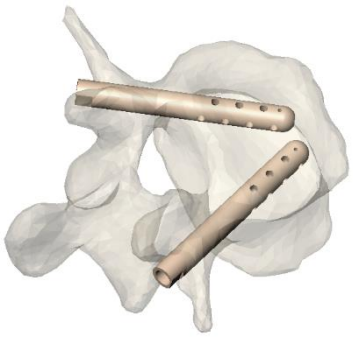
INSTRUCTIONS FOR USE

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© Operative Technique
V-STRUT© Guide Wire and Instrumentation Set – Instructions

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Standard symbols used for labelling

Symbols from ISO 15223-1	
	Do not reuse/Single use - **5.4.2**
	Use by (+ date) - **5.1.4**
	Do not re-sterilize - **5.2.6**
	Sterilized using irradiation - **5.2.4**
	Consult instructions for use - **5.4.3**
	Manufacturer - **5.1.1**
	Do not use if packaging is damaged - **5.2.8**
Symbol from ASTM F2503-20	
	MR Safe

Device description

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.

Refer to the specific Instructions For Use for V-STRUT© Guide Wire and V-STRUT© Instrumentation Set.

V-STRUT© Vertebral Implant is a medical device to be placed in the vertebrae through a minimally invasive procedure. Two devices are implanted in each vertebra to be treated. Each implant is introduced posteriorly through the pedicle up to the anterior vertebral body wall.

V-STRUT© Vertebral Implant exists in 3 different diameters and various lengths to accommodate individual patient's anatomy of thoracic and/or lumbar vertebrae.

The implant is made of radio transparent polymer, PEEK (Polyetheretherketone as per ASTM F2026) and includes visualising markers made of tantalum (as per ASTM F560).

V-STRUT© Vertebral Implant is implanted with a specific instrumentation provided with the implant and is combined in situ with Teknimed F20® bone cement which is a Polymethylmethacrylate (PMMA) bone cement.

A part of the implant is embedded into the pedicle, to provide 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.

Range of sizes and available lengths:

Implant Ø 4.5mm		**Implant** Ø 5.5mm		**Implant** Ø 6.5mm	
Reference	Length (mm)	Reference	Length (mm)	Reference	Length (mm)
34525	25	/	/	/	/
34530	30	/	/	/	/
35435	35	/	/	/	/
34540	40	35540	40	36540	40
34545	45	35545	45	36545	45
34550	50	35550	50	36550	50
34555	55	35555	55	36555	55
34560	60	35560	60	36560	60

A coloured sticker indicates the diameter and the length of the implant in millimetres

Colour of sticker: White
Example

Colour of sticker: Grey
Example:

Colour of sticker: Yellow
Example:

Classification according to the Food and Drug Administration regulation: II

Device packaging

V-STRUT© Vertebral implant is supplied sterile in a double packaging.
To unpack the implant, first open the external package. The internal package is sterile and must be taken by the sterile staff. After that, open the internal packaging and remove the implant from the package.
V-STRUT© Vertebral Implant must not be used if package is opened or damaged, if the expiration date has elapsed, or in any eventuality of other case leading to loss of sterility.

Intended Environment / Setting for use

V-STRUT© Vertebral Implant is intended to be used in an environment equipped with imaging and under required aseptic conditions to perform the surgical procedure.

The implantation of V-STRUT© Vertebral Implant must be performed only by experienced spine practitioners with specific training in the use.

No specific environmental conditions of storage are required for devices preservation: V-STRUT© Vertebral Implant has to be stored in its packaging up to their use and before the expiry date.

Indications For Use

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.

Contraindications

V-STRUT© Vertebral Implant cannot be used in case of:

- Patient clearly improving on conservative treatment
- Any contra-indication / allergy to implant material or cement
- Systemic infection or infection located in the spine
- Any medical condition including but not limited to anemia, coagulation disorders, fibromyalgia, algoneurodystrophy, Paget's disease, uncontrolled diabetes that would preclude the patient from having surgery or would impede the benefit of surgery
- Neurologic signs or symptoms related to the fracture or the impeding pathological fracture
- Any previous surgical treatment (material or cement) in the targeted vertebra
- Less than one third of the original vertebral body height remaining
- Unstable fractures or neoplasms with posterior involvement
- Damages of posterior wall
- Sclerotic cancellous bone
- Pedicles not large enough to accept V-STRUT© instrumentation and implants
- Pregnancy
- Patient under the age of majority

Undesirable Side effects

Side effects possibly associated with the use of V-STRUT© Vertebral Implant are the same as for other percutaneous spinal procedures. Those may include:

- Cement leakage
- Anterior displacement of bone fragments, or vascular puncture
- Hematoma, bleeding, haemorrhage, embolism
- Pain
- Inflammatory reaction, infection, cutaneous necrosis
- Anaphylaxis
- Dural tear, neurological complications
- Secondary fracture, subsidence, fracture of the pedicle, implant migration, implant fracture, or initial lesion aggravation.

Some of these undesirable side effects may lead to lengthening of the procedure or to a new surgery.
This list may not include all complications caused by the surgical procedure itself (including anaesthesia and radiation).
This list may not include all the undesirable side effects related to the cement: refer to the cement manufacturer's instructions for use.

Warnings

Hyprevention declines any responsibility in case of non-compliance with the Instructions For Use.

It is necessary to strictly adhere to proper surgical principles and techniques, to avoid the risk of deep wound infection. Deep wound infection is a serious postoperative complication and may require surgical revision. Deep wound infection may be latent and not manifest itself even for several years postoperatively.

Hyprevention is not responsible for complications arising from incorrect diagnosis, choice of incorrect implant, incorrect combination of implants and/or operative technique nor inadequate asepsis.

The operative technique must be strictly followed.

V-STRUT© Vertebral Implant must not be used for vertebral fracture reduction.

The pedicle damaged or not must allow implant introduction through it.

The cement injection must be stopped immediately if bone cement is detected outside the vertebral body or in the circulatory system during the procedure.

V-STRUT© Vertebral Implant is a single use device and must not be re-sterilised or re-use under any circumstances. It may endanger the patient and cause possible loss of implant functionality or early breakage as it may cause small defects and internal stress patterns.

Precautions

The implant sizing and positioning is planned prior to the intervention. Make sure that the appropriate implant length and diameter is available. The final choice of implant size is determined during the operation.

Before starting the operation, it is necessary to check the presence and the good operational state of all instruments in the container and of the additional equipment required for V-STRUT© implantation (see Additional necessary equipment)

Appropriate imaging techniques during the whole procedure are used to guarantee that the implant is correctly positioned, that no damage is caused to surrounding structures, and that the injected bone cement is correctly located.

Bioresorbable cement, phosphocalcic cement, bone substitute and all cements which do not correspond with the requirements given in these instructions for use must not be used for the V-STRUT© procedure.

Bone cement manufacturer's instructions for use must be carefully followed.

Additional necessary equipment instructions for use must be carefully followed.

V-STRUT© Vertebral Implant must not be used with components of any other systems or manufacturers (except the systems described in section Additional necessary equipment*)* to avoid the failure of the procedure.

Care must be taken to avoid breaching the endplates, anterior wall of the vertebral body and pedicle walls during the surgical procedure.

Excessive insertion forces may cause damage to the implant. A hammer must not be used to insert the implant.

In case of serious complications during the surgical procedure which could jeopardise its success (for example, pedicle fracture), it must be ascertained that a spine or neurosurgeon is available.

Shelf-life

The validated shelf life for V-STRUT© Vertebral Implant is 5 years. It must be stored in its original packaging and removed from this protective packaging only just prior to implantation.

Additional necessary equipment

In order to complete the surgical procedure, the following equipment is necessary:

- Trocar 11G or 13G (length 100 to 150 mm)
- V-STRUT© Bone Filler ref: 32600
- Teknimed F20® bone cement and injection gun

Hyprevention does not provide the cement and its tools for preparation and injection. The instructions for use of the cement's manufacturer must be followed.

Contact Hyprevention for any question related to the choice and the use of cement (see section Manufacturer*).*

Requirements for bone cement:

- Teknimed F20® bone cement
- Quantity of cement: at least 10 cc must be available to fill the implant, the proper amount injected will depend on the size of the implants.

Operative technique

V-STRUT© Vertebral Implant is implanted under anaesthesia by an experienced spine practitioner trained in the operative technique.

The choice of implant is made by the practitioner.

- *Pre-operative: The medical practitioner will check that an implant size (diameter AND length) corresponding to the patient's anatomy is available.*
- *Intra-operative: the final size of the implant(s) will be determined during the drilling for the implant bed (diameter AND length). The drills are provided in each diameter and graduated according to the different implant lengths.*

The validated operative technique is detailed and illustrated in a separate document (ref TEC-HYP02). A summary is placed below.

The main steps of the procedure (performed under imaging control) are as follows:

If necessary, fracture decompression by patient positioning on the table is firstly performed

1. Trocar insertion through the pedicle and until the vertebral body, followed by guide wire insertion
2. Soft tissue dilator and protection tube placement
3. Pre-drilling (diameter 4.5 mm)
4. Drilling (implant diameter and length)
5. Implant insertion
6. Cement injection through the implant via a filler
7. Instrumentation removal

Revision procedure

Should an explantation be necessary, the revision procedure needs to be performed by a practitioner experimented in spine surgery.

Precaution: before removing the implants, an alternative treatment needs to be chosen and available in the operative room.

No specific instrumentation is provided for the implant revision procedure.

The practitioner should remove the device as follows:

- Perform a partial corpectomy on the vertebral body by anterior approach using a standard surgical technique:
  - The implants made of PEEK polymer can be cut by using standard cutting instrumentation as PEEK polymer is similar to normal cortical bone.
  - The bone cement located in the vertebral body will be removed with the vertebral body (as for vertebroplasty revision).
- Part of the implants embedded in the pedicle will be removed:
  - by anterior approach for implants diameter 6.5mm having a unique diameter using forceps to grip and remove the implants,
  - by posterior approach for implants diameter 5.5mm and 4.5mm having 6.5 mm diameter collar at the posterior part avoiding anterior path. A forceps will be used to grip and remove the implants.

Partial corpectomy will be followed by corpectomy device implantation and anterior plate fixation or posterior screws/rods fixation. Contact Hyprevention for any questions regarding the revision procedure.

Disposal

V-STRUT© Vertebral Implant does not require any special handling or unique requirements for disposal. Disposal of the device should be according to standard hospital waste disposal requirements.

MRI Safety Information

V-STRUT© Vertebral Implant do not present any risk for patients in Magnetic Resonance (MR) environment. The V-STRUT® Vertebral Implant is MR Safe.

Request for additional information

For service, technical support, requests for information, please contact Hyprevention at contact@hyprevention.com or at the contact details described in section Manufacturer, or your distributor.

Complaint handling

Any device-related-incident which is believed to represent a safety issue should be immediately reported to Hyprevention at vigilance@hyprevention.com or at the contact details given in section Manufacturer.

Manufacturer

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Distributor

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Email: usa@hyprevention.com – www.hypreventionusa.com

Other country:
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 of the instructions for use: October 25, 2024.