10.10. After the above described working time, OsteoVation QWIK *Inject* and the operative site should not be disturbed for 8 minutes to ensure proper setting.

NOTE: OsteoVation QWIK *Inject* is considered set 10 minutes following implantation at 32°C (90°F).

10.11. Irrigation is **not allowed** during the setting period. Following the 10-minute post-implantation setting period, closure of the surgical site may be commenced.

10.12. OsteoVation QWIK *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. Setting period will be delayed if the temperature of the surgical implantation site is less than 32°C (90°F).

Symbols and Definitions

Single Use Only		REF	Catalogue Number
Use By (Date)		STERILE R	Sterile, Method of Sterilization Using Irradiation
Rx ONLY — Federal Law (U.S.A.) Restricts this device to sale by or on the order of a physician.		LOT	Batch Code (Lot Number)
			Manufacturer (MFR)
Attention, See Instructions for Use Caution, Consult Accompanying Documents		30°C (86°F) / 15°C (59°F)	Store at controlled room temperature between 15° C (59° F) and 30° C (86° F)

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030-1778 Rev. A
LBL 12496-AA

OsteoVation® QWIK *Inject*

Instructions for Use

1. Description:

1.1. OsteoVation® QWIK *Inject* Bone Void Filler is a moldable and biocompatible calcium phosphate/calcium sulfate composite bone void filler. The single-use OsteoVation QWIK *Inject* Kit contains the necessary components for mixing of the bone void filler.

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

2. Indications:

2.1. OsteoVation QWIK *Inject* is indicated to fill bony voids or gaps of the skeletal system (i.e. extremities, posterolateral spine, pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. OsteoVation QWIK *Inject* 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 with bone during the healing process.

3. Contraindications:

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 yet reached skeletal maturity.
3.4. **Not for use in vertebroplasty in the treatment of vertebral compression fractures.**

4. Warnings:

4.1. OsteoVation QWIK *Inject* attains a physiological pH after components are properly mixed - the Calcium Phosphate/Calcium Sulfate Powder and Dilute 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 QWIK *Inject* is a **single use only** product; unused portions of OsteoVation QWIK *Inject* should be discarded and **cannot be re-sterilized**.

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

NOTE: Attempts to reuse or re-sterilize OsteoVation QWIK *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 QWIK *Inject*, mix the

calcium phosphate/calcium sulfate powder and the dilute sodium silicate liquid together to render the material harmless to personnel and the environment.

5. Cautions:

5.1. Use only the components provided with the OsteoVation QWIK *Inject* Kit for the mixing of OsteoVation QWIK *Inject*. Substitution of components may alter the desired results.
5.2. Once the paste has been introduced into the body, it will remain workable for 2 minutes at 32°C (90ºF). Following this 2 minute working period, the material and the site should not be disturbed for an additional 8 minutes to allow for proper initial setting.
5.3. The effects of OsteoVation QWIK *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 or chemotherapy treatments
- Patients who are skeletally immature
- Traumatic open injuries which are predisposed to infection

6. Adverse Reactions:

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. Precautions:

7.1. 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 the bone void filler for the particular desired use.
7.2. Laboratory tests including cytotoxicity, systemic toxicity, intracutaneous irritation, sensitization, and mutagenicity testing have been completed. These non-clinical tests demonstrate the biocompatibility of OsteoVation QWIK *Inject*; however long-term clinical human data has not been studied.
7.3. The long-term effects of extraosseous OsteoVation QWIK *Inject*, or intra-articular OsteoVation QWIK *Inject* (material injected into the joint space) are unknown. Arthritis may be a possible complication of intra-articular OsteoVation QWIK *Inject.*
7.4. Adequate fracture fixation is required prior to injection of OsteoVation QWIK *Inject*.
7.5. Do not over-pressurize the surgical site since it may lead to fat embolization or embolization of the device material into the bloodstream.
7.6. Do not over-pressurize the device because this may lead to extrusion of the device beyond the site of its intended application and damage the surrounding tissue.

8. Sterility:

8.1. All components of the OsteoVation QWIK *Inject* are provided sterile and are intended for single use only. **Do not re-sterilize**.
8.2. 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.

9. Storage:

9.1. The OsteoVation QWIK *Inject* Kit is to be stored at a controlled room temperature between 15ºC to 30ºC (59ºF to 86ºF).

10. 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.

10.1. Implantation of OsteoVation QWIK *Inject* should be performed under sterile or aseptic operating room conditions; image intensification is advised.
10.2. Prepare Implant Site: Remove blood clots and tissue debris; lavage and suction may be used.
10.3. Proper eye protection and surgical gloves must be worn when mixing OsteoVation QWIK *Inject*.
10.4. To mix OsteoVation QWIK *Inject*: When pouring the Calcium Phosphate/Calcium Sulfate 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 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.
10.5. 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 QWIK *Inject.*

10.6. Once mixed, OsteoVation QWIK *Inject* may be delivered to the target site using manual impaction or injection. If delivery via injection is desired, use the sterile spatula to scoop and load OsteoVation QWIK *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 devices other than those recommended or supplied by OsteoMed has not been evaluated.

10.7. OsteoVation QWIK *Inject* will remain injectable for approximately 5 minutes at standard operating room temperatures (19°C to 21°C, 66°F to 70°F).
10.8. If injecting OsteoVation QWIK *Inject*, utilize a retrograde approach to fill the void.

NOTE: Operating room temperature 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 QWIK *Inject* kit should be cooled to below operating room temperature but not to freezing temperatures.

10.9. OsteoVation QWIK *Inject* will remain workable for 2 minutes following implantation into the void.