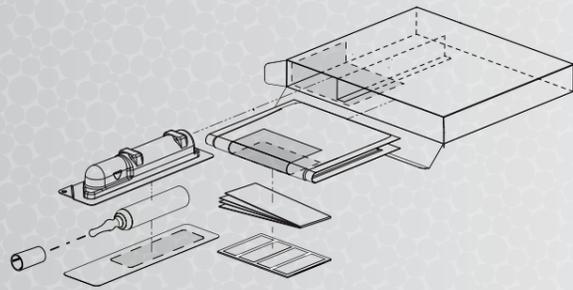


Spine-Fix®

Radiopaque Bone Cement

Storage

Spine-Fix® is supplied sterile, ready to be used in the operation theatre. The cement is to be stored in its original, unopened packaging, in a dry, clean place, away from light and at a temperature of 25°C max. Keep away from ignition source.



Spine-Fix®

Radiopaque Bone Cement

Products

Each dose of Spine-Fix® is presented in two components : the liquid monomer is in a sterile ampoule packaged in a blister and the powder in a sterile double pouch. Single use only. Do not reuse, reprocess or resterilize. For any further information, please refer to the IFU.



DESIGNATION	REFERENCE
Spine-Fix®	T040320S
ADDITIONAL ITEMS APART	
S5 KIT	T060410
EASY KIT	T060409
MINI-MALAX Mixing & injection system	T060406
TEKNIMED NEEDLES	Contact us

Bone cement for Vertebroplasty, Kyphoplasty & Pedicular Screw

Patented



Class IIb
CE 0086

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Distributed by

Manufactured by

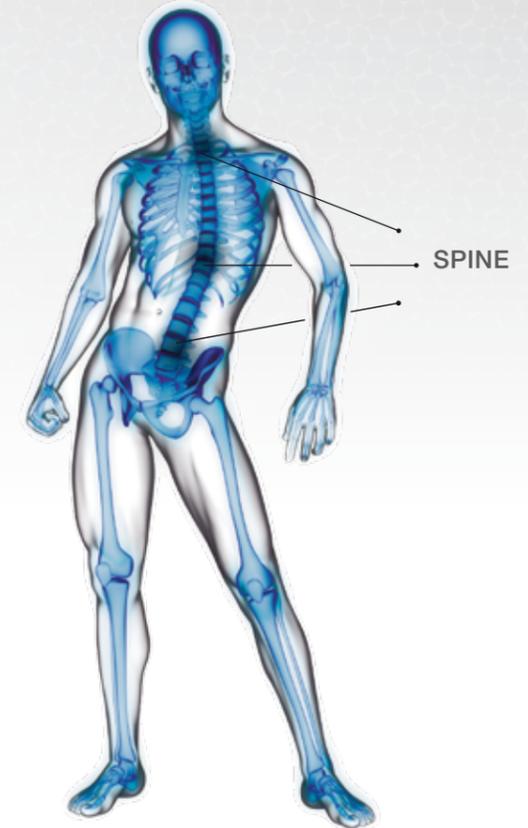


Spine-Fix is a ready to use bone cement with a high amount of radiopaque agent for vertebroplasty, kyphoplasty & pedicular screw injection procedures. Spine-Fix allows an excellent consolidation of the vertebral body with an effective and rapid pain relief.

The handling times of Spine-fix have been specifically developed to give to the surgeon a comfortable application phase.

Indications

Spine-Fix® is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty, kyphoplasty procedure. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma) or malignant lesions (metastatic cancers, myeloma) and augmentation of the fixation strength of pedicular screws or in combined procedures with internal fixation devices intended for pmma augmentation.



LOW VISCOSITY

LOADED WITH HYDROXYAPATITE FOR A BETTER BIOCOMPATIBILITY

EASY & SAFE INJECTION

STANDARD RADIO-OPACITY 35 %

INJECTION TIME: 12MN

Properties

PHYSICO- CHEMICAL COMPOSITION

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

BIOCOMPATIBLE

The 10% HA component gives to the product a better biocompatibility.

EASY INJECTION

The initial low viscosity facilitates mixing and filling of the injection system. Spine-Fix has the right polymerisation time, guarantee of a complete secure process. The physician gets sufficient time to slowly inject and perform filling

of two vertebrae levels with one dose.

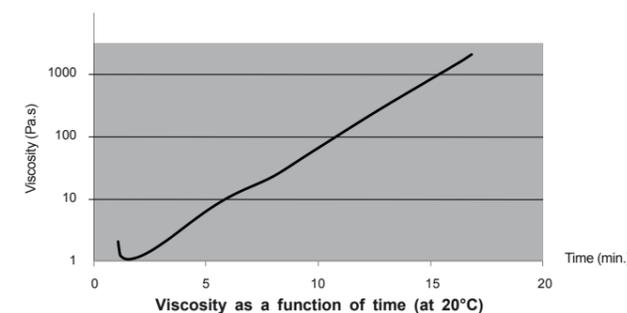
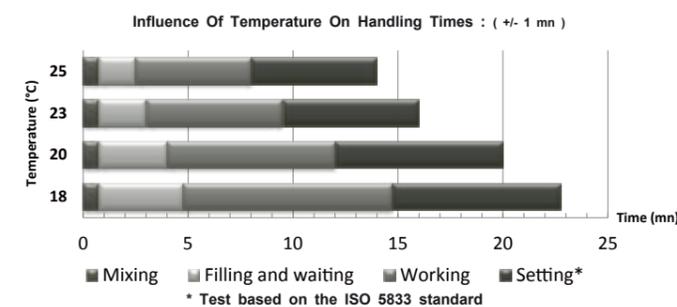
IDEAL VISCOSITY

Spine-fix is not too liquid to avoid leakages into the vertebra "touchy" areas, not too pasty in order to be injected without any problem, through trocar of Gauge 11 to 13.

IDEAL RADIO OPACITY

Spine-Fix® has the right rate of radio-opaque agent (35%) to allow the physician to perfectly follow the flow of the bone cement into the vertebral body during injection time.

Technical data & clinical cases :



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

Patient : 59 years old, osteoporotic vertebral compression fracture Homogenous bone filling

