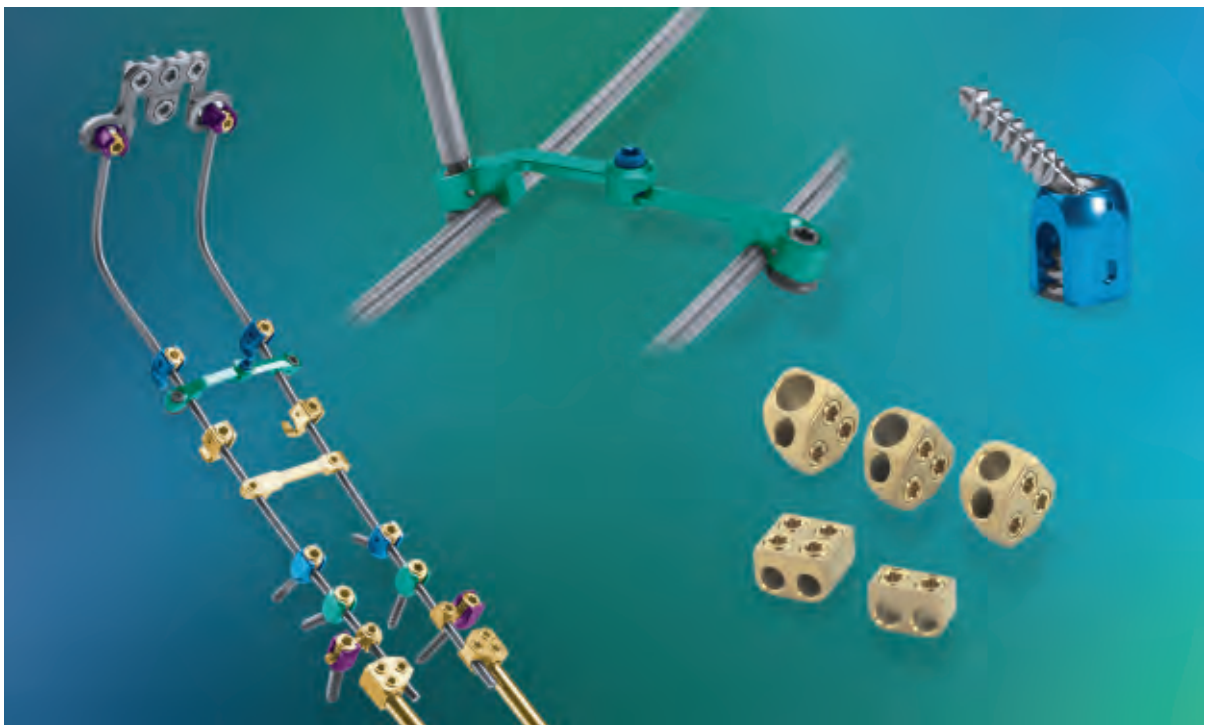


Altius™ M-INI™
Occipito-Cervico-Thoracic System

Surgical Technique



Altius M-INI™



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Introduction

The **Altius M-INI** Occipito-Cervico-Thoracic Spinal Fixation System is a universal system designated to facilitate reconstruction of the cervical and upper thoracic spine. Offering exceptional versatility and ease-of-use, the **Altius M-INI** System features:

- *Top-loading Multi-Axial Screws to simplify construct assembly*
- *Friction fit Screws to maintain seat alignment and facilitate Rod insertion*
- *3.5mm titanium alloy Rods to maximize strength*
- *Innovative Helical Flange™ technology to minimize cross threading*
- *Occipital Plates with sliding connectors to ease Rod engagement*



System Design Features

Altius M-INI OCT System

All implants in the **Altius M-INI OCT System** are manufactured in Titanium alloy, Ti6Al-4V ELI.

Multi-Axial Screws

- Top-loading
- Friction Fit
- Self-tapping
- Up to 56° of conical angulation
- 3.5mm, 4.0mm and 4.5mm diameters
- 10mm-32mm lengths
- 3.5mm x 20mm-50mm Smooth Shank Screws



Preferred Angle Screws

- 45° in the preferred direction, an addition of 15° over the standard screw
- Up to 73° of total sweep
- 3.5mm Diameter, 10-22mm length
- 10° medial and lateral variability in the preferred direction



Occipital Plates

- Low profile
- 4 points of fixation
- Midline and lateral fixation
- 30mm-40mm, 35mm-45mm, 40mm-50mm

Helical Flange Plugs

- Minimize cross threading
- Ease Rod reduction
- Minimize seat splaying



Rods

- 3.5mm diameter
- Pre-contoured
- Pre-cut length
- 3.5mm/4.75mm, 3.5mm/5.5mm and 3.5mm/6.35mm Transitional Rods



Cross Connectors

- Arched, telescoping design
- Fit over challenging anatomy
- 20-80mm variable widths, 4 sizes
- Fixed and adjustable versions available as special order items
- New accessory caddy to fit telescoping connectors



Accessories

- 4.5mm and 6.0mm top-loading **Helical Flange** Hooks
- 3.5/3.5mm, 3.5/4.75mm, 3.5/5.5mm, and 3.5/6.35mm rod connectors



Instrumentation

- Surgeon-designed
- User-friendly

Occipito-Cervical Fixation

The **Altius M-INI** Occipital Plate offers low-profile fixation along the midline of the occiput, where the most bone purchase can be obtained. The plate features four fixation points using 5.0mm screws with fine threads to maximize pullout strength in cortical bone. The Rods affix to the plate using **Helical Flange** Plug technology, which minimizes cross-threading and eases Rod insertion. Pre-contoured Occipital Rods are also available in the standard Occipital Tray.



Cervico-Thoracic Fixation

The **Altius M-INI** OCT System offers a variety of stabilization options in the cervical and upper thoracic spine. Multi-Axial Screws, Cross Connectors, Lateral Connectors and **Helical Flange** Hooks are available to meet the needs of the most challenging cases.

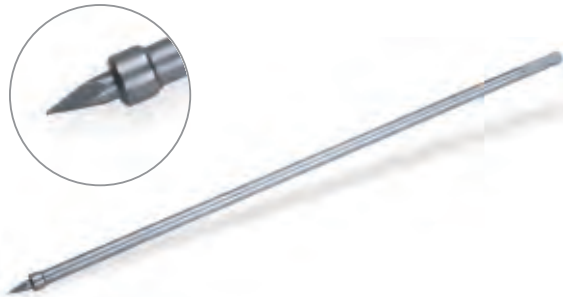
Instruments



1100-9509M Quick Connect Handle-T



1100-9501 Quick Connect Handle-Straight



1200-9004 Awl



1100-9027 10mm Fixed Depth Drill

1100-9028 12mm Fixed Depth Drill

1100-9029 14mm Fixed Depth Drill

1100-9030 16mm Fixed Depth Drill

1100-9031 18mm Fixed Depth Drill

1100-9032 20mm Fixed Depth Drill

1100-9033 22mm Fixed Depth Drill



1200-9011 Adjustable Depth Drill



1200-9010 Drill Guide



1200-9018 Tap Guide



1200-9019 3.5mm Tap

1200-9020 4.0mm Tap

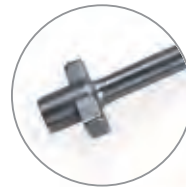
1200-9022 4.5mm Tap



4010 Ball Tip Probe



1200-9015 Probe



1200-9216 Multi-Axial Screw Inserter



1200-9024 Rod Template



1200-9030 Rod Holder

Instruments (Continued)



1200-9031 Rod Gripper



1200-9201 Seat Alignment Tool



1200-9032 Rod Cutter



1200-9036 Bending Iron



1200-9033 Rod Bender



1200-9203 Plug Starter



1200-9225 Hook Inserter



1200-9221 Compressor



1200-9039 Hook Site Elevator



1200-9002 **Helical Flange** Torque Wrench

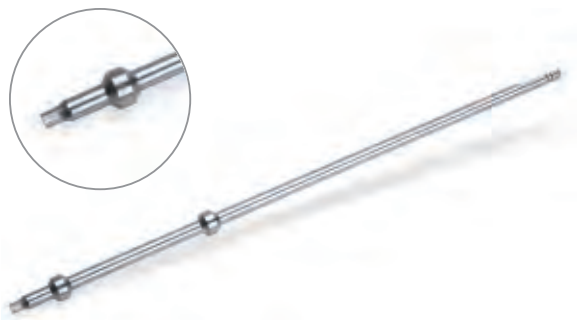


1200-9220 Distractor



1200-9125 **Helical Flange** Torque Wrench-T

Instruments (Continued)



1200-9205 Plug Driver



1200-9230 Rod Reducer



1200-9207 Torque Stabilizer



1200-9232 Cross Connector Stabilizer



1200-9003 Set Screw Driver



1200-9027 Set Screw Torque Wrench



1200-9109M 30-40mm Occipital Plate Template

1200-9110M 35-45mm Occipital Plate Template

1200-9111M 40-50mm Occipital Plate Template



1200-9101M Occipital Drill/Tap Guide



1200-9103 Occipital Drill



1200-9104 Occipital Tap



1200-9100 Plate Holder



1200-9115 Occipital Screw Starter



1200-9114 Multi-Angle Occipital Screw Starter



1200-9105 Occipital Screw Holder

Instruments (Continued)



- 1200-9116 Occipital Torque Stabilizer Handle
- 1200-9121 15° Occipital Torque Stabilizer Adapter
- 1200-9122 30° Occipital Torque Stabilizer Adapter
- 1200-9123 45° Occipital Torque Stabilizer Adapter



1200-9138 Multi-Angle Plug Starter

Surgical Technique

Surgical Approach And Preparation

Availability of appropriate imaging equipment should be confirmed prior to beginning surgery in order to properly identify the anatomic variability of individual patients.

Patients should be placed in the prone position and, when possible, in physiological alignment. Alignment should be confirmed with imaging and direct visualization prior to beginning site preparation.

A standard midline approach may be used to expose the spinous processes and laminae of the vertebrae to be fused. If the procedure includes occipito-cervical fusion, the exposure may be extended to the external occipital protuberance (EOP).

Care must be taken to avoid vital structures including but not limited to the vertebral arteries, nerve roots and the spinal cord.

Cervico-Thoracic Fixation

The **Altius M-INI** OCT System offers a variety of stabilization options in the cervical and upper thoracic spine. Multi-Axial Screws, Cross Connectors, Lateral Connectors and **Helical Flange** Hooks are available to meet the needs of the most challenging cases.



The following Surgical Technique outlines the recommended placement and use of **Altius M-INI** OCT System components. Actual selection of system implants may vary from those described in this technique depending on procedural and anatomical considerations.

Surgical Technique (Continued)

Multi-Axial Screw Placement



The **Altius M-INI** OCT System features top-loading and top-tightening Multi-Axial Screws. Preferred Angle Screws offer 45° in the preferred direction and 28° in the standard direction. Standard Multi-Axial screws offer 56° of conical angulation and have a friction-fit mechanism to maintain screw angulation during placement. Please note that Multi-Axial Screws are intended for use in the upper thoracic spine.

Punch

Following preparation of the relevant posterior spinal elements, determine the entry point and trajectory of the screw.

Mark the entry point using a burr or the included Awl to penetrate the cortical bone. The Awl contains a stop that limits insertion to 8.0mm.

Creating a pilot hole with the Awl penetrates the cortical bone, which will help prevent movement of the Drill and Drill Guide during drilling.

Repeat for all screw placement sites.



Drill

Select the appropriate length of Fixed Depth Drill. Drills are available in lengths of 10mm-22mm in 2.0mm increments and attach to the provided Quick Connect Handles. An Adjustable Depth Drill is also included.

After attaching the appropriate Drill shaft to the Quick Connect Handle, align the Drill Guide with the pilot hole and maintain the desired drill trajectory.

Insert the Drill into the barrel of the Drill Guide and rotate clockwise while advancing the drill down the Drill Guide.

When using Fixed Depth Drills, the appropriate depth is reached when the stop on the Drill shaft contacts the stop on the Drill Guide. When using the Adjustable Depth Drill, the appropriate depth is reached when the desired depth marking on the drill shaft aligns with the depth indicator line etched on the handle of the Drill Guide.

Once the desired depth is reached, gently remove the shaft of the Drill.

A Ball Tip Probe or Probe may be used to confirm that the drill hole remains within the confines of the bone.

The depth of the drill hole can be confirmed using the Depth Gauge by inserting the tip of the Depth Gauge into the drill hole until the tip contacts the bottom of the hole.

Repeat for all screw placement sites.



Surgical Technique (Continued)

Tap

Please note that **Altius M-INI** Multi-Axial Screws are self-tapping and that manual tapping may not be necessary.

Taps are provided in 3.5mm, 4.0mm and 4.5mm diameters and may be used with the Tap Guide.

After attaching the Tap shaft to the Quick Connect Handle, align the Tap Guide with the drill hole and maintain the desired Tap trajectory.

Insert the Tap shaft into the barrel of the Tap Guide and rotate clockwise while advancing the Tap down the Tap Guide until resistance is met.

Remove the Tap by rotating the shaft counter-clockwise.

Repeat for all screw placement sites.



Screw Selection

After drilling/tapping the hole, use the Depth Gauge to confirm the length of Multi-Axial Screw to be inserted. Screw length may be confirmed using the gauge located on the screw caddy.

Multi-Axial Screw Insertion

After confirming the appropriate screw length, load the screw onto the Multi-Axial Screw Inserter by inserting the hex of the screw head into the distal tip of the Screw Inserter.

Secure the screw to the Multi-Axial Screw Inserter by turning the threaded collar on the Multi-Axial Screw Inserter shaft clockwise until the shaft is completely engaged with the seat of the screw.

NOTE: This technique applies to the Preferred Angle Screws as well.



Screw Insertion (Continued)

Insert the Multi-Axial Screw Inserter into the previously drilled/tapped hole by rotating the Inserter clockwise to gently advance the screw to the desired depth.

Once the desired depth is reached, disengage the Multi-Axial Screw Inserter from the Inserter Screw by rotating the threaded collar on the shaft counter clockwise until the Inserter is completely disengaged.

The seat on the Preferred Angle Screw can be manipulated so that it faces the preferred direction in the cephalad or caudal direction. The Preferred Angle Screw has a black laser marking on the seat which delineates where the preferred angle is facing. If the anatomy requires the preferred angle to face medially or laterally, a lateral connector can be utilized for proper seating of the screw.

Repeat for all screw placement sites.



Laminar Helical Flange Hook Placement

The **Altius M-INI** OCT System offers both 4.5mm Standard and 6.0mm Extended **Helical Flange** Hook sizes. Both are top-loading and top-tightening for easy insertion and tightening.



Surgical Technique (Continued)

Hook Insertion

Determine the size of **Helical Flange** Hook required.

Secure the Hook to the Hook Inserter by rotating the threaded collar on the Hook Inserter shaft clockwise until the shaft is completely engaged with the seat of the Hook.

The Hook Site Elevator may be used to elevate the lamina during Hook insertion.

Insert the Hook onto the lamina using the Hook Inserter.

Once the hook is inserted, disengage the Hook from the Hook Inserter by rotating the threaded collar on the Hook Inserter shaft counterclockwise until the Hook is completely disengaged.

Repeat for all Hook placement sites.



Rod Preparation

The Rod Template may be used to determine the appropriate length and curvature of the Rod.



Cut the Rod to the appropriate length using the Rod Cutter and contour the Rod to the appropriate shape using the Rod Bender or Bending Irons. Do not straighten the Rod after bending.



Rod Insertion

The Seat Alignment Tool may be used to align the seat of each screw so that the rod channels of adjacent screws are parallel.

Insert the Rod into the seat of each Screw and Hook using the Rod Holder.

The Rod Reducer or Persuader may be used if additional assistance is required to fully position the Rod into the seat of the Screw or Hook.

Helical Flange Plugs may be inserted and provisionally tightened using the Plug Starter while the Rod Reducer is engaged.



Additional Surgical Options

Screw Positioning

The Compressor and Distractor may be used to perform minor Screw adjustments.

Helical Flange Plug Application



Insert the **Helical Flange** Plug into the seat of the Screw or Hook using the Plug Starter and provisionally tighten.

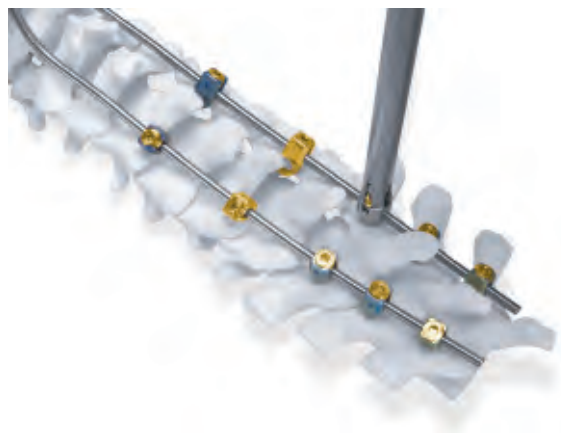
Final Tightening

To maintain torsional stability of the construct, the Torque Stabilizer must be used during final tightening of **Helical Flange** Plugs for both screws and hooks.

Attach the Torque Stabilizer to the seat of the Screw or Hook to be tightened.

Attach the Quick-Connect Plug Driver to the straight or T gold **Helical Flange** Torque Wrench handle and advance the shaft of the assembly down the Torque Stabilizer until it is fully inserted into the **Helical Flange** Plug.

Rotate the handle clockwise until an audible click is heard and tension is released within the handle. The gold **Helical Flange** Torque Wrench will release torque at a minimum of 40 in-lbs.



Linkage To Other Biomet Spinal Systems

Transitional Rods and Rod Connectors are available to link the **Altius M-INI** OCT System with other Biomet Spinal Systems. Transitional Rods and Rod Connectors are offered in 3.5mm/4.75mm, 3.5mm/5.5mm and 3.5mm/6.35mm sizes.



Rod Connector Placement

Approximate the size, length and contour of the Rod to be extended with the Rod to be joined.

Slightly disengage the Set Screws from the Rod Connector by inserting the Set Screw Driver and rotating it counterclockwise.

Slide the Rod Connector onto the 3.5mm **Altius M-INI** Rod so that the Rod passes through the 3.5mm Rod Connector hole and provisionally tighten using the Set Screw Driver.

Insert the Rod to be connected to the 3.5mm **Altius M-INI** Rod through the remaining hole and provisionally tighten.

Perform final tightening by attaching the Set Screw Driver to the blue Set Screw Torque Wrench handle and rotating clockwise until an audible click is heard and tension is released within the handle.

Additional Surgical Options (Continued)

Offset Lateral Connector Placement



The **Altius M-INI** OCT System offers Standard and Variable Offset Lateral Connectors to provide up to 12mm of additional medial-lateral screw placement flexibility. Standard Offset Lateral Connectors are semi-circular with a flat, knurled top. Variable Offset Lateral Connectors are round and offer 360° of rotation in the axial plane.

Offset Lateral Connectors should be attached to the Rod prior to Rod insertion.

Insert the Rod through the selected Offset Lateral Connector in the appropriate position and provisionally tighten the Set Screw using the Set Screw Driver.

The Offset Lateral Connector should be provisionally tightened to maintain position, but loose enough to allow for rotation and/or travel along the Rod.

Place the Connector in the appropriate position.

Repeat for all Offset Lateral Connector sites.

Cross Connector Placement

The **Altius M-INI** OCT System offers three Cross Connector options: Arched Telescoping, Fixed and Adjustable.

Telescoping Cross Connectors



Telescoping Cross Connectors are available in four sizes, accommodating widths of 20-80mm. The **Altius M-INI** cervico-Thoracic Case contains these parts in quantities of two each.

In the event that additional torsional stability is required, a cross connector may be utilized. All Cross Connectors should be attached to the construct after tightening the plugs. Determine the size Cross Connector to be utilized. Attach the Set Screw Torque Handle to the Set Screw Driver Shaft. Apply the Cross Connector to the rods and tighten the screws with the Set Screw Torque Wrench until an audible click is heard, applying 20 in-lbs of force. Tighten the outer set screws, then the central set screw. The Cross Connector Stabilizer may be used to obtain the audible click.

Final Tightening

For Set Screws on Offset Lateral Connectors, Cross Connectors and Rod Connectors, attach the Set Screw Driver to the blue Set Screw Torque Wrench handle and fully insert it into the Set Screw.

Rotate clockwise until an audible click is heard and tension is released within the handle. The blue Set Screw Torque Wrench will release torque at a minimum of 20 in-lbs.



Surgical Technique

Occipito-Cervical Fixation

The **Altius M-INI** Occipital Plate offers low-profile fixation along the midline of the occiput, where the most bone purchase can be obtained. The plate features four fixation points using 5.0mm screws with fine threads to maximize pullout strength in cortical bone. The Rods affix to the plate using **Helical Flange** Plug technology, which minimizes cross-threading and eases Rod insertion. Pre-contoured Occipital Rods are also available in the standard Occipital Tray.



Occipital Plate And Screw Selection

Use the Occipital Plate Templates to select the appropriate Occipital Plate size based on anatomy.

Once an appropriate size Plate has been selected, gently bend the Plate to the appropriate radius. Do not bend the Plate near the sliding connectors. Do not straighten the Plate after bending.

Mark the entry points where the Occipital Bone Screws will be inserted through the holes in the Occipital Plate.

The Occipital Plate should sit flush against the occiput. It may be necessary to remove small amounts of occipital bone to optimize the plate-to-bone interface. Do not remove bone near areas of screw placement.

Determine the lengths of Occipital Bone Screws required via preoperative planning or fluoroscopy.

Drill

Attach the Occipital Drill shaft to a Quick Connect Handle.

Set the Occipital Drill/Tap Guide to the appropriate depth, then lock the Guide by closing and locking the handle.

Visually confirm the appropriate depth in the depth indicator window of the Drill/Tap Guide after the handle is locked.

Insert the Occipital Drill shaft into the barrel of the Drill/Tap Guide and rotate clockwise while advancing the drill down the Occipital Drill/Tap Guide. The appropriate depth is reached when the stop on the Occipital Drill shaft contacts the stop on the Occipital Drill/Tap Guide.

Repeat for all screw placement sites.



Tap

Attach the Occipital Tap shaft to a Quick Connect Handle.

Set the Occipital Drill/Tap Guide to the appropriate depth, then lock the Guide by closing and locking the handle.

Visually confirm the appropriate depth in the depth indicator window of the Occipital Drill/Tap Guide after locking.

Insert the Occipital Tap shaft into the barrel of the Occipital Drill/Tap Guide and rotate clockwise while advancing the Tap down the Drill/Tap Guide. The appropriate depth is reached when the stop on the Tap shaft contacts the stop on the Drill/Tap Guide.

Repeat for all screw placement sites.



Plate And Screw Insertion

Attach the Occipital Screw Starter or Multi-Angle Occipital Screw Starter to a Quick Connect Handle.

Slide the Occipital Screw Holder sleeve over the Occipital Screw Driver shaft. Engage the appropriate length of Occipital Bone Screw by sliding the Occipital Screw Holder sleeve down over the head of the appropriate Occipital Bone Screw. The Occipital Screw Starter or Multi-Angle Occipital Screw Starter may also be used without the Occipital Screw Holder.

Align the Plate with the drilled/tapped holes in the occiput and insert the Screws through the Plate into the drilled/tapped holes by rotating the Occipital Screw Starter/Driver clockwise to gently advance the screw to the desired depth.

Repeat for all screw placement sites.



Surgical Technique (Continued)

Rod Preparation And Insertion

The Rod Template may be used to determine the appropriate length and curvature of the Rod.

Cut the Rod to the appropriate length using the Rod Cutter and contour the Rod to the appropriate shape using the Rod Bender or Bending Irons. Do not straighten the Rod after bending.

Insert the Rod into the rod channel sliding connectors of the Occipital Plate so that approximately 3.0mm-4.0mm of the Rod extends above the channel.

Repeat for all Rods.



Plug Insertion

Insert **Helical Flange** Plugs and Set Screws into the seat(s) of the appropriate implant using the Plug Starter or Set Screw Starter, respectively, and provisionally tighten.

Repeat for the contralateral side.



Final Tightening

The **Altius M-INI** OCT System includes torque-limiting torque wrench handles for quick and easy construct tightening.



To maintain torsional stability of the construct, the Torque Stabilizer must be used during final tightening of **Helical Flange** Plugs for the Occipital Plate.

Attach the Torque Stabilizer to the seat of the plug to be tightened.

Attach the Quick-Connect Plug Driver to the straight or T-**Helical Flange** Torque Wrench Handle (gold) and advance the shaft of the assembly down the Torque Stabilizer until it is fully inserted into the **Helical Flange** Plug.

Rotate clockwise until an audible click is heard and tension is released within the handle. The gold **Helical Flange** Torque Wrench will release torque at a minimum of 40 in-lbs.

Torque-measuring handles may also be available upon request.



Product Information



The **Altius M-INI** OCT System consists of two trays: a **M-INI** Cervico-Thoracic Case (Catalog No. LAMCT) and an Occipital Case (Catalog No. LAOM).

The standard tray contains all of the implants and instruments necessary to implant or explant cervico-thoracic constructs. Additional implant sizes may be available for order individually. The standard case also contains Transitional Rods and Rod Connectors to link the **Altius M-INI** OCT System to Biomet Spine's Polaris™ and Synergy™ Spinal Systems.

The Occipital case contains all of the implants and instruments necessary to implant or explant **Altius M-INI** Occipital Plates.

When fixating the occiput, both the Cervico-Thoracic and Occipital cases must be ordered.

For additional information or to place an order, please contact your Biomet Spine salesperson or call customer service at 1-800-526-2579.

Cervico-Thoracic Case (Catalog No. LAMCT)

Implants

Accessories

Catalog #	Description
1200-2601	Helical Flange Plug
1200-0030	Set Screw
1200-0020	Single Rod Connector – 3.5mm/3.5mm
1200-0021	Double Rod Connector – 3.5mm/3.5mm
1200-0023	Double Rod Connector – 3.5mm/4.75mm
1200-0025	Double Rod Connector – 3.5mm/5.5mm
1200-0027	Double Rod Connector – 3.5mm/6.35mm
1200-1220	20-26mm Telescoping Cross Connector
1200-1221	25-38mm Telescoping Cross Connector
1200-1222	37-62mm Telescoping Cross Connector
1200-1223	46-80mm Telescoping Cross Connector
1200-2605	Offset Lateral Connector
1200-2606	Variable Offset Lateral Connector

Rods

Catalog #	Description
1200-0002	3.5mm Rod – 8cm Length
1200-0005	3.5mm Rod – 18cm Length
1200-0008	3.5mm Rod – 24cm Length
1200-0016	3.5mm Rod – Curved 12cm Length
1200-0011	Transitional Rod – 3.5mm/4.75mm
1200-0013	Transitional Rod – 3.5mm/5.5mm
1200-0015	Transitional Rod – 3.5mm/6.35mm

Hooks

Catalog #	Description
1200-2760	4.5mm Helical Flange Hook
1200-2761	6.0mm Helical Flange Hook

Multi-Axial Screws

Catalog #	Description
1200-2710	3.5mm Dia. x 10mm Length
1200-2712	3.5mm Dia. x 12mm Length
1200-2714	3.5mm Dia. x 14mm Length
1200-2716	3.5mm Dia. x 16mm Length
1200-2718	3.5mm Dia. x 18mm Length
1200-2720	3.5mm Dia. x 20mm Length
1200-2722	3.5mm Dia. x 22mm Length
1200-2810	4.0mm Dia. x 10mm Length
1200-2812	4.0mm Dia. x 12mm Length
1200-2814	4.0mm Dia. x 14mm Length
1200-2816	4.0mm Dia. x 16mm Length
1200-2818	4.0mm Dia. x 18mm Length
1200-2820	4.0mm Dia. x 20mm Length
1200-2822	4.0mm Dia. x 22mm Length
1200-2824	4.0mm Dia. x 24mm Length
1200-2828	4.0mm Dia. x 28mm Length
1200-2920	4.5mm Dia. x 20mm Length
1200-2924	4.5mm Dia. x 24mm Length
1200-2928	4.5mm Dia. x 28mm Length
1200-2932	4.5mm Dia. x 32mm Length

Smooth Shank Multi-Axial Screws

Catalog #	Description
1200-2420	3.5mm Dia. x 20mm Length
1200-2422	3.5mm Dia. x 22mm Length
1200-2424	3.5mm Dia. x 24mm Length
1200-2426	3.5mm Dia. x 26mm Length
1200-2428	3.5mm Dia. x 28mm Length
1200-2430	3.5mm Dia. x 30mm Length
1200-2432	3.5mm Dia. x 32mm Length
1200-2434	3.5mm Dia. x 34mm Length
1200-2436	3.5mm Dia. x 36mm Length
1200-2438	3.5mm Dia. x 38mm Length
1200-2440	3.5mm Dia. x 40mm Length
1200-2442	3.5mm Dia. x 42mm Length
1200-2444	3.5mm Dia. x 44mm Length
1200-2446	3.5mm Dia. x 46mm Length
1200-2448	3.5mm Dia. x 48mm Length
1200-2450	3.5mm Dia. x 50mm Length

Preferred Angle Screws

Catalog #	Description
1200-2510	3.5mm Dia. x 10mm Length
1200-2512	3.5mm Dia. x 12mm Length
1200-2514	3.5mm Dia. x 14mm Length
1200-2516	3.5mm Dia. x 16mm Length
1200-2518	3.5mm Dia. x 18mm Length
1200-2520	3.5mm Dia. x 20mm Length
1200-2522	3.5mm Dia. x 22mm Length

Product Information (Continued)

Instruments

Catalog #	Description
4010	Ball Tip Probe
1100-9022M	Depth Gauge
1100-9027	10mm Fixed Depth Drill
1100-9028	12mm Fixed Depth Drill
1100-9029	14mm Fixed Depth Drill
1100-9030	16mm Fixed Depth Drill
1100-9031	18mm Fixed Depth Drill
1100-9032	20mm Fixed Depth Drill
1100-9033	22mm Fixed Depth Drill
1100-9501	Quick Connect Handle
1100-9509M	Quick Connect Handle-T
1200-9002	Helical Flange Torque Wrench
1200-9003	Set Screw Driver
1200-9004	Awl
1200-9010	Drill Guide
1200-9011	Adjustable Depth Drill
1200-9015	Probe
1200-9018	Tap Guide
1200-9019	3.5mm Tap
1200-9020	4.0mm Tap
1200-9022	4.5mm Tap
1200-9024	Rod Template
1200-9027	Set Screw Torque Wrench
1200-9030	Rod Holder
1200-9031	Rod Gripper
1200-9032	Rod Cutter

Catalog #	Description
1200-9033	Rod Bender
1200-9036	Bending Iron
1200-9125	Helical Flange Torque Wrench-T
1200-9201	Seat Alignment Tool
1200-9203	Plug Starter
1200-9205	Plug Driver
1200-9207	Torque Stabilizer
1200-9216	Multi-Axial Screw Inserter
1200-9220	Distractor
1200-9221	Compressor
1200-9225	Hook Inserter
1200-9230	Rod Reducer
1200-9039	Hook Site Elevator
1200-9232	Cross Connector Stabilizer
1200-9240	3.5mm Rod Persuader

Altius M-INI Occipito-Cervical Case (Catalog No, LAOM)
Implants
Plates

Catalog #	Description
1200-3230	30-40mm Occipital Plate
1200-3235	35-45mm Occipital Plate
1200-3240	40-50mm Occipital Plate

Rods

Catalog #	Description
1200-0010	45° Occipital Rod
1200-0018	60° Occipital Rod
1200-0019	75° Occipital Rod

Occipital Bone Screws

Catalog #	Description
1200-3006	5.0mm Dia. x 6.0mm Length
1200-3007	5.0mm Dia. x 7.0mm Length
1200-3008	5.0mm Dia. x 8.0mm Length
1200-3009	5.0mm Dia. x 9.0mm Length
1200-3010	5.0mm Dia. x 10mm Length
1200-3011	5.0mm Dia. x 11mm Length
1200-3012	5.0mm Dia. x 12mm Length
1200-3013	5.0mm Dia. x 13mm Length
1200-3014	5.0mm Dia. x 14mm Length
1200-3015	5.0mm Dia. x 15mm Length
1200-3016	5.0mm Dia. x 16mm Length
1200-3017	5.0mm Dia. x 17mm Length
1200-3018	5.0mm Dia. x 18mm Length
1200-3019	5.0mm Dia. x 19mm Length
1200-3020	5.0mm Dia. x 20mm Length

Instruments

Catalog #	Description
1200-9100	Plate Holder
1200-9101	Occipital Drill Guide
1200-9103	Occipital Drill
1200-9104	Occipital Tap
1200-9105	Occipital Screw Holder
1200-9108	Occipital Screw Driver
1200-9109M	30-40mm Occipital Plate Template
1200-9110M	35-45mm Occipital Plate Template
1200-9111M	40-50mm Occipital Plate Template
1200-9114	Multi-Angle Occipital Bone Screw Starter
1200-9115	Occipital Bone Screw Starter
1200-9116	Occipital Torque Stabilizer Handle
1200-9121	15° Occipital Torque Stabilizer Adapter
1200-9122	30° Occipital Torque Stabilizer Adapter
1200-9123	45° Occipital Torque Stabilizer Adapter
1200-9138	Multi-Angle Plug Starter
1200-9139	Plug Starter

Closure And Post-Operative Care

- The operative site should be closed per hospital protocol and the surgeon's discretion
- Prior to adequate fusion, the physician may prescribe additional external support to accommodate full load bearing
- The patient should receive adequate instruction regarding the appropriate post-operative activity levels
- The patient should be instructed to report unusual changes at the operative site and the physician should closely monitor the patient if unusual changes are reported

Implant Removal

Removal of the **Altius M-INI** OCT System is performed by reversing the order of the implant procedure.

Indications For Use

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (Occiput-T3), the **Altius** Occipito-Cervico-Thoracic (OCT) System is indicated for:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Atlantoaxial fracture with instability
- Occipitocervical dislocation
- Revision of previous cervical spine surgery
- Tumors

The Occipital Bone Screws are limited to occipital fixation only.

See package insert for complete indications and labeling limitations.

Contraindications

Contraindications include, but are not limited to, infection, systemic, spinal or localized; morbid obesity; signs of local inflammation; fever or leukocytosis; metal sensitivity/allergies to the implant materials; any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count; grossly distorted anatomy due to congenital abnormalities; rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft); any case not needing a bone graft and fusion or where fracture healing is not required; any case requiring the mixing of metals from different components; any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition; any case not described in the indications; any patient unwilling to cooperate with the postoperative instructions; any time implant utilization would interfere with anatomical structures or expected physiological performance.

Warnings

In using metallic surgical implants, the surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including corrosive environments. They should be carefully unpacked and inspected for damage prior to use.
3. Correct handling of the implant is extremely important. Contouring of the metal devices is to be avoided.
4. All implants and instruments must be cleaned and sterilized prior to surgery.
5. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together. The **Altius** OCT System should not be used with components from any other system or manufacturer.
6. As with all orthopaedic implants, the **Altius** OCT System should never be reused under any circumstances.
7. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
8. Postoperative care is important. The patient should be instructed in the limitations of his/her metallic implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.

Sterilization Recommendations

High temperature steam sterilization should be used. All packaging materials must be removed prior to sterilization. The following cycles have been laboratory validated:

Method:	Steam	Steam
Cycle:	Gravity	Prevac
Temperature:	250°F (121°C)	270°F (132°C)
Exposure Time:	60 minutes	8 minutes
Drying:	20 minutes	

Further Information

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

The **Altius M-INI** OCT System can be linked to **Polaris** and **Synergy Spinal Systems** using Rod Connectors and Transitional Rods.

This brochure describes a surgical technique used by Alan S. Hilibrand, M.D., Alexander R. Vaccaro, M.D. and Jeffrey C. Wang, M.D. Biomet Spine as the manufacturer of this device, does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate techniques(s) for said implantation in each individual patient. The contents of this manual are intended to be only a guide and are not intended to set a standard of care.

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