

– FACT SHEET –

HEMIGARD® Adhesive Retention Suture Device

Product Name: HEMIGARD® Adhesive Retention Suture Device

Manufacturer: SUTUREGARD® Medical, Inc.

Purpose: Optimizes suture by enabling injury-free wound closures under tension

Catalog/SKU #: HRD001

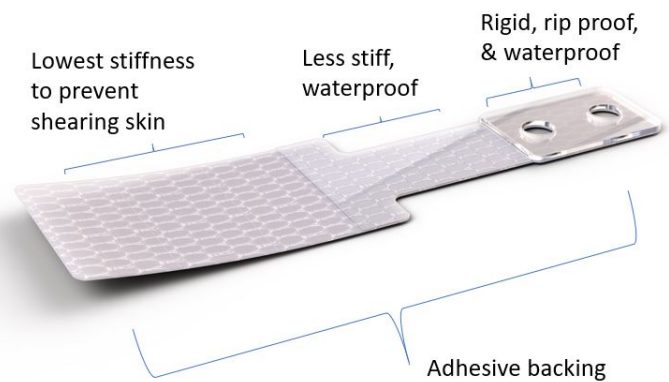
Price: \$300/box of 12-paired devices

FDA Registration: 3015045268 (Class I)

Insurance: Kinsale Insurance Company, Policy #: 0100059727-2

Manufacturing Information: The bottom layer of the HEMIGARD device has adhesive to stick to the skin. The rigid hemi-bridge layer with holes withstands high tension suturing. The top layer is transparent, rigid film to displace the wound tension away from the wound edges.

All components pass biocompatibility FDA/GMP adhesive requirements.



Clinical Case Example:



Arm melanoma excision in very thin, fragile skin. Single HEMIGARD® and 0 nylon retention suture. Layered closure with 4-0 Polysorb and adhesives strips. Limited undermining.

Publications:

[Roybal, L., Blattner, C., Young, J. & Lear, W. \(2020\). A novel adhesive suture retention device for the closure of fragile skin under tension. JAAD Case Reports.](#)

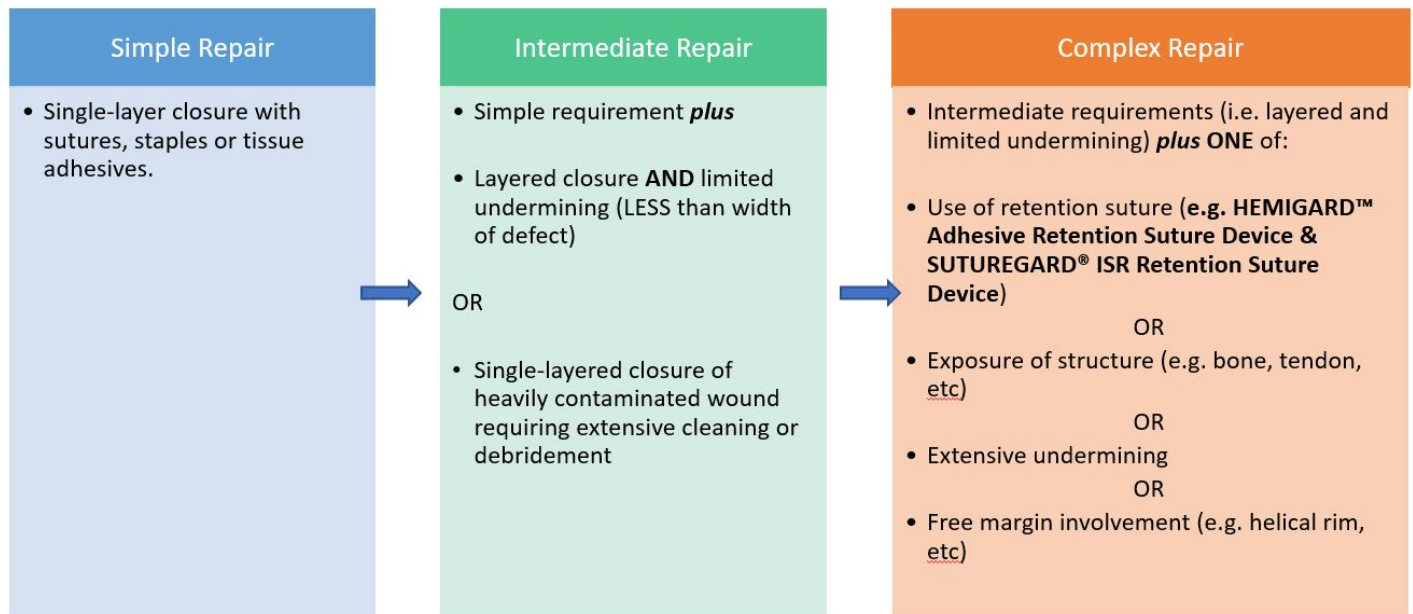
[Lear, W., Roybal, L.I., & Kruzic, J.J. \(2020\). Forces on sutures when closing excisional wounds using the rules of halves. Clinical Biomechanics, 72, 161-163.](#)

Improved Patient Satisfaction: Surgeons can close wounds *simply* that would otherwise tear under the force of sutures. This allows for linear closure in many wounds that would otherwise require more complex care (grafts, flaps or chronic wound care for second intent). Patients report high satisfaction in avoiding these procedures and with the appearance of the final scar.

Reduced Cost of Care: Grafts and flaps are time-intensive, high-risk procedures that create additional wounds. Second intent healing requires ongoing wound care.

Reimbursement:

Reimbursement: Simple vs Intermediate vs Complex Repair Requirements



Common Hospital Committee Questions

Product Name: HEMIGARD® Adhesive Retention Suture Device

Manufacturer: SUTUREGARD® Medical, Inc.

Purpose: Optimizes suture by enabling injury-free wound closures under tension

Catalog/SKU #: HRD001

Price: \$300/box of 12-paired devices

FDA Registration: 3015045268 (Class I)

Impacted products: Requires using USP 2-0 or stronger suture

Which (if any) products will the new product replace and/or reduce usage of?

- Replace: Ethicon Suture Retention Bridge (no longer manufactured)
- Reduce Usage of: Absorbable suture

Which (if any) procedures will the new product replace and/or reduce usage of?

- Replace: Flaps, grafts, second-intent healing (in many cases)
- Reduce Usage of: surgical undermining, negative pressure wound therapy (NPWT), biologic wound dressings (Dermagraft, EpiFix, etc), wound care follow up

Impacted providers/Services:

- Anesthesia: more closures under local anesthesia, office setting, less general anesthetics needed
- Multi-specialty surgeons: allow more simple wound closures, faster closures, reduce risk/complications
- Nurses: simpler aftercare, less wound care required, fewer follow up visits

Will other services or providers be affected? If yes, are they aware of the request? See above

Will others be using the requested product? Yes, the HEMIGARD ARS device is for skin-level wound closure. Specialties that have used the HEMIGARD ARS device include podiatry, emergency medicine, orthopedics, general surgery, plastic surgery, dermatology, and Mohs surgery.

Annual utilization estimates of the new product This depends on surgeon volume. Surgeons closing wounds that are under tension will find that using the HEMIGARD ARS device speeds up their closures and improves wound closure outcomes post-operatively.

Procedures in which the product will be used:

- Excisional wound closures
- Lacerations
- Wounds being closed under tension
- Patients at high-risk for wound dehiscence

Are these procedures predominantly inpatient or outpatient? Depends on specialty.

Online purchasing option:

www.suturegard.store

POs submitted to:

jen@suturegard.com

Contact Information:

SUTUREGARD Medical, Inc.
2397 NW Kings Blvd, Suite 235

Corvallis, OR, 97330

1-844-585-8421

www.suturegard.com