

INSTRUCTIONS FOR USE



NewGen Surgical Skin Stapler

Please read all information carefully.

Failure to properly follow the instructions may lead to serious surgical consequences.

Important: This is designed to provide instructions for use of the NewGen Surgical Skin Stapler. It is not a reference to surgical stapling techniques.

Intended Use

The NewGen Surgical Skin Stapler is a single-patient use instrument designed to deliver rectangular, stainless steel staples for routine wound closure.

www.newgensurgical.com/ifu

Warnings and Precautions

The NewGen Surgical Skin Stapler handle and lever are manufactured with bio-based materials. With these materials, some discoloration, texture variation, or fiber inclusions may be present. Cosmetic appearance does not affect the performance nor sterility of the device.

To ensure proper functioning, keep dry. Do not submerge or excessively expose the handle and lever of the stapler to water or other liquids.

This device is manufactured for single-use only.

Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure that may result in patient injury. Also, reprocessing or resterilization of single-use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

Store in a cool, dry place.

Do not use if product is damaged.

Any serious incident that has occurred in relation to the product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

How Supplied

The NewGen Surgical Skin Stapler is supplied preloaded with stainless steel staples for single patient use. Discard after use.

Formed Staple Dimensions

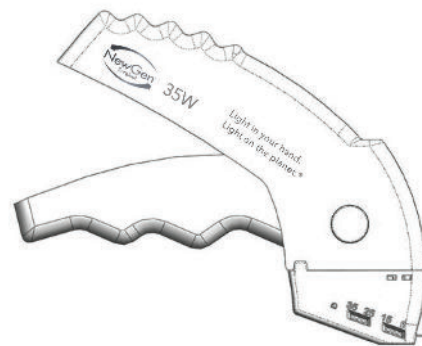
Approximate staple dimensions for wide staples are: a diameter of 0.58 mm, a span of 6.9 mm, and a leg length of 3.9 mm.

Indications

The NewGen Surgical Skin Stapler has application for routine skin closure in a wide variety of surgical procedures.

Contraindications

When it is not possible to maintain at least a 5 mm distance from the stapled skin to underlying bones, vessels, or internal organs, the use of staples for skin closure is contraindicated.



Instructions for Use

Verify compatibility of all instruments and accessories prior to using the instrument (refer to Warnings and Precautions).

1. Using sterile technique, remove the instrument from the package.

To avoid damage:

- a. Do not flip the instrument into the sterile field.
- b. Do not expose to excessive moisture.

2. Evert and approximate skin edges as desired. Several techniques are suggested:

a. With one tissue forcep, pull skin edges together until edges evert. (Illustration 1)

or

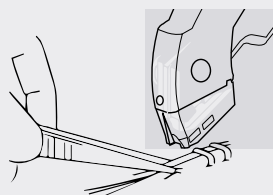
b. With two tissue forceps, pick up each wound edge individually and approximate the edges. (Illustration 2)

or

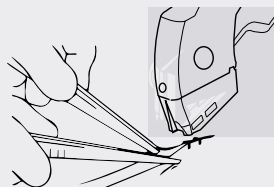
c. Apply tension to either end of the incision, such that the tissue edges begin to approximate themselves. One forcep can be used to ensure that the edges are everted. (Illustration 3)

3. Position the instrument over the everted skin edges, centering the alignment indicator over the incision. (Illustration 4)

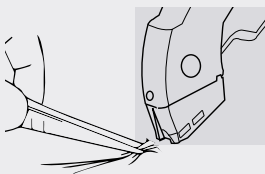
4. Lightly squeeze the lever to the handle until you receive tactile feedback that the firing cycle is complete. Release the lever and remove the instrument from the fired staple.



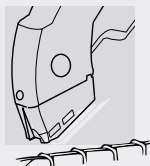
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2



3



4

	Ethylene oxide sterilizable
	See Instructions for Use
	Do not reuse
	Batch code
	Use by YYYY-MM-DD or YYYY-MM
	Manufacturer

	Catalog number
	Do not use if package is opened or damaged
	Latex-free
	DEHP-free
	PVC-free

REF NGS35W

US Patent 9226749, 9572575, 9820739, EP 3094265



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