acumed®

Acu-Loc® NEXT™

Instructions for use

Acu-Loc® NEXT™

US **These instructions are intended for the Operating Surgeon and supporting Healthcare Professionals. The US instructions are intended for users in the United States and its territories.** Rx only

DESCRIPTION

The Acu-Loc® NEXT™ System bone plates, screws and accessories are designed to provide fixation of fractures, fusions, and osteotomies.

INDICATIONS FOR USE

The Acu-Loc® NEXT™ System provides fixation for fractures, fusions, osteotomies, and nonunions of the distal radius and ulna.

CONTRAINDICATIONS

- Active or latent infection
- Sepsis
- Insufficient quantity or quality of bone, osteoporosis
- Patients with confirmed soft tissue or material sensitivity
- Patients who are unwilling or incapable of following post-operative care instructions

These devices are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

WARNINGS & PRECAUTIONS

Warning:

- The treatment or implant may fail, including sudden failure, as a result of:
  - Loose fixation and/or loosening
  - Stress, include stress from inappropriate bending of the implant during surgery
  - Stress concentrations
  - Stress of weight bearing, load bearing, or excessive activity
- Failure is more likely if the implant experiences increased loads due to delayed union, nonunion, or incomplete healing. Failure is more likely if the patient does not follow post-operative care instructions.
- Nerve or soft tissue damage may result from surgical trauma or the presence of an implant.
- Instrument breakage or damage, as well as tissue damage, may occur when an instrument is subjected to excessive loads, excessive speeds, dense bone, improper use or unintended use.
- Implants may cause distortion and/or block the view of anatomic structures on radiographic images.

Precautions:

- The implants and instruments are intended only for professional use by a licensed physician.
- Use devices and instruments in accordance with the Instructions for Use.
- Do not use the sterile product past the use-by date. Refer to the device label.
- Do not use or re-sterilize an implant provided in sterile packaging if the package has been damaged. The sterility may be compromised, and the cleanliness of the implant may be uncertain. Report damaged packaging to your distributor or Acumed.
- Use of this system has not been evaluated in children or individuals that are not skeletally mature.
- Inspect all components preoperatively to ensure utility. Do not attempt a surgical procedure with faulty, damaged, or suspect instruments or implants. Alternate fixation methods should be available intraoperatively.
- Reprocessing and/or reuse of single use devices may result in infection/cross-contamination, and/or sudden failure due to previous stresses.
- Use of implant components from different manufacturers has not been evaluated.
- Use of chemical disinfection may leave residues that adversely affect steam sterilization.
- Steam penetration and device sterilization may be negatively affected by labeling that block tray steam holes.
- Devices may be contaminated with biohazardous materials and/or sharp materials. Observe hospital procedures, practice guidelines, and/or government regulations for the proper handling of biohazardous material and disposal of sharp materials.
- Observe hospital procedures, practice guidelines, and/or government regulations for the proper handling and disposal of sharps.

ADVERSE EFFECTS

Possible adverse effects include:

- Anesthesia-related problems, problems with positioning of the patient (e.g., nausea, vomiting, neurological impairments, etc.) thrombosis, embolism, infection, or injury to other critical structures such as blood vessels, excessive bleeding, etc.
- Pain, discomfort, or abnormal sensations, nerve or soft tissue damage, necrosis of bone or tissue, bone resorption, or inadequate healing from the presence of an implant or due to surgical trauma.
- Swelling, abnormal scarring, impairment in musculoskeletal function, hardware prominence, migration, loosening, bending, or breakage of the implant, malunion, nonunion or delayed union due to prolonged loading or excessive forces which may lead to implant failure and reoperation.
- Implant fracture 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. Consult our document "Metal Sensitivity Statement" at http://www.acumed.net/ifu.
- Injury to user.

Important: *Any adverse event that has occurred in relation to the device should be reported to Acumed through customercomplaints@acumed.net or +1.888.627.9957*

SURGICAL TECHNIQUE

Acumed offers one or more Surgical Techniques to promote the safe and effective use of this system. Consult our Surgical Techniques at www.acumed.net.

Important: Surgical techniques may contain important safety information.

Important: The instruments and implants in this system are intended to be used by suitably trained and qualified surgeons in a hospital operating room setting. Before treatment, the surgeon is advised to read and fully understand all instructions and communicate to the patient any relevant medical information provided therein, including the use, limitations, risks (safety communications), and possible adverse effects of the proposed treatment.

Consult the most recent versions of the Instructions for Use and Surgical Techniques as they are subject to change. Contact Acumed or an authorized agent to request any additional information.

MRI SAFETY INFORMATION

The Acumed Acu-Loc® NEXT™ System has undergone testing for safety in the MR environment and is MR conditional. Consult our publication "Acumed Implants in the MR Environment" at www.acumed.net/ifu for more information.

LIFETIME

- Once installed, implants are expected to provide fixation, fusion and physiological support and have an effective life during bone healing. The implants are biocompatible and may remain implanted at the discretion of the surgeon or patient.
- Multiple-use instruments have a lifetime that is affected by usage, handling, and processing. Assess multiple-use instruments for fitness during pre-sterilization inspection.

STERILITY

- Implants and instruments may be provided either sterile or non-sterile as indicated on the label.
- Non-sterile devices are intended to be sterilized before use.
- Devices purchased and received sterile were exposed to a minimum dose of 25.0 kGy gamma radiation to obtain a minimum sterility assurance level of 10^{-6}.
- ***DO NOT USE IF THE STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.***
- The user facility must clean and disinfect devices prior to sterilization per standard hospital procedures.
- Use of the sterilizer shall comply with the manufacturer's user instructions for sterilizers.
- Non-sterile devices are sterilizable by steam sterilization (autoclaving).

IMPLANTS

MATERIALS

The screws and plates are made of Commercially Pure Titanium (UNS R50400 (CPTi GRADE 2) PER ASTM-F67-13(2017)), Titanium Alloy (TI-6AI-4V PER ASTM F136-13(2021) e1) and cobalt-chrome per ASTM F1537. Consult our document "Metal Sensitivity Statement" at www.acumed.net/ifu for a detailed description of the material composition of Acumed metal implants for the chemical composition of Acumed metal implants.

SINGLE USE

- Implants are intended for single use only, as indicated on the label. This product has not been validated for multiple uses. Reuse of single use implants may increase the risk of failure and cross contamination.
- Dispose of any unused implant that is contaminated with human blood or tissue in accordance with hospital procedures, practice guidelines, and/or government regulations for the proper handling of biohazardous material. Do not process a contaminated implant.

IMPORTANT

- Physiological dimensions limit implant sizes. Select the type and size of implant that best meets the patient's requirements for close adaptation and firm seating with adequate support.
- Implants are designed to hold fractured bones in place during bone healing at the site of fracture. Implants are not designed for excessive loadbearing. Improper selection or improper implantation of the device may increase the possibility of loosening or migration.
- Do not bend the implant except as indicated in the corresponding Surgical Technique Guide. Repeated or excessive bending may weaken the implant and cause failure at a later time.
- Only combine implants when they are intended for that purpose.
- Protect implants against scratching and nicking to prevent stress concentrations, which can result in failure.
- Prevent unused implants from becoming soiled.
- The color of anodized implants may change over time due to processing. This color change does not affect the mechanical properties of the implants.

INSTRUMENTS

The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade polymers.

Multiple Use / Single Use

Acumed instruments are intended for multiple use unless identified on the label for single use only.

Single Use Instruments:

- Do not reuse single use instruments. Reuse or reprocessing of devices labeled as "single use" can result in decreased mechanical and clinical performance of the devices which may result in patient harm.
- Reuse or reprocessing of single use instruments may create a risk of contamination (e.g. due to the transmission of infection material from one patient to another), which may result in patient harm.
- Dispose of single use instruments after use on a single patient, during a single procedure.

Multiple Use Instruments:

- Multiple use instruments are intended for use on a single patient and a single procedure before requiring processing.
- Multiple (limited) use instruments have a limited lifespan. Carefully inspect the instruments before and after each procedure to assure they are in proper operating condition. Instruments which are faulty, damaged, or suspect should not be used.
- Multiple use instruments potentially contaminated with transmissible spongiform encephalopathy (TSE) agents shall not be processed for reuse.

IMPORTANT

- Protect instruments against scratching and nicking to prevent stress concentrations, which can lead to instrument failure.
- Near the point of use: Wipe excess contamination from instruments and prevent any soil from drying. Instruments with substantial or dried soil are particularly difficult to reliably process. Transport contaminated instruments for processing as soon as possible after use.
- Avoid prolonged instrument contact with iodine and saline.
- Handle and transport soiled instruments in a manner that avoids contamination of any unused implants.

PROCESSING

Important: Processing personnel must be qualified with suitable training and experience. Use proper personal protective equipment (PPE) when working with contaminated devices.

IMPORTANT

- All the non-sterile instruments and implants are to be cleaned at the healthcare facility prior to use. Implants are subjected to automated cleaning only.
- Sterile packaged devices are ready for use without processing.
- Promptly perform the processing steps to limit microbial growth and maximize the effectiveness of sterilization.
- Inspect implants for contamination by blood or tissue and dispose of them when found. Do not process contaminated implants.
- Prevent instrument corrosion by minimizing contact with solutions containing iodine, chlorine, and saline or other metal salts.
- Prevent damage to the protective anodization layer on aluminum instruments by avoiding contact with solutions < 4 pH and > 9 pH, especially if they contain sodium carbonate or sodium hydroxide.
- Repeated processing of anodized metals may cause colors to fade but this does not affect the function of the device.
- Avoid cleaning agents containing aldehydes since they can denature and coagulate proteins (fixation).
- Enzymatic detergents are well suited for loosening protein-based contamination.
  - Use a neutral pH enzymatic detergent.
  - Use a low foaming solution to allow visibility of the device during cleaning.
- Closely follow the manufacturer's instructions for the safety, storage, mixing, water quality, exposure time, temperature, replacement, and disposal of cleaning agents.
- Devices potentially contaminated with transmissible spongiform encephalopathy (TSE) agents shall not be processed or reused. These processing instructions are not suitable for the inactivation of TSE agents. Observe hospital procedures, practice guidelines, and/or government regulations for the proper handling and disposal of devices potentially contaminated with TSE agents.
- **Utility water:** Refer to AAMI TIR34* when instructed to use utility water. Utility water is typically municipal or tap water but may require additional treatment to be suitable for use.
- **Critical water**: Refer to AAMI TIR34* when instructed to use critical water. Critical water is highly treated and has very low organic and inorganic content with an endotoxin level under 10 EU/mL. Suitable water may also be specified in national pharmacopeias, national standards, and hospital protocols.

* Association for the Advancement of Medical Instrumentation (AAMI). Water for the reprocessing of medical devices. AAMI TIR34:2014/(R)2017. Arlington, VA.

MANUAL CLEANING

Important: Implants are subjected to automated cleaning only. Contaminated instruments require manual cleaning prior to automated cleaning.

1. Rinse the contaminated instruments under running cold utility water to reduce heavy surface contamination.
2. Dispose of any used instruments intended for single use only.
3. Place the contaminated instruments in enzymatic solution* until completely submerged to minimize the spraying of solution.
4. Actuate all moveable parts to allow detergent to contact all surfaces.
5. Soak for a minimum of ten (10) minutes.
6. Scrub the instruments using a soft-bristled brush to remove all visible debris. Do not use stainless steel or other abrasives as these may damage the surface.
   - When possible, scrub the instruments when totally submerged to minimize the spraying of fluid.
7. Some instruments may require special consideration:
   -Clean the instruments with all parts loosened. Clean the instruments disassembled if they are designed to be taken apart.
   - Use a water jet to flood cleaning solution into challenging areas, such as mating surfaces, springs, coils, cannulations, blind holes, flutes, cutting teeth, and flexible parts to flush out any trapped soil.
   - Operate movable parts and rotate (as necessary) while scrubbing to ensure that all crevices are accessible.
   - Carefully clean cannulated parts and challenging areas using an appropriately sized brush.
   - Optionally, sonicate for 10 to 15 minutes using a fresh, neutral pH ultrasonic cleaning solution. Follow the ultrasonic cleaner and detergent manufacturer's instructions.

   Important: Any previous surface damage may increase due to ultrasonic cleaning.

8. Perform an initial rinse for at least 3 minutes using clean, soft, utility water in the temperature range of 25°C to 35°C (77°F to 95°F) to remove all signs of contamination and cleaning agent.
   - Actuate all movable parts.
   - Flush out cannulations and complex mechanisms.
9. Repeat the previous processing steps if visible residue remains present.
10. Perform a final rinse for at least 1 minute using critical water to displace minerals and other impurities found in utility water. Do not use saline solutions for final rinsing because they may interfere with disinfection and sterilization.
    - Actuate all moving parts.
    - Pay particular attention to cannulations and blind holes as well as hinges and joints between mating surfaces.
    - Rinse cannulations at least three times with a syringe (volume 1-50ml).
11. Remove excess moisture from the instruments using a clean, absorbent, non-shedding wipe.
12. Allow the instruments to thoroughly dry. Any moisture may affect sterilization, and devices may remain wet after the drying period.

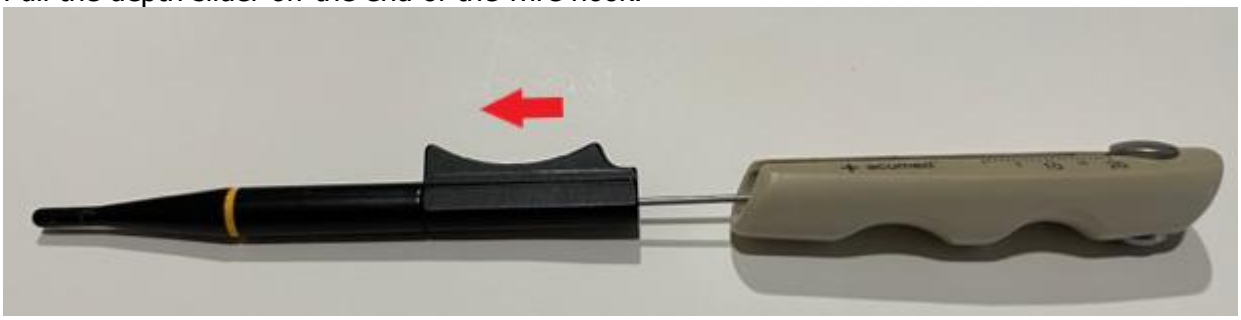
* Manual cleaning was validated using STERIS Prolystica 2X Concentrate Enzymatic Presoak and Cleaner.

IMPORTANT: The Depth Gauge 6-30mm (80-4254) requires disassembly prior to manual cleaning. Follow steps 1-4 below for disassembly instructions. **Reassemble prior to sterilization.**

1. Push the depth slider out to the end of the wire hook.

2. Push down on the wire hook to disengage it (if necessary) from the end of the depth slider and push the slider off.

3. Pull the depth slider off the end of the wire hook.



4. Slide the wire hook assembly out of the depth sizer body and clean and dry components per the cleaning instructions above.

5. Reassemble in reverse order before placing into the appropriate bracketing in the tray (depth gauge should be assembled and in the tray if the automated washer/thermal disinfection is used).

AUTOMATED CLEANING

Important: Contaminated instruments require manual cleaning prior to automated cleaning. Contaminated implants shall not to be reprocessed. Follow the washer-disinfector manufacturer's instructions explicitly.

- Process the devices using a standard washing and thermal disinfection cycle in a washer-disinfector compliant with EN ISO 15883-1 and EN ISO 15883-2 or equivalent national standards.
- Remove all implants if a lubrication phase will be used.
- Process all trays removed from the case (caddy lids remain in place).
- Attach the following instruments to the minimally invasive surgery (MIS) injector or irrigation ports:
  - 80-4071 Small Ratcheting Driver Handle
  - 80-0663 Medium Ratcheting Driver Handle
- Thermal disinfection has been validated* for an A0 ≥ 3000 (at least 5 minutes at 90°C).

* Washer-disinfector processing was validated for fully loaded trays with all parts placed appropriately, with recommended evaluations as listed in EN ISO 15883-1 and EN ISO 15883-2 using a STERIS Reliance® Genfore Washer-Disinfector and STERIS Prolystica 2X Enzymatic Detergent.

PRE-STERILIZATION INSPECTION

- Visually inspect all devices under normal lighting to ensure that cleaning was effective. Pay close attention to all challenging areas.
  - Re-process instruments that are not clean.
  - Replace instruments that cannot be cleaned.
- Inspect the implants and instruments for surface damage, such as nicks, scratches, and cracks. Replace affected devices.
- Assess the instruments for proper use. Operate all parts and connecting mechanisms. Give careful attention to drivers, drill bits and reamers, and instruments used for cutting or implant insertion. Critically assess them for wear, sharp materials, straightness, and corrosion. Replace any instrument that does not perform as intended.
- Inspect all cutting edges under magnification.
  - Replace worn instruments e.g., dull, chipped, cracked, rolled, or otherwise deformed.
  - Run a cotton cloth over the edge to help detect chipping and cracking.

- Verify the legibility of all markings and reference scales. Replace any device that is unreadable.
- Repair, replace, and/or repeat the cleaning of instruments as needed to ensure proper operation before proceeding with sterilization.
- Disassemble the Plate Reduction Knob (80-4351) from the Plate Reduction Shaft (80-4350) before storing in the tray for sterilization.
- Fully replenish the system trays and caddies.

STERILIZATION

- Perform sterilization using a dynamic-air-removal (pre-vacuum) autoclave.
  - Gravity displacement sterilization is not recommended.
  - Immediate use (flash) sterilization is not recommended.
- Ensure the sterilizer's maximum load limit is not exceeded when sterilizing multiple sets or devices.
- Do not stack containers as this might prevent the penetration of steam and inhibit drying.
- Refer to the sterilizer manufacturer's instructions and ensure proper installation, calibration, use, and ongoing maintenance.
- The sterilized items should be allowed to cool to room temperature before handling. This allows for safe handling and prevents condensation.
- Follow current industry best practice guidelines such as ANSI/AAMI ST79:2017*.

* Association for the Advancement of Medical Instrumentation (AAMI). Comprehensive guide to steam sterilization and sterility assurance in health care facilities. AAMI ST79:2017. Arlington, VA

The following table shows the minimum parameters validated* to achieve a required Sterility Assurance Level (SAL) of 10^{-6} for the system

Important:

- Sterilization parameters are only valid for devices that have been cleaned per these instructions and are thoroughly dry.
- Sterilization parameters are only valid when the devices are properly housed in the Acumed storage case part numbers identified in the table.

The Acumed Acu-Loc® NEXT™ System

	The Acumed Acu-Loc® NEXT™ (Aluminum Tray Bases: 80-4382, 80-4401, 80-4403 & Lids: 80-4383, 80-4402, 80-4407) is validated[3] for steam sterilization using one of the below sets of parameters.	
Pre-Vacuum Steam Sterilization	***Acu-Loc® NEXT™* fully loaded system**	
Exposure Temperature:	270°F (132°C)	272°F (134°C)[2]
Exposure Time:	4 minutes	3 minutes
Condition:[1]	Wrapped Set	
Wrapped Dry Time Minimum:	30 minutes with a 30 min wire rack cool down time	30 minutes with a 30 min wire rack cool down time
Wrapped Configuration Details:	Wrap in two layers of 1- ply polypropylene wrap (FDA Cleared) using sequential envelope techniques.	
[1] US customers must use FDA-cleared sterilization packaging/wrap and other accessories appropriate for the cycle parameters recommended in these instructions. Refer to PKGI-76 at www.acumed.net/ifu for sterilization in Aesculap® rigid sterilization containers.		
[2] The devices are compatible with exposure for 18 minutes at 134°C.		
[3] Note: Biological indicator, G. stearothermophilus, was used in sterilization validation. Halyard Health H600 Quick Check (510(k) K234050) wrap was used for the validation.		

POST-STERILIZATION INSPECTION

- Do not store or use sterile devices if they are not dry.
  - Moisture supports the survival of microorganisms.

- Moisture remaining on wrapped or contained products after sterilization could compromise the sterile barrier.
- Moisture can corrode metal and dull sharp edges.

- Inspect the sterile barrier for signs of damage. Do not use the product if the sterile barrier has been compromised.

STORAGE CONDITIONS

STORAGE OF SETS AFTER STEAM STERILIZATION

- Store sterilized devices under controlled conditions in a manner that minimizes the potential for contamination per ANSI/AAMI ST79:2017.
- Refer to sterilization wrap or rigid container manufacturer's IFU for limits on sterile product storage time and storage requirements for temperature and humidity.
- Inspect the sterile barrier for signs of damage. Do not use the product if the sterile barrier has been compromised.

STORAGE OF PACKAGED NON-STERILE AND STERILE PRODUCT

- Devices should be stored in an area that provides protection from dust, pests, and temperature/ humidity extremes.
- Sterile Packaged Product: Inspect the sterile barrier for signs of damage. Do not use the product if the sterile barrier has been compromised.

SAFE DISPOSAL

- Devices may be contaminated with biohazardous materials and/or sharp materials. Observe hospital procedures, practice guidelines, and/or government regulations for the proper handling of biohazardous material and disposal of sharp materials.

Symbols Glossary

Symbol	Description	ISO 15223-1
	Consult the electronic instructions for use (eIFU) at www.acumed.net/ifu	5.4.3
	Sterilized using irradiation	5.2.4
	Double sterile barrier system	5.2.12
	Non-sterile	5.2.7
	Use-by date	5.1.4
	Catalogue number	5.1.6
	Batch code	5.1.5
	Medical device	5.7.7
	Manufacturer	5.1.1
	Date of manufacture	5.1.3
	Do not resterilize	5.2.6
	Do not re-use	5.4.2
	Do not use if package is damaged and consult instructions for use / do not use if the product sterile barrier system or its packaging is compromised	5.2.8
Rx Only	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.	U.S. 21 CFR 801.109
	The reticle is a registered trademark of Acumed. It may appear alone or with the Acumed name.	

Acumed Headquarters
5885 NE Cornelius Pass Road
Hillsboro, OR 97124
USA
Office: +1.888.627.9957
Office: +1.503.627.9957
Fax: +1.503.520.9618
www.acumed.net

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