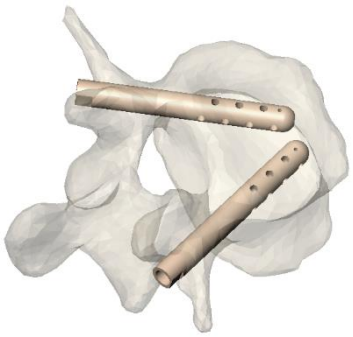
OPERATIVE TECHNIQUE

United States Federal law restricts this device to sale by or on the order of a physician or licensed practitioner

V-STRUT©

Vertebral Implant

V-STRUT© Vertebral Implant is intended for use in the treatment of vertebral fractures.



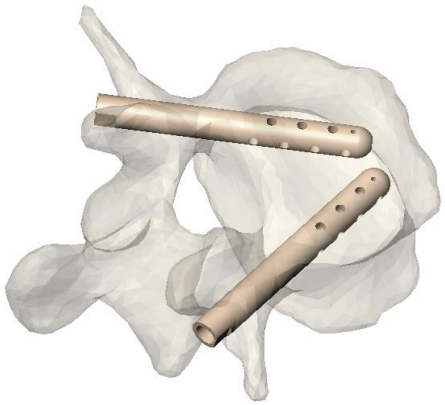
See also the Instructions for Use:

- V-STRUT© Vertebral Implant - Instructions
- V-STRUT© Guide Wire and Instrumentation Kit - Instructions
- V-STRUT© Bone Filler - Instructions

TABLE OF CONTENT

INDICATIONS

V-STRUT© Vertebral Implant is indicated for use in the treatment of vertebral fractures in the thoracic and lumbar spine from T9 to L5. It is intended to be used in combination with Teknimed F20® bone cement.



V-STRUT© Vertebral Implant is placed in the vertebrae through a minimally invasive procedure. Two devices are implanted in each to be treated vertebra. Each implant is introduced posteriorly through the pedicle up to the anterior vertebral body wall. A part of the implant is embedded into the pedicle, thus providing posterior support. The other part of the device, located in the vertebral body, presents lateral perforations, which allow acrylic bone cement diffusion, filling of the vertebral body, implant fixation, and support of the upper endplate. The combination of the implant and the cement allows the treatment of vertebral fractures.

The implant is made of radio transparent PEEK (Polyether ether Ketone) polymer and includes visualizing markers made of Tantalum which make the implant visible in-situ.

The device is intended to be implanted using a Guide Wire and the Instrumentation Kit.

V-STRUT© Vertebral Implant is part of V-STRUT© Transpedicular Vertebral System.

V-STRUT© Transpedicular Vertebral System is composed of:

- V-STRUT© Vertebral Implant
- V-STRUT© Guide Wire
- V-STRUT© Instrumentation Kit

V-STRUT© Bone Filler is used to inject bone cement through V-STRUT© Vertebral Implant. See V-STRUT© Bone Filler Instructions For Use.

References for each item of the V-STRUT© Transpedicular Vertebral System and V-STRUT© Bone Filler are described in section “References”.

In addition to the operative technique, please consult the V-STRUT© Vertebral Implant - Instructions, V-STRUT© Guide Wire and Instrumentation Kit - Instructions and V-STRUT© Bone Filler - Instructions.

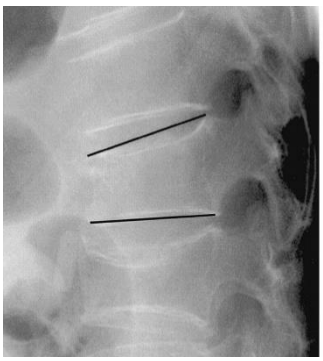
OPERATIVE TECHNIQUE

1. Patient preparation and precautions

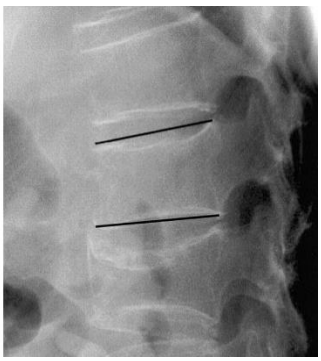
V-STRUT© Vertebral Implant implantation requires a general anesthesia.

The patient lies in prone position on the operating table. Fracture decompression is performed by patient positioning on the table (postural correction using pillows).

BEFORE



AFTER



Imaging equipment must be available for 3D-control of each operative step.

The transpedicular approach requires that the minimal internal pedicle dimension is larger than the implant diameter (see implants sizes in section “References”) in order to avoid pedicle fracture during implant insertion. Pre-operative imaging of the surgical level is therefore mandatory to ensure that the anatomical dimensions are compatible with the V-STRUT© Vertebral Implant range of sizes.

- **This operative technique can only be performed by an experienced spine practitioner trained in the operative technique.**
- **The patient must be immobilized for V-STRUT© Vertebral Implant implantation.**
- **3D-imaging (or at least anteroposterior and lateral) is required during the whole procedure to check the proper progress of the operating steps and the good positioning of the device.**
- **All operative steps are performed with the guidewire securely in place. If the guidewire is pulled out during the procedure, it must be re-inserted immediately, and imaging control is mandatory to check its good repositioning in all planes.**
- **V-STRUT© Vertebral Implant is made of radiotransparent PEEK raw material and it is made visible on imaging by means of tantalum markers positioned at each implant end.**

Before starting the procedure:

- **Ensure that the appropriate instrument kit and an adequate quantity of implants sizes and accessories are available in the operating room (see section “References”).**
- **Ensure that the additional material necessary for the procedure is available, such as Teknimed F20® bone cement, compliant with the V-STRUT© Vertebral Implant Instructions, and its preparation and injection kit (see section “Additional material necessary for the procedure”).**

2. The procedure

The procedure steps are described, for the implantation through the first pedicle and then, repeated for the implantation on the contralateral side.

Positioning of the guide wire

Ref	Quantity	Name	Picture
32300	2	Guide wire	∅ 1.60 mm

One guide wire must be used for each pedicle.

During the whole procedure, ensure that guide wires are not twisted or damaged. If so, it is mandatory to replace the guide wires with new ones.

1. Insert a trocar (not provided by Hyprevention, see “Additional material necessary for the procedure”) centered through the pedicle up to 1/3 of the vertebral body.

2. After removal of the central part of the trocar, insert the guide wire into the trocar. The guide wire needs to be positioned up to MAXIMUM 5 mm from the anterior wall cortex.

3. Remove the trocar.

Positioning of the working tube

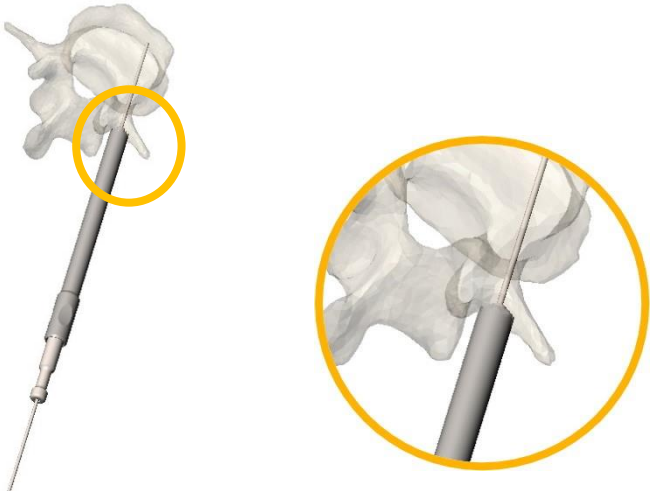
Ref	Quantity	Name	Picture
32020	1	Dilator	
32010	2	Tube	

One tube must be used for each pedicle access.

4. Insert dilator over the guide wire up to the bone.

5. Insert the tube over the dilator up to the bone.

V **Ensure that the distal extremity is in contact with the bone during the whole procedure.**



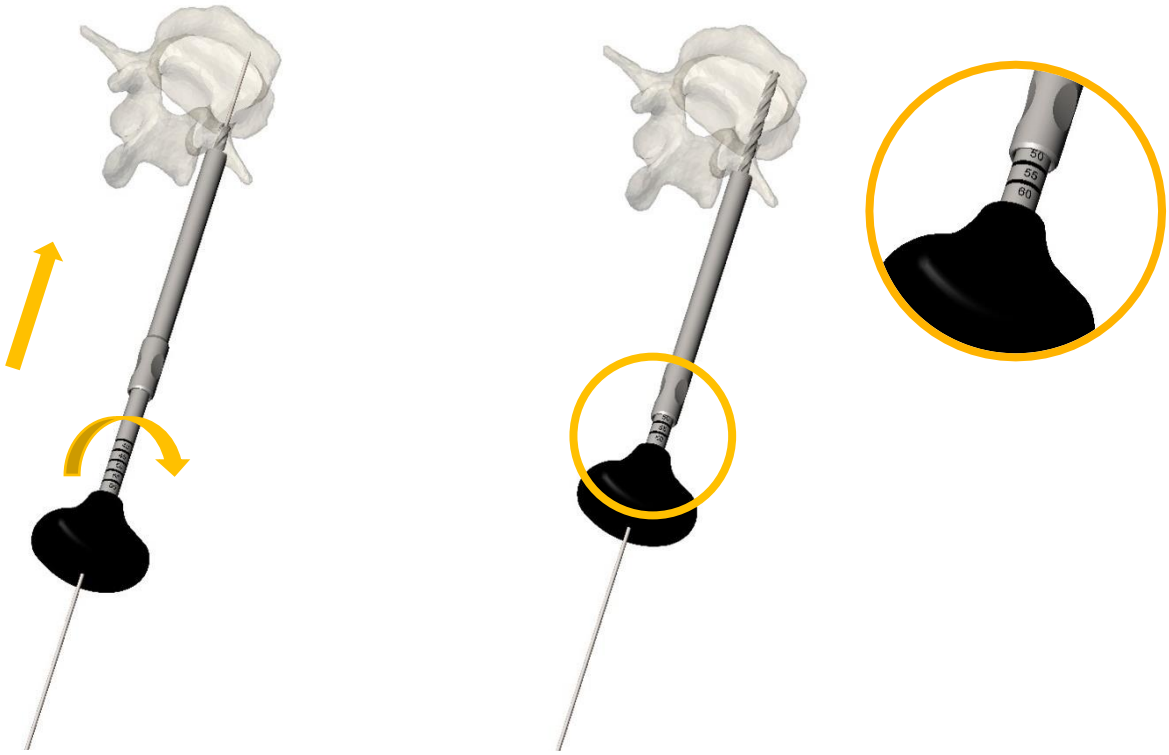
6. Remove the dilator.

Drilling implant location site

Ref	Quantity	Name	Picture
34500	1	Drill 4.5	
35500	1	Drill 5.5	
36500	1	Drill 6.5	

V **Ensure that at least an Ø 5.5 mm device can be inserted in the pedicle without any damage or risk of fracture.**

7. Insert drill Ø 4.5 mm (black handle) over the guide wire through the tube until it reaches the bone, then drill the location site for the implant through the pedicle by turning the handle clockwise.



V **Imaging 3D-control of the drilling progression is required.**

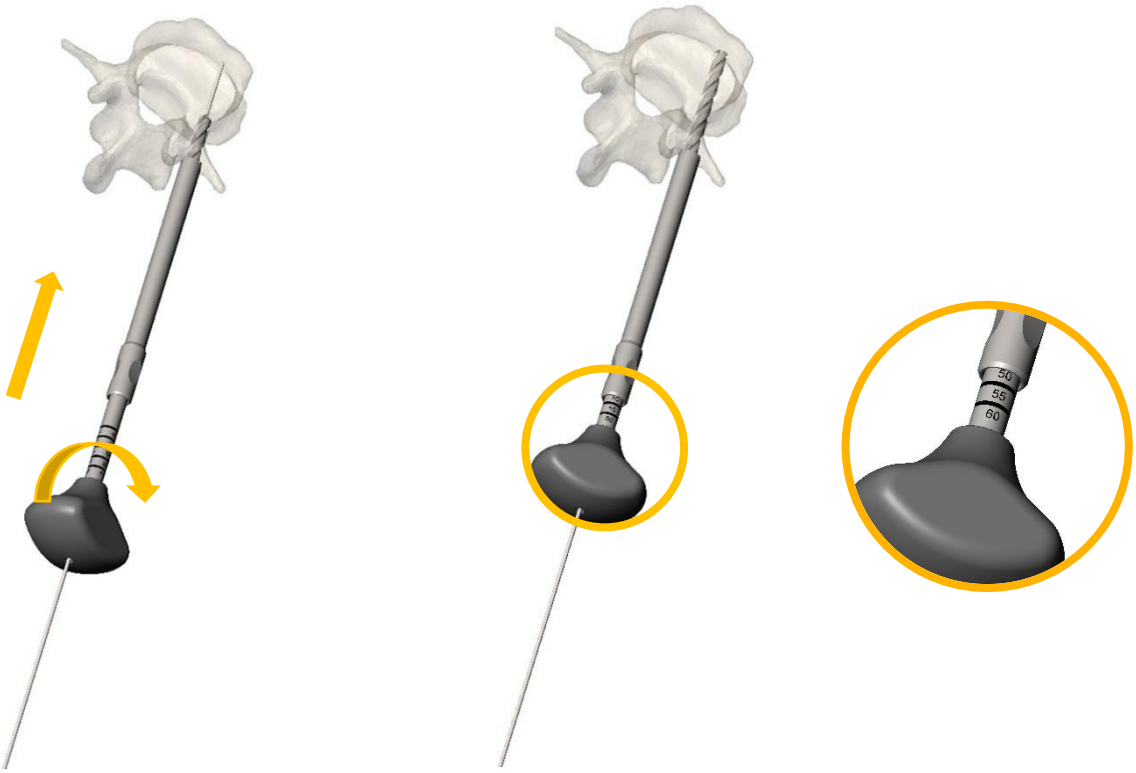
8. Stop drilling when the drill is about 5 to 10 mm from the anterior wall cortex, within the limit of 5 mm MAXIMUM.

9. Remove the drill by turning the handle counterclockwise. Be careful to maintain the guide wire in position during drill removal.

10. Insert drill Ø 5.5 mm (grey handle) over the guide wire through the tube until it reaches the bone, then drill the location site for the implant through the pedicle by turning the handle clockwise.

11. Stop drilling when the drill is about 5 to 10 mm from the anterior wall cortex, positioning the drill between two marker lines and within the limit of 5 mm MAXIMUM.

12. Read the implant size in between the two marker lines of the drill: 40-45-50-55-60 mm.



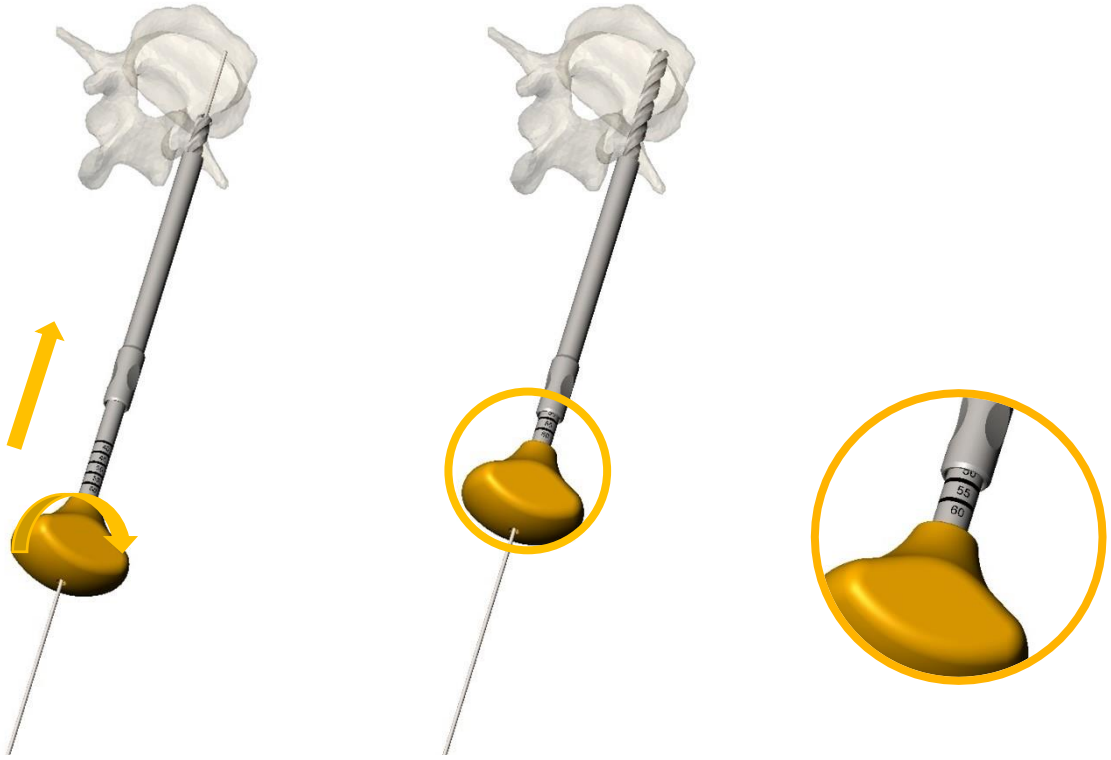
13. Remove the drill by turning the handle clockwise. Be careful to maintain the guide wire in position during drill removal. Make sure the implant bed is cylindrical to allow implant insertion.

V The implant bed may not be too close to the anterior wall thus avoiding cement leakage during cement injection.

V Check that the guide wire does not move during the drilling and does not pierce the anterior cortical wall of the vertebral body.

14. In case of large pedicles, an implant diameter of 6.5 mm can be used. In this case, insert drill Ø 6.5 mm (yellow handle) over the guide wire through the tube until it reaches the bone, then drill the location site for the implant through the pedicle by turning the handle clockwise. Stop drilling when the drill is about 5 to 10 mm from the anterior wall cortex, positioning the drill between two marker lines, and within the limit of 5 mm MAXIMUM.

15. Read the implant size in between the two marker lines of the drill: 40-45-50-55-60 mm.



16. Select the corresponding implant (length and diameter).

Examples

Implant: Ø5.5 L50 mm

Implant: Ø6.5 L50 mm

V **It is recommended to use the same implant diameter of both sides.**

NOTE: Any combination of implants length can be used to fit each patient's anatomy.

Assembling the implant on the implant-holder (gripper + positioner)

Ref	Quantity	Name	Picture
35540 35545 35550 35555 35560 36540 36545 36550 36555 36560	2	Implant	
32050	2	Gripper	
32060	2	Positioner	

One implant must be placed in each pedicle.

Insert the gripper into the positioner.

Insert the implant previously selected into the positioner according to the symbol (a) until the two are in contact (b).

a. 

b. 

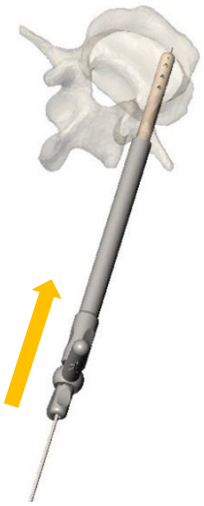
Hold the implant and the positioner in one hand while pushing and screwing the gripper clockwise until you feel resistance.

V **Do not screw the gripper excessively in order not to damage the implant made of polymer.**

V **Ensure that the implant is lined up with the implant-holder. If not, start the assembling again.**

Positioning the implant

17. Insert gently the implant by means of the implant-holder over the guide wire. The implant is radio transparent, yet it has visualizing markers made of tantalum at its anterior and posterior end.



Respect the symbol orientation  on the handle of the implant-holder. The T-handle must be parallel to the axis of the spine.

V **Do not perform the cement injection before insertion of the second implant.**

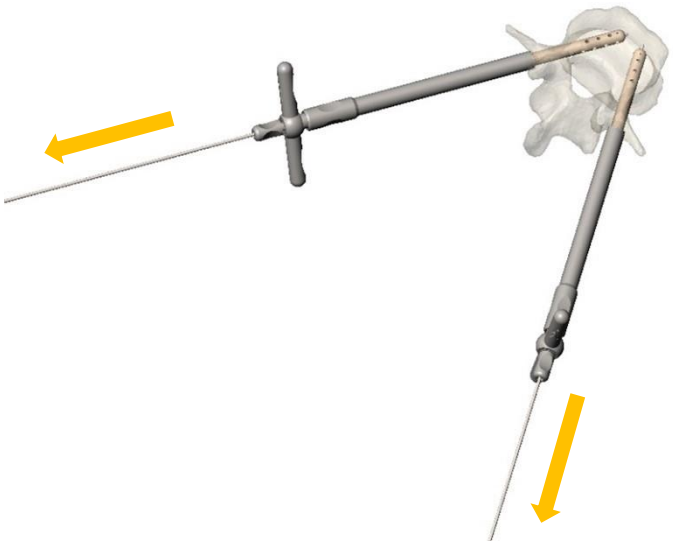
Insertion of the second implant

18. Repeat the steps 1 to 17 through the contralateral pedicle of the vertebra.

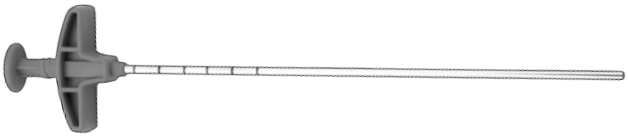
V **Ensure that the second implant will not interfere with the first one when the guide wire is inserted.**

19. Control the implant positioning via imaging, the tantalum markers allow visualization of the ends of the implants.

20. Remove the guide wires.



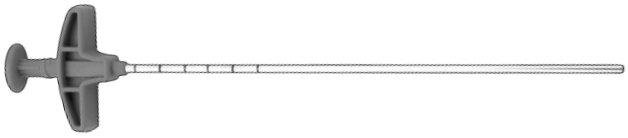
Cement injection

Ref.	Quantity	Name	Picture
32600	2	Bone Filler	

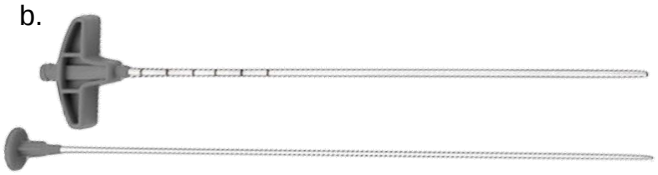
One bone filler must be used for each pedicle.

The below pictures show the bone filler in its entirety with the pusher stylet coming inside (a). The pusher stylet apart from the bone filler (b).

a.



b.



A minimum of 10cc of cement with the corresponding injection material is required separately, in compliance with the V-STRUT© Vertebral Implant Instructions.

V **It is recommended to have at least one bone filler per implant and one additional dose of cement.**

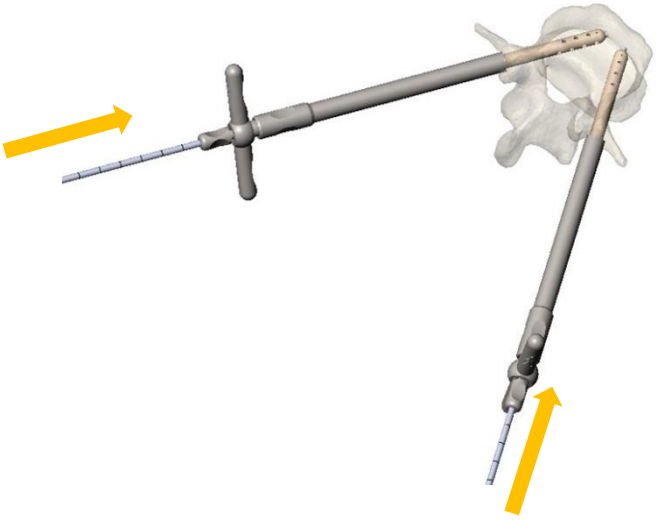
21. Prepare the cement according to Instructions For Use.

V **Respect the manufacturer's instructions to prepare the cement.**

22. Remove the pusher stylet and connect the injection system of the cement to the standard luer-lock connection of two bone fillers and fill them with cement.

23. Prefill the bone filler with cement before inserting it into the implant to prevent air from coming in.

24. Insert gently a bone filler into each implant-holder up to the anterior marker of the implants.



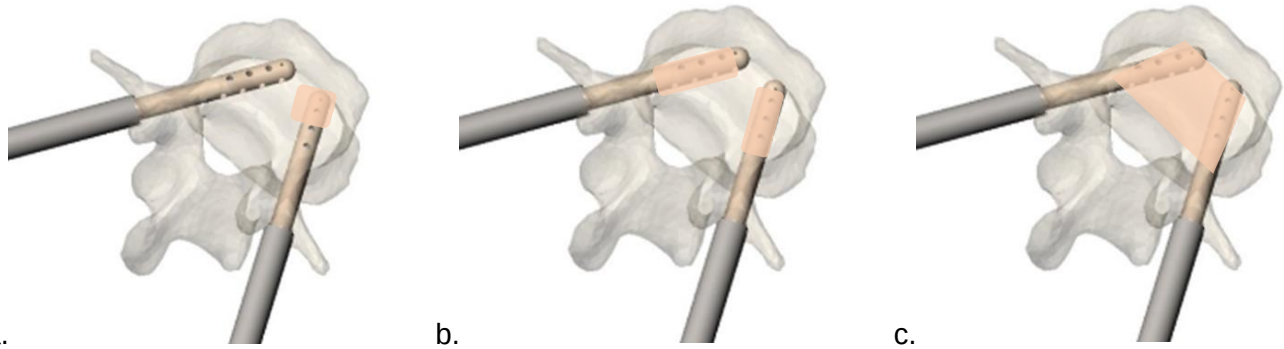
25. Progressively inject the cement in the vertebral body, through the implants, starting from the anterior end. The cement flows out of the implant through its lateral holes.

V Cement injection must be performed carefully in order to avoid any extra vertebral cement leakages.

During injection, ensure that the cement is going through the lateral perforations of the implant and that it is distributed homogeneously (a).

When the cement is about to reach the pedicle (b), stop the injection.

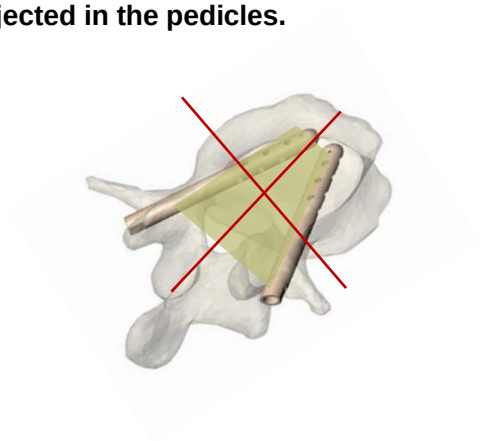
Inject the required quantity of cement to fix both implants (c).



a. b. c.

26. Stop the injection before reaching the pedicles.

V The cement must not be injected in the pedicles.



V The implant-holders must not get into contact with the cement, it may impede implant-holder removal and/or involve the implant removal.

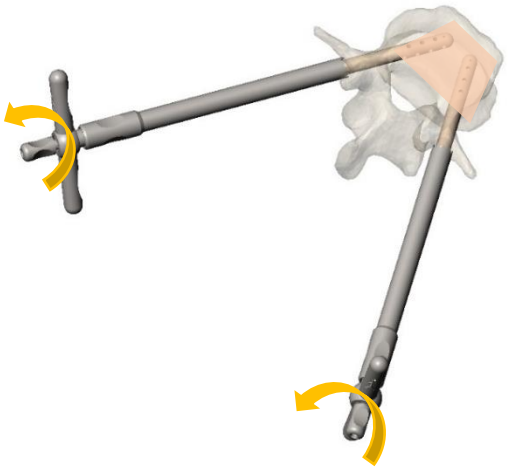
27. Remove bone fillers.

V Review the bone cement Instructions For Use before mobilizing the patient.

3. Instructions removal and suture of incisions

Disassembling the implant–holders.

28. Unscrew the gripper (round handle) while holding the positioner (T shape handle) in position. Remove the gripper when it is fully unscrewed.



29. While removing the positioner (T shape handle), ensure that the implant remains in position (markers control).

30. To prevent the implant from moving back, push it again into its location by pressing the gripper.

31. Remove the tube.

32. Repeat the steps 28 to 31 to remove the instruments on the other side.

V **Ensure by 3D imaging control that the implants are well positioned and there are no remaining cement residues in the tissues.**

33. Suture the incisions.

V **Ensure the patient stay prone position on the operating table (no mobilization) until the cement is polymerized as specified by the cement manufacturer.**

4. Instrument cleaning

At the end of the procedure all instruments must be completely disassembled, as presented in the list of instruments.

Check that the instruments were not damaged during the procedure. It is imperative to replace a damaged instrument as it could injure the patient or compromise the procedure during the next intervention.

V **Ensure that there is no cement residue on/in the instruments.**

V **Ensure that the cutting parts of the drills remain sharp.**

V **Ensure that the laser markings on the drills are always legible in order to select the appropriate implant size.**

V **Ensure that the screw and gripper threads are not damaged.**

Each instrument or part of it will be cleaned individually.

The damaged instruments must be replaced before performing a new procedure.

For instruments / Guide wire cleaning and sterilization see V-STRUT Guide Wire and Instrumentation Kit – Instructions.

5. Revision procedure

See V-STRUT© Instructions For Use.

6. References

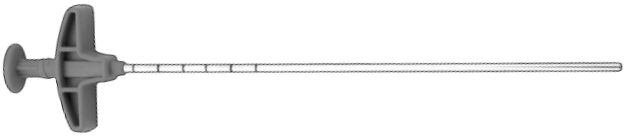
V-STRUT© Implant 5.5

Ref	Length (mm)	Material	Diameter (mm)	Image
35540	40	PEEK	5.5	
35545	45			
35550	50			
35555	55			
35560	60			

V-STRUT© Implant 6.5

Ref	Length (mm)	Material	Diameter (mm)	Image
36540	40	PEEK	6.5	
36545	45			
36550	50			
36555	55			
36560	60			

V-STRUT© Single use accessories

Ref	Quantity	Name	Image
32300	2	Guide Wire	
32600	2	Bone Filler	

V-STRUT© Container

Ref	Quantity	Name	Image
32400	1	Container	

V-STRUT© Reusable instruments

Ref	Quantity	Name	Picture
32010	2	Tube	
32020	1	Dilator	
34500	1	Drill 4.5	
35500	1	Drill 5.5	
36500	1	Drill 6.5	
32050	2	Gripper	
32060	2	Positioner	

All instruments and accessories are in stainless steel, except for the handles of the drills which are in polypropylene.

7. Additional material necessary for the procedure

The following material is not provided by Hyprevention but must be available before V- STRUT© procedure:

- Trocar 11G or 13G - Length 100 to 150 mm
- Teknimed F20® Bone Cement (see the V-STRUT© Vertebral Implant Instructions For Use to choose the appropriate bone cement)
- Corresponding material to prepare and inject the cement

To get the V-STRUT© Vertebral Implant Instructions For Use, refer to the information on the product's label or contact Hyprevention, see details below:

Manufacturer	Distributor
Hyprevention SAS Plateforme Technologique d'Innovation Biomédicale (PTIB) – Hôpital Xavier Arnozan Avenue du Haut Lévêque 33604 PESSAC Cedex – France Phone : +33(0)5 57 10 28 52 Fax : +33(0)5 67 07 10 26 **Email : contact@hyprevention.com** **www.hyprevention.com**	Name and address:

Revision

The revision in force is available on the website instructions.hyprevention.com . Should the user use a copy of this electronic revision he/she is responsible for verifying that he/she uses the version in force.

Copies are available on request at contact@hyprevention.com

Date of the latest revision: November 28, 2022