



## IMPORTANT MEDICAL INFORMATION

MANUFACTURED FOR:  
ORTHOPEDIATRICS  
210 N Buffalo St  
Warsaw, In 46580, USA  
Ph 574-268-6379



English

**NON STERILE**

## PediLoc<sup>®</sup> Locking Plate System

### Description

The PediLoc<sup>®</sup> Locking Plate System includes bone plates and screws for the application of aiding bone fracture repair and healing. The range includes medical devices from Class IIb (93/42/CEE Directive).

### Materials

The bone plates and screws are made from implant grade 316L Stainless Steel.

### Indications & Usage

The OrthoPediatrics PediLoc<sup>®</sup> Locking Plate System is used for pediatric patients as indicated for pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle. Indications for buttressing multi-fragmentary distal femoral fractures include: supracondylar, intra-articular and extra-articular condylar, periprosthetic fractures and fractures in normal or osteopenic bone, non-unions and mal-unions, and osteotomies of the femur.

### 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.

### 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 PediLoc<sup>™</sup> Locking Plate System 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

- Instruments and implants are not sterile when shipped from ORTHOPEDIATRICS.
- All implants and instruments must be sterilized before use. Implants are single use items, instruments may be reused.
- If received packaged, remove all implants from their packaging prior to sterilization. If received as a set, implants and instruments may be sterilized as a set or individually.
- Recesses and hidden areas within an instrument should be inspected periodically to ensure that entrapped or other residual materials are completely removed. Instruments should be cleaned and sterilized as detailed in OrthoPediatrics Instrument Care, Cleaning, and Sterilization Instructions CI-0001.
- ORTHOPEDIATRICS implants and instruments are recommended to be sterilized by the steam autoclaving procedures regularly used in the hospital for wrapped instruments (based on ANSI/AAMI ST79:2006) in accordance with the validated parameters, as detailed in OrthoPediatrics Instrument Care, Cleaning, and Sterilization Instructions CI-0001. See Steam Sterilization Table below for minimum cycle times.

# Packaging Insert



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- 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.

### Steam Sterilization Table:

Cycle	Temperature	Exposure Time	Minimum Drying Time
Gravity	134 °C	30 minutes	30 minutes
Pre-vacuum	134 °C	4 minutes	30 minutes

Note: Drying times will vary according to load size and should be increased for larger loads.

Where there is a concern about TSE/vCJD contamination, the World Health Organization recommends processing through a pre-vacuum steam sterilization cycle for 18 minutes at 134°C (273°F). (WHO/CDS/CSR/APH/ 2000.3, "WHO Infection Control Guidelines for TSE," March 1999).

### 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.

### Important Statement

- It is strictly prohibited to carry out any modification whatsoever on an ORTHOPEDIATRICS instrument or implant. Only ORTHOPEDIATRICS has the competence to carry out such work. If this recommendation is not followed, ORTHOPEDIATRICS disclaims any liability for any subsequent consequences.