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|  **Manufactured for:** | **Australian Sponsor** | Do Not Reuse | Non Sterilece_logo.gif 0086IFU-99-1015-102 Rev A January 2017OrthoPediatrics is a trademark, registered in the United States, of OrthoPediatrics Corp. |
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**Packaging Insert IMPORTANT MEDICAL INFORMATION** English

### OrthoPediatrics® Titanium PediPlate™ Bone Plating System

# Description

The PediPlate system includes instruments, bone plates and screws for the application of aiding bone fracture repair and healing. The range includes medical devices from Class I and Class IIa/IIb (93/42/CEE Directive).

# Materials

The bone plates and bone screws are manufactured from titanium alloy conforming to ASTM F-136. The instruments are made from stainless steel.

# Indications and Usage

The OrthoPediatrics Titanium PediPlate system is used for adult and pediatric patients as indicated for pelvic, small and long bone fracture fixation and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity or arthrodesis. Indications for use include fractures of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, middle hand and middle foot bones, treatment of the calcaneal; hip arthrodesis, and provisional hole fixation; as well as for redirecting the angle of growth of long bones. This is useful for gradually correcting angular deformities in growing children.

Specific pediatric conditions/diseases for which the devices 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
* Valgus or varus deformities of the elbow (humerus)
* Radial or ulnar deviation, flexion or extension deformities of the wrist (radius)

# 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

* Federal (USA) law restricts this device to sale by or on the order of a physician.
* 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.
* The OrthoPediatrics Titanium PediPlate 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.
* Use extreme care in the handling and storage of implants and instruments. Cutting, bending or scratching the surface of metal components can significantly reduce the corrosion, strength, and fatigue resistance of the implant and instrument 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.
* 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.
* Implant Retrieval. The final decision to recover the implant falls to the surgeon. If the patient is suitable, OrthoPediatrics recommends the retrieval of implants as otherwise they may replace the function of the bone and lead to bone reduction and weakening. This is especially important for young and active patients. Routine removal of internal fixation devices after healing may also reduce the occurrence of symptomatic complications of implant breakage, implant loosening or implant related pain.
* Care should be taken not to cut through surgical gloves when handling any sharp-edged surgical instrument and to take into account the risk of infection if a cut appears.

# MRI Safety Information

**Static Magnetic Field**

* Static magnetic field of 1.5 Tesla and 3-Tesla.
* Maximum spatial gradient magnetic field of 3000-Gauss/cm or less
* Maximum whole body average specific absorption rate (SAR) of 1.0 -W/kg or less under Normal mode for 15 minutes of scanning per pulse sequence.

**MRI-Related Heating**

Based on measurements and calculations of RF heating according to ASTM F2182-11a, the OrthoPediatrics Titanium PediPlates are expected to produce a maximum temperature rise of 6.1 °C for a whole body SAR of 1.0 W/kg in a 1.5-Tesla/64-MHz MR system and 4.0 °C for a whole body SAR of 1.0 W/kg in a 3.0-Tesla/128-MHz MR system for a 15-minute scan.

**Artifact Information**

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position to OrthoPediatrics implants. The maximum artifact beyond the implant was 38 mm for the spin echo sequence and 53 mm for the gradient echo sequence in a 3-Tesla MR system (GE Signa HDxt MR System). Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

The presence of other implants or the health state of the patient may require a modification of the MR conditions.

# Adverse Effects

The risks associated with this device are the same as with any metallic internal fixation device. These include, but are not limited to the following:

* Delayed or non-union that may lead to breakage of the implant
* Loss of fixation, attributable to non-union, osteoporosis, unstable comminuted fractures
* Bending, fracture, or migration of the implant
* Metal sensitivity, or allergic reaction to a foreign body
* Limb shortening, or decrease in bone density, due to compression of the fracture or bone resorption Pain, discomfort, or abnormal sensations due to the presence of the device
* Nerve damage due to surgical trauma
* Necrosis of bone
* Infection, both deep and superficial
* Death
* Vascular disorders including thrombophlebitis, pulmonary embolus, wound hematomas, avascular necrosis

These adverse effects include adverse effects that are important considerations for metallic internal fixation devices. These risks and general surgical risks should be explained to the patient prior to surgery.

# Sterilization Information

* Implants and instruments 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 after cleaning and sterilization.
* If received in a package, implants are removed from their packaging prior to sterilization. If received as a set, implants and instruments may be sterilized individually or as a set.
* Recessed and hidden areas within an instrument should be inspected 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.
* The sterilization parameters are only valid for devices that are adequately cleaned.
* **OrthoPediatrics implants and instruments are recommended to be sterilized by 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.**
* Sterilization cycle NOT validated for prion inactivation.
* Other sterilization methods and cycles may also be suitable. However, individuals 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 (for reference only):

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| **Cycle** | **Temperature** | **Exposure Time** | **Minimum Drying Time** |
| Pre-vacuum | 132 ° C | 4 minutes | 30 minutes |

**Note**: Drying times will vary according to the load size and should be increased for larger loads. The autoclave must be properly installed, maintained, and calibrated. Only legally marketed, FDA cleared sterilization wrap/pouches should be used by the end-user for packaging terminally sterilized devices. The autoclave manufacturer’s operating instructions and recommended guidelines for maximum sterilization load should be followed.

# Important Statement

* Please see the Surgical Technique for additional information. To obtain a copy of the Surgical Technique or Instrument Care, Cleaning and Sterilization Instructions CI-0001, please call the Customer Service Group at OrthoPediatrics at 574-268-6379.
* Surgical implants, instruments and packaging should be checked for defects before use and to verify the appropriate sizing.
* Any instrument with heavy scratches, flaws, corrosion, cracked seals, discoloration, or which has been damaged or does not function properly has reached its end of life, and should be discarded following hospital protocol.
* 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.
* Instruments for this system do not require disassembly or special procedures for proper cleaning.

# Storage and Handling

* Medical devices are sensitive to damage. Implants and instruments should be handled with care at all times.
* Storage zones for surgical instruments should be away from areas of humidity to avoid excessive corrosion. This recommendation is equally valid for transport and packaging of surgical instruments.
* Surgical implants, instruments and packaging should be checked for defects before use and to verify the appropriate sizing.