

CERAMENT™|BONE VOID FILLER

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

CERAMENT™|BONE VOID FILLER is an injectable and moldable ceramic bone substitute intended for bone voids. 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 contains iohexol (C-TRU) 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.

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.

The ceramic bone substitute material is placed into the bone void under visual inspection or under radiographic monitoring during open or percutaneous surgery, with the use of the accompanying injection device (ID).

PERFORMANCE

The paste is injectable between 3-5 minutes when using a 16G needle. Molding can be initiated between 7-9 minutes (the paste is moldable for a period of 1 minute), and drillable after 15 minutes. The paste will harden within 15 minutes if not disturbed. All times are from start of mixing.

INTENDED USE

CERAMENT™|BONE VOID FILLER is a ceramic bone void filler intended only for orthopedic applications as a filler for gaps and voids that are not intrinsic to the stability of the bony structure.

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 spine (only during open surgery in spine). These defects may be surgically created osseous defects or osseous defects from traumatic injury to the bone.

CERAMENT™|BONE VOID FILLER provides a bone void filler that resorbs and is replaced by bone during the healing process.

CERAMENT™|BONE VOID FILLER is not intended for use in load bearing applications such as vertebroplasty or kyphoplasty.

INDICATIONS

Voids or gaps not intrinsic to the stability of the bone structure.

CONTRAINDICATIONS

- History of serious reaction to iodine based radio contrast agents.
- Local infection at the site of implantation.
- Pregnancy.
- Breastfeeding.
- Manifest thyroxicosis.
- Load bearing applications.

PRECAUTIONS

- Adhere to sterile surgical technique.

Supportive therapy

- Control active bleeding and remove blood clots and tissue fragments if open surgery.
- Consult and comply with the IFU of any additional utensils.

Device related

- Not intended for weight-bearing areas, unless it can be assumed after thorough examination that in situ osteosynthesis is sufficient for weight-bearing function.
- Avoid intra-articular use.
- Overpressurization during injection should be avoided as intra-medullary injection with any bone void filler may lead to fat embolization or embolization of device into the blood stream.
- Inject carefully under fluoroscopy to avoid leakage.
- No clinical experience with additives.
- No clinical experience with prophylactic use.
- If using CERAMENT in conjunction with allograft or autograft, first apply allograft/ autograft and then fill up with CERAMENT.
- Contact between CERAMENT and bone is a prerequisite for good treatment outcome.
- Do not use if the liquid is discolored or contains precipitate.

Patient related

- Pre existing calcium metabolism disorder (e.g. hypercalcemia).
- A positive history of allergy, asthma, or untoward reactions to iodinated contrast media indicates a need for special caution.
- The risk of serious reactions in connection with use of Iohexol is regarded as minor. However, iodinated contrast media may provoke anaphylactoid reactions or other manifestations of hypersensitivity. A course of action should therefore be planned in advance, with e.g. necessary drugs available for immediate treatment, should serious reaction occur.
- Adequate hydration should be assured before and after contrast media administration. This applies especially to patients with multiple myeloma, diabetes mellitus, renal dysfunction, as well as infants, small children and elderly patients. Young infants (age < 1 year) and especially neonates are susceptible to electrolyte disturbance and hemodynamic alterations.

- Patients with acute cerebral pathology, tumours or a history of epilepsy are predisposed for seizures and merit particular care. Also alcoholics and drug addicts have an increased risk for seizures and neurological reactions.
- Care should also be taken in patients with serious cardiac disease and pulmonary hypertension as they may develop hemodynamic changes or arrhythmias.
- To prevent acute renal failure following contrast media administration, special care should be exercised in patients with pre existing renal impairment and diabetes mellitus as they are at risk. Patients with paraproteinemias (myelomatosis and Waldenström's macroglobulinemia) are also at risk.

WARNINGS

- Only to be used for voids or gaps not intrinsic to the stability of the bone structure and should not be used in load bearing applications, such as vertebroplasty or kyphoplasty.

SIDE EFFECTS

The following complications have been reported to result from ceramic bone substitutes.

- Calcium based bone void fillers may color wound drainage white. This should not be a concern, however be aware of the risk of infection when drainage occurs.
- There have been reports in the literature on idiosyncratic reactions (laryngospasm and tachyarrhythmia) in children up to the age of 15 treated with ceramic bone substitute containing 75-100% calcium sulfate and 0-25% calcium phosphate.

INTERACTIONS

Iohexol related

- There is a risk of the development of lactic acidosis when iodinated contrast agents are administered to diabetic patients treated with metformin.
- A potential risk of transient hepatic dysfunction exists. Particular care is required in patients with severe disturbance of both renal and hepatic function as they may have significantly delayed contrast medium clearance.
- The administration of iodinated contrast media may aggravate the symptoms of myasthenia gravis. In patients with pheochromocytoma undergoing interventional procedures, alpha blockers should be given as prophylaxis to avoid a

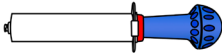
hypertensive crisis. Special care should be exercised in patients with hyperthyroidism. Patients with multinodular goiter may be at risk of developing hyperthyroidism following injection of iodinated contrast media. One should also be aware of the possibility of inducing transient hypothyroidism in premature infants receiving contrast media.

- Patients treated with interleukin - 2 less than two weeks previously have been associated with an increased risk of delayed reactions (flu-like symptoms or skin reactions).

DISCLAIMER

- In cases where it is not possible to establish a sufficient wound closure there might be a risk of skin inflammation reaction and/or prolonged wound drainage.
- Wound complications including hematoma, site drainage, bone fracture, infection, and other complications that are possible with any surgery.

COMPONENTS, COMPOSITIONS & PARTS



CERAMENT™|CMI

Mixing device pre-filled with ceramic bone substitute, a mixture of hydroxyapatite and calcium sulfate.



CERAMENT™|C-TRU

Pre-filled syringe with iodine based mixing liquid. A water-soluble, radio opacity enhancing component (iohexol) with the iodine concentration of 180 mg I/ml.



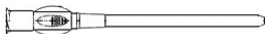
Valve

To connect CERAMENT™|C-TRU and CERAMENT™|ID to CERAMENT™|CMI.



CERAMENT™|ID

Injection device (accuracy of measuring scale \pm 5%). For the 18 ml product, two devices are included.



Tip Extender

2 pcs of Tip Extenders in different length to be used with CERAMENT™|ID facilitating paste injection.

ADDITIONAL UTENSILS NEEDED

Stopwatch

OPTIONAL UTENSILS

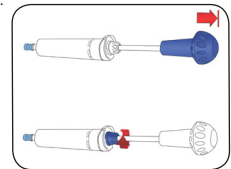
- A cannula or needle with a minimum diameter of 16G
- Bead Mold

DIRECTIONS FOR USE

When handling the CERAMENT™|BONE VOID FILLER adhere to sterile surgical techniques

Step by step instructions

1. Remove the plug on CERAMENT™|CMI and attach the Valve with the clear end to CERAMENT™|CMI by turning it clockwise.
2. Remove the plug and press the CERAMENT™|C-TRU through the blue membrane of the Valve and attach it by turning it clockwise
3. Empty the syringe with CERAMENT™|C-TRU into the CERAMENT™|CMI completely. Keep the plunger pushed to the bottom to avoid back flush. Detach CERAMENT™|C-TRU syringe from the Valve.
4. Retract the blue handle on the CERAMENT™|CMI and remove the red plunger stop.
5. Start the stop watch (t = 0 seconds). Mix for 30 seconds with a frequency of one complete stroke per second.
6. Finish the mixing and:
 - Fully retract the blue handle into its back position.
 - Turn the blue knob clockwise 180° until a "click" is heard.



7. Attach the CERAMENT™|ID to the Valve by pressing it through the blue membrane and turning clockwise. Transfer the paste from the CERAMENT™|CMI immediately. For the 18 ml product, the second syringe should be filled immediately after the first syringe. When the CERAMENT™|ID is completely filled, excess paste will begin to ooze from under the sleeve. Stop filling when this occurs.
8. Detach the filled CERAMENT™|ID from the Valve and remove the red plunger stopper.
9. If applicable attach Tip Extender or an optional needle (minimum 16G) to the CERAMENT™|ID.

- Wait until 3 minutes after start of mixing; carefully inject into the bone gap/void under visual inspection and/or by radiographic monitoring.
- Proceed until the gap/void is completely filled with an adequate amount of paste, as judged by the responsible physician.
- After the paste is in situ, allow to set for a few minutes before any adjustments are done or the wound is closed, especially if bleeding occurs.

Close the wound(s) and follow accepted clinical practice for postoperative care.

RESTRICTIONS

CERAMENT™|BONE VOID FILLER may only be sold and distributed for professional use.

Store A0210 CERAMENT™|BONE VOID FILLER unopened in a clean and dry environment in room temperature (15– 30°C / 59–86°F).

The contents of this document may not be duplicated without written permission from BONESUPPORT AB.

Do not use if any of the packages are open or damaged or if the expiration date has been exceeded.

Excess material and opened but unused items must be discarded. Used material should be discarded in accordance with hospital procedures.

The products are protected by patents, see: <http://bonesupportpatents.com/ifu0007>.

STERILITY

CERAMENT™|BONE VOID FILLER is supplied sterile. The CERAMENT™|CMI is sterilized by gamma irradiation, the CERAMENT™|C-TRU is sterilized by steam and the surface sterilization of the complete device is by ethylene oxide.

The product is intended only for single use and cannot not be re-sterilized by any method and shall not be re-used due to contamination risks.

CAUTION

Federal (US) law restricts this device to sale by or on the order of a physician.

EXPLANATION OF SYMBOLS



Do not use if package is damaged



Caution: Federal (US) law restricts this device to sale by or on the order of a physician.



Time, measured from start of mixing

ORDERING INFORMATION IN USA

Distributed By:

Biomet Biologics, LLC
56 East Bell Drive
Warsaw, IN 46582
www.biometbiologics.com

Ordering Information in the USA

Biomet Part Numbers:
800-4002 (18 ML)
800-4001 (10 ML)
800-4000 (5 ML)

Comments regarding the performance of this device in the USA can be directed to

Attn: Regulatory Dept, Biomet, Inc.,
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A 0210-11 (18 ml) CERAMENT™|BONE VOID FILLER 18 ml
A 0210-08 (10 ml) CERAMENT™|BONE VOID FILLER 10 ml
A 0210-09 (5 ml) CERAMENT™|BONE VOID FILLER 5 ml

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