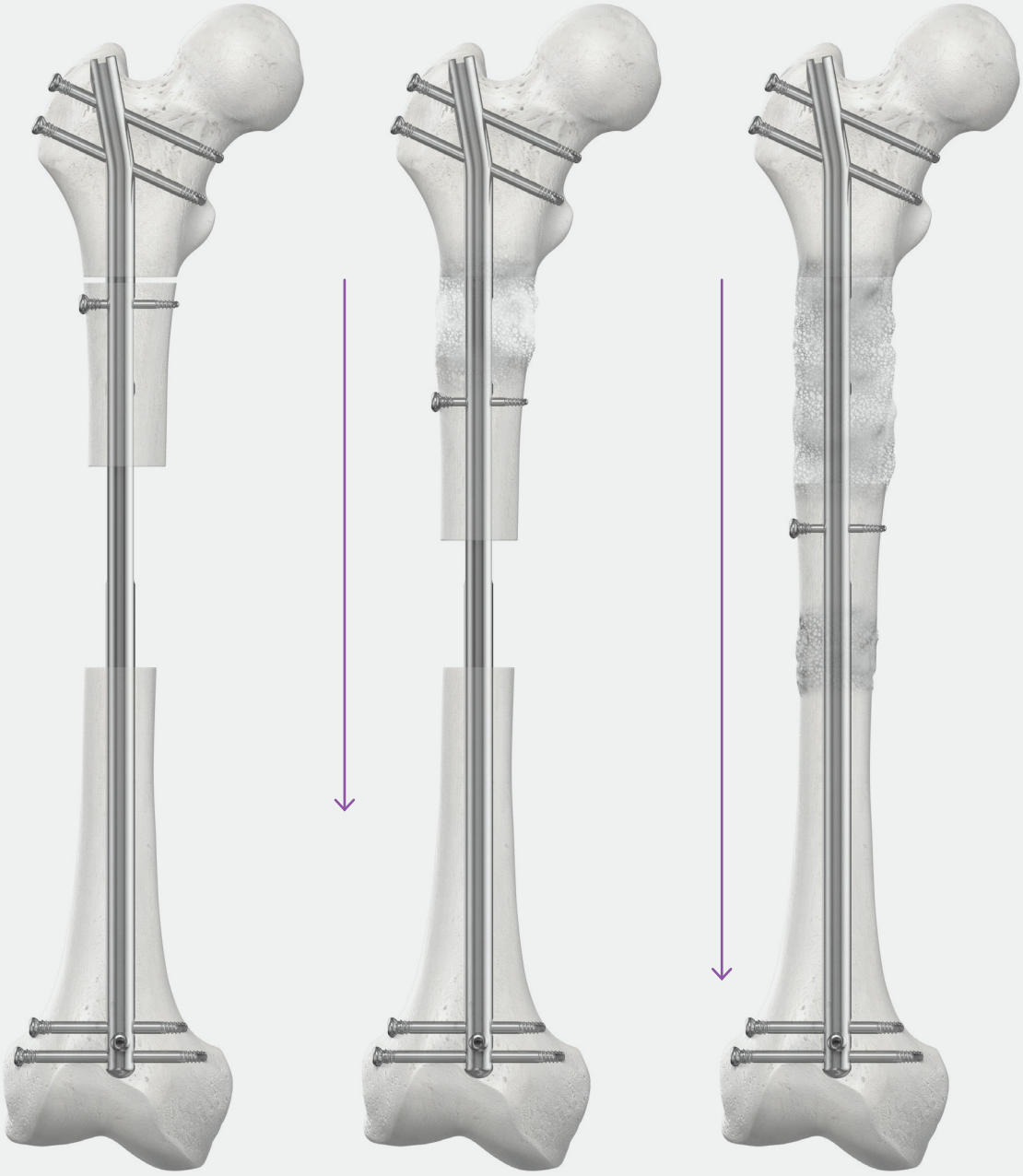


Precice Bone Transport

Femur surgical technique guide

NuVasive
Specialized Orthopedics

Contents

Introduction

Contributing surgeons

Mark T. Dahl, M.D.
Minneapolis, MN

Austin T. Fragomen, M.D.
New York, NY

Matthew P. Gardner, M.D.
Springfield, IL

Thomas Kern, M.D.
Murnau am Staffelsee, Germany

Stephen M. Quinnan, M.D.
Miami, FL

S. Robert Rozbruch, M.D.
New York, NY

J. Tracy Watson, M.D.
Phoenix, AZ

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

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the Precice Bone Transport system. It may not be appropriate for all patients and all patients may not benefit.

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.

For a comprehensive list of indications, contra-indications, warnings and precautions, see page 25 or visit nuvasive.com/eifu.

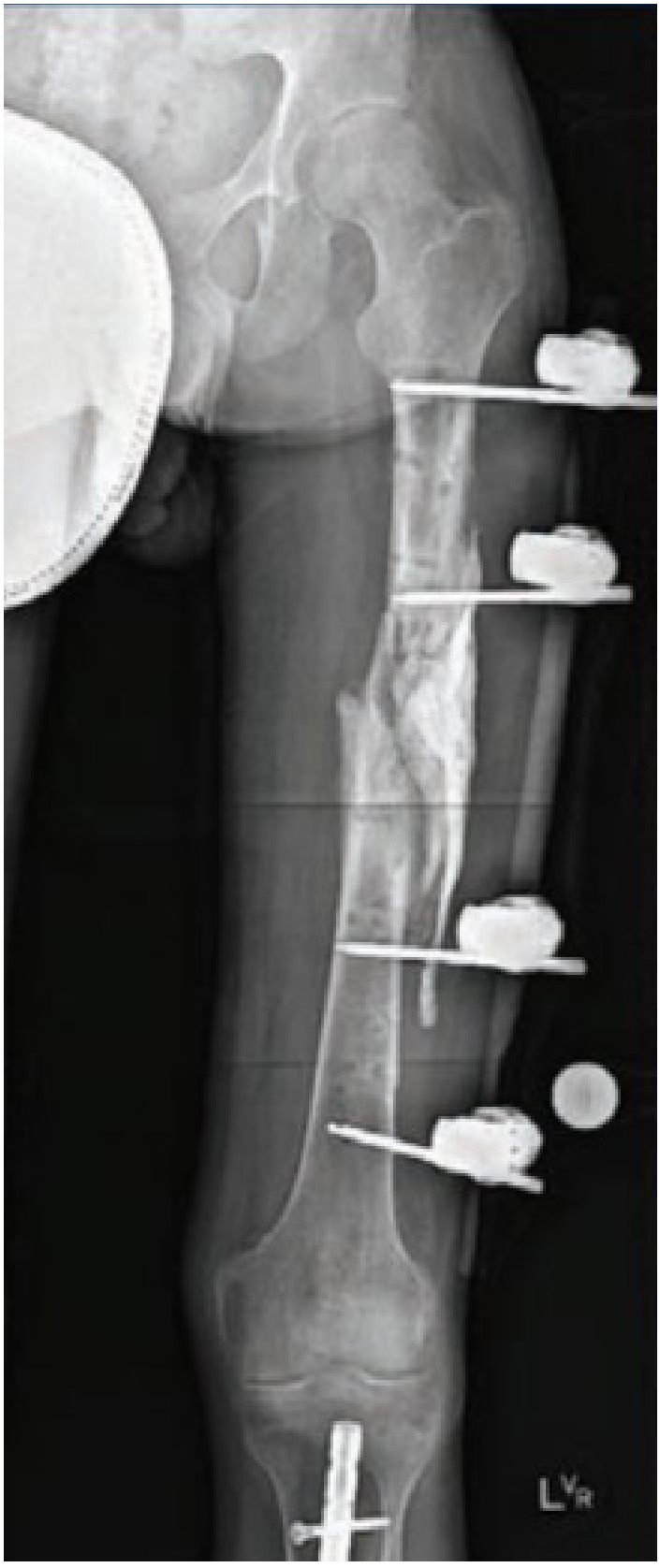
Surgical technique

Preoperative planning

Use the check list below to determine your ideal preoperative plan.

- Defect size
- Canal diameter
- Ideal device length
- Intercalary screw location
- Corticotomy location
- Blocking screw location

Reminder: *The stroke length of the Precice Bone Transport device is dependent on the total length of the device.*



Precice Bone Transport device

Diameters: Ø10 mm, Ø11.5 mm, Ø13 mm

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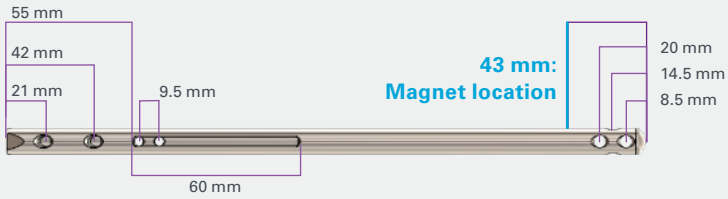
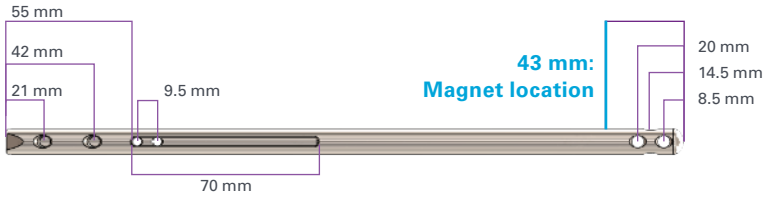
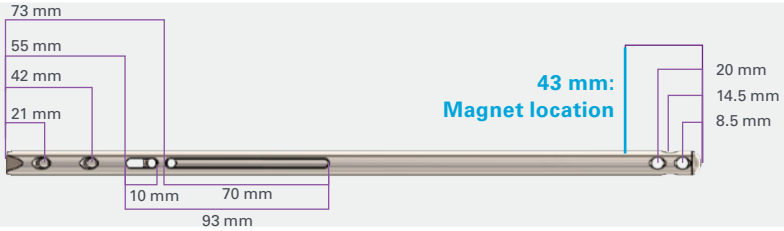
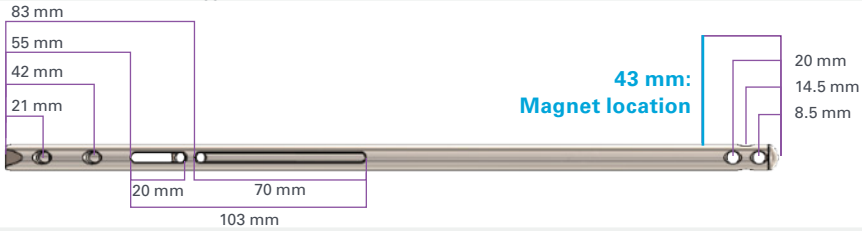
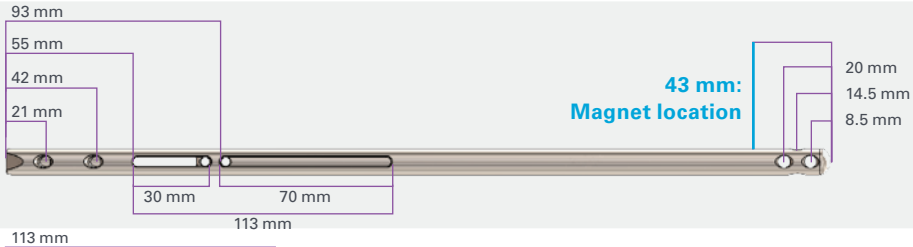
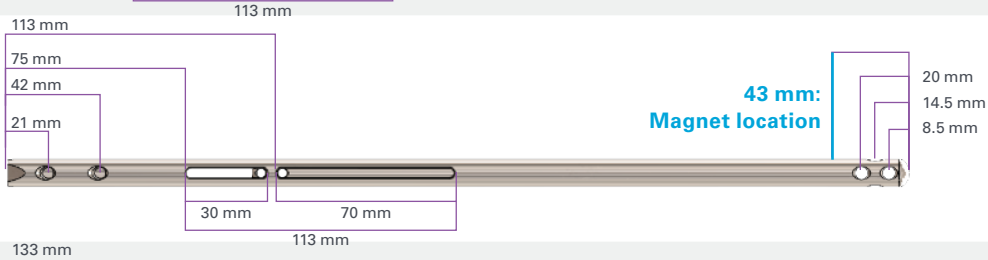
280 mm	60 mm	
300 mm	70 mm	
320 mm	80 mm	
340 mm	90 mm	
360 mm	100 mm	
380 mm	100 mm	
400 mm	100 mm	

Precice Bone Transport device (cont.)

Diameters: Ø10 mm, Ø11.5 mm, Ø13 mm

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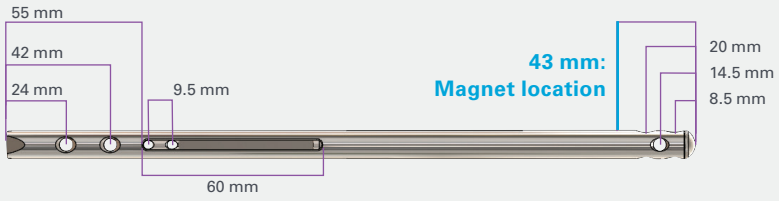
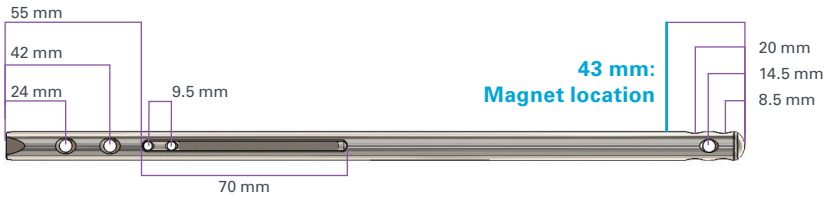
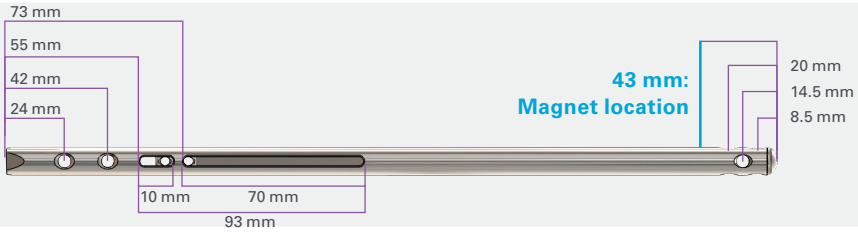
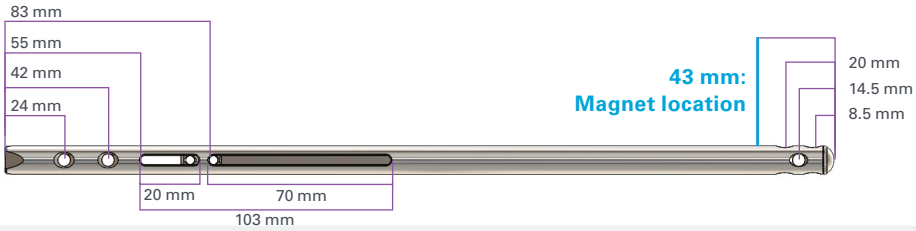
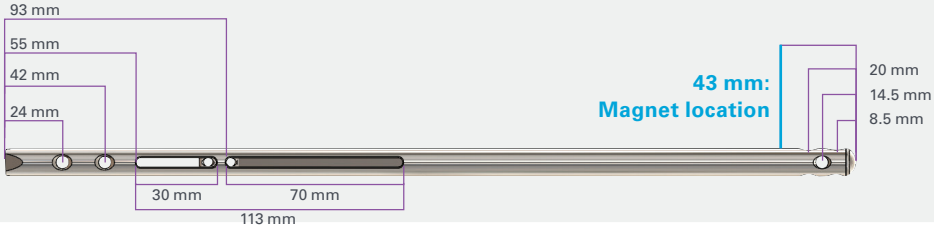
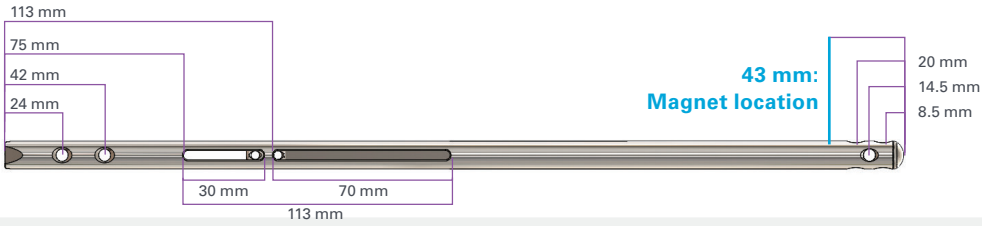
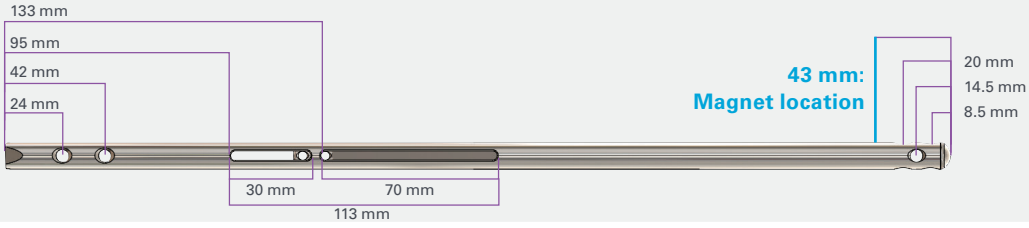
280 mm	60 mm	
300 mm	70 mm	
320 mm	80 mm	
340 mm	90 mm	
360 mm	100 mm	
380 mm	100 mm	
400 mm	100 mm	

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. Alternatively, antegrade femoral nails can be placed with the patient in the lateral position on a radiolucent table. Lateral positioning can be especially useful when a piriformis entry point is selected or in patients with a large body habitus. Regardless of positioning, prep and drape the patient's entire limb from the iliac crest to the foot/ankle using standard sterile technique.

Resection planning

If the defect resection is planned during the same surgical session as implantation of the Precice Bone Transport device, then preoperative planning of the resection is key for determining the most appropriate implant for the reconstruction. The Precice Bone Transport device allows for 60–100 mm of transport, depending on the length of the device chosen. It is often difficult to know the exact extent of resection until the bone is examined intraoperatively. For this reason, it is recommended to have additional options available at the time of surgery.

Using fluoroscopy, mark the pre-determined location where the resection will take place.

To maintain rotational alignment, insert a proximal and distal half pin posterior to the mid-sagittal plane, avoiding insertion sites that may interfere with the Precice Bone Transport device's positioning.

Make an incision and properly debride the resection site. Bone cuts are generally performed with a low energy oscillating saw, such as a Micro-100. The saw blade should be constantly irrigated, preferably with iced saline and intermittent breaks should be taken in order to minimize thermal damage to the bone. Confirm that appropriate instruments have been placed along the sides of the bone being cut in an effort to prevent damage to surrounding soft tissue structures. A chisel or osteotome can be used to test the bone for bleeding and to remove a portion of the cortex when a partial resection is appropriate. It is important that the bone remaining after resection is viable and bleeding. The bone cuts should ideally be made orthogonal to the femoral shaft to achieve optimal bone contact at the time of docking *(Figs. 1, 2)*.

Fig. 1

Fig. 2

Entry site preparation

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 (8–10 cm 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 (IM) 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 Bone Transport device based on preoperative measurements and calculations. Mark the skin at this level as well as the level of the planned femoral osteotomy.

Incision

Piriformis fossa: A skin incision should be made beginning at the level of the greater trochanter. The incision should be extended proximally and slightly posteriorly to align with the gluteus muscle. Expose the piriformis fossa for nail entry.

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

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.

Using A/P and lateral views, percutaneously insert and center a Steinmann pin into the IM 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 Bone Transport implant. Mark the skin at this level and also at the level of the planned corticotomy location.

Incision

Make an incision longitudinally over the Steinmann pin. Either split the patellar tendon longitudinally or go parapatellar depending on the position of the Steinmann pin.

Reaming

Reaming of the canal is performed over the guidewire with flexible reamers and tissue protector beginning with 7 mm and increasing gradually by 0.5 mm increments until the femoral canal is over-reamed by 2 mm greater than the planned diameter of the Precice Bone Transport device. It is important to not use the tourniquet during reaming. The size of the device should be planned for based on the size of the IM canal. Ideally, the implant should be large enough to fill the canal with a 2 mm over-ream. It is recommended to use the smallest diameter implant to achieve this so as to limit excessive reaming of the femoral canal.

Tip: *If the distal segment is past the isthmus, such as in the distal metaphysis, then it is recommended not to over-ream to improve stability of the construct. Reaming and entry site should also be to the center of the distal segment to avoid deformity, especially when presented with a short distal segment.*

Corticotomy site preparation

If preferred, a nail template can be a useful tool to plan and/or confirm the location of your corticotomy. Depending on what style nail is intended to be implanted, either a straight or bent nail template can be used. The nail template can be assembled to the guide arm and placed down the proximal canal. Under fluoroscopy you should be able to visualize the location of each slot to help determine the ideal location for the corticotomy. Once the location is determined it can be marked using a drill bit and the nail template can be removed to complete the corticotomy.

Start by locating your planned corticotomy site and making an incision. Using a drill bit, make one entry hole through the other side of the femoral canal. Confirm that the guidewire has been removed from the canal.

Using a drill bit, make a pass along the posterior cortex. Then, using the same entry hole, make an additional pass along the anterior cortex *(Fig. 3)*. Following these two initial passes, additional holes can be drilled across the canal in the lateral cortex until the corticotomy site is sufficiently weakened.

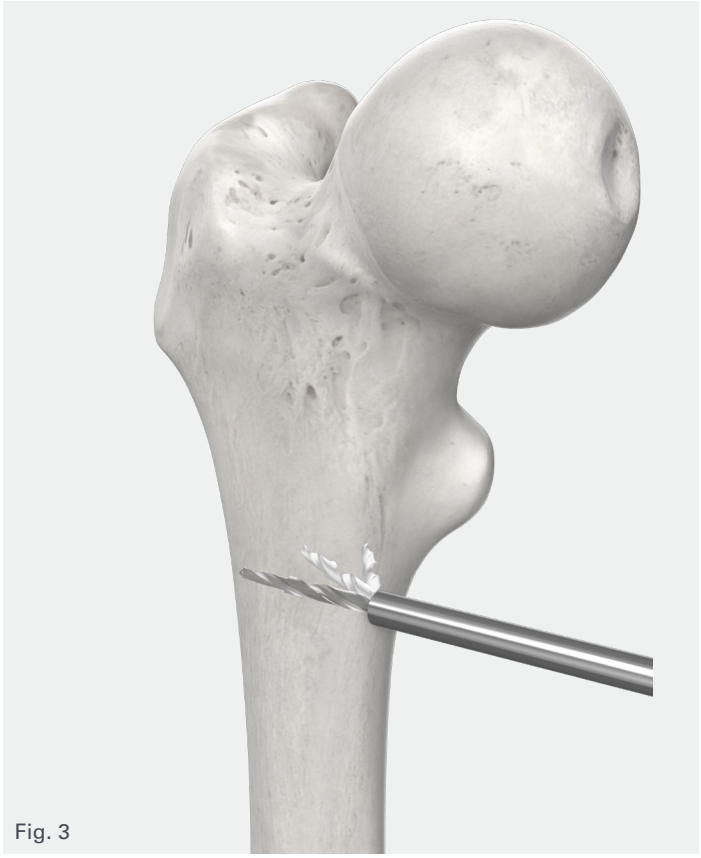


Fig. 3

Altering the Precice Bone Transport device

If the location of the intercalary locking screws of the Precice Bone Transport device needs to be moved for optimal treatment, the fast distractor may be used.

To use the fast distractor first, connect it to an AO quick connect or an OR drill *(Fig. 4)*.

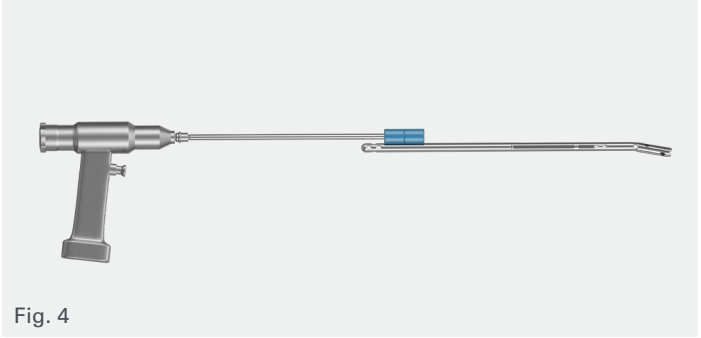


Fig. 4

Hold the fast distractor on the device and slide it until you feel the magnet engage with the Precice Bone Transport device magnet *(Fig. 5)*.

Confirm the drill is in the intended position in order to move the intercalary rod forward or backward for adjustment in the slot.

Cradle the fast distractor and device in your hand.

Start slowly and allow the drill to rotate freely (***do not*** block it by holding too tightly).

Use a ruler to confirm that the intended distraction or compression amount of the distraction rod has been achieved.

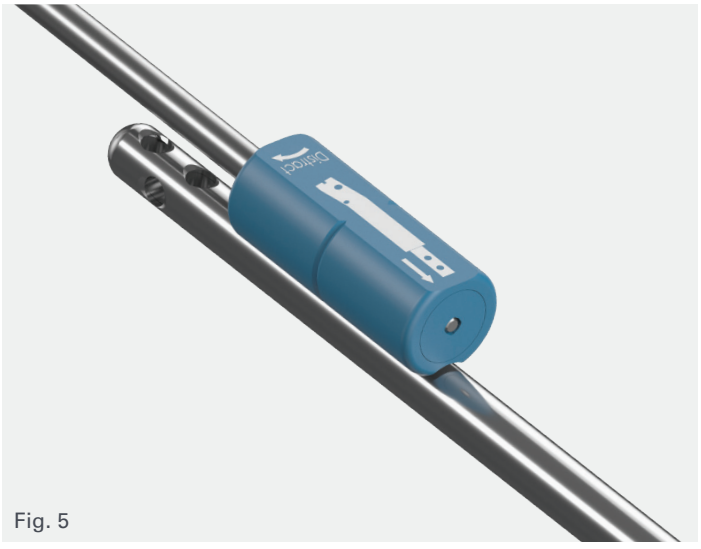


Fig. 5

Guide arm assembly

Align the arrows on the drill guide arm and guide femur targeting arm and assemble by tightening the knob.

Attach the Precice Bone Transport device to the guide arm assembly by inserting the locking rod through the hollow tube of the guide arm and aligning the arrows on the device and guide arm. Engage the threads on the proximal end of the device with the implant locking rod and gently tighten with either the straight or ball hex driver *(Fig. 6)*.

Insert the drill guide into the guide tube and through the targeting guide. Confirm proper alignment of the drill bit through the drill guide and Precice Bone Transport device. Confirm all three proximal screw holes in this manner before insertion.

Once the Precice Bone Transport device has been properly attached to the guide arm assembly, insert the device into the canal. Stop advancing just above the planned corticotomy site.

Fig. 6

Complete corticotomy

It is recommended to use an osteotome to complete the corticotomy *(Figs. 7a, 7b)*. It is imperative to monitor the position of the osteotome as it is advanced into bone to prevent damage to the soft tissues beyond the far cortex. Using an osteotome with a hexagonal handle is very helpful for completing the osteotomy because a wrench can be used to rotate the osteotome within the bone. Alternatively, it is possible to use a temporary half pin in the transport segment in order to rotate the transport segment relative to the proximal segment. To prevent unwanted fracture propagation from the osteotomy site, care should be taken to confirm that the cortex has been adequately weakened by the drill before completing the corticotomy.

Using fluoroscopy, confirm the osteotomy is complete.

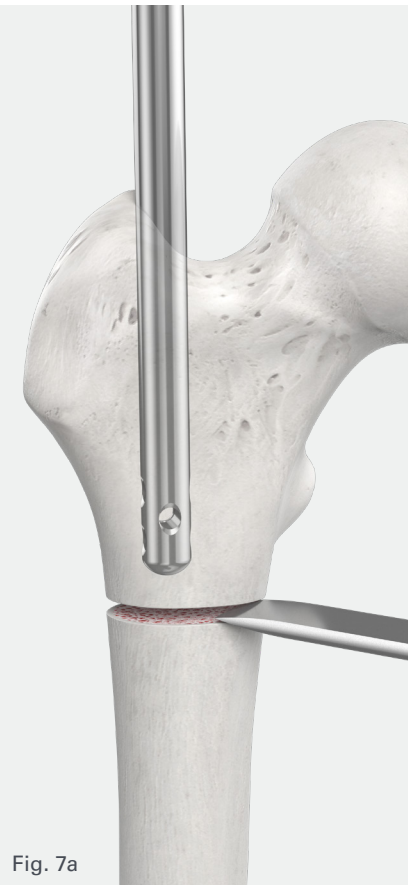


Fig. 7a

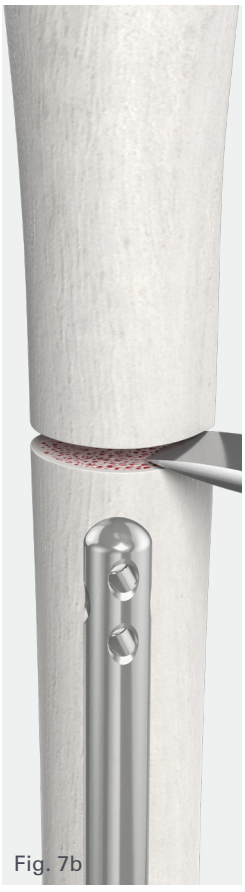


Fig. 7b

Device insertion

Immediately after confirming the corticotomy is complete, gently tap the impactor on the guide arm assembly to advance the Precice Bone Transport device across the gap and into the adjacent bone segment under image intensification *(Figs. 8a, 8b)*. ***Do not*** use excessive force to advance the device, as this can cause damage to the internal mechanism. If necessary, consider reaming the canal by an additional 0.5 to 1 mm. In addition, it is important to confirm that the transport segment does not distract more than a modest amount when the nail is advanced. If this is observed, it may be necessary to use a percutaneously placed half pin or other device to keep the transport segment in place.

Maintain rotational alignment during device insertion and subsequent locking. If not assessed prior to the defect resection, rotational alignment may be confirmed by inserting a proximal and distal half pin prior to completing the corticotomy or by using an external fixator-assisted method.

Fig. 8a

Fig. 8b

Proximal locking screws

Confirm the femur guide arm did not loosen during device insertion prior to proceeding with proximal locking screws. Insert the trocar through the guide tube and place through the 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 near cortex.

Remove the trocar and position the drill guide through the guide tube. Use the 5.0 mm step drill if using the partially threaded screws or the 4.3 mm drill if using the fully threaded screws to penetrate both cortices *(Fig. 9)*. Confirm proper placement under image intensification.

After drilling both cortices, select the appropriate locking screw length by reading the calibration on the drill bit. The screw depth gauge may also be used to read the calibration by sliding it down the guide tube.

Insert the screw capture rod through the cannulated 3.5 mm locking driver. Hand tighten the screw capture rod to the appropriate length locking screw. Attach the 3.5 mm locking driver assembly to the quick connect T-handle or ratcheting straight handle. Remove the drill guide and position the screw into the guide tube to direct it through the Precice Bone Transport device.

Hand tighten the locking screw into both corticles. Remove the quick connect T-handle and untighten the screw capture rod to release the locking screw.

For final tightening, the solid 3.5 mm hex driver can be used to fully seat the screw. Repeat this sequence for the second proximal locking screws *(Figs. 10a, 10b)*.

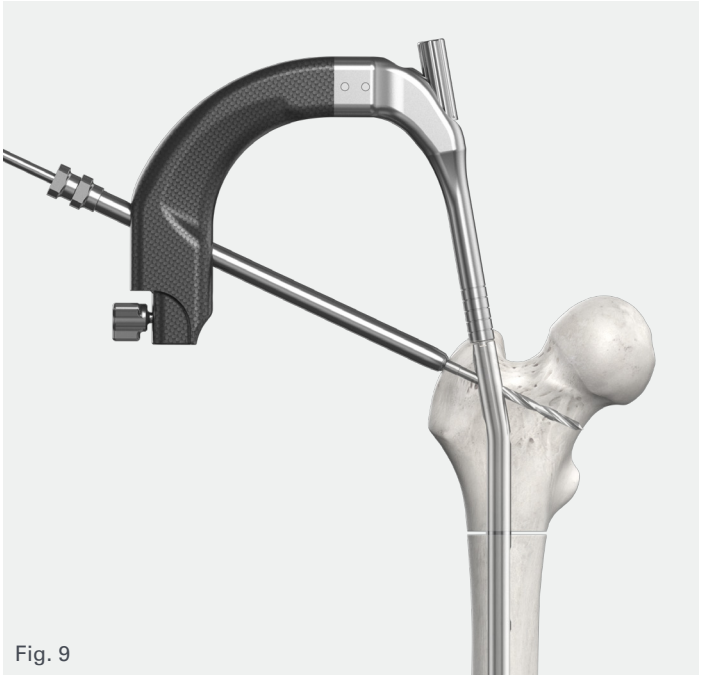


Fig. 9

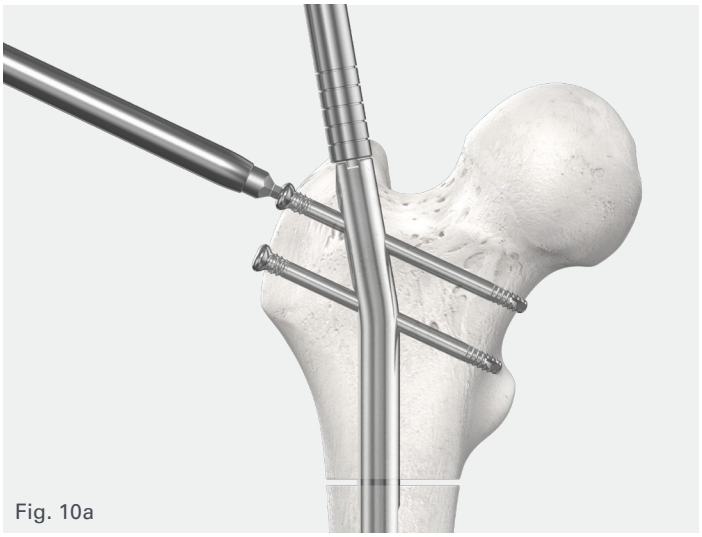


Fig. 10a

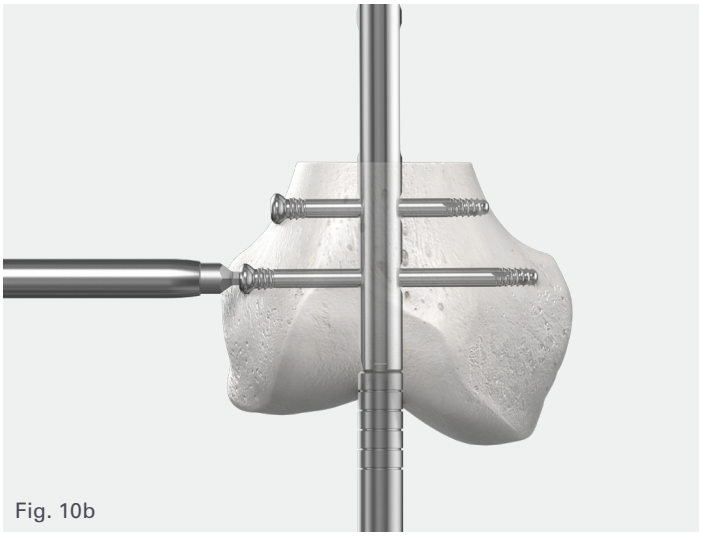


Fig. 10b

Distal locking screws

The free-hand “perfect circles” technique is used to target locking screws in the A/P and M/L distal locking holes of the Precice Bone Transport device.

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 image intensifier. Make a small skin incision here and use the 5.0 mm step drill through the soft tissue sleeve to create the screw’s pilot hole. The soft tissue protector and 5.0 mm step drill to create a pilot hole for the locking screw.

Select the length for the first distal locking screw by reading the measurement off the calibrated drill bit with the soft tissue protector fully seated on the cortex.

The direct AO depth gauge may also be used. Attach the appropriate length locking screw to the screw capture rod and 3.5 mm locking driver. Tighten the locking screw by hand. Repeat steps for additional distal locking screws *(Figs. 11a, 11b)*.

It is recommended to place all three distal screws, especially when presented with a short distal segment in an effort to avoid a second deformity.

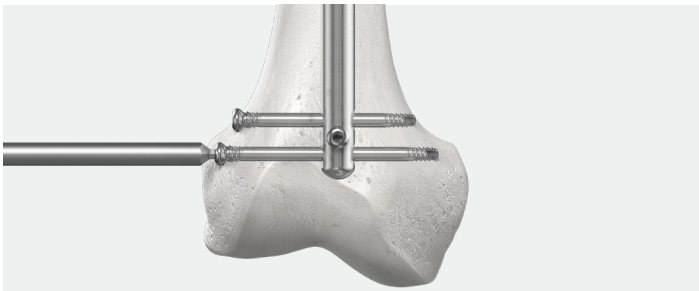


Fig. 11a

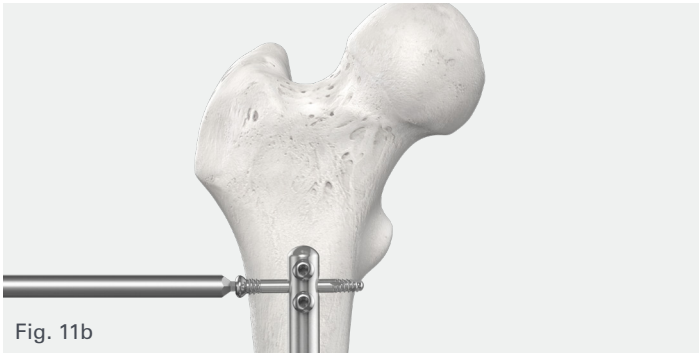


Fig. 11b

Intercalary locking screws

Only one intercalary locking screw is needed for transport. The free-hand “perfect circles” technique should also be used to position locking screws in intercalary locking holes of the Precice Bone Transport device.

If both transport slots are needed, place the intercalary screw in the proximal locking hole so that a screw exchange may be performed.

Align the C-arm in lateral position to view perfect overlapping circles. For the perfect overlapping circle technique, first find the drill hole. Make a small skin incision here. Use the soft tissue protector and 3.5 mm step drill to create a pilot hole for the 3.5 mm locking screw and drill to the far cortex.

Select the length for the locking screw by reading the measurement off the calibrated drill bit with the soft tissue protector fully seated on the cortex.

The depth gauge may also be used. Attach the appropriate length locking screw to the screw capture rod and 3.5 mm locking driver. Tighten the locking screw by hand. Release the screw capture rod and perform final tightening of the screw with the 3.5 mm solid hex driver.

Important: *If the transport distance requires the use of both intercalary slots of the device, then only one of the intercalary screws should be placed during the initial procedure. When the transport has reached the max distance of the first slot, then a second surgery will be needed to remove the first screw and place the second screw in the next slot. Transport can continue after the screws have been exchanged.*

Ancillary fixation

One or more of the following options can be chosen at the surgeon's discretion depending on patient anatomy, location of defect and patient history. It is recommended that the ancillary fixation bridge the defect site.

- Plates
- External fixation
- Cable and pulley systems

Plating with blocking screws

It is recommended that both blocking screws and a supplemental plate be used together. This is the most effective way to prevent both deformities and bridge the bone defect site. Blocking screws can be placed before or after nail insertion to increase stability. The process of distraction osteogenesis generates forces that can cause a shift in alignment despite the presence of multiple locking screws. In an effort to prevent varus deformity, a blocking screw should be inserted anterior to posterior, proximal but near to the osteotomy site and just medial to the Precice Bone Transport device. Similarly, if the distal segment does not have a circumferential endosteal fit, it may require stabilization screws *(Fig. 12)*.

If a distal metaphyseal bone defect is present, a supplemental plate should be placed in order to maintain distal fixation.

External fixation, cable and pulley systems

At the surgeon's discretion, external fixation or a cable and pulley system could be used in conjunction with the Precice Bone Transport device for larger segmental defects.

Fig. 12

End caps (optional)

To accommodate screw placement in variable patient anatomy, end caps can be used to add length to the Precice Bone Transport device. They are available in the 0, 5, 10, 15 and 20 mm lengths *(Figs. 13a, 13b)*.

Fig. 13a

Fig. 13b

Locating the center of the magnet

Evaluate the final construct under image intensification. Locate the center of the magnet within the center of the Precice Bone Transport device by measuring 43 mm from the distal end of the device *(Fig. 14)*.

The Precice Bone Transport device has thick side 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.

To confirm the placement of the external remote controller (ERC) is accurate for the patient's at home transport protocol, use a surgical skin marker to identify the location of the center of the Precice Bone Transport magnet. Provide a surgical marker postoperatively to the patient to refresh the line as it fades. Alternatively, a non-absorbable suture can be placed to mark the location.

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.

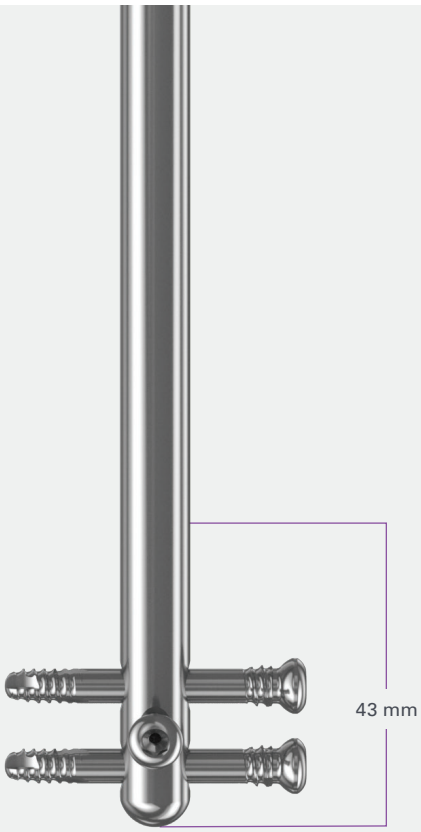


Fig. 14

Programming the ERC

An ERC1, ERC2P, ERC3P or ERC4P may be used with the Precice Bone Transport device.

Depending on which ERC is being used, please refer to the respective operator manual for programming guidelines.

Recommendation: *When using the ERC3P or ERC4P, use of the coupling sensor is optional. If using an ERC1 or ERC2P, this step is unnecessary.*

Max tissue gap

Limb	Device diameter	Max gap (ERC1, ERC2P and ERC3P)	Max gap (ERC4P)
Tibia	10 mm	13 mm	19 mm
	11.5 mm	13 mm	19 mm
	13 mm	13 mm	19 mm
Femur	10 mm	51 mm	64 mm
	11.5 mm	57 mm	69 mm
	13 mm	76 mm	85 mm

Intraoperative magnet check

Depending on whether the construct is an antegrade or retrograde transport, confirm 1–2 mm of intraoperative distraction or compression.

To determine proper function of the Precice Bone Transport device, take a fluoroscopy image before intraoperative distraction or compression and one immediately after the 1–2 mm of distraction or compression. The following are a few indicators of proper function:

1. measure the before and after location of the intercalary slot locking screws *(Fig. 15)*,
2. measure the before and after resection site length *(Fig. 16)*, and
3. measure the before and after corticotomy site length *(Fig. 17)*.

Final closure

Once proper function of the Precice Bone Transport device has been confirmed, the surgical incisions are irrigated and closed in standard fashion. Confirm that the skin mark noting the location of the device's magnet is visible. This will facilitate proper alignment and positioning of the ERC for during the transporting phase.

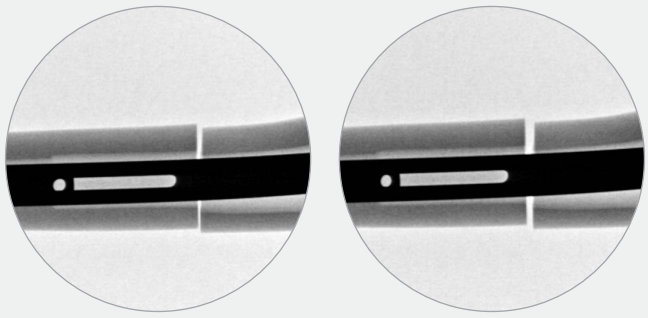


Fig. 15

Fig. 16

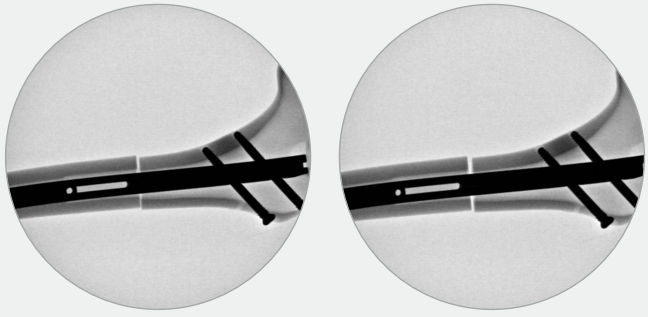


Fig. 17

Postoperative transport protocol

The patient should be brought back to clinic five to seven days postoperative for follow-up fluoroscopy images and training on how and when to use the ERC.

The recommended transport protocol is as such:

- 0.75–1 mm per day (0.25 mm, three to four times per day).

However, transporting prescription may vary due to patient bone quality, age, indication and/or previous treatment history. It is also important to remember that the ERC prescription for the transport protocol can be changed at any time it feels necessary to the surgeon.

Recommendation: *If the transport protocol spans the length of both intercalary slots, it is recommended to setup two ERC prescriptions for the patient. One for the amount of stroke in the first slot and a second for the amount of stroke of the second slot. Continuous running of the ERC without the exchanging of intercalary screws when the transport reaches the bridge portion of the dual slot, may result in difficulty when exchanging the intercalary screw.*

Important: *Patient should be seen every two weeks for follow-up radiographic images to confirm regenerate formation and bony alignment. Transporting protocol with the ERC can also be adjusted at this time if needed.*

Postoperative weight bearing management

Max weight bearing

Device diameter	With partially threaded screws	With fully threaded screws
10 mm	25 lbs/11 kg	25 lbs/11 kg
11.5 mm	190 lbs/87 kg	125 lbs/57 kg
13 mm	250 lbs/114 kg	125 lbs/57 kg

It is recommended that the patient maintain passive and active range of motion postoperatively. Weight bearing protocols should be determined based upon the max loads per the nail diameter implanted. However, the patients bone quality determined intraoperatively should also be a factor when determining their weight bearing protocol at this time.

Absent regenerate ossification

In the event that there is no significant regenerate developed within the first 30 mm of transport, it is highly recommended to slow, stop or reverse the transport.[1]

When reversing the transport, reverse 2–4 mm per day and compress the corticotomy site. Once fully compressed, double the original latency and proceed at half the speed as the initial protocol.

Follow up should be scheduled weekly and it is recommended to get a triple phase bone scan to track the regenerate.

Intercalary screw exchange

Depending on the segmental defect size, exchange of the intercalary locking screw may be required.

Once the first intercalary screw reaches the bridge of the dual slot, transporting must be temporarily suspended for the patient and a second surgery should be performed.

The free-hand "perfect circles" technique should be used to place the second screw in the open intercalary locking hole of the Precice Bone Transport device.

Important: *Do not take out the existing intercalary screw until the second one has been placed.*

Align the C-arm in lateral position to view perfect overlapping circles. For the perfect overlapping circle technique, first find the screw hole.

Make a small skin incision at this location. Use the soft tissue protector to create a pilot hole for the 3.5 mm locking screw.

Select the length for the locking screw by reading the measurement off the calibrated drill bit with the soft tissue protector fully seated on the cortex.

The depth gauge may also be used. Attach the appropriate length locking screw to the screw capture rod and 3.5 mm locking driver. Tighten the locking screw by hand. Release the screw capture rod and perform final tightening of the screw with the 3.5 mm solid hex driver *(Figs. 18a, 18b)*.

Once the second intercalary screw has been placed and the original intercalary screw has been removed, the patient can then resume their prescribed transporting protocol until the intercalary segment is 5 mm from the docking site.

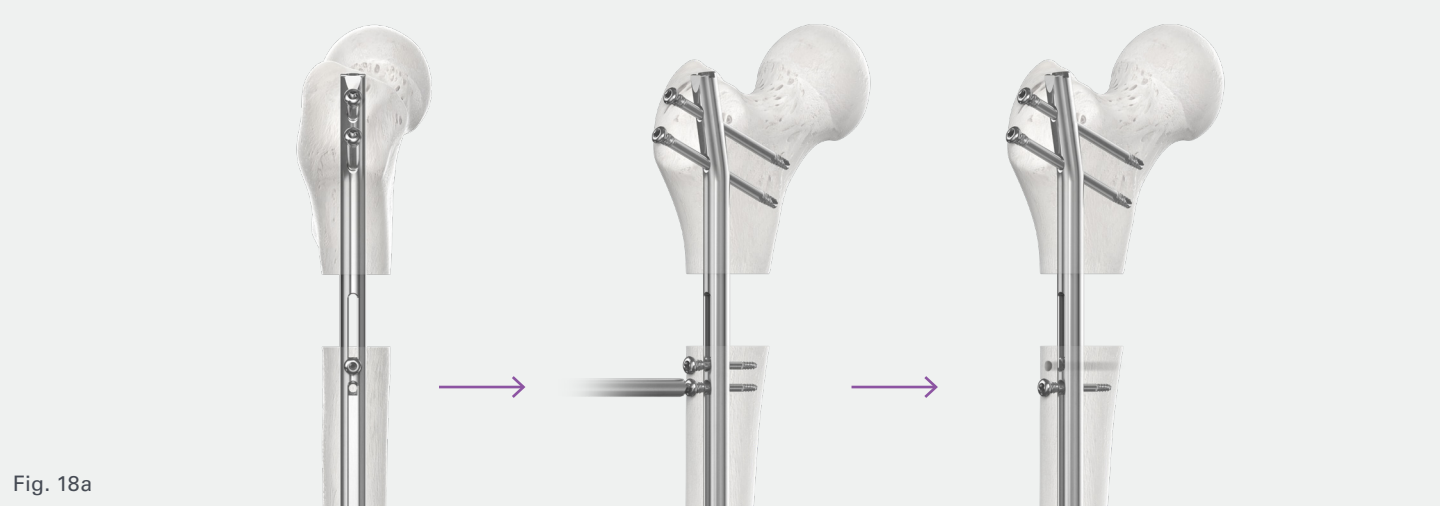


Fig. 18a

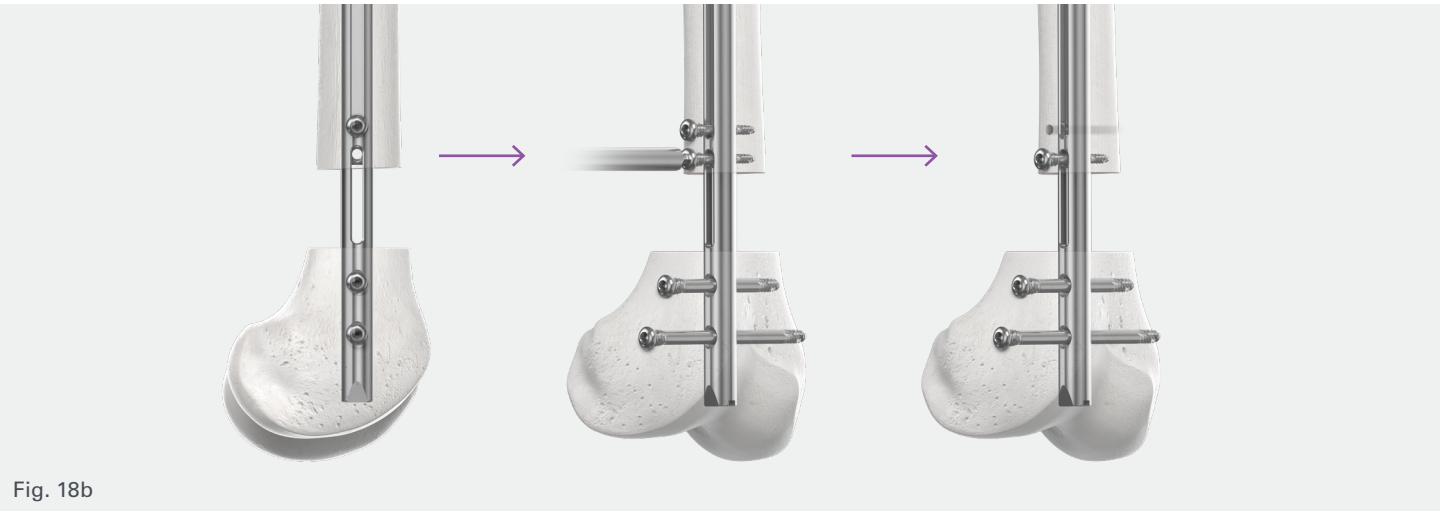


Fig. 18b

Docking site management (optional)

It is recommended to remove any newly formed scar tissue or invaginated skin from the docking site prior to docking. Optimal timing for this is when the two bone ends reach about 5 mm from docking. Use a curette and/or pituitary rongeur to remove scar tissue and create bleeding bone ends. Continue compression postoperatively at the docking site until the two bone ends are compressed together.

If bone grafting is indicated, it is best to bring the bone ends as close to apposition as possible prior to placing graft around the docking site. In this circumstance, it is preferred to bring the bone ends very close to apposition prior to the docking procedure. The Precice Bone Transport device can be backed up 5 mm the morning of the surgery prior to entering the operating room. This allows space to access scar tissue for removal. The bone ends can then be apposed and compressed during surgery and then bone grafting around the sides of the docking site can be performed. Placing bone graft between the ends of the healthy bone ends is discouraged unless there are gaps at the docking site after the ends are compressed together. Instead, the outside of the bone ends can be prepared with mild decortication to accept bone graft around the outside. This method allows the newly formed regenerate to accordion while space is provided for debridement and then apposition of the bone acutely without overstressing the forming regenerate. At this time the patients' weight bearing could be increased to help achieve full union.

Docking site compression and healing

Following the removal of scar tissue at the docking site, the patient should continue compression with the ERC until cortical contact is achieved.

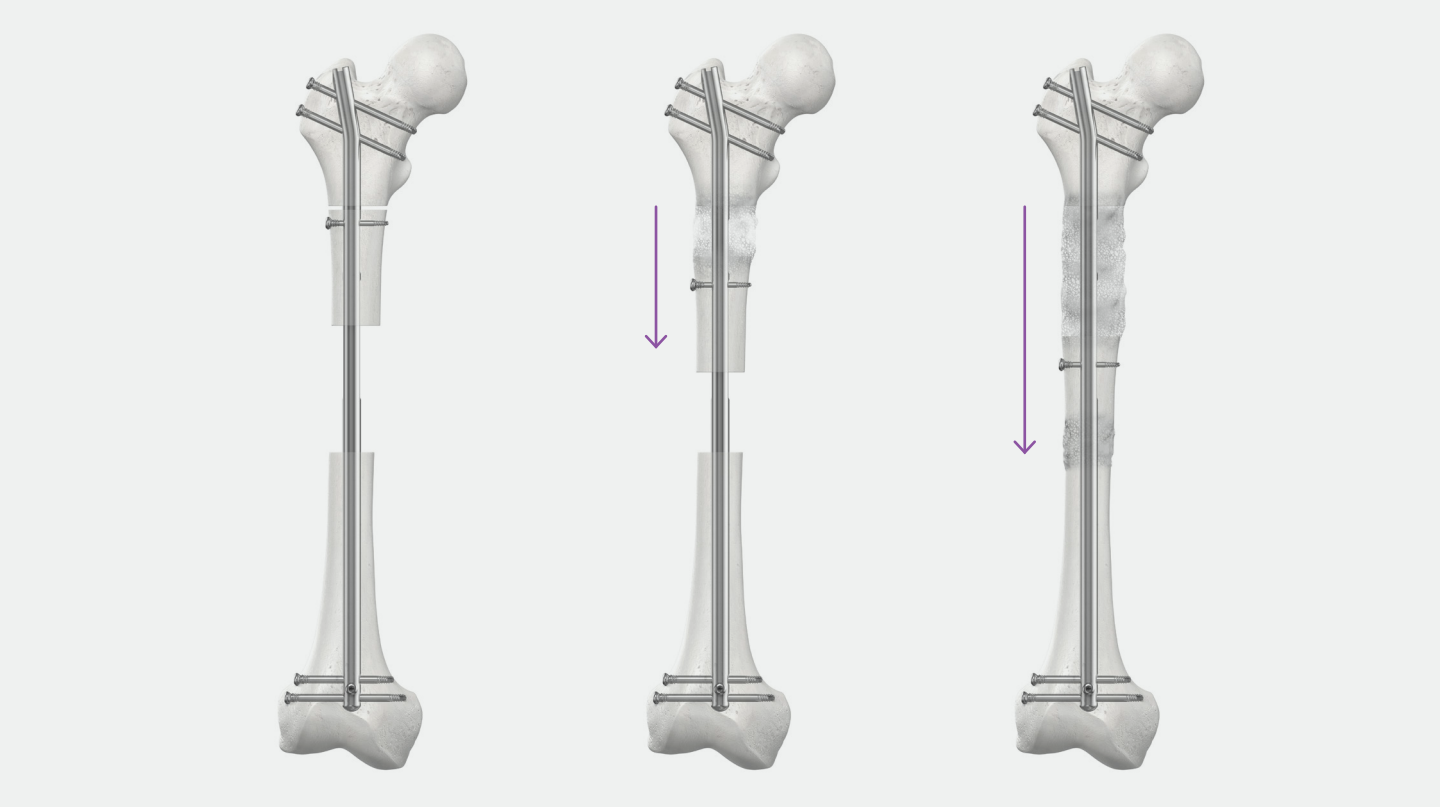
Although compression protocols vary depending on the patient, the recommended docking site compression protocol is as follows:

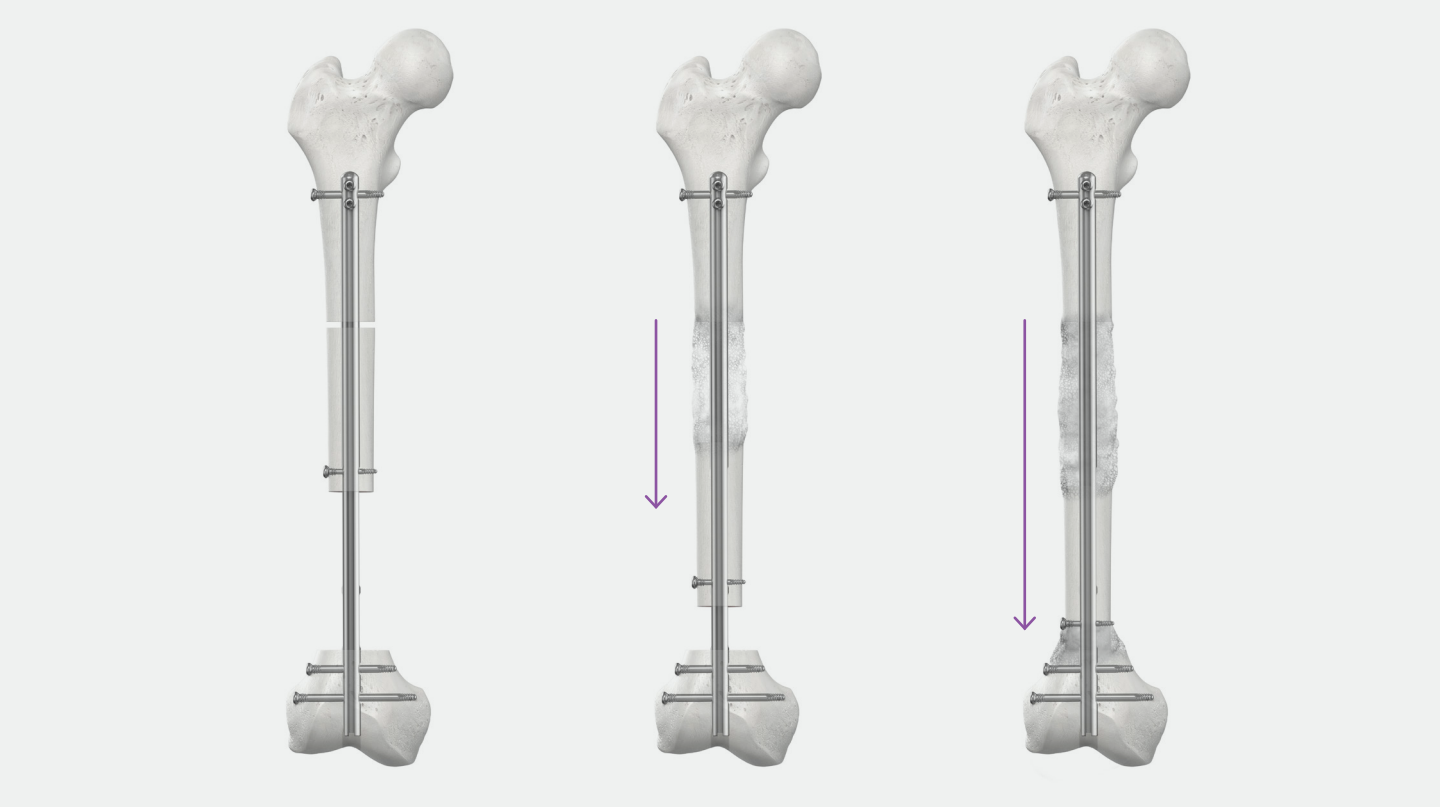
- apply continuous compression until cortical contact is achieved and confirmed radiographically at the docking site, and
- apply 1 mm of compression as needed until bone ends are touching. This can be repeated multiple times over days or weeks to achieve constant bone on bone contact.

Note: *It is important to optimize bone contact and compression to limit motion at the docking site.*

The docking site should be continually monitored during regular follow-ups until union is achieved. Once healing has begun at the docking site and regenerate at the corticotomy site is sufficient, the Precice Bone Transport device can either remain in or be exchanged for a traditional trauma device until full consolidation.

Healing





Device removal

Removal of the Precice Bone Transport device is recommended at 12 months. Each surgeon must determine the appropriate time for removal of the Precice Bone Transport device based upon their clinical evaluation of the patient.

Expose the proximal end of the device by careful removal of overlying bone and soft tissue. Under bi-planar fluoroscopy, drive a K-wire into the proximal end of the device and over-ream with a starting reamer to gain exposure.

Using the image intensifier, locate the distal screws. Make a small incision as required and remove one of the distal locking screws using the 3.5 mm solid hex driver and quick connect T-handle. After the first screw is removed use the appropriate sized Precice retention plug and driver and insert into the vacant distal screw hole *(Fig. 25a–25d)*. Confirm full seating of the retention plug instrument under fluoroscopy *(Fig. 26)*. Once appropriate placement and complete seating is confirmed, the remaining distal screws can be removed.

Again, using the image intensifier, locate the proximal and intercalary locking screws. Make small incisions as required and remove the locking screws using the 3.5 mm solid hex driver and quick connect T-handle. Remove all but one of the locking screws prior to tightly threading the tapered extractor to the Precice Bone Transport device.

If present, the end cap must be removed prior to threading the tapered extractor into the Precice Bone Transport device.

Attach the removal rod to the tapered extractor, remove the final locking screw and proceed with device removal. The slap hammer may be used to assist in device removal as needed.

Perform skin closure with routine techniques.

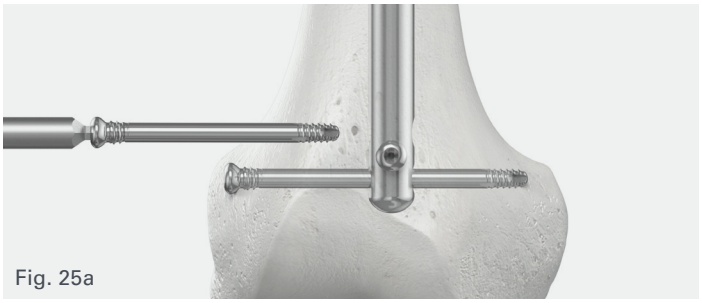


Fig. 25a

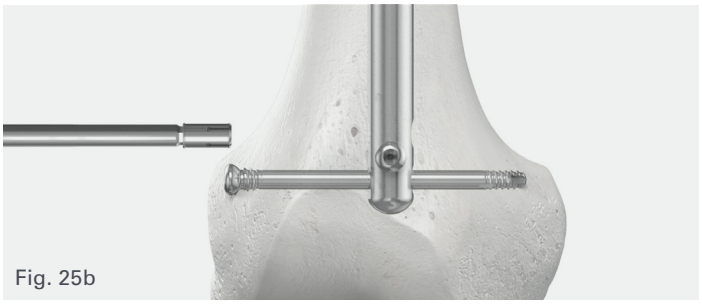


Fig. 25b

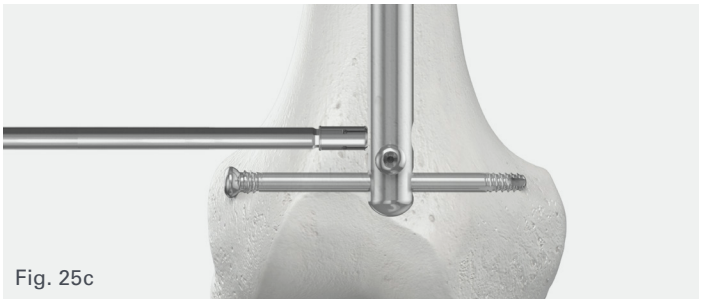


Fig. 25c

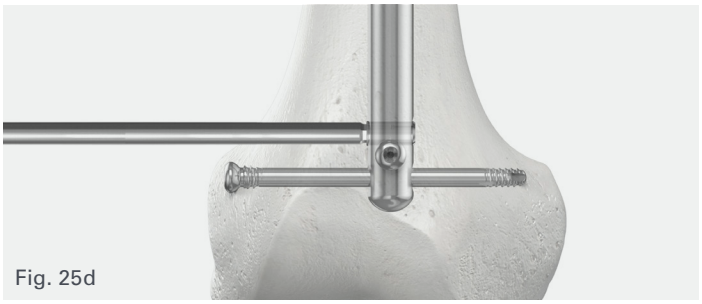


Fig. 25d

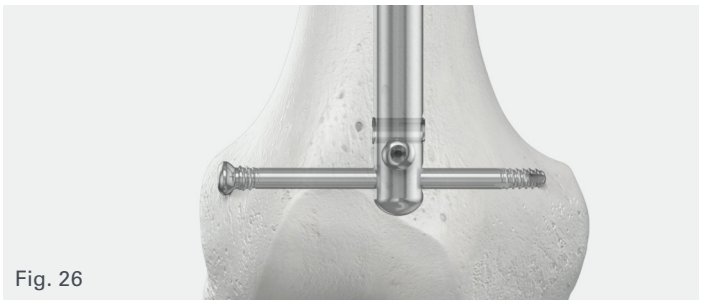
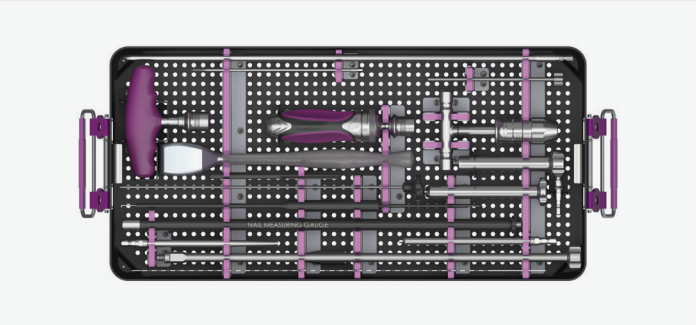


Fig. 26

Trays

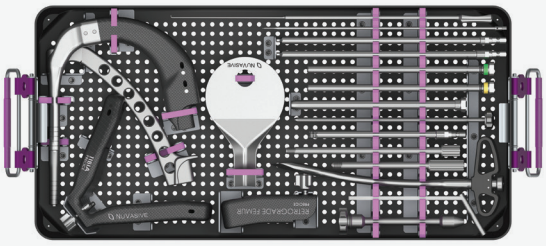
Approach instrumentation (NGI2-000)

Description	Model no.
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
Guidewire chuck	GWC1-000
Nail measuring gauge	NMG1-000
Guidewire pusher	GWP2-000
3.5 mm screwdriver, short solid	SDS2-001
3.5 mm screwdriver, short cannulated	SDS2-000
Screw capture rod, short	CRS1-000
Locking key	LKL2-000
NuVasive 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



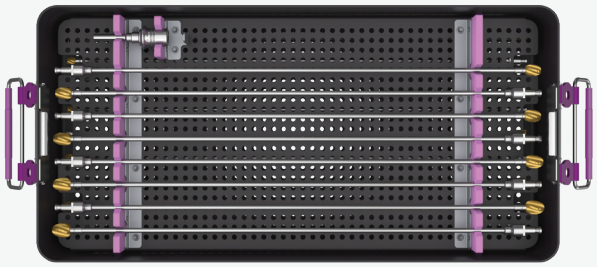
Aiming instrumentation (NGI3-000)

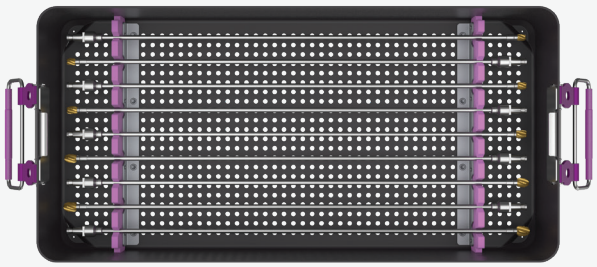
Description	Model no.
Guidewire sleeve	SET2-0001
Soft tissue protector, paddle	STP1-000
Cannulated awl	AWL2-010
Targeting handle, Precice	PGH2-000
Locking bolt	LBT3-000
Locking bolt, suprapatellar	LBT3-001
6 mm ball end hex driver	LBD2-001
6 mm straight hex driver	LBD3-001
Impactor	IMP3-000
Guide tube	GTT2-000
Drill sleeve	DST2-000
Drill sleeve, 4.3 mm	DST3-000
Targeting handle, suprapatellar	PGH2-001
Trocar	TCT2-000
Screw depth gauge dipstick	DGT2-001
3.5 mm screwdriver, long cannulated	SDL2-000
3.5 mm 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



Flexible reamer set (SRT2-000)

Description	Model no.
Flexible reamer, 7 mm	T18151
Flexible reamer, 7.5 mm	T18152
Flexible reamer, 8 mm	T18153
Flexible reamer, 8.5 mm	T18154
Flexible reamer, 9 mm	T18155
Flexible reamer, 9.5 mm	T12065
Flexible reamer, 10 mm	T12066
Flexible reamer, 10.5 mm	T12067
Flexible reamer, 11 mm	T12068
Flexible reamer, 11.5 mm	T12069
Flexible reamer, 12 mm	T12070
Flexible reamer, 12.5 mm	T12071
Flexible reamer, 13 mm	T12072
Flexible reamer, 13.5 mm	T18156
Flexible reamer, 14 mm	T18157
Flexible reamer, 14.5 mm	T18158
Flexible reamer, 15 mm	T18159
Hudson quick connect	LQC2-000





Catalog

	Length	Stroke	Slot configuration	10 mm	11.5 mm	13 mm
Antegrade tibia 10° bend **Model SJ**	280 mm	60 mm	Single slot: 60 mm	BT10-60SJ280-6	BT115-60SJ280-6	-
	300 mm	70 mm	Single slot: 70 mm	BT10-70SJ300-7	BT115-70SJ300-7	-
	320 mm	80 mm	Dual slot: 10 mm, 70 mm	BT10-80SJ320-7	BT115-80SJ320-7	-
	340 mm	90 mm	Dual slot: 20 mm, 70 mm	BT10-90SJ340-7	BT115-90SJ340-7	-
	360 mm	100 mm	Dual slot: 30 mm, 70 mm	BT10-10SJ360-7	BT115-10SJ360-7	-
	380 mm	100 mm	Dual slot: 30 mm, 70 mm	BT10-10SJ380-7	BT115-10SJ380-7	-
	400 mm	100 mm	Dual slot: 30 mm, 70 mm	BT10-10SJ400-7	BT115-10SJ400-7	-
Antegrade femur piriformis straight **Model B**	280 mm	60 mm	Single slot: 60 mm	BT10-60B280-6	BT115-60B280-6	BT13-60B280-6
	300 mm	70 mm	Single slot: 70 mm	BT10-70B300-7	BT115-70B300-7	BT13-70B300-7
	320 mm	80 mm	Dual slot: 10 mm, 70 mm	BT10-80B320-7	BT115-80B320-7	BT13-80B320-7
	340 mm	90 mm	Dual slot: 20 mm, 70 mm	BT10-90B340-7	BT115-90B340-7	BT13-90B340-7
	360 mm	100 mm	Dual slot: 30 mm, 70 mm	BT10-10B360-7	BT115-10B360-7	BT13-10B360-7
	380 mm	100 mm	Dual slot: 30 mm, 70 mm	BT10-10B380-7	BT115-10B380-7	BT13-10B380-7
	400 mm	100 mm	Dual slot: 30 mm, 70 mm	BT10-10B400-7	BT115-10B400-7	BT13-10B400-7
Antegrade femur trochanter 10° bend **Model D**	280 mm	60 mm	Single slot: 60 mm	BT10-60D280-6	BT115-60D280-6	BT13-60D280-6
	300 mm	70 mm	Single slot: 70 mm	BT10-70D300-7	BT115-70D300-7	BT13-70D300-7
	320 mm	80 mm	Dual slot: 10 mm, 70 mm	BT10-80D320-7	BT115-80D320-7	BT13-80D320-7
	340 mm	90 mm	Dual slot: 20 mm, 70 mm	BT10-90D340-7	BT115-90D340-7	BT13-90D340-7
	360 mm	100 mm	Dual slot: 30 mm, 70 mm	BT10-10D360-7	BT115-10D360-7	BT13-10D360-7
	380 mm	100 mm	Dual slot: 30 mm, 70 mm	BT10-10D380-7	BT115-10D380-7	BT13-10D380-7
	400 mm	100 mm	Dual slot: 30 mm, 70 mm	BT10-10D400-7	BT115-10D400-7	BT13-10D400-7
Retrograde femur straight **Model X**	280 mm	60 mm	Single slot: 60 mm	BT10-60X280-6	BT115-60X280-6	BT13-60X280-6
	300 mm	70 mm	Single slot: 70 mm	BT10-70X300-7	BT115-70X300-7	BT13-70X300-7
	320 mm	80 mm	Dual slot: 10 mm, 70 mm	BT10-80X320-7	BT115-80X320-7	BT13-80X320-7
	340 mm	90 mm	Dual slot: 20 mm, 70 mm	BT10-90X340-7	BT115-90X340-7	BT13-90X340-7
	360 mm	100 mm	Dual slot: 30 mm, 70 mm	BT10-10X360-7	BT115-10X360-7	BT13-10X360-7
	380 mm	100 mm	Dual slot: 30 mm, 70 mm	BT10-10X380-7	BT115-10X380-7	BT13-10X380-7
	400 mm	100 mm	Dual slot: 30 mm, 70 mm	BT10-10X400-7	BT115-10X400-7	BT13-10X400-7

Partially threaded, stainless steel screws (not sterile packed)

3.5 mm	
Length	**Model no.**
20 mm	STP3.5-200
22.5 mm	STP3.5-225
25 mm	STP3.5-250
27.5 mm	STP3.5-275
30 mm	STP3.5-300
32.5 mm	STP3.5-325
35 mm	STP3.5-350
37.5 mm	STP3.5-375
40 mm	STP3.5-400
42.5 mm	STP3.5-425
45 mm	STP3.5-450
47.5 mm	STP3.5-475
50 mm	STP3.5-500
55 mm	STP3.5-550
60 mm	STP3.5-600

5.0 mm	
Length	**Model no.**
20 mm	STP5-200
22.5 mm	STP5-225
25 mm	STP5-250
27.5 mm	STP5-275
30 mm	STP5-300
32.5 mm	STP5-325
35 mm	STP5-350
37.5 mm	STP5-375
40 mm	STP5-400
42.5 mm	STP5-425
45 mm	STP5-450
47.5 mm	STP5-475
50 mm	STP5-500
55 mm	STP5-550
60 mm	STP5-600
65 mm	STP5-650
70 mm	STP5-700
75 mm	STP5-750
80 mm	STP5-800

Fully threaded, stainless steel screws (sterile packed)

5.0 mm	
Length	**Model no.**
20 mm	SFT5-200-S
22.5 mm	SFT5-225-S
25 mm	SFT5-250-S
27.5 mm	SFT5-275-S
30 mm	SFT5-300-S
32.5 mm	SFT5-325-S
35 mm	SFT5-350-S
37.5 mm	SFT5-375-S
40 mm	SFT5-400-S
42.5 mm	SFT5-425-S
45 mm	SFT5-450-S
47.5 mm	SFT5-475-S
50 mm	SFT5-500-S
55 mm	SFT5-550-S
60 mm	SFT5-600-S
65 mm	SFT5-650-S
70 mm	SFT5-700-S
75 mm	SFT5-750-S
80 mm	SFT5-800-S
85 mm	SFT5-850-S
90 mm	SFT5-900-S
95 mm	SFT5-950-S
100 mm	SFT5-100-S

Drills

	Part description	Model no.
Use with partially threaded screws	5.0 mm step drill bit, long	SDLO-5.0
	5.0 mm step drill bit, short	SDST-5.0
	3.5 mm step drill bit, short	SDST-3.5
Use with fully threaded screws	4.3 x 152 mm AO drill bit	DBS2-4.3
	4.3 x 355 mm AO drill bit	DBT2-4.3

Additional accessories

Fast distractor

Part description	Model no.
Precice fast distractor	PFD1-000

Nail templates

Part description	Model no.
Bone transport straight nail template	BTS1-000
Bone transport bent nail template	BTB1-000

Stainless steel end caps

Length	Model no.
10/11.5 x 0 mm	SST-010-000
10/11.5 x 5 mm	SST-010-005
10/11.5 x 10 mm	SST-010-010
10/11.5 x 15 mm	SST-010-015
10/11.5 x 20 mm	SST-010-020
13 x 0 mm	SST-013-000
13 x 5 mm	SST-013-005
13 x 10 mm	SST-013-010
13 x 15 mm	SST-013-015
13 x 20 mm	SST-013-020

Removal instruments

Part description	Model no.
Precice retention plug and driver, 10 mm	BT10-RMV01
Precice retention plug and driver, 11.5 mm	BT115-RMV01
Precice retention plug and driver, 13 mm	BT13-RMV01

Important safety information

The **Precice Bone Transport System** is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The Precice Bone Transport System is a sterile, single-use device that is surgically implanted using the instruments and locking screws for osteoplasty lengthening and bone transportation utilizing distraction osteogenesis and compression. The ERC is used daily after implantation to non-invasively adjust the position of the distraction rod.

Intended Use:

The Precice Bone Transport 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 Bone Transport nail.
- Patients in which the Precice Bone Transport nail would cross joint spaces or open epiphyseal growth plates.
- Patients with 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 with maximum bone defect of more than 100 mm.
- Patients with excessive skin damage and inadequate soft tissue covering of the fracture sites.

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® Bone Transport Model	Nail Diameter (mm)	Maximum Distance of Treated Limb Surface to IM Canal (mm)	Max. Patient Weight Bearing Use with partially threaded screws	Max. Patient Weight Bearing Use with fully threaded screws
Tibia	C, SJ	10.0	13	25lbs/11kg	25lbs/11kg
		11.5	13	190lbs/86kg	125lbs/57kg
		13.0	13	250lbs/114kg	125lbs/57kg
Femur	A, B, BT, D, DT, E, V, X, SE, SB, SD, SA	10.0	51	25lbs/11kgs	25lbs/11kg
		11.5	57.2	190lbs/86kg	125lbs/57kg
		13.0	76	250lbs/114kg	125lbs/57kg

Warnings:

- The Precice Bone Transport System cannot withstand the stresses of full weight bearing. The patient should progressively weight bear and use assistive devices as directed by the physician.
- Patients should utilize external support and/or restrict activities as directed by the physician until consolidation occurs.
- Patients with an open fracture may also have soft tissue damage as a result of severe trauma. It is important that soft tissue damage is addressed prior to procedure to minimize the risk of infection.
- The surgeon should closely monitor lengthening progress particularly for longer bone segments or mobilization lengths to prevent incomplete transport.
- The surgeons should account for potential difficulty in removal of the nail due to ingrowth into the slot feature of device.
- 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 Bone Transport System is not recommended in patients with pacemakers.
- The Precice Bone Transport System may not be appropriate for patients with poly-trauma.
- Use of the Precice Bone Transport System in patients with an active infection of the treated bone is not recommended.
- Overream the medullary canal by 2 mm to allow the transported segment to move freely over the nail.
- Patients treated with Precice Bone Transport may need secondary surgery to ensure union at the distal docking site.
- 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 Bone Transport 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.
- The Precice Screws may be provided sterile or non-sterile, take careful note to read packaging if screw is provided sterile or non-sterile.
- Before removing the implants from the package, make sure that the protective packaging is unopened and undamaged. If the packaging is damaged, the implants have to be considered as NON-STERILE and may not be used.
- Note the STERILE expiry date. Implants with elapsed STERILE expiry dates have to be considered as non-sterile
- Patients with implanted Precice Bone Transport nail should not enter an MRI unit.
- The Precice Bone Transport System is unsafe in Magnetic Resonance Imaging environments.
- 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:

- It is recommended that ancillary fixation (e.g. plates, external fixation, cable and pulley system etc.) bridges the defect site.
- Do not use this device without proper training in both device implantation and adjustment. Refer to External Remote Controller (ERC, ERC 2P, ERC 3P or ERC4P) Operator's Manual (OM0005, OM0009, OM0016 or OM0017) for operation of the External Remote Controller.
- Prior to bone consolidation, the patient should not participate in contact sports or other high risk activities that will cause more than 20% of the body weight to be loaded on the treated limb. These activities may resume upon sufficient bone consolidation, but only as directed by the physician.
- Examine all Precice® Bone Transport 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 Bone Transport System is for prescription use only by the order of a physician.
- Device is recommended to 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 Bone Transport 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.
- Do not bend the Precice Bone Transport nail or otherwise modify or damage the implant.
- Follow the ERC Operators Manual (OM0005, OM0009, OM0016 or OM0017) to assure proper alignment between the ERC and magnet of the Precice Bone Transport nail.

Please refer to the Precice Bone Transport system IFU found at **nuvasive.com/eifu** for additional important labeling information.

Notes

Notes

Reference

1. Green, S.A., Dahl, M. Intramedullary Limb Lengthening Principles and Practices. Cham, Switzerland: *Springer*: 2018

NuVasive Specialized Orthopedics, Inc.
101 Enterprise, Suite 100, Aliso Viejo, CA 92656 USA
+1 949.837.3600

EC REP **NuVasive Netherlands B.V.**
Jachthavenweg 109A, 1081 KM Amsterdam, The Netherlands
+31 20 72 33 000

CE 0297

nuvasive.com

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Specialized Orthopedics