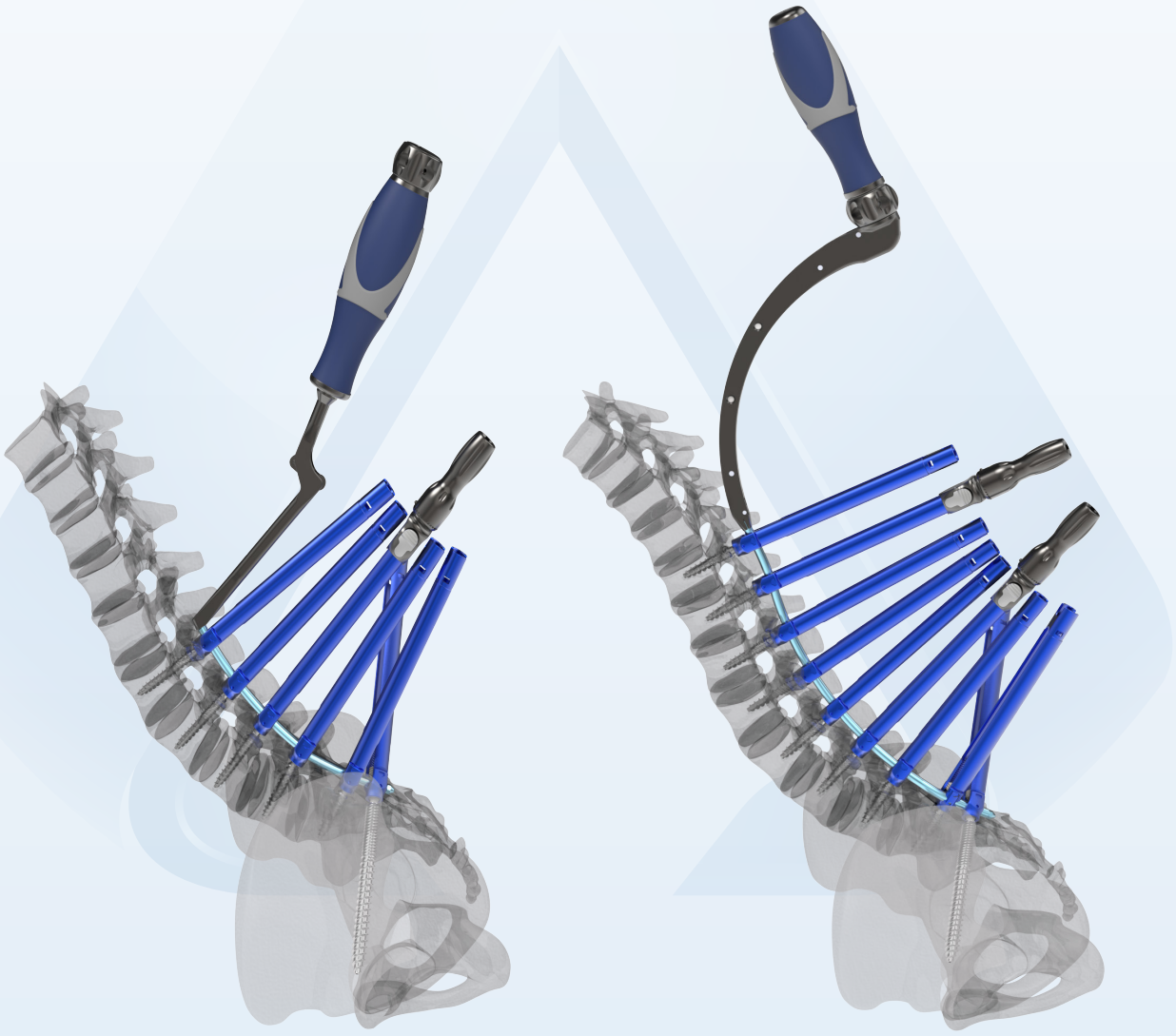
OLYMPIC MIS

MINIMALLY INVASIVE SPINAL FIXATION SYSTEM

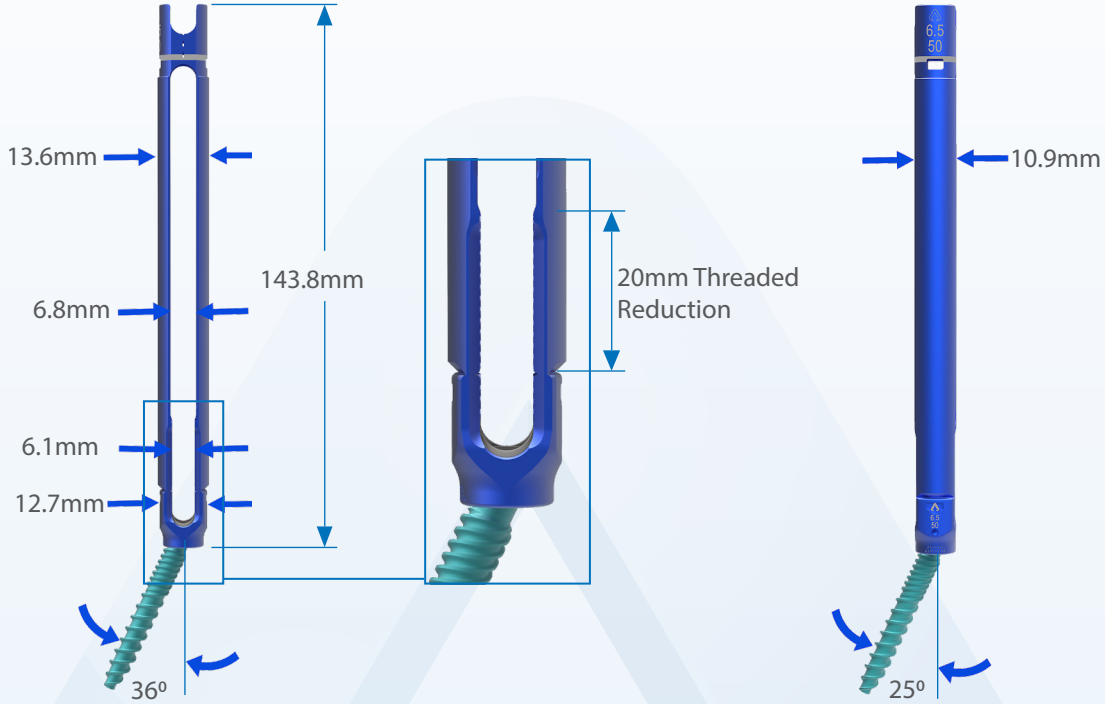
ASTURA MEDICAL

DESIGN RATIONALE

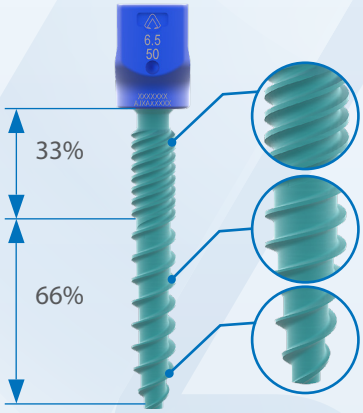
The Olympic Minimally Invasive Surgery (MIS) Spinal Fixation System delivers a new level of intraoperative flexibility and efficiency by allowing the customization to the preferred workflow of the user through the utilization of either a traditional jamshidi/guide wire technique, awl-tap wireless technique, or single-step wireless technique for the placement of MIS pedicle screws. The wide array of implant options and expansive instrumentation delivers a streamlined and reproducible procedural sequence, even when addressing the most complex pathologies with a less invasive approach.



EXTENDED TAB SCREW SPECIFICATIONS



EXTENDED TAB PEDICLE SCREW OPTIONS (CORTICAL CANCELLOUS, CANNULATED)



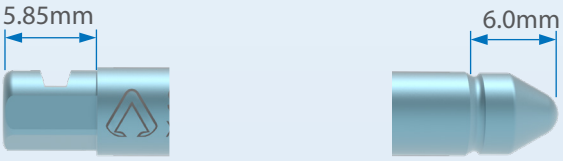
Self-Tapping/ Starting Tip

Ø4.5mm Ø5.5mm Ø6.5mm Ø7.5mm Ø8.5mm Ø9.5mm

ROD OPTIONS

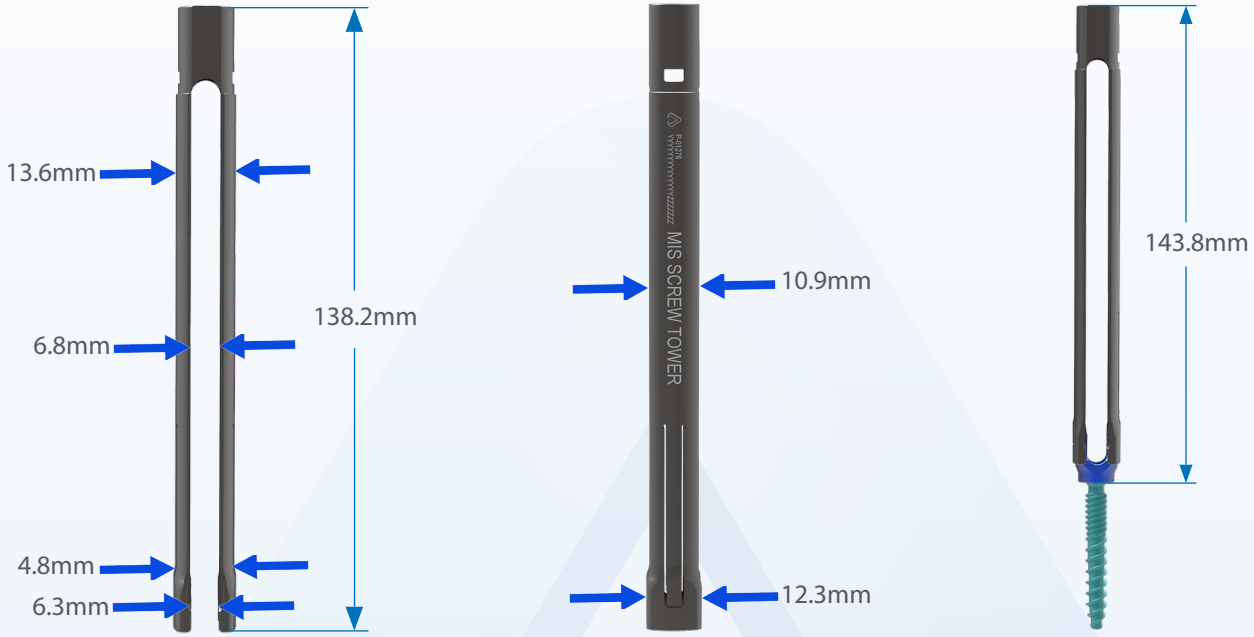
Rods: Ø5.5mm / Ø6.0mm Material: TiCP / CoCr

Straight *Lordotic* *Kyphotic*



SPECIFICATIONS

SCREW TOWER SPECIFICATIONS



SCREW TOWER PEDICLE SCREW OPTIONS (CANNULATED OR NON-CANNULATED)

DUAL LEAD

Ø4.0mm Ø4.5mm Ø5.0mm Ø6.0mm Ø7.0mm Ø8.0mm Ø9.0mm Ø10.0mm

CORTICAL CANCELLOUS

Ø4.0mm Ø4.5mm Ø5.5mm Ø6.5mm Ø7.5mm Ø8.5mm

FULL CORTICAL

Ø4.5mm Ø5.0mm Ø5.5mm Ø6.0mm

1.0 GUIDEWIRE TECHNIQUE

1.1 PREOPERATIVE PLANNING

1.1.1 Identify the affected level using standard techniques with fluoroscopic imaging in the A/P and lateral views. Use preferred intraoperative techniques to locate the pedicles under fluoroscopy to identify the appropriate starting points and trajectory.

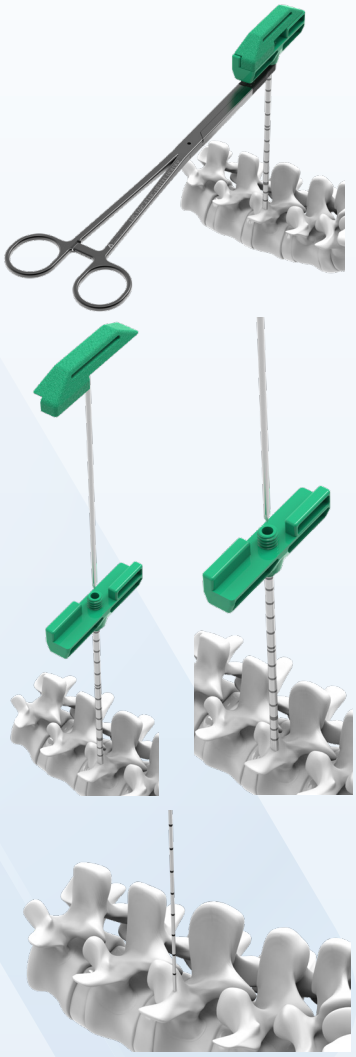
1.2 ACCESS AND GUIDEWIRE INSERTION

1.2.1 Utilize the Targeting Needle (RAN-815N5T-BEV) to locate the pedicle, then set the desired positioning of the Guidewire (AZA025500). Attach the Targeting Needle Holder (AZE030000) to the proximal end of the Targeting Needle to clear the fluoroscopy imaging area. Using standard intraoperative techniques with fluoroscopy, advance the Targeting Needle to the desired path within the pedicle.

1.2.2 Once the desired depth is confirmed using fluoroscopy, remove the inner stylet of the Targeting Needle.

1.2.3 Insert the Guidewire through the Targeting Needle, then using fluoroscopy, advance the Guidewire past the distal end of the Targeting Needle to the desired depth.

1.2.4 Remove the Targeting Needle from the vertebral body, leaving the Guidewire in place within the vertebral body.



1.3 INCISION

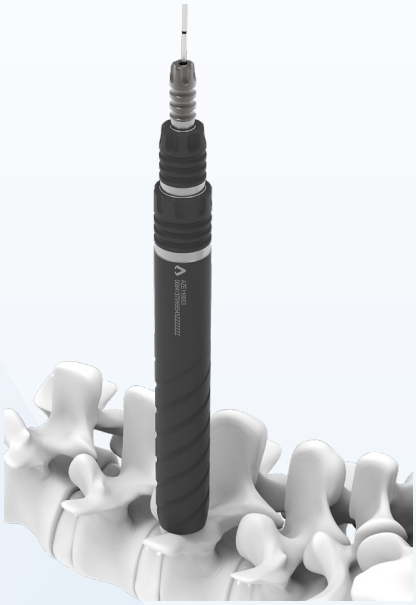
1.3.1 Assemble the Fascial Blade Handle (AZE100000) to the Fascial Blade Tip (AZE100000-02) by inserting the distal end of the Fascial Blade Handle into the threaded opening of the Fascial Blade Tip located within the caddy. Secure by turning the proximal knob of the Fascial Blade Handle in a clockwise direction.

1.3.2 Guide the assembled Fascial Blade Handle and Fascial Blade Tip over the Guidewire. Using the Fascial Blade Tip, create an incision through the skin and fascia.

1.3.3 Remove the assembled Fascial Blade Handle and Fascial Blade Tip.

1.4 PEDICLE PREPARATION

1.4.1 Guide Dilator 1 (AZE110001) over the Guidewire, then down into the incision. Advance Dilator 1 through the soft tissue until it is seated against the pedicle. Confirm correct placement of Dilator 1 through the use of fluoroscopy.



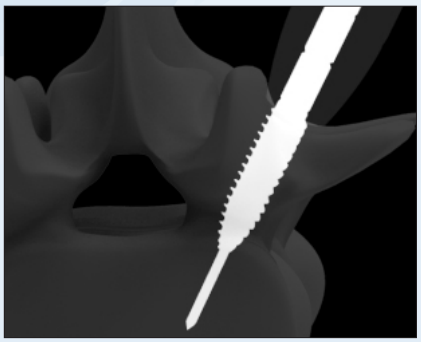
1.4.2 Guide Dilator 2 (AZE110002) over the Guidewire, then over Dilator 1. Advance Dilator 2 through the soft tissue until it is seated against the pedicle. The gray depth band located on Dilator 1 confirms Dilator 2 is fully seated in relation to Dilator 1.

1.4.3 Guide Dilator 3 (AZE110003) over the Guidewire, then over Dilator 2. Advance Dilator 3 through the soft tissue until it is seated against the pedicle. The gray depth band located on Dilator 2 confirms Dilator 3 is fully seated in relation to Dilator 2.

1.4.4 Remove Dilator 1, then select the desired diameter Bone Tap (AZE1200XX) for pedicle screw insertion preparation. Taps are available in 4.5, 5.5, 6.5, 7.5, 8.5 or 9.5mm diameters.

1.4.5 Assemble a Ratchet Handle (EBECDZBBZ, EAECDABEZ or EDECDTBBZ) to the Bone Tap by inserting the proximal end of the Bone Tap into the distal end of the handle. Compress the spring loaded quick-connect ring of the handle to assemble, then ensure the ratcheting handle is set in the FORWARD position. The ¼" square drive of the Bone Tap shaft is fully secured to the handle when the small groove aligns with the distal end of the handle.

1.4.6 Guide the Bone Tap and Ratcheting Handle over the Guidewire into Dilator 2, then advance until it is seated against the pedicle. Rotate clockwise until the desired tapping depth has been achieved. The Bone Tap depth-indicating bands are referenced off of the top of Dilator 2. Notched depth rings located on the distal shaft may also be used for fluoroscopic analysis and confirmation. The first notched ring is 30mm from the distal tip, with additional rings every 10mm. Confirm placement using fluoroscopy.



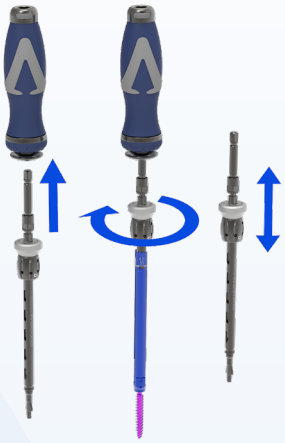
1.5 SCREWDRIVER AND EXTENDED TAB SCREW ASSEMBLY / DISASSEMBLY

1.5.1 Assemble a Ratchet Handle (EBECDZBBZ, EAECDABEZ or EDECDTBBZ) to the MIS Screwdriver, T25 (AZE160000). The ¼" square drive of the Screwdriver shaft is fully secured to the handle when the small groove aligns with the distal end of the handle.

1.5.2 The Extended Tab Screw can be assembled to the Screwdriver in the LOCKED or UNLOCKED position.

1.5.3 Attach the appropriate Extended Tab Screw onto the Screwdriver by inserting the distal end of the Screwdriver into the Extended Tab Screw, then thread the grip clockwise to engage the Screwdriver thread into the base of the Extended Tab Screw.

1.5.4 Set the Screwdriver to the LOCKED position, then ensure the ratcheting handle is set in the FORWARD position.



1.6 SCREW INSERTION / ADJUSTMENT

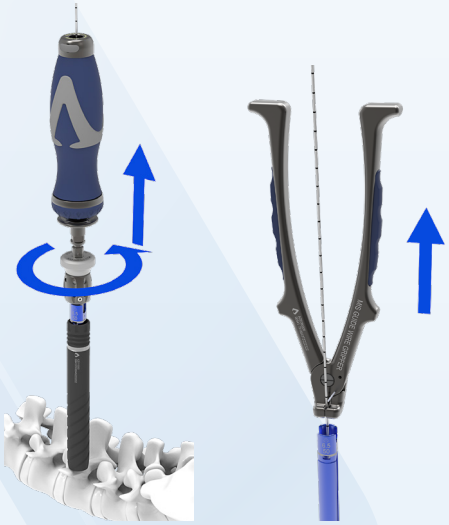
1.6.1 Remove Dilator 2, then guide the Extended Tab Screw, Screwdriver and Ratchet Handle over the Guidewire. Insert the tip of the screw into the Targeting Needle hole, then rotate clockwise until the desired depth is achieved. The depth band located on the Extended Tab Screw indicates depth in relation to Dilator 3.

1.6.2 To disassemble the Screwdriver from the Extended Tab Screw, set the Screwdriver to the UNLOCKED position, then unthread the grip in a counter clockwise direction to disengage the Screwdriver thread from the head of the screw. Pull upward to remove the Screwdriver from the Extended Tab Screw.

1.6.3 If adjustment to the height of the screw is necessary, assemble a Ratchet Handle (EBECDZBBZ, EAECDABEZ or EDECDTBBZ) to the Screw Height Adjuster, T25 (AZE170000). Engage the screw, then rotate to the desired height.

1.6.4 Use the Guide Wire Gripper (AZE080000) to grip the Guidewire, then remove.

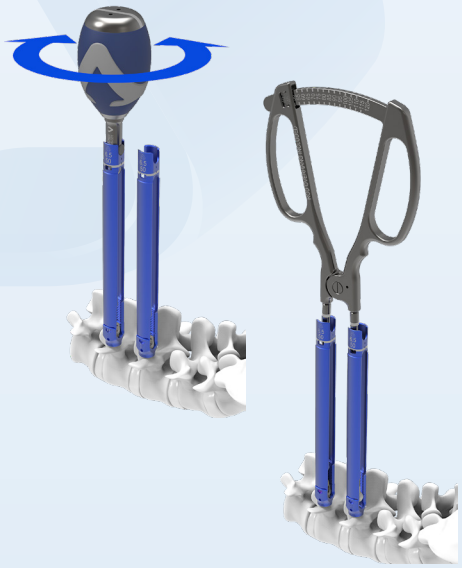
1.6.5 Remove Dilator 3.



1.7 ROD AND SET SCREW INSERTION

1.7.1 Align the Extended Tab Screws using the Screw Head Manipulator (AZE190000).

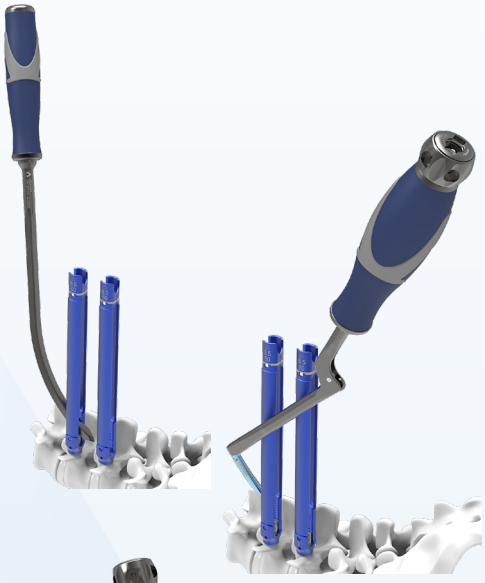
1.7.2 Insert one arm of the Rod Caliper (AZE200000) into each of the cranial and caudal outermost Extended Tab Screws until each leg is fully seated in the screw heads. The depth bands located on the Rod Caliper arms confirm the Rod Caliper is fully seated in relation to the top of the Extended Tab Screw.



1.7.3 This is a direct measurement, so there is no additional calculation required in order to determine proper Rod length.
***Rod overhang is accounted for in the measurement on the Rod Caliper.**

1.7.4 The Rod Bender (AZA027000) can be utilized to help achieve the desired Rod contour. A Rod Cutter may be used to achieve the desired Rod length. It is recommended that Rods are bent in only one direction. Over bending of the Rod may cause it to fracture.
***Caution: Bending the proximal portion of the Rod may compromise the Rod Inserter interface.**

1.7.5 The Curved Tissue Dissector (AZE210000) may be used to create a pathway for passing the Rod through the slots of the Extended Tab Screws. Pass the Curved Tissue Dissector through the most cranial Extended Tab Screw or incision, then advance it through each Extended Tab Screw until the most caudal Extended Tab Screw has been reached.

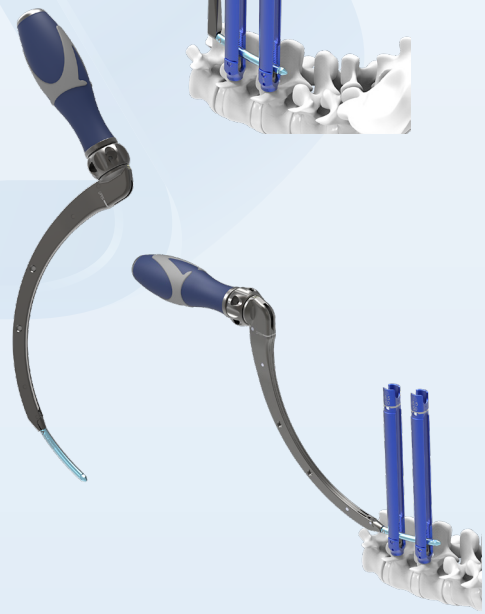


1.7.6 ROD END HELD INSERTION TECHNIQUE

1.7.6.1 For the assembly of the Rod to the Right Angled Rod Inserter (AZE250000) or Percutaneous Rod Inserter (AZE260000), insert the connection end of the Rod into the pocket of the inserter. Ensure that the notch on the connection end of the Rod is facing up towards the handle of the inserter. Secure the Rod by turning the handle of the inserter in a clockwise direction until resistance is met. Confirm rigid attachment by lightly tugging on the Rod.

1.7.6.1.1 Right Angled Rod Inserter: Introduce the Inserter in a cranial to caudal orientation with the handle facing in the caudal direction. Insert the pointed end of the Rod into the most cranial Extended Tab Screw Rod slot opening. Guide the Rod through each of the remaining Extended Tab Screw Rod slot openings while rotating the Rod inserter handle upward until the Rod spans through all of the Extended Tab Screws.

1.7.6.1.2 Percutaneous Rod Inserter: Utilizing a separate incision located cranial to the most cranial Extended Tab Screw, orient the inserter handle facing cranial and insert pointed end of the Rod into the incision. Guide the Rod into the most cranial Extended Tab Screw, then through each of the following Extended Tab Screw Rod slot openings until the Rod spans through all of the Extended Tab Screws.

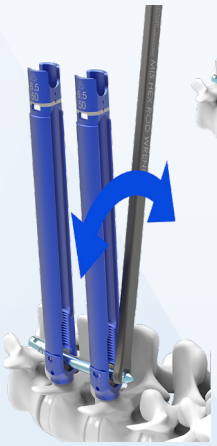


1.7.7 "MINI-OPEN" INSERTION TECHNIQUE

1.7.7.1 The Curved Tissue Dissector (AZE210000) may be used to create a pathway for passing the soft tissue. Pass the Curved Tissue Dissector down through the incision and between each Extended Tab Screw.

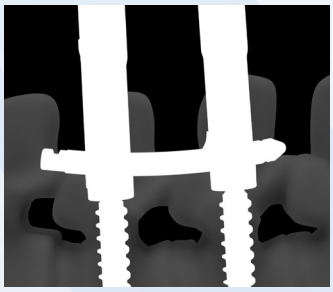
1.7.7.2 For assembly of the Rod to the Kerrison Rod Inserter (AZE240000), grip along the diameter of the Rod (i.e. not the ends). Engage the ratchet to lock the inserter to the Rod.

1.7.7.3 The Rod may be inserted from either a cranial or caudal direction. If a direct downward approach is preferred, the Extended Tab Divider (AZE230000) may be used to split the proximal end of the Extended Tab Screw to allow for passage of the Rod.



1.7.8 Utilize the Hex Rod Wrench (AZE220000) to assist with the positioning of the Rod during passage through the Extended Tab Screws. Insert the Hex Rod Wrench alongside the Extended Tab Screw, then mate it to the pointed hex end of the Rod.

1.7.9 Utilize fluoroscopy to confirm correct Rod placement. The proximal and distal ends of the Rod must be present on the fluoroscopy image.



1.7.10 Load the Set Screw (ABBA00000) to the Set Screw Inserter, T30 (AZE310000). With the Set Screw Inserter knob unthreaded counter-clockwise, insert the distal end of the Set Screw Inserter into the Set Screw. Secure the Set Screw Inserter by threading the knob in a clockwise direction until resistance is met. Confirm attachment by lightly tugging on the Set Screw.

1.7.11 The Stick Fit Tower Attachment Guide, T30 (AZE410000) may also be used for inserting Set Screws. Insert the Stick Fit Tower Attachment Guide into the Set Screw, then apply downward pressure. Confirm attachment by lightly tugging on the Set Screw.

1.7.12 Insert the Set Screw into the Extended Tab Screw to engage with the 20mm of built-in thread. Rotate the Set Screw Inserter clockwise until it is provisionally tightened. Refer to the depth bands located on the Set Screw Inserter for the height of the Set Screw above the Rod by checking the corresponding distance in relation to the top of the Extended Tab Screw.

1.8 ROD REDUCTION

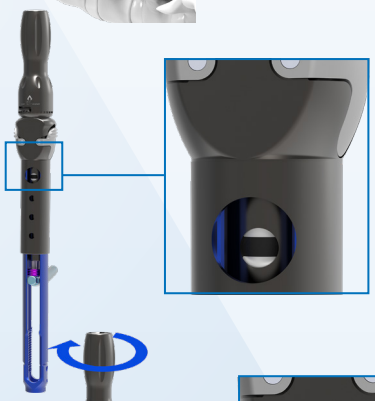
1.8.1 MODERATE REDUCTION (20MM OR LESS)

1.8.1.1 Moderate reduction is achieved from the 20mm of built-in thread of the Extended Tab Screw. Attach a Ratchet Handle (EBECDZBBZ, EAECDABEZ or EDECDTBBZ) to the Set Screw Torque Shaft, T30 (AZE370000), then insert the assembly into the Extended Tab Screw to engage the Set Screw previously loaded by the Set Screw Inserter, T30 (AZE310000).
*__The Set Screw Inserter is not to be used during a reduction technique.__

1.8.1.2 Utilizing the Set Screw Torque Shaft, thread the Set Screw in a clockwise direction until the Rod is seated. The Counter Torque (AZE350000) or Long Counter Torque (AZE360000) may be utilized for stabilization.

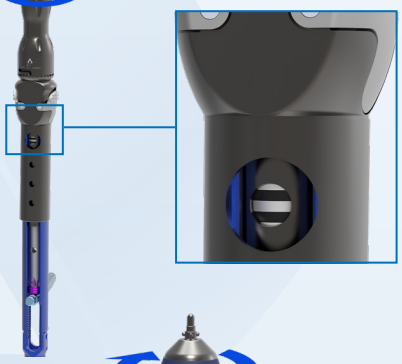
1.8.2 LARGE REDUCTION (UP TO 50MM)

1.8.2.1 Large Reduction is achieved by utilizing the Sequential Reducer (AZE290000). With the Sequential Reducer handle unthreaded counter-clockwise and telescoping shaft inset (indication window shows 1 band), insert the "stick fit" distal end into Set Screw. Confirm attachment by lightly tugging on the Set Screw.



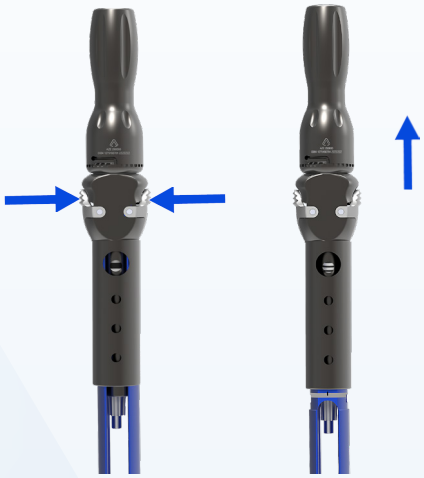
1.8.2.2 Insert the Set Screw and Sequential Reducer assembly into the Extended Tab Screw, then snap it into place using the spring-loaded clips. The reducer will automatically lock onto the screw. Confirm proper engagement of the assembly by giving a light tug upward.

1.8.2.3 To reduce the Rod, turn the handle of the Sequential Reducer until the internal ram reduces the Rod below the threads of the Extended Tab Screw. This is indicated when the knob locks out in the clockwise direction and two bands shown in the indication window. If additional torque is required, Insert the proximal portion (short side) of the Reducer Driver (AZE280000) into the top of the Sequential Reducer knob to increase grip strength.



1.8.2.4 Insert the shafted hexalobe end of the Reducer Driver into the Sequential Reducer to engage the internal drive shaft. While applying light downward force, thread the Set Screw in a clockwise direction to engage the Extended Tab Screw threads. Continue to thread until the Rod is seated into the screw head, as indicated by the "single" depth band located on the Reducer Driver and the three depth bands shown in the indication window.

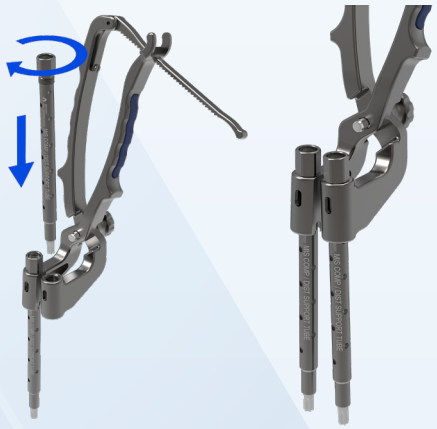
1.8.2.5 Remove the Sequential Reducer by squeezing the release tabs, then pull up. It is not necessary to unthread the reducer.



1.9 COMPRESSION / DISTRACTION

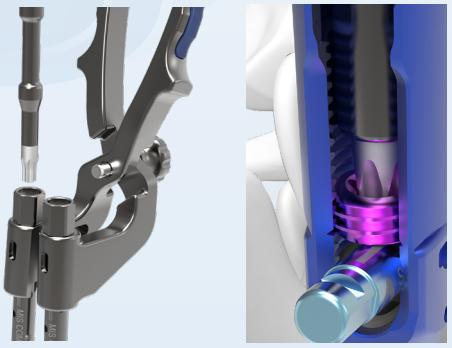
1.9.1 SINGLE LEVEL COMPRESSION / DISTRACTION

1.9.1.1 Insert the Support Tubes (AZE380000) into the Hinged Compressor (AZE330000) or Hinged Distractor (AZE330001), then thread into the housings. Utilize the Hex End Driver (AZE340010) to tighten.



1.9.1.2 Place the assembled Support Tubes and Hinged Compressor or Hinged Distractor into the Extended Tab Screws requiring manipulation. Ensure the top of the Extended Tab Screw is fully seated within the housing of the Hinged Compressor or Distractor. Confirmation is identified by the indication window.

1.9.1.3 Attach a Ratchet Handle (EBECDZBBZ, EAECDABEZ or EDECDTBBZ) to the Set Screw Torque Shaft, T30 (AZE370000), then engage the internal Set Screw Drive Shaft of the Support Tubes. While applying light downward force, orient the Set Screw Drive Shaft of the Support Tube to engage the distal end with the Set Screw.

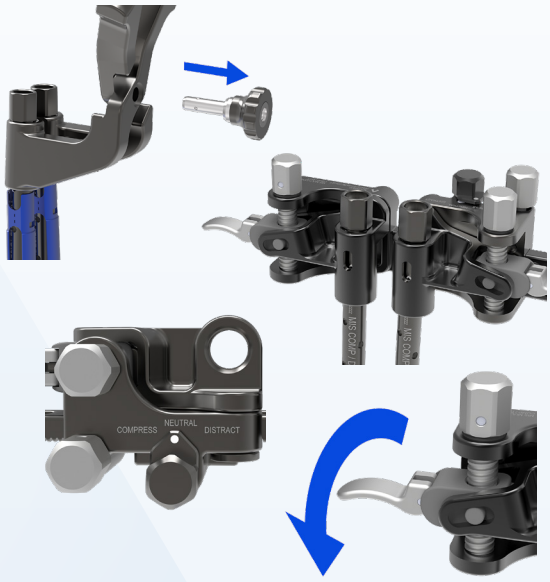


1.9.1.4 Tighten the Set Screw on one side of the motion segment, then leave the Set Screw loose in the adjacent segments to be manipulated.

1.9.1.5 Squeeze the handles until adequate manipulation is attained.

1.9.1.6 Use the Set Screw Torque Shaft and Ratchet Handle to tighten the Set Screw to maintain the manipulation.

1.9.1.7 Removal of the Pull Pin releases tension and eases removal of the Hinged Compressor or Hinged Distractor from the Extended Tab Screws. Press the pull pin button and remove.



1.9.2 MULTI-LEVEL COMPRESSION / DISTRACTION

1.9.2.1 Insert the Support Tubes (AZE380000) into the Multi-Level Compressor/ Distractor (AZE340000), then thread it into the housings. Utilize the Hex End Driver (AZE340010) to tighten.

1.9.2.2 Position the threaded carriage lever to UNLOCK, then rotate the rack slider knob to NEUTRAL.

1.9.2.3 Place the assembled Support Tubes and Multi-Level Compressor/Distractor into the Extended Tab Screws requiring manipulation. Ensure the top of the Extended Tab Screw is fully seated within the housing of the Hinged Compressor or Distractor, as identified by the indication window.

1.9.2.4 Attach the Ratchet Handle (EBECDZBBZ, EAECDABEZ or EDECDTBBZ) to the Set Screw Torque Shaft, T30 (AZE370000), then engage the internal Set Screw Drive Shaft of the Support Tubes. While applying light downward force, orient the Set Screw Drive Shaft of the Support Tube to engage the distal end with the Set Screw.

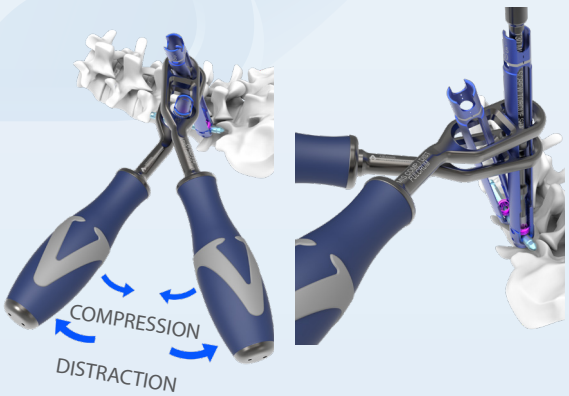
1.9.2.5 Position the threaded carriage levers to LOCK, then position the rack slider knob to the desired COMPRESS or DISTRACT position. Attach a Ratchet Handle (EBECDZBBZ, EAECDABEZ or EDECDTBBZ) to the Hex End Driver to manipulate the rack width or screw angle.

1.9.3 SHORT SEGMENT COMPRESSION/DISTRACTION

1.9.3.1 Slide the first Fulcrum Compressor / Distractor (AZE320000) down with the handle angled to the left, capturing adjacent screws within each opening. Slide the second Fulcrum Compressor / Distractor down over the top of the first with the handle angled to the right, capturing the same screws within each opening.

1.9.3.2 Position the first (bottom) Fulcrum Compressor / Distractor near the point at which the towers cross one another and the second (top) Fulcrum Compressor / Distractor halfway between the first (bottom) Fulcrum Compressor / Distractor and the top of the screw.

1.9.3.3 Compression is achieved by bringing the handles together. Distraction is achieved by pulling the handles away from one another.



1.2 FINAL TIGHTENING

1.2.1 Final tightening of the construct should be performed when all screws and rods are in their final position.

1.2.2 Connect the Offset 100in-lb Torque Limiting T-Handle (ECECGAAZF) to the Set Screw Torque Shaft, T30 (AZE370000).

1.2.3 Insert the assembly into the Counter Torque (AZE350000) or Long Counter Torque (AZE360000).

1.2.4 With the Set Screw Torque Shaft protruding out of the Counter Torque, engage the Extended Tab Screw until it is fully seated.

1.2.5 Slide the Counter Torque down until it is fully seated.

1.2.6 Turn the T-Handle clockwise to tighten. Final tightening is achieved when the T-Handle audibly clicks.

1.3 TAB REMOVAL

1.3.1 Insert the Extended Tab Divider (AZE230000) into the top of the Extended Tab Screw, then squeeze to divide the proximal end of the Extended Tab Screw.

1.3.2 Insert the Tab Breaker over the divided proximal end, then bend the tab outward to break off, then repeat for the other tab.

1.4 IMPLANT REMOVAL

1.4.1 Assemble the Ratcheting T-Handle (EBECDZBBZ) to the Set Screw Torque Shaft, T30 (AZE370000).

1.4.2 Insert the assembly into the Long Counter Torque (AZE360000).

1.4.3 Slide the Long Counter Torque down until the instrument is fully seated over the rod and implant.

1.4.4 Turn the T-Handle counter-clockwise to loosen, then remove the Set Screw.

1.4.5 Repeat for each screw.

1.4.6 Grab the rod using the Kerrison Rod Inserter (AZE240000), then remove the rod.

1.4.7 Assemble the Ratcheting T-Handle (EBECDZBBZ) to the Screw Height Adjuster, T25 (AZE170000).

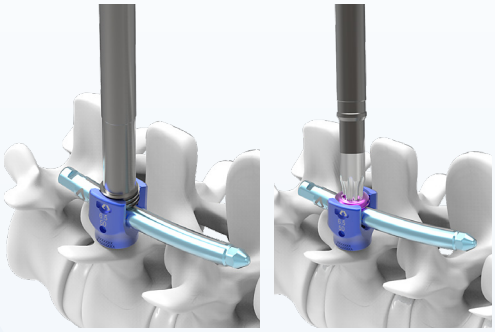
1.4.8 Insert the Screw Height Adjuster into the Screw, then unthread in a counter clockwise direction.

1.5 TOWER RESCUE

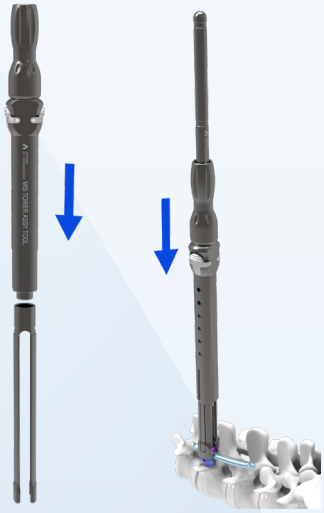
1.5.1 **Without Set Screw:** Thread the Threaded Tower Attachment Guide (AZE410010) into the Polyaxial Screw.

1.5.2 **With Set Screw:** Insert the Stick Fit Tower Attachment Guide, T30 (AZE410000) into the drive feature of the Set Screw.

1.5.3 Insert the Screw Tower (AZE140000) into the Tower Assembly Tool (AZE150000), then snap it into place using the spring-loaded clips. The Tower Assembly Tool will automatically lock onto the Screw Tower. Confirm proper engagement by giving a light tug upward.



1.5.4 Slide the Screw Tower and Tower Assembly Tool over the Threaded Tower Attachment Guide or Stick Fit Tower Attachment Guide down to the Extended Tab Screw. Orient the Screw Tower to click onto the Polyaxial Screw. Confirm proper engagement by giving a light tug upward.



1.5.5 Remove the Tower Assembly Tool by squeezing the release tabs, then pull up.

1.5.6 The Tower Sequential Reducer (AZE540000) must be used in lieu of the Sequential Reducer (AZE290000) if the Screw Tower is in use.

1.6 TOWER REMOVAL

1.6.1 Insert the Tower Remover (AZE390000) into the Screw Tower, then snap it into place using the spring-loaded clips. The Tower Remover will automatically lock onto the Screw Tower. Confirm proper engagement by giving a light tug upward.

1.6.2 Turn the T-Handle of the Tower Remover clockwise 90 degrees, then pull up.

1.6.3 If additional assistance is required to remove the Screw Tower, utilize the Tower Remover Threaded Ram (AZE390010). Insert the Tower Remover Threaded Ram into the Tower Remover, then engage the threads until the distal tip contacts the screw. Turn the T-Handle of the Tower Remover to the 90 degree position, then continue threading the Tower Remover Threaed Ram until the Tower Remover is disengaged from the Polyaxial Screw.

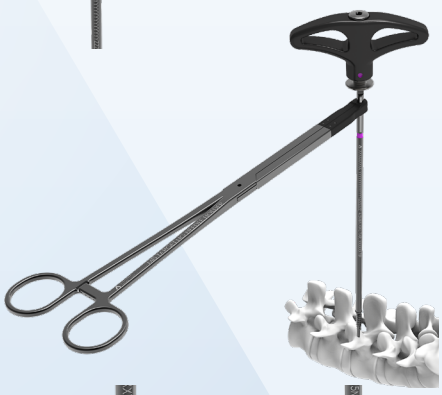
2.0 AWL-TAP TECHNIQUE

2.1 PREOPERATIVE PLANNING

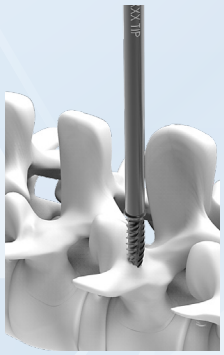
2.1.1 Identify the affected level using standard techniques with fluoroscopic imaging in the A/P and lateral views. Use preferred intraoperative techniques to locate the pedicles under fluoroscopy, then identify the appropriate starting points and trajectory.

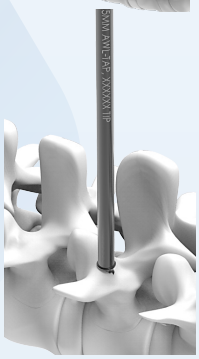
2.2 ACCESS

2.2.1 An Awl-Tap, Beveled Tip (AZE450000) or Awl-Tap, Diamond Tip (AZE450001) can be utilized to locate the pedicle and set the desired positioning. Attach the Awl-Tap Handle (AZE460000) to the Awl-Tap, Beveled Tip or Awl-Tap, Diamond Tip. Attach the Targeting Needle Holder (AZE030000) to the proximal end of the Awl-Tap to clear the fluoroscopy imaging area. Using standard intraoperative techniques with fluoroscopy, advance the Awl-Tap to the desired path within the vertebral body.



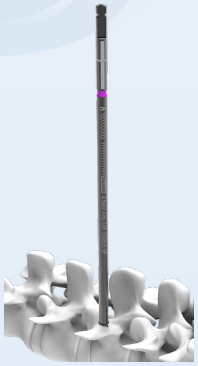
2.2.2 Bevel orientation of the Awl-Tap, Beveled Tip is indicated by an epoxy mark on the Awl-Tap Handle.





2.2.3 Once the tapping portion of the Awl-Tap is reached, begin to turn the Awl-Tap Handle in a clockwise direction until the shoulder of the Awl-Tap contacts the bony anatomy.

2.2.4 Remove the Awl-Tap Handle from the Awl-Tap.



2.3 INCISION – AWL-TAP

2.3.1 Assemble the Wireless Fascial Blade (AZE500000) to the Wireless Fascial Blade Tip (AZE500000-02) by inserting the distal end of the Wireless Fascial Blade into the threaded opening of Wireless Fascial Blade Tip located within the caddy. Secure by turning the proximal knob of the Wireless Fascial Blade in a clockwise direction.

2.3.2 Attach the assembled Wireless Fascial Blade and Tip to the Wireless Fascial Blade Handle (AZE520000). Insert the Wireless Fascial Blade into the Wireless Fascial Blade Handle, then snap it into place using the spring-loaded clips. The Wireless Fascial Blade Handle will automatically lock onto the Wireless Fascial Blade.

2.3.3 Guide the assembled Wireless Fascial Blade over the Awl-Tap. Using the Fascial Blade Tip, create an incision through the skin and fascia.

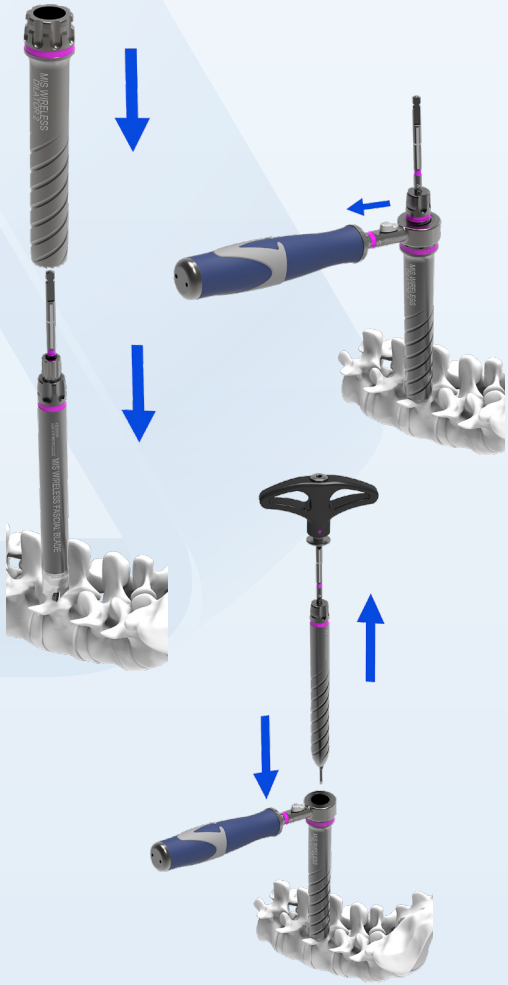
2.3.4 Remove the Wireless Fascial Blade.

2.3.5 Guide Wireless Dilator 1 (AZE470000) (Magenta Band) over the Awl-Tap then into the incision. Advance Wireless Dilator 1 through the soft tissue until it is against the shoulder of the Awl-Tap. Depth is confirmed by the magenta depth band on the Awl-Tap. Wireless Dilator 1 may be attached to the Wireless Fascial Blade Handle if desired.

2.3.6 Guide Wireless Dilator 2 (AZE480000) (Magenta Band) over the Awl-Tap, then over Wireless Dilator 1. Advance Wireless Dilator 2 through the soft tissue until it is seated against the pedicle. The magenta depth band located on Wireless Dilator 1 confirms Wireless Dilator 2 is fully seated in relation to Wireles Dilator1.

2.3.7 Optional: Attach the Wireless Dilator 2 Handle to Wireless Dilator 2 to assist with maintaining the position of Wireless Dilator 2 during the following step.

2.3.8 Remove the Awl-Tap and Wireless Dilator 1. Assemble the Awl-Tap Handle to the Awl-Tap, then unthread the Awl-Tap in a counter clockwise direction. Removal of the Awl-Tap will result in removal of Wireless Dilator 1.



2.3.9 *CONTINUE TO "SECTION 1.5 - SCREWDRIVER AND EXTENDED TAB SCREW ASSEMBLY / DISASSEMBLY"*

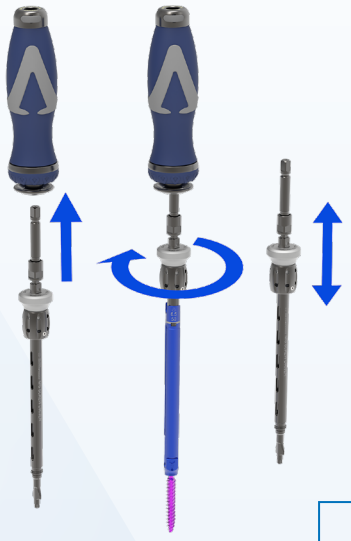
3.0 WIRELESS TECHNIQUE

3.1 PREOPERATIVE PLANNING

3.1.1 Identify the affected level using standard techniques with fluoroscopic imaging in the A/P and lateral views. Use preferred intraoperative techniques to locate the pedicles under fluoroscopy, then identify the appropriate starting points and trajectory.

3.2 SCREWDRIVER, EXTENDED TAB SCREW, AND STYLET ASSEMBLY

3.2.1 Assemble the Axial Ratchet Handle (EAECDABEZ) to the MIS Scredriver,T25 (AZE160000). The ¼" square drive of the Screwdriver shaft is fully secured to the handle when the small groove aligns with the distal end of the handle.



3.2.2 The Extended Tab Screw can be assembled to the Screwdriver in the LOCKED or UNLOCKED position.

3.2.3 Attach the appropriate Extended Tab Screw onto the Screwdriver by inserting the distal end of the Screwdriver into the Extended Tab Screw, then thread the grip clockwise to engage the Screwdriver thread into the base of the Extended Tab Screw.

3.2.4 Set the Screwdriver to the LOCKED position, then ensure the Ratcheting Handle is set in the FORWARD position.

3.2.5 Assemble the Screwdriver Stylet (AZE090001) to the Screwdriver Stylet Shuttle (AZE090000). Pull back on the Screwdriver Stylet Shuttle spring-loaded collar, then insert the distal tip of the Screwdriver Stylet through the slotted opening.

3.2.6 While maintaining the Screwdriver Stylet Shuttle spring-loaded collar in the pulled back position, place the proximal end of the Screwdriver Stylet into the selected screw length corresponding slot as identified on the sides of the Screwdriver Stylet Shuttle. Release the Screwdriver Stylet Shuttle spring-loaded collar.

3.2.7 Insert the assembled Screwdriver Stylet Shuttle and Screwdriver Stylet into the proximal end of the Screwdriver. Press the spring-loaded button located on the proximal cap of Ratcheting Axial Handle to advance the Screwdriver Stylet Shuttle.

3.2.8 Position the Screwdriver Stylet Shuttle to the desired protrusion length (3mm, 6mm, 9mm, 12mm, or 15mm), then release the spring-loaded button. Confirm a locked engagement by tugging upwards on the Screwdriver Stylet Shuttle.

3.3 ACCESS / SCREW INSERTION

3.3.1 Make an incision, then use Dilator or finger palpation to create a pathway to the base of pedicle.

3.3.2 Insert the Screwdriver through the incision, then use the Stylet Tip to dock at the desired location on the pedicle. Advance the Screwdriver Stylet to the desired path within the vertebral body.

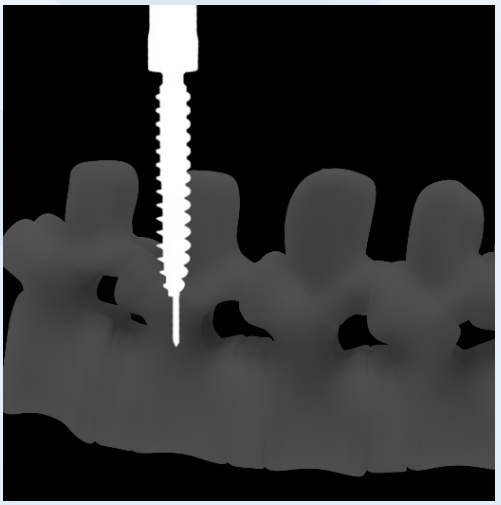
3.3.3 If desired, the spring-loaded button located on the proximal cap of the Ratcheting Axial Handle can be pressed to advance the Screwdriver Stylet protrusion.

3.3.4 Once the threads of the screw contact bone, rotate clockwise until the desired depth is achieved.

4.0 OPTIONAL USE OF TOWER

4.1 PEDICLE PREPARATION (FOR USE WITH TOWER)

4.1.1 Guide Dilator 1 (AZE110001) over the Guidewire into the incision. Advance Dilator 1 through the soft tissue until it is seated against the pedicle. Confirm proper placement using fluoroscopy.



4.1.2 Guide Tower Dilator 2 (AZE530002) (Green Band) over the Guidwire, then over Dilator 1. Advance Tower Dilator 2 through the soft tissue until it is seated against the pedicle. The depth band located on Dilator 1 confirms Tower Dilator 2 is fully seated in relation to Dilator 1.

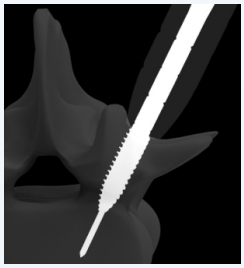
4.1.3 Guide Tower Dilator 3 (AZE530003) (Green Band) over the Guidewire, then over Tower Dilator 2. Advance Tower Dilator 3 through the soft tissue until it is seated against the pedicle. The depth band located on Tower Dilator 2 confirms Tower Dilator 3 is fully seated in relation to Tower Dilator 2.

4.1.4 Remove Dilator 1, then select the correct size Bone Tap (AZE1200XX) for the screw to be used. Then attach the Bone Tap to one of the Ratcheting Handles (EBECDZBBZ, EAECDABEZ or EDECDTBBZ).

4.1.5 Guide the Bone Tap and Ratcheting Handle over the Guidewire into Dilator 2, then advance until it is seated against the pedicle. Rotate clockwise until the desired tapping depth has been achieved. The Bone Tap depth-indicating bands are referenced off the top of Dilator 2. Notched depth rings located on the distal shaft may also be used for fluoroscopic analysis and confirmation. The first notched ring is 30mm from the distal tip, with additional rings every 10mm. Confirm placement using fluoroscopy.

4.2 SCREWDRIVER, SCREW AND SCREW TOWER ASSEMBLY / DISASSEMBLY

4.2.1 Insert the Screw Tower (AZE140000) into the Tower Assembly Tool (AZE150000), then snap it into place using the spring-loaded clip. The Tower Assembly Tool will automatically lock onto the Screw Tower.



4.2.2 Insert the appropriate Screw into the distal end of the Screw Tower, then snap it into place. Confirm proper engagement by giving a light tug on the Screw.

4.2.3 Remove the Tower Assembly Tool by squeezing the release tabs, then pull up.

4.2.4 Assemble the Ratchet Handle (EBECDZBBZ, EAECDABEZ or EDECDTBBZ) and Tower Screwdriver, T25 (AZE550000) by inserting the proximal end of the Tower Screwdriver into the distal end of the handle. Compress the spring-loaded quick-connect ring of the handle to assemble. The ¼" square drive of the Screwdriver shaft is fully secured to the handle when the small groove reaches the distal end of the handle.

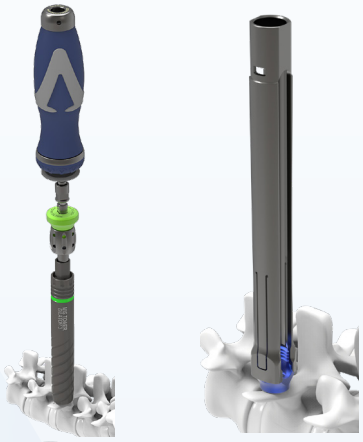
4.2.5 The Screw and Screw Tower assembly can be assembled to the Tower Screwdriver in the LOCKED or UNLOCKED position.

4.2.6 Insert the distal end of the Tower Screwdriver into the Screw Tower, then into the Screw. Thread the grip clockwise to engage the Tower Screwdriver thread into the head of the screw.

4.2.7 Set the Tower Screwdriver to the LOCKED position, then ensure the Ratcheting Handle is set in the FORWARD position.

4.3 SCREW AND SCREW TOWER INSERTION

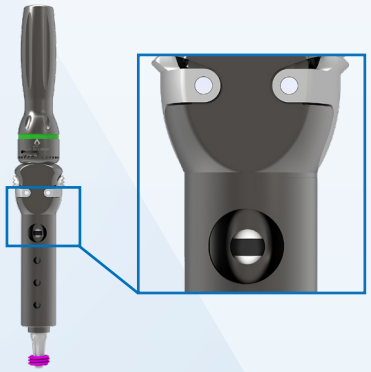
4.3.1 Remove Tower Dilator 2, then guide the Screw, Screw Tower, Screwdriver and Ratchet Handle over the Guidewire. Insert the Screw tip into the pilot hole, then rotate clockwise until the desired depth is achieved.



4.3.2 To disassemble the Tower Screwdriver from the Screw, set the Tower Screwdriver to the UNLOCKED position, then unthread the grip in a counter clockwise direction to disengage the Tower Screwdriver thread from the head of the screw. Pull upward to remove the Tower Screwdriver from the Screw.

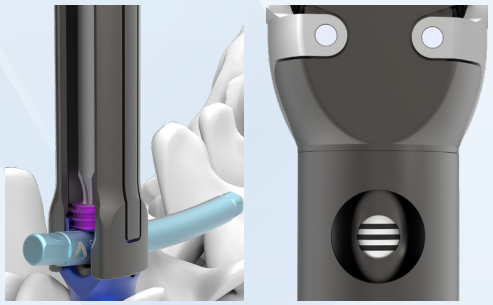
4.4 TOWER ROD REDUCTION

4.4.1 Large Reduction is achieved by utilizing the Tower Sequential Reducer (AZE540000). With the Tower Sequential Reducer handle unthreaded counter-clockwise and telescoping shaft inset (Indication Window Shows 1 Band), insert the "stick fit" distal end into the Set Screw.



4.4.2 Insert the Set Screw and Tower Sequential Reducer assembly into the Screw Tower, then snap it into place using the spring-loaded clip. The reducer will automatically lock onto the Screw Tower.

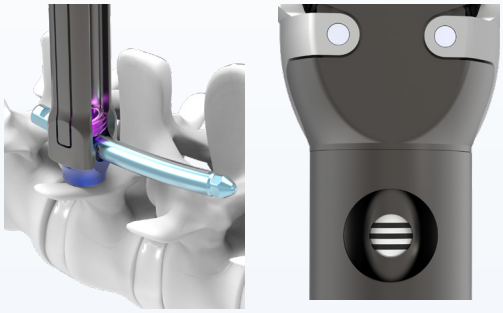
4.4.3 Confirm proper engagement by giving a light tug upward.



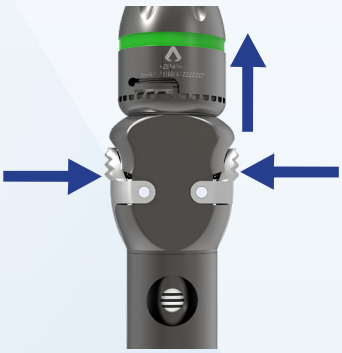
4.4.4 To reduce the rod, turn the handle of the Tower Sequential Reducer until the internal ram reduces the rod below the threads of the screw, as indicated with two bands shown in the indication window.

4.4.5 Insert the proximal portion of the Reducer Driver (AZE280000) into the top of the Sequential Reducer knob to increase grip when additional torque is required.

4.4.1.6 Insert the shafted end of the Reducer Driver into the Tower Sequential Reducer, then engage the internal drive shaft. While applying light downward force, thread the Set Screw in a clockwise direction to engage the Screw threads. Continue to thread until the rod is seated into the screw head, as indicated by the depth band located on the Reducer Driver.



4.4.1.7 Remove the Tower Sequential Reducer by squeezing the release tabs, then pulling up. It is not necessary to unthread the reducer.



4.5 TOWER REMOVAL

4.5.1 Insert the Tower Remover into the Screw Tower, then snap it into place using the spring-loaded clip. The Tower Remover will automatically lock onto the Screw Tower.

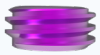
4.5.2 Turn the T-Handle of the Tower Remover clockwise 90°, then pull up.

4.5.3 If additional assistance is required to remove the Screw Tower, utilize the Tower Remover Threaded Ram (AZE390010). Insert the Tower Remover Threaded Ram into the Tower Remover, then engage the threads until the distal tip contacts the screw. Turn the T-Handle of Tower Remover to the 90° position, then continue threading the Tower Remover Threaded Ram until the Tower Remover is disengaged from the Extended Tab Screw.

OLYMPIC MIS IMPLANT OFFERING

SET SCREW

Part Number	Description	Qty
ABBA00000	MIS Set Screw	30

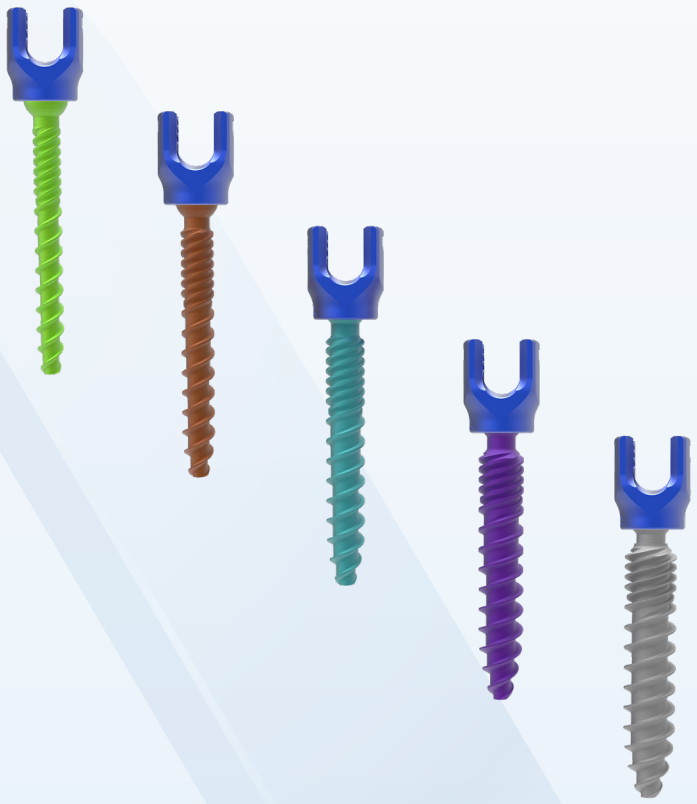


POLYAXIAL SCREW, CANNULATED, EXTENDED TAB (CORTICAL CANCELLOUS)

Part Number	Description	Qty
AJCA45025	Cortical Polyaxial Screw, Cann, Ext Tab, 4.5mm X 25mm	4 / OPT
AJCA45030	Cortical Polyaxial Screw, Cann, Ext Tab, 4.5mm X 30mm	8 / OPT
AJCA45035	Cortical Polyaxial Screw, Cann, Ext Tab, 4.5mm X 35mm	8 / OPT
AJCA45040	Cortical Polyaxial Screw, Cann, Ext Tab, 4.5mm X 40mm	8 / OPT
AJCA45045	Cortical Polyaxial Screw, Cann, Ext Tab, 4.5mm X 45mm	8 / OPT
AJCA55035	Cortical Polyaxial Screw, Cann, Ext Tab, 5.5mm X 35mm	4
AJCA55040	Cortical Polyaxial Screw, Cann, Ext Tab, 5.5mm X 40mm	8
AJCA55045	Cortical Polyaxial Screw, Cann, Ext Tab, 5.5mm X 45mm	8
AJCA55050	Cortical Polyaxial Screw, Cann, Ext Tab, 5.5mm X 50mm	8
AJCA55055	Cortical Polyaxial Screw, Cann, Ext Tab, 5.5mm X 55mm	4
AJCA65035	Cortical Polyaxial Screw, Cann, Ext Tab, 6.5mm X 35mm	4
AJCA65040	Cortical Polyaxial Screw, Cann, Ext Tab, 6.5mm X 40mm	8
AJCA65045	Cortical Polyaxial Screw, Cann, Ext Tab, 6.5mm X 45mm	8
AJCA65050	Cortical Polyaxial Screw, Cann, Ext Tab, 6.5mm X 50mm	8
AJCA65055	Cortical Polyaxial Screw, Cann, Ext Tab, 6.5mm X 55mm	8
AJDA75035	Cortical Polyaxial Screw, Cann, Ext Tab, 7.5mm X 35mm	4
AJDA75040	Cortical Polyaxial Screw, Cann, Ext Tab, 7.5mm X 40mm	8
AJDA75045	Cortical Polyaxial Screw, Cann, Ext Tab, 7.5mm X 45mm	8
AJDA75050	Cortical Polyaxial Screw, Cann, Ext Tab, 7.5mm X 50mm	8
AJDA75055	Cortical Polyaxial Screw, Cann, Ext Tab, 7.5mm X 55mm	8
AJDA85035	Cortical Polyaxial Screw, Cann, Ext Tab, 8.5mm X 35mm	4 / OPT
AJDA85040	Cortical Polyaxial Screw, Cann, Ext Tab, 8.5mm X 40mm	8 / OPT
AJDA85045	Cortical Polyaxial Screw, Cann, Ext Tab, 8.5mm X 45mm	8 / OPT
AJDA85050	Cortical Polyaxial Screw, Cann, Ext Tab, 8.5mm X 50mm	8 / OPT
AJDA85055	Cortical Polyaxial Screw, Cann, Ext Tab, 8.5mm X 55mm	4 / OPT
AJDA85060	Cortical Polyaxial Screw, Cann, Ext Tab, 8.5mm X 60mm	4 / OPT
AJDA85070	Cortical Polyaxial Screw, Cann, Ext Tab, 8.5mm X 70mm	4 / OPT
AJDA85080	Cortical Polyaxial Screw, Cann, Ext Tab, 8.5mm X 80mm	4 / OPT
AJDA85090	Cortical Polyaxial Screw, Cann, Ext Tab, 8.5mm X 90mm	4 / OPT
AJDA85100	Cortical Polyaxial Screw, Cann, Ext Tab, 8.5mm X 100mm	4 / OPT
AJDA95070	Cortical Polyaxial Screw, Cann, Ext Tab, 9.5mm X 70mm	4 / OPT
AJDA95080	Cortical Polyaxial Screw, Cann, Ext Tab, 9.5mm X 80mm	4 / OPT
AJDA95090	Cortical Polyaxial Screw, Cann, Ext Tab, 9.5mm X 90mm	4 / OPT
AJDA95100	Cortical Polyaxial Screw, Cann, Ext Tab, 9.5mm X 100mm	4 / OPT

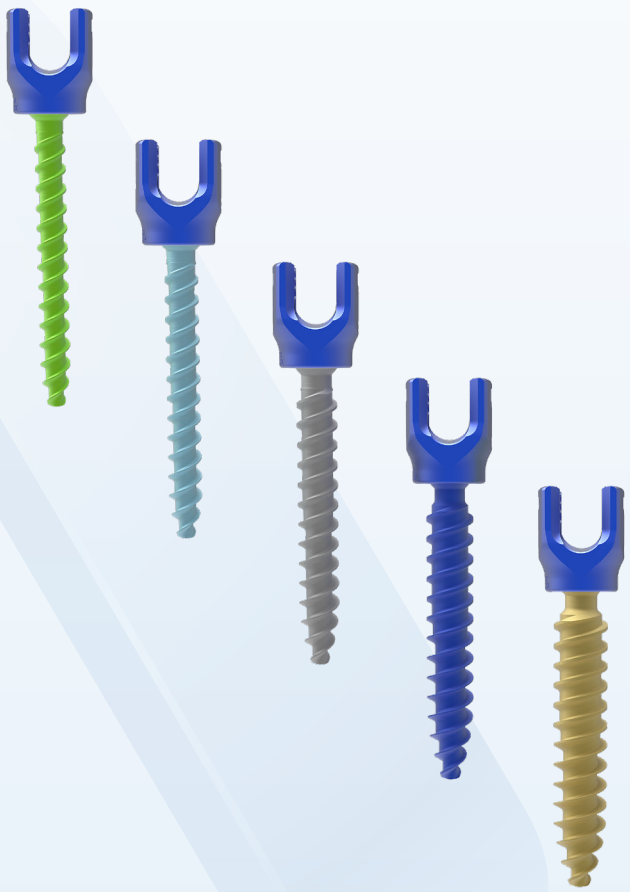
POLYAXIAL SCREW, CANNULATED (CORTICAL CANCELLOUS)

Part Number	Description	Qty
AAEA45020	Cortical Polyaxial Screw, Cannulated, 4.5mm x 20mm	4 / OPT
AAEA45025	Cortical Polyaxial Screw, Cannulated, 4.5mm x 25mm	8 / OPT
AAEA45030	Cortical Polyaxial Screw, Cannulated, 4.5mm x 30mm	8 / OPT
AAEA45035	Cortical Polyaxial Screw, Cannulated, 4.5mm x 35mm	8 / OPT
AAEA45040	Cortical Polyaxial Screw, Cannulated, 4.5mm x 40mm	8 / OPT
AAEA45045	Cortical Polyaxial Screw, Cannulated, 4.5mm x 45mm	8 / OPT
AAEA45050	Cortical Polyaxial Screw, Cannulated, 4.5mm x 50mm	4 / OPT
AAEA55030	Cortical Polyaxial Screw, Cannulated, 5.5mm x 30mm	4 / OPT
AAEA55035	Cortical Polyaxial Screw, Cannulated, 5.5mm x 35mm	8 / OPT
AAEA55040	Cortical Polyaxial Screw, Cannulated, 5.5mm x 40mm	8 / OPT
AAEA55045	Cortical Polyaxial Screw, Cannulated, 5.5mm x 45mm	8 / OPT
AAEA55050	Cortical Polyaxial Screw, Cannulated, 5.5mm x 50mm	8 / OPT
AAEA55055	Cortical Polyaxial Screw, Cannulated, 5.5mm x 55mm	4 / OPT
AAEA65030	Cortical Polyaxial Screw, Cannulated, 6.5mm x 30mm	4 / OPT
AAEA65035	Cortical Polyaxial Screw, Cannulated, 6.5mm x 35mm	8 / OPT
AAEA65040	Cortical Polyaxial Screw, Cannulated, 6.5mm x 40mm	8 / OPT
AAEA65045	Cortical Polyaxial Screw, Cannulated, 6.5mm x 45mm	8 / OPT
AAEA65050	Cortical Polyaxial Screw, Cannulated, 6.5mm x 50mm	8 / OPT
AAEA65055	Cortical Polyaxial Screw, Cannulated, 6.5mm x 55mm	8 / OPT
AAEA65060	Cortical Polyaxial Screw, Cannulated, 6.5mm x 60mm	4 / OPT
AARA75030	Cortical Polyaxial Screw, Cannulated, 7.5mm x 30mm	4 / OPT
AARA75035	Cortical Polyaxial Screw, Cannulated, 7.5mm x 35mm	8 / OPT
AARA75040	Cortical Polyaxial Screw, Cannulated, 7.5mm x 40mm	8 / OPT
AARA75045	Cortical Polyaxial Screw, Cannulated, 7.5mm x 45mm	8 / OPT
AARA75050	Cortical Polyaxial Screw, Cannulated, 7.5mm x 50mm	8 / OPT
AARA75055	Cortical Polyaxial Screw, Cannulated, 7.5mm x 55mm	8 / OPT
AARA75060	Cortical Polyaxial Screw, Cannulated, 7.5mm x 60mm	4 / OPT
AARA85030	Cortical Polyaxial Screw, Cannulated, 8.5mm x 30mm	4 / OPT
AARA85035	Cortical Polyaxial Screw, Cannulated, 8.5mm x 35mm	4 / OPT
AARA85040	Cortical Polyaxial Screw, Cannulated, 8.5mm x 40mm	4 / OPT
AARA85045	Cortical Polyaxial Screw, Cannulated, 8.5mm x 45mm	4 / OPT
AARA85050	Cortical Polyaxial Screw, Cannulated, 8.5mm x 50mm	4 / OPT
AARA85055	Cortical Polyaxial Screw, Cannulated, 8.5mm x 55mm	4 / OPT
AARA85060	Cortical Polyaxial Screw Cannulated, 8.5mm x 60mm	4 / OPT



POLYAXIAL SCREW, CANNULATED (DUAL-LEAD)

Part Number	Description	Qty
AABA45020	Dual-Lead Polyaxial Screw, Cannulated, 4.5mm X 20mm	4 / OPT
AABA45025	Dual-Lead Polyaxial Screw, Cannulated, 4.5mm X 25mm	8 / OPT
AABA45030	Dual-Lead Polyaxial Screw, Cannulated, 4.5mm X 30mm	8 / OPT
AABA45035	Dual-Lead Polyaxial Screw, Cannulated, 4.5mm X 35mm	8 / OPT
AABA45040	Dual-Lead Polyaxial Screw, Cannulated, 4.5mm X 40mm	8 / OPT
AABA45045	Dual-Lead Polyaxial Screw, Cannulated, 4.5mm X 45mm	8 / OPT
AABA45050	Dual-Lead Polyaxial Screw, Cannulated, 4.5mm X 50mm	4 / OPT
AABA50030	Dual-Lead Polyaxial Screw, Cannulated, 5.0mm X 30mm	4 / OPT
AABA50035	Dual-Lead Polyaxial Screw, Cannulated, 5.0mm X 35mm	8 / OPT
AABA50040	Dual-Lead Polyaxial Screw, Cannulated, 5.0mm X 40mm	8 / OPT
AABA50045	Dual-Lead Polyaxial Screw, Cannulated, 5.0mm X 45mm	8 / OPT
AABA50050	Dual-Lead Polyaxial Screw, Cannulated, 5.0mm X 50mm	8 / OPT
AABA50055	Dual-Lead Polyaxial Screw, Cannulated, 5.0mm X 55mm	4 / OPT
AABA60030	Dual-Lead Polyaxial Screw, Cannulated, 6.0mm X 30mm	4 / OPT
AABA60035	Dual-Lead Polyaxial Screw, Cannulated, 6.0mm X 35mm	8 / OPT
AABA60040	Dual-Lead Polyaxial Screw, Cannulated, 6.0mm X 40mm	8 / OPT
AABA60045	Dual-Lead Polyaxial Screw, Cannulated, 6.0mm X 45mm	8 / OPT
AABA60050	Dual-Lead Polyaxial Screw, Cannulated, 6.0mm X 50mm	8 / OPT
AABA60055	Dual-Lead Polyaxial Screw, Cannulated, 6.0mm X 55mm	8 / OPT
AABA60060	Dual-Lead Polyaxial Screw, Cannulated, 6.0mm X 60mm	4 / OPT
AABA70030	Dual-Lead Polyaxial Screw, Cannulated, 7.0mm X 30mm	4 / OPT
AABA70035	Dual-Lead Polyaxial Screw, Cannulated, 7.0mm X 35mm	8 / OPT
AABA70040	Dual-Lead Polyaxial Screw, Cannulated, 7.0mm X 40mm	8 / OPT
AABA70045	Dual-Lead Polyaxial Screw, Cannulated, 7.0mm X 45mm	8 / OPT
AABA70050	Dual-Lead Polyaxial Screw, Cannulated, 7.0mm X 50mm	8 / OPT
AABA70055	Dual-Lead Polyaxial Screw, Cannulated, 7.0mm X 55mm	8 / OPT
AABA70060	Dual-Lead Polyaxial Screw, Cannulated, 7.0mm X 60mm	4 / OPT
AATA80030	Dual-Lead Polyaxial Screw, Cannulated, 8.0mm X 30mm	4 / OPT
AATA80035	Dual-Lead Polyaxial Screw, Cannulated, 8.0mm X 35mm	4 / OPT
AATA80040	Dual-Lead Polyaxial Screw, Cannulated, 8.0mm X 40mm	4 / OPT
AATA80045	Dual-Lead Polyaxial Screw, Cannulated, 8.0mm X 45mm	4 / OPT
AATA80050	Dual-Lead Polyaxial Screw, Cannulated, 8.0mm X 50mm	4 / OPT
AATA80055	Dual-Lead Polyaxial Screw, Cannulated, 8.0mm X 55mm	4 / OPT
AATA80060	Dual-Lead Polyaxial Screw, Cannulated, 8.0mm X 60mm	4 / OPT



OLYMPIC MIS IMPLANT OFFERING

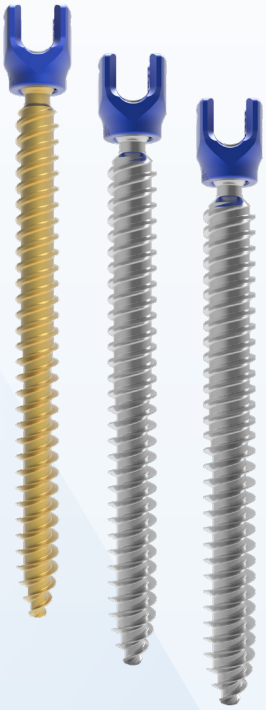
POLYAXIAL SCREWS, NON-CANNULATED (DUAL-LEAD)

Part Number	Description	Qty
AAAA40020	Polyaxial Screw, 4.0mm X 20mm	4
AAAA40025	Polyaxial Screw, 4.0mm X 25mm	8
AAAA40030	Polyaxial Screw, 4.0mm X 30mm	8
AAAA40035	Polyaxial Screw, 4.0mm X 35mm	8
AAAA40040	Polyaxial Screw, 4.0mm X 40mm	8
AAAA40045	Polyaxial Screw, 4.0mm X 45mm	8
AAAA40050	Polyaxial Screw, 4.0mm X 50mm	4
AAAA45020	Polyaxial Screw, 4.5mm X 20mm	4
AAAA45025	Polyaxial Screw, 4.5mm X 25mm	8
AAAA45030	Polyaxial Screw, 4.5mm X 30mm	8
AAAA45035	Polyaxial Screw, 4.5mm X 35mm	8
AAAA45040	Polyaxial Screw, 4.5mm X 40mm	8
AAAA45045	Polyaxial Screw, 4.5mm X 45mm	8
AAAA45050	Polyaxial Screw, 4.5mm X 50mm	4
AAAA50030	Polyaxial Screw, 5.0mm X 30mm	4
AAAA50035	Polyaxial Screw, 5.0mm X 35mm	8
AAAA50040	Polyaxial Screw, 5.0mm X 40mm	8
AAAA50045	Polyaxial Screw, 5.0mm X 45mm	8
AAAA50050	Polyaxial Screw, 5.0mm X 50mm	8
AAAA50055	Polyaxial Screw, 5.0mm X 55mm	8
AAAA60030	Polyaxial Screw, 6.0mm X 30mm	4
AAAA60035	Polyaxial Screw, 6.0mm X 35mm	8
AAAA60040	Polyaxial Screw, 6.0mm X 40mm	8
AAAA60045	Polyaxial Screw, 6.0mm X 45mm	8
AAAA60050	Polyaxial Screw, 6.0mm X 50mm	8
AAAA60055	Polyaxial Screw, 6.0mm X 55mm	8
AAAA60060	Polyaxial Screw, 6.0mm X 60mm	4
AAAA70030	Polyaxial Screw, 7.0mm X 30mm	4
AAAA70035	Polyaxial Screw, 7.0mm X 35mm	8
AAAA70040	Polyaxial Screw, 7.0mm X 40mm	8
AAAA70045	Polyaxial Screw, 7.0mm X 45mm	8
AAAA70050	Polyaxial Screw, 7.0mm X 50mm	8
AAAA70055	Polyaxial Screw, 7.0mm X 55mm	8
AAAA70060	Polyaxial Screw, 7.0mm X 60mm	4
AAAA70065	Polyaxial Screw, 7.0mm X 65mm	3
AAAA70070	Polyaxial Screw, 7.0mm X 70mm	3
AAAA70075	Polyaxial Screw, 7.0mm X 75mm	3
AAAA70080	Polyaxial Screw, 7.0mm X 80mm	3
AAAA70085	Polyaxial Screw, 7.0mm X 85mm	3
AAAA70090	Polyaxial Screw, 7.0mm X 90mm	3
AASA80030	Polyaxial Screw, 8.0mm X 30mm	4
AASA80035	Polyaxial Screw, 8.0mm X 35mm	4
AASA80040	Polyaxial Screw, 8.0mm X 40mm	4
AASA80045	Polyaxial Screw, 8.0mm X 45mm	4
AASA80050	Polyaxial Screw, 8.0mm X 50mm	4
AASA80055	Polyaxial Screw, 8.0mm X 55mm	4
AASA80060	Polyaxial Screw, 8.0mm X 60mm	4
AASA90030	Polyaxial Screw, 9.0mm X 30mm	4
AASA90035	Polyaxial Screw, 9.0mm X 35mm	4
AASA90040	Polyaxial Screw, 9.0mm X 40mm	4
AASA90045	Polyaxial Screw, 9.0mm X 45mm	4
AASA90050	Polyaxial Screw, 9.0mm X 50mm	4
AASA90055	Polyaxial Screw, 9.0mm X 55mm	4
AASA90060	Polyaxial Screw, 9.0mm X 60mm	4

OLYMPIC MIS IMPLANT OFFERING

POLYAXIAL SCREWS, NON-CANNULATED (DUAL-LEAD)

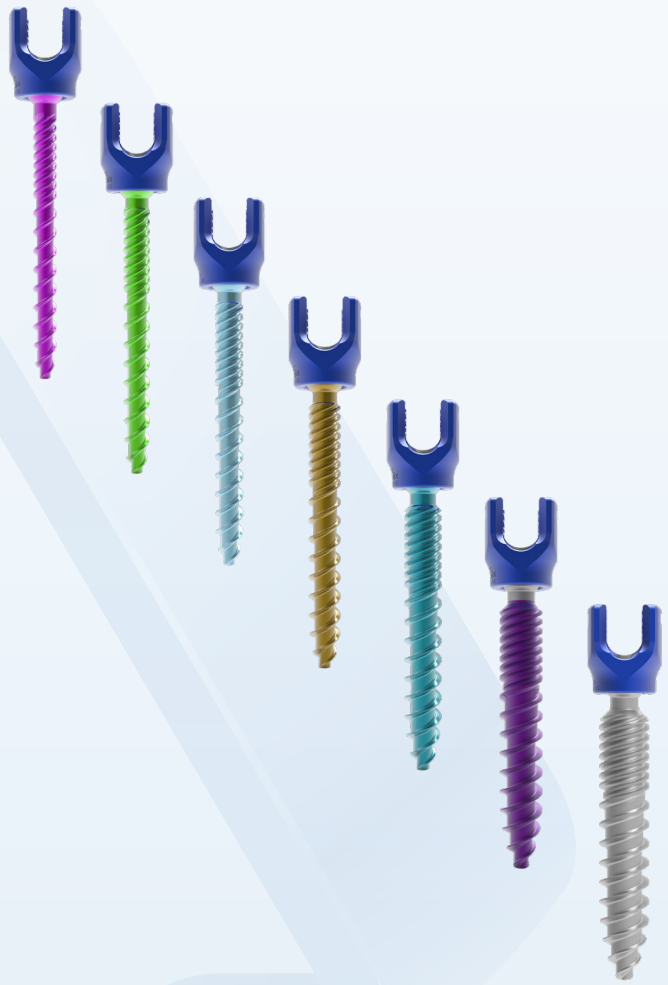
Part Number	Description	Qty
AASA80065	Polyaxial Screw, 8.0mm X 65mm	3*
AASA80070	Polyaxial Screw, 8.0mm X 70mm	3*
AASA80075	Polyaxial Screw, 8.0mm X 75mm	3*
AASA80080	Polyaxial Screw, 8.0mm X 80mm	3*
AASA80085	Polyaxial Screw, 8.0mm X 85mm	3*
AASA80090	Polyaxial Screw, 8.0mm X 90mm	3*
AASA80100	Polyaxial Screw, 8.0mm X 100mm	3*
AASA80110	Polyaxial Screw, 8.0mm X 110mm	3*
AASA80120	Polyaxial Screw, 8.0mm X 120mm	3*
AASA90080	Polyaxial Screw, 9.0mm X 80mm	3*
AASA90090	Polyaxial Screw, 9.0mm X 90mm	3*
AASA90100	Polyaxial Screw, 9.0mm X 100mm	3*
AASA90110	Polyaxial Screw, 9.0mm X 110mm	3*
AASA90120	Polyaxial Screw, 9.0mm X 120mm	3*
AASA00080	Polyaxial Screw, 10.0mm X 80mm	3*
AASA00090	Polyaxial Screw, 10.0mm X 90mm	3*
AASA00100	Polyaxial Screw, 10.0mm X 100mm	3*
AASA00110	Polyaxial Screw, 10.0mm X 110mm	3*
AASA00120	Polyaxial Screw, 10.0mm X 120mm	3*



OLYMPIC MIS IMPLANT OFFERING

POLYAXIAL SCREWS (CORTICAL CANCELLOUS)

Part Number	Description	Qty
AADA40020	Cortical Polyaxial Screw, 4.0mm x 20mm	4
AADA40025	Cortical Polyaxial Screw, 4.0mm x 25mm	8
AADA40030	Cortical Polyaxial Screw, 4.0mm x 30mm	8
AADA40035	Cortical Polyaxial Screw, 4.0mm x 35mm	8
AADA40040	Cortical Polyaxial Screw, 4.0mm x 40mm	8
AADA40045	Cortical Polyaxial Screw, 4.0mm x 45mm	8
AADA40050	Cortical Polyaxial Screw, 4.0mm x 50mm	4
AADA45020	Cortical Polyaxial Screw, 4.5mm x 20mm	4
AADA45025	Cortical Polyaxial Screw, 4.5mm x 25mm	8
AADA45030	Cortical Polyaxial Screw, 4.5mm x 30mm	8
AADA45035	Cortical Polyaxial Screw, 4.5mm x 35mm	8
AADA45040	Cortical Polyaxial Screw, 4.5mm x 40mm	8
AADA45045	Cortical Polyaxial Screw, 4.5mm x 45mm	8
AADA45050	Cortical Polyaxial Screw, 4.5mm x 50mm	4
AADA50030	Cortical Polyaxial Screw, 5.0mm x 30mm	4
AADA50035	Cortical Polyaxial Screw, 5.0mm x 35mm	8
AADA50040	Cortical Polyaxial Screw, 5.0mm x 40mm	8
AADA50045	Cortical Polyaxial Screw, 5.0mm x 45mm	8
AADA50050	Cortical Polyaxial Screw, 5.0mm x 50mm	8
AADA50055	Cortical Polyaxial Screw, 5.0mm x 55mm	8
AADA55030	Cortical Polyaxial Screw, 5.5mm x 30mm	4
AADA55035	Cortical Polyaxial Screw, 5.5mm x 35mm	8
AADA55040	Cortical Polyaxial Screw, 5.5mm x 40mm	8
AADA55045	Cortical Polyaxial Screw, 5.5mm x 45mm	8
AADA55050	Cortical Polyaxial Screw, 5.5mm x 50mm	8
AADA55055	Cortical Polyaxial Screw, 5.5mm x 55mm	8
AADA55060	Cortical Polyaxial Screw, 5.5mm x 60mm	4
AADA65030	Cortical Polyaxial Screw, 6.5mm x 30mm	4
AADA65035	Cortical Polyaxial Screw, 6.5mm x 35mm	8
AADA65040	Cortical Polyaxial Screw, 6.5mm x 40mm	8
AADA65045	Cortical Polyaxial Screw, 6.5mm x 45mm	8
AADA65050	Cortical Polyaxial Screw, 6.5mm x 50mm	8
AADA65055	Cortical Polyaxial Screw, 6.5mm x 55mm	8
AADA65060	Cortical Polyaxial Screw, 6.5mm x 60mm	4
AAPA75030	Cortical Polyaxial Screw, 7.5mm x 30mm	4
AAPA75035	Cortical Polyaxial Screw, 7.5mm x 35mm	8
AAPA75040	Cortical Polyaxial Screw, 7.5mm x 40mm	8
AAPA75045	Cortical Polyaxial Screw, 7.5mm x 45mm	8
AAPA75050	Cortical Polyaxial Screw, 7.5mm x 50mm	8
AAPA75055	Cortical Polyaxial Screw, 7.5mm x 55mm	8
AAPA75060	Cortical Polyaxial Screw, 7.5mm x 60mm	4
AAPA85030	Cortical Polyaxial Screw, 8.5mm x 30mm	4
AAPA85035	Cortical Polyaxial Screw, 8.5mm x 35mm	4
AAPA85040	Cortical Polyaxial Screw, 8.5mm x 40mm	4
AAPA85045	Cortical Polyaxial Screw, 8.5mm x 45mm	4
AAPA85050	Cortical Polyaxial Screw, 8.5mm x 50mm	4
AAPA85055	Cortical Polyaxial Screw, 8.5mm x 55mm	4
AAPA85060	Cortical Polyaxial Screw, 8.5mm x 60mm	4



OLYMPIC MIS IMPLANT OFFERING

POLYAXIAL SCREWS (FULL CORTICAL)

Part Number	Description	Qty
AAUA45025	Full Cortical Polyaxial Screw, 4.5mm x 25mm	8
AAUA45030	Full Cortical Polyaxial Screw, 4.5mm x 30mm	8
AAUA45035	Full Cortical Polyaxial Screw, 4.5mm x 35mm	8
AAUA45040	Full Cortical Polyaxial Screw, 4.5mm x 40mm	8
AAUA45045	Full Cortical Polyaxial Screw, 4.5mm x 45mm	8
AAUA50025	Full Cortical Polyaxial Screw, 5.0mm x 25mm	8
AAUA50030	Full Cortical Polyaxial Screw, 5.0mm x 30mm	8
AAUA50035	Full Cortical Polyaxial Screw, 5.0mm x 35mm	8
AAUA50040	Full Cortical Polyaxial Screw, 5.0mm x 40mm	8
AAUA50045	Full Cortical Polyaxial Screw, 5.0mm x 45mm	8
AAUA55025	Full Cortical Polyaxial Screw, 5.5mm x 25mm	8
AAUA55030	Full Cortical Polyaxial Screw, 5.5mm x 30mm	8
AAUA55035	Full Cortical Polyaxial Screw, 5.5mm x 35mm	8
AAUA55040	Full Cortical Polyaxial Screw, 5.5mm x 40mm	8
AAUA55045	Full Cortical Polyaxial Screw, 5.5mm x 45mm	8
AAUA60025	Full Cortical Polyaxial Screw, 6.0mm x 25mm	8
AAUA60030	Full Cortical Polyaxial Screw, 6.0mm x 30mm	8
AAUA60035	Full Cortical Polyaxial Screw, 6.0mm x 35mm	8
AAUA60040	Full Cortical Polyaxial Screw, 6.0mm x 40mm	8
AAUA60045	Full Cortical Polyaxial Screw, 6.0mm x 45mm	8

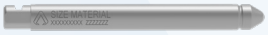
OLYMPIC MIS IMPLANT OFFERING

RODS, STRAIGHT, Ti6Al4VELI, 5.5MM

Part Number	Description	Qty
ACDA55120	5.5mm Rod, MIS, Straight, Ti6Al4VELI, 120mm	4
ACDA55140	5.5mm Rod, MIS, Straight, Ti6Al4VELI, 140mm	4
ACDA55160	5.5mm Rod, MIS, Straight, Ti6Al4VELI, 160mm	4
ACDA55180	5.5mm Rod, MIS, Straight, Ti6Al4VELI, 180mm	4
ACDA55200	5.5mm Rod, MIS, Straight, Ti6Al4VELI, 200mm	4
ACDA55220	5.5mm Rod, MIS, Straight, Ti6Al4VELI, 220mm	4
ACDA55240	5.5mm Rod, MIS, Straight, Ti6Al4VELI, 240mm	4
ACDA55300	5.5mm Rod, MIS, Straight, Ti6Al4VELI, 300mm	4
ACDA55480	5.5mm Rod, MIS, Straight, Ti6Al4VELI, 480mm	4

RODS, STRAIGHT, CoCr, 5.5mm

Part Number	Description	Qty
ACDC55200	5.5mm Rod, MIS, Straight, CoCr, 200mm	4
ACDC55300	5.5mm Rod, MIS, Straight, CoCr, 300mm	4
ACDC55480	5.5mm Rod, MIS, Straight, CoCr, 480mm	4



RODS, STRAIGHT, Ti6Al4VELI, 6.0MM

Part Number	Description	Qty
ACDA60120	6.0mm Rod, MIS, Straight, Ti6Al4VELI, 120mm	4 / OPT
ACDA60140	6.0mm Rod, MIS, Straight, Ti6Al4VELI, 140mm	4 / OPT
ACDA60160	6.0mm Rod, MIS, Straight, Ti6Al4VELI, 160mm	4 / OPT
ACDA60180	6.0mm Rod, MIS, Straight, Ti6Al4VELI, 180mm	4 / OPT
ACDA60200	6.0mm Rod, MIS, Straight, Ti6Al4VELI, 200mm	4 / OPT
ACDA60220	6.0mm Rod, MIS, Straight, Ti6Al4VELI, 220mm	4 / OPT
ACDA60240	6.0mm Rod, MIS, Straight, Ti6Al4VELI, 240mm	4 / OPT
ACDA60300	6.0mm Rod, MIS, Straight, Ti6Al4VELI, 300mm	4 / OPT
ACDA60480	6.0mm Rod, MIS, Straight, Ti6Al4VELI, 480mm	4 / OPT

RODS, STRAIGHT, CoCr, 6.0mm

Part Number	Description	Qty
ACDC60200	6.0mm Rod, MIS, Straight, CoCr, 200mm	4 / OPT
ACDC60300	6.0mm Rod, MIS, Straight, CoCr, 300mm	4 / OPT
ACDC60480	6.0mm Rod, MIS, Straight, CoCr, 480mm	4 / OPT

RODS, LORDOTIC, TiCP, 5.5mm

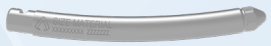
Part Number	Description	Qty
ACJB55030	5.5mm Rod, MIS, Lordotic, TiCP, 30mm	2
ACJB55035	5.5mm Rod, MIS, Lordotic, TiCP, 35mm	4
ACJB55040	5.5mm Rod, MIS, Lordotic, TiCP, 40mm	4
ACJB55045	5.5mm Rod, MIS, Lordotic, TiCP, 45mm	4
ACJB55050	5.5mm Rod, MIS, Lordotic, TiCP, 50mm	4
ACJB55055	5.5mm Rod, MIS, Lordotic, TiCP, 55mm	4
ACJB55060	5.5mm Rod, MIS, Lordotic, TiCP, 60mm	4
ACJB55065	5.5mm Rod, MIS, Lordotic, TiCP, 65mm	4
ACJB55070	5.5mm Rod, MIS, Lordotic, TiCP, 70mm	4
ACJB55075	5.5mm Rod, MIS, Lordotic, TiCP, 75mm	4
ACJB55080	5.5mm Rod, MIS, Lordotic, TiCP, 80mm	4
ACJB55085	5.5mm Rod, MIS, Lordotic, TiCP, 85mm	2
ACJB55090	5.5mm Rod, MIS, Lordotic, TiCP, 90mm	2
ACJB55095	5.5mm Rod, MIS, Lordotic, TiCP, 95mm	2

RODS, LORDOTIC, TiCP, 6.0MM

Part Number	Description	Qty
ACJB60030	6.0mm Rod, MIS, Lordotic, TiCP, 30mm	2 / OPT
ACJB60035	6.0mm Rod, MIS, Lordotic, TiCP, 35mm	4 / OPT
ACJB60040	6.0mm Rod, MIS, Lordotic, TiCP, 40mm	4 / OPT
ACJB60045	6.0mm Rod, MIS, Lordotic, TiCP, 45mm	4 / OPT
ACJB60050	6.0mm Rod, MIS, Lordotic, TiCP, 50mm	4 / OPT
ACJB60055	6.0mm Rod, MIS, Lordotic, TiCP, 55mm	4 / OPT
ACJB60060	6.0mm Rod, MIS, Lordotic, TiCP, 60mm	4 / OPT
ACJB60065	6.0mm Rod, MIS, Lordotic, TiCP, 65mm	4 / OPT
ACJB60070	6.0mm Rod, MIS, Lordotic, TiCP, 70mm	4 / OPT
ACJB60075	6.0mm Rod, MIS, Lordotic, TiCP, 75mm	4 / OPT
ACJB60080	6.0mm Rod, MIS, Lordotic, TiCP, 80mm	4 / OPT
ACJB60085	6.0mm Rod, MIS, Lordotic, TiCP, 85mm	2 / OPT
ACJB60090	6.0mm Rod, MIS, Lordotic, TiCP, 90mm	2 / OPT
ACJB60095	6.0mm Rod, MIS, Lordotic, TiCP, 95mm	2 / OPT
ACJB60100	6.0mm Rod, MIS, Lordotic, TiCP, 100mm	2 / OPT
ACJB60110	6.0mm Rod, MIS, Lordotic, TiCP, 110mm	2 / OPT
ACJB60120	6.0mm Rod, MIS, Lordotic, TiCP, 120mm	2 / OPT

RODS, LORDOTIC, CoCr, 5.5MM

Part Number	Description	Qty
ACJC55030	5.5mm Rod, MIS, Lordotic, CoCr, 30mm	2 / OPT
ACJC55035	5.5mm Rod, MIS, Lordotic, CoCr, 35mm	4 / OPT
ACJC55040	5.5mm Rod, MIS, Lordotic, CoCr, 40mm	4 / OPT
ACJC55045	5.5mm Rod, MIS, Lordotic, CoCr, 45mm	4 / OPT
ACJC55050	5.5mm Rod, MIS, Lordotic, CoCr, 50mm	4 / OPT
ACJC55055	5.5mm Rod, MIS, Lordotic, CoCr, 55mm	4 / OPT
ACJC55060	5.5mm Rod, MIS, Lordotic, CoCr, 60mm	4 / OPT
ACJC55065	5.5mm Rod, MIS, Lordotic, CoCr, 65mm	4 / OPT
ACJC55070	5.5mm Rod, MIS, Lordotic, CoCr, 70mm	4 / OPT
ACJC55075	5.5mm Rod, MIS, Lordotic, CoCr, 75mm	4 / OPT
ACJC55080	5.5mm Rod, MIS, Lordotic, CoCr, 80mm	4 / OPT
ACJC55085	5.5mm Rod, MIS, Lordotic, CoCr, 85mm	2 / OPT
ACJC55090	5.5mm Rod, MIS, Lordotic, CoCr, 90mm	2 / OPT
ACJC55095	5.5mm Rod, MIS, Lordotic, CoCr, 95mm	2 / OPT
ACJC55100	5.5mm Rod, MIS, Lordotic, CoCr, 100mm	2 / OPT
ACJC55110	5.5mm Rod, MIS, Lordotic, CoCr, 110mm	2 / OPT
ACJC55120	5.5mm Rod, MIS, Lordotic, CoCr, 120mm	2 / OPT



OLYMPIC MIS IMPLANT OFFERING

RODS, LORDOTIC, CoCr, 6.0MM

Part Number	Description	Qty
ACJC60030	6.0mm Rod, MIS, Lordotic, CoCr, 30mm	2 / OPT
ACJC60035	6.0mm Rod, MIS, Lordotic, CoCr, 35mm	4 / OPT
ACJC60040	6.0mm Rod, MIS, Lordotic, CoCr, 40mm	4 / OPT
ACJC60045	6.0mm Rod, MIS, Lordotic, CoCr, 45mm	4 / OPT
ACJC60050	6.0mm Rod, MIS, Lordotic, CoCr, 50mm	4 / OPT
ACJC60055	6.0mm Rod, MIS, Lordotic, CoCr, 55mm	4 / OPT
ACJC60060	6.0mm Rod, MIS, Lordotic, CoCr, 60mm	4 / OPT
ACJC60065	6.0mm Rod, MIS, Lordotic, CoCr, 65mm	4 / OPT
ACJC60070	6.0mm Rod, MIS, Lordotic, CoCr, 70mm	4 / OPT
ACJC60075	6.0mm Rod, MIS, Lordotic, CoCr, 75mm	4 / OPT
ACJC60080	6.0mm Rod, MIS, Lordotic, CoCr, 80mm	4 / OPT
ACJC60085	6.0mm Rod, MIS, Lordotic, CoCr, 85mm	2 / OPT
ACJC60090	6.0mm Rod, MIS, Lordotic, CoCr, 90mm	2 / OPT
ACJC60095	6.0mm Rod, MIS, Lordotic, CoCr, 95mm	2 / OPT
ACJC60100	6.0mm Rod, MIS, Lordotic, CoCr, 100mm	2 / OPT
ACJC60110	6.0mm Rod, MIS, Lordotic, CoCr, 110mm	2 / OPT
ACJC60120	6.0mm Rod, MIS, Lordotic, CoCr, 120mm	2 / OPT

RODS, KYPHOTIC, TiCP, 5.5MM

Part Number	Description	Qty
ACKB55040	5.5mm Rod, MIS, Kyphotic, TiCP, 40mm	4 / OPT
ACKB55050	5.5mm Rod, MIS, Kyphotic, TiCP, 50mm	4 / OPT
ACKB55060	5.5mm Rod, MIS, Kyphotic, TiCP, 60mm	4 / OPT
ACKB55070	5.5mm Rod, MIS, Kyphotic, TiCP, 70mm	4 / OPT
ACKB55080	5.5mm Rod, MIS, Kyphotic, TiCP, 80mm	4 / OPT
ACKB55090	5.5mm Rod, MIS, Kyphotic, TiCP, 90mm	4 / OPT
ACKB55100	5.5mm Rod, MIS, Kyphotic, TiCP, 100mm	4 / OPT
ACKB55110	5.5mm Rod, MIS, Kyphotic, TiCP, 110mm	4 / OPT
ACKB55120	5.5mm Rod, MIS, Kyphotic, TiCP, 120mm	4 / OPT
ACKB55150	5.5mm Rod, MIS, Kyphotic, TiCP, 150mm	4 / OPT
ACKB55200	5.5mm Rod, MIS, Kyphotic, TiCP, 200mm	4 / OPT
ACKB55300	5.5mm Rod, MIS, Kyphotic, TiCP, 300mm	4 / OPT

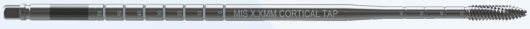
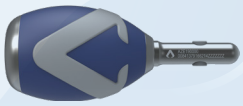
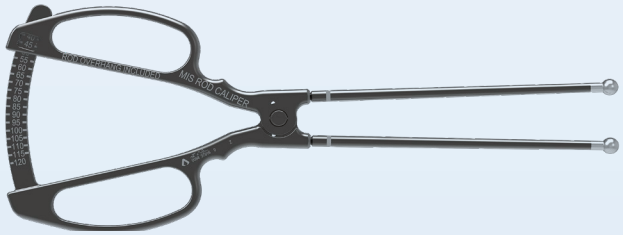
RODS, KYPHOTIC, TiCP, 6.0MM

Part Number	Description	Qty
ACKB60040	6.0mm Rod, MIS, Kyphotic, TiCP, 40mm	4 / OPT
ACKB60050	6.0mm Rod, MIS, Kyphotic, TiCP, 50mm	4 / OPT
ACKB60060	6.0mm Rod, MIS, Kyphotic, TiCP, 60mm	4 / OPT
ACKB60070	6.0mm Rod, MIS, Kyphotic, TiCP, 70mm	4 / OPT
ACKB60080	6.0mm Rod, MIS, Kyphotic, TiCP, 80mm	4 / OPT
ACKB60090	6.0mm Rod, MIS, Kyphotic, TiCP, 90mm	4 / OPT
ACKB60100	6.0mm Rod, MIS, Kyphotic, TiCP, 100mm	4 / OPT
ACKB60110	6.0mm Rod, MIS, Kyphotic, TiCP, 110mm	4 / OPT
ACKB60120	6.0mm Rod, MIS, Kyphotic, TiCP, 120mm	4 / OPT
ACKB60150	6.0mm Rod, MIS, Kyphotic, TiCP, 150mm	4 / OPT
ACKB60200	6.0mm Rod, MIS, Kyphotic, TiCP, 200mm	4 / OPT
ACKB60300	6.0mm Rod, MIS, Kyphotic, TiCP, 300mm	4 / OPT

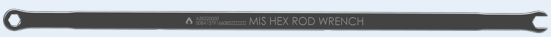
OLYMPIC MIS INSTRUMENT OFFERING

Part Number	Description	Qty	
EAECDABEZ	Ratcheting Axial Handle , 1/4" Sq. MIS Stylet Attachment Back Cap	2	
EBECDZBBZ	T-Handle, Ratchet, 1/4" Sq. Secure Shaft, Cannulated	2	
EDECDTBBZ	Egg, Ratchet, 1/4" Sq. Secure Shaft, Cannulated	1	
RAN-815NRT-BEV	Targeting Needle	1	
AZA025500	Guide Wire, Blunt Tip, 1.4mm x 500mm, Nitinol	OPT	
AZE030000	MIS Targeting Needle Holder	1	
AZE100000	MIS Fascial Blade, Handle	1	
AZE100000-02	MIS Fascial Blade Tip	2	

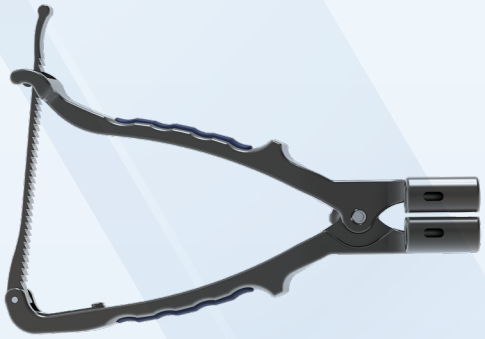
OLYMPIC MIS INSTRUMENT OFFERING

Part Number	Description	Qty	
AZE110001	MIS Dilator 1	1	
AZE110002	MIS Dilator 2	1	
AZE110003	MIS Dilator 3	1	
AZE120045	MIS Cortical Bone Tap, 4.5mm	1	
AZE120055	MIS Cortical Bone Tap, 5.5mm	1	
AZE120065	MIS Cortical Bone Tap, 6.5mm	1	
AZE120075	MIS Cortical Bone Tap, 7.5mm	1	
AZE120085	MIS Cortical Bone Tap, 8.5mm	1	
AZE120095	MIS Cortical Bone Tap, 9.5mm	1	
AZE160000	MIS Screwdriver, T25	2	
AZE170000	MIS Screw Height Adjuster, T25	1	
AZE080000	MIS Guide Wire Gripper	1	
AZE190000	MIS Screw Head Manipulator	1	
AZE200000	MIS Rod Caliper	1	

OLYMPIC MIS INSTRUMENT OFFERING

Part Number	Description	Qty	
AZA027000	Rod Bender	1	
AZE210000	MIS Curved Tissue Dissector	1	
AZE250000	MIS Rod Inserter, Right Angle	1	
AZE260000	MIS Rod Inserter, Percutaneous	1	
AZE240000	MIS Kerrison Rod Inserter	1	
AZE220000	MIS Hex Rod Wrench	1	
AZE310000	MIS Set Screw Inserter, T30	2	

OLYMPIC MIS INSTRUMENT OFFERING

Part Number	Description	Qty	
AZE290000	MIS Sequential Reducer	4	
AZE280000	MIS Reducer Driver	1	
AZE330000	MIS Hinged Compressor	1	
AZE330001	MIS Hinged Distractor	1	
AZE380000	MIS Hinged Compressor / Distractor Support Tube	4	
AZE340000	MIS Multi-Level Compressor / Distractor	2	
AZE340010	MIS Multi-Level Driver	1	
ECXCGAAZX	100 In-lb Torque-Limiting Offset T-Handle, 1/4" Sq.	1	

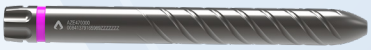
OLYMPIC MIS INSTRUMENT OFFERING

Part Number	Description	Qty
AZE370000	MIS Set Screw Torque Shaft, T30	2
AZE350000	MIS Counter Torque	1
AZE360000	MIS Long Counter Torque	1
AZE230000	MIS Extended Tab Divider	1
AZE400010	MIS Docking Tab Breaker	1
AZE410010	MIS Threaded Tower Attachment Guide	1
AZE410000	MIS Stick Fit Tower Attachment Guide, T30	2
AZE150000	MIS Tower Assembly Tool	1
AZE140000	MIS Screw Tower	8
AZE390000	MIS Tower Remover	1
AZE390010	MIS Tower Remover Threaded Ram	1

OPTIONAL INSTRUMENT OFFERING

Part Number	Description	Qty
AZA026500	Guide Wire, Sharp Tip, 1.4mm x 500mm, Nitinol	10 / OPT
AZE040500	Guide Wire, Blunt Tip, 1.4mm x 500mm, Stainless Steel	10 / OPT
AZA025650	Guide Wire, Blunt Tip, 1.4mm x 650mm, Nitinol	10 / OPT
AZA026650	Guide Wire, Sharp Tip, 1.4mm X 650mm, Nitinol	10 / OPT
EJZCMBBZZ	External 1/4" Sq. w/Trinkle	1 / OPT
AZA060045	Navigated, Cannulated, Cortical Bone Tap, 4.5mm	1 / OPT
AZA060055	Navigated, Cannulated, Cortical Bone Tap, 5.5mm	1 / OPT
AZA060065	Navigated, Cannulated, Cortical Bone Tap, 6.5mm	1 / OPT
AZA060075	Navigated, Cannulated, Cortical Bone Tap, 7.5mm	1 / OPT
AZA060085	Navigated, Cannulated, Cortical Bone Tap, 8.5mm	1 / OPT
AZA060095	Navigated, Cannulated, Cortical Bone Tap, 9.5mm	1 / OPT
AZE430000	MIS Navigated Screwdriver, T25	2 / OPT
AZE5700000	MIS Navigated Iliac Screwdriver, T27	1 / OPT
AZE5600000	MIS Iliac Screwdriver, T27	1 / OPT
AZE5800000	MIS Iliac Screw Height Adjuster, T27	1 / OPT
AZE320000	MIS Compressor / Distractor Fulcrum	2 / OPT
AZE400000	MIS Tab Breaker	1 / OPT
AZE400020	MIS TAB BREAKER COUNTER TORQUE	1

AWL-TAP INSTRUMENT OFFERING

Part Number	Description	Qty	
AZE45000	MIS Awl-Tap, Beveled Tip	4	
AZE450001	MIS Awl-Tap, Diamond Tip	4/OPT	
AZE460000	MIS Awl-Tap Handle	1	
AZE500000	MIS Wireless Fascial Blade	1	
AZE500000-02	MIS Wireless Fascial Blade Tip	2	
AZE520000	MIS Wireless Fascial Blade Handle	1	
AZE470000	MIS Wireless Dilator 1	1	
AZE480000	MIS Wireless Dilator 2	1	
AZE490000	MIS Wireless Dilator 2 Handle	1	

WIRELESS INSTRUMENT OFFERING

Part Number	Description	Qty	
EAECDABEZ	Ratcheting Axial Handle, 1/4" Sq. MIS Stylet Attachment Back Cap	1	
AZE160000	MIS Screwdriver, T25	2	
AZE090000	MIS Screwdriver Stylet Shuttle	2	
AZE090001	MIS Screwdriver Stylet, Nitinol	8	
AZE090003	MIS Navigated Screwdriver Stylet, Nitinol	8	

SCREW TOWER INSTRUMENT OFFERING

Part Number	Description	Qty	
AZE110001	MIS Dilator 1	1	
AZE530002	MIS Tower Dilator 2	2	
AZE530003	MIS Tower Dilator 3	1	
AZE150000	MIS Tower Assembly Tool	1	
AZE140000	MIS Screw Tower	8	
EAECDABEZ	Ratcheting Axial Handle , 1/4" Sq. MIS Stylet Attachment Back Cap	1	
AZE550000	MIS Tower Screwdriver, T25	2	
AZE440000	MIS Navigated Tower Screwdriver, T25	2 / OPT	
AZE540000	MIS Sequential Tower Reducer	4	
AZE280000	MIS Reducer Driver	1	
AZE390000	MIS Tower Remover	1	
AZE390010	MIS Tower Remover Threaded Ram	1	

OLYMPIC MIS
MINIMALLY INVASIVE SPINAL FIXATION SYSTEM

INSTRUCTIONS FOR USE

1.0 IMPORTANT NOTE TO OPERATING SURGEON: OLYMPIC Posterior Spinal Fixation System spinal implants, like any other temporary internal fixation devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions to their activities in the postoperative period and to examine patients postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed. Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used, if a pseudarthrosis develops, or if patients have severe or multiple preoperative curves.The surgeon may remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

2.0 DESCRIPTION: The OLYMPIC Posterior Spinal Fixation System is a top loading thoracolumbar, sacral, and iliac fixation system designed to provide fixation during the fusion process. The system is composed of preassembled polyaxial screws, monoaxial screws, rods, cross connectors, and rod connectors. The system is supported by a comprehensive set of instruments to install the implants within the system. All implant components are manufactured from the materials listed in the table below.

TiCP	ASTM F67
CoCr	ASTM F1537
Ti-6Al-4V ELI	ASTM F136
Elgiloy	ASTM F1058
Nitinol #1	ASTM F2063

The NAVIGATED INSTRUMENT SYSTEM is comprised of nonsterile, reusable instruments including taps and drivers that can be operated manually. These instruments are intended to be used with the Medtronic StealthStation® System (v 2.1.0) and are manufactured from stainless steel, as specified in ASTM F899.

3.0 CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of a physician. All implants are intended for single use only. The OLYMPIC Posterior Spinal Fixation System must not be reused under any circumstances. These instructions for use are designed to assist in use of the OLYMPIC Posterior Spinal Fixation System and are not a reference for surgical techniques.

4.0 INDICATIONS: The Olympic Posterior Spinal Fixation System is intended for immobilization and stabilization of the posterior, non-cervical spine in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudoarthrosis, and/or failed previous fusion. When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Olympic Posterior Spinal Fixation System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Olympic Posterior Spinal Fixation System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach. The OLYMPIC NAVIGATED INSTRUMENTS are intended to be used in the preparation and placement of OLYMPIC PSFS screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy. Refer to the Astura Navigated Instrument system Instructions For Use (INS-00006) regarding the use of these instruments.

5.0 CONTRAINDICATIONS: Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system. Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contraindication. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure. See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES section of this insert.

6.0 POSSIBLE ADVERSE EVENTS

6.1 Bending or fracture of implant.
6.2 Loosening of the implant.
6.3 Metal sensitivity, or allergic reaction to a foreign body.
6.4 Infection, early or late.
6.5 Nonunion, delayed union.
6.6 Decrease in bone density due to stress shielding.
6.7 Pain, discomfort, or abnormal sensations due to the presence of the device.
6.8 Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
6.9 Bursitis.
6.10 Paralysis.
6.11 Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
6.12 Death.
6.13 Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malposition implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
6.14 Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.
6.15 Damage to lymphatic vessels and/or lymphatic fluid exudation.
6.16 Spinal cord impingement or damage.
6.17 Fracture of bony structures.
6.18 Degenerative changes or instability in segments adjacent to fused vertebral levels.
6.19 Pediatric specific:
6.19.1 Pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at an increased risk for device-related injury because of their small stature.

7.0 WARNINGS AND PRECAUTIONS: Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

7.1 Warnings

7.1.1 The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).
The safety and effectiveness of these devices for any other conditions are unknown.

7.1.2 The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

7.1.3 Correct Selection of The Implant Is Extremely Important: The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

7.1.4 Implants Can Break When Subjected to The Increased Loading Associated with Delayed Union or Nonunion: Internal fixation appliances are load-sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

7.1.5 Mixing Metals Can Cause Corrosion: There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerates the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, etc., which come into contact with other metal objects, must be made from like or compatible metals.

7.1.6 PATIENT SELECTION: In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

7.1.6.1 The patient's weight: An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.

7.1.6.2 The patient's occupation or activity: If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

7.1.6. A condition of senility, mental illness, alcoholism, or drug abuse: These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

7.1.6.4 Foreign body sensitivity: The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

7.1.6.5 Smoking: Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

7.1.7 MRI Safety Information: The OLYMPIC Posterior Spinal Fixation System has not been evaluated for safety and compatibility in the MR environment. The OLYMPIC Posterior Spinal Fixation System has not been tested for heating, migration, or image artifact in the MR environment. The safety of OLYMPIC Posterior Spinal Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

7.2 **Precautions**

7.2.1 The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants. Postoperative care is extremely important. The patient must be instructed in the limitations of the metallic implant and be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device. Refer to the individual system surgical technique manuals for additional important information. A surgical technique can be obtained from the local representative or ASTURA MEDICAL.

INSTRUCTIONS FOR USE

7.2.2 During the surgical procedure, the rods may be cut to size and shaped to provide correction and maintain proper anatomic lordotic and kyphotic alignment.

7.2.3 After solid fusion occurs, these devices serve no functional purpose and may be removed. In some cases, removal is indicated because the implants are not intended to transfer or to support forces developed during normal activities. Any decision to remove the device must be made by the physician and the patient taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

7.2.4 These devices are not intended or expected to be the only mechanism for support of the spine. Regardless of the etiology of the spinal pathology, for which implantation of these devices was chosen, it is the expectation and requirement that a spinal fusion or arthrodesis be planned and obtained. Without solid biological support provided by spinal fusion, the devices cannot be expected to support the spine indefinitely and will fail in any of several modes. These modes may include bone-metal interface failure, implant fracture, or bone failure.

7.2.5 Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.

7.2.6 Surgical Implants Must Never Be Reused: An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

7.2.7 Correct Handling of The Implant Is Extremely Important: Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.

7.2.8 Considerations For Removal Of The Implant After Healing: If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

7.2.9 Adequately Instruct The Patient: Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

7.3 **Pediatric Warnings and Precautions**

7.3.1 Special precautions are needed during pediatric use. Care should be taken when using instruments in pediatric patients, since these patients can be more susceptible to the stresses involved in their use.

7.3.2 The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of a smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw mal positioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedure may have a reduced longitudinal spinal growth, or may be at a risk for rotational spinal deformities due to continued differential growth of the anterior spine.

7.3.3 The implantation of the OLYMPIC Posterior Spinal Fixation System in pediatric patients should be peformed only by experienced spinal surgeons with specific training in the use of this system in pediatric patients.

7.3.4 Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection of placement of the implants are important considerations in the successful utilization of the system in pediatric patients.

7.3.5 The selection of proper size, shape, and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

8.0 PREOPERATIVE

8.1 Only patients that meet the criteria described in the indications should be selected.

8.2 Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.

8.3 Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.

8.4 The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

8.5 The surgeon must ensure that all necessary implants and instruments are available and on hand prior to surgery.

8.6 Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The OLYMPIC Posterior Spinal Fixation System components are not to be combined with the components from another manufacturer.

8.7 All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

8.8 All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to all surgeries.

8.9 A surgical technique manual may be obtained from ASTURA MEDICAL or from any of its representatives.

9.0 INTRAOPERATIVE

9.1 Any instruction manuals should be carefully followed.

9.2 At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.

9.3 The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.

9.4 Autogenous bone grafts must be placed in the area to be fused and the graft should be extended from the upper to the lower vertebrae to be fused.

9.5 Bone cement should never be used with this device since this material will make removal of the components difficult or impossible and may affect the properties of the implant. The heat generated from the curing process may also cause neurological damage and bone necrosis.

9.6 Before closing the soft tissues, all of the devices should be securely seated.

9.7 Breakage, slippage, or misuse of the instruments or implant components may cause injury to the patient or the operative personnel.

10.0 POSTOPERATIVE:

10.1 Until X-rays confirm the maturation of the fusion mass, external immobilization (such as bracing or casting) is recommended. Instructions to the patient to reduce stress on the implants are an equally important part of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure.

10.2 Detailed instructions on the use and limitations of the device should be given to the patient. The risk of fatigue and/or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.

10.3 To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.

10.4 The patient should be advised of their inability to bend at the point of spinal fusion and taught to compen sate for this permanent physical restriction in body motion.

10.5 If a non-union develops or if the components loosen and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.

10.6 Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of initial implant removal.

10.7 Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the retrieved OLYMPIC Posterior Spinal Fixation System components should ever be reused under any circumstances.

11.0 **PACKAGING:** Packages for each of the components should be intact upon receipt. All sets and compnents should be carefully checked for completeness and lack of damage prior to use. Damaged packages or products should not be used, and should be returned immediately to ASTURA MEDICAL.

12.0 **CLEANING AND DECONTAMINATION:** Instruments are supplied clean and NOT STERILE, and must be sterilized prior to use.

13.0 CLEANING: All instruments must first be cleaned before sterilization and introduction into a sterile surgical field. Reference LIT-00005 for disassembly and reassembly instructions. Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment. An enzymatic cleaner bath (soak) or a solution of water and neutral pH detergent are effective in removing organic material from instruments. Use distilled water if possible. Instruments should be fully submerged for at least ten (10) minutes. Instruments must be thoroughly cleaned. Be sure dissimilar metal instruments are separated. Confirm that all cannulated and modular instruments are fully disassembled. Ensure that all cannulas are flushed until cleaning solution runs clear and that all instruments are completely immersed. Use a small brush to remove soil from all surfaces of the instrument while fully immersed in the solution. Remove soil from hinges, jaws, tips, box locks, and ratchets. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments. Once instruments are cleaned and disassembled, place instruments in an ultrasonic cleaner with warm enzymatic detergent for a minimum of fifteen (15) minutes. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Rinse instruments under running water for at least one (1) minute to remove solutions. Instruments should never be exposed to cleaning agents containing any peroxides. Users should periodically inspect instruments for corrosion, discoloration, etc., and properly dispose of instruments that show signs of wear and tear.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

14.0 STERILIZATION: Moist heat sterilization is recommended using the Association for the Advancement of Medical Instrumentation (AAMI) guideline ST79:2006 according to the following validated cycle parameters for both implants and instruments:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre Vacuum	270°F(132°C)	4 minutes	30 minutes

Wrap tray with a towel placed between tray and FDA cleared wrap. The Sterility Assurance Level (SAL) is 1 x 10-6, via the indicated methods. No claims of pyrogenicity are made. Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. Always immediately re-sterilize all implants and instruments used in surgery. This process must be performed before handling or returning to ASTURA MEDICAL. It is the end user's responsibility to use only sterilizers and sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications.

15.0 PRODUCT COMPLAINTS: Any Health Care Professional, who has any complaints or who has experienced any dissatisfaction relating to the product quality, durability, reliability, safety, effectiveness and/or performance, should notify ASTURA MEDICAL or its representative. Further, if any of the implanted OLYMPIC Posterior Spinal Fixation System component(s) ever malfunctions, ASTURA MEDICAL or its representative must be notified immediately. If any OLYMPIC Posterior Spinal Fixation System product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor or ASTURA MEDICAL must be notified immediately by telephone, fax or in writing. For all complaints, please include the device name, reference number, and lot number of the component(s), your name, address, and the nature of the event to help ASTURA MEDICAL understand the cause of the complaint. If further information is needed or required, please contact using the company information listed below.

16.0 COMPANY INFORMATION

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