NUVASIVE SPECIALIZED ORTHOPEDICS
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NUVASIVE SPECIALIZED ORTHOPEDICS
PRECICE™ MAX SYSTEM

INSTRUCTIONS FOR USE

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

ENGLISH

WITHIN THE UNITED STATES ONLY

DESCRIPTION

The Precice™ Max System is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The Precice™ Max System implants are manufactured from Titanium 6Al-4V per ASTM F136. The Precice™ Max nail is a sterile single use device that is surgically implanted using the instruments and locking screws for osteoplasty lengthening utilizing distraction osteogenesis. The ERC is used daily after implantation to non-invasively lengthen or shorten the implant to a prescribed length.

During the implantation procedure, the nail can be adjusted in length to provide an appropriate amount of compression for the proper fracture reduction. Following implantation, the Precice™ Max System utilizes distraction osteogenesis to lengthen the limb. Traditional intramedullary surgical techniques are used to implant and secure the proximal and distal sections of the Precice™ Max nail to the target bone. The Precice™ Max nail includes a small internal magnet and gearing. After positioning the External Remote Controller (ERC) against the skin over the internal magnet, activation of the ERC causes the magnet to rotate and either lengthen or shorten the nail.

During the surgical implantation procedure and after the nail has been secured to the bone, the nail can be shortened up to 10mm for femoral and tibial implants to provide compression for fracture reduction. Over a period of days, weeks, or months, sequential distractions are used to produce the target limb length or compensate for any length discrepancies encountered during the fracture reduction process. The Precice™ Max nail remains implanted until bone consolidation has been completed. Once the physician determines that the nail has achieved its intended use and is no longer required, it is removed using standard surgical techniques.

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)	Nitrogen, max	0.05
	Carbon, max	0.08
	Hydrogen, max	0.012
Per ASTM F136 and ISO 5832-3	Iron, max	0.25
	Oxygen, max	0.13
	Aluminum	5.5-6.50
	Vanadium	3.5-4.5
	Titanium	balance

INTENDED USE/INTENDED PURPOSE

The Precice™ Max Nail is intended to stabilize fractures, nonunions, and malunions of the femur, tibia, and humerus. In addition, the Precice™ Nail is intended to provide magnetically controlled lengthening of long bones and/or transporting of bone segments in the femur, tibia, and humerus.

INDICATIONS FOR USE

The Precice™ Max System is indicated for limb lengthening, open and closed fracture fixation, pseudarthrosis, malunions, nonunions, or bone transport of long bones in patients age 18 years and older and indicated for limb lengthening of the femur and tibia in pediatric patients (greater than 12 years old).

USERS

The system is indicated to be used by experienced and trained surgeons with knowledge of orthopedic and neurological surgery techniques.

PATIENT POPULATION

Indicated for skeletally mature patients and pediatric patients (greater than 12 years old), weighing a minimum of 50 lbs. (22.7 kgs).

CLINICAL BENEFITS INCLUDING EXPECTED LIFETIME

When Precice™ Max System is used as intended and according to the instructions for use and labeling, the device is expected to treat patients with limb length discrepancies, segmental bone defects, and complex long bone fractures and fractures that are not healing properly (nonunion or pseudoarthrosis, or malunion).

The expected clinical/therapeutic lifetime of the device is defined as a maximum of 1 year taking into consideration the variability in time needed for bone lengthening, bone transport, and/or bone healing to take place and develop sufficient strength for maintaining stability without any support. This is consistent with current clinical evidence from the state of the art for this type of device. This lifetime is also supported by benchtop testing which has demonstrated 1 year of mechanical life as these types of devices are intended to function mechanically until fusion occurs.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Infection or Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device.
2. Patients with Gustilo open fracture Classification Grade IIIB or IIIC fractures.
3. Patients with pre-existing nerve palsies.
4. Metal allergies and sensitivities.
5. Patients with an irregular bone diameter that would prevent insertion of the Precice™ Max nail.
6. Patients in which the Precice™ Max nail would cross joint spaces or open epiphyseal growth plates.
7. Patients in which there is an obliterated medullary canal or other conditions that tend to retard healing such as blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity.
8. Patients unwilling or incapable of following postoperative care instructions.
9. Patients who are pregnant.

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

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

Limb	Precice™ Max Model	Nail Diameter (mm)	Maximum Distance of Treated Limb Surface to IM Canal (ERC1, ERC2P)	Maximum Distance of Treated Limb Surface to IM Canal (ERC3P)	Maximum Distance of Treated Limb Surface to IM Canal (ERC4P)	Max Patient-Weight
Tibia	C, TJ	10.0	13mm	13mm	13mm	250lbs/114kg
		11.5	13mm	13mm	16mm	250lbs/114kg
		13.0	13mm	13mm	16mm	250lbs/114kg
		14.0	13mm	13mm	16mm	250lbs/114kg
Femur	B, D, TE, TX, TA, TB,TD, X, E	10.0	38mm	38mm	45mm	250lbs/114kg
		11.5	51mm	51mm	75mm	250lbs/114kg
		13.0	51mm	80mm	90mm	250lbs/114kg
		14.0	51mm	80mm	90mm	250lbs/114kg

RESIDUAL RISKS AND POTENTIAL SIDE EFFECTS

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™ Max 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, over-lengthening, 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 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.

Note: the incidence of loss of motion, subluxation, or dislocation at adjacent joints (e.g., hip, knee, ankle/foot) may occur at higher rates in skeletally immature patients less than 13 years of age.

The residual risks identified with using the Precice™ Max 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, increase 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™ Max 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, CAUTION, AND PRECAUTIONS

- The Precice™ Max nail cannot withstand the stresses of full weight bearing for tibia and femur applications. Patients should utilize external support and/or restrict activities until consolidation occurs.
- Patients with an open fracture or prior external fixator treatment resulting in limb length discrepancy may also have soft tissue damage/dormant infections as a result of severe trauma. It is important that soft tissue damage is addressed prior to lengthening 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., shoulder, elbow, hip, knee, and ankle).
- In skeletally immature patients with an open healthy growth plate, the insertion of the Precice™ Max Nail through the growth plate carries the risk of injury to the growth plate that may result in a partial or complete growth arrest with deformity, such as coxa varus deformity.
- Do not use if the sterile packaging has been damaged or is open.
- Metallic implants can loosen, fracture, corrode, migrate, or cause pain.
- Due to the presence of a magnet, use of the Precice™ Max System is not recommended in patients with magnetically susceptible devices. Complications may include short-term or sustained stall or malfunction of the aforementioned devices.
- The Precice™ Max System may not be appropriate for patients with poly-trauma.
- Use of the Precice™ Max System in patients with an active infection of the treated bone is not recommended.
- Smoking, chronic steroid/drug 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™ Max 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.
- The Precice™ Screws and End Caps may be supplied sterile and non-sterile and are for single use only.
- 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™ Max 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 of the Precice™ Max 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, ERC 2P, ERC 3P, or ERC 4P) Operator's Manual (OM0005, OM0009, OM0016, or OM0017) for operation of the External Remote Controller.
- 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.
- The Precice™ Max nail cannot withstand the stresses of full weight bearing. During the limb lengthening phase, as directed by the physician, patients should utilize external support and/or restrict activities that cause more than 20% of body weight to be loaded on the treated limb, loads specified in Table 2 until healing and consolidation occurs. <u>These activities may include but not limited to unassisted walking, going upstairs/downstairs, and caution should be taken with daily activities to avoid damage to the device.</u>

TABLE 2. NAIL DIAMETER AND MAXIMUM PARTIAL WEIGHT BEARING LOAD FOR LIMB LENGTHENING CHART

Nail Diameter (mm)	Maximum Partial Weight Bearing Load for Limb Lengthening
10.0	50lbs/23kg
11.5	50lbs/23kg
13.0	50lbs/23kg
14.0	50lbs/23kg

- Examine all Precice™ Max 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™ Max System is for prescription use only by the order of a physician.
- Device should be removed after implantation time of no more than one year.
- Utilize extreme caution when handling instruments made from magnetic materials such as stainless steel in proximity of the magnet of the Precice™ Max 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.
- Do not bend the Precice™ Max 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, or OM0017) to assure proper alignment between the ERC and magnet of the Precice™ Max nail.
- In a skeletally immature patient with an open proximal femoral growth plate, there is a risk of avascular necrosis (osteonecrosis) of the femoral head with antegrade insertion of the Precice™ Max Nail through the piriformis fossa. It is recommended that nail insertion through the proximal femur always be through the tip of the greater trochanter. Particular care should be taken to avoid nail insertion through the piriformis fossa to reduce the risk of vascular injury to the femoral head.
- Be sure to measure the diameter of the intramedullary canal on preoperative radiographs to ensure it will accommodate the Precice™ Max Nail implant.
- Instructions and training on the proper use of the ERC will be done by your prescribing surgeon or their staff. It is recommended that pediatric patients only perform their daily treatments under the supervision of an adult or guardian.
- The screws are single use only, and if used more than once, it may result in patient harms such as an immunological response, revision surgery or delay in surgery.

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

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

All implants are intended for single use only. 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™ Max System is MR Unsafe. A patient with the implanted Precice™ Max nail must not come near an MRI scanner and must not undergo an MRI scan.

COMPATIBILITY

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

PREOPERATIVE 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™ Max 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™ Max 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™ Max implants if there is any evidence of damage.
4. Refer to Cleaning and Sterilization Instructions (doc # 9400896) 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.

POSTOPERATIVE 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.

LOCKING SCREW STYLES AND SIZES

Screw Diameter	Screw Type	Head Color
4.0 mm	Partially-Threaded	Blue
4.5 mm	Partially-Threaded	Silver
5.0 mm	Partially-Threaded	Green
5.5 mm	Partially-Threaded	Light Blue

TABLE 3: INTERLOCKING SCREW COMPATIBILITY CHART

Precice™ Max Models	Nail Diameter	Proximal Locking Screw	Distal Locking Screw
B-D, TJ, TE, TX, TA, TB, TD, X, E	10.0 MM	5.0 MM	4.0 MM
B-D, TJ, TE, TX, TA, TB, TD, X, E	11.5 MM	5.0 MM	4.5 MM
B-D, TJ, TE, TX, TA, TB, TD, X, E	13.0 MM	5.0 MM	5.0 MM
B-D, TJ, TE, TX, TA, TB, TD, X, E	14.0 MM	5.5 MM	5.0 MM

METHOD OF USE

Please refer to the Surgical Technique for this device. Careful pre-operative diagnosis and planning, meticulous surgical technique, and extended postoperative care by experienced surgeons are essential to procedure success. To obtain a Surgical Technique Manual, please contact your local representative or NuVasive directly at 1-866-GLOBUS1 (OR) 1-866-456-2871. You may also email: info@nuvasive.com

IMPLANTATION PROCEDURE

For fracture reduction applications:

1. Thoroughly clean the instruments according to the parameters in the CLEANING AND DECONTAMINATION FOR NON-STERILE INSTRUMENTS section below.
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 implant and instrument trays prior to the procedure. The Precice™ Max Nail is provided separately in sterile packaging. The Precice™ Screws and End Caps may be provided sterile or non-sterile.
4. Position patient per standard technique.
5. Check for length and rotation by comparison to the unaffected limb.
6. Intra-articular fracture components should be addressed with interfragmentary screw fixation prior to nail insertion. Care should be taken to place the screws in the anterior and posterior aspect of the distal long bone and safely out of the nail's intended path.
7. Identify and access the appropriate entry point for the delivery technique chosen (i.e., antegrade or retrograde).
8. Reduce the fracture using standard surgical technique.
9. Determine the appropriate nail size and configuration to be used.
10. If using flexible reamers, insert a guide wire into the medullary canal and advance until the tip of the wire reaches the intended location. Imaging in two planes is required while advancing the guide wire.
11. Ream the intramedullary canal sequentially in half millimeter increments to a size 2mm larger than the selected nail diameter.
12. After attaching the Drill Guide to the implant, insert the Precice™ Max Nail into the medullary canal under image intensification. Advance the Precice™ Max Nail until the device is properly positioned.
13. Using the Drill Guide mounted to control alignment, secure the proximal portion of the lengthener using proximal locking screws of appropriate length. The head of the screw should be flush with the bone surface. Do not drill additional holes until securing the previous locking screw.
14. Using a free hand technique and fluoroscopic imaging, secure the distal portion of the lengthener using distal locking screws of appropriate length. The head of the screw should be flush with the bone surface.
15. Remove the Drill Guide and associated accessories and carefully irrigate to remove any remaining bone fragments. Attach the End Cap to the proximal end of the Precice™ Max Nail. Carefully irrigate the surgical site to remove any remaining bone fragments.
16. Disassemble the Drill Guide in reverse order from Step 12 prior to cleaning. Clean instruments after use, without allowing instruments to completely dry prior.
17. To provide compression to the reduced fracture, cover the ERC with sterile drape. Locate the ERC magnets over the actuator position and activate the ERC to shorten the implant. The implant may be shortened by up to 20 mm (depending on selected implant) to provide this amount of compression to the reduced fracture. Use radiography to ensure that the implant has retracted the desired amount.
18. Locate the center of the implanted magnet and mark with indelible marker.
19. Close and dress the site using standard techniques.
20. Instruct the patient to maintain the indelible marker mark at the same location.

For limb lengthening applications:

1. Thoroughly clean the instruments according to the parameters in the CLEANING AND DECONTAMINATION FOR NON-STERILE INSTRUMENTS section below.
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 implant and instrument trays prior to the procedure. The Precice™ Max Nail is provided separately in sterile packaging. The Precice™ Screws and End Caps may be provided sterile or non-sterile.
4. Use standard surgical techniques to provide for adequate venting of the intramedullary canal during surgery.
5. After accessing the insertion site, use an awl or sterile entry drill to open the medullary canal. Use care to keep the straight part of the shaft of the instrument parallel to the long axis of the bone shaft.
6. If using flexible reamers, insert a guide wire into the medullary canal and advance until the tip of the wire reaches the intended location. Imaging in two planes is required while advancing the guide wire.
7. Ream the intramedullary canal 2 mm greater than the diameter of the Precice™ Max nail. The cortices must be at least 3mm thick at any location once reamed.
8. Create an osteotomy at the appropriate location in the bone.
   Note: Do not perform the osteotomy in the proximal or distal metaphyseal areas where the larger intramedullary canal diameter may lead to instability of the distracted fragment, and higher bending moments may result in excessive loading of the implant.
9. For tibial cases, also create an osteotomy in the fibula. To ensure that the fibula lengthens with the tibia, consider using screws to secure the osteotomized fibula to the tibia both distally and proximally.
10. After attaching the Drill Guide to the Precice™ Max nail and tightening down the Locking Bolt and Impactor with a tommy bar or 6mm driver, insert the device into the medullary canal under image intensification. Advance the device until it is properly positioned.
11. Use the Drill Guide to control alignment and then secure the proximal portion of Precice™ Max nail using two proximal transverse locking screws of appropriate length. The head of the screw should be flush with the bone surface. Do not drill a second hole until securing the first locking screw. Using a free hand technique and fluoroscopic imaging, secure the distal portion of the Precice™ Max nail using two transverse locking screws of appropriate length. The head of the screw should be flush with the bone surface.
12. Remove the Drill Guide and associated accessories. Attach the End Cap to the proximal end of the Precice™ Max nail. Carefully irrigate the surgical site to remove any remaining bone fragments.
13. Disassemble the Drill Guide in reverse order from Step 10 prior to cleaning. Clean instruments after use, without allowing instruments to completely dry prior.
14. Locate the center of the implanted magnet and mark the patient's skin with indelible marker at this location.
15. Close and dress the site using standard techniques.
16. 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, or OM0017) prior to performing an adjustment of the Precice™ Max 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™ Max 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.
6. The 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. Weekly X-ray imaging to assess actual distraction length, bone regenerate, and device integrity is recommended. There should be consideration for onset of pain in regular follow ups.

IMPLANT REMOVAL PROCEDURES

1. At the time deemed appropriate by the physician, remove the Precice™ Max nail using standard surgical technique.
2. Follow all cleaning and sterilization procedures to prepare the instruments prior to removal.
3. Access the distal end of the Precice™ Max nail and attach the removal instrumentation.
4. Once all of the locking screws have been removed, the Precice™ Max nail can be removed by using the removal tool assembly which consists of the locking rod, removal rod and the slap hammer. Disassemble removal tool assembly prior to reprocessing after the removal surgery.
5. Close and dress the wound using standard surgical techniques.
6. Return the explanted product to NuVasive Specialized Orthopedics, Inc. following instructions provided. Please call 1-866-GLOBUS1 (OR) 1-866-456-2871 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.

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.

STORAGE/HANDLING/DISPOSAL

- Recommended to be stored at ambient temperatures with no special storage conditions required.
    - Ensure that the sterilized tray is stored in areas that provide protection from dust, moisture, insects, and extremes of temperature and humidity.
    - 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: Return the explanted product to NuVasive Specialized Orthopedics, Inc. following instructions provided. Please call 1-866-GLOBUS1 (OR) 1-866-456-2871 to obtain instructions or if you have any questions.

CLEANING AND DECONTAMINATION FOR NON-STERILE INSTRUMENTS

The Precice™ Max Nail is provided sterile. Precice™ Max Screws and End Caps may be provided sterile or nonsterile. Implants are intended for single use only. Sterile implants should NOT be re-sterilized. Return the explanted product to NuVasive Specialized Orthopedics, Inc. following instructions provided.

All non-sterile instruments must first be thoroughly cleaned using the validated methods prescribed in the NuVasive Cleaning and Sterilization Instructions (doc #9400896) 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. Contact your local representative or NuVasive directly for any additional information related to cleaning of NuVasive surgical instruments.

Instruments should always be thoroughly inspected before each use and after a cleaning cycle for broken, worn or damaged instruments. Discontinue use of the device if visible signs of wear are present. This includes cracking, peeling, flaking, rusting, and/or discoloration. Damaged or non-functional instruments should be returned to NuVasive 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 4: 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. 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 5: 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. 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™ Max Nail is provided sterile. Precice™ Max Screws and End Caps may be provided sterile or nonsterile. Implants are intended for single use only. Sterile implants should NOT be re-sterilized. Return the explanted product to NuVasive Specialized Orthopedics, Inc. following instructions provided.

The Precice™ Max nail is provided sterile (gamma sterilization). DO NOT re-sterilize.

All non-sterile implants and instruments are sterilizable by steam autoclave using standard hospital practices, in addition to NuVasive's validated parameters. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the parameters prescribed in the NuVasive Cleaning and Sterilization Instructions (doc #9400896), found on the NuVasive Website, www.nuvasive.com/eifu.

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 or Globus Medical for a specific system should not be used.

For standard open cases, devices are to be packaged in a FDA-cleared sterilization wrap prior to placement in an autoclave.

For information regarding closed cases, please refer to appropriate Instructions for Use provided by the closed case manufacturer.

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 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 and the competent authority of the Member State in which the user and/or patient is established.

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 directly at 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 representative.

℞ only