




TriMed®

IonicFusion Strip

Instructions For Use

Description:

NovaBone® Bioactive Strip™ is an osteoconductive bioactive device used for grafting osseous defects. The device is a mixture of bioactive calcium-phospho-silicate granules and a collagen binder. The bioactive glass particulate is composed solely of elements that exist in normal bone (Ca, P, Na, Si, O). The binder consists of bovine collagen. When hydrated with bone marrow aspirate, the device absorbs fluids to form a flexible graft matrix that is applied directly to the intended graft site. The device is slowly absorbed during graft site healing. During healing, the graft particulate is absorbed and remodeled into new bone. The timeframe for full absorption in humans has not been determined.

Indications for Use:

NovaBone Bioactive Strip bone graft devices are indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone Bioactive Strip is indicated to be gently placed 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. NovaBone Bioactive Strip must be hydrated with autogenous bone marrow aspirate prior to implantation. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Contraindications:

NovaBone Bioactive Strip should not be used:

- 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 cm³.
- 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.
- In patients with a known sensitivity to bovine collagen or collagen-containing products.
- The device is a resorbable salt bone void filler; do not implant in patients with pre-existing calcium metabolism disorders, such as hypercalcemia.
- The device should not be used if the implantation site is infected or necrotic.

Instructions for Use:

The device requires no special handling or storage. Device preparation consists of hydrating the supplied device with autogenous bone marrow aspirate (BMA), followed by direct placement of the device in the bone void. All device packaging should be inspected prior to use to insure maintenance of sterility.

- Remove the packaged device from the outer box.
- After surgical site preparation, open the outer tray using standard technique.
- Pass the inner tray to the sterile field.
- Remove the lid from the inner tray.
- Using aseptic technique, obtain autogenous bone marrow aspirate (BMA) for device hydration. The following chart outlines the approximate BMA volumes needed to hydrate the device sizes. Refer to the outer label for sizing information.

Size on Device Label	Approximate BMA Volume
5.0 cm ³	2.5 mL
10.0 cm ³	5.0 mL
15.0 cm ³	7.5 mL
20.0 cm ³	10.0 mL

- Leave the graft in the inner tray and add BMA to fully saturate. The device should be fully hydrated in less than five (5) minutes.
- Irrigate and suction the prepared surgical site.
- Insert the hydrated graft into the bone void such that it contacts as much viable host bone as possible.
- Remove any excess material and close the surgical site per standard clinical practice.
- Discard all excess material and packaging. The device and packaging cannot be cleaned, reused, or re-sterilized. DO NOT retain excess material for later use.**

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

Surgical Procedure Notes:

The device 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.

Bone formation will occur when blood and blood vessels can infiltrate the graft material. When placing the graft material, do not over compress the device 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 or site loading 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. The device does not possess sufficient mechanical strength to support load bearing defects prior to soft and hard tissue ingrowth. In cases of device use for fracture fixation or in other load bearing sites, 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. Do not implant the device in infected or contaminated sites.

The device is intended for manual application and is not intended for injection through a constrained opening or under high pressure. High pressure injection of the device 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.

Immunological reactions have been reported to occur with bone graft material containing collagen. Such reactions may include transient localized edema, swelling, and rash. Although there is no evidence that the device will be unsafe or ineffective in such patients, the safety and effectiveness of the device in these patients has not been established. Occurrence of one or more of these conditions may require an additional surgical procedure and may also require removal of the bone void filler.

Notes – Collagen:

The device contains collagen derived from bovine tendon, which is classified by the WHO as a Group C tissue, indicating there is no detectable risk of infectivity for Bovine Spongiform Encephalopathy (BSE). In addition, all bovine tendon is obtained from animals born, raised and processed in New Zealand, a country recognized by the World Organization for Animal Health as having a negligible BSE risk. The tissue sourcing and processing procedures result in one of the purest sources of Type I collagen commercially available. This processing involves alkali and acid treatments, which are recognized methods of further inactivation of viruses and transmissible agents such as Spongiform Encephalopathy pathogens.

Precautions:

The device must only be used for the intended indications by surgeons familiar with bone grafting and internal/external fixation techniques. The device must not be used to gain screw purchase or to stabilize screw placement. Instrumentation used for the surgical procedure must gain purchase in the host bone. The surgeon must ensure that the bone void is not overfilled with the device. Instrumentation used in conjunction with the device 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. 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 the expiration date indicated on the device outer label.

STERILE EO



Caution:

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



Manufacturer:

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