

PediPlates®

SURGICAL TECHNIQUE

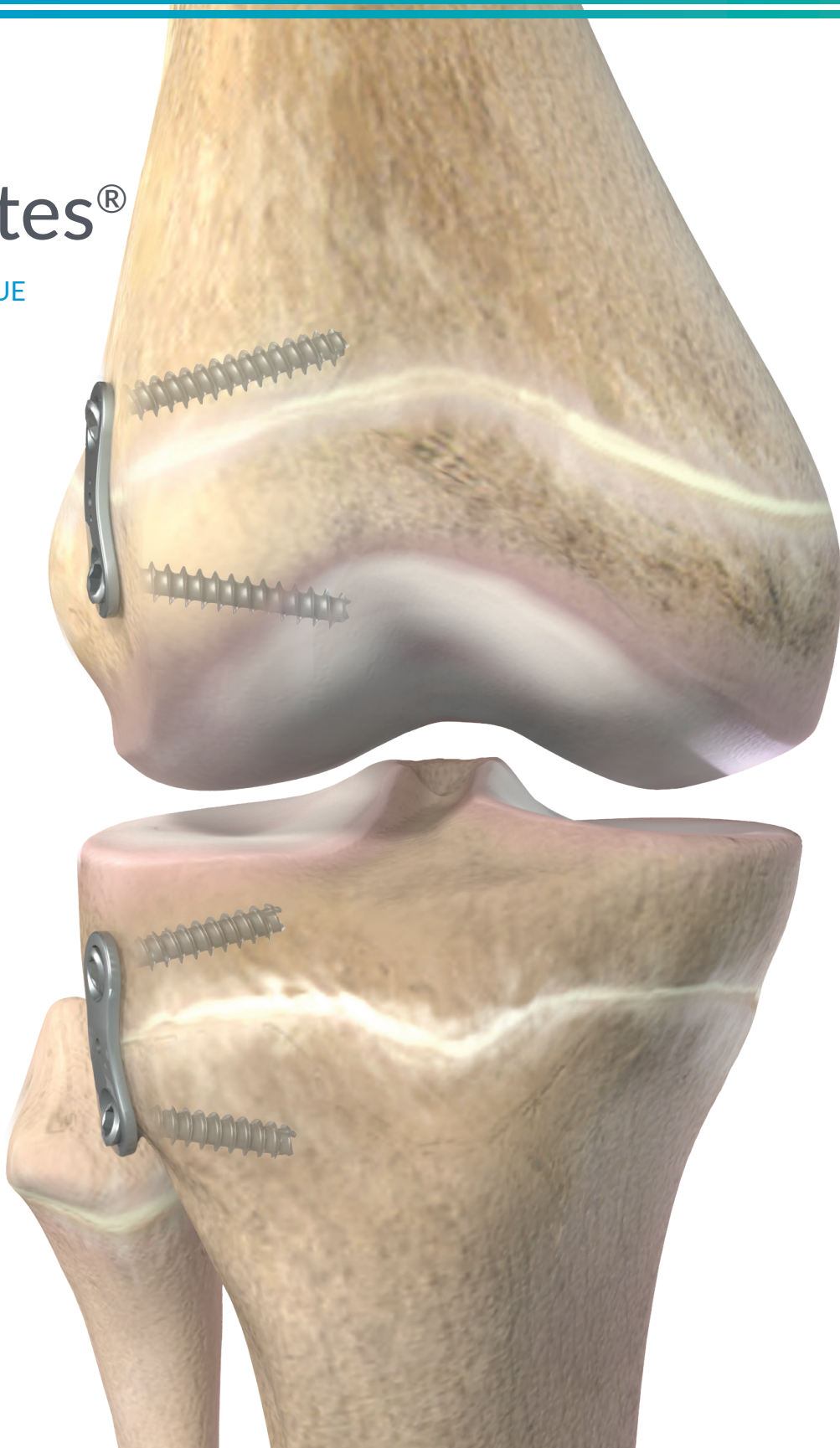




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SYSTEM OVERVIEW

Physeal tethering techniques that do not disrupt the integrity of the physis have grown in popularity recently. These techniques utilize simple plate and screw constructs which span the peripheral part of the physis, resulting in a restraint of the growth that would normally occur there. The implant inhibits growth in the area where the plate and screws are applied. By tethering only one side of the physis, growth is inhibited in that area and not inhibited in other regions of the physis. If both sides of physis are tethered, longitudinal growth may temporarily be retarded (for up to 2 years). This growth tethering is simple, minimally invasive, temporary and reversible. Techniques that take advantage of open growth plates are unique and allow for gradual correction with significantly less morbidity than other forms of growth arrest or inhibition such as stapling or transphyseal screws.

SYSTEM FEATURES

- Stainless steel plates and screws provide excellent strength, resistance to breakage, as well as ease of removal.
- Implants also available in Titanium, for a more comprehensive system offering.
- Multiple plate sizes and configurations offer greater options and more flexibility.
- All screws are self-tapping for easy insertion.
- Utilizes 4.5mm stainless steel cannulated and non-cannulated screws with multiple screw length options.
- Low-profile plates.
- Low-profile screws in Stainless Steel and Titanium for use in areas where soft-tissue irritation is a consideration.
- The O-Plate addresses the majority of patients needing simple two-hole physeal tethering.
- The Delta Plate addresses situations where more flexibility of screw placement is needed by offering maximum diversion of screw placement through the plate.
- The I-Plate provides additional fixation options utilizing four, rather than two screws.

IMPLANT SELECTION

Select the appropriate screw and plate combination with consideration for maximum screw divergence appropriate for the planned degree of angular correction

Stainless Steel Plates

	Max Divergence Angle
I-Plates	38°
O-Plates with 4.5mm Cannulated Screws	30°
O-Plates with 4.5mm Cannulated Screws - Low Profile	26°
O-Plates with 3.5mm Cortical Screws	22°
O-Plates with 4.5mm Solid Screws - Low Profile	22°
H-Plates* with 4.5mm Cannulated Screws	30°
H-Plates* with 4.5mm Cannulated Screws - Low Profile	26°
H-Plates* with 4.5mm Solid Screws - Low Profile	26°

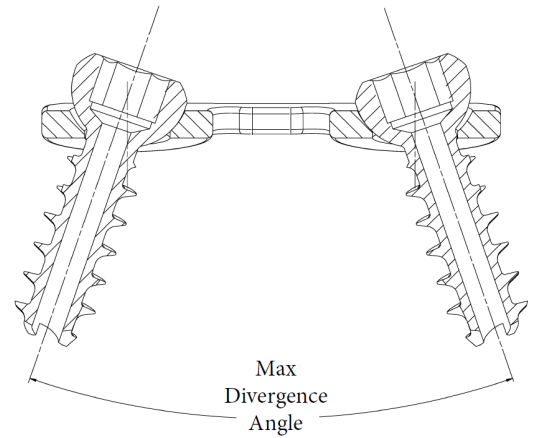
Delta Plates

62°

Titanium Plates

I-Plates	41°
O-Plates	30°

*Limited availability



LATERAL DISTAL FEMORAL PHYSEAL TETHERING SURGICAL TECHNIQUE

Surgical Approach

Identify and locate the distal femoral physis with a metal object and fluoroscopy. Mark the skin and make a small incision longitudinally. Gently dissect down to the peri-chondral ring, being careful not to damage it (Figure 1).

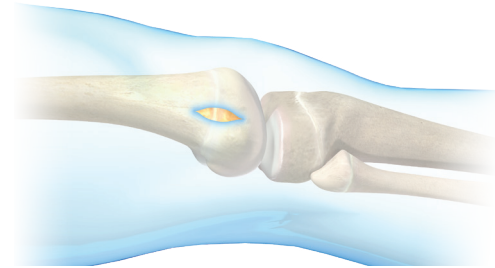


Figure 1
Surgical incision

Place Guide Wire in Physis

Using fluoroscopic confirmation, place the 1.6mm guide wire into the physis ensuring that the guide wire is in the center of the distal femoral condyles, anterior to posterior. Insert the guide wire gently into the physis, about 1cm in depth (Figure 2).

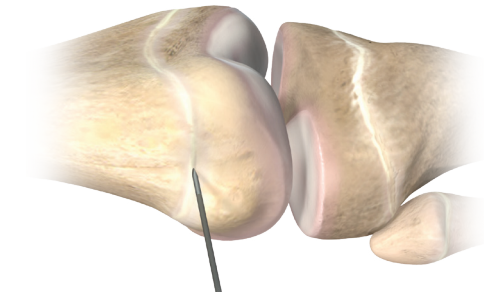


Figure 2
Guide wire insertion into physis

NOTE: Upon placement of guide wires throughout the procedure, ensure there is no damage to the wire. Damage may result in complications with the patient or interactions with other mating devices.

Plate Placement

Select an appropriate sized plate and slide it over the guide wire down to the bone (Figure 3).

CAUTION: Avoid selecting inappropriate sized plate that would allow placement of a screw into the physis or joint space.

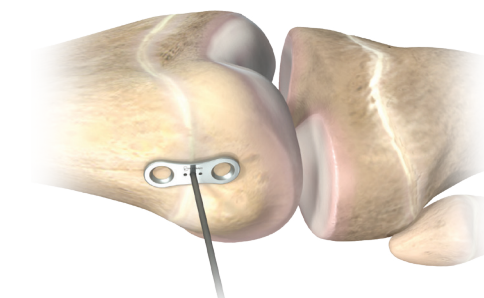


Figure 3
Plate placement

Insert 1.6mm Guide Wire into the Distal Femoral Epiphyseal Bone

Using the self-centering drill guide for the 1.6mm guide wire (Figure 4a and 4b), insert the wire under power into the distal femoral epiphysis making sure that the wire is contained within the epiphysis. If the wire is close to the physis or through the physis, remove it and reposition it. Using fluoroscopy, confirm placement of the 1.6mm guide wire prior to proceeding.

NOTE: Ensure the double drill guide is centered within the epiphyseal hole especially when using a double drill guide without the centering hole (01-1010-010).

NOTE: Prior to drilling, ensure power tool settings are in the forward position and no obstructions are in the path of intended drilling.

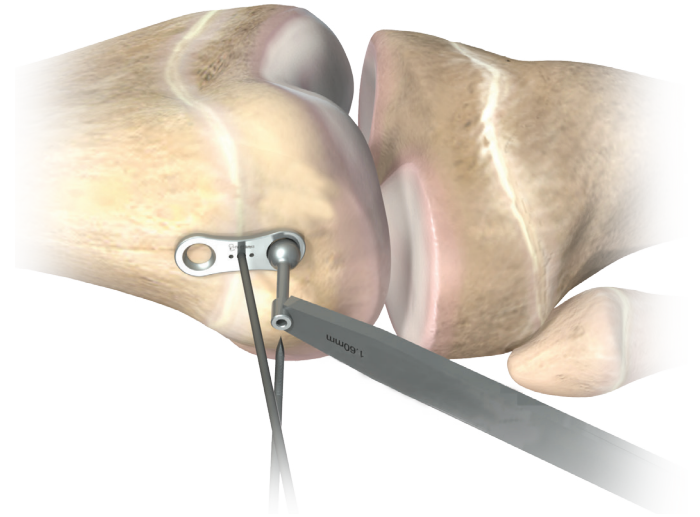


Figure 4a
Guide wire insertion into distal femoral epiphysis



Figure 4b
1.6mm side of drill guide must be used for guide wire insertion

Insert 1.6mm Guide Wire into the Distal Femoral Metaphyseal Bone

Using the drill guide for the 1.6mm guide wire, insert the wire under power into the distal femoral metaphysis making sure to angle away from the physis (Figure 5). Confirm placement of the 1.6mm guide wire with fluoroscopy in the distal femoral metaphysis.

Confirm Plate Positioning

Using fluoroscopy, confirm position of plate and guide wires by taking an A/P image and a lateral image (Figure 6). The ideal plate placement is in the middle of the femoral condyle anterior to posterior and in line longitudinally with the shaft of the femur. It is more important for the plate to be positioned in the center of the distal femoral condyle, than it is to be in line longitudinally. If the plate is positioned too far anterior or too far posterior, recurvatum or procurvatum may be created.

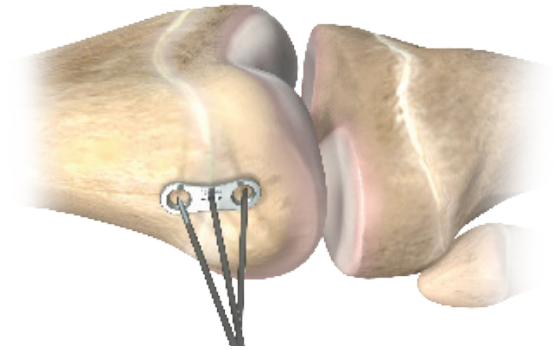


Figure 5
Guide wire insertion into distal femoral metaphysis

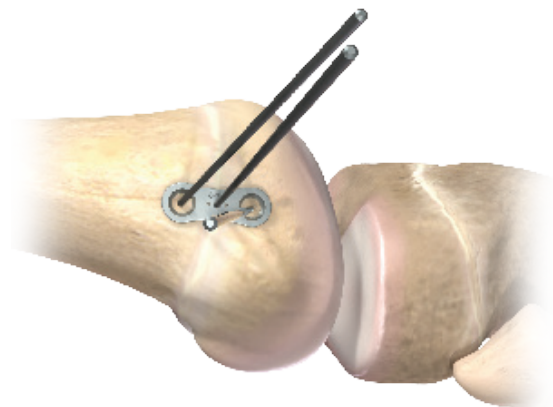


Figure 6
Plate positioning

Measure and Drill for Epiphyseal Screw

Using the direct measuring device, identify the appropriate screw length (Figure 7a). Drill over the 1.6mm guide wire using the 3.2mm cannulated drill bit to pre-drill for insertion of the screw (Figure 7b). It is not necessary to drill past the cortex. The epiphyseal screw should be about one-third of the distance across the segment of the bone.

If using the double drill guide with stop (01-1010-0210), advance the 3.2mm cannulated drill bit until it will no longer advance. This will ensure you have only drilled the near cortex.

NOTE: If the 3.2mm cannulated drill bit does not advance easily over the 1.6mm guide wire, remove the drill bit and check the integrity of the guide wire. If bent or damaged, the 3.2mm cannulated drill bit may cause the guide wire to be inadvertently advanced. If using a drill guide, check to be sure that the drill guide is not damaged.

Insert Epiphyseal Screw

Select the appropriate size of screw from the caddy. Size can be confirmed using the scale on the screw caddy. To obtain accurate measurement, be sure to push the screw forward on the scale so that the screw head makes contact with the edge of the caddy.

Insert screw over guide wire into epiphysis ensuring screw is not tightened completely at this stage of insertion (Figure 8). Confirm placement of the screw using fluoroscopy.

CAUTION: If using a non cannulated screw, be sure to remove the guide wire before inserting the screw. Verify the trajectory of the screw by using fluoroscopy. Pre-drilling the cortex is recommended using the 3.2mm drill bit.

WARNING: Never mix metals.

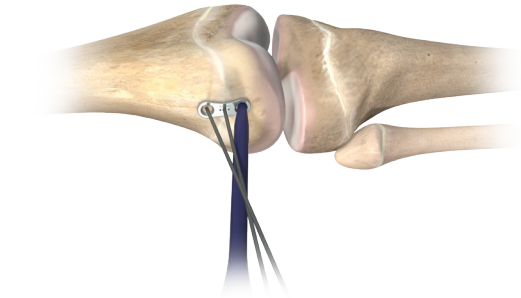


Figure 7a
Read the direct measuring device calibration markings from the end of the guide wire

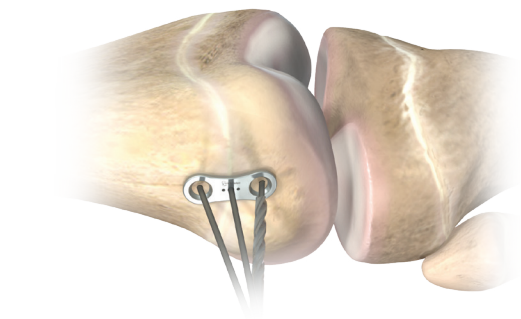


Figure 7b
Drill over guide wire for the epiphyseal screw

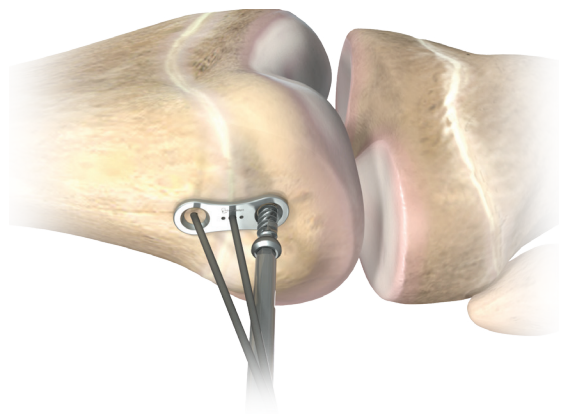


Figure 8
Epiphyseal screw insertion

Measure and Drill for Metaphyseal Screw

Using the direct measuring device, identify the appropriate screw length. Drill over the 1.6mm guide wire using the 3.2mm cannulated drill bit to pre-drill for insertion of the screw. It is not necessary to drill past the cortex. The metaphyseal screw should be about one-third of the distance across the segment of the bone.

As stated earlier, if using double drill guide with stop (01-1010-0210), advance the 3.2mm cannulated drill bit until it will no longer advance. This will ensure that you have only drilled the near cortex.

Insert Metaphyseal Screw

Select the appropriate size of screw from the caddy. Size can be confirmed using the scale on the screw caddy.

Insert screw over guide wire into metaphysis ensuring screw is not tightened completely at this stage of insertion (Figure 9). Confirm placement of the screw using fluoroscopy.

CAUTION: If using non cannulated screws, be sure to remove the guide wire before inserting the screw. Verify the trajectory of the screw by using fluoroscopy. Pre-drilling the cortex is recommended using the 3.2mm drill bit.

WARNING: Never mix metals.

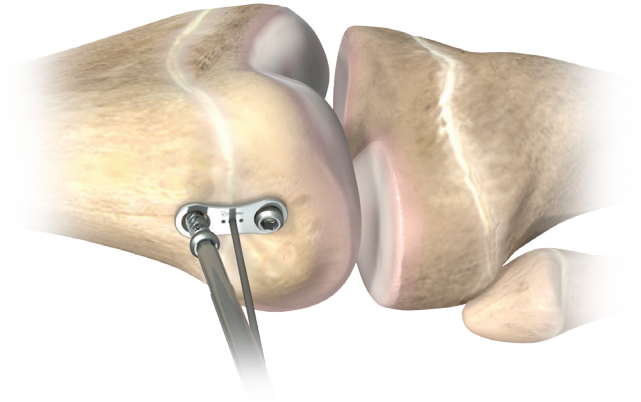


Figure 9
Metaphyseal screw insertion

Final Tightening

Prior to final tightening, remove the physal guide wire. Complete final tightening by alternatively tightening between metaphyseal and epiphyseal screws (Figure 10).

CAUTION: Not removing the physal guide wire before final tightening can result in the pin fracturing and difficult removal of the pin.

NOTE: If needed, use fluoroscopy to confirm plate is flush with the bone. The screws should be fully seated and not enter the physis.

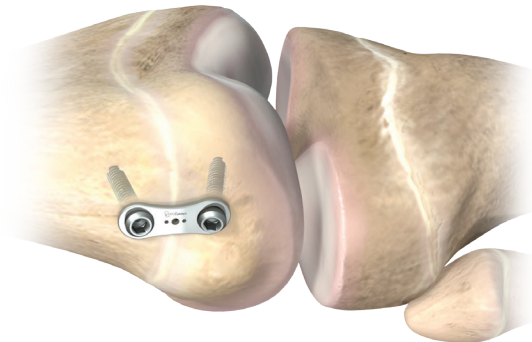


Figure 10
Final tightening of metaphyseal and epiphyseal screws

Closure

Close the wound.

Implant Monitoring

While monitoring patient for degree of angular correction, also monitor the angle of maximum divergence of the screws (see Implant Selection).

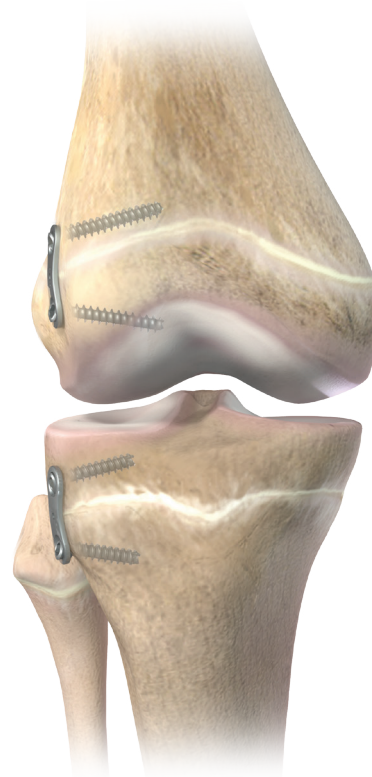
Implant Retrieval

See warnings in this document, IFU-99-1015-001 (stainless steel) and IFU-99-1015-002 (titanium) when planning patient follow-up and implant retrieval.

Technical Tips

Make sure all screws are tightened sequentially and that the plate is adjacent to the bone. It is sometimes necessary to gently bend the plate in order to get it to fit onto the bone. This is often the case in the proximal tibia. If the plate is not adherent to the bone, additional stress may be exerted onto the screws potentially leading to screw breakage.

It is not necessary to drill past the cortex for placement of the screws. Simply drill the outer cortex into the epiphysis/metaphysis with the 3.2mm drill bit. All the screws are self-tapping and are easily inserted into epiphyseal/metaphyseal bone.



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

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 equally important for the successful use of these products.
- 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.
- Timing of removal of implants used for growth modulation is critical> if the implants are left in too long, overcorrection may occur. This could result in additional stress to the implants. Overcorrection is the creation of an angular deformity in the opposite direction to the deformity for which the implant was being used to correct. This would require further surgery to correct this new deformity. For example, a varus deformity could be overcorrected to a valgus deformity. Additional stress to the implants may compromise implant integrity leading to implant failure and/or making removal difficult. Be sure to routinely follow patients throughout growth modulation until the desired clinical outcome is achieved and remove implants accordingly.
- 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.

ADVERSE EFFECTS

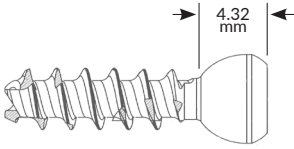
The risks associated with this device are the same as with any metallic internal fixation device. These include, but are not limited to the following:

- Overcorrection resulting in deformity
- Loss of fixation, attributable to osteoporosis
- Bending, fracture, or migration of the implant
- Metal sensitivity, or allergic reaction to a foreign body
- 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

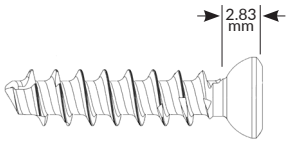
These adverse effects include adverse effects that are important considerations for metallic internal fixation devices. These risks and general surgical risks should be explained to the patient prior to surgery.

O-PLATE AND I-PLATE IMPLANTS

4.5mm CANNULATED SCREWS

Product	Description	Qty	Item Number
	4.5mm x 16mm Cannulated Screw	8	00-1015-316
	4.5mm x 20mm Cannulated Screw	8	00-1015-320
	4.5mm x 24mm Cannulated Screw	8	00-1015-324
	4.5mm x 28mm Cannulated Screw	8	00-1015-328
	4.5mm x 32mm Cannulated Screw	8	00-1015-332
	4.5mm x 36mm Cannulated Screw	8	00-1015-336

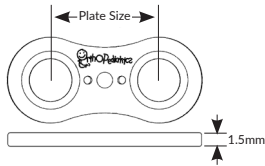
4.5mm LOW PROFILE SCREWS

Product	Description	Qty	Item Number
	LP 4.5mm x 16mm Cannulated Screw	8	00-1015-616
	LP 4.5mm x 20mm Cannulated Screw	8	00-1015-620
	LP 4.5mm x 24mm Cannulated Screw	8	00-1015-624
	LP 4.5mm x 28mm Cannulated Screw	8	00-1015-628
	LP 4.5mm x 32mm Cannulated Screw	8	00-1015-632

4.5mm SOLID SCREWS

Product	Description	Qty	Item Number
	4.5mm x 16mm Solid Screw	8	00-1015-516
	4.5mm x 20mm Solid Screw	8	00-1015-520
	4.5mm x 24mm Solid Screw	8	00-1015-524
	4.5mm x 28mm Solid Screw	8	00-1015-528
	4.5mm x 32mm Solid Screw	8	00-1015-532
	4.5mm x 36mm Solid Screw	8	00-1015-536

O-PLATES

Product	Description	Qty	Item Number
	O-Plate 12mm - Center Hole	4	00-1012-212
	O-Plate 16mm - Center Hole	4	00-1012-216
	O-Plate 20mm - Center Hole	4	00-1012-220
	O-Plate 24mm - Center Hole	4	00-1012-224

I-PLATES

Product	Description	Qty	Item Number
	I-Plate 16mm - Center Hole	2	00-1015-416
	I-Plate 22mm - Center Hole	2	00-1015-422
	I-Plate 32mm - Center Hole	2	00-1015-432

I-PLATE AND O-PLATE INSTRUMENTATION

DRILL AND DRILL GUIDES

Description	Qty	Item Number
AO 3.2mm Cannulated Drill	2	01-1010-009
Double Drill Guide	1	01-1010-010
Self-Centering Drill Guide	1	09-1010-010

GUIDE WIRES

Description	Qty	Item Number
1.6mm Guide Wire, Threaded Cobalt Chrome	10	01-1010-007
1.6mm Guide Wire, Threaded Stainless Steel	10	01-9473-4115
1.6mm Guide Wire, Smooth (optional) Cobalt Chrome	10	01-1050-0039
1.6mm Guide Wire, Smooth (optional) Stainless Steel	10	01-9473-4015

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

SCREWDRIVERS

Description	Qty	Item Number
3.5mm Cannulated Hex Screwdriver, AO fitting	1	01-1010-006
3.5mm Hex Screwdriver, AO fitting	1	01-1010-014

BENDING IRONS

Description	Qty	Item Number
Bending Iron, Right	1	01-1010-002
Bending Iron, Left	1	01-1010-013

MISCELLANEOUS

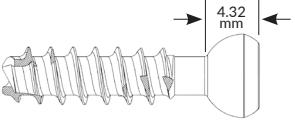
Description	Qty	Item Number
01-1030-009	1	Direct Measuring Device
01-1010-012	1	Depth Gauge
01-1030-001	1	Mini In-line Ratchet w/ small AO push/pull coupling
01-1010-001	1	Mini T-Handle
01-1010-003	1	1.7mm Cleaning Brush
01-1010-004	1	Cleaning Stylet
01-1030-007	1	Self-Holding Screw Forceps

CASE AND TRAY

Description	Qty	Item Number
Case Bottom	1	01-1010-603
Case Tray	1	01-1010-604
Case Lid	1	01-1010-905
Case Screw Caddy	1	01-1010-906
PediPlate Solid Screw Caddy	1	01-1010-951
PediPlate Solid Screw Caddy Lid	1	01-1010-952

PEDIPLATE DELTA

DELTA SCREWS

Product	Description	Qty	Item Number
	4.5mm x 16mm Cannulated Screw, Delta	8	00-1015-0716
	4.5mm x 20mm Cannulated Screw, Delta	8	00-1015-0720
	4.5mm x 24mm Cannulated Screw, Delta	8	00-1015-0724
	4.5mm x 28mm Cannulated Screw, Delta	8	00-1015-0728
	4.5mm x 32mm Cannulated Screw, Delta	8	00-1015-0732
	4.5mm x 36mm Cannulated Screw, Delta	8	00-1015-0736

DELTA PLATES

Product	Description	Qty	Item Number
	PediPlate Delta 12mm	4	00-1012-0312
	PediPlate Delta 16mm	4	00-1012-0316
	PediPlate Delta 20mm	4	00-1012-0320
	PediPlate Delta 24mm	4	00-1012-0324

DELTA-SPECIFIC INSTRUMENTATION

Description	Qty	Item Number
3.2mm Cannulated Drill, Delta	1	01-1010-0209
Double Drill Guide, Delta	1	01-1010-0210

DELTA CASE AND TRAY

Description	Qty	Item Number
PediPlate Delta Base	1	01-1010-0610
PediPlate Delta Case Lid	1	01-1010-0612
PediPlate Delta Tray	1	01-1010-0611
PediPlate Delta Tray Lid	1	01-1010-0615
PediPlate Delta Screw Caddy	1	01-1010-0613
PediPlate Delta Screw Caddy Lid	1	01-1010-0614

I-PLATE AND O-PLATE INSTRUMENTATION

SCREWS

Description	Qty	Item Number
4.5mm Cannulated Screw, Ti, 16mm	8	00-1015-8016
4.5mm Cannulated Screw, Ti 20mm	8	00-1015-8020
4.5mm Cannulated Screw, Ti, 24mm	8	00-1015-8024
4.5mm Cannulated Screw, Ti, 28mm	8	00-1015-8028
4.5mm Cannulated Screw, Ti, 32mm	8	00-1015-8032
4.5mm Cannulated Screw, Ti, 36mm	8	00-1015-8036
4.5mm Solid Screw, Ti, 16mm	8	00-1015-8116
4.5mm Solid Screw, Ti, 20mm	8	00-1015-8120
4.5mm Solid Screw, Ti, 24mm	8	00-1015-8124
4.5mm Solid Screw, Ti, 28mm	8	00-1015-8128
4.5mm Solid Screw, Ti, 32mm	8	00-1015-8132
4.5mm Solid Screw, Ti, 36mm	8	00-1015-8136

PLATES

Description	Qty	Item Number
O-Plate, Ti 12mm	4	00-1015-8212
O-Plate, Ti 16mm	4	00-1015-8216
O-Plate, Ti 20mm	4	00-1015-8220
O-Plate, Ti 24mm	4	00-1015-8224
I-Plate, Ti 16mm	2	00-1015-8416
I-Plate, Ti 22mm	2	00-1015-8422
I-Plate, Ti 32mm	2	00-1015-8432

CASE AND TRAY

Description	Qty	Item Number
Titanium PediPlates Tray	1	01-1012-0001
Titanium PediPlates Lid	1	01-1012-0002
Titanium PediPlates Cannulated Screw Caddy, LP	1	01-1012-0003
Titanium PediPlates Solid Screw Caddy, LP	1	01-1012-0004
Titanium PediPlates Cannulated Screw Caddy Lid, LP	1	01-1012-0005
Titanium PediPlates Solid Screw Caddy Lid, LP	1	01-1012-0006
Titanium PediPlates Plate Caddy	1	01-1012-0011
Titanium PediPlates Plate Caddy Lid	1	01-1012-0012



WARNING: Never mix metals.

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.

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