



INSTRUCTIONS FOR USE

HEMIGARD™ Adhesive Suture Retention Device

STERILE EO

DESCRIPTION

The HEMIGARD™ adhesive suture retention device is a single use, disposable, sterile surgical device to be used with non-absorbable sutures. There are two strips per package. One or more strip(s) is/are to be used on each side of wound in order to retain percutaneous non-absorbable sutures.

INTENDED USE

HEMIGARD™ adhesive suture retention device is indicated for closure of clean, non-contaminated acute (less than 8 hour) surgical skin wounds.

WARNINGS/PRECAUTIONS/REACTIONS

(i) Do not reuse. This product is intended for single use, one patient only. The reuse of single-use devices can cause cross contamination and affect the device safety, performance and effectiveness, exposing patients and staff to unnecessary risk. (ii) Do not attempt to re-sterilize. (iii) Discard open, unused devices. (iv) Do not use if package is wet, open, torn or damaged.

PRECAUTIONS

Excessive force applied for prolonged durations may lead to pressure injury. The amount of force and duration of application that are tolerable will vary with patients and wound location. If the method is used beyond a given wound's tolerability of pressure and/or duration, pressure injury may result.

POSSIBLE ADVERSE EFFECTS

While the device has been designed to protect the peri-wound skin from suture tension, excessive force applied for prolonged durations may lead to pressure injury. Pressure injury may involve damage to the epidermis, dermis, fat or underlying structures such as nerve, muscle or bone. Excessive moisture may also lead to maceration, shear injury and failure of adhesion.

PRODUCT ORDERING

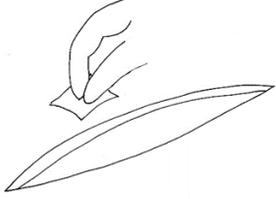
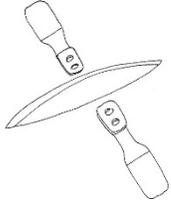
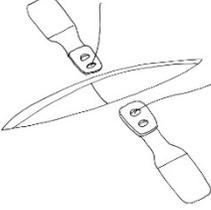
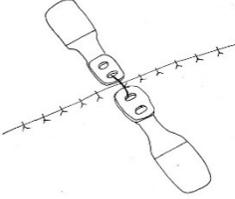
To order directly in the US or for product information, visit us at www.suturegard.com

HOW TO OPEN STERILE PACKAGE

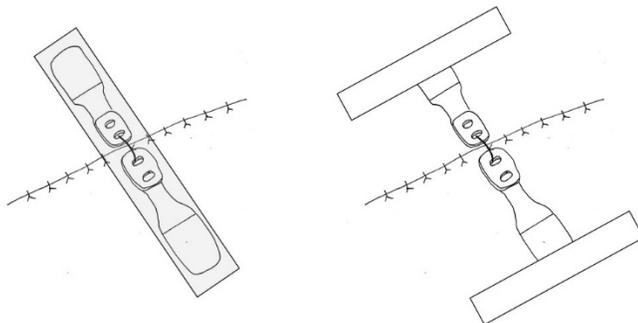
Remove the HEMIGARD™ device from its package in an aseptic environment using talc-free gloved hands.

1. Peel open the package 2. Invert package over sterile field, allowing the two (2) HEMIGARD™ strips to gently fall into sterile field. 3. Discard packaging

SUGGESTED METHOD OF WOUND CLOSURE USING HEMIGARD™ ADHESIVE SUTURE RETENTION DEVICE

	<p>PREPARE SKIN: Ensure areas of adhesion are free of any blood or other materials. Cleanse the skin with alcohol and allow to completely dry. Hair may need to be clipped depending on surgeon preference. Device adhesion to hair-bearing or oily skin may be poor.</p>
	<p>ADHERE STRIPS: Remove the backing strip from adhesive under the rigid, plastic zone with two holes. Adhere this portion facing the wound. Remove the backing from the remainder of the strip and adhere to the skin. Apply pressure to strip to ensure adhesion. Repeat this procedure for the other strip on the other side of the wound.</p>
	<p>RETENTION SUTURE: Perform a large full thickness bite of non-absorbable suture on each side of the wound through one of the holes in the HEMIGARD™ device as in diagram. We recommend large caliber (e.g. nylon 2-0 or larger). Tension is adjusted in the suture ends to appose the wound according to surgeon preference. For wounds under higher tension, further HEMIGARD™ strips and sutures may be required.</p>
	<p>FINISH CLOSURE: We recommend a layered closure be performed to support the HEMIGARD™ device. This should include buried absorbable sutures and some form of top closure (e.g. staples, sutures, steri-strips, glue, etc). OPTIONAL: Apply a strip of retention tape to secure lateral portions of HEMIGARD™ strips.</p>

WOUND CARE



The HEMIGARD™ device has been designed with withstand moisture, but patients should take precaution to avoid intentional soaking of the HEMIGARD™ strips. In the event that the HEMIGARD™ does get wet, allow to air dry. If the lateral portions of the HEMIGARD™ strips start to peel off the skin, then they

should be secured with adhesive tape by the patient (as in diagram)

PATENTS

Pat.: www.suturegard.com/patents

FREQUENTLY ASKED QUESTIONS

What specific wound care should be used?

Due to the wide variety of wound care products and specific wound care considerations, provider experience and judgement must be employed. In general, excessive moisture should be avoided.

Do you recommend any specific way to prepare the skin prior to applying the HEMIGARD™ strips?

Aside from clean, dry skin with clipped hair, we will occasionally apply a barrier film product, such as Cavilon™ or similar, to the wound edges prior to HEMIGARD™ application. If we desire additional adhesion, we may apply an acrylate glue.

How do I close the remaining wound?

Since the HEMIGARD™ devices and large caliber sutures will hold the majority of the wound closure tension, many options exist for closing the remainder of the wound. We will often use buried absorbable sutures with superficial glue or adhesive strips for the remainder of the wound closure.

SYMBOLS USED ON LABELLING

	Caution, consult accompanying documents
	Do not reuse
	Store at room temperature
	Sterilized using ethylene oxide.
	Batch code
	Catalog Number
	Use by date
	U.S. Federal Law restricts this device to sale by or on the order of a licensed physician
	Manufacturer



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