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
5mL	A0535-02	07350055430356
10mL	A0535-01	07350055430349

GMDN code	47255
UMDNS code	37286
Basic UDI-DI	07350055430475S3

REGULATORY INFORMATION

General Information

EU Notified Body (number):	BSI (2797)
EU Classification:	Class III medical device by rules 8, 14 and 18 of the EU Medical Device Regulation 2017/745
UK Approved Body (number):	BSI (0086)
UK Classification:	Class III medical device by rules 8 and 13 of the UK Medical Device Regulation 2002 (SI 2002 NO 619, as amended)

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 and pelvis (only during acetabular revision), that are not intrinsic to the stability of the bony structure. These osseous defects may be: *In skeletally mature patients:* spontaneously occurring, surgically created, re-sulting from traumatic injury to the bone, identified during primary surgery and revision surgery, or osseous defects identified around hardware devices.

BONESUPPORT™

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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.

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	15–30°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 10993-7:2008

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.

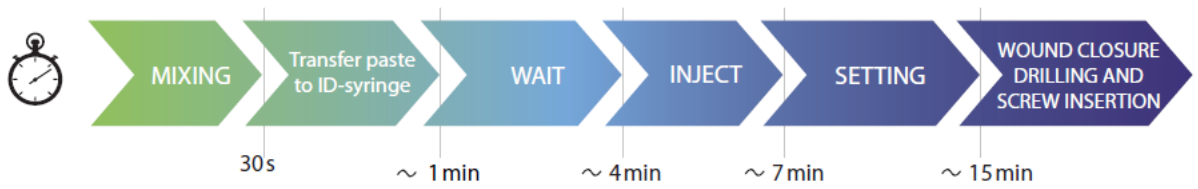
Handling

✓ 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



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