

Instructions for Use

Description: GenMatrix is produced from medical grade calcium sulfate hemihydrate. Calcium sulfate has a long, successful history for bone grafting. Several studies have shown calcium sulfate to be highly biocompatible, biodegradable, nontoxic, hemostatic and angiogenic. It also serves as a guided tissue regeneration material by preventing the growth of soft tissue into bone defects. When implanted in the body, it is absorbed, encouraging the growth of bone as it degrades. It releases calcium ions which combine with phosphorus ions from the body fluid leaving behind a calcium phosphate trellis that supports the growth of bone in the area. Thus it serves as a bioactive and osteoconductive bone-growth scaffold. The graft material is radiopaque, allowing the clinician to make immediate, as well as long range, post-operative observations using standard radiographic techniques.

Indications:

1. As a stand-alone bone graft material.
2. In combination with other bone graft materials to prevent particle migration in osseous defects.
3. To provide a resorbable barrier over other bone graft materials.

Contents of the package:

Each package contains 2 patient-specific kits for a total of 2 grams. The package also comes with regular setting and fast setting solutions.

Examples of use:

Oral Surgery

Post-extraction: To help maintain height and width of alveolar bone, apply an initial layer of GenMatrix and compress it with gauze. Hemostasis will thus be obtained. Continue filling in layers, each time compressing the material with sterile gauze. The alveolus should be filled to slight excess and the soft tissue margins should be approximated with sutures over the hardened GenMatrix.

Periodontics

Infra-osseous defects: After periodontal treatment, fill the defect(s) with GenMatrix, pressing on the root surface. In furcations, GenMatrix can be used alone or under membranes.

Endodontics

Apicoectomy: Following root resection, apply a layer of GenMatrix into the crypt and compress with gauze, thus obtaining hemostasis. Prepare the root end cavity and retrograde fill. Then fill the crypt with GenMatrix, placing it in layers, in slight excess. Wet the final layer with FAST SET liquid to allow for rapid hardening, then suture.

Root perforations: For intra-coronal treatment, use GenMatrix as a matrix. Mix GenMatrix to a creamy consistency and introduce to the pulp chamber. Push it through the perforation into the bone lesion until the latter is completely filled. Clean the cavity with a small sponge soaked in REGULAR SET liquid; wait until the GenMatrix has hardened. Remove GenMatrix from the dentinal walls of the perforation with a rose miller, then close the perforation with fast setting super-EBA or a resin bonding technique.

Open apices: Plug the apical third of the canal with GenMatrix, then remove the material up to 1 mm from the radiographic apex. Fill the canal with your chosen technique.

Implantology

Dehiscence and fenestrations: Reconstruct the bone continuity with GenMatrix. Allow it to harden using the FAST SET liquid and suture.

Mini sinus lifting: Before inserting the implant, fill the bone area with GenMatrix, pressing with an appropriate instrument and pushing the material so that the membrane is raised. Then insert the implant.

Great sinus lifting: GenMatrix can be used as a single implant material or as a matrix mixed with autologous or heterologous bone.

General Recommendations:

1. Control or prevent bleeding.
2. Apply GenMatrix in overlapping layers.
3. Incorporate a minimum amount of liquid with the powder.
4. Opened kit cannot be re-sterilized and reused.
5. Avoid contact with saliva and blood before GenMatrix has completely hardened.

Necessary Instrumentation:

Prepare in advance: 2 tweezers with clamps, spatula
Multiple small nonwoven sterile gauze pads
Sutures

Setting Time:

When mixed with regular set liquid: approximately 15-20 min.

When mixed with fast set liquid: 2-4 min.

Mixing the product:

1. GenMatrix is provided in a small cup packaged in a tyvek pouch. Open this pouch and the cup. Add 3 drops of regular setting solution to GenMatrix powder in the cup. Mix it to form a semi-solid paste.
2. Wait until the mixture comes to a putty-like consistency. Implant it into the defect.

Application of the product:

1. The defect site should be as dry and blood-free as possible. The presence of blood in the defect site slows the setting of the product.
2. After the site is cleaned, apply the putty in small layers compressing it in the defect with a small sterile gauze pad held in a tweezer clamp. It is also possible to compress each layer with a small piece of sterile gauze saturated in fast set liquid. This will improve the compression strength of the reconstruction. A gauze pad is recommended to maintain hemostasis during this compression stage.
3. The last positioned layer, slightly in excess, must be hardened with a sterile gauze pad held with the second tweezer and impregnated with fast set liquid.

Modeling:

If necessary, after the last layer is set with the fast set liquid, it is possible to model the reconstruction using a surgical multiblade bur.

Suturing:

If it is not possible to perform an immediate closure due to insufficient availability of soft tissue, the reconstruction can be left exposed and covered in a second intervention.

Caution: Federal Law restricts this product to sale by or on the order of a licensed dentist or a physician.

Manufactured for:

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