

CERAMENT® G

with Gentamicin

PRODUCT FACT SHEET

THE FIRST & ONLY INJECTABLE ANTIBIOTIC-ELUTING BONE GRAFT INDICATED FOR USE IN THE MANAGEMENT OF BONE INFECTION

COMPOSITION:

CERAMENT Powder	Liquid	Gentamicin Powder
60 wt% α-calcium sulfate hemihydrate (CaS)	Saline: sodium chloride 9 mg/mL liquid	Gentamicin sulfate: providing 17.5 mg of gentamicin/mL of CERAMENT paste (both 5 and 10 mL product)
40 wt% hydroxyapatite (HA) <ul style="list-style-type: none">• A calcium phosphate, with a chemically and structural similarity to the mineral phase of bone• Osteoconductive, which means it forms a direct bond with osteoblasts that form new bone• Engineered in R&D to have a specific size and crystallinity that confers high injectability and slow resorption rate		

REGULATORY INFORMATION:

Regulatory Status:

Medical Device Classification: Class II

FDA Authorized

FDA-Designated Breakthrough Technology

TIP EXTENDERS:

- 11G, 50mm length
- 11G, 100mm length
- Tapered tip

ORDERING INFORMATION

Part #	PRODUCT DESCRIPTION
A0450-11	CERAMENT® G with Gentamicin 5mL
A0450-10	CERAMENT® G with Gentamicin 10mL

TO ORDER, PLEASE CONTACT

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E: us.sales@bonesupport.com

MANUFACTURER

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Product Description:

- CERAMENT G is an implantable bone void filler (device/ drug combination product) indicated for use as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) where there is a need for supplemental bone graft.
- CERAMENT G combines gentamicin sulfate with a bone void filler, consisting of hydroxyapatite and calcium sulfate.
- By eluting gentamicin, CERAMENT G can reduce the recurrence of chronic osteomyelitis from gentamicin-sensitive microorganisms in order to protect bone healing.
- By combining calcium sulfate and hydroxyapatite, a balance is achieved between implant resorption rate and bone remodeling rate. Calcium sulfate acts as a resorbable carrier for hydroxyapatite. Hydroxyapatite has a slow resorption rate and high osteoconductivity providing a scaffold for new bone generation.
- The use of CERAMENT G eliminates the need to harvest autologous bone, thereby avoiding donor site morbidity (e.g., pain, infection, etc.) in patients with a diagnosed infection.
- CERAMENT G may be implanted by an injectable system or inserted as pre-set beads.

Indications:

CERAMENT G is a resorbable, gentamicin-eluting ceramic bone void filler intended for use as a bone void filler in skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) as part of the surgical treatment of osteomyelitis in defects in the extremities.

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CERAMENT G can augment provisional hardware to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

CERAMENT G resorbs and is replaced by bone during the healing process.

CERAMENT[®] G with Gentamicin

INDICATED FOR BONE INFECTION

Packaging Material Specifications:

Latex:	Not made with natural rubber latex
Phthalates:	Not made with phthalates
Storage Conditions:	15–25°C / 59–86°F
Shelf-Life:	36 months
Sterilization:	CERAMENT G is supplied sterile, except for CERAMENT MIXING LIQUID that has a non-sterile outer surface
Sterile:	Yes
Single Use/Disposable:	Yes
Sterilization Methods:	EO, Steam and Gamma Irradiation
EO Residuals:	Fulfills ISO 10993-7:2008

Warnings in IFU:

- CERAMENT G is not indicated for use in the spine, such as vertebroplasty or kyphoplasty.
- Do not use in spine osteomyelitis.
- The presence of gentamicin does not negate the need for systemic antibiotics.
- The safety and effectiveness of CERAMENT G have not been studied in segmental bone defects larger than 1 cm.
- Do not implant more than 30 mL of CERAMENT G. The safety and effectiveness and antibiotic toxicity of larger volumes of CERAMENT G are not known.
- In the clinical dataset used to support marketing of CERAMENT G, a subset of patients who did not experience a recurrence of infection exhibited radiographic evidence of CERAMENT G resorption without complete replacement by bone at timepoints 1 year post-treatment or longer. Surgeons should evaluate the need for additional treatment of these unfilled defects based on defect size, location and other patient-specific factors. While dependent on surgeon discretion and patient medical factors, patients with incomplete bone formation may need additional grafting procedures.
- The clinical dataset used to support marketing of CERAMENT G did not contain demographic details related to race and ethnicity, therefore, the results of the study may not necessarily be applicable to patients of all races and ethnicities.
- The use of CERAMENT G in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit and increases the risk of drug-resistant bacteria.

Contraindications:

- Hypersensitivity to any amino-glycoside antibiotics
- Myasthenia gravis
- Severe renal impairment
- Pre-existing calcium metabolism disorder
- Pregnancy
- Breastfeeding

Packaging Dimensions:

46cm (l) x 18.9cm (w) x 6cm (d)

Cerament Material Properties:

Setting temperature: <43°C
pH: Physiological pH (6 ≤ pH ≤ 10)

Biocompatibility:

The product has been evaluated to be biologically safe to use (no unacceptable biological risks have been found). The components of the implantable paste have been used in humans for decades. The plastic components of the product, that come in direct or in indirect contact with the patient, are all of USP Class VI or equivalent. The glass components that come in direct or in indirect contact with the patient, are of Type I. The final product has been extensively tested with biocompatibility in-vitro and in-vivo tests, following the requirements of ISO 10993.

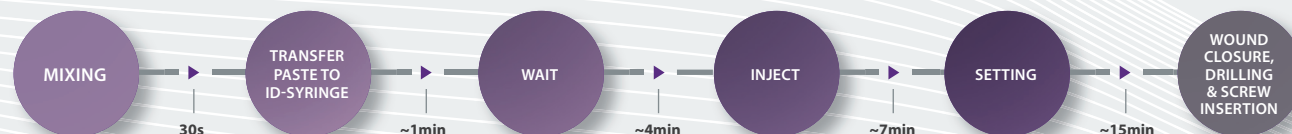
Handling:

- ✓ Injectable
 - ✓ For use with a bead mold (not included in pack)*
 - ✓ Drillable
- *If beads are prepared, wait until final setting at 20 mins

Step 1: Prepare the Gentamicin Solution



Step 2: CERAMENT G Mixing and Setting Time



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