SURGICAL SYNERGY SPINAL WORKFLOW

Image

Navigate

Confirm

SURGICAL TECHNIQUE

SynergyPCF℠ Procedures

with Navigated INFINITY™ System

Medtronic

NAVIGATED SPINAL WORKFLOW

C1-T3 SCREW FIXATION PROCEDURES

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*Navigation not intended for occipital fixation

Surgical Synergy
Spinal Workflow

INSTRUMENTS
AND SET-UP

TECHNOLOGY **OVERVIEW**

O-arm™ Image Acquisition System

Mobile Viewing Station

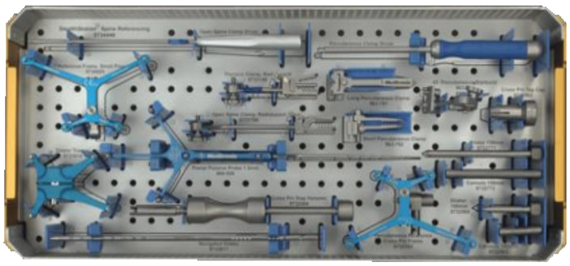
O-arm Imaging System

StealthStation™ S8 Surgical Navigation

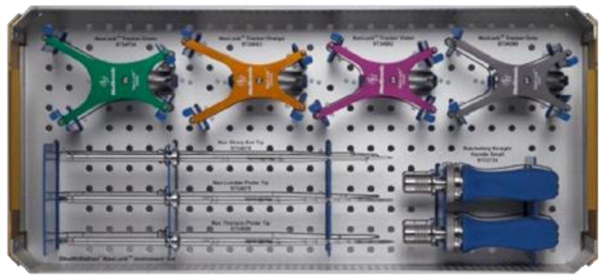
POWEREASE™ System with NavLock™ Tracker

INSTRUMENTS AND **EQUIPMENT**

Need new image from Sonia



StealthStation™ Spine Referencing Set
(9735500)



StealthStation™ NavLock™ Instrument Set
(9734833)

Spheres*
(8801075)

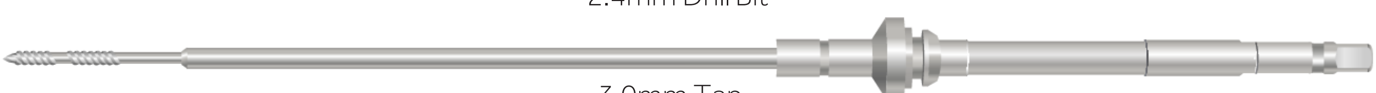
O-arm™ Sterile Tube Drape (optional)*
(9732722)

*Medtronic Surgical Technologies part numbers.

INSTRUMENTS AND **EQUIPMENT**

Adjustable NAV Drill Tap (DT) Guide with Optional Navlock Positioner

2.4mm Drill Bit*

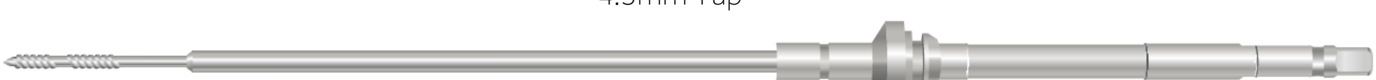


3.0mm Tap

3.5mm Tap

4.0mm Tap

4.5mm Tap



5.0mm Tap

2.5mm Threaded Screwdriver

*Single Use, Disposable Instrument. Do not reuse, reprocess, or re-sterilize.

0° Light Reference
(9733504*)

90° Light Reference
(9733505*)

Countertorque Assembly Driver
(9733649*)

Spine Reference Clamp
(9733037*)

*Medtronic Surgical Technologies part numbers.

EQUIPMENT AND
ROOM SET-UP

For 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 Stealth Station Spine Software. Connect the MVS to the StealthStation System network port with a network cable or a crossover cable.

The equipment set-up for a Posterior Cervical-Upper Thoracic Fusion Procedure has the StealthStation Staff Cart with Camera positioned to ensure instrument and reference frame line of sight.

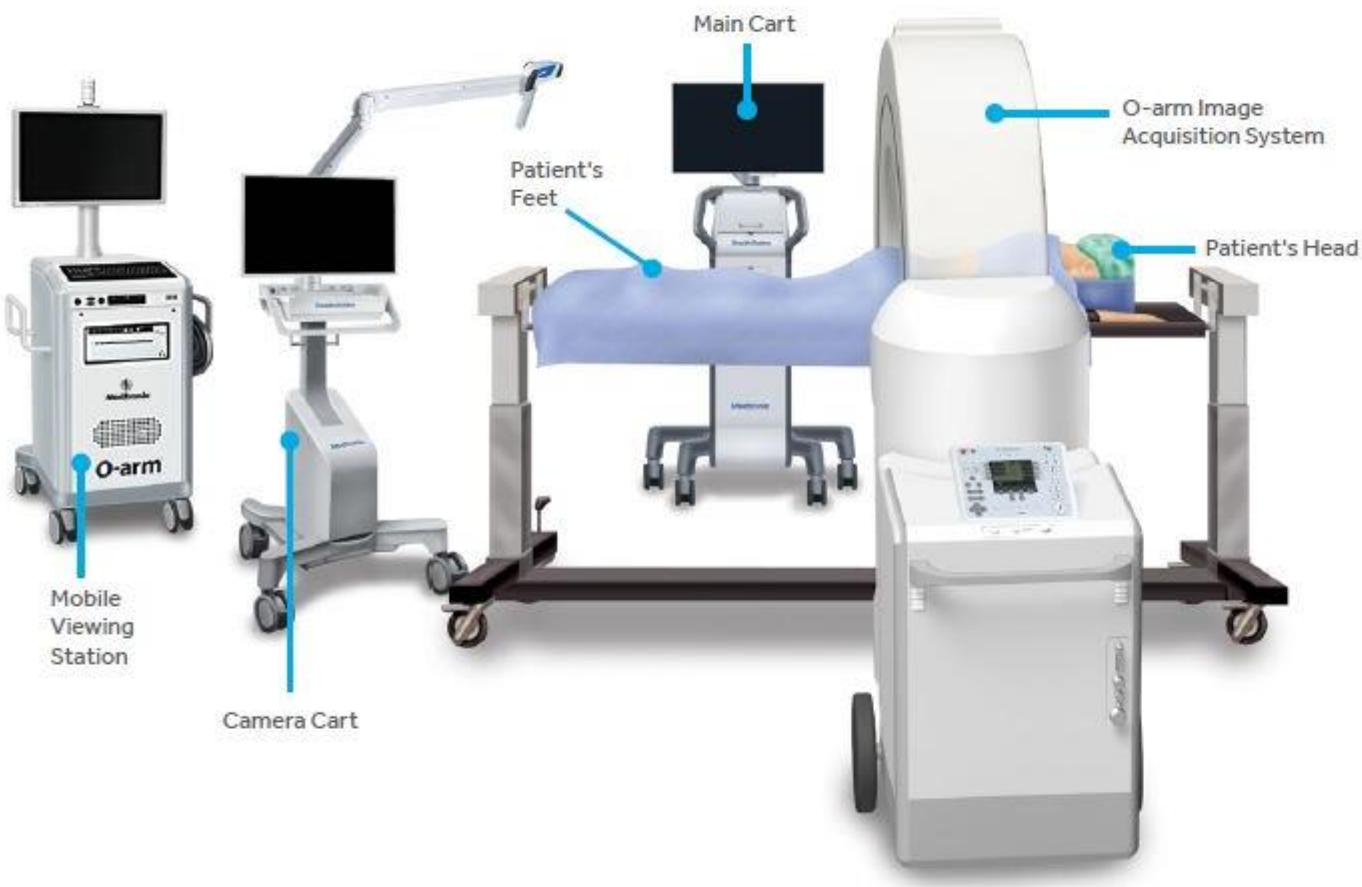


Figure 1

When positioning the O-arm System for the procedure, place it around the patient and translate it toward the area of the anatomy to be imaged, keeping in mind if it is to remain in the sterile field throughout the procedure, the gantry can be "parked" (wagged, tilted, and translated) to allow the surgeon unobstructed access to the surgical site (Figures 2a, 2b, 2c, and 2d).

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

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

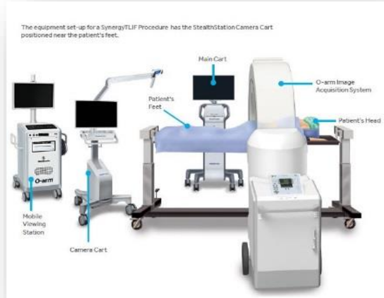


Figure 2a

Figure 2b

Figure 2c

Figure 2d

Helpful Hint

If the O-arm System will remain in the sterile field during the procedure, drape the O-arm System gantry using the O-arm IAS Sterile Tube Drape during the positioning of the system. If the O-arm System will be removed from the sterile field, place and clamp two half-drapes over the sides of the patient prior to positioning in the sterile field maintaining sterility around the patient while closing the gantry of the O-arm System (Figure 2e).

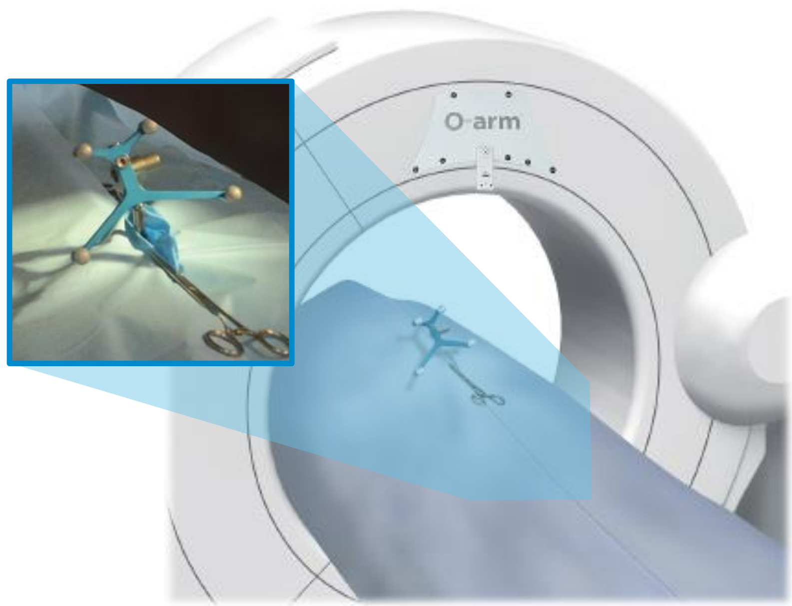


Figure 2e

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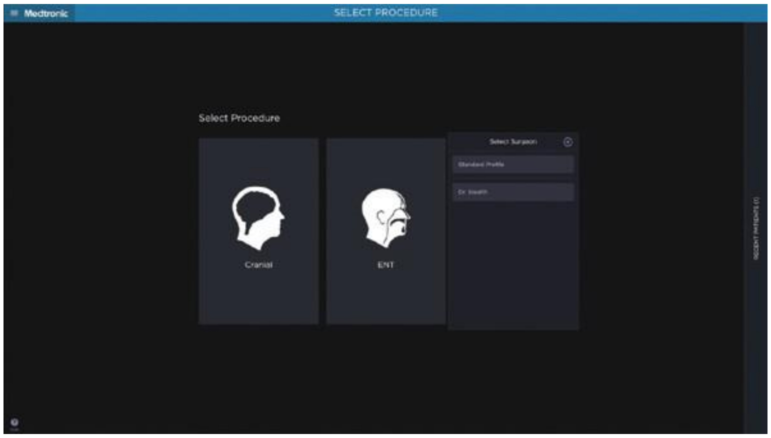
REFERENCING OPTIONS RECOMMENDATIONS

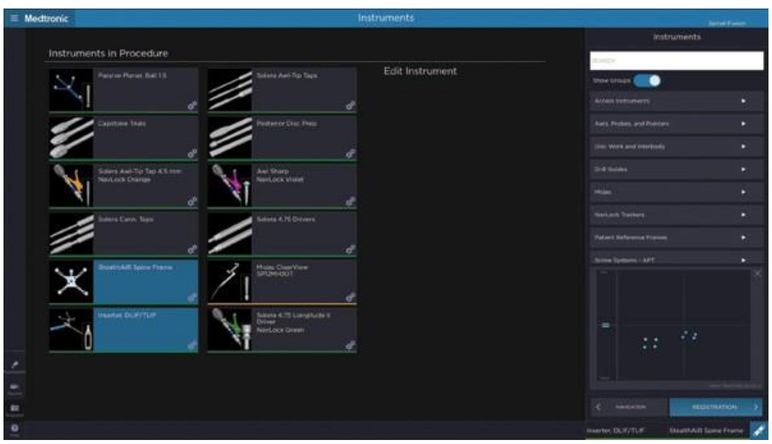
Procedural Levels	C1-C2	C3-C6 Lateral Mass	C3-C6 Pedicle Screws	CT Junction
Frame Choice	Spinous Process Clamp	Spinous Process Clamp	Spinous Process Clamp	Spinous Process Clamp
Level Frame Attachment	C2	C2	C6	No Specified Level; Lowest Level of Proposed Construct
Angle of Frame	Lean Towards Head	Lean Towards Head	Lean Towards Foot	Lean Towards Foot
Camera Position	Head	Head	Foot	Foot
O-arm Spin	Spin After	Spin After	Spin After	Spin After
Recommendation	Retractors Have Been Positioned	Retractors Have Been Positioned	Retractors Have Been Positioned	Retractors Have Been Positioned

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

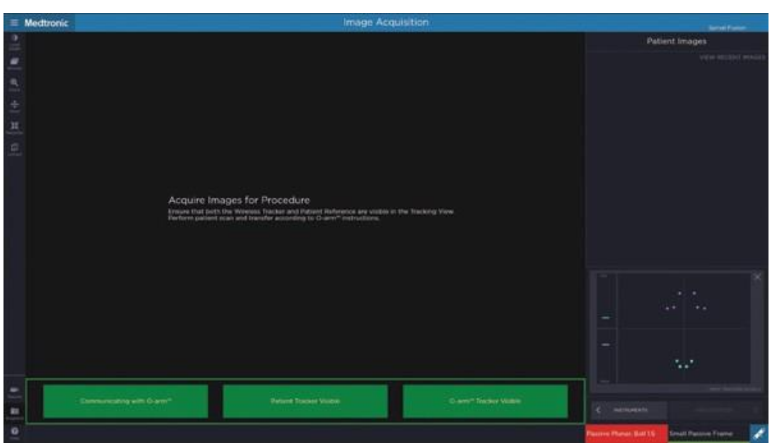


1. Select Procedure and Select Surgeon
Open the "Select Surgeon" menu and select the Primary Surgeon and the Surgical Procedure to be performed.



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.

Note: The correct INFINITY™ Tool Card must be selected. The INFINITY™ Navigated Instruments are *not* interchangeable with prior Medtronic posterior cervical navigation systems, including the VERTEX MAX™ and VERTEX SELECT™ Navigated Instruments.



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

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PROCEDURAL WORKFLOW

VERIFY INSTRUMENTS	- Navigated Drill Bit - Navigated Tap		- Navigated Driver - Navigated Probe
PLACE REFERENCE FRAME	- Spinous Process Clamp with Small Passive Reference Frame	- OR -	- Spinous Process Clamp with Light Reference Frame
ACQUIRE 3D IMAGE	- Drape patient, bring O-arm System in field, and remove after image acquisition	- OR -	- Drape O-arm System, bring in and leave in field after image acquisition
ACCESS, PREPARATION, AND DRILLING	- Determine entry points - Mark skin		- Make skin incisions - Drill pilot holes
TAP/PLACE SCREWS	- Tap and use reverse projection to determine screw length and diameter - Save projection to mark entry point		- Place screw - Repeat for other levels
TAP/PLACE SCREWS ON CONTRALATERAL SIDE	- Tap and use reverse projection to determine screw length and diameter - Save projection to mark entry point		- Place screw - Repeat for other levels
ROD AND SET SCREW PLACEMENT	- Place rods - Place and tighten set screws		
ACQUIRE 3D CONFIRMATION IMAGE	- Assess implant placement		

INSTRUMENT **VERIFICATION**

Attach the Spheres to a Reference Frame and the NavLock Trackers from the NavLock Set. Check the Sphere to ensure they are secure. Next, attach the NavLock Trackers to the instruments.

Place each instrument tip into the divot in the Reference Frame and hold perpendicular **(Figure 3a)** and visible to the camera until a confirmation color is visible. Use the tracking view in the lower right of the screen to ensure the camera is tracking the Reference Frame and instrument correctly **(Figure 3b)**.

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

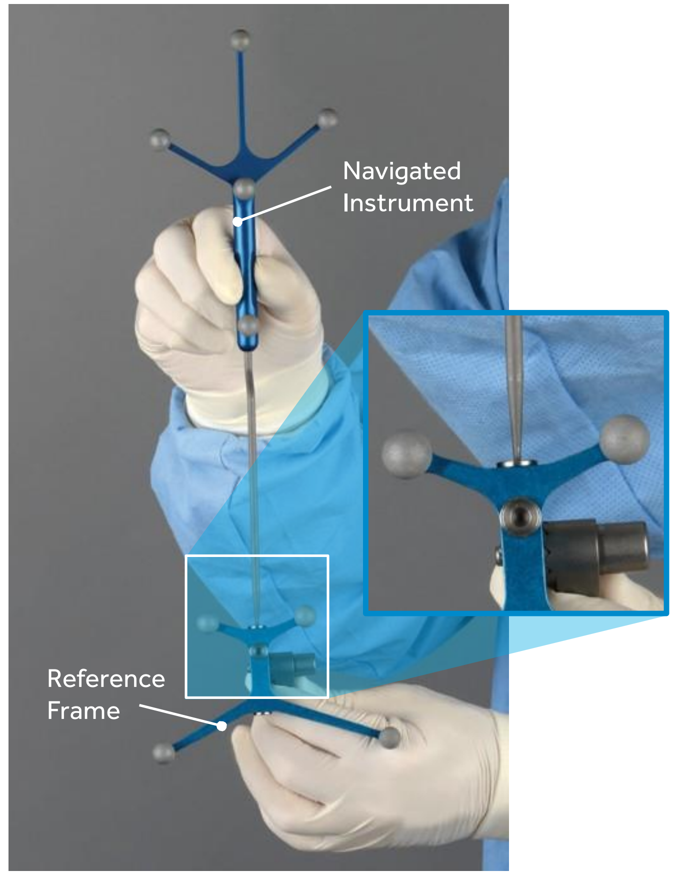


Figure 3a

StealthStation S8
System Software

Figure 3b

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.

Surgical Synergy
Spinal Workflow

PATIENT **PREPARATION**

PATIENT POSITIONING
POSTERIOR APPROACH

For all screw fixation techniques described in the following sections, the patient is placed prone in an appropriate manner to avoid specific pressure points.

A posterior midline incision is made, and the posterior elements are fully exposed to the lateral edge of the lateral masses and facet joints at all levels to be fused.

REFERENCE FRAME **PLACEMENT**

When performing a Navigated Posterior Cervical-Upper Thoracic Procedure, use of the Spinous Process Clamp with the Small Passive Reference Frame or Light Reference Frame is recommended. The clamp should be firmly attached to the desired spinous process that is most appropriate to the planned instrumented levels. Refer to the chart on page 9 for a list of frame placement recommendation options, although placement should always be determined by the medical judgment of the surgeon and specific patient anatomy. (Figures 4a and 4b). The clamp should be within an unobstructed view of the camera and other instruments involved in the procedure.

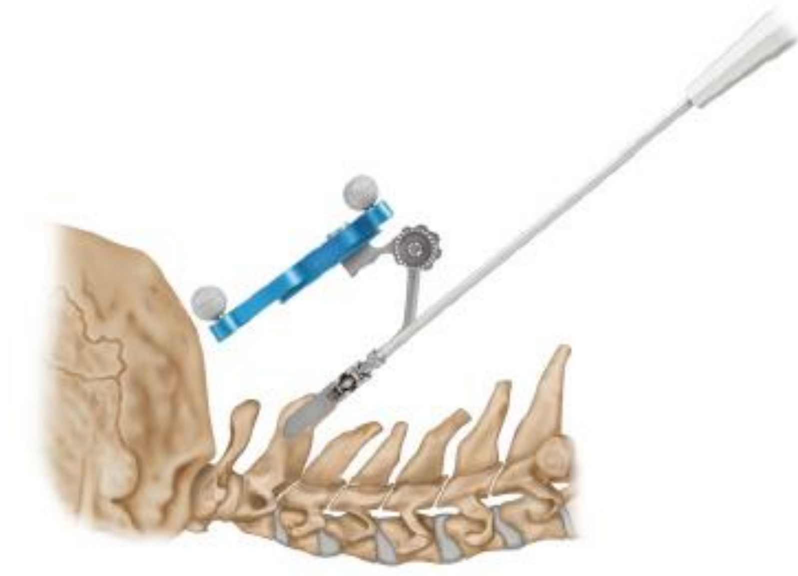


Figure 4a*

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.

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

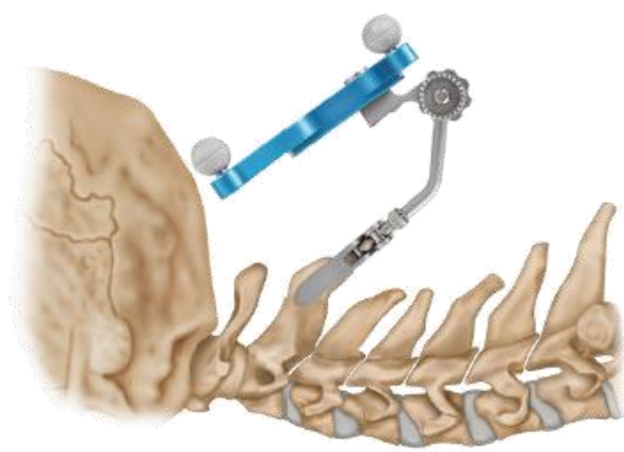


Figure 4b

Helpful Hint

When using the Light Reference Frame, select either the 0° or 90° clamp to provide the most secure fixation to the anatomy while maintaining an unobstructed view to the camera.

* Image shown is for illustrative purposes only. The placement of the Reference Frame in each case should be determined based on the medical judgment of the surgeon. The chart on page 9 can also be referenced for a list of recommendations for placement

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 and into the park position.

O-arm™ System Isodose Curve

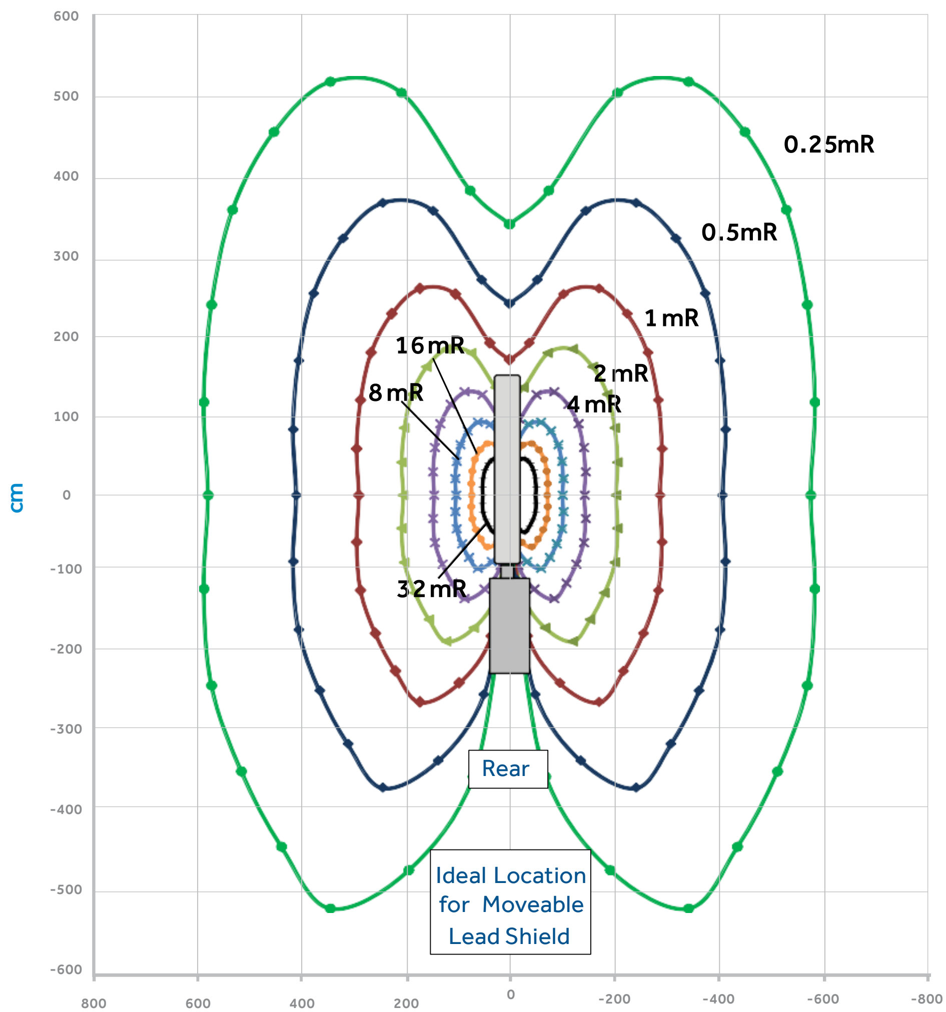


Figure 4

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**

C1 Lateral Mass
Screw Fixation

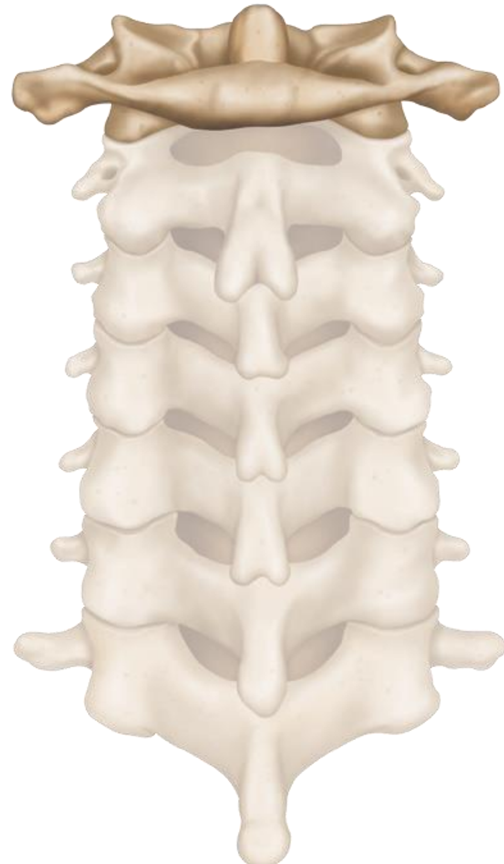
C1 LATERAL **MASS SCREW FIXATION**

PRE-OPERATIVE PLANNING

When placing C1 lateral mass screws, it is recommended that screw hole preparation is completed prior to any decompressive procedures in order to preserve the anatomical landmarks that are used for determining screw entry points and trajectories, and avoiding potential neurological injury while working over the spinal cord with various spinal instruments (**Figure 5**).

Various techniques have been published and should be referenced for further information. Individual patient anatomy should be taken into consideration when conducting preoperative planning in order to determine the appropriate screw placement.

This section follows the technique for C1 lateral mass screw fixation as described by Harms and Melcher.[1,2]



Posterior View of C1

Figure 5

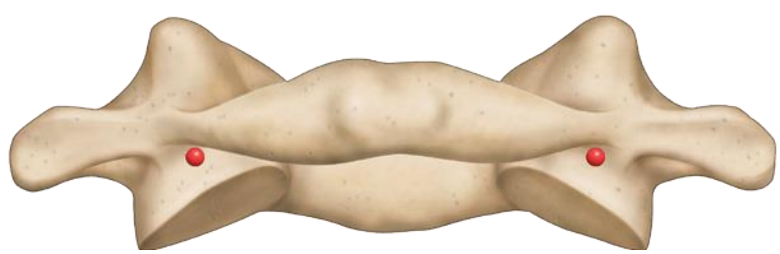
DETERMINING ENTRY POINTS

The dorsal root ganglion of C2 must be carefully retracted caudally to expose the starting point for the C1 lateral mass screw.

The entry point is the middle of the junction of the C1 posterior arch and the midpoint of the posterior inferior part of the C1 lateral mass (Figure 6). An indentation should be made at this entry point so that the drill bit will have a starting point and not skive off the bone.

Important
To help maintain navigational accuracy, perform navigated fixation steps immediately after O-arm System imaging and prior to performing procedural steps that could displace the anatomy.

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



Posterior view of C1

Figure 6

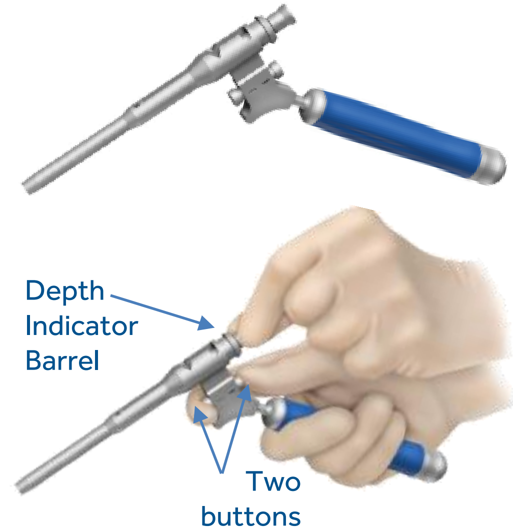
INSTRUMENT ASSEMBLY AND DRILLING

The Adjustable Navigated Drill-Tap (DT) Guide is used when drilling and tapping the bone in preparation for bone screw insertion. The Adjustable DT Guide (NAV3606006) can be used for drilling and tapping depths of 6mm up to 40mm. The depth of the Adjustable DT Guide can be adjusted in 2mm increments to allow for the desired depth that will correspond with the screw length.

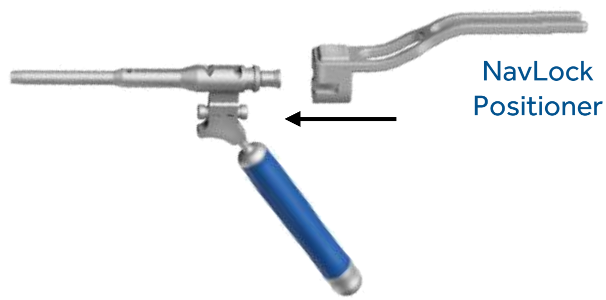
To set the drilling depth of the Adjustable NAV DT Guide, use the index finger and thumb to press the buttons simultaneously, and adjust the depth indicator barrel to the desired depth. Release the two buttons and the guide will automatically lock into position. Prior to drilling or tapping, ensure lock engagement.

The DT Guide has an optional NavLock Positioner that will hold the NavLock Tracker in position to face the camera throughout drilling and tapping.

The NavLock Positioner can be attached to the DT Guide in any of three positions according to surgeon preference and camera positioning. To attach the NavLock Positioner, directly slide it onto the back end of the DT Guide so that it attaches in the desired orientation (Figure 7a, 7b, and 7c))



Adjustable NAV Drill Tap (DT) Guide



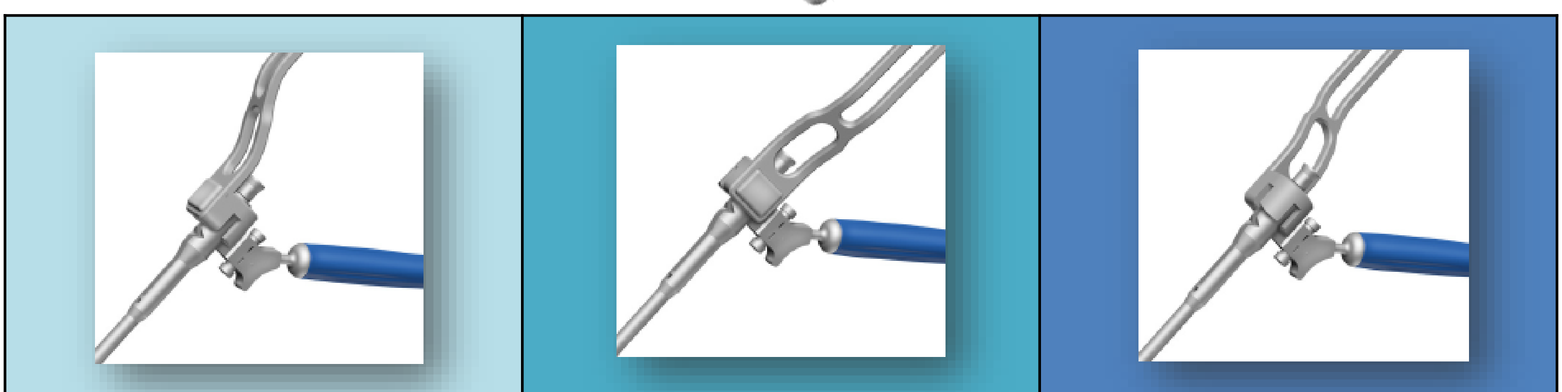


Figure 7a	Figure 7b	Figure 7c

Adjustable NAV Drill Tap (DT) Guide showing three orientation choices of the Optional Navlock Positioner

Note:
As an alternative, the drilling and tapping depth can also be adjusted (following the aforementioned steps) *after* the Navlock Positioner has been attached. The Navlock Positioner does not have to be removed to adjust the depth.

To remove or reposition the NavLock Positioner, depress the square button to release and pull back. (Figure 8)

Figure 8

INSTRUMENT ASSEMBLY AND DRILLING (continued)

Assemble the 2.4mm drill bit, driver handle, and NavLock Tracker, and then place the assembly through the Adjustable DT Guide.

When inserting through the Adjustable DT Guide, align so that the stem of the NavLock Tracker slides into the "fork" of the NavLock Positioner **(Figure 9).**

Figure 9

Place the instrument assembly on the entry point and verify the trajectory using the surgeon monitor (**Figure 10a).** Once confirmed, prepare the pilot holes in the desired trajectory. (see next section for recommended entry points and drilling trajectories).

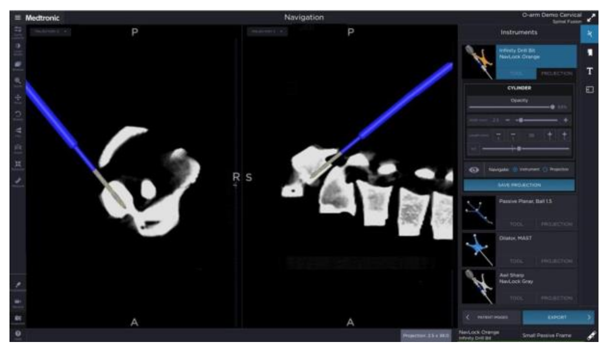


Figure 10a

As an alternative to the manual driver handle, the IPC Powerease System* may be used for drilling **(Figure 10b)**. The IPC Powerease System is a system of powered surgical instruments designed specifically for use in spine surgery.

Use the Navigation system software to drill to the appropriate depth.

Important
If redirecting an instrument, release applied force on the instrument to confirm navigational accuracy. Neglecting to release force while confirming accuracy could result in navigational inaccuracy.

Important
Exercise caution while drilling to limit application of excessive force that could bend the instrument and displace the anatomy, potentially resulting in navigational inaccuracy.

Figure 10b

*The IPC Powerease System are manufactured by Medtronic Xomed, Inc. or either Medtronic Xomed Inc or Medtronic Navigation Inc . Distributed by Medtronic Sofamor Danek USA, Inc.

DRILLING TRAJECTORY

Specific patient anatomy should be taken into consideration based on pre or intraoperative imaging prior to preparing pilot hole for screw insertion.

The drill bit should be angled straight or slightly convergent, approximately 5-10˚ medial **(Figure 11)**, and parallel to the underside of the C1 posterior arch **(Figure 12).** While drilling under navigation, additional orientation can be obtained by directing the tip of the drill bit toward the caudal half of the anterior tubercle of C1.

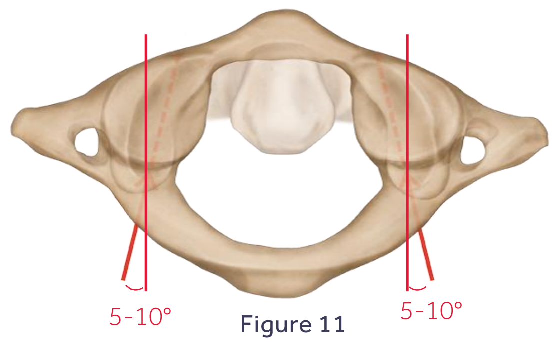


Figure 11

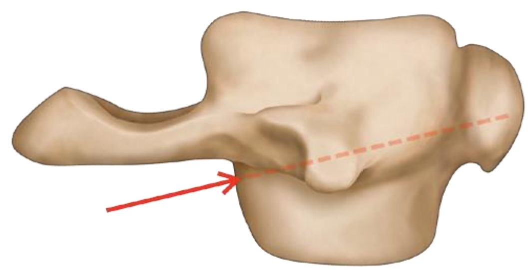


Figure 12

Warning: During navigation, frequently confirm navigational accuracy by touching the tip of the instrument on known anatomical points, including accuracy checkpoints, and comparing the position of the instrument tip in the image with its physical location. If system navigation seems inaccurate and steps to restore accuracy are unsuccessful, abort use of the system.

TAPPING (OPTIONAL) AND SCREW LENGTH MEASUREMENT

Figure 13

INFINITY™ Mullti axial screws are considered self-tapping, therefore this step is considered optional. If tapping is desired, choose the appropriate size tap based on screw diameter. Assemble the tap, driver handle, and NavLock Tracker, and then place the assembly through the DT Guide.

When inserting through the DT Guide, align so that the stem of the NavLock Tracker slides into the "fork" of the NavLock Positioner (refer to Figure 9 on page 20).
Alternatively, the IPC Powerease System* may be used for tapping. The IPC Powerease System is a system of powered surgical instruments designed specifically for use in spine surgery.

Following the same trajectory when drilling, tap to the desired depth (Figure 13). **NOTE: Once the tap has reached the set depth stop, extreme care should be taken to stop threading the tap. If tap rotation continues after contact with the depth stop, the threaded hole will strip.**

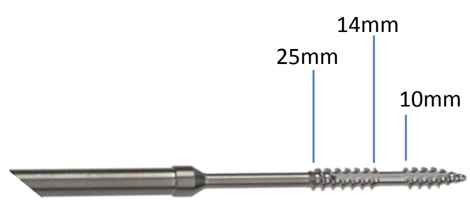


Figure 14

Along with the navigation software to monitor depth while tapping, the thread section indicators on the distal end of the tap can also be used. The first section of threads represents 10mm of depth. The second section of threads starts at 14mm and ends at 25mm. The tap can be used to tap up to 42mm. (Figure 14)

Once the tap has been advanced to the ideal depth, create a reverse projection under the "Projection" tab and then select "Save Projection" (Figures 15a and 15b). This will save the trajectory to be used as a virtual plan which may be recalled during subsequent screw placement. This projection also indicates the screw length and diameter for subsequent screw placement.

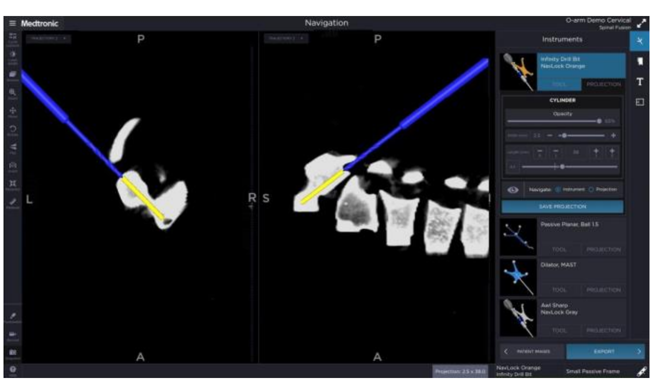


Figure 15a

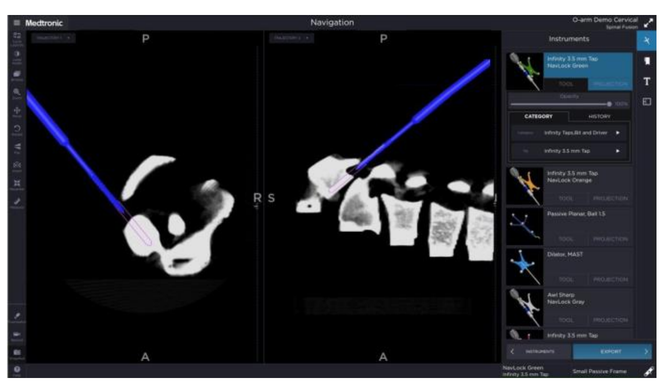


Figure 15b

*The IPC Powerease System are manufactured by Medtronic Xomed, Inc. or either Medtronic Xomed Inc or Medtronic Navigation Inc . Distributed by Medtronic Sofamor Danek USA, Inc.

PROBING AND SCREW MEASUREMENT

The Pedicle Feeler may be used to gently palpate the bone of the C1 lateral mass to assure no breach. The Depth Gauge may be used to determine the appropriate screw length **(Figure 16)**.

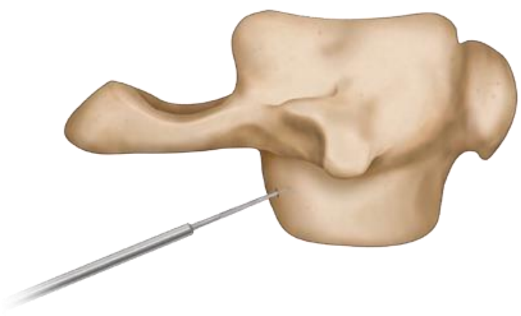


Figure 16

SCREW INSERTION

Next, thread the Navigated Threaded Screwdriver into the head of the screw. Ensure the driver is completely threaded into the screw head. Recall the plan saved during the tapping step. Under the "Tool" tab, select the appropriate screw width and length. Align the screw and driver with the saved plan and advance the screw being careful that the screw assembly is not advanced too far **(Figures 17a, 17b)**. If the screw head is placed against the bone, it will lose its multi-axial capabilities and could compromise screw purchase with additional advancement. This screw insertion process is repeated for additional screws.

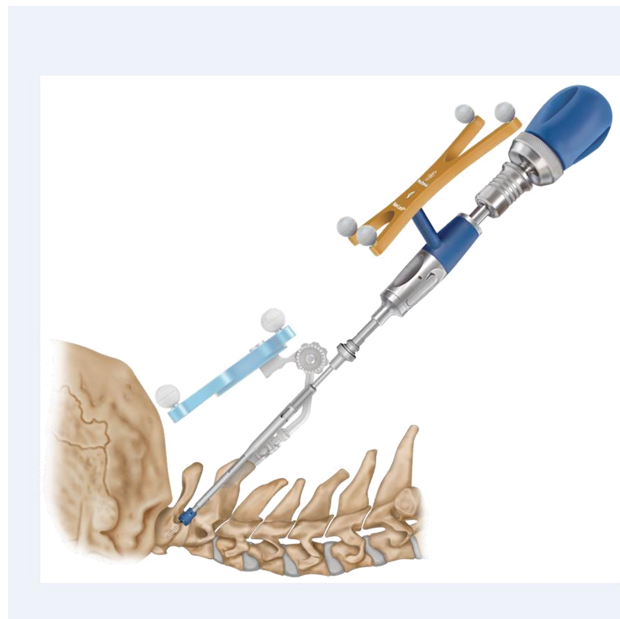


Figure 17a

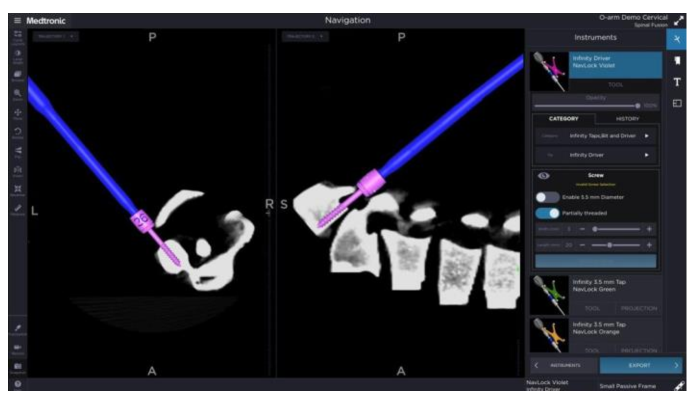


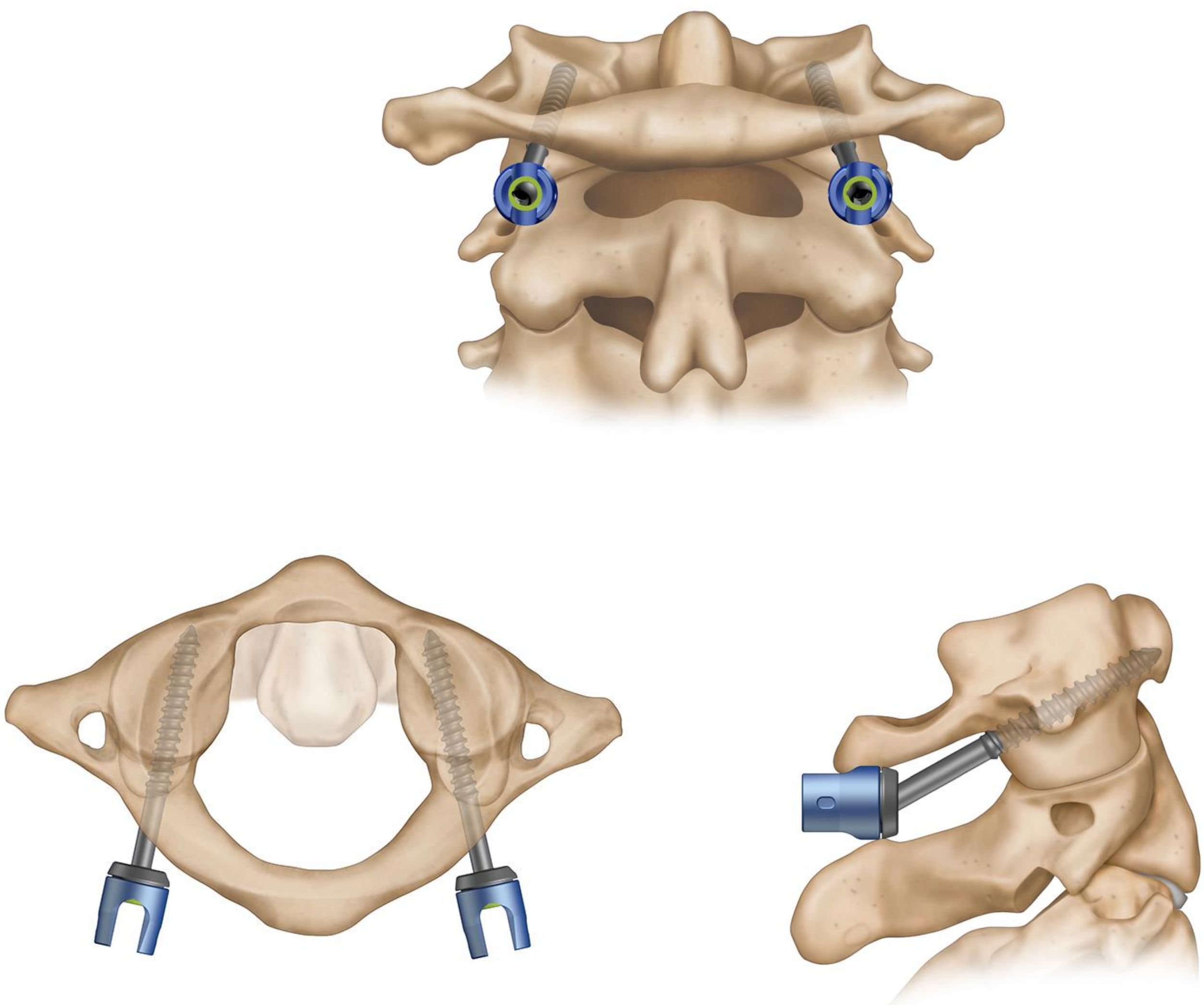
Figure 17b

Important:

To enable accurate navigation of a 5.5 mm diameter screw, ensure that the "Enable 5.5 mm diameter" slider option is selected under the screw selection menu on the StealthStation system. This option should be disabled to navigate screw sizes other than the 5.5mm diameter screw.

FINAL SREW POSITION

Refer to Figure 18 for final screw positioning.



C1 Lateral Mass Screw Fixation

Figure 18

Surgical Synergy
Spinal Workflow

PROCEDURE **STEPS**

C2 Pedicle and Pars Interarticularis Screw Fixation

C2 PEDICLE AND PARS INTERARTICULARIS **SCREW FIXATION**

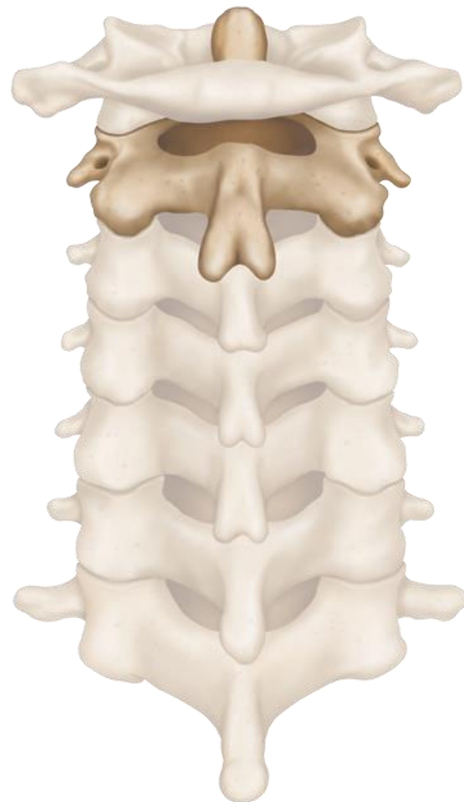
PRE-OPERATIVE PLANNING

The unique anatomy at C2 allows for placement of a screw in the pedicle or pars interarticularis **(Figure 19)**.

When placing C2 screws, it is recommended that screw hole preparation is completed prior to any decompressive procedures in order to preserve the anatomical landmarks that are used for determining screw entry points and trajectories, and avoiding potential neurological injury while working over the spinal cord with various spinal instruments.

Various techniques have been published and should be referenced for further information. Individual patient anatomy should be taken into consideration when conducting preoperative planning in order to determine the appropriate screw placement.

This section follows the technique for C2 pedicle screw fixation as described by Dickman3, and C2 pars interarticularis screw fixation as described by Mummaneni[4] and Foley.



Posterior view of C2

Figure 19

DETERMINING ENTRY POINTS

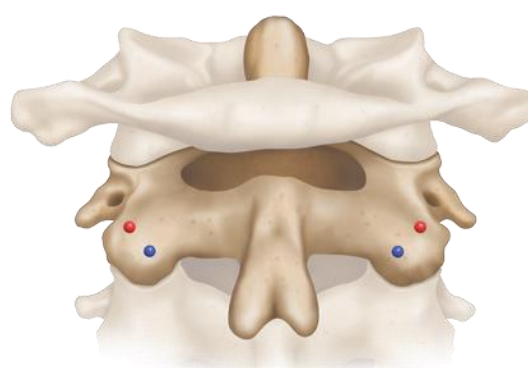
For screw placement in the C2 pedicle, the entry point is 3mm to 4mm above the C2 inferior facet **(Figure 20)**.

For screw placement in the C2 pars interarticularis, the entry point is approximately 3mm superior to the C2-3 facet joint line and 3mm lateral to the lamina-lateral mass junction **(Figure 20)**.

Indentations should be made at the entry points so that the drill bit will have a starting point and not skive off the bone.

C2 Pedicle Screw

C2 Pars Screw



Posterior view of C2

Figure 20

Important
To help maintain navigational accuracy, perform navigated fixation steps immediately after O-arm System imaging and prior to performing procedural steps that could displace the anatomy.

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

INSTRUMENT ASSEMBLY AND DRILLING

For drilling guidelines, refer to page 20.

DRILLING TRAJECTORY

Specific patient anatomy should be taken into consideration based on pre or intraoperative imaging prior to preparing pilot hole for screw insertion.

For screw placement in the **C2 pedicle**, the drill bit should be angled 20˚-30˚ medial and directed into the central axis of the C2 pedicle **(Figure 21)**. In the sagittal plane, the drill bit is angled approximately 20˚ – 30˚ cephalad **(Figure 22)**.

For screw placement in the **C2 pars interarticularis**, the drill bit should be angled slightly medial (10˚ – 15˚) **(Figure 21)**. In the sagittal plane, the drill bit is angled approximately 35˚ cephalad, aiming toward the anterior tubercle of C1 **(Figure 22)**.

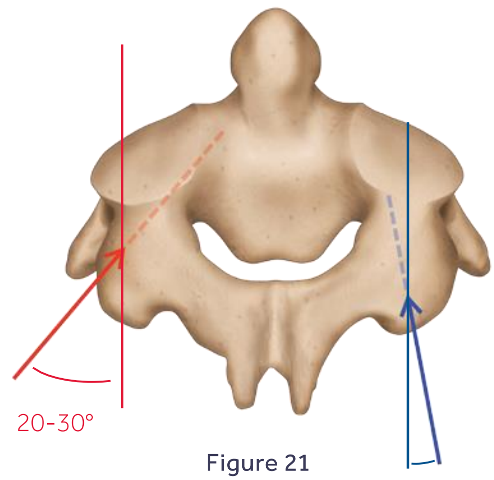


Figure 21

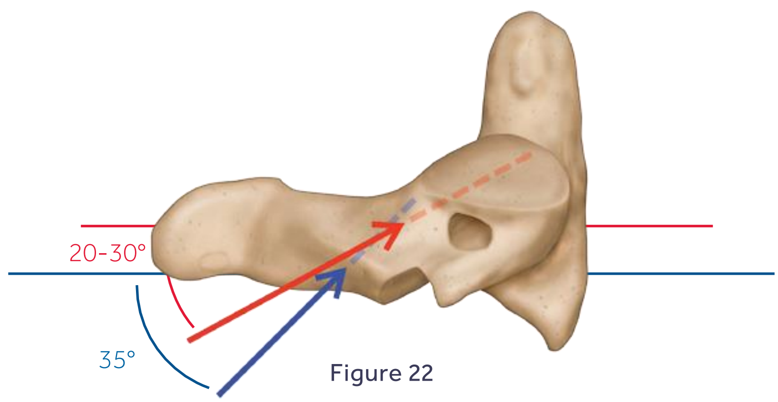


Figure 22

TAPPING (OPTIONAL)

For tapping guidelines, refer to page 22.

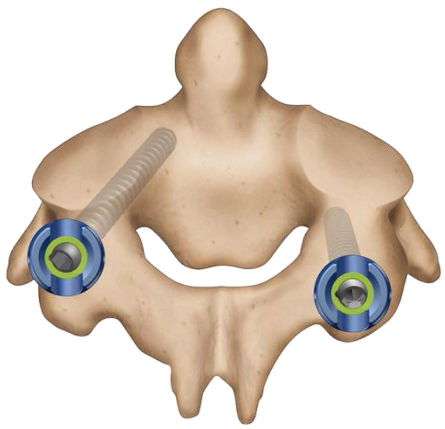
PROBING AND SCREW MEASUREMENT

For probing and screw measurement guidelines, refer to page 23.

Warning: During navigation, frequently confirm navigational accuracy by touching the tip of the instrument on known anatomical points, including accuracy checkpoints, and comparing the position of the instrument tip in the image with its physical location. If system navigation seems inaccurate and steps to restore accuracy are unsuccessful, abort use of the system.

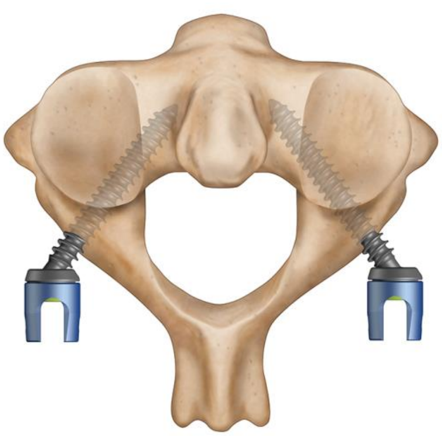
FINAL SCREW POSITION

Refer to **Figure 23** for final screw positioning for a C2 Pedicle and Pars Interarticularis Screw.

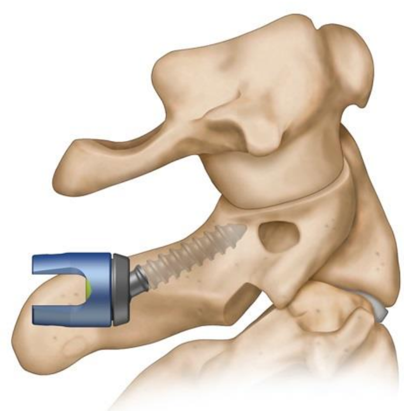


C2 Pedicle and Pars
Interarticularis Screw Fixation

Figure 23



C2 Pedicle Screw



C2 Pars Interarticularis Screw

Surgical Synergy
Spinal Workflow

PROCEDURE **STEPS**

C2 Translaminar Screw Fixation

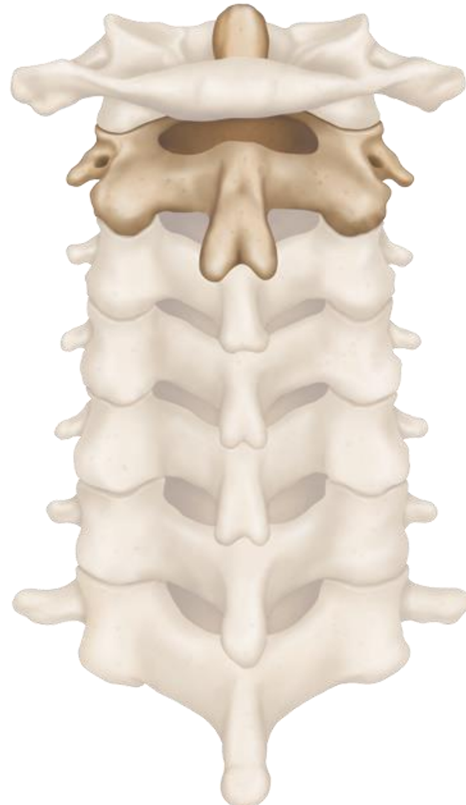
C2 TRANSLAMINAR **SCREW FIXATION**

PRE-OPERATIVE PLANNING

When placing C2 translaminar screws, it is recommended that screw hole preparation is completed prior to any decompressive procedures in order to preserve the anatomical landmarks that are used for determining screw entry points and trajectories, and avoiding potential neurological injury while working over the spinal cord with various spinal instruments.

Various techniques have been published and should be referenced for further information. Individual patient anatomy should be taken into consideration when conducting preoperative planning in order to determine the appropriate screw placement **(Figure 24)**.

This section follows the technique for C2 translaminar screw fixation as described by Wright.6



Posterior view of C2

Figure 24

DETERMINING ENTRY POINTS

For placement of C2 translaminar screws, the first entry point is at the junction of the C2 spinous process and lamina on either the left or right side (surgeon preference), close to the rostral margin of the C2 lamina **(Figure 25)**.

The second entry point is at the junction of the C2 spinous process and lamina on the contralateral side, close to the caudal margin of the C2 lamina **(Figure 25)**.

Indentations should be made at the entry points so that the drill bit will have a starting point and not skive off the bone.

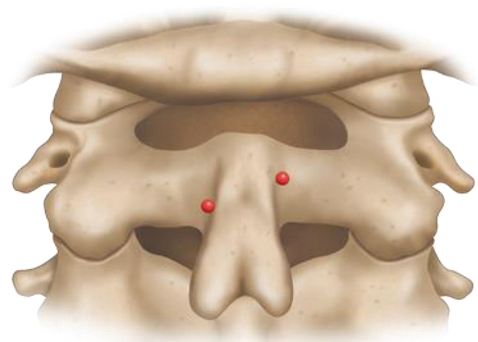


Figure 25

Important
To help maintain navigational accuracy, perform navigated fixation steps immediately after O-arm System imaging and prior to performing procedural steps that could displace the anatomy.

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

INSTRUMENT ASSEMBLY AND DRILLING

For drilling guidelines, refer to page 20.

DRILLING TRAJECTORY

Specific patient anatomy should be taken into consideration based on pre or intraoperative imaging prior to preparing pilot hole for screw insertion.

Once entry points on either side have been established, the contralateral lamina are then drilled, with the drill visually aligned along the angle of the exposed contralateral laminar surface **(Figure 26)**. The trajectory is slightly less than the downslope of the lamina to ensure that any possible cortical breakthrough would occur dorsally through the laminar surface rather than ventrally into the spinal canal.

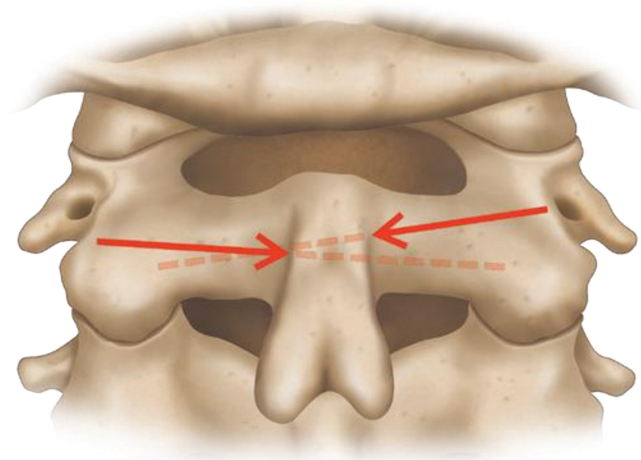


Figure 26

TAPPING (OPTIONAL)

For tapping guidelines, refer to page 22.

PROBING AND SCREW MEASUREMENT

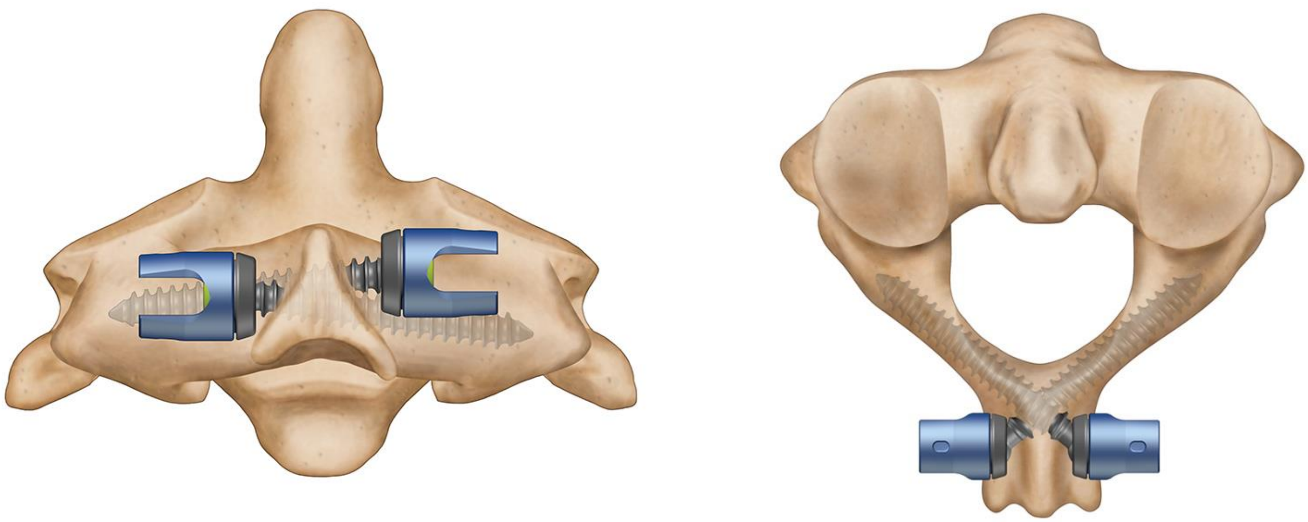
For probing and screw measurement guidelines, refer to page 23.

Specific to the technique for placing translaminar screws, if an anterior breach is detected with the pedicle feeler, a screw should not be placed.

Warning: During navigation, frequently confirm navigational accuracy by touching the tip of the instrument on known anatomical points, including accuracy checkpoints, and comparing the position of the instrument tip in the image with its physical location. If system navigation seems inaccurate and steps to restore accuracy are unsuccessful, abort use of the system.

FINAL SCREW POSITION

Refer to **Figure 27** for final screw positioning.



C2 Translaminar Screw Fixation

Figure 27

Surgical Synergy
Spinal Workflow

PROCEDURE **STEPS**

C1-C2 Transarticular Screw Fixation

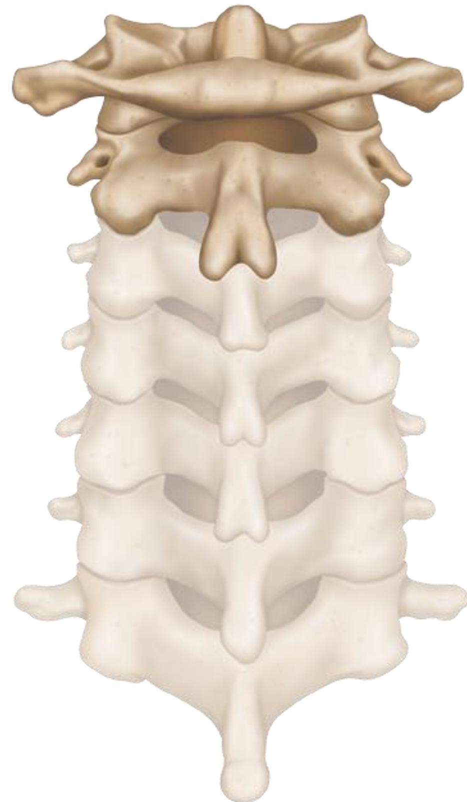
C1-C2 TRANSARTICULAR **SCREW FIXATION**

PRE-OPERATIVE PLANNING

When placing C1-C2 transarticular screws, it is recommended that screw hole preparation is completed prior to any decompressive procedures in order to preserve the anatomical landmarks that are used for determining screw entry points and trajectories, and avoiding potential neurological injury while working over the spinal cord with various spinal instruments.

Various techniques have been published and should be referenced for further information. Individual patient anatomy should be taken into consideration when conducting preoperative planning in order to determine the appropriate screw placement (**Figure 28**).

This section follows the technique for C1-C2 transarticular screw fixation as described by Foley[5] and Fassett and Apfelbaum.[7]



Posterior view of C1-C2

Figure 28

DETERMINING ENTRY POINTS

For placement of C1-C2 transarticular screws, the entry point is 2mm-3mm superior to the C2-3 facet joint line and 3mm lateral to the lamina-lateral mass junction (**Figure 29**).

Indentations should be made at the entry points so that the drill bit will have a starting point and not skive off the bone.

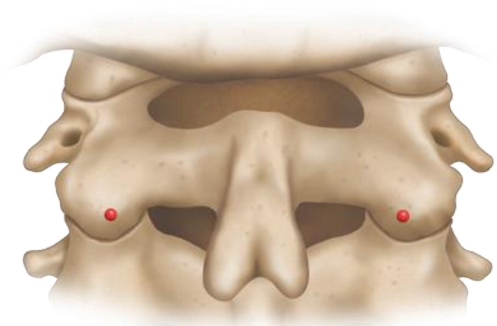


Figure 29

Important
To help maintain navigational accuracy, perform navigated fixation steps immediately after O-arm System imaging and prior to performing procedural steps that could displace the anatomy.

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

INSTRUMENT ASSEMBLY AND DRILLING

For drilling guidelines, refer to page 20.

DRILLING TRAJECTORY

Specific patient anatomy should be taken into consideration based on pre or intraoperative imaging prior to preparing pilot hole for screw insertion.

Once entry points have been established, the medial/lateral trajectory is determined by visualizing the pars interarticularis and manipulating to make the drill bit coaxial with the sagittal axis of the pars, typically 10˚-15˚ medial **(Figure 30)**.

The cephalad/caudal trajectory is assessed Under navigation by aiming toward the anterior tubercle of C1. The drill is advanced slowly through the pars of C2, crosses the C1-C2 joint space, enters the lateral mass of C1, and ends 3mm-4mm posterior to the C1 anterior tubercle **(Figure 31)**.

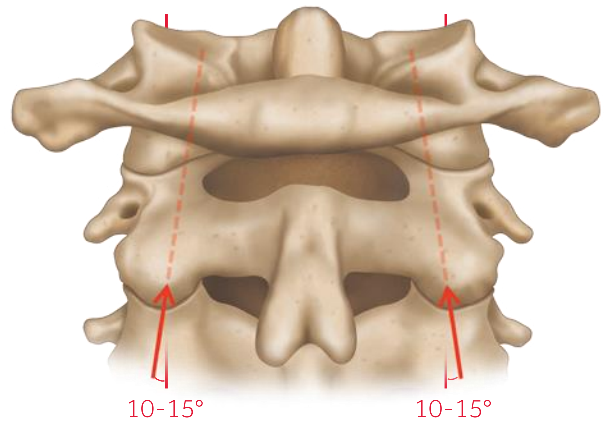


Figure 30

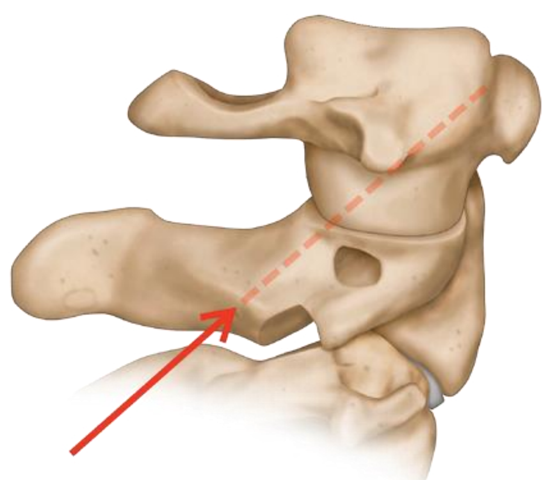


Figure 31

TAPPING (OPTIONAL)

For tapping guidelines, refer to page 22.

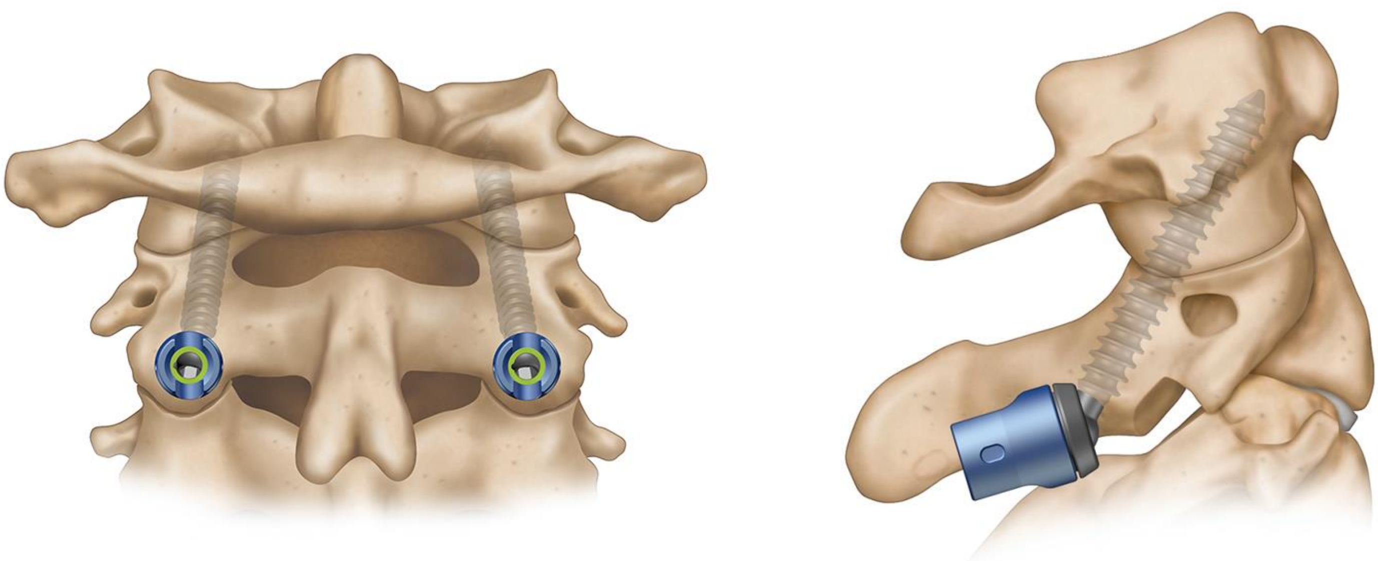
PROBING AND SCREW MEASUREMENT

For probing and screw measurement guidelines, refer to page 23.

Warning: During navigation, frequently confirm navigational accuracy by touching the tip of the instrument on known anatomical points, including accuracy checkpoints, and comparing the position of the instrument tip in the image with its physical location. If system navigation seems inaccurate and steps to restore accuracy are unsuccessful, abort use of the system.

FINAL SCREW POSITION

Refer to **Figure 32** for final screw positioning.



C1-C2 Transarticular Screw Fixation

Figure 32

Surgical Synergy
Spinal Workflow

PROCEDURE **STEPS**

C3-C7 Lateral Mass
Screw Fixation

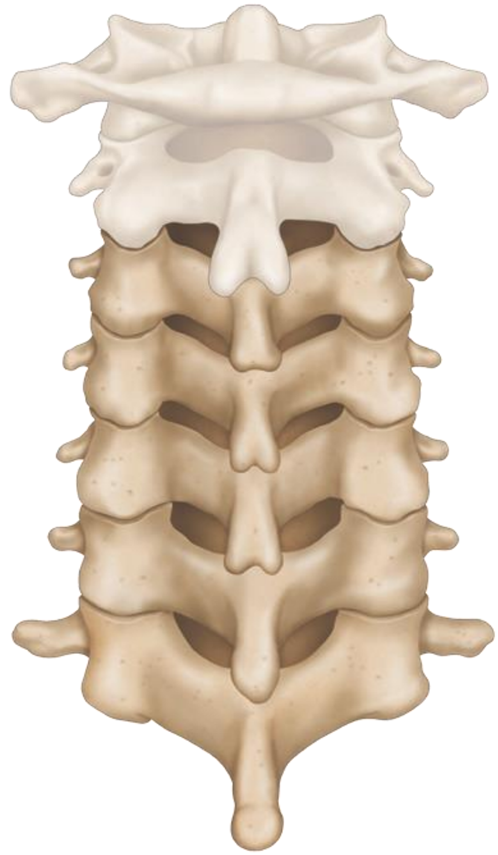
C3-C7 LATERAL MASS **SCREW FIXATION**

PRE-OPERATIVE PLANNING

When placing lateral mass screws, it is recommended that screw hole preparation is completed prior to any decompressive procedures in order to preserve the anatomical landmarks that are used for determining screw entry points and trajectories, and avoiding potential neurological injury while working over the spinal cord with various spinal instruments.

Various techniques have been published for the placement of lateral mass screws and should be referenced for further information. Individual patient anatomy should be taken into consideration when conducting preoperative planning in order to determine the appropriate screw placement **(Figure 33)**.

This section follows the technique for C3-C7 lateral mass screw fixation as described by Dickman.[3]



Posterior view of C3-C7

Figure 33

Important
To help maintain navigational accuracy, perform navigated fixation steps immediately after O-arm System imaging and prior to performing procedural steps that could displace the anatomy.

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

DETERMINING ENTRY POINTS

The lateral mass screw entry point is determined by visualizing the "box" of the lateral mass, which is outlined by the facet joints inferiorly and superiorly, by the medial valley formed where the lamina and lateral mass intersect, and by the lateral aspect of the lateral mass **(Figure 34)**

The entry point is 1mm medial to the center of the lateral mass **(Figures 35)**. An indentation should be made at this intersection so that the drill bit will have a starting point and not skive off the lateral mass.

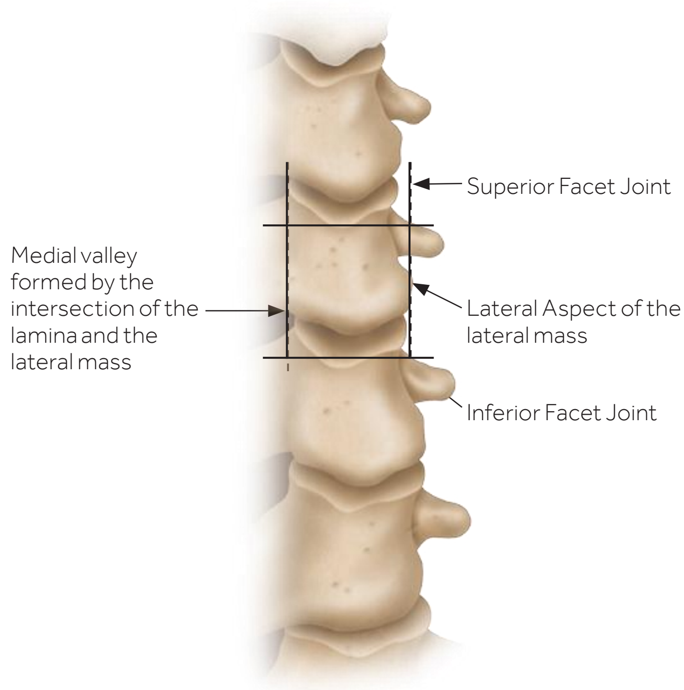


Figure 34

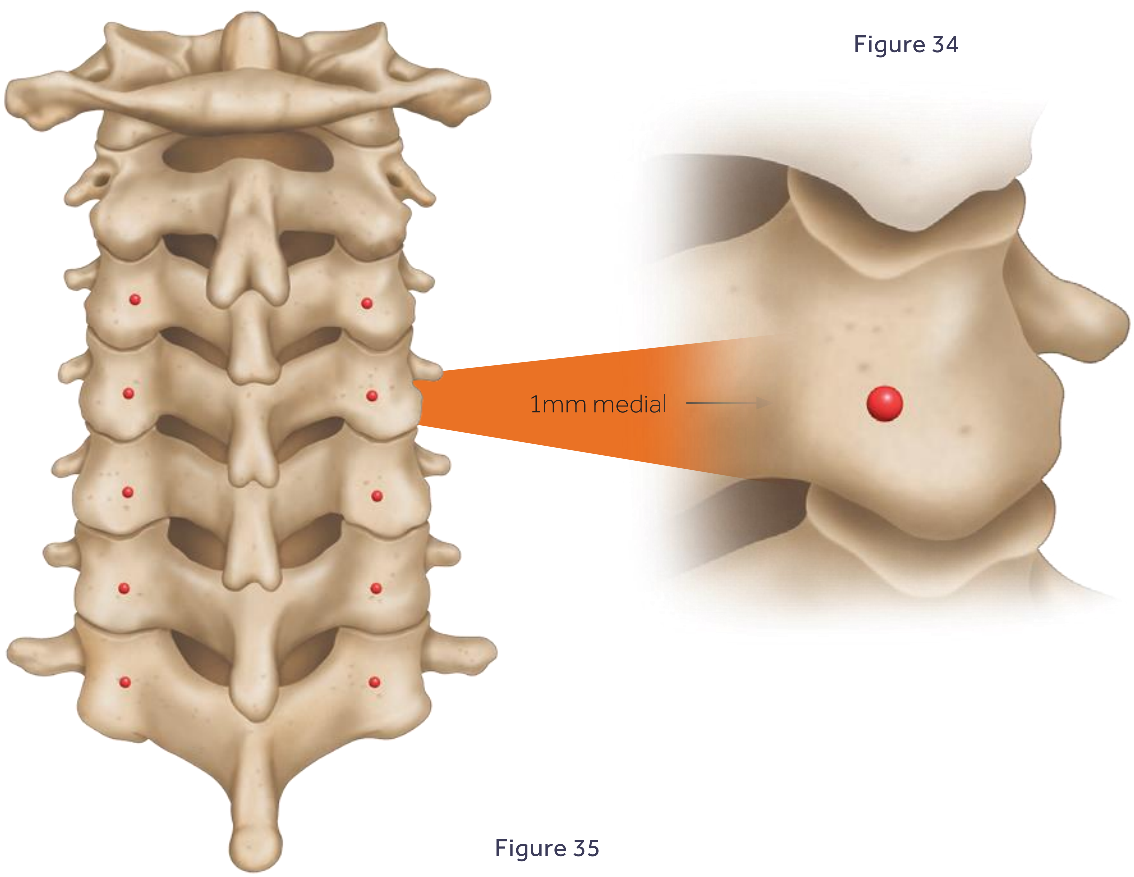


Figure 35

INSTRUMENT ASSEMBLY AND DRILLING

For drilling guidelines, refer to page 20.

DRILLING TRAJECTORY

Specific patient anatomy should be taken into consideration based on pre or intraoperative imaging prior to preparing pilot hole for screw insertion.

Once the entry point has been established, the drill should be placed perpendicular to the lateral mass and then angled 20˚ to 30˚ laterally **(Figure 36)** and approximately 20˚ to 30 ˚cephalad **(Figure 37)**.

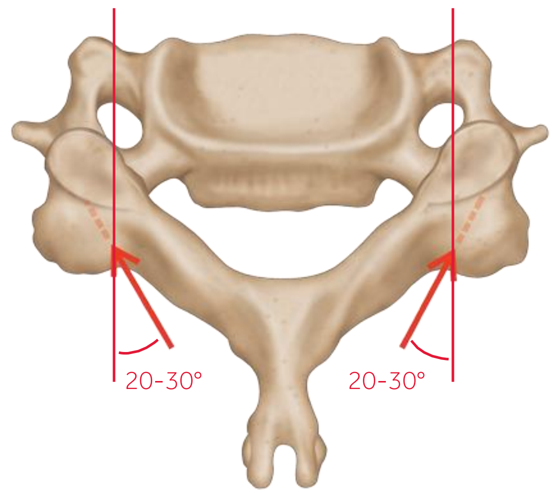


Figure 36

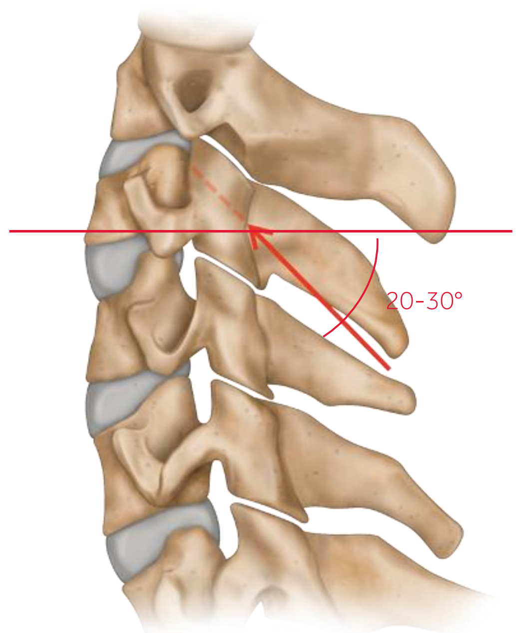


Figure 37

TAPPING (OPTIONAL)

For tapping guidelines, refer to page 22.

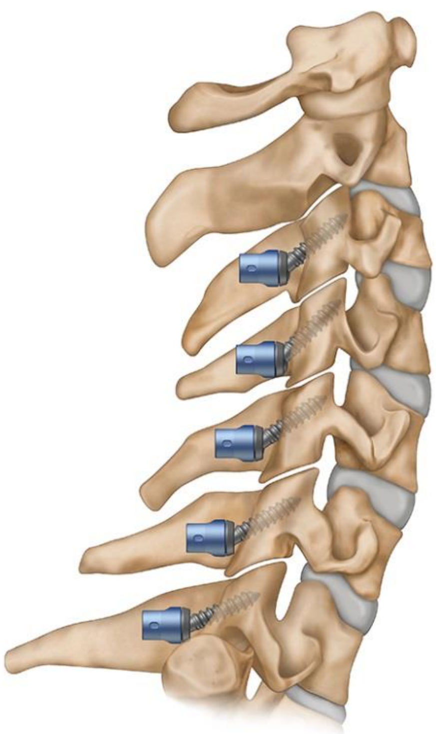
PROBING AND SCREW MEASUREMENT

For probing and screw measurement guidelines, refer to page 23.

Warning: During navigation, frequently confirm navigational accuracy by touching the tip of the instrument on known anatomical points, including accuracy checkpoints, and comparing the position of the instrument tip in the image with its physical location. If system navigation seems inaccurate and steps to restore accuracy are unsuccessful, abort use of the system.

FINAL SCREW POSITION

Refer to **Figure 38** for final positioning.



Lateral Mass Screw
Fixation

Figure 38

Surgical Synergy

Spinal Workflow

PROCEDURE **STEPS**

C3-T3 Pedicle Screw Fixation

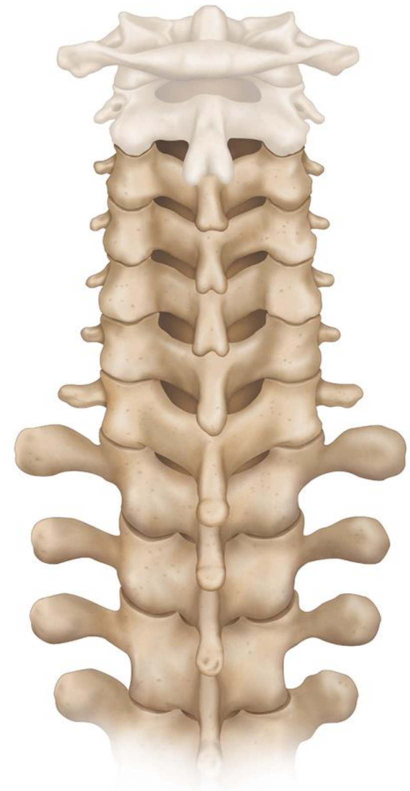
C3-T3 PEDICLE **SCREW FIXATION**

PRE-OPERATIVE PLANNING

When placing C3-T1 pedicle screws, it is recommended that screw hole preparation is completed prior to any decompressive procedures in order to preserve the anatomical landmarks that are used for determining screw entry points and trajectories, and avoiding potential neurological injury while working over the spinal cord with various spinal instruments.

Various techniques have been published and should be referenced for further information. Individual patient anatomy should be taken into consideration when conducting preoperative planning in order to determine the appropriate screw placement.

This section follows the technique for C3-C7 pedicle screw fixation as described by Abumi[8] and Moulton[9] and the technique for T1-T3 pedicle screw fixation as described by Fessler, et al. [10]



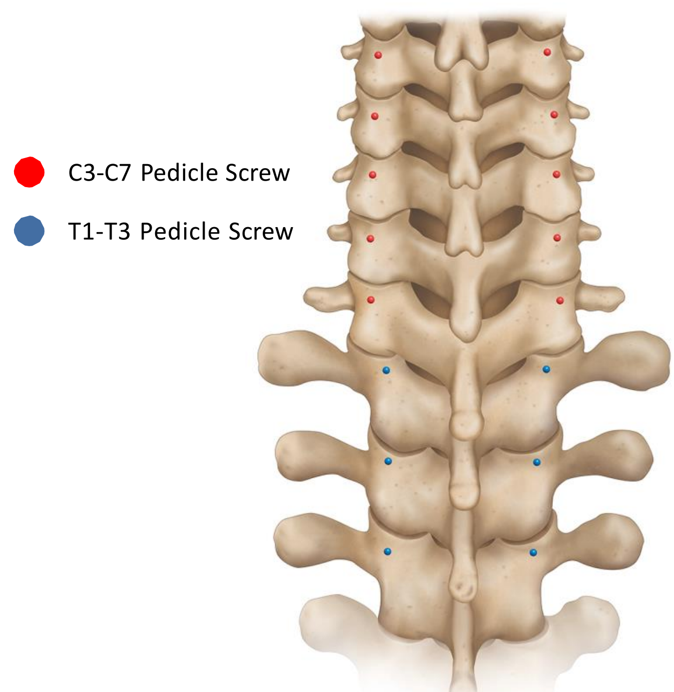
Posterior view of C3-T1

DETERMINING ENTRY POINTS

For screw placement in the pedicles of C3-C7, the entry point is just lateral to the midportion of the lateral mass, and 2mm – 3mm below the inferior facet margin of the cephalad vertebra (Figure 39)

For screw placement in the pedicles of T1-T3, the entry point is identified by the intersection of a horizontal line connecting the transverse processes with a vertical line connecting the middle of the facet joints (Figure 39).

An indentation should be made at the entry points so that the drill bit will have a starting point and not skive off the bone.



Entry Points for C3-T3 Pedicle Screw Fixation

Figure 39

Important
To help maintain navigational accuracy, perform navigated fixation steps immediately after O-arm System imaging and prior to performing procedural steps that could displace the anatomy.

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

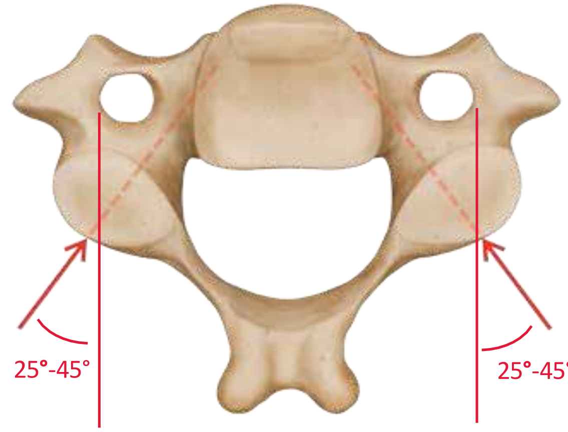


Figure 40

INSTRUMENT ASSEMBLY AND DRILLING

For drilling guidelines, refer to page 22.

DRILLING TRAJECTORY

Specific patient anatomy should be taken into consideration based on pre or intraoperative imaging prior to preparing pilot hole for screw insertion.

For pedicle screw placement in C3-C7, the drill bit should be angled 25˚- 45˚ medial to the midline (Figure 40).

For pedicle screw placement in T1-T3, the drill bit should be angled 10-15º medially and 5º caudally. (Figure 41)

The drill trajectory in the sagittal plane is parallel to the upper endplate of the pedicles (Figure 42).

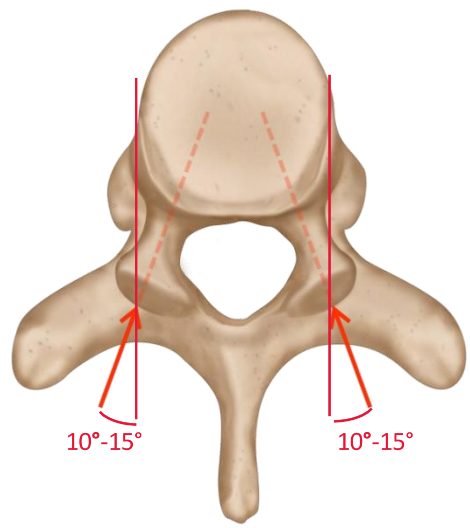


Figure 41

TAPPING (OPTIONAL)

For tapping guidelines, refer to page 22.

PROBING AND SCREW MEASUREMENT

For probing and screw measurement guidelines, refer to page 23.

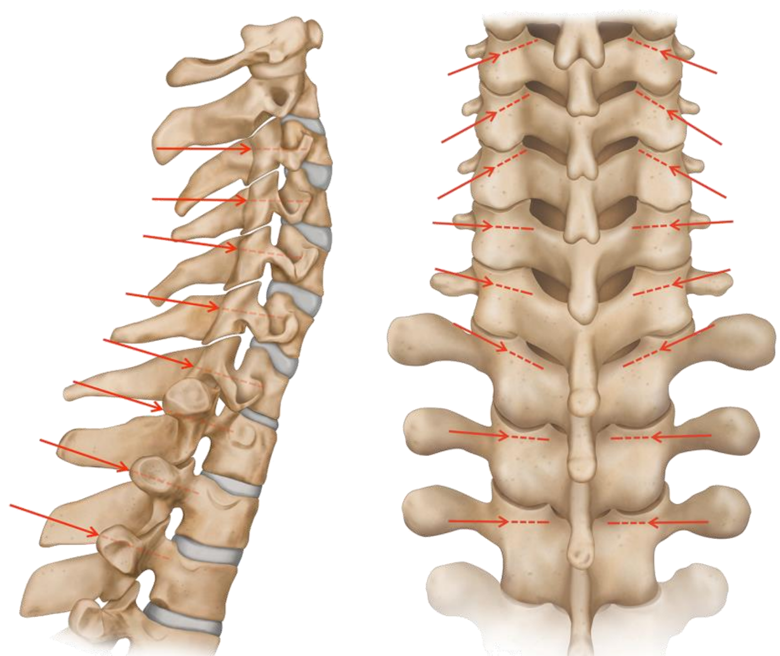


Figure 42

Warning: During navigation, frequently confirm navigational accuracy by touching the tip of the instrument on known anatomical points, including accuracy checkpoints, and comparing the position of the instrument tip in the image with its physical location. If system navigation seems inaccurate and steps to restore accuracy are unsuccessful, abort use of the system.

FINAL SCREW PoSITIONING

Refer to Figure 43 for final screw positioning.

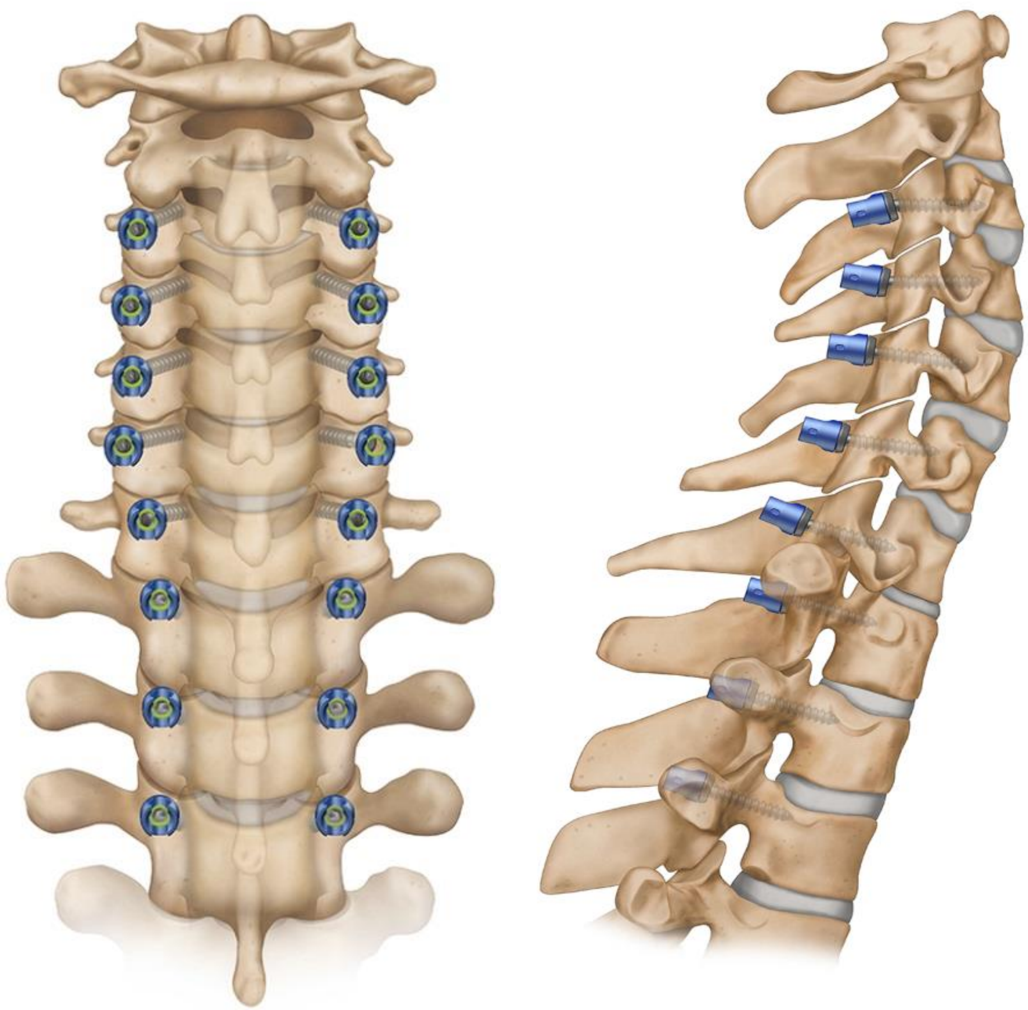


Figure 43

FINAL CONSTRUCT **ASSEMBLY**

After all the screws have been placed, the remainder of the construct may be assembled **(Figure 44)**. Refer to the Vertex Select Reconstruction System* Surgical Technique for detailed information on the remaining steps of construct assembly:

- Rod selection, templating, cutting, bending, placement, and reduction (if needed)
- Compression/distraction
- Use of lateral offset connectors
- Use of rod transition options (dominos, tapered rods, multi axial screw extension connectors)
- Use of Crosslink Connectors
- Final tightening

Once the remainder of the construct has been assembled, and bone graft material has been placed, an intraoperative image of the final construct should be taken to verify accurate placement of all implants prior to wound closure.

If visual confirmation of the 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 14.

*The VERTEX Reconstruction System is indicated for skeletally mature patients.

Figure 44

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 45a)**. 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 construct placement **(Figure 45b)**. Following confirmation, the Reference Frame should be removed.

Figure 45a

BONE GRAFT **PLACEMENT**

Bone Graft must be used when implanting the rod/screw construct.

Closure is accomplished with a few stitches in fascia, a subcuticular skin suture, and Steristrips™.

Figure 45b

IMPLANT **EXPLANTATION**

To remove any of the Vertex Select Reconstruction System* implants described throughout this technique, engage the set screw and multi-axial screw with a 2.5mm Hex Screwdriver and turn counterclockwise until the set screw is disengaged from the implant and the bone screw is disengaged from the bone.

*The VERTEX Reconstruction System is indicated for skeletally mature patients.

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 20**).

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

O-arm™ System Isodose Curve

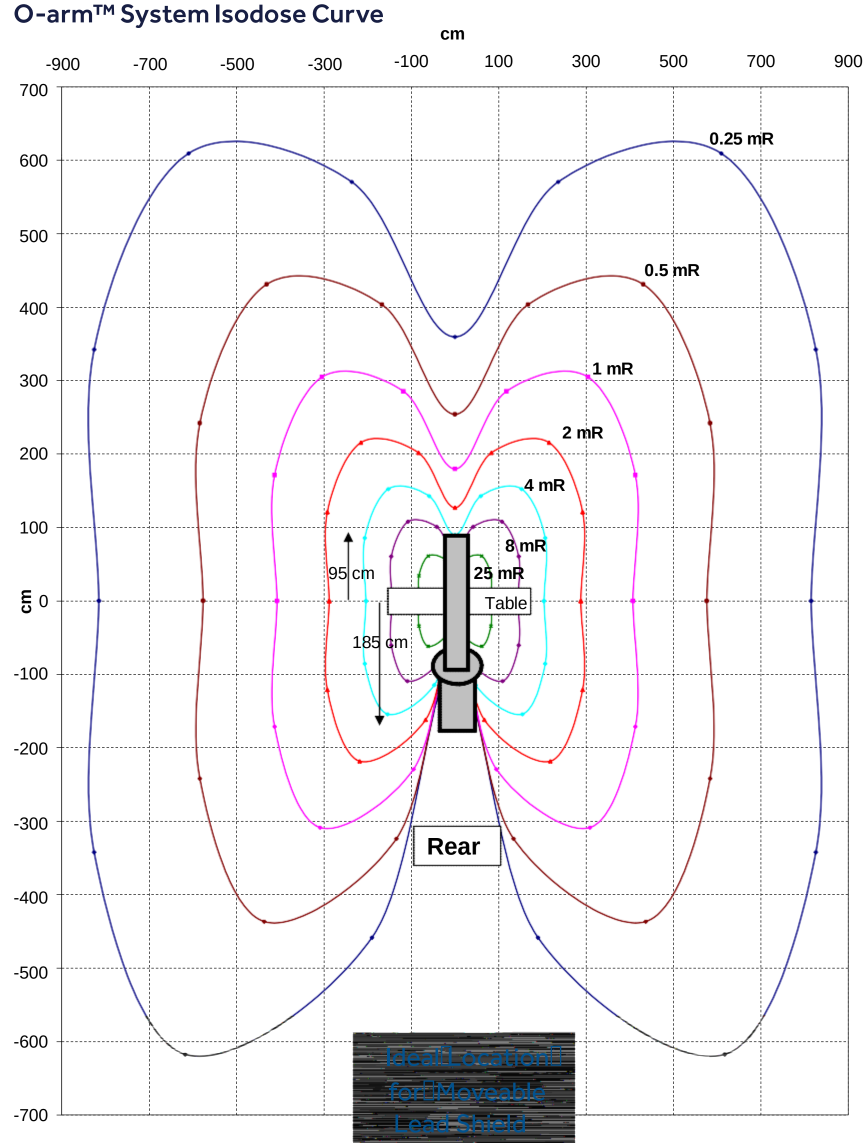


Figure 20

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