Integra® Jarit® Endoscope & Instrument Holder

DEVICE DESCRIPTION
All Integra® Jarit® instruments are carefully inspected before shipment. Because damage may occur during transit, the instruments should be thoroughly inspected upon receipt and prior to use. Before first use, all instruments must be thoroughly cleaned prior to sterilization or high level decontamination. If you have any questions or require additional information regarding your Jarit® instrument Holder, please contact your Jarit® sales representative or Jarit® Technical Services at 1-800-431-1123.

INDICATIONS FOR USE
The Integra® Jarit® Endoscope and Instrument Holder consists of a table-mounted endoscope and instrument holding system intended for use by surgeons to hold instruments, endoscopes and arthroscopes with a diameter of 4mm to 10mm during general diagnostic and therapeutic procedures. The device is also intended for use by qualified surgeons for holding endoscopes during diagnostic and therapeutic neurologic procedures.

The product is supplied non-sterile. Prior to the initial and following each use, the product must be cleaned, disinfected, and sterilized, as well as checked for visible irregularities and malfunctioning according to the indications given in these instructions for use.

WARNING
This product is not to be used for “non-grounded” patient positioning. Special care should be taken when these products are used together with high-frequency applications. Contact between them must be avoided.

CAUTION
The fixation of the articulated arm is based on the principle of friction. Changing the position without loosening the clamping mechanism can cause damage and will shorten the lifespan of the Jarit® Endoscope & Instrument Holder.

DIRECTIONS FOR ASSEMBLY
As with any decontamination procedure, personnel should follow accepted guidelines for hand washing, the use of protective attire, etc., as recommended by A.A.M.I. Standards and Recommended Practice, “Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities,” ANSI/AAMI ST79:2006. Disinfection or sterilization cannot be accomplished without first thoroughly cleaning medical devices/ equipment.

DECONTAMINATION is a two step process.
1. Thorough cleaning and rinsing.
2. Sterilization or disinfection.

A. MANUAL DECONTAMINATION:

PRECLEANING: Remove gross debris from Jarit® Endoscope & Instrument Holder with a lap sponge and sterile water after the procedure to prevent drying on of blood and body fluids, etc. It is important to rinse the Jarit Endoscope & Instrument Holder that has been exposed to blood and saline solution before these substances dry. Blood and body fluids as well as saline solutions are highly corrosive. In addition, blood can produce a stain that is difficult to remove.

PREPARING THE JARIT® ENDOSCOPE & INSTRUMENT HOLDER FOR TRANSPORT TO DECONTAMINATION:
Immediately after the surgical procedure, place the Jarit® Endoscope & Instrument Holder into an instrument tray and cover with a towel. Transport tray in an impervious plastic bag or container to the decontamination environment (keep the outside of the containment clean).
CLEANING: To prevent the formation of biofilm, cleaning should occur as soon as possible after the Jarit® Endoscope & Instrument Holder is used. Biofilm is an accumulation of a biomass of bacteria and extracellular material that tightly adheres itself to the surface of the Jarit® Endoscope & Instrument Holder. It cannot be easily removed, and protects microorganisms from being easily removed by ordinary cleaning/decontamination methods used in hospitals.

Step 1. Pre-Rinse, as necessary with tap water.

WARNING

The central handle of the articulated arm must be tightened during the cleaning, rinsing and disinfection process.

Step 2. Cleaning the Jarit® Endoscope & Instrument Holder: The use of a neutral pH detergents (pH 4±pH and ≤pH) is vital to the maintenance of the Jarit® Endoscope & Instrument Holder. Contact with acidic or alkaline solution will remove the Jarit® Endoscope & Instrument Holders’ protective barrier of chromium oxide, often leading to corrosion, pitting, and breakage. The ideal cleaning agent is nonabrasive, low-foaming and free-rinsing. Using a small clean hand-held brush, remove soil from all surfaces of the Jarit® Endoscope & Instrument Holder. Never use steel wool, wire brushes, scalpel blades or highly abrasive detergent or cleansers to remove soil from the Jarit® Endoscope & Instrument Holder. These will damage the Jarit® Endoscope & Instrument Holders’ protective surface and lead to corrosion. Use a clean soft bristled brush to clean the Jarit® Endoscope & Instrument Holder. A build-up of soil, debris, lubricants, etc. will make it difficult to use the Jarit® Endoscope & Instrument Holder and eventually irreparably damage it. Manual cleaning should remove all visible residue.

WARNING

Instruments made of aluminum alloys will be damaged by basic(pH>9) cleaning agents and solvents.

Step 3. Rinse: Thoroughly rinse the Jarit® Endoscope & Instrument Holder by immersing it in tap water and wiping with a clean, soft cloth.

Step 4. Final Rinse: Should be with “treated water”. Softened or deionized water should be used for the final rinse to better remove detergents etc.

• Softening water removes calcium and magnesium ions that cause water to be hard. Iron ions may also be removed by this treatment.

• Deionization removes ionized salts and particles from the water. Excessively hard water can spot or stain the Jarit® Endoscope & Instrument Holder and excessive chlorine in water can cause pitting of the Jarit® Endoscope & Instrument Holder.

• Deionized water is preferred for the final rinse.

Step 5. Decontaminate Clean Jarit® Endoscope & Instrument Holder: Once the Jarit® Endoscope & Instrument Holder has been cleaned, it must be rendered safe for handling, inspection and assembly.

Step 6. Visual Inspection of the Jarit® Endoscope & Instrument Holder: Visually inspect the Jarit® Endoscope & Instrument Holder for cleanliness and to ensure all parts are in proper working order. Inspection is a vital part of proper care and maintenance. The Jarit® Endoscope & Instrument Holder in need of repair will not perform accurately in surgery and breakage is likely to occur. DO NOT USE a damaged Jarit® Endoscope & Instrument Holder.

B. MECHANICAL DECONTAMINATION

The Jarit® Endoscope & Instrument Holder may be processed in an automatic washer decontaminator/disinfector. Follow the manufacturer’s specifications when using automatic washer decontaminators/disinfectors. They usually require the use of a low foaming, free rinsing detergent with a neutral pH (7.0). A high-foaming detergent may clean effectively but will often leave residual deposits on the Jarit® Endoscope & Instrument Holder and do harm to mechanical washers. Automated washer decontaminator/disinfectors usually have adjustable wash and rinse times. Some washers enable the user to customize extra cycles to process heavily soiled Jarit® Endoscope & Instrument Holders more effectively. Water quality for rinsing cycles should be sterile or germ-poor (maximum 10 germ/ml) and endotoxin-free (maximum 0.25 endotoxin units/ml) water (Aqua purificata). Air used for drying should be filtered. The cleaning and disinfecting apparatus should be serviced and checked regularly.

When choosing cleaning and disinfecting agents, please make sure that they do not contain the following:

• No organic/inorganic, respectively oxidizing acids (pH should not be less than 4, the use of neutral/enzymatic agents is recommended)

• No base (pH should not be higher than 9, the use of neutral/enzymatic agents is recommended).

• Solvents (alcohol, benzene, acetone, ...)

• Phenol

• Chlorine, bromine, iodine

• Chlorine salts (in particular ammonium chloride compounds), chlorinated/ halogenated hydrocarbons

• Oxidizing agents, peroxide, hypochlorite

Donot clean any of the instruments with metal brushes or steel wool. All the instruments should not be exposed at temperatures higher than 137°C(279°F).

Check with a Jarit® Technical Service representative at 1-800-431-1123 for questions regarding processing/delicate, complex and/or multipart instruments by this method.

C. PREPARING THE JARIT® ENDOSCOPE & INSTRUMENT HOLDER FOR STERILIZATION

Drying: Before the Jarit® Endoscope & Instrument Holder is wrapped for sterilization or storage, it must be thoroughly dry. If the Jarit® Endoscope & Instrument Holder is wet when wrapped for sterilization, it is likely to come out of the sterilizer wet. “Wet Packs” are not suitable for use after sterilization because they may be easily contaminated when handled. In addition, remaining moisture, particularly in the hinges, may result in corrosion that will weaken the Jarit® Endoscope & Instrument Holder and lead to breakage during use. Place the Jarit® Endoscope & Instrument Holder into a surgical instrument tray. Prepare the Jarit® Endoscope & Instrument Holder for sterilization using a wrapper or rigid sterilization container that is appropriate for the method of steam sterilization.

WARNING

The central handle of the articulated arm must be open during the sterilization process.

D. TERMINAL STEAM STERILIZATION

After following the decontamination and preparation recommendations, the Jarit® Endoscope & Instrument Holder is ready for sterilization. See also, AAMI Standards and Recommended Practice, “Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities,” ANSI/AAMI ST79:2006. AAMI standards recommend that the sterilizer manufacturer’s written instructions for minimum cycle parameters should also be followed.

Medical device manufacturer’s exposure times to sterilization temperature may need to be longer than the minimum indicated by the sterilizer manufacturer but must never be shorter.

Below are the recommended sterilization parameters:

<table>
<thead>
<tr>
<th>Sterilizer</th>
<th>Exposure Temperature</th>
<th>Exposure Time</th>
<th>Minimum Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum (wrapped)</td>
<td>121°C (250°F)</td>
<td>20 minutes</td>
<td>20-30 minutes</td>
</tr>
<tr>
<td>Pre-vacuum (wrapped)</td>
<td>132°C (270°F)</td>
<td>5 minutes</td>
<td>20-30 minutes</td>
</tr>
<tr>
<td>Pre-vacuum (wrapped)</td>
<td>134°C (273°F)</td>
<td>5 minutes</td>
<td>20-30 minutes</td>
</tr>
</tbody>
</table>

Never use the flash-sterilization.

Do not use hot air-sterilization, irradiation sterilization, formaldehyde or ethylene oxide sterilization, or plasma sterilization.

WARNING

For additional information and inservicing assistance regarding instrument care and handling, contact your local Jarit® representative, or call Jarit® Technical Service Department at 1-800-431-1123.

WARNING

Consult individual national infection control/prevention protocols for specific guidance regarding processing medical devices with suspected exposure to Creutzfeldt-Jakob Disease (CJD).
WARRANTY
Jarit® hereby guarantees the Jarit® Endoscope & Instrument Holders, 620-800, 620-804 and 620-805 for the period of two (2) years from defects in material and workmanship when used normally for its intended purpose. This Warranty shall apply only to the original purchaser. This Warranty shall not apply to any conditions(s) or damage resulting from negligence, misuse, improper handling, improper cleaning, improper maintenance, improper opening techniques, unauthorized repair work or accident. Please direct your questions concerning this Warranty to: Integra LifeSciences Production Corporation 11 Cabot Boulevard Mansfield, MA 02048 USA

RETURNED GOODS POLICY
Products must be returned in unopened packages with manufacturer’s seals intact to be accepted for replacement or credit unless returned due to a complaint of product defect. Determination of a product defect will be made by Integra. Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.

REPAIRS AND MAINTENANCE
Should your instruments require repair or maintenance, contact Jarit® for return authorization and address. Instruments returned to Jarit® for repair must have a statement testifying that each instrument has been thoroughly cleaned and sterilized. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

PRODUCT INFORMATION DISCLOSURE
INTEGRA AND ITS SUBSIDIARIES (“INTEGRA”) AND MANUFACTURER EXCLUDE ALL WARRANTIES, EXCEPT INTEGRA’S APPLICABLE STANDARD WARRANTY WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AS WELL AS ANY EXPRESS OR IMPLIED WARRANTY TO PATIENTS. NEITHER INTEGRA NOR MANUFACTURER SHALL BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. NEITHER INTEGRA NOR MANUFACTURER ASSUME NOR AUTHORIZE ANY PERSON TO ASSUME FOR THEM ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

SYMBOLS USED ON LABELING
- Manufacturer
- Catalog number
- Lot number
- See instructions for use
- Non-sterile - Sterilize prior to use
- Consult instructions for use

Rx ONLY
US Federal Law restricts this device to sale by or on the order of a physician only.