

SPINE SURGERY

Mendec[®]

Line



TECRES

ADVANCING HIGH TECHNOLOGY

"Knowing
that our products
every day improve
the lives of many people.
This is our ambition.
This is our reward."

Giovanni Faccioli, President.



TECRES

Cutting-edge technologies and constant research to improve the lives of many people. This is the vision of Tecres since 1981, operating in synergy with surgeons, Universities and Research Institutes in order to invent, realize and provide the market with safe, effective and innovative products. We are specialized in acrylic resins since 1986 with medical applications in fields such as orthopaedics, spinal surgery and neurosurgery. Our excellence and reliability are recognized in more than 70 Countries around the world.

MENDEC® LINE

Mendec® Line is the complete line for mixing and delivering spine resin in Vertebral Augmentation Procedures. A wide range of spinal resins with different viscosities, also available in the revolutionary all-in-one closed system, and the complete line of accessories ensure great flexibility of choice to the operators. All Mendec® Line resins have barium sulphate mixed inside the powder, in order to provide the surgeon with constant visibility and control over the procedure, and have excellent compression resistance.

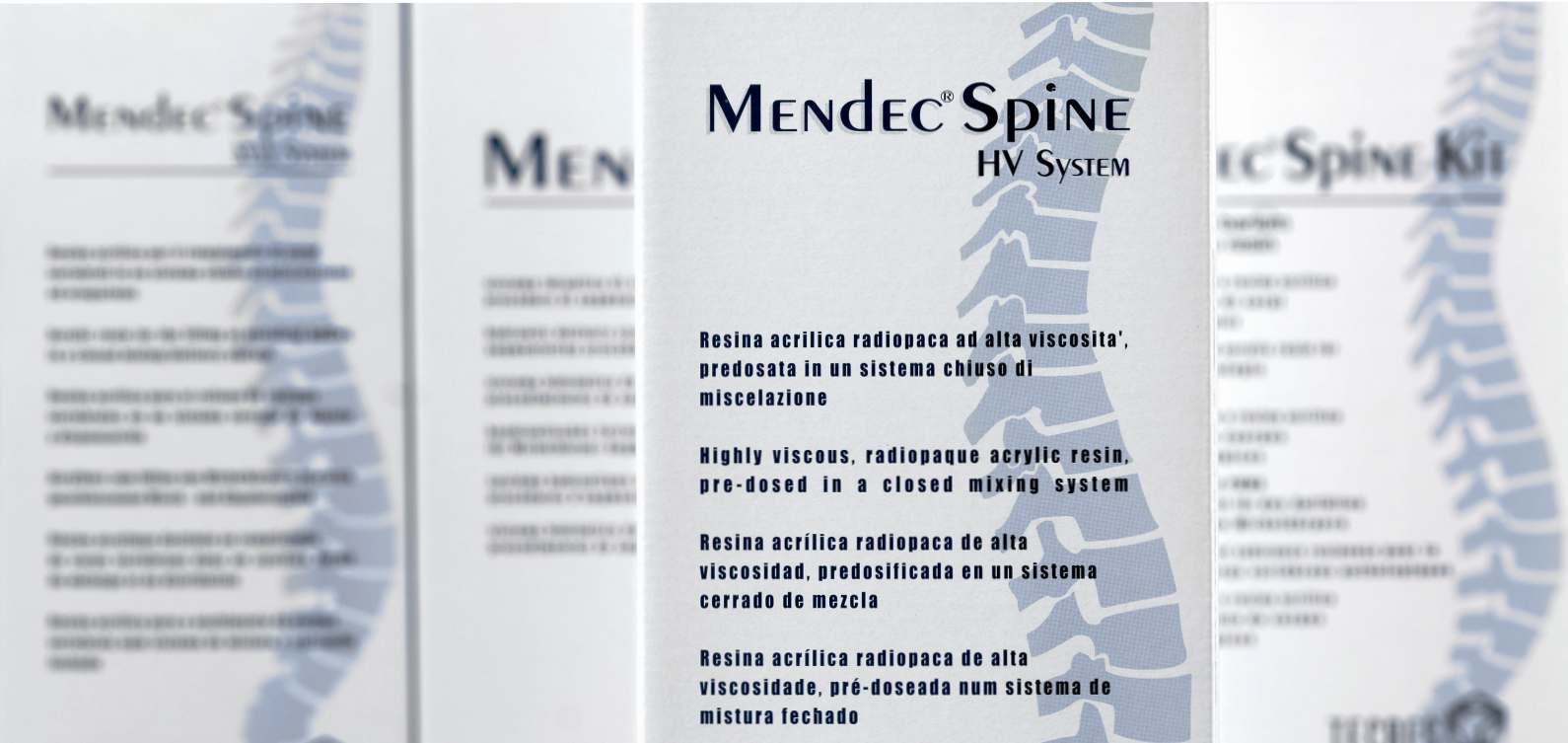


RANGE

INDICATION	VISCOSITY	SPINAL RESIN	DELIVERY SYSTEM
VERTEBROPLASTY	Low	Mendec® Spine	Mendec® Aqua
			Mendec® Spine Kit (resin included)
	Medium	Mendec® Spine MV System	Mendec® Aqua
			Mendec® Spine MV System
	High	Mendec® Spine HV System	Mendec® Aqua
			Xtruder® + HP Connection Tube

INDICATION	VISCOSITY	SPINAL RESIN	DELIVERY SYSTEM
KYPHOPLASTY*	Low	Mendec® Spine	Mendec® Aqua
	High	Mendec® Spine HV System	

*Only resin is provided





MENDEC® SPINE

Mendec® Spine is the user friendly **low viscosity** spine resin. The preparation process is easy and safe, and does not require an external mixer. Its optimal fluidity and its viscosity allow an easy injection for an extended time and enough quantity for multilevel treatment.



ADVANTAGES:

- Easy and user friendly
- Mixing system included

PACKAGE CONTENT:

- 20g of powder
- 9,4g of liquid
- 22,6 cc of volume
- Mixing Container
- Code 1230



MENDEC® SPINE KIT

Mendec® Spine Kit is the complete kit for vertebral augmentation procedures, and does not require any external accessory for both the preparation and the supply of resin. The kit includes Mendec® Spine resin, and Mendec® Spine Gun, a device that enables the application of resin in vertebral bodies with precision and in total security.



ADVANTAGES:

- Easy and user friendly
- Mixing system included
- Delivery system included



Preparation of Mendec® Spine Kit. Scan the QR Code and watch the video tutorial.

PACKAGE CONTENT:

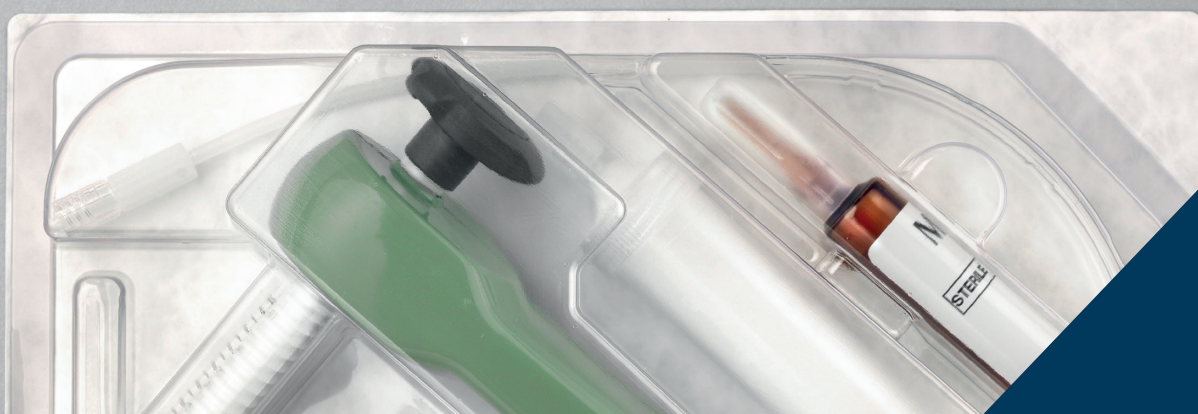
- 20g of powder
- 9,4g of liquid
- 22,6 cc of volume
- Mixing Container
- Delivery Gun
- Connecting Tube
- Code 13C2000



Mixing



Delivery





MENDEC® SPINE MV SYSTEM

Mendec® Spine MV System is a complete all-in-one mixing and delivery kit. This **medium viscosity** kit already has both powder and liquid inside, and it's provided with 19 cm connection tube in order to attach it to the needle and perform the vertebral augmentation procedure. The completely sealed system protects the operators from monomer fumes, and minimize the risk of glass debris inside the resin, or glass-related injuries. Since operators do not come into contact with the material at any stage of the process, the risk of contamination is minimized.

ADVANTAGES:

- Complete All-In-One system for mixing and delivery
- No Waiting Time
- Minimized risk of contamination or glass debris
- Minimized monomer fumes exposure



Preparation of Mendec® Spine MV System. Scan the QR Code and watch the video tutorial



PACKAGE CONTENT:

- 20g of powder
- 9,2g of liquid
- 18,5cc of volume available
- All-In-One mixing & delivery system
- Connecting Tube Code 13C2050



MENDEC® SPINE HV SYSTEM

Mendec® Spine HV System is the first all-in-one mixer preloaded with **high viscosity** spine resin. Thanks to its high viscosity the resin is ready to use right after mixing, with no waiting time. The improved formula allows to extend the working time up to 17:30 minutes*. The completely sealed system protects the operators from monomer fumes, and minimize the risk of glass debris inside the resin, or glass related injuries. Since operators do not come into contact with the material at any stage of the process the risk of contamination is minimized.

ADVANTAGES:

- All-In-One mixing system
- No Waiting Time
- Minimized risk of contamination or glass debris
- Minimized monomer fumes exposure
- Male-male connector included



Preparation of Mendec® Spine HV System. Scan the QR Code and watch the video tutorial



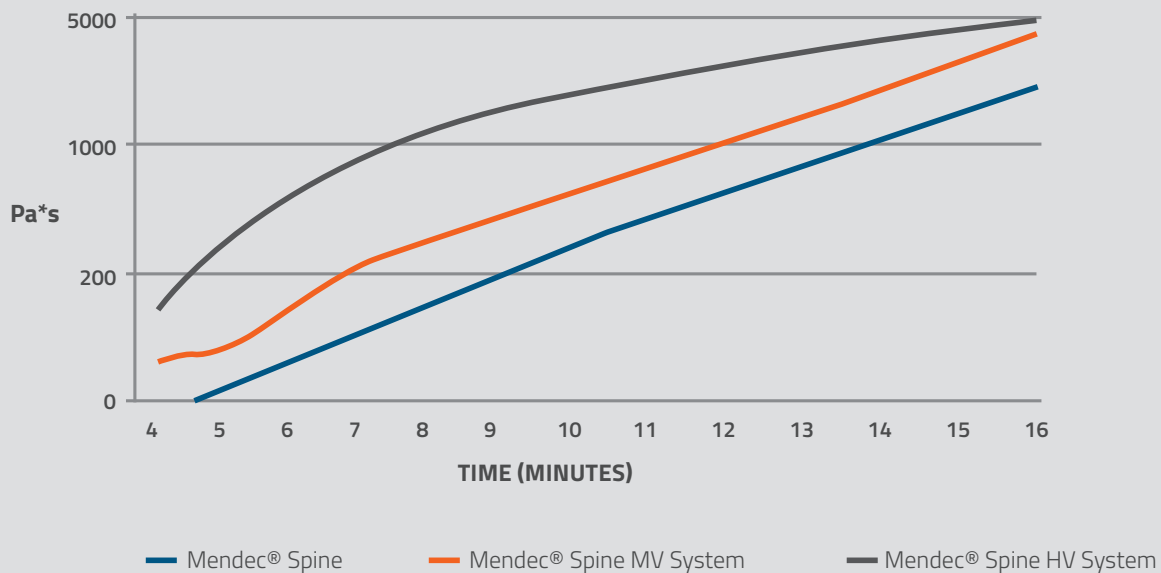
PACKAGE CONTENT:

- 18g of powder
- 8,3g of liquid
- 16,6 cc of volume available
- All-In-One mixing system
- Male-male Connector Code 13C2040

* Time obtained with Mendec® Aqua Hydraulic Delivery System, storage at 20°C and 13 gauge needle

MENDEC® LINE RESINS

VISCOSITY CHART*



Mendec® Line offers 3 different resin viscosities in order to adapt to every surgeon needs. Viscosity is the key factor for reducing the risk of PMMA cement leakage and it should be adapted to the degree of osteoporosis encountered in each patient.¹⁵ It has been shown that with higher resin viscosity the leakage mass decreased.¹⁶

* Data on file

MEDEC® SPINE – LOW VISCOSITY



MIXING TIME	1'
DEVICE FILLING TIME	1'
WAITING TIME	5'
WORKING TIME	10'
SUGGESTED STORAGE TEMPERATURE	23°C
TOTAL VOLUME	22,6 cc

MEDEC® SPINE KIT – LOW VISCOSITY



MIXING TIME	1'
DEVICE FILLING TIME	1'
WAITING TIME	3'
WORKING TIME	6'30"
SUGGESTED STORAGE TEMPERATURE	23°C
TOTAL VOLUME	22,6 cc

MEDEC® SPINE MV SYSTEM – MEDIUM VISCOSITY



MIXING TIME	1'
WAITING TIME	3'
WORKING TIME	5'30"
SUGGESTED STORAGE TEMPERATURE	20°C
TOTAL VOLUME	18,5 cc

MEDEC® SPINE HV SYSTEM – HIGH VISCOSITY



MIXING TIME	1'
MEDEC® AQUA FILLING TIME	1'30"
WAITING TIME	NO WAITING TIME
WORKING TIME*	17'30"
SUGGESTED STORAGE TEMPERATURE	20°C
TOTAL VOLUME	16,6 cc

*Time obtained in combination with Mendec® Aqua, storage at 20°C and 13 gauge needle



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Mendec[®] Aqua:

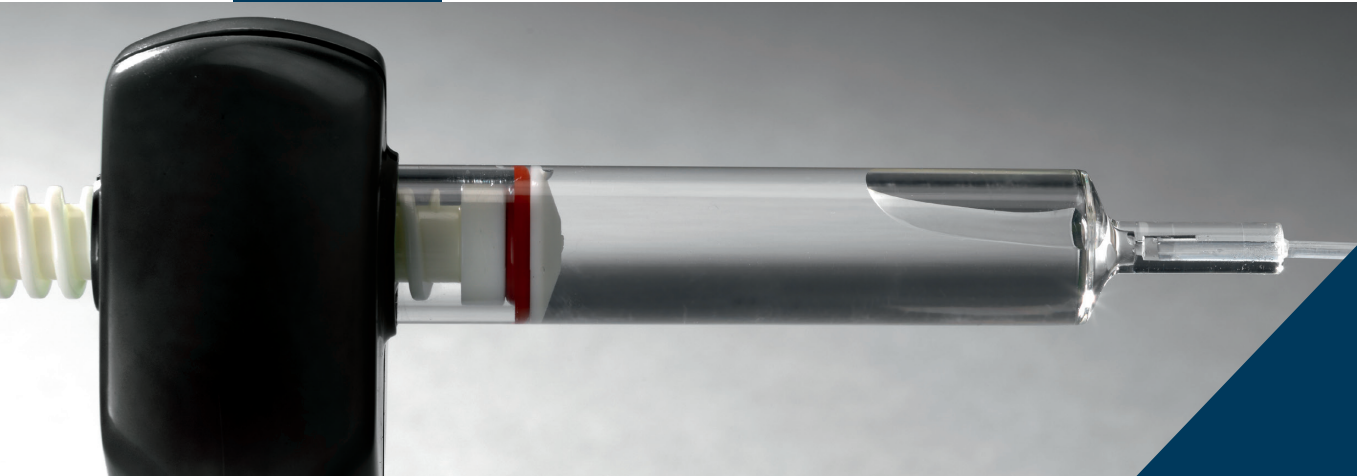
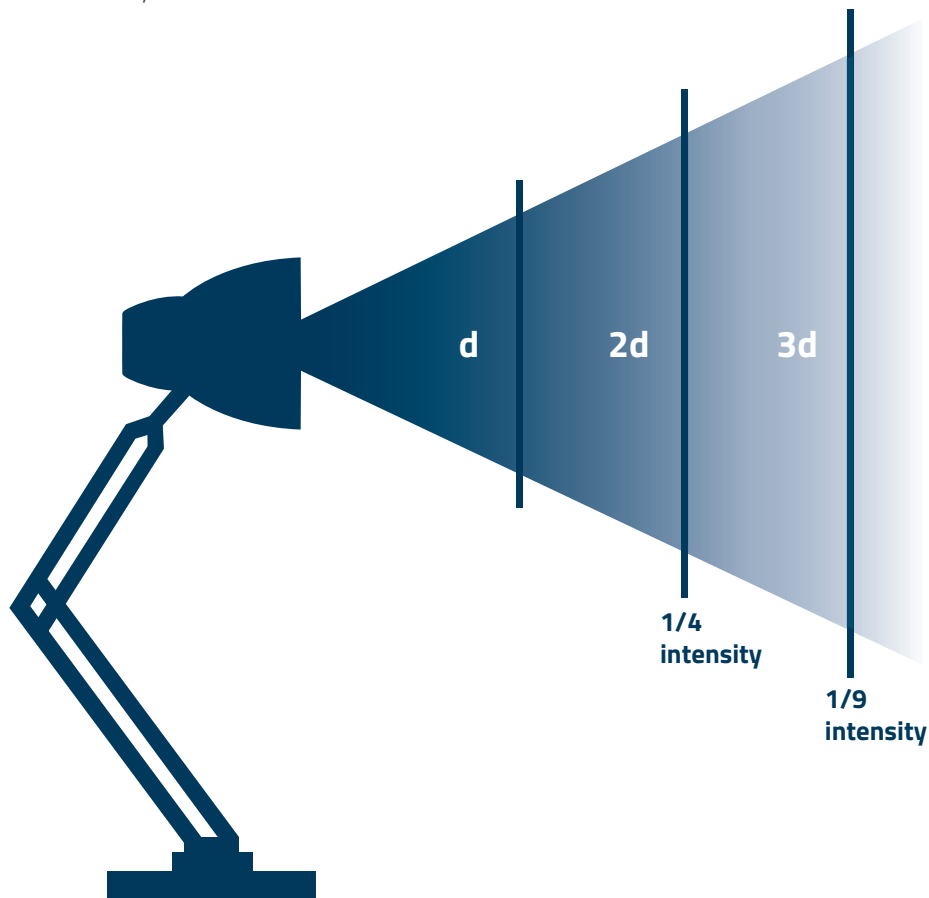
Extend Your Safety



THE ROLE OF DISTANCE IN RADIATION PROTECTION

THE INVERSE SQUARE LAW

The inverse square law describes the principle of dose reduction as the distance from the source increases. It states that a specified physical quantity or intensity (radiation intensity in our case) is inversely proportional to the square of the distance from the source of that physical quantity. Thus if you double the distance you reduce the dose by a factor of four.

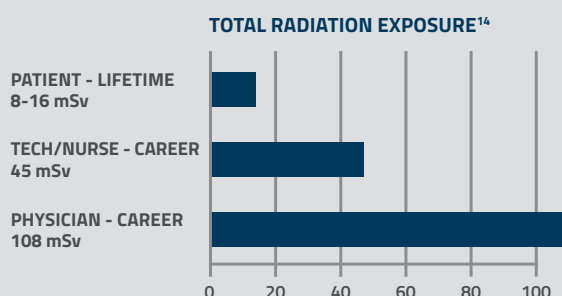


RADIATION RISK

Interventionalists and their staff are exposed to high amounts of radiation due to the long, complicated procedures performed every day and their proximity to the radiation source. The effects of the exposure may not be felt for years to come, since radiation-induced cancers have a biological latency of more than 10 years¹³.

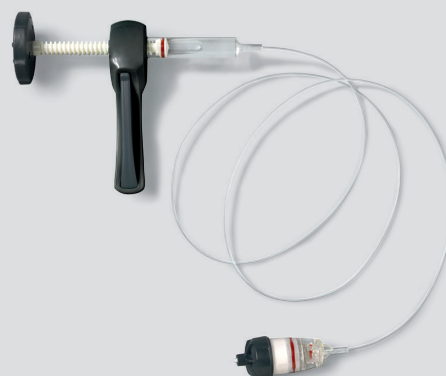
RADIATION EXPOSURE

On any given day exposure to radiation may seem low compared to the dose received by patient. Unfortunately the radiation risk is cumulative, since the radiation exposure occurs throughout the entire career of the operator. The exposure is significantly higher for the operators rather than for the patients¹⁴.



EXTEND YOUR SAFETY WITH MENDEC® AQUA

Mendec® Aqua has been developed with the precise intent to enhance the protection of the operators. The distance from the fluoroscope plays a major role in reducing the absorbed radiation dose. Thanks to its 155 cm tube it allows the operator to stand away from the radiation source, and to significantly reduce radiation exposure.



REDUCE EXPOSURE WITH MI-DOSE¹³

Monitor Exposure: Wear a dosimeter in the cath lab at all times and leverage real-time dose monitoring when available.

Imaging Quality: Maximize the image quality and limit the exposure with appropriate table height, fluoroscopy rate (mA) and kV value.

Distance from source: Distance from X-ray source should be maximized. As distance doubles, exposure decreases by a factor of 4.

Optimal Technique: Monitor orientation and angulation and if possible avoid LAO cranial (highest scatter). Avoid unnecessary fluoroscopy and use virtual collimation, last image hold, and storage of X-ray fluoroscopy.

Shielding: Use personal protective equipment (PPE) and fixed barriers to reduce scatter radiation.

Exposure to the patient: Include factors such as age, gender, obesity, and previous exposure when choosing an imaging modality. Record key exposure metrics in patient records.*

* Recorded by most modern imaging equipment: Total air kerma-area product (KKA).
Peak skin dose (PSD), Fluoroscopic time (FT)

MENDEC® AQUA EXTEND YOUR SAFETY

Mendec® Aqua is the revolutionary hydraulic delivery system for spinal resin, that assures safety & control during vertebral augmentation procedures. It's been designed to easily deliver even high viscosity spinal resins.

ADVANTAGES:

- **Significant Radiation Exposure Reduction:** standing 155 cm away from the radiation beam allows the operator to receive a significantly lower dose of radiation. Similar systems with a length of about 120 cm showed a reduction of 70% of radiation exposure.

- **Hydraulic Power:** the hydraulic system allows to multiply the force applied by the operator, making it 3 times stronger, allowing to easily extrude high viscosity resins.

- **Total extrusion control:** Mendec® Aqua offers total extrusion control. Cement extrusion can be blocked immediately just by screwing the system anti-clockwise.

- **Torque limiter:** the exclusive torque limiter is a mechanism that prevents the pressure applied to become excessive. When the pressure limit is reached the mechanism will idle.



**MENDEC® AQUA
PACKAGE CONTENT:**
hydraulic delivery gun
and 9,9cc cartridge.
Code ASC0020

**MENDEC® AQUA CARTRIDGE
PACKAGE CONTENT**
One 9,9 cc sterile single use
extra Mendec Aqua Cartridge
Code ASC0030

EXTEND YOUR SAFETY WITH OUR SAFEST COMBINATION

MENDEC® AQUA + MENDEC® SPINE HV SYSTEM



Scan the QR code
and discover
how easy is
to extend
your safety

Mendec® Aqua and Mendec® Spine HV System have been study to be our best and safest combination. It combines the benefits of the all-in-one closed system with the benefits of the hydraulic gun.

OPTION A - WITH MENDEC® SPINE HV SYSTEM



OPTION B - WITH OTHER SPINAL RESIN

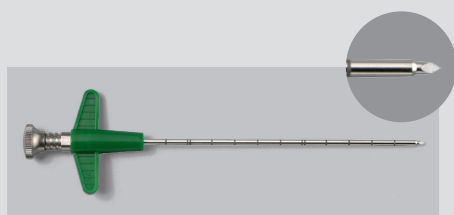


BONE INJECTION NEEDLES

We offer a wide range of needles with different 4 sizes and 2 different tip types.

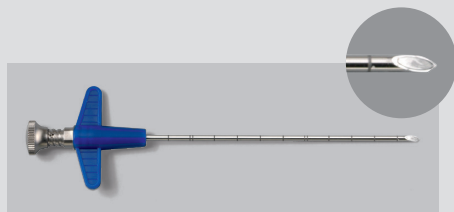
ADVANTAGES:

- Luer-Lock connection system
- Shock resistant metal head
- Ergonomic handle in radiotransparent plastic or steel
- Needle direction marker



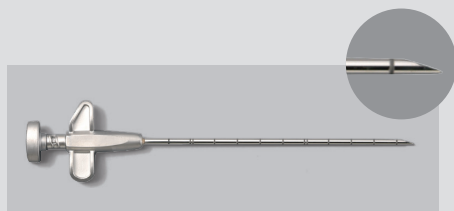
Diamond Tip

9 gauge x 150 mm - Code SPN0915	13 gauge x 120 mm - Code SPN1312
11 gauge x 120 mm - Code SPN1112	15 gauge x 120 mm - Code SPN1512



Beveled Tip

9 gauge x 150 mm - Code ASB0000	13 gauge x 120 mm - Code ASB0020
11 gauge x 120 mm - Code ASB0010	15 gauge x 120 mm - Code ASB0120



Beveled Tip with stainless steel head

9 gauge x 150 mm - Code ASB0080	13 gauge x 120 mm - Code ASB0100
11 gauge x 120 mm - Code ASB0090	15 gauge x 120 mm - Code ASB0110

FREEZER RING

Freezer Ring is a refrigerating device to be used with Mendec® Spine Kit to extend the time available for the resin extrusion. Freezer Ring needs to be stored in freezer before use.

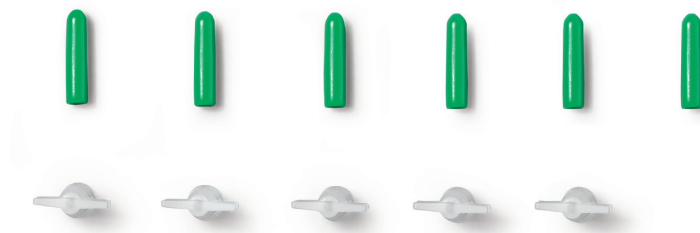
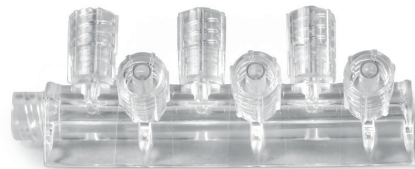


Code ASB0050

MENDEC® V-FILL

Mendec® V-Fill is a manifold that can fill up to six fillers with acrylic resins at the same time. The system perfectly works with Mendec® Spine MV System and Mendec® Spine HV System, but can be connected with any luer lock device. The device is composed by a manifold, 5 luer lock caps, a female-female luer lock connector and 6 vented caps.

Code ASC0000



Preparation of Mendec® V Fill. Scan the QR Code and watch the video tutorial

XTRUDER®

Xtruder® is the device for easy and fast application of spinal resins. The specially designed shape and size of the ergonomic grip allow very easy extrusion of medium and high viscosity resins. Through HP Connection Tube (sold separately) it can be connected to any luer lock needle.

XTruder®
Code ASA0390

HP Connection Tube
Code ASB0250



Scan the QR Code and discover how to use Mendec® Spine HV System with XTruder®



ORDERING INFORMATION

MENDEC® LINE		
CODE	PRODUCT	DETAILS
1230	Mendec® Spine	20 g
13C2000	Mendec® Spine Kit	20 g with extrusion gun
13C2050	Mendec® Spine MV System (EU only)	20 g all-in-one mixing and delivery device
13C2040	Mendec® Spine HV System	18 g all-in-one mixing device
13C2041	Mendec® Spine HV System (US market)	18 g all-in-one mixing device
ASC0020	Mendec® Aqua	Hydraulic delivery gun
ASC0030	Mendec® Aqua Cartridge	9,9cc extra cartridge
ASC0000	Mendec® V-Fill	Manifold
ASB0050	Freezer Ring	

BONE INJECTION NEEDLES	
CODE	PRODUCT
ASB0000	Needle beveled tip 9 Gauge 150 mm
ASB0010	Needle beveled tip 11 Gauge 120 mm
ASB0020	Needle beveled tip 13 Gauge 120 mm
ASB0120	Needle beveled tip 15 Gauge 120 mm
SPN0915	Needle diamond tip 9 Gauge 150 mm
SPN1112	Needle diamond tip 11 Gauge 120 mm
SPN1312	Needle diamond tip 13 Gauge 120 mm
SPN1512	Needle diamond tip 15 Gauge 120 mm
ASB0080	Stainless Steel Needle beveled tip 9 Gauge 150 mm
ASB0090	Stainless Steel Needle beveled tip 11 Gauge 120 mm
ASB0100	Stainless Steel Needle beveled tip 13 Gauge 120 mm
ASB0110	Stainless Steel Needle beveled tip 15 Gauge 120 mm

OTHER ACCESSORIES	
CODE	PRODUCT
ASA0390	XTruder®
ASB0250	HP Connection Tube

BIBLIOGRAPHY

1. Galibert P, Deramond H, Rosat P, Le Gars D, **Preliminary note on the treatment of vertebral angioma by percutaneous acrylic vertebroplasty**, *Neurochirurgie*. 1987;33(2):1668.
2. Carpeggiani P, **Percutaneous vertebroplasty (PVP) using Mendec® Spine** *Clinical Report Sept, 2003*
3. Carpeggiani P, **Percutaneous vertebroplasty: Technical aspects and news** *Review 2004*
4. Carpeggiani P, Puglioli M, Valleriani A, Mazzantini M et al. **Osteoporotic fractures with cleft treated with vertebroplasty: clinical results, pathologic and technical aspects**, *SpineWeek 2004, Porto (Portugal)*
5. Bosniakovic P, **Mendec® Spine Kit Percutaneous vertebroplasty delivery system and acrylic resin** *(Clinical study), Clinical report Jan. 2005*
6. Anselmetti G, Bonaldi G, Baruzzi, Carpeggiani P et al. **Percutaneous vertebroplasty: a multicenter italian experience in over 1700 patients**, *RSNA 2005 Chicago (USA)*
7. Carpeggiani P, **Percutaneous vertebroplasty (PVP) using Mendec® Spine**, *Clinical Report Sept. 2006*
8. Callari G, Vallone S, **Anterior medial transoral C2 Vertebroplasty. A Case Report**, *The Neuroradiology Journal – Vol.20: 2425, April 200*
9. Anselmetti GC, Carpeggiani P, **Multiple levels vertebroplasty: feasibility, safety and efficacy**, *WFITN 2007 Beijing (China) – Sept. 2007*
10. Foo LS, Yeo W, Fook S, Guo CM, Chen JL, Yue WM, Tan SB **Results, experience and technical points learnt with use of the SKy Bone Expander kyphoplasty system for osteoporotic vertebral compression fractures: a prospective study of 40 patients with a minimum of 12 months of follow-up**. *Eur Spine J*. 2007 Nov;16(11):194450
11. Caudana R, Renzi Brivio L, Ventura L, Aitini E, Rozzanigo U, Barai G, **CT-guided percutaneous vertebroplasty: personal experience in the treatment of osteoporotic fractures and dorsolumbar metastases**. *Radiol Med (Torino)*. 2008 Feb;113(1):11433
12. Schils F, Schoojans W, Struelens L, **The surgeon's real dose exposure during balloon kyphoplasty procedure and evaluation of the cement delivery system: a prospective study**, *Eur Spine J* (2013) 22:1758–1764
13. ORSIF - Organization for Occupational Radiation Safety in Interventional Fluoroscopy, **Reduce Radiation Exposure, You Can Have an Impact** *Eposter*
14. ORSIF - Organization for Occupational Radiation Safety in Interventional Fluoroscopy, **Career Exposure in the Cath Lab** *video*
15. Loeffel M. et al. **Vertebroplasty: experimental characterization of polymethylmethacrylate bone cement spreading as a function of viscosity, bone porosity, and flow rate**. *Spine (Phila Pa 1976)*. 2008 May 20;33(12):1352-9
16. Boger A., Wheeler K., **A Medium Viscous Acrylic Cement Enhances Uniformity of Cement Filling and Reduces Leakage in Cancellous Bone Augmentation**, *ISRN Materials Science Volume 2011, Article ID 780510*

TECRES S.p.A.

Via Andrea Doria, 6 - 37066 Sommacampagna (VR) - Italy
T +39 045 9217311 - F +39 0459217330 - www.tecres.it
Cap. Soc. euro 850.000,00 i.v. - C.F. e Reg. Imprese VR 01346810235
P.IVA 02042700233 - REA n° 211053 - Società a socio unico
soggetta ad attività di direzione e coordinamento di Demetra Holding S.p.A.

