| Distributed by: | Manufactured by: |
|---|---|
| **Zimmer Dental Inc.**<br>**Carlsbad, CA 92008 U.S.A.**<br>**Tel: 1.800.854.6691**<br>**Tel: 1.760.929.4300** | TUTOGEN MEDICAL GmbH<br>(an RTI Biologics Inc. company)<br><br>Industriestraße 6, D-91077 Neunkirchen a. Br.<br>Tel.: 09134-9988-0<br>Fax 09134-9988-99<br>e-mail: info@tutogen.de |

290313/####

**INSTRUCTIONS FOR USE**

**IMPORTANT: Read this entire package insert prior to use and follow all instructions carefully. Improper handling, preparation, surgical technique or post-operative care may adversely affect the safety and/or performance of the membrane.**

# CopiOs® Pericardium Membrane

**Collagen Membrane for Guided Bone and Soft Tissue Regeneration**

**STERILE** STERILE R **– for single use only**

Rx only **Caution:** United States of America Federal law restricts this device to sale by or on the order of a licensed physician.

**Product Name**
CopiOs® Pericardium Membrane

**Description**
CopiOs® Pericardium Membrane is a natural collagenous membrane for use in periodontal and/or dental surgical procedures. The membrane is preserved using the multi-step Tutoplast® Process which gently cleans and dehydrates the tissue. The membrane is terminally sterilized by gamma irradiation.

This product has been processed to meet high levels of quality and safety, and has passed quality inspection criteria.

**Mode of Action**
CopiOs® Pericardium Membrane functions as a barrier when applied between bone graft material and soft tissue. The membrane is a biological scaffold that is replaced by newly formed connective tissue.

**INDICATIONS FOR USE**

CopiOs® Pericardium Membrane is intended for use in oral surgical procedures as a resorbable material for:

- augmentation around implants placed in immediate extraction sockets;
- augmentation around implants placed in delayed extraction sockets;
- localized ridge augmentation for later implantation;
- alveolar ridge reconstruction for prosthetic treatment;
- filling of bone defects after root resection, cystectomy, removal of retained teeth;
- guided bone regeneration in dehiscence defects; and
- guided tissue regeneration procedures in periodontal defects.

CopiOs® Pericardium Membrane is provided sterile and is intended for single use only.

Do not re-sterilize or re-use.

**CONTRAINDICATIONS**
- Known hypersensitivity to bovine collagen.
- Active or latent infection at or around the wound site.
- Any disorder or disease that involves an unacceptable increase in the postoperative risk.

**PRECAUTIONS / INSTRUCTIONS**

**Note: Standard sterile technique must be followed for implantation of this membrane.**

Preoperative:

- Store the medical device within the temperature range printed on the outer label in a clean, dry place protected from sunlight.
- Screen patients prior to surgery to confirm they are not hypersensitive to bovine collagen.
- Do not use the membrane until proper storage, package integrity and expiration dating are verified.
- Unused portions of the membrane must be discarded. In order to ensure sterility, do not use on multiple patients or for more than one surgical procedure.
- Do not remove the membrane from the package until just prior to surgery.
- Do not re-sterilize the membrane.
- Improper storage, handling or preparation may damage the membrane and adversely affect its resorption characteristics and/or biomechanical integrity.

**IF THE PRODUCT, LABELING, OR PACKAGING ARE COMPROMISED IN ANY WAY, DO NOT USE THE MEMBRANE. NOTIFY THE DISTRIBUTOR LISTED ABOVE.**

Intraoperative:

- If the membrane is contaminated during the course of the surgical procedure, it must be discarded.
- Prior to rehydration, trim the membrane to fit the defect. It is recommended that the membrane overlap the walls of the defect by at least two millimeters. The free edges of the membrane should not protrude. Proper sizing and placement are essential to prevent gingival connective tissue invasion from below the membrane.
- After sizing, place in sterile 0.9% saline solution or the patient's blood until the membrane becomes soft and flexible.
- The membrane should be secured in place with sutures or other surgical devices to avoid displacement during healing. It is recommended that sutures be placed 2 to 3 mm from the edge of the implant where possible.
- To facilitate proper healing, close the mucoperiosteal flap using a tension-free technique and ensure the membrane is completely covered.

Post-Operative:

- Patients must be monitored closely and instructed to inform the physician of any adverse reactions.
- The clinician should inform the patient to refrain from any activity that could cause the membrane to detach.
- In the event of dehiscence, it may not be necessary to remove the membrane.
- The clinician may recommend the patient use a bacteriocidal mouth rinse until the wound is closed to reduce the risk of contamination.

**ADVERSE REACTIONS**

In very rare cases, local reaction can occur in patients without a history of hypersensitivity to bovine collagen. However, these reactions are typically transient. Immediately report all adverse reactions to the distributor listed above.

Definitions of label symbols

| | | |
|---|---|---|
|  Caution, see instructions for use |  Sterile by gamma irradiation |  Authorized Representative in the European Community |
|  Catalog number |  Lot number |  Serial number |
|  Storage temperature limits |  Do not reuse |  Manufacturer |
|  Use by |  For prescription use only | |

COPIOS® is a registered trademark of Zimmer, Inc.
Tutoplast® is a registered trademark of TUTOGEN MEDICAL GmbH.

TUTOGEN MEDICAL GmbH
(an RTI Biologics Inc. company)

Industriestraße 6, D-91077 Neunkirchen a. Br.
Tel.: 09134-9988-0
Fax 09134-9988-99
e-mail: info@tutogen.de