Antegrade Tibia Operative Technique
The PRECICE® Intramedullary Limb Lengthening System is indicated for limb lengthening of the tibia and femur.

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.

Contributing Surgeons

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THE PRECICE® INTRAMEDULLARY LIMB LENGTHENING SYSTEM

is the latest advancement in 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 into 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 Intramedullary Limb Lengthening System is comprised of the following components:

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

- 8.5 mm nails have a proximal geometry of 10.7 mm located 40 mm from the top of the nail.
- 10.7 mm and 12.5 mm nails have a consistent diameter throughout.

**Intramedullary Nails**
- **Diameter**: 8.5, 10.7, and 12.5 mm
- **Sizes**: 155–365 mm

**Telescoping Rod Diameter (Male)**
- 8.5 mm = 6.5 mm
- 10.7 mm = 8.5 mm
- 12.5 mm = 10.0 mm

**Locking Screws**
- **3.5 mm Locking Screws**
  - Length: 20–60 mm
- **4.0 mm Locking Screws**
  - Length: 20–60 mm
- **5.0 mm Locking Screws**
  - Length: 20–75 mm

**End Cap**
- **Sizes**: Standard
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
- Osteotomy location of tibia
- Soft tissue assessment
- Required implant length

### Table

<table>
<thead>
<tr>
<th>DIAMETER (mm)</th>
<th>LENGTHS (mm)</th>
<th>LOCKING SCREWS (mm)</th>
<th>MAXIMUM DISTRACTION (mm)</th>
<th>PROXIMAL BEND</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.5, 10.7, and 12.5</td>
<td>155, 160, 180, 195, 215, 230, 245, 275, 305, 335, 365</td>
<td>3.5, 4.0, and 5.0</td>
<td>30, 50, and 80</td>
<td>10°</td>
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</table>

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.

### Formula

\[
\text{Limb Length Discrepancy} = (d_2 - d_1) + \text{LIFT} =
\]

*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.
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 12.5 mm diameters with a proximal 10° bend. Over reaming the intramedullary tibial canal by 2.0 mm is recommended to aide in implant insertion. The cortices should be at least 3 mm 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:

A) 3.0 cm (distal distraction rod length)
B) The desired amount of bone lengthening (up to 8.0 cm)
C) Add an additional 4.0 cm to 5.0 cm

This measurement determines the suggested level of the osteotomy.

\[ A + B + C = \text{Measurement from the distal end of the implant to perform osteotomy} \]
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.
ANTEGRADE 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 13 cm unless concurrent peroneal identification and decompression is performed.

Create a 2.5 cm 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, proximal peroneal nerve release, and insert a temporary calcaneal-tibial posterior screw to help prevent equinus from developing during tibial lengthening. 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. To avoid these potential complications, place multiple venting holes in the tibia at the planned osteotomy site prior to reaming.

Make a 1.0 cm 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 152 mm Drill Bit or 5.0 x 152 mm 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.

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.

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.
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 rigid 8.0 mm or 11.0 mm entry drill (8-10 mm). 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 cm to 4.0 cm 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.

Attach an AO quick connect to the reamer prior to reaming the canal with flexible reamers beginning with 7 mm. Increase by 0.5 mm increments until the tibial canal is over-reamed by 2.0 mm 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.

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

TIBIAL ENTRY POINT

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.
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 355 mm 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.
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 mm to 1.0 mm.

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 355 mm 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 mm x 355 mm Drill Bit. 5.0 mm Locking Screws are available in 5 mm increments from 20-75 mm 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 3.5 mm Locking Driver. Hand tighten the Screw Capture Rod to the appropriate length 5.0 mm Locking Screw. Attach the 3.5 mm 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 3.5 mm 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.
**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.

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 3.5 mm Locking Driver. Tighten the Locking Screw by hand. Release the Screw Capture Rod and perform final tightening of the Locking Screw with the 3.5 mm Solid Hex Driver. Repeat steps for additional distal Locking Screws.

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**Size Guide for Nail Diameter**

**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)**

<table>
<thead>
<tr>
<th>LOCKING SCREW SIZE (mm)</th>
<th>8.5 mm NAIL</th>
<th>10.7 mm NAIL</th>
<th>12.5 mm NAIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal</td>
<td>5.0</td>
<td>5.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Distal</td>
<td>3.5</td>
<td>4.0</td>
<td>5.0</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>LOCKING SCREW SIZE (mm)</th>
<th>8.5 mm NAIL</th>
<th>10.7 mm NAIL</th>
<th>12.5 mm NAIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal</td>
<td>5.0</td>
<td>5.0</td>
<td>N/A</td>
</tr>
<tr>
<td>Distal</td>
<td>4.0</td>
<td>4.0</td>
<td>N/A</td>
</tr>
</tbody>
</table>
END CAP PLACEMENT (OPTIONAL)

If desired, an End Cap may be used to help prevent bony ingrowth into the proximal thread of the nail. One standard End Cap is available for all nail sizes.

Secure the End Cap to the 3.5 mm 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 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.

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

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.
**FINAL CLOSURE**

After the 1.0 mm 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 0.5-1.0 mm divided into 2 to 4 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 be limited (8.5 mm = 30 lbs; 10.7/12.5 mm = 50 lbs) 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).
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 ERC2P

1. TIBIA HANDLE
2. FEMUR HANDLE
3. STOP BUTTON
4. LCD CONTROL PANEL SCREEN WITH ALIGNMENT CAMERA
5. GO BUTTON
6. EXTERNAL POWER SUPPLY
PROGRAMMING THE PRESCRIPTION

NuVasive®-Issued Computer

A laptop will be provided with every ERC2P with the Prescription Software.

1. Insert SD Card into the Card Reader.

SD Card Programming

2. Fill in patient prescription information.

3. “Write” card to confirm prescription and “Accept” summary.

Insert SD Card

4. Remove programmed SD card from computer.

5. Insert programmed SD card into ERC2P.

6. Turn on machine and perform lengthening.

LABEL MUST FACE INWARD
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 additional information.

IMPLANT REMOVAL

Removal of the PRECICE implant is recommended at approximately 12-18 months 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 3.5 mm 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. The Slap Hammer may be used to assist in nail removal as needed.

Perform skin closure with routine techniques.
### BASIC INSTRUMENT TRAY

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<tr>
<th>MODEL #</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>1</td>
<td>DBB5-000 Drill Guide</td>
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<td>2</td>
<td>GSB1-000 Guide Tube</td>
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<td>AGB1-000 Drill Guide Arm</td>
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<td>DSD2-035 Soft Tissue Protector</td>
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<td>THD2-000 Quick Connect T-Handle</td>
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<td>TBA1-000 Tommy Bar</td>
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<td>RMB1-000 Slap Hammer</td>
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<td>8</td>
<td>LRB1-000 Locking Rod</td>
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<td>DRD1-000 3.5 mm Solid Hex Driver</td>
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<td>THF3-000 3.5 mm Locking Driver</td>
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<td>CRC3-000 Screw Capture Rod</td>
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### TIBIAL LIMB LENGTHENING SYSTEM
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### SPECIALTY TARGETING TRAY

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<tr>
<td>1</td>
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<td>3</td>
<td>LRB2-000 Locking Rod</td>
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![Diagram of Specialty Targeting Tray](image-url)
## SUPPLEMENTAL INSTRUMENT TRAY

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<td>GWCl-000 Guide Wire Chuck</td>
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<td>LQC1-000 Large AO Quick Connect</td>
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<td>STP1-000 Soft Tissue Protector – Paddle</td>
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<td>STT1-000 Soft Tissue Protector – Tube</td>
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<td>7</td>
<td>XRR1-000 Intraoperative X-ray Ruler</td>
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<td>TCD1-000 Teardrop Cannulated Driver</td>
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![Supplemental Instrument Tray Image](image-url)
### Antegrade Tibia – 10°

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## DRILL BITS

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## CANNULATED ENTRY DRILL BITS

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The PRECICE® Intramedullary Limb Lengthening (IMLL) 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 of the femur and tibia.

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.

Caution: Federal law restricts this device to sale by or on the order of a physician.

CONTRAINDICATIONS:

- 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 for models H, J, K, and U or weighing in excess of 57 kg for the 8.5 and 10.7 mm diameter implants for models N, M, P, and Q.

WARNINGS:

- The PRECICE nail cannot withstand the stresses of full weight bearing. Patient should utilize external support and/or restrict activities until consolidation occurs.
- 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 in patients 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 tibia or femur 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 on the bone regenerate during the lengthening process.
- The PRECICE nail is supplied sterile and is for single use only. 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.

PRECAUTIONS:

- Do not use this device without proper training in both device implantation and adjustment. Refer to External Remote Controller (ERC) Operator's Manual OM0005 for operation of the External Remote Controller.
- During the distraction phase, patient should not participate in contact sports or other high risk activities that cause more than 20% of body weight to be loaded on implanted leg. 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.
- 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.
- Do not bend the PRECICE nail or otherwise modify or damage the implant.
- Follow the ERC Operators Manual (OM0005) to assure proper alignment between the ERC and magnet of the PRECICE nail.
The PRECICE® Intramedullary Limb Lengthening (IMLL) 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 of the femur and tibia. 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 for models H, J, K, and U or weighing in excess of 57 kg for the 8.5 and 10.7 mm diameter implants for models N, M, P, and Q. 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. Caution: Federal law restricts this device to sale by or on the order of a physician.