SUTUREGARD MEDICAL INC

INSTRUCTIONS FOR USE
HEMIGARD® Interlock

STERILE EO

DESCRIPTION
The HEMIGARD® Interlock device is a single use, disposable, sterile surgical device to be used in skin wound closures. There are two pieces per package, each with an adhesive backing. The longer piece with narrow strap has hooks facing down. The shorter piece has loops facing up. The two pieces interlock as detailed below to offload stress from the edges of the wound closure.

INTENDED USE
HEMIGARD® Interlock is indicated for closure of clean, non-contaminated acute (less than 8 hour) surgical skin wounds. For wounds that are wide and/or under tension, HEMIGARD® Interlock should be used in conjunction with other wound closure devices. Closure of the wound prior to deployment of HEMIGARD® Interlock devices may involve a combination of methods and devices including but not limited to absorbable sutures, nonabsorbable sutures, HEMIGARD® ASRD devices, staples, and/or topical adhesives. The choice of adjunctive wound closure devices and methods of use will depend on surgeon experience and preference.

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.

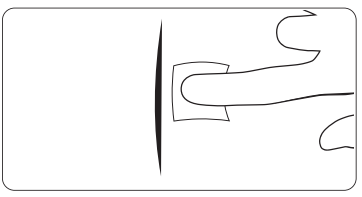
PRECAUTIONS
Excessive force applied for prolonged durations may lead to pressure injury or blistering. The amount of force and duration of application that are tolerable will vary with patients and wound location. If the method is used beyond a given wound's tolerability of pressure and/or duration, pressure injury may result. Excessive moisture from external sources or from sweating may weaken the adhesive and lead to device failure.

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.

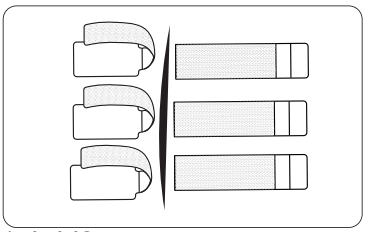
PRODUCT ORDERING
To order directly in the US or for product information, visit us at www.suturegard.com or email orders@suturegard.com.

HOW TO OPEN STERILE PACKAGE
Remove the two HEMIGARD® Interlock pieces from the pouch 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® Interlock pieces to gently fall into sterile field. 3. Discard packaging

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



PREPARE: Prior to use of HEMIGARD® Interlock devices, ensure that skin around wound is free of any blood or other materials. If applicable, degrease 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.



ADHERE: Remove the backing strip from the shorter HEMIGARD® Interlock piece (with loops) and apply with the loop section facing the wound. Remove the backing from the remainder of the strip and adhere to the skin. Remove the backing from the longer HEMIGARD® Interlock piece (with hooks) and apply so that the hooks of the strap will interlock with the loops. Apply pressure to each piece to ensure adhesion to the skin.

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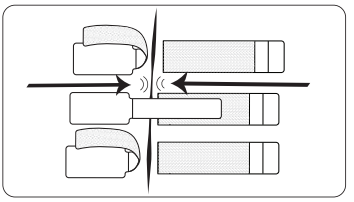
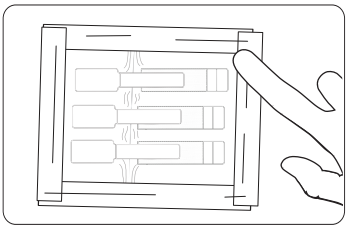


INTERLOCK: While pushing edges of the wound closure together, pull on the strap. This maneuver will visibly reduce stress on the wound edge. Interlock the hooks and loops to secure the closure. If re-tensioning is required, lift the strap, adjust tension and interlock again. Repeat above steps for all HEMIGARD® Interlock devices.



COVER: We recommend keeping the HEMIGARD® Interlock devices covered with a nonadherent dressing to prevent snagging of the device on clothing and other objects. HEMIGARD® Interlock devices may stay in place for up to three weeks.

PATENTS
Pat.: www.suturegard.com/patents

SYMBOLS USED ON LABELING

	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

SUTUREGARD Medical, Inc
4640 S Macadam Avenue, Suite 200D
Portland, Oregon 97239

Modified Date: 2022-10-01
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Revision 1

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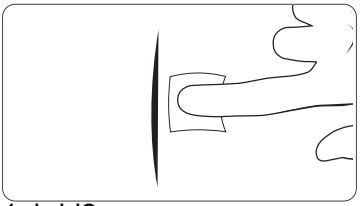

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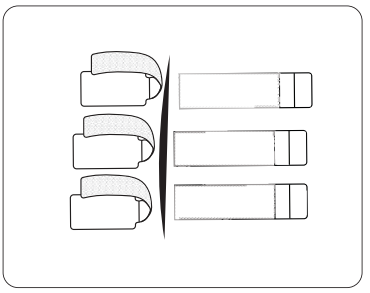

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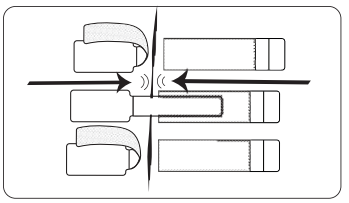

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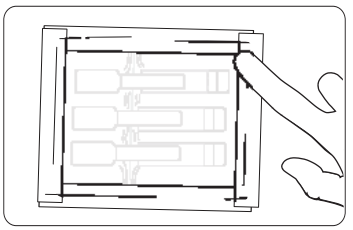

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