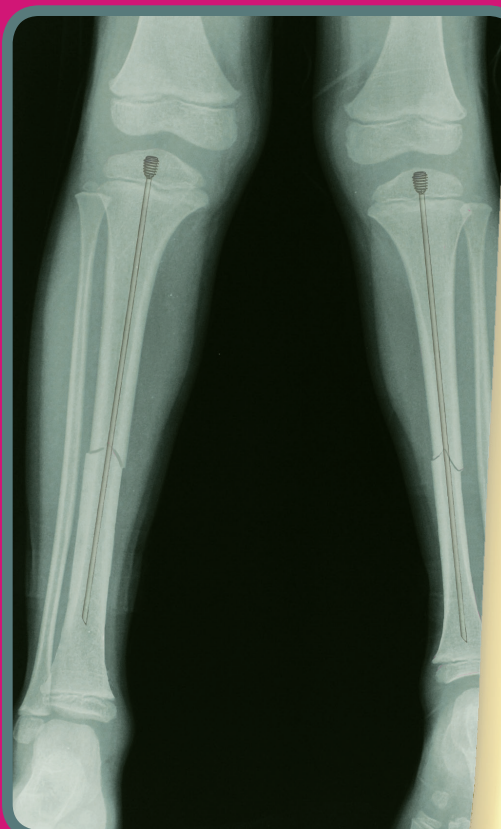




Pega Medical



*A Locking IM Rod that won't back out.
Simple and straight to the point!*



SURGICAL TECHNIQUE



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
- Distal locking option available for additional stability and lengthening over nail procedures
- All-in-one instrumentation designed to ease insertion and removal

The Simple Locking IntraMedullary System

Developed in collaboration with:

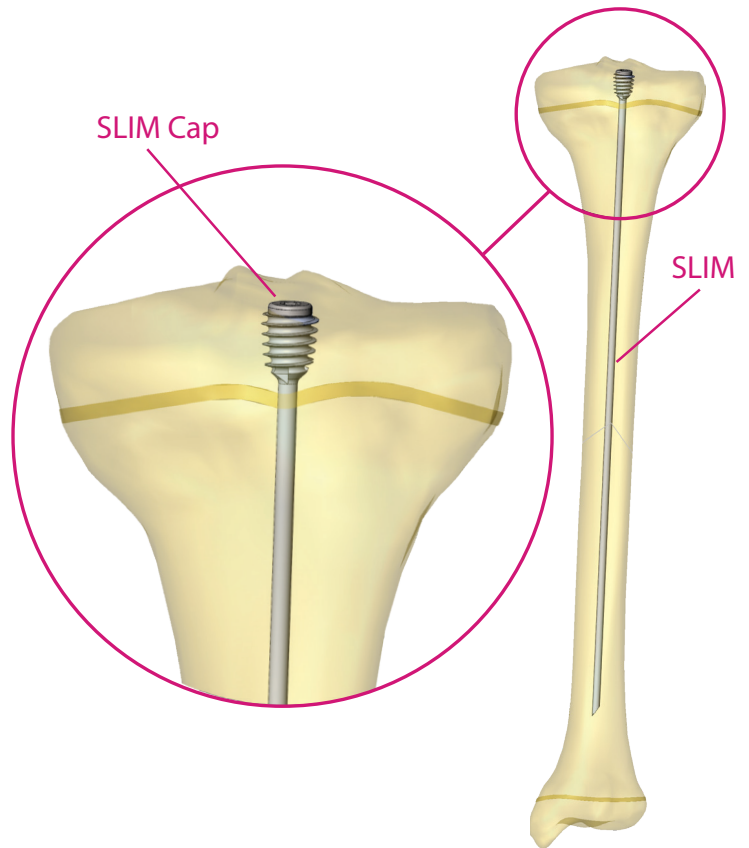
Kishore Mulpuri, MD
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The SLIM (Simple Locking IntraMedullary) System consists of intramedullary fixation devices for use in long bones. The solid shaft and tapered point are designed to facilitate insertion into the medullary canal. Anchorage of the device is achieved through a conical cortical thread, which creates a wedged fixation in the epiphysis in order to reduce the risk of migration. Internal features, such as a hexagonal drive and an internal mechanical thread in the head of the device, allow for capture and guidance during insertion and retrieval. Additional proximal and distal locking holes provide pinning options in poor quality bone.

The SLIM implants are manufactured in medical grade Stainless Steel (SS316L, ASTM F138). The SLIMs are available in seven diameters: 2.0, 2.6, 3.2, 4.0, 4.8, 5.6 and 6.4 mm, from 80 mm up to 400 mm in length.



The 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 the femur, tibia, humerus, ulna and fibula in the pediatric population (child and adolescent), and patients with small intramedullary canals affected by skeletal dysplasias, osteogenesis imperfecta or other bone diseases.

SURGICAL PLANNING

The following procedure is applicable to all intended uses of the SLIM.

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 growth plate. Select the SLIM corresponding to the desired diameter and length from Table 1: SLIM Selection Guide.

SLIM SURGICAL TECHNIQUE

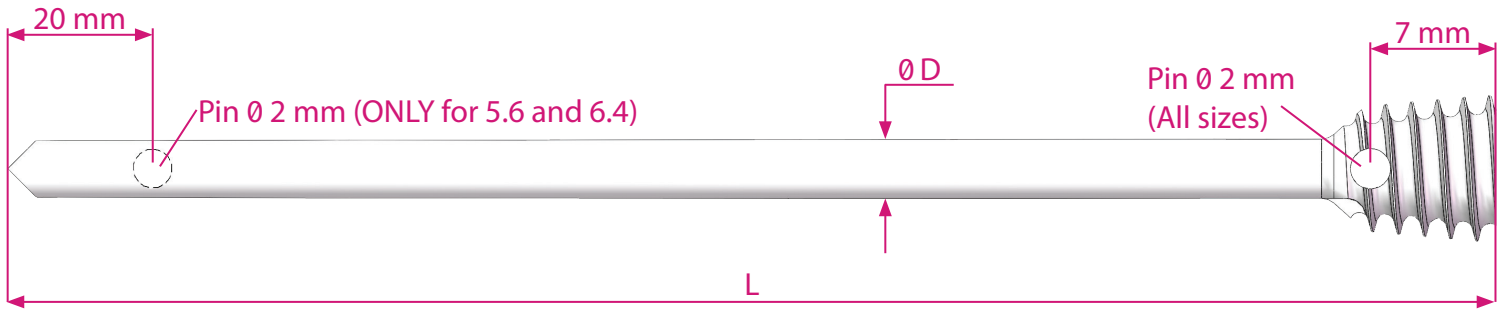


Table 1: SLIM Selection Guide

CATALOG NUMBER							
ØD (mm) DIAMETER L (mm) LENGTH	2.0	2.6	3.2	4.0	4.8	5.6	6.4
80	SLM-20-080	SLM-26-080	SLM-32-080				
90	SLM-20-090	SLM-26-090	SLM-32-090				
100	SLM-20-100	SLM-26-100	SLM-32-100				
110	SLM-20-110	SLM-26-110	SLM-32-110				
120	SLM-20-120	SLM-26-120	SLM-32-120	SLM-40-120	SLM-48-120		
130	SLM-20-130	SLM-26-130	SLM-32-130	SLM-40-130	SLM-48-130		
140	SLM-20-140	SLM-26-140	SLM-32-140	SLM-40-140	SLM-48-140		
150	SLM-20-150	SLM-26-150	SLM-32-150	SLM-40-150	SLM-48-150		
160	SLM-20-160	SLM-26-160	SLM-32-160	SLM-40-160	SLM-48-160	SLM-56-160	SLM-64-160
170	SLM-20-170	SLM-26-170	SLM-32-170	SLM-40-170	SLM-48-170	SLM-56-170	SLM-64-170
180	SLM-20-180	SLM-26-180	SLM-32-180	SLM-40-180	SLM-48-180	SLM-56-180	SLM-64-180
190	SLM-20-190	SLM-26-190	SLM-32-190	SLM-40-190	SLM-48-190	SLM-56-190	SLM-64-190
200	SLM-20-200	SLM-26-200	SLM-32-200	SLM-40-200	SLM-48-200	SLM-56-200	SLM-64-200
220	SLM-20-220	SLM-26-220	SLM-32-220	SLM-40-220	SLM-48-220	SLM-56-220	SLM-64-220
240	SLM-20-240	SLM-26-240	SLM-32-240	SLM-40-240	SLM-48-240	SLM-56-240	SLM-64-240
260	SLM-20-260	SLM-26-260	SLM-32-260	SLM-40-260	SLM-48-260	SLM-56-260	SLM-64-260
280	SLM-20-280	SLM-26-280	SLM-32-280	SLM-40-280	SLM-48-280	SLM-56-280	SLM-64-280
300				SLM-40-300	SLM-48-300	SLM-56-300	SLM-64-300
320				SLM-40-320	SLM-48-320	SLM-56-320	SLM-64-320
340				SLM-40-340	SLM-48-340	SLM-56-340	SLM-64-340
360						SLM-56-360	SLM-64-360
380						SLM-56-380	SLM-64-380
400						SLM-56-400	SLM-64-400

SURGICAL TECHNIQUE

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 in order to allow smooth nail insertion. It is recommended to rectify the canal before insertion of the straight implant as it can tolerate minimal amount of bending before being threaded into its final position.

Antegrade Femur

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.

Retrograde Femur

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.

Antegrade Tibia

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 malleolus.

Retrograde Fibula

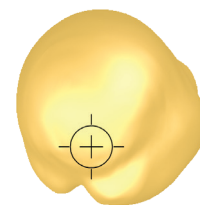
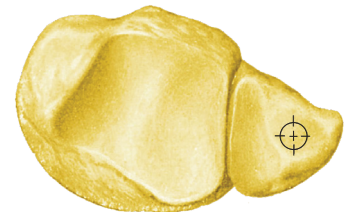
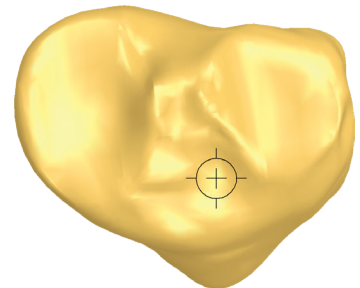
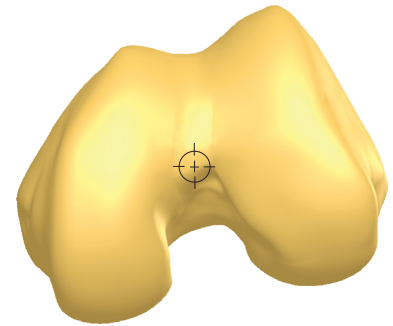
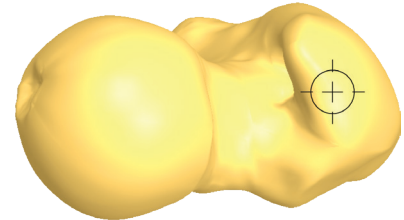
A 1.5 cm longitudinal skin incision is made 1 cm distal to the tip of the lateral malleolus. The entry point is in line with the centre of the medullary canal, at the medial line of the lateral ankle. An antegrade approach is also possible through the tip of the fibular head.

Antegrade Humerus

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.

Antegrade Ulna

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.



STEP 2

CANAL PREPERATION

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

SLIM Size (mm)	Reamer	Guidewire
ø 2.0 - ø 2.6	SLM-DCA026	non cannulated
ø 3.2	SLM-DCA032	ø 1.6 mm SLM-GWR160
ø 4.0	SLM-DCA040	
ø 4.8	SLM-DCA048	ø 2.0 mm SLM-GWR200
ø 5.6	SLM-DCA056	
ø 6.4	SLM-DCA064	

Reaming of the canal can be done percutaneously or through the osteotomy/fracture site. Remove the Reamer and Guidewire when reaming is complete.

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

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

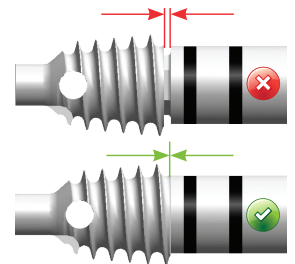
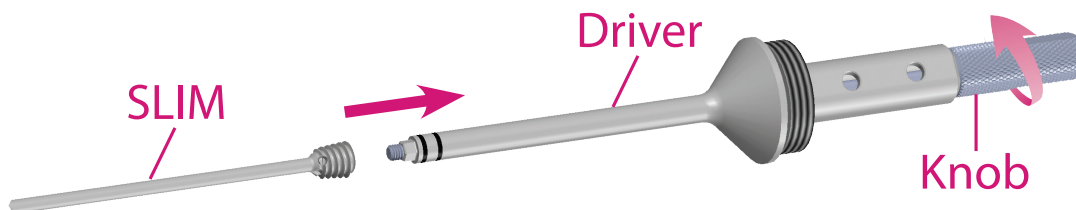
STEP 3

SLIM ASSEMBLY

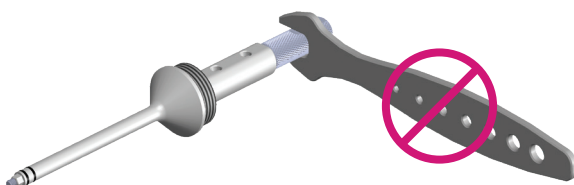
Select the SLIM Driver corresponding to the appropriate SLIM family.

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.



⚠ There should be no space between the SLIM Driver and the SLIM once assembly is completed.

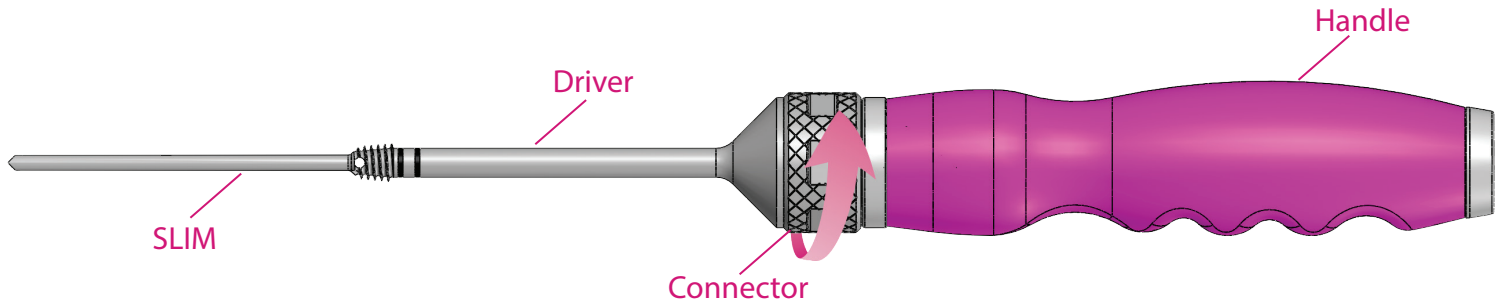


⚠ It is important to finger tighten the Knob onto the SLIM. Do not use the Wrench.

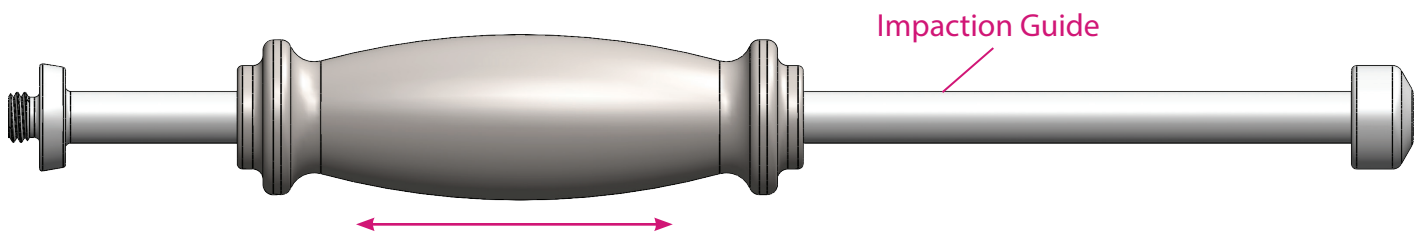


SLIM SURGICAL TECHNIQUE

Insert the SLIM Driver into the SLIM Handle [SLM-HND100] respecting the orientation of the flats. Complete the assembly by tightening the connector clockwise.



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



STEP 4

SLIM INSERTION

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



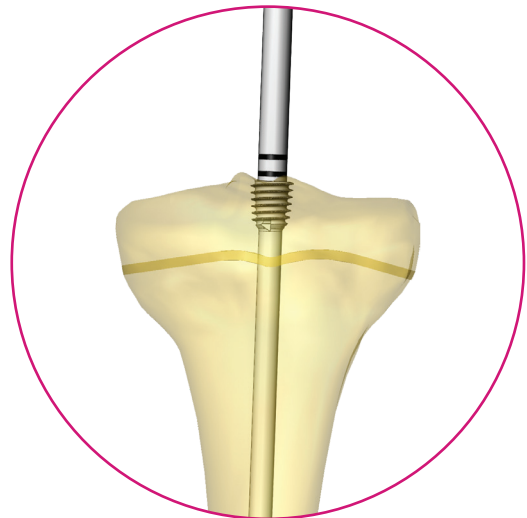
If advancing the SLIM proves difficult, ensure that the SLIM is properly oriented and aligned. Additional reaming might be required.

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 however that no threads are left across the proximal growth plate.



Screw in the head with a clockwise motion in order to complete insertion of the implant. **Do not advance the threaded head by impaction.**



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

STEP 5

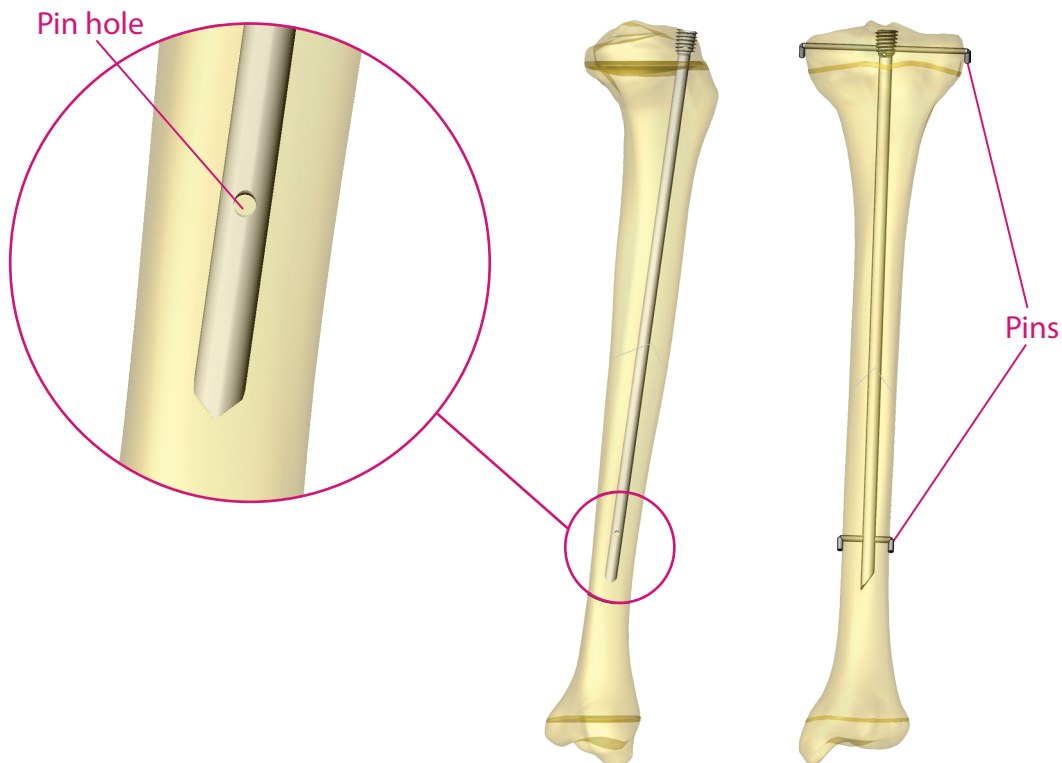
INTERLOCKING (OPTIONAL)

Interlocking of the SLIM is not necessary, but the following options are available:

Table 2: Pin Size Chart

Implant Size (Ø)	Proximal Locking	Distal Locking
Ø 2.0 mm Ø 2.6 mm Ø 3.2 mm	2.0 mm pin	N / A
Ø 4.0 mm Ø 4.8 mm	2.0 mm pin	N / A
Ø 5.6 mm Ø 6.4 mm	2.0 mm pin	2.0 mm pin

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. Place the appropriate pin [Ref Table 2] on the skin over the center of the hole and make a stab incision.



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

SLIM SURGICAL TECHNIQUE

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.



Maintain the Multipurpose Wrench in place while rotating the Knob Wrench counter-clockwise to release the SLIM.



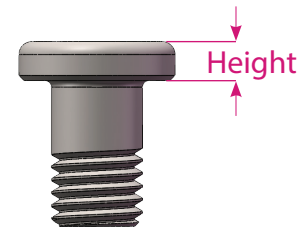
STEP 6

SLIM CAP INSERTION

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

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].



RETRIEVAL OF THE SLIM

- Use the SLIM Cap Driver to remove the Cap.
- Remove any locking pins.
- Follow Step 3 to assemble the SLIM Instrumentation onto the SLIM.
- Unscrew the head of the SLIM via a counter-clockwise rotation.
- Extract the rest of the SLIM by applying gentle blows on the SLIM Impaction Guide with the integrated mass.



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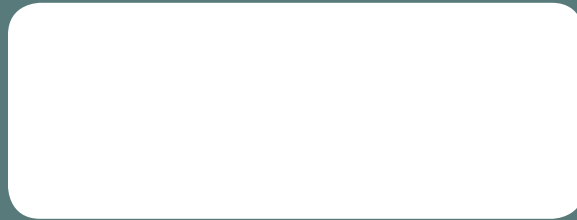
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