

Intramedullary distraction nail FITBONE® ready for Medicine 4.0

Smarter Limb Lengthening



Intelligent electronic systems which allow the execution and personalization of medical treatments and therapies are among of the visions that term Medicine 4.0. Igersheim-based enterprise WITTENSTEIN intens incorporates Medicine 4.0 attributes in its fully implantable mechatronic intramedullary distraction nail FITBONE® and - with its digitally controlled drive technology and smart FITBONE® patient app for mobile end devices - moves mainstream as a supplier of innovative E-Health Technology.

FITBONE® pools drive technology, medicine, electronics and digitalization in one innovative mechatronic implant which executes, monitors and documents extremity corrections of the femur and tibia. The success of the intramedullary distraction nail is based on the superior safety of both product and treatment, and on the ease of use of the intelligent implant system allowing activation and control directly by the patient.

FITBONE® – short hospitalization period, hardly any restrictions in daily life, very good cosmetic results

The fully intramedullary distraction nail FITBONE® is a unique, mechatronic system for the compensation of leg length differences and correction of defective positions. The intramedullary distraction nail is implanted in the medullary cavity of the bone in minimally invasive surgery. A small and light-weight control set communicating with the intramedullary nail allows the patient to directly activate distraction. For this purpose, an external transmitter head is placed on the skin and transmits energy to the receiver implanted subcutaneously as soon as the patient initiates a distraction sequence. Thanks to the simplicity of the small, noiseless and portable control set as well as to the short lengthening period, the distractions can be easily carried during office breaks or even at school. The technology employed offers optimum patient comfort, minimizes pain, prevents infect risks and - from the cosmetic point of view - achieves perfect results. The in-patient periods and subsequent therapies are brief, and so are the mobility restrictions in daily life and the absence times from school, university and job.

The intramedullary distraction nail is implanted exclusively by trained surgeons who learn the particulars of the intramedullary distraction nail and its implantation

technique in special FITBONE® workshops. This method ensures optimum and holistic care and support from the first contact and medical examinations to the explanation of the intramedullary distraction nail at the end of the treatment period. The FITBONE® centers established worldwide have already carried out thousands of successful FITBONE® treatments.

Award-winning electronics control the distraction process

The intramedullary distraction nail is now used together with a newly developed assembly for wireless energy transmission whose 3D design was ranked one of the best in the 3D/Bauraum category in the Design Award 2016 event organized by the FED Fachverband Elektronik Design e. V. This so-called receiver is placed in the subcutaneous fat tissue directly under the skin and so ensures the inductive energy transfer independently of the patient's soft tissue conditions. The contactless energy transfer between transmitter head and implant receiver uses electromagnetic fields for the provision of electric energy to the intramedullary distraction nail.

Special medical requirements on the mechatronic drive system

The FITBONE® is equipped with a miniaturized high-performance drive whose rotary motion is transformed into the linear movement required for the distraction process. By virtue of its special field of application, the material the FITBONE® is made of is strictly bio-compatible and sets high standards on cleanliness and sterility of the implantable system components. The energy consumption during energy transfer between transmitter and receiver for distraction activation - 90 seconds each morning, noon and evening - is limited to just a few watts. The patient does not notice or feel the energy transfer at all. The daily distraction distance of typically 1 mm a day is prescribed by the physician and communicated to the patient for operation of the external FITBONE® control set. The triple feedback feature (two visual and one acoustic signal) the FITBONE® offers ensures gapless distraction monitoring. The patient can be sure that lengthening takes place as scheduled. The functionality of this type of implant is absolutely unique and makes the distraction process considerably safer and more controllable. After complete bone consolidation - typically around





one to one and a half years after implantation - both FITBONE® intramedullary distraction nail and receiver must be explanted. The FITBONE® has been approved for one-time use and is correctly disposed of afterwards.

Ease of use and documentation of treatment via app

Entirely in line with Medicine 4.0 and in the true sense of an innovative E-Health component, the new FITBONE® app allows digital attendance and monitoring of the treatment process. It also offers a variety of additional functions, for example the gapless documentation of the treatment.

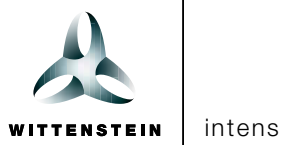
The FITBONE® app for smart phones which can be downloaded free of charge from Google Play Store allows individualized attendance of the treatment and provides the patient with a multitude of helpful functions. The reminder function, for example, can be programmed to call the patient's attention to the scheduled distractions. Appointments, times and distraction sequences can be selected and altered as required and fitting the patient's daily routine. With the snooze function, a distraction sequence can be postponed to a later point in time. The treatment process is displayed graphically and informs the patient on the treatment progress. Besides information material and short video clips, the app provides additional help such as the control set user instructions. As daily companion, the FITBONE® app supports the patient throughout the entire distraction process. The intuitive app surface is suitable for all patients.

While the patient enjoys the FITBONE® app advantages, the entire treatment is automatically documented in the background. All data regarding times, duration, distraction sequences and frequency of distraction as well as treatment-accompanying information are recorded and can be transmitted online via export function to the physician in charge.

FITBONE®: fit for more

In the meantime, the FITBONE® technology has been adapted successfully to allow further indications for extremity corrections. The intramedullary distraction nail now comes in several variants for bone segment transport or stump lengthening after amputation, or for use with growth prostheses after tumor resection. In stump lengthening, for example, this medical measure is necessary when the remaining bone stump is too short to attach a prosthesis in a secure and safe manner. In addition, the FITBONE® technology platform is perfectly suited for future medical applications. Miniaturized designs and the digitalized, personalized treatment of patients are futuristic trends in the Medicine 4.0 era and the enhanced understanding of E-Health. New applications, comprehensive Personal Health Monitoring as well as cross-system global availability of information relevant to treatment require intelligent medical product concepts which make use of the possibilities and advantages of electronics, digitalization and Internet technology - for example for the bi-directional communication between implant and control set, for new monitoring functions or as interfaces to other medical engineering or IT systems. The success depends on how far we are able to improve the patient's well-being and support the organization of healthcare. In any case, the FITBONE® technology and its smart medical mechatronics are standing by and ready for Medicine 4.0.

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