NuVasive Specialized Orthopedics

Precice™ Bone Transport System Instructions for Use

Product Description:

The **Precice™ Bone Transport System** is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The Precice™ Bone Transport Nail is a sterile, single-use device that is surgically implanted using the instruments and locking screws for osteoplasty lengthening and bone transportation utilizing distraction osteogenesis and compression. The Precice™ Bone Transport implants are manufactured from stainless steel (BioDur 108 Alloy) per ASTM F2229. The ERC is used daily after implantation to non-invasively adjust the position of the distraction rod.

During the implantation procedure, the nail can be adjusted to provide an appropriate amount of compression or distraction for transport of the intercalary segment to the docking segment. Following implantation, the Precice™ Bone Transport System utilizes distraction osteogenesis to lengthen the bone. Traditional intramedullary surgical techniques are used to implant and secure the proximal, distal and intercalary sections of the Precice™ Bone Transport nail to the target bone. The Precice™ Bone Transport 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 retract or distract the distraction rod of the nail.

During the surgical implantation procedure and after the nail has been secured to the bone, the distraction rod can be adjusted up to 100mm for femoral and tibial implants to transport and compress the intercalary segment to the docking segment. Over a period of days, weeks, or months, sequential compressions or distractions are used to transport and compress the intercalary segment to the docking segment of the bone to promote healing of the bone. The Precice™ Bone Transport 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.

Intended Use:

The Precice™ Bone Transport System is intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones.

Contraindications:

- Infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device.
- Patients with Gustilo open fracture Classification Grade IIIB or IIIC fractures
- Patients with pre-existing nerve palsies
- Metal allergies and sensitivities.
- Patients with an irregular bone diameter that would prevent insertion of the Precice™ Bone Transport nail.
- Patients in which the Precice™ Bone Transport nail would cross joint spaces or open epiphyseal growth plates.
- Patients with conditions that 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.
- Patients with maximum bone defect of more than 100 mm.
- Patients with excessive skin damage and inadequate soft tissue covering of the fracture sites.

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.

Limb	Precice™ Bone Transport Model	Nail Diameter (mm)	Maximum Distance of Treated Limb Surface to IM Canal (ERC1, ERC2P, ERC3P)	Maximum Distance of Treated Limb Surface to IM Canal (ERC4P)	Max. Patient Weight Bearing *Use with partially threaded screws*	Max. Patient Weight Bearing *Use with fully threaded screws*
Tibia	C, SJ	10.0	13mm	19mm	25lbs/11kg	25lbs/11kg
		11.5	13mm	19mm	190lbs/86kg	125lbs/57kg
		13.0	13mm	19mm	250lbs/114kg	125lbs/57kg
Femur	A, B, BT, D, DT, E, V, X, SE, SB, SD, SA	10.0	51mm	64mm	25lbs/11kgs	25lbs/11kg
		11.5	57.2mm	69mm	190lbs/86kg	125lbs/57kg
		13.0	76mm	85mm	250lbs/114kg	125lbs/57kg

Warnings:

- The Precice™ Bone Transport System cannot withstand the stresses of full weight bearing. The patient should progressively weight bear and use assistive devices as directed by the physician.
- Patients should utilize external support and/or restrict activities as directed by the physician until consolidation occurs.
- 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 prior to procedure to minimize the risk of infection.
- The surgeon should closely monitor lengthening progress particularly for longer bone segments or mobilization lengths to prevent incomplete transport.
- The surgeons should account for potential difficulty in removal of the nail due to ingrowth into the slot feature of device.
- 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™ Bone Transport System is not recommended in patients with pacemakers.
- The Precice™ Bone Transport System may not be appropriate for patients with poly-trauma.
- Use of the Precice™ Bone Transport System in patients with an active infection of the treated bone is not recommended.
- Overream the medullary canal by 2 mm to allow the transported segment to move freely over the nail.
- Patients treated with Precice™ Bone Transport may need secondary surgery to ensure union at the distal docking site.
- 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™ Bone Transport 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 provided sterile or non-sterile, take careful note to read packaging if the implant 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
- Patients with implanted Precice™ Bone Transport nail should not enter an MRI unit.



- The Precice™ Bone Transport System is unsafe in Magnetic Resonance Imaging environments.
- 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.

Precautions:

- It is recommended that ancillary fixation (e.g. plates, external fixation, cable and pulley system etc.) bridges the defect site.
- Do not use this device without proper training in both device implantation and adjustment. Refer to External Remote Controller (ERC, ERC 2P, or ERC 3P) Operator's Manual (OM0005, OM0009, OM0016, or OM0017) for operation of the External Remote Controller.
- Prior to bone consolidation, the patient should not participate in contact sports or other high risk activities that will cause more than 20% of the body weight to be loaded on the treated limb. These activities may resume upon sufficient bone consolidation, but only as directed by the physician.
- Examine all Precice™ Bone Transport System components carefully prior to use to assure proper working condition. If you suspect a component to be faulty or damaged, do not use.

Cautions:

- The Precice™ Bone Transport System is for prescription use only by the order of a physician.
- Device is recommended to 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™ Bone Transport 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™ Bone Transport nail or otherwise modify or damage the implant.
- Follow the ERC Operators Manual (OM0005, OM0009, OM0016, or OM0017) to assure proper alignment between the ERC and magnet of the Precice™ Bone Transport nail.

Stainless Steel Locking Screw Compatibility

Nail Diameter (mm)	Screw Position	Screw Diameter	Screw Type	Screw Lengths (mm)
10.0 11.5 13.0	Proximal Locking/ Distal Locking	5.0 mm	Partial Thread	20-80
			Full Thread	20-100
10.0 11.5 13.0	Distraction Rod	3.5 mm	Partial Thread	20-60

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™ Bone Transport System along with the associated instruments to facilitate correct selection, placement and security of the implant.

Implantation Procedure

For transport applications:

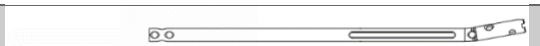
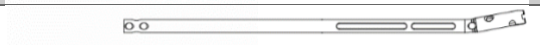
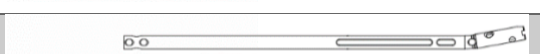
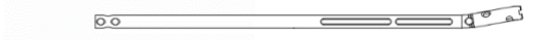
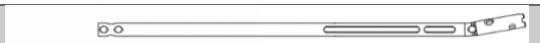
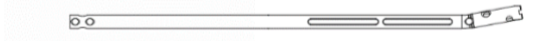
1. Thoroughly clean the instruments according to the parameters in Table 1 or 2 prior to sterilization.
2. Inspect the instruments after cleaning to check for damage prior to sterilization. Functional check should include ensuring mating instruments can be properly assembled and instruments with moving parts are operated to ensure correct operation.
3. Sterilize locking screws and end caps (if provided non-sterile) and instrument trays prior to the procedure. The Precice™ Bone Transport Nail is provided separately in sterile packaging. The Precice™ Screws and End Caps may be provided non-sterile or sterile, check labeling before proceeding.
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 inter-fragmentary 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. Resect the affected bone segment using standard surgical technique. Prepare the bone ends perpendicular to the anatomical axis to allow for bone contact during the docking phase.
8. Determine the appropriate nail size and configuration to be used.
    - The length and position of the intercalary slot is dependent on the implant length. It is recommended to select an implant length that will provide the appropriate amount of transport distance needed for the procedure, as well as facilitate the appropriate position of the corticotomy. The Precice™ Fast Distractor (ref. LC0251) may be used to position the distraction rod to the optimal position
9. Use standard surgical techniques to provide for adequate venting of the intramedullary canal during surgery.
10. Identify and access the appropriate entry point for the delivery technique chosen (i.e., antegrade or retrograde).
11. 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.

12. 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.
13. Ream the intramedullary canal sequentially in half millimeter increments to 2 mm larger than the selected nail diameter.
14. Secure the appropriate Bone Transport Template Nail (Bent or Straight) to the Drill Guide using the locking bolts.
15. Insert the assembled Template Nail into the medullary canal under image intensification. Advance the Template Nail until the device is properly positioned. Using a drill bit, locate the planned corticotomy location and make an entry hole through the bone to mark the location.
16. Withdraw the Template Nail and disassemble it from the Drill Guide. Complete the corticotomy using osteotomes and verify the corticotomy is completely circumferential.
17. Secure the Precice™ Bone Transport Nail to the Drill Guide using the locking bolts. Insert the assembled implant into the medullary canal under image intensification until the implant is properly positioned.
18. Using the Drill Guide mounted to control alignment, secure the proximal portion of the nail 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.
19. Using a free hand technique and fluoroscopic imaging, secure the distal portion of the nail using distal locking screws of appropriate length. The head of the screw should be flush with the bone surface.
20. Using a free hand technique and fluoroscopic imaging, secure distraction rod using locking screws of appropriate length. The head of the screw should be flush with the bone surface.
    - If the transport requires the use of both intercalary slots of the nail, then only the proximal intercalary screw is used during the transport phase. An additional surgery will be needed during the transport phase to exchange the position of the intercalary screw.
21. Ancillary fixation should be used to bridge the defect site. Select one or more of the ancillary fixation options based on patient anatomy, location of defect and patient history. While using a supplemental plate as ancillary fixation, blocking screws should be placed using a free hand technique and fluoroscopic imaging. Note that the Bone Transport Templates should not be used during placement of blocking screws as the template diameter is less than the Precice™ Bone Transport implants. The supplemental plate should be fixated after both the Precice™ Bone Transport device and blocking screws are placed. It is advised that the locking screws of the plate are inserted anterior to the device. External fixation or cable and pulley system could be used in conjunction with the Precice™ Bone Transport device for larger segmental defects at surgeon's discretion.
22. 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™ Bone Transport Nail. Carefully irrigate the surgical site to remove any remaining bone fragments.
23. Disassemble the Drill Guide in reverse order from Step 14 prior to cleaning. Clean instruments after use, without allowing instruments to completely dry prior.
24. Locate the center of the implanted magnet and mark with indelible marker.
25. Close and dress the site using standard techniques.
26. Instruct the patient to maintain the indelible marker mark at the same location.

Screw Exchange Procedure

Depending on the segmental defect, both intercalary slots might be required. Below are the detailed steps to utilize the second intercalary slot.

NOTE: Defects less than 70mm do NOT require a screw exchange procedure.

Nail Length (mm)	Max Defect Size (mm)	Max Transport before Screw Exchange (mm)	Housing Tube Intercalary Slot Configuration
280	60	60*	
300	70	50	
		70*	
320	80	50	
		70	
340	90	50	
		70	
360	100	50	
		70	
380	100	50	
		70	
400	100	50	
		70	

*Screw exchange not required.

1. If both intercalary slots are needed to complete the full transport distance, the progress should be checked regularly under fluoroscopy to monitor when the intercalary screw has reached the end of the first intercalary slot.
2. Verify the second locking hole in the distraction rod is visible within the second intercalary slot.
3. Using a free hand technique and fluoroscopic imaging, secure the second locking hole of the transport rod using a locking screw of appropriate length. The head of the screw should be flush with the bone surface.
4. Remove the first intercalary locking screw. Close and dress the site using standard technique, and resume transport according to the Post-Operative Procedures.
   - **Note:** It is important that the screw exchange is performed in the specified order, to maintain the fixation and position of the intercalary segment.

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™ Bone Transport 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™ Bone Transport nail is located. Carefully place the ERC firmly but comfortably over this area in the correct orientation.
4. Shorten or lengthen the implant to the desired amount, as programmed by the physician and viewed on ERC display screen.
5. Carefully place the ERC back in its storage container and close.

6. The progress should be checked regularly against follow-up radiographic evidence of the rate of transport and the quality of the regenerate. While 1 mm per day is generally recommended, clinical and radiographic examination may show that transporting should progress at a faster or slower pace. Weekly X-ray imaging to assess actual transport length is recommended.

Implant Removal Procedures

1. At the time deemed appropriate by the physician, remove the Precice™ Bone Transport nail using standard surgical technique.
2. Follow all cleaning and sterilization procedures to prepare the instruments prior to removal.
3. Access the proximal end of the Precice™ Bone Transport nail and attach the removal instrumentation.
4. Remove one distal locking screw. Using the Precice™ Bone Transport removal instruments, insert the retention plug into the vacant hole. Confirm full seating of the retention plug under fluoroscopy. Once correct placement and complete seating is confirmed, the remaining screws can be removed.
5. Once all the locking screws have been removed, the Precice™ Bone Transport 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.
6. Close and dress the wound using standard surgical techniques.
7. 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 Sterilization Instructions

The Instrument Tray, Implant Tray, and instruments are provided non-sterile and must be cleaned and sterilized prior to use.

Cleaning Instructions:

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

The Precice™ Bone Transport Nail is provided sterile. Precice™ Bone Transport Screws and End Caps may be provided sterile or non-sterile. Implants are intended for single use only. Sterile implants should NOT be re-sterilized.

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 Implant 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:

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

The Instrument Tray has also been qualified to be sterilized using Aesculap Rigid Containers, US only, using the following configurations and steam sterilization cycle:

Table 4: Aesculap Container Configurations

Base Options		
Description	**Aesculap NUVA PN**	**Nuva PN**
Solid Bottom 4.75"	JK442B (screen printed)	DM-JK442B
	JK442 (laser marked)	DM-JK442B
Lid Options		
Description	**Aesculap NUVA PN**	**Nuva PN**
Aluminum Lid (Purple)	XG349	8803001
Aluminum Lid (Silver)	JK489B	8803002

Table 5: Aesculap Rigid Container Sterilization Recommendations:

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

Precaution:

When sterilizing non-sterile instruments and implants, do not load the tray more than the weight specified in Table 3 or 5 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.

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.

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™ Bone Transport System is MR Unsafe.
- A patient with the implanted Precice™ Bone Transport nail 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™ Bone Transport nail is provided sterilized by Gamma Irradiation Sterilization.
- Please refer to the package label for the expiration date of the Precice™ Bone Transport nail.
- The Precice™ Bone Transport nail is for single-use only.
- Do not sterilize the ERC.
- Do not attempt to re-sterilize the Precice™ Bone Transport Nail. Steam or Ethylene Oxide gas will not reach the internal components.
- 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.globusmedical.com/eifu	See Instructions For Use www.globusmedical.com/eifu
	Expiration Date
STERILE R	Sterilized by Gamma Irradiation

Manufacturer:

Nuvasive Specialized Orthopedics, Inc.
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403

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