PediLoc® Locking Cannulated Blade Plate

SURGICAL TECHNIQUE

OrthoPediatrics®
Leading Innovation in Pediatric Orthopedics

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Surgical Technique: VDRO

Product Information

INDICATIONS

The System is intended for fixation of long bone fractures and osteotomies in all pediatric subgroups (except neonates) and in small stature adults. Specific indications include: intertrochanteric derotation and varus osteotomies, femoral neck and pertrochanteric fractures, intertrochanteric valgus osteotomies, proximal and distal tibial osteotomies and humeral fractures and osteotomies.

PRODUCT FEATURES

The OrthoPediatrics Locking Cannulated Blade Plate System is designed for the fixation of proximal femoral osteotomies and fractures of the proximal femur in all pediatric subgroups, except infants and in some adults with small stature. Specific indications include: proximal femoral osteotomies (intertrochanteric derotation, varus derotation osteotomy), fractures of the proximal femur including basal fractures of the femoral neck and intertrochanteric fractures.

The system has also been successfully used for valgus proximal femoral osteotomies, flexion osteotomies (Imhauser Osteotomy) for residuals of SCFE. Less frequent indications include extension osteotomy of the distal femur, where alternative fixation systems exist (PLEO© DFOS), as well as osteotomies of the proximal and distal tibia, humeral fractures and osteotomies.

The signature feature of the system is cannulation of the blade plate and the instrumentation. This enables control of bone segments throughout the entire procedure. This may be particularly advantageous in fracture fixation, osteopenic bone and in younger children with small bony anatomy.

The PediLoc® Locking Cannulated Blade Plate System includes a broad range of implants, with supporting instrumentation, to permit stable internal fixation for proximal femoral osteotomies across the age range from 12 months to skeletal maturity. Within this age range, the most frequent indications include derotational and angular osteotomies as well as proximal femoral reconstruction as part of more extensive hip reconstruction involving pelvic procedures and other procedures performed during Surgical Hip Dislocation (SHD). It is important to be familiar with the range of implants and instrumentation in order to select the largest, strongest implant for the hip and the child in question. If larger implants are selected, the majority of children can be mobilized soon after surgery and the need for a hip spica can be avoided in the majority of children.

PRE-OPERATIVE STEPS

Patient Positioning

Varus derotation osteotomy (VDRO) is frequently performed on a standard radiolucent operating table, using fluoroscopy to monitor the procedure. AP and lateral radiographs are obtained by ranging the hip from extension/abduction and internal rotation, into a position of flexion abduction and external rotation, to obtain a lateral fluoroscopic view.

This technique works well for the majority of children under 8-10 years (about 50 to 60lbs weight) and for the majority of indications. However, it should be remembered that the guide wire is subject to bending stresses by the soft tissues when the hip is ranged from the AP fluoroscopic view to the lateral fluoroscopic view. This may become hazardous in older children, obese children and teenagers and adults, where bending of the guide wire may result in difficulties such as impaction of the chisel or blade plate. Impaction of the chisel on a bent guide wire may break the wire or cause it to be advanced into the hip joint.

In older or obese children and teenagers, the use of a fracture table should be considered. In this surgical set-up, the fluoroscope is moved to obtain the lateral x-rays, not the child's hip. Bending stresses to the guide wire are avoided.

VDRO is performed under general anesthesia, and when indicated supplemented by epidural analgesia.

Skin preparation and draping should be as for any proximal femoral osteotomy and should consider additional or adjunctive procedures which may need to be performed e.g. pelvic osteotomy or distal procedures in the same limb e.g. children with cerebral palsy.

Surgical Exposure

The proximal femur is exposed utilizing a straight lateral incision, approximately the length of the proposed implant, starting from the tip of the greater trochanter. The deep dissection involves mobilization and preservation of the blood and nerve supply to the vastus lateralis by a sub-vastus approach. In children, the thick periosteum should be divided and elevated using Cobb elevators.

Prerequisite 1: Reduce the hip:

Reduction can be achieved by a closed reduction (in hypotonic conditions where there is no contracture of the hip adductors) or a formal open reduction (e.g. DDH) or adductor release (CP hip displacement). It is a prerequisite to determine from both physical examination, and radiology (either plain films or fluoroscopy), that the hip can be reduced prior to performance of the osteotomy.

Prerequisite 2: Full/adequate hip range of motion:

The second prerequisite is an adequate range of hip motion, especially abduction, remembering that every degree of varus in the osteotomy, reduces available hip abduction range by approximately 2 degrees. If abduction range is not adequate prior to VDRO, it must be obtained by a medial hip release to avoid a hip that is in fixed adduction with poor containment and a limited range of motion.

Determine the Desired Angle of the Correction

The determination of the angle of correction (varus) requires a knowledge of the diagnosis, the current neck shaft angle and the desired neck shaft angle.

Neck shaft angles should ideally be measured with the hip internally rotated to eliminate the effects of parallax, from increased femoral neck anteversion, which is a common feature of conditions such as DDH and neuromuscular diseases. If the neck shaft angle has not been measured accurately from pre-operative radiology, this can be performed as the first step by obtaining a fluoroscopic image with the hip in internal rotation, to a degree that is equal to femoral neck anteversion, typically 30-40°.

Subtract the current from the desired neck shaft angle to calculate the correction angle. (Figure 1).

Select the appropriate plate angle typically 90° or 100°. Add the correction angle to the blade plate angle to obtain the calculated angle (Figure 2). The calculated angle will be used to insert the guide wire using the adjustable angle wire guide, triangular templates, or on occasions, a free hand technique.

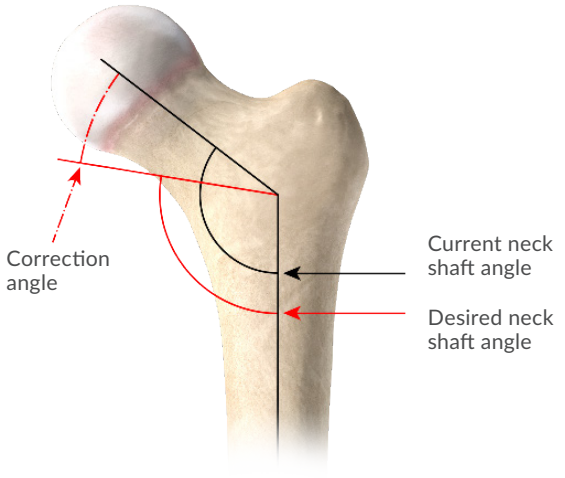

Figure 1

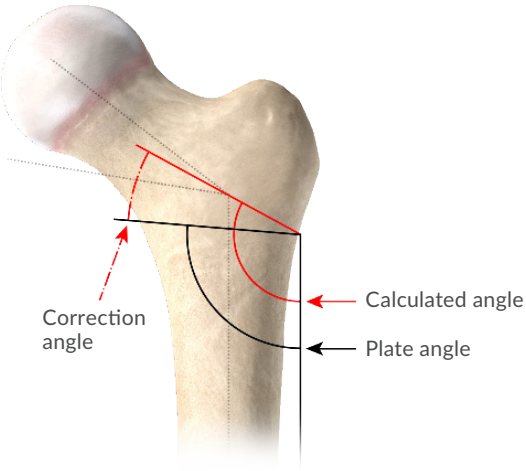

Figure 2

Set and Insert the Guide Wire

Attach the precision angle wire guide to the lateral femur using a bone clamp to hold this in place. Advance a guide wire of appropriate size into the angle slot. Advance the guide wire a short distance (10-15mm) and check with AP fluoroscopy, that the position of the guide wire (and by inference the seating chisel and blade plate) will be in an optimum position on the AP fluoroscopic view. The entry point for the guide wire during VDRO is usually just below the trochanteric physis. However, if the varus correction is small, it may be necessary to traverse the trochanteric physis which is acceptable in older children but should be avoided in younger children with more growth remaining.

It is essential to check the orientation of the guide wire on the lateral view where it should be central in the neck of the femur, so that the largest possible implant can be selected to improve stability and to avoid angulation of the implant within the proximal femur. Angulation in the lateral plane may risk penetration of the implant through the cortex of the anterior or posterior femoral neck, which is a fracture risk as well as a risk of injury to the blood supply to the proximal femur. It also makes precise estimation of the derotation angle more difficult.

Once satisfactory position of the guide wire is confirmed, the guide wire is advanced to within 5-10mm of the calcar or the proximal femoral growth plate (in skeletally immature children).

Insertion of the guide wire in optimum position in both the AP and lateral fluoroscopic projections is the key step to obtain accurate proximal femoral realignment and stable fixation.

Figure 3

Figure 4

Insertion of the Seating Chisel

Select the appropriate chisel from the instrumentation set.

The chisel is inserted over the guide wire using the chisel guide. The handle of the chisel guide can be used for control as well as add flexion or extension in the sagittal plane if this part of the pre-operative plan.

With the seating chisel touching the lateral cortex of the femur, a final check should be made that the seating chisel is appropriate to the size of the femur in addition to the size and weight of the child. The size is best assessed on the lateral view where the narrow isthmus of the neck is the point which determines the size of the implant and safe passage of the chisel. Ideally, the chisel and blade plate, will "fit and fill" the proximal femur with only 2-3mm of clearance necessary on either side of the blade plate on the lateral view. This is the reason why the guide wire must be central in the femoral neck on the lateral view, directed towards the center of the femoral head and without angulation in an anterior or posterior direction.

In adolescents and adults, it is occasionally helpful to use a 2.5mm drill bit to perforate the lateral cortex anterior and posterior to the guide wire to allow easier insertion of the chisel.

Advance the chisel using the mallet to the appropriate depth, which is typically just short of the calcar and at least 5-10mm short of the proximal femoral physis.

> **NOTE:** Use regular fluoroscopic views in both AP and lateral planes to ensure proper advancement and insertion depth of the chisel. Check that the guide wire remains straight and that it is not inadvertently advanced into the hip joint.

The insertion depth of the chisel can be read on either the top or sides of the chisel. This number relates to the size of the implant and the length of the blade to be selected.

Remove the chisel guide while leaving the chisel within the proximal femur.

> **NOTE:** Back out the chisel by 5-10mm to aid in removal following making the osteotomies.

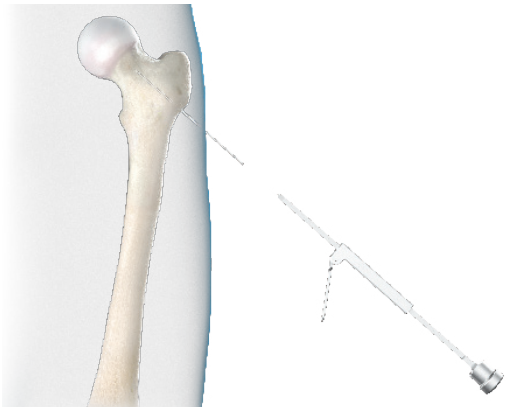

Figure 5

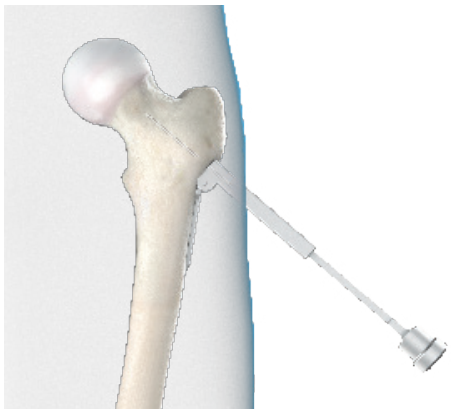

Figure 6

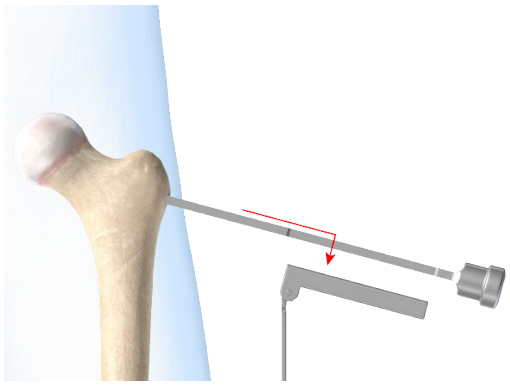

Figure 7

Perform Osteotomy

The osteotomy gauge is used to define the starting point for the first osteotomy at an appropriate distance from the chisel in the inter-trochanteric region. The line of the osteotomy should be checked using fluoroscopy to ensure that it is above the lesser trochanter and that it will exit distal to the femoral neck and not encroach on the calcar and the medial vascular supply.

Advance the saw slowly to make the initial cut. Once the initial cut is complete, the proximal fragment will drift into both varus and flexion. The position is easily controlled using the chisel.

Externally rotate the distal fragment, if required.

> **NOTE:** When precise derotation is required, it is advisable to take additional steps to improve accuracy. These include making a "score" with the oscillating saw in a vertical direction on the anterolateral femur, so that the degree of rotation can be checked by the alteration and position of the two lines.

Make a second cut transversely at the desired level to provide for femoral shortening.

Remove the chisel from the proximal fragment.

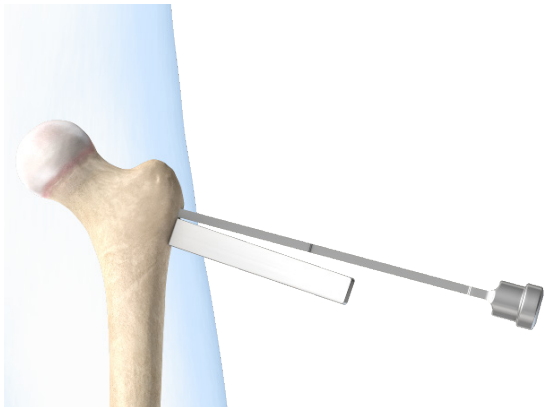

Figure 8

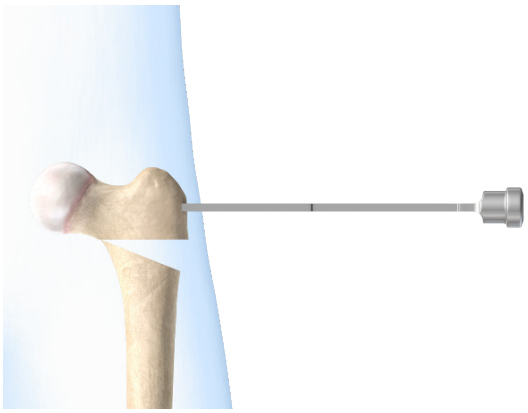

Figure 9

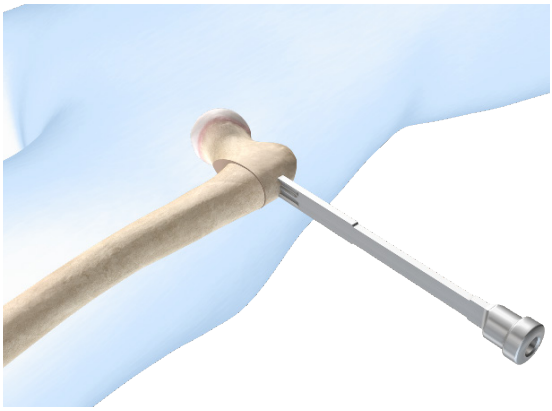

Figure 10

Select the Appropriate Implant

The appropriate implant is selected, to “fit and fill” the proximal femur. It is important to avoid implants that are too small for the size of the femur and the age, weight and activity level of the child. Ideally, the implant should be strong enough to give stable fixation and to avoid the need for a hip spica and to permit early mobilization before bone healing has occurred. This is achievable by careful attention to detail in selecting the largest, longest, most stable implant for the specific child and hip.

A second consideration is the degree of medial offset as this varies across the implant range. The systems' plate offerings allow for medialization of the distal fragment. The amount of medialization ideally relates to the degree of varus correction, to maintain mechanical axis. In children with DDH and LCP, the degree of varus is small and the amount of medialization required is also small. In cerebral palsy, the degree of coxa valga is frequently severe and additional medialization may be required. This can be achieved by a small third recess cut to allow the implant to be impacted to a greater degree around the proximal femur, shifting the distal fragment into a more medial position.

NOTE: All of the implants medialize the distal fragment in relation to the proximal fragment. However if the degree of varus correction is extreme, the distal fragment may still be lateralised to the midline which is undesirable. The chosen implant, is attached to the threaded inserter and advanced over the guide wire.

NOTE: It is important to check that the bending of the guide wire has not occurred during the previous steps as otherwise the blade plate may lock on the bent guide wire and cause advancement of the guide wire into the proximal femur or hip joint.

NOTE: Caution should be taken to avoid glove perforation or injury to the surgeon’s hand from the exposed end of the guide wire during this step.

Threaded Inserter

Attach the implant to the threaded inserter and advance over the guide wire.

NOTE: It is important to check that bending of the guide wire has not occurred during the previous steps.

Figure 11

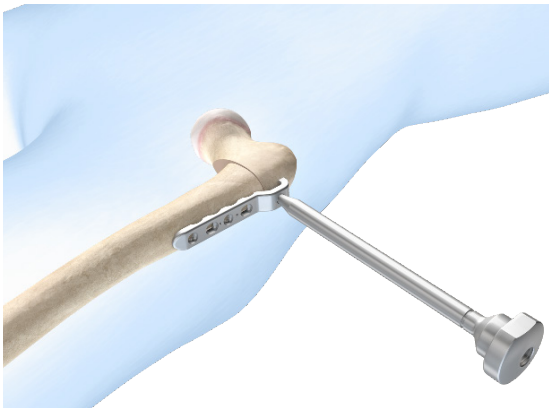

Figure 12

Reduction and Fixation of the Osteotomy

Once the implant has been inserted fully and the position checked on the AP fluoroscopic view, reduction of the osteotomy is performed by manipulation of the distal fragment. This is often easier with the distal fragment/femoral shaft flexed, to line up with the proximal fragment, which is usually in some flexion. Secure the plate against the lateral femur using the bone clamp in the 2nd to last hole of the shaft screw holes. This is a locking screw hole. Ensure that the side plate is parallel to the femur and centered on the shaft. This avoids inadvertent extension or flexion deformity and that all the fixation screws will achieve bicortical fixation.

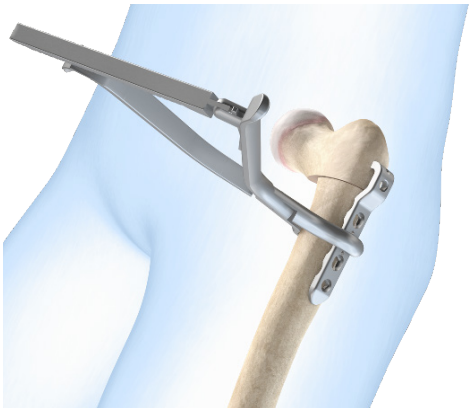

Figure 13

Drill for the Cortical Screw

NOTE: The compression screws should be inserted 1st using non-locking screws. The locking screws should be inserted next and the locking screw in the proximal fragment should be placed last.

Place the gold end of the drill guide into the top compression hole.

NOTE: The internal guide piece of the drill guide can rotate. The arrow should face towards the osteotomy site.

Insert the drill bit into the drill guide and drill through both cortices. If the drill bit is short, change to an appropriate drill size and do not use the calibration lines for measuring. Use the depth gauge to hook on the far cortex to obtain the measurement for the first cortical screw.

NOTE: Both cortices can be tapped using the cortical taps and mini T-handle.

NOTE: The nose of the depth gauge will not fit through the plate and the depth gauge nose may contain a snap feature that could become loose during this process.

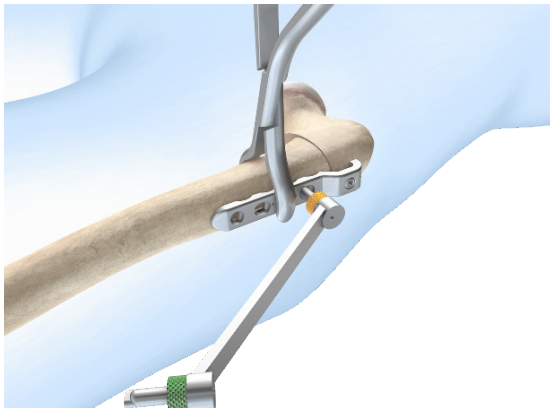

Figure 14

Insert the Cortical Screw

Affix the hexalobe driver to the mini in-line ratchet confirming that the engagement position is in forward or neutral. Identify the appropriate length of cortical screw and insert through both cortices.

Insert the cortical screw.

> **NOTE:** Due to the depth gauge not fitting through the plate, and utilizing dynamic compression, the cortical screw may protrude between 1 and 2mm further than expected, this is acceptable in the majority of situations.

Perform steps 8 and 9 for the 2nd compression hole.

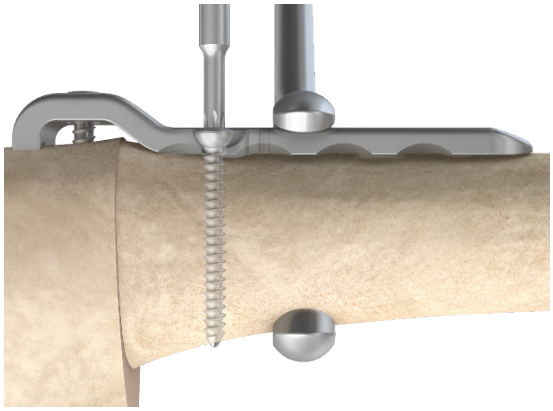

Figure 15

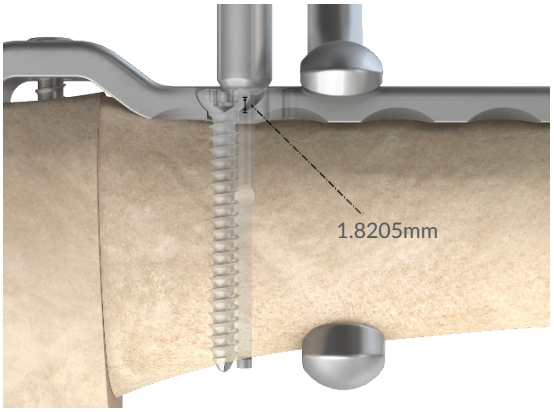

Figure 16

Drill for the Locking Screw

Remove the bone clamp. Locate the locking hole and insert the threaded drill guide into the plate taking care not to cross thread the device. Insert the calibrated drill bit into the threaded drill guide and drill the near cortex. Continue until the far cortex is felt and drill just past this point. Read the measurement from the calibrated drill bit off the back of the threaded drill guide.

NOTE: As an option, both cortices can be tapped using the cortical taps and mini t-handle AO, QC.

Insert the Locking Screw

Identify the appropriately sized screw from the previous step. Affix the mini in-line ratchet confirming forward or neutral engagement to the hexalobe driver. Insert the locking screw.

Perform the above steps for the 2nd shaft locking screw followed by the locking screw in the proximal fragment.

NOTE: The final screw to be inserted is the proximal locking screw. Depending on the orientation of the blade plate and the proximal femur, this screw will be parallel to the blade of the plate and usually a little shorter. Given that this screw should not perforate the proximal femoral neck, it is recommended that this drill hole be performed using fluoroscopic control as the tactile sensation of reaching the far cortex may not be adequate. Typically, the proximal femoral locking screw is 10-15mm shorter than the length of the selected blade plate but should be confirmed fluoroscopically in every case.

Figure 17

Assessment, Wound Closure and After Care

Following final fixation, the stability of the implant, the reduction and the hip joint are assessed both clinically and radiographically using intra-operative fluoroscopy. Occasionally, an arthrogram will help in assessing the stability of the hip and/or the need for a pelvic osteotomy.

The incision is irrigated and closed in layers.

PLATES

INFANT PLATES

Item Number	Angle	Offset	Blade Length	Hole
00-1200-1000	90°	5	25	3
00-1200-1001	90°	5	30	3
00-1200-1002	90°	5	35	3
00-1200-2500	130°	0	25	3
00-1200-2501	130°	0	30	3
00-1200-2502	130°	0	35	3
00-1200-2503	130°	0	40	3
00-1200-2504	130°	0	45	3
00-1200-2505	130°	0	50	3
00-1200-2506	130°	0	55	3
00-1200-2507	130°	0	60	3

CHILD PLATES

Item Number	Angle	Offset	Blade Length	Hole
00-1200-3500	90°	6	25	3
00-1200-3501	90°	6	30	3
00-1200-3502	90°	6	35	3
00-1200-3503	90°	6	40	3
00-1200-3504	90°	6	45	3
00-1200-3505	90°	6	50	3
00-1200-3506	90°	10	25	3
00-1200-3507	90°	10	30	3
00-1200-3508	90°	10	35	3
00-1200-3509	90°	10	40	3
00-1200-3510	90°	10	45	3
00-1200-3511	90°	10	50	3
00-1200-4000	100°	6	25	3
00-1200-4001	100°	6	30	3
00-1200-4002	100°	6	35	3
00-1200-4003	100°	6	40	3
00-1200-4004	100°	6	45	3
00-1200-4005	100°	6	50	3
00-1200-5000	130°	0	40	4
00-1200-5001	130°	0	45	4
00-1200-5002	130°	0	50	4
00-1200-5003	130°	0	55	4
00-1200-5004	130°	0	60	4

ADOLESCENT PLATES

Item Number	Angle	Offset	Blade Length	Hole
00-1200-4500	90°	6	40	4
00-1200-4501	90°	6	45	4
00-1200-4502	90°	6	50	4
00-1200-4503	90°	6	55	4
00-1200-4504	90°	6	60	4
00-1200-4505	90°	6	65	4
00-1200-4506	90°	6	70	4
00-1200-4514	90°	14	40	4
00-1200-4515	90°	14	45	4
00-1200-4516	90°	14	50	4
00-1200-4517	90°	14	55	4
00-1200-4518	90°	14	60	4
00-1200-4519	90°	14	65	4
00-1200-4520	90°	14	70	4
00-1200-7000	130°	0	45	4
00-1200-7001	130°	0	50	4
00-1200-7002	130°	0	55	4
00-1200-7003	130°	0	60	4
00-1200-7004	130°	0	65	4
00-1200-7005	130°	0	70	4
00-1200-7006	130°	0	75	4
00-1200-7007	130°	0	80	4

SCREWS - 3.5mm

SELF TAPPING CORTICAL SCREW WITH T15 HEXALOBE

Item Number	Size
00-0903-2510	10
00-0903-2512	12
00-0903-2514	14
00-0903-2516	16
00-0903-2518	18
00-0903-2520	20
00-0903-2522	22
00-0903-2524	24
00-0903-2526	26
00-0903-2528	28
00-0903-2530	30
00-0903-2532	32
00-0903-2534	34
00-0903-2536	36
00-0903-2538	38
00-0903-2540	40
00-0903-2542	42
00-0903-2544	44
00-0903-2546	46
00-0903-2548	48
00-0903-2550	50
00-0903-2555	55
00-0903-2560	60
00-0903-2565	65
00-0903-2570	70

LOCKING CORTICAL SCREW WITH T15 HEXALOBE

Item Number	Size
00-0903-2610	10
00-0903-2612	12
00-0903-2614	14
00-0903-2616	16
00-0903-2618	18
00-0903-2620	20
00-0903-2622	22
00-0903-2624	24
00-0903-2626	26
00-0903-2628	28
00-0903-2630	30
00-0903-2635	35
00-0903-2640	40
00-0903-2645	45
00-0903-2650	50
00-0903-2655	55
00-0903-2660	60
00-0903-2665	65
00-0903-2670	70

SCREWS - 4.5mm

SELF TAPPING CORTICAL SCREW WITH T20 HEXALOBE

Item Number	Size
00-0907-4510	10
00-0907-4512	12
00-0907-4514	14
00-0907-4516	16
00-0907-4518	18
00-0907-4520	20
00-0907-4522	22
00-0907-4524	24
00-0907-4526	26
00-0907-4528	28
00-0907-4530	30
00-0907-4532	32
00-0907-4534	34
00-0907-4536	36
00-0907-4538	38
00-0907-4540	40
00-0907-4542	42
00-0907-4544	44
00-0907-4546	46
00-0907-4548	48
00-0907-4550	50
00-0907-4555	55
00-0907-4560	60
00-0907-4565	65
00-0907-4570	70
00-0907-4575	75
00-0907-4580	80

LOCKING CORTICAL SCREW WITH T20 HEXALOBE

Item Number	Size
00-0907-4610	10
00-0907-4612	12
00-0907-4614	14
00-0907-4616	16
00-0907-4618	18
00-0907-4620	20
00-0907-4622	22
00-0907-4624	24
00-0907-4626	26
00-0907-4628	28
00-0907-4630	30
00-0907-4632	32
00-0907-4634	34
00-0907-4636	36
00-0907-4638	38
00-0907-4640	40
00-0907-4645	45
00-0907-4650	50
00-0907-4655	55
00-0907-4660	60
00-0907-4665	65
00-0907-4670	70
00-0907-4675	75
00-0907-4680	80

INSTRUMENTATION

POSITIONING GUIDES

Item Number	Description
01-1200-0069	Triangular Positioning Plate 90-40-50°
01-1200-0070	Triangular Positioning Plate 80-70-30°
01-1200-0071	Triangular Positioning Plate 100-60-20°
01-1200-0014	2.0mm Precision Angle Wire Guide
01-1200-0115	2.4mm Precision Angle Wire Guide

HANDLES / INSERTERS

Item Number	Description
01-1010-001	Mini T-Handle, AO QC
01-1030-001	Mini In-line Ratchet
01-1200-0009	Threaded Inserter, Infant/Child
01-1200-0011	Threaded Inserter, Adolescent

GUIDES

Item Number	Description
01-1050-0009	2.5/3.5 Double Drill Guide
01-1200-0002	3.5 Chisel Guide
01-1200-0003	4.5 Chisel Guide
01-1200-0042	3.2mm Threaded Drill Guide
01-1200-0054	2.5mm Neutral & Load Drill Guide
01-1200-0055	3.2mm Neutral & Load Drill Guide
01-1200-0056	3.2/4.5 Double Drill Guide
01-1200-0067	2.5mm Threaded Drill Guide

CLAMPS

Item Number	Description
01-1200-0028	Extractor Clamp
01-1200-0057	Small Bone Clamp
01-1200-0058	Large Bone Clamp
01-1200-0074	Infant Bone Clamp

DRILLS/WIRES/TAPS

Item Number	Description
01-0907-0022	2.0mm X 150mm Guide Wire Cobalt Chrome
01-9473-5115	2.0mm X 150mm Guide Wire Stainless Steel
01-1050-0002	2.5mm Drill Bit
01-1050-0006	3.5mm Cortical Tap
01-1050-0032	2.5mm Calibrated Drill Bit
01-1200-0041	3.2mm Calibrated Drill Bit
01-1200-0050	2.4mm x 150mm Guide Wire
01-1200-0051	3.2mm Drill Bit
01-1200-0052	4.5mm Cortical Tap

IMPACT DEVICES

Item Number	Description
01-1000-016	Solid Hammer
01-1200-0025	Slap Hammer, Large
01-1200-0026	Tuning Fork Extractor
01-1200-0076	Slap Hammer, Small
01-1200-0077	1/2lb Mallet

NOTE: The stainless steel guide wire options listed may not be available in all countries.

INSTRUMENTATION

DIRECT MEASURING DEVICES

Item Number	Description
01-1200-0006	Chisel, Infant
01-1200-0007	Chisel, Child
01-1200-0008	Chisel, Adolescent
01-1200-0060	Osteotomy Gauge, Adolescent
01-1200-0072	3.5mm Depth Gauge
01-1200-0073	4.5mm Depth Gauge
01-1200-0075	Osteotomy Gauge, Infant/Child
01-1200-0200	Cannulated Chisel, Infant - 60mm
01-1200-0506	Line-to-Line Chisel, Infant - 35mm
01-1200-0507	Line-to-Line Chisel, Child - 60mm
01-1200-0508	Line-to-Line Chisel, Adolescent - 80mm
01-1200-0509	Line-to-Line Chisel, Infant - 60mm

DRIVERS

Item Number	Description
01-0903-0005	T15 Hexalobe Retaining Driver, Short
01-1200-0087	T15 Hexalobe Retaining Driver, Long
01-1200-0088	T20 Hexalobe Retaining Driver, Short
01-1200-0089	T20 Hexalobe Retaining Driver, Long

MISCELLANEOUS

Item Number	Description
01-1010-003	1.75 mm Cleaning Brush
01-1010-004	1.6 mm Cleaning Stylet
01-1200-0047	Extractor Clamp Wrench
01-1200-0062	Bending Iron-Right
01-1200-0064	Bending Iron-Left

IMPORTANT MEDICAL INFORMATION

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
- In skeletally immature individuals, long bone epiphysis or trochanteric epiphysis should not be violated by the device. Cessation of growth may take place.

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 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.
- United States: 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.

MRI Safety Information

In non-clinical testing the Orthopediatrics Locking Cannulated Blade Plate 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 4.9 °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.

IMPORTANT MEDICAL INFORMATION

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.

This document is intended exclusively for experts in the field, i.e. physicians in particular, and expressly not for the information of laypersons.

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. The information contained in this document was gathered and compiled by medical experts and qualified OrthoPediatrics employees to the best of their knowledge. The greatest care was taken to ensure the accuracy and ease of the understanding of the information used and presented.

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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

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