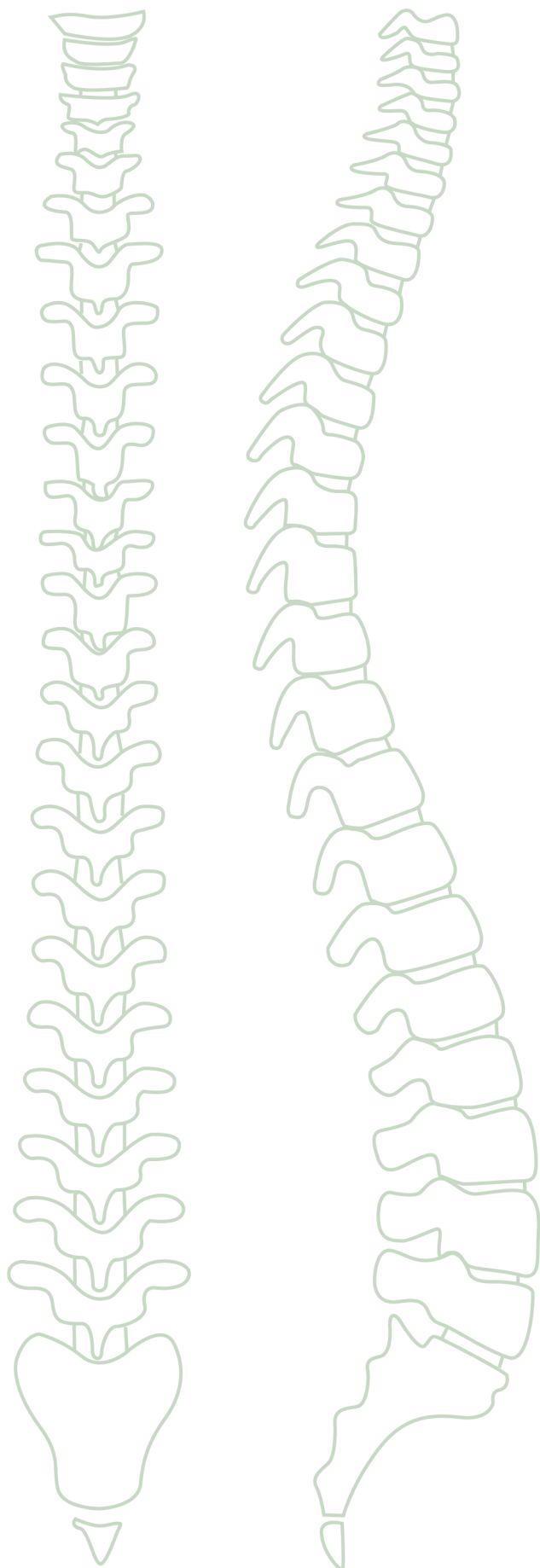




SPINE CATALOGUE



BFBTM
m e d i c a

KYPHOPLASTY

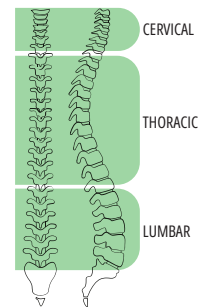
Kyphoplasty is a minimally invasive surgical procedure used to treat vertebral compression fractures (VCFs), often caused by osteoporosis, trauma, or tumors.

The procedure involves inserting a specialized balloon catheter into the fractured vertebra through a small incision. The balloon is then inflated to potentially restore vertebral height and create a confined cavity, which is subsequently filled with biocompatible bone cement to stabilize the spine and relieve pain.

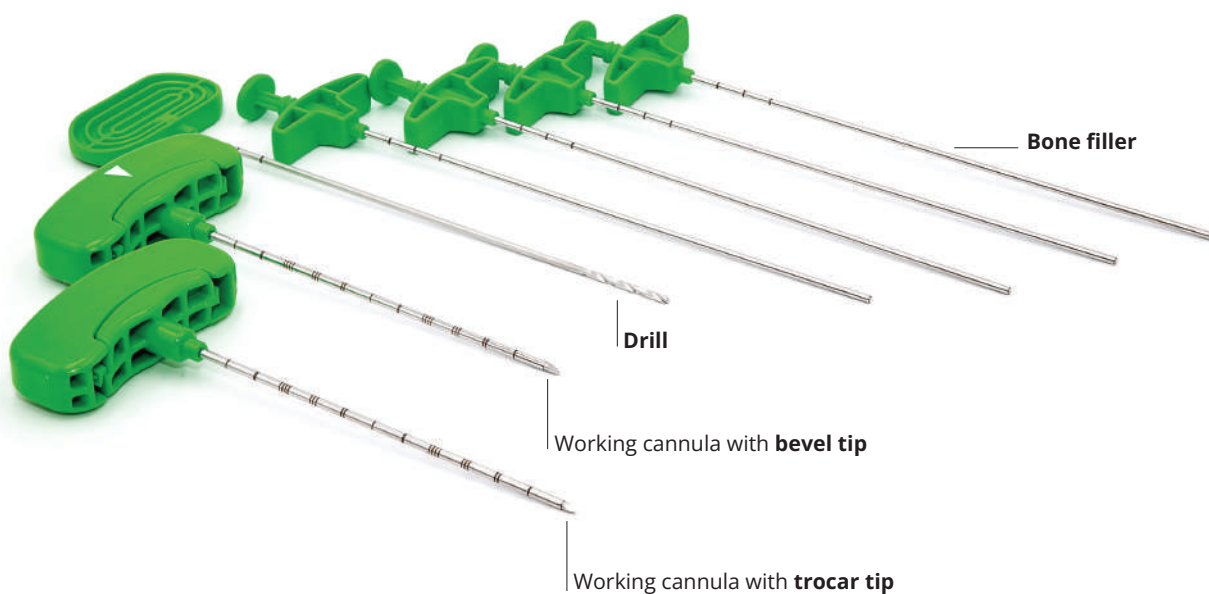
Kyphoplasty potentially helps to improve spinal alignment, reduce deformity, and enhances patient mobility with minimal recovery time.

RENOVA SPINE™

RENOVA SPINE™ is a minimally invasive system to treat fractures, restore vertebral body height and reduce back pain. A vertebral compression fracture (VCF) occurs when the vertebral body fractures and collapses due to osteoporotic conditions, tumours (eg. myeloma) or trauma. After inserting and inflating the balloon catheter into the cavity, the initial anatomical vertebral body condition can be restored. The balloon catheter is then deflated and the cavity created is now filled with bone cement avoiding any leakage.



KYPHOPLASTY FAST APPROACH KIT 13G



Analog inflation device



Digital inflation device



Balloon



2,5 ml Syringes

Ultimate **minimally invasive** solution.

Fast approach: direct percutaneous vertebral access and reduced number of surgical steps.

A **single treatment solution** from the cervical to the lumbar vertebrae.

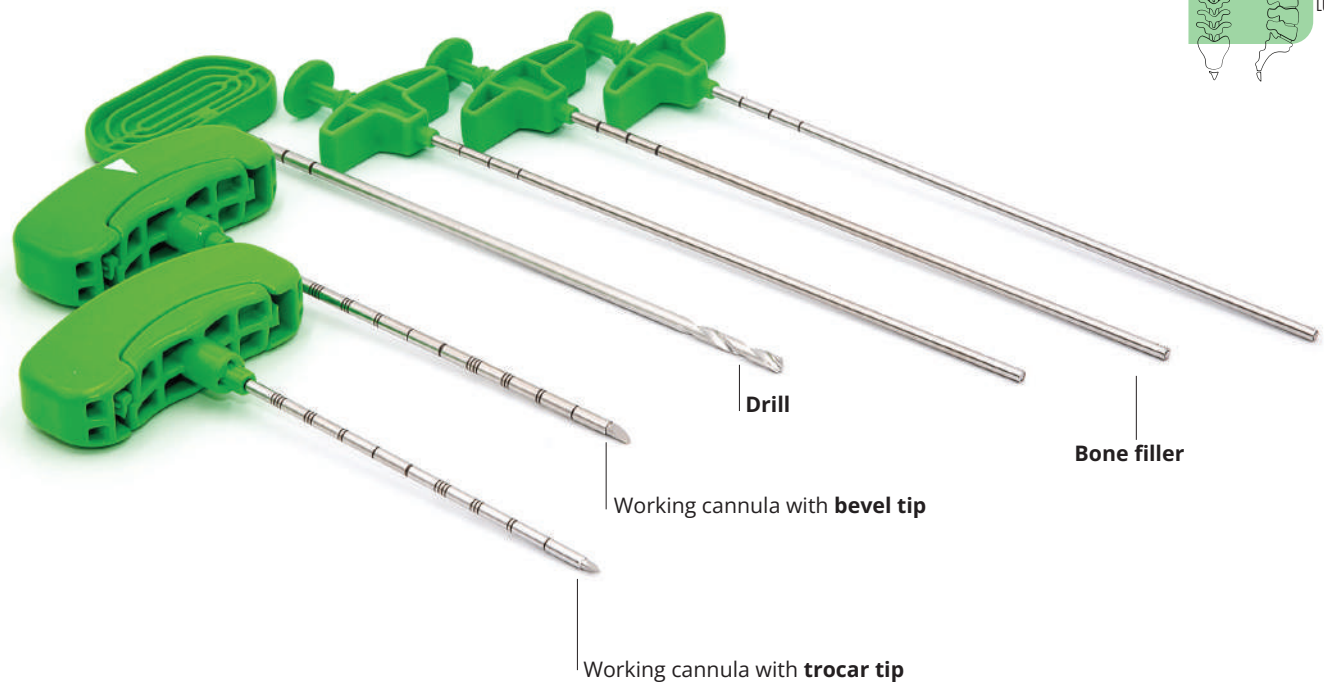
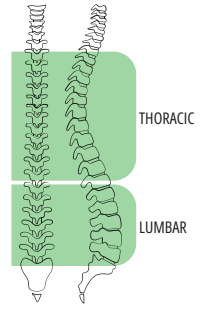
13G balloon catheter inflation up to 400 PSI.

Reduction of back pain.

Fast recovery after treatment.

Cement injection cannulas (bone fillers) included in the kit are compatible with low and medium viscosity cement. With high viscosity cement, EASYNJECT™ is recommended.

KYPHOPLASTY FAST APPROACH KIT 11G



Analog inflation device



Digital inflation device



Balloon



2,5 ml Syringes

Minimally invasive solution.

Reduced profile of cannula and balloon catheter.

Fast approach: direct percutaneous vertebral access and reduced number of surgical steps.

From lower thoracic to lumbar vertebrae.

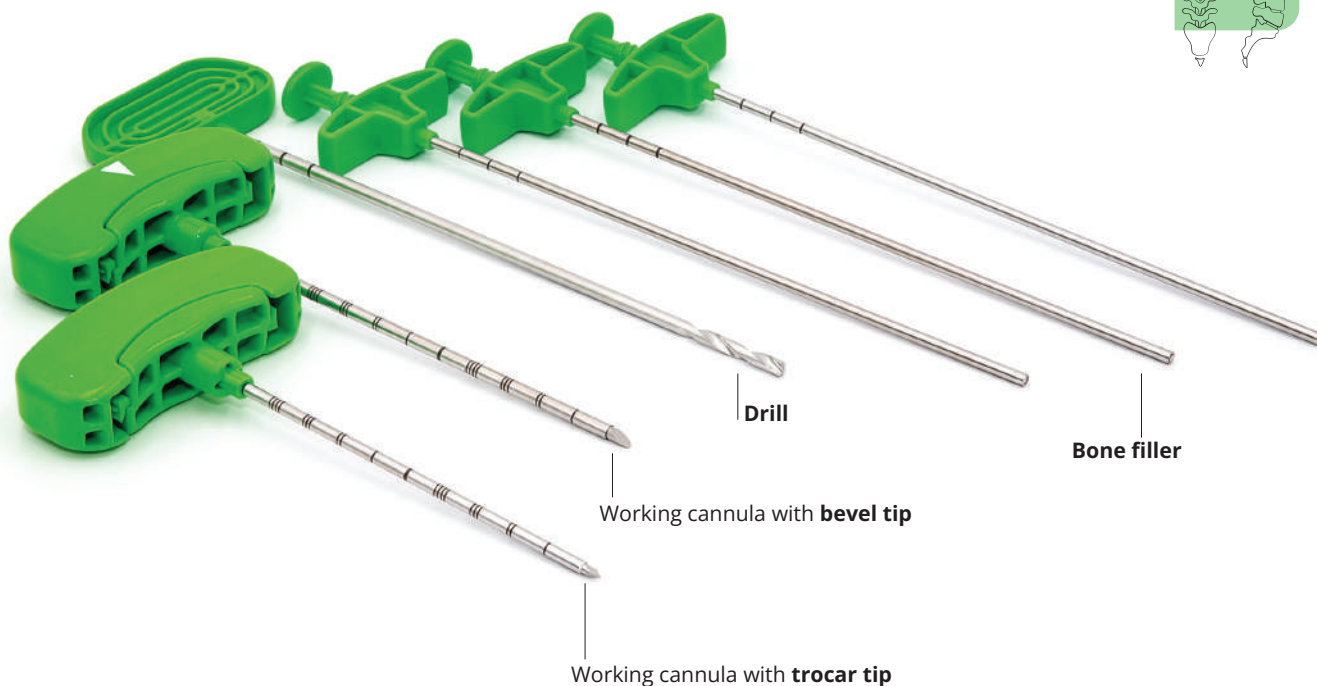
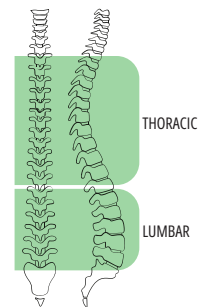
Reduction of back pain.

Fast recovery after treatment.

Cement injection cannulas (bone fillers) in the kit are compatible with low and medium-viscosity cement. With high-viscosity cement, EASYNJECT™ is recommended.

KYPHOPLASTY FAST APPROACH KIT 10G

AVAILABLE IN THE USA ONLY



Digital inflation device



Balloon



2,5 ml Syringes

Hammerable ergonomic handle with special locking system.

Reduced size of the handle for more comfortable use.

Working cannula with two stylets: the operator can choose between bevel or trocar tip.

Digital inflation device available.

Digital inflation device with a 50 cm long tube for fewer X-ray exposure.

Balloon catheter available in three different sizes: 10 mm, 15 mm, 20 mm.

Tools kit with six bone fillers included for a more accurate cement injection.

Surgical technique: FAST APPROACH (valid for 13G,11G and 10G):

Approach & Initial Access

- + The approach can be extrapedicular or transpedicular.
- + Under fluoroscopy, insert the fast-working cannula into the vertebral body until firmly placed (~3mm depth).
- + Hold the cannula in place, remove the stylet, and leave the working cannula in position.

Creating the Pathway

- + Insert the drill through the working cannula and into the vertebral body.
- + Rotate 180° clockwise and counterclockwise to create a pathway for the balloon, then remove the drill.

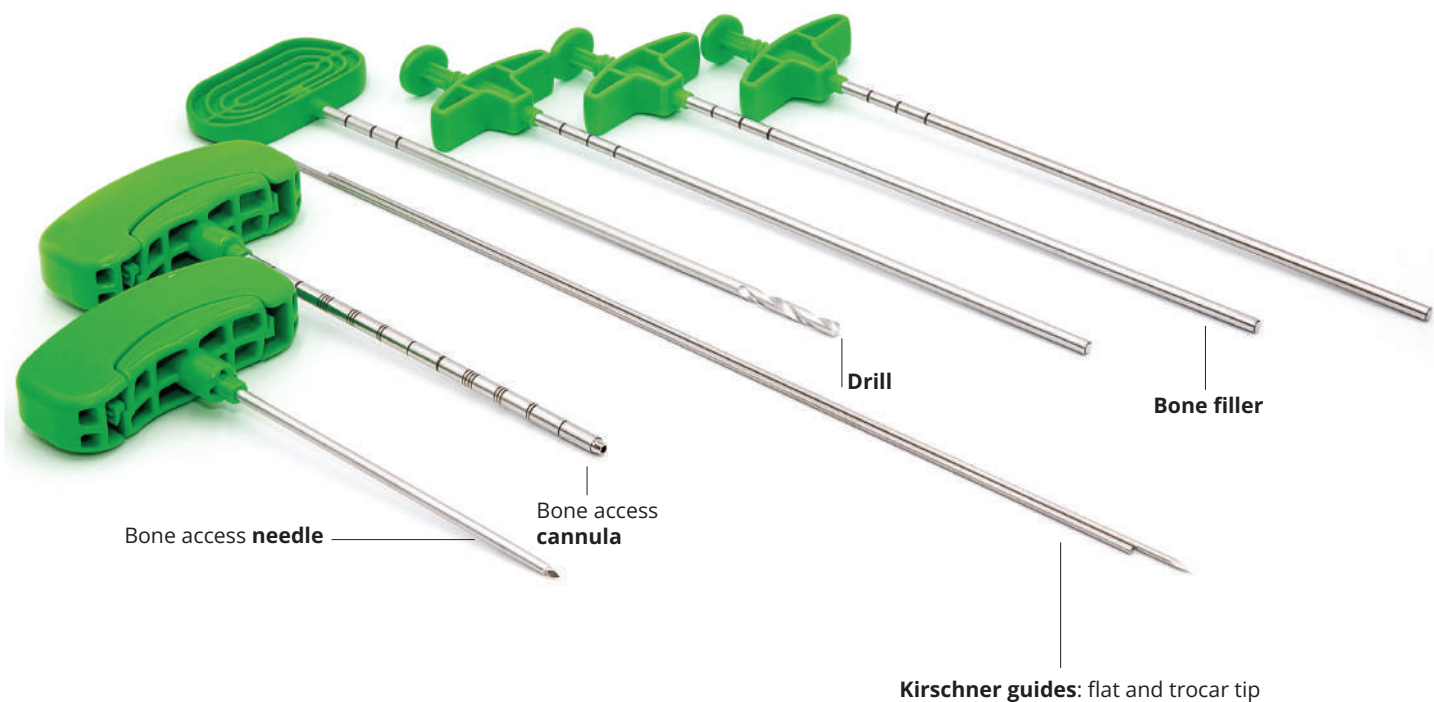
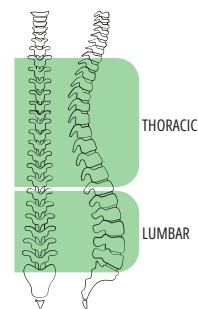
Balloon Inflation

- + Connect the balloon catheter to a preloaded inflation system (contrast medium-to-saline ratio: 1:2).
- + Under fluoroscopic guidance, insert the balloon catheter through the working cannula and position it correctly (AP & lateral view).
- + Inflate the balloon to the desired volume or maximum measurable pressure, then fully deflate by unscrewing the handle of the inflating device..
- + Remove the deflated balloon catheter.

Cement Preparation & Injection

- + While inflating the balloon, begin cement preparation, if necessary.
- + Load Luer-lock syringes with bone cement and transfer it into a bone filler.
- + Inject cement through the working cannula, using a plunger for controlled delivery.
- + Once the cement is placed, remove the bone filler, reinsert the stylet, and carefully extract the working cannula.

KYPHOPLASTY CLASSIC APPROACH KIT 8G



Analog inflation device



Digital inflation device



Balloon



2,5 ml Syringes

Surgical technique: CLASSIC APPROACH (valid for 8G):

Approach & Initial Access

- + The approach can be extrapedicular or transpedicular.
- + Insert the bone access needle, then remove its stylet.
- + Under fluoroscopy, insert the Kirschner wire through the needle's cannula, positioning its tip ~5mm from the anterior vertebral wall (lateral view).
- + Remove the bone access needle, leaving the guide wire in place.
- + Insert the funnel-shaped working cannula & expander, allowing the guide wire to slide inside.
- + Hold the working cannula in place and carefully remove the guide wire.
- + Extract the inner funnel-shaped cannula, leaving only the outer working cannula inside the patient.

Creating the Pathway

- + Insert the drill through the working cannula and into the vertebral body.
- + Rotate 180° clockwise and counterclockwise to create a pathway for the balloon, then remove the drill.

Balloon Inflation

- + Connect the balloon catheter to a preloaded inflation system (contrast medium-to-saline ratio: 1:2).
- + Under fluoroscopic guidance, insert the balloon catheter through the working cannula and position it correctly (AP & lateral view).
- + Inflate the balloon to the desired volume or maximum measurable pressure, then fully deflate by unscrewing the handle of the inflation device.
- + Remove the deflated balloon catheter.

Cement Preparation & Injection

- + While inflating the balloon, begin cement preparation, if necessary.
- + Load Luer-lock syringes with bone cement and transfer it into a bone filler.
- + Inject cement through the working cannula, using a plunger for controlled delivery.
- + Once the cement is placed, remove the bone filler, reinsert the stylet, and carefully extract the working cannula.

ORDER GUIDE - RENOVA SPINE™

Single components can be ordered à la carte.

PROCEDURE	TOOLS	SINGLE COMPONENTS CODES	KIT FOR MONOLATERAL APPROACH	KIT FOR BILATERAL APPROACH
13G	RENOVA SPINE™ kyphoplasty working cannula and bevel tip	RESWB1312C	1	1
	RENOVA SPINE™ kyphoplasty working cannula and trocar tip	RESWTR1312C	-	1
	RENOVA SPINE™ kyphoplasty drill	RESDRI1312C	1	1
	RENOVA SPINE™ balloon catheter	10 mm: RESB10MC 15 mm: RESB15MC 20 mm: RESB20MC	1	2
	RENOVA SPINE™ bone filler	RESFIL1312C1	4	6
	Syringes (2,5 ml)	SI02.5L/L-A	4	4
	Inflation device: digital or analog	Digital: K05-03069 Analog: INFLA30	1	2
11G	RENOVA SPINE™ kyphoplasty working cannula and bevel tip	RESWB1112C	1	1
	RENOVA SPINE™ kyphoplasty working cannula and trocar tip	RESWTR1112C	-	1
	RENOVA SPINE™ kyphoplasty drill	RESDRI1112C	1	1
	RENOVA SPINE™ balloon catheter	10 mm: RESB10PM – RESB10J 15 mm: RESB15PM – RESB15J 20 mm: RESB20PM – RESB20J	1	2
	RENOVA SPINE™ bone filler	RESFIL1112C1	3	6
	Syringes (2,5 ml)	SI02.5L/L-A	4	4
	Inflation device: digital or analog	Digital: K05-03069 Analog: INFLA30	1	2

PROCEDURE	TOOLS	SINGLE COMPONENTS CODES	KIT FOR MONOLATERAL APPROACH	KIT FOR BILATERAL APPROACH
8G	RENOVA SPINE™ kyphoplasty bone access needle	RESOB1110T	1	2
	RENOVA SPINE™ Kyphoplasty working cannula and expander	RESWT0812C	1	2
	RENOVA SPINE™ kyphoplasty Kirschner guide trocar tip	RESFG1128T	1	2
	RENOVA SPINE™ kyphoplasty Kirschner guide flat tip	RESFG1128P	1	2
	RENOVA SPINE™ kyphoplasty drill	RESDRI0812C	1	1
	RENOVA SPINE™ balloon catheter	10 mm: RESB10PM – RESB10J 15 mm: RESB15PM – RESB15J 20 mm: RESB20PM – RESB20J	1	2
	RENOVA SPINE™ bone filler	RESFIL0812C1	3	6
	Syringes (2,5 ml)	SI02.5L/L-A	4	4
	Inflation device: digital or analog	Digital: K05-03069 Analog: INFLA30	1	2

AVAILABLE ONLY FOR THE USA:

10G	RENOVA SPINE™ kyphoplasty working cannula and bevel/trocar tip	RESWBTR1112C-US	1	n.a.
	RENOVA SPINE™ kyphoplasty drill	RESDRI1112C-US	1	n.a.
	RENOVA SPINE™ balloon catheter	10 mm: RESB10PM – RESB10J 15 mm: RESB15PM – RESB15J 20 mm: RESB20PM – RESB20J	1	n.a.
	RENOVA SPINE™ bone filler	RESFIL1112C1-US	3	n.a.
	Syringes (2,5 ml)	SI02.5L/L-A	4	n.a.
	Inflation device: digital	Digital: K05-03069	1	n.a.

VERTEBROPLASTY

Vertebroplasty is a minimally invasive procedure used to treat vertebral compression fractures (VCFs) caused by osteoporosis, trauma, or tumors.

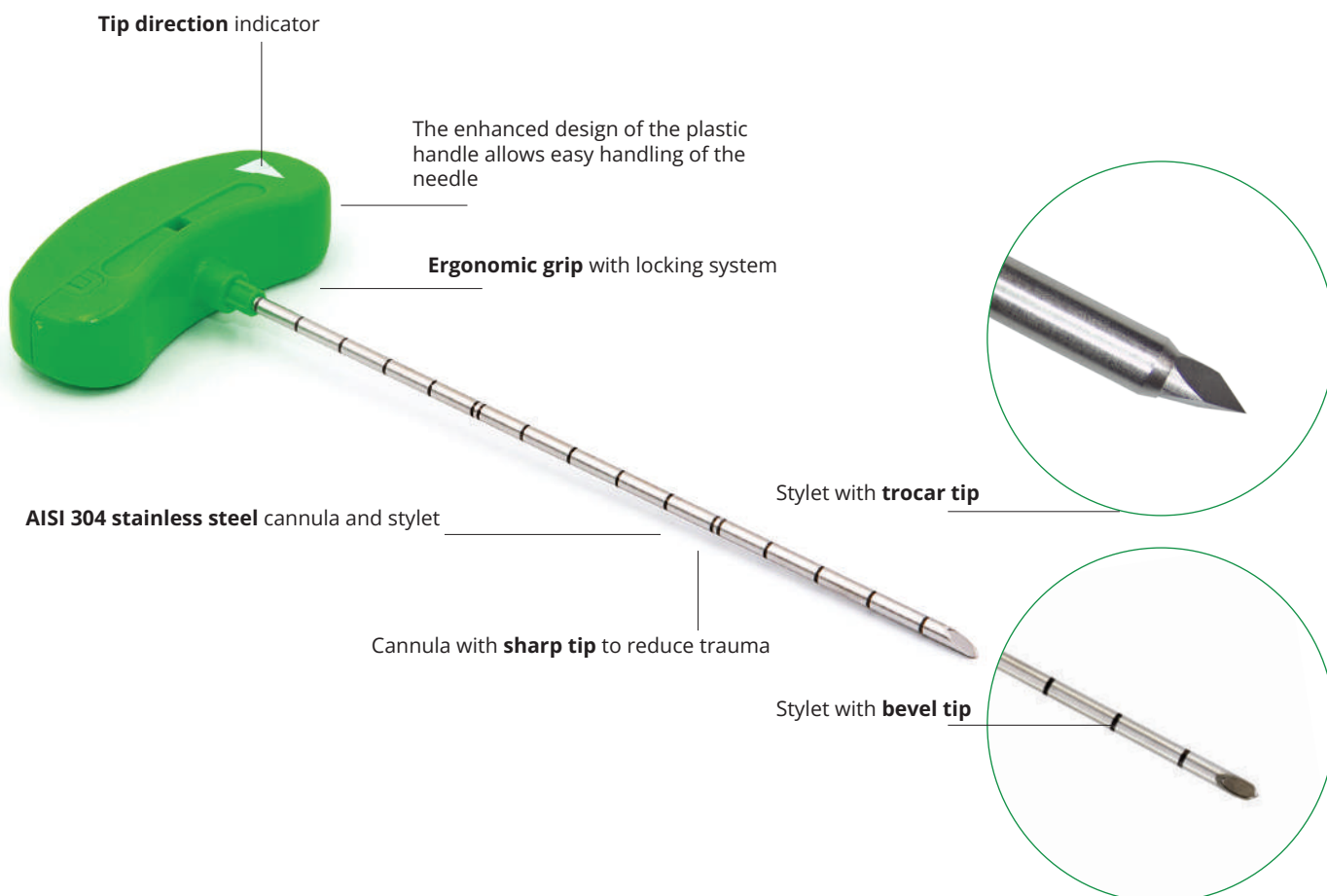
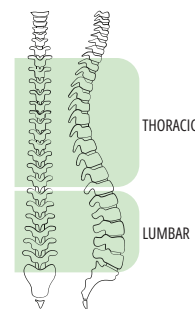
Through a small incision, a needle is guided into the fractured vertebra under imaging guidance, and biocompatible bone cement is directly injected to stabilize the bone, reduce pain, and prevent further collapse.

Unlike kyphoplasty, vertebroplasty does not involve balloon inflation to potentially restore height but effectively reinforces the vertebra, providing rapid pain relief and improved spinal stability.

VERTEBROPLASTIC™

VERTEBROPLASTY NEEDLE – PLASTIC HANDLE

VERTEBROPLASTIC™ is used in Vertebroplasty procedures to inject cement into the vertebral body. Vertebroplasty is a very well-established technique for treating back pain caused by severe osteoporosis or tumours with consequent loss of height or fracture of the vertebral body. A coaxial biopsy can also be performed.



Surgical technique:

- + Under fluoroscopic guidance, **identify the entry point and advance the needle through soft tissue** until it touches the vertebral bone surface.
- + Apply controlled pressure and rotational movements to penetrate the bone, **adjusting the needle's direction under AP and lateral fluoroscopic control**. Light hammer strokes may be used if necessary.
- + **Ensure the needle tip reaches the desired target**, checking depth and positioning continuously.
- + Under lateral fluoroscopic view, **advance the cannula tip to the anterior half of the vertebral body**, ensuring correct placement before PMMA injection. Advance the tip of the cannula until it reaches the anterior half of the vertebral body.
- + **Prepare the bone cement with the CEMIX™ cement mixer.**
- + **Inject the cement connecting the EASYNJECT™ cement delivery system to the VERTEBROPLASTIC™ device.**

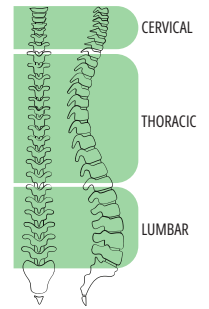
ORDER GUIDE - VERTEBROPLASTIC™

GAUGE	DIAMETER (mm)	LENGTH	BEVEL TIP CODES	TROCAR TIP CODES
11G	3,00	100 mm 120 mm 150 mm	KRVT1110200CBP-A KRVT1112200CBP-A KRVT1115200CBP-A	KRVT1110200CT-A KRVT1112200CT-A KRVT1115200CT-A
13G	2,50	100 mm 120 mm 150 mm	KRVT1310200CBP-A KRVT1312200CBP-A KRVT1315200CBP-A	KRVT1310200CT-A KRVT1312200CT-A KRVT1315200CT-A
15G	1,80	100 mm 120 mm 150 mm	KRVT1510200CBP-A KRVT1512200CBP-A KRVT1515200CBP-A	KRVT1510200CT-A KRVT1512200CT-A KRVT1515200CT-A

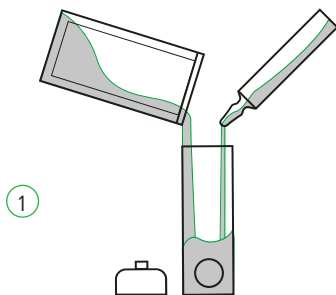
CEMIX™

CEMENT MIXING SYSTEM

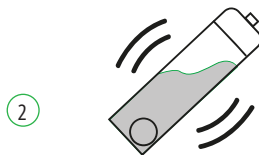
CEMIX™ is a disposable, single-use device, indicated for optimal and homogeneous mixing of PMMA. Thanks to its small size, CEMIX™ can be refrigerated to extend PMMA working time. CEMIX™ is a completely closed system with zero emissions during PMMA handling, beneficial for both patient and OR staff. CEMIX™ can be used both in vertebroplasty and kyphoplasty treatments.



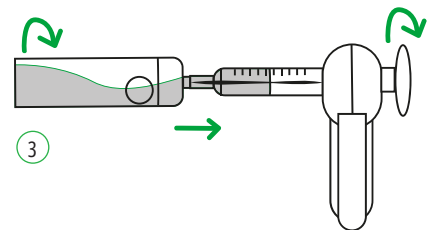
Surgical technique:



1 Unscrew the superior cap of CEMIX™ and place the container in an upright position. Add the powder first, followed by the liquid.



2 Securely close CEMIX™ and mix for 10-20 seconds, adjusting based on room temperature.



3 Invert CEMIX™ (cap facing downward) and draw the cement into standard Luer-lock syringes or to suitable injection systems (EASYNJECT™).

ORDER GUIDE - CEMIX™

CODE: KVTMIXN

VERTEBRAL BIOPSY

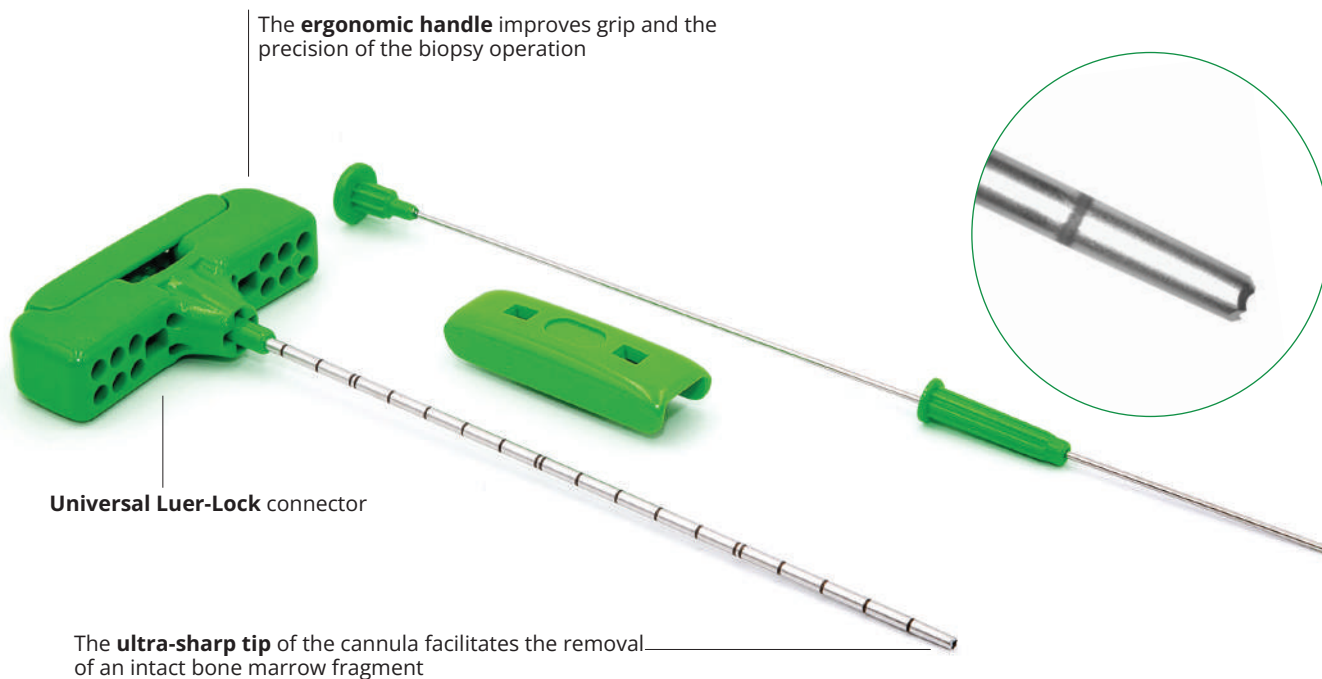
Vertebral biopsy is a minimally invasive procedure performed to obtain a tissue sample from a vertebral body for diagnostic purposes.

It is typically indicated when imaging studies reveal suspicious lesions, tumors, infections (such as osteomyelitis), or unexplained fractures, helping to differentiate between benign and malignant conditions.

The biopsy can be performed using a fine needle (cytological biopsy), which collects cells for microscopic analysis, or a core needle (histological biopsy), which retrieves a larger tissue sample for detailed structural examination. Histological biopsy provides more comprehensive information on tissue architecture, while cytological biopsy is useful for rapid cellular assessment.

VERTEBRAL BIOPSY NEEDLE OPTION 2

For **kyphoplasty and vertebroplasty procedures**



Surgical technique:

- + **Create a working channel** using the kyphoplasty or vertebroplasty tools.
- + **Insert the biopsy needle** (consisting of an external cannula and an internal stylet with a cutting wire) into the working channel, ensuring it extends 2 cm beyond its tip.
- + **Rotate the entire VERTEBRAL BIOPSY NEEDLE 360° twice** to cut the tissue sample internally without dislocating or damaging it.
- + **Remove the system** from the working channel.
- + **Extract the internal stylet with the cutting wire**, and use the finger-protection device and extractor from the opposite side of the handle to deposit the sample.

ORDER GUIDE - VERTEBRAL BIOPSY NEEDLE OPTION 2™

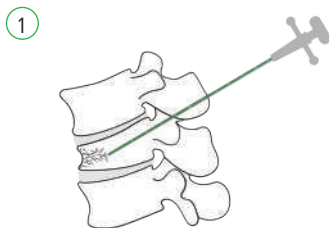
CODES:

RESFU1118.5CD (for kyphoplasty)

RESFU1517C (for vertebroplasty - length 17 cm)

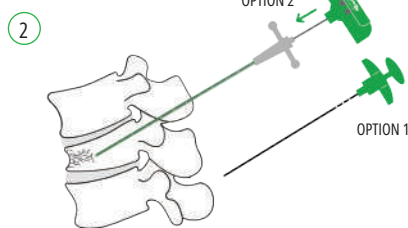
RESFU1520C (for vertebroplasty - length 20 cm)

VERTEBRAL BIOPSY – Complete Surgical Technique



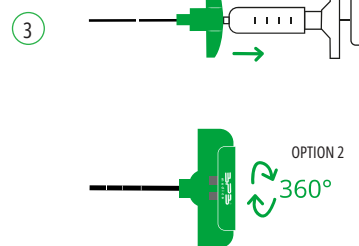
PREPARE THE WORKING CHANNEL

Start by creating a stable working channel using the instruments provided in the RENOVA SPINE™ or vertebroplasty kit.



INTRODUCE THE BIOPSY NEEDLE

Insert the VERTEBRAL BIOPSY DEVICE (Option 1 or 2) into the working channel. Ensure precise positioning at the targeted biopsy location, always under fluoroscopic guidance.



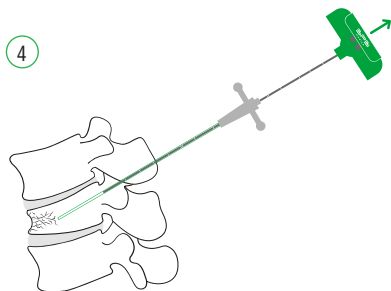
PERFORM THE BIOPSY

OPTION 1

ASPIRATION METHOD: Once the biopsy site is reached with Device Option 1, attach a syringe to the Luer Lock connector and perform an aspiration to collect the tissue sample.

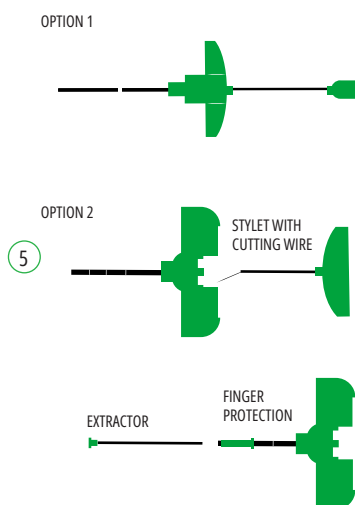
OPTION 2

ROTATIONAL CUTTING: With Device Option 2, rotate the needle 360° twice to internally cut and isolate the tissue sample. This technique avoids displacement or trauma to surrounding structures.



REMOVE THE SYSTEM

For both options, carefully withdraw the entire biopsy system from the working channel, maintaining the integrity of the sample during removal.



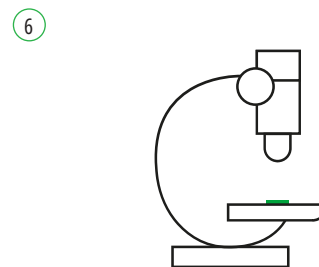
SAMPLE EXTRACTION

OPTION 1

Insert the Extractor from the grip side to push out the sample and place it onto a slide or container for analysis

OPTION 2

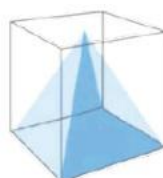
First, extract the internal stylet with cutting wire. Then, insert the finger protection device and the Extractor from the opposite side of the sample to safely retrieve the sample.



FINAL CHECKS AND SAMPLE HANDLING

Ensure that the sample is properly collected and preserved for histological examination. It is now possible to continue with kyphoplasty or vertebroplasty operations.

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