

T040140G / T040340G / T040341G

REF

Basic UDI-DI / IUDI-D de base / UDI-OI báscio / Basis-UDI-DI : 376017740801CS

Surgical cement with gentamicin

Instructions for use

Ciment chirurgical avec gentamicine

Notice d'utilisation

Cemento quirúrgico con gentamicina

Instrucciones de uso

Chirurgischer Zement mit Gentamicin

Gebrauchsanweisung



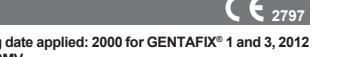
Manufactured in France by / Fabriqué en France par / Fabricado en Francia por / In Frankreich hergestellt von :

TEKNIMED S.A.

65500 VICH EN BIGORRE - FRANCE

Tél. (33)5 34 25 10 60

www.teknimed.com



First CE marking date applied: 2000 for GENTAFIX® 1 and 3, 2012 for GENTAFIX® 3MV

GENERAL INFORMATION

Befor usage must be thoroughly familiarized with the safety rules mentioned in the current instructions for use, as well as the information relating to each product (description, leaflets, etc.). The corresponding information is available from supplier. The healthcare professional should also be informed of the residual risk(s) associated with the product used.

INTENDED USE

GENTAFIX® bone cements are intended for use in cemented arthroplasty procedures (e.g. primary shoulder, hip, knee) and revision (knee) surgery. The corresponding information is available from supplier. The healthcare professional should also be informed of the residual risk(s) associated with the product used.

LIFETIME

GENTAFIX® bone cements are implantable devices whose expected lifetime is 15 years. At the end of this expected lifetime, the cements are not intended to be removed and do not need any maintenance, unless a medical complication would require a surgery.

INDICATIONS

GENTAFIX® bone cements are intended for use in cemented arthroplasty procedures for primary (shoulder, hip, knee) and revision (knee) surgery. GENTAFIX® 1 is indicated for primary (hip, knee) and revision (knee) surgery. GENTAFIX® 3 and 3MV are indicated for primary (hip) and revision (hip, knee) surgery.

TARGET POPULATION

The bone cements are to be used in patients for whom a cemented arthroplasty surgery is indicated.

RECOMMENDED ACCESSORIES

Stérile vacuum mixing and injection system VACUUKIT® T060416 (sold separately).

INSTRUCTIONS FOR USE

Application can be achieved according to the type of cement.

- Procedures other than those listed in the INDICATIONS section, presence of an active or incomplete fixation at the bone site caused by gentamicin non sensitive strains.

- Use in patients with a history of serious neuromuscular disease.

- Hypersensitivity to gentamicin or other constituents of the bone cement.

SIDE EFFECTS AND ADVERSE EVENTS

Undesirable side effects of PMMA bone cements:

- Excessive exothermic reaction.

- Excessive exothermic reaction

