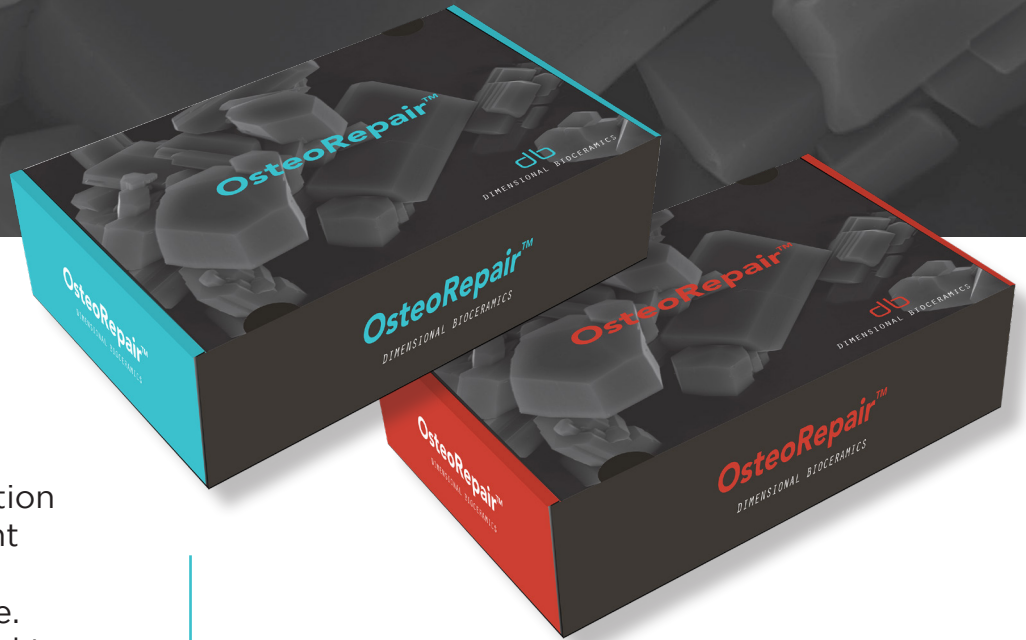


OsteoRepair™



OsteoRepair is a high performance next generation calcium phosphate cement indicated for filling bony defects in cancellous bone. This material was designed to overcome the limitations of the first generation calcium phosphate cements. First generation cements had good compression strength, but were weak in tension, flexural strength and fracture toughness, which combined with poor handling properties, have limited their use in fracture fixation.

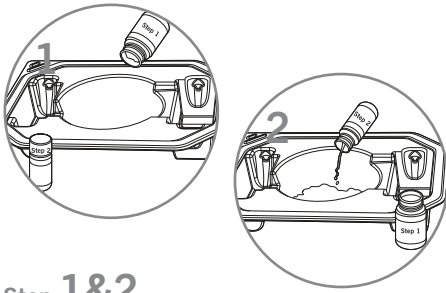
ADVANTAGES

- Biocompatible
- Allows for natural bone remodeling, or healing, while still maintaining the strength of cancellous bone
- Easy to mix and deliver with supplied mixing system
- Fast, hard-setting; approximately 5 minutes at 37°F in wet environment
- Immediate higher compressive strength than cancellous bone
- Can be drilled and inserted with screws
- May be implanted before or after hardware allowing surgeons to maintain their standard surgical technique and allowing precise cement and hardware placement



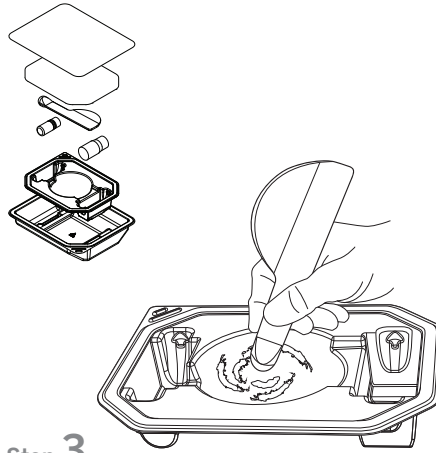
DIMENSIONAL BIO CERAMICS

OsteoRepair™ Paste



Step 1&2

- First, add all of the powder component into the bowl, (tapping the vial with the pestle to ensure all contents are removed from the vial)
- Second, add all of the liquid component into the bowl, (tapping the vial with the pestle to ensure all contents are removed from the vial)
- Start timer



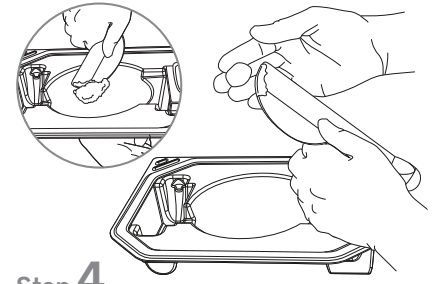
Step 3

- Quickly mix contents using a vigorous circular motion with the pestle for 1 minute; better mixing creates better handling
- The objective is to completely wet the powder and have an even consistency

Note: Material that collects on the pestle must be reincorporated into the mixing process. This is achieved by rolling the pestle on it's own axis, swiping onto the edge, or wiping by finger, and then continuing the mixing process.

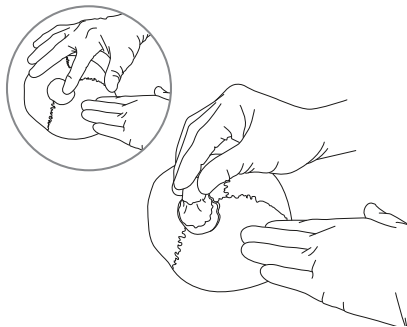
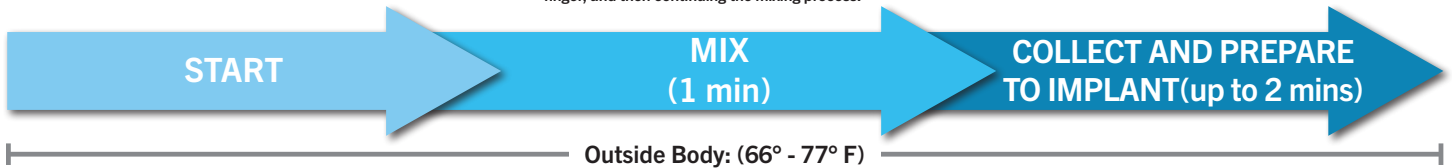
KEY PRINCIPLES THAT MUST BE FOLLOWED

- Prior to use, the product must be at or below 77° F to work properly
- Once the product touches the patient, it needs a warm body temperature (above 90° F) and a wet environment to set properly



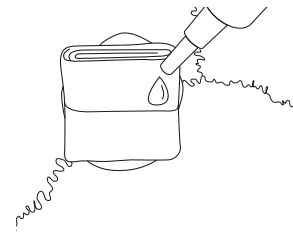
Step 4

- Using the sterile spatula, gather product into one mass and remove from the bowl
- Product can remain on the spatula or be formed into a ball by hand



Step 5

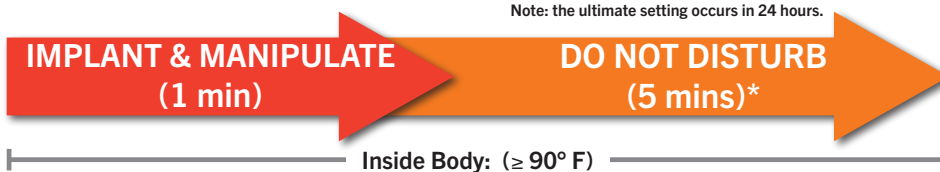
- Start new timer
- Implant material either by spatula or by hand
- Use fingers or spatula to mold into desired shape
- You have up to 1 minute to manipulate the product once it touches the defect



Step 6

- Allow the product to set
- Cover with gauze or lap sponge and irrigate every 30 seconds with warm saline to allow for proper setting; 98.6° F is ideal
- It is very important not to touch the product while it is setting
- After 5 minutes of setting at 90°F or higher, the product should be properly set for soft tissue closure.*

Note: the ultimate setting occurs in 24 hours.



STERILE
Sterilized using irradiation

CAUTION: Rx ONLY

Store at 15 C to 30 C
(59 F to 86 F)

Consult instructions for use

Keep dry

Do not use if package is damaged

Non-pyrogenic

Do not re-use

EC REP

BBI - Trade B.V.
Koekoeklaan 20
1343 AM Almere
The Netherlands

MR

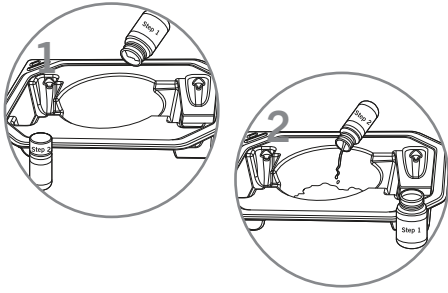
Manufactured by:
Phoenix DeVentures, Inc. Morgan Hill, CA 95037

Manufactured for:
Dimensional Bioceramics, LLC

Distributed by:
KLS-Martin L.P.
11201 Saint Johns Industrial Pkwy S
Jacksonville, FL 32246, USA
800-625-1557
www.klsmartinorthamerica.com

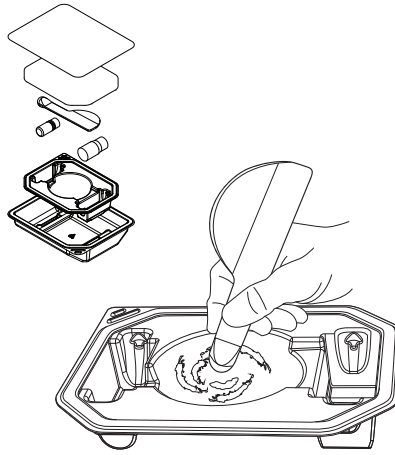
PN 70119

OsteoRepair™ Inject



Step 1&2

- First, add all of the powder component into the bowl, (tapping the vial with the pestle to ensure all contents are removed from the vial)
- Second, add all of the liquid component into the bowl, (tapping the vial with the pestle to ensure all contents are removed from the vial)
- Start timer

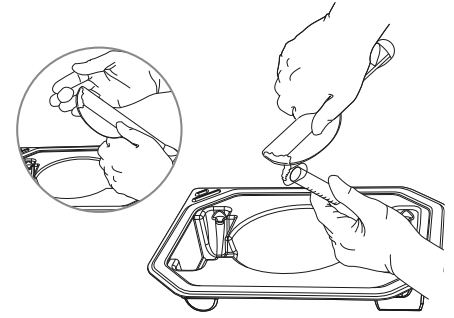


Step 3

- Quickly mix contents using a vigorous circular motion with the pestle for 1 minute; better mixing creates better handling
 - The objective is to completely wet the powder and have an even consistency
- Note: Material that collects on the pestle must be reincorporated into the mixing process. This is achieved by rolling the pestle on it's own axis, swiping onto the edge, or wiping by finger, and then continuing the mixing process.**

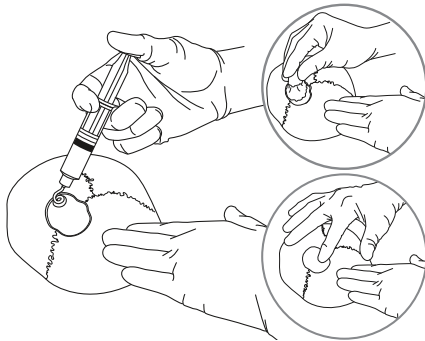
KEY PRINCIPLES THAT MUST BE FOLLOWED

- Prior to use, the product must be at or below 77° F to work properly
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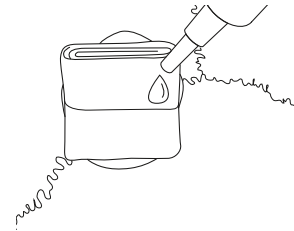
Step 4

- Using the sterile spatula, gather all the product into one mass and remove from bowl
- If using a syringe, use the spatula to back fill the syringe with a continuous scraping motion
- If using as a putty, keep product on spatula or form into a ball by hand



Step 5

- Start new timer
- Implant material either by syringe, spatula or by hand
- Use fingers or spatula to mold into desired shape
- You have up to 2 minutes to manipulate the product once it touches the defect



Step 6

- Allow the product to set
 - Cover with gauze or lap sponge and irrigate every 30 seconds with warm saline to allow for proper setting: 98.6° F is ideal
 - It is very important not to touch the product while it is setting
 - After 6 minutes of setting at 90F or higher, the product should be properly set for soft tissue closure.*
- Note: the ultimate setting occurs in 24 hours.**



STERILE
Sterilized using irradiation

CAUTION: Rx ONLY

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(59 F to 86 F)

Consult instructions for use

Keep dry

Do not use if package is damaged

Non-pyrogenic

Do not re-use

EC REP

BBI - Trade B.V.
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The Netherlands

MR

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

Manufactured by:
Dimensional Bioceramics, LLC

PN 70120, Rev. A

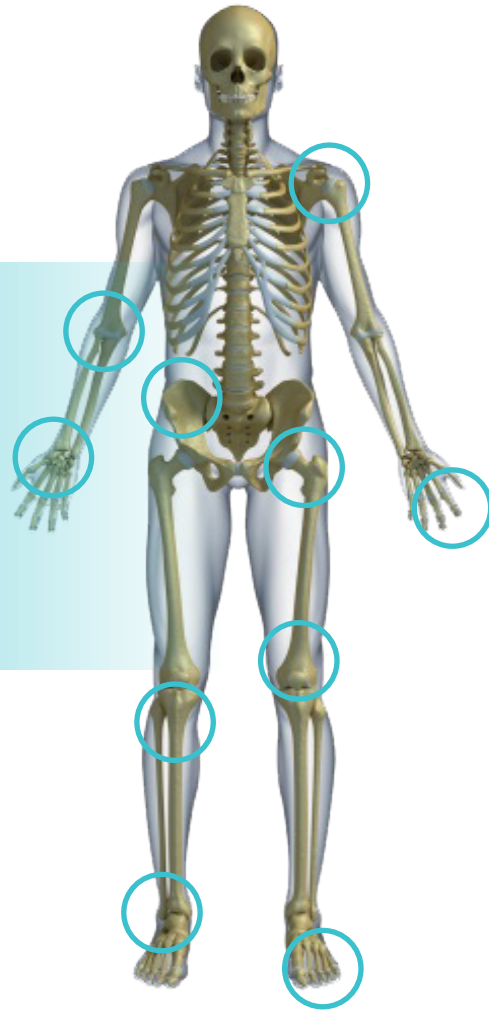
CLINICAL APPLICATIONS

- Simple voids in metaphyseal bone, (*small tumors, cysts, defects*)
- Traumatic fractures that result in bone voids in metaphyseal areas

Fractures of the:

- Distal Radius (*Colles*)
- Proximal Humerous
- Pelvic Bone
- Proximal Femur (*Intertroch, Femoral Neck*)
- Distal Femur
- Tibial Plateau
- Tibial Pilon
- Calcaneus

- Osteotomies (*Distal Radius, Tibial Plateau*)
- All Oncological applications
- Revision Total Joints
- Iliac Crest back fill



ORDERING INFORMATION

Product	Item Number
OsteoRepair Putty 5cc	DB-O-P5CC
OsteoRepair Putty 10cc	DB-O-P10CC
OsteoRepair Inject 5cc <i>Coming Soon</i>	DB-O-I5CC
OsteoRepair Inject 10cc <i>Coming Soon</i>	DB-O-I10CC

db

DIMENSIONAL BIOCERAMICS