WITTENSTEIN | intens

FITBONE® TAA

Clinician Guide
FITBONE® TAA

Clinician Guide FITBONE® TAA
acc. to
Prof. Dr. Dr.med. R. Baumgart
ZEM-Germany
Limb Lengthening Center Munich/ Germany

Copyright

Date of issue of the Operative Technique FITBONE® TAA: 01.10.2019

Contents

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. 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 instructions for use included in this document were originally created in German. All other language versions are translations of the German language instructions.

Reference documents are available for treating physicians at:
https://pro.wittenstein-group.com/process/FITBONE_Extranet/default.aspx

The EC conformity declaration for the FITBONE® TAA System can be found on our website under Downloads (https://intens.wittenstein.de/en-en/downloads/).

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 lengthining 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.

Please observe the contraindications and warnings when selecting patients. The selection is decisive for the success of the treatment.

	**Participation of the surgeon at FITBONE® Certification Course is one of the basic prerequisites for autonomous use of the FITBONE® TAA System.** **Another basic prerequisite is its integration into the existing Centers of Excellence (COE) concept.** **The indication for treatment, intraoperative approach and postoperative aftercare are the responsibility of the surgeon.** **We draw your attention to the fact that you must comply with the prescribed indication and not contravene the contraindications stated.**

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 consisting of control electronics (C) with power cable and Transmitter with coaxial cable (D)

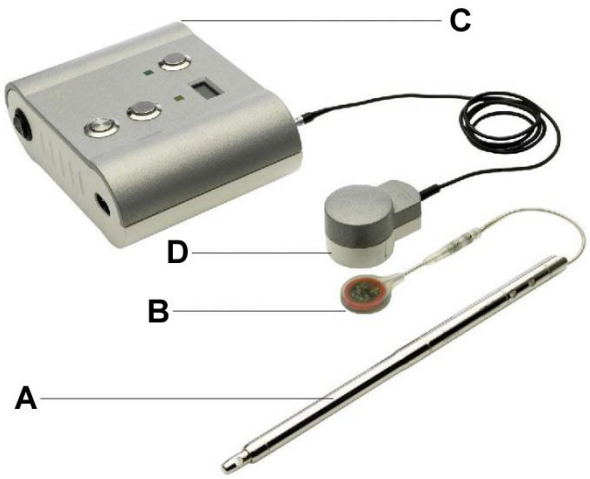


Figure 1.1 FITBONE® TAA System with components

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 power required for the distraction process is transferred 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 its function and operation can be found in the instructions for use of the FITBONE® Control Set.

In addition to the standardized FITBONE® TAA intramedullary lengthening nail, it is also possible to use custom-made products. Custom-made products for other indications (stump lengthening, bone reconstruction for defects after tumor resection or post-traumatic bone loss, or other uses) are available on request, once the necessary approvals have been obtained. These are specially adapted to the specific needs of a particular patient. If necessary, individual consultation and surgical support are available on-site from experts.

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

1.2 Configurations

The FITBONE® TAA intramedullary lengthening nail is available in various configurations. You can view the configurations in the REF FITBONE® TAA, SAA and TAM overview and in the FITBONE® System order form.

You can find the technical data of the different intramedullary lengthing nails FITBONE® in the respective data sheets and dimension sheets. These are provided by the manufacturer upon request.

1.3 Intended use

FITBONE® is an intramedullary lengthening system for limb lengthening of the femur and tibia.

1.4 Indications

Differences in leg length of 20 mm or more.

1.5 Contraindications

- Patients with any open wounds/areas with poor soft tissue coverage near the implant
- 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 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 over 100 kg
- Differences in leg length of less than 20 mm
- Lack of hip head roofing (hip dysplasia) with femoral extensions
- Lack of stability in the surrounding joints
- 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
- Other implanted devices, e.g. insulin pump, implanted defibrillator, neurostimulator and cardiac pacemakers

1.6 Possible side effects

In addition to the general risks associated to the 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

1.7 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:

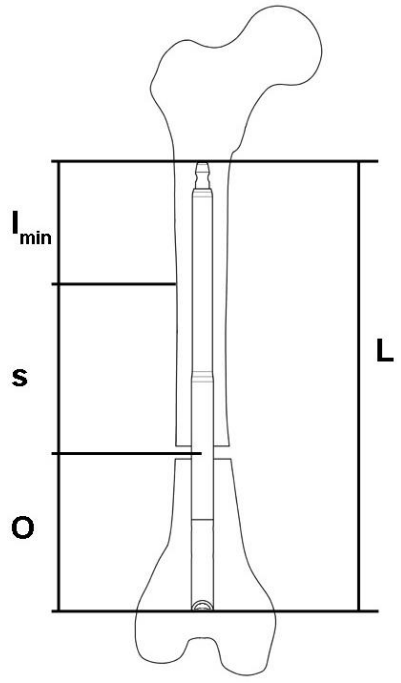
- Anamnesis
- Clinical examination findings with documentation of the range of motion, circulation and neurological status of the extremity
- Diagnostic radiology in the form of long supporting leg X-rays of the upper and lower leg, anterior-posterior and medial-lateral plane (AP and ML plane)
- If necessary, 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 (l_{min}, see graph: Table 1: Dimensions.)

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} ≥ 65 mm: Minimum required coverage after lengthening

Table 1: Dimensions

Dimensions, see Chapter 1.2 “Configurations” "

Configurations"

1.8 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.

A GRID plate (AC 60001464) 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

1.9 Using the GRID plate

Adhere to the following procedure exactly to avoid errors when using the 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.

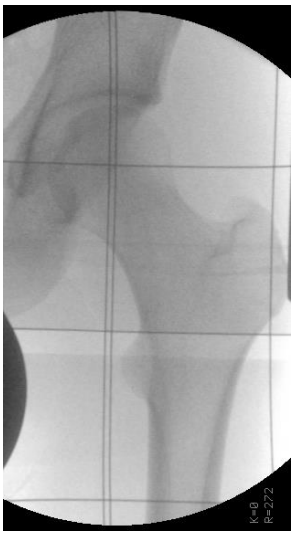


Figure 1.2

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 (Figure 1.2). 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.

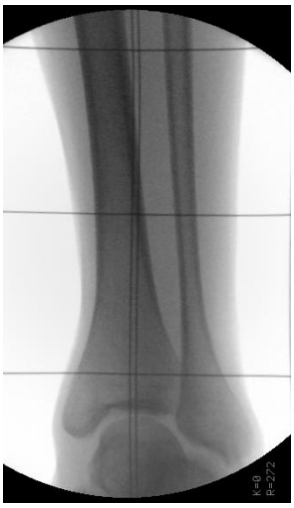


Figure 1.3

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 (Figure 1.3) without changing the rotation of the leg. Save the image for documentation.

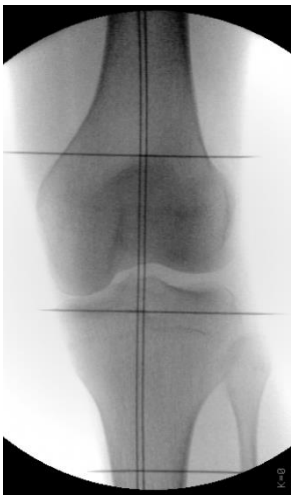


Figure 1.4

For the final step, check the position of the knee. To do this, move the image convertor 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) (Figure 1.4). 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.

1.10 Surgical instruments and required materials

Keep the following surgical instruments available for the FITBONE® TAA operation:

FITBONE® General Tray (AC 60000863)

FITBONE® Reamer Tray 480 mm (AC 60000864)

FITBONE® Instrument trayTAA Instrument Set (AC 60000865)

FITBONE® Extractor Tray TAA/SAA (AC 60000875)

FITBONE® Screw Box (AC 60001108)

FITBONE® Tube-System TAA (AC 60001040)

Recommended tools and surgical 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 (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 hook probes (for explantation only)

Marker and clips

Please keep these surgical instruments in a sterile condition.

1.11 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

Receiverwith coupling (AC 60001615)

Torque wrench to tighten the threaded pins at the bipolar plug connection between intramedullary lengthening nail and Receiver

FITBONE® Control Set consisting of control electronics with power cable and Transmitter with coaxial cable

Stethoscope for monitoring the noise level (AC 60000676)

Instructions for Use FITBONE® Control Set

The FITBONE® TAA Instrument Set described, see Chapter 4 "Instrument Set / screw box", if not yet available for the surgeon

We supply additional locking screws if ordered. No other screws may be used (e.g. made of titanium or with continuous thread).

If requested, the following parts will be provided:

Sterile camera drape (AC 60001562) / Raucodrape®

2 Redon 8 Fr. sterile

2 Cerclage wires Ø 0.8 mm, non-sterile

No accessories other than the components described are permitted.

	**The FITBONE® TAA intramedullary lengthening nail is supplied plasma-sterilized. Indicators on the sterile packaging serve as proof of plasma sterilization. Check both sterile packagings before opening for integrity and expiration date.** **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 lower 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 Sleeve Tray TAA Starter Set.

The Sleeve Tray TAA Starter Set is a medical Instrument Set for minimally invasive implantation of the FITBONE® TAA intramedullary lengthening nail into long bones. Please check the exact designation in the check lists which are included with delivery of the Instrument Set or available on the extranet. The container includes the surgical instruments shown:

Figure 2.1: Sleeve Tray TAA Starter Set

You can see the Sleeve Tray TAA Starter Set (Figure 2.1) on the sleeve tray shown. For FITBONE® SAA operations, the Sleeve Tray TAA Starter Set (AC 60001040) can be upgraded to the Sleeve Tray SAA and TAA (AC 60001066).

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 (AC 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+ (AC 60001029) and 2 mm eccentricity Cone C 13++ (AC 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 CS 15-13 (AC 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.

Figure 2.2: 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® intramedullary lengthening nail in the bone and the reaming direction up to the osteotomy site.**

The Tube T 14/13 – M (AC 60001014) is initially advanced over the cone until it contacts the bone. The associated Tube-Sinker TS 13 (AC 60001033) is used for impaction into the bone.

Figure 2.3: Cone with Tube T14/13—M and Tube-Sinker TS 13

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 inner diameters are provided to guide the reamers concentrically. The outer diameter of the next smaller tube corresponds to the inner diameter of the next larger, i.e., tubes with corresponding inner and outer diameters fit together.

Figure 2.4: Reamer with tubes

Figure 2.5: Tubes of various lengths in the Sleeve Tray TAA Starter Set

The tubes are available in various lengths on the tray (Figure 2.5).

Short tubes are identified by "S" (small), medium tubes by "M" (medium), long tubes by "L" (large) and 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 outer diameter of the reamer is 1 mm smaller than the inner diameter of the respective tube 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 to the height of the osteotomy initially using the rounded, rigid reamers. This is done in stages depending on the implant diameter, from 9 mm to 12 mm according to the preoperative plan while monitoring in two planes via the image converter

The frontally rounded reamers have a cutting length of 200 mm (Figure 2.6). The 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 forehead cutting reamers with a cutting length of 100 mm (Figure 2.6) 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.

Figure 2.6: Reamers, forehead 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 FITBONE® TAA intramedullary lengthening nail is not possible due to an existing deformity of the femur / tibia, the reaming process must be interrupted immediately and another osteotomy performed. It is important to note that the FITBONE® TAA intramedullary nail may not ensure 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.

	**Make sure that the front surfaces remain in corresponding contact at osteotomy level, as otherwise inadequate bone regeneration can be expected.**

2.1.4 Preparation of the medullary cavity before 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 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 and 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 (AC 6000392) can also be used for manual reaming.

	**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 in two planes via the image converter during the reaming process is essential. Improper reaming can lead to heat damage to the bone and serious complications.**

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 step reamer to the depth of the subsequent position of the implant.

2.1.5 Inserting the dummy

	**It must be possible to insert the dummy without resistance. It may be necessary to further ream the medullary cavity while monitoring via the image converter. The Tapping Tool (AC 60000317) is intended solely for later explantation.**

To assemble the targeting device, remove the following components from the instrument tray FITBONE® TAA targeting device and assemble them as shown:

- Drill guide for TAA double-sided (AC 60001175)
- Outrigger for TAA short (AC 60001184)
- Space Holder TAA (AC 60000218)
- Connection bolt TAA canulated (AC 60000310)
- Clamping nut TAA (AC 60000219)
- Open end wrench SW 14/17 (AC 60000689)
- K-wire Ø 3 mm (AC 60001039)
- Setscrew for drill guide (AC 60000003)
- Fastening bolt for drill sleeve (AC 60000175)
- Test pin Ø 4.5 mm (AC 60000688)
- Dummy TAA1180 (AC 60000822) and Dummy TAA1160 (AC 60000832) are included in the instrument set, other required dummies will be shipped with the corresponding system

Below, please find an overview of the dummies with the corresponding intramedullary lengthening nails:

Dummy	Nail
Dummy TAA1140-F-205 (AC 60001248)	FITBONE® TAA1140-F-205 (AC 60001383)
Dummy TAA1160-F-225 (AC 60001139)	FITBONE® TAA1160-F-225 (AC 60001468)
Dummy TAA1180-F-245 (AC 60000822)	FITBONE® TAA1180-F-245 (AC 60001404)
Dummy TAA1140-T-205 (AC 60001244)	FITBONE® TAA1140-T-205 (AC 60001501)
Dummy TAA1160-T-225 (AC 60000832)	FITBONE® TAA1160-T-225 (AC 60001445)
Dummy TAA1180-T-245 (AC 60001495)	FITBONE® TAA1180-T-245 (AC 60001348)
OP-Dummy TAA1380-F-245 (AC 60001623)	FITBONE® TAA1380-F-245 (AC 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.

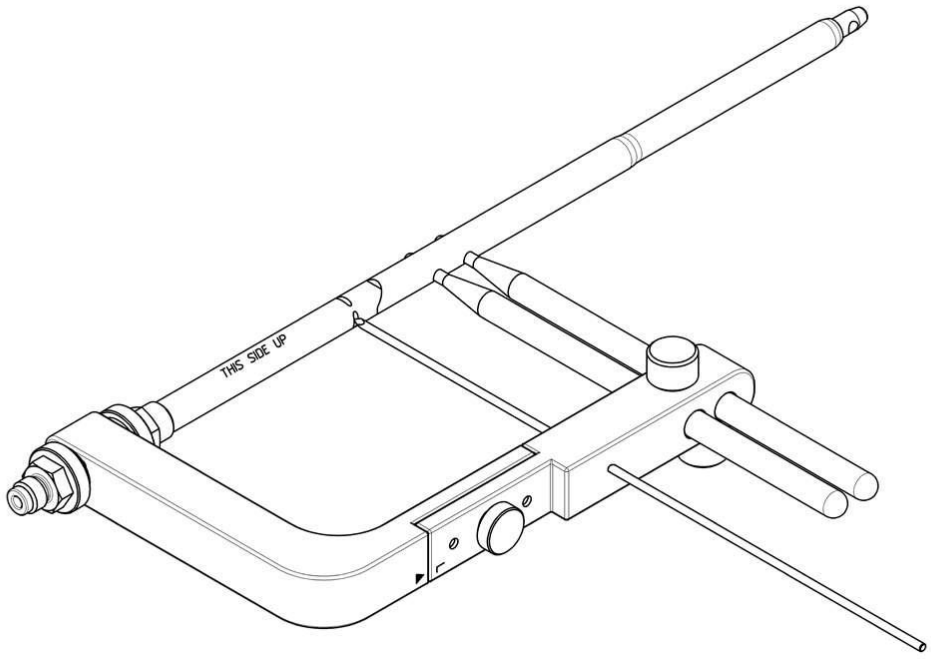


Figure 2.7: Targeting device

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 surgical instruments:

- Drill sleeve, black, Ø 4.5 mm (AC 60000400)
- Trocar Ø 4.5 mm (AC 60000403)
- Drill bit Ø 4.5 mm (AC 60000398)
- Targeting device 45°/ 90° (AC 60001439)
- Wire catcher 90° (AC 60001307)
- Sterile Cerclage wire Ø 0.8 mm
- Redon 8 Fr.

Approach the drill sleeve Ø 4,5 mm (black) 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 targeting device, 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 targeting device 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 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° while securing the Cerclage wire Ø 0.8 mm.

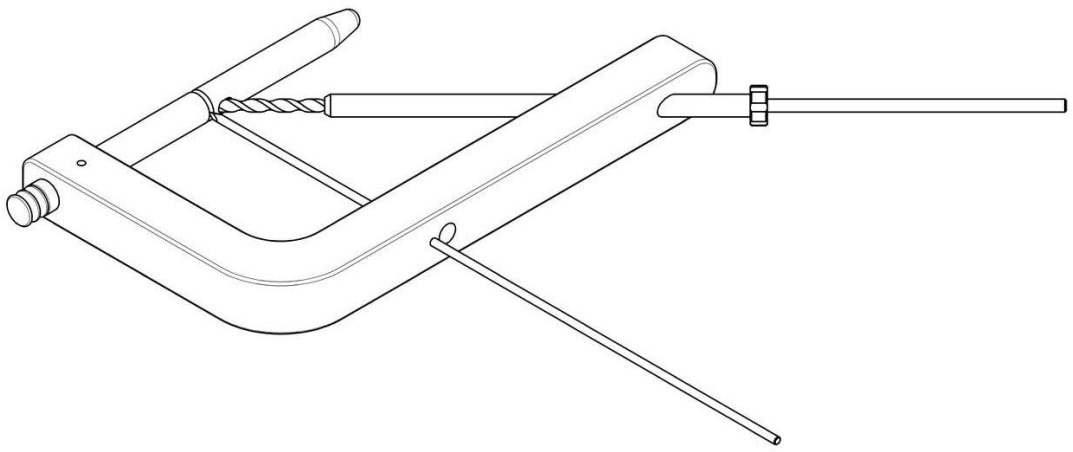


Figure 2.8: Targeting device 45° / 90° for 45° bore

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 targeting device 90° with the wire catcher 45°/ 90°.

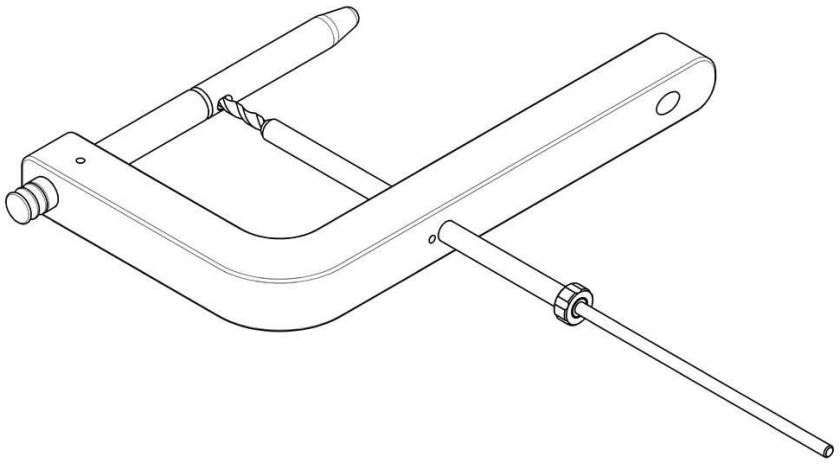


Figure 2.9: Targeting device 45 / 90° for 90° bore

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

	**After unpacking the intramedullary lengthening nail, please check it for damages, especially the bipolar feedline.** **The FITBONE® TAA intramedullary lengthening nail must never be knocked into or out of the medullary canal with a hammer as this could damage the implant.**

Assembly of the targeting device with the FITBONE® TAA intramedullary lengthening nail. (see Figure 2.10):

Required surgical instruments:

- Drill guide for TAA (AC 60001175)
- Outrigger for TAA short (AC 60001184)
- Space Holder TAA (AC 60000218)
- Connection bolt, cannulated (AC 60000310)
- Clamping nut TAA (AC 60000219)
- Dummy TAA11xx (Dummy TAA1180 (AC 60000822) and Dummy TAA1160 (AC 60000832) are included in the Instrument Set. Other dummies needed are shipped with the respective system.
- K-wire Ø 3 mm (AC 60001039)
- Setscrew for drill guide (AC 60000003)
- Fastening bolt for drill sleeve (AC 60000175)
- Test pin Ø 4.5 mm (AC 60000688)
- Open end wrench SW 14/17 (AC 60000689)

The drill guide for TAA is marked with an "R" and "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 center, 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 FITBONE® TAA intramedullary lengthening nail onto the thread of the connection bolt, ensuring that the contours of the intramedullary nail lie flush with the contours of the space holder. Insert both test pins again, they should slide easily into the bore holes of the FITBONE® intramedullary lengthening nail. 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 FITBONE® TAA intramedullary lengthening nail to the space holder. The test pins can now be removed. To make sure that the targeting device does not jam, the test pins must be inserted again.

Now use the assembled targeting device 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. 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 targeting device and tighten the clamping nut between the space holder and targeting device 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 targeting device does not jam, the test pins must be inserted again.

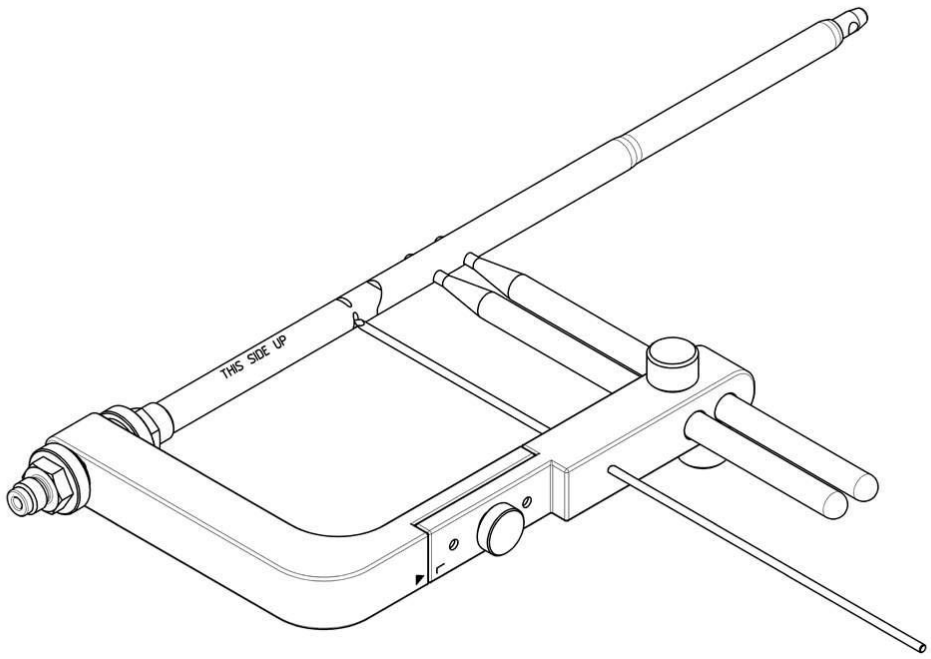


Figure 2.10: Targeting device with FITBONE® TAA intramedullary lengthening nail

Insert the FITBONE® TAA intramedullary lengthening nail into the medullary cavity manually using the targeting device consisting of the required surgical instruments listed above) with the main fragments aligned. 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 targeting device.

Required surgical instruments:

- Drill sleeve, black, Ø 8.0 mm (AC 60000402)
- Drill sleeve, black, Ø 4.5 mm (AC 60000400)
- Trocar Ø 4.5 mm (AC 60000403)
- Drill bit Ø 4.5 mm (AC 60000398)
- Depth gauge for sleeves (AC 60000408)
- Screwdriver SW 3.5 (not cannulated, black handle) (AC 60000576)
- Screwdriver SW 3.5 (cannulated, black handle) (AC 60000406)
- Screw holder, length 325 mm
  for Screwdriver SW 3.5 (cannulated, black handle) (AC 60000384)

The targeting device is used to lock the implant (see also 2.1.7). 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.

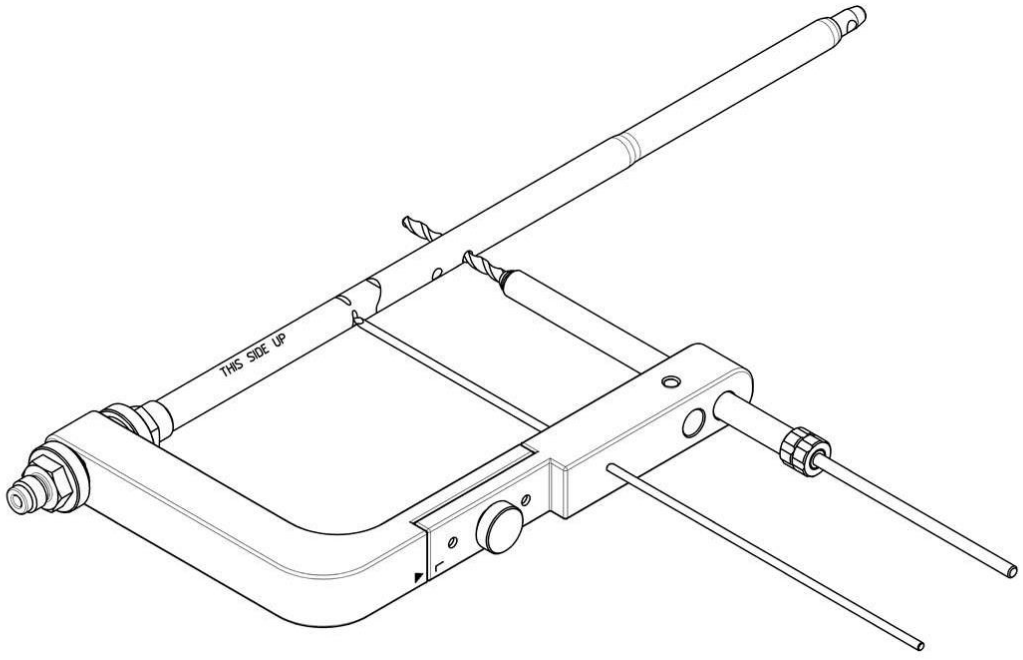


Figure 2.11: Targeting device with FITBONE® TAA intramedullary lengthening nail

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.

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 bipolar plug connection is made accessible. Now insert the connector 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. Please make sure that no tissue or the bipolar feedline itself reaches the adjacent joint

The Receiver can now be removed from the sterile packaging and connected to the FITBONE® TAA intramedullary lengthening nail.

Adhere to the following procedure:

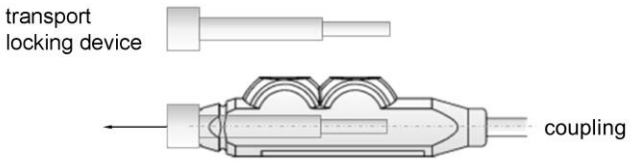
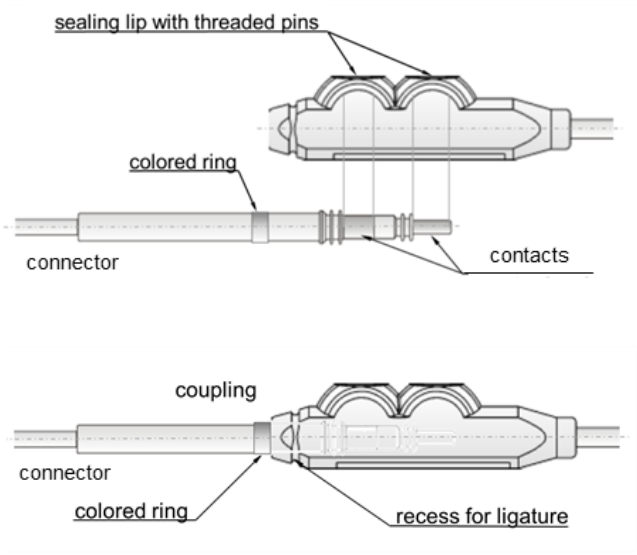


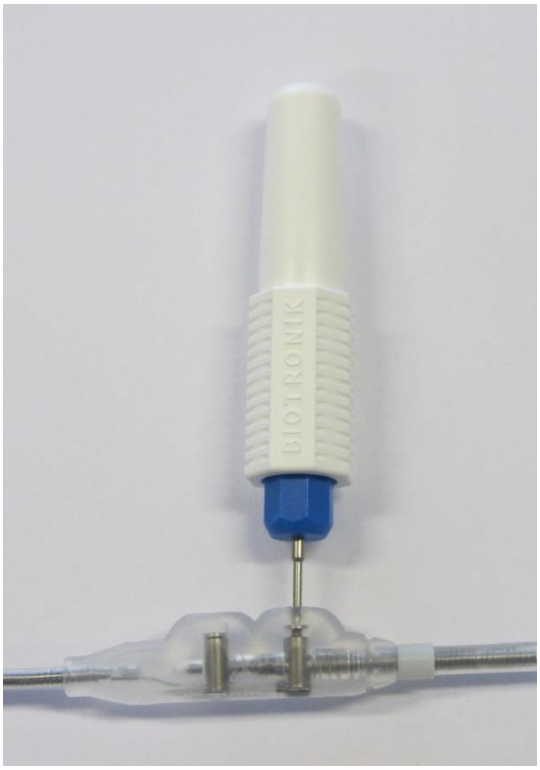
Figure 2.12

Unfasten the threaded pins by pressing and turningthe supplied torque wrench through the sealing lip and remove the transport locking device from the coupling. The transport locking device must not be turned, otherwise there is a risk to twist off the device. In this case residual fragments may cause a problem by assembling the bipolar plug.



Hold the connector and the coupling carefully to prevent bending the bipolar feed line. On the connector for the bipolar plug connection, there is a white colored ring to aid with positioning. Insert the connector into the coupling until the colored ring touches the coupling. Only then it is ensured that the contacts on the connector are positioned correctly relative to the coupling.

Figure 2.13



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 to secure the connector in the coupling until the torque limit is acoustically perceptible (click).

Pull out the torque wrench to allow the silicone seal to close.

Repeat the process for the second threaded pin.

Figure 2.14

Perform a visual inspection of the bipolar plug connection (position of the colored ring). In addition, an intraoperative functional test must be performed to verify the connection (Chapter 2.1.13).

	**The connector must be completely inserted into the coupling. A marking is provided for this purpose.** **Do not hold the coupling or connector with surgical instruments and avoid bending the coupling, connector or bipolar feed line as this can lead to damage or dislocation.**

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.

	**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.**

2.1.13 Intraoperative functional test:

A stethoscope and FITBONE® Control Set are included with the implant. Before the operating room table becomes unsterile, the operating noise of the FITBONE® TAA intramedullary lengthening nail must be checked acoustically and visually. One camera drape each is pulled over the Transmitter and stethoscope complete to check the motor sounds under sterile conditions and can now be used on the patient.

	**More information about their function and operation can be found in the instructions for use FITBONE® Control Set**

	**In doctor mode continuous operation, the Transmitter can reach a maximum temperature of 47.2°C-**

The FITBONE® Control Set must be installed and commissioned according to the information in these instructions for use. In addition, the surgeon has further options for operating the implant:

Under the housing lid (Figure 2.15), there are switches reserved exclusively for the treating physician.

Figure 2.15

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

Figure 2.16

In the "Doc." position, the switch labeled "Doctor" on the front is enabled and can be used to start/stop continuous power transfer. The transfer time is **not** limited to 90 seconds in this mode.

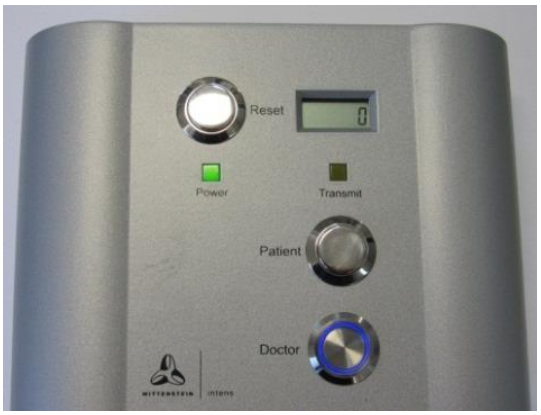
In the "Doc" position, the button labeled "Patient" on the front is disabled and only the switch labeled "Doctor" is enabled.

In the "Pat." position, the switch labeled "Doctor" on the front is disabled and only the button labeled "Patient" is enabled.

The switch labeled "Pulse" / "Perm." allows the attending treating physician to switch from pulse mode to continuous operation. In continuous operation, power is transferred continuously. This leads to a distraction of up to 2 mm per minute.

This mode can be used to preset the implant or to allow a new locking position for proximal locking.

⚠	**Increased caution should be exercised for continuous power transfer. Excessive distraction can cause neuronal damages.**



On the front of the FITBONE® Control Set, the switch labeled "Doctor" lights up blue after being pressed.

Figure 2.17

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 thoroughly 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.

⚠	**Please inform your patients that the area under the housing cover is reserved for the treating physician.**

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

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 surgical instruments:

FITBONE® Extractor Tray TAA/SAA (AC 60000875)

	**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.** **Failure to extraction or delayed extraction of the intramedullary lengthening nail may result in implant fracture with potential infection.** **Please inform your patient about the necessary metal extraction.**

2.5.1 Approach

Removal of all locking screws through stab incisions except for one screw, which should remain temporarily to prevent rotation during insertion of the connection bolt (AC 60000310).

Then approach to the distal end of the nail along existing scar.

2.5.2 Removing the implant

First, remove the Receiver and the connector from the subcutaneous tissue after disconnecting the bipolar feed line. Then locate the bipolar feed line through the approach to the nail end using an ASK hook probe and detach the remaining cable end. Use a ligature in the fastening bolt to insert the cable end. Then screw the cannulated connection bolt into the implant with precise axial alignment. Now remove the remaining locking screw, and twist and pull the FITBONE® TAA intramedullary lengthening nail to remove it (without using a slotted hammer to prevent the bone from chipping).

When handling the removed FITBONE® components, please obey the instructions of your clinic for the handling of explants. In the event of an incident, return the FITBONE® components to the manufacturer after reprocessing so that an examination can be performed.

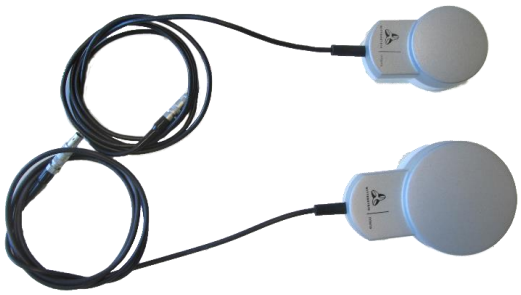
2.6 Retraction function

2.6.1 FITBONE® Retraction Control Set

The Retraction Control Set can be used if medically necessary for a succesful treatment. E.g. unintentional overdistraction.

The FITBONE® Retraction Control Set is required to activate the retraction function. You can recognize this special FITBONE® Retraction Control Set by the label and the larger Transmitter it contains. (see Figure 2.18). The FITBONE® Retraction Control Set is not supplied as standard. If medically necessary, 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 (up) vs. Transmitter FITBONE® Retraction Control Set (down).

Bild 2.18

	**Retraction must not extend beyond the initial total length of the intramedullary lengthening nail as this may result in jamming of the implant. Monitor the retraction by continuous X-ray control during energy transfer.** **The FITBONE® is designed for one-time use (single-use implant). It must not be used for re-implantation.** **The FITBONE® is not suitable for applying compression forces.** **If the Retraction Transmitter is positioned at the wrong angle, accidental distraction cannot be ruled out.** **The stability of the bone is no longer ensured if the nail is retracted after distraction and distracted again (see 1.7 Table 1: Abmessungen).**

2.6.2 Functionality Retraction

The FITBONE® Retraction Control Set is operated exclusively in doctor mode (switch position "Doc") and also analogously to the FITBONE® Control Set you are already familiar with.

The procedure for retraction is as follows:

- Feel the position of the Receiver that has been subcutaneously implanted.
- Place the Retraction Transmitter with the white side on the skin according to the position of the Receiver. If the alignment is correct, the cable outlet of the Receiver is below the cable outlet of the Transmitter (see Figure 1.19). If necessary, the position of the Receiver should be checked by X-ray.
- During retraction, a continuous beep can be heard with the stethoscope.

Figure 2.19

➲ Trigger the power transmission by pressing the „Doc" switch once.

➲ If placed correctly, the yellow „Transmit" LED will flash 5 times within one second. This process indicates that energy is being transmitted.

⚠	**If the yellow "Transmit" LED does not flash, the retraction may not work. In this case, please read chapter 5 "Malfunctions" in the operating instructions for the control set.**

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.

During continuous operation, the tissue between the retraction Transmitter and Receiver may heat up inadmissibly. Interrupt operation for at least 2 minutes after max. 20 seconds.

Figure 1

3 Important notes

3.1 General safety instructions

	**During the active phase and the initial healing phase, the weight-bearing capacity of the FITBONE® TAA intramedullary lengthening nail is limited to partial weight-bearing of 20 kg (sole contact). A load beyond this can lead to fracture of the intramedullary lengthening nail.** **The patient must receive and use walking aids.** **The patient should be prescribed appropriate and regular physiotherapy by a doctor.**

	**The patient must avoid unforeseen / unwanted excess weight-bearing, e.g. by falling or stumbling, as well as full weight-bearing. This can lead to implant breakage.** **If excessive weight-bearing occurs, the patient must contact the treating physician.**

	**The process of distraction should not be interrupted for more than 2 days, as otherwise there is a danger of premature bridging of the bone gap.**
	**Non-ionizing radiation is used for power and data transmission. Electromagnetic impulses can cause interferences.** 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: • - Industrial facilities with wireless power transmission, including production facilities and logistics centers. Please pay attention to any attached warnings for 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 Instructions for Use FITBONE® Control Set.

	Only use components (e.g. power supplies or cables) provided by the manufacturer.

	**The FITBONE® TAA intramedullary lengthening nail and control electronics must not be placed directly beside or stacked with other devices.** Monitor / check the correct functionings of the FITBONE® TAA System if the FITBONE® Control Set is nevertheless positioned in this way.

If the patient is pregnant, leg lengthening will not be initiated. There are no experiences of treatment with FITBONE® during pregnancy. Based on current knowledge, however, no harmful effects are assumed.

3.2 MRI Safety Information

 	Unsafe in Magnetic Resonance Imaging Environments. Assure that patient with implanted nail does not enter the MRI unit. The FITBONE® has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of FITBONE® in the MR environment is unknown. Scanning of a patient who has this device may result in patient injury.

3.3 Precaution

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

Any form of electrical therapy where a current is passed through the body of the patient, like therapeutical X-rays, must be avoided on the affected limb.

- 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.

An interaction between the FITBONE® Control Set and a pacemaker cannot be fully excluded. However, since the transmission range of the Transmitter is very small, there are no harmful effects expected from the FITBONE® Control Set.

3.4 Sterility

The medical devices intended for implantation are H_2O_2-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 4.2 "Cleaning, disinfection, sterilization".

3.5 Single use

The implants are intended for single use.

	**Resterilization of the implants is not permitted.**

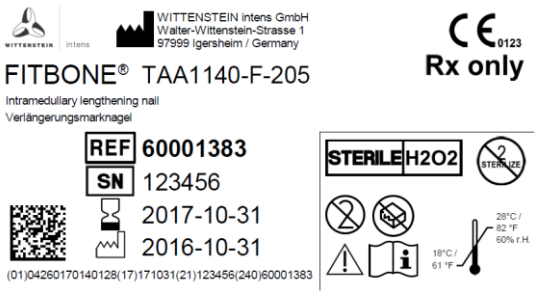
Explants must not be reused as the adequate removal of biological contaminants such as blood, tissue and other substances which may contain resistant pathogens cannot be ensured by cleaning and sterilization.

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

3.7 Packaging and labels

The implantable system components listed are supplied plasma-sterilized in a complete packaging system (see 3.4 "Sterility"). The symbols on the packaging label (in compliance with ISO 15223-1) are explained below:

		Designation
		Manufacturer
	CE 0123	Product designation
	Rx only	Federal law restricts this device to sale by or on the order of a physician. (only on labels for US)
	REF	Reference number
	SN	Serial number
		Use by (expiry date)
		Date of manufacture
	STERILE H2O2	Sterilized in the end packaging (plasma-sterilized)
		Do not resterilize
		Not for reuse
		Do not use if package is damaged
		Follow the safety instructions in the instructions for use
		Follow the instructions for use
		Temperature limitation designates the temperature limits within which the medical device may be stored (upper and lower limit)

Please contact the manufacturer if the label on the packaging is unreadable or damaged.

3.8 Malfunctions

Symptom	Possible cause	Remedy
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

Table 1: 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 of the FITBONE® TAA

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)
- Damage to growth plates in children and adolescents, growth defects with bone deformities

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

- Functional limitations of the limbs
- Delayed or missing bone fracture healing. Spongiosaplasty may be necessary.
- Joint injury, subluxations, luxations, joint stiffening, femoral head necrosis
- Allergic reactions or other intolerance reactions to the implant material
- Remaining or re-emerging shortening, remaining axial and torsional misalignment and, if necessary, further surgical correction
- Infection around the implant components with the need to surgically remove them
- Loosening of the intramedullary lengthening nail
- Osseous eruption of the the intramedullary lengthening nail
- Refraction 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:

- Dysfunction 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 the manufacturer after completion of the treatment. The latter will carry out the necessary 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

- Check List FITBONE® Instrument Set
- Overview of FITBONE® Instrument Set

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

For technical questions, please contact the manufacturer.

WITTENSTEIN intens GmbH
Walter-Wittenstein-Straße 1
97999 Igersheim
Deutschland

Tel.: +49 7931 493-0
Fax: +49 7931 493-10906
E-Mail: info@wittenstein-intens.com

CE 0123

Material	Year of authorization
FITBONE® TAA1140-F-205 (AC 60001383)	2019
FITBONE® TAA1160-F-225 (AC 60001468)	2019
FITBONE® TAA1180-F-245 (AC 60001404)	2009
FITBONE® TAA1140-T-205 (AC 60001501)	2019
FITBONE® TAA1160-T-225 (AC 60001445)	2009
FITBONE® TAA1180-T-245 (AC 60001348)	2019
FITBONE® TAA1380-F-245 (AC 60001422)	2019
Retraction Control Set (AC 60001365)	2019
Receiver (AC 60001780)	2019

WITTENSTEIN intens GmbH · Walter-Wittenstein-Straße 1 · 97999 Igersheim · Germany
Tel. +49 7931 493-0 · info@wittenstein-intens.com

WITTENSTEIN – one with the future

www.wittenstein-intens.com