



HEMIGARD: a Unique Adhesive Retention Suture Device that Reduces the Incidence of Dehiscence

This novel device can prevent serious complications in pedal diabetic wound closure.

BY PAUL KESSELMAN, DPM

Disclaimer: Dr. Kesselman is a paid consultant to SUTUREGARD Medical, the manufacturer of HEMIGARD.

Surgeons familiar with lower extremity surgery appreciate the high incidence of wound dehiscence, particularly in high-risk patients, such as those immunocompromised due to medication and/or age and those who suffer from diabetes and/or peripheral vascular disease. Even in the current era, a recent series on diabetic toe amputation described that 80% of patients fail to heal primarily, with 59% requiring additional revision closure or more proximal amputation.¹

The complications of a surgical wound dehiscence may range from a minor inconvenience which resolves at home with local wound care to a serious complication that may delay discharge from or cause re-admission to the hospital, resulting in multiple returns to the OR, PO or IV antibiotics with their inherent costs and complications. In the setting of the diabetic foot, these additional treatments may still not avoid a major limb amputation, which in and of itself has a high cost and high 5-year mortality rate.

Failed surgical repairs are the leading cause of chronic wounds at a cost of \$13B annually in the US alone². In addition to health system expense, the emotional costs to the patient are formidable, with all too many losing their independence and becoming dependent on family and society because they can no longer work or return to their pre-operative life.

Reactive vs. Proactive

Many lower extremity surgeons operating today utilize a range of closure techniques, decades or centuries old, using basic suture materials. These standard techniques have been adopted by generations of surgeons, who can predictably forecast which surgical incisions will dehisce. Unfortunately, the tried-and-true techniques of the past have not substantially reduced the incidence of wound dehiscence and have instead resulted in a reactive rather than

proactive surgeon attitude towards dehiscence.

This prompts the question: If instead of the surgeon being reactive after a dehiscence took place, what if the surgeon could be proactive and implement a new easy-to-apply, cost-effective technique, replacing the “standard” current wound closure techniques? If we had access to

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such a product—one that is applied at the time of surgery and that significantly reduces the incidence of dehiscence—its consequences would benefit all.

HEMIGARD, a novel adhesive suture retention device (ASRD), is FDA-registered, invented by surgeons and developed by SUTUREGARD Medical, Inc. HEMIGARD is a simple, easy-to-use device that acts as a load transferring skin anchor, and has been shown to reduce skin tearing,

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New Concepts and Studies

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protect wound edge perfusion and significantly reduce lower extremity excisional wound dehiscence when compared with standard layered closures.

The HEMIGARD Load Transfer Effect

Primary closure of a wound is almost always the best option, as the local tissues are uniquely suited to perform the functions required of that anatomic region. Local tissues can be stretched using skin creep and stress relaxation and this allows the surgeon to achieve maximal primary closure before moving up the reconstructive ladder to grafts and flaps. Skin creep does not occur unless high Newton force (>5N) is applied, and this degree of suture force applied to unprotected skin can be traumatic and cause the suture to “cheese-wire” through the local tissues. HEMIGARD permits load transfer, allowing surgeons to apply high Newton force and safely perform skin creep without traumatic consequences leading to anchor point failure.

A high-tension suture can also act as a tourniquet and cause local ischemia and skin necrosis. This effect can be immediate or may be delayed when the onset of post-op swelling increases suture tension. The HEMIGARD load transfer effect protects skin edge perfusion and prevents suture “cheese-wiring”. The benefits of protected skin edge perfusion are especially critical in patients with poor blood flow, such as a diabetic with poor small vessel perfusion. The benefit of sustained mechanical suture support without “cheese-wiring” is also crucial in diabetics, who accrue wound breaking strength more slowly than do non-diabetics. This is a key point in the discussion of why diabetics have such

high complication rates after wound repair. Our conventional sutures simply do not provide support for long enough to allow the extra time needed for a diabetic to achieve secure tissue-to-tissue healing. HEMIGARD can be left in place for many weeks postoperatively and can provide that beneficial sustained mechanical support required for successful diabetic healing.

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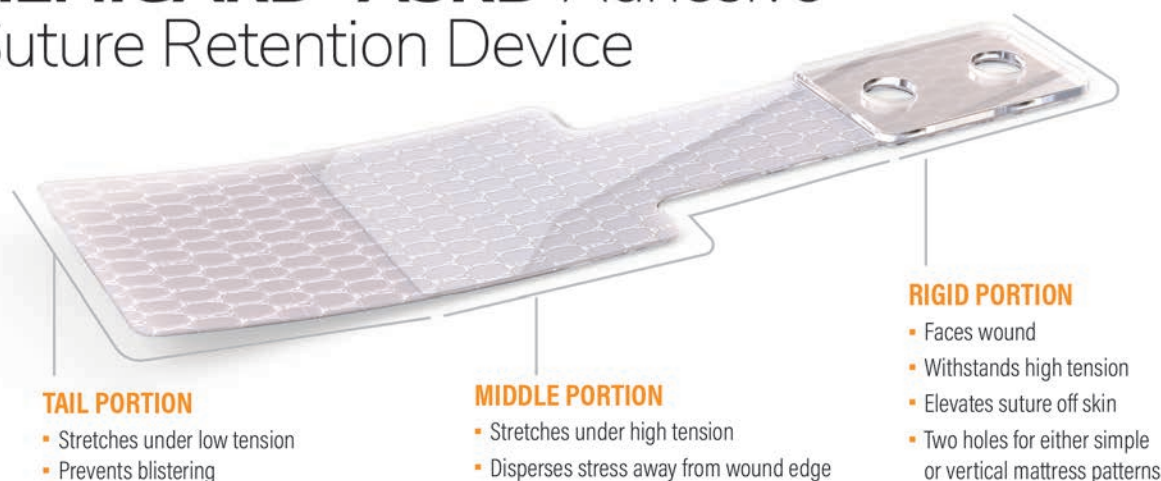
Cost-Effectiveness and Ease of Application

HEMIGARD is cost-effective and easy to apply in almost any patient care setting, including the patient’s home, physician’s office, SNF, wound care facility and Operating Room. It is used in combination with sutures and must be applied by a provider with surgical scope of practice. HEMIGARD looks like a “Butterfly Suture” with two “half wings”, each wing having two holes through which sutures may be placed. The HEMIGARD adheres to the skin and each half is placed 1 cm from the edge of the incision with the holes facing the incision. A full thickness suture of choice is then placed through the reinforced holes of the HEMIGARD strip. Typically, 2-0 or 0 nylon are used for higher tension closures.

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FIGURE 1

HEMIGARD® ASRD Adhesive Suture Retention Device



TAIL PORTION

- Stretches under low tension
- Prevents blistering

MIDDLE PORTION

- Stretches under high tension
- Disperses stress away from wound edge

RIGID PORTION

- Faces wound
- Withstands high tension
- Elevates suture off skin
- Two holes for either simple or vertical mattress patterns



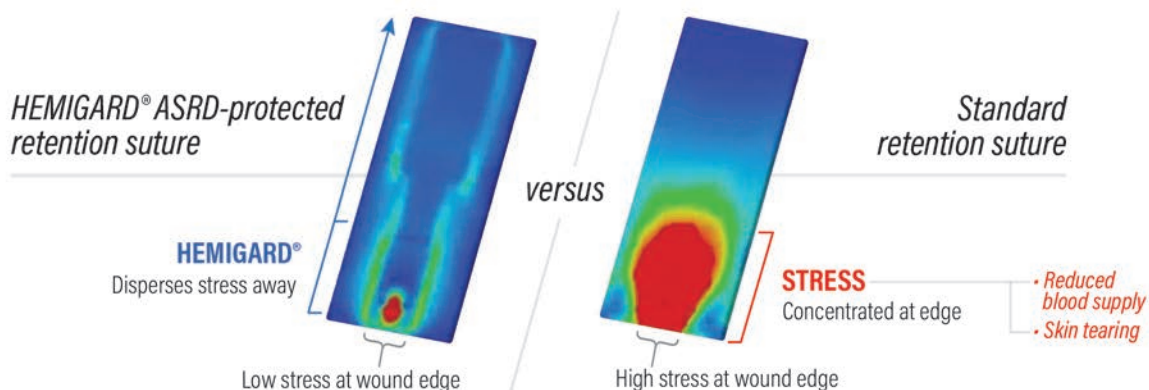
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FIGURE 2

HEMIGARD® ASRD manages wound closure STRESS and TENSION.



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The HEMIGARD is composed of 3 progressively elastic “head, body and tail” zones as shown in Figure 1.

Clinical Evidence

The clinical evidence supporting HEMIGARD is substantial. A presentation at DFCON2021³ presented an 80-patient multi-center study involving diabetic and/or ischemic patients undergoing toe, ray or TMA resections both with and without the HEMIGARD device. Of the 25 patients who had their amputations performed without the HEMIGARD device 16% went on to have complications requiring higher levels of amputation (above or below knee). Of the 55 patients who had their amputations performed with HEMIGARD ASRD and minimal or no dermal sutures, only 1 (1.8%) patients went on to requiring a higher level of amputation (below knee). This represents an 89% reduction in progression to higher level amputation.

Additional studies involving lower leg skin cancer excisional wounds⁴ and ORIF ankle fractures⁵ also determined that the use of HEMIGARD ASRD resulted in ~80% reduction in incidence of lower extremity wound dehiscence and faster healing time.

Diabetic Heel Ulcers

Diabetic heel ulcers with bone involvement present a special challenge, with a risk of below knee amputation. The plantar skin over the heel is particularly difficult to close under tension and is very prone to suture tear-through. A case series of 7 diabetic heel ulcers successfully closed after adequate soft tissue and bone debridement with HEMIGARD offers new possibilities for this challenged group of patients⁶.

The length of the incision will determine the number of HEMIGARD ASRD units required, with additional sutures placed otherwise between applied HEMIGARD. We also recommend examining the closed wound for stress points that become manifest with range of motion. If one identifies a high stress area, HEMIGARD placement can mitigate the risk of wound dehiscence from postoperative range of motion stress. If the surgeon anticipates the entire wound to swell postop, placement every 3 cm of incision length is a good guideline. HEMIGARD may be left in place for two or more weeks until adequate wound strength allows for device removal (see Figure 2).

Reimbursement

Reimbursement for the professional application of HEMIGARD ASRD is most often included in the professional services involved at the time of initial surgical primary incisional closure. Some third-party payors, however, may award a complex wound closure CPT code (131XX) at the time of primary incisional closure or by modifying the surgical CPT with modifier-22, but only if the operative report describes the use of a retention suture and why it was necessary in order to meet coding requirements.

Reimbursement for delayed closure of complex wound (CPT 13160) is frequently used on a subset of wounds, including diabetic foot ulcers and amputation sites that are not amenable to immediate primary surgical closure (e.g., infected, contaminated wounds). The use of HEMIGARD allows for the use of CPT 13160, with its description of complex wound closure.

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Summary

As previously noted, HEMIGARD makes many wounds such as plantar ulcers more amenable to immediate primary wound closure—wounds that otherwise may have required a protracted course of therapy.

HEMIGARD ASRD is a novel device based on a simple principle of load transfer of tension over a broader surface area. Wound tension dispersal protects perfusion and reduces suture induced skin tears at the incision edge. It is simple to apply, requiring no special surgical techniques. HEMIGARD ASRD enables surgeons to now be proactive in closing high risk diabetic and other challenging incisional or excisional wounds. The reduction in postoperative complications and improved surgical outcomes benefit patient, provider and the entire health system.

For more on HEMIGARD including supply and reimbursement information, please visit [https://suturegard.com/HEMIGARD PM](https://suturegard.com/HEMIGARD_PM)

References

¹ Vassalo L et al Healing and Mortality Rates Following Toe Amputation in Type 2 Diabetes *Exp Clin Endocrinol Diabetes* 129(6):438-442, 2021

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⁴ Cole, W et al. Use of a novel adhesive suture retention device in lower leg excisional wound closure: a retrospective review. *Wounds* 33(9), 222-5, 2020.

⁵ Lewson, E et al. Outcomes of layered closure and adjunctive adhesive retention suture device use following ankle fracture open reduction and internal fixation. Presented at American College of Foot and Ankle Surgery 2022.

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Dr. Kesselman is board certified by ABFAS and ABMSP. He is a member of the Medicare Jurisdictional Council for the DME MACs' NSC and provider portal subcommittees. He is a noted expert on durable medical equipment (DME) and an expert for Codingline.com and many third-party payers. Dr. Kesselman is also a medical advisor and consultant to many medical manufacturers and compliance organizations.