

# OsteoVation®

BONE VOID FILLER

INJECT

IMPACT



Rethinking Possibilities, Reshaping Lives

# Indications

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## Neuro Surgery

- Cranioplasty/Craniectomy
- Bur Hole Filling
- Cranial Cuts
- Onlay & Inlay grafting

## Plastic Surgery

- Cranial Reconstruction
- Orbital Reconstruction
- Onlay Grafting

## ENT Surgery

- Frontal Sinus Packing
- Orbital Reconstruction
- Onlay Grafting

## Oral Maxillofacial Surgery

- LeFort Void Packing
- Genioplasty Contouring





RETHINKING  
POSSIBILITIES  
RESHAPING  
LIVES

At OsteoMed, we work alongside surgeons who devote their own lives to improving those of others. Our single goal: rethinking the possibilities that have the power to reshape lives.

With a renewed spirit of innovation and a relentless focus on quality, we offer surgeons a wide range of choices for neurosurgical and craniomaxillofacial procedures.







# OsteoVation<sup>®</sup> Advantage

## **Proven Mechanical Properties**

- Compressive Strength: 50MPa
- Tensile Strength: 6MPa

## **Fast Setting**

- OsteoVation has been specifically designed to set quickly once implanted under normal physiological conditions.

## **Hardware Friendly**

- Shortly after setting, OsteoVation allows for hardware placement.

## **Excellent Wet-Field Characteristics**

- OsteoVation is chemically formulated to set in a wet field environment eliminating the need to meticulously dry the operative site prior to implantation.

## **Isothermic**

- OsteoVation does not release any heat as it sets, preventing tensile thermal injury.

## **Injectable**

- Available in injectable formulation for percutaneous, minimally-invasive delivery.



# Product Specifications

## Composition:

- Powder: Alpha-tricalcium Phosphate
- Liquid: Sodium Silicate

## Packaging Contains:

- OsteoVation Impact: Gamma Irradiation  
Contents Includes: powder, liquid, mixing system (mixing bowl, pestle and spatula)  
390-2103 OsteoVation Impact 3cc  
390-2105 OsteoVation Impact 5cc  
390-2110 OsteoVation Impact 10cc
- OsteoVation Inject: Gamma Irradiation  
Contents Includes: powder, liquid, mixing system (mixing bowl, pestle and spatula)  
390-2005 OsteoVation Inject 5cc  
390-2010 OsteoVation Inject 10cc
- OsteoVation Inject Delivery Kit: Ethylene Oxide and Gamma Irradiation  
Contents Include : (2) 6 ml Luer-Lock Syringe  
(1) 10 ml Luer-Lock Syringe  
(1) 11 ga Aspiration Needle (OsteoVation Delivery Cannula)

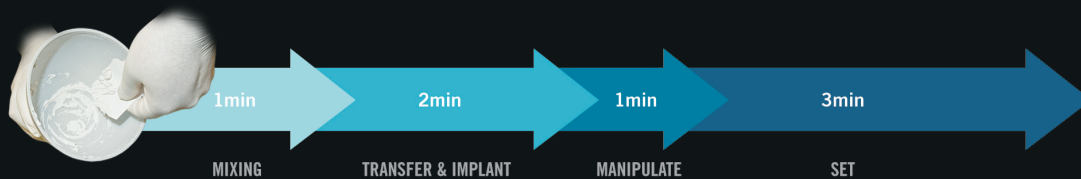
**Shelf Life OsteoVation Impact and OsteoVation Inject : 3 Years**



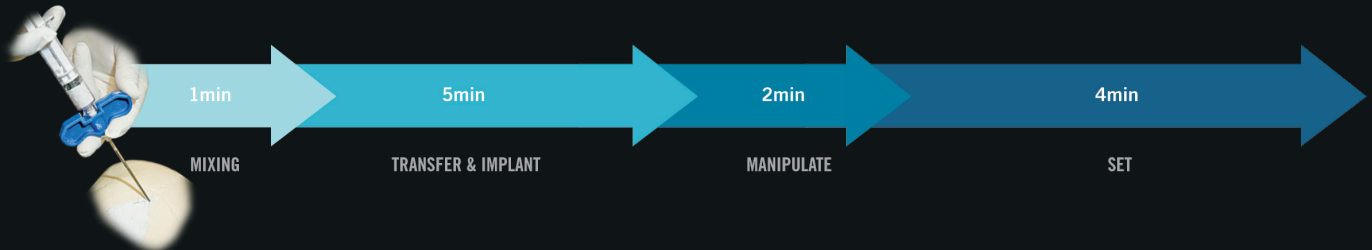


# Handling

## Impact



## Inject

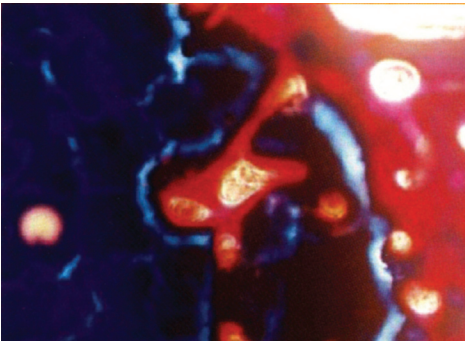


## Optional Screw Placement

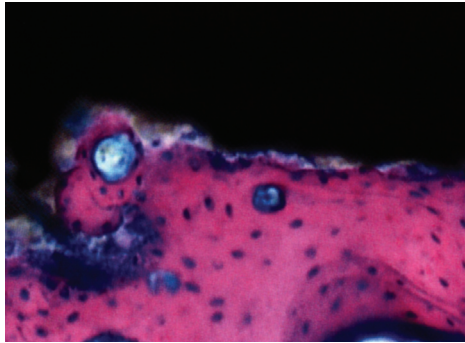
- To drill & insert screw wait additional 2 minutes
- For final tightening and & contouring wait additional 5 minutes

Storage: 59°F (15°C - 30°C)  
OsteoVation must be cooled below 70°F (21°C) prior to use





**Figure 1** Femoral specimen implanted with OsteoVation after one month. Formation of several Haversian canals were observed in and around the implanted region. (Trichrome staining)



**Figure 2** Femoral specimen implanted with OsteoVation after six months. Mature Haversian canals were seen in areas where OsteoVation was originally implanted. (HE staining)

## Drillable Osteoconductive Scaffold

### Composition

Bone remodeling is the healing process whereby old bone is naturally removed and replaced with new bone.

OsteoVation is similar in composition to the mineral phase of bone. A calcium phosphate starting powder is reacted with diluted silicate liquid, and undergoes an isothermic chemical reaction to form crystalline hydroxyapatite, which hardens in vivo to create an Osteoconductive scaffold. Bony ingrowth occurs through the same cell mediated process as the patient's natural bone remodeling.

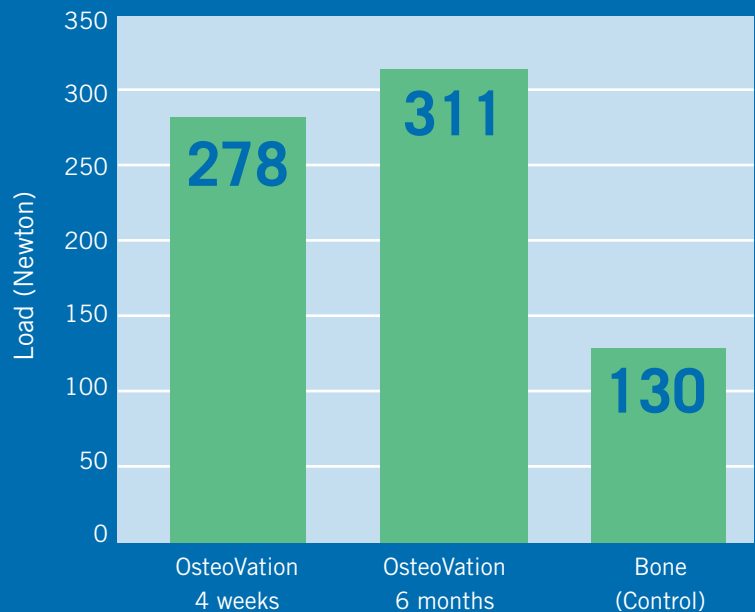
OsteoVation is optimal as a filler for metaphyseal defects due to its high immediate mechanical strength and ability to maintain that strength long term throughout the healing process.

# Biomechanical Analysis

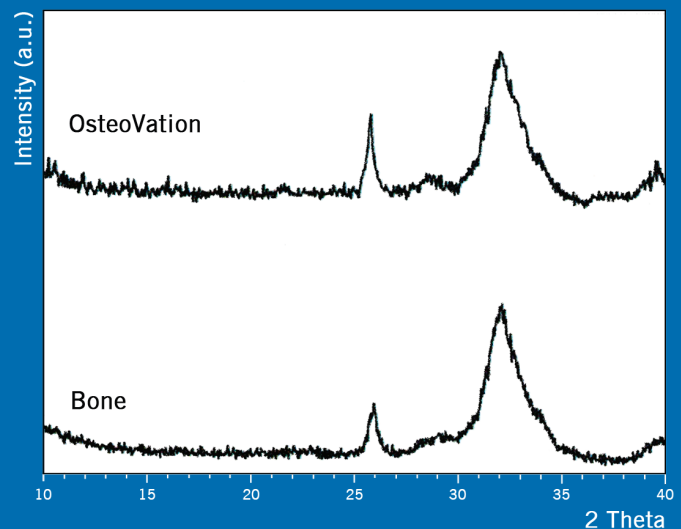
A clinically relevant understanding of long-term strength of defects treated with calcium phosphate bone void fillers (or any other bioactive material) are appropriately evaluated only in vivo. An in vivo biomechanical study was performed at four weeks and six months post implantation to assess the in vivo strength of cancellous bone defects treated with OsteoVation bone void filler during replacement by native cancellous bone.

OsteoVation is radiopaque and is visible under fluoroscopy to allow proper placement of hardware and to ensure the cancellous defect has been completely filled.

OsteoVation can be drilled and screwed into to optimize use of the combination of hardware and bone void filler, essential in treating various bone defects. OsteoVation Impact and Inject can accept hardware after an additional 8 minute setting time in vivo. OsteoVation should be drilled only with fluted bits or screws. Pre-drilling is required before hardware placement.



An in vivo study shows OsteoVation maintains strength above cancellous bone as it gets remodeled.



**Figure 3** Patterns show X-Ray diffraction showing OsteoVation and bone have the same chemical and crystalline composition.





# OsteoVation Impact

- 390-2103 OsteoVation 3cc, Impact Formula
- 390-2105 OsteoVation 5cc, Impact Formula
- 390-2110 OsteoVation 10cc, Impact Formula



# OsteoVation Inject

- 390-2005 OsteoVation 5cc, Inject Formula
- 390-2010 OsteoVation 10cc, Inject Formula
- 390-3000 OsteoVation Inject Delivery Kit

References: Please go to <http://www.osteomed.com/Clinical/OsteoBiologics.html>

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