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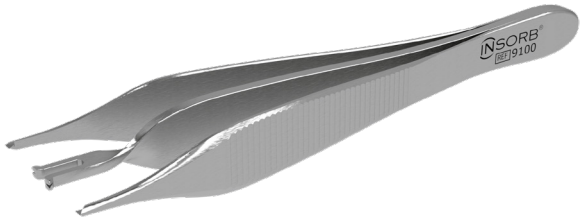

Cooper Surgical
9100 INSORB® |1 Forceps

Instructions for use

PRODUCT DESCRIPTION

The INSORB®|1 Forceps is a reusable, dual-tip, sequentially closing hand-held device specifically designed to enable a single clinician to approximate skin in both general and plastic surgery wound closure.

The sequential closing feature of the INSORB®|1 Forceps enables a clinician to focus on grasping 5 mm of the first wound edge and then proceed to grasp 5 mm of the opposing wound edge with one hand while the other hand operates the INSORB® Stapler.

Tissue grasping technique using the INSORB®|1 Forceps determines two INSORB® Stapler outputs:

- Staple to Staple Spacing.
  This spacing is determined by the clinicians grasp locations along the incision. Grasping as close as possible to the previously placed staple or incision apex minimizes the staple-to-staple interval. The recommended staple-to-staple interval is 7 mm; wider intervals may not be as secure.
- Staple Depth.
  The INSORB® Staple depth within the incision is determined by the amount of tissue the clinician grasps prior to mating the INSORB®|1 Forceps with the stapler. Grasping 5 mm of tissue is recommended to ensure proper INSORB® Staple depth.

The use of this forceps is not required to place INSORB® Staples. Usage of a standard, single Adson forceps is described by the Instructions for Use included with INSORB® Staplers.

CONTRAINDICATIONS

The INSORB®|1 Forceps has no known contraindications.

INDICATIONS FOR USE

The INSORB®|1 Forceps is a hand-held General Surgical Instrument for tissue approximation during skin closure.

HOW SUPPLIED

The INSORB®|1 Forceps is packaged as non-sterile. Device must be cleaned and steam sterilized prior to use.

LIMITATIONS ON REPROCESSING

Repeated reprocessing has minimal effect on the INSORB®|1 Forceps. End of life is determined by wear and damage. Prior to use, inspect the INSORB®|1 Forceps to ensure proper function and condition. Do not use the device if it is damaged, broken, or fails to perform as intended.

WARNINGS

The INSORB®|1 Forceps shall be used in accordance with the REF 9100 Instructions for Use. Read all sections prior to use.

Improper use of the INSORB®|1 Forceps may cause serious injury.

Improper cleaning, sterilization, and maintenance of the INSORB®|1 Forceps may damage and / or render the device non-sterile prior to patient use and could cause serious injury to the patient or health care provider.

PRECAUTIONS

The INSORB®|1 Forceps is intended for surgical use only.

Using the INSORB®|1 Forceps for a task other than that for which it is intended may result in a damaged or broken device.

Only the cleaning and sterilization processes defined within the REF 9100 Instructions for Use have been validated.

PRE-CLEANING INSTRUCTIONS

DO NOT ALLOW INSTRUMENTS TO DRY AFTER USE. Initiate cleaning within 2 hours after use

Immediately following surgery remove excess, gross soil by rinsing or wiping the device and then soaking the INSORB®|1 Forceps for a minimum of 30 minutes in neutral-pH detergent.

AUTOMATIC CLEANING INSTRUCTIONS

1. Ensure all cleaning instructions are followed prior to automatic cleaning.
2. Process the device per the validated cleaning cycle below.
3. After drying, if visible moisture is present, dry the INSORB®|1 Forceps with a clean, lint-free towel.
4. Visually examine the INSORB®|1 Forceps for cleanliness.
5. If visible soil remains, repeat this automatic cleaning procedure.

REF 9100 INSORB®|1 Forceps Validated Cleaning Cycle

Phase	Time	Temperature	Detergent and Concentration
Pre-wash	2 minutes	Cold Tap Water	No detergent
Enzyme Wash	2 minutes	Hot Tap Water	Enzol®, 1 oz. per gallon
Wash	2 minutes	65.5 °C	Valsure® Neutral, ¼ oz. per gallon
Rinse	1 minute	Hot Tap Water	No detergent
Dry	7 minutes	90 °C	No detergent

Immediately proceed from cleaning to the validated Sterlization Cycle below. Do not store instrument prior to sterilization.

STERILIZATION INSTRUCTIONS

REF 9100 INSORB®|1 Forceps Validated Steam Sterilization Cycle	
Sterilizer Type	Pre-vacuum
Preconditioning Pulses	4 pulses
Minimum Temperature	132 °C
Exposure Time	4 minutes
Dry Time	30 minutes
Sterilization Wrap	Halyard® H600 Sequential Sterilization Wrap, Individually wrapped

INSPECTION & MAINTENANCE

Proper care and handling is essential for satisfactory performance of any surgical device. The previous precautions should be taken to ensure long and trouble-free service from your INSORB®|1 Forceps.

Inspect the INSORB®|1 Forceps before each use for broken, cracked, tarnished or corroded surfaces, and chipped or worn parts. If any of these conditions appear, do not use the device and discard it appropriately.

STORAGE

After sterilization, the INSORB®|1 Forceps must remain in sterilization packaging and be stored in a clean, dry environment.

GLOSSARY OF SYMBOLS

Ref #	Symbol	Title	Description	Standard Development Organization
5.1.6		Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1
5.1.5		Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1
5.4.3		Consult instructions for use	Indicates then eed for the user to consult the instructions for use.	ISO 15223-1
5.4.4		Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1
5.2.7		Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	
5.1.1		Manufacturer	Indicates the medical device manufacturer, as defined in EU Directive 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO 15223-1
n.a.	R_x Only	Prescription device	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.	21 CFR 801.109

Made in Germany

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