

Surgical Cement with antibiotic

GENTAFIX® **1**&**3** are radiopaque and self-hardening bone cements

- Containing Gentamicin, an aminoglycoside antibiotic
- Dedicated to arthroplasty surgery
- Allowing immediate and stable anchorage of implants
- Responding to the needs of surgeons, 2 viscosities for 2 types of applications:

GENTAFIX® 1: high viscosity bone cement for manual application

GENTAFIX® 3: low viscosity bone cement with an optimum fluidity for an easy application with syringe or injection gun

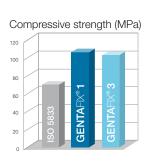


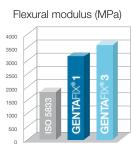
GENTAFIX® 1&3

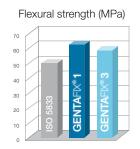
Bone cements advantages

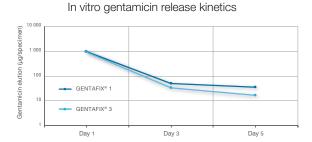
- Mechanical properties above ISO 5833 standard
- Low exothermicity in situ
- Low release of monomer
- Stable fixation of implants
- Barium sulfate as excellent radiopaque agent
- Easy to prepare with a bowl & spatula or in a vacuum mixing system

Mechanical properties higher than ISO 5833 standard¹:









GENTAFIX® bone cements allow local antibiotherapy.

Gentamicin, issued from family of aminosides, has a broad spectrum and is effective against most of the

The quantity of gentamicin contained in one dose of

cement has been optimized to guarantee a long term

bacteria encountered.

release to cure or prevent infections.

(1) Internal reports - Mechanical: CL021913 - GENTAFIX 1 - Intrusion: CL021813 - Release kinetics: CLAV021921

Indications

GENTAFIX® bone cements are intended for use in cemented arthroplasty procedures.

- GENTAFIX® 1 is indicated for primary (shoulder, hip, knee) and revision (knee) surgeries.
- GENTAFIX® 3 is indicated for primary (hip) and revision (hip, knee) surgeries.

Storage & products

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

For any further information, please refer to the IFUs.

REFERENCE

	GENTAFIX® 1 (% w/w)	GENTAFIX® 3 (% w/w)
Liquid phase	14.4g	16.4g
Methylmethacrylate N-Butyl methacrylate N,N Dimethyl-p- toluidine Hydroquinone	84.4 13.2 2.4 20 ppm	84.4 13.2 2.4 20 ppm
Powder phase	41.6g	41.6g
Polymethylmethacrylate Benzoyl Peroxide Gentamicin sulphate (corresponding to 1g base) Barium sulphate	84.3 2.3 3.8 (1.6g) 9.6	84.3 2.3 3.8 (1.6g) 9.6

GENTAFIX® 1 T040140G 41.6 g of powder and 14.4 g of liquid

GENTAFIX® 3 T040340G 41.6 g of powder and 16.4 g of liquid





DESIGNATION



DESIGNATION

REFERENCE

VACUUKIT® T060416 Vacuum mixing & Injection system

Class IIa





DESIGNATION

REFERENCE

SPATULA KIT pack of 10u non sterile

BOWL &

Class I

 $C \in$



T060404

Manufactured by



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