Cem-Ostetic™ Synthetic Bone Putty

The ability to use synthetic bone tissue has enriched the lifestyles of many people. Berkeley Advanced Biomaterials can process a wide variety of large segment and smaller bone graft substitutes for orthopedic and oral or maxillo-facial surgery.

Cem-Ostetic™ contains several calcium-based biocompatible minerals that have been used for decades in orthopedic surgery. These materials are often used to provide an additional source of bone to help the patient heal better. Using synthetic bone can eliminate the need for second site surgery in order to harvest the patient's own bone. It avoids potential transmission of diseases from grafts taken on human or animal cadavers. This procedure is much less painful. Berkeley Advanced Biomaterials is also able to formulate a number of compositions and microstructures that can enhance bone regeneration, provide optimal osteo-conduction and reduce the time for the bone to regain its full health.

All Berkeley Advanced Biomaterials’ synthetic bone materials are carefully controlled. The company is ISO-9001 certified and our manufacturing processes of medical devices follow EN 46001 standards. Our quality assurance system includes chemical and phase analysis (trace elements composition and x-ray analysis) of each batch. After screening and inspection, the bone putty powder is packaged in double-bagged vials under aseptic conditions and subsequently gamma-ray sterilized. Such a procedure ensures that patients receive the highest quality synthetic bone graft or bone putty on the market.

Common Uses of Synthetic Bone Putty:
- Hand or Foot Surgery
- Fracture Repair
- Joint Reconstruction
- Limb Salvage
- Oral or Maxillofacial Surgery
- Scoliosis Surgery
- Spinal Fusion
- Sports Medicine

In addition to these common applications of bone substitute, Berkeley Advanced Biomaterials has the unique expertise to shape its bone graft materials, making it possible for the first time to fabricate entire bones (instead of bone fragments). The Company is also developing methods to treat bone diseases using mixtures of synthetic bone with bio-molecules, anti-cancer agents (e.g. doxorubicin), antibodies, or proteins to fabricate drug delivery devices with sustained release.
Cem-Ostetic™ Bone Putty is a formulation of well-established biocompatible materials. The formulation combines pure calcium-based phases with water and does not involve other materials such as polymers or plasticizing agents. It also does not involve the use of allograft materials, thereby eliminating the risk for transmission of human diseases. The bone putty can safely be used to reconstruct bone tissue in the fields of maxillo-facial surgery, periodontics, spine fusion, and orthopedic surgery. The putty can easily be mixed with or used in conjunction with Bi-Ostetic™ Spongy Granules (bioceramics with interconnected porosity) to enhance osteoconduction and promote bone in-growth, if needed.

Cem-Ostetic™ is a Biocompatible Implant.
Calcium-based implant materials have been the subject of extensive clinical studies for the past 40 years. These studies demonstrated that they have excellent biocompatible properties. Once implanted, the bone putty begins to resorb and is later replaced with natural bone. Significant resorption normally occurs within a few months, making it a natural choice for sparing patients the trauma and morbidity of autograft harvesting. This selection provides a safe and cost effective alternative to autogenous bone grafts or cadaver bone that completely eliminates the potential for disease transmission.

Cem-Ostetic™ is available in sterile vials.
Cem-Ostetic™ comes in the form of a sterile powder in a jar and distilled water in a tube. The doctor or his/her assistant must mix the powder with pure distilled sterile water before implanting the putty (see instructions-for-use). To form the putty, a 4-cc volume of distilled sterile water must be added to a 10-cc volume of powder. Respecting this powder-to-water volume ratio is important in order to obtain consistent and predictable setting times.

Using the ratio recommended above, the putty will begin to harden about 3 minutes after adding the water. During the first 2 minutes, the putty can be handled and molded into any desired shape and digitally placed to the graft site. During the first minute of the mixing operation, the temperature of a 10-cc mixture rises only a few degrees before cooling down to ambient temperature. Five (5) minutes after adding the water, the putty can no longer be remolded and should not be reshaped. When placed in contact with bone and bone cells in the patient, the putty will provide the natural source of hard tissue minerals for new bone in-growth. The powder is ready to mix right off the shelf. No special storage or handling are required. The powder is contained in vials (5 cc to 30 cc). Cem-Ostetic™ bone putty will occupy a total volume close to that of the vial (even after adding water to it). It is important to mix the powder uniformly with the water and place the putty in contact with existing bone to accelerate bone tissue re-growth.
CEM-OSTETIC™ Bone Putty

Calcium-Based Synthetic Bone Putty

Ordering Information

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Description</th>
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<tbody>
<tr>
<td>CemO-05</td>
<td>5 cc</td>
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<tr>
<td>CemO-10</td>
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<td>CemO-20</td>
<td>20 cc</td>
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<tr>
<td>CemO-30</td>
<td>30 cc</td>
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Contraindications
All contraindications related to the use of bone graft substitutes must be observed. These include but are not restricted to all conditions that may influence negatively the healing of bone and surrounding tissue (e.g. lack of vascular flow to the implanted site, clotting disorder, current anti-coagulant therapy, chronic high dose steroid therapy, metabolic disorder or uncontrolled diabetic condition). Infected sites are not suitable for grafting; implants must not be placed in such sites. Good contact between existing bone, bone marrow and the implant is crucial for the graft substitute to function and promote bone regeneration. Care should therefore be taken to maximize the interface with surrounding bone. Vascular circulation to the implant should not be compromised by physical barriers such as scar tissue.

Precautions
These implants are not intended for load-bearing uses. It is important to ensure that the area where the putty has been implanted or injected be properly secured mechanically with rigid fixations to strengthen the surroundings. The entire volume of powder contained in the vials should be mixed carefully for 60 seconds with pure distilled sterile water (4 cc of water for 10 cc of powder). Do not mix with blood, saline water, or other liquids). The putty can be molded for about 2 minutes. It is completely hardened after 5 minutes. Respecting the 4-to-10 water to powder volume ratio is important; changing this ratio may significantly affect the hardening time and the viscosity of the putty. Attempts should not be made to modify the putty or to change its shape after hardening has begun. It is important to maximize contact between existing bone and the putty to ensure proper bone regeneration.

References:

Indications for use
Cem-Ostetic™ Bone Putty is indicated for use as void filler or bone augmentation material in mechanically stabilized areas. This bone putty is indicated for use to fill cranial defects, for spine surgery, and for oral/maxillo-facial surgery.

Warnings
Cem-Ostetic™ Bone Putty are opaque to x-rays. This may mask areas under the implant. The putty must be secured to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained.

Made in the USA (for export only). Dosage for single use only.

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