SURGICAL SYNERGY SPINAL WORKFLOW

Image | Navigate | Confirm

SURGICAL TECHNIQUE

SynergyCorpectomy℠ Posterior Approach

Procedure with StealthStation™ Navigation and O-arm™ Imaging

T2 Stratosphere™ Expandable Corpectomy System
and CD Horizon™ Solera™ System

Medtronic
Further, Together

MICHELSON TECHNOLOGY AT WORK

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Surgical Synergy
Spinal Workflow

INSTRUMENTS **AND IMPLANTS**

INSTRUMENTS
AND EQUIPMENT

O-arm™ Image Acquisition System

Mobile Viewing Station

Camera Cart

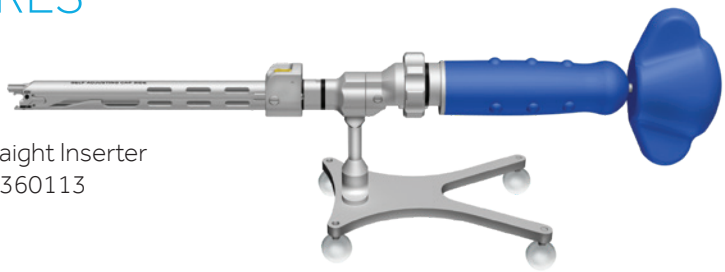
Main Cart

O-arm Imaging System

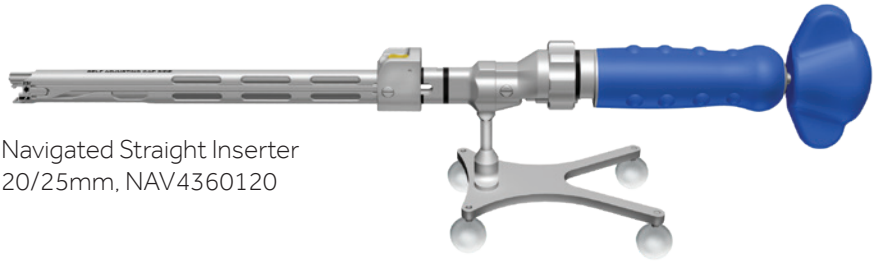
StealthStation™ Surgical Navigation

Navigated Stealth-Midas™ Powered Drilling System

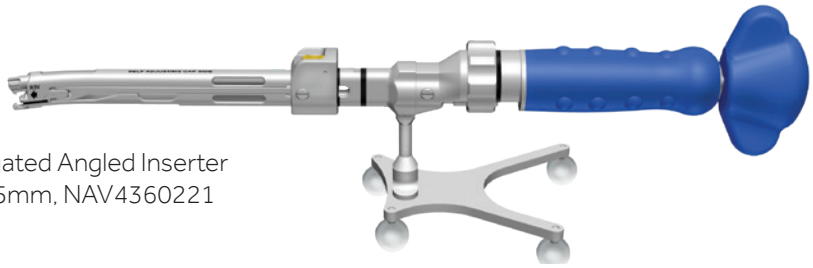
INSERTER FEATURES



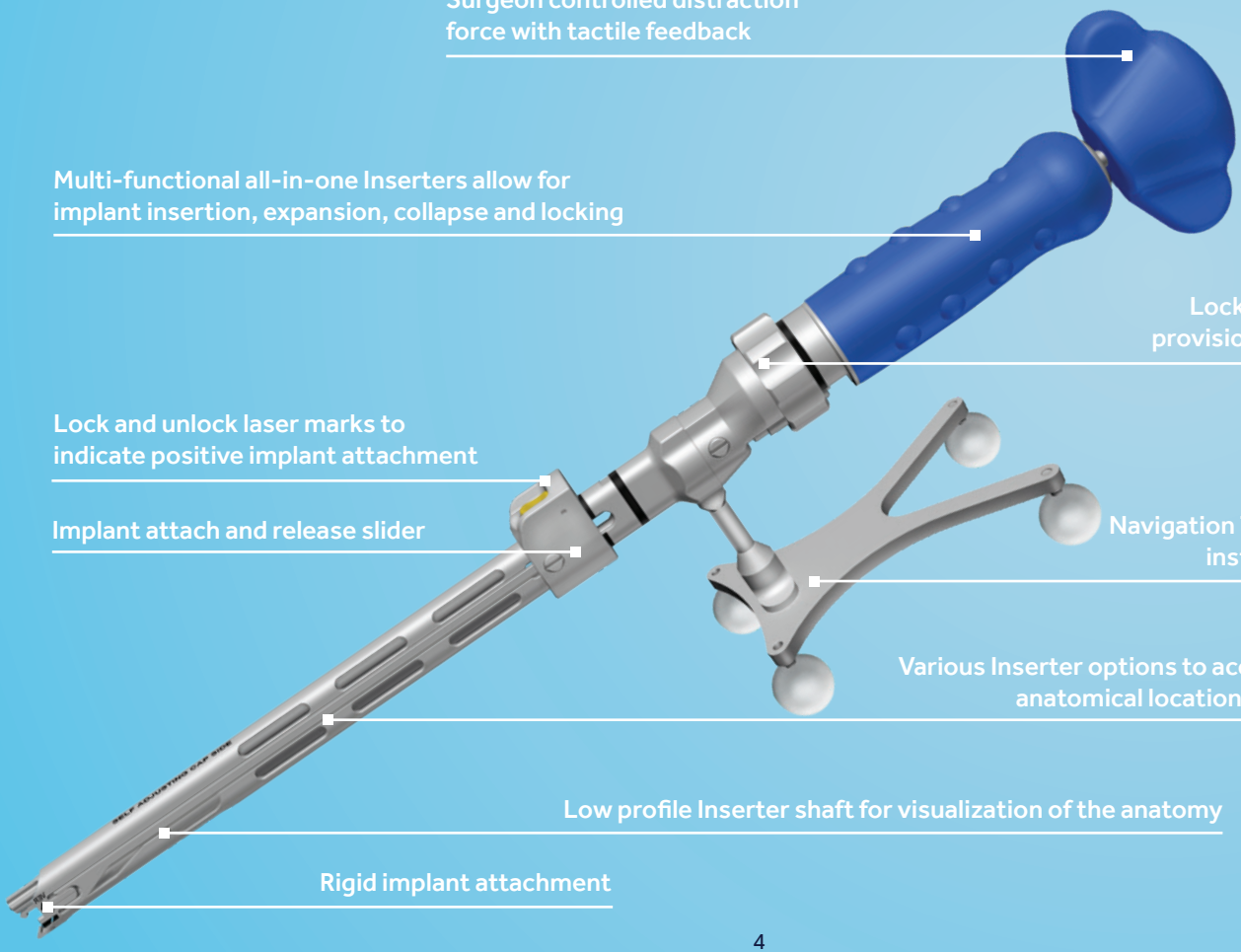
Navigated Straight Inserter
13mm, NAV4360113



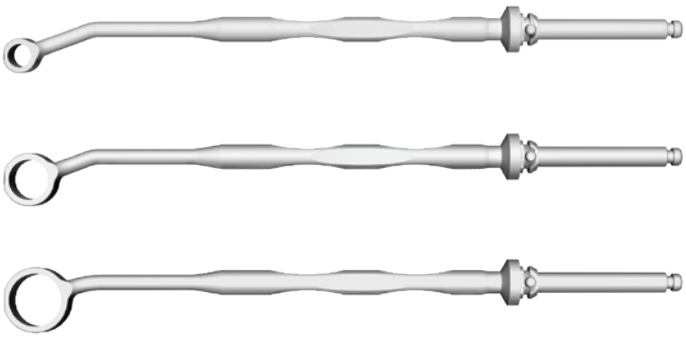
Navigated Straight Inserter
20/25mm, NAV4360120



Navigated Angled Inserter
20/25mm, NAV4360221



ADDITIONAL INSTRUMENTS



Navigated Template
13mm, NAV4361316
20mm, NAV4362022
25mm, NAV4362530

Navigated Extended Template
20mm × 30mm, NAV4360030
FOR LATERAL APPROACH ONLY

Bone Tamp
Small 9359003
Large 9359904

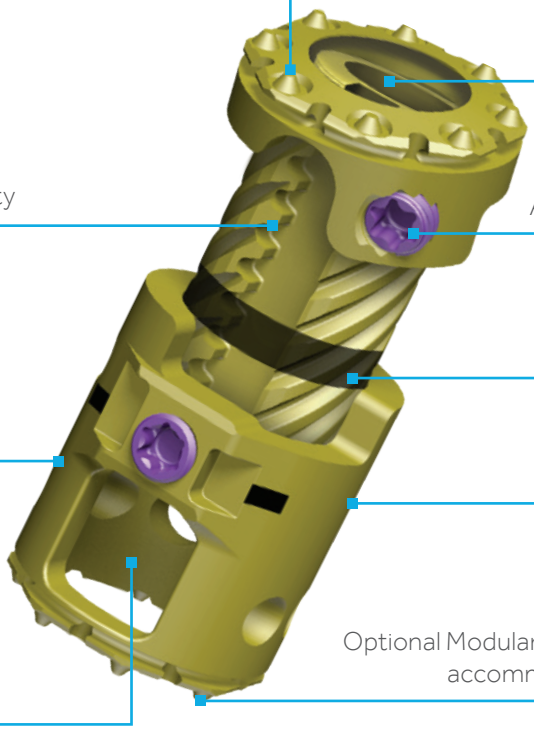
Torque Limiting Handle
T10, SC335010-J
T17, SC230020-J

Driver
T10, 4360513
T17, 4360520

End Cap Removal Tool
4360002

Implant Removal Tool
4360320

T2 STRATOSPHERE
IMPLANTS



Fifteen Centerpiece Options

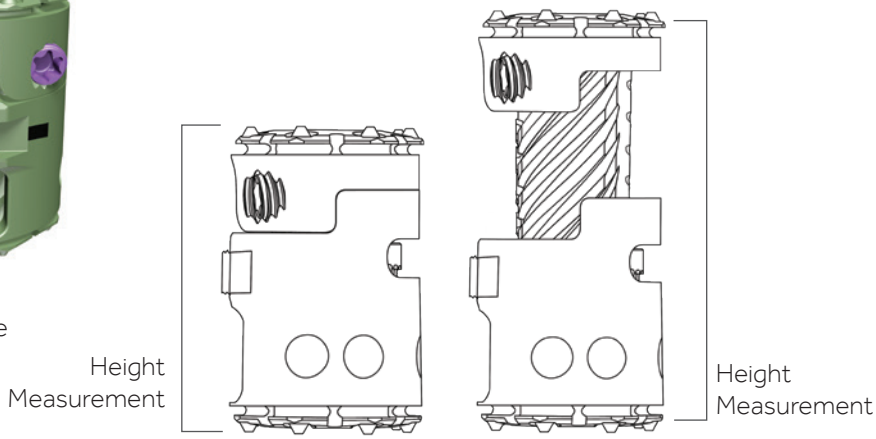
CENTERPIECE DIAMETER COMPARISON

Ø13mm Centerpiece

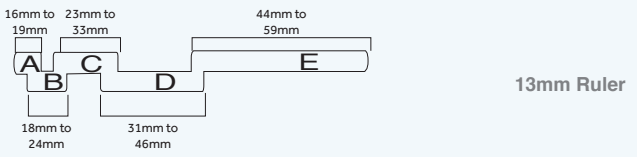
Ø20mm Centerpiece

Ø25mm Centerpiece

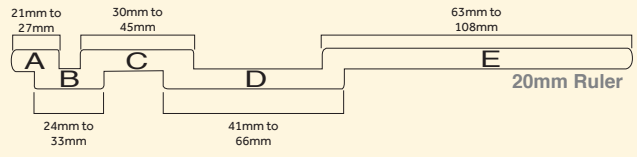
CENTERPIECE HEIGHT COMPARISON



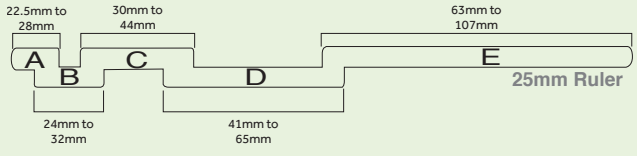
CENTERPIECE IMPLANT SELECTION



Size	Diameter (mm)	Collapsed Height (mm)*	Expanded Height (mm)**	End Cap Compatibility
13A	13	16	19	13mm & 16mm****
13B	13	18	24	13mm & 16mm****
13C	13	23	33	13mm & 16mm****
13D	13	31	46	13mm & 16mm****
13E	13	44	59	13mm & 16mm****



Size	Diameter (mm)	Collapsed Height (mm)*	Expanded Height (mm)**	End Cap Compatibility
20A	20	21	27	20mm & 22mm & 20mm Extended
20B	20	24	33	20mm & 22mm & 20mm Extended
20C	20	30	45	20mm & 22mm & 20mm Extended
20D	20	41	66	20mm & 22mm & 20mm Extended
20E***	20	63	108	20mm & 22mm & 20mm Extended



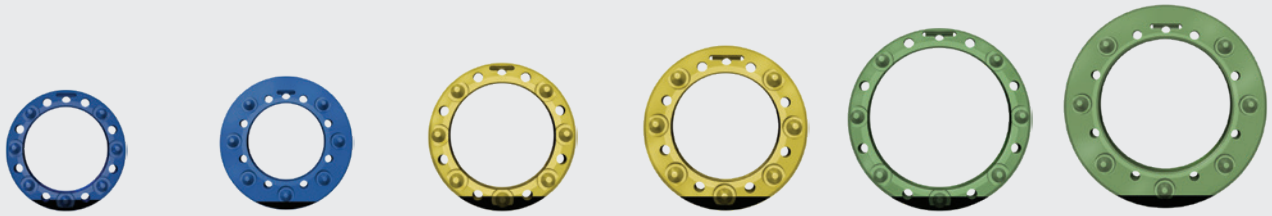
Size	Diameter (mm)	Collapsed Height (mm)*	Expanded Height (mm)**	End Cap Compatibility
25A	25	22.5	28	25mm & 30mm & 25mm Extended
25B	25	24	32	25mm & 30mm & 25mm Extended
25C	25	30	44	25mm & 30mm & 25mm Extended
25D	25	41	65	25mm & 30mm & 25mm Extended
25E***	25	63	107	25mm & 30mm & 25mm Extended

Note: The heights above are measured without End Caps attached to the Centerpiece.

*The collapsed height includes the spikes on the Centerpiece
**The expanded height does not include the spikes on the Centerpiece
***20E and 25E Centerpieces are not included in the set configuration
****For the 13mm Centerpieces, End Caps are cleared for use in the thoracolumbar spine only

Twenty-Three Modular End Cap Options

END CAP DIAMETER COMPARISON



13mm | 16mm | 20mm | 22mm | 25mm | 30mm

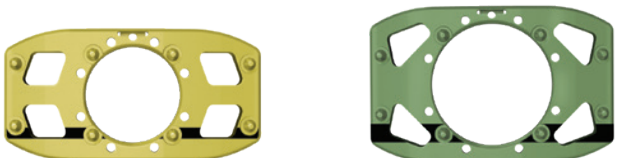
END CAP ANGLE COMPARISON

0 degrees* | 8 degrees | 15 degrees

*Only available in 16mm, 22mm, 30mm End Cap options.

EXTENDED END CAP WIDTH COMPARISON

FOR LATERAL APPROACH ONLY



20mm | 25mm

Lengths available = 30mm, 35mm, 40mm, 45mm
Extended End Caps are only offered in 0 degrees.

Note
Modular End Caps are cleared for use in the thoracolumbar spine only.

Important
Only 0 degree End Caps are available in the StealthStation Software.

Surgical Synergy
Spinal Workflow

SET-UP

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 S7 or S8 System **(Figure 1)**. Plug the MVS into a power source; connect the MVS to the O-arm System, and power on the system. Next, power on the StealthStation System and start the StealthStation™ Spine software. Connect the MVS to the StealthStation System network port with a network cable or a crossover cable.

Note
During the OR set-up, consider the placement of the patient reference frame to ensure StealthStation 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 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.

The equipment set-up for a SynergyCorpectomy Posterior Approach Procedure has the StealthStation Camera Cart positioned near the patient's feet. This set-up will provide the best chance to access all levels of the spine from T1 to L5.

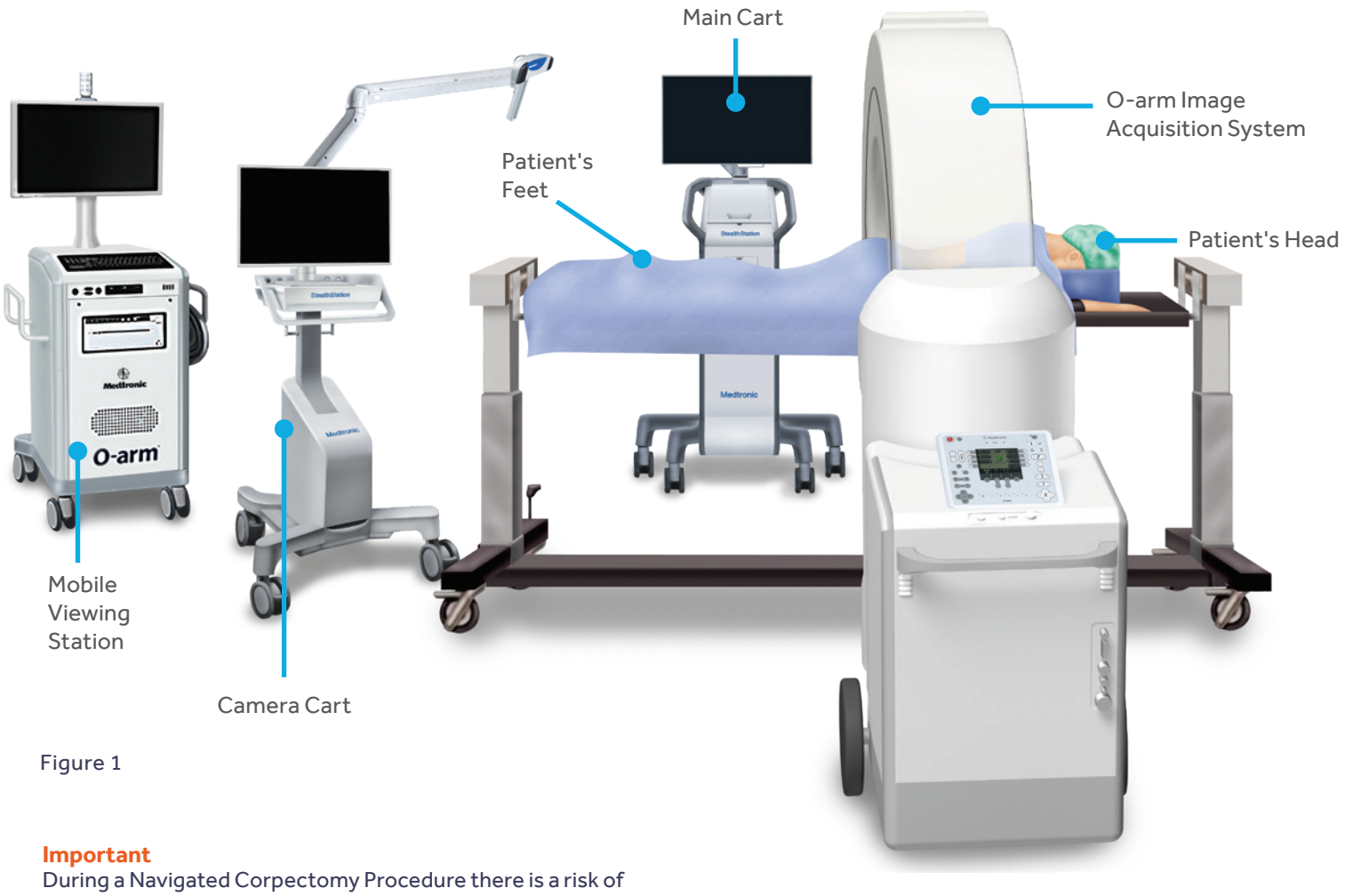
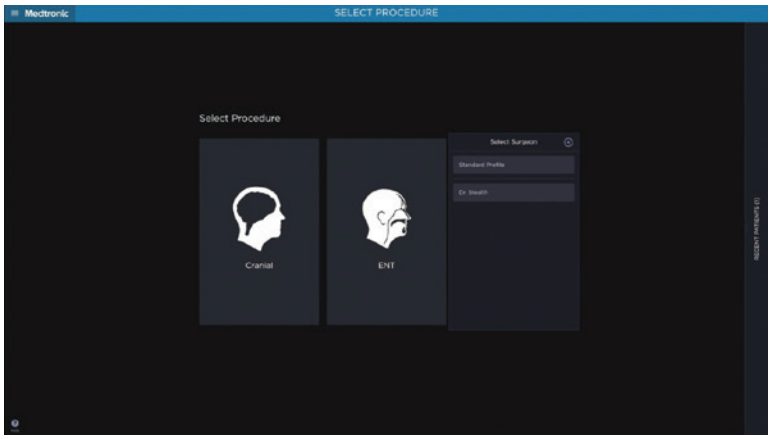


Figure 1

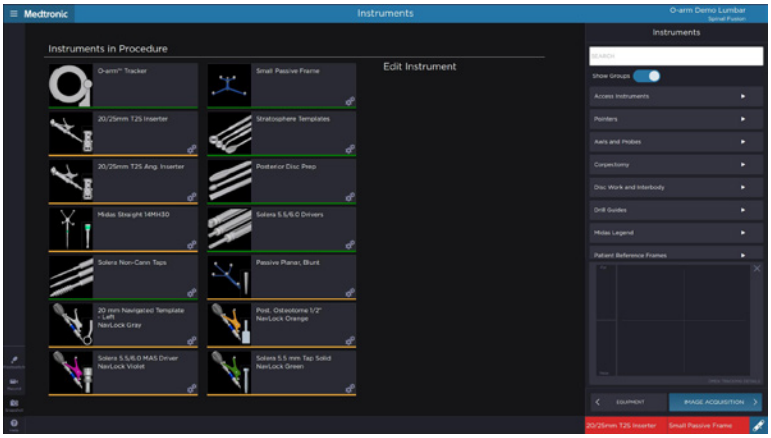
Important
During a Navigated Corpectomy Procedure there is a risk of anatomy shift due to the removal of the vertebral body. It is important throughout the procedure to frequently confirm navigational accuracy by touching the tip of the navigated instrument on known anatomical landmarks.

In the StealthStation Spine Software, complete the "Select Procedure" and then "Select Surgeon" tasks. Continue through the software by completing the "Set-Up Equipment" and "Verify Instruments" tasks to reach the "Acquire Scan" screen.

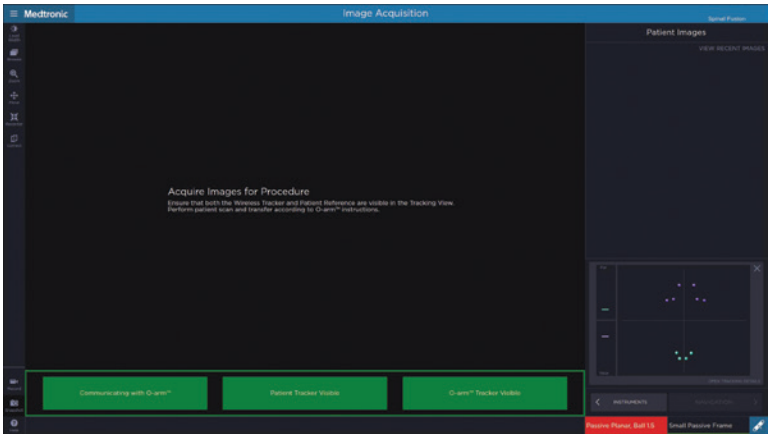
StealthStation Spine Software Workflow



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 CORPECTOMY POSTERIOR APPROACH
PROCEDURAL WORKFLOW

VERIFY INSTRUMENTS
- NavLock™ Trackers
- Stealth-Midas™ Drill
- Navigated Inserter

PATIENT POSITIONING
- Position patient in the prone position
- Position camera at the foot of the bed

SITE ACCESS
- Determine access point
- Mark skin
- Make skin incision

PLACE REFERENCE FRAME
- Percutaneous Reference Pin with Percutaneous Reference Frame*

- OR -

- Spinous Process Clamp with Small Passive Reference Frame

ACQUIRE 3D IMAGE
- Drape patient for O-arm System image acquisition
- Bring O-arm System in field and remove after image acquisition

TAP/PLACE SCREWS
- Tap and use projection to determine screw length and diameter
- Save projection to mark entry point
- Place screws on contralateral side
- Repeat for ipsilateral side
- Repeat for other levels

ROD AND SET SCREW PLACEMENT CONTRALATERAL SIDE
- Place temporary rod on contralateral side
- Place and tighten temporary set screws on contralateral side

VERTEBRAL BODY AND DISC REMOVAL
- Use Navigated Posterior Disc Prep instruments and Stealth-Midas Drill for facetectomy and laminectomy at corpectomy level
- Remove vertebral body using Navigated Posterior Disc Prep instruments and Stealth-Midas Drill
- Remove discs using Navigated Posterior Disc Prep and Stealth-Midas Drill

CORPECTOMY SIZING
- Determine implant footprint using Navigated Templates
- Determine implant height using Navigated Templates
- Select implant size and assemble implant, if necessary

CORPECTOMY DEVICE PLACEMENT
- Place implant on Navigated Inserter
- Place pre-packed bone graft in implant
- Insert and expand the implant
- Lock the implant height
- Lock the implant Self-Adjusting Multi-Axial End Cap (*optional*)
- Remove Inserter
- Place post-pack bone graft in implant

ROD AND SET SCREW PLACEMENT
- Place final rods
- Complete final posterior compression *(optional)*
- Place, tighten, and shear final set screws

ACQUIRE 3D CONFIRMATION IMAGE
- Assess implant placement

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

*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 2a**) 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 2b)**.

- 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.
- I f 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.

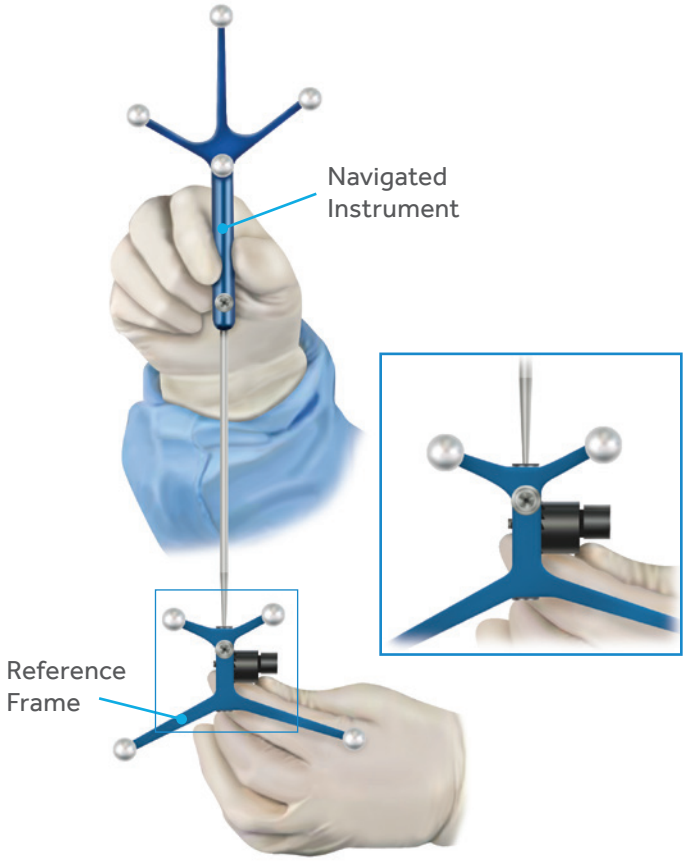
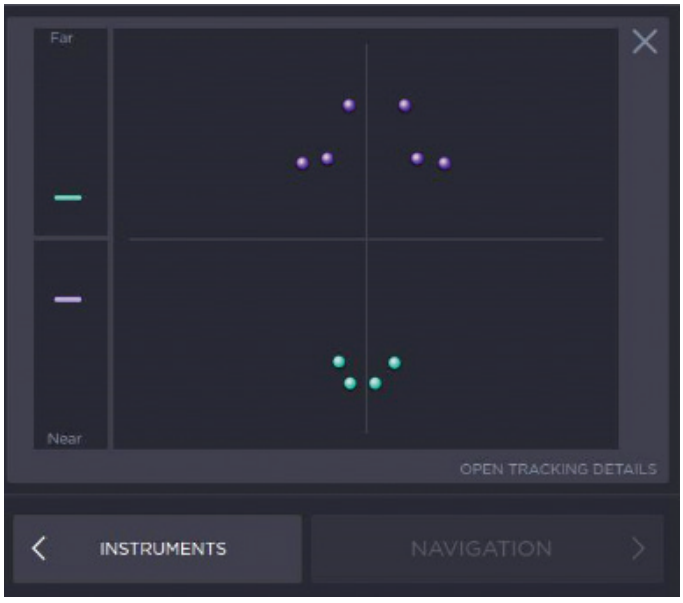


Figure 2a

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 S8
System Software

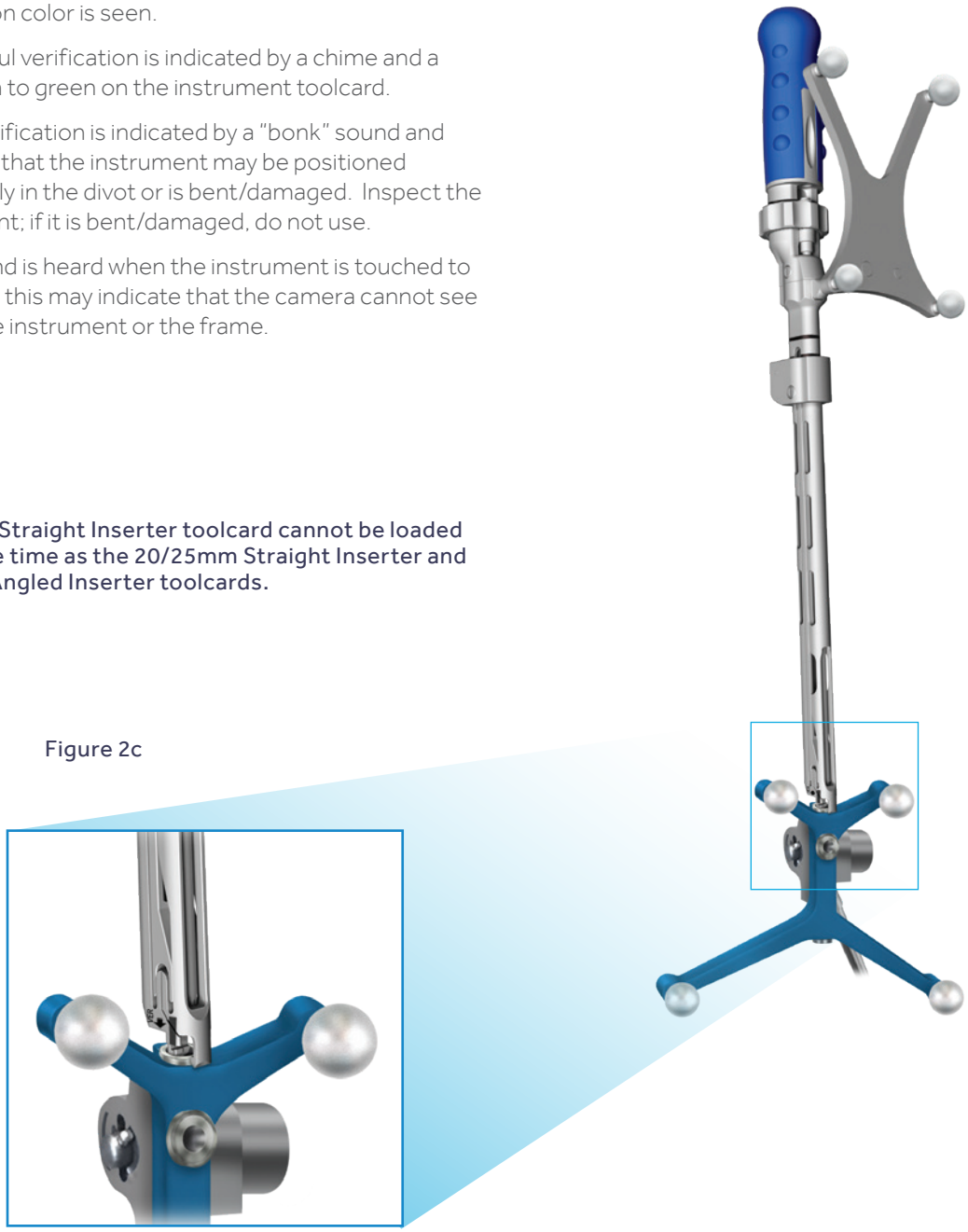
Figure 2b

To verify the T2 Stratosphere Inserters, first remove the blue T-handle from the Inserter. Place the prong labeled "VER" into the Reference Frame divot (**Figure 2c**). Hold perpendicular and visible to the camera until a confirmation color is seen.

- 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.

Important
The 13mm Straight Inserter toolcard cannot be loaded at the same time as the 20/25mm Straight Inserter and 20/25mm Angled Inserter toolcards.

Figure 2c



Surgical Synergy
Spinal Workflow

PATIENT **POSITIONING**

PATIENT POSITIONING AND SURGICAL EXPOSURE

Position the patient in the prone position. The StealthStation Camera Cart should be positioned at the foot of the bed. This set-up will provide the best chance to access all levels of the spine from T1 to L5. This set-up will also provide the best positioning for access around the nerve roots in the lumbar and lower thoracic spine.

Locate the operative levels and perform a standard surgical exposure with access for the corpectomy, screws and temporary rod.

REFERENCE FRAME PLACEMENT

When performing a SynergyCorpectomy Posterior Procedure either a Percutaneous Reference Pin or a Spinous Process Clamp can be used for referencing. If instrumenting above T7, it is recommended to use a Spinous Process Clamp to maintain system accuracy.

Percutaneous Reference Pin

Pins are available in 100mm and 150mm lengths. For L5 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 3a)**. This option is described below.

Using 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.

Make a stab incision and locate the Cannula with the Dilator over the PSIS. Place the Dilator/Cannula into the incision through the tissue until it contacts bone.

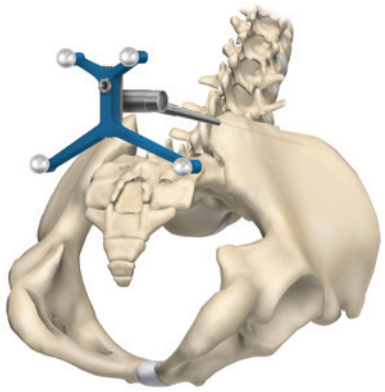


Figure 3a

Helpful Hint
To keep the frame close to the patient and out of the way of surgical instruments, use the 100mm Percutaneous Reference Pin, if possible.

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 the result of relative motion between the Reference Frame and target anatomy, the Reference Frame should be placed near the planned instrumented levels.

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° toward the midline of the patient and then angle it 30° 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 3b)**. Remove the Tap Cap from the pin and attach the Percutaneous Reference Frame to the pin **(Figure 3c)**.

Spinous Process Clamp

The Spinous Process Clamp with the Small Passive Reference Frame can also be used. The clamp should be firmly attached to the spinous process inferior to the planned instrumented levels. With the camera positioned at the patient's feet, the clamp should be within an unobstructed view of the camera and the instruments.

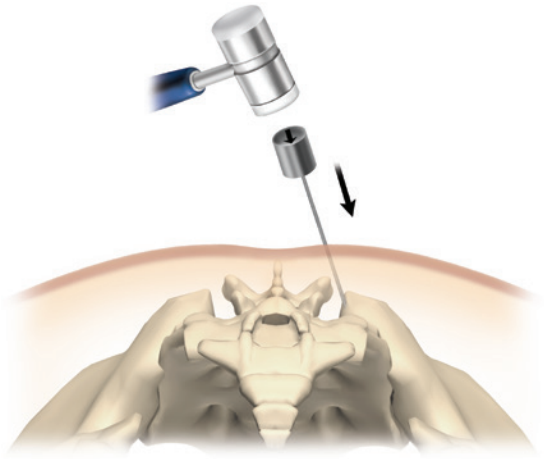


Figure 3b

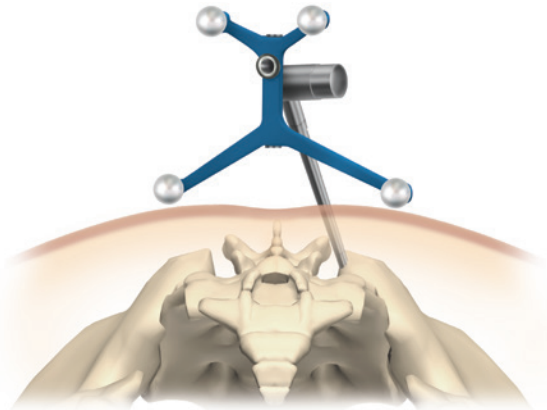


Figure 3c

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 (**Figure 4**).

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.

O-arm™ System Isodose Curve

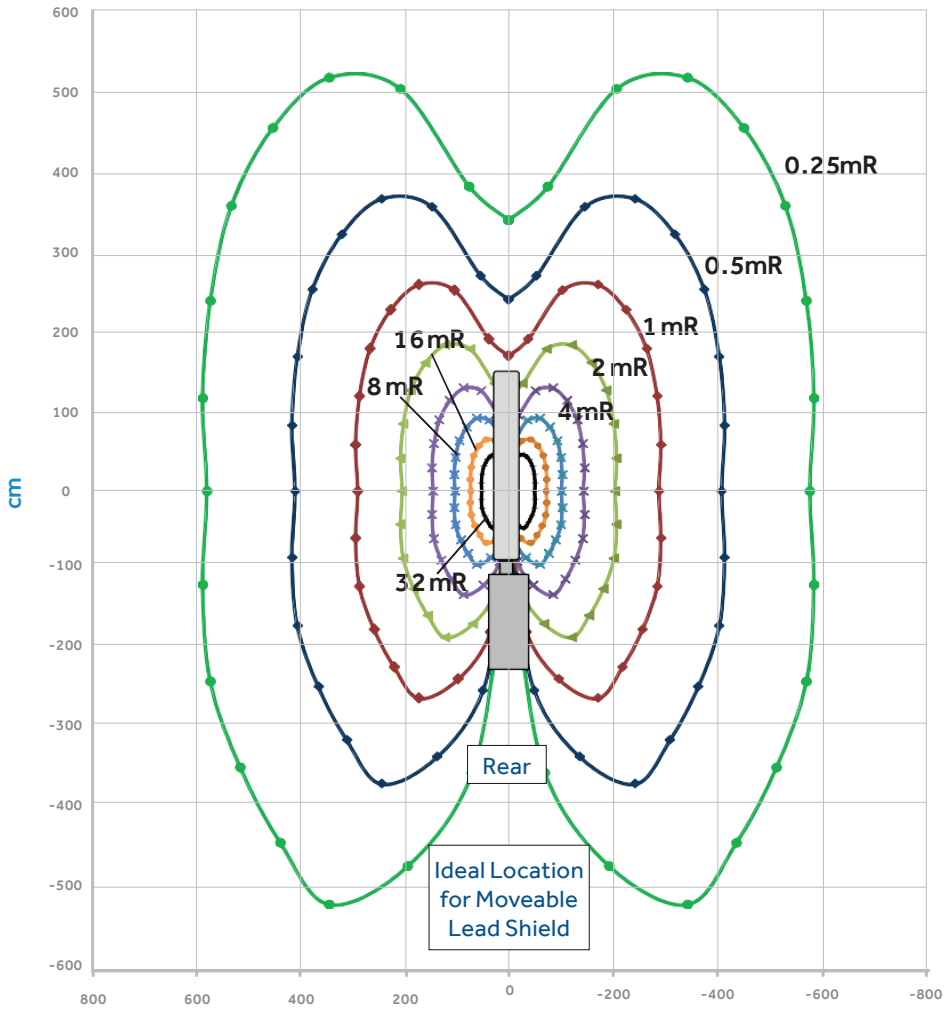


Figure 4

Scatter plot showing the shape of isodose curves for the maximum technique factors for the O-arm™ O2 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

Surgical Synergy
Spinal Workflow

PROCEDURE **STEPS**

PEDICLE PREPARATION
AND SCREW LENGTH MEASUREMENT

Place the Awl Tip Tap on the bone of the pedicle for tapping. A virtual tip projection can be selected under the "Projection" tab to provide additional guidance on trajectory **(Figure 5a)**. Advance the tap to its desired depth. Once the tap has been advanced to the ideal depth, create a reverse projection under the "Projection" tab and then select "Save Projection" **(Figures 5b and 5c)**. This will save the trajectory to be used as a virtual guidewire which may be recalled during subsequent screw placement. This projection also indicates the screw length and diameter for subsequent screw placement.

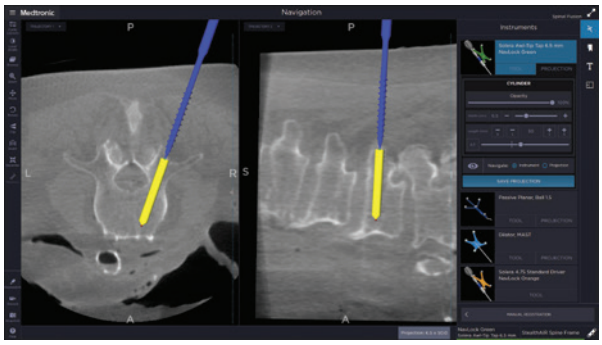


Figure 5a

OPTIONAL
STEP

The Stealth-Midas Navigated Drill can be used to drill a pilot hole prior to tapping. On the StealthStation 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. Choose the "Projection" tab on the StealthStation System to create a projection and select "Save Projection" to save your plan **(Figure 5d)**.

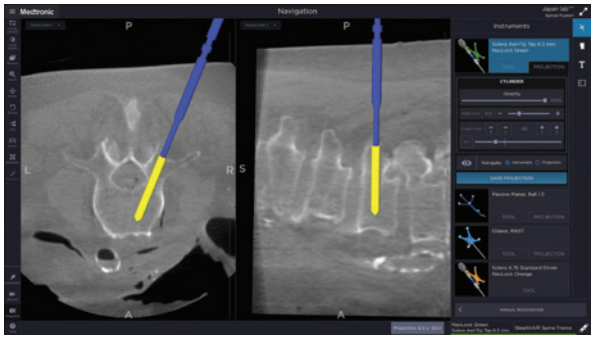


Figure 5b

Important
If planning to use the 20/25mm Navigated Angled Inserter, the defect should be prepared to access the spine on the patient's right side. It may be necessary to switch to the 20mm/25mm Navigated Straight Inserter if the anatomy will not accommodate the 20mm/25mm Navigated Angled Inserter trajectory and limitations.

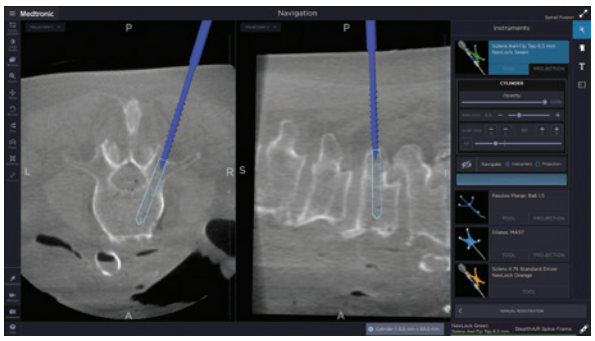


Figure 5c

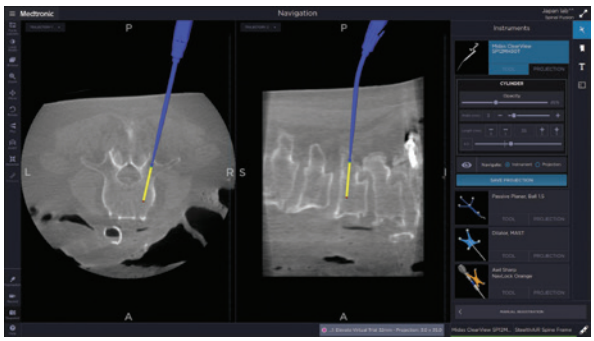


Figure 5d

SCREW INSERTION

Next, thread the navigated driver into the head of the screw. Recall the virtual guidewire if saved during pedicle preparation **(Figure 6a)**. Under the "Tool" tab, select the appropriate screw width and length. Align the screw and driver with the virtual guidewire and advance the screw being careful that the screw is not advanced too far **(Figure 6b)**. If the screw head is placed against the bone, it will lose its multi-axial capabilities and make it difficult to connect the screws during subsequent steps.

Place the remaining screws for the construct. The screw heads should move freely following screw insertion.

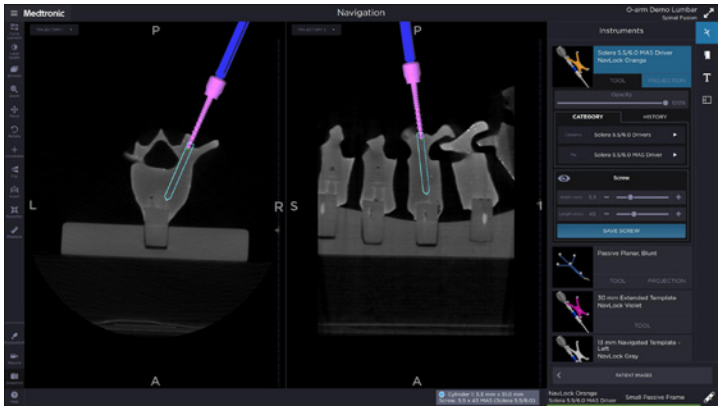


Figure 6a

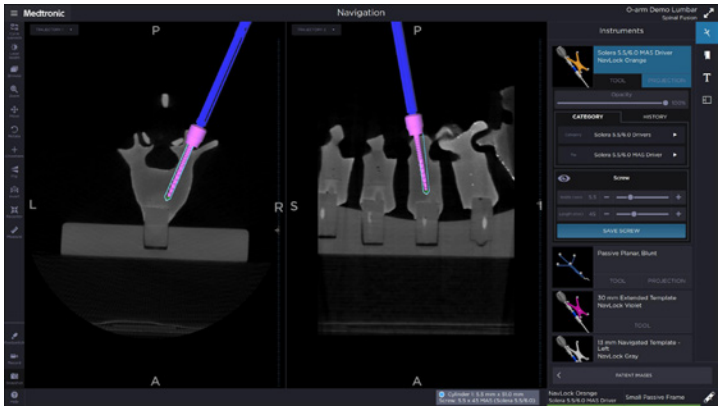


Figure 6b

TEMPORARY ROD AND SET SCREWS

Once the screws are placed, measure the length for the temporary rod, then cut the rod. Use the French Bender to contour the rod. Place the rod on the contralateral side and provisionally secure with set screws. The temporary rod and set screws must remain in place until the corpectomy device is placed to maintain the navigation system accuracy and prevent anatomical shift.

CORPECTOMY
SITE ACCESS

A facetectomy and a laminotomy are performed using the navigated osteotome and other general instruments such as a Kerrison for bony removal (**Figure 7a**).

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, The vertebral body and the discs can now be removed using Navigated Posterior Disc Preparation instruments, Navigated Stealth-Midas Drill, and general instruments until the desired defect is achieved (**Figures 7b and 7c**).

The main goal of this step is to remove a collapsed, damaged, or unstable vertebral body, decompress neural elements, and provide entry and space for a corpectomy device.

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 to the instrument tip in the image with its physical location.

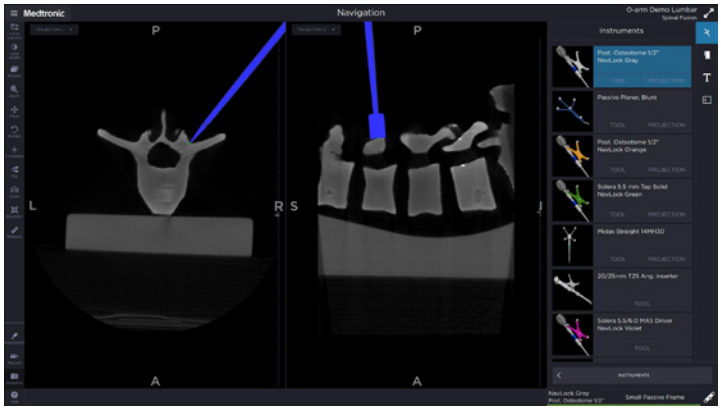


Figure 7a

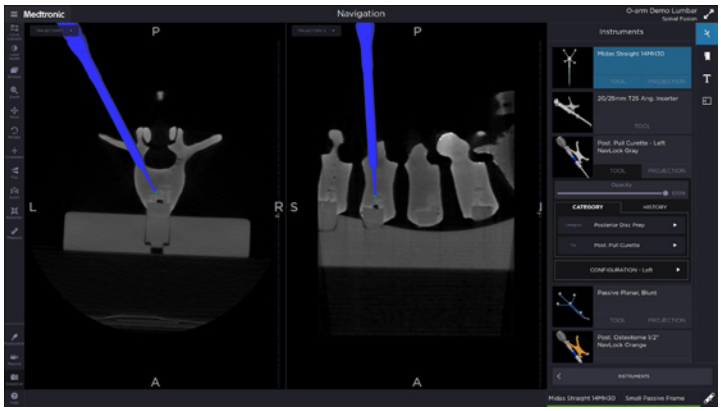


Figure 7b

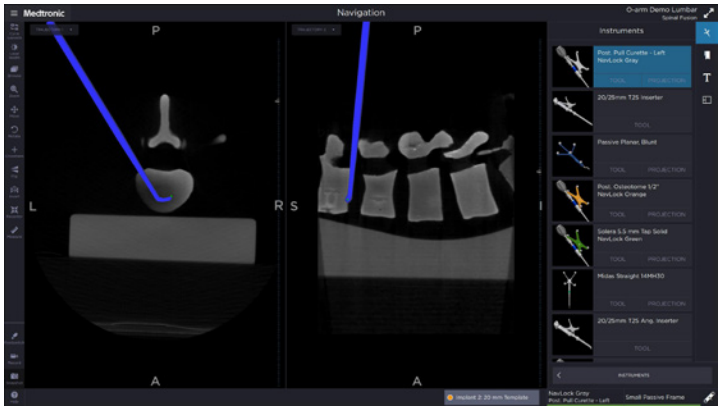


Figure 7c

TEMPLATE MEASURE
IMPLANT FOOTPRINT

On the StealthStation System, choose the "Tool" tab to select an appropriately sized Navigated Stratosphere Template. The Navigated Stratosphere Templates are available in three diameters: 13, 20, 25mm. To approximate the implant size, use the virtual templates on the StealthStation System. The recommended views for templating are Trajectory 1, Trajectory 2, and the Coronal view. Updating Trajectory 1 to Interbody views can help visualize the endplate on which the template is docked (**Figure 8a**).

Place the Template on the endplate and confirm that the footprint size is correct for the defect (**Figure 8b**). If a larger size is needed a larger footprint can be projected by clicking the enable End Cap toggle on the "Tool" tab: 13mm Template can be projected to 16mm diameter, 20mm Template can be projected to 22mm diameter, and 25mm Template can be projected to 30mm diameter. Sweep the Template across the defect to the second endplate, ensure there are no obstructions. Then place the Template on the second endplate and confirm the footprint size is correct for both endplates (**Figure 8c**).

Optional Planning Step

For planning purposes, the Template footprint can be saved (**Figure 8d**). Place the Template on the first endplate and save plan; then touch the Template to the second endplate and save plan. These saved plans can be useful for axial and trajectory planning for implant placement.

Note

The projected sizes 16mm, 22mm, and 30mm diameters will require the addition of Round End Caps to both ends of the Centerpiece.

Note

For template measuring on the StealthStation S7, the user must first select a camera position. Once the user selects either the head or foot camera position from the drop-down menu, the template projection options will be enabled.

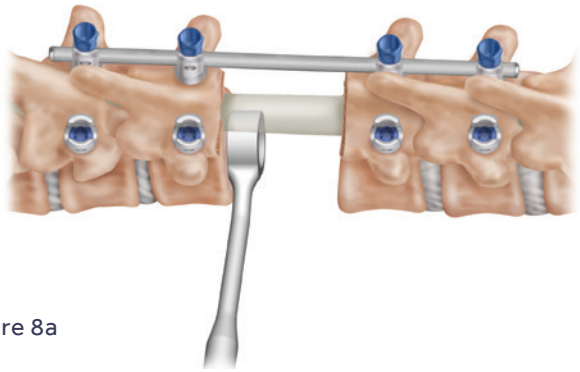


Figure 8a

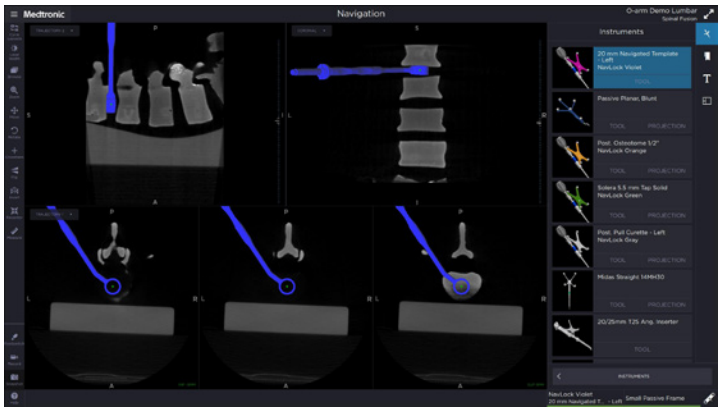


Figure 8b

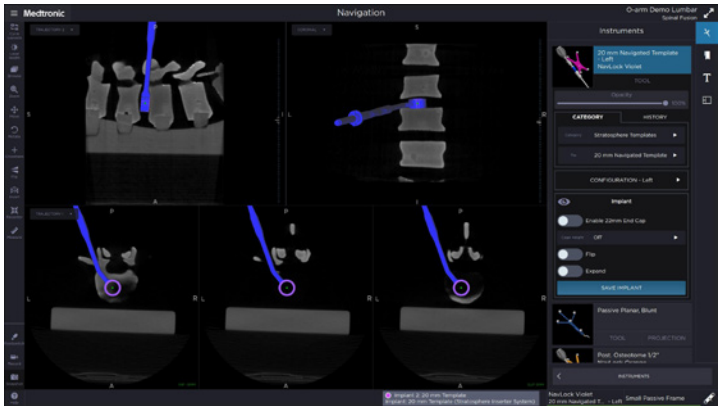


Figure 8c

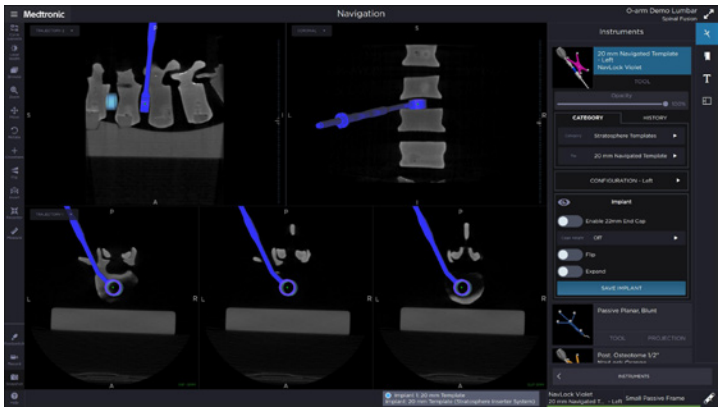


Figure 8d

TEMPLATE MEASURE
IMPLANT HEIGHT

After the footprint is selected, the Template can be used to project the height measurement. Hold the Template on the endplate and select through the various collapsed cage heights on the projection tab in the software. If the height "Tool" is not in the desired direction, the flip toggle can be engaged to reverse the projection direction.The collapsed implant height should be smaller than the defect size and at or below the opposite endplate (**Figure 9a**). Once you have selected the largest collapsed cage height that fits the defect, engage the expand height toggle on the "Tool" tab to confirm the appropriate size implant has been selected. The expanded height represents the maximum expanded height of the cage size selected. The expanded height should be larger than the defect size (**Figure 9b**).

Note

If the expanded height projection is at or below the opposite endplate use the next largest collapsed cage height.

Note

If the engage End Cap toggle is activated the height projected includes the addition of two round 16mm, 22mm, or 30mm End Caps.

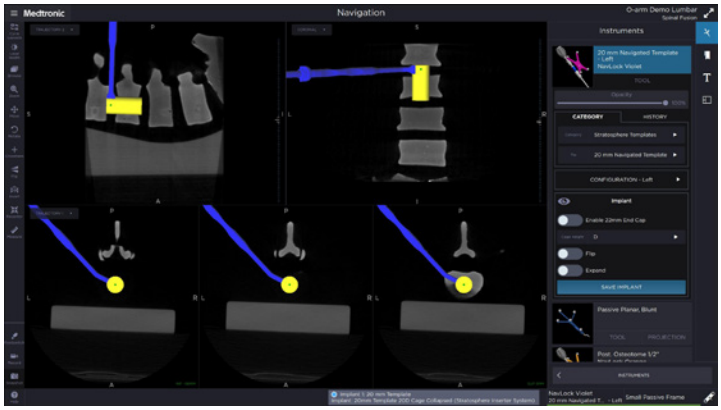


Figure 9a

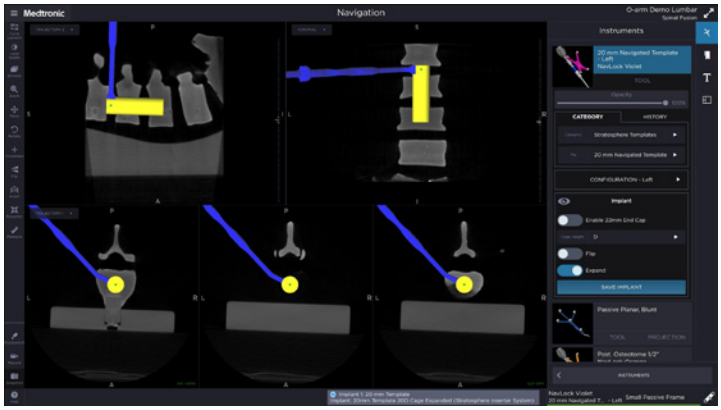


Figure 9b

IMPLANT SELECTION

Centerpiece Measurements

Size	Diameter (mm)	Collapsed Height (mm)*	Expanded Height (mm)**	End Cap Compatibility
13A	13	16	19	13mm & 16mm****
13B	13	18	24	13mm & 16mm****
13C	13	23	33	13mm & 16mm****
13D	13	31	46	13mm & 16mm****
13E	13	44	59	13mm & 16mm****
20A	20	21	27	20mm & 22mm & 20mm Extended
20B	20	24	33	20mm & 22mm & 20mm Extended
20C	20	30	45	20mm & 22mm & 20mm Extended
20D	20	41	66	20mm & 22mm & 20mm Extended
20E***	20	63	108	20mm & 22mm & 20mm Extended
25A	25	22.5	28	25mm & 30mm & 25mm Extended
25B	25	24	32	25mm & 30mm & 25mm Extended
25C	25	30	44	25mm & 30mm & 25mm Extended
25D	25	41	65	25mm & 30mm & 25mm Extended
25E***	25	63	107	25mm & 30mm & 25mm Extended

*The collapsed height includes the spikes on the Centerpiece
**The expanded height does not include the spikes on the Centerpiece
***20E and 25E Centerpieces are not included in the set configuration
****For the 13mm Centerpieces, End Caps are cleared for use in the thoracolumbar spine only

End Cap Height

Round End Caps

0 Degree End Caps (Each)	
Diameter	Height (mm)
13mm & 16mm	1.5mm
20mm & 22mm	1.2mm
25mm & 30mm	1.3mm

Extended End Caps

0 Degree End Caps (Each)	
Width	Height (mm)
20mm	1.2mm
25mm	1.2mm

Note
Additional End Cap height details can be found on the End Cap Height Sizing Guide.

Important
Only 0 degree End Caps are available in the StealthStation Software.

END CAP APPLICATION

In the StealthStation System only 0 degree End Caps are available. The Self-Adjusting Multi-Axial End Cap on the Centerpiece allows for 16 degrees total range of motion circumferentially. Optional Modular End Caps may be applied to accommodate additional footprint options. Optional Modular End Caps are cleared for use in the thoracolumbar spine only.

If additional footprint sizes are necessary, choose the appropriate Modular End Caps. To attach the End Caps a dock and lock technique should be utilized. The Centerpieces have 8 orientation options to attach the End Caps (**Figure 10a**). Center the laser mark over one of the orientation options and dock the End Cap laser mark in the groove on the edge of the Centerpiece (**Figure 10b**). Rotate the End Cap down onto the Centerpiece and press on the top side of the End Cap to snap together (**Figure 10c**). Use the same technique to apply the second End Cap. If End Caps are being applied, the same size End Cap must be attached to both ends of the Centerpiece.

End Cap Detachment

If an End Cap needs to be removed, insert the End Cap Removal Tool into the key hole on the top of the End Cap. Use a cantilever motion to push out on the End Cap tab and lift off the End Cap (**Figure 10d**). Once an End Cap has been removed from an implant, the End Cap should not be re-used.

Note

For the 13mm A-Size Centerpiece a Modular End Cap can only be attached to the Self-Adjusting Multi-Axial End Cap side of the implant. All other Centerpiece sizes allow Modular End Caps to be attached to both ends of the implant.

Figure 10a

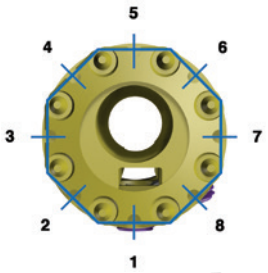


Figure 10b

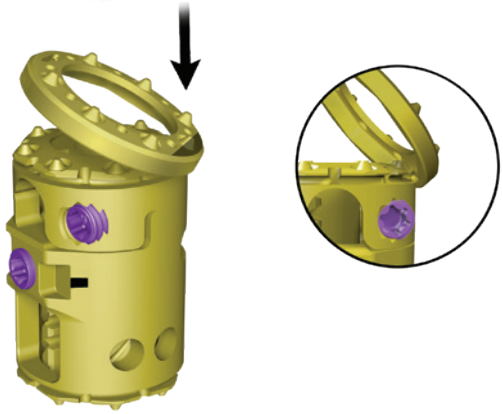


Figure 10c

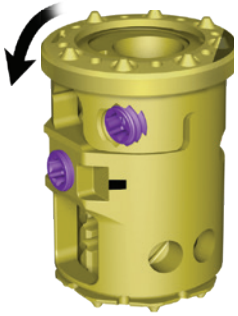


Figure 10d

GRAFT
PRE-PACKING

Once you have assembled the implant, pre-pack the Centerpiece with autograft or allograft material using a Bone Tamp (**Figures 11a and 11b**). Medtronic offers a number of allograft options that can be used with the T2 Stratosphere Expandable Corpectomy System including *UDIWRQw□IPLQHUDOLHG□RQH□ 0DWUL□□

Important
When packing bone graft, ensure that graft does not come in contact with the expansion ring area (**Figure 11c**). Do not over pack the implant with graft.

Thoracolumbar Allograft Options

*UDIWRQw□IPLQHUDOLHG□RQH□DWUL□ □□

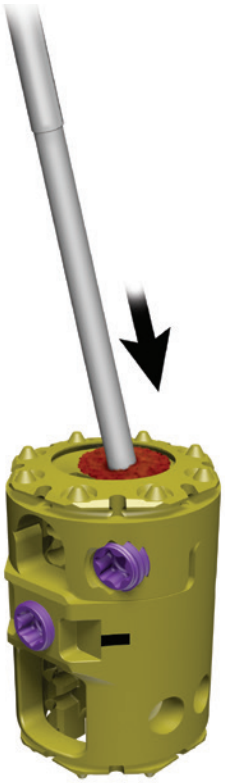


Figure 11a

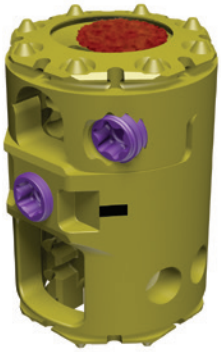


Figure 11b

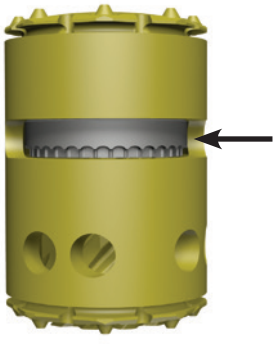
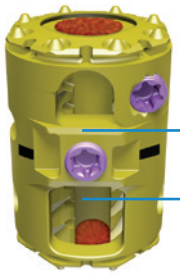


Figure 11c

Align the prongs on the Inserter with the slots on the implant above and below the set screw (**Figure 13a**). Push the implant onto the prongs of the Inserter (**Figure 13b**). The black laser marks on the side of the Inserter and implant can also be used to align the tabs. Press the gold slider button and push the slider forward past the black lock laser mark **(Figure 13c)**. Push the locking ring forward so that the black locking ring laser mark is visible (**Figure 13d**). Push the blue T-handle in and the implant is now connected to the Inserter (**Figures 13e and 13f**). Turn the blue T-handle clockwise and counterclockwise to ensure the implant expands and collapses smoothly.



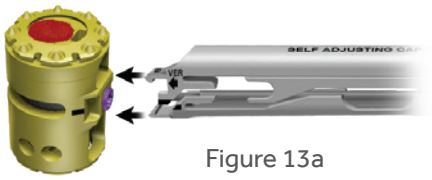


Figure 13a

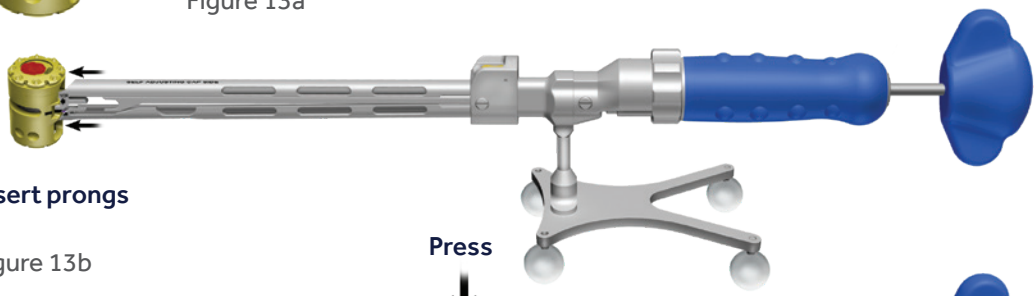


Figure 13b

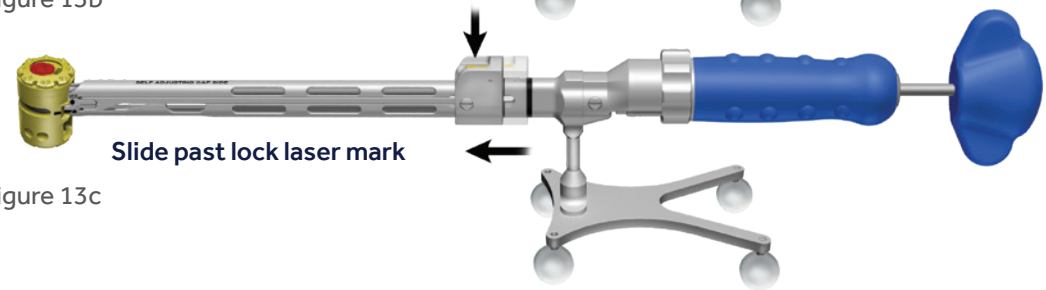


Figure 13c

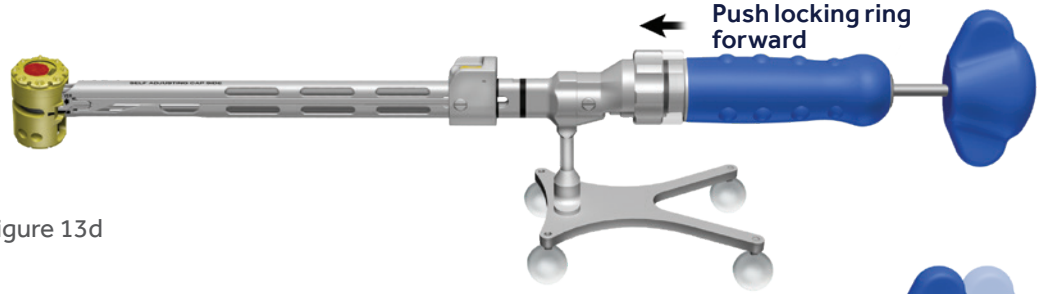


Figure 13d

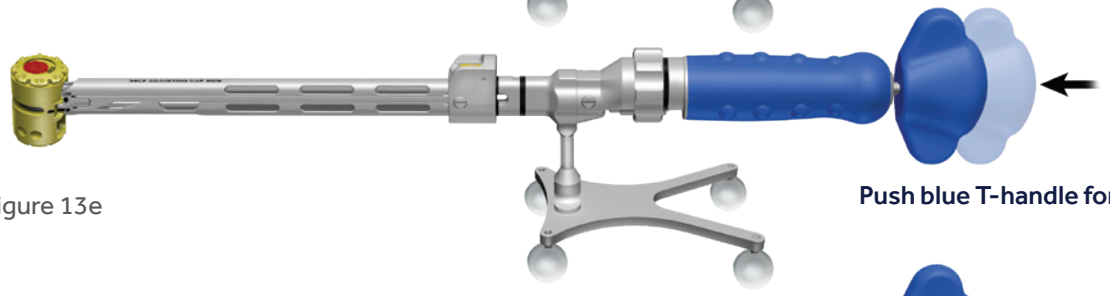


Figure 13e

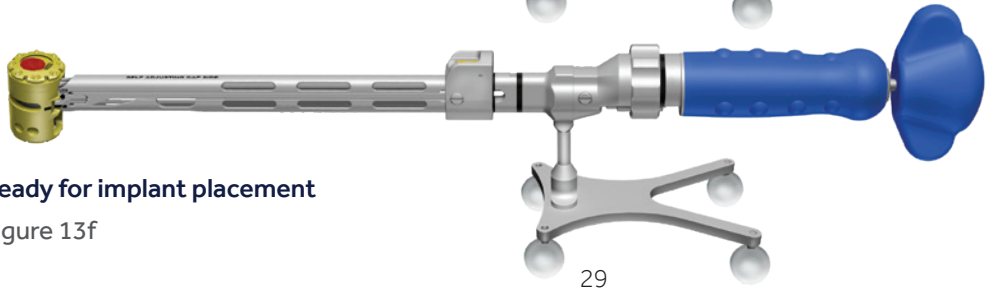


Figure 13f

IMPLANT REPRESENTATION IN SOFTWARE

In the StealthStation software, choose the "Tool" tab to construct the implant in the software. Select the appropriate Centerpiece size from the drop-down menu (**Figure 14a**). If End Caps were attached to the implant, select the appropriate End Cap size from the "Round End Cap" drop down menu. Round End Caps will appear on both ends of the Centerpiece (**Figure 14b**). The recommended views for implant placement are Trajectory 1, Trajectory 2, and the Coronal View. **It is important to note that Trajectory 1 is through the center of the inserter and implant and the vertebral body represented on the screen could be the removed vertebral body. Updating Trajectory 1 to Interbody views can help to visualize the endplate on which the implant is docked.**

Note

On the screen, End Caps are depicted in a pink color with a semi-transparent pink zone. This semi-transparent pink zone represents the maximum possible movement of the End Cap.

Note

The aqua color on the Centerpiece represents the Self-Adjusting Multi-Axial End Cap or expanding end of the Centerpiece and can be used to assist with implant orientation.

Helpful Hint

If using a StealthStation S7, it is recommended to change views from navigate instrument to navigate projection. This ensures that the navigated anatomy shown is through the center/ widest point of the implant.

Note

For the Inserters on the StealthStation S7, the user must first select a camera position. Once the user selects either the head or foot camera position from the drop-down menu, the Inserter projection options will be enabled.

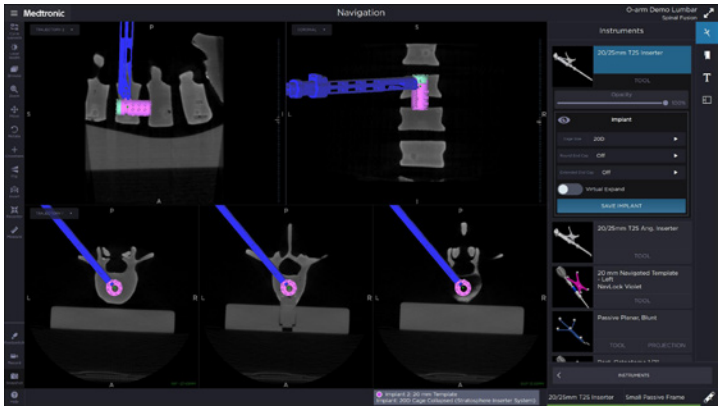


Figure 14a

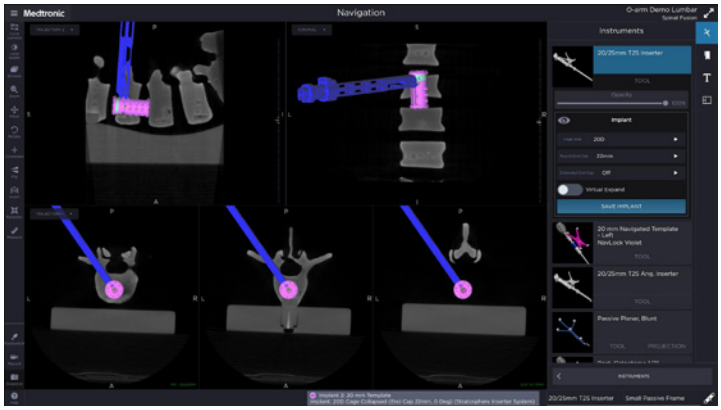


Figure 14b

EXPANDABLE CORPECTOMY
DEVICE PLACEMENT

Position the implant in the defect by docking the implant on the endplate and center axially in the defect created. The previously Saved Plans can be used to align the implant to the endplate (**Figure 15a**). Position the height of the implant in the sagittal and coronal planes in the appropriate trajectory toward the opposite endplate. The Virtual Expand can be toggled on the "Tool" tab to show a virtual position of the maximum expanded state. The Virtual Expand will be a semi-transparent pink color and is provided as guidance for trajectory and sizing (**Figure 15b**).

Rotate the blue T-handle clockwise to expand the implant (**Figure 15c**). The Self-Adjusting Multi-Axial End Cap will self-align to the endplate surface as you expand. The implant can be positioned to expand either cephalad or caudal based on patient anatomy considerations. If the StealthStation Camera Cart is positioned near the feet of the patient, the implant will expand cephalad. The blue T-handle can be turned counterclockwise to collapse the implant if repositioning is necessary. The implant is at the maximum expansion when the silver (13mm Centerpiece) or black (20mm and 25mm Centerpiece) line is fully visible on the implant. The maximum expansion laser mark is 3mm wide to indicate the implant is reaching its full expansion.

During expansion the blue T-handle provides tactile feedback on the endplate distraction forces. After expanding the implant, expansion pressure should be maintained on the blue T-handle until the height set screw is provisionally tightened. If the blue T-handle is released prior to provisional locking, the implant will collapse losing endplate pressure.

Note
If it is necessary to mallet the implant into the defect, the blue T-handle can be removed from the Inserter to access the impactor cap. After malleting, confirm accuracy by touching a known anatomical landmark such as the vertebral endplate.

Important
If any distraction of the defect is performed, another O-arm spin will be necessary to maintain navigation accuracy. Confirm accuracy by using the Navigated Probe to touch on a known anatomical landmark.

Important
When expanding the implant, always push down on the blue T-handle to ensure it is fully engaged with the implant. If at any time a clicking sound is heard during expansion, stop expanding and inspect the implant and Inserter interface prior to proceeding.

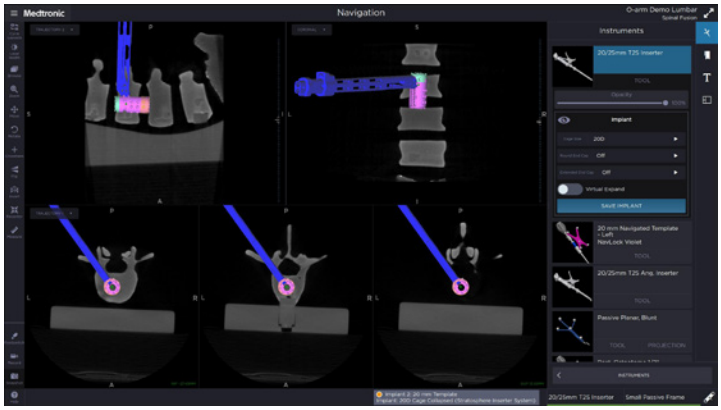


Figure 15a

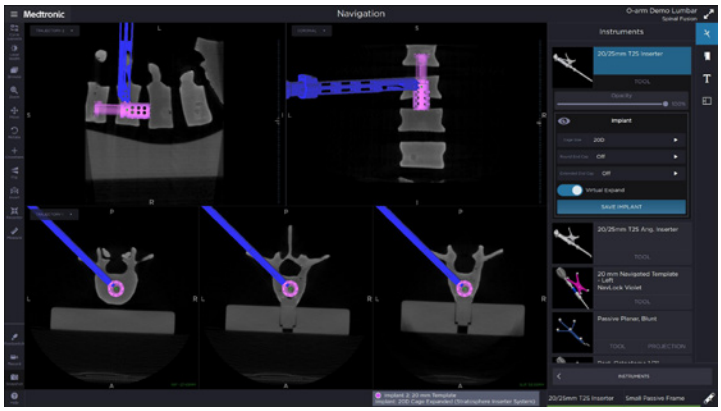


Figure 15b

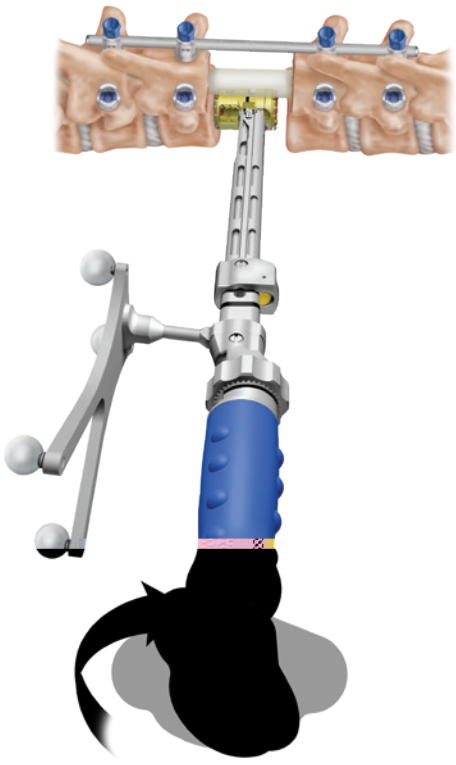


Figure 15c

Final Locking

Once final placement of the implant is achieved, final lock the implant height by inserting the Driver into the hole on the Inserter handle, push down and turn clockwise until the Torque Limiting Handle clicks (**Figure 17a**).

If desired, the Self-Adjusting Multi-Axial End Cap can be locked by placing the Driver in the set screw and turning the Driver clockwise until the Torque Limiting Handle clicks (**Figure 17b**). Although not required, it is recommended to lock the Self-Adjusting Multi-Axial End Cap when possible.

Note
Once final locking is achieved with the Torque Limiting Handle, the implant cannot be re-used.

Figure 17a

Note
If a posterior approach is utilized, the implant height may be locked and a posterior lordosis or kyphosis correction can be performed, if necessary. This correction will not be navigated and imaging should be used to confirm the correction. During this correction, the Self-Adjusting Multi-Axial End Cap will articulate with the endplate maintaining surface to surface contact and Multi-Axial End Cap load distribution. After the correction, the Self-Adjusting Multi-Axial End Cap set screw can be locked to maintain the position.

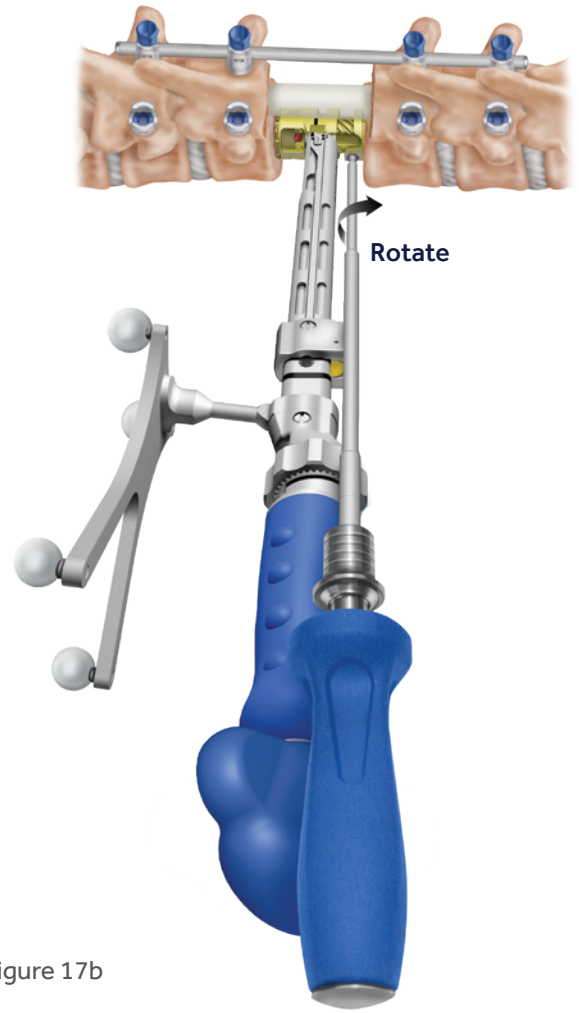


Figure 17b

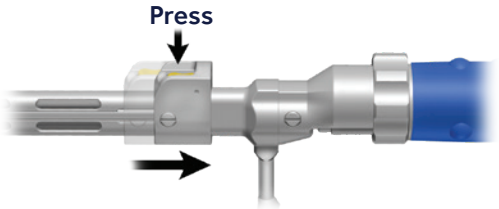
To remove the Inserter, pull back on or remove the blue T-handle and pull back on the locking ring to disengage them from the implant (**Figures 18a and 18b**). Then press the gold slider button on the Inserter and pull the slider back past the black unlock laser mark and hold (**Figure 18c**). Translate the Inserter slightly toward the Self-Adjusting Multi-Axial End Cap and pull back to disengage the Inserter from the implant (**Figure 18d**).

Pull blue T-handle back

Figure 18a

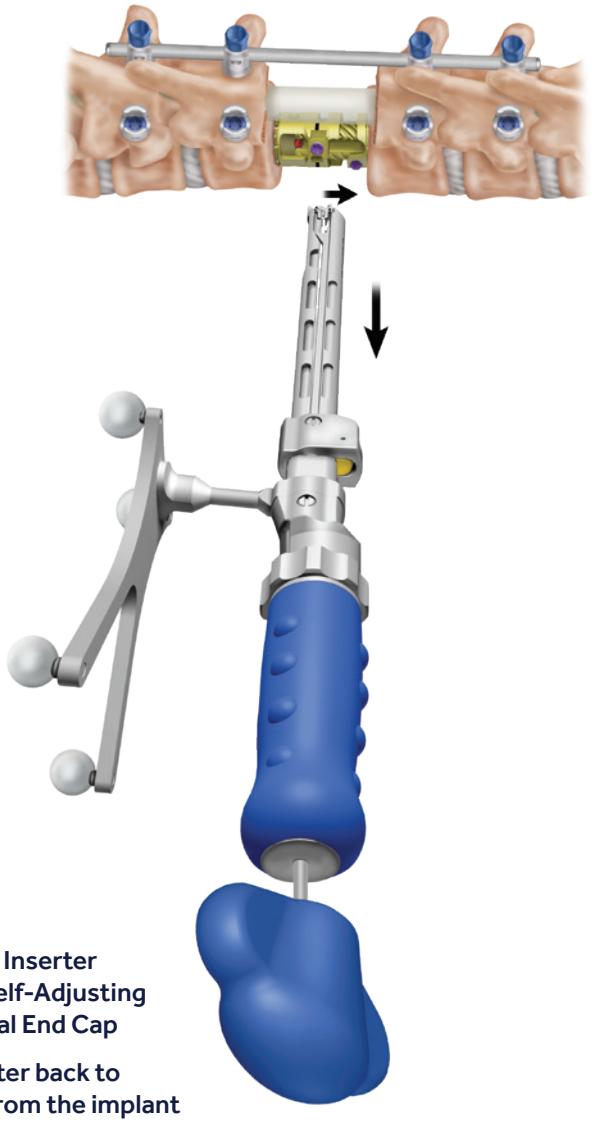
Pull locking ring back

Figure 18b



Slide past unlock laser mark and hold

Figure 18c



Translate Inserter toward Self-Adjusting Multi-Axial End Cap

Pull Inserter back to remove from the implant

Figure 18d

FINAL PLACEMENT AND GRAFT POST-PACKING

Pack additional autograft or allograft inside and around the device (**Figure 19**).

Medtronic offers a number of allograft options for post-packing this device including Grafton™ Demineralized Bone Matrix (DBM).

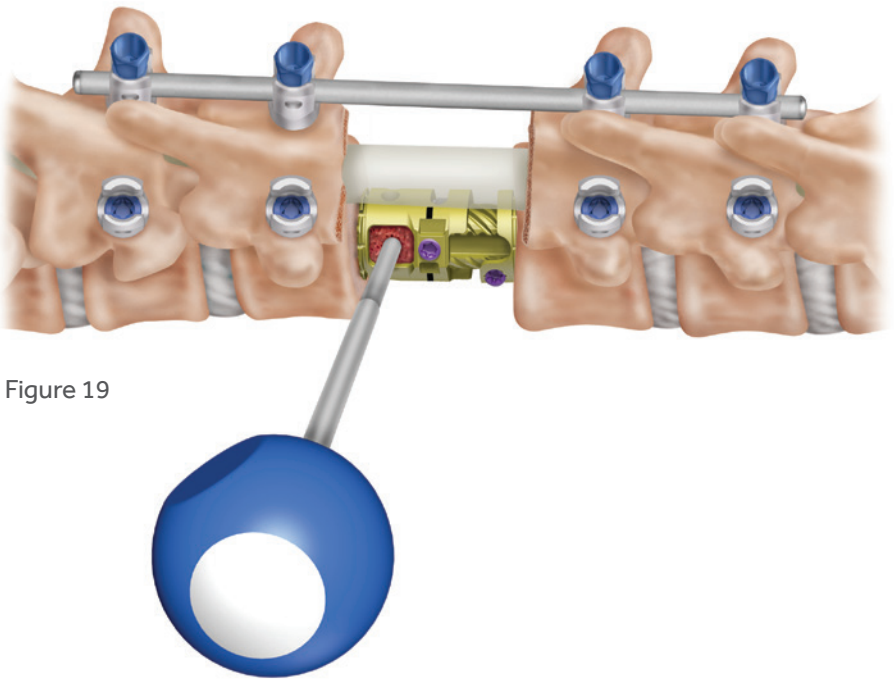
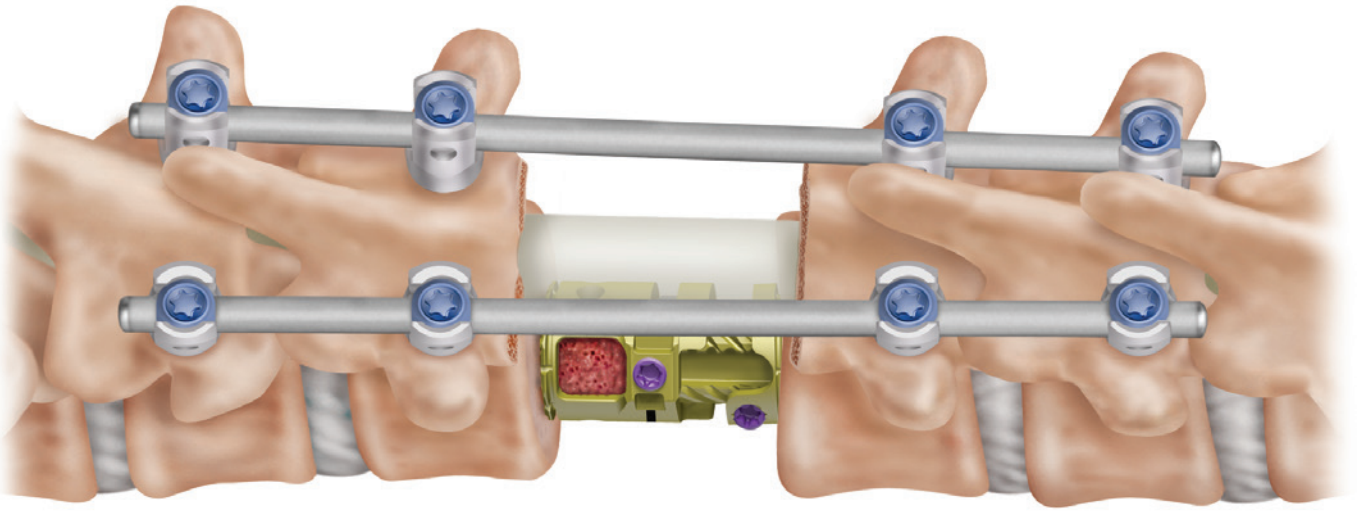


Figure 19

FINAL PLACEMENT OF RODS AND SET SCREWS

Once the T2 Stratosphere device is placed, see the CD Horizon Solera Surgical Technique for detailed instructions on rod placement, compression/distraction and set screw insertion/break off.

If visual confirmation of rod passage is desired prior to the O-arm System confirmation spin, a 2D fluoroscopy image can be performed using the O-arm System following the guidelines listed in the Image Acquisition section on **page 18**.



Final placement

Surgical Synergy
Spinal Workflow

CONFIRMATION

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 20**). 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 corpectomy device placement. Following confirmation, the Reference Frame should be removed.

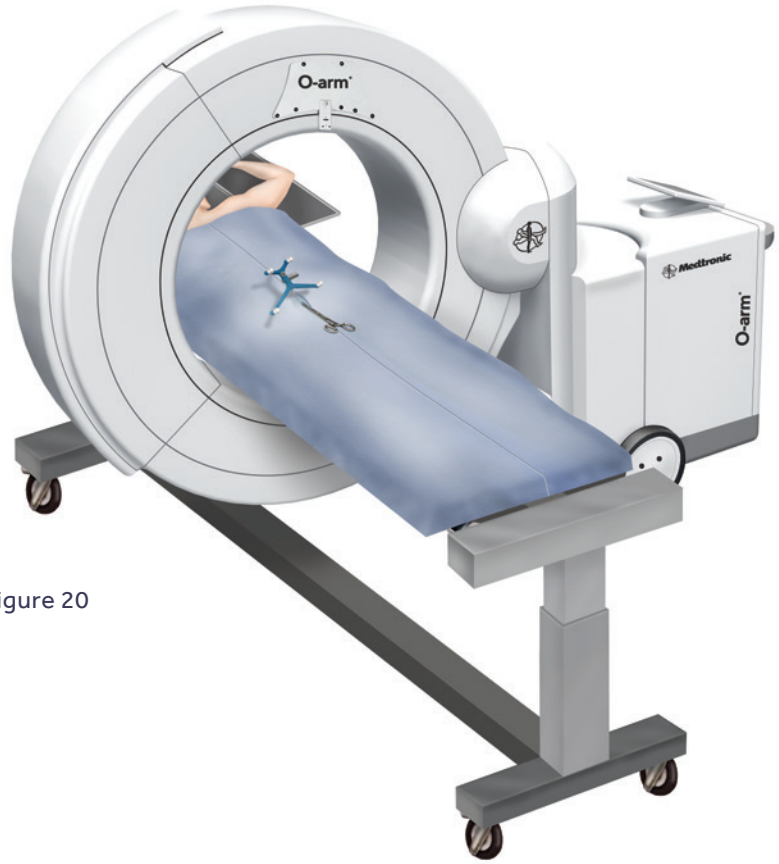


Figure 20

EXPLANTATION

Set screws and rods may be removed by applying a T25 Removal Driver to the Set Screw and turning counterclockwise until the Set Screw is removed. Then the CD Horizon™ Solera™ Screws can be removed by applying the Ball-ended Bonescrew Driver to the screw and turning counterclockwise until the screw is removed from the pedicle.

To explant the implant, grasp the implant with the Implant Removal Tool above and below the set screw (**Figure 21a**).

Use the Driver to turn the implant set screw counterclockwise. The implant height will slightly collapse when it is unlocked. Remove the implant **(Figure 21b)**.

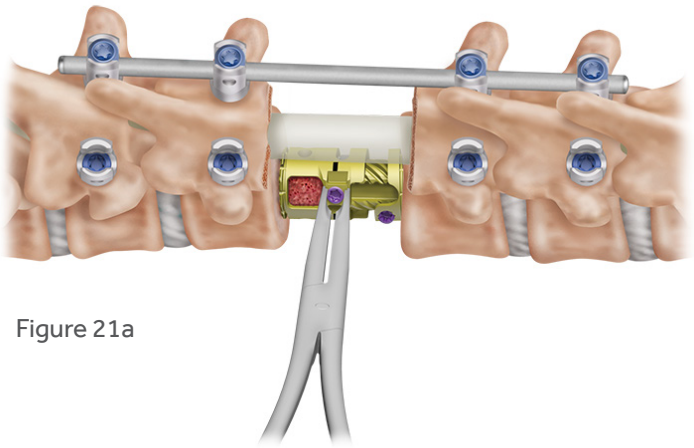


Figure 21a

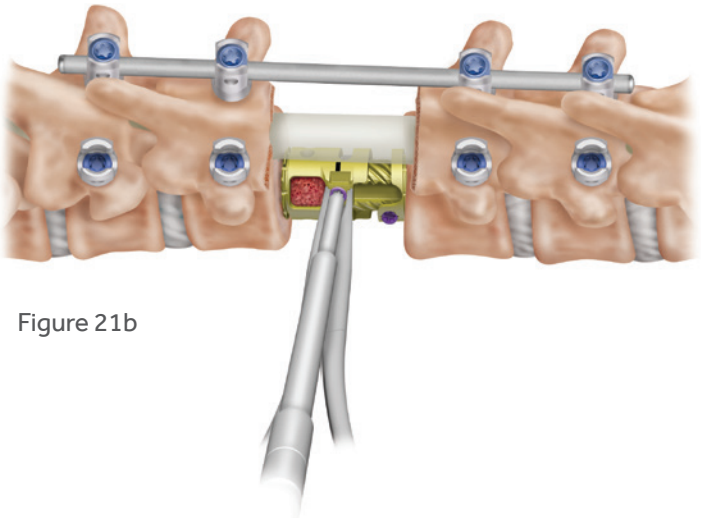


Figure 21b

Surgical Synergy
Spinal Workflow

APPENDIX

IMAGE ACQUISITION
FOR O-ARM 1000

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 (**Figure 22**).

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.

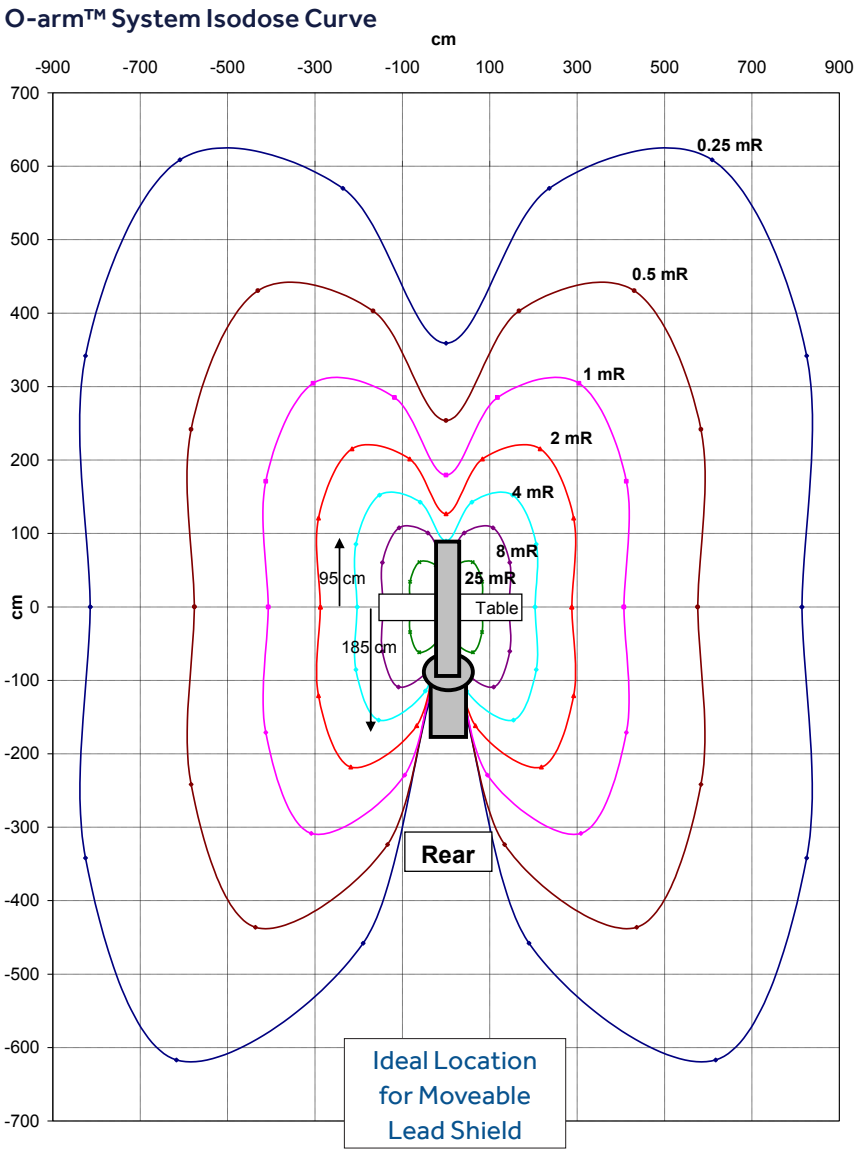


Figure 22

Scatter plot showing the shape of isodose curves for the maximum technique factors for the O-arm 1000.

- Protocol: Abdomen HD3D XL
- Technique: 120 kVp, 600 mAs

PRODUCT ORDERING INFORMATION

SPSXV300
T2 Stratosphere Expandable Corpectomy System 13mm Instrument & Implant Set

CFN	Description	QTY
436013A	13mm, A-size Centerpiece	1
436013B	13mm, B-size Centerpiece	1
436013C	13mm, C-size Centerpiece	1
436013D	13mm, D-size Centerpiece	1
436013E	13mm, E-size Centerpiece	1
4360160	End Cap 16mm, 0°	2
4360138	End Cap 13mm, 8°	2
4360168	End Cap 16mm, 8°	2
4360135	End Cap 13mm, 15°	2
4360165	End Cap 16mm, 15°	2
4360113	13mm Inserter	1
4361316	13mm/16mm Template	1
4360713	13mm Caliper	1
7975116	Loading Block	1
4360320	Implant Removal Tool	1
4360513	T10 Driver	2
SC335010-J	T10 Torque Limiting Handle	1
4360002	End Cap Removal Tool	1
9359003	Small Bone Tamp	1

SPSXV400
T2 Stratosphere Expandable Corpectomy System Extended Templates & Extended End Caps Set

CFN	Description	QTY
4360030	30mm Extended Template	1
4360035	35mm Extended Template	1
4360040	40mm Extended Template	1
4360045	45mm Extended Template	1
436020300	Extended End Cap 20 x 30mm, 0°	2
436020350	Extended End Cap 20 x 35mm, 0°	2
436020400	Extended End Cap 20 x 40mm, 0°	2
436020450	Extended End Cap 20 x 45mm, 0°	2
436025300	Extended End Cap 25 x 30mm, 0°	2
436025350	Extended End Cap 25 x 35mm, 0°	2
436025400	Extended End Cap 25 x 40mm, 0°	2
436025450	Extended End Cap 25 x 45mm, 0°	2

SPSXV350
T2 Stratosphere Expandable Corpectomy System 20/25mm Instrument & Implant Set

CFN	Description	QTY
436020A	20mm, A-size Centerpiece	1
436020B	20mm, B-size Centerpiece	1
436020C	20mm, C-size Centerpiece	1
436020D	20mm, D-size Centerpiece	1
436025A	25mm, A-size Centerpiece	1
436025B	25mm, B-size Centerpiece	1
436025C	25mm, C-size Centerpiece	1
436025D	25mm, D-size Centerpiece	1
4360220	End Cap 22mm, 0°	2
4360300	End Cap 30mm, 0°	2
4360208	End Cap 20mm, 8°	2
4360228	End Cap 22mm, 8°	2
4360258	End Cap 25mm, 8°	2
4360308	End Cap 30mm, 8°	2
4360120	20mm/25mm Inserter	1
4362025	20mm/25mm Template	1
4362230	22mm/30mm Template	1
4360221	20mm/25mm Angled Inserter	1
4360720	20mm/25mm Caliper	1
7975116	Loading Block	1
4360520	T17 Driver	2
SC230020-J	T17 Torque Limiting Handle	1
4360002	End Cap Removal Tool	1
4360320	Implant Removal Tool	1
9359904	Large Bone Tamp	1

SPSXV550
T2 Stratosphere Navigation Instruments

CFN	Description	QTY
NAV4360120	20mm/25mm Navigated Inserter	1
NAV4360113	13mm Navigated Inserter	1
NAV4360221	20mm/25mm Navigated Angled Inserter	1
NAV4361316	13mm Navigated Template	1
NAV4362022	20mm Navigated Template	1
NAV4362530	25mm Navigated Template	1
NAV4360030	30mm Navigated Extended Template	1

IMPORTANT INFORMATION ON THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM

PURPOSE

The T2 Stratosphere™ Expandable Corpectomy System is intended for vertebral body replacement to aid in the surgical correction and stabilization of the thoracolumbar and cervical spine.

DESCRIPTION

The T2 Stratosphere™ Expandable Corpectomy System is an adjustable vertebral body replacement device and features a self- adjusting end cap which provides continuous angulation between 0-8° in any direction to accommodate the patient's anatomical requirements. The T2 Stratosphere™ Expandable Corpectomy devices for use in the thoracolumbar and cervical spine are restricted to the 13mm diameter centerpieces. The T2 Stratosphere™ Expandable Corpectomy System is made of titanium alloy and is provided sterile and non-sterile. This device is inserted between two vertebral bodies in the thoracolumbar or cervical spine and is expanded to aid in the surgical correction and stabilization of the spine. The centerpieces are available in multiple heights. The system also features modular end caps which are available in various angles and diameters, and are only for use in the thoracolumbar spine. The device is not intended to be used as a stand-alone implant.

For Thoracolumbar Corpectomy with an Expandable Device

The device may be implanted through a lateral, oblique, or posterior approach using a minimally invasive technique or implanted through a lateral, oblique, posterior, or anterior approach through a traditional open technique. The device is indicated for single or two-level use in the thoracic and lumbar anterior spine.

The T2 Stratosphere™ Expandable Corpectomy System is intended to be used with supplemental fixation cleared for use in the thoracolumbar spine.

For Cervical Corpectomy with an Expandable Device

The device may be implanted through an anterior approach using a traditional open technique.

The T2 Stratosphere™ Expandable Corpectomy System is intended to be used with supplemental fixation cleared for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation.

Do not use implant components from any other manufacturer with T2 Stratosphere™ Expandable Corpectomy System components. Never use titanium or titanium alloy implants with stainless steel in the same construct. No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

INDICATIONS

The T2 Stratosphere™ Expandable Corpectomy System is a vertebral body replacement device intended for use in the thoracic and lumbar spine (T1-L5) and cervical spine (C2-C7). The T2 Stratosphere™ Expandable Corpectomy System is intended for use in skeletally mature patients.

When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System is used to replace a collapsed, damaged, or unstable vertebral body caused by tumor, trauma (i.e. fracture), or osteomyelitis, or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System may not be used with optional modular end caps. When used in the cervical spine at single or two levels, the T2 Stratosphere™ Expandable Corpectomy System is intended to be used with supplemental fixation for use in the cervical spine. When used at more than two levels, supplemental fixation should include posterior fixation cleared for use in the cervical spine.

When used in the thoracic and lumbar spine, the T2 Stratosphere™ Expandable Corpectomy System is used to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture). The T2 Stratosphere™ Expandable Corpectomy centerpiece may be used with or without optional modular end caps which accommodate individual anatomic requirements. The device is to be used with supplemental fixation cleared for use in the thoracic and lumbar spine.

When used in the cervical spine, the T2 Stratosphere™ Expandable Corpectomy System is intended for use with autograft or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft as an adjunct to fusion. When used in the thoracic and lumbar spine, the T2 Stratosphere™ Expandable Corpectomy System is intended for use with autograft or allograft as an adjunct to fusion. The T2 Stratosphere™ Expandable Corpectomy System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the cervical and/or thoracolumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

CONTRAINDICATIONS

- Any case needing to mix metals from different components.
- Any case not described in the indications.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any patient unwilling to cooperate with postoperative instructions.
- Any non-tumor cases where a bone graft and fusion are unnecessary or where fracture healing is not required.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.
- Fever or leukocytosis.
- Infection (excluding osteomyelitis in the cervical spine) local to the operative site and/or signs of local inflammation.
- Mental illness.
- Morbid obesity.
- Pregnancy.
- Suspected or documented metal allergy or intolerance.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.

Contraindications of this device are consistent with those of other spinal systems.

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.

POSSIBLE ADVERSE EVENTS

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

- Early or late loosening of the components and implant migration.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, and meningitis.
- Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instruments.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss, and/or spasms.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Bone loss or decrease in bone density possibly caused by stress shielding.
- Subsidence of the device into vertebral body(ies).
- Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
- Loss of spinal mobility or function.
- Inability to perform the activities of daily living.
- Non-union (or pseudarthrosis), delayed union, and mal-union.
- Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the bone graft, or at the bone graft harvest site at, above, and/or below the level of surgery.
- Graft donor site complications including pain, fracture, infection, or wound healing problems.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Ileus, gastritis, bowel obstruction, or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, cardiovascular system compromise, and wound necrosis or wound dehiscence.
- 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 anticipated adverse events

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. This system is not intended to be the sole means of spinal support. The T2 Stratosphere™ Expandable Corpectomy System must be used with additional anterior or posterior instrumentation to augment stability. Use of this product without a bone graft may 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 the device(s) could eventually occur.

Preoperative and operating procedures including knowledge of surgical techniques, proper selection and placement of the implant, and good reduction are important considerations in the success of surgery. Installation and positional adjustment of implants must only be done with special equipment and instruments specific to these devices. They must not be used with other instrumentation unless specifically recommended by Medtronic because the combination with other instrumentation may be incompatible and may not be guaranteed.

A device that has been implanted should never be reprocessed or reused under any circumstances. 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.

Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion.

IMPORTANT INFORMATION ON THE T2 STRATOSPHERE™ EXPANDABLE CORPECTOMY SYSTEM

PURPOSE

The T2 Stratosphere™ Expandable Corpectomy System is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine for tumor and trauma pathologies. This system is indicated for single and two-level use in the thoracic and lumbar anterior spine.

DESCRIPTION

The T2 Stratosphere™ Expandable Corpectomy System is an adjustable vertebral body replacement device and features a self- adjusting end cap which provides continuous angulation between 0-8° in any direction to accommodate the patient's anatomical requirements.

This device is inserted between two vertebral bodies in the thoracic and lumbar spine and is expanded to aid in the surgical correction and stabilization of the spine. The device may be implanted through a lateral, oblique, or posterior approach using a minimally invasive technique or implanted through a lateral, oblique, posterior, or anterior approach through a traditional open technique.

The T2 Stratosphere™ Expandable Corpectomy System is intended to be used with supplemental fixation cleared for use in the thoracolumbar spine. The device is not intended to be used as a stand-alone implant.

The T2 Stratosphere™ Expandable Corpectomy System is made of titanium alloy and is provided sterile and non-sterile. The centerpieces are available in multiple diameters and heights. The system also features modular end caps which are available in various angles and geometries.

Do not use implant components from any other manufacturer with T2 Stratosphere™ Expandable Corpectomy System components. Never use titanium or titanium alloy implants with stainless steel in the same construct.

No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

INDICATIONS

The T2 Stratosphere™ Expandable Corpectomy System is a vertebral body replacement device intended for use in the thoracic and lumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture).

The T2 Stratosphere™ Expandable Centerpiece may be used with or without optional modular end caps which accommodate individual anatomic requirements. The device is to be used with supplemental fixation cleared for use in the thoracic and lumbar spine.

The T2 Stratosphere™ Expandable Corpectomy System is intended for use with autograft or allograft, as an adjunct to fusion. The T2 Stratosphere™ Expandable Corpectomy System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with bone graft used at the surgeon's discretion.

CONTRAINDICATIONS

The T2 Stratosphere™ Expandable Corpectomy System is not intended for cervical surgical implantation. Contraindications include:

- Any case needing to mix metals from different components.
- Any case not described in the indications.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any patient unwilling to cooperate with postoperative instructions.
- Any case not needing a bone graft and fusion or where fracture healing is not required.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.
- Signs of local inflammation.
- Fever or leukocytosis.
- Infection local to the operative site and/or signs of local inflammation.
- Mental illness.
- Morbid obesity.
- Pregnancy.
- Suspected or documented metal allergy or intolerance.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.

Contraindications of this device are consistent with those of other spinal systems.

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.

POSSIBLE ADVERSE EVENTS

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

- Early or late loosening of the components and implant migration.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to the implants, debris, corrosion products, including metallosis, staining, tumor formation and/or autoimmune disease.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, and meningitis.
- Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instruments.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, tingling sensation, sensory loss, and/or spasms.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, arachnoiditis, and/or muscle loss.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Bone loss or decrease in bone density possibly caused by stress shielding.
- Subsidence of the device into vertebral body(ies).
- Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
- Loss of spinal mobility or function.

- Inability to perform the activities of daily living.
- Non-union (or pseudarthrosis), delayed union, and mal-union.
- Fracture, microfracture, resorption, damage, penetration, and/or retropulsion of any spinal bone, of the bone graft, or at the bone graft harvest site at, above, and/or below the level of surgery.
- Graft donor site complications including pain, fracture, infection, or wound healing problems.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Ileus, gastritis, bowel obstruction, or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, embolism, stroke, excessive bleeding, phlebitis, damage to blood vessels, cardiovascular system compromise, and wound necrosis or wound dehiscence.
- 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 anticipated adverse events

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the results. This system is not intended to be the sole means of spinal support. The T2 Stratosphere™ Expandable Corpectomy System must be used with additional anterior or posterior instrumentation to augment stability. Use of this product without a bone graft may 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 the device(s) could eventually occur.

Preoperative and operating procedures including knowledge of surgical techniques, proper selection and placement of the implant, and good reduction are important considerations in the success of surgery. Installation and positional adjustment of implants must only be done with special equipment and instruments specific to these devices. They must not be used with other instrumentation unless specifically recommended by Medtronic because the combination with other instrumentation may be incompatible and may not be guaranteed.

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.

Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion.

NOTES

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(800) 268-5346

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.

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

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