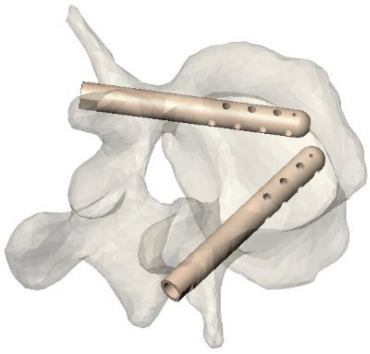
OPERATIVE TECHNIQUE

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 Set - Instructions

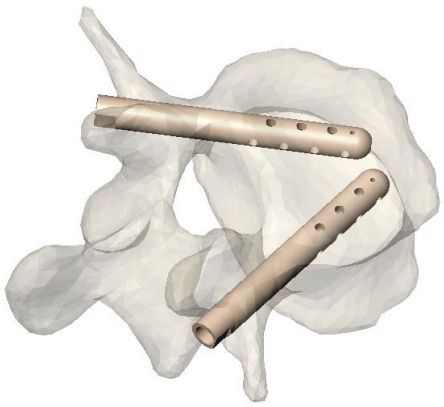
V-STRUT® Bone Filler – Instructions

TABLE OF CONTENT

INDICATIONS

V-STRUT® Vertebral Implant is indicated for use in the treatment of vertebral fractures in the thoracic and lumbar spine.

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 allow the treatment of vertebral fractures.

The implant is made of radio transparent PEEK (Polyetheretherketone) 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 Set.

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 Set.

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

Additional equipment, such as trocar and bone cement, is needed to perform the procedure. See section “Additional necessary equipment”.

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

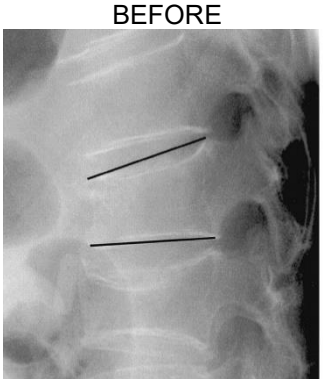
OPERATIVE TECHNIQUE

1. Patient preparation and precautions

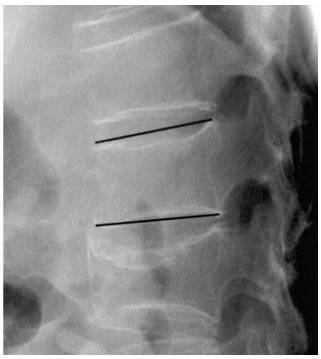
V-STRUT® Vertebral Implant implantation requires anesthesia. The anesthesiologist will decide which type is most appropriate for the patient's condition.

The patient lies in prone position on the operating table. If needed, 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 operating step.

The transpedicular approach requires that the minimal internal pedicle dimension is larger than the implant diameter (see implants sizes in section “V-STRUT® Products list”) to avoid pedicle fracture during implant insertion.

V **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.**

V **This operative technique can only be performed by an experienced spine practitioner trained in the operative technique.**

V **The patient must be immobilized for V-STRUT® Vertebral Implant implantation.**

V **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.**

V **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 prior continuing the procedure.**

V **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:

V **Ensure that the appropriate Instrumentation Set and an adequate quantity of implants sizes and accessories are available in the operating room (see section “PRODUCTS REFERENCES”).**

V **Ensure that the additional necessary equipment for the procedure is available, such as Teknimed F20® bone cement, compliant with the V-STRUT® Vertebral Implant instructions for use, and its preparation and injection Set (see section “Additional necessary equipment”).**

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 and description
32300	1 or 2	Guide wire	∅ 1.60 mm The guide wire is used to define the implant positioning in the vertebrae and used to insert cannulated instruments in their correct positioning.

One guide wire can be used for both pedicles if not damaged or bent.

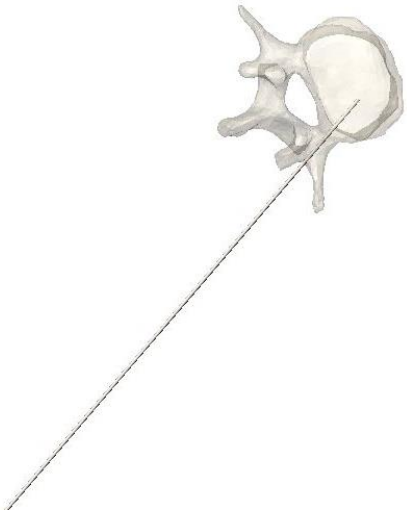
V **During the whole procedure, ensure that guide wire is not twisted or damaged. If so, it is mandatory to replace the guide wire with new one.**

1. Insert a trocar (can be provided by Hyprevention, see section “Additional necessary equipment”) centered through the pedicle up to 1/3 of the vertebral body, centered between superior and inferior endplates.

2. After removal of the central part of the trocar, insert the guide wire into the trocar. It is recommended to position the guide wire up to the midline (between the posterior wall and anterior wall).

3. Remove the trocar.

4. Insert the trocar in the second pedicle (same trocar can be used if not damaged, otherwise take a new trocar).



5. For the second pedicle, the guidewire will be positioned after implant 1 is in place.

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

Positioning of the tube

Ref	Quantity	Name	Picture and description
32020	1	Dilator	 The dilator is a cannulated instrument used to expand a passage through soft tissues from the skin to the pedicle entry.
32010	2	Tube	 The tube is a cannulated instrument used to protect the soft tissue from the passing of the drills and implant-holders.

One dilator is used for both sides. One tube must be used for each pedicle access.

6. Insert dilator over the guide wire up to the bone (pedicle entry).

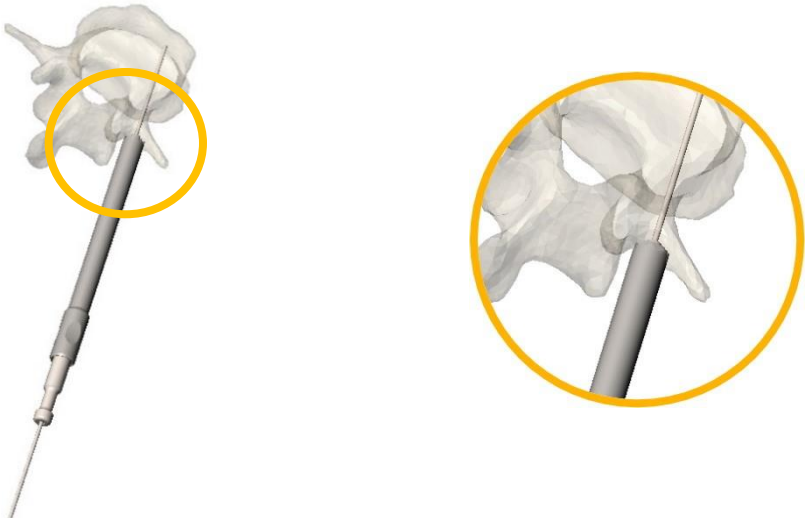
7. Insert the tube over the dilator up to the bone (pedicle entry).

V **Ensure skin incision is large enough for instruments introduction.**

V **Skin incision should preferably follow Langers lines.**

V **Ensure that the distal extremity of the tube is not in contact with the facet joint, but in contact with pedicle entry.**

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



8. Remove dilator. Protection tube is in place.

Drilling implant cavity

Ref	Quantity	Name	Picture and description
34500	1	Drill 4.5	 The drill 4.5 is used for the drilling of 4.5 mm diameter implant cavity from 25 mm to 60 mm long, or as a pre-drilling in case of the use of a 5.5 mm or 6.5 mm diameter implant from 40 mm to 60 mm long.
35500	1	Drill 5.5	 The drill 5.5 is used for the drilling of 5.5 mm diameter implant cavity from 40 mm to 60 mm long, or as a pre-drilling in case of the use of a 6.5 mm diameter implant
36500	1	Drill 6.5	 The drill 6.5 is used for the drilling of 6.5 mm diameter implant cavity from 40 mm to 60 mm.

V **Ensure that at least a Ø 4.5 mm device can be inserted in the pedicle without any damage or risk of fracture.**

V **Implant cavity Ø 4.5 mm is created directly with the drill 4.5 Implant length is from 25 mm to 60 mm.**

V **Implant cavity Ø 5.5 mm or Ø 6.5 mm may require pre-drilling, using a smaller diameter drill, depending on the bone quality and pedicle width. Implant length is from 40 mm to 60 mm.**

9. Drilling or pre-drilling with drill Ø 4.5 mm: insert drill Ø 4.5 mm (black handle) over the guide wire through the tube until it reaches the bone, then drill the cavity for the implant through the pedicle by turning the handle clockwise.

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

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

V **When the drill has entered the vertebral body, the guidewire can be pulled back inside the drill and drilling continues without risk of axis loosening (drill is guided by the pedicle).**

10. Stop drilling when the drill is about 5 to 10 mm from the anterior wall cortex, within the limit of 5 mm MINIMUM (not closer).

11. Read the implant size (in length) in between the two marker lines of the drill: 25-30-35-40-45-50-55-60 mm.

V **If length is measured 25, 30 or 35 mm, an implant Ø 4.5 mm ONLY will be selected.**

V **If length is measured 40, 45, 50, 55 or 60 mm, an implant Ø 4.5 mm, Ø 5.5 mm or Ø 6.5 mm in diameter can be used.**

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

V **When the drill is in the pedicle only, push gently the guidewire into the drilled cavity.**

If the guidewire is pulled out when removing the drill, it must be re-inserted immediately, and imaging control is mandatory to check its good repositioning in all planes prior continuing the procedure.

13. For implant Ø 4.5 mm, select the corresponding implant size (length and diameter).

Example Implant 34550: Ø 4.5 L50 mm

If chosen Implant larger than Ø 4.5 mm, proceed with the following steps. Otherwise, go to step 23.

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

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

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

When the drill has entered the vertebral body, the guidewire can be pulled back inside the drill and drilling continues without risk of axis loosening (drill is guided by the pedicle).

15. Stop drilling when the drill is about 5 mm MINIMUM from the anterior wall cortex (not closer), positioning the drill between two marker lines.

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

17. Remove the drill by turning the handle clockwise (see step 12.). Be careful to maintain the guide wire in position during drill removal. Make sure the implant cavity is cylindrical to allow implant insertion.

V **When the drill is in the pedicle only, push gently the guidewire into the drilled cavity.**

V **If the guidewire is pulled out when removing the drill, it must be re-inserted immediately, and imaging control is mandatory to check its good repositioning in all planes prior continuing the procedure.**

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

18. Select the corresponding implant size (length and diameter).

Example Implant 35550: Ø 5.5 L50 mm

19. 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 cavity 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 MINIMUM (not closer).

V **When the drill has entered the vertebral body, the guidewire can be pulled back inside the drill and drilling continues without risk of axis loosening (drill is guided by the pedicle).**

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

21. Remove the drill by turning the handle clockwise (see step 12.). Be careful to maintain the guide wire in position during drill removal. Make sure the implant cavity is cylindrical to allow implant insertion.

V **When the drill is in the pedicle only, push gently the guidewire into the drilled cavity.**

V **If the guidewire is pulled out when removing the drill, it must be re-inserted immediately, and imaging control is mandatory to check its good repositioning in all planes prior continuing the procedure.**

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

Example	Implant 36550: Ø 6.5 mm L50 mm	

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

V Any combination of implants length and diameter can be used to fit each patient's anatomy.

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

Ref	Quantity	Name	Picture and description
34525 34530 34535 34540 35540 36540 34545 35545 36545 34550 35550 36550 34555 35555 36555 34560 35560 36560	2	Implant	 The implants are provided in 3 diameters and various lengths (see section "V-STRUT® Products list").
32050	2	Gripper	 The gripper is a cannulated instrument. It is the inner part of the implant holder. It is used to hold and introduce the implant into the bone, in a correct position prior to release the implant.
32060	2	Positioner	 The positioner is the outer part of the implant holder. It is used to hold and introduce the implant into the bone in a correct position prior to release the implant.

One implant must be placed in each pedicle.

23. Insert the gripper into the positioner.

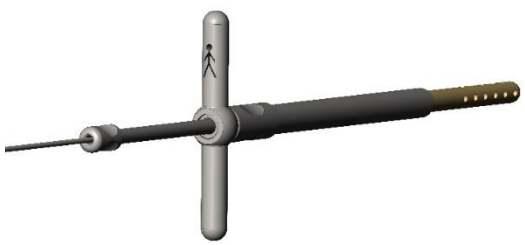
24. Insert the implant previously selected into the positioner according to the symbol ☐ (a) until the two are in contact (b).

a.

b.

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

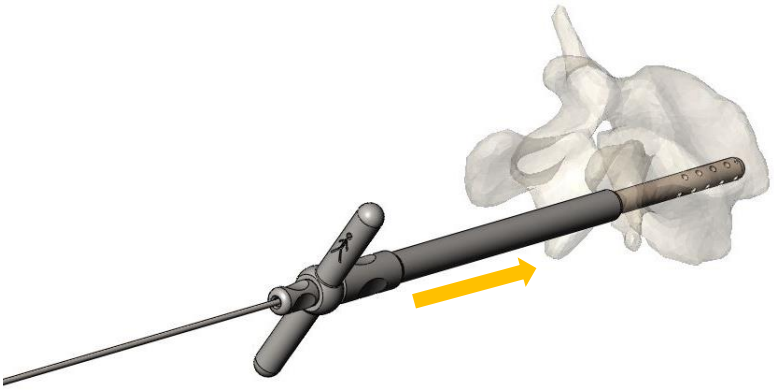
V Do not screw the gripper excessively in order not to damage the implant made of polymer.

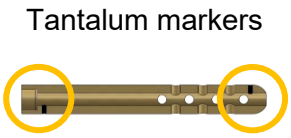


V **Ensure that the implant is lined up with the implant-holder. If not, start assembling again.**

Positioning the implant

26. 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 can be parallel to the axis of the spine or at 45° to orient the lateral holes of the implant for cement injection direction.

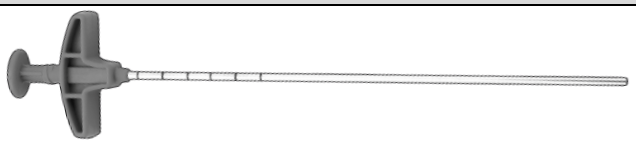
V **It is possible to use a hammer to gently insert the implant into its cavity. Gently tap on T-handle.**

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

Positioning of the second implant

27. Repeat the steps 5 to 26 through the contralateral pedicle of the vertebra.

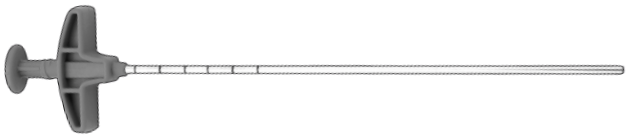
Cement injection

Ref	Quantity	Name	Picture
32600	1 or 2	Bone Filler	 The bone filler is a needle intended to inject bone cement in the vertebral body of the vertebral body through the instrumentation.

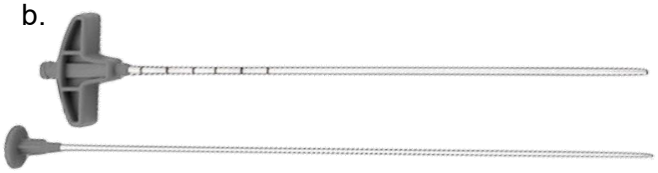
One bone filler can be used for both pedicles or one in each pedicle.

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 (see section “additional necessary equipment”).

28. Prepare the cement according to the manufacturer’s Instructions For Use.

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

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

29. Remove the pusher stylet and connect the injection system to the standard Luer-lock connection of bone filler.

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

31. Remove the guide wire and gently insert the bone filler into the implant-holder up to the center of the vertebral body (midline).

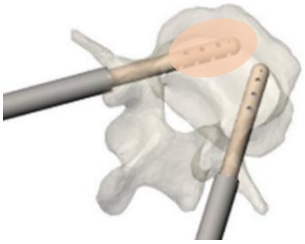
32. Progressively inject the cement into the vertebral body, through the implant. The cement flows out of the implant through its lateral holes.

33. Repeat steps 31 and 32 to inject cement in the second implant.

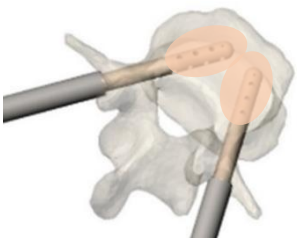
V **Cement injection must be performed carefully to avoid any extravasation / cement leakages.**

During injection, ensure by imaging control that the cement is going through the lateral perforations of the implant and that it is distributed homogeneously on one side (a), and on the other side (b).

a.



b.



V **Cement must not be injected into 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.**

34. Remove bone filler.

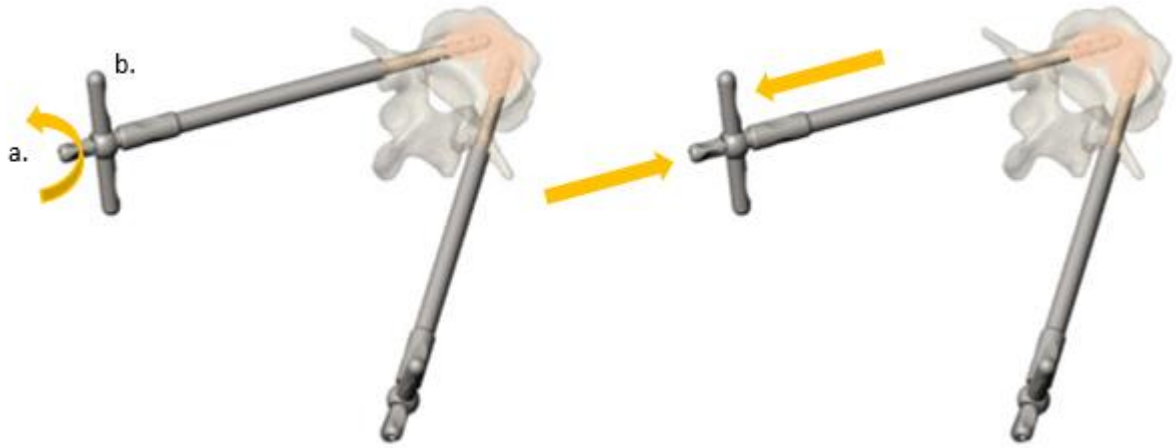
3. Instruments removal and suture of incisions

Disassembling the implant–holders / implants release in-situ.

35. Start on side the cement was injected first.

36. Unscrew the gripper (a. small round handle) while holding the positioner (b. T shape handle) in position, until gripper is fully unscrewed (loose).

37. Push on gripper and pull-out positioner simultaneously to release implant.

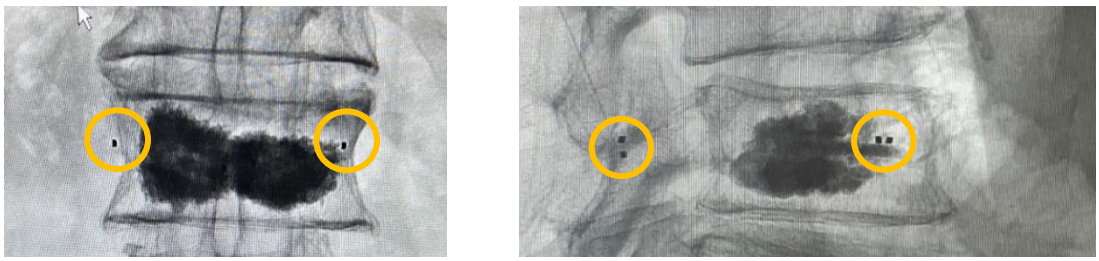


38. Remove implant holder (gripper + positioner), ensure that implant remains in position (markers control).

39. Remove the tube.

40. Repeat steps 36 to 39 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 (it is recommended to be removed cement residues).**



41. Suture the incisions.

42. Ensure the patient stays in a prone position on the operating table (no mobilization) until the cement is polymerized as specified by the cement manufacturer (see Instructions For Use).

4. Instrument Cleaning

At the end of the procedure all instruments must be completely disassembled, as presented in the list of instruments (See section “V-STRUT® Products list”).

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 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.

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

5. Revision Procedure

See V-STRUT® Vertebral Implant – Instructions.

.

6. V-STRUT® Products list

V-STRUT® Implant 4.5

Ref	Diameter (mm)	Length (mm)	Material	Image
34525	4.5	25	PEEK	 Provided sterile in individual packaging.
34530		30		
34535		35		
34540		40		
34545		45		
34550		50		
34555		55		
34560		60		

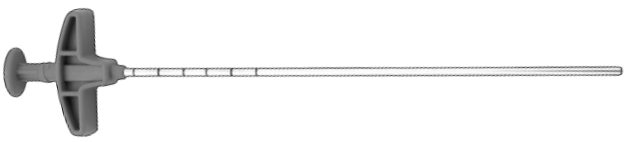
V-STRUT® Implant 5.5

Ref	Diameter (mm)	Length (mm)	Material	Image
35540	5.5	40	PEEK	 Provided sterile in individual packaging.
35545		45		
35550		50		
35555		55		
35560		60		

V-STRUT® Implant 6.5

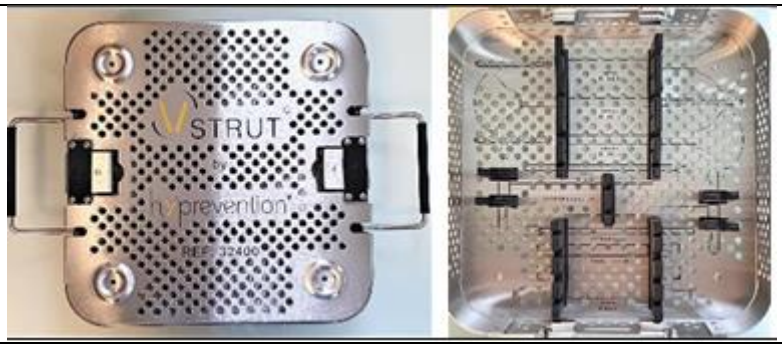
Ref	Diameter (mm)	Length (mm)	Material	Image
36540	6.5	40	PEEK	 Provided sterile in individual packaging
36545		45		
36550		50		
36555		55		
36560		60		

V-STRUT® Single use accessories

Ref	Quantity	Name	Image
32300	1 or 2	Guide wire	Provided non-sterile (See Instructions For Use)
32600	1 or 2	Bone Filler	 Provided sterile in individual packaging (See Instructions For Use)

V-STRUT® Reusable instruments set (ref 32500)

(See Instructions For Use for cleaning and sterilization)

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	
32400	1	Container	

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

7. Additional necessary equipment

The following material must be available before V-STRUT® procedure.

It can be provided by Hyprevention:

- 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), qty 1 or 2.
- Corresponding material to prepare and inject the cement, qty 1 or 2.

V-STRUT® Instructions For Uses in force are available on the website instructions.hyprevention.com.
Or contact Hyprevention, see details below.

MANUFACTURER

Hyprevention SAS
Parc Scientifique Unitec 1
2 Allée Doyen George Brus 33600 Pessac – France
Phone: +33 9 53 33 48 48
Email: contact@hyprevention.com – www.hypreventionusa.com

DISTRIBUTOR

In the USA:

Hyprevention Inc.
1411 Broadway, Fl16
New York, NY 10018 - USA
Phone: +1 (772) 228-3218
Email: usa@hyprevention.com – www.hypreventionusa.com

Other country:
Name and address:

Document 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: October 14, 2025