PediLoc® Tibia







PediLoc®

PediLoc® Tibia Surgical Technique

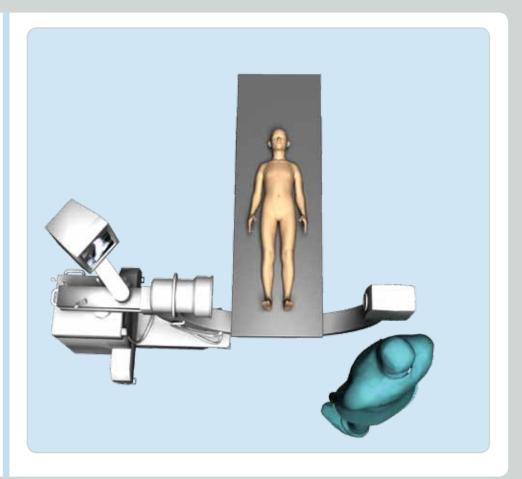
The technique description herein is made available to the healthcare professional to illustrate the author's suggested treatment for an uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the specific patient.

- PediLoc[®] Tibia is indicated for fractures and osteotomies of the proximal and distal 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 neurologic 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 intraoperatively prior to and after derotation of the tibia.
- Read and understand indications, warnings and adverse effects as explained in the IFU prior to use.
- The adverse effects and contraindications listed in the IFU are important considerations. These risks and general surgical risks should be explained to the patient prior to surgery.
- To obtain a copy of the instructions for use (IFU) and cleaning instructions (CI), call OrthoPediatrics[®] customer service at 574-268-6379.



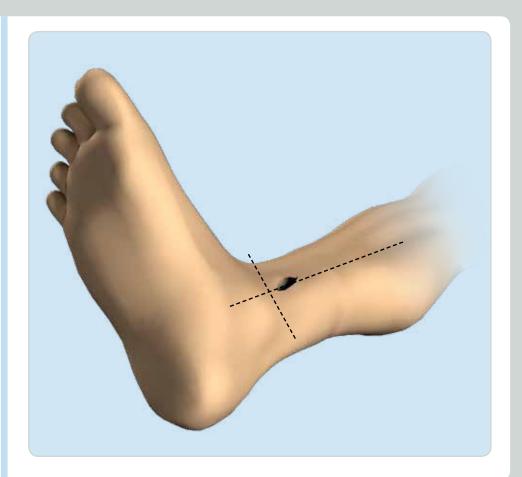
Place the patient supine on a radiolucent operating table. A bump may be placed under the ipsilateral leg in order to facilitate visualization. If a tourniquet is to be used, place a well padded sterile tourniquet around the proximal thigh of the operative leg.

Position the image intensifier and flouroscopy monitor on the opposite side of the operating table for adequate visualization of the surgical procedure. Alternatively, the mini C-arm can be used on the ipsilateral side. Use of flouroscopy is essential to the success of this procedure.



2

Identify and locate the distal tibial physis using flouroscopy and mark the incision location. Make a longitudinal incision anteromedially with the distal end of the incision at the level of the physis. Alternatively, make a transverse incision at the level of the pre-planned osteotomy. Identify and protect the saphenous vein. Incise the periosteum longitudinally, beginning 1.5 cm proximal to the physis and proceeding as far proximal as the incision allows. Complete subperiosteal dissection.



Select one of the plates (narrow medial, wide medial or anterolateral) and position. Once positioned, confirm its position with the C-arm. Mark the area of planned osteotomy.

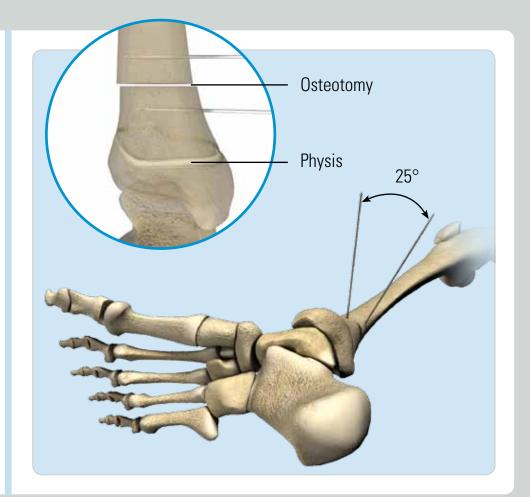


4

Place derotation pins proximal and distal to the planned osteotomy.

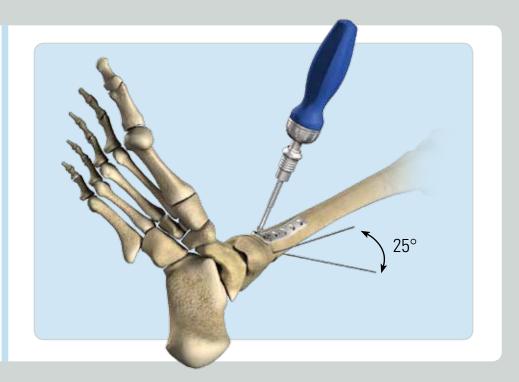
Complete the metaphyseal osteotomy 2.0-2.5 cm proximal to the physis and derotate the distal fragment.

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.



3

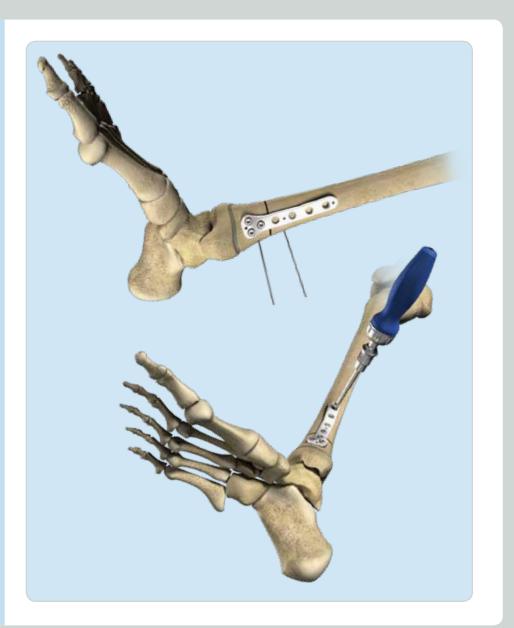
After the osteotomy is complete, secure the distal fragment by placing locking or non-locking cortical bone screws in the distal aspect of the plate. Alternatively, attach screws to the distal fragment prior to completing the osteotomy in order to maintain control of the distal fragment.



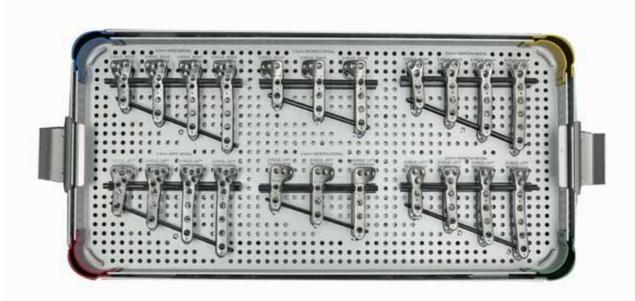
6

Complete the derotation by aligning the derotation pins in the same plane.

Secure the proximal fragment by placing locking or non-locking screws in the proximal fragment. The use of locking screws in the proximal fragment will prevent loss of rotation.



5



3.5mm Wide Medial

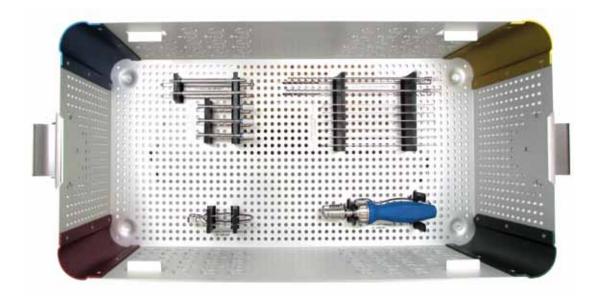
PROD #	ΟΤΥ	PRODUCT
00-0903-3302	1	3.5mm Wide Medial Distal Tibial Locking Compression 2 hole plate left
00-0903-3303	1	3.5mm Wide Medial Distal Tibial Locking Compression 3 hole plate left
00-0903-3304	1	3.5mm Wide Medial Distal Tibial Locking Compression 4 hole plate left
00-0903-3305	1	3.5mm Wide Medial Distal Tibial Locking Compression 5 hole plate left
00-0903-3402	1	3.5mm Wide Medial Distal Tibial Locking Compression 2 hole plate right
00-0903-3403	1	3.5mm Wide Medial Distal Tibial Locking Compression 3 hole plate right
00-0903-3404	1	3.5mm Wide Medial Distal Tibial Locking Compression 4 hole plate right
00-0903-3405	1	3.5mm Wide Medial Distal Tibial Locking Compression 5 hole plate right

3.5mm Narrow Medial

PROD #	ΟΤΥ	PRODUCT
00-0903-3102	1	3.5mm Narrow Medial Distal Tibial Locking Compression 2 hole plate left
00-0903-3103	1	3.5mm Narrow Medial Distal Tibial Locking Compression 3 hole plate left
00-0903-3104	1	3.5mm Narrow Medial Distal Tibial Locking Compression 4 hole plate left
00-0903-3105	1	3.5mm Narrow Medial Distal Tibial Locking Compression 5 hole plate left
00-0903-3202	1	3.5mm Narrow Medial Distal Tibial Locking Compression 2 hole plate right
00-0903-3203	1	3.5mm Narrow Medial Distal Tibial Locking Compression 3 hole plate right
00-0903-3204	1	3.5mm Narrow Medial Distal Tibial Locking Compression 4 hole plate right
00-0903-3205	1	3.5mm Narrow Medial Distal Tibial Locking Compression 5 hole plate right

3.5mm Anterolateral Medial

PROD #	QTY	PRODUCT
00-0903-2102	1	3.5mm Anterolateral Distal Tibial Locking Compression 2 hole plate left
00-0903-2103	1	3.5mm Anterolateral Distal Tibial Locking Compression 3 hole plate left
00-0903-2104	1	3.5mm Anterolateral Distal Tibial Locking Compression 4 hole plate left
00-0903-2202	1	3.5mm Anterolateral Distal Tibial Locking Compression 2 hole plate right
00-0903-2203	1	3.5mm Anterolateral Distal Tibial Locking Compression 3 hole plate right
00-0903-2204	1	3.5mm Anterolateral Distal Tibial Locking Compression 4 hole plate right



3.5mm Screws

PROD #	ΩΤΥ	PRODUCT
000-0903-2510/2560	5	3.5mm Self Tapping Cortical Screw with T15 Hexalobe 10mm through 60mm
00-0903-2565/2570	5	3.5mm Self Tapping Cortical Screw with T15 Hexalobe 65mm and 70mm
00-0903-2610/2656	5	3.5mm Locking Cortical Screw with T15 Hexalobe 10mm through 56mm

Instruments

PROD #	ΩΤΥ	PRODUCT
01-0903-0003	2	T15 Hexalobe Driver
01-0903-0002	3	2.5 mm Threaded Drill Guide
01-1030-007	1	Self-Holding Screw Forceps
01-1050-0032	2	2.5 Drill Bit, Calibrated
01-1050-0039	6	1.60mm Guide Wire
01-1030-001	1	AO Ratchet Handle

May use additional instrumentation from the PediLoc® Small Frag system

PROD #	ΩΤΥ	PRODUCT
01-1050-0025	1	Depth Gauge Short, 10-50mm
01-1050-0026	1	Depth Gauge Long, 10-100mm

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

CAUTION: Devices are supplied non-sterile. Clean and sterilize before use according to instructions.

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

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

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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.



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