CERAMENT® G
with Gentamicin

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	UDI-DI/GTIN
5 mL	A0535-02	07350055430356
10 mL	A0535-01	07350055430349

GMDN code	47255

REGULATORY INFORMATION

General Information

Notified Body:	BSI
Notified Body Number:	2797
Medical Device Classification:	Class III medical device by rules 8, 14 and 18 of the EU Medical Device Regulation 2017/745

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.

BONESUPPORT™

MANUFACTURER

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

E: info@bonesupport.com
W: www.bonesupport.com

CERAMENT® G
with Gentamicin

Description and Clinical Benefit

CERAMENT G is an injectable ceramic bone graft substitute, consisting of Calcium sulfate (60%), Hydroxyapatite (40%), Sodium chloride (5 mg/ mL paste) 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 ingrowth 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.

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	15–30°C / 59–86°F
Shelf-life	36 months from manufacture
Sterilization	CERAMENT G is supplied sterile
Sterile	Yes
Single Use/ disposable	Yes
Sterilization methods	EO, Steam and Gamma Irradiation
EO residuals	Fulfills ISO 10993-7

PACKAGING DIMENSIONS

37.4cm (l) x 18.65cm (w) x 5.35cm (d)

CERAMENT MATERIAL PROPERTIES

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

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.

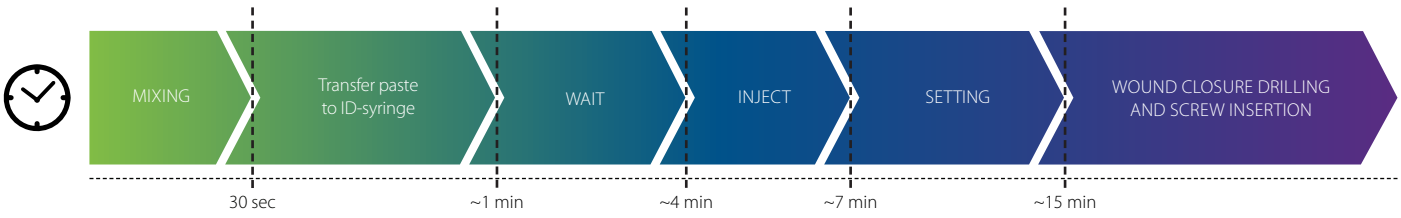
Handling

✓ 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



Availability of CERAMENT® is dependent on its regulatory status in individual markets, contact your local representative.
For complete product information, including indications, contraindications, warnings, precautions and potential adverse events, see package insert.

BONESUPPORT™

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

E: info@bonesupport.com
W: **www.bonesupport.com**

PR-01327-02 en AU CE 07-2025