Vitoss™ BA

Bioactive Bone Graft Substitute

Foam STRIP and Foam PACK

DESCRIPTION: Vitoss Bioactive Foam Bone Graft Substitute is a resorbable porous bone void filler for the repair of bony defects. It is an osteoconductive, porous implant with a trabecular structure that resembles the multidirectional interconnected porosity of human cancellous bone. Pore diameters in the scaffold range from 1 µm to 1000 µm.

Vitoss Bioactive Foam guides the three-dimensional regeneration of bone in the defect site into which it is implanted. When Vitoss Bioactive Foam is placed in direct contact with viable host bone, new bone grows in apposition to the surfaces of the implant. As the implant resorbs, bone and other connective tissues grow into the space previously occupied by the scaffold.

Vitoss Bioactive Foam is osteostimulatory based on in-vitro studies in which calcium phosphate growth was induced on the surface of the Vitoss Bioactive Foam after exposure to simulated body fluid. This phenomenon was not observed in control samples in which there was no bioactive glass component. The osteostimulatory nature of Vitoss Bioactive Foam has not been correlated to human clinical experience.

INTENDED USE AND INDICATIONS: Vitoss Bioactive Foam Bone Graft Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Vitoss Bioactive Foam is indicated for use in the treatment of surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Vitoss Bioactive Foam Bone Graft Substitute is intended to be used for filling bony voids or gaps of the skeletal system (i.e., the extremities, pelvis, and spine, which includes posterolateral fusion procedures) and may be combined with saline, autogenous blood, and/or bone marrow. Following placement in the bony void or gap, the scaffold resorbs and is replaced with bone during the healing process.

CONTRAINDICATIONS: Use of Vitoss Bioactive Foam Bone Graft Substitute is CONTRAINDICATED in the presence of one or more of the following clinical situations:

- ❑ Growth plate fractures;
- ❑ Segmental defects;
- ❑ Conditions where the surgical site may be subjected to excessive impact or stresses, including those beyond the load strength of fixation hardware;
- ❑ Significant vascular impairment proximal to the graft site;
- ❑ Metabolic or systemic bone disorders that affect bone or wound healing;
- ❑ Infected sites;
- ❑ Osteomyelitis at the operative site;
- ❑ Defect site stabilization is not possible;
- ❑ Intraoperative soft tissue coverage is not planned or possible;
- ❑ In direct contact with the articular space;
- ❑ Conditions in which general bone grafting is not advisable.

Vitoss Bioactive Foam must not be used in patients with a history of anaphylaxis, history of multiple allergies, known allergies to bovine collagen, or who are being treated for desensitization to meat products because this product contains bovine collagen.

WARNINGS: Vitoss Bioactive Foam Bone Graft Substitute does not possess sufficient mechanical strength to support reduction of a defect site. Rigid fixation techniques are recommended as needed to assure stabilization of the defect in all planes. Vitoss Bioactive Foam cannot be used to obtain purchase for screws. Screws must gain purchase in the host bone.

Complete postoperative wound closure is essential. Vitoss Bioactive Foam must not be used to repair bone defects where soft tissue coverage cannot be achieved.

The material is only sterile if the package is unopened and undamaged. Single patient use only. DO NOT reuse or resterilize.

PRECAUTIONS: Vitoss Bioactive Foam is intended for use by surgeons familiar with bone grafting and rigid fixation techniques.

Vitoss Bioactive Foam's radiopacity is comparable to that of bone and diminishes as it is resorbed. This moderate radiopacity may mask underlying pathological conditions and must be considered when evaluating X-rays.

ADVERSE EVENTS: The following complications have been reported to result from bone grafting procedures and are considered to be potential complications for Vitoss Bioactive Foam Bone Graft Substitute: Superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, nonunion, wound dehiscence, delayed union, malunion, loss of reduction, refracture, cyst recurrence, hematoma, and cellulitis. Localized immunological reactions consisting of transient localized edema, swelling, and rash have been reported to occur with bone void fillers containing collagen. 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.

DIRECTIONS FOR USE: Familiarization with the device and proper bone grafting and rigid fixation techniques are extremely important. Radiographic evaluation of the defect site is essential to accurately assess the extent of a traumatic defect and to aid in the selection and placement of the bone void filler and fixation devices.

Foam STRIP Vitoss Bioactive Foam STRIP may be used in its given form or shaped to a desirable size using a scalpel or scissors. After shaping, insert the material into the surgical site. Smaller pieces that have been cut from the scaffold may be used to fill in irregularly shaped voids in the defect site.

Vitoss Bioactive Foam STRIP may be mixed with saline, autogenous blood or bone marrow. The material may be inserted into a wet or dry site.

Foam PACK To prepare the Vitoss Bioactive Foam PACK, wet the composite strip with fluid (saline or autogenous blood or bone marrow) per Table 1 and then add the bioactive glass contents provided in the vial. Knead the fluid, composite strip and bioactive glass for at least 60 seconds. After shaping, insert the bone graft substitute into the surgical site.

For best results, Vitoss Bioactive Foam STRIP and PACK must fill the defect and contact as much viable host bone as possible.

Table 1. Directions to properly prepare Vitoss Bioactive Foam PACK

Net Product Volume (per label)	Amount of Bioactive Glass (provided)	Fluid volume
1.2 cc	0.15 g	1.3 cc
2.5 cc	0.25 g	2.4 cc
5 cc	0.5 g	4.5-4.7 cc
10 cc	1.0 g	8.7-9.5 cc

Fixation of the implant site must be sufficient to prevent collapse and deformity secondary to functional loading. Anatomical reduction and rigid fixation in all planes must be obtained to ensure that the graft is not supporting load.

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 defect repairs involving the use of fixation devices.

STERILIZATION: Vitoss Bioactive Foam Bone Graft Substitute is provided sterile by prior exposure to gamma radiation. Vitoss Bioactive Foam cannot be resterilized by any method. Excess material and opened but unused product must be discarded.

Inspect the package of any sterile product for structural integrity prior to use. If the seal of any inner or outer container is broken or otherwise damaged, the product must be assumed to be nonsterile.

STORAGE: Do not freeze or expose to extreme heat. Store at Ambient Temperature.

HOW SUPPLIED: Vitoss Bioactive Foam STRIP Bone Graft Substitute is provided sterile in strip form in a variety of sizes and volumes. Vitoss Bioactive Foam PACK Bone Graft Substitute is provided sterile and includes a composite strip which is mixed with a corresponding amount of bioactive glass (provided in an accompanying glass vial). Vitoss Bioactive Foam PACK is offered in a variety of volumes.

CAUTION: Rx-only.

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Caution, consult accompanying documents
Vorsicht, mitgelieferte Informationen beachten
Avertissement : Consulter la documentation attenante
Attenzione, consultare la documentazione allegata
Precaução, consultar documentos anexos

Let op: raadpleeg begeleidende documentatie
Advertencia, consultar los documentos adjuntos
Var försiktig! Konsultera medföljande dokument
Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα
Forsigtig, se vedlagte dokumenter

Do not re-use
Nicht wiederverwenden
Ne pas réutiliser
Non riutilizzare
Não reutilizar

Niet opnieuw gebruiken
No reutilizar
Får ej återanvändas
Μην επαναχρησιμοποιείτε
Må ikke genbruges

Date of manufacture
Herstellungsdatum
Date de fabrication
Data di fabbricazione
Data de fabrico

Vervaardigingsdatum
Fecha de fabricación
Tillverkningsdatum
Ημερομηνία κατασκευής
Fremstillingsdato

Use by date
Haltbarkeitsdatum
Date de péremption
Data di scadenza
Data de validade

Vervaldatum
Fecha de caducidad
Använd före-datum
Χρησιμοποιήστε πριν την αναγραφόμενη ημερομηνία
Udløbsdato

Sterilized using irradiation
Sterilisiert durch Bestrahlung
Stérilisé par irradiation
Sterilizzato mediante irradiazione
Esterilizado através de irradiação

Gesteriliseerd met behulp van straling
Esterilizado mediante irradiación
Steriliserad med strålning
Αποστειρώθηκε με ακτινοβολία
Steriliseret ved bestråling

Batch code
Chargennummer
Code de lot
Codice di lotto
Código do lote

Batchcode
Código de lote
Satskod
Κωδικός παρτίδας
Partinummer

REF	Catalog number	Catalogusnummer
	Katalognummer	Número de catálogo
	Numéro de catalogue	Katalognummer
	Numero di catalogo	Αριθμός καταλόγου
	Número no catálogo	Katalognummer

	Manufacturer	Fabrikant
	Hersteller	Fabricante
	Fabricant	Tillverkare
	Produttore	Κατασκευαστής
	Fabricante	Producent

Rx Only	By prescription only	Uitsluitend op voorschrift verkrijgbaar.
	Verschreibungspflichtig.	Uso exclusivo con receta médica.
	Sur prescription uniquement.	Receptbelagd.
	Vendita consentita solo dietro prescrizione medica.	Μόνο κατόπιν συνταγής ιατρού.
	Sujeito a receita médica.	Kun efter lægens ordination.

EC REP	European Authorized Representative	Representante autorizado europeo
	Vertretung in Europa	Europeisk auktoriserad representant
	Représentant européen agréé	Εξουσιοδοτημένος αντιπρόσωπος στην Ευρώπη
	Rappresentante europeo autorizzato	Europæisk autoriseret repræsentant
	Representante autorizado na Europa	
	Europese gemachtigde vertegenwoordiger	

	Temperature limitation	Temperatuurgrenzen
	Temperaturbegrenzung	Limitación de temperatura
	Limite de température	Temperaturbegränsning
	Limite di temperatura	Περιορισμός θερμοκρασίας
	Limites de temperatura	Temperaturbegrænsninger

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