



OSTEOVATIONEX[®]

BONE VOID FILLER

- Proven Mechanical Properties
- Hardware Compatible
- Cell-Mediated Remodeling
- Radiopaque



Surgical Technique Guide
with autograft extender instructions

OsteoVationEX[®] Inject Surgical Technique



Preplanning

- Temperature of OsteoVationEX[®] and Operating Room should be 66° – 70°F (19° – 21°C)
- If the OsteoVationEX[®] was exposed to temperatures higher than storage temperature (59°F/ 15°C – 86°F/30°C) it should be cooled in a freezer for 30 minutes before surgery
- Estimate size of void and determine how much OsteoVationEX[®] will be necessary
 - Fluoroscopic imaging is recommended
 - Up to 30cc of OsteoVationEX[®] can be mixed at one time
- Expose and properly prepare the void
- To prepare for the Inject deliver kit:
 - Remove the plunger from the barrel
 - Remove the cannula top
 - Assemble cannula into syringe barrel



Mixing 1 minute

- Empty powder from vial into bowl
 - Always tap out the powder completely before introducing the liquid by tapping on bottle with pestle
- Hold the bowl on the bottom to avoid heating the product
- Mix vigorously to “shear” powder and liquid together using the entire inner surface of the bowl
- Roll the pestle on the side of the bowl to remove any excess OsteoVationEX[®] that collected on the lip and reintroduce the product to the mixture



Transfer & Implant 5 minutes

- Collect the OsteoVationEX[®] paste with spatula or hand
- Hold the syringe at the cannula to avoid transferring heat to the paste
- Backfill the syringe with OsteoVationEX[®]
- OsteoVationEX[®] is packaged with an additional 1cc of volume to account for possible excess remaining in the syringe and/or bowl after transfer
- OsteoVationEX[®] needs a warm (>32 °C, patient’s body temperature) and wet environment (blood) to set properly
- To increase the temperature and moisture at the site:
 - The site may be irrigated gently with warm saline to raise the temperature at the site
 - The tourniquet may be dropped to release blood flow to surgical site
 - A lap may be moistened with warm saline and drizzle over the implanted OsteoVationEX[®] and then set lap over the site to maintain temperature



Transfer & Implant 5 minutes (Continued)

- Implant at the site by syringe
- Be aware of temperature
 - The **HIGHER** the temperature the **FASTER** the setting time
 - The **LOWER** the temperature the **SLOWER** the setting time
- In the event that additional OsteoVationEX® is required to properly fill the void:
 - If less than 2 minutes have passed since OsteoVationEX® was placed in the site more can be added at that time
 - If more than 2 minutes have passed wait 5 minutes total before adding more
 - Do not mix more than 30cc at one time



Implant OsteoVationEX® into the void

Manipulating 2 minutes

- Manipulate at site using hand or spatula only

Setting 4 minutes

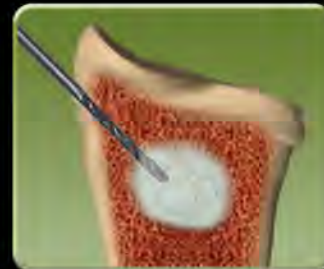
- Do not touch during the setting period
- Crystal structure is forming at this time and touching it disrupts these crystal formations



Crystalline structure of OsteoVationEX® after setting

Drilling (optional)

- OsteoVationEX® must be firmly set for an **additional 4 minutes before** drilling
- Drill must be fluted
- Do not force the drill, let it do the work
- Do not drill into OsteoVationEX® with K-wires
 - You may remove K-wires at this time but you cannot insert them
 - If K-wires are necessary they may be inserted prior to implanting OsteoVationEX®



Prepare for hardware placement

Screw Tightening (optional)

- Screws may be two finger tightened after an **additional 5 minutes**
- Do not over-torque screws
- Power tools for insertion and tightening is not recommended



Hardware placement

Closure

- Irrigate the soft tissue thoroughly to remove any excess OsteoVationEX®

OsteoVationEX[®] Impact Surgical Technique



Preplanning

- Temperature of OsteoVationEX[®] and Operating Room should be 66° – 70°F (19° – 21°C)
- If the OsteoVationEX[®] was exposed to temperatures higher than storage temperature (59°F/ 15°C – 86°F/30°C) it should be cooled in a freezer for 30 minutes before surgery
- Estimate size of void and determine how much OsteoVationEX[®] will be necessary
 - Fluoroscopic imaging is recommended
 - Up to 30cc of OsteoVationEX[®] can be mixed at one time
- Expose and properly prepare the void

Autograft (optional)

- **Harvest morselized cancellous bone (up to 50% by weight)**
 - 3cc kit - up to 7cc autograft
 - 5cc kit - up to 11cc autograft
 - 10cc kit - up to 18cc autograft

Mixing 1 minute

- Empty powder from vial into bowl
 - Always tap out the powder completely before introducing the liquid by tapping on bottle with pestle
- Hold the bowl on the bottom to avoid heating the product
- Mix vigorously to “shear” powder and liquid together using the entire inner surface of the bowl
- Roll the pestle on the side of the bowl to remove any excess OsteoVationEX[®] that collected on the lip and reintroduce the product to the mixture



Autograft (optional)

- **Add harvested autograft mixture to paste**
- **Mix vigorously one additional minute**

Transfer & Implant 2 minutes

- Collect the OsteoVationEX[®] paste with spatula or hand
- Use hand to mold the paste
- OsteoVationEX[®] is packaged with an additional 1cc of volume to account for possible excess remaining in the syringe and/or bowl after transfer
- OsteoVationEX[®] needs a warm (>32 °C, patient’s body temperature) and wet environment (blood) to set properly
- To increase the temperature and moisture at the site:
 - The site may be irrigated gently with warm saline to raise the temperature at the site
 - The tourniquet may be dropped to release blood flow to surgical site
 - A lap may be moistened with warm saline and drizzle over the implanted OsteoVationEX[®] and then set lap over the site to maintain temperature



OsteoVationEX® Impact Surgical Technique

Transfer & Implant 2 minutes (Continued)

- Implant at the site by hand
- Be aware of temperature
 - The **HIGHER** the temperature the **FASTER** the setting time
 - The **LOWER** the temperature the **SLOWER** the setting time
- In the event that additional OsteoVationEX® is required to properly fill the void:
 - If less than 2 minutes have passed since OsteoVationEX® was placed in the site more can be added at that time
 - If more than 2 minutes have passed wait 5 minutes total before adding more
 - Do not mix more than 30cc at one time

Manipulating 1 minute

- Manipulate at site using hand or spatula only

Setting 3 minutes

- Do not touch during the setting period
- Crystal structure is forming at this time and touching it disrupts these crystal formations

Autograft (optional)

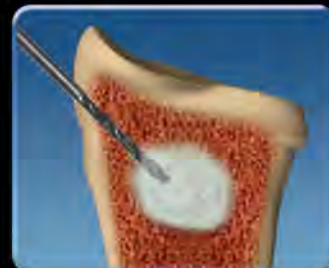
- Allow for an additional **8 minutes** if using autograft mixture



Crystalline structure of OsteoVationEX® after setting

Drilling (optional)

- OsteoVationEX® must be firmly set for an **additional 2 minutes before** drilling
- Drill must be fluted
- Do not force the drill, let it do the work
- Do not drill into OsteoVationEX® with K-wires
 - You may remove K-wires at this time but you cannot insert them
 - If K-wires are necessary they may be inserted prior to implanting OsteoVationEX®



Prepare for hardware placement

Screw Tightening (optional)

- Screws may be two finger tightened after an **additional 5 minutes**
- Do not over-torque screws
- Power tools for insertion and tightening is not recommended



Hardware placement

Closure

- Irrigate the soft tissue thoroughly to remove any excess OsteoVationEX®

OsteoVationEX® is packaged in two forms: inject and impact. Both configurations are mixed in the sterile field wet environment. OsteoVationEX® is radiopaque allowing for complete visualization under fluoroscope and x-r

OsteoVationEX® Inject



- 390-0002 OsteoVationEX®, 2cc, Inject formula
- 390-0003 OsteoVationEX®, 3cc, Inject formula
- 390-0005 OsteoVationEX®, 5cc, Inject formula
- 390-3000 OsteoVationEX®, Inject Delivery System

and are packaged with disposable mixing devices. OsteoVationEX® is engineered to set fast in a warm and dry environment to ensure proper implantation and post surgical monitoring.

OsteoVationEX® Impact



- 390-0203 OsteoVationEX®, 3cc, Impact formula
- 390-0205 OsteoVationEX®, 5cc, Impact formula

The logo for Osteomed, featuring the word "OSTEOMED" in a bold, blue, sans-serif font. The letters are contained within a blue oval shape that has a slight 3D effect, appearing to sit on a dark grey cylindrical base.

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