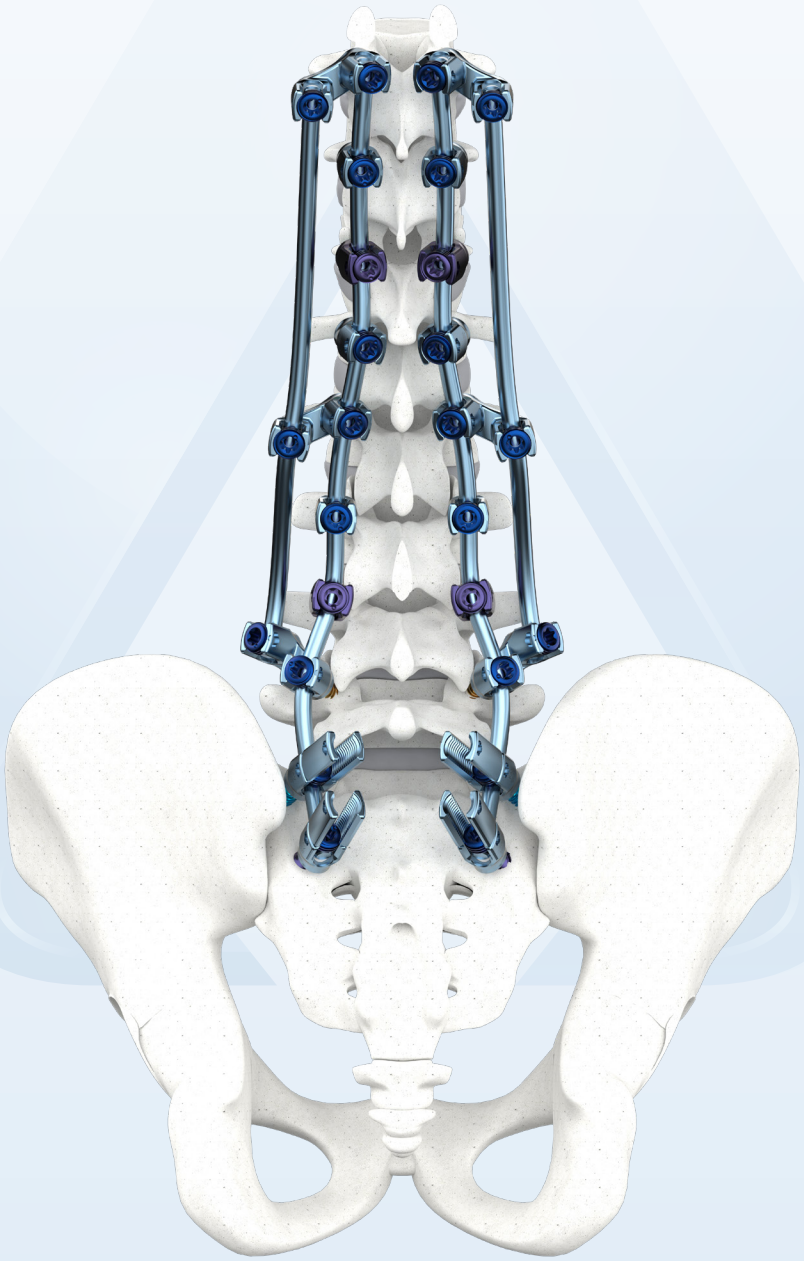
MASADA

MODULAR POSTERIOR SPINAL FIXATION SYSTEM

ASTURA MEDICAL

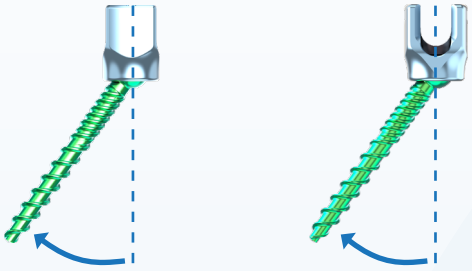
DESIGN RATIONALE

The Masada Modular Posterior Spinal Fixation System is a comprehensive fixation platform that provides a complete range of modular fixation configurations for maximum intraoperative flexibility. Its wide array of tulip heads, screws, and rod options deliver streamlined versatility to address numerous variations of complex pathologies from single-level procedures to multi-level fusions. The modular tulip heads can be connected in-situ or prior to insertion for easy screw-to-screw distraction and improved intraoperative visibility.

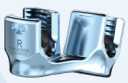


SPECIFICATIONS

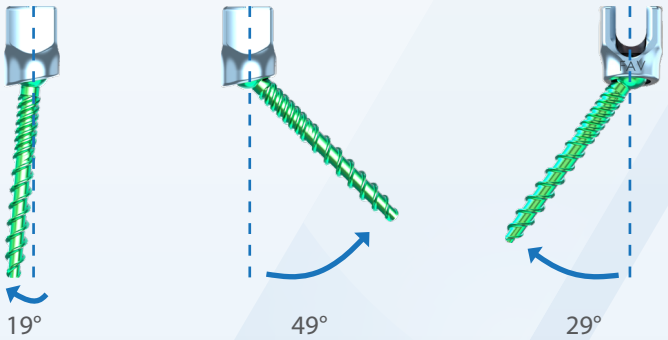
Polyaxial



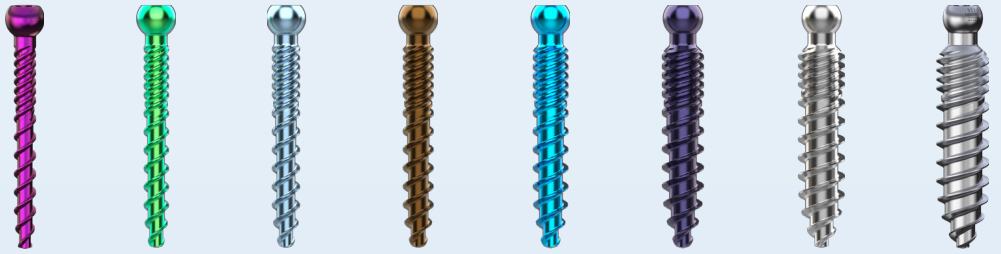
Friction Fit Tulip

TULIPS			
Type	Polyaxial	Favored Angle M/L	Favored Angle C/C
Standard			
High Top			
High Strength			
Dual Head			

Favored Angle C/C



Favored Angle M/L



SPECIFICATIONS

RODS

5.5MM TICP GR4 RODS

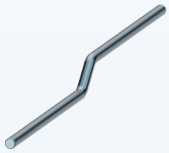
Straight

Lordotic

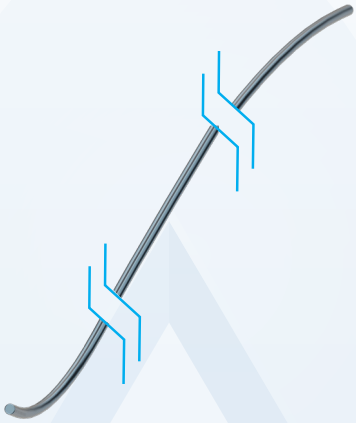
6.0MM TICP GR4 RODS

Straight

Lordotic



Z Rod

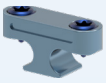


Scoliosis Rod

Hex Rod

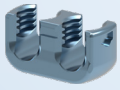
ROD CONNECTORS

OFFSET



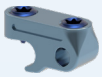
Side Loading / Side Loading

Closed



Top Loading / Top Loading

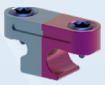
Top Loading / Side Loading



Side Loading/ Closed

INLINE

TRANSITION



EXTENSIONS

LATERAL

Closed

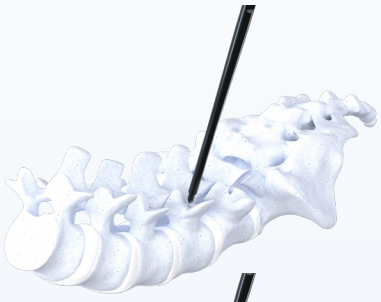
Top Loading

Side Loading

CROSS CONNECTORS

1.0 EXPOSURE

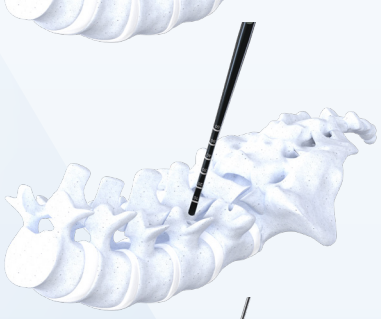
1.1 Identify the affected level using a combination of palpation and fluoroscopy. Using a Midline Approach, incise the skin to the fascial layer. Incise the fascia and use blunt dissection to retract the muscle away from the posterior elements.



2.0 PEDICLE PREPARATION

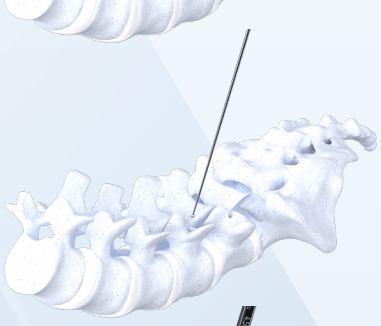
2.1 Create a pilot hole in the pedicle at the junction of the transverse and superior articular processes using the Lumbar Pedicle Awl (AZA001000).

2.2 If in the lumbar spine, use the Lumbar Pedicle Probe (Straight – AZA002001 or Curved – AZA002002) to complete the cannulation of the pedicle.



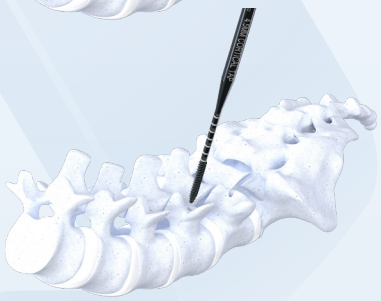
2.3 If in the thoracic spine, use the Thoracic Pedicle Probe (Straight – AZA003001 or Curved – AZA003002).

2.4 Use the Ball Tip Probe (AZA004000) to palpate the pedicle wall to ensure its integrity.

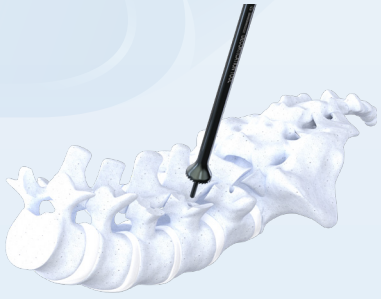


2.5 Select the correct size Bone Tap (AZA059XXX) for the screw to be used and attach to one of the Ratcheting Handles (EAECNZBBZ, EBECNZBBZ or EDECNZBBZ).

2.6 Insert the Bone Tap into the pilot hole and rotate clockwise until the desired tapping depth has been achieved. The Bone Tap has depth-indicating rings that may be used to aid in achieving the correct depth and screw length.



2.7 To ensure optimal clearance for Tulip attachment, use the Decortication Tool (NZA001000) to remove bone that is adjacent to the screw shank.



3.0 SCREW DRIVER AND SCREW ASSEMBLY / DISASSEMBLY

3.1 Assemble a Ratchet Handle (EAECNZBBZ, EBECNZBBZ or EDECNZBBZ) and the Screw Shank Driver (NZA003000) by inserting the proximal end of the Screw Shank Driver 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 Screw Shank Driver shaft is fully secured to the handle when the small groove reaches the distal end of the handle.

3.2 The screw can be assembled to the Screw Shank Driver when the knob is unthreaded counterclockwise, opening the collet tip.

3.3 Insert the appropriate screw into the Screw Shank Driver and thread the knob clockwise to capture the screw with the collet tip.

3.4 If pre-assembling screws, assemble a Ratchet Handle (EAECNZBBZ, EBECNZBBZ or EDECNZBBZ) and the Screw Driver (NZA002000) or High Top Screw Driver (NZA002002) by inserting the proximal end of the Screw Driver 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 Screw Driver shaft is fully secured to the handle when the small groove reaches the distal end of the handle.

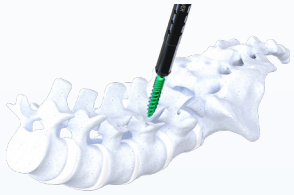
3.5 The pedicle screw can be assembled to the Screw Driver in the LOCKED or UNLOCKED position.

3.6 Attach the appropriate pedicle screw onto the Screw Driver by inserting the distal end of the Screw Driver into the screw and thread the grip clockwise to engage the Screw Driver thread into the head of the screw.

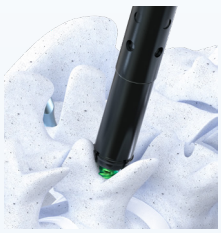
3.7 Set the screw driver to the LOCKED position and ensure the ratcheting handle is set in the FORWARD position.

4.0 SCREW INSERTION AND DISTRACTION

4.1 Insert the screw shank into the pilot hole and rotate clockwise until the desired depth is achieved.



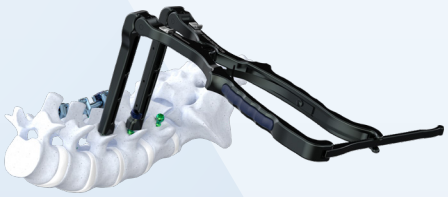
4.1.1 Distal end (collet end) of Screw Shank Driver (NZA003000) can be used as a depth stop to allow minimal Screw Shank Height while maintaining tulip clearance.



4.2 To disassemble the Screw Shank Driver from the screw shank, unthread the knob in a counterclockwise direction until the collet tip is released. Lightly pull upwards to disengage.

4.3 If pre-assembling screws , to disassemble the Screw Driver from the screw, set the Screw Driver to the UNLOCKED position and unthread the grip in a counter clockwise direction to disengage the Screw Driver thread from the head of the screw. Pull upward to remove Screw Driver from pedicle screw.

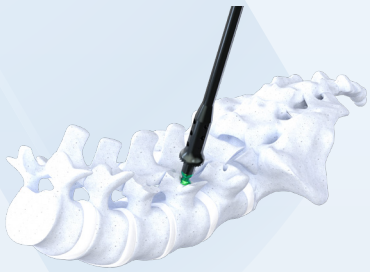
4.4 Distraction can be achieved using the screw shanks prior to Tulip attachment, to accommodate interbody fusion procedures



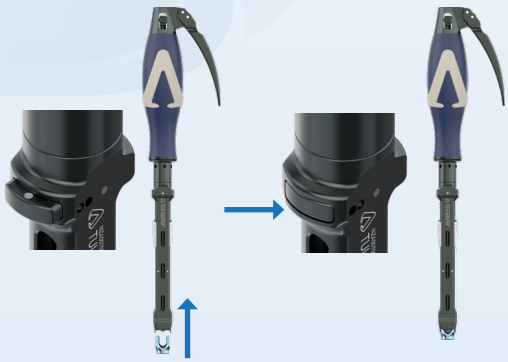
4.4.1 To distract off screw heads, place the distal tips of the Screw Shank Distractor (NZA005000) over the screw heads. Compress the distractor handles to distract. The hinge on the distractor legs can be adjusted to pivot away from the patient for optimal visualization.

5.0 TULIP PREPERATION AND INSERTION

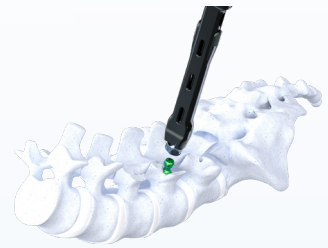
5.1 To ensure optimal clearance for Tulip attachment following screw placement, use the Screw Head Decortication Tool (NZA001001) to remove bone that is adjacent to the screw shank by placing the distal portion of the instrument onto the screw and applying downward force while rotating clockwise.

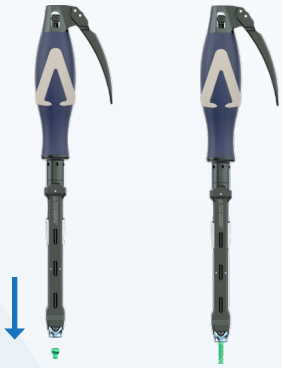


5.2 Insert the appropriate Tulip into the Tulip Inserter (NZA007000) or High-Top Tulip Inserter (NZA007001) and snap it into place using the spring-loaded clip. The Tulip Inserter will automatically lock onto the Tulip. Make sure the locking confirmation button is pressed in prior to use



5.3 Align Tulip over top of Screw Shank and apply downward force until the Tulip snaps onto the Screw Shank.





5.4 Pull the Tulip Inserter lever inward completely up against handle to LOCK the Tulip onto the Screw Shank. The Tulip Inserter locking confirmation button will deploy once the Tulip Inserter lever is fully actuated.

5.5 Remove the Tulip Inserter by first releasing the lever, then squeeze the release tabs and pull up.

5.6 If adjustment to the height of the screw is needed prior to or after Tulip attachment, use the Fixed Inline Handle (EAECAUBBZ) connected to the Screw Height Adjuster (NZA008000) to engage the screw and rotate to the desired height.

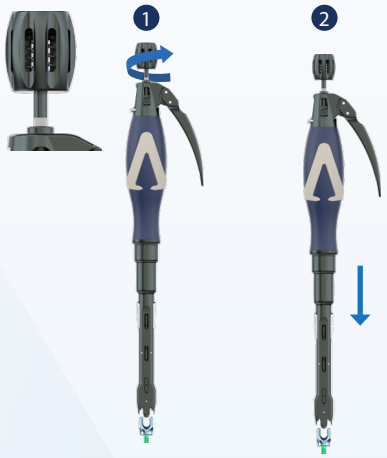
5.7 For easier rod insertion, align the Tulip using the Head Manipulator (AZA007000).

6.0 TULIP REMOVAL

6.1 Tulip Removal from the screw shank; Tulip Unlocker (NZA015000) or High-Top Tulip Unlocker (NZA015001):

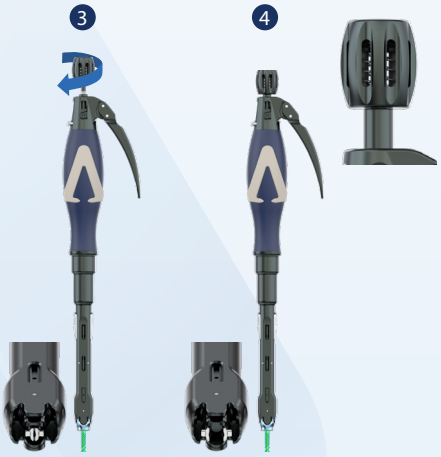
6.1.1 ❶ Prepare instrument for use by rotating knob counterclockwise until lasermark is completely visible. This retracts the internal unlocking mechanism

6.1.2 ❷ Align Tulip Unlocker over top of tulip and apply downward pressure until Tulip snaps into Tulip Unlocker.



6.1.3 ❸ Confirm proper engagement by giving a light tug upward to Tulip Unlocker.

6.1.4 ❹ Rotate knob clockwise until bottomed out and lasermark is no longer visible.



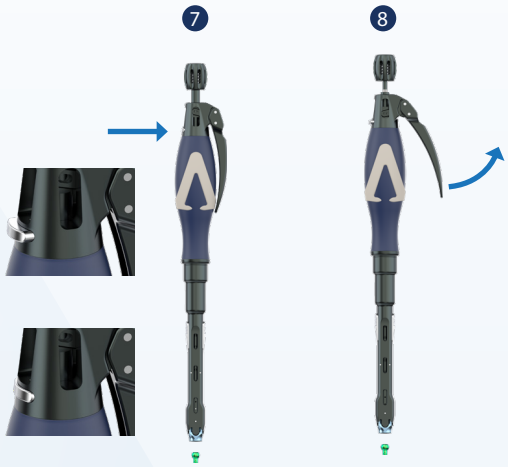
6.1.5 ❺ Compress Tulip Unlocker lever completely against the handle until the proximal latch engages and maintains lever compressed state. There will be an audible click to confirm the proximal latch engaged.5.6.6 Release pressure on the lever. (leaver should be locked in compressed state)

6.1.6 ❻ Pull upward on Tulip Unlocker to remove Tulip from Screw Shank.

6.1.7 To remove Tulip from Tulip Unlocker:

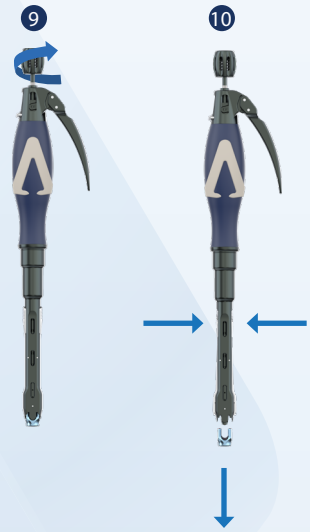
6.1.7.1 ❼ Compress Tulip Unlocker Lever completely against handle and press button to release proximal latch

6.1.7.2 ❽ Release Tulip Unlocker lever back to its uncompressed state.



6.1.7.3 ❾ Rotate back knob counterclockwise until lasermark is completely visible

6.1.7.4 ❿ Squeeze Silver release tabs and remove Tulip from distal end of Tulip Unlocker



7.0 ROD CONTOURING AND INSERTION

7.1 Rod Options: The Masada Modular Posterior Spinal Fixation System supports both Ø5.5mm and Ø6.0mm rods. Ø6.0mm implants and Ø6.0mm supporting instruments are available upon request. Refer to catalog for specific Ø6.0mm implant offerings and instruments.

7.2 Use the Rod Template (AZA032200) to determine the appropriate rod contour and length once the pedicle screws are in place.

7.3 Use the Rod Bender (AZA027000) to achieve the desired rod contour. A rod cutter may be used to achieve the desired rod length.It is recommended that rods be bent in one direction only. Over manipulation and bending may cause fracture of the rod.

7.4 Place the rod into position using the Rod Inserter (AZA009000).

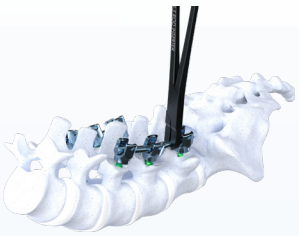
7.5 If the rod needs to be bent when already in position, use the In Situ Rod Benders (Left – AZA02800L and Right – AZA02500R).

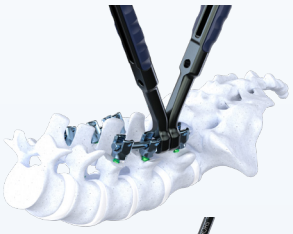
7.6 Load the Set Screws using the Short Set Screw Inserter (AZA017000) or the Long Set Screw Inserter (AZA018000). Align the set screws into the screw head using the alignment feature on the Set Screw and Tulip. Rotate clockwise until provisionally tightened.

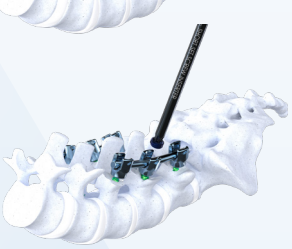
Light Blue Tulip to be used with Dark Blue Set Screw (NCAA00000).

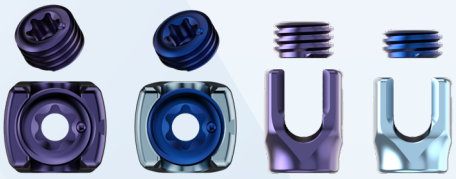
Vector Purple Tulip to be used with Vector Purple Set Screw (NCBA00000).

7.7 To reposition the rod in situ, use the Double Action Rod Gripper (AZA075000), as necessary.



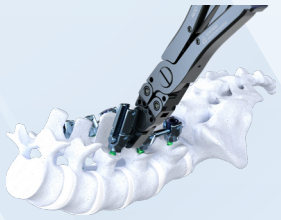






8.0 ROD REDUCTION

8.1 Reduction Overview: The Masada Modular Posterior Spinal Fixation System provides the surgeon with a variety of rod reduction options: High Top Tulips (NABA00000, NAEA00000, NAHA00000), Rod Rocker (AZA012000), Single Action Reducer (NZA010000), Sequential Action Reducer (NZA011000) and Clip Reducer (NZA018000). The surgeon may utilize any one of these methods to fully seat the rod into the implant and allow engagement of the setscrew.



8.2 High Top Screws: High Top tulips are used to allow for spondylolisthesis reduction.

8.2.1 Utilize the set screw to reduce the rod to the screw bushing. Remove the tabs of the high-top tulip using the High-Top Tab Breaker (AZA023000). Align the tab breaker onto one of the tabs and bend the tab outward to break off. Repeat for the other tab.

8.2.2 Once tabs have been removed, unthread the handle from the body portion to remove the broken tabs.

8.3 Rod Rocker: If the rod is slightly proud with respect to the implant, the Rod Rocker (AZA012000) may be used.

8.3.1 Attach the Rod Rocker pins into the lateral pocket features of the implant and rock the handle back to make contact with the rod and force it into the implant.

8.3.2 When the rod is fully seated, insert the Set Screw using the Set Screw Inserter (Short - AZA017000 or Long AZA018000).

8.4 The Sequential Action Reducer (NZA011000) may be used when additional distance is required to seat the rod into the screw head. Long Set Screw Inserter (AZA018000) must be used with Sequential Action Reducer.

8.5 The Clip Reducer (NZA018000) may also be used to reduce the rod when multiple reduction points are necessary.

8.5.1 With the rod in place, position the Sequential Action or Clip Reducer over the implant and snap it into place using the spring-loaded clip. The reducer will automatically lock onto the screw.

8.5.2 Confirm proper engagement by giving a light tug upward.

8.5.3 To reduce the rod, turn the handle of the Sequential Action or Clip Reducer clockwise until the rod is fully seated into the screw head, as indicated by the laser mark lines.

8.5.4 If additional torque is required to complete the reduction, attach the Reducer Driver Attachment (AZA016000) to a Ratchet Handle (EAECNZBBZ, EBECNZBBZ or EDECNZBBZ) and to the Reducer and rotate until reduction is achieved.

8.5.5 Insert a Set Screw through the cannula of the Sequential Action or Clip Reducer using the Long Set Screw Inserter (AZA018000) for the Sequential Action Reducer and Short Set Screw Inserter (AZA017000) for the Clip Reducer and provisionally tighten. Remove the Sequential Action or Clip Reducer by squeezing the release tabs and pull up. It is not necessary to unthread the Reducer.

8.5.6 Optional: Should anatomy prohibit release of Sequential Reducer clips, the Pistol Retriever (NZA019000) can be used to aid in releasing the Sequential Reducer from the installed Tulip.

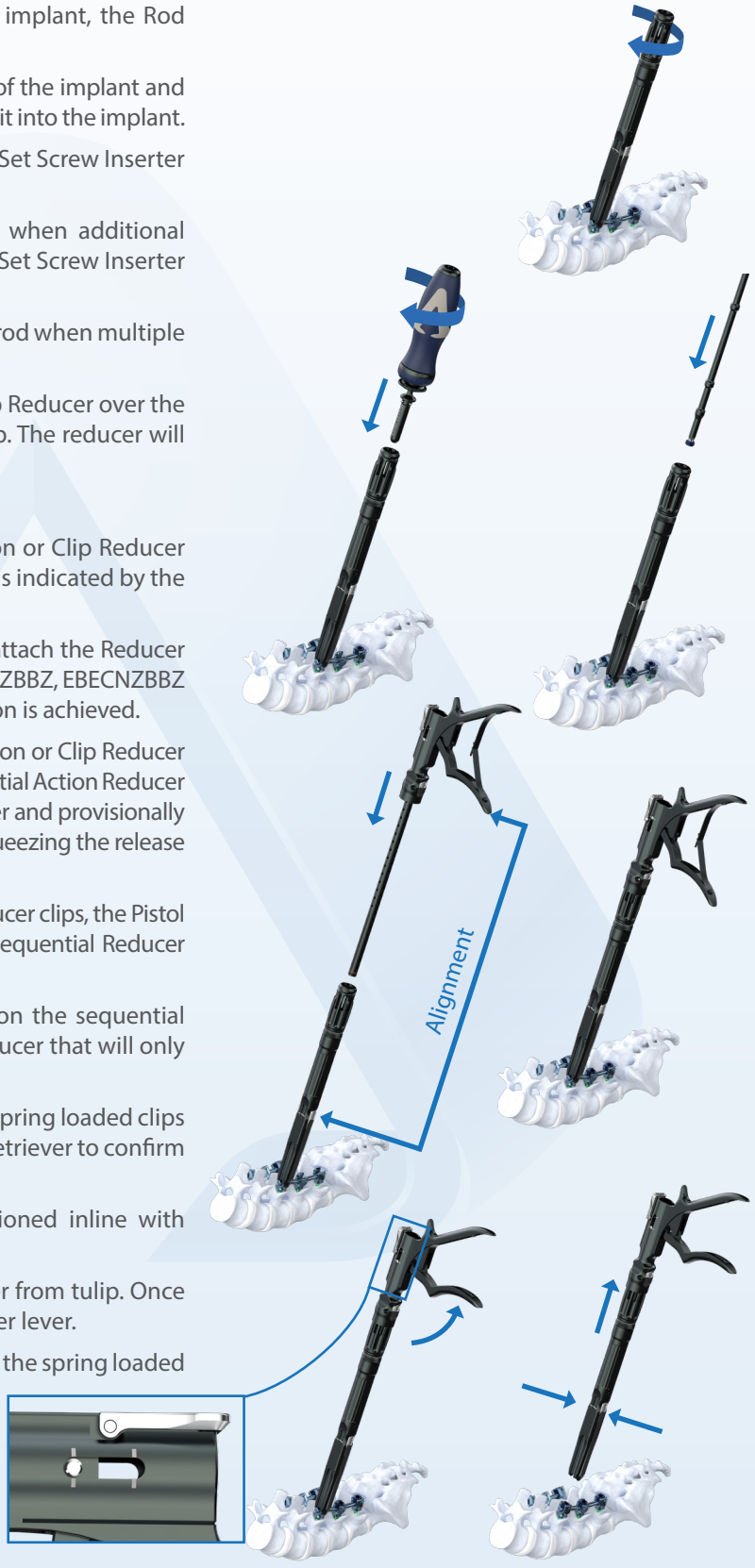
8.5.6.1 Align the Pistol Retriever handle with the silver clips on the sequential reducer. There is an internal groove in the Sequential Reducer that will only allow alignment in one orientation.

8.5.6.2 Slide pistol retriever down into sequential reducer until spring loaded clips engage sequential reducer. Lightly tug upward on pistol retriever to confirm proper engagement.

8.5.6.3 Squeeze pistol retriever lever until indicator is positioned inline with marking.

8.5.6.4 Pull upwards on pistol retriever to lift sequential reducer from tulip. Once removed, flip trigger upwards to release the pistol retriever lever.

8.5.6.5 To remove pistol retriever from sequential reducer, pinch the spring loaded clips and out.



8.6 The Single Action Reducer (NZA010000) can be also used to quickly reduce the rod. Long Set Screw Inserter (AZA018000) must be used with Single Action Reducer.

8.6.1 Release the ratchet handle prior to use by flipping up the lever to the vertical position. Set lever to the horizontal position before use.

8.6.2 With the rod in place, position the Single Action Reducer over the implant and snap it into place using the spring-loaded clip. The reducer will automatically lock onto the screw.

8.6.3 Confirm connection with a light tug upward.

8.6.4 To reduce the rod, squeeze the handle until the rod is fully seated into the screw.

8.6.5 Insert a Set Screw through the cannula of the Single Action Reducer using the Long Set Screw Inserter (AZA018000) and provisionally tighten.

8.6.6 Remove the Single Action Reducer by squeezing the release tabs and pull up. It is not necessary to release the ratchet handle.

9.0 COMPRESSION

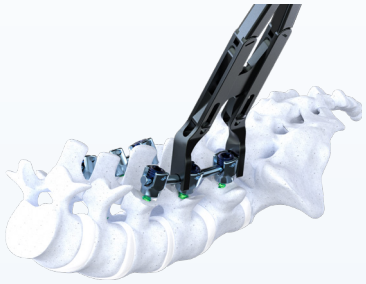
9.1 Compression can be performed at any instrumented level.

9.2 Assemble the Set Screw Torque Shaft (Short - AZA020001 or Long – AZA020002) with the Ratcheting T-Handle (EBECNZBBZ).

9.3 Tighten the Set Screw on one side of the motion segment using the assembly and leave the Set Screw loose in the adjacent segment to be compressed.

9.4 Place the Compressor (AZA030000) tips outside of the screw heads and over the rod. Squeeze the handles until adequate compression is attained.

9.5 Use the Set Screw Torque Shaft and handle to tighten the Set Screw and maintain the compression.



10.0 DISTRACTION

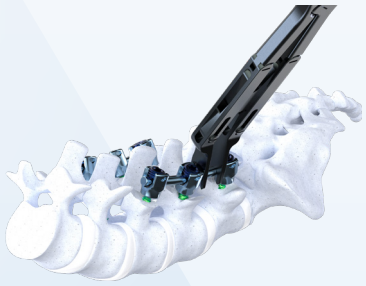
10.1 Distraction can be performed at any instrumented level.

10.2 Assemble the Set Screw Torque Shaft (Short - AZA020001 or Long – AZA020002) with the Ratcheting T-Handle (EBECNZBBZ).

10.3 Tighten the Set Screw on one side of the motion segment using the assembly and leave the Set Screw loose in the adjacent segment to be compressed.

10.4 Place the Distractor (AZA031000) tips in between the screw heads and over the rod. Squeeze the handles until adequate distraction is attained.

10.5 Use the Set Screw Torque Shaft and handle to tighten the Set Screw and maintain the compression.



11.0 FINAL TIGHTENING

11.1 Final tightening of the construct should be performed when all Screws and Rods are in their final position.

11.2 Connect the 100 in-lb Torque Limiting T-Handle (EKECGAAZF) to the Set Screw Torque shaft (Short - AZA020001 or Long – AZA020002).

11.3 The Adjustable Counter Torque (NZA01400X) can accommodate various handle positions in relationship to the rod; Perpendicular ❶ , Angled 45° ❷ Inline ❸. To adjust, rotate back knob in a counterclockwise direction until counter torque shaft is free to rotate. Position counter torque shaft to desired position, then rotate back knob in a clockwise direction until tight.

11.3.1 If additional torque is required to loosen or tighten back knob, use Short Set Screw Inserter (AZA017000) or long Set Screw Inserter (AZA018000) in the T-30 connection within the back knob.

11.4 Insert the assembly into the Adjustable Counter Torque. Adjustable Counter Torque (NZA014003) to be used with Ø5.5 Rods.

11.4.2 6.0 Adjustable Counter Torque (NZA014004) to be used with Ø6.0 Rods.

11.4.3 Adjustable Counter Torque (NZA014001) to be used with Ø5.5 Rods and High-Top Tulip.

11.4.4 6.0 Adjustable Counter Torque (NZA014002) to be used with Ø6.0 Rods and High-Top Tulip.

11.5 With the Set Screw Torque Shaft (Short - AZA020001 or Long – AZA020002) protruding out of the Counter Torque, engage the pedicle screw until fully seated.

11.6 Slide the counter torque down until the instrument is fully seated over the rod and screw.

11.7 Turn T-handle clockwise to tighten. Final tightening is achieved when the T-handle audibly clicks.

12.0 CROSS CONNECTOR SYSTEM

12.1 The Masada Modular Posterior Spinal Fixation System offers Variable Cross Connector implants which can be used to increase the torsional stability of a construct.

12.2 Select the appropriate sized Variable Cross Connector.

12.3 Use the Rod Inserter (AZA009000) to insert the Cross Connector into position. The link should span in between two Rods and connect via the connectors.

12.4 Attach the Cross Connector to both Rods and lock into place by rotating the lateral set screws clockwise using the Rod Connector Driver (AZA024000) and provisionally tighten. Backing out the set screws may be required to engage Cross Connector with Rods. Use Rod Connector Driver to adjust set screw height.

12.5 Provisionally tighten the center screw using the Rod Connector Driver (AZA024000), if using a variable cross connector.

12.6 Attach the 40 in-lbs Torque Limiting T-Handle (EBEZJAAZC) to the Rod Connector Torque Shaft (AZA008000). Final tighten the lateral set screws and center screw of the crosslink by turning the T-handle clockwise. Final Tightening is achieved when the T-handle audibly clicks.

13.0 ROD CONNECTOR IMPLANTS

13.1 The Masada Modular Posterior Spinal Fixation System offers a variety of Rod-to-Rod Connectors, Lateral Connectors and Rod Extensions to help facilitate the procedure.

13.2 Connector Color Indications

13.2.1 DARK BLUE: Use with Ø3.5 Rod

13.2.2 LIGHT BLUE: Use with Ø5.5 Rod

13.2.3 GRAY: Use with Ø5.5* or Ø 6.0 Rod

13.2.4 MAGENTA: Use with Ø6.0** or Ø6.35 Rod

13.2.4.1 * Ø5.5 Rod acceptable except on side loading connectors

13.2.4.2 **Ø6.0 Rod acceptable except on side loading connectors

13.3 To final tighten the Rod Connectors; assemble the 60 in-lbs Torque Limiting T-Handle (EBECJAAZD) with the Rod Connector Torque Shaft (AZA008000), connect to the set screw, and rotate clockwise until the T-Handle provides an audible click. When necessary, the Rod Gripper (AZA010000) can be attached to the rod adjacent to the connector to be used as a counter torque.

13.4 Top Loading Rod Connectors utilize Set Screw (ABAA000XX).

13.4.1 Set Screw 5.5 – Color: Blue (ABAA00055) to be used with Ø5.5 rods.

13.4.2 Set Screw 6.0 – Color: Gray (ABAA00060) to be used with Ø6.0 rods.

13.5 Connect the Offset 100 in-lb Torque Limiting T-Handle (ECECGAAZF) to the Set Screw Torque shaft (Short - AZA020001 or Long – AZA020002).

13.6 Turn T-handle clockwise to tighten. Final tightening is achieved when the T-handle audibly clicks.

14.0 IMPLANT REMOVAL

14.1 Cross Connectors / Rod Connectors

14.1.1 Assemble the Ratcheting T-Handle (EBECNZBBZ) to the Rod Connector Torque Shaft (AZA008000).

14.1.2 Engage the Rod Connector Torque Shaft to the center screw and lateral set screws on the Cross Connector and unthread in a counterclockwise direction.

14.2 Top Loading Connectors

14.2.1 Assemble the Ratcheting T-Handle (EBECNZBBZ) to the Set Screw Torque shaft (Short - AZA020001 or Long – AZA020002).

14.2.2 Engage the Set Screw Torque Shaft to the Set Screw and unthread in a counterclockwise direction.

14.3 Set Screws and Rods:

14.3.1 Assemble the Ratcheting T-Handle (EBECNZBBZ) to the Set Screw Torque Shaft (Short – AZA020001 or Long – AZA020002).

14.3.2 Insert the assembly into the Counter Torque (AZA019000).

14.3.3 Slide the counter torque down until the instrument is fully seated over the rod and implant.

14.3.4 Turn T-handle counter-clockwise to loosen and remove the set screw.

14.3.5 Repeat for each screw.

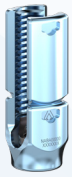
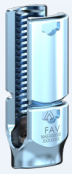
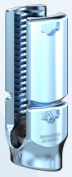
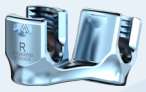
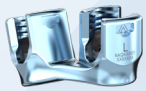
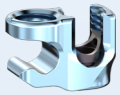
14.3.6 Grab the rod using the Rod Gripper (AZA010000) and remove the rod.

14.3.4 Polyaxial Screw:

14.4.1 Assemble the Ratcheting T-Handle (EBECNZBBZ) to the Screw Height Adjuster (NZA008000).

14.4.2 Engage the Screw Height Adjuster to the Screw and unthread in a counterclockwise direction.

TULIPS

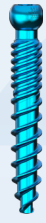
Part Number	Description	Qty	
NAAA00000	Polyaxial, Tulip	16	
NABA00000	High Top, Tulip	8	
NAEA00000	Favored Angle M/L, High Top, Tulip	4	
NAHA00000	Favored Angle C/C, High Top, Tulip	4	
NADA00000	Favored Angle M/L, High Strength, Tulip	4	
NAGA00000	Favored Angle C/C, High Strength, Tulip	4	
NA1A00000	Favored Angle M/L, Tulip	4	
NA2A00000	Favored Angle C/C, Tulip	4	
NAQA00000	Dual Head, Angled, Tulip, Right	4	
NAQA00001	Dual Head, Angled, Tulip, Left	4	
NARA00000	Dual Head, Top / Side Loading	4	
NA3A00000	High Strength, Tulip	8	

SET SCREWS

Part Number	Description	Qty
NCAA00000	Tulip Set Screw, T30	8
NCBA00000	Tulip Set Screw, T30, High Strength	8

CORTICAL SCREWS - STANDARD

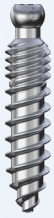
Part Number	Description	Qty
NBG040020	Cortical Screw, 4.0mm x 20mm	4
NBG040025	Cortical Screw, 4.0mm x 25mm	8
NBG040030	Cortical Screw, 4.0mm x 30mm	8
NBG040035	Cortical Screw, 4.0mm x 35mm	8
NBG040040	Cortical Screw, 4.0mm x 40mm	8
NBG040045	Cortical Screw, 4.0mm x 45mm	8
NBG040050	Cortical Screw, 4.0mm x 50mm	4
NBG045020	Cortical Screw, 4.5mm x 20mm	4
NBG045025	Cortical Screw, 4.5mm x 25mm	8
NBG045030	Cortical Screw, 4.5mm x 30mm	8
NBG045035	Cortical Screw, 4.5mm x 35mm	8
NBG045040	Cortical Screw, 4.5mm x 40mm	8
NBG045045	Cortical Screw, 4.5mm x 45mm	8
NBG045050	Cortical Screw, 4.5mm x 50mm	4
NBG050030	Cortical Screw, 5.0mm x 30mm	4
NBG050035	Cortical Screw, 5.0mm x 35mm	8
NBG050040	Cortical Screw, 5.0mm x 40mm	8
NBG050045	Cortical Screw, 5.0mm x 45mm	8
NBG050050	Cortical Screw, 5.0mm x 50mm	8
NBG050055	Cortical Screw, 5.0mm x 55mm	8
NBG055030	Cortical Screw, 5.5mm x 30mm	4
NBG055035	Cortical Screw, 5.5mm x 35mm	8
NBG055040	Cortical Screw, 5.5mm x 40mm	8
NBG055045	Cortical Screw, 5.5mm x 45mm	8
NBG055050	Cortical Screw, 5.5mm x 50mm	8
NBG055055	Cortical Screw, 5.5mm x 55mm	8
NBG055060	Cortical Screw, 5.5mm x 60mm	4
NBG065030	Cortical Screw, 6.5mm x 30mm	4
NBG065035	Cortical Screw, 6.5mm x 35mm	8
NBG065040	Cortical Screw, 6.5mm x 40mm	8
NBG065045	Cortical Screw, 6.5mm x 45mm	8
NBG065050	Cortical Screw, 6.5mm x 50mm	8
NBG065055	Cortical Screw, 6.5mm x 55mm	8
NBG065060	Cortical Screw, 6.5mm x 60mm	4
NBG075030	Cortical Screw, 7.5mm x 30mm	4
NBG075035	Cortical Screw, 7.5mm x 35mm	8
NBG075040	Cortical Screw, 7.5mm x 40mm	8
NBG075045	Cortical Screw, 7.5mm x 45mm	8
NBG075050	Cortical Screw, 7.5mm x 50mm	8
NBG075055	Cortical Screw, 7.5mm x 55mm	8
NBG075060	Cortical Screw, 7.5mm x 60mm	4



CORTICAL SCREWS - STANDARD

Part Number	Description	Qty
NBG085030	Cortical Screw, 8.5mm x 30mm	4
NBG085035	Cortical Screw, 8.5mm x 35mm	4
NBG085040	Cortical Screw, 8.5mm x 40mm	4
NBG085045	Cortical Screw, 8.5mm x 45mm	4
NBG085050	Cortical Screw, 8.5mm x 50mm	4
NBG085055	Cortical Screw, 8.5mm x 55mm	4
NBG085060	Cortical Screw, 8.5mm x 60mm	4

NBG095030	Cortical Screw, 9.5mm x 30mm	4
NBG095035	Cortical Screw, 9.5mm x 35mm	4
NBG095040	Cortical Screw, 9.5mm x 40mm	4
NBG095045	Cortical Screw, 9.5mm x 45mm	4
NBG095050	Cortical Screw, 9.5mm x 50mm	4
NBG095055	Cortical Screw, 9.5mm x 55mm	4
NBG095060	Cortical Screw, 9.5mm x 60mm	4



CORTICAL SCREWS - LONG/ILIAC

Part Number	Description	Qty
NBG075065	Cortical Screw, 7.5mm x 65mm	3
NBG075070	Cortical Screw, 7.5mm x 70mm	3
NBG075075	Cortical Screw, 7.5mm x 75mm	3
NBG075080	Cortical Screw, 7.5mm x 80mm	3
NBG075085	Cortical Screw, 7.5mm x 85mm	3
NBG075090	Cortical Screw, 7.5mm x 90mm	3
NBG085065	Cortical Screw, 8.5mm x 65mm	3
NBG085070	Cortical Screw, 8.5mm x 70mm	3
NBG085075	Cortical Screw, 8.5mm x 75mm	3
NBG085080	Cortical Screw, 8.5mm x 80mm	3
NBG085090	Cortical Screw, 8.5mm x 90mm	3
NBG085100	Cortical Screw, 8.5mm x 100mm	3
NBG085110	Cortical Screw, 8.5mm x 110mm	3
NBG085120	Cortical Screw, 8.5mm x 120mm	3
NBG095065	Cortical Screw, 9.5mm x 65mm	3
NBG095070	Cortical Screw, 9.5mm x 70mm	3
NBG095075	Cortical Screw, 9.5mm x 75mm	3
NBG095080	Cortical Screw, 9.5mm x 80mm	3
NBG095090	Cortical Screw, 9.5mm x 90mm	3
NBG095100	Cortical Screw, 9.5mm x 100mm	3
NBG095110	Cortical Screw, 9.5mm x 110mm	3
NBG095120	Cortical Screw, 9.5mm x 120mm	3

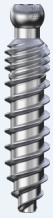
CORTICAL SCREWS - CANNULATED

Part Number	Description	Qty
NBH045020	Cortical Screw, Cannulated, 4.5mm x 20mm	4
NBH045025	Cortical Screw, Cannulated, 4.5mm x 25mm	8
NBH045030	Cortical Screw, Cannulated, 4.5mm x 30mm	8
NBH045035	Cortical Screw, Cannulated, 4.5mm x 35mm	8
NBH045040	Cortical Screw, Cannulated, 4.5mm x 40mm	8
NBH045045	Cortical Screw, Cannulated, 4.5mm x 45mm	8
NBH045050	Cortical Screw, Cannulated, 4.5mm x 50mm	4
NBH050030	Cortical Screw, Cannulated, 5.0mm x 30mm	4
NBH050035	Cortical Screw, Cannulated, 5.0mm x 35mm	8
NBH050040	Cortical Screw, Cannulated, 5.0mm x 40mm	8
NBH050045	Cortical Screw, Cannulated, 5.0mm x 45mm	8
NBH050050	Cortical Screw, Cannulated, 5.0mm x 50mm	8
NBH050055	Cortical Screw, Cannulated, 5.0mm x 55mm	4
NBH055030	Cortical Screw, Cannulated, 5.5mm x 30mm	4
NBH055035	Cortical Screw, Cannulated, 5.5mm x 35mm	8
NBH055040	Cortical Screw, Cannulated, 5.5mm x 40mm	8
NBH055045	Cortical Screw, Cannulated, 5.5mm x 45mm	8
NBH055050	Cortical Screw, Cannulated, 5.5mm x 50mm	8
NBH055055	Cortical Screw, Cannulated, 5.5mm x 55mm	4
NBH065030	Cortical Screw, Cannulated, 6.5mm x 30mm	4
NBH065035	Cortical Screw, Cannulated, 6.5mm x 35mm	8
NBH065040	Cortical Screw, Cannulated, 6.5mm x 40mm	8
NBH065045	Cortical Screw, Cannulated, 6.5mm x 45mm	8
NBH065050	Cortical Screw, Cannulated, 6.5mm x 50mm	8
NBH065055	Cortical Screw, Cannulated, 6.5mm x 55mm	8
NBH065060	Cortical Screw, Cannulated, 6.5mm x 60mm	4
NBH075030	Cortical Screw, Cannulated, 7.5mm x 30mm	4
NBH075035	Cortical Screw, Cannulated, 7.5mm x 35mm	8
NBH075040	Cortical Screw, Cannulated, 7.5mm x 40mm	8
NBH075045	Cortical Screw, Cannulated, 7.5mm x 45mm	8
NBH075050	Cortical Screw, Cannulated, 7.5mm x50mm	8
NBH075055	Cortical Screw, Cannulated, 7.5mm x 55mm	8
NBH075060	Cortical Screw, Cannulated, 7.5mm x 60mm	4

CORTICAL SCREWS - CANNULATED

Part Number	Description	Qty
NBH085030	Cortical Screw, Cannulated, 8.5mm x 30mm	4
NBH085035	Cortical Screw, Cannulated, 8.5mm x 35mm	4
NBH085040	Cortical Screw, Cannulated, 8.5mm x 40mm	4
NBH085045	Cortical Screw, Cannulated, 8.5mm x 45mm	4
NBH085050	Cortical Screw, Cannulated, 8.5mm x 50mm	4
NBH085055	Cortical Screw, Cannulated, 8.5mm x 55mm	4
NBH085060	Cortical Screw, Cannulated, 8.5mm x 60mm	4

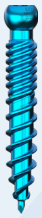
Part Number	Description	Qty
NBH095030	Cortical Screw, Cannulated, 9.5mm x 30mm	4
NBH095035	Cortical Screw, Cannulated, 9.5mm x 35mm	4
NBH095040	Cortical Screw, Cannulated, 9.5mm x 40mm	4
NBH095045	Cortical Screw, Cannulated, 9.5mm x 45mm	4
NBH095050	Cortical Screw, Cannulated, 9.5mm x 50mm	4
NBH095055	Cortical Screw, Cannulated, 9.5mm x 55mm	4
NBH095060	Cortical Screw, Cannulated, 9.5mm x 60mm	4



CORTICAL SCREWS - STYLET

Part Number	Description	Qty
NBL055030	Cortical Screw, Stylet Tip,5.5mm x 30mm	4
NBL055035	Cortical Screw, Stylet Tip,5.5mm x 35mm	8
NBL055040	Cortical Screw, Stylet Tip,5.5mm x 40mm	8
NBL055045	Cortical Screw, Stylet Tip,5.5mm x 45mm	8
NBL055050	Cortical Screw, Stylet Tip,5.5mm x 50mm	8
NBL055055	Cortical Screw, Stylet Tip,5.5mm x 55mm	8
NBL055060	Cortical Screw, Stylet Tip,5.5mm x 60mm	4

Part Number	Description	Qty
NBL065030	Cortical Screw, Stylet Tip,6.5mm x 30mm	4
NBL065035	Cortical Screw, Stylet Tip,6.5mm x 35mm	8
NBL065040	Cortical Screw, Stylet Tip,6.5mm x 40mm	8
NBL065045	Cortical Screw, Stylet Tip,6.5mm x 45mm	8
NBL065050	Cortical Screw, Stylet Tip,6.5mm x 50mm	8
NBL065055	Cortical Screw, Stylet Tip,6.5mm x 55mm	8
NBL065060	Cortical Screw, Stylet Tip,6.5mm x 60mm	4



Part Number	Description	Qty
NBL075030	Cortical Screw, Stylet Tip,7.5mm x 30mm	4
NBL075035	Cortical Screw, Stylet Tip,7.5mm x 35mm	8
NBL075040	Cortical Screw, Stylet Tip,7.5mm x 40mm	8
NBL075045	Cortical Screw, Stylet Tip,7.5mm x 45mm	8
NBL075050	Cortical Screw, Stylet Tip,7.5mm x 50mm	8
NBL075055	Cortical Screw, Stylet Tip,7.5mm x 55mm	8
NBL075060	Cortical Screw, Stylet Tip,7.5mm x 60mm	4

RODS AND CONNECTORS

Part Number	Description	Qty
ACAB55040	5.5 Rod, Straight, TiCP, 40mm	2
ACAB55050	5.5 Rod, Straight, TiCP 50mm	2
ACAB55060	5.5 Rod, Straight, TiCP, 60mm	2
ACAB55070	5.5 Rod, Straight, TiCP, 70mm	2
ACAB55080	5.5 Rod, Straight, TiCP, 80mm	2
ACAB55090	5.5 Rod, Straight, TiCP, 90mm	2
ACAB55100	5.5 Rod, Straight, TiCP, 100mm	2
ACAB60030	6.0 Rod, Straight, TiCP, 30mm	2
ACAB60040	6.0 Rod, Straight, TiCP, 40mm	2
ACAB60050	6.0 Rod, Straight, TiCP, 50mm	2
ACAB60060	6.0 Rod, Straight, TiCP, 60mm	2
ACAB60070	6.0 Rod, Straight, TiCP, 70mm	2
ACAB60080	6.0 Rod, Straight, TiCP, 80mm	2
ACAB60090	6.0 Rod, Straight, TiCP, 90mm	2
ACAB60100	6.0 Rod, Straight, TiCP, 100mm	2
ACBB55035	5.5 Rod, Lordotic, TiCP, 35mm	4
ACBB55040	5.5 Rod, Lordotic, TiCP, 40mm	4
ACBB55045	5.5 Rod, Lordotic, TiCP, 45mm	4
ACBB55050	5.5 Rod, Lordotic, TiCP, 50mm	4
ACBB55055	5.5 Rod, Lordotic, TiCP, 55mm	4
ACBB55060	5.5 Rod, Lordotic, TiCP, 60mm	4
ACBB55065	5.5 Rod, Lordotic, TiCP, 65mm	4
ACBB55070	5.5 Rod, Lordotic, TiCP, 70mm	4
ACBB55075	5.5 Rod, Lordotic, TiCP, 75mm	4
ACBB55080	5.5 Rod, Lordotic, TiCP, 80mm	4
ACBB55085	5.5 Rod, Lordotic, TiCP, 85mm	2
ACBB55090	5.5 Rod, Lordotic, TiCP, 90mm	2
ACBB55095	5.5 Rod, Lordotic, TiCP, 95mm	2
ACBB55100	5.5 Rod, Lordotic, TiCP, 100mm	2
ACBB55110	5.5 Rod, Lordotic, TiCP, 110mm	2
ACBB55120	5.5 Rod, Lordotic, TiCP, 120mm	2
ACBB60030	6.0 Rod, Lordotic, TiCP, 30mm	2
ACBB60035	6.0 Rod, Lordotic, TiCP, 35mm	4
ACBB60040	6.0 Rod, Lordotic, TiCP, 40mm	4
ACBB60045	6.0 Rod, Lordotic, TiCP, 45mm	4
ACBB60050	6.0 Rod, Lordotic, TiCP, 50mm	4
ACBB60055	6.0 Rod, Lordotic, TiCP, 55mm	4
ACBB60060	6.0 Rod, Lordotic, TiCP, 60mm	4
ACBB60065	6.0 Rod, Lordotic, TiCP, 65mm	4
ACBB60070	6.0 Rod, Lordotic, TiCP, 70mm	4
ACBB60075	6.0 Rod, Lordotic, TiCP, 75mm	4
ACBB60080	6.0 Rod, Lordotic, TiCP, 80mm	4
ACBB60085	6.0 Rod, Lordotic, TiCP, 85mm	2
ACBB60090	6.0 Rod, Lordotic, TiCP, 90mm	2
ACBB60095	6.0 Rod, Lordotic, TiCP, 95mm	2
ACBB60100	6.0 Rod, Lordotic, TiCP, 100mm	2
ACBB60110	6.0 Rod, Lordotic, TiCP, 110mm	2
ACBB60120	6.0 Rod, Lordotic, TiCP, 120mm	2

RODS AND CONNECTORS

Part Number	Description	Qty
ACCA55300	5.5 Rod, Hex, Ti6Al4V ELI, 300mm	2
ACCA55500	5.5 Rod, Hex, Ti6Al4V ELI, 500mm	2
ACCC55300	5.5 Rod, Hex, CoCr, 300mm	2 /OPT
ACCC55500	5.5 Rod, Hex, CoCr, 500mm	2
ACCC60300	6.0 Rod, HEX, CoCr, 300mm	4
ACCA60500	6.0 Rod, HEX, Ti6Al4VELI, 500mm	4
ACCC60500	6.0 Rod, HEX, CoCr, 500mm	4
ACEA55003	5.5 Z-Rod, Ti6Al4VELI, 300mm	2
ACEA60003	6.0 Z-Rod, Ti6Al4VELI, 300mm	2
ACHA55550	Scoliosis Rod, TI64, 5.5mm - 550mm	2/OPT
ACHA60550	Scoliosis Rod, TI64, 6.0mm - 550mm	2/OPT
ACHB55550	Scoliosis Rod, COCR, 5.5mm - 550mm	2/OPT
ACHB60550	Scoliosis Rod, COCR, 6.0mm - 550mm	2/OPT
AFAA0WLS0	Lamina Hook, Large	8
AFAA0WMS0	Lamina Hook, medium	8
AFAA0WSS0	Lamina Hook, small	8
AFAA0NLS0	Lamina Hook large, narrow	4
AFAA0NMS0	Lamina Hook medium, narrow	4
AFAA0NSS0	Lamina Hook small, narrow	4
AFAA0WLH0	Lamina Hook, large, extended	2
AFAA0WMH0	Lamina Hook, medium, extended	2
AFAA0WSH0	Lamina Hook, small, extended	2
AFAA0WBS0	Lamina Hook, X Large	2 /OPT
AFBA0WMS0	Lamina Hook medium, ramped	4
AFBA0NMS0	Lamina Hook, medium, ramped, narrow	4
AFBA0WSS0	Lamina Hook small, ramped	4
AFBA0NSS0	Lamina Hook, small, ramped, narrow	4
AFGALNMS0	Ramped Offset Lamina Hook, Medium, Narrow, Left	2
AFGARNMS0	Ramped Offset Lamina Hook, Medium, Narrow, Right	2
AFGALNSS0	Ramped Offset Lamina Hook, Small, Narrow, Left	2
AFGARNSS0	Ramped Offset Lamina Hook, Small, Narrow, Right	2
AFGALWMS0	Ramped Offset Lamina Hook, Medium, Wide, Left	2 /OPT
AFGARWMS0	Ramped Offset Lamina Hook, Medium, Wide, Right	2 /OPT
AFGALWSS0	Ramped Offset Lamina Hook, Small, Wide, Left	2 /OPT
AFGARWSS0	Ramped Offset Lamina Hook, Small, Wide, Right	2 /OPT
AFDARWLS0	Offset Hook, large, right	2
AFDALWLS0	Offset Hook, large, left	2
AFDARWSS0	Offset Hook, small, right	2
AFDALWSS0	Offset Hook, small, left	2

RODS AND CONNECTORS

Part Number	Description	Qty
AFEA0PLS0	Pedicle Hook, large	2
AFEA0PMS0	Pedicle Hook, medium	4
AFEA0PSS0	Pedicle Hook, small	4
AFEA0PPS0	Pedicle Hook, extra small	2
AFFARWBS0	Transverse Process Hook, x large, right	2
AFFALWBS0	Transverse Process Hook, x large, left	2
AFFARWLS0	Transverse Process Hook, large, right	2
AFFALWLS0	Transverse process Hook, large, left	2
ADAA00001	5.5 / 6.0 Cross Link, variable, xxsml	2
ADAA00002	5.5 / 6.0 Cross Link, variable, xsml	2
ADAA00003	5.5 / 6.0 Cross Link, variable, sml	2
ADAA00004	5.5 / 6.0 Cross Link, variable, med	2
ADAA00005	5.5 / 6.0 Cross Link, variable, lrg	2
ADAA00006	5.5 / 6.0 Cross Link, variable, xlrg	2
ADAA00007	5.5 / 6.0 Cross Link, variable, xxlrg	2
ADBA00016	5.5 / 6.0 Cross Link fixed, 16mm	2/OPT
ADBA00019	5.5 / 6.0 Cross Link fixed, 19mm	2/OPT
ADBA00022	5.5 / 6.0 Cross Link fixed, 22mm	2/OPT
ADBA00025	5.5 / 6.0 Cross Link fixed, 25mm	2/OPT
ADBA00028	5.5 / 6.0 Cross Link fixed, 28mm	2/OPT
ADBA00031	5.5 / 6.0 Cross Link fixed, 31mm	2/OPT
ADBA00034	5.5 / 6.0 Cross Link fixed, 34mm	2/OPT
ADBA00037	5.5 / 6.0 Cross Link fixed, 37mm	2/OPT
AEKA55L12	Rod Extension Connector, Left, 5.5, 5.5, Side Loading, Double, Wide, 300mm	1
AEKA55R12	Rod Extension Connector, Right, 5.5, 5.5, Side Loading, Double, Wide, 300mm	1
AEKA55L24	Rod Extension Connector, Left, 5.5, 6.0, Side Loading, Double, Wide, 300mm	1
AEKA55R24	Rod Extension Connector, Right, 5.5, 6.0, Side Loading, Double, Wide, 300mm	1
AEAA55015	Lateral Rod Connector, 5.5, Closed, 15mm	2
AEAA55030	Lateral Rod Connector, 5.5, Closed, 30mm	2
AEAA55045	Lateral Rod Connector, 5.5, Closed, 45mm	2
AEAA55060	Lateral Rod Connector, 5.5, Closed, 60mm	2
AEBA60015	Lateral Rod Connector, 6.0, Top Loading, 15mm	2
AEBA60030	Lateral Rod Connector, 6.0, Top Loading, 30mm	2
AEBA60045	Lateral Rod Connector, 6.0, Top Loading, 45mm	2
AEBA60060	Lateral Rod Connector, 6.0, Top Loading, 60mm	2
AECA55015	Lateral Rod Connector, 5.5, Side Loading, 15mm	2
AECA55030	Lateral Rod Connector, 5.5, Side Loading, 30mm	2
AECA55045	Lateral Rod Connector, 5.5, Side Loading, 45mm	2
AECA55060	Lateral Rod Connector, 5.5, Side Loading, 60mm	2
AEAA63515	Lateral Rod Connector, 6.35, Closed, 15mm	2
AEAA63530	Lateral Rod Connector, 6.35, Closed, 30mm	2
AEAA63545	Lateral Rod Connector, 6.35, Closed, 45mm	2
AEAA63560	Lateral Rod Connector, 6.35, Closed, 60mm	2
AECA60015	Lateral Rod Connector, 6.0, Side Loading, 15mm	2
AECA60030	Lateral Rod Connector, 6.0, Side Loading, 30mm	2
AECA60045	Lateral Rod Connector, 6.0, Side Loading, 45mm	2
AECA60060	Lateral Rod Connector, 6.0, Side Loading, 60mm	2

RODS AND CONNECTORS

Part Number	Description	Qty
AEDA55002	Inline Rod Connector, 5.5, Medium	2
AEDA63502	Inline Rod Connector, 6.35, Medium	2
AELA35102	Inline Transition Rod Connector, Medium, 3.5mm, 5.5mm	2
AELA35106	Inline Transition Rod Connector, Medium, 3.5mm, 6.35mm	2
AELA55002	Inline Transition Rod Connector, Medium, 5.5mm, 6.35mm	2
AEEA55002	Offset Rod Connector, 5.5, Wide	2
AEEA55016	Offset Rod Connector, 5.5, Double, Wide Medium	2
AEFA55001	Offset Rod Connector, 6.0, 5.5, Std, Top/Side Loading	2
AEFA55003	Offset Rod Connector, 6.0, 5.5, X Wide, Top/Side Loading	2
AEFA55004	Offset Rod Connector, 6.0, 5.5, XXWide, Top/Side Loading	2
AENA55002	Offset Rod Connector, 5.5, Single, Wide, Side / Side Loading	2
AENA55003	Offset Rod Connector, 5.5, Single, X Wide, Side / Side Loading	2
AENA55004	Offset Rod Connector, 5.5, Single, XX Wide, Side / Side Loading	2
AENA55012	Offset Rod Connector, 5.5, Double, Wide, Side / Side Loading	2
AERA60001	Offset Rod Connector, 6.0, 6.0, Std, Top/Top Loading	2
AERA60003	Offset Rod Connector, 6.0, 6.0, X Wide, Top/Top Loading	2
AERA60004	Offset Rod Connector, 6.0, 6.0, XX Wide, Top/Top Loading	2
AEEA63502	Offset Rod Connector, 6.35, Wide	2
AEEA63512	Offset Rod Connector, 6.35, Double, Wide Medium	2
AEFA60001	Offset Rod Connector, 6.0, 6.0, Std, Top/Side Loading	2
AENA60002	Offset Rod Connector, 6.0, Single, Wide, Side/Side Loading	2
AENA60012	Offset Rod Connector, 6.0, Double, Wide, Side/Side Loading	2
AEFA63501	Offset Rod Connector, 6.0, 6.35, Std Top/Side Loading	2
AERA35001	Offset Rod Connector, 6.0, 3.5, Std, Top/Top Loading	2
AEHA55004	Offset Transition Rod Connector, Wide, Closed/Side Loading, 5.5mm, 5.5mm	2
AEHA55007	Offset Transition Rod Connector, X Wide, Closed/Side Loading, 5.5mm, 5.5mm	2
AEHA55010	Offset Transition Rod Connector, XX Wide, Closed/Side Loading, 5.5mm, 5.5mm	2
AEHA63501	Offset Transition Rod Connector, Std, Closed/Side Loading, 6.35mm, 6.0mm	2
AEGA35102	Offset Transition Rod Connector, Wide, 3.5mm, 5.5mm	2
AEGA35104	Offset Transition Rod Connector, Wide, 3.5mm, 6.35mm	2
AEHA35102	Offset Transition Rod Connector, Wide, Closed/Side Loading, 3.5mm, 5.5mm	2
AEHA35104	Offset Transition Rod Connector, Wide, Closed/Side Loading, 3.5mm, 6.0mm	2
AEHA55002	Offset Transition Rod Connector, Std, Closed/Side Loading, 5.5mm, 6.0mm	2
AEHA55003	Offset Transition Rod Connector, Std, Closed/Side Loading, 5.5mm, 6.35mm	2
AEMA55001	Offset Transition Rod Connector, 5.5, 6.0, Single, Side / Side Loading	2
AEMA55002	Offset Transition Rod Connector, 5.5, 6.35, Single, Side / Side Loading	2
AEMA55006	Offset Transition Rod Connector, 5.5, 3.5, Single, Wide, Side / Side Loading	2
AEMA60001	Offset Transition Rod Connector, 6.0, 6.35, Single, Side / Side Loading	2
AEMA60004	Offset Transition Rod Connector, 6.0, 3.5, Single, Wide, Side / Side Loading	2
AEMA55011	Offset Transition Rod Connector, 5.5, 6.0, Double, Side / Side Loading	2
AEMA55012	Offset Transition Rod Connector, 5.5, 6.35, Double, Side / Side Loading	2
AEMA55016	Offset Transition Rod Connector, 5.5, 3.5, Double, Wide, Side / Side Loading	2
AEMA60011	Offset Transition Rod Connector, 6.0, 6.35, Double, Side / Side Loading	2
AEMA60014	Offset Transition Rod Connector, 6.0, 3.5, Double, Wide, Side / Side Loading	2

Part Number	Description	Qty
EAECNZBBZ	Axial Handle, L, 1/4 Sq, Ratchet 2.0, Aluminum Core, Internal, Cannulated, Cannulated Cap	
EBECNZBBZ	T-Handle, L, 1/4 Sq, Ratchet 2.0, Aluminum Core, Internal, Cannulated, Cannulated Cap	
EAECAUBBZ	Axial Handle, L, 1/4 Sq, Fixed, Aluminum Core, Internal, Cannulated, Cannulated Cap	
EDECNZBBZ	EGG, L , 1/4 Sq, Ratchet 2.0, Aluminum Core, Internal, Cannulated, Cannulated Cap	
EJZCMBBZZ	Power Driver Attachment	
EKECGAAZF	100 IN-LB Double Clutch T-Handle Torque	
EKECGAAZJ	90 IN-LB Double Clutch T-Handle Torque	
EBECJAAZC	T-Handle, L, 1/4 Sq, Torque, Stainless Steel Core, Internal, Non-Cannulated, 40 IN-Lbs	

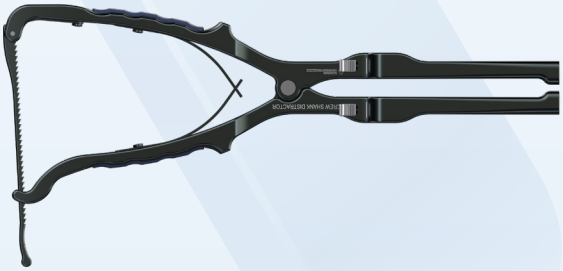




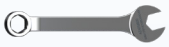



Part Number	Description	Qty
AZA002001	Lumbar Pedicle Probe, Straight	1
AZA002002	Lumbar Pedicle Probe, Curved	1
AZA003001	Thoracic Pedicle Probe, Straight	1
AZA003002	Thoracic Pedicle Probe, Curved	1
AZA004000	Ball Tip Probe	2
NZA001000	Decortication Tool	1
NZA001001	Screw Head Decortication Tool	1
AZA059035	Cortical Tap, 3.5mm	1
AZA059040	Cortical Tap, 4.0mm	1
AZA059045	Cortical Tap, 4.5mm	1
AZA059050	Cortical Tap, 5.0mm	1
AZA059055	Cortical Tap, 5.5mm	1
AZA059065	Cortical Tap, 6.5mm	1
AZA059075	Cortical Tap, 7.5mm	1
AZA059085	Cortical Tap, 8.5mm	1
NZA003000	Screw Shank Driver	2
NZA004000	Stick Fit Screw Shank Driver	2
NZA007000	Tulip Inserter, Axial	2
AZA007000	Head Manipulator	1

Part Number	Description	Qty	
AZA032200	200mm Rod Template	1	
AZA027000	Rod Bender	1	
AZA009000	5.5 / 6.0 Rod Inserter	1	
AZA075000	Double Action Rod Gripper	1	
AZA011000	Rod Pusher	1	
AZA012000	Rod Rocker	1	
NZA010000	Pistol Reducer	1	

Part Number	Description	Qty	
NZA011000	Sequential Reducer	2	
NZA018000	Clip Reducer	2 /OPT	
AZA016000	Reducer Driver	1	
NZA019000	Retreiver, Pistol	1	
AZA078000	Iliac Probe, Straight	1 /OPT	
NZA005000	Screw Shank Distractor	1	
NZA015000	Tulip Unlocker	1	
AZA008000	Rod Connector Torque	2	
NZA008000	Screw Height Adjuster	1	
AZA017000	Short Set Screw Inserter	2	
AZA018000	Long Set Screw Inserter	2	

Part Number	Description	Qty	
AZA031000	Parallel Distractor	1	
AZA030000	Parallel Compressor	1	
NZA014003	5.5 Adjustable Counter Torque	1	
AZA049001	Knurled Set Screw Inserter, Dual Ended	1 /OPT	
AZA020001	Short Set Screw Torque Shaft	2	
AZA020002	Long Set Screw Torque Shaft	1	
AZA024000	Cross Link Provisional Driver	1	

Part Number	Description	Qty	
AZA058000	Screw Driver Wrench	1	
NZA003001	Screw Shank Driver, Cannulated	2 /OPT	
NZA002000	Screw Driver	2 /OPT	
NZA002010	Iliac Screw Driver	2 /OPT	
AZA001000	Lumbar Pedicle Awl	1 /OPT	
AZA05200R	Pedicle Marker, Right	1 /OPT	
AZA05200L	Pedicle Marker, Left	1 /OPT	
AZA054000	Pedicle Marker Inserter	1 /OPT	
NZA007001	Tulip Inserter, Axial, High Top	1	
NZA015001	High Top Tulip Unlocker	1	
AZA023000	High Top Tab Breaker	1	

Part Number	Description	Qty
AZA02800L	5.5 In Situ Rod Bender, Left	1
AZA02800R	5.5 In Situ Rod Bender, Right	1
AZA02900L	6.0 Insitu Rod Bender, Left	1
AZA02900R	6.0 Insitu Rod Bender, Right	1
AZA059060	Cortical Tap, 6.0mm	1
AZA059070	Cortical Tap, 7.0mm	1
AZA059080	Cortical Tap, 8.0mm	1
NZA017075	Cortical Iliac Tap, 7.5mm	1
NZA017065	Cortical Iliac Tap, 6.5mm	1
NZA017085	Cortical Iliac Tap, 8.5mm	1
NZA017095	Cortical Iliac Tap, 9.5mm	1
NZA017105	Cortical Iliac Tap, 10.5mm	1
NZA002021	Navigated, Screw Driver, Cannulated	1 /OPT
NZA023035	Navigated, Cortical, Stylet Tip, Tap, 3.5mm	1
NZA023040	Navigated, Cortical, Stylet Tip, Tap, 40mm	1
NZA023045	Navigated, Cortical, Stylet Tip, Tap, 4.5mm	1
NZA023050	Navigated, Cortical, Stylet Tip, Tap, 50mm	1
NZA023055	Navigated, Cortical, Stylet Tip, Tap, 5.5mm	1
NZA023060	Navigated, Cortical, Stylet Tip, Tap, 60mm	1
NZA023065	Navigated, Cortical, Stylet Tip, Tap, 6.5mm	1
NZA023070	Navigated, Cortical, Stylet Tip, Tap, 70mm	1
NZA023075	Navigated, Cortical, Stylet Tip, Tap, 7.5mm	1
NZA023080	Navigated, Cortical, Stylet Tip, Tap, 80mm	1 /OPT
NZA023085	Navigated, Cortical, Stylet Tip, Tap, 8.5mm	1 /OPT
NZA023090	Navigated, Cortical, Stylet Tip, Tap, 90mm	1 /OPT
NZA023095	Navigated, Cortical, Stylet Tip, Tap, 9.5mm	1 /OPT
NZA023100	Navigated, Cortical, Stylet Tip, Tap, 10.0mm	1 /OPT
NZA023105	Navigated, Cortical, Stylet Tip, Tap, 10.5mm	1 /OPT

MASADA
MODULAR SPINAL FIXATION SYSTEM

INSTRUCTIONS FOR USE

1.0 IMPORTANT NOTE TO OPERATING SURGEON: MASADA Modular 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:

2.1 **Pedicle Screw system:** The MASADA Modular 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, rod connectors, and hooks. 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.

Pedicle System	
Material	Conforming Standard
TiCP	ASTM F67
CoCr	ASTM F1537
Ti-6Al-4V ELI	ASTM F136
Elgiloy	ASTM F1058
Titanium	ASTM F2026
Nitinol #1	ASTM F2063

2.2 **Sublaminar Band system:** The MASADA sublaminar band designed to stabilize a vertebrae during the fusion process. The system is composed of sublaminar bad cerclages and band 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.

Sublaminar Band System	
Material	Conforming Standard
TiCP	ASTM F67
CoCr	ASTM F1537
Ti-6Al-4V ELI	ASTM F136
Titanium	ASTM F2026
PET	N/A
N/A	N/A

2.3 **Navigated Instrument System:** The MASADA navigated instruments are 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 MASADA Modular Spinal Fixation System must not be reused under any circumstances. These instructions for use are designed to assist in use of the MASADA Modular Spinal Fixation System and are not a reference for surgical techniques.

4.0 INDICATIONS:

4.1 **Pedicle Screw System:** The MASADA Modular 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 MASADA Modular Spinal Fixation System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The MASADA Modular Spinal Fixation System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

4.2 **Sublaminar Band System:** The MASADA sublaminar band is a temporary implant for use in orthopedic surgery. The band system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

-Spinal trauma surgery, used in subliminar or facet wiring techniques.
-Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age or older, adult scoliosis, kyphosis and spondylolisthesis.
-Spinal degenerative surgery, as an adjunct to spinal fusions.

The MASADA sublaminar band may also be used in conjunction with other medical grade implants made of similar metals whenever "wiring" may help secure the attachment of the other implants.

4.3 **Navigated Instrument System:** The MASADA navigated instruments are intended to be used in the preparation and placement of MASADA 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.

7.1.6.3 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 MASADA Modular Spinal Fixation System has not been evaluated for safety and compatibility in the MR environment. The MASADA Modular Spinal Fixation System has not been tested for heating, migration, or image artifact in the MR environment. The safety of MASADA Modular 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.

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 MASADA Modular Spinal Fixation System in pediatric patients should be performed 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 MASADA Modular 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 compensate 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 MASADA Modular 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 components 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: All devices, with the exception of the sublaminar bands, are supplied clean and NOT STERILE, and must be sterilized prior to use.
The sublaminar bands are provided packaged gamma sterilized and no additional cleaning or sterilization is needed by the end user.

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.
The sublaminar bands are provided packaged post-gamma sterilization. The Sterility Assurance Level (SAL) is 1 x 10^{-6}. No additional cleaning or sterilization is needed by the end user.

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 MASADA Modular Spinal Fixation System component(s) ever malfunctions, ASTURA MEDICAL or its representative must be notified immediately.
If any MASADA Modular 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

Astura Medical
4949 W Royal Ln
Irving, TX 75063
Phone: 469-501-5530
Email: info@asturamedical.com

INS-00016, MASADA SYSTEM INSTRUCTIONS FOR USE, REVA
TEM-00041, PACKAGE INSERT TEMPLATE, REVC

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