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ELEVATING SURGERY®

BIOACTIVE MORSELS

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Instructions For Use

Indications for Use:

NovaBone Porous Bone Graft Scaffold is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Porous 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.

Description:

NovaBone Porous is an osteoconductive bioactive material used for bone defect grafting. NovaBone Porous is composed of elements that exist naturally in normal bone (Ca, P, Na, Si, O). The material contained in this package is of a bulk porous form, having a multidirectional interconnected porosity.

The material composition used in NovaBone Porous undergoes a time-dependent kinetic modification of the device surfaces that occurs when implanted in living tissue. Specifically, the surface reaction results in the formation of a calcium phosphate layer 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, infiltrating the porous structure of the device and allowing complete repair of the defect as the device is absorbed.

Contraindications:

NovaBone Porous should not be used in patients who:

1. Use medication known to affect the skeleton (e.g. chronic glucocorticoid usage >10mg/day for the previous 3 months). Estrogen replacement therapy is allowed.
2. Need chronic anticoagulant therapy (e.g. heparin). Prophylactic use of Coumadin or aspirin postoperatively is allowed.
3. Have 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. Have a large osseous defect where the total volume of a single defect exceeds 30 cm^3.

Warnings:

Possible complications are the same as to be expected of autogenous bone grafting procedures. NovaBone Porous 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.

Precaution:

NovaBone Porous is intended for use by surgeons familiar with bone grafting and internal/external fixation techniques. NovaBone Porous must not be used to gain screw purchase or to stabilize screw placement. Instrumentation used in conjunction with NovaBone Porous 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 Porous should be thoroughly wetted with blood or sterile saline before application. Place NovaBone Porous bulk devices in the fluid such that it soaks up the blood or saline into its porous structure. For particulate devices, add approximately 0.4 ml of fluid for each 1 cm3 of NovaBone Porous and mix to moisten the particulate uniformly. The wetted NovaBone Porous device can then be inserted directly into the prepared graft site.

These instructions are intended as guidelines for the use of NovaBone as a part of established techniques. They are not intended to replace or change standard grafting techniques associated with instrumented 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 Porous device and any required fixation devices.

Surgical Procedure Notes:

NovaBone Porous 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.

The NovaBone Porous device may be shaped intraoperatively to best fill the defect. Shaping should be conducted with a sterile surgical instrument such as rongeurs, forceps, or a scalpel.

Regeneration will occur best when blood and blood vessels can infiltrate the graft material. When placing the graft material, do not compress the material into the site or blot away the blood/moisture in the placed graft material. Excessive compression may crush the device.

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.

Stability:

The device is provided STERILE unless 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. Do not use after the expiration date.

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