

INSTRUCTIONS FOR USE



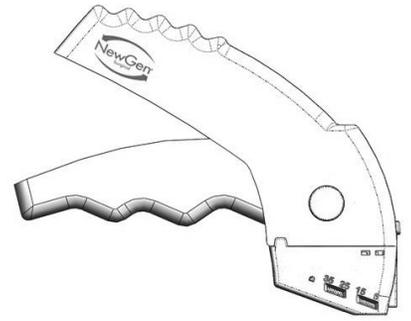
NewGen Surgical Skin Stapler

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.

www.newgensurgical.com/ifu



Warnings and Precautions

The NGS35 handle and lever are manufactured with plant-based, sustainably-sourced materials. With natural materials, some discoloration and texture variation may be present; this does not affect the performance or 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 and sterilized 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 in turn may result in patient injury, illness, or death. 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.

How Supplied

The NewGen Surgical Skin Stapler is supplied sterile and 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.

Device Description

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

Instructions for Use

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

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

To avoid damage:

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

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

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

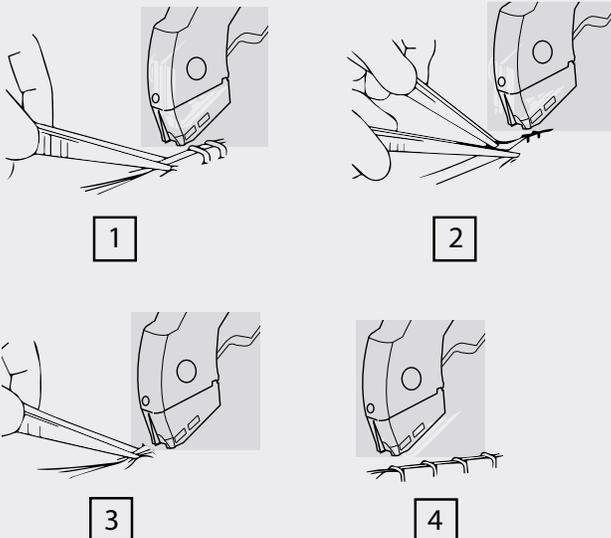
OR

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

OR

- 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)

- Position the instrument over the everted skin edges, centering the alignment indicator over the incision. (Illustration 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.



	Sterilized using ethylene oxide		Manufacturer
	See Instructions for Use		Catalog number
	Do not reuse		Keep Dry
	Batch code		Do not use if package is opened or damaged
	Use by YYYY-MM-DD or YYYY-MM		Latex free
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.		

 NGS35W

US Patent 9226749, 9572575



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