NOTE: The efficacy of alternative delivery methods other than those recommended or supplied by OsteoMed has not been evaluated.

9.7 OsteoVation EX *Inject* will remain injectable for approximately 5 minutes at standard operating room temperatures (19°C to 21°C, 66°F to 70°F).

9.8 If injecting OsteoVation EX *Inject*, utilize a retrograde approach to fill the void.

NOTE: Operating room temperatures above 21°C (70°F) may adversely affect product performance, specifically mixing and injection. If the operating room temperature is above 21°C (70°F) the entire OsteoVation EX *Inject* kit should be cooled to below operating room temperature, but not to freezing temperatures.

9.9 OsteoVation EX *Inject* will remain workable for 2 minutes following implantation into the void.

9.10 After the above described working time, OsteoVation EX *Inject* and the operative site should not be disturbed for 4 minutes to ensure proper initial setting.

NOTE: OsteoVation EX *Inject* is considered initially set 6 minutes following implantation at 32°C (90°F).

9.11 Following the 6 minute setting period, implants may be placed and then closure of the surgical site may be commenced. The ultimate strength of the material is reached 24 to 72 hours post implantation.

9.12 OsteoVation EX *Inject* is designed to set in a wet surgical environment at body temperature. If a tourniquet is used during the procedure, the surgical site may be at a temperature that is under the desired temperature for proper setting. 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).

Distributed by: OSTEOMED L. P.
3885 Arapaho Road
Addison, Texas, 75001
972-677-4600
www.osteomedcorp.com

Manufactured by Skeletal Kinetics®

STERILE R

Single Use Only

See directions for use

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

CE 0050

Skeletal Kinetics, LLC
10201 Bubb Road
Cupertino, CA 95014-4167
USA
408-366-5000

EC REP

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

030-1377, Rev. D
LBL 10628 – AF

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OSTEOMED®

OSTEOVATIONEX® BONE VOID FILLER

Inject Bone Void Filler

Product Insert with

Instructions for Use

1.0 Description:

1.1 OsteoVation EX *Inject* Bone Void Filler is an injectable and biocompatible calcium phosphate bone void filler. The single-use OsteoVation EX *Inject* Kit contains the necessary components for mixing of the bone void filler.

1.2 The OsteoVation EX *Inject* sterile kit contains: Calcium Phosphate Powder, Dilute Sodium Silicate Liquid, and a Mixing System (Mixing Bowl, Pestle and spatula).

2.0 Indications:

2.1 OsteoVation EX *Inject* is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. OsteoVation EX *Inject* is indicated only for bony voids or gaps that are not intrinsic to the stability of the boney structure and is non-suitable for use in kyphoplasty procedures. The product provides a bone void filler that is replaced by bone during the healing process.

3.0 Contraindications:

OsteoVation EX *Inject* is not designed or sold for any use except as indicated.
DO NOT use OsteoVation EX *Inject* IN THE PRESENCE OF ANY CONTRAINDICATION:

3.1 The presence of infection or suspected infection.
3.2 Implantation into areas where bone tissue is not viable.
3.3 Patients who have not reached skeletal maturity.

4.0 Warnings:

4.1 OsteoVation EX *Inject* attains a physiological pH after components are properly mixed - the Calcium Phosphate Powder and Sodium Silicate Liquid 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 OsteoVation EX *Inject* is a **single use only** product; unused portions of OsteoVation EX *Inject* must be discarded and **cannot be re-sterilized**.

NOTE: All components of OsteoVation EX *Inject* must be cooled to at or below 21°C (70°F) prior to use.

NOTE: Attempts to reuse or re-sterilize OsteoVation EX *Inject* may result in patient injury and may expose the patient to the risk of transmitting infectious disease.

NOTE: Before disposal of any unused OsteoVation EX *Inject*, mix the Calcium Phosphate Powder and the Dilute Sodium Silicate Liquid together to render the material harmless to personnel and the environment.

5.0 Precautions:

5.1 Use only the components provided with the OsteoVation EX *Inject* Kit for the mixing of OsteoVation EX *Inject*. Substitution of components may alter the desired results.

5.2 The paste remains injectable and implantable for up to 5 minutes at room temperature (19°C to 21°C, 66°F to 70°F). Once the paste has been introduced into the body, it will remain workable for 2 minutes at body temperature 32°C (90°F). Following this 2 minute working period, the material and the site should not be disturbed for an additional 4 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 OsteoVation EX *Inject* for the particular desired use.

5.4 Laboratory tests including cytotoxicity, systemic toxicity, intracutaneous irritation, sensitization, and mutagenicity testing have been completed. These non-clinical tests demonstrate the biocompatibility of OsteoVation *Inject*, however long term clinical human data has not been studied.

5.5 The long-term effects of extraosseous OsteoVation EX *Inject* or intra-articular OsteoVation EX *Inject* (material injected into the joint space) are unknown. Arthritis may be a possible complication of intra-articular OsteoVation EX *Inject*.

5.6 The effects of OsteoVation EX *Inject* on patients with the following indications are not known

- Documented Renal Disease
- Pregnancy/nursing
- Cardiovascular disease precluding elective surgery
- History of chronic infection
- Radiation and/or chemotherapy post-implantation
- Patients who are skeletally immature
- Traumatic open injuries which are predisposed to infection

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 Adverse tissue reaction.
6.3 Transient hypercalcemia.
6.4 Incomplete bone in-growth, delayed union, and non-union.
6.5 Fracture of the newly formed bone.
6.6 As with any surgical procedure, certain adverse reactions may be associated with the treatment. Potential risks may include but not be limited to the following: Anesthetic or post anesthetic reactions (such as hypoxemia), allergic reactions, damage to nerves or blood vessels, pulmonary emboli, need for additional surgeries or even death.

7.0 Sterility:

7.1 All components of the OsteoVation EX *Inject* are provided sterile (gamma) 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 OsteoVation EX *Inject* Kit is to be stored at a 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 OsteoVation EX *Inject* should be performed under sterile or aseptic operating room conditions and image intensification is advised.

9.2 Prepare Implant Site. 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 OsteoVation EX *Inject*.

9.4 To mix OsteoVation EX *Inject:* When pouring the Calcium Phosphate Powder into the mixing bowl, gently tap the vial to ensure maximum transfer of powder. After powder vial is empty, slowly pour the Liquid 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 or until homogeneous 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 OsteoVation EX *Inject*.

9.6 Once mixed, OsteoVation EX *Inject* may be delivered to the targeted site using manual impaction or injection. If delivery via injection is desired, use the sterile spatula to scoop and load OsteoVation EX *Inject* out of the mixing bowl and into either a sterile delivery syringe supplied by OsteoMed or a commercially available sterile delivery syringe.