stryker

SpineJack® system

controlled anatomical restoration

Product overview

SpineJack® system

controlled anatomical restoration

It is common practice for a fracture of any weight-bearing joint to first be reduced, then stabilised. The concept of SpineJack® system is to achieve a biomechanical restoration to allow early mobilisation and weight-bearing.

Anatomical reduction means restoration of the geometry of the whole vertebral body, which includes the cortical rings and endplates.

Anatomical restoration consists of achieving sagittal and coronal balance. These are key factors for kyphosis management and reduction of adjacent level fractures.[1-5,7]

Vertebral endplate restoration has been described as having a positive influence on disc creeping, disc degeneration, compensatory curvatures or facet joint arthritis.[1,6,8-11]

Studies have shown a correlation between vertebral deformation and clinical problems such as post-traumatic kyphosis, which has been depicted as a serious post-traumatic deformity.[2,12]

Within this context, the SpineJack® system implant provides clinicians with a fully controlled and comprehensive treatment option for vertebral compression fractures (VCFs). This enables anatomical restoration and stabilisation.

Anatomical restoration

To achieve **anatomical restoration** after a VCF, consider the following:

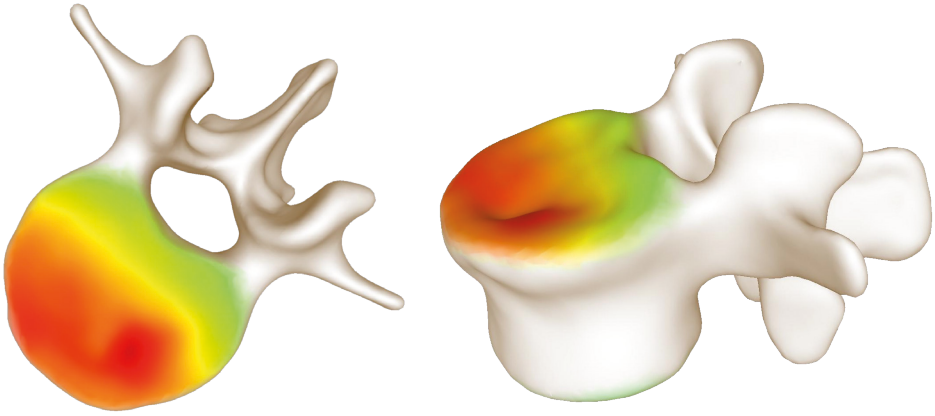
- Controlled uni-directional craniocaudal expansion to restore **sagittal angulation**
- Adaptation of implant's expansion to restore **coronal angulation**
- Adaptation of implant's positioning for **endplate restoration**

Height restoration measurement

The anatomical restoration achieved by SpineJack® system has been shown using 3D reconstructions of pre and post-op CT scans.[13] The superimposition of these images allows accurate measurement of vertebral body height restoration.

Colour-coded **3D mapping** provides visualisation of the amount of vertebral body height restoration.

Green: lowest restoration area
Red: highest restoration area



A continuum in control

Implant positioning

Controlled by specific instrumentation

Implant positioning in both sagittal and transverse planes can help achieve the best fit for the fracture's shape and the patient's anatomy.

Implant expansion

Controlled by millimetric implants expansion

Millimetric expansion of the implant can be maintained until the biomaterial is injected.

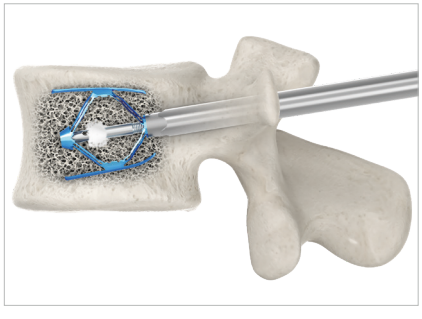
Optimal PMMA cement positioning and interdigitation

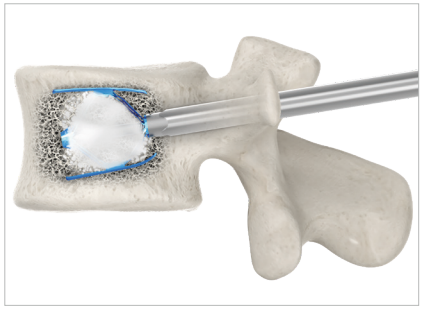
Controlled by PMMA cement fixed pathway and preservation of surrounding trabecular bone

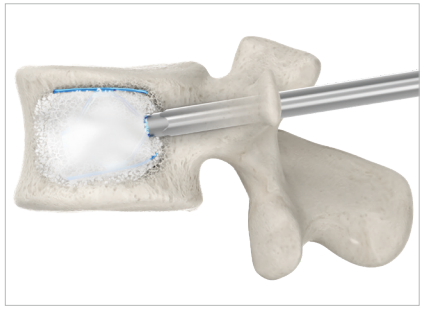
Fixed pathway for the insertion of PMMA cement through the implant helps minimize the risk of posterior leakage. Preserving the surrounding trabeculae by a craniocaudal expansion allows for better interdigitation, thereby improving fixation and the bone healing process[14-17].

Depending on the quality of the preserved trabecular structure, Stryker offers a range of **injectable PMMA cements:**

- Cohesion® Bone Cement (CM0300)
- VertaPlex™ HV Radiopaque Bone Cement Twin Pack (0406-622-000)
- VertaPlex™ Radiopaque Bone Cement Twin Pack (0406-422-000)







Surgical technique guide

The SpineJack® system is indicated for use in the anatomical reduction of vertebral compression fractures that may result from osteoporosis, trauma (VCF type A Magerl classification) and malignant lesions (myeloma or osteolitic metastasis).

SpineJack® system

Surgical steps

Kit composition

1 - Preparation kit

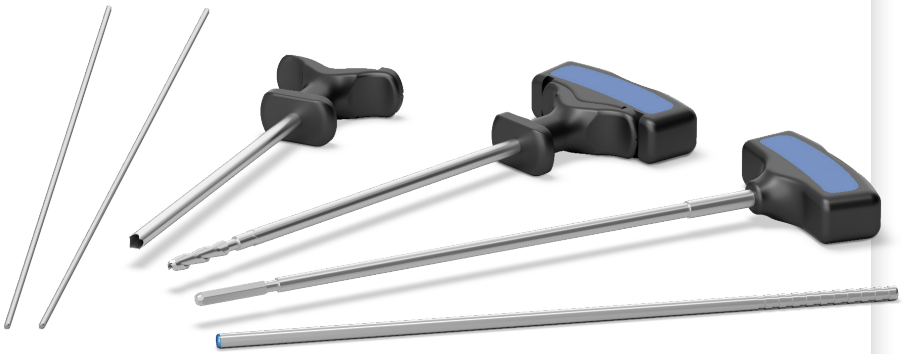
Guidewire (2)

Working cannula

Reamer with working cannula

Template

Cannula plug



SpineJack® preparation kits	
KP004	Preparation kit Ø 4.2mm (unit)
KP001	Preparation kit Ø 5.0mm (unit)
KP058	Preparation kit Ø 5.8mm (unit)

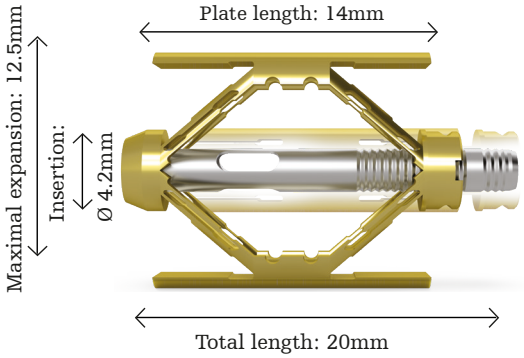
2 - Expansion kits

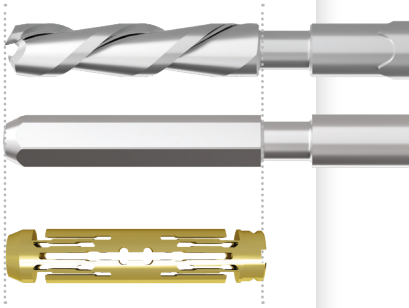
SpineJack® expansion kits	
KE004	Expansion kit Ø 4.2mm (unit)
KE001	Expansion kit Ø 5.0mm (unit)
KE058	Expansion kit Ø 5.8mm (unit)

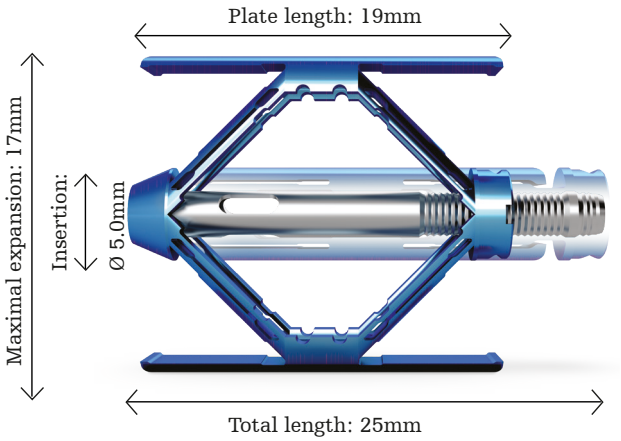
Implant dimensions

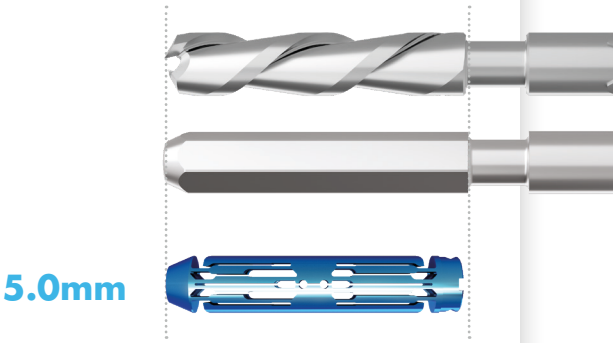
Full control over positioning

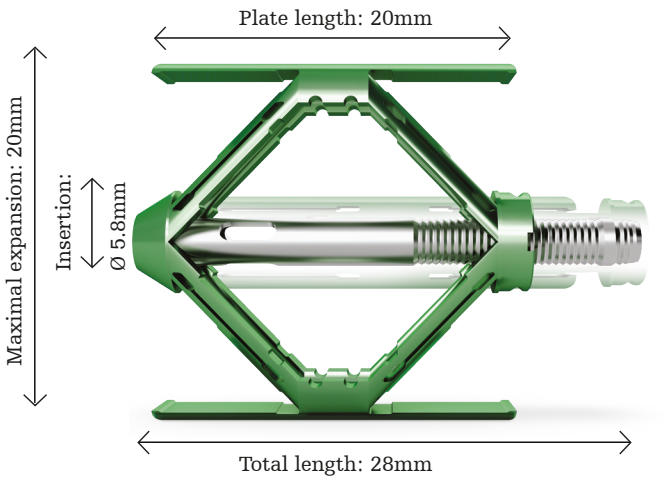
The instrumentation has been developed to give complete sequential control throughout each stage of the procedure. During each step, you can control the positioning of the implant and adjust it to the desired position.

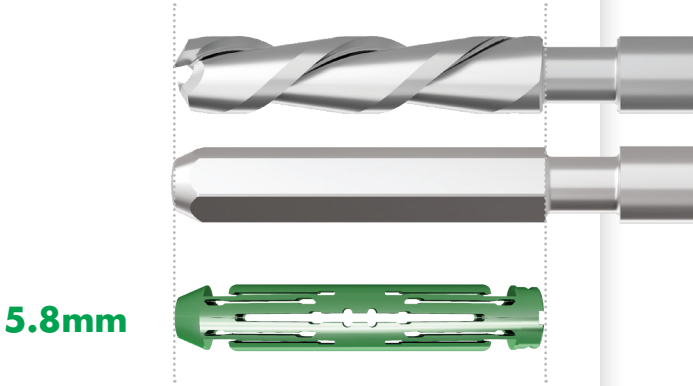












Preoperative planning strategy

Fracture mobility assessment

SpineJack® system is designed to treat mobile VCF's that may result from osteoporosis, trauma and malignant lesions. Assessment of the fracture's mobility prior to operating is recommended in order to maximize fracture reduction.

Implant positioning

The extent of fracture reduction depends largely on the positioning of the implant within the vertebral body. Therefore, it is recommended to map the optimal placement of the implant prior to surgery. The placement of 2 implants is often advised to achieve optimal anatomical restoration.

Vertebral dimensions

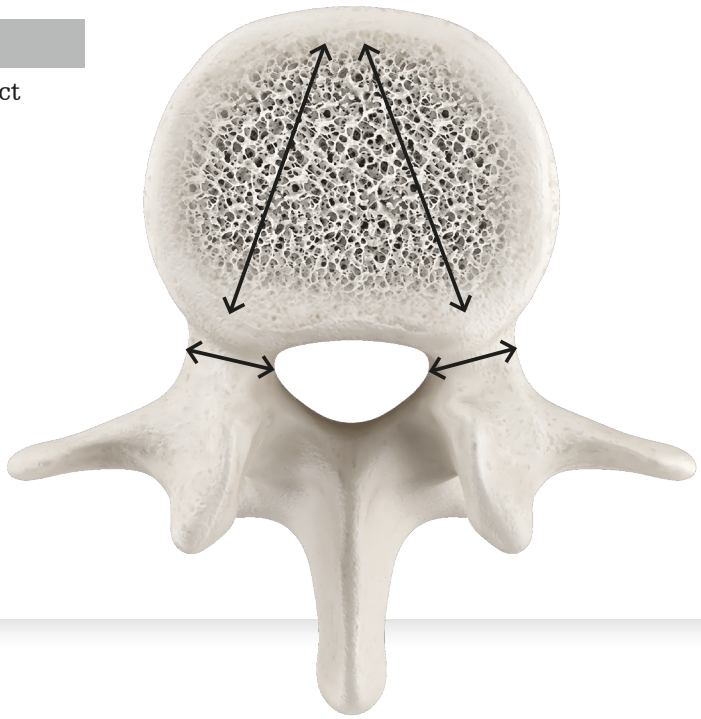
In order to ensure an optimal fit of SpineJack® implants, a CT scan of the vertebral body prior to surgery is required to confirm the adequacy of the vertebral dimensions. Access to the vertebral body requires a pedicle with a minimum diameter of 5mm: diameter KE004 + 0.8mm: 5mm.

Optimal implant fit chart

Pedicle diameter	Recommended kit
5.0-5.8mm	4.2mm
5.8-6.6mm	5.0mm
6.6mm and over	5.8mm

Tips and tricks

Consider vertebral body length to select the appropriate implant size.

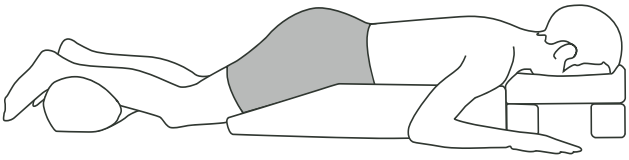


Positioning and anaesthesia

Patient positioning

The patient is placed in a prone position to minimise loading on the fractured vertebra.

A hyper-lordotic position is recommended for lumbar fractures.



Tips and tricks

For all levels to be treated with SpineJack® system, pre-operatively assess the following on CT scans:

1. The inner diameter of the pedicle in order to define the largest size implant (including working cannula) which can potentially be inserted through the pedicle.
2. The inner diameter of the vertebral body in order to define the largest size implant which can be opened in the vertebral body.
3. The ideal positioning of the SpineJack® implant(s) for VCFs is described in the document "Positioning of the SpineJack®"[18].

Anaesthesia

General, local or regional anaesthesia can be used depending on clinician preference and the patient's condition.

Controlled anatomical restoration

According to the preoperative planning strategy, a trocar is used under fluoroscopic control to determine the path to the vertebral body and to optimally position the implants (craniocaudal and mediolateral angles).

The entry point for the trocar tip should be inside the pedicle ring, close to its lateral wall, on the AP view. After advancing through the pedicle tunnel and reaching the posterior wall of the vertebral body, on the sagittal view, the tip of the trocar should be inside the pedicular ring, close to its medial wall, on the AP view.

Access to the vertebral body requires a pedicle with a minimum diameter of at least 5mm.

- Perform access procedure for both implants before implant site preparation.
- Fluoroscopic control must be used at every step of vertebral body access.
- Exercise caution to avoid anterior wall perforation while the guidewire is inserted.

Vertebral body access

Step 1

Trocar

- Insert the trocar through the pedicle into the posterior one-third of the vertebral body.
- Remove the inner part of the trocar.
- Order trocars separately. This includes:
  - Beveled Trocar 11G
  - Diamond Trocar 11G

Guidewire

- Insert the guidewire through the trocar halfway into the vertebral body.
- Remove the tube portion of the trocar.

Tips and tricks

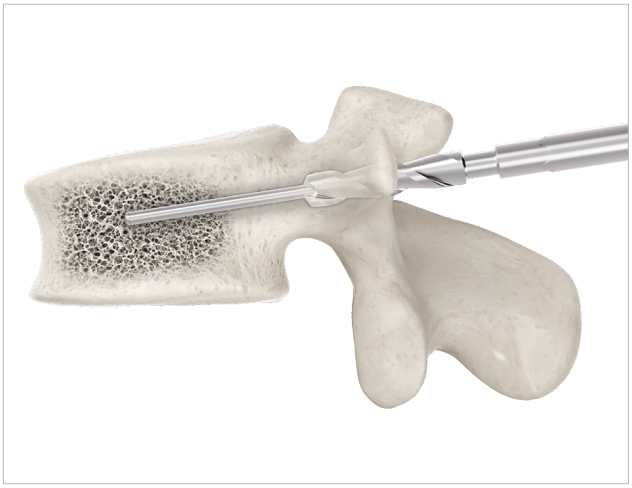
In wedge fractures, place implants as anterior as possible. These fractures retract slightly when opening.

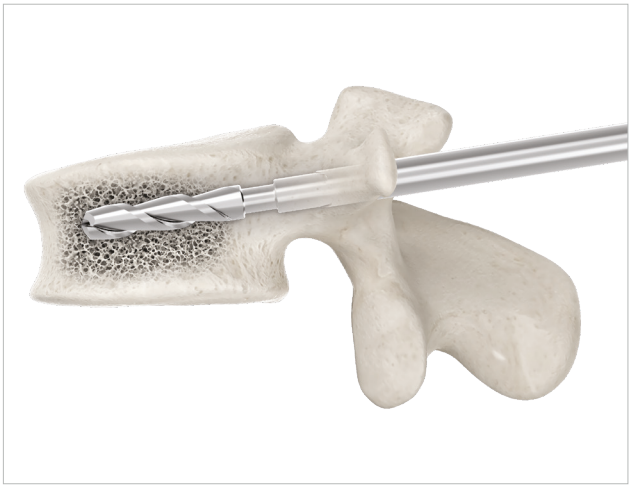
Tips and tricks

There is no need to impact the guidewire into cancellous bone.

Implant site preparation

Step 2





Guidewire and reamer

- Insert the preassembled reamer/ working cannula over the guidewire into the vertebra.
- Rotate the set to open the surface of the cortical bone.

Reamer

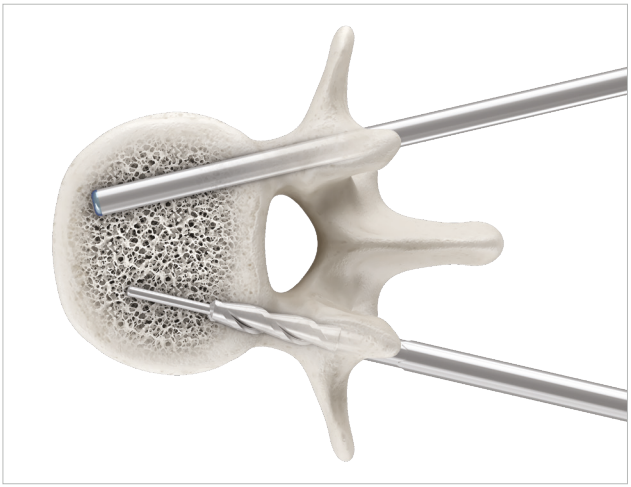
- Drill into the posterior one-third of the vertebral body.
- Remove the guidewire.
- Continue to drill until the desired position of the implant is reached.
- Disconnect the reamer from the working cannula. Unscrew and pull to remove the reamer from the vertebra, leaving the working cannula in place. The working cannula remains in place to act as a guide for the remaining instruments.

Tips and tricks

Do not change the direction of the reamer while the guidewire is still inside. This may cause the guidewire to bend and lead to difficulties removing it.

Implant site preparation

Step 2



Template

- Clean the implant site with the template.

Cannula plug

- Insert the cannula plug to the same depth as the template in order to:
  - visualise the depth of the first implant in order to position the second implant accordingly (radiopaque marker).
  - stabilise the working cannula on the first site while the second implant site is prepared.
  - stop the bleeding while the second implant site path is prepared.
- Repeat the preparation steps for the second implant site.

Tips and tricks

The instrumentation has been developed to provide full control over implant placement. The reamer and template allow for precise positioning of the implant.

Tips and tricks

Beware not to push the working cannula deeper after drilling. Next steps will be adapted to the position of the working cannula.

Implant insertion and expansion

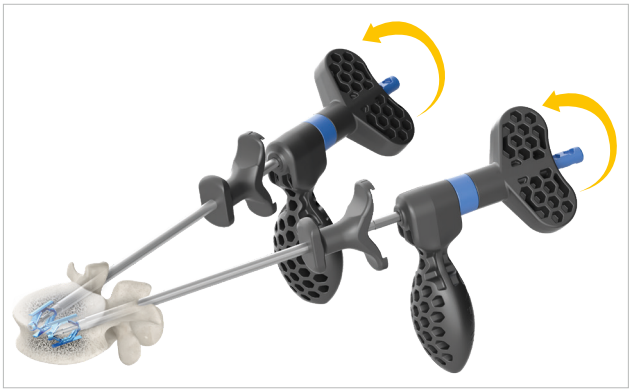
Step 3

Prepare both implant sites before the insertion and expansion of the implants. One reamer is used to prepare both implants sites, so it should be assembled with the second working cannula. Use fluoroscopic controls at all times throughout implant site preparation.

Insert SpineJack® implants

- Insert an implant expander into each prepared path.

The orientation of the implant is gauged using the palm-held grey handle. Exercise caution to ensure that the desired orientation is achieved before expansion.

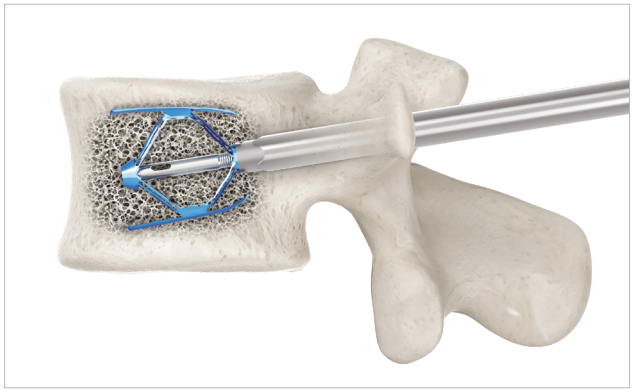


Expand SpineJack® implants

- Begin expansion on one implant by holding the palm handle with one hand and rotating the butterfly handle clockwise with the other hand.

Tips and tricks

SpineJack® system wings have been designed to allow for plastic deformations in order to adapt to the patient-specific bone conditions and vertebral endplate shape.

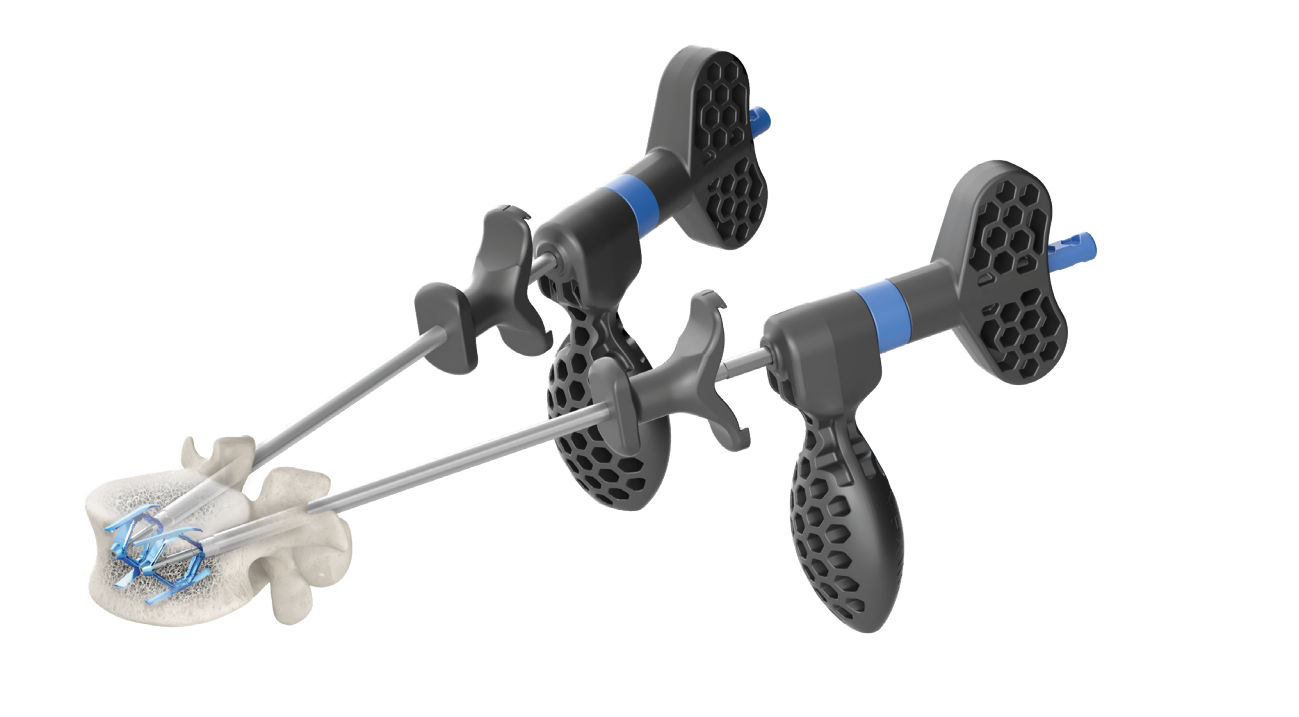


Reduce fracture

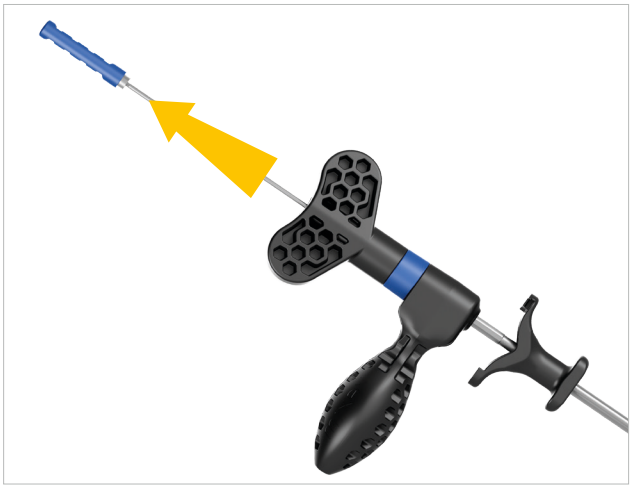
- Continue turning the handles until the desired vertebral body reduction is achieved.
- Use fluoroscopic controls regularly throughout the implant's expansion to ensure the desired fracture reduction is achieved.
- After each handle rotation, allow time for the bone to adjust to the implant's expansion.
- Once the expansion of the implant has started the implant cannot be closed again.

Expander removal

Step 4



- Unscrew the quick release pin counterclockwise to release the implant.



- Pull the quick release pin in the same direction, leaving the working cannula and the implant expander tube in place.

Tips and tricks

In rare cases, bone resistance may lead you to unscrew the grey handle by four or five turns before you unscrew the colored pin.

PMMA cement preparation and injection

Step 5

Use SpineJack® system in combination with the following PMMA cements:

- Cohesion® Bone Cement (CM0300)
- VertaPlex™ HV Radiopaque Bone Cement Twin Pack (0406-622-000)
- VertaPlex™ Radiopaque Bone Cement Twin Pack (0406-422-000)

• Prepare bone cement.

• TC05003/TC04003: prepare the cement with the Vexim Cement Mixing System (VCMS001).

• TC05004/TC04004: prepare the cement with:

- Vexim Cement Injection Kit (VCIK001)
- Masterflow™ Injection System (MF001)
- PCD Precision System with Long 90 Extension Tube (0506-486-000)
- Autoplex System Disposable Cement Mixer (0605-887-000)

SpineJack® cement pushers	
TC04003	Cement pusher for Ø 4.2mm (6 pack)
TC05003	Cement pusher for Ø 5.0mm (6 pack)
TC05003	Cement pusher for Ø 5.8mm (6 pack)

SpineJack® injector transfer tubes	
TC04004	Injector transfer tube for Ø 4.2mm (6 pack)
TC05004	Injector transfer tube for Ø 5.0mm (6 pack)
TC05004	Injector transfer tube for Ø 5.8mm (6 pack)

Internal volume

TC05003/TC05004 (5.0mm and 5.8mm) = 1.8cc

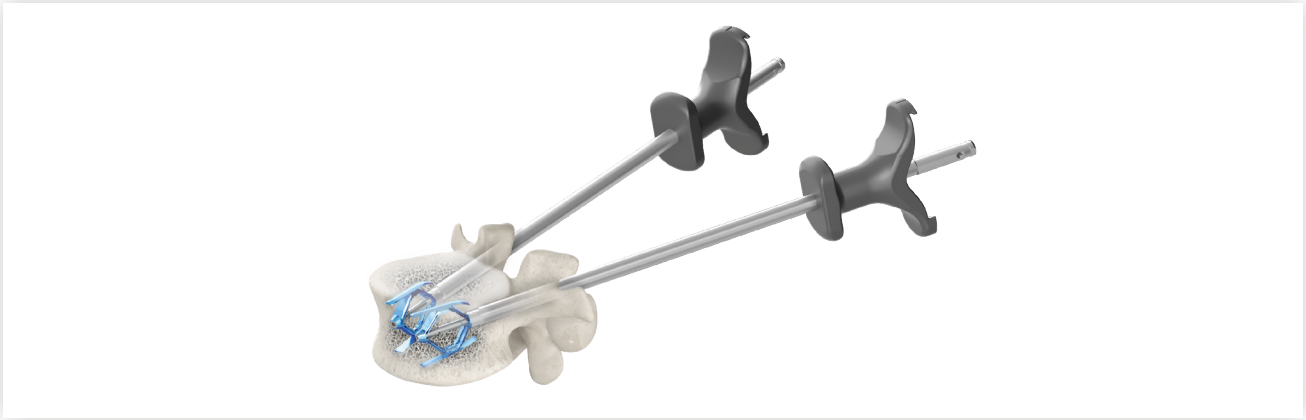
Internal volume

TC04003/TC04004 (4.2mm) = 0.9cc

Injection Systems are additional instruments and should be ordered separately.

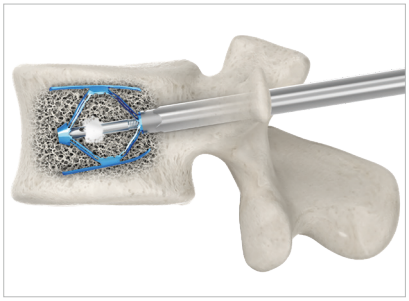
PMMA cement preparation and injection

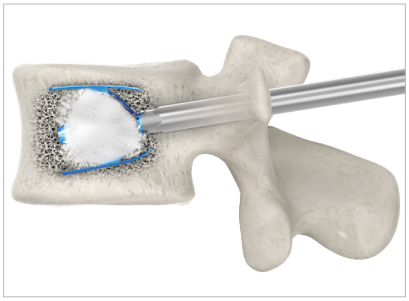
Step 5

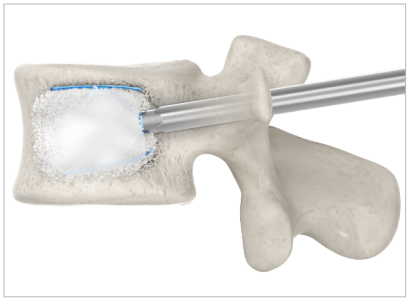


Cement injection with cement pushers

- Insert the cement pusher into the working cannula/implant expander.
- TC05003/TC04003: Push the mandrel to inject PMMA cements.
- Remove empty cement pusher.
- Insert another cement pusher and continue PMMA cement injection.
- Inject PMMA cement in both sides of the vertebra.
- Continue the process until the desired quantity of PMMA cement has been injected.







Cement injection with injector transfer tube

- Insert one injector tranfer tube (TC05004/TC04004) into each working cannula and clip them.
- Connect the luer lock of the chosen injection system to the injector transfer tube (TC05004/TC04004).
- Use the chosen injection system.
- When the desired quantity of PMMA cement has been injected, unclip the injector transfer tube.

Tips and tricks

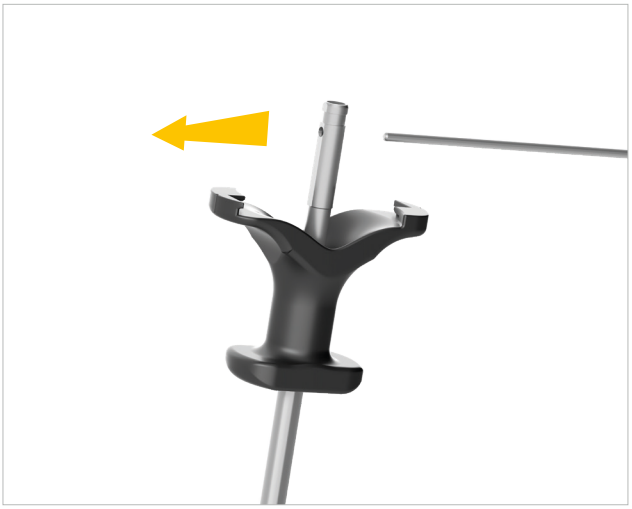
Rotate the cement pushers a few times before removal. This will help prevent the creation of a “cement mouse tail” in the pedicle.

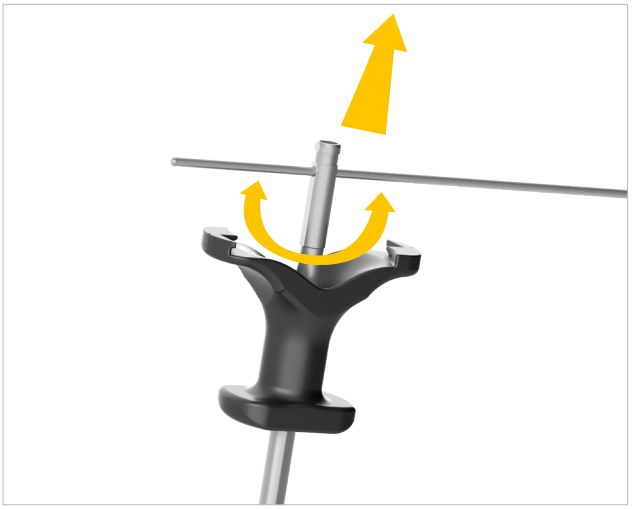
Tips and tricks

For osteoporotic VCFs, PMMA cement injection is critical to long-term results. It is recommended to inject bone cement so as to bridge the superior and inferior endplates. Use fluoroscopic controls during injection to monitor the flow.

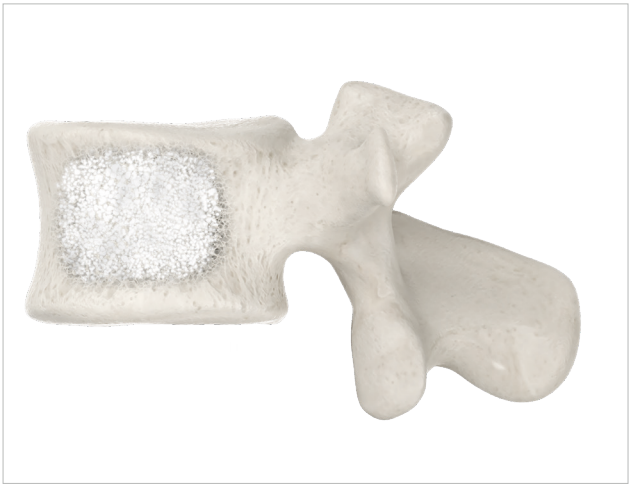
PMMA cement preparation and injection

Step 5





- Remove the cement pusher or the injector transfer tube.
- Insert a guidewire into the hole of the upper extremity of the implant expander tube, placed inside of the working cannula.
- Simultaneously rotate and pull the guidewire and expander tube to disconnect the working cannula and expander tube from the implant.
- Remove the guidewire, working cannula and expander tube from the patient's body.



- Close the surgical access.

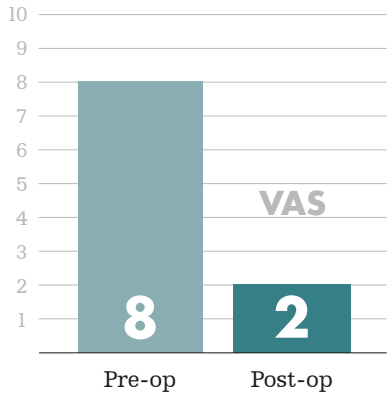
Clinical cases

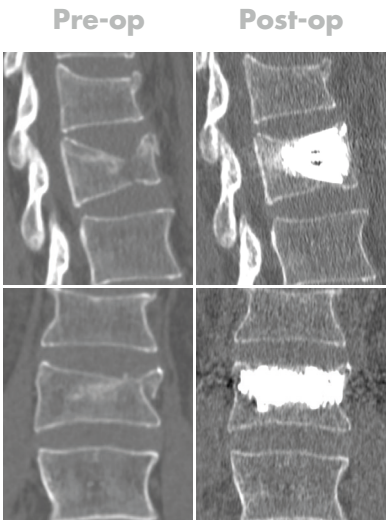
Trauma

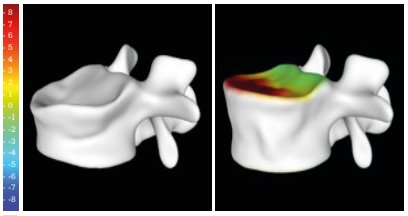
45-year-old patient

A.2.3 fracture in L1 after a fall from a ladder.

Hospital stay = two days







Pre-op and post-op superior endplate reconstructions

Trauma

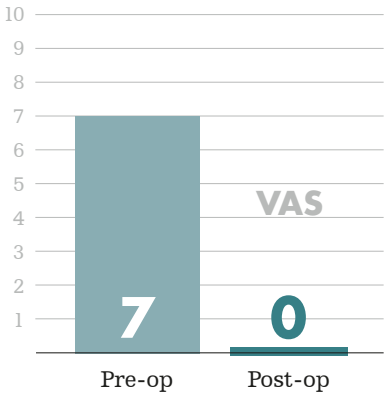
57-year-old patient

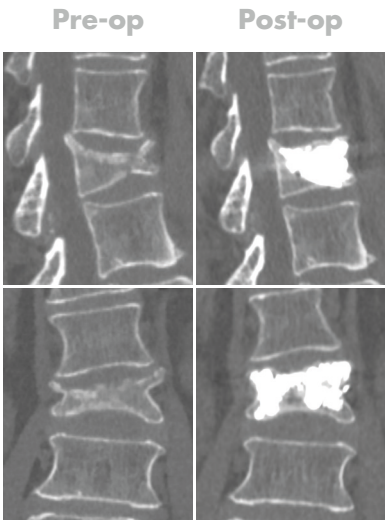
A.3.2 fracture in L1 after a fall from her bed.

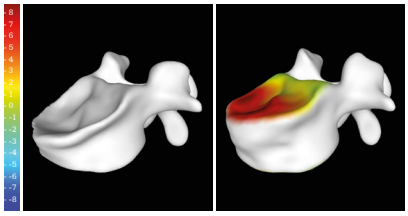
Low energy trauma in osteoporotic bone.

Surgery on fracture day+7.

Hospital stay = two days







Pre-op and post-op superior endplate reconstructions

Osteoporotic

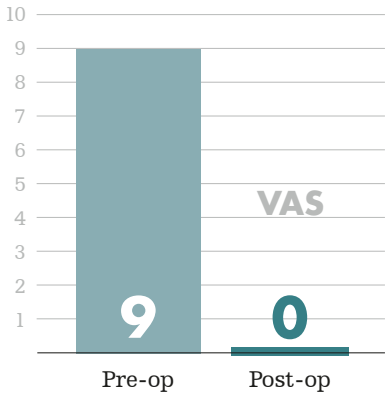
83-year-old patient

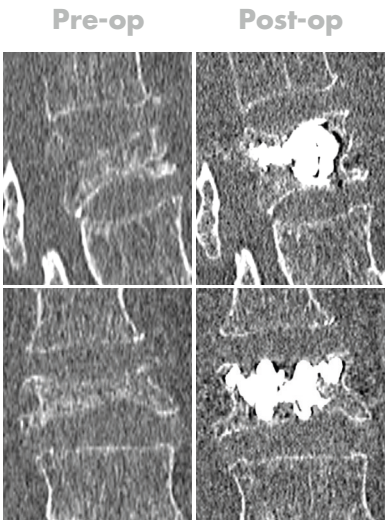
A.3.3 fracture in L1 after a fall accident.

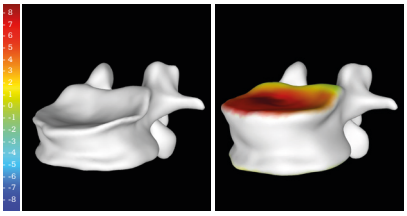
Traumatic VCF in osteoporotic bone.

Surgery on fracture day+10.

Hospital stay = two days







Pre-op and post-op superior endplate reconstructions

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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Interventional Spine

The SpineJack® system is indicated for use in the anatomical reduction of vertebral compression fractures that may result from osteoporosis, trauma (VCF type A Magerl classification) and malignant lesions (myeloma or osteolitic metastasis).

Complications are rare. Serious adverse events, some with fatal outcome, associated with the use of bone cements for vertebroplasty, kyphoplasty and sacroplasty include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism and cardiac embolism. Although it is rare, some adverse events have been known to occur up to one year post-operatively. Additional risks exist with the use of bone cement. Please see the IFU for a complete list of potential risks.

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