

Dimensional Bioceramics

- 9.7 OsteoRepair Paste will remain moldable and implantable for approximately 2 minutes at standard operating room temperatures (21°C to 19°C, 70°F to 66°F).
- 9.8 OsteoRepair Paste will remain workable for 1 minute following implantation.
- 9.9 After the above described working time, OsteoRepair Paste and the operative site should not be disturbed for an additional 5 minutes to ensure proper initial setting.
- NOTE: Initial set up time for OsteoRepair Paste is 6 minutes following implantation at 32°C (90°F).**
- 9.10 Closure of the surgical site may be commenced following the 6 minute implantation setting period. The ultimate strength of the material is reached 24 to 72 hours post implantation.
- 9.11 OsteoRepair Paste is designed to set in a wet surgical environment at body temperature. Initial and hard setting periods will be delayed if the temperature of the surgical implantation site is equal or less than 32°C (90°F).
- 10.0 MRI SAFETY INFORMATION: The OsteoRepair Paste is MRI safe.



STERILE

Sterilized using
irradiation



Do not
re-use



See
Instructions
for Use



Do not use if
package is
damaged

Rx
ONLY

Federal law (USA)
Restricts the
device to sale BY
OR on the order
of a physician

Store at 15°C to 30°C (59°F to 86°F)



Non-pyrogenic



Keep Dry



Manufactured by:
Phoenix DeVentures, Inc.
Morgan Hill, CA 95037, USA

Manufactured for:
Dimensional Bioceramics, LLC

Distributed by:
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DIMENSIONAL BIO CERAMICS

OsteoRepair™ Paste

Bone Void Filler Instruction for Use

Patient Label -----

PN 70130, Rev. A

OsteoRepair™ Paste



Bone Void Filler

- 1.0 Description:**
- 1.1 OsteoRepair™ Paste Bone Void Filler is a moldable and biocompatible calcium phosphate bone void filler. The single-use OsteoRepair Paste Kit contains the necessary components for mixing of the bone void filler, and is available in three sizes (3 cc, 5 cc, and 10 cc).
- 1.2 The OsteoRepair Paste sterile kit contains: Calcium Phosphate Powder, Liquid Vial, and a Mixing System (Mixing Bowl, Pestle and Spatula).
- 2.0 Indications for Use:**
- 2.1 OsteoRepair Paste Bone Void Filler is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. OsteoRepair Paste is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.
- 3.0 Contraindications:**
OsteoRepair Paste is not designed or sold for any use except as indicated. DO NOT use OsteoRepair Paste IN THE PRESENCE OF ANY CONTRAINDICATION:
- 3.1 Use in any infected site or surgical site located near an infection.
- 3.2 Use in areas where supporting bone is not viable, or is incapable of supporting or anchoring the implant.
- 3.3 Use in patients with an abnormal calcium metabolism, metabolic bone disease, a recent untreated infection or immunological abnormalities.
- 3.4 Use in patients who undergo or are to undergo an immunosuppression therapy.
- 3.5 Use in patients with acute traumatic injuries with open wounds close to the defect which are likely to become infected.
- 3.6 Use in patients having received or are to receive chemotherapy or radiation therapy at or near the implant site.
- 4.0 Warnings:**
- 4.1 OsteoRepair Paste attains a physiological pH after components are properly mixed - the Calcium Phosphate Powder and Liquid Vial components may be irritants separately.
- 4.1.1 Skin Exposure: Wash exposed area with soap and water. Seek medical attention if irritation develops.
- 4.1.2 Eye Exposure: Flush thoroughly with running water. Seek medical attention if irritation develops.
- 4.2 OsteoRepair Paste is a single use only product; unused portions of OsteoRepair Paste must be discarded and cannot be re-sterilized.
- 4.2.1 Concurrent use of any other agents not indicated may effect the setting time and/or the safety and efficacy of this medical device.
- 4.2.2 Complete postoperative wound closure is essential. OsteoRepair Paste must not be used to repair bone defects where soft tissue coverage cannot be achieved.
- NOTE: All components of OsteoRepair Paste must be cooled to at or below 21°C (70°F) prior to use.**
- NOTE: Attempts to reuse or re-sterilize OsteoRepair Paste may result in patient harm and may expose the patient to the risk of transmitting infectious disease.**
- NOTE: Before disposal of any unused OsteoRepair Paste, mix the Calcium Phosphate Powder and the Liquid Vial together to render the material harmless to personnel and the environment.**
- 5.0 Precautions:**
- 5.1 Use only the components provided with the OsteoRepair Paste Kit for the mixing of OsteoRepair Paste. Substitution of components may alter the desired results.
- 5.2 The paste remains moldable and implantable for up to 2 minutes at room temperature (21°C to 19°C, 70°F to 66°F). Once the paste has been introduced into the body, it will remain workable for 1 minute at 32°C (90°F). Following this 1 minute working period, the material and the site should not be disturbed for an additional 5 minutes to allow for proper initial setting. The material will continue to cure in the next 24 to 72 hours after implantation to reach its maximum strength.

5.3 The medical professional is responsible for using his/her best medical judgment when using this device. Prior to the implantation of this bone void filler, the medical professional should develop a preoperative plan which takes into account the mixing, delivery, working and setting times of OsteoRepair Paste for the particular desired use.

5.4 The effects of OsteoRepair Paste on patients with the following indications are not known:

- Documented Renal Disease
- Metabolic bone disease
- Pregnancy/nursing
- Sinus obliteration
- Infection during the last three months
- Radiation and/or chemotherapy post-implantation
- Cardiovascular disease precluding elective surgery
- Patients who are skeletally immature

6.0 Adverse Reactions:

A successful result is not achieved in every single surgical case. Reoperation to remove or replace the implant may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur. The occurrence of any of the following applications is possible and may require reoperation and/or removal of the implant.

Complications may include but are not limited to:

- 6.1 Infection of the soft tissue and/or bone (osteomyelitis) and fever.
- 6.2 Transient hypercalcemia.
- 6.3 Adverse tissue reaction – tenderness / redness / edema.
- 6.4 Seroma / hematoma or infection.
- 6.5 Fracture of newly formed bone
- 6.6 Incomplete bone in-growth, delayed union and non-union.

7.0 Sterility:

7.1 All components of the OsteoRepair Paste are provided sterile and are intended for single use only. Do not re-sterilize.

7.2 Sterile product packaging should be inspected for flaws and integrity prior to opening. In the presence of such a flaw, the product must be considered non-sterile and appropriately discarded.

8.0 Storage:

8.1 The OsteoRepair Paste Kit is to be stored at a controlled room temperature between 15°C to 30°C (59°F to 86°F).

9.0 Instructions for Use:

The operating physician should be experienced in current advances in surgical techniques and standard operating procedures. Additional training from a company representative is recommended.

- 9.1 Implantation of OsteoRepair Paste should be performed under sterile or aseptic operating room conditions and image intensification is advised.
- 9.2 Implant Site Preparation: Remove blood clots and tissue debris, lavage and suction may be used.
- 9.3 Proper eye protection and surgical gloves must be worn when mixing OsteoRepair Paste.
- 9.4 Mix OsteoRepair Paste by pouring the Calcium Phosphate Powder vial into the mixing bowl; gently tap the vial to ensure maximum transfer of powder. After powder vial is empty, slowly pour the Liquid vial into the mixing bowl. After the liquid has been poured, gently tap the vial to ensure that all of the liquid has been transferred from the vial into the mixing bowl.
- 9.5 Using the pestle, mix the Powder and Liquid together for approximately 1 minute using a circular stirring motion. The objective is to completely wet the powder with the liquid and ensure a proper mix.

NOTE: During the mixing process material may collect on the pestle. This material must be reincorporated into the mixing process to ensure a proper mix of OsteoRepair Paste.

9.6 Once mixed, OsteoRepair Paste may be delivered to the targeted site using manual impaction.