

VIPER[®] Cortical Fix Fenestrated Screw System

Surgical Technique
for OPEN & MIS Procedures

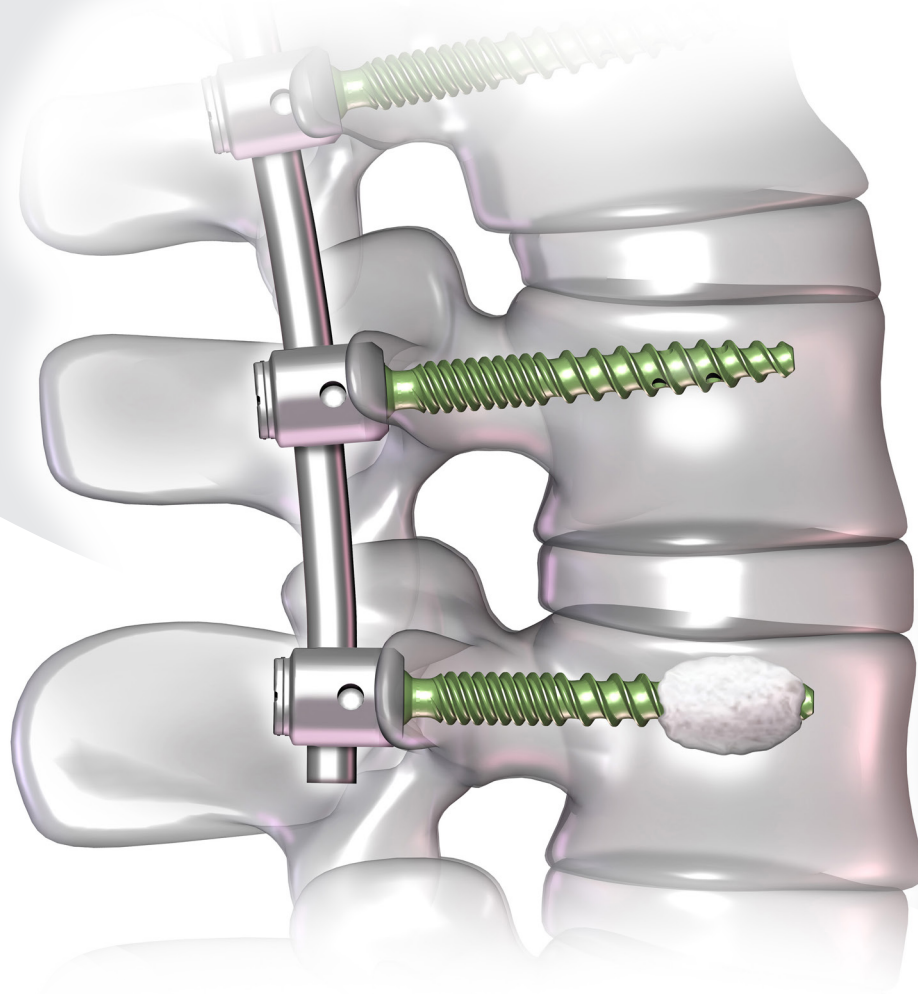


 Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

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Product Overview

Introduction

The VIPER® Cortical Fix Fenestrated Screw System (VIPER CFFS System) provides enhanced fixation in both the pedicle and vertebral body. The Cortical Fix Thread Form doubles the number of contact points within the cortical wall of the pedicle and increases the resistance to axial pull-out forces.¹

The VIPER CFFS System is intended to be used with the CONFIDENCE SPINAL CEMENT SYSTEM™ or the V-MAX™ Mixing and Delivery System and the VERTEBROPLASTIC® Radiopaque Resinous Material or the VERTECEM V+ Cement Kit to provide immobilization and stabilization of the spinal segments in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine in patients with diminished bone quality (e.g. osteoporosis, osteopenia, metastatic disease). It is intended to provide temporary internal support and fixation while fusion mass is consolidating or a fracture is healing, or for the palliative reconstruction of the tumor patients.

This Surgical Technique describes Open and MIS procedures and instrumentation that are specific to the VIPER CFFS System with the CONFIDENCE System and VERTECEM V+ Cement System. When using the VIPER CFFS, it is important to refer to the appropriate EXPEDIUM® System or VIPER® 2 System for the comprehensive surgical technique and system information.

For cement augmentation refer to the package inserts and the Surgical Technique for the CONFIDENCE System and VERTECEM V+ Cement System.

¹ DHF-100465-MEMO28 (Test data on file with DePuy Synthes Spine)

Features and Benefits

TOP NOTCH™ Feature

The TOP NOTCH Feature enables instruments from the EXPEDIUM System and the VIPER System to connect directly to the implants and simplifies intraoperative maneuvers.

Constant Thread Lead

The innovative thread form allows for a smooth transition between the dual and quad lead thread during insertion.

Cortical Thread Form

Cortical Thread Form provides enhanced pedicle fixation.

Fenestrations

1.6 – 1.75 mm fenestration diameters allow for optimal cement delivery and screw fixation.

Optimized Tip

Self-tapping and self-centering tip allows for insertion with or without tapping.

Cannulation

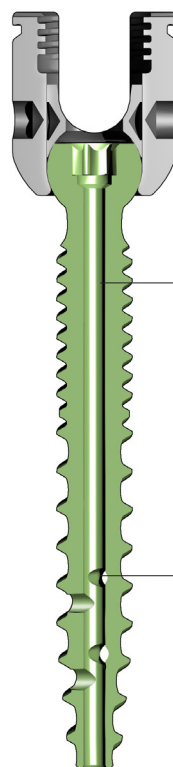
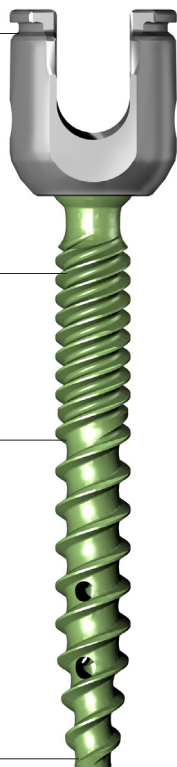
1.75 mm diameter allows for injection of cement through the screw.

TOP NOTCH Feature

Cortical Thread Form

Constant Thread Lead

Optimized Tip



Cannulation

Fenestrations

Open Surgical Technique

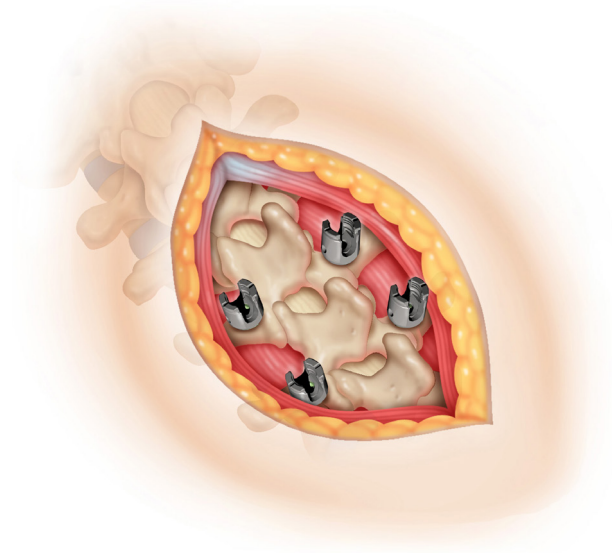
Step 1

Screw preparation and delivery

Refer to the EXPEDIUM 5.5 Spine System Surgical Technique for pedicle targeting, preparation, and screw insertion.

Warnings:

- Fenestrated screw lengths should be measured on a preoperative scan for optimal fenestration positioning. Refer to the screw measurement guide on page 17.
- Fenestrated screws should NOT be placed bicortically. It is very important not to breach the pedicle wall or anterior cortex of the vertebral body during pedicle targeting, preparation or screw insertion to avoid cement extrusion into the retroperitoneal space. Appropriate imaging techniques such as fluoroscopy should be used to confirm screw placement.

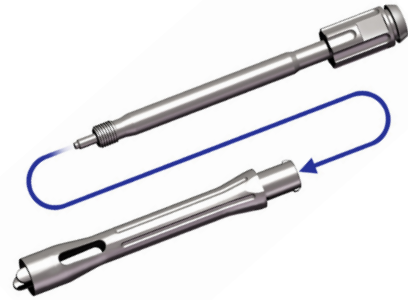


Open Procedure Cement Delivery

Step 2

Assembly of the alignment guide

Check that the alignment device is clear of any cement prior to use. Insert the alignment device into the alignment sleeve and push the two pieces together until you hear an audible 'click'.



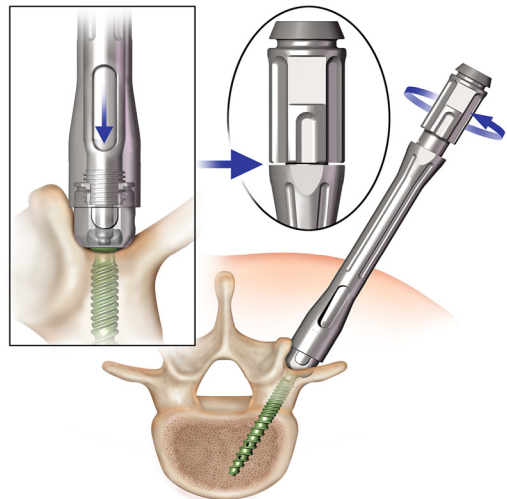
Step 3

Alignment of the screw

Align the tabs of the alignment sleeve with the rod slot in the screw head, ensuring that the soft tissue does not impinge on the connection of the alignment sleeve to the screw head.

Thread the assembled alignment guide into the screw head. This will align the screw shank to the screw head.

Confirm that the alignment device is fully seated by checking that it is flush with the top of the alignment sleeve when fully threaded into the screw head.



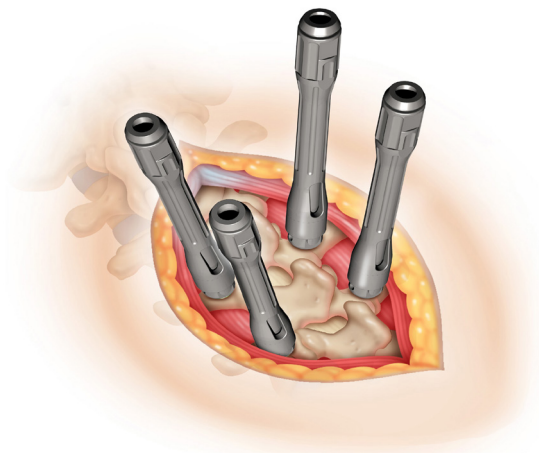
Step 4

Attachment of additional alignment guides

Repeat Step 3 until alignment guides are attached to all levels intended for augmentation. Do not mix the CONFIDENCE System cement until correct alignment is confirmed at all levels.

Warning: If a biopsy is completed prior to screw placement, care must be taken not to place the tip of the biopsy needle beyond the desired location of the screw tip in order to reduce the risk for cement leakage or extravasation.

Precaution: The alignment guide **MUST** be used for each screw intended for cement augmentation. Without the alignment guide, there is a potential risk of cannula breakage. Use of the alignment guide will prevent undue stress from being applied to the cannula.



Cement Preparation

Step 5

Cement preparation*

Once the screws are in place and the alignment guides are attached to the levels selected to be augmented, prepare the CONFIDENCE System cement.

Precaution: For cement preparation refer to the CONFIDENCE System package inserts and Surgical Technique.

Step 6

Connection of open cannula to the cement reservoir

Thread the CONFIDENCE System reservoir onto the open cannula.

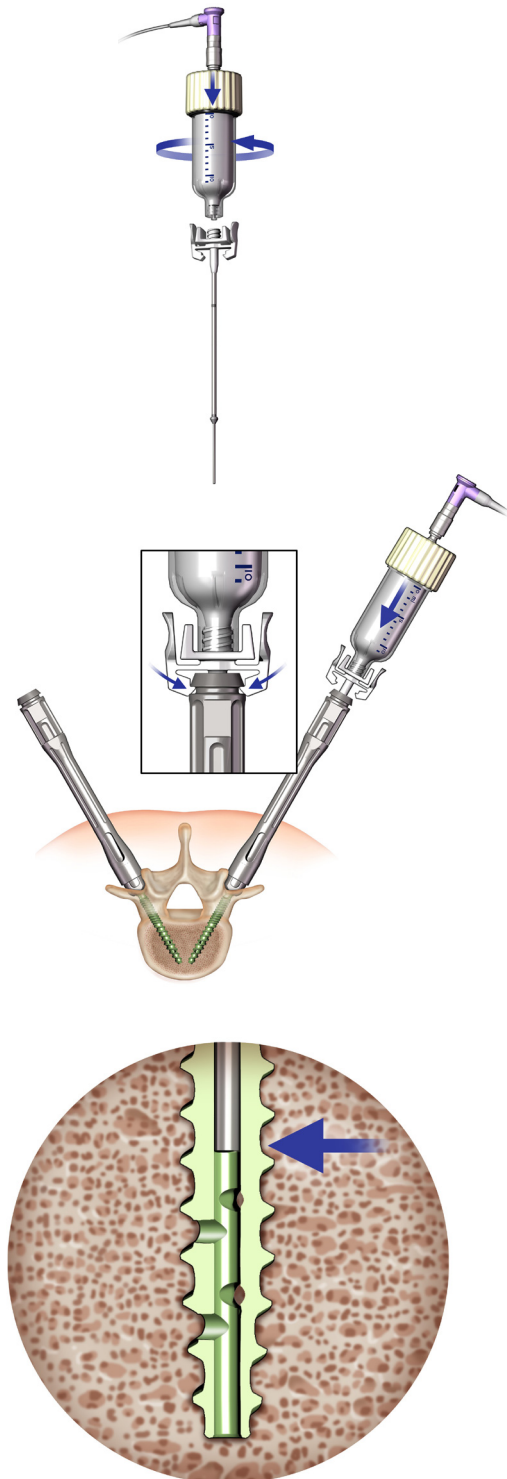
Step 7

Attachment of cement cannula to open alignment guide

Place the open cannula with cement reservoir through the alignment guide and into the screw shank. The cannula will click onto the alignment guide. Once the open cannula is attached correctly to the top of the alignment guide it will be approximately 19.5 mm inside the screw shank.

Precautions:

- To ensure that the cannula is correctly positioned to deliver cement, the cannula **MUST** click into place before proceeding to the next step.
- If there is any difficulty inserting the open cannula into the screw shank, ensure that the alignment device is properly threaded into the screw head.



Cannula position with correct attachment

* For instructions for use with the VERTECEM V+ Cement System refer to page 16

Cement Delivery

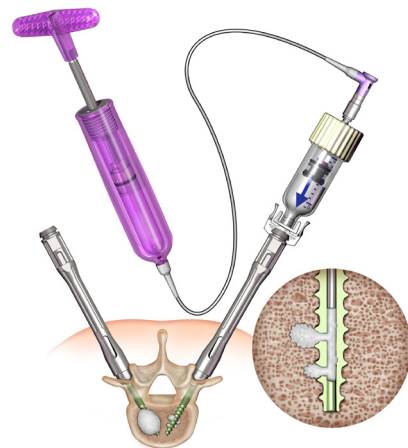
Step 8

Cement delivery

For cement delivery refer to the CONFIDENCE System package inserts and Surgical Technique.

Use fluoroscopy throughout the procedure to verify and monitor cement flow as appropriate.

Warning: Controlled cement delivery is essential to proper screw augmentation. Overly aggressive cement injection may result in cement leakage and unsatisfactory results. Immediately stop cement injection if extravasation is detected.



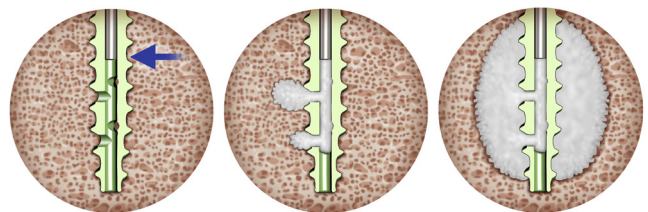
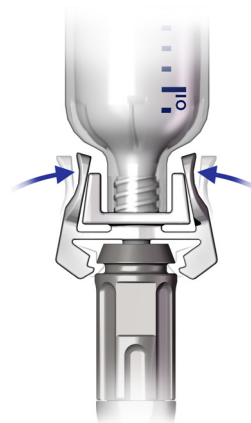
Step 9

Removal of open delivery cannula

When the appropriate amount of cement has been introduced, stop cement introduction as indicated in the CONFIDENCE System Surgical Technique.

Disengage the cannula from the alignment guide by depressing the tabs on each side of the cannula.

Precaution: Prior to disengaging the cannula it is essential to confirm that cement flow has stopped by rotating the CONFIDENCE System handle counterclockwise 3-4 full turns.



Cement delivery

Subsequent Level Augmentation

Step 10

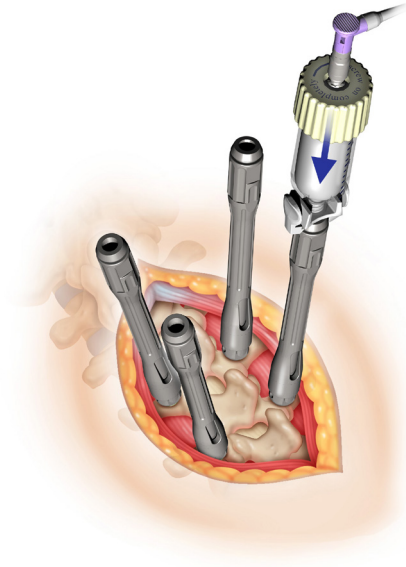
Subsequent level augmentation

Place the existing cannula and cement reservoir into the next alignment guide and repeat the procedure as described in step 8.

Repeat for each desired vertebral level, ensuring that cement flow has stopped between each level.

If an additional cement package is needed, remove the existing cannula and attach a new cannula.

If additional cement is needed beyond its working time, dispose of the cement and cannula. Use a new cannula and mix a new dose of cement for the remaining screws.



Step 11

Removal of open alignment guides

After cement introduction, the alignment devices can be unthreaded from the screw head.

Precautions:

- After cement injection, no torsional movement should be applied to the screw throughout the cement setting time as outlined in the CONFIDENCE System package insert.
- At the end of the procedure, any opened cannulas must be discarded.



Open Rod Insertion and Locking

Step 12

Open rod insertion and locking

Choose the appropriate length rod with the desired contour and place into the Polyaxial screw heads.

Capture the rod into the implant by inserting the single innie setscrew.

Once the cement is set in accordance with the guidelines in the CONFIDENCE System Surgical Technique, insert the hexlobe shaft into the T-Handle torque wrench, set to 80lbs. and final tighten as outlined in the EXPEDIUM System Surgical Technique.

Precaution: After cement injection no torsional movement should be applied to the screw during the cement setting time as outlined in the CONFIDENCE System and VERTECEM V+ Cement System Surgical Technique Guides.

MIS Surgical Technique

Step 1

Screw preparation and delivery

Refer to the VIPER System Surgical Technique for pedicle targeting, preparation, and screw insertion.

Warnings:

- Fenestrated screw lengths should be measured on a preoperative scan to determine optimal fenestration positioning. Refer to the screw measurement guide on page 17.
- Fenestrated screws should NOT be placed bicortically. It is very important not to breach the pedicle wall or anterior cortex of the vertebral body during pedicle targeting, preparation or screw insertion to avoid cement extrusion into the retroperitoneal space. Appropriate imaging techniques such as fluoroscopy should be used to confirm screw placement.

Precaution: Do not remove the VIPER Screw Extension after screw insertion. The extensions must remain in place throughout cement delivery.



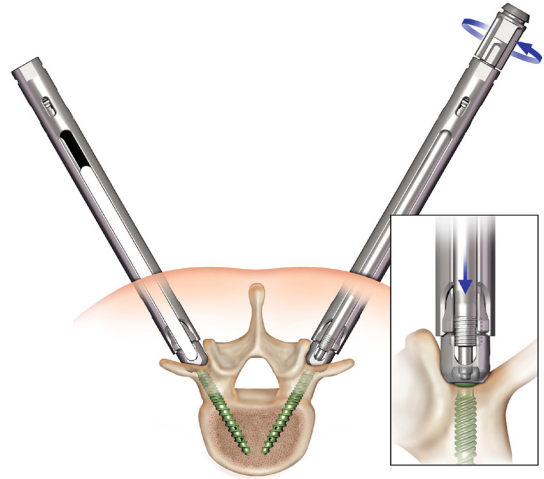
MIS Procedure Cement Delivery

Step 2

Insertion of MIS alignment device

Check that the alignment device is clear of any cement prior to use.

Insert the MIS alignment device into the VIPER System extension and thread it into the screw head. Confirm that the alignment device is fully seated by checking that it is flush with the extension when fully threaded into the screw head.



Step 3

Attachment of additional alignment devices

Repeat Step 2 until alignment devices are attached to all levels intended for augmentation. Do not mix the CONFIDENCE System cement until correct alignment is confirmed at all levels.

Warning: If a biopsy is completed prior to screw placement, care must be taken not to place the tip of the biopsy needle beyond the desired location of the screw tip in order to reduce the risk for cement leakage or extravasation.

Precaution: The alignment device **MUST** be used for each screw intended for cement augmentation. Without the alignment device, there is a potential risk of cannula breakage. Use of the alignment device will prevent undue stress from being applied to the cannula.



Cement Preparation

Step 4

Cement preparation*

Once the screws are in place and the alignment devices are attached to the levels selected to be augmented, prepare the CONFIDENCE System cement.

Precaution: For cement preparation refer to the CONFIDENCE System package inserts and surgical technique guide.

Step 5

Connection of MIS cannula to the cement reservoir

Thread the CONFIDENCE System reservoir onto the MIS cannula.

Step 6

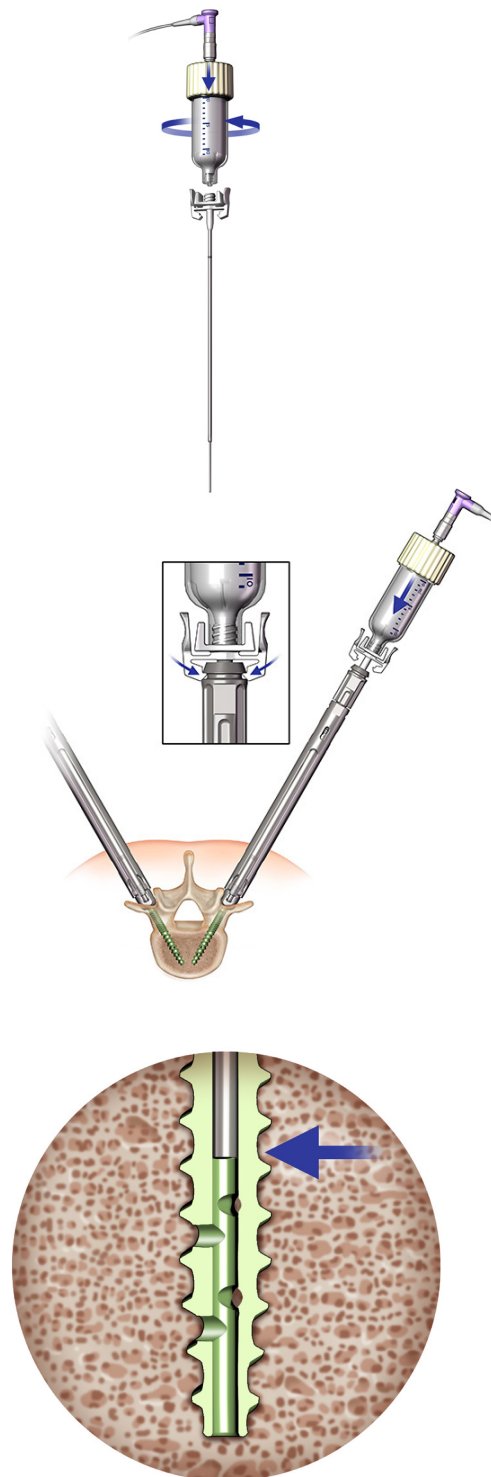
Attachment of cement cannula to MIS alignment device

Place the MIS cannula with cement reservoir through the MIS alignment device and into the screw shank. The cannula will click onto the alignment device.

Once the MIS cannula is attached correctly to the top of the alignment guide it will be approximately 19.8 mm inside the screw shank.

Precautions:

- To ensure that the MIS cannula is correctly positioned to deliver cement, the cannula **MUST** click into place before proceeding to the next step.
- If there is any difficulty inserting the MIS cannula into the screw shank, ensure that the alignment device is properly threaded into the screw head.



Cannula position with correct attachment

* For instructions for use with the VERTECEM V+ Cement System refer to page 19

Cement Delivery

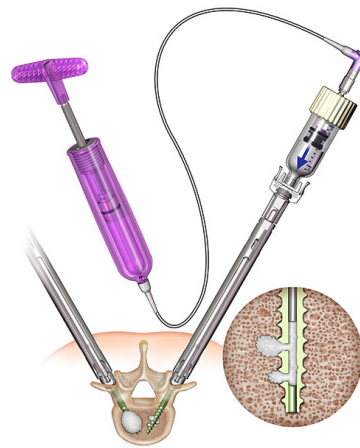
Step 7

Cement delivery

For cement delivery refer to the CONFIDENCE System package inserts and Surgical Technique to introduce the cement through the delivery cannula.

Use fluoroscopy throughout the procedure to verify and monitor cement flow as appropriate.

Warning: Controlled delivery is essential to proper screw augmentation. Overly aggressive cement injection may result in cement leakage and unsatisfactory results. Immediately stop cement injection if extravasation is detected.



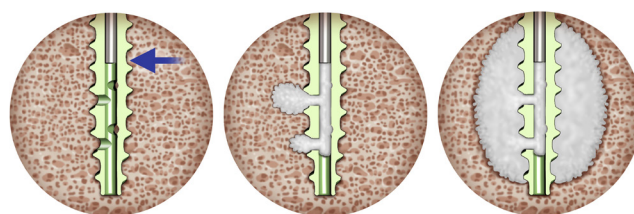
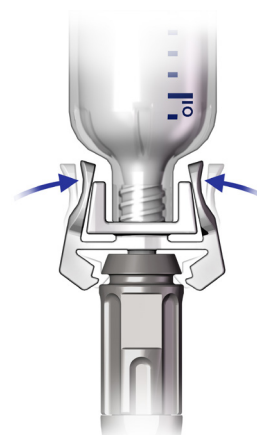
Step 8

Removal of MIS delivery cannula

When the appropriate amount of cement has been introduced, stop cement introduction as indicated in the CONFIDENCE System Surgical Technique.

Disengage the MIS cannula from the alignment device by depressing the tabs on each side of the cannula and remove it from the screw as soon as cement injection is complete and flow has stopped through the cannula.

Precaution: Prior to disengaging the cannula it is essential to confirm that cement flow has stopped by rotating the CONFIDENCE System handle counterclockwise 3-4 full turns.



Cement delivery

Subsequent Level Augmentation

Step 9

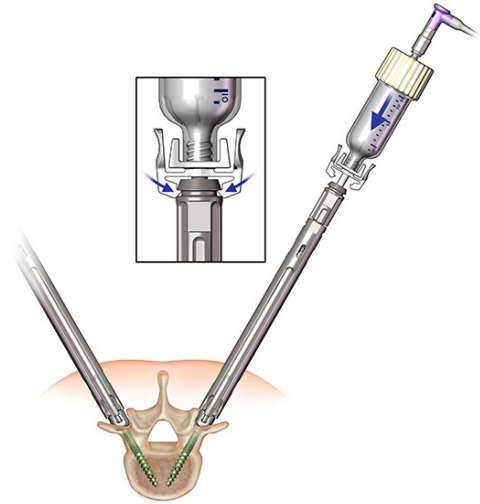
Subsequent level augmentation

Place the existing cannula and cement reservoir into the next alignment guide and repeat the procedure as described in steps 6 and 7.

Repeat for each desired vertebra, ensuring that cement flow has stopped between each level.

If an additional cement package is needed, remove the existing cannula and replace with a new cannula.

If additional cement is needed beyond its working time, dispose of the cement and cannula. Use a new cannula and mix a new dose of cement for the remaining screws.



Step 10

Removal of MIS alignment devices

After the cement introduction, the alignment devices can be unthreaded from the screw head.

Precautions:

- After cement injection, no torsional movement should be applied to the screw throughout the cement setting time outlined in the CONFIDENCE System package insert.
- At the end of the procedure, any opened cannulas must be discarded.



MIS Rod Insertion and Locking

Step 11

MIS rod insertion and locking

Choose the appropriate length rod with the desired contour and place into the Polyaxial screw heads.

Capture the rod into the implant by inserting the single innie setscrew.

Once the cement is set in accordance with the guidelines in the CONFIDENCE Cement System and VERTECEM V+ Cement System Surgical Technique Guides, insert the hexlobe shaft into the T-Handle torque wrench, set to 80lbs. and final tighten as outlined in the VIPER System Surgical Technique.

Precautions:

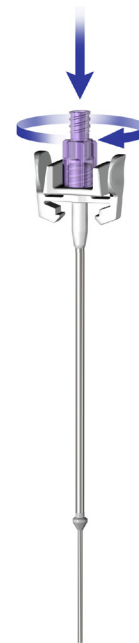
- **After cement injection no torsional movement should be applied to the screw throughout the cement setting time as outlined in the CONFIDENCE System and VERTECEM V+ Cement System Surgical Technique Guides.**
- **Final tightening should be conducted in accordance with the VIPER System Surgical Technique.**

VERTECEM V+ Cement System Open Technique

Step 1

Luer Lock Attachment

Thread the CONFIDENCE System Luer Lock adapter (283999001) onto the Open Cannula.



Step 2

Cement Preparation

Once the screws are in place and the alignment guides are attached to the levels selected to be augmented prepare the VERTECEM V+ Cement System.

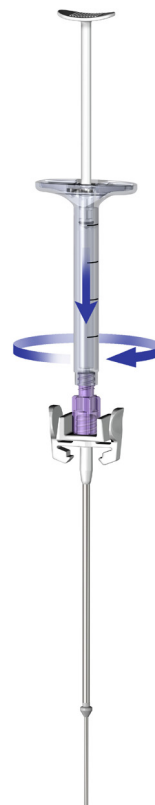
Precaution:

- For cement preparation refer to the VERTECEM V+ Cement System package inserts and Surgical Technique Guide.

Step 3

Connection of open cannula to VERTECEM V+ Syringe

Thread the Syringe onto the preassembled CONFIDENCE Luer Lock adapter and Open Cannula.



VERTECEM V+ Cement System Open Technique

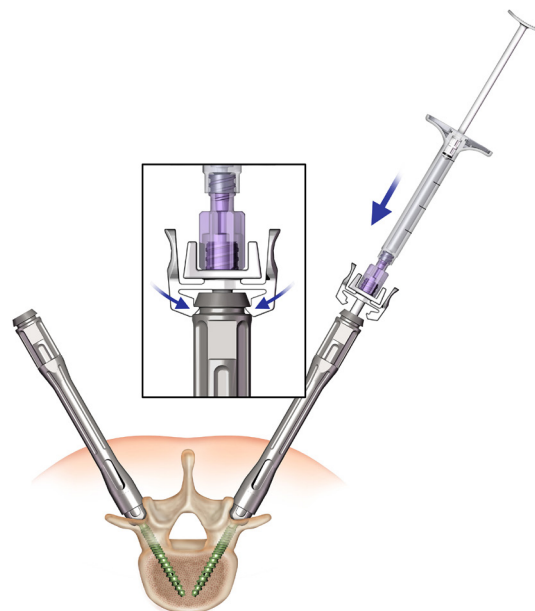
Step 4

Attachment of cement cannula to open alignment guide

Place the Open Cannula through the alignment guide and into the screw shank. The cannula will click onto the alignment guide. Once the Open Cannula is attached correctly to the top of the alignment guide it will be approximately 19.5mm inside the screw shank.

Precautions:

- To ensure that the cannula is correctly positioned to deliver cement, the cannula **MUST** click into place before proceeding to the next step.
- If there is any difficulty inserting the open cannula into the screw shank, ensure that the alignment device is properly threaded into the screw head.



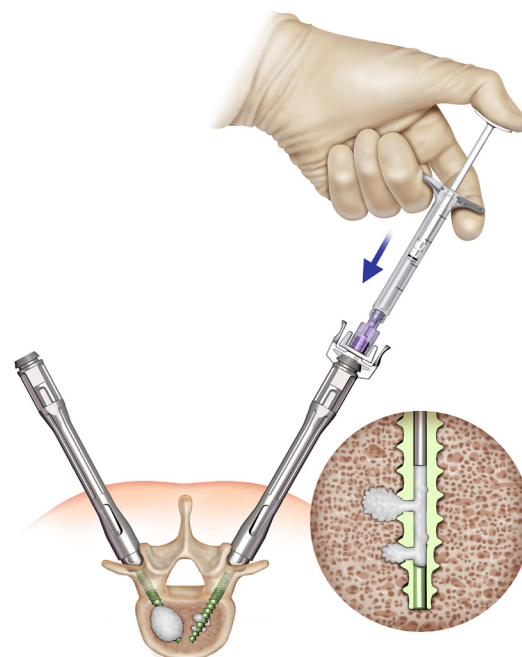
Step 5

Cement Delivery

For cement delivery refer to the VERTECEM V+ Cement System Surgical Technique guide.

Use fluoroscopy throughout the procedure to verify and monitor cement flow as appropriate.

Warning: Controlled cement delivery is essential to proper screw augmentation. Overly aggressive cement injection may result in leakage and unsatisfactory results. Immediately stop cement injection if extravasation is detected.



VERTECEM V+ Cement System Open Technique

Step 6

Removal of open delivery cannula

When the appropriate amount of cement has been introduced stop the cement introduction as indicated in the VERTECEM V+ Cement System Surgical Technique Guide.

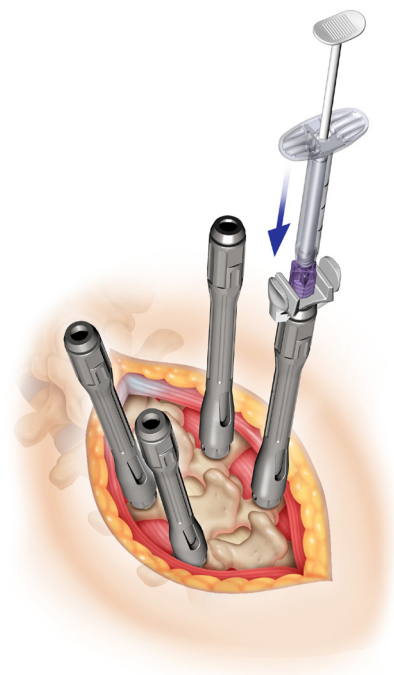
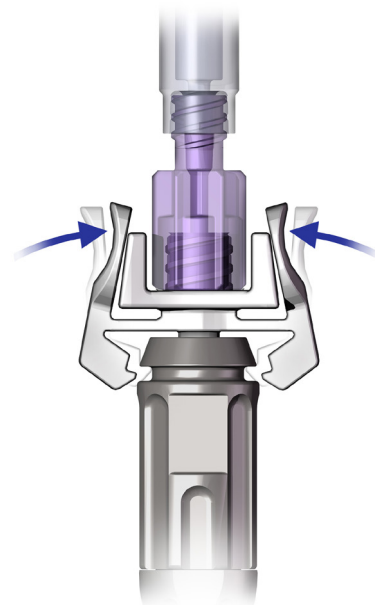
Disengage the cannula from the alignment guide by depressing the tabs on each side of the cannula.

Step 7

Subsequent level augmentation

Place the existing cannula with Luer Lock attached into the next alignment guide and repeat the procedure as described in step 5. Repeat for each desired level.

If additional cement is required beyond its working time, dispose of the cement and cannula. Use a new cannula and mix a new dose of cement for the remaining screws.



VERTECEM V+ MIS Technique

Step 1

Luer Lock Attachment

Thread the CONFIDENCE Luer lock adapter (283999001) onto the MIS Cannula.

Step 2

Cement Preparation

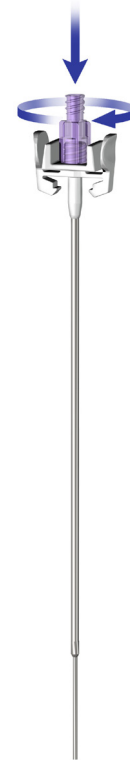
Once the screws are in place and the alignment devices are attached to the levels selected to be augmented prepare the VERTECEM V+ Cement System.

Precaution: For cement preparation refer to the VERTECEM V+ Cement System package inserts and Surgical Technique Guide.

Step 3

Connection of MIS cannula to VERTECEM V+ Syringe

Thread the Syringe onto the preassembled CONFIDENCE Luer lock adapter and MIS Cannula.



VERTECEM V+ MIS Technique

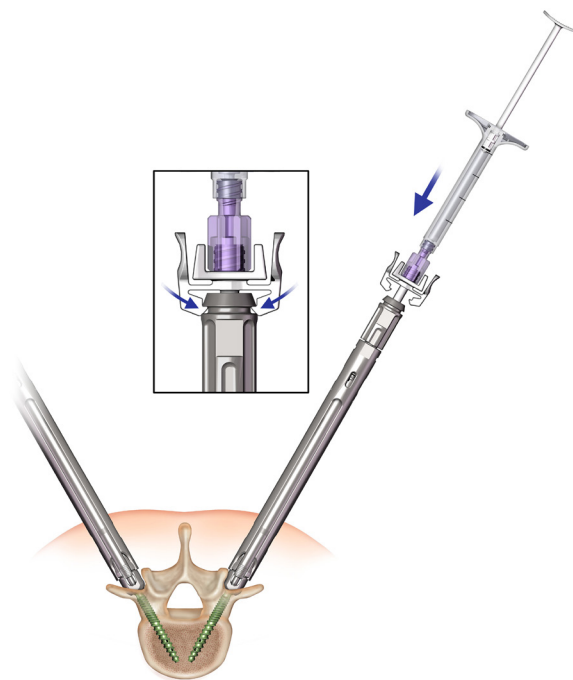
Step 4

Attachment of cement cannula to MIS alignment guide

Place the MIS Cannula through the alignment device and into the screw shank. The cannula will click onto the alignment device. Once the MIS Cannula is attached correctly to the top of the alignment device it will be approximately 19.8mm inside the screw shank

Precautions:

- To ensure that the cannula is correctly positioned to deliver cement, the cannula **MUST** click into place before proceeding to the next step.
- If there is any difficulty inserting the open cannula into the screw shank, ensure that the alignment device is properly threaded into the screw head.



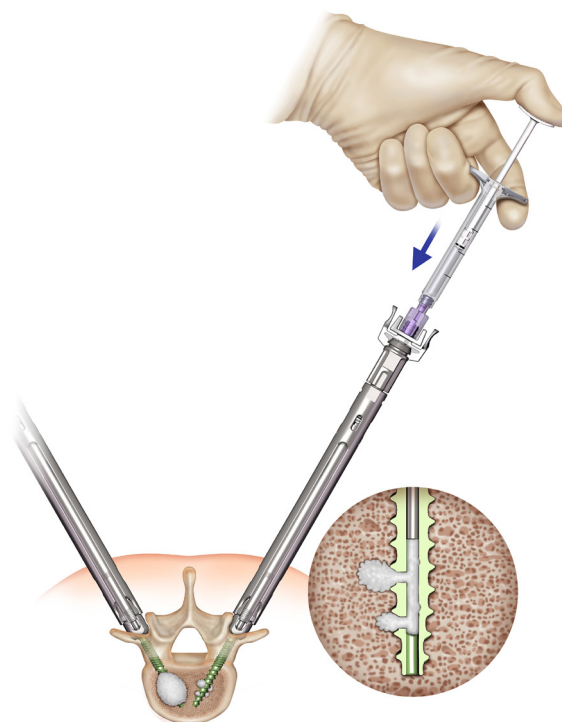
Step 5

Cement Delivery

For cement delivery refer to the VERTECEM V+ surgical technique guide.

Use fluoroscopy throughout the procedure to verify and monitor cement flow as appropriate.

Warning: Controlled cement delivery is essential to proper screw augmentation. Overly aggressive cement injection may result in leakage and unsatisfactory results. Immediately stop cement injection if extravasation is detected.



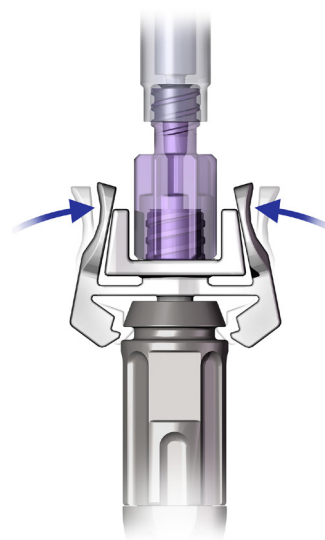
VERTECEM V+ MIS Technique

Step 6

Removal of MIS delivery cannula

When the appropriate amount of cement has been introduced stop the cement introduction as indicated in the VERTECEM V+ Surgical Technique Guide.

Disengage the cannula from the alignment device by depressing the tabs on each side of the cannula.

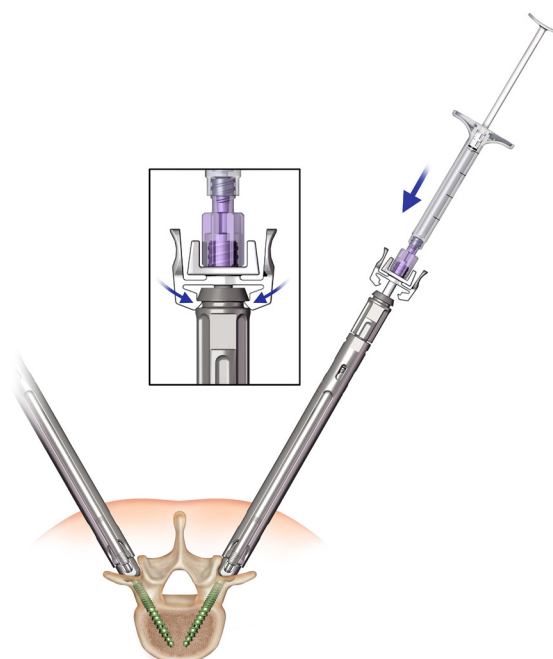


Step 7

Subsequent level augmentation

Place the existing cannula with luer lock attached into the next alignment guide and repeat the procedure as described in step 5. Repeat for each desired level.

If additional cement is needed beyond its working time, dispose of the cement and cannula. Use a new cannula and mix a new dose of cement for the remaining screws.



Residual Cement Removal

Residual cement removal

After use, the alignment devices must be visually inspected for any residual cement.

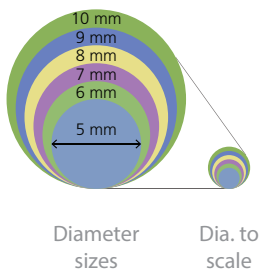
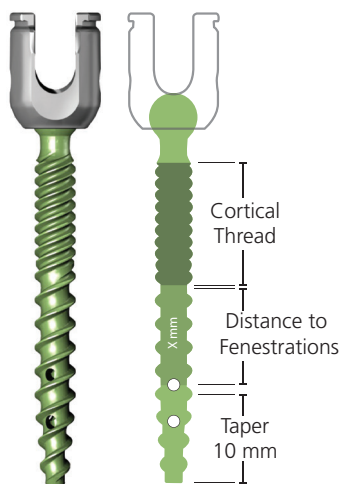
If cement remains in the alignment device, insert the Stylet through the alignment device and rotate to ensure any cement is removed.

Insert the Mini-Stylet into the threaded tip of the alignment device.

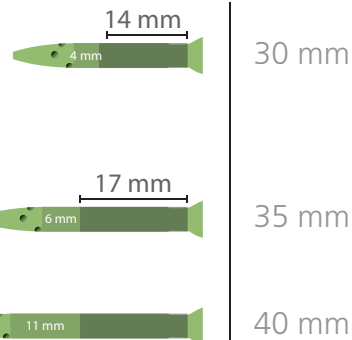
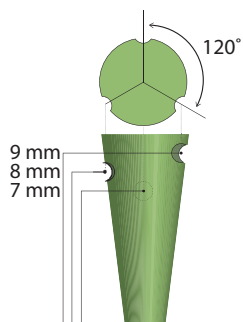
If cement remains in the device, repeat cleaning steps above or return it to DePuy Synthes Spine.



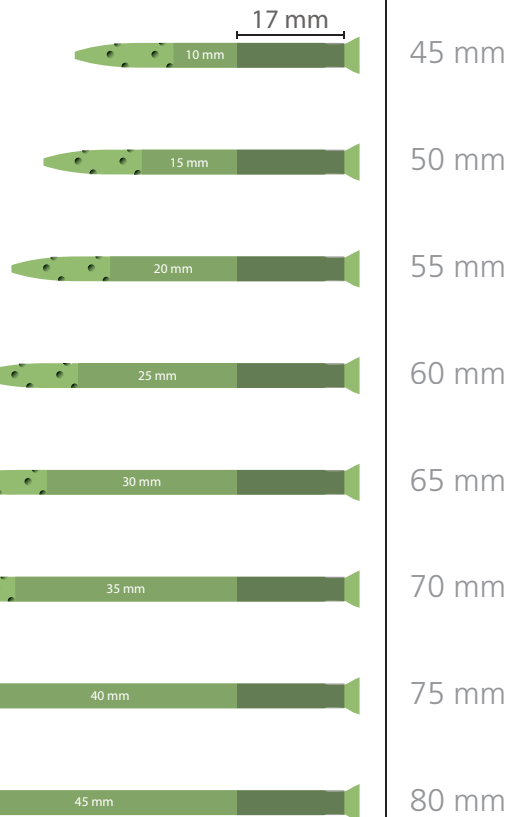
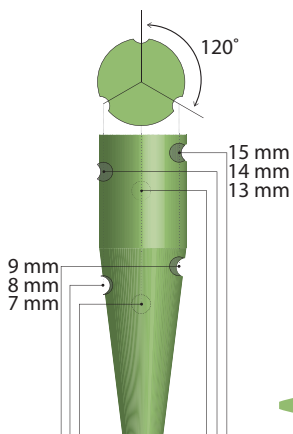
Measurement Guide



3 Fenestrations



6 Fenestrations

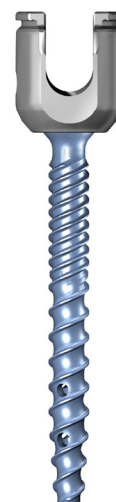


All values are rounded to the nearest whole number.

Product Catalogue

Implants

Item Number	Description
186727530	5.5 TI CORT FIX FEN 5 mm x 30 mm
186727535	5.5 TI CORT FIX FEN 5 mm x 35 mm
186727540	5.5 TI CORT FIX FEN 5 mm x 40 mm
186727545	5.5 TI CORT FIX FEN 5 mm x 45 mm
186727550	5.5 TI CORT FIX FEN 5 mm x 50 mm
186727555	5.5 TI CORT FIX FEN 5 mm x 55 mm
186727560	5.5 TI CORT FIX FEN 5 mm x 60 mm
186727565	5.5 TI CORT FIX FEN 5 mm x 65 mm
186727570	5.5 TI CORT FIX FEN 5 mm x 70 mm
186727575	5.5 TI CORT FIX FEN 5 mm x 75 mm
186727580	5.5 TI CORT FIX FEN 5 mm x 80 mm
186727630	5.5 TI CORT FIX FEN 6 mm x 30 mm
186727635	5.5 TI CORT FIX FEN 6 mm x 35 mm
186727640	5.5 TI CORT FIX FEN 6 mm x 40 mm
186727645	5.5 TI CORT FIX FEN 6 mm x 45 mm
186727650	5.5 TI CORT FIX FEN 6 mm x 50 mm
186727655	5.5 TI CORT FIX FEN 6 mm x 55 mm
186727660	5.5 TI CORT FIX FEN 6 mm x 60 mm
186727665	5.5 TI CORT FIX FEN 6 mm x 65 mm
186727670	5.5 TI CORT FIX FEN 6 mm x 70 mm
186727675	5.5 TI CORT FIX FEN 6 mm x 75 mm
186727680	5.5 TI CORT FIX FEN 6 mm x 80 mm



Product Catalogue

Implants

Item Number	Description
186727730	5.5 TI CORT FIX FEN 7 mm x 30 mm
186727735	5.5 TI CORT FIX FEN 7 mm x 35 mm
186727740	5.5 TI CORT FIX FEN 7 mm x 40 mm
186727745	5.5 TI CORT FIX FEN 7 mm x 45 mm
186727750	5.5 TI CORT FIX FEN 7 mm x 50 mm
186727755	5.5 TI CORT FIX FEN 7 mm x 55 mm
186727760	5.5 TI CORT FIX FEN 7 mm x 60 mm
186727765	5.5 TI CORT FIX FEN 7 mm x 65 mm
186727770	5.5 TI CORT FIX FEN 7 mm x 70 mm
186727775	5.5 TI CORT FIX FEN 7 mm x 75 mm
186727780	5.5 TI CORT FIX FEN 7 mm x 80 mm
186727830	5.5 TI CORT FIX FEN 8 mm x 30 mm
186727835	5.5 TI CORT FIX FEN 8 mm x 35 mm
186727840	5.5 TI CORT FIX FEN 8 mm x 40 mm
186727845	5.5 TI CORT FIX FEN 8 mm x 45 mm
186727850	5.5 TI CORT FIX FEN 8 mm x 50 mm
186727855	5.5 TI CORT FIX FEN 8 mm x 55 mm
186727860	5.5 TI CORT FIX FEN 8 mm x 60 mm
186727865	5.5 TI CORT FIX FEN 8 mm x 65 mm
186727870	5.5 TI CORT FIX FEN 8 mm x 70 mm
186727875	5.5 TI CORT FIX FEN 8 mm x 75 mm
186727880	5.5 TI CORT FIX FEN 8 mm x 80 mm



Product Catalogue

Implants

Item Number	Description
186727930	5.5 TI CORT FIX FEN 9 mm x 30 mm
186727935	5.5 TI CORT FIX FEN 9 mm x 35 mm
186727940	5.5 TI CORT FIX FEN 9 mm x 40 mm
186727945	5.5 TI CORT FIX FEN 9 mm x 45 mm
186727950	5.5 TI CORT FIX FEN 9 mm x 50 mm
186727955	5.5 TI CORT FIX FEN 9 mm x 55 mm
186727960	5.5 TI CORT FIX FEN 9 mm x 60 mm
186727965	5.5 TI CORT FIX FEN 9 mm x 65 mm
186727970	5.5 TI CORT FIX FEN 9 mm x 70 mm
186727975	5.5 TI CORT FIX FEN 9 mm x 75 mm
186727980	5.5 TI CORT FIX FEN 9 mm x 80 mm
186727030	5.5 TI CORT FIX FEN 10 mm x 30 mm
186727035	5.5 TI CORT FIX FEN 10 mm x 35 mm
186727040	5.5 TI CORT FIX FEN 10 mm x 40 mm
186727045	5.5 TI CORT FIX FEN 10 mm x 45 mm
186727050	5.5 TI CORT FIX FEN 10 mm x 50 mm
186727055	5.5 TI CORT FIX FEN 10 mm x 55 mm
186727060	5.5 TI CORT FIX FEN 10 mm x 60 mm
186727065	5.5 TI CORT FIX FEN 10 mm x 65 mm
186727070	5.5 TI CORT FIX FEN 10 mm x 70 mm
186727075	5.5 TI CORT FIX FEN 10 mm x 75 mm
186727080	5.5 TI CORT FIX FEN 10 mm x 80 mm



Instruments

2797-26-401 Open Alignment Device



2797-26-509 Open Alignment Sleeve



2797-26-500 Open Cannula (sterile single use)



2797-26-508 MIS Cannula (sterile single use)



2797-26-403 Stylet



2797-26-511 Mini Stylet



2797-26-400 MIS Alignment Device



2839-99-001 Confidence Adapter



Indications for use

The VIPER® Fenestrated Screw System is intended to be used with the CONFIDENCE SPINAL CEMENT SYSTEM™ or the V-MAX™ Mixing and Delivery System and the VERTEBROPLASTIC® Radiopaque Resinous Material or the VERTECEM V+ Cement Kit to provide immobilization and stabilization of spinal segments in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine in patients with diminished bone quality (e.g., osteoporosis, osteopenia, metastatic disease). It is intended to provide temporary internal support and fixation while fusion mass is consolidating or fracture is healing, or for the palliative reconstruction of the tumor patients.

Contraindications

The use of VIPER® Fenestrated Screw System is contraindicated in patients presenting with any of the following conditions:

- Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices.
- Acute compromise of the vertebral body or walls of the pedicles and disruption of the posterior cortex.
- Anatomical damage of the vertebra that prevents safe screw implantation.
- Active or incompletely treated infection.
- Coagulation disorders, or severe cardiopulmonary disease.
- Haemorrhagic diathesis.
- Spinal stenosis > 20% caused by retropulsed fragments.
- Vertebral body collapse to less than 1/3 (33%) original height.
- Coagulopathy or inability to reverse anti-coagulant therapy (both during and approximately 24 hours post-procedure).
- Allergic reaction to any of the components of the cement or metal used.
- Relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.

Warnings

1. Refer to the VIPER/VIPER2 System and VIPER Fenestrated Screw Cannulas package insert for warnings associated with the use of the VIPER/VIPER2 System and VIPER Fenestrated Screw Cannulas.
2. Depending on the cement used, refer either to the package inserts of the CONFIDENCE SPINAL CEMENT SYSTEM Kit and the CONFIDENCE Spinal Cement or the V-MAX Mixing and Delivery Device and the VERTEBROPLASTIC Radiopaque Resinous Material or the VERTECEM V+ Cement Kit for a list of warnings associated with the cement use. [Follow the time temperature chart for mixing, delivery, and setting time of the cement used very carefully.](#)
3. The VIPER® Fenestrated Screws should NOT be placed bicortically. It is very important not to breach the pedicle wall or the anterior cortex of the vertebral body to avoid cement extrusion into the retroperitoneal space. This may result in

serious complications, including cement extravasation, embolism or even death, especially if the cement is inadvertently delivered through the tip of the screw.

4. Pay special attention to the delivery system instructions from the corresponding package insert. Aggressive cement injection may result in cement leakage or extravasation.
5. Accurate pedicle preparation, screw sizing and placement must be practiced, as well as a careful cement delivery technique. There may be an increased risk of cement egress into pedicle if the screw length is too short for the vertebral body, or if excessive cement volume is pumped into the vertebral body.
6. When using cement to augment multiple screws or levels, attention must be paid not to exceed the working time of the cement prior to completion of cement delivery through the screw. When the cement working time is close to completion, a new cement package should be opened to mix and deliver cement through the next screw/level.
7. It is critical that NO torsion movement should be applied to the screw after injecting the cement in order to avoid breaking the cement bridges between screw and bone.
8. Do not continue injection beyond the working time of the cement. After cement introduction is complete, the VIPER® Fenestrated Screw Cement Cannula must be removed immediately. The cement setting while the cannula is still connected to the screw may lead to difficulty in removal, and a new cannula may be required for additional levels.
9. Strict adherence to good surgical principles and techniques is essential. Deep wound infection is a serious post-operative complication and may require total removal of the embedded cement. Deep wound infection may be latent and may not manifest itself even for several years post-operatively.
10. Hypotensive reactions may occur with any procedure that involves cement use and some may progress to cardiac arrest. For this reason, patients should be monitored for any change in blood pressure during and immediately following the application of the cement.
11. Following cement introduction, positioning of the patient should be maintained securely throughout the setting phase as described in package inserts for either the CONFIDENCE SPINAL CEMENT SYSTEM or the Vertebroplastic Radiopaque Resinous Material or the VERTECEM V+ Cement Kit depending on which cement was used.
12. The long-term safety and efficacy of the VIPER® Fenestrated Screw System with cement augmentation have not yet been established.
13. The safety and efficacy of the VIPER® Fenestrated Screw System in pregnant women or in children has not yet been established.
14. The mixing/delivery device is designed for single use with one package of spinal cement. If additional material is needed, use a second CONFIDENCE SPINAL CEMENT SYSTEM 11cc Kit or V-MAX Mixing and Delivery Device.
15. Do not re-sterilize any components packaged sterile. They are for single patient use only. These components are sterile only if the package is unopened and undamaged. DePuy Spine will not be responsible for any product that is re-sterilized.

Appendix

16. Extreme caution should be exercised when there is disruption to the posterior cortex of the vertebral body or the pedicle as this increases the risk of cement extravasation into the neural foramen or spinal canal.
17. Cement leakage can also occur when injecting CONFIDENCE 11cc High Viscosity Spinal Cement or VERTEBROPLASTIC Radiopaque Resinous Material or VERTECEM V+ Cement Kit if cement enters a blood vessel or if unseen microfractures are prevalent.
18. If the CONFIDENCE 11cc High Viscosity Spinal Cement is seen outside of the vertebral body or in the circulatory system during the procedure, immediately stop injecting the cement. If using the CONFIDENCE Spinal Cement Delivery System, turn the pump handle counter-clockwise to stop the injection of the cement.
19. You may wish to consider the additional precaution of using Computerized Tomography (CT) guidance for high-risk cases.
20. Assure that all system components are firmly connected prior to cement introduction. Improperly secured connections could result in the unintended disconnection of components.
21. Always cancel the pressure within the system when cement introduction is no longer desired per the CONFIDENCE SPINAL CEMENT SYSTEM 11cc Kit package insert.
22. Do not attempt to force the injection of material if excessive resistance is felt. Always determine the cause of the resistance and take appropriate action.
23. Inadequate fixation or unanticipated post-operative events may affect device performance causing failure in any of several modes. These modes may include bone-metal, bone-cement and cement-metal interface, implant fracture or bone failure.
5. If surgeon chooses to complete a biopsy prior to screw placement, care should be taken not to place the tip of the biopsy needles beyond the desired location of the screw tip in order to reduce leakage or extravasation risk.
6. VIPER® Fenestrated Screws System implants and instruments must never be reused. An explanted implant should never be reimplanted. Even though a device appears undamaged after explanting, it may have small defects and internal stress patterns that may lead to early breakage.
7. Reuse of single use implants and instruments may compromise device performance and patient safety and can also cause cross-contamination leading to patient infection.
8. These procedures should only be performed in medical settings where emergency surgery is available.
9. The CONFIDENCE SPINAL CEMENT SYSTEM 11cc Kit is designed for use only with CONFIDENCE 11cc High Viscosity Spinal Cement. The device may not be compatible with alternate materials. The V-MAX Mixing and Delivery Device is designed for use only with VERTEBROPLASTIC Radiopaque Resinous Material or VERTECEM V+ Cement System. The device may not be compatible with alternate materials.

Precautions

1. 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. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but must also be aware of the mechanical and metallurgical limitations of metallic surgical implants. The surgeon should also be familiar with the principles and technique of spinal cement delivery, including possible side effects and limitations, and with the physiology and pathology of the selected anatomy.
2. A thorough pre-operative check-up of the patient must be carried out before the operation.
3. Postoperative care is extremely important. The patient must be instructed in the limitations of the metallic implant and be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instructions could lead to failure of the implant and possible need thereafter for additional surgery to remove the device.
4. During the application of the cement, radiological control is essential so that the operator can follow the progress of the filling and stop the procedure if the slightest leakage of cement is detected. Use appropriate imaging techniques such as fluoroscopy or CT imaging guidance to confirm correct screw placement, absence of damage to surrounding structures and appropriate location of injected cement.



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