2. PMA P850007

1. PMA P850007/S20

following outcomes (1, 2)
patients presenting 859 individual fractures treated with Physio-Stim resulted in the
their own after nine or more months. In addition, Orthofix Patient Registry Data of 729

The effect of Physio-Stim PEMF on fracture non-unions was demonstrated in an open

Succes Rates

Primary Treatment Sites: Distal Tibia and Fibula, Tarsals and Metatarsals

Success Rates

The effect of Physio-Stim PEMF on fracture non-unions was demonstrated in an open

Guided Growth™ System®

Guided Growth™ System®

REFERENCES


Guided Growth™ System®


• Examination of Bone Angular Deformities: Experimental Analysis of Singles versus Dual plates. Guyer KH, TA.


• Charcot foot - 13. Severe end-stage

• Severe end-stage

• Distal tibial fractures treated with hybrid external fixation. Babis GC, Kontovazenitis P, Evangelopoulos DS, Procallus

• Temporary external fixation for the management of complex intra- and periarticular fractures of the lower

• Correction of Bone Angular Deformities: Experimental Analysis of Staples Versus 8-plate. Goyeneche RA,

• Current understanding of the effects of PEMF on fracture nonunion. Bortolazzi R, Christodoulidis A, Bartolozzi P.


• Treatment of 103 displaced tibial diaphyseal fractures with a radiolucent unilateral external fixator. Dall’oca C,

• Current understanding of the effects of PEMF on fracture nonunion. Bortolazzi R, Christodoulidis A, Bartolozzi P.


• Treatment of 103 displaced tibial diaphyseal fractures with a radiolucent unilateral external fixator. Dall’oca C,

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**Galaxy UNYCO™**

**Indications**
Open or closed fractures of the long bones; infected and aseptic non-unions; joint pathologies/injuries

**Principles**
- Fast and easy assembly
- Sterile pre-assembled functional blocks
- Single packed sterile kits and components
- Stable temporary and definitive fixation
- MRI conditional*  

*Up to 1.5 T. See Instruction for Use (PQ GAL) and Operative Technique (GF-1102-OPT-E0)

**Advantages**
- Temporary External Fixation System based on unicortical screw technology
- Fewer steps in the operative technique
- Designed to avoid contamination of the medullary canal
- Designed to facilitate the conversion from temporary to definitive fixation
- Designed for an anatomically invasive approach
- Case of use, modular and versatile compatible with Galaxy Fixation System
- Sterile packed kits ready to use, ideal for DCO
- MRI Conditional*

*Up to 1.5 T. See Instruction for Use (PQ GAL) and Operative Technique (GF-1102-OPT-E0)

**ProCallus™**

**Indications**
Distal tibia and pilon fractures; ankle arthrodesis (articulated ankle clamp)

**Principles**
- Stable
- MRI compatible
- High flexibility
- Sterile kit options

**Minirails & Calcaneal Fixator**

**Indications**
Open or closed fractures of the long bones; infected and aseptic non-unions; joint pathologies/injuries

**Principles**
- Fast and easy assembly
- Sterile pre-assembled functional blocks
- Single packed sterile kits and components
- Stable temporary and definitive fixation
- MRI conditional*  

*Up to 1.5 T. See Instruction for Use (PQ PFX) and Operative Technique (PF-0902-OPT-E0)

**XCaliber**

**Indications**
Articular and pilon fractures of the distal tibia

**Principles**
- Stainless-steel packaged complete kits, ready to use
- Radiolucent
- Lightweight
- Includes XCaliber Detachable Screws, HR coated, proven protection against loosening

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**Galaxy Fixation System™**

**Indications**
Minirails M100 and M400 Series: fractures and correction of deformities.
Calcaneal Fixator: articular fractures of the calcaneus, oblique or coronal-calcanal bone fractures not involving the subtalar joint

**Principles**
- Few instruments: simple, convenience of use
- Small, unilateral design (more comfortable for the patient)
- Calcaneal Fixator: highly versatile with built-in swivelling and distraction capability
- Enables microesthetic means of ligamentotaxis and subtalar joint reduction; minimal internal fixation may also be used.

Available in a sterile, ready to use kit which includes: fixator, bone screws and all instruments necessary for the application

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**TrueLok**

**Indications**
Limb lengthening, fracture fixation, treatment of non union and pseudoarthrosis

**Principles**
- Simple: pre-assembled functional blocks easy to connect and operate with reduced number of components
- Stable

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**TL-HEX™**

**Indications**
Limb lengthening by metaphyseal or epiphyseal distractions, fixation of open fractures, treatment of non union or pseudoarthrosis of long bones and correction of bone or soft tissue defects or deformities

**Principles**
- Simple: TL-HEX offers pre-assembled and universal components, easy to operate and assemble
- Stable: stability due to its unique aluminium-stainless steel and patented metal-plastic interface
- Versatile: The distinctive strut design allows for independent rapid and gradual adjustments resulting in a greater overall adjustment range

The TrueLok RockerRail consists of two aluminium rails with a soft sole providing safety elevation for the frame upon attachment. The aim of the TrueLok RockerRail is to help protecting the foot and help with patient comfort. The TrueLok RockerRail is fully compatible with the TrueLok and TL-HEX systems.

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**FOOT & ANKLE**

**ProCallus™**

**Indications**
Distal tibia and pilon fractures; ankle arthrodesis (articulated ankle clamp)

**Principles**
- Stable
- Sterile, including hybrid and ankle clamp
- Reducent component (articulated ankle clamp)

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