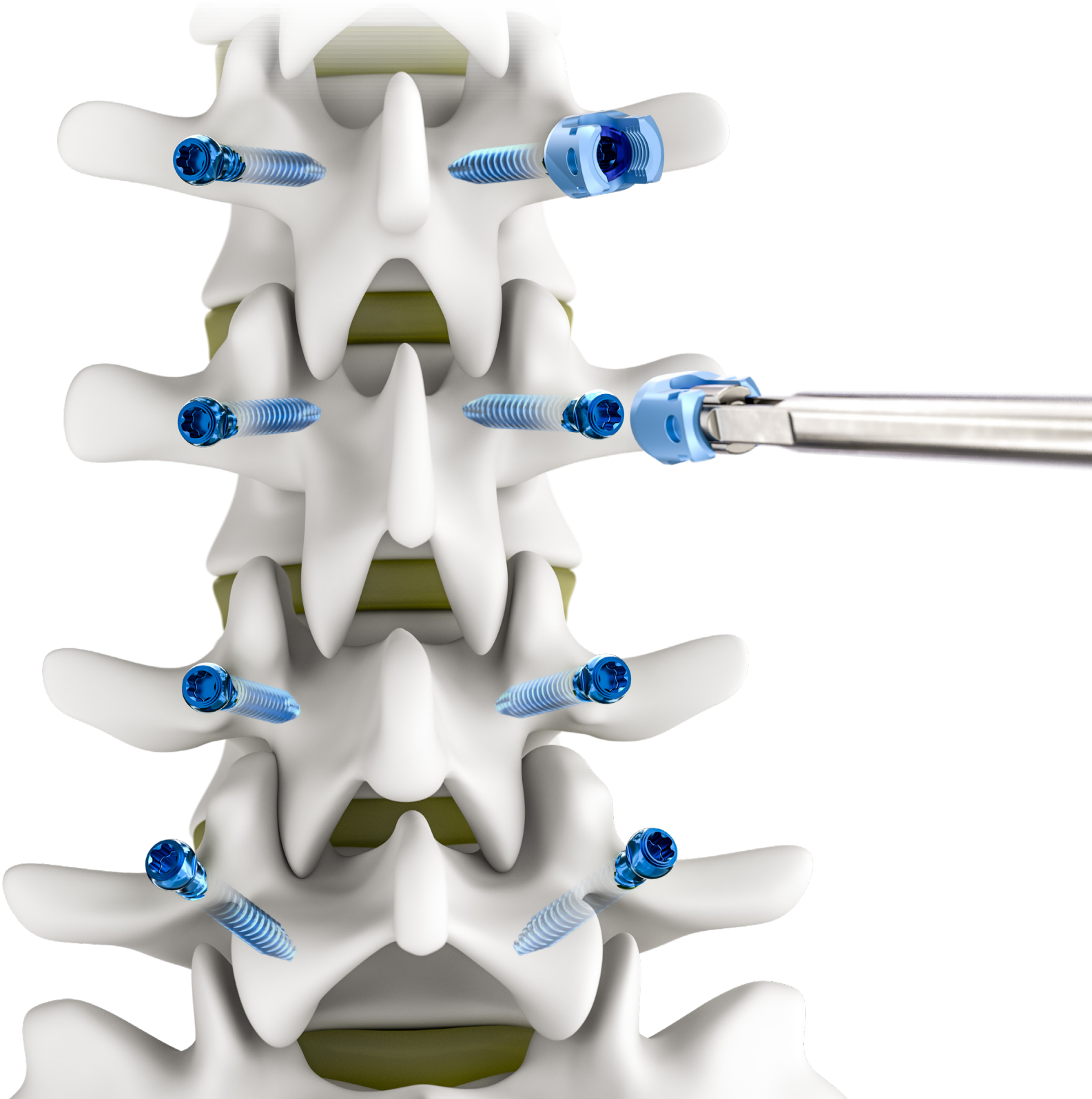
Medtronic

PEDICLE TRAJECTORY SURGICAL TECHNIQUE

CD Horizon™ ModuLex™ 5.5

Spinal System



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Instruments

Depth Stop Sleeve

Shank Sleeve

Non-navigated
Shank Driver

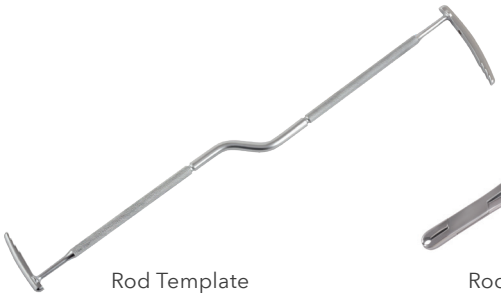
NAV Driver

Decortication Tool
5597160
Shown assembled with T-Handle MT25 Driver 5597185.

Head Turner

Provisional Driver

Set Screw Break Off Driver



Rod Template

Rod Holder

Swizzle Stick

Countertorque

Distractor

Locking Head Inserter

Interbody access and preparation

Posterior access to the surgical site for discectomy and interbody graft placement can be facilitated using the METRx™ II system, MAST™ Quadrant system or a general instrument retractor; alternatively surgeons may choose to expose the posterior spinal elements including the disc space via a traditional midline or paramedian approach. In addition, surgeons may choose to access the intervertebral disc space via an Oblique Lateral Interbody Fusion (OLIF), a Direct Lateral Interbody Fusion (DLIF), or an Anterior Lumbar Interbody Fusion (ALIF) procedure to perform the discectomy and interbody placement from an anterior or lateral approach. For detailed instructions regarding the use of these systems and/or procedures please refer to their respective surgical techniques.

If performing the discectomy and interbody placement from a posterior approach perform either a unilateral or bilateral facetectomy along with a total discectomy at each operative level. If reducing a spondylolisthesis, releasing these elements will help to reduce the spondylolisthesis. Bilateral facetectomy will create more mobility than unilateral facetectomy.

Preoperative planning and set up

Review of the preoperative images is useful in determining the optimal starting point and screw trajectory. Suggested skin incisions, measured laterally from the anatomic midline, can be found in **Figure 1**.

Important

The starting point is rarely directly over the pedicle. If using fluoroscopy or surgical navigation a radiolucent table and frame should be utilized and the surgeon should confirm that adequate images can be obtained prior to draping the patient.

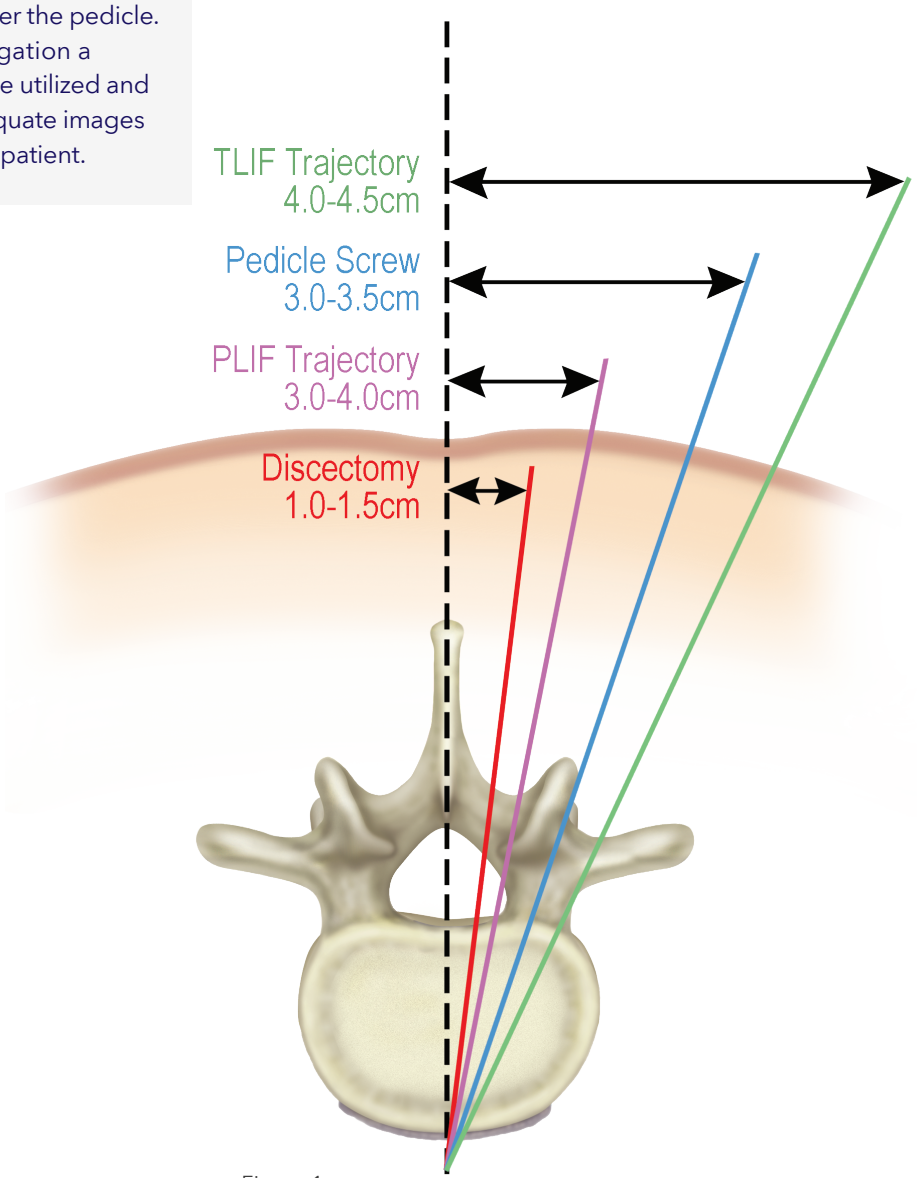


Figure 1

When using the CD Horizon™ ModuLex™ spinal system, the patient should be placed in the prone position and efforts should be made to achieve the desired lordosis of the spine. Prior to skin incision, it is recommended to verify that adequate fluoroscopic images of the pedicles can be obtained in both the anterior –posterior (AP) and lateral views. To assist with accurate pedicle cannulation, perfect AP and lateral images should be obtained on fluoroscopic images. On the AP images, the spinous process should appear midway between the pedicle and the pedicles should appear symmetric. On the lateral image, the vertebral endplates should appear as a straight line (not circle) and the pedicles should overlap completely and appear as a single pedicle.

If using fluoroscopy, verify adequate fluoroscopic images of the pedicles can be obtained in both an AP and lateral view before proceeding **(Figure 2)**.

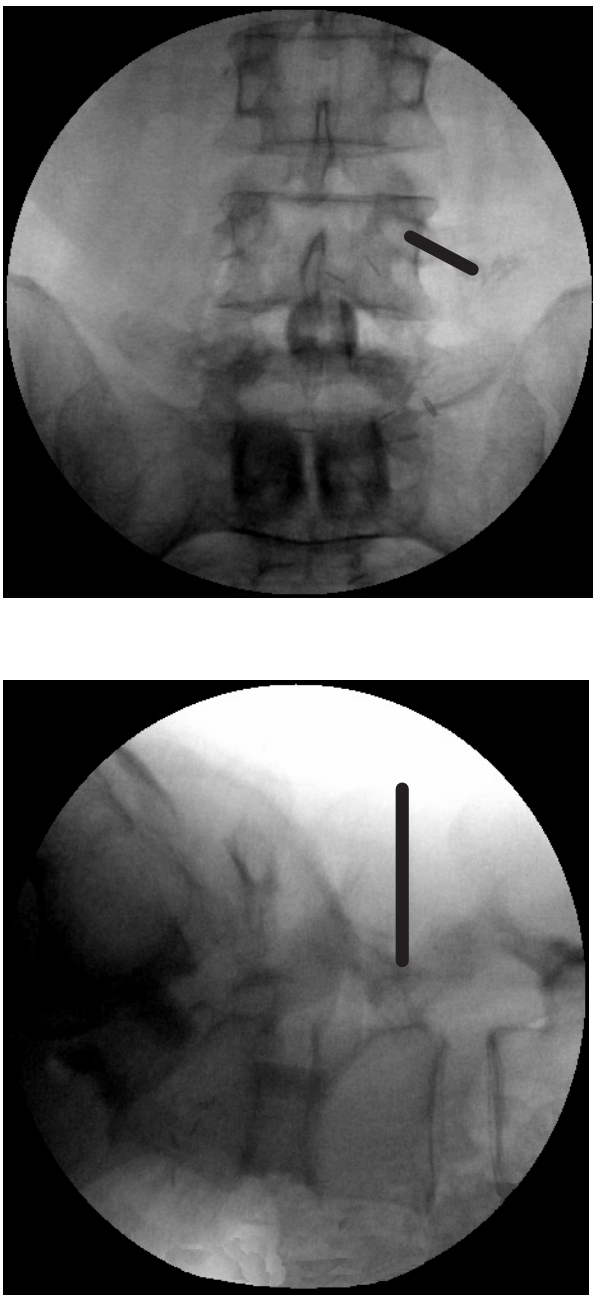


Figure 2

Positioning of skin incisions

A 22-gauge spinal needle may be used to verify the appropriate location of the skin incisions. The needle is positioned on the skin directly over the pedicle on an AP image. The needle is then moved laterally 1cm to 2 cm and inserted through the skin to the intersection of the facet and transverse process **(Figures 3a and 3b)**.

Figure 3a

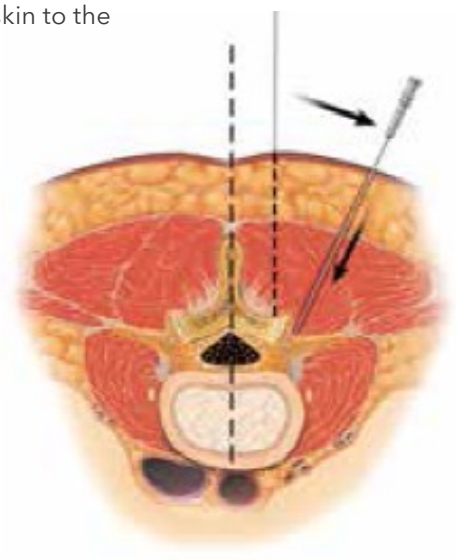


Figure 3b

Important

The skin incision is slightly lateral to the pedicle (~ 1cm) on fluoroscopy. This will help to ensure the needle follows the normal lateral to medial trajectory of the pedicle.

Both AP and lateral images confirm that the appropriate starting place has been determined (**Figures 4a and 4b**).

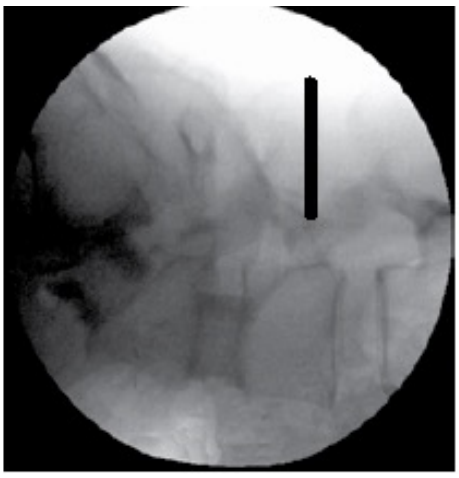


Figure 4a

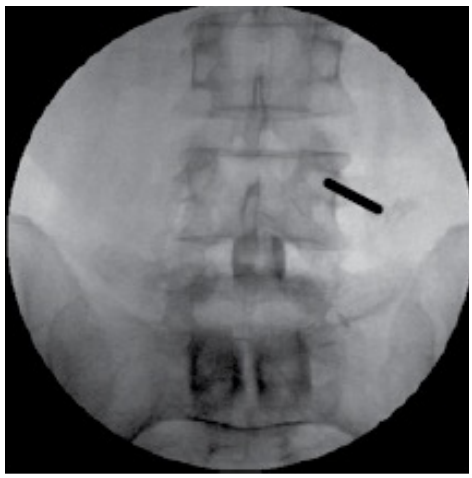


Figure 4b

Two ways to access pedicles

The **first method** involves a posterior midline incision technique that can be used if an open method is preferred and direct visualization of the pedicles is required.

The **second method** involves creating a paramedian incision that extends from the most superior to the most inferior pedicle to be instrumented. This incision starting point should be lateral to the facet approximately halfway between the facet and the tip of the transverse process depending on the size of the patient and the depth of the wound. It is important to open the spinal muscular fascia to permit passage of the rod down the incision and through the muscular plane.

Consider pedicle anatomy

Consider the pedicle as roughly a cylindrical structure. As the pedicle is traversed, the trajectory should allow the screw shank to remain lateral to the medial pedicle wall **(Figure 5)**.

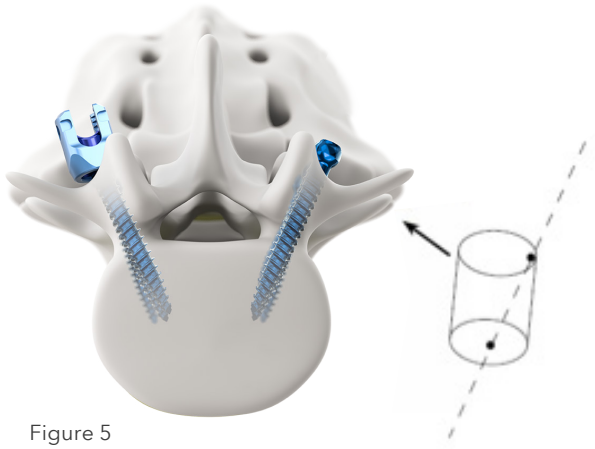


Figure 5

Important

The ideal starting point is at the intersection of the facet and the transverse process (the lateral edge of the cylinder) (**Figures 6a and 6b**).

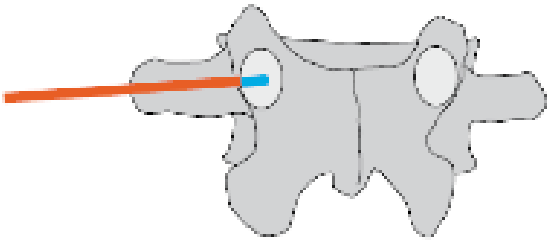


Figure 6a

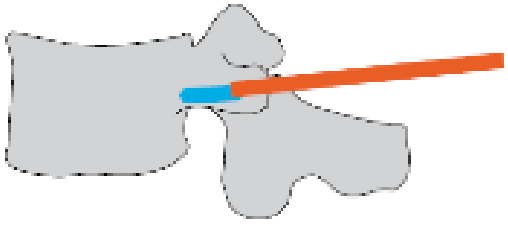


Figure 6b

Pedicle preparation

The pedicle may be prepared by using a Midas Rex™ burr or a NIM™ pedicle probe to create a pilot hole. The surgeon may then tap the desired screw trajectory along the pedicle. Alternatively, the surgeon may decide to start with the tapping step or not tap based on the patient's bone quality. Use a ball tipped probe to palpate the pedicle walls and confirm there are no breaches.

Alternatively, the IPC™ Powerease™ system may be used for drilling and tapping **(Figure 7)**. The IPC™ Powerease™ system is a system of powered surgical instruments designed specifically for spine surgery. The taps from the CD Horizon™ ModuLex™ instrument sets are fully integrated with the Stealth Station™ and O-Arm™ systems. The awl tip taps from the CD Horizon™ Solera™ instrument sets may be used when placing the ATS shanks if desired by the surgeon. For comprehensive instructions refer to the IPC™ Powerease™ user manual. Free-running EMG can be used to monitor for any nerve root irritation during this procedure.

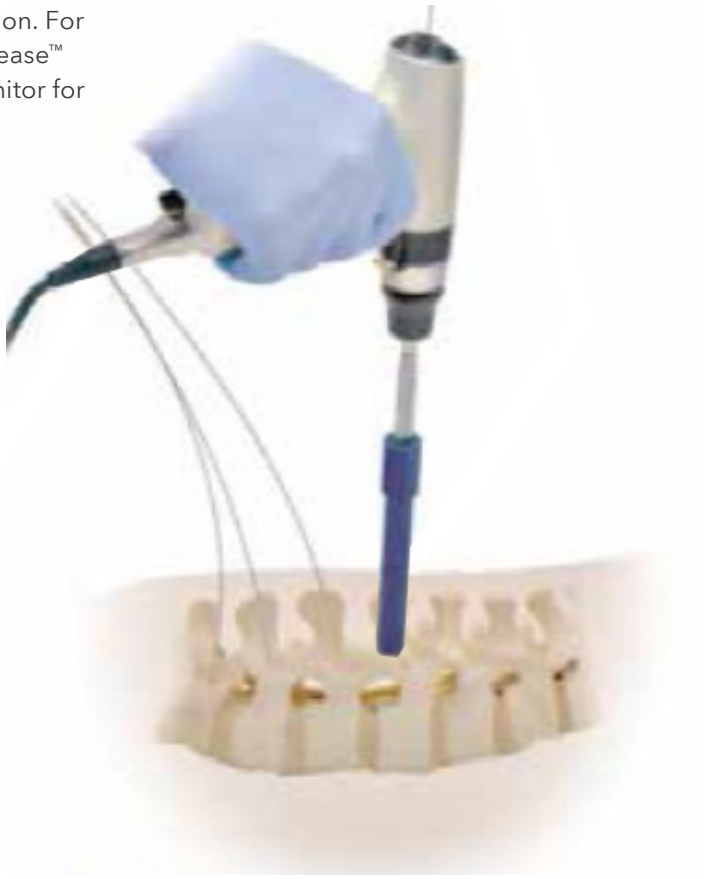


Figure 7

Assembly of the shank driver

To assemble the shank driver follow these steps:

1. Select the depth stop sleeve and the non-NAV shank driver (**Figure 8**).
2. Slide the selected driver sleeve over the shank driver. All shank sleeves require alignment with the shank driver. The tab on the shank driver must be aligned with the tab on the shank sleeve as shown below (**Figures 9a, 10, 11**).

Figure 8

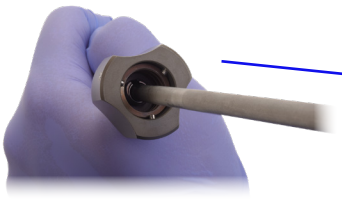


Figure 9

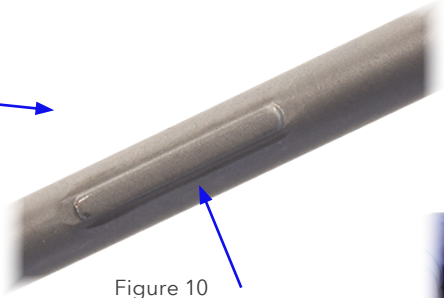


Figure 10

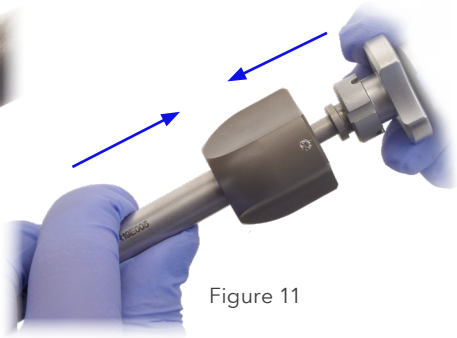


Figure 11

If the gray scallops of the shank sleeve are visible the instruments are not aligned (**Figures 12a, 12b, and 12c**).

Figure 12a

Rotate the shank sleeve until scallops are aligned.

Figure 12b

Aligned

Top view of instrument with shank sleeve and scallops aligned

Figure 12c

3. Push down and rotate the shank sleeve until scallops are aligned (**Figure 12d**).

Figure 12d

Attachment of screwdriver to the screw shank

Non-Sterile Packed Screws in Tray

1. Ensure the collet tip is fully exposed (**Figure 13**) by turning the dark gray knob counter clockwise (**Figure 14**) until resistance is felt.

Figure 13

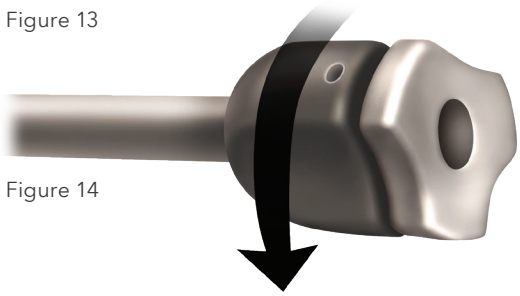


Figure 14

2. Select the appropriate screw shank diameter and length by both preoperative measurement and intraoperative observation. The screw diameter and length can be confirmed from labeling and/or using a screw confirmation gage.
3. Place the driver hexalobe into the shank head, while in tray (**Figure 15**).
4. Slide collet over sphere, while maintaining engagement of the driver hexalobe in the shank head (**Figure 16**).
5. Thread sleeve clockwise, until resistance is felt (**Figures 17a and 17b**).

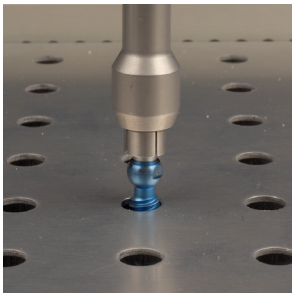


Figure 15

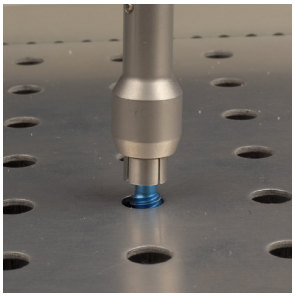


Figure 16

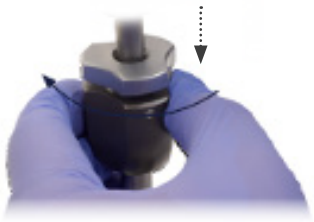


Figure 17a

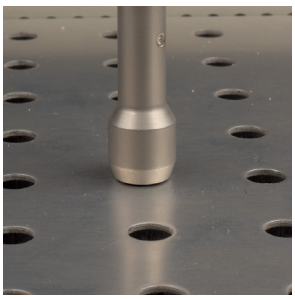


Figure 17b

6. Verify that the shank is properly attached to the driver (**Figures 18a and 18b**).

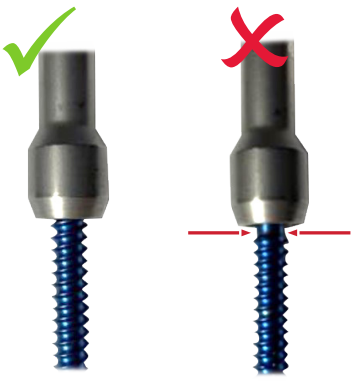


Figure 18a

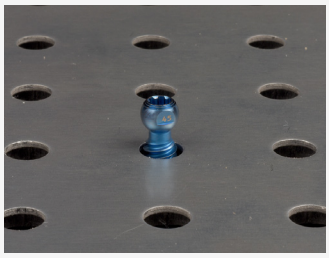
Figure 18b

Attach the driver to the Quick Connect Handle (G900000) or to the IPC™ Powerease™ system by snapping into place (**Figure 19**).

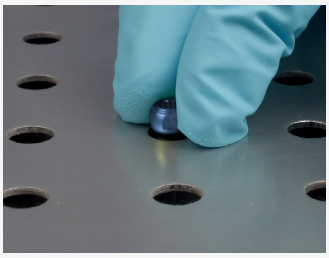
Figure 19

Important

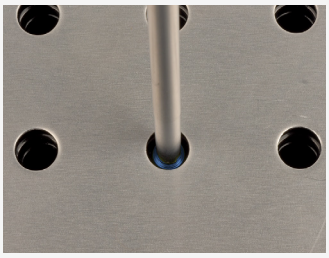
The screw shank tray is color coded to match the color of the screws. The holes in the tray have varying depths to accommodate different screw shank lengths. If a screw shank is placed in the wrong location, remove by hand if the shank head is partially exposed. If the shank head is sunk in the tray, engage the shank driver to the shank head and pull out at an angle to retrieve screw shank.



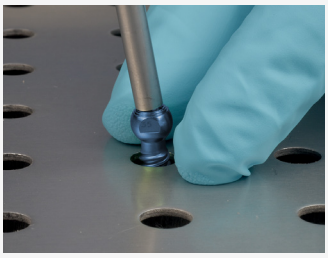
Ideal shank position in tray



Removing partially exposed screw shank by hand



Removing shank head sunk in tray



Sterile Packed Screws

1. Ensure the collet tip is fully exposed (**Figure 20**) by turning the dark gray knob counter clockwise (**Figure 21**) until resistance is felt.

Figure 20

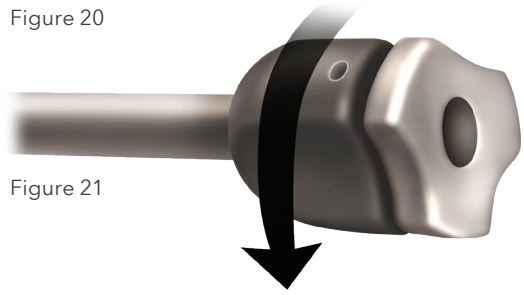


Figure 21

2. Select the appropriate screw shank diameter and length by both preoperative measurement and intraoperative observation. The screw diameter and length can be confirmed from labeling and/or using a screw confirmation gage.

Helpful Hint

Hold the driver assembly in dominant hand and hold the shank firmly in non-dominant hand.

3. Place the driver hexalobe into the shank head (**Figures 22a and 22b**)

Figure 22a

Figure 22b

4. Slide collet over sphere, while maintaining engagement of the driver hexalobe in the shank head (**Figure 23**).

Figure 23

5. Thread sleeve clockwise, until resistance is felt (**Figure 24**).

Figure 24

6. Verify that the shank is properly attached to the driver (**Figures 25a and 25b**)

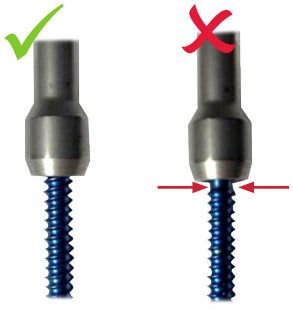


Figure 25a

Figure 25b

Attach the driver to the Quick Connect Handle (G900000) or to the IPC™ Powerease™ system by snapping into place (**Figure 26**).

Figure 26

Placement of screw shank

After the desired screw shank (ATS, cortical, Osteogrip™ or Titan nanoLOCK™) has been attached to the driver, insert the screw shank in the previously tapped screw hole. If using the depth stop sleeve, advance the screw shank until the depth stop touches the bony surface. This should leave enough space to attach the head. If using the shank sleeve, carefully advance the screw shank along the previously determined trajectory. Do not over-advance the screw shank thereby causing the shank sphere to be buried into the bone. This is to help ensure that the multi-axial screw head can be attached at the end of the procedure. To determine if appropriate space is present to attach a multi-axial screw head to the shank: Place the T-handle driver through the Reamer and engage the drive features in the driver to the shank (**Figure 27**), once engaged, slide the reamer down over the sphere of the shank. If the black line is fully visible (**Figure 28**) then the shank is at an appropriate height that will allow for head placement. Ideally, two threads of the shank should be visible outside of the bone.

If the screw shank is over-advanced the surgeon may utilize one of three methods of adjusting the screw shank:

1. Rotate the screw shank counterclockwise until the sphere in no longer resting on bone.
2. Use the reamer to remove bone around the screw sphere to create adequate room to attach the head (**Figure 29a**).
3. Use the inner driver of the reamer to back the shank out of the bone (**Figure 29b**).

Important

Compatibility with CD Horizon™ modular spinal system The CD Horizon™ modular heads may also be used with the CD Horizon™ ModuLex™ 5.5 shanks (ATS or Titan nanoLOCK™) with a 4.5mm diameter or larger. In addition, the Osteogrip™ shanks from the CD Horizon™ modular spinal system can be used with CD Horizon™ ModuLex™ 5.5 heads. Ensure that the appropriate head inserter and set screws are used. The CD Horizon™ modular head inserter and set screw must be used when attaching the CD Horizon™ modular heads while the CD Horizon™ ModuLex™ 5.5 head inserter and set screw must be used when attaching the CD Horizon™ ModuLex™ 5.5 heads.

Important:

It is advised that intraoperative imaging be used to aid screw placement, and the screws should not be used for bicortical fixation.

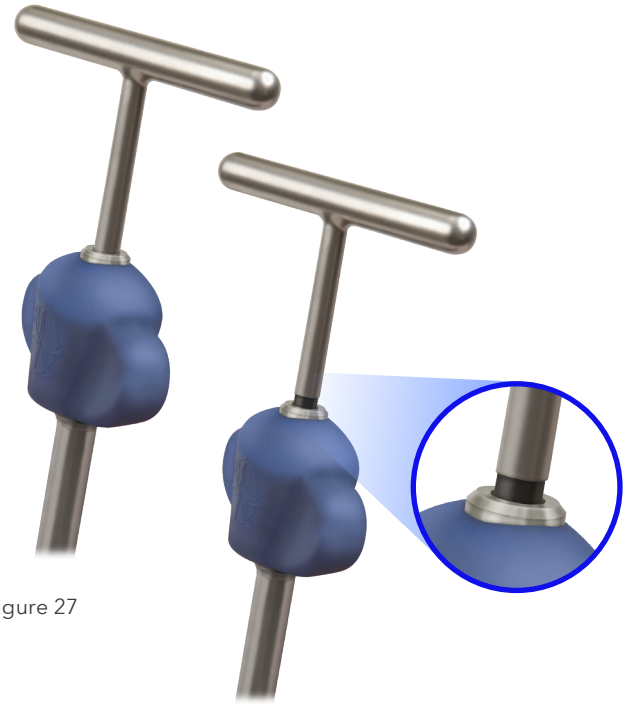


Figure 27

Figure 28

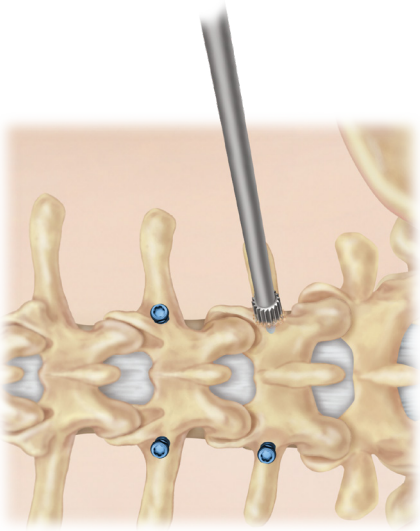


Figure 29a

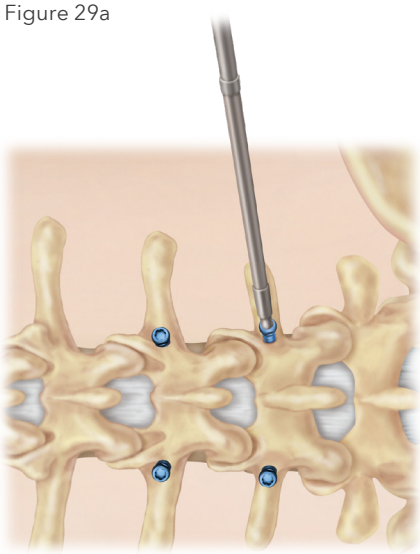


Figure 29b

Decompression and discectomy

The surgeon should follow their standard method of decompression and discectomy. If needed, the surgeon should begin removing the inferior articular process on the level(s) where an interbody will be placed or any bone that needs to be removed to allow for decompression. Once the surgeon is ready to distract, the set includes both anatomy based and shank based distraction options in two lengths long and short. The short legs accommodate blades of up to 8 cm while the long legs should be used with blades longer than 8cm. In addition, the surgeon may use intradiscal distraction such as scissor jack per their typical distraction technique.

Assembling the modular distraction system

Begin by locating the distractor arm and distractor rack in the modular distraction system standalone tray (**Figure 30**). Slide the arm over the rack with the locking ratchet in the neutral position (**Figure 31**). Slide the locking ratchet so that the uncovered arrow points to the desired direction of motion (**Figure 32**). The distractor is now fully assembled and ready for use.

Figure 30

Figure 31

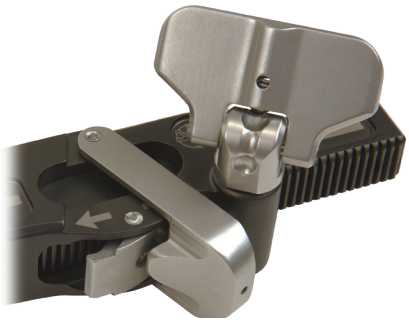


Figure 32

Using the modular distraction system

The distractor is designed using a gear system that drives the mechanism creating distraction. To distract, turn the thumbwheel counterclockwise and to compress turn the thumbwheel clockwise. Ensure that the flywheel is oriented upward when using the distractor.

Anatomy based distraction options

If anatomical distraction is needed, the modular distraction system offers distractor legs that can interact with either the spinous processes (**Figure 33a**) or the laminae (**Figure 33b**).

Figure 33a: Spinous Process Distractor Attachment

Figure 33b: Lamina Distractor Feet Attachment

Select the appropriate length and type of distractor attachments and insert them into the distractor legs. All anatomy based distractor attachments are designed such that they can only be assembled onto the distractor in the appropriate orientation. Place the distractor assembly in the wound and position the feet against the appropriate anatomy, either the spinous process (**Figure 34a**) or the lamina (**Figure 34b)**. Turn the thumbwheel counterclockwise on the distractor rack to distract the anatomy the appropriate amount.

Figure 34a:
Spinous Process Distraction

Figure34b:
Laminar Distraction

Screw shank based distraction options

In addition, there are three screw shank-based distraction options: lassos (**Figure 35a**), hooks (**Figure 35b**) and eyelets (**Figure 35c**).

Figure 35a: Lasso Attachment

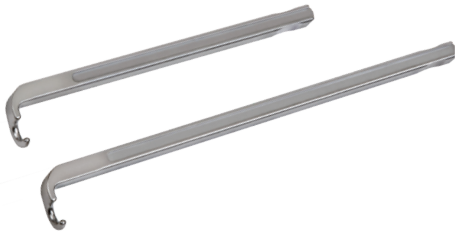


Figure 35b: Hook Attachment

Figure 35c: Eyelet Attachment

Select the appropriate length and type of distractor attachments and insert them into the distractor legs.

To assemble the disposable lasso to the modular posts, slide the narrower portion of the lasso into the slot with the lasso extending out of the distractor leg (**Figures 36a and 36b**), rotate it a quarter turn (**Figure 39c**), pull down slightly, then turn the locking nut a quarter turn to tighten it (**Figure 36d**).

Figure 36a

Figure 36b

Figure 36c

Figure 36d

If the lasso method of distraction is selected, insert the lasso attachment assembly to the distractor legs. Lower the lasso assembly over the screw shanks until they are resting even with the screw shank neck. Next, attach the distractor assembly to the lasso attachment by sliding the distractor legs over the lasso attachments (**Figure 37**). Turn the thumbwheel counterclockwise to distract the appropriate amount.

If the hook method of distraction is selected, insert the hook attachments to the distractor legs. Lower the hooks until they are around the neck of the screw shank (**Figure 38**). Turn the thumbwheel counterclockwise on the distractor rack to distract the anatomy the appropriate amount.

If the eyelet method of distraction is selected, insert the eyelet attachments to the distractor legs. Lower the eyelets until they are around the neck of the screw shank (**Figure 39**). Turn the thumbwheels counterclockwise on the distractor to distract the anatomy the appropriate amount.

Important

The use of excessive force on the screw shank especially in the setting of low bone density may lead to loosening of the screw and loss of fixation at the bone-screw interface.

Note

Disengage the locking ratchet to release the distractor before removal. Care should be taken to prevent the modular distractor legs from falling into the wound.

Figure 37

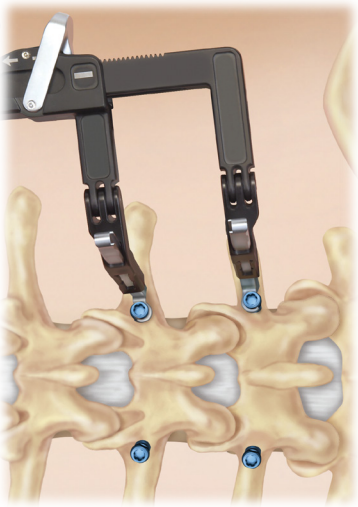


Figure 38

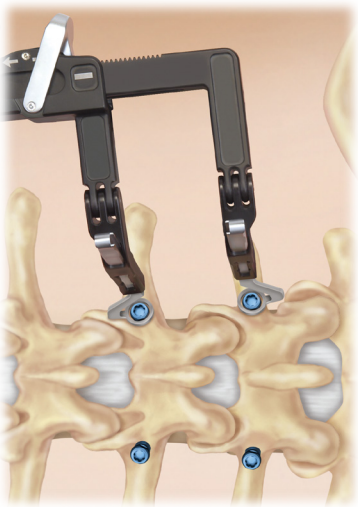


Figure 39

Interbody (Optional)

Refer the appropriate interbody surgical technique for Interbody trialing and placement instructions.

Optional bone reaming

After placing screw shanks, the bone reamer can be utilized for decortication around the screw shank (**Figure 40**). It can also be used to create sufficient space for head assembly. The bone reamer removes adjacent anatomy around the screw sphere that may impede attachment of the head.

Important

Take care not to damage the superior articular facet when reaming.

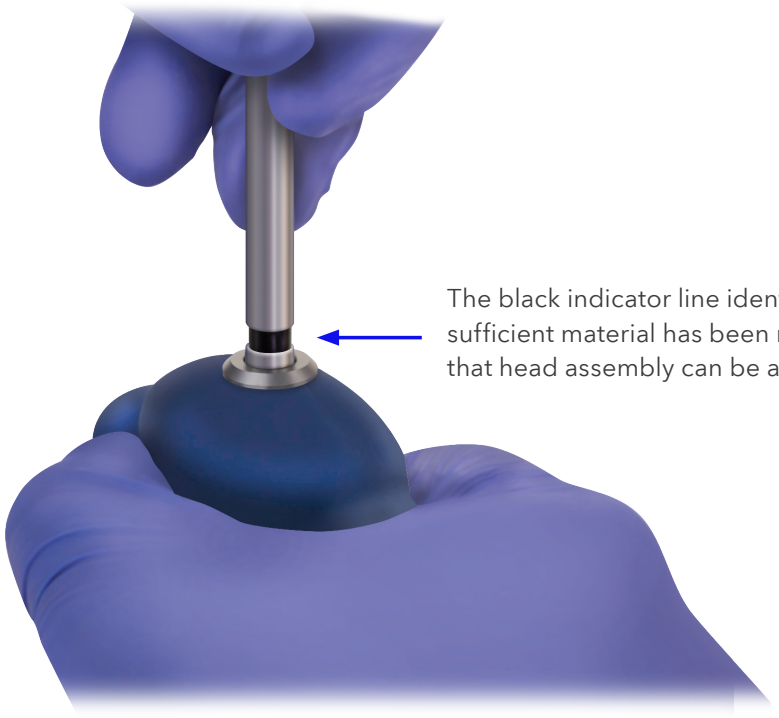


Figure 40

Head Attachment – locking head inserter

Prior to head insertion, ensure the screw shank is clear of any anatomical debris or bone grafting material. The Locking Head Inserter (**Figure 41**) will be used to attach the desired head assemblies onto the screw shanks.

Figure 41

Ensure that the handles of the Locking Head Inserter are completely open prior to loading a head onto the instrument. If the black line is visible (**Figure 42a**), the handles are not in the open position. To release the handles to their open position, press the blue trigger without squeezing the gray handles. The black line should no longer be visible (**Figure 42b**).

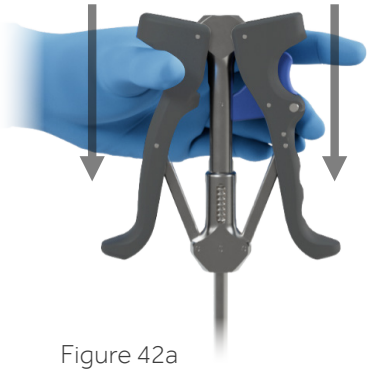


Figure 42a

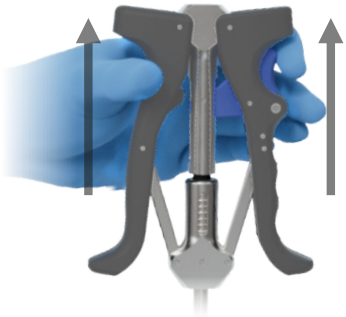


Figure 42b

The inserter can be attached to the head in the sterile packaging (**Figure 43a**), or the head can be placed on the tip of the inserter by hand. The inserter handles should be aligned with the rod slots for placement. Once the head assembly is loaded, lightly squeeze the gray handles of the inserter to provisionally secure head assembly (**Figure 43b**).

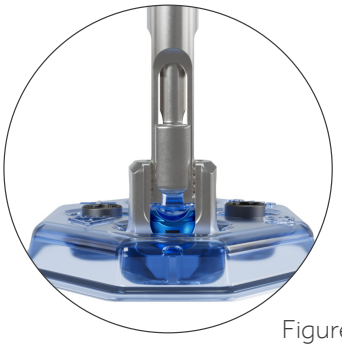


Figure 43a

squeeze

Figure 43b

release

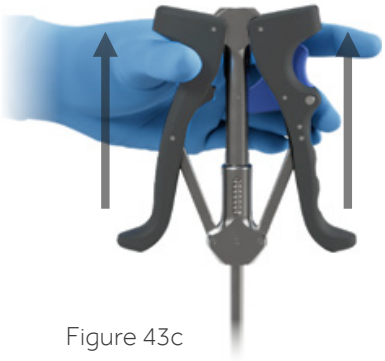


Figure 43c

Important

Do not push the blue locking trigger while squeezing the gray handles until the user is ready to final lock the head assembly onto the shank. If the handles are fully squeezed as shown in **Figure 44** (which is only possible when the blue trigger is squeezed along with the grey handles), the head will progress into its fully locked state and will no longer attach to a screw shank. The black laser mark on the tulip crown will disappear and the head will be in its locked state. If this occurs, the head will not attach to a shank and will be unusable.

Figure 44

Placement and locking of a modular head requires a 4-step process:

1) Attach

2) Confirm

3) Squeeze

4) Release

Step 1 - Attach

Attach the head onto the shank by pushing the assembled head and inserter downwards onto the screw shank (**Figure 45**). For uni-axial head placement, the gray inserter handles should be positioned parallel to screw flats. Laser marks on the inserter align with the rod slot of the uni-axial head and the handles are oriented in the direction of the rod. It is recommended to position the gray handles roughly in the cephalad/caudal direction and slowly rotate the instrument while gently pushing downwards.

Important

If you are not able to attach the head to the screw shank, either back out the screw shank or use the decortication tool to add additional clearance and then re-attach the head to the screw shank.

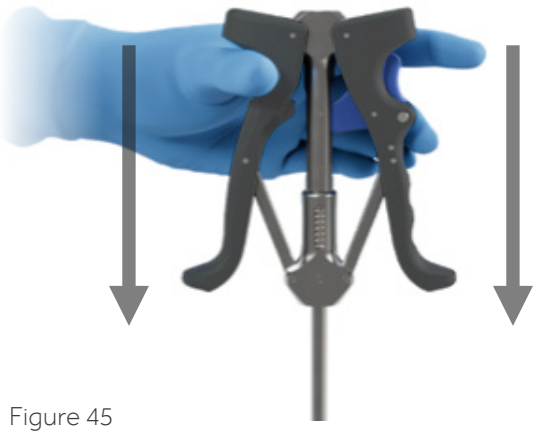


Figure 45

Step 2 - Confirm

Confirm preliminary attachment by pulling up slightly on the inserter (**Figure 46**).

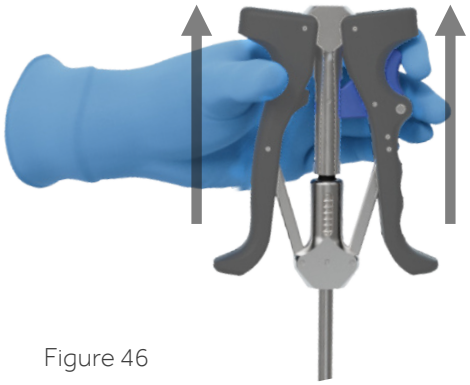


Figure 46

Important

Do not squeeze the blue trigger during this step.

Note

Once a head has been provisionally placed, the connection is irreversible. The heads are designed with a one-way connection that cannot be removed once attached.

Step 3 - Squeeze

After confirming preliminary attachment of the head to the shank, push and hold the blue locking trigger and then fully squeeze they gray handles to final lock the head onto the screw shank. Note the black laser mark line which is only visible when both the gray handles and blue trigger are fully pressed (**Figure 47**).

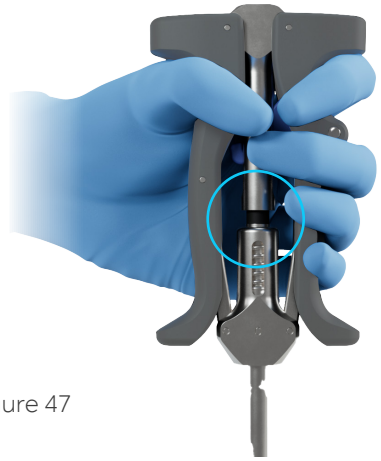


Figure 47

Step 4 - Release

To remove the inserter from the head after final locking, release the gray handles and remove the instrument (**Figure 48**).

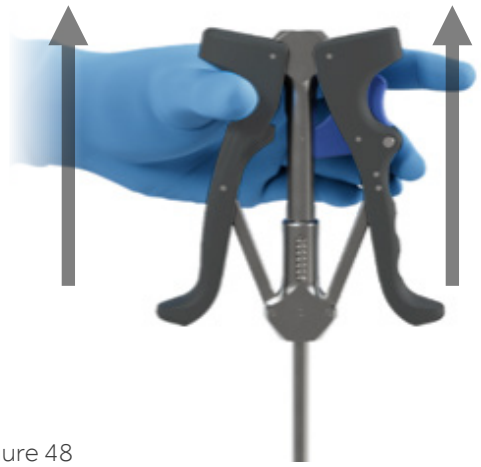


Figure 48

Note

If the handles are released too slowly, the blue trigger may need to be pushed to return the gray handles to a completely open state. If this occurs, you will still be able to see the black line on the inserter. To release the inserter from the implant, push the blue trigger without squeezing the gray handles.

If the head will not attach to shank the surgeon should check that there is enough shank visible to attach the head. This can be accomplished by placing the reamer over the shank. If the black line is visible then the shank is appropriately placed.

If the line is not visible the surgeon has two options:

i. Back out screw shank using the inner shaft from the reamer (**Figure 49a**).

ii. Use reamer to remove bone from around the shank (**Figure 49b**).

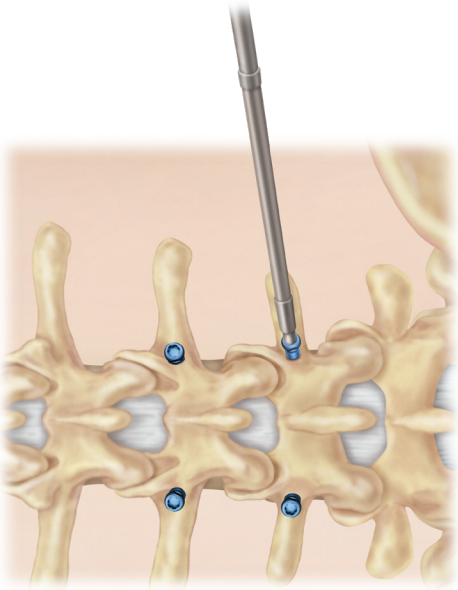


Figure 49a

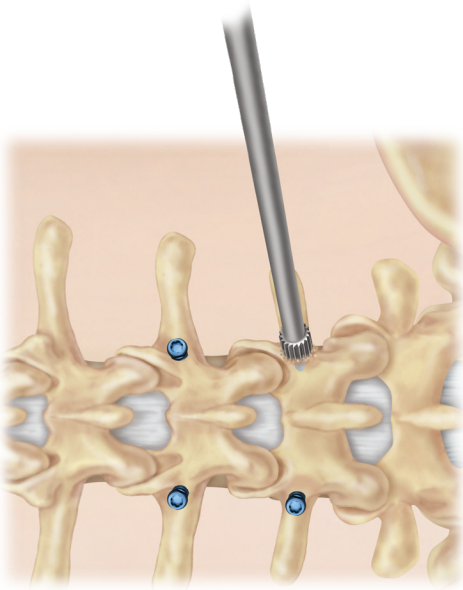


Figure 49b

Rod placement

Select the appropriate length rod using the rod template tools or the surgeon's preferred method.

Using the rod holder, place the rod into the saddle of the tulip heads (**Figures 50a and 50b**).

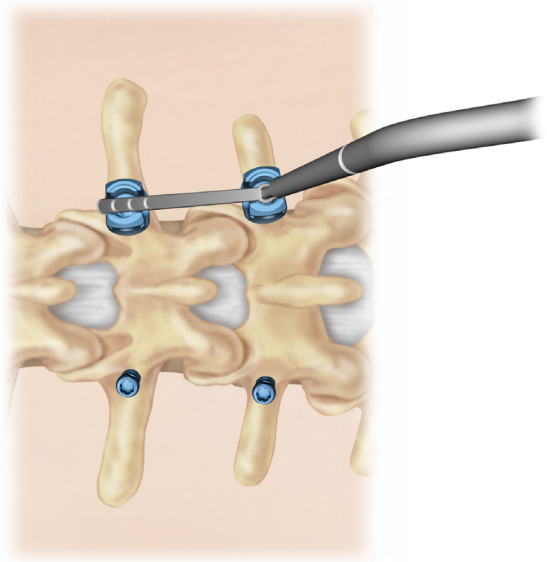


Figure 50a

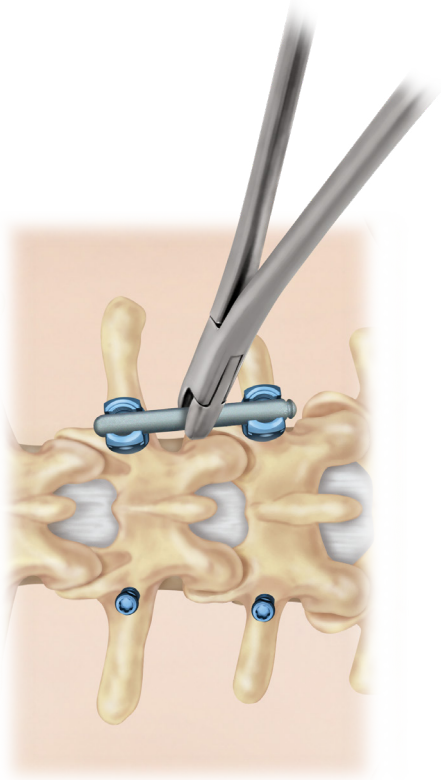


Figure 50b

Set screw instrumentation

Swizzle stick and provisional driver instruments come equipped with a self-retaining mechanism. Simply insert the setscrew onto the instruments. Use either the swizzle stick or the provisional driver (**Figures 51a and 51b**) to provisionally tighten the set screws into the screw assembly.

If compression is desired, use the compressor to compress the construct at each level.

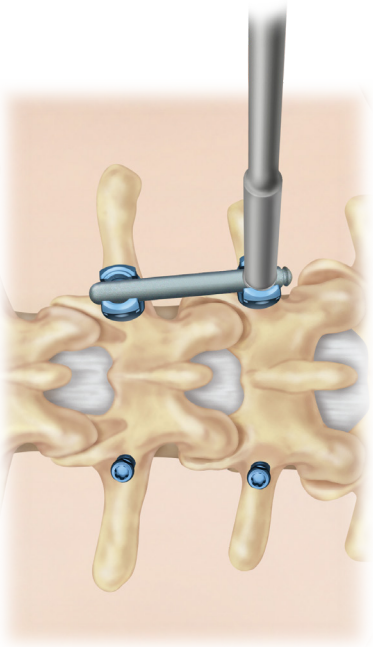


Figure 51a

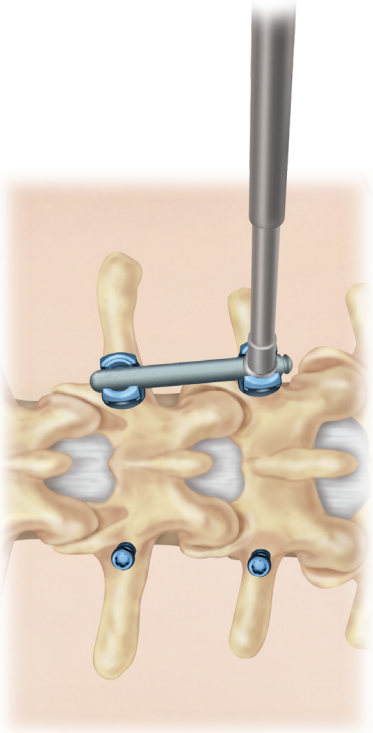


Figure 51b

Final tightening

Using the set screw break off driver and the counter torque positioned fully over the head and on the rod, break off the set screws (**Figure 52**). The set screw break off driver will retain the break off portion of 8 set screws so multiple set screws can be broken off with it.

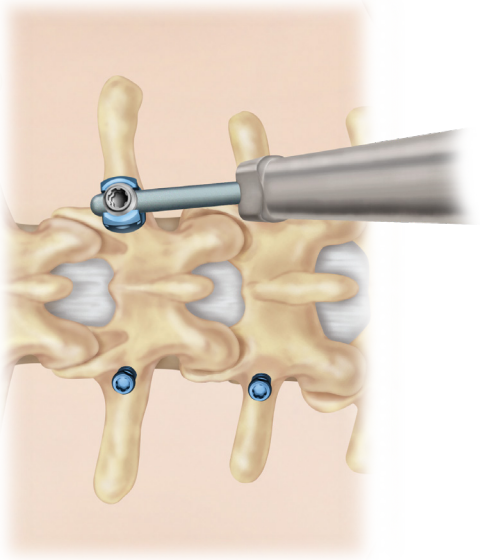


Figure 52

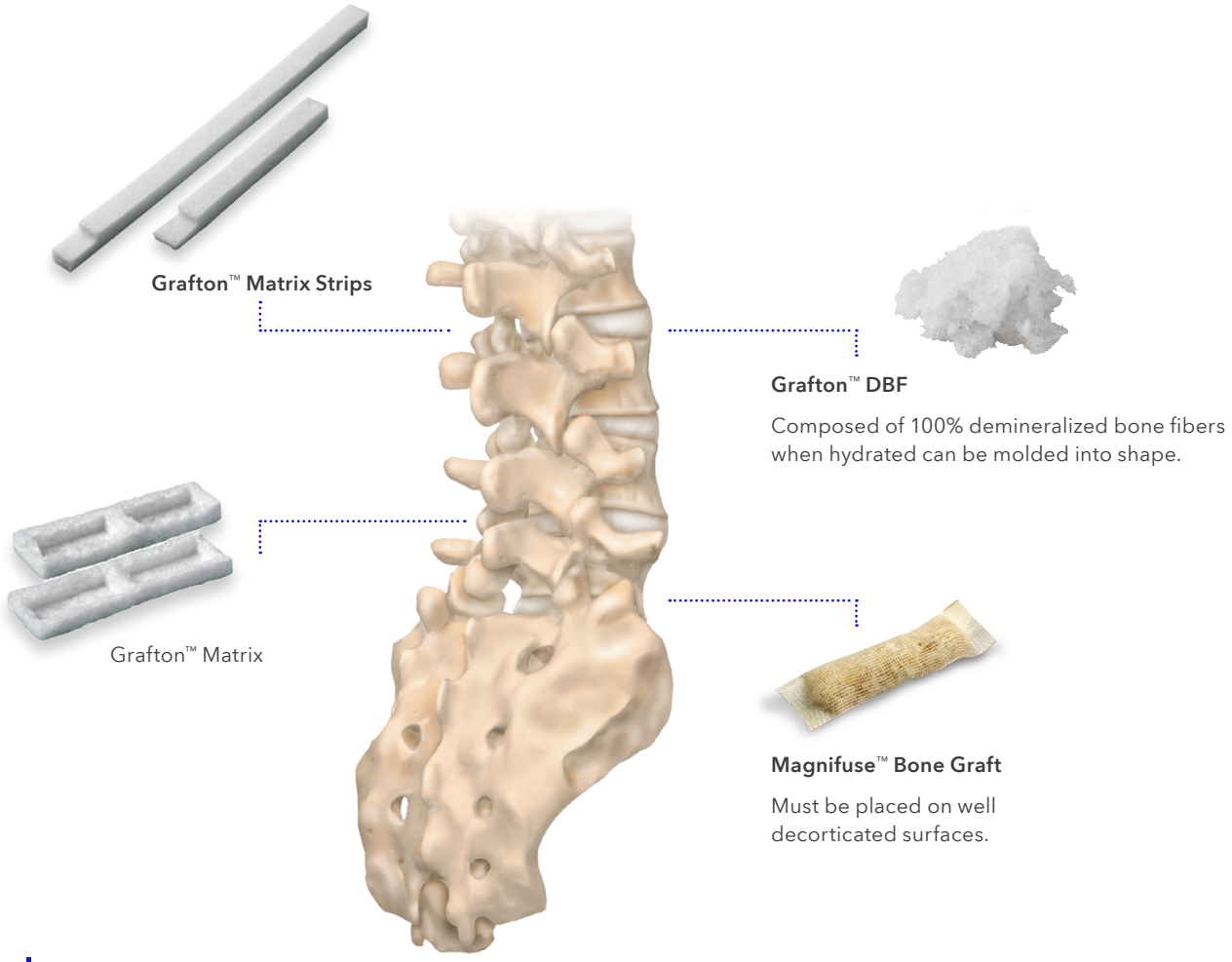
Using Powerease™ to break off set screws:

1. Insert Breakoff Driver Adapter into Set Screw Break Off Shaft (SSBO).
2. Push SSBO Lock Button and insert IPC™ Powerease™ SSBO counter torque.
3. Connect this instrument to the IPC™ Powerease™ handle.
4. Place over set screw, push handle down until the counter torque captures the head (**Figure 53**), and squeeze trigger until a mechanical click is felt.
5. Repeat step four for all set screws.

Figure 53

Additional grafting

When posterior fixation is used, a number of Medtronic bone graft options are available as fillers for bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. Precise placement of the bone graft (autograft or allograft bone) is essential to facilitate fusion. These options are intended to be used as a supplement to posterior instrumentation. Some examples are shown below.



Grafton™ Matrix Strips

Grafton™ DBF

Composed of 100% demineralized bone fibers when hydrated can be molded into shape.

Grafton™ Matrix

Magnifuse™ Bone Graft

Must be placed on well decorticated surfaces.

Implant explantation

To remove the set screws and the pedicle screws, attach the obturator to the break off driver working end. Insert the obturator tip into the set screw and turn counterclockwise until the set screw has been removed. To remove the screw insert, insert the obturator tip into the screw and turn counterclockwise until the screw has been removed.

Note:

Use caution as the obturator instrument does not retain the set screw during removal.

Navigated workflow

Technology overview

O-arm™ Image Acquisition System

O-arm™ Imaging System

Mobile Viewing Station

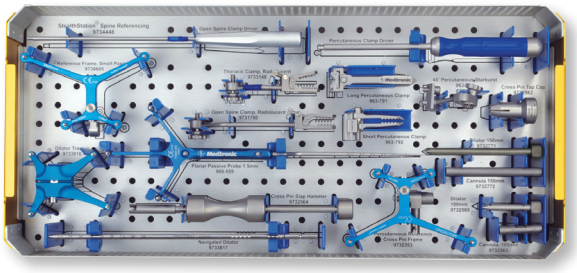
Main Cart

Camera Cart

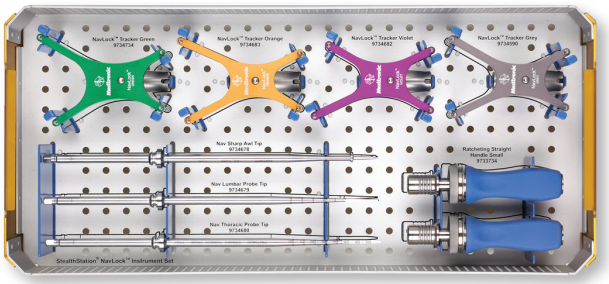
StealthStation™ Surgical Navigation

Navigated Stealth-Midas™ Powered Drilling System

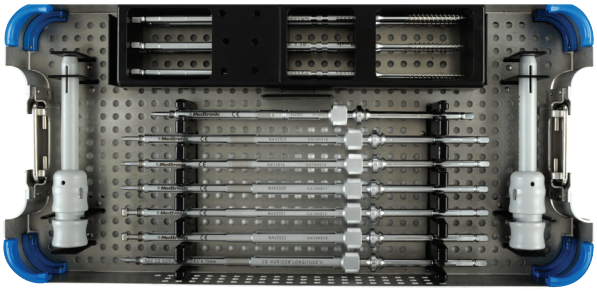
Instruments and equipment



StealthStation™ Spine Referencing Set



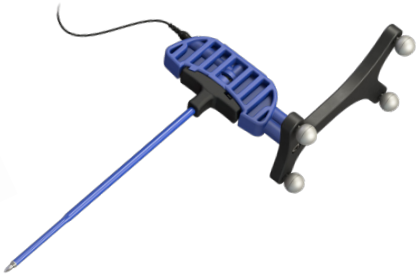
StealthStation™ NavLock™ Instrument Set



Optional - Tapping for ATS
Navigated CD Horizon™ Solera™ Complete
Percutaneous Taps/Drivers Set

Spheres
(8801074)

Disposable Perc Pin
100mm (9733235)
150mm (9733236)



Navigated PAK Needle
(9733498)

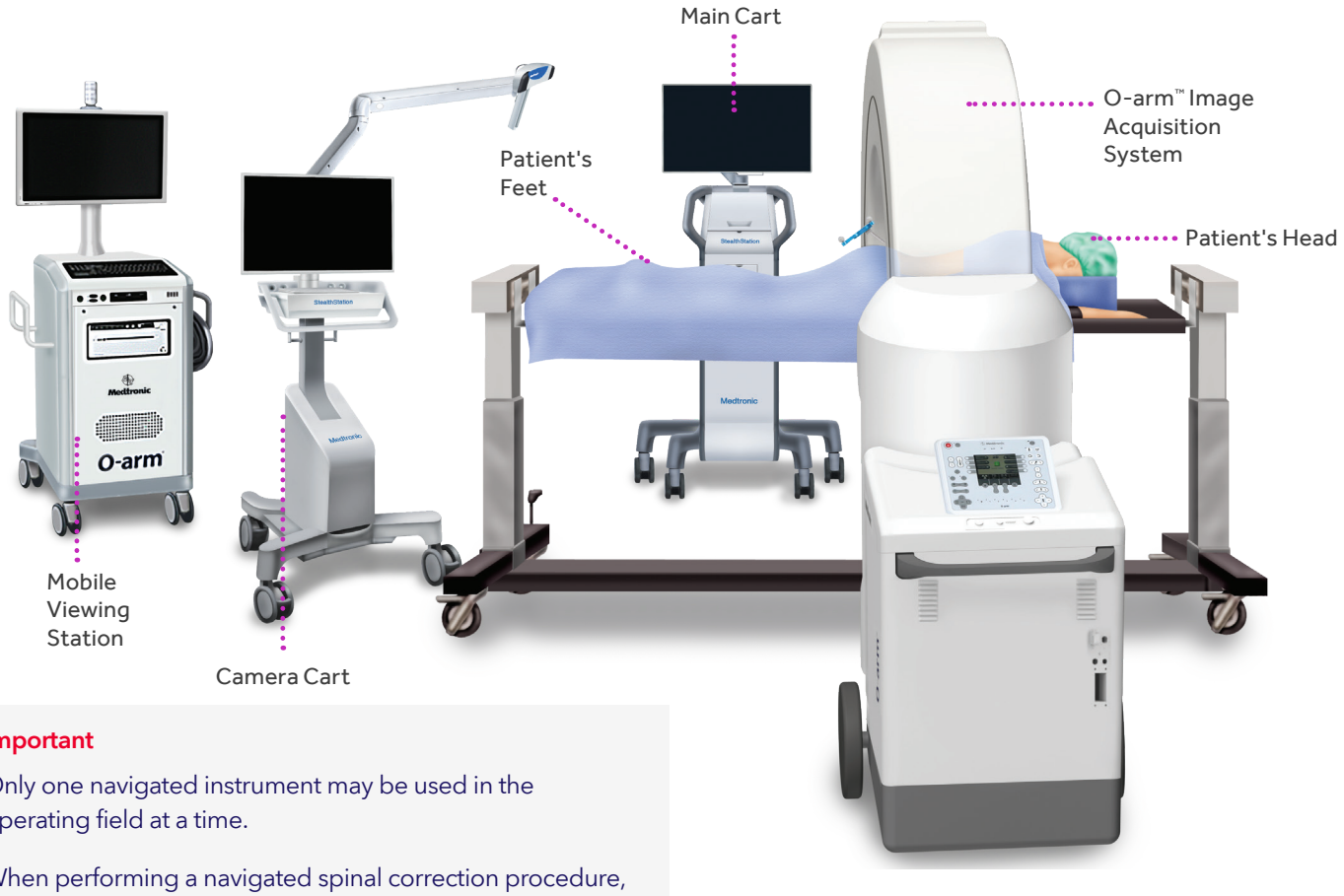
O-arm™ Sterile Tube
Drape (optional)
(9732722)

Navigation equipment and room set up

For a navigated surgery, the OR should be equipped with the O-arm™ image acquisition system, the mobile viewing station (MVS), and the StealthStation™ system. Consult the StealthStation™ system and O-arm™ imaging system manuals for complete indications, warnings, precautions, important medical information, and instruction on equipment and OR set up, reference frame placement, registration, and StealthStation™ spine software workflow such as correct procedure selection, instrument verification, and image acquisition.

When determining the best angle to position the StealthStation™ camera, the anatomy of the patient must be taken into account. Use preoperative images, if available, to assess the angles of the pedicles and the severity of the spinal curvature to determine the most ideal placement of the camera to maintain line of sight with the navigated instruments and reference frame.

Example equipment setup for navigated posterior fixation procedure that has the StealthStation™ camera cart positioned near the patient's feet.



Important

Only one navigated instrument may be used in the operating field at a time.

When performing a navigated spinal correction procedure, it is recommended to conduct the pedicle preparation and implant insertion steps starting with the most distal spinal level and then move proximal toward the reference frame. This methodology of working toward the reference frame, as screws are inserted, allows for the accuracy of screw trajectories to be maintained.

Important

Ensure the reference frame is properly secured to patient anatomy. Neglecting to verify that the reference frame is secure could result in navigational inaccuracy if the hardware moves in relation to the anatomy after registration is complete.

Note

During the OR set up, consider the placement of the patient reference frame to ensure StealthStation™ system camera has direct line of sight to both the patient reference frame and instrument trackers. It's recommended to aim the instrument tracker towards the StealthStation™ system camera during use. Consider the best balance in camera position to view the patient reference frame and instrument trackers given the surgical procedure and set up.

When positioning the O-arm™ system for the procedure, place it around the patient table approximately seven inches closer cephalad from the anatomy to be imaged (**Figure 53a**). The gantry should then be translated in the direction of the patient's feet for imaging. This will allow the gantry to be placed in a "park" position and remain in the sterile field throughout the procedure, if desired (**Figure 53b**).

The camera should be positioned at the head end of the patient table so that the camera has an unobstructed line-of-sight to the Reference Frame which will be placed into the patient. Position the surgeon's monitor near the patient's side, opposite from the surgeon.

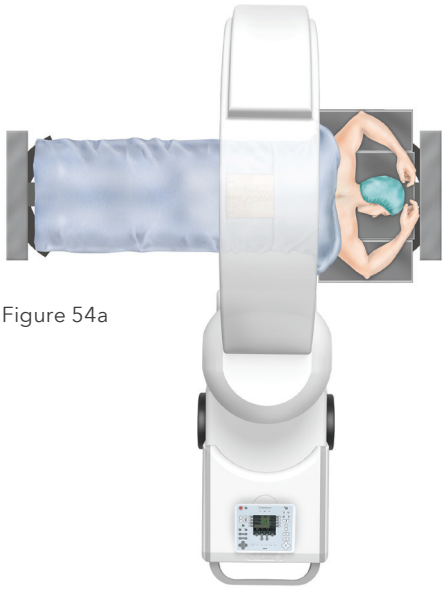


Figure 54a

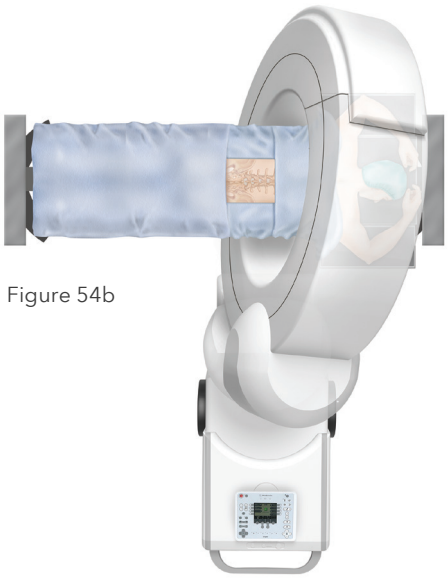


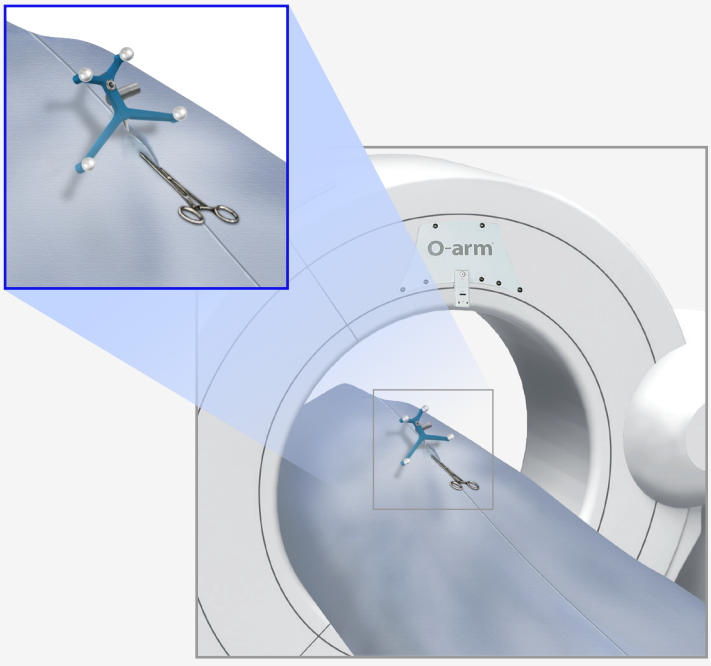
Figure 54b

Helpful Information

If the O-arm™ system will remain in the sterile field during the procedure, drape the O-arm™ system gantry using the O-arm™ IAS sterile tube drape during the positioning of the system. If the O-arm™ system will be removed from the sterile field, place and clamp two half-drapes over the sides of the patient prior to positioning in the sterile field maintaining sterility around the patient while closing the gantry of the O-arm™ system.

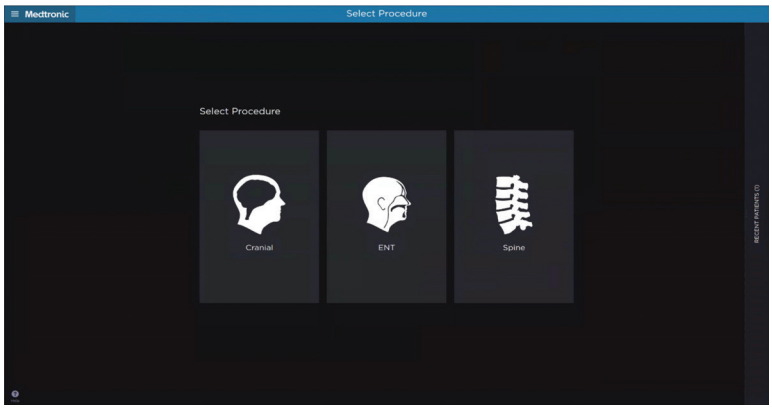
Be sure that the reference frame is visible to the StealthStation™ camera after draping and be sure that any clamps placed on the drapes do not interfere with O-arm™ system acquisition.

In the StealthStation™ spine software, complete the "Select Surgeon" and then "Select Procedure" tasks. Continue through the software by completing the "Set Up Equipment" and "Verify instruments" tasks to reach the "Acquire Scan" Screen.



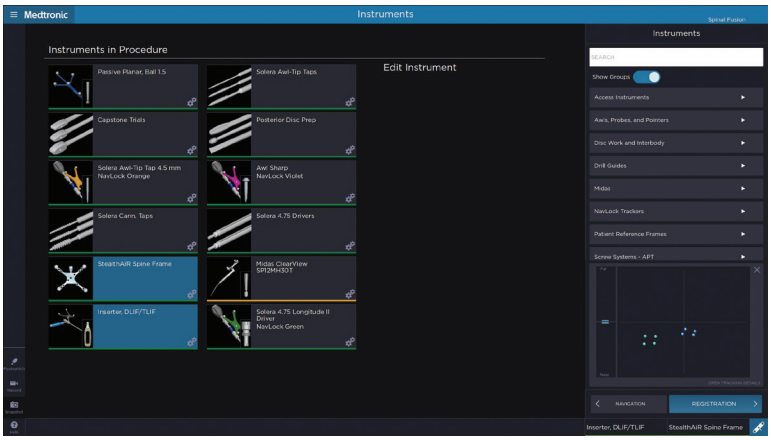
Place the patient in the prone position, lying flat on a Jackson spine top table or a Jackson table with the Wilson frame.

StealthStation™ Spine Software Workflow



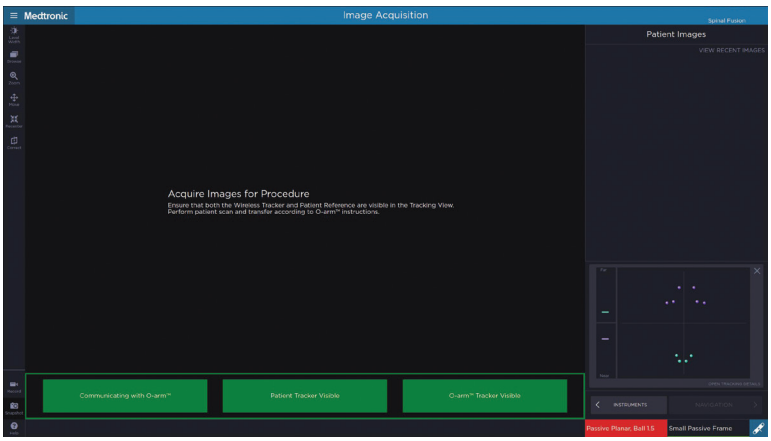
1. Select Procedure and Select Surgeon

Open the "Select Surgeon" menu and select the Primary Surgeon and the Surgical Procedure to be performed.



2. Verify Instruments

Check that the toolcards for all the navigated instruments needed for the procedure are shown on this screen. Instruments can be verified now or during a later step, but the toolcard for the instrument must appear on this screen to be verified and tracked.



3. Acquire Scan

The navigation system will remain on this screen until the O-arm™ system image acquisition step has been performed.

Synergy TLIF™ procedural workflow

It is recommended to verify navigated accuracy anytime changes are made to the navigation set-up (for example the camera position is changed),

VERIFY INSTRUMENTS	• Passive planar ball-tipped probe • Navigated tap • Navigated shank driver		• Navigated trial • Navigated interbody inserter • Stealth-Midas™ drill
PATIENT POSITIONING	• Position patient in the prone position • Position camera at head of the bed		
SITE ACCESS	• Determine access point • Mark skin		• Make skin incision
PLACE REFERENCE FRAME	• Spinous process clamp with small passive reference frame	**- Or -**	• Percutaneous reference pin with percutaneous reference frame
ACQUIRE 3D IMAGE	• Drape patient, bring O-arm™ system in field, and remove after image acquisition	**- Or -**	• Drape O-arm™ system, bring in and leave in field after image acquisition
DETERMINE STARTING POINTS	• Stealth-Midas™ drill may be used to create starting points		
PEDICLE ACCESS PREPARATION	• Tap (power optional) and use projection to determine screw length and diameter		• Place screw shanks • Repeat for other levels
BONY PREPARATION/ DECOMPRESSION/ DISCECTOMY	• Proceed with desired surgical steps including bony work and decortication • Use Stealth-Midas™ drill for facetectomy and laminectomy		• Use navigated posterior disc prep instruments if necessary • Repeat for other levels
INTERBODY PLACEMENT	• Refer to the appropriate navigated interbody workflow guide		
INSERT/LOCK HEADS	• Open sterile packaged implants • Load head onto inserter • Secure head assembly to shank using the head inserter		
ROD AND SET SCREW PLACEMENT	• Place rods • Compress, if desired • Place, tighten, and shear set screws		
ACQUIRE 3D CONFIRMATION IMAGE	• Assess implant placement		

Note

If using a percutaneous reference pin with percutaneous reference frame this may be placed prior to the site access.

Instrument verification

Attach the Spheres to a blue Reference Frame from the Spine Referencing Set and the NavLock™ trackers from the NavLock™ set. Check the Spheres to ensure they are secure. Next, attach the NavLock™ trackers to the instruments.

Place each instrument tip into the divot in the blue Reference Frame and hold perpendicular (**Figure 55**) and visible to the camera until a confirmation color is seen. Use the tracking view in the lower right of the screen to ensure the camera is tracking the Reference Frame and instrument correctly (**Figure 56**).

- Successful verification is indicated by a chime and a transition to green on the instrument toolcard.
- Failed verification is indicated by a "bonk" sound and indicates that the instrument may be positioned improperly in the divot or is bent/damaged. Inspect the instrument; if it is bent/damaged, do not use.
- If no sound is heard when the instrument is touched to the divot, this may indicate that the camera cannot see either the instrument or the frame.

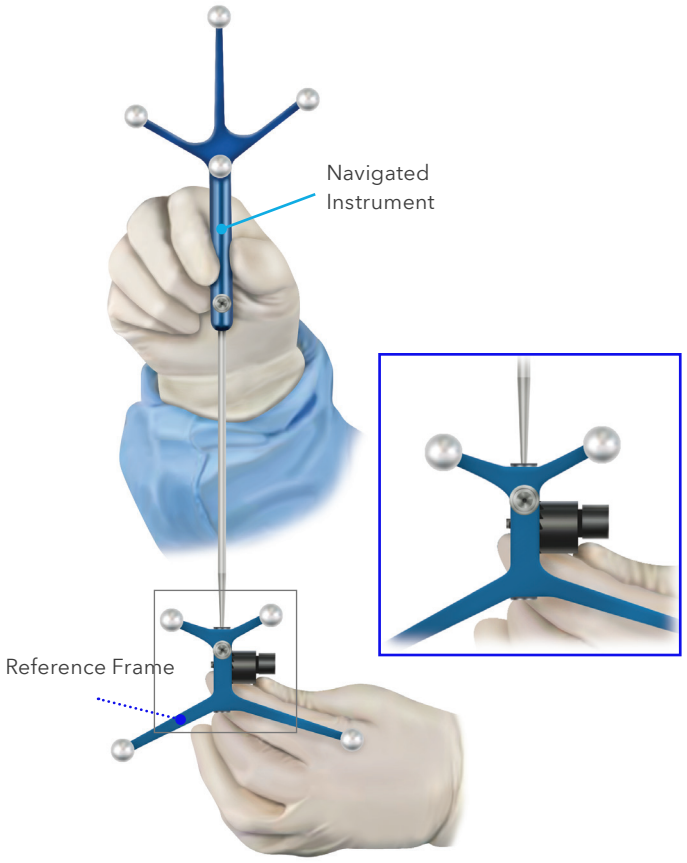


Figure 54

Helpful Hint

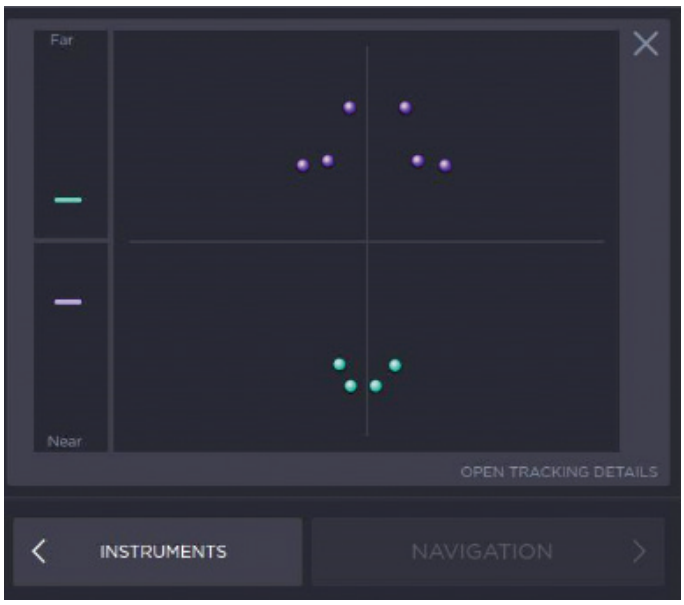
Assigning an instrument to a specific-colored NavLock™ tracker will eliminate the need to switch the tracker from one instrument to the next throughout the procedure. As an example, the grey tracker could be assigned to the tap and the orange tracker could be assigned to the driver.

Helpful Hint

OR Staff can verify instruments before the surgeon enters prior to reference frame placement.

Important

Posterior Disc Prep instruments are verified with default instruments and not the actual tip.



StealthStation™ system software

Figure 55

Reference frame placement

When performing a Synergy TLIF™ procedure, use of the spinous process clamp with the small passive reference frame is recommended. The clamp should be firmly attached to the spinous process superior to the planned instrumented levels. With the camera positioned at the patient's head, the frame should be within an unobstructed view of the camera and the instruments.

Alternatively, the percutaneous reference pin with the percutaneous reference frame can also be used. Pins are available in 100mm and 150mm lengths. For L5-S1 procedures, the surgeon should consider medializing the pin to avoid line-of-sight obstructions between the camera and the navigated instruments.

The preferred method places the pin down the posterior superior iliac spine (PSIS) much like the trajectory of an iliac screw, which drops the reference frame out of the way and does not pose potential line-of-sight obstacles between the camera and the screw placement (**Figure 57**). This option is described below.

Upon palpation, locate the PSIS on the patient. Mark the skin a little medial and inferior to the PSIS to verify the appropriate location to place the pin.

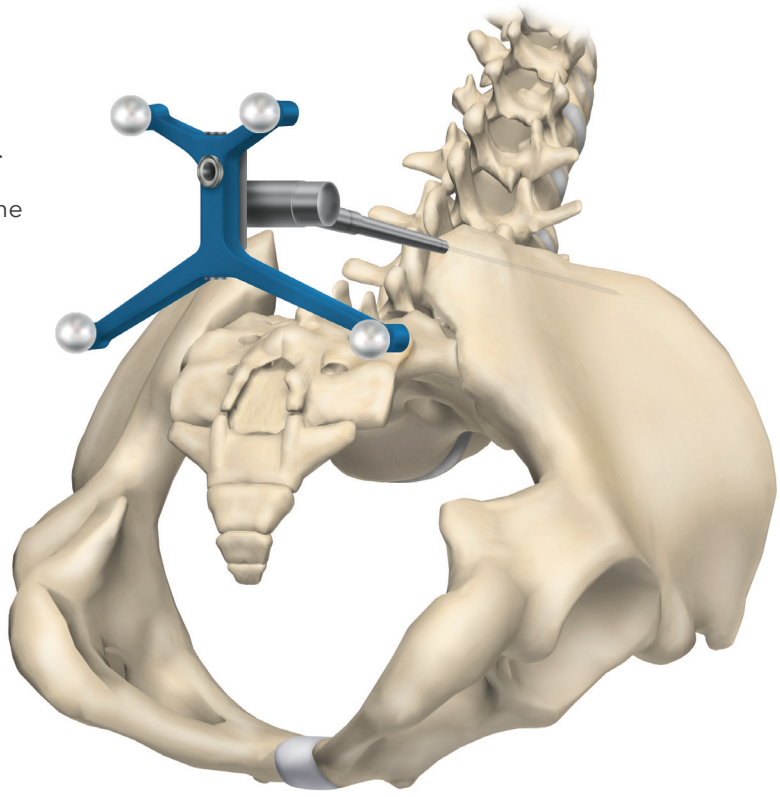


Figure 57

Make a stab incision and locate the cannula with the dilator over the PSIS. Place the dilator/cannulas into the incision through the tissue until it contacts bone. Once docked, the dilator/cannula assembly is tapped with a mallet to make an indentation in the bone for the pin. While holding the cannula in place, remove the dilator and insert the pin through the cannula. Place the tap cap on the pin and rotate the cap so the arrow on the tap cap points toward the camera. Orient the pin/tap cap assembly approximately 30 degrees toward the midline of the patient and then angle it 30 degrees toward the foot of the patient.

Use an impactor to drive the pin into the bone until the tap cap contacts the top of the cannula (**Figure 58a**). Remove the tap cap from the pin and attach the percutaneous reference frame to the pin (**Figure 58b**).

Important

Ensure the reference frame is properly secured to anatomy. Neglecting to verify that the reference frame is secured could result in navigational inaccuracy if the hardware moves in relation to the anatomy after registration is complete.

Note

To minimize the potential for navigation inaccuracy as a result of relative motion between the reference frame and target anatomy, the reference frame should be placed near the planned instrumented levels.

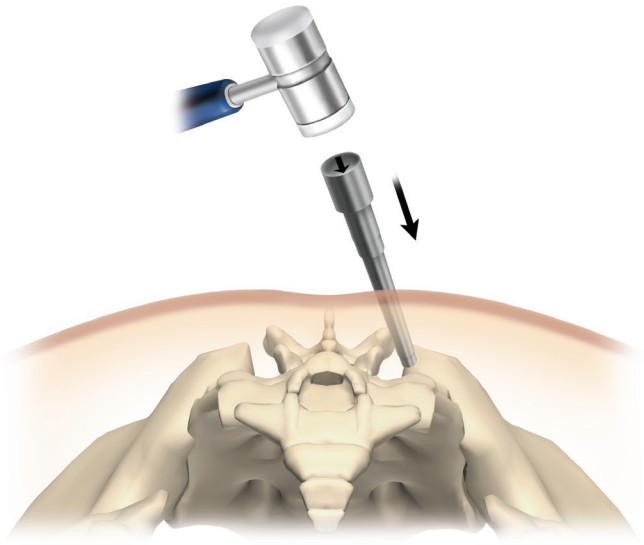


Figure 58a

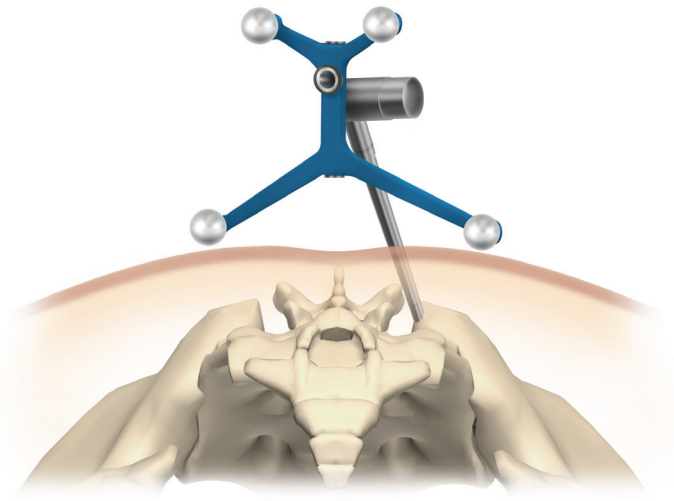


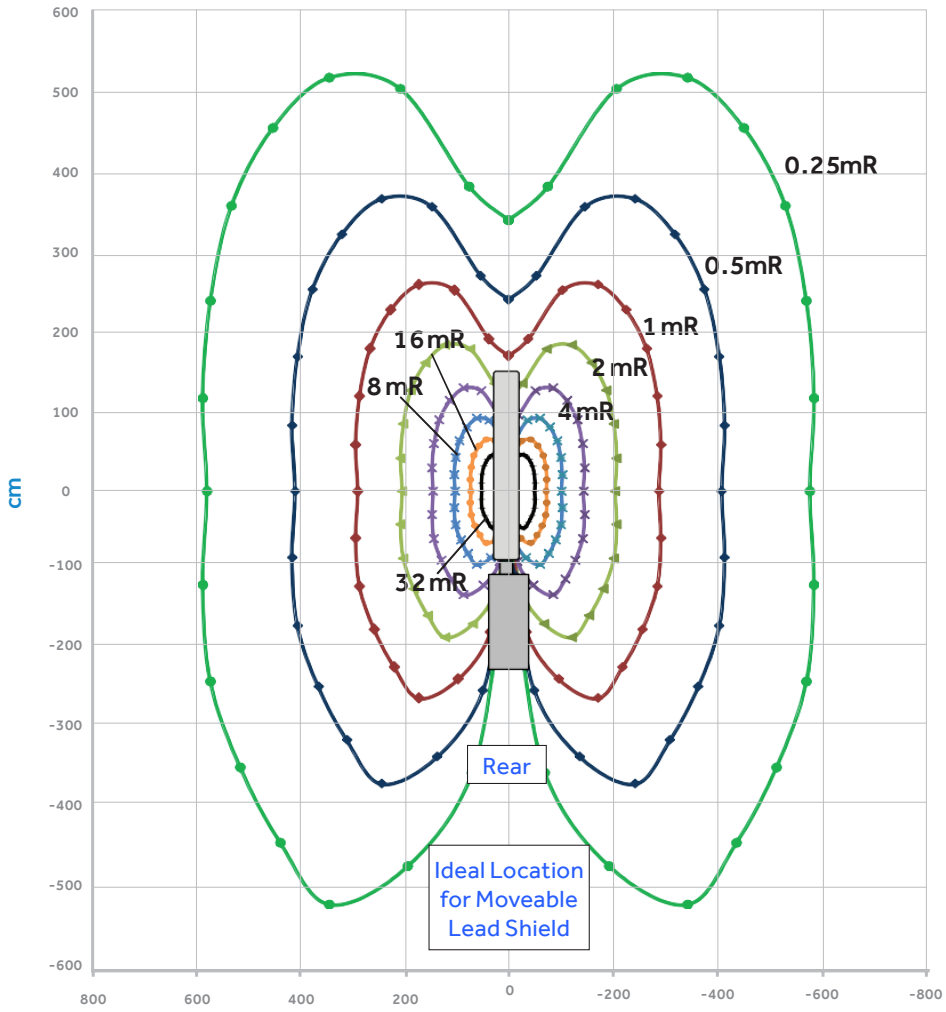
Figure 558b

Image acquisition

At any time when fluoroscopy is used (2D or 3D acquisition) all personnel who are not wearing protective lead apparel should stand at least 15 feet (457.2cm) from the O-arm™ system with a certified moveable lead shield between themselves and the O-arm™ system to avoid unnecessary radiation exposure.

Establish the surgery site using 2D fluoroscopy scout images as needed. On the control panel, select the patient size, anatomy, and orientation. With the patient isocenter, position the O-arm™ system gantry to perform a 3D spin. Following the 3D spin, the images are transferred automatically to the StealthStation™ system. Should 2D images or a second 3D spin be desired, four preset O-arm™ system gantry positions may be set up and saved. Once the images are transferred, the O-arm™ system can be moved out of the way and into the park position.

O-arm™ System Isodose Curve



Scatter plot showing the shape of isodose curves for the maximum technique factors for the O-arm™ 02 imaging system. Please refer to the end of this surgical technique for more information on the shape of isodose curves for the O-arm™ 1000.

- Protocol: abdomen standard large
- Technique: 120 kVp, 330 mAs

Pedicle preparation

The pedicle may be prepared by using a Midas Rex™ burr or a NIM™ pedicle probe to create a pilot hole. The surgeon may then tap the desired screw trajectory along the pedicle. Alternatively, the surgeon may decide to start with the tapping step or not tap based on the patient's bone quality. Use a ball tipped probe to palpate the pedicle walls and confirm there are no breaches.

Alternatively, the IPC™ Powerease™ system may be used for drilling and tapping **(Figure 59)**. The IPC™ Powerease™ system is a system of powered surgical instruments designed specifically for spine surgery. The taps from the CD Horizon™ ModuLex™ instrument sets are fully integrated with the StealthStation™ and O-arm™ systems. The awl tip taps from the CD Horizon™ ModuLex™ instrument sets may be used with placing the ATS shanks if desired by the surgeon. For comprehensive instructions refer to the Powerease™ user manual.

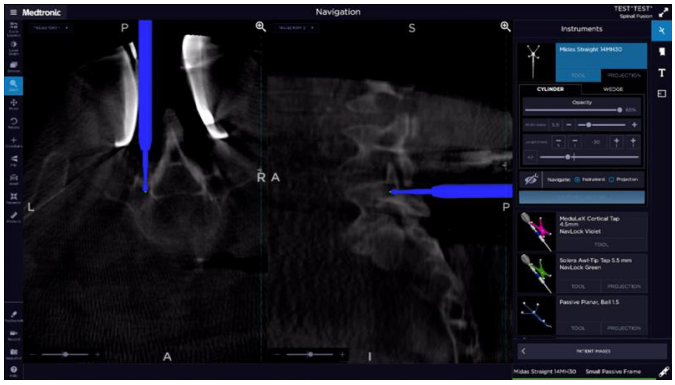


Figure 59

On the StealthSstation™ system, choose the "Tool" tab to select the appropriate Stealth-Midas™ tip to display the Stealth-Midas™ dissecting tool. Use the Stealth-Midas™ to drill at the desired trajectory. Select "Save Projection" to save your plan.

Free-running EMG can be used to monitor for any nerve root irritation during this procedure.

Assembly of the shank driver

To assemble the shank driver follow these steps:

1. Select the shank driver sleeve and NAV driver (**Figure 60**).
2. Slide the selected driver sleeve over the shank driver. All shank sleeves require alignment with the shank driver. The tab on the shank driver must be aligned with the tab on the shank sleeve as shown below (**Figures 60a, 60b, 60c**).

Figure60

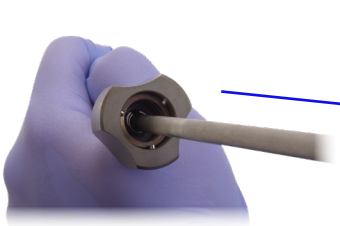


Figure 60a

Figure 60b

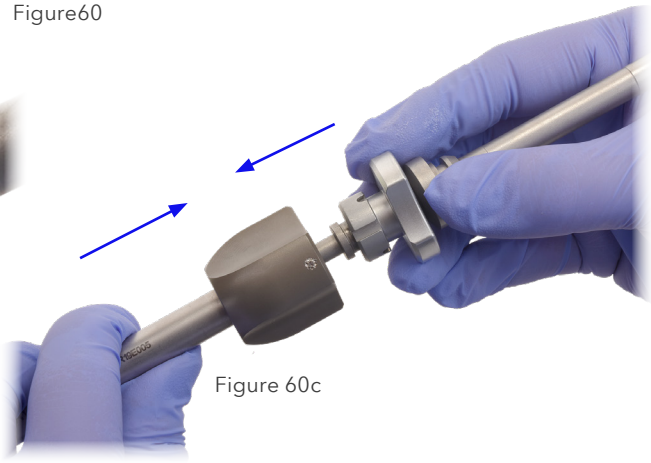


Figure 60c

If the gray scallops of the shank sleeve are visible the instruments are not aligned (**Figures 61a, and 62b**).

Figure 61a

Rotate the shank sleeve until scallops are aligned.

Figure 62b

Aligned

Top view of instrument with shank sleeve and scallops aligned

3. Push down and rotate the shank sleeve until scallops are aligned (**Figure 63**).

Figure 63

Attachment of screwdriver to the screw shank

Non-Sterile Packed Screws in Tray

1. Ensure the collet tip is fully exposed (**Figure 64**) by turning the dark gray knob counterclockwise (**Figure 65**) until resistance is felt.

Figure 64

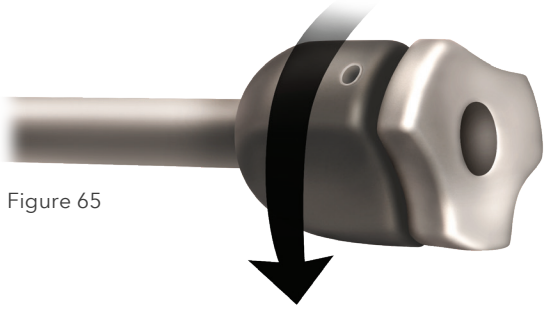


Figure 65

2. Select the appropriate screw shank diameter and length by both preoperative measurement and intraoperative observation. The screw diameter and length can be confirmed from labeling and/or using a screw confirmation gage.
3. Place the driver hexalobe into the shank head, while in tray (**Figure 66**).
4. Slide collet over sphere, while maintaining engagement of the driver hexalobe in the shank head (**Figure 67**).
5. Thread sleeve clockwise, until resistance is felt (**Figures 68a and 68b**).

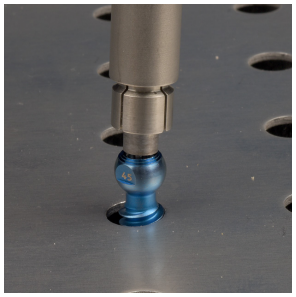


Figure 66

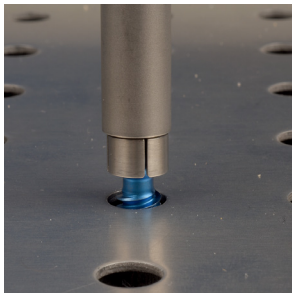


Figure 67

Figure 68a

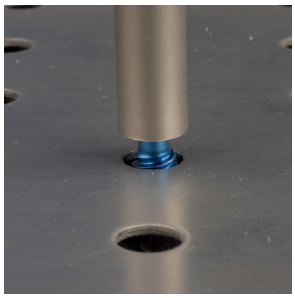


Figure 68b

6. Verify that the shank is properly attached to the driver (**Figures 69a and 69b**).

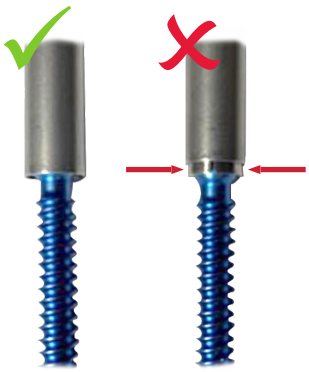


Figure 69a

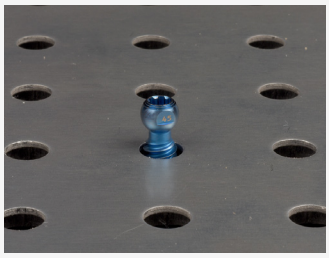
Figure 69b

Attach the driver to the Quick Connect Handle (G900000) or to the IPC™ Powerease™ system by snapping into place (**Figure 70**).

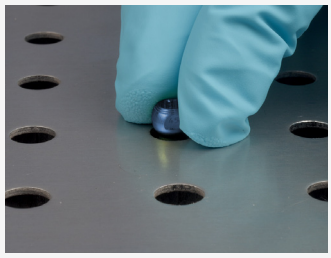
Figure 70

Important

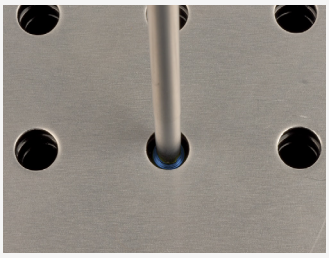
The screw shank tray is color coded to match the color of the screws. The holes in the tray have varying depths to accommodate different screw shank lengths. If a screw shank is placed in the wrong location, remove by hand if the shank head is partially exposed. If the shank head is sunk in the tray, engage the shank driver to the shank head and pull out at an angle to retrieve screw shank.



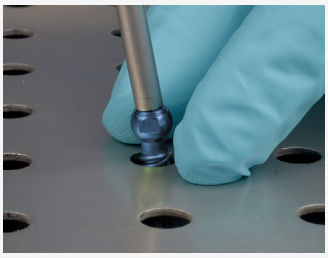
Ideal shank position in tray



Removing partially exposed screw shank by hand



Removing shank head sunk in tray



Sterile Packed Screws

1. Ensure the collet tip is fully exposed (**Figure 71**) by turning the dark gray knob counterclockwise (**Figure 72**) until resistance is felt.
2. Select the appropriate screw shank diameter and length by both preoperative measurement and intraoperative observation. The screw diameter and length can be confirmed from labeling and/or using a screw confirmation gage.

Figure 71

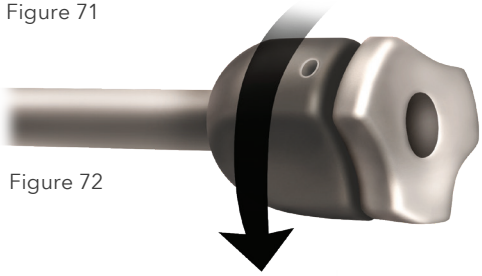


Figure 72

Helpful Hint

Hold the driver assembly in dominant hand and hold the shank firmly in non-dominant hand.

3. Place the driver hexalobe into the shank head **(Figures 73a and 73b)**.
4. Slide collet over sphere, while maintaining engagement of the driver hexalobe in the shank head (**Figure 74**).
5. Thread sleeve clockwise, until resistance is felt (**Figure 75**).

Figure 73a

Figure 73b

Figure 74

Figure 75

6. Verify that the shank is properly attached to the driver (**Figures 76a and 76b**).

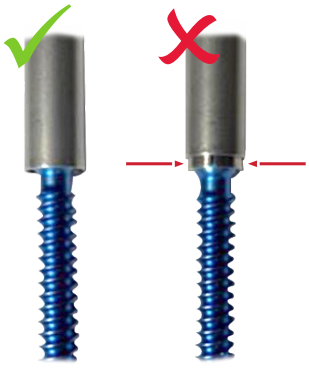


Figure 76a

Figure 76b

Attach the driver to the Quick Connect Handle (G900000) or to the IPC™ Powerease™ system by snapping into place (**Figure 77**).

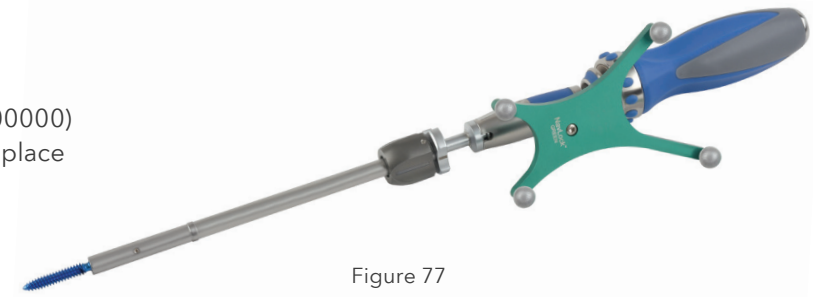


Figure 77

Placement of screw shank

After the desired screw shank (ATS, cortical, Osteogrip™ or Titan nanoLOCK™) has been attached to the driver, insert the screw shank in the previously tapped screw hole. Under the ModuLex™ tool card select the appropriate "Tip" aligned with the sleeve attached to the driver. Under the "Tool" tab, select the appropriate screw shank width and length.

Align the screw and driver with the virtual guidewire and advance the screw being careful that the screw shank is not advanced too far. Advance the screw shank along the previously determined trajectory. On the navigation screen, an aquamarine depth stop line will be visible. Do not advance the screw shank beyond where the aquamarine line meets the bone. This is to help ensure that the multi-axial screw head can be attached at the end of the procedure.

To determine if appropriate space is present to attach a multi-axial screw head to the shank: Place the t-handle driver through the Reamer and engage the drive features in the driver to the shank (**Figure 78**), once engaged, slide the reamer down over the sphere of the shank. If the black line is fully visible (**Figure 79**) then the shank is at an appropriate height that will allow for head placement. Ideally, two threads of the shank should be visible outside of the bone. A virtual screw head could also be projected on the navigation screen for verification (**Figures 80a and 80b**)

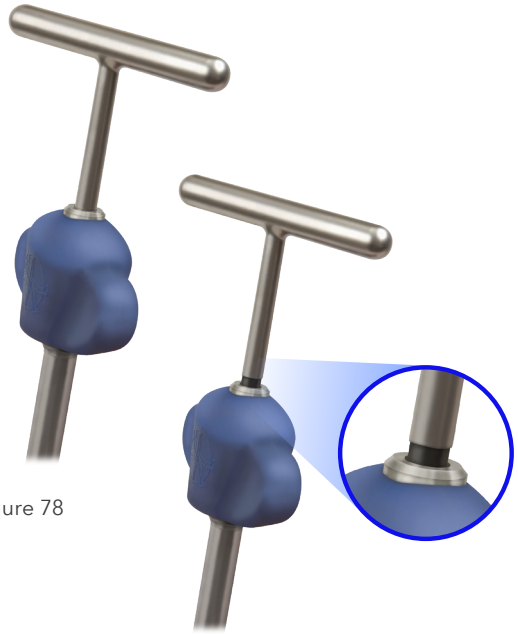


Figure 78

Figure 79

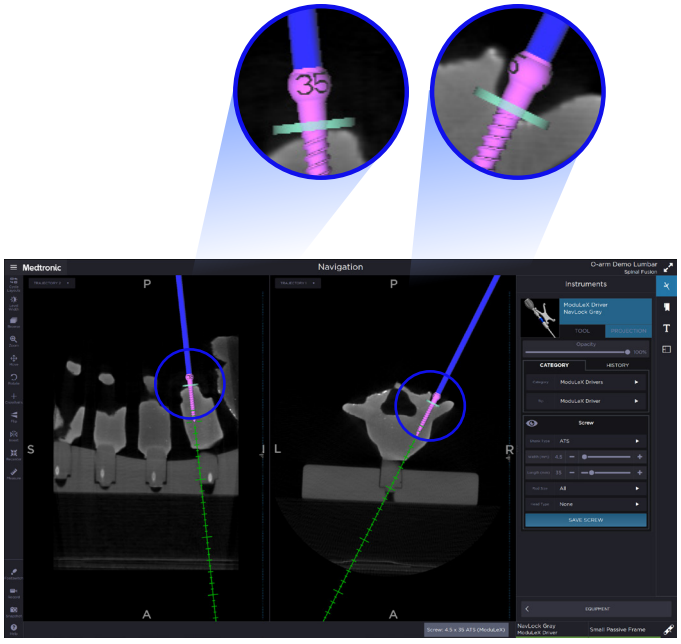


Figure 80a

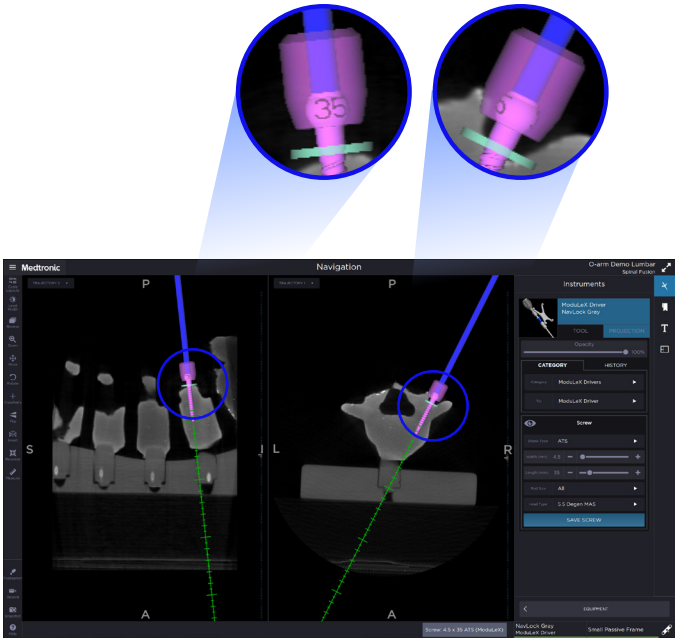


Figure 80b

If the screw shank is over-advanced the surgeon may utilize one of three methods of adjusting the screw shank:

1. Rotate the screw shank counterclockwise until the sphere in no longer resting on bone.
2. Use the reamer to remove bone around the screw sphere to create adequate room to attach the head (**Figure 81**).
3. Use the inner driver of the reamer to back the shank out of the bone (**Figure 82**).

Important

Compatibility with CD Horizon™ modular spinal system The CD Horizon™ modular heads may also be used with the CD Horizon™ ModuLex™ 5.5 shanks (ATS or Titan nanoLOCK™) with a 4.5mm diameter or larger. In addition, the Osteogrip™ shanks from the CD Horizon™ Modular spinal system can be used with CD Horizon™ ModuLex™ 5.5 heads. Ensure that the appropriate head inserter and set screws are used. The CD Horizon™ modular head inserter and set screw must be used when attaching the CD Horizon™ modular heads while the CD Horizon™ ModuLex™ 5.5 head inserter and set screw must be used when attaching the CD Horizon™ ModuLex™ 5.5 heads.

Important

It is advised that intraoperative imaging be used to aid screw placement, and the screws should not be used for bicortical fixation.

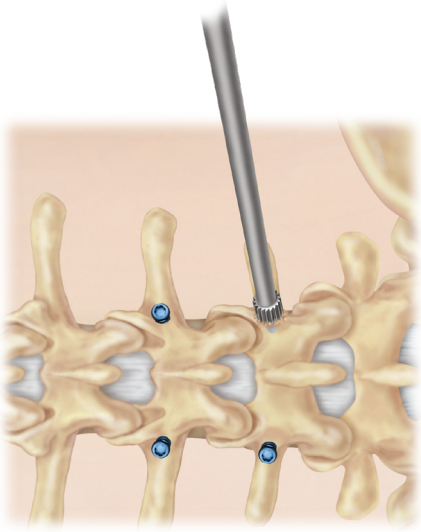


Figure 81

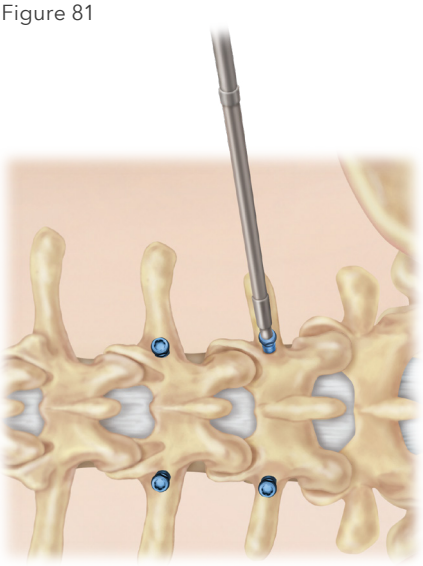


Figure 82

Decompression and discectomy

The surgeon should follow their standard method of decompression and discectomy. They may wish to use the navigated posterior disc prep instruments. If needed, the surgeon should begin removing the inferior articular process on the level(s) where an interbody will be placed or any bone that needs to be removed to allow for decompression. Once the surgeon is ready to distract, the set includes both anatomy based and shank based distraction options in two lengths long and short. The short legs accommodate blades of up to 8 cm while the long legs should be used with blades longer than 8cm. In addition, the surgeon may use intradiscal distraction such as scissor jack per their typical distraction technique.

Optional (navigated posterior disc prep)

On the StealthStation™ system, select the "Tool" tab to select the appropriate navigated instrument tip. Insert the navigated instruments into the appropriate NavLock™ tracker, confirm accuracy by touching the tip of the instrument on a known anatomical point, and use the instrument in the disc space until the desired result is achieved.

Important
Make sure the navigated disc prep instruments were verified with a default tip such as an awl or tap. Use the "Tool" tab when choosing the applicable tip for the disc prep working end.

Important
During navigation, it is important to frequently confirm navigational accuracy by touching the tip of the navigated disc prep instrument on known anatomical points, including accuracy checkpoints, and comparing the position of the instrument tip in the image with its physical location.

Assembling the modular distraction system

Begin by locating the Distractor Arm and Distractor Rack in the modular distraction system standalone tray (**Figure 83**). Slide the arm over the rack with the locking ratchet in the neutral position (**Figure 84**). Slide the locking ratchet so that the uncovered arrow points to the desired direction of motion (**Figure 85**). The distractor is now fully assembled and ready for use.

Figure 83

Figure 84

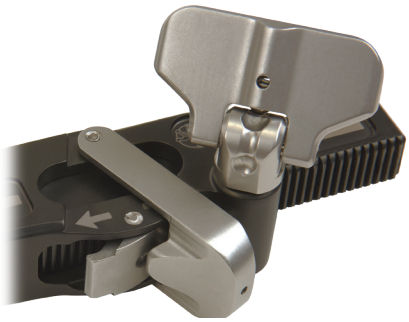


Figure 85

Using the modular distraction system

The distractor is designed using a gear system that drives the mechanism creating distraction. To distract, turn the thumbwheel counterclockwise and to compress turn the thumbwheel clockwise. Ensure that the flywheel is oriented upward when using the distractor.

Anatomy based distraction options

If anatomical distraction is needed, the modular distraction system offers distractor legs that can interact with either the spinous processes (**Figure 86a**) or the laminae (**Figure 86b**).

Figure 86a: Spinous Process Distractor Attachment

Figure 86b: Lamina Distractor Feet Attachment

Select the appropriate length and type of distractor attachments and insert them into the distractor legs. All anatomy based distractor attachments are designed such that they can only be assembled onto the distractor in the appropriate orientation. Place the distractor assembly in the wound and position the feet against the appropriate anatomy, either the spinous process (**Figure 87a**) or the lamina (**Figure 87b)**. Turn the thumbwheel counterclockwise on the distractor rack to distract the anatomy the appropriate amount.

Figure 87a:
Spinous Process Distraction

Figure 87b:
Laminar Distraction

Screw shank based distraction options

In addition, there are three screw shank-based distraction options: lassos (**Figure 88a**), hooks (**Figure 88b**) and eyelets (**Figure 88c**).

Figure 88a: Lasso Attachment

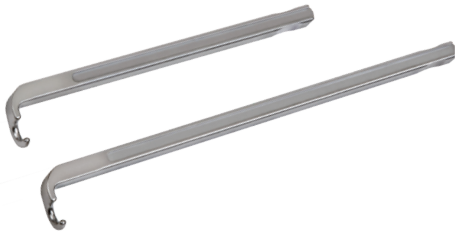


Figure 88b: Hook Attachment

Figure 88c: Eyelet Attachment

Select the appropriate length and type of distractor attachments and insert them into the distractor legs.

To assemble the disposable lasso to the modular posts, slide the narrower portion of the lasso into the slot with the lasso extending out of the distractor leg (**Figures 89a and 89b**), rotate it a quarter turn (**Figure 89c**), pull down slightly, then turn the locking nut a quarter turn to tighten it (**Figure 89d**).

Figure 89a

Figure 89b

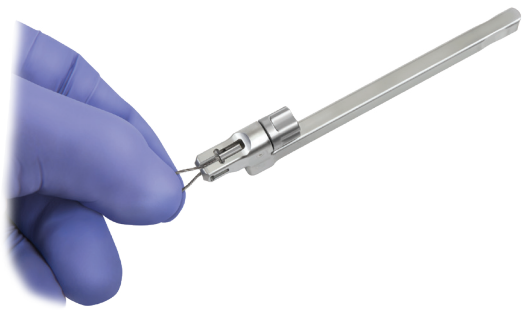


Figure 89c

Figure 89d

If the lasso method of distraction is selected, insert the lasso attachment assembly to the distractor legs. Lower the lasso assembly over the screw shanks until they are resting even with the screw shank neck. Next, attach the distractor assembly to the lasso attachment by sliding the distractor legs over the lasso attachments (**Figure 90**). Turn the thumbwheel counterclockwise to distract the appropriate amount.

If the hook method of distraction is selected, insert the hook attachments to the distractor legs. Lower the hooks until they are around the neck of the screw shank (**Figure 91**). Turn the thumbwheel counterclockwise on the distractor rack to distract the anatomy the appropriate amount.

If the eyelet method of distraction is selected, insert the eyelet attachments to the distractor legs. Lower the eyelets until they are around the neck of the screw shank (**Figure 92**). Turn the thumbwheels counterclockwise on the distractor to distract the anatomy the appropriate amount.

Important

The use of excessive force on the screw shank especially in the setting of low bone density may lead to loosening of the screw and loss of fixation at the bone-screw interface.

Note

Disengage the locking ratchet to release the distractor before removal. Care should be taken to prevent the modular distractor legs from falling into the wound.

Figure 90

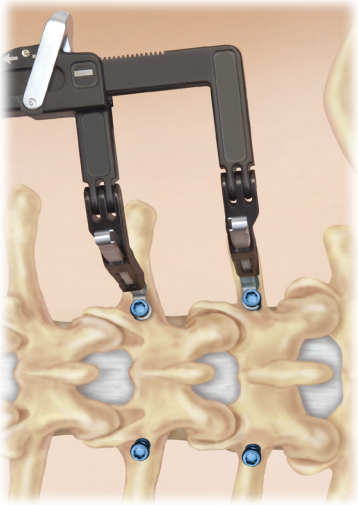


Figure 91

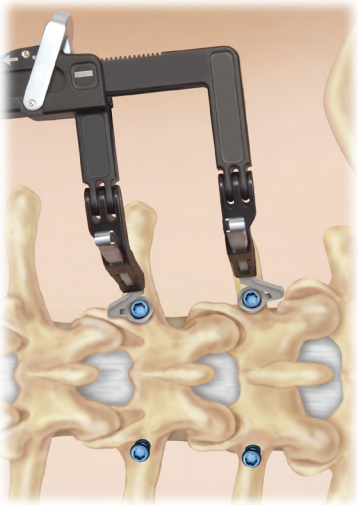


Figure 92

Interbody (optional)

Refer the the appropriate Interbody Surgical Technique for Interbody trialing and placement instructions.

Optional bone reaming

After placing screw shanks, the bone reamer can be utilized for decortication around the screw shank (**Figures 93a and 93b**). It can also be used to create sufficient space for head assembly. The bone reamer removes adjacent anatomy around the screw sphere that may impede attachment of the head.

Important

Take care not to damage the superior articular facet when reaming.

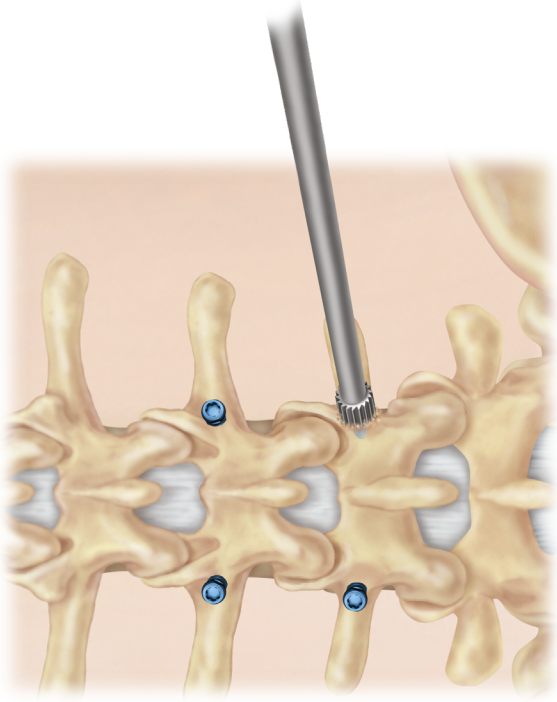


Figure 93a

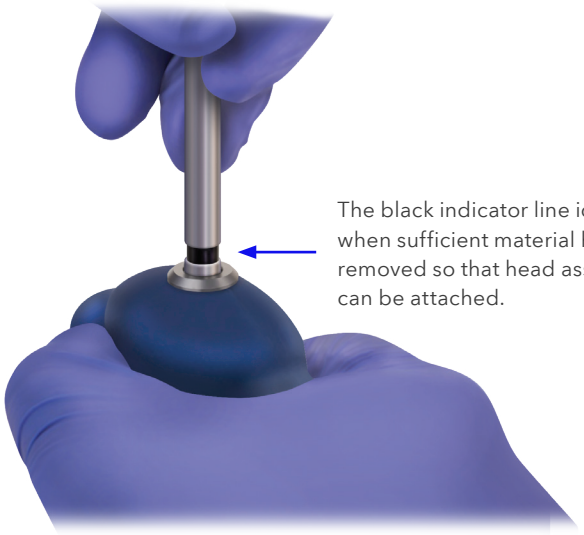


Figure 93b

Option A for Head Attachment – locking head inserter

Prior to head insertion, ensure the screw shank is clear of any anatomical debris or bone grafting material. The Locking Head Inserter (**Figure 94**) will be used to attach the desired head assemblies onto the screw shanks.

Figure 94

Ensure that the handles of the Locking Head Inserter are completely open prior to loading a head onto the instrument. If the black line is visible (**Figure 95a**), the handles are not in the open position. To release the handles to their open position, press the blue trigger without squeezing the gray handles. The black line should no longer be visible (**Figure 95b**).

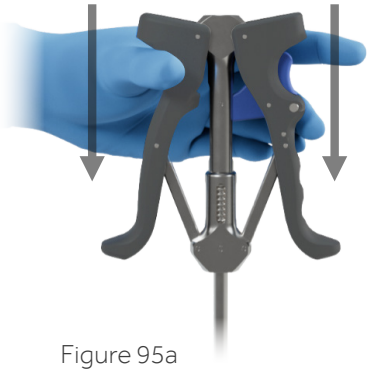


Figure 95a

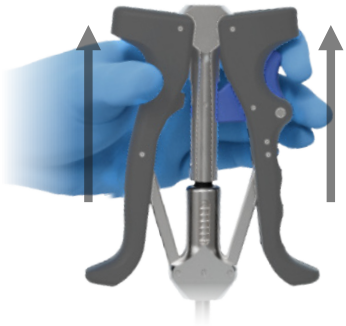


Figure 95b

The inserter can be attached to the head in the sterile packaging (**Figure 96a**), or the head can be placed on the tip of the inserter by hand. The inserter handles should be aligned with the rod slots for placement. Once the head assembly is loaded, lightly squeeze the gray handles of the inserter to provisionally secure head assembly (**Figure 96b**).

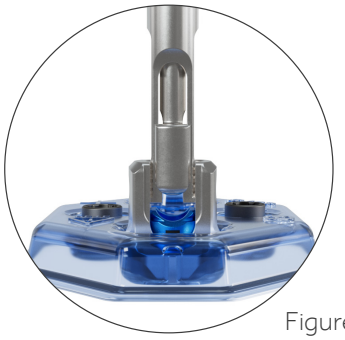


Figure 96a

squeeze

Figure 96b

release

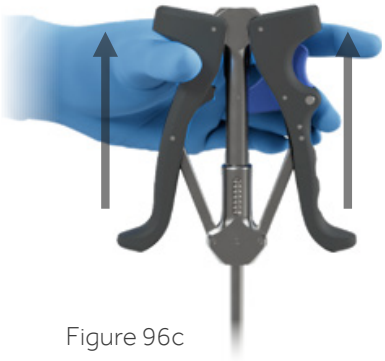


Figure 96c

Important

Do not push the blue locking trigger while squeezing the gray handles until the user is ready to final lock the head assembly onto the shank. If the handles are fully squeezed as shown in **Figure 97** (which is only possible when the blue trigger is squeezed along with the grey handles), the head will progress into its fully locked state and will no longer attach to a screw shank. The black laser mark on the tulip crown will disappear and the head will be in its locked state. If this occurs, the head will not attach to a shank and will be unusable.

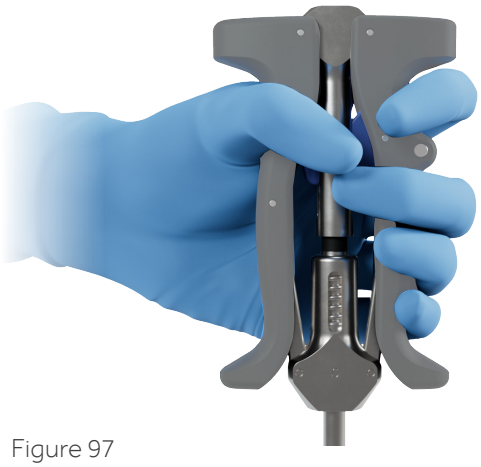


Figure 97

Placement and locking of a modular head requires a 4-step process:

1) Attach

2) Confirm

3) Squeeze

4) Release

Step 1 - Attach

Attach the head onto the shank by pushing the assembled head and inserter downwards onto the screw shank (**Figure 98**). For uni-axial head placement, the gray inserter handles should be positioned parallel to screw flats. Laser marks on the inserter align with the rod slot of the uni-axial head and the handles are oriented in the direction of the rod. It is recommended to position the gray handles roughly in the cephalad/caudal direction and slowly rotate the instrument while gently pushing downwards.

Important

If you are not able to attach the head to the screw shank, either back out the screw shank or use the decortication tool to add additional clearance and then re-attach the head to the screw shank.

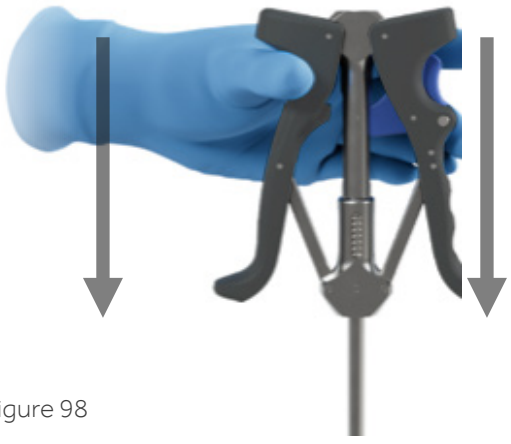


Figure 98

Step 2 - Confirm

Confirm preliminary attachment by pulling up slightly on the inserter (**Figure 99**).

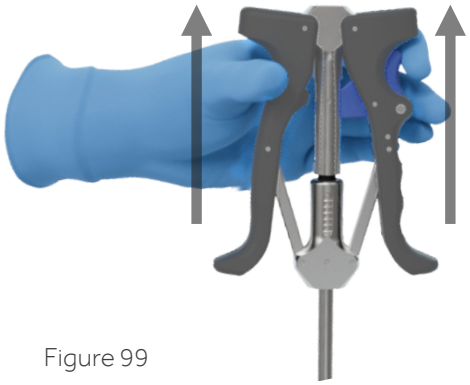


Figure 99

Important

Do not squeeze the blue trigger during this step.

Note

Once a head has been provisionally placed, the connection is irreversible. The heads are designed with a one-way connection that cannot be removed once attached.

Step 3 - Squeeze

After confirming preliminary attachment of the head to the shank, push and hold the blue locking trigger and then fully squeeze they gray handles to final lock the head onto the screw shank. Note the black laser mark line which is only visible when both the gray handles and blue trigger are fully pressed (**Figure 100**).

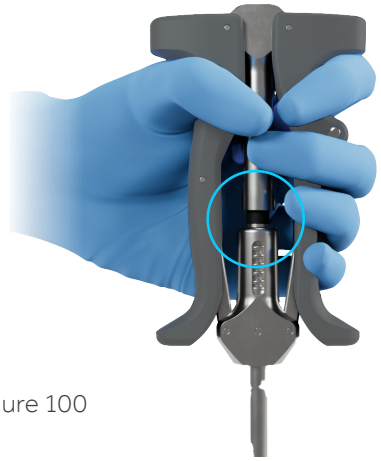


Figure 100

Step 4 - Release

To remove the inserter from the head after final locking, release the gray handles and remove the instrument (**Figure 101**).

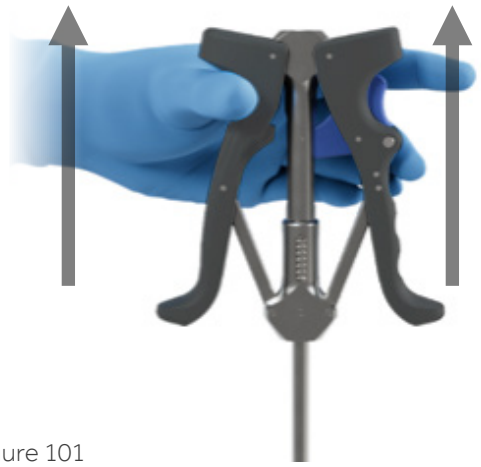


Figure 101

Note

If the handles are released too slowly, the blue trigger may need to be pushed to return the gray handles to a completely open state. If this occurs, you will still be able to see the black line on the inserter. To release the inserter from the implant, push the blue trigger without squeezing the gray handles.

Rod placement

Select the appropriate length rod using the rod template tools or the surgeon's preferred method.

Using the rod holder, place the rod into the saddle of the tulip heads (**Figures 102a and 102b**).

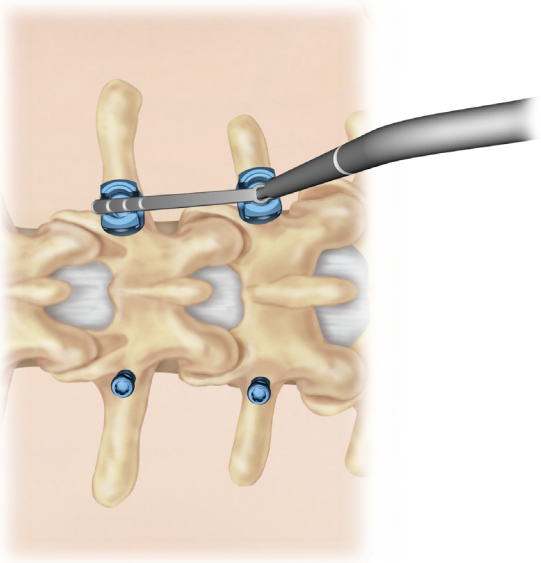


Figure 102a

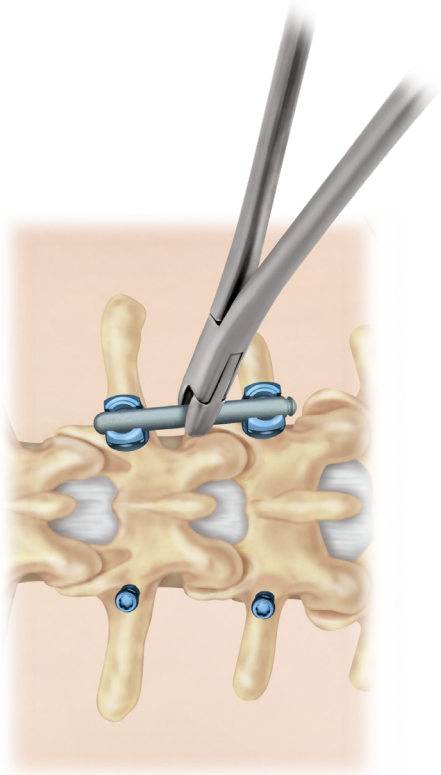


Figure 102b

Set screw instrumentation

Swizzle stick and provisional driver instruments come equipped with a self-retaining mechanism. Simply insert the setscrew onto the instruments. Use either the swizzle stick or the provisional driver (**Figures 103a and 103b**) to provisionally tighten the set screws into the screw assembly.

If compression is desired, use the compressor to compress the construct at each level.

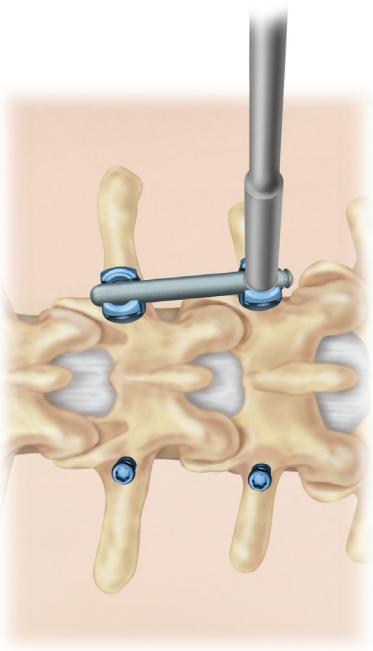


Figure 103a

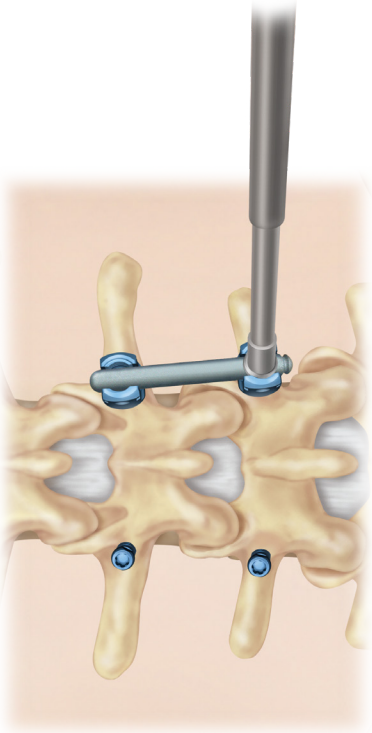


Figure 103b

Confirmation

Optional confirmation image acquisition:

The reference frame should be left in place during the confirmation image acquisition to ensure that navigation can still be performed if any changes are required.

With the patient isocenter, position the O-arm™ system to perform a 3D image acquisition (**Figure 104**). During the acquisition process all personnel who are not wearing protective lead apparel should stand at least 15 feet from the O-arm™ system with a certified moveable lead shield between themselves and the O-arm™ system to avoid unnecessary radiation exposure. Perform the image acquisition to confirm screws, rods, and interbody placement. Following confirmation, the Reference Frame should be removed.

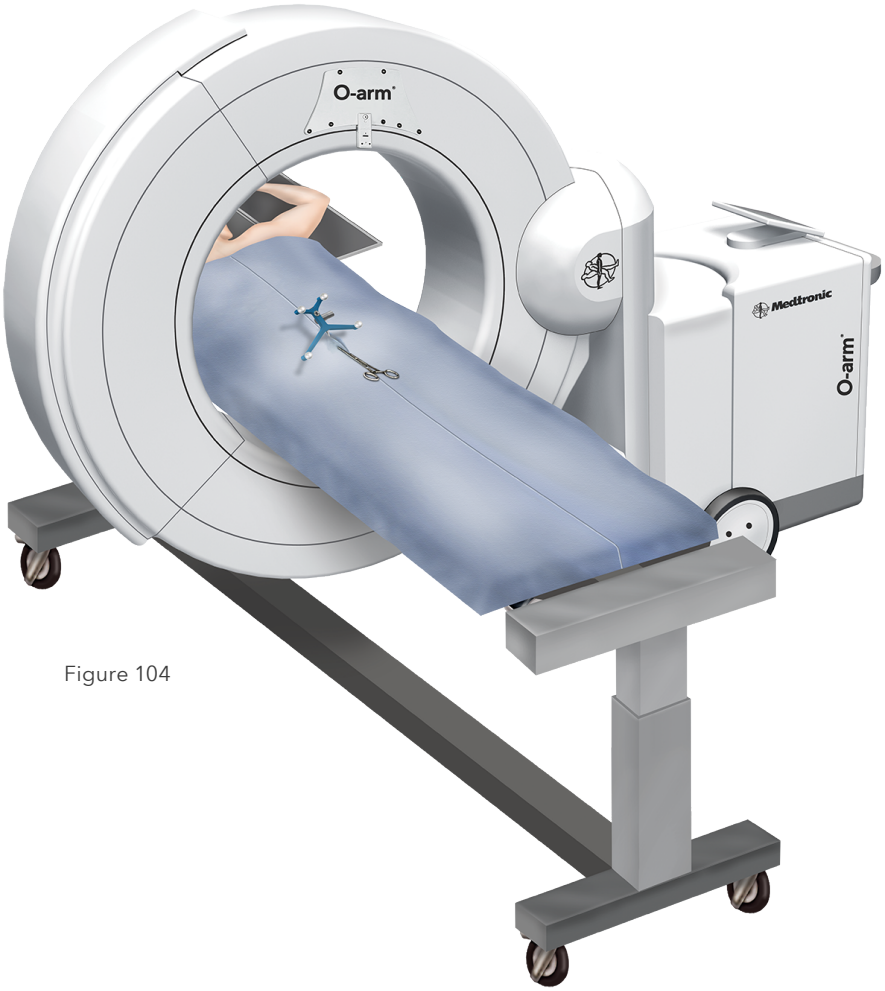


Figure 104

Final tightening

Using the set screw break off driver and the counter torque positioned fully over the head and on the rod, break off the set screws (**Figure 105**). The set screw break off driver will retain the break off portion of 8 set screws so multiple set screws can be broken off with it.

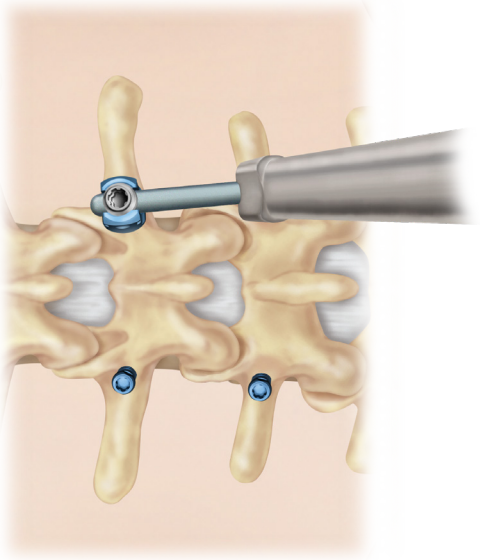


Figure 105

Using Powerease™ to break off set screws:

1. Insert Breakoff Driver Adapter into Set Screw Break Off Shaft (SSBO).
2. Push SSBO Lock Button and insert IPC™ Powerease™
   SSBO counter torque.
3. Connect this instrument to the IPC™ Powerease™ handle.
4. Place over set screw, push handle down until the counter torque captures the head (**Figure 106**), and squeeze trigger until a mechanical click is felt.
5. Repeat step four for all set screws.

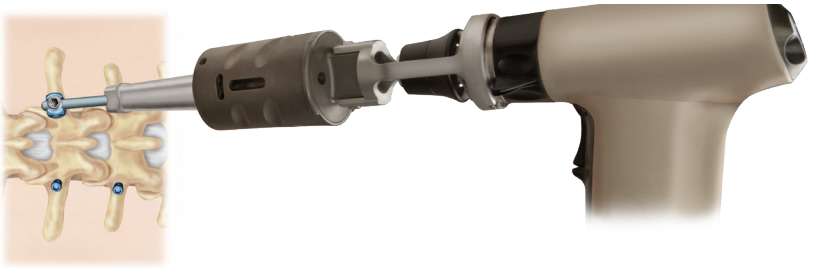
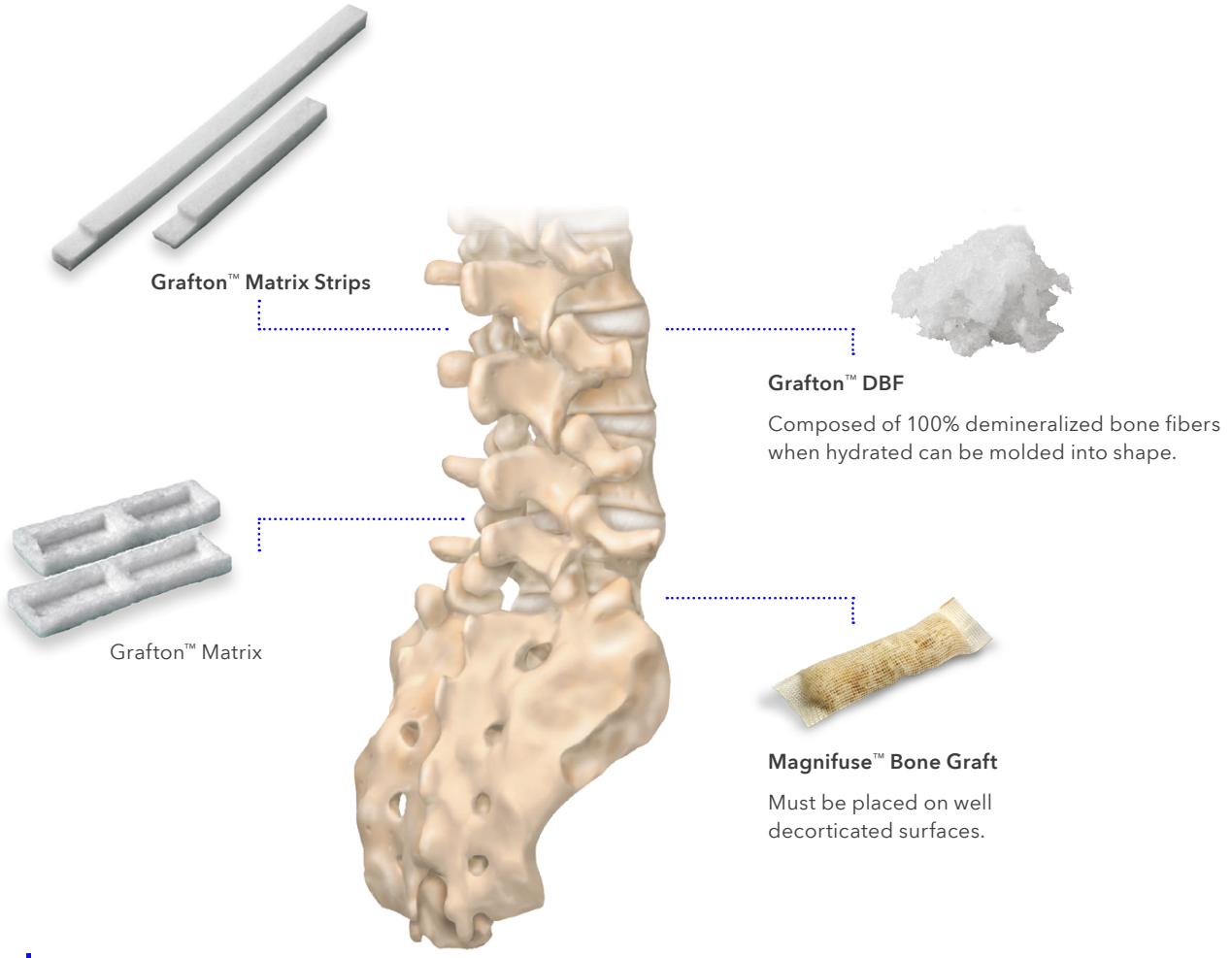


Figure 106

Additional grafting

When posterior fixation is used, a number of Medtronic bone graft options are available as fillers for bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. Precise placement of the bone graft (autograft or allograft bone) is essential to facilitate fusion. These options are intended to be used as a supplement to posterior instrumentation. Some examples are shown below.



Grafton™ Matrix Strips

Grafton™ DBF

Composed of 100% demineralized bone fibers when hydrated can be molded into shape.

Grafton™ Matrix

Magnifuse™ Bone Graft

Must be placed on well decorticated surfaces.

Implant explantation

To remove the set screws and the pedicle screws, attach the obturator to the break off driver working end. Insert the obturator tip into the set screw and turn counterclockwise until the set screw has been removed. To remove the screw insert, insert the obturator tip into the screw and turn counterclockwise until the screw has been removed.

Note:

Use caution as the obturator instrument does not retain the set screw during removal.

Product ordering information

ATS Shank Set SPS03151		
CFN	Description	Qty
55900204530	ATS 4.5 × 30	4
55900204535	ATS 4.5 × 35	4
55900204540	ATS 4.5 × 40	4
55900205530	ATS 5.5 × 30	4
55900205535	ATS 5.5 × 35	6
55900205540	ATS 5.5 × 40	8
55900205545	ATS 5.5 × 45	8
55900205550	ATS 5.5 × 50	6
55900206530	ATS 6.5 × 30	4
55900206535	ATS 6.5 × 35	6
55900206540	ATS 6.5 × 40	8
55900206545	ATS 6.5 × 45	8
55900206550	ATS 6.5 × 50	8
55900206555	ATS 6.5 × 55	8
55900207540	ATS 7.5 × 40	4
55900207545	ATS 7.5 × 45	6
55900207550	ATS 7.5 × 50	4
55900207555	ATS 7.5 × 55	4
5598036	Screw confirmation tool	1
5598902	ATS shank tray	1
1850097	Generic lid	1

Sterile Suitcase SPS03155		
CFN	Description	Qty
559200006	Single set screw and single head	4
559200007	Two set screws and two heads	12
559200008	Four pack set screw and four heads	10
G559300145	Sterile connector 4.5/5.0	2
G559300156	Sterile connector 5.5/6.0	2
2762-01-0003	Light source	3
G5598019	Lasso	6
5598916	Suitcase	1

CD Horizon™ ModuLeX™ Osteogrip Shank Set, 4.5-8.5 SPS03228		
CFN	Description	Qty
55900504525	4.5mm × 25mm	4
55900504530	4.5mm × 30mm	6
55900504535	4.5mm × 35mm	8
55900504540	4.5mm × 40mm	8
55900504545	4.5mm × 45mm	6
55900504550	4.5mm × 50mm	4
55900505525	5.5mm × 25mm	4
55900505530	5.5mm × 30mm	6
55900505535	5.5mm × 35mm	8
55900505540	5.5mm × 40mm	12
55900505545	5.5mm × 45mm	12
55900505550	5.5mm × 50mm	8
55900505555	5.5mm × 55mm	4
55900506530	6.5mm × 30mm	6
55900506535	6.5mm × 35mm	6
55900506540	6.5mm × 40mm	12
55900506545	6.5mm × 45mm	16
55900506550	6.5mm × 50mm	12
55900506555	6.5mm × 55mm	8
55900506560	6.5mm × 60mm	4
55900507530	7.5mm × 30mm	4
55900507535	7.5mm × 35mm	6
55900507540	7.5mm × 40mm	8
55900507545	7.5mm × 45mm	8
55900507550	7.5mm × 50mm	8
55900507555	7.5mm × 55mm	6
55900507560	7.5mm × 60mm	4
55900508540	8.5mm × 40mm	4
55900508545	8.5mm × 45mm	4
55900508550	8.5mm × 50mm	4
55900508555	8.5mm × 55mm	4
5598036	Screw Confirmation Tool	1
5598917	ModuLeX Osteogrip Screw Shank Tray	1
1850097	Generic Outer Lid	1

CD Horizon ModuLex™ nanoLOCK™ Shank Set, 4.5-8.5 SPS03227		
CFN	Description	Qty
55904504525	4.5mm × 25mm	4
55904504530	4.5mm × 30mm	4
55904504535	4.5mm × 35mm	4
55904504540	4.5mm × 40mm	4
55904504545	4.5mm × 45mm	4
55904504550	4.5mm × 50mm	4
55904505525	5.5mm × 25mm	4
55904505530	5.5mm × 30mm	6
55904505535	5.5mm × 35mm	6
55904505540	5.5mm × 40mm	8
55904505545	5.5mm × 45mm	8
55904505550	5.5mm × 50mm	8
55904505555	5.5mm × 55mm	4
55904506530	6.5mm × 30mm	4
55904506535	6.5mm × 35mm	4
55904506540	6.5mm × 40mm	8
55904506545	6.5mm × 45mm	8
55904506550	6.5mm × 50mm	8
55904506555	6.5mm × 55mm	6
55904506560	6.5mm × 60mm	4
55904507530	7.5mm × 30mm	4
55904507535	7.5mm × 35mm	4
55904507540	7.5mm × 40mm	4
55904507545	7.5mm × 45mm	4
55904507550	7.5mm × 50mm	4
55904507555	7.5mm × 55mm	4
55904507560	7.5mm × 60mm	4
55904508540	8.5mm × 40mm	4
55904508545	8.5mm × 45mm	4
55904508550	8.5mm × 50mm	4
55904508555	8.5mm × 55mm	4
25600001	Suitcase	1

5.5 CP Ti Rod Tray SPS03156		
CFN	Description	Qty
1552000025	5.5mm pre-bent commercially pure titanium 25mm	4
1553201030	5.5mm pre-bent commercially pure titanium 30mm	4
1553201035	5.5mm pre-bent commercially pure titanium 35mm	4
1553201040	5.5mm pre-bent commercially pure titanium 40mm	4
1553201045	5.5mm pre-bent commercially pure titanium 45mm	4
1553201050	5.5mm pre-bent commercially pure titanium 50mm	4
1553201055	5.5mm pre-bent commercially pure titanium 55mm	4
1553201060	5.5mm pre-bent commercially pure titanium 60mm	4
1553201070	5.5mm pre-bent commercially pure titanium 70mm	4
1553201080	5.5mm pre-bent commercially pure titanium 80mm	4
1553201090	5.5mm pre-bent commercially pure titanium 90mm	4
1553201100	5.5mm pre-bent commercially pure titanium 100mm	4
1553201110	5.5mm pre-bent commercially pure titanium 110mm	4
1553201120	5.5mm pre-bent commercially pure titanium 120mm	4
5598904	5/5 Ti cp rod tray	1
1850097	Generic lid	1

General Instruments - Set 1 SPS03152‡		
CFN	Description	Qty
G900000	Quick connect handles	2
8350293	Lenke lumbar probe	1
8350294	Lenke thoracic probe	1
9960106	Universal modular handle	1
7480100	Dual ended feeler probe	1
5598905	Upper tray	1
5598034	Head turner	1
5598030	Rod template	1
5598037	Reamer	1
5598038	T-handle driver	1
5598035	Head inserter†	2
5598009	Head inserter handle	2
5598906	Gen instrument lower 1	1
1850097	Generic lid	1

†Head inserter (CFN 5598035) is only compatible with CD Horizon™ ModuLeX™ system 5.5mm heads.

‡Only one General Instruments Set 1 should be ordered.

General Instruments - Set 1 SPS03237‡		
CFN	Description	Qty
G900000	Quick connect handles	2
8350293	Lenke lumbar probe	1
8350294	Lenke thoracic probe	1
7480100	Dual ended feeler probe	1
5598919	General instrument upper tray with locking head inserter	1
5598034	Head turner	1
5598030	Rod template	1
5597160	Reamer	1
5597185	T-Handle MT25 Driver	1
5599130	Locking head inserter (AIS)	2
5598920	Gen instrument lower 1	
1850097	Generic lid	1

Head insertion sets shown with Locking Head Inserter (CFN 5599130) available in SPS03237.

General Instruments - Set 2 SPS03153		
CFN	Description	Qty
5598045	Breakoff driver adaptor	1
5598200	Obturator/set screw removal adaptor	1
7480162	French bender	1
5480140V	Provisional driver handle	1
5598039	Break-off driver	2
5598041	Swizzle stick	2
5598043	Provisional driver	1
5598907	Gen instrument upper 2	1
8350312	Rod holder	1
5598061	IPC™ Powerease™ countertorque	1
7480136	Beale reducer	1
5584150	Countertorque	1
5598033	Compressor	1
5598908	Gen instrument lower 2	1
1850097	Generic lid	1

Fluoro Screw Placement and Prep Set SPS03157		
CFN	Description	Qty
5591045	Ø4.5, Manual cortical tap	1
5591055	Ø5.5, Manual cortical tap	1
5591065	Ø6.5, Manual cortical tap	1
5591075	Ø7.5, Manual cortical tap	1
5598031	Non-nav shank driver	2
5598032	Depth stop sleeve	2
5598909	Fluoro screw placement/prep tray	1
1850049	Generic lid	1

Navigated Driver Set SPS03158		
CFN	Description	Qty
NAV5598300	Nav driver	2
NAV5598301	Shank driver sleeve	2
5598910	Nav driver tray	1
1850049	Generic lid	1

Distraction Set SPS03139		
CFN	Description	
5598007	Modular distraction frame, rack	1
5598008	Modular distraction frame, gear box	1
5598011	Spinous process distractor, left, short	1
5598012	Spinous process distractor, right, short	1
5598013	Spinous process distractor, left, long	1
5598014	Spinous process distractor, right, long	1
5598015	Lasso distractor, short	2
5598016	Lasso distractor, long	2
5598020	Hook distractor, left, short	1
5598021	Hook distractor, right, short	1
5598022	Hook distractor, left, long	1
5598023	Hook distractor, right, long	1
5598024	Laminar distractor, right, short	1
5598028	Laminar distractor, left, short	1
5598025	Laminar distractor, right, long	1
5598029	Laminar distractor, left, long	1
5598026	Eyelet distractor, short	2
5598027	Eyelet distractor, long	2
5598915	Distraction tray	1
1850097	General lid	1

Important product information on The CD Horizon™ Spinal System

PURPOSE
The CD Horizon™ spinal system is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, or sacral spine.

DESCRIPTION
The CD Horizon™ spinal system consists of a variety of shapes and sizes of rods, hooks, screws, Crosslink™ plates, staples, and connecting components, as well as implant components from other Medtronic spinal systems which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

A subset of CD Horizon™ spinal system components may be used for posterior pedicle screw fixation in pediatric cases. These constructs may be comprised of a variety of shapes and sizes of rods (ranging in diameter from 3.5 to 6.35mm), hooks, screws, Crosslink™ plates and connecting components. Similar to the CD Horizon™ implants used in adult cases, these components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain components within the CD Horizon™ spinal system are specifically excluded for use in pediatric patients. These include PEEK rods, Shape Memory Alloy Staples, Spire™ plates, and Dynalok™ bolts. Screws used in pediatric cases are only cleared for use via a posterior approach. Components used in pediatric cases are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, and medical grade cobalt-chromium-molybdenum alloy.

Certain implant components from other Medtronic spinal systems can be used with the CD Horizon™ spinal system in non-pediatric cases. These components include TSRH™ rods, hooks, screws, plates, Crosslink™ plates, connectors, staples and washers, GDLH™ rods, hooks, connectors and Crosslink™ bar and connectors; Liberty™ rods and screws; Dynalok™ Plus and Dynalok Classic™ bolts along with rod/bolt connectors; and Medtronic multi-axial rods and screws. Note: certain components are specifically designed to connect to specific rod diameters, while other components can connect to multiple rod diameters. Care should be taken so the correct components are used in the spinal construct.

CD Horizon™ hooks are intended for posterior use only. CD Horizon™ staples and CD Horizon™ Eclipse™ rods and associated screws are intended for anterior use only. However, for patients of smaller stature and pediatric patients, CD Horizon™ 4.5mm rods and associated components may be used posteriorly.

CD Horizon™ spinal system implant components are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, medical grade cobalt-chromium-molybdenum alloy, or medical grade PEEK Optima-LT1. Certain CD Horizon™ spinal system components may be coated with hydroxyapatite. No warranties, expressed or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

Never use stainless steel and titanium implant components in the same construct.

Medical grade titanium, titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy may be used together. Never use titanium, titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy with stainless steel in the same construct.

The CD Horizon™ spinal system also includes anterior staples made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium, titanium alloy, and cobalt-chromium-molybdenum alloy. Do not use with stainless steel. These staples are not to be used in pediatric patients.

PEEK Optima-LT1 implants may be used with titanium or cobalt-chromium-molybdenum alloy implants. CD Horizon™ PEEK rods are not to be used in pediatric patients. PEEK rods are only to be used with the associated pedicle screws as well as interbody fusion devices in the anterior spinal column.

To achieve best results, do not use CD Horizon™ spinal system implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic document. As with all orthopaedic and neurosurgical implants, none of the CD Horizon™ spinal system components should ever be reused under any circumstances.

INDICATIONS
The CD Horizon™ spinal system with or without Sextant™ instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (DDD - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD Horizon™ spinal system titanium, cobalt chrome, and stainless steel implants may also be used for the same indications as an adjunct to fusion.

With the exception of DDD, CD Horizon™ Legacy™ 3.5mm rods and associated components may be used for indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, CD Horizon™ spinal system titanium, cobalt chrome, and stainless steel implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD Horizon™ spinal system is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD Horizon™ PEEK rods are intended to provide posterior supplemental fixation when used with an interbody fusion cage for patients diagnosed with DDD. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level. This device is intended for 1-2 level use in the lumbosacral spine (L2 – S1) in skeletally mature patients. Devices are intended for use with an interbody fusion cage at the instrumented level and is not intended for stand-alone use.

The CD Horizon™ Spire™ plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: DDD, spondylolisthesis, trauma, and/or tumor.

To achieve additional levels of fixation, CD Horizon™ spinal system rods may be connected to the Vertex™ Reconstruction System with the Vertex™ rod connector. Refer to the Vertex™ Reconstruction System package insert for a list of Vertex™ indications.

CONTRAINDICATIONS
Contraindications include:

- Active infectious process or significant risk of infection (immunocompromise).
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Grossly distorted anatomy caused by congenital abnormalities.
- Medical or surgical conditions 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.
- Suspected or documented metal allergy or intolerance.
- Cases not needing a bone graft and fusion.
- Cases where implant components selected for use would be too large or too small to achieve a successful result.
- Patients having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Patients in which implant use would interfere with anatomical structures or expected physiological performance.
- CD Horizon™ Spire™ plate and CD Horizon™ PEEK rods are specifically contraindicated for use in pediatric patients.
- Patients unwilling to follow postoperative instructions.
- Cases not described in the indications.

Nota bene: although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

- Severe bone resorption.
- Osteomalacia.
- Severe osteoporosis.

POTENTIAL ADVERSE EVENTS

All adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes:

- Early or late loosening of components.
- Disassembly, bending, or breakage of components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, or general corrosion) including metallosis, staining, tumor formation, or autoimmune disease.
- Pressure on skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, or pain.
- Bursitis.
- Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of neurological function (e.g. sensory or motor) including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, or development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, or visual deficits.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, muscle loss.
- Urinary retention, loss of bladder control, or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves or pain.
- Fracture, microfracture, resorption, damage, or penetration of spinal bone (including the sacrum, pedicles, or vertebral body) or bone graft or bone graft harvest site at, above, or below the level of surgery.
- Retropulsed graft.
- Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery.
- Non-union (or pseudarthrosis), delayed union, or mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Inability to perform activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stresses shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Ileus, gastritis, bowel obstruction, loss of bowel control, or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Reproductive system compromise including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems (e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.)
- Change in mental status.
- Death.

Note: additional surgery may be necessary to correct some of these potential adverse events.

ADDITIONAL POTENTIAL ADVERSE EVENTS FOR PEDIATRIC PATIENTS

- Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions and/or distorted anatomy).
- Pedicle screw malpositioning, with or without neurological or vascular injury.
- Proximal or distal junctional kyphosis.
- Pancreatitis.

WARNING

Safety and effectiveness of pedicle screw spinal systems were 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 degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). Safety and effectiveness of this device for any other conditions are unknown. Implants are not prostheses. In the absence of fusion, instrumentation and/or one or more of its components can be expected to pull out, bend, or fracture as a result of exposure to every day mechanical stresses.

These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level. CD Horizon™ PEEK rods are intended for 1-2 level use in the lumbosacral spine (L2 – S1) in skeletally mature patients. This device is not a prosthesis and is not intended for standalone use.

A device that has been implanted should never be reprocessed or reused under any circumstances. Sterile packaged devices should also never be resterilized. Reprocessing or reuse may compromise the structural integrity of these implants and create a risk of contamination of the implants which could result in patient injury, illness, or death.

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS

Warning: safety and effectiveness of this device was not established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

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 risk of pedicle screw malpositioning and neurological or vascular injury. Patients not skeletally mature that undergo 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.

Other adverse events related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk for device-related injury because of their smaller stature.

ADDITIONAL WARNING FOR THE CD HORIZON™ SPIRE™ SPINOUS PROCESS PLATE

Consider the extent of decompression, as well as the amount of intact bone remaining on the spinous processes, when using the CD Horizon™ Spire™ plate as the sole supplemental fixation for an interbody fusion procedure.

PRECAUTIONS

Implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting risk of serious injury to patients.

Successful results are not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly, and/or breakage of devices will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of implants are important considerations in successful use of the system. Further, proper selection and compliance of patients greatly affect results. Patients who smoke were shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS

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 risk of serious injury to patients.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of implants are important considerations in successful use of the system in pediatric patients.

Selection of proper size, shape, and design of the implant for patients is crucial to the safe use of this device in pediatric patients.

Physician note: although the physician is the learned intermediary between the company and the patient, the important medical information in this document should be conveyed to the patient.

!USA For US Audiences Only

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

IMPLANT SELECTION

Selection of proper size, shape, and design of implants for patients is crucial to success of the procedure. Implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending, or loosening of devices before the healing process is complete which may result in further injury or the need to remove the device prematurely.

DEVICE FIXATION

In cases where a percutaneous posterior approach is used, refer to the CD Horizon™ Sextant™ surgical technique. CD Horizon™ spinal system instrumentation contains rods and implants of various diameters, which are intended to be used with device specific instruments. For self-breaking plugs, always hold the assembly with the counter torque device. Tighten and break-off the head of the plug to leave the assembly at optimum fixation security. After the upper portion of the self-breaking plug is sheared off, further re-tightening is not necessary and not recommended. The head portion should not remain in the patient. After the upper portion of the self-breaking plug is sheared off, re-adjustment is not possible unless the plug is removed and replaced with a new one.

When using DTT Transverse Links, the M6 plug should be tightened between 8 and 9Nm. (70 to 80 inch-lbs). CD Horizon™ PEEK rods are not to be used in pediatric patients. PEEK rods are only to be used with the associated pedicle screws as well as interbody fusion devices in the anterior spinal column.

PREOPERATIVE

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and pre dispositions such as those addressed in the contraindications should be avoided.
- Care should be used when handling and storing implant components. Implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
- An adequate inventory of implants should be available at the time of surgery; normally a quantity in excess of what is expected to be used.
- 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 all parts and necessary instruments are present before surgery. CD Horizon™ spinal system components are not to be combined with components from another manufacturer.
- Unless sterile packaged, all devices should be sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

- Extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to patients or operative personnel.
- Rods should not be repeatedly or excessively bent. Rods should not be reverse-bent in the same location. Use great care to ensure implant surfaces are not scratched or notched since such actions may reduce the functional strength of the construct. If rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
- Use an imaging system to facilitate surgery.
- To insert a screw properly, a guide wire should first be used, followed by a sharp tap. Caution: be careful the guide wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure the guide wire does not advance during tapping or screw insertion. Remove the guide wire and ensure it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.
  Caution: do not over-tap or use a screw/bolt that is either too long or too large. Over-tapping, using an incorrectly sized screw/bolt, or accidentally advancing the guidewire during tap or screw/bolt insertion may cause nerve damage, hemorrhage, or the other possible adverse events listed in this document. If screws/bolts are being inserted into spinal pedicles, use as large a screw/bolt diameter as will fit into each pedicle.
- Bone graft must be placed in the area to be fused and graft material must extend from the upper vertebrae to the lower vertebrae being fused.
- To ensure maximum stability, two or more Crosslink™ plates or DTT Transverse Links on two bilaterally placed, continuous rods should be used whenever possible.
- Bone cement should not be used because safety and effectiveness of bone cement is not determined for spinal uses, and this material will make removal of components difficult or impossible. Heat generated from the curing process may also cause neurologic damage and bone necrosis.
- Before closing soft tissues, provisionally tighten (finger tighten) all nuts or screws, especially screws or nuts that have a break-off feature. Once this is completed, go back and firmly tighten all screws and nuts. Recheck the tightness of all nuts or screws after finishing to ensure none loosened during the tightening of other nuts or screws. Failure to do so may cause loosening of other components.

POSTOPERATIVE

The physician's postoperative directions and warnings to patients, and the corresponding patient compliance, are extremely important.

- Detailed instructions on use and limitations of the device should be given to patients. If partial weight-bearing is recommended or required prior to firm bony union, patients must be warned that bending, loosening, and/or breakage of devices are complications which may occur as a result of excessive or early weight-bearing or muscular activity. Risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if patients are active, debilitated, or demented. Patients should be warned to avoid falls or sudden jolts in spinal position.
- To allow the maximum chances for a successful surgical result, patients or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. Patients 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. Patients should be advised not to smoke tobacco, use nicotine products, or consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
- Patients should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on implants. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of devices. It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if components loosen, bend, or break, devices should be revised or removed immediately before serious injury occurs. Patients must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
- CD Horizon™ spinal system implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, removal is indicated because implants are not intended to transfer or support forces developed during normal activities. If deviced are not removed following completion of its intended use, one or more of the following complications may occur: (1) corrosion, with localized tissue reaction or pain; (2) migration of implant position possibly resulting in injury; (3) risk of additional injury from postoperative trauma; (4) bending, loosening, and breakage which could make removal impractical or difficult; (5) pain, discomfort, or abnormal sensations due to the presence of devices; (6) increased risk of infection; (7) bone loss due to stress shielding; and (8) potential unknown or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
- Retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, CD Horizon™ spinal system components should never be reused under any circumstances.

VISUAL INSPECTION
Visually inspect all sterile barrier packaging before use. If the sterile barrier is damaged or the integrity is compromised, do not use the product. Contact Medtronic for return information.

Visually inspect the device before use. If the device is damaged, do not use the product. Contact Medtronic for return information.

PACKAGING
Devices may be supplied sterile or non-sterile. Packages for each of the components should be intact upon receipt. Once the seal on the sterile package is broken, the product should not be re-sterilized. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked to ensure there is no damage prior to use. Damaged packages or products should not be used and should be returned to Medtronic.

STERILIZATION
Unless marked sterile and clearly labeled as such in an unopened sterile package provided by Medtronic, all implants used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam-sterilized by the hospital using one of the sets of process parameters in Table 1.

Table 1: Sterilization cycle parameters for the US and its territories

Method	Cycle	Temperature	Exposure time	Minimum dry time[1]
Steam	Dynamic-air-removal	270°F (132°C)	4 minutes	30 minutes
Steam	Dynamic-air-removal	275°F (135°C)	3 minutes	30 minutes

Note: because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment. It is the user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) cleared by the Food and Drug Administration (FDA) for the selected sterilization cycle specifications (time and temperature). Sterilization cycles listed in Table 2 are not considered by the FDA to be standard sterilization cycles.

*For medical facilities located outside the US and its territories, some non-US health care authorities recommend sterilization according to these parameters to minimize the risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

Table 2: Sterilization cycle parameters for medical facilities outside the US and its territories

Method	Cycle	Temperature	Exposure time	Minimum dry time[1]
Steam	Dynamic-air-removal	273°F (134°C)	4 minutes	30 minutes
Steam	Dynamic-air-removal	273°F (134°C)	20 minutes*	30 minutes

[1]Minimum dry times were validated using sterilizers having vacuum drying capabilities. Drying cycles using ambient atmospheric pressure may require longer dry times. Refer to the sterilizer manufacturer's recommendations.

Only sterile products should be placed in the operative field. The general instruments used with this device are provided non-sterile. Refer to the instrument package insert for sterilization parameters and requirements. No implant should be reused once it comes into contact with human tissue or body fluid. Always immediately clean and re-sterilize instruments used in surgery. This process must be performed before handling or (if applicable) returning to Medtronic.

MRI INFORMATION
The CD Horizon™ spinal system has not been evaluated for safety, heating, migration, or compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the CD Horizon™ spinal system in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PRODUCT COMPLAINTS
For product problems, contact Medtronic.

FURTHER INFORMATION
Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is required, contact Medtronic.

EC REP
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EXPLANATION OF SYMBOLS

EC REP	Authorized representative in the European Community
Rx only	Caution : Federal (USA) law restricts the sale and/or the use of this device to or on the order of a physician
	Do not reuse
LOT	Batch code
	Manufacturer
REF	Catalog number
NON STERILE	Non sterile
!USA	For US audiences only
CE	For US audiences on
CE 0123	For US audiences on
STERILE R	Sterilized using irradiation
STERILE EO	Sterilized using ethylene oxide
	Use by date
	Consult instructions for use at this website.

Please contact your Sales Representative or Customer Service for the most up-to-date version of the package insert

Important Product Information Grafton™ DBM and Grafton Plus™ DBM

INDICATIONS FOR USE

Grafton™ DBM and Grafton Plus™ DBM are intended for use as a bone graft extender, bone graft substitute, and bone void filler in bony voids or gaps of the skeletal system (i.e., spine, pelvis, and extremities) not intrinsic to the stability of the bony structure. The voids or gaps may be surgically created defects or defects created by traumatic injury to the bone.

Grafton™ DBM (excluding the Orthoblend form) and Grafton Plus™ DBM are also intended to be packed into bony voids or gaps to fill and/or augment dental intraosseous, oral, and cranio-/maxillofacial defects. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone, including periodontal/infrabony defects; alveolar ridge augmentation (sinusotomy, osteotomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation. Grafton™ DBM and Grafton Plus™ DBM may be used alone in a manner comparable to autogenous bone chips or allograft bone particulate (demineralized freeze dried bone), or they may be mixed with either allograft or autograft bone or bone marrow as a bone graft extender. Grafton™ DBM and Grafton Plus™ DBM are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. Grafton™ DBM and Grafton Plus™ DBM are absorbed/remodeled and replaced by host bone during the healing process. Note: The user should consider the fact that Grafton™ DBM Crunch contains demineralized bone chips approximately 3 mm (±1 mm) in determining the appropriateness of this allograft for use in small defects.

CAUTION

This allograft may contain trace amounts of antibiotics (gentamicin), surfactant, and other processing solutions. Caution should be exercised if the patient is allergic to these antibiotics or chemicals. Grafton Plus™ DBM Paste contains starch. Therefore, caution should be exercised in using Grafton Plus™ DBM Paste in a patient with a starch allergy and/or amylase deficiency.

Important product information Mastergraft™ Strip

Mastergraft™ Strip is to be combined with autogenous bone marrow and is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure and can be used as a bone graft extender. The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.

RISK STATEMENT

This product is not intended to provide structural support during the healing process;

therefore, Mastergraft™ is contraindicated where the device is intended as structural support in the skeletal system.

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medtronic.com

Consult instructions for use at this website
www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser.
For best results, use Adobe Acrobat® Reader with the browser.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Medtronic