SUTUREGARD MEDICAL

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HEMIGARD® ARS

ADHESIVE RETENTION SUTURE DEVICE

SUTUREGARD® MEDICAL INC

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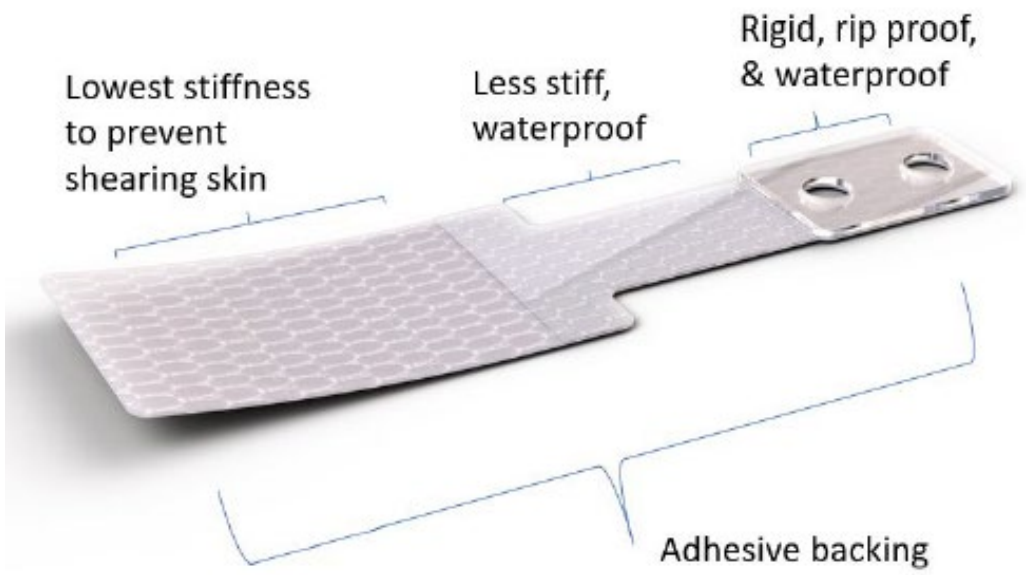
EXECUTIVE SUMMARY

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 CLINCIALLY PROVEN TO IMPROVE CLINICAL OUTCOMES, REDUCE COSTS AND HEIGHTEN PATIENT SATISFACTION.

HEMIGARD ADHESIVE SUTURE RETENTION DEVICE



HEMIGARD® ARS DEVICE HAS A THREE-ZONE TECHNOLOGY TO ALLOW SKIN WOUND CLOSURE WITHOUT TEARING SKIN AND OUTPERFORMING STANDARD LAYERED CLOSURE

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)

PRODUCT INFORMATION

CLINICAL INDICATIONS

FRAGILE SKIN

WOUND UNDER TENSION

EXCISIONAL DEFECT

WOUND CLOSURES AT RISK OF DEHISCENCE

ACTUAL SIZE: 2.5” X 0.5”

PRODUCT BENEFITS

MUTLIPLE 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

PRODUCT INFORMATION

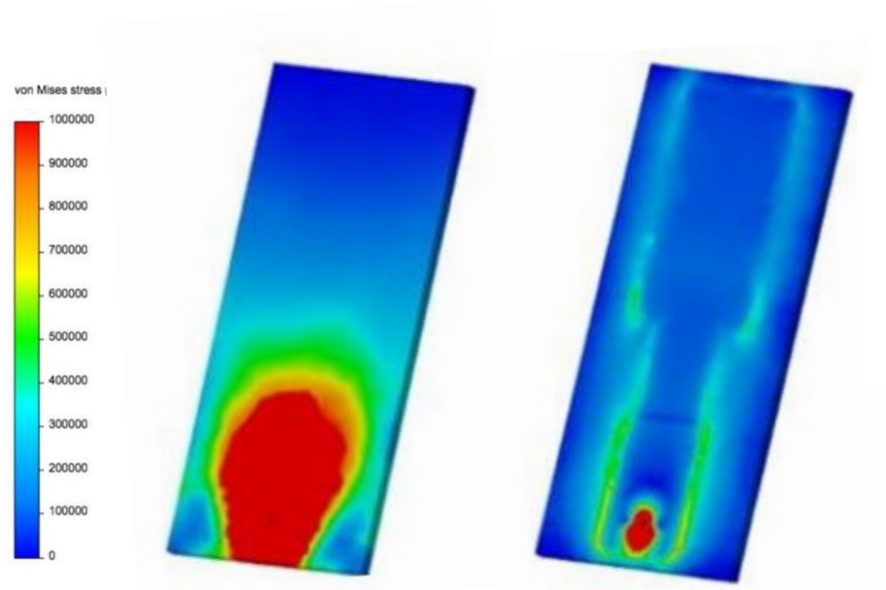
HOW IS HEMIGARD® ARS BETTER THAN STANDARD SUTURE-BASED CLOSURE?

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



Sutures place STRESS at wound edge

HEMIGARD® ARS disperses suture stress away from wound edge

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.

Prepare

Clean and thoroughly DRY a 6cm long area for the HEMIGARD® ARS strips on each side of the wound.

Adhere

Place HEMIGARD® ARS strips so that the hole closer to the wound is 10mm from the wound edge. Ensure adhesion of the strips to skin.

Suture

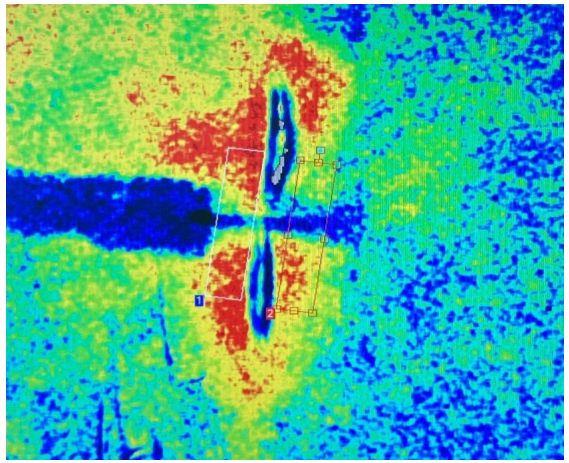
Suture 2-0 nylon (or similar) suture through the holes of the HEMIGARD® ARS and full thickness skin prior to closing the wound.

Finish Closure

After placing additional dermal or percutaneous sutures, staples, or glue, ensure that the HEMIGARD® ARS strips remain DRY for AT LEAST 5-7 days.

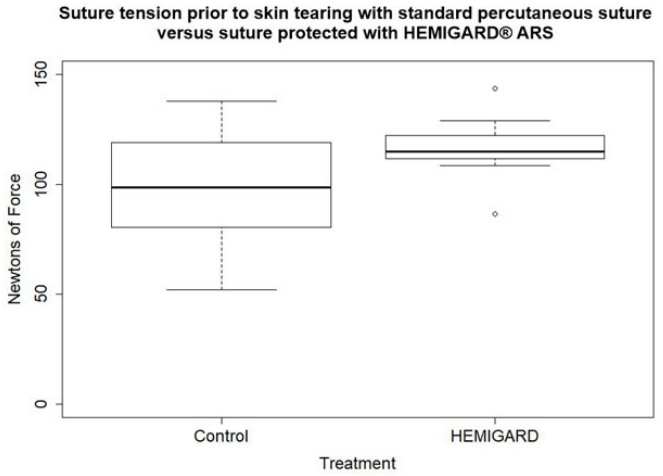
CLINICAL / ECONOMIC OVERVIEW

BETTER PERFUSION + LESS SKIN TEARING = BETTER OUTCOMES



HEMIGARD® ARS SKIN ANCHOR (LEFT SIDE OF WOUND) HAS 25% HIGHER PERFUSION THAN STANDARD SUTURES (RIGHT SIDE OF WOUND)

(Stoecker et al)



UNPROTECTED SUTURES TEAR SKIN

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

(Pearson et al)

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

CLINICAL / ECONOMIC OVERVIEW

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

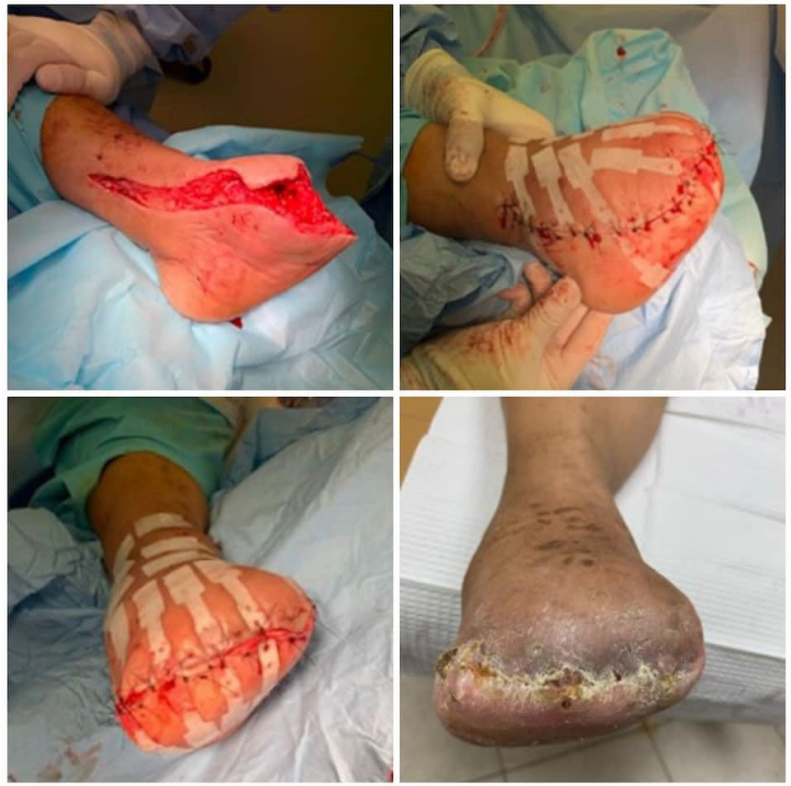
FASTER

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.**



Curran et al. Risk factors and indications for readmission following lower extremity amputation in the ACS-NSQIP. J Vasc Surg (2104) 60(5): 1315-24.

Thorud et al. Reoperation and reamputation after transmetatarsal amputation: A systematic review and meta-analysis. J Foot Ankle Surg (2016) 55(5): 1007-12.

Sipala et al. Use of a novel adhesive suture retention device in non-traumatic diabetic lower extremity amputations: A multicenter review. DFCON 2021

CLINICAL / ECONOMIC OVERVIEW

FINANCIAL IMPACT OF HEMIGARD® ARS DEVICE IN SURGICAL ONCOLOGY

CLOSE MORE WOUNDS - FASTER AND WITH ENHANCED REIMBURSEMENT

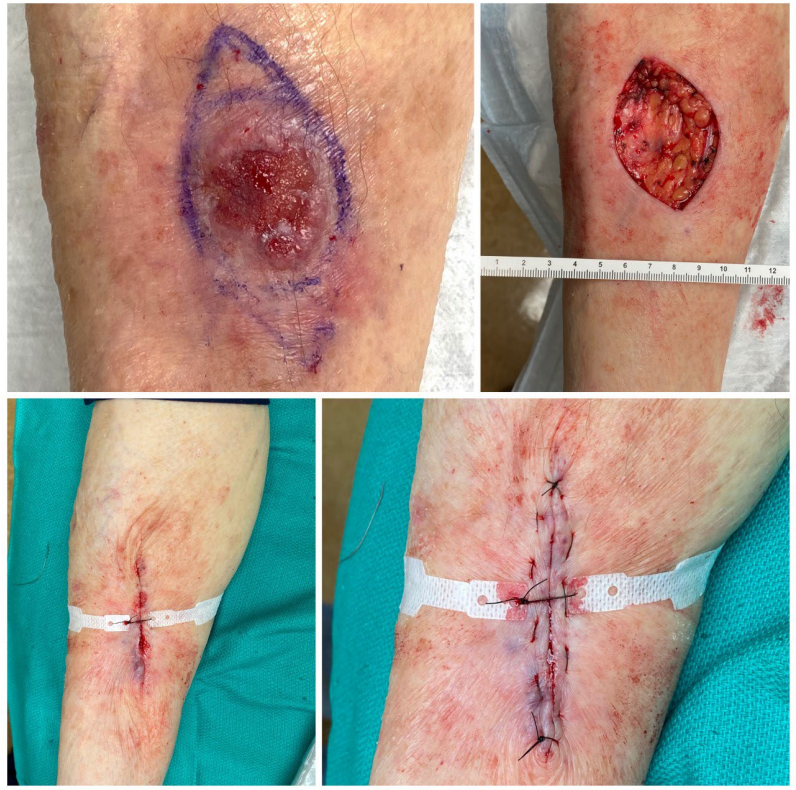
With HEMIGARD® ARS, Surgeons do not need to perform wide undermining and can reduce dermal absorbable sutures. This can save 20-30 minutes of operative time.

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



Cole et al. Use of a novel adhesive suture retention device in lower leg excisional closure: A retrospective review. Wounds (2021) 33(9): 222-5.

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*

Stoecker et al. Enhanced perfusion of elliptical wound closures using a novel suture retention device. Health Science Reports 4(3): e364.
- 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

Cole et al. Use of a novel adhesive suture retention device in lower leg excisional closure: A retrospective review. Wounds (2021) 33(9): 222-5.
- HEMIGARD ARS reduced lower extremity excisional surgery dehiscence by 89% compared to standard layered closure in two-center study

Cole et al. The use of a novel suture retention device to prevent surgical wound dehiscence. Podiatry Management: 135-40.
- 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.

Pearson et al. Suture pullout in human cadaveric skin: Evaluation of HEMIGARD augmentation versus suture alone. AOFAS 2021.
- Using ex vivo human skin, 26% higher suture tension prior to skin failure using HEMIGARD versus standard sutures.

Roybal et al. Use of a novel adhesive suture retention wound closure device to prevent patient follow-up visits during the COVID-19 pandemic. JAAD Case Reports. (2020) 6: 593-7.
- HEMIGARD ARS elevates suture above skin, which prevented ingrowth and allowed patient removal of own sutures.

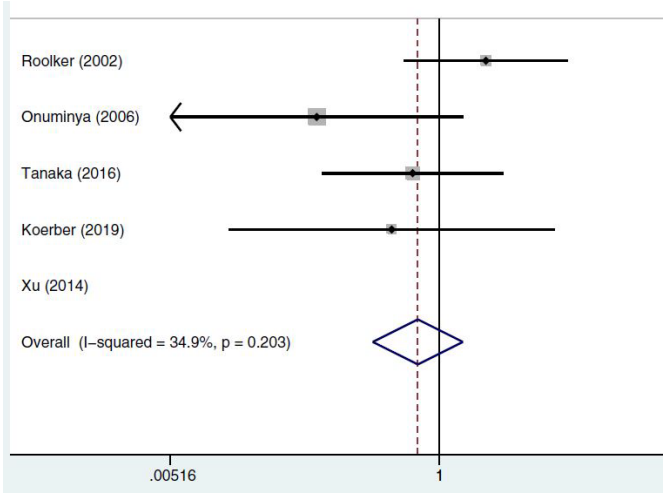
Roybal et al. A novel adhesive suture retention device for the closure of fragile skin under tension. JAAD Case Reports. (2020) 6: 109-14.
- Initial case series of use of HEMIGARD ARS in cutaneous oncology

Click on any of the above titles for URL links to publications

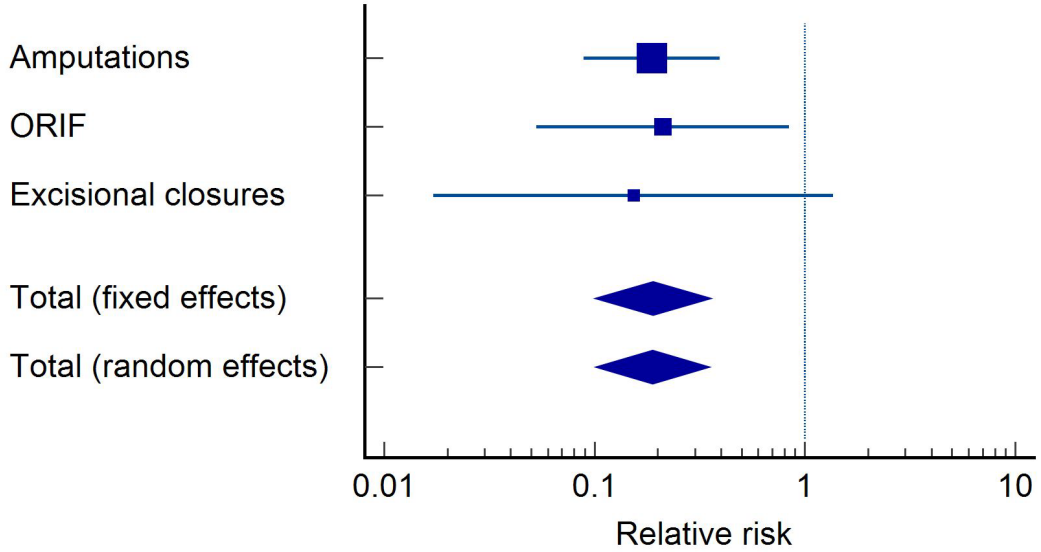
How does HEMIGARD® differ from Zip® Surgical?

	HEMIGARD® ASRD	Zip Surgical Skin Closure Device
FDA Product Code	**KGS** (Retention Device, Suture)	**KGX** (Tape and Bandage, Adhesive)
Use in high- and low-tension wounds?	HEMIGARD has been **tested in very high tension intraoperative and postoperative wound closures**.	Per Zip Instruction for Use*: "**Do not use in high tension wounds** which cannot easily be approximated with fingers or forceps"*
Need for dermal sutures?	HEMIGARD can be used **without the need for dermal sutures.**	Per Zip Instructions for Use: *"**APPLY SUPPORTING SUTURES**" - "apply subcutaneous and/or deep, tension reducing sutures"*
Need to carefully align skin edges prior to use of device?	The HEMIGARD is the initial step in wound closure and can be **solely used to complete the entire process of apposing wound edges**.	Per Zip Instructions for Use: *"For best results, the **distance between adjacent incision edges should be 5mm or less**."* Similar to other products under the FDA KGX category, (such as steri-strips), Zip is used only after wound tension and edge-to-edge distance has already been managed.
Claims	**> 80% reduction in wound dehiscence** versus standard layered closure (see next page) **25% better perfusion** versus standard sutures **> 26% higher suture tension without skin tearing** versus standard sutures	Less removal pain versus staples Better cosmesis versus staples Meta-analyses of clinical studies have found zipper-type devices (including Zip) to be **INEFFECTIVE** in reducing wound dehiscence (see next page)

Comparison to zipper-type devices



Meta-analysis shows that "zipper type" devices do NOT reduce wound dehiscence[4]

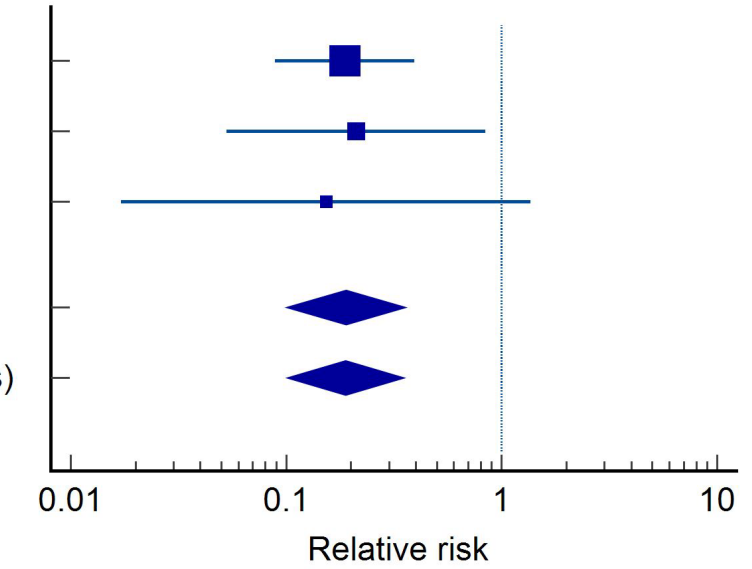


Use of HEMIGARD reduces risk of dehiscence by 81% ($p<0.001$)

[1] Cole et al. Use of a novel adhesive suture retention device in lower leg excisional closure: A retrospective review. Wounds (2021) 33(9): 222-5.
[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)
[4] Xie et al. A novel zipper device versus sutures for wound closure after surgery: a systematic review and meta-analysis. Int Wound J (2020); 17(6): 1725-37.

Comparison to incisional negative pressure wound therapy (iNPWT)

Study or Subgroup	NPWT Events	NPWT Total	Standard dressing Events	Standard dressing Total	Weight	Risk Ratio M-H, Random, 95% CI
1.6.1 Orthopaedic: hip/knee arthroplasty						
Gillespie 2015	1	35	1	35	0.8%	1.00 [0.07 , 15.36]
Newman 2019	1	79	4	80	1.3%	0.25 [0.03 , 2.22]
Subtotal (95% CI)		**114**		**115**	**2.2%**	**0.43 [0.08 , 2.35]**
Total events:	2		5			
Heterogeneity: Tau² = 0.00; Chi² = 0.60, df = 1 (P = 0.44); I² = 0%						
Test for overall effect: Z = 0.97 (P = 0.33)						
1.6.2 Orthopaedic: limb fracture						
WHIST 2019a	2	714	7	687	2.6%	0.27 [0.06 , 1.32]
Subtotal (95% CI)		**714**		**687**	**2.6%**	**0.27 [0.06 , 1.32]**
Total events:	2		7			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.61 (P = 0.11)						



Meta-analysis shows that iNPWT does NOT reduce wound dehiscence[4]

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

[1] Cole et al. Use of a novel adhesive suture retention device in lower leg excisional closure: A retrospective review. Wounds (2021) 33(9): 222-5.
[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)
[4] Norman et al. Negative pressure wound therapy for surgical wounds healing by primary closure. Cochrane Database of Systematic Reviews (2020), Issue 6. Art. No: CD009261

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 (11400-11446) or malignant (11600-11646) lesions, excisional preparation of a wound bed (15002-15005), or debridement of an open fracture or open dislocation.

CPT® code	Description	RVU
13100	Complex repair to the trunk of 2.5cm or less	9.5
13101	Complex repair to the trunk of 2.5cm to 5.0cm	11.24
13102	Complex repair to the trunk; each additional 5.0cm or less	3.45
13120	Complex repair to the scalp, arms and/or legs of 2.5cm or less	9.94
13121	Complex repair to the scalp, arms and/or legs of 2.5cm to 5.0cm	12.13
13122	Complex repair to the scalp, arms and/or legs; each additional 5.0cm or less	3.79
13131	Complex repair to forehead, cheeks, chin, mouth, neck, axillae, hands and/or feet of 2.5cm or less	10.95
13132	Complex repair to forehead, cheeks, chin, mouth, neck, axillae, hands and/or feet of 2.5cm to 5.0cm	13.53
13133	Complex repair to forehead, cheeks, chin, mouth, neck, axillae, hands and/or feet; each additional 5.0cm or less	5.09
13151	Complex repair to eyelids, nose, ears and/or lips of 2.5cm or less	12
13152	Complex repair to eyelids, nose, ears and/or lips of 2.5cm to 5.0cm	14.4
13153	Complex repair to eyelids, nose, ears and/or lips; each additional 5.0cm or less	5.53

PLEASE SEE CODING GUIDE FOR COMPLETE REIMBURSEMENT INFORMATION

SUPPLY CHAIN SPECIFICS

FDA REGISTRATION INFORMATION

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

1 to 2 of 2 Results for **Proprietary Name :** *hemigard*

Results per Page 10

New Search[6]

Establishment Name	▲7 ▼8	Registration Number	Current Registration Yr
DEMETECH CORP.[9]	FL/USA	1064584	2020
• Retention Device, Suture - HemiGard Adhesive Suture Retention Device; SutureGard Suture Retention Device[10]			Contract Manufacturer
SUTUREGARD MEDICAL, INC.[11]	OR/USA	3015045268	2020
• Retention Device, Suture - HEMIGARD ADHESIVE RETENTION SUTURE DEVICE; SUTUREGARD INTRAOPERATIVE SKIN RELAXATION RETENTION SUTURE DEVICE; SUTUREGARD™ Device; SUTUREGARD™ Tissue Expansion Device[12]			Specification Developer

SUPPLY CHAIN SPECIFICS

PRODUCT CATALOG

ITEM	DESCRIPTION
PRODUCT NAME	HEMIGARD® ARS (ADHESIVE RETENTION SUTURE) DEVICE
MANUFACTURER	SUTUREGARD® MEDICAL INC.
SKU	HRD001
PRICE	AVAILABLE UPON REQUEST

SUPPLY CHAIN SPECIFICS

ORDERING INFORMATION

CONTACT INFORMATION
SUTUREGARD® MEDICAL INC.
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ORDERS@SUTUREGARD.COM