NuVasive Specialized Orthopedics, Inc.

Precice® Plating System Instructions for Use

Product Description:
The Precice Plating System is comprised of an implantable plate, screws, reusable instruments, and a hand-held External Remote Controller (ERC). The Precice Plate is a sterile single use device that is surgically affixed to the indicated bone(s) using locking and non-locking screws and instrumentation. Following implantation, the Precice Plating System utilizes distraction osteogenesis to lengthen the limb. The ERC can be programmed to the specific needs of the patient and is used daily after implantation to non-invasively lengthen or shorten the implant to a prescribed length.

The Precice Plate's internal mechanism includes a small magnet and gearing system. To adjust the Precice Plate's length, the External Remote Controller (ERC) is positioned against the skin over the implant. Magnet(s) inside the ERC magnetically couple with the corresponding magnet inside the Precice Plate. When the ERC is actuated, the ERC's magnets will rotate the plate's magnet/drive mechanism to either lengthen or shorten the plate.

Over a period of days, weeks, or months, sequential distractions with the ERC are used to produce the target limb length or compensate for any length discrepancies encountered during the fracture reduction process. The Precice Plate remains implanted until bone consolidation has been completed. Once the physician determines that the plate has achieved its intended use and is no longer required, it is removed using standard plate extraction surgical techniques.

Intended Use:
The Precice Plate is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, and non-unions of long bones, in pediatric and small stature adult patients.

Contraindications:

- Infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device.
- Patients with Gustilo-Anderson open fracture Classification Grade IIIB or IIIC fractures
- Metal allergies and sensitivities.
- Patients whose distance from the skin surface to the Precice Plate is greater than the maximum ERC soft tissue gap limitation.
- Patients with an irregular bone shape/size that would prevent accurate placement of the Precice Plate.
- Patients whose condition tend to retard healing such as blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity.
- Patients unwilling or incapable of following postoperative care instructions.

Warnings:

- The Precice Plate is not designed to withstand the stresses of weight bearing. For humeral applications, patients should limit use of the treated limb and should not stress or bear any weight on the treated limb unless instructed by a physician. Patients should utilize external support and/or restrict activities until consolidation occurs.
- Patients with an open fracture resulting in limb length discrepancy may also have soft tissue damage 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.
- Do not use if the sterile packaging has been damaged or has been opened.

- Metallic implants can loosen, fracture, corrode, migrate, or cause pain.
- Due to the presence of a magnet, use of the Precice Plate is not recommended in patients with pacemakers.
- Use of the Precice Plate 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.
- The Precice Plate is supplied sterile and is for single use only. The Precice Plate has not been tested to be cleaned or sterilized for multiple uses. If the Precice Plate is used more than once, the device may not be sterile and could cause a serious infection.
- The Precice Plate is unsafe in Magnetic Resonance Imaging environments.
- The Precice Screws may be provided sterile or non-sterile, take careful note to read packaging if screw is provided sterile or non-sterile.
- 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 Plate should only be retracted by the physician. Retraction should be monitored and confirmed using radiography or on the back table with the Precice Fast Distractor.
- Humeral distraction with the Precice Plate may cause traction on nerves.
- If 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 will require assistance from another person when using the Precice Plate and ERC to lengthen the humerus.

Precautions:

- 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) Operator's Manual for operation of the External Remote Controller.
- During the distraction phase, patient should avoid high risk activities such as contact sports. These activities may resume upon sufficient bone consolidation, but only as determined by the physician.
- Examine all Precice Plate system components carefully prior to use to allow for proper working condition. If you suspect a component to be faulty or damaged, do not use.

Cautions:

- The Precice Plating 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 Plate, as materials will be attracted to each other.
- Do not bend the Precice Plate or otherwise modify or damage the implant.
- Follow the ERC Operators Manual to confirm alignment between the ERC and magnet of the Precice Plate.
- Physical therapy before, during and after treatment, and progressive weight bearing instructions should be at the discretion of the surgeon.
- Physical therapy should be considered prior to the lengthening procedure to address abnormally tight muscular, tendinous structures.
- It is the surgeon's responsibility to discuss all relevant risks with the patient prior to surgery.
- Take care to avoid notching and bending implants. Screw fracture or stripping may occur if excessive torque is applied during insertion.
- To avoid damage to the plate, the construct cannot be constrained while performing the osteotomy. It is highly recommended that screws be temporarily removed to un-constrain the construct when performing the osteotomy.
- When moving the plate to perform the osteotomy, it is recommended that the osteotomy location be marked prior to removing the plate. Careful planning of the osteotomy location is critical to avoid bone fracture at the screw sites adjacent to the plate's distraction gap.
- It is recommended that distal tibial osteotomies are not performed when using the PRECICE Plate.

Procedures

Careful pre-operative diagnosis and planning, meticulous surgical technique, and extended postoperative care by experienced surgeons are essential to procedure success. Prior to use, the surgeon should be specifically trained in the use of the Precice Plating System along with the associated instruments to facilitate correct selection, placement and security of the implant.

Implantation Procedure

The Precice Plate can be applied with conventional open or percutaneous techniques. These plates may be used in conjunction with other treatment modalities for deformity correction at the discretion of the treating physician.

Limb lengthening applications

Prior to any lengthening procedure, a careful examination of the limb should be conducted to identify abnormally tight structures. Certain tough fibrous bands and musculotendinous structures have a tendency to create deformities during lengthening. Prophylactic soft tissue releases should be considered to reduce the likelihood of bone deformity and soft tissue contractures, subluxations, and dislocations.

1. Thoroughly clean the instruments according to the parameters in Table 1 or 2 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 locking screws (if provided non-sterile) and instrument trays prior to the procedure. The Precice Plate is provided separately in sterile packaging. Due to the mechanical complexity of the Precice Plate, it is recommended to have a spare implant available for each surgery. Screws are provided non-sterile or sterile, check labeling before proceeding.
4. Determine the best implant type considering the amount of length needed, the ideal location of the osteotomy, and the patient's boney contouring.
5. Incision size and type are indication-specific and can also vary according to surgeon preference.
6. The plate is slowly inserted into the incision and carefully tunneled along the periosteum. Fluoroscopy may assist the surgeon in guiding the plate into position. Once the plate is fully advanced, it can be provisionally affixed to bone.
7. Once templated, remove the plate to improve visibility and access to the osteotomy location Create an osteotomy at the appropriate location. 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.
8. Position the plate on the appropriate aspect of the bone. Adjust the Precice Plate into the final position and use fluoroscopy to confirm proper alignment.
9. Screw holes are prepared and filled with screws in a stepwise fashion.
    - Thread the locking drill guide to plate hole being prepared. Taking care not to over-plunge into soft tissues, pass the drill bit through the guide, penetrating the bone.
    - Once the proper screw length is determined, the screw is introduced until the head securely engages and seats within the hole of the plate.
    - Once all screws are introduced, final tightening can ensue to confirm all are sufficiently locked to the plate.
10. The final construct is evaluated for stability and proper alignment on x-ray.
11. Locate the center of the implanted magnet and mark the patient's skin with indelible marker to denote the ERC application site.
12. The Precice Plate should be tested with the ERC before the patient leaves the operating room. One to two millimeters of distraction is typically enough to observe if the implant is functioning properly. This can be visualized directly at the osteotomy site or on fluoroscopy.
13. Once plate function is verified, the surgical site is irrigated and closed in the standard fashion with sterile dressing applied post closure.
14. Instruct the patient to maintain the indelible mark at the same location on their limb to ensure the ERC is applied to the correct location for the duration of treatment.

Fracture reduction applications

1. Thoroughly clean the instruments according to the parameters in Table 1 or 2 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 locking screws (if provided non-sterile) and instrument trays prior to the procedure. The Precice Plate is provided separately in sterile packaging. Due to the mechanical complexity of the Precice Plate, it is recommended to have a spare implant available for each surgery. Screws are provided non-sterile or sterile, check labeling before proceeding.
4. Determine the best implant type considering the fracture pattern, the ideal location of the

compression/distraction gap, and the patient's boney contouring.

5. Once the incision is made, the plate is slowly inserted and carefully tunneled along the periosteum. Fluoroscopy may assist the surgeon in guiding the plate into position. Once the plate is fully advanced, it can be provisionally affixed to bone. Intra-articular fracture components should be addressed with supplemental fixation as needed prior to application of the Precice Plate.
6. Position the plate on the appropriate aspect of the bone. Adjust the Precice Plate into the final position and use fluoroscopy to confirm proper alignment.
7. Screw holes are prepared and filled with screws in a stepwise fashion.
    - Thread the locking drill guide to plate hole being prepared. Taking care not to over-plunge into soft tissues, pass the drill bit through the guide, penetrating the bone.
    - Once the proper screw length is determined, the screw is introduced until the head securely engages and seats within the hole of the plate.
    - Once all screws are introduced, final tightening can ensue to confirm all are sufficiently locked to the plate.
8. The final construct is evaluated for stability and proper alignment on x-ray.
9. Locate the center of the implanted magnet and mark the patient's skin with indelible marker to denote the ERC application site.
10. The Precice Plate should be tested with the ERC before the patient leaves the operating room. One to two millimeters of distraction is typically enough to observe if the implant is functioning properly. This can be visualized directly at the fracture site or on fluoroscopy. Once the implant is confirmed functional, the Precice Plate is retracted to compress the fracture before the incision is closed.
11. Once plate function is verified, the surgical site is irrigated and closed in the standard fashion with sterile dressing applied post closure.

12. Instruct the patient to maintain the indelible mark at the same location on their limb to ensure the ERC is applied to the correct location for the duration of treatment.

Post-Operative Procedures

1. Read the External Remote Controller (ERC) Operator's Manual prior to performing an adjustment of the Precice Plate.
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 Plate is located. Carefully place the ERC comfortably but firmly over this area in the correct orientation.
4. Compress or distract the implant to the desired amount, as viewed on ERC display screen. Compression 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 for long bones, 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 is recommended.

Implant Removal Procedures

At the time deemed appropriate by the physician, the Precice Plate can be removed.

1. Follow all cleaning and sterilization procedures to prepare the instruments prior toremoval.
2. Once all screws have been removed, the Precice Plate is explanted.
3. Close and dress the wound using standard surgical techniques.
4. Return the explanted product to NuVasive Specialized Orthopedics, Inc. Please call 1-855-435-5477 to obtain instructions or if you have any questions.

Cleaning and Sterilization Instructions

The Instrument Tray, Locking Screw Tray (if screws are provided non-sterile), and instruments are provided non-sterile and must be cleaned and sterilized prior to use. Locking Screws are provided non-sterile or sterile, check labeling before proceeding. Sterilization instructions only pertain to non-sterile locking screws.

Thoroughly clean and inspect the trays and instruments for damage prior to loading, wrapping, and sterilization. Disassemble the Instrument Tray and Locking Screw 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.

The recommended cleaning instructions for the Instrument Tray, Locking Screw Tray, and instruments are as follows:

Table 1: 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 2: 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 soil.
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 Instructions:

After cleaning the instrument tray and instruments, prior to sterilization, inspect all parts of the tray and instruments for damage. A functional inspection should also be performed where possible. Mating devices should be checked for proper assembly and devices with moving parts should be operated to check for correct operation. Load the base tray with the specified instruments or locking screws 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 Instrument and Locking Screw Trays have been qualified to be sterilized in a double wrapped configuration with a legally marketed, FDA cleared sterilization wrap (Such as CSR Wrap), using the following steam sterilization cycle:

Table 3: Double Wrapped Sterilization Recommendations:

	Minimum Sterilization Temperature	Sterilization Time (Minutes)	Drying Time (Minutes)	Cool Down Time (Minutes)	Maximum Tray Weight
Pre-vacuum steam sterilization cycle	132° C	4	Minimum 30	Minimum 40	25 lbs

Precaution:

When sterilizing instruments and locking screws, do not load the tray more than the weight specified in Table 3 above.

Limits of Reuse:

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:

Recommended storage of the Instrument Tray is at controlled ambient temperature 20°-24°C (68°-75°F). Ensure that the sterilized tray is stored in areas that provide protection from dust, moisture, insects, and extremes of temperature and humidity.

MRI Information:

- The Precice Plate is MR Unsafe.
- A patient with the implanted Precice Plate must not come near an MRI scanner and must not undergo an MRI scan.

Other Information:

- Upon removal from the package, compare the descriptions on the label with the package contents (product number and size)
- Packages for each of the components should be intact upon receipt. All implants should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to NuVasive Specialized Orthopedics.
- The Precice Plate is provided sterilized by Gamma Irradiation Sterilization.
- Please refer to the package label for the expiration date of the Precice Plate.
- The Precice Plate is for Single Use Only.
- Do not sterilize the ERC.
- Do not attempt to re-sterilize the Precice Plate. Steam or Ethylene Oxide gas will not reach the internal components of the Precice Plate.
- Do not use if package is damaged or sterile barrier is broken.

Table 6: Symbols Definition:

Symbol	Definition
	Unsafe in Magnetic Resonance Imaging (MRI) Environments
	For Single Use Only, Do not re-use
	Do not use if package is damaged
	Do not Resterilize
	Non-Sterile
Rx Only/ 	Federal (US) law restricts the sale of this device for use by or on the order of a physician.
	Manufacturer
	Date of Manufacture
REF	Model Number
LOT	Lot Number
 www.nuvasive.com/eifu	See Instructions For Use www.nuvasive.com/eifu
	Expiration Date
STERILE R	Sterilized by Gamma Irradiation

Manufacturer:

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