9.7 OsteoVation *Impact* will remain moldable and implantable for approximately 2 minutes at standard operating room temperatures (19°C to 21°C, 66°F to 70°F).

9.8 OsteoVation *Impact* will remain workable for 1 minute following implantation.

9.9 After the above described working time, OsteoVation *Impact* and the operative site should not be disturbed for an additional 3 minutes to ensure proper initial setting.

NOTE: Initial set up time for OsteoVation *Impact* is 4 minutes following implantation at 32°C (90°F).

NOTE: If screw insertion is desired, a pilot hole should be placed in OsteoVation *Impact* following the post implantation setting period of 4 to 8 minutes (4 minutes if OsteoVation is not exposed to air; 8 minutes if OsteoVation is exposed to air) with subsequent screw insertion (1.6 or 2.0mm). Final tightening of the screw can occur after an additional 5 minutes. During final tightening the screw head should remain flush with the surface of OsteoVation, not any deeper.

9.10 Closure of the surgical site may be commenced, following the 4 minute implantation setting period. The ultimate strength of the material is reached 24 to 72 hours post implantation.

9.11 OsteoVation *Impact* 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
USA
972-677-4600
www.osteomedcorp.com

The contents of this package are covered under patent 6,375,935, 6,719,933 and other pending patents.

Skeletal Kinetics® and its logo are registered trademarks of Skeletal Kinetics, LLC.

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

030-1403, Rev. G
LBL 10510 - AJ

OSTEOMED®

OSTEOVATION® BONE VOID FILLER

Impact Bone Void Filler

Instructions for Use

1.0 Description:

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

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

2.0 Indications:

2.1 OsteoVation *Impact* is a calcium phosphate bone void filler indicated for the repair or filling of neurosurgical bur holes, other craniofacial defects and craniotomy cuts with a surface area no larger than $25cm^2$ OsteoVation *Impact* may be used in the restoration or augmentation of bony contours of the craniofacial skeleton, including the fronto-orbital, malar, and mental areas. The product provides a bone void filler that resorbs and is replaced by bone during the healing process.

3.0 Contraindications:

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

3.1 Use in any infected site or surgical site located near an infection.

3.2 Use for stress-bearing applications (e.g. mandibular segment replacement)

3.3 Use in areas where surrounding bone is not viable, or is incapable of supporting or anchoring the implant.

3.4 Use in patients who have not reached an age in which skull growth is essentially complete

3.5 Use in patients with an abnormal calcium metabolism, metabolic bone disease, a recent untreated infection or immunological abnormalities.

3.6 Use in patients, who undergo or are to undergo an immunosuppression therapy

3.7 Use in patients with acute traumatic injuries with open wounds close to the defect which are likely to become infected.

3.8 Use in patients having received or are to receive chemotherapy or radiation therapy at or near the implant site

4.0 Warnings:

4.1 OsteoVation *Impact* 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 *Impact* is a **single use only** product; unused portions of OsteoVation *Impact* must be discarded and cannot be re-sterilized.

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

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

NOTE: Before disposal of any unused OsteoVation *Impact*, 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 *Impact* Kit for the mixing of OsteoVation Substitution of components may alter the desired results.

5.2 The paste remains moldable and implantable for up to 2 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 32°C (90°F). Following this 1 minute working period, the material and the site should not be disturbed for an additional 3 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 *Impact* for the particular desired use.

5.4 The effects of OsteoVation *Impact* 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
- Defects due to disease or congenital malformation
- Cardiovascular disease precluding elective surgery
- Patients less than 18 years of age

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 Tissue thinning over implant site.

6.2 Tenderness/redness/edema

6.3 Seroma/hemotoma or infection.

6.4 Swelling/fluid collection/Infection of the soft tissue and/or bone (osteomyelitis) and fever.

7.0 Sterility:

7.1 All components of the OsteoVation *Impact* 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 OsteoVation *Impact* 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 OsteoVation *Impact* 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 OsteoVation *Impact*

9.4 To mix OsteoVation *Impact*: When 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 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 OsteoVation *Impact*.

9.6 Once mixed, OsteoVation *Impact* may be delivered to the targeted site using manual impaction.