OPERATIVE TECHNIQUE

Fitbone™

Intramedullary Lengthening System

Fitbone Antegrade Femur Trochanteric Application

ORTHOFIX®
ORTHOPEDICS

Fitbone™

Intramedullary Lengthening System

Table of Contents

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please kindly refer to the product IFU PQFBO and to the reusable medical devices IFU PQRMD that contain instructions for use of the product.

PRE-OPERATIVE PREPARATION

Pre-operative planning

In order to achieve the best clinical result possible, the following examinations are advised:

- History
- Clinical examination including range of motion, circulation and neurological status of both extremities
- Diagnostic radiology
- Tests for Calcium and Vitamin D deficiency
- If necessary, CT with torsion measurement

Limb length discrepancy (LLD) and angular and torsional deformities are determined from physical examination and long-standing radiographs (LSR) (see below).
Pre-planning must be carried out in order to adequately prepare for Fitbone surgery. Planning can be performed with or without using the Reverse Planning Method (RPM) as described by Baumgart*.
When using an intramedullary lengthening nail in the femur, lengthening will occur close to the anatomical axis. This will result in a mechanical axis deviation and the creation of a valgus deformity. If this is not taken into consideration during pre-planning, the overall limb alignment will be affected.
The RPM will help in planning the acute deformity correction and lengthening pre-operatively.
The osteotomy site is determined pre-operatively from the X-rays according to the required deformity correction (if applicable) and the curvature in the lateral plane.
To ensure biomechanical stability, the Fitbone nail must be sufficiently implanted within the proximal and distal bone segments.

This can be determined by applying the following:

- Osteotomy low point = 40mm from distal tip of nail + amount of lengthening required in mm
- Osteotomy high point = Below the lesser trochanter

X-ray instruction: How to take long-standing radiographs

Long-standing radiographs **(LSR, Figure 2)** are routinely used for analyzing deformities and planning corrections of axial and longitudinal malalignment of the lower limbs in the frontal plane. In order to obtain reproducible radiographs, the following criteria should be taken into consideration:

- Film-size should be 1200 x 400mm
- Distance from focus to film should be 3 meters
- The x-rays should be calibrated (e.g. calibration ball at bone level)
- The central beam should be focused on the knee joint gap
- The patella should face forward if not dislocated or subluxated due to an underlying condition
- Limb length discrepancy should be compensated (i.e. blocks)
- The weight load should be equal on both sides

In addition to the LSR, a true lateral view of the affected bone is necessary. Alternatively, a radiograph scanner can be used if the patient can remain motionless during the scan.

** Baumgart R: The Reverse Planning Method for Lengthening of the Lower Limb Using a Straight Intramedullary Nail with or without Deformity Correction- A New Method, Oper Orthop Traumatol 2009, No. 2: 221-233*

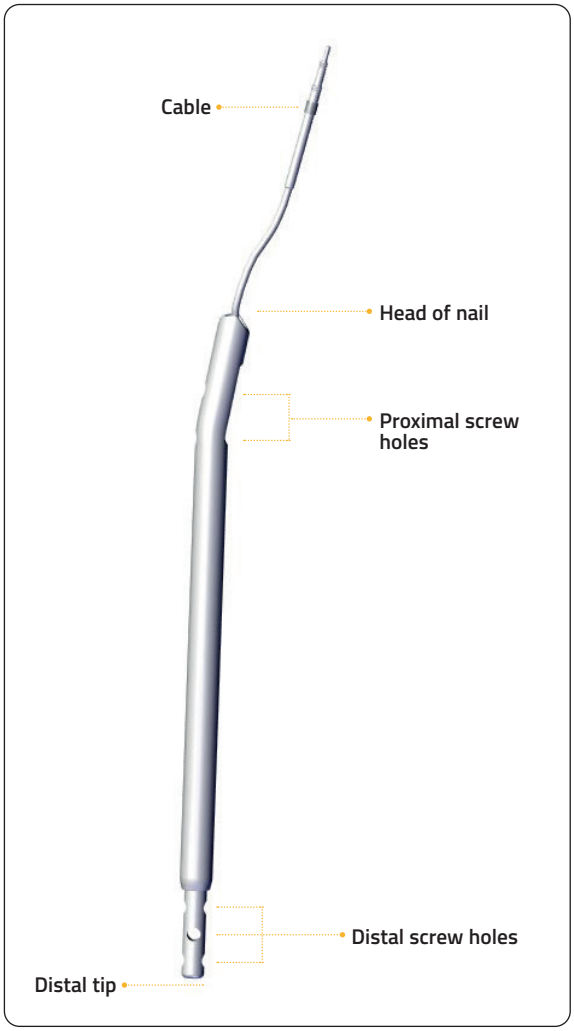


Fig. 1 Fitbone Trochanteric Nail

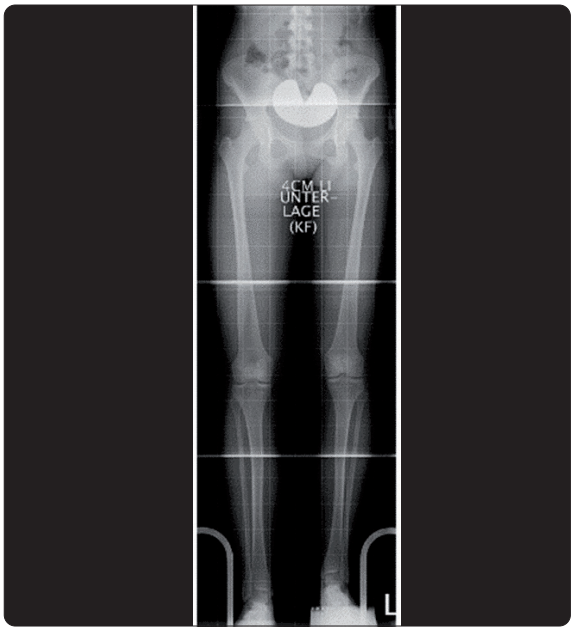
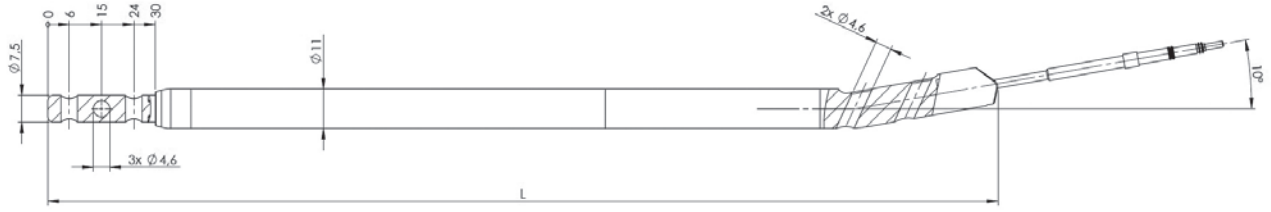


Fig. 2 Long-standing X-ray

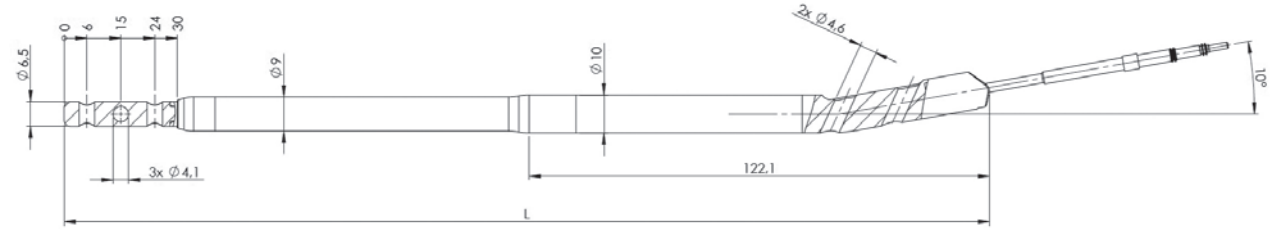
FITBONE TROCHANTERIC NAIL, SCREW AND REVISION SCREW TYPES

11 Ø – NAIL



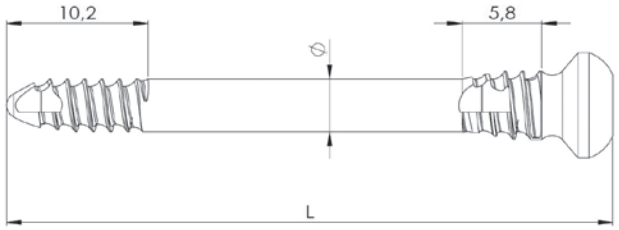
Ø	L	STROKE
11	225mm	40mm
11	245mm	60mm
11	From 265 to 365 (20mm increment)	80mm

9-10 Ø – NAIL



Ø	L	STROKE
9-10	225mm	40mm
9-10	245mm	60mm
9-10	From 265 to 365 (20mm increment)	80mm

Standard screws



Ø	L
4.0mm	From 20 to 80 (2.5mm increment)
4.5mm	From 20 to 80 (2.5mm increment)

Revision screws

Ø	L
4.0mm	From 20 to 80 (2.5mm increment)
4.5mm	From 20 to 80 (2.5mm increment)

Grid plate

Part #	Description
60001464	FITBONE GRID PLATE

The GRID plate can be used to assist Fitbone surgeries, to ensure correct limb alignment and deformity correction. The GRID plate consists of a plastic body with transverse and longitudinal nonradiolucent metal wires running through the plate. The wires can easily be seen under x-rays and are extremely beneficial in helping to achieve correct limb alignment.

The GRID plate is placed on the operating table underneath the cushion. Never position the GRID plate directly under the patient. Placing the GRID plate directly under the patient can lead to damage and injury.

The GRID plate must rest flat over the surface of the operating table.

Technical features of the grid
Material: Pertinax RI4 0000 (Hartpapier) PF CP 201 HP 2061

Dimensions: 37.6mm x 128.2mm.

Space between longitudinal and transverse wires: 50mmSpace between the double wires: 1mm (shown in bold in **Fig. 3**)

The surgery takes place with the patient supine and the leg in full extension. **(Fig. 4)**

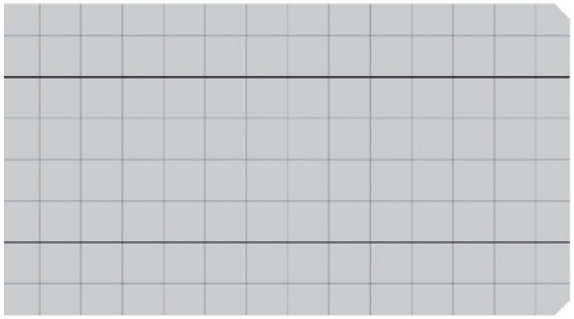


Fig. 3 GRID Plate

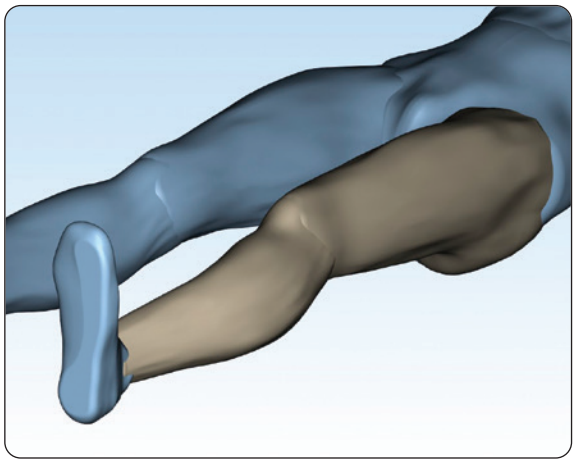


Fig. 4 Leg in full extension

INSERTION

Patient positioning

If using the GRID plate, place directly on the radiolucent table, secure centrally and cover completely with the base or padding. Place the patient in supine position and cover the entirety of the opposite side, leaving the leg to be operated uncovered and free to move. The position of the untreated leg can vary depending on surgeon's preference. Ensure the C-arm can reach the hip joint without coming into contact with the padding of the table.

Prior to any measurement using the grid plate, make sure that the C-arm is placed vertically above the double line: align the path of the beam perpendicular to the surface of the plate. The double line and the joint being analyzed should be located exactly in the center of the screen to minimize parallax errors. To measure the alignment (not under load) position the patient´s hip joint on the double line, with the patella facing forwards **(Fig. 5)**. Do not change the position of the hip joint and rotation of the extremity during the measurement. Move the C-arm longitudinal towards the ankle joint maintaining the double line in the center of the screen. Place the center of the ankle joint on the double line, maintaining the patella facing forward. Maintain leg position and move the C-arm longitudinally along the double line towards the knee joint.

Measure the distance between the center of the knee joint and the double line **(Fig. 6)**. Compare the alignment to the pre-operative planning. If the alignment matches, then proceed with surgery.

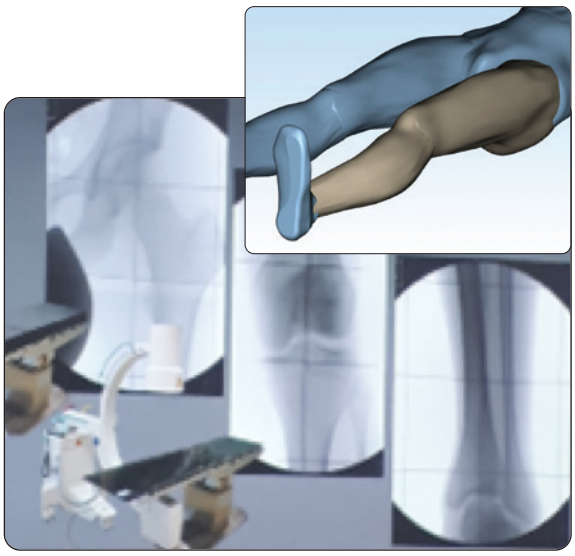


Fig.5 Patient positioning

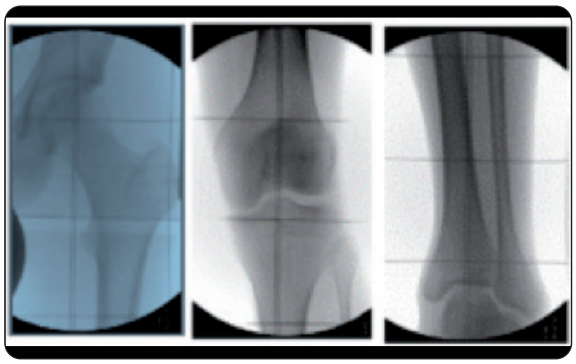


Fig. 6 Hip, knee and ankle joint position

Implant positioning

With the image intensifier, locate the tip of the greater trochanter using a wire placed over the skin. Mark the level of the tip of the greater trochanter on the skin using a surgical skin marker.

Place the trial nail correctly over the femur **(Fig. 7)** ensuring the proximal end of the nail is positioned at the entry point and inside the bone. The trial nail is an exact replica of the Fitbone Trochanteric nail, with the exception of the motor and cable.

Using the surgical pen, mark the distal tip of the nail and the desired osteotomy site on the skin. Insert either a skin

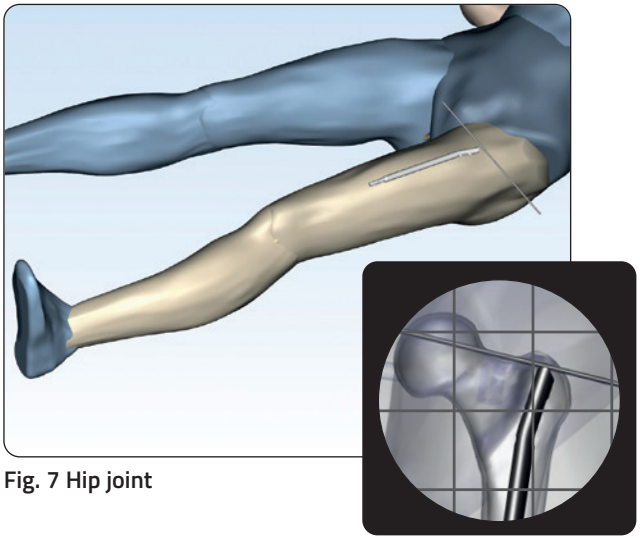


Fig. 7 Hip joint

staple or tape a syringe needle at each location **(Fig. 8)**.

In addition, mark the longitudinal axis of the palpable femur laterally on the skin.

If preferred, osteotomy site preparation can be performed at this stage.

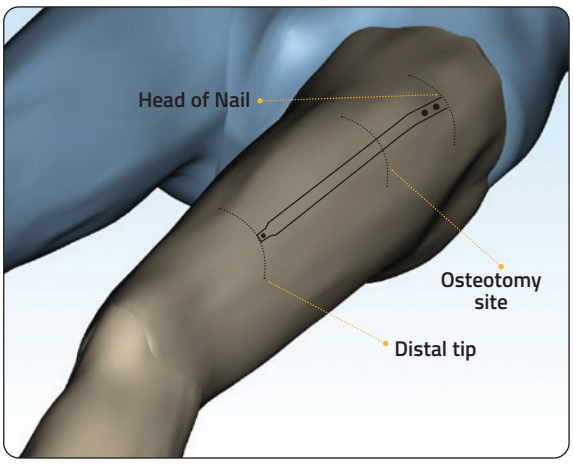


Fig. 8 Osteotomy and nail position marking

Insertion of half-pins for rotation control

Part #	Description
99-941550	SELFDRILLING XCALIBER CYLINDRICAL SCREW SHAFT D6MM THREAD 5MM L180/50QC STERILE

With the leg in full extension, insert two 5mm half-pins, to ensure correct rotational alignment.

Insert the first half-pin in the supracondylar region, parallel to the dorsal and the distal knee joint line and below the distal tip of the planned nail position (see skin mark) **(Fig. 9)**.

If no rotational correction is required, insert the second half-pin in the proximal femur, at the level of the lesser

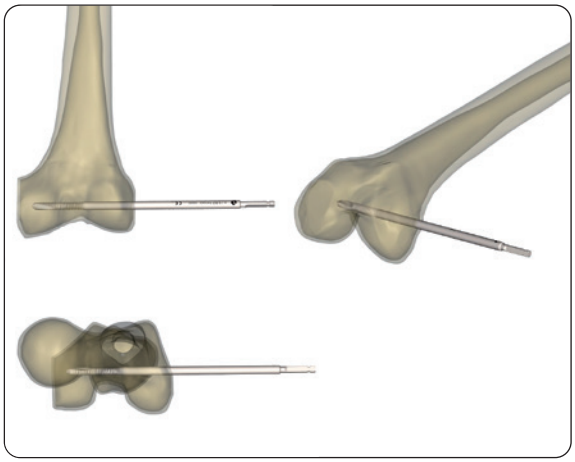


Fig. 9 Distal half-pin position

trochanter, posterior to the path of the nail and parallel to the first screw **(Fig. 10)**.

If correction of a rotational deformity is required, insert the distal half-pin at the desired angulation correction, in

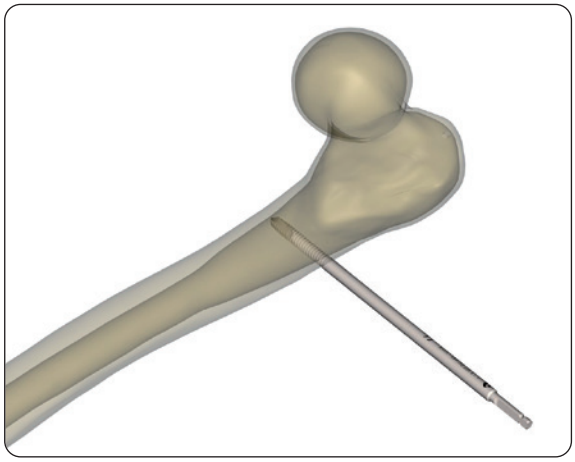


Fig. 10 Proximal half-pin position

relation to the proximal screw.

Post correction should see both half-pins parallel.

The half-pins should be used as reference points for checking and manipulating the bone fragments **(Fig. 11)**.

PRECAUTION: Bone screws might be used to avoid unintentional axial and torsional deviations. These must be placed in such a way that they do not interfere with the insertion of the Fitbone Trochanteric Nail into the medullary canal.

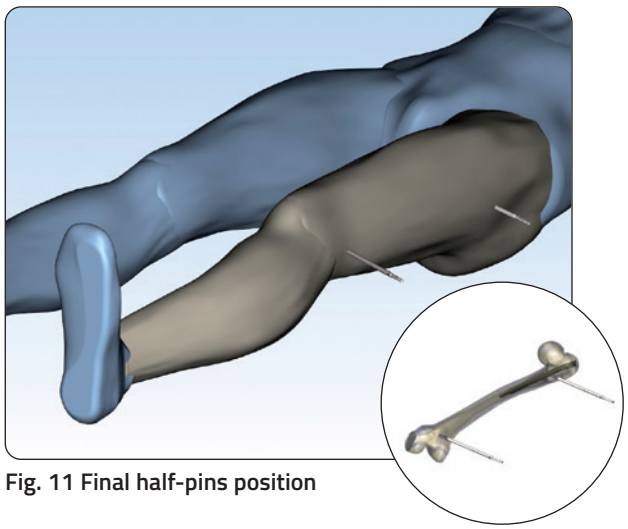


Fig. 11 Final half-pins position

Entry point targeting

Part #	Description
99-60001039	FITBONE KIRSCHNER WIRE L280MM D3MM STERILE

The entry point will be influenced by the individual's anatomy. Typically, the entry point will be positioned lateral to the tip of the greater trochanter in the AP view, and central in the trochanter when viewed laterally **(Fig. 12)**.

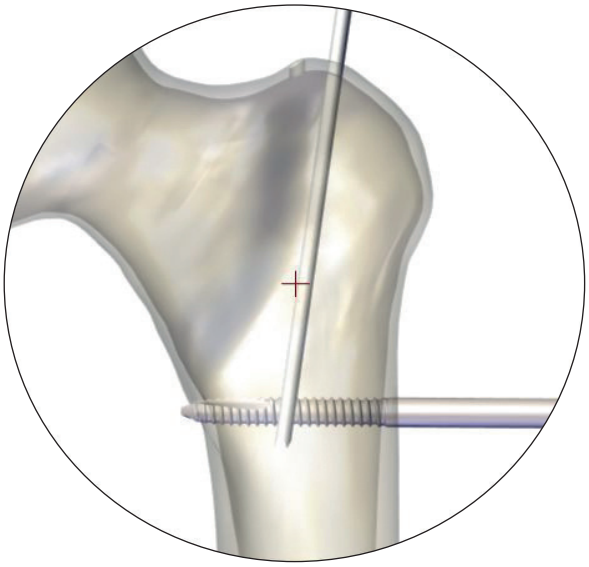


Fig. 12 Entry point

Palpate the posterior edge of the greater trochanter and make a 2-4cm skin incision, approximately 3 fingers proximal to the tip of the greater trochanter **(Fig. 13)**.

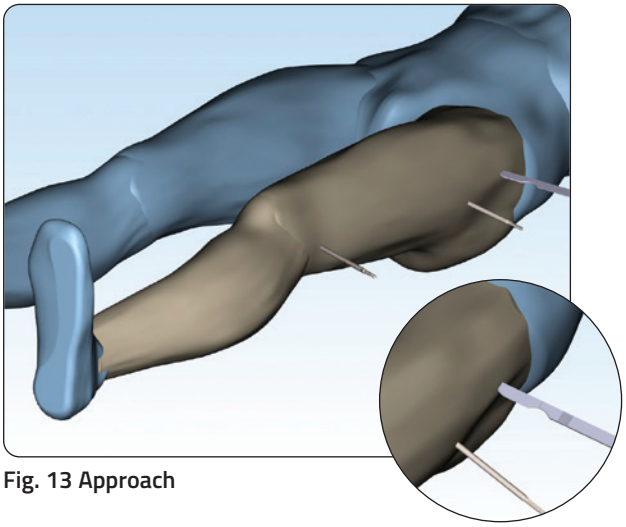


Fig. 13 Approach

To gain entry to the intramedullary canal, slightly internally rotate the leg to eliminate the anatomic anteversion of the femoral head. The femur will now present straight under fluoroscopy.

Use scissors to prepare a small soft tissue tunnel to gain access to the tip of the trochanter. Make sure to palpate the tunnel to enable the k-wire to reach the bone without soft tissue interference.

Insert the k-wire 1-2cm lateral to the tip of the greater trochanter **(Fig. 14)**.

PRECAUTION: Under fluoroscopy, verify that the 3.0mm guide wire position allows adequate clearance on the lateral side of the femur for the opening awl and for the entry reamer.

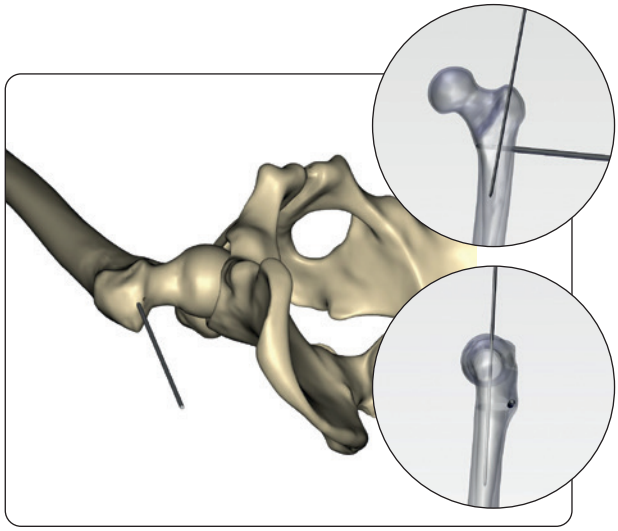


Fig. 14 K-wire entry point

Entry point opening

Part #	Description
183260	CANNULATED AWL
700230	ENTRY REAMER GUIDE

Insert the entry reamer guide over the k-wire followed by the cannulated awl **(Fig. 15)**.

Open the entry point around 2 to 3 cm in depth, by gently advancing the cannulated awl over the k-wire with a twisting motion. Take care to avoid the medial cortex.

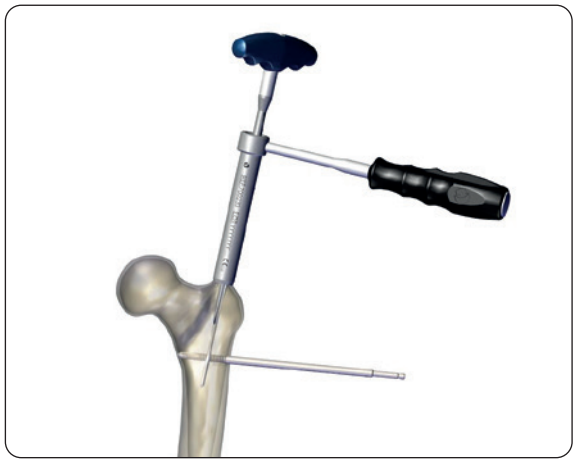


Fig. 15 Entry point opening

Remove the cannulated awl leaving the k-wire and entry reamer guide in place **(Fig. 16)**.

PRECAUTION: If the 3.0mm guide wire used for opening the entry point is damaged or bent, a new guide wire must be used for insertion of the proximal reamer.

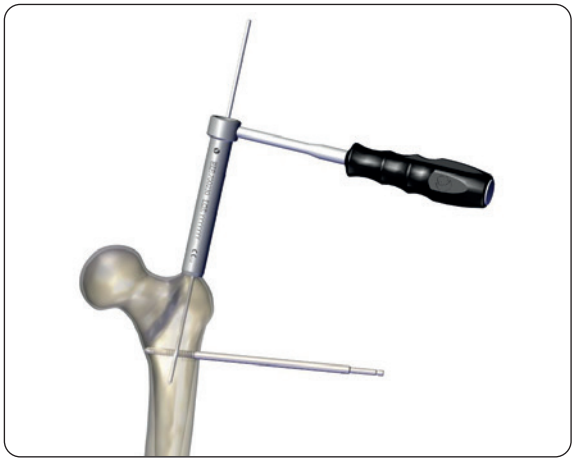


Fig. 16 K-wire position

Osteotomy site preparation

Part #	Description
700275	SIZING GUIDE
700213	DISTAL TISSUE GUIDE
99-700183	DISTAL DRILL BIT D4.5MM QC STERILE

If preferred, this can be performed directly after implant positioning.

Align the sizing guide over the femoral axis at the level of the entry point. Using the image intensifier, confirm the implant size and the position of the proximal screws **(Fig. 17)**.

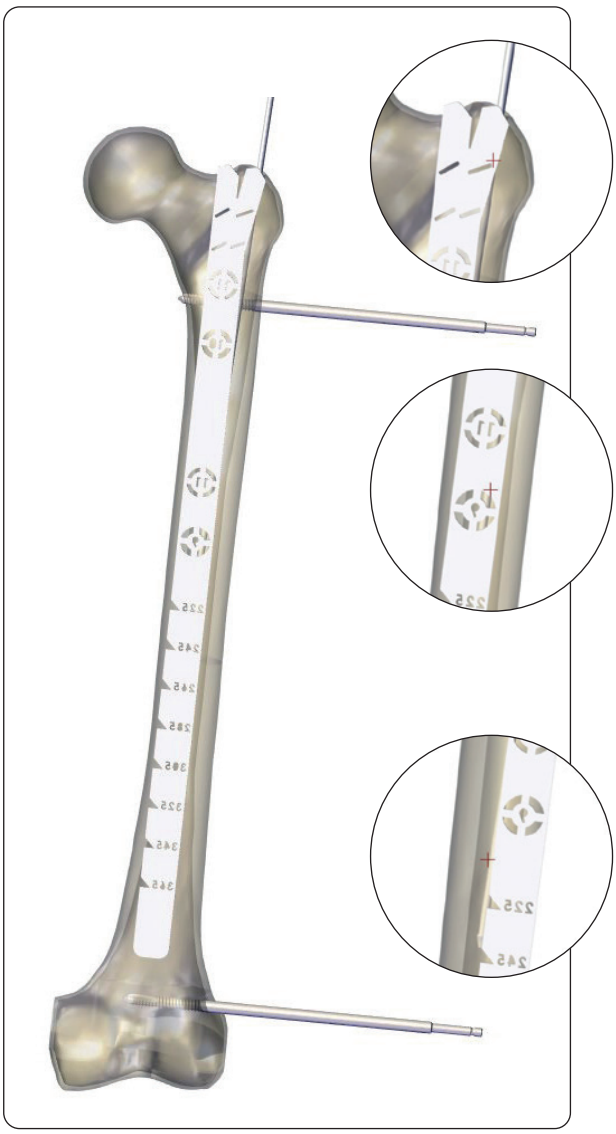


Fig. 17 Sizing guide

Pre-drill the holes necessary to perform percutaneous osteotomy at the previously marked level **(Fig. 18)**.The use of an image intensifier and soft tissue protector sleeve while drilling is recommended. Perform the holes perpendicular to the bone, changing the angulation of 10/15° each time. Bone preparation using this technique stimulates bone healing at the osteotomy site.

Take care not to use excessive force and consequently fracture the bone during osteotomy preparation.

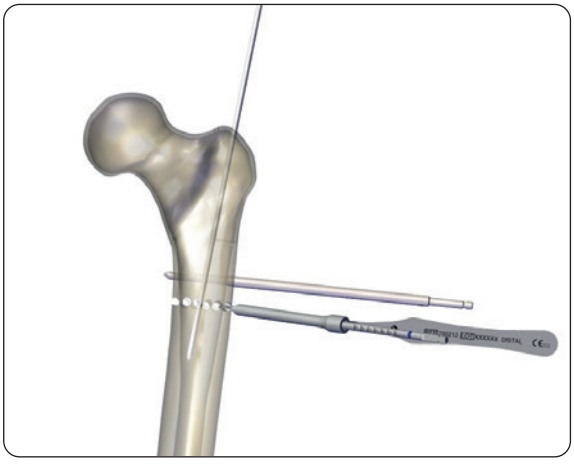


Fig. 18 Osteotomy pre-drilling holes

Proximal reaming

Part #	Description
700270	ENTRY REAMER D12MM
700271	ENTRY REAMER D13MM
700230	ENTRY REAMER GUIDE

Select the correct entry reamer based upon nail size. Advance the entry reamer over the k-wire on power.

9-10mm nail = 12mm entry reamer

11-11mm nail = 13mm entry reamer

PRECAUTION: The entry reamer tip should be screened to avoid inadvertently driving the reamer further than intended (pay particular attention not to ream further than the medial cortex).

The correct insertion depth for the entry reamer can be verified according to the following options **(Fig. 19)**:

- **Option 1:** stop reaming when the proximal groove (external marking) of the entry reamer is at the level of entry reamer guide.
- **Option 2:** under fluoroscopy, stop reaming when the distal groove (internal marking) of the entry reamer is at the level of the greater trochanter.

Remove the entry reamer, entry reamer guide and k-wire.

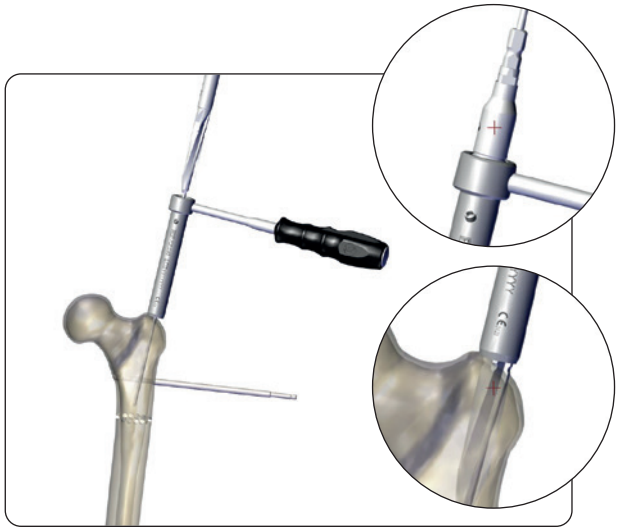


Fig. 19 Left: entry reamer insertion; Right: entry reamer external marking (above) and internal marking (below)

Distal reaming

Part #	Description
700276	RULER
173276	RULER SUPPORT
99-173281	GUIDE WIRE WITH OLIVE D. 3X980mm STERILE
172991	FLEXIBLE REAMER SYSTEM BOX

In preparation for distal reaming, manually insert the guide wire with olive until impaction with the distal femur is felt. This can be confirmed using x-ray in AP and lateral views.

If required, a further nail size check can be performed using the ruler and ruler support **(Fig. 20)**.

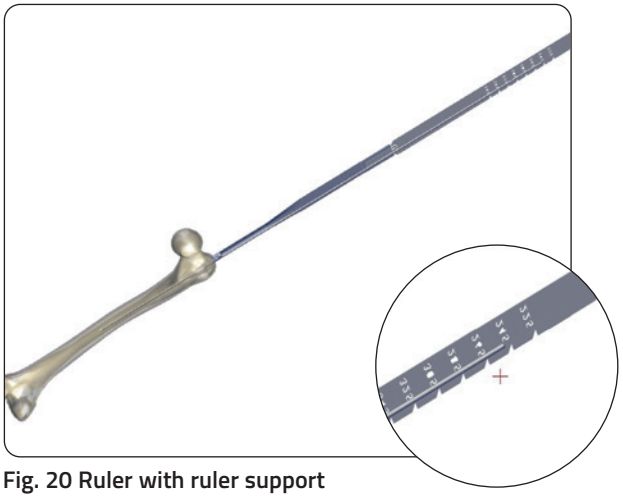


Fig. 20 Ruler with ruler support

Place the entry reamer guide over the guide wire with olive. Insert the 8mm reamer over the guide wire and advance in the medullary canal to the desired depth indicated by the skin staple **(Fig. 21)**. Using the flexible reamers, progressively enlarge the femoral canal (0.5mm increments) to a diameter 1.0-2.0mm greater than that of the proximal diameter of the nail to be implanted:

- 11/11 nail ream to 12/13mm
- 9/10 nail ream to 11/12mm

PRECAUTION: Advance the reamer with steady, moderate pressure. Do not force the reamer. Partially retract the reamer often to clear debris from the medullary canal. Advancement of the reamer tip should be screened using fluoroscopy to prevent inadvertently damaging the distal femoral physis

Remove the reamer, the entry reamer guide and the guide wire with olive.

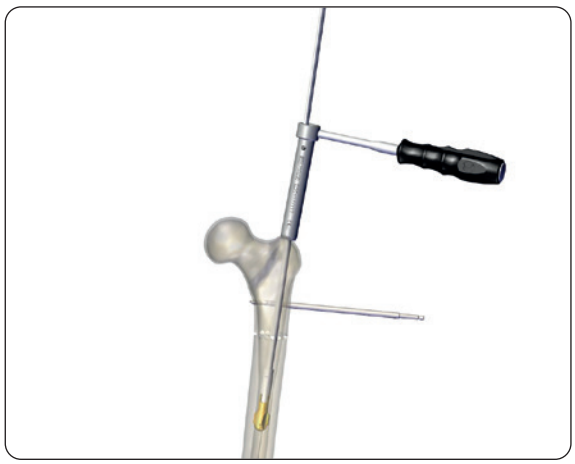


Fig. 21 Distal reaming

Trial nail preparation

Part #	Description
700100	TARGETING HANDLE
700101	TARGETING HANDLE - SHORT
700110	LOCKING BOLT
700XYYY	FITBONE TROCHANTERIC TRIAL NAIL LYYYMM DXMM
700325	6MM HEX SCREWDRIVER
351351	LOCKING CAM
700302	PROXIMAL TISSUE GUIDE
700212	TROCAR D4.5MM
99-700182	PROXIMAL DRILL BIT D4.5MM QC STERILE
99-60001039	FITBONE KIRSCHNER WIRE L280MM D3MM STERILE

Select the most appropriate targeting handle according to clearance between patient's leg and distal portion of handle **(Fig. 22)**.

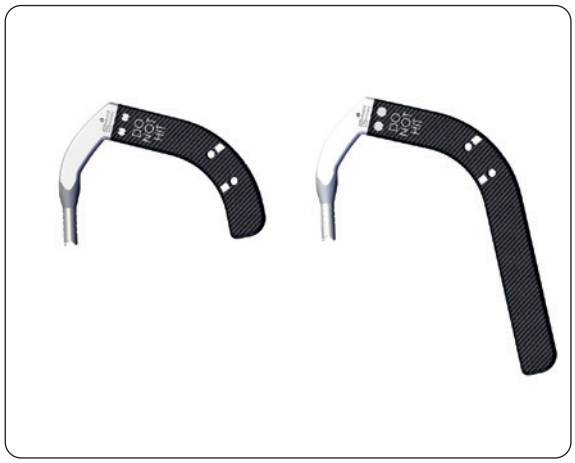


Fig. 22 Targeting handles

Insert the locking bolt into the targeting handle **(Fig. 23)**.

Fig. 23 Locking bolt insertion

Ensure the tooth on the targeting handle sits within the cut-out of the trial nail **(Fig. 24)** .

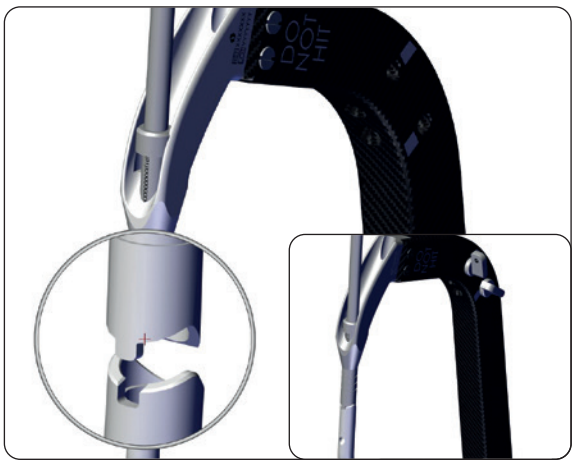


Fig. 24 Targeting handle and nail alignment

Secure with the 6mm hex screwdriver **(Fig. 25)**.

Fig. 25 Trial nail connection

In order to check correct nail assembly, insert the proximal tissue guides with the trocars through the targeting handle and pass the proximal drills through the trocar. The drills should pass freely through the trial nail **(Fig. 26a)**. The locking cams are used to secure the proximal tissue guides in place.

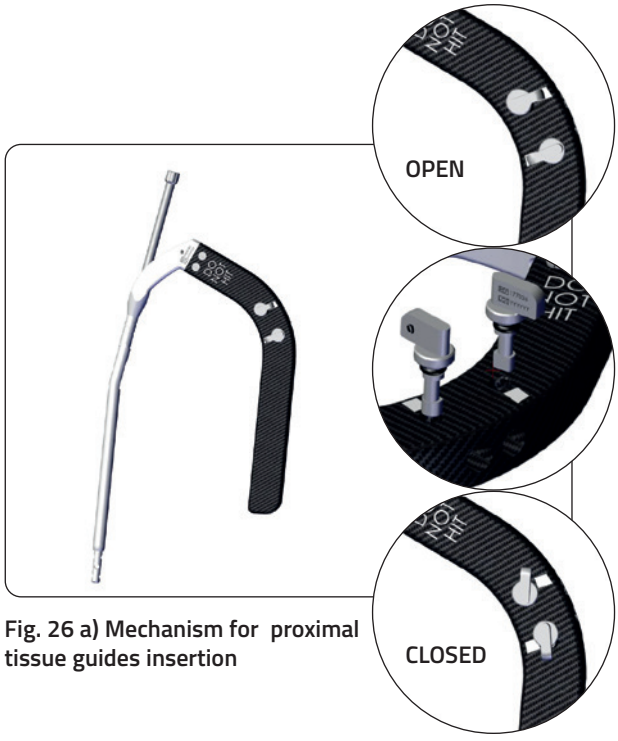


Fig. 26 a) Mechanism for proximal tissue guides insertion

The proximal drills should pass freely and be seen exiting the trial nail **(Fig. 26b)**.

Fig. 26 b) Correct nail assembly confirmation

Trial nail insertion and osteotomy finalization

Part #	Description
700200	OSTEOTOME
60000689	OPEN END WRENCH SW 14/17

The trial nail is used to confirm the medullary canal is appropriately prepared for the Fitbone Trochanteric Nail.

It must be possible to insert the nail without impaction. Small rotational forward movements should be used to insert the nail into the bone. If excessive resistance upon nail insertion is experienced, remove the nail and ream a further 0.5-1.0mm and try once again.

Insert the trial nail to the level of the osteotomy.

Complete the osteotomy with the osteotome. Gently rotate the osteotome with the aid of the wrench to confirm the osteotomy is complete **(Fig. 27a and 27b)**.

Ensure the rotational reference half-pins are parallel before advancing the nail.

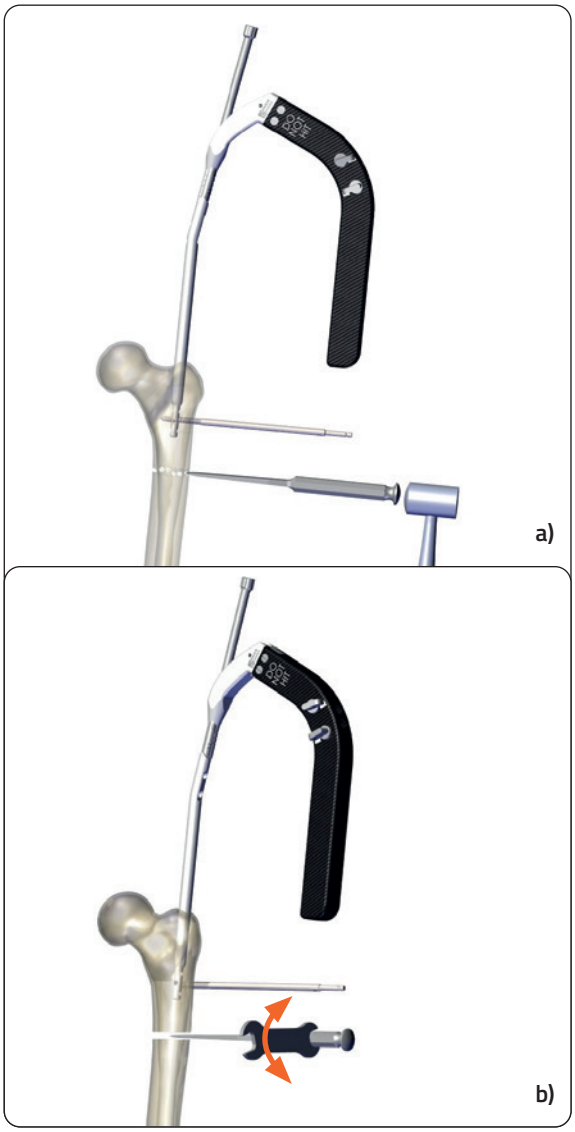


Fig. 27 a) and b) Osteotomy finalization

Using the image intensifier, confirm the trial nail position matches that of the pre-operative plan. The distal reference groove seen on the targeting handle can be used to verify the nail is at the planned depth **(Fig. 28)** .The reference grooves are positioned at a distance of 10, 15 and 20mm from the proximal end of the nail.

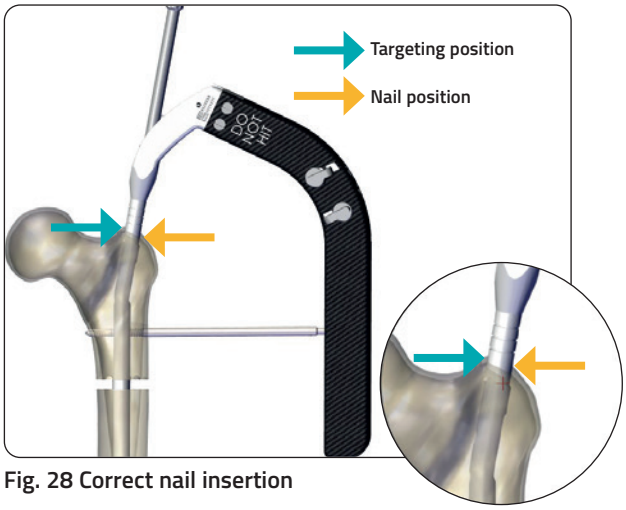


Fig. 28 Correct nail insertion

Perform a further positioning check by inserting a k-wire in the dedicated hole on the targeting handle **(Fig. 29)**. The positioning of the k-wire under fluoroscopy indicates the proximal end of the nail. It is advised to check trial nail positioning under fluoroscopy.

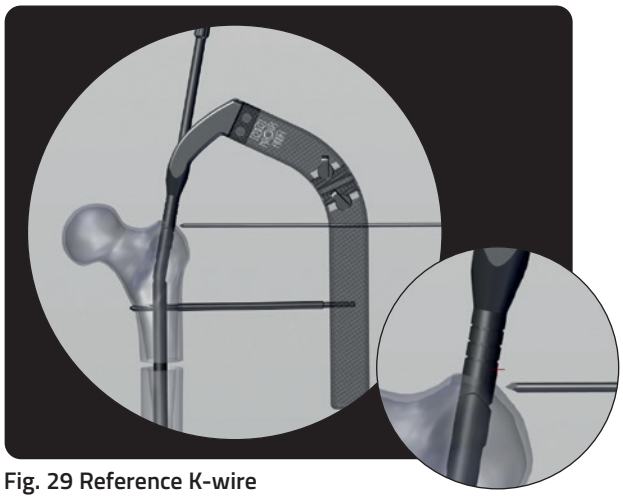


Fig. 29 Reference K-wire

Blocking screws insertion

Part #	Description
700213	DISTAL TISSUE GUIDE
99-700183	DISTAL DRILL BIT D4.5MM QC STERILE
700320	SHORT SCREWDRIVER
700319	SHORT SCREWDRIVER RETENTION ROD

If required, blocking screws to achieve correct alignment can be inserted.

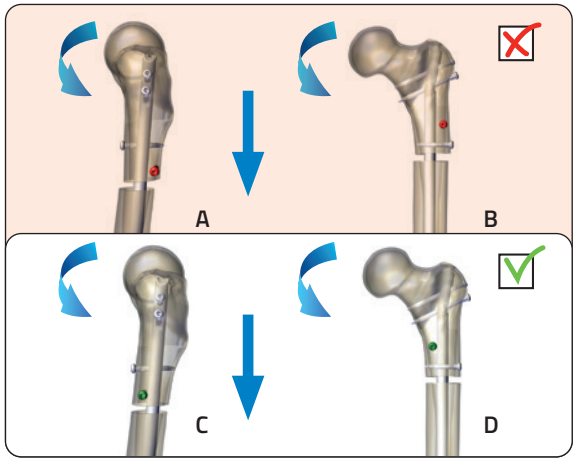


Fig. 30 Alignment and blocking screws

The anterior or posterior screw achieves correct alignment in the lateral view and the medial screw in the AP view **(Fig. 31 and 32)**.

The 4.5mm locking screws can be inserted as blocking screws with the trial nail in place **(Fig. 32)**.

PRECAUTION: Perform additional corrections or place blocking screws only with the trial nail inside the bone, never while the Fitbone Trochanteric Nail is inserted.

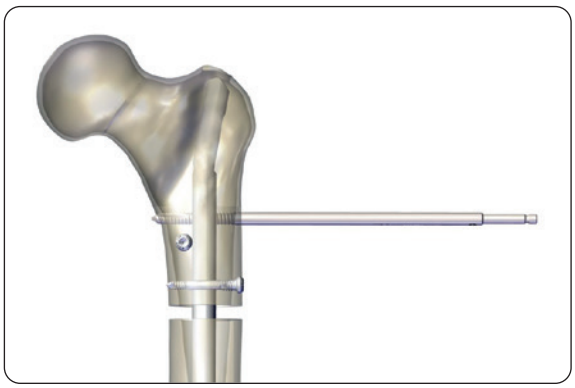


Fig. 31 Blocking screws position

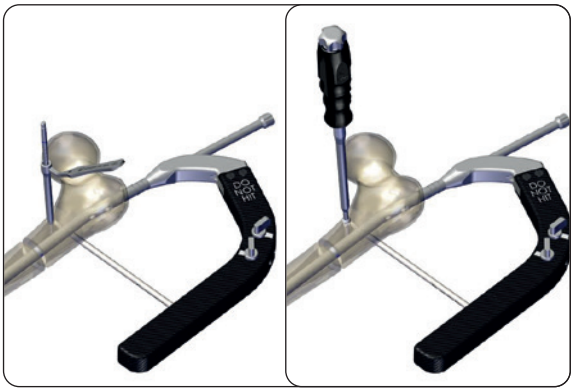


Fig. 32 Blocking screws insertion

Intraoperative functionality test

Part #	Description
60001644	FITBONE CONTROL SET FOR ACTIVATION OF INTRAMEDULLARY LENGTHENING NAIL US PLUG 115V
60001562	LOHMANN&RAUSCHER RAUCODRAPE REF 15966
60000676	KAWE STETHOSCOPE 06.10100.94
60001780	FITBONE SUBCUTANEOUS ENERGY RECEIVER

To confirm the Fitbone Trochanteric Nail is functioning correctly, an intraoperative functionality test must be performed before inserting it into the bone. To minimize the risk of contamination of the implants, do not remove them entirely from their packaging. Expose only the end of the cable of the nail and the coupling of the receiver.
Remove the transport locking device from the receivers coupling. Place a drop of saline on the plug of the cable and insert into the coupling **(Fig. 33)**. Place the stethoscope and transmitter in sterile drapes.

PRECAUTION: Make sure the white ring (see blue circle in Figure 33) is in connection with the start of the coupling.

Prepare the stethoscope, the receiver and the camera bag

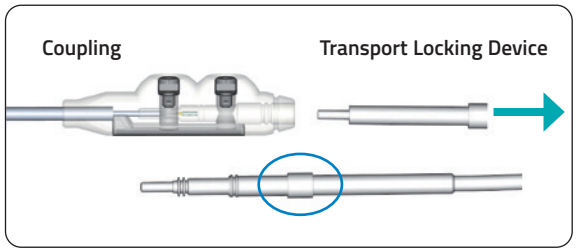


Fig. 33 Transport locking device removal

The transmitter is placed on the receiver and stethoscope on the nail.

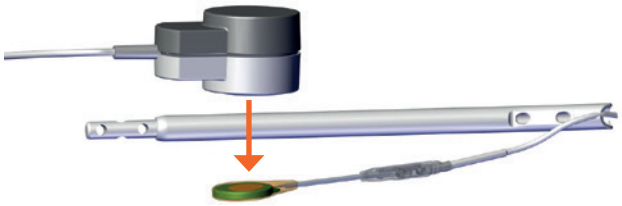
The Fitbone trochanteric nail is activated via the control set and the motor of the nail must be heard, alongside seeing the energy transmission light flashing on the control set **(Fig. 34)**.

For the intraoperative test, the doctor ("Doc.") and pulsating ("Pulse") settings are recommended.
Remove the switch cover cap from the control set. The surgeon can now choose between the patient/doctor mode, labelled "Pat" and "Doc", respectively, and pulse or permanent operation, labelled "Pulse" and "Perm", respectively **(Fig. 35)**.

Once the function of the nail has been confirmed, disconnect the receiver from the coupling.

PRECAUTION: Intraoperative Functional Test: Prior to implanting the Fitbone Trochanteric Nail, check the functionality of the Fitbone Trochanteric Nail by activating it via the FITBONE Control Set. The operating noise of the Fitbone Trochanteric Nail (using the supplied stethoscope) and the flashing control light will confirm the functionality.

Place the transmitter on the receiver



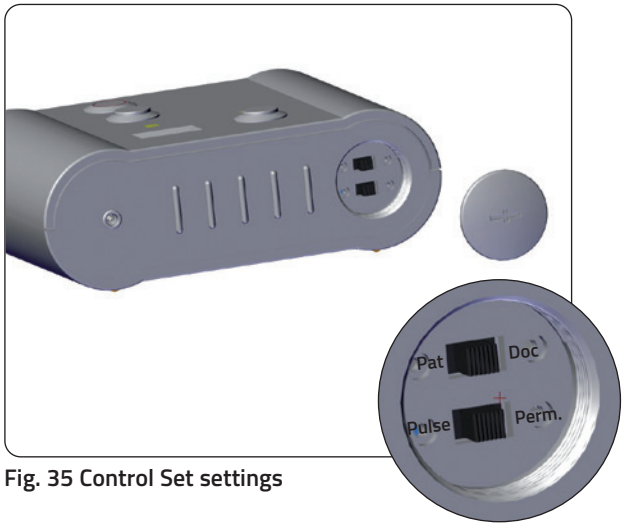
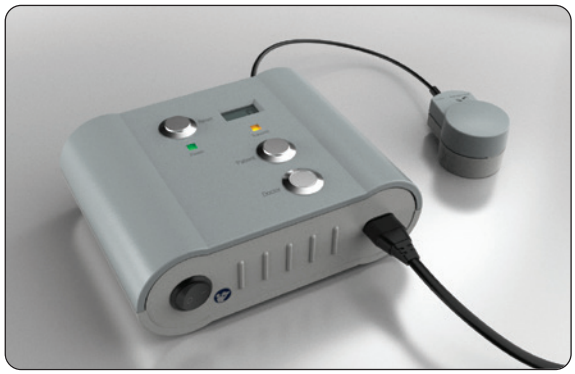


Fig. 35 Control Set settings

Switch on the control set.
Put the transmitter and the stethoscope in the camera bag.



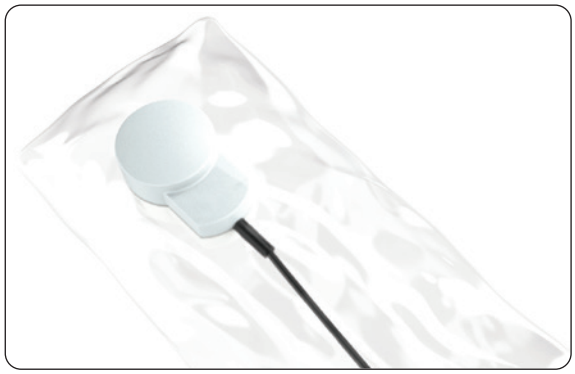


Figure 34 Intraoperative functionality test
Press Doctor, check :
the countdown
the yellow flashing,
the sound of the motor
1 pulse = 0,033mm lengthening

Final nail preparation and proximal locking check

Part #	Description
700100	TARGETING HANDLE
700101	TARGETING HANDLE - SHORT
700110	LOCKING BOLT
700325	6MM HEX SCREWDRIVER
351351	LOCKING CAM
700302	PROXIMAL TISSUE GUIDE
700212	TROCAR D4.5MM
99-60001039	FITBONE KIRSCHNER WIRE L280MM D3MM STERILE
99-700182	PROXIMAL DRILL BIT D4.5MM QC STERILE

Insert the locking bolt into the targeting handle. Carefully pass the cable of the Fitbone Trochanteric nail into the cannulation of the locking bolt **(Fig. 36)**.

Align the tooth of the targeting handle with the cut-out of the Fitbone Trochanteric nail and secure with the 6mm Hex screwdriver **(Fig. 37 and 38)**.

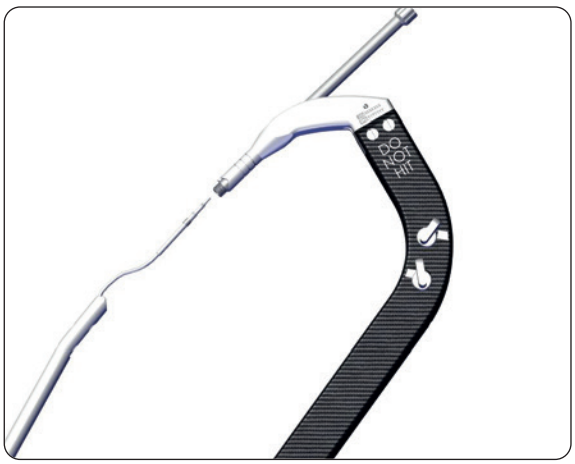


Fig. 36 Locking bolt insertion

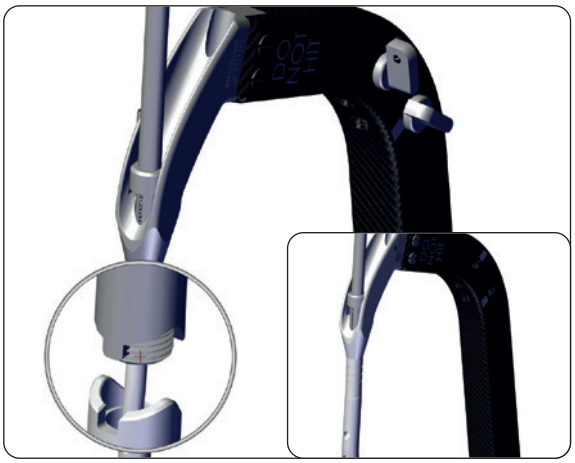


Fig. 37 Targeting handle and nail alignment

Fig. 38 Final nail connection

In order to check correct nail assembly, insert the tissue guide and trocar through the targeting arm and pass the proximal drill through the trocar. The proximal drills should pass freely and be seen exiting the nail **(Fig. 39)**.

PRECAUTION: Make sure the holes of the targeting handle and the holes of the Fitbone Trochanteric Nail are perfectly aligned prior to surgery.

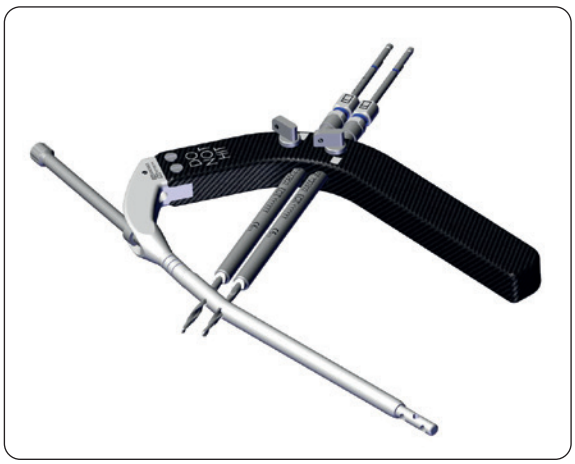


Fig. 39 Proximal locking check

Nail insertion

Part #	Description
700100	TARGETING HANDLE
700101	TARGETING HANDLE - SHORT
700110	LOCKING BOLT
351351	LOCKING CAM
99-60001039	FITBONE KIRSCHNER WIRE L280MM D3MM STERILE

Insert the nail into the femur using the previously described technique. Ensure the reference markings match the ones of the pre-plan **(Fig. 40)**.

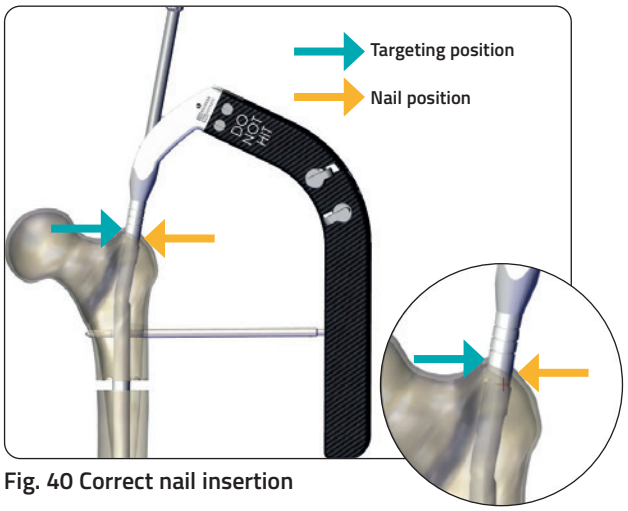


Fig. 40 Correct nail insertion

It is advised to check nail positioning under fluoroscopy in AP and lateral planes. Insert a k-wire in the dedicated hole of the targeting handle and verify the depth of the nail under fluoroscopy **(Fig. 41)**.

WARNING: Never use a hammer to drive or remove the Fitbone Trochanteric Nail into/from the medullary cavity as doing so could damage the implant.

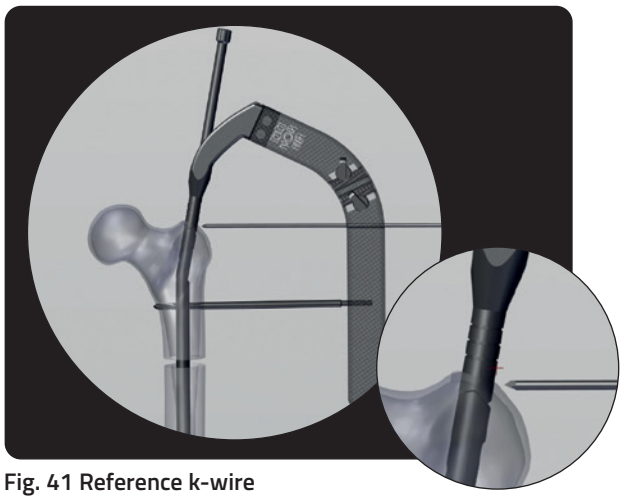


Fig. 41 Reference k-wire

Proximal screws insertion

Part #	Description
700302	PROXIMAL TISSUE GUIDE
700212	TROCAR D4.5MM
700282	LONG SCREWDRIVER
700213	LONG SCREWDRIVER RETENTION ROD
99-700182	PROXIMAL DRILL BIT D4.5MM QC STERILE

Insert the trocar into the proximal tissue guide.
Advance the proximal tissue guide and trocar through the targeting handle to determine the skin insertion point.

Make a 1 cm incision at the insertion point and bluntly dissect through the soft tissues to allow the proximal tissue guide and trocar to pass down to bone **(Fig. 42)**.

PRECAUTION: To ensure the correct proximal locking screw length, the tip of the trocar must go flat against the bone.

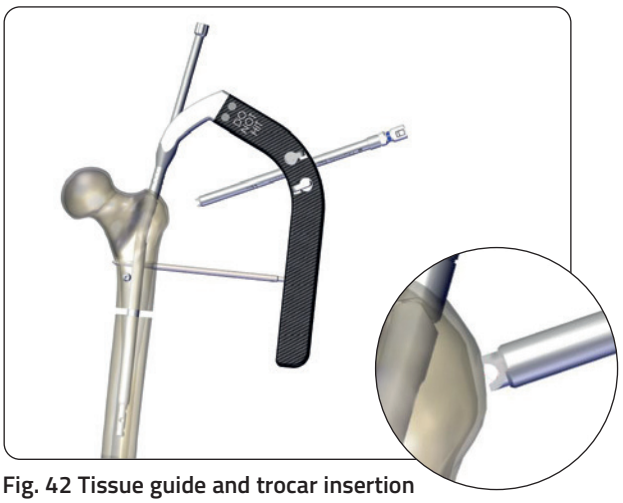


Fig. 42 Tissue guide and trocar insertion

Secure the proximal tissue guide to the targeting handle by closing the locking cam. Insert the proximal drill through the trocar, starting with the upper locking screw hole. Drill bi-cortically, ensuring the distal tip of the proximal drill penetrates the far cortex **(Fig. 43)**.

Do not drill beyond the far cortex. Penetrate the far cortex only.

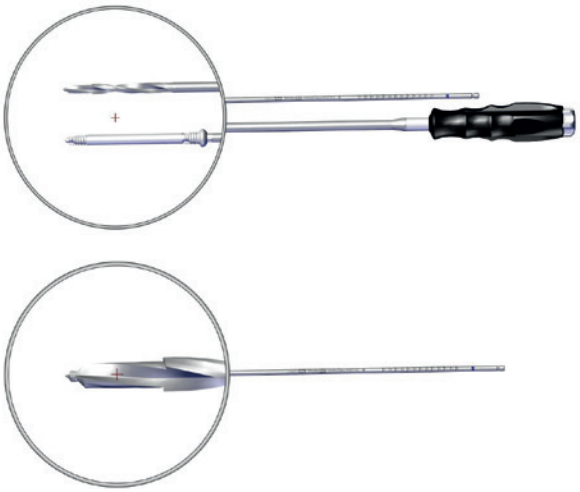


Fig. 43 Screw profile

Measure the screw length using the gauge on the shaft of the drill **(Fig. 44)**.

PRECAUTION: Choosing the appropriate length for the proximal locking screw is critical for the effective and safe stabilization of bone fragments. The length of the screw should be determined by using the dedicated instruments as described in the operative technique.

Remove the trocar and the proximal drill leaving the proximal tissue guide in place.

PRECAUTION: After proximal locking screw length measurements, make sure to hold the targeting handle in the same position: any movement of the targeting handle may result a mismatch between the screw and the hole.

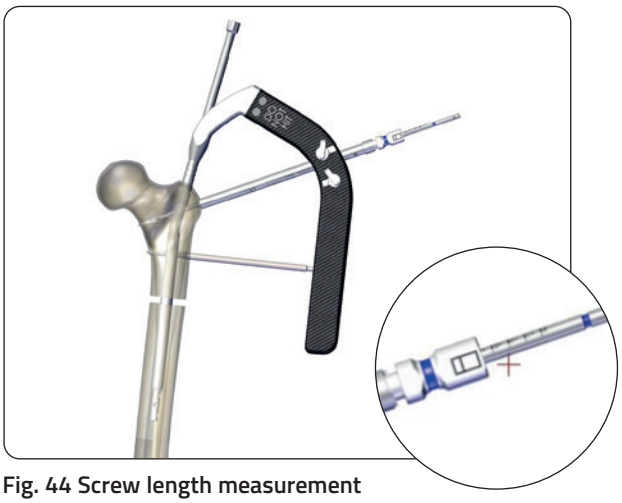


Fig. 44 Screw length measurement

Insert the locking screw using the long screw driver with retention rod through the proximal tissue guide and advance until the screw head is seated on the bone **(Fig. 45)**.

PRECAUTION: Overtightening of the screw should be avoided and the head of the screw should come just in contact with the cortex. Stop insertion when resistance is felt.

Verify the locking screw position under fluoroscopy.

In instances of poor bone quality and subsequent insufficient fixation when using standard screws, the revision screw option can be utilized.

Remove the proximal tissue guide from the targeting handle by opening the locking cam.

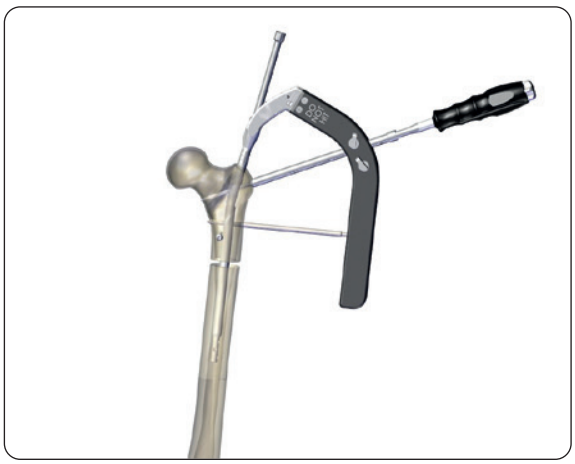


Fig. 45 First proximal screw insertion

Using the same process, insert the second proximal locking screw **(Fig. 46)**.

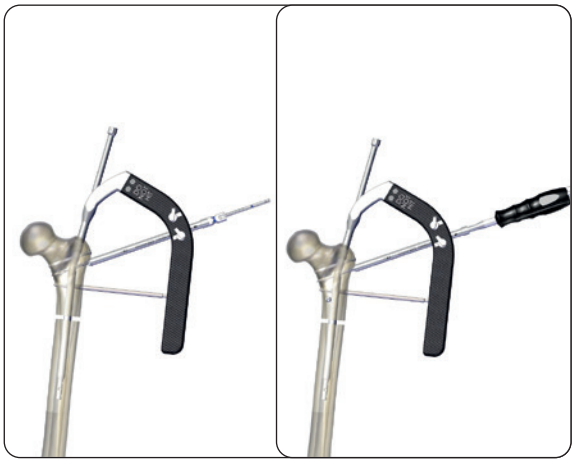


Fig. 46 Second proximal screw insertion

Distal screws insertion

Part #	Description
700213	DISTAL TISSUE GUIDE
99-700183	DISTAL DRILL BIT D4.5MM QC STERILE
99-700184	DISTAL DRILL BIT D4.0MM QC STERILE
700277	DISTAL SCREW SIZING GAUGE
700320	SHORT SCREWDRIVER
700319	SHORT SCREWDRIVER RETENTION ROD

Before performing distal locking, check that the rotational reference half-pins are parallel to avoid misalignment.

Distal locking screws are inserted using the free-hand technique under fluoroscopy.

The correct size distal screw and distal drill must be used according to the Fitbone nail being used:

- 9-10mm nail = 4mm distal screw / yellow drill
- 11-11mm nail = 4.5mm distal screw / blue drill

A maximum of three distal screws can be inserted (2xML, 1xAP) **(Fig. 47)**.

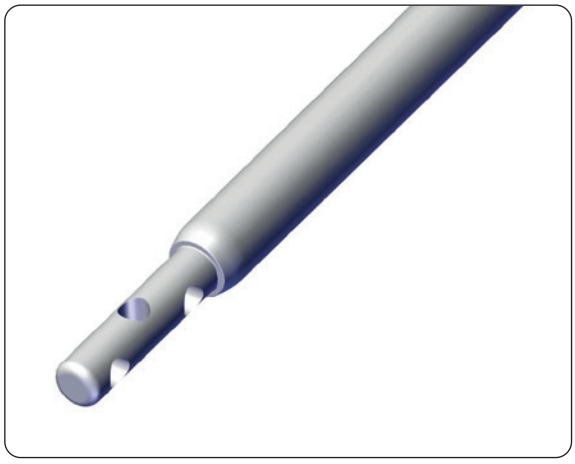


Fig. 47 Distal screw hole options

A minimum of two distal screws should be used to ensure stable fixation.

Locate screw hole position under fluoroscopy and perform a 1-2cm incision. Bluntly dissect through the tissues to create a soft tissue tunnel to gain access to the bone. With the assistance of the distal tissue guide, drill bi-cortically ensuring the distal tip of the drill penetrates the far cortex **(Fig. 48)**.

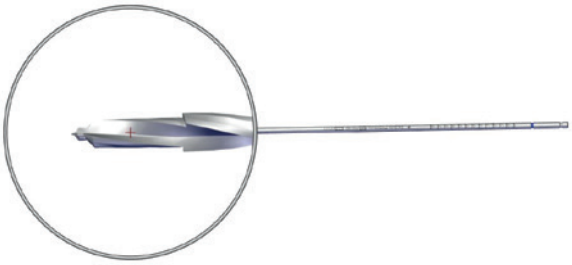


Fig. 48 Drill profile

Do not drill beyond the far cortex. Penetrate the far cortex only.

Measure the screw length using the gauge on the shaft of the drill **(Fig. 49)**.

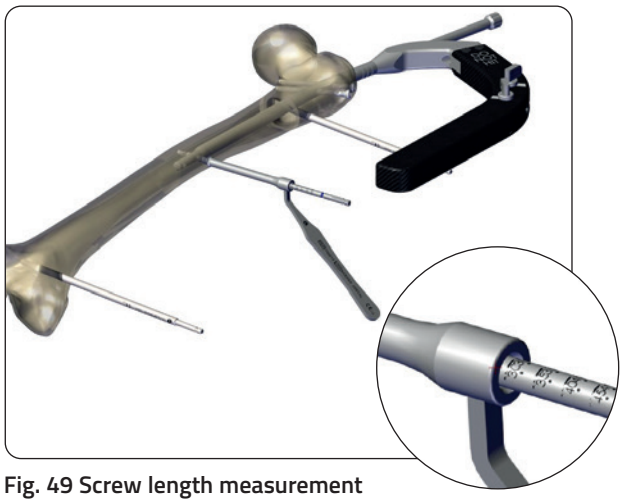


Fig. 49 Screw length measurement with drill bit gauge

Alternatively, distal screw length can be measured using the distal screw sizing gauge **(Fig. 50)**.

If the measurement reading sits between screw sizes, choose the longer one.

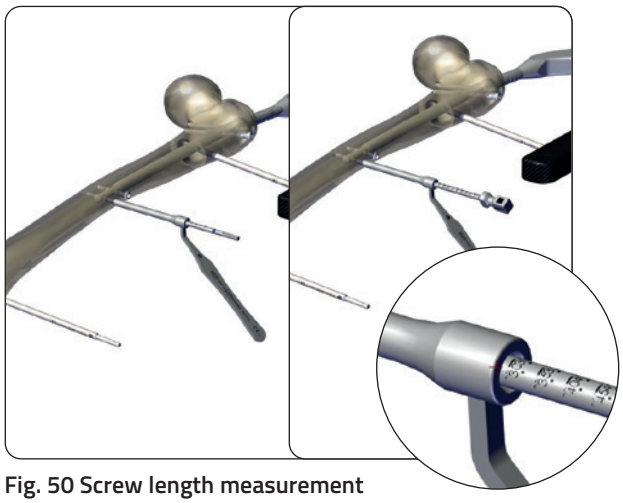


Fig. 50 Screw length measurement with screw sizing gauge

Using the short screwdriver with retention rod, insert the locking screw through the distal tissue guide and advance until the screw head is seated on the bone **(Fig. 51)**.

Verify the locking screw position under fluoroscopy.

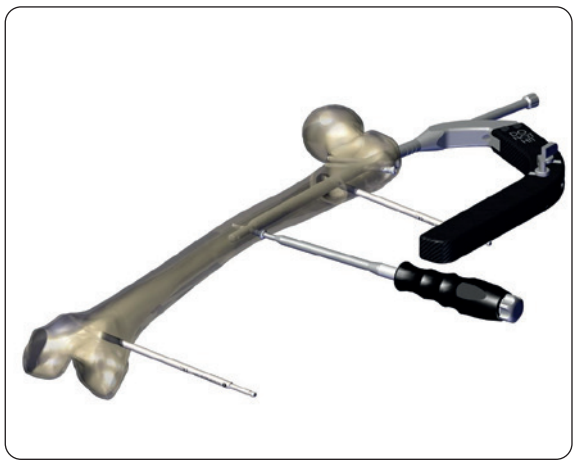


Fig. 51 First distal screw insertion

Insert a further 1 or 2 screws according to pre-operative planning **(Fig. 52)**.

In instances of poor bone quality and subsequent insufficient fixation when using standard screws, the revision screw option can be utilized.

Remove the rotational reference half-pins.

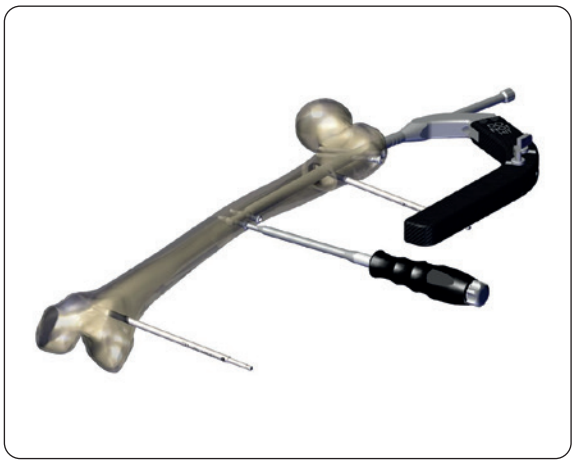


Fig. 52 Second distal screw insertion

Targeting handle removal

Part #	Description
700325	6MM HEX SCREWDRIVER

Use the screwdriver to loosen the locking bolt on the targeting handle **(Fig. 53)**.

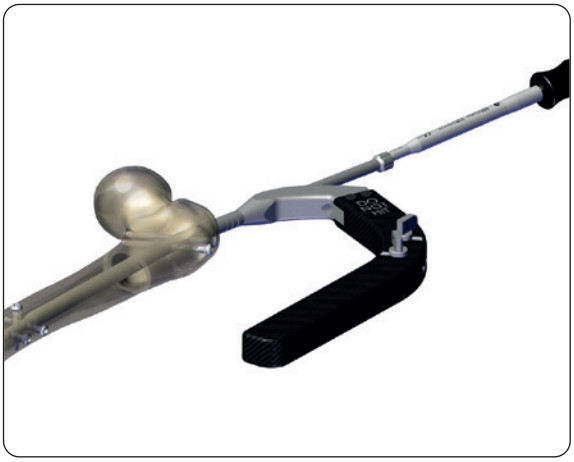


Fig. 53 Releasing the nail

Carefully remove the targeting handle, taking care not to damage the cable **(Fig. 54)**.

Make sure that the cable is not trapped in the soft tissue canal and can be easily mobilized.

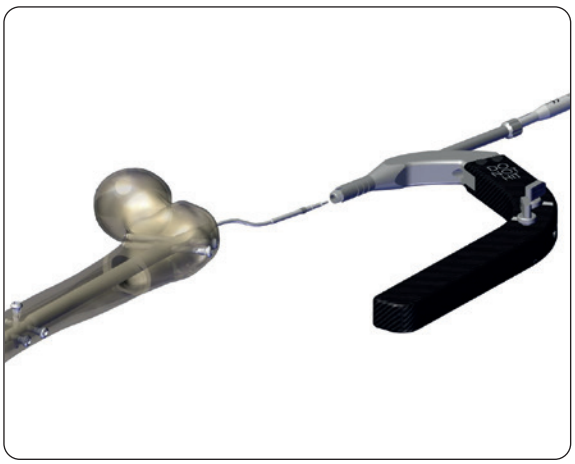


Fig. 54 Removing the targeting guide

Receiver positioning

Part #	Description
60001780	FITBONE SUBCUTANEOUS ENERGY RECEIVER
60001622	BIOTRONIK TORQUE WRENCH 395121

Clean the plug of the cable to remove any blood (this can act as an isolator). Remove the transport locking device from the receivers coupling.

Place a drop of saline on the plug of the cable and insert into the coupling **(Fig. 55)**.

PRECAUTION: Make sure the white ring (see blue circle in Figure 55) is in connection with the start of the coupling.

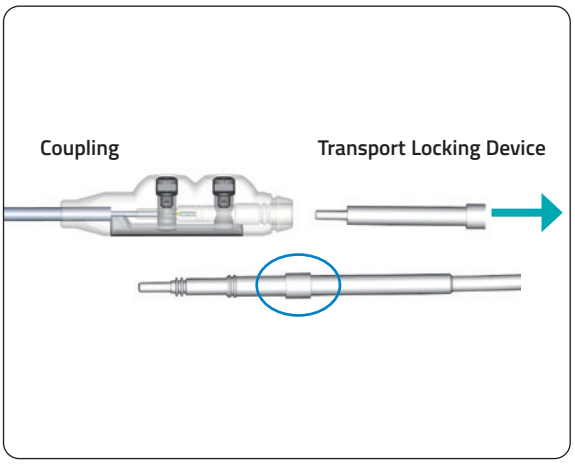


Fig. 55 Transport locking device removal

Lock the cable into the Receiver's Coupling by tightening both screws with the torque wrench. An audible click is heard when the required torque is reached **(Fig. 56)**.

PRECAUTION: Do not hold the coupling or cable with surgical instruments and avoid bending the coupling or cable as this can lead to damage or unwanted disconnection.

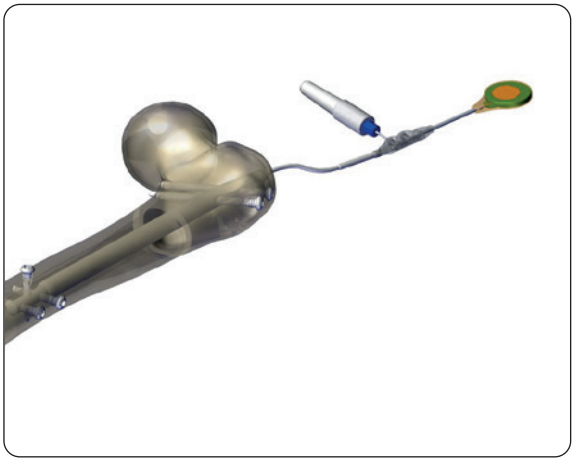


Fig. 56 Distal fixation

The receiver should be placed directly underneath the skin antero-laterally. For this purpose, use scissors to prepare an 80 to 100mm subcutaneous skin pocket **(Fig. 57)**.

The receiver should be in a position in which the cable is not coiled and avoids any sharp bends or kinks along the length of the cable.

PRECAUTION: Power transfer is optimal at approximately 5mm distance from the receiver. Avoid distances of more than 10mm under the skin as such distances can negatively affect the function of the treatment system.

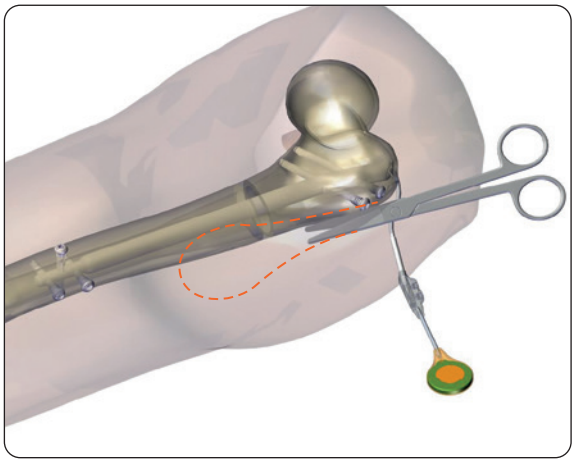


Fig. 57 Skin pocket preparation

Mark the receiver's position on the surface of the skin **(Fig. 58)**.

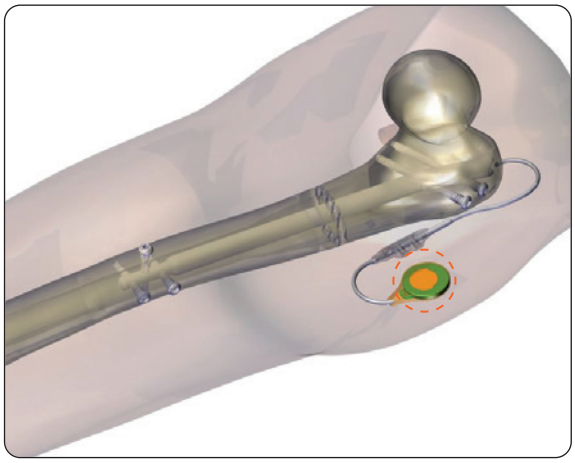


Fig. 58 Receiver final position and marking

Final Intraoperative test

Part #	Description
60001644	FITBONE CONTROL SET FOR ACTIVATION OF INTRAMEDULLARY LENGTHENING NAIL US PLUG 115V
60001562	LOHMANN&RAUSCHER RAUCODRAPE REF 15966
60000676	KAWE STETHOSCOPE 06.10100.94

Upon skin closure, perform a second intraoperative functionality test as described on page 16.

Place the transmitter and the stethoscope in separate sterile drapes, such as an endoscopic camera drape or ultrasound wand drape **(Fig. 59 and 60)**.

Fig. 59 Inserting the transmitter in the sterile drape

Perform a final functional test, ensuring the motor of the Fitbone can be heard during lengthening.

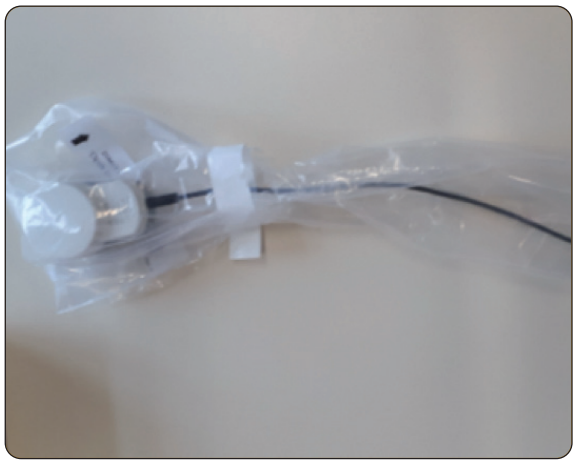


Fig. 60 Inserting the transmitter in the sterile drape

Control set settings for intraoperative test

Remove the switch cover cap from the control set. The surgeon can now choose between the patient/doctor mode, labelled "Pat" and "Doc", respectively, and pulse or permanent operation, labelled "Pulse" and "Perm", respectively **(Fig. 61)**.

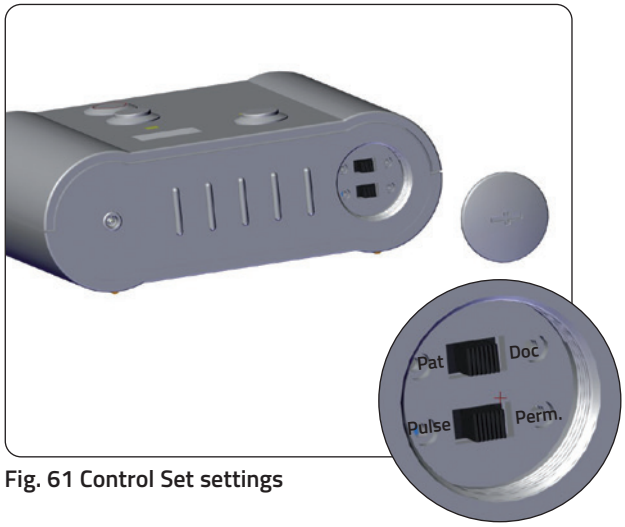


Fig. 61 Control Set settings

In the "Doc" position, the switch labelled "Doctor" on the front is enabled as well as the Pulse and Continuous modes **(Fig. 62)**.

Pressing the "Doctor" button while in the "Doc" and "Pulse" position will result in a continuous repetition of 1 second energy transmission and 9 sec break, until released.

Pressing the "Doctor" button while in the "Doc" and "Perm" position will result in a continuous energy transmission until released. This leads to a distraction rate of up to 2mm per minute. This mode can be used to preset the implant or to allow a new locking position for distal locking. Use of continuous operation mode must be interrupted after a maximum of 1 minute for a minimum of 2 minutes to prevent excessive heat in the tissue between the transmitter and receiver. In doctor mode continuous operation, the transmitter can reach a maximum temperature of 47.2 °C.

In the "Pat" position, the button labelled "Patient" on the front is enabled. In the "Pat" position, the permanent mode is blocked and will not lead to energy transmission.

Pressing the "Patient" button while in the "Pat." and "Pulse" position will result in a 90 second distraction cycle consisting of 9 repetitions of 1 second energy transmission and 9 sec pause between each distraction.

Pressing the "Patient" button while in the "Pat." and "Perm" position will not result in any energy transmission.

More information about the function and operation can be found in the instructions for use Fitbone Control Set.

For the intraoperative test, the doctor ("Doc.") and pulsating ("Pulse") settings are recommended.

For the intraoperative final test, connect the transmitter to the Fitbone Control Set and place it on the skin directly above the receiver. Place the stethoscope on the patella. In the recommended settings, press the "Doctor" button and use the stethoscope to confirm correct functioning of the motor **(Fig. 63)**.

Before handing over the Fitbone Control Set to the patient, set the switches to “Pat.” and “Pulse” and put the switch cover back in place.

Thoroughly disinfect the Fitbone Control Set surface with a cloth moistened with 70% alcohol solution before handing over the set to the patient.

PRECAUTION: Please advise your patients not to remove the switch cover from the Control Set and not to touch the switches.

Fig. 62 Control Set

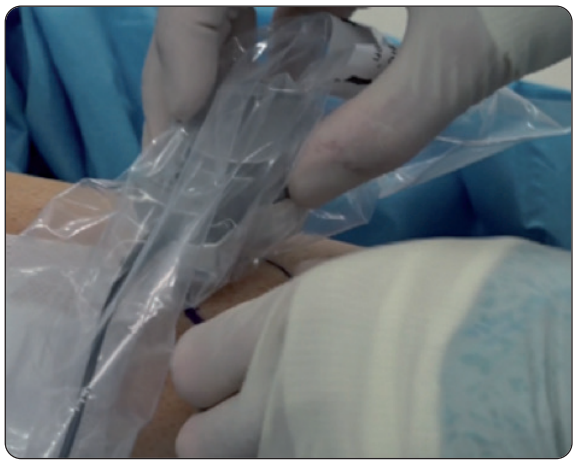
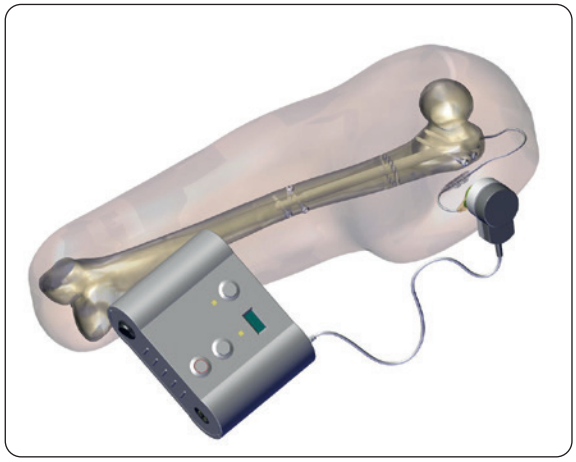


Fig. 63 Final test under sterile conditions



REMOVAL

Patient positioning

Place the patient in supine position, cover the opposite side and the foot of the leg to be operated. Leave the entire hip accessible **(Fig. 1)**.

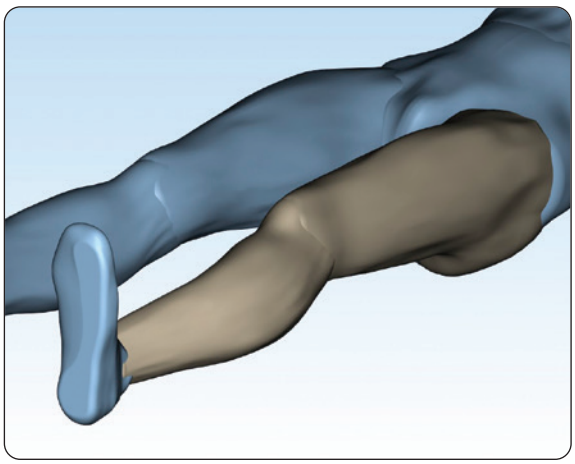


Fig. 1 Patient positioned

Nail Marking

Using a skin marker, mark the position of the nail, locking screws and blocking screws. The skin marking will aid orientation and positioning during surgery **(Fig. 2)**.

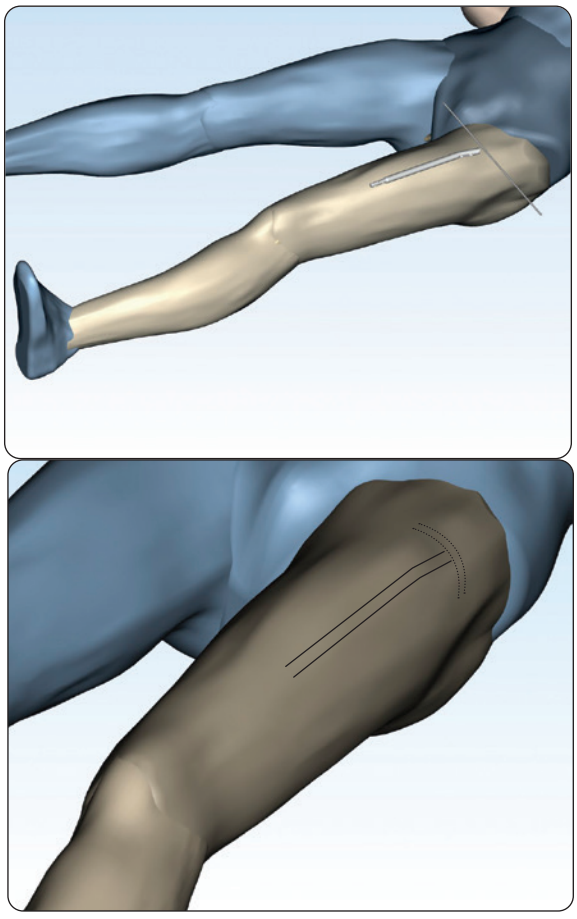


Fig. 2 External nail position

Distal and blocking screws removal

Part #	Description
700320	SHORT SCREWDRIVER
700319	SHORT SCREWDRIVER RETENTION ROD

Locate the distal screws under fluoroscopy and make a skin incision to gain access **(Fig. 3)**.

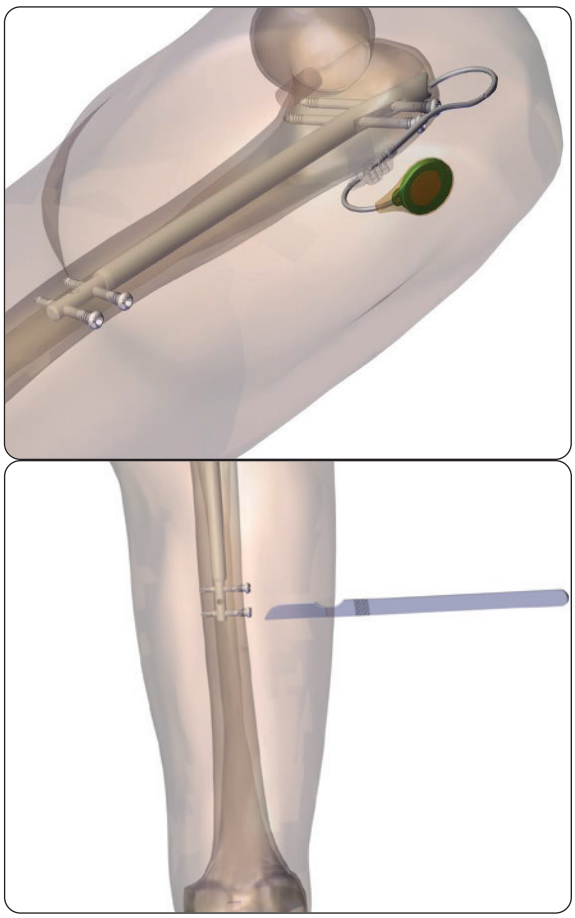


Fig. 3 Distal screws location and skin opening

If required, use a 5-8mm chisel to remove any bone obstructing access to the screws. Engage the first screw with the short screwdriver and retention rod **(Fig. 4)** and remove **(Fig. 5)**. Repate the same process to remove any

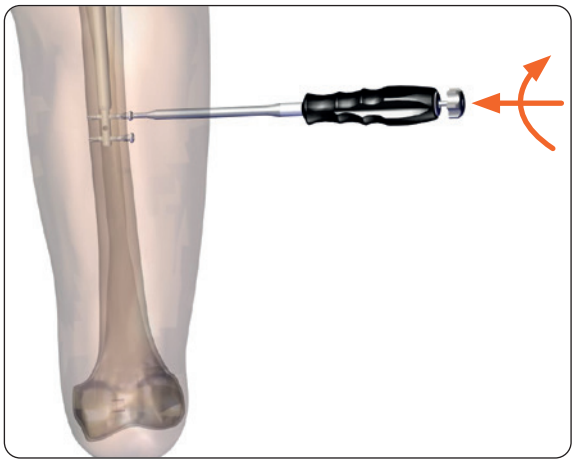


Fig. 4 Engagement of distal screw with the short screwdriver and retention rod

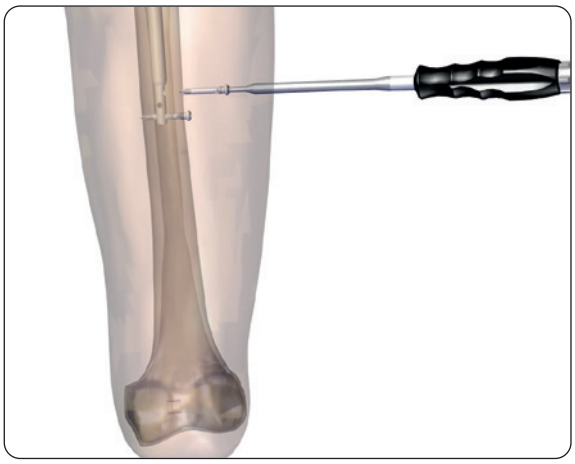


Fig. 5 Distal screw removal

Receiver removal

Part #	Description
183978	Plier Cutter D15mm

Make a skin incision along the scar of the insertion point **(Fig. 6)**.

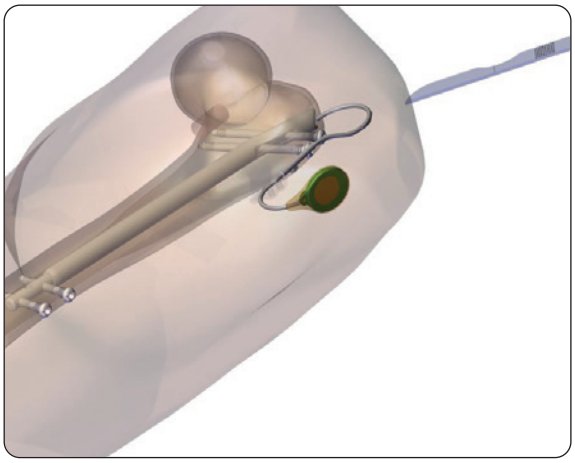


Fig. 6 Entry point incision

Locate and palpate the receiver under the skin **(Fig. 7)**.

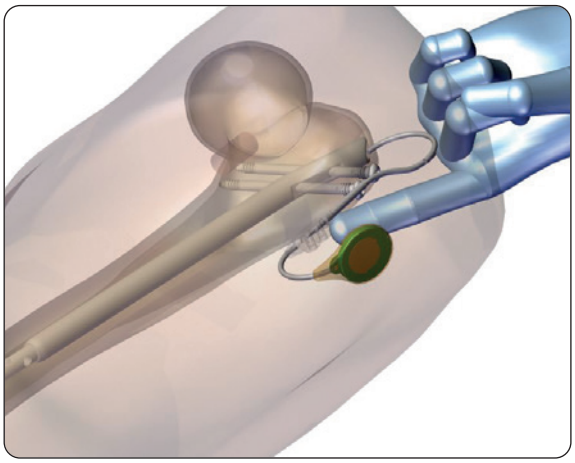


Fig. 7 Receiver location

Mobilize the coupling and remove from the skin pocket **(Fig. 8)**.

Dissection may be required to mobilize the receiver and coupling.

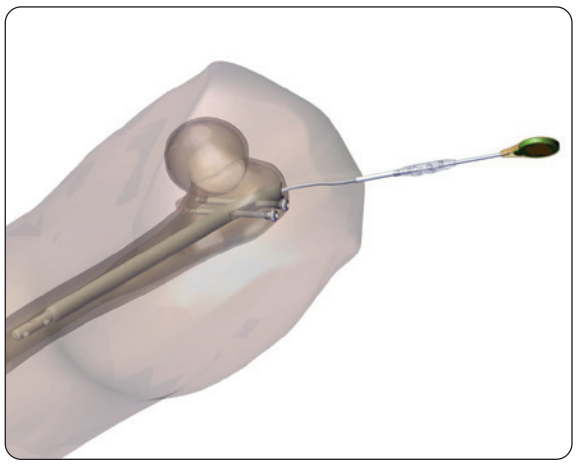


Fig. 8 Receiver extraction

Secure the cable with a clamp and cut the cable proximally before the thicker part of the silicone but distal to the clamp **(Fig. 9 and 10)**.

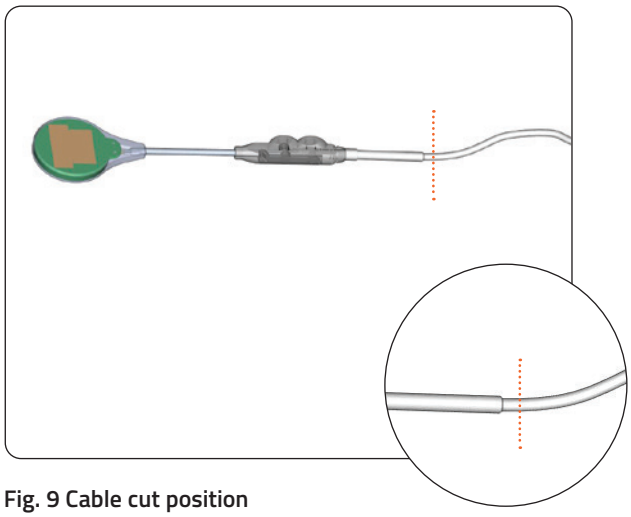


Fig. 9 Cable cut position

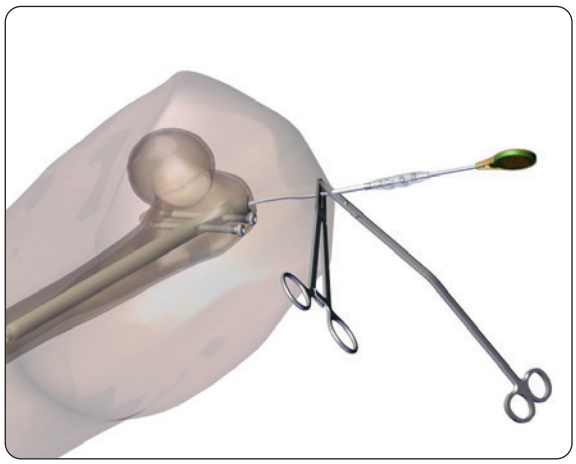


Fig. 10 Cutting the cable

Remove the coupling and the receiver **(Fig. 11)**.

Remove the clamp from the cable and secure a suture to the cable.Locate the position of the nail inside the bone. If required, use fluoroscopic guidance to assist on identifying nail location.

Perform a blunt dissection to create a soft tissue tunnel to gain access to the top of the nail.

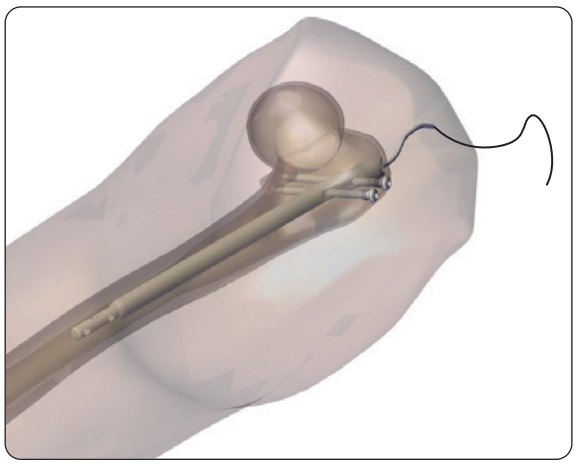


Fig. 11 Securing the cable with a suture

Pass the suture through the cannulated reamer. Take up any suture slack to guide the reamer into position. Remove any newly formed bone or soft tissue blocking nail extraction pathway **(Fig. 12)**.

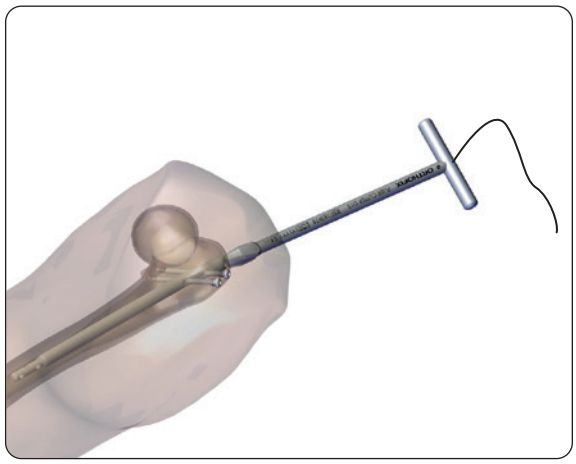


Fig. 12 Bone removal

Now proceed by connecting the nail and the Conical Mallet Adaptor.

Connecting the nail and the Conical Mallet Adaptor

Part #	Description
700336	M8 CONICAL MALLET ADAPTOR
91017	UNIVERSAL ALLE WRENCH
SMN 173370	SMN SYSTEM SLIDING HAMMER ASSEMBLY

Pass the suture and cable through the Conical Mallet Adaptor **(Fig. 13)**.

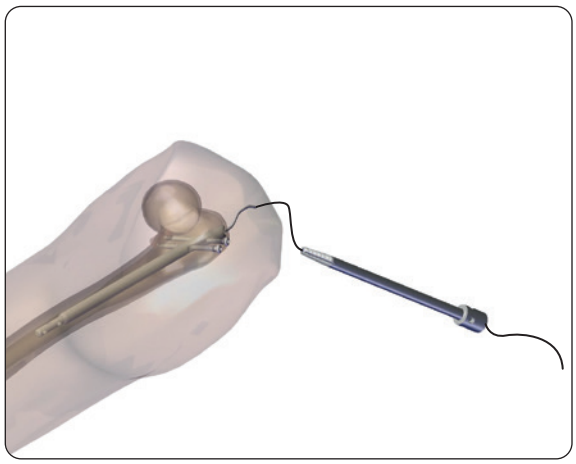


Fig. 13 Passing the cable through the conical mallet adaptor

Screw the Conical Mallet Adaptor clockwise into the nail and tighten it by using the universal Allen Wrench **(Fig. 14)**.

Check with manual movements and under fluoroscopy, that the connection bolt is fully inserted into the nail. The connection bolt and nail should appear aligned longitudinally in the AP view.

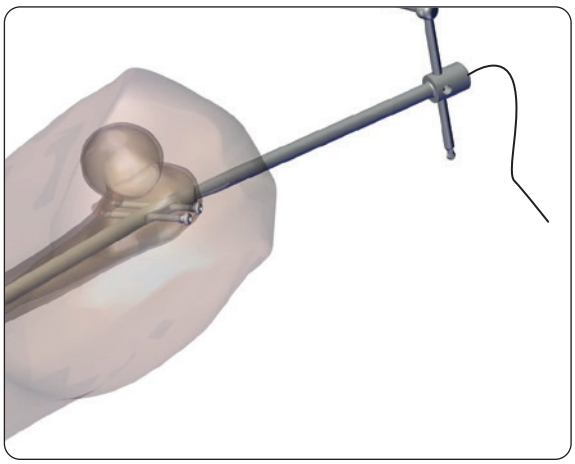


Fig. 14 Securing the Conical Mallet Adaptor

Nail extraction

Part #	Description
700320	SHORT SCREWDRIVER
700319	SHORT SCREWDRIVER RETENTION ROD

Use the short screwdriver and retention rod to remove proximal screws **(Fig. 15)**.

Partially remove the final locking screws, ensuring the nail can pass upon extraction. Do not fully remove the screws, as should the connection to the nail become compromised, the screws can be reinserted to secure the nail once again.

If required, the broken screw, stripped thread screw and damaged screw head techniques described later in the operative technique can be used.

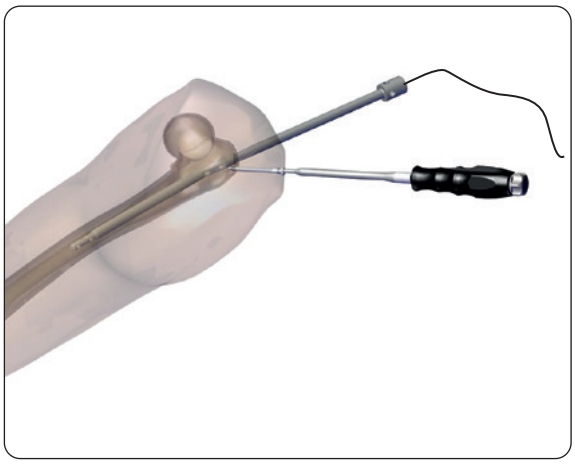


Fig. 15 Proximal screw disengagement

Connect the sliding hammer assembly to the conical mallet adaptor **(Fig. 16)**.

Use the sliding hammer to remove the nail. A combination of high repetitions and light to moderate force is advised.

Alternatively, it is possible to extract the nail with the slotted mallet by impacting the Conical Mallet Adaptor.

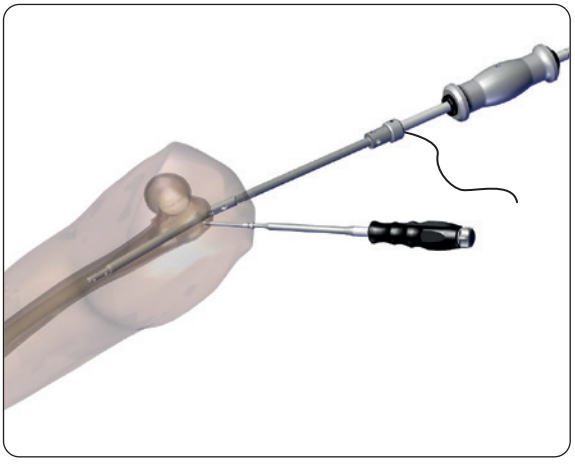


Fig. 16 Sliding hammer assembly connection and nail extraction

Upon nail extraction, fully remove the final locking screws **(Fig. 17)**.

Flush the wound to remove any debris and confirm under fluoroscopy.

Perform a final check under fluoroscopy to ensure the site is free from debris.

Perform a layered skin closure of all surgical sites.

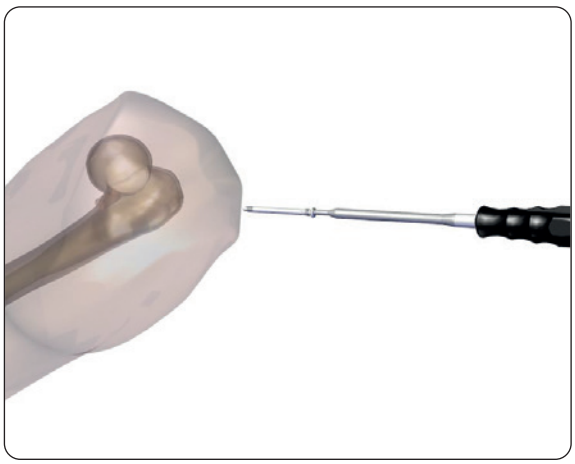
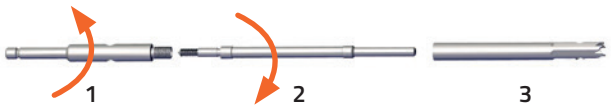


Fig. 17 Fully screws removal

DAMAGED SCREW REMOVAL

Part #	Description
700320	SHORT SCREWDRIVER
700319	SHORT SCREWDRIVER RETENTION ROD
700501	HOLLOW REAMER D4.5MM
177380	SLOTTED MALLET
700503	SCREW HOLDER
183337	SCREW EXTRACTOR SIZE 3.5-9MM

Screw removal – broken screw



1. Shaft
2. centering pin
3. Reamer tube

Disengage the screw extraction sleeve **(Fig. 19)**, remove the centering pin (component 2), and connect the shaft (components 1) and the reamer tube (component 3) to each other **(Fig. 20)**.

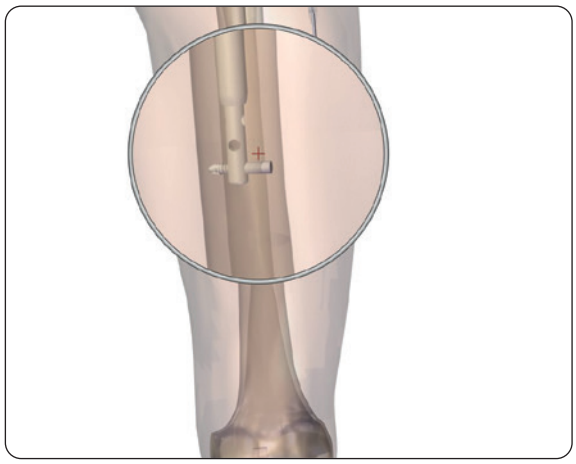


Fig. 18 Broken screw

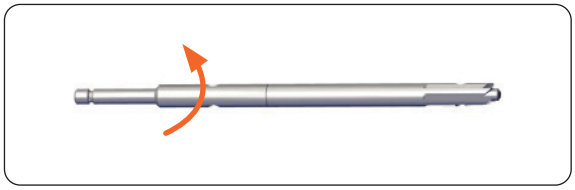


Fig. 19 Screw extraction sleeve disengagement

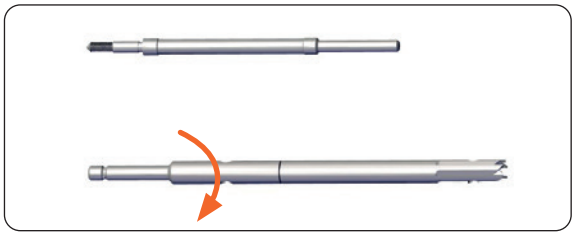


Fig. 20 Preparation of instrument components

Connect components 1 and 3 to the drill **(Fig. 21)**.

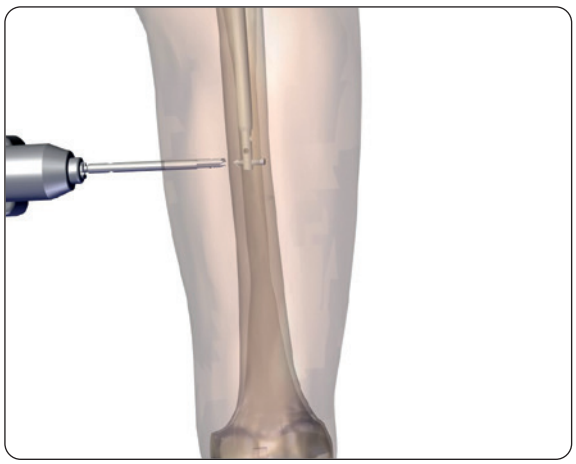


Fig. 21 Connection to the drill bit

Carefully, approach the screw from the medial side. Place the hollow reamer over the tip of the screw and advance the reamer over the screw. Open the bone until reaching the broken screw **(Fig. 22)**.

Disconnect the shaft (component 1) from the drill and leave the reamer tube (component 3) in place. Component 2 can now be inserted into component 3 and will move independently.

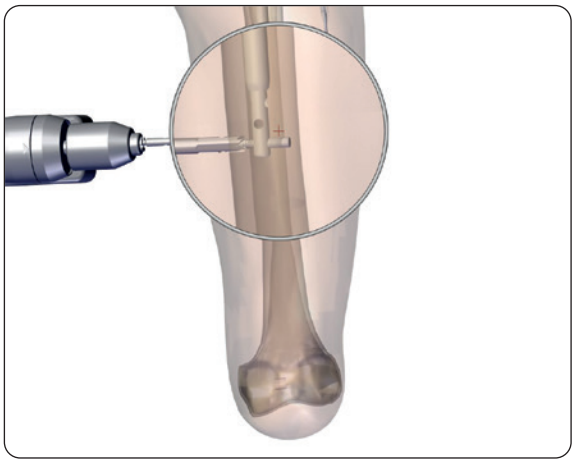


Fig. 22 Bone opening

Using a mallet and pliers, advance component 2 to push out the broken screw through the lateral side **(Fig. 23a,b and c)**.

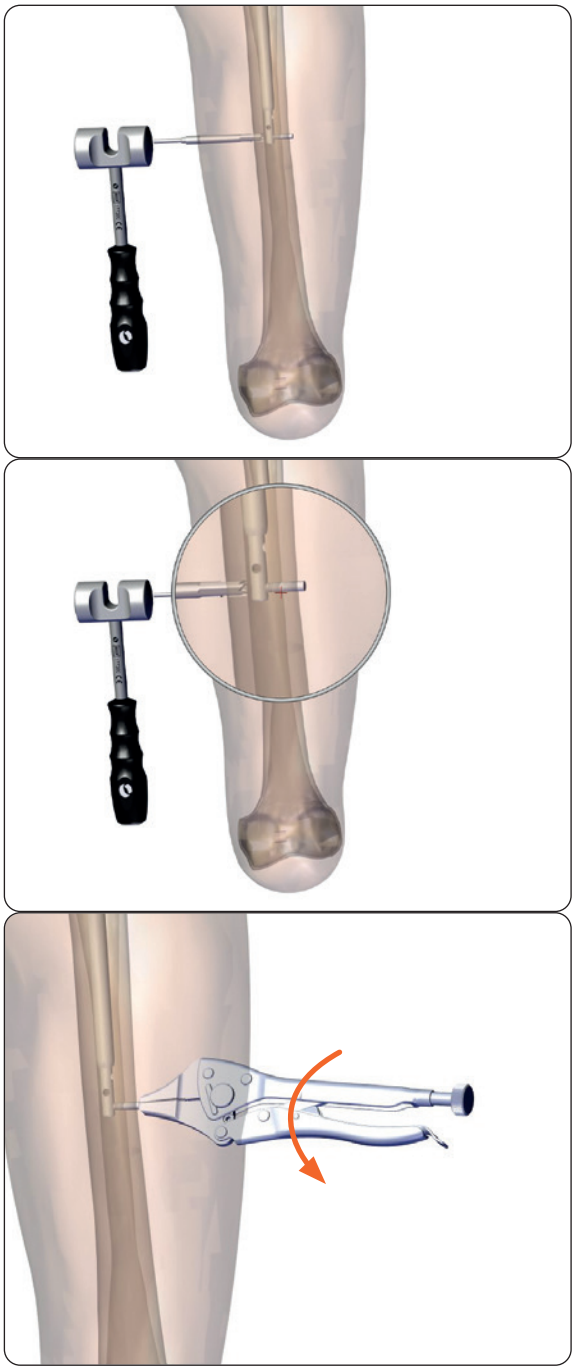


Fig. 23a, 23b, 23c Broken screw head removal

Screw removal – stripped thread

In the instance of a stripped thread screw, the screw holder **(Fig. 24)** can be used to engage and remove the screw.

Fig. 24 Screwdriver and screw holder

With the screwdriver in place, advance the screw holder down the shaft of the driver and engage the screw head by sliding the teeth of the holder between the bone and screw head **(Fig. 25)**.

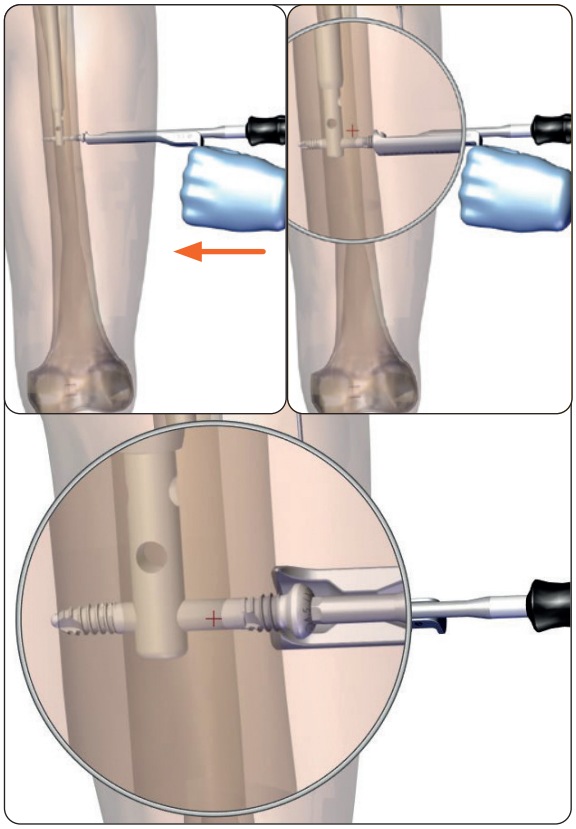


Figure 25 Stripped screw engagement

Remove the screw **(Fig. 26)**.

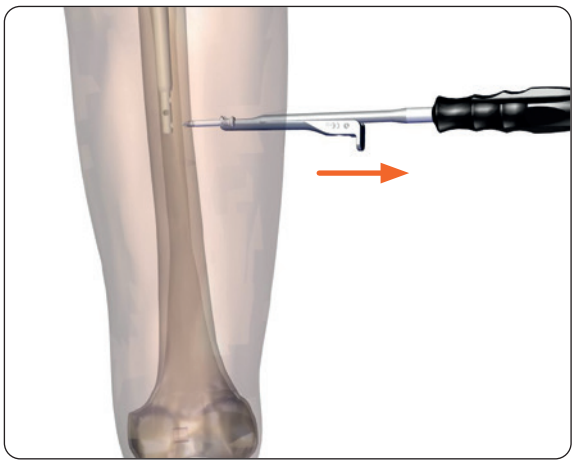


Fig. 26 Stripped screw removal

Screw removal - damaged screw head

In the instance of a damaged screw head, use the screw extractor to engage the screw and remove **(Fig. 27)**.

Rotate the screw extractor anti-clockwise to engage the screw head. Continue to rotate in the same direction to remove the screw.

Remove any blocking screws if present.

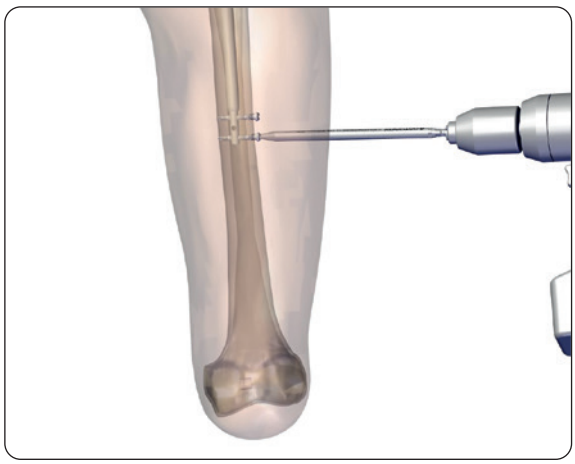


Fig. 27 Screw extractor

Please refer to the "Instructions for Use PQFBT, PQFBP and PQFBR" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, possible adverse events, MRI (Magnetic Resonance Imaging) safety information and sterilization.

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