

LA #:

LA000854

Revision:

B

INCISIVE Surgical
Page 1 of 1

Specification – Label

--INTERNAL USE ONLY--

IFU, INSOB 8-STAPLE STAPLER

Purpose of Part or Design

Instruction for Use (IFU) for INSOB Shorty Model 1008, English Only

Supplier Name, Supplier ID# and Contact Info

IFU can be printed by office copiers or by external printers for High Volume Orders (example: Imagine Print Solutions ASIMA001)

Size, Dimensions, Color, Configuration, Catalog Number, or Model Number

Printed onto white "Laser" paper (24 lb) and folded to approximately 5-1/2" x 7"

Item	Description	C = 0 Sampling Plan	Inspection Method
1	Artwork (revision printed on page 4 in block)	10	Visual
2	Folded Dimensions: 5-1/2"±1/16" x 7"±1/16"	10	Steel Rule or Caliper
3	Legibility	10	Visual

ENGLISH / EN
INSORB
REF 1008

The INSOB Subcuticular Skin Stapler places an absorbable staple in the dermis to achieve an assisted skin closure. The device prevents tissue in the path of two surgically-advanced needles to capture a precise fiber of dermis on both sides of the incision. A right, angled absorbable staple with clear anchors secures the closure. INSOB Staples are made of an absorbable copolymer derived from lactide and glycolic acids which degrade in vivo by hydrolysis and steam sterilization. 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 - Plunger
C - Compression Arms
D - Needle Path
E - Trigger
F - Jaw
G - Trigger Main Lockout
H - Absorbable Subcuticular Staple

Final Staple Length: 1.5mm
Final Staple Width: 40% strength at 10 days strength at 21 days

IMPORTANT:
Failure to properly follow the instructions may lead to various surgical consequences. These directions are designed to describe the use of the INSOB Stapler. They are NOT a reference to surgical stapling techniques.

PRODUCT DESCRIPTION:
The INSOB Subcuticular Skin Stapler is a sterile, single patient use device containing INSOB Absorbable Staples for skin closure.

INDICATIONS:
Synthetic absorbable INSOB Staples are intended for use in the subcuticular closure of skin where an absorbable tissue fastener is desired for temporary tissue approximation.

CONTRAINDICATIONS:

- Do NOT use the stapler on ear tissue if an effective tissue closure can not be achieved.
- Do NOT place a staple where the needle path is obstructed or a solution with any solvent may be administered to the tissue which is too thin to permit an effective tissue capture.
- Do NOT use the stapler on tissue which is too thin to permit an effective tissue capture.
- Do NOT use when suboptimal or necessary or desired since INSOB staples are nonabsorbent.
- Do NOT use where prolonged tissue approximation beyond that needed for normal skin tissue closure is necessary or desired.

PRECAUTION:
TENSION: Placement of deep supporting sutures is required to ensure closure integrity when excessive tension on the wound edge is or may be present, e.g. high tension areas, high BMI, excisions, and/or wounds that may experience significant swelling. These sutures must be placed at least 1cm from the wound edge to allow sufficient tissue to cover the Triangles on the nose of the Stapler. See graphic at right.

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 tension, surfacing staples, paronychia, pustules, superficial staples, anxiety, and compressed osseous, e.g., nasal, hypertrophic scar, scar widening, discoloration, and hyperpigmentation.

OTHER NOTES:

- FORCEPS:** Closure may also be completed with two (2) Adson Forceps or the INSOB Forceps.
- EXCISIONS:** If the Staples are used to close the deep dermal layer in excisional closures, a subcuticular running suture placed above the Staples is encouraged.
- NEEDLE DAMAGE:** ANY contact with a foreign or other sharp (FRL) object damage to the needles and compromise performance. If ANY damage is suspected, or if the device is not operating smoothly, discard and replace.
- ANTI-REVERSE:** The stapler includes an anti-reverse mechanism to insure users reverse the plunger fully before release. If necessary, pull the plunger firmly backward to override the anti-reverse.
- SCAR TISSUE:** Full excision of all scar tissue to origin tissue edges may be required to achieve an effective wound closure.
- REMOVING STAPLES DURING SURGERY:** Grasp the base of the staple and pull firmly to extract.
- POST-OPERATIVE WOUND ACCESS:** To partially or fully open the incision, use scissors to cut the backhead of the Stapler. It is not necessary to remove staple fragments.
- SINGLE PATIENT USE:** Do NOT sterilize. Staple strength is affected by heat, humidity, and radiation. Sterilization with compromised performance and wound integrity, which may result in a wound separation. Properly dispose of all opened products whether used or unused.
- WOUND CARE:** The use of adhesive dressings or skin glue is encouraged for external wound protection. This device provides an interrupted closure which allows immediate post-operative drainage that will be sealed at 14-21°C (57-70°F).
- STORAGE:** AT 14-21°C (57-70°F)
- DO NOT EXPOSE TO 30°C (122°F):** Avoid prolonged exposure to elevated temperatures. Do NOT use the stapler if the temperature scale on the front face of the carrier has changed to RED.

INSORB Shorty Skin Closure Technique:

1 GRASP 5mm & LIFT

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.

* To ensure Staples are placed at 7mm intervals

2 MATE & FIRE

While maintaining the lift, place the nose into the wound to firmly MATE the Stapler with the Adson forceps directly below the arrow and FIRE the Stapler by depressing the plunger until the final audible click, then release. Lift straight up to remove the Stapler - do not pull backwards.

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.

To minimize superficial or external Staple placements in Ports and Short Incisions:

- The compression arms close sequentially when depressing the plunger to allow the user to grasp tissue edges individually.
- Ensure both Triangles are covered by skin. If necessary, rock Stapler side-to-side when in tissue or tight spaces, e.g. final Staple placement.
- Reverse the direction of closure for final Staple placement.

NEEDLE SAFETY:
The INSOB Stapler complies with the Needle-Sharp Safety and Prevention Act as a U.S. 21066 defined DSDP (device with engineered sharps injury prevention). The INSOB Stapler's built-in safety features effectively reduce the risk of an accidental needlestick. The Standard Precautions Checklist contains the need for employees to select safer needle devices and to involve employees in identifying and selecting those devices.

Recall #101 Stage 1
Stage 2
Stage 3
Stage 4
Stage 5
Stage 6
Stage 7
Stage 8
Stage 9
Stage 10
Stage 11
Stage 12
Stage 13
Stage 14
Stage 15
Stage 16
Stage 17
Stage 18
Stage 19
Stage 20
Stage 21
Stage 22
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Stage 93
Stage 94
Stage 95
Stage 96
Stage 97
Stage 98
Stage 99
Stage 100

Continuation: Not used on external sites. Not used with FRL or penetration point (FRL, No. 102) electrocautery (ECP). Not used with substance of any type (Common ECPs per REACH #2) the INSOB (ECP). Not used with external products. Not used with laser devices. Not used with alcohol-based hand rubs.

Caution: DO NOT TYPICAL (ECP) use needles from boxes to skin, dissection, and use only on the order of a physician.

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Packaging and Storage Conditions:

Printed as required.

Handling Precautions, Safety Issues, or Environmental/Waste Requirements:

Not Applicable.

Shelf Life:

Not Applicable.

Revision History:

Revision	Description of Change	Final	DCO #	Date
A	Initial Release	CJS	002306	12/10/14
B	UPDATED ARTWORK FOR BETTER CONTRAST. ADDED TOLERANCE FOR DIMENSIONS OF PAPER.	MER	002384	3/13/15