PediLoc® Extension Osteotomy Plate (PLEO)

OrthoPediatrics®
Leading Innovation in Pediatric Orthopedics

System Overview

Surgical Technique

Product Information

INDICATIONS

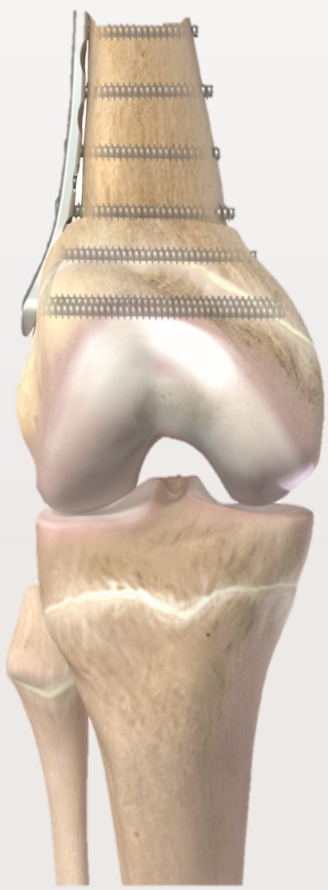
The OrthoPediatrics PediLoc® Locking Plate System is used for pediatric patients as indicated for pelvic, small and long bone fractures, including those of tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle. Indications for buttressing multi 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.

PRODUCT OVERVIEW

The OrthoPediatrics PediLoc® Extension Osteotomy Plate (PLEO) is a part of the OrthoPediatrics PediLoc® System and consists of 3.5mm and 4.5mm plates, left and right side specific.

The PediLoc Extension Osteotomy Plate (PLEO) is designed to fit the anatomy of the distal femur in children and adolescents above the distal femoral physis. The distal portion of the plate is designed to allow for three locking screws to be placed in the distal bone segment at an angle parallel to the distal femoral physis. The proximal portion of the plate is designed to accept locking or non-locking screws.

Plates are pre-contoured to minimize intraoperative plate bending and contouring, with a scalloped undersurface that is designed to be periosteal sparing. Plates are also low profile to reduce the potential for damage to the surrounding soft tissues.



1
PREPARATION

Determine the extent of distal femoral extension desired. The degree of distal femoral extension is determined from clinical examination and a lateral x-ray of the knee in maximum extension. Measure the tibio-femoral angle on the lateral projection.

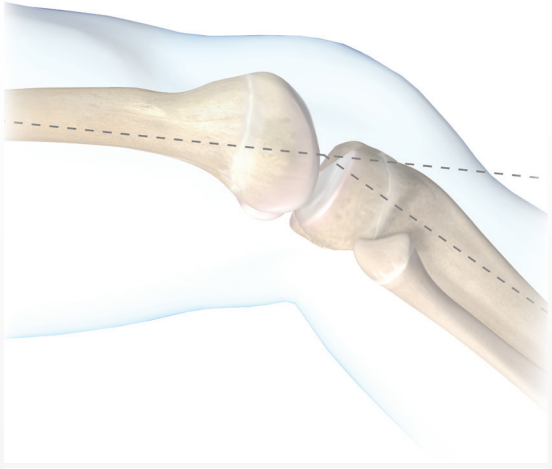


FIGURE 1: Determine extent of distal femoral extension desired

2
PATIENT POSITIONING

Position the patient supine on a radiolucent operating table. Visualization of the hip, knee and ankle joint with the image intensifier is necessary.

Prep and drape the affected lower extremity up to the hip. Drape to allow maximal exposure of the hip as well as the lower extremity.

3
INCISION

Using fluoroscopy, mark out the level of the distal femoral physis. Make a standard lateral approach to the distal femur. If planning a concomitant patellar tendon shortening, curve the distal portion of the incision anteriorly over the patellar tendon.

Perform a standard lateral approach to the distal femur. Superficial dissection may extend distal to the level of the physis to allow the deeper dissection to extend just proximal to the physis.

Split the iliotibial band and expose the vastus lateralis. Separate the vastus lateralis from the lateral intermuscular septum and expose the distal femur subperiosteally.

Dissect as far distally as possible approaching the physis. Beware not to injure the perichondrial ring.

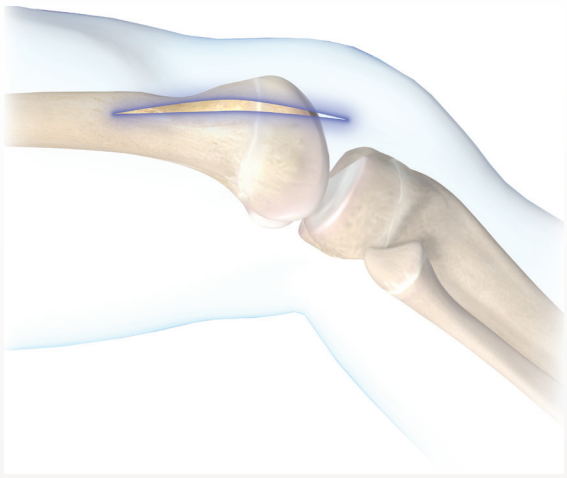


FIGURE 2: Make incision using standard lateral approach

4
PLATE POSITIONING

Place a 2.0mm guide wire parellel to and just proximal to the distal femoral physis, slightly anterior to the midpoint of the femur. This will help with translation later in the procedure.

Slide the plate over the guide wire to ensure that all the screw holes in the distal flared portion of the plate will engage bone. The shaft of the plate should be in line with the tibia, not the femoral shaft. This will account for the extension created after osteotomy.

If needed, readjust the guide wire to a position that is slightly anterior to the mid axis of the distal femur and just proximal to the physis to ensure that all the distal locking screw holes will engage bone in the angled position.

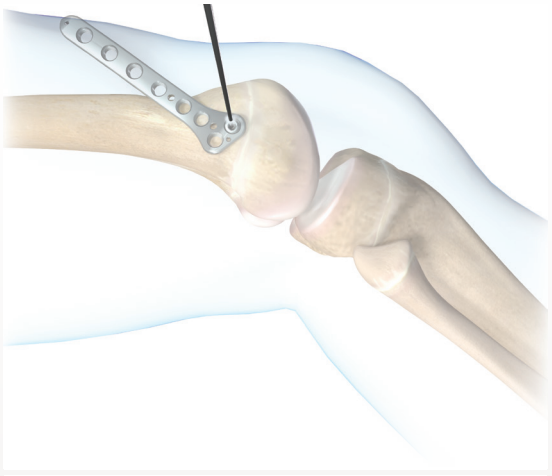


FIGURE 3: Position plate using guide wire

Using fluoroscopy, hold the plate against the shaft of the distal lateral femur. Sometimes the plate will need to be contoured to prevent excess valgus following osteotomy. Utilize the threaded drill guides in the distal holes while contouring to prevent damage to the internal threads.

FIGURE 4: Hold plate against distal femur shaft

5
PROVISIONAL PLATE FIXATION

Place the knee in the maximally extended position. Using the plate holder, align the plate with the long axis of the tibia. In the appropriately angled position, insert the three distal locking screws in the plate for provisional fixation. Hold the plate during the first screw to ensure the plate does not rotate.

1. *Note: If using the 3.5mm plate, use the 2.5mm drill bit for 3.5mm locking screws.*

2. *Note: If using the 4.5mm plate, use the 3.2mm drill bit for 4.5mm locking screws.*

Mark the level of the osteotomy proximal to the flare on the plate and remove the plate. Score the lateral femur to prevent malrotation when fixing the osteotomy. Alternatively, place k-wires such that after the osteotomy, you may rotate the femur to accomplish de-rotation at the same time as extension.

3. *Note: It is recommended to avoid placing the osteotomy in the location of the screw hole on the plate.*

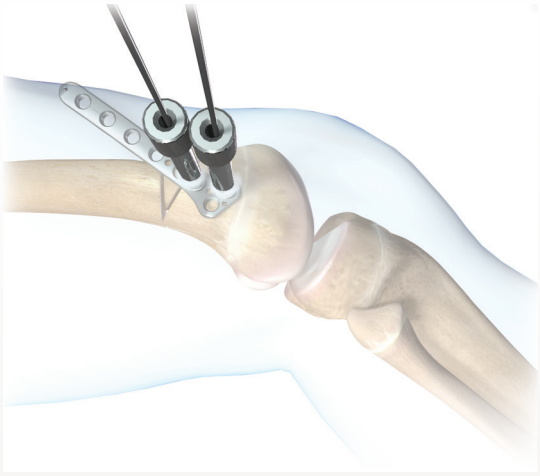


FIGURE 5: Align plate with the long axis of the bone

6
PERFORM OSTEOTOMY

Using an oscillating saw, cut the femur perpendicular to the long axis of the femur and parallel to the growth plate.

1 *Note: Deviations from this technique may result in angular deformity.*

Make a second cut to match the angle of correction desired and remove the wedge of bone.

Once the osteotomy is completed, perform a trial reduction. Pay careful attention to the tension created posteriorly and also to translation. The distal fragment should be translated posteriorly to minimize the anterior bump.

2 *Note: If performing the procedure bilaterally, shortening the femur should be strongly considered. Taking a wedge of bone out will make subsequent reduction easier and prevent lengthening the path of the neurovascular structures. If performing the osteotomy unilaterally, shorting is usually not necessary.*

3 *Note: Overall, consider shortening if tension on the neurovascular structures is significant. If there is too much tension posteriorly, shorten the femur initally by a hemi-wedge anteriorly on the distal fragment or shaving the distal anterior prominence to allow a better match between the angulated distal fragment and the proximal shaft.*

Orient the long axis of the handle in desired position of osteotomy. Handle is available in right and left.

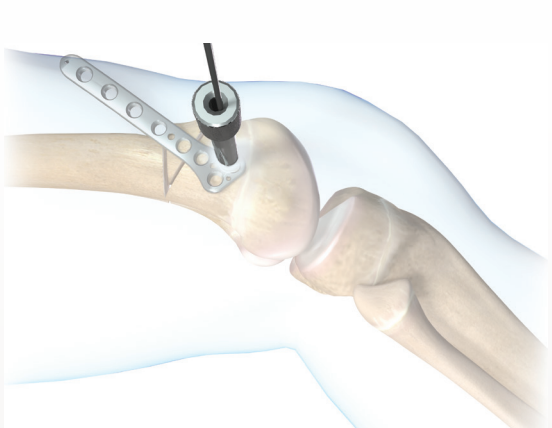


FIGURE 6: Perform osteotomy and trial reduction

7
PLATE ATTACHMENT

Once trial reduction looks satisfactory, apply the plate with single locking screw distally. Align the plate and observe the coronal plate alignment, watching for excess valgus. If needed, contour the plate further to resist valgus.

Attach the plate distally and proximally. Use locking screws distally and locking or standard screws proximally.

1. *Note: If using the 3.5mm plate, use the 2.5mm drill bit for locking and non-locking screws.*
2. *Note: If using the 4.5mm plate, use the 3.2mm drill bit for locking and non-locking screws.*
3. *Note: Take care to select the appropriate screw size and diameter. If screw is not desired length, remove and replace.*
4. *Note: Be sure to use Hex Driver for screw insertion, and avoid cross-threading.*

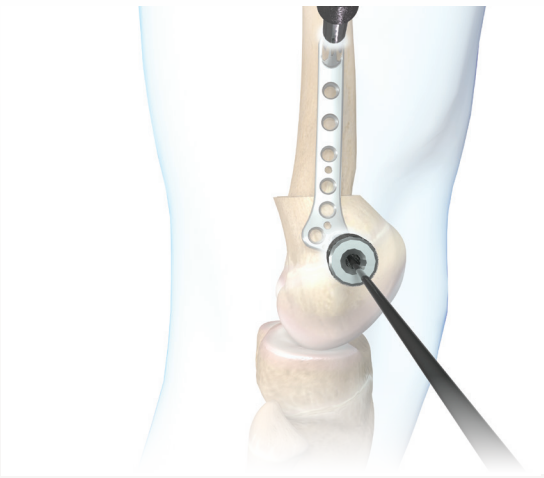


FIGURE 7: Apply plate using single locking screw

3.5MM PLATES

Item Number	Qty	Description	Holes
00-1065-3004	2	3.5mm Contour Locking Compression Femur Plate Right	4
00-1065-3006	2	3.5mm Contour Locking Compression Femur Plate Right	6
00-1065-3008	2	3.5mm Contour Locking Compression Femur Plate Right	8
00-1065-3104	2	3.5mm Contour Locking Compression Femur Plate Left	4
00-1065-3106	2	3.5mm Contour Locking Compression Femur Plate Left	6
00-1065-3108	2	3.5mm Contour Locking Compression Femur Plate Left	8

INSTRUMENTS

Item Number	Qty	Description
01-1065-0010	5	Plate Fixation Pin 30mm
01-1050-0014	2	Bending Iron
01-1065-3030	1	3.5mm Plate Handle

CASE & TRAY

Item Number	Qty	Description
01-1065-3500	1	3.5mm Locking Compression Femur Plate Case Base
01-1065-3510	1	3.5mm Locking Compression Femur Plate Case Inner Tray
01-1065-3520	1	3.5mm Locking Compression Femur Plate Case Lid

4.5MM PLATES

Item Number	Qty	Description	Holes
00-1065-4004	2	4.5mm Contour Locking Compression Femur Plate Right	4
00-1065-4006	2	4.5mm Contour Locking Compression Femur Plate Right	6
00-1065-4008	2	4.5mm Contour Locking Compression Femur Plate Right	8
00-1065-4104	2	4.5mm Contour Locking Compression Femur Plate Left	4
00-1065-4106	2	4.5mm Contour Locking Compression Femur Plate Left	6
00-1065-4108	2	4.5mm Contour Locking Compression Femur Plate Left	8

INSTRUMENTS

Item Number	Qty	Description
01-1065-0010	5	Plate Fixation Pin 30mm
01-1050-0014	2	Bending Iron
01-1065-4030	1	4.5mm Plate Handle

CASE & TRAY

Item Number	Qty	Description
01-1065-4500	1	4.5mm Locking Compression Femur Plate Case Base
01-1065-4510	1	4.5mm Locking Compression Femur Plate Case Inner Tray
01-1065-4520	1	4.5mm Locking Compression Femur Plate Case Lid

3.5MM T15 MODULAR SCREW CADDY

Item Number	Qty	Description
00-0903-2510	6	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 10mm
00-0903-2512	6	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 12mm
00-0903-2514	6	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 14mm
00-0903-2516	6	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 16mm
00-0903-2518	6	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 18mm
00-0903-2520	6	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 20mm
00-0903-2522	6	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 22mm
00-0903-2524	6	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 24mm
00-0903-2526	6	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 26mm
00-0903-2528	6	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 28mm
00-0903-2530	6	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 30mm
00-0903-2532	4	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 32mm
00-0903-2534	4	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 34mm
00-0903-2536	4	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 36mm
00-0903-2538	4	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 38mm
00-0903-2540	4	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 40mm
00-0903-2542	4	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 42mm
00-0903-2544	4	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 44mm
00-0903-2546	4	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 46mm
00-0903-2548	4	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 48mm
00-0903-2550	4	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 50mm
00-0903-2555	4	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 55mm
00-0903-2560	4	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 60mm
00-0903-2565	4	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 65mm
00-0903-2570	4	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 70mm

3.5mm Non-Locking
Cortical Screw
Full Thread
00-0903-25XX

3.5MM T15 MODULAR SCREW CADDY

Item Number	Qty	Description
00-0903-2610	6	3.5mm Locking Cortical Screw with T15 Hexalobe, size 10mm
00-0903-2612	6	3.5mm Locking Cortical Screw with T15 Hexalobe, size 12mm
00-0903-2614	6	3.5mm Locking Cortical Screw with T15 Hexalobe, size 14mm
00-0903-2616	6	3.5mm Locking Cortical Screw with T15 Hexalobe, size 16mm
00-0903-2618	6	3.5mm Locking Cortical Screw with T15 Hexalobe, size 18mm
00-0903-2620	6	3.5mm Locking Cortical Screw with T15 Hexalobe, size 20mm
00-0903-2622	6	3.5mm Locking Cortical Screw with T15 Hexalobe, size 22mm
00-0903-2624	6	3.5mm Locking Cortical Screw with T15 Hexalobe, size 24mm
00-0903-2626	6	3.5mm Locking Cortical Screw with T15 Hexalobe, size 26mm
00-0903-2628	6	3.5mmLocking Cortical Screw with T15 Hexalobe, size 28mm
00-0903-2630	6	3.5mm Locking Cortical Screw with T15 Hexalobe, size 30mm
00-0903-2632	4	3.5mm Locking Cortical Screw with T15 Hexalobe, size 32mm
00-0903-2634	4	3.5mm Locking Cortical Screw with T15 Hexalobe, size 34mm
00-0903-2636	4	3.5mm Locking Cortical Screw with T15 Hexalobe, size 36mm
00-0903-2638	4	3.5mmLocking Cortical Screw with T15 Hexalobe, size 38mm
00-0903-2640	4	3.5mm Locking Cortical Screw with T15 Hexalobe, size 40mm
00-0903-2642	4	3.5mm Locking Cortical Screw with T15 Hexalobe, size 42mm
00-0903-2644	4	3.5mm Locking Cortical Screw with T15 Hexalobe, size 44mm
00-0903-2646	4	3.5mm Locking Cortical Screw with T15 Hexalobe, size 46mm
00-0903-2648	4	3.5mm Locking Cortical Screw with T15 Hexalobe, size 48mm
00-0903-2650	4	3.5mm Locking Cortical Screw with T15 Hexalobe, size 50mm
00-0903-2655	4	3.5mm Locking Cortical Screw with T15 Hexalobe, size 55mm
00-0903-2660	4	3.5mm Locking Cortical Screw with T15 Hexalobe, size 60mm
00-0903-2665	4	3.5mm Locking Cortical Screw with T15 Hexalobe, size 65mm
00-0903-2670	4	3.5mm Locking Cortical Screw with T15 Hexalobe, size 70mm

3.5mm Locking Cortical Screw Full Thread 00-0903-26XX

4.5MM T20 MODULAR SCREW CADDY

Item Number	Qty	Description
00-0907-4510	6	4.5mm Non-Locking Cortical Screw Full Thread, 10mm
00-0907-4512	5	4.5mm Non-Locking Cortical Screw Full Thread, 12mm
00-0907-4514	6	4.5mm Non-Locking Cortical Screw Full Thread, 14mm
00-0907-4516	5	4.5mm Non-Locking Cortical Screw Full Thread, 16mm
00-0907-4518	6	4.5mm Non-Locking Cortical Screw Full Thread, 18mm
00-0907-4520	5	4.5mm Non-Locking Cortical Screw Full Thread, 20mm
00-0907-4522	6	4.5mm Non-Locking Cortical Screw Full Thread, 22mm
00-0907-4524	5	4.5mm Non-Locking Cortical Screw Full Thread, 24mm
00-0907-4526	6	4.5mm Non-Locking Cortical Screw Full Thread, 26mm
00-0907-4528	5	4.5mm Non-Locking Cortical Screw Full Thread, 28mm
00-0907-4530	6	4.5mm Non-Locking Cortical Screw Full Thread, 30mm
00-0907-4532	5	4.5mm Non-Locking Cortical Screw Full Thread, 32mm
00-0907-4534	6	4.5mm Non-Locking Cortical Screw Full Thread, 34mm
00-0907-4536	5	4.5mm Non-Locking Cortical Screw Full Thread, 36mm
00-0907-4538	6	4.5mm Non-Locking Cortical Screw Full Thread, 38mm
00-0907-4540	5	4.5mm Non-Locking Cortical Screw Full Thread, 40mm
00-0907-4542	6	4.5mm Non-Locking Cortical Screw Full Thread, 42mm
00-0907-4544	5	4.5mm Non-Locking Cortical Screw Full Thread, 44mm
00-0907-4546	6	4.5mm Non-Locking Cortical Screw Full Thread, 46mm
00-0907-4548	5	4.5mm Non-Locking Cortical Screw Full Thread, 48mm
00-0907-4550	6	4.5mm Non-Locking Cortical Screw Full Thread, 50mm
00-0907-4555	4	4.5mm Non-Locking Cortical Screw Full Thread, 55mm
00-0907-4560	4	4.5mm Non-Locking Cortical Screw Full Thread, 60mm
00-0907-4565	4	4.5mm Non-Locking Cortical Screw Full Thread, 65mm
00-0907-4570	4	4.5mm Non-Locking Cortical Screw Full Thread, 70mm
00-0907-4575	4	4.5mm Non-Locking Cortical Screw Full Thread, 75mm
00-0907-4580	4	4.5mm Non-Locking Cortical Screw Full Thread, 80mm

4.5mm Non-Locking
Cortical Screw
Full Thread
00-0907-45XX

4.5MM T20 MODULAR SCREW CADDY

Item Number	Qty	Description
00-0907-4610	6	4.5mm Locking Cortical Screw Full Thread, 10mm
00-0907-4612	6	4.5mm Locking Cortical Screw Full Thread, 12mm
00-0907-4614	6	4.5mm Locking Cortical Screw Full Thread, 14mm
00-0907-4616	6	4.5mm Locking Cortical Screw Full Thread, 16mm
00-0907-4618	6	4.5mm Locking Cortical Screw Full Thread, 18mm
00-0907-4620	6	4.5mm Locking Cortical Screw Full Thread, 20mm
00-0907-4622	6	4.5mm Locking Cortical Screw Full Thread, 22mm
00-0907-4624	6	4.5mm Locking Cortical Screw Full Thread, 24mm
00-0907-4626	6	4.5mm Locking Cortical Screw Full Thread, 26mm
00-0907-4628	6	4.5mm Locking Cortical Screw Full Thread, 28mm
00-0907-4630	6	4.5mm Locking Cortical Screw Full Thread, 30mm
00-0907-4632	6	4.5mm Locking Cortical Screw Full Thread, 32mm
00-0907-4634	6	4.5mm Locking Cortical Screw Full Thread, 34mm
00-0907-4636	6	4.5mm Locking Cortical Screw Full Thread, 36mm
00-0907-4638	6	4.5mm Locking Cortical Screw Full Thread, 38mm
00-0907-4640	6	4.5mm Locking Cortical Screw Full Thread, 40mm
00-0907-4642	4	4.5mm Locking Cortical Screw Full Thread, 42mm
00-0907-4644	4	4.5mm Locking Cortical Screw Full Thread, 44mm
00-0907-4646	4	4.5mm Locking Cortical Screw Full Thread, 46mm
00-0907-4648	4	4.5mm Locking Cortical Screw Full Thread, 48mm
00-0907-4650	4	4.5mm Locking Cortical Screw Full Thread, 50mm
00-0907-4655	4	4.5mm Locking Cortical Screw Full Thread, 55mm
00-0907-4660	4	4.5mm Locking Cortical Screw Full Thread, 60mm
00-0907-4665	4	4.5mm Locking Cortical Screw Full Thread, 65mm
00-0907-4670	4	4.5mm Locking Cortical Screw Full Thread, 70mm
00-0907-4675	4	4.5mm Locking Cortical Screw Full Thread, 75mm
00-0907-4680	4	4.5mm Locking Cortical Screw Full Thread, 80mm

4.5mm Locking Cortical Screw Full Thread 00-0907-46XX

T15/T20 MODULAR INSTRUMENT SET

Item Number	Qty	Description
01-0903-0005	1	T15 Hexalobe Retraining Driver, Short
01-0907-0022	4	2.0 x 150mm Guide Wire
01-0999-2001	1	Long Insert (0-100mm)
01-1010-004	1	Cleaning Stylet
01-1030-001	2	Mini In-Line Ratchet
01-1050-0002	2	Drill Bit 2.5mm
01-1050-0006	1	Cortical Tap 3.5mm
01-1050-0009	1	3.5/2.5 Double Drill Guide
01-1050-0032	2	2.5 Calibrated Drill Bit
01-1200-0014	1	Precision Wire Guide 2.0mm
01-1200-0041	2	3.2mm Drill Bit, Calibrated
01-1200-0042	3	3.2mm Threaded Drill Guide
01-1200-0051	2	3.2mm Drill Bit
01-1200-0052	1	4.5mm Tap
01-1200-0054	1	2.5mm diam. Neutral & Load End Green/Gold Drill Guide
01-1200-0055	1	4.5mm diam. Neutral & Load End Green/Gold Drill Guide
01-1200-0056	1	Double Drill Sleeve 4.5mm/3.2mm
01-1200-0057	1	Small Bone Clamp
01-1200-0058	1	Large Bone Clamp
01-1200-0062	1	Bending Iron - Right
01-1200-0064	1	Bending Iron - Left
01-1200-0067	3	2.5mm Threaded Drill Guide
01-1200-0069	1	Triangular Positioning Plate 90-40-50 Degrees
01-1200-0070	1	Triangular Positioning Plate 80-70-30 Degrees
01-1200-0071	1	Triangular Positioning Plate 100-60-20 Degrees
01-1200-0074	1	Infant Bone Clamp
01-1200-0078	1	3.5mm Depth Gauge Sleeve (long)
01-1200-0079	1	4.5mm Depth Gauge Sleeve (long)
01-1200-0087	1	T15 Hexalobe Retaining Driver, Long
01-1200-0088	1	T20 Hexalobe Retaining Driver, Short
01-1200-0089	1	T20 Hexalobe Retaining Driver, Long
01-1030-007	1	Screw Forceps
01-0907-1200	1	Tray 1: Base Tray for 3.5 T15 and 4.5 T20 Screw Instrumentation
01-0907-5535	1	OrthoPediatrics Lid

PediLoc® PLEO

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.

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.

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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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