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PAN MEDICAL | US CORPORATION

RADIOPAQUE BONE CEMENT FOR VERTEBROPLASTY AND KYPHOPLASTY

TECHNICAL REPORT

DESCRIPTION

OSTEOFLEX® is a PMMA bone cement, specially designed for percutaneous bone augmentation procedures.

Its composition has been optimized to give the best properties to the surgeons to treat patients in a safety way.

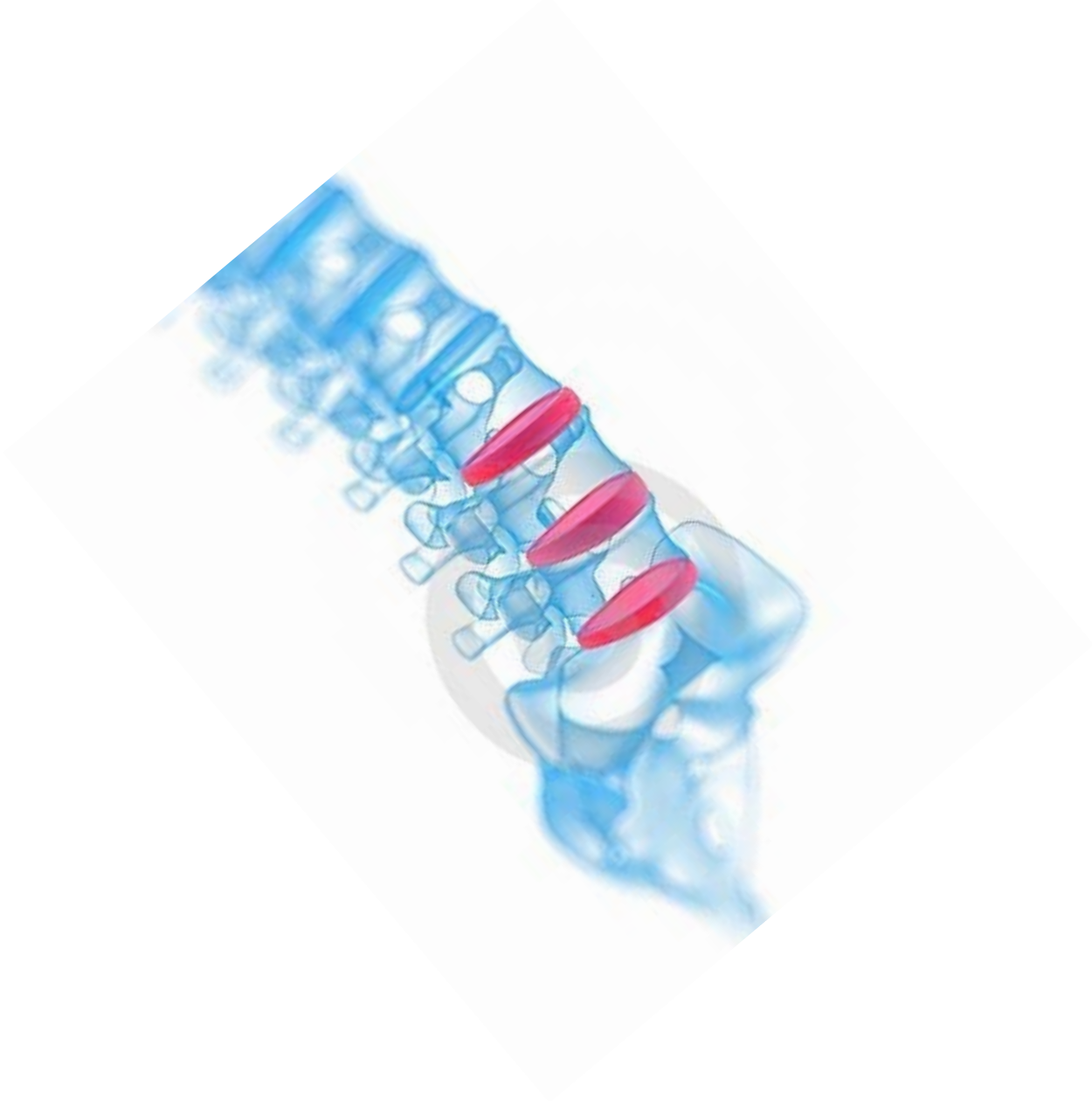
After a fast mixing time, **OSTEOFLEX®** is ready to use in a paste form.

It is a medium viscosity bone cement with a very low exothermicity.

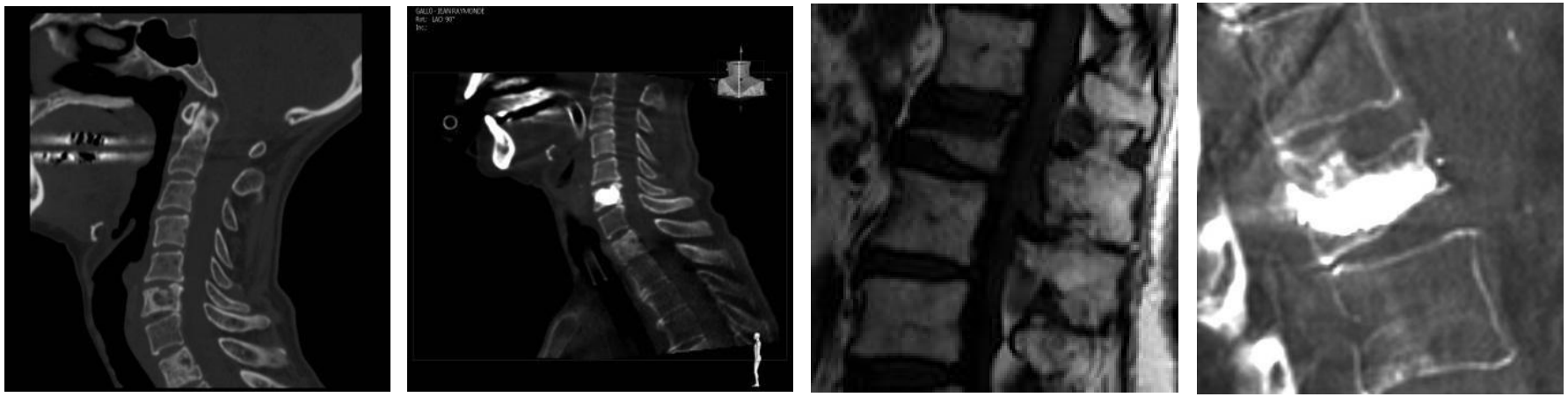
INDICATIONS

OSTEOFLEX® is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

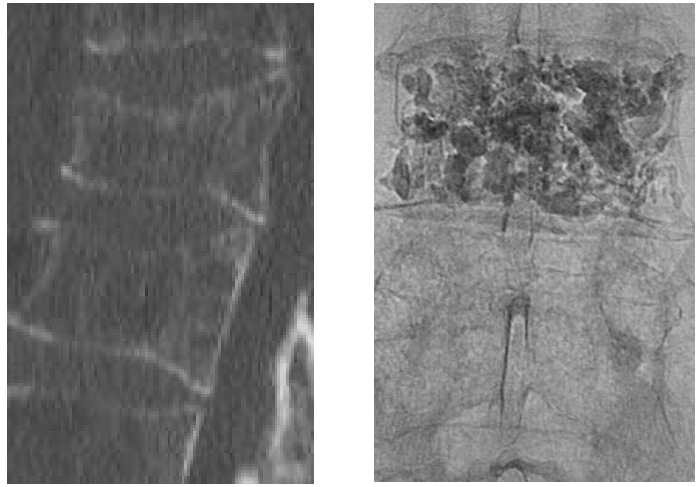
- Painful osteoporotic vertebral compression fractures
- Benign symptomatic lesions (haemangioma)
- Malignant lesions (tumors, metastasis lesions, myeloma)



CLINICAL DATA



Treatment of vertebral myeloma



Treatment of L2 vertebral myeloma

SPECIAL PROPERTIES

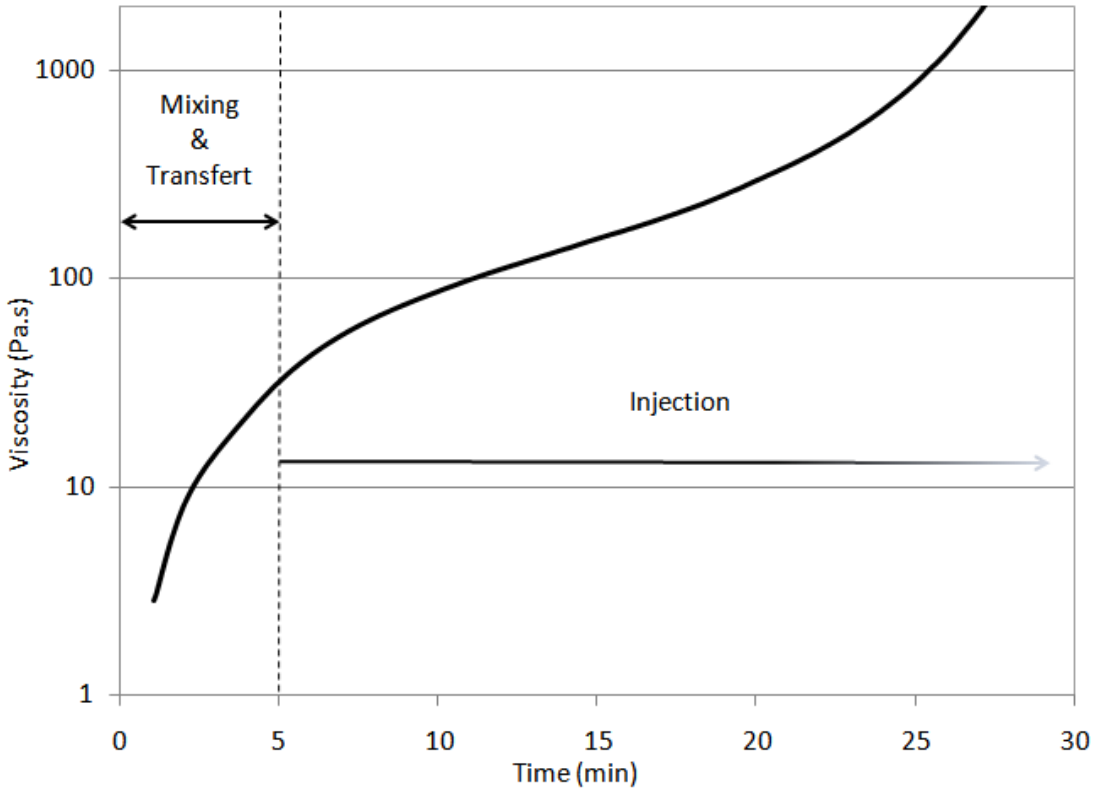
Viscosity

The viscosity curve of **OSTEOFLEX®** follows a particular profile with a long working time up to 20 minutes.

The viscosity kinetics and setting time of **OSTEOFLEX®** have been specifically designed for a safe application.

It is a medium viscosity bone cement able to suitably flow from the injection system through a trocar into the bone.

This special and stable viscosity over a period of 20 minutes is largely enough to perform a continuous radiological injection checking.

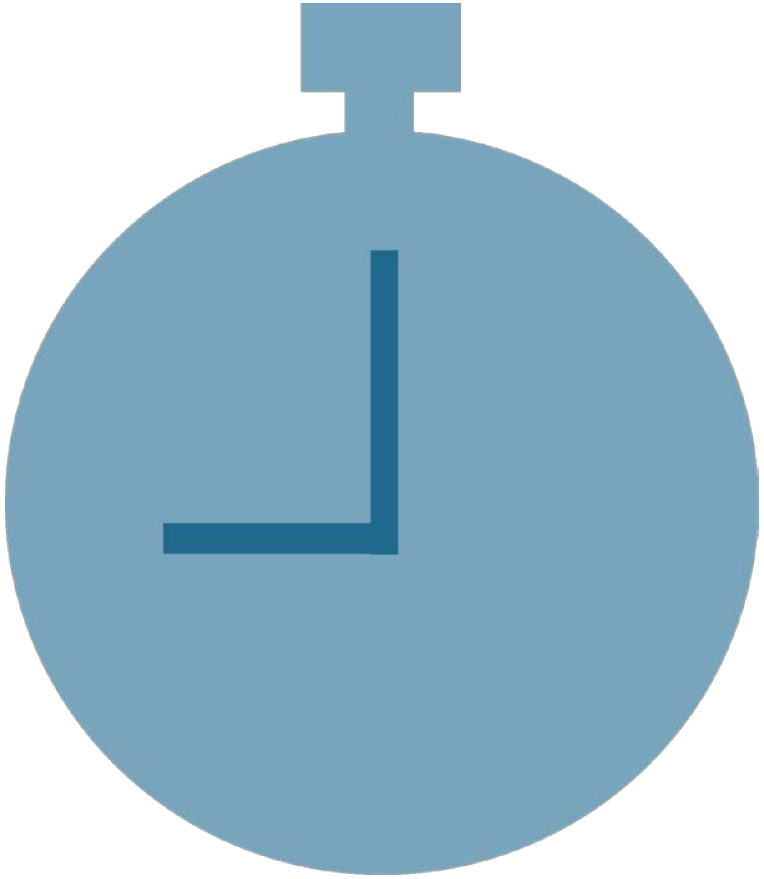


Viscosity profile of OSTEOFLEX® at 20°C

APPLICATION TIME

The long working time of **OSTEOFLEX®** (20 minutes) is sufficient to:

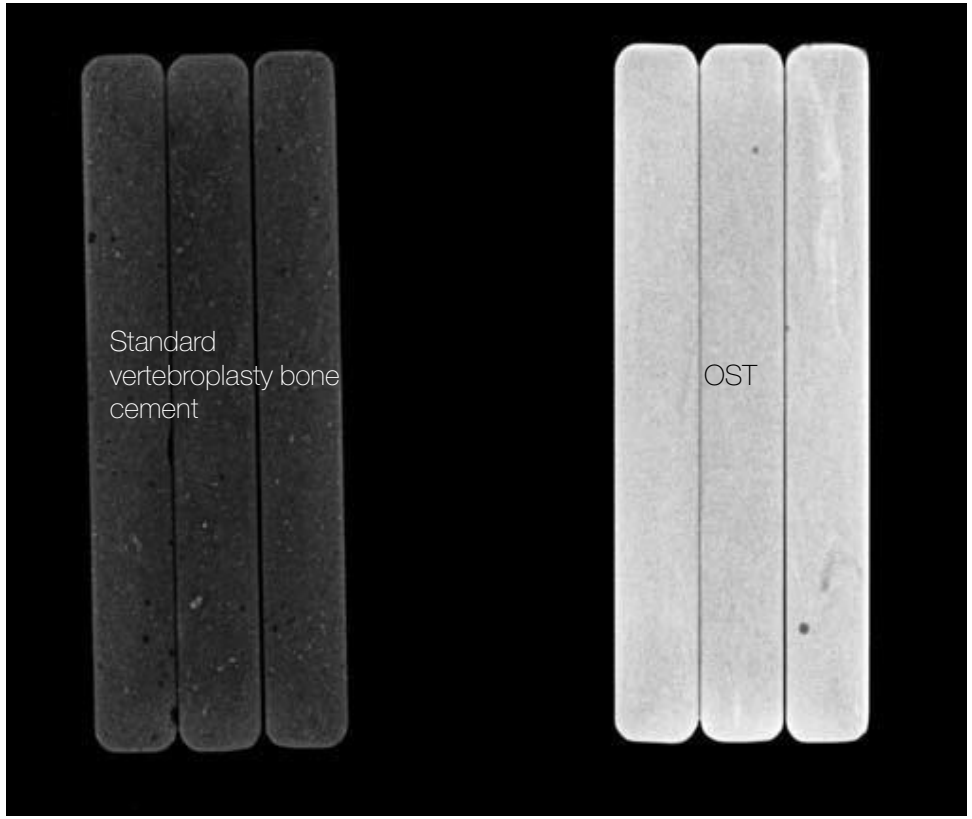
- Inject the cement into the vertebral body
- Take time to check via different views
- Work comfortably under CT scan
- Perform a multi level injection procedure.



RADIOPACITY

OSTEOFLEX® has a high rate of zirconium dioxide opacifier for an ideal and maximum visibility during injection.

It can be used either under fluoroscopy or CT scan.

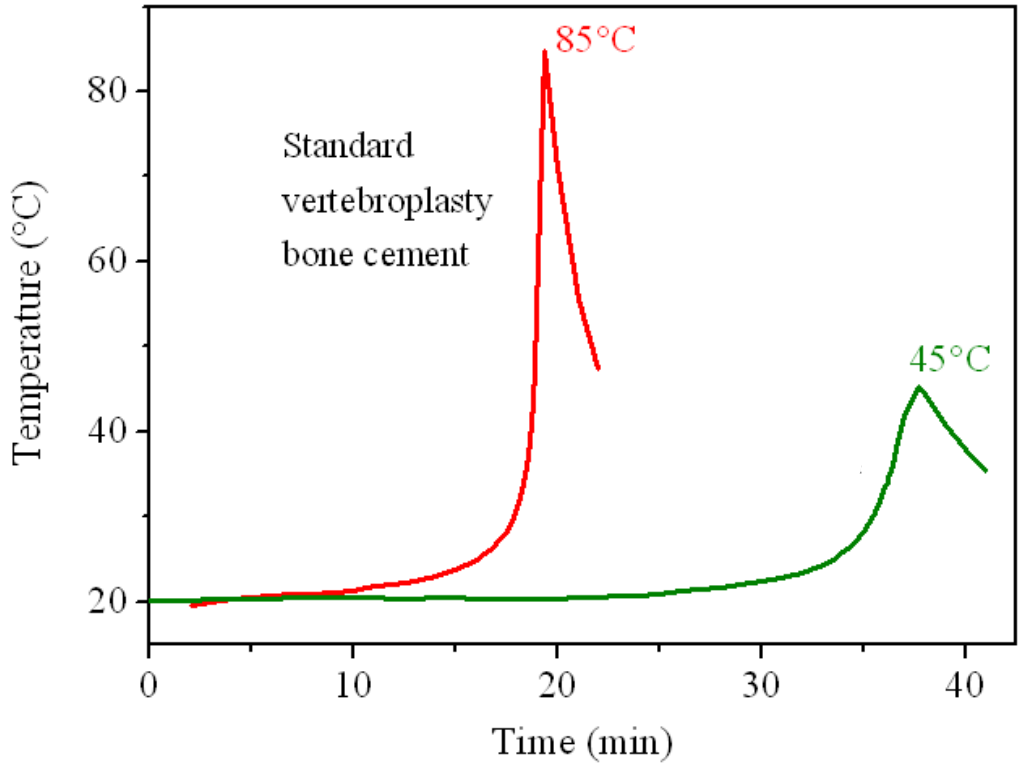


OSTEOFLEX® radiopacity

LOW EXOTHERMIC REACTION

The maximum temperature during the setting is about 45°C (according to ISO5833 standard).

This extraordinary low exothermic reaction of **OSTEOFLEX®** prevents the risk of thermic necrosis of bone tissue, in comparison with standard bone cements.



PREPARATION AND INJECTION

Mixing phase

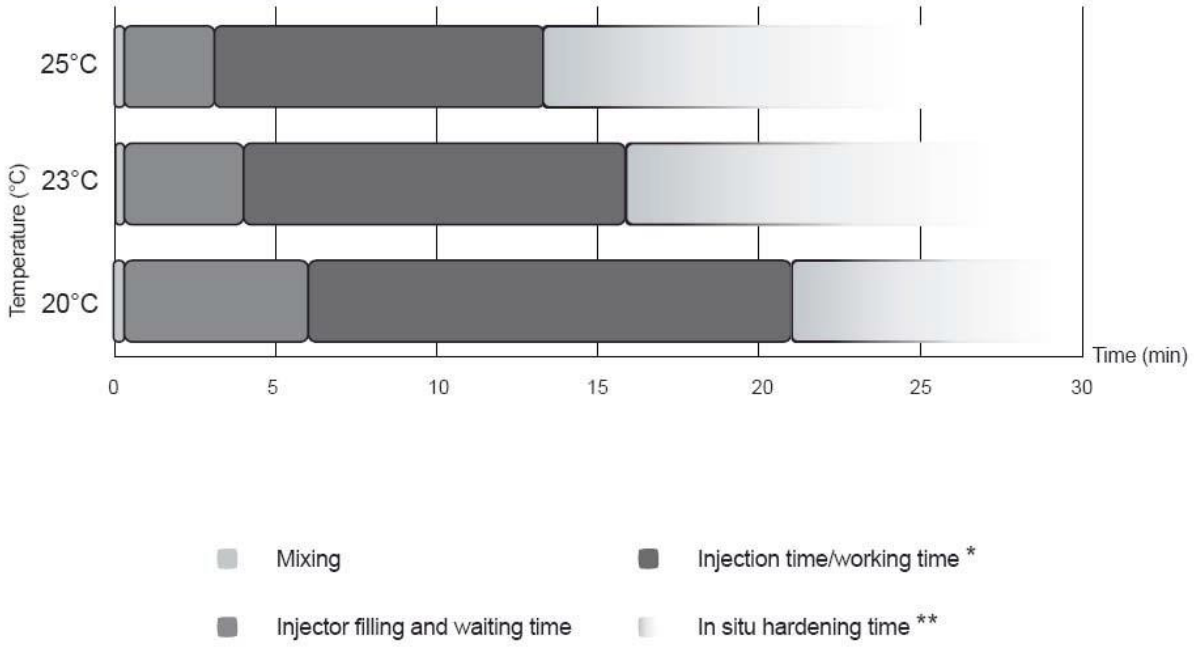
- The two components (powder and liquid) have to be mixed correctly for 30 seconds in the shaker.

Filling the syringe

- Transfer the cement into syringes.

Injecting phase (up to 20 minutes)

- No waiting time is required. Immediately after filling the injector (approx. 5 minutes after beginning the mixing process), the cement becomes a paste, ready to be injected safely.
- This paste constitution corresponds to the best viscosity preventing leakage.
- Still injectable up to 20 minutes at 20°C.
- The injection of cement must take place under continuous radiological guidance. When the operator estimates that the vertebral filling is satisfactory or when a risk of leak of cement becomes apparent, the injection can be stopped.



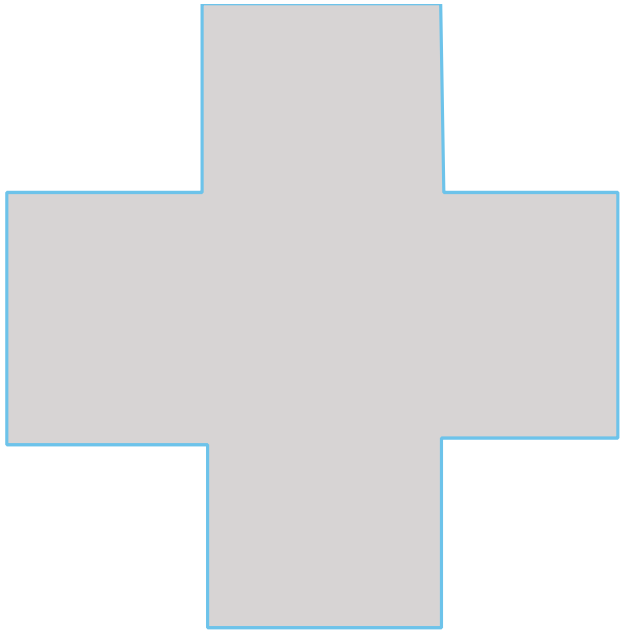
As usually recommended, when the cement injection is finished, keep the patient in place for 15 minutes to get a complete in situ polymerization of the cement.

PRODUCT CLASSIFICATION

Class: IIb medical device

Applicable directive: 93/42/EEC

OSTEOFLEX® comes in the form of a sterile liquid ampoule of monomer and a sterile powder pouch of powder polymer.



MEDICAL DEVICES

PACKAGING AND STERILISATION

The liquid in the ampoule is sterilized by ultra-filtration, and the ampoule blister is sterilized using ethylene oxide. The powder is inside a double sterile pouch. This double pouch is sterilized by 25 kGy gamma rays.

Disposable, single use only.

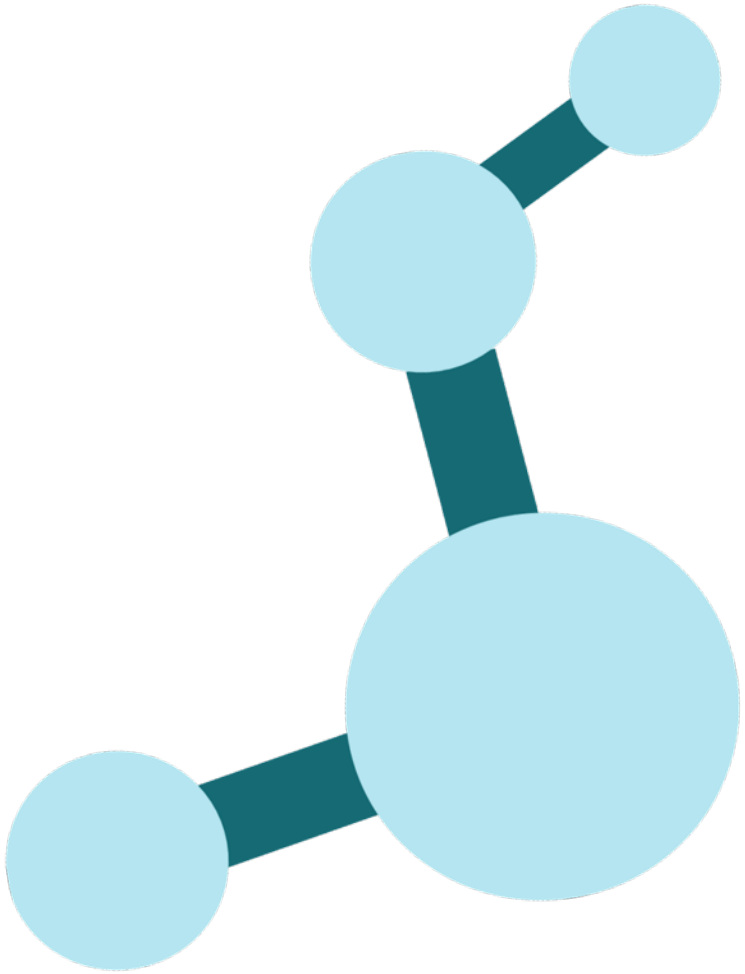
COMPOSITION

Powder

Poly methyl methacrylate and copolymer
Benzoylperoxide
Zirconium Dioxide

Liquid

Methyl methacrylate
N-N dimethyl-p-toluidine
Hydroquinone



Pan Medical Ltd
Barnett Way
Barnwood
Gloucester
GL4 3RT

www.pan-medical.co.uk

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