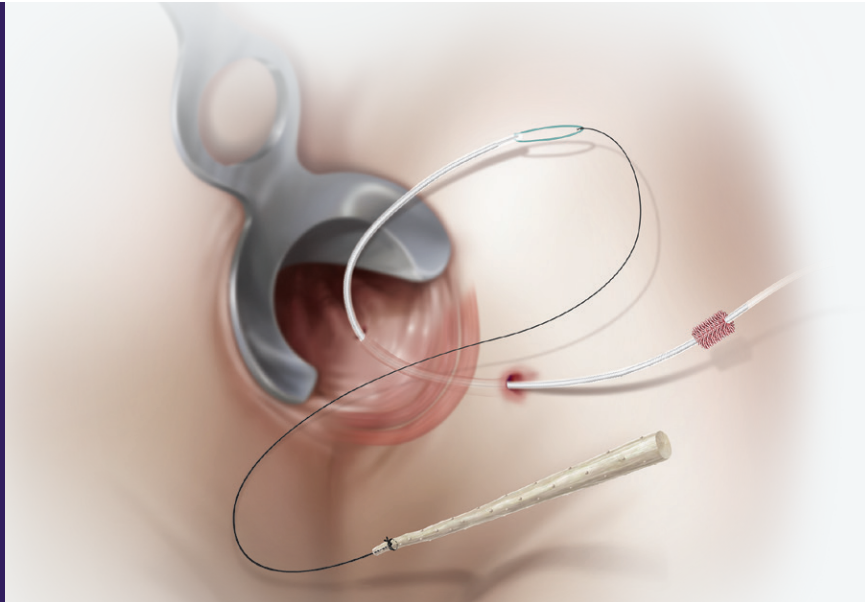


The Biodesign Anal Fistula Plug is for implantation to reinforce soft tissue where a rolled configuration is required for repair of anorectal fistulas.



- 1 If there are any signs of sepsis or infection is present, allow the tract to mature and stabilize for 6–8 weeks before placing the plug. After inspecting the seton and fistula, irrigate the tract with hydrogen peroxide or a similar fluid. Cut the seton and attach a suture to the cut end.

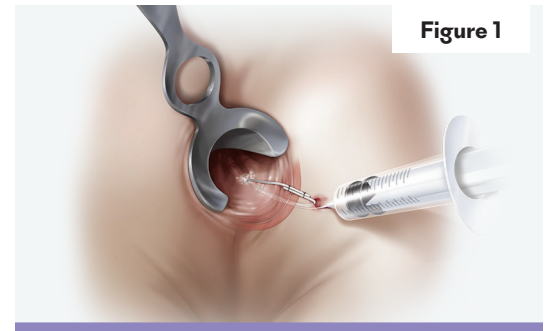


Figure 1

- 2 Tie the suture to the fistula brush. Pull the brush into the fistula tract. Using a back-and-forth motion, clean and remove nonvascular tissue. A small amount of blood at the tract opening and on the brush's bristles indicates adequate debridement. Avoid mechanically debriding the fistula tract in a way that could widen the tract and make it harder to close.

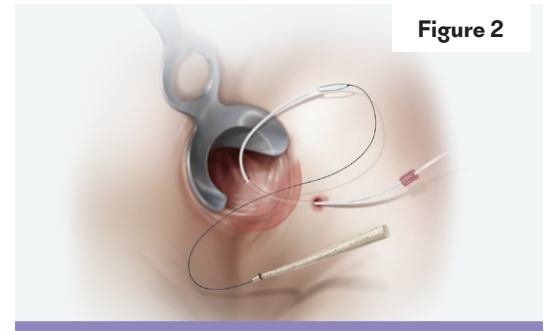


Figure 2

- 3 Hydrate the plug in sterile saline or lactated Ringer's solution for no more than 2 minutes. Tie the plug onto the suture. Use hydrogen peroxide or a similar fluid to irrigate the tract again and flush out loose debris.

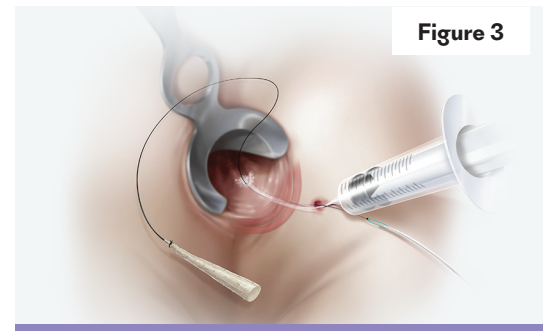


Figure 3

4 Using a suitable resorbable suture, secure the internal end of the plug to the adjacent tissue, obtaining adequate bites of sphincter muscle. Some options for affixation include:

a. Blind-pass technique: Pull the plug, narrow end first, into the fistula tract until there is slight resistance. Affix the plug using 2-0 long-term absorbable suture on a UR-6 or comparable needle. Adjacent to the internal opening, pass a stitch deep into the sphincter muscles and directly through the center of the plug, exiting on the opposite side. Gently pull the plug partially out of the internal opening to verify that the stitch went directly through the plug. Pull the plug back to its original position. Remove any slack from the sutures in the fistula tract.

b. Direct-visualization technique: Place the plug as described for the blind-pass technique. Pull the plug partially out of the internal opening. Adjacent to the internal opening, pass a stitch deep into the sphincter muscles, exiting through the internal opening without piercing the plug. Continue the stitch by passing the needle directly through the center of the plug. Enter the internal opening and pass the stitch deep into the sphincter muscles, exiting on the opposite side.

5 Repeat the previous step, depending on which technique was used, and make a stitch perpendicular to the first stitch.

Tie off the sutures over the top of the plug, effectively pulling the mucosal layer over the top of the plug. No part of the plug should be visible at the internal opening. Trim any external portion of the plug flush with the skin. Slightly enlarge the external opening to facilitate drainage. Drainage is expected for a minimum of 2 weeks and can continue up to 12 weeks. Provide the patient with the postoperative patient guide as their compliance with the guide directly affects procedural success. **See the IFU for additional details.**

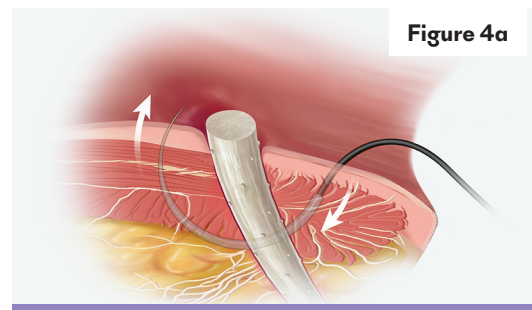


Figure 4a

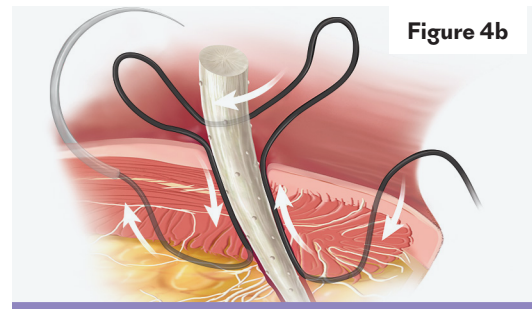


Figure 4b

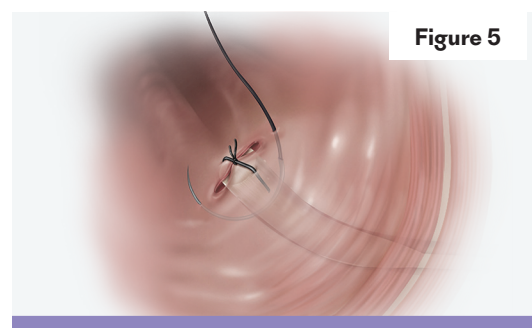


Figure 5

RISK INFORMATION: BIODESIGN ANAL FISTULA PLUG

INTENDED USE

The Biodesign® Anal Fistula Plug is for implantation to reinforce soft tissue where a rolled configuration is required, for repair of anorectal fistulas. The plug is supplied sterile and is intended for one-time use.

This product is intended for use by trained medical professionals.

CONTRAINDICATIONS

• The plug is derived from a porcine source and should not be used in patients sensitive to porcine materials. • **Not for vascular use.**

PRECAUTIONS

• The plug is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease. • **Do not resterilize.** • Do not implant the plug in a grossly infected or abscessed fistula tract. • **Asepsis should**

be used until there is no evidence of acute inflammation, purulence, or excessive drainage. Allow the tract to mature and stabilize for six to eight weeks before placing the plug.

• Ensure that the plug is hydrated prior to placement, cutting, or suturing. • Expect some drainage for two to four weeks. Drainage can continue for up to 12 weeks after the procedure as the plug is incorporated and the fistula tract closes.

POTENTIAL COMPLICATIONS

Complications that can occur with the plug include: • Abscess • Allergic reaction • Bleeding • Delayed or failed incorporation • Extrusion • Fistula recurrence • Induration • Infection • Inflammation • Migration • Redness • Sepsis • Swelling

ERI_FP0037-03N

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