NuVasive
Specialized Orthopedics™

PRECICE®

ADJUSTABLE SOLUTIONS
FOR ORTHOPEDICS

Antegrade Tibia Operative Technique

NuVasive
Specialized Orthopedics™

CONTENTS

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

This Surgical Technique offers guidance but, as with any such technique guide each surgeon must consider the particular needs of each patient and make appropriate clinical decisions as required.

All non-sterile devices must be cleaned and sterilized before use. Multi-component instrument assemblies must be disassembled prior to cleaning. Please refer to the corresponding Instructions For Use.

It is the surgeon's responsibility to discuss all relevant risks with the patient prior to surgery.

THE PRECICE® SYSTEM

is the latest advancement in lengthening osteoplasty utilizing distraction osteogenesis. Interaction between magnets in the device and an External Remote Controller (ERC) allow for precise, adjustable, and customizable distraction throughout the lengthening phase of treatment.

Following osteotomy and during the lengthening phase, the PRECICE implant is gradually lengthened based on the patient's requirements with the hand-held ERC. The patient's lengthening prescription can be entered in to the ERC, by their physician. When the desired length is achieved, intramedullary fixation continues to provide stability throughout the consolidation phase.

PRECICE SYSTEM COMPONENTS

The PRECICE System is comprised of the following components:

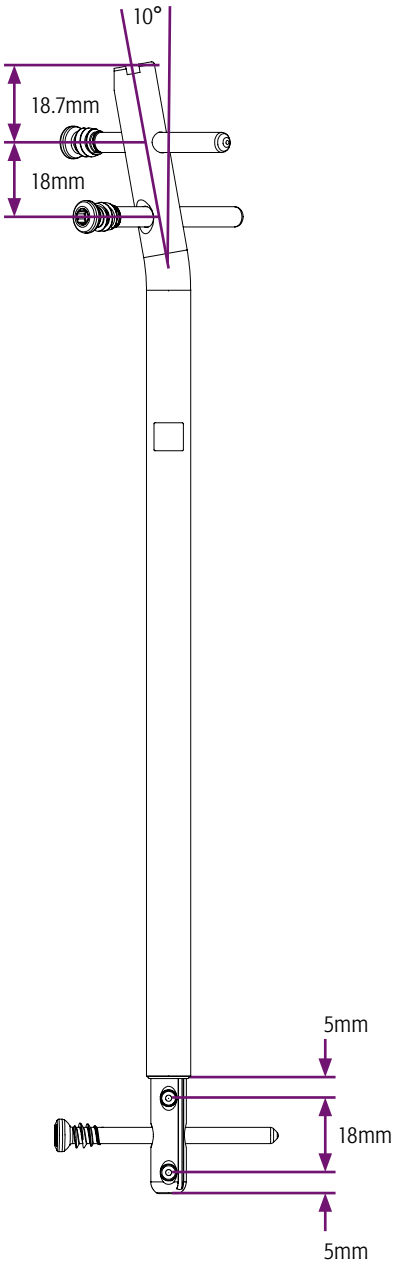
- Intramedullary Nail
- Proximal and Distal Locking Screws
- End Cap (Optional)
- Instrument Tray
- External Remote Controller (ERC)

INTRAMEDULLARY NAILS

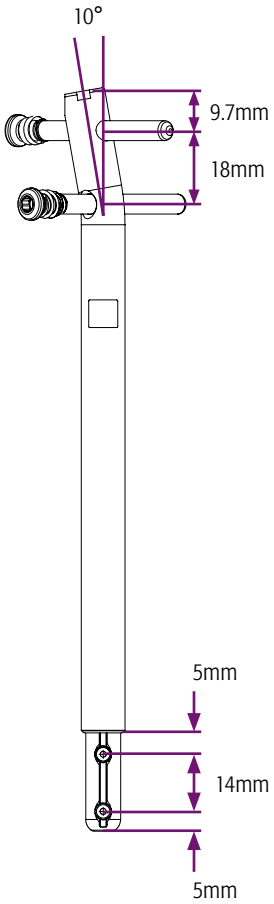
Diameter 8.5, 10.7, and 12.5mm
Sizes 155–365mm

ANTEGRADE TIBIA

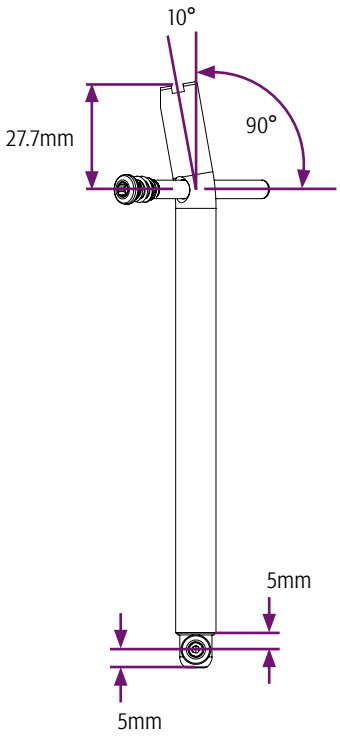
365mm – 195mm



180mm



155mm



FULLY THREADED SCREWS

4.0mm Fully Threaded Screw
Length: 20–50mm (2.5mm increments)
50-100mm (5.0mm increments)

Core Diameter: 3.4mm

5.0mm Fully Threaded Screw
Length: 20–50mm (2.5mm increments)
50-100mm (5.0mm increments)

Core Diameter: 4.3mm

LOCKING SCREWS

3.5mm Locking Screws
Length: 20–60mm

4.0mm Locking Screws
Length: 20–60mm

5.0mm Locking Screws
Length: 20–75mm

Telescoping Rod Diameter (Male)

8.5mm Nail: 6.5mm
10.7mm Nail: 8.5mm
12.5mm Nail: 10.0mm

End Cap

Diameter: 10.7 and 12.5mm

Note: the 10.7mm end caps are compatible with the 8.5 PRECICE devices

Sizes

0mm 5mm 10mm 15mm 20mm

LIMB LENGTH DISCREPANCY CALCULATION

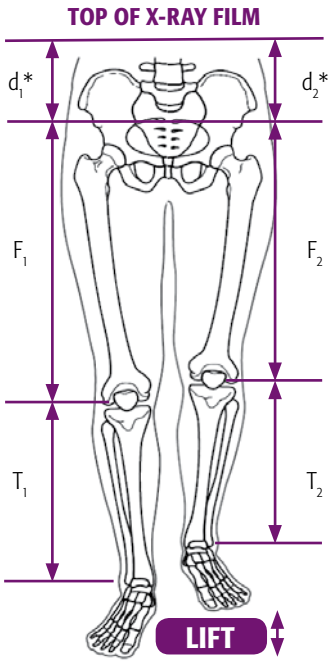
Careful preoperative evaluation and planning, proper surgical technique, and extended postoperative care are essential for success of limb lengthening procedures.

Preoperative evaluation is performed to determine:

- Limb length discrepancy
- Intramedullary diameter
- Required implant length
- Osteotomy location of tibia
- Soft tissue assessment

DIAMETER (mm)	LENGTHS (mm)	MAXIMUM DISTRACTION (mm)	PROXIMAL BEND	LOCKING SCREWS (mm)	FULLY THREADED SCREWS (mm)
8.5, 10.7, and 12.5	*155, 180, 195, 215, 230, 245, 275, 305, 335, 365*	*50 and 80*	*10°*	*3.5, 4.0, and 5.0*	*4.0 and 5.0*

Digital templates for the PRECICE® implants can be found in TraumaCad® software. As an alternative, the Limb Length Discrepancy Calculation can aid in calculating femoral limb length discrepancies and determine which PRECICE implant is needed. Tibial and femoral lengths calculate segmental differences which helps to determine which segment to address.



CONTRALATERAL LIMB (mm)		TREATMENT LIMB (mm)	
d_1=		d_2=	
F_1=		F_2=	
T_1=		F_2=	

*d1 and d2 are measured from the sacroiliac (SI) joint line reference line to the top of the x-ray image; use a magnification marker on x-ray image to improve the accuracy of measurements

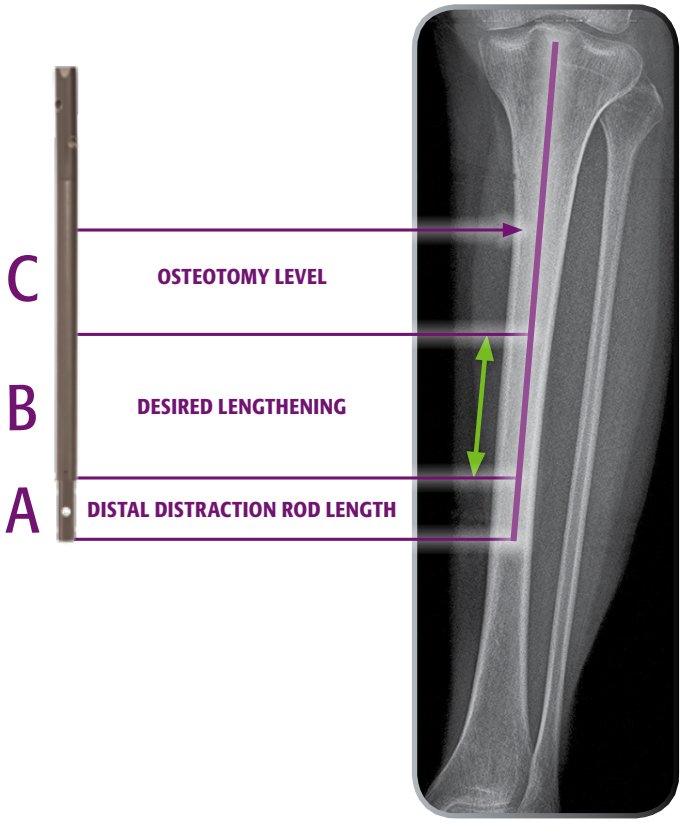
Limb Length Discrepancy = (d2-d1) + LIFT =

OSTEOTOMY CALCULATION

These are general guidelines. The osteotomy level may be influenced by the presence of a sagittal or frontal plane deformity that may require correction. In all cases, it is imperative that adequate distal segment coverage be maintained at the end of lengthening for biomechanical stability.

The PRECICE® tibial implant is available in 8.5, 10.7, and 12.5mm diameters with a proximal 10° Herzog bend. Over reaming the intramedullary tibial canal by 2.0 mm is recommended to aide in implant insertion. The cortices should be at least 3mm thick at any location once reamed.

With radiographs that include a magnification marker, measure from the level of the joint line to the location of the distal end of the PRECICE implant.



Calculate the following to determine the measurement from the distal end of the implant.

	P2	SHORT GEN I	SHORT GEN II
A	3.0cm	2.4cm	1.0cm
B	Up to 8.0cm	Up to 5.0cm	Up to 5.0cm
C	4.0 – 5.0cm		

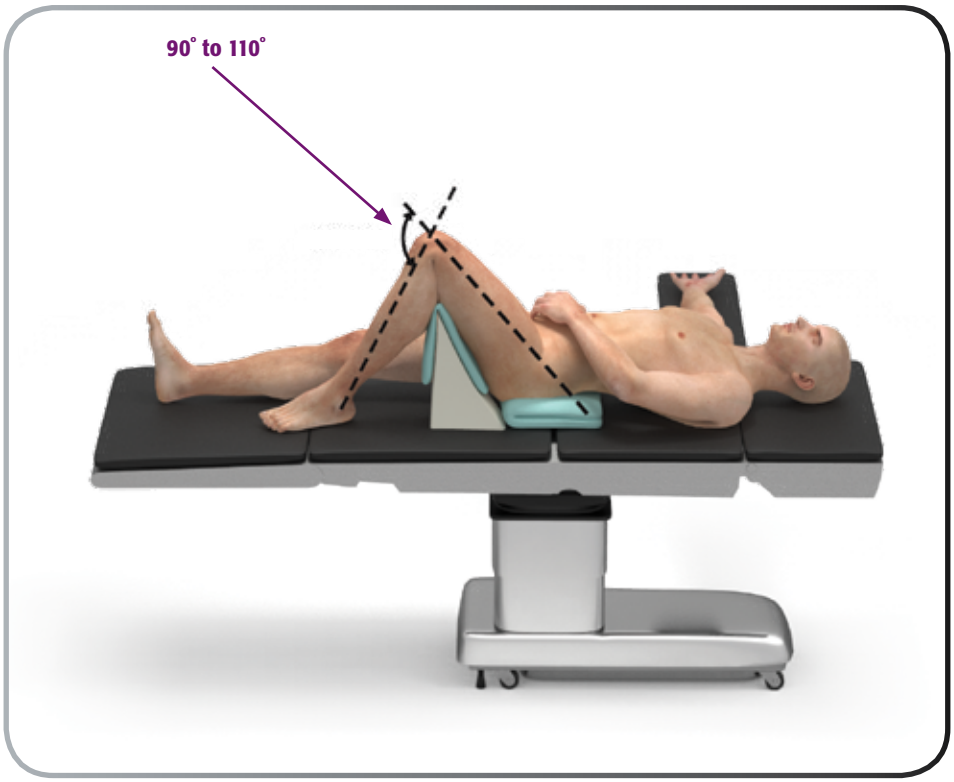
This measurement determines the suggested level of the osteotomy.

A + B + C = Measurement from the distal end of the implant to perform osteotomy

PATIENT POSITIONING

Place the patient supine on a radiolucent table and position the knee for a tibial nailing procedure. Position a small bump under the ipsilateral sacroiliac joint. A triangle may also be helpful for patient positioning and nail insertion. Fluoroscopic visualization of the entire tibia is essential and should be confirmed prior to prepping and draping the patient's entire limb from the iliac crest to the foot/ankle.

Locate the joint line using a wire or similar technique. Use a surgical marking pen to mark the site.



OSTEOTOMY OF THE FIBULA

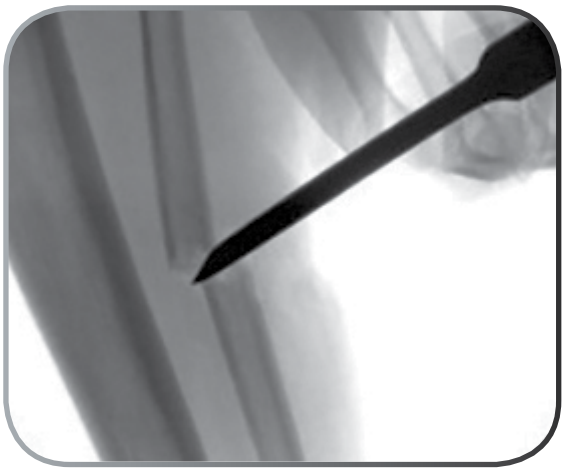
Osteotomy of the fibula is an essential surgical step when performing tibial lengthening.

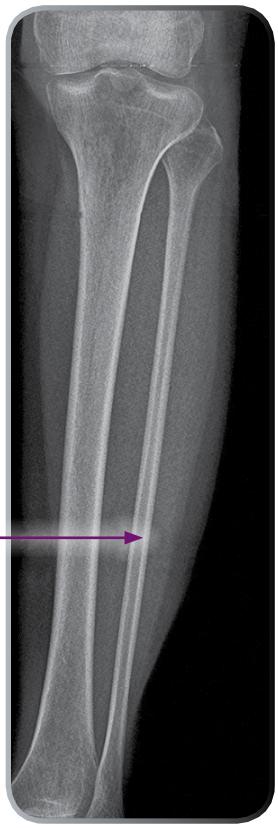
It is recommended that the fibula osteotomy be performed at a different level than the tibial osteotomy to reduce the risk of soft tissue swelling that may lead to compartment syndrome. The fibular osteotomy should not be performed within the proximal 13cm unless concurrent peroneal identification and decompression is performed.

Create a 2.5cm posterolateral incision at the junction of the middle and distal third of the fibula. Dissect the interval between the peroneal muscles and the soleus muscle along the posterolateral intramuscular septum. Lift the peroneal muscles anteriorly to expose the fibula. Using a small periosteal elevator carefully separate the periosteum from the bone of the fibula circumferentially. Insert two small retractors to protect surrounding tissues.

Using a Kirschner wire (K-wire), create multiple drill holes in the fibula at the site of the planned osteotomy.

Prior to completing the fibular osteotomy, use retractors to protect the peroneal artery and its two venae comitantes which are medial to the fibula. A small osteotome is used to complete the osteotomy.





Verify and confirm completion of the fibula osteotomy.

SOFT TISSUE AND NERVE RELEASE

Depending on clinical requirements, the surgeon may consider performing a gastrocsoleus recession (Vulpius procedure), a gastrocnemius fascia release,[1] proximal peroneal nerve release,[2] and insert a temporary calcanenal-tibial posterior screw to help prevent equinus from developing during tibial lengthening.[3]

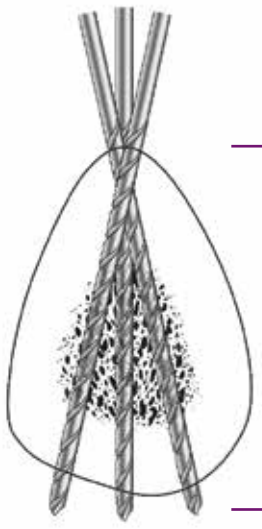
A prophylactic percutaneous anterior and lateral compartment fasciotomy should be performed. Prophylactic antibiotics should be given prior to elevating the tourniquet.

VENTING OF THE TIBIAL INTRAMEDULLARY CANAL

Intramedullary reaming of a closed bone generates high intramedullary pressures that have been associated with complications such as fat embolism.[4] To avoid these potential complications, place multiple venting holes in the tibia at the planned osteotomy site prior to reaming.

Make a 1.0cm incision over the anterior tibial crest at the determined osteotomy site. Elevate the periosteum medially and laterally with a small periosteal elevator. Using the 4.0 x 152mm Drill Bit or 5.0 x 152mm Drill Bit, make one entry hole anteriorly and three exit holes posteriorly.

- Venting reduces pressure on the bone marrow during reaming and implant insertion.
- Venting creates egress for bone marrow at the osteotomy site during reaming.
- Venting drill holes will facilitate the osteotomy.
- Reamings which exit the vent holes will act as prepositioned bone graft at the distraction gap.



[1]Herzenberg JE, Lamm BM, Corwin C, et al. Isolated recession of the gastrocnemius muscle: the Baumann procedure. *Foot Ankle Int* 2007;28(11):1154-9.
[2]Nogueira MP, Paley D, Bhave A, et al. Nerve lesions associated with limb-lengthening. *J Bone Joint Surg Am* 2003;85-A(8):1502-10.
[3]Belthur MV, Paley D, Jindal G, et al. Tibial lengthening: extraarticular calcaneotibial screw to prevent ankle equinus. *Clin Orthop Relat Res* 2008;466(12):3003-10.
[4]Kröpfl A, Berger U, Neureiter H, et al. Intramedullary pressure and bone marrow fat intravasation in unreamed femoral nailing. *J Trauma* 1997;42(5):946-54.

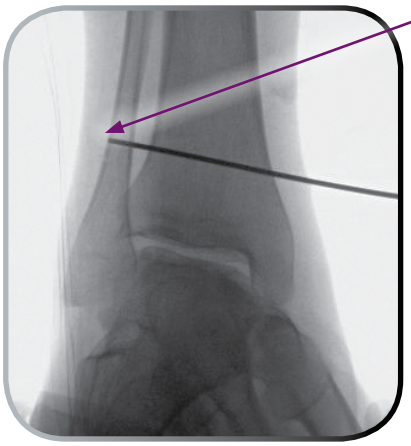
SYNDESMOTIC SCREWS

To enable the fibula to lengthen with the tibia and to provide stabilization, proximal and distal bone screws are used to secure the fibula to the tibia.

DISTAL SYNDESMOTIC SCREW

Care should be taken to stabilize the distal tibiofibular joint and the screw should be positioned prior to insertion of the PRECICE implant.

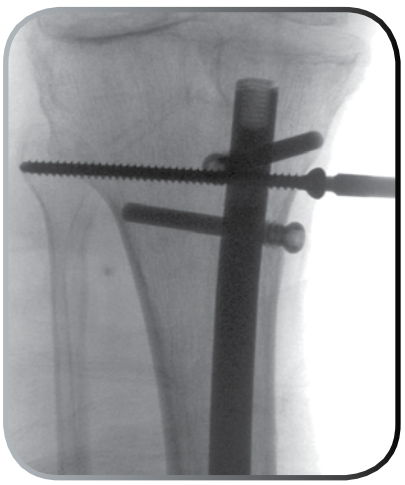
Insert a K-wire percutaneously into the distal fibula just above the distal syndesmosis. The K-wire is driven in either an oblique or transverse fashion in a proximal/medial direction through the tibia. The K-wire should emerge from the anteromedial surface of the tibia. Make a small incision where the K-wire exits medially and then drill in a retrograde direction with a cannulated drill bit through all four cortices. An appropriate length and diameter fully-threaded cortical screw is inserted from medial to lateral securing the distal tibiofibular joint. Confirm that threads engage all four cortices.



DISTAL SYNDESMOTIC SCREW LOCATION

PROXIMAL SYNDESMOTIC SCREW

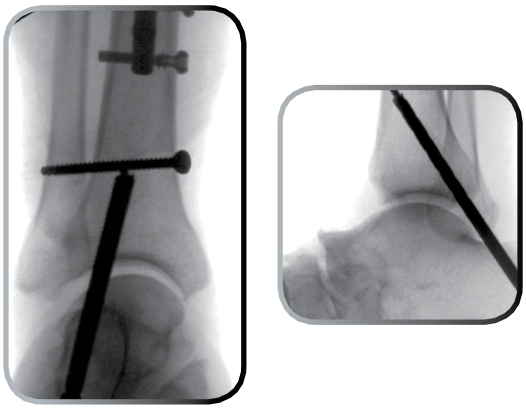
After the PRECICE implant has been positioned, a proximal screw can be inserted at the level of the fibular head (see page 18). Take care to avoid the peroneal nerve as it wraps around the fibular neck.



Proximal 5.0mm Locking Screws positioned with the addition of a proximal fibular syndesmotic screw placed posterior to the nail.

EXTRA-ARTICULAR CALCANEOTIBIAL SCREW

To help prevent equinus contracture, a temporary extra-articular screw may be used to stabilize the ankle joint during tibial lengthening. This example demonstrates the use of a cannulated fully threaded screw.



ENTRY POINT AND INTRAMEDULLARY REAMING

Flex the knee to assist in finding the proximal entry point. Insert a Steinmann pin percutaneously into the proximal tibia just anterior to the joint line in-line with the tibial shaft. Verify and confirm location under biplanar fluoroscopic guidance. A more distal entry point may result in damage to the posterior cortex during nail insertion.

The center point of the portal is located slightly medial to the lateral tibial spine as visualized on the A/P radiograph and immediately adjacent and anterior to the anterior articular margin as visualized on the true lateral radiograph. The A/P starting position can be adjusted for planned angular deformity or to target the distal tibial segment.

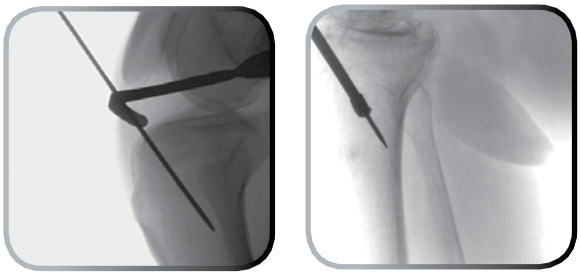
Make a small vertical incision around the pin and spread the soft tissues using hemostats.

After confirming correct pin placement on A/P and lateral radiograph views, position a soft tissue protector and ream over the Steinmann pin with a cannulated 8.0mm or 11.0mm entry drill (8-10mm). Protect the patellar tendon with retractors.

Using a guidewire chuck, insert a ball tip guide wire into the entry hole and down the length of the tibia about 3.0 to 4.0cm beyond the planned distal end of the nail.

Release the tourniquet if one was used for the fibular osteotomy. Blood flow through the tibia during reaming can help conduct heat away from the bone and reduce the risk of thermal injury. Close the anterior incision with a simple running suture to prevent egress of the bony reamings.

Ream the canal with flexible reamers beginning with 8mm. Increase by 0.5mm increments until the tibial canal is over-reamed by 2.0mm greater than the planned diameter of the PRECICE® implant. A guidewire pusher may be used to secure the guidewire when removing the flexible reamers from the canal.



TIBIAL ENTRY POINT

There are three diameters of PRECICE tibial implants available: 8.5, 10.7, and 12.5mm.

TIBIA GUIDE ARM ASSEMBLY

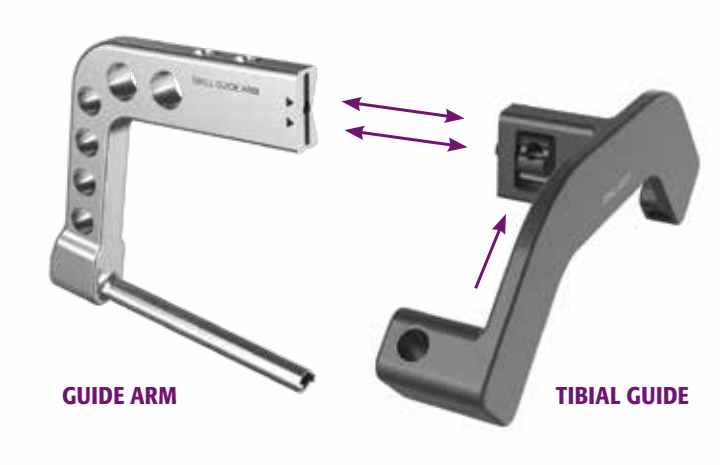
In preparation for insertion of the implant into the intramedullary canal, construct the Tibial Guide Arm Assembly. Align the arrows on the Drill Guide Arm and Tibial Guide and assemble by tightening the knob.

Attach the assembled PRECICE implant to the Tibial Guide Arm Assembly by inserting the Locking Rod through the hollow tube of the Tibial Guide and aligning the arrows on the implant and Drill Guide Arm. Engage the threads on the proximal end of the implant with the Implant Locking Rod and gently tighten with the Tommy Bar.

Insert the Drill Guide into the Guide Tube and through the Tibial Guide. Verify correct alignment of the 5.0 x 355mm Drill Bit through the Drill Guide and PRECICE implant. Confirm both proximal screw holes in this manner.

Once the PRECICE implant has been properly attached to the Tibial Guide Arm Assembly, place the construct aside in the sterile field until ready for insertion into the intramedullary canal.

STANDARD PRECICE INSTRUMENTATION



SHORT PRECICE INSTRUMENTATION

All SHORT Tibia Nails will utilize the SHORT Tibia Drill Guide and SHORT Locking rod found in the PRECICE Specialty Tray. They must be used with the Standard Drill Guide Arm found in the PRECICE Instrument Tray.

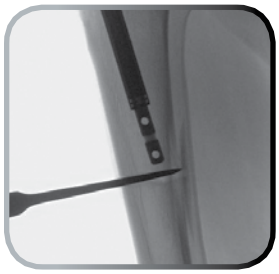
OSTEOTOMY OF THE TIBIA

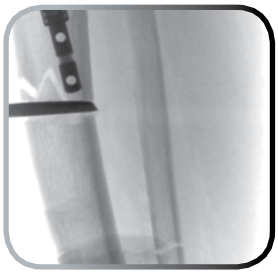
Hyperflex the knee and insert the PRECICE® implant with the Tibial Guide Arm Assembly until the distal tip of the nail is just proximal to the planned osteotomy site where the vent holes were placed. Verify this location under image intensification.

Keeping the knee flexed, remove simple running suture and use an osteotome to complete the osteotomy. Use caution to avoid neurovascular injury and soft tissue damage. An irregular or comminuted osteotomy is acceptable. Ensure that the osteotomy created is completely circumferential. Verify the osteotomy is complete with multi-planar image intensification. With the knee flexed, gentle anterior pressure should be applied to the tibia during osteotomy. This will prevent acute flexion of the osteotomy site once completed.

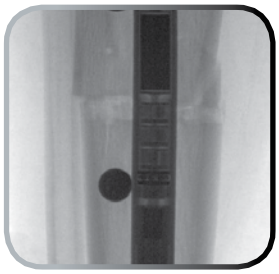
Immediately after confirming the osteotomy, gently tap the Short Impactor on the Tibial Guide Arm Assembly to advance the PRECICE implant across the gap and into the distal tibia. If the cut cortex of the distal segment prevents insertion, stop advancing the device, adjust the reduction, and try again. Excessive force on the PRECICE nail may damage the internal mechanism. If necessary, consider reaming the canal by an additional 0.5 to 1.0mm.

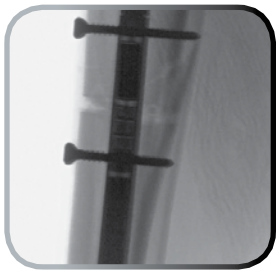
Maintain rotational alignment during implant insertion and subsequent locking. Rotational alignment may be confirmed by inserting a proximal and distal half pin prior to completing the osteotomy. Alternatively, check the thigh-foot axis before the osteotomy and then again before distal locking.





The use of osteotomes is always recommended as this is a low-energy osteotomy method that helps avoid an exaggerated inflammatory response and the potential for thermal necrosis.





A stellate tibial osteotomy may be preferred over a traditional transverse osteotomy to allow more surface area for healing. The osteotomy may be performed with the leg fully extended and manually reduced while flexing the knee for nail insertion. If maintaining control of an angular corrective osteotomy is desired, then consider the use of blocking screws.

PROXIMAL LOCKING SCREWS

Confirm Tibial Guide Arm did not loosen during nail insertion prior to proceeding with proximal locking screws. Position the Trocar through the Guide Tube and place through the Tibial Guide Arm. Make a small stab incision where the Trocar contacts the skin. Advance the Trocar through the tissue until the tip is seated against the cortex. Verify with image intensifier that the Guide Tube is positioned on the tibial cortex.

Remove the Trocar and position the Drill Guide through the Guide Tube. Use the 5.0 x 355mm Drill Bit to penetrate both cortices. Confirm correct placement under image intensification.

After drilling both cortices, select the appropriate Locking Screw length by reading off the calibration on the 5.0 x 355mm Drill Bit. 5.0mm Locking Screws are available in 5mm increments from 20-75mm lengths. The screw gauge may also be used to read the calibration by sliding it down the guide tube.

Insert the Screw Capture Rod through the cannulated 3.5mm Locking Driver. Hand tighten the Screw Capture Rod to the appropriate length 5.0mm Locking Screw. Attach the 3.5mm Locking Driver with the Screw Capture Rod to the Quick Connect T-handle or Teardrop Cannulated Handle. Remove the Drill Guide and position the screw into the Guide Tube to direct it through the PRECICE implant.

Hand tighten the Locking Screw into the near cortex. Remove the Quick Connect T-handle and untighten the Screw Capture Rod to release the Locking Screw. Use the 3.5mm Solid Hex Driver attached to the Quick Connect T-handle to achieve final secure fixation and to fully seat the Locking Screw. Repeat this sequence for the second proximal Locking Screw.

TIBIAL GUIDE ARM ASSEMBLY WITH 5.0 X 355mm DRILL BIT IN POSITION PRIOR TO NAIL INSERTION.

STANDARD INSTRUMENTATION

SHORT INSTRUMENTATION

After securing the proximal 5.0mm Locking Screws, untighten the Locking Rod from the PRECICE implant to remove the Tibial Guide Arm Assembly.

DISTAL LOCKING SCREWS

The free-hand technique is used to position Locking Screws in the A/P and M/L distal locking holes of the PRECICE® implant.

Depending upon which Locking Screw is to be inserted, align the C-arm in either the A/P or lateral position to view perfect overlapping circles. For the perfect overlapping circle technique, first find the drill hole using the finger hole of an instrument. Make a small skin incision here. Use the Soft Tissue Protector and appropriate diameter drill bit to create a pilot hole for the Locking Screw.

Size Guide for Nail Diameter

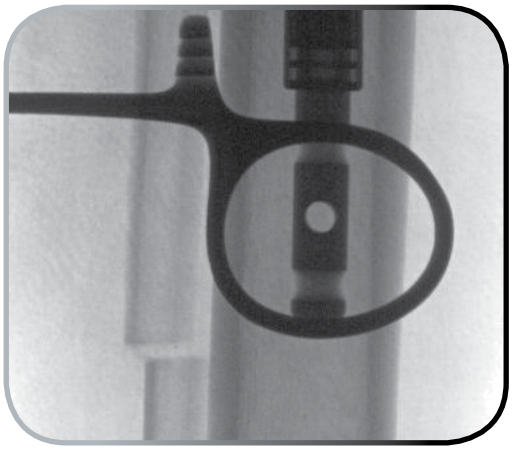
APPLIES TO ALL P2 AND SHORT GEN I NAILS; (180mm – 365mm)
MODELS: **A, B, C, D, E, J, K, H, AND U** *(two proximal, two distal screw holes)*

	8.5mm NAIL		10.7mm NAIL		12.5mm NAIL	
	Proximal	Distal	Proximal	Distal	Proximal	Distal
LOCKING SCREW SIZE (mm)	*5.0*	*3.5*	*5.0*	*4.0*	*5.0*	*5.0*

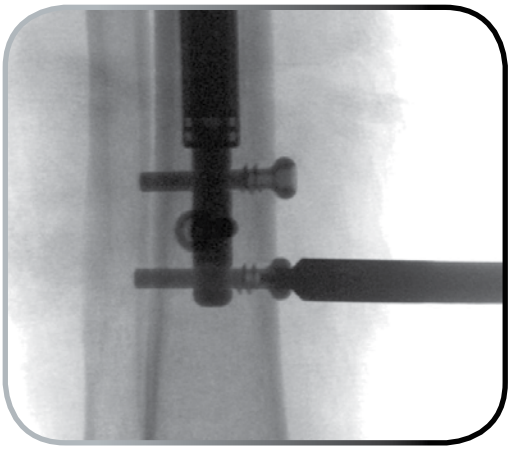
APPLIES TO SHORT GEN II NAILS; (175mm – 150mm)
MODELS: **Q, M, P, AND N** *(two proximal, two distal screw holes)*

	8.5mm NAIL		10.7mm NAIL		12.5mm NAIL	
	Proximal	Distal	Proximal	Distal	Proximal	Distal
LOCKING SCREW SIZE (mm)	*5.0*	*4.0*	*5.0*	*4.0*	*N/A*	*N/A*

Select the length for the first distal Locking Screw by reading the measurement off the calibrated drill bit with the Soft Tissue Protector fully seated on the cortex. The Direct AO Depth Gauge may also be used. Attach the appropriate length Locking Screw to the Screw Capture Rod and 3.5mm Locking Driver. Tighten the Locking Screw by hand. Release the Screw Capture Rod and perform final tightening of the Locking Screw with the 3.5mm Solid Hex Driver. Repeat steps for additional distal Locking Screws.



Find the drill hole by first using the finger hole of an instrument. Confirm positioning with image intensifier.



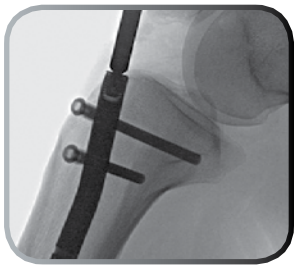
There are three distal Locking Screw options.

END CAP PLACEMENT (OPTIONAL)

If desired, an End Cap may be used to help prevent bony ingrowth into the proximal thread of the nail. End Caps are available in two diameters: 10.7mm and 12.5mm. End Caps are also available in various lengths; 0, 5, 10, 15, 20mm options.

Secure the End Cap to the 3.5mm Locking Driver and Screw Capture Rod. Attach this assembly to the Quick Connect T-handle. Use image intensification to confirm positioning and take care not to cross-thread the End Cap.

Turn the Quick Connect T-handle clockwise until the End Cap fully sits inside the proximal portion of the nail. Untighten the Screw Capture Rod to release the End Cap.



CONFIRMATION OF END CAP POSITIONING

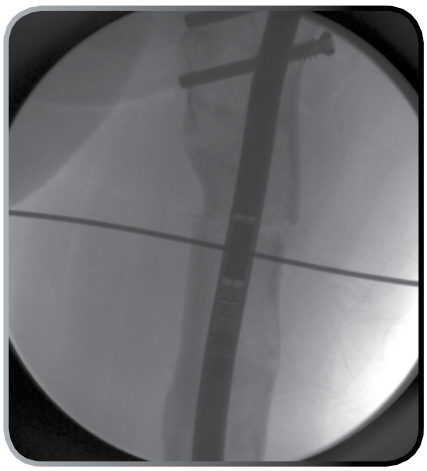
LOCATING THE CENTER OF THE MAGNET

Evaluate the final implant construct under image intensification. Locate the magnet within the PRECICE implant (see reference images). Be sure the C-arm is perpendicular to the implant to visualize the correct position of the central magnet.

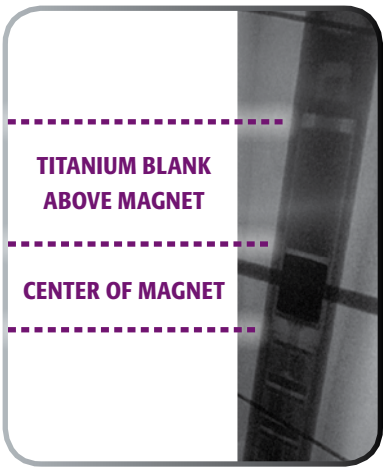
Use a surgical skin marker to put a transverse line on the patient's skin directly over the location of the center of the PRECICE magnet. Provide a surgical marker postoperatively to the patient to refresh the line as it fades.

Caution should be taken as the magnets in the ERC will attract metal objects, including surgical instruments (refer to the Operator's Manual for complete Instructions for Use prior to using the ERC).

PRECICE IMPLANT REFERENCE IMAGE



THE STEINMANN PIN IS PLACED OVER THE SKIN TO ASSIST IN MAGNET LOCATION



PRECICE REFERENCE IMAGE 8.5mm

INTRAOPERATIVE EXTERNAL REMOTE CONTROL (ERC) DISTRACTION

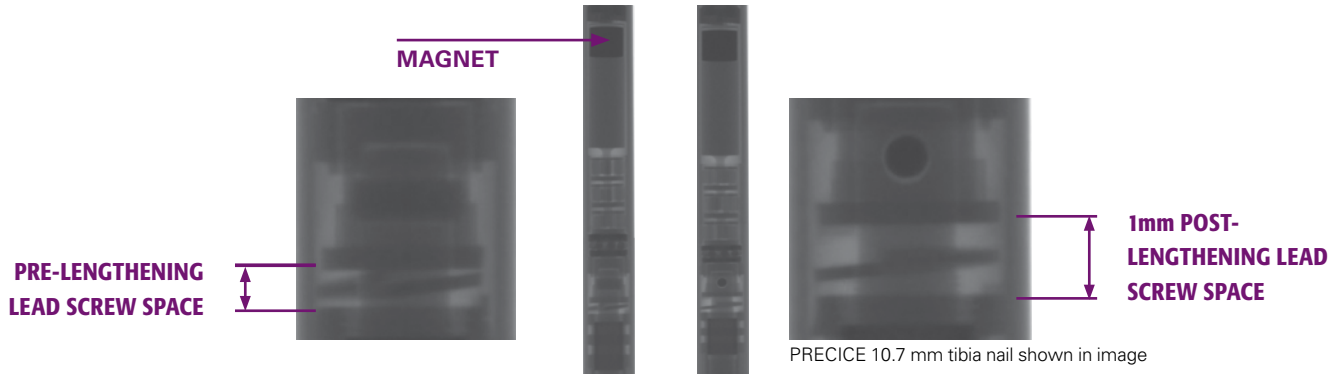
Place the ERC in a sterile bag and place it directly over the transverse mark on the skin. Make sure you have properly aligned the ERC on the patient's tibia and the magnets are pointed toward the patient's feet.

Use the implant locator window on the ERC to properly position it over the mark on the patient's skin.

Activate the ERC to distract the PRECICE® implant 1.0-2.0mm. This verifies correct functioning of the system. It takes six or seven minutes to achieve 1.0mm of lengthening. After functioning verification, it is not necessary to retract the PRECICE implant.

ERC 1 + ERC2P = 7 minutes
ERC3P = 6 minutes

Confirm under image intensification that the lengthening has occurred by comparing the pre-lengthening image to the post-lengthening image. The Lead Screw space should demonstrate distraction.



PRECICE 10.7 mm tibia nail shown in image

ENTERING THE PRESCRIPTION

1. Turn on the ERC3P and type in the physician passcode

2. Choose "Prescription" from the menu

3. Select Prescription 1 (or 2 if bi-lateral)

4. Input prescription information

5. Review and confirm the prescription

Correct alignment of the ERC to the patient's femur. Always point arrows on ERC toward patient's feet.

ERGONOMICALLY FRIENDLY HANDLE FOR TIBIA LENGTHENING

PRECICE® FAST DISTRACTOR

1. Attach Fast Distractor to AO quick connect on OR Drill
2. Hold the Fast Distractor on the nail and slide it until you feel the magnet engage with the PRECICE implant magnet (PRECICE implant will "click" into place)
3. Ensure drill is in the forward position (Clockwise - Do not retract)
4. Cradle the fast distractor and nail in your hand
5. Start slowly and allow the drill to rotate freely (do not block it by holding too tightly)
6. Use a ruler to confirm the proper distraction amount has been achieved

Important:

Do not pre-distract the PRECICE device to its maximum potential distraction length (stroke). The maximum pre-distraction length must be 5mm less than the maximum PRECICE nail stroke length.

FINAL CLOSURE

After the 1.0mm lengthening of the PRECICE® implant, the surgical incisions are irrigated and closed in standard fashion. Sterile dressings are applied and the lower leg is placed in a CAM boot for postoperative comfort and proper foot/ankle positioning and alignment.

Make certain that the skin mark noting the location of the magnet within the PRECICE implant is prominent and visible. This will facilitate proper alignment and positioning of the ERC for future lengthening during the distraction phase.

POSTOPERATIVE MANAGEMENT

Patients should be mobilized the first few days after surgery, but must avoid full weight-bearing throughout the entire lengthening phase.

> ***Note***
>
> *No more than 20% of the patient's body weight should be loaded onto the leg with the implanted PRECICE implant.*

Each surgeon must prescribe a lengthening protocol for his/her patient. Factors to consider when determining daily lengthening rate include bone quality, location and trauma of the osteotomy, patient age, and comorbidities.

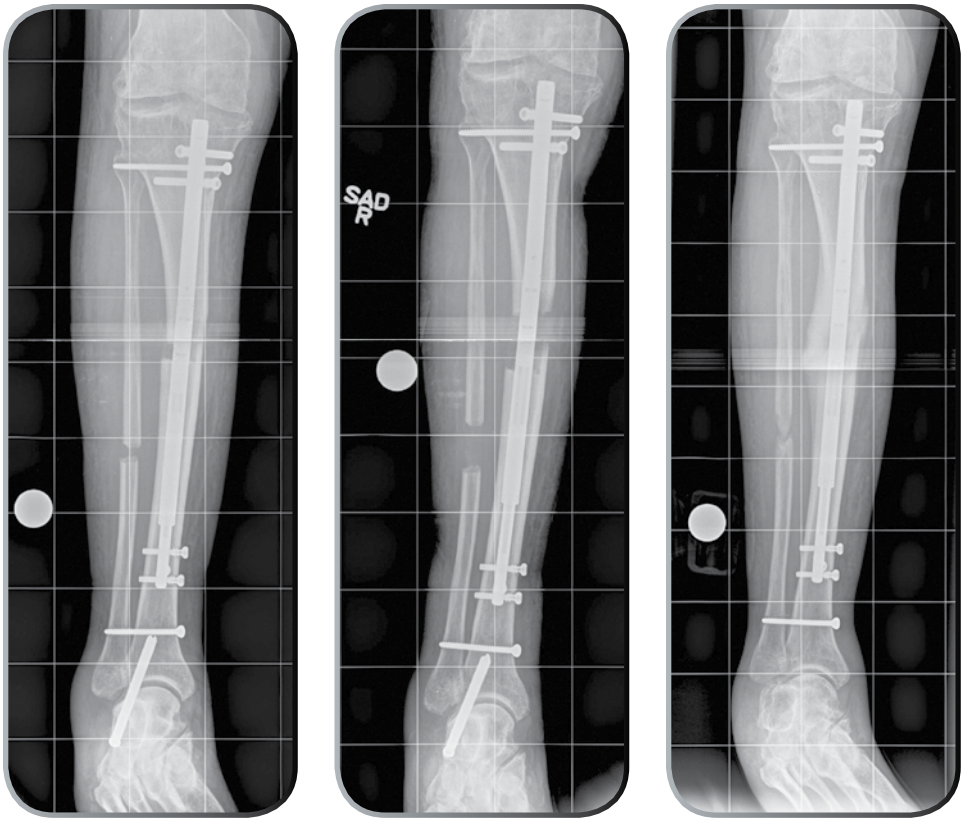
Daily lengthenings can range from 0.5-0.75mm divided into 2 to 3 sessions. Lengthening typically starts after a latency period of 7 to 8 days after initial implantation. Weekly clinical and radiographic evaluations by the surgeon are important to review the patient's progression. The ERC can be programmed to optimize the patient's lengthening prescription (refer to ERC Operator's Manual for complete programming instructions). During this phase, daily physiotherapy includes the following:

- Hip extension and abduction
- Full knee flexion/extension
- Ankle dorsiflexion above neutral
- Maximum ankle plantarflexion

LENGTHENING TO CONSOLIDATION

During the lengthening phase, patient compliance to the planned lengthening prescription is important. Adherence to proper use of the ERC in addition to postoperative rehabilitation protocols must be emphasized. It is the physician's responsibility to carefully monitor the patient's progress with regular radiographs and to make any necessary change to the daily lengthening prescription. The physician may adjust or reverse a prescription to best meet the needs of the patient.

After the distraction phase has been completed, the patient's weight-bearing status must remain limited (8.5mm = 30lbs; 10.7/12.5mm = 50lbs) until bony healing. Once 3 out of 4 cortices have consolidated and at the physician's discretion, the patient is advanced to weight bearing as tolerated.



The physician and his/her staff should train the patient on how to properly use the ERC. The ERC Operator's Manual (included with the ERC) may be referenced at any time for complete programming instructions.

In this example the extra-articular screw was removed at the end of the lengthening phase to allow ankle range of movement (ROM).

CONSOLIDATION PHASE

The PRECICE® implant cannot withstand the stresses of full weight bearing. The patient should utilize external support and/or restrict activities until consolidation occurs. The consolidation phase should occur with the PRECICE implant in place.

Increase partial weight-bearing to full weight-bearing only after careful clinical and radiographic evaluation of the patient.

Full weight bearing is only permitted when there is solid healing of at least three out of four cortices on the A/P and lateral radiographs as determined by the physician.

If bone healing is delayed, consider using adjunctive measures such as ultrasound bone stimulation or bone grafting. Encourage the patient to maintain a healthy diet with adequate vitamin D and calcium. Consider measuring vitamin D levels and using supplements as needed.

Please refer to the Instructions for Use for the PRECICE implant for additional information.

EXTERNAL REMOTE CONTROLLER (ERC) INTRODUCTION

The ERC uses strong permanent magnets to distract the PRECICE® implant. The following are important considerations and precautions when using the ERC. For complete instructions, contraindications, warnings, and cautions please refer to the Operator's Manual.

- Weekly X-ray imaging to assess actual distraction length is recommended.
- Only use the External Remote Controller in a manner consistent with the Operator's Manual. Any alternative use may result in injury or damage to property.
- This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the External Remote Controller or shielding the location.

- Persons with a pacemaker or a similar medical aid should not handle or be exposed to the External Remote Controller. The strong magnetic fields may affect the operation of such devices.
- The External Remote Controller uses strong permanent magnets. Misuse of this system can cause serious personal injury. Make sure the work area is free of metal objects before use. This includes personal items such as jewelry, watches, keys, and cellular phones. Always return the system to its protective case when not in use.
- Only operate the External Remote Controller by holding onto both of the handles provided.
- The External Remote Controller may be pulled away from your hands if brought too close to other magnetic objects. Always maintain a firm grip on the External Remote Controller and be very aware of other objects in your work area. Also, tools or other hazardous objects may leap towards the External Remote Controller if brought too close.
- Never place the External Remote Controller near electronic media or appliances. The strong magnetic field may damage magnetic media such as floppy disks, credit cards, magnetic I.D. cards, cassette tapes, video tapes, or other such devices. It can also damage televisions, VCRs, computer monitors, and other CRT displays.

- This device has not been tested for compatibility in magnetic resonance imaging (MRI) environments and should not enter an MRI unit.

FEATURES OF THE ERC3P

IMPLANT REMOVAL

PRECICE® implant removal is recommended at 1 year provided radiological evidence of full bone consolidation is present. Each surgeon must determine the appropriate time for removal of the PRECICE implant based upon their clinical evaluation of the patient.

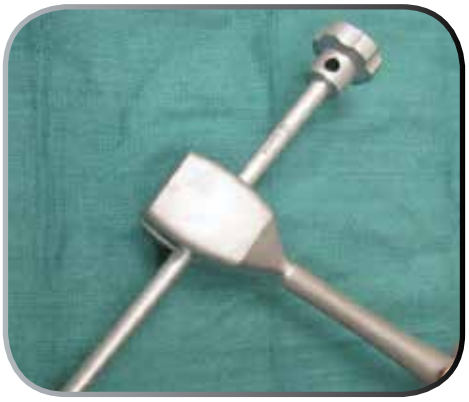
Exsanguinate the leg and apply a thigh tourniquet. Expose the proximal end of the implant by careful debridement of heterotopic bone and soft tissue. Under bi-planar fluoroscopy, drive a K-wire into the proximal end of the nail and over-ream with a starting reamer to gain exposure.

Using the image intensifier, locate the proximal and distal locking screws. Make small incisions as required and remove the locking screws using the 3.5mm Solid Hex Driver and Quick Connect T-handle. Remove all but one of the locking screws prior to tightly threading the Tapered Extractor to the PRECICE implant. If present, the End Cap must be removed prior to threading the Tapered Extractor into the PRECICE implant.

Attach the Removal Rod to the Tapered Extractor, remove the final locking screw, and proceed with nail removal, by gently backslapping the slotted mallet. Caution should be taken to avoid side loads and mallet should always be held along axis of force.

Perform skin closure with routine techniques.

PRECICE IMPLANT, TAPERED EXTRACTOR, AND REMOVAL ROD ASSEMBLY.



SLAP HAMMER POSITIONED OVER REMOVAL ROD.

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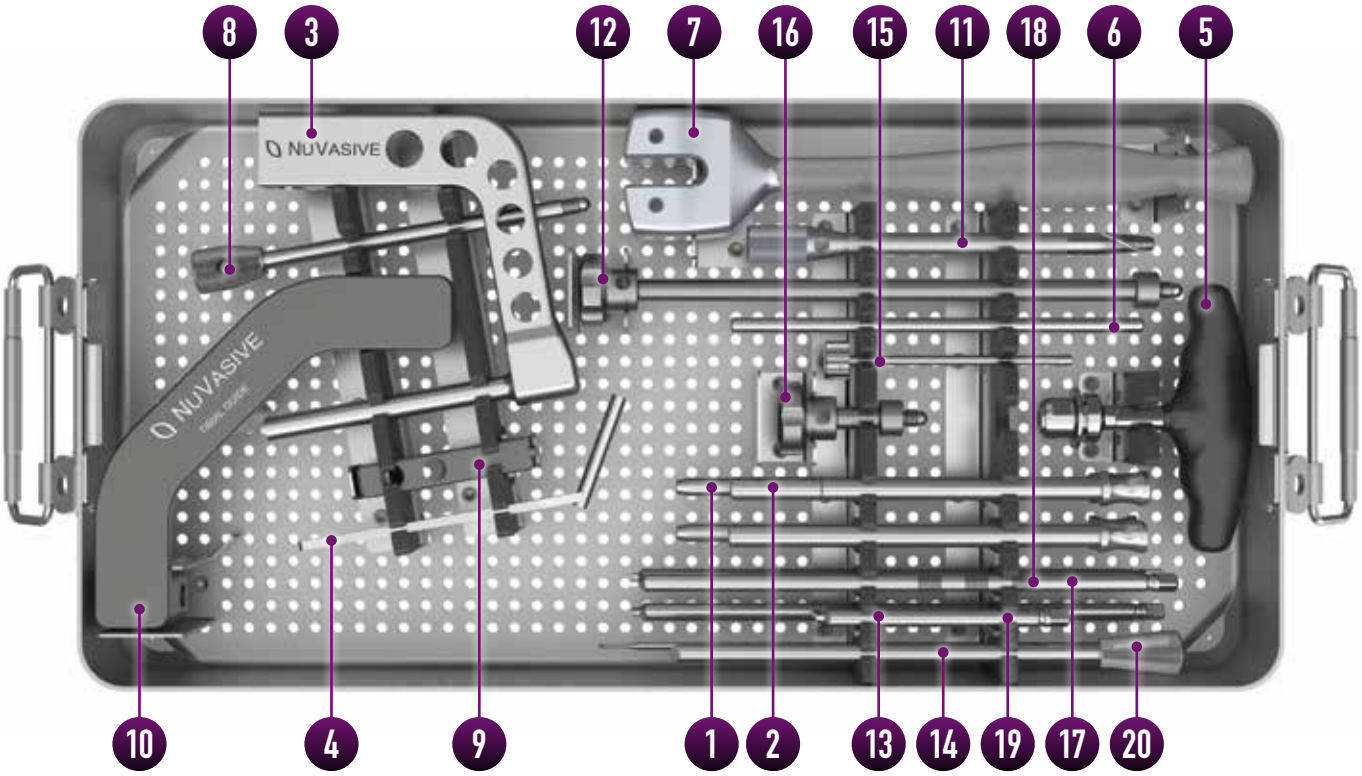
STANDARD INSTRUMENT TRAY

	MODEL #	DESCRIPTION
1	DBB5-000	Drill Guide
2	GSB1-000	Guide Tube
3	AGB1-000	Drill Guide Arm
4	DSD2-035	Soft Tissue Protector
5	THD2-000	Quick Connect T-handle
6	TBA1-000	Tommy Bar
7	RMB1-000	Slap Hammer
8	LRB1-000	Locking Rod
9	SNB1-000	Retrograde Femoral Guide
10	CBB1-000	Tibial Guide

	MODEL #	DESCRIPTION
11	CTA1-000	Tapered Extractor
12	RRB1-000	Removal Rod
13	THE1-000	4.0mm Locking Driver
14	PRB1-000	Trocar
15	LKA1-000	Locking Key
16	IMA1-000	Short Impactor
17	DRD1-000	3.5mm Solid Hex Driver
18	DRE1-000	4.0mm Solid Hex Driver
19	THF3-000	3.5mm Locking Driver
20	CRC3-000	Screw Capture Rod



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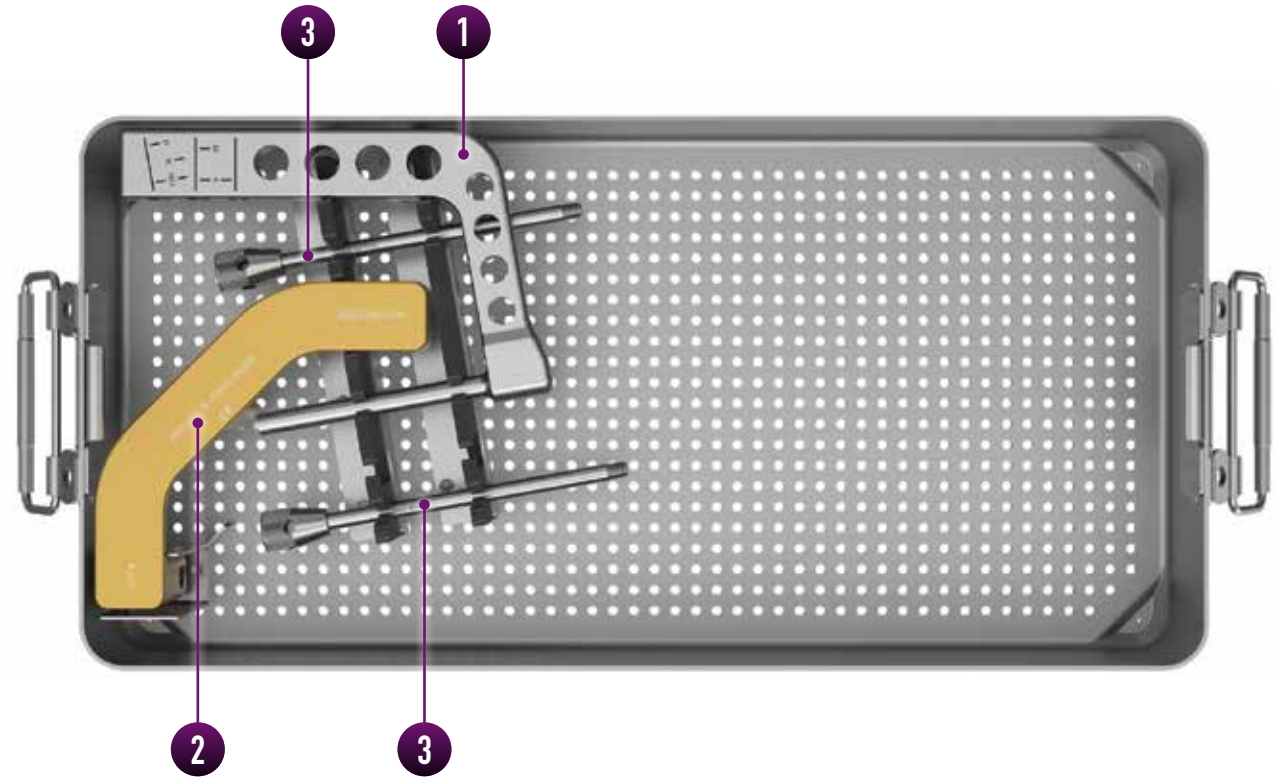
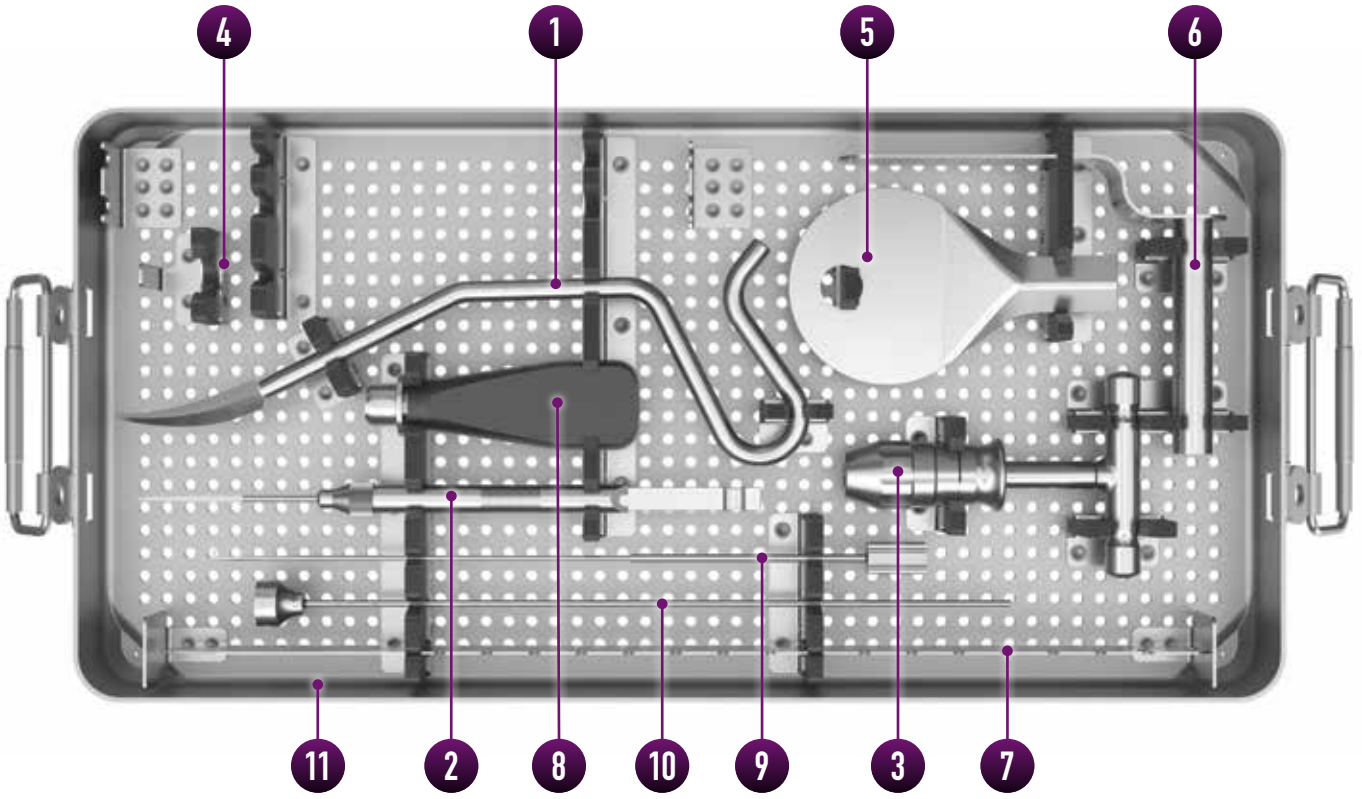
SPECIALTY TARGETING TRAY

	MODEL #	DESCRIPTION
1	AGB2-000	Drill Guide Arm, Short Nail
2	CBB2-000	Tibial Drill Guide, Short Nail
3	LRB2-000	Locking Rod



SUPPLEMENTAL INSTRUMENT TRAY

	MODEL #	DESCRIPTION
1	DPA1-000	11mm Diamond Point Awl
2	DGA1-000	Direct AO Depth Gauge
3	GWC1-000	Guide Wire Chuck
4	LQC1-000	Large AO Quick Connect
5	STP1-000	Soft Tissue Protector – Paddle
6	STT1-000	Soft Tissue Protector – Tube
7	XRR1-000	Intraoperative X-ray Ruler
8	TCD1-000	Teardrop Cannulated Driver
9	PSG1-000	Screw Gauge
10	GWP1-000	Guide Wire Pusher
11	ITS2-000	Supplemental Instrument Tray



ANTEGRADE TIBIA – 10°

		8.5mm	10.7mm	12.5mm
LENGTH	DISTRACTION	MODEL #	MODEL #	MODEL #
155mm	50mm	P8.5-50Q155	P10.7-50Q155	-
180mm	50mm	P8.5-50J180	P10.7-50J180	-
195mm	50mm	P8.5-50C195	P10.7-50C195	P12.5-50C195
215mm	50mm	P8.5-50C215	P10.7-50C215	**P12.5-50C215**
230mm	50mm	P8.5-50C230	P10.7-50C230	P12.5-50C230
245mm	80mm	P8.5-80C245	P10.7-80C245	P12.5-80C245
275mm	80mm	P8.5-80C275	P10.7-80C275	P12.5-80C275
305mm	80mm	P8.5-80C305	P10.7-80C305	P12.5-80C305
335mm	80mm	P8.5-80C335	P10.7-80C335	P12.5-80C335

TIBIAL LIMB LENGTHENING SYSTEM

LOCKING SCREWS



3.5mm - GREY		4.0mm - BLUE		5.0mm - GREEN	
PART #	LENGTH	PART #	LENGTH	PART #	LENGTH
LSB3-020	20mm	LSC4-020	20mm	LSC5-020	20mm
LSB3-025	25mm	LSC4-025	25mm	LSC5-025	25mm
LSB3-030	30mm	LSC4-030	30mm	LSC5-030	30mm
LSB3-035	35mm	LSC4-035	35mm	LSC5-035	35mm
LSB3-040	40mm	LSC4-040	40mm	LSC5-040	40mm
LSB3-045	45mm	LSC4-045	45mm	LSC5-045	45mm
LSB3-050	50mm	LSC4-050	50mm	LSC5-050	50mm
LSB3-055	55mm	LSC4-055	55mm	LSC5-055	55mm
LSB3-060	60mm	LSC4-060	60mm	LSC5-060	60mm
-	-	-	-	LSC5-065	65mm
-	-	-	-	LSC5-070	70mm
-	-	-	-	LSC5-075	75mm

FULLY THREADED SCREWS


4.0mm - PURPLE		5.0mm - GOLD	
PART #	LENGTH	PART #	LENGTH
PP2559-200	20mm	PP2560-200	20mm
PP2559-225	22.5mm	PP2560-225	22.5mm
PP2559-250	25mm	PP2560-250	25mm
PP2559-275	27.5mm	PP2560-275	27.5mm
PP2559-300	30mm	PP2560-300	30mm
PP2559-325	32.5mm	PP2560-325	32.5mm
PP2559-350	35mm	PP2560-350	35mm
PP2559-375	37.5mm	PP2560-375	37.5mm
PP2559-400	40mm	PP2560-400	40mm
PP2559-425	42.5mm	PP2560-425	42.5mm
PP2559-450	45mm	PP2560-450	45mm
PP2559-475	47.5mm	PP2560-475	47.5mm
PP2559-500	50mm	PP2560-500	50mm
PP2559-550	55mm	PP2560-550	55mm
PP2559-600	60mm	PP2560-600	60mm
PP2559-650	65mm	PP2560-650	65mm
PP2559-700	70mm	PP2560-700	70mm
PP2559-750	75mm	PP2560-750	75mm
PP2559-800	80mm	PP2560-800	80mm
PP2559-850	85 mm	PP2560-850	85mm
PP2559-900	90mm	PP2560-900	90mm
PP2559-950	95mm	PP2560-950	95mm
PP2559-000	100mm	PP2560-000	100mm

END CAPS

10.7mm DIAMETER		12.5mm DIAMETER	
MODEL #	LENGTH	MODEL #	LENGTH
CPA2-000	0mm	CPA3-000	0mm
CPA2-005	5mm	CPA3-005	5mm
CPA2-010	10mm	CPA3-010	10mm
CPA2-015	15mm	CPA3-015	15mm
CPA2-020	20mm	CPA3-020	20mm

Note: 10.7mm End Caps are also compatible with the 8.5mm PRECICE Devices.

EXTERNAL REMOTE CONTROLLERS/ STERILE BAG/FAST DISTRACTOR

MODEL #	DESCRIPTION
-	ERC 1
-	ERC 2
-	ERC 3
STRLBGPKG	Sterile Bag*
PFD1-000	Fast Distactor

*U.S. only

**EMEA only

LOCKING SCREW SIZE GUIDE FOR NAIL DIAMETER

8.5mm	
PROXIMAL	DISTAL
5.0mm	3.5mm

8.5mm	
PROXIMAL	DISTAL
5.0mm	4.0mm

10.7mm	
PROXIMAL	DISTAL
5.0mm	4.0mm

10.7mm	
PROXIMAL	DISTAL
5.0mm	4.0mm

12.5mm	
PROXIMAL	DISTAL
5.0mm	5.0mm

12.5mm	
PROXIMAL	DISTAL
-	-

Note: Applies to all P2 and Short Gen I Nails; Models: A, B, C, D, E,J, K, H, and U (two proximal, two distal screw holes)

Note: Applies to all P2 and Short Gen II Nails; Models: Q, M, P, and N (one proximal, one distal screw holes)

ENTRY DRILLS/DRILL BITS

MODEL #	DESCRIPTION
DBA3-152	Drill Bit, 3.5mm, Short
DBB4-152	Drill Bit, 4.0mm, Short
DBC5-152	Drill Bit, 5.0mm, Short
DBA5-355	Drill Bit, 5.0mm, Long
DBT2-4.3	Calibrated Drill Bit, 4.3mm, Long
DBS2-4.3	Calibrated Drill Bit, 4.3mm, Short
DBT1-4	Drill Bit, 4.0mm
DBT1-5	Drill Bit, 5.0mm
DBT2-5	Cannulated Drill Bit, 5.0mm
CED1-008	Cannulated Entry Drill, 8mm
CED1-011	Cannulated Entry Drill, 11mm

GUIDE WIRES/PINS

MODEL #	DESCRIPTION
WIR2-175	2mm x 175mm Drill Tip K-wire
WIR2-229	2mm x 229mm Guide Wire Single Trocar
NU-0101-900S*	3.0mm x 900mm Ball Nose Guide Wire
NU-S0100-000	3.2mm x 330 Threaded Pin
NU-S0110-000	3.2mm x 330 Trocar Tip Pin
012-1874-012ST5	2.5mm x 900mm Ball Nose Guide Wire**

SCREW TRAY/MODULES/CADDIES

MODEL #	DESCRIPTION
STA1-000 (3 slots)	Tray
SMA1-3.5	3.5mm Module + Pegs
SMC1-4.0	4.0mm Module + Pegs
SMC1-5.0	5.0mm Module + Pegs
TSM1-040	4.0mm Module + FT Screws
TSM1-050	5.0mm Module + FT Screws
STU1-001 (4 slots)	Tray
SCA3P	3.5mm Caddy + Pegs
SCA4P	4.0mm Caddy + Pegs
SCA5P	5.0mm Caddy + Pegs
SCA4	4.0mm Caddy + FT Screws
SCA5	5.0mm Caddy + FT Screws

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IMPORTANT SAFETY INFORMATION

The PRECICE® System is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The PRECICE 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.

INTENDED USE:

The PRECICE 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 Gusilo open fracture Classification Grade IIIB or IIIC fractures
- Patients with pre-existing nerve palsies
- Metal allergies and sensitivities.
- Patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 51 mm for the femoral, or 13 mm for the tibial, 10.7, 11.5, and 12.5 mm diameter implant.
- Patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 38 mm for the femoral, or 10 mm for the tibial, 8.5, 9.0, 9.5 and 10.5 mm diameter implant.
- Patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 25.4 mm for the 8.5 mm diameter humeral implant that is from 165mm to 210mm in pre-distracted length.
- Patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 51 mm for the 8.5 mm diameter humeral implant that is 225 mm to 300 mm in pre-distracted length.
- Patients with an irregular bone diameter that would prevent insertion of the PRECICE nail.
- Patients in which the PRECICE nail would cross joint spaces or open epiphyseal growth plates.
- 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.
- Patients unwilling or incapable of following postoperative care instructions.

WARNINGS:

- The PRECICE nail cannot withstand the stresses of full weight bearing for tibia and femur applications. For humerus applications, patients should not bear any weight on the treated limb. 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 involved 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 is open.
- Metallic implants can loosen, fracture, corrode, migrate, or cause pain.
- Due to the presence of a magnet, use of the PRECICE System is not recommended inpatients with pacemakers.
- The PRECICE System may not be appropriate for patients with poly-trauma.
- Use of the PRECICE System in patients with an active infection of the treated bone is not recommended.
- Smoking, chronic steroid use and the use of other anti-inflammatory drugs have been determined to affect bone healing and could potentially have an adverse effect of the bone regenerate during the lengthening process.
- The PRECICE 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.
- Assure that patient with implanted PRECICE nail does not enter MRI unit. Effect of high magnetic field of MRI unit has not been studied with respect to the implanted magnet, and is therefore unknown.
- Unsafe in Magnetic Resonance Imaging environments. The PRECICE System has not been evaluated for safety and compatibility in the MR environment. The PRECICE System has not been tested for heating or migration in the MR environment.
- The PRECICE Nail should be retracted only by a physician. Retraction should be monitored and confirmed using radiography.
- To avoid dislocation or subluxation of the shoulder joint with the Humeral Nail, careful preoperative planning should be done to determine the correct lengthening prescription. The typical lengthening prescription for lengthening is 1 mm/day.
- Compression and distraction of the Humeral Nail should be performed postoperatively, while the patient is awake to monitor their neurovascular status and radial nerve.
- 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 ERC to lengthen the humerus.
- Humeral nail distraction may cause traction on nerves.

PRECAUTIONS:

- 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, or OM0016) for operation of the External Remote Controller.
- During the distraction phase, patient should not participle in contact sports or other high risk activities that cause more than 20% of body weight to be loaded on the treated limb. These activities may resume upon sufficient bone consolidation, but only as determined by the physician.
- Examine all PRECICE 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 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 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. Failure to follow this caution may result in pulling biologic material that may have adhered to the rod into the internal space of the Nail.
- Do not bend the PRECICE nail or otherwise modify or damage the implant.
- Follow the ERC Operators Manual (OM0005, OM0009, or OM0016) to assure proper alignment between the ERC and magnet of the PRECICE nail.

NOTES

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NOTES

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For more information about this product, please contact your local sales representative.

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CE 0297

Rx Only.
The PRECICE® System is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The PRECICE nail is a sterile single use device that is surgically implanted using the instruments and locking screws. The ERC is used daily after implantation to non-invasively lengthen or shorten the implant to a prescribed length. The PRECICE System is intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones. Contraindications include infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device, metal allergies and sensitivities, patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 51 mm for the 10.7 and 12.5 mm diameter implants or greater than 38 mm for the 8.5 mm diameter implant, patients with an irregular bone diameter that would prevent insertion of the PRECICE nail, patients in which the PRECICE nail would cross joint spaces or open epiphyseal growth plates, 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, patients unwilling or incapable of following postoperative care instructions, patients weighing in excess of 114 kg for the 10.7 and 12.5 mm diameter implants (models A-G, H, J, K, and U) or weighing in excess of 57 kg for the 8.5 and 10.7 mm diameter implants models (A-G, H, J, K, U, M, N, P, Q, V, and X). The implantable device is only to be used by a trained licensed physician. Please refer to the PRECICE IMLL System instructions for use for complete Important Safety Information.

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