CERAMENT® V
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 hydro-chloride, 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
10 mL	A0451-03

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 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 e.g. 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.

Description

CERAMENT V is a fast-setting, injectable and moldable ceramic bone graft substitute intended for the filling of bone voids/gaps. The material consists of powder and liquid components. The major constituents of the powders are hydroxyapatite, calcium sulfate hemihydrate and vancomycin. The liquid component (C-TRU) contains iohexol as a radio opacification enhancer. Mixing the components, with the combined mixing injection device (CMI), results in a viscous material intended to set ex-vivo or in-vivo. CERAMENT V delivers 66 mg vancomycin/ml paste. By combining hydroxyapatite and calcium sulfate 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 vancomycin, colonization with vancomycin sensitive microorganisms can be prevented in order to protect bone healing. The ceramic bone graft substitute material is placed into the bone defect under visual inspection or under radiographic monitoring during open or percutaneous surgery.

Contraindications

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

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 Commission regulation No 722/2012 and 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 10993-7:200

Packaging dimensions

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

CERAMENT MATERIAL SPECIFICATIONS:

Setting temperature	<43°C
Initial compressive strength	45–48 MPa (dry conditions), 5–7 MPa (wet conditions)
Initial microporosity	20–40 %
Initial pore size	Average pore size 1 micron
pH	6.6 ≤ pH ≤ 7.0 (vancomycin is effective in the range 6.4 – 8)

Biocompatibility

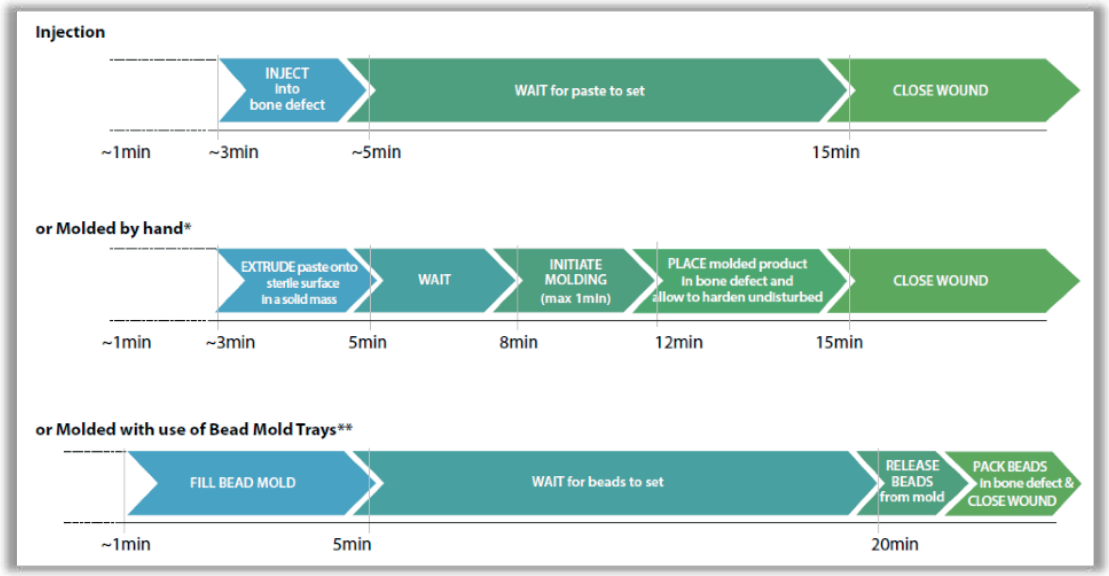
The product has been evaluated to be biological safe to use (no unacceptable biological risks have been found). The components of the implantable paste have been used in humans for decades. The plastic components of the product, that comes in direct or in indirect contact with the patient, are all of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

Compatibility

✓Autograft, allograft, hardware



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