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REV AUTHORED BY G PITTS	DATE 02/21/13	 HOLOGIC [®] A FAMILY OF COMPANIES	Osteoporosis Assessment LORAD [®] Breast Cancer Detection DirectRay [®] Digital Imaging FLUOROSCAN [®] C-arm Imaging		 SIGNATURES ON FILE
REV DRAFTED BY G PITTS	DATE 02/21/13		TITLE IFU, MYOSURE INSTRUMENT TRAY	DOCUMENT NUMBER AW-07649-001	
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REV. RELEASE DATE: 03/06/2013					

MyoSure®

Instrument Tray Instructions for Use

INDICATIONS FOR USE/INTENDED USE

The MyoSure® Instrument Tray is intended to enclose, protect, and organize the MyoSure® Rod Lens Hysteroscope, MyoSure® Removable Outflow Channel, and associated components, during sterilization and storage.

The MyoSure® Instrument Tray must be used in conjunction with a sterilization wrap that is cleared by FDA for the indicated sterilization cycle, and may be stored for up to 30 days in accordance with the wrap manufacturer's instructions.

The MyoSure® Instrument Tray has been validated for the following sterilization cycles:

Prevacuum Steam	Gravity Steam	STERRAD® 100S™
132°C (270°F)	132 °C (270 °F)	59% H2O2
4 minutes exposure	15 minutes exposure Normal Cycle Setting	Normal Cycle Setting
30 minutes dry time	30 minutes dry time	
Contents - 1 MyoSure® Rod Lens Hysteroscope, 1 Removable Outflow Channel, 2 Seal Caps, 2 Light Guides	Contents - 1 MyoSure® Rod Lens Hysteroscope, 1 Removable Outflow Channel, 2 Seal Caps, 2 Light Guides	Contents - 1 MyoSure® Rod Lens Hysteroscope, 1 Removable Outflow Channel, 2 Seal Caps, 2 Light Guides

CONTRAINDICATIONS

Stacking of trays and overloading of the units will adversely affect sterilization and drying effectiveness. DO NOT STACK trays in the sterilization chamber.

CARE AND CLEANING RECOMMENDATIONS

- Pre-Rinse soiled trays in tap water for 2 minutes
- Both physical and chemical (enzymatic detergent) processes may be necessary to clean soiled items. Follow enzymatic detergent manufacturer's instructions
- Chemical (enzymatic detergent) cleaners alone may not remove all soil and debris; therefore, a careful manual cleaning of each item with a soft sponge or cloth is essential.
- For difficult access areas, a clean, soft-bristled brush is recommended.
- Repeat cleaning steps if visible contamination of tray components is observed.
- Once the items have been cleaned, they should be thoroughly rinsed with clean water to remove any detergent or chemical residue before sterilization.

- Hologic recommends the use of a mild enzymatic detergent with a near neutral pH.
- Do not use solvents, abrasive cleaners, metal brushes, or abrasive pads.
- Trays may be placed in mechanical cleaning equipment

CAUTION: Always inspect tray components for cleanliness and confirm that there is no visual contamination prior to use.

CAUTION: Trays are reusable but may eventually be damaged. Always inspect tray components for cracking, chipping, or other signs of damage before use. Make sure all latches and handles are secure and in working order. Damaged trays should be removed from service. Minor Surface cosmetic changes may occur with long-term use or after Sterrad® processing.

CAUTION: Only use accessory components that have been designed and tested for use in MyoSure® Instrument Trays.

STERILIZATION RECOMMENDATIONS

Do not overload trays. Place and arrange tray contents in accordance with Figure 1 to facilitate sterilant contact with all objects in the tray.

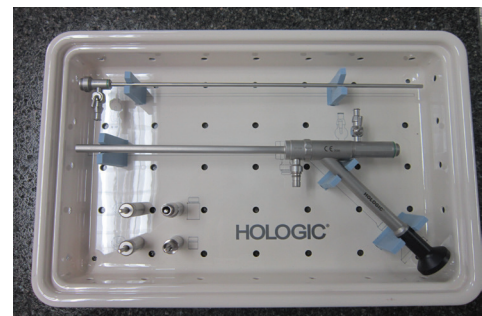


FIGURE 1

Process the tray according to the sterilization wrap manufacturer's instructions prior to sterilization to maintain sterility of internal components/items and for proper aseptic presentation to the surgical field. Product may be maintained for up to 30 days after sterilization in accordance with the wrap manufacturer's instructions.

STEAM STERILIZATION

Performance of the MyoSure® Instrument Tray has been verified in the following steam autoclave cycles for sterilization of the MyoSure® Rod Lens Hysteroscope and accessory components.

TABLE 1 - STEAM PRE-VACUUM STERILIZATION PARAMETERS	
Temperature	270°F (132°C)
Exposure Time	4 minutes
Dry Time	30 minutes
Validated Device Load	≤ 5 lbs. (1 MyoSure® Rod Lens Hysteroscope 1 Removable Outflow Channel, 2 seal caps, 2 light guides)
Validated Sterilizer Load	Single tray in an otherwise empty sterilization chamber

TABLE 2 - STEAM GRAVITY DISPLACEMENT STERILIZATION PARAMETERS	
Temperature	270°F (132°C)
Exposure Time	15 minutes
Dry Time	30 minutes
Validated Device Load	≤ 5 lbs. (1 MyoSure® Rod Lens Hysteroscope 1 Removable Outflow Channel, 2 seal caps, 2 light guides))
Validated Sterilizer Load	Single tray in an otherwise empty sterilization chamber

Variables that may affect drying times include: loading density of the case/tray, instrument configuration, total contents of the sterilizer, steam quality, equipment maintenance, and others.

CAUTION: Do not load trays into sterilizer on sides or upside down with lid side on the shelf or cart. Load trays on cart or shelf, so that the lid is always facing upward. This will allow for proper drying. The MyoSure® Instrument Tray is designed to drain in this position.

CAUTION: After the autoclave door is opened, all trays must be allowed to cool thoroughly. Place trays on a rack or shelf with linen cover until cooling is complete. The potential for condensation may increase if the tray is not allowed to cool properly.

If condensation is observed, verify that the steam, which is being used for sterilization processing, has a quality of more than 97%. Also confirm that the sterilizers have been inspected for routine maintenance in accordance with manufacturer recommendations.

STERRAD® STERILIZATION

The MyoSure® Instrument Tray has been validated for use with the STERRAD® 100S™ System.

TABLE 3 - STERRAD® STERILIZATION SUMMARY	
Sterilizer Model #	STERRAD® 100S™
Sterilizer Cycle	STERRAD® 100S™ cycle
Validated Device Load	≤ 5 lbs. (1 MyoSure® Rod Lens Hysteroscope, 1 Removable Outflow Channel, 2 seal caps, 2 light guides))

Refer to the STERRAD® 100S™ User’s Guide for additional warnings, precautions, and more information about the STERRAD® 100S™ sterilization process.

WARNING: Hydrogen peroxide is corrosive and concentrated hydrogen peroxide is toxic. Wear chemical resistant latex, PVC (vinyl), or nitrile gloves

whenever handling a load after a cycle cancellation, or if any moisture is noted on a load following a completed cycle.

SERVICE – ACCESSORIES

The following are replacement parts for the MyoSure® Instrument Tray:

REF	DESCRIPTION
40-903	MyoSure® Instrument Tray

WARRANTY, SERVICE, AND REPAIR

WARRANTY INFORMATION

THE MYOSURE® INSTRUMENT TRAY AND ACCESSORIES ARE PROVIDED “AS IS” WITH NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. CUSTOMER IS RESPONSIBLE FOR ANY REPAIR OR REPLACEMENT OF THE MYOSURE® INSTRUMENT TRAY.

TECHNICAL SUPPORT AND PRODUCT RETURN INFORMATION

Contact Hologic Technical Support if the MyoSure® Instrument Tray fails to operate as intended.

Hologic Technical Support United States:

Phone: 1.800.442.9892 (toll-free) or 1.508.263.2900
 Fax: 1.508.229.2795


FOR FURTHER INFORMATION

If further information on this product is needed, please contact Hologic Customer Service at 800-442-9892 in the U.S., or your authorized representative.

In USA contact:

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 250 Campus Drive
 Marlborough, MA 01752
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