

CERAMENT® G Product Fact Sheet



COMPOSITION:

CERAMENT Powder	Liquid	Gentamicin Powder
60 wt% α-calcium sulfate hemihydrate (CaS)		
 40 wt% hydroxyapatite (HA) 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 	• Saline: sodium chloride 9 mg/mL	Gentamicin sulfate; providing 17.5 mg of gentamicin/mL of CERAMENT paste (both 5 and 10 mL product)

TIP EXTENDERS:

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

SIZE AND ORDER CODES:

Volume	Order code	
5mL	A0450-03	
10mL	A0450-01	

GMDN code 47255 UMDNS code 37286

Manufacturer:

BONESUPPORT AB Scheelevägen 19 IDEON Science Park SE-223 70 Lund Sweden

Email: info@bonesupport.com www.bonesupport.com

REGULATORY INFORMATION:

Regulatory Status

Notified Body: BSI Notified Body Number: 2797

Medical Device Classification: Class III by rule 8 and 13 of the

Council Directive 93/42/EEC amended by Directive 2007/47/EC

Intended Use

CERAMENT G is a resorbable ceramic bone graft substitute intended to fill gaps and voids in the skeletal system to promote bone healing.

CERAMENT G provides a void/gap filler that during the surgical procedure can augment hardware and bone alignments.

Gentamicin is included in CERAMENT G to prevent colonization of Gentamicin sensitive microorganisms in order to protect bone healing.

Indications

CERAMENT G is indicated to be placed into bone voids or gaps in the skeletal system, i.e. extremities, spine, and pelvis that is not intrinsic to the stability of the bony structure. These osseous defects may be e.g. spontaneous occurring, surgically created, resulting from traumatic injury to the bone during primary surgery and revision surgery, or osseous defects identified around hardware devices.

Description

CERAMENT G is bone graft substitute which is injectable and moldable into beads, consisting of Calcium sulfate, Hydroxyapatite and Gentamicin sulfate. CERAMENT G delivers 17.5 mg Gentamicin/ml paste. By combining Calcium sulfate and Hydroxyapatite an optimal balance is achieved between implant resorption rate and bone in growth rate. Calcium sulfate acts as a resorbable carrier for hydroxyapatite. Hydroxyapatite has a slow resorption rate, high osteoconductivity promoting bone in growth, and gives long term structural support to the newly formed bone. By adding Gentamicin, colonization with Gentamicin sensitive microorganisms can be prevented in order to protect bone healing. The ceramic bone substitute material is placed into the bone void under visual inspection.

Contraindications

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

Warnings in IFU

Addition of Gentamicin does not negate the need for systemic antibiotics

PACKAGING MATERIAL SPECIFICATIONS:

Latex Not made with natural rubber latex **Animal tissue** Comission regulation No 722/2012

does not apply

Phthalates Not made with phthalates

Storage conditions 15–25°C / 59–77°F

Shelf-life 24 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

Packaging dimensions

4.6cm (l) x 18.9cm (w) x 6cm (d)

CERAMENT MATERIAL SPECIFICATIONS:

Setting temperature

Initial compressive

strength 30–50 MPa (dry conditions),

<43°C

20-40 %

9–12 MPa (wet conditions)

Initial microporosity

Initial pore size pH

Average pore size 1 micron $7.0 \le pH \le 7.2$ (Gentamicin

effectiveness reduced at pH

6.4 or lower)

Biocompatibility

The product has been evaluated to be biological 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 10993-1.

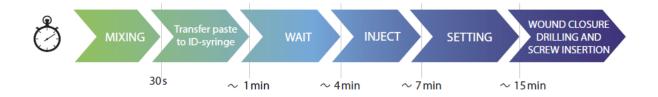
Handling

- ✓ Injectable
- ✓ For use with a bead mold (not included in pack)*
- ✓ Drillable

*If beads are prepared, wait until final setting at 20 mins

Compatibility

✓ Autograft, allograft, hardware





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