

Surgical Technique Guide

VAIL™

Occipito-Cervico-Thoracic
Spinal Fixation System



Designed to promote fusion of the occipito-cervico-thoracic region of the spine (occiput-T3) in skeletally mature patients.

The following general Surgical Technique Guide is for illustrative purposes only. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as to the best treatment for each patient. Detailed preoperative clinical and diagnostic evaluation followed by carefully executed surgical technique is essential. Only those individuals with specialized training and experience in spinal surgery should attempt to use the Vail™ Occipito-Cervico-Thoracic Spinal Fixation System.

This surgical technique guide introduces the **Vail™ Occipito-Cervico-Thoracic Posterior Spinal Fixation System**. You will find it versatile and easy to use. In this preface I would like to point out some of the great features of this outstanding system.

The Vail system is intended to promote fusion of the occipito-cervico-thoracic region of the spine (occiput-T3) in skeletally mature patients. Its components allow for the fixation of the occiput, cervical vertebrae, and upper thoracic vertebrae (T1-T3). In addition, constructs can be extended by including the occiput using an occipital plate. They can be extended inferiorly towards the thoracic and lumbar spine using a variety of rods and connectors.

The implants offer a wide array of benefits such as the polyaxial screws that can be used in a time-saving, self-tapping fashion. The occipital plate allows for midline fixation and features an adjustable rod housing that makes rod placement and locking nut placement fast and easy. A universal joint screw driver is available which helps to keep the surgical exposure to a minimum. The plate and screws are swiftly connected using the wide variety of pre-cut and pre-bent rods included in the system. The persuader engages the side of the screw head very close to the top of the tulip which allows for rapid and convenient access. The locking nuts thread easily and prevent cross threading. Finally, also new are adjustable low-profile screw head-to-screw head cross connectors.

In summary, the Vail system represents a state of the art spinal fixation system. It succeeds in turning posterior stabilization of the occipito-cervico-thoracic region into a most pleasant experience for us. I encourage you to try it out.

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Neurosurgeon
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The **Vail™ Occipito-Cervico-Thoracic (OCT) Spinal Fixation System** provides a simple and comprehensive solution to promote fusion of the occipito-cervico-thoracic spine from the occiput through T3. Along with simple intuitive instrumentation, the Vail system includes occipital plates, rods, hooks, polyaxial screws, rod-to-rod connectors, head-to-head crossbars and offset connectors. The system components can be assembled in a variety of configurations, allowing the surgeon to tailor the construct to the particular needs of the patient.

FEATURES:

- A complete posterior fixation system for Occipito-Cervico-Thoracic procedures
- Designed with unique implant features to improve implant performance
 - Reverse buttress thread reduces the chance of cross threading the set screw or splaying the screw head
 - Low-profile screw head allows for optimal screw and rod placement with 60° range of motion
 - Thoracic polyaxial and smooth shank screws feature a tapered minor diameter thread designed to condense the bone and provide superior bone purchase
 - Midline occipital bone plate fixation with optional lateral fixation points
 - Adjustable occipital plate rod housing for ease of rod alignment
- Instrumentation designed by surgeons to simplify and streamline procedures



PREOPERATIVE PREPARATION

- Review and inspect all instrumentation and implants prior to sterilization.
- Implants and instruments are provided non-sterile and must be cleaned and sterilized prior to use.
- Replace or add any needed components for the planned surgery.
- Primary surgeon must be fully experienced with the required posterior, occipito-cervico-thoracic instrumentation techniques.

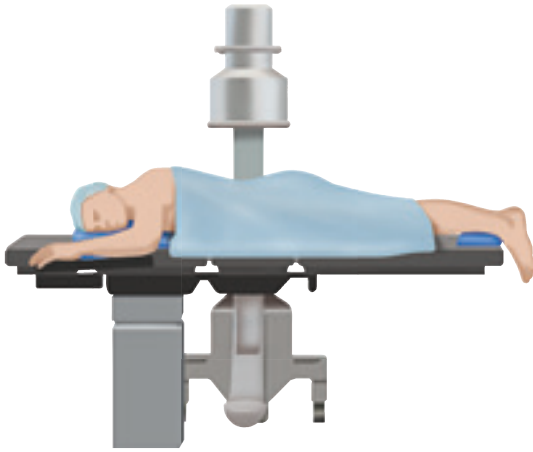


Figure 1
Patient positioning

SURGICAL EXPOSURE AND SITE PREPARATION

- Patient positioning is critical for occipito-cervical fusion procedures.
- The patient should be placed on the operating table in the prone position with the patient's head securely immobilized.
- Confirm proper patient position by direct visualization before draping, and by radiograph.
- Always use caution when positioning the patient, as physiological alignment may not be attainable.
- Perform a standard midline subperiosteal exposure of the portion of the cervico-thoracic spine to be fused.
- Complete a wide exposure extending to the lateral aspect of the facet joints in the cervical spine and the transverse processes in the thoracic spine.
- Extend the exposure to the external occipital protuberance if the fusion will include the occiput.
- Be mindful of avoiding injury to the vertebral arteries, spinal cord and C2 nerve roots in the upper cervical spine. Care must also be taken to avoid the facet capsules and interspinous ligaments at levels that will not be fused.

HOOK PLACEMENT

Cervical hooks are available in throat depths of 4.5mm and 6.0mm (Figure 1).



Figure 1

1.

- Prepare the lamina using the **lamina probe** (Figure 2).



Figure 2

2.

- Determine the appropriate size hook with the **hook sizer** (Figure 3).

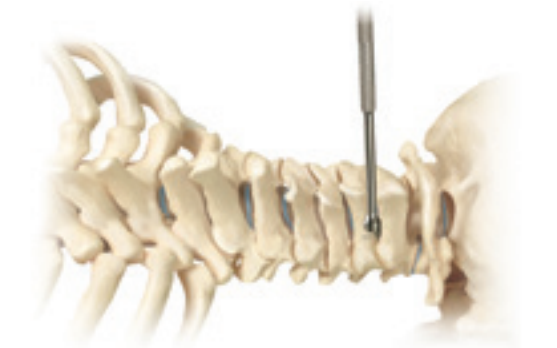


Figure 3

3.

- Attach selected hook to the **hook inserter** (Figure 4).

Note: The hooks are intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1–T3) spine.



Figure 4

THORACIC PEDICLE SCREW PREPARATION

The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.



Figure 5



Figure 6



Figure 7a

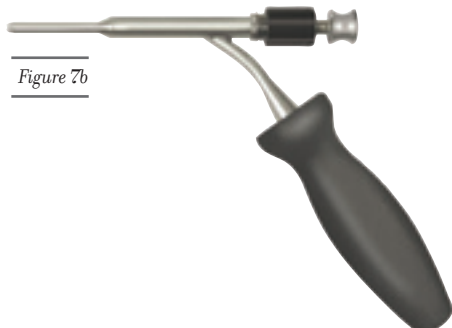


Figure 7b

4.

- The **awl** is used to penetrate the outer cortex of the pedicle and cannot be inserted beyond **10mm** (Figure 5).

5.

- Either the **pedicle probe** or drill is used to localize the pedicle and open a pathway. Correct insertion of the instrument will allow the probe to follow a path of least resistance without violating the pedicle walls (Figure 6).

Note: The pedicle probes are laser marked at 10mm intervals to display depth and aid in appropriate screw length selection.

6.

- Use the drill diameter appropriate to the desired screw (3.5mm or 4.0mm). A 14mm drill guide – **fixed*** (Figure 7a) or **variable**** (Figure 7b) is available to assist in drill and screw trajectory. Twist drills are available in 3.5mm and 4.0mm diameters.

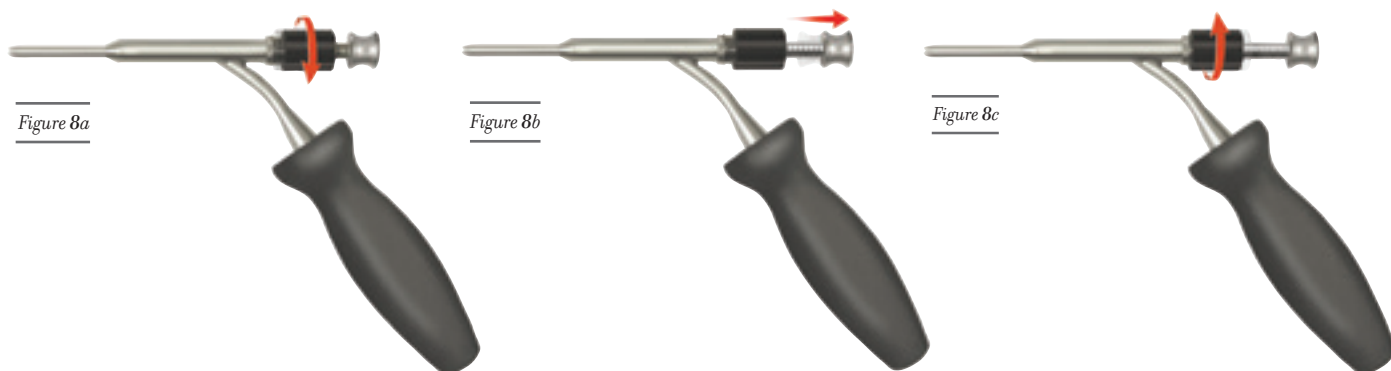
*10mm, 12mm and 16mm fixed guides are available upon request.

** The variable range is 8-56mm.

THORACIC PEDICLE SCREW PREPARATION (CONTINUED)

- The variable guide is adjusted by rotating the black thumb wheel counterclockwise (*Figure 8a*), then pulling the internal sleeve to the desired length (*Figure 8b*), and then tightening the black thumb wheel by rotating it clockwise (*Figure 8c*). Ensure sleeve is locked by gently pulling upward.

Note: Do not remove the thumb wheel.



7.



Figure 9

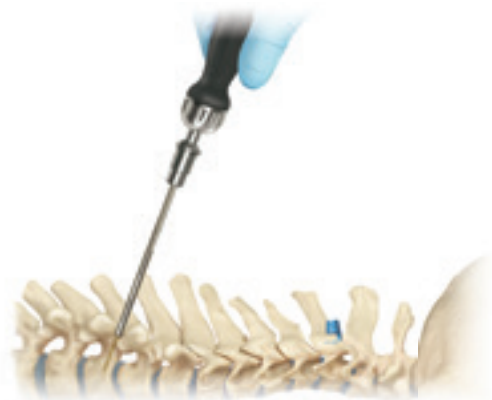


Figure 10

- Verify the depth and integrity of the pedicle walls of the hole with either the **depth measure** or the **pedicle sounder** (Figure 9).
- Taps may be used, although the Vail™ thoracic polyaxial screws have a self-tapping tip. Taps are sized exactly as the corresponding pedicle screw. Taps are available in three diameters: **3.0mm**, **3.5mm** and **4.0mm** and are attached to the **straight ratcheting handle** (Figure 10).
- The taps are laser marked in 4mm increments to display depth when used with the **tap sleeve** (Figure 11).
- As an alternative to individual drills and taps, **3.5mm drill/tap combo** and **4.0mm drill/tap combo** instruments are available (Figure 12).

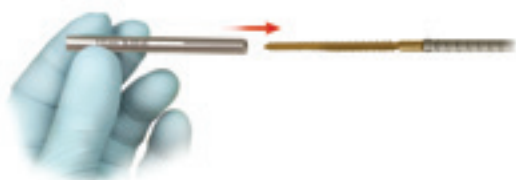


Figure 11

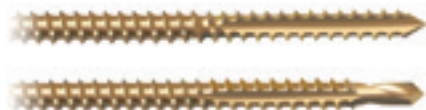


Figure 12

8.

The pedicle screws are inserted with the **bone screw driver** which is attached to the **ratcheting straight handle**.

- The bone screw driver consists of 3 elements:
 - a. **bone screw driver (shaft)**
 - b. **bone screw driver (sleeve)**
 - c. **bone screw driver (straw)**



BONE SCREW DRIVER (SHAFT)



BONE SCREW DRIVER (SLEEVE)



BONE SCREW DRIVER (STRAW)



BONE SCREW DRIVER ASSEMBLY

9.

Loading a screw onto the bone screw driver:

- Draw the sleeve with the straw upward toward the handle (*Figure 13a*).
- Orient the prongs of the screw driver with the screw head slots and insert (*Figure 13b*).

Tip: Be sure to hold the screw and NOT the housing for this step. Otherwise there is a chance the screw will turn with the driver and not seat properly.

Note: The prongs of the screw driver tip need to align and engage into the corresponding screw head slots. It is helpful to gently rotate the screw driver to allow the prongs to align with the grooves in the screw head.

*Note: Check for the gap between the tulip and the driver to indicate the driver has been seated properly (*Figure 13c*).*

- With the prongs properly seated, the sleeve assembly is threaded into the screw head by rotating clockwise (*Figure 13d*).
- The ratcheting handle should be set for proper rotation direction (clockwise or neutral for insertion). This is accomplished by rotating the metal collar on the handle.

Tip: Put the handle in reverse and tighten the sleeve against the handle in order to get the screw tighter on the driver. This helps prevent tissue and hands from releasing the screw from the driver prematurely.



Figure 13a



Figure 13b

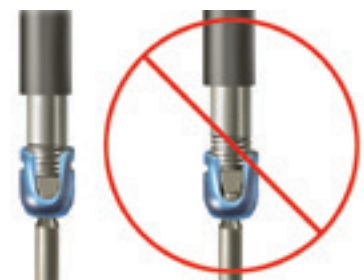


Figure 13c



Figure 13d



Figure 14

10.

Once the desired insertion depth is achieved, the screw is disengaged from the screw driver (*Figure 14*).

- Grasp and maintain the position of the ratchet handle/screw driver shaft assembly.
- Unthread the sleeve from the screw head and remove.
- Confirm appropriate implant location radiographically.

Note: For subsequent screw removal or height adjustment, the screw loading sequence must be used. Do not attempt to turn the screw without the sleeve threaded into the screw head as this may cause the driver tips to be damaged.

SCREW HEAD ADJUSTMENT

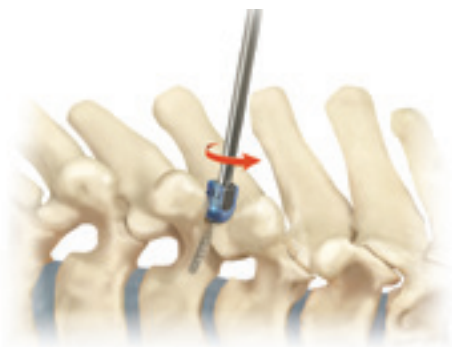


Figure 15

11.

The polyaxial screw head may be positioned and aligned by using the **bone screw driver** or **head turner** (*Figure 15*).

OCCIPITAL PLATE PREPARATION

With the hooks placed in the cervical region, the distance between the rods can be determined using the **rod templates**. Once the distance between the construct rods is determined, the desired **occipital plate template** can be selected. The dotted lines on the plate template represent the travel range of the outside edge of the rods.

12.

- With the plate template (*Figure 16a*) as a guide, use the **plate bender** (*Figure 16b*) to contour the plate to fit the anatomy. The plate can be bent to a maximum of 12 degrees. Only contour the plate in the bend relief areas to avoid impairing the rod housing adjustment.
- The occipital plate can be held using the **plate inserter**.

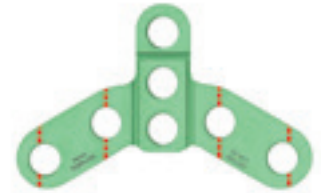


Figure 16a



Figure 16b

13.

- Using fluoroscopy, determine the length of occiput bone screws desired. Select the desired **occipital fixed drill guide** for occipital bone screw depth preparation.

14.

- Drilling can be accomplished through the occipital plate or by pre-marking hole placement and drilling directly on the bone. Drill through the fixed depth drill guide to the desired depth and trajectory with the **fixed 4.5mm drill bit**, or **quick connect 4.5mm drill bit** with the **flexible shaft** for complex anatomy. To provide additional stability, the **holding forceps** may be utilized (*Figure 17a,b*).



Figure 17a



Figure 17b

15.

- Use the **depth measure** to confirm the depth and select the corresponding screw length. The depth measure must sit directly on the bone surface.

16.

- With the same occipital fixed depth guide used for drilling, tap with the **fixed 4.5mm tap** or **quick connect 4.5mm tap** with the **flexible shaft** for complex anatomy. To provide additional stability, the **holding forceps** may be utilized.

17.

- Insert and provisionally tighten the selected 4.5mm occipital screw utilizing the **fixed occiput screw driver** or **quick connect occiput screw driver** with the **universal joint shaft** for complex anatomy. To provide additional stability, the **holding forceps** may be utilized (*Figure 18*).

Note: 5.25mm occipital screws are also available if the 4.5mm screw has less than optimal fixation.



Figure 18

18.

- Insert the remaining occipital bone screws in the same manner. Only final tighten once the construct is fully assembled.

Note: If lateral occipital screws are used, housing adjustment will be limited.

ROD PREPARATION

When No Occipital Plate Is Being Used

- Once all the hooks and screws are placed, choose an appropriately sized rod. A **rod template** is available to determine the length and curvature of a rod.
- Rod length can be adjusted using the **rotary rod cutter**. The rotary rod cutter has an offset cutting length of 3.5mm which has to be taken into account when aligning the rod for cutting. A 3.5mm indication is engraved into the rotary rod cutter to assist in compensating for the offset of the cut line (*Figure 19a,b*).

Note: The cartridge of the rod cutter must be reset before cutting by rotating the tumbler counterclockwise until the two white lines are aligned (Figure 19c).



Figure 19a



Figure 19b



Figure 19c

- The Vail™ system includes straight and curved rods in a range of sizes. If rod bending/contouring is required, a rod bender (*Figure 20*) or *in situ* benders (left and right) may be utilized.



Figure 20

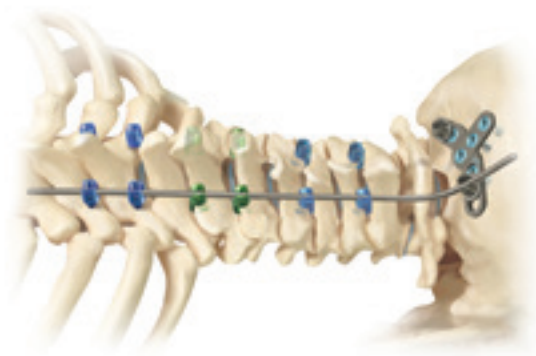


Figure 21

Occipital Rod Contouring and Fixation

- Contour the **rod template** to fit the anatomy and to seat fully in the cervical and upper thoracic bone anchors. Create the occipito-cervical bend and ensure sufficient rod length to connect with the occipital plate (*Figure 21*).



Figure 22

- With the rod template as a guide, use the **occipital rod bender** to contour both rods to fit the anatomy (*Figure 22*).
- The length of the **occipital 4.0–3.5mm diameter rods** can be adjusted using the **rotary rod cutter, 4.0mm diameter**. The rotary rod cutter has an offset cutting length of 3.5mm which has to be taken into account when aligning the rod for cutting. See the instructions on the previous page on how to use the rod cutter properly.

Note: When planning to use the 4.0–3.5mm pre-bent rods, the cervical hooks will only attach to the 3.5mm diameter section of the rods.

19.

- Using the **rod holder**, place the selected rod into the hook and/or polyaxial screw heads (*Figure 23a*).
- Provisional set screw tightening may be needed to stabilize the rod.
- If additional rod manipulation is required for set screw placement, the **rod pusher** or **rod rocker** may be used to introduce the rod into the hook and/or polyaxial screw head. The rod rocker uses a levering action (*Figure 23b*).

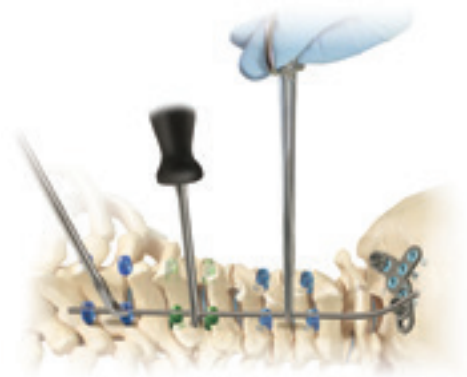


Figure 23a

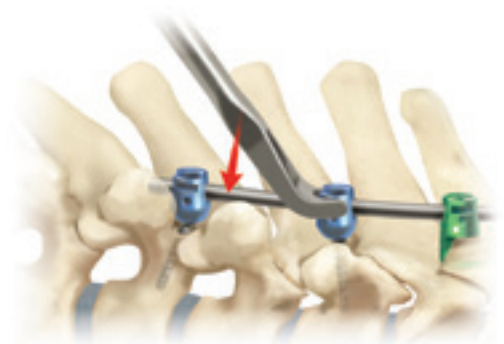


Figure 23b

- Alternatively, the **rod persuader, top loading** generates significant force to approximate the hook and/or polyaxial screw head and rod. Place the arms into the grooves on both sides of the screw head and gradually squeeze the pistol grip until ratcheting stops. Introduce the set screw and provisionally tighten. To disengage the instrument from the hook and/or polyaxial screw, release the ratchet lock (*Figure 24a,b*).

Tip: For the rod persuader, top loading, tilt the persuader sideways to introduce the tips into the screw head grooves and then rotate the persuader vertically while sliding it sideways.



Figure 24a

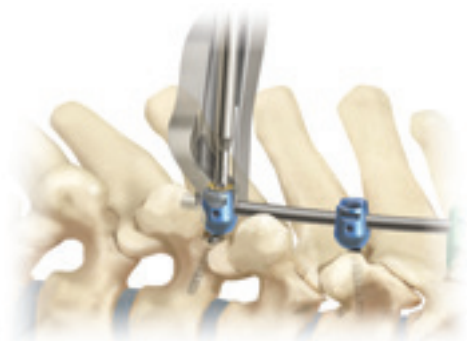
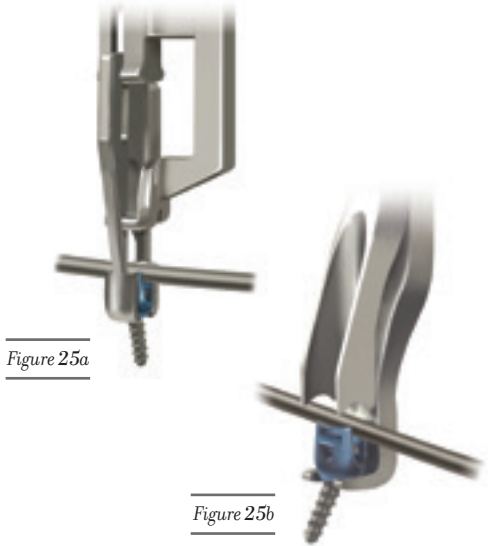


Figure 24b



Additional rod persuader styles are available as special order items.

- **Rod Persuader** — top loading over screw head, cupping around base and side for hook or polyaxial screw head (*Figure 25a*).
- **Rod Persuader, Bottom Loading** — side bottom loading, fork tips engage base polyaxial screw head (*Figure 25b*).

Note: If excessive force is needed to capture the rod into the hook or polyaxial screw head, re-contouring the rod should be considered.

Figure 25a

Figure 25b



Figure 26

- Once the rod is fully seated, the remaining set screws may be placed to secure the rod. The reverse buttress thread design of the set screw requires the set screw to be oriented correctly prior to insertion. If it is loaded onto the set screw starter upside down, it will not engage the screw head. Ensure the gold top surface is visible prior to insertion (*Figure 26*).
- The **set screw starter** is a self-retaining instrument designed for initial threading and provisional tightening of the set screws. Take care to avoid high torques, as this may damage the instrument tip (*Figure 27*).

Tip: It is helpful to initiate the set screw engagement with a complete counterclockwise turn. During the counterclockwise turn, a tactile click will indicate that the lead thread is in an ideal position to engage. Once the click is felt, the clockwise tightening direction should be started.

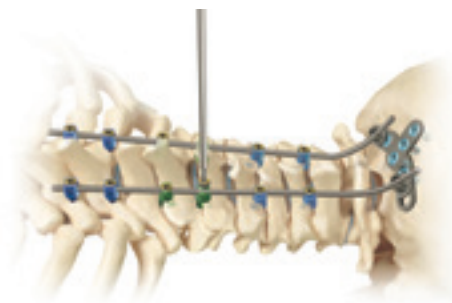


Figure 27

20.

- Once the rod has been fully seated into all of the hook or polyaxial screw heads and set screws are in place prior to final tightening, compression or distraction may be accomplished using either the **compressor** (*Figure 28a*) or **distractor** (*Figure 28b*) respectively.

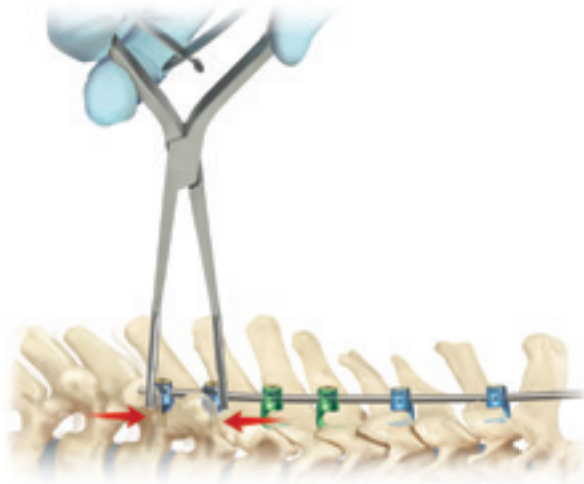


Figure 28a

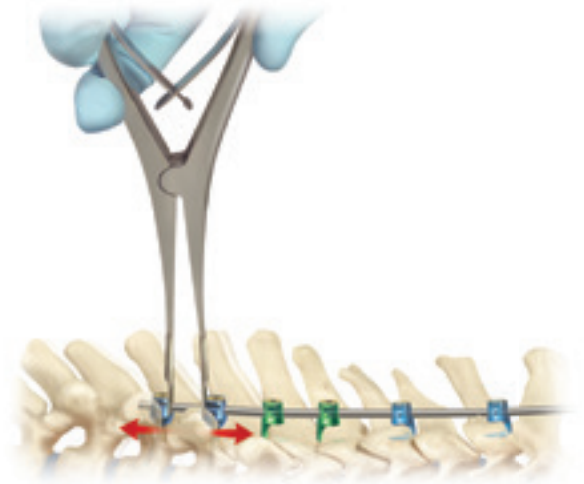


Figure 28b

21.



TORQUE LIMITING HANDLE



SET SCREW FINAL TIGHTENER



COUNTER TORQUE HANDLE

- Final tightening of the hooks and polyaxial screws is performed using the following three instruments:
 - a. **torque limiting handle**, identified by the grey handle
 - b. **set screw final tightener**
 - c. **counter torque handle**
- Attach the torque limiting handle to the set screw tightener, set the torque limiting handle into the forward or fixed position and insert into the counter torque handle.

22.

- While retracting the counter torque distal tip to visualize engagement with the set screw, place the tip of the set screw tightener into the set screw for final tightening.

23.

- Lower the counter torque over the hook and/or polyaxial screw head engaging the rod and rotate the torque limiting handle clockwise until a snap is heard (*Figure 29*).

Note: Final tightening is accomplished at 24 in-lb (2.71 Nm).

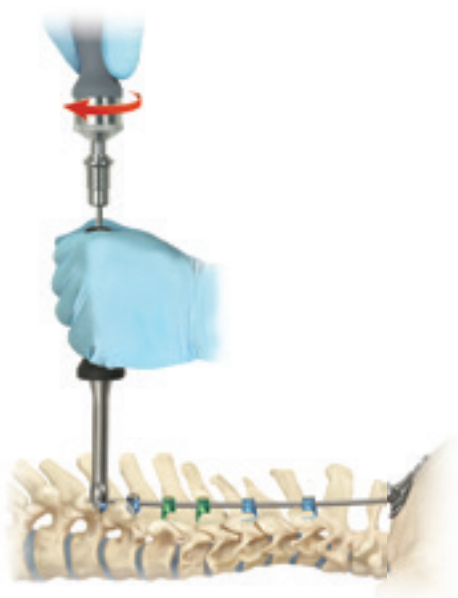


Figure 29

HEAD-TO-HEAD CROSSBAR PLACEMENT

The head-to-head crossbands are designed to give additional construct stability by utilizing the heads of the polyaxial screws or hooks for fixation.

24.

- The **crossband double set screw** is removed from the caddy and initially positioned into the selected polyaxial screw or hook heads using the **set screw starter** (Figure 30).

Note: The double set screw replaces the standard Vail™ set screw.

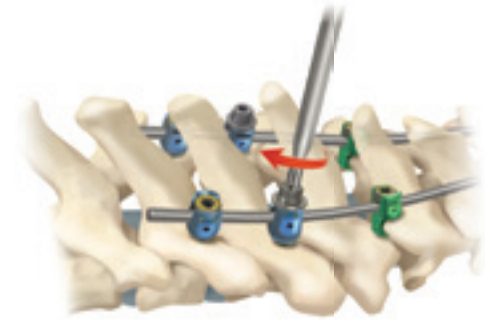


Figure 30

25.

- Final tightening of the crossband double set screw, polyaxial screw (or hook) and rod assembly is performed using the **counter torque handle**, **torque limiting handle**, and the **set screw final tightener**. Lower the counter torque handle over the screw head engaging the rod, and rotate the torque limiting handle clockwise until a snap is heard. Final tightening is accomplished at 24 in-lb (2.71 Nm) (Figure 31).



Figure 31

26.

- Select the appropriate size **crossband**. If crossband contouring is required, *in situ* benders (left and right) may be utilized. Place the crossband over the double set screws.

FINAL TIGHTENING OF THE SMALL NUT

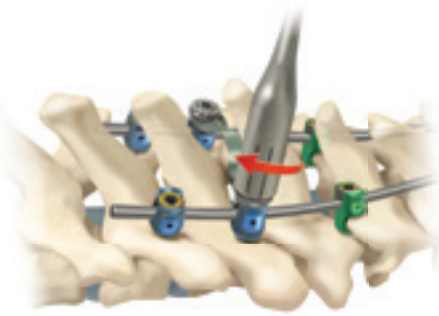


Figure 32

27.

- Introduction of the **small nut** and final tightening is performed by using the torque limiting handle and the **head to head driver**. The small nut is removed from the caddy using the head to head driver and engaged on the double set screw. The torque limiting handle is rotated clockwise until a snap is heard. Final tightening is accomplished at 24 in-lb (2.71 Nm). Counter torque can be applied if preferred using the **rod gripper** or counter torque (*Figure 32*).

Note: If a revision is necessary, utilize the nut removal instrument to disengage the small nut from the driver.

FINAL TIGHTENING: OCCIPITAL BONE SCREWS AND OCCIPITAL PLATE SET SCREWS

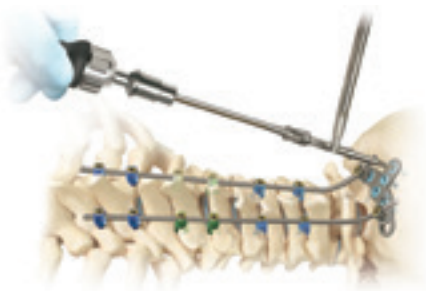


Figure 33

Final tightening of the occipital bone screws is done by utilizing the fixed occiput screw driver or quick connect occiput screw driver with the universal joint shaft. To provide additional stability, the holding forceps may be utilized (*Figure 33*).



Figure 34a

28.

- Perform final tightening of the occipital set screws utilizing the **torque limiting handle** and either the gold tip **fixed set screw driver** or the **quick connect set screw driver** with the **universal joint shaft** and **occipital counter torque**. Final tightening is accomplished at 24 in-lb (2.71 Nm). To provide additional stability, the holding forceps may be utilized (*Figure 34a,b*).



Figure 34b

29.

- 3.5mm rod constructs may be joined using two **cross connector hooks** with a **straight D-rod**. To connect rod constructs, place the cross connector hooks over the longitudinal rods (*Figure 35*).

Tip: Insert the set screw into the hook, then use the set screw and set screw starter to manipulate the hook into position.

- Secure with a D-rod and **set screws**. For final tightening, use a **counter torque handle**, **torque limiting handle** with a grey handle, and the **set screw final tightener**.

Note: Rod contouring can be done using the rod bender, and rod cutting can be done using the rod cutter.

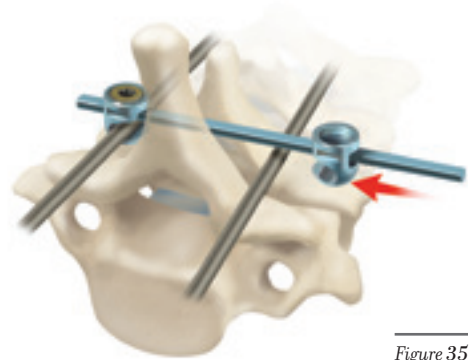
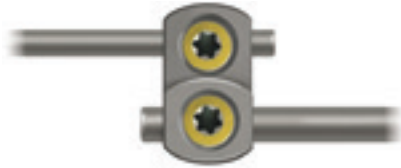


Figure 35

30.



ROD-TO-ROD CONNECTOR



ROD-TO-ROD CONNECTOR



ROD-TO-ROD CONNECTOR

ROD-TO-ROD AND OFFSET CONNECTORS

- A series of **rod-to-rod connectors** may be used to join rod constructs. Use the torque limiting handle for final tightening of the set screw.
- Use the **10mm offset rod** or **15mm offset rod** to facilitate the attachment of a screw to a rod when the two are not in alignment.

ADDITIONAL OPTIONS

- The Vail™ system is indicated for connecting to the Silverton® and Telluride® Spinal Fixation Systems and the Silverton-D® Deformity System.

ADDITIONAL IMPLANTS

- Additional implants are available to assist in building constructs appropriate for the patient's anatomy. 3.5–5.5mm transition rods are available to cross the cervical-thoracic junction. Additional sizes of screws are also available upon request:
 - 3.5mm rod housing x 4.5mm diameter screw
 - 5.5mm rod housing x 4.0mm diameter screw
 - 4.0mm rod housing x 3.5mm/4.0mm diameter smooth shank
 - 3.5mm rod housing x 3.5mm/4.0mm diameter smooth shank.

31.

- Close wound and dress in the usual fashion.

REMOVING THE VAIL™ OCCIPITO-CERVICO-THORACIC POSTERIOR SPINAL FIXATION SYSTEM *(IF NECESSARY)*

1. Particularly in young active patients, implants may loosen, fracture, corrode, migrate, and increase the risk of infection, cause pain, or stress shield bone – even after normal healing. The surgeon should consider the risks and benefits when deciding whether or not to remove an implant. Implant removal should be followed by careful postoperative management to avoid re-fracture. If the patient is older and has a low activity level, the surgeon may elect not to remove the implant in order to eliminate the risks of another surgery.
2. Deterioration of the device after bone consolidation cannot be considered to constitute a dysfunction or deterioration in the characteristics of the implant. The implant can be removed after the consolidation of the bone graft.
3. If a nonunion develops or if the components loosen, bend, and/or break, revise and/or remove the device(s) immediately before serious injury occurs. Failure to immobilize a delayed nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening or breakage of the device(s).
4. Never reuse explanted surgical implants.
5. To remove or revise the BIOMET Vail™ OCT implants, reverse the order of implantation instructions as described in this technique. Set screws should be loosened using the counter torque handle, set screw final tightener and the ratcheting handle (not the torque limiting handle).

VAIL™ INSTRUMENTS



Rod Cutter, Rotary, 3.5mm Diameter • 7902-1011



Drill, Twist, 3.5mm Diameter • 7921-3510



Drill Guide, Fixed, 14mm • 7921-3514



Drill Guide, Variable • 7921-3540



Depth Measure • 7922-1101



Sounder Pedicle • 7922-1201



Probe, Pedicle • 7922-1202



Awl • 7922-1203



Tap, 3.0mm Diameter • 7922-3040



Tap/Drill, 3.5mm Diameter • 7922-3510



Tap Sleeve • 7922-3512



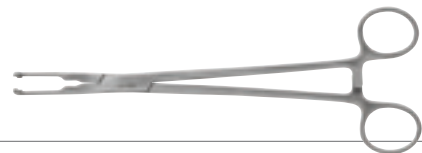
Handle, Ratcheting (Black) • 7923-1001



Driver Straw, Black* • 7923-2006



Probe, Lamina • 7924-1001



Inserter, Hook • 7924-1002



Sizer, Hook • 7924-1003



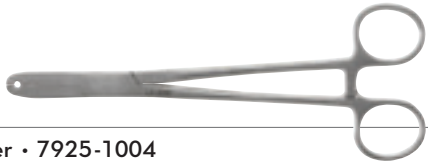
Rod Pusher • 7925-1002



Head Turner • 7925-1003

* Special Order

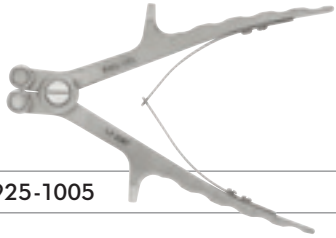
VAIL™ INSTRUMENTS (CONTINUED)



Rod Holder • 7925-1004



Rod Rocker • 7925-1016



Rod Bender • 7925-1005



Handle, Counter Torque • 7926-1001



In Situ Bender - Left • 7925-1006



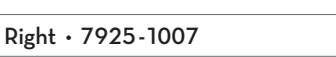
Set Screw Final Tightener, Long • 7926-1005



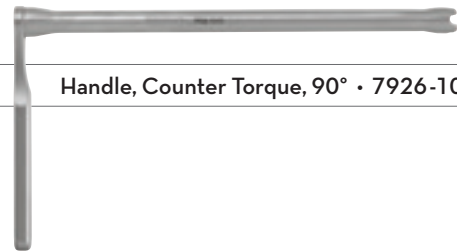
In Situ Bender - Right • 7925-1007



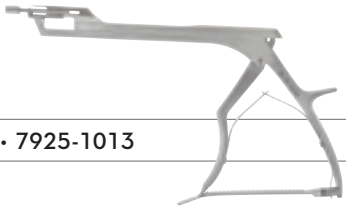
Set Screw Starter, Long* • 7926-1008



In Situ Bender - Right • 7925-1007



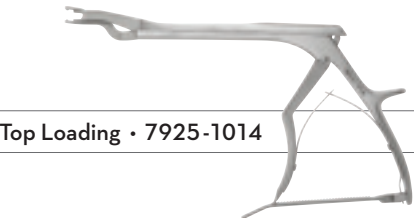
Handle, Counter Torque, 90° • 7926-1010



Rod Persuader • 7925-1013



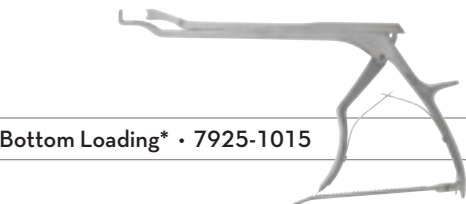
Handle, Torque Limiting • 7927-2002



Rod Persuader, Top Loading • 7925-1014



Compressor • 7930-1001



Rod Persuader, Bottom Loading* • 7925-1015

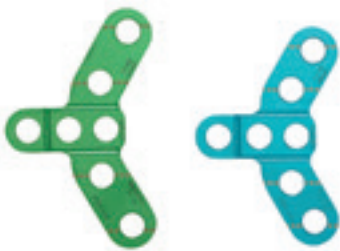
* Special Order



Distractor • 7930-1002



Malleable Rod Template (Disposable/Single Use) • 7931-0100



Occiput Template, Malleable, 43mm • 7931-0243
Occiput Template, Malleable, 49mm • 7931-0249



Rod Template, Malleable, Long, Occipital • 7931-0250



Drill Guide, Fixed, Occipital, 6/8mm • 7941-2006
Drill Guide, Fixed, Occipital, 10/12mm • 7941-2010
Drill Guide, Fixed, Occipital, 14/16mm • 7941-2014



Drill, Fixed, Occipital, 4.5mm • 7941-4510



Drill, Quick Connect, Occipital, 4.5mm • 7941-4520



Tap, Quick Connect, Occipital, 3.7mm • 7942-3720



Tap, Fixed, Occipital, 4.5mm • 7942-4510



Tap, Quick Connect, Occipital, 4.5mm • 7942-4520



Screw Driver, Quick Connect, Occipital • 7943-1001



Set Screw Driver, Quick Connect • 7943-1002



Screw Driver, Fixed, Occipital • 7943-1011



Set Screw Driver, Fixed • 7943-1012



Forceps, Plate Inserter, Occipital • 7945-1002

VAIL™ INSTRUMENTS (CONTINUED)



Handle, Counter Torque, Occipital • 7946-1001



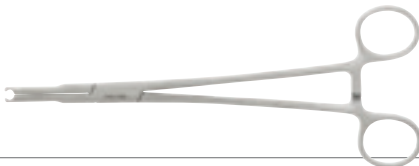
Shaft, Fixed, Occipital • 7946-1005



Joint Shaft, Universal, Occipital • 7946-1002



Rod Cutter, Rotary, 4.0mm Diameter • 7946-1011



Forceps, Shaft Holding, Occipital • 7946-1003



Shaft, Flex, Occipital • 7946-1004



French Rod Bender, Occipital, 3.5mm and 4.0mm • 7946-1015



Smooth Shank Polyaxial Pedicle Screws

Part #	Diameter	Length
7911-3524	3.5mm	24mm
7911-3528	3.5mm	28mm
7911-3532	3.5mm	32mm
7911-3536	3.5mm	36mm
7911-3540	3.5mm	40mm
7911-3544*	3.5mm	44mm
7911-4028	4.0mm	28mm
7911-4032	4.0mm	32mm
7911-4036	4.0mm	36mm
7911-4040	4.0mm	40mm
7911-4044*	4.0mm	44mm



Titanium Curved Rods, Pre-Cut

Part #	Diameter	Length
7901-1030	3.5mm	30mm
7901-1050	3.5mm	50mm
7901-1075	3.5mm	75mm



Titanium Straight Rods, Pre-Cut

Part #	Diameter	Length
7901-0075	3.5mm	75mm
7901-0125	3.5mm	125mm
7901-0225*	3.5mm	225mm
7901-0240	3.5mm	240mm

* Special Order

Smooth Shank Polyaxial Screw - Rod 4.0mm

Part #	Diameter	Length
7918-3528	3.5mm	28mm
7918-3532	3.5mm	32mm
7918-3536	3.5mm	36mm
7918-3540	3.5mm	40mm
7918-4028	4.0mm	28mm
7918-4032	4.0mm	32mm
7918-4036	4.0mm	36mm
7918-4040	4.0mm	40mm



Occipital Pre-Bent Rods 3.5mm

Part #	Diameter	Length
7901-3125	3.5mm	125mm
7901-4125	4.0-3.5mm	125mm
7901-4225	4.0-3.5mm	225mm

Cobalt Chrome Straight Rods 3.5mm

Part #	Diameter	Length
7901-5125	3.5mm	125mm

Cobalt Chrome Pre-Bent OCT Rods 3.5mm

Part #	Diameter	Length
7901-8225	3.5mm	75x125mm

VAIL™ IMPLANTS (CONTINUED)



Cross Connectors

Part #	Description	Length
7907-0075	Cross Connector, D Rod	75mm
7907-1029	Cross Connector Hook	



Occipital Plate

Part #	Size
7905-7043	43mm
7905-7049	49mm



Offset Connectors

Part #	Description	Length
7904-1010	Rod Offset Connector	10mm
7904-1015	Rod Offset Connector	15mm
7904-1030	Rod Offset Connector	30mm



Occipital Screws

Part #	Diameter	Length
7906-4506	4.5mm	6mm
7906-4507	4.5mm	7mm
7906-4508	4.5mm	8mm
7906-4509	4.5mm	9mm
7906-4510	4.5mm	10mm
7906-4511	4.5mm	11mm
7906-4512	4.5mm	12mm
7906-4513	4.5mm	13mm
7906-4514	4.5mm	14mm
7906-4515	4.5mm	15mm
7906-4516	4.5mm	16mm
7906-5306	5.3mm	6mm
7906-5307	5.3mm	7mm
7906-5308	5.3mm	8mm
7906-5309	5.3mm	9mm
7906-5310	5.3mm	10mm
7906-5311	5.3mm	11mm
7906-5312	5.3mm	12mm
7906-5313	5.3mm	13mm
7906-5314	5.3mm	14mm
7906-5315	5.3mm	15mm
7906-5316	5.3mm	16mm



Rod-to-Rod Connectors

Part #	Description	Length
7904-3010	Rod-to-Rod, Small	3.5mm to 3.5mm, 7.25mm gap
7904-3012*	Rod-to-Rod, Large	3.5mm to 3.5mm, 10mm gap
7904-4020	Rod-to-Rod, Small	3.5mm to 5.5mm, 9.25mm gap
7904-4022*	Rod-to-Rod, Large	3.5mm to 5.5mm, 12mm gap
7904-4030	Rod-to-Rod, Small (OAL 16mm)	3.5mm to 2x5.5mm, 7.25mm gap
7904-4032*	Rod-to-Rod, Large (OAL 18.75mm)	3.5mm to 2x5.5mm, 10mm gap



Hooks

Part #	Description	Length
7903-1045	Hook	Small
7903-1060	Hook	Large

* Special Order

IMPORTANT INFORMATION ON THE VAIL™ OCCIPITO-CERVICO-THORACIC (OCT) SPINAL FIXATION SYSTEM

DEVICE DESCRIPTION

The Vail™ system is a typical posterior attachment spinal fixation system composed of an anatomically scaled series of occipital plates and screws, lamina hooks, upper thoracic pedicle screws, longitudinal rods, offset connectors, rod-to-rod connectors, cross connectors, blocker set screws and a dedicated surgical instrument set. The components are used to build a construct to provide stabilization of spinal segments from the occiput to T3 to support fusion. The system offers the surgeon a variety of implant components from which to assemble a suitable construct according to the individual patient's needs and requirements.

INDICATIONS FOR USE

When intended to promote fusion of the occipito-cervico-thoracic region of the spine (occiput-T3) in skeletally mature patients, the Vail system is indicated for the following: degenerative disc disease (as defined by neck and back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; spinal stenosis; trauma/fracture/dislocation; atlanto-axial fracture with instability; occipito-cervical dislocation; failed previous fusion and/or tumor. The use of occipital bone screws is limited to placement in the occiput only. The use of polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

CONTRAINDICATIONS

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome. Contraindications include, but are not limited to:

- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.
- Acute or chronic infectious diseases of any etiology or localization.
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone, which would inhibit rigid device fixation.
- Morbid obesity. An overweight or obese patient can produce loads on the spinal system that can lead to failure of the fixation of the device or failure of the device itself.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Open wounds.
- Pregnancy.

- Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood cell (WBC) count, or a marked left shift in the WBC differential count.
- A case not needing bone graft or fusion.
- Any case requiring the mixing of components from two different systems.
- Any case requiring the mixture of stainless steel with titanium, or stainless steel with cobalt chrome implant components.
- Co-mingling of titanium and stainless steel components within the same construct or using components from other manufacturers' systems.
- Fever or leukocytosis.
- Signs of local infection or inflammation.
- Previous history of infection.
- Alcoholism or smoking.
- Senility, mental illness or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Any patient unwilling to follow postoperative instructions.
- Inadequate tissue coverage over the operative site.
- Any case not described in the indications.

POSSIBLE COMPLICATIONS

While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices but cannot be evaluated *in vivo*, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone. Possible complications include but are not limited to:

- Early or late loosening of any or all the components.
- Bending or breakage of any or all of the components.
- Screw back out, possibly leading to implant loosening and/or reoperation for device removal.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis and/or pain.
- Bursitis. Tissue or nerve damage caused by improper positioning and placement of the implants.
- Non-union or delayed union. Pseudarthrosis. Mal-union.
- Infection.

IMPORTANT INFORMATION ON THE VAIL™ OCCIPITO-CERVICO-THORACIC (OCT) SPINAL FIXATION SYSTEM (CONTINUED)

- Loss of neurological function (e.g., sensory and/or motor) including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development of continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, visual deficits and/or cauda equine syndrome.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to lymphatic vessels and/or lymphatic fluid exudation, damage to blood vessels or other types of cardiovascular system compromise. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
- Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc).
- Loss of or increase in spinal mobility or function.
- Herniated nucleus.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Degenerative changes or instability in segments adjacent to fused vertebral levels.
- Graft donor site complications including pain, fracture or wound healing problems.
- Sensitivity to a metallic foreign body, including possible tumor formation.
- Dural tear or leak leading to surgical repair.
- Loss of spinal curvature, correction, height and/or reduction.
- Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level of surgery.
- Inability to perform the activities of daily living.
- Gastrointestinal, urological or reproductive system compromise, including sterility, loss of consortium and sexual dysfunction.
- Changes in mental status.
- Reoperation.
- Death.

WARNINGS

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This implant system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases of non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. 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.


Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of the consequences. Obese, malnourished and/or alcoholic patients are also poor candidates for spinal fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spinal fusion.

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grade 3 and 4) of the L5–S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other condition are unknown.

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those patients without previous surgery.

PRECAUTIONS

- Vail™ implants are for single use only. Never reuse any implant even if it appears unmarked or undamaged. Reuse of the implant components may result in reduced mechanical performance, malfunction or failure of the device. Any implant implanted and then removed must be discarded. Use only new implants for each case.
- The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- 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.
- Explain the risks associated with neurosurgery, general surgery, orthopedic surgery and the use of general anesthesia to the patient before surgery. It is recommended that the advantages and disadvantages of using implants, as well as alternative treatment methods, be explained to the patient.
- Preoperatively: The surgeon must be fully conversant with all aspects of the surgical technique and know the indications and contraindications of this type of implant. The surgeon must be acquainted before the operation with the specific technique for insertion of the product which is available from the manufacturer. As part of the preoperative examination, the surgeon must check that no biological, biomechanical or other factors will affect the correct conduct of the operation and the postoperative period.
- Perform a careful preoperative review to be sure that all necessary implant components are available and that the instrument set is complete and in working order prior to initiating surgery.
- Before use, inspect all instrumentation for possible damage, wear or non-function. Do not use or process damaged or defective instruments. Contact your local BIOMET SPINE representative or dealer for repair or replacement.
- Intraoperatively: The correct selection of the type and size of implant appropriate to the patient and the positioning of the implant are extremely important.
- Failure to place the set screw as instructed (gold top surface is visible prior to insertion) could result in a failure of the instrumentation to properly lock in place as intended. This may result in patient injury.
- Postoperatively: Patients must be informed of the precautions to be taken in their everyday life to guarantee a maximum implant service life. It is recommended that regular postoperative follow-up is undertaken to detect early signs of failure of the implants and to consider the action to be taken. Deterioration of the device after bone consolidation cannot be considered to constitute a dysfunction or deterioration in the characteristics of the implants. The implant can be removed after bony healing.
- The use of an instrument for tasks other than those for which they are indicated may result in damaged or broken instruments and unpredictable surgical outcomes.
- Do not apply excessive force or stress. Misuse can damage instruments or implants and result in undesirable surgical outcomes.
- The implant and instrument components of the Vail system should NOT be used with the implant or instrument components from any other manufacturer. The Vail system may be connected to the BIOMET SPINE Spinal Fixation Systems. The titanium components of the Vail system should never be used with stainless steel implant components.
- Verify that the torque handle recalibration date printed on the torque handle label is beyond the date of the surgery to ensure proper operation of this instrument.
- The Vail system has not been tested for safety and compatibility in the magnetic resonance (MR) environment. The Vail system has not been tested for heating or migration in the MR environment.
- Mixing of dissimilar metals can accelerate or initiate the corrosion process. Titanium components must NOT be used together in building a construct that involves other implant materials. Titanium and cobalt chrome may be used together within the same construct.



PRODUCT COMPLAINTS – Communicate suspected deficiencies in product quality, identity, durability, reliability, safety, effectiveness and/or performance directly to BIOMET SPINE by email: spinecomplaints@biomet.com or phone: **866.956.7579**. When filing a complaint, please provide the component name(s), part number(s), lot number(s), your name and address, the nature of the complaint, surgeon name and the date you became aware of the complaint. Sterilize and return all component(s) to your local BIOMET SPINE representative. Notify BIOMET SPINE immediately of an incident resulting in patient death or serious injury.

If further directions for use of this system are needed, contact BIOMET SPINE Customer Service by email: spinecustomerservice@biomet.com, phone: **866.378.4195** or fax: **303.443.7501**.

At BIOMET, engineering excellence is our heritage and our passion. For over 25 years, through various divisions worldwide, we have applied the most advanced engineering and manufacturing technology to the development of highly durable systems for a wide variety of surgical applications.

VAIL™

Occipito-Cervico-Thoracic
Spinal Fixation System

To learn more about this product, contact your local BIOMET Sales Representative today.

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