OSTEOREMEDIES®
ADVANCED MEDICAL TECHNOLOGIES

OSTEOBOOST® SELECT™
Resorbable Bead Kit

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Caution: U.S. Federal Law restricts this product to sale by or on the order of a physician or hospital.

STERILE R — RADIATION STERILIZED

SINGLE USE ONLY

℞ ONLY

DO NOT RESTERILIZE

INSTRUCTIONS FOR USE

IMPORTANT PRODUCT INFORMATION
Please read before use

ENGLISH

These instructions-for-use refer specifically to OsteoRemedies osteoconductive bone void filler formulated as a moldable putty and its bead convenience kit.

Description
OsteoBoost Select is a bio-engineered mixture of calcium-based inorganic compounds. After it is implanted, OsteoBoost Select resorbs and is later replaced by natural bone. It provides a safe alternative to human or animal cadaver bone that completely eliminates the potential for disease transmission. The distilled sterile water contained in the vial is indicated to be poured into the jar containing the powder and mixed with it to form a viscous putty. Once mixed with water for 60 seconds, the putty can be placed in contact with bone chips, or demineralized bone matrix to enhance bone reconstruction. It can also be molded into specific shapes. When mixed with the indicated amount of sterile distilled water, the putty begins hardening after 2 minutes. The putty is accompanied with a convenience kit that can be used to mold beads.

Intended Use
OsteoBoost Select is an osteoconductive putty that is intended to be used to fill voids and gaps that are not intrinsic to the stability of the bone structure. These gaps or voids may be located in the extremities, spine, pelvis, or cranium.
The putty may be shaped and pressed into the void by hand or inserted into a syringe and injected into the surgical site. The paste set *in situ* or *ex situ* provides a void filler that can augment hardware to support bone fragments during the surgical procedure. The set putty acts as a temporary support medium and is not intended to provide structural support during the healing process. The implant is radio-opaque. It is biocompatible and resorbs in the body as bone in-growth occurs.

Contraindications
OsteoBoost Select is not designed or sold for any use except as indicated. Do not use OsteoBoost Select in the presence of any contraindication. The implant will not function if the implanted site is not well vascularized. The implant is contraindicated where it is intended as structural support in the skeletal system (e.g. mandibular segment replacement).

Warnings
The entire device is sterilized by gamma irradiation. Content of package is STERILE unless opened or damaged. Read expiration date before use. Do not use if expiration date has been exceeded.
Dosage is for SINGLE USE ONLY. Any attempt to re-sterilize or re-use may cause a loss of functionality or contaminate the device.
OsteoBoost Select putty must be prepared within one hour after opening the package. Exposure to excessive heat or humidity prior to mixing components will compromise results.
OsteoBoost Select is opaque to x-rays. This may mask areas under or above the implant on the radiograph.
The implant must be secured to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained.
OsteoBoost Select does not possess sufficient mechanical strength for load-bearing uses. It is important to ensure that the implantation site has been properly secured mechanically with standard internal fixation. External stabilization alone is not sufficient.

Precautions
OsteoBoost Select is not intended for load-bearing uses. It is important to ensure that the area where the putty has been implanted be properly secured mechanically with rigid fixations to strengthen the surroundings. OsteoBoost Select is not intended for treatment of vertebral compression fractures and iliac crest backfill. Highly pressurized applications of the putty into a tightly confined space with ready venous or arterial access are not recommended, as the potential for formation of emboli is unknown. The putty must be secured to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained. Injection of the putty may cause pressurization that could lead to tissue fragments embolization or embolization of the device into the blood stream. The filler may extrude into soft tissues (e.g. facial applications or illiac crest backfill) and cause inflammation. Do not overfill the site.
The entire volume of sterile water contained in the vial should be quickly mixed with the powder contained in the jar to form a dough. The dough must then be kneaded by hand to ensure that the water is properly mixed with the powder. The putty will not harden if the powder is first placed in contact with blood or other liquids prior to mixing with water. The putty can be molded during the first 3 minutes after the water is in contact with the powder. Past these 3 minutes, the implant must be left alone for at least 2 minutes so that it can harden properly; changing the shape of the implant will make it crumble. Implant preparation takes a total of about 5 minutes. Using all the water from the vial is important. Using less water will compromise the hardening. Using more water will increase viscosity (increasing the risk of having the paste leak or embolize) and will increase the hardening time (the dough may actually not harden). Again, do not attempt to change the shape of the dough once hardening has begun (3 minutes after first contact between the water and the powder) or it will crumble.
When using the convenience kit to create beads, the bead will harden in at least 5 minutes. Once hard, it is recommended to wait for the beads to dry for an additional 5 minutes.
It is very important to maximize contact between existing bone and the putty to ensure proper bone regeneration. The effect of implanting the device in patients with the following conditions is unknown:

- documented renal disease
- metabolic bone disease
- pregnancy and nursing
- radiation bone therapy
- long-term infection
- cardiovascular disease precluding elective surgery.

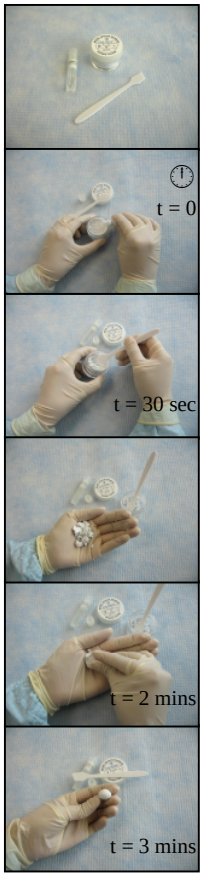
The effect of OsteoBoost Select in pediatric patients is not well documented. The effect of mixing the powder with any substance except for STERILE water (including antibiotics or serum) is not known. Closed suction or drainage is highly recommended to prevent wound fluid accumulation.

Potential Adverse Reactions
Possible adverse reactions may include but are not limited to the following: total resorption of the graft, malunion, pseudoarthrosis, hypersensitivity, thrombophlebitis, embolus, loss of fixation, neurological complication, and deformity at site. As with any other orthopedic and grafting procedures, wound complications may occur which include hematoma, edema, swelling and fluid accumulation, tissue thinning, infection, and other complications that may result from surgery.

Preoperative Procedure
In the incidence of an open fracture, initial debridement and wound management should be performed. Exercise care to minimize periosteal stripping. Infections must be treated and sepsis eradicated prior to the graft procedure. Use prophylactic antibiotic coverage as appropriate.

Surgical Procedure
All procedures should be performed in the operative room under aseptic conditions. Follow accepted procedures for grafting with fixation. Initial debridement and wound management should be performed in an open fracture. Exercise care to minimize periosteal stripping.

Mixing and Application



Step 1
Open Package.

Step 2
Add Water.

Step 3
Mix 30 Seconds.

Step 4
Transfer Dough into Hand.

Step 5
Knead by Hand.
Mold Implant.
Complete in Fewer
Than 2 Minutes.

Step 6
Let Implant Harden for
3 Minutes.

Step 1: **Open** both outer and inner pouches. Open jar of powder and vial of distilled water. The proper amount of water to add is pre-measured.
Step 2: **Pour entire amount of water** into jar containing the powder. The jar can be used as a mixing container.
Step 3: **Mix thoroughly for 30 seconds using spatula**.
Step 4: Once the powder is wet, it forms a dough. Remove dough from the jar and **transfer it into the hand.**
Step 5: Knead dough firmly until it becomes homogenous.
Quickly mold putty into desired shape or pack into surgical site and let implant harden. For best results, this process must be completed within **2 minutes** after adding water to the powder. Once the putty begins to harden, it is no longer workable and may crack under pressure. To eliminate the potential for cracking the implant, the molding process must be completed within 3 minutes after the water is first in contact with the powder. To repair or smoothen tiny cracks, a few drops of sterile water can be used.
Step 6: **Let implant harden for at least 2 minutes** either letting it dry on the preparation table or secure implant mechanically in the surgical site. The set material will appear somewhat dry and stable to the touch. Secure the implanted site to **prevent micro-motion and implant migration**. When excess fluid is present in the surgical field, allow up to 30 minutes for the material to set. Cauterization, suction, and application of bone wax (if needed) can be used to reduce bleeding. If the dough has not set satisfactorily, remove the implant and start over with a new package of OsteoBoost Select.

Powder	Implant
5 g	5 cc
10 g	10 cc

USE ONLY STERILE WATER
Nominal quantities of OsteoBoost Select powder and putty.

THE PUTTY WILL NOT HARDEN IF FIRST PLACED IN CONTACT WITH BLOOD OR OTHER LIQUIDS PRIOR TO MIXING WITH WATER. ALWAYS USE RECOMMENDED VOLUME OF WATER.

Storage Conditions

Optimal Storage Conditions: 15-30˚C (59-86F) in a secure and dry environment. DO NOT FREEZE. The water vial may crack if package goes below 0°C (32F). DO NOT EXPOSE DEVICE TO EXCESSIVE HEAT. Device may lose functionality if frozen or exposed to temperatures above 55˚C (131F). It is the responsibility of the distribution intermediary and/or end user clinician to maintain the device intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

Convenience Kit

The 5cc and 10cc convenience kits include one mat to create three different sized beads: X-Small, Small, and Medium. One side of the mat can be used to create small and medium beads (see Fig. 1). The second side of the mat can be used to create X-Small beads (see Fig. 2).

Figure 1: Small and Medium Bead Cavities

Figure 2: X-Small Bead Cavities

After completing Step 1 through 3 of the Mixing and Application Section, the moldable putty can be transferred onto the chosen side of the blue mat. The spreading spatula can then be used to fill in the holes of the desired bead size (see Fig. 3).

Figure 3: Apply the soft putty onto the mat to fill holes in as much as possible.

Once the holes are filled, allow the putty and harden for at least 5 minutes and release the beads into a sterile pan.

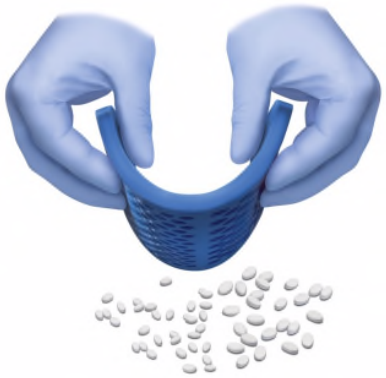


Figure 4: Release beads onto a sterile pan.

The beads are now ready to be implanted into the void to be filled.

Shelf Life and Disposal

The expiration date is printed on the label.
DO NOT USE AFTER THE EXPIRATION DATE.
OsteoBoost Select is environment-friendly. No special disposal is necessary. Packaging material is recyclable.

Other Information

OsteoBoost Select bone void filler is a sterile and osteoconductive bone graft substitute. The product is provided with detailed instructions-for-use.
OsteoBoost Select is packaged in plastic or glass jars. The components are sealed in translucent pouches and placed in an additional box for transport and storage. Included with this instructions-for-use leaflet are supplementary labels for patient documentation. The sterile jar containing the powder is designed to also serve the function of mixing container. The spatula can be used to mix the components.

Manufactured by Berkeley Advanced Biomaterials, Berkeley, CA (USA).
Note: Responsibility for proper selection of patients, adequate training, experience in the choice and placement of the implant, and for the choice of post-operative follow-up procedures rests entirely with the physician. In case of complaint or for further information on the product and its uses, please contact Berkeley Advanced Biomaterials at the address above.