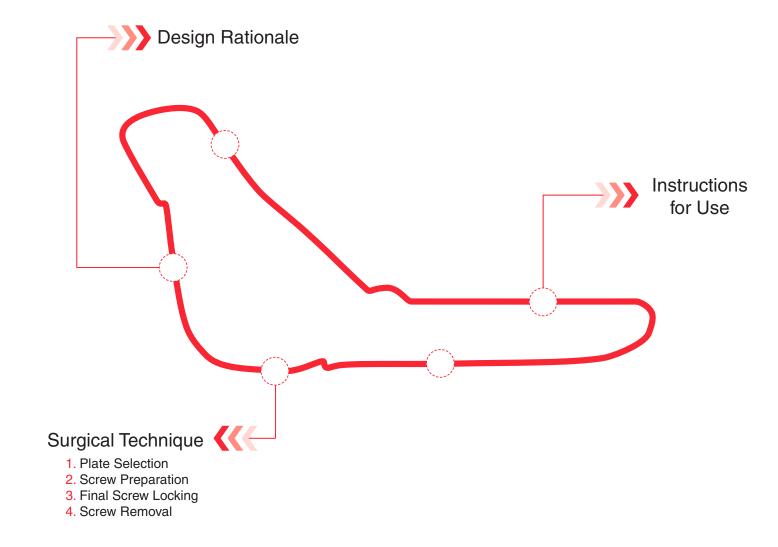


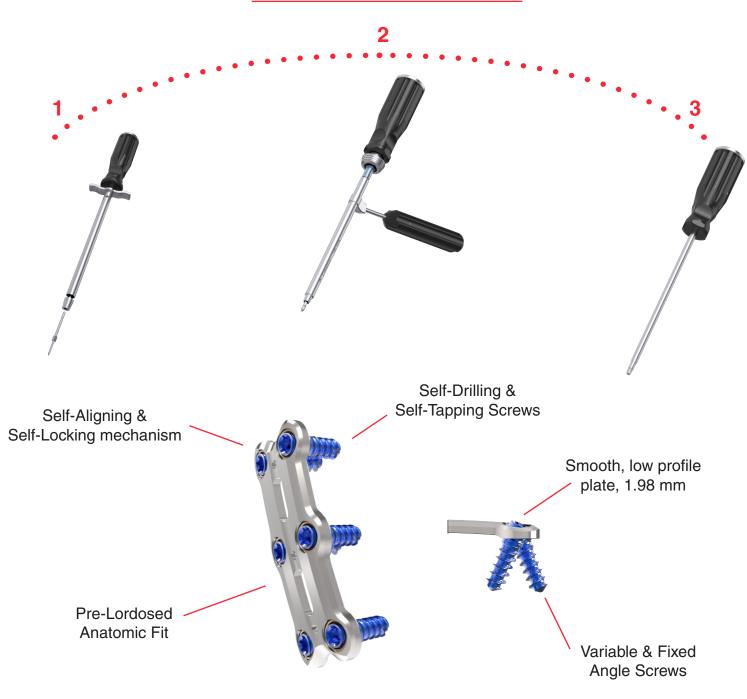


Monza Cervical Plate System Surgical Technique

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DESIGN RATIONALE



INDICATIONS FOR USE

The Altus Spine Monza Cervical Plate System is intended for anterior interbody fixation of the cervical spine. The system is indicated for use in temporary stabilization of the anterior spine during the development of the cervical spine fusions in patients with degenerative disc disease (as defined by neck pain of the discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies); trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudosarthrosis and/or failed previous fusions. The Altus Spine Cervical Plate System can be implanted in the sub-axial cervical spine from the C3 through C7 levels.

Please refer to product insert (PI-004) for complete system description, warnings and precautions

*Covered by U.S. Patent No.: 7,524,325.

Other U.S. and foreign patents additionally pending

1. PLATE SELECTION

SIZE THE PLATE

Ensure the cephalad and caudad screw holes cover the intended vertebrae

Seat the plate flush to the anterior surface of the cervical vertebrae; remove osteophytes and flaws as necessary

To load Fixation Pin into Utility Driver, pull back the "T" handle and insert the Fixation Pin, and then release the handle to lock it in place

Insert the trocar tip of the Fixation Pin into the fixation holes of the plate (located both inferior and superior to the middle slot)

2. SCREW HOLE PREPARATION

CENTRALIZER

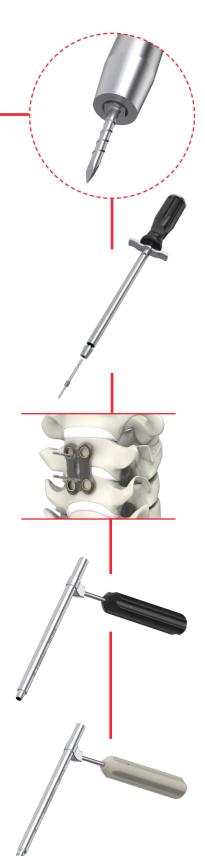
The Variable Angle Centralizer is a variable angle guide used for screw hole preparation for Variable Angle Screws; it has a black handle

The Rigid Centralizer is a fixed angle guide used for screw hole preparation of Fixed Angle Screws to ensure that the preparation trajectory is 10° (gold), 0° (green) cephalad/caudad and 7° medial; it has a gray handle

Screw Holes can be prepared by using the Trocar Drill, Trocar Awl, or Twist Drill in conjunction with any of the centralizers

Note: The Variable Angle Centralizer and the Rigid Centralizer will be referred to as Centralizer moving forward

Note: The following technique is applicable for both the Self-Tapping and Self-Drilling Screws



2. SCREW HOLE PREPARATION (CONT.)

HOLE PREPARATION

Choose from the Awl, Twist Drill, or Cervical Tap for hole preparation

Use of a Centralizer is required for hole preparation

Assemble selected instrument to the Quick Connect Handle; pull the plunger of the handle and insert the shaft into the handle. At full insertion, release the plunger and rotate until it "clicks" into place

Engage the distal tip of the Centralizer with appropriate screw hole

Angle the Centralizer in the appropriate cephalad or caudal direction, maintaining medial-lateral position neutral to the plate

Insert the desired Hole Preparation instrument Handle Assembly through the Centralizer to desired depth

Note: Awl includes a preset stop at 11mm, and the Tap has a preset stop at 16mm





2. SCREW HOLE PREPARATION (CONT.)

Assemble the Trocar Drill to the Utility Driver

Engage the distal portion of the drill in the locking ring of the plate, this will ensure that the prepared screw path is within the locking limits of the plate

Utilizing steady, firm pressure, insert the drill into the bone to the desired depth by twisting the handle while applying pressure

Note: Trocar Drill includes a preset stop at 11mm



3. FINAL SCREW LOCKING

INSERT SCREWS

Assemble the Dual Ended Screw Driver Shaft with the Quick Connect Handle, or use the standard Screw Driver

Load screw by pressing the T15 driver tip into the head of selected screw; lightly tap the top of the Screw Driver to full engage screw head

Insert screw; repeat steps for each screw

Note: It is recommended to leave the screw head slightly proud and unlocked until all screws are placed

FINAL LOCKING AND IMPLANT FIXATION

Confirm plate placement and screw purchase

Achieve final locking by re-engaging the driver with the screw head rotating clockwise until the screw head is below the Locking Ring of the plate

Repeat final locking steps for each blocker

Note: Confirmation of screw placement can be achieved via the following methods:

Suction may be applied to the locking ring to confirm it is locked into place

The screws may be observed via X-Ray to confirm screws are flush with the plates

The audio click of the screw while inserting

Visually significant amount of the ring can be seen, approximately 3/4ths



4. SCREW REMOVAL

OPTION 1:

REMOVE SCREWS WITH SCREW DRIVER

Insert the tip of the Ring Release Tool directly over the screw head

Insert the Cervical Screw Driver through the Ring Release Tool

Note: Ensure the Ring Release Tool is seated flush against the plate's locking ring, and the top of the driver is firmly seated in the head of the screw

Apply downward pressure on the plate's locking ring with the Ring Release Tool and remove the screw by turning the driver counterclockwise

OPTION 2:

REMOVE SCREWS WITH SCREW EXTRACTOR

Engage drive tip into screw

Restrain Ring Release Sleeve on the outer shaft, rotate the knob counterclockwise to lock the instrument into the screw head

Press outer Ring Release Sleeve into the plate's ring pocket to restrain ring

Apply downward pressure on the Ring Release Sleeve while rotating the handle counterclockwise to back out the screw

Note: If bone quality is poor and screw is free spinning, pull the screw out of pocket while maintaining pressure on the plate ring with Ring Release Sleeve

