

US

FitboneTM

Intramedullary Lengthening System

CLINICIAN GUIDE

FitboneTM TAA

INSTRUCTIONS FOR USE



Orthofix Srl

Via delle Nazioni 9 - 37012 Bussolengo (VR) Italy

Tel. 0039 (0) 45 6719000 - Fax 0039 (0) 45 6719380



Table of Contents

1	General information	4
	1.1 Overview of FITBONE™ TAA System Components	4
	1.2 Configurations	5
	1.3 Indications for Use	5
	1.4 Contraindications	5
	1.5 Possible side effects	5
	1.6 Preoperative preparation	5
	1.7 Positioning the patient	6
	1.8 Using the FITBONE Grid Plate	6
	1.9 Surgical instruments and required materials	7
	1.10 Accessories	8
2	FITBONE TAA Operative Technique	8
	2.1 Implantation technique	8
	2.1.1 Approach	8
	2.1.2 Preparation of the medullary cavity up to the planned osteotomy site	9
	2.1.3 Osteotomy	10
	2.1.4 Preparation of the medullary cavity after the osteotomy	11
	2.1.5 Inserting the dummy	11
	2.1.6 Cable conduit in the distal femur (not required in the tibia)	13
	2.1.7 Implantation of the FITBONE TAA	14
	2.1.8 Locking	15
	2.1.9 Locking bore free hand	15
	2.1.10 Fibula osteotomy	15
	2.1.11 Connecting the Receiver	15
	2.1.12 Placement of the Receiver	17
	2.1.13 Intraoperative functional test	17
	2.2 Postoperative care	18
	2.3 Distraction phase	19
	2.4 Load	19
	2.5 Metal extraction	19
	2.6 System overview	20
	2.6.1 FITBONE Retraction Control Set	20
	2.6.2 Functionality Retraction	21

3	Important notes	22
	3.1 General safety instructions	22
	3.2 MRI Safety Information	22
	3.3 Precaution	23
	3.4 Sterility	23
	3.5 Single use	23
	3.6 Environmental conditions	23
	3.7 Packaging and labels	24
	3.8 Malfunctions	26
	3.9 Medical risks	27
	3.10 Maintenance	27
4	Instrument Set / screw box	27
	4.1 Check list / overview	27
	4.2 Cleaning, disinfection, sterilization	27

1 General information

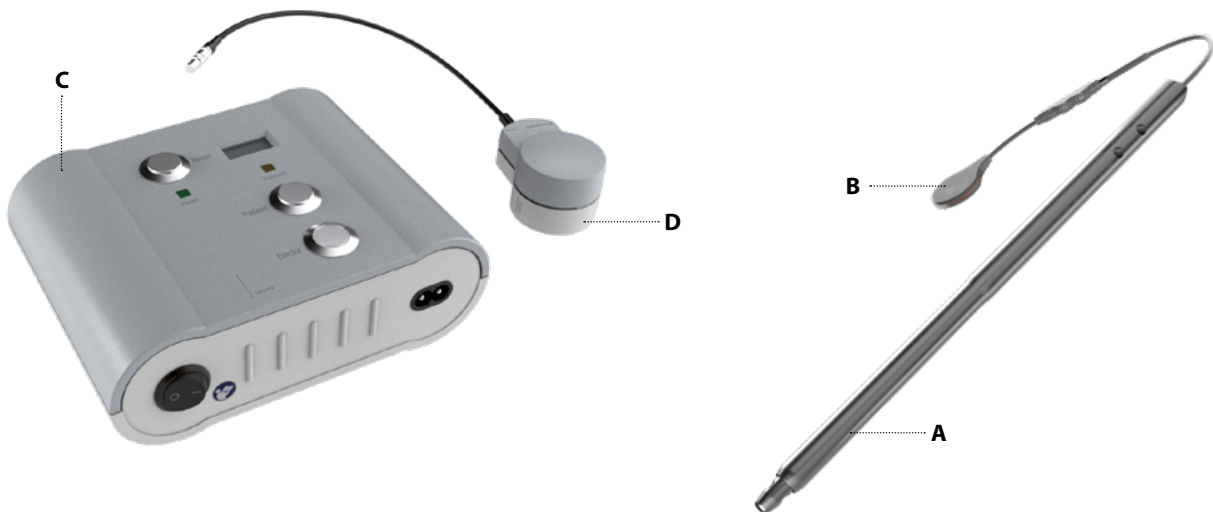
The Clinician Guide for the FITBONE™ TAA includes information on the FITBONE TAA System including the FITBONE Control Set, its functions and operation, and a handling recommendation for implantation. The operative technique summary is provided by Prof. Dr. med. R. Baumgart, ZEM-Germany, Limb Lengthening Center Munich / Germany. Please read this Clinician Guide before operation and startup so that you are familiar with the capabilities of the lengthening nail and the FITBONE Control Set and can make optimal use of its functions. This handling recommendation does not replace any medical training and reflects only approved uses of the device.

The FITBONE TAA System makes it possible to perform femoral and tibial lengthening without the use of external fixators. With appropriate preoperative planning, it is possible to make axial and torsional corrections as part of limb lengthening. The following description provides information on implantation of the intramedullary lengthening nail FITBONE and postoperative operation of the FITBONE Control Set. It is assumed that the implanting surgeon is familiar with the technique for callus distraction and corrective treatments of the lower extremities, and has mastered all procedures from analysis of the deformity and planning through to surgery and aftercare. It is also assumed that the surgeon is familiar with the technique for intramedullary nailing to treat bone fractures and recognized osteotomy techniques.



Participation of the surgeon in a FITBONE training course is one of the basic prerequisites for autonomous use of the FITBONE TAA System. The indication for treatment, intraoperative procedure and postoperative aftercare are the responsibility of the surgeon.

1.1 Overview of FITBONE™ TAA System Components



1. FITBONE TAA (A) intramedullary lengthening nail with bipolar feed line for the Receiver
2. Receiver (B) with coupling
3. FITBONE Control Set, comprising the control electronics (C) with power cable and Transmitter with coaxial cable (D)

The FITBONE TAA System consists of the intramedullary lengthening nail (A) with a Receiver (B) connected by a bipolar feed line. The external FITBONE Control Set consists of control electronics (C) and a Transmitter (D). The energy required for the distraction process is transmitted to the Receiver implanted beneath the skin by applying the Transmitter. There is no contact between the implanted intramedullary lengthening nail and the surface of the body.



More information about their function and operation can be found in the Instructions for Use for the FITBONE Control Set.



The supplied components constitute a treatment system and must not be substituted under any circumstances without the written consent of the manufacturer.

1.2 Configurations

The FITBONE TAA intramedullary lengthening nail is available in various configurations. You can find the technical data of the different intramedullary lengthening nails FITBONE in the respective data sheets and dimension sheets. These are provided by the manufacturer upon request.

1.3 Indications for Use

FITBONE TAA is an intramedullary lengthening system for limb lengthening of the femur and tibia. FITBONE TAA intramedullary lengthening system is indicated for adult and pediatric (greater than 12 through 21 years of age) patients.

1.4 Contraindications

- Patients with any open wounds or areas with poor soft tissue coverage near the operative site. Patients with anatomic deformities which prevent the device from fitting
- Patients with poor bone quality that would prevent adequate fixation of the device
- Patients with compromised capacity for healing
- Patients with metal allergies and sensitivities
- Patients in which the implant would cross open, healthy epiphyseal growth plates
- Blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity
- Insufficient intramedullary space which would lead to cortical weakening or vascular damage during an implantation
- Patients with a body weight of > 100 kg for TAA11/13
- Patients with a body weight of > 50 kg for TAA09
- Differences in leg length of less than 20 mm
- No free access for proximal insertion of the intramedullary lengthening nail (e.g. coxa valga)
- No reliable exclusion of bone infection
- Expected non-compliance, mentally ill patient or patient with clouded consciousness
- Pregnancy

1.5 Possible side effects

In addition to the general risks involved in surgical intervention, the following side effects may occur in some cases despite correct treatment:

- slight tingling to severe pain in the affected limb, particularly during and after distraction
- temporary limited mobility of the affected limb

1.6 Preoperative preparation

As the FITBONE enables almost complete correction of existing deformities, a comprehensive analysis of the leg geometry must be conducted first.

The following examination procedures are required for this:

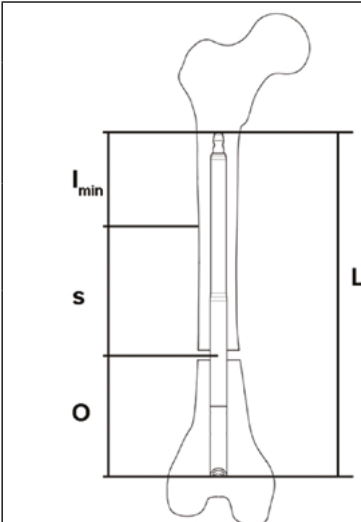
- Anamnesis
- Clinical examination findings with documentation of the range of motion, circulation and neurological status of the extremity
- Diagnostic radiology in the form of long supporting leg X-rays of the upper and lower leg, anterior-posterior and medial-lateral plane (AP and ML plane)
- If necessary, leg-length CT with torsion angle measurement and exact leg length determination

The Reverse Planning Method according to Prof. Dr. Dr. med. R. Baumgart is recommended [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] is recommended.

The osteotomy height is determined on the basis of preoperative planning according to the required corrective actions and patient-specific anatomical characteristics.

To stabilize the bond between the implant and bone after successful callus distraction, sufficient coverage of the distal implant shaft and control of the proximal fragment of at least 65 mm is required (Imin, see the following graphic "Tbl-1").


When determining the height of the osteotomy, you must take account of the planned distraction distance.

	L: Overall length of the implant
	O: Osteotomy height based on FITBONE
	s: Planned distraction distance
	$l_{\min} = L - O - s$ $l_{\min} \geq 65 \text{ mm}$: Minimum required coverage after lengthening

i Dimensions, see Chapter 1.2 "Configurations"

1.7 Positioning the patient

The surgery is performed in the normal surgical fashion, according to institutional protocol, with the patient in the supine position on a radiolucent operating table. Coverage up to the costal arch is such that unrestricted use of the image converter from the femoral head to the ankle joint is possible at any time. The leg to undergo surgery must be freely movable. Observe the measures for radiation protection or dose reduction. The FITBONE Grid Plate () is recommended for optimization during the surgery and to monitor the course of the Mikulicz line. The grid plate is placed flat at the foot of the operating table and secured centrally. The padding of the operating table must cover the grid plate completely. When selecting the operating table, make sure that the image converter can reach the grid plate over the entire length orthogonally and no metal parts are embedded in the operating table. The grid plate is 1282 mm x 376 mm and 3 mm thick. A radiopaque metal lattice is incorporated into the grid plate with a line spacing of 50 x 50 mm. There are two longitudinal double lines at a distance of 200 mm for better orientation.

	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.
---	---

Please follow the storage and cleaning instructions when cleaning and storing the grid plate.

1.8 Using the FITBONE Grid Plate

Adhere to the following procedure exactly to avoid errors when using the FITBONE Grid Plate:
 As the rotation in the hip joint is of central importance for measurement X-rays, the leg must first be brought to the correct rotational position and then held throughout the measurement. The patella is usually aligned ventrally. In all cases, the rotation should correspond to the preoperative plan in the frontal plane. The image converter is first aligned with its direction of travel parallel to the operating table, so that the C-arm can be moved with the longitudinal slide orthogonally to the operating table.



Depending on the side to be examined, the right or left double line of the grid plate is first positioned exactly at the center of the image section at the level of the hip joint by moving the longitudinal slide. The positioning slide is locked in this position. Only then is the patient positioned until the center of the respective femoral head is located precisely in the middle of the double line. We recommend that you save the image for documentation.

Important:

The image section must be moved to the left so that the double line is in the middle of the image.



Now move the image converter to the level of the ankle. With the image converter and operating table arranged in parallel (as described above), the double line generally remains centered in the image section. Subsequent minor corrections can be made to the longitudinal positioning slide of the C-arm. Now also position the ankle exactly at the center on the double line without changing the rotation of the leg. Save the image for documentation.



For the final step, check the position of the knee. To do this, move the image converter again parallel to the table up to the level of the knee, keeping the double line in the center of the image. Once the double line is centered in the image again (make subsequent corrections with the longitudinal slide if necessary), assess the position of the knee joint relative to the double line (connecting line between the centre of the femoral head and the center of the ankle). Save the image for documentation.



**Align the beam path perpendicular to the surface of the plate.
The double line must be located precisely in the center of the image for the evaluation. Do not change the position and rotation of the extremity during the measurement.**

Note:

Marking the condylar axis, implant length and osteotomy height on the skin facilitates intramedullary reaming according to the plan. The corresponding dummy, markers and, if necessary, staple clips can be used for this purpose.

1.9 Surgical instruments and required materials

Keep the instruments intended for the following trays available for the FITBONE TAA operation:

- FITBONE General Tray (6990863)
- FITBONE Reamer Tray TAA (6990864)
- FITBONE Instrument Tray TAA (6990865)
- FITBONE Extractor Tray LITE TAA (6990875)
- FITBONE Screw Box (6991108)
- FITBONE Tube System TAA Basic (6991040)

For TAA09 operations, you also require the instruments intended for the following trays:

- FITBONE Instrument Tray TAA09 (6991967)
- FITBONE Loan Extraction Tray TAA 09-11 (6992062)

For TAA13 operations, you also require the instruments for the following trays:

- FITBONE Instrument Tray TAA13 (6992059)
- FITBONE Loan Extraction Tray TAA 13 (6992065)

Alternatively, you can use the instrument trays for TAA13 operations mentioned above if the following instrument is available to you:

- FITBONE Dummy TAA1380-F-245 (60001623)

Recommended tools and instruments in addition to the FITBONE instrument set:

- Knee roll (D=12 mm, D=18 mm, D=24 mm) height 150 mm 200 mm, 250 mm
- Support pillow (100 x 200 x 40 mm)
- Osteotomy instrument set (suitable drill, tissue protection and chisel)
- Slotted hammer (for explantation only)
- Cancellous bone funnel
- 2 Schanz screws Ø 5 mm
- Drive for large bone surgery with corresponding attachments and right-angle gearheads

- ASK examining hooks (for explantation only)
 - Marker and clips
- Please keep these instruments in a sterile condition.

1.10 Accessories

A FITBONE TAA system delivery for one patient includes the following components:

- FITBONE TAA intramedullary lengthening nail with bipolar feed line for the Receiver
- Receiver with coupling, for distraction and retraction of the intramedullary lengthening nail (60001780)
- Torque wrench for tightening the screws of the bipolar plug connection between the intramedullary lengthening nail and the Receiver
- FITBONE Control Set, comprising the control electronics with power cable and Transmitter with coaxial cable (60001644)
- Stethoscope for monitoring the noise level
- Instructions for Use of the FITBONE Control Set (PQFBP)
- The FITBONE TAA instrument set described, see Chapter 1 "Instrument Set / screw box", if not yet available to the surgeon
- We supply additional locking screws if ordered. No other screws may be used.

Please have the following available:

- sterile camera drape, dimensions 13 x 250 cm , reverse folded (e.g. Lohmann & Rauscher "Raucodrape®" REF 15966)
- 2 Redon Drains, size 8, sterile, length 500mm, material: PVC, with X-ray contrast strip (e.g. B. Braun "REDON-DRAINS" REF U2110800 / PZN 8827354)
- 2 Cerclage wire, Ø 0.8 mm, length 1.000 mm, material: 1.4441 (e.g. Mede Technik "Cerclagedraht" REF KH.3308.1000)

No accessories other than the components described are permitted.



The FITBONE TAA intramedullary lengthening nail is delivered in plasma sterilized condition. Indicators on the sterile packaging serve as proof of plasma sterilization. Check the sterile packaging (both) for integrity and expiration date before opening. Do not use if the sterile packaging is damaged.

2 FITBONE TAA Operative Technique

2.1 Implantation technique

The following description outlines the correction of femoral or tibial length discrepancy without axial and torsional correction with retrograde implantation of a FITBONE TAA. Therefore, it only includes the implantation of the intramedullary lengthening nail and does not examine the specific features of any corrective actions.



If the leg is not deformed, make sure that the osteotomy does not result in axial and torsional deviations. The insertion of Schanz screws for torsional control is therefore strongly recommended. 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.

2.1.1 Approach

The approach is retrograde as with conventional intramedullary nailing: In the femur between the lower edge of the patella and tibial tuberosity and in the tibia between the bottom edge of the patella and tibial tuberosity with preservation of the posterior cruciate ligament attachment. A traverse skin incision (approx. 20 mm) is favorable cosmetically. Then divide the patellar tendon longitudinally. Open the medullary cavity while monitoring via the image converter and using the FITBONE Tube-System TAA . The FITBONE Tube-System TAA is a medical instrument set for minimally invasive implantation of the FITBONE TAA intramedullary lengthening nail in long bones. Please check the exact designation in the checklists that you receive along with the instrument set.

Placement of the cone:

First, locate the correct point of insertion for the femur in the bony notch and for the tibia on the bony tibial plateau at maximum knee flexion using a K-wire Ø 3 mm (60001039) while monitoring in two planes via the image converter. Pay attention to the correct rotational alignment of the femur/ tibia in the a.p. and lateral beam path.

If the K-wire Ø 3 mm is inserted more than 2 mm from the target position, it must be repositioned. Eccentric cones with 1 mm eccentricity Cone C 13+ (60001029) and 2 mm eccentricity Cone C 13++ (60001030) are available for precise corrections (less than 2 mm). There are two differently sized notches on the impact end of the eccentric cones. Make the correction in the direction of the larger notch.

Once the K-wire Ø 3 mm is positioned according to the plan and the required cone has been selected, insert and impact the cone using the K-wire Ø 3 mm. Never impact the cone using a striking tool directly, use the associated Cone-Sinker CS15-13 (60001036) instead. Always use the Cone-Sinker CS 15-13 to impact the eccentric cones also. The Cone-Sinker CS 15-13 can then be removed.



Cone with K-wire and Sinker CS 15-13

Placement of the tube:

	Direct use of striking tools to impact a cone or tube can damage the surgical instruments. Use the corresponding Cone-Sinker CS and Tube-Sinker TS (CS=Cone-Sinker, TS=Tube-Sinker) to avoid damage.
	Axial correction is determined definitely by the choice of the entry point for the FITBONE TAA intramedullary lengthening nail in the bone and the reaming direction up to the osteotomy site.

The Tube T14/13-M (60001014) is initially advanced over the cone until it contacts the bone. The associated Tube-Sinker TS13 (60001033) is used for impaction into the bone.



Cone with Tube T14/13 - M and Tube-Sinker TS13

2.1.2 Preparation of the medullary cavity up to the planned osteotomy site

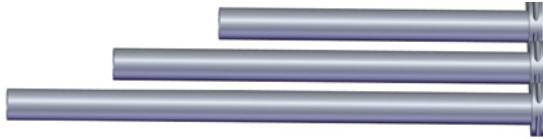
The Tube T 14/13 – M forms a channel for processing the bone. The tube remains in situ during all reaming processes, allowing the reamers to be changed without damaging soft tissue. Tubes of different inside diameters are provided to guide the reamers concentrically. The outside diameter of the next smaller tube corresponds to the inside diameter of the next larger, i.e., tubes with corresponding inner and outside diameters fit together.



Reamer with tubes

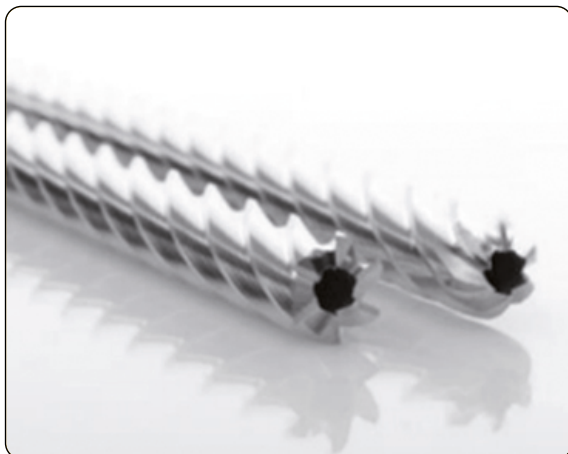
The tubes are available in various lengths on the tray.

Medium tubes are identified by "M" (medium), long tubes by "L" (large), extra long tubes by "XL" (extra large).



If shaft reaming is complicated, it may be advantageous to protect the channel in the already tailored metaphyseal region while diaphyseal reaming is performed. Longer tubes can be used for this purpose. When using rigid reamers, make sure that the inside diameter of the respective tube is 1 mm greater than the outside diameter of the reamer to leave space for the material removed. Failure to do so can lead to jamming and subsequently damage the tubes. The medullary cavity is reamed directly using the rounded, rigid reamers to the height of the osteotomy initially. This is done in stages, depending on the diameter of the implant and under monitoring via the image converter in two planes: Starting with 9 mm up to 12 mm (for TAA09/11; TAA13: up to 13 mm), according to the preoperative plan.

- The front-rounded reamers have a cutting length of 200 mm. These tools are used to open and straighten the medullary cavity. To secure the entry point at all times and avoid unintended displacements, the use of tubes is strongly recommended.
- The front-cutting reamers with a cutting length of 100 mm make it possible to correct medullary cavity reaming in any direction. However, there is a significantly higher risk of excessive cortical weakening and even perforation.



Reamers, front-cutting (left) and rounded (right)



It is strongly recommended that you monitor the entire reaming process with the image converter in two planes to detect any reaming errors in good time.


If preparation of the medullary cavity up to the planned height of the osteotomy according to the diameter of the intramedullary lengthening nails FITBONE TAA is not possible due to an existing deformation of the femur/tibia, the reaming process must be interrupted immediately, and another osteotomy performed. It is important to note that the intramedullary lengthening nail FITBONE TAA may not provide adequate stabilization if an additional osteotomy is performed and appropriate precautions must be taken (e.g. by attaching a plate) to ensure that distraction only occurs at the required site.



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.


2.1.3 Osteotomy

A minimally invasive technique is used to perform the osteotomy according to the preoperative plan. Use a suitable osteotomy instrument (not part of the FITBONE Instrument Set). The type of osteotomy which is most advantageous depends on the height in question and the corrective actions planned.

	<p>Make sure that the front surfaces remain in corresponding contact at osteotomy level, as otherwise inadequate bone regeneration can be expected.</p>
---	--


2.1.4 Preparation of the medullary cavity after the osteotomy

After completion of the osteotomy, align both main fragments in two planes according to the preoperative plan. Use the rigid reamers to prepare the diaphyseal medullary cavity to receive the implant. The cortical bone must not be weakened excessively to prevent an increased risk of fracture or any impact on bone regeneration. Both main fragments are aligned according to the preoperative plan, and the medullary cavity of the main diaphyseal fragment is gradually reamed from 9 mm to 11 mm (for TAA11; TAA09: up to 9 mm; TAA13: up to 13 mm) with repeated monitoring in two planes via the image converter. Depending on the severity of the antecurvature, the entry point of the reamer with the femur in the proximal main fragment (with the tibia in the distal main fragment) must be shifted ventrally and the beam path moved dorsally to the middle of the diaphyseal fragment. End-cutting reamers are used for this purpose. The T-handle (60000392) can also be used for manual reaming.

	<p>Make sure that the ventral circumference is not weakened at the proximal end of the ream (risk of fracture). In the diaphyseal region, corrective possibilities are limited, and the risk of perforation is high if the reaming procedure is not monitored. Repeated monitoring by the image converter in two planes during the reaming process is essential. Improper reaming can lead to heat damage to the bone and serious complications.</p>
---	---

Final preparation of the medullary cavity is carried out using the respective step reamer with the same geometry as the selected FITBONE TAA intramedullary lengthening nail. Insert the stepped reamer to the depth of the subsequent position of the implant.

2.1.5 Inserting the dummy

	<p>It must be possible to insert the dummy without resistance. It may be necessary to ream the medullary cavity further under monitoring by the image converter. The FITBONE Tapping Tool (60000317) is intended solely for later explantation.</p>
---	--

To assemble the drill guide, remove the following components from the instrument tray FITBONE TAA and assemble them as shown:

- FITBONE Drill Guide TAA (60001175)
- FITBONE Outrigger TAA (60001184)
- FITBONE Space Holder TAA (60000218)
- FITBONE Connection Bolt TAA (60000310)
- FITBONE Clamping Nut TAA (60000219)
- FITBONE Open End Wrench SW 14/17 (60000689)
- FITBONE Kirschner –wire L280mm Ø 3 mm (60001039)
- FITBONE Setscrew (60000003)
- FITBONE Fastening Bolt M6 L9mm (60000175)
- FITBONE Test Pin Ø 4.5 mm (60000688)
- Dummies

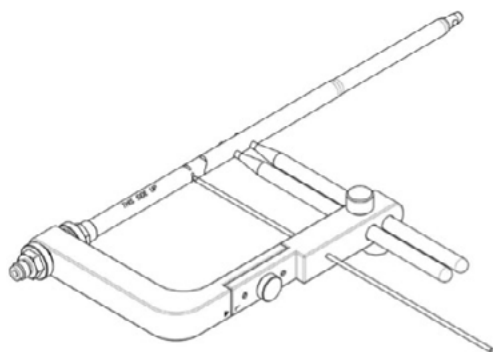
An overview of the dummies with corresponding intramedullary lengthening nails is listed below:

Dummy	Nail
FITBONE Dummy TAA0940-F-200 (60001925)	FITBONE Intramedullary Lengthening Nail TAA0940-F-200 (60001921)
FITBONE Dummy TAA0960-F-220 (60001854)	FITBONE Intramedullary Lengthening Nail TAA0960-F-220 (60001764)
FITBONE Dummy TAA1140-F-205 (60001248)	FITBONE Intramedullary Lengthening Nail TAA1140-F-205 (60001383)
FITBONE Dummy TAA1160-F-225 (60001139)	FITBONE Intramedullary Lengthening Nail TAA1160-F-225 (60001468)
FITBONE Dummy TAA1180-F-245 (60000822)	FITBONE Intramedullary Lengthening Nail TAA1180-F-245 (60001404)
FITBONE Dummy TAA0940-T-200 (60001927)	FITBONE Intramedullary Lengthening Nail TAA0940-T-200 (60001928)
FITBONE Dummy TAA0960-T-220 (60001855)	FITBONE Intramedullary Lengthening Nail TAA0960-T-220 (AC 60001856)
FITBONE Dummy TAA1140-T-205 (60001244)	FITBONE Intramedullary Lengthening Nail TAA1140-T-205 (AC 60001501)
FITBONE Dummy TAA1160-T-225 (60000832)	FITBONE Intramedullary Lengthening Nail TAA1160-T-225 (60001445)
FITBONE Dummy TAA1180-T-245 (60001495)	FITBONE Intramedullary Lengthening Nail TAA1180-T-245 (60001348)
FITBONE Dummy TAA1380-F-245 (60001623)	FITBONE Intramedullary Lengthening Nail TAA1380-F-245 (60001422)

Assembly of the targeting device with the dummy:

First, guide the connection bolt through the space holder and tighten the clamping nut from the opposite side of the outrigger on the thread of the space holder. Place the dummy on the thread of the connection bolt. Make sure that the contours of the dummy lie flush with the contours of the space holder. Insert the dummy into the medullary cavity manually using the targeting device while aligning the main fragments. This process is used to check whether the medullary cavity has been adequately prepared for the actual implant and if the correction result can be achieved. The notch on the Space Holder TAA is used for depth orientation and must be aligned in the a.p. beam path with the bony contour of the notch. Precise alignment with the bony contour of the notch is important to guide the bipolar feed line through the bore in the lateral condyle later in the procedure. Remove the outrigger by loosening the connection bolt. The dummy remains in the bone initially. With the knee joint at full extension, alignment of the extremity can be checked on the grid plate underneath according to the preoperative plan. Correct the path of the intramedullary nail both in the proximal and distal main fragments by re-reaming and, if necessary, by inserting locking screws as blocking screws until both main fragments are aligned precisely as per the preoperative plan. The blocking screws are to be inserted together with the dummy- not together with the intramedullary lengthening nail.

The dummy can now be removed again using the connection bolt.



Targeting device

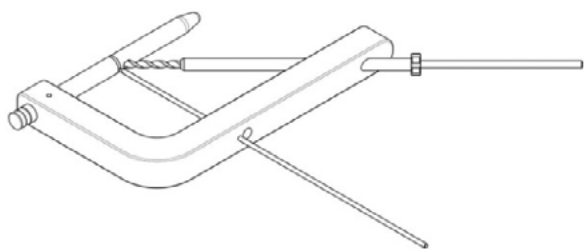
2.1.6 Cable conduit in the distal femur (not required in the tibia)

In order to be able to connect the bipolar feed line of the implant to the Receiver later, a bore must be drilled through the condyle via which the bipolar feed line is guided.

Required instruments:

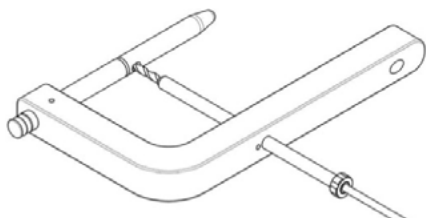
- FITBONE Drill Sleeve Ø 4.5 mm (black) (60000400)
- FITBONE Trocar Ø 4.5 mm (60000403)
- FITBONE Drill Bit Ø 4.5 mm (60000398)
- FITBONE Targeting Device 45/90° (60001439)
- FITBONE Wire Catcher 90° (60001307)
- Sterile cerclage wire Ø 0.8 mm
- Redon 8 Fr.

Approach for the drill sleeve Ø 4.5 mm is to be made through a 20 mm lateral incision at the level of the later distal locking screws and an epifascial preparation, approx. 20 - 30 mm ventrocaudally. Insert the targeting device 45/90° through the opening of the medullary cavity until the marking notch is precisely at the level of the bony notch (as when inserting the dummy). Alternatively, a K-wire Ø 3 mm can also be passed through the bore in the drill guide, which is also aligned with the bony notch. Insert the drill sleeve Ø 4.5 mm (black) with the trocar through the 45° bore in the targeting device 45/90° via the lateral approach to the bone and align the drill guide by rotating it approx. 30° ventrally to prevent the locking screws from damaging the bipolar feed line later. Create a 4.5 mm bore with the drill bit Ø 4.5 mm up to the central stop in the targeting device 45/90°. Now impact the drill sleeve Ø 4.5 mm (black) into the ventrolateral cortex to prevent the targeting device 45/90° from slipping when removing the drill bit Ø 4.5 mm later. The drill bit Ø 4.5 mm can be removed. A double cerclage wire Ø 0.8 mm can then be inserted in the drill sleeve Ø 4.5 mm (black) that exits distally from the targeting device 45/90°. Now remove the targeting device 45/90° under fixation of the cerclage wire Ø 0.8 mm.



Drill guide 45°/90° for 45° bore


With the growth plate open, a 90° bore can be made with the targeting device 45/90° instead of the 45° bore so that the bore does not go through the growth plate. The cerclage wire Ø 0.8 mm can be guided out of the drill guide 90° with the wire catcher 90°.



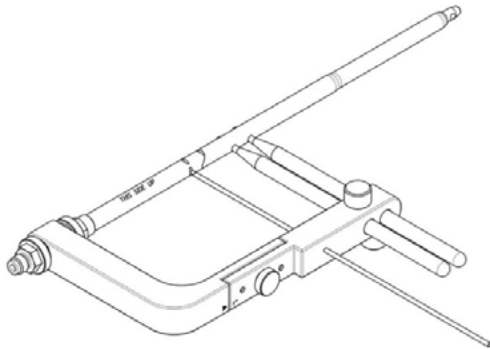
Targeting Device 45/90° for 90° bore

Next, pull a Redon 8 Fr. through via the double cerclage wire Ø 0.8 mm so that the Redon goes through the condylar drilled hole. Now secure the Redon so that it cannot accidentally slide out of the condylar drilled hole. In a later step, the bipolar feed line will be guided through the condylar drilled hole via the Redon.

2.1.7 Implantation of the FITBONE TAA

	<p>After unpacking the intramedullary lengthening nail, check it for integrity, especially the bipolar feed line. Never use a hammer to drive the intramedullary lengthening nail FITBONE TAA into/from the medullary cavity as doing so could damage the implant.</p>
---	---

Assembly of the drill guide with the FITBONE TAA intramedullary lengthening nail



Drill guide with FITBONE TAA intramedullary lengthening nail

Required instruments:

- FITBONE Drill Guide TAA 60001175)
- FITBONE Outrigger TAA (60001184)
- FITBONE Space Holder TAA (60000218)
- FITBONE Connection Bolt TAA(60000310)
- FITBONE Clamping Nut TAA (60000219)
- Dummy (see overview of all available dummies in 1.1.5 "Inserting the dummy")
- FITBONE Kirschner wire L280mm Ø 3 mm (60001039)
- FITBONE Setscrew (60000003)
- FITBONE Fastening Bolt M6 L9mm(60000175)
- FITBONE Test Pin Ø 4.5 mm (60000688)
- FITBONE Open End Wrench SW14/17 (60000689)

The drill guide TAA is marked with an "R" and an "L". These markings stand for "Right" and "Left" and are necessary as the bore holes in the FITBONE TAA intramedullary lengthening nail are not arranged in the centre but are slightly eccentric. Mount the outrigger according to the extremity to undergo surgery, so that e.g. the "R" faces laterally for retrograde implantation in the right femur or the "R" faces medially in the right tibia. Place the space holder in the mount of the outrigger with the inscription "This side up" on the space holder facing the ceiling. Then guide the connection bolt through the space holder and screw the clamping nut loosely onto the thread of the space holder from the opposite side of the outrigger. Place the dummy onto the thread of the connection bolt, ensuring that the contours of the intramedullary nail are flush with the contours of the space holder. Insert both test pins again, they should slide easily into the bore holes of the FITBONE TAA dummy. When mounted correctly, both test pins should move easily and slide precisely into the bore holes of the dummy. Once this has been done, first tighten the clamping nut, which secures the space holder to the outrigger and then the connection bolt, which secures the dummy to the space holder. The test pins can now be removed. To make sure that the drill guide does not jam, the test pins must be inserted again. Now use the assembled drill guide to insert the implant. First loosen the clamping nut on the space holder TAA slightly. Remove the implant from the sterile packaging and insert the bipolar feed line into the cannulated connection bolt. Then, place the intramedullary nail on the thread of the connection bolt so that the contours of the implant are aligned flush with the contours of the space holder. Now insert both test pins into the bore holes of the jig and tighten the clamping nut between the space holder and jig and then the fastening bolt. When mounted correctly, both test pins should insert easily into the drill guide and be able to slide into the bore holes on the implant again. The test pins can now be removed. To make sure that the drill guide does not jam, the test pins must be inserted again. Insert the FITBONE TAA intramedullary lengthening nail into the medullary cavity by hand using the drill guide (consisting of the required instruments listed above) in alignment with the main fragment. The notch on the Space Holder TAA is used for orientation and for the femur must be aligned with the bony contour of the notch in the a.p. beam path, and for the tibia with the bony contour of the tibial plateau in the lateral beam path. Alternatively, a K-wire Ø 3 mm can also be passed through the bore hole in the drill guide for TAA. Precise alignment with the bony contour of the notch is important to guide the bipolar feed line through the condylar drilled hole later in the procedure.

2.1.8 Locking

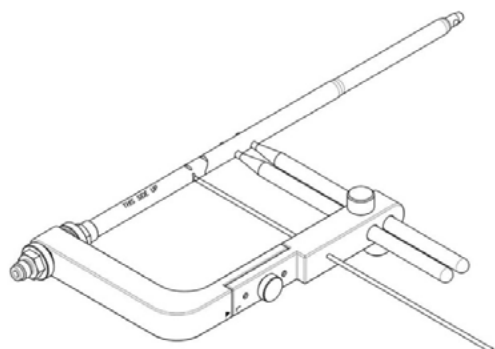
For the femur, the distal locking bore holes and for the tibia, the proximal locking bore holes can be set with the drill guide.

Required surgical instruments:

- FITBONE Drill Sleeve Ø 8.0 mm (green) (60000402)
- FITBONE Drill sleeve Ø 4.5 mm (black) (60000400)
- FITBONE Trocar Ø 4.5 mm (60000403)
- FITBONE Drill Bit Ø 4.5 mm (60000398)
- FITBONE Depth Gauge (60000408)
- FITBONE Screwdriver SW3.5 (not cannulated, black handle) (60000576)
- FITBONE Screwdriver SW 3.5 cannulated (black handle) (60000406)
- FITBONE Screw Holder M2 L325 mm (cannulated, black handle) 60000384)

The targeting device is used to lock the implant (see also 1.1.7 "Implantation of the FITBONE TAA"). For the tibia, align the targeting device in the frontal plane. Combine both drill sleeves with the Trocar Ø 4.5 mm and insert them into the opening of the drill guide for TAA. After drilling, the drill sleeve, black can be removed and the appropriate length of the locking screws determined using the depth gauge. Secure the screws to the screwdriver SW 3.5 cannulated and screw holder and then insert them. Use the screwdriver SW 3.5 (not cannulated) to tighten the screws. The placement and correct position of the screws must be checked both in the a.p. and lateral beam path while monitoring via the image converter.

The targeting device can only be disassembled once the distal locking screws are secured. Remove the drill sleeves and K-wire Ø 3 mm if necessary for this purpose. Loosen the connection bolt to disconnect the implant and targeting device and remove the targeting device.



Drill guide with FITBONE TAA intramedullary lengthening nail

2.1.9 Locking bore free hand

For the femur, the proximal locking bore should be drilled preferably with a radiolucent right-angle gearhead; for the tibia, the distal locking bore. X-ray monitoring is always required as usual for conventional locking intramedullary nails. This is fastened using a locking screw (TAA09: Ø 4mm (short thread) TAA11/13: Ø 4.5 mm (short or long thread)).



Imprecisely set locking holes (oval, funnel-shaped, ragged) do not allow the implant to be fastened sufficiently. If the implant is insufficiently fastened, it may be helpful to use revision screws.

2.1.10 Fibula osteotomy

Depending on the distraction length, introduction of a distal setscrew and if necessary also a proximal setscrew between the tibia and fibula is recommended. The fibular osteotomy can then be performed using a minimally invasive technique.

2.1.11 Connecting the Receiver

By disassembling the jig, the bipolar feed line with the plug connection is made accessible. Now insert the plug connection into the perforated end of the Redon without kinking the bipolar feed line and secure it with a ligature. Now pull the Redon distally through the condylar drilled hole created earlier, so that the bipolar feed line exits laterally. Make sure that no tissue

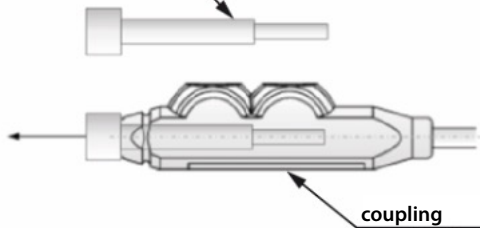
material or the feed line itself enters the adjacent joint. The Receiver can now be removed from the sterile packaging and connected to the intramedullary lengthening nail FITBONE TAA.



After unpacking the Receivers, check it for integrity, especially the bipolar feed line.

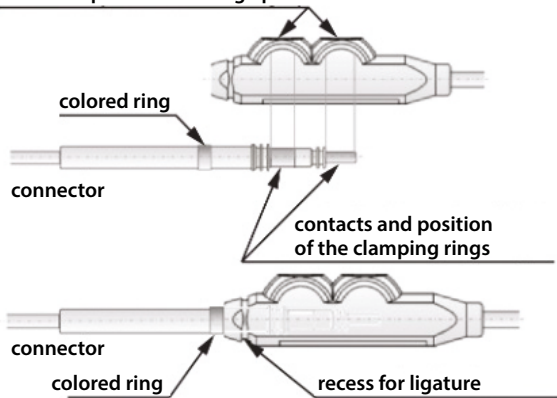
For this purpose, follow the procedure below:

transport locking device

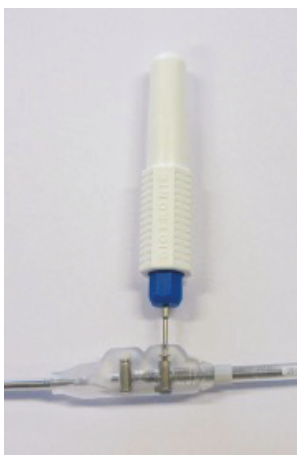


Press and turn the supplied torque wrench through the sealing lip, loosen the threaded pins and pull the transport locking device from the coupling. The transport locking device must not be turned to prevent it from breaking because fragments remaining in the bushing would prevent smooth insertion of the plug connection.

threaded pins with sealing lip




Make the connection between the connector and coupling as short as possible to prevent the bipolar feed line from kinking. On the connector for the bipolar plug connection, there is a white ring to aid with positioning. Insert the connector into the coupling until the coloured ring touches the coupling. Only then is it ensured that the contacts on the connector are positioned correctly in the coupling.




Press and turn the supplied torque wrench through the sealing lip to access the threaded pin. Turn the threaded pin in the coupling with the torque wrench until the torque wrench limit can be heard (click) to secure the connector in the coupling. Pull out the torque wrench to allow the silicone seal to close. Repeat the process for the second threaded pin.

Perform a visual inspection of the connection (position of the shade guide). In addition, an intraoperative functional test (Chapter 2.1.13 "Intraoperative functional test") must be performed to verify the connection.

	<p>The connector must be inserted into the coupling completely. A marking is provided for this purpose. Do not hold the coupling or connector with surgical instruments and avoid bending the coupling, connector or supply line as this can lead to damage or dislocation.</p>
---	--



2.1.12 Placement of the Receiver

For the femur, place the Receiver epifascially and laterally, and for the tibia, ventrolaterally in the subcutaneous tissue via the existing approach. For this purpose, use scissors to prepare an 80 to 100 mm subcutaneous pocket so that the Receiver lies close enough to the surface and power transfer is ensured at all times. Insert the Receiver into the prepared subcutaneous pocket (identification plate facing outward). Then push the bipolar plug connection into the pocket also

	<p>The ideal distance between Receiver and Transmitter is approx. 5 mm. Power transfer is optimal at this distance. Avoid distances of more than 10 mm as such distances can negatively impact the function of the treatment system.</p>
---	---

2.1.13 Intraoperative functional test

A stethoscope and a FITBONE Control Set are supplied with the implant. Before the sterility at the OR table is removed, the distraction procedure of the FITBONE TAA intramedullary lengthening nail must be checked acoustically (listening for the operating noise using the stethoscope) and visually (control light flashing during energy transmission). One sterile sleeve is pulled completely over each Transmitter and stethoscope to check the motor sounds under sterile conditions and can now be used on the patients.

	<p>More information about their function and operation can be found in the Instructions for Use for the FITBONE Control Set.</p>
	<p>In continuous Doctor mode operation, the Transmitter can reach a maximum temperature of 47.2 °C.</p>

The FITBONE Control Set must be installed and commissioned according to the information in the Instructions for Use for the FITBONE Control Set. The surgeon also has further options for operating the implant:



Under the housing cover, there are switches reserved exclusively for the attending physician.



You can choose between the patient/doctor (labelled "Pat."/"Doc.") and pulse/continuous operation (labelled "Pulse"/"Perm.") settings.

In the "Doc." position, the switch labelled "Doctor" on the front is enabled and can be used to start/ stop continuous energy transmission. The transmission time is not limited to 90 seconds in this mode. In the "Doc." position, the button labelled "Patient" on the front is disabled and only the switch labelled "Doctor" is enabled. In the "Pat." position, the switch labelled "Doctor" on the front is disabled and only the button labelled "Patient" is enabled. The switch labelled "Pulse" / "Perm." allows the attending physician to switch from pulse mode to continuous operation. In continuous operation, energy is transmitted continuously. This leads to a distraction of up to 2 mm per minute. This mode can be used to pre-set the implant or to allow a new locking position for proximal locking.



Increased caution should be exercised for continuous energy transmission. Excessive distraction can cause neuronal damage.



On the front of the FITBONE Control Set, the switch labelled "Doctor" lights up blue when pressed.

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. Before handing over the FITBONE Control Set to the patient, restore the factory settings of both switches under the "Pat." and "Pulse" cap. Then, clean the surface of the FITBONE Control Set to remove any contamination before handing it over to the patient. Use a cloth dampened with 70% alcohol solution for this purpose.



Please advise your patients that only the attending physician is permitted to use the area under the housing cover.

Wound closure completes the surgery. Make sure not to damage the bipolar feed line.

2.2 Postoperative care

In the recovery room, the extremity is fully extended from the start. An ice pack is recommended in the area of the osteotomy. The first mobilization takes place on the first postoperative day. A load of up to 20 kg on the affected leg is permitted. Stacked shoes are used to compensate for differences in leg length. 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 which 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. The information above applies to any type of upper and lower leg lengthening and underline the importance of regular clinical controls, not the FITBONE TAA specifically.



Ultrasound and magnetic field therapies are not permitted during the active phase of distraction and while the FITBONE TAA intramedullary lengthening nail is in the bone.

2.3 Distraction phase

Distraction begins on about the fifth postoperative day or at the instruction of the treating physician as described in the Instructions for Use FITBONE Control Set by applying the Transmitter and pressing the control elements on the control electronics. The rate of distraction depends on the expected or radiologically detectable bone regeneration and the soft tissue conditions and can be varied, starting from 1 mm/day. 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. We recommend using the distraction log included with the Instructions for Use FITBONE Control Set.



The distraction rate for adolescents can deviate due to the accelerated rate of growth, and can lead to an earlier formation of new bone.

2.4 Load

During the distraction phase, the implant load must not exceed 20 kg (flat foot contact). In the course of the consolidation phase, weight-bearing can be increased depending on bone consolidation.

2.5 Metal extraction

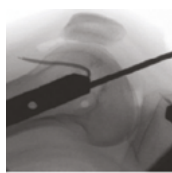
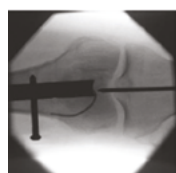
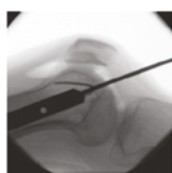
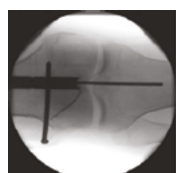
Required instruments:

- FITBONE Extractor Tray Lite TAA (6990875) or
- FITBONE Loan Extraction Tray TAA 09/11 (6992062) or
- FITBONE Lone Extraction Tray TAA13 (6992065)



The FITBONE TAA is not a permanent implant and must be removed. Removal of the implant is recommended when the regenerated bone can support a sufficient load and the stability of the bone has been restored. In general, a period of 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.

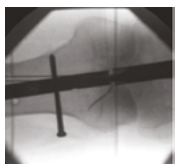
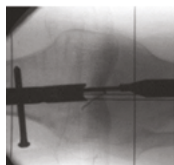
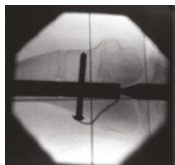
1. Make an incision to remove the proximal screw.
2. Make a 2 cm incision along the existing lateral scar near the knee joint. Expose the cable, moving towards the connector and Receiver. Cut the cable and remove the connector and Receiver.
3. Identify the two distal screws. Remove one of the two screws and retract the second one slightly, but leave it in the bone.
4. Position the leg at a 30° angle
5. Make a transversal skin incision underneath the patella along the existing scar. Split the patella tendon and feed a 3 mm K-wire under C-arm control into the centre of the nail.
6. If the K-wire is positioned in the centre of the FITBONE, use the centric cone C13 for the next step. If no central position was reached, use the eccentric cone C13+ to change the position by 1 mm, or the cone C13++ to change the position by 2 mm (if available).



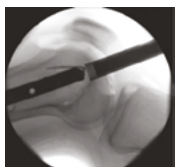
AP

lateral

7. Insert the Cone C13 (figure 2 or the eccentric cone C13+ with the Cone Sinkers CS 15-13 to enlarge the access through the tendon and fasten it into the notch in the bone.



8. Use the thin-walled tube T14/13 and insert it centrally into the FITBONE using the Tube Sinkers TS 13.



9. Use the straight 12 mm sharp reamer and remove the bone material in the tube.

10. The remaining bone fragments are removed using an arthroscopic hook. To do this, take hold of the cable and pull it out through the ducts. The cable is located in the anterior lateral corner.
11. The cable is fastened with a cord and the cord is inserted into the TAA connecting pin. The TAA connecting pin can only be inserted through the 13 mm duct and can only reach the thread of the FITBONE when aligned axially.
12. Once the FITBONE is fastened securely with the screw, the last remaining distal screw is removed and the FITBONE can be extracted through the 13 mm tube. Twist and pull the intramedullary lengthening nail FITBONE TAA to remove this (without using a slotted hammer to prevent the bone from chipping).

Please observe the requirements of your clinic or hospital about the handling of explants when handling the extracted FITBONE components. In case of an incident, please return the FITBONE components after preparation to the manufacturer so that an investigation can be carried out.


2.6 System overview

2.6.1 FITBONE Retraction Control Set

The Retraction Control Set (60001871) can be used if it is medically required for the treatment success, e.g. for unintended overdistraction. For activation of the retraction functionality, the FITBONE Retraction Control Set is required. You can recognise this specific FITBONE Retraction Control Set from its label and the greater Retraction Transmitter, which is included. The FITBONE Retraction Control Set is not included in the standard scope of delivery. If medically required, it can be ordered from WITTENSTEIN Intens or your distributor. The Retraction Control Set must not be handed over to the patient.



Transmitter FITBONE Control Set (top) vs. Transmitter FITBONE Retraction Control Set (bottom).

	<p>Retraction must not be carried out over the initial total length of the intramedullary lengthening nail since this might cause jamming of the implant. During energy transmission, monitor the retraction with continuous X-ray monitoring. FITBONE is intended for single use (single-use implant). It must not be retracted or extended multiple times, or used for re-implantation. The FITBONE implant is not suitable for applying compression forces. If the Retraction Transmitter is positioned in an incorrect angle, an unintended distraction cannot be excluded. Stability of the bone is no longer guaranteed if the nail was retracted after a distraction and then distracted again (see table "Tbl-1").</p>
---	--

2.6.2 Functionality Retraction

The FITBONE Retraction Control Set is only operated in Doctor mode (switch position "Doc") and similarly to the FITBONE Control Set with which you are already familiar.


The retraction procedure is as follows:

- Feel for the position of the Receiver, which has been implanted subcutaneously.
- Place the retraction Transmitter according to the position of the Receiver with the white side on the skin. When aligned correctly, the cable outlet of the Receiver is under the cable outlet of the Transmitter. If required, the position of the Receiver is to be checked with X-ray.

i During retraction, a continuous beep can be heard with the stethoscope. This beeping sound should be monitored during retraction.



- Initiate energy transmission by pressing the "Doc" switch once.
- ➞ If placement is correct, the yellow "Transmit" LED will flash 5 times within one second. This indicates energy transmission.

	<p>If the yellow "Transmit" LED remains off, retraction might not work. In this case, please read the chapter "Malfunctions" in the Instructions for Use of the Control Set.</p>
---	--

The number of pulses for a certain retraction length corresponds to the number of pulses for a distraction. This means that the nail retracts up to 2 mm in one minute. **In continuous operation, the tissue between retraction Transmitter and Receiver might heat up excessively.** Please interrupt the operation after max. 20 seconds for min. 2 minutes. Retract it only as much as it has already been distracted.

3 Important notes

3.1 General safety instructions

	<p>During the active phase and the early healing phase, the carrying capacity of the intramedullary lengthening nail FITBONE TAA is limited to a partial load of 20 kg (contact with the sole of the foot). Any exceeding load may cause the intramedullary lengthening nail to break.</p> <ul style="list-style-type: none"> • The patient must receive and use walking aids. • The patient should be prescribed appropriate, regular physical therapy by the doctor
	<p>The patient must avoid unforeseen/unwanted excess weight-bearing, e.g. by falling or stumbling, as well as full weight-bearing. This may cause the intramedullary lengthening nail to break.</p> <ul style="list-style-type: none"> • If excessive weight-bearing does occur, the patient must contact the attending physician.
	<p>The distraction phase should not be interrupted for longer than 2 days at most because the risk of premature bone bridging is otherwise present.</p>
	<p>Non-ionising radiation is used for energy and data transmission. Electromagnetic and magnetic pulses can cause malfunctions.</p> <ul style="list-style-type: none"> • Note that radio equipment with transmission frequencies below 500 kHz may inadvertently lengthen the intramedullary lengthening nail. Keep away from potential sources of such electromagnetic fields as, for example: <ul style="list-style-type: none"> - Industrial equipment with wireless energy transmission, including production facilities and logistics centres. Please observe any posted warnings relating to increased electromagnetic radiation. - Radio masts / radio towers used as time-signal transmitters. • Comply with the special safety precautions with regard to electromagnetic compatibility (EMC) according to the FITBONE Control Set Instructions for Use. • Only use the components (e.g. power supply units or cables) provided by the manufacturer.
	<p>The FITBONE TAA intramedullary lengthening nail and control electronics must not be placed directly beside or stacked with other devices.</p> <ul style="list-style-type: none"> • Monitor/check the correct operation of the FITBONE TAA System if the FITBONE Control Set is nevertheless positioned in this way.

Leg lengthening is not started in the case of a pregnancy. There are no experiences of treatment with FITBONE during pregnancy. However, according to the current state of knowledge, no adverse effects can be assumed.

3.2 MRI Safety Information

 	<p>FITBONE is MR unsafe.</p> <ul style="list-style-type: none"> • Keep away from MRI examination rooms.
------	---

3.3 Precaution

The treating physician will decide about the risk and benefit of the following treatments.

Any form of electrical therapy in which current is passed through the patient's body should be avoided on the affected limb, as should therapeutic ultrasound.

- If this cannot be avoided, the function of the FITBONE TAA intramedullary lengthening nail must be carefully monitored to immediately identify any disruptions.
- If medical treatments are required in which an electric current is passed through the patient's body from an external source, turn off the control electronics and advise the patient to carefully monitor the functioning of the device during distraction over the next 4 to 5 days.

Except for diagnostic X-rays, the manufacturer has no experience with how the FITBONE TAA intramedullary lengthening nail responds to high-energy ionizing radiation. Such treatments must be avoided for the duration of the distraction phase, if possible.

- If such treatments are necessary, it is your decision to perform the MRI as the treating physician.

The leakage currents expected in the body of the patient when using defibrillators can negatively affect the FITBONE TAA intramedullary lengthening nail. Therefore, the use of deribrillators should be avoided if possible.

- If the use of a defibrillator cannot be avoided, carefully monitor the function of the implant during distraction in the following 4 to 5 days.

3.4 Sterility


The medical devices intended for implantation are H2O2-plasma-sterilized and are supplied in a packaging system comprising a sterile barrier system and protective packaging in a sales packaging. The sterile barrier system and the protective packaging are only soft packs with a chemical indicator. Chemical indicators on both sterile bags provide proof of plasma sterilization. To open, tear the sterile bags at the respective sealed seam. The outer packaging (protective packaging) is used to forward the device to the operating room area. Check the protective packaging for damage or perforation before surgery. If it is damaged, it can no longer be considered aseptic. The implants must not be used.

Note the expiration date on the package.

For information on sterilization of Instrument Set and screws, see Chapter 1.2 "Cleaning, disinfection, sterilization".

3.5 Single use

The implants are intended for single use.

	Restertilization of the implants is not permitted.
---	---

Explants must not be reused as the adequate removal of biological contaminants such as blood, tissue and other substances which may contain resistant pathogens cannot be ensured by cleaning and sterilization.
























3.6 Environmental conditions


Environmental conditions during transport in the packaging	- 29 °C to + 50 °C
Environmental conditions during storage in the packaging	Room temperature (18 °C to 28 °C) Air humidity: < 60 % relative humidity

Tbl-3: Environmental conditions

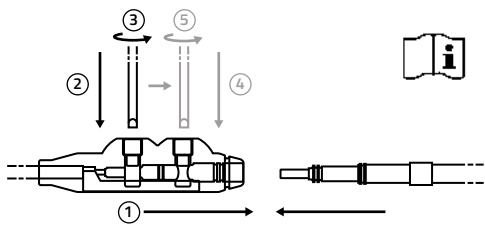
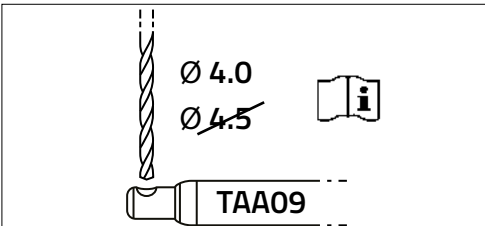
3.7 Packaging and labels

The implantable system components are delivered in a plasma-sterilized condition in a packaging system (see 1.4 "Sterility"). The symbols on the label (according to ISO 15223-1) are explained below:

Symbol	Description
	Medical Device
 	Consult instructions for use or consult electronic Instructions for Use CAUTION: Consult instructions for use for important cautionary information
	Single Use. Do not re-use Orthofix note: discard appropriately after use (treatment) on patient
	Do not resterilize
	Sterile. Sterilized using irradiation
	Sterilized using vaporized hydrogen peroxide
	Non-sterile
	Double sterile barrier system
	Unique Device Identifier
 	Catalogue number Batch code
	Use-by date (year-month-day)
 	CE marking in conformity to applicable European Directives/Regulations
 	Date of manufacture Manufacture
	Do not use if package is damaged and consult instructions for use
	The item is known to pose hazards in all MRI environments.
	Serial number
Rx Only	CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician
	Electric voltage
	Follow instruction for use
	Non-ionizing electromagnetic radiation

Symbol	Description
	<p>Disposal. In accordance with the WEEE 2012/19/UE Directive, the product and all its parts (cable, batteries, accessories, etc.) may not be treated as domestic waste.</p> <p>Please return the FITBONE Control Set to Orthofix after completion of the treatment.</p>

TbI-4: Label

Symbol	Description
	<p>Please connect Intramedullary Lengthening Nail and Receiver via the bipolar plug connection. Please also note the instructions for connecting the connector and coupling in the Operative Technique.</p>
	<p>For the Intramedullary Lengthening Nail TAA09, use 4.0 drill for the locking hole on the telescope side (freehand locking). Please also note the instructions for drilling locking holes in the Operative Technique.</p>

TbI-5: Label 4.0 drill

Please contact the manufacturer if the label on the packaging is damaged or not legible.

3.8 Malfunctions

Malfunction	Possible cause	Actions
Switch Doctor: Malfunction / no function	Control electronics defective	Replacement device / contact the manufacturer
Button Patient: Malfunction / no function	Control electronics defective	Replacement device / contact the manufacturer
Power LED does not light up	Power cable not plugged in	Plug in power cable
	Power supply inadequate	Try another outlet
	Power cable defective	Replace / replacement device
	Power supply defective	Replacement device / contact the manufacturer
	Control electronics defective	Replacement device / contact the manufacturer
Flashing LED (transmit active) yellow: Does not light up / does not flash	Transmitter in the wrong position	Check the position of the Transmitter
	Coaxial cable not plugged in	Check coaxial cable connection
	Control electronics defective	Replacement device / contact the manufacturer
	Transmitter defective	Replacement device / contact the manufacturer
Flashing LED (transmit active) yellow: Incorrect flashing frequency / lit continuously	Transmitter in the wrong position	Check the position of the Transmitter
	Control electronics defective	Replacement device / contact the manufacturer
Patient / Doctor switch setting: Malfunction / no function	Control electronics defective	Replacement device / contact the manufacturer
Pulse counter (digital display): No display or faulty display	Control electronics defective	Replacement device / contact the manufacturer
Identify incorrect distraction rate using X-ray examinations	Receiver in the wrong position	Adjust the distraction intervals each day
No distraction	Inadequate distraction force	Adjust the distraction intervals each day
	Receiver: Bipolar feed line / connector defective	Revision surgery with implant replacement

Tbl-6: Malfunctions

Possible component damage due to dropping

Possible damage due to dropping - differences in extracorporeal components (control electronics and Transmitter) and implanted components. For extracorporeal components, possible damage can be identified by visual inspection and functional testing. The implanted components must be functionally tested (distraction) and examined acoustically via a stethoscope.

3.9 Medical risks

Possible risks related to the surgical intervention are:

- Injury to blood vessels, nerves, muscles or tendons. The consequences can be circulatory disturbances, functional disturbances, sensory disturbances, nerve pain, paralysis of the leg or a loss of the limb. Reconstructive interventions may be necessary.
- Thromboses, Embolism with respiratory distress, lung damage and even death
- Bone, soft tissue or joint infections
- Swelling and possibly bleeding of soft tissue, compartment syndrome
- Severe local circulatory disturbances which can lead to loss of limbs.
- Numbness around the scar
- Hyperreactions of the skin
- Positioning injury to the healthy limbs, buttocks or head
- General infections up to blood poisoning
- Risks related to blood transfusion (e.g. HIV, hepatitis)

Possible risks related to distraction treatment after surgery for leg lengthening are among others:

- Functional limitations of the limbs
- Delayed or absent bone osteotomy healing.
- Joint injury, subluxations, luxations, joint stiffness, femoral head necrosis
- Allergic reactions to the implant material
- Remaining or re-emerging shortening, remaining axial misalignment and, if necessary, further surgical correction
- Loosening of the intramedullary lengthening nail
- Latrogenous fractures
- Fracture of the bone after explantation of the implant
- Too frequent or excessive distraction can lead to overstretching of the nerve fibres, which, in some cases, can result in temporary nerve damage or permanent paralysis

System-related risks:

- Malfunction of the intramedullary lengthening nail or Receiver with necessity of a re-operation to replace the components

3.10 Maintenance

Repair and maintenance work on the FITBONE Control Set may only be carried out by WITTENSTEIN intens GmbH.

All components of the FITBONE Control Set must be returned to your FITBONE supplier after completion of the treatment. An authorized body will perform the required safety checks and maintenance. Modifications and repairs to the FITBONE Control Set by unauthorized persons void the warranty and liability of the manufacturer.

4 Instrument Set / screw box

4.1 Check list / overview

- Overview of instrument set and locking screws

4.2 Cleaning, disinfection, sterilization

Cleaning, disinfection and sterilization of the Instrument Set and locking screws is the responsibility of the hospital that supplied the Instrument Set on loan. For this purpose, validated processes must be used. The manufacturer provides the user with the Application Note for Care, Cleaning and Sterilization of Instruments.



Manufactured by:
ORTHOFIX Srl
Via Delle Nazioni 9, 37012 Bussolengo
(Verona), Italy
Telephone +39 045 6719000,
Fax +39 045 6719380
www.orthofix.com