PediLoc® Tibia
SURGICAL TECHNIQUE

OrthoPediatrics™
Leading Innovation in Pediatric Orthopedics

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INDICATIONS

PediLoc® Tibial Plates are indicated for fractures, osteotomies and non-unions of the pediatric tibia.

When used in the European Union and the United Kingdom:
OrthoPediatrics® PediLoc™ Tibial Plates are indicated for osteotomies of the pediatric tibia.

This technique guide is limited to discussion of distal tibial rotational osteotomies.

Tibial torsion with resultant lever arm dysfunction is a common development in children with Cerebral Palsy. A distal tibial rotational osteotomy is indicated when this torsion is of functional consequence. Proximal tibial osteotomies have a higher risk of neurological damage and compartment syndrome.

In the majority of cases, a fibular osteotomy is not required. If the correction is significant (>30°) a fibular osteotomy should be considered.

A sterile tourniquet is recommended for this procedure. By using a sterile tourniquet, the surgeon can check the thigh-foot angle intra-operatively, prior to and after derotation of the tibia.

SURGICAL TECHNIQUE

1
Patient Positioning

Place the patient supine on a radiolucent operating table. Place a positioning bump under the ipsilateral leg to facilitate visualization. If a tourniquet is to be used, place a well-padded, sterile tourniquet around the proximal thigh of the operative leg. Position the image intensifier and fluoroscopy monitor on the opposite side of the operating table for adequate visualization of the surgical procedure. Alternatively, a mini C-arm can be used on the ipsilateral side. Fluoroscopy is essential for a successful procedure.

Before proceeding with the osteotomy, flex the hip and knee to 90 degrees and do a final check of the thigh-foot axis. Confirm the degree of in-toeing or out-toeing and the amount of correction you want to achieve.

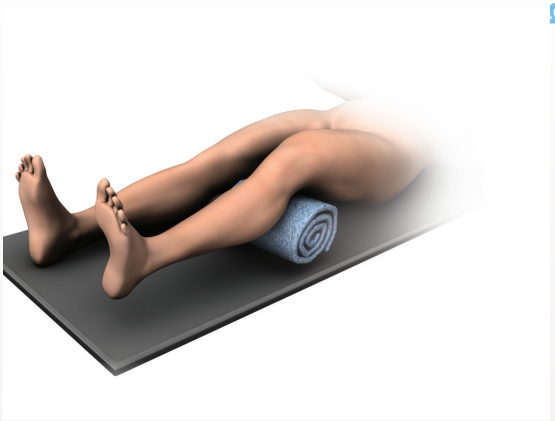

FIGURE 1: Patient positioning

2
Initial Incision

Identify and locate the distal tibial physis using fluoroscopy and mark the location of the incision. Make a longitudinal incision anteromedially, with the distal end of the incision at the level of the physis. Alternatively, a transverse incision can be made at the level of the preplanned osteotomy. Identify and protect the saphenous vein. Make a longitudinal incision in the periosteum. Begin 1.5cm proximal to the physis and proceed as far proximal as the incision allows. Complete subperiosteal dissection.

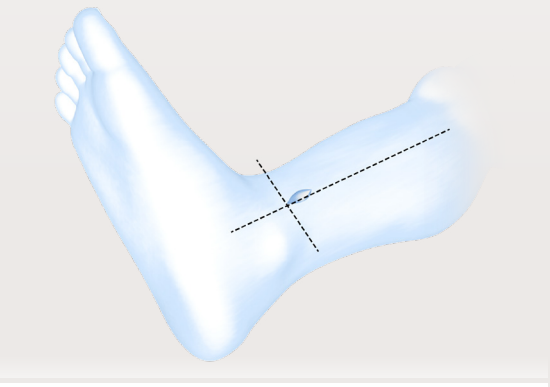

FIGURE 2: Longitudinal incision

3
Select Plate

Select either a narrow medial, wide medial or anterolateral plate, and place in the correct position. Confirm the correct position of the plate with the C-arm. Mark the area of planned osteotomy.

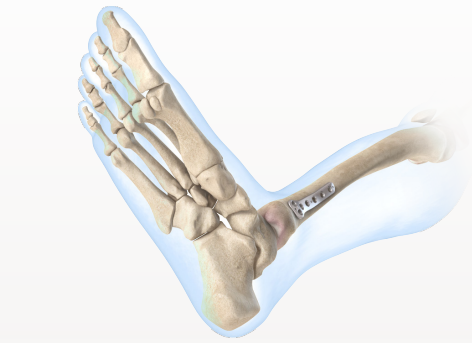

FIGURE 3: Plate selection

4
Perform Osteotomy

Place derotation pins proximal and distal to the planned osteotomy leaving room to place the implant. Pins should be placed to match the deformity. The proximal pin is the reference pin. The distal pin indicates the degree of correction to be achieved. Figure 4 shows an example of out-toeing that requires a 25 degree inward (clockwise) rotation of the distal fragment. The pins will then be aligned after performing the osteotomy and derotation.

Complete the metaphyseal osteotomy 2.0–2.5cm proximal to the physis.

1 *Note: The osteotomy must be parallel to the physis and perpendicular to the long axis of the tibia; otherwise, derotation will lead to angular deformity.*

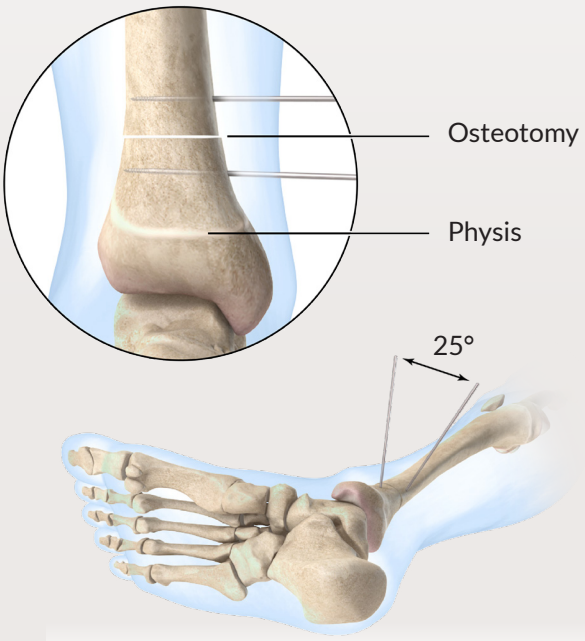

FIGURE 4: Example derotational guide pin placement

5
Screw Preparation

Ensure threaded drill guide is threaded into the plate on-axis with the locking hole to prevent subsequent cross-threading of the locking screw

FIGURE 5

Screw length can be read off the calibrated drill bit from the back side of the threaded drill guide.

Alternatively, depth for screw length can be read off of the back edge of the depth gauge sleeve. The bump on the back end of the depth gauge scale indicates the orientation of the hook on the probe

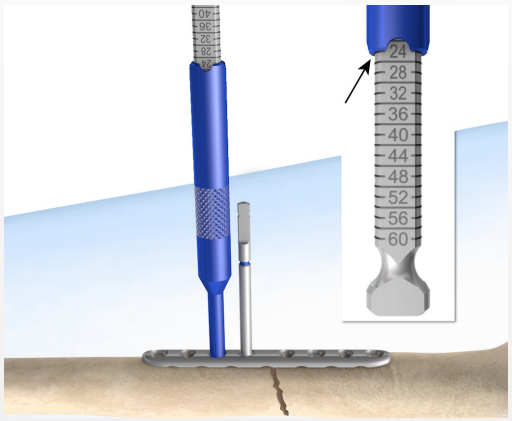

FIGURE 6

6
Place Screws

Following osteotomy, secure the distal fragment by placing locking or non-locking cortical bone screws in the distal aspect of the plate.

Alternatively, attach screws to the distal fragment before completing the osteotomy to maintain control of the distal fragment.

Avoid placing the plate such that a screw hole is directly over the osteotomy site.

Care should be taken when inserting screws near a growth plate, joint space, or another screw/implant. Use fluoroscopy to check final placement.

Continue to tighten until no additional axial rotation occurs. Over-tightening of a screw can lead to driver fracture, stripping of the screw hexalobe, or damage to the screw/plate interface.

Under tightening or cross-threading of a locking screw can lead to weakening of construct strength. Ensure locking screws are on-axis with the locking hole and tightened such that no additional rotation occurs.

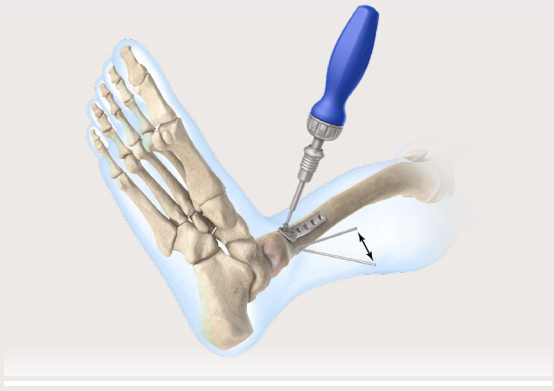

FIGURE 7: Place screws to secure distal fragment

7

Complete Derotation

Complete the derotation by aligning the derotation pins until they reach the same plane.

Care should be taken to ensure the osteotomy (or fracture) is fully reduced.

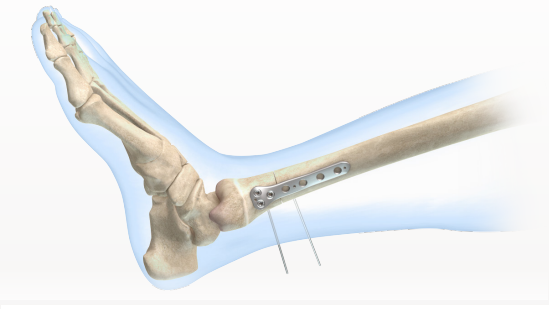

FIGURE 8a: Align derotation pins to complete derotation

Secure the proximal fragment by placing locking or non-locking screws in the proximal fragment. Loss of rotation can be prevented by using locking screws in the proximal fragment.

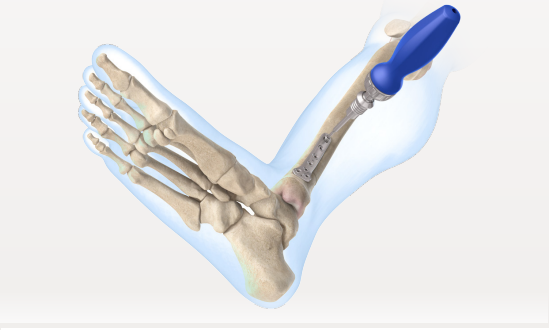

FIGURE 8b: Place screws to secure proximal fragment

Implant Removal:

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.

Product information

3.5mm LEFT NARROW MEDIAL DISTAL LOCKING COMPRESSION PLATES

Item Number	Qty	Description	Holes
00-0903-3102	1	3.5mm Narrow Medial Distal Tibial Locking Compression Plate	2
00-0903-3103	1	3.5mm Narrow Medial Distal Tibial Locking Compression Plate	3
00-0903-3104	1	3.5mm Narrow Medial Distal Tibial Locking Compression Plate	4
00-0903-3105	1	3.5mm Narrow Medial Distal Tibial Locking Compression Plate	5
00-0903-3106	1	3.5mm Narrow Medial Distal Tibial Locking Compression Plate	6
00-0903-3108	1	3.5mm Narrow Medial Distal Tibial Locking Compression Plate	8

3.5mm RIGHT NARROW MEDIAL DISTAL LOCKING COMPRESSION PLATES

Item Number	Qty	Description	Holes
00-0903-3202	1	3.5mm Narrow Medial Distal Tibial Locking Compression Plate	2
00-0903-3203	1	3.5mm Narrow Medial Distal Tibial Locking Compression Plate	3
00-0903-3204	1	3.5mm Narrow Medial Distal Tibial Locking Compression Plate	4
00-0903-3205	1	3.5mm Narrow Medial Distal Tibial Locking Compression Plate	5
00-0903-3206	1	3.5mm Narrow Medial Distal Tibial Locking Compression Plate	6
00-0903-3208	1	3.5mm Narrow Medial Distal Tibial Locking Compression Plate	8

3.5mm LEFT WIDE MEDIAL DISTAL LOCKING COMPRESSION PLATES

Item Number	Qty	Description	Holes
00-0903-3302	1	3.5mm Wide Medial Distal Tibial Locking Compression Plate	2
00-0903-3303	1	3.5mm Wide Medial Distal Tibial Locking Compression Plate	3
00-0903-3304	1	3.5mm Wide Medial Distal Tibial Locking Compression Plate	4
00-0903-3305	1	3.5mm Wide Medial Distal Tibial Locking Compression Plate	5
00-0903-3306	1	3.5mm Wide Medial Distal Tibial Locking Compression Plate	6
00-0903-3308	1	3.5mm Wide Medial Distal Tibial Locking Compression Plate	8

3.5mm RIGHT WIDE MEDIAL DISTAL LOCKING COMPRESSION PLATES

Item Number	Qty	Description	Holes
00-0903-3402	1	3.5mm Wide Medial Distal Tibial Locking Compression Plate	2
00-0903-3403	1	3.5mm Wide Medial Distal Tibial Locking Compression Plate	3
00-0903-3404	1	3.5mm Wide Medial Distal Tibial Locking Compression Plate	4
00-0903-3405	1	3.5mm Wide Medial Distal Tibial Locking Compression Plate	5
00-0903-3406	1	3.5mm Wide Medial Distal Tibial Locking Compression Plate	6
00-0903-3408	1	3.5mm Wide Medial Distal Tibial Locking Compression Plate	8

Product information

3.5mm LEFT ANTEROLATERAL DISTAL LOCKING COMPRESSION PLATES

Item Number	Qty	Description	Holes
00-0903-2102	1	3.5mm Anterolateral Distal Tibial Locking Compression Plate	2
00-0903-2103	1	3.5mm Anterolateral Distal Tibial Locking Compression Plate	3
00-0903-2104	1	3.5mm Anterolateral Distal Tibial Locking Compression Plate	4

3.5mm RIGHT ANTEROLATERAL DISTAL LOCKING COMPRESSION PLATES

Item Number	Qty	Description	Holes
00-0903-2202	1	3.5mm Anterolateral Distal Tibial Locking Compression Plate	2
00-0903-2203	1	3.5mm Anterolateral Distal Tibial Locking Compression Plate	3
00-0903-2204	1	3.5mm Anterolateral Distal Tibial Locking Compression Plate	4

3.5mm LOCKING SCREW, T15 HEXALOBE, SELF TAPPING

Item Number	Qty	Description	Length
00-0903-2610	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	10mm
00-0903-2612	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	12mm
00-0903-2614	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	14mm
00-0903-2616	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	16mm
00-0903-2618	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	18mm
00-0903-2620	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	20mm
00-0903-2622	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	22mm
00-0903-2624	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	24mm
00-0903-2626	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	26mm
00-0903-2628	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	28mm
00-0903-2630	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	30mm
00-0903-2632	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	32mm
00-0903-2634	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	34mm
00-0903-2636	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	36mm
00-0903-2638	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	38mm

Product information

3.5mm LOCKING SCREW, T15 HEXALOBE, SELF TAPPING CONTINUED

Item Number	Qty	Description	Length
00-0903-2640	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	40mm
00-0903-2642	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	42mm
00-0903-2644	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	44mm
00-0903-2646	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	46mm
00-0903-2648	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	48mm
00-0903-2650	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	50mm
00-0903-2652	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	52mm
00-0903-2654	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	54mm
00-0903-2656	5	3.5mm Locking Screw, T15 Hexalobe, self tapping	56mm

3.5mm CORTICAL SCREW, T15 HEXALOBE, SELF TAPPING

Item Number	Qty	Description	Length
00-0903-2510	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	10mm
00-0903-2512	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	12mm
00-0903-2514	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	14mm
00-0903-2516	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	16mm
00-0903-2518	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	18mm
00-0903-2520	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	20mm
00-0903-2522	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	22mm
00-0903-2524	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	24mm
00-0903-2526	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	26mm
00-0903-2528	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	28mm
00-0903-2530	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	30mm
00-0903-2532	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	32mm
00-0903-2534	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	34mm
00-0903-2536	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	36mm
00-0903-2538	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	38mm

3.5mm CORTICAL SCREW, T15 HEXALOBE, SELF TAPPING CONTINUED

Item Number	Qty	Description	Length
00-0903-2540	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	40mm
00-0903-2542	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	42mm
00-0903-2544	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	44mm
00-0903-2546	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	46mm
00-0903-2548	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	48mm
00-0903-2550	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	50mm
00-0903-2552	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	52mm
00-0903-2554	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	54mm
00-0903-2556	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	56mm
00-0903-2558	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	58mm
00-0903-2560	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	60mm
00-0903-2565	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	65mm
00-0903-2570	5	3.5mm Cortical Screw, T15 Hexalobe, self tapping	70mm

INSTRUMENTATION

Item Number	Qty	Description
01-0903-0005	2	T15 Retaining Driver, Short
01-0903-0002	3	2.5mm Threaded Drill Guide
01-1030-001	1	AO Ratchet Handle
01-1030-007	1	Self-Holding Screw Forceps
01-1050-0032	2	2.5mm Drill Bit, Calibrated
01-1050-0039	6	1.6mm Guide Wire
01-1200-0080	1	3.5mm Depth Gauge (Blue), 10 - 60mm
01-0999-2002	1	Scale, 10 - 60mm

CASE & TRAY

Item Number	Qty	Description
01-0903-5001	1	PediLoc Tibia Case Shell
01-0903-5002	1	PediLoc Tibia Implant Plates Tray
01-0903-5003	1	PediLoc Tibia Screw Caddy
01-0903-5004	1	PediLoc Tibia Case Lid
01-0903-1001	1	PediLoc Tibia Implant Set - 6 & 8 Hole Plates
01-0999-1001	1	OrthoPediatrics Lid, Small

IMPORTANT MEDICAL INFORMATION

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 PediLoc™ Distal Tibia 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.
- 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.
- USA: The System has not been tested for safety and compatibility with MRI. Risks of heating, migration, or image artifacts may exist. Physician experience should dictate acceptability of the use of MRI.
- 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.

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.

MR conditions have been established by non-clinical testing for use Outside the United States.

MRI Safety Information

MRI Safety Information for PediLoc Tibial Plate System

In non-clinical testing the OrthoPediatrics PediLoc Tibial Plate System implants were determined to be MR-Conditional. A patient with this device can be safely scanned immediately after device placement under the following conditions:

Static Magnetic Field

- Static magnetic field of 1.5 Tesla and 3.0 Tesla.
- Maximum spatial gradient magnetic field of 2000 Gauss/cm or less
- Maximum whole body average specific absorption rate (SAR) of 1.0 W/kg or less for 15 minutes of scanning per pulse sequence.

MRI-Related Heating

Based on measurements and calculations of RF heating according to ASTM F2182, the OrthoPediatrics implants are expected to produce a maximum temperature rise of 6.1 °C for a whole body SAR of 1.0 W/kg 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 55 mm for the spin echo sequence and 60 mm for the gradient echo sequence in a 3.0 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.

CAUTION: Federal law restricts this device to sale by or the order of a Physician.

CAUTION: Devices are supplied Non-Sterile. Clean and sterilize before use according to instructions.

CAUTION: Implants components are single-use. Do not reuse.

CAUTION: The device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine

CAUTION: Only those instruments and implants contained within this system are recommended for use with this technique. Other instruments or implants used in combination or in place of those contained within this system is not recommended.

NOTE: This technique has been provided by one of our medical advisors only as guidance and it is not intended to limit the methods used by trained and experienced surgeons.

Instructions For Use (IFU), cleaning instructions, and surgical techniques may be obtained by calling OrthoPediatrics® Customer Service at 574-268-6379. Read and understand indications, warnings, and adverse effects explained in IFU's prior to use.

CE 2797 *CE Mark is valid only if also printed on the product label or device itself*

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The information on the products and/or procedures contained in this document in of general nature and does not represent medical advice or recommendations. Since this information does not constitute any diagnostic or therapeutic statement with regard to any individual medical case, individual examination and advising of the respective patient are absolutely necessary and are not replaced by this document in whole or in part.

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