Integra® Jarit® REUSABLE RIGID ENDOSCOPES

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.

Indications for Use: The rigid endoscopes are optical surgical instruments to be used by trained physicians to allow illumination and observation of body cavities, hollow organs, and canals during various endoscopic surgical procedures.

Handling and Operating Scopes: Integra® Jarit® scopes should be handled and operated by personnel completely familiar with their use. Prior to each surgical procedure, the scope should be cleaned and sterilized as stated in the "Integra® Jarit® Reusable Rigid Endoscopes Recommended Cleaning Procedure" section. The scope should be inspected and operationally tested prior to use. A failure to make a complete inspection to assure the proper operation and function of the scope may result in unsatisfactory performance. **Do not use if the scope does not perform successfully.** Handle the scope with care, always grasping the eyepiece or body part. Do not allow other instruments to come into contact with the lens. Gently insert into and remove from cannulas. Endoscopes and attached light sources should not be used for more than four hours without a break. Prolonged use could increase the endoscope's surface temperature over the body temperature. Use of a scope for a task other than that for which it is intended could result in a damaged or broken scope. In order to insure the warranties and guarantees as stated below, scopes in need of repair must be sent to Integra Jarit. Please contact Jarit Technical Services at 800-431-1123 for return authorization and address.

WARNING: Dicard instrument after suspected Creutzfeldt-Jakob Disease (CJD) exposure; the Jarit® Reusable Rigid Endoscopic instruments have not been validated to withstand the chemical and thermal exposures recommended to eradicate prions.

Do not flash sterilize Jarit® Reusable Rigid Endoscopic instruments. The instruments have not been validated for flash sterilization.

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

Note: Scope is reusable, and packaged non-sterile.

Integra® Jarit® REUSABLE RIGID ENDOSCOPES RECOMMENDED CLEANING PROCEDURE

As with any cleaning procedure, personnel should follow accepted guidelines for hand washing, attire, etc. as those recommended by AAMI Standards and Recommended Practices ,"Good Hospital Practice: Handling and Biological Decontamination for Reusable Medical Devices (American National Standard)".

Removable parts, such as light guide connectors and adapters, should be cleaned separately. Stopcocks should be in the open position.

CLEANING

STEP 1. Maintain Moisture: Immediately after use, place the scopes in a tray/container and cover with a towel moistened with sterile distilled water.

STEP 2. Enzymatic Soak: Immerse scopes in an approved enzymatic solution per enzyme manufacturer's recommendations. Make sure all bubbles escape any cavity by rotating or tipping the device.

STEP 3. Rinse: Remove from enzymatic soak after the time period recommended by the enzymatic manufacturer and rinse with tap water.

STEP 4. Clean Scopes: Using a small, soft-bristled, clean brush, clean the optical portions of the scope while immersed in the cleaning solution. Clean the shaft of the scope by wiping with a soft cloth such as a disposable lap sponge. Clean the distal window, eyepiece window and fiber end of the light post with a cotton tip, non-plastic applicator (or a soft cloth) moistened with 70% isopropyl alcohol. **DO NOT place in ultrasonic cleaner or washer-sterilizer.**

STEP 5. Rinse: Rinse the scope by immersing in demineralized water and wiping with clean, soft cloth.

STEP 6. Visual Inspection: Visually inspect the scope for cleanliness. Inspect the windows for any residue or fingerprints.

STEP 7. Dry: Scopes must be thoroughly dried. Remaining moisture may result in corrosion.

AUTOCLAVABLE SCOPE STERILIZATION

After following the above 7-step cleaning method, Jarit® autoclavable scopes are ready for sterilization. Independent laboratory testing has validated steam sterilization as an effective sterilization process for Jarit® reusable autoclavable scopes. Wrapped or containerized scopes were validated to be sterile at a 10 minute, 273 °F (134 °C) prevacuum cycle. As recommended by the AAMI Standards and Recommended Practices Volume 1, 1992, the sterilizer manufacturer's written instructions for cycle parameters should be followed. After sterilization, the scope must be allowed to cool at room temperature. **DO NOT** attempt to accelerate the normal cooling process.

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 Jarit. 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. 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
REF	Catalog number
LOT	Lot number
	See instructions for use
	Non-sterile - Sterilize prior to use
	Consult instructions for use
Rx ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner

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