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INSTRUCTIONS FOR USE

GORE BIO-A Fistula Plug

INTENDED USE

The GORE BIO-A Fistula Plug is intended for use in the reinforcement of soft tissue in the repair of anorectal fistulas.

CONTRAINDICATIONS

NOT FOR RECONSTRUCTION OF CARDIOVASCULAR DEFECTS.

DESCRIPTION

As packaged, the GORE BIO-A Fistula Plug is a tailorable, bioabsorbable device intended to occupy the fistula tract (i.e., defect) until the bioabsorbable nature of the material allows the body to fill the defect with native tissue. The device is comprised of a disk attached to multiple tubes.

The GORE BIO-A Fistula 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 vivo* studies with this copolymer indicate the bioabsorption process should be complete by the end of six months.¹

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

- Do not resterilize the GORE BIO-A Fistula Plug.
- If the removal of tubes from the device is desired during tailoring, care should be taken to leave behind as little material at the disk as possible. Additionally the tubes toward the interior of the disk should be removed first to facilitate proper seating of the device at the internal (primary) opening.
- When placing the suture at the distal ends of the tubes for device placement, care should be taken to avoid excessive fold-over of the tubes during deployment. The suture should be thrown approximately 3 mm from the distal ends of the tubes.
- The MINIPAX® desiccant pouch included in the device package is not for implantation.
- If the MINIPAX® desiccant pouch has been compromised or damaged, discard the product.

ADVERSE REACTIONS

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

INSTRUCTIONS

For all uses, the GORE BIO-A Fistula Plug can be tailored with sharp, sterile surgical scissors to fit the specific defect size.

PREPARATION

- Prepare the patient and surgical site using standard techniques appropriate for anal fistula repair.
- Remove the device from its sterile packaging using aseptic technique.
- Using sharp sterile scissors, trim the disk diameter to a size appropriate for the defect allowing for adequate fixation of the disk to the rectal mucosa. Care should be taken to avoid the creation of sharp edges or corners when trimming the disk.
- Individual tubes can be removed from the device to accommodate the diameter of the fistula tract. When removing tubes, begin with the center-most tubes, carefully cutting the tube as close to the disk as possible (proximally adjacent) without compromising tube attachment.
- To facilitate introduction and deployment of the device in the fistula tract, it is recommended that a suture be used to gather the tubes and pull the device through the fistula tract. To do so, run a suture through the distal ends of the tubes. A bite depth of approximately 3 mm is recommended to ensure adequate suture retention strength (Figure 1).

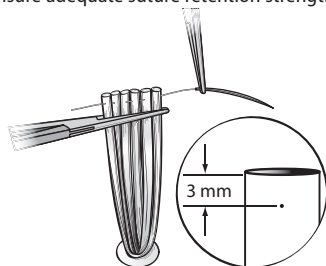


FIGURE 1

Note: The use of a resorbable suture is recommended to minimize the potential that any permanent material is implanted.

- The GORE BIO-A Fistula Plug does not need to be hydrated prior to use. However, to facilitate passage of the tubes through the fistula tract, briefly immerse the entire device in sterile saline.

DEVICE PLACEMENT

- Use standard techniques to define, clean and prepare the fistula tract. If necessary, the tract may be defined with a curette to remove any granulation tissue.
- Insert a fistula probe or other suitable instrument through the fistula tract, entering through the external (secondary) opening and exiting via the internal (primary) opening.
- Grasp the suture attached to the distal end of the GORE BIO-A Fistula Plug.
- Gently draw the suture into the internal (primary) opening of the fistula tract. Continue to draw the suture through the fistula tract.
- Once the suture is visible at the external (secondary) opening, slowly draw the GORE BIO-A Fistula Plug into the defect until slight resistance is felt and the device disk is securely seated at the internal (primary) opening (Figures 2a, 2b, 2c).

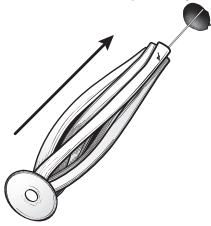


FIGURE 2a

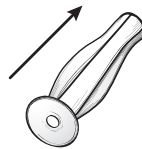


FIGURE 2b



FIGURE 2c

Note: Take care to ensure that disk lies flat and is well apposed to the rectal mucosa at the internal (primary) opening of the fistula tract.

- After the device is properly positioned in the fistula tract, one of the following fixation methods should be used to secure the disk at the internal (primary) opening.

Fixation Method I

- Using a suitable resorbable suture, secure the disk of the GORE BIO-A Fistula Plug to the adjacent tissue, obtaining adequate bites of rectal wall to prevent device migration and minimize the potential for leakage of bowel contents into the fistula tract (Figure 3).

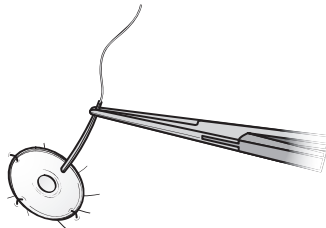


FIGURE 3

Fixation Method II

- Using a suitable resorbable suture, close the rectal mucosa over the disk portion of the device to prevent device migration and minimize the potential for leakage of bowel contents into the fistula tract (Figure 4).



FIGURE 4

- Note:** If the internal (primary) opening is dimpled or recessed, consider limited mobilization of the mucosa prior to suture placement to ensure adequate closure.
- After the GORE BIO-A Fistula Plug is properly positioned within the fistula tract and the disk is secured at the internal (primary) opening, carefully trim any excess tubes that protrude beyond the perianal skin at the external (secondary) opening (Figure 5).

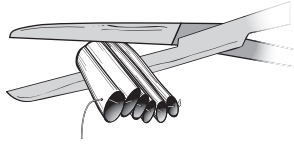


FIGURE 5


- Note:** To allow for natural drainage of the fistula tract in the post-operative period, the external (secondary) opening of the fistula tract should not be closed completely.
- To complete the procedure, place a sterile dressing over the implant site.


REFERENCE

¹Katz 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

 Catalogue Number

 Batch Code


 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.

 Do Not Resterilize

 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



AM0175-ML2



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JUNE 2009