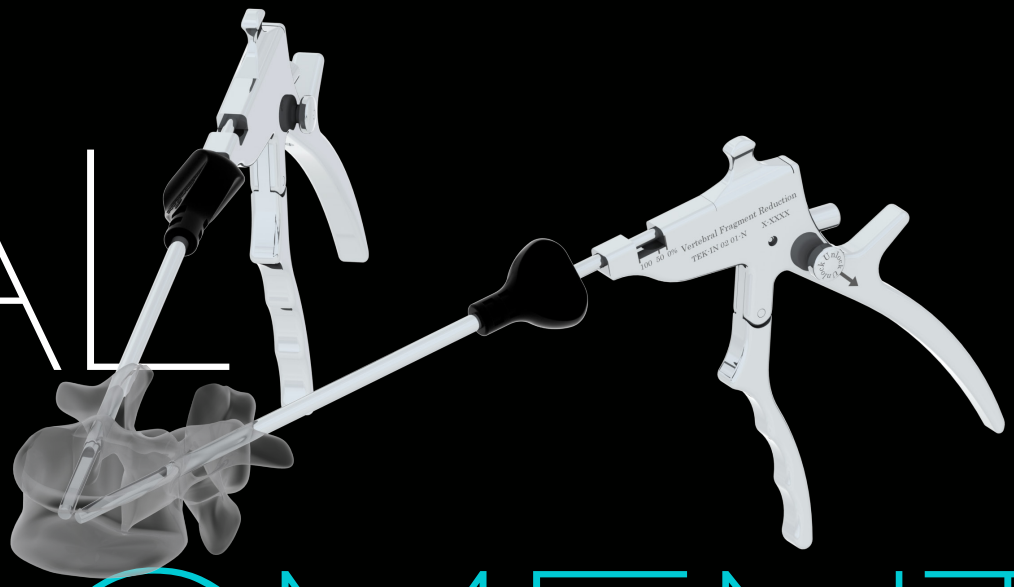
TEKTONA®

BY SPINEART

VERTEBRAL FRAGMENT REDUCTION

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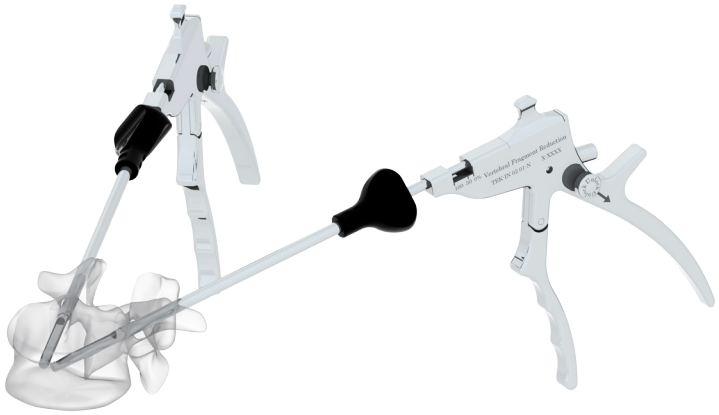
CONTENT

CONCEPT AND DESIGN



INDICATIONS

TEKTONA® is designed to repair the fracture of vertebral compression fractures (type A1, A2 and A3 according the Magerl Classification), with or without underlying pathologies affecting the bone quality such as osteoporosis and malignant lesions (myeloma or osteolytic metastasis).

* The amount that is needed to stabilize the fracture depends mostly on the type of bone quality.
The worse the bone structure is, the more bone cement is needed in order to achieve and maintain a good result.

INTRODUCTION

VERTEBRAL COMPRESSION FRACTURES (VCF)

Vertebral Compression Fractures (VCF) are most common between the levels T9 – L2*, located in the thoraco-lumbar junction.

VERTEBRAL BODY ACCESS

A transpedicular or extra pedicular approach is used for the fragment reduction restoration of VCF with the TEKTONA®.

According to the preoperative planning strategy, a trocar is used under fluoroscopy control to determine the path to the vertebral body and to optimally position the vertebral fragment reduction instrument.

PATIENT AND ANESTHESIA

The patient should be in the prone position to minimize load on the fractured vertebra.

A hyper-lordotic position is recommended for lumbar fracture

General or local anesthesia can be used depending on clinicians' preferences and patients' condition.

* Nevitt MC et al. *Bone*. 1999;25:613–619.
Cooper C et al. *J Bone Min Res*. 1992;7:221–227.

TECHNICAL FEATURES

CONTROLLED EXPANSION

- Mechanism to reduce VCF controlled unidirectional craniocaudal distraction force

MAINTAINING THE RESTORATION

- Blocking system - allows the reduction and the fragments to be maintained during the procedure.

Warning
Always remove the vertebral fragment reduction instrument before you inject the bone cement.

MULTIPLE LEVELS

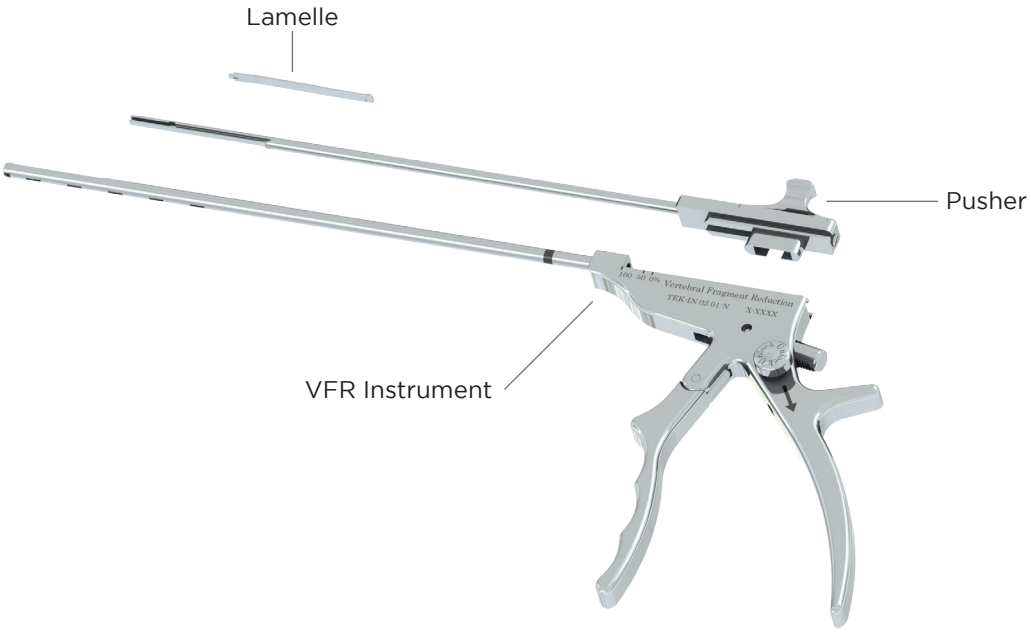
- Treatment suitable for multiple levels

PRESERVING THE TRABECULAR STRUCTURE

- High cement interdigitation
- Optimal fracture stabilization

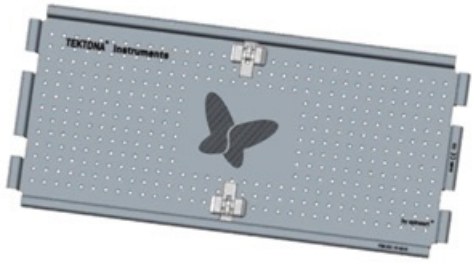
(The amount of bone cement needed to stabilize the fracture depends largely on the bone quality.)

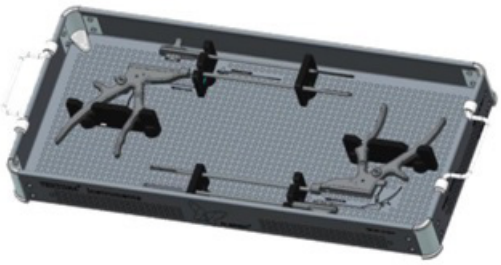
VERTEBRAL FRAGMENT REDUCTION INSTRUMENT(VFR)



DESCRIPTION	REFERENCE
VERTEBRAL FRAGMENT REDUCTION	TEK-IN 02 01-N
LAMELLE	TEK-IN 01 40-S

INSTRUMENTS





DESCRIPTION	REFERENCE
VETEBRAL FRAGMENT REDUCTION KIT	TEK-BX 10 02-N
VETEBRAL FRAGMENT REDUCTION INSTRUMENT	TEK-IN 02 01-N

PRODUCTS

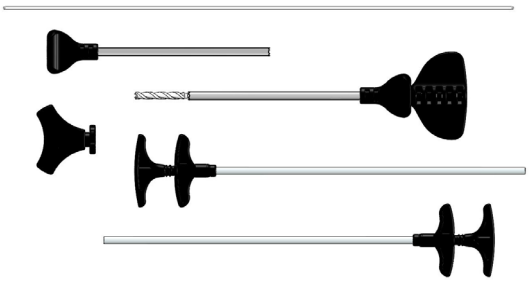
DESCRIPTION	REFERENCE
VETEBRAL FRAGMENT REDUCTION	TEK-IN 02 01-N
VETEBRAL FRAGMENT REDUCTION KIT	TEK-BX 10 02-N
SINGLE LEVEL BOX	TEK-IN B0 00-S
LAMELLE	TEK-IN 01 40-S
PREPARATION KIT	TEK-IN 30 00-S
MENDEC HV SPINE SYSTEM	13C2040
MALE-MALE CONNECTOR	893 00
TROCART 11 GAUGE	RAN-11125NBB

SINGLE LEVEL BOX

DESCRIPTION	REFERENCE
SINGLE LEVEL BOX	TEK-SL B0 00-S

SINGLE LEVEL BOX CONTENT		TEK-SL B0 00-S
QTY	DESCRIPTION	REFERENCE
1	PREPARATION KIT	TEK-IN 30 00-S
1	LAMELLE PACK (2 PER PACK)	TEK-IN 01 40-S
1	TROCARS BEVEL TIP PACK (2 PER PACK)	RAN-11125NBB
1	MENDEC HV SPINE CEMENT PACK	13C2040
1	MALE-MALE CONNECTOR	893 00

PREPARATION KIT CONTENT		TEK-IN 30 00-S
QTY	DESCRIPTION	REFERENCE
2	K-WIRE	TEK-IN 13 01-S
2	CEMENT FILLERS	TEK-IN 07 02-S
2	WORKING CANNULA	TEK-IN 03 01-S
1	REAMER	TEK-IN 05 01-S
1	K-WIRE HANDLE	TEK-IN



One working cannula is alreay involved on the reamer.

INSTRUMENTS

K-WIRE BLUNT TIP Ø2mm	TEK-IN 13 01-S

CEMENT FILLER	TEK-IN 07 02-S

K-WIRE HANDLE	TEK-IN 14 01-S

TROCAR 11 GAUGE	RAN-11125NBB

WORKING CANNULA	TEK-IN 03 01-S

VERTEBRAL FRAGMENT REDUCTION INSTRUMENT	TEK-IN 02 01-N

REAMER ø5 mm	TEK-IN 05 01-S

LAMELLE	TEK-IN 01 40-S

PREOPERATIVE CONSIDERATIONS

FRACTURE MOBILITY ASSESSMENT

TEKTONA® 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 maximize the fragment reduction.

VERTEBRAL DIMENSIONS

In order to ensure an optimal fit of the VFR (Vertebral Fracture Reduction instrument), a CT or MRI scan of the vertebral body prior to surgery is needed to confirm the adequacy of the vertebral dimensions.

VFR INSTRUMENT POSITIONING

The placement of two instruments is often recommended to achieve an optimal fragment reduction.

ANESTHESIA

A general or local anesthesia can be performed depending on the clinician's preference and the patient's condition.

PATIENT POSITIONING

The patient is placed in a prone position. The patient must be placed so that it minimizes the compression load on the fractured vertebra. A hyper-lordotic position is recommended for lumbar fractures in order to support the reduction.

IMPORTANT

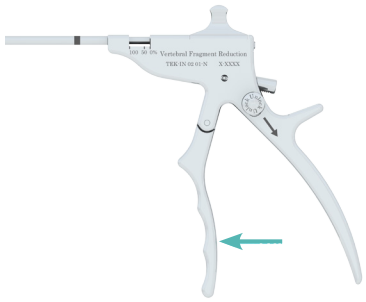
Please assess pre-operatively on your CT scans, for all levels to be treated with TEKTONA®:

The inner diameter of the pedicle in order to define the size of the working cannula (5.5mm) and which can potentially be inserted through the pedicle.

TECHNICAL INSTRUCTION
INSTRUMENT ASSEMBLY

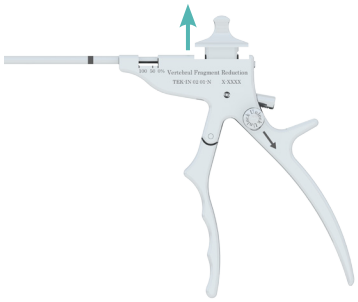
STEP **1**

Handle in standard position (completely open).
Make sure the handle stays in standard position for eachh step.



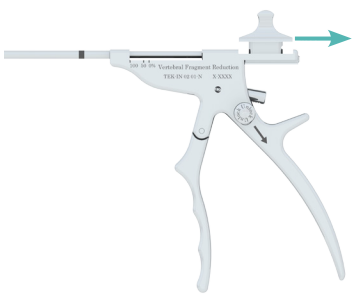
STEP **2**

Unlock the pusher of the VFR instrument.



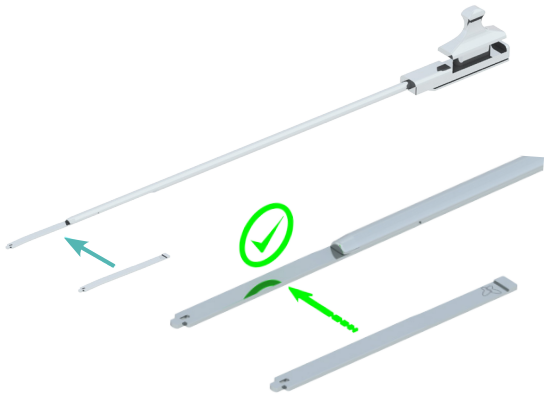
STEP **3**

Remove pusher.



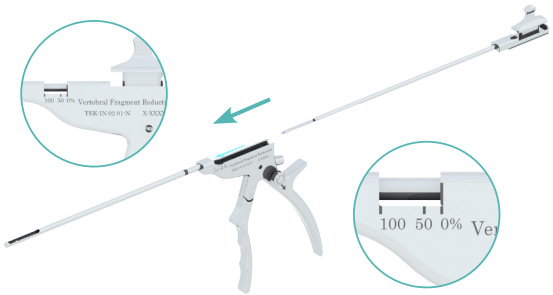
STEP **4**

Insert the lamella lateraly into the pusher.



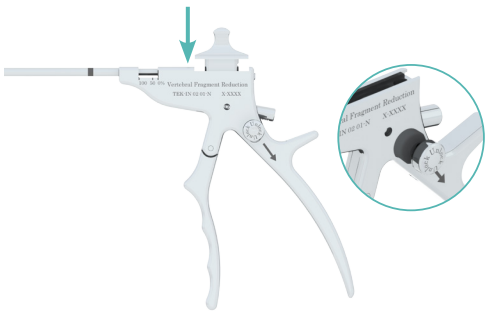
STEP **5**

Insert the pusher into the VFR instrument up to the 0% mark (Unlock pusher).

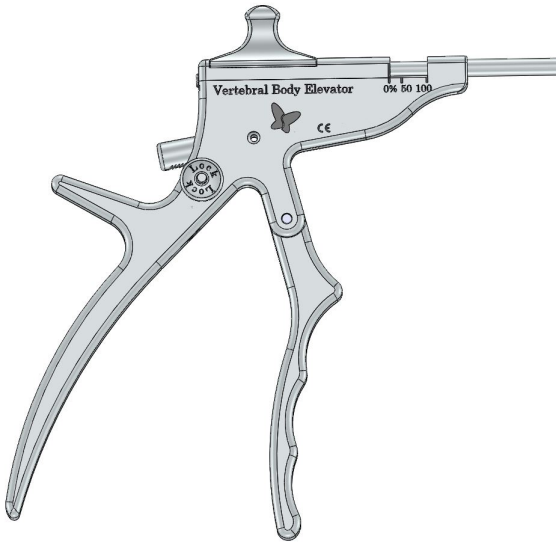


STEP **6**

Lock the pusher, handle in standard position (completely open).



TECHNICAL INSTRUCTION BLOCKING SYSTEM



Button on the right hand side of the VFR instrument

Its only purpose is to eliminate the blocking system. The blocking system can be made operational again by pushing this button.

Button at the left side of the handle of the VFR system

The blocking system is always operational in the standard position. To disable the blocking system just push the button down (see arrow). While doing this it is recommended to always keep the handle under control.

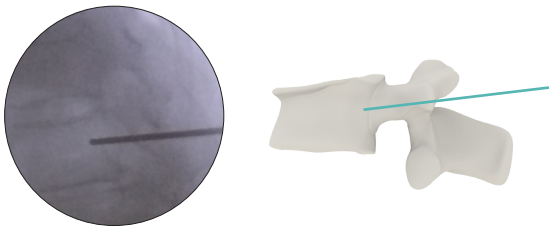
Pushing both buttons down and to the right

Blocking system is now disabled. In this position the lamella will always return to its original position. To reactivate the blocking system it is required to push the right button.

Warning
While activating or disabling the blocking system it is recommended to always keep the handle under control.

SURGICAL TECHNIQUE

STEP **1**

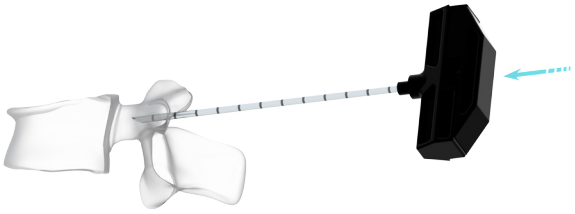


INITIAL NEEDLE PLACEMENT

Verify trajectory into the vertebral body to ensure proper fracture reduction.

Be aware of superior and inferior pedicle margins.

STEP **2a**

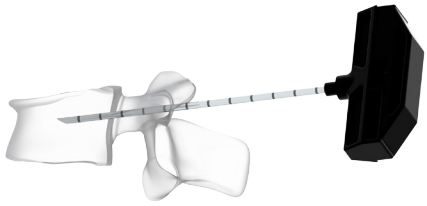


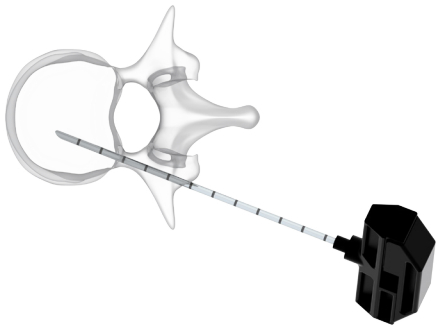
PEDICLE TARGETING

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.

STEP **2b**





PEDICLE TARGETING

Insert the Trocar through the pedicle by one third of the depth of the vertebral body.

Fluoroscopic control needs to be used at every step of vertebral body access.

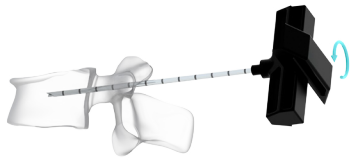
Caution should be taken to avoid anterior wall perforation while the guidewire is inserted.

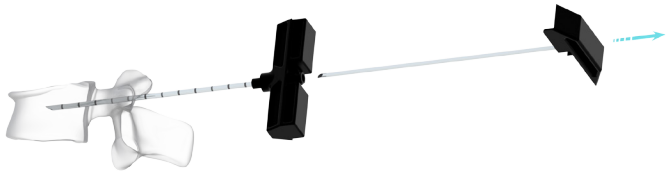
SURGICAL TECHNIQUE

STEP **3**

REMOVING THE TROCAR

Remove the inner shaft of the trocar by unscrewing the top knob before pulling on it.





STEP **4**

GUIDE K-WIRE INSERTION

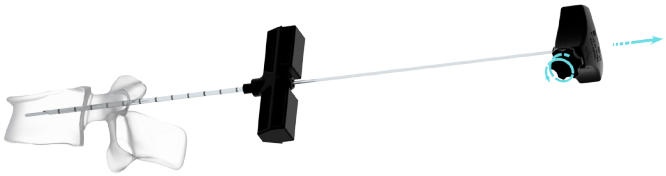
Assemble the guide k-wire with its handle.

Insert the guide k-wire through the trocar into half of the depth of the vertebral body.

STEP **5**

GUIDE K-WIRE HANDLE REMOVAL

Once the guide k-wire is in place, remove the guide k-wire handle, followed by the trocar.



SURGICAL TECHNIQUE

STEP **6**

REMOVING THE TROCAR

Remove the tube part of the Trocar, leaving the guide k-wire in place.

STEP **7**

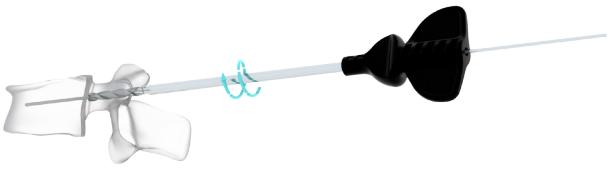
DRILL AND WORKING CANNULA INSERTION

Preassemble the reamer/working cannula and slide over the guide k-wire to the vertebra.

Rotate the reamer to open the surface of the cortical bone.

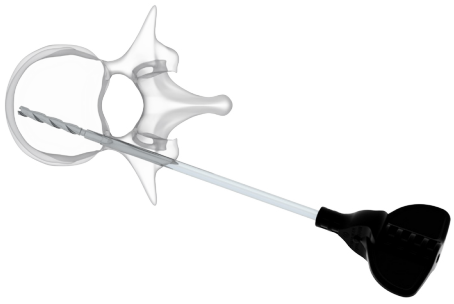
STEP **8**

DRILLING ACTION



Start rotating the reamer to open the surface of the cortical bone.

Drill as far as possible in the direction of the anterior wall. This will allow the opening of the lamelles in different positions.



The reamer can be used for high density bones.

Always check with fluoroscopic control when using the reamer.

SURGICAL TECHNIQUE

STEP **9**

REMOVING THE GUIDE WIRE

Remove the K-wire as soon as stability of the reamer in the vertebral body is achieved.

This will confirm that the K-wire will not penetrate the anterior wall during drilling.

Always perform this procedure under fluoroscopic control.

STEP **10**

REMOVING THE DRILL

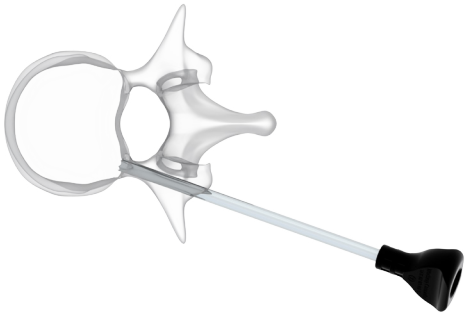
Disconnect the reamer from the working cannula.

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 following instruments.

The bone on the reamer will allow a biopsy if needed.

Both sites can be prepared before the actual change in Vertebral Fragment Reduction instruments.



SURGICAL TECHNIQUE

STEP **11**

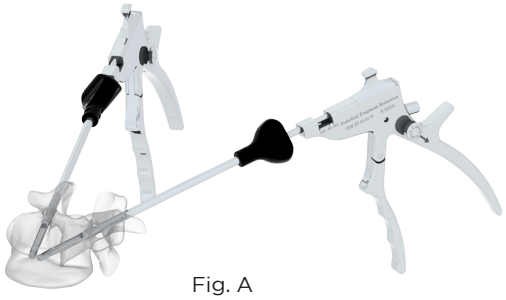
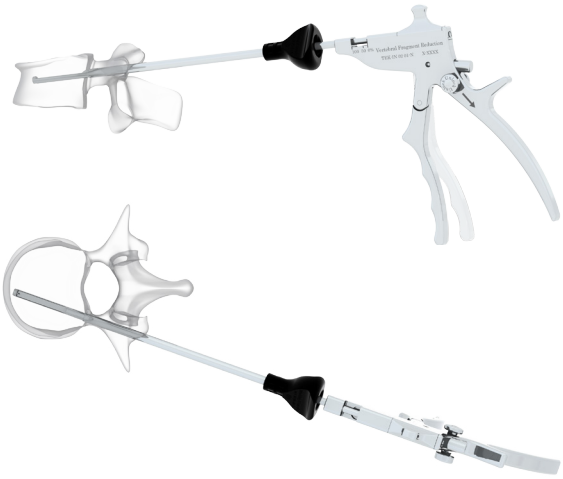


Fig. A



VFR USE

Insert a VFR instrument into each prepared side path (Fig. A).

The VFR instrument handle represents the axis of expansion of the lamelle.

Begin the expansion of the lamelle simultaneously with the handle (Fig. B).

Fluoroscopic controls should be used regularly throughout the insertion of the instrument and expansion to ensure correct positioning.

Please refer to the VFR Assembly Guide for information on how to assemble to VFR.

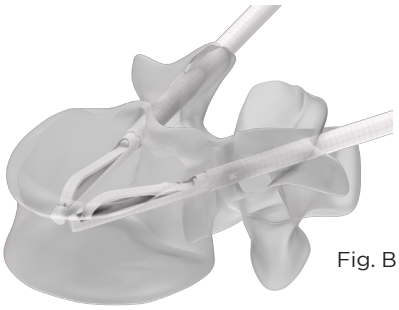
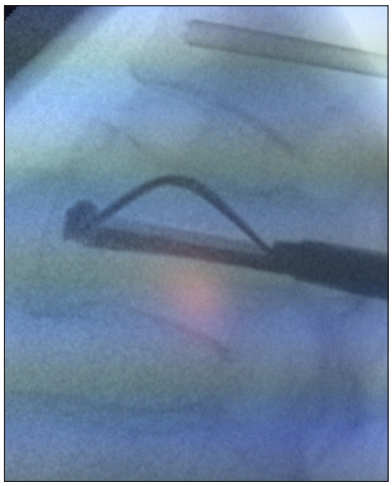


Fig. B



PRECAUTIONS OF USE

Fluoroscopic controls should be used regularly to ensure correct positioning and lamelle expansion according to the fragment reduction desired.

After each trigger of the handle, allow time for bone expansion.

Once the desired expansion is reached, remove the VFR instrument, but leave the Working Cannula in place.

Tip: if some bone is blocked between the pusher and the lamelle, remove the pusher from the VFR before taking out the instrument. The lamelle will not disconnect due to its shape.

SURGICAL TECHNIQUE

STEP **12**

REMOVING THE VFR

Unlock the handle of the instrument (fig. A).

Fig. A

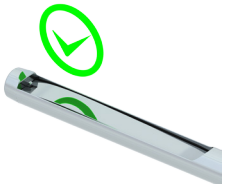


Fig. B

Make sure that the lamelle is in its original position, completely horizontal (fig. B).

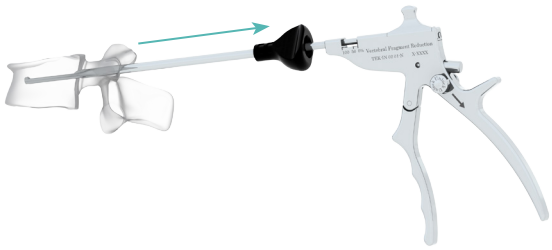


Fig. C

Remove the instrument from the working cannula (fig. C).

FIXATION LAMELLA

The lamella is only fixated in the pusher. This is important as the lamella can always be removed together with the instrument.

SURGICAL TECHNIQUE

STEP **13**

FILLING THE CEMENT FILLERS

Prepare and mix the cement according to Tecres® cement surgical technique. Once the cement is ready, plug the cement injection device onto the bone filler (a bone filler contains 2.5cc of bone cement) using the connection that comes in the cement package.

For all Mendec HV information, we refer you to the technical brochure.

Additional video tutorial available.

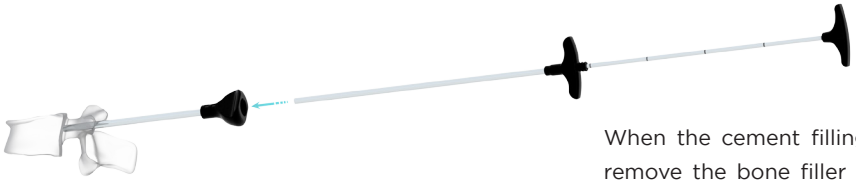
STEP **14**

INJECTION

Carefully monitor the preparation and application of the Mendec HV bone cement. Connect the connection (fig 1) before injecting the cement into the cement fillers. Once the working time has been reached the injecting of the cement can start.

Slide the bone filler through the Working Cannula, and push to run the cement in the vertebra. Always do so simultaneously and under fluoroscopy control.

Once the injection of the bone cement is completed, both bone fillers must be removed before the bone cement reaches its hardening time.



Rotate the bone filler clockwise in order to stop cement injection before withdrawing the cement filler from the pedicle.

When the cement filling procedure is over, you can remove the bone filler and the working cannula. An X-Ray check can be performed at this stage.

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C A N M E D M E D I K A L

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