



hudson
medical products

REF: _____

Quantity: 1



Main Office Address 30 N Gould
St. Suite 37859, Sheridan, WY 82801
P: 307-241-5007
Support@adHUDSON.com
www.adHUDSON.com



This device is non-sterile, sterilize before use.
See enclosed instructions for use.

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Instructions for Use

Quality Statement

Ad Hudson is dedicated to providing innovative high quality specialty surgical instrumentation. Ad Hudson guarantees that all of our products have been manufactured by skilled instrument craftsmen, using only quality materials. Every effort is made to manufacture the finest quality surgical instruments at exacting specifications. Ad Hudson surgical instruments comply with the FDA Directives and bear the Mark.

Warranty

Ad Hudson products are warranted to be free from defects in material and workmanship when used under normal condition for its intended purpose for 3 years from invoice date. Any instrument that proves to be defective during this period, Ad Hudson will, at its sole discretion, either repair or replace the defective product at no charge. Ad Hudson shall not be held responsible for consequential or indirect damage arising from the sale or use of any product.

Please note:

CLAMPS: Ad Hudson Clamps are indicated for use for temporary or partial occlusion of blood vessels during surgical procedures.

ENDOSCOPE ACCESSORIES: Ad Hudson Endoscope accessories are indicated for use in endoscopic surgical procedures to provide minimally invasive handling during the instrument's intended purpose. Clamps and Forceps are used to grasp tissue or other items in the surgical field, while Scissors are to cut tissue or other items and Needle Holders are employed during the suturing process.

NEEDLE HOLDERS: Ad Hudson Needle Holders are designed to hold needles according to the chart located in the introduction section of our Specialty Catalog. Holding objects or needles larger than those suggested will void the Ad Hudson warranty.

DIAMOND KNIVES: Ad Hudson's Diamond Knives are made of natural diamonds and are warranted to be free from defects in material and workmanship when used under normal condition for its intended purpose for 1 year from Invoice date.

SCISSORS: Ad Hudson Scissors are designed to cut specific tissue or vessels as indicated by the product name and/or description. Cutting suture, gauze, or wire with Ad Hudson scissors will void the Ad Hudson warranty. The Sharpness of Ad Hudson Scissors is guaranteed for 1 year.

MICS INSTRUMENTS: MICS Instruments are warranted to be free from defects in material and workmanship when used under normal condition for its intended purpose for 1 year from Invoice date.

INSTRUMENT STERILIZATION TRAYS: Ad Hudson instrument sterilization trays are warranted for 1 year from invoice date against defects in material or workmanship.

TITANIUM: The color of Ad Hudson Titanium instruments may vary due to the anodizing process or alloy used. Shading or loss of blue color may also occur after sterilization. This is not a defect in the instrument or material and will not affect the performance of your high quality Ad Hudson instrument.

Cleaning Instructions:

Please note for preparation of cleaning:

- 1) When applicable, instruments should be cleaned in the open unlocked position.
- 2) Black coated and color anodized components may be negatively affected if aggressive cleaning mediums or appliances (e.g. extreme acidic/alkaline, abrasives) are used. A pH neutral cleaner, which may or may not contain enzymes, is recommended. Exposure to chlorides or hydrogen peroxide may negatively affect the coating or colorization of components.

Manual Cleaning Instructions:

- 1) Rinse and/or flush under warm flowing tap water to remove visible debris for a minimum of 30 seconds.
- 2) Ultrasonically clean using a detergent solution prepared according to the manufacturer's instructions for a minimum of 10 minutes.
- 3) Completely immerse the instruments in a detergent solution prepared according to the manufacturer's instructions.
- 4) Scrub all instruments with an appropriately sized soft nylon bristle brush for a minimum of one minute, paying particular attention to crevices and hard to clean areas.
- 5) For applicable instruments, such as suction tubes, insert the supplied wire mandrel to dislodge potentially trapped soil.
- 6) Scrub cannulations with an appropriately sized soft nylon bristle brush for a minimum of 30 seconds.
- 7) Flush instruments with cannula by inserting a cleaning cannula and attaching appropriately sized syringe filled with cleaning solution. Flush cannula two times with approximately 50 mL of cleaning solution each time.
- 8) Flush suction tubes by inserting syringe with appropriately-sized needle into lumen near thumb grip. Flush lumen three times with approximately 1 mL each time with cleaning solution.
Please note: Remove wire mandrel from within suction tube lumen and process alongside suction tube.
- 9) Rinse with flowing Critical Water for a minimum of 30 seconds.
- 10) Dry the instruments using absorbent, low-lint wipes to remove excess water.

Automated Cleaning Instructions:

- 1) Use only washer/disinfector machines that have been validated in accordance with ISO 15883.
- 2) Perform pre-cleaning to remove gross contaminants as follows:
 - a. Submerge and soak in a pH neutral detergent solution prepared according to the manufacturer's instructions for a minimum of 1 minute.
 - b. Flush any cannulations that may be present.
 - c. While still submerged, remove visible soil by scrubbing with an appropriately sized soft nylon bristle brush for a minimum of 3 minutes.
 - d. Rinse with flowing Critical Water for a minimum of 30 seconds.
- 3) Load instruments into washer/disinfector in accordance with the manufacturer's instructions.
- 4) Arrange instruments with curved surfaces and cannulations facing downward to prevent pooling of water.
- 5) Operate the washer/disinfector cycle according to the manufacturer's instructions.
 - a. Recommended minimal washer/disinfector parameters:
 - i. Heated Wash at 140°F (60°C) for 2 minutes
 - ii. Heated Tap Water Rinse at 140°F (60°C) for 20 seconds
 - iii. Heated purified Water Rinse at 180°F (82°C) for 1 minute
 - iv. Forced Air Drying at 240°F (116°C) for 9 minutes

Note: Automated cleaning may not be suitable for instruments with long lumens, ball joints, or stainless steel cables (e.g. suction tubes and surgical arms). Such instruments should undergo a manual cleaning prior to sterilization.

Manual cleaning instructions for articulating and flex arms:

- 1) Turn tightening knob counter-clockwise to loosen the internal cable to enable movement of the surgical arm beads to allow fluid to flow between each link prior to placing arm in sonicator.
- 2) Ultrasonically clean arms using a detergent solution prepared according to the manufacturer's instructions for a minimum of 10 minutes.

- 3) Completely immerse the instruments in a detergent solution prepared according to the manufacturer's instructions.
- 4) Scrub all instrument surfaces with an appropriately sized soft nylon bristle brush for a minimum of 1 minute.
- 5) Rinse surgical arm with flowing Critical Water for a minimum of 30 seconds.
- 6) Manually dry surgical arm using clean, absorbent, low-lint wipes to remove excess water.

Surgical arm inspection before use:

- 1) Inspect entire assembly for damage.
- 2) Hold arm assembly at column and tighten central tightening knob clockwise.
- 3) Check to make sure that arm is rigid at all three joints.
- 4) Insert column into rail clamp, tighten column tightening lever and make sure that it holds securely.

Sterilization Instructions

Lubricate: For instruments with moving parts, lubricate joints with a steam-permeable, water soluble instrument lubricant prior to sterilization.

Sterilize:

- 1) Instruments should be sterilized in the open, loosened, or unlocked position.
- 2) Instruments should be sterilized by standard process parameters using steam with established procedures.
- 3) The following sterilization process parameters have been validated to be effective.

Gravity

- The Gravity Displacement autoclave process is to sterilize the instruments at 250°F (121°C) for 30 minutes and 30-minute dry time.

Prevacuum

- A Prevacuum autoclave process is to sterilize the instruments at 270°F (132°C) for 4 minutes and 30-minute dry time.
- A Prevacuum autoclave process is to sterilize the instruments at 273°F (134°C) for 3 minutes and 30-minute dry time.

Autoclave temperatures should not surpass 280°F (137°C), as handles, insulation or other non-metallic parts may be affected. (Note: Contact your steam autoclave manufacturer to confirm appropriate temperatures and sterilization times.)

Store:

Instruments should be stored in a clean dry area with tip protectors. Please examine instrument for wear and tear prior to use for functionality and damage. Proper examination may be guided by manuals such as "Inspecting Surgical Instruments" by Rick Schultz. Please contact Ad Hudson customer service for information on how to obtain this manual.

⚠ Warning/Precautions:

- 1) CAUTION: US Law restricts this device to sale by or on the order of a physician.
- 2) Product is intended to be used by trained surgeons.
- 3) With proper care and use, these devices can last a lifetime. Normal repeated use has minimal effect on these instruments. End of life is normally determined by wear and damage due to use. Dispose of at end of life in accordance with national regulations and approved hospital practices for surgical instrumentation disposal.
- 4) Use of this instrument for any purpose, or in any manner other than those described here may cause instrument damage or failure which could result in serious patient injury or death. If needed, all Ad Hudson metal products or fragments thereof can be located by means of an X-Ray.

Company Information:

For more information on this product or any products mentioned in this IFU please contact:

Ad Hudson Medical Product

Main Office Address 30 N Gould
St. Suite 37859, Sheridan, WY 82801
P: 307-241-5007
Support@adhuson.com www.adhuson.com