INSTRUCTIONS FOR USE



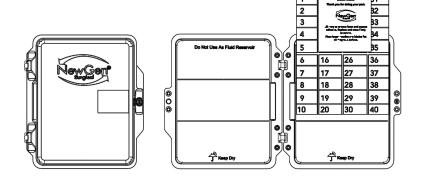
NewGen Surgical Needle Counters

Please read all information carefully.

Intended Use

The NewGen Surgical Needle Counter is a single-use, sterile device designed to safely facilitate correct count and disposal of needles and blades during surgical procedures.

www.newgensurgical.com/ifu



Warnings and Precautions

NewGen Surgical Needle Counters are manufactured with natural materials. With these materials, some discoloration, texture variation, or fiber inclusions may be present. Cosmetic appearance does not affect the performance, safety, nor sterility of the device.

To ensure proper functioning, keep dry. Do not use as a fluid reservoir. Do not submerge or expose the needle counter to water or other liquids.

To ensure secure closure, do not separate needle counter box.

When using needle counters with magnets, caution should be used during procedures with materials or equipment which may be adversely affected by magnetic fields.

ASTM F2132 compliant for puncture resistance. Do not use excessive force that could compromise the integrity of the needle counter box.

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.

Supports OSHA recommendations for safe sharps handling. Always refer to sharps protocol for your facility.

Store in a cool, dry place.

Do not use if product is damaged. Do not use if package is open or 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.

Instructions for Use

- 1. Remove tabs to expose adhesive on the front and back of the needle counter container.
- 2. Open needle counter and place on flat surface.
 - 2a. For foam block configurations, remove the adhesive backing, replace, and press firmly to secure foam.
- 3. Place used needles into container during procedure; one per numbered space.
- 4. Place larger needles and blades flat on magnetic surface.
- 5. Securely close needle counter once container is at capacity and/or procedure has ended.
- 6. Dispose the needle counter in compliance with facility guidelines for disposing of sharps.

STERILE EO	Sterilized using ethylene oxide
<u> </u>	See Instructions for Use
2	Do not reuse
LOT	Batch code
	Use by YYYY-MM-DD or YYYY-MM
	Manufacturer

REF	Catalog number
	Keep dry
	Do not use if package is opened or damaged
LANEX	Latex-free
DENP	DEHP-free
PNC	PVC-free

REF

NGSNC20MA, NGSNC30MA, NGSNC40FMMA, NGSNC60MA, NGSNC80FFMMA

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