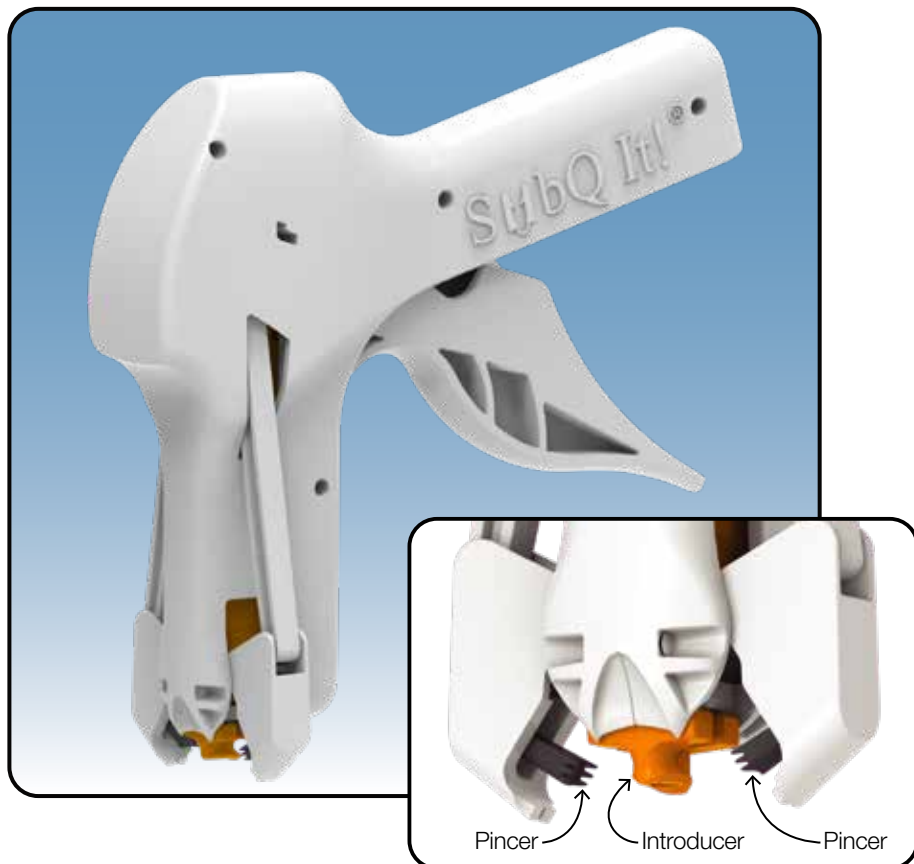


Bioabsorbable Subcuticular Closure



INSTRUCTIONS FOR USE

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



DEVICE DESCRIPTION

THE SUBQ IT! BIO-ABSORBABLE SUBCUTICULAR CLOSURE DEVICE is preloaded with 10 bio-absorbable fasteners, sufficient for up to 6 short incisions requiring 1-2 fasteners each or an incision up to 10 cm long. The driver inserts SubQ It! Fasteners into the underside of the dermis to obtain wound closure.

THE SUBQ IT! FASTENER is only 5.3 mm long and weighs 0.006 grams. It is molded from a polyglycolic/polylactic acid copolymer, a well-established material for resorbable medical devices. Fasteners maintain 80% of their strength for 21 days to support healing and then degrade by hydrolysis and are absorbed by normal physiological processes in subsequent months.



READ INSTRUCTIONS FOR USE ON INSIDE PAGES

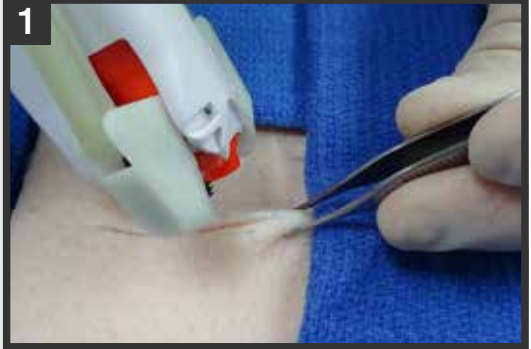
In-service training is necessary prior to clinical use of the SubQ It! system.



Longer Incisions

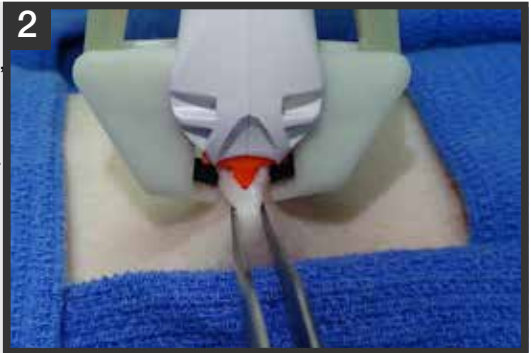
[1b] Lift Tissue at Distal Apex

Using forceps, grasp apex of incision and LIFT to present tissue edges to the SubQ It! driver.



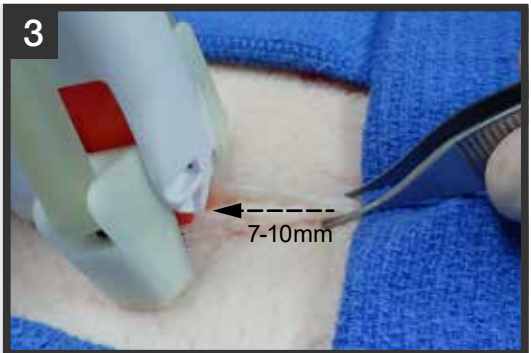
[2b] Mate with Forceps and Fire

Place the orange Introducer into incision, covering both sides evenly with tissue. Partially squeeze the handle to close pincers and verify capture on both sides. If necessary, release handle and reposition. When correct positioning is confirmed, fully squeeze the handle to deploy the fastener.



[3b] Reposition for Additional Fasteners

Maintain orange Introducer within the wound edges and move approximately 7-10mm.



[4b] Repeat Until the Incision is Closed

Grasp tissue at dimples of the previous fastener, lift tissue, and repeat steps 2 and 3. Assess closure by spreading the wound. Additional fasteners may be added if needed.



[1a] Tail-first Insertion

Using forceps, open side of the incision. Place pointed tail of Introducer into incision first and rock forward to fully insert Introducer.



[2a] Lift Edges and Pinch

Reposition forceps to the apex and lift to cover both sides of the Introducer. Edges should be equal and brought high enough to be captured by black pincers. Partially squeeze the handle to close pincers and verify capture on both sides. If necessary, release handle and reposition.



[3a] Expected Appearance

When correct positioning is confirmed, fully squeeze the handle to deploy the fastener. Once full deployment is achieved, the handle will release, and the device can be removed. Assess closure by spreading wound.



OTHER NOTES:

1. REPOSITION: Do not squeeze handle beyond engagement point until ready to insert fastener. If handle is already squeezed beyond engagement point and you wish to reposition, either (a) deploy fastener and remove after deployment, or (b) forcefully open the handle to overcome the single direction mechanism. Obtain another device if handle is forcefully opened as remaining fasteners may jam.

2. JAMS: If device jams while engaged with tissue, forcefully open the handle to overcome the single direction mechanism and allow for removal of device from tissue. Obtain another device.

IF FASTENER IS NOT SECURE: If an unsecure or misplaced fastener is to be removed during surgery, pull gently on the unsecured leg with hemostat forceps and cut the fastener with scissors close to the tissue.

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.

POSTOPERATIVE CARE: Apply postoperative dressing of choice as you would for surgical incisions closed with interrupted subcuticular sutures.

STORAGE: Store at 15-30°C (59-86°F).

DO NOT EXPOSE TO 49°C (120°F): Keep away from heat. Do NOT use the SubQ It! device if the temperature dot on the shelf box is blackened.

NEEDLESTICK SAFETY: The SubQ It! driver complies with the Needlestick Safety and Prevention Act as a U.S. OSHA-defined SESIP (sharps with engineered sharps injury protections) effectively reducing the risk of an exposure incident.

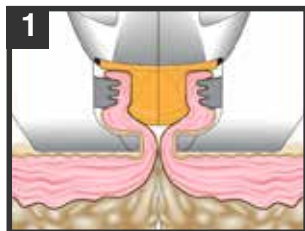
DISPOSAL: Dispose of driver in a designated sharps container.

SubQ It!®

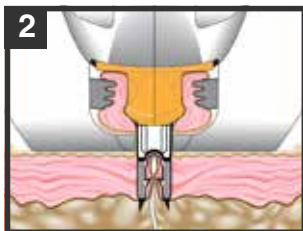
Bioabsorbable Subcuticular Closure

PRINCIPLES OF OPERATION

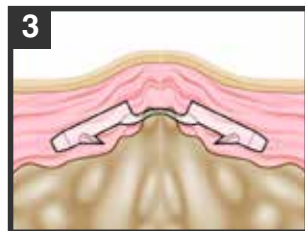
1. The barbed legs of the fastener are hollow and supported by surgical needles during insertion.
2. Once inserted, the needles are retracted leaving the fastener engaged in the dermal tissue.
3. The barbs catch and the bridge flexes under tension, holding the two sides of the incision in apposition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



SubQ It! Stapler Everts Tissue



Fastener Inserted into Dermis Under The Skin



Set Back Dermal Technique with SubQ It! Fastener

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! bio-absorbable subcuticular skin stapler 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 3mm thick or dermis is less than 1mm thick.
2. Do not use on tissue that is too thick. Tissue is too thick if it impedes device from fully closing.
3. Do not insert fasteners if bone or other obstructions (e.g. nerve, tendon, vein, pacemaker, venous access port, etc.) are within 10 mm of the bottom of the feet.
4. Do not use on incisions through scar tissue as barbs may not engage securely.
5. 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.

WARNINGS

1. Single Patient Use - DO NOT re-sterilize. Bio-absorbable fasteners are degraded by heat, humidity, and excess radiation.

PRECAUTIONS

1. SubQ It! has not been evaluated on incisions over joints which will be flexed during healing and results may be variable.
2. Note needle path and do not squeeze handle if needle exposure would cause harm. A safety stop blocks needles from being exposed after the last fastener is deployed. Do not attempt to force handle to overcome the safety stop.

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, 9,232,943, 10,045,777, 10,441,278, 10,758,227, 11,826,049 ; China ZL 200780032463.4;

Japan 5667976; Australia 2007269655; Canada 2,655,197; Hong Kong HK1123961; Europe EP 2,034,904 and 2,762,089; other patents pending.

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Stapler assembled in U.S.A.
using U.S. and foreign
parts.