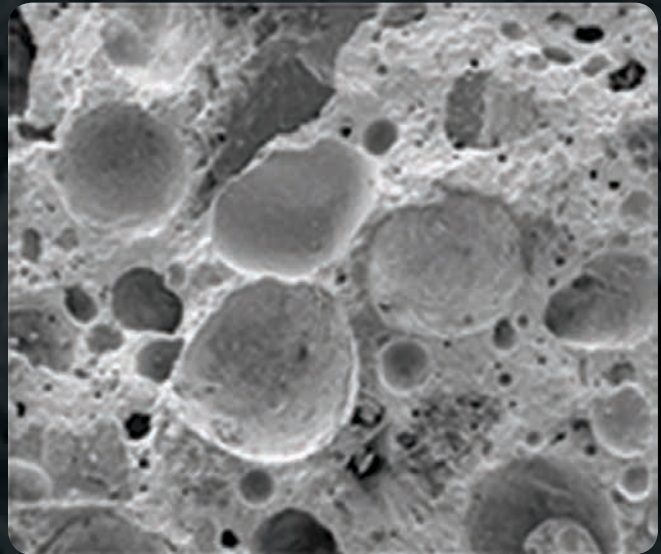


OsteoVation® QWIK

Bone Void Filler



SURGICAL TECHNIQUE GUIDE

IMPACT & INJECT FORMULATIONS



Rethinking Possibilities, Reshaping Lives

System Overview

OsteoVation QWIK is a bone void filler consisting of a proprietary composite of calcium phosphate and calcium sulfate granules. The unique formulation creates a macroporous construct, allowing faster remodeling, while maintaining targeted compressive strength. In addition to promoting faster bony in-growth, the system offers surgeons an efficient surgical technique. Impact and Inject formulas are available which provide options for either a traditional open or minimally-invasive surgical procedures. Both formulations are osteoconductive and provide a scaffold to enhance the bone during the healing process.

OsteoVation QWIK is indicated to fill bony voids or gaps of the skeletal system. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. OsteoVation QWIK 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.



Advantages

Macroporous Construct

The unique formulation creates a rapid generation of porosity that allows faster ingrowth of host bone.

Controlled Remodeling

OsteoVation QWIK features an optimized ratio of calcium phosphate and calcium sulfate granules which allows controlled remodeling while maintaining strength during the bone healing process.

Fast-Setting Isothermic

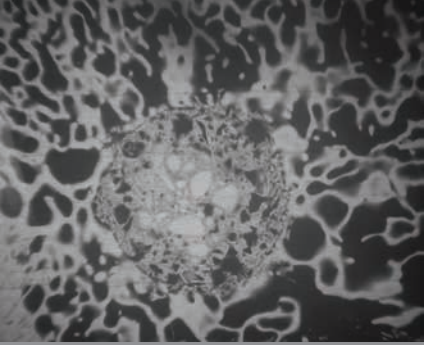
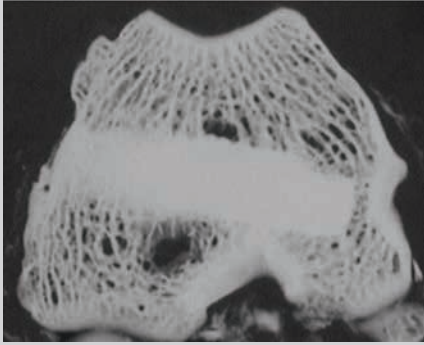
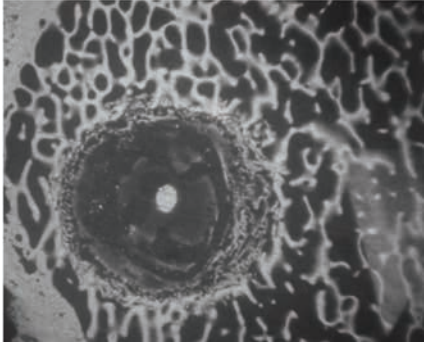
OsteoVation QWIK is designed to set quickly once implanted in a wet environment at the patient's normal body temperature. OsteoVation QWIK is also isothermic and does not damage adjacent tissue as it sets.

Impact & Inject Formulations

Impact and Inject formulations accommodate traditional open or minimally-invasive surgical procedures.



Micro x-ray analysis was performed following implantation of OsteoVation QWIK in sheep femurs and tibiae (Fig. 1). The results were then compared to a calcium phosphate bone void filler (Fig. 2) and a calcium sulfate bone void filler (Fig. 3) at four weeks post-implantation.

OsteoVation QWIK	Calcium Phosphate	Calcium Sulfate
		
New bone formation can be observed at the periphery and within porous areas of the implant. (Fig.1)	Excellent direct bone apposition to the cement, but very little remodeling. (Fig.2)	Almost an entire implant has been resorbed with very little new bone generation. (Fig.3)

*The results of the study confirm the biocompatibility, resorption and bone formation following implantation of OsteoVation QWIK.

*Data on file at Skeletal Kinetics

Pre-Planning

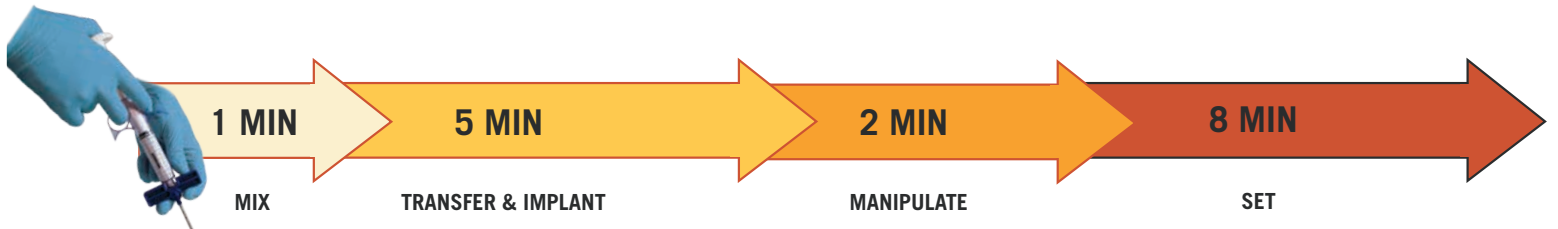
Temperature

- Temperature of the Operating Room should be between 19°C to 21°C (66°F to 70°F).
- The core temperature of the OsteoVation QWIK vials should be less than or equal to 21°C (70°F).
- OsteoVation QWIK needs a warm (body temperature) and wet environment (blood) to set properly.
- Higher temperatures will speed up setting; lower temperatures will slow down setting.
- To increase temperature at the surgical site:
 - ✓ Gently irrigate the site with warm saline.
 - ✓ Place warm, wet lap sponges over OsteoVation QWIK.
 - ✓ If applicable, release the tourniquet to increase blood flow.

Surgical Technique

Inject Formulation

It is important to ensure all of the surgical time has been accounted for intra-operatively for each surgical step.



1 Mix - 1 Minute

- Empty the powder vial into the bowl. Ensure that all the powder has been removed from the vial.
- Hold the base of the bowl to avoid transferring heat to the product. Add content from the liquid vial to the bowl and mix vigorously.
- Ensure the powder and liquid are completely mixed and produce a uniform consistency.



2 Transfer and Implant - 5 Minutes

- Use the spatula to collect the paste from the bowl and transfer to the OsteoVation QWIK Inject Delivery Kit
- Care should be taken to not hold the body of the syringe, ensuring heat is not transferred to the product.
- Backfill the syringe with OsteoVation QWIK and deliver to the target surgical site.



3 Manipulate - 2 Minutes

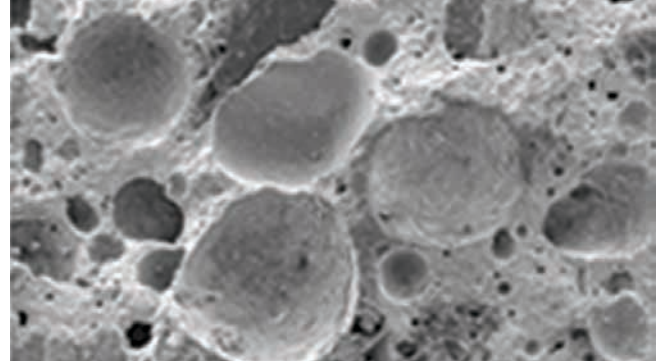
- Manipulate OsteoVation QWIK at the surgical site taking care to completely fill the bony void.

4

Set - 8 Minutes

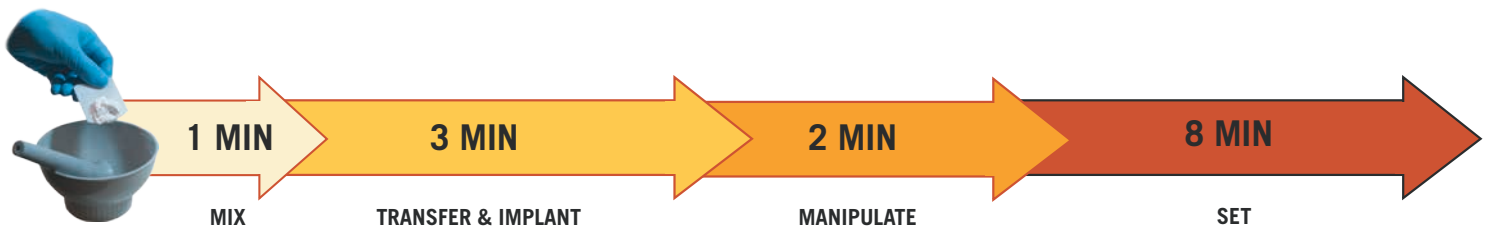
- Allow OsteoVation QWIK to set within the surgical site for the allotted time. It is important to not disturb or touch the product while setting.

Prior to closure, thoroughly irrigate the surgical site and remove any excess OsteoVation QWIK.



Impact Formulation

It is important to ensure all of the surgical time has been accounted for intra-operatively for each surgical step.



1

Mix - 1 Minute

- Empty the powder vial into the bowl. Ensure that all the powder has been removed from the vial.
- Hold the base of the bowl to avoid transferring heat to the product. Add content from the liquid vial to the bowl and mix vigorously.
- Ensure the powder and liquid are completely mixed and produce a uniform consistency.



2

Transfer & Implant - 3 Minutes

- Collect paste from the bowl via hand or the sterile-packed spatula and deliver to the target surgical site.



Surgical Technique

3

Manipulate - 2 Minutes

- Manipulate OsteoVation QWIK at the surgical site, taking care to completely fill the bony void.

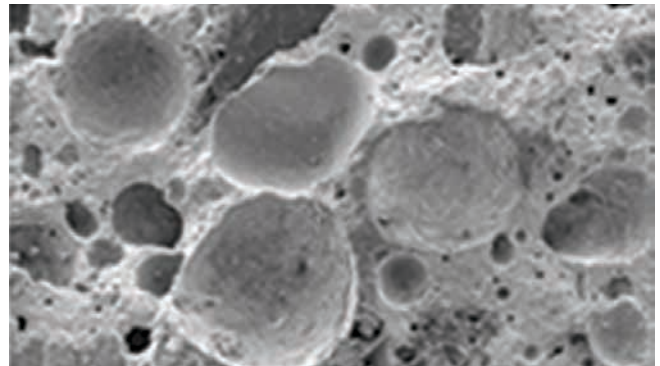


4

Set - 8 Minutes

- Allow OsteoVation QWIK to set within the surgical site for the allotted time. It is important to not disturb or touch the product while setting.

Prior to closure, thoroughly irrigate the surgical site and remove any excess OsteoVation QWIK.



System Components

Inject



390-4002 OsteoVation QWIK, 2cc Inject Formula

390-4003 OsteoVation QWIK, 3cc Inject Formula

390-4005 OsteoVation QWIK, 5cc Inject Formula

390-6000 OsteoVation QWIK, Inject Delivery Kit

2cc, 3cc, and 5cc Kit Contents: Powder and Liquid Vials, Bowl, Pestle and Spatula.

Inject Delivery System Contents: Syringe and Cannula

Impact



390-4203 OsteoVation QWIK, 3cc Impact Formula

390-4205 OsteoVation QWIK, 5cc Impact Formula

3cc and 5cc Kit Contents: Powder and Liquid Vials, Bowl, Pestle and Spatula.

Complementary Products:



fps™
foot plating system



ExtremiFix™

2.0mm, 2.4mm, 3.0mm, 4.0mm
Cannulated Screw System



hps™
hand plating system



Large Cannulated Screws

6.5mm and 7.3mm cannulated screw system



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