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
cripples to the stability of the bony structure. NovaBone is indicated to the pertinently 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 Putty is an osteoconductive bioactive device used for grafting osseous defects. It is a
pre-mixed composite of bioactive calcium-phosphate particulate and a synthetic, absorbable binder.
The bioactive particulate is composed solely of elements that exist normally in bone (Ca, P, Si, O). The
absorbable binder is a combination of polyurethane and heparin. 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 graft site 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 particulate that is not
bioactive.

This apatite layer provides scaffolding onto which the patient’s new bone will grow allowing complete
repair of the defect.

Contraindications:
NovaBone Putty 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
is prohibited
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
osteoarthritis.
4. Have a large bony defect where the total volume of a single defect exceeds 30 cm³.

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.

1. Remove the double packaged device from the outer box.
2. Place the NovaBone Putty into the inner container either manually with forceps or
similar instrument.
3. Ignite and suction the graft site, then press the graft device into the site, molding to the
desired contours.
4. Remove any excess material and close as per standard practice.

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 instrumented stabilization.

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

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 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.

1. Over-pressurization of the graft site may lead to device extrusion beyond the intended application site or to embolization of fat or the device
2. Over-pressurization of the graft site may lead to device over-pressurization, which may
3. Any device and site reactions result in the formation of a calcium phosphate layer on the
4. Complications that may arise as a result of surgery may include: superficial wound infection, deep

NovaBone Putty does not possess sufficient mechanical strength to support load bearing defects
resulting from trauma to the bone. Standard postoperative practices for the treatment of
instrumented stabilization should be followed to ensure adequate bone formation.

Manufacturer:

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