

Packaging Insert



IMPORTANT MEDICAL INFORMATION

MANUFACTURED FOR:
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English

NON STERILE

Pedi-Flex Flexible Nail System

Description

The Pedi-Flex Nail System includes flexible nails for the application of aiding bone fracture repair and healing. The range includes medical devices from Class IIb (93/42/CEE Directive).

Materials

The flexible nails are made from implant grade 316L.

Indications & Usage

- The PediFlex Flexible Nail System is intended for fixation of diaphyseal fractures of long bones where the medullary canal is narrow or flexibility of the implant is required. This includes upper extremity fractures in all patients and lower extremity fractures in pediatric or small stature patients. In pediatric patients, the flexibility of the nail allows it to be inserted at a point that does not disturb or disrupt the growth plate.

Contra-Indications

- Metallic bone fixation devices should not be used in patients with:
 - active infections in or near the fixation site,
 - a demonstrated sensitivity to metals,
 - an inability to follow a post-operative regimen.
- Pedi-Flex Nails may not be used for the treatment of unstable fractures such as long oblique or long spiral fractures.

Warnings

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation. Pre-operative procedures, knowledge of applicable surgical techniques, good reduction of bone fragments, proper patient selection and correct placement of the implants are all equally important for the successful use of these products.
- Use extreme care in the handling and storage of implants. Cutting, bending or scratching the surface of metal components can significantly reduce the corrosion, strength, and fatigue resistance of the implant system.
- Repeat use of a surgical implant is strictly forbidden. Each implant used once must be disposed of properly. This is the same even where it appears to be intact. The device may have small faults or internal stresses that if the item is re-used may lead to fatigue failure.
- Implant Retrieval. The final decision to recover the implant falls to the surgeon. If the patient is suitable, we recommend the retrieval of implants as otherwise they may replace the function of the bone and lead to bone reduction and weakening, this is particularly important for young and active patients. Routine removal of internal fixation devices after fracture healing may also reduce the occurrence of symptomatic complications of implant breakage, implant loosening and implant related pain.
- Mixing of implants from different suppliers is not recommended for reasons of metallurgy, mechanics and design. We decline all responsibility in the case of implants from different sources being mixed.
- The Pedi-Flex Nail is not intended for the treatment of lower extremity fractures in adults.
- The Pedi-Flex Nail is not intended to support the patient's weight as excessive loads may cause the device to fail. Weight bearing will depend upon the fracture pattern and stability, patient compliance and other associated injuries. Progression of weight bearing should be at the discretion of the surgeon.
- Federal (USA) law restricts this device to sale by or on the order of a physician.

Adverse Effects

- Loss of fixation, attributable to non-union, unstable comminuted fractures
- Delayed or nonunion that may lead to implant breakage
- Loosening or migration of the implant
- Bending, fracture, or migration of the implant
- Decrease of bone density due to stress shielding
- Infections, both deep and superficial
- Limb shortening due to compression of the fracture or bone resorption
- Allergies and other metal sensitivity reactions to device materials
- Vascular disorders including thrombophlebitis, pulmonary embolus, wound hematomas, avascular necrosis.

Sterilization

- This implant is not sterile when shipped from ORTHOPEDIATRICS.
- All implants must be sterilized before use.
- Remove all implants from their packaging prior to sterilization.
- ORTHOPEDIATRICS implants are recommended to be sterilized by the steam autoclaving procedure regularly used in the hospital for wrapped instruments (based on ANSI/AAMI ST79:2006), as detailed in OrthoPediatrics Instrument Care, Cleaning, and Sterilization Instructions CI-0001.
- Other sterilization methods and cycles may also be suitable. However, individuals and hospitals are advised to validate whichever method they deem appropriate at their institution and in accordance with the autoclave manufacturer's recommendations.
- ETO sterilization and cold sterilization techniques are not recommended. ORTHOPEDIATRICS disclaims any liability for any problem further to the use of these sterilization methods.

Storage and Handling

- Medical devices are sensitive to damage. Implants should be handled with care at all times.
- Surgical implants and the packaging should be checked for defects before use and to verify the appropriate sizing.