INSTRUCTIONS FOR USE
SUTUREGARD® Intraoperative Skin Relaxation Device

STERILE | EO

DESCRIPTION
SUTUREGARD® Intraoperative skin relaxation device is comprised of two components: (1) a sterile deformable suture bridge with soft elastomer covering and (2) a sterile circular suture guide with central aperture to collect suture ends.

INTENDED USE
The SUTUREGARD® Intraoperative Skin Relaxation Device is indicated for intraoperative support and/or skin stress-relaxation of non-contaminated, acute surgical wounds of **LESS THAN 3.0 cm** width.

WARNINGS
(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 re-sterilize the bridge or suture guide. (iii) Discard open, unused devices. (iv) Do not use if package is open, torn or damaged.

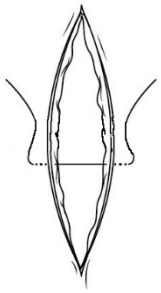
PRECAUTIONS
Excessive force applied for prolonged durations may lead to pressure injury. The amount of force and duration of application that are tolerable will vary with patients and wound location. If the method is used beyond a given wound's tolerability of pressure and/or duration, pressure injury may result. For those reasons, we recommend minimizing the duration and tension as much as possible. In clinical trials, most stress-relaxation occurs within the first 30 minutes of application. (www. suturegard.com/ publications)

POSSIBLE ADVERSE EFFECTS
While the device has been designed to absorb the force of a high-tension suture, 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.

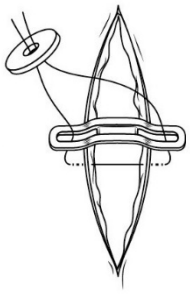
PRODUCT ORDERING
To order directly in the US or for product information, visit us at www.suturegard.com

SUGGESTED METHOD OF SUTUREGARD® INTRAOPERATIVE SKIN RELAXATION

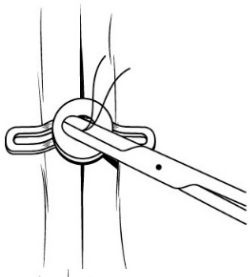
The SUTUREGARD® Intraoperative Skin Relaxation Device is indicated for intraoperative support and/or skin stress-relaxation of acute, non-contaminated surgical wounds of **LESS THAN 3.0 cm** width. The SUTUREGARD® Intraoperative Skin Relaxation Device should be selected for use depending upon patient condition, surgical experience, surgical technique, condition of peri-wound skin, wound size and wound tension. **The device must be removed within 5 hours of application**. In most instances, the device will be removed within 60 minutes of initial placement.



SUTURE: It is recommended to use a large caliber (e.g. USP 2-0 or larger) nonabsorbable (e.g. nylon) suture with appropriate needle to puncture skin. The suture is placed with large bite size (e.g. 10mm) so that the suture passes through the full thickness of skin on each side of the wound. We STRONGLY recommend removal of the surgical needle at this point.

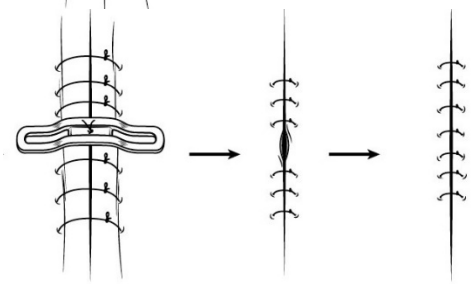


THREAD: Insert one suture end into each slot of the SUTUREGARD® bridge with the centrally elevated eversion bump pointing away from the skin (as shown). Optionally, the suture ends may be inserted through the SUTUREGARD® washer (as shown).



STRETCH: Apply tension to suture ends and secure with a clamp (as illustrated) or knot. If a clamp is used, it can be un-clamped to allow tension re-adjustment every 5-10 minutes (or at discretion of surgeon) and re-clamped.

CAUTION: Excessive suture tension may impart pressures on skin that may lead to pressure injury. The ability of a wound to tolerate pressure is dependent on many variables and requires surgeon judgement on a case-by-case basis.



CLOSE: Close sides of wound with suture and/or staples.

REMOVE the SUTUREGARD® bridge and washer from the wound. DISCARD the SUTUREGARD® bridge and washer immediately after removal.

The central portion of the wound can be closed or allowed to heal second intent as per surgeon preference.

HOW TO OPEN STERILE PACKAGE

Remove the SUTUREGARD 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 bridge and suture guide (washer) to gently fall into sterile field.
3. Discard packaging

FREQUENTLY ASKED QUESTIONS

How much tension can be applied to the wound?

In clinical trials of SUTUREGARD® device-assisted stress-relaxation, up to 25 Newtons (2.5 kg) of force has been applied to the suture. With such tensions, adverse events are uncommon (less than 10%) and include superficial pressure injury. In most cases, such injury heals within several weeks of routine wound care.

How do I prepare the wound for stress-relaxation?

The wound should be prepared with a standard surgical preparation at the start of the procedure. Prior to applying tension to the suture, the skin around the wound should be clean and dry.

How do I care for the wound after surgery?

The SUTUREGARD® bridge and washer **MUST** be removed and discarded prior to the final wound closure and application of dressings. Wound care and support (e.g. staple, suture) removal can be according to surgeon preference.

What kind of clamp do you recommend to secure the sutures?

We typically use the lightest available hemostat. Use of a heavier hemostat or needle driver will put asymmetrical pressure on the SUTUREGARD® device, increasing the risk of pressure injury.


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

PRODUCT ISSUES/COMPLAINTS

To report issues or problems with the use of this device, please contact SUTUREGARD Medical, Inc. at (844) 585-8431.

DemeTECH Corporation 14175 NW 60 Ave
Miami Lakes, FL 33014, USA

Modified Date:	2019-06-25
Document Number:	IFU-SRD-001
Revision:	1