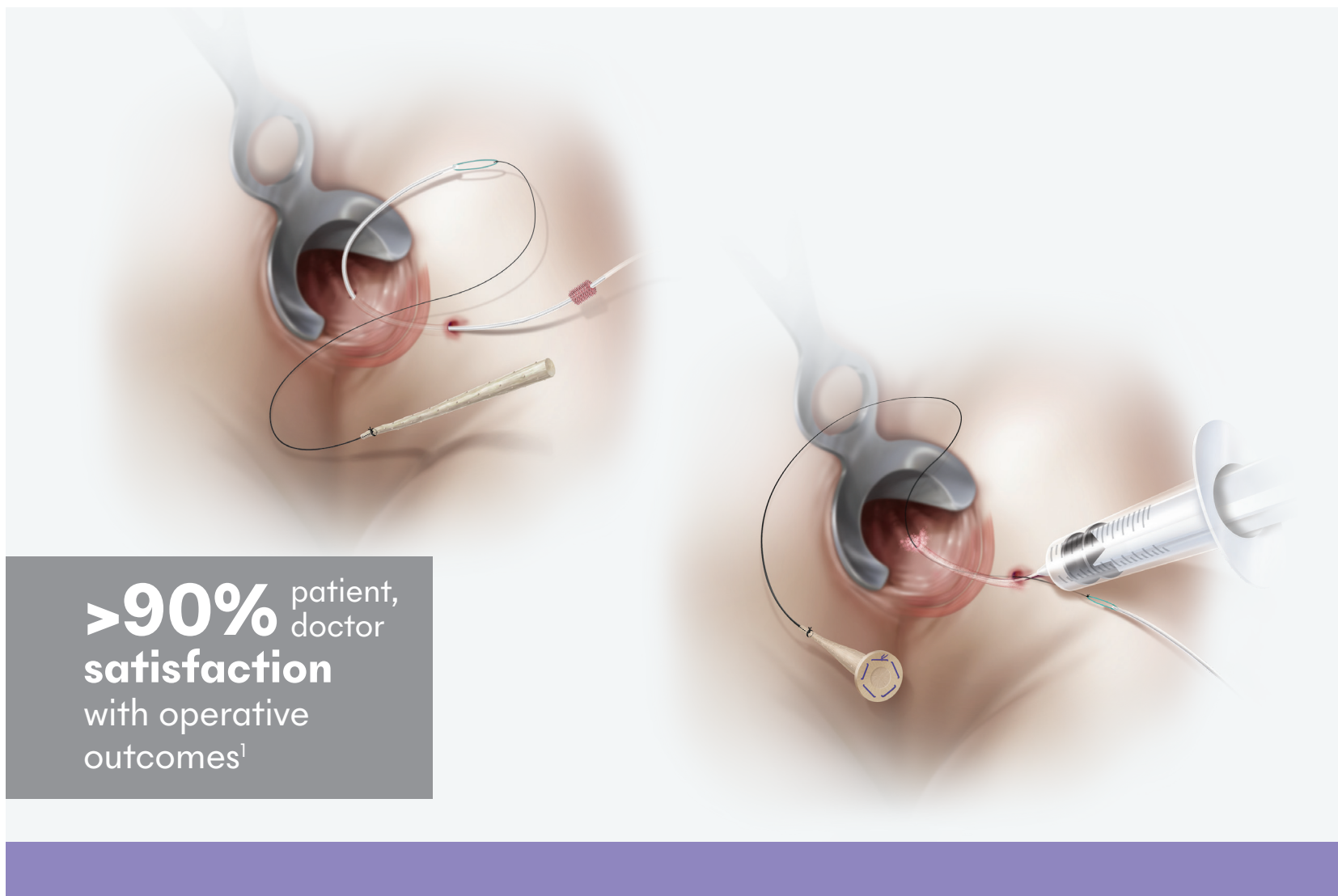


Biodesign® Colorectal Portfolio

Incontinence shouldn't be inevitable



Biodesign Fistula Plugs minimize the risk of postoperative incontinence and provide biologic, minimally invasive options for sphincter-sparing fistula repair.²

Evergen™



Graft information

Biodesign Anal Fistula Plug Set

For implantation to reinforce soft tissue where a rolled configuration is required, for repair of anorectal fistulas

Order number	Reference part number	Size
G53614	C-AFPS-0.6X9.5	0.6 x 9.5cm

Graft features

- Manufactured in the U.S.
- Biologic xenograft made from porcine SIS
- Non-crosslinked, non-dermis
- Easily hydrated in the operating room
- No special orientation or sidedness
- Off-the-shelf graft that does not require special storage
- Does not require AATB tissue tracking
- MRI safe

Each plug set includes:

- Biodesign Anal Fistula Plug
- Fistula brush
- Irrigation catheter
- 2-0 polyglycolic acid (PGA) absorbable suture with DUR-6 needle
- 0 silk nonabsorbable suture
- 10 ml Luer-lock syringe



Graft information

Biodesign Fistula Plug

For implantation to reinforce soft tissue for repair of recto-vaginal or anorectal fistulas

Order number	Reference part number	Size
G54612	C-FPS-0.2	0.2cm
G54613	C-FPS-0.4	0.4cm
G54614	C-FPS-0.7	0.7cm

Each plug set includes:

- Biodesign Fistula Plug
- Fistula brush
- Irrigation catheter
- 2-0 polyglycolic acid (PGA) absorbable suture with DUR-6 needle
- 0 silk nonabsorbable suture
- 10 ml Luer-lock syringe

Graft features

- Manufactured in the U.S.
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- MRI safe

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. • **A**

seton 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

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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

ERI_FP0073-01I

REFERENCES

1. Chen ZW, Zheng Y, Zhao R, Wang ZJ. Treatment of anal fistula using a decellularized porcine small intestinal submucosa plug: A non-inferiority trial. *Medicine*. 2022;101(29):e29110.
2. van Koperen PJ, Bemelman WA, Gerhards MF, et al. The anal fistula plug treatment compared with the mucosal advancement flap for cryptoglandular high transsphincteric perianal fistula: a double-blinded multicenter randomized trial. *Dis Colon Rectum*. 2011;54(4):387-393.
Note: The name of the product has changed since this trial was published.

Biodesign grafts are manufactured by Cook Biotech Incorporated.

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