

PRECICE®

ADJUSTABLE SOLUTIONS
FOR ORTHOPEDICS

Antegrade and Retrograde Femur Operative Technique



CONTENTS

Introduction	2
PRECICE® Antegrade Femur Preoperative Planning	4
Limb Length Discrepancy Calculation	4
Antegrade Entry Osteotomy Calculation	5
PRECICE Antegrade Femur Operative Technique	6
Technical Details	6
Implant Selection	9
Patient Positioning	9
Soft Tissue Release	9
Antegrade Entry Point	10
Surgical Incision	10
Venting of the Femoral Intramedullary Canal	11
Intramedullary Reaming	11
Antegrade Femoral Guide Arm Assembly	12
Osteotomy of the Femur	13
Proximal Locking Screws	14
Distal Locking Screws	15
End Cap Placement (Optional)	16
Locating the Center of the Magnet	16
Intraoperative External Remote Controller (ERC) Distraction	17
Entering the Prescription	17
PRECICE Fast Distractor	18
PRECICE® Retrograde Femur Preoperative Planning	19
Limb Length Discrepancy Calculation	19
Retrograde Femur Osteotomy Calculation	20

CONTENTS

PRECICE® Retrograde Femur Operative Technique	21
Technical Details	21
Implant Selection	24
Patient Positioning	24
Soft Tissue Release	24
Retrograde Entry Point	25
Surgical Incision	25
Venting of the Femoral Intramedullary Canal	26
Intramedullary Reaming	26
Femoral Guide Arm Assembly	27
Osteotomy of the Femur	28
Distal Locking Screw	29
Proximal Locking Screw	30
End Cap Placement (Optional)	31
Locating the Center of the Magnet	31
Intraoperative External Remote Control (ERC) Distraction	32
Entering the Prescription	32
PRECICE Fast Distractor	33
Postoperative Treatment	34
Final Closure	34
Postoperative Management	34
Lengthening to Consolidation	35
Consolidation Phase	35
Postoperative Lengthening	36
External Remote Controller (ERC) Introduction	36
Features of the ERC3P	37
Implant Removal	38
Femoral Limb Lengthening System	39
Important Safety Information	45

INTRODUCTION

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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.

INTRODUCTION

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 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.

PRECICE SYSTEM COMPONENTS

The PRECICE System comprises 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 150–365mm



PRECICE® ANTEGRADE FEMUR PREOPERATIVE PLANNING

LIMB LENGTH DISCREPANCY CALCULATION

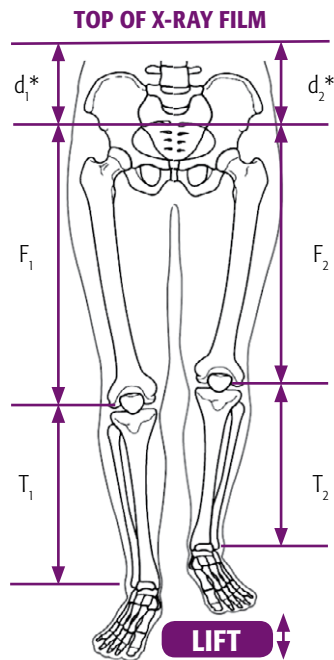
Careful preoperative evaluation and planning, proper surgical technique, and extended postoperative care are essential for success of limb lengthening procedures.

Preoperative evaluation is performed to determine:

- Limb length discrepancy
- Intramedullary diameter
- Required implant length
- Osteotomy location of femur
- 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	150, 165, 175, 190, 215, 245, 275, 305, 335, 365	50 and 80	10° or straight	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)	
$d_1 =$		$d_2 =$	
$F_1 =$		$F_2 =$	
$T_1 =$		$T_2 =$	

*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 to improve the accuracy of measurements

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

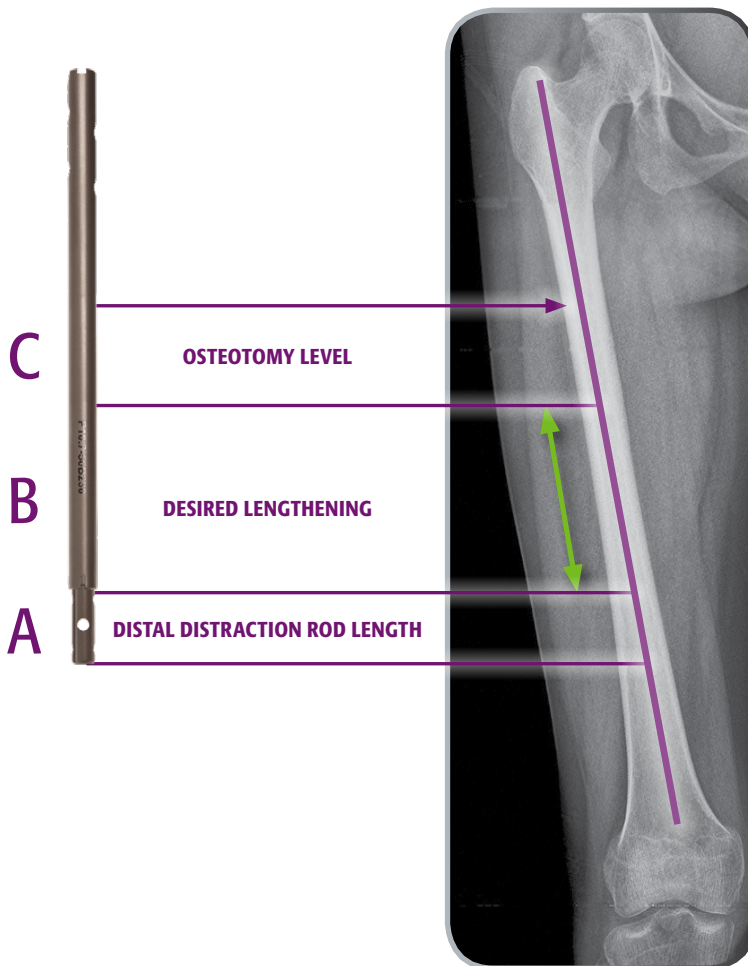
PRECICE® ANTEGRADE FEMUR PREOPERATIVE PLANNING

ANTEGRADE ENTRY 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® antegrade femoral implant is available in 8.5, 10.7, and 12.5mm diameters with a proximal 10° bend or straight option. Over-reaming the intramedullary femoral canal by 2.0mm is recommended to aid 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	4.0 – 5.0cm	4.0 – 5.0cm

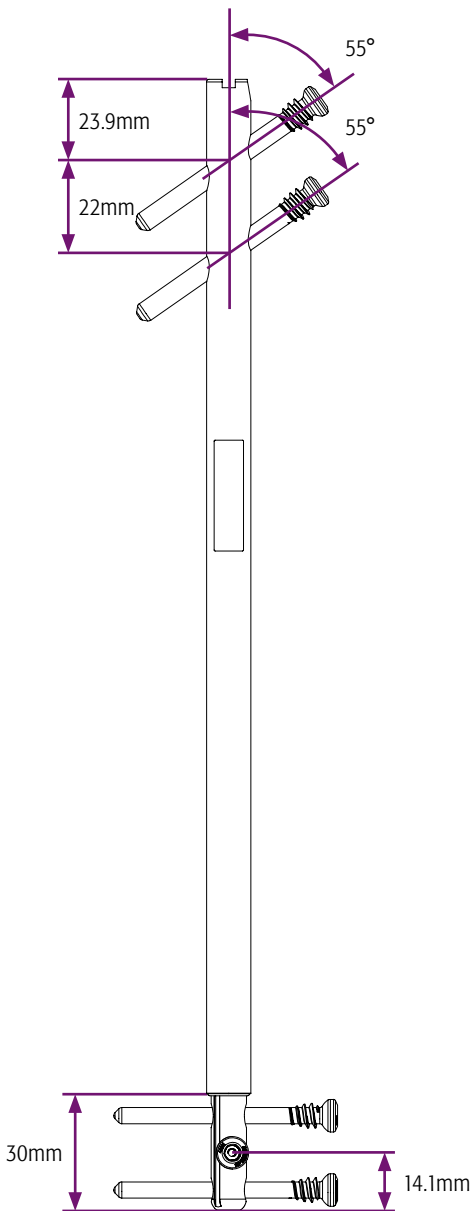
This measurement determines the suggested level of the osteotomy.

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

PRECICE® ANTEGRADE FEMUR OPERATIVE TECHNIQUE

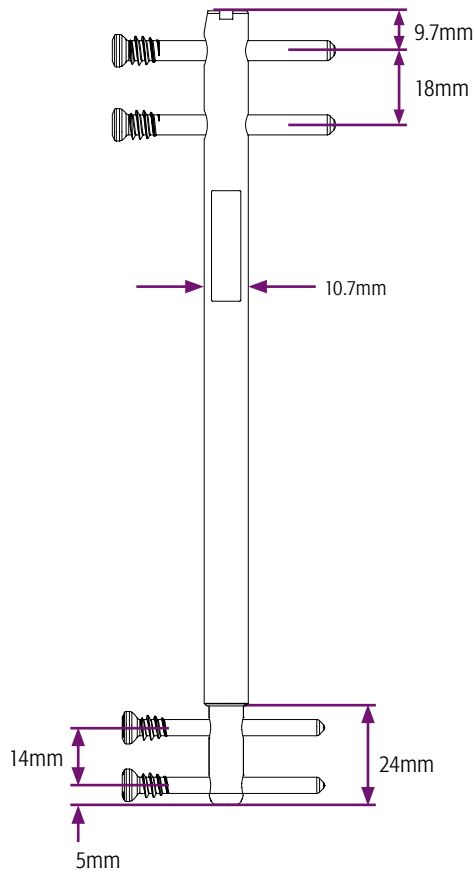
TECHNICAL DETAILS

Antegrade Femur Piriformis



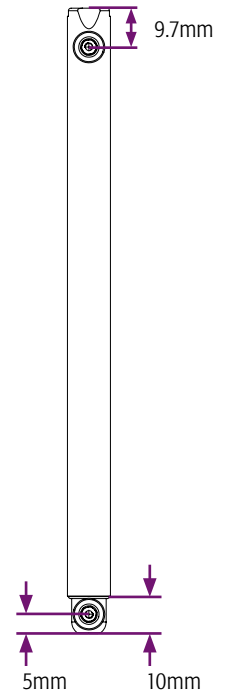
365mm – 215mm

Universal Femur – Straight



190mm

Universal Femur – Straight

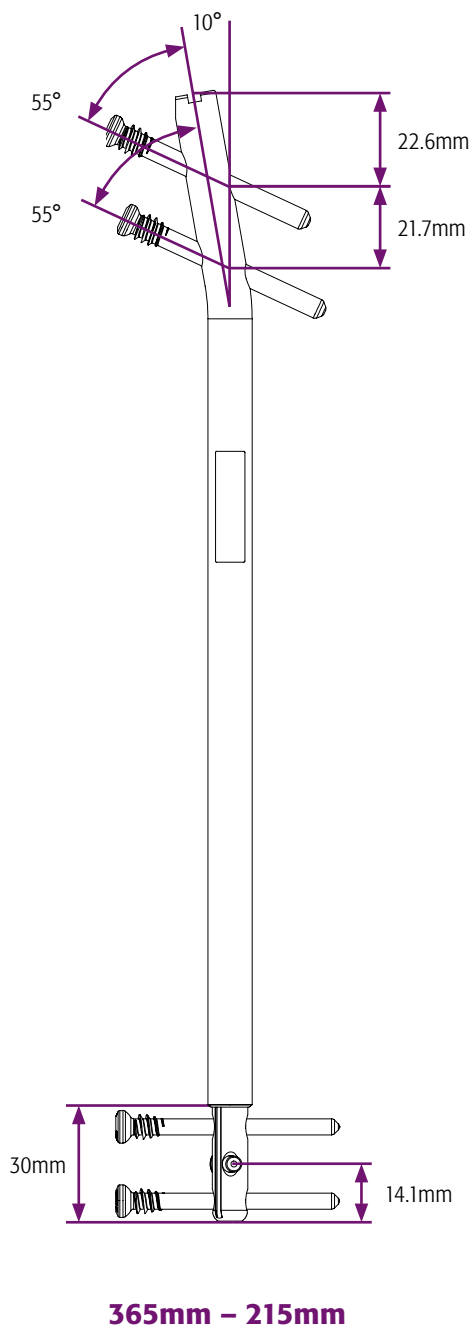


160mm – 150mm

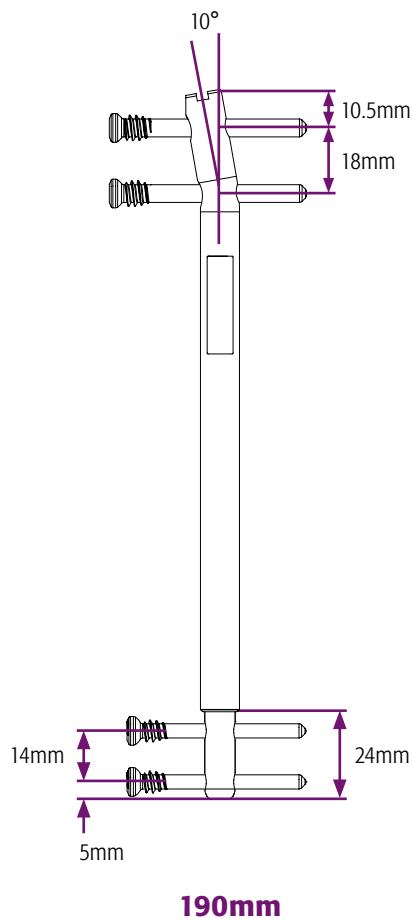
PRECICE® ANTEGRADE FEMUR OPERATIVE TECHNIQUE

TECHNICAL DETAILS

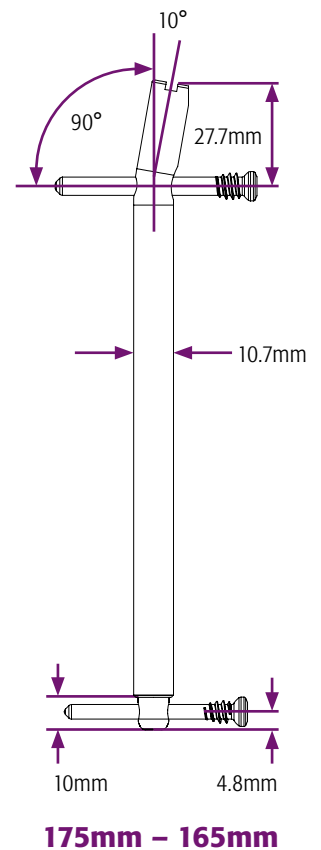
Antegrade Femur Trochanteric 10°



Antegrade Femur Trochanteric 10°



Antegrade Femur Trochanteric 10°



PRECICE® ANTEGRADE FEMUR OPERATIVE TECHNIQUE

TECHNICAL DETAILS

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)



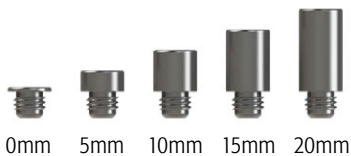
8.5mm Nail: 6.5mm
10.7mm Nail: 8.5mm
12.5mm Nail: 10.0mm

End Cap

Diameter: 10.7 and 12.5mm

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

Sizes



PRECICE® ANTEGRADE FEMUR OPERATIVE TECHNIQUE

IMPLANT SELECTION

Two options are available for PRECICE antegrade femoral implants:

- Trochanteric entry (10° Proximal Bend)
- Piriformis fossa entry

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 due to the risk of femoral head avascular necrosis.

In all cases, it is imperative that adequate distal segment coverage (by the larger female portion of the nail) be maintained at the end of lengthening for biomechanical stability.

PATIENT POSITIONING

Place the patient supine on a radiolucent table with a bump under the ipsilateral hemisacrum.

Confirm with the image intensifier that true A/P and cross table lateral views 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.

Antibiotic prophylaxis should be given prior to making an incision.

SOFT TISSUE RELEASE

Depending on clinical requirements, consider performing a routine transverse release of the distal fascia lata. This is done through a 2-3cm 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 from the anterior border to the intermuscular septum posteriorly, including a portion of the intermuscular septum itself.



PRECICE® ANTEGRADE FEMUR OPERATIVE TECHNIQUE

ANTEGRADE ENTRY POINT

Locate the tip of the greater trochanter or the piriformis fossa by laying a Steinmann pin on the skin and using fluoroscopy. Use a surgical marking pen to denote this location (8-10cm proximal to greater trochanter).

Based on the determined surgical approach, locate the appropriate entry point for piriformis fossa or greater trochanter insertion.

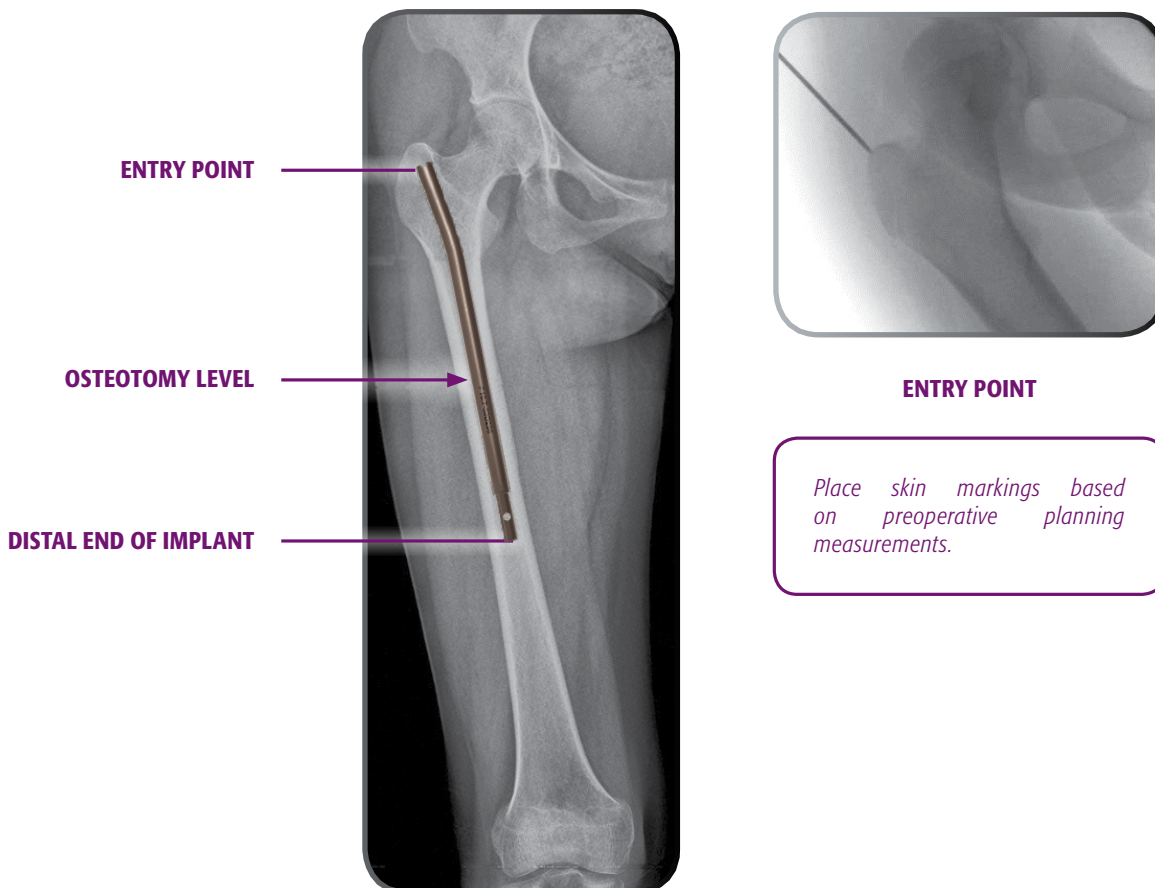
Using A/P and lateral image intensification views, percutaneously insert and center a Steinmann pin into the intramedullary canal.

Next, use an intraoperative x-ray ruler to measure from the entry point on the proximal femur to the distal end of the PRECICE® implant based on preoperative measurements and calculations. Mark the skin at this level and also at the level of the planned femoral osteotomy.

SURGICAL INCISION

Piriformis Fossa: a skin incision is made beginning at the level of the greater trochanter extending proximal and slightly posterior, in line with the gluteus muscle, exposing the piriformis fossa for nail insertion.

Trochanteric: the tip of the greater trochanter should be located by manual palpation and a horizontal skin incision is made from the greater trochanter to the iliac crest.



PRECICE® ANTEGRADE FEMUR OPERATIVE TECHNIQUE

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! 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 4.0 x 152mm Drill Bit or 5.0 x 152mm Drill Bit. Make one entry hole lateral and three exit holes medially. Additional holes may be used to facilitate the osteotomy.

INTRAMEDULLARY REAMING

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

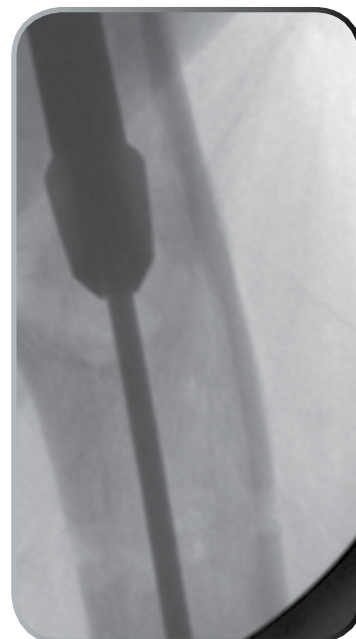
Make a small vertical incision around the pin and spread the soft tissues using hemostats.

After confirming correct pin placement on 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 into the intramedullary canal.

Insert a ball tip guide wire using a guidewire chuck 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 8.0mm 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. Use a guide wire pusher to secure guide wire when removing the flexible reamer from the canal.

There are three diameters of PRECICE antegrade femoral implants: 8.5mm, 10.7mm, and 12.5mm.



¹Kröpfl 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.

PRECICE® ANTEGRADE FEMUR OPERATIVE TECHNIQUE

ANTEGRADE FEMORAL GUIDE ARM ASSEMBLY

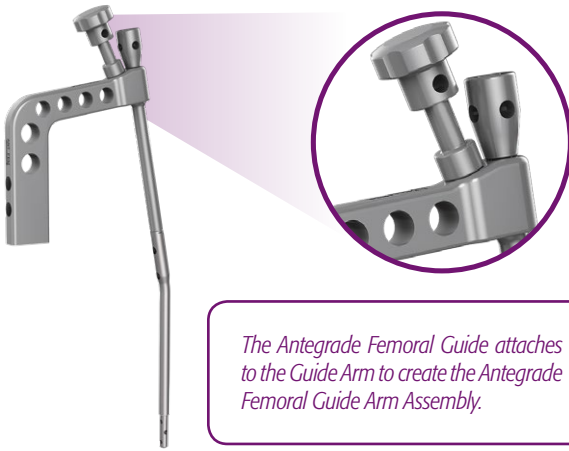
Attach the PRECICE® implant to the Guide Arm by inserting the Locking Rod through the hollow tube of the Drill Guide Arm and aligning the arrows on the implant and guide arm. Engage the threads on the proximal end of the implant with the Locking Rod and gently tighten with the Tommy Bar.

Note

Do not over-tighten the locking rod. Applying excessive force to the Tommy Bar may affect the proximal screw targeting accuracy.

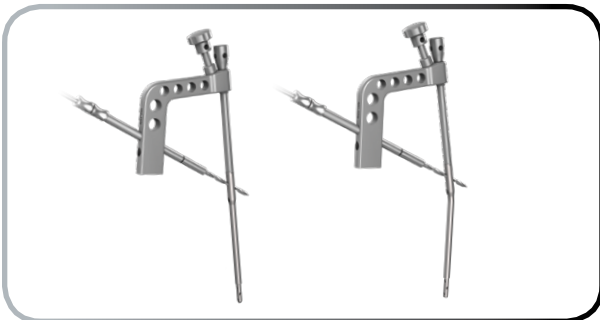
Verify correct alignment of the 5.0 x 355mm Drill Bit through the Guide Tube, Drill Guide, and PRECICE implant. Confirm both proximal screw holes in this manner. Once the PRECICE implant has been properly attached to the Antegrade Femoral Guide Arm Assembly, place the construct aside in the sterile field until ready for insertion into the intramedullary canal.

DEVICE AND ANTEGRADE FEMORAL GUIDE ARM ATTACHMENT



The Antegrade Femoral Guide attaches to the Guide Arm to create the Antegrade Femoral Guide Arm Assembly.

ANTEGRADE FEMORAL GUIDE ARM ASSEMBLY

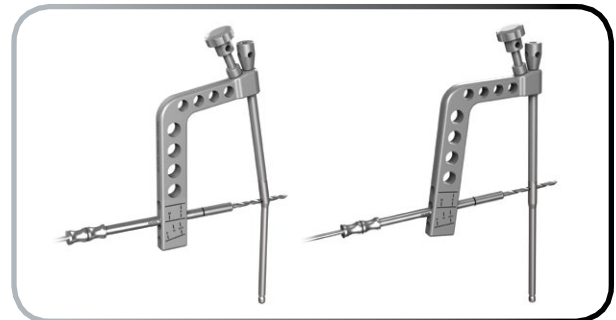


Antegrade Femoral Guide Arm Assembly accommodates both trochanteric and piriformis fossa entry implants.

PRECICE SHORT



PRECICE SHORT



Note

150-190mm PRECICE Devices utilize the Femoral Guide Arms from the PRECICE Specialty Tray.

PRECICE® ANTEGRADE FEMUR OPERATIVE TECHNIQUE

OSTEOTOMY OF THE FEMUR

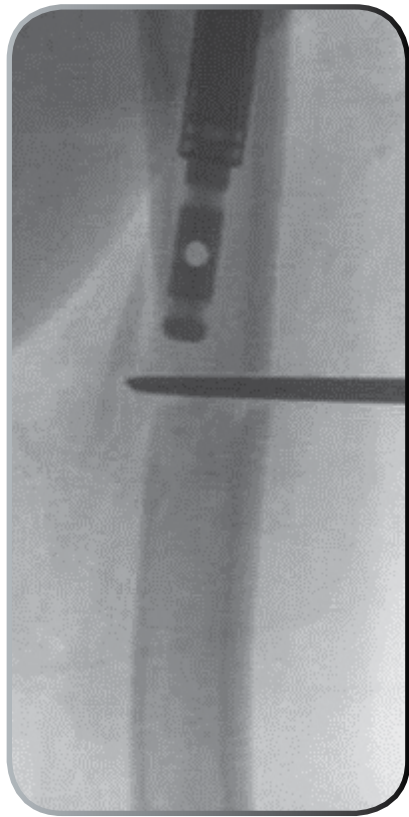
After the reaming of the canal is complete, remove the guide wire. Insert the PRECICE implant with the Antegrade Femoral Guide Arm Assembly into the intramedullary canal until the distal tip of the nail is just proximal to the planned osteotomy site where the vent holes were drilled. Verify this location under image intensification.

Pins may be inserted for a temporary external fixator if assistance maintaining rotational alignment or concurrent osteotomy correction is needed (prior to the osteotomy).

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 completed circumferentially. Verify the osteotomy is complete with multiplanar image intensification and evidence of translation at the osteotomy site for lengthening osteoplasty of the bone.

Immediately after confirming completion of 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.



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.

If the tip of the PRECICE nail stops around the level of 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 0.5 to 1.0mm.

PRECICE® ANTEGRADE FEMUR OPERATIVE TECHNIQUE

PROXIMAL LOCKING SCREWS

Confirm Antegrade Femoral Guide Arm Assembly did not loosen during nail insertion prior to proceeding with proximal locking screws. Position the Trocar through the Guide Tube and place through the Guide Arm. Confirm proper screw trajectory by ensuring the Antegrade Drill Guide Assembly is parallel with the floor. 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 5.0 x 355mm Drill Bit to penetrate both cortices. Confirm correct placement under image intensification.

Select the appropriate length screw by reading 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 can also be used by sliding it down the guide tube and reading the calibration.

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

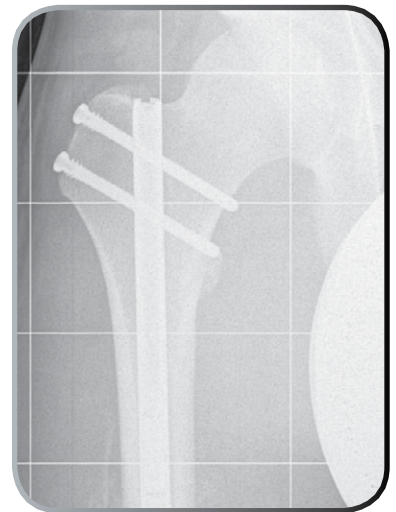


P2

Antegrade Femoral Guide Arm Assembly with 5.0 x 355mm Drill Bit in position prior to nail insertion.



PRECICE SHORT



Proximal 5.0mm Locking Screws positioned.

PRECICE® ANTEGRADE FEMUR OPERATIVE TECHNIQUE

DISTAL LOCKING SCREWS

The freehand 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 to create a pilot hole for the locking screw.

Size Guide for Nail Diameter

APPLIES TO ALL P2 AND SHORT GEN I NAILS; (365mm – 180mm)
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 (*One Proximal, One 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 could 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, though two distal screws may be satisfactory.

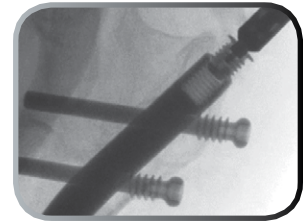
PRECICE® ANTEGRADE FEMUR OPERATIVE TECHNIQUE

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. The 10.7mm End Caps are compatible with both the 8.5mm and 10.7mm PRECICE devices. End Caps are also available in various lengths: 0, 5, 10, 15, and 20mm.

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 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

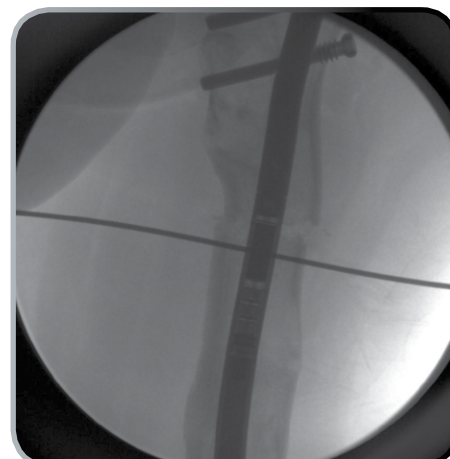
Evaluate the final implant construct under image intensification. Locate the magnet within the PRECICE® implant (see reference images). Be sure the C-arm is perpendicular to the implant to visualize the correct position of the central magnet.

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® ANTEGRADE FEMUR OPERATIVE TECHNIQUE

INTRAOPERATIVE EXTERNAL REMOTE CONTROLLER (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 femur and the magnets are pointed toward the patient's feet.

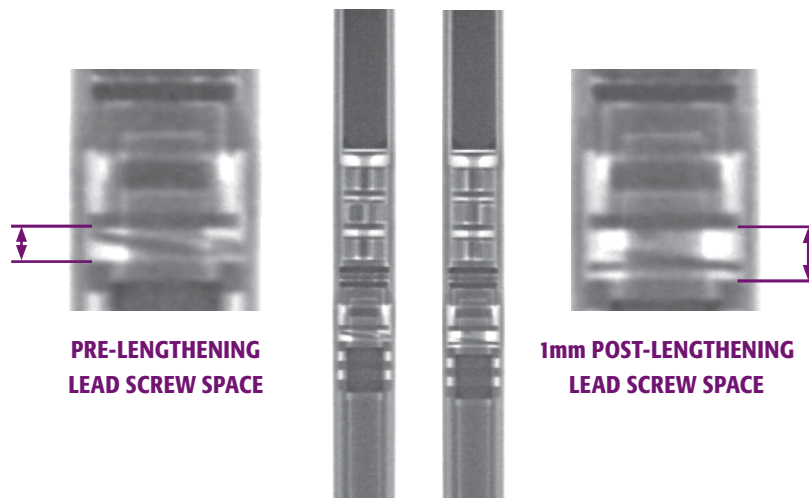
Use the implant locator window on the ERC to properly position it over the mark on the patient's skin.

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.



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



PRECICE® ANTEGRADE FEMUR PREOPERATIVE PLANNING

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.

PRECICE® RETROGRADE FEMUR PREOPERATIVE PLANNING

LIMB LENGTH DISCREPANCY CALCULATION

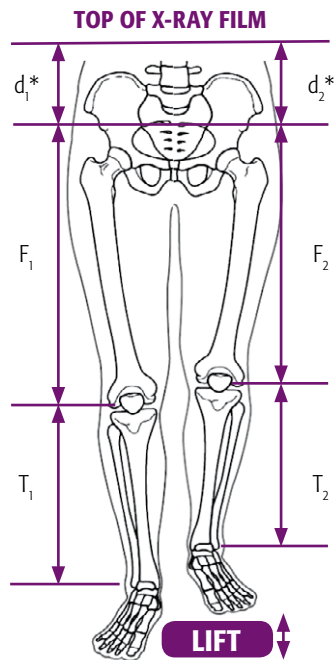
Careful preoperative evaluation and planning, proper surgical technique, and extended postoperative care are essential for success of limb lengthening procedures.

Preoperative evaluation is performed to determine:

- Limb length discrepancy
- Intramedullary diameter
- Required implant length
- Osteotomy location of femur
- 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	150, 165, 175, 190, 215, 245, 275, 305, 335, 365	50 and 80	10° or straight	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 =		T 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 to improve the accuracy of measurements

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

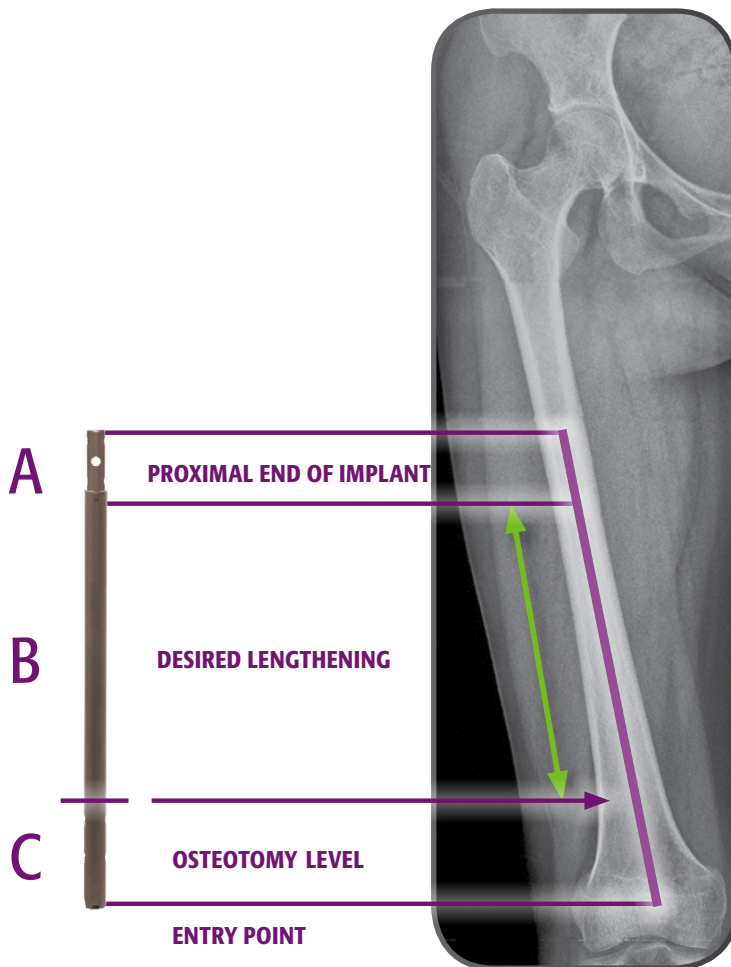
PRECICE® RETROGRADE FEMUR PREOPERATIVE PLANNING

RETROGRADE FEMUR 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 proximal segment coverage be maintained at the end of lengthening for biomechanical stability.

In general, it is recommended to use shorter rather than longer implants to assist with nail insertion and to prevent a mismatch in nail to bony curvature. The PRECICE retrograde femoral implant is available in 8.5, 10.7, and 12.5mm diameters with a proximal 10° bend or straight option. 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.

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



Calculate the following to determine the measurement from the proximal 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	4.0 – 5.0cm	4.0 – 5.0cm

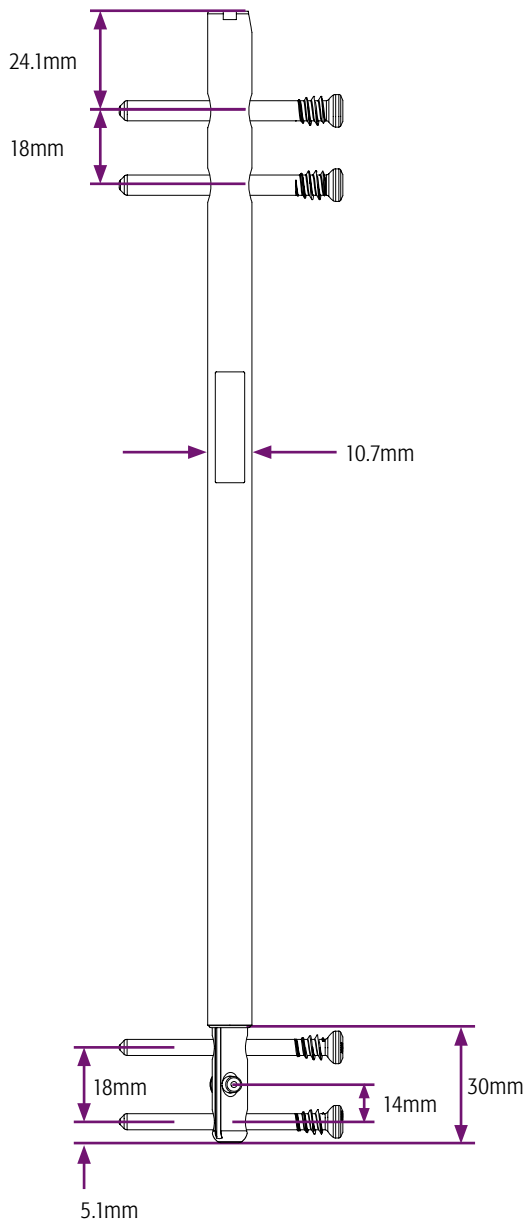
This measurement determines the suggested level of the osteotomy.

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

PRECICE® RETROGRADE FEMUR OPERATIVE TECHNIQUE

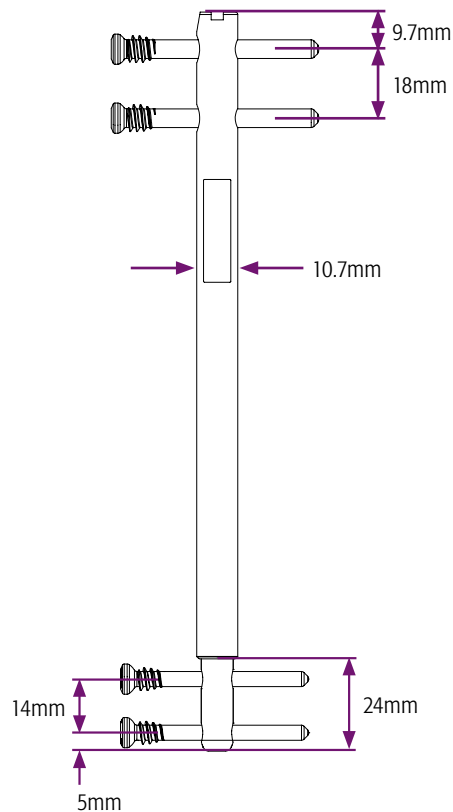
TECHNICAL DETAILS

Retrograde Femur Straight



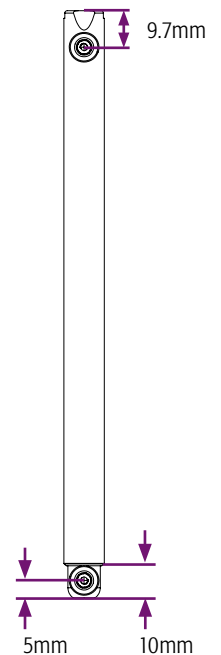
365mm – 215mm

Universal Femur – Straight



190mm

Universal Femur – Straight

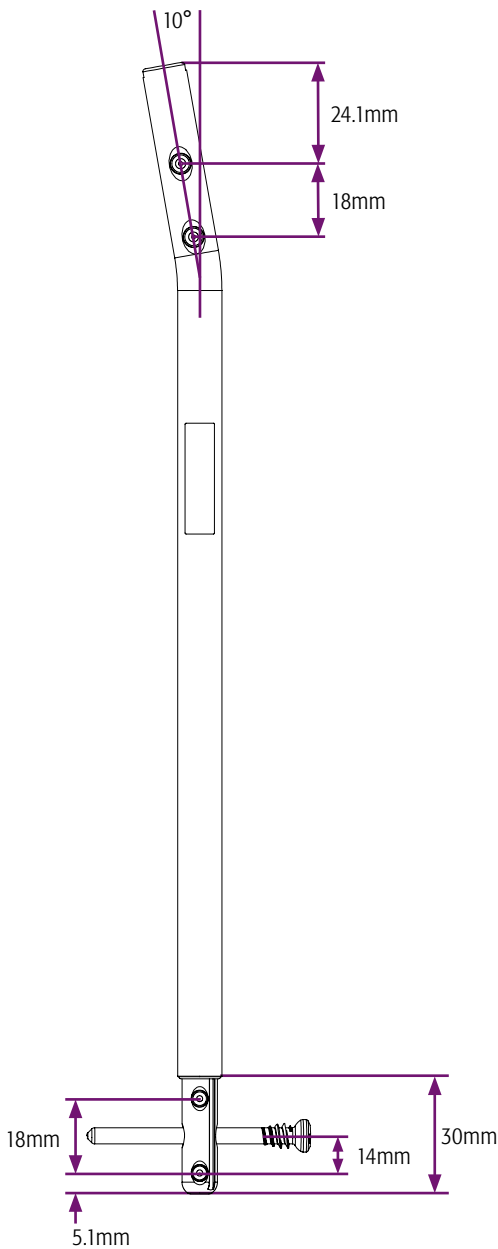


160mm – 150mm

PRECICE® RETROGRADE FEMUR OPERATIVE TECHNIQUE

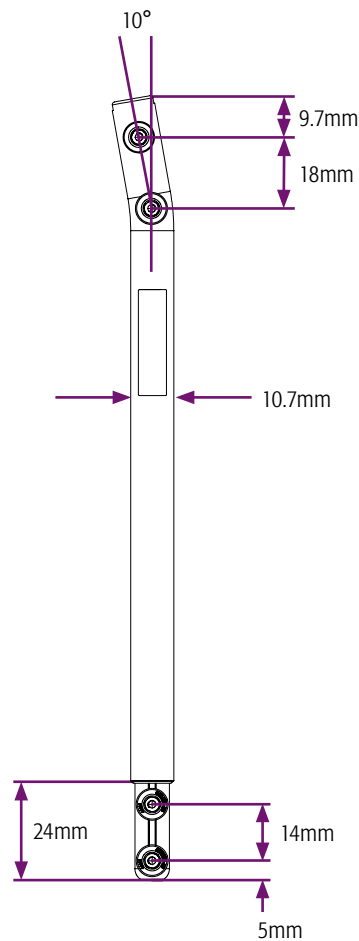
TECHNICAL DETAILS

Retrograde Femur 10°



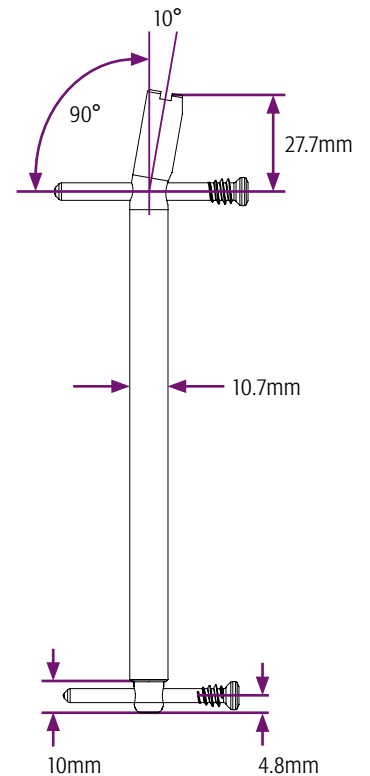
365mm – 215mm

Retrograde Femur 10°



190mm

Retrograde Femur 10°



175mm – 165mm

PRECICE® RETROGRADE FEMUR OPERATIVE TECHNIQUE

TECHNICAL DETAILS

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: 3.4mm

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

PRECICE® RETROGRADE FEMUR OPERATIVE TECHNIQUE

IMPLANT SELECTION

Two options are available for PRECICE retrograde femoral implants:

- Retrograde 10° Bend
- Retrograde Straight

The choice of implant type is dependent on patient anatomy, age, surgeon experience, and preference.

PATIENT POSITIONING

Place the patient supine on a radiolucent table. It is recommended to position a small bump under the ipsilateral hemisacrum.

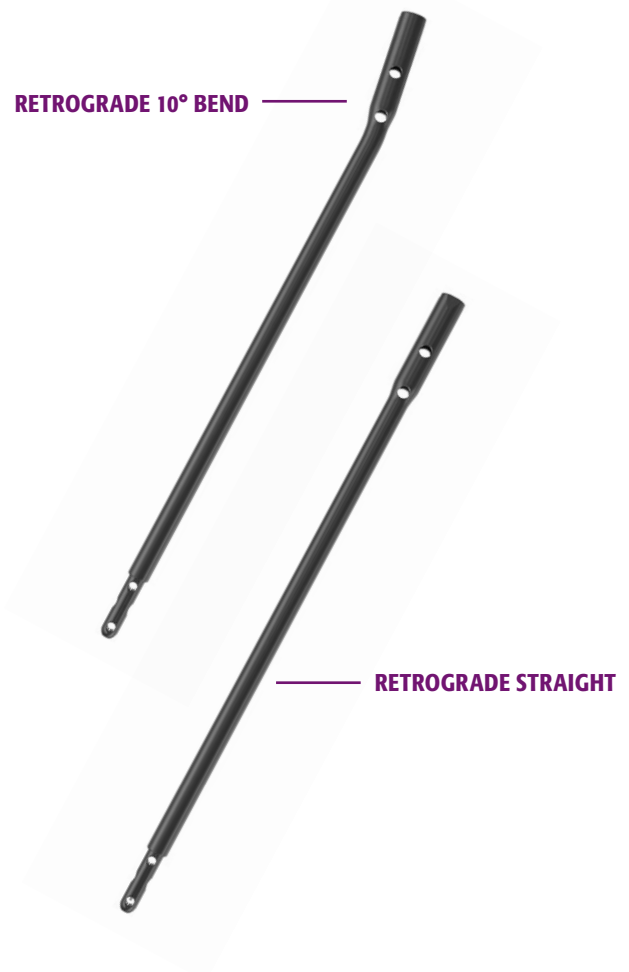
Confirm with the image intensifier that true A/P and cross table lateral views of the hip are possible. Prep and drape the patient's entire limb from the iliac crest to the foot/ankle using standard sterile technique.

Antibiotic prophylaxis should be given prior to making an incision.

SOFT TISSUE RELEASE

Depending on clinical requirements, consider performing a routine transverse release of the distal fascia lata. This is done through a 2-3cm 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 from the anterior border to the intermuscular septum posteriorly, including a portion of the intermuscular septum itself.



PRECICE® RETROGRADE FEMUR OPERATIVE TECHNIQUE

RETROGRADE ENTRY POINT

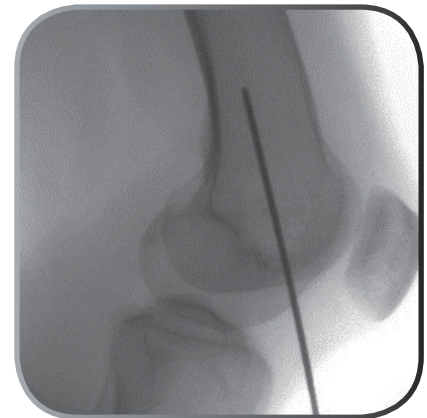
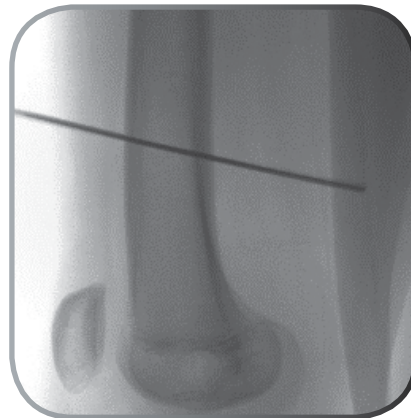
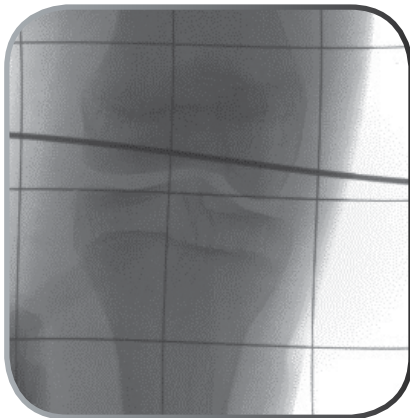
With the image intensifier, locate the joint line using a wire placed over the skin to find the intercondylar notch of the distal femur. On the lateral view, mark the apex of any distal bow present.

The entry point will be positioned with the knee slightly bent at the apex or slightly posterior to the Intercondylar Notch on the M/L radiograph. This point may be found by palpating a distinct ridge anterior to the posterior cruciate ligament (PCL).

Using A/P 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. Use a ruler to measure from the entry point on the distal femur to the distal end of the PRECICE® implant. Mark the skin at this level and also at the level of the planned femoral osteotomy.

SURGICAL INCISION

Make a 2.5cm incision longitudinally over the percutaneous Steinmann pin. Either split the patellar tendon longitudinally or go parapatellar depending on the position of the Steinmann pin.



PRECICE® RETROGRADE FEMUR OPERATIVE TECHNIQUE

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! 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 4.0 x 152mm Drill Bit or 5.0 x 152mm Drill Bit. Make one entry hole lateral and three exit holes medially. Additional lateral holes may be used to facilitate the osteotomy.

INTRAMEDULLARY REAMING

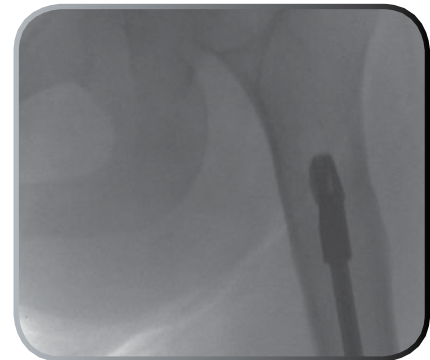
Verify and confirm the proper entry location of the Steinmann pin under biplanar fluoroscopic guidance.

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

After confirming correct pin placement on A/P and lateral radiograph views, position a soft tissue protector and ream over the Steinmann pin with a rigid 8.0mm or 11.0mm entry drill 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.

Attach an AO quick connect to the reamer. Ream the canal with flexible reamers beginning with 8.0mm 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. Use a guide wire pusher to secure guide wire when removing the flexible reamer from the canal.



There are three diameters of PRECICE retrograde femoral implants: 8.5mm, 10.7mm, and 12.5mm.

¹Kröpfl 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.

PRECICE® RETROGRADE FEMUR OPERATIVE TECHNIQUE

FEMORAL GUIDE ARM ASSEMBLY

Connect the Retrograde Femoral Guide to the Guide Arm. Attach the PRECICE® implant to the Retrograde Femoral Guide Arm Assembly by inserting the Locking Rod through the top of the Guide Arm and aligning the arrows on the implant with those on the Guide Arm. Engage the threads on the proximal end of the implant with the Locking Rod and gently tighten with the Tommy Bar.

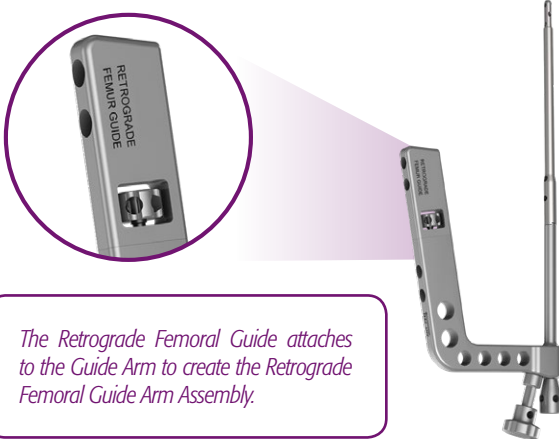
Note

Do not over-tighten the locking rod. Applying excessive force to the Tommy Bar may affect the proximal screw targeting accuracy.

Verify correct alignment of the 5.0 x 355mm Drill Bit through the Guide Tube, Drill Guide, and PRECICE implant. Confirm both distal locking screw holes in this manner.

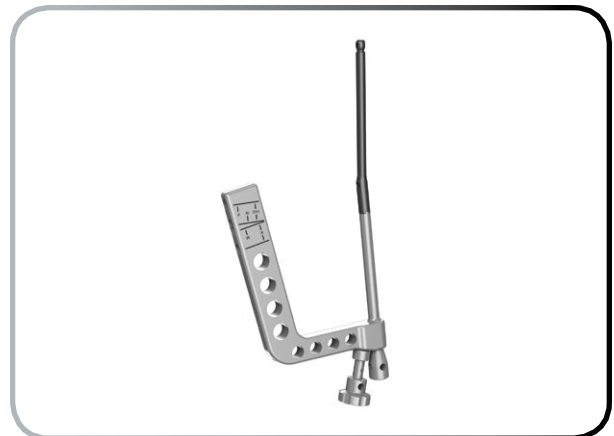
Once the PRECICE implant has been properly attached to the Retrograde Femoral Guide Arm Assembly, place the construct aside in the sterile field until ready for insertion into the intramedullary canal.

DEVICE AND RETROGRADE FEMORAL GUIDE ARM ATTACHMENT

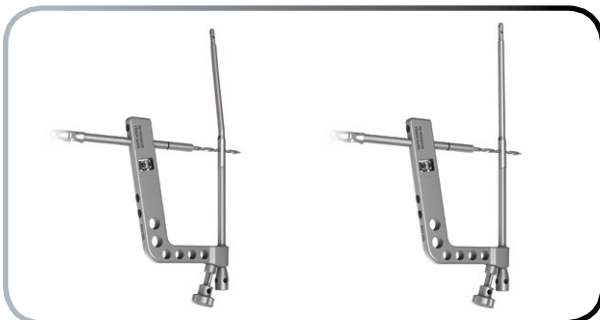


The Retrograde Femoral Guide attaches to the Guide Arm to create the Retrograde Femoral Guide Arm Assembly.

PRECICE SHORT

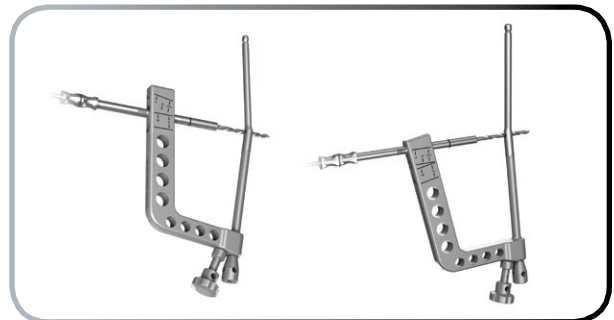


RETROGRADE FEMORAL GUIDE ARM ASSEMBLY



The Retrograde Femoral Guide Arm Assembly accommodates both the Straight and 10° Distal Bend PRECICE implants.

PRECICE SHORT



PRECICE® RETROGRADE FEMUR OPERATIVE TECHNIQUE

OSTEOTOMY OF THE FEMUR

After the reaming of the canal is complete, remove the guide wire. 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 the planned osteotomy site where the vent holes were drilled. Verify this location under image intensification.

Pins may be inserted for a temporary external fixator if assistance maintaining rotational alignment or deformity correction is required.

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 completed circumferentially. Verify the osteotomy is complete with multiplanar image intensification and evidence of translation at the osteotomy site for lengthening osteoplasty of the bone.

Immediately after confirming the osteotomy, gently tap the Short Impactor attached to the Retrograde 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.



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.

If the tip of the PRECICE nail stops around the level of 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.

PRECICE® RETROGRADE FEMUR OPERATIVE TECHNIQUE

DISTAL LOCKING SCREW

Confirm Retrograde Femoral Guide Arm Assembly did not loosen during nail insertion prior to proceeding with proximal locking screws. 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 5.0 x 355mm Drill Bit to penetrate both cortices. Confirm correct placement under image intensification.

Select the appropriate length screw by reading the calibration on the 5.0 x 355mm Drill Bit. 5.0mm Locking Screws are available in 5mm increments from 20-75mm lengths.

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 Screw Capture Rod to the Quick Connect T-handle. Remove the Drill Guide and position the screw into the Guide Tube to direct it through the PRECICE® implant.

Hand tighten the screw 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. After securing the distal 5.0mm Locking Screws, untighten the Locking Rod from the PRECICE implant to remove the Retrograde Guide Arm Assembly.

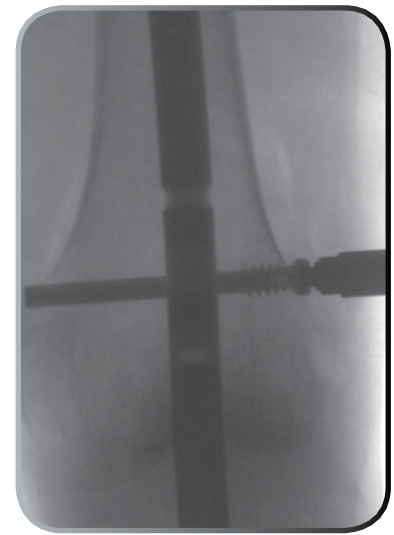


P2

Retrograde Femoral Guide Arm Assembly with 5.0 x 355mm Drill Bit in position prior to nail insertion.



PRECICE SHORT



Distal 5.0mm Locking Screws positioned.

PRECICE® RETROGRADE FEMUR OPERATIVE TECHNIQUE

PROXIMAL LOCKING SCREW

The free hand technique is used to position Locking Screws in the A/P and M/L proximal 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 to create a pilot hole for the locking screw.

Size Guide for Nail Diameter

APPLIES TO ALL P2 AND SHORT GEN I NAILS; (365mm – 180mm)
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

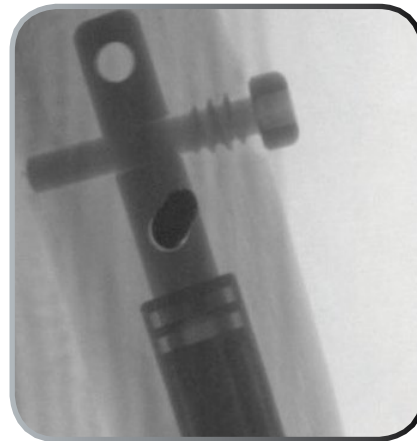
APPLIES TO SHORT GEN II NAILS; (175mm – 150mm)
MODELS: Q, M, P, AND N (*One Proximal, One Distal screw holes*)

	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 can 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 proximal Locking Screws.



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



There are locations for three proximal Locking Screw options, though two distal Locking Screws may be satisfactory.

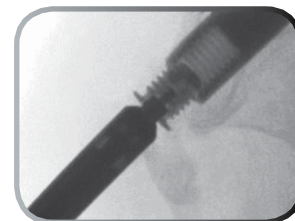
PRECICE® RETROGRADE FEMUR OPERATIVE TECHNIQUE

END CAP PLACEMENT (OPTIONAL)

If desired, an End Cap may be used to help prevent bony ingrowth into the distal 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, and 20mm.

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



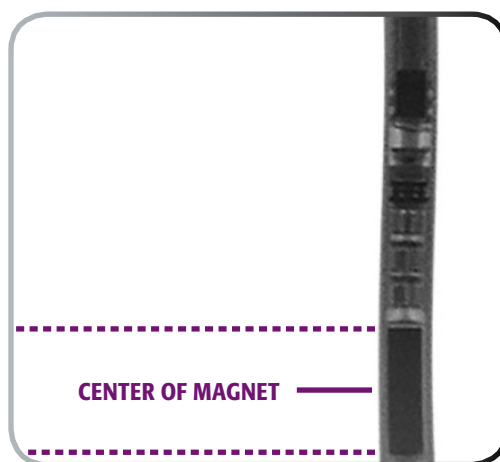
**CONFIRMATION OF
END CAP POSITIONING**

LOCATING THE CENTER OF THE MAGNET

Evaluate the final implant construct under image intensification. Locate the magnet within the PRECICE implant (see reference 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. 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).



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

PRECICE® RETROGRADE FEMUR OPERATIVE TECHNIQUE

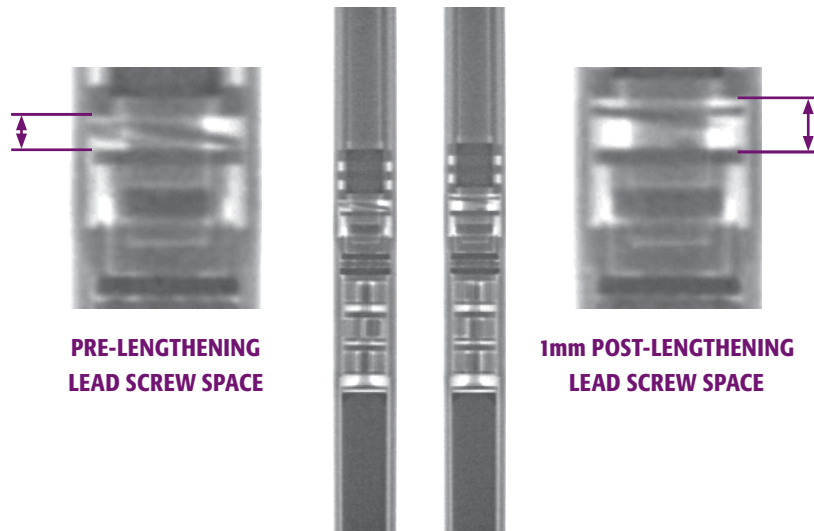
INTRAOPERATIVE EXTERNAL REMOTE CONTROL (ERC) DISTRACTION

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 femur and the magnets are pointed toward the patient's feet.

Use the implant locator (camera) 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 seven minutes to achieve 1.0mm 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.



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.

PRECICE® RETROGRADE FEMUR OPERATIVE TECHNIQUE

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.

POSTOPERATIVE TREATMENT

FINAL CLOSURE

After the intraoperative distraction 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 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. 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 invasiveness of the 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. During this phase, daily physiotherapy includes the following:

- Hip extension and abduction
- Full knee flexion/extension
- Ankle dorsiflexion to neutral

Please refer to ERC Operator's Manual for complete programming instructions.

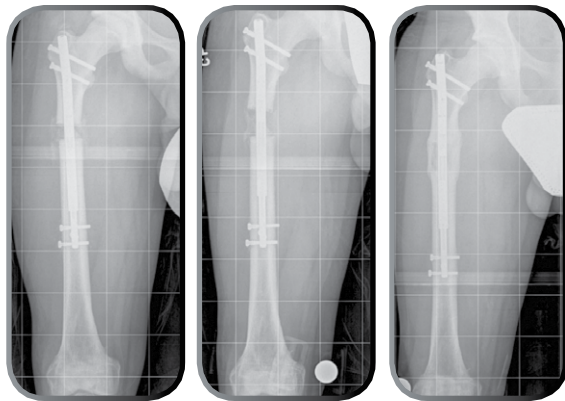
POSTOPERATIVE TREATMENT

LENGTHENING TO CONSOLIDATION

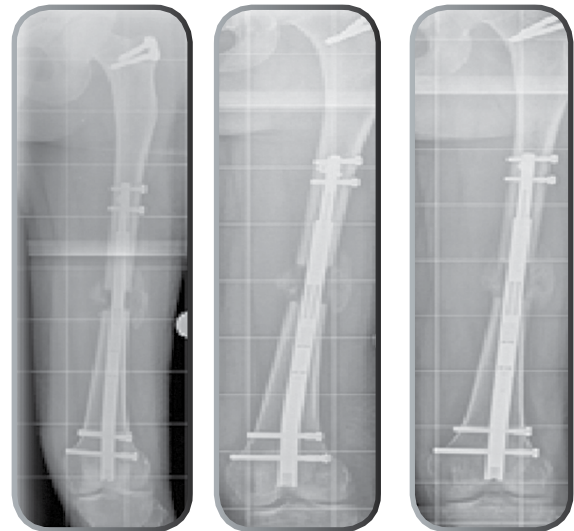
During the lengthening phase, patient compliance to the planned lengthening prescription is important. Adherence to proper use of the ERC in addition to postoperative rehabilitation protocols must be emphasized. It is the physician's responsibility to carefully monitor the patient's progress with regular 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 (8.5mm = 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.

ANTEGRADE FEMUR



RETROGRADE FEMUR



The physician and his/her 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.

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.

POSTOPERATIVE LENGTHENING

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.



POSTOPERATIVE LENGTHENING

FEATURES OF THE ERC3P



IMPLANT REMOVAL

IMPLANT REMOVAL

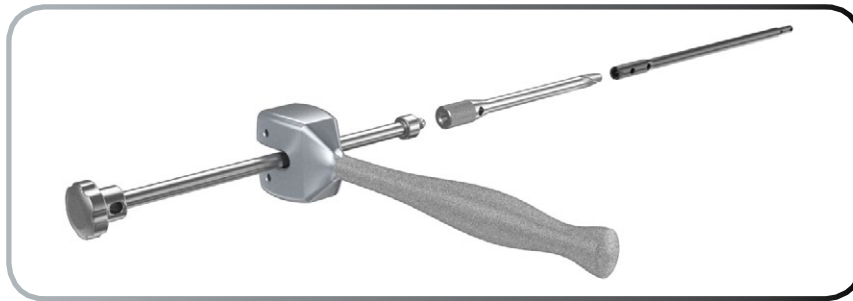
PRECICE® implant removal is recommended at 1 year provided radiological evidence of full bone consolidation is present. Each surgeon must determine the appropriate time for removal of the PRECICE implant based upon their clinical evaluation of the patient.

Exsanguinate the leg and apply a thigh tourniquet (for retrograde nail). 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 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**

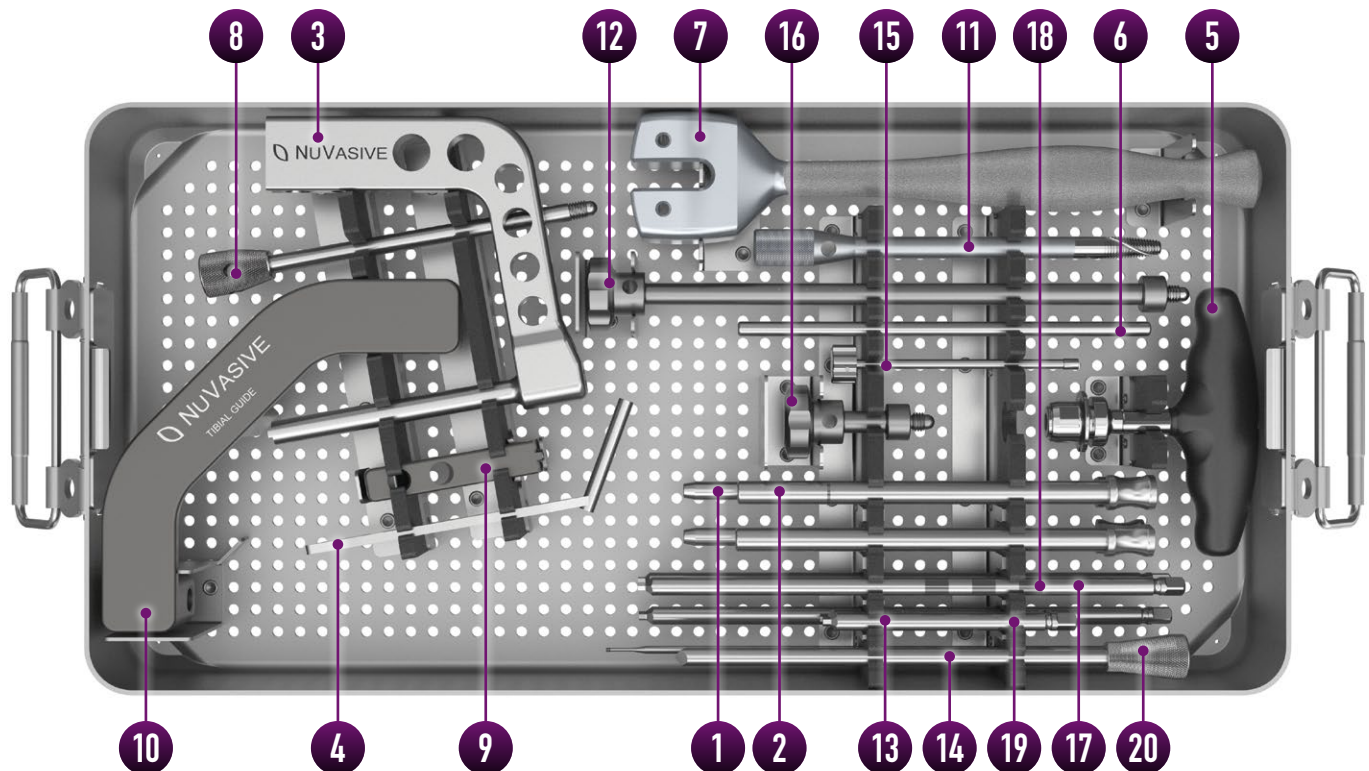
Please refer to the Instructions for Use for additional information.

FEMORAL LIMB LENGTHENING SYSTEM

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

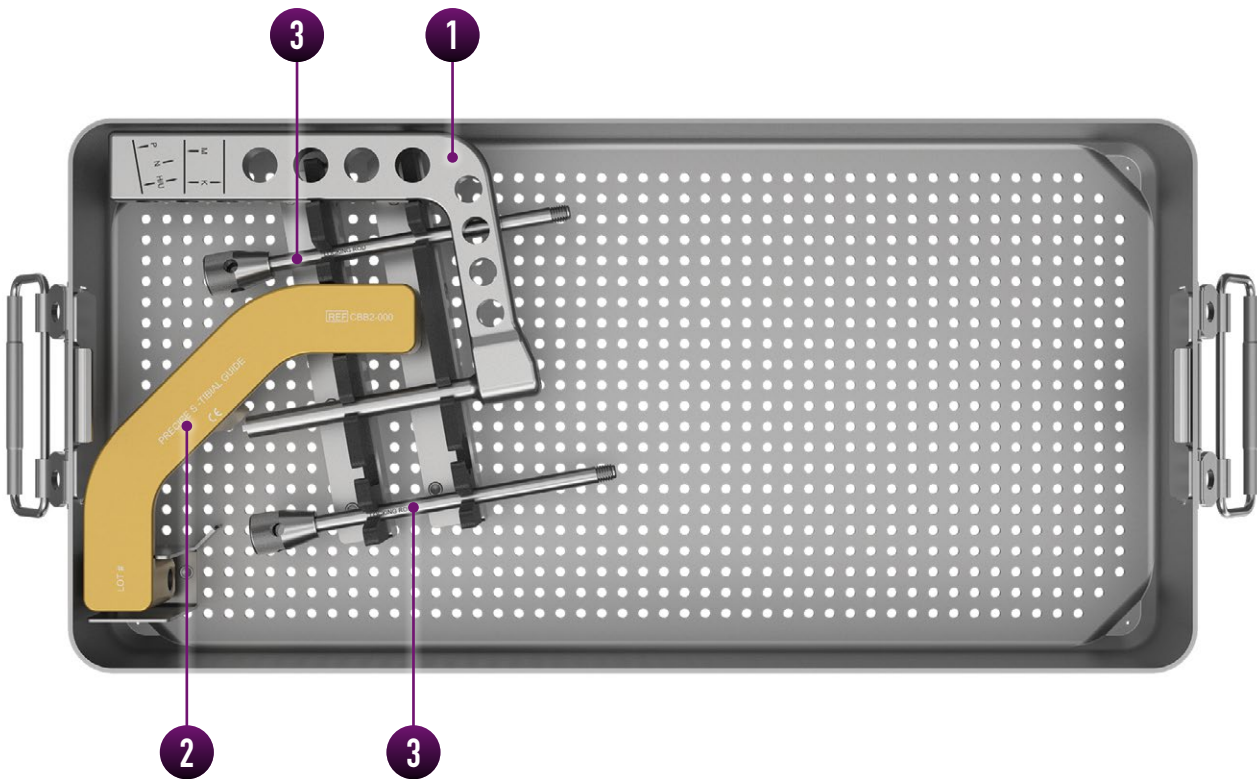
MODEL #	DESCRIPTION
11	CTA1-000 Tapered Extractor
12	RRB1-000 Removal Rod
13	THE1-000 4.0mm Locking Driver
14	PRB1-000 Trocar
15	LKA1-000 Locking Key
16	IMA1-000 Short Impactor
17	DRD1-000 3.5mm Solid Hex Driver
18	DRE1-000 4.0mm Solid Hex Driver
19	THF3-000 3.5mm Locking Driver
20	CRC3-000 Screw Capture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



FEMORAL LIMB LENGTHENING SYSTEM

SPECIALTY TARGETING TRAY

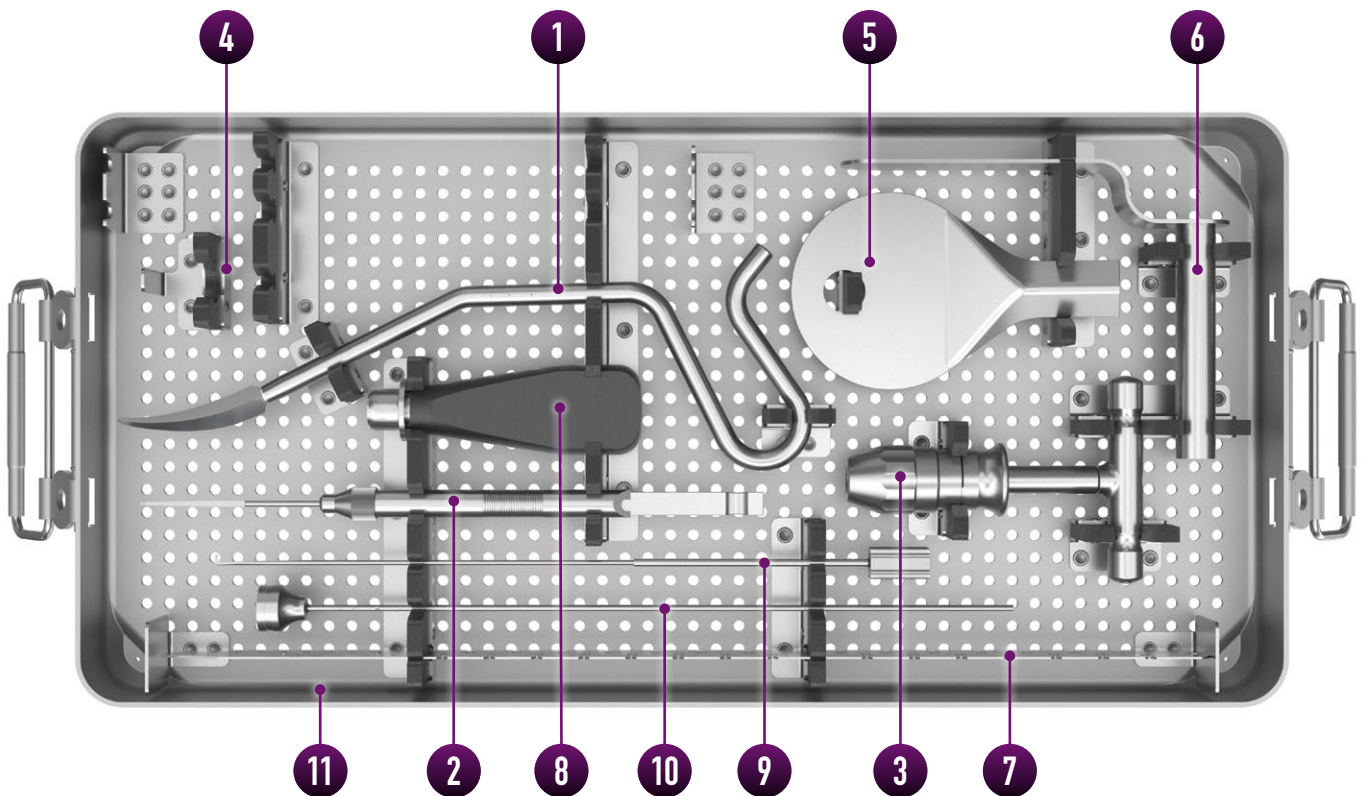
	MODEL #	DESCRIPTION
1	AGB2-000	Drill Guide Arm, Short Nail
2	CBB2-000	Tibial Drill Guide, Short Nail
3	LRB2-000	Locking Rod



FEMORAL LIMB LENGTHENING SYSTEM

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



FEMORAL LIMB LENGTHENING SYSTEM

ANTEGRADE FEMUR TROCHANTERIC – 10°

LENGTH	STROKE	PRECICE®		
		8.5mm	10.7mm	12.5mm
165mm	50mm	P8.5-50M165		
175mm	50mm	P10.7-50M175		
190mm	50mm	P8.5-50K190	P10.7-50K190	P12.5-50K190
215mm	50mm	P8.5-50D215	P10.7-50D215	P12.5-50D215
245mm	80mm	P8.5-80D245	P10.7-80D245	P12.5-80D245
275mm	80mm	P8.5-80D275	P10.7-80D275	P12.5-80D275
305mm	80mm	P8.5-80D305	P10.7-80D305	P12.5-80D305
335mm	80mm	P8.5-80D335	P10.7-80D335	P12.5-80D335
365mm	80mm		P10.7-80D365	P12.5-80D365

RETROGRADE FEMUR – 10°

LENGTH	STROKE	PRECICE		
		8.5mm	10.7mm	12.5mm
165mm	50mm	P8.5-50P165		
175mm	50mm	P10.7-50P175		
190mm	50mm	P8.5-50H190	P10.7-50H190	P12.5-50H190
215mm	50mm	P8.5-50A215	P10.7-50A215	P12.5-50A215
245mm	80mm	P8.5-80A245	P10.7-80A245	P12.5-80A245
275mm	80mm	P8.5-80A275	P10.7-80A275	P12.5-80A275
305mm	80mm		P10.7-80A305	P12.5-80A305
335mm	80mm		P10.7-80A335	P12.5-80A335

ANTEGRADE FEMUR – PIRIFORMIS STRAIGHT

LENGTH	STROKE	PRECICE		
		8.5mm	10.7mm	12.5mm
215mm	50mm	P8.5-50B215	P10.7-50B215	P12.5-50B215
245mm	80mm	P8.5-80B245	P10.7-80B245	P12.5-80B245
275mm	80mm	P8.5-80B275	P10.7-80B275	P12.5-80B275
305mm	80mm		P10.7-80B305	P12.5-80B305
335mm	80mm		P10.7-80B335	P12.5-80B335
365mm	80mm		P10.7-80B365	P12.5-80B365

RETROGRADE FEMUR – STRAIGHT

LENGTH	STROKE	PRECICE		
		8.5mm	10.7mm	12.5mm
215mm	50mm	P8.5-50E215	P10.7-50E215	P12.5-50E215
245mm	80mm	P8.5-80E245	P10.7-80E245	P12.5-80E245
275mm	80mm	P8.5-80E275	P10.7-80E275	P12.5-80E275
305mm	80mm		P10.7-80E305	P12.5-80E305
335mm	80mm		P10.7-80E335	P12.5-80E335
365mm	80mm		P10.7-80E365	P12.5-80E365

UNIVERSAL FEMUR – STRAIGHT

LENGTH	STROKE	PRECICE		
		8.5mm	10.7mm	12.5mm
150mm	50mm	P8.5-50N150		
160mm	50mm	P10.7-50N160		
190mm	50mm	P8.5-50U190	P10.7-50U190	P12.5-50U190

FEMORAL 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

FEMORAL LIMB LENGTHENING SYSTEM

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 Distractor

*U.S. only

**EMEA only

LOCKING SCREW SIZE GUIDE FOR NAIL DIAMETER

8.5mm	
PROXIMAL	DISTAL
5.0mm	3.5mm

10.7mm	
PROXIMAL	DISTAL
5.0mm	4.0mm

12.5mm	
PROXIMAL	DISTAL
5.0mm	5.0mm

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)

8.5mm	
PROXIMAL	DISTAL
5.0mm	4.0mm

10.7mm	
PROXIMAL	DISTAL
5.0mm	4.0mm

12.5mm	
PROXIMAL	DISTAL
-	-

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

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 Gussilo 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 participate 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.




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

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Rx Only

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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, U, V, and X) or weighing in excess of 57 kg for the 8.5 and 10.7 mm diameter implants models (A-G, H, J, K, U, N, M, 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.

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

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