Precice Stryde

Antegrade Femur Operative Technique

NUVASIVE
Specialized Orthopedics

Contents

Introduction

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

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

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

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

The Precice Stryde 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 Stryde 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.

Stryde System Components

The Stryde System comprises the following components:

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

Intramedullary Nails

Diameter: 10.0, 11.5, and 13.0mm
Sizes: 235-365mm

Antegrade Femur Preoperative Planning

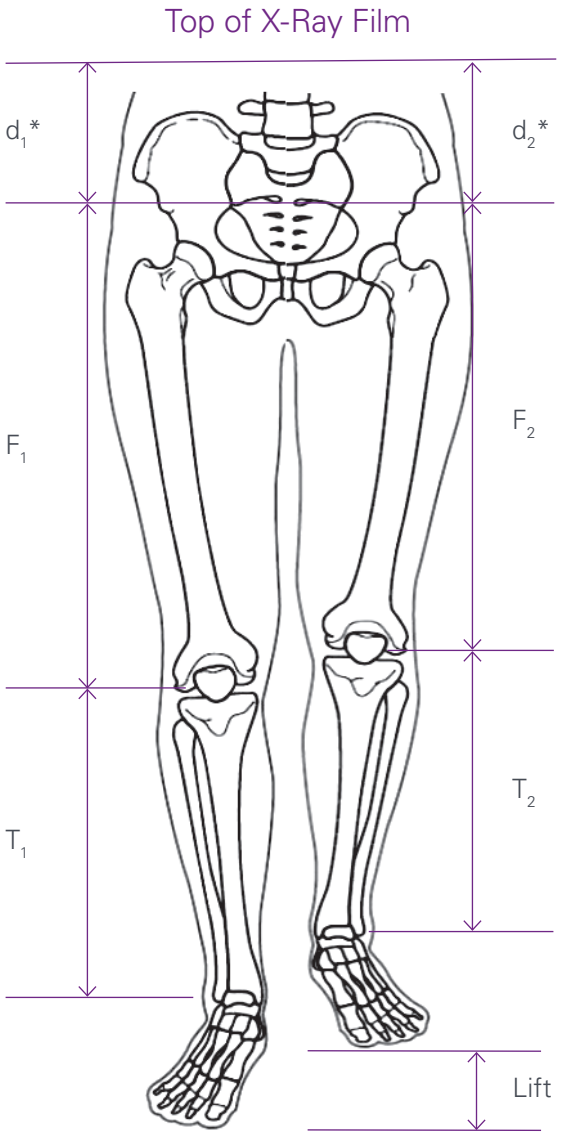
Limb Length Discrepancy Calculation

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)	10.0, 11.5, and 13.0
Lengths (mm)	235, 250, 265, 280, 305, 335, 365
Maximum Distraction (mm)	50, 65, and 80
Proximal Bend	10° or straight
Partially Threaded Locking Screws (mm)	4.0, 4.5, and 5.0



Digital templates for the Stryde 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 Stryde implant is needed. Tibial and femoral lengths calculate segmental differences which helps to determine which segment to address.

Limb Length Discrepancy = (d2-d1) + Lift

Contralateral Limb (mm)	Treatment Limb (mm)
d_1=	d_2=
F_1=	F_2=
T_1=	T_3=

*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

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 Stryde antegrade femoral implant is available in 10.0, 11.5, and 13.0mm 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.

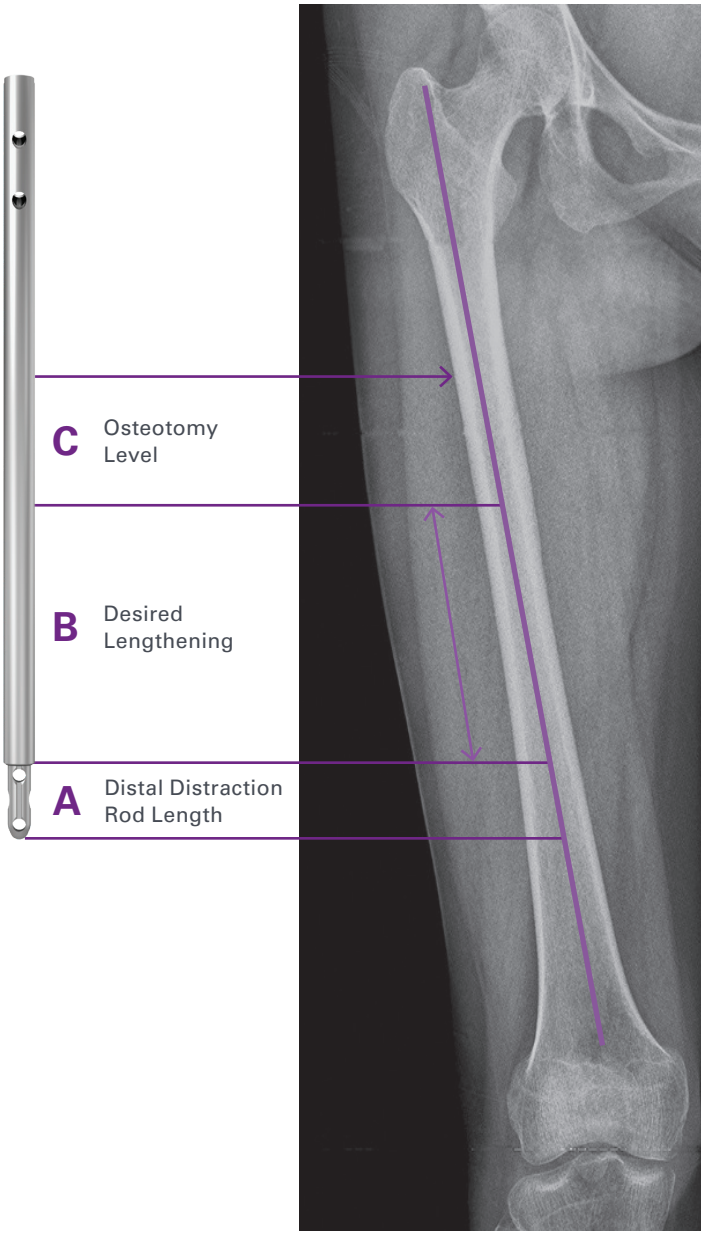
With radiographs that include a magnification marker, measure from the level of the joint line to the location of the distal end of the Stryde implant.

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

A	3.0cm
B	Up to 8.0cm
C	4.0-5.0cm

This measurement determines the suggested level of the osteotomy.

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

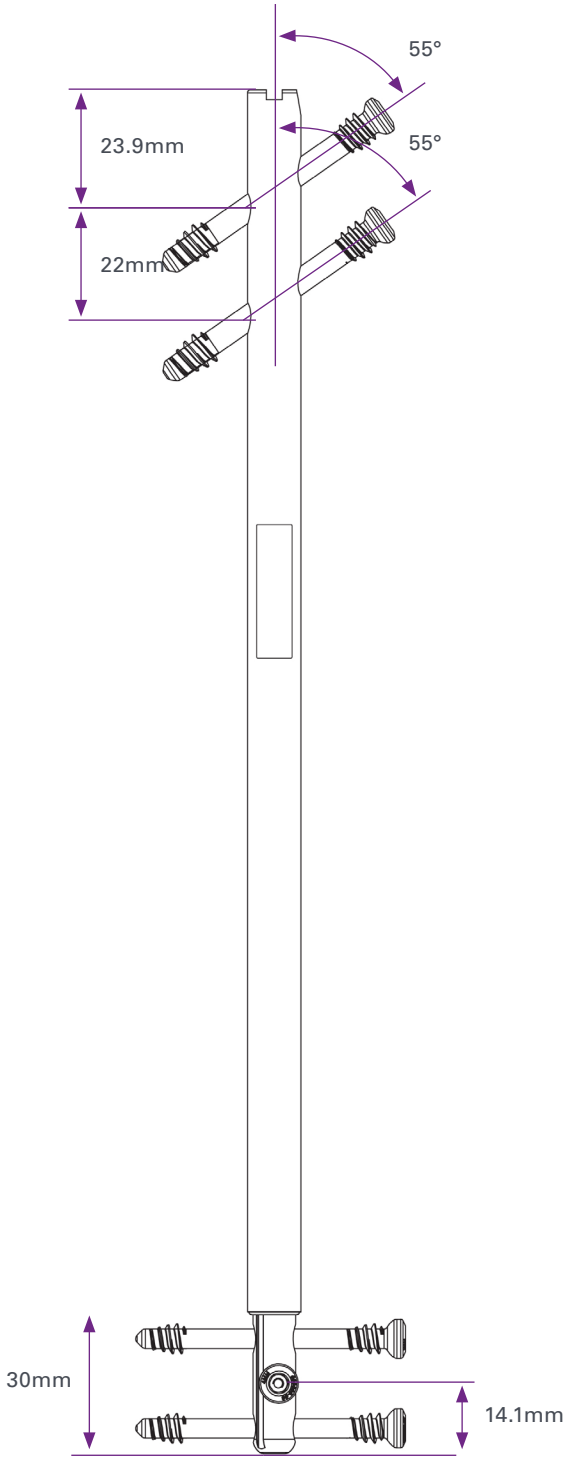


Antegrade Femur Operative Technique

Technical Details

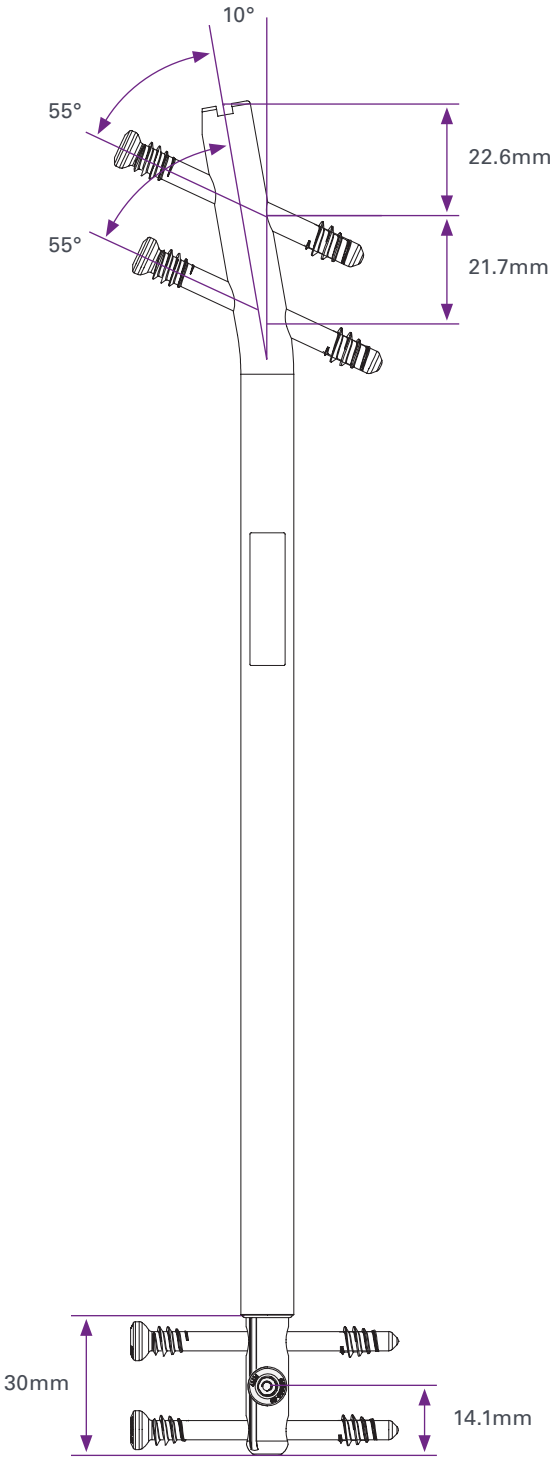
Antegrade Femur Piriformis

235–365mm



Antegrade Femur Trochanteric 10°

235–365mm



Technical Details (cont.)

Telescoping Rod Diameter (Male)

10mm Nail: 7.2mm

11.5mm Nail: 8.5mm

13.0mm Nail: 10.0mm

End Cap

Diameter: 11.5 and 13.0mm

Note: *the 11.5mm end caps are compatible with the 10mm Stryde devices*

Sizes:

Length
0mm
5mm
10mm
15mm
20mm

Partially Threaded Locking Screws

4.0mm Partially Threaded Locking Screws
Length: 20–75mm

4.5mm Partially Threaded Locking Screws
Length: 20–80mm

5.0mm Partially Threaded Locking Screws
Length: 20–80mm

Implant Selection

Two options are available for Stryde 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 (avn).

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.

Note: *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.

Antegrade Femur Trochanter 10° Bend

Antegrade Femur Piriformis Straight

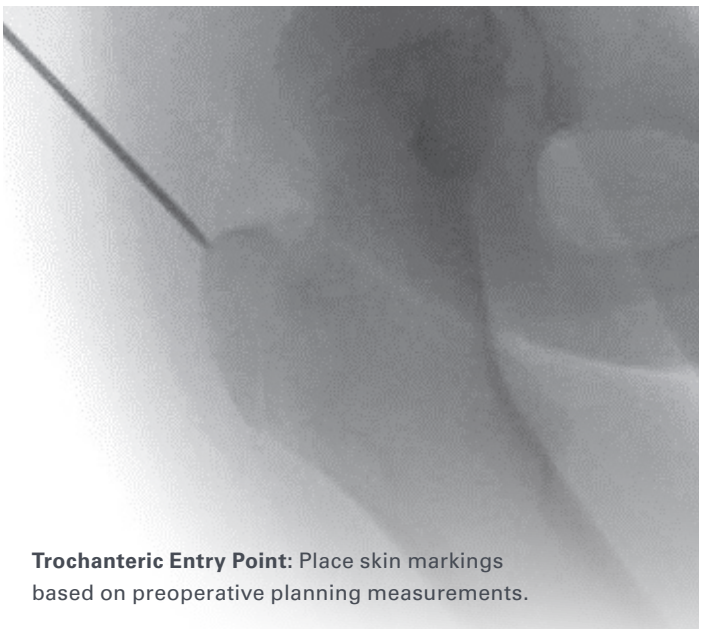
Antegrade Entry Point

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 Stryde implant based on preoperative measurements and calculations. Mark the skin at this level and also at the level of the planned femoral osteotomy.

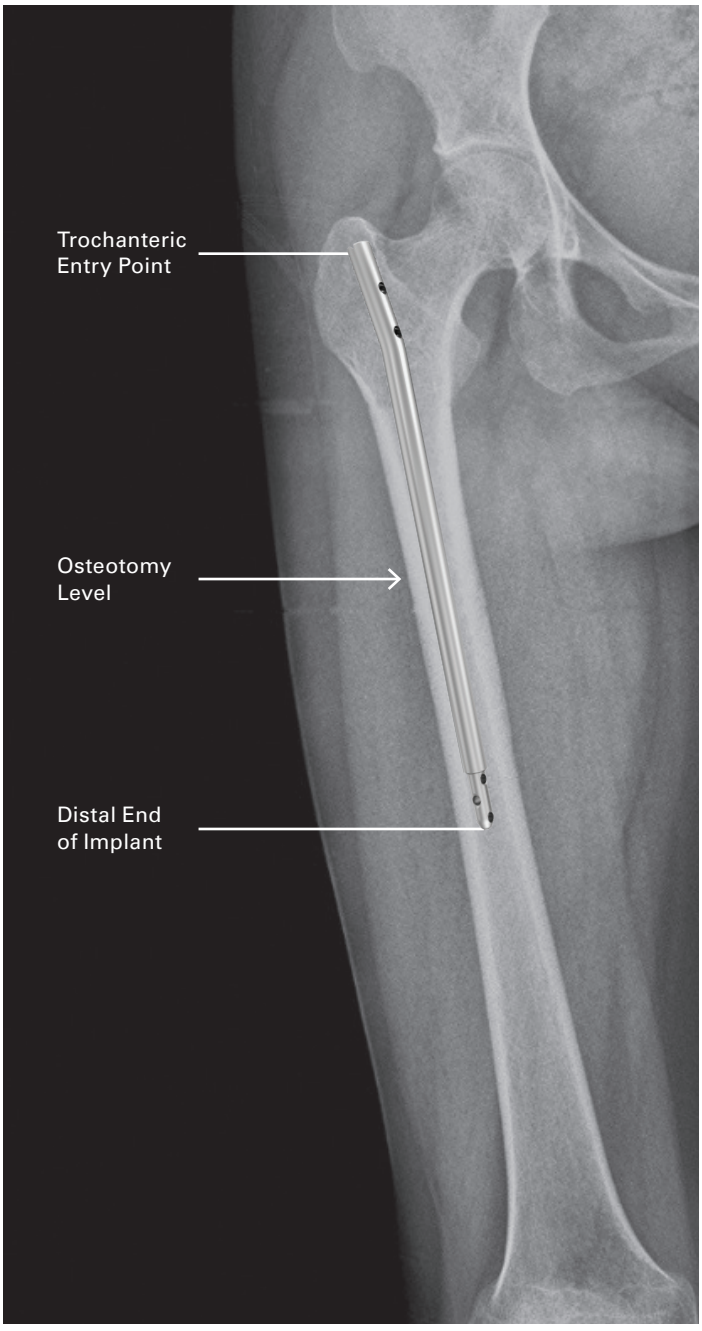


Trochanteric Entry Point: Place skin markings based on preoperative planning measurements.

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.



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.
- 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 155mm Step Drill Bit or 5.0 x 155mm Step 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.

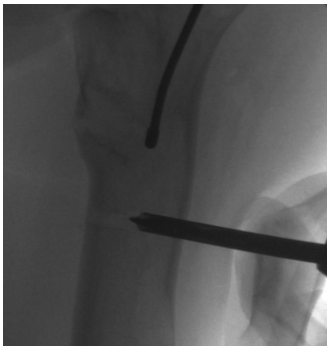
Make a small vertical incision around the pin and spread the soft tissues using hemostats.

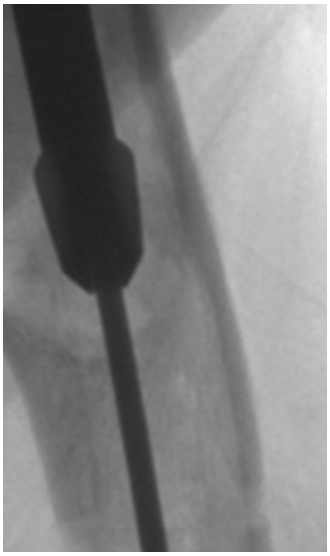
After confirming correct pin placement on A/P and lateral radiograph views, position a soft tissue protector and ream over the Steinmann pin with a rigid 8.0mm or 11.0mm cannulated entry drill into the intramedullary canal.

Insert a ball tip guide wire using a guide wire 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 7.0mm and increasing by 0.5mm increments until the femoral canal is over-reamed by 2.0mm greater than the planned diameter of the Stryde implant. Use a guide wire pusher to secure guide wire when removing the flexible reamer from the canal.

Note: *There are three diameters of Stryde antegrade femoral implants: 10.0mm, 11.5mm, and 13.0mm.*





1. Kröpfl A, Berger U, Neureiter H, et al. Intramedullary pressure and bone marrow fat intravasation in unreamed femoral nailing. *J Trauma* 1997;42(5):946-54.

Antegrade Femoral Guide Arm Assembly

Attach the Stryde implant to the Guide Arm by inserting the Locking Bolt 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 Bolt and tighten with the 6mm Hex Driver.

Note: *Do not over-tighten the Locking Bolt. Applying excessive force to the 6mm Hex Driver may affect the proximal screw targeting accuracy.*

Verify correct alignment of the 5.0 x 340mm Step Drill Bit through the Guide Tube, Drill Sleeve, and Stryde implant. Confirm both proximal screw holes in this manner.

Once the Stryde 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.

Antegrade Femoral Guide Arm Assembly

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

Antegrade Femoral Guide Arm Assembly

Osteotomy of the Femur

After the reaming of the canal is complete, remove the guide wire. Insert the Stryde 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).

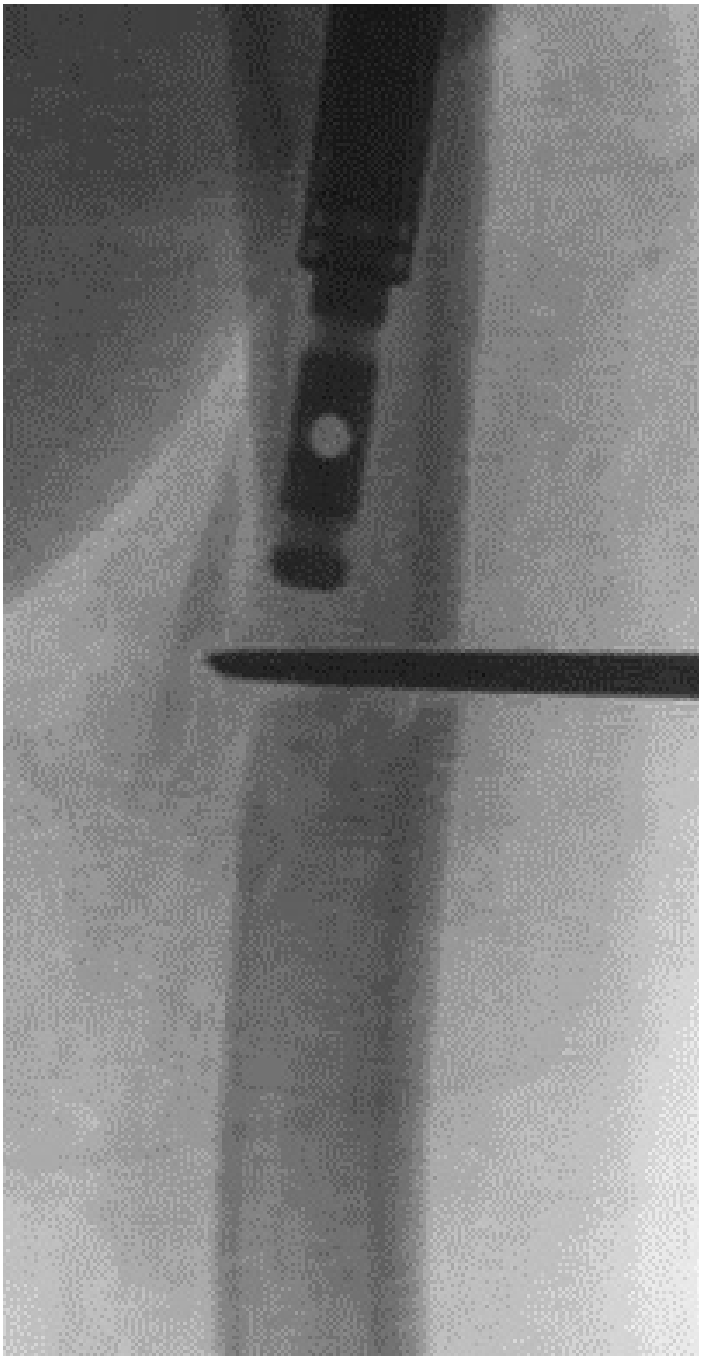
Use an osteotome to complete the osteotomy. Use caution to avoid neurovascular injury and soft tissue damage. An irregular or comminuted osteotomy is acceptable. Ensure that the osteotomy created is completed circumferentially. Verify the osteotomy is complete with multiplanar image intensification and 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 Stryde 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.

Note: *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 Stryde 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 Stryde nail may damage the internal mechanism. If necessary, consider reaming the canal by an additional 0.5 to 1.0mm.



Proximal Locking Screws

Confirm Antegrade Femoral Guide Arm Assembly did not loosen during nail insertion prior to proceeding with proximal locking screws. Assemble the Guide Tube with the Drill Sleeve and Trocar (Triple Sleeve) and place through Femoral 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 Drill Sleeve is positioned on the femoral cortex.

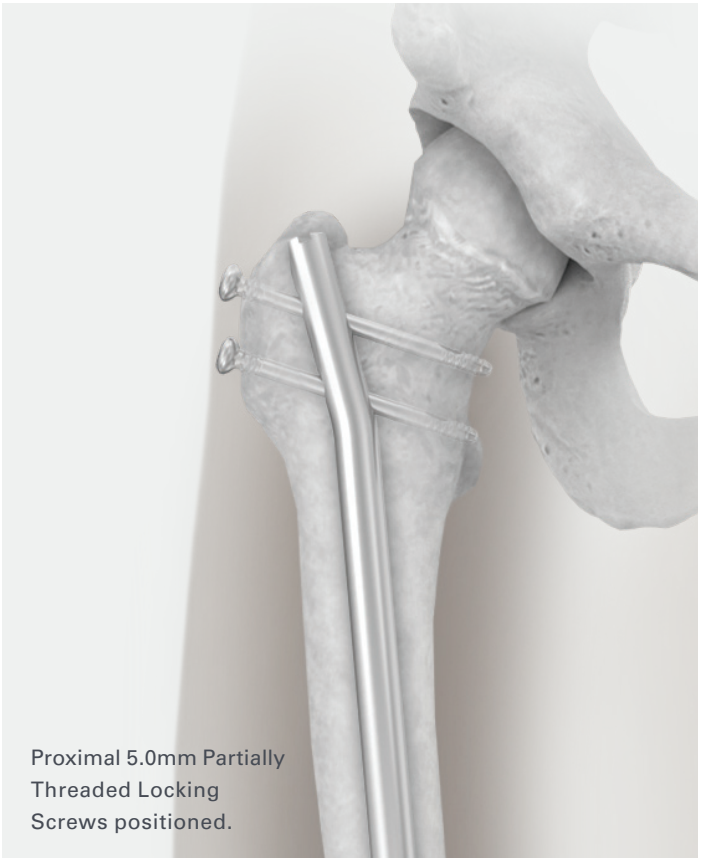
Remove the Trocar leaving the Drill Sleeve and Guide Tube in place. Use the 5.0 x 340mm Step Drill Bit to penetrate both cortices. Confirm correct placement under image intensification.

Select the appropriate length Partially Threaded Locking Screw by reading the calibration on the 5.0 x 340mm Step Drill Bit. 5.0mm Partially Threaded Locking Screws are available in 2.5mm increments from 20-50mm lengths and 5mm increments from 50-80 mm 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 5.0mm Partially Threaded 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 Sleeve and position the screw into the Guide Tube to direct it through the Stryde 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. Repeat this sequence for the second proximal Partially Threaded Locking Screw. After securing the proximal 5.0mm Partially Threaded Locking Screw, untighten the Locking Bolt from the Stryde implant to remove the Antegrade Guide Arm Assembly.

Antegrade Femoral Guide Arm Assembly with 5.0 x 340mm Step Drill Bit



Proximal 5.0mm Partially Threaded Locking Screws positioned.

Distal Locking Screws

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

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 Partially Threaded Locking Screw.

Applies to all Stryde Nails; (235mm-365mm) Models: B and D (Two Proximal, Three Distal screw holes)		
		Locking Screw Size
10.0mm Nail	Proximal	5.0mm
	Distal	4.0mm
11.5mm Nail	Proximal	5.0mm
	Distal	4.5mm
10.0mm Nail	Proximal	5.0mm
	Distal	5.0mm

Select the length for the first distal Partially Threaded 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 Partially Threaded Locking Screw to the Screw Capture Rod and 3.5mm Locking Driver. Tighten the Partially Threaded Locking Screw by hand. Release the Screw Capture Rod to release the screw. Repeat steps for additional distal Partially Threaded Locking Screws.

Note: *There are three distal screw options, though two distal screws may be satisfactory.*

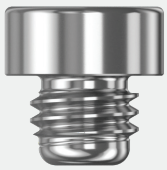
Select the length for the first distal Partially Threaded Locking Screw by reading the measurement off the calibrated drill bit with the Soft Tissue Protector fully seated on the cortex. The Direct AO Depth Gauge could also be used. Attach the appropriate Partially Threaded Locking Screw to the Screw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

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: 11.5mm and 13.0mm. The 11.5mm End Caps are compatible with both the 10.0mm and 11.5mm Stryde 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.



End Cap

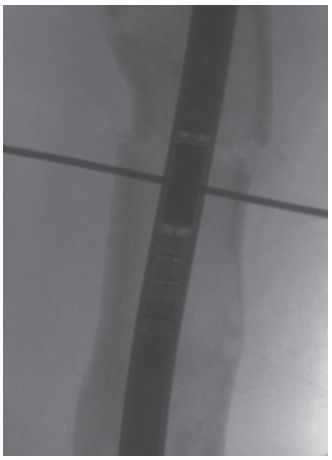
Locating the Center of the Magnet and C-arm Adjustment Guidance

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

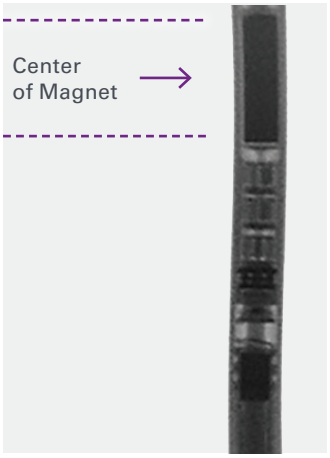
Stryde has thick steel implant walls and visibility of the internal components may require C-arm adjustments. It is recommended to double magnification down (Mag 2), center over the magnet, and column adjust to the nail. If these steps are followed, a manual change to the kVp settings is no longer necessary and may result in better image quality.

Use a surgical skin marker to put a transverse line on the patient's skin directly over the location of the center of the Stryde 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.



Stryde implant reference image

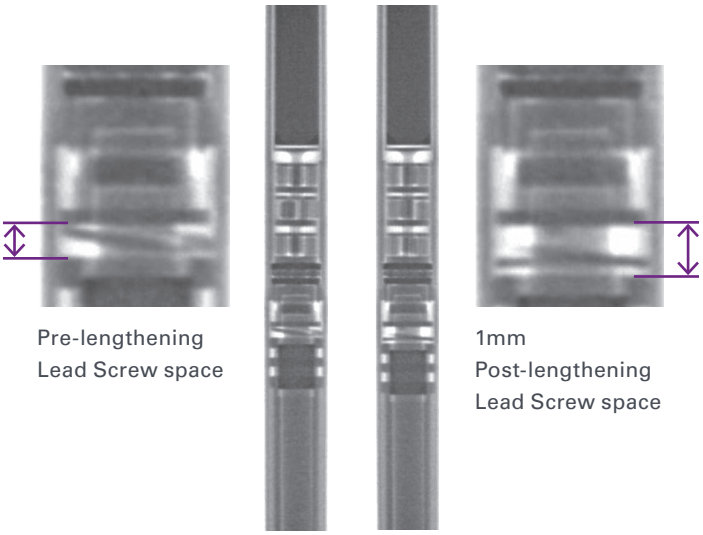
Intraoperative External Remote Controller (ERC) Distraction

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 Stryde 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 Stryde 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.



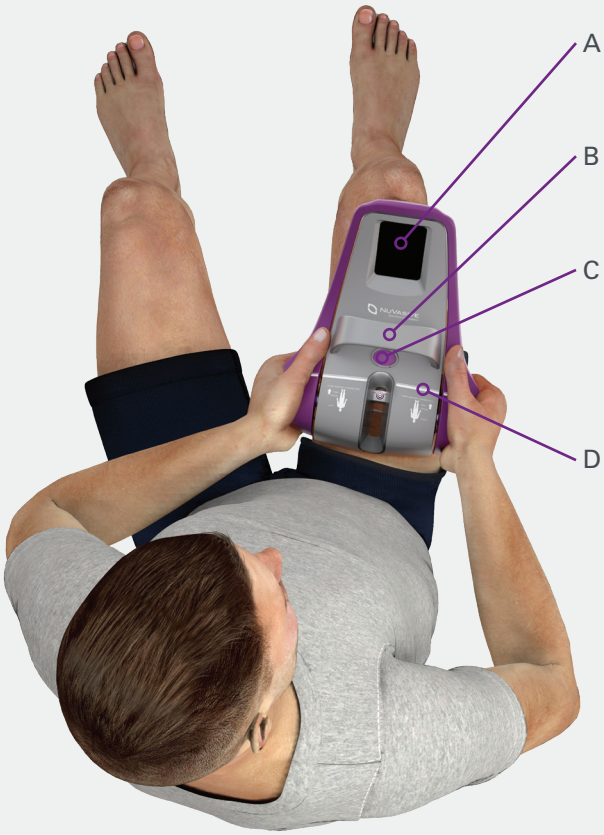
Pre-lengthening
Lead Screw space

1mm
Post-lengthening
Lead Screw space

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

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



A Touch screen for easy programming
B Carrying handle for transportation
C Simple control button for starting and stopping the ERC
D Alignment line for aligning the ERC over the implant magnet

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 Stryde implant magnet (Stryde 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 Stryde device to its maximum potential distraction length (stroke). The maximum pre-distraction length must be 5mm less than the maximum Stryde nail stroke length.*

Postoperative Treatment

Final Closure

After the intraoperative distraction of the Stryde 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 Stryde 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 follow Stryde weight bearing guidance during both the lengthening and consolidation phases. Please see chart below:

Device diameter	Max weight bearing
10.0mm	150lbs
11.5mm	200lbs
13.0mm	250lbs

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.

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 (10.0mm=150k=lbs; 11.5mm=200lbs; 13.0mm=250lbs) 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.

Consolidation Phase

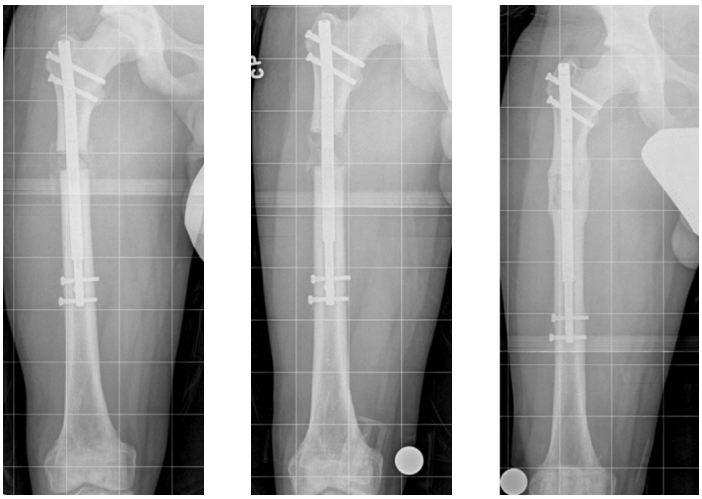
The Stryde implant cannot withstand the stresses of full weight bearing. The patient should utilize external support (i.e. crutches) and/or restrict activities until consolidation occurs. The consolidation phase should occur with the Stryde implant in place.

Increase to unrestricted 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.

Antegrade Femur



Note: *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.*

Postoperative Lengthening

External Remote Controller (ERC) Introduction

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

- Weekly x-ray imaging to assess actual distraction length is recommended.
- Only use the External Remote Controller in a manner consistent with the Operator's Manual. Any alternative use may result in injury or damage to property.
- This equipment may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the External Remote Controller or shielding the location.
- Persons with a pacemaker or a similar medical aid should not handle or be exposed to the External Remote Controller. The strong magnetic fields may affect the operation of such devices.
- The External Remote Controller uses strong permanent magnets. Misuse of this system can cause serious personal injury. Make sure the work area is free of metal objects before use. This includes personal items such as jewelry, watches, keys, and cellular phones. Always return the system to its protective case when not in use.
- Only operate the External Remote Controller by holding onto both of the handles provided.
- The External Remote Controller may be pulled away from your hands if brought too close to other magnetic objects. Always maintain a firm grip on the External Remote Controller and be very aware of other objects in your work area. Also, tools or other hazardous objects may leap towards the External Remote Controller if brought too close.
- Never place the External Remote Controller near electronic media or appliances. The strong magnetic field may damage magnetic media such as floppy disks, credit cards, magnetic I.D. cards, cassette tapes, video tapes, or other such devices. It can also damage televisions, VCRs, computer monitors, and other CRT displays.
- This device has not been tested for compatibility in magnetic resonance imaging (MRI) environments and should not enter an MRI unit.

Features of the ERC3P

Touch screen for easy programming

Carrying handle for transportation

Simple control button for starting and stopping the ERC

Alignment line for aligning the ERC over the implant magnet

Implant Removal

Implant Removal

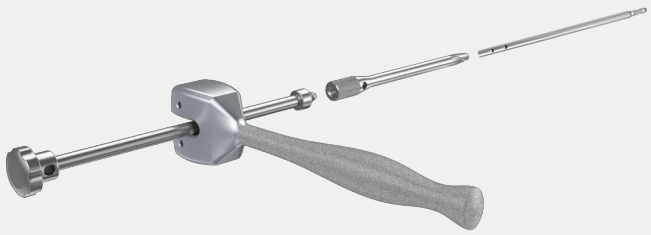
Stryde implant removal is recommended at 1 year provided radiological evidence of full bone consolidation is present. Each surgeon must determine the appropriate time for removal of the Stryde implant based upon their clinical evaluation of the patient.

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 Partially Threaded 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 Stryde implant. If present, the End Cap must be removed prior to threading the Tapered Extractor into the Stryde 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 the mallet should always be held along the axis of force.

Perform skin closure with routine techniques.



Stryde implant, Tapered Extractor, and Removal Rod assembly

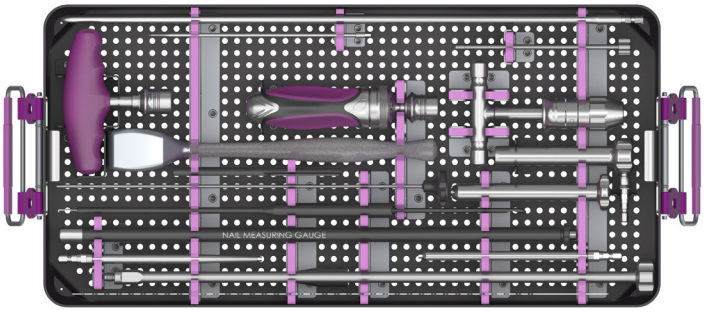
Femoral Limb Lengthening System

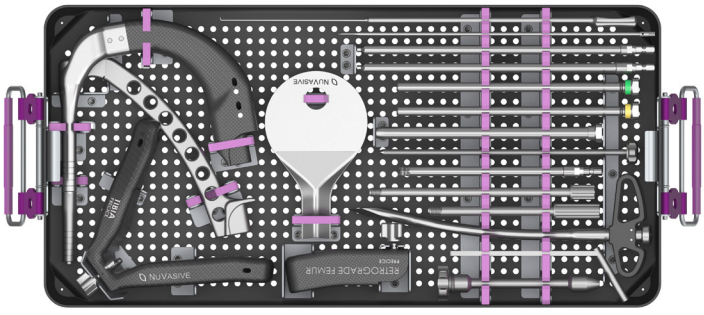
Approach Instrumentation (NGI2-000)

Description	Model #
Radiographic Ruler	XRR2-000
Soft Tissue Protector Tube	STS2-000
Honeycomb	HCB2-000
Mallet Null	RMB1-000
Fracture Reducer	FXR2-000
NuVa T-Handle, J-Hall	THD3-000
Guide Wire Chuck	GWC1-000
Nail Measuring Gauge	NMG1-000
Guide Wire Pusher	GWP2-000
3.5mm Screwdriver, Short Solid	SDS2-001
3.5mm Screwdriver, Short Cannulated	SDS2-000
Screw Capture Rod, Short	CRS1-000
Locking Key	LKL2-000
NuVa Handle, Straight Long Ratchet, J-Hall	HDL3-000
Direct Measuring Sleeve	DMS2-000
Screw Depth Gauge	SDG3-000
Tapered Extractor	CTA1-000
Removal Rod	RVR1-000

Aiming Instrumentation (NGI3-000)

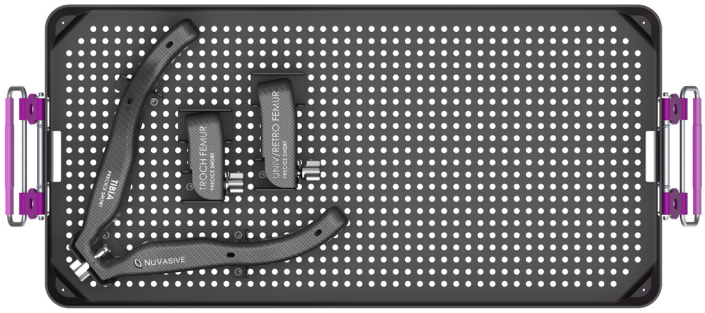
Description	Model #
Guide Wire Sleeve	SET2-0001
Soft Tissue Protector - Paddle	STP1-000
Cannulated Awl	AWL2-010
Targeting Handle, Precice	PGH2-000
Locking Bolt	LBT3-000
Locking Bolt, Suprapatellar	LBT3-001
6mm Ball End Hex Driver	LBD2-001
6mm Straight Hex Driver	LBD3-001
Impactor	IMP3-000
Guide Tube	GTT2-000
Drill Sleeve	DST2-000
Drill Sleeve, 4.3mm	DST3-000
Targeting Handle, Suprapatellar	PGH2-001
Trocar	TCT2-000
Screw Depth Gauge Dipstick	DGT2-001
3.5mm Screwdriver, Long Cannulated	SDL2-000
3.5mm Screwdriver, Long Solid	SDL2-001
Capture Rod, Long	CRS2-000
Soft Tissue Protector	DSD2-035
Targeting Arm, Tibia, Precice	PGA1-000
Targeting Arm, Retro Femur, P2	PGA1-001





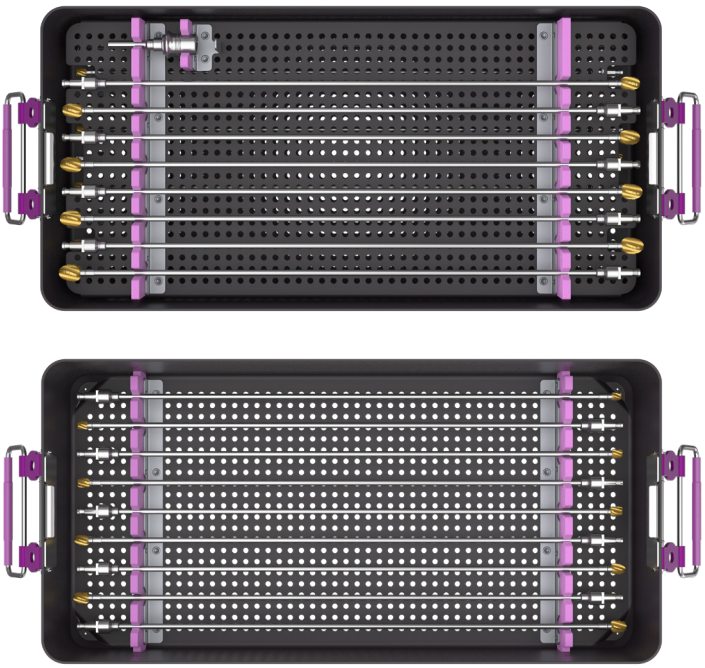
Auxillary Instrumentation (NGI4-000)

Description	Model #
Targeting Arm Tibia Short / UNYTE	PGA1-002
Targeting Arm Femur Univ / Retro (Precice S)	PGA1-004
Targeting Arm Femur Trochanteric (Precice S)	PGA1-003



Flexible Reamer Set (SRT2-000)

Description	Model #
Flexible Reamer, 7.0mm	T18151
Flexible Reamer, 7.5mm	T18152
Flexible Reamer, 8.0mm	T18153
Flexible Reamer, 8.5mm	T18154
Flexible Reamer, 9.0mm	T18154
Flexible Reamer, 9.5mm	T12065
Flexible Reamer, 10.0mm	T12066
Flexible Reamer, 10.5mm	T12067
Flexible Reamer, 11.0mm	T12068
Flexible Reamer, 11.5mm	T12069
Flexible Reamer, 12.0mm	T12070
Flexible Reamer, 12.5mm	T12071
Flexible Reamer, 13.0mm	T12072
Flexible Reamer, 13.5mm	T18156
Flexible Reamer, 14.0mm	T18157
Flexible Reamer, 14.5mm	T18158
Flexible Reamer, 15.0mm	T18159
Hudson Quick Connect	LQC2-000



Antegrade Femur–Trochanteric 10°

Stryde				
Length	Stroke	10.0mm	11.5mm	13.0mm
235mm	50mm	PS10.0-50D235	PS11.5-50D235	PS13.0-50D235
250mm	65mm	PS10.0-65D250	PS11.5-65D250	PS13.0-65D250
265mm	80mm	PS10.0-80D265	PS11.5-80D265	PS13.0-80D265
280mm	80mm	PS10.0-80D280	PS11.5-80D280	PS13.0-80D280
305mm	80mm	PS10.0-80D305	PS11.5-80D305	PS13.0-80D305
335mm	80mm	PS10.0-80D335	PS11.5-80D335	PS13.0-80D335
365mm	80mm	PS10.0-80D365	PS11.5-80D365	PS13.0-80D365

Antegrade Femur–Piriformis Straight

Stryde				
Length	Stroke	10.0mm	11.5mm	13.0mm
235mm	50mm	PS10.0-50B235	PS11.5-50B235	PS13.0-50B235
250mm	65mm	PS10.0-65B250	PS11.5-65B250	PS13.0-65B250
265mm	80mm	PS10.0-80B265	PS11.5-80B265	PS13.0-80B265
280mm	80mm	PS10.0-80B280	PS11.5-80B280	PS13.0-80B280
305mm	80mm	PS10.0-80B305	PS11.5-80B305	PS13.0-80B305
335mm	80mm	PS10.0-80B335	PS11.5-80B335	PS13.0-80B335
365mm	80mm	PS10.0-80B365	PS11.5-80B365	PS13.0-80B365

Partially Threaded Locking Screws

4.0mm		4.5mm		5.0mm	
Catalog #	Length	Catalog #	Length	Catalog #	Length
STP4-200	20mm	STP4.5-200	20mm	STP5-200	20mm
STP4-225	22.5mm	STP4.5-225	22.5mm	STP5-225	22.5mm
STP4-250	25mm	STP4.5-250	25mm	STP5-250	25mm
STP4-275	27.5mm	STP4.5-275	27.5mm	STP5-275	27.5mm
STP4-300	30mm	STP4.5-300	30mm	STP5-300	30mm
STP4-325	32.5mm	STP4.5-325	32.5mm	STP5-325	32.5mm
STP4-350	35mm	STP4.5-350	35mm	STP5-350	35mm
STP4-375	37.5mm	STP4.5-375	37.5mm	STP5-375	37.5mm
STP4-400	40mm	STP4.5-400	40mm	STP5-400	40mm
STP4-425	42.5mm	STP4.5-425	42.5mm	STP5-425	42.5mm
STP4-450	45mm	STP4.5-450	45mm	STP5-450	45mm
STP4-475	47.5mm	STP4.5-475	47.5mm	STP5-475	47.5mm
STP4-500	50mm	STP4.5-500	50mm	STP5-500	50mm
STP4-550	55mm	STP4.5-550	55mm	STP5-550	55mm
STP4-600	60mm	STP4.5-600	60mm	STP5-600	60mm
STP4-650	65mm	STP4.5-650	65mm	STP5-650	65mm
STP4-700	70mm	STP4.5-700	70mm	STP5-700	70mm
STP4-750	75mm	STP4.5-750	75mm	STP5-750	75mm
–	–	STP4.5-800	80mm	STP5-800	80mm

Step Drill Bits

4.0mm	
Catalog #	Length
SDST-4.0	155mm

4.5mm	
Catalog #	Length
SDST-4.5	155mm

5.0mm	
Catalog #	Length
SDST-5.0	155mm

5.0mm	
Catalog #	Length
SDLO-5.0	340mm

Cannulated Entry Drill Bits

8.0mm	
Catalog #	Length
CED1-008	260mm

11.0mm	
Catalog #	Length
CED1-011	260mm

Sterile Wires and Misc. Disposables

Catalog #	Description
0101-900S	3.0 x 900mm Ball Tip Guide Wire
NU-S0100-000	3.2 x 330mm Threaded Pin
NU-S0110-000	3.2 x 330mm Trocar-Tip Pin
12-1874-12ST1	2.5 x 900mm Ball Tip Guide Wire (EMEA Only)
PFD1-000	Precice Fast Distractor
STRLBGPRG	ERC Sterile Bag

End Caps

10.0/11.5mm	
Length	Catalog #
0mm	SST-010-000
5mm	SST-010-005
10mm	SST-010-010
15mm	SST-010-015
20mm	SST-010-020

13.0mm	
Length	Catalog #
0mm	SST-013-000
5mm	SST-013-005
10mm	SST-013-010
15mm	SST-013-015
20mm	SST-013-020

Important Safety Information

PRODUCT DESCRIPTION

The Precice Stryde System is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The Stryde 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 Stryde System is intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones.

CONTRAINDICATIONS

- Infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device.
- Patients with Gustilo open fracture Classification Grade IIIB or IIIC fractures
- Patients with pre-existing nerve palsies
- Metal allergies and sensitivities.
- Patients with an irregular bone diameter that would prevent insertion of the Precice Stryde nail.
- Patients in which the Precice Stryde 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.

Please refer to the table below for contraindications with regard to weight and maximum distance of the treated limb to the surface of the intramedullary canal.

Limb	Precice Stryde Model	Nail Diameter	Maximum Distance of Treated Limb Surface to IM Canal	Maximum Patient Weight
Tibia	C, SJ	10.0	13	150lbs/69kg
		11.5	13	200lbs/91kg
		13.0	13	250lbs/114kg
Femur	A,B,D,E V, X	10.0	50	150lbs/69kg
		11.5	65	200lbs/91kg
		13.0	80	250lbs/114kg

WARNINGS

- The Precice Stryde nail cannot withstand the stresses of full weight bearing. Patients should utilize external support and/or restrict activities as directed by the physician 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 appears to have been previously opened.
- Metallic implants can loosen, fracture, corrode, migrate, or cause pain.
- Due to the presence of a magnet, use of the Precice Stryde System is not recommended in patients with pacemakers.
- The Precice Stryde System may not be appropriate for patients with poly-trauma.
- Use of the Precice Stryde 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 Stryde 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.
- Patients with implanted Precice Stryde nail should not enter an MRI unit.
  - 

- The Precice Stryde System is unsafe in Magnetic Resonance Imaging environments.
- The Precice Stryde Nail should be retracted only by a physician. Retraction should be monitored and confirmed using radiography.
- There is a possibility of nerve or soft tissue damage and/or weakness related to either surgical trauma or the presence of the implant. Advise the patient to notify the surgeon of any experienced pain, numbness, or weakness while undergoing treatment.

PRECAUTIONS

- 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 will cause a load to the treated limb in excess of the maximum patient weight, as identified in the contraindications.
- Examine all Precice Stryde 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 Stryde 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 Stryde 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 Stryde 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 Stryde nail.

Notes

Notes

Rx Only.

The Precice Stryde System is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The Stryde 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 Stryde System is intended for limb lengthening of the femur and tibia. Contraindications include infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device, metal allergies and sensitivities, patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 80mm for the 13.0mm diameter implant, 65 mm for the 11.5 mm implant and 50mm for the 10.0mm diameter implant, patients with an irregular bone diameter that would prevent insertion of the Stryde nail, patients in which the Stryde nail would cross joint spaces or open epiphyseal growth plates, patients in which there are 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, 150lbs for the 10.0mm diameter implant, 200lbs for the 11.5mm diameter implant and 250lbs for the 13.0 mm implant. The implantable device is only to be used by a trained licensed physician. Please refer to the Precice Stryde System instructions for use for complete Important Safety Information.

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