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EXECUTIVE SUMMARY

SUTUREGARD® MEDICAL INC. WAS FOUNDED IN 2016 WITH THE PURPOSE OF BRINGING TO MARKET TECHNOLOGIES FOCUSED ON MAKING CHALLENGING WOUND CLOSURE SIMPLER, SAFER AND QUICKER.

THE HEMIGARD® ADHESIVE RETENTION SUTURE (ARS) DEVICE REPRESENTS THE NEXT EVOLUTION IN SKIN WOUND CLOSURE TECHNOLOGY.

THE HEMIGARD® ARS DEVICE IS CLINICALLY PROVEN TO IMPROVE CLINICAL OUTCOMES, REDUCE COSTS AND HEIGHTEN PATIENT SATISFACTION.
HEMIGARD ADHESIVE SUTURE RETENTION DEVICE

Purpose: Optimize suture-based skin closure by reducing skin tearing, improving perfusion and reducing dehiscence versus standard closure.

Manufacturer: Suturegard® Medical Inc. (SKU: HRD001)

Latex free

DUNS: 08-007-2274  SAM: QMMFCC3JL2W9

FDA Registration: 3015045268 (Class I)

Insurance: Kinsale Insurance Co. Policy # 01000059727-2

Device Identified (UDI): 00860007834202

GTIN: 10860007834209 (box)  00860007834202 (pouch)

HEMIGARD® ARS Device has a three-zone technology to allow skin wound closure without tearing skin and outperforming standard layered closure.

Lowest stiffness to prevent shearing skin
Less stiff, waterproof
Rigid, rip proof, & waterproof
Adhesive backing
PRODUCT INFORMATION

CLINICAL INDICATIONS

FRAGILE SKIN
WOUND UNDER TENSION
EXCISIONAL DEFECT
WOUND CLOSURES AT RISK OF DEHISCENCE

PRODUCT BENEFITS

MULTIPLE CLINICAL TRIALS SHOW OVER 80% REDUCED LOWER EXTREMITY WOUND DEHISCENCE VERSUS STANDARD LAYERED CLOSURE

26% HIGHER TENSION PRIOR TO SKIN TEARING VERSUS STANDARD SUTURES

25% HIGHER PERFUSION VERSUS STANDARD SUTURES

REDUCED NEED FOR UNDERMINING

REDUCE OR ELIMINATE NEED FOR DERMAL SUTURES

ELIMINATE SUTURE INGROWTH

REDUCE FLAPS, GRAFTS, SECOND INTENT

ACTUAL SIZE: 2.5” X 0.5”
HOW IS HEMIGARD® ARS BETTER THAN STANDARD SUTURE-BASED CLOSURE?

HEMIGARD® ARS OFFLOADS STRESS FROM THE WOUND EDGE.

WOUND EDGE STRESS CAUSES SKIN TEARING AND REDUCES PERFUSION (BLOOD SUPPLY).

WHAT MINIMUM SIZE OF RETENTION SUTURE IS RECOMMENDED?

SIZE 2-0 NYLON IS RECOMMENDED.
HOW DOES IT WORK?

HOW DOES HEMIGARD ARS WORK?

THE SURGEON USES COMMON SUTURING EQUIPMENT, TECHNIQUE AND MATERIALS (NYLON SUTURE).

ADHERE A HEMIGARD ARS STRIP TO CLEAN, DRY SKIN ON EACH SIDE OF WOUND

SUTURE THROUGH THE HEMIGARD ARS HOLES.

THE HEMIGARD ARS STRIPS BOLSTER THE SKIN AND OFFLOAD STRESS FROM THE WOUND EDGES.

HOW LONG DOES THE HEMIGARD ARS STAY ON THE WOUND?

THE HEMIGARD ARS IS INTENDED TO STAY ON THE WOUND AND PROTECT THE CLOSURE FOR UP TO 2 WEEKS.
HEMIGARD® ARS SKIN ANCHOR (LEFT SIDE OF WOUND) HAS 25% HIGHER PERFUSION THAN STANDARD SUTURES (RIGHT SIDE OF WOUND)

(Stoecker et al)

BETTER PERFUSION + LESS SKIN TEARING = BETTER OUTCOMES

81-89% REDUCTION IN LOWER EXTREMITY WOUND DEHISCENCE VERSUS STANDARD LAYERED CLOSURE

89% REDUCTION IN NEED FOR SUBSEQUENT AMPUTATION WHEN USED IN FOOT AMPUTATIONS

REDUCE OR ELIMINATE DERMAL ABSORBABLE SUTURES

HEMIGARD ARS ALLOWS 26% HIGHER SUTURE TENSION PRIOR TO SKIN TEARING THAN STANDARD SUTURES

(Pearson et al)
CLINICAL / ECONOMIC OVERVIEW

FINANCIAL IMPACT OF HEMIGARD® ARS DEVICE IN FOOT & ANKLE SURGERY – AMPUTATION

FASTER

With HEMIGARD® ARS, surgeons can avoid time-consuming and risky wide undermining and reduce - or eliminate - dermal absorbable sutures for skin closure. This can save 20-30 minutes of OR time. This equals $700 - $1860 of direct OR time savings.

BETTER

Up to 80% of foot amputations suffer wound dehiscence with 16-25% requiring re-amputation.

In a multi-center study, the rate of re-amputation was reduced from 16% using standard layered closure to 1.8% using HEMIGARD® ARS (89% reduction) . With an average cost of over $70,000 per amputation, this resulted in $9940 of postoperative savings per case.

Sipala et al. Use of a novel adhesive suture retention device in non-traumatic diabetic lower extremity amputations: A multicenter review. DFCON 2021
CLOSE MORE WOUNDS - FASTER AND WITH ENHANCED REIMBURSEMENT

With HEMIGARD® ARS, Surgeons do not need to perform wide undermining and can reduce dermal absorbable sutures. This can save 20-30 minutes of operative time.

Use of HEMIGARD® ARS with some dermal absorbable sutures allows coding of complex linear closure (CPT® 131XX) because it involves use of retention sutures.

BETTER

Use of HEMIGARD® ARS for lower extremity excisional wound closures in a two-center clinical study resulted in 89% fewer wound dehiscences and allowed 89% more wound to be closed than standard layered closure.

Use of HEMIGARD® ARS in surgical oncology resulted in $400 of added revenue per case, faster closure of cases and with fewer complication compared to standard layered closure.

CLINICAL / ECONOMIC OVERVIEW

Sipala et al. Use of a novel adhesive suture retention device in non-traumatic diabetic lower extremity amputations: A multicenter review. DFCON 2021
- HEMIGARD ARS reduced diabetic foot amputation wound dehiscence by 81% compared with standard layered closure in five-center study
- HEMIGARD ARS reduced need for subsequent amputation by 89% compared with standard layered closure
- HEMIGARD ARS reduced or eliminated need for dermal sutures

- Using non-contact perfusion measurement, the wound edges of lower extremity wounds closed with HEMIGARD ARS had 25% higher perfusion than those closed using standard sutures

- HEMIGARD ARS reduced lower extremity excisional surgery dehiscence by 89% compared to standard layered closure in two-center study

- A case study in a patient with bilateral Charcot foot reconstructions. The procedure with HEMIGARD ARS did not have dehiscence, but the side with standard layered closure had lengthy postoperative complications.

- Using ex vivo human skin, 26% higher suture tension prior to skin failure using HEMIGARD versus standard sutures.

- HEMIGARD ARS elevates suture above skin, which prevented ingrowth and allowed patient removal of own sutures.

- Initial case series of use of HEMIGARD ARS in cutaneous oncology
How does HEMIGARD® differ from Zip® Surgical?

<table>
<thead>
<tr>
<th><strong>HEMIGARD® ASRD</strong></th>
<th><strong>Zip Surgical Skin Closure Device</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FDA Product Code</strong></td>
<td>KGS (Retention Device, Suture)</td>
</tr>
<tr>
<td><strong>Use in high- and low-tension wounds?</strong></td>
<td>HEMIGARD has been tested in very high tension intraoperative and postoperative wound closures.</td>
</tr>
<tr>
<td><strong>Need for dermal sutures?</strong></td>
<td>HEMIGARD can be used without the need for dermal sutures.</td>
</tr>
<tr>
<td><strong>Need to carefully align skin edges prior to use of device?</strong></td>
<td>The HEMIGARD is the initial step in wound closure and can be solely used to complete the entire process of apposing wound edges.</td>
</tr>
<tr>
<td><strong>Claims</strong></td>
<td>&gt; 80% reduction in wound dehiscence versus standard layered closure (see next page) 25% better perfusion versus standard sutures &gt; 26% higher suture tension without skin tearing versus standard sutures</td>
</tr>
<tr>
<td></td>
<td>Meta-analyses of clinical studies have found zipper-type devices (including Zip) to be INEFFECTIVE in reducing wound dehiscence (see next page)</td>
</tr>
</tbody>
</table>
Comparison to zipper-type devices

Meta-analysis shows that “zipper type” devices do NOT reduce wound dehiscence

Use of HEMIGARD reduces risk of dehiscence by 81% (p<0.001)

2 Sipala et al. Use of a novel adhesive suture retention device in non-traumatic diabetic lower extremity amputations: A multicenter review. DFCON 2021
3 Lewson et al. Outcomes of layered closure and adjunctive adhesive retention suture device use following ankle fracture open reduction and internal fixation. (Under review)
Comparison to incisional negative pressure wound therapy (iNPWT)

Meta-analysis shows that iNPWT does NOT reduce wound dehiscence

Use of HEMIGARD reduces risk of dehiscence by 81% (p<0.001)

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2 Sipala et al. Use of a novel adhesive suture retention device in non-traumatic diabetic lower extremity amputations: A multicenter review. DFCON 2021
3 Lewson et al. Outcomes of layered closure and adjunctive adhesive retention suture device use following ankle fracture open reduction and internal fixation. (Under review)
SUPPLY CHAIN SPECIFICS

CODING / REIMBURSEMENT

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).

PLEASE SEE CODING GUIDE FOR COMPLETE REIMBURSEMENT INFORMATION
SUPPLY CHAIN SPECIFICS

CODING / REIMBURSEMENT

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 (11400-11445) or malignant (11600-11645) lesions, excisional preparation of a wound bed (15002-15005), or debridement of an open fracture or open dislocation.

<table>
<thead>
<tr>
<th>CPT® code</th>
<th>Description</th>
<th>RVU</th>
</tr>
</thead>
<tbody>
<tr>
<td>13100</td>
<td>Complex repair to the trunk of 2.5cm or less</td>
<td>9.5</td>
</tr>
<tr>
<td>13101</td>
<td>Complex repair to the trunk of 2.5cm to 5.0cm</td>
<td>11.24</td>
</tr>
<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>6.94</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>
</tr>
<tr>
<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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<tr>
<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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<tr>
<td>13132</td>
<td>Complex repair to forehead, cheeks, chin, mouth, neck, axillae, hands and/or feet of 2.5cm to 5.0cm</td>
<td>13.53</td>
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<tr>
<td>13133</td>
<td>Complex repair to forehead, cheeks, chin, mouth, neck, axillae, hands and/or feet; each additional 5.0cm or less</td>
<td>5.09</td>
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<tr>
<td>13151</td>
<td>Complex repair to eyelids, nose, ears and/or lips of 2.5cm or less</td>
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<tr>
<td>13152</td>
<td>Complex repair to eyelids, nose, ears and/or lips of 2.5cm to 5.0cm</td>
<td>14.4</td>
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<tr>
<td>13153</td>
<td>Complex repair to eyelids, nose, ears and/or lips; each additional 5.0cm or less</td>
<td>5.83</td>
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</tbody>
</table>

PLEASE SEE CODING GUIDE FOR COMPLETE REIMBURSEMENT INFORMATION
## FDA REGISTRATION INFORMATION

**Establishment Registration & Device Listing**

<table>
<thead>
<tr>
<th>Establishment</th>
<th>Registration Number</th>
<th>Current Registration Yr</th>
<th>Manufacturer Type</th>
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<tbody>
<tr>
<td>DEMETECH CORP.</td>
<td>1064584</td>
<td>2020</td>
<td>Contract Manufacturer</td>
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<tr>
<td>SUTUREGARD MEDICAL, INC.</td>
<td>3015945288</td>
<td>2020</td>
<td>Specification Developer</td>
</tr>
</tbody>
</table>

- Retention Device, Suture, HEMIGARD Adhesive Suture Retention Device; SUTUREGARD Suture Retention Device
- Retention Device, Suture, HEMIGARD ADHESIVE RETENTION SUTURE DEVICE; SUTUREGARD INTRAOPERATIVE SKIN RELAXATION RETENTION SUTURE DEVICE; SUTUREGARD™ Device; SUTUREGARD™ Tissue Expansion Device
<table>
<thead>
<tr>
<th>ITEM</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRODUCT NAME</td>
<td>HEMIGARD® ARS (ADHESIVE RETENTION SUTURE) DEVICE</td>
</tr>
<tr>
<td>MANUFACTURER</td>
<td>SUTUREGARD® MEDICAL INC.</td>
</tr>
<tr>
<td>SKU</td>
<td>HRD001</td>
</tr>
<tr>
<td>PRICE</td>
<td>AVAILABLE UPON REQUEST</td>
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</table>
SUPPLY CHAIN SPECIFICS

ORDERING INFORMATION

CONTACT INFORMATION
SUTUREGARD® MEDICAL INC.
2397 NW KINGS BLVD, SUITE 235
CORVALLIS, OR 97330
844.585.8421
WWW.SUTUREGARD.COM

For pricing or submission of purchase orders:
ORDERS@SUTUREGARD.COM