HEMIGARD®
Adhesive Retention Suture Device

Close More Wounds, Faster, Better, Simpler

Clinical Indications
› Fragile skin
› Wound under tension
› Excisional defect
› Skin needing post-operative support
› Wound at-risk of dehiscence

Benefits*
› Reduce wound dehiscence
› Prevent skin tearing
› 12X stronger than dermal sutures
› 4X stronger than retention sutures
› Increase perfusion by 25%
› Reduce undermining
› Reduce dermal sutures
› Faster closures
› Support for 2 weeks
› Eliminate suture ingrowth
› Reduce flaps, grafts, second intent
› Reimbursement CPT 131XX

*See publications on website

SUTUREGARD Medical, Inc
www.sutureGARD.com
info@suturegard.com
1-844-585-8421
2397 NW Kings Blvd
Suite 235
Corvallis, Oregon 97330

BUY NOW ONLINE
www.sutureGARD.store
1. ADHERE
   1 cm from wound edge on clean, dry skin

2. SUTURE
   2-0 nylon through holes and full thickness skin

3. CLOSE
   Adjust suture tension and knot

4. FINISH
   Finish closure with sutures, staples or glue

Multi-Specialty Use

Amputation

Foot & Ankle Surgery

Trauma/ER

Surgical Oncology
Estimate

ADDRESS
Hospital

ESTIMATE # 1011
DATE 09/25/2020
EXPIRATION DATE 09/30/2021

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTIVITY</th>
<th>DESCRIPTION</th>
<th>QTY</th>
<th>RATE</th>
<th>AMOUNT</th>
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<tbody>
<tr>
<td>HRD001</td>
<td></td>
<td>HEMIGARD Adhesive Retention Suture device - 1 box of 12 sterilized pouches. Each pouch contains 2 halves of 1 HEMIGARD device, one for each side of the wound.</td>
<td>1</td>
<td>300.00</td>
<td>300.00</td>
</tr>
</tbody>
</table>

| SUBTOTAL   | 300.00 |
| TAX        | 0.00   |
| TOTAL      | $300.00|

Accepted By

Accepted Date
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:


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

**Simple Repair**
- Single-layer closure with sutures, staples or tissue adhesives.

**Intermediate Repair**
- Simple requirement **plus**
  - Layered closure AND limited undermining (LESS than width of defect)
  - OR
  - Single-layered closure of heavily contaminated wound requiring extensive cleaning or debridement

**Complex Repair**
- Intermediate requirements (i.e. layered and limited undermining) **plus ONE** of:
  - Use of retention suture (e.g. HEMIGARD™ Adhesive Retention Suture Device & SUTUREGARD® ISR Retention Suture Device)
  - OR
  - Exposure of structure (e.g. bone, tendon, etc.)
  - OR
  - Extensive undermining
  - OR
  - Free margin involvement (e.g. helical rim, etc.)
Common Hospital Committee Questions

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

Which (if any) products will the new product replace and/or reduce usage of? None

Which (if any) procedures will the new product replace and/or reduce usage of? In some cases, using the HEMIGARD® ARS device will replace second-intent healing. Fewer deep (absorbable) sutures are required. Less wound undermining is required.

Impacted providers/Services: Reduction in general anesthesia (fewer flaps and grafts) and for wound care (reduction in second intent and flaps/grafts)

Will other services or providers be affected? If yes, are they aware of the request? No

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.

Are these procedures predominantly inpatient or outpatient? Depends on specialty. Podiatry will use outpatient and inpatient. Dermatology is largely outpatient, etc.

Contact Information:
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www.suturegard.com

Online purchasing option: www.suturegard.store
POs submitted to: jen@suturegard.com
2020 Coding and Reimbursement Guidelines for
HEMIGARD® ARS and SUTUREGARD® ISR Devices

The following information is shared for educational purposes only. While SUTUREGARD® Medical believes this information to be correct, coding and reimbursement decisions by AMA, CMA and payers are subject to change. Thus, providers should discuss appropriate coding and reimbursement with their payers.

FDA Regulatory Clearance:

The HEMIGARD® ARS and SUTUREGARD® ISR devices are both FDA registered as suture retention devices (21 CFR § 878.4930). The HEMIGARD® ARS device is intended to support a retention suture in a wound closure and be retained up to two weeks postoperatively. The SUTUREGARD® ISR device is intended to support a retention suture intraoperatively to facilitate skin relaxation and be retained up to 2 hours (though, most effect is seen within 30 minutes).

Value Analysis Significance:

Both devices help providers with the most difficult and time-consuming portions of their wound closures. Fact sheets for purchasing committees can be found here: HEMIGARD ARS Fact Sheet and SUTUREGARD ISR Fact Sheet

Coding Considerations:

Coders provide a uniform language for describing services rendered by health providers. The selection of codes depends on the precise details and necessity of the surgical procedure. It is the sole responsibility of the health care provider to correctly prepare claims submitted to insurance companies and other payers.

Physician’s Professional Fee:

The code chosen for a given wound closure may include a simple, intermediate, or complex repair, etc. Fulfilling complex repair requirements is possible with the HEMIGARD® ARS and SUTUREGARD® ISR devices when the devices are used to place a retention suture and all other requirements are met. The HEMIGARD® ARS and SUTUREGARD® ISR are classified by the U.S. Food & Drug as suture retention devices (Sec. 878.4930).

Continues on reverse.
Complex repair (CPT® codes 13100 to 13153) includes the repair of wounds that, in addition to the requirements for intermediate repair, require at least one of the following: exposure of bone, cartilage, tendon, or named neurovascular structure; debridement of wound edges (e.g., traumatic lacerations or avulsions); extensive undermining (defined as distance equal to or greater than the maximum width of the defect, measured perpendicular to the closure line along at least one entire edge of the defect); involvement of free margins of helical rim, vermilion border, or nostril rim; placement of retention sutures. Necessary preparation includes creation of a limited defect for repairs or the debridement of complicated lacerations or avulsions. Complex repair does not include excision of benign (11400-11446) or malignant (11600-11646) lesions, excisional preparation of a wound bed (15002-15005), or debridement of an open fracture or open dislocation.

<table>
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<tr>
<th>CPT® code</th>
<th>Description</th>
<th>RVU</th>
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<tbody>
<tr>
<td>13100</td>
<td>Complex repair to the trunk of 2.5cm or less</td>
<td>9.5</td>
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<tr>
<td>13101</td>
<td>Complex repair to the trunk of 2.5cm to 5.0cm</td>
<td>11.24</td>
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<tr>
<td>13102</td>
<td>Complex repair to the trunk; each additional 5.0cm or less</td>
<td>3.45</td>
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<tr>
<td>13120</td>
<td>Complex repair to the scalp, arms and/or legs of 2.5cm or less</td>
<td>9.94</td>
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<tr>
<td>13121</td>
<td>Complex repair to the scalp, arms and/or legs of 2.5cm to 5.0cm</td>
<td>12.13</td>
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<td>13122</td>
<td>Complex repair to the scalp, arms and/or legs; each additional 5.0cm or less</td>
<td>3.79</td>
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<td>13131</td>
<td>Complex repair to forehead, cheeks, chin, mouth, neck, axillae, hands and/or feet of 2.5cm or less</td>
<td>10.95</td>
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<td>13132</td>
<td>Complex repair to forehead, cheeks, chin, mouth, neck, axillae, hands and/or feet of 2.5cm to 5.0cm</td>
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<td>13133</td>
<td>Complex repair to forehead, cheeks, chin, mouth, neck, axillae, hands and/or feet; each additional 5.0cm or less</td>
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<td>13151</td>
<td>Complex repair to eyelids, nose, ears and/or lips of 2.5cm or less</td>
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<td>13152</td>
<td>Complex repair to eyelids, nose, ears and/or lips of 2.5cm to 5.0cm</td>
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<td>13153</td>
<td>Complex repair to eyelids, nose, ears and/or lips; each additional 5.0cm or less</td>
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Example Medicare Reimbursement Rates, 2019:

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<tr>
<th>Full Reimbursement (Excision)</th>
<th>2.5cm</th>
<th>5.0cm</th>
<th>7.5cm</th>
<th>10.0cm</th>
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<tr>
<td>Simple</td>
<td>$96.24</td>
<td>$116.70</td>
<td>$116.70</td>
<td>$137.16</td>
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<tr>
<td>Intermediate</td>
<td>$255.38</td>
<td>$326.23</td>
<td>$326.23</td>
<td>$335.71</td>
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<tr>
<td>Complex</td>
<td>$376.63</td>
<td>$459.61</td>
<td>$459.61</td>
<td>$603.21</td>
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<table>
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<tr>
<th>50% Reimbursement (MPPR)</th>
<th>2.5cm</th>
<th>5.0cm</th>
<th>7.5cm</th>
<th>10.0cm</th>
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<tr>
<td>Simple</td>
<td>$48.12</td>
<td>$58.35</td>
<td>$58.35</td>
<td>$68.58</td>
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<tr>
<td>Intermediate</td>
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<td>$163.12</td>
<td>$163.12</td>
<td>$167.85</td>
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<tr>
<td>Complex</td>
<td>$188.31</td>
<td>$229.80</td>
<td>$229.80</td>
<td>$301.60</td>
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August 2020
<table>
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<tr>
<th>Establishment Name</th>
<th>Registration Number</th>
<th>Current Registration Yr</th>
<th>Proprietary Name</th>
<th>Product Code</th>
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<td>DEMETECH CORP</td>
<td>1064584</td>
<td>2020</td>
<td>Retention Device, Suture - HemiGard Adhesive Suture Retention Device; SutureGard Suture Retention Device</td>
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<td>SUTUREGARD MEDICAL, INC.</td>
<td>3015045268</td>
<td>2020</td>
<td>Retention Device, Suture - HEMIGARD ADHESIVE RETENTION SUTURE DEVICE; SUTUREGARD INTRAOPERATIVE SKIN RELAXATION RETENTION SUTURE DEVICE; SUTUREGARD™ Device; SUTUREGARD™ Tissue Expansion Device</td>
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</tbody>
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Can't find what you're looking for? [Try a new search](#)
HEMIGARD® Adhesive Retention Suture (ARS) device

- Reduced wound dehiscence (manuscript under review)
  - Two-center, retrospective clinical study of lower extremity excisional wounds closed with HEMIGARD versus standard closure without HEMIGARD. These wound closures have a 26% rate of dehiscence in the literature. In this study (n=54), there was a 24% rate of dehiscence in the control group. In HEMIGARD closures (n=37), there was a reduction to 2.3% rate of dehiscence (p<0.05). The one dehiscence with HEMIGARD occurred several days after the HEMIGARD removal at postop day 14.

- Improved perfusion versus standard retention sutures (manuscript under review)
  - Single center, split-wound study comparing perfusion of HEMIGARD-protected retention suture versus standard retention suture within same excisional wound closure under tension. Laser speckle contrast analysis (LASCA) technology used as non-contact and non-invasive perfusion measurement (Perimed PSI NR). Perfusion was 25% higher in wound edges protected with HEMIGARD than in wound edges without HEMIGARD.

- Biomechanics of HEMIGARD function (manuscript under review)
  - Finite element analysis (FEA) of skin wound closure under varying tensions. Modeling performed by expert in FEA. Inputs to FEA based on literature, bench modeling and ex vivo tissue. Demonstrated reduction of stress at wound edge and dispersal of stress further from wound edge with HEMIGARD compared with standard retention suture.

  - Case series documenting lack of suture ingrowth in wounds closed with single HEMIGARD protected suture. Lack of ingrown sutures and slight elevation of suture allowed for patient removal of own sutures at home and prevention of need for follow-up during COVID-19 pandemic.

  - Original case series in dermatology literature on use of HEMIGARD to allow closure of wounds under tension in a variety of body sites. Documentation of successful wound closure in patient with torn skin edges, which would otherwise preclude primary closure.

  - Case report of removal of squamous cell carcinoma presenting as non-healing wound and its subsequent removal and closure using HEMIGARD.

- Cole W (manuscript accepted)
  - Case report of patient with bilateral Charcot reconstruction. Foot closed with standard method had dehiscence, months of wound care and ultimate infection necessitating removal of hardware. Foot closed with HEMIGARD healed without complications.
SUTUREGARD® Intraoperative Skin Relaxation (ISR) device

  - Single site clinical study of intraoperative stress-relaxation using SUTUREGARD ISR. Use of SUTUREGARD ISR to stress-relax scalp wounds resulted in 65% lower tension at wound closure. All wounds could be closed without need for flaps/grafts and healed without complications.

  - Case series of excisional wounds in which SUTUREGARD ISR used with “punctureless” (no percutaneous suture) method. All wounds could be closed without need for flaps/grafts and healed without complications.

  - Initial case series of excisional wounds stress-relaxed with SUTUREGARD ISR. Both scalp and lower extremity wounds demonstrated stress-relaxation (less tension) and creep (reduced width) after use of SUTUREGARD ISR. All wounds could be closed without need for flaps/grafts and healed without complications.