

FITBONE® Product Information

Smarter Limb Lengthening



Favorite Implant Technology for Bone growth with Operation support and Networking with Experts

FITBONE® smarter limb lengthening:

- · Cutting edge german engineering.
- Several thousand cases since 1997, an implant-related technical failure rate of significantly less than 1% with the 4th generation of implants.
- Holistic treatment concept for limb lengthening and correction of axial and torsional deformities in one surgery.
- Unique customized solutions for bone transport and tumor prosthesis based on mature FITBONE® technology.
- · No over-reaming necessary.
- Accurate and controlled limb lengthening due to threefold visual and audible control feedback for efficient working distraction.
- · Comfortable lengthening process because of the small, lightweight and silent Control Set.
- There is no interference with magnetic instruments or devices.
- · No accidential retraction by the patient possible.

FITBONE® was developed in **cooperation** with Professor R. Baumgart MD, ZEM-Germany.

FITBONE® is an intramedullary lengthening system intended for limb lengthening of the femur and tibia. The device is used for correcting leg length discrepancies. With appropriate preoperative planning, it is possible to make axial and torsional corrections as part of limb lengthening.

Custom-made devices may be requested for other indications: lengthening of short residual limbs; bone transport for defects after tumor resection; humerus; other bone reconstruction.

Reliability / Quality / Experience: more than thousands of surgeries since 1997 and an implant-related technical failure rate of **less than 1%** with the 4th generation of implants.

Why the FITBONE® System?



Source: Krieg AH, UKBB Basel

"The potential advantages are many: fewer scars. improved aesthetics, better body image and psychological wellbeing, no irritation through pins and wires. reduced uncommon infections. pain. secondary deviation axial avoided, less joint stiffness, higher activity level during lengthening consolidation, faster rehabilitation, less risk of neurovascular compromise due to wire or screw insertion. and improvement in the ability work during and treatment."

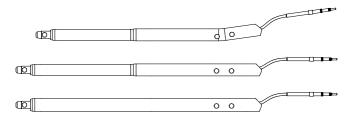
(Hasler CC, Krieg AH. Current concepts of leg lengthening. J Child Orthop. 2012;6:89-104)

Device portfolio

FITBONE® TAA

Standard lengthening nail: standard FITBONE® instruments

TAA	Telescope Active Actuator
Features	Nail for limb lengthening Custom-made devices for humerus and tumor prosthesis (MUTARS® BioXpand from implantcast GmbH)
Indications	Correction of leg length discrepancies of femur and tibia
Dimension	 Max. lengthening: 80 mm Diameter: 11/12 mm or 13 mm Total length: 163 mm to 245 mm Different end piece combinations
Insertion	Retrograde & antegrade



FITBONE® SAA

Custom-made device:

special instruments and specific surgical techniques

SAA	Segment Active Actuator
Features	Nail for limb lengthening with best results in stabilization
Indications	Correction of leg length discrepancies of the femur; can be used for corrections adjacent to the knee joint
Dimension	Max. lengthening: 80 mm Diameter: 13 mm Total length: 280 mm to 500 mm
Insertion	Antegrade



FITBONE® FSA / TSA

Custom-made device: experience with FITBONE® TAA is required

FSA / TSA	Femur / Tibia Segment Actuator
Features	Nail for bone transport and additional lengtheningAlso available with Herzog curve
Indications	Bone defect after resection, also for correction of leg length discrepancies of femur or tibia
Dimension	 Bone transport and additional lengthening: 80 mm in total Diameter: 11/12 mm or 13 mm Total length: 290 mm to 510 mm
Insertion	Retrograde & antegrade

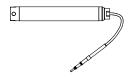


FITBONE® TAM

Custom-made device:

special instruments and specific surgical techniques

TAM	Telescope Active Mechanism
Features	2 designs: Nail for residual limb lengthening Actuator for tumor prosthesis (MUTARS® Xpand from implantcast GmbH)
Indications	Prosthesis lengthening after bone tumor resection
Dimension	Max. lengthening: 100 mmDiameter: 16 mmTotal length: 113 mm to 163 mm



All you need for smarter limb lengthening

- The external Control Set consists of control electronics and transmitter. The energy needed for the distraction process is provided to the subcutaneously implanted receiver via the external transmitter. There is no direct connection between implanted receiver and body surface (significantly reduced infection risk).
- The Control Set can be initiated as early as during surgery, i.e. distraction can be started intraoperatively and runs continuously if required – quick an easy system check during surgery with threefold feedback.
- The patient sends impulses (three times per day) to the implanted receiver during the distraction phase at home.



All the support you need

- Training at "Center of Excellence" ensures the highest quality and safety for surgeons and patients
- · Assistance with planning of initial cases
- · Technical support during surgical procedures
- · Regular training events (FITBONE® User Meetings, workshops)
- · Networking with FITBONE® experts

All the instruments you need

- Starter sets for all FITBONE® TAA & FSA / TSA implant insertion and removal included.
- Instruments for custom-made FITBONE® Systems and complementary tools are provided by WITTENSTEIN intens GmbH – worldwide. The package includes additional Instrument Sets for FITBONE® SAA and for FITBONE® TAM.
- Rigid step reamers fit in the exact implant size: over-reaming is not necessary.
- Radiolucent grid guide to aid achievement of desired axis alignment during surgery.

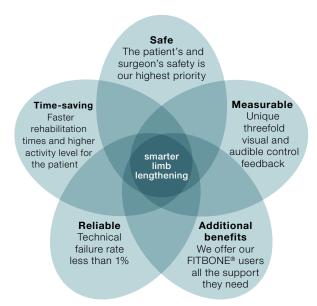


COE Concept - Quality and Safety first

Selected orthopedic surgery centers throughout the world are trained to become Centers of Excellence (COE) for the FITBONE® treatment. Due to our excellent technical FITBONE® product and our well trained surgeons, FITBONE® is one of the safest limb lengthening devices in the world.

Key Factors

- · Long term experience in limb lenghtening
- COE Concept enables FITBONE® users to act in the field of limb lenghtening on a very high and safe level
- Participation in COE training program and coaching in the Reverse Planning Method invented by Professor R. Baumgart MD, ZEM-Germany.
- Participation in FITBONE® User Meetings
- · Sharing experience within the COE network



WITTENSTEIN intens GmbH

Walter-Wittenstein-Straße 1 97999 Igersheim Germany

Tel. +49 7931 493-0 Fax +49 7931 493-10906 info@wittenstein-intens.com www.wittenstein-intens.com

WITTENSTEIN – one with the future www.wittenstein-intens.com