OPERATIVE TECHNIQUE

Fitbone™

Intramedullary Lengthening System

Fitbone TAA
Tibia Application

ORTHOFIX®
ORTHOPEDICS

Fitbone™

Intramedullary Lengthening System

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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™ 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 Instructions For Use for the complete list of indications, warnings, precautions, and other important medical information.

SURGERY PLANNING - TIBIA

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. 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 position of the screws (including blocking screws).

At least 65mm of the telescopic housing **(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 telescoping housing of the nail that needs to be within the distal bone fragment upon completion of 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. 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.

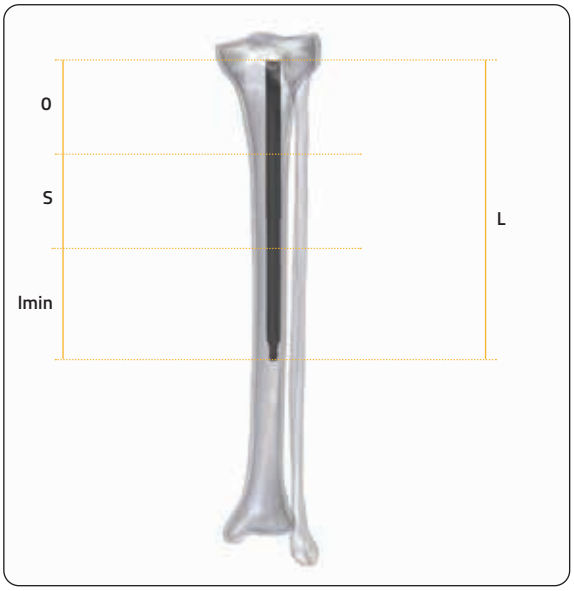


Fig. 1a

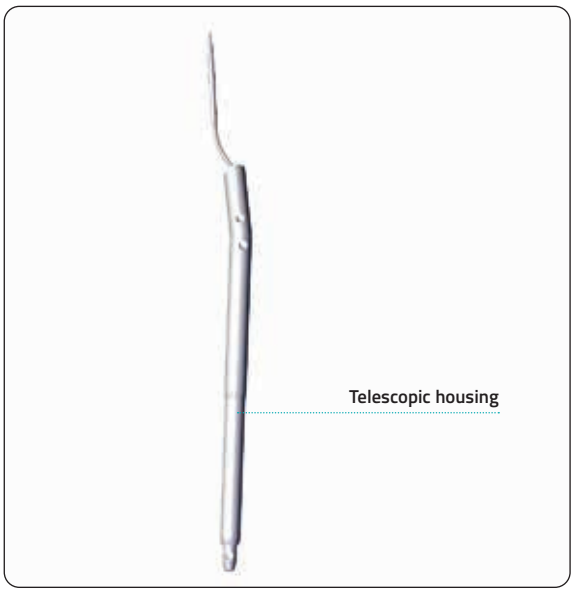


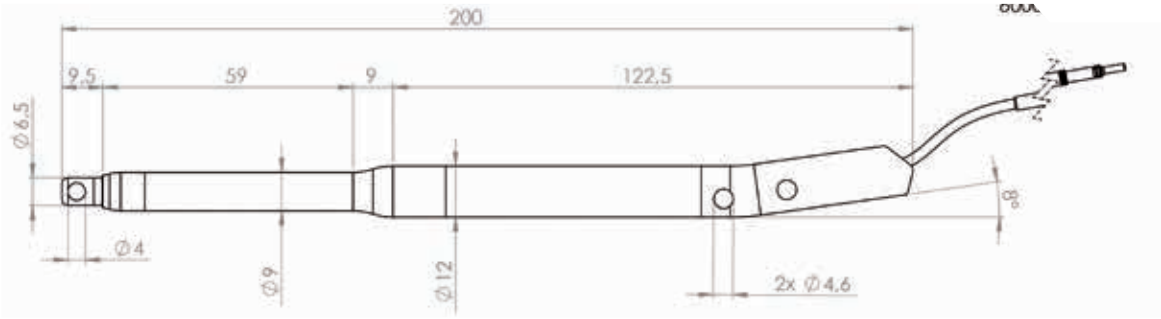
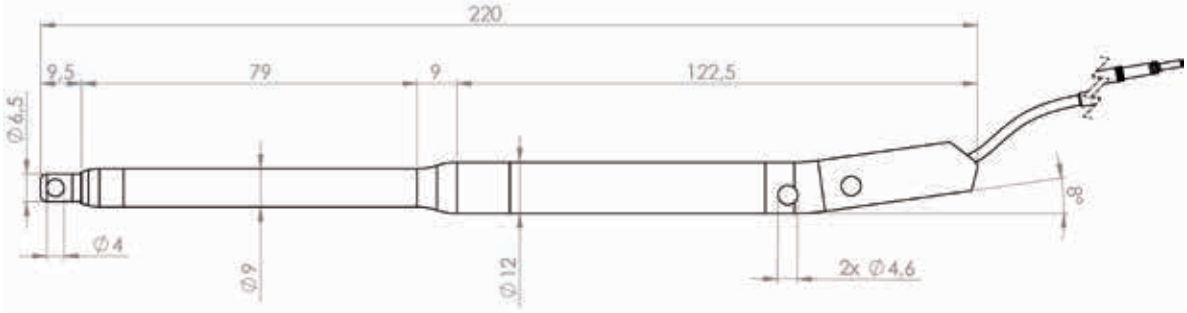
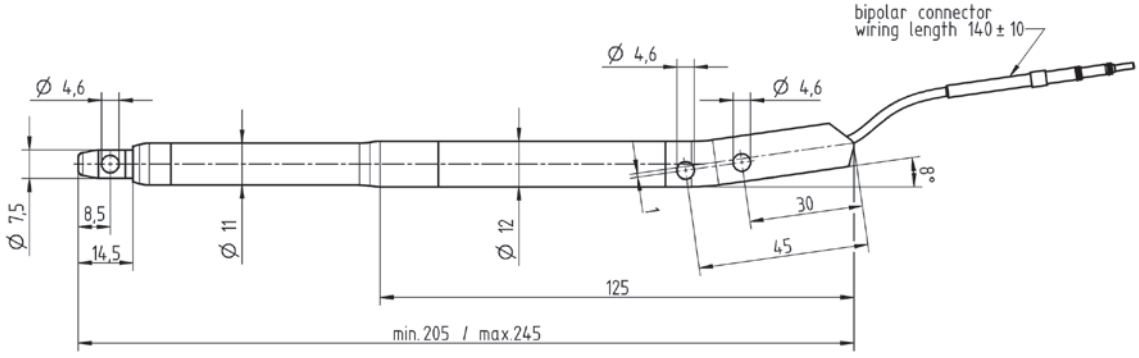
Fig. 1b

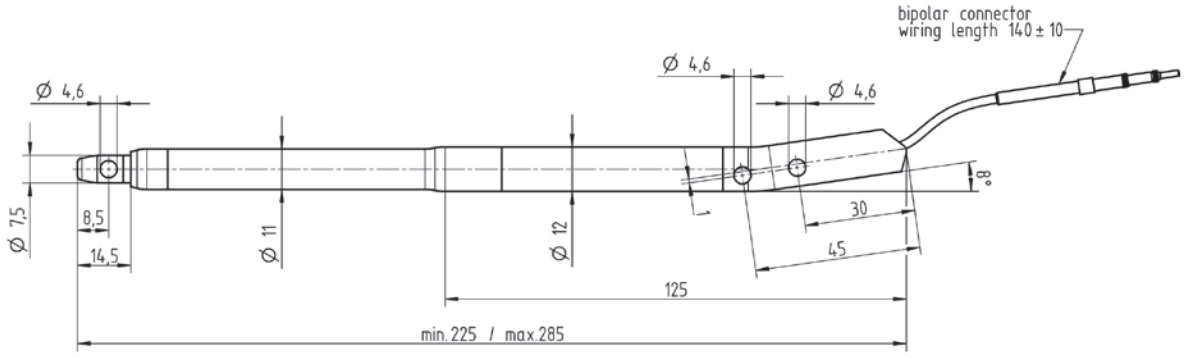
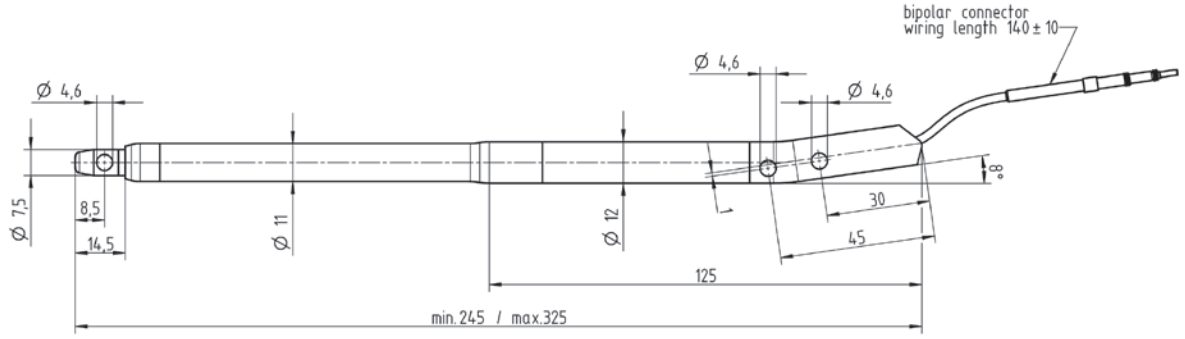
Fig. 1 Representation of O, S, L and lmin (a); Telescopic housing of the nail (b)

* *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)
		Tibia Variants			
60001928 (OUS & US)	TAA0940-T-200	200	9	40	240
					
60001856 (OUS & US)	TAA0960-T-220	220	9	60	280
					
60001501 (OUS) **60001501-00-0 (US)**	TAA1140-T-205	205	11	40	245
					

Part #	FITBONE TAA variants	Initial total length (mm)	Diameter (mm)	Stroke (mm)	Max Total length after distraction (mm)
		Tibia Variants			
60001445 (OUS) **60001445-00-0 (US)**	TAA1160-T-225	225	11	60	285
					
60001348 (OUS) **60001348-00-0 (US)**	TAA1180-T-245	245	11	80	325
					

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

Long-standing radiographs (LSR, see figure 2) 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 the 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 ensured that the patient does not move during the scan.

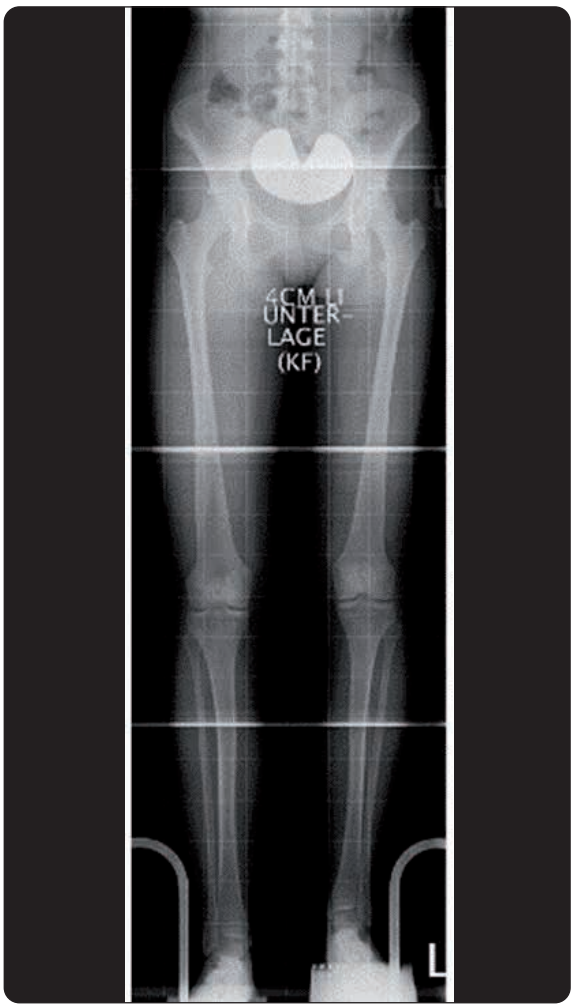


Fig. 2 Long-standing X-ray

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 radiopaque 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. Along these double lines the joints can be positioned for 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 **Fig. 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 the hip joint without coming into contact with the pillow on the table.

Prior to any measurement using the GRID double line, make sure that the C-arm is placed perpendicular to the surface of the plate and vertically above the plate. The double line must be located exactly in the center of the image for the evaluation. Place the center of the hip joint, with the patella faced forward, on the double line. Do not change the position of the hip and move only the extremity for further measurements. By placing the double line in the center, parallax errors are minimized.

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 the joint on the double lines, while maintaining hip and patella position.

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.

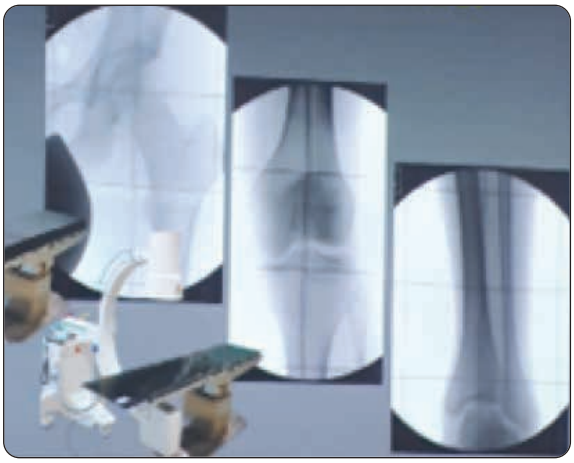


Fig. 4 Patient positioning

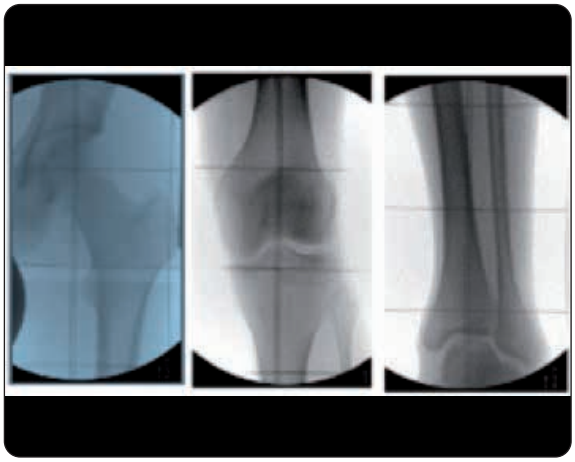


Fig. 5 Hip, knee and ankle joint position

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)**

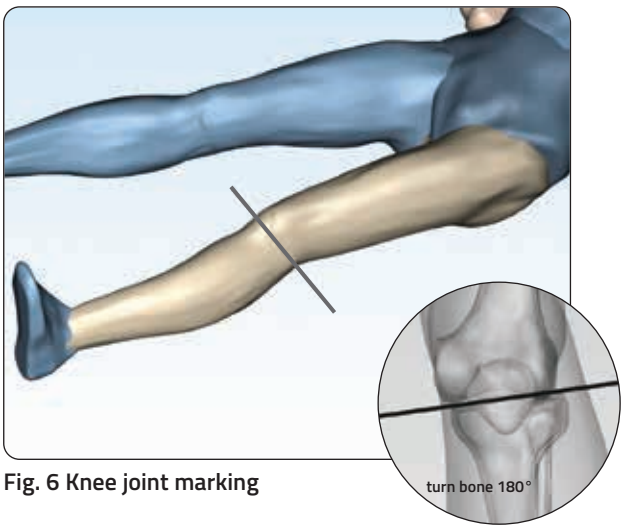


Fig. 6 Knee joint marking

Place the dummy nail correctly over the tibia **(Fig. 7)** and mark the distal end on the skin, ensuring the proximal end of the nail is marked underneath the entry point in order to ensure that the nail will be inside the bone.

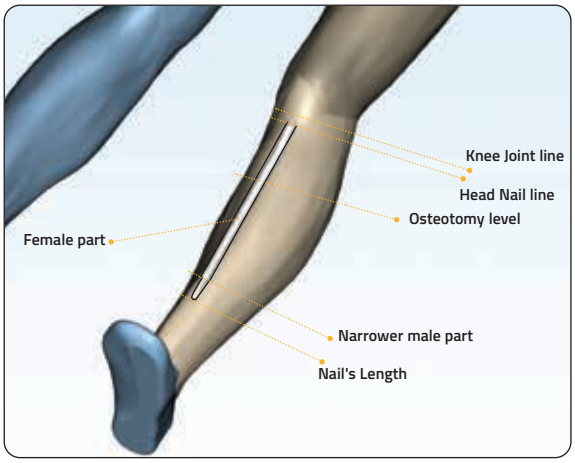


Figure 7 Dummy nail contour marking

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. 8)**. Optionally, the change in diameter of the nail can also be marked.

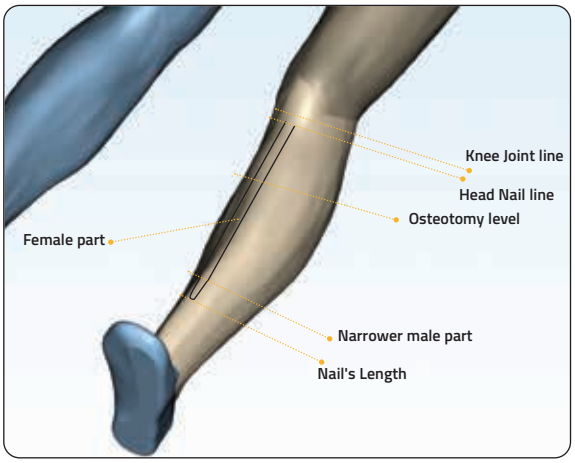


Figure 8 Osteotomy and nail position marking

Insertion bone screws for torsion control

With the leg in full extension, insert two 4.5 or 5mm bone screws, to ensure correct torsional alignment.

Insert the first screw at the supracondylar region of the femur, parallel to the distal and dorsal level of the knee joint **(Fig. 9)**.

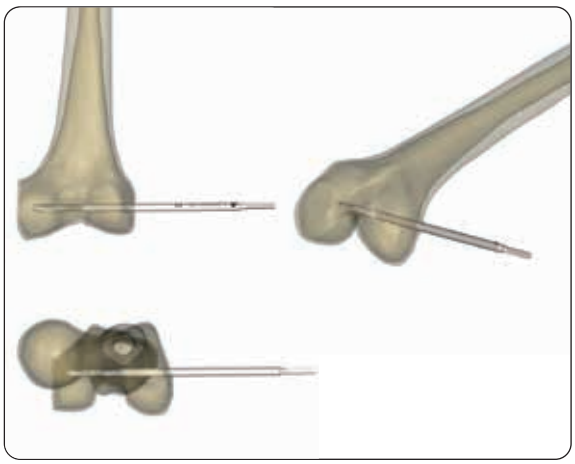


Fig. 9 Distal femur bone screw position

With the leg in full extension, insert the second screw at the distal aspect of the tibia, parallel to the first screw if torsional corrections are not needed **(Fig. 10)**.

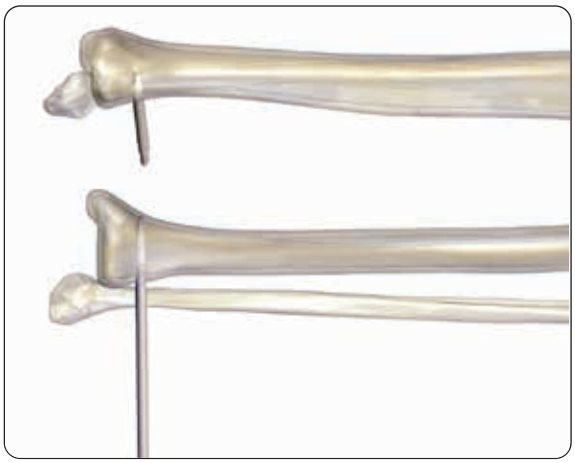


Fig. 10 Distal tibia bone screw position

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. 11)**.

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.

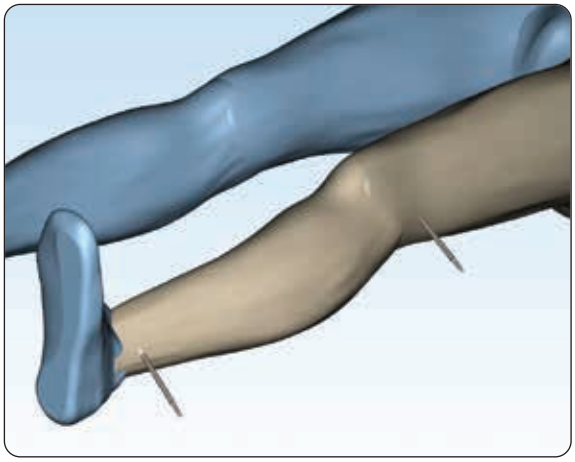


Fig. 11 Final position bone screws

PATIENT POSITIONING

Infrapatellar approach

Place the knee in maximum flexion during the surgical procedure. **(Fig. 12)**

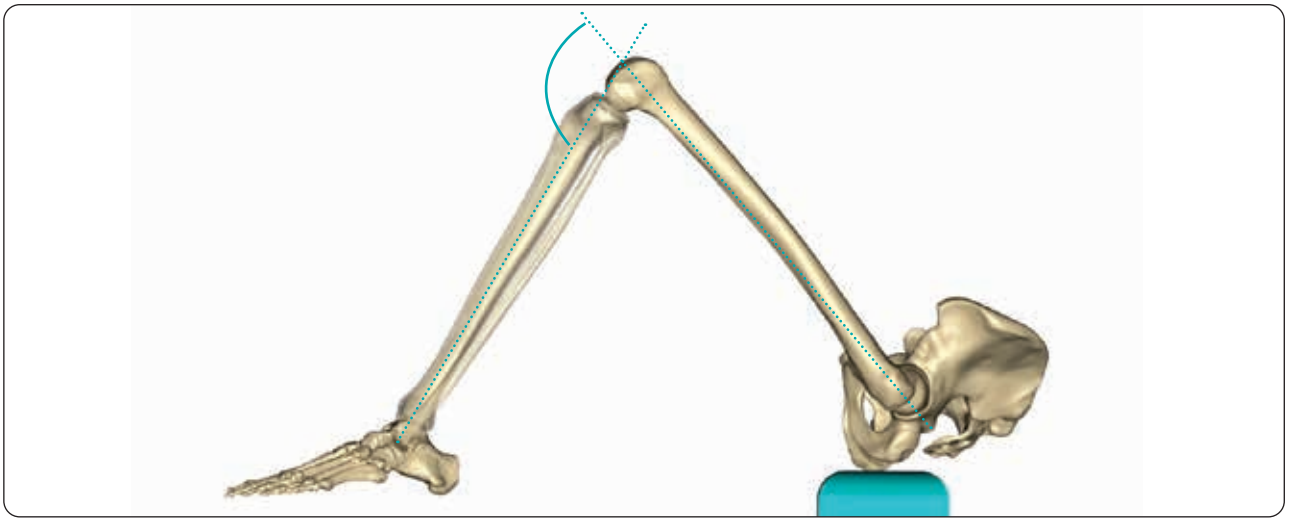


Fig. 12 Patient positioning infrapatellar approach

Suprapatellar approach

This is a semi-extended approach. A sufficiently sized sterile covered removable support **(Fig. 13)** should be used to maintain the knee flexed at about 30° during the following surgical procedure.

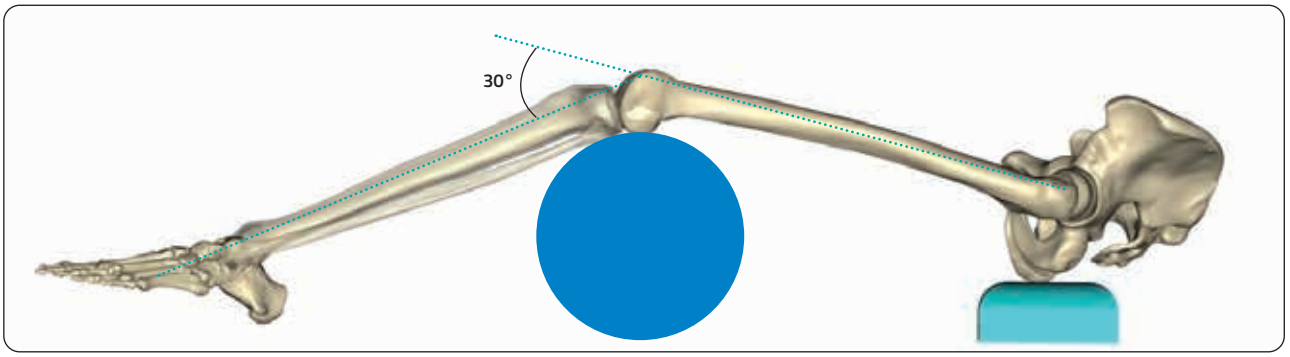


Fig. 13 Patient positioning suprapatellar approach

APPROACH AND INITIAL REAMING

Infrapatellar approach

Make a 20mm transverse skin cut between the lower border of the patella and the tuberosities **(Fig. 14)**. Split the patella tendon longitudinally **(Fig. 15)**.

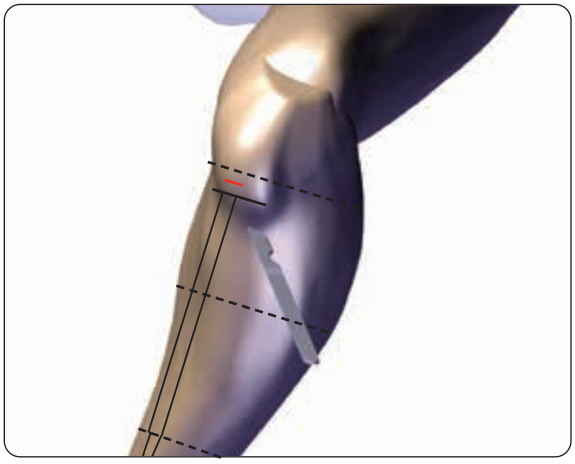


Fig. 14 Skin cut infrapatellar approach

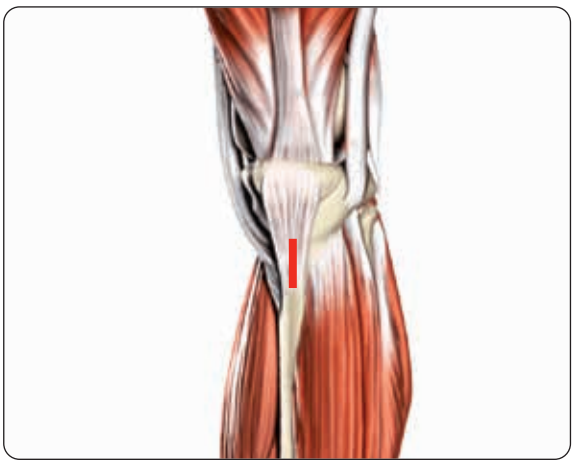


Fig. 15 Patella tendon cut infrapatellar approach

Suprapatellar approach

Make a 20mm transverse skin cut 20mm above the patella **(Fig. 16)**. Split the quadriceps tendon longitudinal **(Fig. 17)**.

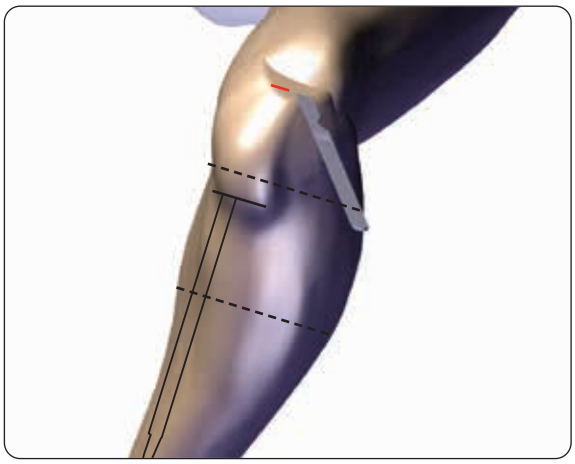


Fig. 16 Skin cut suprapatellar approach

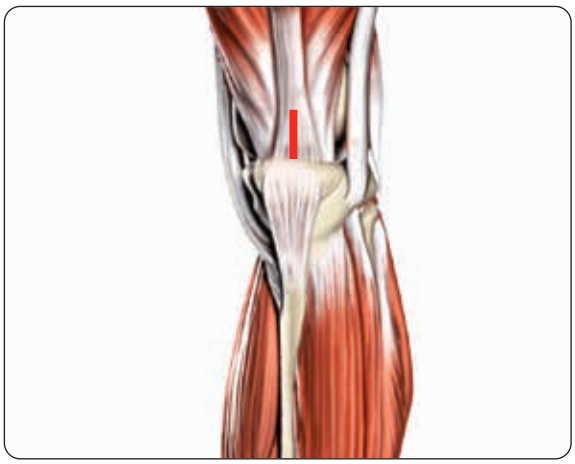


Fig. 17 Patella tendon cut suprapatellar approach

Infrapatellar approach

Locate the center of the bone canal under x-ray guidance using an AP-view. Insert a 3mm K-wire at the bony tibial plateau with the knee in flexion **(Fig. 18)**. The K-wire should not be inserted more than 2 mm away from the target position. Direct the K-wire according to your planning. The K-wire can be inserted to the osteotomy level to guide the rigid reamer.

Double-check position with the C-arm AP and lateral **(Fig. 19)**.

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.

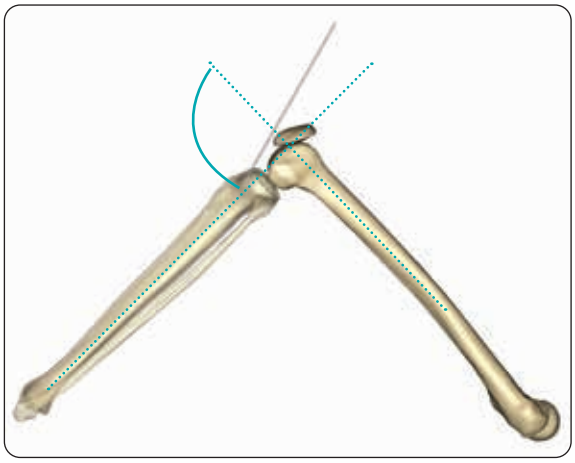


Fig. 18 K-wire insertion at maximum knee flexion (infrapatellar approach)

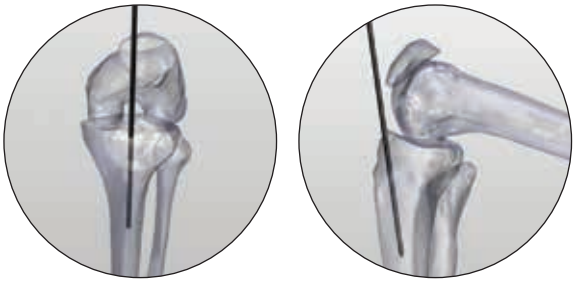


Fig. 19 K-wire position (infrapatellar approach)

Suprapatellar approach

With the knee in 30° flexion, insert a 3mm K-wire at the anterior aspect of the tibia **(Fig. 20)** behind the patella. The K-wire should be inserted exactly at the target position. Direct the K-wire according to your planning. The K-wire can be inserted to the osteotomy level to guide the rigid reamer.

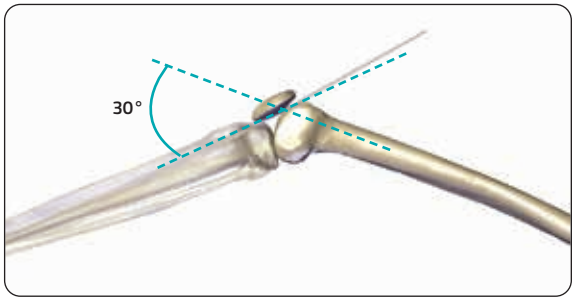


Fig. 20 K-wire insertion (suprapatellar approach)

Double-check position with the C-arm AP and lateral **(Fig. 21)**.

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.

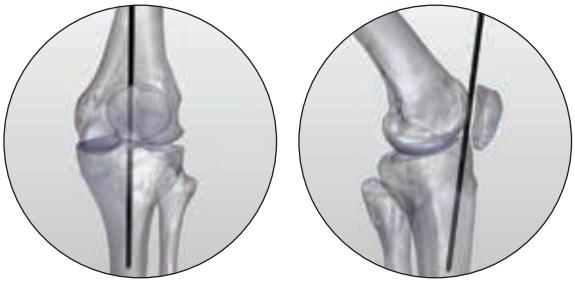


Fig. 21 K-wire position (suprapatellar approach)

Cones and tubes

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

Infrapatellar approach

If K-wire positioning is correct, insert the centered cone C13. If the position of the K-wire has to be corrected, use C13+, or C13++ to correct 1 or 2mm in any direction. The notch at the end of the cone will help in achieving 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 over the cone. **(Fig. 22a)**

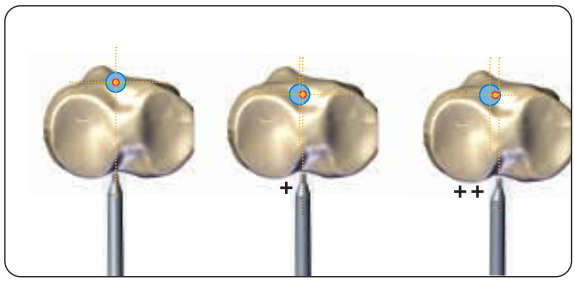


Fig. 22a Cone variations

Fig. 22b Infrapatellar cone

Suprapatellar approach

When using the suprapatellar approach, use the C13 RP suprapatellar cone. The conical part of the C13 RP suprapatellar cone is 20mm longer than the standard approach cones and has a smooth conical surface to aid insertion **(Fig. 23a and 23b)**. Before insertion slide the working tube T14/13 over the cone. After passing the patella use the tube-sinker (TS 13) and push the tube just in front of the tibia head. Then replace the C13 RP by centrical or excentrical cone if correction is needed.

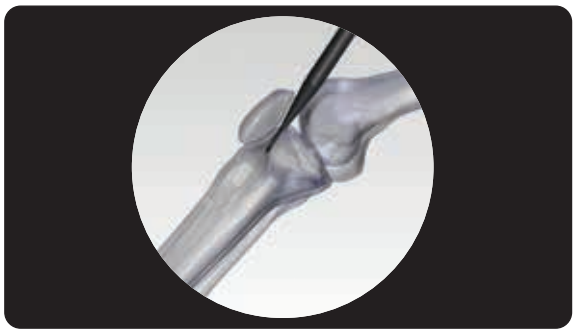


Fig. 23a Suprapatellar Cone insertion

Fig. 23b Suprapatellar Cone

Cones insertion

Infrapatellar

Using a mallet and the cone sinker (CS 15-13), insert the cone into the bone. To ensure stability the cone should be inserted at least up to the depth of the teeth. **(Fig. 24)**

Suprapatellar

Using a mallet and the cone sinker (CS 15-13), insert the suprapatellar cone (RP cone) into the bone.

If the bone size and stability allow, insert the conical part of the tube into the bone. This will prevent damaging the tube. If the suprapatellar cone is not available use a normal cone and insert it at least up to the depth of the teeth.

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

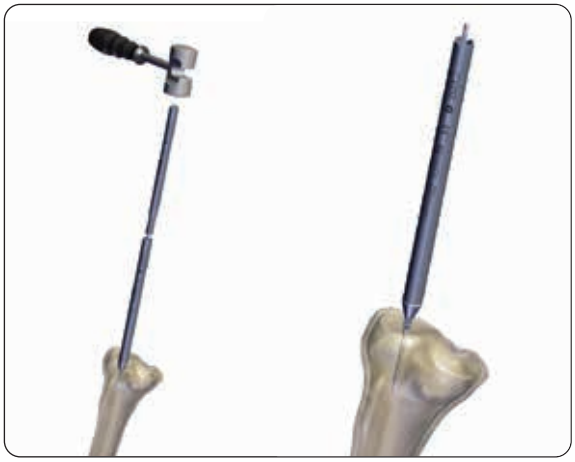


Fig. 24 Cone insertion

REF	Cone Sinker	REF	Cone	REF	Working Tube
60001036	CS 15-13	60001028	C13	60001014	Tube T14/13
		60001029	C13+		
		60001030	C13++		
		60001061	C15+		
		60001062	C15++		
60001036	CS 15-13	60001888	C13RP	60001014	Tube T14/13

Table 1 Cones, Cone Sinker and Working tube assembly

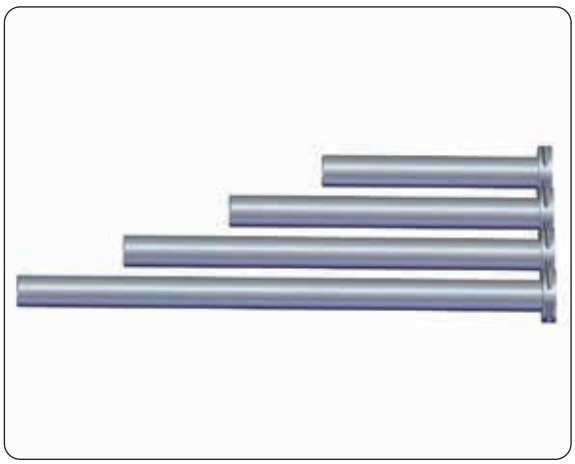


Fig. 25 Tubes (S, M, L and XL)

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 of 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. 25)**

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

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

Table 2 Tubes and Reamers assembly

Working tube insertion

Use the tube-sinker to insert the tube into the bone, according to **Table 3**.

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

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		

Table 3 Tubes and Tube sinker assembly

The working tube should be inserted about 5-10 mm into the bone, making sure the tube is stable inside the bone and the insertion angle of the reamer is orientated according to your planning. For the infrapatella approach use either an S or M T14/13 tube, and an M or L for the suprapatellar approach. **(Figure 26a and 26b)**

Remove the cone and K-wire, leaving the working tube firmly in place.

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

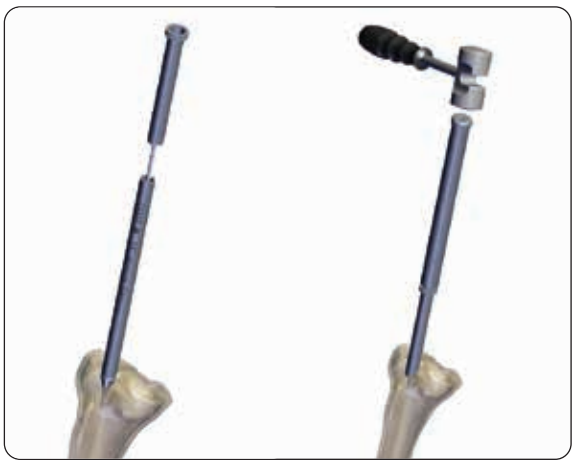


Fig. 26a Working tube insertion

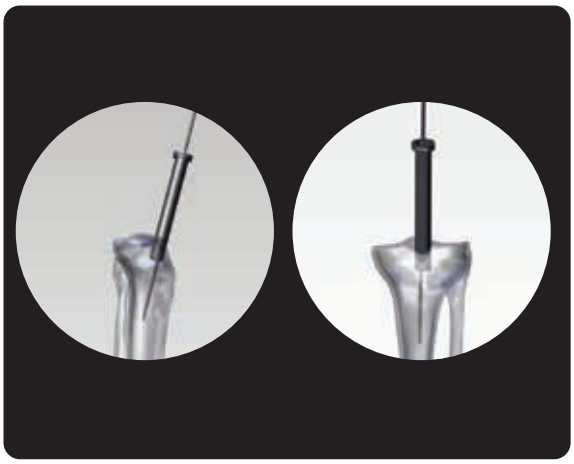


Fig. 26b Final working tube position

INITIAL REAMING

The FITBONE System includes two different types of reamers **(Fig. 27)**:

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. The use of tubes at all times is strongly recommended to maintain planned alignment and avoid any unintended alignment deviations.

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

Venting

If required, venting holes can be drilled to reduce pressure and allow bone debris to exit, 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 quickly.

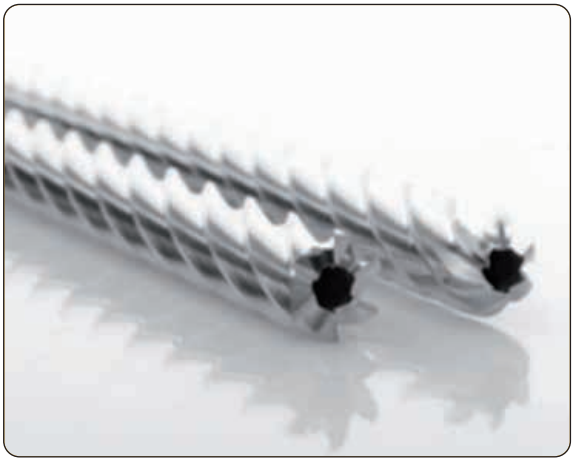


Fig. 27 Front cutting reamer (Left), rounded reamer (Right)

REAMING STEPS

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

These steps allow acute correction according to preoperative-plan. **(Fig. 28)**

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

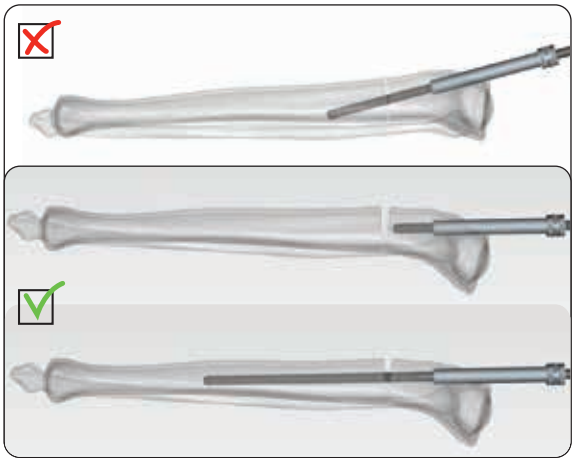


Fig. 28 Reaming with rigid reamers

PREPARATION OF THE PROXIMAL MEDULLARY CAVITY PRIOR TO OSTEOTOMY

Reduce the internal diameter of the working tube to 10mm by inserting the T13/12 tube, followed by the T12/10 tube (working tube + 2 additional tubes in place). Use a 9mm rounded reamer up to the planned osteotomy level, checking reaming pathway under fluoroscopy in AP and lateral planes.

In case of very small or calcified bones, start with an 8mm reamer.

Work your way through the reamers up to 12mm, replacing the tubes sequentially, ensuring a 1mm difference between reamer and tube diameter is maintained **(Fig. 29)**. There is also a 12.5mm reamer available if required.

Check reaming pathway under fluoroscopy in AP and lateral planes throughout the reaming. **(Fig. 30)**

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

Reaming can be performed under power or by hand using the T-handle for greater control.

Fig. 29 Reducing the reaming channel

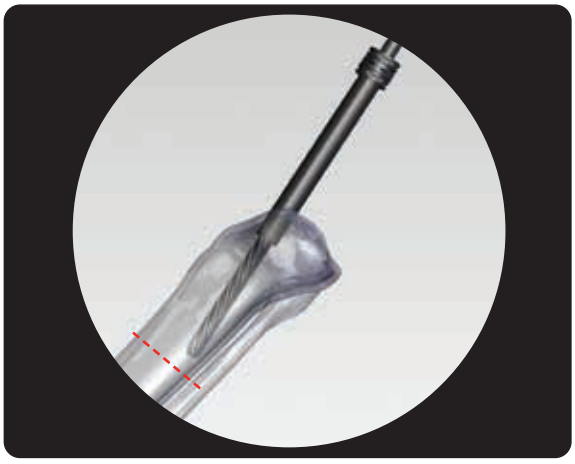


Fig. 30 Reaming up to the osteotomy

OSTEOTOMY

Percutaneous multiple drill holes osteotomy with a tissue protector sleeve while drilling the osteotomy is recommended **(Fig. 31)**.

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

Upon completion of osteotomy and bone correction, begin reaming of the distal fragment. Following the same process as before, reaming the distal segment to the planned tip of the nail, as indicated by the skin marker.

For TAA09, ream up to 9mm only.

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

PRECAUTION: Do not weaken the cortex as this could increase the risk of fracture during treatment.

If the correct position cannot easily be reached, use the front cutting reamers to carefully widen the midshaft canal where it is needed. The front cutting reamer will aggressively remove sclerotic or cortical bone, thus the process has to be controlled under AP and lateral fluoroscopy at all times.

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

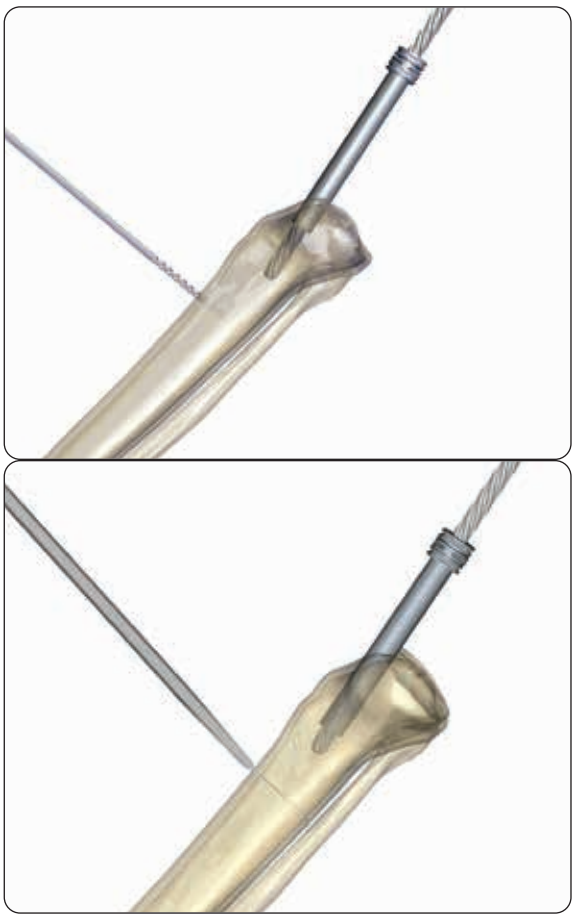


Fig. 31 Osteotomy

DISTAL REAMING AND STEP REAMER

The final ream is performed using the appropriate step reamer. **(Fig. 32)**

Reaming can also be performed by hand, using the T-handle in order to achieve better control. The canal should be reamed only up to the level of the tip of the implant, initially marked on the skin.

There is a dedicated step reamer for each nail, exactly matching implant dimensions. For this reason, no overreaming is required.

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

The step reamer should be used with the working tube T14/13 for TAA11 and TAA09 nails.

Fig. 32 Final reaming

FITBONE	REF	Step Reamer	REF	Dummy	REF
TAA0940-T-200	60001928	TAA0940	60001938	TAA0940-T-200	60001927
TAA0960-T-220	60001856	TAA0960	60001849	TAA0960-T-220	60001855
TAA1140-T-205	60001501	TAA1140	60001528	TAA1140-T-205	60001244
TAA1160-T-225	60001445	TAA1160	60001415	TAA1160-T-225	60001248
TAA1180-T-245	60001348	TAA1180	60001179	TAA1180-T-245	60001495

Table 4 - Overview FITBONE, Step Reamer and Dummy

EXTRACTING THE WORKING TUBE

The working tube is removed using the tube extractor clamp. **(Fig. 33)**

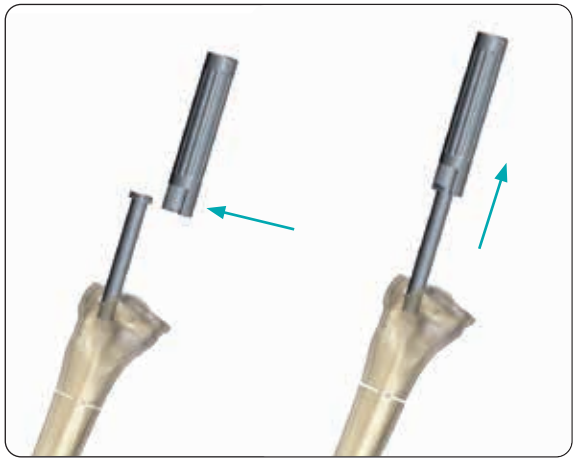
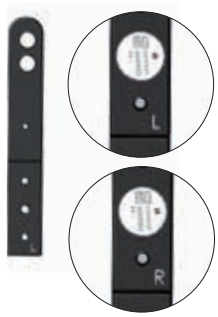


Fig. 33 Working tube extraction

DUMMY PREPARATION

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. 34)** and lock it in place **(Fig. 35)**.

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

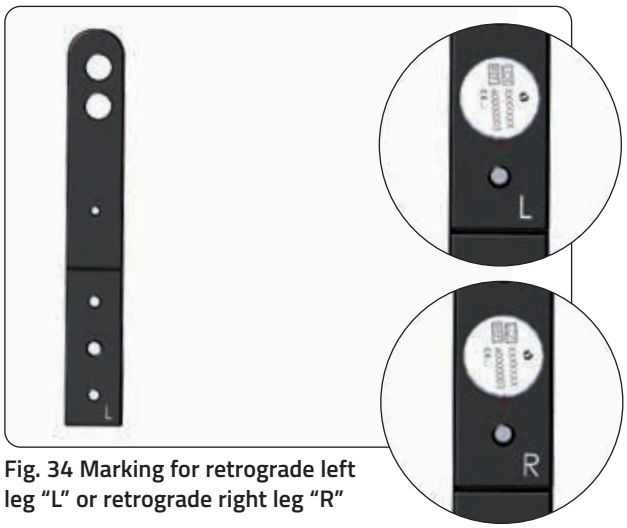


Fig. 34 Marking for retrograde left leg "L" or retrograde right leg "R"

Fig. 35 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. 36)**

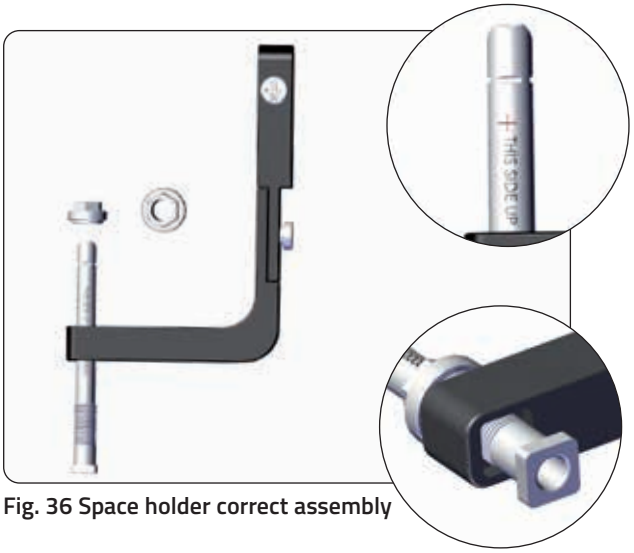


Fig. 36 Space holder correct assembly

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. 37)**

NOTE: The space holder is adapted to both intra- and suprapatellar approach.

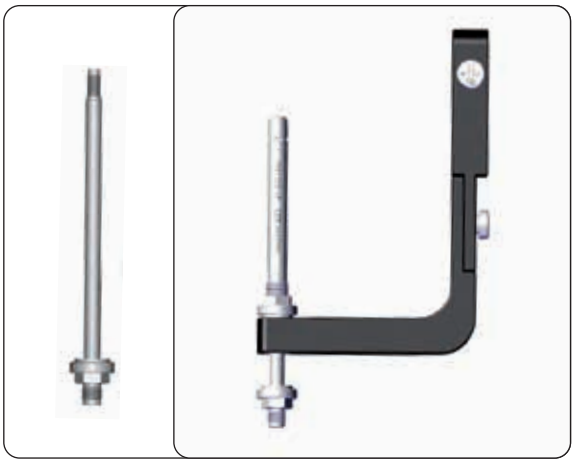


Fig. 37 Space holder fixation

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 outrigger **(Fig. 38)** and inserted into the tibia to confirm the final nail can be inserted at the planned depth (5-10mm below bone entry point) and alignment.

NOTE: The jig is placed medially, with locking screws being introduced medial to lateral.

Fig. 38 Dummy nail assembly

Dummy insertion

Insert the dummy nail into the tibia to confirm planned nail position is achieved. The drill guide portion of the jig can be removed for better visualization under x-ray.

Ensure the space holder marker on the jig is at the level of the entry point. This indicates that the nail is sufficiently implanted in the bone to a depth of 5-10mm. It is advised to check nail positioning under fluoroscopy in AP and lateral planes **(Fig. 39)**.

Remove the jig and the working tube to control alignment and insert blocking screws as needed.

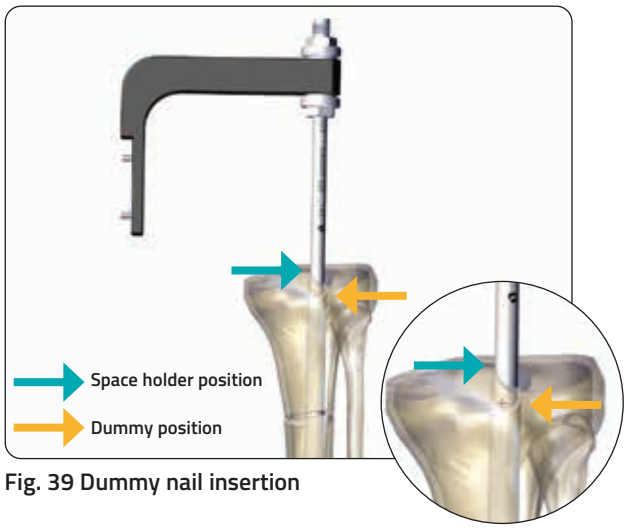


Fig. 39 Dummy nail insertion

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. **(Fig. 40)**

If blocking screws are required, the regular 4.5mm FITBONE screws can be inserted with (or without) the dummy nail in place. **(Fig. 41)**

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.

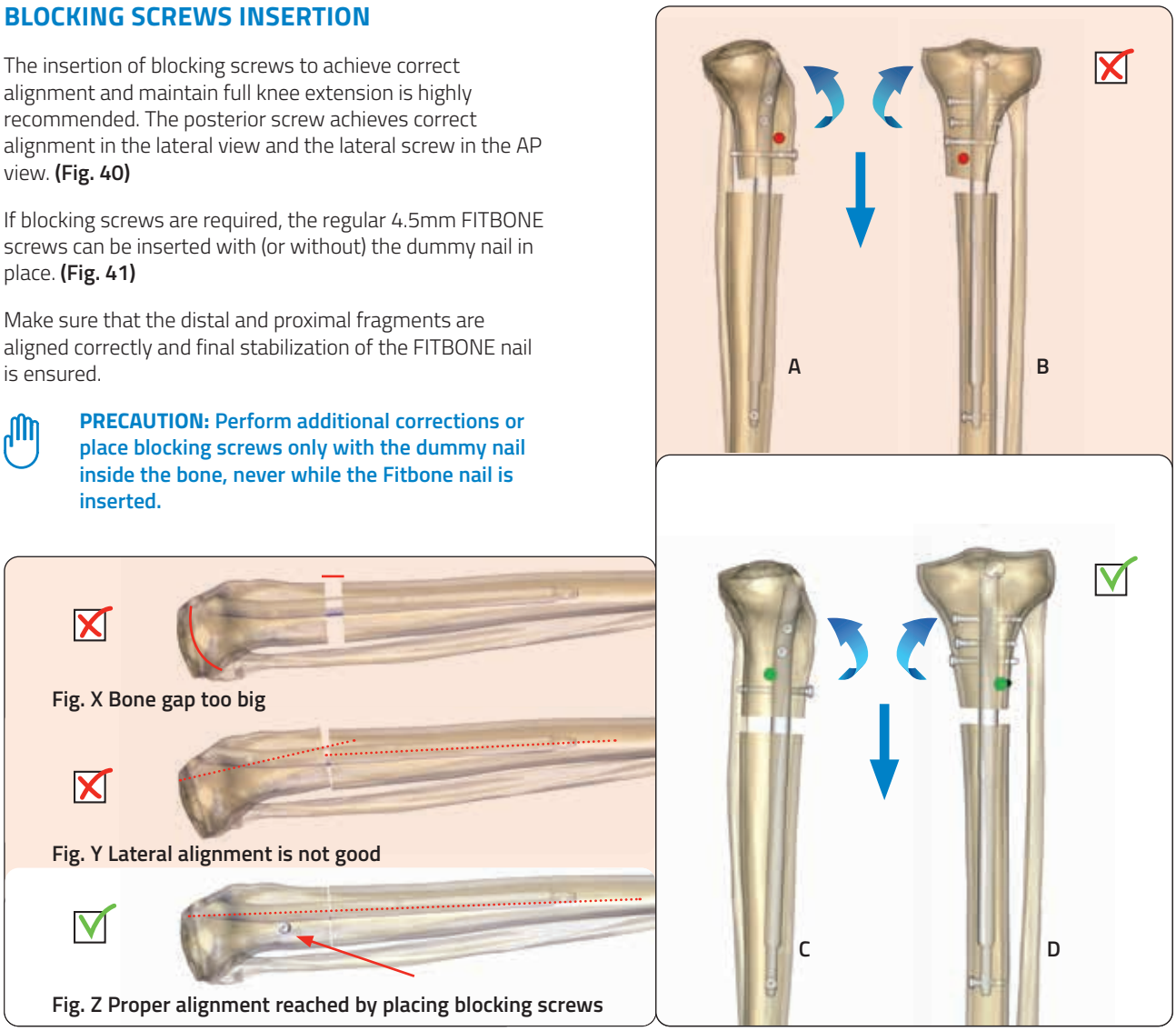


Fig. 40 Alignment and blocking screws

41 Blocking screw insertion

Alignment Control

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).

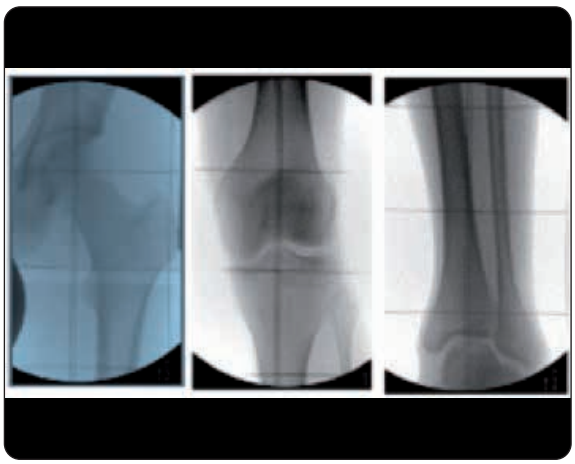


Fig. 42 Alignment control

Perform additional reaming or correct alignment if needed.

FITBONE Intraoperative Functionality Test

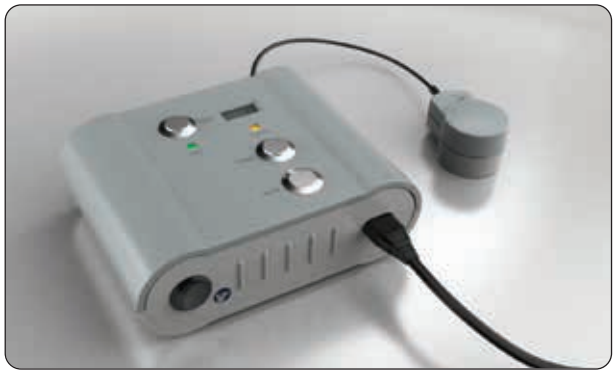
To confirm the FITBONE is functioning correctly, an intraoperative functionality test has to be performed before inserting it into the bone. To minimize the risk of contamination of the implants, do not remove them entirely from their packaging at this stage and expose only the end of the cable of the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

Insert the cable of the nail in the coupling of the receiver as explained on page 29 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.

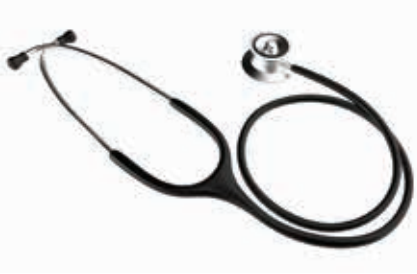
PRECAUTION: Intraoperative Functional Test
Prior to implanting the Fitbone nail, check the functionality of the nail by activating it via the control set. The operating noise of the nail (using the supplied stethoscope) and the flashing control light will confirm the functionality.



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

INSERTION OF THE FITBONE NAIL

Insert the cable of the nail carefully into the cannulated connection bolt and attach the FITBONE nail to the handle in correct orientation **(Fig. 44)**. Attach the drill guide to the handle and insert the test pins into the drill guide and make sure they pass through the holes in the nail easily without friction.

Refer to pages 23-24 for potential problems and solutions.

Lock the nail firmly in place using two wrenches simultaneously **(Fig. 45)**. Remove the test pins.

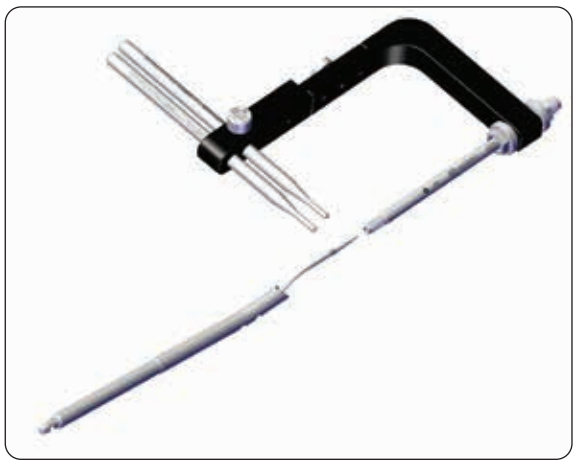


Fig. 44 Final nail assembly

Fig. 45 Final nail locking

Insert the nail to the pre-panned depth. **(Fig. 46)**

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.

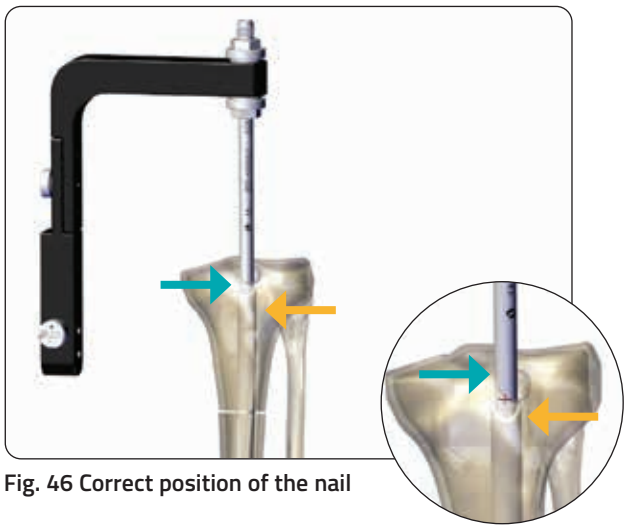


Fig. 46 Correct position of the nail

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. 47)**

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

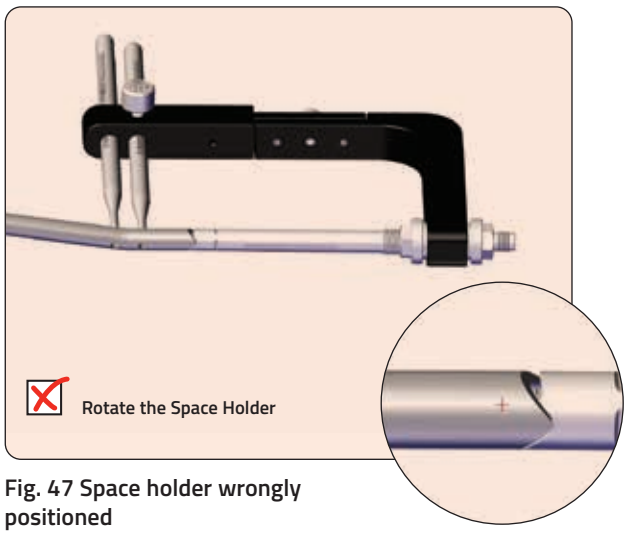


Fig. 47 Space holder wrongly positioned

2) The Space Holder is not completely flush with the Drill Guide Assembly. (Figure 48)

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.

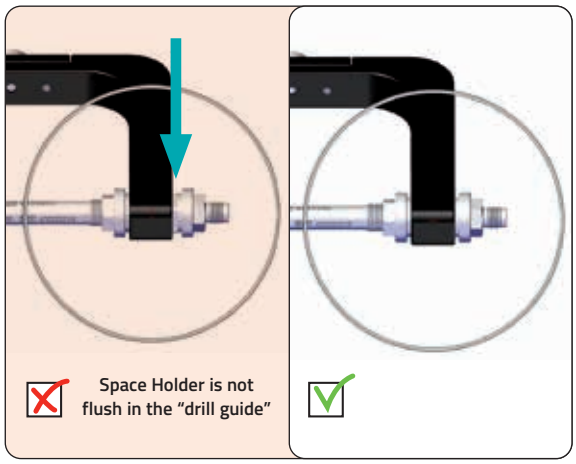


Fig. 48 Space holder wrongly inserted

3) The FITBONE is wrongly placed. (Figure 49)

Corrective action: Unlock the "Connection Bolt Cannulated" and rotate the FITBONE 180°.

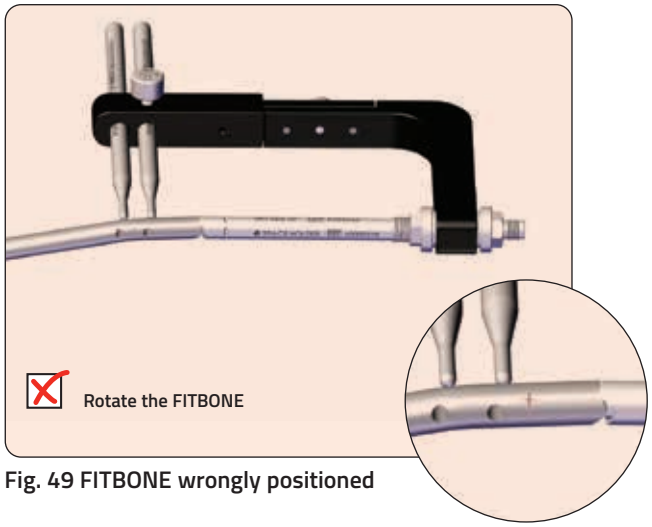


Fig. 49 FITBONE wrongly positioned

4) The FITBONE is loosely fixed to the "connection bolt cannulated". **(Fig. 50)**

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

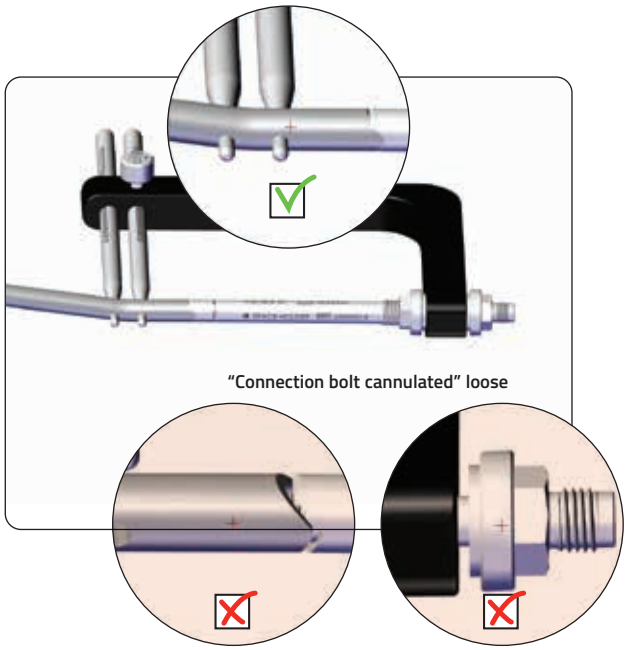


Fig. 50 Connection bolt loose

Inserting the proximal locking screws

The proximal 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 4.5mm into one of the two holes in the drill guide TAA.

Insert the sleeves with the trocar through the medial incision splitting the soft tissue. **(Fig. 51)**

Drill bi-cortically and measure with the FITBONE depth gauge the correct screw length.

Select the correct 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 complete the tightening with the solid driver. **(Fig. 52)**

Insert the second proximal locking screw using the same procedure.

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

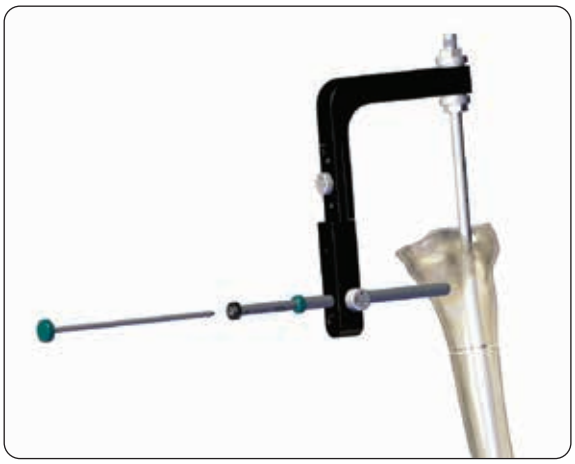


Fig. 51 Drill sleve insertion

Fig. 52 Locking screw hole drill, length measurement and screw positioning

Cable management in suprapatellar approach

Make a 20mm transverse skin cut between lower border of patella and tuberosities ensuring preservation of the posterior cruciate ligament attachment. **(Fig. 53)**

Split the patella tendon longitudinal for cable management. Check ap and lateral where the cable is located and take it out with arthoscopy hook. **(Fig. 54)**

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.

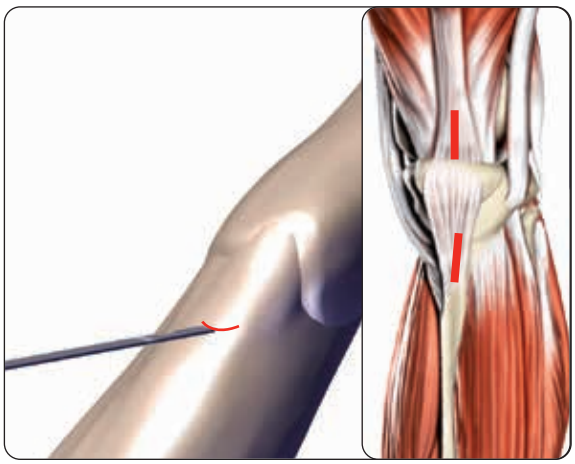


Fig. 53 Additional skin cut in suprapatellar approach (L); patella tendon cut in suprapatellar approach (R)

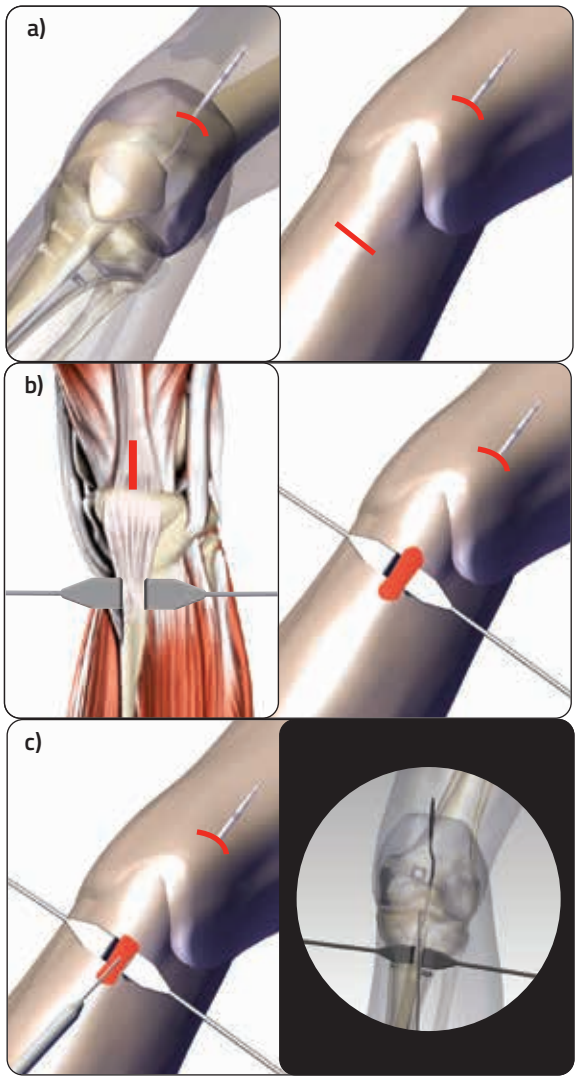


Fig. 54 a) Cable position in suprapatellar approach; b) Splitting of the patella tendon; c) Detection of the cable.

Infrapatellar approach

Use the wrench to loosen the upper securing bolt on the jig **(Fig. 55)**.

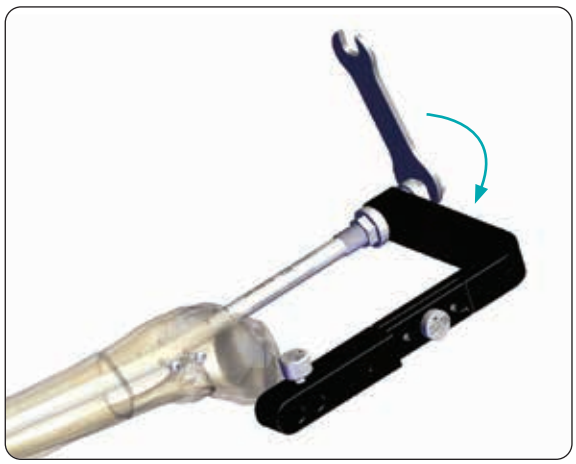


Fig. 55 Loosening the nail

Carefully remove the jig without damaging the cable **(Fig. 56)**.

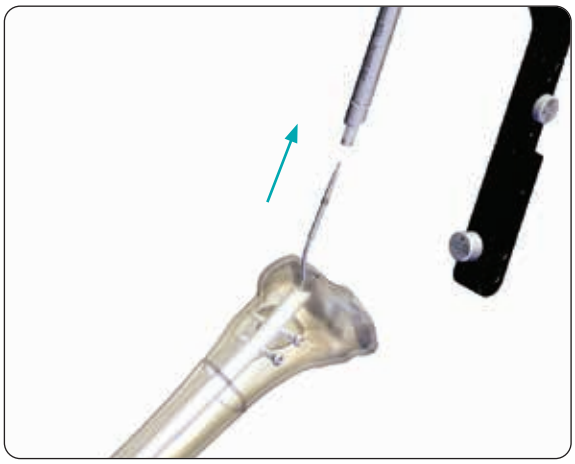


Fig. 56 Cable position infrapatellar approach

Infrapatellar approach

Position the leg in full extension. Detect the cable through the infrapatellar approach by an arthroscopy hook splitting the patella tendon **(Fig. 57)** and keep it open using Langenbeck hooks **(Fig. 58)**.

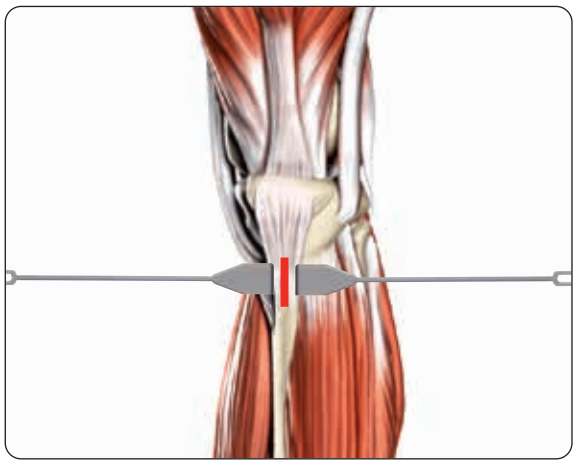


Fig. 57 Patella tendon splitting

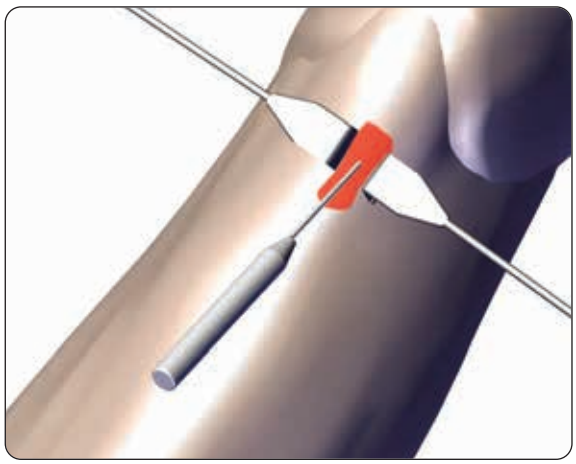


Fig. 58 Detection of the cable

Extract the cable carefully with the potential help of an anatomical hook **(Fig. 59)**.

Do not take the cable with sharp instruments like surgical forceps to avoid damaging the cable. Do not press the cable with clamps or kink it.

NOTE: Handle the cable extremely carefully. Kinking will damage the cable.

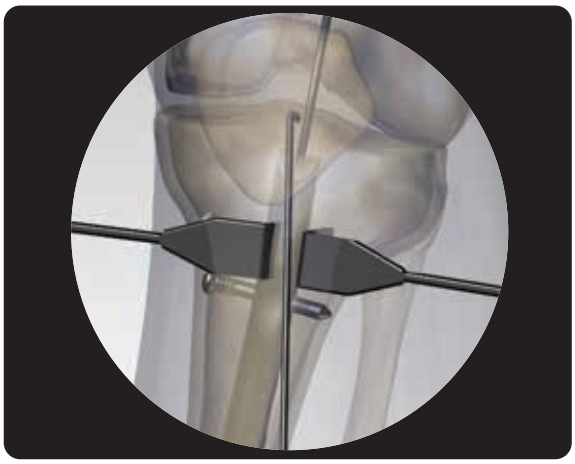


Fig. 59 Catching of the cable

Securing the cable position at the patella tendon

Position the cable distally at the level of the tibial tuberosity. Secure the cable in position by suturing the patella tendon together, directly above the cable. **(Fig. 60)**

PRECAUTION: If the cable is not secured, patella tendon movement may result in damage to the cable.

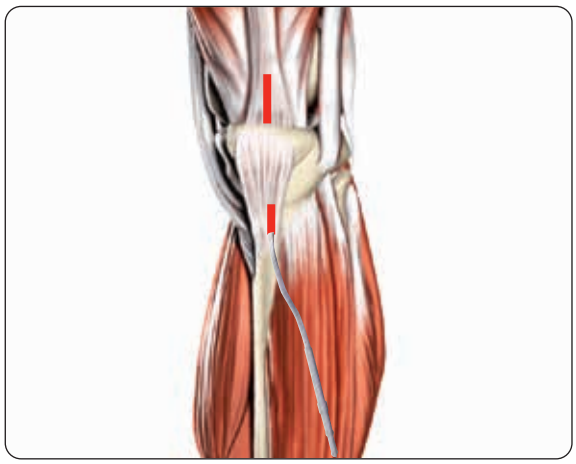


Fig. 60 Final cable position

Inserting the distal locking screw

Before performing distal locking - and with the leg in full extension - check that both bone screws are parallel to avoid torsional malignment.

Distal locking screw is inserted using the free-hand technique under fluoroscopy. **(Fig. 61)**

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

NOTE: 4mm screws with only short thread option are used for all TAA09 FITBONE nail variants. 4.5mm screws with long and short thread options are used for all TAA11 FITBONE nail variants. The longest thread possible, without interaction between nail and thread, should be selected.

Remove the initially implanted bone screws for torsion control.

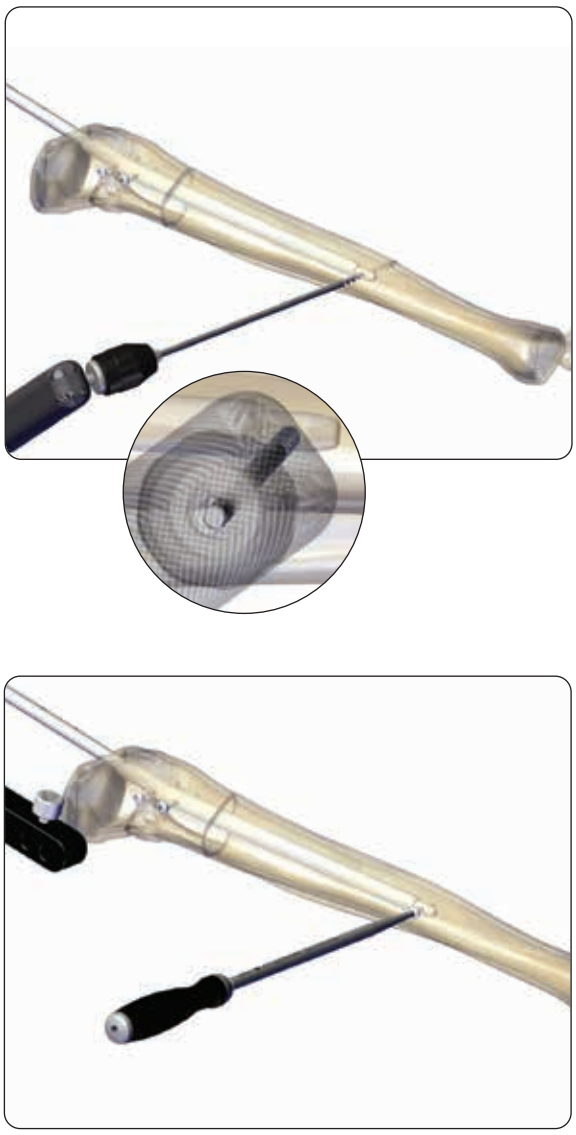


Fig. 61 Distal screw positioning

Positioning the Receiver

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

Remove the Transport Locking Device from the Receiver's Coupling, put a drop of sterile water on it and insert the plug of the cable. **(Fig. 62)**

PRECAUTION: Make sure the white ring (see blue circle in Fig. 62) is in connection with the start of the coupling.

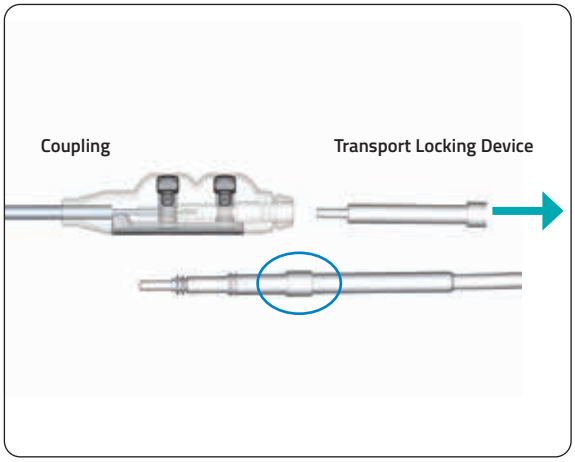


Fig. 62 Transport locking device removal

Lock the cable into the Receiver's Coupling by tightening both screws with the torque wrench, until an audible click is heard. **(Fig. 63)**

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.

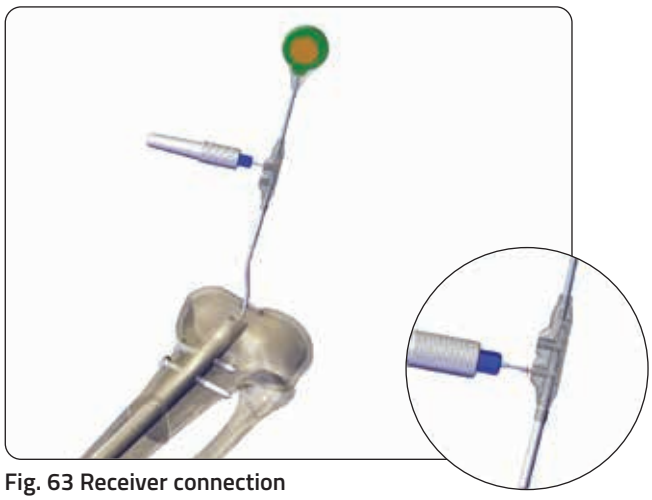


Fig. 63 Receiver connection

A minimal invasive fasciotomy (Vollmer Fasciotome) of the tibia anterior compartment is recommended. This should be performed before receiver placement.

The receiver should be placed directly underneath the skin antero-laterally, at a position where there is sufficient soft-tissue. For this purpose, use scissors to prepare an 80-100mm subcutaneous skin pocket **(Fig. 64)**.

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

Mark the position of the receiver on the skin. **(Fig. 66)**

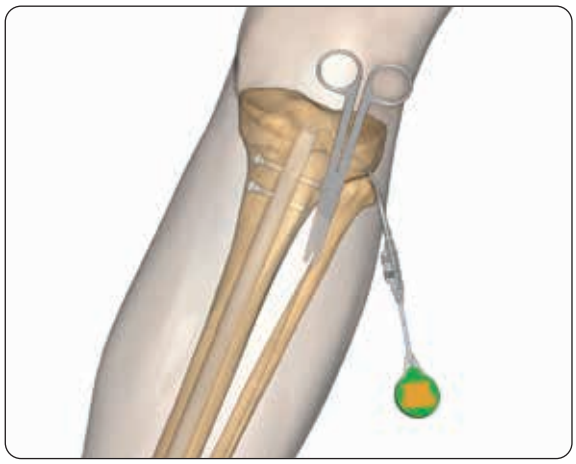


Fig. 64 Subcutaneous skin pocket

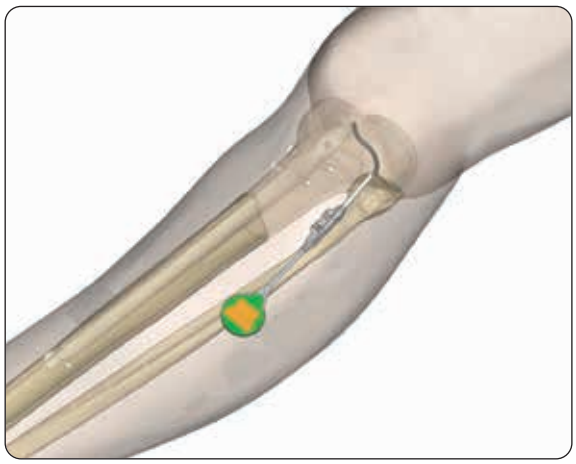


Fig. 65 Receiver final position

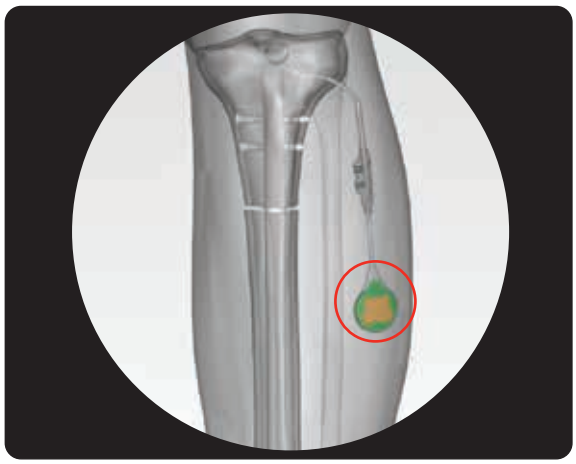


Fig.66 Receiver marking

FIBULA OSTEOTOMY

A screw (3.5-4mm short-threaded screw) proximal of the syndesmosis for fixing the fibula to the tibia is recommended in all cases **(Fig. 68)**. For lengthenings greater than 40mm, an additional screw to fix the fibula head is recommended.

Perform a fibula osteotomy in the distal third **(Fig. 67)**. To ensure a complete osteotomy and avoid early fusion, it is recommended to resect approx. 5mm of fibula.

Fig. 67 Fibula osteotomy

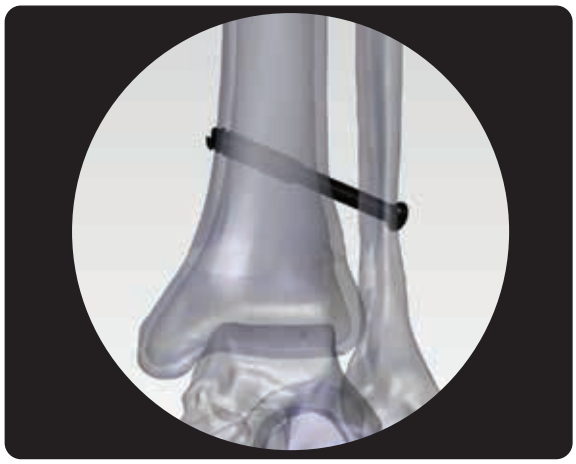


Fig. 68 Fibula fixation

FINAL INTRAOPERATIVE TEST

Upon skin closure perform a final intraoperative functionality test as described above.

Place the transmitter and the stethoscope in separate sterile endoscopic camera drapes. **(Fig. 71 and 72)** Perform a final functional test, ensuring the motor of the Fitbone can be heard during lengthening.

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 labelled "Pat." and "Doc" and pulse or continuous operation, respectively labelled "Pulse" and "Perm." **(Fig. 69)**

Fig. 69 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. 70)**

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 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 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 break.

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.

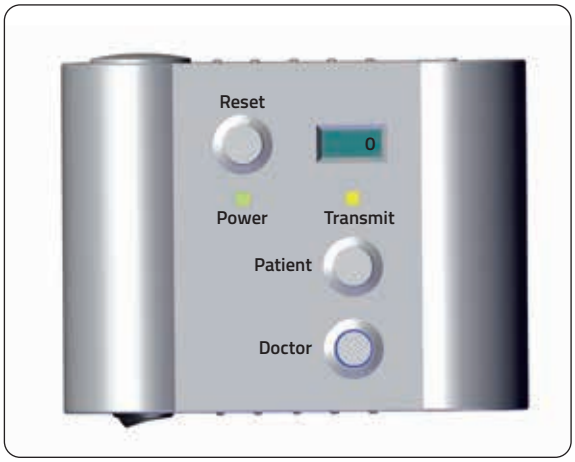


Fig. 70 Control Set

Fig. 71 Inserting the transmitter in the sterile endoscopic camera protection covers

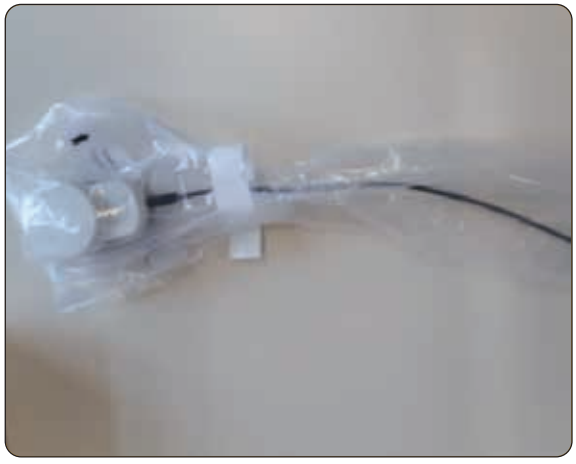


Fig. 72 Transmitter steril covered

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

For the final intraoperative test, connect the transmitter to the FITBONE Control Set and place it on the skin, 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. 73)**. The "Doctor" button will light up blue after being pressed. **(Fig. 74)**

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 in order to remove soiling on the surface of the FITBONE Control Set 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 touch the switches.

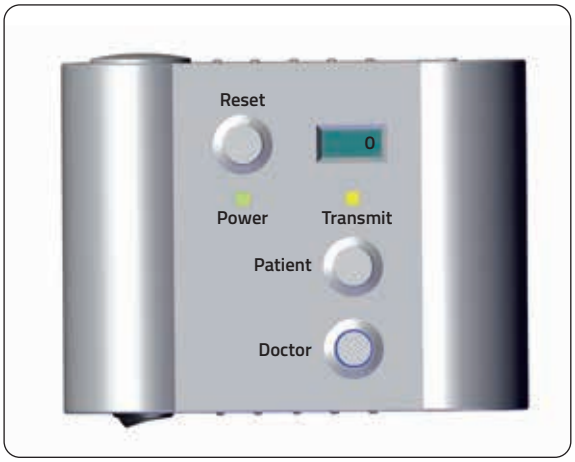


Fig 73 Doctor mode active conditions

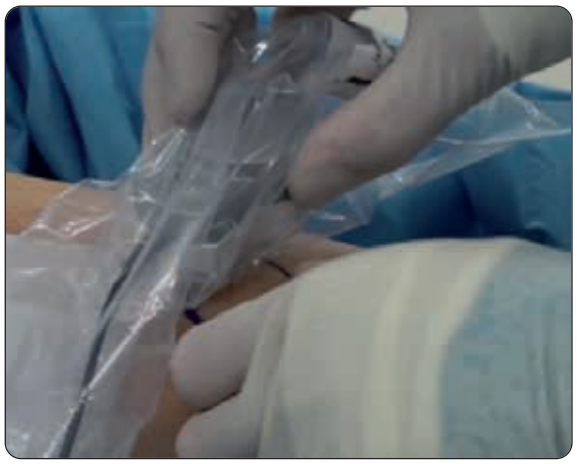


Fig. 74 Final test under sterile

POST-OPERATIVE CARE

In the recovery room, the operated extremity should be 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 exceeding 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.

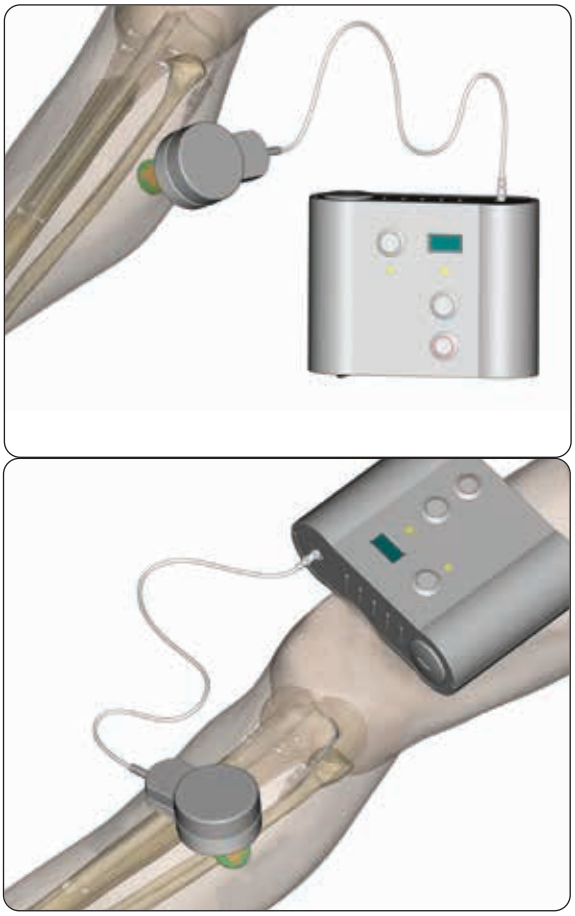


Fig. 75 Post-op lengthening

Chronological sequence of leg lengthening

1. **Initial surgery** – duration 2 to 4 hours. In-patient stay - Duration approximately 4-5 days. Surgery duration 3 to 4 hours. Physiotherapy and mobilization on crutches in the days after the surgery. Start of distraction approx. 5-10 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 3x 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 1- 3 days. Implant removal approximately 1 to 1.5 years after implantation, full weight bearing upon discharge.

NOTE: IMPLANT REMOVAL 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 1 ½ 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.

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.

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

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