Fitbone™

Intramedullary Lengthening System
Value Analysis Summary

Transport and Lengthening System

ORTHOFIX

Table Of Contents

SUMMARY

The treatment of bone defects in lower limbs from a traumatic, infectious or malignant condition is effectively performed by distraction osteogenesis with motorized intramedullary nails. This procedure improves patient comfort, reduces treatment time and minimizes complications. **The Fitbone Transport and Lengthening System is the only intramedullary motorized device commercially available that allows for bone transport or lengthening in the femur or tibia using one device.** Additionally, the device can be used to treat bone defects up to 80mm without revision of interlocking fixation, potentially reducing the likelihood for additional surgeries.

FITBONE TRANSPORT AND LENGTHENING OVERVIEW

Marketing History

Previous versions of the Fitbone nail have been used for bone transport (8,9) since 2011 in Europe and 2017 in USA. These were provided to surgeons as custom made devices by the previous manufacturer (Wittenstein GMBH).

Fitbone Transport and Lengthening System Description

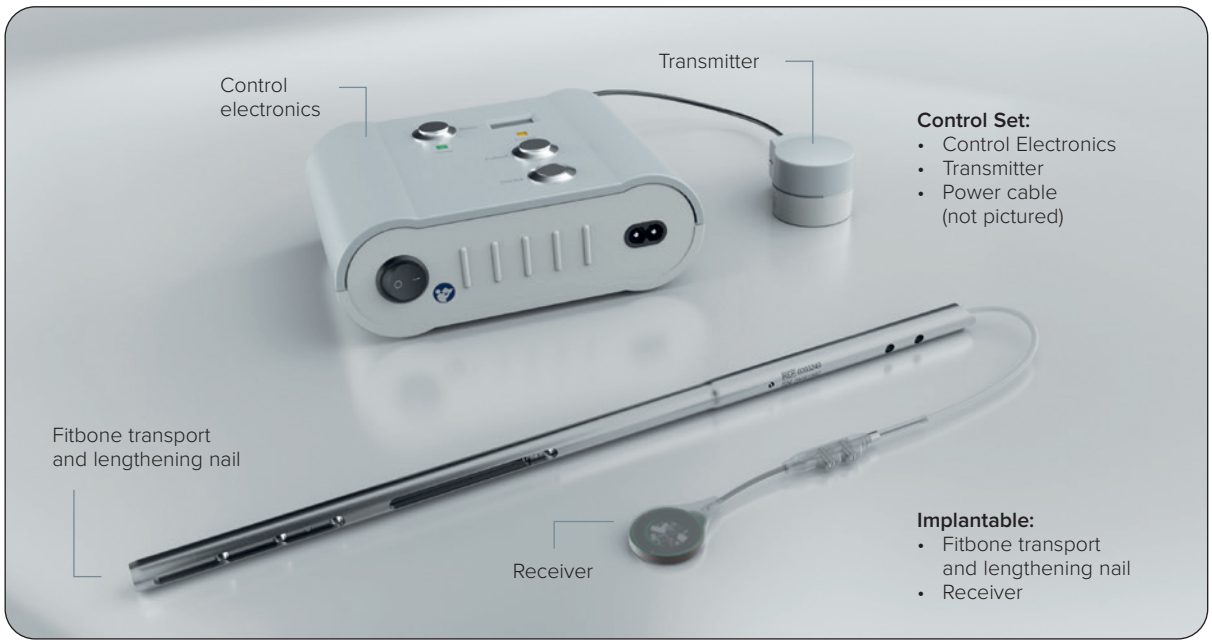
The Fitbone Transport and Lengthening System consists of an intramedullary nail connected to a receiver by a bipolar feed line, locking from outside of the body, by placing screws, and an external Control Set consisting of control electronics with a Transmitter. The surgical instrumentation and additional components are provided to facilitate the surgical process.

Indications: The Fitbone Transport and Lengthening System is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, malunions, non-unions, or bone transport of the long bones. The Fitbone Transport and Lengthening System is indicated for adult only.

Material: Stainless Steel (AISI 316LVM)

Distraction force: 1200N (120kg)

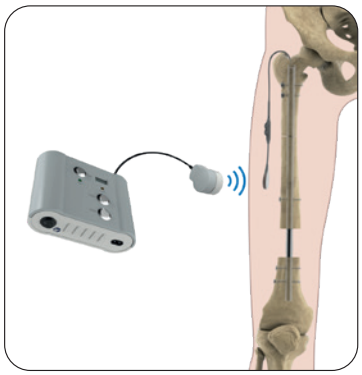
Surgical Approach: Femur antegrade and retrograde; tibia antegrade.



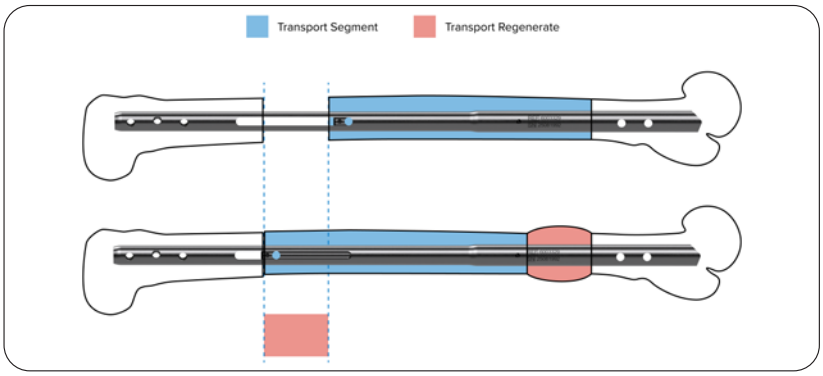
The Fitbone Transport Nail (TN) or Transport Lengthening Nail (TLN) is implanted into the medullary canal of the femur or tibia. The nail is connected to the bone by locking screws through medial-lateral and AP holes in the nail. The energy needed for the distraction process is transmitted from the outside of the body by placing the external transmitter over the implanted receiver, which is placed in the subcutaneous tissue during surgery.

The Fitbone Transport and Lengthening System consists of two main implant configurations:

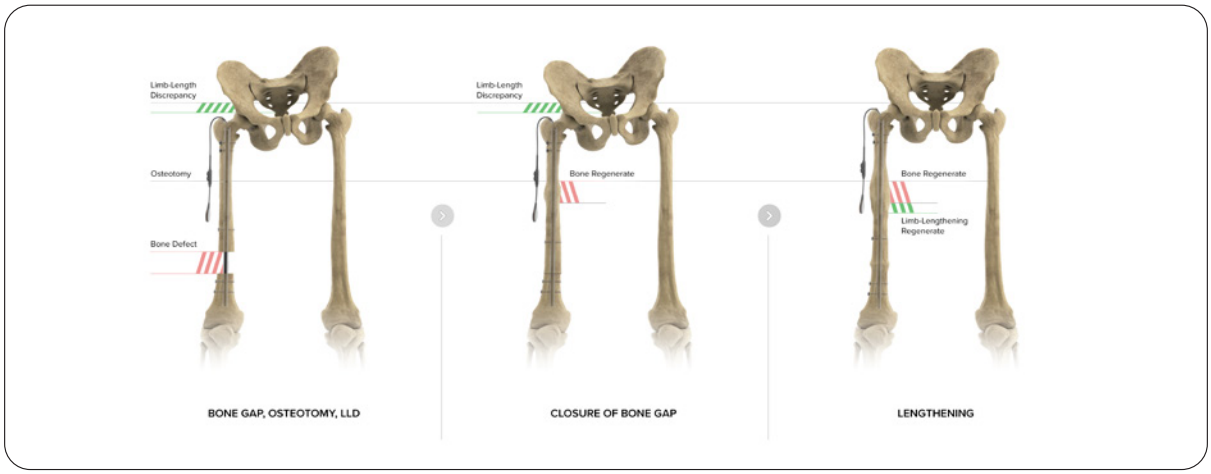
Fitbone Transport Nails (Fitbone TN)	Fitbone Transport and Lengthening Nails (Fitbone TLN)
	
Fitbone TN Femur Antegrade	Fitbone TLN Femur
	
Fitbone TN Femur Retrograde	
	
Fitbone TN Tibia Antegrade	Fitbone TLN Tibia Antegrade



Energy Transfer



Fitbone Transport Nail (Fitbone TN)



Fitbone Transport and Lengthening Nail (Fitbone TLN)

BONE TRANSPORT[1]

What is a Bone Transport

Bone transport is a method to grow new bone in a limb where there is a missing section of bone (bone defect) due to an infection, tumor, trauma, or congenital condition. This method was first described by Ilizarov and its basic principle is to grow new bone between two segments as they are gradually pulled apart. The goal of this treatment is to fill the defect with new bone and restore equal limb length and function for the patient.

Bone Defect Treatment Options

Historically, amputation has been used to manage large bone defects in lower limbs that are considered unreconstructible. However, amputation is now viewed as a measure of last resort when a functional foot is present. There are multiple methods for the treatment of bone defects, which are summarized below.

- Posterolateral Tibial Bone Grafting
  This method has been long used to fuse the fibula to the tibia with or without a bone defect present. The approach is done posterior to the fibula and tibia along the posterior aspect of the intraosseous membrane. In this procedure, graft traditionally harvested from the posterior ilium is applied to the exposed bone that is previously partially denuded to allow intraosseous bleeding to reach the graft. This technique is often used to treat persistent nonunion with infection since it does not involve direct contact with the infected area. However, a persistent deformity is a common occurrence in this method.

- Fibula-pro-tibia Grafting
  In this method, an intact fibula is united above and below the tibial bone defect without necessarily filling the tibial defect or restoring tibial continuity. In young patients, the fibula can hypertrophy for future weight-bearing once union occurs. One of the disadvantages of this method is a tendency of the limb to deform into varus, as the fixation is often insufficient.

- Induced Membrane Technique
  This technique was developed by Masquelet and is useful for bone defects 3cm to 8cm in length. Any infection that might be present is required to be completely eliminated by serial debridement and local and systemic antibiotic therapy before reconstruction. Excellent healing rates are reported, but duration to union can be as long as 33 months before weight-bearing can occur.

- Bone Transport
  Bone Transport has become an established method for the treatment of large bone defects, and it can be realized by using a variety of external and internal devices based on distraction osteogenesis. Bone transport can be done by using ring and monolateral fixators and motorized intramedullary systems.

Monolateral Fixator *LRS*	Hexapod Fixator *TL-HEX™*	Ring Fixators *TrueLok™ and TrueLok™ EVO Fixators*	Motorized Bone Transport Nail *Fitbone™ TN*
			

FITBONE TRANSPORT OR LENGTHENING SYSTEM COMPETITIVE COMPARISON

As of the current market landscape, there are no alternative intramedullary transport or transport and lengthening nails available in the United States. Motorized intramedullary lengthening nails can be used in a plate-assisted bone segment transport (PABST), but this approach requires the use of a plating system as well.

Features	Intramedullary Nails	PABST	External Fixators	Monorail
Scar tissue formation	Low[3,4,5]	High	High[3,4,5,6]	High
Patient comfort	High[9]	High	Low	Medium
Pin infections risks	No	No	Yes[7]	Yes[7]
Lengthening and transport	Yes	No	Yes	Yes
Soft tissue transfix	No[5]	No[10,11]	Yes[5,10]	Yes[5,10]

Soft tissue damage	Low	High[11]	High	High
Pain due to soft tissue transfix	No	No	Yes[7]	Yes[7]
Ability to achieve distraction osteogenesis through the intramedullary canal	Yes	Yes	No	No
Risk of bone angulation	Low[9]	Low	Medium[7]	High[7]
Long work absentism	Low[9]	Low[9]	High[9]	High[9]
Treatment time	Lower than External Fixators and monorails[9,10]	Lower than External Fixators and monorails[9,10]		
Flexibility for osteotomy positioning	Medium	Medium	High	High
Length of defect	Moderate	Moderate	Long	Long

PEER-REVIEWED PUBLICATIONS FITBONE TRANSPORT AND LENGTHENING SYSTEM

Patient Outcomes

1. Baumgart R, Betz A, Schweiberer L. A fully implantable motorized intramedullary nail for limb lengthening and bone transport. Clin Orthop Relat Res. 1997 Oct;(343):135-43. PMID: 9345218.

Highlights: First description reported in the English literature about bone transport with an intramedullary nail containing a fully implantable, motorized and programmable sliding mechanism. Twelve Fitbone implants were evaluated, 11 were implanted for limb lengthening and one was implanted in patient that had a 12cm defect after tumor resection. In the case of bone defect, the segment transport worked well without any problems. There was no infection and no axial deformity. Immediately after chemotherapy, delayed bone formation was seen.

2. Kold S, Christensen KS. Bone transport of the tibia with a motorized intramedullary lengthening nail - a case report. Acta Orthop. 2014 Apr;85(2):211-3. doi: 10.3109/17453674.2014.887953. Epub 2014 Jan 30. PMID: 24479621; PMCID: PMC3967267.

Highlights: This is the first case report using a Fitbone TSA* nail. The author describes the case of a 53-year- old male that suffered a OTA classification 43-A2.3 closed fracture of the distal tibia and fibula(2). After several surgeries the patient was referred to the author's institution and had a loose tibial plate with broken screws. The tibia had a varus deformity of 16 degrees and was 2.2cm shortened. A non-union site was present and found to be loose.

In the case discussion the author mentions that use of an intramedullary nail for bone transport instead of an external fixator probably facilitates early full joint motion, as the skin and muscles are not transfixated. It is also mentioned that patient satisfaction and quality of life during and after the lengthening procedure favor the use of intramedullary bone transport.

*Note: Fitbone TSA and FSA were precursors to the current nail design.

3. Accadbled F, Thévenin Lemoine C, Poinsot E, Baron Trocellier T, Dauzere F, Sales de Gauzy J. Bone reconstruction after malignant tumour resection using a motorized lengthening intramedullary nail in adolescents: preliminary results. J Child Orthop. 2019 Jun 1;13(3):324-329. doi: 10.1302/1863-2548.13.190016. PMID: 31312273; PMCID: PMC6598045.

Highlights: The aim of this study was to evaluate the Fitbone Nail for bone lengthening and bone transport after malignant tumor resection in adolescents. This study is based on the results of 8 patients who underwent wide excision of a malignant tumor of the lower limb followed by bone lengthening and/or transport using Fitbone Intramedullary Nail configurations. Bone transport was performed in 3 cases (from 14 to 18 years old) with 6cm, 3cm and 2cm, respectively. Transport was followed by 3cm and 4cm bone lengthening in 2 cases. Bone union was obtained in all three cases after a mean 10 months (6 to 17). Mean healing index was 50 days per cm (30 to 87). One patient had a planned docking procedure during which a loose locking screw was revised. The authors conclude that the Fitbone nails are safe and reliable for bone lengthening and transport after malignant tumor resection in adolescents. They allow biological reconstruction with satisfactory clinical and radiological results, low complication rate, and nearly normal function.

Note: The nails in these 3 publications, Fitbone TSA and FSA, were released in various markets by Wittenstein and were precursors to the current nail design

Comparison Studies

1. Dahl, Mark Thomas MDa; Morrison, Stewart MBBS, FRACS(Orth)b. Segmental Bone Defects and the History of Bone Transport. Journal of Orthopaedic Trauma 35():p S1-S7, October 2021.

Highlights: In this article the cause of segmental bone defects is described and the past and present options of care are reviewed. It presents a brief description of distraction osteogenesis and how the Ilizarov method was used to treat bone defects with circular external fixation leading to the latest method of transport with motorized internal lengthening nails.

2. Iobst CA, Frost MW, Rölfing JD, Rahbek O, Bafor A, Duncan M, Kold S. Radiographs of 366 removed limb-lengthening nails reveal differences in bone abnormalities between different nail types. Bone Joint J. 2021 Nov;103-B(11):1731-1735. doi: 10.1302/0301-620X.103B.BJJ-2021-0549.R1. Epub 2021 Aug 20. PMID: 34414785.

Highlights: In this study radiological bone abnormalities between STRYDE®, PRECICE®, and FITBONE Nails prior to nail removal have been compared. The results of the study showed that bone abnormalities at the interface of telescoping nail parts were present in the majority of STRYDE Nails, but only very rarely with FITBONE or PRECICE Nails. The authors concluded that the low prevalence of radiological changes at the junctional interface of 242 FITBONE and 98 PRECICE Nails at the time of nail removal does not warrant clinical concerns.

Surgical Technique

1. Kähler Olesen, Ulrik MD*; Herzenberg, John E. MD, FRCSC†. Bone Transport With Internal Devices. Techniques in Orthopaedics 35(3):p 219-224, September 2020.

Highlights: This article describes, through clinical examples and illustrations, two techniques (PABST and bone transport through an intramedullary dedicated bone transport nail) for internal bone transport and their variations, including tips and tricks, and the authors suggested treatment protocol. Indications, surgical planning, surgical technique, possible complications and post-op protocol are described in this article.

FITBONE TRANSPORT AND LENGTHENING SYSTEM DEVELOPMENT HISTORY

The Fitbone SAA was developed in partnership between Prof. Baumgart and Wittenstein Intens GmbH in Germany. The Fitbone products were acquired by Orthofix in March 2020. The improved Fitbone transport and lengthening system was launched by Orthofix in 2024.

SYSTEM KEY COMPONENTS

The Fitbone Transport and Lengthening System includes the Fitbone TN and TLN nail variants, Fitbone Receiver, Fitbone Control Set and Fitbone Instruments. The cost of all materials is included in the overall costs of the Fitbone System.

ADDITIONAL SUPPLIES THAT WILL BE UTILIZED WITH THIS PRODUCT

Description	Quantity	Dimensions	Part Number
Knee roll*	1		
Flexible shaft adapter	1		**172210**
Drill bit 4.5mm	1	Diameter: 4.5mm Length: 160mm	
Surgical stapler*	1		
Slotted mallet	1		**177380**
Surgical skin marker*	1		
Osteotomy instruments* - 4mm drill - Osteotomes - Drill guide 4mm			
ASK hook proves* (only for removal if required)	1		

*These items are not supplied by Orthofix and must be supplied via the hospital's own materials.

DISPOSABLE PRODUCTS (FOR SINGLE PATIENT USE)

Part Number	Description	Sterile	Further Information
99-941550 **941550**	Self-drilling XCaliber cylindrical screw shaft D6mm thread 5mm L180/60QC or Self-drilling XCaliber cylindrical screw shaft D6mm thread 5mm L180/60QC	Yes No	Shaft Diameter: 6mm Thread Diameter: 5mm Length: 180mm
	Endoscope camera protection cover*		
	Camera drape*	Yes	Dimensions: 13 x 250cm, reverse folded
	Redon drainage*		Length: 50cm Internal Diameter: 1.5mm External Diameter: 2.5mm
	Cerclage wire*		Diameter: 0.8mm Length: 1m
60001039	Fitbone Kirschner wire D3 L280	No	Diameter: 3mm Length: 280mm
60001622	Biotronik torque wrench 395121	Yes	Key-width: (hexagon) 0.9mm

*These items are not supplied by Orthofix and must be supplied via the hospital's own materials.

COMPANY CONTACT

Orthofix Customer Service
(800) 535 4492 toll free (7 a.m. – 7 p.m. CST)
(800) 445 1923 fax
customerservice@orthofix.com

TRAINING

Your sales representative will train the staff regarding the Fitbone Transport and Lengthening System including instrumentation.

For physician training opportunities please contact your sales representative.

LIST OF MARKETING MATERIALS

- Fitbone Control Set Quick Patient Guide
- Fitbone Control Set Quick Surgeon Guide
- Fitbone Retraction Control Set Quick Guide
- Fitbone Instrument Trays Layout
- Fitbone Transport and Lengthening System Instrument Trays Layout (Additional Instruments)
- Fitbone Transport and Lengthening System Product Sheet
- Fitbone X-ray Instruction
- Implant card

INSTRUCTIONS FOR USE AND SURGICAL TECHNIQUES

- Instructions for Use Fitbone Transport and Lengthening System
- Instructions for Cleaning, Sterilization and Maintenance
- Instructions for Use Fitbone Control Set
- Fitbone Transport and Lengthening System Antegrade Femur Application
- Fitbone Transport and Lengthening System Retrograde Femur Application
- Fitbone Transport and Lengthening System Tibia Application

PACKAGING

- The Fitbone TN and TLN implants and receiver are individually packaged and provided sterile.
- Most of the Fitbone instruments are reusable and are provided in instrument trays (see ″Disposable Products″ section).
- For the implantation of a TN and TLN Ø13mm nails, additional instruments are required.

FITBONE TRANSPORT AND LENGTHENING SYSTEM PRODUCT CONFIGURATIONS

The Fitbone Transport and Lengthening System is commercially available in a variety of configurations to better accommodate different bone anatomies inherent in bone defect applications. Refer to the Fitbone Transport and Lengthening System Product Sheet for full listing of all configurations available.

FITBONE TRANSPORT AND LENGTHENING SYSTEM INSTRUMENTS

Fitbone Transport Nails (Fitbone TN) and Fitbone Transport and Lengthening Nails (Fitbone TLN) are implanted by using the same instruments required for the Fitbone Intramedullary Lengthening System. For the full listing of all instruments please refer to the brochures ″Instrument Tray Layouts Fitbone Intramedullary Lengthening System″ (FB-2026-PL-E0) and ″Fitbone Transport and Lengthening System Additional Instruments″ (FB-2305-PL-US).

BIBLIOGRAPHY

1. Dahl, Mark Thomas MDa; Morrison, Stewart MBBS, FRACS(Orth)b. Segmental Bone Defects and the History of Bone Transport. Journal of Orthopaedic Trauma 35():p S1-S7, October 2021.
2. Marsh JL, Slongo TF, Agel J, Broderick JS, Creevey W, DeCoster TA, Prokuski L, Sirkin MS, Ziran B, Henley B, Audigé L. Fracture and dislocation classification compendium 2007: Orthopaedic Trauma Association Classification, Database and Outcomes Committee. J Orthop Trauma (Suppl 10) 2007;21(S1)(S133)
3. Peter R. Calder, Maritz Laubscher, and W. David Goodier. The role of the intramedullary implant in limb lenghtening. 2017.
4. A. Handlbauer and R. Ganger. Ergebnisse nach beinverlängerung und achskorrektur mit einem voll implantierbaren, motorisierten, intramedullären Verlängerungsmarknagel, 2013.
5. M. Kücükkaya, Ö. Karakoyun, S. Sökücü, and R. Soydan. Femoral Lengthening and Deformity Correction Using the Fitbone Motorized Lengthening Nail. Journal of Orthopaedic Science, 20(1):149 – 154, January 2015
6. Quinnan SM, Lawrie C (2017) Optimizing Bone Defect Reconstruction-Balanced Cable Transport With Circular External Fixation. J Orthop Trauma. 2017 Oct;31(10):e347-e355.
7. Cole JD, Justin D, Kasparis T, DeVlught D, Knobloch C (2001) The intramedullary skeletal kinetic distractor (ISKD): first clinical results of a new intramedullary nail for lengthening of the femur and tibia. Injury. 2001 Dec;32 Suppl 4: SD pp 129-139.
8. Kold S, Christensen KS. Bone transport of the tibia with a motorized intramedullary lengthening nail - a case report. Acta Orthop. 2014 Apr;85(2):211-3.
9. Kähler Olesen, Ulrik MD*; Herzenberg, John E. MD, FRCSC†. Bone Transport With Internal Devices. Techniques in Orthopaedics 35(3):p 219-224, September 2020.
10. Rauchbauer, etal. Fibula-Assisted Segment Transport (FAST) for Defect Reconstruction after Resection of Tibial Adamantinoma: Report of Two Treatments. Case Reports in Orthopedics. May 2021.
11. Gardner and Beason. Plate-Assisted Bone Segment Transport Versus Precice Bone Transport Nail. J Orthop Trauma 35(10), October 2021.

Fitbone™

Intramedullary Lengthening System

Please refer to the **Instructions for Use PQFBT, PQFBP and PQFBR** supplied with the product for specific information on indications for use, contraindications, warnings, precautions, possible adverse events, MRI (Magnetic Resonance Imaging) safety information and sterilization.

Products may not be available in all markets because product availability is subject to regulatory and/or medical practices in individual markets. Please contact your Orthofix representatives if you have any questions about the availability of Orthofix products in your area.

***Manufactured by:**
ORTHOFIX Srl
Via Delle Nazioni 9, 37012 Bussolengo
(Verona), Italy
Telephone: +39 045 6719000
Fax: +39 045 6719380
www.orthofix.com

*If not otherwise indicated on the product label.

Rx Only

Distributed by:

orthofix.com
FB-2304-PL-US C 12/24

ORTHOFIX®