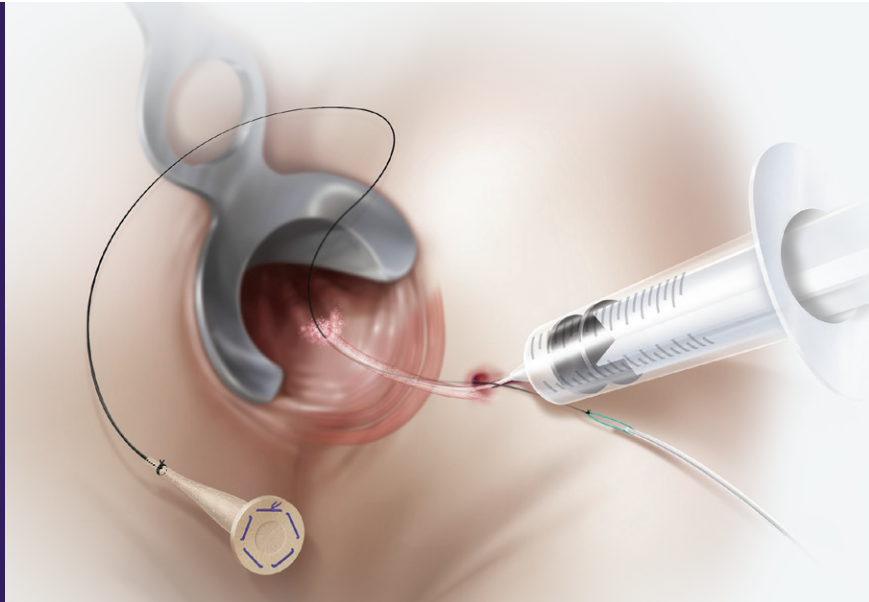


The Biodesign Fistula Plug is for implantation to reinforce soft tissue for repair of recto-vaginal or anorectal fistulas.



- 1 If there are any signs of sepsis or infection, allow the tract to mature and stabilize for 6–8 weeks before placing the plug. Crohn's patients should be in a state of remission. 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.

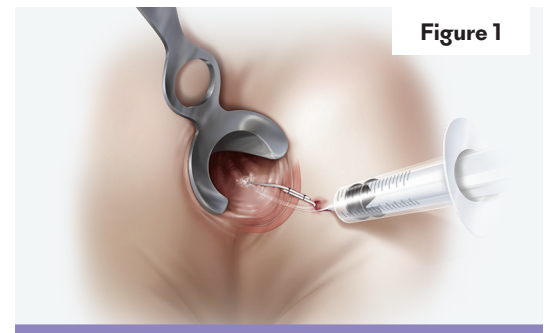


Figure 1

- 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.

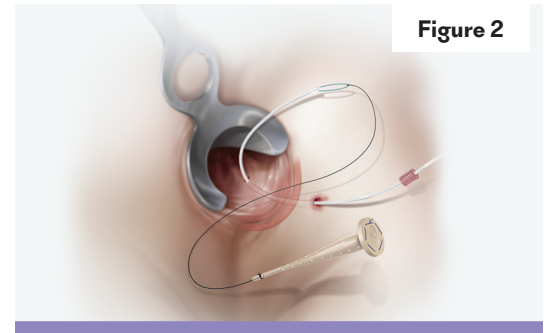


Figure 2

- 3 Hydrate the plug in sterile saline or lactated Ringer's solution for no more than 2 minutes. The longer the hydration time, the more pliable the plug will be and the harder it will be to suture in place. Tie the plug onto the suture. Use hydrogen peroxide or a similar fluid to irrigate the tract again and flush out loose debris.

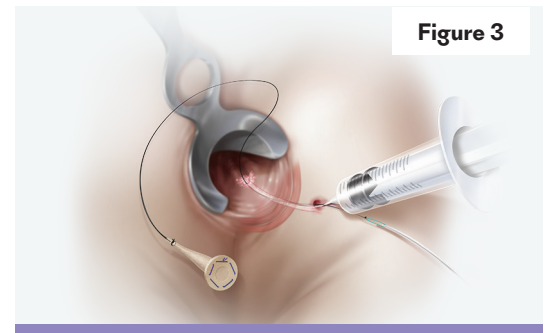


Figure 3

4a Superficial placement: Pull the plug, narrow end first, into the fistula tract until the button is flush against the mucosa. Affix the plug using a suitable resorbable suture on a UR-6 or comparable needle. Place a minimum of 4 sutures through the center of the plug and deep into the sphincter muscles.

4b Submucosal placement: Create small mucosal flaps or undermine the mucosa circumferentially to create a small pocket that can accommodate the button portion of the plug. Place the plug as described in step 4a; the button portion should be flush with the internal sphincter. Reapproximate the mucosal edges to completely cover the button.

5 Trim any external portion of the plug flush with the skin. Slightly enlarge, but do not close, 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.**

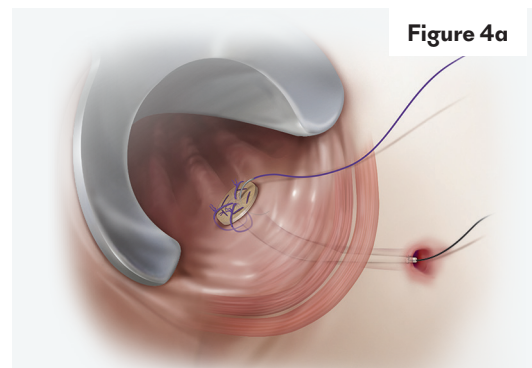


Figure 4a

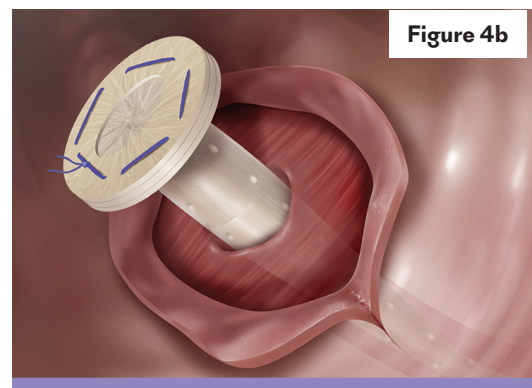


Figure 4b

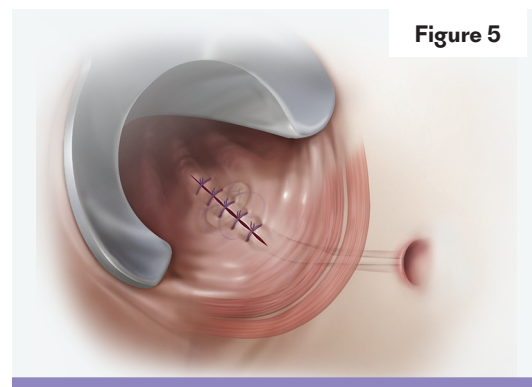


Figure 5

RISK INFORMATION: BIODESIGN FISTULA PLUG

INTENDED USE

The Biodesign® Fistula Plug is for implantation to reinforce soft tissue for repair of recto-vaginal or anorectal fistulas. The plug is supplied sterile and is intended for one time use.

This product is intended for use by medical professionals trained in the repair of recto-vaginal and anorectal fistulas.

CONTRAINDICATIONS

• This device is derived from a porcine source and should not be used for 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. • **A seton should be used until there is no evidence of acute inflammation, purulence, or excessive drainage. Allow the tract to stabilize and mature for at least six to eight weeks before placing the plug.** • Ensure that the plug is hydrated prior to placement, cutting, or suturing. • Placement of the plug in fistula tracts less than 1 cm in length can result in incomplete incorporation and/or expulsion.

POTENTIAL COMPLICATIONS

Complications that can occur with the Fistula Plug include, but are not limited to: • Abscess • Allergic reaction • Delayed or failed incorporation of the device • Erosion • Extrusion • Fistula recurrence • Incontinence to stool or flatus • Induration • Infection • Inflammation • Migration • Seroma formation

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Biodesign grafts are manufactured by Cook Biotech Incorporated.

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