TEKTONA®

VERTEBRAL FRAGMENT REDUCTION

C O N T E N T

CONCEPT AND DESIGN

The TEKTONA® system was designed to assist in the reduction of vertebral body fractures in a percutaneous surgical approach. It is used in combination with bone cement marketed for vertebroplasty or kyphoplasty procedures.

The TEKTONA® system comprises a flexible lamella (Nickel-Titanium) that can be expanded by the action of a Vertebral Fragment Reduction (VFR) instrument. The VFR instrument has a ratcheting mechanism that can maintain the shape of the lamella during the fracture reduction procedure.

The TEKTONA® system comprises a Cement-filler device with a standard Luer Lock connection.

AT A GLANCE

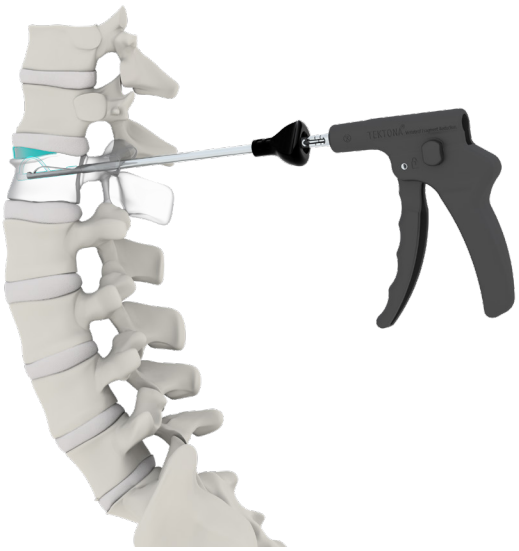
Progressive Expansion
Multiplanar Fragment Reduction
Controlled Height Restoration
Multiple Levels

INDICATIONS

The TEKTONA® system is indicated to treat moderate to severe pain caused by vertebral body compression fractures (VCF) located between T7 and L5, secondary to osteopenia, multiple myeloma and/or trauma, and presenting kyphotic deformities and risk of progressive vertebral height loss.

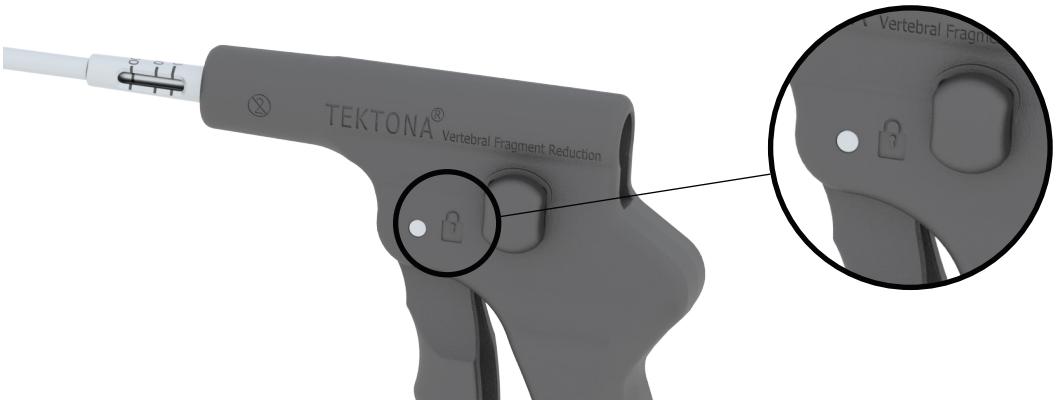
TECHNICAL FEATURES

VERTEBRAL FRAGMENT REDUCTION



The VFR* instrument is used to perform the vertebral fragment reduction and enable controlled expansion.

RATCHETING MECHANISM



The VFR instrument can be locked once expanded to maintain restoration.

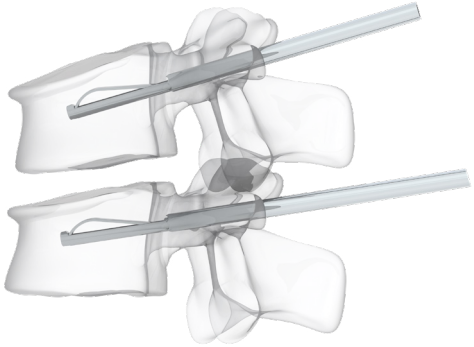
* Vertebral Fragment Reduction

TECHNICAL FEATURES

MULTIPLE EXPANSION

The VFR instrument offers 3D controlled expansion capacities while preserving the trabecular structure.

MULTIPLE LEVELS



The treatment is suitable for multiple levels.

TECHNICAL FEATURES

NITINOL LAMELLA

The Lamella is made of Nitinol; this material provides sufficient flexibility for different elevation maneuvers to be carried out during vertebral fragment reduction.

TECHNICAL FEATURES

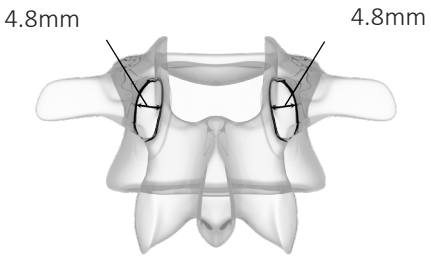
RANGE OF SIZES

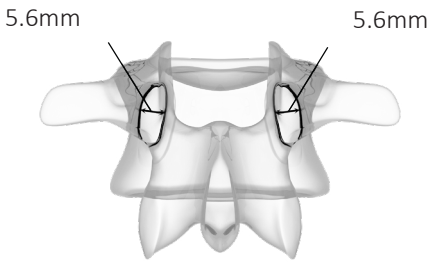
SMALL

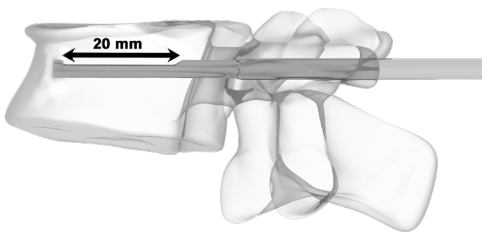
LARGE

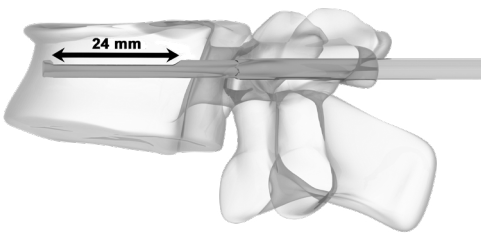
Two Sizes are available to fit different anatomies of vertebrae.

DIMENSIONS	SMALL	LARGE
VFR INSTRUMENT DIAMETER	4mm	4.8mm
WORKING CANNULA DIAMETER	4.8mm	5.6mm
LAMELLA LENGTH	20mm	24mm









INSTRUMENT SET

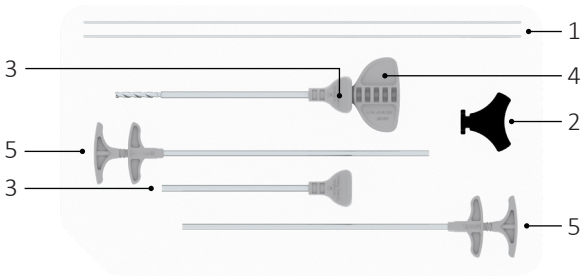
ONE LEVEL BOX

REFERENCE	DESCRIPTION
TEK-SL B0 06-S	TEKTONA ONE LEVEL BOX - SMALL

REFERENCE	DESCRIPTION	QTY
TEK-IN 02 03-S	VERTEBRAL FRAGMENT REDUCTION INSTRUMENT - SMALL	1
TEK-IN 30 01-S	PREPARATION KIT - SMALL	1

PREPARATION KIT CONTENT

#	REFERENCE	DESCRIPTION	QTY
1	TEK-IN 13 02-S	BLUNT WIRE Ø2MM	2
2	TEK-IN 14 02-S	HANDLE WIRE	1
3	TEK-IN 03 02-S	WORKING CANNULA - SMALL	2*
4	TEK-IN 05 02-S	DRILL Ø4MM – SMALL	1
5	TEK-IN 07 03-S	CEMENT FILLER - SMALL	2

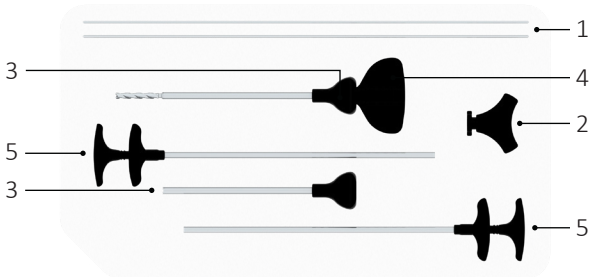


REFERENCE	DESCRIPTION
TEK-SL B0 05-S	TEKTONA ONE LEVEL BOX - LARGE

REFERENCE	DESCRIPTION	QTY
TEK-IN 02 02-S	VERTEBRAL FRAGMENT REDUCTION INSTRUMENT - LARGE	1
TEK-IN 30 02-S	PREPARATION KIT - LARGE	1

PREPARATION KIT CONTENT

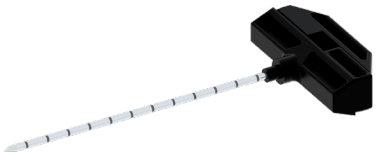
#	REFERENCE	DESCRIPTION	QTY
1	TEK-IN 13 02-S	BLUNT WIRE Ø2MM	2
2	TEK-IN 14 02-S	HANDLE WIRE	1
3	TEK-IN 03 03-S	WORKING CANNULA - LARGE	2*
4	TEK-IN 05 03-S	DRILL Ø5MM – LARGE	1
5	TEK-IN 07 04-S	CEMENT FILLER - LARGE	2



*One Working cannula is delivered already assembled on the Drill.

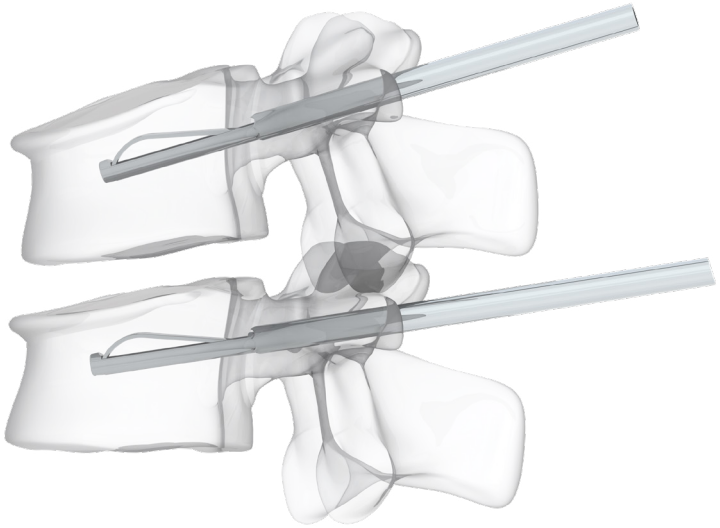
INSTRUMENT SET

ONE-LEVEL PROCEDURE



INSTRUMENT	REFERENCE
11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (NOT FENESTRATED, BEVEL STYLET)	RAN-1115N5B
11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (FENESTRATED)	RAN-1115
TEKTONA HV BONE CEMENT	TEK-BC HV 00-S

MULTIPLE-LEVEL PROCEDURES



For additional level, references could be ordered separetly.

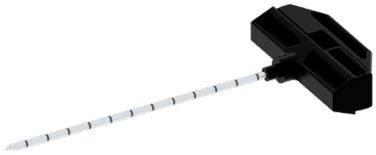
INSTRUMENT	REFERENCE
11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (NOT FENESTRATED, BEVEL STYLET)	RAN-1115N5B
11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (FENESTRATED)	RAN-1115
WORKING CANNULA-SMALL (X2)	TEK-IN 03 02-S
WORKING CANNULA-LARGE (X2)	TEK-IN 03 03-S
VFR INSTRUMENT SMALL	TEK-IN 02 03-S
VFR INSTRUMENT LARGE	TEK-IN 02 02-S
TEKTONA HV BONE CEMENT	TEK-BC HV 00-S
CEMENT FILLER-SMALL (X2)	TEK-IN 07 03-S
CEMENT FILLER-LARGE (X2)	TEK-IN 07 04-S

INSTRUMENTS

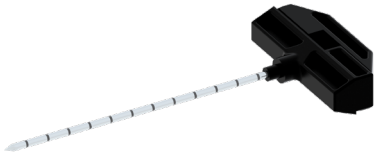
VERTEBRAL FRAGMENT REDUCTION INSTRUMENT – LARGE + REMOVAL HANDLE — TEK-IN 02 02-S

VERTEBRAL FRAGMENT REDUCTION INSTRUMENT - SMALL + REMOVAL HANDLE — TEK-IN 02 03-S

11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (NOT FENESTRATED, BEVEL STYLET) — RAN-1115N5B



11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (FENESTRATED) — RAN-1115



WORKING CANNULA - LARGE — TEK-IN 03 03-S

WORKING CANNULA - SMALL — TEK-IN 03 02-S

DRILL Ø5 MM - LARGE — TEK-IN 05 03-S

DRILL Ø4 MM - SMALL — TEK-IN 05 02-S

INSTRUMENTS

CEMENT FILLER - LARGE	TEK-IN 07 04-S

CEMENT FILLER - SMALL	TEK-IN 07 03-S

BLUNT WIRE Ø2MM	TEK-IN 13 02-S

HANDLE WIRE	TEK-IN 14 02-S

TEKTONA HV BONE CEMENT	TEK-BC HV 00-S

SURGICAL TECHNIQUE

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 fragment reduction.

_PATIENT POSITIONING

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

_VERTEBRAL DIMENSIONS

A CT or MRI scan of the vertebral body and the pedicles prior to surgery is required to confirm the adequacy of the vertebral dimensions, in order to ensure an optimal fit of the VFR instrument.

_ANESTHESIA

General or local anesthesia can be administered depending on the clinician's preference and the patient's condition.

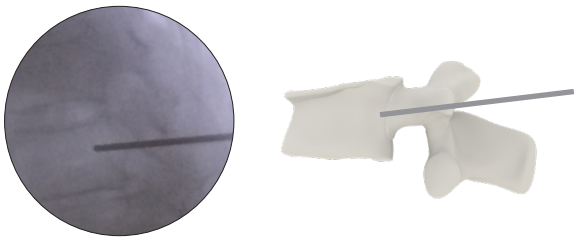
_IMPORTANT

Please use a preoperative CT scan to assess the inner diameter of the pedicle for all levels to be treated with TEKTONA® in order to determine whether the working cannulas (Small: Ø4.8mm or Large: Ø5.6mm) can potentially be inserted.

Dimension of the Vertebral body need to be assessed in order to confirm the size selection of the active part of the VFR instrument (Small: 20mm and Large: 24mm).

SURGICAL TECHNIQUE

_STEP 1



INITIAL TROCAR PLACEMENT

Verify trajectory into the vertebral body.

Sufficient margin should be allowed for safe passage of the subsequent instrumentation.

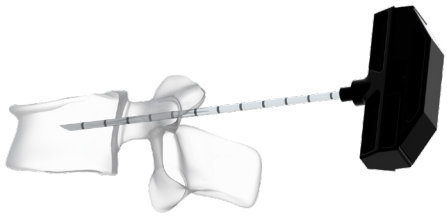
_STEP 2A

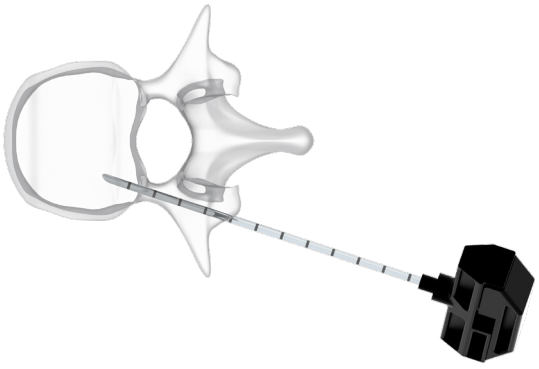
PEDICLE TARGETING

The entry point for the Trocar tip should be inside the pedicle ring, close to its lateral wall, on the anterio-posterior (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 must be used at every step of vertebral body access process. Caution should be taken to avoid anterior wall perforation.

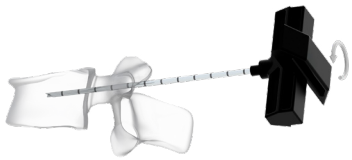
INSTRUMENT	REFERENCE
11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (NOT FENESTRATED, BEVEL STYLET)	RAN-1115N5B
11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (FENESTRATED)	RAN-1115

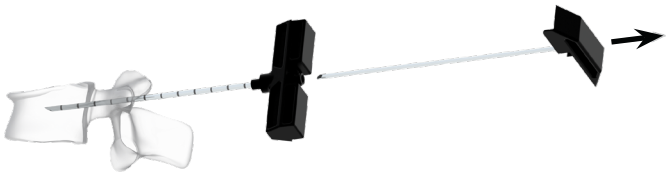
SURGICAL TECHNIQUE

_STEP 3

REMOVING THE INNER SHAFT

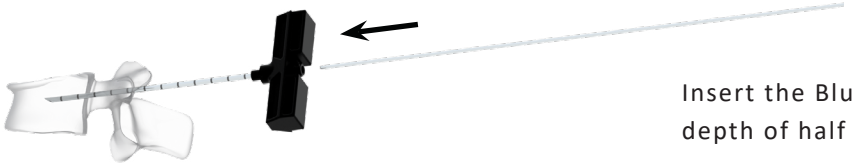
Remove the inner shaft of the Trocar by unscrewing the knob on the top and removing it as shown.





_STEP 4

BLUNT WIRE INSERTION

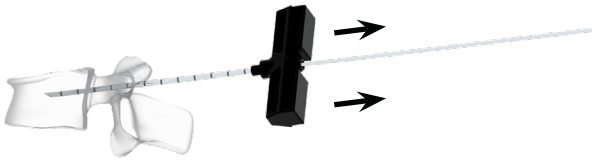


Insert the Blunt wire through the Trocar to a depth of half of the vertebral body

INSTRUMENT	REFERENCE
11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (NOT FENESTRATED, BEVEL STYLET)	RAN-1115N5B
11 GAUGE X 15CM BONE MARROW ASPIRATION NEEDLE (FENESTRATED)	RAN-1115
BLUNT WIRE Ø2MM	TEK-IN 13 02-S

_STEP 5

REMOVING THE TROCAR



Remove the Trocar, leaving the Blunt wire in place.

SURGICAL TECHNIQUE

_STEP 6

DRILL AND WORKING CANNULA INSERTION

Preassemble the Drill/Working cannula and slide over the Blunt wire to the vertebra.

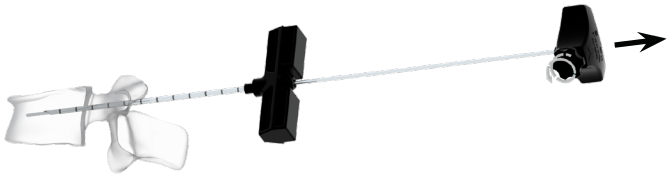
_STEP 7

DRILLING ACTION

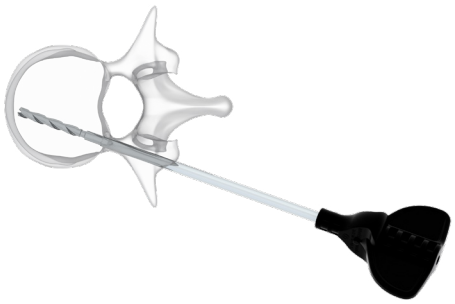
Start rotating the Drill to open the surface of the cortical bone.

Drill as far as possible in the direction of the anterior wall. This will allow more control during fracture reduction.

Assemble the Handle Wire on the blunt wire.



Remove the Blunt wire as soon as stability of the Drill in the vertebral body has been achieved. This will prevent the Blunt wire from accidently perforating the anterior wall of the vertebral body while drilling.

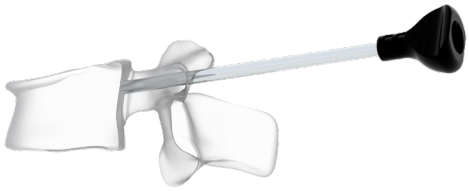


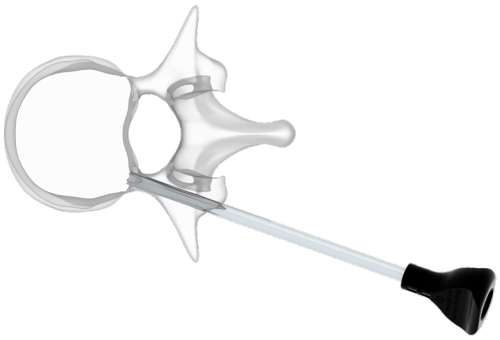
⚠ **WARNING:** Always check with fluoroscopic control when using the Drill.

INSTRUMENT	REFERENCE
DRILL Ø5MM - LARGE	TEK-IN 05 03-S
DRILL Ø4MM - SMALL	TEK-IN 05 02-S
WORKING CANNULA - LARGE	TEK-IN 03 03-S
WORKING CANNULA - SMALL	TEK-IN 03 02-S
BLUNT WIRE Ø2MM	TEK-IN 13 02-S
HANDLE WIRE	TEK-IN 14 02-S

SURGICAL TECHNIQUE

_STEP 8





REMOVING THE DRILL

Disconnect the Drill from the Working cannula. Unscrew and pull as shown to remove the Drill from the vertebra, leaving the Working cannula in place.

The Working Cannula must remain in place, to act as a guide for the other instruments.

PRECAUTION:
Make sure that the Working Cannula goes beyond the posterior wall.

NOTE: Bone fragments on the Drill can be used for biopsy if required.

INSTRUMENT	REFERENCE
DRILL Ø5MM - LARGE	TEK-IN 05 03-S
DRILL Ø4MM - SMALL	TEK-IN 05 02-S
WORKING CANNULA - LARGE	TEK-IN 03 03-S
WORKING CANNULA - SMALL	TEK-IN 03 02-S

_STEP 9 - OPTION

PREPARATION SITE ON THE OPPOSITE SIDE

Repeat Step 1 to Step 8 on the opposite side.

Both sites should be prepared before continuing to Step 10.

_STEP 10

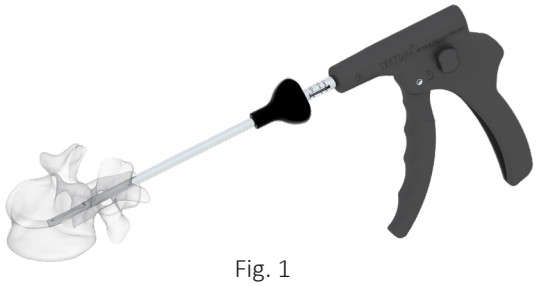


Fig. 1

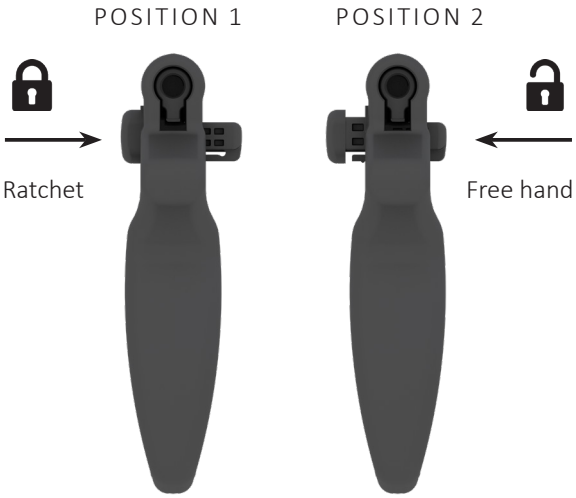
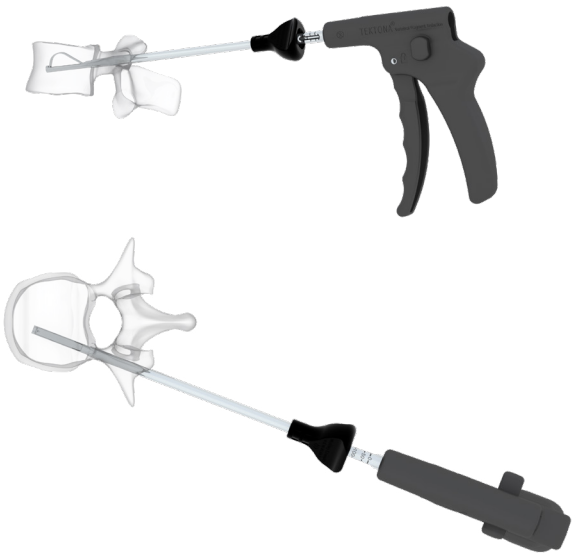


Fig. 2



USING VFR INSTRUMENT

Insert a VFR instrument into the Working cannula (Fig. 1). Engage either ratchet or free hand position to expand the lamella. Start expansion of the Lamella by squeezing the handle (Fig. 2).

Button on the handle activates free hand or ratchet position.

- Pressing the button on the right side engages the free hand position for a tactile feedback.
- Pressing the button on the left side engages the ratchet position.

PRECAUTION:
You should always keep the handle under control while activating or disabling the ratcheting mechanism.

Once the Lamella expanded, the passage from Free hand to Ratchet position is possible to remain in the chosen position.

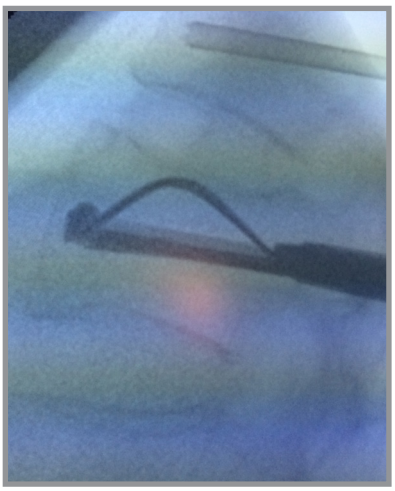
Allow time for bone expansion following each squeeze of the handle.

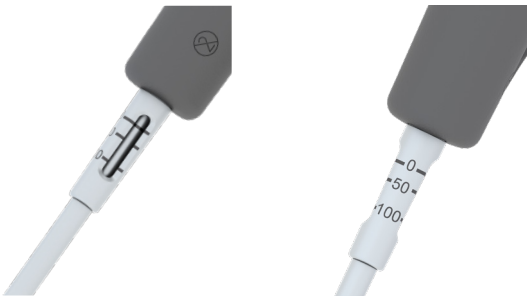
Make sure to come back to neutral position (lamella not expanded) before rotating the VFR instrument.

⚠ **WARNING:** Rotating the VFR instrument in expanded position may damage the instrument and the vertebral body.

NOTE: The expansion plane of the Lamella is in the same plane as the VFR instrument handle.

INSTRUMENT	REFERENCE
VERTEBRAL FRAGMENT REDUCTION INSTRUMENT - SMALL	TEK-IN 02 03-S
VERTEBRAL FRAGMENT REDUCTION INSTRUMENT – LARGE	TEK-IN 02 02-S
WORKING CANNULA - LARGE	TEK-IN 03 03-S
WORKING CANNULA - SMALL	TEK-IN 03 02-S





NOTE: The graduation on the side of the instrument informs on the percentage of the lamella expansion.

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

_STEP 11

Fig. 1

Fig. 2

REMOVING THE VFR INSTRUMENT

Once the desired expansion has been achieved, come back to neutral position.
Check that the button is in Free hand position.
Use fluoroscopy to make sure that the Lamella is in its original position, not expanded. (Fig. 1)
Remove the VFR instrument from the Working cannula. (Fig. 2)

PRECAUTION: If the Lamella does not return to its original position and safe removal of the VFR instrument is not possible, use the removal handle to disassemble the VFR instrument. See rescue solution p.25.

⚠ **WARNING:** Do Not Re-assemble the Instrument once diassembled.

INSTRUMENT	REFERENCE
VERTEBRAL FRAGMENT REDUCTION INSTRUMENT - SMALL	TEK-IN 02 03-S
VERTEBRAL FRAGMENT REDUCTION INSTRUMENT – LARGE	TEK-IN 02 02-S
WORKING CANNULA - LARGE	TEK-IN 03 03-S
WORKING CANNULA - SMALL	TEK-IN 03 02-S

_STEP 12

CEMENT PREPARATION

TEKTONA® is used in combination with bone cement marketed for vertebroplasty or kyphoplasty procedures. Spineart recommends the use of TEKTONA® HV Bone cement which has been specifically tested with TEKTONA®.

1

1 Hold the device in one hand through the ampoule handle and strike it against the palm of the other hand 5-6 times to unpack the powder.

2

2 Place the device on a flat surface. Press the push-knob to break the ampoule containing the monomer.

3

3 Transfer the liquid by pulling up and then pushing down the push-knob. Repeat the cycle until complete transfer in the mixing chamber. If the device is locked after breaking the ampoule, unscrew the push-knob to ensure mobility of the device and enable liquid transfer.

INSTRUMENT	REFERENCE
TEKTONA HV BONE CEMENT	TEK-BC HV 00-S

SURGICAL TECHNIQUE

4

4 Screw clockwise push-knob to lock the device (half a turn).

5

5 Turn the device and place it on a flat surface. Start mixing by pushing and pulling the mixing knob and simultaneously turn the mixing knob in both directions for about 1 minute.

⚠ **WARNING :** do not turn the mixing knob while the mixing rod is in the position of maximum excursion, this could cause premature rod removal.

6

6 At the end of the mixing phase, remove the rod by bringing it to the position of maximum excursion. Then, screw the rod counterclockwise.

7

7 Remove the air from the mixing chamber. Hold the device upright, screw the push-knob slowly into the threaded section and push it slowly into the non-threaded section.

INSTRUMENT	REFERENCE
TEKTONA HV BONE CEMENT	TEK-BC HV 00-S

_STEP 13

FILLING THE CEMENT FILLER

Connect the device to a cement filler through the luer-lock connection using the male-male connector.

Transfer the cement from the device to the cement fillers. All cement fillers used for the procedure need to be filled.

NOTE: Small Cement Filler contains 2cc and Large Cement Filler contains 2.5cc

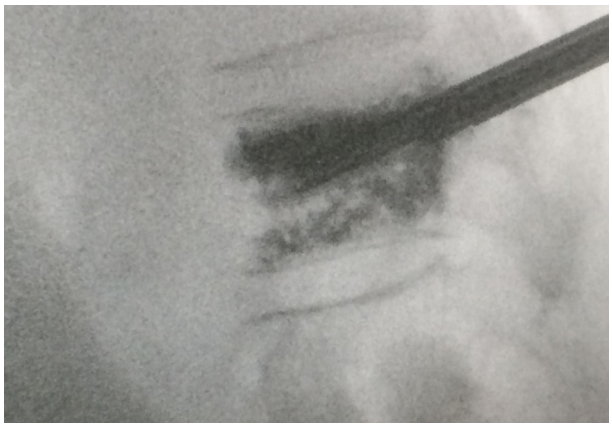
INSTRUMENT	REFERENCE
TEKTONA HV BONE CEMENT	TEK-BC HV 00-S
CEMENT FILLER - LARGE	TEK-IN 07 04-S
CEMENT FILLER - SMALL	TEK-IN 07-03 S
WORKING CANNULA - LARGE	TEK-IN 03 03-S
WORKING CANNULA - SMALL	TEK-IN 03 02-S

_STEP 14

INJECTION

Use the Cement filler to inject the cement into the vertebral body. Check the cement viscosity is optimal for delivery before injection into the vertebra.

Insert one Cement filler into the Working cannula and push the plunger to inject the cement.



Each laser mark corresponds to 0.5cc of cement.

⚠ **WARNING:** Always use fluoroscopy to control cement flow during the delivery.

After injecting the cement through the Cement filler, remove the Cement filler and the Working cannula. Rotating the Cement filler before its retrieval may help to prevent the cement from flowing backwards.

⚠ **WARNING:** Both VFR instruments and cement fillers shall be removed before the cement hardens.

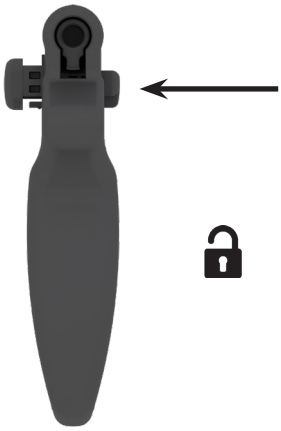
A final fluoroscopic control can be performed at this stage.

INSTRUMENT	REFERENCE
TEKTONA HV BONE CEMENT	TEK-BC HV 00-S
CEMENT FILLER - LARGE	TEK-IN 07 04-S
CEMENT FILLER - SMALL	TEK-IN 07-03 S
WORKING CANNULA - LARGE	TEK-IN 03 03-S
WORKING CANNULA - SMALL	TEK-IN 03 02-S

SURGICAL TECHNIQUE

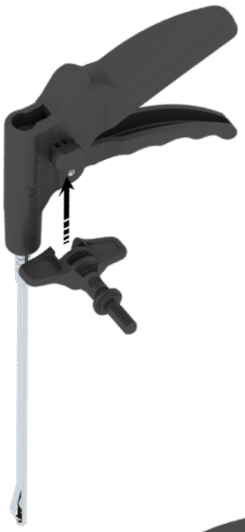
The following steps are useful if the Lamella does not return to its original position and safe removal of the VFR instrument is not possible.

_OPTION RESCUE SOLUTION



STEP 1

Press the button on the right side to engage the free hand position.



STEP 2

Connect the removal handle to the button on the left side (from down to up) in surgical conditions.

STEP 3

Push the handle from down to up while pulling out the removing handle with the button.

SURGICAL TECHNIQUE

STEP 4

Insert the removal handle into the back of the VFR instrument by screwing it until we cannot screw anymore.

PRECAUTION: Do not squeeze the VFR Instrument handle while screwing the removal handle.

STEP 5

Pull out the removal handle connected to the pusher to extract from the VFR completly.

STEP 6

Remove the VFR instrument from the vertebral body.

⚠ **WARNING:** Do not reassemble the VFR instrument once disassembeled.

REFERENCE OF THE IFU	TEK-IF VF ST-E	REVISION OF THE FINAL IFU	OCT-2019

_STERILITY

The TEKTONA® system comprises sterile single-use devices only.
Reprocessing of single use devices is strictly forbidden and would expose the patient to risks of serious health deterioration. Re-use of a single use device does not make it possible to ensure structural integrity nor achievement of the assigned performances over time and may result in premature rupture. Such re-use may also result in infection in the patient.
If sterile devices or their packaging seems to be damaged, if the expiry date is exceeded or in the event that sterility cannot be guaranteed, the device shall not be used.
The Vertebral Fragment Reduction instrument is delivered sterile.
Please refer to the individual package labeling.

_DESCRIPTION

The TEKTONA® system was designed to assist in the reduction of vertebral body fractures in a percutaneous surgical approach. It is used in combination with bone cement marketed for vertebroplasty or kyphoplasty procedures. The TEKTONA® system comprises a flexible lamella (Nickel-Titanium) that can be expanded by the action of a Vertebral Fragment Reduction instrument (VFR instrument). The VFR instrument has a ratchet mechanism that can maintain the shape of the lamella during the fracture reduction procedure. The TEKTONA® system comprises a cement filler device (cannula) with a standard luer-lock connection. Specific information is indelibly marked on the devices.

_INDICATIONS

The TEKTONA® system is indicated to treat moderate to severe pain caused by vertebral body compression fractures (VCF) located between T7 and L5, secondary to osteopenia, multiple myeloma and/or trauma, and presenting kyphotic deformities and risk of progressive vertebral height loss.

_CONTRAINDICATIONS

- Inadequate pedicle dimension affecting safe passage of the instrumentation;
- Instability of posterior wall and/or pedicles;
- Consolidated fractures ;
- Fractures of B or C according to Magerl classification;
- Vertebral compression fracture with neurological disorder;
- Need for spinal decompression;
- Systemic and/or spinal infections;
- Known allergies to bone cement material and/or nickel-titanium;
- Cardiovascular disease which is not controlled by the treatment;
- Patient at risk with a spontaneous or therapeutical coagulation trouble that cannot be treated;
- Pregnancy or breast-feeding female;

We recommend to check if the treated fracture is considered as fresh and not consolidated. Consolidated fracture could limit the efficacy of the Tektona system in repositioning interbody bone fragments.

_SIDE EFFECTS

Perioperative:

Symptomatic cement leak, hemostatic problems, neurologic and/or vascular injury.

Postoperative:

Secondary fracture, pulmonary embolism, neurological disorder, cardiovascular or vascular disorder, lymphatic disorders, deep infection.

Serious adverse device effects:

Secondary fracture, symptomatic cement leak, pulmonary embolism, motor loss, epidural hematoma.

_WARNINGS

Because this is a technically demanding procedure presenting a risk of serious injury to the patient, only experienced surgeons with adequate training should perform this procedure. Every surgeon who uses TEKTONA® must take each patient's clinical state and medical status into consideration and be fully familiar with procedures involving the use of this type of

instrumentation and the potential complications in each case. Abnormal use of the device may lead to risks of serious injury, health deterioration of the patient.

The performance and safety of TEKTONA® was not yet confirmed for treatments of more than two adjacent levels, or for fractures of A2, A3.2 or A3.3 according to Magerl classification. Clinical experience of TEKTONA in combination with bone cements specifications other than those of TEKTONA HV Bone Cement or Mendec Spine HV System (TECRES Medical, Verona, Italy) is limited.

The benefits of this surgical procedure may not meet the patient's expectations, possibly requiring more surgery. Patients undergoing this surgical procedure shall, therefore, be informed.

_SURGERY METHODS

The surgeon is responsible for familiarizing him/herself with the surgical technique, by studying the relevant published articles, consulting experienced colleagues, and receiving training in the surgical technique.

Precautions: Preoperative planning by magnetic resonance imaging (MRI) and/or computed tomography (CT) are required to assess the fragmentation of the fracture, as well as to verify suitable dimensions of the vertebral body and pedicle, and the integrity of the vertebral body posterior wall. The pedicle shall allow passage of the working cannula (Size Small: diameter 4.8mm or Size Large: diameter 5.6mm) and the integrity of the posterior wall of the vertebral body shall be confirmed.

The patient shall be placed in a prone and hyper-lordotic position. Fluoroscopic monitoring is required to control the safe trajectory, operation and removal of the instrumentation.

If needed, two vertebral fragment reduction instruments are used to achieve effective reduction of the fracture.

Always use fluoroscopy to control cement flow during the delivery. Injection of the cement may only be executed after removal of the VFR instruments from the body. Always check with fluoroscopic control when using the Drill.

Your local representative should have communicated the handbook describing the surgical technique. In any case, the handbook is readily available by contacting either your local representative or directly Spineart®.

_HANDLING PRECAUTIONS

No effort has been spared to ensure that only the highest-quality materials and expertise have been deployed in producing the instrumentation.

Prior to usage, the surgeon shall verify the proper functioning of the VFR instrument and the intended behavior of the lamella.

If required, the lamella may be extracted by connecting the removal handle to the VFR instrument and pulling it out of the instrument. This may happen if morsels of bone are preventing the lamella to collapse.

_STORAGE CONDITION

It is mandatory that sterile-delivered devices are stored in their original packaging, in a clean, dry location under normal conditions.

_FURTHER INFORMATION

If further directions for use of this system are needed, please check with the Spineart® Customer Service. If further information is needed or required, please see the addresses on this document.

N O T E

N O T E

S P I N E A R T

CE 1984

TEKTONA VERTEBRAL FRAGMENT
REDUCTION SYSTEM :
SPINEART SA
CHEMIN DU PRÉ-FLEURI 3
1228 PLAN-LES-OUATES
SWITZERLAND

CE 0086

TEKTONA HV BONE CEMENT :
MANUFACTURED BY :
TECRES S.P.A.
VIA A. DORIA, 6 - SOMMACAMPAGNA
VERONA (ITALY)

NOV-2019 - REF.:TEK-BR 02 31-E