CERAMENT® BONE VOID FILLER

PRODUCT FACT SHEET

COMPOSITION

CERAMENT Powder	Liquid
60 wt% α-calcium sulfate hemihydrate (CaS)	
40 wt% hydroxyapatite (HA) • A calcium phosphate, with a chemical 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, shape and crystallinity that confers high injectability and slow resorption rate	**Iohexol** (CERAMENT C-TRU) • Radiocontrast agent, containing 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

TIP EXTENDERS

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

SIZE AND ORDER CODES

Volume	Order code	UDI-DI/GTIN
18mL	A0580-01	07350055430486
10mL	A0580-02	07350055430493
5mL	A0580-03	07350055430509

GMDN code	17751

MANUFACTURER

BONESUPPORT AB,
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REGULATORY INFORMATION

General Information

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

Intended Use

CERAMENT BONE VOID FILLER is a resorbable ceramic bone graft substitute intended to fill gaps and voids in the skeletal system to promote bone healing. CERAMENT BONE VOID FILLER provides a void/gap filler that during the surgical procedure can augment hardware and bone alignments.

Indications

CERAMENT BONE VOID FILLER 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.

CERAMENT® BONE VOID FILLER

Description

CERAMENT BONE VOID FILLER is an injectable and moldable ceramic bone graft substitute, consisting of Calcium sulfate (60%) and Hydroxyapatite (40%). The liquid component (CERAMENT C-TRU) contains iohexol (220 mg/ mL paste, ie. iodine concentration 102 mg/ mL paste) as a radio-opacification enhancer. 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.

Contraindications

- Hypersensitivity to iohexol or to any of the excipients (Trometamol, Sodium calcium edetate, Hydrochloric acid), included in CERAMENT C-TRU
- Local infection at the site of implantation
- Pregnancy
- Breastfeeding
- Manifest thyrotoxicosis

PACKAGINING MATERIAL SPECIFICATIONS

Latex:	Not made with natural rubber latex
Animal tissue:	Commission regulation No 722/2012 does not apply
Phthalates:	Not made with phthalates
Storage conditions:	15–30°C / 59–86°F
Shelf-life:	48 months
Sterilization:	CERAMENT CMI: gamma irradiation CERAMENT C-TRU liquid: steam Complete device: surface sterilized with ethylene oxide
Sterile:	Yes
Single Use/disposable:	Yes
Sterilization methods:	EO, Steam & 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

Biocompatibility

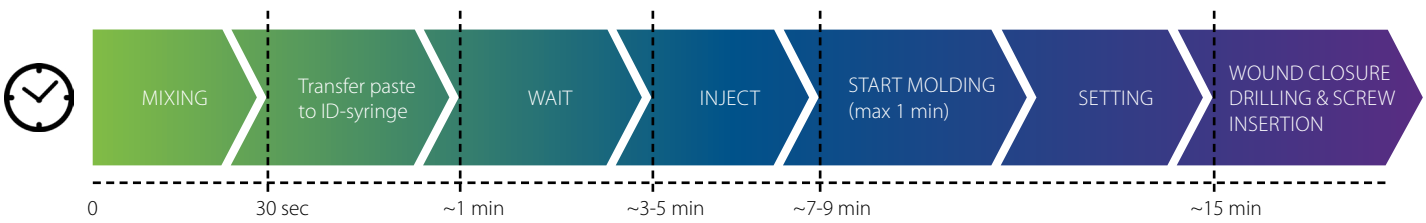
The product has been evaluated to be biological safe to use (no unacceptable biological risks have been found).
The components of the implantable paste have been used in humans for decades. The plastic components of the product, that come in direct or in indirect contact with the patient, are all of USP Class VI or equivalent. The final product has been extensively tested with biocompatibility in-vitro and in-vivo tests, following the requirements of EN 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)
✓ Drillable

Compatibility

✓ Autograft, allograft, hardware



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