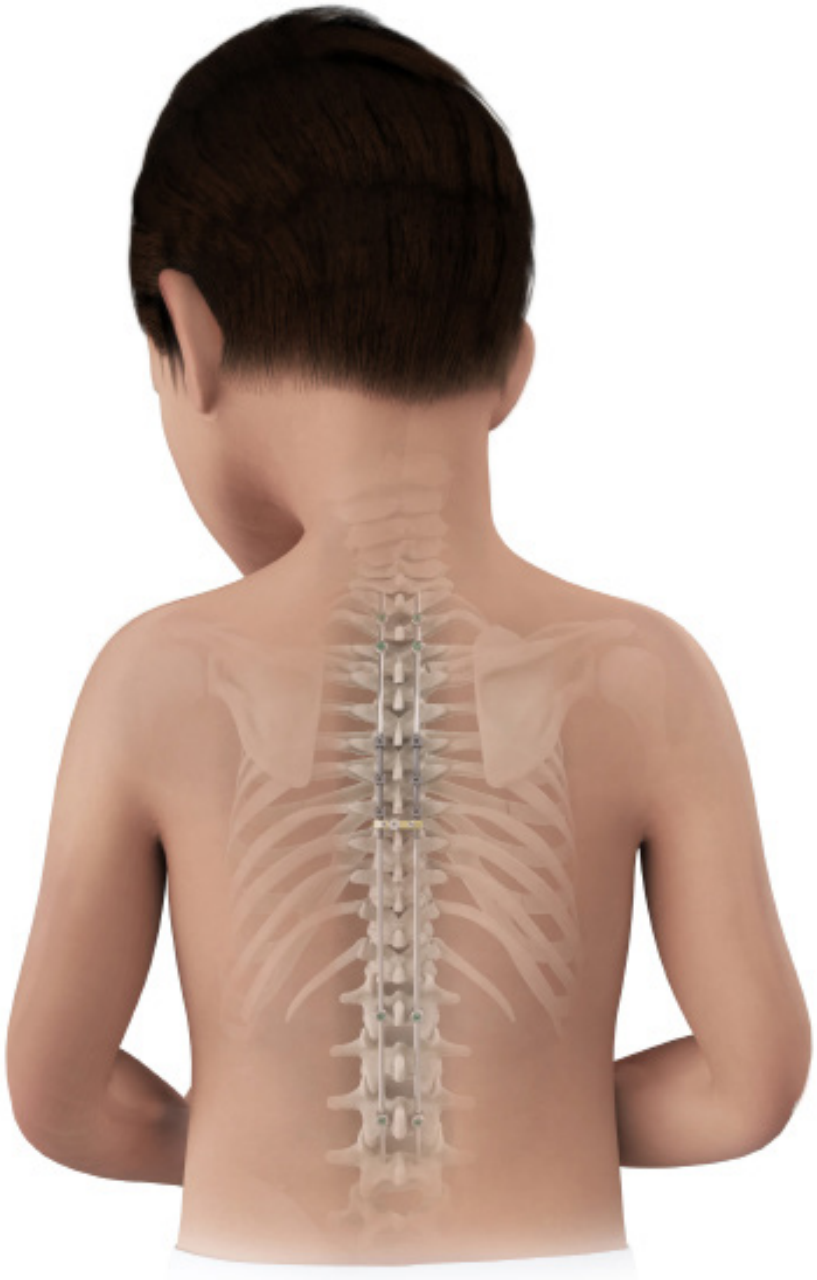
VerteGlide™ Spinal Growth Guidance System

SURGICAL TECHNIQUE



OrthoPediatrics®
Leading Innovation in Pediatric Orthopedics

TABLE OF CONTENTS

System Overview

VerteGlide Surgical Technique

Important Medical Information

Overview

The VerteGlide Spinal Growth Guidance System is designed for patients with Early Onset Scoliosis and aims to correct the deformity with a fusion at the apex of the curve while allowing for growth guidance along the rest of the spine. The VerteGlide Spinal Growth Guidance system includes 4.5mm and 5.5mm rod diameters and is compatible with the RESPONSE 4.5/5.0 or 5.5/6.0 systems.

Indications for Use

The VerteGlide Spinal Growth Guidance System is indicated for skeletally immature patients less than 10 years of age with the potential for additional spinal growth who require surgical treatment for correction and maintenance of the correction of severe, progressive, life-threatening early onset deformities, including early-onset scoliosis, which are associated with or at risk of thoracic insufficiency syndrome for the following subset of patients:

- Patients who may require serial magnetic resonance imaging;
- Patients with small stature;
- Patients with low body weight, compromised tissue coverage adjacent to spinal implants, or increased risk of implant associated wound healing adverse events;
- Patients at risk for implant prominence following surgery;
- Patients with hyperkyphotic spinal deformities; OR
- Patients at elevated risk of cardiac arrest/ sudden death from anesthesia associated with additional spinal surgery.

The VerteGlide Guided Growth System is intended to be removed after skeletal maturity.

The VerteGlide Navigation Compatible Instruments are intended to be used during the preparation and placement of the VerteGlide Spinal Growth Guidance System screws. The VerteGlide Navigation Compatible Instruments have the option to be used with or without Medtronic StealthStation® System. Use of VerteGlide Navigation Compatible Instruments with Medtronic StealthStation® System during spinal surgery can assist the surgeon in precisely locating anatomical structures in the VerteGlide Spinal Growth Guidance System procedures. The Medtronic StealthStation® System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

PEDICLE SCREWS

Open Screws

4.5MM Screw Shank Sea Foam | 5.0MM Screw Shank Dark Blue | 5.5MM Screw Shank Gold | 6.0MM Screw Shank Green | 6.5MM Screw Shank Light Blue

VerteGlide Implant Classification

Each pedicle screw size is designed with a unique color identifier as shown in the illustration above. The screw shank colors are used to differentiate the diameter of the screw. Pedicle screws are offered in open and closed configurations. The closed screws do not require a set screw; alternatively, they offer a smaller profile. These can be identified by the closed profile of the tulip head. The open screws then contain an opening in the tulip head that the rod can be reduced into, with a tulip head that displays a traditional U-shaped profile.

NOTE: The Open Screws allow for rod reduction while the Closed screws offer a lower profile. Consider soft tissue coverage when planning the location of open/closed screws and the selection of the 4.5 or 5.5 mm rod/screw sizes.

NOTE: The system is compatible with existing Response 4.5/5.0 and 5.5/6.0 fusion pedicle screws for use at the apex of the spine. Refer to Response surgical techniques for implant information about these screws.

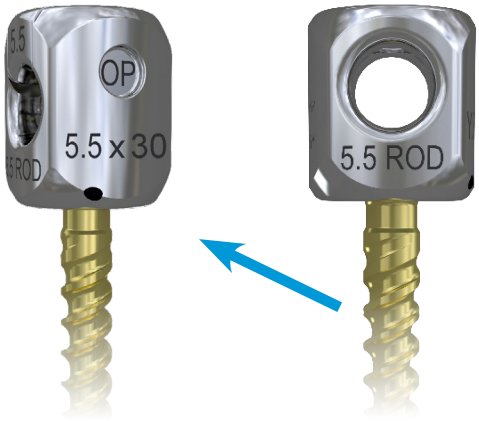
WARNING: Fusion screw compatibility with the VerteGlide system include sizes 4.5-6.5 mm screw diameters. Do not use 4.0 mm diameter fusion screws with the VerteGlide system.

Closed Screws

4.5 diameter identified by black ring

5.5 Closed Screw

4.5 Closed Screw

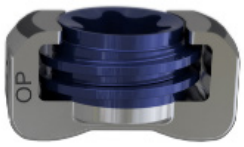


VerteGlide Implant Classification *(cont.)*

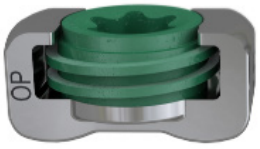
The 4.5 and 5.5 screw designs both include highly polished CoCr tulip heads that are silver in color. Screw shank colors remain the same between both rod diameter size options. In addition to markings that indicate 4.5 and 5.5, the 4.5 tulip heads (both closed and open) also contain a solid black ring around the top of the tulip head to differentiate from the 5.5.

Screw diameter and length are indicated on the side surface of the tulip head.

Set Screws



4.5mm Set Screw Assembly



5.5mm Set Screw Assembly

Rods

4.5mm & 5.5mm Standard Rods

4.5mm & 5.5mm Offset Rods

VerteGlide Implant Classification *(cont.)*

The VerteGlide set screws are comprised of a pre-assembled set screw and housing. The 4.5 set screws are **blue** and the 5.5 set screws are **green.**

Rods are offered in 4.5 and 5.5mm diameters in 500mm overall length. The VerteGlide rods contain a grit-blasted center section to be used at the apex of the curve for the fusion screws, while the ends of the rod remain polished smooth for the sliding screws.

The grit-blasted section is offered in lengths of 60, 90, and 120mm depending on the length of the fusion section needed. The rods are offered in both a standard and offset geometry.

IMPLANTS

VerteGlide Polyaxial Pedicle Screws, Open

4.5mm Rod System: Screws, Open

Item Number	Description
00-1721-4520	4.5MM X 20MM
00-1721-4525	4.5MM X 25MM
00-1721-4530	4.5MM X 30MM
00-1721-4535	4.5MM X 35MM
00-1721-4540	4.5MM X 40MM
00-1721-4545	4.5MM X 45MM
00-1721-4550	4.5MM X 50MM
00-1721-5020	5.0MM X 20MM
00-1721-5025	5.0MM X 25MM
00-1721-5030	5.0MM X 30MM
00-1721-5035	5.0MM X 35MM
00-1721-5040	5.0MM X 40MM
00-1721-5045	5.0MM X 45MM
00-1721-5050	5.0MM X 50MM
00-1721-5520	5.5MM X 20MM
00-1721-5525	5.5MM X 25MM
00-1721-5530	5.5MM X 30MM
00-1721-5535	5.5MM X 35MM
00-1721-5540	5.5MM X 40MM
00-1721-5545	5.5MM X 45MM
00-1721-5550	5.5MM X 50MM
00-1721-6020	6.0MM X 20MM
00-1721-6025	6.0MM X 25MM
00-1721-6030	6.0MM X 30MM
00-1721-6035	6.0MM X 35MM
00-1721-6040	6.0MM X 40MM
00-1721-6045	6.0MM X 45MM
00-1721-6050	6.0MM X 50MM
00-1721-6520	6.5MM X 20MM
00-1721-6525	6.5MM X 25MM
00-1721-6530	6.5MM X 30MM
00-1721-6535	6.5MM X 35MM
00-1721-6540	6.5MM X 40MM
00-1721-6545	6.5MM X 45MM
00-1721-6550	6.5MM X 50MM

5.5mm Rod System: Screws, Open

Item Number	Description
00-1723-4520	4.5MM X 20MM
00-1723-4525	4.5MM X 25MM
00-1723-4530	4.5MM X 30MM
00-1723-4535	4.5MM X 35MM
00-1723-4540	4.5MM X 40MM
00-1723-4545	4.5MM X 45MM
00-1723-4550	4.5MM X 50MM
00-1723-5020	5.0MM X 20MM
00-1723-5025	5.0MM X 25MM
00-1723-5030	5.0MM X 30MM
00-1723-5035	5.0MM X 35MM
00-1723-5040	5.0MM X 40MM
00-1723-5045	5.0MM X 45MM
00-1723-5050	5.0MM X 50MM
00-1723-5520	5.5MM X 20MM
00-1723-5525	5.5MM X 25MM
00-1723-5530	5.5MM X 30MM
00-1723-5535	5.5MM X 35MM
00-1723-5540	5.5MM X 40MM
00-1723-5545	5.5MM X 45MM
00-1723-5550	5.5MM X 50MM
00-1723-6020	6.0MM X 20MM
00-1723-6025	6.0MM X 25MM
00-1723-6030	6.0MM X 30MM
00-1723-6035	6.0MM X 35MM
00-1723-6040	6.0MM X 40MM
00-1723-6045	6.0MM X 45MM
00-1723-6050	6.0MM X 50MM
00-1723-6520	6.5MM X 20MM
00-1723-6525	6.5MM X 25MM
00-1723-6530	6.5MM X 30MM
00-1723-6535	6.5MM X 35MM
00-1723-6540	6.5MM X 40MM
00-1723-6545	6.5MM X 45MM
00-1723-6550	6.5MM X 50MM

IMPLANTS

VerteGlide Polyaxial Pedicle Screws, Closed

4.5mm Rod System: Screws, Closed

Item Number	Description
00-1722-4520	4.5MM X 20MM
00-1722-4525	4.5MM X 25MM
00-1722-4530	4.5MM X 30MM
00-1722-4535	4.5MM X 35MM
00-1722-4540	4.5MM X 40MM
00-1722-5020	5.0MM X 20MM
00-1722-5025	5.0MM X 25MM
00-1722-5030	5.0MM X 30MM
00-1722-5035	5.0MM X 35MM
00-1722-5040	5.0MM X 40MM
00-1722-5520	5.5MM X 20MM
00-1722-5525	5.5MM X 25MM
00-1722-5530	5.5MM X 30MM
00-1722-5535	5.5MM X 35MM
00-1722-5540	5.5MM X 40MM
00-1722-6020	6.0MM X 20MM
00-1722-6025	6.0MM X 25MM
00-1722-6030	6.0MM X 30MM
00-1722-6035	6.0MM X 35MM
00-1722-6040	6.0MM X 40MM
00-1722-6520	6.5MM X 20MM
00-1722-6525	6.5MM X 25MM
00-1722-6530	6.5MM X 30MM
00-1722-6535	6.5MM X 35MM
00-1722-6540	6.5MM X 40MM

5.5mm Rod System: Screws, Closed

Item Number	Description
00-1724-4520	4.5MM X 20MM
00-1724-4525	4.5MM X 25MM
00-1724-4530	4.5MM X 30MM
00-1724-4535	4.5MM X 35MM
00-1724-4540	4.5MM X 40MM
00-1724-5020	5.0MM X 20MM
00-1724-5025	5.0MM X 25MM
00-1724-5030	5.0MM X 30MM
00-1724-5035	5.0MM X 35MM
00-1724-5040	5.0MM X 40MM
00-1724-5520	5.5MM X 20MM
00-1724-5525	5.5MM X 25MM
00-1724-5530	5.5MM X 30MM
00-1724-5535	5.5MM X 35MM
00-1724-5540	5.5MM X 40MM
00-1724-6020	6.0MM X 20MM
00-1724-6025	6.0MM X 25MM
00-1724-6030	6.0MM X 30MM
00-1724-6035	6.0MM X 35MM
00-1724-6040	6.0MM X 40MM
00-1724-6520	6.5MM X 20MM
00-1724-6525	6.5MM X 25MM
00-1724-6530	6.5MM X 30MM
00-1724-6535	6.5MM X 35MM
00-1724-6540	6.5MM X 40MM

IMPLANTS *(cont.)*

Cobalt Chrome Rod (CoCr) 4.5 x 500 mm

Item Number	Description
00-1725-4560	60MM FUSION, OFFSET
00-1725-4590	90MM FUSION, OFFSET
00-1725-4512	120MM FUSION, OFFSET
00-1726-4560	60MM FUSION
00-1726-4590	90MM FUSION
00-1726-4512	120MM FUSION

Cobalt Chrome Rod (CoCr) 5.5 x 500 mm

Item Number	Description
00-1725-5560	60MM FUSION, OFFSET
00-1725-5590	90MM FUSION, OFFSET
00-1725-5512	120MM FUSION, OFFSET
00-1726-5560	60MM FUSION
00-1726-5590	90MM FUSION
00-1726-5512	120MM FUSION

VerteGlide Open Set Screw Assemblies

Item Number	Description
00-1721-0010	4.5mm Set Screw Assembly
00-1723-0010	5.5mm Set Screw Assembly

Cross Connectors

Any cross-connector that can be used with the Response system is compatible for use on the grit-blast section of the VerteGlide rods.

Rod Clamps

4.5mm Rod Clamp
00-1721-0045

5.5mm Rod Clamp
00-1723-0055

INSTRUMENTS

4.5mm Specific Instruments

VerteGlide 4.5mm Rod Bend Checker
01-1721-2500

4.5mm Provisional Rod
01-1721-0450

VerteGlide 4.5mm Open Pedicle Screw Driver
01-1721-1000

VerteGlide 4.5mm Closed Pedicle Screw Driver
01-1722-1000

VerteGlide 4.5mm Manual Counter Torque Tube
01-1721-1500

5.5mm Specific Instruments

VerteGlide 5.5mm Rod Bend Checker
01-1723-2500

5.5mm Provisional Rod
01-1723-0550

VerteGlide 5.5mm Manual Counter Torque Tube
01-1723-1500

VerteGlide 5.5mm Open Pedicle Screw Driver
01-1723-1000

VerteGlide 5.5mm Closed Pedicle Screw Driver
01-1724-1000

NOTE: Ensure the correct Response 4.5/5.0 or 5.5/6.0 set is present along with the VerteGlide Universal and correct VerteGlide size-specific sets so that the full scope of instruments needed to create a VerteGlide construct is available.

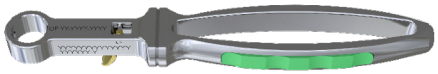
INSTRUMENTS

Universal Instruments

VerteGlide Final Torque Driver
01-1720-6000

Navigated Thoracic Lenke Probe
01-1720-0220

VerteGlide Provisional Set Screw Driver
01-1720-0500



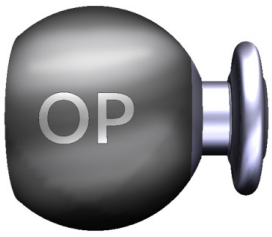
Counter Torque Handle
01-1720-0150

VerteGlide Reverse Action Rocker
01-1720-0275

VerteGlide Rocker
01-1720-0250

Navigated Cannulated Lenke Probe
01-1720-0200

Navigated Cannulated Lenke Probe - Insert
01-1720-0210



Cannulated Lenke Probe Ball Handle
01-1720-0230

INSTRUMENTS

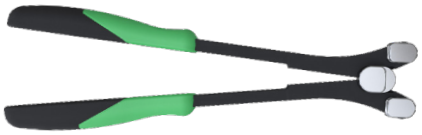
Universal Instruments

1.2mm Guide Wire (600mm)
01-1720-0300

Navigated Round Awl
01-1720-0100

Rod Template
01-1720-0045

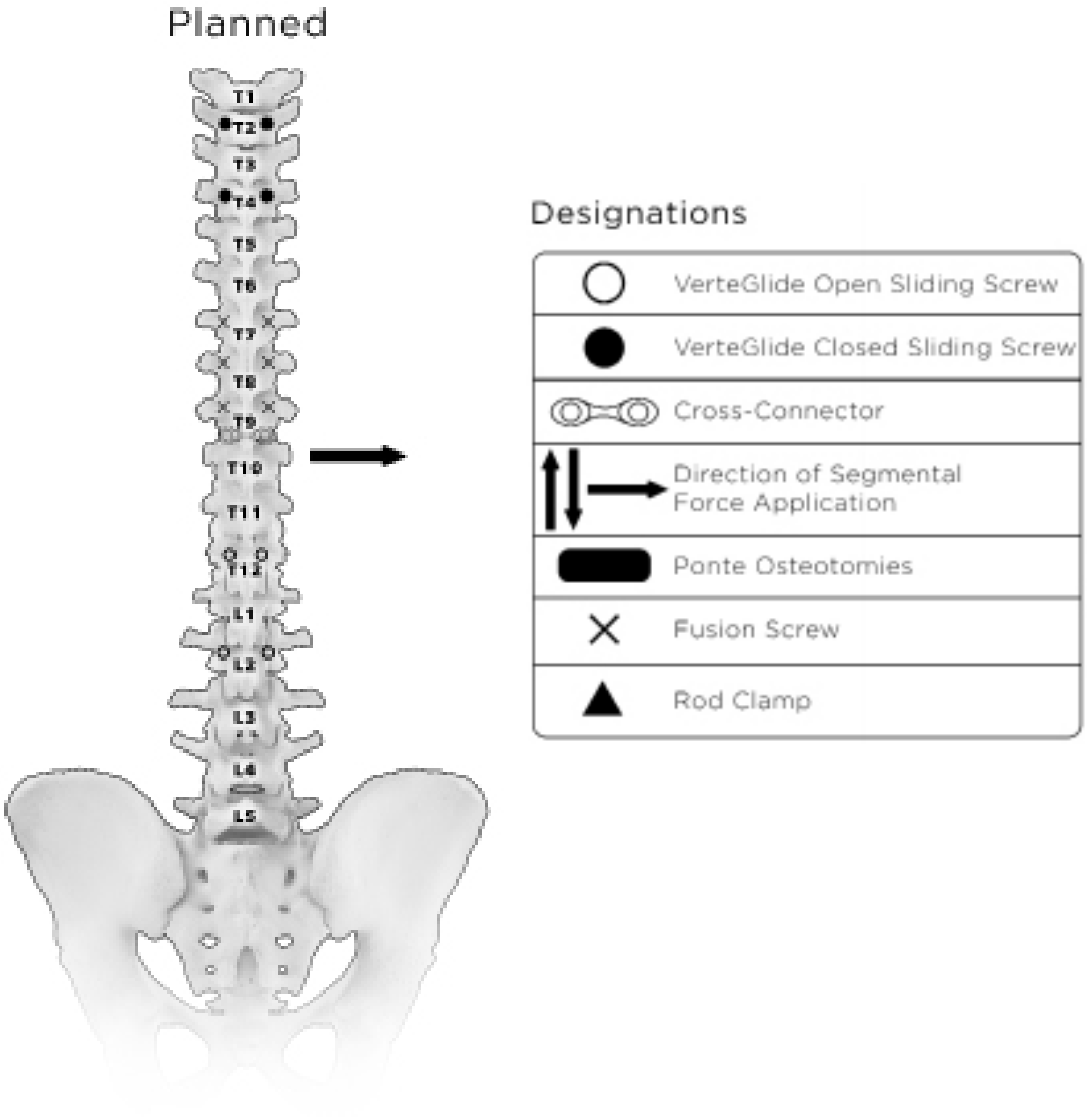
VerteGlide 3.5mm Tap
01-1720-3500



Soft Bend French Bender
01-1720-0400

VerteGlide 4.0-5.5mm Cannulated Tap
01-1720-4000
01-1720-4500
01-1720-5000
01-1720-5500

OPERATIVE PLANNING CHART



Preoperative Planning

Preoperative planning using radiographic, CT, or MRI imaging and physical reviews are important to assess the curve and select the appropriate treatment.

This includes (but is not limited to) radiographic and physical reviews. Radiographic CT, or MRI reviews should include anterior-posterior, sagittal and axial images to capture the structural nature of the three potential curves.

Decision making should include the number of operative levels (both fusion and non-fusion), corrective maneuver, curve flexibility, implant placement location, rod placement sequences, and tightening or correction techniques.

The use of an operative planning chart can be very helpful for surgical planning. When displayed in the operating room, it can serve as guidance for the surgical team. The chart on this page can be removed from this document and posted for easy reference.

NAVIGATION SYSTEM SETUP

The OrthoPediatrics Navigation Instruments are manual surgical instruments that may be used in conjunction with the Medtronic® StealthStation® S8 System. This technique describes how to register OrthoPediatrics Navigation Instruments to this version of the Medtronic® StealthStation®.

CAUTION: OrthoPediatrics is not a navigation provider. The navigation system must be set up per the manufacturer's instructions. Instructions for use and handling of third-party navigation systems are the responsibility of the hospital and navigation company. Refer to the appropriate Medtronic® navigation system Instructions for Use and/or Surgical Technique Guide for details regarding the navigation system. A field assessment should be performed by positioning the navigated instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system. If the inputs result in the correct and anticipated outputs, functional verification is confirmed.

WARNING: Navigated instruments are highly accurate and sensitive medical devices that must be handled with extreme care. If you drop or otherwise damage any instrument, do not use it in a surgical case. Any instrument that is suspected of being damaged, inaccurate, or cannot be registered or verified must not be used in a surgical case and must be returned to OrthoPediatrics immediately. Failure to do so may lead to serious injury to the patient. Additionally, all navigated instruments and StealthStation® tracking instruments must be continuously verified for correct registration with the StealthStation® software. Positional accuracy must be continuously monitored intraoperatively. Immediately discontinue use of the navigated instruments if an inaccuracy is detected.

NOTE: For information on the use of disposable reflective marker spheres, refer to the appropriate Medtronic® navigation system user guide.

Initial Setup

- Turn on StealthStation and log in
- Select "SYNERGY SPINE" to start setup for spine navigation.
- Select the desired surgeon profile from the "SURGEON PROFILE" tab.
- Select the desired procedure from the "SELECT PROCEDURE" tab.
- Ensure that all necessary equipment (monitors, O-arm, etc.) are connected to the StealthStation

Patient Reference Setup

- There are several reference frame options available to accommodate the preferred access to the patient: the Percutaneous Reference Pin, the Open Spine Clamp, the Thoracic Spine Clamp, and the Mast Clamp.
- Install the desired patient reference frame according to the manufacturer's instructions.
- Attach 4 reflective spheres onto the patient reference frame. Ensure all 4 spheres have a clear sightline to the system's registering camera.

Instrument Setup

- On the " VERIFY INSTRUMENTS" tab on the StealthStation, add one NavLock tracker for each instrument being used in the surgery by selecting it from the "ADD/ REMOVE INSTRUMENTS" window.

Assign the tracker to an instrument by choosing one of the following from the dropdown menu:

- Screwdrivers: select "Standard Driver"
- Taps: select "XXmm Tap", with XX representing diameter.
- Navigated Cannulated Lenke Probe and Navigated Thoracic Lenke Probe: select "Straight Pedicle Probe"

- Attach each NavLock tracker to its assigned instrument. Attach the tracker (array) by sliding it over the end of the instrument until it is attached securely. Do not place NavLock trackers onto instruments that have not been assigned.
- Attach 4 reflective spheres to each NavLock tracker.

REGISTERING INSTRUMENTS TO THE STEALTHSTATION

- Aim the camera in the direction of the patient reference frame. Use the Tracking View window to confirm that the reference frame and trackers are in range and can be tracked by the system. Blue dots indicate successful tracking and yellow dots indicate blocked/ malfunctioning spheres. The blue triangle indicates how close/far the camera is from the reference frame.
- Place the distal tip of each instrument, one at a time, into the divot on the patient reference frame. Hold the instrument as perpendicular to the reference frame as possible.
- Successful registration is indicated on the instrument tool card on the VERIFY INSTRUMENTS tab. The card transitions from blue to green once registered, and an audible notification is heard.
- If registration is unsuccessful, the card remains blue and an audible notification plays. Ensure sterile spheres are clean and that both the instrument and reference frame are visible in the tracking view.Repeat steps until the instrument is successfully registered.

ACQUIRING SCANS

- After installing patient reference frame, obtain 3D CT images of the desired anatomical area.
- Transfer images to the StealthStation.

PERFORMING OPERATION

After registering the desired instruments and uploading the obtained 3D CT images, perform the surgery as indicated

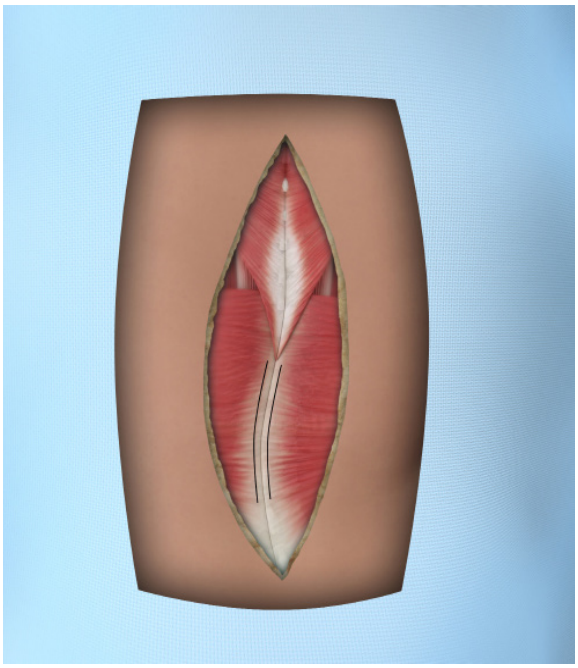
Refer to the VERTEGLIDE NAVIGATION INFORMATION - REFERENCE TABLE at the back of this surgical technique to confirm the correct corresponding Medtronic instrument and implant for each VerteGlide Navigation-compatible instrument and implant.

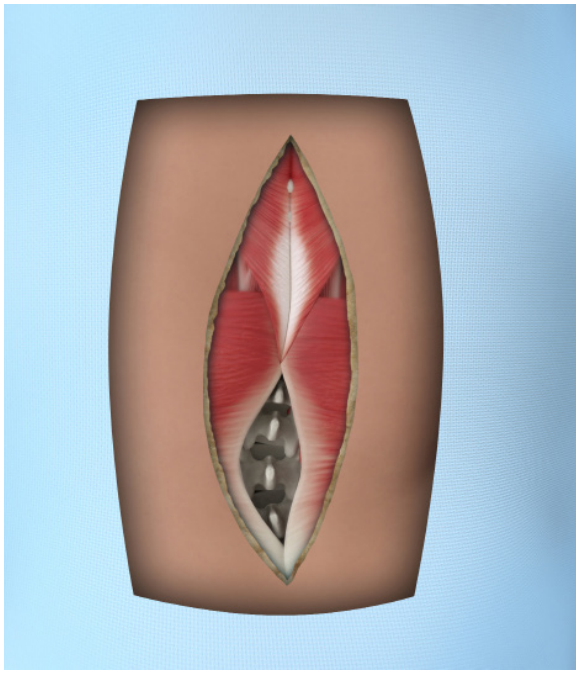
WARNING: The following implants and instrument are compatible with the Medtronic® StealthStation® S8 System.a field assessment should be performed by positioning the navigated instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system. If the inputs result in the correct and anticipated outputs, functional verification is confirmed. For further detail on the StealthStation® S8, please reference the StealthStation® S8 user manual.

WARNING: If an instrument fails to register under the provided toolcard number, do not proceed or attempt to register under any other toolcard number.

Patient Positioning

Patient should be placed prone on a radiolucent table suitable for circumferential intraoperative imaging.





Approach & Surgical Exposure

Create a longitudinal skin incision from the planned upper instrumented vertebra to the lower instrumented vertebra.

Subperiosteal dissection should only be performed at the levels where fusion screws will be placed (2-5 levels). At these levels, expose spinous processes, laminae, facets, and transverse processes. Perform Ponte osteotomies at these levels if desired.

Take care not to disrupt the facet joints above or below the fusion levels. The subperiosteal surgical exposure at the apex of the curve is done in order to fuse and align the spine to neutral alignment at these levels.

To address the growing components of the spine, the VerteGlide sliding screws are placed at proximal and distal ends of the construct through the muscle to allow for postoperative growth.

At the sliding screw levels, create bilateral paraspinal fascial incisions 1cm off midline. Then perform a blunt dissection through the paraspinal muscles down to the periosteum.

Pedicle Preparation & Screw Placement

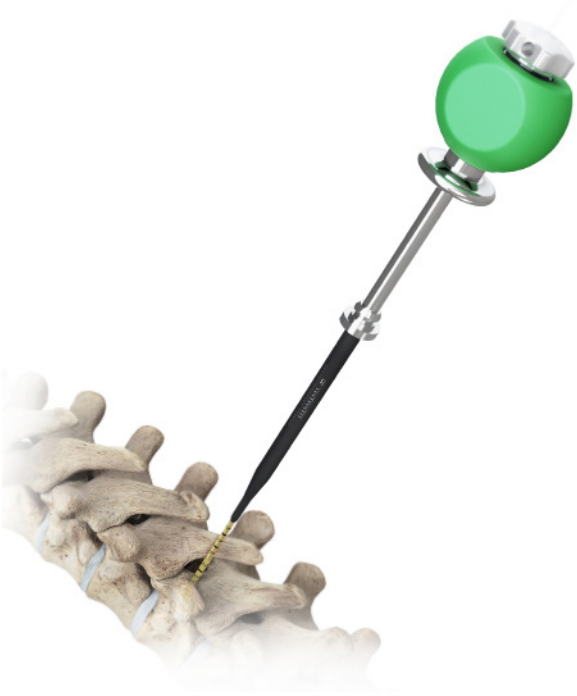
Pedicle Preparation & Screw Placement for Apical Fusion

The VerteGlide Spinal Growth Guidance System is used in conjunction with either RESPONSE 5.5/6.0 or RESPONSE 4.5/5.0 Spine Systems at the apex of the curve.

Reference ST-1300-01-01 (RESPONSE 5.5/6.0) or ST-1600-01-01 (RESPONSE 4.5/5.0) for available implant options, pedicle preparation and screw placement technique, and instructions regarding the use of these systems. The use of uniaxial screws will allow for more effective derotation and corrective maneuvers at the apex fusion. Polyaxial screws can also be used.

Place all fusion screws per the applicable technique.

WARNING: Fusion screw compatibility with the VerteGlide system includes sizes 4.5 - 6.5 mm screw diameters. Do not use 4.0 mm diameter fusion screws with the VerteGlide system.



Pedicle Preparation for VerteGlide Sliding Screws

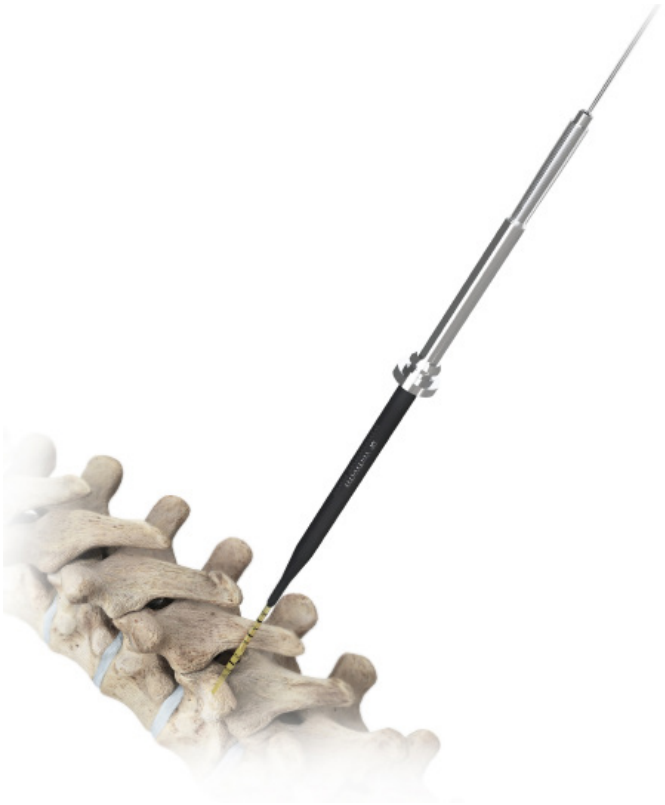
The VerteGlide technique can be used with navigation or a guidewire method of introducing pedicle screws.

Create a 3mm deep posterior cortical breach with the Pedicle Awl or burr. Gentle twisting of the handle with light pressure is the safest way to advance the awl.

WARNING: The VerteGlide Awl has a longer tip than the Response Awl in order to go through the muscle. Use caution when using this instrument. Do not use the VerteGlide Awl to prepare for the fusion screws in the section where bone is fully exposed.

The Navigated Cannulated Lenke Probe or the Navigated Thoracic Lenke Probe may be used at the cortical breach to identify the soft, funnel-shaped cancellous bone, which indicates the entrance to the pedicle. Slowly advance the tip of the probe approximately 20-25 mm as indicated by markings on the probe. Incrementally check the intrapedicular position with the feeler probe. Fluoroscopy may also be used throughout the pedicle preparation steps to confirm appropriate depth and trajectory.

The Navigated Thoracic Lenke Probe is available to provide a smaller diameter opening than the Navigated Cannulated Lenke Probe. This instrument should be used with the 4.5 mm diameter VerteGlide screws.

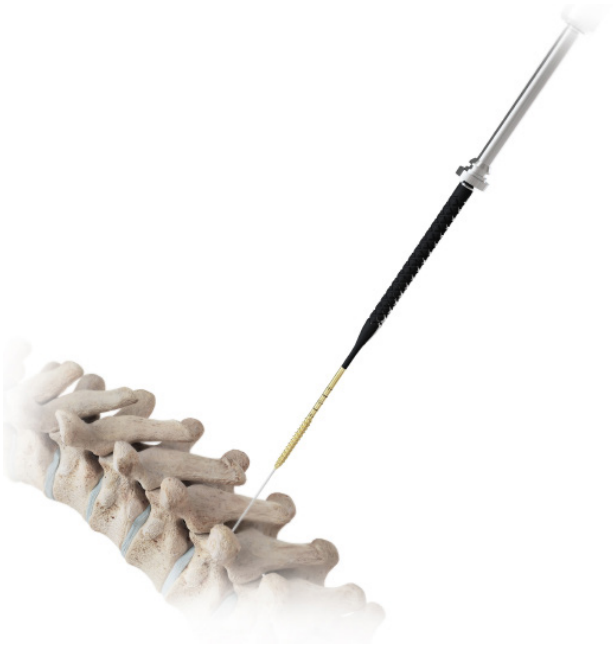


WARNING: Due to the smaller size of of the Navigated Thoracic Lenke Probe use caution to ensure the tip does not bend.

WARNING: Do NOT use the Navigated Cannulated Lenke Probe for pedicles intended for 4.5 mm diameter screws as the resulting hole diameter will be larger than the minor diameter of the screw, potentially compromising fixation strength.

Pedicle Preparation for VerteGlide Sliding Screws

Rotate the probe 90° to ensure adequate room for the screw. At each step, the feeler probe should be used to confirm intrapedicular position. Unscrew the Probe Insert from the Probe Housing of the Cannulated Lenke Probe and pull up to remove the insert. Insert the 1.2mm guidewire through the Probe Housing and into the pedicle until it is retained in the bone. The handle and insert may also be removed simultaneously.



Pedicle Preparation for VerteGlide Sliding Screws *(cont.)*

Once the guidewire is inserted, pull up on the Cannulated Lenke to remove it from the pedicle, leaving the guide wire in place.

> **WARNING:** Inspect guidewires for damage or bends prior to use. A bent guidewire can cause binding in the instrument and lead to unintentional advancement.

> **NOTE:** Due to the small diameter of the 3.5mm tap, this instrument is not cannulated and therefore will not work over a guidewire.

VerteGlide screws are self-tapping, therefore tapping is optional. Screws may placed with or without tapping. Select the appropriate VerteGlide Tap to tap the pedicle. Use a Tap 1mm smaller than the intended screw diameter. Tap over the guidewire to the desired depth ~25-30mm maximum. Once desired depth is reached, remove the tap, being careful not to withdraw the guidewire.

> **WARNING:** While tapping, ensure the guidewire does not advance with the instrument. Ensure the guidewire has no bends or kinks that would cause unintentional advancement.

> **NOTE:** VerteGlide taps are optimized for use with VerteGlide screws and Response taps are optimized for use with Response screws.

Open Screw Insertion

Closed Screw Insertion

Screw Placement for VerteGlide Sliding Screws

Confirm if closed or open screws will be used at each level. Closed screws are offered to provide a lower vertical profile for use in the upper thoracic spine if needed.

Note that closed screws have a lower profile and do not include a set screw, requiring the rod to be inserted into the tulip head from the side.

Screw Placement for VerteGlide Sliding Screws *(cont.)*

Select the appropriate screw and VerteGlide Pedicle Screwdriver based on the correct system size (4.5mm or 5.5mm) and screw type (Open or Closed). Attach the screw to the screwdriver by first engaging the hexalobe tip of the Pedicle Screw Driver with the mating hexalobe feature in the screw shank.

Then rotate the pedicle screwdriver to engage the threads with the threads of the pedicle screw tulip head until hand tight.

WARNING: The correct VerteGlide driver must be used with the respective VerteGlide screw type to ensure accuracy of the navigation system.

Slowly advance the VerteGlide screw down the pedicle to ensure proper tracking. Advance the screw until the bottom of the tulip head is flush with the muscle layer; this prevents disruption of the bone and allows for adequate motion of the tulip head.

Fluoroscopy may be used to confirm appropriate screw position and size.

Once the desired depth is reached, remove the pedicle screwdriver. To disengage the driver from the screw, turn the threading knob counterclockwise, then gently rock the driver to disengage the tip of the hex from the screw. The Guidewire can then also be removed.

WARNINGS:

- While inserting the screw, ensure the guidewire does not advance with the instrument. Ensure the guidewire has no bends or kinks that would cause unintentional advancement. Ensure pedicle screws are sized appropriately for patient's anatomy. Anteriorly, too large of pedicle screw could lead to a vertebral body breach. Too large of diameter of screw can damage the pedicle (loss of integrity) and violate the cord space. Insufficient length and/or diameter can lead to insufficient fixation, loosening, and pullback.

- Proper screw orientation and depth is critical for avoiding bone, vascular, and/or nerve damage.

- Plan the placement of VerteGlide Screws, Fusion Screws, Cross Connector(s), and Rod Clamps to align appropriately with the smooth and rough portions of the rods. VerteGlide screws should only be placed on the smooth section of the rod, and fusion screws, cross-connectors, and rod clamps should only be placed on the rough portion of the rod. Placing components on the incorrect surface can result in construct failure and/or excessive wear. Account for patient growth and patient motion when choosing rod length and screw placement.

- 4.5 VerteGlide Rods are only intended to be used with 4.5 VerteGlide Pedicle Screws and 4.5/5.0 RESPONSE Fusion Screws. 5.5 VerteGlide Rods are only intended to be used with 5.5 VerteGlide Pedicle Screws and 5.5/6.0 RESPONSE Fusion Screws. Mixing sizes can result in construct failure and/or excessive wear.

Size and Contour Rods

Use the VerteGlide Rod Template to confirm the length and location of the fusion section, the overall rod length, and desired sagittal contour. As noted previously ensure the rough and smooth portions of the rod will fall into the fusion and sliding screws, respectively after the rod is contoured. Fusion section lengths are offered in 60mm, 90mm, and 120mm. Ensure there is adequate room for a cross-connector or a rod clamp to also be placed on the rough section of the rod. Use a surgical marker to mark on the rod template the length and location of the fusion section as well as the top and bottom of the construct.

Cut the rod to length per the template using the Rod Cutter, leaving extra rod length on each end for growth (approximately 2 cm or as desired based on patient and the number of vertebral levels spanned). Bend the sagittal contour of the rod as desired using the Soft Bend French Bender. This French Bender is designed to provide more gradual bends and avoid any point bends to ensure the sliding screws can move smoothly over the rod.

The above steps should be performed for both rods to ensure equivalent bends on either side of the construct.

WARNING: Too little kyphosis of the rods in the upper thoracic region may cause prominence of the rods postoperatively. Excessive lordosis of the rods in the lumbar region can also produce prominence.

Use the appropriate size (4.5 or 5.5) VerteGlide Rod Checker to confirm the sliding screws move smoothly over any bends.

WARNING: Use only the bending and contouring instruments described in this technique to bend/contour the rod. Do not overbend or re-bend rods in the same location as this can weaken the rod.

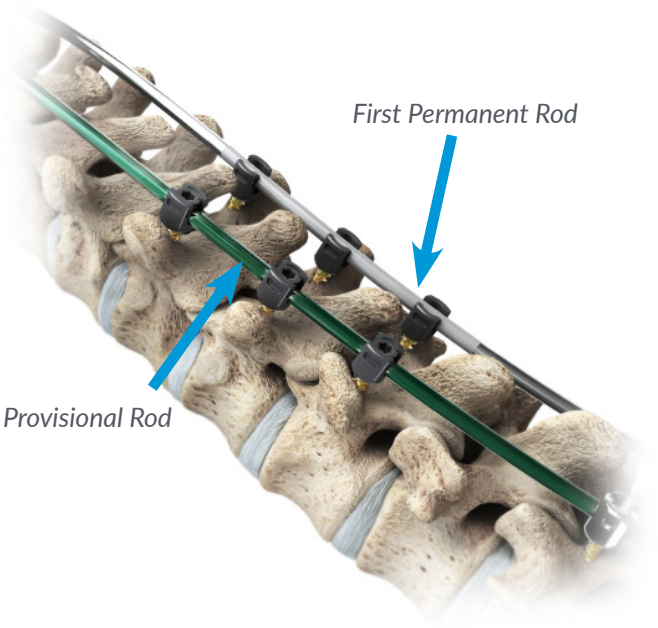
WARNING: Rod stiffness, a function of rod material and diameter, should be appropriate for the patient's size, deformity, and bone quality. Excessively stiff rods may lead to construct failure or screw pullout and excessively compliant rods may lead to inadequate correction.

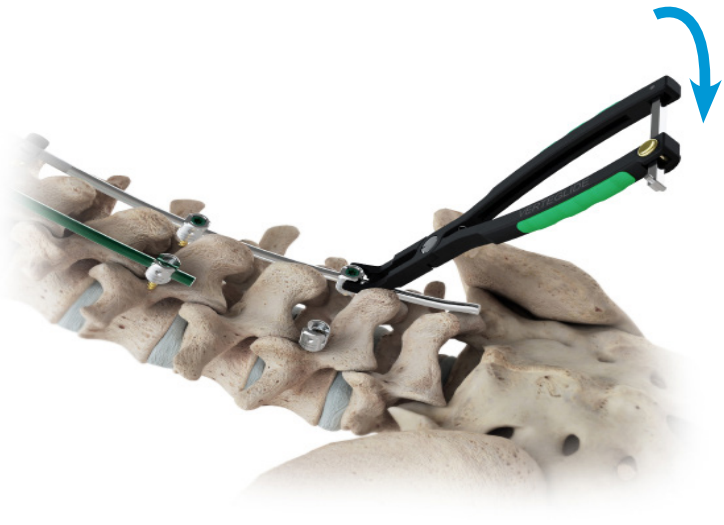
Placement of Provisional Rod (Convex Side)

Cut the provisional rod to the desired length. The provisional rod should span the apex and may extend into the sliding screws. Perform any pre-placement rod contouring or bending needed. Place the provisional rod on the convex side of the curve.

Rotate the rod to a corrected position with all spinal planes in neutral alignment. Provisionally tighten apical fusion screws to secure the rod in the desired rotational position. Further correction can be achieved with Coronal and/or In Situ Benders and compression over the apical fusion levels.

Once correction is achieved, provisionally tighten the apical fusion set screws.





Placement of First Permanent Rod *(Concave Side)*

Placement of the first permanent rod is usually on the on the concave side of the curve. If closed head screws are used at the top of the construct, the VerteGlide rod will have to be inserted through those implants first before reducing into other top-opening screws.

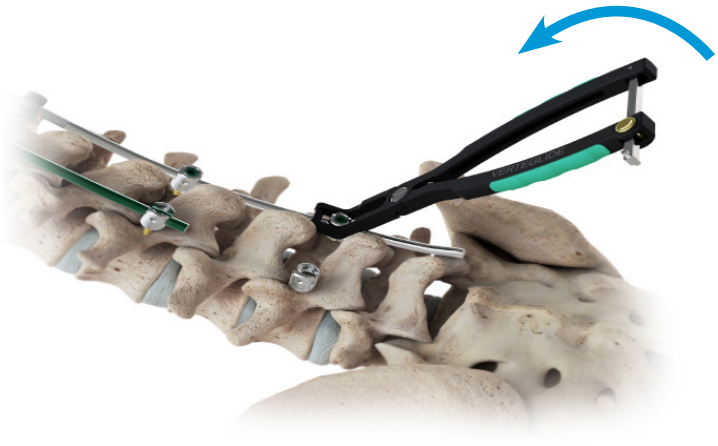
Confirm that the VerteGlide sliding screws will not contact the rough portion of the rod. Rod Grippers may be used to assist with placement and rotation of the rod.

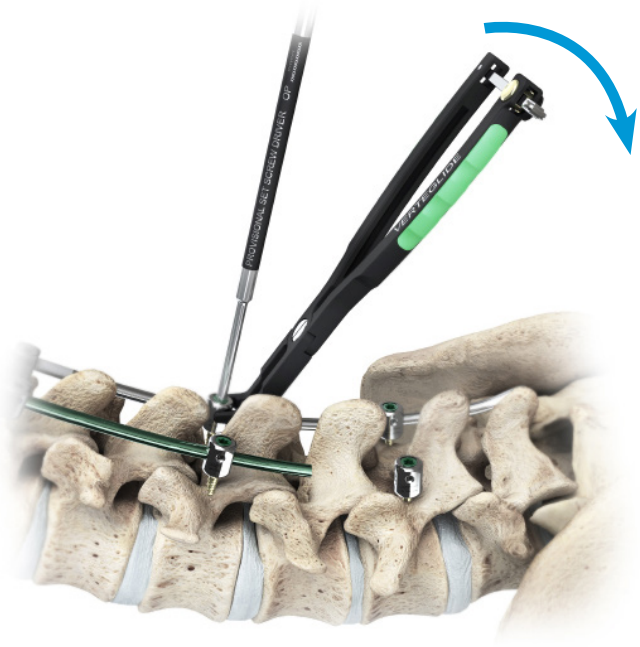
Reduce the rod into the apical screws per the appropriate fusion technique. Introduce set screws to loosely capture the rod in place.

Use the VerteGlide Rocker to reduce the rod into the open sliding screws. Grasp the sides of the implant with the rocker cam above the rod. Lever the Rocker backwards over the rod to seat the rod into the tulip head of the implant. If the rod is too far away from the tulip head to attach the rocker, the crossbar of the rocker may act as a pusher to push the rod down further and allow the instrument to be connected. Care should be exercised to mitigate risk of overloading a screw and cause loosening.

Alternatively, the VerteGlide Reverse Action Rocker is available to push the rod down from the opposite side if necessary. Coronal and/or In Situ Benders may also be used at this step as needed.

WARNING: Coronal and/or In Situ Benders should be used to impart gradual bends to the rod; avoid sharp point bends.





Placement of First Permanent Rod *(Concave Side) cont.*

While using the rocker to fully seat the rod, apply the set screw assembly to each open sliding screw using the VerteGlide Provisional Driver and hand-tighten. Note that the set screws for the VerteGlide open sliding screws are pre-assembled into a set screw housing. The wings of the set screw housing fit within the open space of the tulip head.

Ensure that the set screw assembly is aligned properly prior to tightening. To avoid cross threading of the set screw, it is advised to turn the set screw counterclockwise until a click is felt, ensuring that the set screw is lined up correctly.

Then proceed with clockwise tightening of the set screw.

> **NOTE:** The Response mini reducers are not compatible with the VerteGlide sliding screws. The VerteGlide Rocker or Reverse Action Rocker are the available tools for reduction into the sliding screws.

WARNING: Ensure the rod is fully reduced with the VerteGlide Rocker or Reverse Action Rocker prior to introduction of the set screw assemblies. Continue holding the rod in a fully reduced position until the set screw assembly is fully seated. Advancement of the set screw assembly should NOT be used as a means of reducing the rod.

WARNING: Use care when performing corrective maneuvers. Excessive force and/or displacement can cause bone and nerve damage. Watch the screw/bone interface with all correction maneuvers.

Place Second Permanent Rod *(Convex Side)*

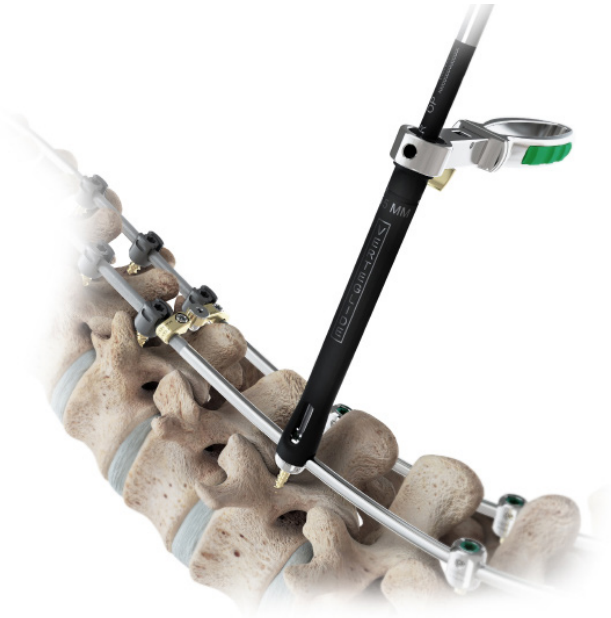
Remove the provisional rod from the convex side of the curve. Repeat the steps from the section on rod placement of the first rod for the second rod. All set screws (fusion and sliding) on both sides should be provisionally tightened at this point.

If required, set screws can be loosened and additional de-rotation/deformity correction can be performed. Re-tighten screws until all set screws (fusion and sliding) on both sides have been provisionally tightened.

WARNING: If the sliding screws are loosened and retightened for any reason, ensure the Rocker is used to fully reduce the rod so there is no upward force on the set screw during provisional tightening.

Additional Deformity Correction *(Optional)*

If additional deformity correction is needed after both permanent rods are in place, derotate the apex of the spine using the preferred fusion system technique. After derotation, lock correction in by provisionally tightening all fusion set screws if they have not been already.



Final Tightening

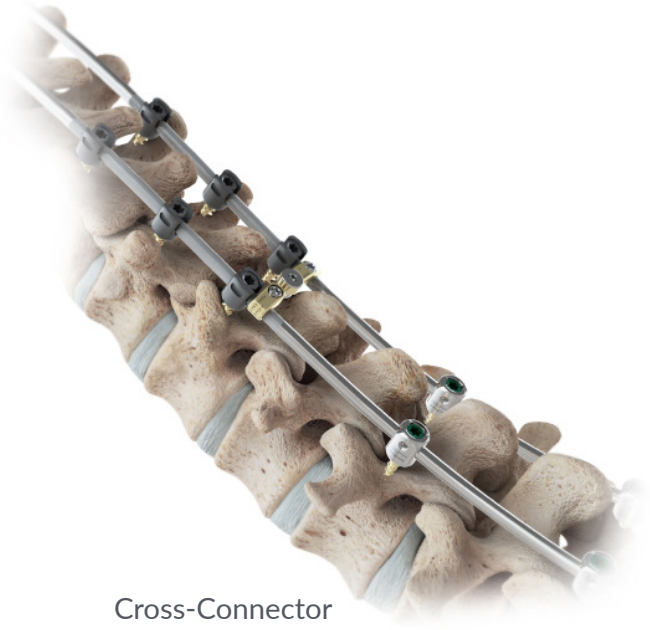
Final tighten fusion screws and cross-connectors. Follow the final tightening instructions described in ST-1300-01-01 or ST-1600-01-01 to avoid damaging screws and to ensure the fusion construct is properly locked.

Final tighten sliding screws. First, attach the Counter-Torque Handle to the appropriate VerteGlide Counter-Torque Tube (4.5 or 5.5) and place over the sliding screw.

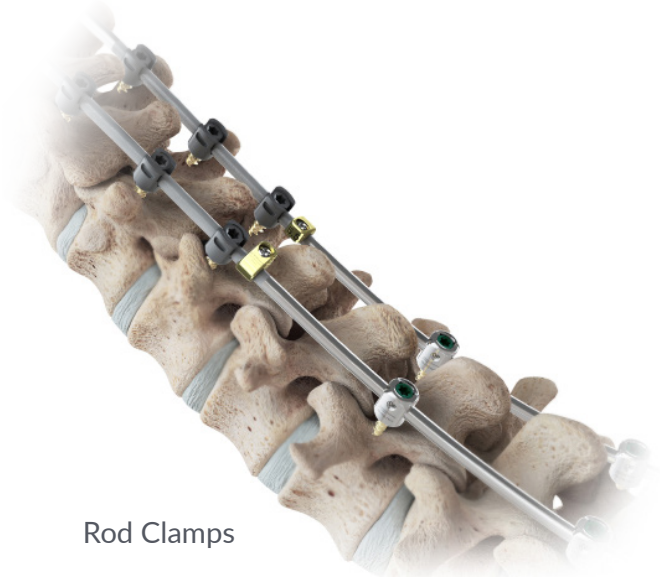
WARNING: Ensure set screws are fully seated prior to final tightening. Use the VerteGlide Rocker or ReverseRocker to fully reduce the rod if additional seating of the set screw is needed. If the set screws are not fully seated, there is increased risk that the set screw will not tighten appropriately due to up-force from the rod.

While holding the counter-torque securely, use the Fixed/Ratcheting T-Handle, the manual 12 Nm torque limiter, and the VerteGlide Final Driver to manually tighten the sliding set screws (2 clicks each). Ensure the counter-torque remains axially aligned with the tulip head during tightening.

NOTE: The sliding screws are not approved for use with power final tightening.



Cross-Connector



Rod Clamps

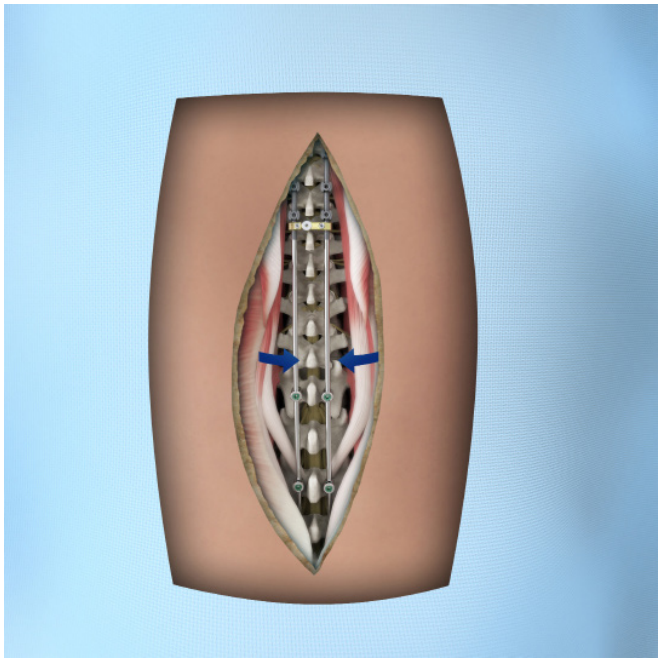
Place Cross-Connector

Place a RESPONSE Cross Connector just caudal to the apical screws, ensuring it is positioned on the rough portion of the rod. More than one may be placed if desired. Reference ST-1300-01-01 or ST-1600-01-01 for details on the measurement, selection, contouring, application, and final tightening of Cross Connectors.

In the event a crosslink cannot be placed, rod clamps can be used to prevent rod migration in the event of a rod fracture. The clamps are not intended to provide any structural support to the construct. Ensure the clamps do not interfere with the sliding motion of the VerteGlide Screws. The clamps should be locked to the rough portion of the rod to achieve maximal fixation.

Place a Rod Clamp of the appropriate size (4.5 or 5.5 mm) onto each of the rods. The set screw can be placed laterally or medially. Provisionally tighten using the Small Set Screw Driver to secure the clamp to the rod and ensure proper seating. Final tighten using the 7 Nm torque limiter and Small Set Screw Driver until an audible click is heard from the torque limiter. Repeat these steps for the opposite side rod clamp.

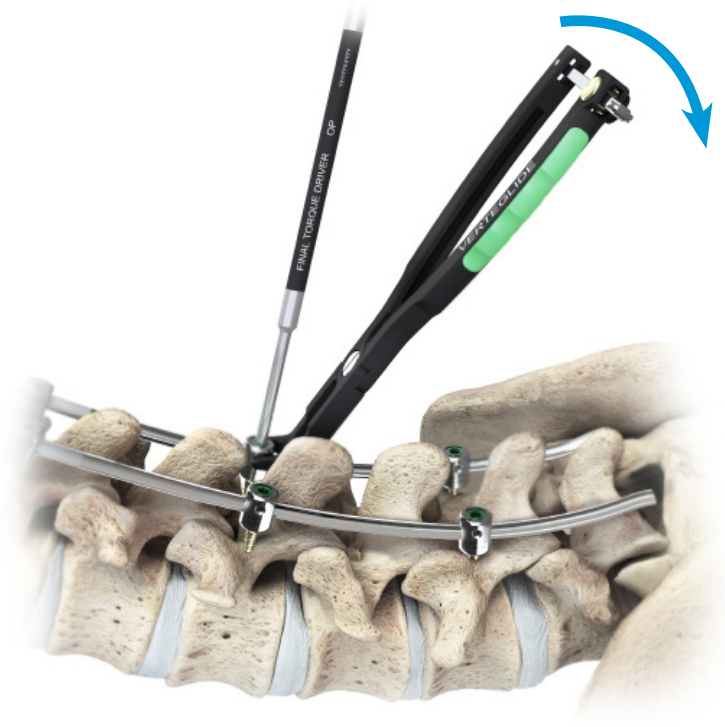
> **WARNING:** The set screw of the rod clamp should point posteriorly so that the clamping action of the set screw acts along the neutral axis of the rod.



Closure

AP and lateral x-rays may be used to confirm desired correction and alignment prior to closure. Rods projecting cranially and caudally should be parallel on the PA view. On the lateral projection kyphosis cranially and variable sagittal position caudally depending upon the lower instrumented vertebrae. At the apex of the curve where the fusion screws are located, apply bone graft to the decorticated posterior elements.

Bring the muscle and overlying fascia to the midline to cover the implants, securing with interrupted sutures. A running suture reinforces the midline fascial closure. A drain may be desired. It is generally recommended post-operatively to use a clamshell plastic brace with lining.



Explantation

Reference the appropriate Response surgical technique for removal of the fusion set screws, fusion screws, and cross-connector. The same instructions to remove the cross-connector can be used to remove the rod clamps.

While using the VerteGlide Rocker to off-load anatomical forces, loosen the set screw with the VerteGlide Final Set Screw Driver and Fixed T-Handle.

> **WARNING:** Failure to off-load the rod during set screw removal may lead to difficulty removing the set screws.

Once all set screws have been removed, gently lift the rod from the caudal end of the construct until it is disengaged from the VerteGlide screws and the fusion screws at the apex. If closed screws were used at the cephalad portion of the construct, slide the rod out of the closed screws.

Use the appropriate size and type VerteGlide Pedicle Screw Driver to remove the VerteGlide Open and Closed Screws. Use of the appropriate system instruments are recommended for removal; however, in the case these are not available note that the VerteGlide screw bodies use a T20 hexalobe and VerteGlide set screws use a T27 hexalobe. Response 4.5/5.0 screw bodies use a T15 hexalobe and set screws use a T27 hexalobe. Response 5.5/6.0 screw bodies use a T20 hexalobe and set screws use a T30 hexalobe.

> **WARNING:** The VerteGlide System is only intended to provide growth guidance until skeletal maturity and should not be relied upon for permanent stabilization of the spine. VerteGlide and RESPONSE implants are considered single use; **DO NOT REUSE ANY ALTERED COMPONENTS IN A REVISION SCENARIO.** Unaltered components are still subject to original limitations on implantation time. VerteGlide Screws and Rods cannot be reused in a fusion construct. The RESPONSE Fusion Screws have not been tested to support re-use in a conversion to fusion.

VERTEGLIDE NAVIGATION INFORMATION - REFERENCE TABLES

The tables below identify the correct corresponding Medtronic instrument and implant when using StealthStation Navigation

NAVIGATION COMPATIBLE INSTRUMENT LIST

Part Number	Description	Medtronic StealthStation Instrument Tool Card Description	Medtronic Instrument Tool card Part Number
01-1720-0100	Navigated Round AWL	Navigated AWL	9734678
01-1720-0220	Navigated Thoracic Lenke Probe	Navigated Lenke Probe	9734679
01-1720-0200	Navigated Cannulated Lenke Probe		
01-1720-0210	Navigated Cannulated Lenke Probe - Insert		9734679
01-1720-0230	Navigated Cannulated Lenke Prove - Handle		
01-1720-3500	VerteGlide 3.5mm Tap	Navigated 3.5mm Tap	9733509
01-1720-0040	VerteGlide 4.0mm Solid Tap	Navigated 4.0mm Tap	9733510
01-1720-4000	VerteGlide 4.0mm Cannulated Tap	Navigated 4.0mm Tap	9733510
01-1720-4500	VerteGlide 4.5mm Cannulated Tap	Navigated 4.5mm Tap	9733512
01-1720-5000	VerteGlide 5.0mm Cannulated Tap	Navigated 5.0mm Tap	9734299
01-1720-5500	VerteGlide 5.5mm Cannulated Tap	Navigated 5.5mm Tap	9734300
01-1721-1000	4.5 Open VerteGlide Pedicle Screw Driver	Navigated CD Horizon Legacy 5.5mm Driver	9734274
01-1722-1000	4.5 Closed VerteGlide Pedicle Screw Driver		9734274
01-1723-1000	5.5 Open VerteGlide Pedicle Screw Driver		9734274
01-1724-1000	5.5 Closed VerteGlide Pedicle Screw Driver		9734274

NAVIGATION COMPATIBLE IMPLANT LIST

Part No	Part Description	Corresponding StealthStation Tool-Card	Medtronic Toolcard Part Number
00-1721-4520	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 20mm, Open	Solera Ø 4.5 x 20mm	54840004520
00-1722-4520	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 20mm, Closed		
00-1723-4520	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 20mm, Open		
00-1724-4520	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 20mm, Closed		
00-1721-4525	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 25mm, Open	Solera Ø 4.5 x 25mm	54840004525
00-1722-4525	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 25mm, Closed		
00-1723-4525	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 25mm, Open		
00-1724-4525	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 25mm, Closed		
00-1721-4530	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 30mm, Open	Solera Ø 4.5 x 30mm	54840004530
00-1722-4530	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 30mm, Closed		
00-1723-4530	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 30mm, Open		
00-1724-4530	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 30mm, Closed		
00-1721-4535	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 35mm, Open	Solera Ø 4.5 x 35mm	54840004535
00-1722-4535	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 35mm, Closed		
00-1723-4535	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 35mm, Open		
00-1724-4535	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 35mm, Closed		
00-1721-4540	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 40mm, Open	Solera Ø 4.5 x 40mm	54840004540
00-1722-4540	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 40mm, Closed		
00-1723-4540	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 40mm, Open		
00-1724-4540	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 40mm, Closed		
00-1721-4545	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 45mm, Open	Solera Ø 4.5 x 45mm	54840004545
00-1722-4545	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 45mm, Closed		
00-1723-4545	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 45mm, Open		
00-1724-4545	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 45mm, Closed		
00-1721-4550	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 50mm, Open	Solera Ø 4.5 x 50mm	54840004550
00-1722-4550	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 50mm, Closed		
00-1723-4550	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 50mm, Open		
00-1724-4550	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 50mm, Closed		
00-1721-4555	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 55mm, Open	Solera Ø 4.5 x 55mm	54840004555
00-1722-4555	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 55mm, Closed		
00-1723-4555	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 55mm, Open		
00-1724-4555	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 55mm, Closed		
00-1721-4560	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 60mm, Open	Solera Ø 4.5 x 60mm	54840004560
00-1722-4560	Verteglide 4.5 Polyaxial Pedicle Screw 4.5mm X 60mm, Closed		
00-1723-4560	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 60mm, Open		
00-1724-4560	Verteglide 5.5 Polyaxial Pedicle Screw 4.5mm X 60mm, Closed		

Part No	Part Description	Corresponding StealthStation Tool-Card	Medtronic Toolcard Part Number
00-1721-5020	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 20mm, Open	Solera Ø 4.5 x 20mm	54840004520
00-1722-5020	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 20mm, Closed		
00-1723-5020	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 20mm, Open		
00-1724-5020	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 20mm, Closed		
00-1721-5025	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 25mm, Open	Solera 5.5/6.0 MAS Ø 5.0 x 25mm	55840005025
00-1722-5025	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 25mm, Closed		
00-1723-5025	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 25mm, Open		
00-1724-5025	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 25mm, Closed		
00-1721-5030	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 30mm, Open	Solera 5.5/6.0 MAS Ø 5.0 x 30mm	55840005030
00-1722-5030	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 30mm, Closed		
00-1723-5030	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 30mm, Open		
00-1724-5030	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 30mm, Closed		
00-1721-5035	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 35mm, Open	Solera 5.5/6.0 MAS Ø 5.0 x 35mm	55840005035
00-1722-5035	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 35mm, Closed		
00-1723-5035	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 35mm, Open		
00-1724-5035	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 35mm, Closed		
00-1721-5040	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 40mm, Open	Solera 5.5/6.0 MAS Ø 5.0 x 40mm	55840005040
00-1722-5040	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 40mm, Closed		
00-1723-5040	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 40mm, Open		
00-1724-5040	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 40mm, Closed		
00-1721-5045	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 45mm, Open	Solera 5.5/6.0 MAS Ø 5.0 x 45mm	55840005045
00-1722-5045	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 45mm, Closed		
00-1723-5045	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 45mm, Open		
00-1724-5045	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 45mm, Closed		
00-1721-5050	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 50mm, Open	Solera 5.5/6.0 MAS Ø 5.0 x 50mm	55840005050
00-1722-5050	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 50mm, Closed		
00-1723-5050	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 50mm, Open		
00-1724-5050	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 50mm, Closed		
00-1721-5055	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 55mm, Open	Solera 5.5/6.0 MAS Ø 5.0 x 55mm	55840005055
00-1722-5055	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 55mm, Closed		
00-1723-5055	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 55mm, Open		
00-1724-5055	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 55mm, Closed		
00-1721-5060	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 60mm, Open	Solera 5.5/6.0 MAS Ø 5.0 x 60mm	55840005060
00-1722-5060	Verteglide 4.5 Polyaxial Pedicle Screw 5.0mm X 60mm, Closed		
00-1723-5060	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 60mm, Open		
00-1724-5060	Verteglide 5.5 Polyaxial Pedicle Screw 5.0mm X 60mm, Closed		
00-1721-5520	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 20mm, Open	Solera Ø 4.5 x 20mm	54840004520
00-1722-5520	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 20mm, Closed		
00-1723-5520	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 20mm, Open		
00-1724-5520	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 20mm, Closed		

Part No	Part Description	Corresponding StealthStation Tool-Card	Medtronic Toolcard Part Number
00-1721-5525	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 25mm, Open	Solera 5.5/6.0 MAS Ø 5.5 x 25mm	55840005525
00-1722-5525	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 25mm, Closed		
00-1723-5525	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 25mm, Open		
00-1724-5525	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 25mm, Closed		
00-1721-5530	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 30mm, Open	Solera 5.5/6.0 MAS Ø 5.5 x 30mm	55840005530
00-1722-5530	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 30mm, Closed		
00-1723-5530	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 30mm, Open		
00-1724-5530	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 30mm, Closed		
00-1721-5535	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 35mm, Open	Solera 5.5/6.0 MAS Ø 5.5 x 35mm	55840005535
00-1722-5535	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 35mm, Closed		
00-1723-5535	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 35mm, Open		
00-1724-5535	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 35mm, Closed		
00-1721-5540	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 40mm, Open	Solera 5.5/6.0 MAS Ø 5.5 x 40mm	55840005540
00-1722-5540	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 40mm, Closed		
00-1723-5540	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 40mm, Open		
00-1724-5540	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 40mm, Closed		
00-1721-5545	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 45mm, Open	Solera 5.5/6.0 MAS Ø 5.5 x 45mm	55840005545
00-1722-5545	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 45mm, Closed		
00-1723-5545	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 45mm, Open		
00-1724-5545	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 45mm, Closed		
00-1721-5550	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 50mm, Open	Solera 5.5/6.0 MAS Ø 5.5 x 50mm	55840005550
00-1722-5550	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 50mm, Closed		
00-1723-5550	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 50mm, Open		
00-1724-5550	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 50mm, Closed		
00-1721-5555	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 55mm, Open	Solera 5.5/6.0 MAS Ø 5.5 x 55mm	55840005555
00-1722-5555	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 55mm, Closed		
00-1723-5555	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 55mm, Open		
00-1724-5555	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 55mm, Closed		
00-1721-5560	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 60mm, Open	Solera 5.5/6.0 MAS Ø 5.5 x 60mm	55840005560
00-1722-5560	Verteglide 4.5 Polyaxial Pedicle Screw 5.5mm X 60mm, Closed		
00-1723-5560	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 60mm, Open		
00-1724-5560	Verteglide 5.5 Polyaxial Pedicle Screw 5.5mm X 60mm, Closed		
00-1721-6020	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 20mm, Open	Solera Ø 4.5 x 20mm	54840004520
00-1722-6020	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 20mm, Closed		
00-1723-6020	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 20mm, Open		
00-1724-6020	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 20mm, Closed		

Part No	Part Description	Corresponding StealthStation Tool-Card	Medtronic Toolcard Part Number
00-1721-6025	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 25mm, Open	Solera 5.5/6.0 MAS Ø 6.0 x 25mm	55840006025
00-1722-6025	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 25mm, Closed		
00-1723-6025	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 25mm, Open		
00-1724-6025	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 25mm, Closed		
00-1721-6030	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 30mm, Open	Solera 5.5/6.0 MAS Ø 6.0 x 30mm	55840006030
00-1722-6030	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 30mm, Closed		
00-1723-6030	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 30mm, Open		
00-1724-6030	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 30mm, Closed		
00-1721-6035	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 35mm, Open	Solera 5.5/6.0 MAS Ø 6.0 x 35mm	55840006035
00-1722-6035	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 35mm, Closed		
00-1723-6035	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 35mm, Open		
00-1724-6035	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 35mm, Closed		
00-1721-6040	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 40mm, Open	Solera 5.5/6.0 MAS Ø 6.0 x 40mm	55840006040
00-1722-6040	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 40mm, Closed		
00-1723-6040	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 40mm, Open		
00-1724-6040	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 40mm, Closed		
00-1721-6045	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 45mm, Open	Solera 5.5/6.0 MAS Ø 6.0 x 45mm	55840006045
00-1722-6045	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 45mm, Closed		
00-1723-6045	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 45mm, Open		
00-1724-6045	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 45mm, Closed		
00-1721-6050	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 50mm, Open	Solera 5.5/6.0 MAS Ø 6.0 x 50mm	55840006050
00-1722-6050	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 50mm, Closed		
00-1723-6050	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 50mm, Open		
00-1724-6050	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 50mm, Closed		
00-1721-6055	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 55mm, Open	Solera 5.5/6.0 MAS Ø 6.0 x 55mm	55840006055
00-1722-6055	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 55mm, Closed		
00-1723-6055	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 55mm, Open		
00-1724-6055	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 55mm, Closed		
00-1721-6060	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 60mm, Open	Solera 5.5/6.0 MAS Ø 6.0 x 60mm	55840006060
00-1722-6060	Verteglide 4.5 Polyaxial Pedicle Screw 6.0mm X 60mm, Closed		
00-1723-6060	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 60mm, Open		
00-1724-6060	Verteglide 5.5 Polyaxial Pedicle Screw 6.0mm X 60mm, Closed		
00-1721-6520	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 20mm, Open	Solera Ø 4.5 x 20mm	54840004520
00-1722-6520	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 20mm, Closed		
00-1723-6520	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 20mm, Open		
00-1724-6520	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 20mm, Closed		

Part No	Part Description	Corresponding StealthStation Tool-Card	Medtronic Toolcard Part Number
00-1721-6525	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 25mm, Open	Solera 5.5/6.0 MAS Ø 6.5 x 25mm	55840006525
00-1722-6525	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 25mm, Closed		
00-1723-6525	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 25mm, Open		
00-1724-6525	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 25mm, Closed		
00-1721-6530	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 30mm, Open	Solera 5.5/6.0 MAS Ø 6.5 x 30mm	55840006530
00-1722-6530	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 30mm, Closed		
00-1723-6530	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 30mm, Open		
00-1724-6530	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 30mm, Closed		
00-1721-6535	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 35mm, Open	Solera 5.5/6.0 MAS Ø 6.5 x 35mm	55840006535
00-1722-6535	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 35mm, Closed		
00-1723-6535	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 35mm, Open		
00-1724-6535	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 35mm, Closed		
00-1721-6540	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 40mm, Open	Solera 5.5/6.0 MAS Ø 6.5 x 40mm	55840006540
00-1722-6540	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 40mm, Closed		
00-1723-6540	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 40mm, Open		
00-1724-6540	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 40mm, Closed		
00-1721-6545	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 45mm, Open	Solera 5.5/6.0 MAS Ø 6.5 x 45mm	55840006545
00-1722-6545	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 45mm, Closed		
00-1723-6545	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 45mm, Open		
00-1724-6545	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 45mm, Closed		
00-1721-6550	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 50mm, Open	Solera 5.5/6.0 MAS Ø 6.5 x 50mm	55840006550
00-1722-6550	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 50mm, Closed		
00-1723-6550	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 50mm, Open		
00-1724-6550	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 50mm, Closed		
00-1721-6555	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 55mm, Open	Solera 5.5/6.0 MAS Ø 6.5 x 55mm	55840006555
00-1722-6555	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 55mm, Closed		
00-1723-6555	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 55mm, Open		
00-1724-6555	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 55mm, Closed		
00-1721-6560	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 60mm, Open	Solera 5.5/6.0 MAS Ø 6.5 x 60mm	55840006560
00-1722-6560	Verteglide 4.5 Polyaxial Pedicle Screw 6.5mm X 60mm, Closed		
00-1723-6560	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 60mm, Open		
00-1724-6560	Verteglide 5.5 Polyaxial Pedicle Screw 6.5mm X 60mm, Closed		

IMPORTANT MEDICAL INFORMATION

Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

Metallic bone fixation devices should not be used in patients with:

- Active systemic infection or infection localized to the site of implant
- Material allergy or intolerance, documented or suspected
- An inability to follow a post-operative regimen
- Inadequate soft tissue coverage over the operative site
- Inadequate bone strength for fixation of device
- Absent diaphragmatic function
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any patient in which implant utilization would interfere with anatomical structures or expected physiologic performance

Relative contraindications include any condition that produces loads on the device that could lead to failure (i.e., obesity).

Warnings

- This device has the potential to generate cobalt chrome wear debris. Please refer to the "Important Information Related with Metallic Wear Debris" section further below for additional information.
- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Use extreme care in handling and storage of implants and instruments. Cutting, bending or scratching the surface of metallic components can significantly reduce fatigue, strength or corrosion resistance of the implant or instrument.
- Mixing of implants from different suppliers is not recommended for reasons of metallurgy, mechanics and design. OrthoPediatrics declines all responsibility in the case of implants from different sources being mixed.
- Repeat use of a surgical implant is strictly forbidden. Each implant, once used, must be disposed properly. Even though the device may appear intact, the device may have small faults or internal stresses that if the implant was re-used may lead to fatigue failure.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged surgical instrument and to take into account the risk of infection if a cut appears.
- Devices labeled for single use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices includes but is not limited to significant degradation in device performance, cross-infection, and contamination.
- The safety and effectiveness of devices 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 neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown."

MRI Safety Information

A person with the VerteGlide Spinal Growth Guidance System implants may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	VerteGlide Spinal Growth Guidance System
Static Magnetic Field Strength (B0)	1.5T and 3.0T
Maximum Spatial Field Gradient	20 T/m (2,000 Gauss cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 min of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact

Precautions

- The implantation of devices should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the instrumentation. Pre-operative procedures, knowledge of applicable surgical techniques, proper patient selection, correction selection and placement of implants are all equally important for the successful use of these products.
- Postoperative care is extremely important. The patient must be instructed in the limitations of the metallic implant regarding weight bearing and body stresses on the device prior to firm bone healing. Until the bone is fully healed, the patient should not return to activities that include heavy lifting, twisting, bending, stooping, running, or strenuous walking. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and the possible need thereafter for additional surgery to remove the device.
- Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
- These devices are not intended or expected to be the only mechanism for permanent support of the spine. Eventual conversion to fusion is expected at skeletal maturity. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing. Resultant failure modes may include bone- metal interface failure, implant fracture or bone failure.
- Implant Retrieval. The final decision to recover the implant falls to the surgeon. If the patient is suitable, OrthoPediatrics recommends the retrieval of implants as otherwise they may replace the function of the bone and lead to bone reduction and weakening. This is especially important for young and active patients. Routine removal of internal fixation devices after healing may also reduce the occurrence of symptomatic complications of implant breakage, implant loosening or implant related pain.
- It is important that the surgeon exercise extreme caution when working in close proximity to vital organs, nerves, or vessels, and that the forces applied while correcting the position of the instrumentation is not excessive, such that it might cause injury to the patient.
- There are particular risks involved in the use of instruments used for bending and cutting rods. The use of these types of instruments can cause injury to the patient by virtue of the extremely high forces involved. Do not cut rods in situ. The physical characteristics required for many instruments does not permit them to be manufactured from implantable materials,

and if any broken fragments of the instruments remain in the body of a patient, they could cause allergic or infectious consequences.

- Over-bending, notching, striking and scratching of the implants with any instrument should be avoided to reduce the risk of breakage and wear. Under no circumstances should rods be sharply or reverse bent, because doing so could significantly reduce the fatigue life of the rod and increase the risk of breakage. When the configuration of the bone cannot be fitted with an available device and contouring of the device is absolutely necessary, contouring should be performed only with the proper bending equipment, and should be performed gradually and with great care to avoid notching or scratching the device. Surgeons should ensure placement provides adequate soft tissue coverage over implants.
- Pediatric growth constructs typically require repeated planned-lengthening procedures until a determination is made that the patient is ready for a final fusion procedure. Patients of these procedures are more susceptible to post-operative infections and wound-healing issues, as well as the potential for implant breakage requiring unplanned surgical procedures. The physician should discuss these and all other potential complications with the patient and the patient's guardian.
- While the final decision on implant removal is up to the surgeon and the patient, in most patients' removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) corrosion, with localized tissue reaction or pain; (2) migration of implant position possibly resulting in injury; (3) risk of additional injury from postoperative trauma; (4) bending, loosening, and breaking which could make removal impractical or difficult; (5) pain, discomfort, or abnormal sensations due to the presence of the device, (6) possible increased risk of infection; (7) bone loss due to stress shielding; and (8) potential unknown or unexpected long term effects such as carcinogenesis.
- Patients implanted with the devices should not be braced. The devices are designed to allow for thoracic cavity growth and the restrictive nature of a brace would not help the condition but defeat its purpose.

Potential Adverse Effects

The potential adverse effects include, but are not limited to the following:

- Loss of fixation or implant breakage attributable to delayed or non-union
- Change in spinal curvature or loss of spinalcorrection
- Disassembly, bending, fracture, loosening or migration of the implant
- Implant prominence (symptomatic orasymptomatic)
- Decrease of bone density due to stress shielding
- Infections, both deep and superficial
- Skin breakdown or wound complications
- Allergies and other metal sensitivity reactions to device materials
- Foreign body (allergic) reaction to implants, debris, or corrosion products (from crevice, fretting, or general corrosion) including metallosis, staining, tumor formation, or autoimmune disease
- Vascular damage due to surgical trauma or presence of the device resulting in catastrophic bleeding
- Respiratory complications, including pulmonaryeffusion, pneumothorax, and hemothorax
- Gastrointestinal complications, including superiormesenteric artery syndrome
- Death
- Screw mal-position and back out, possibly leadingto implant loosening and/or reoperation for device removal
- Dural tears experienced during surgery could result in the need for further surgery for dural repair, chronic CSF leak or fistula and meningitis
- Pain, discomfort or abnormal sensations due to the presence of the device
- Nerve or spinal cord damage, including loss of neurologic function, due to surgical trauma or presence of the device
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone including the sacrum, pedicles, or vertebral body
- Degenerative changes or instability in segments adjacent to instrumented vertebral levels or ribs
- Pancreatitis
- Unintended fusion
- Proximal or distal kyphosis
- Bursitis
- Pressure on the skin from component parts in patient with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, or pain
- Post-operative change in spinal curvature, loss of correction, height, or reduction.

Potential Adverse Effects *(cont.)*

- Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.)
- Urinary retention or loss of bladder control or other types of urological system compromise
- Scar formation possibility causing neurological compromise or compression around nerves or pain
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, or muscle loss
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery
- Loss or increase in spinal mobility or function
- Inability to perform the activities of daily living
- Change In mental status
- Hypertension, embolism, stroke, or other types of cardiovascular system compromise
- Hematoma, seroma, edema, wound necrosis, or wound dehiscence
- Hemorrhage, damage to blood vessels, thrombophlebitis, or occlusion
- Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise

These adverse effects include adverse effects that are important considerations for metallic internal fixation devices. These risks and general surgical risks should be explained to the patient prior to surgery.

Important Information Related with Metallic Wear Debris

CoCr Metal Debris

The VerteGlide Growth Guidance System employs the use of CoCr components in a sliding motion to facilitate growth. The sliding motion of the metal surfaces generates a small amount of metal debris. Metal ions (e.g. cobalt and chromium) may result in local or systemic responses in the body.

Information for Surgeons

- Consider your patient's individual characteristics. Treatment options for early-onset scoliosis have unique benefits and risks which will result in different outcomes in different patient populations.
- The VerteGlide Growth Guidance System should be used only after determining that the benefits of using a metal-on-metal implant system outweigh the risks.
- Due to the potential for metallic wear debris, the system should not be implanted in:
  - Patients with known moderate to severe renal insufficiency
  - Patients with known metal sensitivity (e.g. cobalt, chromium, nickel)
  - Patients with suppressed immune systems
  - Patients currently receiving high doses of corticosteroids

Risks of Metal Debris

The potential risks associated with metal wear debris may include, but are not limited to:

- Loosening
- Osteolysis
- Elevated metal ion levels in the tissue around the implant and in the blood
- Development of an adverse local tissue reaction (ALTR) such as a local inflammatory reaction, soft tissue mass, and/or tissue necrosis (sometimes called pseudotumor)
- Development of potential systemic events related to elevated metal ion levels
- Early revision surgery

Certain patients have an increased risk for greater wear of the device or for an adverse local tissue reaction (ALTR) and require closer follow-up. These patients may include:

- Female patients
- Patients receiving high doses of corticosteroids
- Patients with evidence renal insufficiency
- Patients with suppressed immune systems
- Patients with suboptimal alignment of device components
- Patients with suspected metal sensitivity (e.g. cobalt, chromium, nickel)
- Patients who are severely overweight (BMI >40)
- Patients with high levels of physical activity

Patient Follow-up

- At the time of hospital discharge, schedule the patient for routine office follow-up.
- At the time of hospital discharge, review with the patient or caregiver the signs/symptoms of adverse events.
- Patient follow-up visits should include:
  - Check for asymptomatic local swelling or masses; and
  - Assessment of organs and systems for changes including systemic adverse events in cardiovascular, nervous, endocrine (especially thyroid) and renal systems.
  - Appropriate radiographs to check for implant positioning

Pay close attention to signs of the following local and systemic symptoms or complications associated with metal debris:

- Local symptoms or complications may include:
  - Hypersensitivity (allergic type reaction)
  - Loosening
  - Infection
  - Osteolysis (bone loss)
  - Soft tissue mass or pseudotumor
- Systemic symptoms or complications may include:
  - General hypersensitivity reaction (skin rash)
  - Cardiomyopathy
  - Neurological changes including sensory changes (auditory, or visual impairments)
  - Psychological status change (including depression or cognitive impairment)
  - Renal function impairment
  - Thyroid dysfunction (including neck discomfort, fatigue, weight gain or feeling cold

Recognize that localized lesions associated with reactions to metal debris may also present with pain or a variety signs and symptoms may include:

- Local nerve palsy
- Palpable mass
- Local swelling

Additional Testing for Symptomatic Patients

- In patients with symptoms, history, physical examination, laboratory tests, and x-ray radiographs may be indicated.
- In some patients, cross-sectional imaging may be indicated.
- Patients who develop symptoms may be considered for metal ion testing. It is important to note that at the current time, there is insufficient evidence in the U.S. demonstrating a correlation between a metal ion level in isolation and the presence of localized lesions, clinical outcomes and/or the need for revision surgery.

Device Revisions

- At this time, there is not enough evidence to provide a science-based recommendation for a threshold value of metal ion levels in the blood that would serve as a trigger for revision.
- All VerteGlide implants should be replaced for a definitive fusion at the age of skeletal maturity.
- The decision to revise a patient's VerteGlide implant prior to skeletal maturity should be made in response to the overall clinical scenario and results of diagnostic testing.
  - In extreme cases, adverse local tissue reactions (ALTR) may significantly damage periprosthetic bone, muscle, and nerves. Therefore, patients with progressing ALTR, may be considered for earlier revision to prevent extensive damage.
- If a patient is suspected to have developed metal sensitivity, carefully select the materials of the revision components (potentially avoiding materials with nickel or chromium).

Notes

CAUTION: Federal law restricts this device to sale by or the order of a Physician.

CAUTION: Devices are supplied Non-Sterile. Clean and sterilize before use according to instructions.

CAUTION: Implants components are single-use. Do not reuse.

CAUTION: Only those instruments and implants contained within this system are recommended for use with this technique. Other instruments or implants used in combination or in place of those contained within this system is not recommended, unless otherwise stated.

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