ZDERM™
collagen soft tissue matrix

ENGLISH

DESCRIPTION:

ZDERM™ Collagen Soft Tissue Matrix is a cross-linked resorbable matrix engineered from highly purified Type I collagen fibers derived from porcine Achilles tendon for use in periodontal, oral, and maxillofacial surgery. The product is composed of two structures: a smooth outer layer that acts as a barrier membrane and a porous matrix layer to allow cell invasion and tissue ingrowth. The product is oriented so that the porous layer is in contact with the host tissue to facilitate tissue integration. ZDERM™ is provided in various sizes where it can be easily trimmed for appropriate fit and sutured into place during surgery.

ZDERM™ is provided sterile, non-pyrogenic, and for single use only.

INDICATIONS FOR USE

ZDERM™ is intended to support localized gingival augmentation to increase keratinized tissue.

ZDERM™ is indicated for:
- Localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants
- Covering of implants placed in immediate or delayed extraction sockets

CONTRAINDICATION

ZDERM™ should not be used where:
- Symptomatic infection or inflammation exists
- In individuals with a known allergy to collagen of animal origins

PROPERTIES / ACTIONS:

The low antigenicity and excellent biocompatibility favor the use of ZDERM™ in dental surgery. The long fibered microstructures of ZDERM™ readily absorb fluid. The coherent collagen fibers of ZDERM™ form a basic tissue matrix. As a result, the matrix adheres well to the surrounding and underlying tissues. Inflammatory reactions have not been observed but cannot be excluded. ZDERM™ is approximately 1.5 - 5 mm thick. Fixation by sutures or pins is possible.

INSTRUCTIONS FOR USE:

The general principles of sterile handling and patient medication must be followed when using ZDERM™.
- The defect is exposed by means of (a) properly prepared flap(s) and the usual surgical procedures are undertaken.
- When using ZDERM™ for extraction socket management, the defect is filled with a space maintaining material, such as autologous bone or bone substitute. Such defects should not be overfilled.
- The ZDERM™ is cut, if needed, to the required size and shape with surgical scissors. ZDERM™ must remain dry during trimming and application to the defect.
- The film side must face outwards, away from underlying bone, and the non-film side must face toward the bone. The film side is confirmed by location of the chamfer on the upper left corner when the short side of the membrane is oriented horizontally. For round membranes, the film side contains an impression.
- The matrix is applied over the prepared site and stabilized using 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.
- Fixation or suturing is possible for ZDERM™. Fixation or suturing of the matrix may be indicated, depending on the nature of the particular defect and to avoid displacement of the matrix.
- After placement of ZDERM™, the mucoperiosteal flap can be sutured over the matrix; however, primary closure is not required for device performance.

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. 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 rare event that 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.

PRECAUTIONS:

ZDERM™ should be used with special caution in patients with autoimmune diseases or uncontrolled metabolic diseases (e.g. diabetes, osteomalacia, thyroid disorder), 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.

Complete wound closure should be attempted when possible.

Healing of soft tissues might be compromised in patients with insufficiently vascularized soft tissues (e.g. in smokers).

The material has not been tested in pregnant or lactating women or in children.

SIDE EFFECTS

The following potential side effects may arise post-surgery after placing the product 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 packaging is designed for **single use only**. Do not reuse or re-sterilize ZDERM™. The product 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.

STERILIZATION:

The device is gamma irradiated. Do not resterilize.

The device is magnetic resonance (MR) safe.

HOW SUPPLIED:

ZDERM™ is packaged sterile in double packaging. Each double packaging contains one matrix.

Catalogue Numbers	Sizes
ZD1520TK	15 mm x 20 mm (Thick)
ZD1540TK	15 mm x 40 mm (Thick)
ZD2030TK	20 mm x 30 mm (Thick)
ZD3040TK	30 mm x 40 mm (Thick)
ZD10TK	10 mm Round
ZD1520TN	15 mm x 20 mm (Thin)
ZD1540TN	15 mm x 40 mm (Thin)
ZD2030TN	20 mm x 30 mm (Thin)
ZD3040TN	30 mm x 40 mm (Thin)

Caution

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

LABELING SYMBOLS

Symbols may be used on package labeling for easy identification.

	Expiration date
	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
	Do not resterilize
LOT	Lot number
R_X Only	Federal (USA) law restricts this device to sale by or on the order of a physician or dentist
REF	Catalogue number
MR	Magnetic Resonance (MR) Safe
	Non-pyrogenic
	Manufacturer

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

Distributed by:
Osteogenics Biomedical, Inc.
4620 71st Street, Bldg 78-79
Lubbock, TX 79424 USA
806-796-1923
www.osteogenics.com