

1.0	Description:	<p>1.1 OsteoVation™EX <i>Inject</i> Bone Void Filler is an injectable and biocompatible calcium phosphate bone void filler. The single-use OsteoVation™EX <i>Inject</i> Bone Void Filler Kit contains the necessary components for mixing of the bone void filler.</p> <p>1.2 The OsteoVation™EX <i>Inject</i> Bone Void Filler sterile kit contains: Calcium Phosphate Powder, Sodium Silicate Liquid, and a Mixing System (Mixing Bowl, Pestle and spatula).</p>	<p>5.5 long term clinical human data has not been studied. The long-term effects of extraosseous OsteoVation™EX <i>Inject</i> Bone Void Filler or intra-articular OsteoVation™EX <i>Inject</i> (material injected into the joint space) are unknown. Arthritis may be a possible complication of intra-articular OsteoVation™EX <i>Inject</i> Bone Void Filler.</p> <p>5.6 The effects of OsteoVation™EX <i>Inject</i> Bone Void Filler on patients with the following indications are not known:</p> <ul style="list-style-type: none"> • 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
2.0	Indications:	<p>2.1 OsteoVation™EX <i>Inject</i> Bone Void Filler 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 <i>Inject</i> Bone Void Filler is indicated only for bony voids or gaps that are not intrinsic to the stability of the boney structure. The product provides a bone void filler that is replaced by bone during the healing process.</p>	
3.0	Contraindications:	<p>OsteoVation™EX <i>Inject</i> Bone Void Filler is not designed or sold for any use except as indicated. DO NOT use OsteoVation™EX <i>Inject</i> Bone Void Filler IN THE PRESENCE OF ANY CONTRAINDICATION:</p> <p>3.1 The presence of infection or suspected infection.</p> <p>3.2 Implantation into areas where bone tissue is not viable.</p> <p>3.3 Patients who have not reached skeletal maturity.</p>	<p>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:</p> <p>6.1 Infection of the soft tissue and/or bone (osteomyelitis) and fever.</p> <p>6.2 Adverse tissue reaction.</p> <p>6.3 Transient hypercalcemia.</p> <p>6.4 Incomplete bone in-growth, delayed union, and non-union.</p> <p>6.5 Fracture of the newly formed bone.</p> <p>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.</p>
4.0	Warnings:	<p>4.1 OsteoVation™EX <i>Inject</i> Bone Void Filler attains a physiological pH after components are properly mixed - the Calcium Phosphate Powder and Sodium Silicate Liquid components may be irritants separately.</p> <p>4.1.1 Skin Exposure: Wash exposed area with soap and water. Seek medical attention if irritation develops.</p> <p>4.1.2 Eye Exposure: Flush thoroughly with running water. Seek medical attention if irritation develops.</p> <p>4.2 OsteoVation™EX <i>Inject</i> Bone Void Filler is a single use only product; unused portions of OsteoVation™EX <i>Inject</i> Bone Void Filler must be discarded and cannot be re-sterilized.</p> <p>NOTE: All components of OsteoVation™EX <i>Inject</i> Bone Void Filler must be cooled to below 21°C (70°F) prior to use.</p> <p>NOTE: Attempts to reuse or re-sterilize OsteoVation™EX <i>Inject</i> Bone Void Filler may result in patient harm and may expose the patient to the risk of transmitting infectious disease.</p> <p>NOTE: Before disposal of any unused OsteoVation™EX <i>Inject</i> Bone Void Filler, mix the Calcium Phosphate Powder and the Dilute Sodium Silicate Liquid together to render the material harmless to personnel and the environment.</p>	<p>7.0 Sterility:</p> <p>7.1 All components of the OsteoVation™EX <i>Inject</i> Bone Void Filler are provided sterile (gamma) and are intended for single use only. Do not re-sterilize.</p> <p>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.</p> <p>8.0 Storage:</p> <p>8.1 The OsteoVation™EX <i>Inject</i> Bone Void Filler Kit is to be stored at a controlled room temperature between 15°C and 30°C (59°F to 86°F).</p> <p>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.</p> <p>9.1 Implantation of OsteoVation™EX <i>Inject</i> Bone Void Filler should be performed under sterile or aseptic operating room conditions and image intensification is advised.</p> <p>9.2 Implant Site Preparation: Remove blood clots and tissue debris, lavage and suction may be used.</p> <p>9.3 Proper eye protection and surgical gloves must be worn when mixing OsteoVation™EX <i>Inject</i> Bone Void Filler.</p> <p>9.4 Mix OsteoVation™EX <i>Inject</i> Bone Void Filler by pouring the Calcium Phosphate Powder into the mixing bowl, while tapping the vial to ensure maximum transfer of powder. Pour the liquid into the mixing bowl, while tapping the vial to ensure maximum transfer of liquid.</p> <p>9.5 Using the pestle, mix the Powder and Liquid together for approximately 1 minute using a circular stirring motion.</p> <p>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 <i>Inject</i> Bone Void Filler.</p> <p>9.6 Once mixed, OsteoVation™EX <i>Inject</i> Bone Void Filler may be delivered to the targeted site using manual impaction or injection. If delivery via injection is desired,</p>
5.0	Precautions:	<p>5.1 Use only the components provided with the OsteoVation™EX <i>Inject</i> Bone Void Filler Kit for the mixing of OsteoVation™EX <i>Inject</i> Bone Void Filler. Substitution of components may alter the desired results.</p> <p>5.2 The paste remains injectable and implantable for up to 3 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 1 minute at body temperature (37°C, 98.6°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.</p> <p>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 <i>Inject</i> Bone Void Filler for the particular desired use.</p> <p>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™ <i>Inject</i> Bone Void Filler, however</p>	<p>030-1377, Rev. C LBL 10628- AB</p>

use the sterile spatula to scoop and load OsteoVation™ *Inject* out of the mixing bowl and into either a sterile delivery syringe supplied by OsteoMed or a commercially available sterile delivery syringe.

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

- 9.7 OsteoVation™EX *Inject* Bone Void Filler will remain injectable for approximately 3 minutes at standard operating room temperatures (19°C to 21°C, 66°F to 70°F).
- 9.8 If injecting OsteoVation™EX *Inject* Bone Void Filler, utilize a retrograde approach to fill the void.
- 9.9

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* Bone Void Filler kit should be cooled to below operating room temperature, but not to freezing temperatures.

- 9.10 OsteoVation™EX *Inject* Bone Void Filler will remain workable for 1 minute following implantation.
- 9.11 After the above described working time, OsteoVation™EX *Inject* Bone Void Filler and the operative site should not be disturbed for an additional 5 minutes to ensure proper initial setting.

NOTE: Initial set up time for OsteoVation™EX *Inject* Bone Void Filler is 6 minutes following implantation at 32°C (90°F).

- 9.12 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.
- 9.13 OsteoVation™EX *Inject* Bone Void Filler 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 less than body temperature (37°C, 98.6°F).

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OsteoVation™EX ***Inject* Bone Void Filler** **Product Insert with** **Instructions for Use**