Indications

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

**ENT Surgery**
- Frontal Sinus Packing
- Orbital Reconstruction
- Onlay Grafting

**Oral Maxillofacial Surgery**
- LeFort Void Packing
- Genioplasty Contouring

**Plastic Surgery**
- Cranial Reconstruction
- Orbital Reconstruction
- Onlay Grafting
At OsteoMed, we work alongside surgeons who devote their lives to improving those of others. Our goal: rethinking the possibilities that have the power to reshape lives.

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

Isothermal
• 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:
  390-3000 Delivery Kit
  (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

Optional Screw Placement
- To drill & insert screw for OsteoVation Impact wait an additional 4 to 8 minutes. (4 minutes if OsteoVation is not exposed to air: 8 minutes if OsteoVation is exposed to air)
- To drill & insert screw for OsteoVation Inject wait an additional 6 to 12 minutes. (6 minutes if OsteoVation is not exposed to air: 12 minutes if OsteoVation is exposed to air)
- For final tightening and contouring wait additional 5 minutes. (Applies for both Impact and Inject)

Storage: 59°F (15°C - 30°C)
OsteoVation must be cooled below 70°F (21°C) prior to use
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.
References: Please go to http://www.osteomed.com/Clinical/OsteoBiologics.html

Hydroxyapatite Cement Resistant to Fragmentation Following Full Cerebrospinal Fluid Bathing
Michael G. Muhonen, MD,* Anna Lonyai, BSc,1 Franklin D. Westhout, MD2

Improved Flexural Strength of a Novel Craniomaxillofacial Cement
Lin, J; Yetkinler, D N; Delaney, D; Nguyen, H; Constantz, B R

Increased Fracture Toughness Improves Clinical Utility of a Novel Calcium Phosphate Cement
Lin, J; Lee, WJ; Yetkinler, DN; Constantz, BK; Orthopaedic Research Society Transactions Vol. 31, Chicago, Illinois

Optimization of the Osteoinductiveness and Mechanical Properties of Calcium Phosphate Bone Cement Using Demineralized Bone Matrix
Banik, P; Karkar, V; Somayaji, S Orthopaedic Research Society Transctions Vol.29, San Francisco, California, 2004

In Vitro and In Vivo Evaluation of Two Calcium Phosphate Cements
Yetkinler, D N; Delaney, D; Constantz, B R Orthopaedic Research Society Transactions Vol.29, San Francisco, California, 2004

In vivo assessment of Callous/OsteoVation calcium phosphate cement containing autologous bone
S. Jalota, D. C. Delaney and D.N. Yetkinler; Annual Meeting, Society for Biomaterials, April 21 - 25, 2010, Seattle, WA.