

Low Viscosity Bone Cement for Vertebroplasty, Kyphoplasty & Pedicular Screw Augmentation







SPINE-FIX® is a bone cement with a high amount of radiopaque agent for vertebroplasty, kyphoplasty & pedicular screw augmentation procedures. SPINE-FIX® allows consolidation of the vertebral body with an effective and rapid pain relief.

Its composition has been designed to get the most suitable viscosity for pedicular screw augmentation



SPINEFIX® is indicated for the fixation of pathological fractures of bone using cementoplasty procedures such as vertebroplasty and kyphoplasty. Painful vertebral compression fractures of the vertebral body may result from osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma). It can also be used for augmentation of the fixation strength of pedicular screws or in combined procedures with internal fixation devices intended for pmma augmentation.

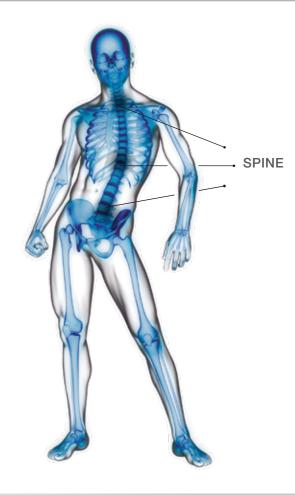
### COMPOSITION

### Powder (21g):

Polymethylmethacrylate	64.4
Benzoyl peroxide	0.6 9
Barium sulfate	25.0 9
Hydroxyapatite	10.0 9

### **Liquid (9.2g):**

Methyl Methacrylate	97.6 %
N-N dimethyl-p-toluidine	2.4 %
Hydroquinone	20 ppm



# Technical data & clinical cases:

#### PHYSICO- CHEMICAL COMPOSITION

Two components PMMA bone cement : polymer powder containing HA particles and liquid monomer.

### BIOCOMPATIBLE

Compliant to ISO 10993-1

#### **EASY INJECTION**

The initial low viscosity facilitates mixing and filling of the injection system. SPINE-FIX® has a polymerisation time wich guarantees a complete secure process. The physician gets sufficient time to slowly inject and perform filling of two vertebrae levels with one dose.

#### VISCOSITY

Thanks to its low viscosity SPINE-FIX® is suitable for cementoplasty procedures such as vertebroplasty, kyphoplasty and pedicle augmentation.

#### **RADIO OPACITY**

The level of radio-opaque agent (35%) provides a good contrast allowing the physician to visualize the flow of the bone cement into the vertebral body during injection time.

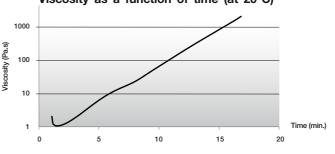
#### VOLUME

After mixing the injectable volume is up to 10mL, for 1 or 2 vertebrae.

# Influence Of Temperature On Handling Times: (+/- 1 mn)



Viscosity as a function of time (at 20°C)



The viscosity of SPINE-FIX® Cement allows an infiltration into the cancellous bone. Trabecular fixation is enhanced and micromovements within the vertebra are avoided.

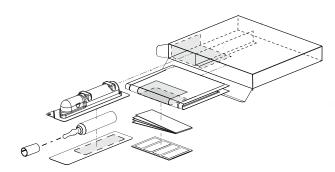




# Storage & Products

Bone cements are delivered sterile. They must be stored in their unopened original packaging away from the light, at a maximum temperature of 25°C.

Keep away from ignition source.





SPINE-FIX® is a two components bone cement: the liquid monomer is in a sterile ampoule packaged in a blister and the powder in a sterile double pouch. Single use. Do not re-sterilize. For any further information, please refer to the IFU.

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DESIGNATION	REFERENCE	
SPINE-FIX®	T040320S	Class IIb
S5M <sup>®</sup> EASYKIT <sup>®</sup> M MINI-MALAX Mixing & injection system	T060407 T060415 T060406	Class Is
Vertebroplasty Needles	Contact us	





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### Distributed by

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