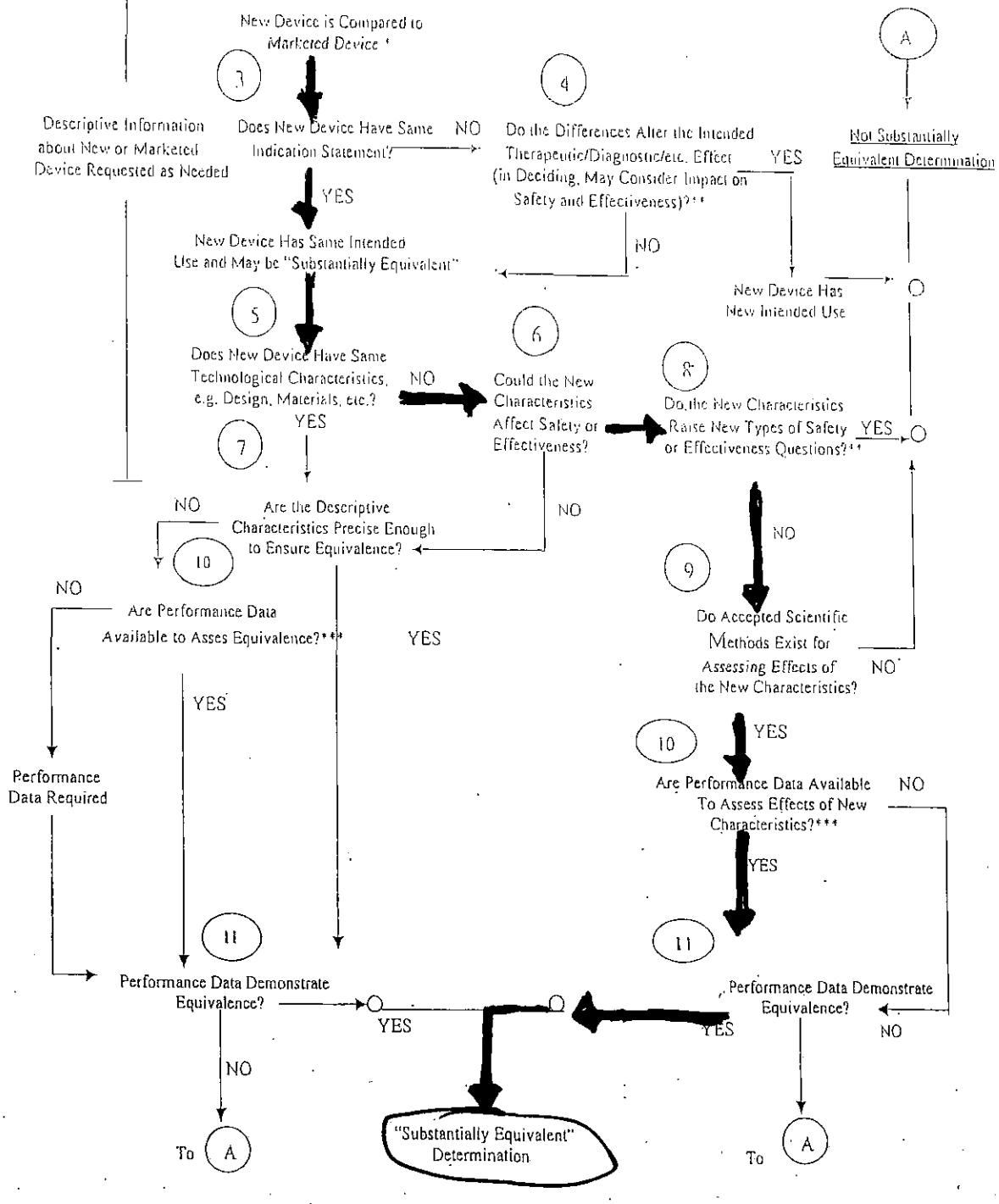
(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Product Specifications & Design

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.