CERAMENT®
BONE VOID FILLER

PRODUCT FACT SHEET

COMPOSITION

CERAMENT Powder

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

Liquid

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

SIZE AND ORDER CODES

VOLUME	ORDER CODE	TIP EXTENDERS
5mL	A0210-09	11G, 50mm length
10mL	A0210-08	11G, 100mm length
18mL	A0210-11	Tapered tip

GMDN Code
17751

Manufacturer
BONESUPPORT AB
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REGULATORY

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

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.

PACKAGING SPECIFICATIONS

Dimensions	**37.4cm (l) x 18.65cm (w) x 5.35cm (d)**
Latex	Not made with natural rubber latex
Animal tissue	Commission regulation No 722/2012 does not apply
Phthalates	Not made with phthalates
Storage	15–30°C / 59–86°F
Shelf-life	48 months
Sterilization	CERAMENT CMI: gamma irradiation CERAMENT G-TRU liquid: steam Complete device: surface sterilized with ethylene oxide

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.

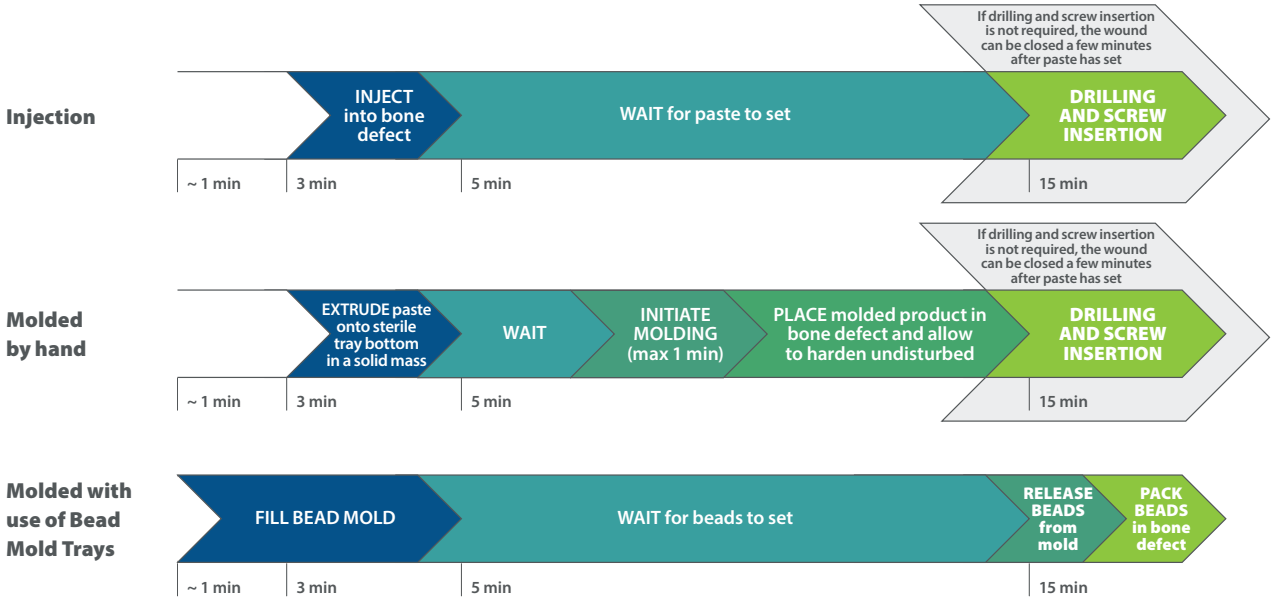
The final product has been extensively tested with biocompatibility in-vitro and in-vivo tests, following the requirements of EN ISO 10993-1.

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



Availability of CERAMENT is dependent on regulatory status in individual markets, contact your local representative. For complete product information, including indications, contraindications, warnings, precautions and potential adverse events, see package insert.

BONESUPPORT™

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