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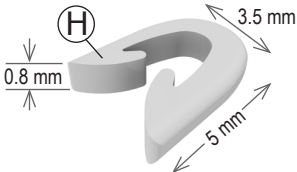
INSORB[®]
SUBCUTICULAR SKIN STAPLER

ALL 2000 SERIES STAPLERS

REF 2030

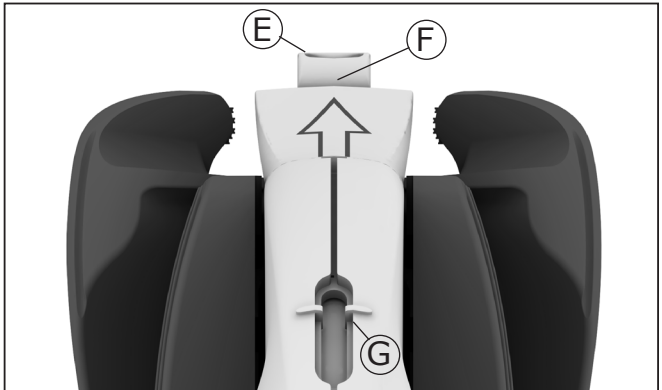
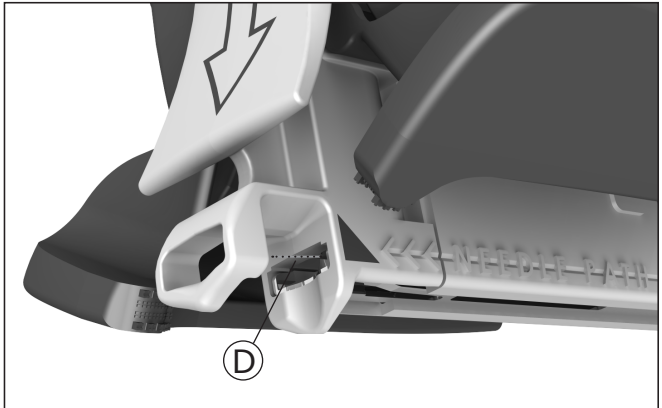
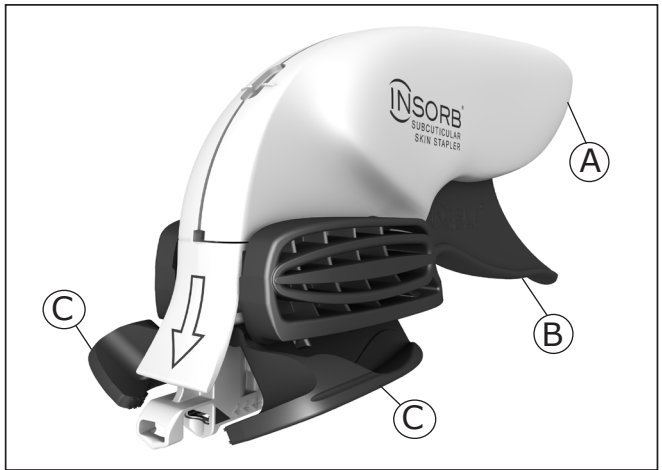
The INSORB Subcuticular Skin Stapler places an absorbable staple horizontally in the dermis to achieve an everted skin closure. The device presents tissue in the path of two surgically-sharpened needles to capture a precise 'bite' of dermis on both sides of the incision. A rigid, u-shaped absorbable staple with cleats secures the closure. INSORB Staples are made of an absorbable copolymer derived from lactic and glycolic acids which degrade in vivo by hydrolysis and then metabolized. Absorption begins as a loss of tensile strength without an appreciable loss of mass. At 10-12 weeks, the staple is approximately one-half its original mass, and the remainder is absorbed during the subsequent months.

- (A) Handle
- (B) Lever
- (C) Compression Arms
- (D) Needle Path
- (E) Nose
- (F) Forceps Mate Location
- (G) Staple Counter
- (H) Absorbable Staple



Post Operative Strength Profile

60% strength at 7 days
40% strength at 14 days
15% strength at 21 days



IMPORTANT:

Failure to properly follow the instructions may lead to serious surgical consequences. These directions are designed to assist in the use of the INSORB Stapler. It is NOT a reference to surgical stapling techniques.

PRODUCT DESCRIPTION:

The INSORB Subcuticular Skin Stapler is a sterile, single patient use device containing INSORB Absorbable Staples for skin closure.

INDICATIONS:

Synthetic absorbable INSORB Staples are intended for use in abdominal, thoracic, gynecologic, orthopedic, plastic and reconstructive surgery for the subcuticular closure of skin where an absorbable tissue fastener is desired for temporary tissue approximation.

CONTRAINDICATIONS:

1. Do NOT use the staple on scar tissue if an effective tissue capture can not be achieved.
2. Do NOT place a staple where the needle path is obstructed or a collision with any object may occur.
3. Do NOT use the staple on tissue which is too thin to permit an effective tissue capture.
4. Do NOT use the staple on tissue which is too thick to permit an effective tissue capture.
5. Do NOT use when radiopacity is necessary or desired since INSORB staples are radiotransparent.
6. Do NOT use where prolonged tissue approximation beyond that needed for normal skin tissue closure is necessary or desired.

PRECAUTION:

- TENSION - Placement of supporting sutures or other closure augmentation may be required to ensure closure integrity when excessive tension on the wound edge is or may be present, e.g. high-tension areas, obese patients, excisions, or wounds that may experience significant swelling.

ADVERSE REACTIONS:

Adverse reactions may include wound separation, infection, bleeding, hematoma, seroma, skin edge necrosis, pain, acute inflammation, erythema, edema, swelling, excessive itching, irritation, bruising, drainage, prolonged wound eversion, surfacing staples, percutaneous staples, anxiety, and compromised cosmesis, e.g., keloid, hypertrophic scar, scar widening, discoloration, and hyperpigmentation.

OTHER NOTES:

- TISSUE DRAPE –External perforation of the skin with a staple or superficial staples will occur if the tissue is not properly draped across the “Blue Triangles”.
- NEEDLE DAMAGE– ANY contact with a forceps, previously placed staple or other object WILL cause damage to the needles. If ANY damage is suspected, or if the device is not operating smoothly, discard and replace the device.
- SCAR TISSUE –Full excision of all scar tissue to virgin tissue edges may be required to achieve an effective wound closure.
- REMOVING STAPLE DURING SURGERY Grasp the back of the staple and pull firmly to extract. Alternative: retract and cut away the exposed portion of the staple with scissor.
- FORCEPS - Closure may also be completed with two (2) Adson Forceps or the INSORB|1 Forceps.
- SINGLE PATIENT USE - Do NOT resterilize. Staple strength is affected by heat, humidity, and excess radiation. Resterilization may result in wound separations. Dispose of all opened products whether used or unused in a designated sharps container.
- WOUND CARE – The use of adhesive strips is encouraged. The INSORB Staple provides an interrupted closure which allows post-operative drainage that may be noted at the first dressing change.
- STORE AT 20-25°C (68-77°F)
- DO NOT EXPOSE TO 50°C (122°F) – Avoid prolonged exposure to elevated temperatures. Do NOT use the staplers if the temperature dot on the front flap of the carton is RED.

INSTRUCTIONS

1

GRASP 5mm & LIFT

2

MATE & FIRE

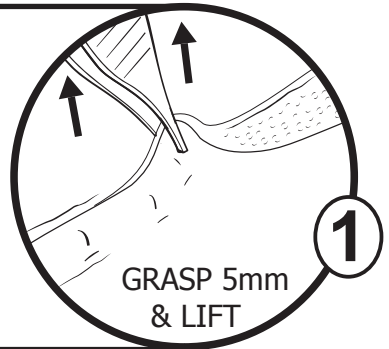
Cover the Blue Triangles (▲) for Proper Subcuticular Placement

- In TIGHT SPACES, rock Stapler side-to-side.
- For final Staple placement, reverse the direction of closure.

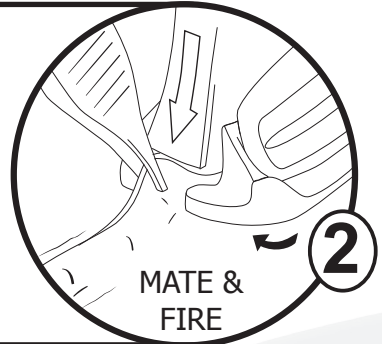
FOR USE:

- Remove the red tab prior to use.

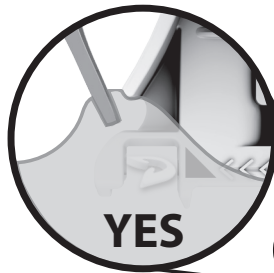
Using 1 Adson forceps, GRASP 5mm of the tissue at an apex or directly above a previously placed staple and LIFT to present tissue to the Stapler.



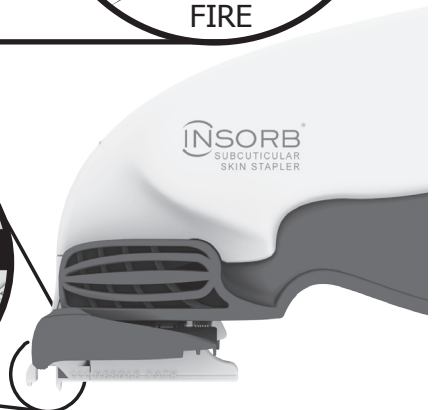
Firmly MATE the Stapler with the Adson forceps directly below the arrow and FIRE the Stapler with a smooth deliberate squeeze until audible click, then release. Lift straight up to remove the Stapler.



Blue Triangles **NOT** Covered
External Placement



Blue Triangles Covered
Subcuticular Placement



NOTE: Grasping more than 5mm of tissue and/or not firmly mating the Stapler and forceps may result in placing Staples too deep and/or too far apart which may compromise wound integrity.



Horizontal, Subcuticular, Absorbable Staples placed at 7mm intervals

NEEDLESTICK SAFETY:

The INSORB Stapler complies with the Needlestick Safety and Prevention Act as a U.S. OSHA-defined SESIP (sharps with engineered sharps injury protections). The INSORB Stapler's built-in safety features effectively reduce the risk of an exposure incident. The Bloodborne Pathogens Standard clarifies the need for employers to select safer needle devices and to involve employees in identifying and selecting these devices.

Read IFU	Single Patient Use	Store away from HEAT	Do NOT Use if damaged	Batch Code	Expiration Date	Sterile - Gamma	CE Mark 0086

Certifications: INSORB Staplers contain NO Latex, NO PVC and NO plasticizers used in PVC, like Di(2-ethylhexyl)phthalate (DEHP).
 INSORB Staplers contain NO Substances of Very High Concern (SVHC) per REACH (EC) No 1907/2006 (ECHA)
 INSORB Staplers contain NO medicinal products, NO human blood derivatives, and NO animal derived materials

Caution: Federal (USA) law restricts this device to sale, distribution, and use by, or on the order of, a physician.

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