OPERATIVE TECHNIQUE

Fitbone™

Intramedullary Lengthening System

Fitbone TAA Retrograde Femur Application

ORTHOFIX®
ORTHOPEDICS

Fitbone™

Intramedullary Lengthening System

Table of Contents

The principles of the described operative technique and instruments are based on ideas of Professor Rainer Baumgart MD (trauma surgeon and engineer) and his personal experience of more than 2000 implanted Fitbone (Fitbone hereinafter) distraction nails.

Orthofix wishes to thank Professor Baumgart for his contribution to the development of this operative technique.

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 see the Clinician Guide for the complete list of indications, warnings, precautions, and other important medical information.

SURGERY PLANNING - FEMUR RETROGRADE

Pre-operative preparation

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

- Anamnesis
- 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).

The Reverse Planning Method (RPM) described by Baumgart* can be used for pre-operative planning. When using a nail for lengthening the femur, the lengthening occurs close to the anatomical axis and will result in axis deviation and distal femoral valgus, affecting the overall alignment of the entire limb if not compensated for. The RPM will help the surgeon in the pre-operative planning of the acute deformity correction and lengthening.

The osteotomy site is determined pre-operatively from the X-rays according to the required deformity correction and the curvature in the lateral plane.

At least 65mm of the telescopic housing of the nail **(lmin, see Fig. 1)**, must be within the distal bone fragment, at the end of lengthening.

The minimum length of the implant to be selected can be calculated using the following formula:

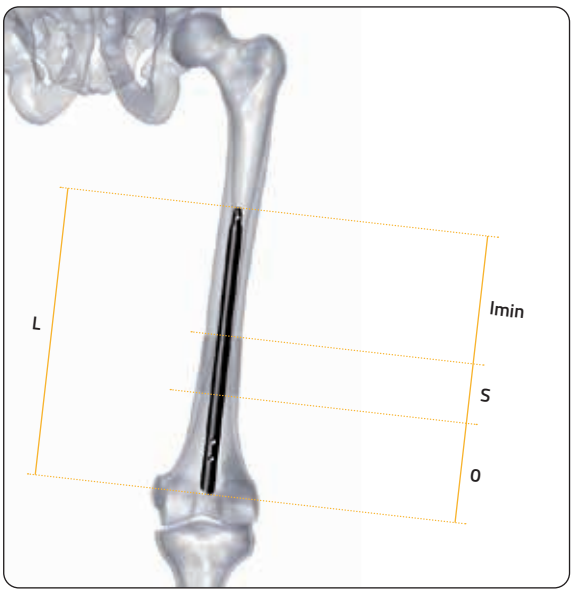
lmin = L - S - O

lmin is the distal portion of the telescopic housing of the nail that needs to be within the distal bone fragment upon complexation lengthening. Characteristics of the patient and the bone (e.g. curvature) should also be taken into consideration when selecting the nail length to ensure sufficient coverage of the telescopic part after lengthening.

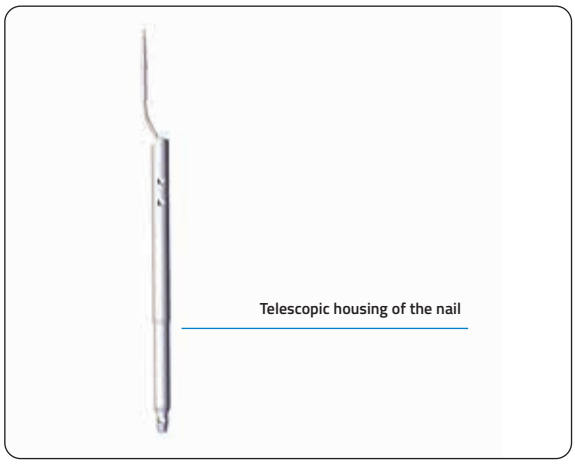
S is the amount of lengthening planned.

O is the distance from the osteotomy site to the nail insertion site at the knee. The sum of these numbers equals the minimum total nail length.

Maintain a distance of at least 10mm between screw (locking or blocking) and osteotomy.



(a)



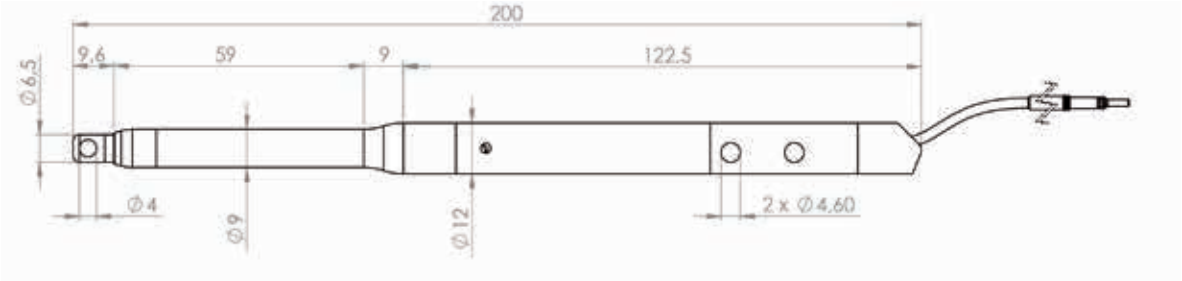
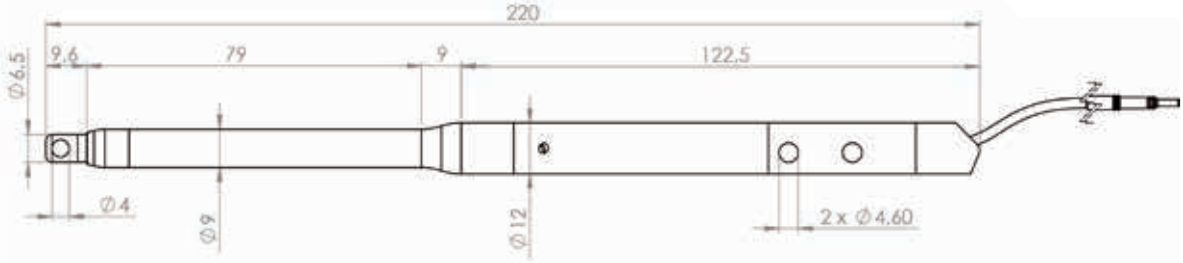
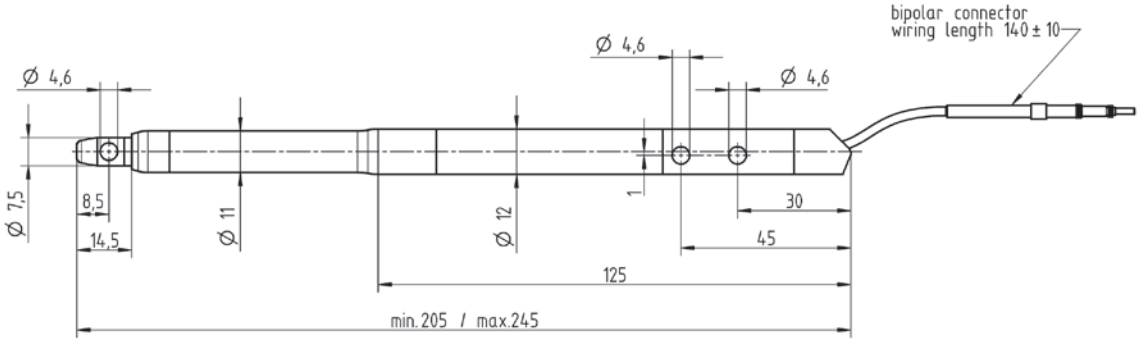
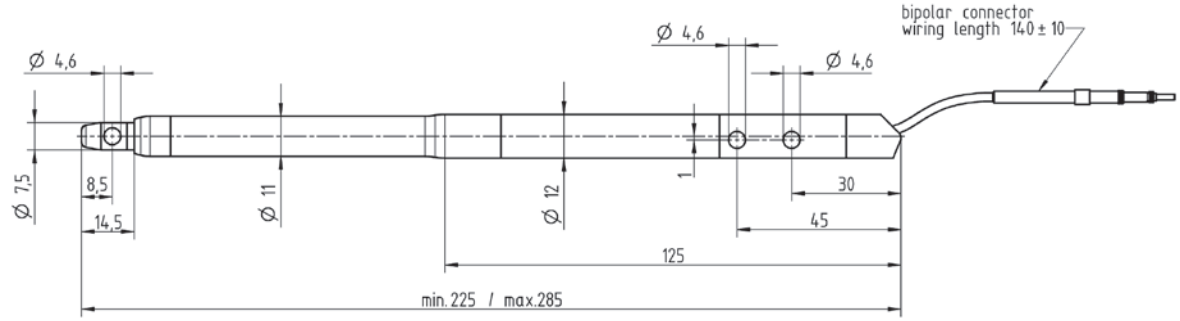
(b)

Fig. 1 Representation of O, S, L and lmin (a); Telescopic housing of the nail (b)

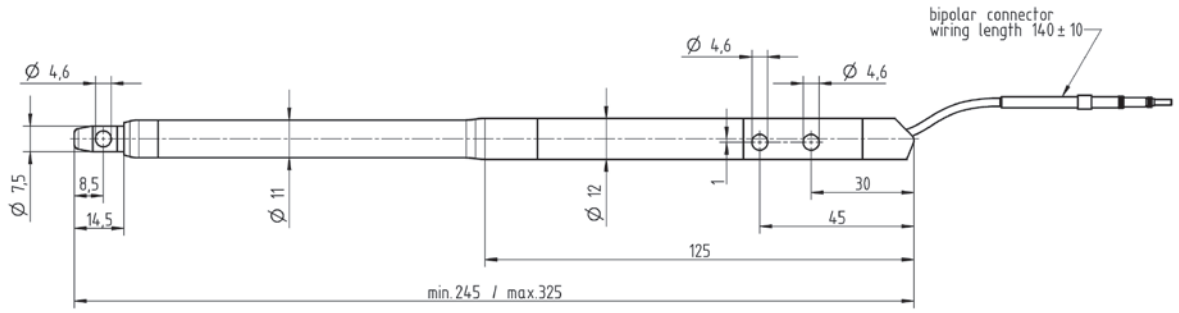
* *Baumgart R: The Reverse Planning Method for Lengthening of the Lower Limb Using a Straight Intramedullary Nail with or without Deformity Correction- A New Method, Oper Orthop Traumatol 2009, No. 2: 221-233.*

The following variants of the implantable Fitbone system components are CE marked.

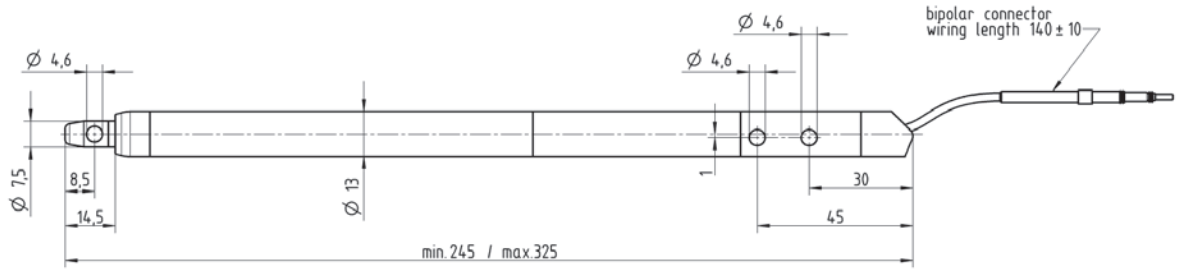
Fitbone TAA Intramedullary Nail Types

Part #	Fitbone TAA variants	Initial total length (mm)	Diameter (mm)	Stroke (mm)	Max Total length after distraction (mm)
		Femur Variants			
60001921 (OUS & US)	TAA0940-F-200	200	9	40	240
					
60001764 (OUS & US)	TAA0960-F-220	220	9	60	280
					
60001383 (OUS) 60001383-00-0 (US)	TAA1140-F-205	205	11	40	245
					
60001468 (OUS) 60001468-00-0 (US)	TAA1160-F-225	225	11	60	285
					

Part #	Fitbone TAA variants	Initial total length (mm)	Diameter (mm)	Stroke (mm)	Max Total length after distraction (mm)
		Femur Variants			
60001404 (OUS) 60001404-00-0 (US)	TAA1180-F-245	245	11	80	325



60001422 (OUS) 60001422-00-0 (US)	TAA1380-F-245	245	13	80	325



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

Long-standing radiographs (LSR) are routinely used for analysing 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 pathological positioned
- Limb length discrepancy should be compensated
- 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 is able to remain still during the scan.

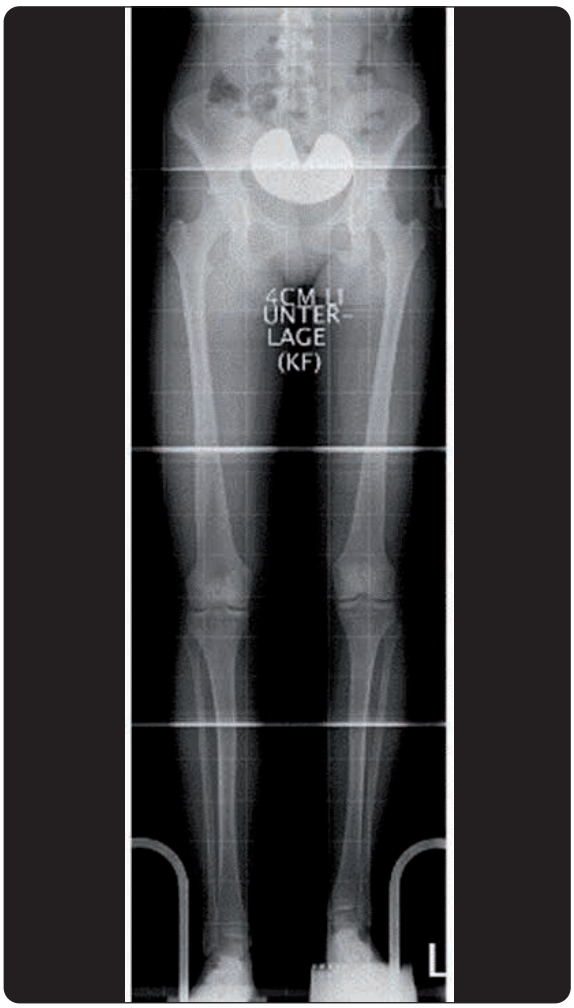


Fig. 2 Long-standing X-ray

SURGERY

Grid Plate (60001464)

The GRID plate is recommended in Fitbone surgeries to ensure the correct limb alignment and deformity correction during the surgery and for the final result. It consists of a plastic plate with transverse and longitudinal non-radiolucent metal wires that can be easily seen under x-rays. The GRID plate is placed on the operating table underneath the cushion. Never put the GRID plate under the patient directly without padding. The material can crack and lead to injury if the GRID plate does not rest flat over the entire surface. It has two double metal wires placed longitudinally. The hip and ankle joints, along with the patella, can be positioned along the lines to achieve correct alignment.

Technical features

Material: Pertinax RI4 0000 (Hartpapier) PF CP 201 HP 2061

Dimensions: 376mm x 1282mm
Space between longitudinal and transverse wires: 50mm
Space between the double wires: 1mm (shown in bold in the image 3)

Fig. 3 GRID Plate

Patient positioning

Place the GRID plate directly on the radiolucent table, secure it centrally and cover it completely with the padding.

Place the patient in supine position and cover on the opposite side completely, leaving the leg to be operated on uncovered and free to move.

Make sure that the C-arm can reach hip joint without coming into contact with the pillow on 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 beam path perpendicular to the surface of the plate. The double line must be located exactly in the center of the screen for the evaluation at all time. By placing the double line in the center, parallax errors are minimised.
To measure the alignment (not under load), position the patient´s hip joint on the double line with patella faced forward.

Move the C-arm longitudinally towards the ankle joint, placing it on the double line as well, maintaning the patella facing forward.

Keep the leg in position and move the C-arm longitudinally towards the knee joint to measure the distance between the center of the knee joint to the double line. **(Fig. 5)**

Compare the alignment with preoperative planning. If the alignment matches that of the pre-operative plan, then proceed with surgery.

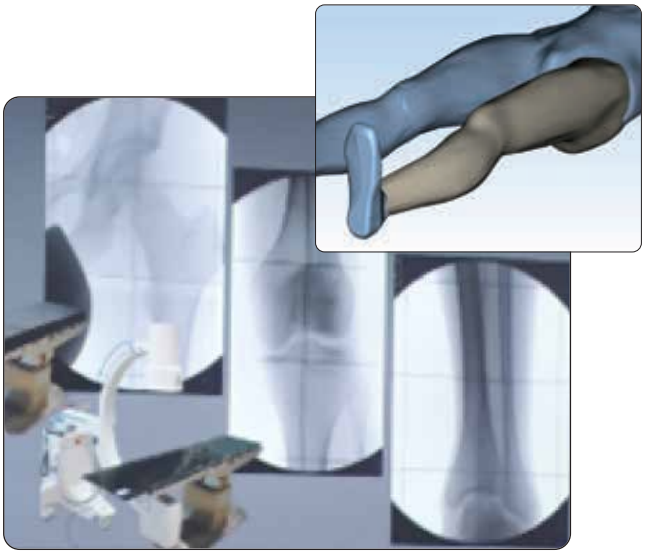


Fig. 4 Patient positioning

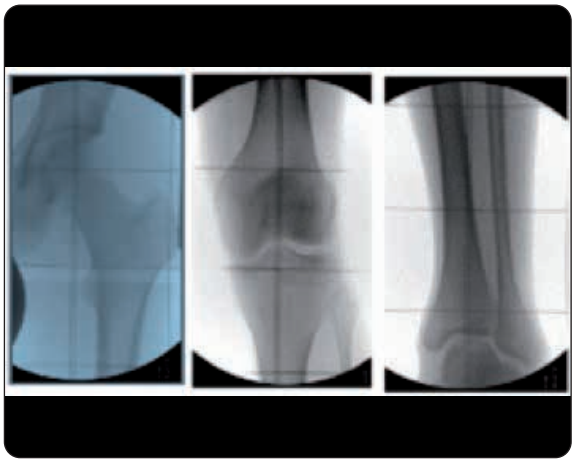


Fig. 5 Hip, knee and ankle joint position

Patient marking

With the image intensifier, locate the knee joint line using a wire placed over the skin.

Mark the level of the knee joint on the skin using a surgical skin marker. **(Fig. 6)**

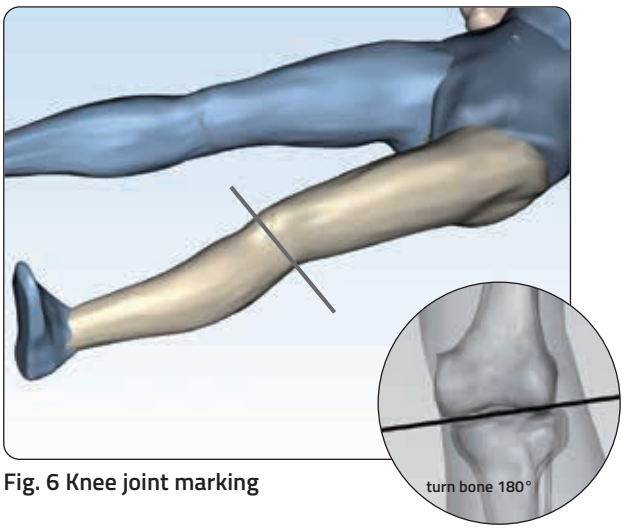


Fig. 6 Knee joint marking

The dummy nail is a trial nail that has the same geometry as the Fitbone nail but has no motor and no cable.

Place the dummy nail correctly over the femur and mark the proximal end on the skin, ensuring the distal end of the nail is marked 1cm proximal (depth) to the intercondylar notch.

Mark the end of the nail and the osteotomy level according to the pre-operative plan (e.g. RPM) with the pen and, in addition, with a surgical stapler **(Fig. 7)**. Optionally, the change in diameter of the nail can also be marked. **(Fig. 7)**

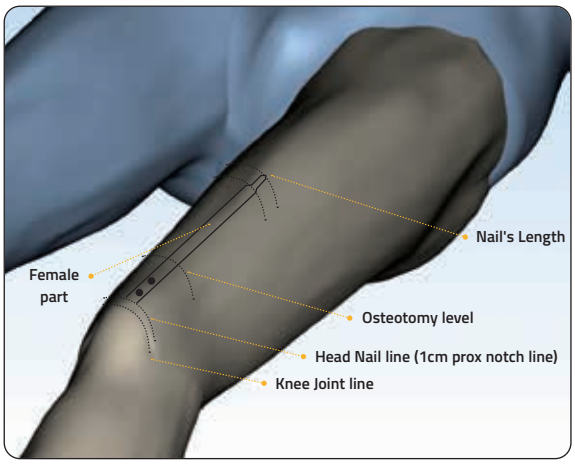


Fig. 7 Osteotomy and nail position marking

Insertion bone of screws for torsion control

Insert two 4.5 or 5mm bone screws, to ensure correct torsional alignment.

Insert the first screw in the supracondylar region of the femur, parallel to the distal and dorsal level of the knee joint, posterior to the path of the nail. **(Fig. 8)**

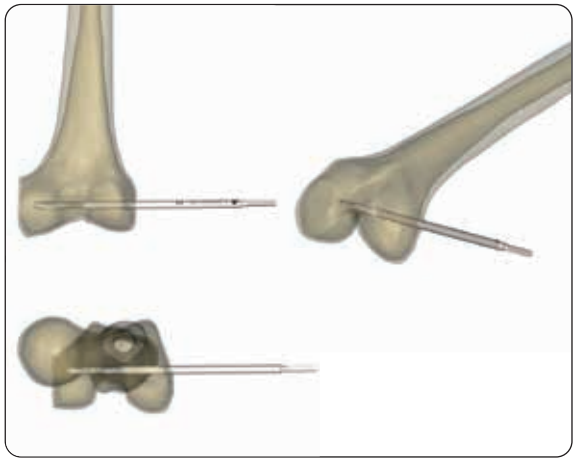


Fig. 8 Distal bone screw position

The second screw is inserted in the proximal femur, at the level of the lesser trochanter, parallel to the first screw if torsional corrections are not needed. **(Fig. 9)**

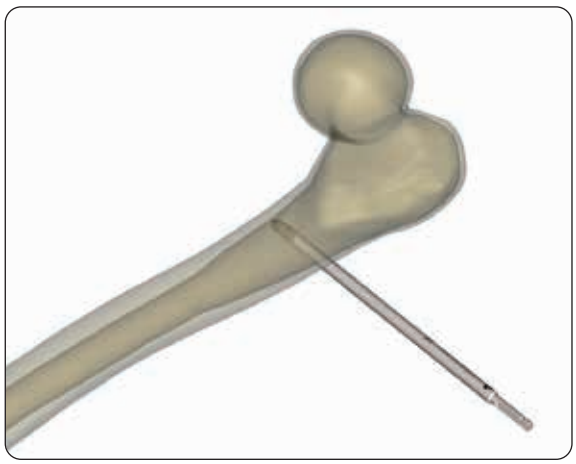


Fig. 9 Proximal bone screw position

To ensure torsional alignment, the distal screw should be inserted in relation to the proximal screw and at the torsional correction angle required. Post correction should see both screws parallel. **(Fig. 10)**

These screws should be used as reference points for checking and manipulating the bone fragments.

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 intramedullary lengthening nail into the medullary canal.

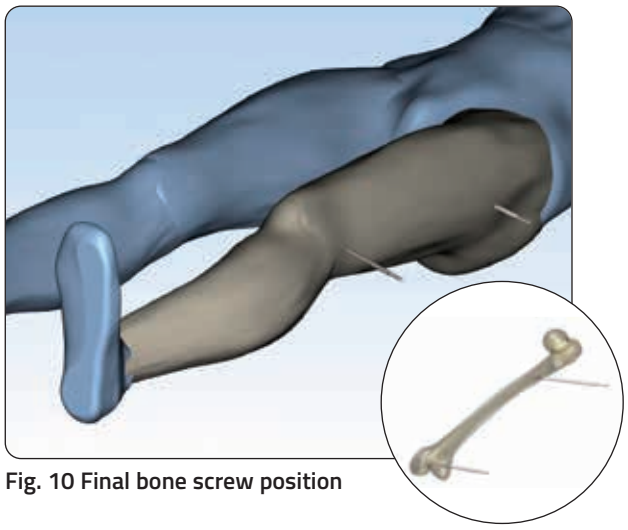


Fig. 10 Final bone screw position

APPROACH AND INITIAL REAMING

A sufficiently sized sterile covered removable support **(Fig. 11)** should be used to maintain the knee flexed at about 30° during the following surgical procedure.

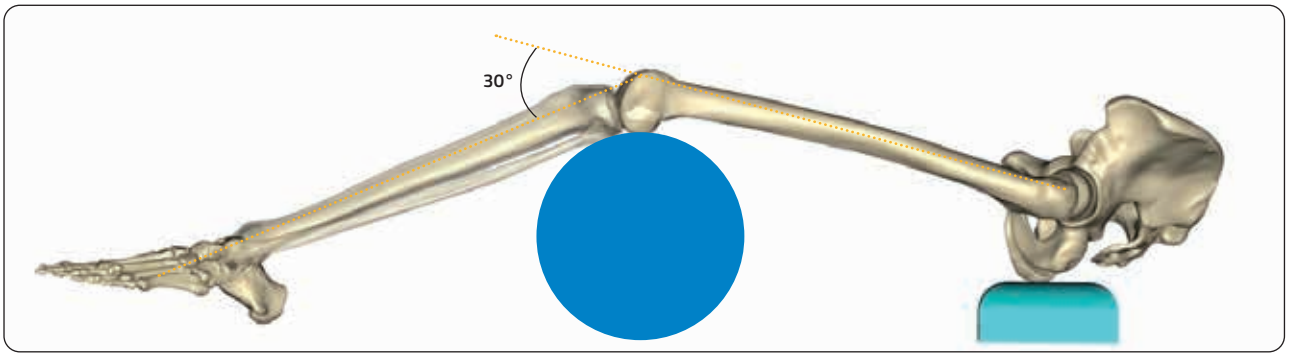


Fig. 11 Patient positioning

Make a 20mm transverse skin cut between lower border of patella and tuberosities. Split patella tendon longitudinally.

K-wire entry point

With the knee in 30° flexion **(Fig. 11)**, insert the 3mm K-wire in the centre of the intercondylar notch in AP view **(Fig. 12)** and in the center of the femoral axis in lateral view. Direct the K-wire according to your planning. Double-check position with the C-arm AP and lateral.

The choice of the entry point for the Fitbone TAA intramedullary lengthening nail and the reaming direction up to the osteotomy site will determine the axial alignment.

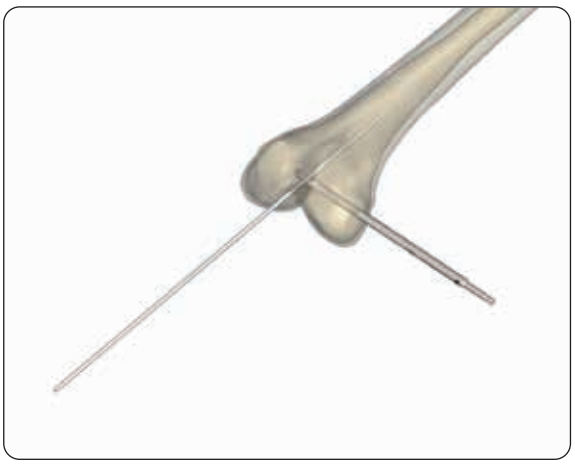


Fig. 12 K-wire entry point

Cones and tubes

Cones and tubes are recommended to perform minimally invasive and accurate reaming.

Cones

If K-wire positioning is correct, insert the centered cone C13 or C15. If the position of the K-wire has to be corrected, use C13+, C15+ or C13++ or C15++ to correct 1 or 2mm in any direction. A notch at the end of the cone will help achieve the correct orientation. If correction of more than 2mm is needed remove and re-insert the K-wire in the corrected position. Optionally, before inserting the cone over the K-wire, slide the working tube T14/13 or T16/15 over the cone. **(Fig. 13)**

Cones insertion

For insertion of the cone use the cone sinker CS 15-13 and hammer the tip of the cone into the bone **(Fig. 14)**. The cone should be inserted at least up to the depth of the teeth to ensure stable positioning. The hexagonal shape of the tip will prevent the cone slipping backwards and in the case of eccentric cone, prevent the cone rotating loose.

PRECAUTION: do not directly hammer the cone because that will damage the cone end and tubes will not slide on the cone as required.

REF	Cone Sinker	REF	Cone	REF	Working Tube
60001036	CS 15-13	60001028	C13	60001014	Tube T14/13
		60001029	C13+		
		60001030	C13++		
60001036	CS 15-13	60001060	C15	60001050	Tube T16/15
		60001061	C15+		
		60001062	C15++		

Table 1. Cones, Cone Sinker and Working Tube assembly

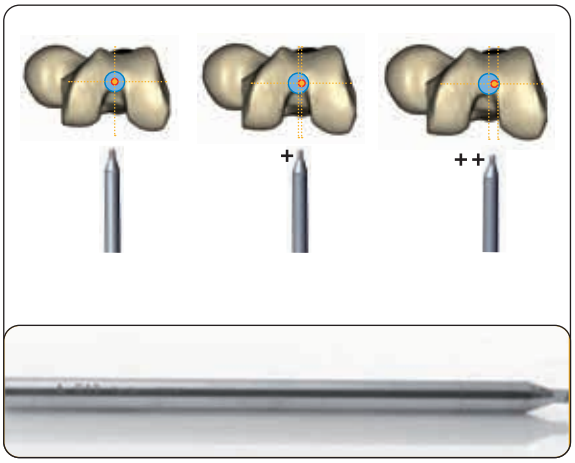


Fig. 13 Cone types entry point C13, C13+ and C13++

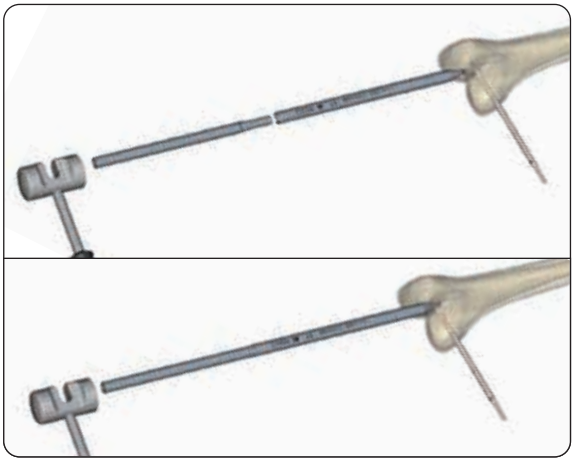


Fig. 14 Cone insertion

Tubes

The Fitbone Tubing System has several key functions to assist in delivering a successful surgery. The tubes protect soft tissues, guide the reamers along the planned alignment, assist in the removal of reamed bone debris and protect the bone canal once reamed.

In order to guide the reamers along the planned alignment, tubes are placed in sequence inside one another.
Table 2 provides an overview of which tubes should be used with each reamer.

Please note that at least 1mm space is needed between the reamer and the inner diameter of a tube to prevent material from blocking the reamer while reaming.

There are four different tube lengths S (Small), M (Medium), L (Large) and XL (Extra Large). **(Fig. 15)**

NOTE: depending on the Set provided, not all tubes may be available.

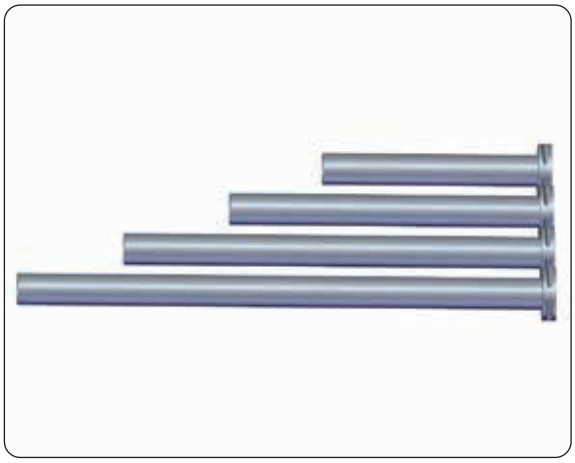


Fig. 15 Tubes (S, M, L and XL)

Tube	S REF	M REF	L REF	XL REF	Reamer	Front cutting reamer REF	Rounded Reamer REF
Tube T12/09	60001048	60001018	60001022	60001026	Reamer D8.0		60000411
Tube T12/10	60001047	60001017	60001021	60001025	Reamer D9.0	60000412	60000413
Tube T12/11	60001046	60001016	60001020	60001024	Reamer D10.0	60000414	60000415
Tube T13/12	60001045	60001015	60001055	60001059	Reamer D10.5		60000416
					Reamer D11.0	60000417	60000418
Tube T14/13	60001044	60001014	60001054	60001058	Reamer D11.5		60000833
					Reamer D12.0	60000419	60000420
Tube T15/14	Not available	60001051	60001053	60001057	Reamer D12.5		60000716
					Reamer D13.0	60000421	60000422
Tube T16/15	Not available	60001050	60001052	60001056	Reamer D13.5		60000423

Table 2. Tubes and Reamers assembly

Working tube insertion

Use the tube-sinker to insert the tube through the femoral notch **(Fig. 16, 17)**, according to **Table 3**.

For the TAA09 and 11 nails, Tube14/13 must be used (Short or medium as available)

For the TAA13 nail, Tube 16/15 must be used (Short or medium, depending on availability)

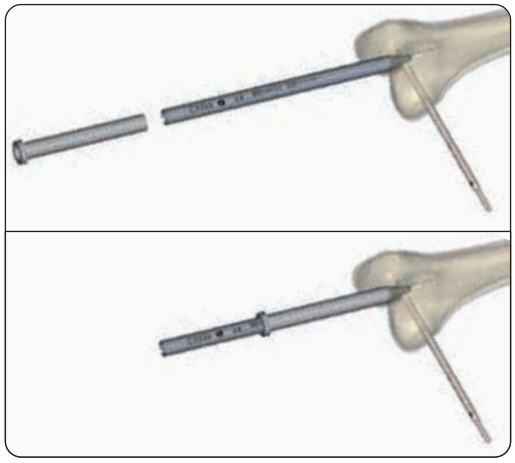


Fig. 16 Working Tube insertion

Tube	S REF	M REF	L REF	XL REF	Tube Sinker	REF
Tube T12/09	60001048	60001018	60001022	60001026	TS 13	60001033
Tube T12/10	60001047	60001017	60001021	60001025		
Tube T12/11	60001046	60001016	60001020	60001024		
Tube T13/12	60001045	60001015	60001055	60001059		
Tube T14/13	60001044	60001014	60001054	60001058		
Tube T15/14	Not available	60001051	60001053	60001057	TS 15	60001064
Tube T16/15	Not available	60001050	60001052	60001056		

Table 3.

Fig. 17 Working Tube insertion

The working tube should be inserted approximately 5-10mm, making sure the tube is stable into the intercondylar notch and the insertion angle of the reamer is orientated according to your planning. **(Fig. 18)**

The working tube will stay in place as long as the leg is in a 30° position.

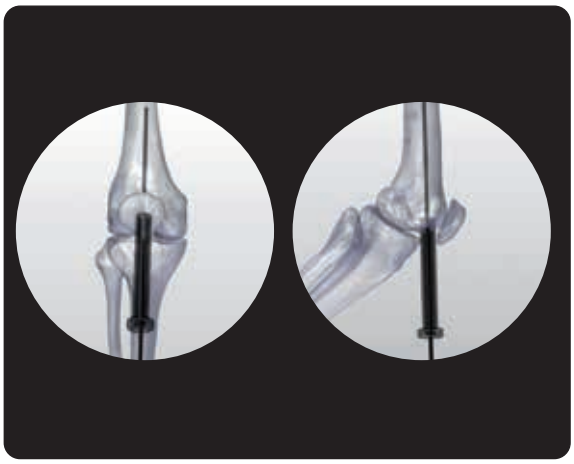


Fig. 18 Tube final position (AP and lateral views)

Remove the cone and the K-wire, leaving the working tube in place. **(Fig. 19)**

WARNING: if an eccentric cone has been used, do not rotate it while removing.

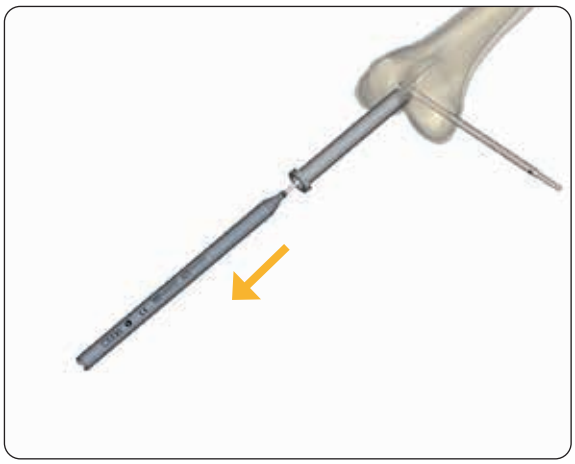


Fig. 19 Cone and k-wire removal

INITIAL REAMING

The Fitbone System includes two different types of reamers **(Fig. 20)**:

1. Rounded reamer
2. Front cutting reamer

The rounded reamers have a cutting length of 200mm and are used to open and straighten the medullary cavity. To secure the entry point at all times and to avoid unintended displacements, the use of tubes is strongly recommended.

The front cutting reamers with a cutting length of 100mm make it possible to open and correct the medullary cavity reaming in any direction.

WARNING: there is a risk of excessive cortical weakening and even perforation, leading to a fracture during treatment, particularly with the front cutting reamers.

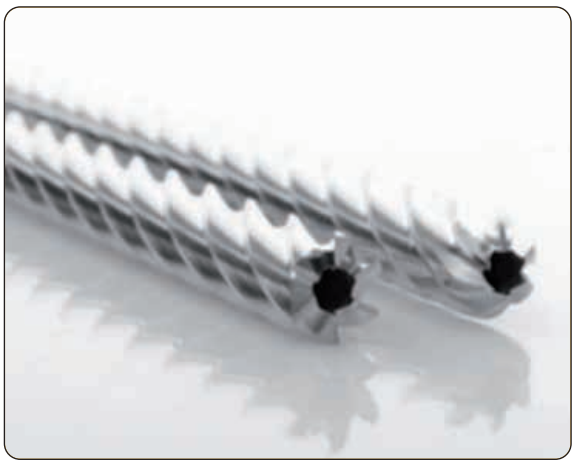


Fig. 20 Front cutting reamer (Left), rounded reamer (Right)

Venting

If required, venting holes can be drilled to reduce pressure and allow bone debris to exit. This can be done either at this stage or later in the procedure.

PRECAUTION: monitor the entire reaming process with the image intensifier in two planes to detect any reaming errors in time.

PRECAUTION: never use reamers with a flexible shaft as this can lead to unnecessary weakening of the wall or cause the Fitbone TAA intramedullary lengthening nail to jam later.

REAMING STEPS

- Ream up to the osteotomy
- Perform osteotomy
- Ream to the final tip position of the nail
- Perform final ream with step reamer

These steps allow acute correction according to preoperative-plan if needed. **(Figure 21)**

NOTE: it is very important to follow the reaming steps mentioned above in order to avoid breaching the posterior cortex.

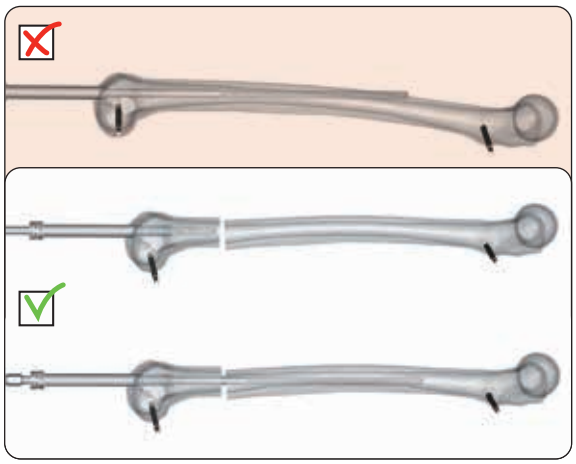


Fig. 21 Reaming with rigid reamers

PREPARATION OF THE DISTAL MEDULLARY CAVITY PRIOR TO OSTEOTOMY

Open the notch with a 12mm front cutting reamer through the working tube about 2cm into the bone.

Reduce tube diameter for concentric reaming by inserting the tubes T13/12 and T12/09 or T12/10. Ream with a 8mm or 9mm rounded reamer up to the planned osteotomy assisted by AP and lateral fluoroscopy.

For TAA 09 and 11, continue with 10mm, 11mm and finally with 12mm reamer, changing the inner tubes corresponding to the reamer in use, see also **Table 2**. **(Fig. 23)**

For TAA 13, continue with 10mm, 11,mm, 12mm and finally with the 13mm reamer, changing the inner tubes corresponding to the reamer in use, see also **Table 2**. **(Fig. 23)**

There is also a 13.5mm reamer available if required.

Double-check the canal after each reaming with AP and lateral fluoroscopy.

NOTE: the inner diameter is the smallest number and the outer diameter the largest, e.g. 13/12 means 13mm outer and 12mm inner diameter.

(If needed, a L or an XL tube can be used up to the osteotomy level to protect the distal bone fragment when reaming the diaphysis later on).

NOTE: Where there is minimal antecurvature and in cases where no deformity correction is required, a single stage reaming technique to the tip of the nail can be performed prior to osteotomy. If using this technique, the creation of venting holes prior to reaming is highly recommended.

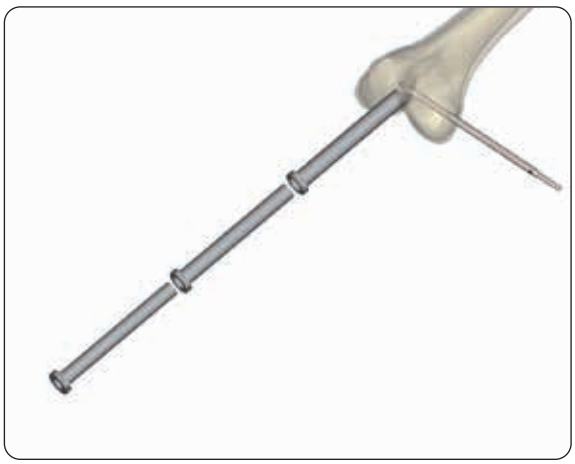


Fig. 22 Reducing the reaming channel

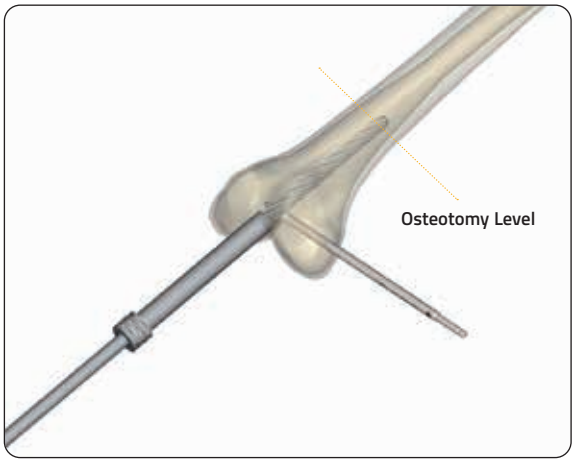


Fig. 23 Reaming up to the osteotomy

OSTEOTOMY

Perform percutaneous osteotomy at the previously marked level. **(Fig. 24)**

The use of a tissue protector sleeve while drilling the osteotomy is recommended.

Once the osteotomy has been performed, manipulate the limb into the correct alignment according to the pre-operative plan (RPM).

Keep the reference bone screws parallel, assuming the steps on **page 6** have been followed as suggested.

After reaching the pre-planned position, maintain by hand or with the osteotome in place. An external fixator can be attached to the screws to retain the corrected alignment.

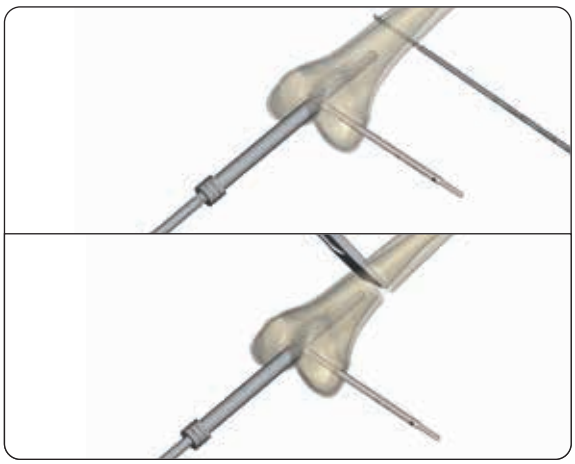


Fig. 24 Osteotomy

PROXIMAL REAMING AND STEP REAMER

Upon completion of osteotomy and bone correction, begin reaming of the proximal fragment.

If required, insert an XL tube across the osteotomy and into the proximal fragment. This will assist in holding the proximal fragment in the pre-planned position and provide protection to the previously reamed distal bone when performing proximal reaming.

Following the same process as before, ream the proximal segment to the planned tip of the nail, as indicated by the skin marker **(Fig. 25)**.

For TAA09, ream up to 9mm only.

For TAA11, gradually ream from 8mm or 9mm up to 11mm using rounded reamers.

For TAA13, gradually ream from 8mm or 9mm up to 13mm, using rounded reamers.

Reaming can also be performed by hand, using the T-handle in order to have more control.

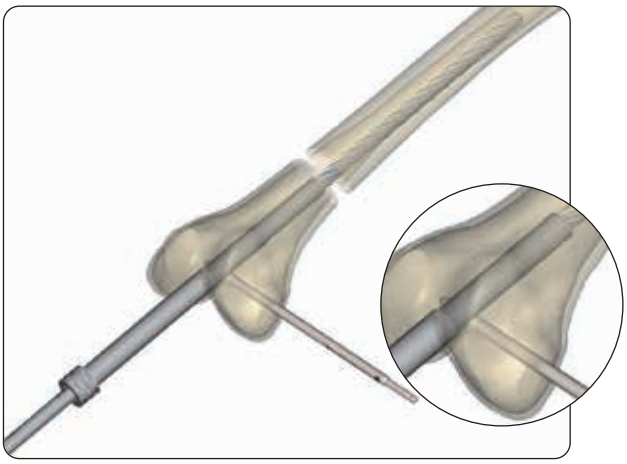


Fig. 25 Distal reaming and use of L or XL tube to protect previously reamed bone

There is a dedicated step reamer for each nail, exactly matching implant dimensions. No over-reaming is required. **(Table 4)**

The step reamers are available for each diameter and length (Ø 9mm, length: 40mm and 60mm; Ø 11mm, length: 40mm, 60mm and 80mm).

In case of TAA13 nails, the final reamer to be used is the Ø 13mm reamer. Ream with the 13.5mm reamer if the bone is sclerotic. There is no step reamer since the nail is Ø 13 mm along the entire length.

The step reamer should be used with the working tube

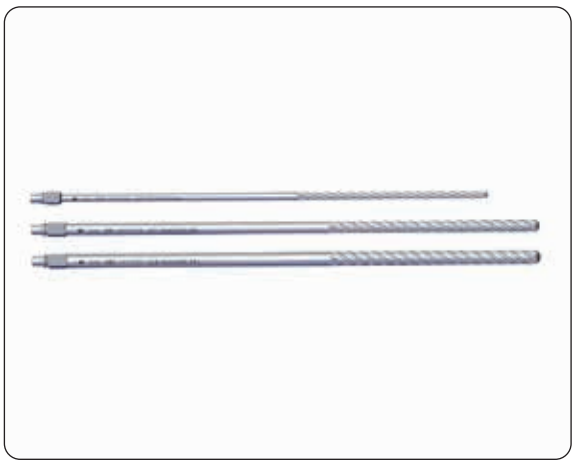


Fig. 26 Step reamers TAA0940, TAA1160 and rounded reamer 13mm

T14/13 for TAA11 and TAA09.

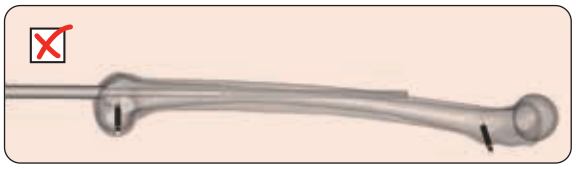


Fig. 27 Weakening of the anterior cortex

Fitbone	REF	Step Reamer	REF	Dummy	REF
TAA0940-F-200	60001921	Step Reamer TAA0940	60001938	Dummy TAA0940-F-200	60001925
TAA0960-F-220	60001764	Step Reamer TAA0960	60001849	Dummy TAA0960-F-220	60001855
TAA1140-F-205	60001383	Step reamer TAA1140	60001528	Dummy TAA1140-F-205	60001248
TAA1160-F-225	60001468	Step reamer TAA1160	60001415	Dummy TAA1160-F-225	60001139
TAA1180-F-245	60001404	Step reamer TAA1180	60001179	Dummy TAA 1180-F-245	60000822
TAA1380-F-245	60001422	Reamer D13.0 L200 L480 rounded	60000422	Dummy TAA1380-F-245	60001623

Table 4. Overview Fitbone, Step Reamer and Dummy

PRECAUTION: do not weaken the anterior cortex; as this could increase the risk of fracture during treatment. (Fig 27)

If the correct position cannot easily be reached, use the front cutting reamers to widen the midshaft canal posteriorly. The front cutting reamer will aggressively remove posterior cortex thus the process has to be controlled under AP and lateral fluoroscopy very carefully at all times.

WARNING: Never use front cutting reamers in the area of the final position of the tip of the Fitbone.

EXTRACTING THE WORKING TUBE

The working tube is removed using the tube extractor clamp. **(Fig. 28)**

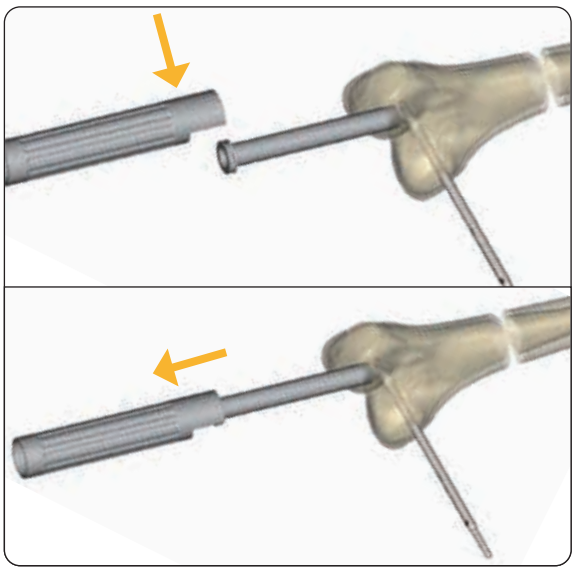
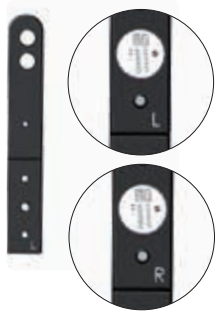


Fig. 28 Extracting the working tube

DUMMY PREPARATION

Fitbone Drill Guide TAA	Fitbone Outrigger TAA	Fitbone Space Holder TAA	Fitbone Clamping Nut TAA	Fitbone Connection Bolt TAA
				
The Fitbone drill guide TAA is bilateral since it can be used for left leg "L" or right leg "R"	The Fitbone outrigger TAA is the main body of jig	The Fitbone space holder is the part of the jig to which the Fitbone dummy/ nail will be assembled and it has a notch that is used as a reference mark to correctly position the Fitbone into the bone.	The Fitbone clamping nut is used to fix the space holder into the outrigger TAA.	The Fitbone connection bolt TAA is used to fix the dummy/nail through its thread

If a check of the proper assembly of the jig is preferred, the drill guide can be attached and the check can be performed. Attach the drill guide TAA to the outrigger TAA, paying attention to the indication "L" and "R" **(Fig. 29)** and lock it in place **(Fig. 30)**.

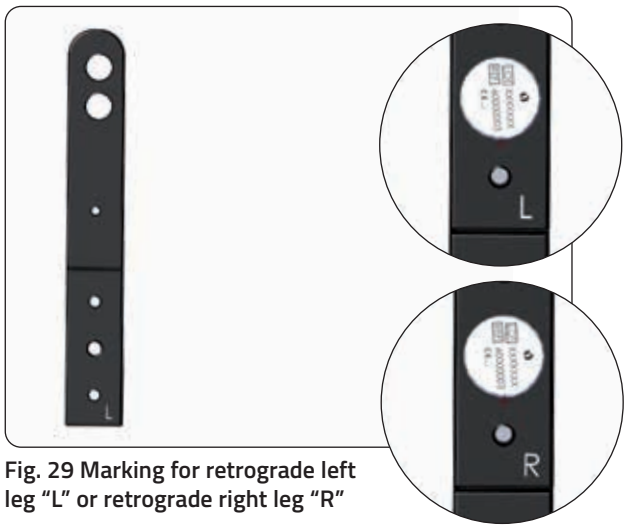


Fig. 29 Marking for retrograde left leg "L" or retrograde right leg "R"

Fig. 30 Drill guide fixation

Insert the Space Holder TAA into the squared hole in the back of the handle, making sure that the marking “THIS SIDE UP” is facing upwards, and lock it by hand using the clamping nut TAA. **(Fig. 31)**

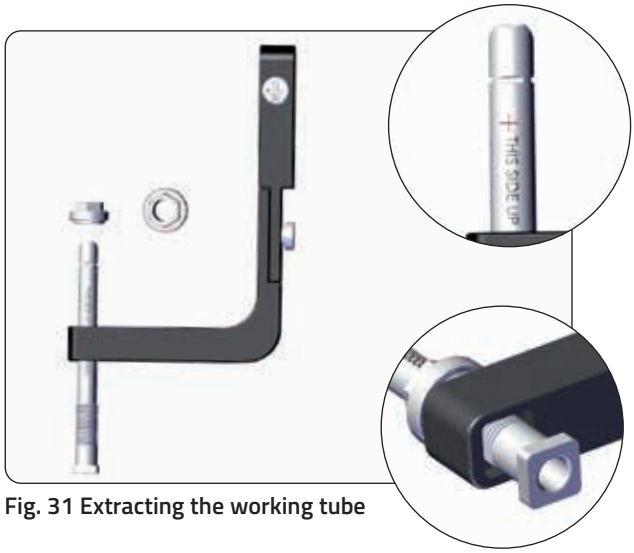


Fig. 31 Extracting the working tube

Insert the “connection bolt cannulated” into the “space holder” and fix the assembly by screwing the “clamping nut TAA” on the thread of the “space holder”. **(Fig. 32)**

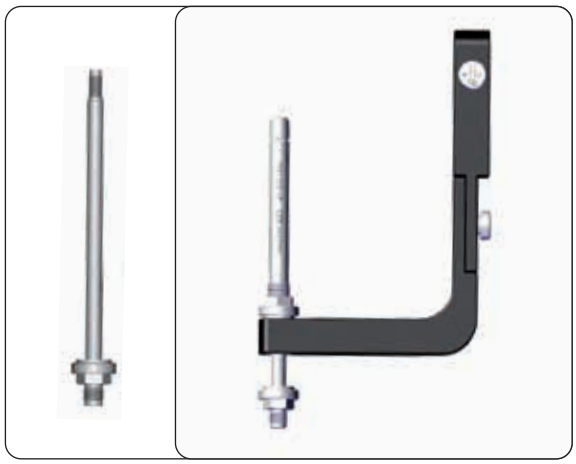


Fig. 32 Space holder fixation

INSERTION OF THE DUMMY NAIL

The dummy nail is used to confirm the medullary canal is appropriately prepared for the Fitbone nail to be implanted, and it must be possible to insert it without resistance and without hammering. Refer to **Table 4** for the correct combination of dummy nail and step reamer based on the selected Fitbone nail.

The dummy nail should be connected to the jig **(Fig. 33)** and inserted into the femur to make sure that the actual nail can be inserted at the planned depth (10mm in the bone) and alignment.

Ensure the space holder marker on the jig is at the level of the notch (Fig. 34). This indicates that the nail is sufficiently implanted in the bone to a depth of 10mm. It is advised to check nail positioning under fluoroscopy in AP and lateral planes.

The drill guide portion of the jig can be removed for better visualization under x-ray.

After removal of the working tube, place the leg in full extension. Control the alignment with the double line grid as described previously.

The double line should be centered on the hip and ankle joints and should pass the knee joint as planned (RPM).

Perform additional reaming or correct alignment if needed.

Fig. 33 Dummy nail assembly

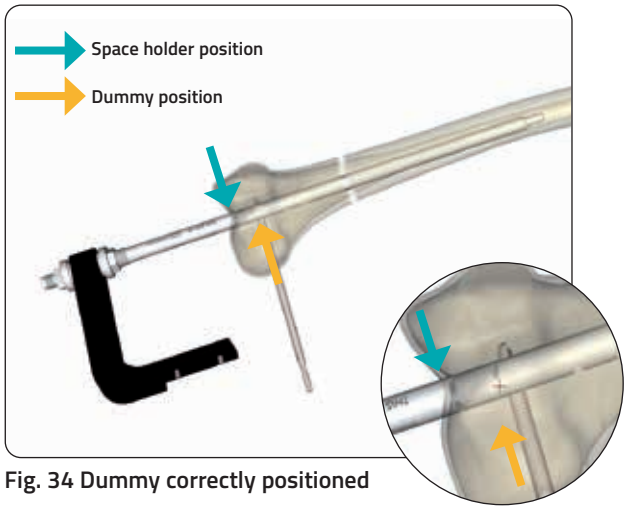


Fig. 34 Dummy correctly positioned

BLOCKING SCREWS INSERTION

The insertion of blocking screws to achieve correct alignment and maintain full knee extension is highly recommended. The posterior screw achieves correct alignment in the lateral view and the lateral screw in the AP view. **(Figure 35)**

If blocking screws are required, the regular 4.5mm Fitbone screws can be inserted with (or without) the dummy nail in place.

Make sure that the distal and proximal fragments are aligned correctly and final stabilization of the Fitbone nail is ensured.

PRECAUTION: perform additional corrections or place blocking screws only with the dummy nail inside the bone, never while the Fitbone nail is inserted.

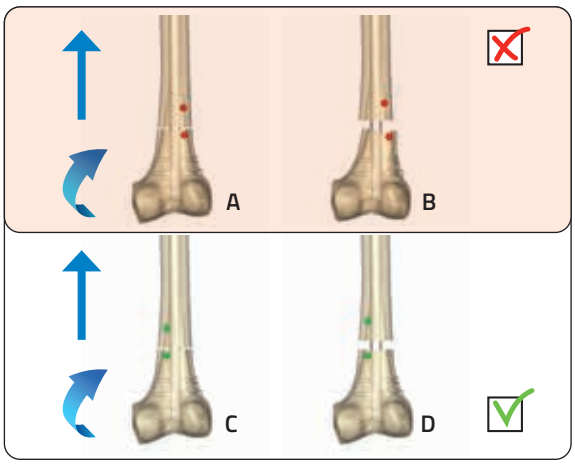


Fig. 35 Alignment blocking screws

Fig. 36 Blocking screw placement

TUNNEL PREPARATION FOR THE PLACEMENT OF THE NAIL CABLE

Cerclage Wire Insertion

The following steps describe how to create the hole through the lateral femoral condyle to connect the coaxial cable of the Fitbone TAA to the Receiver.

Remove the dummy nail, place it on the skin and mark where the two distal locking screws will be. If not using the osteotomy incision, make a 2cm skin incision (standard lateral approach).

Insert the Targeting Device 45°/90° into the femur, making sure that its marking notch is exactly at the level of the intercondylar notch **(Blue arrow, Fig. 37)** to prevent the nail from blocking the path of the cable.

Rotate the targeting device between 30° anteriorly from the lateral plane **(Fig. 38)** to prevent the locking screws from damaging the cable when finally inserted.

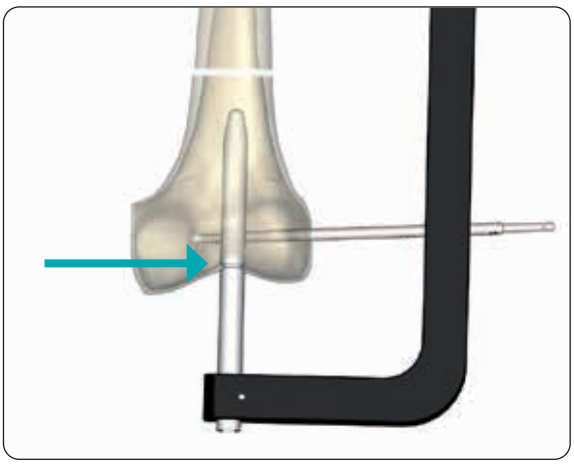


Fig. 37 Correct position of the targeting device 45°/90°

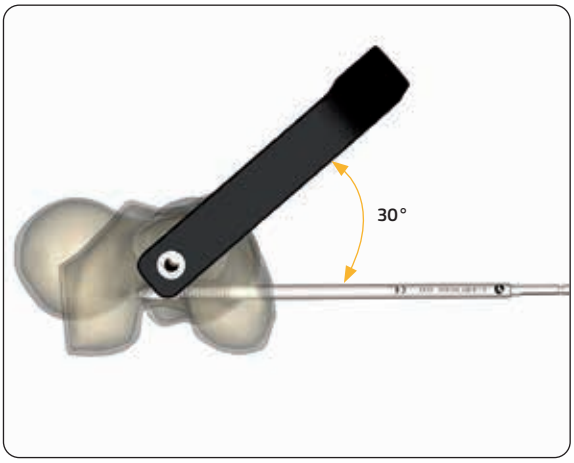


Fig. 38 30° angulation targeting device

Insert the drill sleeve D. 4.5 black, into the 45° hole of the targeting device **(Fig. 39)**. Insert it via the lateral skin cut previously performed.

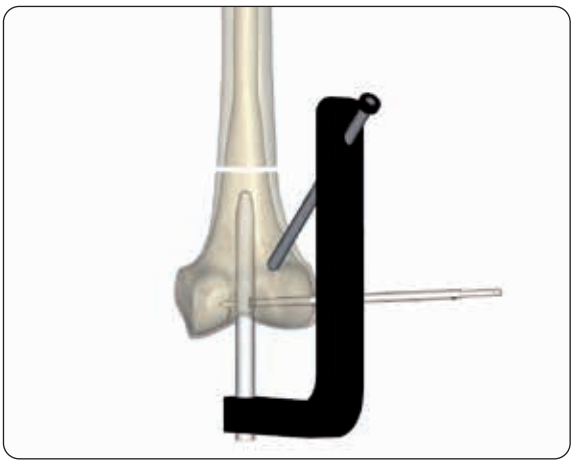


Fig. 39 Drill guide insertion

Use the cone sinker to impact the drill sleeve 5mm into the bone, securing its position. The fascia will not hinder with the passage of the cerclage wire.

Use the long 4.5 drill bit until a hard stop is felt **(Fig. 40)**. The drill bit will be directed by the drill sleeve into the hole of the targeting device.

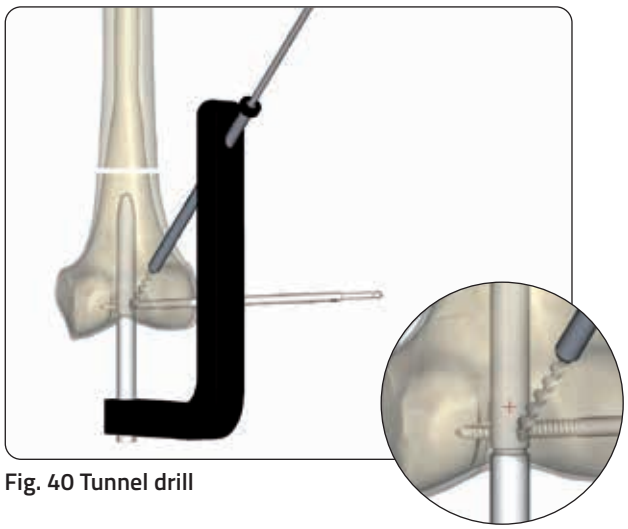


Fig. 40 Tunnel drill

Place leg in a 30° angle as before and check alignment before proceeding.

Bend a 0.8mm cerclage wire in half and close the loop with clamp or pliers. **(Fig. 41)**

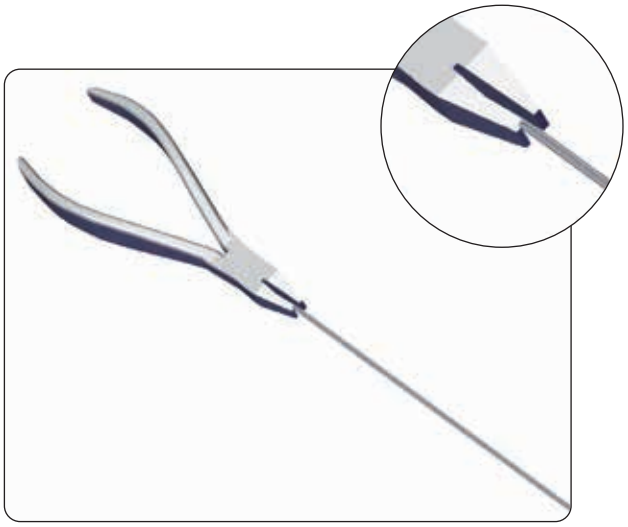


Fig. 41 Cerclage wire preparation

Remove the drill bit and insert the cerclage wire with the closed end forward into the drill sleeve until it exits from the distal end of targeting device. **(Fig. 42)**

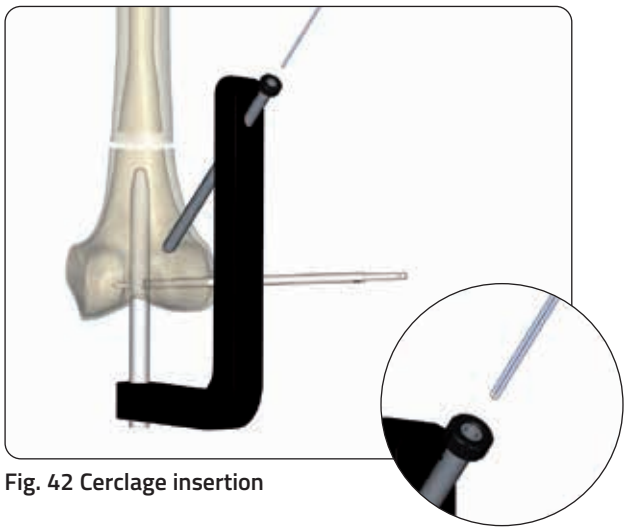


Fig. 42 Cerclage insertion

Remove the targeting device, keeping the cerclage wire in place. **(Fig. 43)**

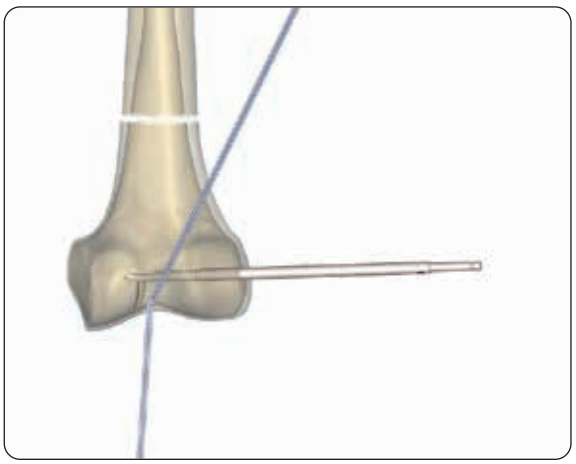


Fig. 43 Targeting device removal

Drainage tube placement

Insert the distal end of the cerclage wire into the drainage tube (Fr. 8, 50cm). Fix the end of the cerclage wire inside the drainage tube by either pushing the wire firmly into the drainage tube or with suture thread **(Fig. 44)**. Pull the cerclage wire proximally, ensuring that the drainage tube will not slip off the wire.

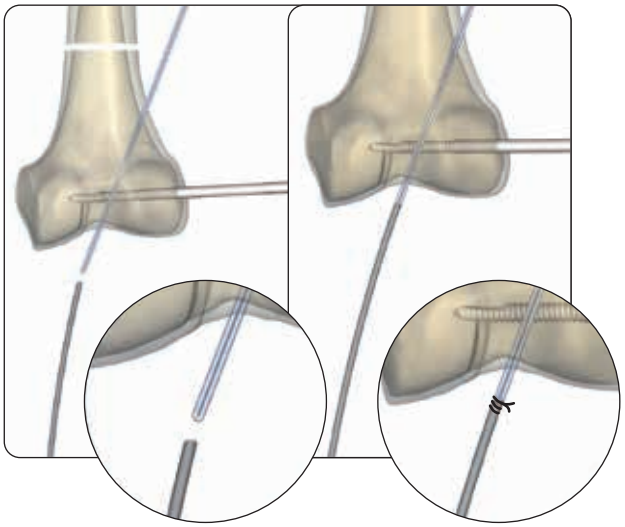


Fig. 44 Redon/cerclage wire connection

Remove the cerclage wire, leaving the drainage tube in place. **(Fig. 45)**

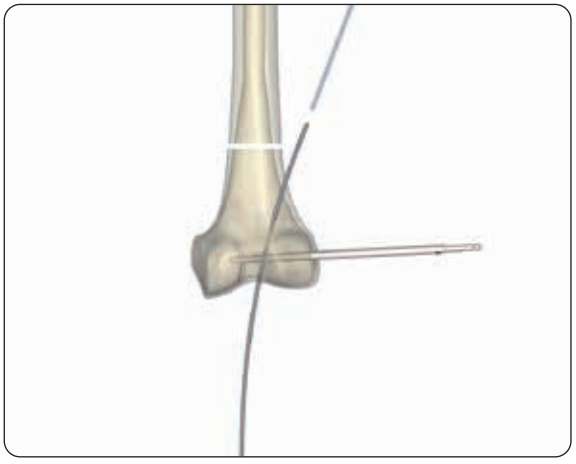


Fig. 45 Redon placement

Tie a double knot in the drainage tube to prevent it from moving. **(Fig. 46)**

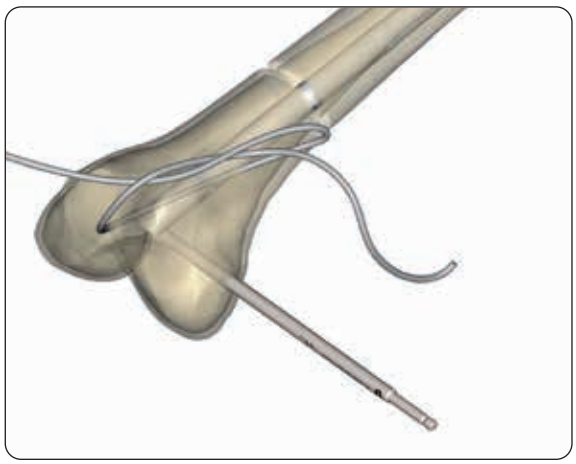


Fig. 46 Redon final position

Fitbone Intraoperative Functionality Test

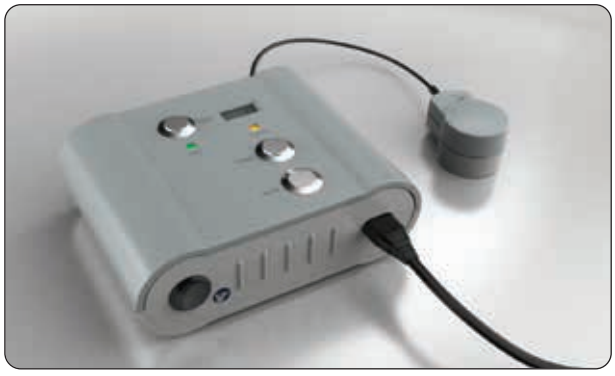
To confirm the Fitbone is functioning correctly, an intraoperative functionality test has to be performed before inserting it into the bone. To minimize the risk of contamination of the implants, do not remove them entirely from their packaging at this stage and expose only the end of the cable of the nail and the coupling of the receiver.

Insert the cable of the nail in the coupling of the receiver as explained on page xx without tightening the screws.

Place the stethoscope and transmitter in sterile drapes to ensure sterility. The transmitter is placed on the receiver and stethoscope on the nail. The Fitbone is activated via the control set and the motor of the nail must be heard, along with seeing the energy transmission light flashing on the control set.

For the intraoperative test, the doctor ("Doc.") and pulsating ("Pulse") settings are recommended, see page 31.

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



Prepare the stethoscope, the receiver and the camera bag

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

Place the transmitter on the receiver

Press Doctor, check :
The countdown
The yellow flashing
The sound of the motor
1 pulse = 0,033 mm lengthening

Fitbone assembly (left retrograde femur)

Fitbone Preparation

Insert the cable of the nail carefully into the cannulated connection bolt and attach the Fitbone nail to the handle in correct orientation. **(Fig. 48)**

Attach the drill guide to the handle and insert the test pins into the drill guide and make sure that they pass through the holes in the nail easily without friction. **(Fig. 49)**

Refer to **page 26** for potential problems and solutions.

Lock the nail firmly in place using two wrenches simultaneously. **(Fig. 49)** Remove the test pins.

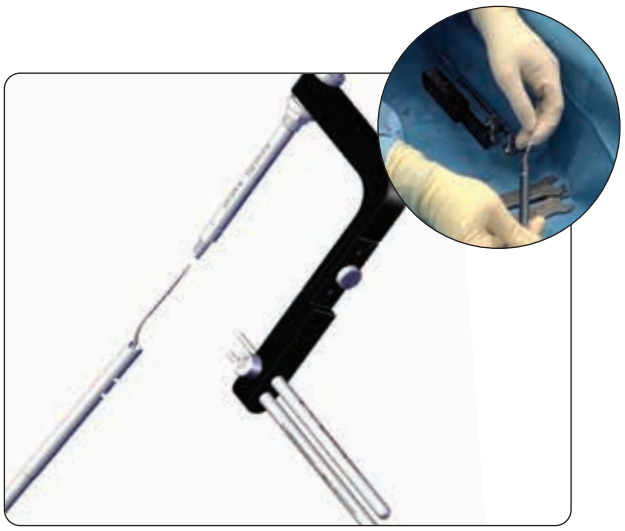


Fig. 48 Final nail/jig assembly

Fig. 49 Fixating the nail into the jig

Fitbone Insertion

Insert the nail into the femur, making sure that the marking notch is at the level of the bony notch **(Fig. 50)** so that the nail is inserted into the bone to the planned depth.

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

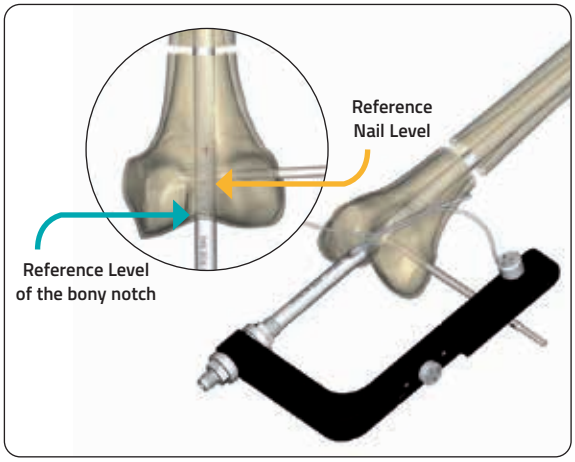


Fig. 50 Fitbone insertion

POTENTIAL PROBLEMS AND SOLUTIONS

1. The marking "THIS SIDE UP" on the Space Holder is not facing upwards and the connection between drill guide assembly and Fitbone is loose. **(Fig. 51)**

Corrective action: Place the Space Holder correctly with "THIS SIDE UP" facing upwards.

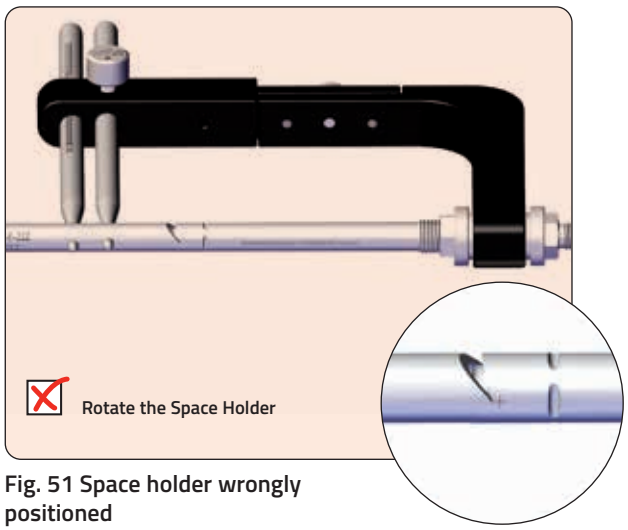


Fig. 51 Space holder wrongly positioned

2. The Space Holder is not completely flush with the Drill Guide Assembly. **(Fig. 52)**

Corrective action: Insert the Space Holder correctly, making sure that the squared end is placed into the square hole in the back of the handle.

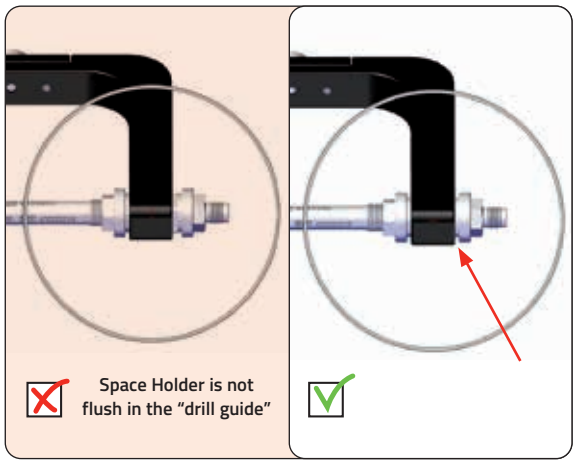


Fig. 52 Space holder wrongly inserted

3. The Fitbone is wrongly placed. **(Fig. 53)**

Corrective action: Unlock the "Connection Bolt Cannulated" and rotate the nail.

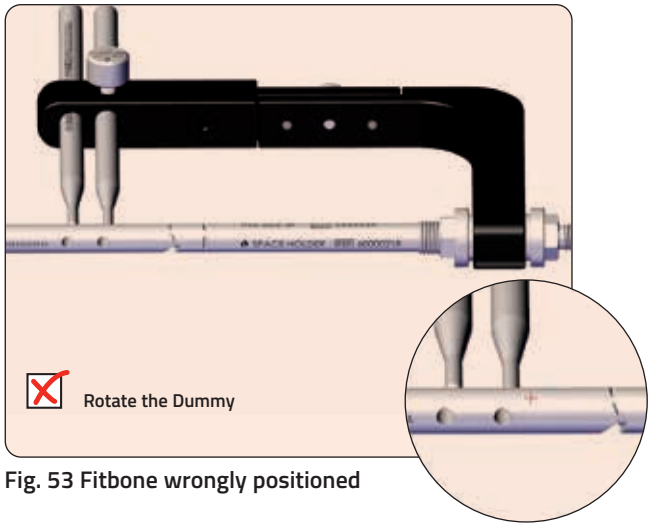


Fig. 53 Fitbone wrongly positioned

4. The Fitbone is loosely fixed to the "connection bolt cannulated". **(Fig. 54)**

Corrective action: Tighten the Connection Bolt Cannulated firmly. The fixation has to be tight.

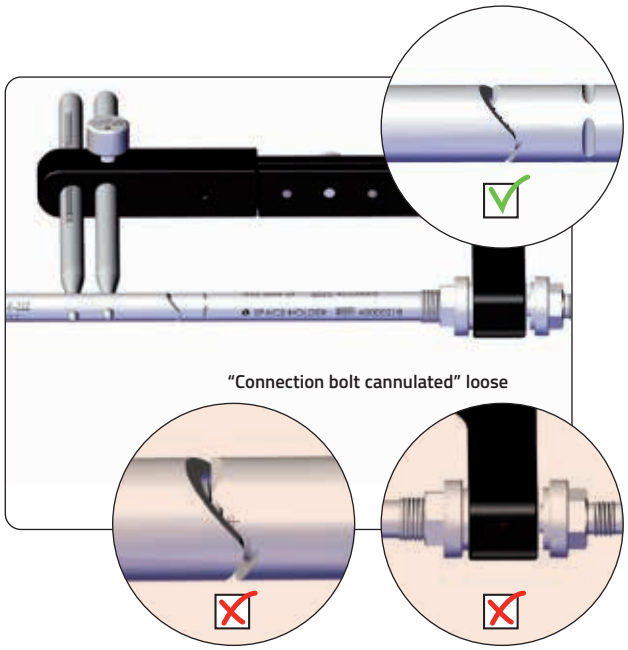


Fig. 54 Connection bolt loose

Inserting the distal locking screws

The distal screws have a diameter of 4.5mm in all Fitbone TAA nails. They are available in long and short threaded options. Select the longest thread possible without interaction between thread and nail occurring.

Insert an 8.0mm drill sleeve (green) together with a 4.5mm drill sleeve (black) and the Trocar Ø 4.5mm into one of the two holes in the drill guide TAA.

Insert the sleeves with the trocar through the lateral incision splitting the soft tissue. **(Fig. 55)**

Drill through both cortices and use the Fitbone depth gauge to measure the correct screw lengths.

Select the correct length screw and introduce through the drill sleeve (green), using the cannulated SW 3.5 driver. Once it can be felt that the thread has engaged the bone, disengage the cannulated driver and tighten fully with the solid driver. **(Fig. 56)**

Insert the second distal locking screw using the same procedure.

Check correct both screw position and length under fluoroscopy in AP and lateral planes.

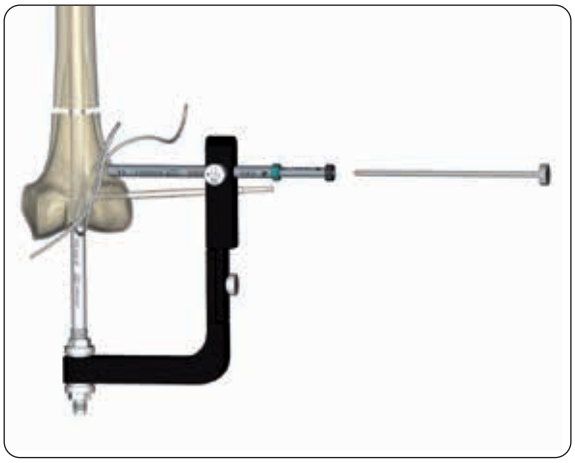


Fig. 55 Drill sleeve insertion

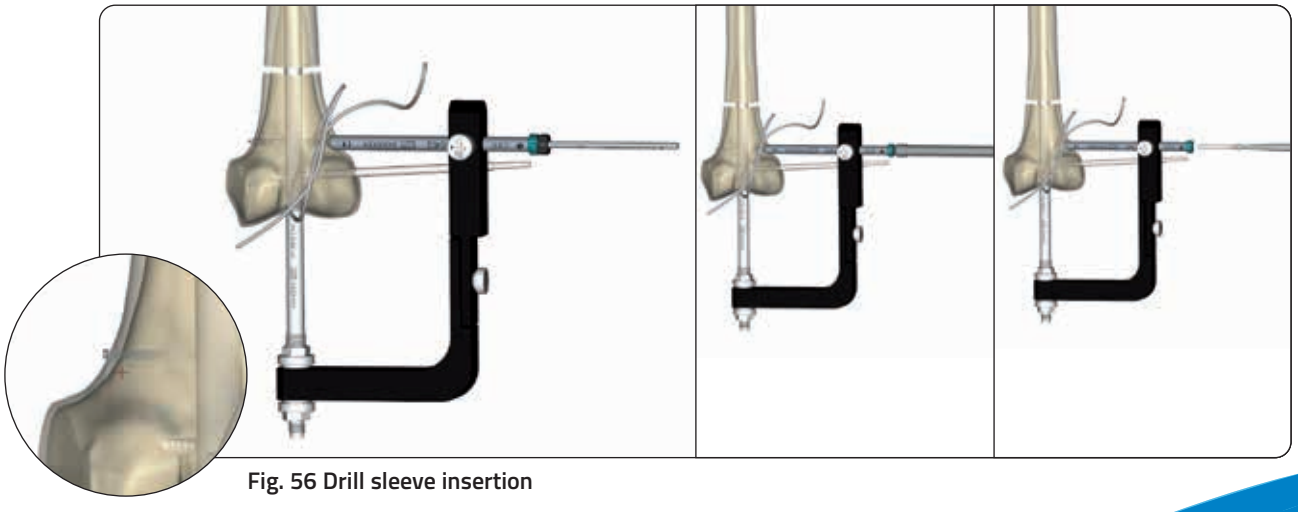


Fig. 56 Drill sleeve insertion

JIG REMOVAL

Use the wrench to loosen the upper securing bolt on the jig. Carefully remove the jig without damaging the cable.

PASSING THE CABLE

Untie the drainage tube and insert the metal tip of the cable into its distal end. Fix the metal tip of the cable with a suture into the drainage tube. **(Fig. 57)**

PRECAUTION: the drainage tube should slide without any resistance through the bony canal and the bipolar feedline should not enter and affect the adjacent joint. If not, check if the implant is inserted deeply enough (distance to notch 1cm).

Carefully pull the drainage tube from the lateral cortex, while feeding the cable through the incision at the knee, enabling the safe passage of the cable.

PRECAUTION: The cable must enter the bony tunnel as close as possible to the point it exits from the implant. If not, it may occur that a fiber of the patella tendon is captured, which might cause severe damage to the cable. (Fig. 58)

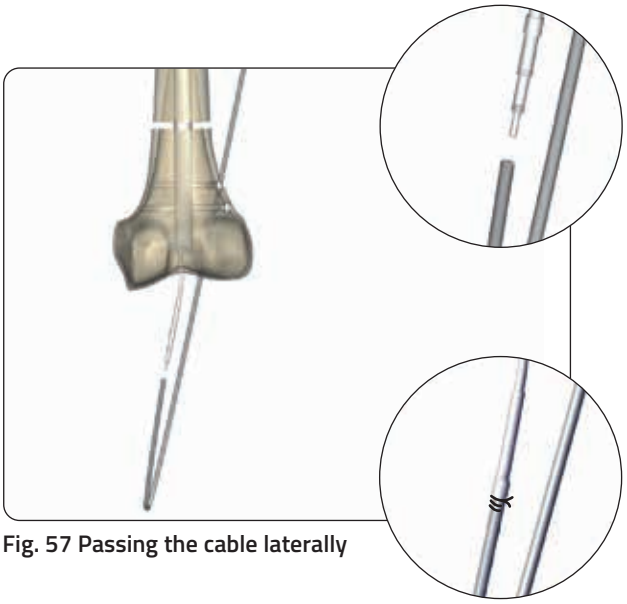


Fig. 57 Passing the cable laterally

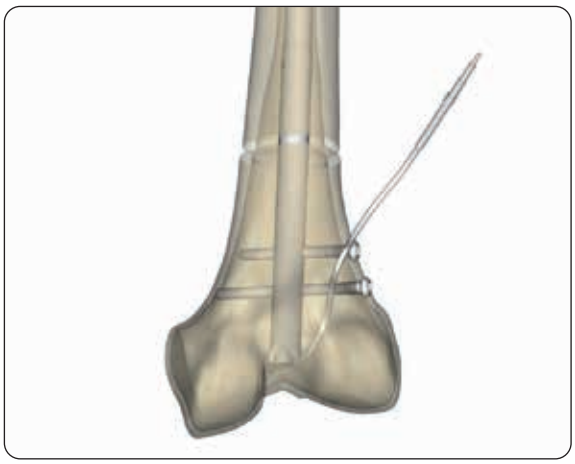


Fig. 58 Final cable position

INSERTING THE PROXIMAL LOCKING SCREW

Before performing distal locking, check that both bone screws are parallel to avoid torsional misalignment.

The proximal locking screw is inserted using the free-hand technique under fluoroscopy.

Drill bi-cortically using the appropriate drill and check the screw length with the depth gauge.

NOTE: 4mm screws with a single thread option are used for all TAA09 Fitbone nail variants. 4.5mm screws with two thread options are used for all TAA11 and TAA13 Fitbone nail variants. The longest thread possible, without interaction between nail and thread, should be selected. (Fig. 58)

Remove the initially implanted bone screws for torsion control.

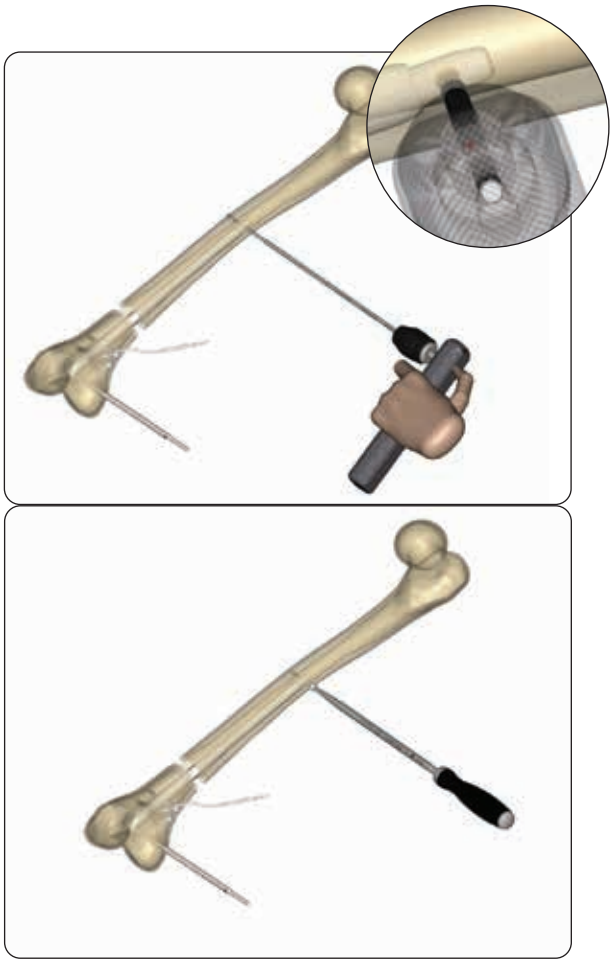


Fig. 59 Placement of the proximal screw

Positioning the Receiver

Clean the plug of the cable properly to remove any blood (as it can act as an isolator).

Remove the Transport Locking Device from the Receiver's Coupling, place a drop of sterile water on the plug of the cable, and insert into the coupling. **(Fig. 60)**

PRECAUTION: make sure the white ring (see blue circle in Fig. 60) is in connection with the start of the coupling.

Lock the cable into the Receiver's Coupling by tightening both screws with the torque wrench until an audible click is heard. **(Fig. 61)**

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.

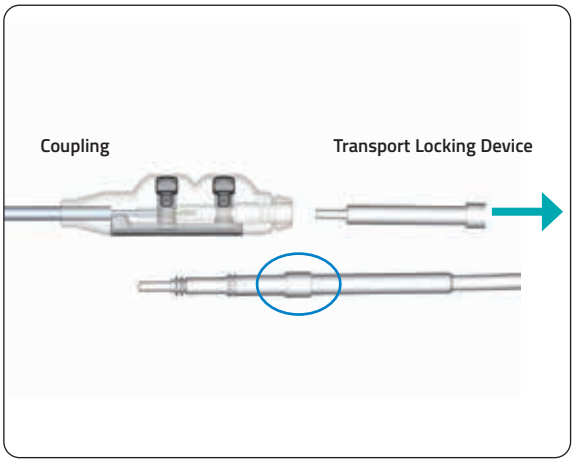


Fig. 60 Transport locking device removal and white ring

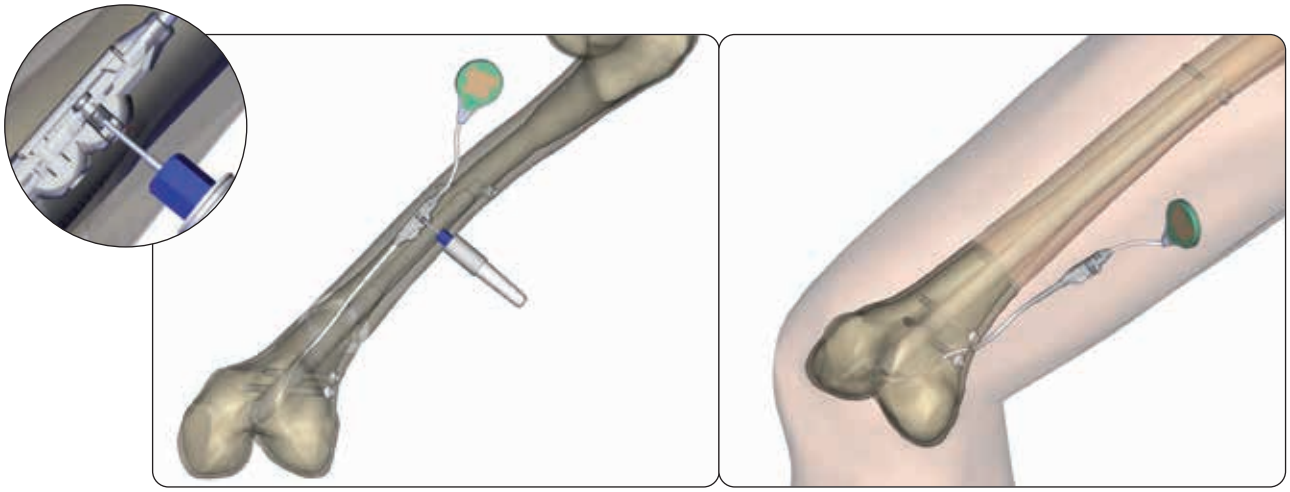


Fig. 61 Receiver connection

The Receiver should now be placed directly underneath the skin ventro-lateral. For this purpose, use scissors to prepare an 80 to 100mm subcutaneous pocket. **(Fig. 62)**

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 functioning of the treatment system.

Mark the position of the Receiver on the skin. **(Fig. 63)**

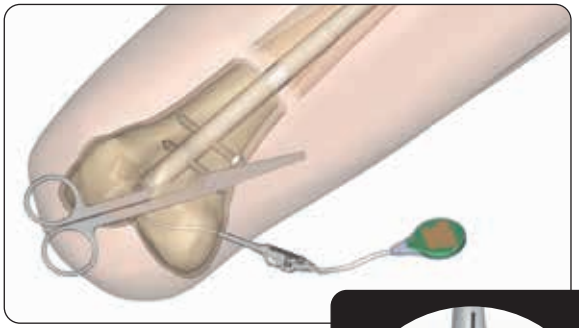


Fig. 62 Subcutaneous pocket preparation

Fig. 63 Receiver final position

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, respectively labeled “Pat.” and “Doc”, and pulse or continuous operation, respectively labeled “Pulse” and “Perm.” **(Fig. 64)**

In the “Doc.” position, the switch labeled “Doctor” on the front is enabled as well as the Pulse and Continuous modes. **(Fig. 65)**

Pressing the “Doctor” button while in the “Doc” and “Pulse” position will result in a continuous repetition of 1 second energy transmission ,followed by a 9 second pause between each distraction, 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 proximal 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°.

In the “Pat.” position, the button labeled “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 followed by a 9 second pause.

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.

Fig. 64 Test Control Set Settings

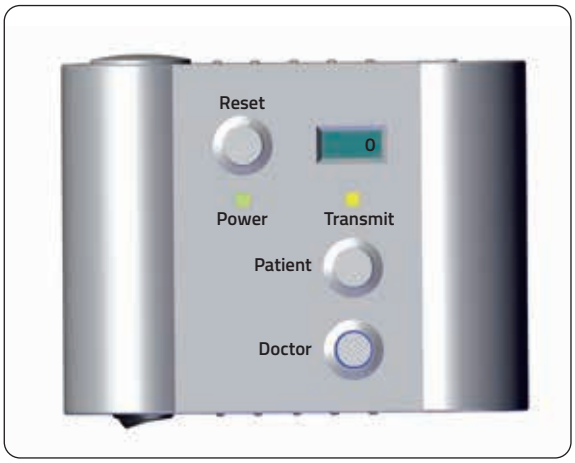


Fig. 65 Control Set

Intraoperative test

Place the Transmitter and the stethoscope in separate sterile endoscopic camera drapes. The stethoscope enables the surgeon to hear the motor of the Fitbone while lengthening.

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

For the intraoperative test, connect the Transmitter to the Fitbone Control Set and place it on the skin where the Receiver is. 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. The "Doctor" button will light up blue after being pressed.

NOTE: 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 clean and 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 underneath.

Fig. 66 Inserting the Transmitter in the sterile endoscopic camera protection covers

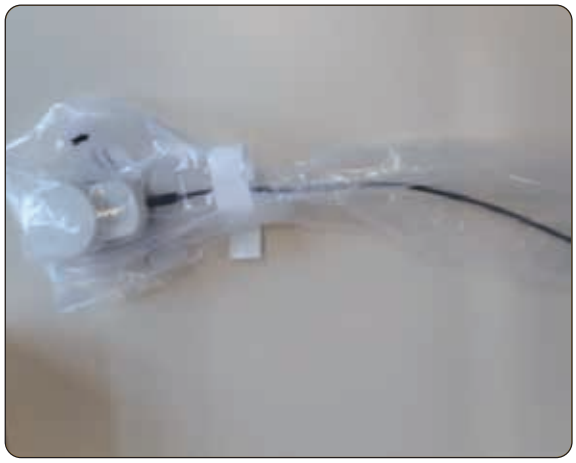


Fig. 67 Final position of the Transmitter in the endoscopic camera protection covers

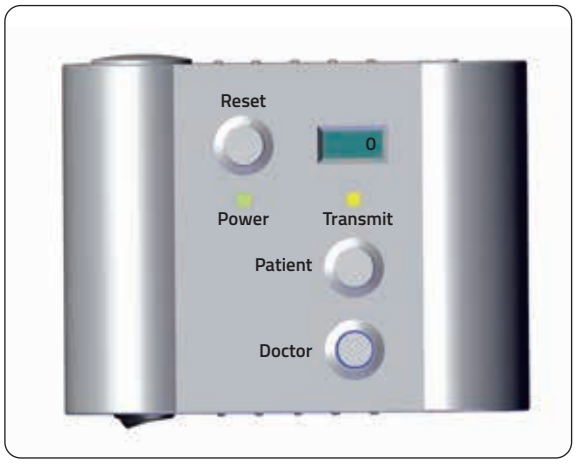


Fig. 68 Doctor mode active

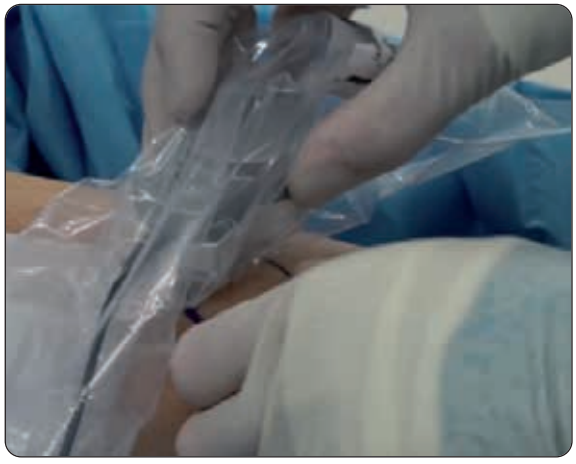


Fig. 69 Final test under sterile conditions

POST-OPERATIVE CARE

In the recovery room, the operated extremity should be positioned fully extended at all times. An ice pack is recommended in the area of the osteotomy. The first mobilization takes place on the first postoperative day.

PRECAUTION: during the distraction and consolidation phase, weight-bearing on the operated leg should be partial and limited to 20 kg (contact with the sole of the foot). Any excess load may cause the Fitbone TAA to break.

Physical therapy is initially limited to the prevention of pulmonary and thromboembolic complications. Exercising of the knee joint starts from the fourth postoperative day. The following measures are recommended:

- Manual therapy techniques (physiological movement, additional movement)
- Muscle relaxation techniques in supine position, tilted with healthy leg lifted as support
- Posterior/anterior movement of the femur in the prone position and maximum hip extension
- Extension movements with gentle traction

Other measures that can be used as required, particularly during and after the consolidation phase, include nerve mobilization techniques, strength improvement measures (PNF, MTT), improvement in proprioception and gait training.

Distraction begins on approximately the fifth postoperative day or at the instruction of the treating surgeon as described in the Instructions for Use Fitbone Control Set by applying the Transmitter and pressing the control elements on the control electronics. Usually distraction should be done 3 times a day: in the early morning, the late evening and once between. The rate of distraction depends on the expected or radiologically detectable bone regeneration and the soft tissue conditions, and can be varied by modification of the intervals. During the distraction phase, check the rate of distraction regularly and correct it if necessary by giving the patient new instructions. In addition, the patient should keep a distraction log to identify malfunctions and patient non-compliance in a timely manner.

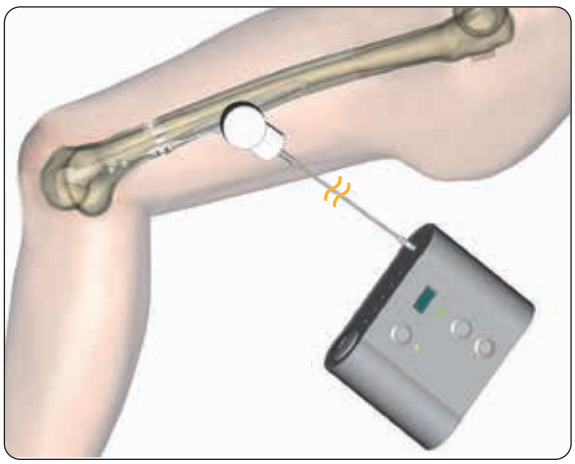


Fig. 70 Patient lengthening

Chronological sequence of leg lengthening

1. **Initial surgery – duration 2 to 4 hours. In-patient stay -** Duration approximately 3-5 days. Physiotherapy and mobilization on crutches in the days after the surgery. Start of distraction approx. 5 days after surgery.

2. **Distraction phase (0.5 to 1mm per day).** Check-ups at the hospital every 1 to 2 weeks. Partial weight bearing at 20 kg, physiotherapy close to home 2 or 3 times per week.

3. **Consolidation phase -** Duration 2 to 3 days per mm of lengthening. Check-ups at the hospital every 2 to 6 weeks. Partial weight bearing at 20 kg, physiotherapy close to home 1 to 3 times per week.

4. **Remodeling phase - approx. 6 to 12 months after consolidation. -** Checkups at the hospital every 6 to 12 weeks, full weight-bearing, gait training and ability to engage in "low-impact" sport activities.

REMOVAL OF THE NAIL

1. **In-patient stay -** Duration approximately 3 days. Implant removal approximately 1 to 1.5 years after implantation, full weight bearing upon discharge.

NOTE: the Fitbone TAA is not a permanent implant and must be removed. Removal of the implant is recommended when, according to the treating surgeon, the regenerated bone can support a sufficient load. In general, removal 1 to 1½ years after implantation is recommended. If the explantation is delayed or not carried out, the Fitbone intramedullary lengthening nail may break.

2. **Final examination.** Approximately 3 months after removal of the implant.

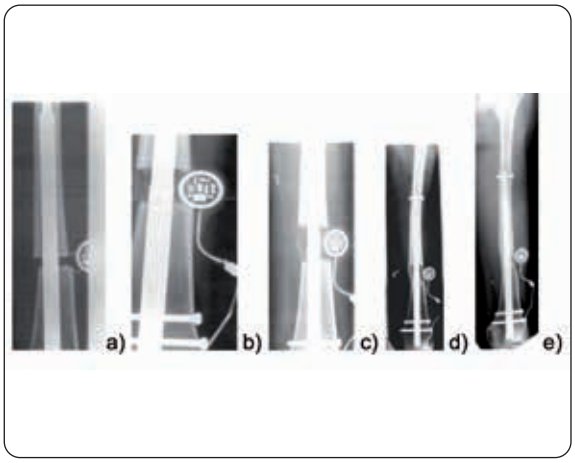


Fig. 71 Post-operative X-rays

a) 1 week after surgery
b) 4 weeks after surgery
c) 2.5 months after surgery (distraction completed)
d) 4 months after surgery (ossification in progress)
e) 1 year after surgery (ossification completed)

Please refer to the “Instructions for Use PQFBC, PQFBP and PQFBR” supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

Distributed by:

Manufacturer info is available on the product labels and relevant IFUs.

CE 0123

orthofix.com

FB-2020-OPT-E0 B 05/23 (0425816)

ORTHOFIX®
ORTHOPEDICS