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***NUVASIVE SPECIALIZED ORTHOPEDICS***
***PRECICE™ ANKLE SALVAGE SYSTEM***

**INSTRUCTIONS FOR USE**

**For symbols glossary, please refer to www.globusmedical.com/eIFU**

**ENGLISH**

**WITHIN THE UNITED STATES ONLY**

## DESCRIPTION

The Precice™ Ankle Salvage System is comprised of a telescoping intramedullary nail, locking screws, end cap, and associated general instruments. The Precice™ Ankle Salvage System is compatible with an External Remote Controller (ERC). The general instruments are for preparation of the tibio-talo and talo-calcaneal (TTC) joints as well as insertion and fixation of the nail into the intramedullary canal of the tibia via a retrograde approach through the plantar aspect of the calcaneus. Screw targeting instruments, as well as instruments for implant removal are part of the Precice™ Ankle Salvage System. The Precice™ Ankle Salvage System implants are manufactured from Titanium 6Al-4V per ASTM F136.

The Precice™ Ankle Salvage nail is supplied sterile and is a single-use device. The implant's internal mechanism includes a small magnet and drivetrain system. To adjust the nail's length, the ERC is positioned against the skin directly over the implant magnet. Magnets inside the ERC magnetically couple with the magnet inside the nail. When the ERC is actuated, the ERC's magnets will rotate the nail's magnet/drive mechanism to either lengthen or shorten the nail construct. The ERC can be used to compress the TTC joints following adequate joint preparation and successful implantation of the nail construct. Over a period of days, weeks, or months, additional ERC adjustments can be performed as needed to maintain compression for tibio-talo-calcaneal fusion. The nail remains implanted until the bone has healed, and the physician has determined that the construct has achieved its intended use. At the time of removal, the nail is explanted using standard extraction surgical techniques.

The Precice™ Ankle Salvage System may also be used for distraction osteogenesis to address a limb length discrepancy that may present after tibio-talo-calcaneal fusion. Following surgery, the ERC can be programmed to the specific needs of the patient to non-invasively adjust the implant to a prescribed length.

**CHEMICAL COMPOSITION FOR MATERIALS USED IN IMPLANTABLE DEVICES (COMPOSITION BY WT. %)**

| Material and Standard (if applicable) | Element | Composition Wt. % |
|---|---|---|
| **Titanium Alloy (Ti-6Al-4V ELI) Per ASTM F136** | Nitrogen, max | 0.05 |
| | Carbon, max | 0.08 |
| | Hydrogen, max | 0.012 |
| | Iron, max | 0.25 |
| | Oxygen, max | 0.13 |
| | Aluminum | 5.5-6.50 |
| | Vanadium | 3.5-4.5 |
| | Titanium | balance |

## INDICATIONS FOR USE

The Precice™ Ankle Salvage System is indicated for tibio-talo-calcaneal fusions in adults. When used for tibio-talo-calcaneal fusion, the Precice™ Ankle Salvage System may be used for open and closed fracture fixation, pseudarthrosis, mal-unions, non-unions, or bone transport of long bones adjacent to the fusion site. The device may be used for subsequent limb lengthening once tibio-talo-calcaneal fusion has been achieved.

## USERS

Experienced and trained orthopedic surgeons with knowledge of orthopedic and neurological surgery techniques.

## PATIENT POPULATION

Indicated for adults weighing a minimum of 50 lbs.

## CLINICAL BENEFITS INCLUDING EXPECTED LIFETIME

When the Precice™ Ankle Salvage System is used as intended and according to the instructions for use and labeling, the device is intended for tibio-talo-calcaneal fusions. After tibio-talo-calcaneal fusion has been achieved it may subsequently be used for limb lengthening.

The expected clinical/therapeutic lifetime of the device is defined as a maximum of 2 years.

## CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Active infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device.
2. Patients with an insufficient quantity or quality of bone to permit fusion of the joints or stabilization of the arthrodesis.
3. Patients with an insufficient plantar pad.
4. Patients having an intact asymptomatic subtalar joint.
5. Patients with Gustilo open fracture Classification Grade IIIB or IIIC fractures.
6. Metal allergies and sensitivities.
7. Patients with an irregular bone diameter that would prevent insertion of the Precice™ Ankle Salvage nail.
8. Patients in which there is an obliterated medullary canal or other conditions that tend to retard healing such as blood supply limitations, severe peripheral vascular disease or evidence of inadequate vascularity.
9. Patients with severe longitudinal deformity
10. Patients with significant tibial malalignment (>10 degrees in either sagittal or coronal plane)
11. Patients unwilling or incapable of following postoperative care instructions.

Please refer to the table below for contraindications with regard to weight and maximum distance of the treated limb to the surface of the intramedullary canal.

| Nail Diameter | Nail Length | Maximum Distance of Treated Limb Surface to IM Canal | Maximum Patient Weight for Limb Lengthening |
|---|---|---|---|
| 10.0mm | 200–250mm | 25mm | 150lbs/69kg |
| | 300–350mm | 13mm | |
| 11.5mm | 200–250mm | 25mm | 200lbs/91kg |
| | 300–350mm | 13mm | |
| 13.0mm | 200–250mm | 25mm | 250lbs/114kg |
| | 300–350mm | 13mm | |

## POTENTIAL ADVERSE EVENTS AND COMPLICATIONS, AND RESIDUAL RISKS

As this is a major surgical procedure, there are known complications associated with orthopedic surgery such as bone fractures, nonunion, delayed union, malunion, premature healing (consolidation), decrease in bone density due to stress shielding, inadequate screw fixation, difficulty with nail or screw removal, early or late infection that may result in the need for additional surgeries, damage to blood vessels or nerves, deep venous thrombosis or pulmonary emboli, acute local inflammatory response, loss of sensory and/or motor function or paralysis, pain, and/or permanent deformity.

The following list of failures and adverse events are possible with the Precice™ Ankle Salvage System. Failure to follow the contraindications, warnings, cautions and precautions listed in this IFU may increase the likelihood of these events.

- Soft tissue contractures, loss of joint motion, subluxation and/or dislocation could result in pain or surgical intervention to resolve. Preventative measures should be considered such as but not limited to proactive examinations, change of prescription, bracing, physical therapy, and tissues releases.
- Local tissue discoloration (i.e., metallosis), osteolysis, local acute inflammatory response, pain or other harms associated with exposure to wear debris, metal nanoparticles, and elevated titanium serum ion levels (including neurological issues and the risks associated with reproductive and developmental toxicity).
- Exposure to biohazards or non-biocompatible materials potentially leading to immunological response, pain, skin irritation/rash/sensitization, developmental toxicity related harms and/or infection and which may require medical intervention such as revision surgery.
- Loss of distraction or uncontrolled lengthening which may lead to pain, loss of correction, extension of treatment, progression of deformity, increased limb length discrepancy, overlengthening, poor regenerate and/or necessitate revision surgery.
- Implant bending, fracture, loosening, disassociation and/or loss of fixation resulting in medical intervention such as revision surgery.
- Failure to lengthen or compress which may lead to delays in surgery (leading to additional blood loss and extended exposure to anesthesia), extension of treatment, suboptimal correction, and/or necessitate revision or reoperation.
- Treatment complications from anatomical compatibility issues due to implant configuration selection, implant removals and/or implant sterility which may lead to delays in surgery (leading to additional blood loss and extended exposure to anesthesia), inability to complete the procedure and/or cancellation of the procedure, or may result in pain, abnormal sensations and/or suboptimal correction.

The residual risks identified with using the Precice™ Ankle Salvage System are:

- Local tissue discoloration (i.e., metallosis), osteolysis, local acute inflammatory response, or other harms associated with exposure to wear debris, metal micro and nanoparticles, and elevated titanium serum ion levels (including neurological issues and the risks associated with reproductive and developmental toxicity.
- Over distraction of the nail can increase the risk of tissue damage, soft tissue contractures, loss of joint motion, and could result in pain or surgical intervention to resolve. Preventive measures should be considered such as but not limited to proactive examinations, change of prescription, bracing, physical therapy, and tissue releases.
- Immunological response, pain, skin irritation/rash/sensitization, and/or infection which may occur in the event a patient is allergic to a material used in the implant or exposed to non-biocompatible materials. In rare events, the severity of the reaction could necessitate revision surgery.
- Loss of distraction, uncontrolled distraction, over or under distraction, or device failure including but not limited to bending, fracture, loosening, dissociation, and/or loss of fixation may lead to pain, loss of correction, extension of treatment, progression of deformity, increased defect size, poor regenerate, nerve damage, tissue damage, suboptimal result, and/or necessitate revision surgery.
- Risks inherent to invasive surgical procedures associated with site access and preparation, anatomical compatibility issues due to implant selection and placement, and achievement of correction which cannot be eliminated. These risks include delays in surgery (leading to additional blood loss or extended exposure to anesthesia), inability to complete the procedure and/or cancellation of the procedure, infections, pain, loss of correction, suboptimal results, progression of deformity, tissue damage, and minor nerve injuries. While rare, these risks also include major nerve and/or tissue damage which may necessitate revision surgery.
- Sterilization failures, sterile barrier compromise, and implant corrosion which may cause or contribute to infections and immunological reactions. In some instances, treatment of these events may require surgical intervention including revision surgery.

- Use of the Precice™ Ankle Salvage nail in patients with programmable or active implants such as pacemakers which may cause short-term or sustained stall or malfunction of programmable or active implants.

**WARNINGS, CAUTIONS, PRECAUTIONS**

- The Precice™ Ankle Salvage nail cannot withstand the stresses of full weight bearing. During TTC fusion phase, as directed by the physician, patients should immobilize and/or utilize external support until there is radiological evidence of consolidation or good contact between bone segments, so that load sharing can be anticipated. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact, as determined by the physician. During the limb lengthening phase, as directed by the physician, patients should utilize external support and/or restrict activities that exceed the weight loads specified in Table 1 until healing and consolidation occurs.

**TABLE 1: NAIL DIAMETER AND MAXIMUM LOADED WEIGHT FOR LIMB LENGTHENING CHART**

| Nail diameter (mm) | Maximum Patient Weight for Limb Lengthening | Maximum Loaded Weight for Limb Lengthening |
|---|---|---|
| 10 | 150lbs/69kg | 25lbs/11kg |
| 11.5 | 200lbs/91kg | 50lbs/23kg |
| 13 | 250lbs/114kg | 50lbs/23kg |

- Patients with an open fracture may also have soft tissue damage as a result of severe trauma. It is important that soft tissue damage is addressed, and soft tissue are healed prior to implantation to minimize the risk of infection.
- Limb lengthening also involves soft tissues; it is important to allow the soft tissue to heal prior to the lengthening procedure and previous/current incision sites should be monitored
- Limb lengthening may be associated with restriction or loss of motion (contractures), subluxation, and dislocation of adjacent joints (e.g.knee, and ankle).
- Careful observation as well as physical therapy, splinting or bracing, adjustments to the lengthening protocol, and possible prophylactic surgical procedures may be necessary to reduce the risk of adjacent joint contractures, subluxations, or dislocations.
- Do not use if the sterile packaging has been damaged or appears to have been previously opened.
- Metallic implants can loosen, fracture, corrode, migrate, or cause pain.
- Due to the presence of a magnet, use of the Precice™ Ankle Salvage System is not recommended in patients with pacemakers.
- The Precice™ Ankle Salvage System may not be appropriate for patients with poly-trauma.
- Use of the Precice™ Ankle Salvage System in patients with an active infection of the treated bone is not recommended.
- Smoking, chronic steroid use and the use of other anti-inflammatory drugs have been determined to affect bone healing and could potentially have an adverse effect of the bone regenerate during the lengthening process. Additionally, patients should be evaluated for narcotic dependencies associated with pain management.
- The Precice™ Ankle Salvage nail is supplied sterile and is for single-use only. The nail has not been tested to be cleaned or sterilized for multiple uses. If the nail is used more than once, the device may not be sterile and could cause a serious infection.
- Before removing the implants from the package, make sure that the protective packaging is unopened and undamaged. If the packaging is damaged, the implants have to be considered as NON-STERILE and may not be used.
- Note the STERILE expiry date. Implants with elapsed STERILE expiry dates have to be considered as non-sterile.
- The Precice™ Ankle Salvage Nail should be retracted only by a physician. Retraction should be monitored and confirmed using radiography.
- There is a possibility of nerve or soft tissue damage and/or weakness related to either surgical trauma or the presence of the implant. Advise the patient to notify the surgeon of any experienced pain, numbness, or weakness while undergoing treatment.
- Patients with the Precice™ Ankle Salvage System should not be implanted with more than two devices at a time and the patients weight should be a minimum of 50 lbs. Failure to follow this criteria may result in the potential adverse events and complications described above.
- Do not use this device without proper training in both device implantation and adjustment. Refer to External Remote Controller (ERC 1, ERC 2P, ERC 3P, or ERC 4P Operator's Manual (OM0005, OM0009, OM0016, OM0017) for operation of the External Remote Controller.
- Patients should not participate in contact sports or other high-risk activities. For limb lengthening applications, patients should not cause more than the maximum amount of weight listed in **Table 1** to be loaded on the treated limb. These activities may resume upon sufficient bone consolidation, but only as determined by the physician.
- Examine all Precice™ Ankle Salvage System components carefully prior to use to assure proper working condition. If you suspect a component to be faulty or damaged, do not use.
- The Precice™ Ankle Salvage System is for prescription use only by the order of a physician.
- Device should be removed after implantation time of no more than two years.
- Utilize extreme caution when handling instruments made from magnetic materials such as stainless steel in proximity of the magnet of the Precice™ Ankle Salvage nail, as materials will be attracted to each other.
- After the surgical procedure is complete, if retraction is needed during the lengthening or consolidation phase, retract the device no more than the amount lengthened the preceding day to avoid unnecessary compression.
- Do not bend the Precice™ Ankle Salvage nail or otherwise modify or damage the implant. During insertion of the nail, there should be caution in not hitting/impacting the nail.
- Follow the ERC Operators Manual (OM0005, OM0009, OM0016, OM0017) to assure proper alignment between the ERC and magnet of the Precice™ Ankle Salvage nail.
- When sterilizing instruments, do not load the tray more than 25 pounds.
- Be sure to measure the diameter of the intramedullary canal on preoperative radiographs to ensure it will accommodate the Precice™ Ankle Salvage nail.
- Instructions and training on the proper use of the ERC will be done by your prescribing surgeon or their staff.

Care should be taken to ensure that all components are ideally fixated prior to closure.

**TABLE 2: INTERLOCKING SCREW COMPATIBILITY CHART**

| Nail diameter (mm) | Screw approach/ location | Screw diameter (mm) | Interlocking screw type(s) | Screw lengths (mm) |
|---|---|---|---|---|
| 10 | medial to lateral tibia | 4.0 | Partially-threaded | 20-55 |
| | | | Fully threaded | 20-55 |
| 11.5 | medial to lateral tibia | 4.5 | Partially-threaded | 20-55 |
| | | | Fully threaded | 20-55 |
| 13 | medial to lateral tibia | 5.0 | Partially-threaded | 20-55 |
| | | | Fully threaded | 20-55 |
| 10, 11.5, 13 | lateral to medial calcaneus | 5.0 | Partially-threaded | 20-55 |
| 10, 11.5, 13 | posterior to anterior calcaneus | 6.0 | Partially-threaded, standard and headless | 60-110 |

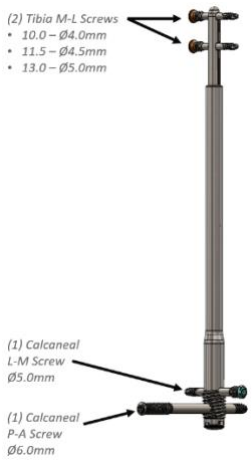


**FIGURE 1: INTERLOCKING SCREWS AND NAIL**

**PATIENT EDUCATION**

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

**SINGLE USE/DO NOT RE-USE**

Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents.

**MRI SAFETY INFORMATION**

The Precice™ Ankle Salvage System is unsafe in Magnetic Resonance Imaging environments. A patient with the implanted Precice™ Ankle Salvage nail must not come near an MRI scanner and must not undergo an MRI scan.

**COMPATIBILITY**

Do not use the Precice™ Ankle Salvage System with components of other systems. Unless stated otherwise, NuVasive Specialized Orthopedics devices are not to be combined with the components of another system or other manufacturer.

**PRE-OPERATIVE WARNINGS**

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the Precice™ Ankle Salvage System implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
   **For Sterile Implants:** Assure highly aseptic surgical conditions and use aseptic technique when removing the Precice™ Ankle Salvage System implant from its packaging. Inspect the implant and packaging for signs of damage, including scratched or damaged devices or damage to the sterile barrier. Do not use the Precice™ Ankle Salvage System implants if there is any evidence of damage.
4. Refer to Cleaning and Sterilization Instructions below for all non-sterile parts.
5. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

**POST-OPERATIVE WARNINGS**

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration as well as to other complications. To ensure the earliest possible detection of such catalysts of

device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

**METHOD OF USE**

Please refer to the Surgical Technique for this device (doc # 9514370 A).

Careful pre-operative diagnosis and planning, meticulous surgical technique, and extended postoperative care by experienced surgeons are essential to procedure success.

**IMPLANTATION PROCEDURE**

**For TTC Fusion applications**

1. Thoroughly clean the instruments according to the parameters in **Table 3** or **Table 4** prior to sterilization.
2. Inspect the instruments after cleaning to check for damage prior to sterilization. Functional check should include ensuring mating instruments can be properly assembled and instruments with moving parts are operated to ensure correct operation.
3. Sterilize non-sterile implant and instrument trays prior to the procedure. The Precice™ Ankle Salvage nail is provided separately in sterile packaging. The Precice™ Ankle Salvage screws and end caps may be provided sterile or non-sterile.
4. Position patient as indicated by patient factors and surgeon preference.
5. During surgical site exposure, incision size and location is dictated by patient factors and surgeon preference. If a trans-fibular approach is elected, carefully resect the fibula by performing an osteotomy proximal to the tibiotalar joint line.
6. After surgical exposure of the tibio-talo-calcaneal (TTC) joints, joint distraction instrumentation can be used to aid debridement and preparation of the joint surfaces. Joint preparation techniques vary according to surgeon preference. The amount of boney resection is largely dependent on bone quality, as all compromised tissue must be removed to expose viable bleeding bone. Although the Precice™ Ankle Salvage System can be used to restore limb length following TTC fusion, take care to avoid excessive boney resection that may result in limb shortening.
7. Pre-operative planning and surgeon preference often guide nail size selection. Intraoperatively, nail size can be assessed radiographically by aligning the radiographic ruler on the limb to help determine nail length and diameter.
8. Once the desired implant is selected, prepare the nail's entry site starting with a small incision on the plantar aspect of the foot to directly visualize the desired nail entry point on the calcaneus. With the joint positioned in neutral alignment, insert an entry guide wire into the calcaneus in a retrograde fashion to indicate the nail's intended path. Advance the guide wire through the calcaneus and talus and into the intramedullary canal of the distal tibia. Once satisfied with the wire's positioning, use the cannulated entry reamer over the guide wire to create the nail's initial pathway into the tibial canal.
9. Once the tibial intramedullary canal is breached with the entry reamer, the entry guide wire is exchanged for a ball tip guide wire for use with cannulated flexible reamers. Using multiplanar image guidance, advance the guide wire proximally with the guide wire driver until the tip reaches the desired location.
10. Ream the intramedullary canal progressively in half millimeter increments to a size 1mm larger than the selected nail diameter. When exchanging flexible reamers, the guide wire pusher can be used to maintain the position of the guide wire.

    Note: The diameter of the Precice™ Ankle Salvage nail is not constant. The proximal portion of the nail corresponds to its specified diameter (10, 11.5 or 13mm). The distal portion of the nail features a larger diameter (12, 13 or 14mm) and should be reamed to size to ensure proper engagement of the distal nail threads.
11. Attach the appropriate size nail to the insertion T-handle with the locking bolt. Use the 6mm ball hex driver to securely tighten the connection. Next, attach the short impactor to the insertion T-handle.
12. Insert the nail into the calcaneus, advancing into the canal until the distal nail threads contact the calcaneal bone. If additional force is needed to provisionally insert the nail, use the slotted mallet to gently impact the nail into position.
13. Once the nail's distal threads engage the bone, rotate the insertion T-handle clockwise to advance the implant while gaining purchase in the calcaneal bone. Use the P-A screw locator to assess the nail's depth and rotational alignment. Using fluoroscopy, verify that the nail is inserted to the desired depth by locating the chamfer on the end of the insertion T-handle relative to the plantar aspect of the calcaneus.
14. Once desired nail positioning is confirmed, attach the targeting arm to the insertion T-handle in the L-M orientation and secure with the locking nut. Insert the guide tube/drill sleeve assembly into the L-M hole of the targeting arm. Use the trocar or starter drill to penetrate the cortex, then prepare the screw hole using the 5.0mm calibrated drill. Drill depth/screw length can be determined using the drill bit's calibrations relative to the drill sleeve. Attach the appropriate length 5.0mm screw to the self-retaining screwdriver. Remove the drill sleeve and insert the screw into the prepared hole through the guide tube.
15. If manual reduction of the TTC joints is required, attach the short impactor to the targeting arm and strike with the slotted mallet to compress the joint space. Verify under fluoroscopy that adequate boney apposition has been achieved.
16. Once the L-M calcaneal screw is inserted and TTC joints reduced, pass the set screw driver through the locking bolt to engage and tighten the nail's pre-loaded set screw.
17. In preparation for the insertion of the M-L tibial screws, loosen the locking nut to disengage the targeting handle from the insertion T-handle. Rotate the targeting arm 180 degrees into the M-L screw targeting position and secure the connection by re-tightening the locking nut. Insert the guide tube/drill sleeve assembly into the M-L hole of the targeting arm. Pass the starter drill to create the initial pilot hole in the near cortex and then pass the appropriately sized drill bit bi-cortically to finish preparing the screw hole. Note: The diameter of the nail's M-L *tibial screws varies according to nail diameter.* After determining the drill depth/screw length, attach the appropriate length and diameter screw to the self-retaining screwdriver. Remove the drill sleeve and insert the screw into the prepared hole through the guide tube. Using fluoroscopy, confirm the screw has passed through the screw hole of the nail. Repeat these steps to prepare and insert the second M-L tibial screw.

    Note: Tibial screw sites in nail lengths beyond 200mm are prepared using a freehand technique and fluoroscopic imaging.
18. After inserting both the L-M calcaneal and M-L tibial screws, loosen the locking nut and reposition the targeting arm for P-A calcaneal screw insertion. Insert the guide tube/drill sleeve assembly into the P-A hole of the targeting arm. Use the trocar or starter drill to penetrate the near cortex, then prepare the screw hole using the 6.0mm drill bit. Note the depth of the drill/screw length by reading the drill bit's calibrations relative to the drill sleeve. Attach the appropriate length 6.0mm screw (headed or headless) to the self-retaining screwdriver. Remove the drill sleeve and insert the screw into the prepared hole through the guide tube.
19. Once all interlocking screws have been inserted, remove the targeting and insertion instrumentation. Use the self-retaining screwdriver to insert the end cap into the distal end of the nail.
20. Locate the center of the implanted magnet and mark the patient's skin with indelible marker at this location. Position the External Remote Controller (ERC) over the mark and retract the nail 1mm to initiate compression of the TTC joints. Verify that the nail is functioning via fluoroscopic evaluation and apply additional compression as needed.
21. Close and dress the site using standard techniques.

**For Limb Lengthening Applications**

1. Thoroughly clean the instruments according to the parameters in **Table 3** or **Table 4** prior to sterilization.
2. Inspect the instruments after cleaning to check for damage prior to sterilization. Functional check should include ensuring mating instruments can be properly assembled and instruments with moving parts are operated to ensure correct operation.
3. Sterilize non-sterile implant and instrument trays prior to the procedure.
4. Position patient as indicated by patient factors and surgeon preference.
5. Prior to the osteotomy, overall construct stability should be re-evaluated and should include an assessment of all screw sites. Fully threaded screws must be exchanged for partially threaded screws during the lengthening phase of the procedure.
6. Method and location of the tibial osteotomy is dictated by patient factors and surgeon preference and must be performed cautiously to avoid damaging contact with the Precice™ Ankle Salvage nail. Surgeons should avoid the use of powered cutting tools in preparation of the osteotomy.
7. If intact, perform an osteotomy of the fibula to allow it to lengthen in conjunction with the tibia.
8. Use multiplanar fluoroscopy to help confirm osteotomy completeness.
9. Locate the center of the implanted magnet and mark the patient's skin with indelible marker at this location. Position the ERC over the mark and actuate the nail 1mm to verify functionality.
10. Close and dress the site using standard techniques.
11. Instruct the patient to maintain the indelible marker mark at the same location on their limb.

**POST-OPERATIVE PROCEDURES**

1. Read the External Remote Controller (ERC) Operator's Manual (OM0005, OM0009, OM0016, OM0017) prior to performing an adjustment of the Precice™ Ankle Salvage nail.
2. Determine the amount of adjustment required to compensate for any length discrepancy between the treated limb and the unaffected limb or any additional compression or distraction desired.
3. Identify the mark on the limb where the magnet in the Precice™ Ankle Salvage nail is located. Carefully place the ERC firmly but comfortably over this area in the correct orientation.
4. Retract or distract the implant to the desired amount, as viewed on ERC display screen. Retraction should only be performed by a physician with the aid of radiography.
5. Carefully place the ERC back in its storage container and close.progress and efficacy of lengthening should be checked regularly against follow-up radiographic evidence of the rate of lengthening and the quality of the regenerate. While 1 mm per day is generally recommended, clinical and radiographic examination may show that lengthening should progress at a faster or slower pace. Bi-weekly X-ray imaging to assess actual distraction length is recommended.

**IMPLANT REMOVAL PROCEDURE**

1. At the time deemed appropriate by the physician, remove the Precice™ Ankle Salvage nail using standard removal techniques.
2. Follow all cleaning and sterilization procedures in **Table 3** or **Table 4** to prepare the instruments prior to removal.
3. Access the distal end of the Precice™ Ankle Salvage nail. Remove the end cap followed by the P-A screw using the self-retaining screwdriver.
4. Loosen the set screw with the set screwdriver and remove the L-M screw using the Self-retaining screwdriver.
5. Keep a minimum of one point of fixation in the tibia to maintain the nail's position when attaching removal instrumentation. Thread the inner shaft of the extractor to the distal portion of the nail in a clockwise motion and use the 3.5mm hex driver to securely tighten the connection. With the inner shaft secured into the implant, remove any existing M-L tibial screws using the self-retaining screwdriver.
6. Thread the outer sleeve of the extractor over the inner shaft in a counterclockwise motion until the it contacts the distal surface of the nail (a black line on the inner extractor will protrude from outer sleeve).
7. While holding the inner extractor in place with the 3.5mm hex driver for counter torque, turn the outer sleeve in a counterclockwise direction to disengage the nail's threads from the bone. With the threaded portion disengaged, the removal rod may be attached to the outer sleeve of the extractor to facilitate removal via impaction from the slotted mallet.
8. After explanting the Precice™ Ankle Salvage nail, disassemble the extractor assembly prior to reprocessing.
9. Close and dress the wound using standard surgical techniques.
10. Return the explanted product to NuVasive Specialized Orthopedics, Inc. Please call 1-855-435-5477 to obtain instructions or if you have any questions.

**PACKAGING**

Packages for each of the components should be intact upon receipt. All implant and instrument sets should be carefully examined for completeness, and for lack of damage and wear, prior to use. Damaged packages or products that show wear should not be used, and should be returned to NuVasive Specialized Orthopedics.

Instruments provided non-sterile can be single-use or reusable. Discard single-use instruments after use. Reusable instruments should be reprocessed using instructions provided below.

All implants and instruments provided sterile are intended for single use only. Do not use if package is opened or damaged. This product should NOT be re-sterilized. Discard single-use instruments after use.

The Instrument Trays are designed to organize, protect, and transport instruments during sterilization and subsequent storage.

The instrument trays are reusable and actual limits of reuse for the instrument trays are based upon the proper handling, use, care and cleaning of the trays. The end of tray life is to be determined by wear and damage due to use and through the inspection of the trays after the cleaning and sterilization cycles. Discontinue use of the device if visible signs of wear are present. This includes cracking, peeling, flaking, rusting, and/or discoloration. Always inspect the instrument trays and its components between uses. For trays and instruments that are no longer functional, or exhibit excessive wear and tear, please return them to NuVasive Specialized Orthopedics for replacement.

**STORAGE/HANDLING/DISPOSAL**

- Recommended to be stored at ambient temperatures with no special storage conditions required.
- Before removing the implants from the package, make sure that the protective packaging is unopened and undamaged. If the packaging is damaged, the implants have to be considered as NON-STERILE and may not be used.

- Upon removal from the package, compare the descriptions on the label with the package contents (product number and size)
- Note the STERILE expiry date. Implants with elapsed STERILE expiry dates have to be considered as non-sterile and may not be used.
- Take particular care that aseptic integrity is assured during removal of the implant from the inner packaging.
- Open the packages carefully. Take suitable measures to ensure that the implant does not come into contact with objects that could damage its surfaces. Use only the recommended instruments for implantation of the implants. Damaged implants must not be used.
- Material Disposal Instruction: The implant/device must be disposed of in accordance with applicable local regulations for handling of biological medical waste.

**CLEANING AND DECONTAMINATION**

All non-sterile instruments must first be thoroughly cleaned using the validated methods prescribed below before sterilization and introduction into a sterile surgical field. Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization. The validated cleaning methods include both manual and automated cleaning. Visually inspect the instruments following performance of the cleaning instructions to ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible, contamination is present at visual inspection, repeat the cleaning steps. Contaminated instruments should not be used, and should be returned to NuVasive Specialized Orthopedics. Contact your local representative or NuVasive Specialized Orthopedics directly for any additional information related to cleaning of NuVasive Specialized Orthopedic surgical instruments.

Instruments should always be thoroughly inspected before each use and after a cleaning cycle for broken, worn or damaged instruments. Damaged or non-functional instruments should be returned to NuVasive Specialized Orthopedic representative for replacement.

The instrument tray and instruments are provided non-sterile and must be cleaned and sterilized prior to use. Thoroughly clean and inspect the trays and instruments for damage prior to loading, wrapping, and sterilization. Disassemble the instrument tray by removing the lid from the tray base. Remove the instruments from the instrument holders.

Note: Do not allow instruments to completely dry prior to cleaning.

**TABLE 3: MANUAL CLEANING RECOMMENDATIONS**

| Step | Solution | Time (Minutes) | Temperature | Instruction |
|---|---|---|---|---|
| 1 | pH Neutral Hospital Grade Enzymatic Detergent | 14-15 Minutes | Room Temperature | Disassemble instrument trays, remove the instruments from the instrument holders, and disassemble instruments before immersing, soaking, and performing the cleaning. Immerse and soak for required time. |
| 2 | pH Neutral Hospital Grade Enzymatic Detergent | As required per detergent instruction | Room Temperature | Clean thoroughly. Scrub all external surfaces with a soft bristle brush until all visible soil has been removed. It is important to make sure all areas of the tray and instruments are cleaned. Ensure that the holes and lumens are effectively cleaned by using a small diameter brush (tight-fitting, soft and non- metallic) or pipe cleaner to clean holes and lumens. Inspect for visible soil on exposed surfaces. Pay attention to threads, hinges and occluded areas of the instrument trays and instruments, and any hard- to-reach areas. Inspect for visible soil on exposed surfaces and make sure there is no visible soil on the exposed surfaces. |
| 3 | Distilled or Reverse Osmosis (RO) Water | 2-3 | Warm, as delivered from hot water tap | Rinse thoroughly for required time immediately after Step 2. Ensure water flows through all surfaces, perforations, holes and lumens. Inspect for visible soil on exposed surfaces and make sure there is no visible soil. Particular attention should be given to surfaces, perforations, lumens, hinges, and holes. |
| 4 | pH neutral hospital-grade enzymatic detergent | 15 Minutes | 40-60°C | Immerse and sonicate the instruments for the required time.<br><br>The instrument trays do not require sonication. |
| 5 | Distilled or RO water | 2-3 | Warm, as delivered from hot water tap | Rinse thoroughly for required time immediately after Step 4. Ensure water flows through all surfaces, perforations, holes, and lumens. Visually inspect the trays and instruments for visible soil or detergent. Particular attention should be given to surfaces, perforations, lumens, hinges, and holes. Tools such as lighting, magnifying glass, or boroscope may be used to inspect lumens or holes for visible soil. Perform an additional rinse if soil or detergent is still present and visually inspect. Repeat cleaning process if soil or detergent is still present. |
| 6 | Air | As required | Ambient | Allow to air dry in clean area. Blow perforations, holes, and lumens or any internal areas with clean air using filtered air source or syringe. |

**TABLE 4: AUTOMATIC CLEANING RECOMMENDATIONS**

| Step | Solution | Time (Minutes) | Temperature | Instruction |
|---|---|---|---|---|
| 1 | pH Neutral Hospital Grade Enzymatic Detergent | As required | Room Temperature | Disassemble instrument trays, remove the instruments from the instrument holders, and disassemble instruments before immersing, soaking, and performing the cleaning. For instruments or trays with complex design features such as perforations, lumens, holes, threads or a hard to reach area, it is necessary to soak the instruments and manually scrub all external and internal surfaces with a soft bristle brush, a small diameter brush (tight-fitting, soft and non-metallic) or pipe cleaner until all visible soil has been removed prior to automatic reprocessing to improve the removal of adherent |
| 2 | pH neutral hospital- grade enzymatic detergent | 15 Minutes | 40-60°C | Immerse and sonicate the instruments for the required time by the manufacturer.<br><br>The instrument trays do not require sonication. |
| 3 | Distilled or reverse osmosis (RO) water | 2-3 | Warm, as delivered from hot water tap | Rinse thoroughly for required time immediately after Step 2. Ensure water flows through all surfaces, perforations, holes and lumens. |
| 4 | N/A | N/A | N/A | Load the lid, tray base, and insert tray such that all surfaces of the trays are exposed to the cleaning solutions. Load the instruments so that cannulations, lumens or holes can drain. Do not place heavier instruments on top of delicate instruments. |
| 5 | Distilled or RO Water | 6 | Cold | Pre-wash |
| 6 | pH Neutral Hospital Grade Enzymatic Detergent | 10 | 55°C | Wash |
| 7 | Distilled or RO Water | 30 | N/A | Rinse |
| 8 | Distilled or RO Water | 5 | 93°C | Final Rinse |
| 9 | N/A | Vary | Room Temperature | Dry |
| 10 | N/A | N/A | N/A | Visually inspect the trays and instruments for dryness and visible soil or detergent. Particular attention should be given to surfaces, cannulas, hinges, lumens or holes. Tools such as lighting, magnifying glass, or boroscope may be used to inspect long cannulas, lumens or holes for visible soil. If soil or detergent is visible, repeat cleaning. |

**STERILIZATION**

The Precice™ Ankle Salvage Nail is provided sterile. Precice™ Ankle Salvage Screws and End Caps may be provided sterile or nonsterile.

All non-sterile implants and instruments are sterilizable by steam autoclave using standard hospital practices, in addition to NuVasive Specialized Orthopedics' validated parameters. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the parameters prescribed below.

After cleaning the instrument tray and instruments, inspect all parts of the tray and instruments for damage before sterilization. A functional inspection should also be performed where possible. Mating devices should be checked for proper assembly and devices with moving parts should be manipulated to check for correct operation. Load the tray with the specified instruments and secure the tray lid. Ensure that the tray base and lid can be secured using the latches and handles. If you suspect the tray or an instrument to be damaged, do not use the tray and/or instrument and contact NuVasive Specialized Orthopedics, Inc. for a replacement and/or repair.

The instruments can be sterilized using the provided standard open cases or Case Medical SteriTite closed cases, Aesculap closed cases (standard or PrimeLine Lid), and One Tray closed cases. Small baskets, trays, and other types of accessories, especially with covers or lids, not provided by NuVasive Specialized Orthopedics for a specific system should not be used.

In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the following parameters:

| |
|---|
| **Method:** Steam |
| **Cycle:** Pre-vacuum |
| **Temperature:** 270° (132°C) |
| **Exposure Time:** 4 minutes |
| **Minimum Dry Time*:** 30 Minutes |
| **Minimum Cool Down Time:** 40 Minutes |
| **Maximum Tray Weight:** 25 lb. |

*Dry time is the period which steam is removed from the chamber and the chamber pressure is reduced to permit the evaporation of condensate from the load either by prolonged evacuation or by the injection and extraction of hot air or other gases. Drying time may vary due to load configuration, wrapping method, and material. Therefore, dry time may be repeated if moisture is present on the wrap and/or the instruments.

For non-sterile Implants and Instruments provided in Globus sets, follow below instructions:

Nonsterile implants and instruments have been validated to ensure an SAL of $10^{-6}$. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 $in^2$ total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For Implants and Instruments provided non-sterile, sterilization is recommended (wrapped or containerized) as follows:

| Method | Cycle Type | Temperature | Exposure Time | Drying Time |
|---|---|---|---|---|
| Steam | Pre-vacuum | 132°C (270°F) | 4 minutes | 30 minutes |

*These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.*

**COMPLAINTS**

Report any malfunction or issues to Complaints at 1-866-GLOBUS1 (OR) 1-866-456-2871. You may also email: complaints@nuvasive.com.

**INFORMATION**

Any serious incident that has occurred in relation to the device should be reported to the manufacturer.

To obtain a Surgical Technique Manual or should any information regarding the products or their uses be required, please contact your local representative or NuVasive Specialized Orthopedics directly 1-866-GLOBUS1 (OR) 1-866-456-2871. You may also email: info@nuvasive.com.

The responsibility resides with the user to ensure that the most current version of the IFU is used. To obtain a paper copy of current or historical Instructions for Use, please contact your local NuVasive Specialized Orthopedics representative.

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