Integra® Jarit®

Video Assisted Thoracic Surgery (VATS) Instruments

Instructions for Use/English

Indications

Integra® Jarit® Video Assisted Thoracic Surgery (VATS) Instruments are manually operated instruments designed to perform specific functions such as cutting, grasping, clamping, dissecting, probing, draining, aspirating, suturing or ligating during open, mini-open, or thoracoscopic surgical procedures.

Contraindication

Instruments should not be used for anything other than their intended use.

Warning

DO NOT flash sterilize the Integra® Jarit® Video Assisted Thoracic Surgery (VATS) Instruments. The instruments have not been validated for flash sterilization.

Discard instrument after suspected Creutzfeldt-Jakob Disease (CJD) exposure; the Integra® Jarit® Video Assisted Thoracic Surgery (VATS) instruments have not been validated to withstand the chemical and thermal exposures recommended to eradicate prions.

Pre-Use, Handling, and Inspection of Instruments

- Read the Instructions for Use and keep them in a safe place.
- Use the product only in accordance with its intended use, see **Indications**.
- Use of an instrument for a task other than that for which it is intended could result in a damaged or broken instrument, or one which provides an unsatisfactory performance.
- Instruments should be handled and operated by personnel completely familiar with their use, assembly, and disassembly.
- Instruments must be rendered safe for handling, inspection, and assembly by wearing appropriate personal protection equipment (PPE) as promulgated by OSHA and AORN.
- Inappropriate use of instruments will lead to damage that is usually not repairable.
- Instruments must be thoroughly inspected upon receipt and prior to use to assure proper functioning. Failure to make a complete inspection to assure proper operation and function of instrument may result in unsatisfactory performance.
- Integra® Jarit® Video Assisted Thoracic Surgery (VATS) Instruments are supplied non-sterile and must be pre-cleaned, cleaned, visually examined, lubricated, and sterilized prior to use. Please see pre-cleaning, cleaning, visual examination, lubrication, and sterilization procedures below.
- Check screws on instruments after ultrasonic cleaning. Vibration from ultrasonic cleaning may cause them to loosen or fall out.
- Prior to each use, inspect the product for: loose, bent, broken, cracked, worn, or fractured components.
- Do not use the product if it is damaged or defective.
- Replace any damaged components immediately with original spare parts.
- Store products in a dry, clean and safe place.

Pre-Cleaning, Cleaning, and Sterilization Procedures

Before using the instruments pre-clean, clean (manual or automated), dry, visually examine, lubricate, and sterilize following the procedures below.

Personnel should follow accepted guidelines as recommended in ANSI/AAMI ST79:2006, A1:2008, A2:2009 -Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Pre-cleaning:

Pre-cleaning should occur as soon as possible after instrumentation is used.

1. Remove gross debris from surgical instruments with a lap sponge and sterile water after use to prevent drying of blood and body fluids on the instruments.
2. Place instruments in an instrument tray/container and saturate all surfaces for five (5) minutes with a pre-cleaning enzymatic product such as Integra® Miltex® Instrument Prep Enzyme Foam.

   Note 1: Other foam, spray or gel products, intended for use with surgical instruments, are available to keep soil moist but have not been validated for use with Integra® Jarit® Video Assisted Thoracic Surgery (VATS) Instruments.

Cleaning:

Cleaning should occur as soon as possible after instrumentation is pre-cleaned.

After performing steps 1-4 below, perform either "Manual Cleaning" or "Automated Cleaning".

1. Thoroughly rinse instrument with distilled water for two (2) minutes.
2. Prepare Integra® Miltex® EZ-Zyme® All-Purpose Enzyme Cleaner solution per manufacturer's recommendations/instructions for correct dilution and temperature.
3. Immerse fully opened instruments in the prepared Integra® Miltex® EZ-Zyme® All-Purpose Enzyme Cleaner solution for ten (10) minutes.
4. Thoroughly rinse instrument with lukewarm distilled water for two (2) minutes.
5. Proceed either to "Manual Cleaning" or "Automated Cleaning" procedures below:

Manual Cleaning

1. Prepare Integra® Miltex® EZ-Zyme® All-Purpose Enzyme Cleaner solution per manufacturer's recommendations/instructions for correct dilution and temperature.

   Note 2: Other cleaning reagents/detergents are available but have not been validated for use with Integra® Jarit® Video Assisted Thoracic Surgery (VATS) instruments.
2. Using a small, clean hand-held brush, remove soil from all surfaces of instrument while fully immersed in solution. Remove soil from jaws, ends of inserts, and hinge mechanism.
3. Use a soft bristled brush to clean the working channel of the shaft components.

   Note 3: Never use steel wool, wire brushes, scalpel blades, or highly abrasive detergent or cleansers to remove soil as these will damage the instruments' protective surface and lead to corrosion.
4. Vigorously flush channels with 50 ml of distilled water. Rinse thoroughly and aggressively for two (2) minutes with distilled water.
5. Using Midmark Model M550 ultrasonic cleaner sonicate instruments for ten (10) minutes according to the following:
   - Prepare Integra® Miltex® EZ-Zyme® All-Purpose Enzyme Cleaner solution per manufacturer's recommendations/instructions for correct dilution and temperature and place in the Midmark Model M550 ultrasonic cleaner.
   - Condition (de-gas) ultrasonic cleaner for 5 minutes.
   - Place instruments in the manufacturer's instrument tray.
   - Ensure instruments are in the open position.
   - Keep different metal types separated (i.e., separate stainless steel from non-anodized aluminum, brass, copper, and chrome-plating to avoid possible transfer of one metal plating to another).
   - Place tray with the instruments into the Midmark Model M550 ultrasonic cleaner.
   - Sonicate instruments for ten (10) minutes.

   Note 4: Other ultrasonic cleaners may be available but have not been validated for use with Integra® Jarit® Video Assisted Thoracic Surgery (VATS) instruments.
6. Remove instruments from sonicator and rinse for two (2) minutes with distilled water.
7. Visually inspect instrument for cleanliness and ensure all parts are in proper working order.
8. Place instruments in a wire basket. Then, place wire basket with instruments in a drying cabinet, such as a 3M Cabinet (Model 33AA) for 30 minutes at 55°C.

   Note 5: Other drying cabinets or drying methods may be available but have not been validated for use with Integra® Jarit® Video Assisted Thoracic Surgery (VATS) instruments.
13. Inspect instruments for visual dryness.
14. Lubricate cleaned and dried instruments using Integra® Miltex® Spray Lubricant before sterilization.

Automated Cleaning

1. Place instruments in a wire basket.
   - Ensure instruments are in the open position.
   - Keep different metal types separated (i.e., separate stainless steel from non-anodized aluminum, brass, copper, and chrome-plating to avoid possible transfer of one metal plating to another).
2. Place wire baskets in an automatic washer-sterilizer or washer-disinfector, such as a Steris HAMO LS-1000 Washer-Disinfector. Using the parameters/detergents listed in the table below clean the instruments.

Treatment	Time (mm:ss)	Temperature	Cleaner
Presoak	02:00	25°C (77°F)	Water
Enzymatic Wash	04:00	60°C (140°F)	Steris Prolystica 2X Concentrate Enzymatic Cleaner
Wash (Cleaning)	02:00	55°C (131°F)	Steris Prolystica 2X Concentrate Neutral Detergent
Rinse	02:00	70°C (158°F)	Water
Dry	15:00	80°C (176°F)	N/A

   Note 6: Other automatic washer-sterilizer or washer-disinfector specific parameters may be available but have not been validated for use with Integra® Jarit® Video Assisted Thoracic Surgery (VATS) instruments.
3. Remove instruments from automatic washer.
4. Visually inspect instrument for cleanliness and ensure all parts are in proper working order.
5. Place instruments in a wire basket. Then, place wire basket with instruments in a drying cabinet, such as a 3M Cabinet (Model 33AA) for 30 minutes at 55°C.

   Note 7: Other drying cabinets or drying methods may be available but have not been validated for use with Integra® Jarit® Video Assisted Thoracic Surgery (VATS) instruments.
6. Visually inspect instrument to ensure they are thoroughly dry.
7. Lubricate cleaned and dried instruments using Integra® Miltex® Spray Lubricant before sterilization.

Sterilization

After cleaning the reusable instruments, sterilize them using the following procedure:

1. Place the cleaned, dried, and lubricated instruments in SPSmedical self-seal pouches and seal the pouches. Make sure that all instrument parts especially hinges are opened inside the pouch.
2. Place pouches in a pre-vacuum sterilization chamber using the following parameters to achieve Sterility Assurance Level (SAL) of 10-6:

   Recommended steam sterilization parameter to achieve Sterility Assurance Level (SAL) of 10-6:

Sterilizer Type	Configuration	Temperature	Exposure Time
Pre-Vacuum	Wrapped	132°C (270°F)	4 min

For EU only:

Sterilizer Type	Configuration	Temperature	Exposure Time
Pre-Vacuum	Wrapped	132°C (270°F)	3 min

Note 8: Other sterilization wrappers, such as polypropylene wrap or cotton muslin may be appropriate for the steam method of sterilization but have not been validated for use with Integra® Jarit® Video Assisted Thoracic Surgery (VATS) instruments.

Storage Conditions:

Store suitably packaged and sterilized instruments in a dry, clean, and dust-free environment.

Maintenance Procedures

Improper, ineffective, and insufficient maintenance can reduce the life of an instrument and will invalidate the instrument's warranty.

Protect Instruments: The use of deionized water, careful preliminary cleaning, use of neutralized pH solutions, adherence to manufacturer's instructions, and visual inspection will help to keep instruments performing accurately and free of stains.

Certain compounds are highly corrosive to stainless steel and will cause serious damage. Instruments should never be exposed to:

- Aqua regia
- Iodine
- Ferric chloride
- Sulfuric acid
- Hydrochloric acid

The following substances should be avoided whenever possible; rinse with copious amounts of water immediately if instruments are inadvertently exposed to any of the following substances:

- Aluminum chloride
- Mercury chloride
- Barium chloride
- Potassium permanganate
- Bichloride of mercury
- Potassium thiocyanate
- Calcium chloride
- Saline
- Carbolic acid
- Sodium hypochlorite
- Chlorinated lime
- Stannous chloride
- Dakin's solution

Any kind of corrosion will lead to rust on steel. Rust particles can be transferred from one instrument to another; therefore, remove corroding instruments from service to prevent formation of rust on other instruments.

Protect sharp cutting edges and fine working ends of inserts during all maintenance procedures. Avoid loading heavy items on top of delicate and hollow instruments.

Diagnosing Spots and Stains: It is common for instruments to become stained or spotted. Adhering to proper technique during cleaning and sterilizing procedures will prevent most staining occurrences. The following identifies some of the various instrument-related problems hospitals may encounter.

- Brown Stains: Detergents containing polyphosphates may dissolve copper elements in the sterilizer resulting in brown stains. A dull blue or brown stain is the result of oxidation on the surface.
- Black Stains: Black stains may be the result of contact with ammonia.
- Light or Dark Spots: Spots are often the result of the mineral content in the water used for rinsing, use of non-neutral instrument or an unclean sterilizer chamber.
- Rust Deposits: It is very unlikely for surgical grade steel to rust. Rust colored spots usually appear in localities where water has high iron content.

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 Integra for return authorization and address. Instruments returned to Integra 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.

Warranties and Guarantees

Should your instruments require repair or maintenance, contact Integra for return authorization and address. Instruments returned to Integra 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 [1]

Catalog number

Lot Number

Caution! See Warnings and Precautions


Consult Instruction for Use

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

[1] Company responsible for a device marketed under its own name regardless of whether "manufactured for" or "manufactured by" the company.


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