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	<43°C
Initial compressive strength	30–50 MPa (dry conditions), 9–12 MPa (wet conditions)
Initial microporosity	20–40 %
Initial pore size	Average pore size 1 micron
pH	7.0 ≤ pH ≤ 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.

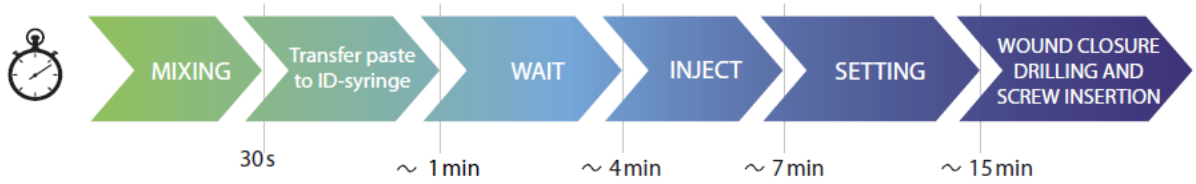
Handling

- ✓ 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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PR 0935-03 en EU 2021-02