SURGICAL SYNERGY SPINAL WORKFLOW

Image
Navigate
Confirm

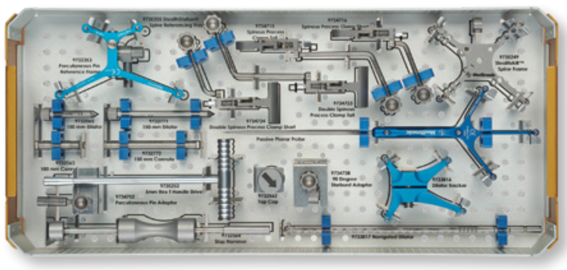
SURGICAL TECHNIQUE

SynergyCorpectomy℠ Lateral Approach Procedure with StealthStation™ Navigation and O-arm™ Imaging

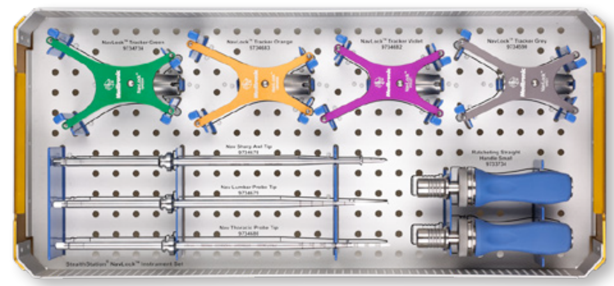
T2 Stratosphere™ Expandable Corpectomy System

Medtronic
Further, Together

MICHELSON TECHNOLOGY AT WORK



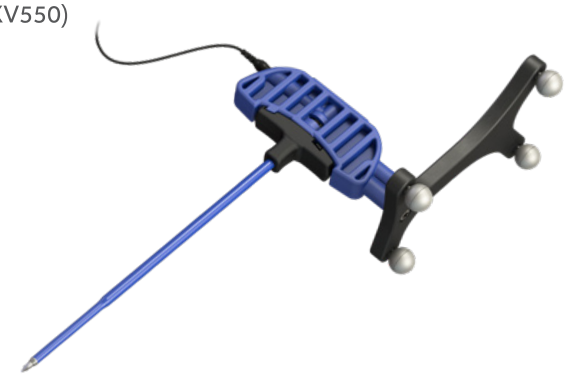
StealthStation Spine Referencing Set
(9735500)



StealthStation NavLock™ Instrument Set
(9734833)

Navigated T2 Stratosphere Instrument Set
(SPSXV550)

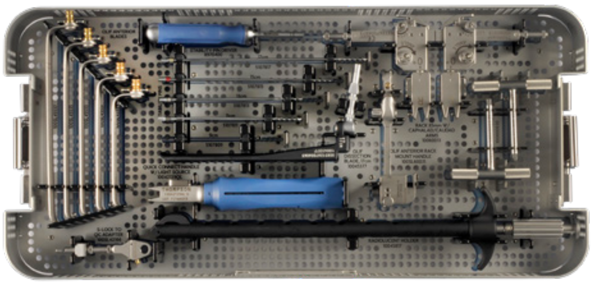
O-arm Sterile Tube
Drape (*optional*)
(9732722)



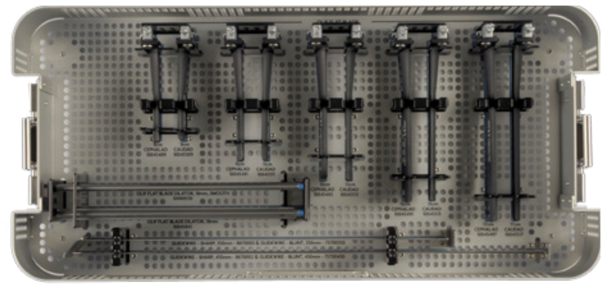
Navigated NIM PAK Needle
(9733498)

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

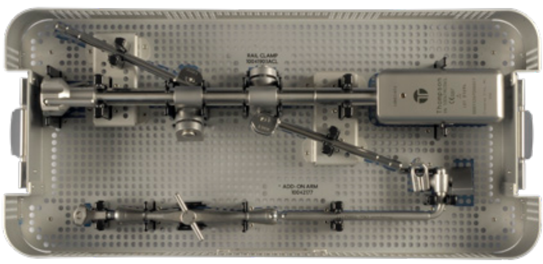
Spheres
(8801074)



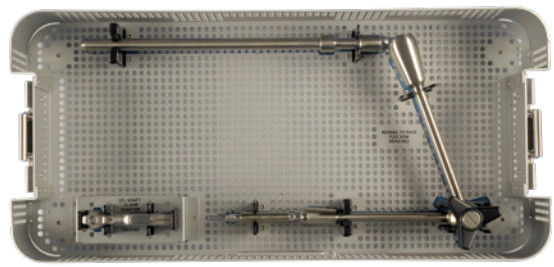
OLIF25 Access- R Core Set



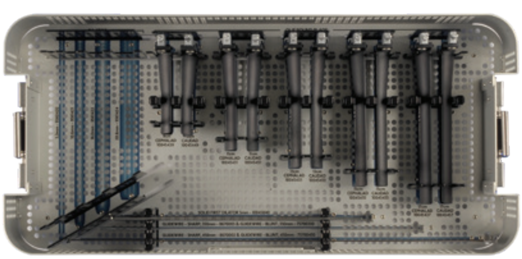
OLIF25 Access- R Flat Blades Set



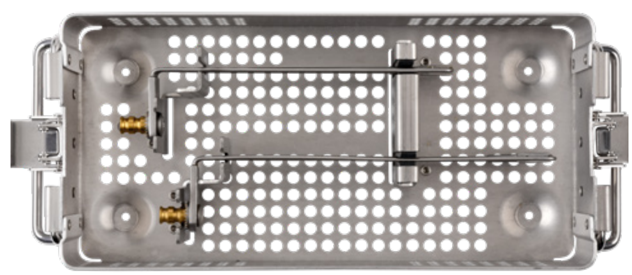
OLIF Table Mount + Articulating Arm Set
(SPSOL552)



Flex Arm Set



OLIF25 Access- R Round Blades Set
(SPSXV600)



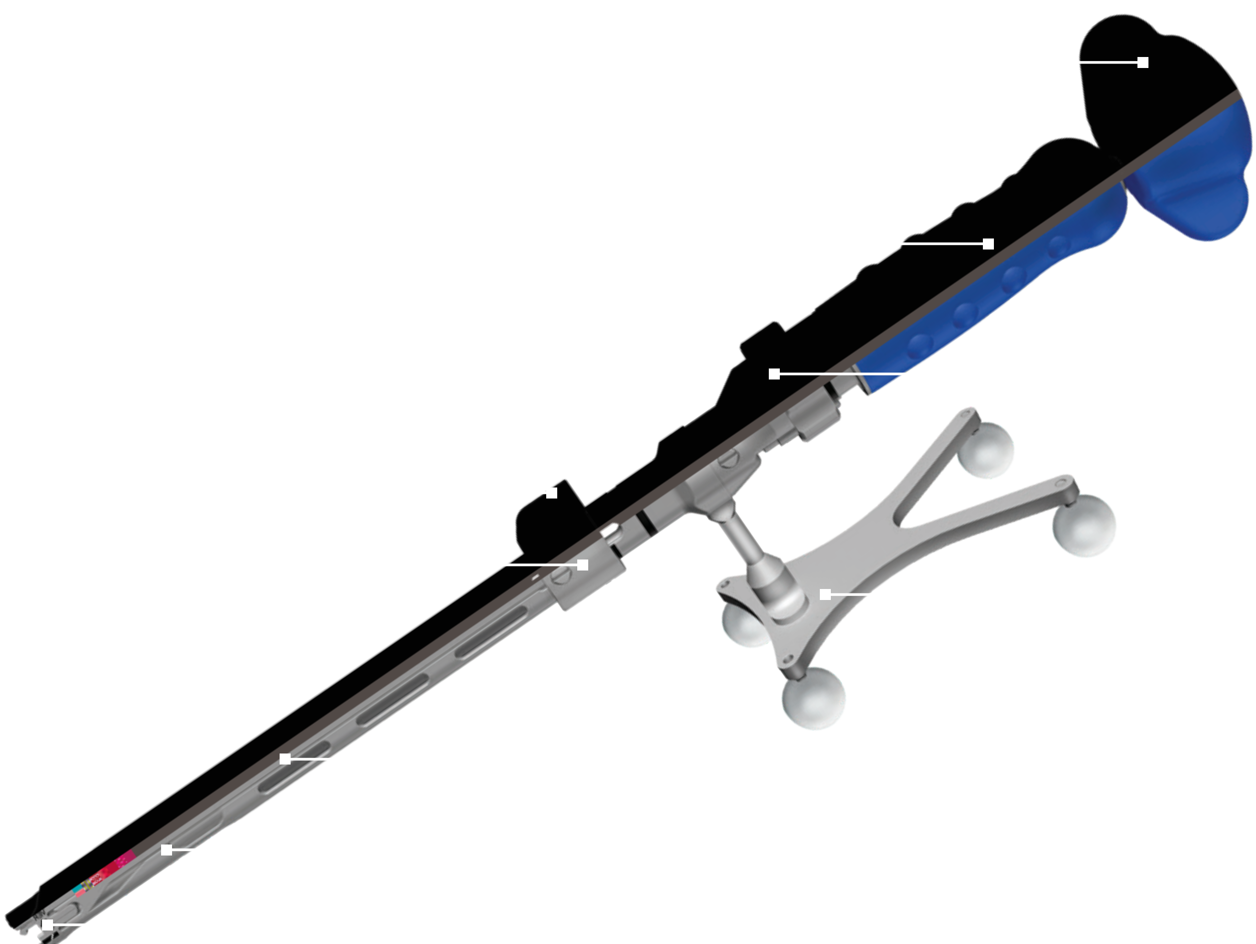
Thompson Lung Blades Set

INSERTER
FEATURES

Navigated Straight Inserter
13mm, NAV4360113

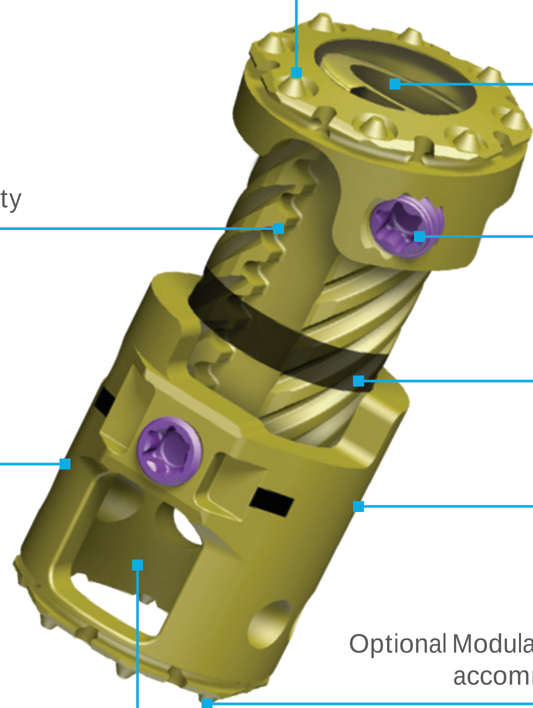
Navigated Straight Inserter
20/25mm, NAV4360120

Navigated Angled Inserter
20/25mm, NAV4360221
FOR POSTERIOR APPROACH ONLY



5

T2 STRATOSPHERE
IMPLANTS

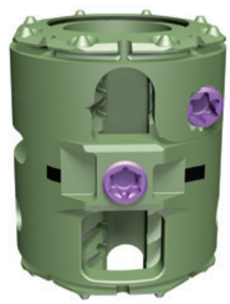


Fifteen Centerpiece Options

CENTERPIECE DIAMETER COMPARISON

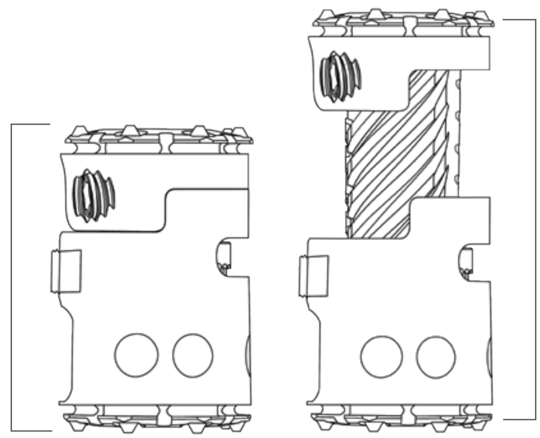
Ø13mm Centerpiece

Ø20mm Centerpiece

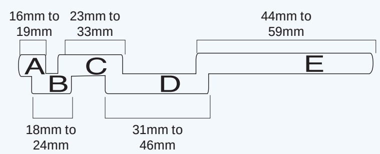


Ø25mm Centerpiece

CENTERPIECE HEIGHT COMPARISON

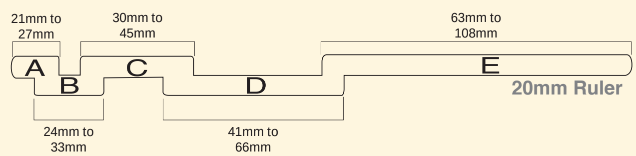


CENTERPIECE IMPLANT SELECTION



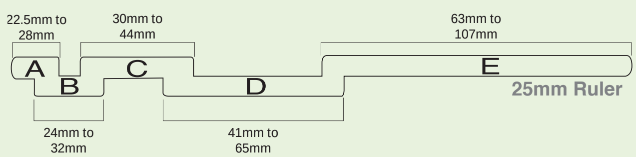
13mm Ruler

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****



20mm Ruler

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



25mm Ruler

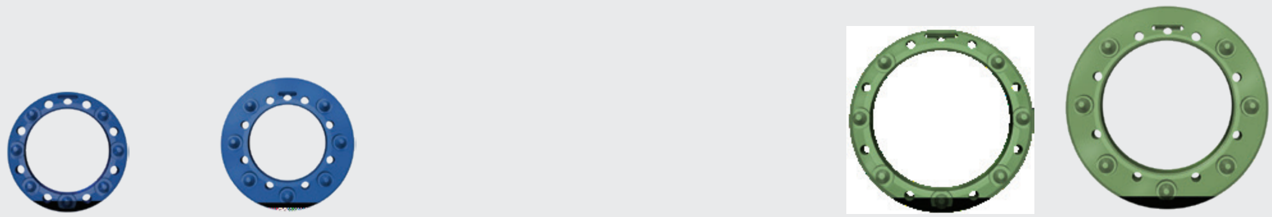
Size	Diameter (mm)	Collapsed Height (mm)*	Expanded Height (mm)**	End Cap Compatibility
25A	25	22.5	28	25mm & 30mm & 25mm Extended
25B	25	24	32	25mm & 30mm & 25mm Extended
25C	25	30	44	25mm & 30mm & 25mm Extended
25D	25	41	65	25mm & 30mm & 25mm Extended
25E***	25	63	107	25mm & 30mm & 25mm Extended

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

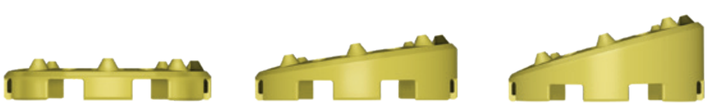
Twenty-Three Modular End Cap Options

END CAP DIAMETER COMPARISON



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

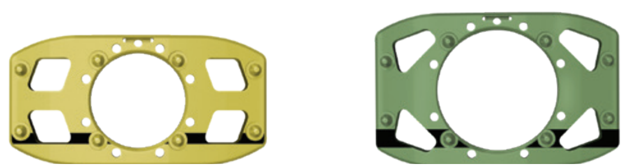
END CAP ANGLE COMPARISON



0 degrees* 8 degrees 15 degrees

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

EXTENDED END CAP WIDTH COMPARISON



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 is 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 Lateral 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.

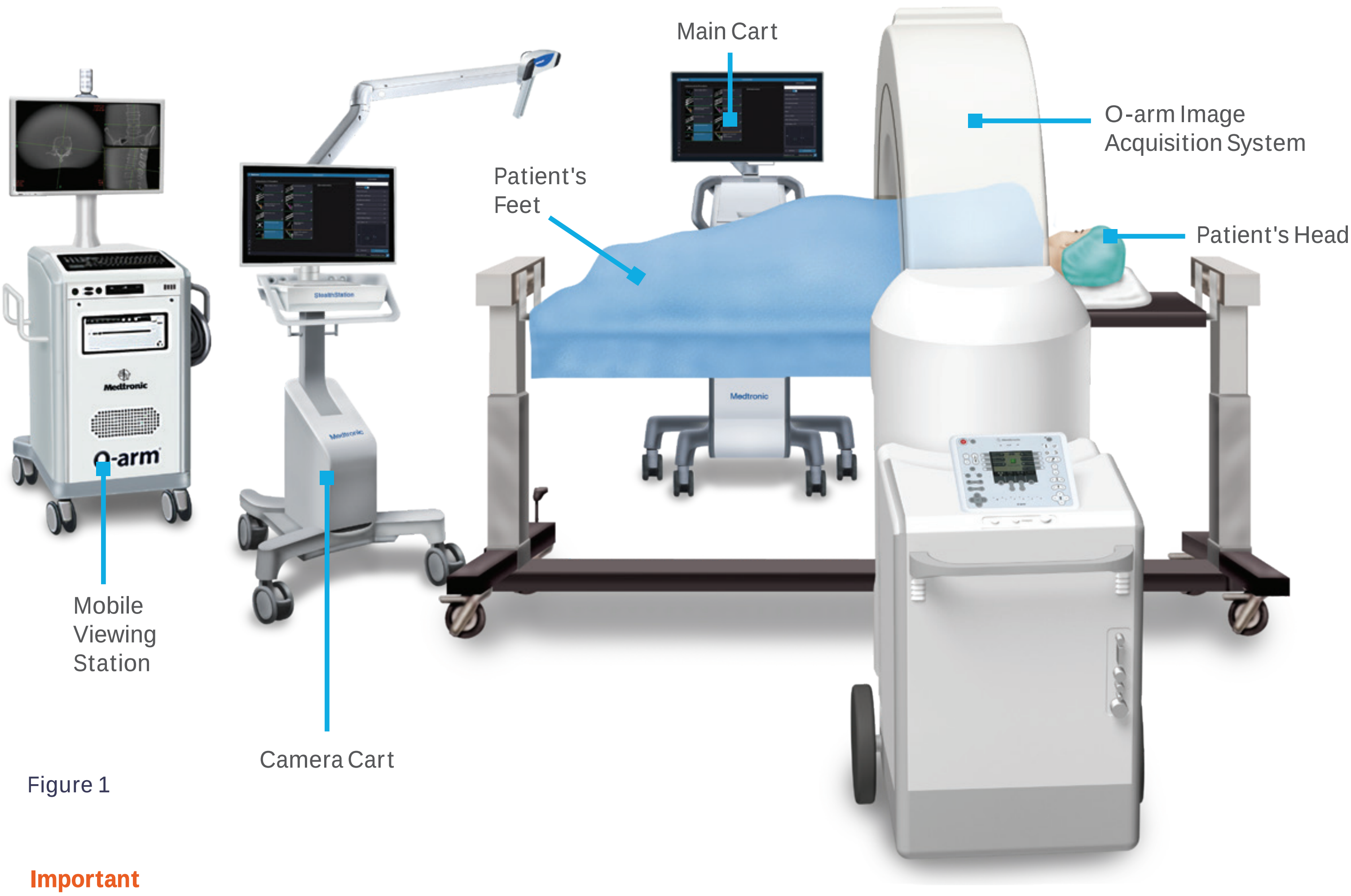


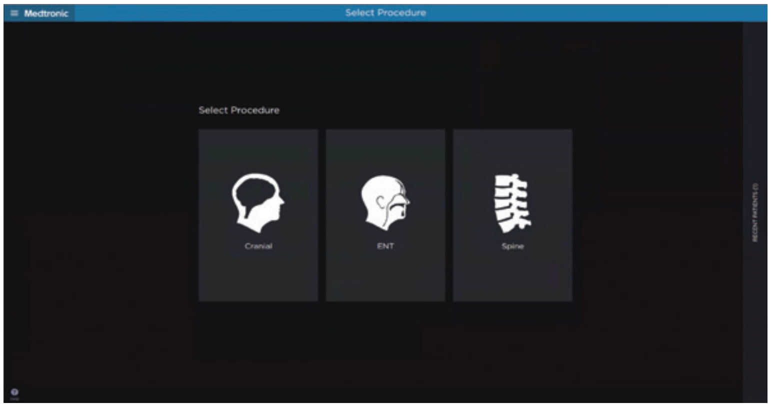
Figure 1

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.

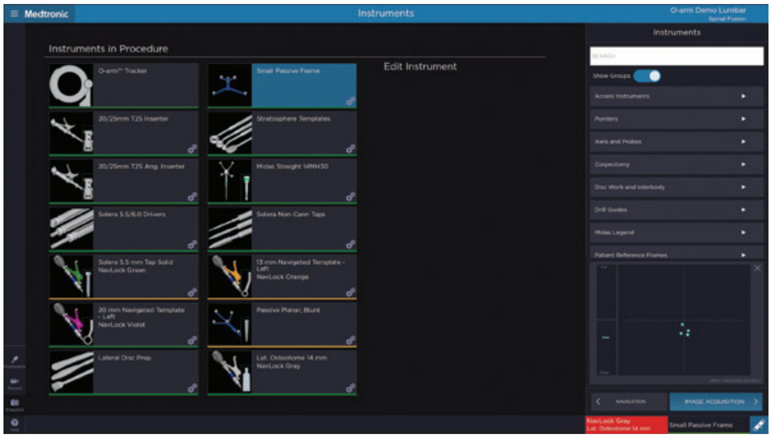
If doing a Navigated Lateral Corpectomy with full vertebral body removal it is recommended to place posterior screws and rods prior to removing the vertebral body to mitigate possible anatomical shift.

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.

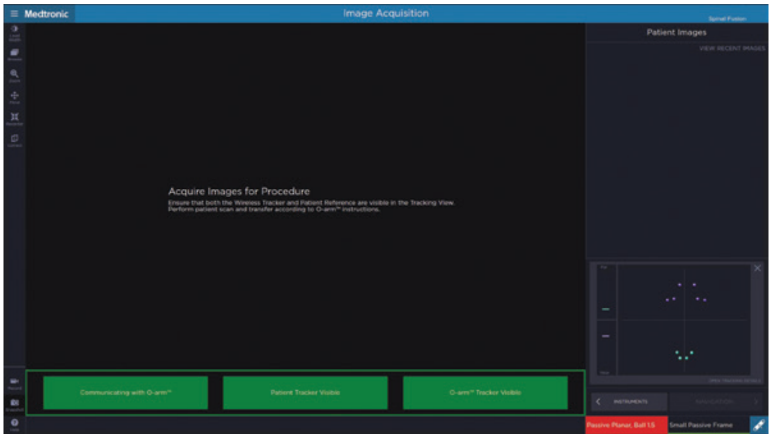
StealthStation Spine Software Workflow



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 LATERAL APPROACH
PROCEDURAL WORKFLOW

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

VERIFY INSTRUMENTS	▪ NavLock™ Trackers ▪ Direct Lateral Dilator with MAST Dilator Tracker ▪ Passive Planar Probe ▪ Stealth-Midas™ Drill ▪ Navigated Inserter
PATIENT POSITIONING	▪ Position patient in the right lateral decubitus, or left-side-up position ▪ Position camera at the foot of the bed
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
SITE ACCESS	▪ Determine access point ▪ Mark skin ▪ Make skin incision ▪ Place lateral access system
VERTEBRAL BODY AND DISC REMOVAL	▪ Remove vertebral body using Navigated Lateral Disc Prep instruments and Stealth-Midas Drill ▪ Remove discs using Navigated Lateral 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
ACQUIRE 3D CONFIRMATION IMAGE	▪ Assess implant placement

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.

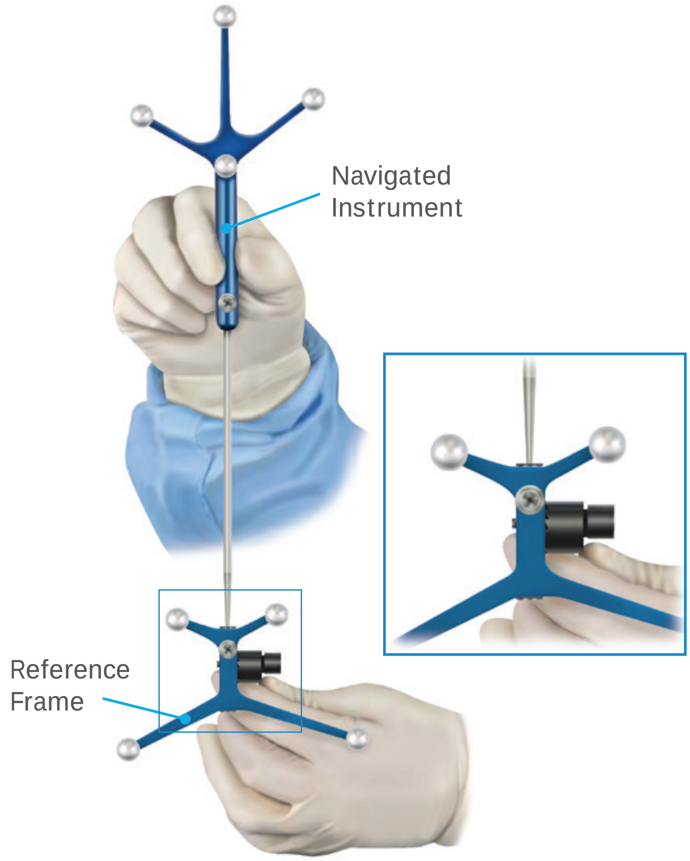
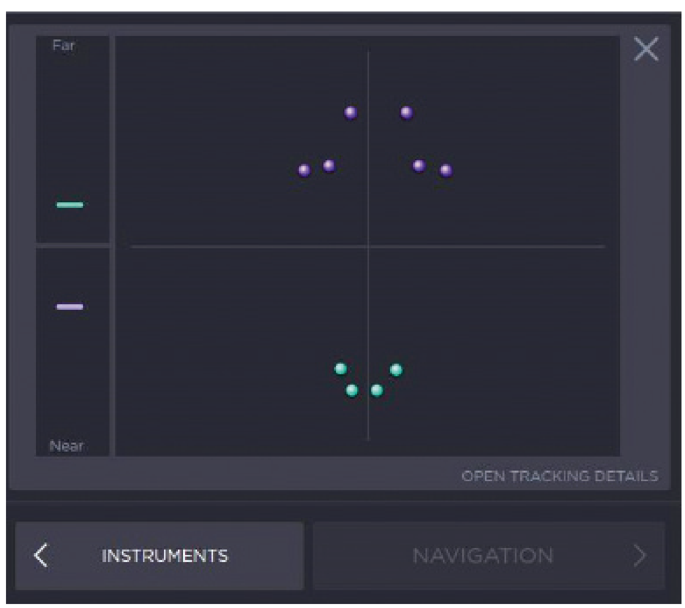


Figure 2a

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
Navigated Anterolateral Disc Preparation instruments are verified with default instruments and not the actual tip.



StealthStation
System Software

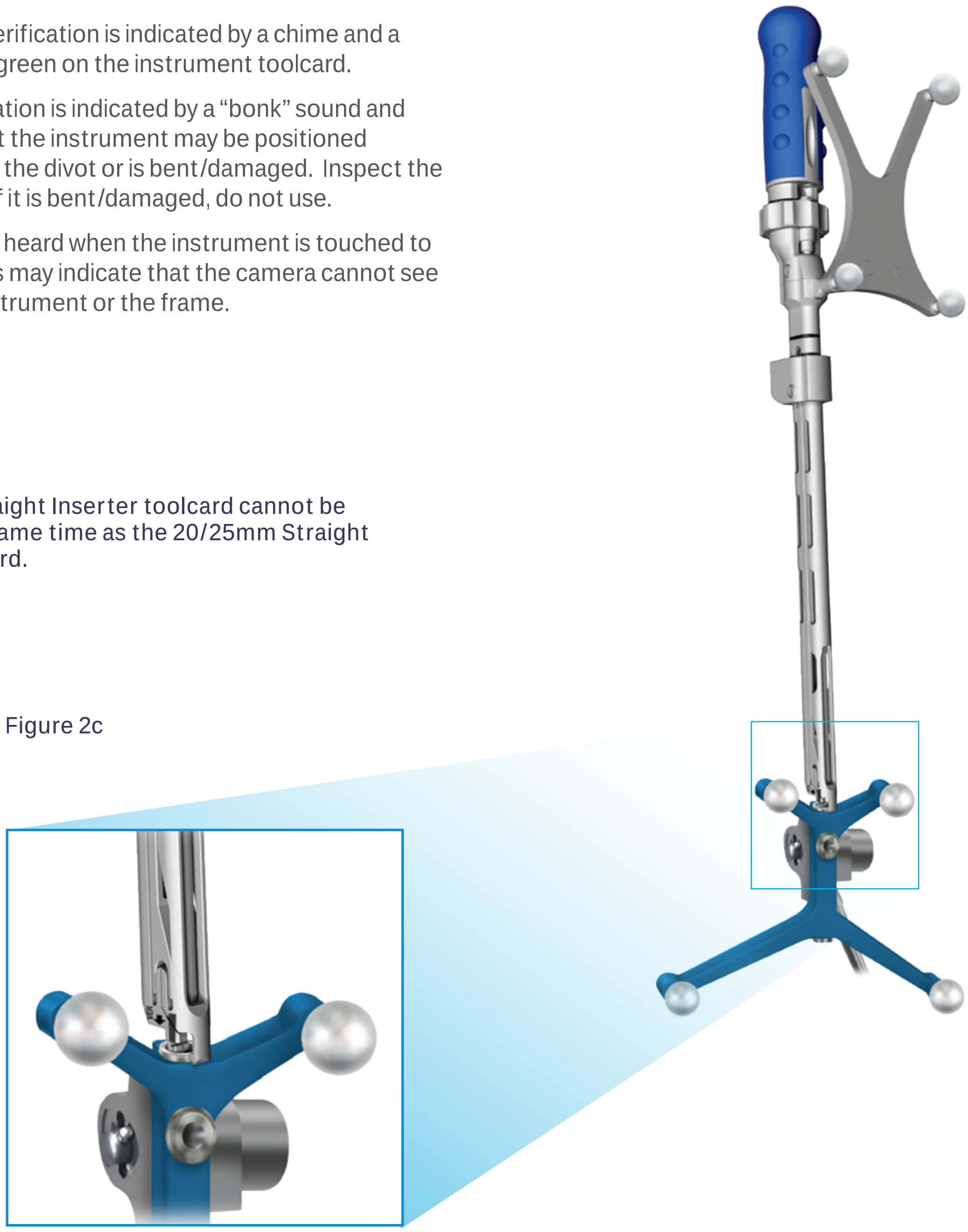
Figure 2b

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 toolcard.

Figure 2c



Surgical Synergy
Spinal Workflow

PATIENT **POSITIONING**

PATIENT POSITIONING

Right lateral decubitus, or left side up, is the preferred position for an oblique or lateral approach based on vasculature positioning. However, the surgeon should consider ease of access, surgeon preference, and the preoperative images in determining which side to approach. Use of a radiolucent Jackson Spine flat table top is recommended. Breaking the surgical table is not required for this procedure. Bend the patient's arm at the elbow if the O-arm System will remain parked during the procedure (Figure 3).

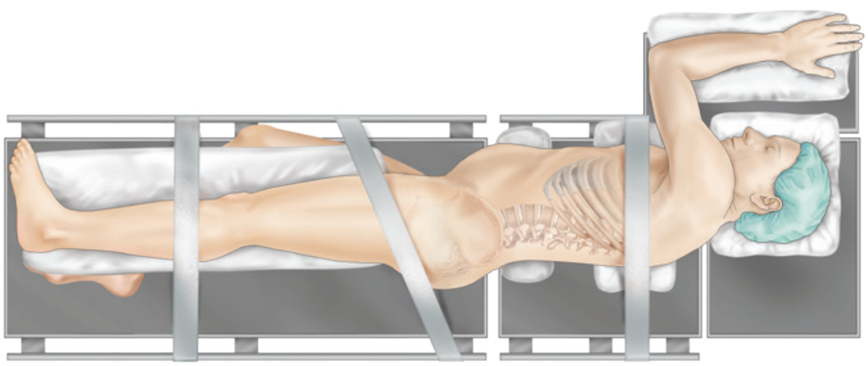


Figure 3

REFERENCE FRAME PLACEMENT

When performing a SynergyCorpectomy Lateral 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. 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.

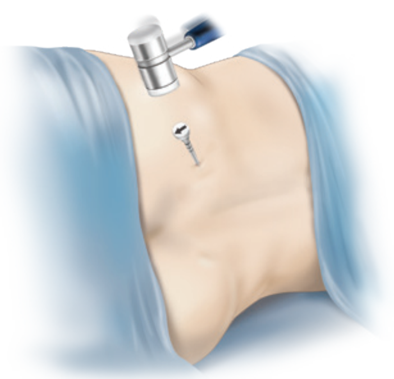


Figure 4a

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 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 4a). Remove the Tap Cap from the pin and attach the Percutaneous Reference Frame to the pin (Figure 4b).

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 4b

Important
If using a Spinous Process Clamp reference frame for lateral procedures, be aware of line-of-sight between the navigation camera and the reference frame.

Ensure there is a clear camera view of the reference frame and that no obstructions will contact the reference frame position. Any movement of the reference frame will affect navigation accuracy. Continue to check accuracy throughout the procedure by using the probe to touch on a known anatomical landmark such as a spinous process or vertebral endplate.

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 5).

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

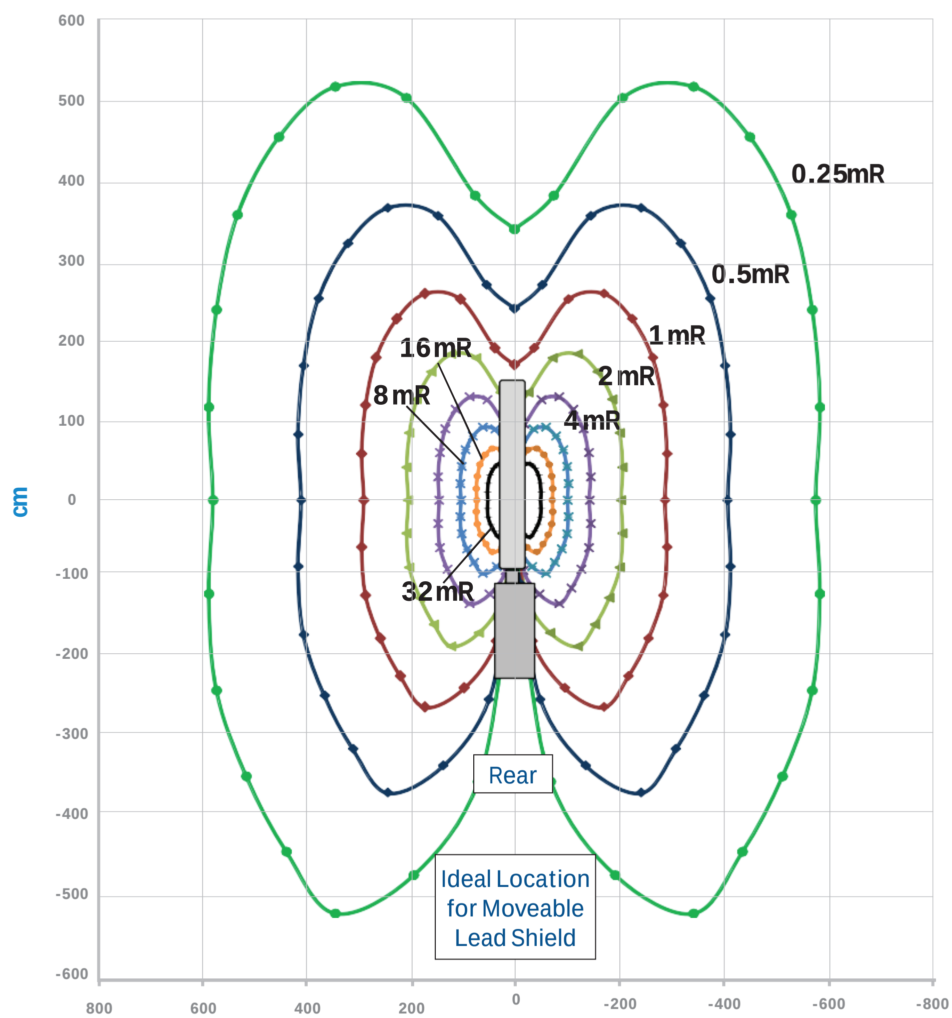


Figure 5

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

Surgical Synergy
Spinal Workflow

PROCEDURE
STEPS

LOCALIZATION

Use the narrow Passive Planar Ball-tipped Probe to locate the collapsed, damaged, or unstable vertebral body or bodies (Figure 6a). Mark the skin incision location. A projection can be helpful to locate the trajectory to the disc space. Under "Select Projection" on the StealthStation System, add a tip extension to the tip of the instrument (Figure 6b). The projection may be lengthened as needed to accommodate patient size.

After patient positioning, attach the Table Mount being sure to position it behind the patient's shoulder (Figure 6c). The Flex Arm will then need to be secured into place by attaching it to the Table Mount (Figure 6d).

Figure 6a

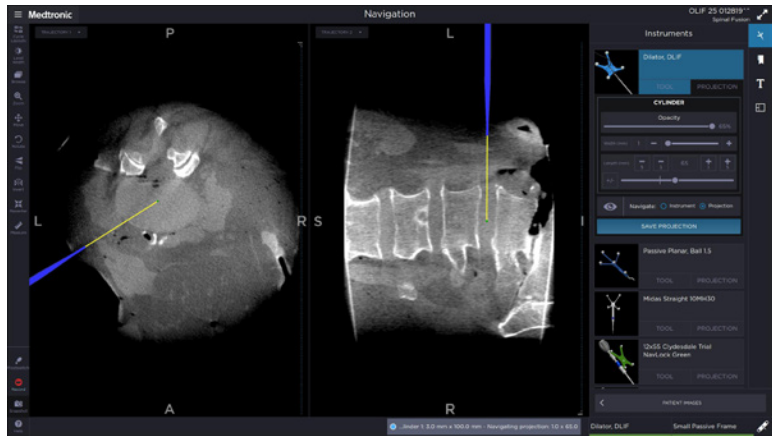


Figure 6b

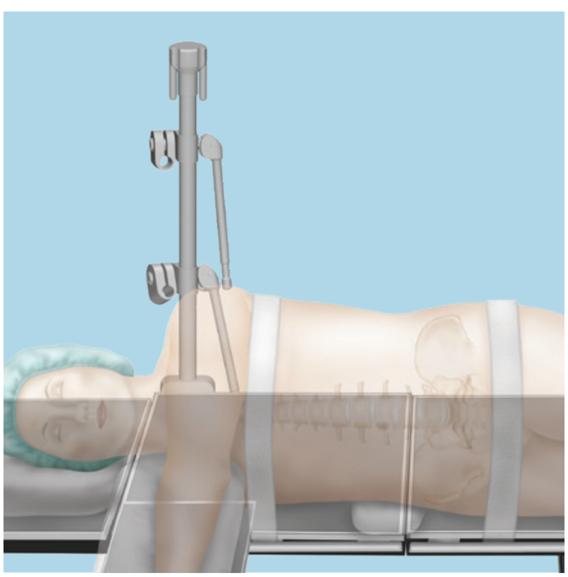


Figure 6c

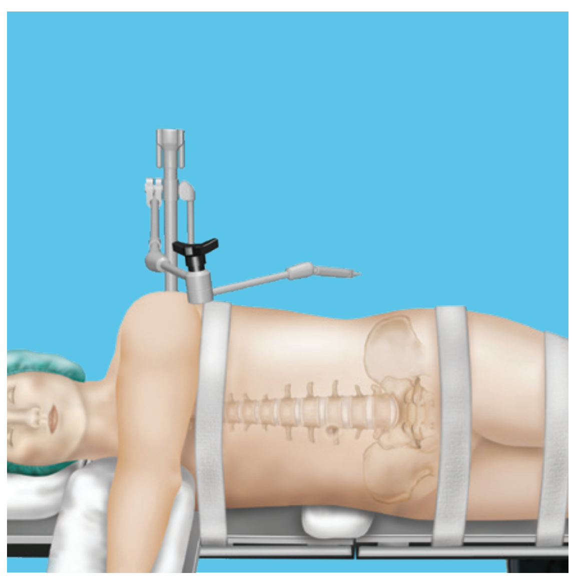


Figure 6d

CORPECTOMY
SITE ACCESS

After making a single skin incision, dissect down to the vertebral body in the standard fashion. Use the Direct Lateral Dilator/MAST Dilator to visualize where the retractor will be positioned on the spine (Figure 7).

Note
At any point during the procedure, navigation accuracy can be evaluated by using the first Direct Lateral Dilator/MAST™ Dilator Tracker on known bony landmarks.

Figure 7

RETRACTOR PLACEMENT

Use the graduated markings on the Dilator and select the appropriate Retractor Blades. Attach the blades to the OLIF25 Retractor base and attach the Shaft Clamp Adaptor to one side of the rack. Place the retractor assembly into the access site (Figures 8a and 8b). The retractor should be advanced with gentle downward pressure docking on the vertebral body. The Dilator can be used to help guide the retractor to the bone. The retractor assembly is then attached to the Flex Arm using the Quick Connect to Shaft Clamp Adaptor to provisionally maintain retractor position.

It is important to align the Retractor Blades so that the opening between them is parallel to the vertebral endplates.

Figure 8a

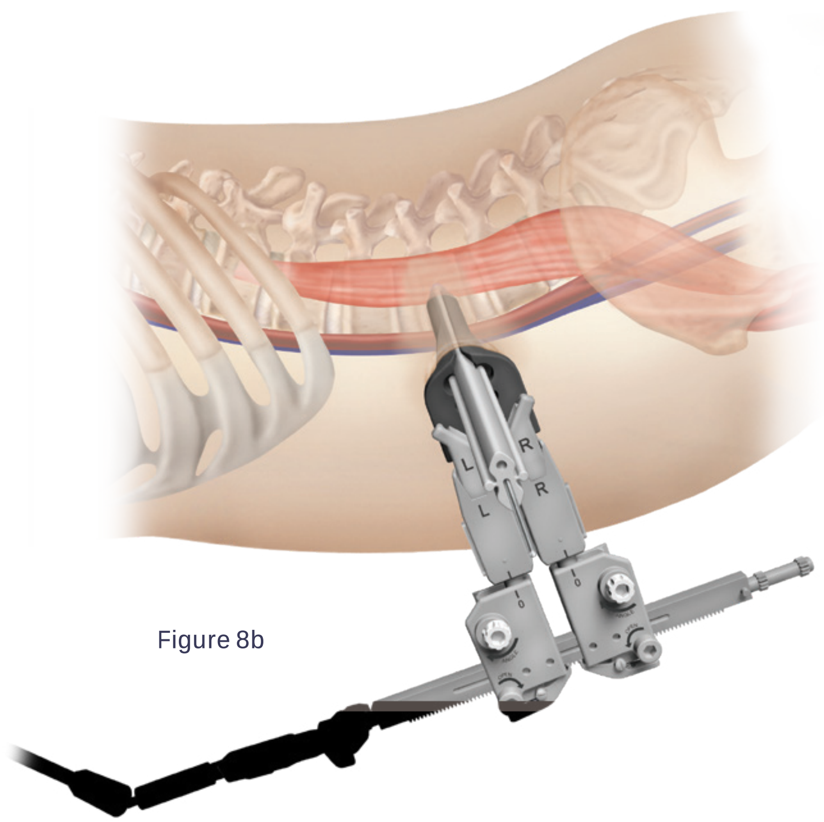


Figure 8b

TEMPLATE MEASURE
IMPLANT FOOTPRINT

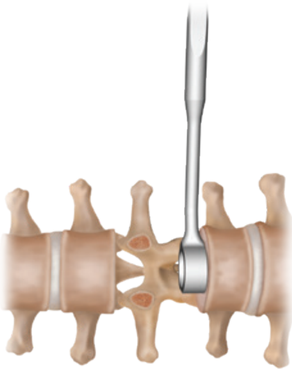


Figure 11a

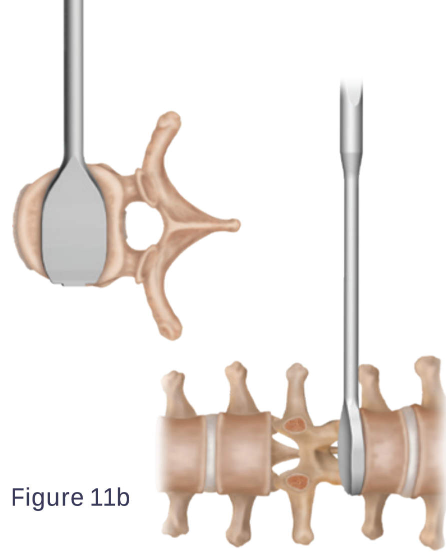


Figure 11b

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. There is also a 30mm Extended Template for the lateral approach. 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 Sagittal view. Updating Trajectory 1 to Interbody views can help visualize the endplate on which the template is docked (Figure 11c).

Place the Template on the endplate and confirm that the footprint size is correct for the defect (Figures 11a and 11b). 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. If the Extended 30mm Template is used, insert the distal tip of the instrument into the defect. The 30mm template is 20mm wide, 25mm width can be projected by selecting the width toggle on the "Tool" tab. To modify the length projections, select the length drop down on the "Tool" tab. The length will be projected proximally (Figure 11d). The extended Template projected lengths are available in 30mm, 35mm, 40mm, and 45mm. 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.

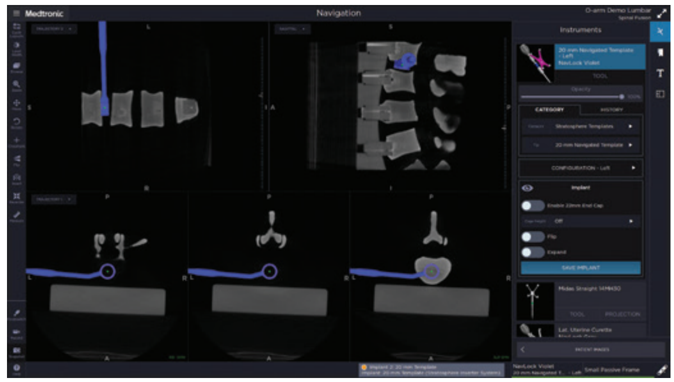


Figure 11c

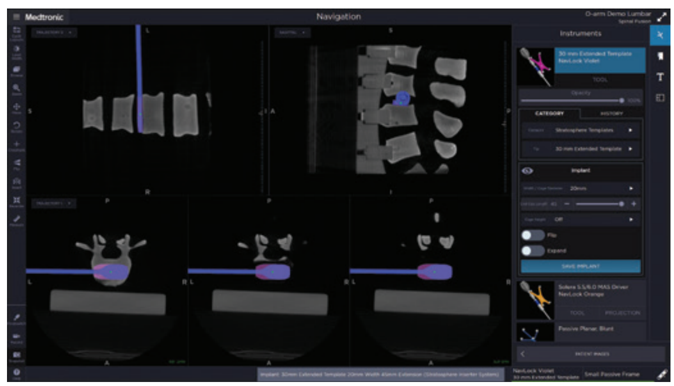


Figure 11d

Optional Planning Step

For planning purposes, the Template footprint can be saved (Figure 11e). 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 and Extended Template will require the addition of 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 11e

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 projection 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 12a). 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 12b).

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. The height projection for the Extended Template includes the addition of two Extended End Caps on the Centerpiece.

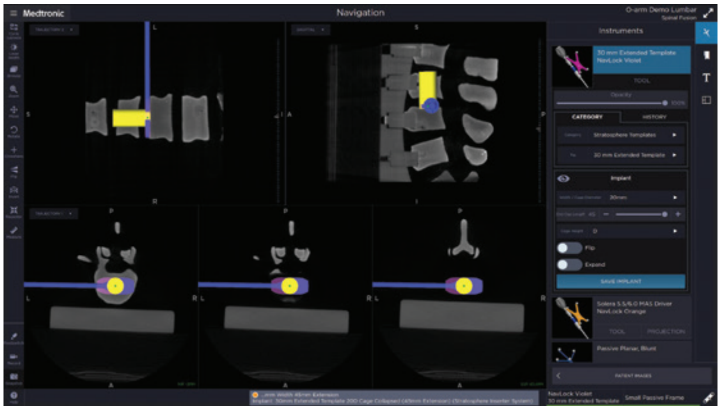


Figure 12a

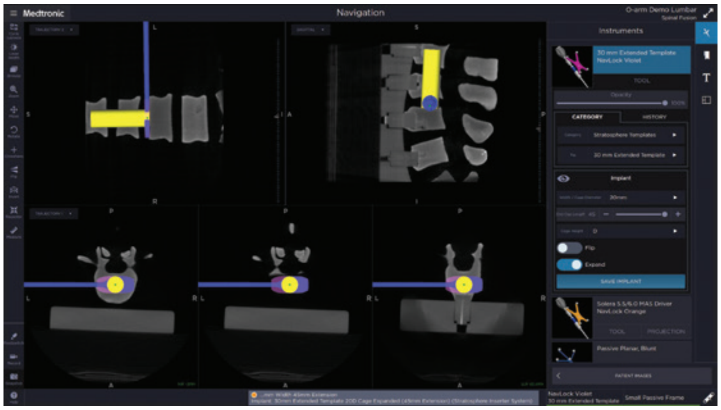


Figure 12b

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 13a). 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 13b). Rotate the End Cap down onto the Centerpiece and press on the top side of the End Cap to snap together (Figure 13c). 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 13d). Once an End Cap has been removed from an implant, the End Cap should not be re-used.

Note

For the A-Size Centerpieces 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.

Important

The Extended End Caps must be in line with the height set screw.

Figure 13a

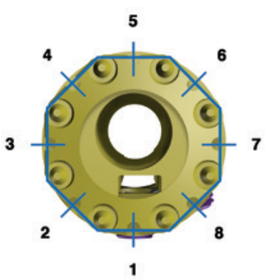
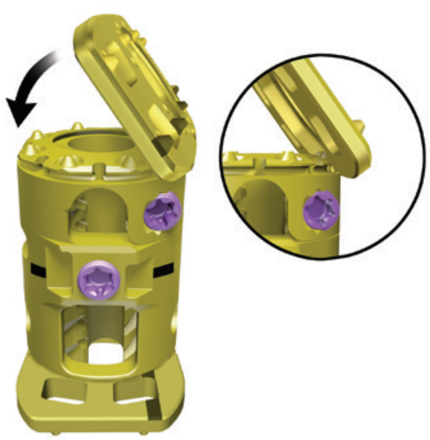


Figure 13b



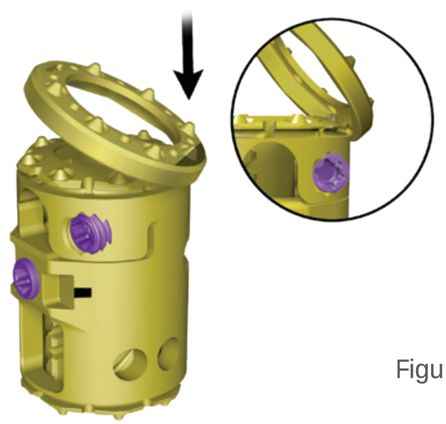
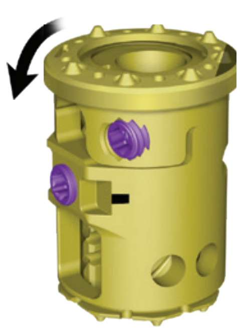


Figure 13d

Figure 13c



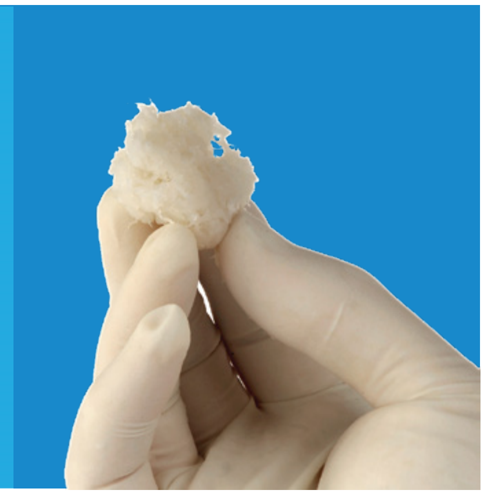
GRAFT
PRE-PACKING

Once you have assembled the implant, pre-pack the Centerpiece with autograft or allograft material using a Bone Tamp (Figures 14a and 14b). Medtronic offers a number of allograft options that can be used with the T2 Stratosphere Expandable Corpectomy System including Grafton™ Demineralized Bone Matrix (DBM).

Important
When packing bone graft, ensure that graft does not come in contact with the expansion ring area (**Figure 14c**). Do not over pack the implant with graft.

Thoracolumbar Allograft Options

Grafton™ Demineralized Bone Matrix (DBM)



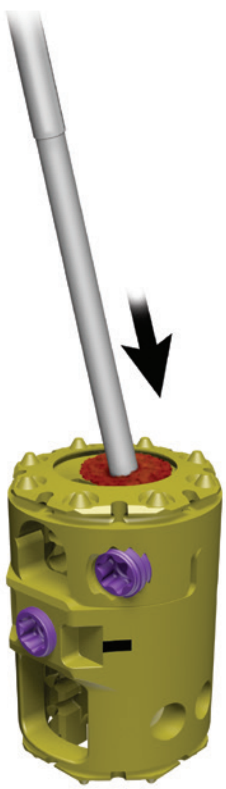


Figure 14a

Figure 14b

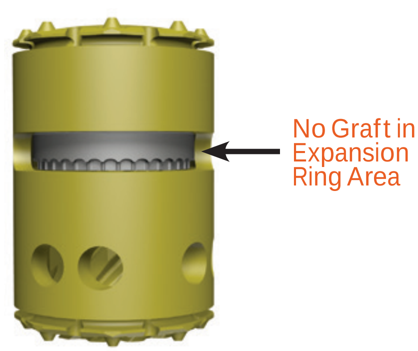


Figure 14c

IMPLANTATION

Choose the appropriate Navigated Inserter that correlates with the implant. Use the 13mm Navigated Inserter for the 13mm Centerpieces and the 20mm/25mm Navigated Straight Inserter for the 20mm or 25mm Centerpieces.

First, hold the Inserter so the gold button is facing up. Slightly pull back or remove the blue T-handle from the Inserter (Figure 15a). Pull back on the locking ring (Figure 15b). Press the gold slider button on the Inserter and pull the slider back past the black unlock laser mark and hold (Figures 15c and 15d). Hold the implant so the Self-Adjusting Multi-Axial End Cap faces the gold button on the Inserter (Figure 15e).

Important
Confirm that the Centerpiece height expands and collapses smoothly, before attachment to the inserter. Confirm that the End Cap is unlocked and that it freely rotates. If locked, use the Driver to unlock the set screws until resistance is felt. Do not fully remove the set screws.

Figure 15a

Figure 15b

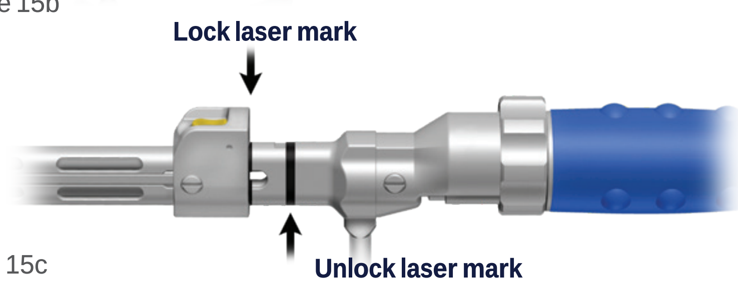


Figure 15c

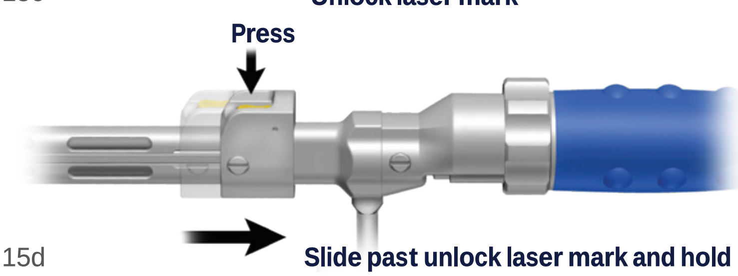


Figure 15d

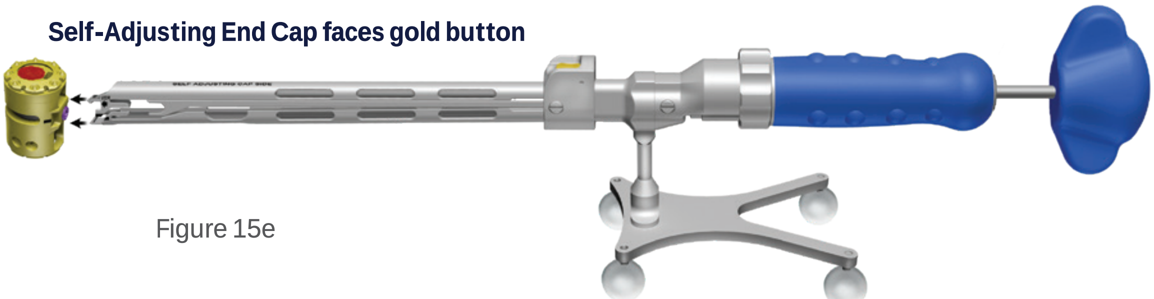


Figure 15e

Align the prongs on the Inserter with the slots on the implant above and below the set screw (Figure 16a). Push the implant onto the prongs of the Inserter (Figure 16b). 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 16c). Push the locking ring forward so that the black locking ring laser mark is visible (Figure 16d). Push the blue T-handle in and the implant is now connected to the Inserter (Figures 16e, 16f, and 16g). Turn the blue T-handle clockwise and counterclockwise to ensure the implant expands and collapses smoothly.

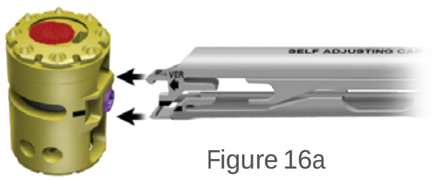
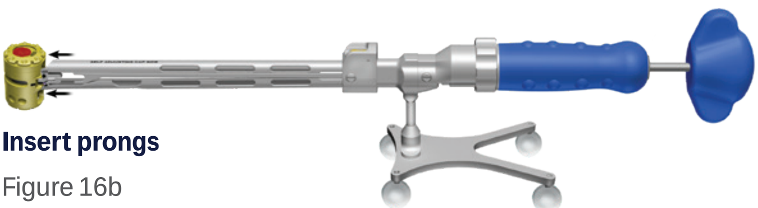


Figure 16a



Insert prongs

Figure 16b

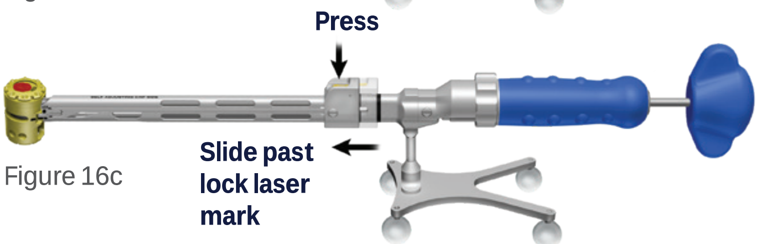


Figure 16c

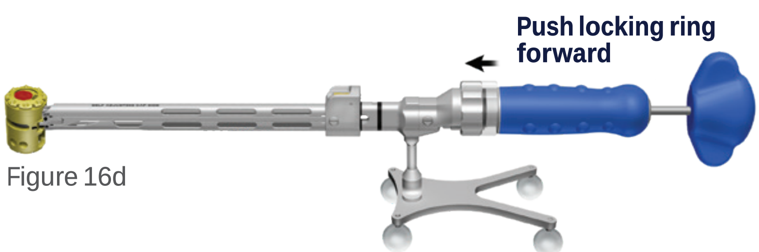
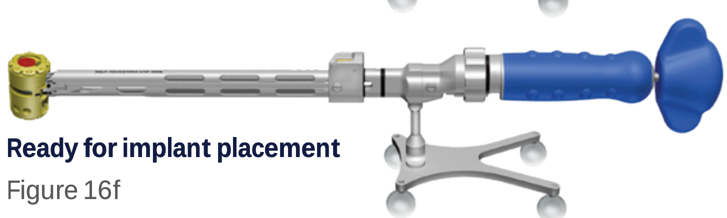


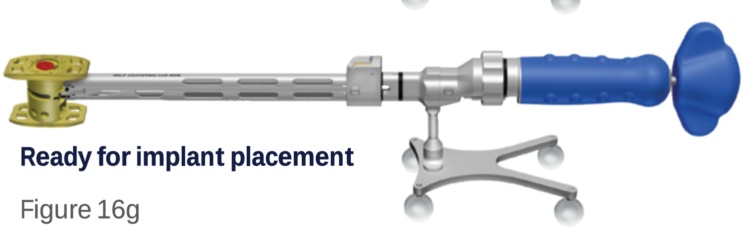
Figure 16d

Figure 16e



Ready for implant placement

Figure 16f

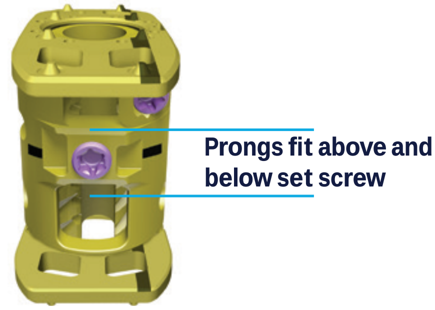


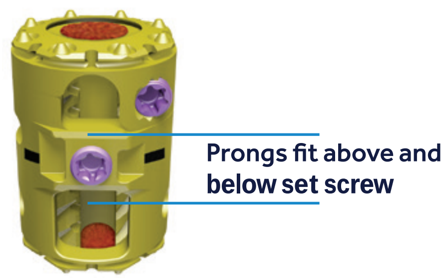
Ready for implant placement

Figure 16g

Important

If Extended Caps are attached to the Centerpiece, ensure they are aligned with the Inserter shaft (**Figure 16g**). This is the only Extended End Cap position available in the StealthStation System.





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. If End Caps were attached to the implant, select the appropriate End Cap size from the "Round End Cap" or "Extended End Cap" drop down menu. End Caps will appear on both ends of the Centerpiece (Figure 17). The recommended views for implant placement are Trajectory 1, Trajectory 2, and the Sagittal 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.

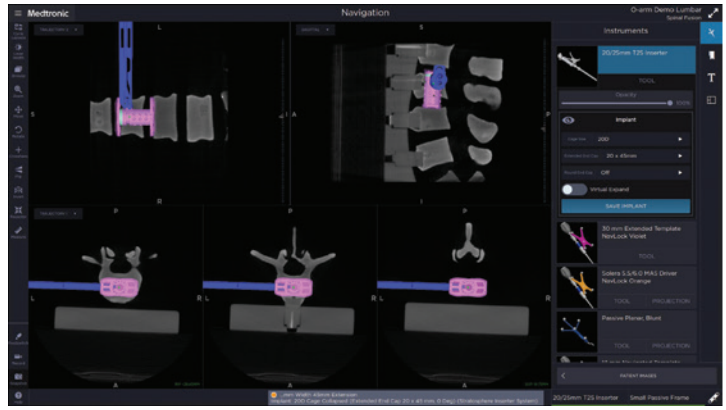


Figure 17

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 18a). 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 18b).

Rotate the blue T-handle clockwise to expand the implant (Figure 18c). 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.

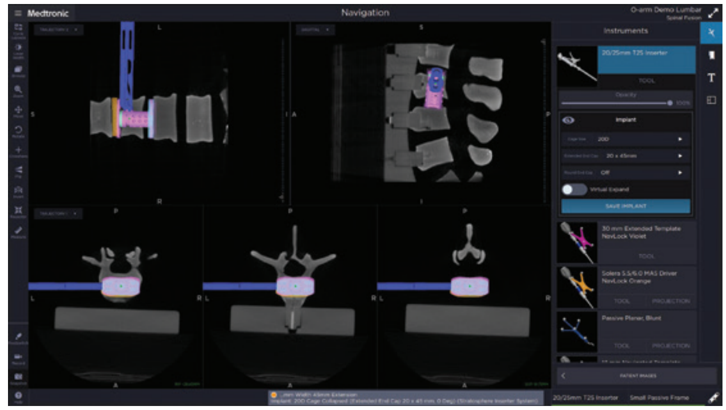


Figure 18a

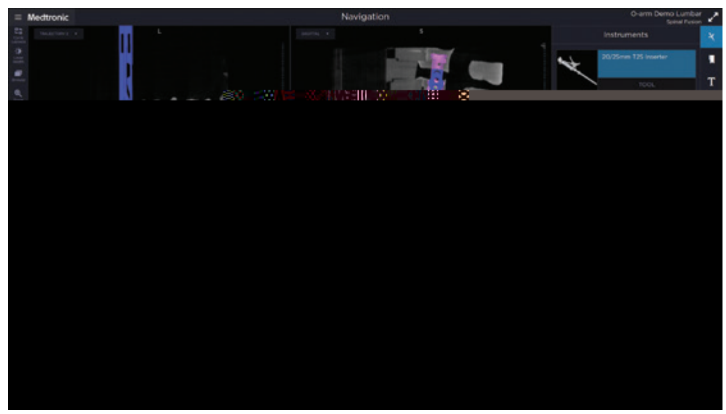


Figure 18b

Figure 18c

FINAL PLACEMENT AND GRAFT POST-PACKING

Pack additional autograft or allograft inside and around the device (Figure 22).

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

Remove the retractor system and close all surgical wounds.

Figure 22

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.

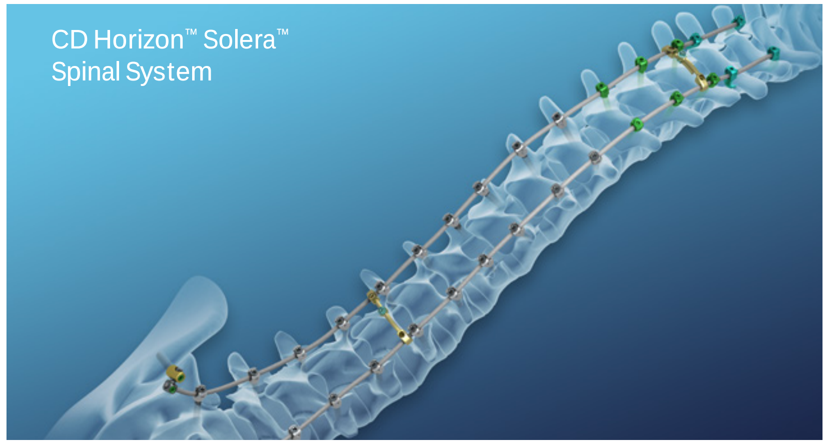
With the patient isocenter, position the O-arm System to perform a 3D image acquisition (Figure 23). During the acquisition process all personnel who are not wearing protective lead apparel should stand at least 15 feet from the O-arm System with a certified moveable lead shield between themselves and 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.

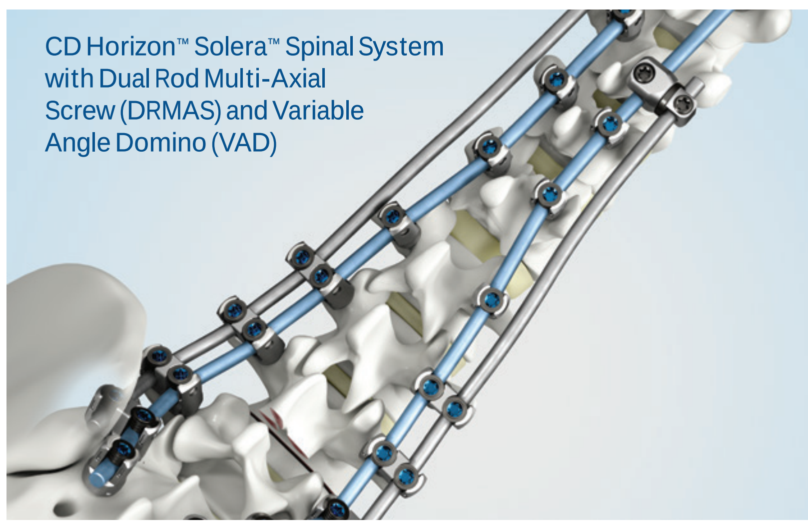
Figure 23

SUPPLEMENTAL **FIXATION**

Thoracolumbar Supplemental Fixation

Apply posterior supplemental fixation cleared for use in the thoracolumbar spine such as the CD Horizon Systems shown below. These can be placed according to the appropriate navigated workflow. T2 Stratosphere Expandable Corpectomy System is NOT a stand-alone system.





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 24a).

Use the Driver to turn the implant set screw counterclockwise. The implant height will slightly collapse when it is unlocked. Remove the implant (Figure 24b).

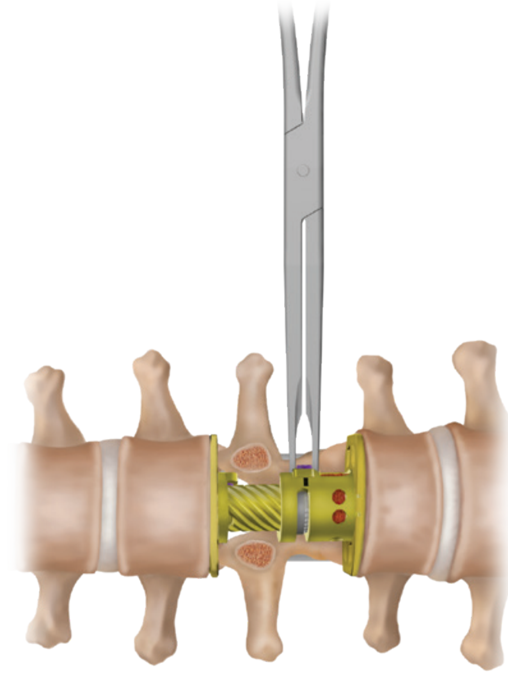


Figure 24a

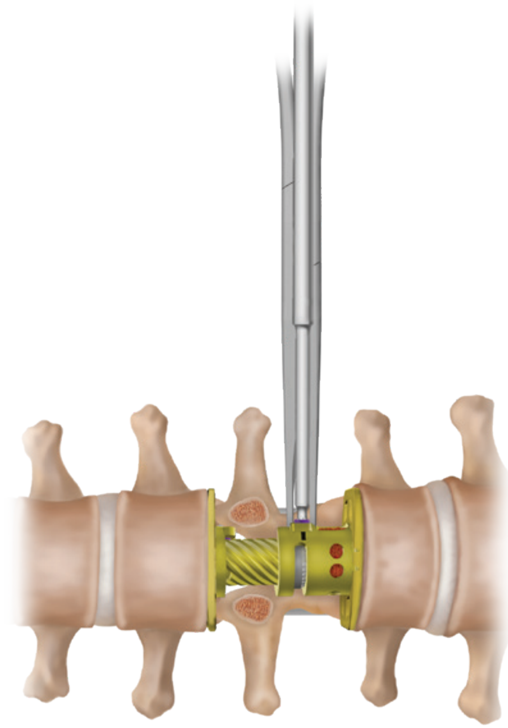


Figure 24b

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 25).

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.

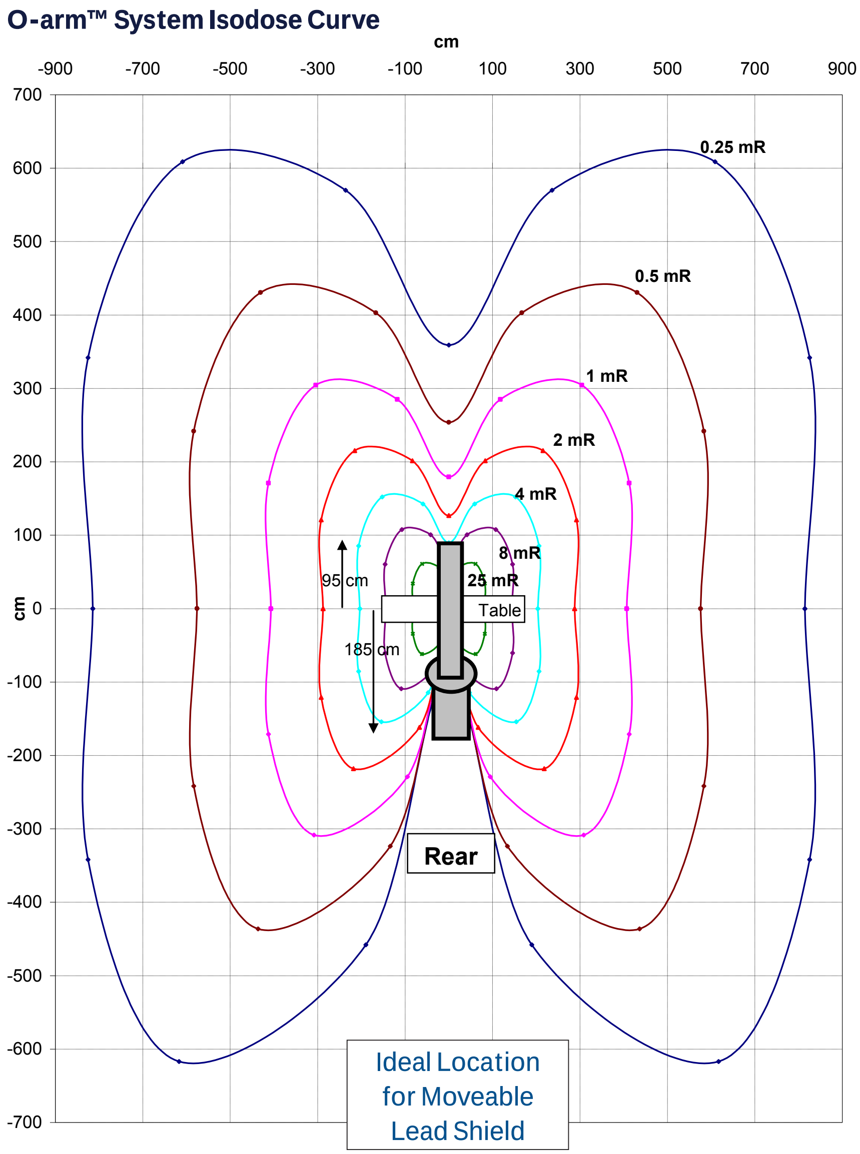


Figure 25

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 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 3.5mm 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. All screws used in pediatric cases are only cleared for use via a posterior approach. All of the 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 that 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.

The 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 stainless steel, titanium or cobalt-chromium-molybdenum alloy implants. CD HORIZON™ PEEK Rods are not to be used with CROSSLINK™ Plates or in pediatric patients.

To achieve best results, do not use any of the 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, the CD Horizon™ Legacy™ 3.5mm rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted below.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the 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™ 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 (as previously defined), spondylolisthesis, trauma, and/or tumor.

In order to achieve additional levels of fixation, the 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 the Vertex™ indications of use.

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.

- Any other 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.
- Suspected or documented metal allergy or intolerance.
- Any case not needing a bone graft and fusion.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- The CD Horizon™ Spire™ plate and the CD Horizon™ PEEK rods are specifically contraindicated for use in pediatric patients.
- Any patient unwilling to follow postoperative instructions.
- Any case 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 of the possible 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 any or all of the components.
- Disassembly, bending, or breakage of any or all of the 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 the 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 the 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 or 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 any 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 the 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 or 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

The safety and effectiveness of pedicle screw spinal systems have been 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). The safety and effectiveness of this device for any other conditions are unknown. The implants are not prostheses. In the absence of fusion, the 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.

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: the safety and effectiveness of this device has not been 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.

The 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 the 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

The 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 a risk of serious injury to the patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the 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 the device(s) will eventually occur.

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

The 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 a risk of serious injury to the patient.

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

The selection of the proper size, shape, and design of the implant for each patient 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 given in this document should be conveyed to the patient.

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

EC REP
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel: + 31 45 566 80 00

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone 800 933 2635 (In U.S.A.)
901 396 3133 (Outside of U.S.A.)
Fax 901 396 0356

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

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

- The device is not intended to be implanted from a posterior cervical approach. 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 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.

Medtronic

Medtronic
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132

(901) 396-3133
(800) 876-3133
Customer Service: (800) 933-2635

medtronic.ca

Medtronic Canada
Canadian Headquarters

99 Hereford Street
Brampton, ON L6Y 0R3

(905)460-3800
(800) 268-5346

NIM PAK II is manufactured by:

Boston Endo-Surgical Technologies
Division of Lacey Manufacturing Co.,
LLC 1146 Barnum Avenue
Bridgeport, CT 06610 USA

Tel: 203.336.0121
www.pepbe-st.com

Thompson SURGICAL INSTRUMENTS

Thompson Surgical Instruments, Inc.
10170 East Cherry Bend Road
Traverse City, MI 49684

(800) 227-7543 (In USA)
(231) 922-0177 (Outside USA)
Fax: (231) 922-0174

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.