

INSTRUCTIONS FOR USE FOR:



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INSTRUCTIONS FOR USE

GORE BIO-A® Tissue Reinforcement

INTENDED USE

The GORE BIO-A® Tissue Reinforcement is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIO-A® Tissue Reinforcement may be used include, but are not limited to, hernia repair (in non-load bearing applications), muscle flap reinforcement, and general tissue reconstructions.

CONTRAINDICATIONS

NOT FOR RECONSTRUCTION OF CARDIOVASCULAR DEFECTS.

DESCRIPTION

As packaged, the GORE BIO-A® Tissue Reinforcement is a tailorable, bioabsorbable material intended to be a temporary bridge of defects until the bioabsorbable nature of the device allows the body to fill the defect with native tissue.

The implanted GORE BIO-A® Tissue Reinforcement is a porous fibrous structure composed solely of synthetic bioabsorbable poly(glycolide: trimethylene carbonate) copolymer. Degraded via a combination of hydrolytic and enzymatic pathways, the copolymer has been found to be both biocompatible and nonantigenic. *In vivo* studies indicate the bioabsorption process should be complete by the end of six months.¹

In repairs requiring high strength, a permanent overlay patch is strongly recommended.

The GORE BIO-A® Tissue Reinforcement is provided STERILE for single use only. The GORE BIO-A® Tissue Reinforcement has been sterilized by gamma radiation. Provided the package is stored at room temperature and is not compromised in any way, it will serve as an effective barrier until the "use by" (expiration) date printed on the box.

PRECAUTIONS

- The GORE BIO-A® Tissue Reinforcement is not designed to be a load-bearing prosthesis.
- Due to the bioabsorbable nature of the GORE BIO-A® Tissue Reinforcement, a permanent overlay patch is strongly recommended for those repairs which have a high strength requirement.
- Do not resterilize the GORE BIO-A® Tissue Reinforcement.
- The MINIPAX® desiccant pouch included in the device package is not for implantation.
- If the MINIPAX® desiccant pouch has been compromised, discard product.

ADVERSE REACTIONS

Possible adverse reactions may include, but are not limited to, infection, inflammation, adhesions and seroma formation.






INSTRUCTIONS

Using aseptic technique, trim the GORE BIO-A® Tissue Reinforcement to the desired size using sharp surgical scissors. In repairs requiring high strength (e.g., groin hernia repair), a permanent overlay patch is strongly recommended. The GORE BIO-A® Tissue Reinforcement may be suture-tacked to host tissue for stabilization.

The MINIPAX® desiccant pouch included in the device package is not for implantation. If the MINIPAX® desiccant pouch has been compromised, discard product.

REFERENCE



¹Katz AR, Mukherjee DP, Kaganov AL, Gordon S. A new synthetic monofilament absorbable suture made from poly(trimethylene carbonate). *Surgery, Gynecology & Obstetrics* 1985;161(3):213-222.


DEFINITIONS Use By Caution Consult Instructions for Use Do Not Re-Use REF Catalogue Number LOT Batch Code EC REP European Authorized Representative STERILE

Contents sterile unless package has been opened or damaged.

 STERILE R

Contents sterile unless enclosed package has been opened or damaged. Sterilized by irradiation.

 Configured For Hiatal Hernia Repair Do Not Resterilize

 Rx Only CAUTION: USA Federal Law restricts the sale, distribution, or use of this device to, by, or on the order of a physician.

 Store in a cool dry place



AN0290-ML2



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For international contact and additional product information,
visit **www.goremedical.com**



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