

Orthofix Pediatric Solutions



**Pioneers in Pediatric
Limb Reconstruction
Continuously Providing
Innovative Solutions**



Dedicated Pediatric Solutions

We are always looking to the future – whether that is the brighter future we can provide for our patients, or the innovative pediatric solutions that can help facilitate medical advancements. For more than 40 years, our medical devices have been used to help children around the world. The Orthofix team researches, designs, and produces many of the leading orthopedic treatment options available globally and provides the support and information that everyone involved in the surgery and healing process needs.

Orthofix boasts an unrivaled level of in-house expertise within the field of pediatric orthopedics. Our well-rounded product portfolio features both internal and external fixation solutions enabled by state-of-the-art digital planning tools.

“Free the child’s potential,
and you will **transform**
him into the world”

Maria Montessori

TL-HEX TrueLok Hexapod System®

It consists of hardware and associated software for simplified deformity correction and trauma management.



TL-HEX TrueLok Hexapod System[®]

Hardware

① Excellent Stability

Unique strut head design increases frame stability

② Fast Locking

One set screw locks down both struts

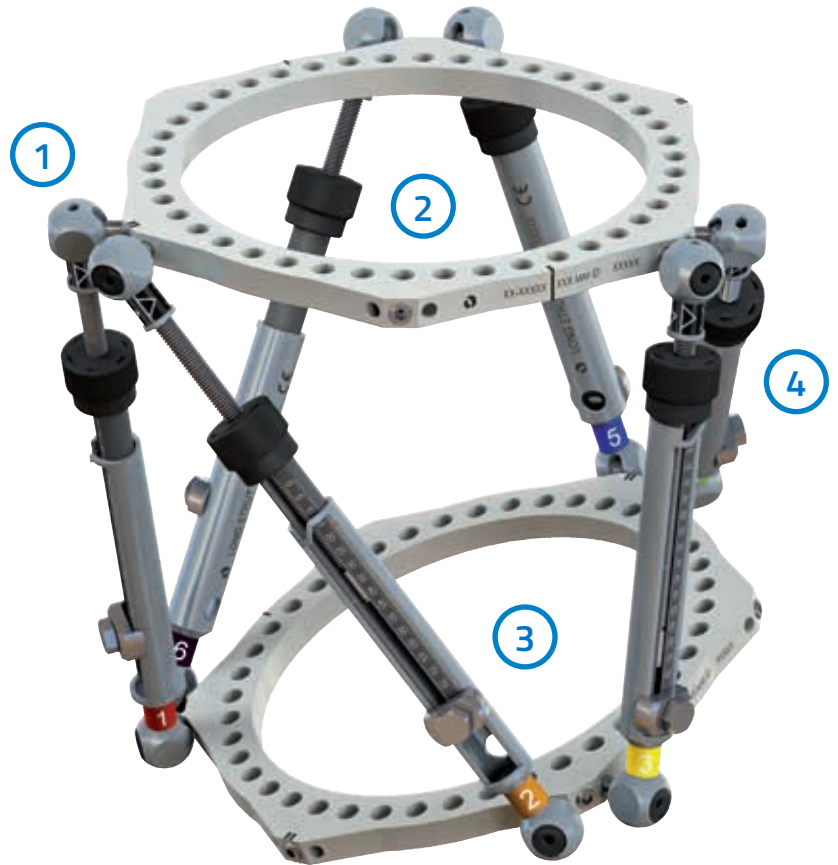
NEW SET SCREW DESIGN

③ Rapid Adjustment

TL-HEX Struts consist of two telescoping aluminum tubes, which can be locked together at various lengths using the side locking bolt and clamp washer

④ Easy Adjustment

Simple pull and click method for patient adjustment



Software

The intuitive and user friendly web-based TL-HEX Software is empowering all surgeons who want comprehensive support throughout pre/intra/post operative phases.

The **HEX-ray™** Integrated Module is designed to facilitate pre-operative planning and post-operative correction. By uploading digital x-ray images on the software, the surgeon can obtain:

- Measurement calculation
- Frame templates in preplanning
- Automatic data input into TL-HEX Software

Patient Support Tools

Orthofix Treatment with the TL-HEX TrueLok Hexapod System™ is not exactly child's play. However, playing games can support the treatment process and give kids the "power" to face the challenge. Orthofix has developed a set of tools specifically designed for pediatric patients.



3-6
years old

KIT FOR KIDS

Varied fun games to entertain the young patient and help the surgeon and the parents explain their treatment. It should be delivered by the surgeon or care team members and it includes tips for parents and caregivers.



7-12
years old

COMIC STRIP

Two very "normal" pre-teen kids find the rings and the struts and in putting these items together, they enter a magic world where they have the chance to become superheroes. The story of Tommy and Linda does not exactly reflect the TL-HEX treatment. It is intended as the launch "platform" to mySuperheroAcademy™ edugame.



10-15
years old

mySuperheroAcademy™

A quiz area designed to educate pediatric patients during the pre-surgery meetings with the orthopedic surgeon or the care team members.

Four match3 and eight runner games will entertain patients 10-15 years old. Unlocking code required (printed on the comic strip).



18+
years old

myHEXplan™

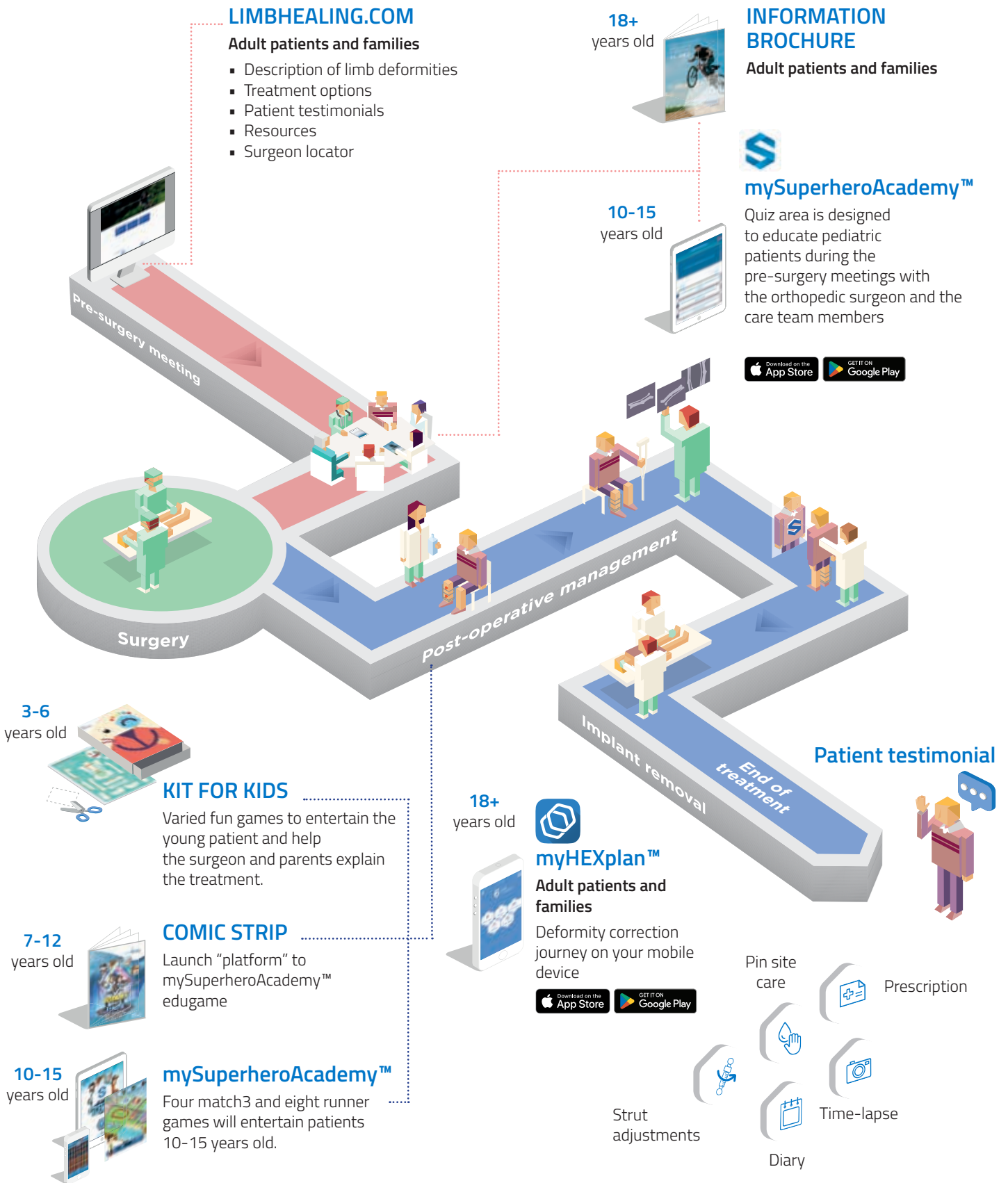
Adult patients and families

A successful treatment with TL-HEX is not simply a matter of correct strut adjustment. The TL-HEX patient is supported from the first day after surgery until the device removal, through all the treatment phases, with reminders about pin site care and strut adjustments, mood self-assessment and insights into the treatment.



Care HEXcellence

We are not just suppliers of pediatric products – we immerse ourselves in the process and offer help and support before, during and after surgery.



Some materials/services may not be available in your Country. Please contact your sales representatives for availability.

MJ-Flex The New Metaizeau Nail™

An intramedullary implant system specifically designed for Elastic Stable Intramedullary Nailing (ESIN) fracture fixation.



LRS pediatric

The Pediatric LRS System aims to successfully treat congenital and post-traumatic deformities in children.

Galaxy Fixation™

Galaxy Fixation is a modular external fixation system for fracture treatments of lower and upper limbs.



Agile Nail™

Designed to address femoral fractures and deformity correction procedures. It consists of antegrade intramedullary nails for the femur with respective end-caps and locking screws.



eight-Plate Guided Growth System +™

An extra-periosteal plate that uses the robust growth potential of the child's physis to gently guide correction of angular deformity.

Small DAF

A modular system intended as a means for stabilization of bone segments in a broad range of indications, including fractures and angular corrections (hemicallosis).



JuniOrtho™ Plating System

A complete plating system developed to address the specific demands of advanced deformity and trauma reconstruction of the lower extremities.

Hardware

Adjustable Instrument Tray

Modular and interchangeable instrument trays



Sterile Single-Use Implants and Tools

Optimal efficiency and cost reduction



Anatomical Design

Comprehensive options with locking and non-locking screws



OrthoNext™

Software



Software

The pre-planning software option streamlines the implant selection in the surgery room for the surgical procedure.

- **Accurate:** accurate calibration, measurements and templating.
- **Ease of use:** guided planning process and simple user interface.
- **Streamlined surgery and time-saving:** pre-operative surgical plan available with appropriate instrument tray and hardware device selection.



Fitbone™

The FITBONE™ TAA Intramedullary Lengthening System is intended for limb lengthening of the femur and tibia. With appropriate preoperative planning, it is possible to make axial and torsional corrections as part of limb lengthening. It is also indicated for use on adolescents (pediatric >12 years of age).

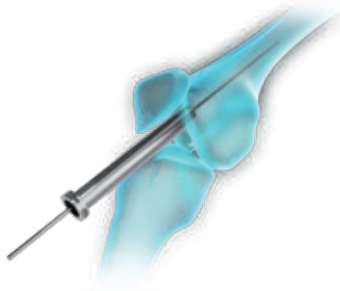
Precision

Instruments designed not only for lengthening but for optimal limb alignment

Protection of soft-tissues with minimally-invasive instrumentation

Safe alignment assessment and blocking screw placement with dummy (trial) nail

Strong stainless steel nail with dedicated trial for accuracy^{2,3,4} and final check



Safe reaming via a minimally-invasive approach⁴



Optimal limb alignment via unique instrumentation to assist in correction^{2,3,4}

Power

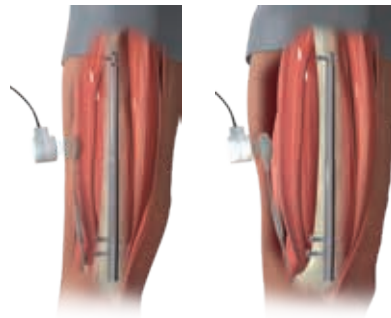
Reliable power direct to the nail¹

High distraction force independent of nail size¹

No soft-tissue limitation

Power transferred to the nail with a small portable control set

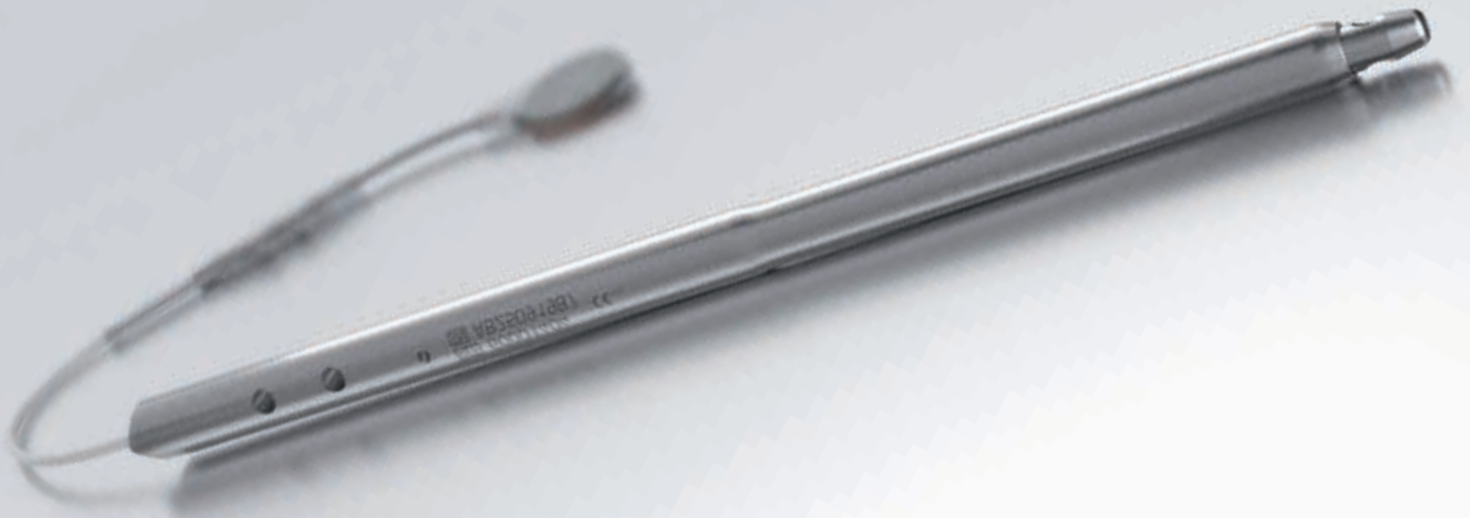
No magnets within the control set, therefore, no interference with magnetic instruments or devices



No need for unreliable magnetic fields



Reliable power no matter the size of patient or implant¹



Fit

Bone is reamed to exactly fit the implant

No over-reaming necessary⁵



Optimal fit for accuracy



Bone-conserving

OrthoNext™

Software



Software

Dedicated Reverse Planning
Method module for lengthening nails

Easy to use

**Optimising limb alignment
and lengthening**

Accurate calibration, measurements and
templating

Optimised inventory sent to OR

Indications



TL-HEX TrueLok Hexapod System®



The TL-HEX System is intended for limb lengthening by metaphyseal or epiphyseal distractions, fixation of open and closed fractures, treatment of non-union or pseudoarthrosis of long bones, and correction of bony or soft tissue defects or deformities.



Agile Nail™



The Agile Nail is intended for insertion in the medullary canal of a femur for the alignment and the stabilization of fractures and for the correction of deformities. It is indicated for the treatment of subtrochanteric fractures and of femoral shaft fractures in pediatric patients, with the exception of newborns and infants, and in adult patients with an appropriate medullary canal. The indications include: prophylactic nailing of impending pathologic fractures; fixation of femurs that have been surgically prepared (osteotomy); nonunions and malunions; reconstruction following tumor resection and grafting, and bone lengthening and shortening.



JuniOrtho™ Plating System



The JPS is indicated for internal fixation and stabilization of femoral and tibial fractures, osteotomies, mal-unions and non-unions.

Specific condition/diseases for which the device is indicated include: varus, valgus, rotational and/or shortening osteotomies, femoral neck and/or pertrochanteric fractures, proximal and distal metaphyseal fractures, pathological and impending pathological fractures.



eight-Plate Guided Growth System +™



Indicated for gradually correcting angular growth deformities in growing children. Specific conditions/diseases for which the device will be indicated include: valgus, varus or flexion, extension deformities of the knee (femur and/or tibia); valgus, varus, or plantar flexion deformities of the ankle.



Fitbone™



The FITBONE™ TAA Intramedullary Lengthening System is intended for limb lengthening of the femur and tibia. With appropriate preoperative planning, it is possible to make axial and torsional corrections as part of limb lengthening.

Benefits to Surgeon

Benefits to Patient

TL-HEX

- Simple: it provides simplified Hardware and Software for both Deformity and Trauma management.
- Stable: it provides exceptional stability due to its unique aluminum-stainless steel and metal-plastic interface.
- Versatile: the distinctive strut design allows for acute and gradual adjustment in deformity correction and complex trauma procedures.

- Stability with proven limited movements at the bone site may enhance the bone healing and reduce pain
- 0.5mm increments in the correction permits a gradual correction of the deformity
- Aluminium rings make the system lighter
- Dedicated support materials for patients
- No need for a second surgery for removal (compared to internal fixation)

Agile Nail

- Diameter from 7mm up to 10mm
- Titanium alloy implants
- Procurvation design for easy insertion
- Optimized and lean instrumentation
- Jig with patented locking mechanism

- Minimally invasive (small diameter for nails and screws)
- Early weight-bearing as tolerated by the patient and under surgeon discretion
- Titanium alloy implants to avoid allergic reaction to nickel
- 10° proximal bending to facilitate the lateral insertion of the nail and to reduce the impact on the growth plate
- Small proximal diameter of the nail for reduced invasiveness

JPS

- Multiple sizes available: 3.0-3.5-5.0mm
- Anatomical design to fit proximal femur, distal femur, proximal tibia and distal tibia
- Optimized and lean instrumentation
- Sterile implants
- Sterile single use tools (drills and wires) to provide optimal efficiency
- Color coded implant boxes
- Adjustable instrument tray
- Dedicated software pre-planning option

- Anatomical implant to facilitate the bone fit
- Early weight-bearing as tolerated by the patient and under surgeon discretion
- Stainless steel implant to facilitate implant removal
- Multiple sizes available to offer the best option based on patient anatomy

eight-Plate Plus

- Plate sizes: 12, 16 and 20mm
- Cannulated and solid screw options
- Titanium alloy implants
- Optimized and lean instrumentation
- Central "dome" designed to aid application and removal across the growth plate

- Minimally invasive
- Early weight-bearing as tolerated by the patient and under surgeon discretion
- Titanium alloy implants to avoid allergic reaction to nickel
- Low profile plates

Fitbone

- Cutting-edge German engineering
- Several thousand devices implanted since 1997
- No over-reaming necessary
- Accurate and controlled limb lengthening achieved with threefold visual and audible control feedback
- There is no interference with magnetic instruments or devices
- Accidental retraction is not possible

- Comfortable lengthening process facilitated with the small, lightweight and silent Control Set
- Reliable feedback from the system throughout the lengthening process
- A small, light-weight silent Control Set
- Little scarring, short hospitalization and quick reintegration into daily routines
- Minimal risk of infection

Indications

MJ-Flex The New Metaizeau Nail™



The MJ-FLEX is indicated to treat:

- upper extremity and clavicle fractures in all patients except newborns and infants;
- lower extremity fractures in pediatric patients, except newborns and infants, where the flexibility of the implant is paramount not to disrupt the growth plate;
- lower extremity fractures in small adults where the medullary canal is narrow.

Galaxy Fixation™



The Galaxy Fixation System is intended to be used for bone stabilization in trauma and orthopaedic procedures, both on adults and all pediatric subgroups except newborns as required.

Small DAF



The small DAF™ is a modular system intended as a means for stabilization of bone segments in a broad range of indications, including fractures and angular corrections.

LRS Pediatric



Limb reconstruction and lengthening due to fresh fracture, nonunion with major soft tissue defect, and bone loss with shortening.

Benefits to Surgeon

Benefits to Patient

MJ-Flex

- Developed to allow direct visual control of the alignment of the nail tip in the medullary canal, thus potentially reducing exposure to the image intensifier during insertion of the nail and the surgery time
- The flat surface allows the nail to bend on a proper plane
- Dedicated instrumentation for a streamlined optech
- A great variety of nails in several diameters both in titanium and stainless steel

- Stability of the osteosynthesis in all planes due to the superior medullary canal filling versus standard cylindrical nails
- Developed to limit X-ray exposure during insertion due to the unique shape that allows visual control of nail orientation
- Minimally invasive device

Galaxy Fixation

- For temporary and definitive fracture fixation
- Quick and ready to use: sterile kits, sterile single-packed components, instruments and implant trays
- Cylindrical self-drilling bone screws with 4 and 5mm thread diameters
- Ergonomic: specific pediatric clamps and rods
- Versatile: compatible with Orthofix circular and monolateral external fixation devices

- Galaxy Fixation Components are designed to fit specific pediatric anatomy
- Mechanical performance and low profile frames
- Minimally invasive approach
- Designed to allow early weight-bearing (at surgeon discretion) and functional recovery
- Easy device removal

Small DAF

- Telescopic fixator's body to cover a wide range of applications
- Compatible with other Orthofix Systems for complex surgeries
- Ball and socket mechanism for clamp orientation and stability

- Small sizes specifically developed for patient comfort
- Compression distraction unit with simple turning mechanism
- No need for a second surgery for removal (compared to internal fixation)

LRS Pediatric

- Flexibility - versatility
- Stability and safety in corrections
- Short learning curve

- Small sizes specifically developed for the patient's comfort
- Compression distraction unit with simple turning mechanism
- No need for a second surgery for removal (compared to internal fixation)

References

TL-HEX TrueLok Hexapod System®

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MJ-Flex The New Metaizeau Nail™

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Small DAF

- Bone lengthening with extra-articular arthrodesis of the hip using external fixation. Mesa PA. *Strategies Trauma Limb Reconstr.* 2008 Sep; 3(2):75-81.



Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.



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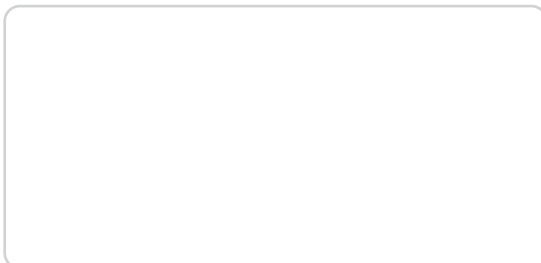
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CE₀₁₂₃

Fitbone™

**Manufacturer info is available
on the product labels and relevant IFUs.**

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