BiFORM®
Bioactive Moldable Matrix

INSTRUCTIONS FOR USE

DEVICE DESCRIPTION

BiFORM® Bioactive Moldable Matrix is composed of anorganic bone mineral, bioactive glass, and type I collagen that can be molded to fit the bone defect. It is an osteoconductive, bioactive, porous implant that allows for bony ingrowth across the graft site. The bone graft matrix is slowly resorbed and replaced by new bone tissue during the natural healing process.

The anorganic bone mineral component of the bone graft matrix is a natural, porous bone graft material produced by removal of all organic components from bovine bone. The composition of the anorganic bone mineral meets ASTM F1581 standard specifications for composition of anorganic bone for surgical implants. The bioactive glass component of the device is made of 45S5 Bioactive Glass and meets ASTM F1538 standard specifications for glass and glass ceramics biomaterials for implantation. The purified type I collagen is derived from bovine deep flexor Achilles tendon.

The product is available in various sizes and is provided sterile, non-pyrogenic, and for single use only.

INDICATIONS

BiFORM® Bioactive Moldable Matrix is intended for use as a bone void filler for voids or gaps, that are not intrinsic to the stability of the bony structure. The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, pelvis, intervertebral disc space, and posterolateral spine). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.

In the posterolateral spine and intervertebral disc space, BiFORM® Bioactive Moldable Matrix is combined with either autogenous bone marrow or autograft with saline and can also be used with autograft as a bone graft extender. When used in intervertebral body fusion procedures, BiFORM® Bioactive Moldable Matrix must be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

CONTRAINDICATIONS

Use of BiFORM® Bioactive Moldable Matrix 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, including pre-existing calcium metabolism disorders (e.g., hypercalcemia);
- 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.

BiFORM® Bioactive Moldable Matrix 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

BiFORM® Bioactive Moldable Matrix does not possess sufficient mechanical strength to support reduction of a defect site. The bone graft matrix is not indicated for use in load-bearing applications; standard internal or external stabilization techniques must be followed to obtain rigid stabilization.

Do not overfill the bone defect with BiFORM® Bioactive Moldable Matrix. Overfilling of the defect can result in reduction of the porosity of the matrix structure when the product is compressed.

Complete postoperative wound closure is essential. BiFORM® Bioactive Moldable Matrix must not be used to repair bone defects where soft tissue coverage cannot be achieved.

PRECAUTIONS

BiFORM® Bioactive Moldable Matrix is intended for use by surgeons familiar with bone grafting and rigid fixation techniques.

BiFORM® Bioactive Moldable Matrix should be secured to prevent motion and migration; use in areas where the product can be adequately contained.

Radiopacity of BiFORM® Bioactive Moldable Matrix 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.

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.

BiFORM® Bioactive Moldable Matrix is for single use only. The product cannot be reused or re-sterilized. Open, unused product 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 following complications have been reported to result from bone grafting procedures and are considered to be potential complications for BiFORM® Bioactive Moldable Matrix: superficial wound infection, deep wound infection, deep wound infection with osteomyelitis, nonunion, wound dehiscence, delayed union, malunion, loss of reduction, transient hypercalcemia, refracture, cyst recurrence, material fracture, altered handling characteristics leading to failure, device protrusion, dislodgement, migration or extravasation (leakage), inadequate bone formation or lack of bone formation, hematoma, cellulitis, pain/discomfort, fever, redness, inflammation, fluid accumulation, wound drainage, debridement or irrigation, lack of osseointegration, impaired healing, loss of motor function, decreased range of motion, sensory deficit, allergic or immune response, blood pressure change, hematoma and death. 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 revision/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.

Caution: The device is indicated for use in combination with autologous bone marrow or autograft in posterolateral spine applications and indicated for standalone use in the pelvis and extremities.

1. Select appropriate matrix size based on the size of the defect and remove the product from its sterile package. If desired, cut the matrix using a scalpel or scissors to obtain appropriate size.

USE WITH BONE MARROW ASPIRATE (BMA)

a. Bone marrow aspirate (BMA) should be obtained immediately prior to implantation and should be aspirated

in a 1:1 ratio of bone marrow to BiFORM® Bioactive Moldable Matrix (e.g. 1ml of bone marrow for each 1cc of BiFORM® Bioactive Moldable Matrix).
b. Add a small amount of heparin (20 units heparin/1mL marrow) to prevent the bone marrow aspirate from clotting.
c. Mold using kneading technique.

USE WITH AUTOGRAFT

a. Hydrate the matrix using sterile, normal saline.
b. The moldable device should be used with autograft on a 40:60 ratio basis (device:autograft).
c. Place the appropriate amount of autograft to the defect site prior to placing the moldable device.

2. Gently pack/mold the material into the defect site; avoid overfilling or compressing the treatment site.
3. Smaller pieces that have been cut from the product may be used to fill in irregularly shaped voids in the defect site.
4. For best results, BiFORM® Bioactive Moldable Matrix must fill the defect and contact as much viable host bone as possible.
5. 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.
6. Close the site using standard closure techniques.

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.

HOW SUPPLIED

BiFORM® Bioactive Moldable Matrix is provided sterile, non-pyrogenic, and for one time use only.

STORAGE

Store at Room Temperature (15°C/59°F - 30°C/86°F). Do not freeze or expose to extreme heat.

CAUTION

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

LABELING SYMBOLS

Symbols may be used on package labeling for easy identification.

	Use by
	Do Not Reuse
	Do not use if the product sterilization barrier or its packaging is compromised.
	Consult instructions for use
STERILE R	Sterilized using irradiation
LOT	Lot number
℞ ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician
REF	Catalogue number
	Temperature limitation
	Manufacturer

Manufacturer:
Collagen Matrix, Inc.
15 Thornton Road
Oakland, NJ 07436 USA

Manufactured for:
Sanara MedTech Inc.
1200 Summit Ave. Suite 414
Fort Worth, TX 76102
1-800-205-7719