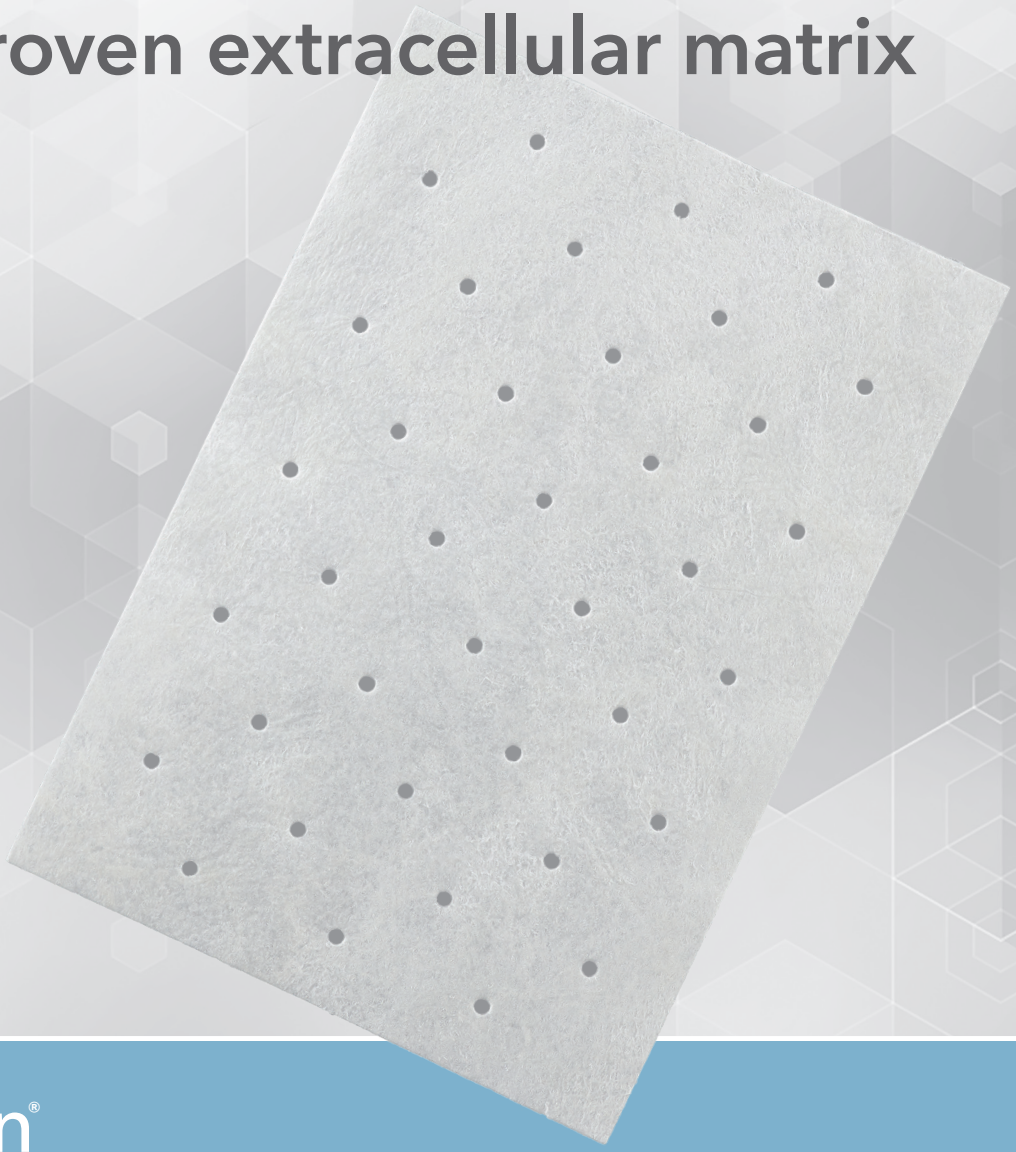
PLASTIC AND RECONSTRUCTIVE SURGERY

Remodeling patient tissue with a proven extracellular matrix



Biodesign®
PLASTIC SURGERY MATRIX

COOK® BIOTECH

cookbiotech.com

Studied and proven

Biodesign Plastic Surgery Matrix can be used across a range of reconstructive procedures. It is sourced from porcine small intestinal submucosa (SIS), a naturally occurring biomaterial. SIS remodels into new patient tissue, providing a pliable, long-lasting repair. The technology behind Biodesign tissue-repair products is supported by more than:

1500
Published articles

500
Clinical publications

10
Articles with > 5 years follow-up

Biodesign Plastic Surgery Matrix is indicated for implantation to reinforce soft tissue where weakness exists in patients requiring soft-tissue repair or reinforcement in plastic and reconstructive surgery.

Ready-to-use sizes

Tension-free placement[1]

Minimal rehydration time[2]

Order Number	Reference Part Number	Size (cm)
G52867	C-SLH-6H-4X7	4 x 7
G52865	C-SLH-6H-7X10	7 x 10
G52866	C-SLH-6H-7X20	7 x 20

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

[1] Glasberg SB, D'Amico RA. Use of regenerative human acellular tissue (AlloDerm) to reconstruct the abdominal wall following pedicle TRAM flap breast reconstruction surgery. *Plast Reconstr Surg.* 2006;118:8-15.
[2] Cook Biotech Inc. internal report #07-033.

BIODESIGN® PLASTIC SURGERY MATRIX

INTENDED USE: The Biodesign® Plastic Surgery Matrix is for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. The matrix is supplied sterile and 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.** PLASTIC SURGERY MATRIX This symbol means the following: Plastic Surgery Matrix. This product is intended for use by trained medical professionals.

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

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. • Matrix is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken. • Discard matrix if mishandling has caused possible damage or contamination, or if the matrix is past its expiration date. • Ensure that the matrix is rehydrated prior to cutting or suturing. • Matrix performance has not been evaluated with suture spacing greater than 2mm. • Ensure that all layers of the matrix are secured when suturing. • Suturing more than one matrix together may decrease matrix performance. • No studies have been done to evaluate the reproductive impact with the clinical use of the matrix. • The matrix may not have sufficient strength to support stresses encountered in some ventral hernias or large-area, body-wall repairs. • Patients undergoing radiation therapy may not experience normal wound healing. • No studies have been done to examine the effect of concomitant radiation with matrix placement. • Failure to securely suture the matrix to healthy, well-vascularized tissue may result in lack of incorporation of matrix. **NOTE: When implanting the matrix in patients with thin skin, transient, post-operative redness may be seen.**

POTENTIAL COMPLICATIONS: The following complications are possible with the use of surgical graft materials. If any of these complications occur and cannot be resolved, consider the removal of the matrix: • Infection • Acute or chronic inflammation (Initial application of surgical graft materials may be associated with transient, mild, localized inflammation.) • Allergic reaction • Seroma formation

See package insert for full product information.

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