



IonicFusion Putty Plus

Bioactive Bone Graft

Instructions For Use

Indications for Use:

NovaBone MacroPor-Si⁺– Bioactive Bone Graft is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone MacroPor-Si⁺ is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities 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 MacroPor-Si⁺ 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 MacroPor-Si⁺ 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 bioactive particulate is present in two forms, both as a small non-porous powder and a larger porous particulate having a multidirectional interconnected porosity. The absorbable binder is a combination of polyethylene glycol and glycerin. The device requires no mixing or preparation prior to application. The non-hardening device 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 progressive particulate absorption with time. The timeframe for full absorption in humans has not been determined, but is expected to be at least 12 months.

Contraindications:

NovaBone MacroPor-Si⁺ should not be used:

1. In patients who use medications known to affect the skeleton (e.g. chronic glucocorticoid usage >10mg/day for the previous 3 months). Estrogen replacement therapy is allowed.
2. In patients that need chronic anticoagulant therapy (e.g. heparin). Prophylactic use of Coumadin or aspirin postoperatively is allowed.
3. 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.
4. In a large osseous defect where the total volume of a single defect exceeds 30 cm³.
5. In load-bearing applications; it does not possess sufficient mechanical strength to support load-bearing defects prior to hard tissue ingrowth.
6. For vertebroplasty or kyphoplasty procedures.
7. 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.
8. To gain screw purchase or to stabilize screw placement.

Instructions for Use:

NovaBone MacroPor-Si⁺ 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 MacroPor-Si⁺ device is intended to be used alone without mixing.

1. Remove the double packaged device from the outer box.
2. After surgical site preparation, open the outer peel pouch using standard technique and pass the inner container to the sterile field.
3. For tray packaging:
 - a. Hold the inner container in one hand with the tab facing up and pull up on the tab.
 - b. Remove the NovaBone MacroPor-Si⁺ device from the inner container either manually or with forceps or similar instrument.
4. Irrigate and suction the graft site, then press the graft device into the site, molding to the desired contours.
5. Remove any excess material and close as per standard practice.
6. 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 MacroPor-Si⁺ as a part of established techniques. They are not intended to replace or change standard grafting techniques associated with instrumental stabilization.



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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 MacroPor-Si⁺ device and any required fixation device.

Surgical Procedure Notes:

NovaBone MacroPor-Si⁺ 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 MacroPor-Si⁺ 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 practices 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.

Warnings:

Possible complications are the same as to be expected of autogenous bone grafting procedures. NovaBone MacroPor-Si⁺ 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 MacroPor-Si⁺ is intended for manual application and is not intended for injection through a constrained opening or under high pressure. High pressure injection of NovaBone MacroPor-Si⁺ 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.

Precaution:

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

Stability:

The device is provided STERILE unless the package is open or damaged. Resterilization is not possible. Do not use if the sterile packaging is damaged. The content of each package is designed for single use only. Discard any remainder and all packaging. Do not use after the expiration date.

STERILE R



Caution:

Federal law (USA) restricts this device to sale by or on the order of a physician.



Manufacturer:

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