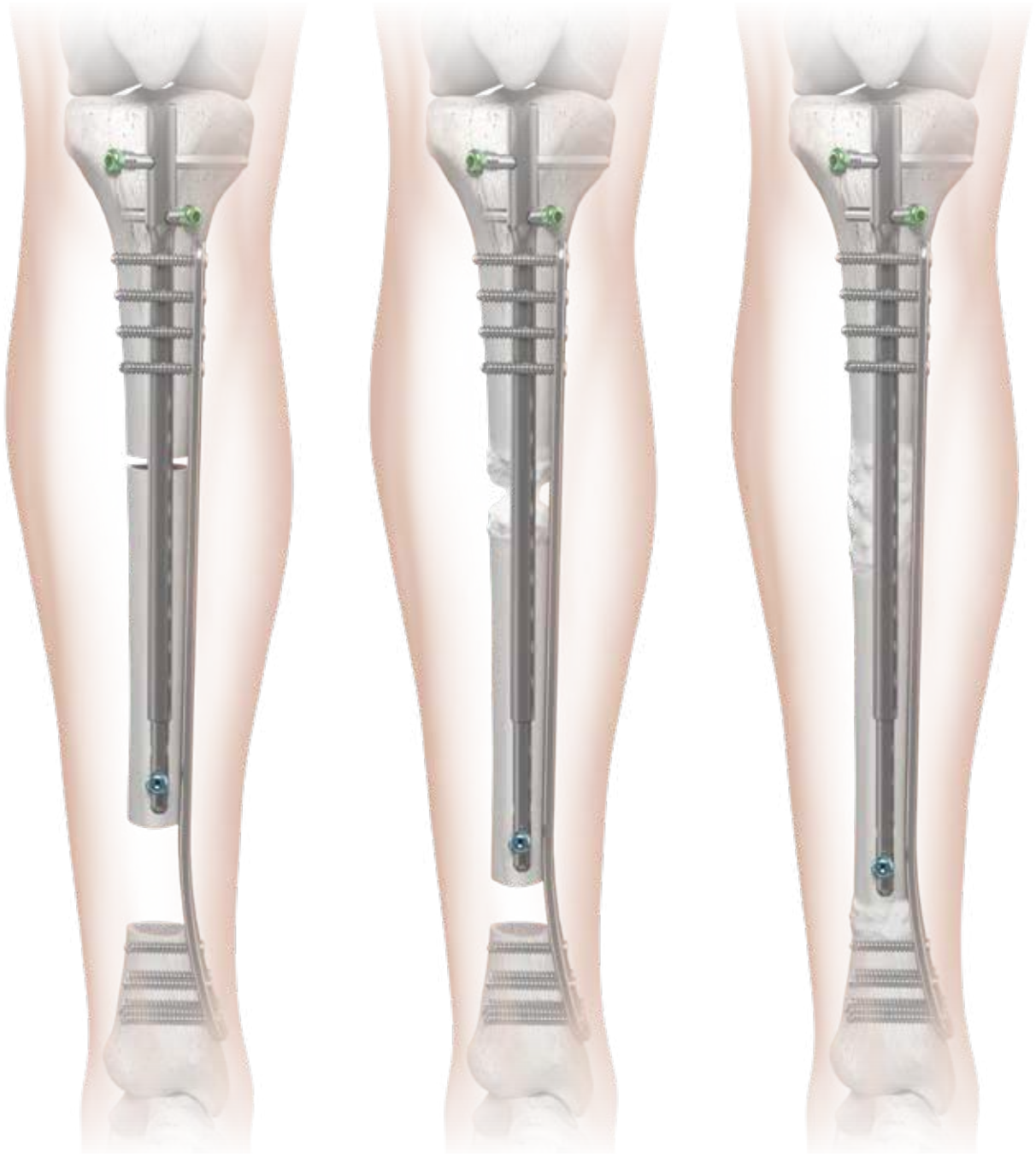
PRECICE®

Plate Assisted Bone Segment Transport (PABST) Tibia Surgical Technique Guide



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Contents

Introduction

CONTRIBUTING SURGEON

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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 Guide 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.

PRECICE® PABST Tibia Surgical Technique Guide

1 PRE-OP PLANNING

It is important to note that pre-operative planning is vital to the success of this procedure.

Planning the defect resection:
Obtain a good full-length A/P and lateral films of the impacted limb. Recognize any deformity and plan for the correction in the initial procedure.

Then, measure the defect size and plan for the resection. Decide if the transport will be a retrograde (pull) or antegrade (push) type of transport. (The location of the defect will determine retrograde or antegrade transport.)

Planning the plate selection:
The longest medial plate possible is recommended to prevent inevitable medial drift. The plate should be used to include the defect and allow for an appropriate-sized transport segment. The defect and intercalary segment must be contained between the proximal and distal fixation points of the plate.

Antegrade "PUSH" Transport
When planning the placement of your plate for an Antegrade (Push) Transport, it is recommended that at least 4 screws are able to be inserted above the corticotomy

Retrograde "PULL" Transport
When planning the placement of your plate for an Retrograde (Pull) Transport, it is recommended that at least 4 screws are able to be inserted below the corticotomy

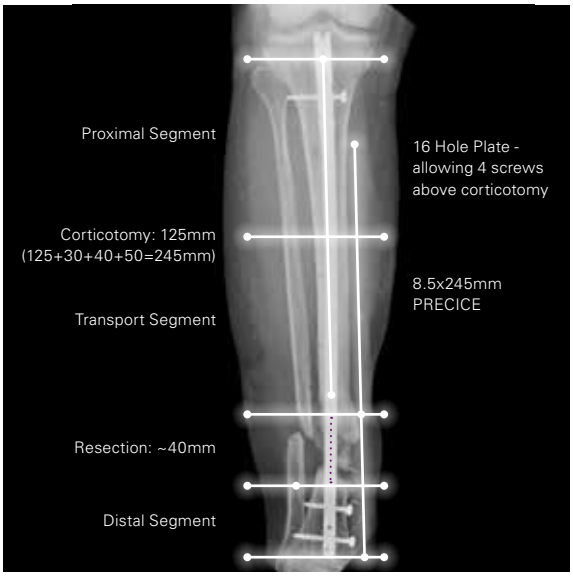
Planning for the PRECICE device:
When deciding on nail length, keep in mind that the distal portion of your nail should span the full length of the intercalary segment.

When considering nail diameter, it is important to note the size of the patient's canal as well as the placement of the plate's locking screws.

If needed, the Fast Distractor is available to distract the PRECICE device to your desired length prior to implantation. Instructions on how to use the Fast Distractor can be found on page 7.

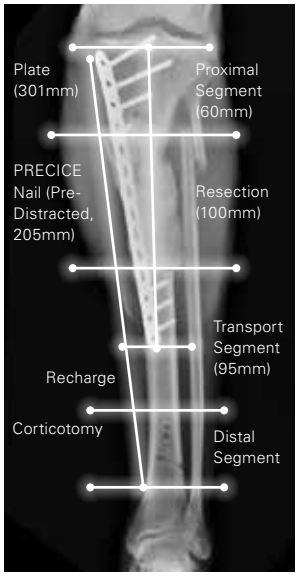
Note

Keep in mind that the maximum stroke of the PRECICE device is either 50mm or 80mm, depending on the length of nail that is chosen. If a defect exceeds this, the placement of the nail and the size of the transport segment must be carefully planned to allow for two transport runs with a lengthening or shortening period after the stroke length of the nail has been met.



ANTEGRADE (PUSH) TRANSPORT

(Fig. 1)



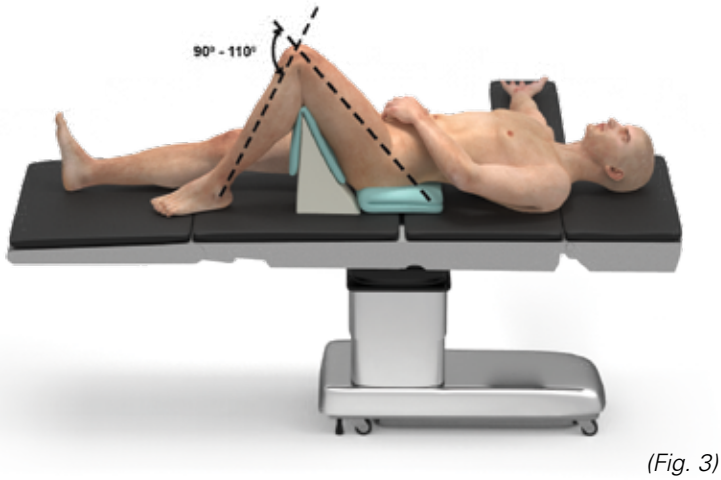
RETROGRADE (PULL) TRANSPORT

(Fig. 2)

2 PATIENT POSITIONING

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

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

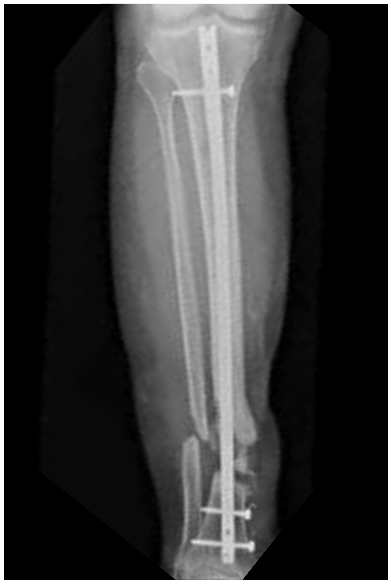


(Fig. 3)

3 RESECTION PLANNING

Use fluoroscopy imaging to locate the area where planned resection will take place.

Make an incision at this site to properly debride and assess how much bone needs to be resected.



(Fig. 4)

4 REMOVE EXISTING HARDWARE

Remove existing hardware and properly realign bone.

(Fig. 5)

5 RESECTION

Using an oscillating saw, under continuous irrigation, resect all dead and/or previously infected bone.

IMPORTANT: If patient has an infected non-union, it is recommended to treat the infection first and only use the PABST procedure after the infection is no longer detected.

It is important to apply continuous irrigation to minimize the potential for thermal necrosis.

Tip

Cut bone perpendicular to the anatomic axis to allow for flat edges to meet during docking.

(Fig. 6)

(Fig. 7)

6 MEDIAL PLATE POSITIONING

Select the longest distal medial tibial plate to accommodate the entire construct.

> ***Note***
> *A medial plate is preferred to prevent potential medial drift.*

Be sure your planned corticotomy site is distal to at least 4 proximal or distal (depending on the location of the defect) screw holes of the plate.

When positioning the medial plate, mark the proximal screw hole locations to be sure you have planned the appropriate amount of space for the PRECICE device to be inserted posterior to the plate. However, **DO NOT** fix the plate proximally at this time.

After you have located and marked the proximal screw holes, insert the distal plate screws.

(Fig. 8)

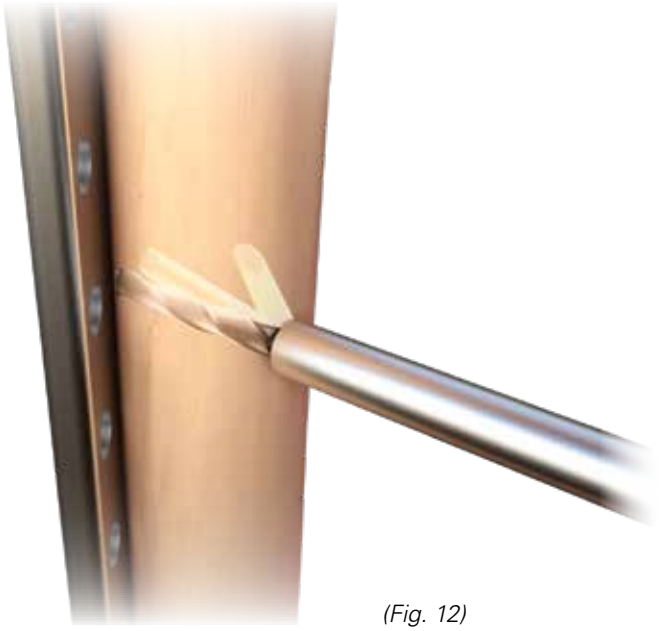
(Fig. 9)

(Fig. 10)

7 VENTING (AS APPROPRIATE)

If additional venting is needed, pivot the proximal end of the plate out of the way and perform your venting of the tibial intramedullary canal at the corticotomy site.

(Fig. 11)



(Fig. 12)

8 REAMING

Ream the tibial canal by 0.5mm increments until it is over-reamed by 2.0mm greater than the planned diameter of the PRECICE® device.

(Fig. 13)

(Fig. 14)

FAST DISTRACTOR - OPTIONAL

The Fast Distractor can be used to distract the PRECICE device to your desired length prior to implantation.

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

Drill Speed Approximate Distraction Rate
- 1,500 rpm, 7mm/minute
- 750 rpm, 3.5mm/minute

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

9 TIBIA GUIDE ARM ASSEMBLY

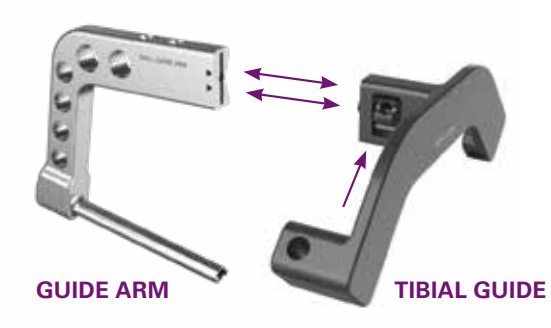
Align the arrows on the Drill Guide Arm and Tibial Guide and assemble by tightening the knob.

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

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

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

STANDARD PRECICE INSTRUMENTATION



(Fig. 15)

SHORT PRECICE INSTRUMENTATION

(Fig. 16)

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

10 CORTICOTOMY

If venting was not already performed, make an incision at the planned corticotomy site to expose the plate.

Advance the PRECICE® device down the intramedullary canal, stopping superior to the planned corticotomy site.

Move the plate anteriorly or posteriorly to allow for corticotomy.

Using an osteotome, carefully complete the corticotomy.

After the corticotomy has been made, advance the PRECICE device through the intercalary segment.

(Fig. 17)

(Fig. 18)

(Fig. 19)

(Fig. 20)

11 PROXIMAL LOCKING SCREWS

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

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

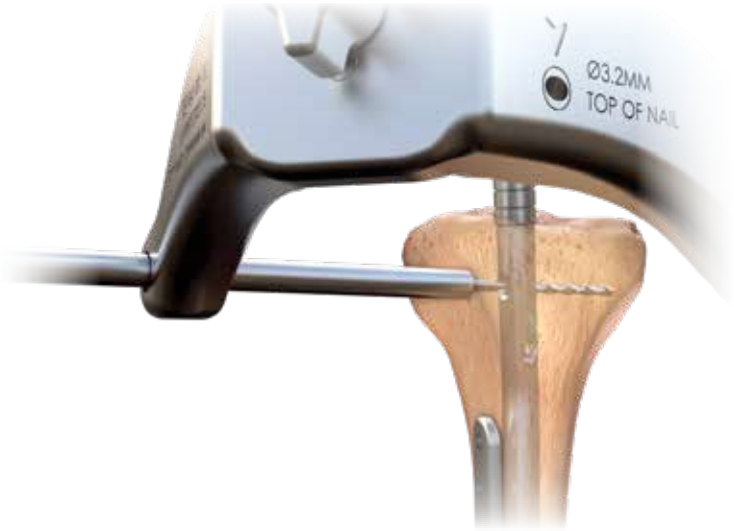
After drilling both cortices, select the appropriate Locking Screw length by reading off the calibration on the Drill Bit. The Screw Gauge may also be used to read the calibration by sliding it down the Guide Tube.

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

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

TIBIAL GUIDE ARM ASSEMBLY WITH DRILL BIT IN POSITION PRIOR TO NAIL INSERTION.

(Fig. 21)



(Fig. 22)

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

12 DISTAL LOCKING SCREWS

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

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

SIZE GUIDE FOR NAIL DIAMETER

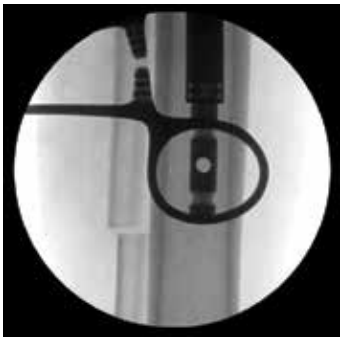
APPLIES TO ALL P2 AND SHORT GEN I NAILS; MODELS: A, B, C, D, E, J, K, H, AND U (two proximal, two distal screw holes)

	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; MODELS: Q, M, P, AND N (two proximal, two distal screw holes)

	8.5mm NAIL		10.7mm NAIL		12.5mm NAIL	
	Proximal	Distal	Proximal	Distal	Proximal	Distal
Locking Screw Size (mm)	5.0	4.0	5.0	4.0	N/A	N/A

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



(Fig. 23)

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

(Fig. 24)

13 PROXIMAL PLATE FIXATION

After the proximal and distal screws of the PRECICE implant have been completed, the proximal plate screws can now be placed. It is important that the drilling of the proximal screw holes, should be done under fluoroscopy to be sure they will be placed anterior to the PRECICE device to mitigate any damage to the device. Once this is confirmed, screws can then be placed. It is recommended to place at least 4 screws above the coritcotomy site in an antegrade (push) transport or 4 screws below in a retrograde (pull) transport.

(Fig. 25)

(Fig. 26)

14 LOCATING THE CENTER OF THE MAGNET

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

15 PROGRAMMING THE ERC FOR O.R. USE

1. Turn on the ERC3P and type in the physician passcode
2. Choose "Operating Mode" from the menu
3. Select Nail Size
4. Select Approach
5. Press the Controller Button when it is **Green**!

(Fig. 27)

Note

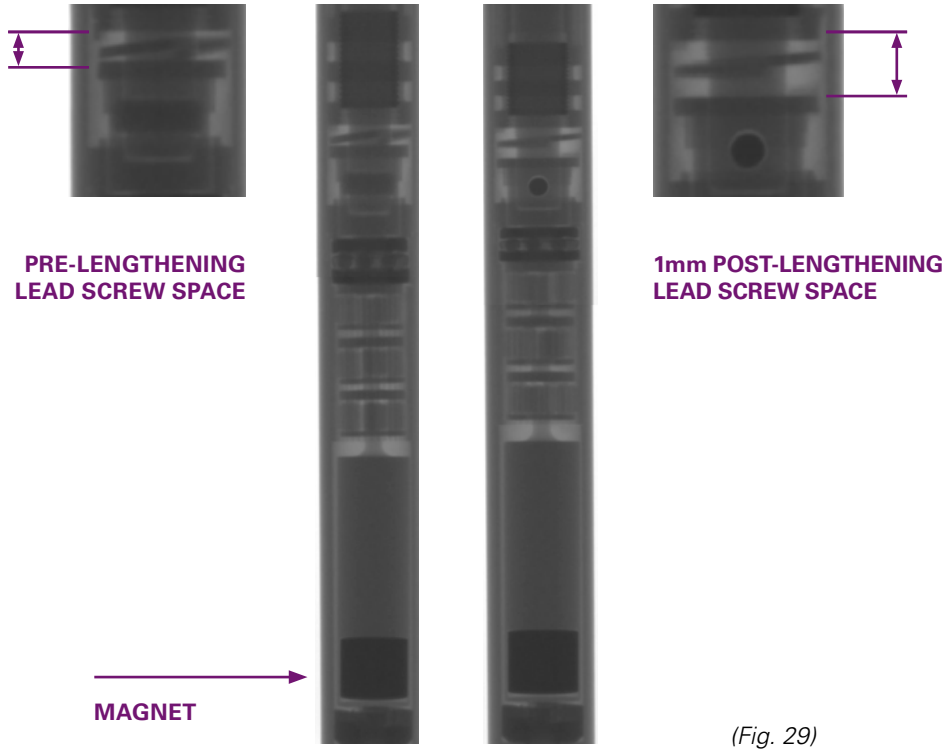
If the magnet detection feature is on, initialization will need to be performed before the lengthening session begins.

16 INTRAOPERATIVE COMPRESSION OR DISTRACTION

Depending on whether the construct is an antegrade or retrograde transport, confirm 2mm of intraoperative distraction or compression.

(Fig. 28)

17 MAGNET CHECK



(Fig. 29)

PRECICE 10.7 mm tibia nail shown in image

18 POST-OP TRANSPORT PROTOCOL

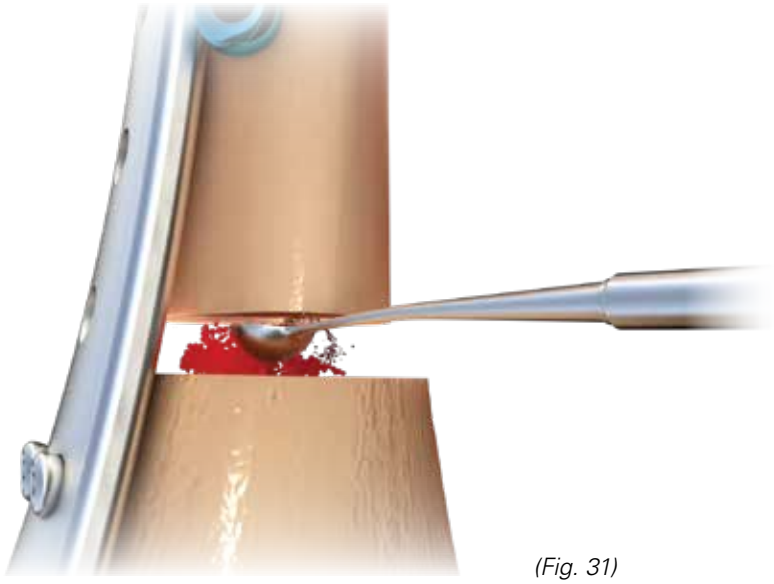
- Non-weight bearing
- 7-14 day latency period, depending on soft tissues
- 0.25mm distraction 3x per day
- Protocol may vary depending on patient's needs

Ergonomically friendly handle for tibia lengthening

(Fig. 30)

19 DOCKING SITE MANAGEMENT

When the two bone ends reach about 1cm to docking, it is recommended to plan for scar tissue removal. At this time optional bone graft with osteoinductive properties may also be used.



(Fig. 31)

20 DOCKING SITE COMPRESSION

Continue compression at docking site until cortical contact is achieved.

The recommended Docking Site Compression Protocol is as follows:

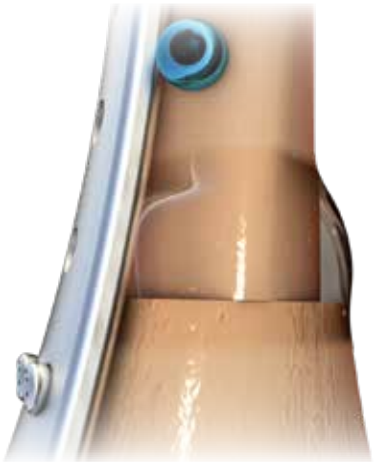
- Apply continuous compression until cortical contact is achieved and confirmed radiographically at the docking site.
- About 1mm of compression can be applied per week for two weeks, or as needed until bone ends are touching.

However, each patient is different, therefore the compression protocol should meet the patient's needs.

Keep in mind that the standard PRECICE® weight bearing guidelines still apply.

Once healing has begun at the docking site and regenerate at the corticotomy site is sufficient, the PRECICE device can either be exchanged for a traditional Trauma Nail or continue to follow the PRECICE weight bearing guidelines until full healing has been achieved.

(Fig. 32)



(Fig. 33)

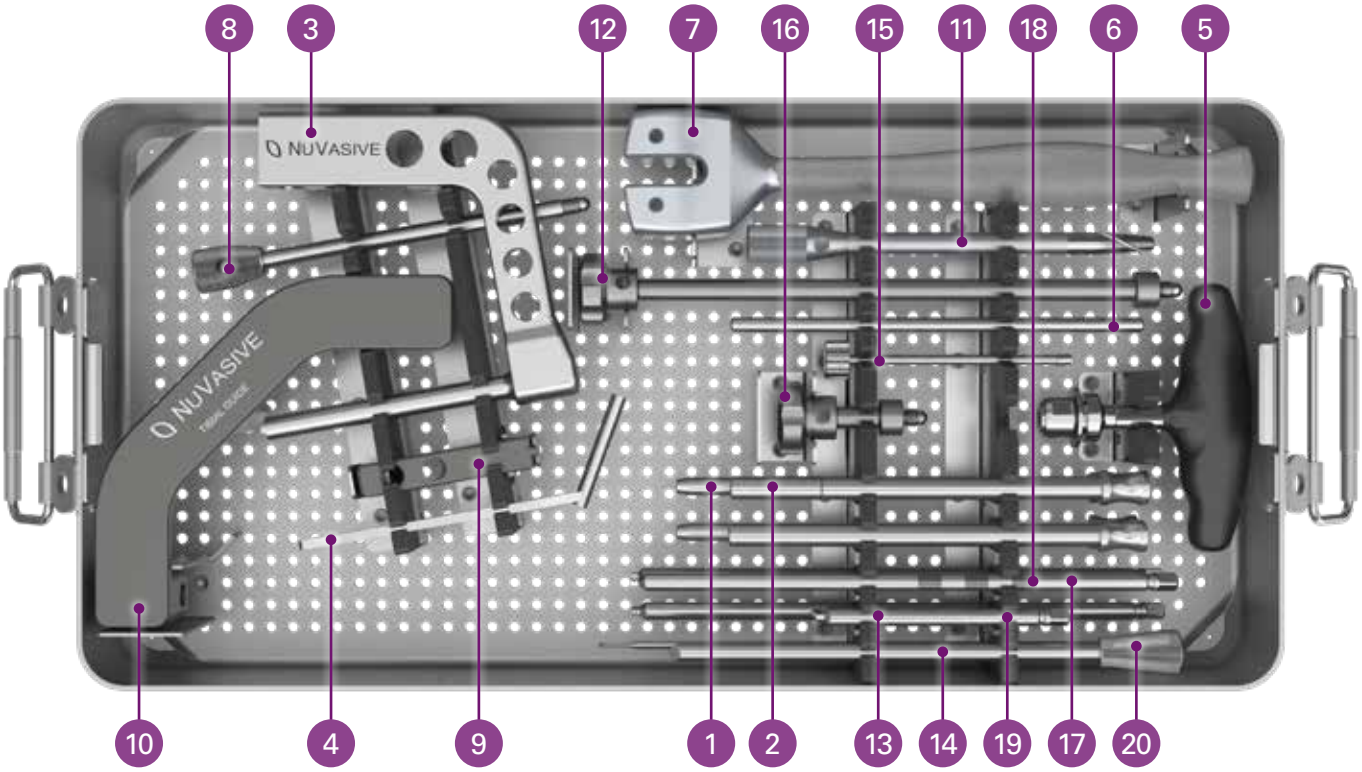
(Fig. 34)

PRECICE® PABST 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

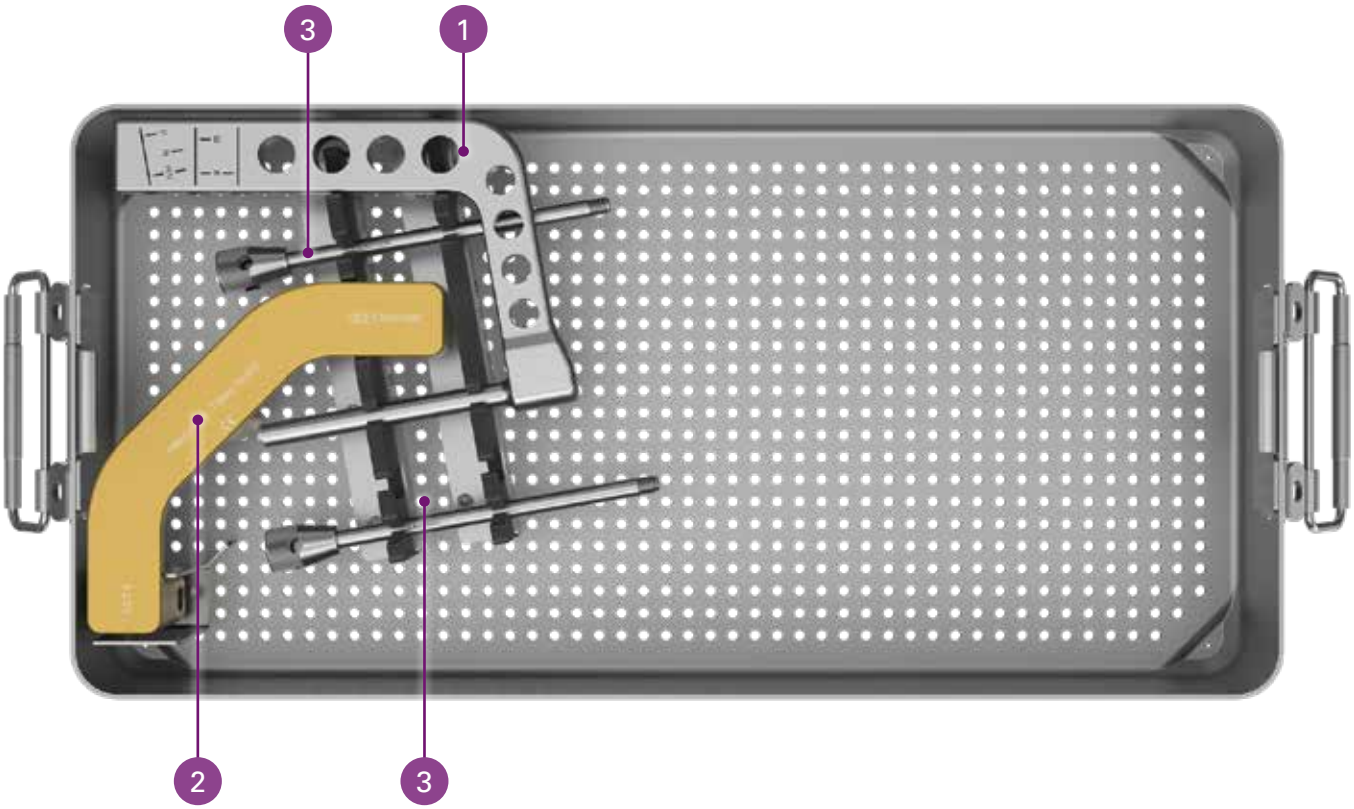
	MODEL #	DESCRIPTION
11	CTA1-000	Tapered Extractor
12	RRB1-000	Removal Rod
13	THE1-000	4.0mm Locking Driver
14	PRB1-000	Trocar
15	LKA1-000	Locking Key
16	IMA1-000	Short Impactor
17	DRD1-000	3.5mm Solid Hex Driver
18	DRE1-000	4.0mm Solid Hex Driver
19	THF3-000	3.5mm Locking Driver
20	CRC3-000	Screw Capture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



PRECICE® PABST System

SPECIALTY TARGETING TRAY

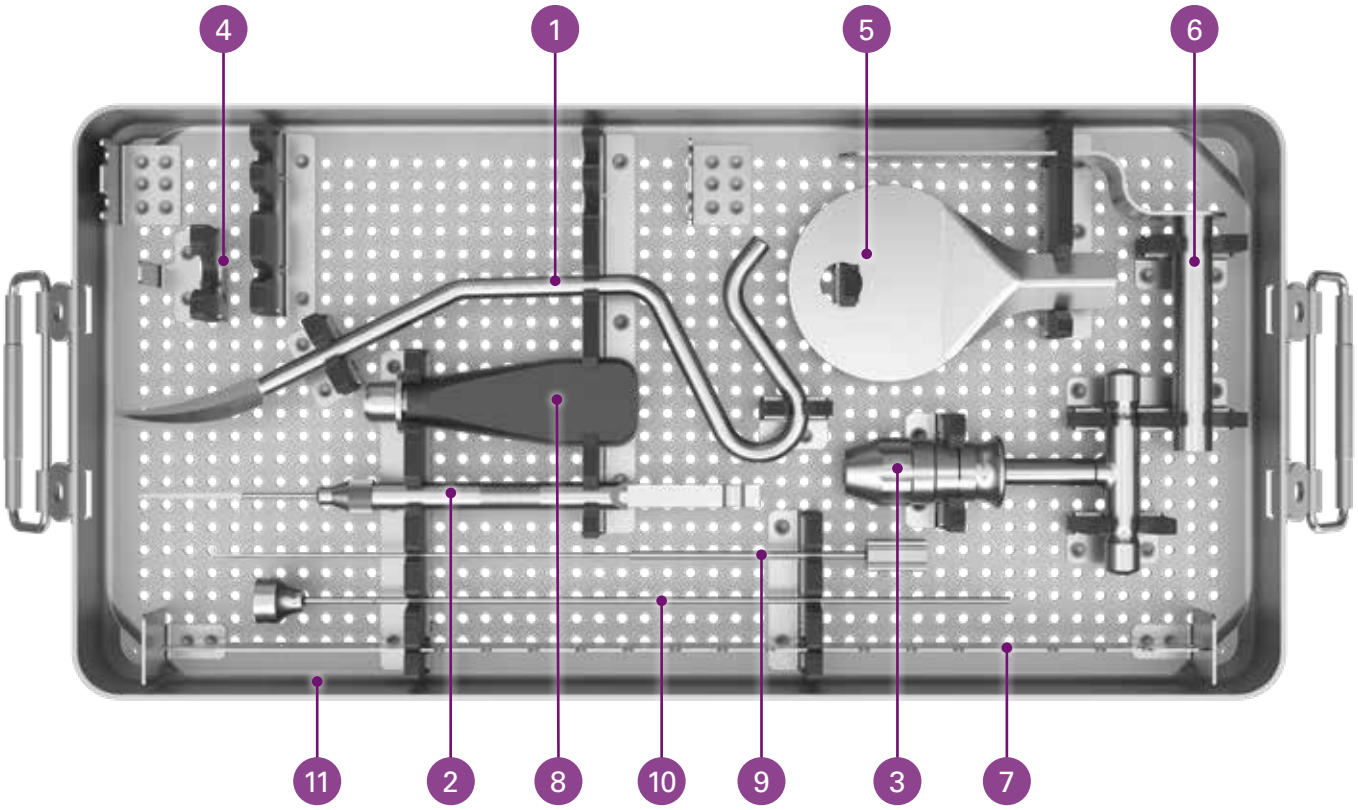
	MODEL #	DESCRIPTION
1	AGB2-000	Drill Guide Arm, Short Nail
2	CBB2-000	Tibial Drill Guide, Short Nail
3	LRB2-000	Locking Rod



PRECICE® PABST 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



PRECICE® PABST System

ANTEGRADE TIBIA – 10°

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

PRECICE® PABST 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
TSA4-020	20mm	TSA5-020	20mm
TSA4-022.5	22.5mm	TSA5-022.5	22.5mm
TSA4-025	25mm	TSA5-025	25mm
TSA4-027.5	27.5mm	TSA5-027.5	27.5mm
TSA4-030	30mm	TSA5-030	30mm
TSA4-032.5	32.5mm	TSA5-032.5	32.5mm
TSA4-035	35mm	TSA5-035	35mm
TSA4-037.5	37.5mm	TSA5-037.5	37.5mm
TSA4-040	40mm	TSA5-040	40mm
TSA4-042.5	42.5mm	TSA5-042.5	42.5mm
TSA4-045	45mm	TSA5-045	45mm
TSA4-047.5	47.5mm	TSA5-047.5	47.5mm
TSA4-050	50mm	TSA5-050	50mm
TSA4-055	55mm	TSA5-055	55mm
TSA4-060	60mm	TSA5-060	60mm
TSA4-065	65mm	TSA5-065	65mm
TSA4-070	70mm	TSA5-070	70mm
TSA4-075	75mm	TSA5-075	75mm
TSA4-080	80mm	TSA5-080	80mm
TSA4-085	85mm	TSA5-085	85mm
TSA4-090	90mm	TSA5-090	90mm
TSA4-095	95mm	TSA5-095	95mm
TSA4-100	100mm	TSA5-100	100mm

PRECICE® PABST System

DRILL BITS

3.5mm		4.0mm		5.0mm	
PART #	LENGTH	PART #	LENGTH	PART #	LENGTH
DBA3-152	152mm	DBB4-152	152mm	DBA5-355	355mm

CANNULATED ENTRY DRILL BITS

8.0mm		11.0mm	
PART #	LENGTH	PART #	LENGTH
CED1-008	260mm	CED1-011	260mm

DRILL BITS GUIDE

DRILL BITS	SCREWS
3.5mm Drill	3.5mm Peg 4.0mm Fully Threaded
4.0mm Drill	4.0mm Peg
4.3mm Drills*	5.0mm Fully Threaded
5.0mm Drills*	5.0mm Peg

*Available in both long and short drill options

END CAPS

8.5/10.7mm*		12.5mm	
PART #	LENGTH	PART #	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

*10.7mm End Caps are also compatible with the 8.5mm PRECICE® Devices.

FAST DISTRACTOR

MODEL #	DESCRIPTION
PFD1-000	Fast Distractor,Sterile, Single Use

NuVasive
Specialized Orthopedics™

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 device is a sterile single use device that is surgically implanted using the instruments and locking screws for osteoplasty lengthening utilizing distraction osteogenesis. The ERC is used daily after implantation to non-invasively lengthen or shorten the implant to a prescribed length.

INTENDED USE:

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

CONTRAINDICATIONS:

- Infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device.
- Patients with Gusilo open fracture Classification Grade IIIB or IIIC fractures.
- Patients with pre-existing nerve palsies.
- Metal allergies and sensitivities.
- Patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 51mm for the femoral, or 13mm for the tibial, 10.7, 11.5, and 12.5mm diameter implant.
- Patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 38mm for the femoral, or 10mm for the tibial, 8.5, 9.0, 9.5 and 10.5mm diameter implant.
- Patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 25.4mm for the 8.5mm 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 51mm for the 8.5mm diameter humeral implant that is 225mm to 300mm in pre-distracted length.
- Patients with an irregular bone diameter that would prevent insertion of the PRECICE device.
- Patients in whom the PRECICE device would cross joint spaces or open epiphyseal growth plates.
- Patients in whom 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 device 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.
- In cases where 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 in patients with pacemakers.
- The PRECICE System may not be appropriate for patients with polytrauma.
- 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 device 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 device does not enter MRI unit. Unsafe in Magnetic Resonance Imaging environments.
- The PRECICE device should be retracted only by a physician. Retraction should be monitored and confirmed using radiography.
- The typical prescription for lengthening is 1mm/day.
- 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 participle in contact sports or other high risk activities that cause more than 20% of body weight to be loaded on the treated limb. These activities may resume upon sufficient bone consolidation, but only as determined by the physician.
- Examine all PRECICE System components carefully prior to use to assure proper working condition. If you suspect a component to be faulty or damaged, do not use.

Important Safety Information

FAST DISTRACTOR PRECAUTIONS:

- The PRECICE Fast Distractor is supplied sterile and is for single use only. The Fast Distractor has not been tested to be cleaned or sterilized for multiple uses. If the Fast Distractor is used more than once, the device may not be sterile and could cause a serious infection and may not function as intended. Do not re-sterilize the device.
- Do not use the Fast Distractor if the sterile pouch has been damaged or is open.
- Do not pre-distract the PRECICE nail to its maximum potential distraction length (stroke). The maximum pre-distraction length must be 5mm less than the maximum PRECICE nail stroke length.
- Before using the PRECICE Fast Distractor, remove and discard all protective packaging materials.
- Please refer to the manufacturer's Instructions for Use for the O.R. drill with regard to the recommended duty cycle.
- The Fast Distractor can not be used after the nail has been implanted.

CAUTIONS:

- The PRECICE System is for prescription use only by the order of a physician.
- Utilize extreme caution when handling instruments made from magnetic materials such as stainless steel in proximity of the magnet of the PRECICE device, 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 device 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 device.

NuVasive
Specialized Orthopedics™

Notes

Notes

℞ Only

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

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Rx Only.

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

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