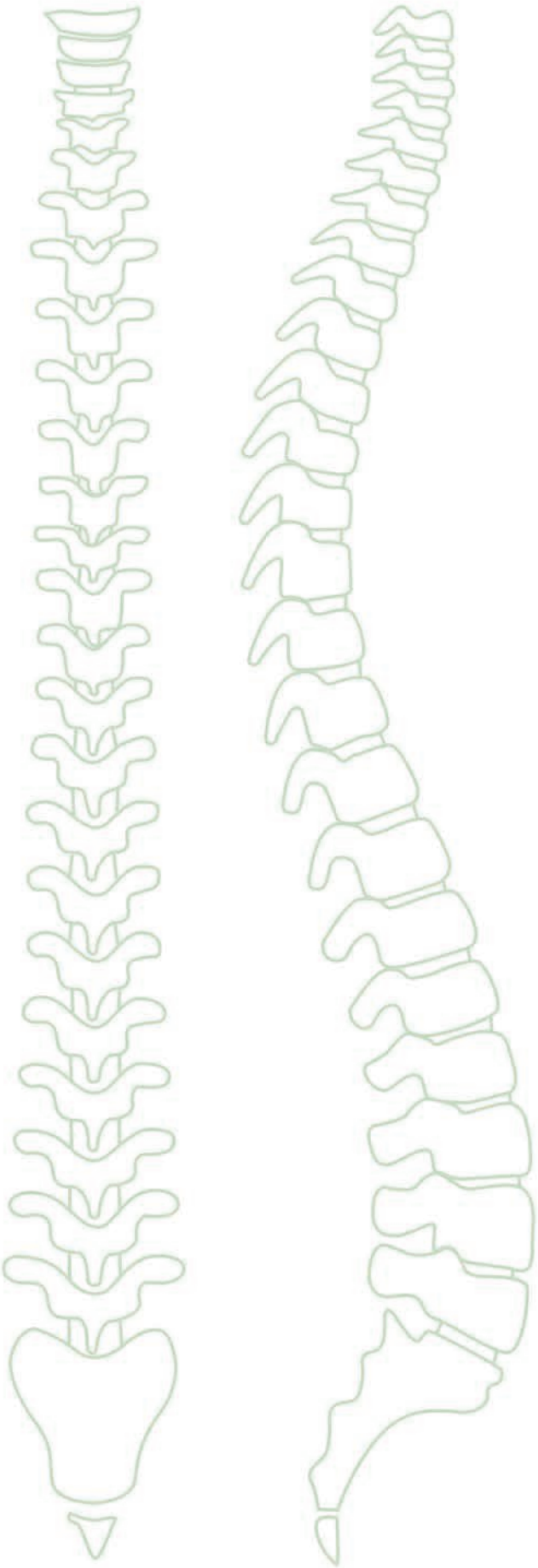
SPINE CATALOGUE



3P3 medica™

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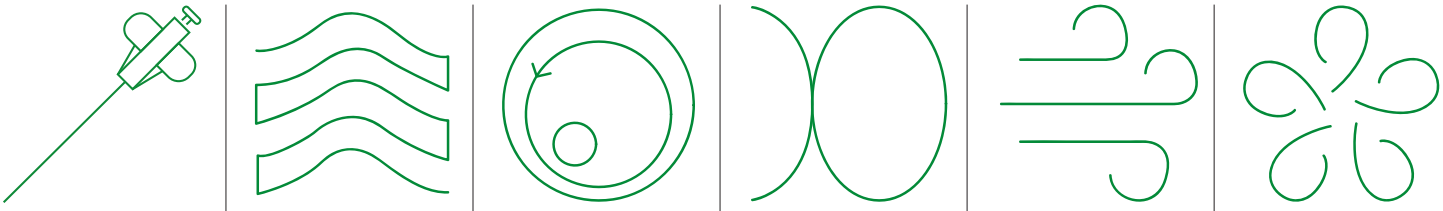
BPB MEDICA™

BPB MEDICA™ is a leading Italian-based healthcare manufacturer, known for its fully integrated, in-house production of innovative medical and surgical devices.

With every stage managed internally, we guarantee **exceptional quality**, **customisation** and **reliability**, making BPB MEDICA™ a preferred partner for healthcare professionals worldwide.

At BPB MEDICA™, we advance in line with the needs of patients, doctors, and hospital staff by leveraging our technical expertise, state-of-the-art technology, and commitment to excellence.

Key Product Lines:



BIOPSY | **SPINE** | **ORTHO-BIOLOGICS & REGENERATIVE MEDICINE** | **ASSISTED REPRODUCTION** | **INTENSIVE CARE** | **AESTHETIC**

Through a commitment to **quality, product distinction**, and **advanced production technologies** across each category, BPB MEDICA™ has established itself as a comprehensive solutions provider in healthcare.

Research & Development:

Continuous Innovation: Our commitment to continuous innovation drives our R&D Department to develop solutions that meet emerging clinical needs, support better patient outcomes, and adhere to industry-leading standards.

Our R&D Department focuses on refining production standards and developing new products, performing ongoing functional testing in collaboration with Quality Control, and ensuring our products meet rigorous standards, even under extreme conditions.

Client-Centric Development: Every product we create is inspired by a commitment to address specific clinical needs, improve patient outcomes, and offer healthcare providers tools that enhance safety and precision.

In-House Manufacturing Advantage

End-to-End Production Process: every step, from conceptual design to final packaging, is completed under one roof, ensuring consistent quality and rapid response to client needs.

Technological Sophistication:

+ **ISO 8 Cleanroom Facility:** Vital for maintaining sterility and ensuring high-quality assembly and packaging.
+ **Metal Refinishing and Moulding Departments:** specialised equipment that allows for advanced processes such as echogenic marking and precise moulding, which make BPB MEDICA™'s products unique.
+ **OEM & Private Label Services:** clients can access à la carte production services, customizing products with their branding, colours, and unique specifications.
+ **Computerized warehouse with reliable permanent stock:** availability for top-selling items, with 24-hour shipment options.

Dedicated Customer Support:

The Regulatory and Quality Departments offer comprehensive support covering:

+ Quality Systems.
+ Regulatory Affairs.
+ Technical Documentation.
+ Clinical Experimentation.
+ Vigilance and Training.
+ Marketing Support: video tutorials, case studies, training sessions and ongoing participation in major medical congresses.

Continuous Commitment to Quality and Compliance

BPB MEDICA™ continuously performs rigorous quality checks:

+ **Incoming Controls:** Dimensional, visual, documental, and functional checks.
+ **In-Process Controls:** Visual and functional controls with sampling or 100% control.
+ **Finished Product Controls:** 100% packaging checks, including post-sterilization inspection.

This thorough quality process ensures that every BPB MEDICA™ product delivered meets the highest standards for safety and performance

Certifications

Commitment to Compliance: BPB MEDICA™'s dedication to quality has earned certifications such as CE and ISO 13485, ensuring safety, reliability and market access worldwide

FDA Establishment Registration marks BPB MEDICA™ as a trusted provider for the U.S. market

ISO 13485
BUREAU VERITAS
Certification

FDA Establishment
Registration number: 9617616
FEI Number*: 300327275

Biopsybell is registered with **EUDAMED** under SRN IT-MF-000011601, as required by MDR Regulation (EU) 2017/745

Milestones and Growth:

1999: Foundation with the BIOPSY product line

2014: Launch of SPINE line of products

2018: Launch of ASSISTED REPRODUCTION line of products

2019: Launch of ORTHO-BIOLOGICS line of products

2020: Launch of AESTHETIC line of products

2022: Acquisition by BPunto3/Wallaby Group in 2022, further supporting global growth

Why BPB MEDICA™?

- **Full in-house production** and quality control.
- **Comprehensive product range** and **customization.**
- **Global presence** with a proven track record.
- **Strong customer support** and regulatory guidance.

JOIN US in advancing healthcare with products that prioritize **safety, precision,** and **efficacy**!

THE EVOLUTION OF MINIMALLY INVASIVE SPINE PROCEDURES

The evolution of minimally invasive spine surgery has been marked by significant advancements, particularly in percutaneous discectomy, vertebroplasty, and kyphoplasty.

Percutaneous discectomy emerged in the 1970s as a less invasive alternative to open discectomy, initially utilizing chemonucleolysis before progressing to mechanical and laser-assisted techniques.

Vertebroplasty was pioneered in the 1980s in France as a treatment for painful vertebral compression fractures, involving the percutaneous injection of bone cement to stabilize the spine.

Building upon vertebroplasty, kyphoplasty was introduced in the late 1990s, incorporating an inflatable balloon to potentially restore vertebral height before cement injection, further improving pain relief and spinal alignment.

These procedures have revolutionized spinal care, offering patients faster recovery times and reduced surgical risks compared to traditional open surgery.

PERCUTANEOUS DISCECTOMY

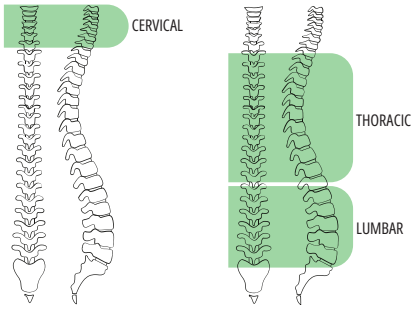
Intervertebral discs act as cushions between spinal vertebrae, with a tough outer layer and a soft, gel-like center. Over time, injury, wear and tear, or aging can cause a disc to bulge or rupture (herniate), leading to severe pain by compressing nearby nerves.

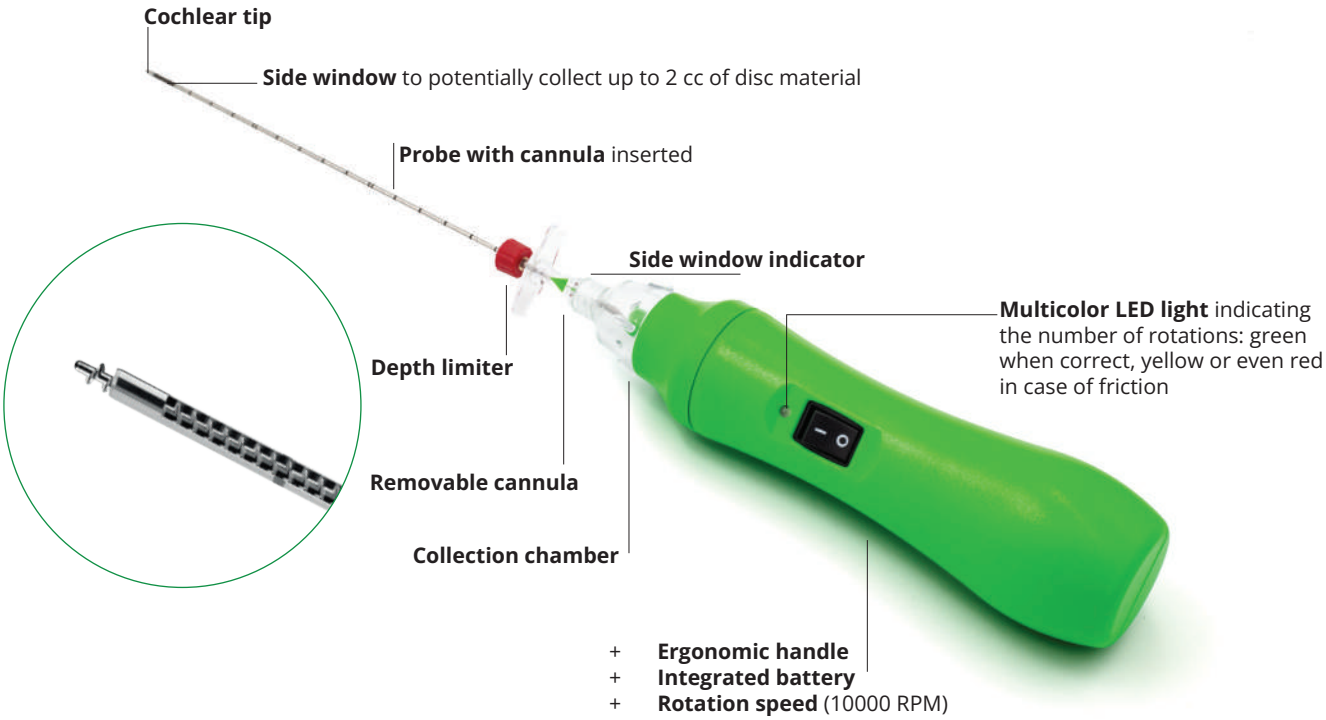
Traditionally, open surgery was used to relieve this pressure by removing part of the herniated disc. However, mechanical percutaneous discectomy offers a minimally invasive alternative. Using a specific device, disc material is mechanically extracted, decompressing the affected nerve and alleviating pain.

This technique preserves surrounding structures, reduces trauma, shortens recovery time, and can be performed under local anesthesia, making it a preferred option for many patients.

DISKOM™

With **DISKOM**™ pressure on nerve roots and surrounding tissues can be significantly reduced by removing disc herniation through a minimally invasive procedure.





Surgical technique (thoraco-lumbar percutaneous discectomy):

+ Under fluoroscopy, introduce the access needle with its stylet into the disc.
+ Remove the stylet and introduce the probe into the cannula.
+ Lock the probe to the access needle through the Luer-lock connection.
+ Switch the probe on.
+ Carry out a continuum movement in an anteroposterior direction, for 2/3 minutes and simultaneously proceed with a rotary movement.
+ Disc material is then removed and collected along the probe stylet or into the collection chamber.
+ After switching off remove the device. WARNING: do not remove the introducer without the stylet or the discectomy probe inside.

Surgical technique (cervical percutaneous discectomy):

+ Under fluoroscopic guidance, identify the target disc and the safe anterior access corridor, between the carotid sheath laterally and the trachea–oesophageal plexus medially.
+ After local anaesthesia, introduce the access needle with its stylet through the anterior approach, advancing carefully into the disc space under continuous lateral and anteroposterior fluoroscopic control.
+ Remove the stylet and introduce the probe into the cannula.
+ Lock the probe to the access needle through the Luer-lock connection.
+ Switch the probe on.
+ Perform a gentle anteroposterior movement for 1–2 minutes, combined with slow rotary movements, while maintaining stable needle positioning.
+ Disc material is then removed and collected along the probe stylet or into the collection chamber.
+ After switching off, remove the device. WARNING: do not remove the introducer without the stylet or the discectomy probe inside.

ORDER GUIDE - DISKOM™

PROCEDURE	SIZES	LENGTH	CODES
Cervical	19G	8 cm	DKR1908CDFL10
Thoracic/Lumbar	17G	16 cm	DKR1716CDFL10

KYPHOPLASTY

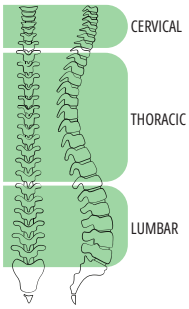
Kyphoplasty is a minimally invasive surgical procedure used to treat vertebral compression fractures (VCFs), often caused by osteoporosis, trauma, or tumors.

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.

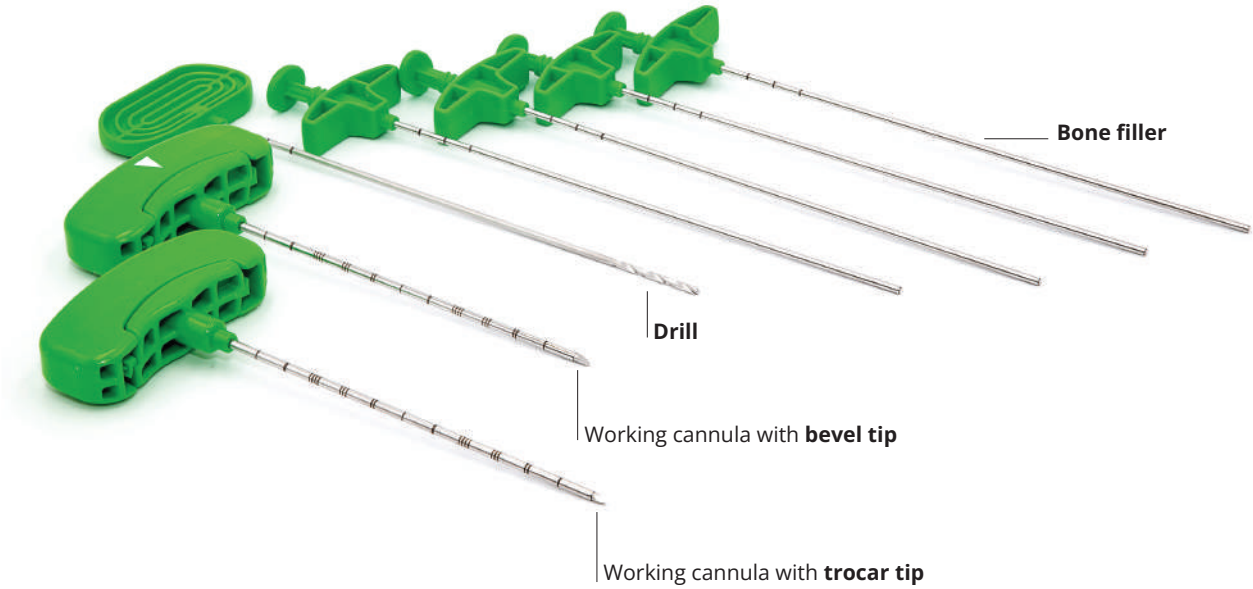
Kyphoplasty potentially helps to improve spinal alignment, reduce deformity, and enhances patient mobility with minimal recovery time.

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.

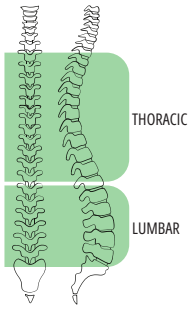
13G balloon catheter inflation up to 400 PSI.

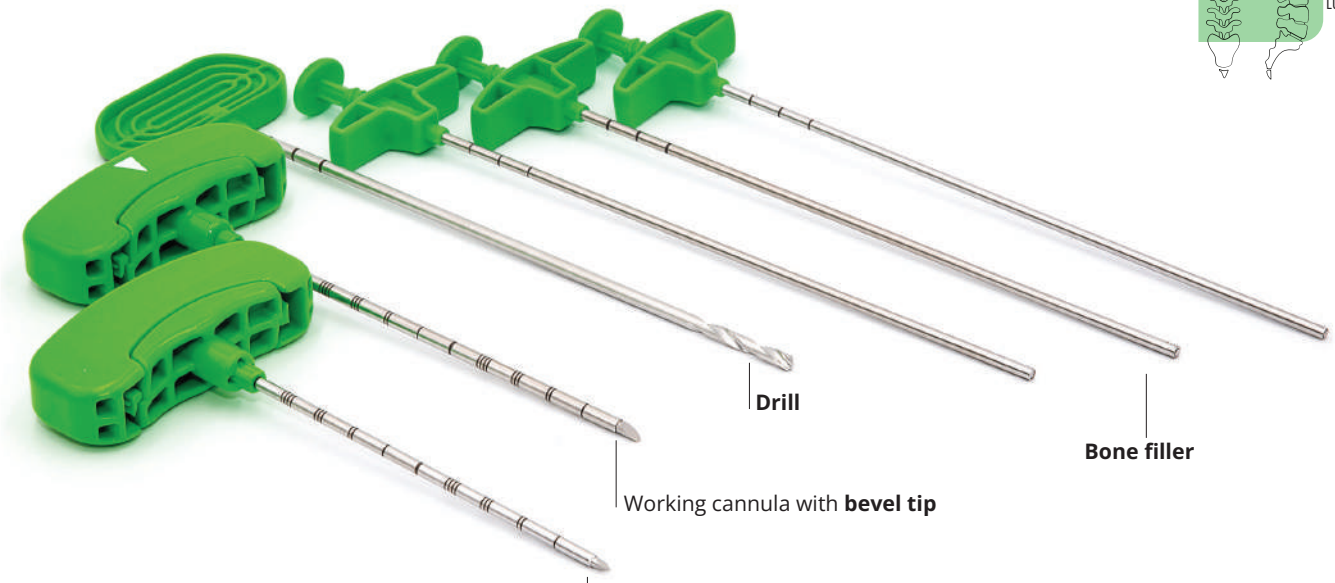
Reduction of back pain.

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.

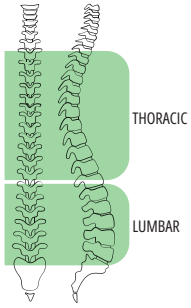
Reduction of back pain.

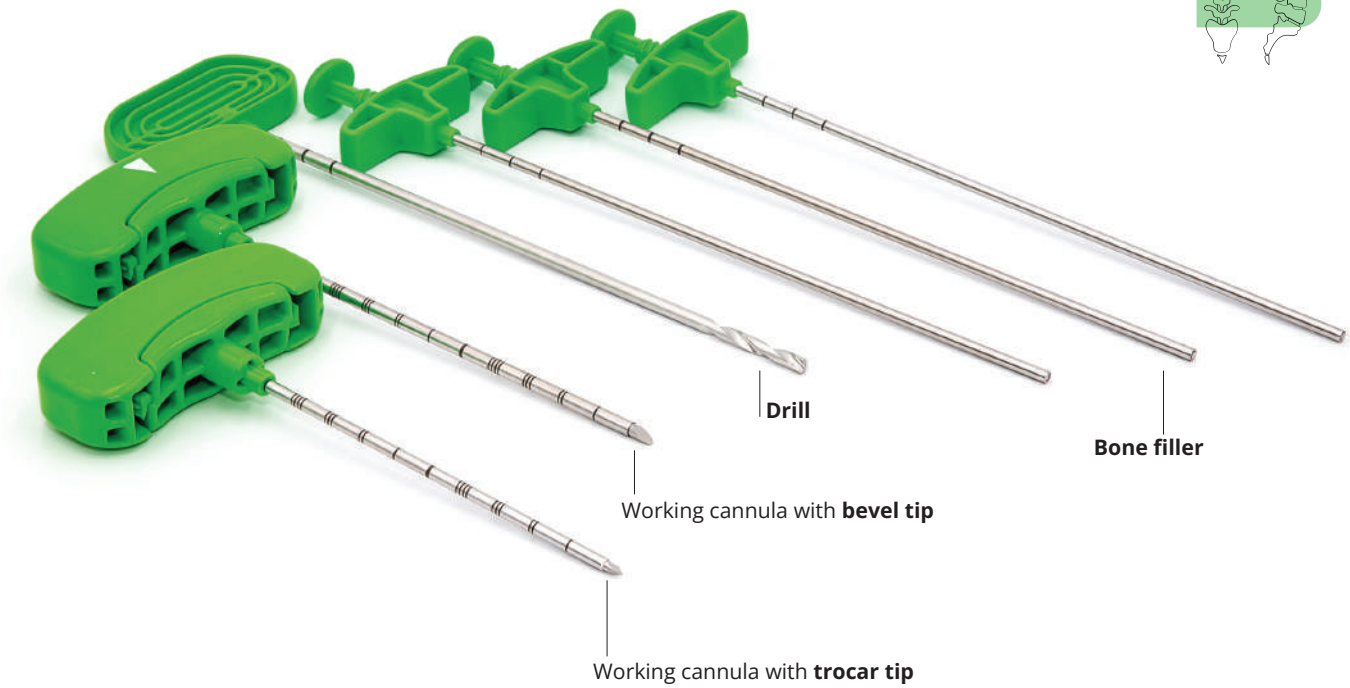
Fast recovery after treatment.

Cement injection cannulas (bone fillers) included 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.

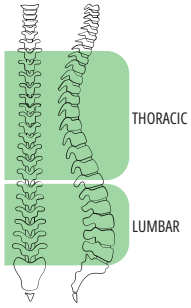
Balloon Inflation

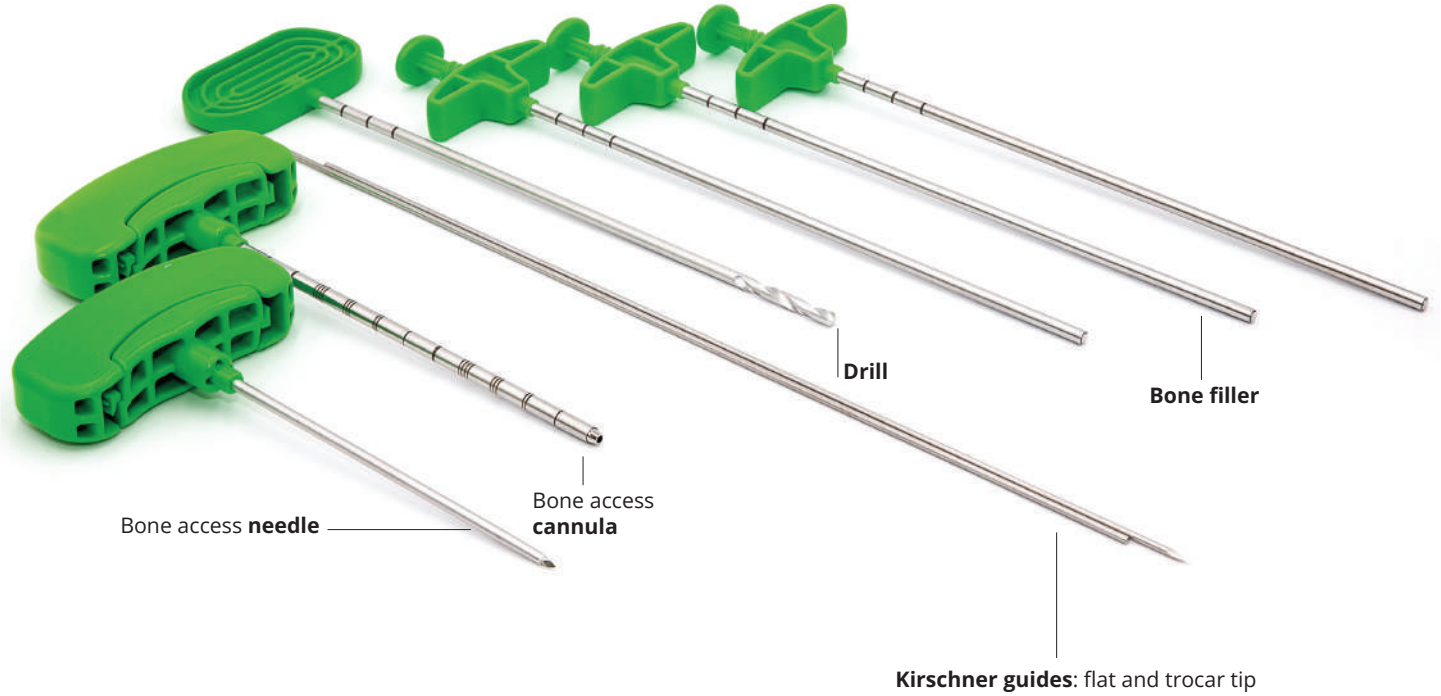
+ Connect the balloon catheter to a preloaded inflation system (contrast medium-to-saline ratio: 1:2).
+ Under fluoroscopic guidance, insert the balloon catheter through the working cannula and position it correctly (AP & lateral view).
+ Inflate the balloon to the desired volume or maximum measurable 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.

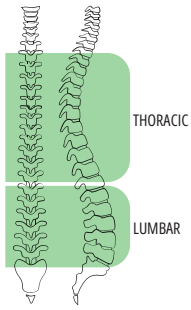
Through a small incision, a needle is guided into the fractured vertebra under imaging guidance, and biocompatible bone cement is directly injected to stabilize the bone, reduce pain, and prevent further collapse.

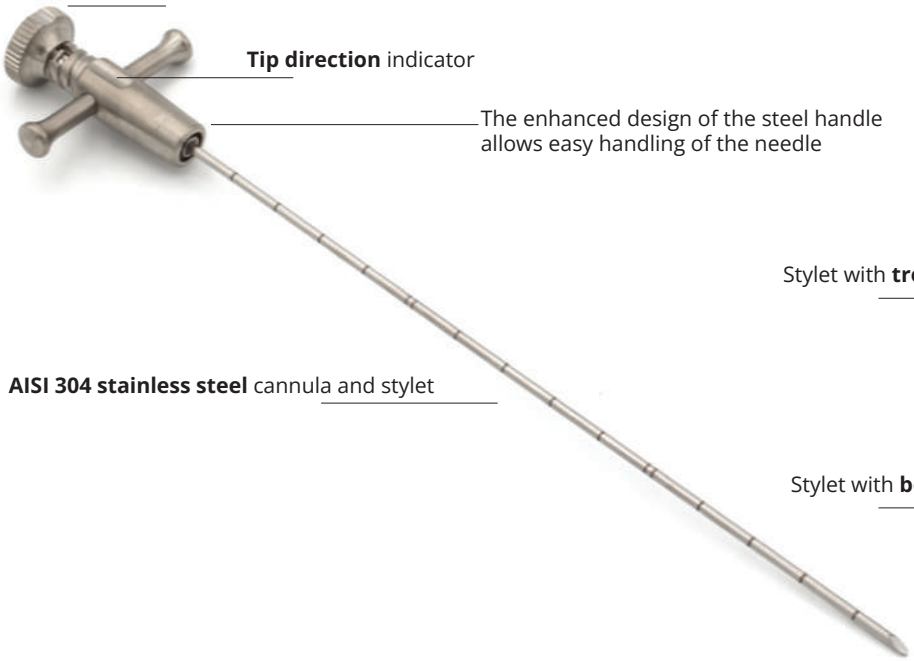
Unlike kyphoplasty, vertebroplasty does not involve balloon inflation to potentially restore height but effectively reinforces the vertebra, providing rapid pain relief and improved spinal stability.

VERTEBROSTEEL™

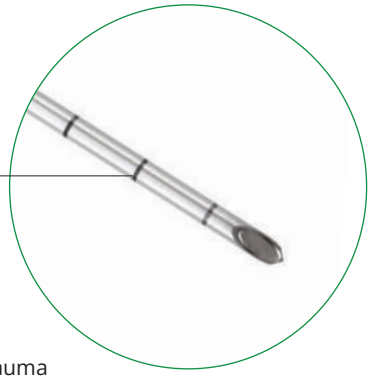
VERTEBROPLASTY NEEDLE – STEEL HANDLE

VERTEBROSTEEL™ 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.





Stylet with **trocar tip**



Stylet with **bevel tip**

Cannula with **sharp tip** to reduce trauma

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 VERTEBROSTEEL™ device.**

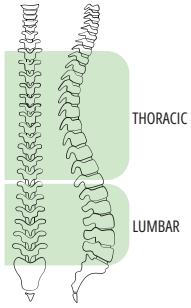
ORDER GUIDE - VERTEBROSTEEL™

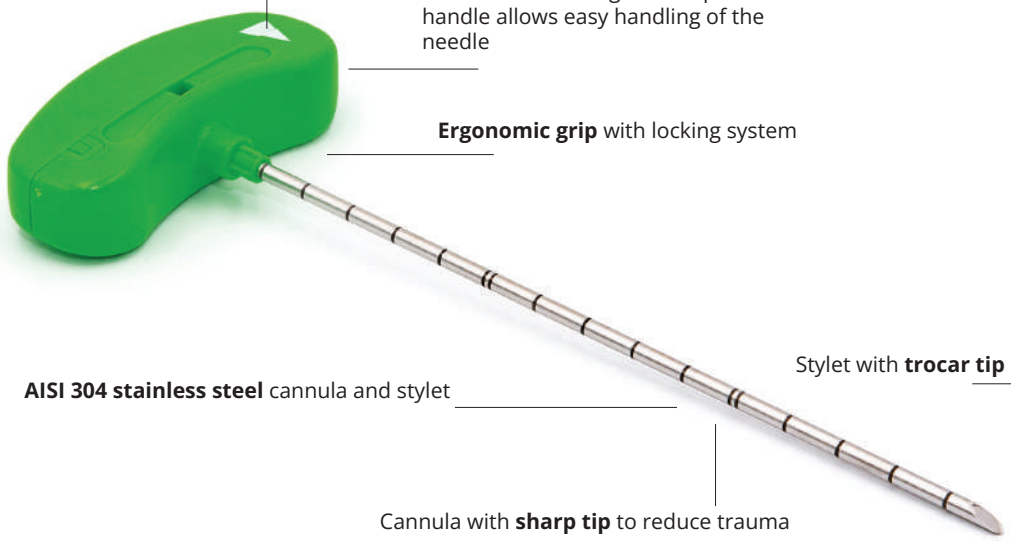
GAUGE	DIAMETER (mm)	LENGTH	BEVEL TIP CODES	TROCAR TIP CODES
11G	3,00	100 mm 120 mm 150 mm	KMFVT1110000C-A KMFVT1112000C-A KMFVT1115000C-A	KMFVT1110000CT-A KMFVT1112000CT-A KMFVT1115000CT-A
13G	2,50	100 mm 120 mm 150 mm	KMFVT1310000C-A KMFVT1312000C-A KMFVT1315000C-A	KMFVT1310000CT-A KMFVT1312000CT-A KMFVT1315000CT-A
15G	1,80	100 mm 120 mm 150 mm	KMFVT1510000C-A KMFVT1512000C-A KMFVT1515000C-A	KMFVT1510000CT-A KMFVT1512000CT-A KMFVT1515000CT-A

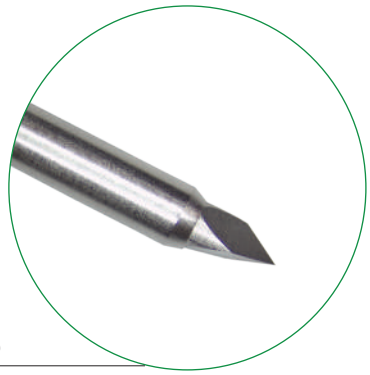
VERTEBROPLASTIC™

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.**

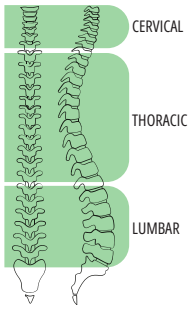
ORDER GUIDE - VERTEBROPLASTIC™

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

BONE CEMENT & DELIVERY SYSTEMS

BONE CEMENT

SPINOS FULFILLS ALL REQUIREMENTS FOR BONE CEMENT IN SPINAL SURGERY



SPINOS benefits

+ **SPINOS can be used for vertebroplasty and kyphoplasty.**
+ **Approved for the augmentation of pedicle screws where bone quality is poor**, e.g. in patients with osteoporosis or degenerative or neoplastic changes.
+ **Short mixing time and fast achievement of application viscosity**.The composition of the polymers ensures a high initial cohesion and therefore reduces the risk of cement leakage. After a short waiting time, the cement attains an ideal viscosity for application.
+ **Long application time.** Both components (powder 24 g and liquid 10 ml) bind quickly to a homogenous paste with a suitable viscosity for percutaneous injection. After a short mixing time, the surgeon has sufficient time for the transfer of SPINOS in the application instruments followed by a long application time.
+ **High radiopacity with 45% ZrO2.** The addition of zirconium dioxide (ZrO2) allows an optimal X-ray visualisation of SPINOS for safe use.
+ **Good fatigue strength.** The composition of SPINOS guarantees optimized mechanical properties which exceed the respective requirements of the ISO 5833 standard. Thanks to its medium viscosity, SPINOS can be used with suitable approved PMMA cement application tools.

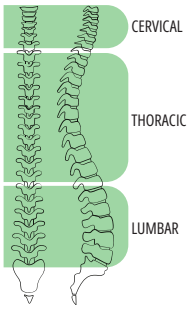
ORDER GUIDE

CODES:
01-350 (AVAILABLE ONLY OUTSIDE U.S.)
01-0309 (BONOS INJECT, ONLY FOR U.S.)

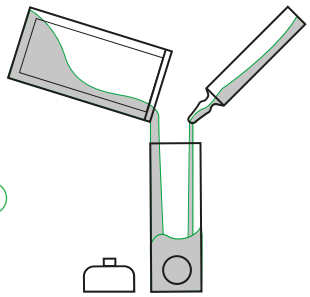
CEMIX™

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.

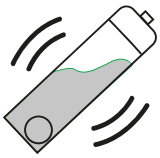


Surgical technique:



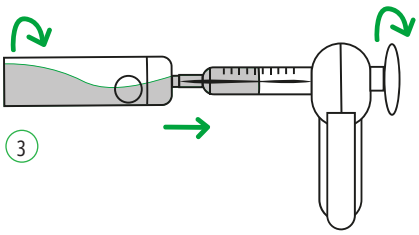
1

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

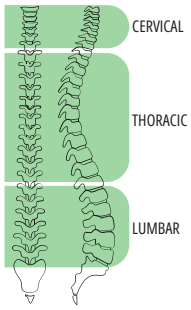
Invert CEMIX™ (cap facing downward) and draw the cement into standard Luer-lock syringes or to suitable injection systems (EASYNJECT™).

ORDER GUIDE - CEMIX™

CODE: KVTMIXN

EASYNJECT™

CEMENT DELIVERY SYSTEM



Straight extension

Curved extension

Compatible with low, medium and high viscosity bone cement.

Ergonomic handle.

10ml single-use syringe included.

Millimetric advancement of the plunger, that allows a very accurate and controlled injection of cement.

Allows fast and direct injection, simply pressing the button on the handle and pushing the plunger.

Allows rapidly stopping the cement flow by turning 180° counterclockwise the plunger.

Two types of extension tube available: **straight or curved.**

Surgical technique:

+ **Connect CEMIX™ to the Luer of EASYNJECT™** after mixing the cement.
+ Ensure the **safety lock is disengaged.**
+ **Press the release button** (right side of the gun handle) and pull the plunger to aspirate the cement.
+ **Disconnect CEMIX™** and attach the extension tube.
+ **Connect the other end of the extension tube to the vertebroplasty needle.**

Inject Cement:

+ For precise, **controlled injection,** rotate the gun's plunger.
+ For fast, direct injection, **press the release button and push the plunger.**

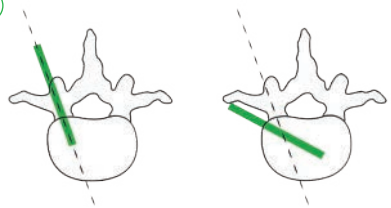
ORDER GUIDE - EASYNJECT™

CODES:

KVTGUN-DS with straight extension
KVTGUN-DS1 with curved extension

VERTEBROPLASTY – Complete Surgical technique

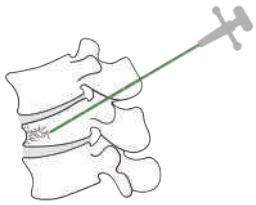
1



CHOOSE THE ACCESS ROUTE

Select either a transpedicular or extrapedicular access depending on the patient's vertebral anatomy and the location of the target area.

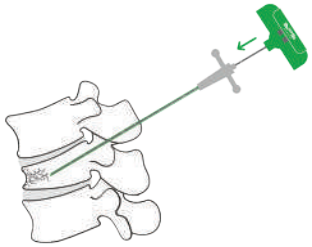
2



CREATE THE ACCESS

Insert the vertebroplasty needle (VERTEBROSTEEL™ or VERTEBROPLASTIC™) through the pedicle under fluoroscopic guidance. Carefully advance the cannula tip until it reaches the anterior half of the vertebral body, confirming positioning throughout.

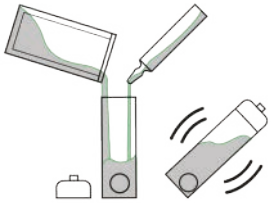
3



PERFORM A VERTEBRAL BIOPSY (OPTIONAL):

At this stage, a vertebral bone biopsy can be performed to investigate possible neoplastic lesions, aiding in diagnosis and treatment planning.

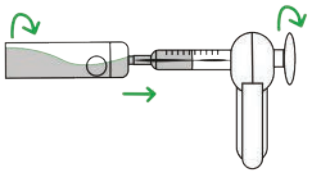
4



PREPARE THE CEMENT

Mix the PMMA bone cement using a dedicated system. The procedure kit includes BONE CEMENT, the CEMIX™ Cement Mixing System, and the EASYNJECT™ Cement Delivery System.

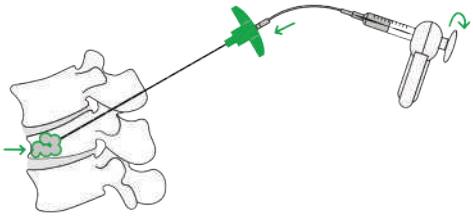
5



LOAD THE DELIVERY SYSTEM

Fill the cement delivery device with the prepared PMMA.

6



INJECT THE CEMENT

Connect the delivery system to the vertebroplasty needle and perform a slow, controlled injection of PMMA into the vertebral body under fluoroscopic monitoring.

VERTEBRAL BIOPSY

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

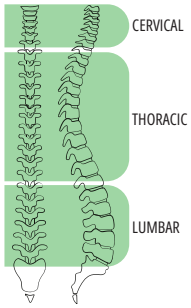
It is typically indicated when imaging studies reveal suspicious lesions, tumors, infections (such as osteomyelitis), or unexplained fractures, helping to differentiate between benign and malignant conditions.

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 NEEDLES

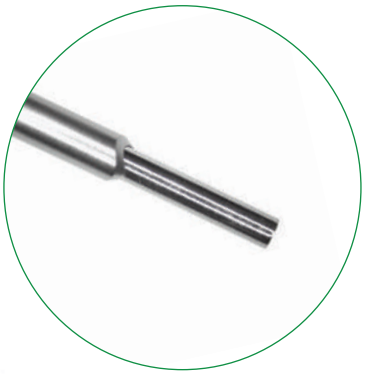
OUTSIDE U.S. ONLY

The VERTEBRAL BIOPSY NEEDLES allow users to perform bone marrow biopsies during kyphoplasty and vertebroplasty procedures.



VERTEBRAL BIOPSY NEEDLE OPTION 1

For **kyphoplasty procedure**



Surgical technique:

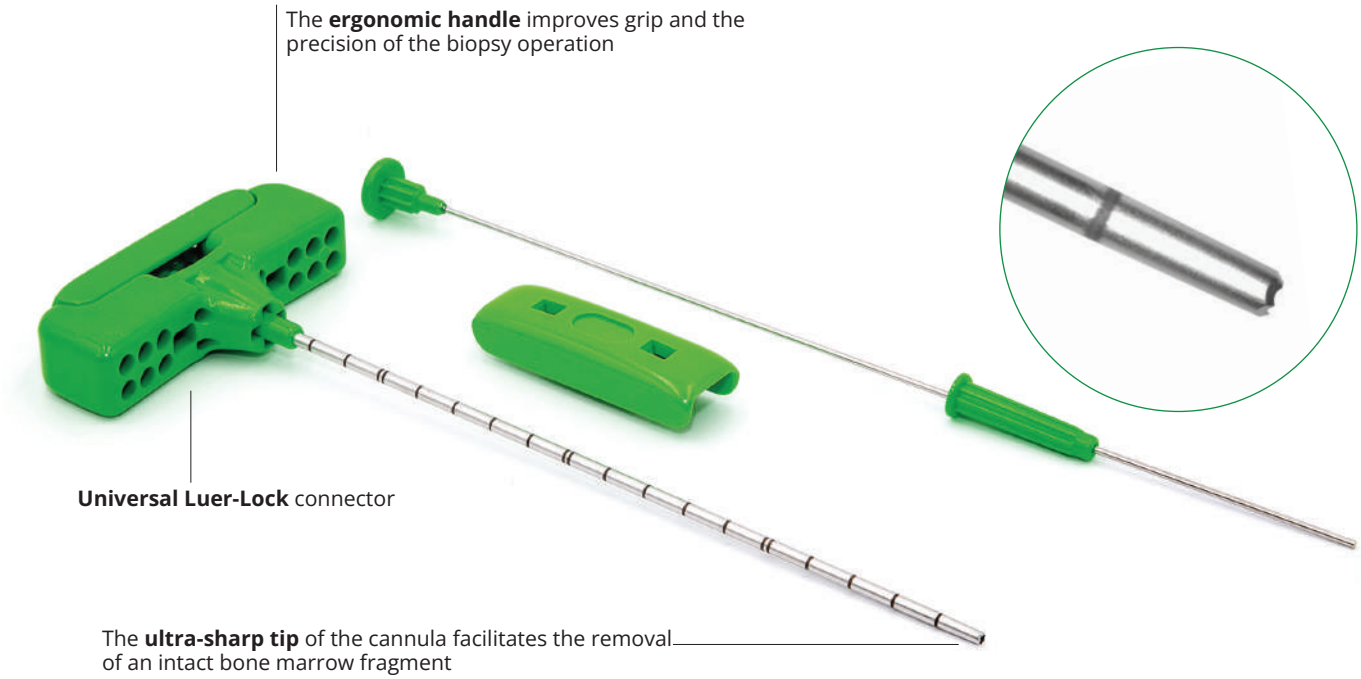
+ **Create a working channel using RENOVA SPINE™** kyphoplasty tools.
+ **Insert the biopsy needle** through the working channel.
+ Once the target site is reached, **attach a syringe to the Luer Lock connector and aspirate the sample**.
+ **Remove the system from the patient**, then use the extractor to deposit the sample.

ORDER GUIDE - VERTEBRAL BIOPSY NEEDLE OPTION 1™

CODE: RESBIO1112CP

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.

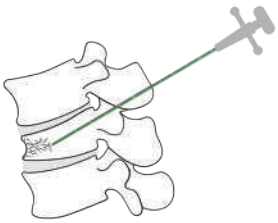
ORDER GUIDE - VERTEBRAL BIOPSY NEEDLE OPTION 2™

CODES:

RESFU1118.5CD (for kyphoplasty)
RESFU1517C (for vertebroplasty - length 17 cm)
RESFU1520C (for vertebroplasty - length 20 cm)

VERTEBRAL BIOPSY – Complete Surgical Technique

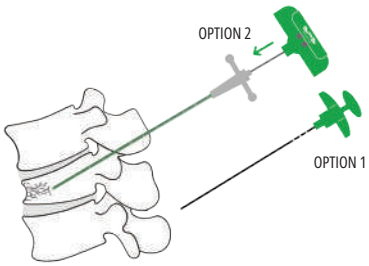
1



PREPARE THE WORKING CHANNEL

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

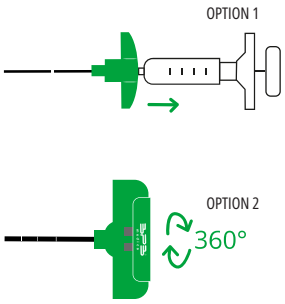
2



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.

3



PERFORM THE BIOPSY

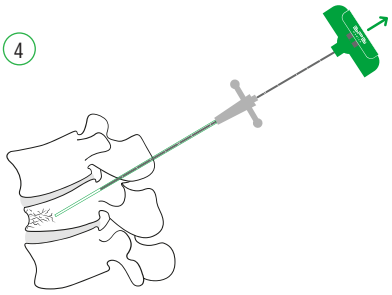
OPTION 1

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.

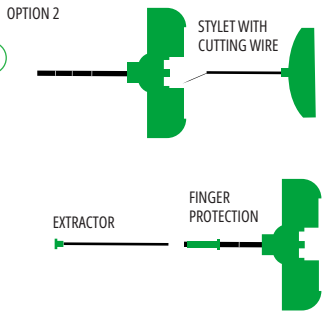
4



REMOVE THE SYSTEM

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

5



SAMPLE EXTRACTION

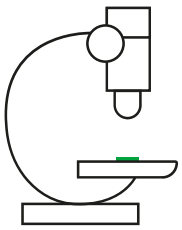
OPTION 1

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 grip to safely retrieve the sample.

6



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.

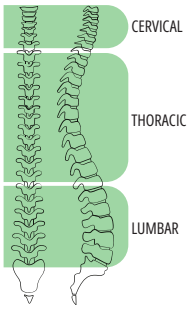
COMPLEMENTARY DEVICES

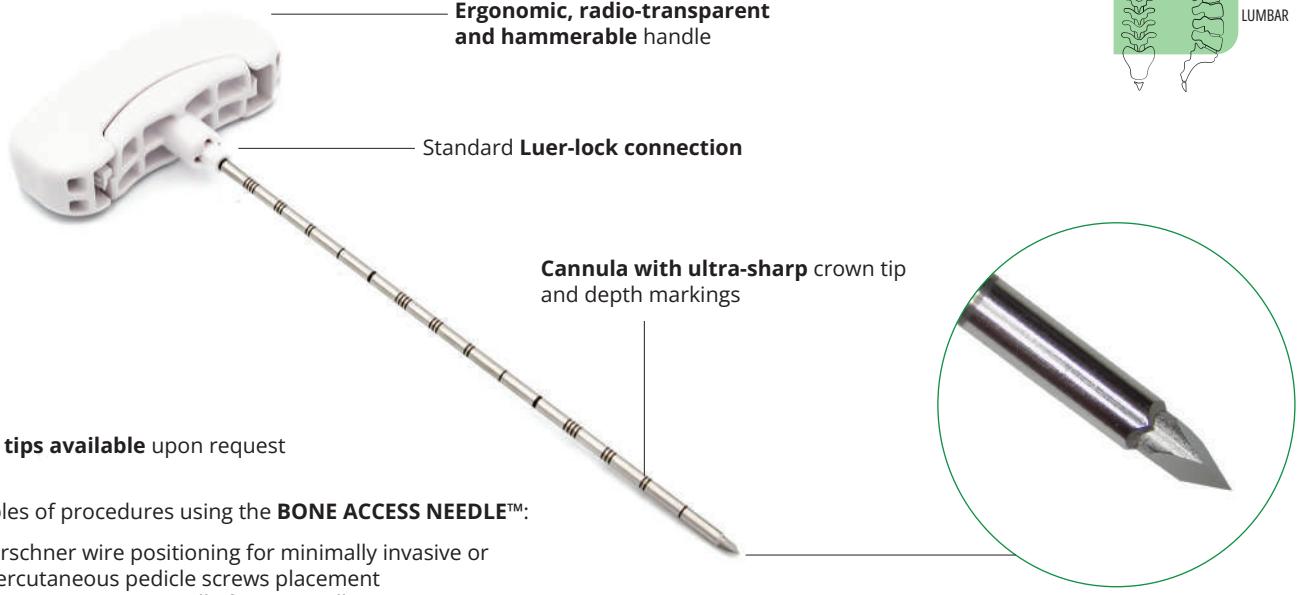
Our Complementary Devices section includes specialized instruments designed to enhance precision and stability in spinal and orthopedic procedures. The BONE ACCESS NEEDLE™ is a versatile stylet suitable for various bone access applications, joint trauma management, and minimally invasive surgical (MIS) treatments.

Additionally, our fully customized screw augmentation system SCREWFIX™ is tailored to the specific screw type, length, and diameter, offering different tip options for bone augmentation and stabilization using cannulated and/or fenestrated pedicle screws, ensuring optimal fixation and surgical outcomes.

BONE ACCESS NEEDLE™

BONE ACCESS NEEDLE™ features make them ideal for every kind of bone access.





Other tips available upon request

Examples of procedures using the **BONE ACCESS NEEDLE™**:

+ Kirschner wire positioning for minimally invasive or percutaneous pedicle screws placement
+ Use as an access needle for minimally invasive joint trauma treatment.

Surgical technique:

+ For pedicle screw insertion, use X-ray imaging to locate the pedicles, **make a ~25 mm skin incision, and dissect down to the pedicle.**
+ **Insert the needle through the incision,** align it with the pedicle trajectory, and penetrate the pedicle cortex under fluoroscopic guidance.
+ **Once the target position is confirmed, remove the stylet.** If using a guidewire (or Kirschner wire) for pedicle screw insertion, insert it through the needle cannula and guide it through the pedicle.
+ Once the bone access procedure has been completed, **reinsert the stylet into the cannula and remove the entire cannula-stylet system.**

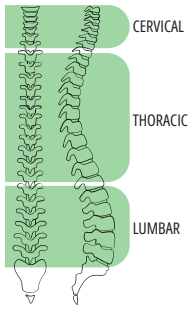
ORDER GUIDE - BONE ACCESS NEEDLE™

GAUGE	DIAMETER (mm)	LENGTH	CODES
8G	4,00	100 mm 120 mm 150 mm	BAN0810CDT BAN0812CDT BAN0815CDT
11G	3,00	100 mm 120 mm 150 mm	BAN1110CDT BAN1112CDT BAN1115CDT
13G	2,50	100 mm 120 mm 150 mm	BAN1310CDT BAN1312CDT BAN1315CDT

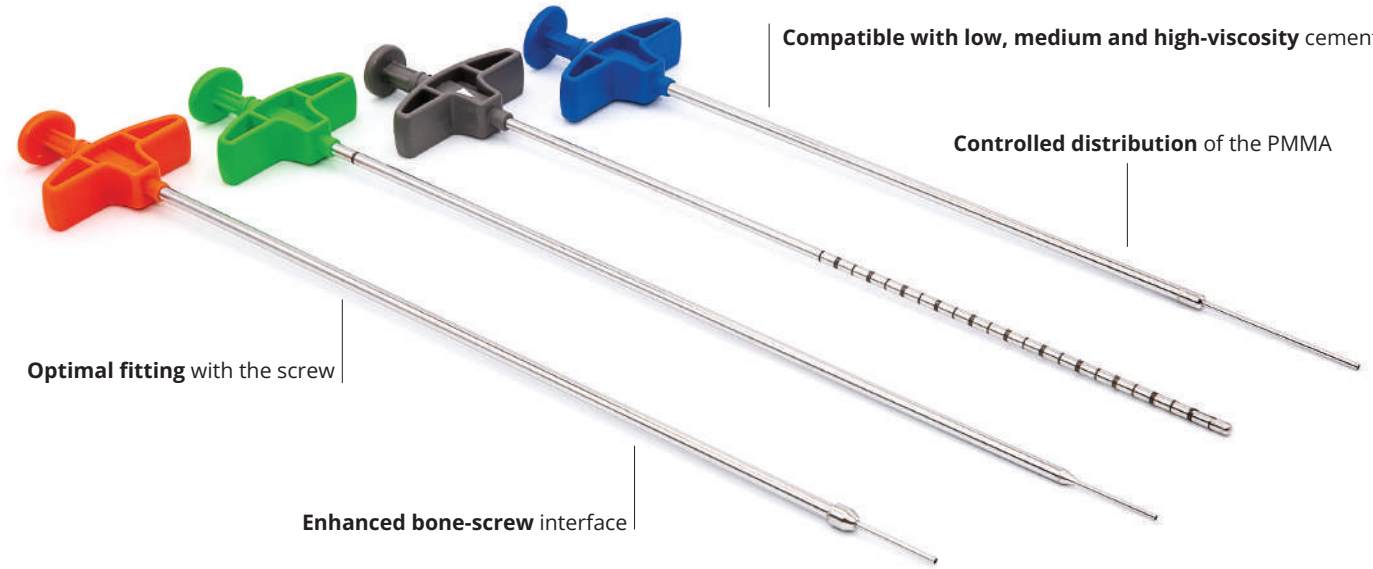
SCREWFIX™

SCREW AUGMENTATION SYSTEM

SCREWFIX™ is a useful instrument in bone augmentation stabilization using cannulated and/or fenestrated pedicle screws. Thanks to SCREWFIX™, the PMMA is injected through the screw for better screw fixation in osteoporotic conditions.



Fully customized device based on the screw type, length and diameter.



Different types of tips are available:

Straight tip: same diameter for the entire length of the device.

Variable diameter tip for easier insertion through the screw.

Variable diameter tip with a joint that allows the cannula to be locked into the screw.

Lateral windowed tip for precise and directional cement injection.

Surgical technique:

+ **Access** to the bone.
+ **Place the screw.**
+ **Set up the PMMA.**
+ **Insert PMMA** through the **SCREWFIX™** up the distal part.
+ **Insert SCREWFIX™** through the screw.
+ **Inject PMMA through the cannula** with the pusher.

MESENCHYMAL STEM CELLS PROCEDURES

Mesenchymal stem cells (MSCs) from bone marrow (BM-MSCs) and adipose tissue (AD-MSCs) are increasingly used in spine surgery for their regenerative potential.

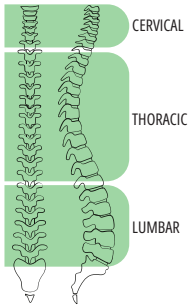
BM-MSCs, rich in osteogenic properties, are commonly applied in spinal fusion procedures to enhance bone regeneration and improve graft integration.

AD-MSCs, which are more abundant and easier to harvest, exhibit strong anti-inflammatory and immunomodulatory effects, making them valuable for treating certain degenerative states of the intervertebral disc and reducing chronic inflammation.

Both types of MSCs are used in biological therapies to promote tissue repair, reduce pain, and potentially delay or avoid invasive surgical interventions.

ADIPO-STEM DUO™

MICROFRAGMENTATION & PURIFICATION KIT FOR ADIPOSE TISSUE MSCs

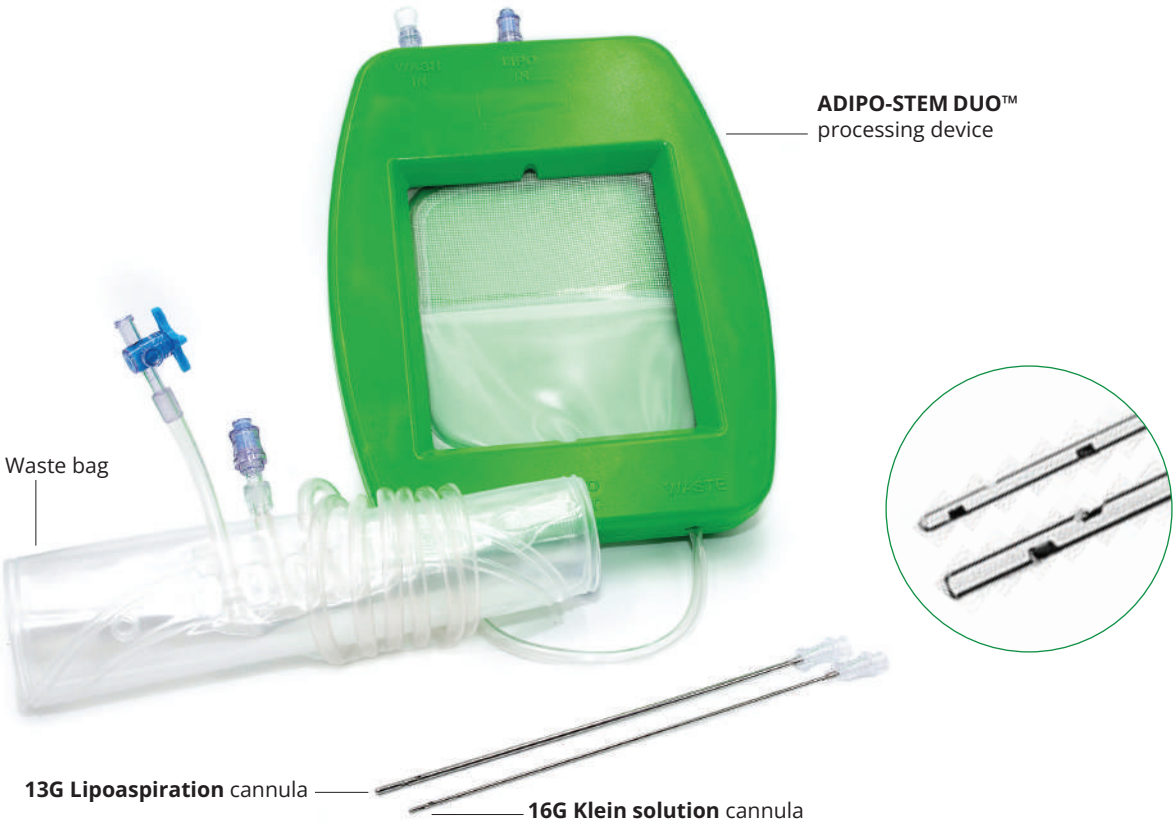


ADIPO-STEM DUO™ is a closed-circuit single-use kit for adipose tissue microfragmentation and purification without any centrifuge and with minimal manipulation. **The filtering system microfragments the adipose tissue while maintaining its biological properties and maximizing the regenerative potential.** The entire processing phase of the liposuctioned tissue occurs inside the device thanks to continuous saline solution washing. This allows reducing the cellular stress eliminating any traumatic action that may damage the extracellular matrix and its essential trophic and anti-inflammatory function.

The collection and processing bag is equipped with two filters:

+ **The first filter microfragments the adipose tissue** while retaining the eventual fibrotic tissue;
+ **The second filter with a denser mesh retains the microfragmented adipose tissue** that is washed with saline solution eliminating all the oily and blood residues which might cause inflammation of the treated tissues.

The **final micro-fragmented and purified product is an autologous adipose tissue that keeps the biological properties of the original tissue intact** and can easily be injected even through very thin needles.



TIME EFFICIENT

+ Processes up to 400 ml of adipose tissue in 10 minutes.
+ Centrifuge free: saving on time, personnel and tools.
+ All-in-one system that processes, purifies and microfragments a high-quality adipose tissue rich in mesenchymal cells.

MINIMAL MANIPULATION

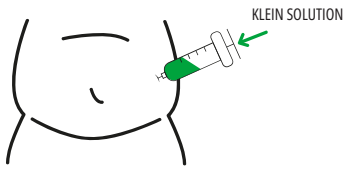
+ Preservation of the biological properties of the cells.
+ Complete preservation of tissue architecture and stromal niche components.
+ Continuous saline solution washing eliminates any traumatic action that may damage the extracellular matrix.

EASY TO USE

+ No centrifugation is required.
+ Simple and reproducible technique in a single surgical time.
+ Compared to centrifugation, minimizes staff training, or preparation and clean-up.
+ Only 1 operator is required.

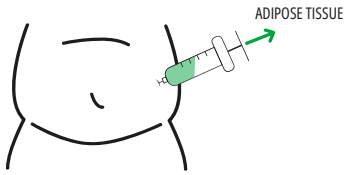
Surgical technique:

1



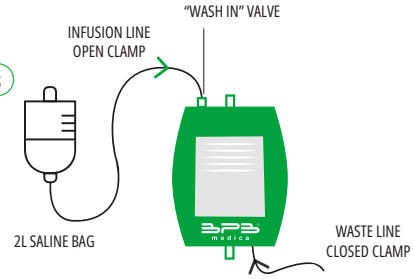
Infiltrate the Klein solution.

2



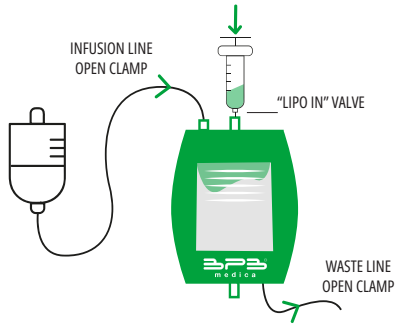
Harvest the adipose tissue using the VacLok syringe. We recommend to generate a soft negative pressure by blocking the VacLok in increments of 10 cc.

3



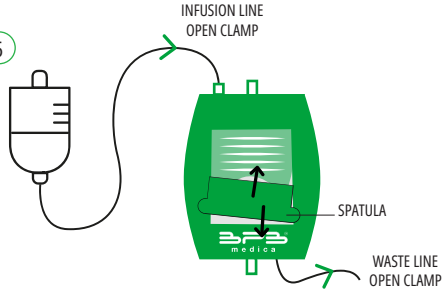
Close the waste line clamp bag tube. Connect a 2L saline bag to the device's "WASH IN" valve and fill the bag with around 150 ml of saline solution.

4



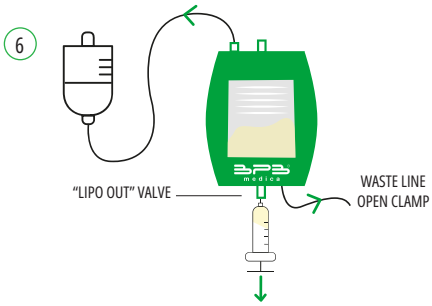
Insert the harvested adipose tissue in the device's "LIPO IN" valve and open the waste line clamp to eliminate residues.

5



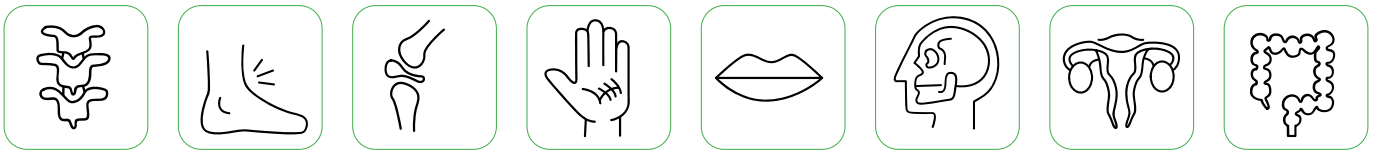
Gently move the spatula up and down until the fat tissue turns pale yellow and the waste liquid becomes transparent.

6



Close the infusion line clamp and use the spatula one more time to remove the remaining contents. Retrieve the adipose tissue from the LIPO-OUT valve.

Applications:



SPINAL SURGERY | VULNOTHERAPY | ORTHOPAEDICS & SPORT MEDICINE | PAIN THERAPY & WOUND HEALING | RECONSTRUCTIVE AND PLASTIC SURGERY | MAXILLOFACIAL SURGERY | UROGYNAECOLOGICAL SURGERY | COLOPROCTOLOGY

ORDER GUIDE - ADIPO-STEM DUO™

CODE: ADPKIT-002

STANDARD KIT COMPOSITION

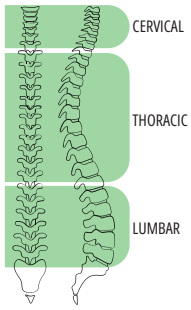
1× ADIPO-STEM DUO™ filtrating system with waste bag
1× Infusion line with clamp
1× Open clamp
1× Klein solution cannula, 16G
1× Lipo-aspiration cannula, 13G
1× Infiltration needle, 20G × 90 mm
2× Combi caps, LLF/LLM
2× Luer connectors, LLF/LLF
2× VacLok syringes, 60 ml
2× Syringes, 60 ml
2× Syringes, 10 ml
2× Syringes, 3 ml

OUTSIDE U.S. ONLY
EU ONLY: Physicians and healthcare professionals must verify for each type of application the homofunctionality of use.

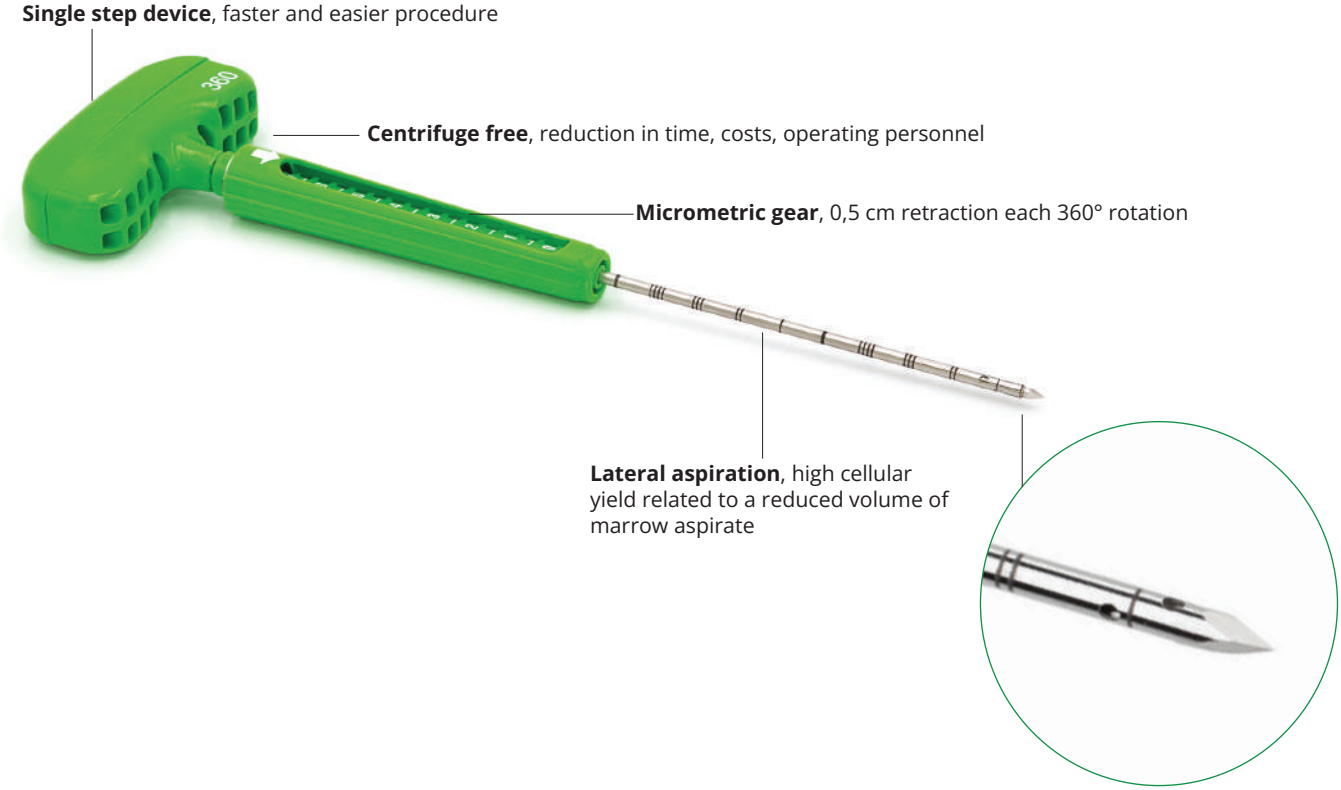
BONE-STEM™

BONE MARROW MESENCHYMAL STEM CELLS ASPIRATION KIT

BONE-STEM™ is a disposable device for the selective aspiration of mesenchymal cells from the bone marrow which, with its innovative features, optimises the cellular yield and minimises the contamination of peripheral blood thanks to a micrometric system for lateral aspiration and the close distal tip of the trocar.



Single step device, faster and easier procedure



Centrifuge free, reduction in time, costs, operating personnel

Micrometric gear, 0,5 cm retraction each 360° rotation

Lateral aspiration, high cellular yield related to a reduced volume of marrow aspirate

Closed & sealed distal tip, no peripheral blood contamination

INNOVATIVE

- Closed & sealed distal tip: guarantees a high cellular yield.
- 100% lateral aspiration: no peripheral blood contamination.
- Micrometric gear: 0,5 cm cannula retraction every 360° rotation.

EASY TO USE

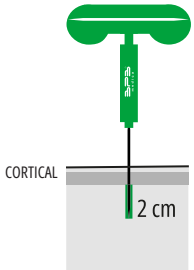
- Single-step device: faster and easier procedure.
- Point of care therapy: minimally invasive procedure.
- Residual retraction control thanks to the numbers printed on the gear window.

CONVENIENT

- Centrifuge-free: saving on time, personnel and tools.
- No processing time: ready-to-use bone marrow MSC concentrate.
- Minimizes staff training, or preparation and clean-up.

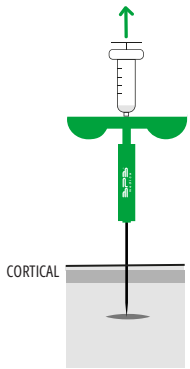
Surgical technique:

1



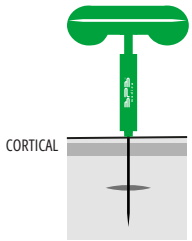
Insert and advance the BONE-STEM™ just beyond the edge of the cortical bone, keeping the stylet attached.

2



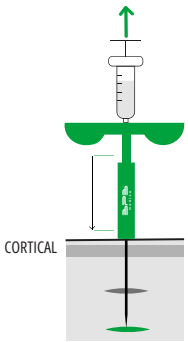
Remove the stylet, connect the VacLok syringe and aspirate 1 ml of bone marrow.

3



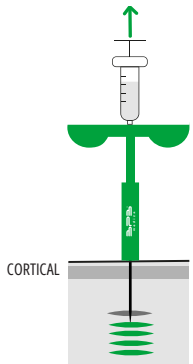
Reinsert the stylet, and advance the device to the deepest desired depth.

4



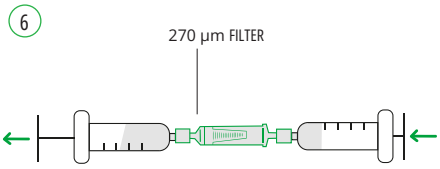
Adjust the gear so that it makes contact with the skin. Remove the stylet again, reconnect the VacLok syringe and aspirate a second ml of bone marrow.

5



Retract the BONE-STEM™ to the next aspiration target (positioned approximately 1 cm above the previous point) by rotating the handle 360° counterclockwise twice. Keep the gear steady while retracting. Aspirate 1 ml of bone marrow per cm of retraction, repeating this retraction/aspiration process for additional collection points. Refer to the residual excursion (in cm) marked on the gear.

6



Upon completing the aspirations, remove the BONE-STEM™. If necessary, use the provided 270 µm filtering system to remove bone debris or clots (not available in the U.S).

ORDER GUIDE - BONE-STEM™

CODE: kit BST1110C-01

STANDARD KIT COMPOSITION

1x BONE-STEM™ MSCs aspiration device
1x 270 µm filtering system (not available in the U.S.)
1x VacLok AT syringe 20 ml
1x Injection syringe 10 ml (not available in the U.S.)

BONE-STEM™
MSCs aspiration device

Aspiration syringe

Filtering system
(not available in the U.S.)

Injection syringe
(not available in the U.S.)

EU ONLY: Physicians and healthcare professionals must verify for each type of application the homo-functionality of use.

WEBSITE

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