CoreLink

Instructions for Use

VerteFrame™ Silicated Bone Void Filler

Rx only

Prescription use only: US Federal law restricts this device to sale by or on the order of a physician.

Description

VerteFrame™ Silicated Bone Void Filler is resorbable, osteoconductive and cancellous bone-like bone regeneration material prepared from silicated β-tricalcium phosphate (β-TCP) and porcine collagen for filling and bridging degenerative or traumatic bone defects.
The matrix structure supports the three-dimensional regeneration of bone tissue. In contact with vital bone, the synthetic ceramic material is resorbed by the body over a period of months and is simultaneously replaced by local, autologous bone.
VerteFrame™ Silicated Bone Void Filler is radiopaque.

Indications for Use

VerteFrame™ Silicated Bone Void Filler is intended to fill bony voids or gaps of the skeletal system (posterolateral spine). These osseous defects may be surgically created or from traumatic injury to the bone and are not intrinsic to the stability of the bony structure. In the posterolateral spine VerteFrame™ Silicated Bone Void Filler is to be mixed with autograft bone. The device resorbs and is replaced with bone during the healing process.

Contraindications

- Acute and chronic infections in the operative field (soft tissue infections; inflammatory, bacterial bone diseases; osteomyelitis). For patients receiving antibiotic therapy, it is at the user's discretion whether to employ VerteFrame™ Silicated Bone Void Filler based on a benefit/risk analysis.
- Severe metabolic disorders, such as severe, uncontrolled or poorly controlled diabetes
- Metabolic or systemic bone diseases which impact bone or wound healing
- Disorders of calcium metabolism
- Steroid treatment
- Drugs that interfere with calcium metabolism
- Immunosuppressive therapy
- Endocrine bone diseases
- Radiation therapy in the surgical region
- Nicotine abuse
- Use in the region of an active epiphyseal plate
- Significant vascular damage in the region of the implantation site
- Insufficient soft tissue coverage
- Direct contact with the articular cavity
- Known allergies to porcine collagen or other protein allergies

Warning

VerteFrame™ Silicated Bone Void Filler cannot assume a load-bearing function. Additional osteosynthetic measures may be required depending on the nature and localization of the bone defect to be treated.

The radiopacity of VerteFrame™ Silicated Bone Void Filler is similar to that of cancellous bone and decreases as resorption increases. This moderate radiopacity may mask pathological conditions.

Precautions

The graft must be secured to prevent potential migration and should only be used in surgical procedures where bone grafts are adequately contained.
Completely fill the bony defect, ensuring maximal contact between VerteFrame™ Silicated Bone Void Filler and the host bone.
Do not over fill the bony voids or gaps with the VerteFrame™ Silicated Bone Void Filler product, as this may lead to extrusion of the product beyond the site of its intended application and damage to the surrounding tissues.
Remove any excess material before closure.

Adverse Events

Potential adverse events that may occur relative to the placement of bone void fillers include:

- Revisions and/or removals
- Superficial wound or deep wound infection
- Pain/discomfort, swelling, redness, fever, inflammation
- Fluid accumulation
- Delayed or nonunion, lack of osseointegration, inadequate bone formation
- Altered handling characteristics leading to failure
- Protrusion, dislodgement, migration, or extravasation (leakage)
- Allergic/immune response
- Hematoma
- Cyst

Side effects None known to date.

Interactions No interactions between VerteFrame™ Silicated Bone Void Filler and medicinal products or other medical devices have been reported to date.

Method of application

- VerteFrame™ Silicated Bone Void Filler may only be used by or under the supervision of medical professionals with experience in the necessary surgical techniques and the use of biomaterials. The choice of formulation and the exact surgical procedure depend on the localization, nature, and extent of the defect.
- Before implanting the bone regeneration material, bone remnants, connective and necrotic tissue must be carefully removed. VerteFrame™ Silicated Bone Void Filler requires direct contact with bleeding vital bone and thorough debridement of the bone is essential before implantation.
- VerteFrame™ Silicated Bone Void Filler can be cut to the required size with a scalpel or scissors if necessary. VerteFrame™ Silicated Bone Void Filler must be hydrated with sterile saline before implantation.
- VerteFrame™ Silicated Bone Void Filler must be used with autograft as a bone graft extender in the posterolateral spine. Combine VerteFrame™ Silicated Bone Void Filler with morselized autograft bone at a ratio of 1:1 by volume.

VerteFrame™ Silicated Bone Void Filler allows plastic deformation and can be adapted to match the individual defect.

Shelf life and storage

VerteFrame™ Silicated Bone Void Filler is intended for single use only, packaged gamma-sterilized, and must not be re-sterilized. Leftover material and opened, unused material must be discarded. The product must not be used if the sterile pack is visibly damaged.
VerteFrame™ Silicated Bone Void Filler should be kept in the outer carton in a dry place at room temperature and should not be used after the expiry date.

Presentation

99203-02 VerteFrame™ Silicated Bone Void Filler, 25mm x 25mm x 4mm, 2.5 cc
99203-05 VerteFrame™ Silicated Bone Void Filler, 50mm x 25mm x 4mm, 5.0 cc
99203-10 VerteFrame™ Silicated Bone Void Filler, 100mm x 25mm x 4mm, 10.0 cc

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SYMBOLS LEGEND

ANSI/AAMI/ ISO 15223-1:2021 Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied — Part 1: General requirements.

Symbol	Title of Symbol (Reference Number)	Meaning of Symbol
	Use-by date (5.1.4)	Indicates the date after which the medical device is not to be used.
LOT	Batch code (5.1.5)	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Catalogue number (5.1.6)	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Double sterile barrier system (5.2.12)	Indicates two sterile barrier systems
	Do not re-use (5.4.2)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
STERILIZE	Do not resterilize (5.2.6)	Indicates a medical device that is not to be resterilized.
STERILE R	Sterilized using irradiation (5.2.4)	Indicates a medical device that has been sterilized using irradiation.
	Consult instructions for use (5.4.3)	Indicates the need for the user to consult the instructions for use.
	Do not use if package is damaged (5.2.8)	Indicates a medical device that should not be used if the package has been damaged or opened.
	Keep away from sunlight (5.3.2)	Indicates a medical device that needs protection from light sources
	Keep dry (5.3.4)	Indicates a medical device that needs to be protected from moisture
	Manufacturing date (5.1.3.)	Indicates the date on which the medical device was manufactured
	Manufacturer (5.1.1)	Indicates the medical device manufacturer
UDI	Unique Device Identifier (5.7.10)	Indicates a carrier that contains Unique Device Identifier information
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Information last updated 30th March 2023
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