



UNIFUZE™ Block Bone Graft Matrix

Description:

UNIFUZE™ Block is a collagen mineral composite matrix processed into strip form for surgical implantation. The principle components of UNIFUZE™ Block are bovine type I collagen and anorganic bovine bone mineral. The mineral particles are dispersed within collagen fibers forming a three-dimensional open porous matrix consisting of 80% bone mineral and 20% collagen. UNIFUZE™ Block is provided as a sterile, dry material that is hydrated with autogenous bone marrow at the point of use. UNIFUZE™ Block is fully resorbed during the natural process of bone formation and remodeling.

Indications:

UNIFUZE™ Block, combined with autogenous bone marrow, is intended for use in filling bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone.

Contraindications:

UNIFUZE™ Block must not be used in patients with osteomyelitis at the operative site.

UNIFUZE™ Block 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:

UNIFUZE™ Block should not be used in fractures of the growth plate, segmental defects, direct contact with the articular space, and open fractures.

Precautions:

Caution should be exercised when treating individuals with bleeding diatheses of any etiology.

UNIFUZE™ Block should not be used to treat large defects that in the surgeon's opinion would fail to heal spontaneously. UNIFUZE™ Block must be used with internal or external fixation as indicated or required.

Use of Nonsteroidal Anti-inflammatory (NSAIDs) medications may delay graft healing. Use of alternate means of pain control should be considered whenever possible. Abstinence from smoking during and after treatment is highly advised.

If there is any evidence of compromised sterility (e.g., torn packaging), the device must not be used.

UNIFUZE™ Block cannot be re-sterilized. Open, unused products must be discarded. In vivo stability may be adversely affected if re-sterilized. Cross-contamination and infection may occur if re-used.

Adverse Effects:

The complications and inherent risks associated with bone grafting surgery are not anticipated to increase with the use of UNIFUZE™ Block. Potential complications of surgery include wound infection, reaction to medications or anesthesia, pain, thromboembolism, cardiac or pulmonary complications and blood loss. Potential postoperative risks include, but are not limited to hematoma, urinary retention, thrombophlebitis, and continued pain. Also, all patients will be exposed to the same risks associated with any bone grafting procedure such as fracture, migration, resorption or rejection of the graft, delayed union, nonunion, or pseudoarthrosis. These complications may require re-grafting or revision. In addition, in some instances UNIFUZE™ Block may need to be removed from the body, thus creating the need for a second surgery.

The possibility exists also for failure of the implant due to incorrect surgical technique, patient noncompliance during postoperative rehabilitation, and other unforeseen problems. A small number of patients may experience localized immunological reactions to this device that generally consist of 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.

UNIFUZE™ Block has not been used in clinical studies to treat patients with metabolic bone disease, significant vascular disorders or clotting disorders, uncontrolled diabetes, ankylosing spondylitis, achondroplasia, or in patients undergoing

anticoagulation therapy, immunosuppressive therapy, or steroid therapy. No clinical data exists for use of UNIFUZE™ Block in children or pregnant women.

Directions for Use:

The procedure must be performed in an operating room under aseptic conditions. The patient should be anesthetized or sedated, as required. After adequately exposing the bone requiring grafting, the bones should be debrided until healthy bleeding bone is exposed throughout the graft site.

1. Determine the number of UNIFUZE™ Block strips to be used based on the size or volume of the defect to be filled.
2. Aspirate bone marrow to matrix on an estimated 1:1 basis (e.g., use approximately 8-10mL bone marrow for each 10cc UNIFUZE™ Block strip).
3. Transfer the aspirate immediately into a sterile bowl.
4. Add a small amount of heparin (20 units heparin/1mL marrow) to prevent the bone marrow aspirate from clotting.
5. Hydrate each UNIFUZE™ Block with bone marrow just prior to implantation – NOTE: Hydration should require less than 1 minute.
6. Gently pack the defect maintaining the structure of UNIFUZE™ Block and the saturated bone marrow aspirate.
7. If irrigation is used, it must be performed prior to placement of UNIFUZE™ Block.

How Supplied:

UNIFUZE™ Block is provided sterile, non-pyrogenic, and for one time use only. Each unit of UNIFUZE™ Block contains single or multiple strips of various sizes.

Storage:

Store at room temperature (15°C - 30°C). Do not freeze or expose to extreme heat.

Caution:

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

Labeling Symbols:

Symbols may be used on some international package labeling for easy identification.



Attention, See Instructions For Use



Use By



Do Not Reuse

LOT

Lot Number

STERILE R

Sterilized Using Irradiation



Temperature Limitation

REF

Catalog Number

Rx Only

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



Manufacturer

 **Manufacturer:**

Collagen Matrix, Inc.
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