

PediLoc® Femur

3.5/4.5mm Contour Plates

SURGICAL TECHNIQUE

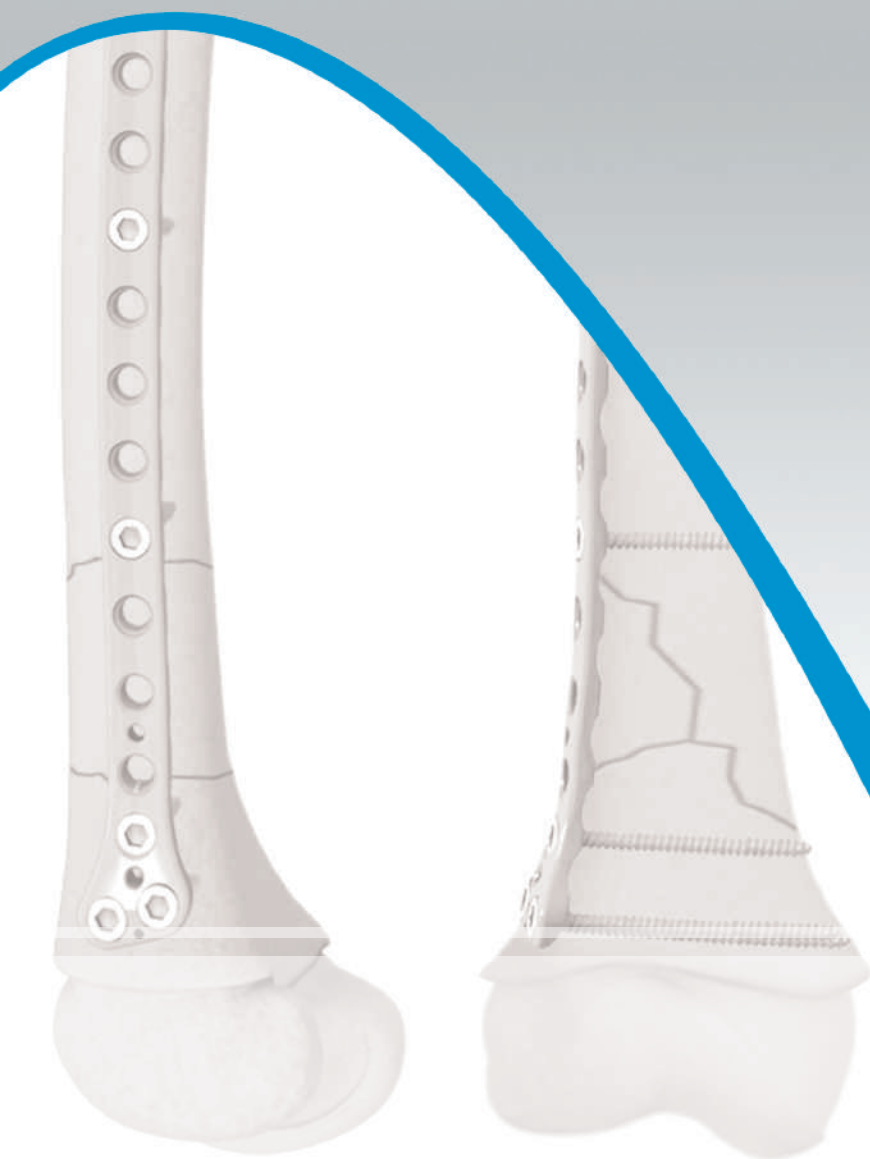


TABLE OF CONTENTS

System Overview

Indications	4
Product Overview.	5
Design Features - Contoured Femur Plate	6
Pre-operative Planning	7

Surgical Technique

Patient Positioning	9
Incision	9
Plate Positioning	10
Screw Insertion	11
Post Op Management & Plate Removal	13

Product Information

PediLoc Plate Implant Set	14
3.5mm Non-Locking Cortical Full Thread Screws	16
3.5mm Locking Cortical Full Thread Screws.	17
4.5mm Non-Locking Cortical Full Thread Screws	18
4.5mm Locking Cortical Full Thread Screws.	19
T15/T20 Modular Instrument Set	20

INDICATIONS

The PediLoc Contour Femur Plate 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.

PRODUCT OVERVIEW

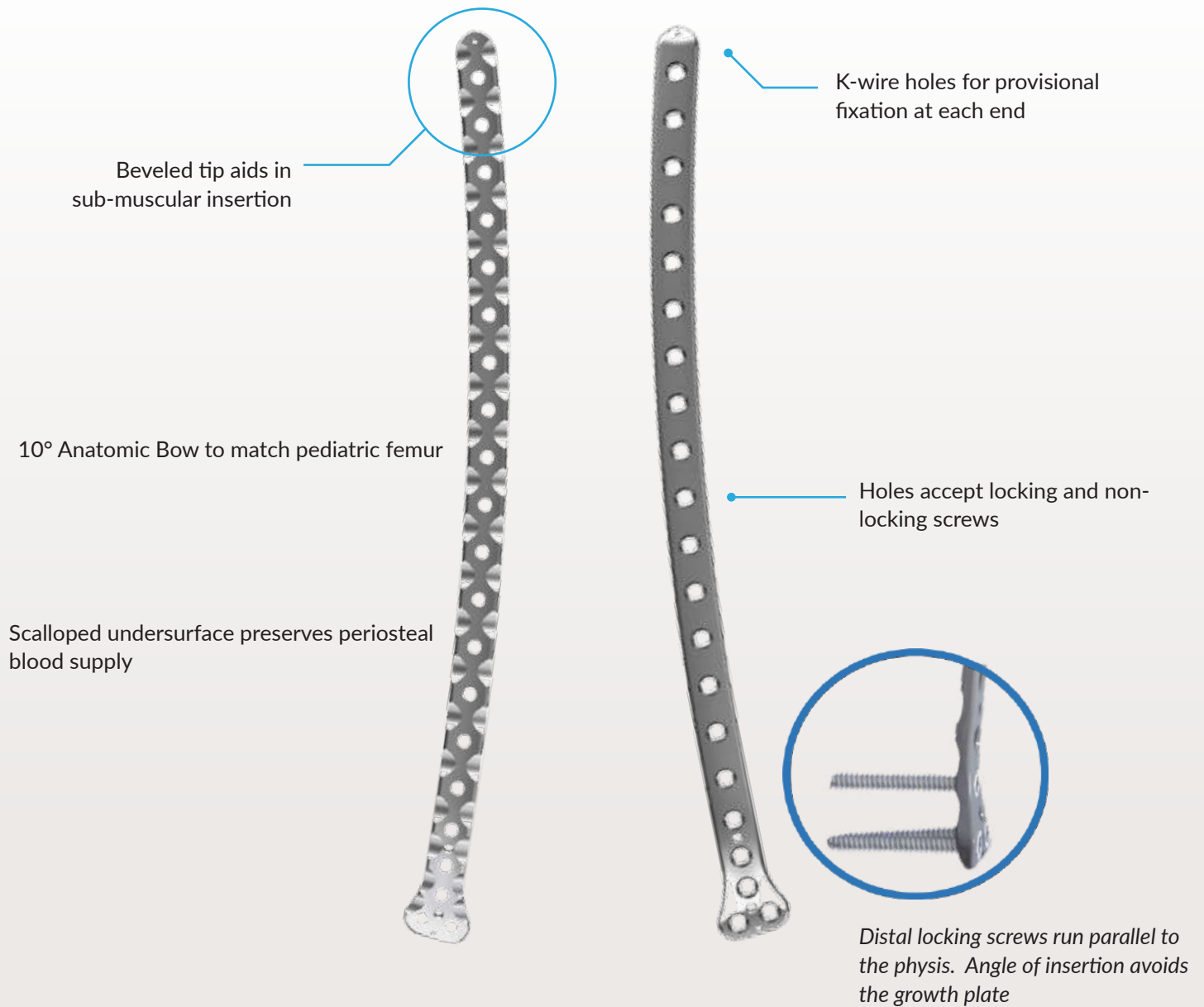
The PediLoc Contour Femur Plate was designed to adhere to the principles of internal fixation:

- **Anatomic Reduction:** the Contour Femur Plate is contoured to fit the femur of a child, aiding the surgeon in anatomic reduction.
- **Stable Fixation:** the design of the Contour Femur Plate allows the surgeon to achieve stable, internal fixation with locking and non-locking screws. This stable fixation encourages direct bone healing, rather than relying upon callus formation to achieve early stability.
- **Non-Traumatic Surgical Technique:** the Contour Femur Plate can be inserted sub-muscularly, thus avoiding periosteal stripping.
- **Early Mobilization:** the OrthoPediatics Contour Femur Plate provides anatomic reduction, stable fixation and is minimally invasive. These features allow patients to regain early mobility, thus limiting down time for patients and parents.

All PediLoc implants are manufactured using the highest quality 316L stainless steel for strength and durability.

- The anatomic shape of the Contour Femur Plate provides excellent fit against the surface of the femur.
- All screw holes accept locking or non-locking screws using a stacked combination hole design.
- Provisional fixation holes at the end of the plates allow temporary plate alignment and do not interfere with screw placement.
- Scalloped undersurface helps protect periosteal blood supply.

DESIGN FEATURES - CONTOUR FEMUR PLATES

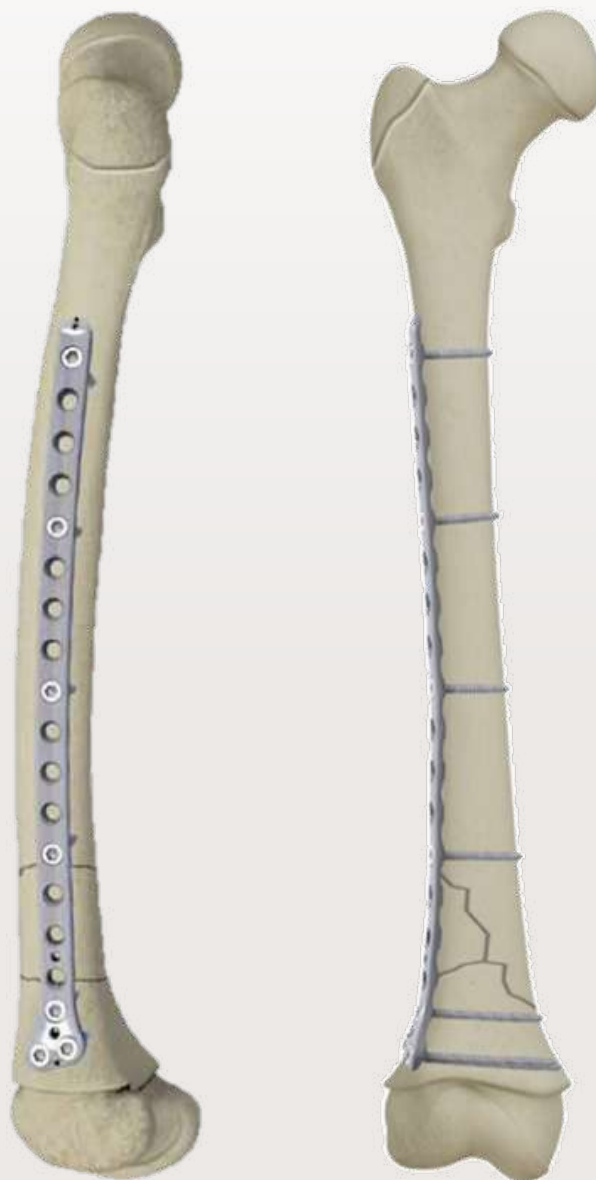


PRE-OPERATIVE PLANNING

Determine whether a 3.5mm or 4.5mm plate will be necessary depending on the age of the patient, and size of the femur.

- Looking at the location of the fracture, decide whether you need the diaphyseal/bowed femur plate or the distal metaphyseal contour femur plate.
- Under sterile prep, the length and contour of the plate can be determined by holding the plate over the thigh and visualizing the femur under C-arm imaging.

In general, a longer plate allows for better mechanical advantage over a shorter plate. Allow for 3 screws above and below the fracture site if possible.





SURGICAL TECHNIQUE

1

Patient Positioning

Position the patient supine using either a fracture table or a radiolucent table (free leg technique) (Figure 1). A small bump can be placed under the ipsilateral hip in order to make visualization of the femur easier. Bring the C-arm in from the contralateral side in order to visualize the fracture and determine the length of the plate (10 hole to 16 hole plates are most common). Prep the entire leg and lateral hip area to allow proximal extension of the surgical exposure if necessary. Maintain traction on the femur through use of a femoral distractor, external fixator, fracture table or by applying manual traction.



FIGURE 1: Patient positioning

2

Incision

Make a small incision (2cm) over the distal femur (Figure 2), and expose the distal end of the vastus lateralis (Figure 3). Elevate the vastus lateralis and expose the distal end of the femur. Using a Cobb elevator, dissect the plane between the periosteum of the femur and the vastus lateralis. Insert the plate underneath the vastus and above the periosteum, feeling the femur while advancing the plate.

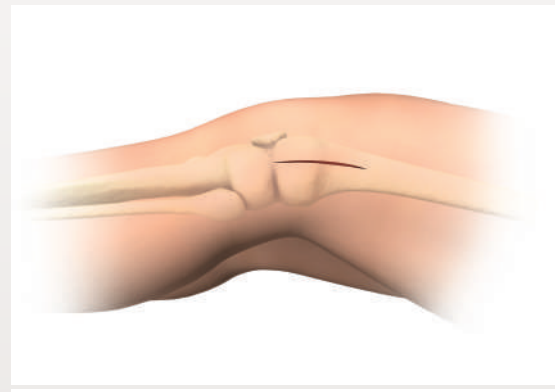


FIGURE 2: Make a small incision over distal femur

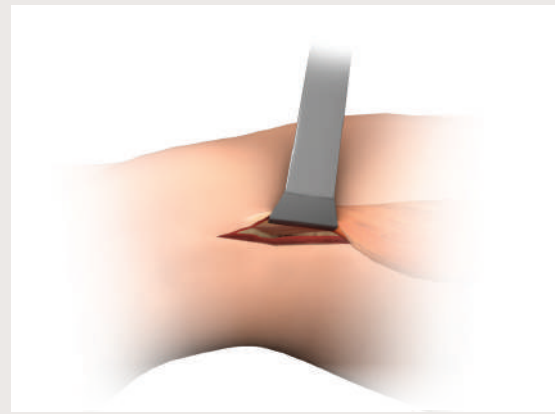


FIGURE 3: Expose distal end of vastus lateralis

3

Plate Positioning

Using the appropriate 3.5/4.5mm Plate Holder, insert the plate into the incision and begin to advance the plate proximally. Alternatively, the distal targeting guide or threaded drill guide instrument add-on may be used to insert and advance the plate proximally (Figure 4).

Make sure that the plate is aligned with the shaft anterior to posterior. If the plate is not aligned with the shaft on the lateral x-ray projection, withdraw the plate a few centimeters and re-advance.

Reduce the femur fracture while advancing the plate. Traction, with or without a temporary external fixator, may be necessary to maintain reduction.

Take an AP C-arm image to confirm that the plate is positioned correctly on the distal femur and is in proper alignment with the distal flare. Take a lateral C-arm image to confirm good positioning of the plate and sagittal alignment. Provisional fixation with k-wires and/or plate fixation pins may be necessary to maintain the position of the plate on the femoral shaft (Figure 5).

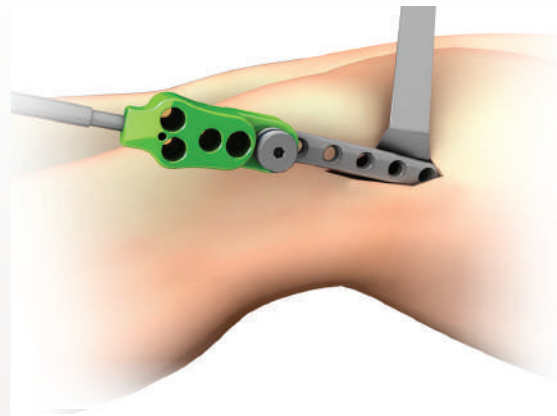


FIGURE 4: Insert plate into the incision and advance proximally

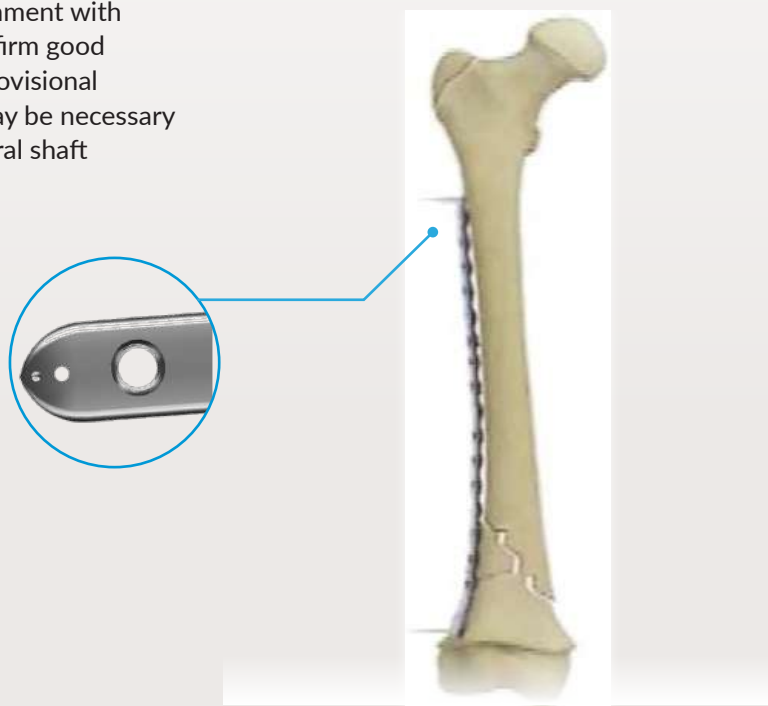


FIGURE 5: Utilize k-wires and/or plate fixation pins to maintain position of plate, if necessary

4

Screw Insertion

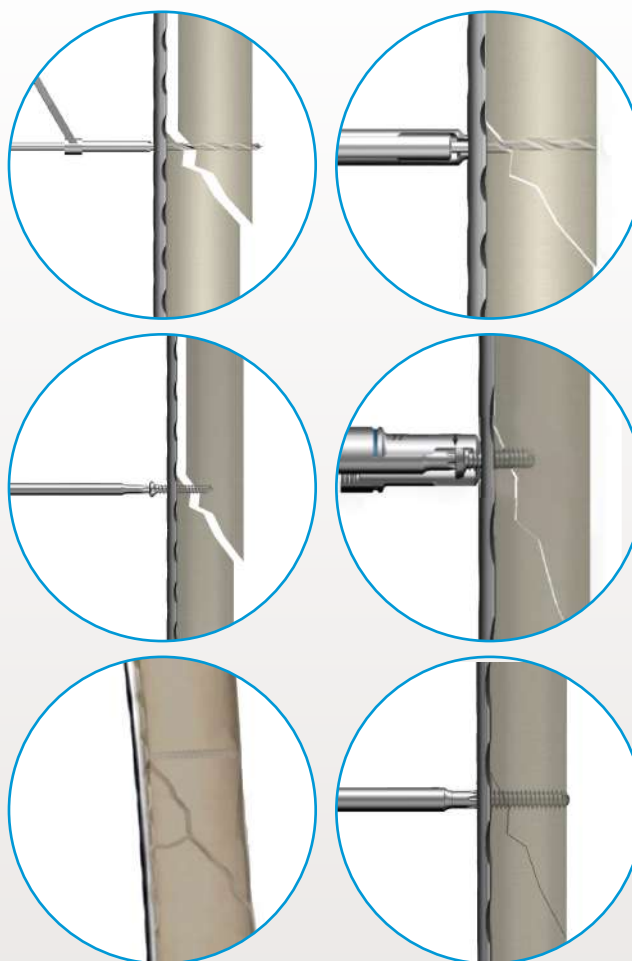
Place the screws in the plate using the near-near/far-far concept.

Try to place screws with the greatest screw spread to create the strongest construct. Place screws in the proximal fragment as close to the fracture as possible and as far away from the fracture as possible. Place screws in the distal fragment as close to the fracture as possible and as far away as possible.

- Reduce the femur to the plate using non-locking screws.
- After reducing the femur to the plate, place screws percutaneously or through an open incision.
- For percutaneous screws in the shaft of the femur, obtain a true lateral C-arm view of the plate and the femur. Make a small stab incision with a #15 blade scalpel over the desired hole in the plate. Bluntly dissect down to the plate.
- If using a locking screw, attach the appropriate 2.5mm or 3.5mm threaded drill guide to the desired hole. Drill the bone with the appropriate bit and measure to determine screw length. Insert the screw until full seated. All screws are self-tapping so pre-tapping should not be necessary. If it is difficult to advance the screw in dense cortical bone, pre-tap the cortex to make screw insertion easier.
- Alternatively, if 3.5 or 4.5mm locking screw guides with inner drill sleeve instrument add-ons are available, attach to the desired hole. Drill the bone with the appropriate bit and measure to determine screw length. Remove the inner drill sleeve. Insert the screw until the top of the screw head aligns with the marked arrow on the locking screw guide. Remove the locking screw guide and fully seat the screw.
- If using a non-locking screw use the free-hand technique. Using the 2.5mm/3.5mm drill guide and appropriate drill bit, drill free-hand, measure and insert the screw.

Non-Locking Screw

Locking Screw

**FIGURE 6:** Place screws and reduce

Stab incision for screw insertion

**FIGURE 7:** Make a stab incision

- For percutaneous screw insertion, tie a Vicryl suture around the screw head to avoid losing the screw in the soft tissue.
- Place at least 3 screws (6 cortices) above and below the fracture for maximum stability.
- Maximize the screw spread for greatest construct stability (Figure 8).
- Take a final AP and lateral radiograph to assess fracture alignment and plate placement.



FIGURE 8: Maximize screw spread for construct stability

5

Post-Op Management

Patients are allowed to begin knee and hip range of motion exercises in the hospital and are treated with crutches and toe-touch weight bearing for approximately 4 weeks until radiographic evidence of healing is enough to allow transition to full weight bearing.

- No casting or brace is necessary postoperatively. Most pediatric patients are fully weight bearing by eight weeks.

Plate Removal

- Position the patient supine on a radiolucent operating table. With fluoroscopic assistance, remove the plate percutaneously through the previously made incisions.
- Using a Cobb elevator, separate the plate from the underlying bone.
- Once all the screws have been removed, rotate the plate to further break up the adhesions between the vastus lateralis and the plate. Use a Kocher or a threaded drill guide in the distal end of the plate as a handle to rotate the plate.
- Use the same surgical incisions for removal of the implants. Additional incisions are rarely needed for removal.

PRODUCT INFORMATION

3.5MM PEDILOC FEMUR SET

Item Number	Description	Holes	Length (mm)
00-1065-3004	3.5mm Contour Locking Compression Femur Plate, Right	4	86.00
00-1065-3006	3.5mm Contour Locking Compression Femur Plate, Right	6	114.00
00-1065-3008	3.5mm Contour Locking Compression Femur Plate, Right	8	141.83
00-1065-3010	3.5mm Contour Locking Compression Femur Plate, Right	10	169.72
00-1065-3012	3.5mm Contour Locking Compression Femur Plate, Right	12	197.55
00-1065-3014	3.5mm Contour Locking Compression Femur Plate, Right	14	225.29
00-1065-3016	3.5mm Contour Locking Compression Femur Plate, Right	16	252.90
00-1065-3104	3.5mm Contour Locking Compression Femur Plate, Left	4	86.00
00-1065-3106	3.5mm Contour Locking Compression Femur Plate, Left	6	114.00
00-1065-3108	3.5mm Contour Locking Compression Femur Plate, Left	8	141.83
00-1065-3110	3.5mm Contour Locking Compression Femur Plate, Left	10	169.72
00-1065-3112	3.5mm Contour Locking Compression Femur Plate, Left	12	197.55
00-1065-3114	3.5mm Contour Locking Compression Femur Plate, Left	14	225.29
00-1065-3116	3.5mm Contour Locking Compression Femur Plate, Left	16	252.90



3.5mm Contour Locking Compression Left
00-1065-3XXX

4.5MM PEDILOC FEMUR SET

Item Number	Description	Holes	Length (mm)
00-1065-4004	4.5mm Contour Locking Compression Femur Plate, Right	4	96.00
00-1065-4006	4.5mm Contour Locking Compression Femur Plate, Right	6	132.00
00-1065-4008	4.5mm Contour Locking Compression Femur Plate, Right	8	168.00
00-1065-4010	4.5mm Contour Locking Compression Femur Plate, Right	10	203.67
00-1065-4012	4.5mm Contour Locking Compression Femur Plate, Right	12	239.30
00-1065-4014	4.5mm Contour Locking Compression Femur Plate, Right	14	274.76
00-1065-4016	4.5mm Contour Locking Compression Femur Plate, Right	16	310.03
00-1065-4018	4.5mm Contour Locking Compression Femur Plate, Right	18	345.06
00-1065-4104	4.5mm Contour Locking Compression Femur Plate, Left	4	96.00
00-1065-4106	4.5mm Contour Locking Compression Femur Plate, Left	6	132.00
00-1065-4108	4.5mm Contour Locking Compression Femur Plate, Left	8	168.00
00-1065-4110	4.5mm Contour Locking Compression Femur Plate, Left	10	203.67
00-1065-4112	4.5mm Contour Locking Compression Femur Plate, Left	12	239.30
00-1065-4114	4.5mm Contour Locking Compression Femur Plate, Left	14	274.76
00-1065-4116	4.5mm Contour Locking Compression Femur Plate, Left	16	310.03
00-1065-4118	4.5mm Contour Locking Compression Femur Plate, Left	18	345.06



4.5mm Contour Locking Compression Femur Left
00-1065-4XXX

3.5MM T15 MODULAR SCREW CADDY

Item Number	Description
00-0903-2510	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 10mm
00-0903-2512	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 12mm
00-0903-2514	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 14mm
00-0903-2516	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 16mm
00-0903-2518	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 18mm
00-0903-2520	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 20mm
00-0903-2522	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 22mm
00-0903-2524	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 24mm
00-0903-2526	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 26mm
00-0903-2528	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 28mm
00-0903-2530	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 30mm
00-0903-2532	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 32mm
00-0903-2534	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 34mm
00-0903-2536	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 36mm
00-0903-2538	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 38mm
00-0903-2540	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 40mm
00-0903-2542	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 42mm
00-0903-2544	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 44mm
00-0903-2546	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 46mm
00-0903-2548	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 48mm
00-0903-2550	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 50mm
00-0903-2555	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 55mm
00-0903-2560	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 60mm
00-0903-2565	3.5mm Self Tapping Cortical Screw with T15 Hexalobe, size 65mm
00-0903-2570	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	Description
00-0903-2610	3.5mm Locking Cortical Screw with T15 Hexalobe, size 10mm
00-0903-2612	3.5mm Locking Cortical Screw with T15 Hexalobe, size 12mm
00-0903-2614	3.5mm Locking Cortical Screw with T15 Hexalobe, size 14mm
00-0903-2616	3.5mm Locking Cortical Screw with T15 Hexalobe, size 16mm
00-0903-2618	3.5mm Locking Cortical Screw with T15 Hexalobe, size 18mm
00-0903-2620	3.5mm Locking Cortical Screw with T15 Hexalobe, size 20mm
00-0903-2622	3.5mm Locking Cortical Screw with T15 Hexalobe, size 22mm
00-0903-2624	3.5mm Locking Cortical Screw with T15 Hexalobe, size 24mm
00-0903-2626	3.5mm Locking Cortical Screw with T15 Hexalobe, size 26mm
00-0903-2628	3.5mm Locking Cortical Screw with T15 Hexalobe, size 28mm
00-0903-2630	3.5mm Locking Cortical Screw with T15 Hexalobe, size 30mm
00-0903-2632	3.5mm Locking Cortical Screw with T15 Hexalobe, size 32mm
00-0903-2634	3.5mm Locking Cortical Screw with T15 Hexalobe, size 34mm
00-0903-2636	3.5mm Locking Cortical Screw with T15 Hexalobe, size 36mm
00-0903-2638	3.5mm Locking Cortical Screw with T15 Hexalobe, size 38mm
00-0903-2640	3.5mm Locking Cortical Screw with T15 Hexalobe, size 40mm
00-0903-2642	3.5mm Locking Cortical Screw with T15 Hexalobe, size 42mm
00-0903-2644	3.5mm Locking Cortical Screw with T15 Hexalobe, size 44mm
00-0903-2646	3.5mm Locking Cortical Screw with T15 Hexalobe, size 46mm
00-0903-2648	3.5mm Locking Cortical Screw with T15 Hexalobe, size 48mm
00-0903-2650	3.5mm Locking Cortical Screw with T15 Hexalobe, size 50mm
00-0903-2655	3.5mm Locking Cortical Screw with T15 Hexalobe, size 55mm
00-0903-2660	3.5mm Locking Cortical Screw with T15 Hexalobe, size 60mm
00-0903-2665	3.5mm Locking Cortical Screw with T15 Hexalobe, size 65mm
00-0903-2670	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	Description
00-0907-4510	4.5mm Non-Locking Cortical Screw Full Thread, 10mm
00-0907-4512	4.5mm Non-Locking Cortical Screw Full Thread, 12mm
00-0907-4514	4.5mm Non-Locking Cortical Screw Full Thread, 14mm
00-0907-4516	4.5mm Non-Locking Cortical Screw Full Thread, 16mm
00-0907-4518	4.5mm Non-Locking Cortical Screw Full Thread, 18mm
00-0907-4520	4.5mm Non-Locking Cortical Screw Full Thread, 20mm
00-0907-4522	4.5mm Non-Locking Cortical Screw Full Thread, 22mm
00-0907-4524	4.5mm Non-Locking Cortical Screw Full Thread, 24mm
00-0907-4526	4.5mm Non-Locking Cortical Screw Full Thread, 26mm
00-0907-4528	4.5mm Non-Locking Cortical Screw Full Thread, 28mm
00-0907-4530	4.5mm Non-Locking Cortical Screw Full Thread, 30mm
00-0907-4532	4.5mm Non-Locking Cortical Screw Full Thread, 32mm
00-0907-4534	4.5mm Non-Locking Cortical Screw Full Thread, 34mm
00-0907-4536	4.5mm Non-Locking Cortical Screw Full Thread, 36mm
00-0907-4538	4.5mm Non-Locking Cortical Screw Full Thread, 38mm
00-0907-4540	4.5mm Non-Locking Cortical Screw Full Thread, 40mm
00-0907-4542	4.5mm Non-Locking Cortical Screw Full Thread, 42mm
00-0907-4544	4.5mm Non-Locking Cortical Screw Full Thread, 44mm
00-0907-4546	4.5mm Non-Locking Cortical Screw Full Thread, 46mm
00-0907-4548	4.5mm Non-Locking Cortical Screw Full Thread, 48mm
00-0907-4550	4.5mm Non-Locking Cortical Screw Full Thread, 50mm
00-0907-4555	4.5mm Non-Locking Cortical Screw Full Thread, 55mm
00-0907-4560	4.5mm Non-Locking Cortical Screw Full Thread, 60mm
00-0907-4565	4.5mm Non-Locking Cortical Screw Full Thread, 65mm
00-0907-4570	4.5mm Non-Locking Cortical Screw Full Thread, 70mm
00-0907-4575	4.5mm Non-Locking Cortical Screw Full Thread, 75mm
00-0907-4580	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	Description
00-0907-4610	4.5mm Locking Cortical Screw Full Thread, 10mm
00-0907-4612	4.5mm Locking Cortical Screw Full Thread, 12mm
00-0907-4614	4.5mm Locking Cortical Screw Full Thread, 14mm
00-0907-4616	4.5mm Locking Cortical Screw Full Thread, 16mm
00-0907-4618	4.5mm Locking Cortical Screw Full Thread, 18mm
00-0907-4620	4.5mm Locking Cortical Screw Full Thread, 20mm
00-0907-4622	4.5mm Locking Cortical Screw Full Thread, 22mm
00-0907-4624	4.5mm Locking Cortical Screw Full Thread, 24mm
00-0907-4626	4.5mm Locking Cortical Screw Full Thread, 26mm
00-0907-4628	4.5mm Locking Cortical Screw Full Thread, 28mm
00-0907-4630	4.5mm Locking Cortical Screw Full Thread, 30mm
00-0907-4632	4.5mm Locking Cortical Screw Full Thread, 32mm
00-0907-4634	4.5mm Locking Cortical Screw Full Thread, 34mm
00-0907-4636	4.5mm Locking Cortical Screw Full Thread, 36mm
00-0907-4638	4.5mm Locking Cortical Screw Full Thread, 38mm
00-0907-4640	4.5mm Locking Cortical Screw Full Thread, 40mm
00-0907-4642	4.5mm Locking Cortical Screw Full Thread, 42mm
00-0907-4644	4.5mm Locking Cortical Screw Full Thread, 44mm
00-0907-4646	4.5mm Locking Cortical Screw Full Thread, 46mm
00-0907-4648	4.5mm Locking Cortical Screw Full Thread, 48mm
00-0907-4650	4.5mm Locking Cortical Screw Full Thread, 50mm
00-0907-4655	4.5mm Locking Cortical Screw Full Thread, 55mm
00-0907-4660	4.5mm Locking Cortical Screw Full Thread, 60mm
00-0907-4665	4.5mm Locking Cortical Screw Full Thread, 65mm
00-0907-4670	4.5mm Locking Cortical Screw Full Thread, 70mm
00-0907-4675	4.5mm Locking Cortical Screw Full Thread, 75mm
00-0907-4680	4.5mm Locking Cortical Screw Full Thread, 80mm



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

PRODUCT INFORMATION

T15/T20 MODULAR INSTRUMENT SET

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

3.5MM PEDILOC FEMUR CASE & TRAY

Item Number	Description
01-1065-3500	3.5mm Locking Compression Femur Plate Case Base
01-1065-3511	3.5mm Locking Compression Femur Plate Case Inner Tray
01-1065-3520	3.5mm Locking Compression Femur Plate Case Lid

4.5MM PEDILOC FEMUR CASE & TRAY

Item Number	Description
01-1065-4500	4.5mm Locking Compression Femur Plate Case Base
01-1065-4511	4.5mm Locking Compression Femur Plate Case Inner Tray
01-1065-4520	4.5mm Locking Compression Femur Plate Case Lid

Notes

This image shows a full page of blank, lined paper. It features approximately 20 horizontal blue lines spaced evenly across the page, typical of notebook paper. The lines are a medium blue color and extend from the left edge to the right edge. There are no margins, text, or other markings on the page.



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: 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.

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