

Distal Femoral Osteotomy System

SURGICAL TECHNIQUE



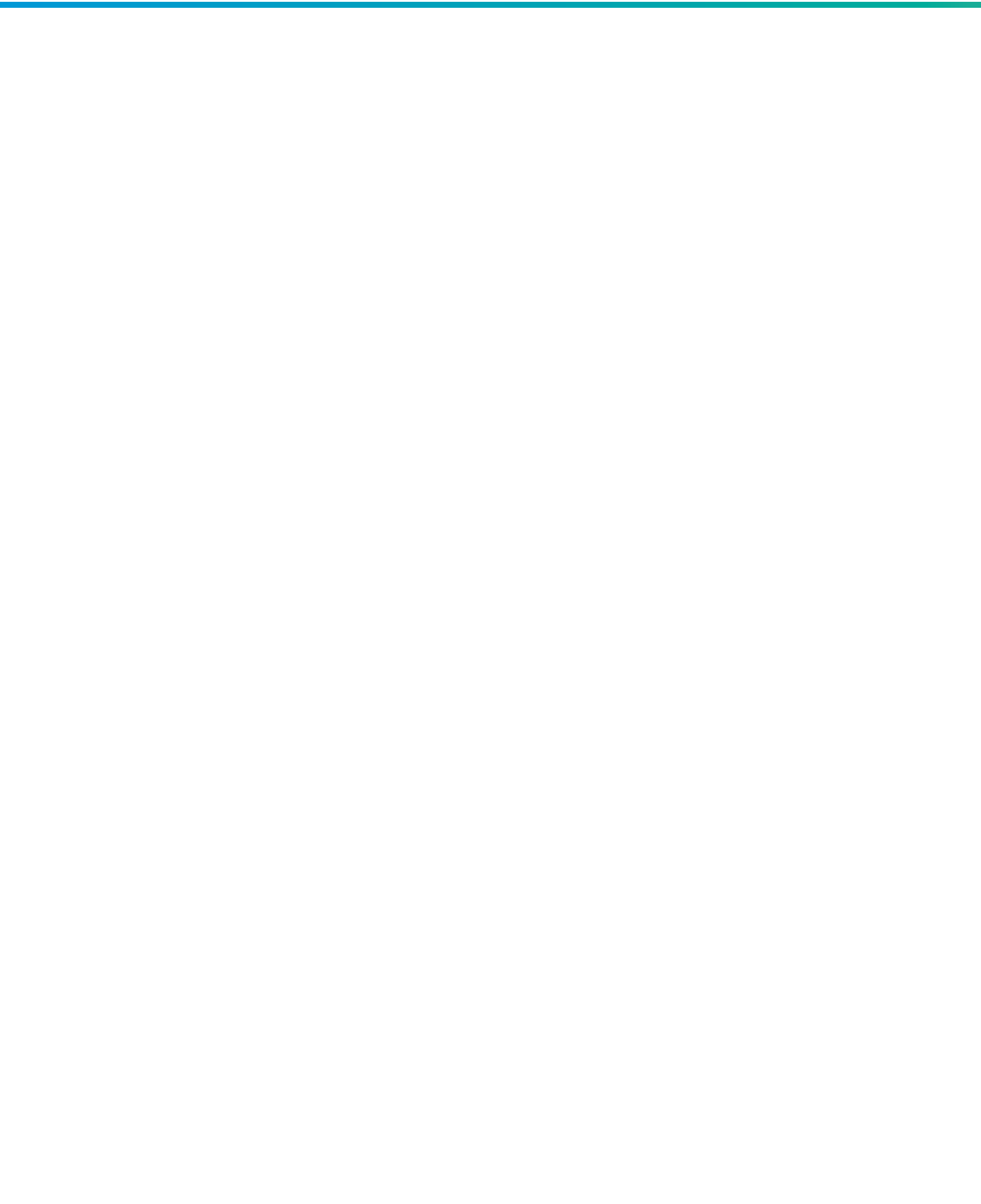


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INDICATIONS

The OrthoPediatrics Distal Femoral Osteotomy System (DFOS) is intended for temporary internal fixation and stabilization of long bone fractures and osteotomies, mal-unions and non-unions, in pediatric and small stature adults.

Description

The OrthoPediatrics Distal Femoral Osteotomy System includes plates and screws used for internal fixation to facilitate bone healing and repair after osteotomy of the distal femur.

This system includes plates with different offsets, which can be used with 3.5mm and 4.5mm cannulated or solid screws. System components are manufactured from stainless steel for increased strength and ease of removal.

Implant contents of the system include:

- 3.5mm 80° plate with 5° flare, no offset and 4 or 6 holes
- 3.5mm 90° plate with 5° flare, no offset and 4 or 6 holes
- 3.5mm 90° plate with 18° flare, 4mm offset and 4 or 6 holes
- 3.5mm 90° plate with 18° flare, 8mm offset and 4 or 6 holes
- 4.5mm 80° plate with 5° flare, no offset and 4 or 6 holes
- 4.5mm 90° plate with 5° flare, no offset and 4 or 6 holes
- 4.5mm 90° plate with 18° flare, 4mm offset and 4 or 6 holes
- 4.5mm 90° plate with 18° flare, 8mm offset and 4 or 6 holes

NOTE: In addition to the contents of the Distal Femoral Osteotomy System set, the following implants and instrumentation are required to perform this procedure:

- 3.5mm or 4.5mm cannulated and/or solid screws (part families 00-0903-25XX, 00-0903-26XX, 00-0907-37XX, 00-0907-45XX, 00-0907-46XX and 00-0907-47XX)
- 3.5mm or 4.5mm Locking Proximal Femur instrumentation

NOTE: In order to ensure proper mating of the sawblade with the cut slots on the cut guides, refer to the cut slot width marked on the individual cut guides.

Within this system, size identification is aided by colors:

- Blue - 3.5mm instruments and implants
- Green - 4.5mm instruments and implants

PLATES

The distal cluster of the Distal Femoral Osteotomy Plates consist of three locking holes X, Y and Z (see Figure 1).

The shaft of the plates contain two types of holes: locking (1) and dynamic compression (2), as shown.

The dynamic compression slots are oriented so that compression is directed toward the location of the osteotomy.

The locking holes allow for insertion of locking or cortical screws. Using cortical screws, 20° of angulation can be obtained in both the longitudinal and transverse planes.

The dynamic compression slots allow for insertion of cortical screws with the ability to obtain 60° of longitudinal angulation and 10° of transverse angulation.

Maximum achievable compression per dynamic compression slot is 1.5mm.

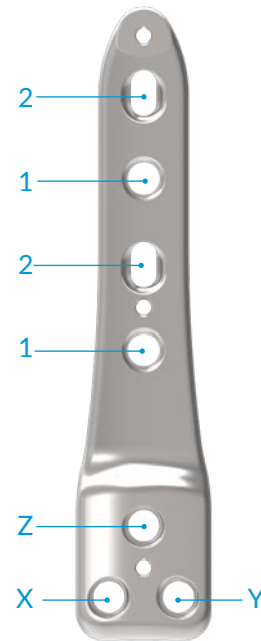


Figure 1: 3.5mm 90° DFOS Plate, 18° Flare, 4mm Offset

SURGICAL TECHNIQUE

Preoperative Planning And Patient Positioning

If performing an extension osteotomy, 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.

If performing a wedge osteotomy, the degree of coronal plane correction is determined from clinical examination and a full-length, standing x-ray. First, draw a line from the center of the femoral head to a target alignment point at the center of the knee joint. A second line is drawn from the center of the tibial-talar joint to the target alignment point used in the first line. The degree of correction required can be found by measuring the proximal angle formed by the two lines.

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.

If a sterile tourniquet will fit, apply sterile tourniquet to the upper thigh.

Give antibiotics per usual protocol. Exsanguinate the leg, and inflate the tourniquet.

Surgical Approach And Exposure

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 then 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, taking care not to injure the perichondrial ring.

If performing an extension osteotomy, proceed to page 7.

If performing an opening wedge osteotomy (coronal plane correction), proceed to page 12.

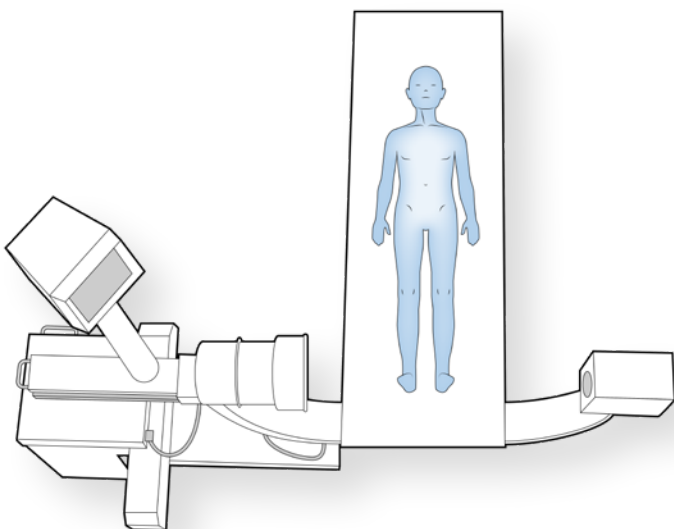


Figure 2: Patient positioning

Item Number	Description
01-1050-1100	Initial Pin Guide Distal Head, 3.5mm Cannulated Screws
01-1050-1110	Initial Pin Guide Distal Head, 3.5mm Solid Screws
01-1050-1120	Initial Pin Guide Distal Head, 4.5mm Cannulated Screws
01-1050-1130	Initial Pin Guide Distal Head, 4.5mm Solid Screws

Table 1

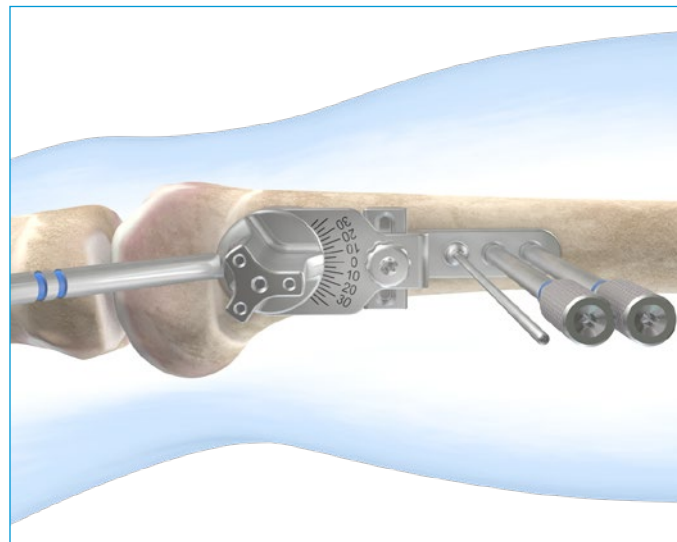


Figure 3: Locate and align proximal portion of initial pin guide

Extension Osteotomy

Placement of Initial Guide Wires

Pre-load the proximal shaft portion of the initial pin guide with two 1.6mm wire guides. Based on the size of implant to be used and the type of screws desired in the distal fragment, select the appropriate distal head portion of the initial pin guide (see Table 1) and assemble it to the proximal shaft portion.

NOTE: Incorrect selection of distal head may result in inaccurate guide wire placement for the distal cluster of screws for the desired implant

NOTE: When assembling the two 1.6mm wire guides, ensure the wire guides are not cross-threaded and are perpendicular to the shaft to ensure proper orientation of the proximal cut guide

Place the initial pin guide on the lateral aspect of the femur, locating it proximal to the distal femoral physis. Provisionally fix the proximal shaft of the initial pin guide to the diaphysis of the femur, using an olive wire or bone clamp through the provisional fixation hole (Figure 3).

NOTE: To ensure accuracy of guide wire placement for the cutting guides, care should be taken to ensure that the proximal shaft of the initial pin guide is parallel and flush with the diaphysis of the femur

NOTE: The X, Y and Z holes of the distal head correspond to the screws on the implant, so care should be taken to not place them too close to the physis

With the proximal shaft of the initial pin guide parallel to the diaphysis of the femur, insert a 1.6mm guide wire into each of the 1.6mm wire guides.

NOTE: This will prevent any unwanted rotation of the shaft of the guide while the distal cluster placement is obtained

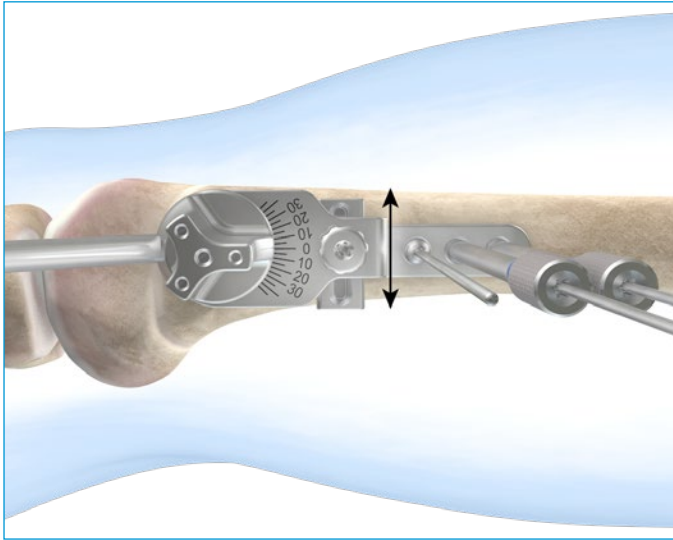


Figure 4: Translation of distal cluster of screws

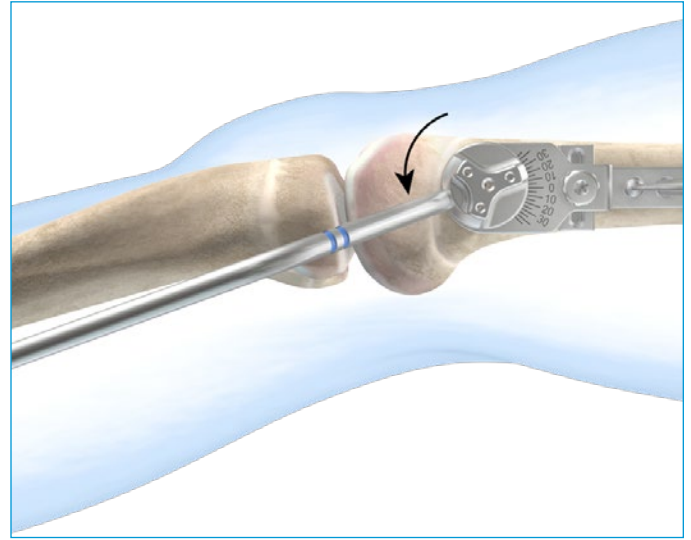


Figure 5: Set angle of distal osteotomy

Extension Osteotomy (cont.)

Placement of Initial Guide Wires (cont.)

If desired, the distal cluster can be translated anteriorly (Figure 4), to accommodate for posterior shift of the distal fragment upon reduction, which both minimizes anterior bump and maintains the mechanical axis in the sagittal plane. Tighten the locking bolt using a T15 or T20 hexalobe driver.

With the knee maximally extended, rotate the handle of the initial pin guide such that it is parallel with the long axis of the tibia (Figure 5). Doing so will correct for the angle of flexion contracture. Angular markings on the initial pin guide can be used as a reference.

NOTE: As rotation of the handle sets the angle of extension correction, care should be taken to compare the angle obtained from the pin guide with the angle obtained during pre-operative planning.

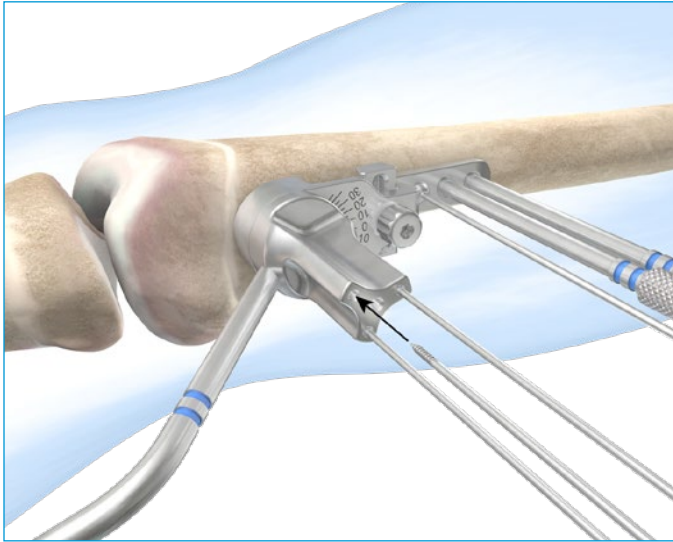


Figure 6: Insert guide wires

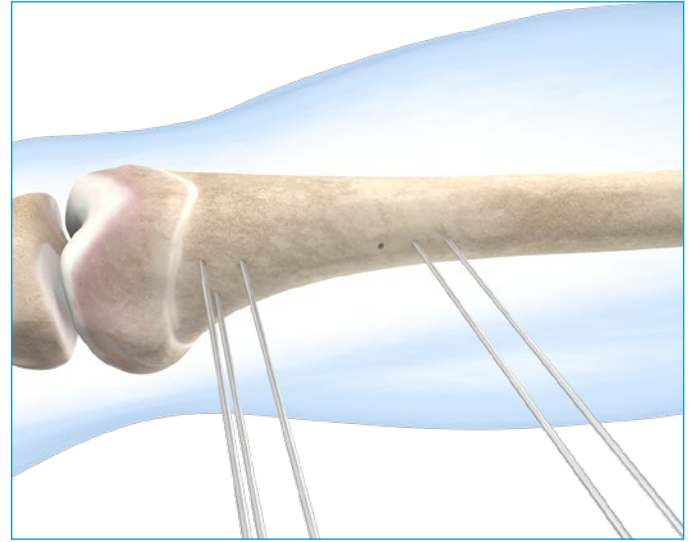


Figure 7: Remove initial pin guide

Extension Osteotomy (cont.)

Placement of Initial Guide Wires (cont.)

While maintaining the handle of the initial pin guide parallel with the axis of the tibia, insert the appropriate size guide wires into the X, Y and Z holes of the distal cluster (Figure 6).

NOTE: These guide wires will provide fixation for the distal cut guide, as well as set the trajectory and location for the three distal screws of the implant.

NOTE: If desired, fill only the X and Y holes, and leave the Z hole open to provide more clearance with the sawblade when the distal cut is made.

NOTE: To prevent penetrating guide wires through the medial cortex, monitor the position of the guide wire using fluoroscopy.

Remove the olive wire (or bone clamp), and slide the pin guide off of the femur (Figure 7).

NOTE: There is no need to remove the 1.6mm threaded wire guides first, as all guide wires are parallel to one another.

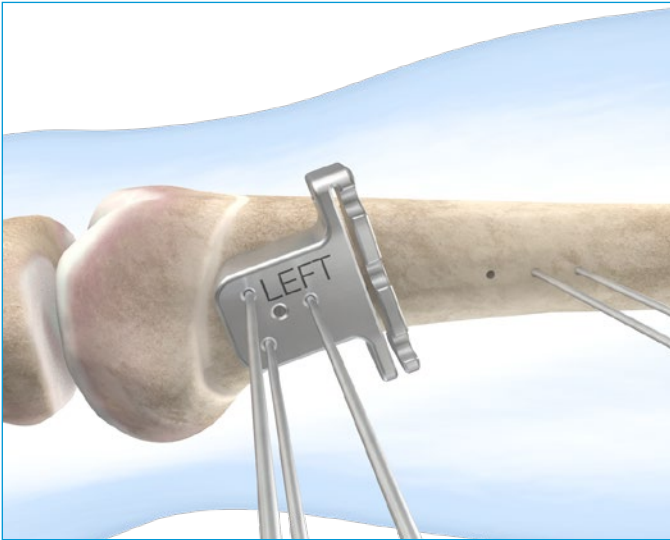


Figure 8: Placement of distal cut guide

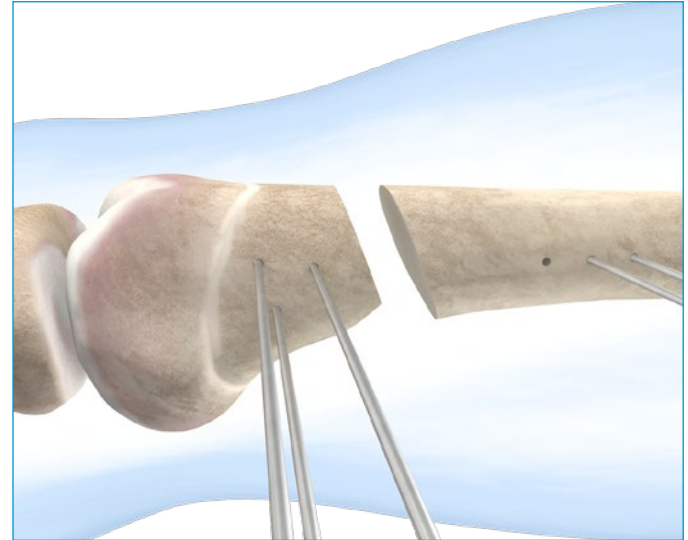


Figure 9: Create the distal osteotomy

Create Distal Osteotomy

Select the appropriate distal cut guide (see Table 2) and slide it over the distal guide wires. The marking for the appropriate side (right or left) should be able to be read (facing away from the bone), and the open side of the cut slot should be towards the posterior aspect of the femur (Figure 8).

Item Number	Description
01-1050-1500	Distal Cut Guide, 3.5mm Cannulated Screws
01-1050-1510	Distal Cut Guide, 3.5mm Solid Screws
01-1050-1600	Distal Cut Guide, 4.5mm Cannulated Screws
01-1050-1610	Distal Cut Guide, 4.5mm Solid Screws

TABLE 2

NOTE: Incorrect selection of the distal cut guide may result in the guide not fitting over or causing damage to the previously placed wires. Additionally, the osteotomy may not be in an ideal location relative to the implant geometry.

Create the distal osteotomy. An olive wire can be used in the middle hole of the distal cut guide to cinch it down to the bone and prevent vibration/movement of the cut guide while the osteotomy is being created. Once the osteotomy is created, remove the olive wire and distal cut guide but leave the distal guide wires in place (Figure 9).

NOTE: Be careful to only insert the olive wire just until the sphere touches the distal cut guide face. Over-tightening will cause the distal cut guide trajectory to be changed.

NOTE: The spike on the posterior aspect of the distal fragment may need to be removed in order to preserve the vessels and soft tissues in the posterior capsule of the knee joint.

CAUTION: Care should be taken to ensure the cut slot of the distal cut guide is perpendicular to the diaphysis of the femur in the coronal plane, to prevent unwanted varus/valgus deformity

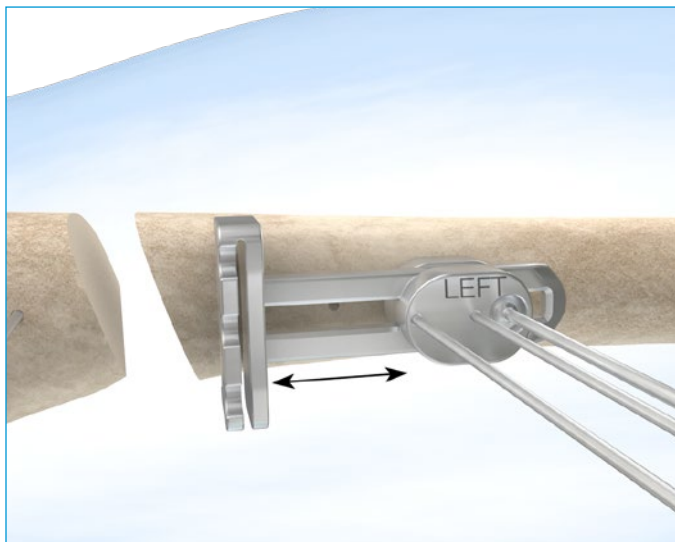


Figure 10: Set desired shortening



Figure 11: Create the proximal osteotomy

Create Proximal Osteotomy

Select the appropriate orientation of the proximal cut guide (right or left) and slide it over the two 1.6mm guide wires on the proximal fragment. The marking for the appropriate side should be able to be read (facing away from the bone), and the open side of the cut slot should be over the posterior aspect of the femur.

Slide the proximal cut guide proximally/distally until the level of desired shortening is obtained, and fix in place using a 30mm olive wire (Figure 10).

NOTE: The olive wire should be used to lock the proximal cut guide in place to prevent an undesirable amount of shortening.

CAUTION: Ensure that the cut slot is perpendicular to the diaphysis of the femur in the coronal and sagittal planes

Make the proximal cut and remove the proximal cut guide as well as the olive wire and the two 1.6mm guide wires (Figure 11).

Once the osteotomies have been completed, proceed to page 14 for fixation and reduction.

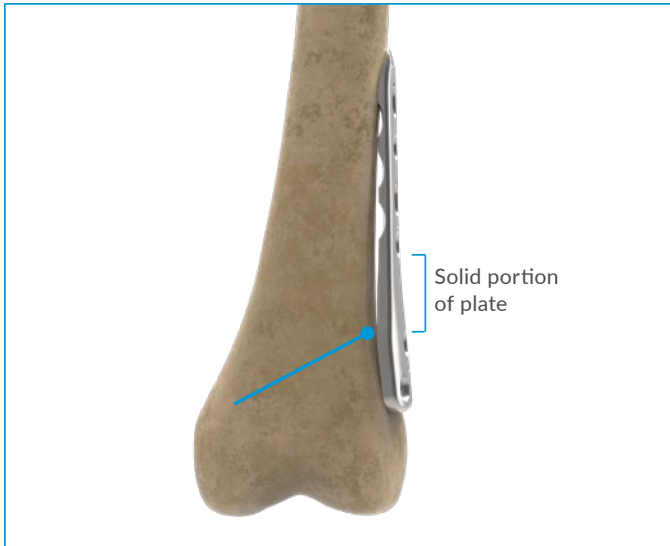


Figure 12: Locate start of oblique osteotomy

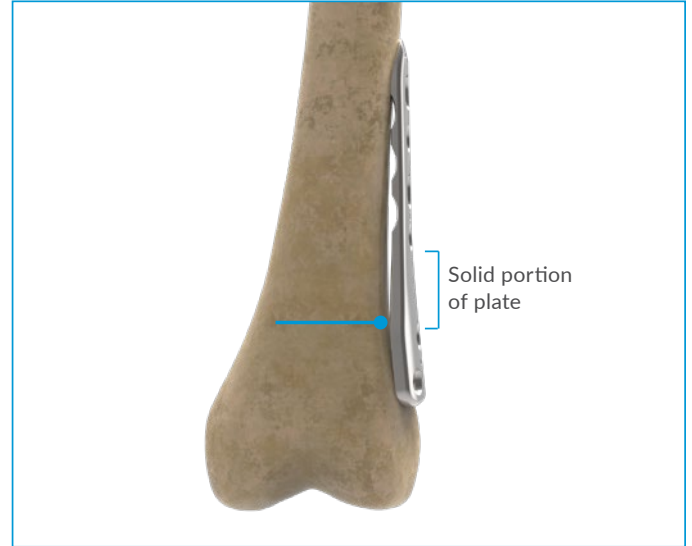


Figure 13: Locate start of transverse osteotomy

Opening Wedge Osteotomy

Locate and Create Osteotomy

Place desired plate on the lateral aspect of distal femur to locate start of osteotomy. The start point of the osteotomy should be located near the distal end of the solid portion of the plate (Figures 12 & 13).

NOTE: Approximately 1cm of medial bone should be preserved to minimize the risk of cortical hinge fracture.

NOTE: If distal femoral physis is closed, plate can be positioned more distally, if desired.

Remove plate and create osteotomy. Hinge open the osteotomy and place a wedge-shaped graft matching the desired correction angle.

Place plate with appropriate threaded wire guides across osteotomy and secure with a clamp. Proceed to page 14 for screw placement.

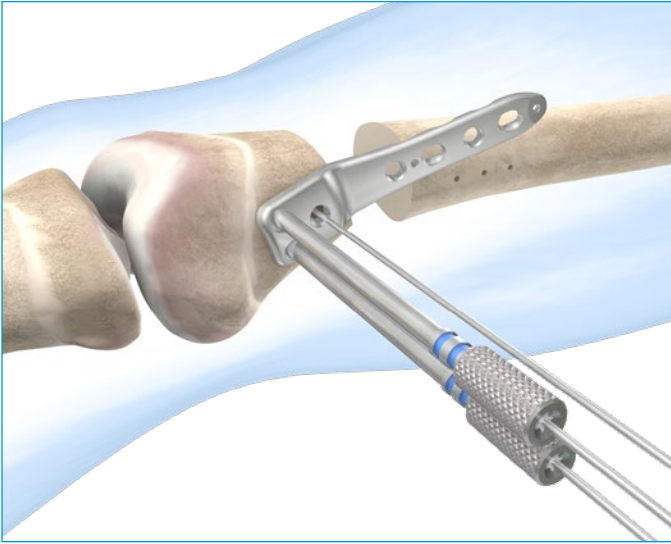


Figure 14: Slide implant over distal guide wires

	3.5mm Plate		4.5mm Plate	
	Solid Screws	Cannulated Screws	Solid Screws	Cannulated Screws
Guide Towers	Single Blue Band	Double Blue Band	Single Green Band	Double Green Band
Guide Wires	2.5mm x 200mm	1.6mm x 230mm	3.2mm x 200mm	2.0mm x 230mm

Table 3

Common Steps

Distal Fixation

Mate the appropriate threaded towers (see Table 3) in the X and Y holes of the distal cluster on the desired implant. Slide the construct over the three guide wires on the distal fragment (Figure 14).

NOTE: If only the X and Y guide wires were placed in the distal fragment with the initial pin guide, three threaded wire guides (or three threaded drill guides) should be attached to the X, Y and Z holes. This will ensure proper trajectory of the Z hole.

NOTE: Take care not to cross-thread the towers onto the plate as this may lead to wire trajectories that prohibit the screws from locking into the plate.

NOTE: Be sure to use the correct combination of plate, guide towers, and guide wires. Smaller diameter wires will fit through larger diameter towers, but may lead to difficulty locking the screws to the plate. Furthermore, the guide towers for solid screws and cannulated screws are different lengths. Using the wrong wires and towers may lead to an incorrect screw measurement at a later step.

CAUTION: Ensure that the distal fragment sits within the offset of the plate. In order to facilitate this, a chamfer may need to be added on the lateral edge of the osteotomy surface.

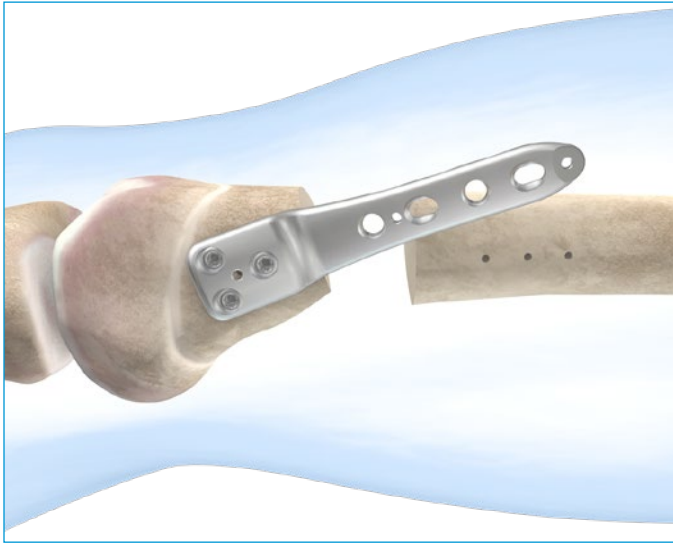


Figure 15: Insert distal screws

Common Steps (cont.)

Distal Fixation (cont.)

Fill the three distal holes on the implant with desired screws. Fill the Z hole first, then remove the threaded towers from the X and Y holes individually and fill (Figure 15). This will help maintain the orientation of the implant on the distal fragment.

	3.5mm Plate		4.5mm Plate	
	Solid Screws	Cannulated Screws	Solid Screws	Cannulated Screws
Direct Measuring Device	Blue	Blue	Green	Green
Measurement	Guide Tower On	Guide Tower Off	Guide Tower On	Guide Tower Off
End of Measuring Device	Back End	Front End (Nose)	Back End	Front End (Nose)

Table 4

Locking Solid Screw Placement

Measure the appropriate screw length using the scale on the back of the tower.

NOTE: The measurement for screw length varies between solid and cannulated screws. Be sure to use the correct combination of direct measuring device, tower on/off, and the correct end of the measuring device. Failure to do so may result in an incorrect screw length (See table 4).

Remove the tower and guide wire and, if necessary, manually tap the near cortex. Fully insert the chosen screw with the solid driver. Complete all steps for a given screw before moving on to the next screw.

CAUTION: In poor quality bone the trajectory of the screw can be altered if excessive pressure is applied during insertion. This can lead to the screw head not locking into the plate.

CAUTION: Failure to adequately tighten the locking screw into the plate may lead to screw back-out.

Cannulated Screw Placement

Remove the tower and measure for the appropriate screw length.

NOTE: The measurement for screw length varies between solid and cannulated screws. Be sure to use the correct combination of direct measuring device, tower on/off, and the correct end of the measuring device. Failure to do so may result in an incorrect screw length (See Table 4).

Use the cannulated drill bit to open the near cortex. It is not necessary to drill the full depth of the wire. If necessary, manually tap the near cortex with the cannulated tap. Pass the chosen screw over the wire and insert with the cannulated driver.

CAUTION: If the wire is bent, the cannulated drill and/or driver may advance the wire further or may not pass over the wire at all. If this is the case, mate the corresponding tower to the plate and exchange the wire.

Once the screw is nearly fully seated, remove the guide wire. Final tightening should be performed with a solid (non-cannulated) driver. Complete all steps for a given screw before moving on to the next screw.

CAUTION: Failure to adequately tighten the locking screw into the plate may lead to screw back-out.

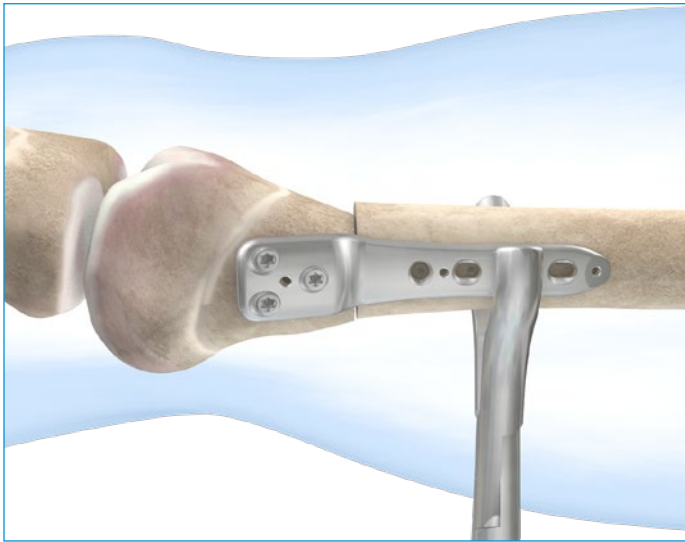


Figure 16: Reduce distal and proximal fragments

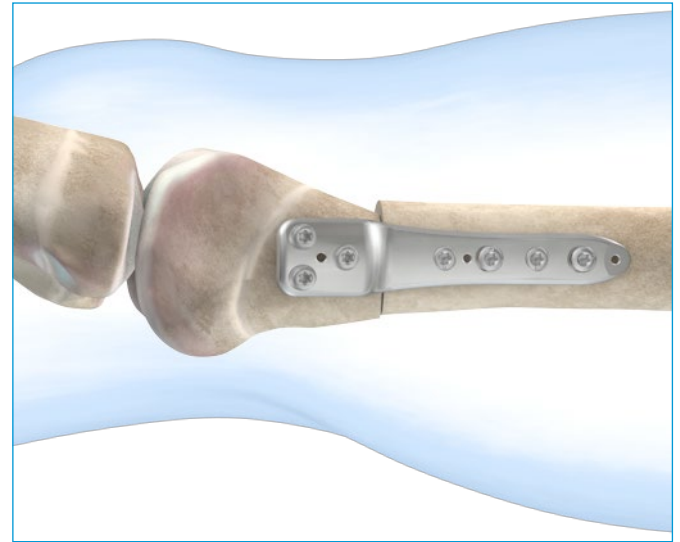


Figure 17: Insert proximal shaft screws

Reduction

Using the appropriate bone clamp—small or large—reduce the distal and proximal fragments in the desired orientation (Figure 16). Optimal fixation is achieved when the plate is aligned with the femoral shaft axis in the AP and lateral planes. Any internal or external rotation can be accounted for in this step.

NOTE: When reducing the plate to the femoral shaft after placing the distal screws, positioning the bone clamp in the first locking hole will lead to subsequent interference with a compression screw in the first dynamic slot. Compression should be applied through the second dynamic slot to avoid this interference.

Proximal Fixation

Fill the proximal holes of the implant with desired screws (Figure 17).

The DFOS family of plates features alternating compression slots and locking holes along the plate shaft. If compression is desired, appropriately placed cortical screws must be inserted prior to any locking screws.

Dynamic Compression Screw Placement

Position the appropriate drill bit at the distal end of the compression slot using either the GOLD side of the neutral/load drill guide, or the size-matched side of the double drill guide.

Drill through both cortices and measure with the appropriate depth gauge.

Insert the chosen screw until the head begins to engage the plate. When engagement begins, simultaneously release some of the pressure exerted by the bone clamp and fully seat the screw into the plate.

With the screw fully seated, the clamp can be removed. If a second compression screw is desired, repeat the steps above. When the head of the second screw begins to engage the plate, loosen the first screw just enough (about $\frac{1}{2}$ turn) to allow the plate to slide further along the femoral shaft. Fully seat the second screw and then re-tighten the first screw.

Static Screw Placement

Position the appropriate drill bit at the center or the proximal end of the compression slot using either the GREEN side of the neutral/load drill guide, or the size-matched side of the double drill guide.

Drill through both cortices and measure with the appropriate depth gauge.

Insert the chosen screw until fully seated in the plate. Repeat steps for additional screws, as needed.

Static screws can also be placed through the locking holes. The same procedure is followed, however, the double drill guide must be used, as the oblong ends of the neutral/load drill guide will not fit in the locking holes.

Locking Solid Screw Placement

Mate the appropriate threaded drill guide (tower) to the plate and insert the size-matched calibrated drill bit.

Drill through the near cortex and stop when the far cortex is reached. Note the depth of the drill by reading the calibrations on the back of the tower.

Drill through the far cortex.

Remove the tower. If necessary, manually tap both cortices.

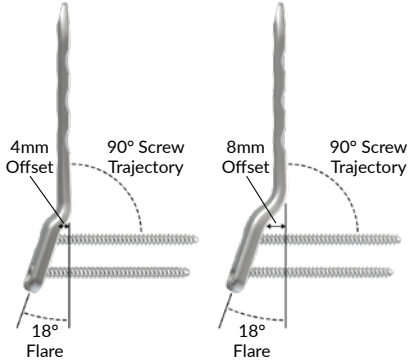
Insert the chosen screw.

Locking screws should be the last screws placed, as they create a fixed-angle construct, limiting any potential movement between the plate and the bone.

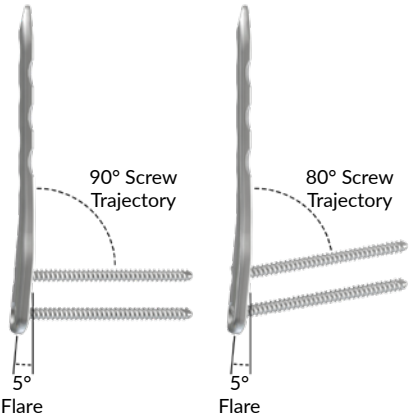
CAUTION: Failure to adequately tighten the locking screw into the plate may lead to screw back-out. Confirm all screws are fully locked prior to closing the incision.

PLATES

18° FLARE PLATES, WITH OFFSET

Product	Description	Item Number	Holes
	3.5mm 90° DFOS Plate, 18° Flare, 4mm Offset	00-1050-5104	4
	3.5mm 90° DFOS Plate, 18° Flare, 4mm Offset	00-1050-5106	6
	3.5mm 90° DFOS Plate, 18° Flare, 8mm Offset	00-1050-5204	4
	3.5mm 90° DFOS Plate, 18° Flare, 8mm Offset	00-1050-5206	6
	4.5mm 90° DFOS Plate, 18° Flare, 4mm Offset	00-1050-6104	4
	4.5mm 90° DFOS Plate, 18° Flare, 4mm Offset	00-1050-6106	6
	4.5mm 90° DFOS Plate, 18° Flare, 8mm Offset	00-1050-6204	4
	4.5mm 90° DFOS Plate, 18° Flare, 8mm Offset	00-1050-6206	6

5° Flare Plates, NO offset

Product	Description	Item Number	Holes
	3.5mm 90° DFOS Plate, 5° Flare, No Offset	00-1050-5004	4
	3.5mm 90° DFOS Plate, 5° Flare, No Offset	00-1050-5006	6
	4.5mm 90° DFOS Plate, 5° Flare, No Offset	00-1050-6004	4
	4.5mm 90° DFOS Plate, 5° Flare, No Offset	00-1050-6006	6
	3.5mm 80° DFOS Plate, 5° Flare, No Offset	00-1050-7004	4
	3.5mm 80° DFOS Plate, 5° Flare, No Offset	00-1050-7006	6
	4.5mm 80° DFOS Plate, 5° Flare, No Offset	00-1050-8004	4
	4.5mm 80° DFOS Plate, 5° Flare, No Offset	00-1050-8006	6

INSTRUMENTATION

Description	Item Number
Initial Pin Guide Proximal Shaft	01-1050-1000
Initial Pin Guide Distal Head, 3.5mm Cannulated Screws	01-1050-1100
Initial Pin Guide Distal Head, 3.5mm Solid Screws	01-1050-1110
Initial Pin Guide Distal Head, 4.5mm Cannulated Screws	01-1050-1120
Initial Pin Guide Distal Head, 4.5mm Solid Screws	01-1050-1130
Distal Cut Guide, 3.5mm Cannulated Screws	01-1050-1500
Distal Cut Guide, 3.5mm Solid Screws	01-1050-1510
Distal Cut Guide, 4.5mm Cannulated Screws	01-1050-1600
Distal Cut Guide, 4.5mm Solid Screws	01-1050-1610
Proximal Cut Guide	01-1050-1900
1.6mm Threaded Wire Guide	01-0907-0005
1.6mm X 230mm Guide Wire	01-0907-0020
2.0mm x 150mm Guide Wire, 6.5mm Olive, 30mm Thread	01-1050-1830
2.0mm x 150mm Guide Wire, 6.5mm Olive, 45mm Thread	01-1050-1845



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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