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 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

TIP EXTENDERS:

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

SIZE AND ORDER CODES:

Volume	Order code
5mL	A0210-09
10mL	A0210-08
18mL	A0210-11

GMDN code	17751
UMDNS code	37286

Manufacturer:
BONESUPPORT AB
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IDEON Science Park
SE-223 70 Lund
Sweden

US Office:
BONESUPPORT INC.,
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USA

REGULATORY INFORMATION:

Regulatory Status

Cleared by FDA	Yes, through 510(k)
Regulation Number	21CFR 888.3045
Classification Product Code	MQV
Device Classification Name	Filler, Bone Void, Calcium Compound
Combination Product	Yes

Indications

CERAMENT® BONE VOID FILLER is indicated to be injected, or placed, into bony voids or gaps in the skeletal system, i.e. extremities, pelvis, and posterolateral spine (only during open surgery in spine). These defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 9 years old), or osseous defects created as a result of either surgery or traumatic injury to the bone.

Description

CERAMENT® BONE VOID FILLER is a fast-setting, injectable and moldable ceramic bone graft substitute intended for filling bone voids/gaps. The material consists of a powder and a liquid component. The major constituents of the powder are hydroxyapatite and calcium sulfate hemihydrate. The liquid component (C-TRU) contains Iohexol as a radio-contrast enhancer. Mixing the components, with the combined mixing injection (CMI) device, results in a viscous material intended to set ex vivo or in vivo. By combining hydroxyapatite and calcium sulfate a 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.

The ceramic bone graft substitute is placed into the bone defect under visual inspection or under radiographic monitoring during open or percutaneous surgery. The paste may be injected into the defect, molded by hand and digitally placed into the defect, or used to prepare beads that are placed into the defect. The accompanying injection device (ID) and Tip Extenders may be used to facilitate the filling of the bone defect.

When fully set in vivo, CERAMENT®|BONE VOID FILLER is drillable and can be used to augment hardware during the surgical procedure.

Contraindications

- Hypersensitivity to Iohexol or to any of the excipients
- Local infection at the site of implantation
- Pregnancy
- Breastfeeding
- Known hyperthyroidism or autonomous thyroid adenoma
- Load bearing applications

PACKAGING 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 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 SPECIFICATIONS:

Setting temperature	<43°C
Initial compressive strength	65–75 MPa (dry conditions), 10–12 MPa (wet conditions)
Initial microporosity	20–40 %
Initial pore size	Average pore size 1 micron

Biocompatibility

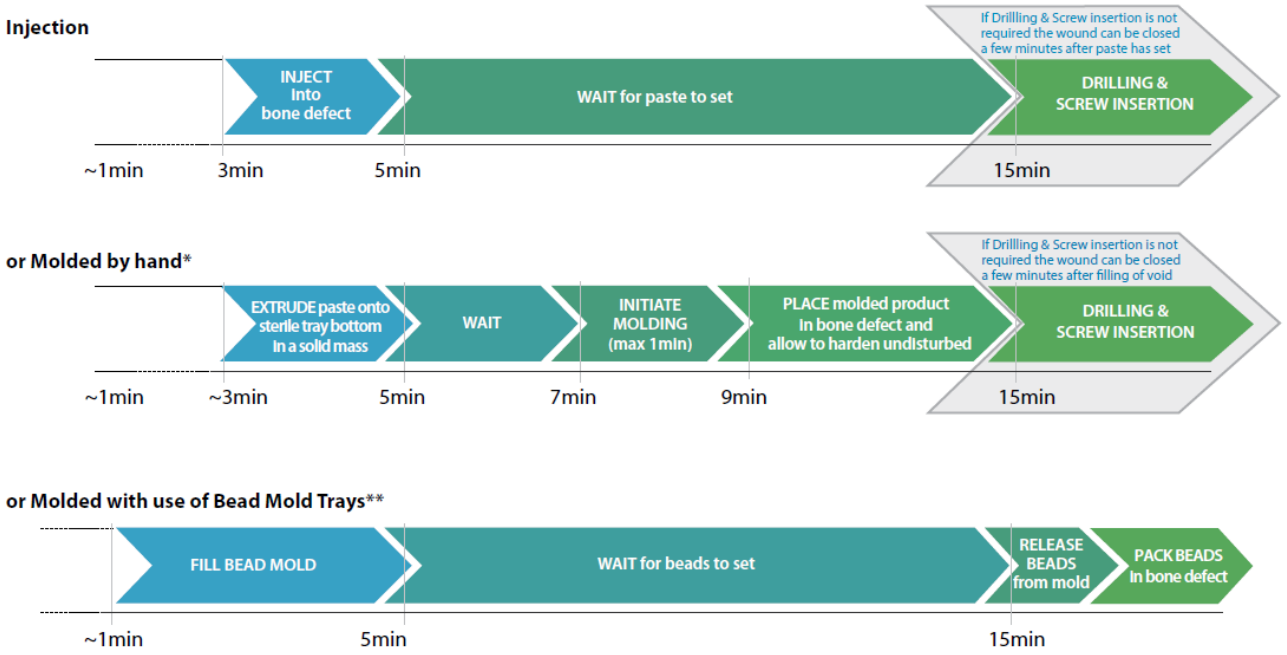
The product has been evaluated to be biologically safe to use (no unacceptable biological risks have been found). The components of the implantable paste have been used in humans for decades. The plastic components of the product, that come in direct or in indirect contact with the patient, are all of 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

✓Hardware



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