CERAMENT® V
with Vancomycin

PRODUCT FACT SHEET

COMPOSITION

CERAMENT Powder	Liquid	Vancomycin 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 to have a specific size and crystallinity that confers high injectability and slow resorption rate	**Iohexol** (CERAMENT C-TRU) • Radio contrast agent, with an iodine concentration of 180 mg iodine/mL • Iohexol release is (a) by wash-out of body fluids soaking through micropores, and (b) through calcium sulphate resorption • > 80% is eliminated from the body within 24 hours	• Vancomycin hydrochloride, provides a final concentration of 66 mg of vancomycin/mL of CERAMENT paste

TIP EXTENDERS

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

SIZE AND ORDER CODES

Volume	Order code	UDI-DI/GTIN code
10 mL	A0581-01	07350055430516

GMDN code	47255

MANUFACTURER

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

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

Vancomycin is included in CERAMENT V to prevent colonization of vancomycin sensitive microorganisms in order to protect bone healing.

Indications

CERAMENT V is indicated to be placed into bone voids or gaps in the skeletal system, i.e. extremities and pelvis (only during acetabular revision) not intrinsic to the stability of the bony structure. These osseous defects may be: ***In skeletally mature patients:*** spontaneously occurring, surgically created, resulting from traumatic injury to the bone, identified during primary surgery and revision surgery, or osseous defects identified around hardware devices.

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Description

CERAMENT V is an injectable and moldable ceramic bone graft substitute, consisting of Calcium sulfate (60%), Hydroxyapatite (40%) and Vancomycin hydrochloride. The liquid component (CERAMENT C-TRU) contains iohexol (206 mg/ mL paste, ie. iodine concentration 95 mg/ mL paste) as a radio-opacification enhancer. CERAMENT V delivers 66 mg Vancomycin/ 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 newly formed bone.
By adding Vancomycin, colonization with Vancomcyin sensitive microorganisms can be prevented in order to protect bone.

Contraindications

- Hypersensitivity to Vancomycin hydrochloride
- Hypersensitivity to iohexol or any of the excipients (trometamol, sodium calcium edetate, hydrochloric acid), included in CERAMENT C-TRU
- Pregnancy
- Breastfeeding
- Manifest thyrotoxicosis

Warnings in IFU

Addition of CERAMENT V does not negate the need for systemic antibiotics.

PACKAGING MATERIAL SPECIFICATIONS

Latex	Not made with natural rubber latex
Animal tissue	Complies with ISO 22442-1
Phthalates	Not made with phthalates
Storage conditions	15–25°C / 59–77°F
Shelf-life	24 months
Sterilization	CERAMENT CMI: gamma irradiation CERAMENT C-TRU liquid: steam CERAMENT VANCOMYCIN vial: filtration sterilized and aseptically filled Surface sterilization of the complete device: ethylene oxide
Sterile	Yes
Single Use/ disposable:	Yes
Sterilization methods:	EO, Steam, Aseptic filling 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	6.6 ≤ pH ≤ 7.0 (vancomycin is effective in the range 6.4 – 8)

Biocompatibility

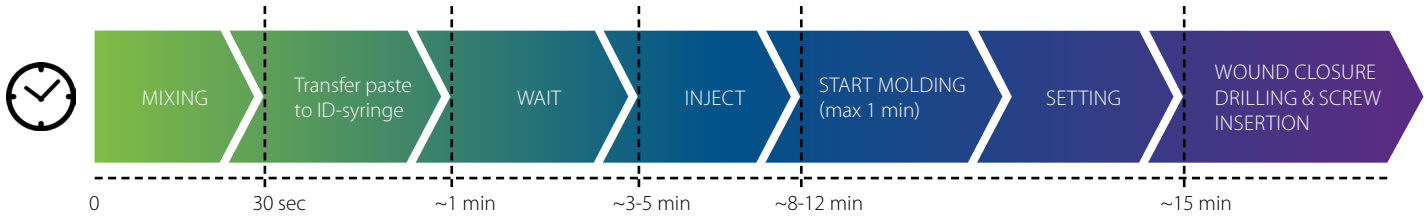
The product has been evaluated to be biological safe to use (no unacceptable biological risks have been found). The components of the implantable paste have been used in humans for decades. The plastic components of the product, that comes in direct or in in-direct with the patient, are all of USP Class VI or equivalent. The glass components that comes in direct or in in-direct 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
- ✓ Drillable
- ✓ Moldable (by hand) – for up to 1 minute
- ✓ For use with a bead mold tray (not included in pack)

Compatibility

- ✓ Autograft, allograft, hardware



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