

Omni™ Instrument Tray

Instructions for Use

Read these instructions completely prior to using the Omni Instrument Tray. The Omni Instrument Tray is compatible with the Omni Hysteroscopy Sets (REF 60-250-1 and REF 60-250-2) that contain the following components:

Catalogue Number	Product
60-200	Omni Hysteroscope
60-201	Omni 3.7mm Diagnostic Sheath
60-202	Omni 5.5mm Operative Sheath
60-203	Omni 6mm Operative Sheath
40-201	MyoSure Rod Lens Hysteroscope Removable Outflow Channel
50-201XL	MyoSure XL Rod Lens Hysteroscope Removable Outflow Channel
40-900	Storz Light Guide Adapter
40-901	Wolf Light Guide Adapter

INDICATIONS FOR USE/INTENDED USE

The Omni Instrument Tray is intended to enclose, protect, and organize The Omni Hysteroscope, Sheaths, and Removable Outflow Channels during sterilization and storage.

The Omni Instrument Tray must be used in conjunction with a sterilization wrap that is cleared by FDA for the indicated sterilization cycles.



SQUEEZE LEVERS TO UNLOCK LID

FIGURE 1

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

Prevacuum Steam	STERRAD®
132°C (270°F) 4 minutes exposure 35 minutes dry time	- STERRAD 100S Short - STERRAD NX Standard - STERRAD 100NX Standard
Contents: - 1 Omni Hysteroscope - 1 Removable Outflow Channel - 1 XL Removable Outflow Channel - 1 Omni 3.7mm Diagnostic Sheath - 1 Omni 5.5mm Operative Sheath - 1 Omni 6mm Operative Sheath - 3 Seal Caps - 2 Light Guide Adapters	Contents: - 1 Omni Hysteroscope - 1 Removable Outflow Channel - 1 XL Removable Outflow Channel - 1 Omni 3.7mm Diagnostic Sheath - 1 Omni 5.5mm Operative Sheath - 1 Omni 6mm Operative Sheath - 3 Seal Caps - 2 Light Guide Adapters

CONTRAINDICATIONS

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

CARE AND CLEANING RECOMMENDATIONS

- 1) Remove Instrument tray lid from base.
- 2) Pre-Rinse soiled trays and lids in warm 32°C-43°C (90°F-110°F) tap water for 2 minutes.
- 3) Both physical and chemical (enzymatic detergent) processes may be necessary to clean soiled items.
- 4) Tray should be soaked in an enzymatic neutral pH cleaner, such as Enzol or Neodisher Mediclean Forte.
 - a) If using Enzol solution:
 - i) Prepare Enzol solution according to manufacturer’s instructions of 1oz per gallon using warm tap water.
 - ii) Fully immerse the tray and lid in prepared Enzol solution.
 - iii) Allow to soak for 1 minute in prepared Enzol solution.

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b) If using Neodisher Mediclean Forte solution:

- i) Prepare Neodisher Mediclean Forte solution according to manufacturer’s instructions of 5/8oz per gallon using warm tap water.
- ii) Fully immerse the tray and lid in prepared Neodisher Mediclean Forte solution.
- iii) Allow to soak for 10 minutes in prepared Neodisher Mediclean Forte solution.

- 5) After the appropriate soak time for the Chemical (enzymatic detergent) cleaner selected, clean the tray and lid using a soft sponge or cloth.
- 6) For difficult access areas, use of a clean, soft-bristled brush while articles are still immersed is recommended.
- 7) Repeat cleaning steps 2-6 if visible contamination of tray components is observed.
- 8) Once the items have been cleaned, they should be thoroughly rinsed with clean, warm tap water 32°C-43°C (90°F-110°F) for at least 1 minute to remove any detergent or chemical residue before sterilization.
- 9) Dry the tray and lid with a lint free cloth or filtered compressed air.
- 10) Do not use solvents, abrasive cleaners, metal brushes, or abrasive pads.

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 100S Short, STERRAD NX Standard, and STERRAD 100NX Standard processing.

CAUTION: Only use accessory components that have been designed and tested for use in Omni Instrument Tray.

STERILIZATION RECOMMENDATIONS

Do not overload trays. Place and arrange tray contents in accordance with Figure 2 to facilitate sterilant contact with all objects in the tray.

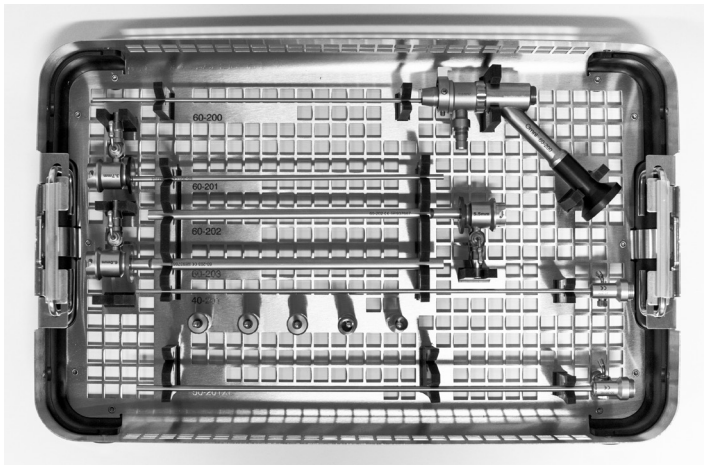


FIGURE 2

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 Omni Instrument Tray has been validated in the following steam autoclave cycles for sterilization of the Omni Hysteroscope and accessory components.

TABLE 1 - STEAM PRE-VACUUM STERILIZATION PARAMETERS	
Temperature	132°C (270°F)
Exposure Time	4 minutes
Dry Time	35 minutes
Validated Device Load	≤ 5 lbs. (1 Omni Hysteroscope, 1 Removable Outflow Channel, 1 XL Removable Outflow Channel, 1 Omni 3.7mm Diagnostic Sheath, 1 Omni 5.5mm Operative Sheath, 1 Omni 6mm Operative Sheath, 3 Seal Caps, 2 Light Guide Adapters)
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 Omni 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 Omni Instrument Tray has been validated for use with the STERRAD 100S Short, STERRAD NX Standard, and STERRAD 100NX Standard cycles.

TABLE 2 - STERRAD STERILIZATION SUMMARY	
STERRAD Cycle	- STERRAD 100S Short - STERRAD NX Standard - STERRAD 100NX Standard
Validated Device Load	≤ 5 lbs. (1 Omni Hysteroscope, 1 Removable Outflow Channel, 1 XL Removable Outflow Channel, 1 Omni 3.7mm Diagnostic Sheath, 1 Omni 5.5mm Operative Sheath, 1 Omni 6mm Operative Sheath, 3 Seal Caps, 2 Light Guide Adapters)

Refer to the STERRAD® User’s Guides for additional warnings, precautions, and more information about the STERRAD 100S Short, STERRAD NX Standard, and STERRAD 100NX Standard sterilization cycles.

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 Omni Instrument Tray:

REF	DESCRIPTION
60-903	Omni Instrument Tray

WARRANTY, SERVICE, AND REPAIR**WARRANTY INFORMATION**

THE OMNI 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 OMNI INSTRUMENT TRAY.

TECHNICAL SUPPORT AND PRODUCT RETURN INFORMATION

Contact Hologic Technical Support if the Omni 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:



Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
Toll Free Phone: 1-800-442-9892
Toll Free Fax: 1-800-409-7591

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

EC	REP	European Representative
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The Omni Instrument Tray is
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HOLOGIC[®]

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