

PediFlex Advanced Elastic Stable Intramedullary Nails

SURGICAL TECHNIQUE



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INDICATIONS

The OrthoPediatics PediFlex™ Nail System is intended for fixation of diaphyseal fractures of long bones where the medullary canal is narrow or flexibility of the implant is required. This includes upper extremity fractures in all patients and lower extremity fractures in pediatric or small stature patients. In pediatric patients, the flexibility of the nail allows it to be inserted at a point that does not disturb or disrupt the growth plate.



IMPLANT SELECTION

The flexible intramedullary nails are available in both stainless steel and titanium. The stainless steel nails have a greater stiffness value than the titanium nails of the same size. Surgeon preference dictates the appropriate material type for the nail based on the stiffness required to stabilize the fracture and allow for appropriate healing.

- 1 *Note: For a complete listing of available sizes, please refer to the Product Information at the end of this technique guide.*

CAUTION: *Never mix implant materials.*

INSERTER ASSEMBLY & USE

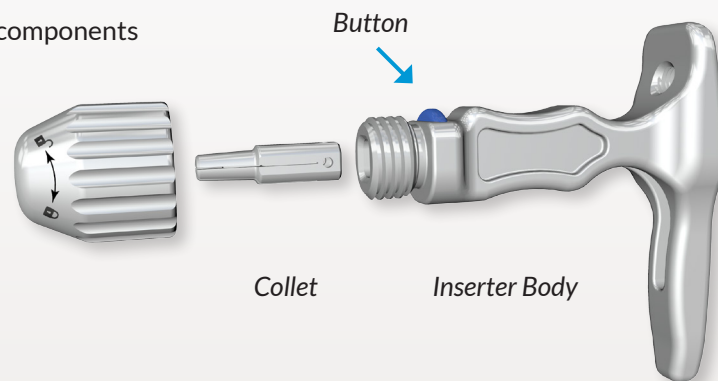
The redesigned PediFlex inserter has three main components, shown in Figure 1.

1. Inserter Body
2. Knob
3. Collet

- 1 *Note: Collets are specifically designed to work with one nail size. Multiple Collets for each size nail are provided in the set.*

After selecting the appropriate nail size for the procedure, choose the corresponding Collet before assembling Inserter.

FIGURE 1: Inserter components



Assembly instructions:

1. Depress and hold button on Inserter body
2. Insert Collet into square hole following the direction of the arrow
3. Release button
4. Install Knob and rotate a turn to ensure thread engagement
5. The Inserter is now ready for use

Use:

1. Insert nail into tip of Collet
2. Rotate Knob in the locking direction, as shown by arrows, to grip the nail
3. Tighten the Knob firmly by hand
4. NOTE: no additional tools are required for tightening
5. Impact the rear face of the Inserter using the Slotted Mallet
6. Rotate the Knob in the opposite direction to release the nail

- 1 *Note: The Inserter, Knob, and Collet should be disassembled and returned to their respective locations in the tray for cleaning and sterilization.*
- 2 *Note: Collets are designed to be reused, but should be discarded and replaced if they exhibit a decrease in functionality.*
- 3 *Note: Inspect Inserter before and after each use for fractures or cracks.*

PATIENT POSITIONING - FEMUR FRACTURES

Position the patient supine on a radiolucent operating table (Figure 2). The limb (or both limbs, in the case of bilateral fractures) can be prepared and draped free. This facilitates simultaneous irrigation and debridement of open femur fractures or fixation of an ipsilateral tibia fracture. In order to bring the fracture out to length, an assistant may be required to apply manual traction.

Alternatively, place the patient on a fracture table in a supine position. Carefully pad the post to protect the perineum. Apply traction to the affected limb using a well-padded boot. Slightly externally rotate the limb to match the proximal fragment, which tends to externally rotate slightly when the patient is positioned on the fracture table. Prep and drape the lower extremity using split sheets to allow circumferential access to the thigh. Cover the image intensifier with a sterile drape to visualize the hip and femur.

The proximal femur can be best visualized by arcing the intensifier so the beam is directed from posteromedial to anterolateral. This allows the surgeon to see the externally rotated proximal femur in a non-rotated anteroposterior projection.

IMPLANT SELECTION

Measure the diameter of the intramedullary canal of the femur to be stabilized (Figure 3). For femur fractures, two nails of equal size that fill up approximately 80% of the intramedullary canal are adequate. *For example, if the intramedullary canal is 8cm in diameter, two 3.0mm nails would be sufficient ($8 \times .8 = 6.4\text{mm}/2 = 3.2\text{mm}$).*

- 1 *Note: For a complete listing of available sizes, please refer to the Product Information at the end of this technique guide.*

CAUTION: *Never mix implant materials.*

*Shown to the right:
Intramedullary canal diameter = 8.0mm.
Nail diameter = 3.0mm each.*



FIGURE 2: Place patient supine



FIGURE 3: Select

RETROGRADE FEMORAL NAILING

Using a metal object and fluoroscopy, mark the skin at the level of the distal femoral physis. Make a small (1cm) longitudinal incision approximately 2cm above the distal femoral physis (Figure 4).

1 *Note: Avoid crossing the physis with the flexible nail.*

Using a drill bit or an awl larger than the diameter of the flexible nail, begin preparing an entry point in the bone perpendicular to the long axis of the femur until the drill bit/awl begins to engage the cortex. Once the drill bit/awl engages the cortex, angle the drill bit/awl proximally so that a channel is created in the bone for insertion of the flexible intramedullary nail.

2 *Note: Use caution not to perforate the far cortex.*

Insert one intramedullary nail at a time (Figure 5).

3 *Note: It is often necessary and helpful to create a bend in the flexible intramedullary nail that will correspond to the apex of the fracture when the nail is inserted (Figure 6).*

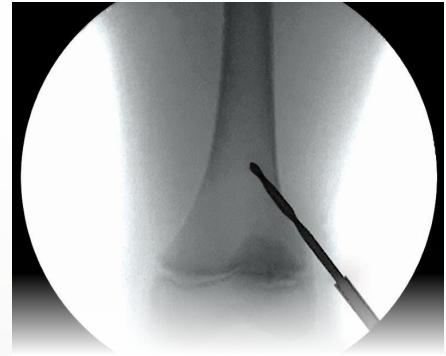


FIGURE 4: Make small incision above distal femoral physis



FIGURE 5: Insert one nail at a time

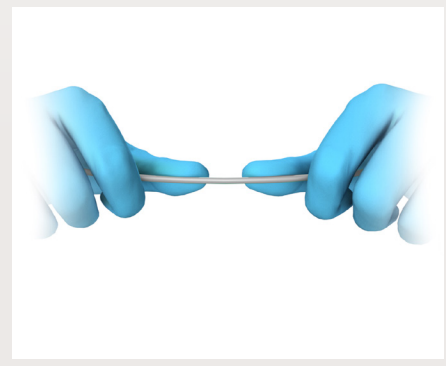


FIGURE 6: Create a bend that corresponds to the apex of the fracture

Insert the flexible intramedullary nail into the previously drilled hole and advance by hand until resistance is felt, making sure the entry point does not cross the epiphysis or physis. Using the Slotted Mallet, advance the nail, making sure to keep the round portion of the tip against the far cortex.

CAUTION:

1. *Verify that the interface between the nail Inserter and the nail is tight to avoid debris generation.*
2. *Do not point the flexible intramedullary nail toward the cortex, as it is possible to advance the nail through the cortex.*
3. *If significant resistance is felt, remove the flexible intramedullary nail and re-drill the entry hole for the nail, enlarging it.*

Advance one flexible intramedullary nail to the fracture site. Repeat on the opposite side of the affected bone. Once both flexible intramedullary nails reach the fracture site, advance one nail just past the fracture. Before advancing the first nail further, advance the second nail past the fracture. Once both nails cross the fracture, advance both nails.

CAUTION:

1. *Insert both nails just past fracture site prior to driving single nail to final position, thereby preventing unanticipated fracture displacement.*

Insert the nails proximally reaching the proximal femoral metaphysis. Leave the nails just short of the final position desired, 0.5cm-1.0cm. (The nails will be advanced using a bone tamp for final positioning.)

Cut the nails distally, leaving a portion of the nail protruding from the cortex. Using a bone tamp, advance the nail to the position desired.



Note: Leave a piece of flexible nail long enough to be able to retrieve once the femur has properly healed. Failure to do so may require additional dissection of soft tissue and removal of surrounding bone in order to access the intramedullary nail.

CAUTION:

1. *Leaving the flexible intramedullary nail too long may lead to patient discomfort and skin irritation.*

PATIENT POSITIONING - TIBIA FRACTURES

Position the patient supine on a radiolucent table (Figure 7). It is rarely necessary to utilize a fracture table for this procedure.

Apply manual traction to the affected limb to achieve proper length and rotation. Prepare and drape the affected extremity, or if bilateral, both extremities.

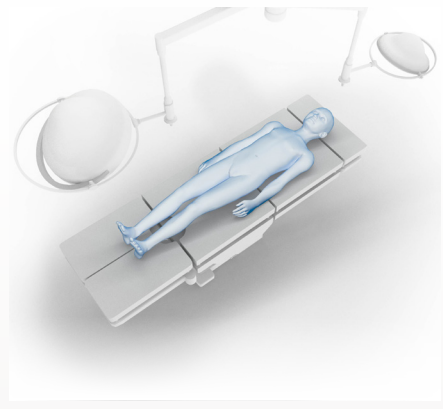


FIGURE 7: Place patient supine

IMPLANT SELECTION

Measure the diameter of the intramedullary canal of the tibia to be stabilized (Figure 8). For tibia fractures, two flexible intramedullary nails of equal size are desired.

For tibia fractures, two nails of equal size that fill-up approximately 80% of the intramedullary canal are adequate. *For example, if the intramedullary canal is 6.2cm in diameter, two 2.5mm nails would be sufficient ($6.2 \times .8 = 4.96\text{mm}/2 = 2.48\text{mm}$).*

- 1 *Note: For a complete listing of available sizes, please refer to the Product Information at the end of this technique guide.*

CAUTION: *Never mix implant materials.*



FIGURE 8: Select implant

ANTEGRADE TIBIAL NAILING

Using a metal object, mark the skin at the level of the proximal tibial physis. Make a small (1cm) longitudinal incision approximately 1-2cm below the proximal tibial physis.

1 *Note: Avoid crossing the physis with the flexible nail.*

Using a drill bit or an awl larger than the diameter of the flexible nail, begin preparing an entry point in the bone perpendicular to the long axis of the femur until the drill bit/awl begins to engage the cortex. Once the drill bit/awl engages the cortex, angle the drill bit/awl proximally so that a channel is created in the bone for insertion of the flexible intramedullary nail (Figure 9).

2 *Note: Use caution not to perforate the far cortex.*

Insert one intramedullary nail at a time (Figure 10).

3 *Note: It is often necessary and helpful to create a bend in the flexible intramedullary nail that will correspond to the apex of the fracture when the nail is inserted (Figure 11).*



FIGURE 9: Insert drill bit into proximal tibia

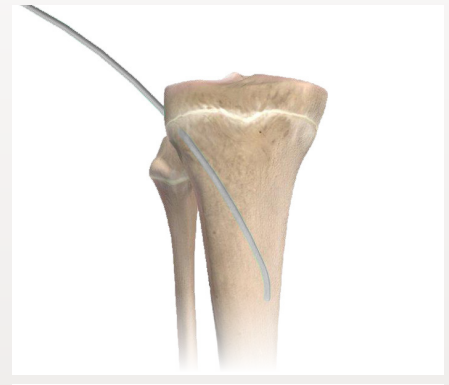


FIGURE 10: Insert nail

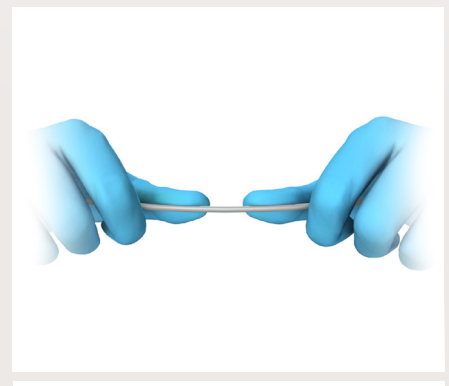


FIGURE 11: Create a bend that corresponds to the apex of the fracture

Insert the flexible intramedullary nail into the previously drilled hole and advance by hand until resistance is felt, making sure the entry point does not cross the epiphysis or physis. Using the Slotted Mallet, advance the nail, making sure to keep the round portion of the tip against the far cortex.

CAUTION:

1. *Verify that the interface between the nail inserter and the nail is tight to avoid debris generation.*
2. *Do not point the flexible intramedullary nail toward the cortex, as it is possible to advance the nail through the cortex.*
3. *If significant resistance is felt, remove the flexible intramedullary nail and re-drill the entry hole for the nail, enlarging it.*

Advance one flexible intramedullary nail to the fracture site. Repeat on the opposite side of the affected bone. Once both flexible intramedullary nails reach the fracture site, advance one nail just past the fracture. Before advancing the first nail further, advance the second nail past the fracture. Once both nails cross the fracture, advance both nails.

CAUTION:

1. *Insert both nails just past fracture site prior to driving single nail to final position, thereby preventing unanticipated fracture displacement.*

Advance the nails distally to reach the distal tibial metaphysis. Leave the nails just short of the final position desired, 0.5cm-1.0cm. (The nails will be advanced using a bone tamp for final positioning.)

Cut the nails distally, leaving a portion of the nail protruding from the cortex. Using a bone tamp, advance the nail to the position desired.

1

Note: Leave a piece of flexible nail long enough to be able to retrieve once the tibia has properly healed. Failure to do so may require additional dissection of soft tissue and removal of surrounding bone in order to access the intramedullary nail.

CAUTION:

1. *Leaving the flexible intramedullary nail too long may lead to patient discomfort and skin irritation.*

PATIENT POSITIONING - FOREARM FRACTURES

Position the patient supine on a standard operating table with a radiolucent arm board (Figure 12).

Prepare and drape the affected limb allowing access to the elbow and wrist.

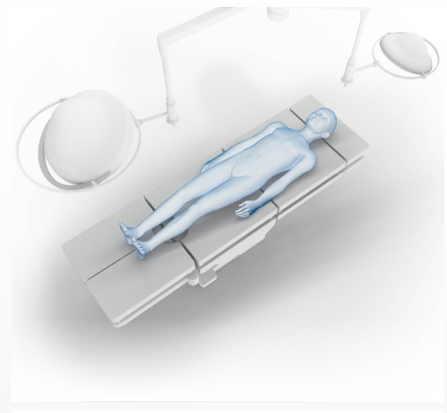


FIGURE 12: Place patient supine

IMPLANT SELECTION

It is not necessary to fill the entire canal of the radius or ulna in order to obtain stabilization.

Select a nail that will easily insert into the intramedullary canal, no larger than 70-80% of the inner diameter of the radius or ulna (Figure 13).

- 1 Note: For a complete listing of available sizes, please refer to the Product Information at the end of this technique guide.

CAUTION: Never mix implant materials.



FIGURE 13: Select implant

RADIUS NAIL INSERTION

Using a metal object, mark the skin at the level of the distal radial physis and make a mark at Lister's tubercle (Figure 14).

Make a small incision just proximal to Lister's tubercle, dorsally.

① *Note: Avoid crossing the physis with the flexible nail.*

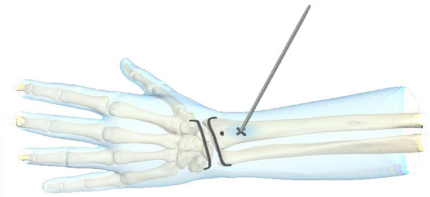


FIGURE 14: Mark the skin at the level of the distal radial physis

Alternatively, a medial starting point may be used at the same level, just proximal to the level of Lister's tubercle (Figure 15).



FIGURE 15: Select a medial starting point just proximal to Lister's tubercle

ULNA NAIL INSERTION

Using a metal object, mark the skin at the level of the ulna apophysis. Make a small incision just proximal to the ulna apophysis (Figure 16) or just distal to the ulna apophysis (Figure 17). Either entry point is acceptable.

- 1 Note: Avoid crossing the physis with the flexible nail.



FIGURE 16: Mark the skin at the level of the ulna apophysis



FIGURE 17: Make a small incision just proximal or distal to the ulna apophysis

Advance the nail by hand as far as it will go. If resistance is felt, attach the Flexible Nail Inserter and advance the nail using light strikes with the mallet (Figure 18).

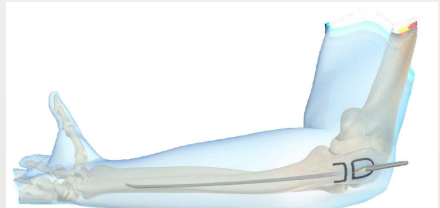


FIGURE 18: Advance the nail by hand

If it is difficult to advance the nail across the fracture site into the distal segment of bone, make a small incision to assist with manual reduction of the fracture (Figure 19).



FIGURE 19: Make a small incision to assist with manual fracture reduction

Insert the nail distally, reaching near the physis of the distal ulna but not across. Leave the nail just short of the final position desired, 0.5cm-1.0cm. (The nail will be advanced using a bone tamp for final positioning.)

Cut the nail proximally, leaving a portion of the nail protruding from the cortex of the proximal ulna (Figure 20). Using a bone tamp, advance the nail to the position desired.



FIGURE 20: Leave the nail just short of the final position desired

- 1** *Note: A bend may be placed at the end of the ulna nail in order to reduce soft tissue irritation and facilitate removal.*

PATIENT POSITIONING - HUMERUS FRACTURES

Position the patient supine on a standard operating table with a radiolucent arm board (Figure 21).

Prepare and drape the affected limb insuring access to the distal humerus as well as the proximal humerus. Standard humeral nailing is done retrograde. However, antegrade nailing is also appropriate.

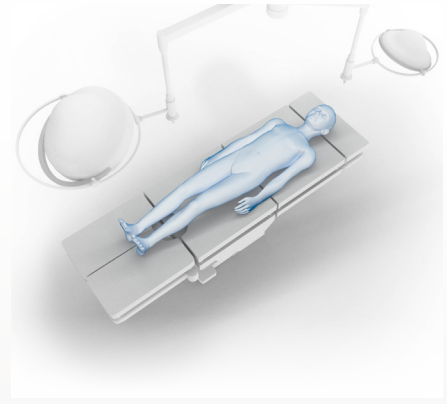


FIGURE 21: Place patient supine

IMPLANT SELECTION

Measure the diameter of the intramedullary canal of the humerus to be stabilized (Figure 22). For humeral fractures, two flexible intramedullary nails of equal size are desired.

For humeral fractures, two nails of equal size that fill up approximately 80% of the intramedullary canal are adequate. *For example, if the intramedullary canal is 5.0mm in diameter, two 2.0mm nails would be sufficient ($5.0\text{mm} \times .8 = 4.5\text{mm}/2 = 2.25\text{mm}$).*

- 1 Note: If the nails are too large, it may be difficult to insert them. If the nails are too small, inadequate stabilization may occur.
- 2 Note: For a complete listing of available sizes, please refer to the Product Information at the end of this technique guide.

CAUTION: Never mix implant materials.



FIGURE 22: Select implant

RETROGRADE HUMERAL NAILING

Using a metal object, mark the skin approximately 2cm proximal to the olecranon fossa (Figure 23).

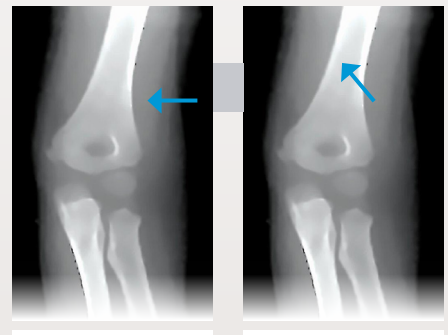


FIGURE 23: Mark skin 2cm proximal to olecranon fossa

Make a small (0.5-1.0cm) incision just proximal to the olecranon fossa on the medial or lateral aspect of the humerus (Figures 24a & 24b).

Using a drill bit larger than the diameter of the flexible nail, begin drilling perpendicular to the long axis of the humerus until the drill bit begins to engage the cortex. Once the drill bit engages the cortex, angle the drill bit proximally so that a channel is created in the bone for insertion of the flexible intramedullary nail.

Alternatively, a small bone awl may be used. Position the small bone awl perpendicular to the long axis of the humerus and using a twisting motion, advance the bone awl through the cortex. Once the bone awl is through the cortex, angle it proximally creating a channel for insertion of the flexible intramedullary nail.



FIGURES 24a & 24b: Make a small incision proximal to olecranon fossa on the medial or lateral aspect of the humerus

Insert the flexible intramedullary nail into the previously drilled hole and advance by hand until resistance is felt, making sure the entry point does not cross the epiphysis or physis. Using the Slotted Mallet, advance the nail, making sure to keep the round portion of the tip against the far cortex.

CAUTION:

1. *Verify that the interface between the nail Inserter and the nail is tight to avoid debris generation.*
2. *Do not point the flexible intramedullary nail toward the cortex, as it is possible to advance the nail through the cortex.*
3. *If significant resistance is felt, remove the flexible intramedullary nail and re-drill the entry hole for the nail, enlarging it.*

Advance one flexible intramedullary nail to the fracture site. Repeat on the opposite side of the affected bone. Once both flexible intramedullary nails reach the fracture site, advance one nail just past the fracture. Before advancing the first nail further, advance the second nail past the fracture. Once both nails cross the fracture, advance both nails.

CAUTION:

1. *Insert both nails just past fracture site prior to driving single nail to final position, thereby preventing unanticipated fracture displacement.*

Advance the nails proximally reaching the proximal humeral metaphysis. Leave the nails just short of the final position desired, 0.5cm-1.0cm. (The nails will be advanced using a bone tamp for final positioning.)

Cut the nails distally, leaving a portion of the nail protruding from the cortex. Using a bone tamp, advance the nail to the position desired.



Note: Leave a piece of flexible nail long enough to be able to retrieve once the humerus has properly healed. Failure to do so may require additional dissection of soft tissue and removal of surrounding bone in order to access the intramedullary nail.

CAUTION:

1. *Leaving the flexible intramedullary nail too long may lead to patient discomfort and skin irritation.*

IMPLANT REMOVAL

Using a metal object and fluoroscopy, mark the skin at the level of the previously implanted flexible intramedullary nail. Create a small incision at the mark. Insert the PediFlex Extractors to gain an initial grip on the end of the nail.

A small 'tooth' feature has been provided on one side of the Extractor jaws to aide initial grip on the nail (Figure 25). The sharp tooth can be used to clear away bone which has grown around the end of the implant.

The Extractors can be held at an angle and lightly malleted around the nail. This style grip can be used to begin extraction (Figures 26a & 26b).

Once ~10mm of nail has been exposed the nail can be loaded directly into the Extractors and removal can continue (Figure 27).

- ① *Note: Slap Hammer threads should be fully tightened prior to and during use.*

CAUTION:

1. *Excessive force can result in the fracture of the nail.*
2. *Excessive force can damage the jaws of the Extractor.*

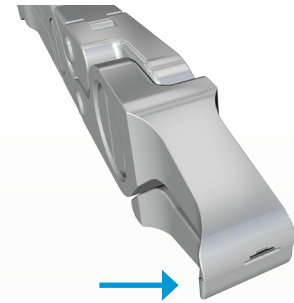
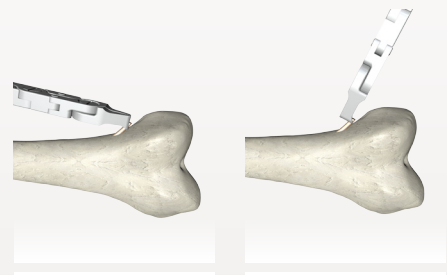


FIGURE 25: Tooth feature of Extractor jaws



FIGURES 26a & 26b: Possible orientations of extractors to obtain initial grip on implant

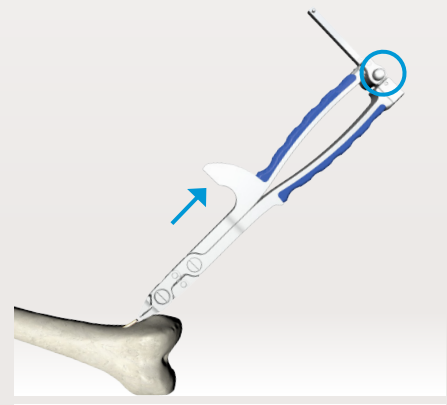


FIGURE 27: Orientation of Extractors to implant during removal. Arrow shows preferred impact location. Circle shows push-button release to obtain initial grip on implant

STAINLESS STEEL NAILS

Item Number	Qty	Description	Length (mm)
00-1001-0015	4	1.5mm x 300mm SS Flexible IM Nail	300
00-1001-0020	4	2.0mm x 300mm SS Flexible IM Nail	300
00-1001-0025	4	2.5mm x 300mm SS Flexible IM Nail	300
00-1001-0030	4	3.0mm x 400mm SS Flexible IM Nail	400
00-1001-0035	4	3.5mm x 400mm SS Flexible IM Nail	400
00-1001-0040	4	4.0mm x 450mm SS Flexible IM Nail	450

TITANIUM NAILS

Item Number	Qty	Description	Length (mm)
00-1001-0115	4	1.5mm x 300mm Ti Flexible IM Nail	300
00-1001-0120	4	2.0mm x 300mm Ti Flexible IM Nail	300
00-1001-0125	4	2.5mm x 300mm Ti Flexible IM Nail	300
00-1001-0130	4	3.0mm x 400mm Ti Flexible IM Nail	400
00-1001-0135	4	3.5mm x 400mm Ti Flexible IM Nail	400
00-1001-0140	4	4.0mm x 450mm Ti Flexible IM Nail	450
00-1001-0145	4	4.5mm x 450mm Ti Flexible IM Nail	450

INSTRUMENTATION

Item Number	Qty	Description	Length (mm)
01-1000-004	1	Sliding Mass / Slap Hammer	--
01-1000-008	1	2.0 & 2.7 Double Drill Guide	--
01-1000-009	2	2.7mm Drill Bit	--
01-1000-010	2	3.2mm Drill Bit	--
01-1000-011	2	4.5mm Drill Bit	--
01-1000-012	1	3.2 & 4.5 Double Drill Guide	--
01-1000-013	1	Flex Nail Cutter	--
01-1000-014	2	2.0mm Slotted Drill Bit	--
01-1000-015	1	F-Tool	--
01-1000-019	1	Small Beveled Tamp - 5mm	--
01-1000-020	1	Large Beveled Tamp - 8mm	--
01-1000-022	1	Rod Cutter	--
01-1000-023	1	Rod Bender	--
01-1000-025	2	5.0mm Drill Bit	--
01-1000-026	1	5.0 Drill Guide	--
01-1001-1001	2	Insertor Body	--
01-1001-1003	2	Insertor Knob, Solid	--
01-1001-2000	1	PediFlex Extractor	--
01-1001-1015	4	Collet, 1.5mm	--
01-1001-1020	4	Collet, 2.0mm	--
01-1001-1025	4	Collet, 2.5mm	--
01-1001-1030	4	Collet, 3.0mm	--
01-1001-1035	4	Collet, 3.5mm	--
01-1001-1040	4	Collet, 4.0mm	--
01-1001-1045	4	Collet, 4.5mm	--
01-1001-0016	1	Slotted Mallet	--

IMPLANT & INSTRUMENT TRAYS

Item Number	Qty	Description	Length (mm)
01-1001-9010	1	PediFlex Outer Container 1	--
01-1001-9011	1	PediFlex Instrument Tray 1	--
01-1001-9012	1	PediFlex Instrument Tray 2	--
01-1001-9020	1	PediFlex Outer Container 2	--
01-1001-9021	1	PediFlex Instrument Tray 3	--
01-1001-9022	1	PediFlex SS Implant Tray	--
01-1001-9023	1	PediFlex Ti Implant Tray	--

CAUTION: Federal law restricts this device to sale by or the order of a Physician.

CAUTION: Devices are supplied Non-Sterile. Clean and sterilize before use according to instructions.

CAUTION: Implants components are single-use. Do not reuse.

CAUTION: The device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

CAUTION: Only those instruments and implants contained within this system are recommended for use with this technique. Other instruments or implants used in combination or in place of those contained within this system is not recommended.

This technique has been provided by one of our medical advisors only as guidance and it is not intended to limit the methods used by trained and experienced surgeons.

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