



# IonicFusion Putty

## Bioactive Synthetic Graft

### Instructions For Use

#### Indications for Use:

NovaBone Putty – Bioactive Synthetic Graft is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Putty is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, posterolateral spine, and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

NovaBone Putty is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

#### Description:

NovaBone Putty is an osteoconductive bioactive device used for grafting osseous defects. It is a pre-mixed composite of bioactive calcium-phospho-silicate particulate and a synthetic, absorbable binder. The bioactive particulate is composed solely of elements that exist naturally in normal bone (Ca, P, Na, Si, O). The absorbable binder is a combination of polyethylene glycol and glycerin. The device requires no mixing or preparation prior to application. The non-hardening putty is supplied ready-to-use, to be applied directly to the intended graft site. The binder is then absorbed from the site such that only the bioactive particulate remains.

Upon absorption of the binder, the particulate material remaining undergoes a time-dependent kinetic modification of the surface that occurs when implanted in living tissue. Specifically, a series of surface reactions results in the formation of a calcium phosphate layer on the particles that is substantially equivalent in composition and structure to the hydroxyapatite found in bone mineral. This apatite layer provides scaffolding onto which the patient's new bone will grow allowing complete repair of the defect. Animal testing has demonstrated that the majority of the particulate material is absorbed within six months of implantation, with >98% of the material being absorbed by 12 months. The timeframe for full absorption in humans has not been determined, but is expected to be at least 12 months.

#### Contraindications:

NovaBone Putty should not be used in:

- In patients who use medication known to affect the skeleton (e.g. chronic glucocorticoid usage >10mg/day for the previous 3 months). Estrogen replacement therapy is allowed.
- In patients that need chronic anticoagulant therapy (e.g. heparin). Prophylactic use of Coumadin or aspirin postoperatively is allowed.
- In patients with a systemic metabolic disorder known to adversely affect bone healing and mineralization (e.g. insulin-dependent diabetes, renal osteodystrophy, Paget's disease), other than primary osteoporosis.
- In a large osseous defect where the total volume of a single defect exceeds 30 cm<sup>3</sup>.
- In load-bearing applications; it does not possess sufficient mechanical strength to support load-bearing defects prior to hard tissue ingrowth.
- For vertebroplasty or kyphoplasty procedures.
- In cases of fracture fixation or where load support is required unless standard internal or external stabilization techniques are followed to obtain rigid stabilization in all planes.
- To gain screw purchase or to stabilize screw placement.

#### Warnings:

Possible complications are the same as to be expected of autogenous bone grafting procedures. NovaBone Putty does not possess sufficient mechanical strength to support load bearing defects prior to soft and hard tissue ingrowth. In cases of fracture fixation, standard internal or external stabilization techniques must be followed to obtain rigid stabilization in all planes.

Complications that may arise as a result of surgery may include: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, delayed union, loss of reduction, failure of fusion, loss of bone graft, graft protrusion and / or dislodgement, and general complications that may arise from anesthesia and / or surgery.

NovaBone Putty is intended for manual application and is not intended for injection through a constrained opening or under high pressure. The syringe packaging must not be modified to permit high pressure delivery of the device. High pressure injection of NovaBone Putty should not be conducted as it could result in device over-pressurization, which may lead to device extrusion beyond the intended application site or to embolization of fat or the device into the bloodstream. The recommended maximum dispensing rate is one pull per second for the MIS system.

#### Precaution:

NovaBone Putty is intended for use by surgeons familiar with bone grafting and internal/external fixation techniques. NovaBone Putty must not be used to gain screw purchase or to stabilize screw placement. Instrumentation used in conjunction with NovaBone Putty must gain purchase in the host bone. Standard postoperative practices for the treatment and rehabilitation associated with bone grafting must be strictly followed.

#### Instructions for Use:

NovaBone Putty requires no special handling or mixing procedures prior to use. All device packaging should be inspected prior to use to insure maintenance of sterility. The NovaBone Putty device may be used alone or mixed with autogenous bone.

#### MIS Cartridge System Configuration

- Remove the double packaged device from the outer box.
- After surgical site preparation, open the outer sterile package using standard technique and pass the inner tray to the sterile field.
- Hold the inner tray in one hand with the pull tab at the lower right and pull up on the tab where indicated to expose the device components.
- Prepare the NovaBone Putty dispensing handle for use.
  - Remove the dispensing handle from the inner tray
  - Press up on the black lever at the rear of the handle (under the plunger) and lightly pull back on the plunger to ensure it is all the way back. Release lever.
  - Holding the handle flat in your right hand, press down on the white tube connector at the front of the handle to ensure it is properly seated.
- Prepare the NovaBone Putty cartridge for use.
  - Remove one pre-filled NovaBone Putty cartridge from the inner tray.
  - Twist and remove the cap from one end of the cartridge.
  - With the dispensing handle in one hand, slowly twist the cartridge onto the tube connector at the front of the handle.
- Once the cartridge is threaded in place, pull and release the dispensing handle one time to advance the plunger into the cartridge. The system is now ready for use.

**Note:** If the plunger does not advance, lightly push the plunger forward with one hand and pull handle one time with the other. This should engage the ratchet system for further operation.

- After graft site preparation per standard procedures, irrigate and suction the graft site
- Remove the second cap from the end of the NovaBone Putty Cartridge
  - If use of the optional cartridge tip is desired, slowly twist the tip onto the open end of the cartridge.
- Place the tip of the cartridge or applicator tip at the graft site and squeeze the handle repeatedly to dispense the desired amount of NovaBone Putty.
  - Each cycle of the handle will express 0.25cc on NovaBone Putty. The handle plunger is marked to indicate the total volume expressed.



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- If the NovaBone Putty cartridge has been emptied and additional NovaBone Putty is required to fill the graft site, remove the empty cartridge and replace with a separate filled cartridge.
  - Press up on the black lever at the rear of the handle and lightly pull back on the plunger, pulling it all the way back out of the cartridge until it stops.
  - If the optional cartridge tip was used, slowly twist the tip and remove from the cartridge for placement on the next cartridge.
  - Twist the empty cartridge off the cartridge connector and discard the cartridge.
  - Remove another pre-filled NovaBone Putty cartridge from the inner tray.
  - Remove the cap from one end of the cartridge and attach the cartridge as before.
  - If desired, thread the applicator tip onto the end of the new cartridge.
  - Repeat as needed for additional cartridges.

**Note:** If the plunger is mistakenly pulled forward during cartridge replacement, press up on the black lever at the back of the handle and gently pull the plunger completely toward the back of the handle.

- Once the graft site is filled, remove any excess material and close the site as per standard practice.
- Discard any excess material and packaging. Neither the material nor its packaging, including the handle and cartridges, can be cleaned, reused, or re-sterilized.

#### Tray and Syringe Configurations

- Remove the packaged device from the outer box.
- After surgical site preparation, open the outer peel pouch using standard technique and pass the inner container to the sterile field.
- For tray packaging:
  - Hold the inner container in one hand with the tab facing up and pull up on the tab.
  - Remove the NovaBone Putty device from the inner container either manually or with forceps or similar instrument.
- For syringe packaging:
  - Hold the syringe container in one hand and express the desired amount either into a sterile dish or into the defect site itself.
- Irrigate and suction the graft site, then press the graft device into the site, molding to the desired contours.
- Remove any excess material and close as per standard practice.
- Discard any excess material and packaging. Neither the material nor its packaging can be reused or re-sterilized.

These instructions are intended as guidelines for the use of NovaBone Putty as a part of established techniques. They are not intended to replace or change standard grafting techniques associated with instrumental stabilization.

#### Preoperative Preparation:

Radiographic evaluation of the defect site is essential to accurately assess the extent of the defect and to aid in the selection and placement of the NovaBone Putty device and any required fixation devices.

#### Surgical Procedure Notes:

NovaBone Putty should fill the defect and contact viable bone as much as possible. Some bleeding should be observed originating from the host bone to indicate viability.

Regeneration will occur best when blood and blood vessels can infiltrate the graft material. When placing the graft material, do not over compress the NovaBone Putty material into the site such that it may be forced into unintended areas.

#### Postoperative Notes:

Postoperative patient management should follow the same regimen as similar cases utilizing autogenous bone grafting. Standard postoperative practice should be followed, particularly as applicable to sites involving the use of fixation devices. The patient should be cautioned against premature ambulation as per physician's orders to ensure reduced loading to prevent collapse and deformity.

#### Material Notes – Osteostimulation:

NovaBone Putty is an osteostimulative and osteoconductive device. Osteostimulation is defined as an accelerated bone formation process, characterized by the active stimulation of osteoblast proliferation and differentiation in an osseous defect. This stimulatory action has been demonstrated during *in vivo* tests to be more rapid than simple osteoconduction.<sup>1,2</sup> These tests have been supported by *in vitro* cell culture tests, which demonstrate the mechanisms of cell stimulation as being the result of cellular interaction with the ionic dissolution products released from NovaBone during its absorption.<sup>3-6</sup> Clinical data on this acceleration of bone formation in the human has not been established.

NovaBone has only been demonstrated to form bone in osseous defects. NovaBone therefore is not osteoinductive. Such osteoinductive devices can be characterized by their ability to form new bone tissue in non-osseous (soft tissue) sites.

#### Stability:

This device is provided STERILE unless package is open or damaged. Do not use if the sterile packaging is damaged. The content of each package is designed for single use only. The device cannot be reused after implantation due to risk of device or patient contamination. Excess material cannot be saved for later use due to risk of contamination and infection; all excess material and packaging must be discarded. Device cleaning and resterilization are not possible. Do not use after expiration date.

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#### Manufacturer:

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#### References:

- Oonishi H, Kushitani S, Yasukawa E, Iwaki H, Hench LL, Wilson J, Tsuji E, Sugihara T: Particulate Bioglass Compared with Hydroxyapatite as a Bone Graft Substitute. *Clin Orthop*. 334:316-325, 1997.
- Fujishiro Y, Hench LL, Oonishi H: Quantitative Rates of *In vivo* Bone Generation for Bioglass and Hydroxyapatite Particles as Bone Graft Substitute. *J Mater Sci: Material in Medicine*, 8:649-652, 1997.
- Vrouwenvelder WCA, Groot CG, de Groot K: Histological and Biochemical Evaluation of Osteoblasts Cultured on Bioactive Glass, Hydroxyapatite, Titanium Alloy and Stainless Steel. *J. Biomed Res*, 27:465-475, 1993.
- Xynos ID, Hukkanen MVJ, Batten JJ, Buttery LD, Hench LL, Polak JM: Bioglass 45S5 Stimulates Osteoblast Turnover and Enhances Bone Formation *In vitro*: Implications and Applications for Bone Tissue Engineering. *Calcif Tissue Int*, 67:321-329, 2000.
- Xynos ID, Edgar AJ, Buttery LDK, Hench LL, Polak JM: Ionic Products of Bioactive Glass Dissolution Increase Proliferation of Human Osteoblasts and Induce Insulin-Like Growth Factor II mRNA Expression and Protein Synthesis. *Biochem Biophys Res Comm*, 276:461-465, 2000.
- Bosetti M, Cannas M: The Effect of Bioactive Glasses on Bone Marrow Stromal Cells Differentiation. *Biomaterials*, 26(18):3873-3879, 2005.