WITTENSTEIN | intens

FITBONE® Control Set

Instructions for Use



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Revision: 01

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Dear FITBONE® Patient

For your planned limb lengthening (distraction), a device has been implanted which needs to be turned on by you several times a day. Your doctor will instruct you on how often and how long to turn it on. Your doctor will also show you how to do it before you leave the office. Limb lengthening by continuous force has been happening since the last century.

Until just a few years ago, only external devices were available for limb lengthening, but it is now also possible to use fully implanted systems. This involves cutting through the bone through a small incision and inserting the device into the middle of the bone to keep it stable. After a waiting period that is about 5 to 10 days, the device is turned on using the transmitter. From then on, a lengthening of about 1 mm / day occurs by placing a transmitter on the outside of your skin near a receiver located under your skin. The receiver can be felt through the skin from the outside. The special feature of this method is that the equipment is under the skin and not extending through the skin like the older styles of limb lengthening equipment and the patient does not feel the lengthening process. New bone regenerate grows in the resulting gap from the daily lengthening. After the distraction phase, the body repairs the gap into solid, highly weight-bearing bone.

You will need to turn on the device yourself each day by placing the transmitter on the skin in the way your doctor explained. For a detailed description, see Chapter 4 “Operation” in these Instructions for Use.

The correct timing is important for successful treatment.
If distraction is too slow, the bone gap may be healed too early, making further distraction impossible.

Distraction at too fast a rate can cause damage to the blood vessels and nerves, and reduce bone regrowth so much that the gap created in the bone cannot subsequently be healed.

The doctordoctor will set the distraction rate for each patient, will help you understand how the rate is set and provide you with a log indicating the daily distraction rates. See Chapter 9 “Distraction Log” and Chapter 10 “Comments and Special Notes”.

To utilize the full functionality of the system, compliance with the handling instructions described below and the doctors directions is essential.

Your manufacturer,
WITTENSTEIN intens GmbH

1 Introduction

These Instructions for Use provide information about the FITBONE® System, particularly about the function and operation of the Control Set, consisting of the control electronics with power cable and the transmitter with coaxial cable.

These Instructions for Use were originally prepared in German; all other language versions are translations of those instructions.

Store these Instructions for Use together with the Control Set.

Please read through these Instructions for Use carefully before using the FITBONE® System for the first time so that you are familiar with the features of the intramedullary lengthening nail and Control Set and can make optimal use of their functions.

Make sure that you are trained with the operation of the Control Set during your hospitalization. Do not hesitate to ask your doctor for clarifications of unclear statements or other questions immediately.

You must follow the directions of your doctor.

Along with the Control Set, you will receive an Implant ID card. You should always carry with you.

The EC conformity declaration for your implant can be found on our homepage under Downloads (http://www.wittenstein-intens.de/fitbone/de/#wp_downloads).

1.1 Information symbols

The following information symbols are used:

- Indicates an action to be performed

➲ Indicates the result of an action

ⓘ Provides additional information on handling

1.2 Signal words and symbols

The following signal words are used to indicate possible hazards, prohibited actions, and important information:

	⚠ DANGER **This signal word indicates an imminent danger resulting in serious injury or even death.**
	⚠ WARNING **This signal word indicates a potentially imminent danger that may result in serious injury or even death.**
	⚠ CAUTION **This signal word indicates a possible danger that can result in minor to serious injury.**
	NOTICE **This signal word indicates a possible danger that can result in material damage.**
	A note without a signal word indicates usage tips or especially important information for using the Control Set.

The following safety symbols are used to indicate possible hazards, prohibited actions, and important information:

	
General danger	Electric voltage

2 System Description

2.1 Intended use / Indications for use

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

2.2 Contraindications

- Patients with any open wounds/areas with poor soft tissue coverage near the operative site
- Patients with an anatomic deformity that prevents 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, preventing secure implantation (vascular damage, cortical weakening)
- Patients with a body weight of over 100 kg
- Differences in leg length of less than 20 mm
- No free access for proximal insertion of the intramedullary lengthening nail (e.g. coxa valga)
- No reliable exclusion of bone infection
- Expected non-compliance, mentally ill patient or patient with clouded consciousness
- Pregnancy

2.3 Safety

<table>
<tr><td></td><td>⚠ WARNING

Risk from non-explantation of the intramedullary lengthening nail and receiver:
• The intramedullary lengthening nail and receiver must be explanted after consolidation is completed. The system is not designed for permanent implantation. Please agree upon the necessary explantation date with your doctor.</td></tr>
<tr><td></td><td>During the active phase and the initial healing phase, the weight-bearing capacity of the intramedullary lengthening nail is limited to partial weight bearing of 20 kg.
• Follow the directions of your doctor to be sure how 20 kg of weight bearing feels to you.</td></tr>
<tr><td></td><td>Unanticipated/undesired overstresses of the bone, particularly during the active distraction phase and the early healing phase, can damage the intramedullary lengthening nail.
• Always avoid full weight bearing, and also falling or stumbling.
• If this happens, make a note in the distraction log and inform your doctor immediately.</td></tr>
<tr><td></td><td>The following symptoms indicate health risks:
- Sudden onset of severe pain
- Sensory disturbances, numbness or other severe abnormal sensations
- Severe cooling of the leg
- Paleness or bluish discoloration of the skin
- Severe warming or redness of the leg
- Sudden onset of fever not attributable to another cause
• In these cases, contact your doctor where your intramedullary lengthening nail was implanted urgently (i.e. at any time of day or night.</td></tr>
</table>

<table>
<tr><td></td><td>⚠ CAUTION

Non-ionizing radiation is used for power and data transmission. Electromagnetic pulses can cause malfunctions.
• Please note that transmitting devices with transmitting frequencies below 500 kHz can cause an unintended lengthening of the intramedullary lengthening nail.
Keep away from potential sources of these electromagnetic fields like:
- Industrial energy transmission environments including productions plants and logistic centers. Look for posted warning signs for elevated levels of electromagnetic radiation
- Radio Masts / Towers for radio transmitted time code
• Observe the special safety measures concerning electromagnetic compatibility (EMC) outlined in the documents accompanying these instructions (see Chapter 11 “Electromagnetic Compatibility”).</td></tr>
</table>

	**⚠ CAUTION** **The distraction process should not be interrupted for more than 2 days, as there is a danger of premature bridging of the bone gap.**
	**Damage to the implanted system components** • If injections are necessary near the implanted device, inform your doctor so that no implanted system components (e.g. receiver) are damaged.

Leg lengthening will not be started during pregnancy. There have been no experiences to date regarding treatment using the FITBONE® during pregnancy. Based on current knowledge, no harmful effect is expected.

- If you become pregnant during a lengthening treatment, notify your doctor immediately.
- Please note that treatment of the leg cannot continue without X-ray examinations, which should also be avoided during pregnancy.
- From a medical perspective, it is therefore highly recommended that precautions be taken against becoming pregnant for the entire treatment of your leg.

2.3.1 In the following cases, the doctor decides about risks and benefits

All forms of electrical therapy in which current conducts through the patient's body must be avoided at the concerned limb, as must therapeutic ultrasound.

- If this cannot be avoided, the functioning of the intramedullary lengthening nail must be monitored careful to detect any resulting malfunctions in time.
- If medical treatment is necessary in which electrical current from an external source is conducted through the patient's body, switch off the control electronics, and carefully monitor the functioning of the device during distraction in the subsequent 4 – 5 days.

The manufacturer is not aware of any experiences involving reactions of the intramedullary lengthening nail due to high-energy ionizing radiation, with the exception of diagnostic X-rays. However, such treatments should always be omitted for the duration of the distraction phase.

- Discuss this with your doctor.

The expected leakage currents in the patient's body when using defibrillators can lead to impairment of the intramedullary lengthening nail. Such applications should therefore be avoided if possible.

- If such an application cannot be avoided, carefully monitor the functioning of the device during distraction in the subsequent 4 – 5 days.

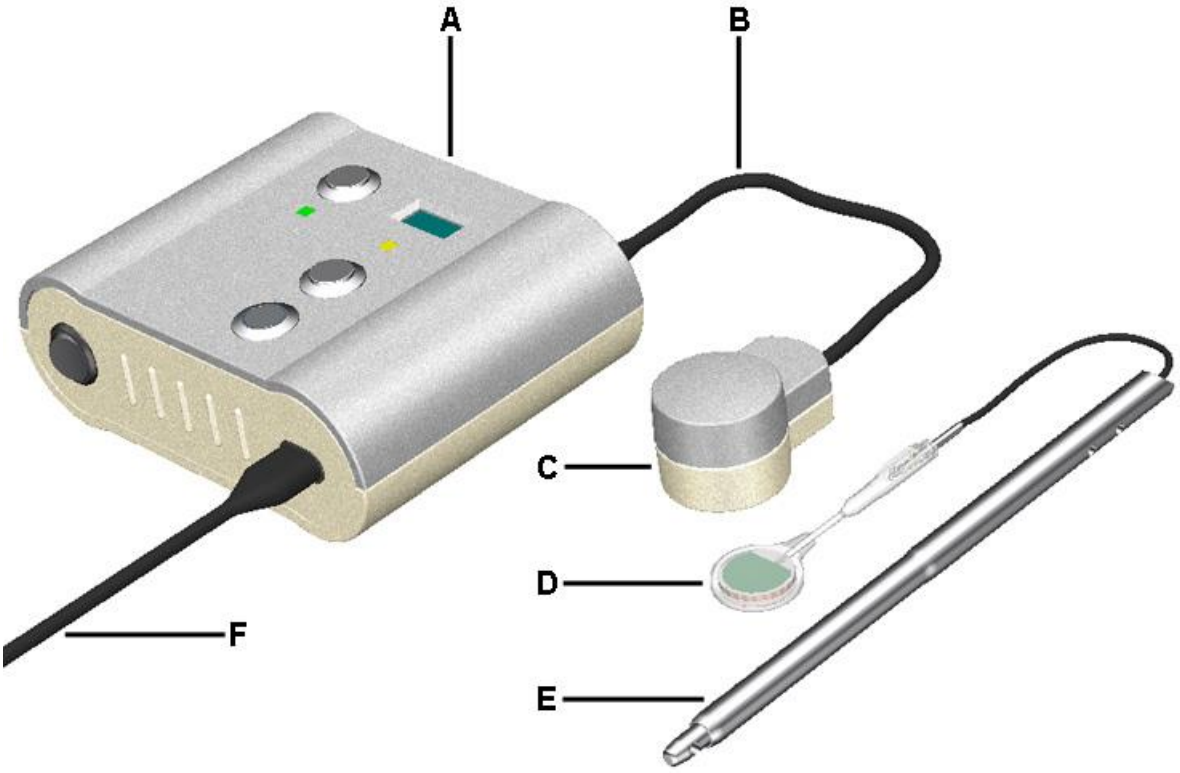
Finally, interaction between the Control Set and a pacemaker cannot be ruled out completely. However, as the emission range of the transmitter is very small, no negative effects are expected from the Control Set.

2.4 MRI Safety Information

	**⚠ WARNING** Unsafe in Magnetic Resonance Imaging Environments. The patient implanted with the FITBONE® should not enter the MRI unit. • The FITBONE® has not been evaluated for safety and compatibility in the MR environment. • The safety of FITBONE® in the MR environment is unknown.

2.5 System Overview

The FITBONE® System consists of the following implanted and non-implanted system components:



A Control electronics
B Coaxial cable
C Transmitter
D Receiver with coupling
E Intramedullary lengthening nail with bipolar feed line
F Power cable

Control electronics (A)

Transmitter (C) with coaxial cable (B)

Power cable (F)

} Non-implanted system components = Control Set

Intramedullary lengthening nail with bipolar feed line (E)

Receiver with coupling (D)

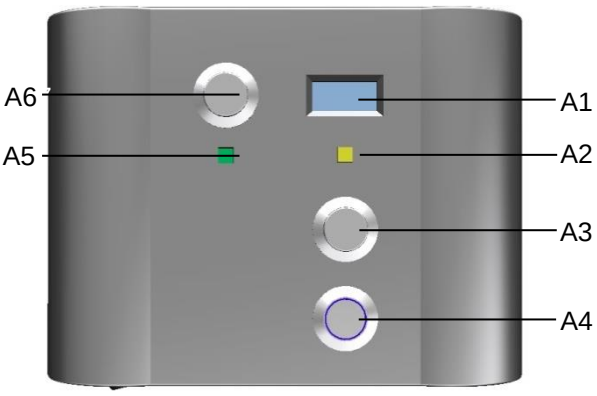
} Implanted system components

Every patient receives a stethoscope for acoustic distraction monitoring.
The handling instructions are provided during the in-patient stay in the clinic.

⚠ WARNING

The supplied system components comprise a treatment system and are not to be replaced or combined with other devices in any case without written approval by the manufacturer.

The **components** of the control electronics are shown in the figure below:



Front view

A1 Display
Shows the number of transmitted pulses.

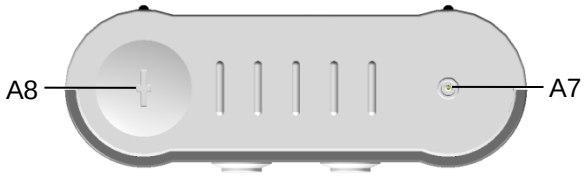
A2 Transmit LED
Indicates power transmission.

A3 Patient button
Starts power transmission.

A4 Doctor switch
Lights up blue when activated. It may be operated by the doctor only.

A5 Power LED
Indicates that the mains power is on.

A6 Reset button
For resetting the counter once the daily target has been reached or at the end of the lengthening.

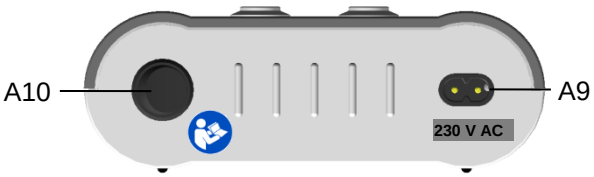


Top view

A7 Connection for the coaxial cable
The transmitter is plugged into this socket.

A8 Housing lid
The area under the housing lid is reserved exclusively for the doctor.

Any modification can lead to malfunctions and severe medical complications.



Bottom view

A9 Mains connection
The control electronics is connected to the main power supply using this connection.

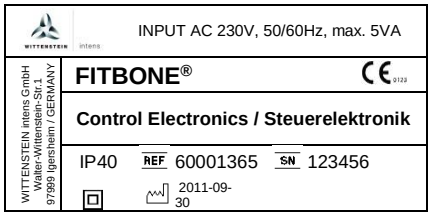
A10 On/Off switch
To switch the device on and off.
Switch position 0: The control electronics are switched off.
Switch position I: The control electronics are switched on.

The Instructions for Use must be followed.

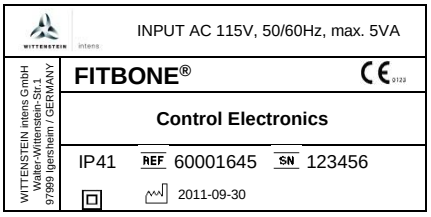
230 V AC Information about the voltage level of the mains supply (230 V AC or 115 V AC)

The identification plate can be found on the backside of the control electronics, which contains information on the device. The symbols on the identification plate (in compliance with ISO 15223-1) are explained below:

Control electronics for 230 V power supply (e.g. in Europe)

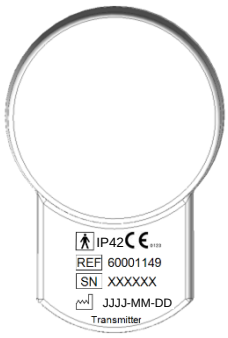


Control electronics for 115 V power supply (e.g. in the USA)

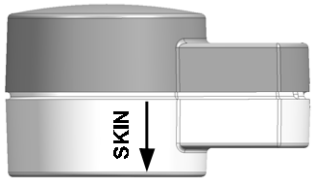


REF	Reference number or article code of control electronics
SN	Serial number (e.g. 123456)
	Production date (indicated as year / month / day, e.g. 2011-09-30)
	Protection class II device in compliance with EN 60601-1
IP 40	Protected against the intrusion of solid impurities greater than or equal to 1 mm diameter / not protected against the intrusion of water
IP 41	Protected against the intrusion of solid impurities greater than or equal to 1 mm diameter / protected against the intrusion of dripping water
CE 0123	CE mark

There are also labels on the transmitter with the following specifications in compliance with ISO 15223-1:

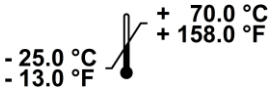






REF	Reference number or article code of transmitter
SN	Serial number
	Production date (indicated as year / month, e.g. 2011-09-30))
SKIN	Points to the surface that should be placed on the skin for power transmission for distraction
	Protection against electric shock Type BF applied part in compliance with EN 60601-1
CE 0123	CE mark

The symbol on backside of the FITBONE® Control Set packaging has the following specification in compliance with ISO 15223-1:



Temperature limitation:
Indicates the temperature limits (upper and lower limit) to which the medical device can be safely exposed.

Lower limit: -25.0 °C (-13.0 °F)
Upper limit: +70.0 °C (+158.0 °F)

3 Safety Relating to the FITBONE® Control Set

3.1 Using the FITBONE® Control Set

The Control Set may only be used in combination with the intramedullary lengthening nail according to the Instructions for Use for the FITBONE® Control Set.



⚠ CAUTION

The control electronics may only be connected to the main power supply that provide 230 V or 115 V specified on its identification plate. It has no internal voltage converter.

- If you are in a country with a different main power supply, you must use a converter.

A commercially available socket adapter is not adequate.

3.2 Contraindications

If the FITBONE® Control Set is used as intended, health risks arising from its use are excluded.



⚠ CAUTION

The following symptoms indicate a defect in the FITBONE® Control Set:

- **Externally visible damage to the device**
- **The control light does not flash as described even after several attempts**
- **No running noise can be heard during the distraction process**

- In such cases, it is sufficient to contact the hospital or the doctor **on the next day**.

3.3 General safety instructions

	**⚠ DANGER** **Electrical shock resulting from damage to the FITBONE® Control Set** • Only switch on the control electronics if the device and power cable are undamaged.
	**Lethal voltages inside the control electronics and transmitter** • Make sure that the housing on both devices always remains sealed and undamaged so that no internal part can be touched accidentally. • Do not remove the housing on the control electronics or the transmitter. • Only have the devices opened by specialists employed by the manufacturer. • Never submerge the control electronics or transmitter in water and do not use them outdoors. The principles of electrical safety apply here as with any other commercially available electrical device e.g. hair dryer, electric razor, etc.

	**⚠ WARNING** **Damage due to incorrect power supply** • Only connect the device to power sources that meet the electrical requirements on the identification plate. • Only use grounded sockets. • If you plan to travel abroad, please discuss this with your doctor. • Only use components (e.g. power supplies or cables) that have been also supplied by the manufacturer. • Combination with other devices as outlined in Chapter 2.5 “System Overview” is prohibited.
	**Deviations from the specifications endanger the treatment objective and can result in severe medical injury including loss of the leg.** • Ensure that distraction is performed carefully and correctly.

	**⚠ CAUTION** **Damage to the control electronics due to mechanical stress** • Avoid dropping the device or exposing the device to strong external forces, Store the FITBONE® Control Set in a safe place after every use. • If the control electronics fall on the ground, check the device for external damage. If you see any such damage, do not use the device again. Contact your doctor as soon as possible. The doctor will promptly organize a replacement. If no external damage is visible, check the functions during the next power transmission using the LED displays and the stethoscope: - The yellow control light must flash during power transmission. - When listening to the functioning of the intramedullary lengthening nail using the stethoscope, the running sound with which you are already familiar must be audible. • If one of these two functions is not detected, contact your doctor as soon as possible. The doctor will promptly organize a replacement.
	**Caution when using chemicals** • Do not use any chemicals on the FITBONE® Control Set these can damage the device. • If soiled, clean the device and accessories with a soft, lint-free cloth moistened with water.
	**Hazard due to missing Instructions for Use** • If the Instructions for Use are lost, request a replacement from your doctor.
	**Hazard if incorrectly stored** • The FITBONE® Control Set must not be placed directly beside or stacked with other electronic devices. If this is unavoidable, carefully monitor the functioning of the device during distraction in the subsequent 4 – 5 days.

	**⚠ CAUTION** **Damage to the FITBONE® Control Set due to extreme temperatures** • Protect the control electronics from extremely high (not above 70 °C) and low (not below -25 °C) temperatures. Avoid direct sunlight, extreme humidity (> 93 %), and e.g. overnight storage in a vehicle.
	**Damage to the FITBONE® Control Set due to ambient conditions** • Do not use the FITBONE® Control Set at an altitude of over 4000 meters above sea level. • Only use the FITBONE® Control Set in closed, dry rooms.
	**Operating duration** • The FITBONE® Control Set is not suitable for continuous operation. Please switch it off immediately after lengthening (see also Chapter 7.4).
	**Combination with other devices** • The FITBONE® Control Set must not be used together with devices that are not described as accessories in these Instructions for Use.

	NOTICE **Disposal** In the interest of environmental protection, the device must be disposed of properly by the manufacturer. Please return the device to your doctor after your treatment is complete.

4 Operation

4.1 Leg lengthening time sequence

The leg lengthening time sequence is as follows:

Surgical consultation:
About 6 weeks before the planned surgery date

Hospitalization (about 10 days):
Surgery the day after admission. Duration of surgery 3 – 8 hours. In the days after surgery, physiotherapy and mobilization on walking aids.
Distraction begins around 5 days after surgery.

Distraction phase (0.5 – 1 mm per day):
Check-ups in the clinic every 1 – 2 weeks. Partial weight-bearing of 20 kg, physiotherapy near home 3x per week.

Consolidation phase (2 – 3 days per mm extension):
Check-ups in the clinic every 1 – 2 weeks. Partial weight-bearing of 20 kg, physiotherapy near home 1 – 3x per week.

Full weight-bearing (about 6 – 12 months):
Check-ups in the clinic every 6 – 12 weeks, ability to take part in “low-impact” types of sport.

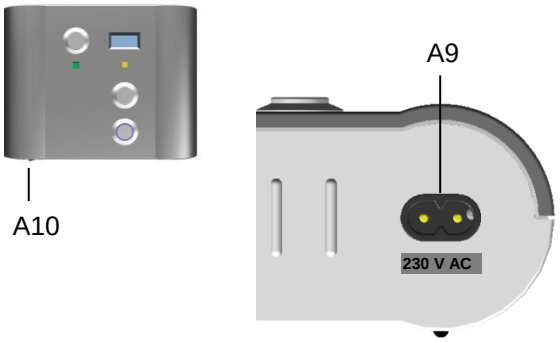
Hospitalization (about 3 days):
Removal of the implant about 1–1½ years after implantation, full weight-bearing on discharge.

Final examination:
About ½ year after removing the implant; afterwards full weight-bearing, including “high-impact” types of sport.

Source: ZEM: Beinverlängerungszentrum München (Limb Lengthening Center Munich), Prof. Dr. Dr. med. Rainer Baumgart

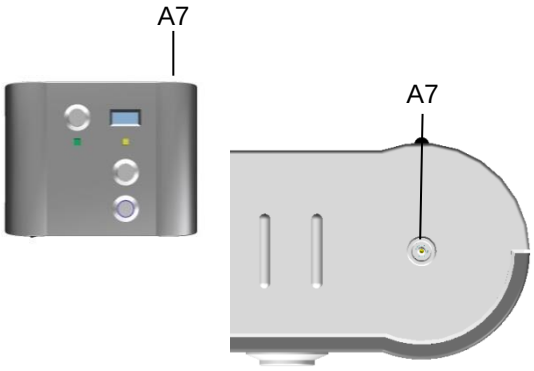
4.2 Preparation for distraction

The doctor will show you how to operate the FITBONE® Control Set during your hospitalization. Hence, you as the patient are the operator of the FITBONE® Control Set.
Notes and instructions can be written in Chapter 10 “Comments and Special Notes” for your reference after leaving the hospital.
The preparation for distraction always follows a set sequence.

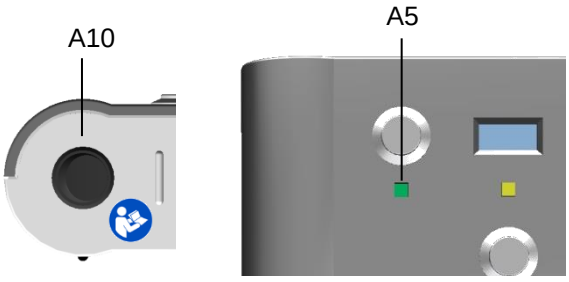


- Use the supplied power cable to connect the control electronics to the socket for the power cable (A9), and connect it to the main power supply.
  Make sure that you connect it to the correct mains voltage.

ⓘ If you plan to travel abroad, please discuss this with your doctor.



- Connect the transmitter's coaxial cable to the control electronics using the socket for the coaxial cable (A7).



- Switch on the control electronics using the on/off switch (A10) (see figure on left).

➲ The green LED indicator (A5) (see figure on right) indicates that the mains power is on.

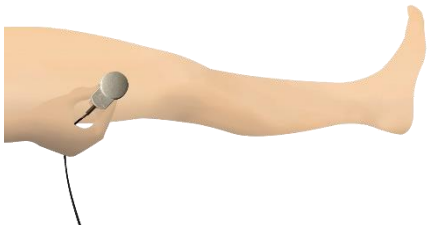
4.3 Performing the distraction

The diagram sequence below outlines the operation of the control electronics.

	• **When applying the transmitter, make sure to position your leg as indicated by your doctor.**

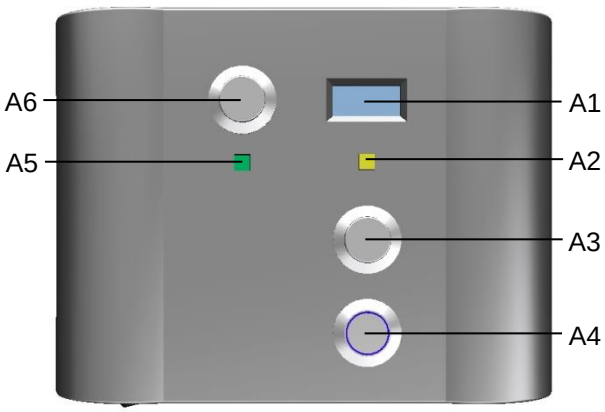
- Feel for the position of the receiver, which is located under your skin.
- With the white side on the skin, apply the transmitter at the position of the receiver.

ⓘ For thighbone (femur) lengthening, the transmitter must be applied to the thigh.



ⓘ Similarly, for a shinbone (tibia) extension the transmitter must be applied to the shin.





- Initiate power transmission by pressing the “Patient” button (A3) once.

➲ If correctly positioned, the yellow “Transmit” LED (A2) flashes 5 times within 1 second. This process repeats every 9 seconds and indicates that energy is being transmitted.

➲ At the same time, a brief running noise can be heard through the stethoscope placed on the leg next to the transmitter.

ⓘ The process ends after 9 flashing sequences (equal to 9 pulses), i.e. a total of 90 seconds.

After every power transmission, 9 more pulses should appear on the display (A1) than at the start of each distraction process.

ⓘ This display can be reset to “0” using the Reset button (A6).

Your doctor will specify in the distraction log when and how often you should initiate this type of cycle with 9 pulses.



⚠ CAUTION

If the yellow transmit LED does not flash or if no running noise can be heard during the individual transmission processes, read Chapter 5 “Operating Faults”.

- The distraction process should not be interrupted for more than 2 days as there is a danger of the new bone regenerate being bridged, which endangers the further course of the treatment, unless the doctor recommends otherwise.

- Once the distraction has been completed, switch off the control electronics (A10) and disconnect the power cable.

If necessary, the transmitter can be disconnected from the control electronics and the entire FITBONE® Control Set placed into the packaging.

- To detach the transmitter, grip the cable's metal connector on the transmitter.

Outpatient, standardized sonography, and X-ray examinations with superimposition of the distraction path document the correct course of distraction at defined time intervals.

4.3.1 Too few pulses transmitted

If too few pulses are transmitted during a distraction, an additional distraction must be attempted to apply the missing pulses.

- To do this, start a new distraction as described in Chapter 4.3 “Performing the distraction“.
- Apply the missing pulses, then stop transmission once the number of pulses (generally 9 pulses) specified by your doctor has been transmitted.
- To end power transmission, lift the transmitter off your leg and switch the device off as described in Chapter 4.3 ”Performing the distraction”.

4.4 Maintaining the distraction log

	Maintaining the distraction log helps to monitor and document the progress of treatment.

- If the number of the pulses monitored acoustically with the stethoscope does not match the specifications of your doctor, please note this under Anomalies in Chapter 9 “Distraction Log”.

4.5 Returning the FITBONE® Control Set

- Once the active distraction phase has ended, the FITBONE® Control Set must be returned to your doctor. **No** component of the FITBONE® Control Set may be disposed of. These components are the property of the manufacturer and are only provided on loan.

The manufacturer would be grateful if you could also return the Instructions for Use with your comments after completing the treatment. The manufacturer is also interested in receiving further information as suggestions for improvements.

5 Operating Faults

Malfunction	Possible cause	Action
The device cannot be switched on. Power LED (green) does not light up.	Not connected to main power supply, power cable not plugged in	Mains voltage is insufficient; check connection to main power supply, plug into another power socket if necessary
	Defective power cable	Contact the doctor
The Transmit LED (yellow) does not flash, the counter does not count, and no motor sound is audible.	Not connected to main power supply, power cable not plugged in	Plug in power cable
	Control electronics not switched on.	Switch on control electronics
	The Doctor switch was pressed instead of the Patient button (now lit blue)	Release the Doctor switch by pressing it again, and then repeat distraction as described in Chapter 4.3.
Transmit LED (yellow) does not flash during power transmission, but remains lit for one second. The display does not count pulses. Motor sound may be audible.	Coaxial cable of the transmitter not connected to control electronics.	Check plug connection
	Distance range of 8–12 mm needed between transmitter and receiver for correct power transmission is exceeded	Change position of transmitter, reduce distance to receiver (e.g. by pressing on the transmitter) or reposition the transmitter
	Coaxial cable of the transmitter is defective	Contact your doctor
Running noise of the motor during the distraction cannot be heard through the stethoscope.	Distance too great between transmitter and receiver	Reduce distance to receiver (e.g. by pressing on the transmitter) or reposition transmitter
	Incorrect positioning of the stethoscope	Change position of stethoscope
	Intramedullary lengthening nail temporarily overloaded	Check position of transmitter and keep trying until distraction starts again
	Wrong mains voltage	Check that you are supplying your device with the correct mains voltage (the required mains voltage is shown on the identification plate and on the label next to the socket).
	System failure	Contact your doctor
LCD display continuously counts incorrectly.	LCD display defective	Contact your doctor
	Transmission rate not correct	Reposition transmitter
Too few pulses during a distraction process	Incorrect positioning of transmitter	See Chapter 4.3.1 “Too few pulses transmitted”.
	The plug is pulled out or off switch pressed during the procedure	

As a possible malfunction is not an emergency, it is sufficient to inform your doctor the next day. The doctor will promptly organize a replacement. In the meantime, you should continue attempting to transmit power.

If you are unsure whether the extension was carried out correctly, please also contact your doctor the following day.

ⓘ The intramedullary lengthening nail is designed not to perform distraction if the load is too high in order to avoid damaging the system. It may also be that a regular distraction process is suddenly possible again after several unsuccessful attempts to transmit power. Physiotherapeutic exercises benefit the distraction process. The instructions of your doctor should be followed in relation to these exercises.

In the event of defects or malfunctions, switch off the FITBONE® Control Set and contact your doctor. Do not attempt to repair it yourself, only the manufacturer is able to make repairs. Failure to follow these instructions may render the device unsafe.
If you have problems starting the FITBONE® Control Set or need help doing this, please contact your doctor.

6 Care Instructions

6.1 Technical safety checks and maintenance

Repair and maintenance of the FITBONE® Control Set may only be carried out by specialists employed by the manufacturer. These maintenance tasks are performed after each treatment is completed.

If modifications and repairs are made to the devices by unauthorized persons, the warranty and liability of the manufacturer are voided. In addition, there is a possible risk of electric shock from tampering with the FITBONE® Control Set, see chapter 3.3 “General safety instructions”.

6.2 Care and cleaning

Clean the FITBONE® Control Set occasionally, or immediately if it becomes soiled.



⚠ CAUTION

Before each cleaning, the device must be switched off and disconnected from main power supply.

Use a moistened cloth to clean the device, and clean it by hand.
Do not use any cleaning agents



⚠ CAUTION

Make sure that no water penetrates the device.
The device must not be touched with wet hands when it is connected; ensure that no water splashes onto the device. The device may only be operated when fully dry.

7 Technical Specifications

7.1 Technical specifications for the control electronics of the 230 VAC FITBONE® Control Set

Mains voltage 230 VAC + 10 % / - 15 %, 50/60 Hz (power input from main power supply max. 5 VA) see identification plate.

Mains plug 2-pin in compliance with DIN 49464/VDE, with 1.8-meter power cable 2 x 0.75 in compliance with CEE/VDE.

RF transmission power, output max. 1.5 watt (magnetic field)
Frequency 75 – 90 kHz, load-dependent, physically determined.

Dimensions of transmitter ∅ 45 mm x height 36 mm x length 63 mm
Weight of transmitter about 120 grams.

Control electronics and transmitter are in protection class II construction, i.e. in protective insulated design.

The internal electrical transformer is a safety transformer also in protection class II in compliance with VDE 0551/EN 60742/IEC 742.

7.2 Technical specifications of the control electronics of the 115 VAC FITBONE® Control Set

Mains voltage 115 VAC + 10 % / - 15 %, 50/60 Hz (power input from main power supply max. 5 VA); see identification plate.

Mains plug 2-pin in compliance with UL/CSA NEMA 1-15 P type 201, with 1.8 meter power cable 2x18 AWG T.

RF transmission power, output max. 1.5 watt (magnetic field)
Frequency 75-90 kHz, load-dependent, physically determined.

Dimensions of transmitter 45 mm diameter x height 36 mm x length 63 mm
Weight of transmitter about 120 grams.

Control electronics and transmitter are in protection class II construction, i.e. in protective insulated design.

The internal electrical transformer is a safety transformer also in protection class II in compliance with VDE 0570/IEC 61558-2-6/ENEC10 (VDE), UL 5085-1/-2/CSA22.2 no. 66.

7.3 Environmental conditions

Environmental conditions during operation	+5 °C to +40 °C, between 15 % and 93 % relative humidity, non-condensing
Environmental conditions during transport and storage between treatments	-25 °C to +70 °C, max. 93 % relative humidity, non-condensing



⚠ CAUTION

In continuous operation doctor mode, the transmitter can reach a maximum temperature of 47.2 °C.

7.4 Operating duration

	Duration
Operation in patient mode	3 minutes max.
Operation in doctor mode	5 minutes max.

Service life of the FITBONE® Control Set: 160 days.

8 Implant ID

During your hospitalization, you will receive an Implant ID containing the identification data of the implanted system components and other important information.

- Please carry this A7-format document with you at all times to permit identification of the intramedullary lengthening nail whenever necessary, e.g. at airport security checks.



9 Distraction Log

9.1 Description

You can use the distraction log to record comments, e.g. indication errors by the control lights, absent running noise or pain.

- Please make sure to provide this information so that the doctor can use it to optimize the treatment process.

	NOTICE
	Maintaining the distraction log helps to monitor and document the progress of treatment. **The instructions of the doctor must be followed.**

FITBONE®
Distraction Log

Patient (name, date of birth): _____

Diagnosis: _____

Date of surgery: _____

_____

Distraction target: _____ mm

Example of a distraction log

This value is entered only by the doctor at X-ray examinations

Month: *January*								
Date	**1**	**2**	**3**	**4**	**5**	**ΔL total mm**	**Pain status***	**Anomalies**
1	*9*	*9*	*9*				*0*	
2	*7*	*8*	*7*				*2*	*Slight pulling in the leg*
3	*6*	*6*	*6*	*6*			*0*	

*Pain on an imaginary scale from 0 (no pain) to 10 (strongest pain)

The number of the pulses to be transmitted (= TARGET) are entered here.
TARGET is specified by the doctor.

Any deviation noticed should be recorded in the Anomalies / Pain status columns.
If necessary, the data from the interim examinations by the doctor can be logged here also.

9.2 Form

Month 1

Month _____								
Date	**1**	**2**	**3**	**4**	**5**	**ΔL total mm**	**Pain status***	**Anomalies**
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
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16								
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24								
25								
26								
27								
28								
29								
30								
31								

*Pain on an imaginary scale from 0 (no pain) to 10 (strongest pain)

Month 2

Month _____								
Date	**1**	**2**	**3**	**4**	**5**	**ΔL total mm**	**Pain status***	**Anomalies**
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
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24								
25								
26								
27								
28								
29								
30								
31								

*Pain on an imaginary scale from 0 (no pain) to 10 (strongest pain)

Month 3

Month _____								
Date	**1**	**2**	**3**	**4**	**5**	**ΔL total mm**	**Pain status***	**Anomalies**
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
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31								

*Pain on an imaginary scale from 0 (no pain) to 10 (strongest pain)

10 Comments and Special Notes

11 Electromagnetic Compatibility

Guidance and manufacturer´s declaration – electromagnetic emission

The FITBONE® System is intended for use in the electromagnetic environment specified below. The customer or the user of the FITBONE® System should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The FITBONE® System uses RF power only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The FITBONE® System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The FITBONE® System is intended for use in the electromagnetic environment specified below. The customer or the user of the FITBONE® System should assure that it is used in such an environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and fluctuations in the supply voltage IEC 61000-4-11	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	< 5 % U_T (> 95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (> 95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FITBONE® System requires continued operation during power mains interruptions, it is advisable to power the FITBONE® System using an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	10 A/m	Magnetic fields at the mains power frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidelines and manufacturer's declaration – electromagnetic immunity

The FITBONE® System is intended for use in the electromagnetic environment specified below. The user of the FITBONE® System should ensure that it is used in such an environment.

Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	Portable and mobile radio communications equipment should be used no closer to any part of the FITBONE® System, including cables, than the recommended separation distance calculated from the equation applicable to the transmission frequency. **Recommended separation distance** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz $d = 2.34\sqrt{P}$ 800 MHz to 2.5 GHz where *p* is the rated output of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). The field strength of stationary radio transmitters, as determined by an on-site survey,[a] should be below the compliance level for all frequencies.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for mobile/cordless telephones and terrestrial radio equipment, amateur radio stations, AM and FM radio transmitters and TV transmitters cannot be predicted with accuracy in theory. To assess the electromagnetic environment due to fixed transmitters, a site survey should be considered. If the measured field strength at the location where the FITBONE® System is used exceeds the applicable compliance level above, the FITBONE® system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the FITBONE® System.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidelines and manufacturer's declaration – electromagnetic immunity

Recommended separation distances between portable and mobile RF communications equipment and the FITBONE® System.

The FITBONE® System is intended for use in an electromagnetic environment in which the RF disturbance variables are controlled. The user of the FITBONE® System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FITBONE® System as indicated below, according to the output power of the communications equipment.

Rated output of transmitter W	**Separation distance *d* according to transmission frequency [m]**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.34\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.34
10	3.7	3.7	7.4
100	11.7	11.7	23.4

For transmitters with a maximum rated output that is not listed in the table above, the recommended separation distance d in metres (m) can be estimated using the equation from the relevant column, where P is the maximum rated output of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 For 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Please contact the manufacturer at the following address with any technical queries:

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