



## **WITTENSTEIN intens GmbH:**

### **Upgraded CE mark and new receiver function for FITBONE®**

**On October 11, 2019, five more FITBONE® TAA intramedullary lengthening nails from WITTENSTEIN intens GmbH received the European CE mark. This is further official confirmation of the high product safety and technological performance achieved by the medical device manufacturer's fully implantable limb lengthening nail. The CE mark will also be granted for the innovative, completely redesigned and award winning FITBONE® Receiver with enhanced functionality.**

The upgraded certification means that in the future seven FITBONE® nails in the TAA series will bear the CE mark. This symbol is a mandatory marking for medical devices and a declaration of compliance with numerous legal and standard requirements, which are verified by a notified body in the framework of a conformity assessment procedure. As Roman Stauch, Managing Director of WITTENSTEIN intens GmbH, explains, the very comprehensive safety measures in place for the FITBONE® System were an important aspect for TÜV Süd Product Service GmbH of Munich, the certification body responsible: "The CE marking requirements were met in every respect and without exception. Under the European Economic Community's Active Implantable Medical Devices Directive, therefore, FITBONE® has various warranted characteristics with benefits for patients and attending physicians alike: among other things, the intramedullary lengthening nail is guaranteed to be biocompatible and the risk of infection reduced to a minimum. We also commit ourselves to keeping a close watch on our manufacturing processes – throughout the entire product lifecycle."

The upgraded certification applies to the following FITBONE® nails: TAA1140-F-205, TAA1180-F-245, TAA1380-F-245 (for femur) and TAA1140-T-205 and TAA1160-T-225 (for tibia).

October 11, 2019

WITTENSTEIN develops customized products, systems and solutions for highly dynamic motion, maximum-precise positioning and smart networking for mechatronic drive technology.



The FITBONE® System consists of an intramedullary lengthening nail, a receiver and an external control set.

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## **New receiver function improves safety during the leg lengthening process**

The completely redesigned receiver, which is now about 45 percent smaller in size, is another innovative feature of FITBONE®, the intramedullary lengthening system. The receiver has simultaneously been enhanced with a retraction function, which lets the attending physician reverse any actions inadvertently carried out by the patient. For example, if the lengthening nail is accidentally extended too far, the physician can in future retract it again if necessary.

## **Maximum comfort during leg lengthening**

FITBONE®, the smart intramedullary lengthening nail, is a unique mechatronic system for compensating leg length discrepancies. It can simultaneously be used to correct deformities of the femur and tibia. FITBONE® is implanted in the bone in a minimally invasive surgical procedure while the receiver is placed directly beneath the skin. Patients can control the distraction process themselves three times a day using the external FITBONE® Control Set. The visual and audible impulses for monitoring the implant system deserve particular mention here because they help patients perform the distraction safely, independently and in a controlled way.

Thanks to the FITBONE® app and full treatment documentation, the lengthening process can be constantly monitored. Both the procedure itself and its performance at the programmed times can be recorded by the patient in this way. The FITBONE® app also provides patients with other valuable information. This enhanced functionality – unprecedented with implants of this kind – makes the leg lengthening process much safer and easier to control.

Texts and photographs in printable quality can be downloaded from [presse.wittenstein.de](http://presse.wittenstein.de)

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**Pictures (all © WITTENSTEIN SE):**



**01-win-fitbone-ce-zertifikat**

The CE mark is further official confirmation of the high product safety and technological performance achieved by WITTENSTEIN intens' fully implantable limb lengthening nail.



**02-win-fitbone-receiver**

The redesigned FITBONE® Receiver has been enhanced with new functions and is now about 45 percent smaller in size.



**03-win-fitbone-set**

The FITBONE® System consists of an intramedullary lengthening nail, a receiver and an external control set.



**04-win-fitbone-nagel**

The upgraded certification means that seven FITBONE® nails in the TAA series now bear the CE mark.

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#### **WITTENSTEIN intens GmbH**

Intelligent implants based on miniaturized drive technology are the main focus of WITTENSTEIN intens' activities. To take just one example: FITBONE® is the world's only motorized, controllable and fully implantable intramedullary distraction nail for lengthening human limbs. It is used to compensate leg length discrepancies and carry out axial and torsional corrections. This mechatronic system facilitates an economical treatment concept characterized by a high level of patient comfort as well as short hospitalization and therapy periods.

WITTENSTEIN intens GmbH is one of six Business Units of WITTENSTEIN SE.

#### **WITTENSTEIN SE – one with the future**

With around 2900 employees worldwide and sales of €436.4 million in 2018/19, WITTENSTEIN SE enjoys an impeccable reputation for innovation, precision and excellence in the field of mechatronic drive technology – not just in Germany but internationally. The group comprises six pacesetting Business Units with separate subsidiaries for servo gearboxes, servo actuator systems, medical technology, miniature servo units, innovative gearing technology, rotary and linear actuator systems, nanotechnology and electronic and software components for drive technologies. Through its 60 or so subsidiaries and agents in approximately 40 countries, WITTENSTEIN SE ([www.wittenstein.de](http://www.wittenstein.de)) is additionally represented in all the world's major technology and sales markets.

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