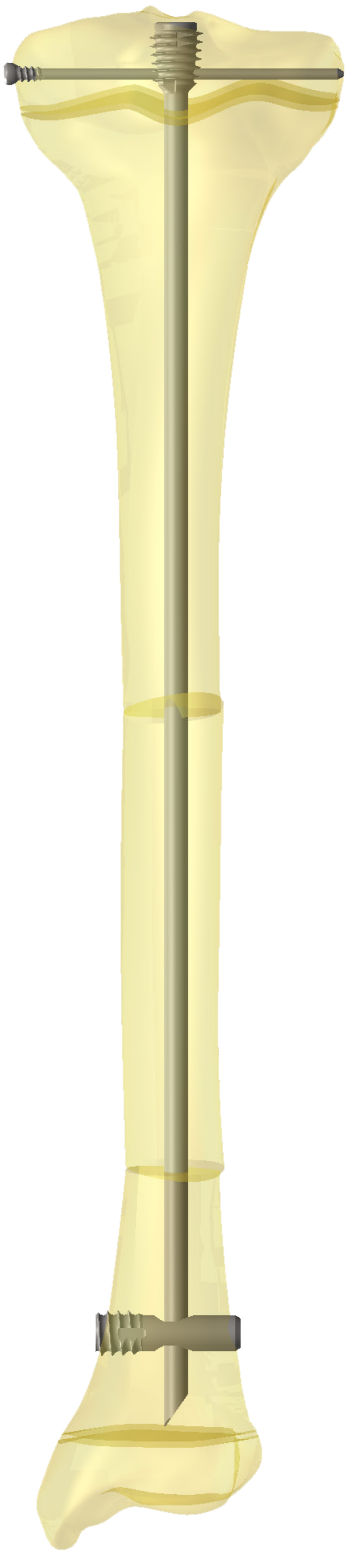
slm

Simple Locking • IntraMedullary System™

SURGICAL TECHNIQUE



OrthoPediatrics® CANADA

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Product Information

Indications

The SLIM (Simple Locking IntraMedullary) System is a new generation of pediatric orthopedic nails specifically designed to create a stable fixation in long bones with small canals.

Features and Benefits:

- Diameter ranges from Ø 2.0 - 6.4 mm
- Threaded head designed to reduce risk of implant migration
- Proximal and distal locking options available for additional stability and lengthening over nail procedures
- All-in-one instrumentation designed to ease insertion and removal

The Simple Locking IntraMedullary (SLIM) System is intended as a temporary implant for alignment, stabilization and fixation of long bones that have been surgically prepared (osteotomy) for correction of deformities, or have sustained fractures due to trauma or disease. This includes:

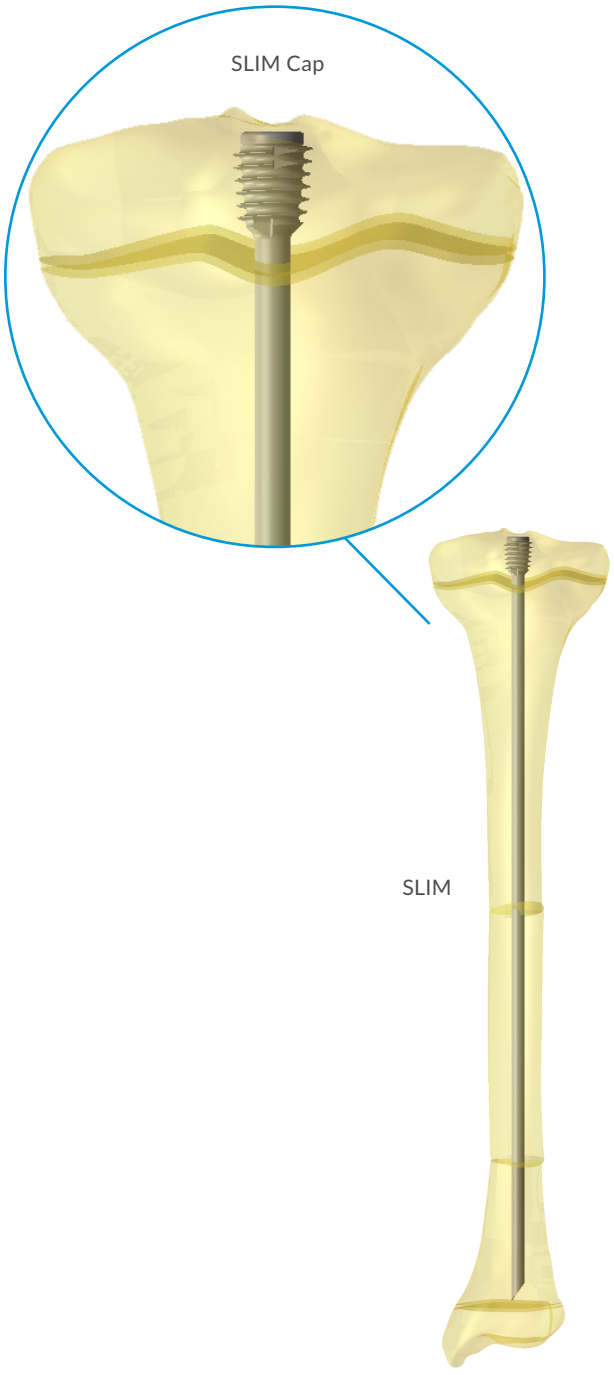
Femur and tibia in the pediatric population (child and adolescent), and small-stature adults such as patient with small intramedullary canals affected by skeletal dysplasias, osteogenesis imperfecta or other bone diseases.

Humerus, ulna, fibula in all patient populations.

Indications (cont.)

The solid shaft, beveled point, and pre-determined or blank length options are designed for easy insertion in the medullary canal. Anchorage of the device is achieved through a conical cortical thread to obtain a stable fixation in the epiphyses or cortical bone, which aims to reduce the risk of migration.

Internal features, such as a hexagonal drive and an internal mechanical thread in the head of the device, are designed for capture and guidance during insertion and retrieval. Additional proximal and distal locking holes allow supplemental pinning using pins or Pega Pegs when required. The Bullets allow fixation of smaller diameter shafts that cannot be cross-pinned due to their size.



Sizes Available

The SLIM implants are manufactured in medical grade Stainless Steel (SS316L, ASTM F138). **The rods are available in seven diameters: 2.0, 2.6, 3.2, 4.0, 4.8, 5.6 and 6.4 mm, from 80mm up to 400 mm in length**, and the 400 mm blanks allow the surgeon to customize the length of the rod.

Surgical Planning

Diameter Considerations

Selection of the SLIM's diameter is based on the size of the isthmus of the medullary canal.

Length Considerations

The SLIM length can be determined preoperatively using x-ray imaging. The length of the SLIM can also be determined or confirmed intraoperatively after reduction. Under image intensification, place the SLIM over the affected limb and confirm the length. For patients with open physes, the SLIM's tip should end prior to the distal growth plate.

Note: Select the SLIM corresponding to the desired diameter and length OR select a SLIM Blank (400 mm) of the desired diameter from Table 1: SLIM Selection Guide. Refer to Table 2 (Step 6): For Interlocking Options.

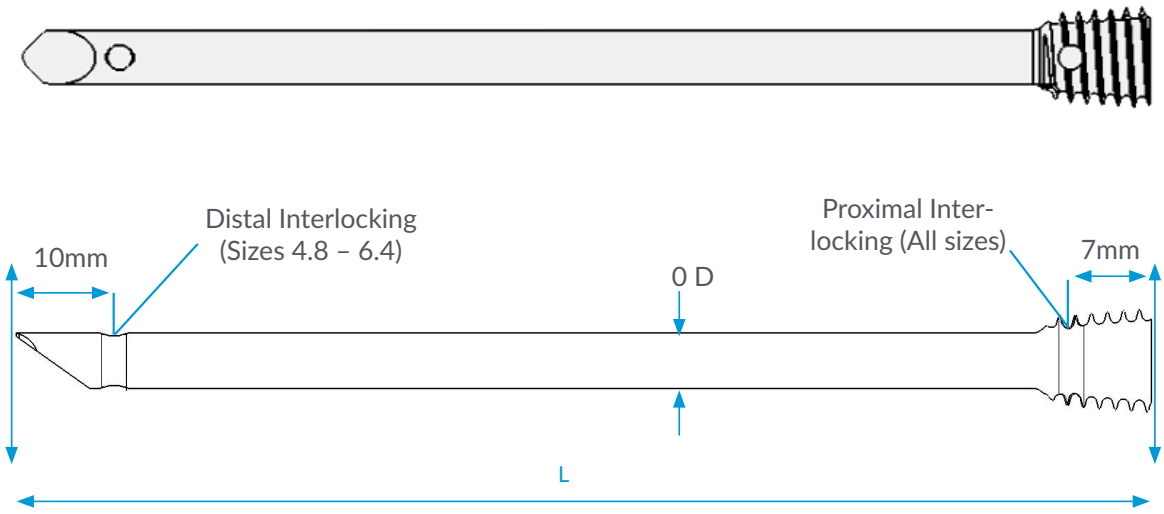


Table 1: SLIM Selection Guide

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</table>

Surgical Technique

Note: The surgical technique should be performed under image intensification (C-arm) using a radiolucent table.

Step 1 Entry Point / Incision

For all indications, adequate reaming must be performed to allow smooth nail insertion. It is recommended to rectify the canal before insertion of the straight implant as it can tolerate a minimal amount of bending before being threaded into its final position.

Antegrade Femur (Fig. 1)

Through a classic lateral approach, the femur is exposed subperiosteally. An entry point through the tip of the greater trochanter is used to avoid the Piriformis fossa.

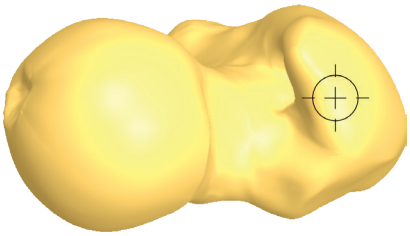
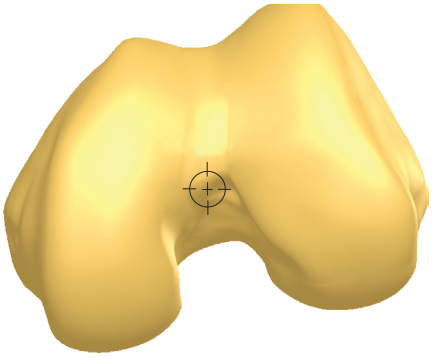


Figure 1

Retrograde Femur (Fig. 2)

The incision is made centered over, but not through the patellar ligament. Special care should be taken not to injure the medial and lateral menisci, the articular cartilage or the ACL. The entry point is located in the middle of the intercondylar notch (AP), anterior and lateral to the femoral attachment of the posterior cruciate ligament. On the lateral view, it should be located in the extension of the Blumensaat's intercondylar roof line.

Figure 2



Antegrade Tibia (Fig. 3)

The incision is made centered over, but not through, the patellar ligament. Special care should be taken not to injure the medial and lateral menisci, the articular cartilage or the ACL. The entry point should be in line with the anatomical axis, medial to the lateral tibial eminence or just lateral to the midline. A retrograde approach is also possible through the medial malleolous.

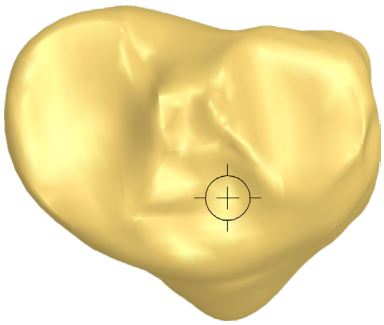


Figure 3

Retrograde Fibula (Fig. 4)

A 1.5 cm longitudinal skin incision is made 1 cm distal to the tip of the laletal malleolous. The entry point is in line with the centre of the medullary canal, at the medial line of the lateral ankle. An antegrade approach is also possible through the tip of the fibular head.

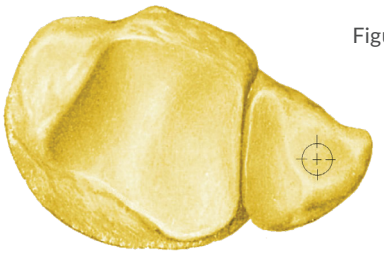
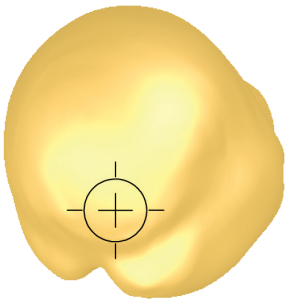


Figure 4

Antegrade Humerus (Fig. 5)

A skin incision is made from the AC joint to the beginning of the deltoid fibers splitting the deltoid fibers and underlying supraspinatus tendon. Special care should be taken not to damage the coracoacromial ligament and subdeltoid bursa. The entry point in the humeral head should be in line with the bicipital groove, which is aligned with the intramedullary canal or slightly lateral to avoid the rotator cuff.

Figure 5



Antegrade Ulna (Fig 6.)

A 1.5 cm longitudinal incision is made from the tip of the olecranon (proximal part of the ulna). The entry point is in line with the center of the medullary canal and in the center of the upper olecranon process. A retrograde approach is also possible from the distal metaphysis posteriorly.

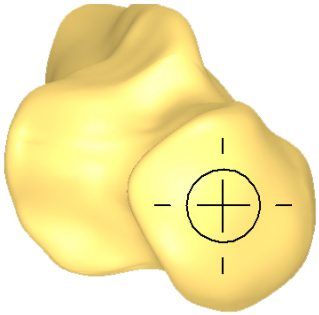


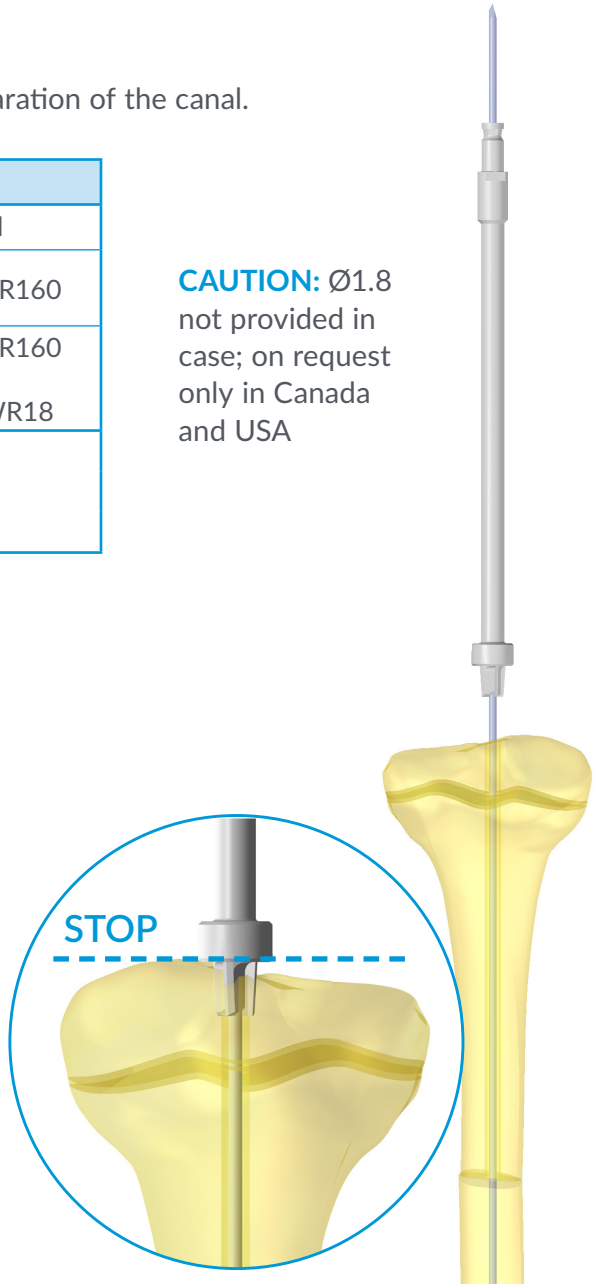
Figure 6

Step 2 Canal Preparation

Select the appropriate Reamer from the table below for preparation of the canal.

SLIM Size (mm)	Reamer	Guidewire
Ø 2.0 - Ø 2.6	GIN-DCA026	Non cannulated
Ø 3.2	SLM-DCA032	Ø 1.6 mm, SLM-GWR160
Ø 4.0	SLM-DCA040	Ø 1.6 mm, SLM-GWR160 or Ø 1.8 mm, SLM-GWR18
Ø 4.8	SLM-DCA048	Ø 2.0 mm SLM-GWR200
Ø 5.6	SLM-DCA056	
Ø 6.4	SLM-DCA064	

CAUTION: Ø1.8 not provided in case; on request only in Canada and USA



Reaming of the canal can be done percutaneously or through the osteotomy/fracture site.

Using a steady pressure, drill with the corresponding Reamer up to but not past the growth plate most distal from the entry point.

Remove the Reamer and Guidewire when reaming is complete.

For percutaneous reaming, a Tissue Protector [GIN-TPR100] is provided. Reaming can also be done manually using the provided Jacob Chuck T-Handle [GIN-JCH100].

CAUTION: Do not force the Reamer when advancing becomes difficult. Partially retract the Reamer in order to clean out debris.

Step 3 Countersink Reaming of the Head (Optional)

The SLIM head is conical and includes a self-cutting feature. For hard cortical bone, Countersink Reamers are provided to facilitate SLIM insertion. Select the appropriate Countersink Reamer from the table below for preparation of the canal entry for the SLIM's thread.

Reaming of the countersink is done percutaneously. Using a steady pressure, drill until the Countersink Reamer stopper reaches the bone surface as shown.

Countersink Reamers are to be used with a powered drill (Small Hudson connection).

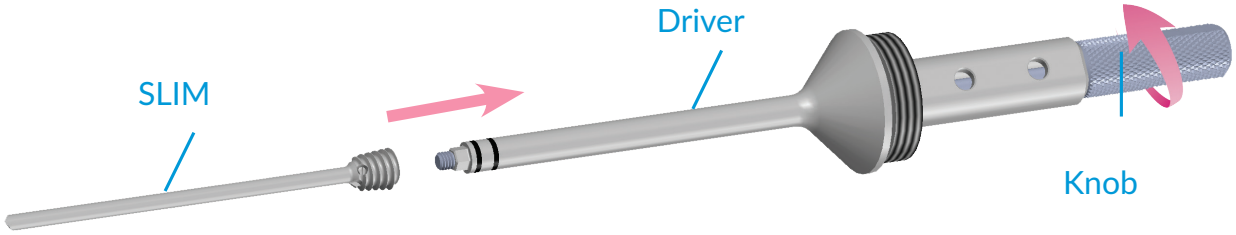
SLIM Size (mm)	Countersink Reamer	Guidewire
Ø 2.0 - Ø 2.6	SLM-CNR101	Countersink Reamers all cannulated for 2.0 Guidewire or less
Ø 3.2		
Ø 4.0	SLM-CNR102	
Ø 4.8		
Ø 5.6	SLM-CNR103	
Ø 6.4		

Step 4 SLIM Assembly

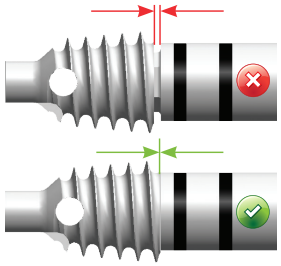
Select the SLIM Driver corresponding to the appropriate SLIM family

SLIM family	Driver
Ø 2.0 - 2.6 - 3.2	SLM-DRV123
Ø 4.0 - 4.8 - 5.6 - 6.4	SLM-DRV146

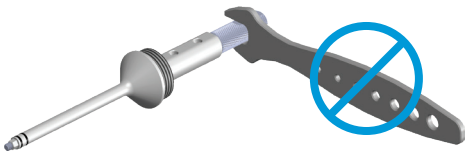
Mount the SLIM onto the Driver by turning the knob clockwise.



CAUTION: There should be no space between the SLIM Driver and the SLIM once assembly is completed



CAUTION: It is important to finger tighten the Knob onto the SLIM. Do not use the Wrench.

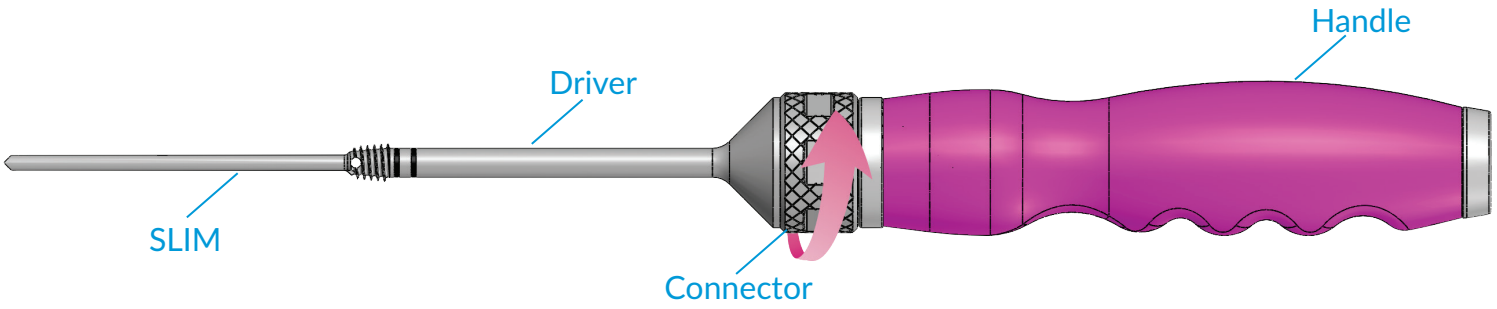


Step 4 Cont. SLIM Assembly

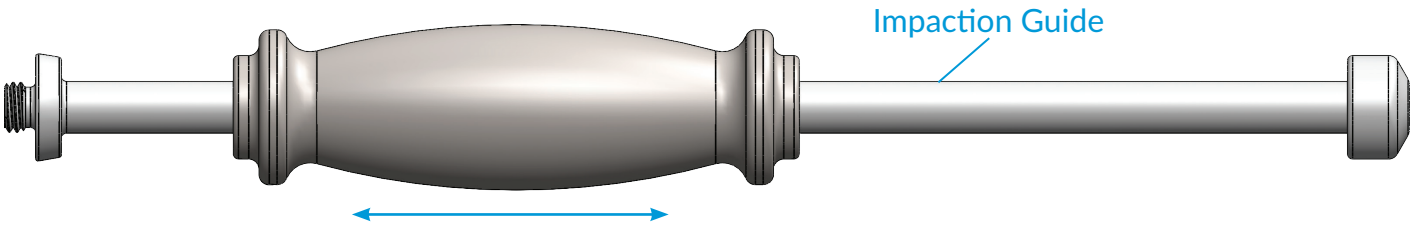
Insert the SLIM Driver into the SLIM Handle

[SLM-HND100] respecting the orientation of the flats. Complete the assembly by tightening the connector clockwise.

CAUTION: Do not use wrenches to tighten the connector; finger-tight is sufficient.



If impaction is necessary, the SLIM Impaction Guide [SLM-IPT100] can be threaded onto the SLIM Handle.



Step 5 SLIM Insertion

Advance the SLIM through the medullary canal until the conical head reaches the cortex.

When interlocking is desired, keep the handle and driver attached to the SLIM Rod and proceed to STEP 6.

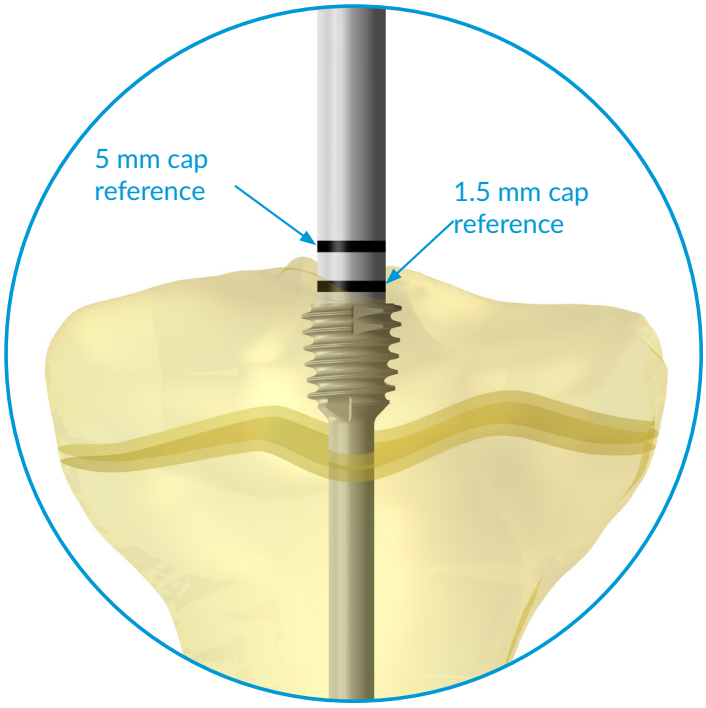
CAUTION: If advancing the SLIM proves difficult, ensure that the SLIM is properly oriented and aligned. Additional reaming may be required.

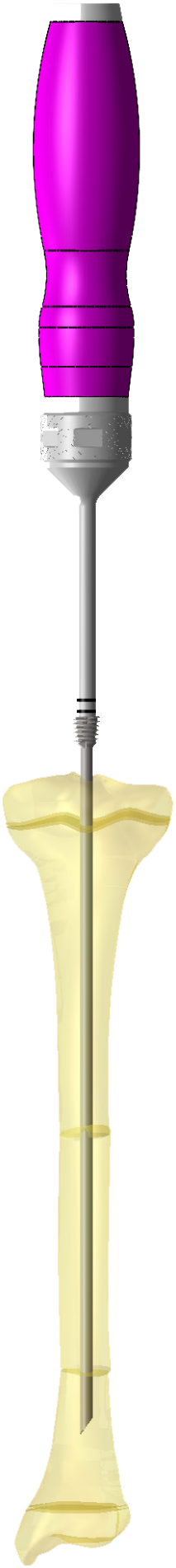
Monitor and control the SLIM's advancement in both the AP and Lateral planes to avoid misalignment.

The threaded portion of the head should be completely inserted in the epiphysis, making sure that no threads invade the proximal physis.

CAUTION: The handle should remain supported during insertion to avoid bending of the implant caused by the weight of the instrument.

CAUTION: Do not advance the threaded head by impaction.





Step 6 InterLocking (optional)

If interlocking of the SLIM is desired, the following options are available.

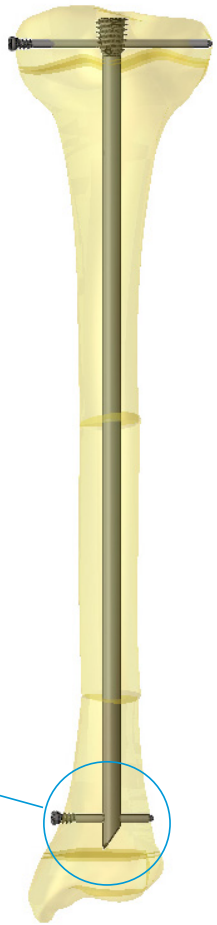
Table 2: Interlocking Options

Implant Size (Ø)	Proximal Locking	Distal Locking
Ø 2.0 mm	Ø 2.0 mm Pega Peg or Pin	Ø 4.8 mm Bullet
Ø 2.6 mm		
Ø 3.2 mm		Ø 6.0 mm Bullet
Ø 4.0 mm		
Ø 4.8 mm	Ø 2.0 mm Pega Peg or Pin	Ø 2.0 mm Pega Peg or Pin
Ø 5.6 mm *	Ø 2.4 mm Pega Peg or Pin	Ø 2.4 mm Pega Peg or Pin
Ø 6.4 mm *	Ø 2.8 mm Pega Peg or Pin	Ø 2.8 mm Pega Peg or Pin

CAUTION: The diameter of the Bullet, Pins, or Pegs should be selected based on bone diameter. The maximum diameter should not be greater than one-third of the bone diameter.

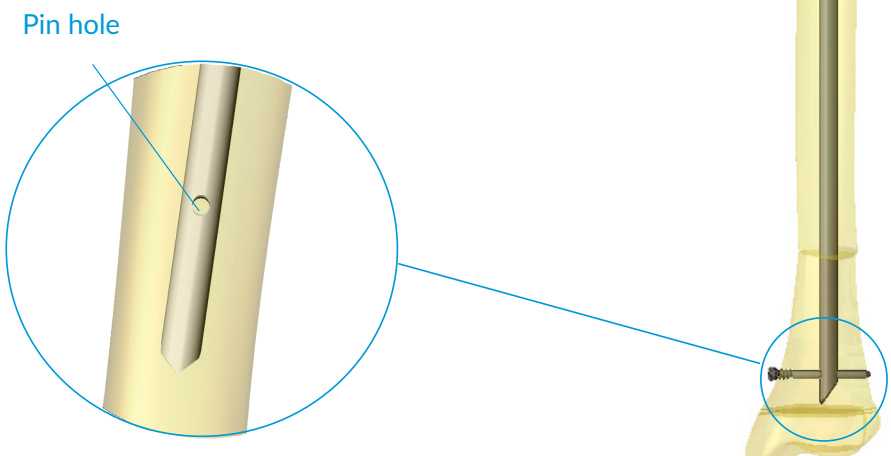
Note: * Please note that previous versions of the 5.6 and 6.4mm SLIM Nails have Distal and Proximal Locking holes for Ø 2.0 mm Peg. Verify locking hole size by pin gaging with a wire or Pega Peg. For Pega Peg and Bullet specifications, see page 16

Align the C-arm with the hole until a perfect circle is visible in the center of the screen. The SLIM can be rotated via the handle to help with this alignment. Make a stab incision over the center of the hole.



A. Pin Locking Technique

Advance the pin through the hole in the SLIM, through the far cortex, to lock the SLIM in place. Cut or bend the pin to secure in place.



B. Pega Peg Technique

Select the Peg size matching the SLIM Rod from Table 2. Using a steady pressure, drill with the corresponding Peg Drill all the way through the far cortex. Use the Depth Gage [GIN-DPG200] to directly measure the required Peg length.

Advance the Interlocking Peg through the drilled hole and the SLIM, up to the far cortex. Thread the Peg until flush with the lateral cortex to secure the SLIM in place.

Depth gage measurement accommodates for correct placement of implant: Pega Peg head should contact lateral cortex and distal end should be past far cortex.

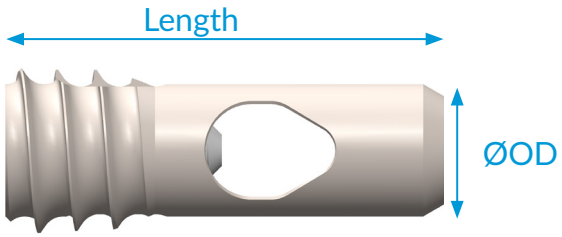
Peg Size	Peg Drill	Torx Screwdriver
Ø 2.0mm	Ø 2.0mm, PEG-PGD120	T8 GIN-TRX800
Ø 2.4mm	Ø 2.4mm, PEG-PGD124	
Ø 2.8mm	Ø 2.8mm, PEG-PGD128	

C. Bullet Technique

Length Considerations: The length is determined intra-operatively after selecting the insertion point in the bone. Direct measurement is done using the Depth Gage.

The SLIM should already be partially inserted into the medullary canal before proceeding to the Bullet technique (see STEP 1 to STEP 5).

Bullet OD	Length
Ø 4.8 mm	16 to 60mm (4mm Increments)
Ø 6.0 mm	



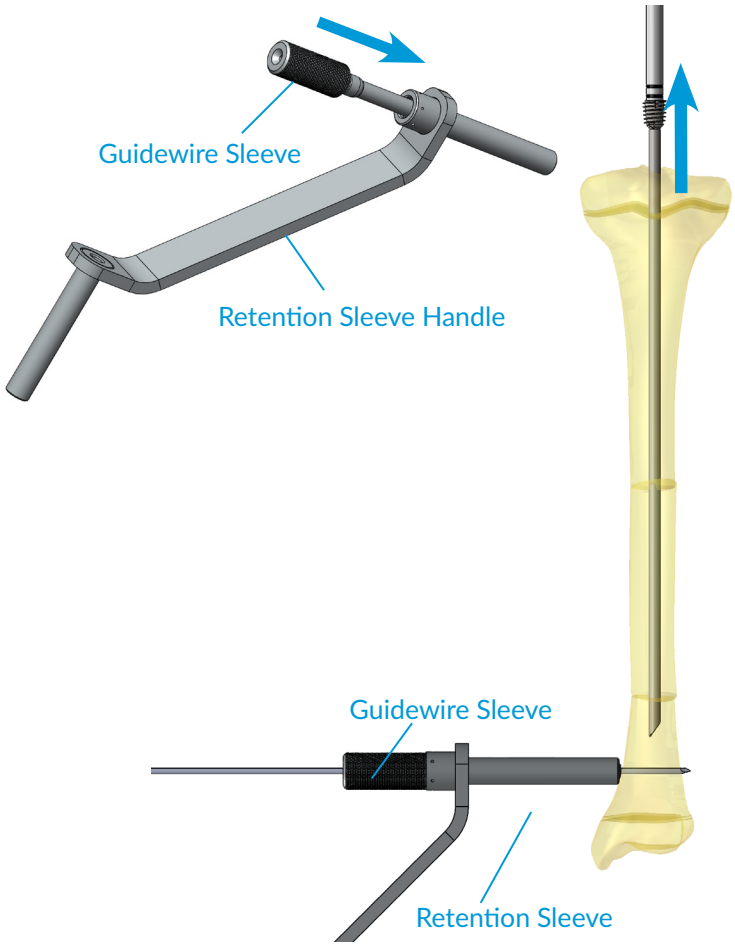
Step 6.1 Guidewire Placement

Assemble the Guidewire Sleeve [BLT-GWS100] into the Retention Sleeve Handle [BLT-RSH100]; it should click into place.

Under image intensification, insert the 2.0mm Guidewire [BLT-GWR200] through the Guidewire Sleeve, at the desired Bullet position, until the guidewire makes contact with the SLIM.

Validate the position of the guidewire under C-arm visualization in both AP and Lateral views.

Back up the SLIM above the Bullet's entry point, then advance the Guidewire through the far cortex.



Step 6.2 Bullet Drilling

Remove the Guidewire Sleeve from the Retention Sleeve Handle.

The Bullet size should have already been selected from Table 2 to match the SLIM Rod size.

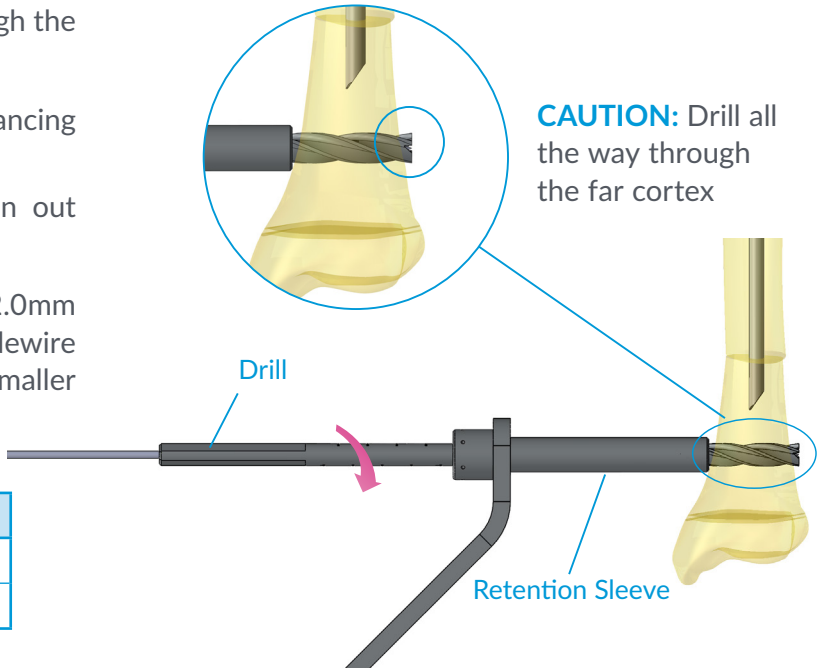
Select the appropriate drill matching the Bullet.

Using a steady pressure, drill all the way through the far cortex.

> **CAUTION:** Do not force the drill when advancing becomes difficult.
>
> Partially retract the drill in order to clean out debris.

While the drill is still in place, switch the 2.0mm Guidewire [BLT-GWR200] for the 1.1mm Guidewire [BLT-GWR100]. The Bullet's cannulation is smaller than the drill's.

Bullet	Drill
4.8 mm	BLT-BDR148
6.0 mm	BLT-BDR160



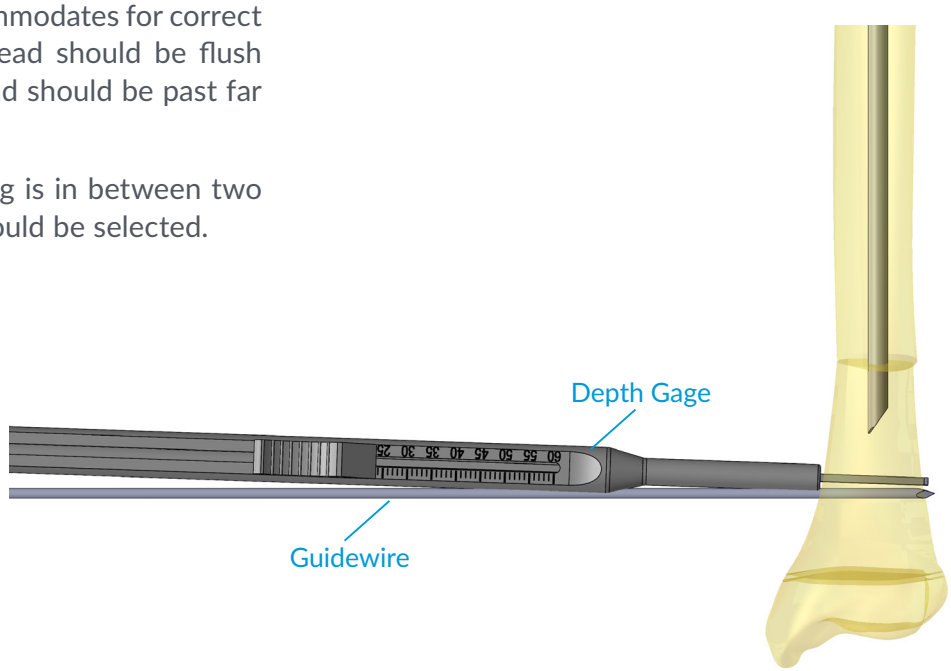
Step 6.3 Bullet Length Measurement

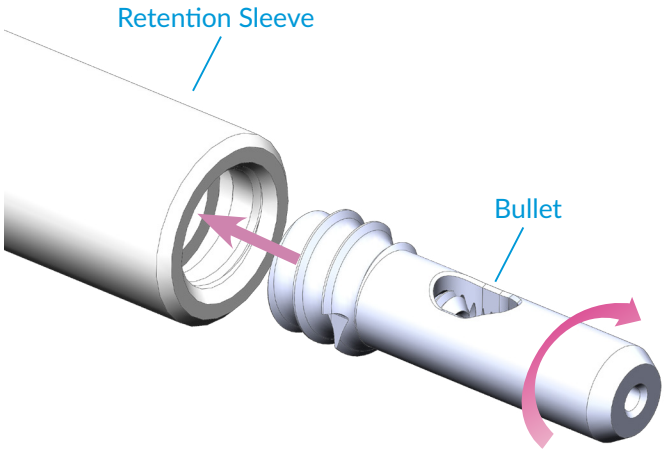
Insert the Depth Gage [GIN-DPG200] along the Guidewire through the drilled hole.

For accurate measurement, rest the nose against the lateral cortex, and ensure the hook rests against the far cortex.

Depth gage measurement accommodates for correct placement of implant: Bullet head should be flush with lateral cortex and distal end should be past far cortex.

CAUTION: When the reading is in between two lengths, the longer Bullet should be selected.





Step 6.4

Bullet Insertion

If Retention is desired, thread the Bullet implant clockwise into the appropriate side of the Retention Sleeve Handle until it bottoms out.

Step 6.4 Cont. Bullet Insertion

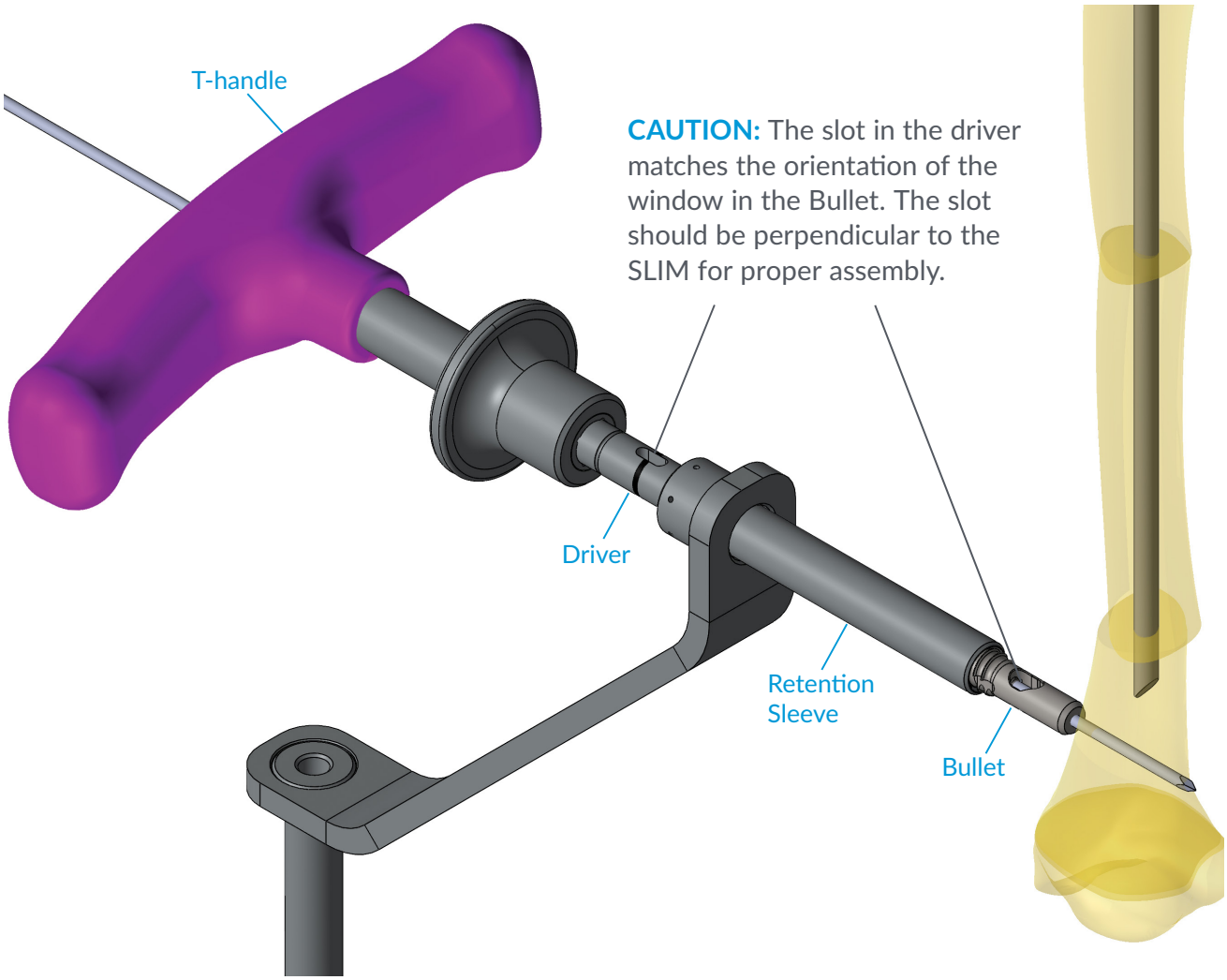
Assemble the T-Handle [BLT-AXH100] onto the Bullet Driver [BLT-BLD100].

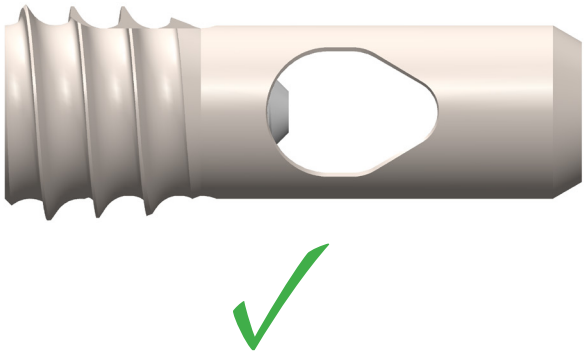
Slide the Bullet Driver through the Retention Sleeve until it bottoms out in the Bullet implant. The Driver will bottom out in the implant when the slot on the driver and the slot on the Bullet are in the same orientation.

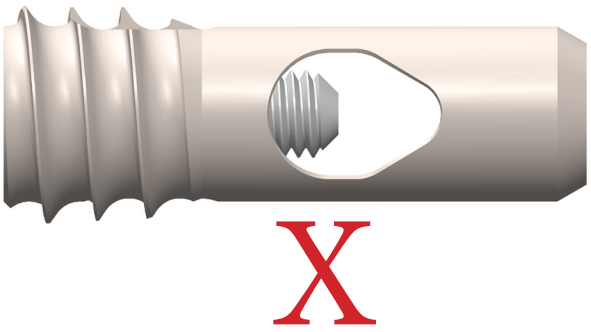
Insert the prepared Bullet over the Guidewire. The window must align with the canal to allow insertion of SLIM. Thread the Bullet to its final position.

CAUTION: Hold the Retention Sleeve Handle firmly against the cortex in order to ensure simultaneous unthreading of the Bullet from the Handle and threading into the bone.

Once adequate position and orientation is achieved, remove the T-Handle and Guidewire, while maintaining the Bullet Driver in place inside the Retention Sleeve Handle.







Step 6.5 SLIM Advancement

Before advancing the SLIM implant, ensure the Bullet set screw is retracted to avoid obstruction.

Advance the SLIM through the Bullet and thread the SLIM into the proximal epiphysis to its final position.

Make sure that threads do not invade the proximal physis.

CAUTION: Do not advance the threaded head of the SLIM by impaction.

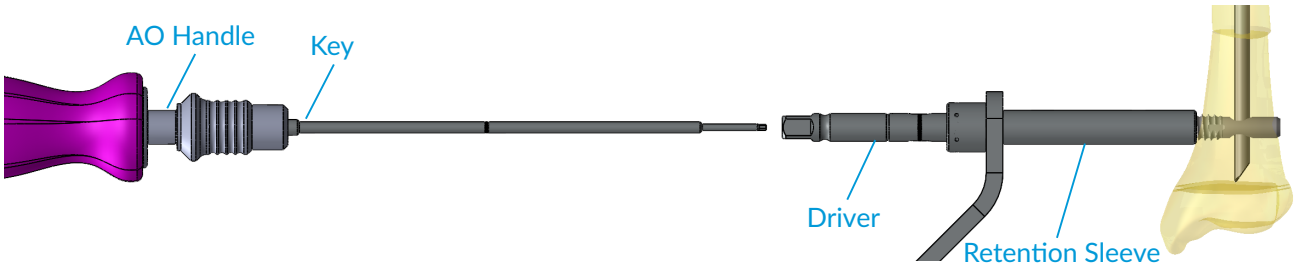
CAUTION: Validate the position of the SLIM in both the AP and Lateral planes.

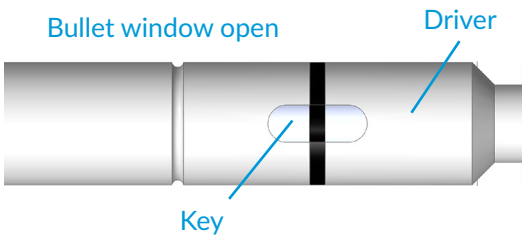
The SLIM must be inside the Bullet before proceeding to locking of the Bullet onto the SLIM

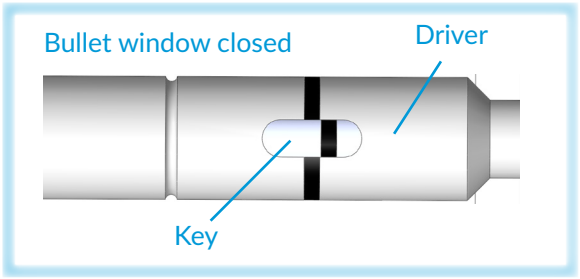
Step 6.6 Bullet Locking

Connect the Bullet Key [BLT-BKY100] onto the A-O Handle [BLT-AOH100].

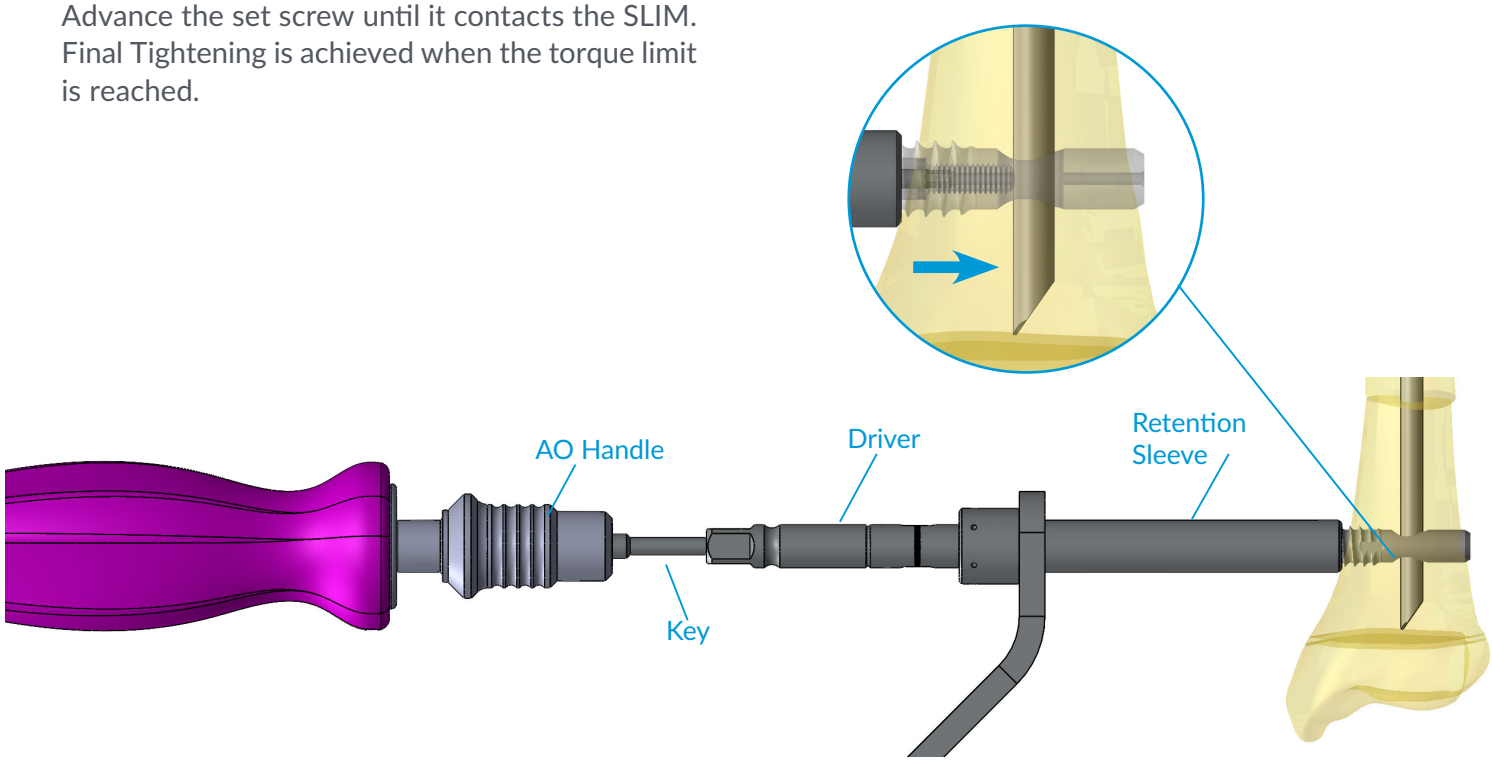
Insert the Bullet Key through the Bullet Driver until it bottoms out in the Bullet's internal set screw using the markings on the instruments.







Advance the set screw until it contacts the SLIM. Final Tightening is achieved when the torque limit is reached.

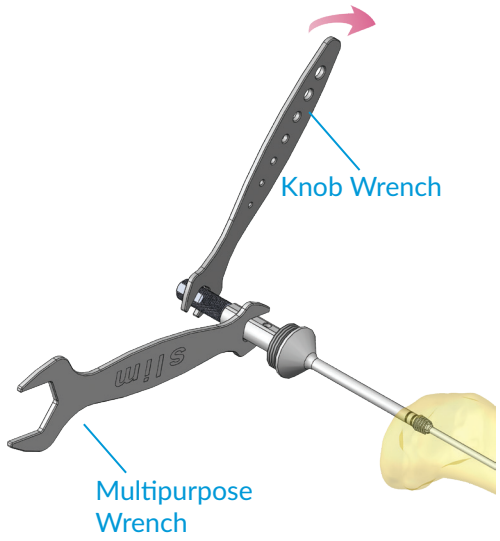


Step 7 Final Disassembly of SLIM Instruments

Once the SLIM is fully inserted, remove all instrumentation.

If unscrewing the SLIM Handle or SLIM Driver proves difficult, the Multipurpose Wrench [SLM-MPW100] and the Knob Wrench [SLM-KNW100] can be used to facilitate disassembly.

CAUTION: Maintain the Multipurpose Wrench in place while rotating the knob wrench counter-clockwise to release the SLIM.



Step 8 SLIM Cap Instertion

Select the appropriate Cap from the table below to protect the internal features and facilitate future removal of the SLIM.

CAUTION: The use of caps is highly recommended to protect the internal thread.

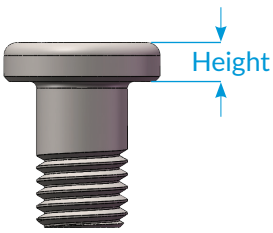
If not used, insertion of the driver for removal can be significantly more difficult due to bone ingrowth.

Table 3: Cap Selection

SLIM Size	HEIGHT	
	1.5 mm	5.0 mm
Ø 2.0 mm Ø 2.6 mm Ø 3.2 mm	SLM-CAP-315	SLM-CAP-350
Ø 4.0 mm Ø 4.8 mm Ø 5.6 mm Ø 6.4 mm	SLM-CAP-415	SLM-CAP-450

Thread the Cap into the SLIM's head with the SLIM Cap Driver [SLM-CDR100].

SLIM Cap Driver



Step 9 Post-Operative Care

If adequate fixation has been achieved, no cast immobilization is required. The patient can be allowed toe-touch weight bearing or weight bearing as tolerated on crutches or a walker depending of the patient size and fracture stability.

Proper consolidation should be observed prior to full weight bearing.

Ensure that consolidation is complete prior to the removal of the device.

Step 10 Retrieval of the SLIM System

The following are the standard steps for removal of the SLIM Rod:

1. Use the SLIM Cap Driver to remove the Cap.
2. Follow Step 4 to assemble the SLIM Driver Assembly onto the SLIM.
3. Unscrew the head of the SLIM via a counter-clockwise rotation.
4. Extract the rest of the SLIM by gently tapping and using the Impaction Guide with the integrated mass.

CAUTION: Careful cleaning of internal features from bone and soft tissue ingrowths prior to removal may be required if a cap was not used.

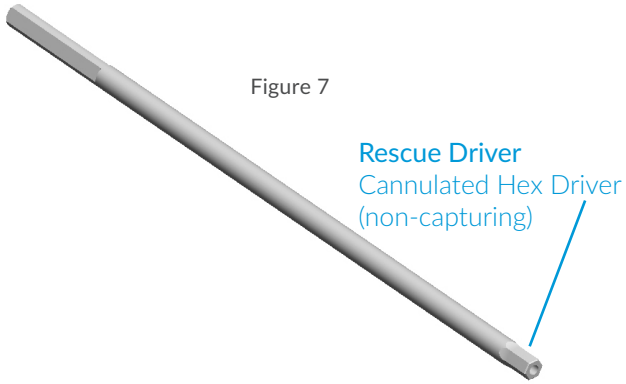


Figure 7

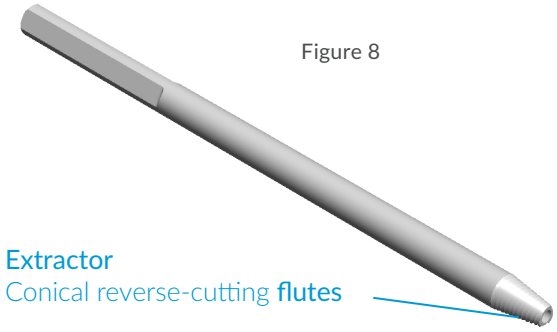


Figure 8

Alternative Removal Methods

SLIM family	Rescue Driver	Extractor
Ø 2.0 - 2.6 - 3.2	SLM-RSC123	SLM-EXT123
Ø 4.0 - 4.8 - 5.6 - 6.4	SLM-RSC146	SLM-EXT146

Option 1:

In the case that the cap was not used and the internal thread is clogged, the SLIM Rescue Drivers (fig. 7) can be used to unscrew the SLIM.

Option 2:

If removal is impossible with the Rescue Drivers, the Extractors ("Easy-Out") can be used in counter-clockwise to unscrew the SLIM (fig. 8)

CAUTION: Not recommended for use in low-density bone if risk of fracture or complications is a concern.

When Interlocking Has Been Used

Pin

Pull out any locking pins by grabbing with forceps (not provided).

Pega Peg

Unscrew any Pega Pegs using the T8 Torx screwdriver provided.

Bullet

First, unthread the set screw with the Bullet Key and AO Handle. Follow the standard steps listed above to remove the SLIM Rod from the bone.

Once the SLIM Rod has been removed, the Bullet can be fully unthreaded from the bone using the Bullet Driver and Axial Handle.

Patients should be instructed to avoid any type of sport activities or strenuous work during the postoperative or post implant removal healing period.

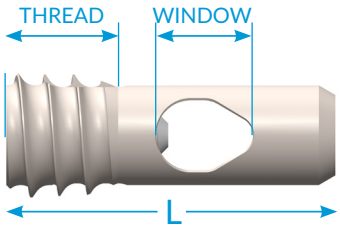
PegaPegs

For Small Nail Interlocking

Ø 2.0 PEGS		
L	Catalog #	Description
16	PEG-20-016	PEG Ø2.0 x 16mm
20	PEG-20-020	PEG Ø2.0 x 20mm
24	PEG-20-024	PEG Ø2.0 x 24mm
28	PEG-20-028	PEG Ø2.0 x 28mm
32	PEG-20-032	PEG Ø2.0 x 32mm
36	PEG-20-036	PEG Ø2.0 x 36mm
40	PEG-20-040	PEG Ø2.0 x 40mm
44	PEG-20-044	PEG Ø2.0 x 44mm
48	PEG-20-048	PEG Ø2.0 x 48mm
52	PEG-20-052	PEG Ø2.0 x 52mm
56	PEG-20-056	PEG Ø2.0 x 56mm
60	PEG-20-060	PEG Ø2.0 x 60mm

Ø 2.4 PEGS		
L	Catalog #	Description
16	PEG-24-016	PEG Ø2.4 x 16mm
20	PEG-24-020	PEG Ø2.4 x 20mm
24	PEG-24-024	PEG Ø2.4 x 24mm
28	PEG-24-028	PEG Ø2.4 x 28mm
32	PEG-24-032	PEG Ø2.4 x 32mm
36	PEG-24-036	PEG Ø2.4 x 36mm
40	PEG-24-040	PEG Ø2.4 x 40mm
44	PEG-24-044	PEG Ø2.4 x 44mm
48	PEG-24-048	PEG Ø2.4 x 48mm
52	PEG-24-052	PEG Ø2.4 x 52mm
56	PEG-24-056	PEG Ø2.4 x 56mm
60	PEG-24-060	PEG Ø2.4 x 60mm

Ø 2.8 PEGS		
L	Catalog #	Description
16	PEG-28-016	PEG Ø2.8 x 16mm
20	PEG-28-020	PEG Ø2.8 x 20mm
24	PEG-28-024	PEG Ø2.8 x 24mm
28	PEG-28-028	PEG Ø2.8 x 28mm
32	PEG-28-032	PEG Ø2.8 x 32mm
36	PEG-28-036	PEG Ø2.8 x 36mm
40	PEG-28-040	PEG Ø2.8 x 40mm
44	PEG-28-044	PEG Ø2.8 x 44mm
48	PEG-28-048	PEG Ø2.8 x 48mm
52	PEG-28-052	PEG Ø2.8 x 52mm
56	PEG-28-056	PEG Ø2.8 x 56mm
60	PEG-28-060	PEG Ø2.8 x 60mm



BULLET

Interlocking Reinvented

Ø4.8 BULLET - for Interlocking of SLIM 2.0 & 2.6			
L	Catalog #	Thread	Window
16	BLT-48-016	5mm	4.0mm
20	BLT-48-020	7mm	4.5mm
24	BLT-48-024	8mm	5.0mm
28	BLT-48-028		5.5mm
32	BLT-48-032	9mm	6.0mm
36	BLT-48-036		6.5mm
40	BLT-48-040	10mm	7.0mm
44	BLT-48-044		7.5mm
48	BLT-48-048	11mm	8.0mm
52	BLT-48-052		8.5mm
56	BLT-48-056	12mm	9.0mm
60	BLT-48-060		9.5mm

Ø6.0 BULLET - for Interlocking of SLIM 3.2 & 4.0			
L	Catalog #	Thread	Window
16	BLT-60-016	n/a	n/a
20	BLT-60-020	7mm	5.5mm
24	BLT-60-024	8mm	6.0mm
28	BLT-60-028		6.5mm
32	BLT-60-032	9mm	7.0mm
36	BLT-60-036		7.5mm
40	BLT-60-040	10mm	8.0mm
44	BLT-60-044		8.5mm
48	BLT-60-048	11mm	9.0mm
52	BLT-60-052		9.5mm
56	BLT-60-056	12mm	10.0mm
60	BLT-60-060		10.5mm

Notes

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

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

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

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

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

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