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

<table>
<thead>
<tr>
<th>Phase</th>
<th>Time</th>
<th>Temperature</th>
<th>Detergent and Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-wash</td>
<td>2 minutes</td>
<td>Cold Tap Water</td>
<td>No detergent</td>
</tr>
<tr>
<td>Enzyme Wash</td>
<td>2 minutes</td>
<td>Hot Tap Water</td>
<td>Enzol®, 1 oz. per gallon</td>
</tr>
<tr>
<td>Wash</td>
<td>2 minutes</td>
<td>65.5 °C</td>
<td>Valsure® Neutral, ¼ oz. per gallon</td>
</tr>
<tr>
<td>Rinse</td>
<td>1 minute</td>
<td>Hot Tap Water</td>
<td>No detergent</td>
</tr>
<tr>
<td>Dry</td>
<td>7 minutes</td>
<td>90 °C</td>
<td>No detergent</td>
</tr>
</tbody>
</table>
Immediately proceed from cleaning to the validated Sterilization Cycle below. Do not store instrument prior to sterilization.

**STERILIZATION INSTRUCTIONS**

<table>
<thead>
<tr>
<th>Ref #</th>
<th>Symbol</th>
<th>Title</th>
<th>Description</th>
<th>Standard Development Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1.6</td>
<td>REF</td>
<td>Catalogue number</td>
<td>Indicates the manufacturer’s catalogue number so that the medical device can be identified.</td>
<td>ISO 15223-1</td>
</tr>
<tr>
<td>5.1.5</td>
<td>LOT</td>
<td>Batch code</td>
<td>Indicates the manufacturer’s batch code so that the batch or lot can be identified.</td>
<td>ISO 15223-1</td>
</tr>
<tr>
<td>5.4.3</td>
<td>Consult instructions for use</td>
<td>Indicates the need for the user to consult the instructions for use.</td>
<td>ISO 15223-1</td>
<td></td>
</tr>
<tr>
<td>5.4.4</td>
<td>Caution</td>
<td>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.</td>
<td>ISO 15223-1</td>
<td></td>
</tr>
<tr>
<td>5.2.7</td>
<td>Non-sterile</td>
<td>Indicates a medical device that has not been subjected to a sterilization process.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1.1</td>
<td>Manufacturer</td>
<td>Indicates the medical device manufacturer, as defined in EU Directive 90/385/EEC, 93/42/EEC and 98/79/EC.</td>
<td>ISO 15223-1</td>
<td></td>
</tr>
<tr>
<td>n.a.</td>
<td>Rx Only</td>
<td>Prescription device</td>
<td>Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.</td>
<td>21 CFR 801.109</td>
</tr>
</tbody>
</table>

**LOSSARY OF SYMBOLS**

**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.

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Distributed by:

CooperSurgical
95 Corporate Drive
Trumbull, CT 06611 USA
Phone: (800) 243-2974
Fax: (800) 262-0105
**International:**
Phone: +1 (203) 601-9818
Fax: +1 (203) 601-4747
www.coopersurgical.com

REDA Instrumente GmbH • Gänsäcker 34, 78532 Tuttlingen • Germany
Phone: +49 7462 9445-0 • Fax: +49 7462 9445-20

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