PRODUCT DATA SHEET

COMPANY	
Company Name Street Address City, State, Zip Country	
EMAIL	Firstname.lastname@coopersurgical.com
PHONE	+00 00 00 00 00 00

VIGILANCE CONTACT	
Contact Name	
EMAIL	EmailAddress@coopersurgical.com
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PRODUCT

INSORB® Subcuticular Skin Stapler

PRODUCT CODE

2030-E

DIMENSIONS

Staple:

- Thickness: 0.8 mm
- Width: 3.5 mm
- Length: 5 mm

Stapler:

- Length: 165.1 mm
- Height: 92.2 mm
- Width: 1.19 mm

COMPONENTS

A. Handle
B. Lever
C. Compression Arms
D. Staple

MATERIALS

- Copolymer of poly-Lactide and poly-Glycolide

DEVICE DESCRIPTION

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

INTENDED USE

The INSORB® Subcuticular Skin Stapler is intended for skin closure. Synthetic absorbable INSORB Staples are intended for use in the subcuticular closure of skin where an absorbable tissue fastener is desired for temporary tissue approximation.

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95 Corporate Drive, Trumbull, CT 06611

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CONTRAINDICATIONS

Due to the risk of wound dehiscence, do not use when more than 21 days of tissue approximation 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 1 cm from the wound edge to allow sufficient tissues to cover the Blue Triangles on the nose of Stapler.

RECOMMENDED STORAGE INSTRUCTIONS

- Store at 16°-25° Celsius (61°-77° Fahrenheit).
- DO NOT EXPOSE TO 50°C (122°F) – Avoid prolonged exposure to elevated temperatures. Do NOT use the staplers if the temperature circle on the front flap of the carton has changed to RED.

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Composition materials in direct contact with the patient	Staple: Copolymer of poly-Lactide and poly-Glycolide
FDA Statement	Absent
CE Mark	MDR 768190 MDR 768070
Classification	EU Class III implantable FDA CLASS II
Notified body number	BSI 2797
EU REP	CooperSurgical Distribution B.V. Celsiusweg 35 5928 PR Venlo The Netherlands
Manufacturer	CooperSurgical, Inc.
Single Use	Yes
Country of Origin	USA
Sterilization	Yes
Sterilization address	Sterigenics, Inc. 1003 Lakeside Drive, Gurnee, IL 60031 USA 847-855-0999
Sterilization method	RAD
Shelf Life	2 Years / 24 Months
Biological origin	Absence
Natural Rubber Latex	Absence
DEHP	Absence
Phthalate	Absence
Packaging 2030 - 6 Each / Box	Dimensions: Depth: 7.9 in (20 cm) Height: 8.2 in (21 cm) Width: 6.2 in (18 cm) Weight: 2 lb (907 g)
GTIN	Level 1: 00888937027228 Level 2: 20888937027222

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