RSB SPINE

InterPlate® C-Ti Anterior Cervical Plate

Surgical Technique

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Patent Numbers: 6,984,234 *6,235,034 *8,100,976 *7,985,255
9,278,009 * 9,713,537 B2
Other patents pending and applied for

MKBR 1023 1.0

Indications and Features

Indications:

The InterPlate C-Ti is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion

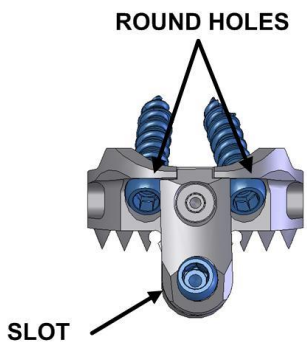
WARNING: The InterPlate C-Ti is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Features:

DYNAMIC SUBSIDENCE CONSTRAINT

Constraint increases as subsidence occurs, which is facilitated by the unique tapered tooth design on the bottom of the implant. As the opposing vertebral bodies settle onto the graft and implant, the tapered teeth embed into the vertebral body. This allows for early dynamic graft loading, with increased resistance to subsidence as the teeth embed further into the vertebral body. Experimental data indicates that projections like teeth significantly improve torsional and flexural rigidity.

FIGURE 1.



The dynamic performance of the InterPlate is also facilitated by the slotted caudal screw tab (Figure 1), which allows for the screw head to move freely in the slot as subsidence occurs. The length of the slot is matched to the height of the teeth so that when the teeth are fully embedded the screw is at the end of the slot.

EASE OF USE

The InterPlate set is easy to use with very few instruments required for implantation. The set includes *Sizers*, which help in choosing the correct fitting implant. The set also includes an *Implant Inserter* and a *Round Hole Guide Tube* for proper screw positioning, but the *Self-Drilling, Self-Tapping Screws* allow for freehand screw placement if desired. The *Torque Limiting Cover Driver* is designed to properly lock the Screw Cover in place. The set is compact and lightweight.

BRIDGING FLUSH FIT™

The anterior face of the InterPlate is essentially flush with the anterior surface of the spine.

SCREW FIXATION WITH BACKOUT PREVENTION

Expulsion of the implant is resisted by three screws. The cephalad screws are triangulated to increase pullout resistance. All three screws are trapped beneath a screw cover to prevent backout.

AUTOGRAFT VOLUME

The open interior of the InterPlate accommodates a large volume of autograft material. See the Appendix for detailed sizing information.

PERIPHERAL SUPPORT

The InterPlate is located around the perimeter of the endplate facilitating load transfer through the cortical shell.

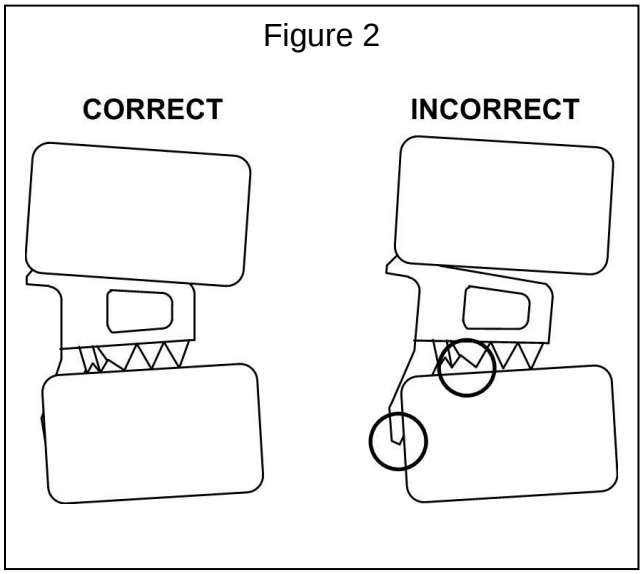
Surgical Approach

Use the appropriate anterior surgical approach for cervical discectomy and fusion.

Surgical Technique

Surface Preparation

Figure 2

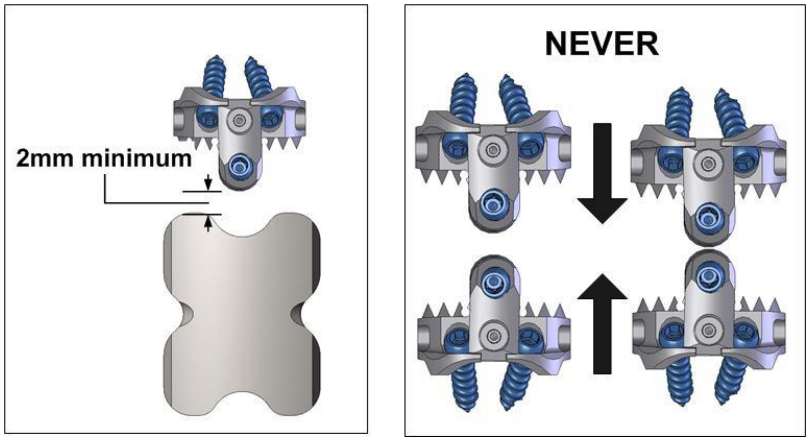


The InterPlate is pre-lordosed. The anterior lip or beak of the vertebra may need to be nibbled away to accommodate the slotted caudal screw tab of the InterPlate. The InterPlate™ *Sizer* has a tab attached to it that can be used to indent the anterior lip by impacting the *Sizer*, or a drill, rongeur, or other instrument can be used. The goal is to create a small slot on the anterior lip to allow for the InterPlate tab to seat properly. The teeth should be flush with the surface of the vertebra (Figure 2). The InterPlate slot screw tab should be in the indentation created on the anterior lip of the vertebra (Figure 2).

It is important to preserve the anterolateral cortical shell of the vertebrae at screw insertion sites.

Remember to account for potential settling of the InterPlate. Allow at least a 2mm gap between the tab and adjacent hardware. (Figure 3).

Figure 3.

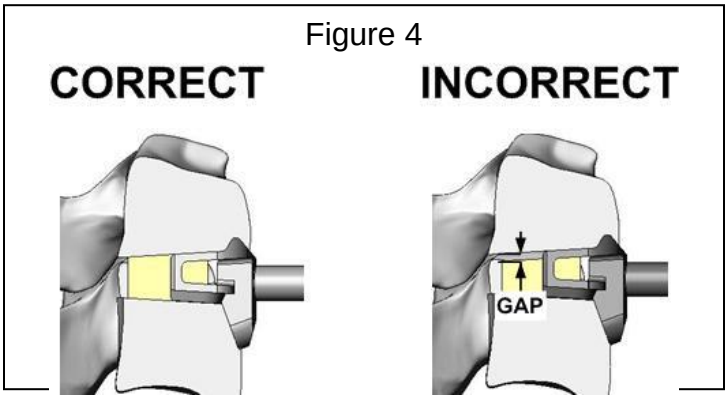


InterPlate Selection

After complete discectomy and graft placement select an appropriate InterPlate by using the *Sizer* to determine the correct fit. The *Sizer* should fit snuggly, but not tightly over the implanted autograft. Only gentle impaction should be required to insert the *Sizer*. The correct InterPlate will usually be the same as the graft size (Figure 4). For example, use a 10mm x 12mm InterPlate with a 10mm x 12mm graft. Countersink the graft 1-3mm. **In the medial-lateral direction, the width of the graft plus the InterPlate wings should fit within the available exposure.**

Do not release distraction until after the implant has been inserted. Only gentle impaction should be required to insert the InterPlate.

Figure 4



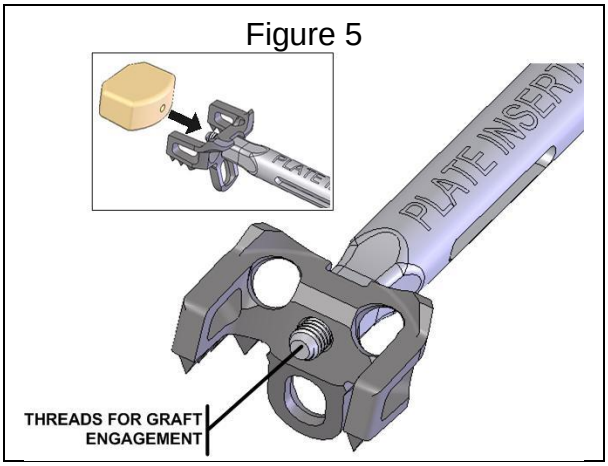
InterPlate Insertion

Three options are available for InterPlate insertion:

- The *Guide Tube* can be used to insert the InterPlate over the graft and it can remain in place while the round hole bone screws are inserted.

- The *Inserter* can be used to place the InterPlate over the graft. It can remain in place to steady the InterPlate while the round hole screws are inserted free hand, or it can be removed and replaced by the *Guide Tube*.

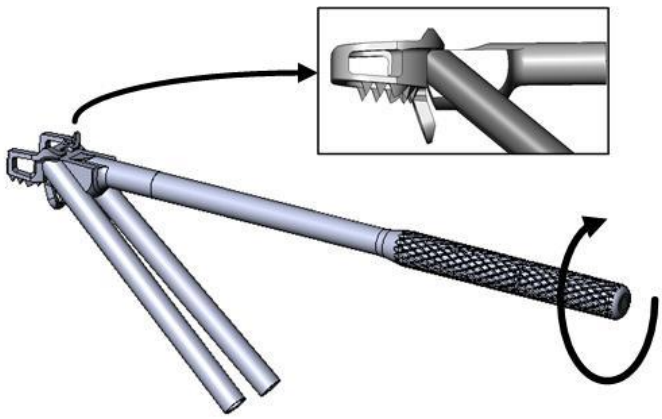
Figure 5



- The *Plate Inserter* **or** *Graft inserter/Guide* can be used to insert the InterPlate and autograft together. **The threads on these devices pass through the InterPlate cover screw hole and can be screwed into a hole punched into the graft (Figure 5).** The *Center Punch* can be used to create a pilot hole for threading the *Plate Inserter* or *Graft Inserter/Guide* into the autograft.

Screw Placement

Figure 6



The *Round Hole Guide Tube* locks to the InterPlate while preparing the round hole screw site and can also be used as an inserter (Figure 6). The *Center Punch* fits into the guide tube. The screw can also be driven through the guide tube. Shoulders on the *Center Punch* prevent it from passing through the plate. Gently tap the end of the guide tube handle to be certain the plate is seated. It is recommended that the first screw be put in one of the two round cephalad screw holes. The pilot hole can be prepared with the *Center Punch*. The screws are *Self-Drilling and Self-Tapping*. If the *Center Punch* is used, it can be left in place in one hole to help steady the implant while the other screw is driven into the opposing screw hole. The single slotted (caudal)

screw hole is prepared freehand. **The *Graft Inserter/Guide* can be used in a similar manner.**

The *Inserter* attaches to the InterPlate using the cover screw hole and can be used in place of the *Round Hole Guide Tube* if the freehand technique is preferred.

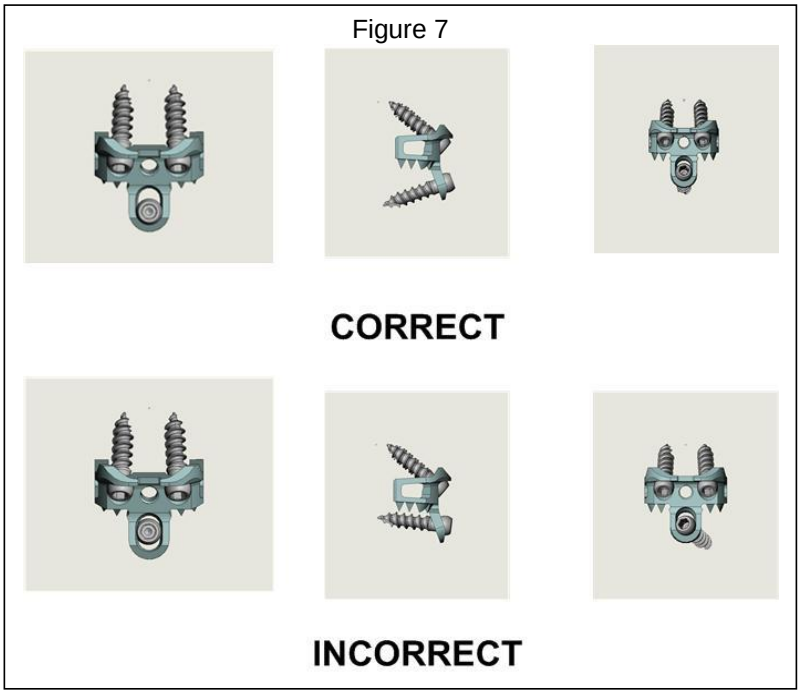
Round Hole Guide Tube

The *Round Hole (cephalad) Guide Tube* provides 3.5 degree angulation toward the midline and 40 degree cephalad angulation. The *Round Hole Guide Tube* attaches to the implant and can be used to insert the InterPlate into the proper position.

The *Round Hole Guide Tube* has a threaded shaft that screws into the cover screw hole of the InterPlate by turning the top of the guide tube handle, attaching the guide to the plate. ***Ensure that the guide tube docking mechanism is fully engaged before attempting to screw through the guide tube (Figure 6 inset).***

There is no Guide Tube for the slotted (caudal) hole. Screw hole preparation and screw insertion are completed freehand. ***The slot screw must be located at the caudal end of the slot to permit adequate travel. It should be aligned perpendicular to the slot (Figure 7).***

Figure 7



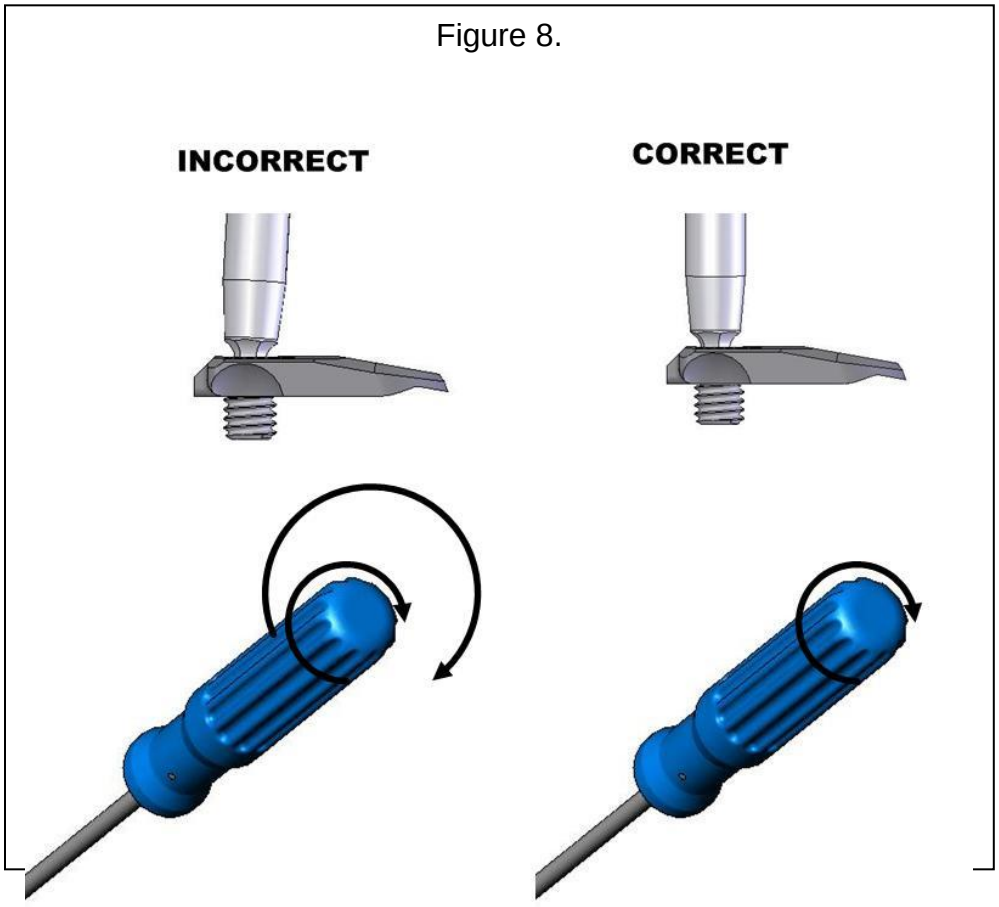
Screw Selection and Insertion

The bone screws are available in two sizes. Always start with a smaller screw first. If the screw loses purchase in the bone convert to a larger screw. Remove the screws from the caddy using the self-retaining *Bone Screw Driver*. Do not use bone wax for screw retention. It may actually inhibit retention or cause the driver to slip in the screw hex.

When driving a bone or cover screw, insure that the driver is fully seated in the screw and that the axis of the screw and driver are collinear (Figure 8). When turning a driver, be certain that the instrument rotates about its own axis, and does not wobble (Figure 8). This will insure that holes are not distorted and minimize the chance of cross-threading screws.

With the guide tube in place, insert the *Center Punch* into the tube and prepare a pilot hole. Insert the screw and tighten it until the mark on the *Bone Screw Driver* shaft is even with the top of the guide tube. This will leave the screw head slightly "proud", to allow for final tightening once the guide tube is removed.

Figure 8.



Once all of the screws have been partially seated, tightening can be completed. Tighten them like lug nuts; gradually and sequentially. Starting with one of the cephalad round hole screws, tighten the screw until it contacts the plate. Next tighten the single caudal screw. Then tighten the other round hole screw, and re-tighten the other screws following the same pattern. Impaction of the center punch will provide some idea of the bone quality. Use this information as a guide as to how much torque can be safely applied to the screw. ***Do not over torque the screw; it will strip out of the bone***. The head of the screw must be fully seated in the plate or there is a possibility that the cover will not fit properly.

The self-drilling, self-tapping features of the screw design can be used to simplify screw insertion. Place the guide on the InterPlate, or use a freehand technique and insert the *Center Punch*. Create a starting hole by tapping the *Center Punch* handle with a small mallet. Remove the *Center Punch* and insert the screw.

Bone Screw Cover

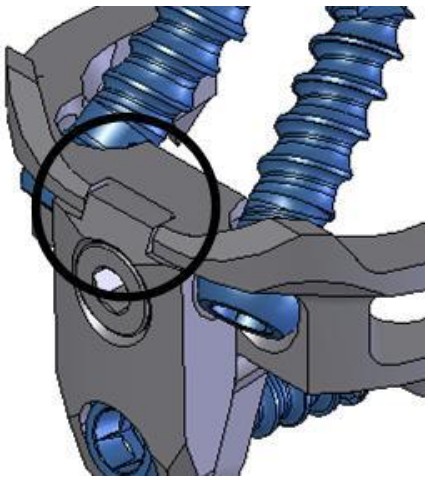
The bone screw cover should only be attached using the *Cover Screw Driver* to insure that adequate torque is applied and to prevent damage to the cover screws. To insert the driver shaft into the handle, retract the collar on the handle and insert the shaft. Rotate the shaft until it drops into the handle. When fully inserted, the ring around the shaft will line up with the end of the handle fitting. Release the collar and twist and pull the shaft to insure that it is locked.

When retrieving a cover from the caddy, make certain the driver is fully seated in the cover screw hex and that the axis of the screw and driver are in line. When turning the driver, be certain that the instrument rotates about its own axis, and does not wobble.

The cover will not be flush with the plate if the bone screws are not fully seated. If it is difficult to seat a bone screw, loosen all of the screws and retighten them using the alternating pattern described above.

The covers are made to match the implant height. For example, only use a 10mm cover with a 10mm plate. Matching plates and covers are stored together in the plate caddy. A "key" and slot are used to help prevent mismatch between the cover and plate (Figure 9). If the cover and plate do not seem to fit properly, compare the sizes etched on each part.

Figure 9



Remove the cover from the instrument case using the driver. Position the driver and screw directly over the hole in the plate. Tighten the cover screw. If the cover initially rotates, straighten it out until it is trapped in the recess in the plate. If it is difficult to start the cover screw it may be because the tip of the cover screw is impinging on the graft beneath the plate. Use the *Center Punch* to clear out the cover screw hole. If it is difficult to tighten the cover screw, the cover screw threads may be engaging both the cover and the plate. Remove the cover assembly and insure that the cover screw threads are clear of the cover. ***Tighten the cover screw until the driver releases. There will be click that is heard and felt. The driver only needs to click once.***

Confirming Proper Installation

A lateral x-ray should be used to confirm that the bone screws are in the desired locations, and further confirm that the screw covers are fully seated. An AP view may be used to document alignment.

If Implant misalignment or improper screw position is apparent, consideration should be given to repositioning the implant.

Revision

USE THE STANDARD DRIVERS TO REMOVE SCREWS.

ONLY USE THE SCREW EXTRACTORS TO REMOVE STRIPPED SCREWS.

NEVER USE THE SCREW EXTRACTORS TO DRIVE SCREWS.

The Bone Screw Extractor has a ***RED*** T-Handle. The Cover Screw Extractor has a ***YELLOW*** T-Handle. To use the Screw Extractor, gently tap the extractor into the stripped screw. Make sure the extractor is fully seated in the screw hex. ***BE CAREFUL NOT TO WIGGLE THE EXTRACTOR IN THE SCREW HEAD; THE TIP MAY SNAP OFF.***

The *Plate Extractor* can be used to remove a plate. Thread the extractor into the cover screw hole. Use the slap hammer to loosen and remove the plate.

Refer to the package insert for a complete list of warnings, precautions, indications, and contraindications.

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APPENDIX

InterPlate C-Ti Dimensions

Key implant dimensions are shown in the following figures. Dimensions that change with implant size are represented by a letter. Table 1 lists the values of these dimensions for the different implant sizes.

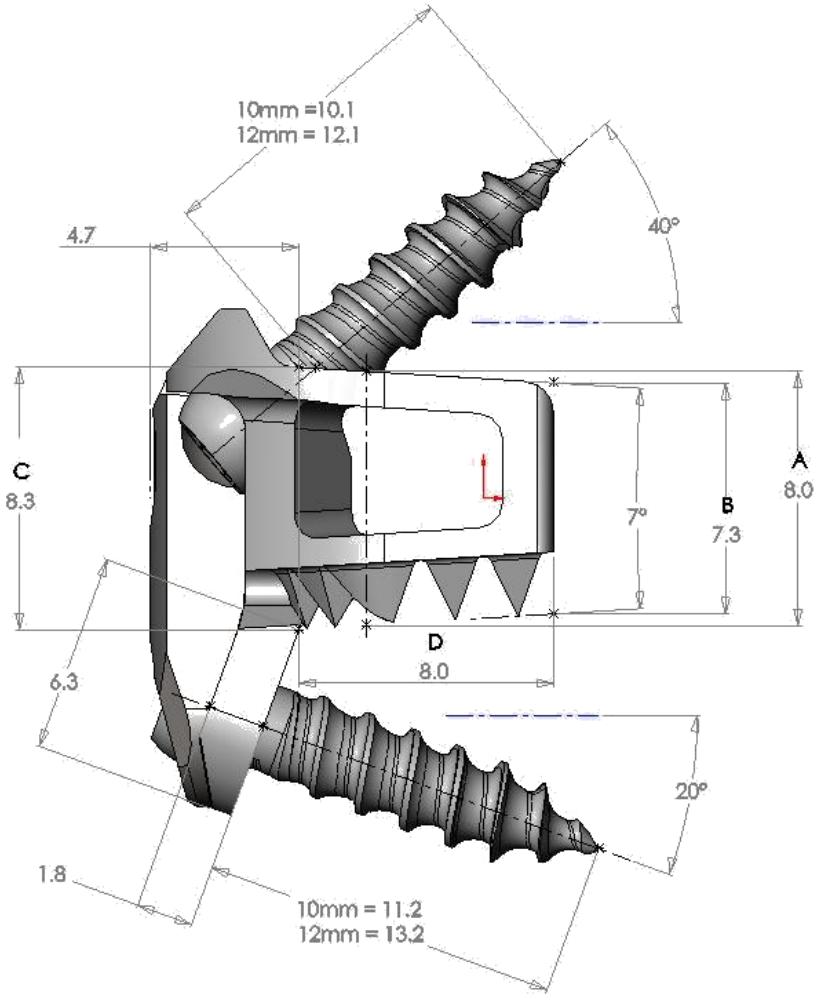

Fig. 1

8x15mm InterPlate™ Assembly

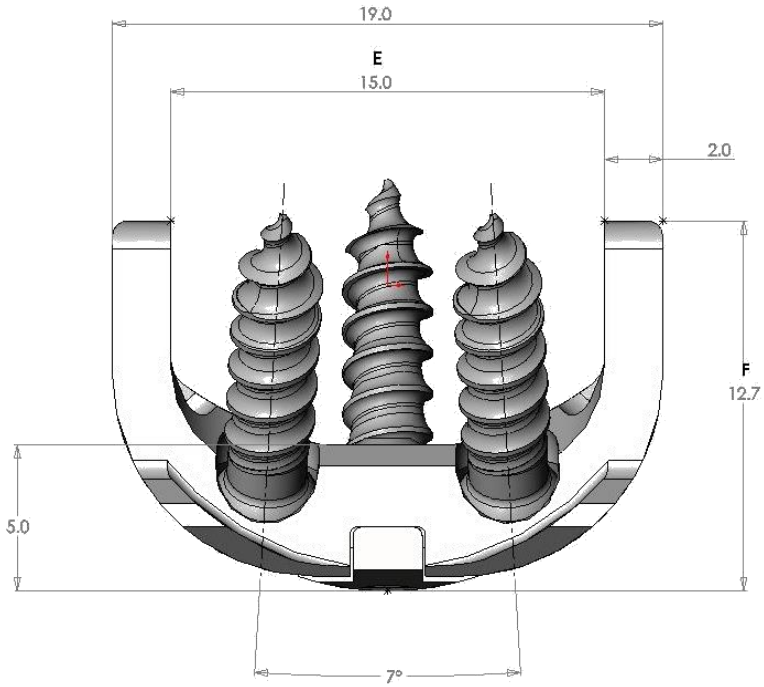

Fig. 2

8x15mm InterPlate™ Assembly

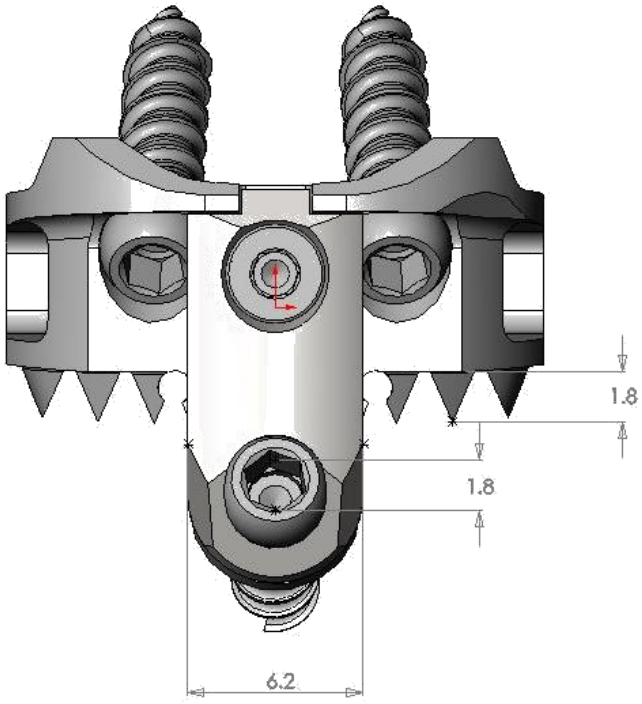

Fig. 3

8x15mm InterPlate™ Assembly

Table 1

	6x12	7x12	8x12	9x12	10x12	6x15	7x15	8x15	9x15	10x15
A) Nominal Height	6.0	7.0	8.0	9.0	10.0	6.0	7.0	8.0	9.0	10.0
B) Wing Height - Posterior	5.3	6.3	7.3	8.3	9.3	5.3	6.3	7.3	8.3	9.3
C) Wing Height - Anterior	6.2	7.2	8.2	9.2	10.2	6.3	7.3	8.3	9.3	10.3
D) Wing Depth	7.0	7.0	7.0	7.0	7.0	8.0	8.0	8.0	8.0	8.0
E) Width	12.0	12.0	12.0	12.0	12.0	15.0	15.0	15.0	15.0	15.0
F) Depth	11.7	11.7	11.7	11.7	11.7	12.7	12.7	12.7	12.7	12.7

Bone Screws

Standard Screw 3.4mm diameter, 10mm thread length

Rescue Screw 3.7mm diameter, 10mm thread length

Screw Range of Motion

Superior screws can rotate 34° in sagittal plane and 18° medial/lateral.

Inferior (tab) screw can rotate 16° conically about its axis while translating 1.8mm along the tab slot. Additional screw rotation in the sagittal plane is permitted while translating along the slot.