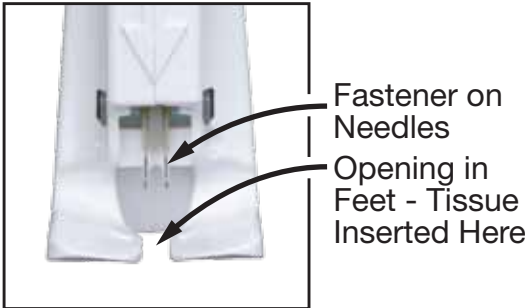
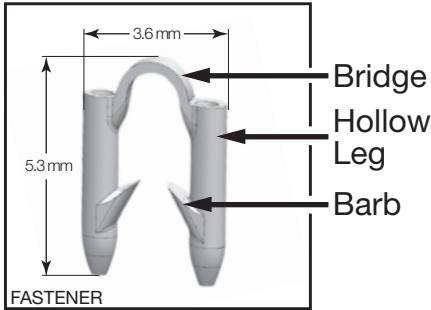


SubQ It!®

Bioabsorbable Skin Closure System

REF 404010



DEVICE DESCRIPTION

THE SUBQ IT! BIOABSORBABLE SKIN CLOSURE SYSTEM is comprised of a manual stapler preloaded with 10 bioabsorbable fasteners, sufficient for up to 6 short incisions requiring 1-2 fasteners each or an incision up to 10 cm long. The stapler inserts SubQ It! fasteners into the underside of the dermis that is exposed by everting the skin edges over the device feet to obtain a subcutaneous closure.

THE SUBQ IT! FASTENER is only 5.3 mm long and weighs 0.006 grams. It is molded from a polyglycolic/poly-lactic acid copolymer, a well-established material for resorbable medical devices. The fastener degrades by hydrolysis and is absorbed by normal physiological processes. After 6-9 weeks the fastener is sufficiently integrated that it cannot be palpated and is completely absorbed in subsequent months.



READ INSTRUCTIONS FOR USE ON THE FOLLOWING PAGES

In-service training is necessary prior to clinical use of the SubQ It! system.





INSTRUCTIONS FOR USE

Requires two people. Tasks for **ASSISTANT** and **SURGEON** are summarized here.

These directions do not replace requirement for in-service training prior to clinical use.

1 Remove Safety Lock



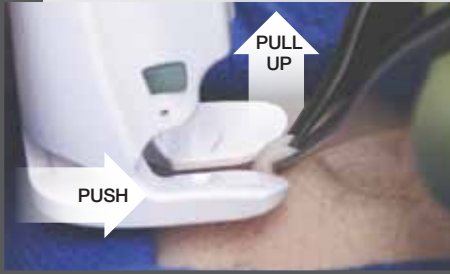
ASSISTANT: Using sterile technique, remove the SubQ It! Stapler from the foil pouch and remove the safety lock by a twisting/pulling motion.

2 Raise Tissue with Adson Forceps



SURGEON: Use two Adson forceps to firmly grasp up to 3 mm of tissue on each side at the point to be fastened. Bring forceps together and pull up to allow feet to slide around dermal tissue.

3 Slide Stapler into Position



ASSISTANT: Slide the SubQ It! stapler into position immediately below the forceps. If the tissue is thick, pushing the body of the stapler with your other hand as shown, and/or using a rocking motion will help gather tissue into the opening in the feet.

SURGEON: Hold tissue above the feet and tell assistant when the tips of Adsons are aligned with the Forceps Locators.

4 Press Forceps into Locators



ASSISTANT: Hold stapler up so that forceps can be pressed into Forceps Locators.

SURGEON: Press tips of Adsons into Forceps Locators and press down to lower stapler to skin surface.

CAUTION: if the plunger is pressed down partially and released without penetrating tissue, the fastener will fall from the needles and/or jam the mechanism.

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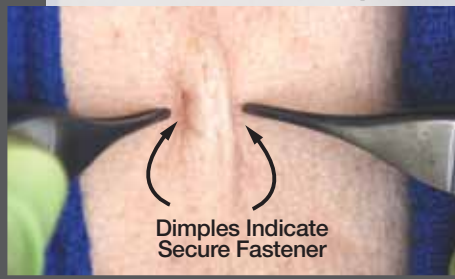
5 Press Plunger Down Until it Stops



SURGEON: When satisfied with position tell assistant to deploy staple.

ASSISTANT: Hold stapler firmly against the skin surface and press plunger down in a smooth and deliberate motion until it stops. If plunger will not advance, due to all fasteners being deployed, or mechanical problems, inform Surgeon and obtain another stapler.

6 Release and Remove Stapler



ASSISTANT: Release thumb pressure and allow plunger to retract. Lift stapler to remove or reposition for the next staple.

SURGEON: Release Adson forceps and allow tissue to fold closed. Examine incision for secure apposition - small dimples and mildly raised appearance. If a fastener is not secure it may be removed (see OTHER NOTES) or another fastener may be added nearby.

7 Expected Appearance



SURGEON: If additional sutures are needed repeat from step 2, spacing fasteners approximately 7-10 mm apart. When finished, confirm that incision is secure and no more fasteners are needed. Additional fasteners may be placed between previous ones if needed.

OTHER NOTES

ADSON FORCEPS: Two Adson forceps with mouse tooth tips must be used. Do not attempt to use smooth tipped forceps. Be careful not to allow tissue to slip out of forceps after needles are engaged as this will bend needles.

IF FASTENER IS NOT SECURE: If security of a fastener is questionable, it may be left in place, adding another fastener nearby to strengthen the incision. If an unsecured fastener is to be removed during surgery, pull gently on the unsecured leg with hemostat forceps. Clip the unsecured portion of the fastener with scissors close to the tissue and remove. Replace with another fastener.

IF INCISION NEEDS TO BE REOPENED: Use hemostat forceps to find and pinch bridge section of each fastener. Clip on each side of forceps close to the tissue with scissors and remove.

NEEDLE DAMAGE: Needles may be damaged if they strike forceps or other obstruction. Do not use if needles are bent or plunger does not operate smoothly. If any damage is suspected discard and replace device.

POSTOPERATIVE CARE: Apply postoperative dressing of choice for surgical incisions. With water tight dressings, the incision area may be bathed within 24 hours and dressing removed by the patient in 3-5 days.

STORAGE: Store at 15-30°C (59-86°F).

DO NOT EXPOSE TO 50°C (122°F): Keep away from heat. Do NOT use the SubQ It! device if the temperature dot on the foil pouch is blackened.

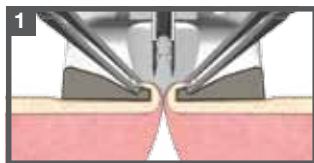
DISPOSAL: Dispose of stapler in a designated sharps container.

SubQ It!®

Bioabsorbable Skin Closure System

PRINCIPLES OF OPERATION

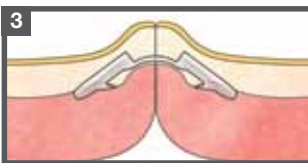
1. The barbed legs of the fastener are hollow and supported by surgical needles during insertion.
2. Once inserted, the needles are retracted leaving the fastener imbedded in the dermal tissue.
3. The barbs catch and the bridge flexes under tension, holding the two sides of the incision in



Adson Forceps used to fold each side of incision over foot to expose sub-dermal tissue.



Needles drive fastener legs into tissue and then retract, barbs on each leg catch in tissue.



Legs spread angularly, incision is held together by tensile strength of the bridge.

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

INDICATION FOR USE / INTENDED USE

The SubQ It! Bioabsorbable Skin Closure System is intended for use in humans for 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 on tissue that is too thin. Tissue is too thin if a full pinch is less than 3 mm across.
2. Do not use on tissue that is too thick. Tissue is too thick if it cannot be inserted between the feet.
3. Do not use if critical tissue or implanted device is within 10 mm of skin surface (i.e. nerve, tendon, vein, pacemaker, venous access port, etc.).
4. Do not use on incisions that can only be brought together under excessive tension or incisions that will be placed under excessive force within 7 days of surgery. Other modalities should be used to relieve tension and properly appose the skin edges.

WARNING

1. DO NOT remove Safety Lock until ready for use. Note needle path and do not press plunger down if needle exposure would cause harm. A safety stop blocks needles from being exposed after last fastener is deployed. Do not attempt to force plunger down against safety stop.
2. Single Patient Use - DO NOT resterilize. Bioabsorbable fasteners are degraded by heat, humidity, and excess radiation.

PRECAUTIONS

1. SubQ It! has not been evaluated on incisions through scar tissue and results may be variable.
2. SubQ It! has not been evaluated on incisions over joints which will be flexed during healing and results may be variable.

ADVERSE REACTIONS

Adverse reactions may include swelling, bruising, acute inflammation, erythema, edema, drainage, hematoma, surfacing fasteners, dehiscence, necrosis, scar widening, discoloration and hyperpigmentation.

Patents protecting this device:
U.S. 8,506,591 and 9,232,943; China
ZL 200780032463.4; Japan5667976;
Australia 2007269655; Canada
2,655,197; Europe EP 2,034,904 and
2,762,089; other patents pending.

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