

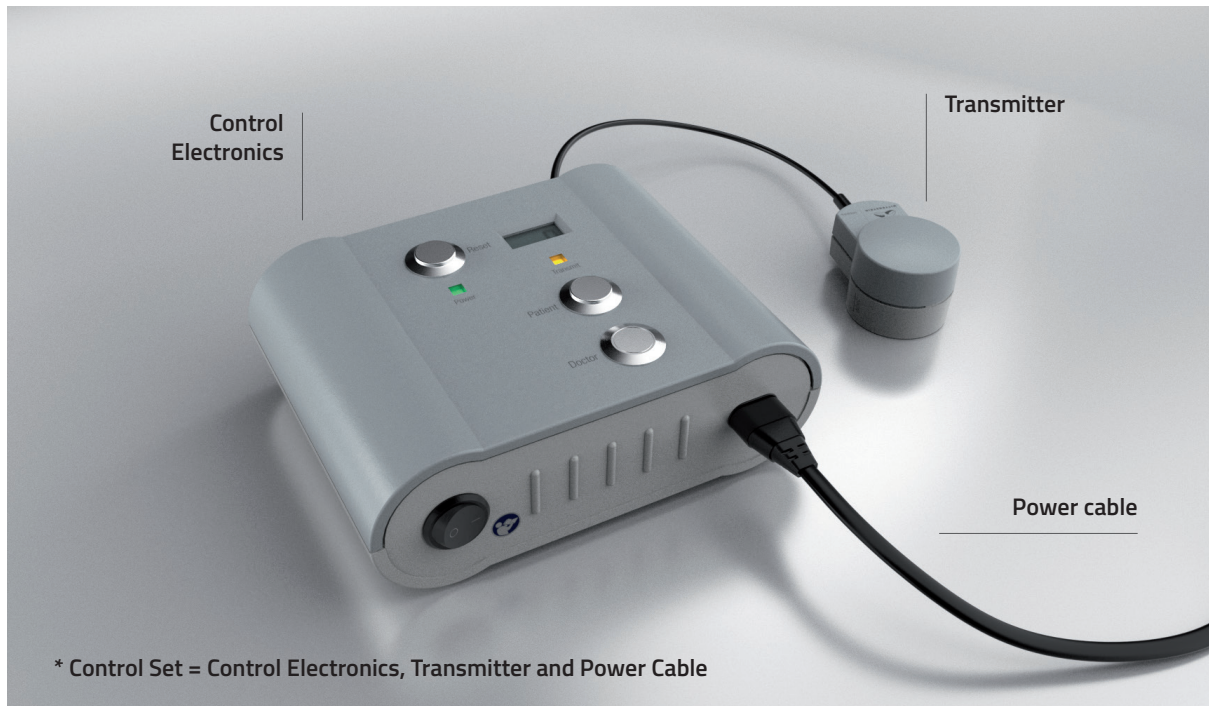
QUICK GUIDE FOR PATIENTS

Fitbone™

Intramedullary Lengthening System



Control Set* components



Instructions for lengthening



▶ Open the Control Set box.



▶ Take out the Control Electronics.



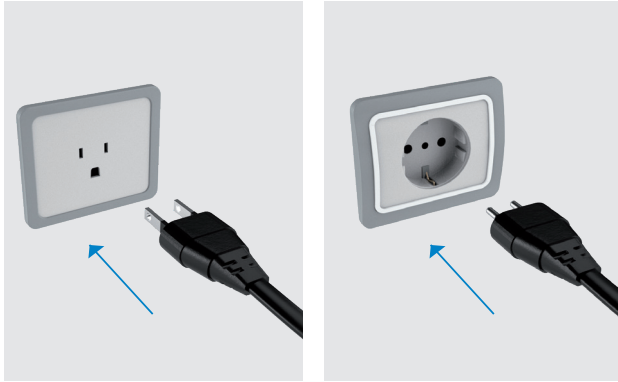
▶ Take out the power cable.



▶ Take out the transmitter.



▶ Connect the power cable to the Control Electronics.



▶ Plug in the power cable.



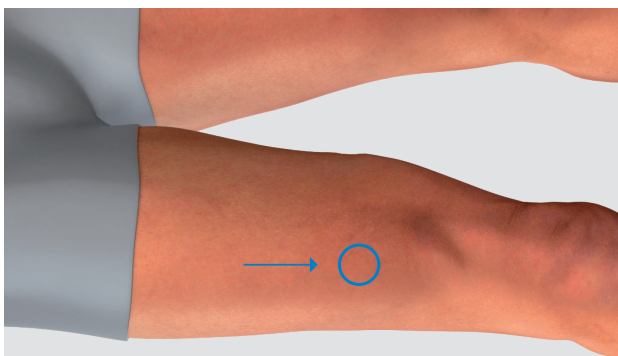
▶ Plug the Transmitter into the Control Electronics.



▶ Turn on the Control Electronics.



▶ Place the stethoscope earbuds in the ears.



▶ Locate the receiver under your skin.
▶ The receiver will be located under the skin, on the outside (lateral) part of the treated section of the leg (femur or tibia).



▶ Find the marking "SKIN" on the transmitter indicating the side to be in contact with skin.



▶ Place the Transmitter at the position of the Receiver, with the white side on your skin.
▶ Place the stethoscope on your knee cap (patella) to hear the motor.



▶ Initiate energy transmission by pressing the "Patient" button once.



If placement is correct, the yellow "Transmit" LED will flash 5 times within one second. You'll also see the counting on the display.

▶ This process is repeated every 9 seconds without any need to press the "Patient" button again and indicates to you that energy is being transmitted to the receiver.

You should hear the motor working through the stethoscope. If you cannot hear it, try repositioning the stethoscope.



The process ends after 9 flashing sequences or a total of 90 seconds. You will see the 9 impulses shown at the display. Make sure that you also hear the 9 impulses being transmitted to the motor.

▶ Nine impulses should be shown on the display at the end of each distraction process. If an insufficient number of impulses is transmitted during a distraction, you must try to perform an additional distraction in order to compensate for the missing impulses.

Perform the remaining missing impulses and end the transmission when the number of impulses specified by your treating physician (generally 9 impulses) has been reached.



By pressing the reset button, the counter will return to 0 (zero).

- ▶ You can reset every 9 impulses or after you finish the number of impulses, according to the instructions of your treating physician.
- 27 impulses is equivalent to 1mm.



- ▶ Turn off the Control Electronics and disconnect the cables.



Avoid pulling on the cable of the Transmitter.



Protect the Transmitter's cable from harm.

If you have any questions or concerns, please refer to your treating physician.

Troubleshooting

Malfunction	Possible cause	Actions
The device cannot be switched on. Power LED (green) does not light up	No connection to the mains power supply, power cable not plugged in	Insufficient main voltage: check connection to the mains power supply, connect to a different socket if necessary
	Power cable defective	Contact your treating physician
Transmit LED (yellow) does not flash, counter does not respond and no motor noise is audible	No connection to the mains power supply, power cable not plugged in	Plug in the power cable
	Control electronics not switched on	Switch on the control electronics
	The Doctor switch has been operated instead of the Patient button (now lights up blue)	Release the Doctor switch by operating it again and repeat distraction in accordance with section 4.3 "Performance of distraction" in Instructions for Use Fitbone™ Control Set
Transmit LED (yellow) does not flash during energy transmission, but lights up continuously for one second. No transmission impulse is counted on the display. The motor noise may be audible	Coaxial cable of the Transmitter not connected to the Control Electronics	Check the plug connection
	Distance range of 8 to 12mm between Transmitter and Receiver, which is required for correct energy transmission, has been exceeded	Change the Transmitter position or reduce the distance to the Receiver (for example by pressing the Transmitter button) or reposition the Transmitter
	Transmitter coaxial cable faulty	Contact your treating physician
No motor running noise audible via the Stethoscope during distraction	Excessive distance between the Transmitter and Receiver	Reduce the distance to the Receiver (for example by pressing on the Transmitter) or reposition the Transmitter
	Incorrect positioning of the Stethoscope	Change the position of the Stethoscope
	Intramedullary lengthening nail temporarily overloaded	Check the position of the Transmitter and keep trying until distraction takes place
	Incorrect voltage supply	Check whether you are supplying your device with the correct mains voltage (required mains voltage is indicated on the type plate and on the label next to the socket)
	System failure	Contact your treating physician
LCD display constantly fails to count correctly	LCD display faulty	Contact your treating physician
	Incorrect transmission rate	Reposition the Transmitter
Insufficient number of impulses during a distraction procedure	Incorrect positioning of the Transmitter	Please refer to section "Insufficient impulses transmitted" underneath
	Plug is disconnected during the procedure or OFF button is pressed	

Insufficient impulses transmitted

If an insufficient number of impulses is transmitted during a distraction, you must try to perform an additional distraction in order to compensate for the missing impulses.

- For this purpose, start a new distraction as described in section "Instructions for distraction" above.
- Perform the remaining missing impulses and end the transmission when the number of impulses specified by your treating physician (generally 9 impulses) has been reached.
- To end the energy transmission, raise the Transmitter from your leg and switch off the device as described in the section "Instructions for lengthening".

Because a potential malfunction does not constitute an emergency, it is sufficient if you inform your treating physician the following day. He or she will promptly ensure a replacement. In the meantime, you should continue trying to transmit energy. If you are uncertain whether the lengthening procedure has been performed correctly, you should also contact your physician the following day.

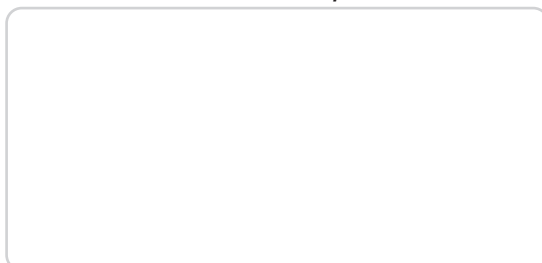
To prevent damage to the system, the intramedullary lengthening nail is designed not to perform distraction under excessive loads. It is therefore entirely possible that following several unsuccessful attempts to transmit energy, a regular distraction procedure can suddenly again be performed. Physiotherapy exercises benefit the distraction process. Please observe the instructions of your treating physician.

In the event of faults or malfunctions, switch off the Fitbone™ Control Set. Do not perform any interventions yourself and only have repairs carried out by the manufacturer. Non-observance of the above instructions may jeopardize the safety of the device. Should you have any problems during initial operation of the Fitbone™ Control Set or require assistance in this regard, please contact your treating physician.

**For a full list of warnings and further information, please refer to
the Instructions for Use Fitbone™ Control Set.**

Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the "Instructions for Use" supplied with the product for specific information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

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