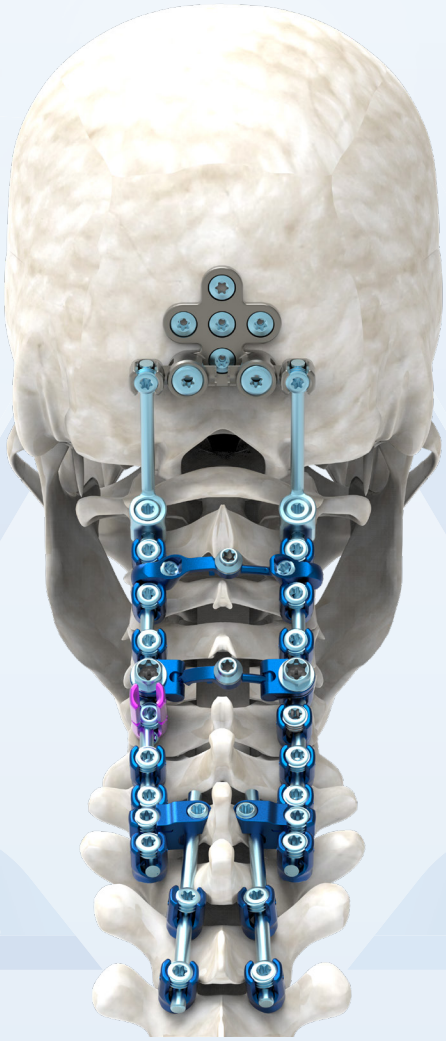
BRIDALVEIL

OCCIPITAL CERVICAL THORACIC SYSTEM

ASTURA MEDICAL

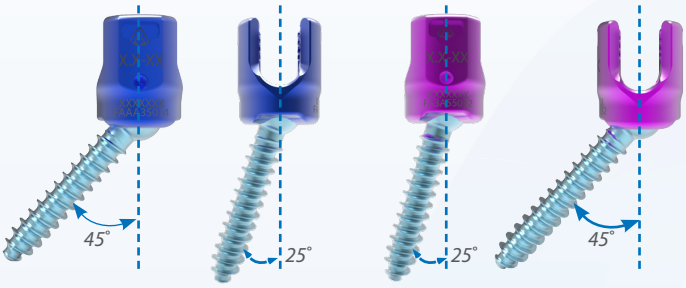
DESIGN RATIONALE

BRIDALVEIL Occipital-Cervical-Thoracic System by ASTURA MEDICAL is a comprehensive system designed to address the most complex posterior craniocervical, cervical, and thoracic anatomical challenges where spinal fixation is required. The intuitive design and breadth of implants and instruments ensures a seamless transition across multiple segments of the spine.

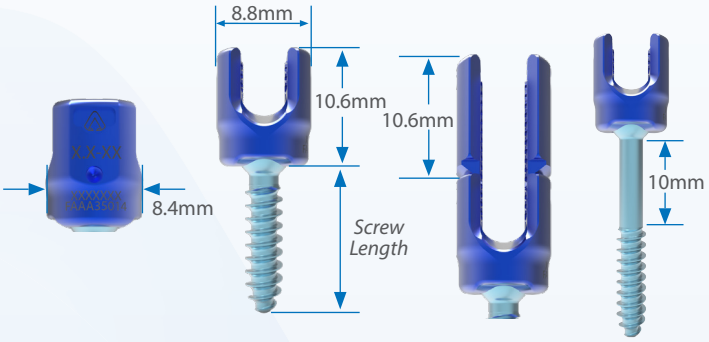


CERVICAL / THORACIC IMPLANT OVERVIEW

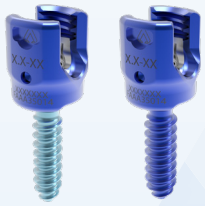
POLYAXIAL SCREWS



Cranial Caudal Bias (C/C) *Medial Lateral Bias (M/L)*



Single-Lead, C/C & M/L



Ø3.5mm Ø4.0mm

Dual-Lead, M/L

Ø4.5mm Ø5.0mm Ø5.5mm

Single-Lead, C/C, Smooth Shank

Ø3.5mm Ø4.0mm

Single-Lead, C/C, High Top

Ø3.5mm Ø4.0mm

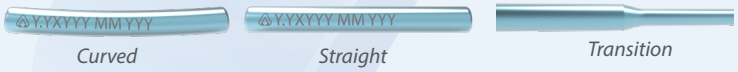
Dual-Lead, M/L, High Top

Ø4.5mm Ø5.5mm

Self-Starting / Self-Tapping Screw Tip

RODS

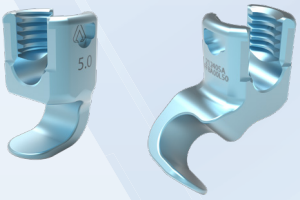
Ø3.5 & Ø4.0, Material: Ti6Al4V ELI, CoCr



Curved *Straight* *Transition*

HOOKS

Laminar *Offset*

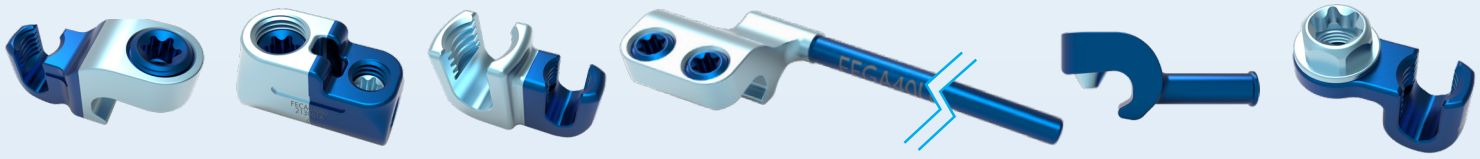


CROSS CONNECTORS

Rod-to-Rod *Head-to-Head Variable* *Head-to-Rod*

ROD CONNECTORS

Offset *Inline* *Transition* *Extensions* *Lateral Rod connector* *Screw Top*



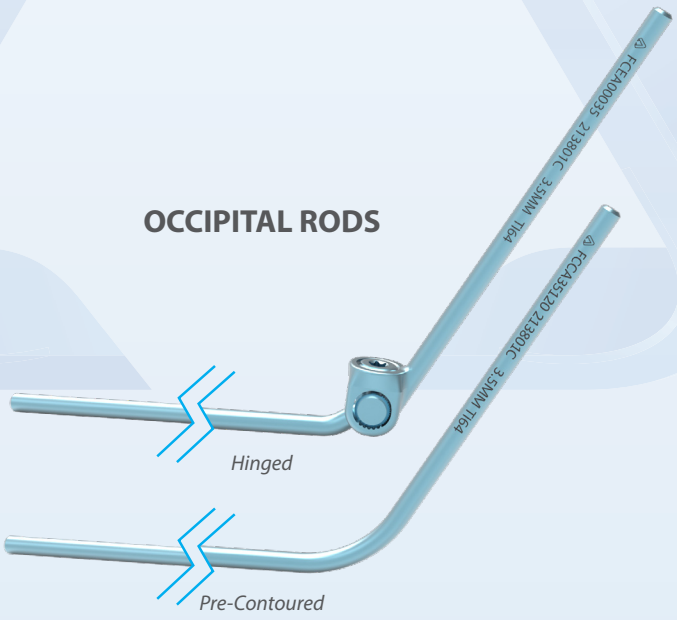
OCCIPITAL IMPLANT OVERVIEW

OCCIPITAL PLATES

OCCIPITAL SCREWS

Ø4.5mm *Ø5.25mm*

OCCIPITAL RODS



Hinged

Pre-Contoured

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 SCREW PREPARATION

2.1 Cervical Spine

2.1.1 Select the Drill Bit (Fixed – FZ03000XX or Adjustable – FZ1100000) for the screw to be used and the associated Drill Guide (Fixed – FZ0200000 or Adjustable – FZ1000000).

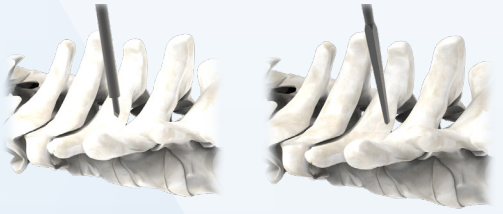
2.1.2 If using the Adjustable Drill and Drill Guide, set the Drill Guide to the desired depth.

2.1.3 Insert the Drill Bit into the Drill Guide, then drill to the desired depth and trajectory.

2.2 Thoracic Spine

2.2.1 Create a pilot hole at the determined entry point for the screw using the Cortical Awl (FZ1400000).

2.2.2 Use Straight Probe (FZ1500010) or Curved Probe (FZ1500020) to create a pathway through the pedicle into the vertebral body.



2.3 Cervical or Thoracic

2.3.1 Use the Ball Tip Probe (Short – FZ1600010 or Long – FZ1600020) to palpate the wall of the pedicle or lateral mass to ensure its integrity.

2.3.2 Confirm the depth of the hole using the Depth Gauge (FZ1700000).

2.3.3 Select the correct size Bone Tap (FZ1200XXX) and associated Tap Sleeve (FZ48000XX), then attach to one of the Axial AO Handles (Fixed – EACEASADZ or Ratchet – EACEDSAAZ).

2.3.4 Tap the hole by rotating the tap clockwise until the desired depth has been achieved. The Bone Tap has depth indicators that may be used to aid in achieving the correct depth.

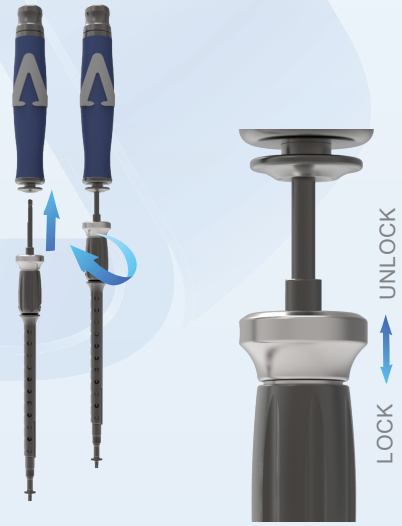
3.0 SCREWDRIVER AND SCREW ASSEMBLY

3.1 Assemble the Axial AO Ratchet Handle (EACEDSAAZ) and the T13 Modular Screwdriver (FZ1800002) by inserting the proximal end of the Screwdriver into the distal end of the handle. Compress the spring loaded quick connect ring of the handle to assemble.

3.2 The screw can be assembled to the Screwdriver in the LOCKED or UNLOCKED position.

3.3 Attach the appropriate polyaxial screw onto the Screwdriver by inserting the distal end of the Screwdriver into the screw and thread the grip clockwise to engage the Screwdriver thread into the head of the screw.

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



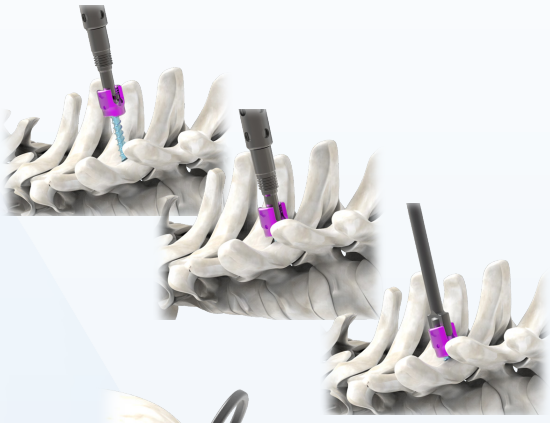
4.0 SCREW INSERTION / DISASSEMBLY / ADJUSTMENT

4.1 Insert the polyaxial screw into the tapped hole, then rotate clockwise until the desired depth is achieved.

4.2 To disassemble the Screwdriver from the polyaxial screw, set the Screwdriver to the UNLOCKED position and 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 screw.

4.3 Align the polyaxial screw heads using the Head Manipulator (FZ4700000) to allow for insertion of the rod.

4.4 If adjustment to the height of the screw is needed, use the Axial AO Fixed Handle (EACEASADZ) connected to the T13Screw Height Adjuster (FZ2000000) to engage the screw, then adjust to the desired height.



5.0 HOOK SELECTION AND INSERTION

5.1 Identify which landmarks of the cervical lamina will receive hooks.

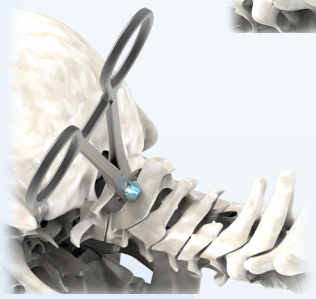
5.2 Remove soft tissue and ligamentous connections as necessary to provide visualization of the entire lamina and margins of the spinal canal.

5.3 Prepare the lamina as necessary.

5.4 Select the appropriate hook.

5.5 Attached the Hook Holder (FZ4900020) to the proximal body of the hook.

5.6 Slide the hook underneath the lamina at the prepared site.



6.0 ROD AND SET SCREW INSERTION

6.1 Rod Options: The BRIDALVEIL Occipital Cervical Thoracic System supports both Ø3.5mm or Ø4.0mm rods in Cobalt Chrome (CoCr) and Titanium Alloy (TI64).

6.2 Use the Rod Template (FZ2100XXX) to determine the appropriate rod contour and length.

6.3 Use the Rod Bender (FZ2300000) and the Rod Cutter (FZ220000) to achieve the desired rod contour and length.

6.3.1 Cutting takes place at center of instrument (6.5mm from either facet).

6.4 Place the rod into position using the Rod Inserter (FZ2600000).

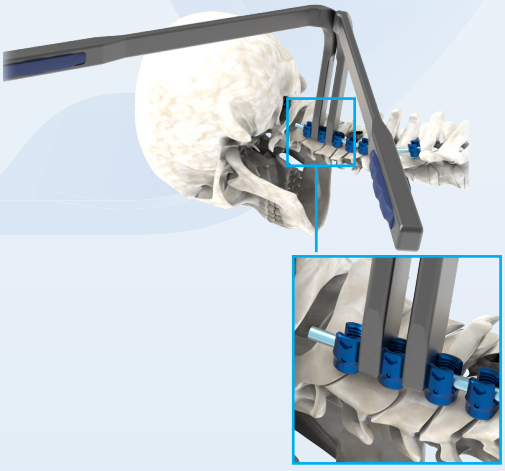
6.5 If the rod needs to be bent once set in position, use the In Situ Benders (Coronal – FZ25000XX or Sagittal – FZ24000XX).

6.6 To reposition the rod In Situ, use the Rod Gripper (FZ2700000) or Hex Rod Wrench (FZ4400000), as necessary.

6.7 Load the Set Screw (FBAA00000) using the T15 Set Screw Inserter (Short – FZ3300020 or Long – FZ3300010) by pressing the tip of the Set Screws Inserter into the Set Screw. Coaxially align the Set Screws with the screw head and rotate clockwise until provisionally tightened.

7.0 ROD REDUCTION

7.1 Reduction Overview: The BRIDALVEIL Occipital Cervical Thoracic System provides the surgeon with a variety of rod reduction options: High Top Screws (FABAXXXXX), Rod Rocker (FZ2800000), Pistol Reducer (FZ2900000) Sequential Reducer (FZ3000000), and Clip Reducer (FZ3100000). The surgeon may utilize any of these methods to fully seat the rod into the implant and allow engagement of the Set Screw.



7.2 High Top Screws: High Top Screws are used to allow for increased rod reduction. The T13 High Top Screwdriver (FZ1800003) is required when using High Top Screws.

7.2.1 Utilize the Set Screw to reduce the rod to the screw bushing. Remove the tabs of the High Top Screw using the High Top Counter Tab Breaker (FZ6200000) and the Rod Inserter (FZ2600000). Engage the High Top Counter Tab Breaker onto the screw head. Grip the tab with the Rod Inserter and then force medial or lateral until tab breaks from the screw head. Repeat for opposite tab.

7.3 Rod Rocker: If the rod is slightly proud with respect to the screw head, the Rod Rocker (FZ2800000) may be used to help facilitate Set Screw insertion.

7.3.1 Attach the Rod Rocker pins into the lateral pocket features of the implant, then rock the handle back to engage the rod and force it into the implant.

7.3.2 When the rod is fully seated, insert the Set Screw using the T15 Set Screw Inserter (Short – FZ3300020 or Long – FZ3300010).

7.4 Clip Reducer (FZ3100000) and **Sequential Reducer** (FZ3000000): These devices may be used to reduce the rod when multiple reduction points are necessary.

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

7.4.2 Confirm proper engagement by giving a light tug upward.

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

7.4.4 If additional torque is required to complete the reduction, attach the Reducer Driver (FZ3200000) to the Axial AO Ratchet Handle (EACEDSAAZ) and insert into the Sequential Reducer or Clip Reducer. Rotate until the rod is fully seated into the screw head as indicated by the laser mark lines.

7.4.5 Insert a Set Screw through the cannula of the Sequential Reducer or Clip Reducer using the T15 Long Set Screw Inserter (FZ3300010) for the Sequential Reducer and the T15 Short Set Screw Inserter (FZ3300020) for the Clip Reducer, then provisionally tighten. Remove the Sequential Reducer or Clip Reducer by squeezing the release tabs and pulling up. It is not necessary to unthread the reducer.

7.5 Pistol Reducer (FZ2900000): This device can be used to quickly reduce the rod in a single action.

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

7.5.2 With the rod in place, position the Pistol Reducer over the screw and snap it into place using the spring-loaded clip. The Pistol Reducer will automatically lock onto the screw head.

7.5.3 Confirm connection with a light tug upward.

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

7.5.5 Insert a Set Screw through the cannula of the Pistol Reducer using the T15 Long Set Screw Inserter (FZ3300010) and provisionally tighten.

7.5.6 Remove the Pistol Reducer by squeezing the release tabs and pulling up. It is not necessary to release the ratchet handle.

8.0 COMPRESSION

8.1 Compression can be performed at any instrumented level.

8.2 Assemble the T15 Set Screw Torque Shaft (Short – FZ3700010 or Long – FZ3700020) with the Axial AO Ratchet Handle (EACEDSAAZ).

8.3 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.

8.4 Place the Compressor (Hinged – FZ3400000 or Parallel – FZ3400010) tips outside of the screw heads and over the rod. Squeeze the handles until adequate compression is attained.

8.5 Use the T15 Set Screw Torque Shaft and handle to provisionally tighten the Set Screw to maintain the compression.

9.0 DISTRACTION

9.1 Distraction can be performed at any instrumented level.

9.2 Assemble the T15 Set Screw Torque Shaft (Short – FZ3700010 or Long – FZ3700020) with the Axial AO Ratchet Handle (EACEDSAAZ).

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 Distractor (Hinged – FZ3500000 or Parallel – FZ3500010) tips in between the screw heads and over the rod. Squeeze the handles until adequate distraction is attained.

9.5 Use the T15 Set Screw Torque Shaft and handle to provisionally tighten the Set Screw to maintain the distraction.

10.0 FINAL TIGHTENING

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

10.2 Connect the 26.5 in-lbs. Torque Limiting T-Handle (EBEEJAAZA) to the T15 Set Screw Torque Shaft (Short – FZ3700010 or Long – FZ3700020).

10.3 Insert the assembly into the Counter Torque (Offset – FZ3600004 or Axial FZ3600030).

10.4 With the T15 Set Screw Torque Shaft (Short – FZ3700010 or Long – FZ3700020) protruding out of the Counter Torque, engage the Set Screw until fully seated.

10.5 Slide the Counter Torque down until the instrument is fully seated over the rod and screw.

10.6 Turn the 26.5 in-lbs. Torque Limiting T-Handle clockwise to tighten. Final tightening is achieved when the T-Handle audibly clicks.

11.0 CROSS CONNECTOR SYSTEMS

11.1 The BRIDALVEIL Occipital Cervical Thoracic System offers Variable Cross Connector implants which can be used to increase the torsional stability of a construct.

11.2 Rod-to-Rod Variable Cross Connector

11.2.1 Select the appropriate sized Rod-to-Rod Variable Cross Connector (FDAA000XX).

11.2.2 Use the Rod Inserter (FZ2600000) to insert the Cross Connector into position.

11.2.3 Attach the Cross Connector to both Rods and lock into place by rotating the lateral Set Screws clockwise using the T15 Short Set Screw Inserter (FZ3300020) and provisionally tighten. Use the T15 Short Set Screw Inserter to adjust Set Screw height.

11.2.4 Provisionally tighten the center screw using the T15 Short Set Screw Inserter (FZ3300020).

11.3 Head-to-Head Cross Connector

11.3.1 Use the Long or Short T15 Set Screw Inserter (FZ3300010, FZ3300020) to thread the Extended Set Screws (FDBA00010) into the screw heads.

11.3.2 Connect the 26.5 in-lbs. Torque Limiting T-Handle (EBEEJAAZA) to the T15 Set Screw Torque Shaft (Short – FZ3700010 or Long – FZ3700020).

11.3.3 Insert the assembly into the Counter Torque (Offset – FZ3600004 or Axial FZ3600030).

11.3.4 With the T15 Set Screw Torque Shaft (Short – FZ3700010 or Long – FZ3700020) protruding out of the Counter Torque, engage the Set Screw until fully seated.

11.3.5 Slide the Counter Torque down until the instrument is fully seated over the rod and screw.

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

11.3.7 Select the appropriate sized Variable Head-to-Head Cross Connector (FDDA000XX).

11.3.8 Use the Rod Inserter (FZ2600000) to place a Head-to-Head Variable Cross Connector (FDDA000XX) onto the Extended Set Screw and provisionally tighten the hex nuts using the T30 Head-to-Head Connector Torque Shaft (FZ4500000).

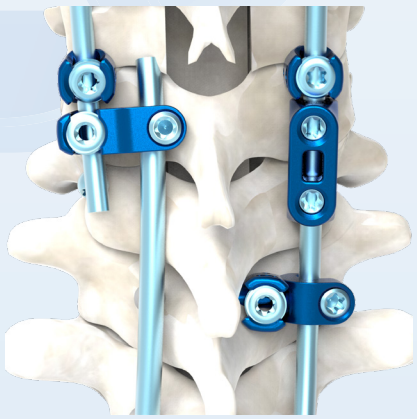
11.4 Head-to-Rod Connectors

11.4.1 Attach the Head-to-Rod Connector (FDBA00020) to the transverse rod using the T15 Set Screw Inserter to thread the Set Screw to the rod. 11.4.2 Use the Rod Inserter (FZ2600000) to place a Head-to-Head Variable Cross Connector (FDDA000XX) onto the final tightened Extended Set Screw and Head-to-Rod Connector and provisionally tighten the hex nuts using the T30 Head-to-Head Connector Torque Shaft (FZ4500000).

11.5 Cross Connector Final Tightening

11.5.1 Once the Cross Connector is in the desired position, attach the 26.5 in-lbs Torque Limiting T-Handle (EBEEJAAZA) to the T30 Head-to-Head Connector Torque Shaft (FZ4500000) for tightening of the hex nuts or the T15 Rod Connector Torque Shaft (FZ4100000) for tightening of the center nut and lateral Set Screws.

11.5.2 Final tighten by turning the T-Handle clockwise. Final tightening is achieved when the T-Handle audibly clicks.



12.0 ROD CONNECTORS

12.1 The BRIDALVEIL Occipital Cervical Thoracic System offers a variety of Rod-to-Rod Connectors, Lateral Connectors, Rod Extensions, and Cable Connectors to help facilitate the procedure.

12.2 Connector Color Indications

12.2.1 DARK BLUE: Use with Ø3.5mm or Ø4.0mm Rod.

12.2.1.1 Use the Light Blue 3.5/4.0mm Set Screw (FBAA00000) with Top Loading Connectors.

12.2.2 LIGHT BLUE: Use with Ø5.5mm or Ø6.0mm Rod.

12.2.2.1 Use the Dark Blue 5.5/6.0mm Set Screw (FELA00000) with Top Loading Connectors.

12.2.3 MAGENTA: Use with Ø6.35mm Rod.

12.3 Connector Set Screw Color Indications

12.3.1 LIGHT BLUE (Small): Tighten with T15 3.5/4.0mm Rod Connector Torque Shaft (FZ4100000) using the "AO" 26.5 in-lbs. Torque Limiting T-Handle (EBEEJAAZA).

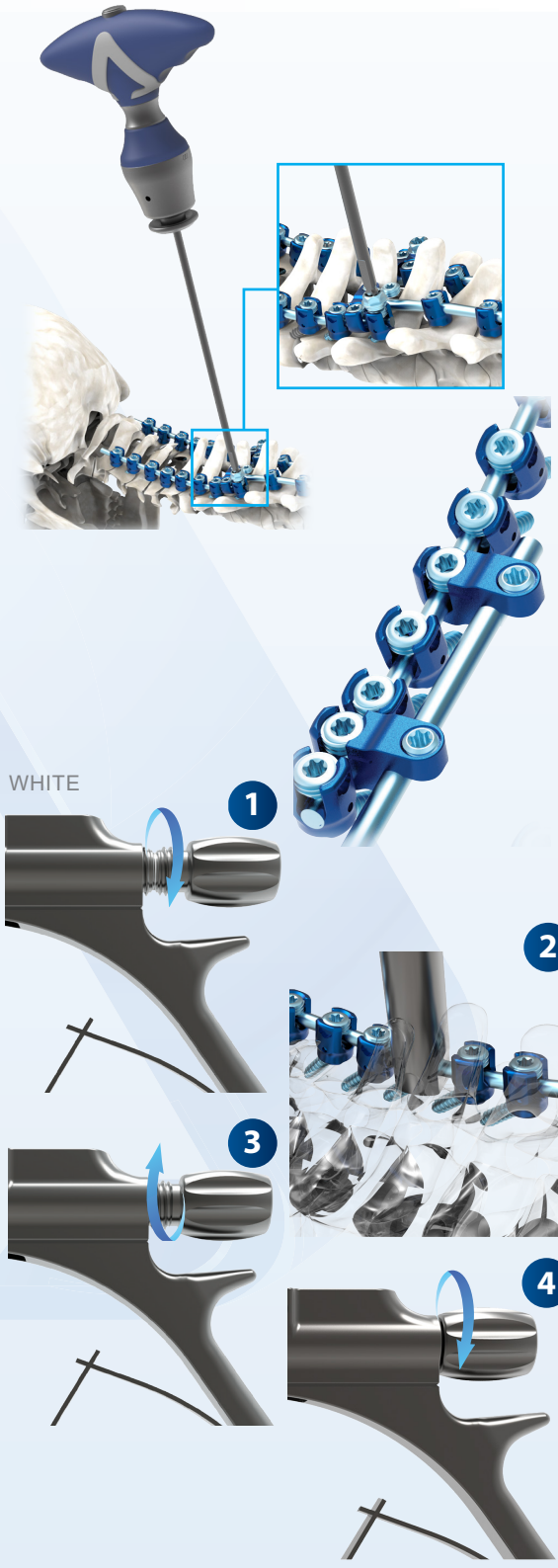
12.3.2 DARK BLUE (Large): Tighten with T25 5.5/6.0mm Rod Connector Torque Shaft (FZ4200000) using the "¼ Square" 60 in-lbs. Torque Limiting T-Handle (EBECJAAZD).

Connector Color	Rod Diameter (mm)	Set Screw Color	Set Screw Torque
Dark Blue	Ø3.5 / Ø4.0	Light Blue	26.5 in-lbs
Light Blue	Ø5.5 / Ø6.0	Dark Blue	60 in-lbs
Magenta	Ø6.35	Dark Blue	60 in-lbs

12.4 To final tighten the Rod Connectors; assemble the correct Torque Limiting T-Handle with the correct Rod Connector Torque Shaft, connect to the Set Screw, and rotate clockwise until the T-Handle provides an audible click.

12.5 Rod-to-Rod Connectors are to be used when connecting two separate constructs. Do not use the BRIDALVEIL Screw Top Rod Connector, as the mechanical strength is not adequate for stable fixation of two separate constructs.

12.6 BRIDALVEIL Occipital Cervical Thoracic System cable connectors are available for connection to the Titanium Songer™ Spinal Cable System.



13.0 SCREW HEAD MOBILIZATION

13.1 The BRIDALVEIL polyaxial screw head is capable of remobilization to regain variability.

13.1.1 To regain polyaxial variability, set the Screw Head Mobilizer (FZ4300000) to the NEUTRAL position by threading the knob until the WHITE groove is visible.

13.1.2 With the Screw Head Mobilizer In the NEUTRAL position, position the Screw Head Mobilizer over the implant and snap it into place using the spring-loaded clip. The Screw Head Mobilizer will automatically lock onto the screw.

13.1.3 Thread the knob in a clockwise direction until resistance is felt.

13.1.4 Squeeze the handle to regain mobilization. Mobilization is achieved when the Screw Head Mobilizer audibly clicks. Verify polyaxial variability by rotating the Screw Head Mobilizer instrument prior to releasing the handle.

13.1.5 Release the handle, then disengage the spring-loaded clip by threading the knob in a counter clockwise direction until it stops. Pull up on the Screw Head Mobilizer to remove the instrument from the screw.

14.0 IMPLANT REMOVAL

14.1 Rod-to-Rod Cross Connector / Head-to-Rod Connector

14.1.1 Assemble the AO Axial Ratcheting Handle (EACEDSAAZ) to the T15 Rod Connector Torque Shaft (FZ4100000).

14.1.2 Engage the T15 Rod Connector Torque Shaft to the center nut and lateral Set Screws on the Cross Connector, then unthread in a counter clockwise direction.

14.1.3 Engage the T15 Rod Connector Torque Shaft to the Head-to-Rod Connector Set Screws and unthread in a counter clockwise direction.

14.2 Rod Connectors

14.2.1 Assemble the AO Axial Ratcheting Handle (EACEDSAAZ) to the T30 Head-to-Head Connector Torque Shaft (FZ4500000).

14.2.2 Engage the T30 Head-to-Head Connector Torque Shaft to the hex nuts on the Head-to-Head Connectors, then unthread in a counter clockwise direction.

14.3 Rod Connectors / Hooks

14.3.1 Assemble the AO Axial Ratcheting Handle (EACEDSAAZ) to the Rod Connector Torque Shaft (Dark Blue Set Screw – FZ4100000 or Light Blue Set Screw – FZ4200000).

14.3.2 Engage the Rod Connector Torque Shaft to the Set Screw, then unthread in a counter clockwise direction.

14.4 Set Screws and Rods:

14.4.1 Assemble the AO Axial Ratcheting Handle (EACEDSAAZ) to the T15 Set Screw Torque Shaft (Short – FZ3700010 or Long – FZ37000202).

14.4.2 Insert the assembly into the Counter Torque (Offset – FZ3600004 or Axial – FZ3600030).

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

14.4.4 Turn handle counter-clockwise to loosen and remove the Set Screw.

14.4.5 Repeat for each screw.

14.4.6 Grab the rod using the Rod Gripper (FZ2700000) and remove the rod.

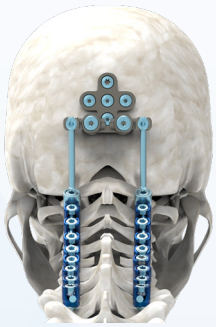
14.5 Polyaxial Screw:

14.5.1 Assemble the AO Axial Ratcheting Handle (EACEDSAAZ) to the T13 Screw Height Adjuster (FZ2000000).

14.5.2 Engage the T13 Screw Height Adjuster to the Screw, then unthread in a counter clockwise direction.

1.0 EXPOSURE

1.1 Use a midline incision to expose the desired portion of the occiput.

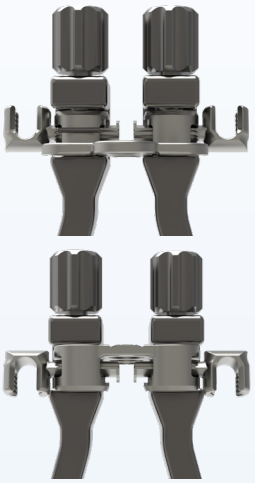


2.0 PLATE/SCREW SELECTION

2.1 BRIDALVEIL Occipital Cervical Thoracic System contains "Midline Plates" in three different widths (Small, Medium, Large) and Bilateral Plates (Right, Left) to accommodate a variety of patient anatomy.

2.2 Select the Occipital Plate (FGAA000XX or FHAA000XX) that will best fit the patient anatomy.

Bilateral plate size	Width Variability	
	Min.	Max.
Small	31mm	33mm
Medium	36mm	42mm
Large	41mm	51mm



3.0 PLATE BENDING

3.1 The BRIDALVEIL Occipital Plate can be contoured to fit a patient's anatomy using the Plate Bending Irons (Right – FZ7600010 and Left – FZ7600020).

4.0 SCREW HOLE DRILLING

4.1 Drill With Drill Guide

4.1.1 Select the Drill Bit (Straight – FZ65000XX, Flexible – FZ6600000) for the screw to be used and the associated Drill Guide (Fixed – FZ630XXXX or Adjustable – FZ6400000).

4.1.2 If using the Adjustable Drill Guide, set to the desired depth.

4.1.3 Insert the Drill Guide into the plate hole.

4.1.4 Insert the drill into the Drill Guide, then drill to the desired depth.

4.2 Angled Driver

4.2.1 Insert the desired Angled Drill Bit (FZ74000XX) into the distal end of the Angled Driver by pulling the sleeve back and inserting. Tug on the Drill to confirm that is it securely attached. Attach the Modular Egg Handle (EDDEATAAZ) or power drill to the AO Connector on the proximal end of the Angled Driver to drill to the desired depth.

4.3 Hold and stabilize the Occipital Plate at the desired location of the occiput using the Occipital Plate Holder (FZ6000000).

4.4 Use the Ball Tip Probe (Short – FZ1600010 or Long – FZ1600020) to probe the hole to ensure proper depth.

5.0 SCREW TAPPING

5.1 Tap With Guide

5.1.1 Select the Tap (Straight – FZ67000XX, Flexible – FZ68000XX or Angled – FZ75000XX) for the screw to be used and a Drill Guide (Fixed – FZ630XXXX or Adjustable – FZ6400000).

5.1.2 If using the Adjustable Drill Guide, set to the desired depth.

5.2 Angled Driver

5.2.1 Insert the desired Angled Tap (FZ6800XXX) into the distal end of the Angled Driver by pulling the sleeve back and inserting. Tug on the Tap to confirm that is it securely attached. Attach the Modular Egg Handle (EDDEATAAZ) to the AO Connector on the proximal end of the Angled Driver.

5.2.2 Insert the Drill Guide and Tap into the Occipital Plate hole, then tap to desired depth using a clockwise motion. Once the desired depth has been achieved, remove Tap by rotating in the counterclockwise motion.

6.0 SCREW INSERTION

6.1 Screwdriver with and without Guide

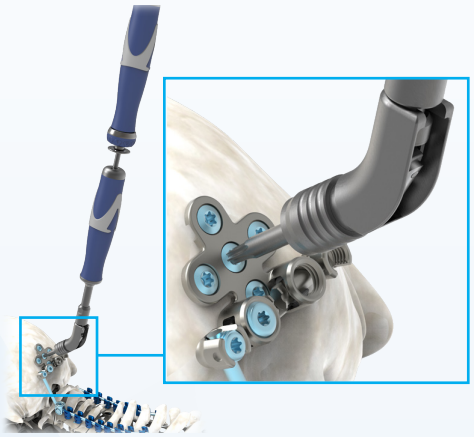
6.1.1 Assemble the Axial AO Ratchet Handle (EACEDSAAZ) and the T15 Screwdriver (Straight – FZ6900000, Flexible – FZ7000000 or Angled FZ7300000) by inserting the proximal end of the Screwdriver into the distal end of the handle. The T15 Occipital Allen Driver (FZ8000000) can also be used if necessary.

6.2 Angled Driver

6.2.1 Insert the Angled Screwdriver Bit (FZ6800XXX) into the distal end of the Angled Driver by pulling the sleeve back and inserting. Tug on the Tap to confirm that is it securely attached. Attach the Modular Egg Handle (EDDEATAAZ) to the AO Connector on the proximal end of the Angled Driver.

6.3 Attach the appropriate Occipital Screw (FJAA450XX or FJAA525XX) onto the Screwdriver by inserting the distal end of the Screwdriver into the screw. The driver will stick into the screw head.

6.4 Insert the Occipital Screw into the tapped hole and rotate clockwise until the desired depth is achieved.



7.0 ROD INSERTION

7.1 Rod Options: The BRIDALVEIL Occipital Cervical Thoracic System supports both Ø3.5mm and Ø4.0mm rods in Pre-Contoured or Hinged, Titanium Alloy (TI64) or Cobalt Chrome (CoCr).

7.2 Use the Rod Template (FZ2100XXX) to determine the appropriate rod contour.

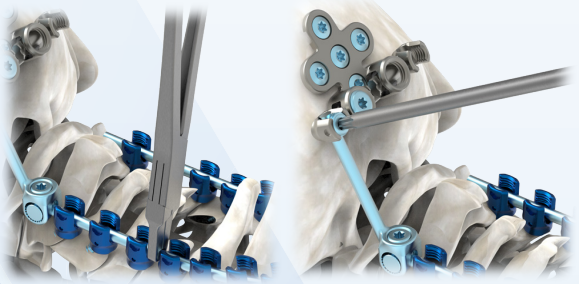
7.3 Use the Rod Bender (FZ2300000) and the Rod Cutter (FZ220000) to achieve the desired rod contour and length.

7.3.1 If using the Hinged Rod, use the T15 Screwdriver to provisionally lock the rod at the desired angle. This proper alignment of the hinge spline mechanisms and ultimate locking performance.

7.4 Place the rod into position using the Rod Inserter (FZ2600000).

7.5 If the rod needs to be bent when already in position, use the In Situ Bender (Coronal – FZ25000XX or Sagittal – FZ24000XX).

7.6 To reposition the rod In Situ, use the Rod Gripper (FZ2700000) or Hex Rod Wrench (FZ4400000) as necessary



8.0 SET SCREW INSERTION AND PROVISIONAL TIGHTENING

8.1 Assemble the Axial AO Ratchet Handle (EACEDSAAZ) and the T15 Screwdriver (Straight – FZ6900000, Flexible – FZ7000000 or Angled - FZ7300000) by inserting the proximal end of the Screwdriver into the distal end of the handle. Load the Set Screws using the T15 Set Screw Inserter (Short – FZ3300020 or Long – FZ3300010). Align the Set Screws into the screw head, then rotate clockwise until provisionally tightened.

8.2 Use the chosen driver to insert the Set Screw into the laterally extending rod connector portion of the occipital plate. Do not tighten; rod must be able to slide within connector.

8.3 Use the chosen driver to insert Set Screw into cervical hooks and/or screws. Do not tighten; rod must be able to slide within connector.

8.4 Use the chosen driver to provisionally tighten the medial Plate Locking Screws.

9.0 FINAL TIGHTENING

9.1 Final tightening of the construct should be performed when all rods are in their final position and in the sequence listed below.
- 9.1.1 Cervical Fixation (Hooks and/or Screws)
- 9.1.2 Medial Occipital Plate Set Screws
- 9.1.3 Lateral Occipital Plate Set Screws
- 9.1.4 Hinge Rod (If Necessary)

9.2 Connect the 26.5 in-lbs. Torque Limiting T-Handle (EBEEJAAZA) to the T15 Occipital Torque Shaft (Straight – FZ7100000, Flexible – FZ7200000 or Angled Driver – FZ7300000).

9.3 If using the T15 Occipital Angled Driver (FZ7300000), attach the Angled Driver Torque Bit (FZ7900000) to the distal end of the Driver.

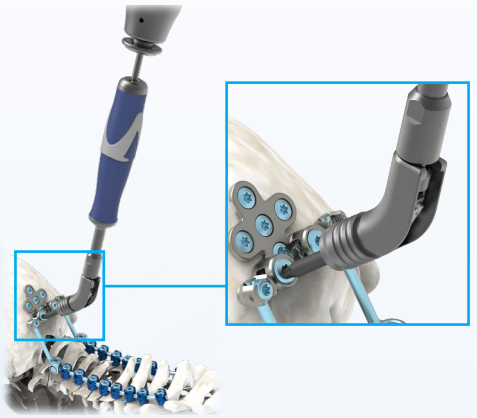
9.4 Insert the assembly into the Occipital Plate Counter Torque (FZ8100000).

9.5 With the Torque Shaft protruding out of the Counter Torque, engage the screw head until fully seated.

9.6 Slide the Counter Torque down until the instrument is fully seated over the rod and screw head.

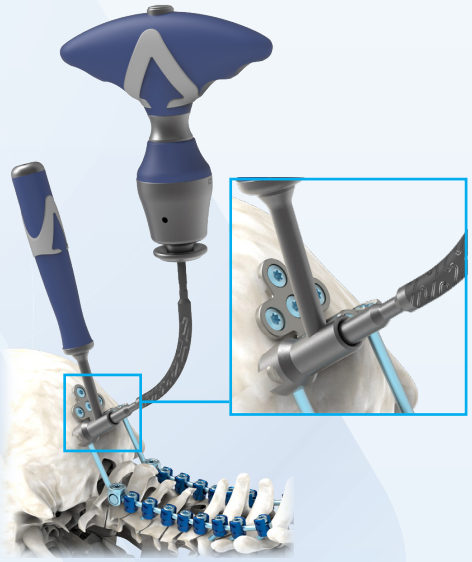
9.7 Turn T-Handle clockwise to tighten. Final tightening is achieved when the T-Handle audibly clicks.

9.8 To final tighten the Hinged Rod Locking Set Screw, stabilize the rod using the Offset Counter Torque (FZ3600004) on the adjacent cervical rod then tighten with the Torque shaft and 26.5 in-lbs. Torque Limiting T-Handle (EBEEJAAZA).



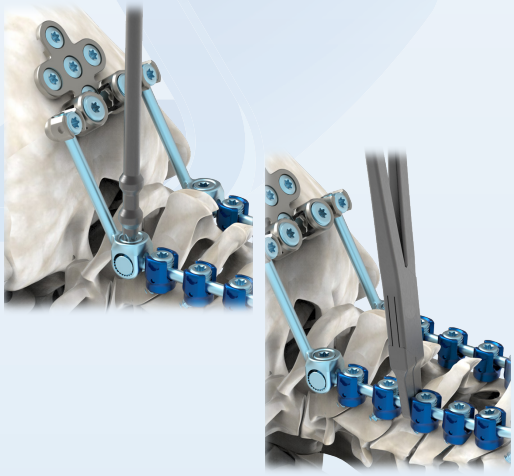
10.0 IMPLANT REMOVAL

10.1 Set Screws and Rods:
- 10.1.1 Assemble the AO Axial Ratcheting Handle (EACEDSAAZ) to the T15 Occipital Torque Shaft (Straight – FZ7100000, Flexible – FZ7200000 or Angled Driver – FZ7300000).
- 10.1.2 If using the Occipital Angled Driver (FZ7300000), attach the T15 Angled Driver Torque Bit (FZ7900000) to the distal end of the Driver.
- 10.1.3 Insert the assembly into the Counter Torque (Offset – FZ3600004 or Axial – FZ3600030).
- 10.1.4 Slide the Counter Torque down until the instrument is fully seated over the rod and screw.
- 10.1.5 Turn handle counter-clockwise to loosen and remove the Set Screw.
- 10.1.6 Repeat for each screw.
- 10.1.7 Grab the rod using the Rod Gripper (FZ2700000) and remove the rod.



10.2 Screws:
- 10.2.1 Assemble the Axial AO Ratchet Handle (EACEDSAAZ) and the T15 Screwdrive (Straight – FZ6900000, Flexible – FZ7000000 or Angled FZ7300000) by inserting the proximal end of the Screwdriver into the distal end of the handle. Compress the spring loaded quick connect ring of the handle to assemble.
- 10.2.2 If using the Angled Screwdriver (FZ7300000), attach the T15 Angled Screwdriver Bit (FZ7800000) to the distal end of the Screwdriver.
- 10.2.3 Insert the tip of the Screwdriver into the screw and turn handle counter-clockwise to loosen and remove the screw.
- 10.2.4 Repeat for each screw.

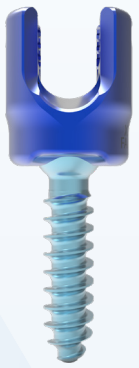
10.3 Plate: Remove the plate using the Occipital Plate Holder (FZ6000000).

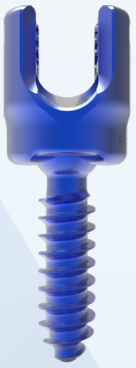


BRIDALVEIL STANDARD IMPLANT OFFERING

POLYAXIAL SCREWS, C/C, SINGLE-LEAD

Part Number	Description	Qty/Set
FAAA35008	Polyaxial Screw, C/C, Single-Lead, 3.5mmx8mm	4
FAAA35010	Polyaxial Screw, C/C, Single-Lead, 3.5mmx10mm	4
FAAA35012	Polyaxial Screw, C/C, Single-Lead, 3.5mmx12mm	12
FAAA35014	Polyaxial Screw, C/C, Single-Lead, 3.5mmx14mm	12
FAAA35016	Polyaxial Screw, C/C, Single-Lead, 3.5mmx16mm	8
FAAA35018	Polyaxial Screw, C/C, Single-Lead, 3.5mmx18mm	8
FAAA35020	Polyaxial Screw, C/C, Single-Lead, 3.5mmx20mm	6
FAAA35022	Polyaxial Screw, C/C, Single-Lead, 3.5mmx22mm	6
FAAA35024	Polyaxial Screw, C/C, Single-Lead, 3.5mmx24mm	6
FAAA35026	Polyaxial Screw, C/C, Single-Lead, 3.5mmx26mm	6
FAAA35028	Polyaxial Screw, C/C, Single-Lead, 3.5mmx28mm	4
FAAA35030	Polyaxial Screw, C/C, Single-Lead, 3.5mmx30mm	4
FAAA35032	Polyaxial Screw, C/C, Single-Lead, 3.5mmx32mm	4
FAAA35034	Polyaxial Screw, C/C, Single-Lead, 3.5mmx34mm	4
FAAA35036	Polyaxial Screw, C/C, Single-Lead, 3.5mmx36mm	4
FAAA40008	Polyaxial Screw, C/C, Single-Lead, 4.0mmx8mm	4
FAAA40010	Polyaxial Screw, C/C, Single-Lead, 4.0mmx10mm	4
FAAA40012	Polyaxial Screw, C/C, Single-Lead, 4.0mmx12mm	4
FAAA40014	Polyaxial Screw, C/C, Single-Lead, 4.0mmx14mm	4
FAAA40016	Polyaxial Screw, C/C, Single-Lead, 4.0mmx16mm	4
FAAA40018	Polyaxial Screw, C/C, Single-Lead, 4.0mmx18mm	4
FAAA40020	Polyaxial Screw, C/C, Single-Lead, 4.0mmx20mm	4
FAAA40022	Polyaxial Screw, C/C, Single-Lead, 4.0mmx22mm	4
FAAA40024	Polyaxial Screw, C/C, Single-Lead, 4.0mmx24mm	4
FAAA40026	Polyaxial Screw, C/C, Single-Lead, 4.0mmx26mm	4
FAAA40028	Polyaxial Screw, C/C, Single-Lead, 4.0mmx28mm	4
FAAA40030	Polyaxial Screw, C/C, Single-Lead, 4.0mmx30mm	4
FAAA40032	Polyaxial Screw, C/C, Single-Lead, 4.0mmx32mm	4
FAAA40034	Polyaxial Screw, C/C, Single-Lead, 4.0mmx34mm	4
FAAA40036	Polyaxial Screw, C/C, Single-Lead, 4.0mmx36mm	4





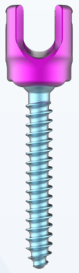
POLYAXIAL SCREWS, M/L, DUAL-LEAD

Part Number	Description	Qty/Set
FAWA45020	Polyaxial Screw, M/L, Dual-Lead, 4.5mmx20mm	4
FAWA45024	Polyaxial Screw, M/L, Dual-Lead, 4.5mmx24mm	4
FAWA45028	Polyaxial Screw, M/L, Dual-Lead, 4.5mmx28mm	4
FAWA45032	Polyaxial Screw, M/L, Dual-Lead, 4.5mmx32mm	4
FAWA45036	Polyaxial Screw, M/L, Dual-Lead, 4.5mmx36mm	4
FAWA45040	Polyaxial Screw, M/L, Dual-Lead, 4.5mmx40mm	4
FAWA50020	Polyaxial Screw, M/L, Dual-Lead, 5.0mmx20mm	4
FAWA50024	Polyaxial Screw, M/L, Dual-Lead, 5.0mmx24mm	4
FAWA50028	Polyaxial Screw, M/L, Dual-Lead, 5.0mmx38mm	4
FAWA50032	Polyaxial Screw, M/L, Dual-Lead, 5.0mmx32mm	4
FAWA50036	Polyaxial Screw, M/L, Dual-Lead, 5.0mmx36mm	4
FAWA50040	Polyaxial Screw, M/L, Dual-Lead, 5.0mmx40mm	4
FA3A55020	Polyaxial Screw, M/L, Dual-Lead, 5.5mmx20mm	6 / OPT
FA3A55024	Polyaxial Screw, M/L, Dual-Lead, 5.5mmx24mm	8 / OPT
FA3A55028	Polyaxial Screw, M/L, Dual-Lead, 5.5mmx28mm	8 / OPT
FA3A55032	Polyaxial Screw, M/L, Dual-Lead, 5.5mmx32mm	8 / OPT
FA3A55036	Polyaxial Screw, M/L, Dual-Lead, 5.5mmx36mm	8 / OPT
FA3A55040	Polyaxial Screw, M/L, Dual-Lead, 5.5mmx40mm	6 / OPT

BRIDALVEIL STANDARD IMPLANT OFFERING

POLYAXIAL SCREW, ML, #1, ML, 3.5mm-XXmm

Part Number	Description	Qty/Set
FANA35008	Polyaxial Screw, ML, #1, 3.5mmx8mm	4
FANA35010	Polyaxial Screw, ML, #1, 3.5mmx10mm	4
FANA35012	Polyaxial Screw, ML, #1, 3.5mmx12mm	12
FANA35014	Polyaxial Screw, ML, #1, 3.5mmx14mm	12
FANA35016	Polyaxial Screw, ML, #1, 3.5mmx16mm	8
FANA35018	Polyaxial Screw, ML, #1, 3.5mmx18mm	8
FANA35020	Polyaxial Screw, ML, #1, 3.5mmx20mm	6
FANA35022	Polyaxial Screw, ML, #1, 3.5mmx22mm	6
FANA35024	Polyaxial Screw, ML, #1, 3.5mmx24mm	6
FANA35026	Polyaxial Screw, ML, #1, 3.5mmx26mm	6
FANA35028	Polyaxial Screw, ML, #1, 3.5mmx28mm	4
FANA35030	Polyaxial Screw, ML, #1, 3.5mmx30mm	4
FANA35032	Polyaxial Screw, ML, #1, 3.5mmx32mm	4
FANA35034	Polyaxial Screw, ML, #1, 3.5mmx34mm	4
FANA35036	Polyaxial Screw, ML, #1, 3.5mmx36mm	4



POLYAXIAL SCREW, ML, #1, ML, 4.0mm-XXmm

Part Number	Description	Qty/Set
FANA40008	Polyaxial Screw, ML, #1, 4.0mmx8mm	4
FANA40010	Polyaxial Screw, ML, #1, 4.0mmx10mm	4
FANA40012	Polyaxial Screw, ML, #1, 4.0mmx12mm	4
FANA40014	Polyaxial Screw, ML, #1, 4.0mmx14mm	4
FANA40016	Polyaxial Screw, ML, #1, 4.0mmx16mm	4
FANA40018	Polyaxial Screw, ML, #1, 4.0mmx18mm	4
FANA40020	Polyaxial Screw, ML, #1, 4.0mmx20mm	4
FANA40022	Polyaxial Screw, ML, #1, 4.0mmx22mm	4
FANA40024	Polyaxial Screw, ML, #1, 4.0mmx24mm	4
FANA40026	Polyaxial Screw, ML, #1, 4.0mmx26mm	4
FANA40028	Polyaxial Screw, ML, #1, 4.0mmx28mm	4
FANA40030	Polyaxial Screw, ML, #1, 4.0mmx30mm	4
FANA40032	Polyaxial Screw, ML, #1, 4.0mmx32mm	4
FANA40034	Polyaxial Screw, ML, #1, 4.0mmx34mm	4
FANA40036	Polyaxial Screw, ML, #1, 4.0mmx36mm	4

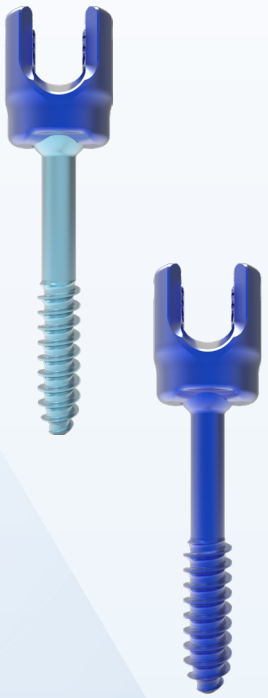
POLYAXIAL SCREW, ML, #2, ML, 5.5mm-XXmm

Part Number	Description	Qty/Set
FA3A55020	POLYAXIAL SCREW ML, #2, 5.5mmx20mm	6
FA3A55024	POLYAXIAL SCREW ML, #2, 5.5mmx24mm	8
FA3A55028	POLYAXIAL SCREW ML, #2, 5.5mmx28mm	8
FA3A55032	POLYAXIAL SCREW ML, #2, 5.5mmx32mm	8
FA3A55036	POLYAXIAL SCREW ML, #2, 5.5mmx36mm	8
FA3A55040	POLYAXIAL SCREW ML, #2, 5.5mmx40mm	6

BRIDALVEIL STANDARD IMPLANT OFFERING

POLYAXIAL SCREWS, C/C, SINGLE-LEAD, SMOOTH SHANK

Part Number	Description	Qty/Set
FACA35018	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 3.5mmx18mm	2
FACA35020	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 3.5mmx20mm	2
FACA35022	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 3.5mmx22mm	2
FACA35024	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 3.5mmx24mm	2
FACA35026	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 3.5mmx26mm	2
FACA35028	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 3.5mmx28mm	2
FACA35030	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 3.5mmx30mm	2
FACA35032	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 3.5mmx32mm	2
FACA35034	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 3.5mmx34mm	2
FACA35036	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 3.5mmx36mm	2
FACA35038	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 3.5mmx38mm	2
FACA35040	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 3.5mmx40mm	2
FACA40018	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 4.0mmx18mm	2
FACA40020	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 4.0mmx20mm	2
FACA40022	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 4.0mmx22mm	2
FACA40024	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 4.0mmx24mm	2
FACA40026	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 4.0mmx26mm	2
FACA40028	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 4.0mmx28mm	2
FACA40030	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 4.0mmx30mm	2
FACA40032	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 4.0mmx32mm	2
FACA40034	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 4.0mmx34mm	2
FACA40036	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 4.0mmx36mm	2
FACA40038	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 4.0mmx38mm	2
FACA40040	Polyaxial Screw, C/C, Single-Lead, Smooth Shank, 4.0mmx40mm	2



POLYAXIAL SCREWS, HIGH TOP

Part Number	Description	Qty/Set
FABA35012	Polyaxial Screw, C/C, Single-Lead, High Top, 3.5mmx12mm	2 / OPT
FABA35014	Polyaxial Screw, C/C, Single-Lead, High Top, 3.5mmx14mm	2 / OPT
FABA35016	Polyaxial Screw, C/C, Single-Lead, High Top, 3.5mmx16mm	2 / OPT
FABA35018	Polyaxial Screw, C/C, Single-Lead, High Top, 3.5mmx18mm	2 / OPT
FABA35020	Polyaxial Screw, C/C, Single-Lead, High Top, 3.5mmx20mm	2 / OPT
FABA35022	Polyaxial Screw, C/C, Single-Lead, High Top, 3.5mmx22mm	2 / OPT
FABA40012	Polyaxial Screw, C/C, Single-Lead, High Top, 4.0mmx12mm	2 / OPT
FABA40014	Polyaxial Screw, C/C, Single-Lead, High Top, 4.0mmx14mm	2 / OPT
FABA40016	Polyaxial Screw, C/C, Single-Lead, High Top, 4.0mmx16mm	2 / OPT
FABA40018	Polyaxial Screw, C/C, Single-Lead, High Top, 4.0mmx18mm	2 / OPT
FABA40020	Polyaxial Screw, C/C, Single-Lead, High Top, 4.0mmx20mm	2 / OPT
FABA40022	Polyaxial Screw, C/C, Single-Lead, High Top, 4.0mmx22mm	2 / OPT
FAYA45024	Polyaxial Screw, M/L, Dual-Lead, High Top, 4.5mmx24mm	2 / OPT
FAYA45028	Polyaxial Screw, M/L, Dual-Lead, High Top, 4.5mmx28mm	2 / OPT
FAYA45032	Polyaxial Screw, M/L, Dual-Lead, High Top, 4.5mmx32mm	2 / OPT
FAYA45036	Polyaxial Screw, M/L, Dual-Lead, High Top, 4.5mmx36mm	2 / OPT
FAYA45040	Polyaxial Screw, M/L, Dual-Lead, High Top, 4.5mmx40mm	2 / OPT
FA4A55024	Polyaxial Screw, M/L, Dual-Lead, High Top, 5.5mmx24mm	2 / OPT
FA4A55028	Polyaxial Screw, M/L, Dual-Lead, High Top, 5.5mmx28mm	2 / OPT
FA4A55032	Polyaxial Screw, M/L, Dual-Lead, High Top, 5.5mmx32mm	2 / OPT
FA4A55036	Polyaxial Screw, M/L, Dual-Lead, High Top, 5.5mmx36mm	2 / OPT
FA4A55040	Polyaxial Screw, M/L, Dual-Lead, High Top, 5.5mmx40mm	2 / OPT

BRIDALVEIL STANDARD IMPLANT OFFERING

STRAIGHT RODS

Part Number	Description	Qty/Set
FCAA35025	Straight Rod, Titanium, 3.5mmx25mm	4
FCAA35030	Straight Rod, Titanium, 3.5mmx30mm	4
FCAA35035	Straight Rod, Titanium, 3.5mmx35mm	4
FCAA35100	Straight Rod, Titanium, 3.5mmx100mm	3
FCAA35200	Straight Rod, Titanium, 3.5mmx200mm	3
FCAA35400	Straight Rod, Titanium, 3.5mmx400mm	3
FCAA40200	Straight Rod, Titanium, 4.0mmx200mm	3
FCAA40400	Straight Rod, Titanium, 4.0mmx400mm	3
FCAB35400	Straight Rod, Cobalt Chrome, 3.5mmx400mm	3
FCAB40400	Straight Rod, Cobalt Chrome, 4.0mmx400mm	3

LORDOTIC RODS

Part Number	Description	Qty/Set
FCBA35040	Lordotic Rod, Titanium, 3.5mm-40mm	4
FCBA35050	Lordotic Rod, Titanium, 3.5mm-50mm	4
FCBA35060	Lordotic Rod, Titanium, 3.5mmx60mm	4
FCBA35070	Lordotic Rod, Titanium, 3.5mmx70mm	4
FCBA35080	Lordotic Rod, Titanium, 3.5mmx80mm	4
FCBA35090	Lordotic Rod, Titanium, 3.5mmx90mm	4
FCBA35100	Lordotic Rod, Titanium, 3.5mmx100mm	4
FCBA35110	Lordotic Rod, Titanium, 3.5mmx110mm	4
FCBA40040	Lordotic Rod, Titanium, 4.0mmx40mm	4
FCBA40050	Lordotic Rod, Titanium, 4.0mmx50mm	4
FCBA40060	Lordotic Rod, Titanium, 4.0mmx60mm	4
FCBA40070	Lordotic Rod, Titanium, 4.0mmx70mm	4
FCBA40080	Lordotic Rod, Titanium, 4.0mmx80mm	4
FCBA40090	Lordotic Rod, Titanium, 4.0mmx90mm	4
FCBA40100	Lordotic Rod, Titanium, 4.0mmx100mm	4
FCBA40110	Lordotic Rod, Titanium, 4.0mm x110mm	4

TRANSITION RODS

Part Number	Description	Qty/Set
FCDA35555	Transition Rod, Ti6al4veli, 3.5mm-5.5mmx500mm	3
FCDA40555	Transition Rod, Ti6al4veli, 4.0mm-5.5mmx500mm	3
FCDB35555	Transition Rod, Cocr, 3.5mm-5.5mmx500mm	3
FCDB40555	Transition Rod, Cocr, 4.0mm-5.5mmx500mm	3

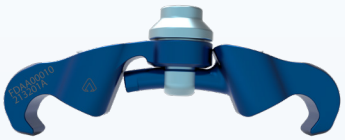
SET SCREWS

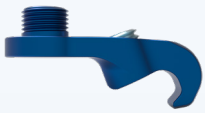
Part Number	Description	Qty/Set
FBAA00000	Polyaxial Screw, Set Screw, Ti6al4veli (T15)	30
FDBA00010	Extended Set Screw (T15)	6

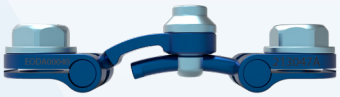
BRIDALVEIL STANDARD IMPLANT OFFERING

CROSS CONNECTORS

Part Number	Description	Qty/Set
FDAA00010	3.5 / 4.0 Variable Cross Connector, Sml	2
FDAA00020	3.5 / 4.0 Variable Cross Connector, Med	2
FDAA00030	3.5 / 4.0 Variable Cross Connector, Lrg	2
FDAA00040	3.5 / 4.0 Variable Cross Connector, Xlg	2
FDBA00020	Head-To-Rod Connector	2
FDDA00010	Head-To-Head Variable Cross Connector, Sml	2
FDDA00020	Head-To-Head Variable Cross Connector, Med	2
FDDA00030	Head-To-Head Variable Cross Connector, Lrg	2
FDDA00040	Head-To-Head Variable Cross Connector, Xlg	2







LATERAL ROD CONNECTORS

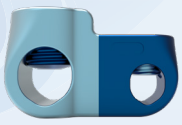
Part Number	Description	Qty/Set
FEBA14010	3.5 / 4.0 Lateral Rod Connector, Side Loading, 10mm	2
FEBA14015	3.5 / 4.0 Lateral Rod Connector, Side Loading, 15mm	2

INLINE ROD CONNECTORS

Part Number	Description	Qty/Set
FECA04040	Inline Transition Rod Connector, 3.5 / 4.0mm, 3.5 / 4.0mm	2
FECA04060	Inline Transition Rod Connector, 3.5 / 4.0mm, 5.5 / 6.0mm	2

OFFSET ROD CONNECTORS

Part Number	Description	Qty/Set
FEDA04040	Offset Rod Connector, Closed, 3.5 / 4.0mm - 3.5 / 4.0mm	2
FEDA04060	Offset Rod Connector, Closed, 3.5 / 4.0mm - 5.5 / 6.0mm	2
FEEA00000	Screw Top Rod Connector, Top Loading	4
FEHA04060	Offset C Rod Connector, Open, 3.5 / 4.0mm - 5.5 / 6.0mm	2



BRIDALVEIL STANDARD IMPLANT OFFERING

OFFSET ROD CONNECTORS

Part Number	Description	Qty/Set
FEHA04040	3.5 / 4.0 Offset Rod Connector, Side/Side Loading	2
FEIA04040	"W" Rod Connector, Top Loading, 3.5 / 4.0mm - 3.5 / 4.0mm	2
FEIA04060	"W" Rod Connector, Top Loading, 3.5 / 4.0mm - 5.5 / 6.0mm	2

FEKA04040	Offset Connector, Top/Side Loading, 3.5 / 4.0mm - 3.5 / 4.0mm	2
FEKA04060	Offset Connector, Top/Side Loading, 3.5 / 4.0mm - 5.5 / 6.0mm	2

FELA00000	5.5 / 6.0 Top Loading Rod Connector Set Screw (T25)	4

ROD EXTENSION CONNECTORS

Part Number	Description	Qty/Set
FEGA40L06	Rod Extension, Left Side-Loading, 3.5 / 4.0mm x 4.0mm x 300mm	2
FEGA40R06	Rod Extension, Right Side-Loading, 3.5 / 4.0mm x 4.0mm x 300mm	2
FEGA60L06	Rod Extension, Left Side-Loading, 5.5 / 6.0mm x 4.0mm x 300mm	2
FEGA60R06	Rod Extension, Right Side-Loading, 5.5 / 6.0mm x 4.0mm x 300mm	2

CABLE CONNECTORS

Part Number	Description	Qty/Set
FEJA40000	Cable Connector 3.5 / 4.0mm	4

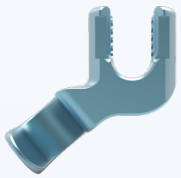
LAMINAR HOOKS

Part Number	Description	Qty/Set
FFAA00050	Laminar Hook, 5.0mm	4 / OPT
FFAA00060	Laminar Hook, 6.0mm	4 / OPT
FFAA00070	Laminar Hook, 7.0mm	4 / OPT
FFAA00080	Laminar Hook, 8.0mm	4 / OPT

BRIDALVEIL STANDARD IMPLANT OFFERING

OFFSET HOOKS

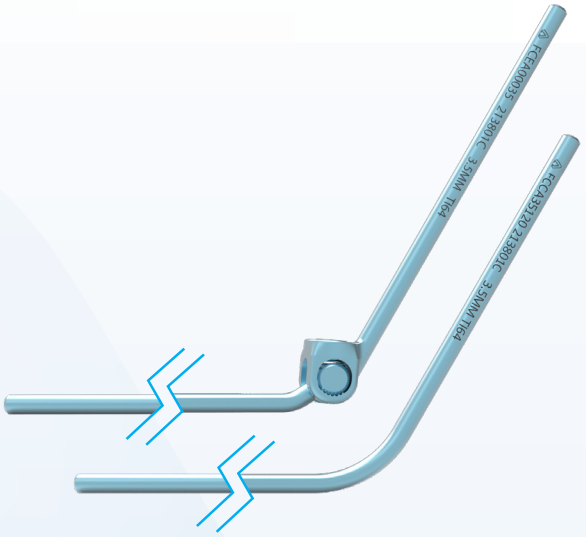
Part Number	Description	Qty/Set
FFBA00L50	Offset Hook, Left, 5.0mm	2 / OPT
FFBA00R50	Offset Hook, Right, 5.0mm	2 / OPT
FFBA00L60	Offset Hook, Left, 6.0mm	2 / OPT
FFBA00R60	Offset Hook, Right, 6.0mm	2 / OPT
FFBA00L70	Offset Hook, Left, 7.0mm	2 / OPT
FFBA00R70	Offset Hook, Right, 7.0mm	2 / OPT
FFBA00L80	Offset Hook, Left, 8.0mm	2 / OPT
FFBA00R80	Offset Hook, Right, 8.0mm	2 / OPT



BRIDALVEIL OCCIPITAL IMPLANT OFFERING

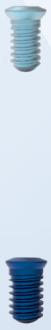
OCCIPITAL RODS

Part Number	Description	Qty/Set
FCCA35120	Occipital Rod, Titanium, 3.5mm-120°	3
FCCA40120	Occipital Rod, Titanium, 4.0mm-120°	3
FCCB35120	Occipital Rod, Cobalt Chrome, 3.5mm-120°	3
FCCB40120	Occipital Rod, Cobalt Chrome, 4.0mm-120°	3
FCEA00035	Hinge Rod, Ti6al4veli, 3.5mm	3
FCEA00040	Hinge Rod, Ti6al4veli, 4.0mm	3
FCEB00035	Hinge Rod, Cocr, 3.5mm	3
FCEB00040	Hinge Rod, Cocr, 4.0mm	3



OCCIPITAL SCREWS

Part Number	Description	Qty/Set
FJAA45006	Occipital Screw, 4.5mmx06mm	6
FJAA45007	Occipital Screw, 4.5mmx07mm	6
FJAA45008	Occipital Screw, 4.5mmx08mm	6
FJAA45009	Occipital Screw, 4.5mmx09mm	6
FJAA45010	Occipital Screw, 4.5mmx10mm	6
FJAA45011	Occipital Screw, 4.5mmx11mm	6
FJAA45012	Occipital Screw, 4.5mmx12mm	6
FJAA45013	Occipital Screw, 4.5mmx13mm	6
FJAA45014	Occipital Screw, 4.5mmx14mm	6
FJAA45015	Occipital Screw, 4.5mmx15mm	6
FJAA45016	Occipital Screw, 4.5mmx16mm	6
FJAA52506	Occipital Screw, 5.25mmx06mm	6
FJAA52507	Occipital Screw, 5.25mmx07mm	6
FJAA52508	Occipital Screw, 5.25mmx08mm	6
FJAA52509	Occipital Screw, 5.25mmx09mm	6
FJAA52510	Occipital Screw, 5.25mmx10mm	6
FJAA52511	Occipital Screw, 5.25mmx11mm	6
FJAA52512	Occipital Screw, 5.25mmx12mm	6
FJAA52513	Occipital Screw, 5.25mmx13mm	6
FJAA52514	Occipital Screw, 5.25mmx14mm	6
FJAA52515	Occipital Screw, 5.25mmx15mm	6
FJAA52516	Occipital Screw, 5.25mmx16mm	6



OCCIPITAL PLATES

Part Number	Description	Qty/Set
FGAA00010	Occipital Plate, Sml, 31mm-33mm	2
FGAA00020	Occipital Plate, Med, 36mm-42mm	2
FGAA00030	Occipital Plate, Lrg, 41mm-51mm	2
FHAA00010	Lateral Occipital Plate, Left	2
FHAA00020	Lateral Occipital Plate, Right	2

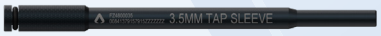
FBAA00000	Polyaxial Screw, Set Screw, Ti6al4veli (T15)	6

BRIDALVEIL CORE INSTRUMENT OFFERING

Part Number	Description	Qty/Set
FZ2100120	Rod Template, 120mm	1
FZ2100400	Rod Template, 400mm	1
FZ1500010	Straight Probe	1
FZ1500020	Curved Probe	1
FZ1800002	T13 Polyaxial Screwdriver, Modular	2
FZ1600010	Ball Tip Probe, Short	1
FZ1600020	Ball Tip Probe, Long	1
FZ1700000	Depth Gauge	1
EACEASADZ	Axial Small AO, Fixed, Spin Top	2
EACEDSAAZ	Axial Small AO, Ratchet	2
EDDEATAAZ	Egg, AO, Fixed	1
EBEEJAAZA	T Handle, AO, Torque Limiting, 26.5 in-lbs	1

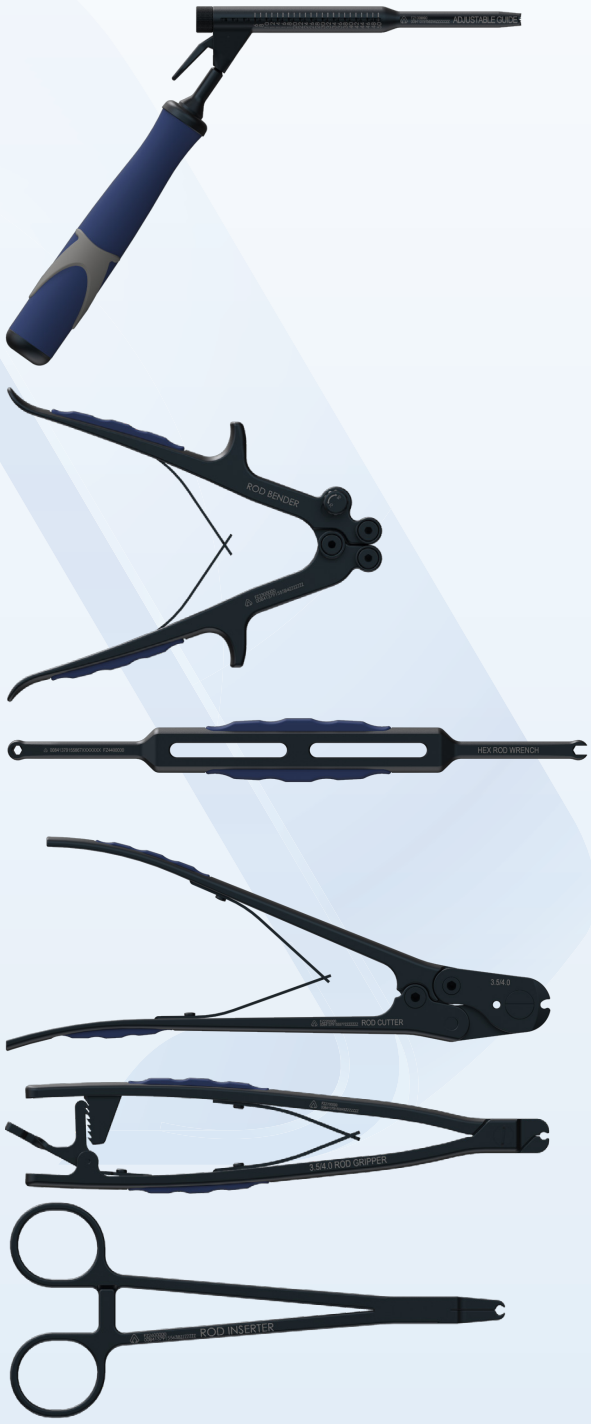
BRIDALVEIL STANDARD IMPLANT OFFERING

Part Number	Description	Qty/Set
EBECJAAZD	T-Handle, 1/4" Sq., Torque Limiting, 60 in-lbs	1
FZ1200130	3.0mm Single-Lead, Tap	1
FZ1200135	3.5mm Single-Lead, Tap	1
FZ1200040	4.0mm #2, Tap	1
FZ1200045	4.5mm #2, Tap	1
FZ1200050	5.0mm #2, Tap	1
FZ1100000	Adjustable Drill, 2.4mm	2
FZ0300010	Fixed Drill, 2.4mmx10mm	2
FZ0300012	Fixed Drill, 2.4mmx12mm	2
FZ0300014	Fixed Drill, 2.4mmx14mm	2
FZ0300016	Fixed Drill, 2.4mmx16mm	2
FZ4800030	3.0mm Tap Sleeve	1
FZ4800035	3.5mm Tap Sleeve	1
FZ4800040	4.0mm Tap Sleeve	1
FZ4800045	4.5mm Tap Sleeve	1
FZ0200000	Fixed Drill Guide	1



BRIDALVEIL CORE INSTRUMENT OFFERING

Part Number	Description	Qty/Set
FZ1000000	Adjustable Drill Guide	1
FZ2300000	Rod Bender	1
FZ4400000	Hex Rod Wrench	1
FZ2200000	3.5 / 4.0mm Rod Cutter	1
FZ2700000	3.5 / 4.0mm Rod Gripper	1
FZ2600000	Rod Inserter	1



BRIDALVEIL STANDARD IMPLANT OFFERING

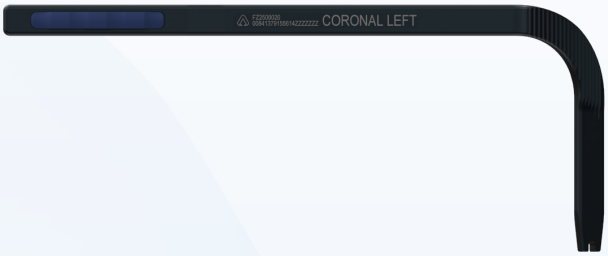
Part Number	Description	Qty/Set
FZ2800000	Rod Rocker	1
FZ4900020	Hook Inserter, Angled	1 / OPT
FZ4700000	Head Manipulator	1
FZ3200000	Reducer Driver	1
FZ3000000	Sequential Reducer	2
FZ3100000	Clip Reducer	2
FZ2900000	Pistol Reducer	1
FZ3300010	T15 Long Set Screw Inserter	2
FZ3300020	T15 Short Set Screw Inserter	2
FZ3800000	T25 5.5 / 6.0mm Rod Connector Set Screw Inserter	1

BRIDALVEIL CORE INSTRUMENT OFFERING

Part Number	Description	Qty/Set
FZ3600006	Offset Counter Torque, Directional, Perpendicular	1
FZ3600005	Offset Counter Torque, Directional, Parallel	1/ OPT
FZ3600040	Axial Counter Torque	1
FZ3700020	T15 Long Set Screw Torque Shaft	2
FZ3700010	T15 Short Set Screw Torque Shaft	2
FZ4100000	T15 3.5 / 4.0mm Rod Connector Torque Shaft	2
FZ4200000	T25 5.5 / 6.0mm Rod Connector Torque Shaft	2
FZ2000000	T13 Screw Height Adjuster Shaft	1
FZ4500000	T30 Screw Cross Connector Torque Shaft	2
FZ4600000	Screw Cross Connector Nut Remover	1
FZ2500010	Coronal In Situ Bender, Right	1

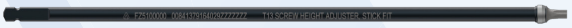
BRIDALVEIL CORE INSTRUMENT OFFERING

Part Number	Description	Qty/Set
FZ2500020	Coronal In Situ Bender, Left	1
FZ2400020	Sagittal In Situ Bender, Right	1
FZ2400010	Sagittal In Situ Bender, Left	1
FZ3400000	Hinged Compressor	1
FZ3500000	Hinged Distractor	1
FZ3400010	Parallel Compressor	1 / OPT



BRIDALVEIL CORE INSTRUMENT OFFERING

Part Number	Description	Qty/Set
FZ3500010	Parallel Distractor	1 / OPT
FZ1400000	Cortical Awl	1 / OPT
FZ1800003	T13 High Top Polyaxial Screwdriver, Modular	1 / OPT
FZ5100000	Stick Fit Screw Height Adjuster	1 / OPT
FZ6200000	High Top Counter Tab Breaker	1 / OPT
FZ4300000	Screw Head Mobilizer	1

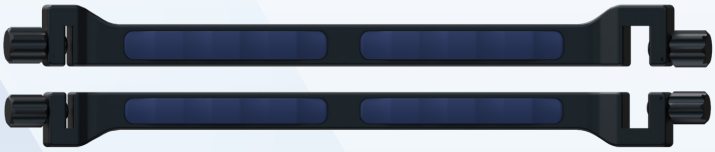


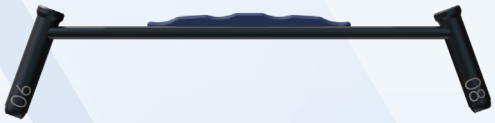
BRIDALVEIL NAVIGATED INSTRUMENT

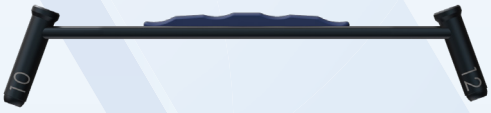
Part Number	Description	Qty/Set	
FZ1300130	Navigated Tap, 3.0mm #1	1	
FZ1300135	Navigated Tap, 3.5mm #1	1	
FZ1300040	Navigated Tap, 4.0mm #2	1	
FZ1300045	Navigated Tap, 4.5mm #2	1	
FZ1300050	Navigated Tap, 5.0mm #2	1	
FZ1900000	Navigated Polyaxial Screwdriver	1	

BRIDALVEIL OCCIPITAL SPECIFIC INSTRUMENT OFFERING

Part Number	Description	Qty/Set
FZ6000000	Occipital Plate Holder	1
FZ7600010	Plate Bending Iron, Right	1
FZ7600020	Plate Bending Iron, Left	1
FZ6300608	Occipital Fixed Drill Guide, 06mm/08mm	1
FZ6301012	Occipital Fixed Drill Guide, 10mm/12mm	1
FZ6301416	Occipital Fixed Drill Guide, 14mm/16mm	1
FZ6301899	Occipital Fixed Drill Guide, 18mm/Screw	1
FZ6400000	Occipital Adjustable Drill Guide	1
FZ6500037	Occipital Drill Straight, 3.7mm	2
FZ6600037	Occipital Drill Flexible, 3.7mm	2
FZ6700450	Occipital Tap, Straight, 4.5mm	1
FZ6700525	Occipital Tap, Straight, 5.25mm	1





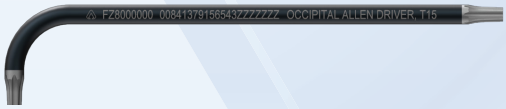


BRIDALVEIL OCCIPITAL SPECIFIC INSTRUMENT OFFERING

Part Number	Description	Qty/Set
FZ6800450	Occipital Tap, Flexible, 4.5mm	1
FZ6800525	Occipital Tap, Flexible, 5.25mm	1
FZ6900000	T15 Occipital Screwdriver, Straight	1
FZ7000000	T15 Occipital Screwdriver, Flexible	1
FZ7100000	T15 Occipital Torque Driver, Straight	2
FZ7200000	T15 Occipital Torque Driver, Flexible	2

FZ7300000	Occipital Angled Driver	1

FZ8000000	T15 Occipital Allen Driver	1



FZ8100000	Occipital Plate Counter Torque	1

FZ7400006	Angled Drill Bit, 6mm	2

FZ7400008	Angled Drill Bit, 8mm	2

FZ7400010	Angled Drill Bit, 10mm	2

BRIDALVEIL OCCIPITAL SPECIFIC INSTRUMENT OFFERING

Part Number	Description	Qty/Set	
FZ7400012	Angled Drill Bit, 12mm	2	
FZ7400014	Angled Drill Bit, 14mm	2	
FZ7400016	Angled Drill Bit, 16mm	2	
FZ7500450	Angled Tap Bit, 4.5mm	1	
FZ7500525	Angled Tap Bit, 5.25mm	1	
FZ7800000	T15 Angled Screwdriver Bit	2	
FZ7900000	T15 Angled Torque Bit	2	
BZ9700000	Bridalveil, Instrument Tray 2	1	
BZ9800000	Bridalveil, Instrument Tray 1	1	
BZ9900000	Bridalveil, Implant Tray	1	

1.0 IMPORTANT NOTE TO OPERATING SURGEON: BRIDALVEIL 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 BRIDALVEIL Occipital Cervical Thoracic System (OCTS) is an occipito-cervical-thoracic fixation system to provide fixation during the fusion process. The system is composed of preassembled lateral mass/pedicle polyaxial screws, Set Screws, hooks, rods, cross connectors, rod connectors, and occipital plates and screws. 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.

Material	Conforming Standard
CoCr	ASTM F1537
Ti-6Al-4V ELI	ASTM F136
Elgiloy	ASTM F1058
Nitinol SINGLE-LEAD	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 BRIDALVEIL OCTS must not be reused under any circumstances. These instructions for use are designed to assist in use of the BRIDALVEIL OCTS and are not a reference for surgical techniques.

4.0 INDICATIONS: The BRIDALVEIL Occipital Cervical Thoracic System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The BRIDALVEIL Occipital Cervical Thoracic System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the BRIDALVEIL Occipital Cervical Thoracic System may be connected to the OLYMPIC Posterior Spinal Fixation System rods and connectors. Transition rods with differing diameters may also be used to connect the BRIDALVEIL Occipital Cervical Thoracic System to the OLYMPIC Posterior Spinal Fixation System. Refer to the OLYMPIC Posterior Spinal Fixation System package insert for instructions for use and indications for use.

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 relativecontraindications 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. Malpositioned 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.

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 donot 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 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.

7.1.2 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.

7.1.3 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

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

7.1.4.1 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.

7.1.4.2 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.

7.1.4.3 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.

7.1.4.4 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.

7.1.4.5 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.

The BRIDALVEIL OCTS has not been evaluated for safety and compatibility in the MR environment. The BRIDALVEIL OCTS has not been tested for heating, migration, or image artifact in the MR environment. The safety of BRIDALVEIL OCTS 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 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 dmanding 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.

7.2.2 BRIDALVEIL OCTS components should not be used with components from other manufacturers. Stainless steel components may interfere with the quality of imaging obtained using MRI.

INSTRUCTIONS FOR USE

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

7.2.4 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.

7.2.5 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.

7.2.6 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.

7.2.7 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.

7.2.8 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.

7.2.9 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.

7.2.10 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.

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 BRIDALVEIL OCTS 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 BRIDALVEIL OCTS from any of its representatives.

8.10 Use of cross sectional imaging (i.e., CT and/or MRI) for posterior cervical screw placement is recommended due to the unique risks in the cervical spine. The use of planar radiographs alone may not provide the necessary imaging to mitigate the risk of improper screw placement. In addition, the use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

9.0 INTRAOPERATIVE

9.1 Any instruction manual 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 orcasting) 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 BRIDALVEIL OCTS 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 proucts should not be used, and should be returned immediately to BRIDALVEIL OCTS.

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. 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:

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

Wrap tray with a towel placed between tray and FDA cleared wrap. 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 BRIDALVEIL OCTS. 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. This statement is not required for the parameters listed above.

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 BRIDALVEIL OCTS component(s) ever malfunctions, ASTURA MEDICAL or its representative must be notified immediately. If any BRIDALVEIL OCTS 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 BRIDALVEIL OCTS 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
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INSTRUCTIONS FOR USE

BRIDALVEIL NAVIGATED INSTRUMENT SYSTEM

INSTRUCTIONS FOR USE

1.0 IMPORTANT NOTE TO OPERATING SURGEON: As with any major surgical procedure, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur are: early or late infection, which may result in the need for additional surgeries, damage to blood vessels, spinal cord or peripheral nerves, pulmonary emboli, loss of sensory and/or motor function, impotence, permanent pain and/or deformity. Rarely, some complications may be fatal.

2.0 DESCRIPTION: The BRIDALVEIL 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 Synergy Spine and Trauma 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. These instructions for use are designed to assist in use of the BRIDALVEIL NAVIGATED INSTRUMENT SYSTEM and are not a reference for surgical techniques.

4.0 INDICATIONS: The BRIDALVEIL NAVIGATED INSTRUMENTS are intended to be used in the preparation and placement of BRIDALVEIL 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.

5.0 CONTRAINDICATIONS: The BRIDALVEIL NAVIGATED INSTRUMENT SYSTEM, as with other orthopedic instruments, is contraindicated for use in patients with:

5.1 Active infectious process or significant risk of infection (immuno¬compromise).
5.2 Signs of local inflammation.
5.3 Fever or leukocytosis.
5.4 Morbid obesity.
5.5 Pregnancy.
5.6 Mental illness.
5.7 Grossly distorted anatomy caused by congenital abnormalities.
5.8 Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
5.9 Suspected or documented metal allergy or intolerance.
5.10 Any case not needing a bone graft and fusion.
5.11 Any case where the implant components selected for use would be too large or too small to achieve a successful result.
5.12 Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
5.13 Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
5.14 Any patient unwilling to follow postoperative instructions.
5.15 Any case not described in the indications.
5.16 The BRIDALVEIL NAVIGATED INSTRUMENT SYSTEM is designed for use with BRIDALVEIL screws and the Medtronic SteathStation® System, as such all contraindications applicable to the BRIDALVEIL screws and/or the Medtronic StealthStation® System are also applicable to the BRIDALVEIL NAVIGATED INSTRUMENT SYSTEM. Refer to the Astura BRIDALVEIL Posterior Spinal Fixation System Instructions For Use (INS-00006) regarding the contraindications for OLYMPC PSFS screws.

6.0 POSSIBLE ADVERSE EVENTS

Potential adverse events include, but are not limited to:

6.1 Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy).
6.2 Pedicle screw malpositioning, with or without neurological or vascular injury.
6.3 Proximal or distal junctional kyphosis.
6.4 Pancreatitis.
6.5 Device component fracture.
6.6 Fracture of the vertebra.
6.7 Neurological injury.
6.8 Vascular or visceral injury.
6.9 Foreign body (allergic) reaction to instruments, debris and corrosion products, including metallosis, straining, tumor formation, and/or auto-immune disease.
6.10 Infection.
6.11 Pain, discomfort, or abnormal sensations due to the presence of the device.
6.12 Hemorrhage.
6.13 Death.
6.14 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.
6.14.1 The system should not be used with screw systems other that the BRIDALVEIL system.
6.14.2 The instruments should be inspected for damage prior to use. If they are bent or damaged in any way, they should not be used, regardless of navigated or manual procedures.
6.14.3 During navigated use, the instruments should be continually assessed for accuracy (e.g. intraoperatively checking the projected tip of the instrument against a pedicle to ensure proper tracking).
6.14.4 Discontinue the use of navigation instruments in the event of a registration failure or suspected inaccuracy. The instruments should not be used with the navigation system, and the instruments should be inspected for damage before continuing with the traditional, non-navigated procedure.
6.14.5 The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of 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 malpositioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may have reduced longitudinal spinal growth or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine.
6.14.6 The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.
6.14.7 Preoperative and operative procedures, including knowledge of surgical techniques, good reduction and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.
6.14.8 The selection of the proper size, shape and design of the implant for each patient is crucial to the safe use of the device in pediatric patients.
6.14.9 The safety and effectiveness of pedicle screw 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 neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition are unknown.
6.14.10 The benefit of spinal fusion utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
6.14.11 The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of the pedicle screw spinal system because they are technically demanding procedures presenting a risk of serious injury to the patient.
6.14.12 The safety, efficacy and performance of the system have been established for conditions in which the system is used as intended and when used as identified in the Indications for Use. Performance of the system has not been evaluated for use that is contrary to the Intended Use, Indications for Use or for use that in contraindicated. Failure to use the system as indicated could detrimentally affect the performance of its components.
6.14.13 ASTURA MEDICAL does not warrant Medtronic Navigation Software. It is the sole responsibility of the user to ensure instrument calibration and/or registration.

7.0 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.

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

9.0 CLEANING: All instruments must first be cleaned before sterilization and introduction into a sterile surgical field. 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 warm distilled water. 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 distilled water and 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 warm running distilled 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.

10.0 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:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Prevacuum	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 BRIDALVEIL NAVIGATED INSTRUMENT SYSTEM. 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.
This statement is not required for the parameters listed above.

11.0 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 NAVIGATED INSTRUMENT SYSTEM instruments ever malfunctions, ASTURA MEDICAL or its representative must be notified immediately. If any BRIDALVEIL NAVIGATED INSTRUMENT 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.

12.0 COMPANY INFORMATION

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