



SurgiMate® Premium Fixed Head Skin Stapler

RX ONLY • NON-STERILE
SINGLE PATIENT USE ONLY • DISPOSABLE
NOT MADE WITH NATURAL RUBBER LATEX

IMPORTANT

Read carefully and completely before use. These instructions are a reference for the DeRoyal SurgiMate Skin Stapler. It is not a guide for surgical stapling practices. Carefully inspect device and packaging before use.

INTENDED USE

The DeRoyal SurgiMate Skin Stapler is intended to be used for skin closure of wounds, incisions or lacerations of the epidermis. The skin stapler applies one staple each time the handle is compressed. The staple points penetrate the skin and then turn to form a closed staple, which holds the tissue of the wound line together. The skin stapler should be used for skin closure only of the epidermis and is not intended for use within the body or for deeper layers of the corium (dermis) or other connective tissue. The skin stapler is intended for use by a licensed practitioner.

INDICATIONS

The DeRoyal SurgiMate Skin Stapler may be used for skin closure in a wide variety of surgical procedures including, but not limited to, gynecological, orthopedic, cardiovascular, urological, thoracic and plastic surgery procedures.

PRECAUTIONS

When it is not possible to maintain at least 6.5mm distance when using staples between the skin surface and underlying bone, vessels or viscera, the use of the skin stapler is contraindicated.

DeRoyal intends that non-sterile products for use in sterile environments be further processed by our customers, including further packaging



or sterilization according to their own validated processes. These products are to be sterilized by ETO, as other sterilization methods have not been validated by DeRoyal and may damage the product, which could cause a device malfunction or injury to the patient.

CAUTIONS

- Never reuse or sterilize the disposable skin stapler handle or staples once the package has been opened. Re-sterilization may compromise the integrity of the skin stapler.
- Do not attempt to reload staples into the stapler.
- The staples are made of stainless steel and are not absorbable or dissolvable.
- The skin stapler should be used for skin closure only of the epidermis and is not intended for use within the body or for deeper layers of the corium (dermis) or other connective tissue.

DIRECTIONS FOR USE

1. Approximate the tissue with forceps. Two forceps may be used to grasp equal portions of tissue on either side of the wound. The forceps are pulled together until the tissue edges are apposed and everted. Hold forceps jaws close to the stapler jaws for most controllable results. For tighter staple, grasp and present more tissue on each edge with forceps. One forceps may be used to approximate the tissue by grasping a substantial ridge of centered tissue from both edges of the wound and closing until the edges are apposed and everted. Approximation may be assisted by applying mild traction with skin hooks at each end of the wound.
2. Gently place the skin stapler jaws on the skin surface close to the forceps. Align the staple



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placement arrow with the center of the wound. The handle of the stapler should be held at an angle of approximately 35° to the surface of the skin.

3. The stapler may be held lightly on the skin or 1 to 2mm slightly above the skin surface if greater distance between the back span and tissue surface is desired. Slowly depress the handle and squeeze the trigger fully until an audible “click” is heard to place and form the staple. The SurgiMate design and staple sizing facilitate visibility of the staple placement. The staple may be “pre-cocked” in any position or held in a partially closed position by the internal mechanism of the stapler.
4. Lift the stapler straight up after each staple is placed. The stapler releases staples freely without manual adjustment to disengage the staples.
5. Repeat steps 1 through 4, placing the staples approximately 1/4” apart until the entire wound has been closed. The skin stapler applies one staple each time the handle is compressed. The staple points penetrate the skin and then turn to form a closed staple, which holds the tissue of the wound line together.

FORMED STAPLE DIMENSIONS

The staples are produced from surgical grade 316L stainless steel.

STYLE	DIMENSIONS	DIAMETER
Wide	6.5 mm wide x 4.7mm high	.60mm
Regular	5.7 mm wide x 3.9 mm high	.53 mm

WARNINGS

- It is not necessary to press the skin stapler into the skin to get the proper “bite.” The skin stapler should just “kiss” the skin surface or be raised slightly above the skin surface.
- The skin stapler should be used for skin closure only of the epidermis and is not intended for use within the body or for deeper layers of the corium (dermis) or other connective tissue.

CAUTION: Federal U.S.A. law restricts this device to sale or use by or on the order of a physician (or properly licensed practitioner).

WARRANTY

DeRoyal products are warranted for ninety (90) days from the date of shipment from DeRoyal as to product quality and workmanship. **DEROYAL'S WRITTEN WARRANTIES ARE GIVEN IN LIEU OF ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**



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