

CERAMENT® BONE VOID FILLER

Product Fact Sheet



COMPOSITION:

Com Control.	
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 	 lohexol (CERAMENT C-TRU) Radiocontrast agent with an iodine concentration of 180 mg iodine/mL lohexol 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	A0210-06
10mL	A0210-05
18mL	A0210-10

GMDN code 17751 UMDNS code 37286

Manufacturer:

Sweden

BONESUPPORT AB Scheelevägen 19 IDEON Science Park SE-223 70 Lund

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 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.

Description

CERAMENT BONE VOID FILLER is an fast setting, injectable and moldable ceramic bone graft substitute material intended for 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-opacification 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 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.

The ceramic bone substitute material is placed into the bone void 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 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 lohexol or to any of the excipients
- Local infection at the site of implantation
- Pregnancy

Sterilization

- Breastfeeding
- Manifest thyroxicosis

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

> 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 PROPERTIES:

Setting temperature

<43°C

Biocompatibility

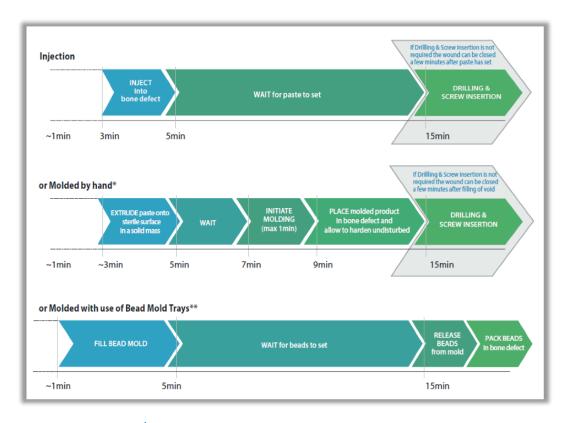
The product has been evaluated to be biological safe to use (no unacceptable biological risks have been found). The components of the implantable paste have been used in humans for decades. The plastic components of the product, that come in direct or in indirect contact with the patient, are all of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