INSTRUCTIONS FOR USE FOR:

HERNIA PLUG

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INSTRUCTIONS FOR USE
GORE BIO-A HERNIA PLUG

INTENDED USE
The GORE BIO-A Hernia Plug is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE BIO-A Hernia Plug may be used include, but are not limited to, hernia repair (groin, abdominal and umbilical regions).

CONTRAINDICATIONS
NOT FOR RECONSTRUCTION OF CARDIOVASCULAR DEFECTS.

DESCRIPTION
As packaged, the GORE BIO-A Hernia Plug 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 device is comprised of a disk attached to multiple tubes.

The implanted GORE BIO-A Hernia Plug 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 vitro studies indicate that the GORE BIO-A Hernia Plug can be expected to retain measurable mechanical strength through four to five weeks.

In vivo studies indicate the bioabsorption process should be complete by the end of six months.[1]

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

The GORE BIO-A Hernia Plug is provided STERILE for single use only. The GORE BIO-A Hernia Plug 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.

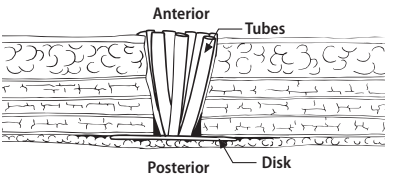
PRECAUTIONS
- Due to the bioabsorbable nature of the GORE BIO-A Hernia Plug, an overlay patch is strongly recommended for those repairs which have a high strength requirement.
- Do not resterilize the GORE BIO-A Hernia Plug.
- Use of multiple GORE BIO-A Hernia Plugs in a single repair has not been reported.
- 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

For all uses, the GORE BIO-A Hernia Plug can be tailored with sharp surgical scissors to fit the specific defect size. In repairs requiring high strength (e.g., groin hernia repair), an overlay patch is strongly recommended.

In instances where the defect passes through a major tissue plane, the preformed GORE BIO-A Hernia Plug is inserted, disk first, into the defect.



The disk will temporarily collapse during passage through the tissue. Once the disk has entered a space (e.g., the preperitoneal space in inguinal hernia repair), the disk will expand to its original diameter. (NOTE: In instances where a space does not exist, finger dissection may be required, or the device can be trimmed to fit the void space). Once the disk has fully expanded, withdraw the device slightly to obtain purchase of the disk on the posterior wall of the defect. The tubes of the device can then be suture-tacked to the sides of the defect for stabilization.

REFERENCE

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

DEFINITIONS

Use By

Attention, See 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.

Disk

Do Not Resterilize

QTY Quantity

℞ 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

Tubes

AM0194-ML1

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APRIL 2009