Vertu® Stand-Alone, No Profile ACDF

Surgical Technique

Simply Intuitive.
Stability Refined.

SPINAL ELEMENTS
Surgical Technique

The Vertu Stand-Alone, No Profile ACDF System is an elegant design solution that meets basic and advanced clinical needs for ACDF. Decompression, sagittal alignment, stabilization, fusion, and minimal intra-operative tissue disruption are facilitated through an intuitive and simplified alternative to the traditional ACDF.

Indications for Use
The Spinal Elements® Vertu Cervical Interbody System is a stand-alone interbody fusion device intended for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be implanted via an open, anterior approach and packed with autogenous bone. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with these devices.

The implant is designed to accommodate two screws. Two screws should be used to ensure adequate fixation of the implant.

Note to the Surgeon
Implantation of the device should be performed only by experienced spinal surgeons with specific training in the use of this device. This is a technically demanding procedure presenting a risk of serious injury to the patient.
Implant Overview

Implant Footprints
• 14mm x 12mm
• 16mm x 14mm
• 18mm x 15mm

Lordosis
• Parallel (0°)
• Lordosed (7°)

Sizes
• All footprints available in 6mm – 12mm sizes (in 1mm increments)

Implant Construct Screw Angulation
• 35° cephalad/caudal screw orientation angle
• 12° medial screw orientation angle
• Balanced lag screw design facilitates graft compression
Implant Overview

Multiple Screw Options for Fixation

- 4.0mm and 4.5mm diameter Self-tapping screws
- All screws available in 10mm – 16mm lengths (in 2mm increments)
- Variable Angle Screw design offers additional angulation to accommodate any intra-operative implant position shifts or screw/pilot hole misalignment
Instrument Overview

Vertu instruments are offered in straight, flexible, and fixed-angle options to accommodate each patient’s unique anatomy.

<table>
<thead>
<tr>
<th></th>
<th>Awl</th>
<th>Drill</th>
<th>Tap</th>
<th>Screw</th>
<th>Lock</th>
</tr>
</thead>
<tbody>
<tr>
<td>Straight</td>
<td><img src="image" alt="Awl Straight" /></td>
<td><img src="image" alt="Drill Straight" /></td>
<td><img src="image" alt="Tap Straight" /></td>
<td><img src="image" alt="Screw Straight" /></td>
<td><img src="image" alt="Lock Straight" /></td>
</tr>
<tr>
<td>Flexible</td>
<td><img src="image" alt="Awl Flexible" /></td>
<td><img src="image" alt="Drill Flexible" /></td>
<td><img src="image" alt="Tap Flexible" /></td>
<td><img src="image" alt="Screw Flexible" /></td>
<td><img src="image" alt="Lock Flexible" /></td>
</tr>
<tr>
<td>Fixed Angle</td>
<td><img src="image" alt="Awl Fixed Angle" /></td>
<td><img src="image" alt="Drill Fixed Angle" /></td>
<td><img src="image" alt="Tap Fixed Angle" /></td>
<td><img src="image" alt="Screw Fixed Angle" /></td>
<td><img src="image" alt="Lock Fixed Angle" /></td>
</tr>
</tbody>
</table>
Surgical Approach & Disc Preparation

Position the patient for anterior cervical access.

Perform an ACDF approach to expose and identify the operative disc level. Distract with standard instrumentation as needed to perform a discectomy.
Endplate Preparation

Rasp

The Rasp may be used to prepare the endplates so that vascularization of the bone graft material is optimized without compromising structural support of the endplate.
Implant Sizing

Trial

The Trial is used to determine implant size under direct visualization or x-ray. Start with the smallest footprint and size.

Note: Vertu Trials are undersized by 1mm relative to their Implant counterparts to improve the penetration of implant teeth into the endplates.

Vertu Trials and implant screw pocket rings are color coded by size.

Caution: Implants should not be used for trial sizing. The depth stop on the Trial allows for countersinking the Trial up to 2mm.

Note: Sizing for a snug fit will prevent implant migration during screw placement.
**Implant Insertion**

**Implant Inserter**

Select the Inserter that corresponds to the identified Implant footprint and connect the Handle.

Release the Inserter grips by untightening the knob on the shaft. Snap the Implant into place and secure by tightening the knob.
Implant Preparation

Packing Block

Use the Packing Block to pack bone graft material into the aperture of the Vertu Implant.

Caution: Do not pack bone graft material into the Vertu implant screw holes, as this may interfere with proper screw placement.
Implant Insertion

Implant Inserter

Insert the Implant by tapping lightly on the back of the Handle.

Confirm Implant position, depth, and endplate coverage with direct visualization and x-ray.

Note: The tantalum marker on the Vertu Implant is located 1mm from the posterior edge.

Note: The anterior face of the Implant should be flush with the anterior surface of the vertebral bodies. Any overhanging osteophytes or hypertrophic growth that may cause interference with the pilot hole preparation or screw placement must be removed.

Note: “In-setting” the Implant may also cause interference of instrumentation with the anterior endplates.
Inserter Removal

Implant Inserter

Untighten the knob of the Implant Inserter to release the Implant.

Remove the Implant Inserter and release distraction.
Implant Positioning

Tamp

The Tamp is used to make fine adjustments to Implant position. Do not apply excessive force with the Tamp.

Note: The anterior face of the Implant should be flush with the anterior surface of the vertebral bodies. Any overhanging osteophytes or hypertrophic growth that may cause interference with the pilot hole preparation or screw placement must be removed.

Note: “In-setting” the Implant may also cause interference of instrumentation with the anterior endplates.
Pilot Hole Prep

Angled Punch Awl

Seat the tip of the Angled Punch Awl into the screw pocket of the Vertu Implant. Ensure the tip is fully seated in the screw pocket.

Rotate the safety lock collar on the Punch Awl in either direction to disengage the safety lock.

Note: Always inspect the screw pocket of the Vertu Implant and remove any tissue or bone graft material that may interfere with instrument engagement.

Note: Remove any osteophytes or hypertrophic growth that may interfere with pilot hole preparation instrumentation.
Pilot Hole Prep

Angled Punch Awl (continued)

With the safety lock collar in the unlocked position, impact the Handle of the Punch Awl to create the pilot hole. Confirm pilot hole trajectory and depth with x-ray while the Punch Awl tip is fully deployed.

Note: Every Awl, Punch Awl, and Drill in the Vertu System will puncture the endplate and create a 2.0mm diameter pilot hole that extends 8mm beyond the Implant.

Note: The safety lock collar on the Angled Punch Awl is spring-loaded and will rotate back to the locked position if not held in place.

Optional: A Straight Punch Awl is also available.
Pilot Hole Prep

Optional: Handheld Guide

Several other options are available for pilot hole preparation. Awls, Drills and Taps are available as straight, flexible, and fixed angle. See page 5 for details.

All handheld drills and awls must be used with the Handheld Guide. Spring-loaded punch awls engage directly with the Implant screw pocket and do not need to be used with the Handheld Guide.

Carefully seat the tip of the Handheld Guide into the screw pocket of the Vertu Implant. Ensure the tip is fully seated in the screw pocket.

Note: The Handheld Guide is fully seated when the tip drops securely into the screw pocket and the gold end is no longer visible.

With the Handle attached, advance the desired instrument until it fully seats with the Handheld Guide. Confirm proper angulation with x-ray.

Note: Every Awl, Punch Awl, and Drill in the Vertu System will puncture the endplate and create a 2.0mm diameter pilot hole that extends 8mm beyond the Implant.

Note: Always inspect the screw pocket of the Vertu Implant and remove any tissue or bone graft material that may interfere with instrument engagement.
Screw Insertion

Screw

Several options are available for screw insertion. Screws may be loaded, inserted, and driven with straight, flexible, or fixed-angle screwdrivers, depending on patient anatomy.

Determine the desired Screw diameter and length for screw fixation and select the most suitable screwdriver for screw placement.

Load the desired screw onto the Screwdriver with a stab and grab action directly from the caddy.
Screw Insertion

Fixed Angled Screwdriver

Drive the Screw into the vertebral body ensuring the implant is lagged securely. The screw should be fully seated within the screw pocket of the Implant.

Note: Confirm screw placement and angulation with x-ray.

Note: It may be advantageous to advance each screw a little at a time, to maintain proper implant position.
Vertu® | Stand-Alone, No Profile ACDF

Surgical Technique

Screw Locking

Vertu Screws are locked with an internal locking screw mechanism built into the screw head. This locking screw has a reverse thread. As the locking screw rises it pushes the nitinol clip against the screw pocket locking the Screw into position.

Unlocked

Locked

Nitinol Clip
Locking Screw
Bone Screw
PEEK
Screw Locking

Fixed Angle Breakaway Driver

Insert the Breakaway Driver into the head of the internal locking screw and turn clockwise until a click is reached.

The locking torque is 2 in-lbs.

Optional: Screws may also be locked with the Flexible Breakaway Driver and the Straight Breakaway Driver.

Note: Prior to final locking confirm screw placement and angulation with x-ray.
Vertu® | Stand-Alone, No Profile ACDF

Final Implant Position

Reconfirm the Screws are through the endplates and into the vertebral bodies with x-ray.

Reconfirm full seating of both screws within the Implant pockets by identifying symmetric screw head overlap indicated by a diamond shape.
Vertu™ | Stand-Alone, No Profile ACDF

www.spinalelements.com/vertu

www.spinalelements.com/distributors/vertu
Implantation of devices should be performed only by experienced spinal surgeons with specific training in the use of this device. This is a technically demanding procedure presenting a risk of serious injury to the patient.

Preoperative and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and positioning of the device, are crucial for successful utilization of this device by the surgeon. Further, the proper care and cleaning of the device after surgery will greatly affect the results. The physician should consider the level of implantation, patient weight, height, size, and other implant device and surgeon factors that may have an impact on the performance of the device. Patients who smoke have been shown to have a greater incidence of non-union, osteolysis, and pseudoarthrosis than those not advised of this fact and warned to stop smoking.

These patients should be advised of this fact and warned of this risk.

These implants have not been tested for heating or migration in the Magnetic Resonance environment.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Physician Note: The physician is the learned intermediary between the company and the patient. The indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

PREOPERATIVE MANAGEMENT
1. The surgeon should consider for surgery only those patients diagnosed and treated for deformity.
2. The surgeon should not consider for surgery those patients contraindicated for the use of this device.
3. Patients resistant to follow post-operative restrictions on exercise and activity will have poorer outcomes.
4. Patients should not be instructed to use the implant.
5. Any patient with medical or surgical condition which would preclude the potential benefit of spinal implant surgery.

8. Rapid joint disease, bone absorption, osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
9. Any case where the implant components selected for use would be too large or too long for the patient.
10. Any patient having inadequate tissue coverage over the operative site.
11. Any patient in whom implant utilization would interfere with anatomical structures or expected physiological performance.
12. Any patient who has had previous exposure to metallic, non-biodegradable implants.
13. Use or multiple use.

INTRAOPERATIVE INSTRUCTIONS
1. Extreme caution should be used around the spinal cord and nerve roots, especially in the lumbar area, to avoid any loss of neurological functions.
2. Breakage, slippage, or misplacement of implants or components may cause injury to the patient or operative personnel.
3. Implants should be attached to the corresponding inserter such that they are fully seated on the inserter. Care should be taken not to over-tighten the implant to the inserter.
4. Implants should not be rotated or turned with the inserter once they have been implanted. This may lead to damage of the implant and/or the inserter.
5. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
6. All implants and instruments should be handled by the surgeon using a dexterity technique to avoid handling the implants. Damage to the implants may affect their performance.
7. All components should be handled by the surgeon utilizing proper surgical techniques.
8. If the surgeon experiences difficulty in inserting screws (i.e. hard torque), use a soft bristle brush paying particular attention to the surgical area.
9. Drift guide should be used to limit the angle of drifting and subsequent penetration. Insertion angles greater than what the drill guide allows may prevent adequate locking of the screw.
10. To threaded screws, insertion angles greater than what the drill guide allows may prevent adequate locking of the screw.

11. Before the closing of the soft tissues, all screws should be secured to the device body by activating the locking mechanism as described.

12. Postoperative management by the surgeon, including instruction and follow-up visits, should be performed with the patient's best interests in mind. In the presence of these devices with a soft bristle brush paying particular attention to hard-to-reach areas. A syringe, wire guide, and/or pipe cleaner should be used to clean lumens/cannulations or other hard-to-reach areas.

13. Removable syringes, de-oxidized (ROI/DI) water for a minimum of three minutes to remove any residual cleaner. Flush all hard to-reach areas.

14. Preoperative (equivalent neutral pH detergent) according to manufacturer recommendations using warm tap water. Fully immerses in devices in detergent solution and allow to soak for a minimum of three minutes. Scrub all external shafts with a soft bristle brush paying particular attention to hard-to-reach areas. A syringe, wire guide, and/or pipe cleaner should be used to clean lumens/cannulations or other hard-to-reach areas.

15. Wash the Breakaway Driver until an audible "click" is heard, indicating

**CLEANING AND MAINTENANCE**

All implants and instruments must be free of packaging material prior to sterilization. All instruments must be free of any visible blood, tissue, or debris. The following steps should be followed:

1. Remove from the detergent solution and rinse with reverse osmosis/de-ionized (ROI/DI) water for a minimum of three minutes to remove any residual cleaner. Flush all hard to-reach areas.

**STERILIZATION**

Implants and instruments are provided non-sterile and must be sterilized before use. Non-sterile implants and instruments should be autoclaved sterilized using one of the following validated cycle parameters.

<table>
<thead>
<tr>
<th>Method</th>
<th>Cycle Type</th>
<th>Sterilization</th>
<th>Exposure Time</th>
<th>Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam Gravity</td>
<td>Steam</td>
<td>270°F(132°C)</td>
<td>45 minutes</td>
<td>40 minutes</td>
</tr>
<tr>
<td>Steam Pre-vacuum</td>
<td>Pre-vacuum</td>
<td>15 minutes</td>
<td>40 minutes</td>
<td>40 minutes</td>
</tr>
</tbody>
</table>

Sterilization parameters were validated by ANSI/AAMI/ISO 17665-1:2006: Sterilization of Health Care Products – Moist Heat – Part 1. This guide to steam sterilization and sterility assurance in health care facilities. These parameters were validated to a sterilization assurance level (SAL) of 10^-3. This sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user’s responsibility to use only sterilizers and accessories that have been validated at the same parameters. It is also the responsibility of the user to ensure the quality and performance of the sterilization cycle (e.g. biocidal indicators, and sterilization cassettes) that have been cleaned and maintained in accordance with the guidelines of the sterilization cycle specifications (time and temperature).

**INFORMATION**

For additional information regarding any of Spinal Elements’ devices, please contact Spinal Elements, Inc. Customer Service at (760) 605-0121.

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.