INTRAMEDULLARY LIMB LENGTHENING SYSTEM
OPERATIVE TECHNIQUE: FEMUR

Contributing Surgeons
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The PRECICE® Intramedullary Limb Lengthening System is indicated for limb lengthening of the tibia and femur.

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

All non-sterile instruments must be cleaned and sterilized before use. Multi-component instrument assemblies must be disassembled for 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® 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 requirements with the hand held ERC. The physician’s lengthening prescription can be entered into the ERC. When the desired length is achieved, intramedullary fixation continues to provide stability throughout the consolidation phase.

The PRECICE Intramedullary Limb Lengthening System is comprised of the following components:

- Actuator Rods
- Modular Extension Rods
- Proximal and Distal Locking Screws
- Instrument Tray
- ERC™ (External Remote Controller)
PRE-OPERATIVE ASSESSMENT

Careful pre-operative evaluation and planning, proper surgical technique and extended post-operative care are essential for success of limb lengthening procedures.

Pre-operative evaluation is performed to determine:
- Surgical Approach (Antegrade, Retrograde)
- Limb Length Discrepancy
- Intramedullary Diameter
- Required Implant Length
- Osteotomy Location of Femur
- Soft Tissue Assessment

Femoral Implant Sizes

<table>
<thead>
<tr>
<th>Diameter (mm)</th>
<th>10.7 and 12.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lengths (mm)</td>
<td>230, 255, 280, 305, 330, 355</td>
</tr>
<tr>
<td>Locking Screws (mm)</td>
<td>4.0 and 5.0</td>
</tr>
</tbody>
</table>
| Maximum Distraction (cm) | 6.5
  Reversible - Can shorten if necessary |
| Surgical Approaches | Antegrade - Trochanteric or Piriformis Retrograde |

Limb Length Discrepancy Calculation

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

\[ d_1 = \quad d_2 = \]

\[ F_1 = \quad F_2 = \]

\[ T_1 = \quad T_2 = \]

* \(d_1\) and \(d_2\) are measured from the top of the femoral head reference line to the top of the x-ray image; use a magnification marker on x-ray to ensure accurate measurements

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.
Antegrade Femoral Implant Selection

Two options are available for PRECICE antegrade femoral implants:

1. Piriformis Fossa Entry
2. Trochanteric Entry (10° Proximal Bend)

The choice of entry is dependent on patient anatomy, age, surgeon experience and preference. Piriformis fossa entry should only be performed on skeletally mature patients.

The choice of 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.
PRE-OPERATIVE PLANNING

Femur Osteotomy Level Calculation

These are general guidelines. The osteotomy level should be determined pre-operatively using AP, lateral and plain x-rays. From the tip of the greater trochanter or piriformis fossa, measure with a ruler where the distal end of the PRECICE implant will be placed. The femoral implant length is determined primarily by the level of the maximum bowing on the lateral x-ray. Performing the osteotomy at this level straightens the natural curve of the femur allowing insertion of the straight PRECICE implant. In all cases, it is imperative that adequate distal segment coverage be maintained for biomechanical stability.

In general, it is recommended to use shorter rather than longer implants. The PRECICE femoral implant is available in 10.7mm and 12.5mm diameters. Over reaming the intramedullary femoral canal by 2.0mm is recommended to aid in implant insertion. The cortices must be at least 3mm thick at any location once reamed.

Femur Implant Lengths

- 23.0cm (230mm Extension Rod)
- 25.5cm (255mm Extension Rod)
- 28.0cm (280mm Extension Rod)
- 30.5cm (305mm Extension Rod)
- 33.0cm (330mm Extension Rod)
- 35.5cm (355mm Extension Rod)

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

A) 3.0cm (distal distraction rod length)
B) The desired amount of bone lengthening (up to 6.5cm)
C) Add an additional 4.0 to 5.0cm

\[ A + B + C = \text{Measurement from the Distal End of the Implant to Perform Osteotomy} \]

This measurement determines the suggested level of the osteotomy.
Soft Tissue Release

Depending on clinical requirements, consider performing a routine transverse release of the distal fascia lata. This is done through a 2.5cm longitudinal incision at the level of 1.0cm proximal to the superior pole of the patella. If this release is performed more proximally, an unsightly myofascial hernia may result.

The fascia lata is dissected and transversely incised to the midline anteriorly and to the intermuscular septum posteriorly, including a portion of the intermuscular septum itself.
Patient Positioning

Place the patient supine on a radiolucent table. Position a small bump under the ipsilateral sacroiliac joint. Confirm with the image intensifier that a true AP and cross table lateral view of the hip are possible. Prep and drape the patient’s entire limb from the iliac crest to the foot/ankle using standard sterile technique. An antibiotic prophylaxis injection may be given prior to making an incision.
Entry Point and Pre-Operative Considerations

Locate the tip of the greater trochanter or the piriformis fossa by laying a wire on the skin and using fluoroscopy. Use a surgical marking pen to denote this location.

Based on the determined surgical approach, locate the appropriate entry point for piriformis fossa or greater trochanter insertion. Using AP and lateral views, percutaneously insert and center a Steinmann pin into the intramedullary canal.

Next, use a ruler to measure from the entry point on the proximal femur to the distal end of the PRECICE implant based on pre-operative measurements and calculations. Mark the skin at this level and also at the level of the planned femoral osteotomy.
Intramedullary reaming of a closed bone generates high intramedullary pressures that have been associated with complications such as fat embolism\(^1\). To avoid these potential complications, place multiple venting holes in the femur at the planned osteotomy site prior to reaming.

- 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.


Make a 1.0cm longitudinal incision at the lateral thigh near the determined osteotomy site. Dissect bluntly with a straight hemostat down to the lateral femur. Insert a small periosteal elevator and lift the anterior periosteum and the posterior periosteum including the linea aspera. Using a percutaneous technique, drill at least one lateral and three medial holes with the short solid 5.0mm drill bit. Make one entry hole lateral and three exit holes medially.
Intramedullary Reaming

Verify and confirm the proper entry location (trochanteric or piriformis fossa approach) of the Steinmann pin under biplanar fluoroscopic guidance.

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

After confirming correct pin placement on AP and Lateral radiograph views, position a soft tissue protector and ream over the Steinmann pin with a rigid 8.0mm or 9.0mm entry reamer into the intramedullary canal.

Insert a ball tip guide wire into the entry hole and down the length of the femur about 4.0 to 5.0cm beyond the planned distal end of the nail.

Ream the canal with flexible reamers beginning with 8.5mm and increasing by 0.5mm increments until the femoral canal is over-reamed by 2.0mm greater than the planned diameter of the PRECICE implant.

There are two diameters of PRECICE femoral implants: 10.7mm and 12.5mm
ANTEGRADE FEMUR: OPERATIVE TECHNIQUE

PRECICE Implant Assembly

Select the appropriate diameter of Actuator (10.7 mm or 12.5 mm) and the desired Extension Rod (See Product Reference Guide on page 41).

Extension Rods are supplied non-sterile and must be sterilized prior to use. Refer to the corresponding product Instructions for Use for complete sterilization guidelines.

Using sterile technique, assemble the PRECICE implant by removing the set screw from the Actuator. Place the square end of the Extension Rod over the square end of Actuator.

Reinsert the set screw through the large hole in the Extension Rod and tighten using the hex driver. The two ends of the set screw will be flush with Extension Rod.
ANTEGRADE FEMUR: OPERATIVE TECHNIQUE

Femoral Guide Arm Assembly

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

Verify correct alignment of the 5.0mm 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 Femoral Guide Arm Assembly, place the construct aside in the sterile field until ready for insertion into the intramedullary canal.
ANTEGRADE FEMUR: OPERATIVE TECHNIQUE

Osteotomy of the Femur

Insert the PRECICE implant with the Femoral Guide Arm into the intramedullary canal 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.

Pins may be inserted for a temporary external fixator if maintaining rotational alignment is necessary.

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.

*Important: Verify the osteotomy is complete with multiplanar image intensification.*

Immediately after confirming the osteotomy, gently tap the Short Impactor on the Femoral Guide Arm to advance the PRECICE implant across the gap and into the distal femur. The implant should slide easily into the proper position and aggressive hammering should be avoided at all times. Using biplanar C-arm views, confirm the reduction.

Properly position the implant prior to inserting the locking screws.

*If the tip of the PRECICE nail gets hung up on the cut cortex of the distal segment, 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 0.5mm to 1.0mm.*
Proximal Locking Screws

Two 5.0mm proximal locking screws are positioned through the implant with the Femoral Guide Arm.

Position the Trocar through the Guide Tube and place through the Femoral 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 femoral cortex.

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

Select the appropriate length screw by reading the calibration on the Long 5.0mm Drill. 5.0mm screws are available in 5.0mm increments from 20mm to 75mm lengths.

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

Hand tighten the screw through the implant and into the near cortex. Remove the Quick Connect T-Handle and untighten the Screw Capture Rod to release the 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 screw. Repeat this sequence for the second proximal screw.
**ANTEGRADE FEMUR: OPERATIVE TECHNIQUE**

**End Cap Placement (Optional)**

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

If desired, a standard End Cap is available and can be positioned.

Using the cannulated 3.5mm Hex Driver and Screw Capture Rod assembly, secure the End Cap to the Screw Capture Rod. Attach the assembly to the Quick Connect T-Handle. Use image intensification to confirm positioning and take care not to cross-thread the End Cap.

Turn clockwise until the End Cap fully seats against the top of the nail. Untighten the Screw Capture Rod to release the End Cap.

**Confirmation of End Cap positioning.**
ANTEGRADE FEMUR: OPERATIVE TECHNIQUE

Distal Locking Screws

The free hand technique is used to position 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 M/L 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 drill size to drill the pilot hole for the locking screw.

- **10.7mm diameter implant utilize 4.0mm distal locking screws. Use the Short 4.0mm Drill Bit.**

- **12.5mm diameter implants utilize 5.0mm distal locking screws. Use the Short 5.0mm Drill Bit.**

Select the length for the first distal screw by reading the measurement off the drill bit with the Soft Tissue Protector fully seated on the cortex. Attach the appropriate length locking screw to the Screw Capture Rod and cannulated 3.5mm Hex Driver assembly. Tighten the screw by hand. Attach the assembly to the Quick Connect T-Handle. Release the Screw Capture Rod and perform final tightening of the screw with the 3.5mm Solid Hex Driver.
ANTEGRADE FEMUR: OPERATIVE TECHNIQUE

Intra-Operative External Remote Control (ERC) Distraction

Evaluate the final implant construct under image intensification. Locate the magnet and gear box within the PRECICE implant (See Reference Image). 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.

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 prior to using the ERC).
ANTEGRADE FEMUR: OPERATIVE TECHNIQUE

Intra-Operative External Remote Control (ERC) Distraction

Place the ERC in a sterile bag and place it over the mark indicating the location of the internal magnet. Make sure you have properly aligned the ERC on the patient’s femur and the magnets are pointed toward the patient’s feet (Refer to the ERC operators manual).

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 1.0mm. This verifies correct functioning of the system. It takes seven minutes to achieve 1.0mm of lengthening.

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.

Correct Alignment of the ERC to the Patient’s Femur; Always Point Arrows on ERC Toward Patient’s Feet
Retrograde Femoral Implant Selection

Two options are available for PRECICE retrograde femoral implants:

Intercondylar Entry 10° Proximal Bend
Intercondylar Entry Straight

The choice of implant is dependent on patient anatomy, age, surgeon experience, and preference.
PRE-OPERATIVE PLANNING

Femur Osteotomy Level Calculation

These are general guidelines. The osteotomy level should be determined pre-operatively using AP, lateral, and plain x-rays. From the entry point of the intercondylar notch, measure with a ruler where the proximal end of the PRECICE implant will be located. The femoral implant length is determined primarily by the level of the maximum bowing on the lateral x-ray. Performing the osteotomy at this level straightens the natural curve of the femur allowing insertion of the straight PRECICE implant. In all cases, it is imperative that adequate proximal segment coverage be maintained for biomechanical stability. It is recommended to use shorter rather than longer implants. The PRECICE femoral implant is available in 10.7mm and 12.5mm diameters. Over reaming the intramedullary femoral canal by 2.0mm is recommended to aid in implant insertion. The cortices must be at least 3 mm thick at any location once reamed.

Femur Implant Lengths
- 23.0cm (230mm Extension Rod)
- 25.5cm (255mm Extension Rod)
- 28.0cm (280mm Extension Rod)
- 30.5cm (305mm Extension Rod)
- 33.0cm (330mm Extension Rod)
- 35.5cm (355mm Extension Rod)

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

A) 3.0cm (proximal distraction rod length)
B) The desired amount of bone lengthening (up to 6.5cm)
C) Add an additional 4.0 to 5.0cm

\[ A + B + C = \text{Measurement from the Proximal End of the Implant to Perform Osteotomy} \]

This measurement determines the suggested level of the osteotomy.
Soft Tissue Release

Depending on clinical requirements, consider performing a routine transverse release of the distal fascia lata. This is done through a 2.5cm longitudinal incision at the level of 1.0cm proximal to the superior pole of the patella. If this release is performed more proximally, an unsightly myofascial hernia may result.

The fascia lata is dissected and transversely incised to the midline anteriorly and to the intermuscular septum posteriorly, including a portion of the intermuscular septum itself.
Patient Positioning

The patient is placed in a supine position on a radiolucent table. Position a small bump under the ipsilateral sacroiliac joint. Confirm with the image intensifier that a true AP and cross table lateral view of the femur are possible. Prep and drape the patient’s entire limb from the iliac crest to the foot/ankle using standard sterile technique. An antibiotic prophylaxis injection may be given prior to making an incision.
Entry Point and Pre-Operative Considerations

With the image intensifier, locate the joint line using a wire placed over the skin to find the intercondylar notch of the distal femur. On the lateral view, mark the apex of any distal bow present.

Using AP and lateral views, percutaneously insert and center a Steinmann pin into the intramedullary canal. The entry point should be in line with the long axis of the femoral shaft.

Make a 2.5cm incision longitudinally over the patellar tendon. Either split the patellar tendon longitudinally or go parapatellar depending on the patient's anatomy.
VENTING OF THE FEMORAL INTRAMEDULLARY CANAL

Intramedullary reaming of a closed bone generates high intramedullary pressures that have been associated with complications such as fat embolism\(^1\). To avoid these potential complications, place multiple venting holes in the femur at the planned osteotomy site prior to reaming.

- 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.

- Reaming's which exit the vent holes will act as prepositioned bone graft at the distraction gap.

Make a 1.0cm longitudinal incision at the lateral thigh near the determined osteotomy site. Dissect bluntly with a straight hemostat down to the lateral femur. Insert a small periosteal elevator and lift the anterior periosteum and the posterior periostem including the linea aspera. Using a percutaneous technique, drill at least one lateral and three medial holes with the short solid 5.0mm drill bit. Make one entry hole lateral and three exit holes medially.

Intramedullary Reaming

Verify and confirm the proper entry location of the Steinmann pin under biplanar fluoroscopic guidance.

After confirming correct pin placement on AP and Lateral radiograph views, position a soft tissue protector and ream over the Steinmann pin with a rigid 8.0mm or 9.0mm entry reamer into the intramedullary canal.

Insert a ball tip guide wire into the entry hole and into the length of the femur about 4.0 to 5.0cm beyond the planned distal end of the nail.

Ream the canal with flexible reamers beginning with 8.5mm and increasing by 0.5mm increments until the femoral canal is over-reamed by 2.0mm greater than the planned diameter of the PRECICE implant.

*The PRECICE implant should not be difficult to insert. If necessary, consider over reaming the canal by an additional 0.5mm to 1.0mm.*
RETROGRADE FEMUR: OPERATIVE TECHNIQUE

PRECICE Implant Assembly

Select the appropriate diameter of Actuator (10.7 mm or 12.5 mm) and the desired Extension Rod (See Product Reference Guide on page 41).

Extension Rods are supplied non-sterile and must be sterilized prior to use. Refer to the corresponding product Instructions for Use for complete sterilization guidelines.

Using sterile technique, assemble the PRECICE implant by removing the set screw from the Actuator. Place the square end of the Extension Rod over the square end of Actuator.

Reinsert the set screw through the large hole in the Extension Rod and tighten using the hex driver. The two ends of the set screw will be flush with Extension Rod.
Femoral Guide Arm Assembly

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

Verify correct alignment of the 5.0mm Drill Bit through the Drill Guide and PRECICE implant. Confirm both distal screw holes in this manner.

Once the PRECICE implant has been properly attached to the Retrograde Femoral Guide Arm Assembly, place the construct aside in the sterile field until ready for insertion into the intramedullary canal.
RETROGRADE FEMUR: OPERATIVE TECHNIQUE

Osteotomy of the Femur

Insert the PRECICE implant with the Retrograde Femoral Guide Arm Assembly into the intramedullary canal until the distal tip of the nail is just below to the planned osteotomy site where the vent holes were placed. Verify this location under image intensification.

Insert pins for a temporary external fixator if maintaining rotational alignment is necessary.

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.

Important: Verify the osteotomy is complete with multiplanar image intensification.

Immediately after confirming the osteotomy, gently tap the Short Impactor on the Femoral Guide Arm Assembly to advance the PRECICE implant across the gap and into the proximal femur. Using biplanar C-arm views, confirm the reduction.

Properly position the implant prior to inserting the locking screws.
RETROGRADE FEMUR: OPERATIVE TECHNIQUE

Distal Locking Screws

Two 5.0mm distal locking screws are positioned through the implant with the Retrograde Femoral Guide Arm Assembly.

Position the Trocar through the Guide Tube and place through the Retrograde Femoral Guide Arm Assembly. 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 femoral cortex.

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

Select the appropriate length screw by reading the calibration on the Long 5.0mm Drill. 5.0mm screws are available in 5.0mm increments from 20mm to 75mm lengths.

Insert the Screw Capture Rod through the cannulated 3.5mm Hex Driver. Hand tighten the Screw Capture Rod to the appropriate length 5.0mm screw. Attach the 3.5mm Hex Driver with Screw Capture Rod in place to the Quick Connect T-Handle. Remove the Drill Guide and position the screw into the Guide Tube to direct it into the PRECICE implant. Hand tighten the screw through the implant and into the near cortex. Remove the Quick Connect T-Handle and untighten the Screw Capture Rod to release the 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 screw. Repeat this sequence for the second distal screw.
RETROGRADE FEMUR: OPERATIVE TECHNIQUE

End Cap Placement (Optional)

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

If desired, a standard End Cap is available and can be positioned.

Using the cannulated 3.5mm Hex Driver and Screw Capture Rod assembly, secure the End Cap to the Screw Capture Rod. Attach the assembly to the Quick Connect T-Handle. Use image intensification to confirm positioning and take care not to cross-thread the End Cap.

Turn clockwise until the End Cap fully seats against the top of the nail. Untighten the Screw Capture Rod to release the End Cap.

Confirmation of End Cap positioning.
RETROGRADE FEMUR: OPERATIVE TECHNIQUE

Proximal Locking Screws

The free hand technique is used to position screws in the A/P and M/L proximal locking holes of the PRECICE retrograde femur implants.

Depending upon which locking screw is to be inserted, align the C-Arm in either the A/P or M/L 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 drill size to drill the pilot hole for the locking screw.

- **10.7mm diameter implant utilize 4.0mm proximal locking screws. Use the Short 4.0mm Drill Bit.**

- **12.5mm diameter implants utilize 5.0mm proximal locking screws. Use the Short 5.0mm Drill Bit.**

Select the length for the first proximal screw by reading the measurement off the drill bit with the Soft Tissue Protector fully seated on the cortex. Attach the appropriate length locking screw to the Screw Capture Rod and cannulated 3.5mm Hex Driver assembly. Tighten the screw by hand. Attach the assembly to the Quick Connect T-Handle. Release the Screw Capture Rod and perform final tightening of the screw with the 3.5mm Solid Hex Driver.
Intra- Operative External Remote Control (ERC) Distraction

Evaluate the final implant construct under image intensification. Locate the magnet and gear box within the PRECICE implant (See Reference Image). 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.

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 prior to using the ERC).
Intra-Operative External Remote Control (ERC) Distraction

Place the ERC in a sterile bag and place it over the mark indicating the location of the internal magnet. Make sure you have properly aligned the ERC on the patient’s femur and the magnets are pointed toward the patient’s feet (Refer to the ERC operators manual).

Use the implant locator window on the ERC to properly position it over the mark on the patient’s skin. Confirm that the ERC is programmed for retrograde implant.

Activate the ERC to distract the PRECICE implant 1.0mm. This verifies correct functioning of the system. It takes seven minutes to achieve 1.0mm of lengthening.

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.
ANTEGRADE/ RETROGRADE FEMUR: OPERATIVE TECHNIQUE

Final Closure

After the 1.0mm lengthening of the PRECICE implant, the surgical incisions are irrigated and closed in standard fashion.

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

Post-Operative Management

Patients should be mobilized the first few days after surgery, but must avoid full weight-bearing throughout the entire lengthening phase. 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 their patient. Factors to consider when determining daily lengthening rate include bone quality, location and trauma of osteotomy, patient age, and comorbidities.

Daily lengthenings are typically 1.0mm divided into 3 to 4 sessions. Lengthening typically starts 5 to 7 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 (Please 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 to neutral

Anti-coagulation treatments are an option during this phase.
LENGTHENING PHASE UTILIZING THE EXTERNAL REMOTE CONTROLLER (ERC)

During the lengthening phase, patient compliance to the planned lengthening prescription is important. Adherence to proper use of the ERC in addition to post-operative rehabilitation protocols must be emphasized. It is the physician’s responsibility to carefully monitor the patient’s progress with routine x-rays and to make any necessary changes to the daily lengthening prescription. The physician may adjust or reverse a prescription to best meet the needs of the patient.

After the bone lengthening phase has been completed, the patient’s weight-bearing status must be limited. Clinical and radiographic evaluations by the physician are necessary to ensure bony consolidation.

Lengthening to Consolidation Images

The physician and their staff will 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.
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 (OM0005).

- 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.

Please refer to the Operator’s Manual for a full list of precautions, warnings and contraindications.
EXTERNAL REMOTE CONTROLLER (ERC)

ERC Quick Reference Guide

A physician access password is required to enter the patient’s required lengthening prescription or make edits during the distraction phase. To access the surgeon password screen and to make adjustments to lengthening parameters press **F9**.

After inputting the surgeon passcode, **F9** allows adjustments of the following:
- Patient Distracting Data
- Distraction Values
- Antegrade / Retrograde Approach

Proper selection of **ANTEGRADE** or **RETROGRADE** for **PRECICE** femoral implants is imperative. Select based on surgical approach.

Main Operating Display and Button Function

<table>
<thead>
<tr>
<th>Button</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>F6</strong></td>
<td>Main Operating Screen</td>
</tr>
<tr>
<td>①</td>
<td>Target Distraction Per Session</td>
</tr>
<tr>
<td>②/③</td>
<td>Increase/Decrease Distraction Value</td>
</tr>
<tr>
<td>④/⑤</td>
<td>Distraction Progress for Current Session</td>
</tr>
<tr>
<td>⑥/⑦</td>
<td>Scroll Up/ Scroll Down</td>
</tr>
<tr>
<td>⑧</td>
<td>Antegrade/ Retrograde Verification</td>
</tr>
<tr>
<td><strong>F1</strong></td>
<td>Activate ERC/ Stop ERC</td>
</tr>
</tbody>
</table>

The ERC will stop automatically after the session length has been reached.

Please refer to the Operator’s Manual for detailed instructions on the proper use of the ERC.
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 AP/LAT views as determined by the physician.

If bone healing is delayed, consider using adjunctive measures such as ultrasound bone stimulation or bone grafting. Make sure the patient maintains a healthy diet with adequate Vitamin D and Calcium. Consider measuring levels and using supplements as need.
PRECICE IMPLANT REMOVAL

Removal of the PRECICE implant is recommended within 12 months of implantation provided that radiological evidence of full bone consolidation is present. Each surgeon must determine the best time for removal of the PRECICE implant based upon clinical evaluation of the patient.

Operative Technique for PRECICE Implant Removal

Exsanguinate the leg and apply a thigh tourniquet. Expose the proximal end of the implant by careful debridement of heterotopic bone and soft tissue.

Using the image intensifier, locate the proximal and distal locking screws. Make small incisions and untighten the screws using the 3.5mm Solid Hex Driver and Quick Connect T-Handle. Remove all but one of the locking screws prior to attaching the Removal Rod.

If present, remove the End Cap using the 3.5mm Hex Driver, Screw Capture Rod, and Quick Connect T-Handle assembly.

Thread the Implant Removal Rod into the proximal threads of the implant. Remove the final locking screws and then gently remove the PRECICE implant. The Slap Hammer may be used to assist in implant removal.

Perform skin closure with routine techniques.
<table>
<thead>
<tr>
<th>Overall Implant Length</th>
<th>Antegrade Piriformis Extension Rods</th>
<th>Antegrade Trochanteric Extension Rods</th>
<th>Retrograde 10° Extension Rods</th>
<th>Retrograde Straight Extension Rods</th>
</tr>
</thead>
<tbody>
<tr>
<td>230mm</td>
<td>ERB1-230</td>
<td>ERB2-230</td>
<td>ERA1-230</td>
<td>ERE1-230</td>
</tr>
<tr>
<td>255mm</td>
<td>ERB1-255</td>
<td>ERB2-255</td>
<td>ERA1-255</td>
<td>ERE1-255</td>
</tr>
<tr>
<td>280mm</td>
<td>ERB1-280</td>
<td>ERB2-280</td>
<td>ERA1-280</td>
<td>ERE1-280</td>
</tr>
<tr>
<td>305mm</td>
<td>ERB1-305</td>
<td>ERB2-305</td>
<td>ERA1-305</td>
<td>ERE1-305</td>
</tr>
<tr>
<td>330mm</td>
<td>ERB1-330</td>
<td>ERB2-330</td>
<td>ERA1-330</td>
<td>ERE1-330</td>
</tr>
<tr>
<td>355mm</td>
<td>ERB1-355</td>
<td>ERB2-355</td>
<td>ERA1-355</td>
<td>ERE1-355</td>
</tr>
<tr>
<td>Actuator (167mm)</td>
<td>LAA1-065</td>
<td>LAA2-065</td>
<td>LAA1-065</td>
<td>LAA2-065</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Locking Screws</th>
<th>10.7mm Diameter Implants</th>
<th>12.5mm Diameter Implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.0 Green</td>
<td>Proximal 5.0mm</td>
<td>Proximal 5.0mm</td>
</tr>
<tr>
<td>(20mm – 75mm)</td>
<td>Distal 4.0mm</td>
<td>Distal 5.0mm</td>
</tr>
<tr>
<td>4.0 Blue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(20mm – 60mm)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Contact Ellipse Technologies Inc., Customer Service
1-855-435-5477
for assistance and ordering information.
<table>
<thead>
<tr>
<th>Model #</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DBB5-000</td>
</tr>
<tr>
<td>2</td>
<td>GSB1-000</td>
</tr>
<tr>
<td>3</td>
<td>AGB1-000</td>
</tr>
<tr>
<td>4</td>
<td>DSD1-045</td>
</tr>
<tr>
<td>5</td>
<td>THD2-000</td>
</tr>
<tr>
<td>6</td>
<td>TBA1-000</td>
</tr>
<tr>
<td>7</td>
<td>RMB1-000</td>
</tr>
<tr>
<td>8</td>
<td>LRB1-000</td>
</tr>
<tr>
<td>9</td>
<td>SNB1-000</td>
</tr>
<tr>
<td>10</td>
<td>CBB1-000</td>
</tr>
<tr>
<td>11</td>
<td>CTA1-000</td>
</tr>
<tr>
<td>12</td>
<td>RRB1-000</td>
</tr>
<tr>
<td>13</td>
<td>THE1-000</td>
</tr>
<tr>
<td>14</td>
<td>PRB1-000</td>
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<tr>
<td>15</td>
<td>LKA1-000</td>
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<tr>
<td>16</td>
<td>IMA1-000</td>
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<tr>
<td>17</td>
<td>DRD1-000</td>
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<tr>
<td>18</td>
<td>DRE1-000</td>
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<td>20</td>
<td>CRD1-000</td>
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<td>21</td>
<td>HDA1-000</td>
</tr>
</tbody>
</table>
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.

Please refer to the Instructions For Use and External Remote Controller (ERC) Operator’s Manual supplied with the product for specific information on the indications for use, contraindications, warnings, precautions, cautions and sterilization. These documents are also available by contacting Ellipse Technologies, Inc.

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