



acumed[®]
Instrument and Accessory Information

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ACUMED® INSTRUMENT AND ACCESSORY INFORMATION

FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON

DESCRIPTION: Acumed Reusable Surgical Instruments and Accessories are available for a wide variety of surgical techniques and implant systems. Proper care and inspection after each use is critical.

SURGICAL INSTRUMENT MATERIAL SPECIFICATIONS: The instruments are made of various grades of stainless steel, titanium, aluminum, and polymers evaluated for biocompatibility.

SURGICAL INSTRUMENT INFORMATION FOR USE:

Instruments provided with this system may be single use or reusable.

- The user must refer to the instrument's label to determine whether the instrument is single use or reusable. Single use instruments are labeled with a "do not re-use" symbol as described in the Symbol Legend section, below.
- Single use instruments must be discarded after a single use.
- Reusable instruments have a limited lifespan. Prior to and after each use, reusable instruments must be inspected where applicable for sharpness, wear, damage, proper cleaning, corrosion and integrity of the connecting

mechanisms. Particular care should be paid to drivers, drill bits and instruments used for cutting or implant insertion.

SURGICAL INSTRUMENT WARNINGS: For safe effective use of any Acumed instrument, the surgeon must be familiar with the instrument, the method of application, and the recommended surgical technique. Instrument breakage or damage, as well as tissue damage, can occur when an instrument is subjected to excessive loads, excessive speeds, dense bone, improper use or unintended use. The patient must be cautioned, preferably in writing as to the risks associated with these types of instruments.

SURGICAL INSTRUMENT PRECAUTIONS: Single use surgical instruments shall never be reused. Previous stresses may have created imperfections, which can lead to a device failure. Protect instruments against scratching and nicking, such stress concentrations can lead to failure.

CLEANING:

Instrument Cleaning: Acumed Instruments and Accessories must be thoroughly cleaned before reuse, following the guidelines below:

Warnings & Precautions

- Decontamination of reusable instruments or accessories should occur immediately after completion of the surgical procedure. Do not allow contaminated instruments to dry prior to cleaning/ reprocessing. Excess blood or debris should be wiped off to prevent it from drying onto the surface.
- All users should be qualified personnel with documented evidence of training and competency. Training should be inclusive of current applicable guidelines and standards and hospital policies.
- Do not use metal brushes or scouring pads during manual cleaning process.
- Use cleaning agents with low foaming surfactants for manual cleaning in order to see instruments in the cleaning solution. Cleaning agents must be easily rinsed from instruments to prevent residue.
- Mineral oil or silicone lubricants should not be used on Acumed instruments.
- Neutral pH enzymatic and cleaning agents are recommended for cleaning reusable instruments. It is very important that alkaline cleaning agents are thoroughly neutralized and rinsed from instruments.
- Surgical instruments must be dried thoroughly to prevent rust formation, even if manufactured from high grade stainless steel.
- All instruments must be inspected for cleanliness of surfaces, joints, and lumens, proper function, and wear and tear prior to sterilization.

- Anodized aluminum must not come in contact with certain cleaning or disinfectant solutions. Avoid strong alkaline cleaners and disinfectants or solutions containing iodine, chlorine or certain metal salts. Also, in solutions with pH values above 11, the anodization layer may dissolve.

Manual Cleaning/Disinfection Instructions

1. Prepare enzymatic and cleaning agents at the use-dilution and temperature recommended by the manufacturer. Fresh solutions should be prepared when existing solutions become grossly contaminated.
2. Place instruments in enzymatic solution until completely submerged. Actuate all moveable parts to allow detergent to contact all surfaces. Soak for a minimum of twenty (20) minutes. Use a nylon soft bristled brush to gently scrub instruments until all visible debris is removed. Pay special attention to hard to reach areas. Pay special attention to any cannulated instruments and clean with an appropriate bottle brush. For exposed springs, coils, or flexible features: Flood the crevices with copious amounts of cleaning solution to flush out any soil. Scrub the surface with a scrub brush to remove all visible soil from the surface and crevices. Bend the flexible area and scrub the surface with a scrub brush. Rotate the part while scrubbing to ensure that all crevices are cleaned.
3. Remove the instruments and rinse thoroughly under running water for a minimum three (3) minutes. Pay special attention to cannulations, and use a syringe to flush any hard to reach areas.
4. Place the instruments, fully submerged, in an ultrasonic unit with cleaning solution. Actuate all moveable parts to allow

detergent to contact all surfaces. Sonicate the instruments for a minimum of ten (10) minutes.

5. Remove the instruments and rinse in deionized water for a minimum of three (3) minutes or until all signs of blood or soil are absent in the rinse stream. Pay special attention to cannulations, and use a syringe to flush any hard to reach areas.
6. Inspect instruments under normal lighting for the removal of visible soil.
7. If visible soil is seen, repeat the sonication and rinse steps above.
8. Remove excess moisture from the instruments with a clean, absorbent, nonshedding wipe.

Combination Manual/Automated Cleaning and Disinfecting Instructions

1. Prepare enzymatic and cleaning agents at the use-dilution and temperature recommended by the manufacturer. Fresh solutions should be prepared when existing solutions become grossly contaminated.
2. Place instruments in enzymatic solution until completely submerged. Actuate all moveable parts to allow detergent to contact all surfaces. Soak for a minimum of ten (10) minutes. Use a nylon soft bristled brush to gently scrub instruments until all visible debris is removed. Pay special attention to hard to reach areas. Pay special attention to any cannulated instruments and clean with an appropriate bottle brush. *Note: Use of a sonicator will aid in thorough cleaning of instruments.*

Using a syringe or water jet will improve flushing of difficult to reach areas and any closely mated surface.

3. Remove instruments from enzyme solution and rinse in deionized water for a minimum of one (1) minute.
4. Place instruments in a suitable washer/ disinfector basket and process through a standard washer/disinfector cycle. The following minimum parameters are essential for thorough cleaning and disinfection.

Step	Description
1	Two (2) minute prewash with cold tap water
2	Twenty (20) second enzyme spray with hot tap water
3	One (1) minute enzyme soak
4	Fifteen (15) second cold tap water rinse (X2)
5	Two (2) minute detergent wash with hot tap water (64–66°C/146–150°F)
6	Fifteen (15) second hot tap water rinse
7	Ten (10) second purified water rinse with optional lubricant (64-66°C/146–150°F)
8	Seven (7) minute hot air dry (116°C/240°F)
<i>Note: Follow washer/disinfector manufacturer's instructions explicitly</i>	

Automated Cleaning/Disinfection Instructions

- Automated washer/dryer systems are not recommended as the only cleaning method for surgical instruments.
- An automated system may be used as a follow up process to manual cleaning.
- Instruments should be thoroughly inspected prior to sterilization to ensure effective cleaning.

STERILITY:

System components are nonsterile.

Non-Sterile Product: Unless clearly labeled as sterile and provided in an unopened sterile package provided by Acumed, all implants and instruments must be considered nonsterile, and sterilized by the hospital prior to use. Sterilization of nonsterile devices has been validated using the sterilization parameters listed below, where devices are provided in fully-loaded trays with all parts placed appropriately.

Sterilization Methods

- Consult your equipment manufacturer's written instructions for specific sterilizer and load configuration instructions.
- Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: 2010 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.














- Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: 2010 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Gravity Displacement Autoclave:	
Exposure Temperature:	270° F (132° C)
Exposure Time:	40 minutes
Dry Time:	30 minutes
Pre-Vacuum Autoclave:	
Exposure Temperature:	270° F (132° C), or 273°F to 279°F (134°C to 137°C)
Exposure Time:	8 minutes
Dry Time:	30 minutes

STORAGE INSTRUCTIONS: Store in a cool dry place and keep away from direct sunlight. Prior to use, inspect product package for signs of tampering, or water contamination. Use oldest lots first.

APPLICABILITY: These materials contain information about products that may or may not be available in any particular country or may be available under different trademarks in different countries. The products may be approved or cleared by governmental regulatory organizations for sale or use with different indications or restrictions in different countries. Products may not be approved for use in all countries. Nothing contained on these materials should be construed as a promotion or solicitation for any product or for the use of any product in a particular way which is not authorized under the laws and regulations of the country where the reader is located.

FURTHER INFORMATION: To request further material, please see the contact information listed on this document.

SYMBOL LEGEND	
	Consult instructions for use
	Caution
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Use-by date
	Catalogue number
	Batch code
	Authorized representative in the European Community
	Manufacturer
	Date of manufacture
	Do not re-sterilize
	Do not re-use
	Upper limit of temperature

Cautions: Federal Law (USA) restricts this product sale by or on the order of a physician or hospital. Professional Use Only.