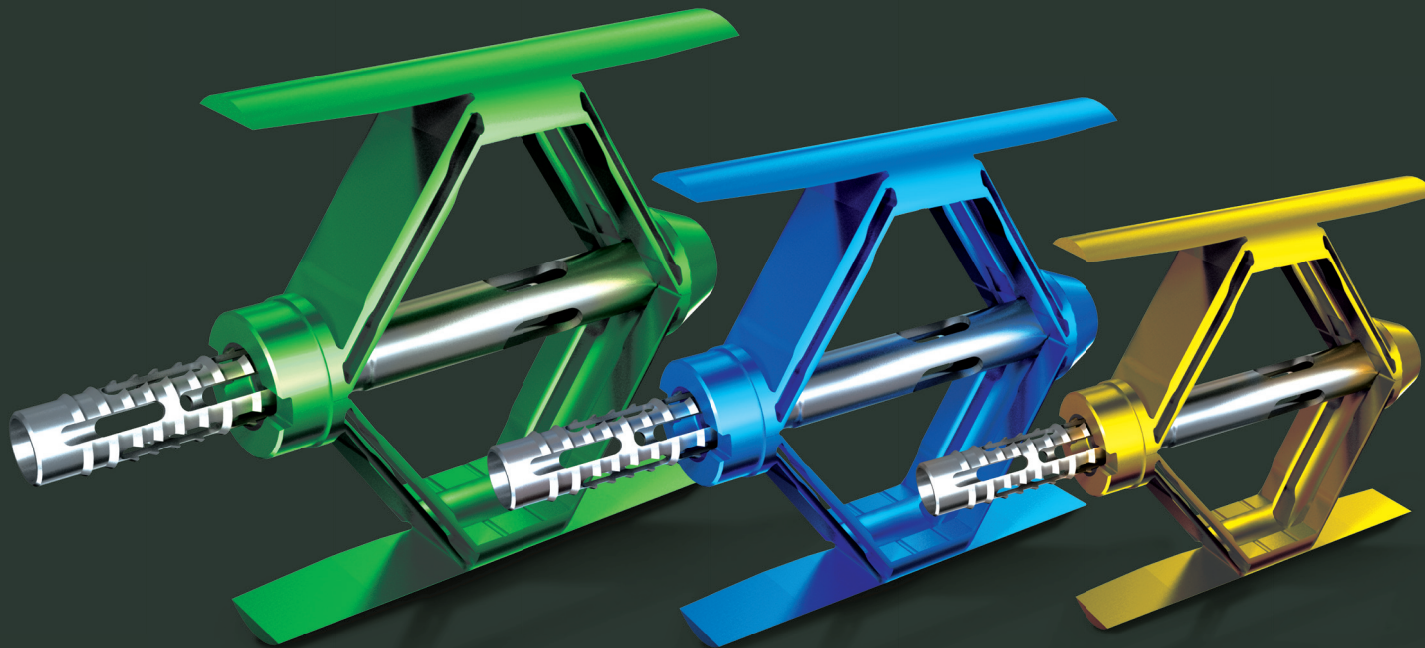


SpineJack®

Ø 5.8 mm | Ø 5.0 mm | Ø 4.2 mm

Controlled Anatomical Restoration

Introducing the Surgical Technique



SpineJack®

The SpineJack® System is designed for the
Anatomical Reduction of Vertebral Compression Fractures of traumatic origin
(VCF type A Magerl Classification), with or without underlying pathologies
affecting the bone quality such as osteoporosis and malignant lesions
(Myeloma or osteolytic metastasis).

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Pre-operative SpineJack® Information	Kit Composition & Implant Dimensions	p.04
	Preoperative Planning Strategy	p.06
	Patient Positioning and Anaesthesia	p.06
<hr/>		
SpineJack® Surgical Steps and Vexim Biomaterials	1. Vertebral Body Access	p.07
	2. Implant Site Preparation	p.08
	3. Implant Insertion & Expansion	p.09
	4. Expander Removal	p.10
	5. Biomaterial Preparation and Injection	p.10

Guidewire (blunt) x2



Working Cannula



Reamer with Working Cannula



Template



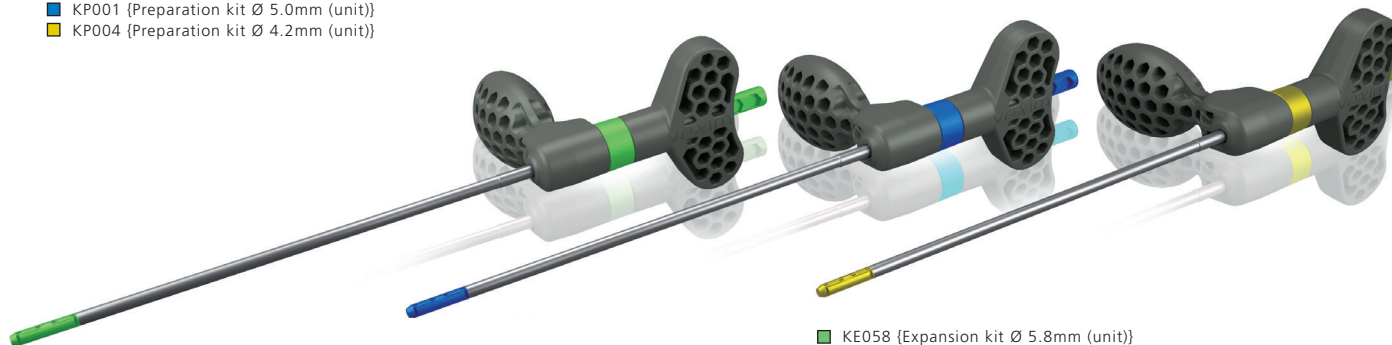
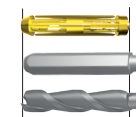
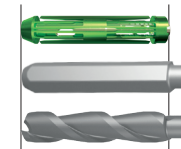
Cannula plug



- KP058 {Preparation kit Ø 5.8mm (unit)}
- KP001 {Preparation kit Ø 5.0mm (unit)}
- KP004 {Preparation kit Ø 4.2mm (unit)}

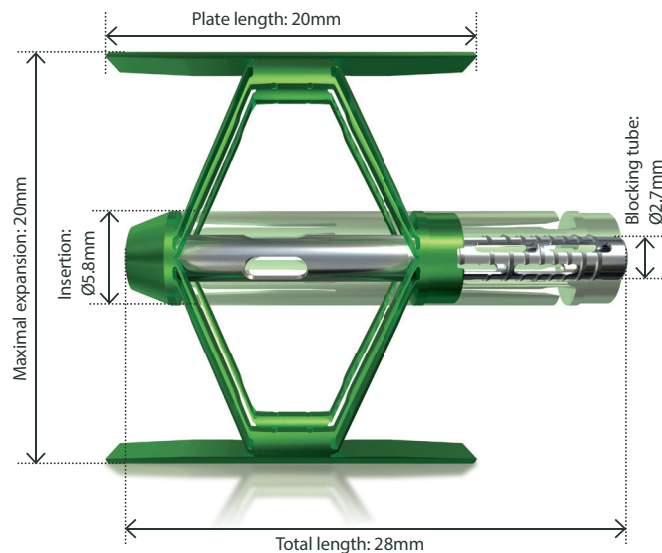
Full control over positioning

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

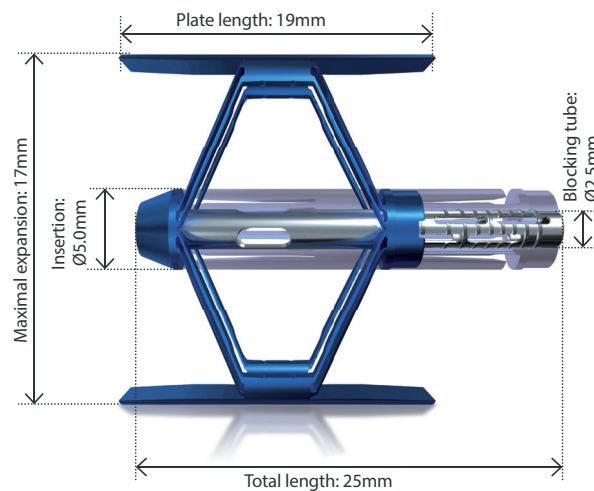


- KE058 {Expansion kit Ø 5.8mm (unit)}
- KE001 {Expansion kit Ø 5.0mm (unit)}
- KE004 {Expansion kit Ø 4.2mm (unit)}

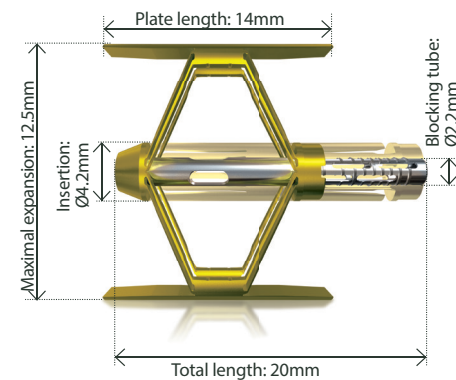
SpineJack® 5.8



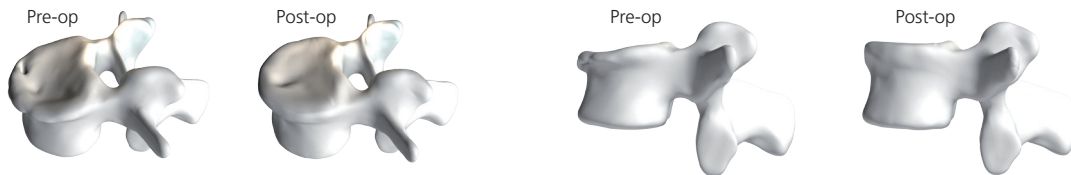
SpineJack® 5.0



SpineJack® 4.2



Preoperative / Planning Strategy



Fracture mobility assessment

SpineJack® is indicated for the treatment of mobile vertebral compression fractures. Assessment of the fracture's mobility prior to operating is therefore recommended in order to maximise fracture reduction.

Vertebra dimensions

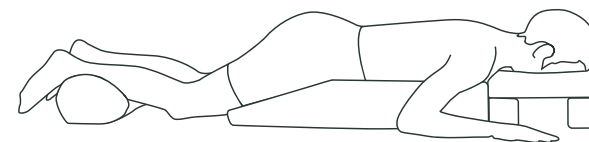
In order to ensure an optimal fit of SpineJack® implants, a CT scan of the vertebral body prior to surgery is needed to confirm the adequacy of the vertebral dimensions. Access to the vertebral body requires a pedicle with a minimum diameter of 5mm (diameter KE 004 + 0.8 mm → 5mm):

6,6 mm  5,8 mm  5,0 mm 

Implant positioning

The placement of 2 implants is often recommended to achieve an optimum anatomical restoration. The extent of fracture reduction depends largely on the positioning of the implant within the vertebral body. It is therefore recommended to map the optimal placement of the implants prior to surgery.

Patient / Positioning & Anaesthesia



Patient positioning

The patient is placed in prone position. The patient must be placed to minimise loading on the fractured vertebra. A hyper-lordotic position is recommended for lumbar fractures.

Anaesthesia

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

TIPS & TRICKS

1. Please assess pre-operatively on your CT scans, for all levels to be treated with SpineJack® :

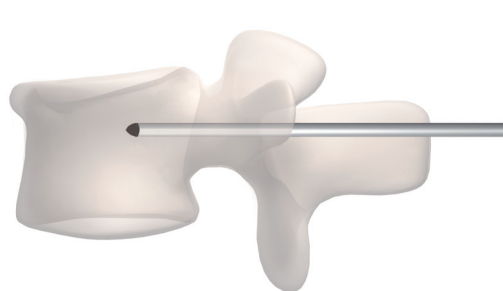
1. The inner diameter of the pedicle in order to define the biggest size implant (including working cannula) which can potentially be inserted through the pedicle.
2. The inner diameter of the vertebral body in order to define the biggest size implant which can be opened in the vertebral body.
3. The ideal positioning of the SpineJack implant(s) in all different types of fractures is described in the document "Positioning of the SpineJack®". Part Number: SJPOSBOOK.

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 (cranio-caudal angle, medio-lateral angle).

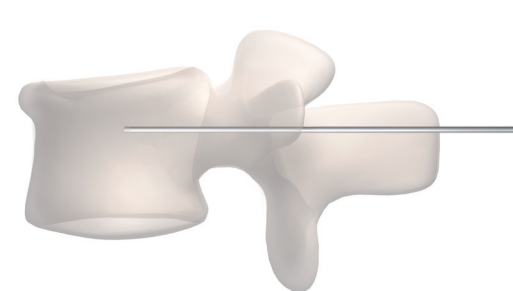
The entry point for the trocar tip should be inside the pedicle ring, close to its lateral wall, on the AP view. While moving forward in the pedicle tunnel and reaching the posterior wall of the vertebral body, on the sagittal view, the tip of the trocar should be inside the pedicular ring, close to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

Access to the vertebral body requires a pedicle with a minimum diameter of at least 5mm. (See page 6, 'Vertebra dimensions')

- Access for both implants can be performed before implant site preparation.
- Fluoroscopic control needs to be used at every step of vertebral body access.
- Caution should be taken to avoid anterior wall perforation while the guidewire is inserted.



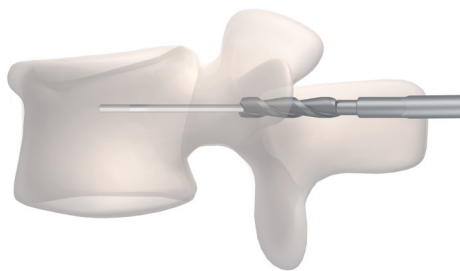
- Insert the trocar through the pedicle 1/3 of the depth of the vertebral body.
- Remove the inner part of the trocar.
- Trocars should be ordered separately :
TNBV11U: Beveled Trocar 11G
TNDI11U: Diamond Trocar 11G



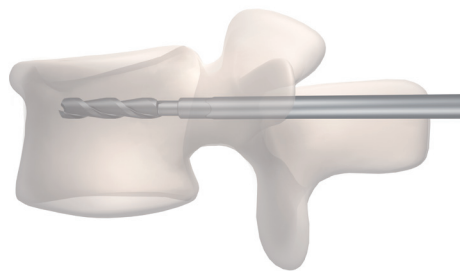
- Assemble the guidewire with its handle.
- Insert the guidewire through the trocar into 1/2 of the depth of the vertebral body.
- Remove the guidewire handle, followed by the tube portion of the trocar.

TIPS & TRICKS

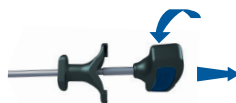
2. In wedge fractures place implants as anterior as possible, since they retract slightly when opening.



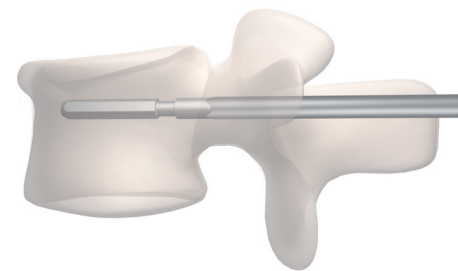
- Slide the reamer/working cannula preassembled over the guidewire to the vertebra.
- Rotate the set to open the surface of the cortical bone.



- Drill into 1/3 of the vertebral body.
- Remove the guidewire.
- Continue to drill until the desired position of the implant is reached.



1. Disconnect the reamer from the working cannula.
2. 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 following instruments.



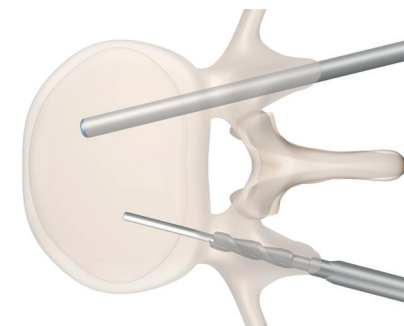
- Clean the implant's site with the template.

TIPS & TRICKS

3. Multi controlled implant positioning: the instrumentation has been developed to always give full control over the implant positioning. The reamer and template will give you the exact positioning of the implant.

TIPS & TRICKS

4. Beware NOT to push the working cannula deeper accidentally after drilling, as the next steps will be adapted to working cannula position (template, etc.)

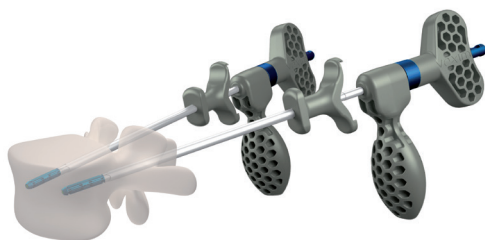


- Insert the cannula plug to the same depth as the template in order to:
 - Stop the bleeding while the second implant site path is prepared.
 - Visualise the depth of the first implant in order to position the second implant accordingly (radiopaque marker).
 - Stabilise the working cannula on the first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

The preparation of both implant sites can be performed before the placement of the actual implants.

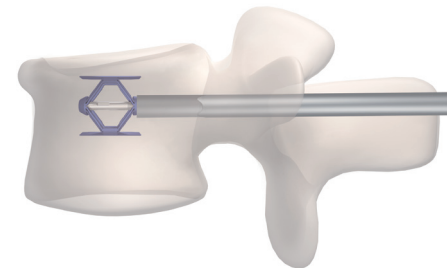
The same reamer is used for both implant site preparations, and should therefore be assembled with the second working cannula for the second implant site preparation.

Fluoroscopic controls must be used at all times throughout the implant site preparations.



- Insert an implant expander into each prepared path.

The orientation of the implant is gauged using the palm-held grey handle. Caution should be taken to ensure that the desired orientation is achieved before expansion.



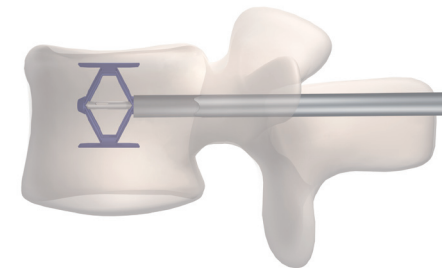
- Begin the expansion of the implants simultaneously by rotating the expanders' butterfly handles clockwise.

TIPS & TRICKS

5. After having finalised the "bed of the implant" with the template, move the instrument gently in a cranio-caudal motion to ease the opening of the implant in the next step.

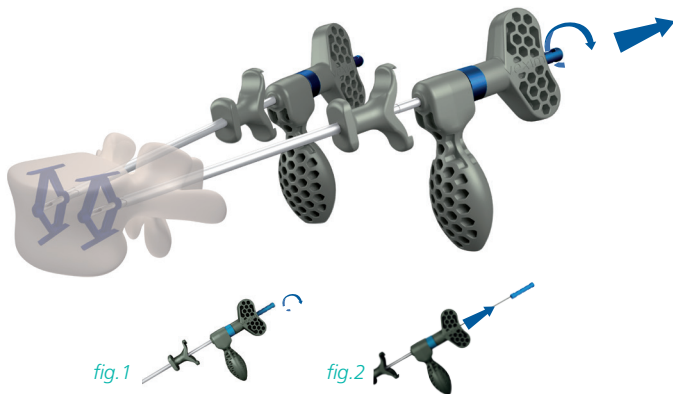
TIPS & TRICKS

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



- Continue turning the handles until the desired vertebral body reduction is achieved.
- Fluoroscopic controls should be used regularly throughout the implant's insertion and expansion to ensure correct positioning and expansion according to the fracture reduction desired.
- 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.

Step 4 / Expander Removal



1. Unscrew the quick release pin counter-clockwise to release the implant.
2. Pull the quick release pin in the same direction leaving the working cannula and the implant expander tube in place.

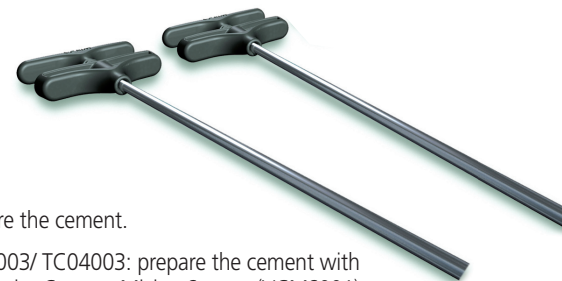
TIPS & TRICKS

7. In rare cases, the resistance of the bone can lead to the necessary unscrewing of the grey handle four or five turns before unscrewing the blue pin. A safety release mechanism is incorporated in the design of the implant fixation thread and will work by releasing the implant from the implant holder shaft when excessive force is applied (>200kg)

It is recommended to use the SpineJack® System in combination with Vexim Biomaterials and Vexim Injection Systems which have been specifically developed for use with SpineJack® to optimise safety.

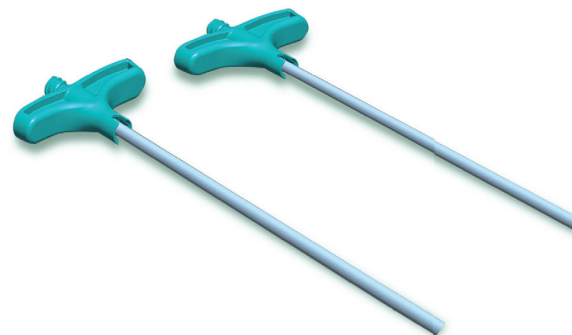
Vexim Injection Systems are additional instruments and should be ordered separately.

Step 5 / Biomaterial Preparation & Injection



- TC05003 {Cement Pusher for SJ Ø 5.8mm (6 Pack)}
- TC05003 {Cement Pusher for SJ Ø 5.0mm (6 Pack)}
- TC04003 {Cement Pusher for SJ Ø 4.2mm (6 Pack)}

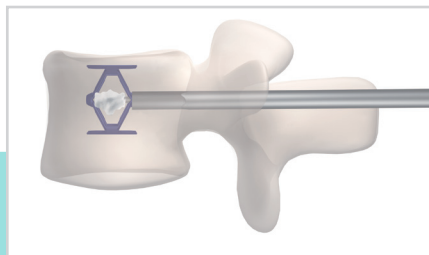
- Prepare the cement.
- TC05003/ TC04003: prepare the cement with the Vexim Cement Mixing System (VCMS001).
- TC05004/ TC04004: prepare the cement with the Vexim Cement Injection Kit (VCIK001) or the Masterflow™ Injection System (MF001) and use the Vexim Injector Transfer Tube to deliver the cement into the vertebral body.



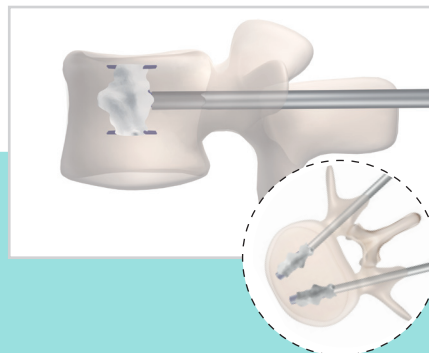
- TC05004 {Injector Transfer Tube for SJ Ø 5.8mm (6 Pack)}
- TC05004 {Injector Transfer Tube for SJ Ø 5.0mm (6 Pack)}
- TC04004 {Injector Transfer Tube for SJ 4,2mm (6 pack)}



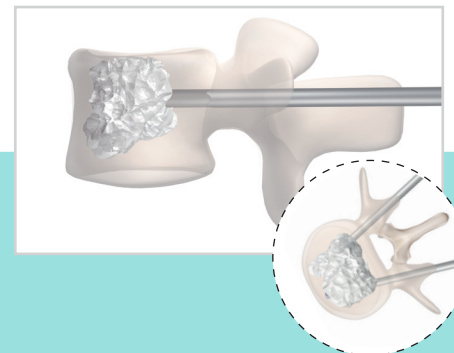
- Insert the cement pusher into the working cannula/implant expander.
- TC05003/TC04003: Push the mandrel to inject Vexim Biomaterials.



- Remove empty cement filler.
- Insert another cement filler and continue biomaterial injection.



- Continue the process until the desired quantity of Vexim Biomaterials has been injected.



- Inject Vexim Biomaterials in both sides of the vertebra.

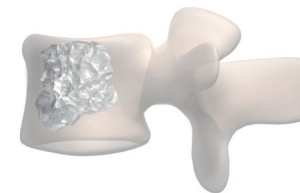
- When the desired quantity of Vexim Biomaterials has been injected unclip the injector transfer tube.

TIPS&TRICKS

8. The cement fillers should be rotated a few times before removal to prevent creation of a "cement mouse tail" in the pedicle.

TIPS&TRICKS

9. Vexim Biomaterials injection is critical to long-term results, and therefore should be injected so as to bridge the superior and inferior endplates. Fluoroscopic controls should be used during injection to monitor the flow.



- Simultaneously rotate and remove the cement pusher or the Injector Transfer Tube, the working cannula and the implant expander.
- Close the surgical access.



fig.1

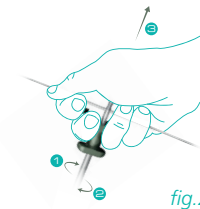


fig.2

10. **fig.1** Remove the Cement Pusher or the Injector Transfer Tube.

Introduce a guide-wire inside the hole of the upper extremity of the implant expander tube, placed inside of the working cannula.

fig.2 Apply a rotative force associated to the pull-out force, to dissociate the working cannula and the expander tube from the implant. Remove the working cannula and the expander tube from the patient's body.

ADVICE

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