

Mucograft®

Collagen Matrix

Composition:

Mucograft® is a pure collagen matrix obtained by standardized, controlled manufacturing processes. The matrix is made of porcine collagen without further cross-linking or chemical treatment. The collagen is extracted from veterinary certified pigs and is carefully purified. Mucograft® is sterilized in double blisters by Gamma-irradiation.

Mucograft® has a bilayer structure:

The compact layer consists of compact collagen which has cell occlusive properties and allows tissue adherence as a prerequisite for favorable wound healing. This layer has a smooth texture with appropriate elastic properties to accommodate suturing.

A second layer consists of a thick, porous collagen spongy structure. This spongy surface is placed next to the host tissue to facilitate organization of the blood clot and to promote formation of new blood vessels and tissue integration.

Properties / Action

The low antigenicity and excellent biocompatibility favor the use of Mucograft® in dental surgery. The long-fibered microstructure of Mucograft® readily absorbs fluid. The matrix retains its structural integrity even when wet. Mucograft® is approximately 2.5–5.0 mm thick. Fixation by sutures or pins is possible. The coherent collagen fibers swell and form a unified basic tissue structure. As a result, the matrix adheres well to the surrounding and underlying tissues. Inflammatory reactions have not been observed, but cannot be excluded.

Indications

Mucograft® is indicated for:

- covering of implants placed in immediate or delayed extraction sockets;
- localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants;
- alveolar ridge reconstruction for prosthetic treatment;
- recession defects for root coverage.

Instructions for use

The general principles of sterile handling and patient medication must be followed when using Mucograft®:

- The defect is exposed by means of (a) properly prepared flap(s) and the usual surgical procedures in creating a properly prepared site are undertaken.
- The defect is filled, if needed, with a space-maintaining material, such as autologous bone or bone substitute (e.g. Bio-Oss®). Such defects should not be overfilled.
- The Mucograft® matrix is cut to the required size and shape with surgical scissors.
- The compact layer should face upwards, away from underlying bone, and the spongy surface should face toward bone.
- The matrix is applied over the prepared site and stabilized using resorbable sutures or the flap. Excessive pressure should be avoided as it may compress the matrix.
- Complete penetration of the matrix by blood and exudates allows close adaptation and adhesion of the matrix to the underlying surface and facilitates the formation of a blood clot within the Mucograft® matrix.
- Due to the high tensile strength of this matrix, fixation or suturing is possible. Fixation or suturing of the matrix may be indicated, depending upon the nature of the particular defect and to avoid displacement of the matrix. After placement in covered sites, the mucoperiosteal flap should be sutured over the matrix without tension.

Special instructions for use in Periodontology

A basic requirement for successful periodontal treatment includes eradicating the underlying bacterial infection as well as adequate oral hygiene. Therefore, prior to surgical intervention, patients must receive a hygiene phase of treatment, consisting of oral hygiene instructions, scaling and root planing, and occlusal adjustment when indicated. A postoperative maintenance phase can help to ensure long-term therapeutic success.

Post-operative care

The usual postoperative care and medication should be given. Further prosthetic treatment should only be carried out after a healing period to ensure complete soft tissue regeneration. Previous studies have indicated that soft tissue healing, i.e., wound closure and the resolution of normal inflammation, occurs within 4–8 weeks. But clinical judgment, taking into account the healing of both soft and hard tissues in the treated patient, should be applied before prosthetic treatment. In case of bacterial contamination rinsing with appropriate bactericidal solutions is recommended.

In the event that early matrix removal is necessary, the tissues adjacent to the matrix should be anesthetized with a local anesthetic. An incision should then be made immediately adjacent to the residual matrix. Following careful reflection of the surrounding tissue, the remaining portion of the matrix can be excised and the area debrided to remove any inflamed or infected tissue.

Limitations for use

Contraindications

Mucograft® should not be placed where active infection or inflammation exists. Before placement, the surgeon should be confident that any active or recent infection has been properly treated. Patients with known allergy to collagen should not be treated with Mucograft®.

Precautions:

Mucograft® should be used with special caution in patients with uncontrolled metabolic diseases (e.g. diabetes, osteomalacia, thyroid disorder) or autoimmune diseases, as well as in case of a prolonged corticosteroid therapy or radiotherapy in the oral cavity. In addition it is not recommended to use the matrix in more than one layer. The material has not been tested on pregnant or lactating women.

Side effects:

In addition the following potential side effects, resulting from the surgical process, may arise after placing a matrix into the oral cavity: soft tissue dehiscence, hematoma, increased sensitivity and pain, redness and inflammation.

Storage and Handling

Do not use after the expiration date. The content of the double blister is designed for **single use only**. Do not reuse or resterilize Mucograft®. The matrix should be handled using sterile gloves or sterile instruments. The matrix is sterile unless the package has been opened, damaged, or otherwise contaminated.

Store in a dry place at room temperature (15–25 °C/ 59–77 °F).

Presentation:

Mucograft® is packed in sterile double blisters. Each double blister contains one matrix.

Sizes 15 x 20 mm
20 x 30 mm

Distributed by:

Osteohealth Company

One Luitpold Drive
P.O. Box 9001
Shirley, NY 11967-4799

Manufacturer:

Geistlich Pharma AG

Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland
Product of Switzerland

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Caution:

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