Ankle Plating System 3

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Ankle Plating System 3

FOR THE PERSONAL ATTENTION OF THE OPERATING SURGEON AND SUPPORTING HEALTHCARE PROFESSIONALS

DESCRIPTION: The Acumed Ankle Plating System 3 contains bone plates, screws and accessories. The system is designed to provide fixation for ankle fractures including fractures of the distal tibia and fibula.

INDICATIONS: The Acumed Ankle Plating System 3 includes orthopedic implants with the following indications:

- Lateral Fibula Plates, Posterolateral Fibula Plates, Posteromedial Distal Tibia Plates, Posterolateral Distal Tibia Plates, and Medial Anti-Glide Plates are intended for use for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula, particularly in osteopenic bone.
- Hook Plates and Locking Peg Hook Plates are intended for fixation of fractures, osteotomies, and non-unions of small bones, including the tibia and fibula.
- The Cannulated Screws are generally intended for fixation of fractures, fusions, and osteotomies of large and small bones appropriate for the size of the device, which may include the following: fractures of the small joints, such as ankle fractures; fractures of the fibula, malleolus, and distal tibia; avulsion fractures; and other small fragment, cancellous bone fractures. Washers may be used with screws in certain applications.

CONTRAINDICATIONS: Contraindications for the system are active or latent infection; sepsis; insufficient quantity or quality of bone; and soft tissue or material sensitivity. If material sensitivity is suspected, tests should be performed prior to implantation. Patients who are unwilling or incapable of following postoperative care instructions are contraindicated for these devices. These devices are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine .

IMPLANT MATERIAL SPECIFICATIONS: The implants are made of commercially pure titanium per ASTM F67 or titanium alloy per ASTM F136.

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

IMPLANT INFORMATION FOR USE: Physiological dimensions limit the sizes of implant appliances. The surgeon must select the type and size that best meets the patient's requirements for close adaptation and firm seating with adequate support. Although the

physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

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 TECHNIQUES: Surgical techniques are available describing the uses of this system. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. In addition, it is the responsibility of the surgeon to be familiar with relevant publications and consult with experienced associates regarding the procedure before use. Surgical techniques can be found on the Acumed website (acumed.net).

IMPLANT WARNINGS: For safe effective use of the implant, the surgeon must be thoroughly familiar with the implant, the methods of application, instruments, and the recommended surgical technique for the device. The device is not designed to withstand the stress of weight bearing, load bearing, or excessive activity. Improper insertion of the device during implantation can increase the possibility of loosening or migration. The patient must be cautioned, preferably in writing, about the use, limitations, and possible adverse effects of this implant. These cautions include the possibility of the device or treatment failing as a result of loose fixation and/ or loosening, stress, excessive activity, or weight bearing or load bearing, particularly if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing, and the possibility of nerve or soft tissue damage related to either surgical trauma or the presence of the implant. The patient must be warned that failure to follow postoperative care instructions can cause the implant and/ or treatment to fail. The implants may cause distortion and/or block the view of anatomic structures on radiographic images. The components of these systems have not been tested for safety, heating, or migration in the MRI environment. Similar products have been tested and described in terms of how they may be safely used in post-operative clinical evaluation using MRI equipment [1].

[1] *Shellock, F. G. Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2011 Edition. Biomedical Research Publishing Group, 2011.*

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.

IMPLANT PRECAUTIONS: An implant shall never be reused. Previous stresses may have created imperfections, which can lead to a device failure. Instruments shall be inspected for wear or damage prior to usage. Protect implants against scratching and nicking. Such stress concentrations can lead to failure. Bending plates multiple times may weaken the device and could lead to premature implant fracture and failure. Mixing implant components from different manufacturers is not recommended for metallurgical, mechanical and functional reasons. The benefits from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are not uncommon.

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.

ADVERSE EFFECTS: Possible adverse effects are pain, discomfort, or abnormal sensations and nerve or soft tissue damage due to the presence of an implant or due to surgical trauma. Fracture of the implant may occur due to excessive activity, prolonged loading upon the device, incomplete healing, or excessive force exerted on the implant during insertion. Implant migration and/or loosening may occur. Metal sensitivity, histological, allergic or adverse foreign body reaction resulting from implantation of a foreign material may occur. Nerve or soft tissue damage, necrosis of bone or bone resorption, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.

CLEANING:

Implant Cleaning: Implants should not be reused. Acumed does not recommend cleaning of implants provided sterile. Implants provided non-sterile that have not been used, but have become soiled, should be processed according to the following:

Warnings & Precautions

- Resterilization of the implants should not be performed if the implant comes into contact with contamination (e.g. biological tissue contact, such as bodily fluids/ blood) unless the single use device (SUD) has been reprocessed by an authorized facility who has received appropriate regulatory clearance for such. Cleaning a SUD after it comes into contact with human blood or tissue constitutes reprocessing.
- Do not use an implant if the surface has been damaged. Damaged implants should be discarded.
- Users should wear appropriate personal protective equipment (PPE).
- All users should be qualified personnel with documented evidence of training and competency. Training should be

inclusive of current applicable guidelines, standards and hospital policies.

Manual Processing

Equipment: Soft bristled brush, neutral enzymatic cleaner or neutral detergent with a pH ≤ 8.5.

1. Prepare a solution using warm tap water and detergent or cleaner. Follow the enzymatic cleaner or detergent manufacturer's recommendations for use paying close attention to the correct exposure time, temperature, water quality, and concentration.
2. Carefully wash the implant manually. Do not use steel wool or abrasive cleaners on implants.
3. Rinse implant thoroughly with DI or purified water. Use DI or purified water for final rinse.
4. Dry the implant using a clean, soft, lint-free cloth to avoid scratching the surface.

Ultrasonic Processing

Equipment: Ultrasonic cleaner, neutral enzymatic cleaner or neutral detergent with a pH ≤ 8.5. Note: Ultrasonic cleaning may cause additional damage to implants that have surface damage.

1. Prepare a solution using warm tap water and detergent or cleaner. Follow the enzymatic cleaner or detergent manufacturer's recommendations for use paying close attention to the correct exposure time, temperature, water quality, and concentration.
2. Clean implants ultrasonically for a minimum of 15 minutes.
3. Rinse implant thoroughly with DI or purified water. Use DI or purified water for final rinse.
4. Dry the implant using a clean soft, lint-free cloth to avoid scratching the surface.

Mechanical Processing

Equipment: Washer/disinfector, neutral enzymatic cleaner or neutral detergent with a pH ≤ 8.5.

Cycle	Minimum Time (minutes)	Minimum Temperature/Water	Type of Detergent
Pre-wash	2	Cold tap water	N/A
Enzyme Wash	2	Warm tap water	Neutral enzymatic pH ≤ 8.5
Wash II	5	Warm tap water (>40°C)	Detergent with pH ≤ 8.5
Rinse	2	Warm DI or purified water (>40° C)	N/A
Dry	40	90°C	N/A

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)
Note: Follow washer/disinfector manufacturer's instructions explicitly	

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 may be provided sterile or nonsterile.

Sterile Product: Sterile product was exposed to a minimum dose of 25.0-kGy gamma irradiation. Acumed does not recommend resterilization of sterile-packaged product. If sterile packaging is damaged, the incident must be reported to Acumed. The product must not be used and must be returned to Acumed.

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.

- 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.
- Consult your equipment manufacturer's written instructions for specific sterilizer and load configuration instructions.
- Gravity-displacement steam sterilization is not recommended.
- Flash sterilization is not recommended.

Prevacuum Steam Sterilizer Parameters[1]

Tray Case Part Numbers:	80-2340 and 80-2341
Condition:	Wrapped
Preconditioning Vacuum Pulses:	3
Exposure Temperature:	270° F (132° C)
Exposure Time:	4 minutes
Dry Time:	30 minutes
Cooling Time[2]:	30 minutes

[1]Values in this table reflect the minimum parameters validated to achieve the required Sterility Assurance Level (SAL), for a fully loaded tray with all parts placed appropriately.

[2]Cooling time describes the validated interval following dry time and prior to handling. This interval is included for safe handling and the prevention of contamination; see ANSI/AAMI ST79:2010 Section 8.8.1.

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 resterilize
	Do not re-use
	Upper limit of temperature
	Acumed Small Fragment Base Set Required

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