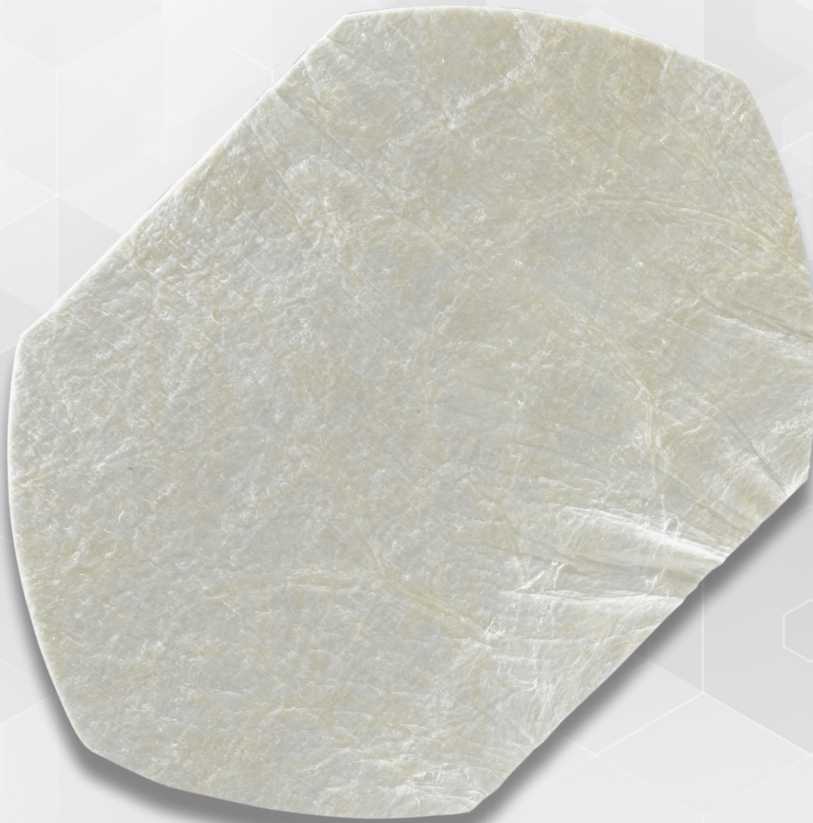


Providing a solution for penile curvature¹⁻⁵



Biodesign[®]
PEYRONIE'S REPAIR GRAFT



BIODESIGN® PEYRONIE'S REPAIR GRAFT

Repair penile curvature without donor site surgery.

The Biodesign Peyronie's Repair Graft is intended for implantation to reinforce soft tissue where weakness exists in the urological anatomy, including but not limited to repair of tunica albuginea defects and reinforcement in the repair of Peyronie's disease.

The graft is sourced from porcine small intestinal submucosa (SIS), a naturally occurring biomaterial that remodels into new patient tissue, providing a pliable, long-lasting repair.⁶

Studies have shown preservation of erectile function in addition to long-term penile straightening with the Biodesign Peyronie's Repair Graft.¹⁻⁵

Penile-curvature repair procedures performed with the Biodesign graft do not require additional surgery to obtain donor tissue.^{4,7}

| Order Number | Reference Part Number | Size cm |
|--------------|-----------------------|---------|
| G47654 | SLH-4-PR1 | 4 x 10 |
| G47655 | SLH-4-PR2 | 7 x 10 |

Some products or part numbers may not be available in all markets.

¹ Rosenhammer B, Sayedahmed K, Fritsche HM, Burger M, Kubler H, Hatzichristodoulou G. Long-term outcome after grafting with small intestinal submucosa and collagen fleece in patients with Peyronie's disease: a matched pair analysis. *Int J Impot Res.* 2019;31:256-262.

² Morgado A, Morgado MR, Tomada N. Penile lengthening with porcine small intestinal submucosa grafting in Peyronie's disease treatment: long-term surgical outcomes, patients' satisfaction and dissatisfaction predictors. *Andrology.* 2018;6:909-915.

³ Kovac JR, Brock GB. Surgical outcomes and patient satisfaction after dermal, pericardial, and small intestinal submucosal grafting for Peyronie's disease. *J Sex Med.* 2007;4:1500-1508.

⁴ Lee EW, Shindel AW, Brandes SB. Small intestinal submucosa for patch grafting after plaque incision in the treatment of Peyronie's disease. *Int Braz J Urol.* 2008;34:191-197.

⁵ Lue K, Emtage JB, Martinez DR, Yang C, Carrion R. Excision and patch grafting of a lateral Peyronie's plaque - utilizing a longitudinal "window" approach. *Sex Med.* 2015;3:86-89.

⁶ Franklin ME Jr, Trevino JM, Portillo G, Vela I, Glass JL, Gonzalez JJ. The use of porcine small intestinal submucosa as a prosthetic material for laparoscopic hernia repair in infected and potentially contaminated fields: long-term follow-up. *Surg Endosc.* 2008;22:1941-1946.

⁷ Valente P, Gomes C, Tomada N. Small intestinal submucosa grafting for Peyronie disease: outcomes and patient satisfaction. *Urology.* 2017; 100:117-124.

BIODESIGN® PEYRONIE'S REPAIR GRAFT

INTENDED USE

The Cook® Biodesign® Peyronie's Repair Graft is intended for implantation to reinforce soft tissue where weakness exists in the urological anatomy, including but not limited to repair of tunica albuginea defects and reinforcement in the repair of Peyronie's disease. The graft is intended for one-time use.

Rx ONLY This symbol means the following:

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

PEYRONIE'S REPAIR GRAFT This symbol means the following: Peyronie's Repair Graft

This product is intended for use by trained medical professionals.

CONTRAINDICATIONS: This graft is derived from a porcine source and should not be used for patients with known sensitivity to porcine materials.

PRECAUTIONS: • This device 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.** Discard all open and unused portions. • Graft is sterile if

the package is dry, unopened and undamaged. Do not use if the package seal is broken. • Discard graft if mishandling has caused possible damage or contamination, or if the device is past its expiration date. • Ensure that the graft is rehydrated prior to suturing. • Graft performance has not been evaluated with suture spacing greater than 2 mm. • Ensure that all layers of the graft are secured when suturing.

POTENTIAL COMPLICATIONS: The following complications are possible when surgical graft materials are used in the penis. If any of these conditions occur and cannot be managed medically, careful graft removal should be considered: • infection • Acute or chronic inflammation (Initial application of surgical graft materials may be associated with transient, mild, localized inflammation) • Allergic reaction

NOTE: Graft failure resulting in a lack of soft tissue reinforcement may lead to reoccurrence of the Peyronie's plaque. If this occurs, additional surgical intervention to remove the plaque may be necessary.

NOTE: *De novo* post-operative erectile dysfunction is a known complication associated with reconstructive procedures in the penis. If post-operative erectile dysfunction occurs, graft removal may exacerbate erectile changes. Therefore, graft removal is not recommended. Alternative medical and surgical treatments should be considered.

See package insert for full product information.

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