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VERTEX SELECT®

Reconstruction System

C1-C7 Screw Fixation Surgical Technique

Adjustability.
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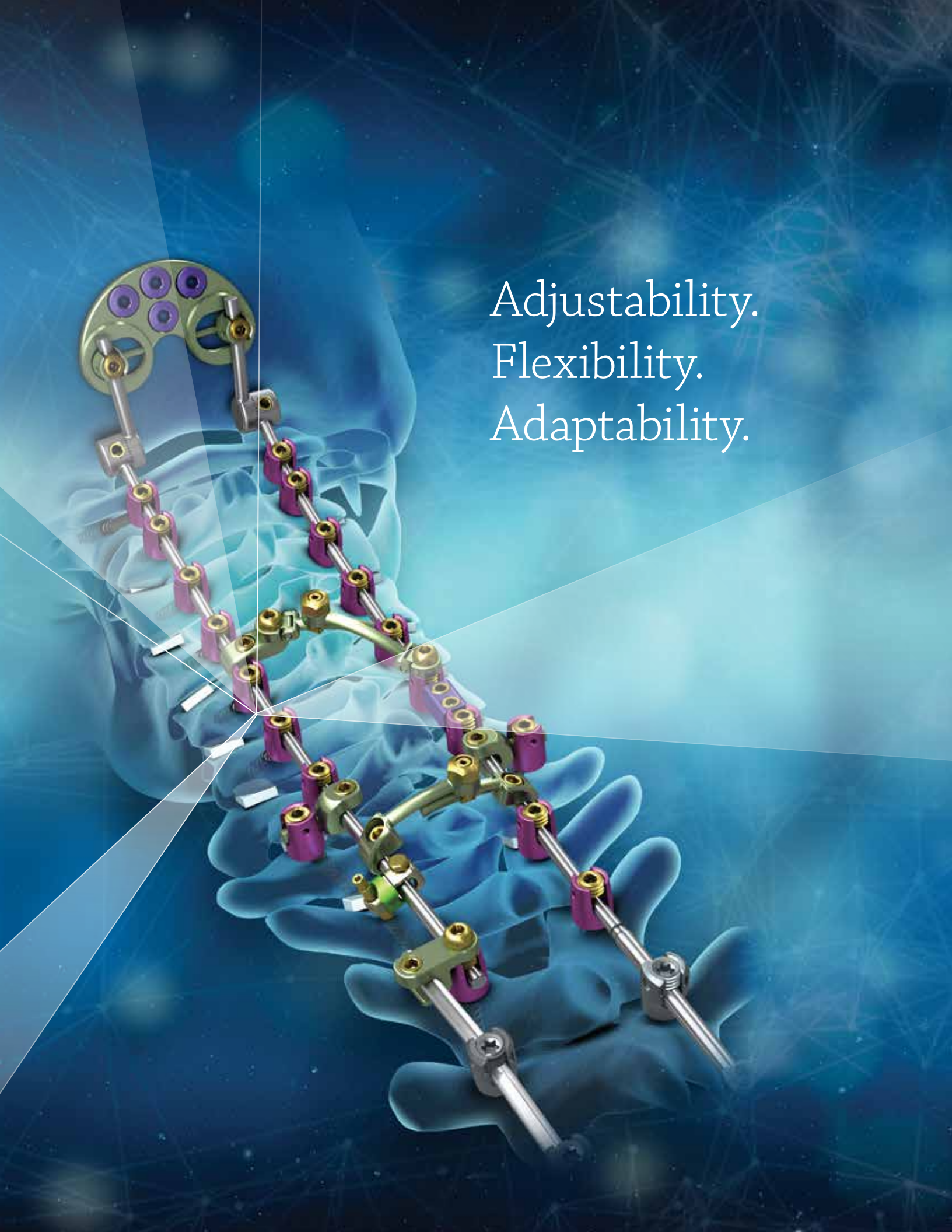
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C1-C7 Screw Fixation Surgical Technique

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.

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.

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]

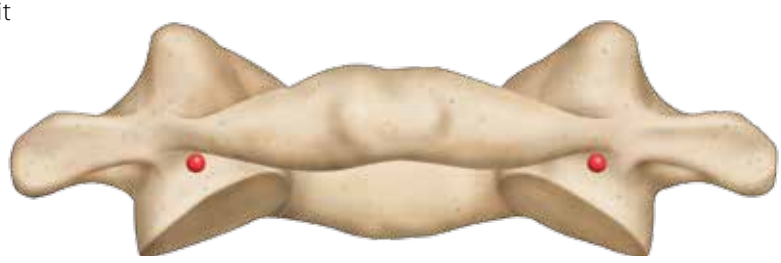
Posterior View of C1

Figure 1

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 2**). 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.



Posterior view of C1

Figure 2

C1 Lateral Mass Screw Fixation *Continued*

Drilling

The Adjustable Drill Guide can be used for drilling the desired depths from 6mm up to 52mm. The depth of the Drill guide can be adjusted in 2mm increments to allow for desired drill depth that will correspond with the lateral mass screw length.

The drilling depth is adjusted by pressing the slide forward while adjusting the measuring tube to the desired drill depth. Once the slide reaches the desired depth, rotate the slide into the locked position and prepare the pilot hole in the desired trajectory (**Figure 3**).

Figure 3

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 4**), and parallel to the underside of the C1 posterior arch (**Figure 5**). When drilling under fluoroscopic control, additional orientation can be obtained by directing the tip of the drill bit toward the caudal half of the anterior tubercle of C1.

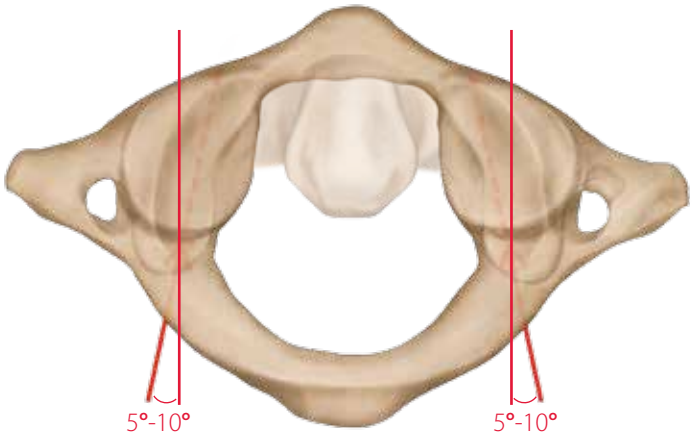


Figure 4

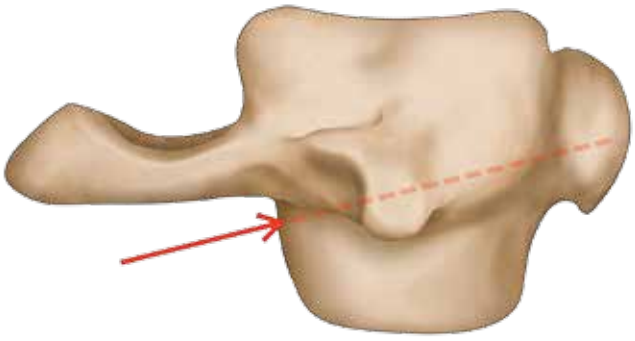


Figure 5

C1 Lateral Mass Screw Fixation *Continued*

Tapping (Optional)

Vertex screws are self-tapping, therefore this surgical step is considered optional. If tapping is desired, place the Tap Sleeve over the end of the Tap Shaft (**Figure 6**) to visualize the depth of the tap in bone. The trajectory of the tap should follow the same trajectory as outlined for drilling.

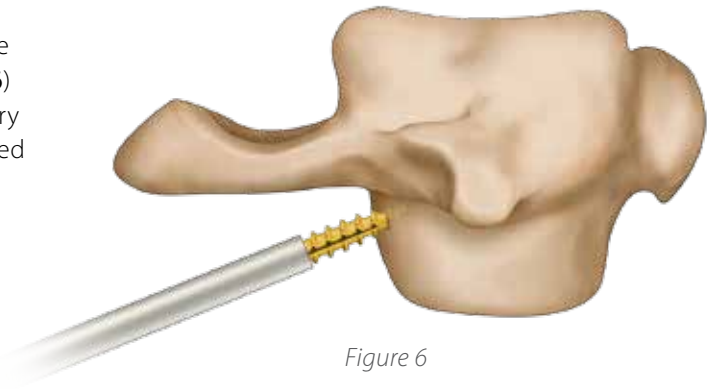


Figure 6

Note

*The gold anodized tip of the tap represents the first 10mm of thread (***Figure 7***).*

Figure 7

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 8**).

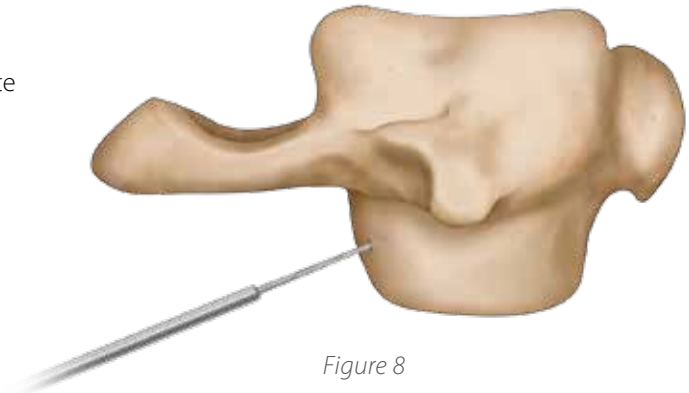


Figure 8

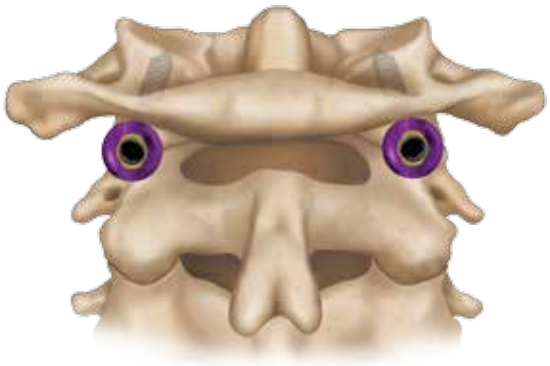
C1 Lateral Mass Screw Fixation *Continued*

Screw Insertion

Once the desired screw length is selected, the screw is attached to the Quick Release Self-Holding Screwdriver or the Threaded Screwdriver along with the Universal Handle, and inserted into the bone.

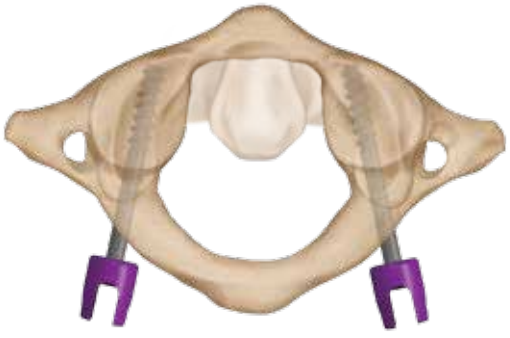
Refer to **Figure 9** for final screw positioning.

Confirmation of the screw position can be made using radiographs or intraoperative fluoroscopy.



C1 Lateral Mass Screw Fixation

Figure 9



C2 Pedicle and Pars Interarticularis Screw Fixation

C2 Pedicle and Pars Interarticularis Screw Fixation

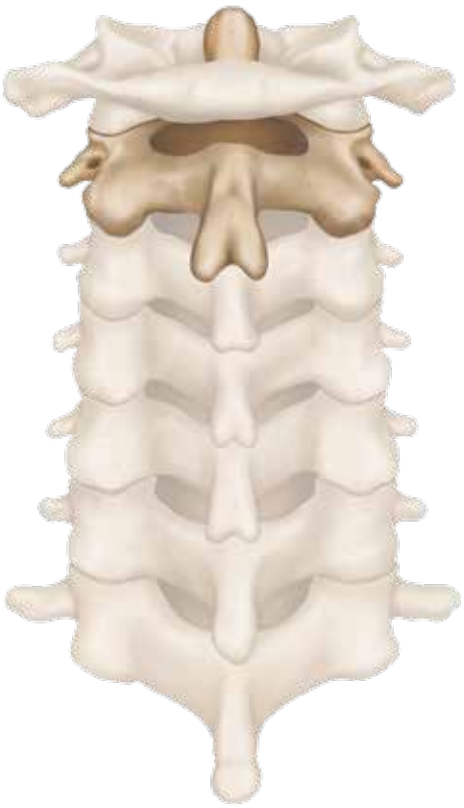
Pre-Operative Planning

The unique anatomy at C2 allows for placement of a screw in the pedicle or pars interarticularis.

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 Dickman[3], and C2 pars interarticularis screw fixation as described by Mummaneni[4] and Foley.[5]



Posterior view of C2

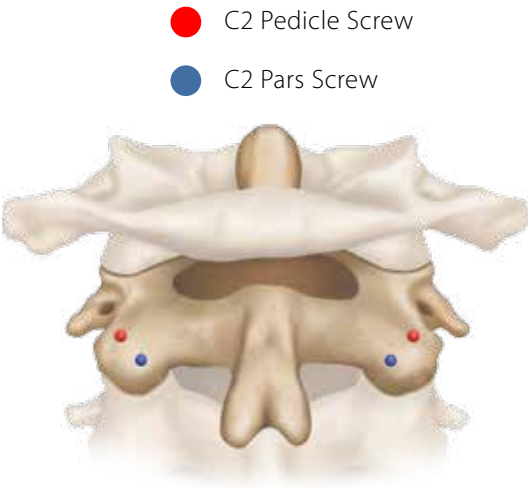
Figure 10

Determining Entry Points

For screw placement in the C2 pedicle, the entry point is 3mm – 4mm above the C2 inferior facet (**Figure 11**).

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 11**).

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



Posterior view of C2

Figure 11

C2 Pedicle and Pars Interarticularis Screw Fixation *Continued*

Drilling

For drilling guidelines and operation of the adjustable drill guide, refer to page 4.

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 12**). In the sagittal plane, the drill bit is angled approximately 20˚-30˚ cephalad (**Figure 13**).

For screw placement in the **C2 pars interarticularis**, the drill bit should be angled slightly medial (10˚-15˚) (**Figure 12**). In the sagittal plane, the drill bit is angled approximately 35˚ cephalad, assessed fluoroscopically by aiming toward the anterior tubercle of C1 (**Figure 13**).

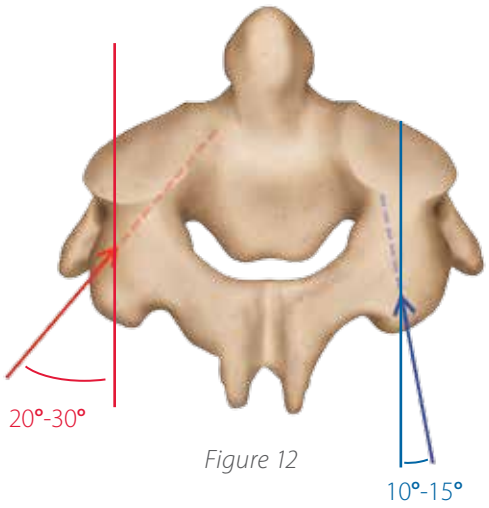


Figure 12

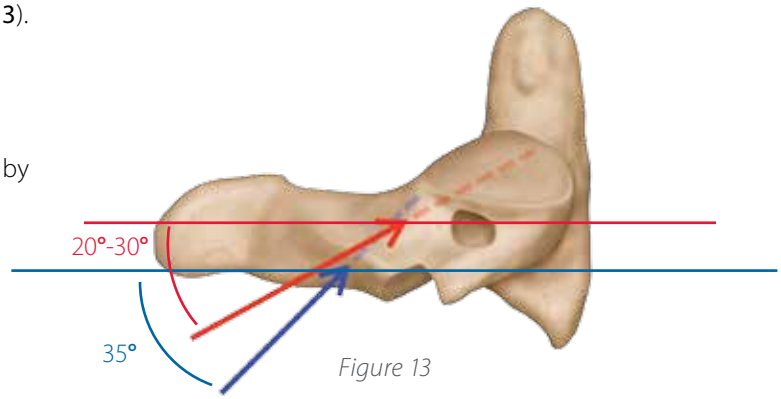


Figure 13

Tapping (Optional)

For tapping guidelines, refer to page 5.

Probing and Screw Measurement

For probing and screw measurement guidelines, refer to page 5.

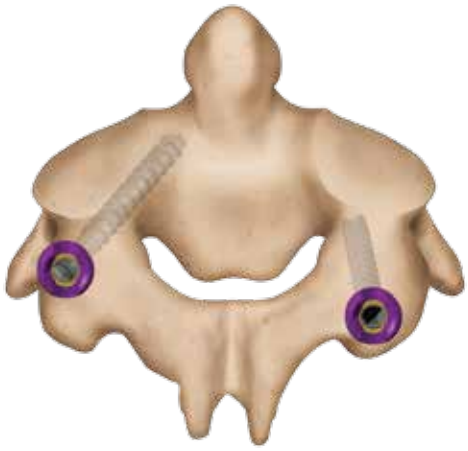
C2 Pedicle and Pars Interarticularis Screw Fixation *Continued*

Screw Insertion

Once the desired screw length is selected, the screw is attached to the Quick Release Self-Holding Screwdriver or the Threaded Screwdriver along with the Universal Handle, and inserted into the bone.

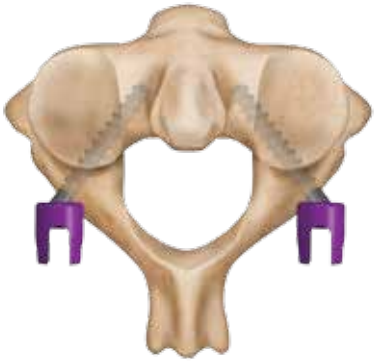
Refer to **Figure 14** for final screw positioning for a C2 Pedicle and Pars Interarticularis Screw.

Confirmation of the screw position can be made using radiographs or intraoperative fluoroscopy.

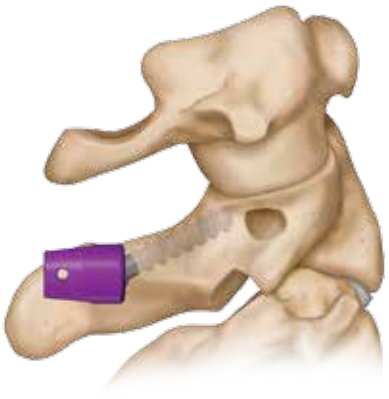


C2 Pedicle and Pars Interarticularis Screw Fixation

Figure 14



C2 Pedicle Screw



C2 Pars Interarticularis Screw

C2 Translaminar Screw Fixation

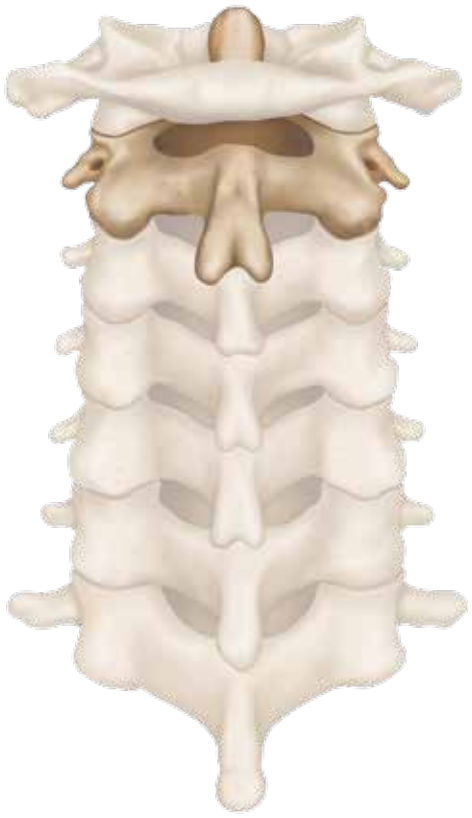
C2 Translaminar Screw Fixation

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.

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



Posterior view of C2

Figure 15

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 16**).

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 16**).

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

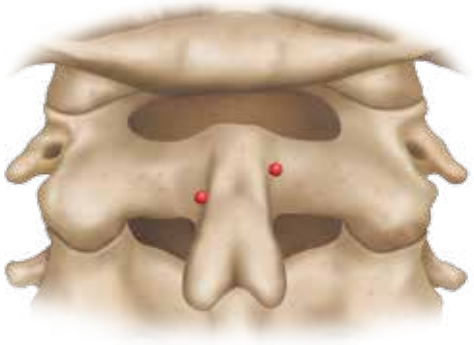


Figure 16

C2 Translaminar Screw Fixation *Continued*

Drilling

For drilling guidelines and operation of the adjustable drill guide, refer to page 4.

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 17**). 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.

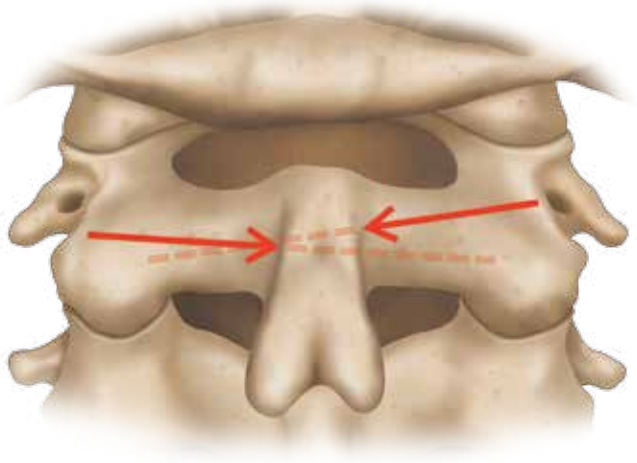


Figure 17

Tapping (Optional)

For tapping guidelines, refer to page 5.

Probing and Screw Measurement

For probing and screw measurement guidelines, refer to page 5.

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

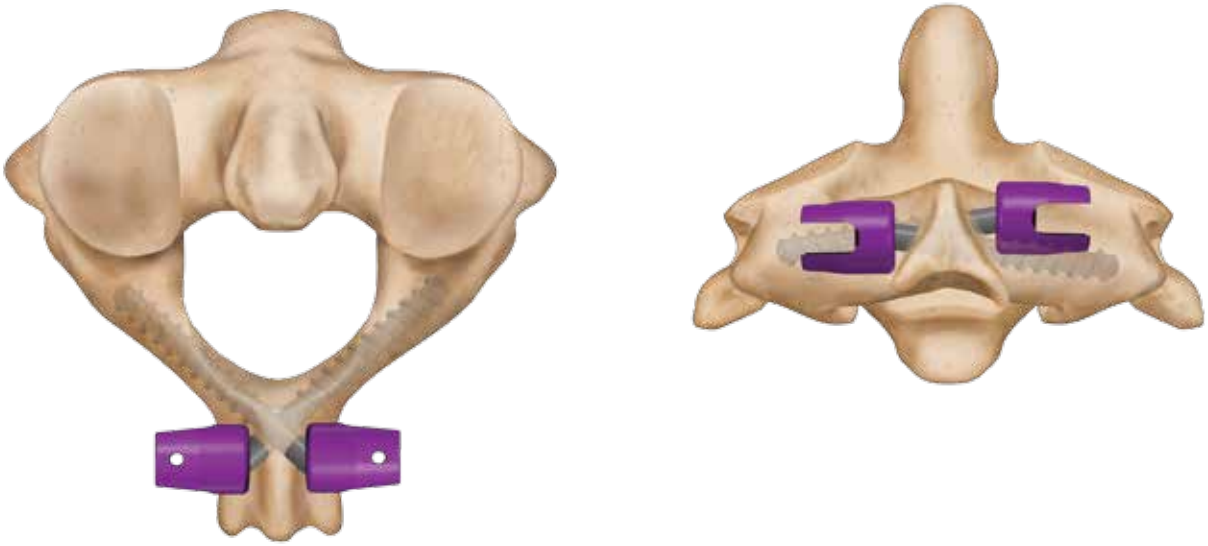
C2 Translaminar Screw Fixation *Continued*

Screw Insertion

Once the desired screw length is selected, the screw is attached to the Quick Release Self-Holding Screwdriver or the Threaded Screwdriver along with the Universal Handle, and inserted into the bone.

Refer to **Figure 18** for final screw positioning.

Confirmation of the screw position can be made using radiographs or intraoperative fluoroscopy.



C2 Translaminar Screw Fixation

Figure 18

C1-C2 Transarticular Screw Fixation

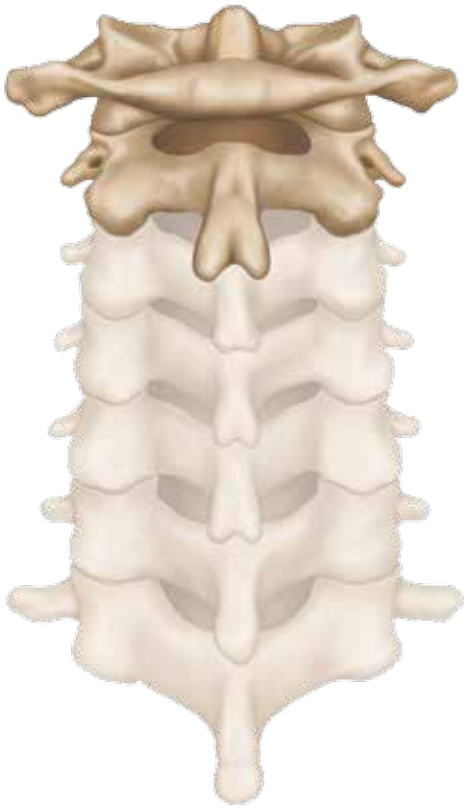
C1-C2 Transarticular Screw Fixation

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.

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 19

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 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.

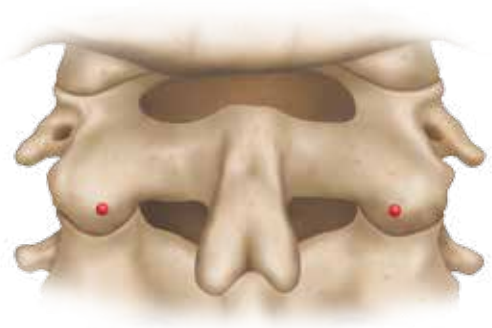


Figure 20

C1-C2 Transarticular Screw Fixation *Continued*

Drilling

For drilling guidelines and operation of the adjustable drill guide, refer to page 4.

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 21**).

The cephalad/caudal trajectory is assessed fluoroscopically 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 22**).

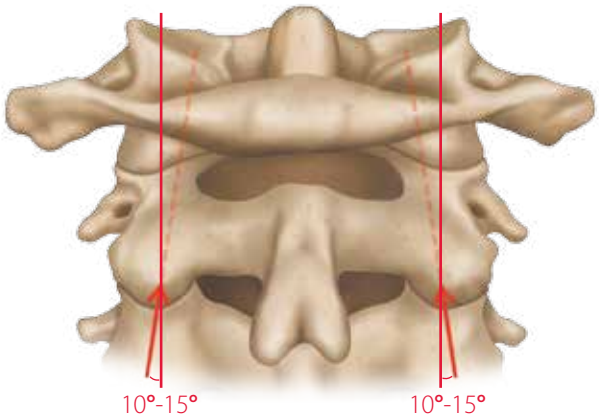


Figure 21

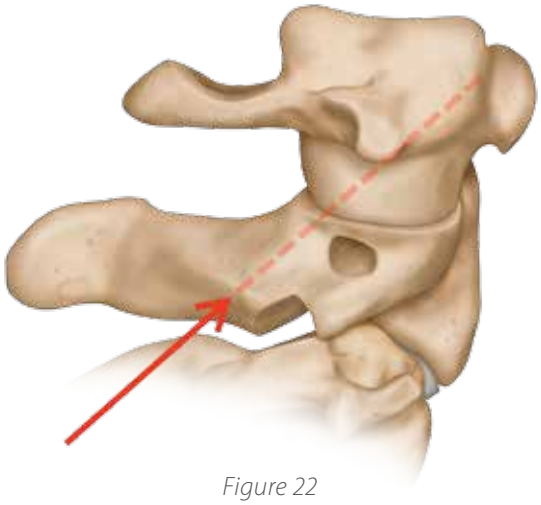


Figure 22

Tapping (Optional)

For tapping guidelines, refer to page 5.

Probing and Screw Measurement

For probing and screw measurement guidelines, refer to page 5.

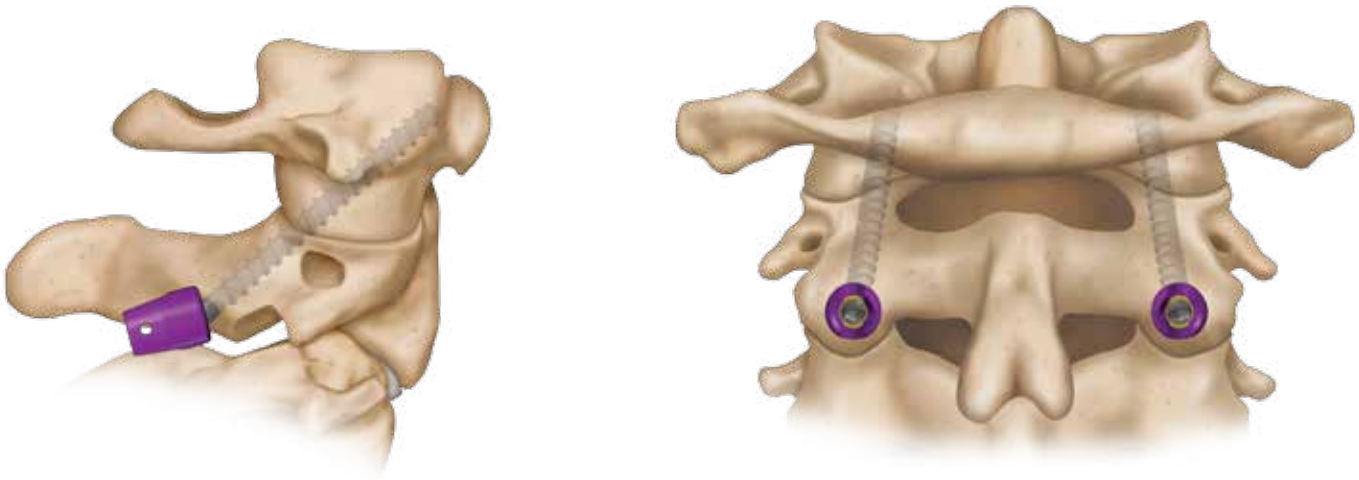
C1-C2 Transarticular Screw Fixation *Continued*

Screw Insertion

Once the desired screw length is selected, the screw is attached to the Self-Holding Screwdriver along with the Universal Handle, and inserted into the bone.

Refer to **Figure 23** for final screw positioning.

Confirmation of the screw position can be made using radiographs or intraoperative fluoroscopy.



C1-C2 Transarticular Screw Fixation

Figure 23

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.

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

Posterior view of C3 – C7

Figure 24

C3 – C7 Lateral Mass Screw Fixation *Continued*

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 25**).

The entry point is 1mm medial to the center of the lateral mass (**Figures 26**). 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.

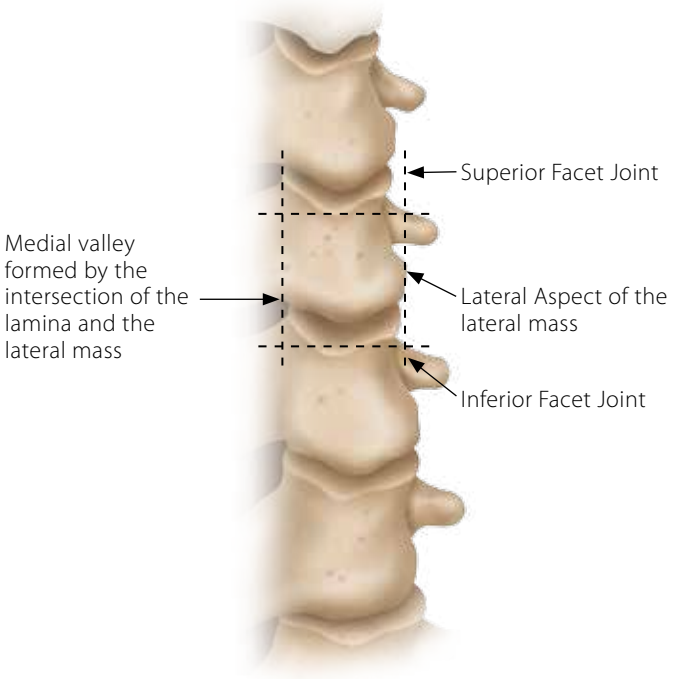


Figure 25

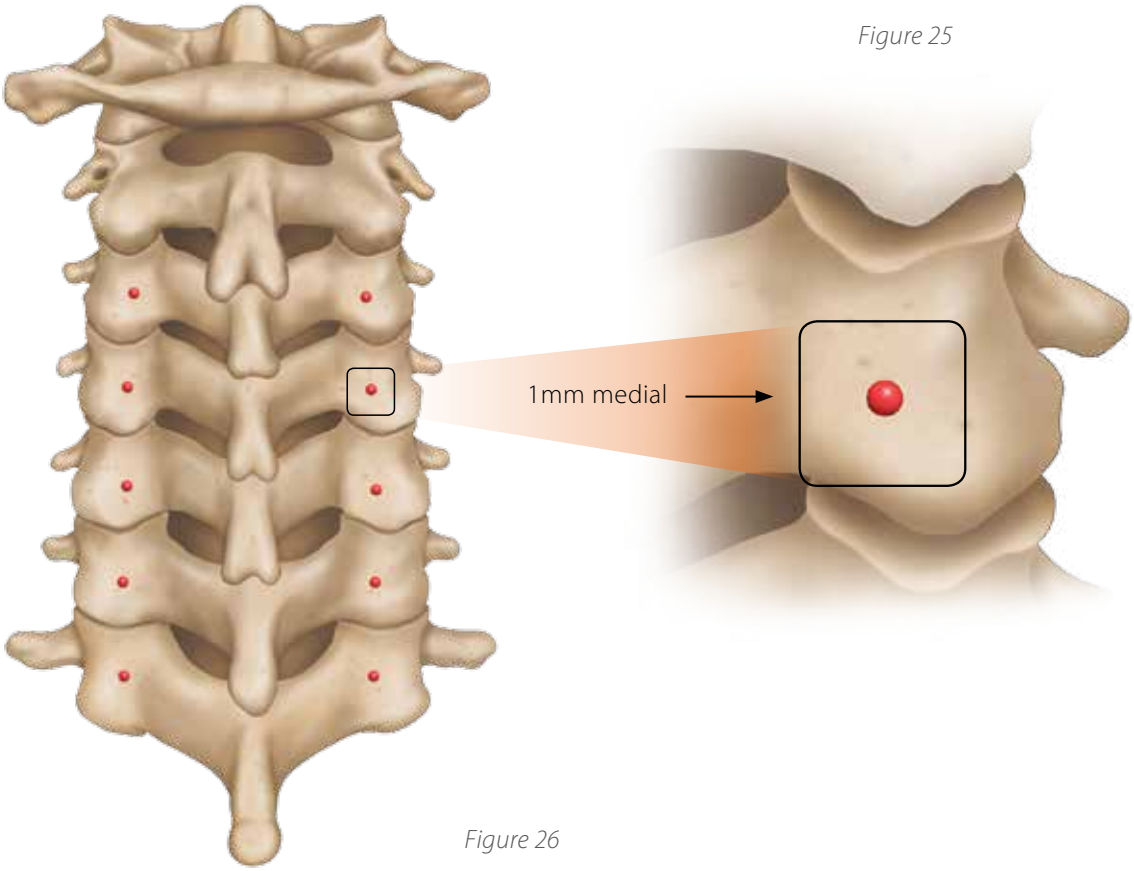


Figure 26

C3 – C7 Lateral Mass Screw Fixation *Continued*

Drilling

For drilling guidelines and operation of the adjustable drill guide, refer to page 4.

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˚ – 30˚ laterally (**Figure 27**) and approximately 20˚ – 30 ˚cephalad (**Figure 28**).

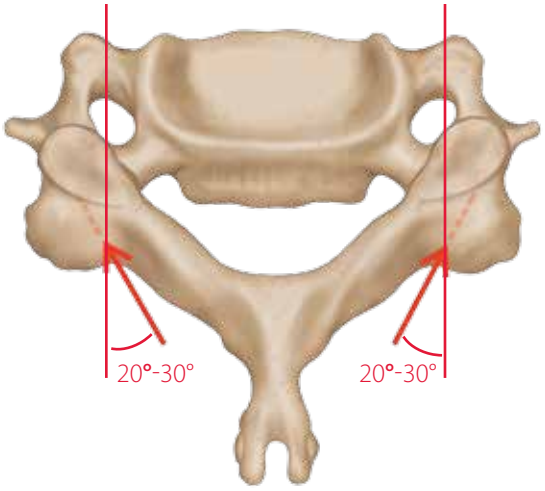


Figure 27

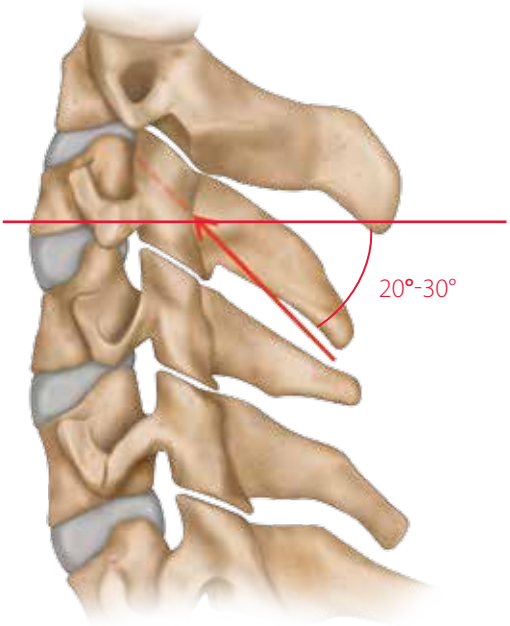


Figure 28

Tapping (Optional)

For tapping guidelines, refer to page 5.

Probing and Screw Measurement

For probing and screw measurement guidelines, refer to page 5.

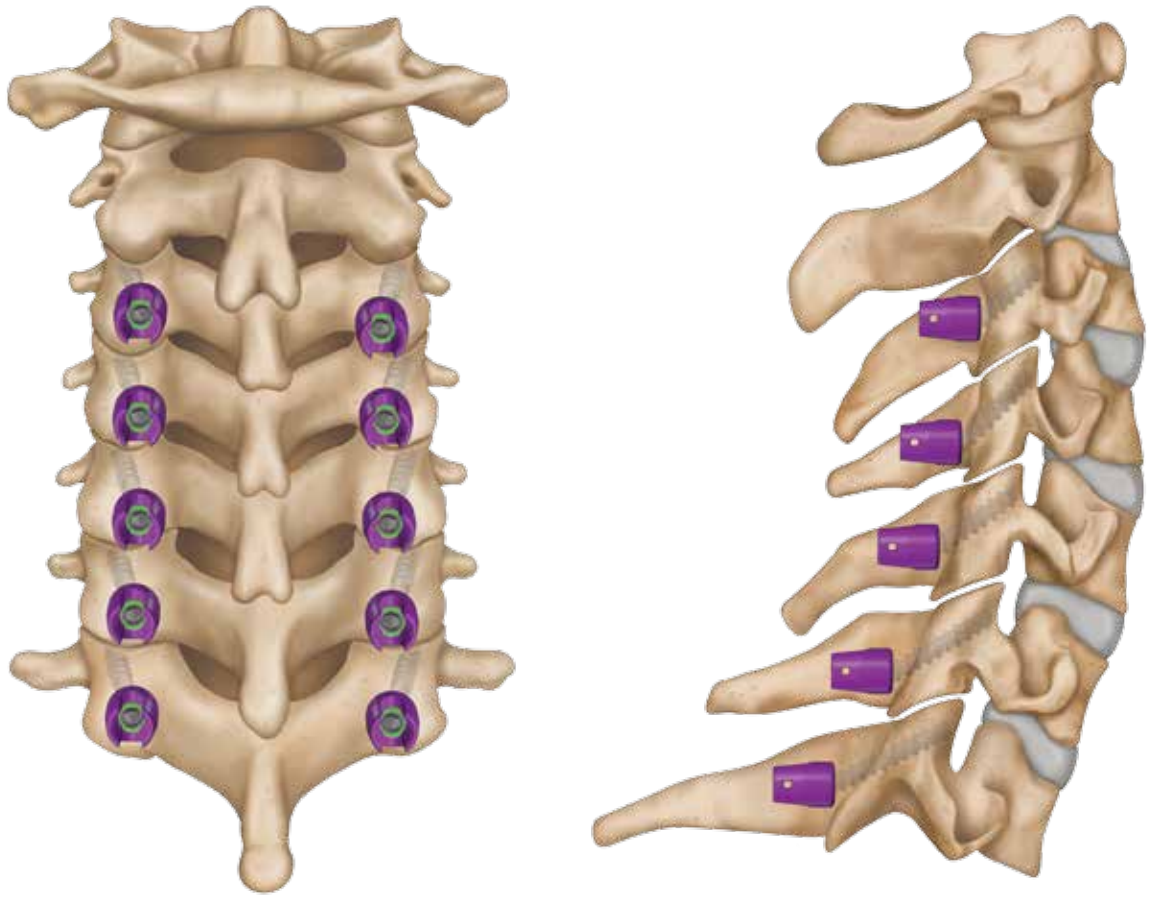
C3 – C7 Lateral Mass Screw Fixation *Continued*

Screw Insertion

Once the desired screw length is selected, the screw is attached to the Quick Release Self-Holding Screwdriver or the Threaded Screwdriver along with the Universal Handle, and inserted into the bone. Additional screws are placed using the same technique.

Refer to **Figure 29** for final screw placement.

Confirmation of screw positions can be made using radiographs or intraoperative fluoroscopy.



C3 – C7 Lateral Mass Screw Fixation

Figure 29

C3-C7 Pedicle Screw Fixation

C3-C7 Pedicle Screw Fixation

Pre-Operative Planning

When placing C3-C7 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]

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 31**).

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

Posterior view of C3 – C7

Figure 30

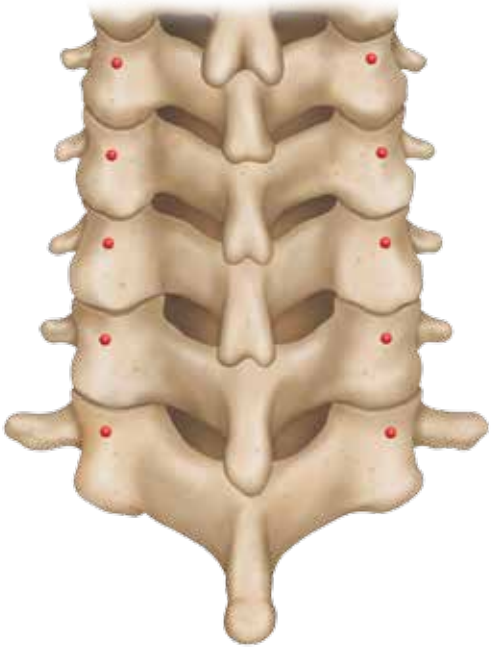


Figure 31

C3-C7 Pedicle Screw Fixation *Continued*

Drilling

For drilling guidelines and operation of the adjustable drill guide, refer to page 4.

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 32**).

For C3-C4, the drill trajectory in the sagittal plane is slightly cephalad. For C5-C7, the drill trajectory in the sagittal plane is parallel to the upper endplate of the pedicles (**Figure 33**).

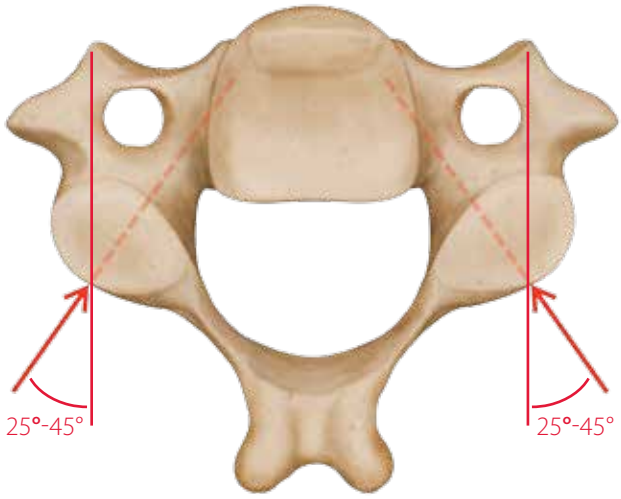


Figure 32

Tapping (Optional)

For tapping guidelines, refer to page 5.

Probing and Screw Measurement

For probing and screw measurement guidelines, refer to page 5.

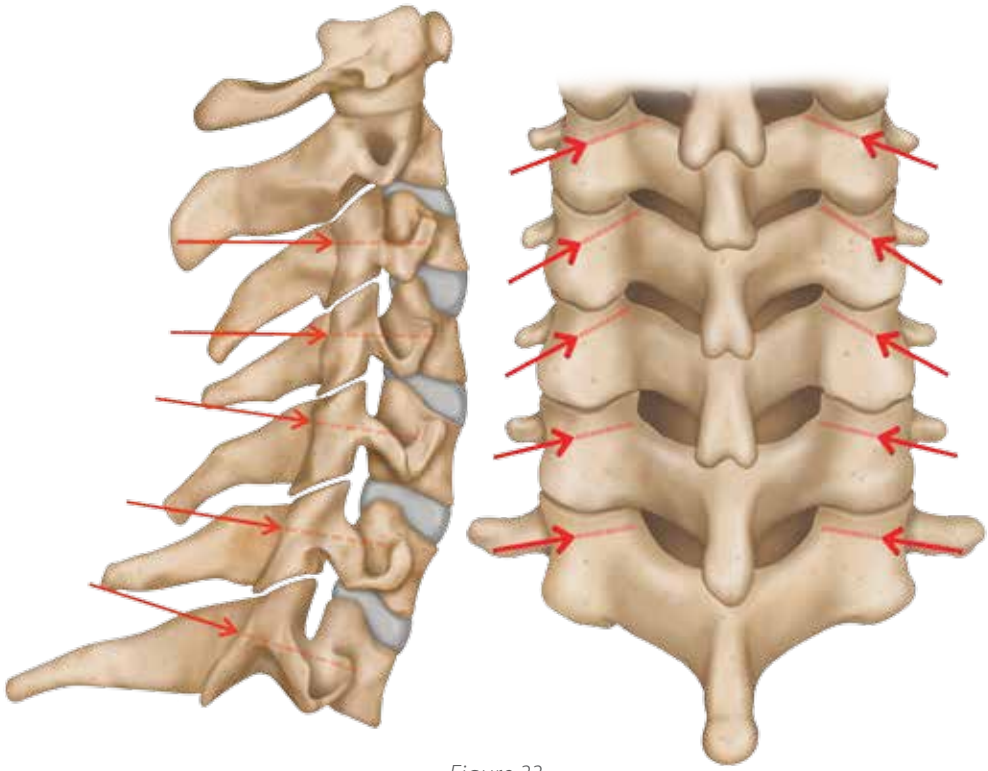


Figure 33

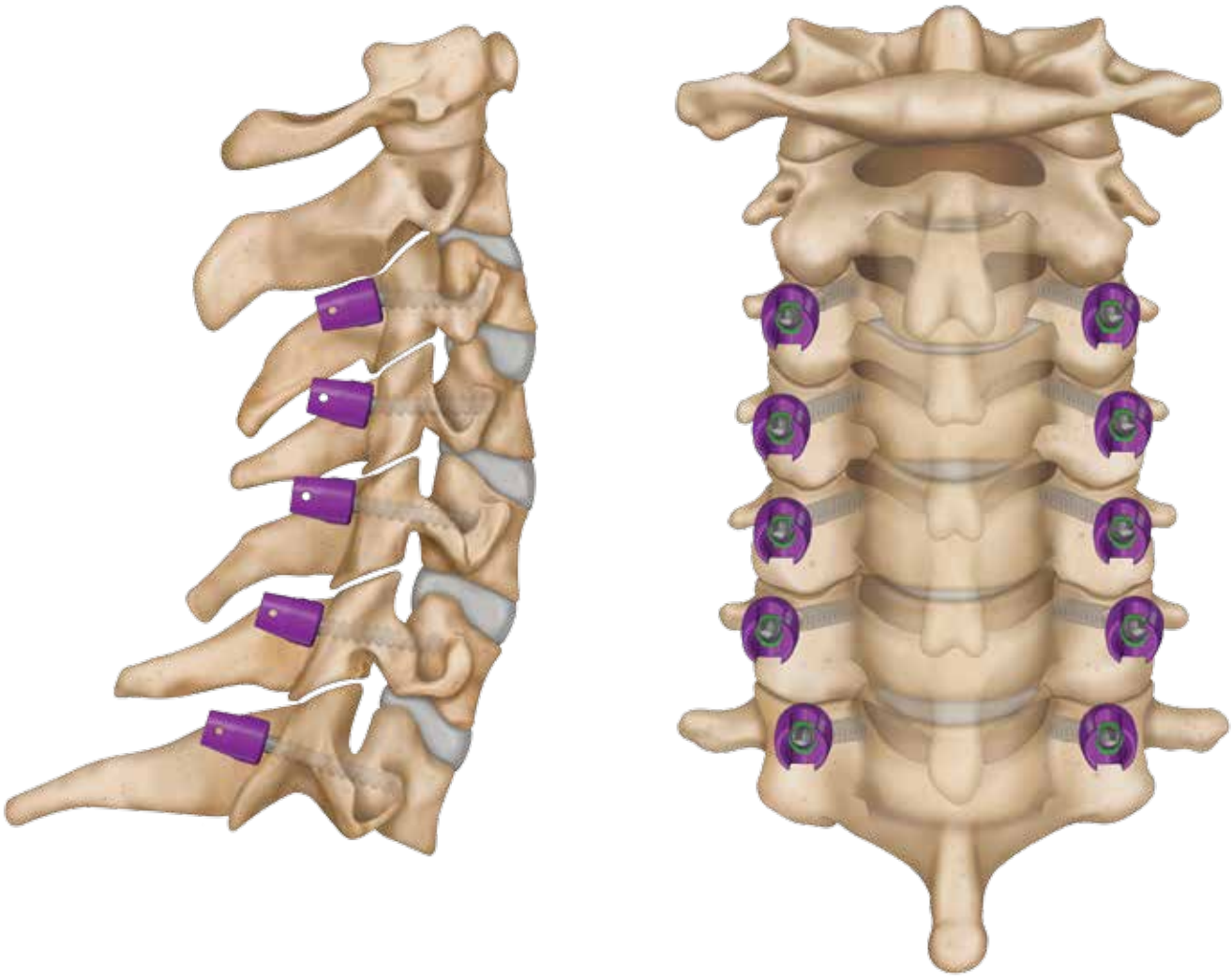
C3-C7 Pedicle Screw Fixation *Continued*

Screw Insertion

Once the desired screw length is selected, the screw is attached to the Quick Release Self-Holding Screwdriver or the Threaded Screwdriver along with the Universal Handle, and inserted into the bone.

Refer to **Figure 34** for final screw positioning. Additional screws are placed using the same technique.

Confirmation of the screw position can be made using radiographs or intraoperative fluoroscopy.



C3-C7 Pedicle Screw Fixation

Figure 34

Final Construct Assembly

After all the screws have been placed, the remainder of the construct may be assembled (**Figure 35**). 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.

Figure 35

References

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4 Mummaneni, P. (2002). Posterior cervical fixation using a new polyaxial screw and rod system: Technique and surgical results. *Neurosurgery Focus*, 12(January), 1-5.

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Important Information on the VERTEX® Reconstruction System

PURPOSE

The VERTEX® Reconstruction System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the craniocervical, cervical, and/or upper thoracic spine (occiput-T3).

DESCRIPTION

The VERTEX® Reconstruction System is a posterior system, which consists of a variety of shapes and sizes of plates, rods, hooks, screws, multi-axial screws, and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case. Titanium ATLAS® cable may be used with this system at the surgeon's discretion. See the package inserts of both of those systems for labeling limitations.

The VERTEX® Reconstruction System is fabricated from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium. Medical grade titanium, medical grade titanium alloy, and/or medical grade cobalt chromium may be used together. Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same construct. The VERTEX® Reconstruction System includes a retaining ring for the multi-axial screw made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium, titanium alloy, and cobalt chromium implants only. The posted screw connectors and some multi-axial screws contain elastomeric stakes made of silicone adhesive commonly used in implantable medical devices. Do not use with stainless steel. No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

To achieve best results, do not use any of the VERTEX® Reconstruction System implant components with components from any other system or manufacturer unless specifically labeled to do so in this or another Medtronic document. As with all orthopedic and neurosurgical implants, none of the VERTEX® Reconstruction System components should ever be reused under any circumstances.

INDICATIONS

The VERTEX® Reconstruction System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The VERTEX® Reconstruction System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the VERTEX® Reconstruction System may be connected to the CD HORIZON® Spinal System rods with the VERTEX® rod connectors. Transition rods with differing diameters may also be used to connect the VERTEX® Reconstruction System to the CD HORIZON® Spinal System. Refer to the CD HORIZON® Spinal System package insert for a list of the CD HORIZON® Spinal System indications of use.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- 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.
- 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, but is not limited to:

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/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, and/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, and/or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
- Neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or 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 and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body), and/or bone graft or bone graft harvest site at, above, and/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.
- 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.

WARNINGS AND PRECAUTIONS

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, and/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.

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 severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Precaution: The implantation of spinal screw systems should be performed only by experienced spinal surgeons with specific training in the use of this spinal screw system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

This system was designed for single patient use only. Never, under any circumstances, reuse a VERTEX® Reconstruction System device. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.

Precaution: The implantation of spinal fixation systems should be performed only by experienced spinal surgeons with specific training in the use of these spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant diameter and length.

Precaution: Pre-Operative Planning - Use of cross sectional imaging (i.e., CT and/or MRI) for posterior cervical screw placement is recommended due to the unique risks in the cervical spine. The use of planar radiographs alone may not provide the necessary imaging to mitigate the risk of improper screw placement. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

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.

!USA **FOR US AUDIENCES ONLY**

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

Notes

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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.

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

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

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