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FITBONE® TAA Surgical Technique for tibia / femur

FITBONE - fully implantable active intramedullary nail for callus distraction

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highly precise, low-backlash planetary gearing.

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In aeronautics, robotics, mechanical engineering, elevators.

And in people.

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Introduction / System Component Overview

Introduction

This guide describes the FITBONE TAA implant as well as its control electronics, functions and operation.

Please read these user instructions carefully before you start working with the unit. Only by familiarizing yourself with the capabilities of the implant and its control electronics can you make best use its functions.

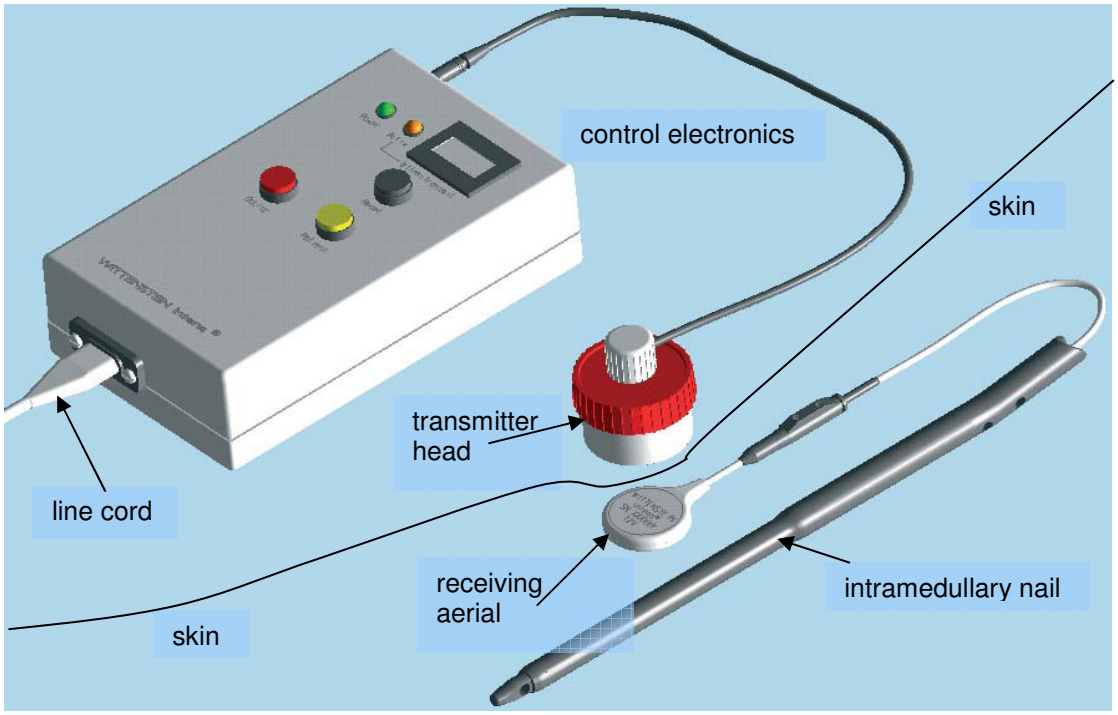
The user instructions are subject to the producer's responsibility. The success of this form of therapy, however, lies within the responsibility of the operating surgeon.

System Components

1. line cord for 220 V / 50 Hz power connection
2. line cord plug-in
3. control electronics
4. coax plug-in
5. transmitter head with line cord
6. receiver aerial
7. FITBONE TAA with bipolar line cord (fully implantable intramedullary nail)

☞ **The components of this consignment constitute an inseparable system and must not be replaced without prior consent by the producer.**

FITBONE system components



1. General

The FITBONE TAA system allows femur and tibia distractions with simultaneous axial correction without the use of external fixation. The following instructions will inform about the implantation and post-operative operation of the medical product.
It is essential, that only well-experienced and especially trained physicians treat the patients with FITBONE. The surgeon must be familiar with lower extremity distractions and corrections and have complete command of all surgical steps and processes from malposition analysis over the planning stage to surgery itself. Perfect knowledge of simple intramedullary nail placement for corrections and of the standard osteotomy techniques is taken for granted. Basic prerequisite for the correct application of the FITBONE TAA system is the surgeon's participation in one of our FITBONE workshops where we teach the particular implantation technique. The FITBONE TAA system is a technique where the system components are tailored to the patient's specific requirements. The following reference guide gives a close description of the special instruments. The indication and intra-operative process lie, however, within the surgeon's responsibility.

1.1 Indication

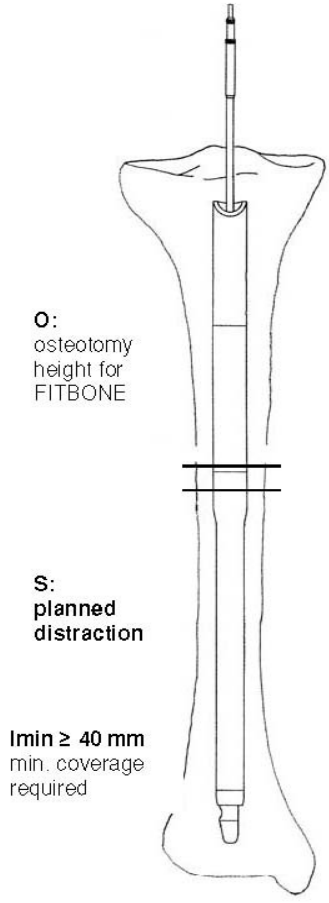
- Tibial and femural length differences of 20 mm and more, with or without axial malpositions.
- Patients up to a body weight of 100 kg.

1.2 Contraindication

- **Too narrow medullary cavity to allow safe implantation (vascular damage, weakening of the cortical substance of the bone)**
- **Insufficient roofing of the head of femur (congenital dislocation of hip) in case of femural distractions**
- **Anterograde femoral distraction: no free access possibility for proximal intramedullary nail insertion (coxa valga)**
- **Infection cannot be excluded**
- **Patients likely not to comply as expected; patients with psychological problems or impaired consciousness**
- **General contraindications against limb distraction**
- **Pregnancy**
- **Implanted fibrillator, neurostimulator or cardiac pacemaker**
- **Chromium/nickel allergy. Implant made of steel!**
- **Other implantable devices such as insulin pumps require careful consideration by the attending physician. We do not avail of any information related to the subject.**

1.3 Pre-operative Planning

As the FITBONE TAA is a complex system which consists of various components and allows thus a nearly perfect correction of all types of malpositions, the physician will first of all have to carry out a comprehensive analysis of the geometry of the leg in question.



The following examinations need to be carried out:

- Clinical examination findings with documentation of the mechanical axis, blood circulation and sensitivity
- Full-length standing anterior-posterior as well as lateral X-ray views of tibia and femur
- Leg length CT with measurement of torsion angle and exact leg length

The height of osteotomy is determined in correspondence with the planning criteria and anatomic facts specific to the patient.

To keep implant and bone stable after callus distraction, the distal implant shaft and bone segment guide need be covered to a sufficient length (at least 40 mm).

The goal length must absolutely be taken into consideration.

1.4 Patient positioning

The patient is placed in supine position on a standard radiolucent operating room table.

The leg is draped in such a way as to allow all-time and unlimited use of the image intensifier from femoral head to ankle joint.

2. FITBONE TAA Surgical Technique

2.1 Implantation technique tibia/femur

The following reference guide presents a tibia/femur reduction without axial and torsional malpositions.

It describes intramedullary nail insertion without expanding on the particularities of any corrective measures.

☞ **Exclude osteotomy to cause axial and torsional deviations.**

2.1.1 Surgical approach

Access between lesser patella and T. tibiae (see conventional medullary nailing). For cosmetic reasons, a diagonal incision of approx. 2 cm should be favored. Split the patellar tendon longitudinally in its midline and set an awl. Monitor accessing via image intensifier in both planes.

☞ **The entry spot of the intramedullary nail into the bone and drill direction to the osteotomy are decisive for axial correction.**

2.1.2 Preparation of the medullary cavity to the planned point of osteotomy

The medullary canal is opened in steps with the rounded rigid reamer until it conforms to the implant diameter. The tissue protector sheaths remain in situ during reaming to allow soft-tissue sparing drill exchange.

- The sharp front-cutting reamers allow correction of the intramedullary canal in all directions; there is, however, a high risk of excessive weakening or perforation of the cortical substance of the bone.
- The front-rounded reamers have a cutting length of 200 mm; these tools allow straightening of the intramedullary canal; they too, however, bear the risk of excessive shifting of the medullary cavity entry spot in the tibial plateau / condylar area which may cause severe complications.

☞ **We do recommend close image intensifier monitoring of the entire reaming process in two planes, in particular by means of AP and lateral views so as to recognize deviations from the wanted drilling direction in time.**

If due to a deformation of tibia or femur the intramedullary canal cannot be enlarged to fit the diameter of the intramedullary nail all the way to the goal osteotomy, reaming has to be interrupted in time and a further osteotomy created in a critical spot. Please note that the intramedullary nail does not guarantee sufficient stability in case of an additional osteotomy. Measures need to be taken (e.g. application of a plate) so that distraction concerns the bone segments in question only.

☞ **Never use reamers with flexible shafts as this may eventually deadlock the FITBONE TAA.**

2.1.3 Osteotomy

Create the osteotomy as planned pre-operatively. Separate the bone where it is most advantageous for the intended corrective measures.

Standard osteotomy instrumentation:
- intramedullary saw
- Gigli saw
- drill and chisel

☞ **It is essential that the bone segment surfaces remain in communicating contact as otherwise bone regeneration will be insufficient.**

For tibia distraction, the fibula needs to be separated entirely.

2.1.4 Preparation of the distal intramedullary cavity

Bone osteotomy is followed by the alignment of proximal boring and diaphyseal shaft angle in the sense of an antecurvature.

By means of the rigid drills, the intramedullary canal is prepared for insertion of the proposed implant. Please note that in the last drilling phase the canal must be overdrilled to a width of 0.5 mm greater than the proposed implant diameter.

There must be no excessive weakening of the cortical substance of the bone in any spot. Excessive weakening may cause fractures and, around the osteotomy site, allow only incomplete bone regeneration.

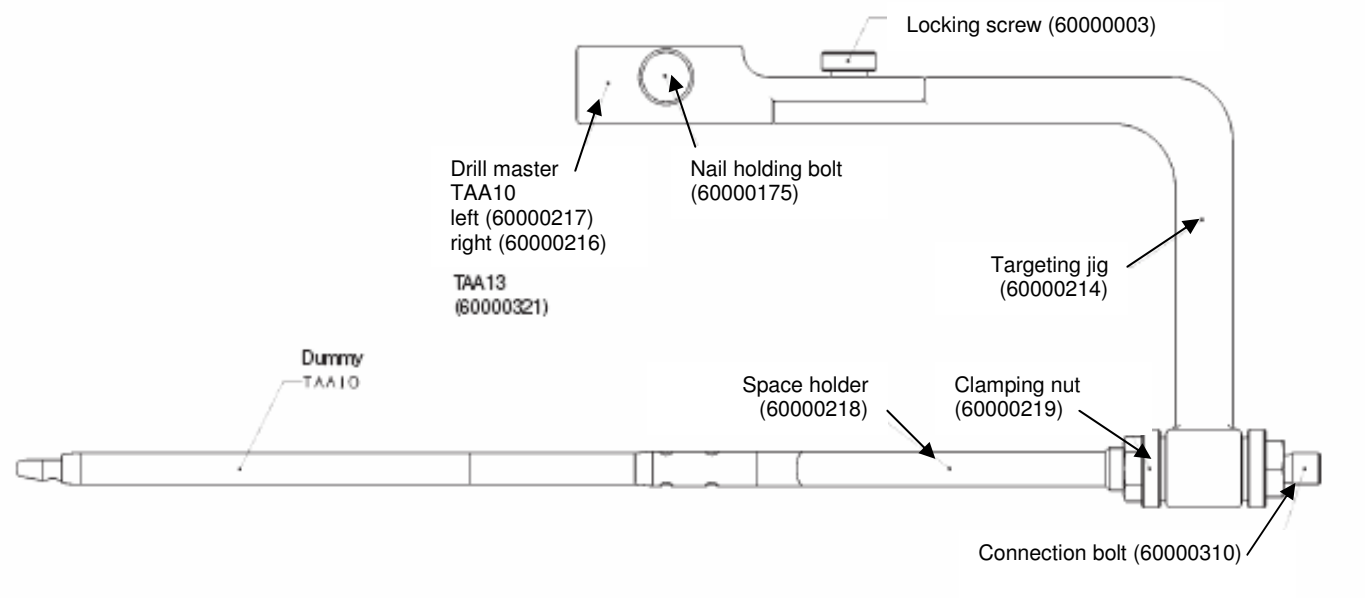
☞ **The diaphyseal area allows only limited corrections and the danger of perforation is high in case of non-monitored drillings. Image intensification on two planes during drilling is essential. Improperly executed drilling may cause heat damage to the bone and lead thus to severe complications.**

2.1.5 Assembly of the targeting jig

☞ **Never use a hammer to drive the FITBONE TAA into or remove it from the intramedullary canal as this may cause severe damage to the implant. Insertion must be smooth and without resistance. To identify resistances, the respective nail dummy is inserted first. Monitor any additional drilling with the image intensifier.**

The tapping tool (6000317) is meant for later explantation ONLY!

Use the components contained in the FITBONE TAA TARGETING JIG instrument tray and assemble them according to the illustration below.
The bipolar line cord is carefully pushed into the space holder and thus protected during implantation and subsequent locking.



Further instruments (for explantation only)

- tapping tool (60000317)
- connection bolt for tapping tool (60000310)

2.1.6 Insertion of the dummy

The test implant for the FITBONE TAA intramedullary nail (dummy) is inserted in the intramedullary canal by hand by means of the targeting jig. The dummy test is to determine whether the intramedullary cavity has been opened sufficiently for the actual implant. The respective dummies are included in the FITBONE TAA instrument tray.

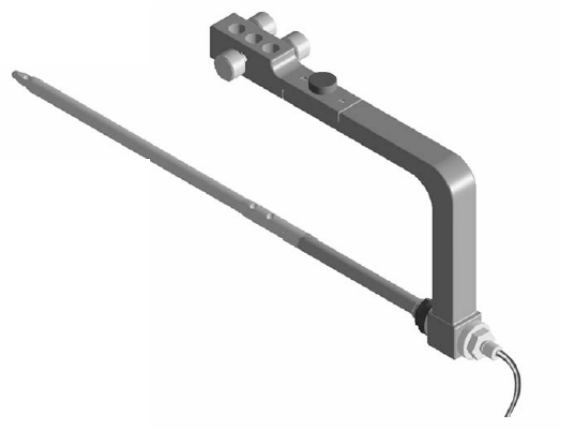
2.1.7 Cable duct / particularity – femur retrograde

Use a 4.5 mm drill to pre-drill the cable duct in the lateral condyle. From the lateral wall of the intramedullary canal boring, prepare the cable duct at a 45° angle in the front plane immediately subchondral to proximal.

2.1.8 Insertion of the FITBONE TAA

Insert the FITBONE TAA intramedullary nail into the medullary canal by hand by means of the targeting jig. Position the distal segment in correspondence to pre-operative planning so as to allow smooth and non-violent insertion of the intramedullary nail.

If you are using the FITBONE TAA with Herzog curvature for tibia distraction, the main segments return to their original physiological position which was abandoned during drilling.



The FITBONE TAA is consigned plasma sterilized and separately from the receiving aerial.

Before opening the FITBONE TAA kit, make sure that the original packaging is undamaged and within the expiry date (EXP). Submit the sterile packaging including additional stickers for the in-hospital documentation to the same check.

☞ **Do NOT use the contents of either FITBONE TAA kit or sterile packaging if damaged!**

2.1.9 Proximal locking (tibia example)

Required instruments

- Drill guide sleeve, green, Ø 8.0 mm (60000402)
- Drill guide sleeve, black, Ø 4.5 mm (60000400)
- Trocar Ø 4.5 mm (60000403)
- Twist drill Ø 4.5 mm (60000398)

☞ **On the short version with two proximal locking holes only use the inner two bore holes. For safety purposes, close the outer third hole of the targeting jig with a holding bolt (60000175, see section 2.1.5).**

Proximal locking is carried out with the help of the targeting jig.

Once the proximal locking screws are in place, the targeting jig can be taken off.

Especially in medial position, the screws should not protrude from the bone contour more than very slightly as this can be painful for the patient.

Check the placement of the screws using the image intensifier in both antero-posterior and lateral planes.

2.1.10 Distal locking hole (tibia example)

The distal locking hole is drilled without help of the targeting jig (e.g. radiolucent bevel gearing). X-ray monitoring is required and follows the routine used for all standard intramedullary locking nails.

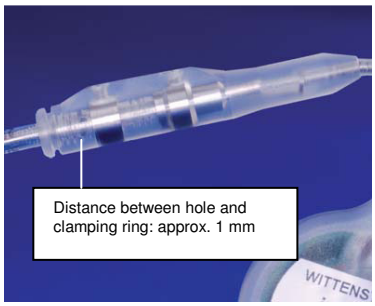
2.1.11 Placement of the antikink sleeves

The targeting jig has already been taken off.

The FITBONE TAA kit contains sterile antikink silicone sleeves: a longer one with lesser diameter and a shorter one with greater diameter. The sleeves, first the longer one, then the shorter one, have to be pulled over the line cord before the receiving aerial is connected. The sleeves keep the line cord from bending and the tissue from growing into the connection thread on the TAA. The antikink-sleeve technique facilitates the later explantation of the FITBONE TAA considerably.

2.1.12 Connection of the receiving aerial / tibia

When the targeting jig is taken off, the cable with plug-in connector becomes accessible. Connect the plug to the receiving aerial coupling.



!!!! Push the plug completely into the coupling. Pay attention to the mark on the coupling

2.1.13 Connection of the receiving aerial / femur

When the targeting jig is taken off, the cable with plug-in connector becomes accessible. Use the cerclage wire and a small-lumen Redon drainage to pull the cable through the hole in the lateral condyle and out of the incision. Make sure not to bend or damage the cable! Finally, connect the plug to the receiving aerial coupling.

- **Do NOT tighten the two locking screws in the coupling piece with any other tool than the enclosed torque wrench (audible ratcheting).**
  Then seal the screw heads with a drop of silicone (dry for about 20 minutes; longer drying times are necessary in case of low air humidity).
  To secure the plug-in connection, apply an additional ligature of non-absorbable suture material (3.0 strong) for strain relief. When applying the knot, make sure the thread does not cut into the silicone material.

2.1.14 Preparation of the subcutaneous pouch for placement of the receiving aerial

The receiving aerial is placed epifascially, laterally in the hypodermic tissue. With a blunt pair of scissors, prepare a pouch long 80 to 100 mm with its end petering out immediately subepidermally. The subepidermal immediacy allows sufficient surface placement of the receiving aerial to guarantee all-time energy infeed. Apply a purse-string suture at the upper end of the channel and clamp it temporarily.

- **The perfect distance between receiving aerial and transmitter head is approx. 5 mm**
  This distance guarantees optimum power transmission.
  Do not exceed distances of 10 mm as this would affect the functionality of the system.

2.1.15 Placement of the receiving aerial

With its label to the outside, the receiving aerial is inserted in the prepared subcutaneous pouch. Then accommodate the coupling piece in the pouch also and close the purse-string suture. Next step is the suture of the patellar tendon. During suturing make sure not to damage the cable. Surgery finishes with the closing of the wound.

2.2 Intraoperative function check

- with control electronics (non-sterile)
- transmitter head with line cord (sterile)
- stethoscope (sterile)

The implant comes with sterile stethoscope and sterile transmitter head. Use them to carry out an acoustic check of the drive running noise before suspending sterility in the operating room.

2.3 Post-operative care

In the anesthetic recovery room, accommodate the limb on a cushion at a 30° angle. We recommend the application of ice to the osteotomy area. First-time mobilization the day after surgery.
Leg length differences are compensated by means of shoe elevation. Physiotherapy should be limited to the prevention of pulmonary and thromboembolic complications.

Knee joint exercises from day 4 after surgery. We recommend the following measures:
- Manual therapy techniques (physiologic movements, additional movement)
- Muscle relaxation techniques in supine position with healthy leg upright in counterposition
- Posterior/anterior femur movement in face-down position and maximum hip extension
- Extension movements at slight traction

Further measures that can be carried out if necessary, in particular during and after consolidation are: nerve mobilization techniques, muscle improvement measures (PNF, MTT), proprioception and gait improvement.

The above indications are not specific to the FITBONE TAA but to all types of lower and upper leg distractions and emphasize the necessity of regular checks in hospital. During the distraction phase, the intervals range from daily to two times a week. It remains within the physician's judgment whether to continue or interrupt the distraction process and which measures need to be taken in which particular situation.

2.4 Distraction phase

Distraction commences on the day 5 after surgery as described in sections 3.2 and 3.3 with the application of the transmitter head and the activation of the operator elements on the control electronics. The distraction rate depends on the expected or radiologically recognizable bone regeneration and can vary from the standard 1 mm per day. During the distraction phase the distraction rate needs to be checked at regular intervals and corrected if need be (new patient instructions). It is paramount that the patient himself keeps exact records so that malfunctions can be recognized in due time. We recommend the use of the enclosed distraction record sheets.

2.5 Stress

During the distraction phase, the implant must not be subjected to partial loads of more than 20 kg (plantar contact). In the course of consolidation, the load can be increased in dependence of the bone regenerate.

2.6 Metal removal

The implant can be removed when the new regenerate guarantees adequate carrying capacity and absolute return of bone stability. The required special instruments come in a separate tray (see "Instrumentation" overview).

2.6.1 Access

Remove all locking screws via stab incisions. Then access the proximal nail end along the existing scar.

2.6.2 Implant removal

Remove the aerial from the subcutaneous tissue. Cut the cable about 5 cm above its entry into the intramedullary nail. Remove the silicone antikink sleeves (small and large). Undo the tapping tool (60000310) connector screw which shows a cable holder bore hole. In general, the FITBONE TAA can be pulled out easily and without the use of the hammer.

☞ **Ultrasonic and magnetic field therapy must not be applied during the active phase of distraction and as long as the FITBONE TAA is implanted in the bone.**

3 Operation of the control electronics

The control electronics unit is operated outside of the human body and consists of three components (see illustration on page 2):

1. Line cord (1.)
2. Control electronics (3.)
3. Transmitter head (5.)

Patient cooperation is essential for the success of the entire therapy. For this reason, the patient needs to be thoroughly familiarized with the operation of the control electronics during his/her hospitalization. Patient training lies within the responsibility of the hospital.

Distraction should begin about but not before 5 days after surgery.

Daily distraction amounts to about 1 mm. One distraction interval (patient mode) takes 90 seconds. A uniform distribution of the distraction intervals over the whole day facilitates healing and spares the surrounding soft tissue.

Commissioning / power supply

Use the enclosed line cord to connect the control electronics to a 220 V power supply. The green LED shows that voltage is impressed. Connect the transmitter head to the control electronics via coaxial cable.

Control unit – front
The front of the control electronics features a yellow button (patient), a red switch (physician), a black reset button and an LCD.

Control unit – back
The inside of the housing lid accommodates a slide switch and an LCD to be used by the **physician only**. The LCD outputs the overall amount of pulses transferred.

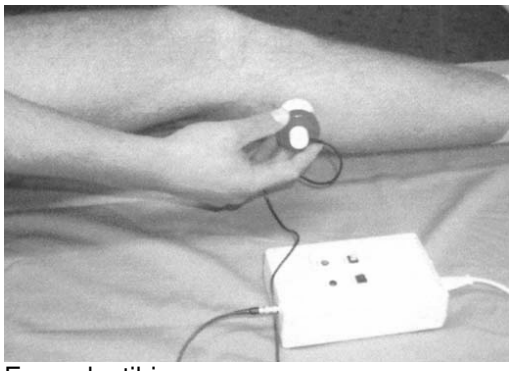
The patient must be instructed not to carry out any changes as they could cause malfunctions and thus health disorders.

Placement of the transmitter head

The yellow LED flashes (1-second on and offs) when energy is transferred, i.e. transmitter head and receiving are positioned correctly. Without the correct distance of the two components to each other there can be no electrical transmission and therefore no distraction.

If the yellow LED instead of flashing shows a permanent signal, the correct position of transmitter head and receiving aerial to each other has **not yet** been found. Move the transmitter head until the precise position is located and the LED starts flashing.

☞ **Prior to placing the transmitter head make sure that the patient has adopted a relaxed position (observe muscular tone).**



Example: tibia

☞ **To prevent the coaxial line from disconnecting from the control electronics, the plug-in connector comes with a lock that unlocks only when the plug is pulled out of the aluminum housing. Any direct pulling of the cable or dropping of the transmitter head may damage the system.**
In such a case, the patient needs to get in touch with his physician immediately so that we can supply replacement.

3.3 Electrical transmission

Connect the electronic control to the power supply and place the enclosed stethoscope on the kneecap. Then place the transmitter head over the receiving aerial (you can feel it running your hand over the patient's skin).

Push the yellow button to transmit the signal. If both components are in the correct position to each other, a short sequence of flashes which is repeated every 10 seconds and lasts about 1 second indicates that energy is being transferred. During each flashing sequence, the running noise of the drive can be checked over the stethoscope.

The process ends after 9 flashing sequences, each of them accompanied by the brief running noise of the drive. The entire transmission process takes 90 seconds.

The LCD must now display 9 pulses more than at the beginning of the distraction.

After the electrical transmission, note down the number of acoustically (stethoscope) monitored flashing intervals on the enclosed distraction report sheet.

In the distraction report sheet the physician specifies how often to carry out distraction, .e. 9-single-pulse intervals.

The distraction report sheet also provides space for individual notes and comments, e.g. incorrect LED outputs, missing running noise or x-ray checks that were carried out.

The success of the treatment not only depends on the number of daily intervals but also their uniform distribution over the whole day. Daily intervals and their distribution are specified by the physician.

The control electronics blackboxes the number of single pulses transferred. The physician has thus the possibility to check whether transmission has succeeded or not.

The patient absolutely needs to fill in the necessary data so as to support healing.

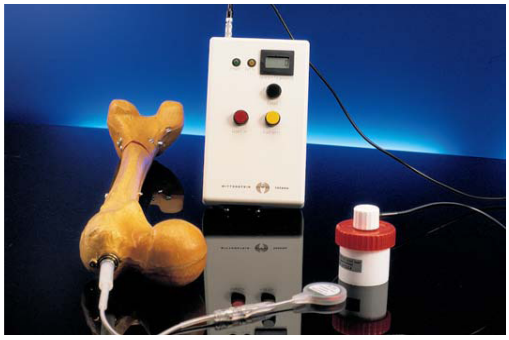
If the control LED does not flash but lights up at 10-second intervals, the transmitter head has not been placed correctly over the receiving aerial. Feel for the implanted receiving aerial and place the transmitter head directly over it.

The absence of the running noise of the drive during individual transmission intervals does not give reason for worries but should be noted in the distraction report sheet. If, however, the next distraction interval is not accompanied by any running noise either and all attempts to find the correct position fail despite the flashing control LED, you should contact the manufacturer.

The absence of running noise by itself does not constitute an emergency. Inform the manufacturer as early as the next working day and keep trying to transfer energy, ***if need be with the substitute electronic control that has been provided to the hospital***.

NOTE:
The drive has been conceived in such a way as not to carry out any distraction in case of extensive loads in order not to damage the system. It is highly probable that your fruitless attempts to transfer energy are suddenly followed by regular distraction intervals.

Physiotherapy can contribute to a smooth distraction process.



During hospitalization, it is of utmost importance that the attending physician instructs the patient on the operation of the control electronics. It is the physician's responsibility to determine 1) the amount of distractions the patient needs to carry out 2) at which times a day.

Please add your notes and instructions to the last pages of the patient information so as to make them available to the patient at home.

It is the patient's responsibility to note the number of distractions and 2) times a day they were carried out in the distraction report sheet. In regular x-ray fluoroscopy, the physician checks the correspondence of distraction report sheet and actual progress.

☞ **The daily filling in of the distraction report sheets facilitates monitoring and documentation of the treatment progress.**

3.4 **Safekeeping of the control electronics**

The control electronics must be kept in a safe place and taken out only for the time needed for distraction. The patient receives a transport box to be used for all-time safekeeping of the control electronics.

The control electronics need to be protected against excessive heat (do not expose to more than 50°C) and cold (do not expose to less than –5°C). Never expose the device to direct solar radiation nor leave it in the car during the cold season or over night.

4 Important information

4.1 General safety instructions

☞ **The intramedullary distraction nail load-bearing capacity is limited, in particular during the active phase of distraction and early stage of recovery.**

Unforeseen / unwanted excessive partial or full loads on the leg in question caused, for example, by falling or tripping, should be absolutely avoided.
If they do happen, the patient is to get in touch with the hospital immediately.

Distraction must not be interrupted for more than two days in order to avoid bridging of the new bone regenerate.

4.2 Electrical safety

Never immerse control electronics or transmitter head in water! Observe the electrical safety guidelines valid for standard home appliances such as hairdryers, shavers etc.

We recommend the patient to keep the user instructions consigned with the control electronics close to the device or in an easily accessible place.

As the patient himself operates the device, he needs to receive detailed instructions as well as the user instructions consigned with the control electronics

Technical safety of the control electronics also depends on a stable supply voltage. If the patient plans vacationing abroad during the active distraction phase, we recommend that he coordinates such plans with the manufacturer.

Connect the control electronics to properly installed socket outlets with earthing contact.

Prior to treatment, carry out a trial run to check proper functioning of the device (see 2.9).

4.3 Mechanical safety

Do not bump or drop the device.

If the control unit does suffer a fall, check it for outside damage. If the device is visibly damaged, get in touch with the manufacturer at once. He will provide replacement immediately.

If there are no visible outside damages, check the device functions during the next transmission (stethoscope and LEDs):
1. the yellow LED must flash during transmission,
2. the familiar running noise must be audible when listening to the implant functions through the stethoscope.

If one or both functions are down, contact the manufacturer immediately so that he can supply replacement at short notice.

The implanting hospital has a substitute control unit in stock (see patient implant ID).

4.4 Sterility

The medical products provided for implantation are consigned in sterilized state. Their sterility can be guaranteed only as long as packaging is intact and undamaged.
SEE EXPIRY DATE ON THE PACKAGING!

4.5 One-time use

The implants are meant for one-time use only. The explants must not be reused as any later cleaning and sterilization procedure cannot guarantee total removal of biological residues such as blood, tissue and other substances that may contain resistant germs.

4.6 Packaging

The medical products provided for implantation are consigned sterilized in sealed, two-layer package additionally protected by the transport box. Absolute sterility of the products can be guaranteed only if the sterile package is neither damaged nor opened.

4.7 Interaction

Nuclear magnetic resonance imaging and the use of defibrillators may disturb the implant functions and are therefore contraindicated.

4.8 Accessories

Enclosed components:
- the described instruments, see enclosed “Instruments overview”;
- locking screws, enclosed; do not use any other screws;
- transport box for control electronics;
- stethoscope for running noise monitoring;
- description of the surgical technique;

- user instructions for the patient plus distraction report sheet;
- implant ID request form.

No other than the above listed components are allowed as accessories.

4.9 Failures

Possible failure sources (component)	**Possible failures**	**Failure elimination**
1. Control electronics		
S 2 Physician switch	malfunction / no function	replacement unit / contact manufacturer
S 3 Patient button	malfunction / no function	replacement unit / contact manufacturer
Power pack / line cord	unplugged line cord defective line cord insufficient supply voltage defective power pack	plug in line cord replace try different wall outlet replace / contact manufacturer
Power supply LED	does not light up despite mains supply	replace / contact manufacturer
Yellow flash LED (transmitter active)	does not light up / flash	check transmitter head position check coax connection replace / contact manufacturer
	wrong flashing sequence / permanent light	check transmitter head position replace / contact manufacturer
Patient-to-physician switch	defective switch	replace / contact manufacturer
Pulse counter (digital display) counts the pulses transmitted	defective or faulty display	replace / contact manufacturer
2. Transmitter head	faulty HF energy output	replace / contact manufacturer
3. Receiving aerial	wrong distraction speed to be determined via x-ray checks	adjust distraction intervals per day
3.1 bipolar line cord plus coupling	defective line cord / plug-in connector	repeat surgery and exchange implant
4. FITBONE TAA	insufficient distraction force	adjust distraction intervals per day
4.1 bipolar line cord plus connector	defective line cord / plug-in connector	repeat surgery and exchange implant

! If there is no response, repeat the transmission cycle several times !

Possible component damage through fall

The components, both the extracorporeal (control electronics and transmitter head) and the implanted ones, can be damaged when they fall on hard surfaces.
Extracorporeal component damage can be determined through visual and functional checks.
The implanted components need to be subjected to a functional (distraction) and running noise (stethoscope) check.

Electromagnetic/magnetic disturbances

There should not be any interferences in the patient's home or hospital environment.
Do not carry out any MR checks during treatment as we cannot guarantee the MR resistance of the components. If MR checks cannot be avoided, the component functions need to be checked immediately afterwards.

Malfunctions caused by insufficient power supply

Such malfunctions may happen in case of power supply failures or insufficiencies. All patient travels abroad need to be discussed with the physician. The implanted medical product does not have an own internal energy source.

Sanitary safety

The implanted components are consigned in 2-layer sterile packaging which, in turn, is consigned in a safe transport box. If either the

packaging or the transport container are damaged, the contained components MUST NOT be implanted.

Operation outside the prescribed environment

As “prescribed environment” we understand the climatic and technical conditions and guidelines in central Europe. The patient is the decisive factor for the implanted component. See section 7 for the use of the extracorporeal components.
The manufacturer cannot be held responsible for any environmental conditions other than those specified for Europe.

4.10 Medical Risks

We distinguish between the general risks in surgery and the medical risks brought about by the system.

General risks in surgery may be but are not limited to the following items:

- **Injury of blood vessels, neighboring tissue (e.g. tendon/muscle) and/or nerves. Possible consequences: dysesthesia, neuralgia or leg paralysis.**
- **Reconstructive blood vessel interventions and/or blood transfusions may become necessary.**
- **Pulmonary embolism by pressing intermedullary particles into the venous blood circulation system.**
- **Swelling and soft tissue hematoma.**
- **In very rare cases severe local circulatory disorder with limb loss.**
- **Bone, soft tissue or joint infections.**
- **Treatment and further operations; additional functional restrictions cannot always be excluded.**
- **Dysesthesia around the scars.**
- **Skin overreaction.**
- **Delayed osteotomy healing which may lead to a system overload.**
- **Danger of pseudarthrosis if the bone does not heal.**
- **In very rare cases ankylosis, necrosis of the femoral head as a consequence of the surgical intervention.**
- **We recommend to inject heparin as prophylactic measure against thrombosis and embolism.**
- **Allergic reaction to the implant material.**
- **Distraction pain.**

System risks:

1) Electrical current
- The direct voltage impressed is so low that it bears absolutely no danger to the patient's conduction system of the heart in case of faulty FITBONE insulation.
- Power transmission is so short that the high frequencies do not endanger the patient.

2) Mechanical data
- Premature full load on the implant may break the FITBONE TAA and thus lead to an infection or toxic reaction due the direct contact with non-sterile parts.
- Any failure of the FITBONE TAA drive system is detected by regular x-ray checks.

☞ Attention ☜

- **The patient must be equipped with and use walkers**
- **Regular physiotherapy as prescribed by the physician. The exercises should not cause strong pains**
- **The load on the operated leg must not exceed 20 kg (foot sole contact) during the active phase. The loads may be increased after the distraction phase and in dependence of the bone regenerate.**

4.11 Maintenance

- **Service and maintenance jobs on the control electronics and the transmitter heads may be carried out by WITTENSTEIN intens GmbH only!**

These components need to be returned to the manufacturer after use!

All warranty claims become null and void if non-authorized persons carry out modifications or repairs on the components.

- Ask the manufacturer for authorized service and maintenance personnel.
- Make sure that during cleaning no liquid penetrates the device housing and reaches the internal components.
- Use a slightly humid (NOT WET) cloth to clean the external system components.
- Never immerse the device in water nor clean under running water.

Any wrong handling or installation bears the risk of severe damage to both health and material.

FITBONE-Implants are shipped and delivered with back up implants and devices for using, if necessary, within the surgery and during the distraction phase. Replacement parts are therefore normally not necessary. In case of the need of replacement parts the

FITBONE HOTLINE
Tel. +49 7931-493-10484

is established.

5. Implant ID

Every patient is given an implant ID with the identification data of the implanted medical products plus important further information.

4.12 Care and cleaning of the control unit

Cleaning is taken care of during normal device maintenance by:

WITTENSTEIN intens GmbH
Walter-Wittenstein-Straße 1
D – 97999 Igersheim (Germany)

4.13 Safety checks / customer service

Once the active distraction phase is finished, the entire control electronics with transmitter head and case are to be returned to the manufacturer prior to any re-use. The necessary safety checks and maintenance works will be carried out at the manufacturer.

The control electronics conform to protection class II, i.e. follow the protective insulation design standards.
The internal power transformer is a safety transformer and also conforms to protection class II of VDE 0551/EN 60742/IEC 742.

6. Explants

The explants are to be returned to the manufacturer after their use.

7. Technical Data

Technical data of the control electronics:	
Supply voltage	230 V ± 5%, 50 Hz
System capacity	max. 6 VA
Mains plug	2-pole DIN 49464 / VDE
Supply connection	1.5 m, 2 x 0.75 m flat (CEE/VDE)
Housing	protection class II, protective insulation
HF transmitting power	max. 1.5 Watts (magnetic field)
Frequency	75 to 90 KHz, load-dependent, dep. on physical conditions
Dimensions	
Control electronics	155 x 92 x 45 mm
Transmitter head	diameter x height: 35 mm x 35 mm
Weight	
Control electronics	approx. 450 gr
Transmitter head	approx. 75 gr
Technical data of the transmitter head:	
Input	75 to 90 KHz, magnetic field lines of the transmitter head of the signal transmitter
Output	DC 12 V / 0.75 W
Permissible ambient conditions	
Storage temperature	for extracorporeal components and for implant components in their sterile packing - 5°C to max. 50°C

8. Distraction report sheet

The report sheet documents the distraction process and is thus of great help to both patient and physician in charge.

☞ The distraction report sheet is described in detail in the control electronics user instructions. It is consigned together with the control electronics.

9. Instruments overview

General tray I

Item	Item number	Description
10	60000432	Tissue protector for femur
20	60000438	Guide rod, 30 mm long, for reamer Diameter: 10 mm, total length: 520 mm
30	60000440	Guide rod, 50 mm long, for reamer Diameter: 13 mm, total length: 480 mm
40	60000392	T-handle for reamer, short (190 mm) with AO connection, cannulated, 3.6
50	60000393	T-handle for reamer, long (330 mm) with AO connection, cannulated, 3.6

General tray II

Item	Item number	Description
10	60000398	Twist drill, 300 mm long, 4.5 mm in diameter
20	60000400	Drill sleeve, 4.5 mm in diameter (black)
30	60000402	Drill sleeve, 8.0 mm in diameter (green)
40	60000403	Trocar, 4.5 mm in diameter
50	60000405	Trocar (T-handle), 4.5 mm in diameter
60	60000384	Screw holder …mm for screwdriver (cannulated, black handle)
70	60000406	Screwdriver, SW 3.5 (cannulated, black handle)
80	60000407	Allen screwdriver T-handle, SW 3.5
90	60000408	Depth gauge for sleeve (one piece)
100	60000317	Tapping tool

Reamer tray

Item	Item number	Description
10	60000411	Reamer, diameter 8.0 mm. long cutting edge = 200 mm, rounded
20	60000412	Reamer, diameter 9.0 mm. short cutting edge = 100 mm, front-cutting
30	60000413	Reamer, diameter 9.0 mm. long cutting edge = 200 mm, rounded
40	60000414	Reamer, diameter 10.0 mm. short cutting edge = 100 mm, front-cutting
50	60000415	Reamer, diameter 10.0 mm. long cutting edge = 200 mm, rounded
60	60000316	Reamer, diameter 10.5 mm. long cutting edge = 200 mm, rounded
70	60000417	Reamer, diameter 11.0 mm. short cutting edge = 100 mm, front-cutting
80	60000418	Reamer, diameter 11.0 mm. long cutting edge = 200 mm, rounded
90	60000833	Reamer, diameter 11.5 mm. long cutting edge = 200 mm, rounded
100	60000419	Reamer, diameter 12.0 mm. short cutting edge = 100 mm, front-cutting
110	60000420	Reamer, diameter 12.0 mm. long cutting edge = 200 mm, rounded
120	60000716	Reamer, diameter 12.5 mm. long cutting edge = 200 mm, rounded
130	60000421	Reamer, diameter 13.0 mm. short cutting edge = 100 mm, front-cutting
140	60000422	Reamer, diameter 13.0 mm. long cutting edge = 200 mm, rounded
150	60000423	Reamer, diameter 13.5 mm. long cutting edge = 200 mm, rounded
160	60000425	Reamer, diameter 14.0 mm. short cutting edge = 100 mm, rounded
170	60000426	Reamer, diameter 15.0 mm. short cutting edge = 100 mm, rounded
180	60000397	Cleaning brush, diameter 5 mm, length 500 mm, head length 100 mm
190	60000427	Clamping device 230 x 60 for sieve tray

Targeting jig for FITBONE TAA 10/13

Item	Item number	Description
10	60000217	Drill master TAA 10 / TAA 11 left
20	60000216	Drill master TAA 10 / TAA 11 right
30	60000321	Drill master TAA 13
40	60000175	Holding bolt TAA 13 for drill sleeve
50	60000003	Locking screw for drill master
60	60000218	Space holder TAA 10 / TAA 11
70	60000219	Clamping nut
80	60000214	Targeting jig
90	60000310	Connection bolt for tapping tool, cannulated (implantation and explantation)
100	60000633	Dummy TAA 1040, straight
110	60000635	Dummy TAA 1040, curved
120	60000761	Dummy TAA 1040, long
130	60000832	Dummy TAA 1160
140	60000822	Dummy TAA 1180
150	60000247	Dummy TAA 13
160	60000689	Spanner 14/17

FITBONE TAA metal extractor tray

Targeting jig for FITBONE TAA 10/13

Item	Item number	Description
10	60000536	Screwdriver SW 5, length 400 mm (cannulated, black handle)
20	60000513	Screw holder M4, length 4.. mm (cannulated, black handle)
30	60000557	Allen screwdriver T-handle, SW 5 (non-cannulated), length 400 mm
40	60000310	Connection bolt for tapping tool, cannulated (explantation TAA 10/13)
50	60000406	Screwdriver SW 3.5 (cannulated, black handle)
60	60000384	Screw holder 265 mm for screwdriver (cannulated, black handle)
70	60000318	Space holder
80	60000317	Tapping tool
90	60000683	Holding bolt, short, 40 mm SAA 13
100	60000515	Explantation support SAA 13
110	60000689	Spanner 14/17
Screws for static locking / proximal locking screw 4.5 mm, smooth shaft, long thread		
120	60000365	length 30 mm
130	60000366	length 35 mm
140	60000367	length 40 mm
150	60000368	length 45 mm
160	60000369	length 50 mm
170	60000410	Screw gripper

☞ **Screwdrivers SW 3.5 and SW 2.5 (non cannulated, black handle) need to be provided by the hospital (small fragment tray) for all metal extractions!**

Screw box with distal and proximal locking screws

Item	Item number	Description
Distal locking screw 5.8 mm, non-stop thread		
10	60000272	length = 80 mm
20	60000271	length = 75 mm
30	60000270	length = 70 mm
40	60000269	length = 65 mm
50	60000268	length = 60 mm
60	60000267	length = 55 mm
70	60000266	length = 50 mm
80	60000265	length = 45 mm
90	60000264	length = 40 mm
100	60000263	length = 35 mm
110	60000262	length = 30 mm
Proximal locking screw 4.5 mm, smooth shaft, short thread		
120	60000260	length = 50 mm
130	60000259	length = 45 mm
140	60000258	length = 40 mm
150	60000257	length = 35 mm
160	60000256	length = 30 mm
170	60000255	length = 25 mm
180	6000254	length = 20 mm
Proximal locking screw 4.5 mm, smooth shaft, long thread		
190	6000572	length = 80 mm
200	6000571	length = 75 mm
210	6000570	length = 70 mm
220	6000569	length = 65 mm
230	6000568	length = 60 mm
240	6000567	length = 55 mm
250	6000369	length = 50 mm
260	6000368	length = 45 mm
270	6000367	length = 40 mm
280	6000366	length = 35 mm
290	6000365	length = 30 mm
300	6000364	length = 25 mm
310	6000363	length = 20 mm
320	6000410	Screw gripper
330	6000503	Cannulated screw 3.5x40 mm VG

10. Screw box overview