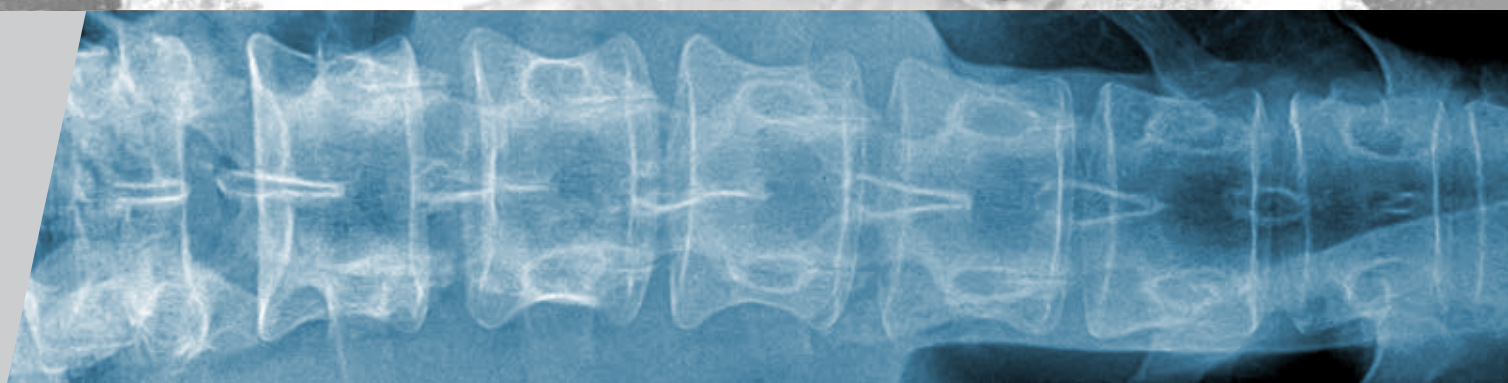




F20[®]

Radiopaque Bone Cement



Medium Viscosity Bone Cement
for Vertebroplasty & Kyphoplasty

 **Teknimed**

F20[®]

Radiopaque Bone Cement

F20[®] is a medium viscosity, low exothermic, self-curing bone cement with a high content of radiopaque agent for an optimized and safe level of visualization during percutaneous vertebral bone augmentation procedures.

Its composition has been designed to get the most suitable handling properties for surgeon's convenience.



Properties

PHYSICO-CHEMICAL COMPOSITION

Bone cement with two components. PMMA bone cement made of powder polymer and liquid monomer

BIOCOMPATIBLE

Compliant to ISO 10993-1.

EASILY INJECTABLE

The long working time of 22 minutes at 20° C allows to perform a multi level injection procedure.

VISCOSITY

The medium viscosity of **F20[®]** allows an homogeneous bone filling and prevents leakages.

RADIO-OPACITY

F20[®] has a high content of opacifier for an ideal and maximum visibility during injection.

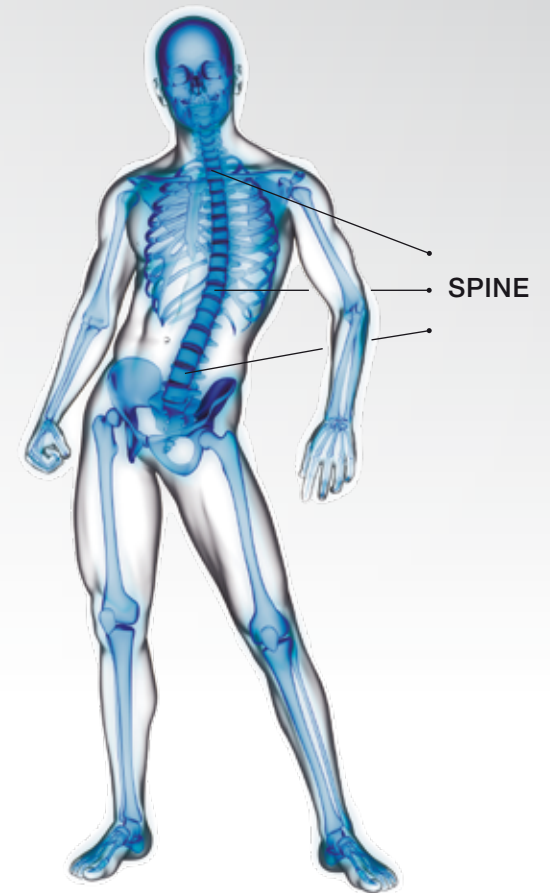
LOW EXOTHERMICITY (less than 45°C)

F20[®] prevents necrosis of bone tissues thanks to its low exothermic reaction which is much lower than other vertebroplasty bone cements.



Indications

The **F20[®]** is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures of the vertebral body may result from osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).



COMPOSITION

Powder (25.8g):

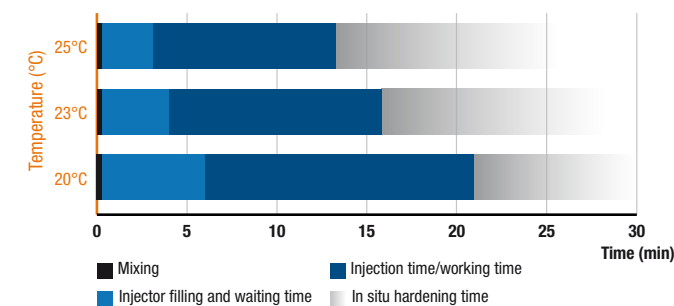
Poly methyl methacrylate	19.2 %
Methyl methacrylate/styrene copolymer	35.3 %
Benzoyl peroxide	0.5 %
Zirconium Dioxide	45 %

Liquid (9.2g):

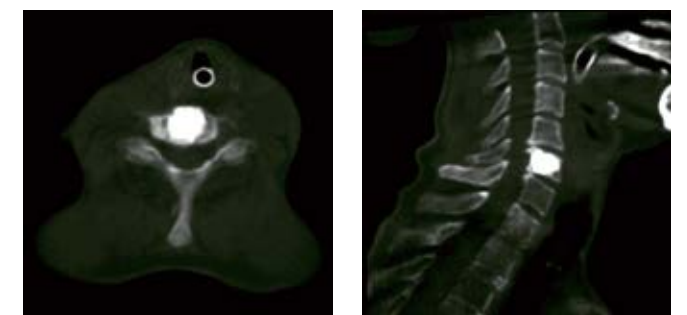
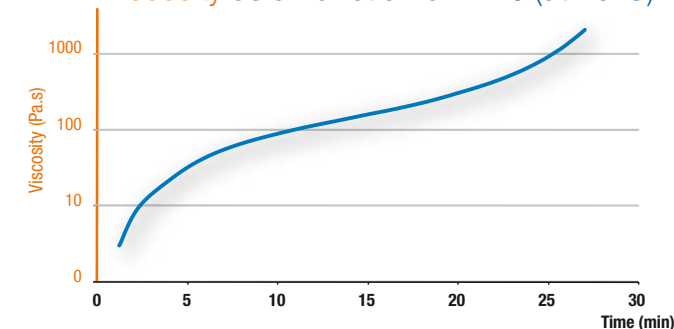
Methyl methacrylate	99.3 %
N-N dimethyl-p-toluidine	0.7 %
Hydroquinone	20 ppm

Technical data & Clinical cases :

Handling Times as a Function of Temperature:
(+/- 1 min)



Viscosity as a Function of Time (at 20°C)



CERVICAL **F20[®]** APPLICATION

F20[®] cement has an ideal injection time and viscosity to perform the procedure to provide the patient pain relief.

F20[®] has a working time that provides the ability to perform multiple levels without concern for early cement setting.

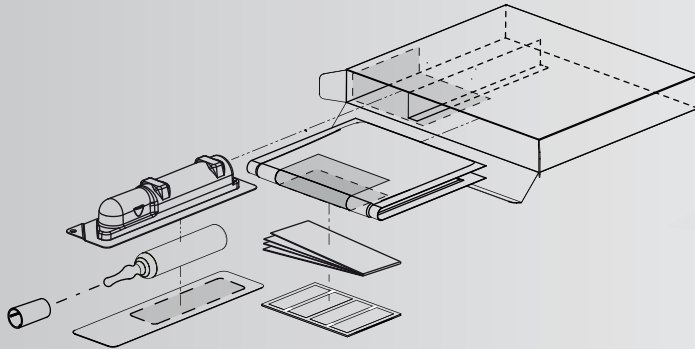
F20[®]

Radiopaque Bone Cement

Storage

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.



Products

Each dose of F20[®] is packaged in two sterile components :the liquid monomer in a sterile ampoule and the powder polymer within a sterile double pouch. Single use only. Do not reuse, reprocess or resterilize. For any further information, please refer to the IFU.



DESIGNATION	REFERENCE	
F20 [®]	T040520	Class IIb
ADDITIONAL ITEMS APART		
S5M [®] KIT MedV+ [®]	T060407 T060417	Class Is
Vertebroplasty Needles	Contact us	



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CAUTION:

U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) or on the physician's prescription.

This device is cleared to be sold on US market

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