HOLOGIC®

Omni®
Instrument Tray

REF 60-903-1

Instructions for Use

Read these instructions completely prior to using the Omni Instrument Tray.

Description

The Omni Instrument Tray is compatible with the following product sets: Omni Hysteroscopy Standard Kit (60-250-1), Omni Hysteroscopy Light Kit (60-250-2), Omni 30 Hysteroscope Standard Kit (60-250-30-1) or Omni 30 Hysteroscope Light Kit (60-250-30-2).

Part Number	Product
60-200	Omni Hysteroscope
60-200-30	Omni Hysteroscope 30 Degree
60-201	3.7mm Diagnostic Sheath
60-201-30	Omni 30 Degree 3.7 mm Diagnostic Sheath
60-202	5.5mm Operative Sheath
60-202-30	Omni 30 Degree 5.5 mm Operative Sheath
60-203	6mm Operative Sheath
60-203-30	Omni 30 Degree 6 mm Operative Sheath
40-201	MyoSure Rod Lens Hysteroscope Outflow Channel
40-201-30	Omni 30 Degree Outflow Channel
50-201XL	MyoSure XL Rod Lens Hysteroscope Outflow Channel
50-201XL-30	Omni 30 Degree XL Outflow Channel
40-900	Storz Light Guide Adapter
40-901	Wolf Light Guide Adapter
40-904	MyoSure Hysteroscope and Outflow Channel Seal Cap

Indications for 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.

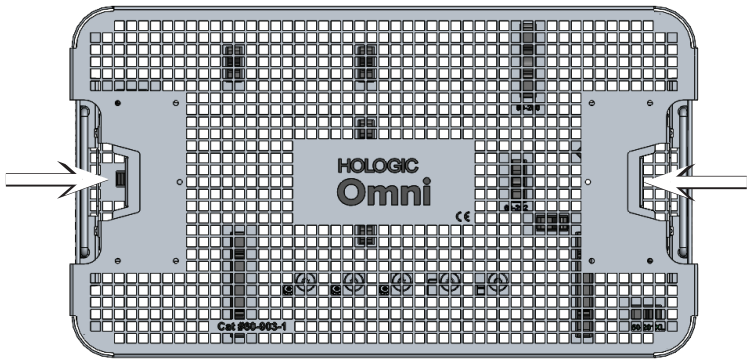

Figure 1. Squeeze the locking lever to open the lid

Intended User

The Omni Instrument Tray is intended to be used by Scrub Techs or Nurses and Reprocessing Technicians.

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 Instructions

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 Neodisher Mediclean Forte or enzymatic neutral pH cleaner, such as Enzol.
   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.
   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: The expected overall lifetime of the Omni Instrument Tray is about 200 uses from first use or until the tray becomes 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 Instructions

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

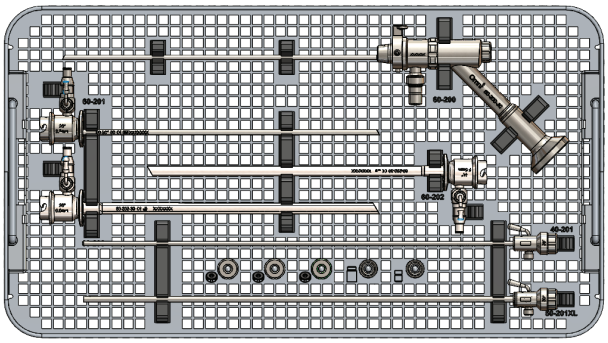

Figure 2.

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

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

Pre-Vacuum Steam
132°C (270°F) for 4 minutes and 35 minutes dry time
UK Cycle
134-137°C for 3-4 minutes and 30 minutes dry time. Do not exceed 140°C.
World Health Organization:
134°C for 18 minutes and 35 minutes dry time.

Steam sterilization cycles were validated with ≤ 5lb device load (1 Omni Hysteroscope, 1 Removable Outflow Channel, 1XL 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) and as a single tray in an otherwise empty sterilization chamber.

Trays should be wrapped in two layers of 1-ply polypropylene wrap (Halyard Health H600 or equivalent).

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 the following STERRAD sterilization cycles:

STERRAD Sterilization Summary
- STERRAD 100S Short - STERRAD NX Standard - STERRAD 100NX Standard

STERRAD sterilization cycles were validated with ≤ 5lb device load (1 Omni Hysteroscope, 1 Removable Outflow Channel, 1XL 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.

Trays should be wrapped with two layers of a sterilization wrap that is cleared by the FDA for the indicated sterilization cycle (Halyard Health H400 or equivalent).

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.

Technical Specifications

REF: 60-903-1

Omni Instrument Tray	
Length:	16.2 in
Width:	9.0 in
Height:	2.3 in

SERVICE ACCESSORIES:

The following are replacement parts for the Omni Instrument Tray:

REF	Description
60-903-1	Omni Instrument Tray

Warranty, Service, and Repair

WARRANTY

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.

FOR MORE 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.

For technical support or reorder information in the United States, please contact:

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
USA
Phone: 800-442-9892
www.hologic.com

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

European Representative

EC REP Hologic BV
Da Vincilaan 5
1930 Zaventem
Belgium
Phone: +32 2 711 46 80

Report any complaints or problems in the quality, reliability, safety, or performance of this product to Hologic. If the device has caused or added to patient injury, immediately report the incident to Hologic Authorized Representative and Competent authority of the respective member state or country. The Competent Authorities, for medical devices, are usually the individual Member States’ Ministry of Health, or an agency within the Ministry of Health.

Symbols Glossary

Symbol	Standard Reference & Symbol Number	Title of Symbol	Description of Symbol
EC REP	EN ISO 15223-1, 5.1.2	Authorized representative in the European Community	Indicates the Authorized representative in the European Community.
LOT	EN ISO 15223-1, 5.1.5 ISO 7000, 2492	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	EN ISO 15223-1, 5.1.6 ISO 7000, 2493	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	EN ISO 15223-1, 5.4.4 ISO 7000, 0434A IEC 60601-1, Table D.1, 10	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
CE	European Medical Directive 93/42/EEC, Article 17 and Annex XII	European Conformity	Indicates the medical device conforms to European Medical Directive 93/42/EEC and meets applicable health, safety, and environmental requirements. If the mark is accompanied by a number, conformity is verified by the indicated notified body.
	EN ISO 15223-1, 5.4.3 ISO 7000, 1641 IEC 60601-1, Table D.1, 11	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO/DIS 15223-1, 5.7.11 ISO 7000, 6049	Country of manufacture	To identify the country of manufacture of products.
	EN ISO 15223-1, 5.1.3 ISO 7000, 2497	Date of manufacture	Indicates the date when the medical device was manufactured.
	BS EN 15986 Annex B	Does not contain the presence phthalates	Indicates patient contact parts do not contain the presence phthalates.
	EN ISO 15223-1, 5.1.1 ISO 7000, 3082	Manufacturer	Indicates the medical device manufacturer.
MD	ISO/DIS 15223-1, 5.7.7	Medical device	Indicates the item is a medical device
	ISO 7000, 2794	Packaging unit	To indicate the number of pieces in the package.
UDI	ISO/DIS 15223-1, 5.7.10	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information

CE

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