



## FREQUENTLY ASKED QUESTIONS

### PRODUCT: NEEDLE COUNTERS



### Product Composition

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#### **Q: What materials are the Needle Counters made of?**

A: The NewGen Surgical Needle Counter outer box is made from bagasse, a by-product of sugarcane production. The hinges, latch, foam, and magnet are similar to those found in existing needle counters in use today and are made from medical-grade quality materials. All components of the Needle Counters meet biocompatibility standards based on ISO 10993 - Biological Evaluation of Medical Devices.

#### **Q: Does the Product include any chemicals of concern?**

A: The NewGen Surgical Needle Counter box is Prop 65 compliant and latex-free. In addition, the NewGen Surgical Needle Counter box is free of intentionally added BPA or BPA-derived plastics, mercury, phthalates, and PVC.

All materials considered for NewGen Surgical products are analyzed with the Smart Sustainable Design™ guidelines and our internal green chemistry policy, otherwise known as the "Do Not Use" list. Our suppliers source materials that adhere to our claim of being free of chemicals of concern, and are transparent with these materials by way of, but not limited to, Material Safety Data Sheets (MSDS) and third-party certifications. All materials used in NewGen Surgical products have been validated through a third party to be free of chemicals of concern.

## Product Sustainability

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### **Q: What makes the NewGen Surgical Needle Counters sustainable?**

A: NewGen Surgical designs single-use products used every day in the O.R. through a lens of sustainability to reduce and eliminate plastic waste. The NewGen Surgical Needle Counter box is made entirely of bagasse.

Using bagasse as a feedstock, NewGen Surgical is contributing to the circular economy community through upcycling, the process of transforming by-products and waste materials into new materials for better environmental value. This reduction of new raw materials for new products results in a reduction of energy usage, air and water pollution, and greenhouse gas emissions. By converting to NewGen Surgical products, you do your part in reducing plastic pollution and associated CO<sub>2</sub>e GHG emissions.

### **Q: Is the packaging considered sustainable?**

A: Yes. At NewGen Surgical, responsible packaging is part of our Smart Sustainable Design™.

- Needle Counter Pouch: The pouch is Dupont Transition Tyvek (HDPE, #2) sealed to a film (LDPE, #4). Flexible sterile medical device packaging contributes a small amount to the waste stream compared with other packaging materials. Tyvek film pouches are an efficient use of material and provide protection that allows for sterilization, storage, and ultimately aseptic presentation – all with a few grams of material.
- Needle Counter Shelf and Case Box: The shelf and case boxes are 100% recyclable.
- Bulk Non-Sterile: The Needle Counters are double bagged in a corrugated box.

### **Q: Is the foam block or magnet in the NewGen Surgical Needle Counter sustainable?**

A: No, the foam and magnet are sourced from the same supply chain used by other needle counter manufacturers. We do not currently have a suitable alternative to the current foam and magnet that meets our Smart Sustainable Design requirements of performance, sustainability, and economics. We continue to research this area for future product enhancements.

## Product Clinical Performance

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### **Q: Can this product be sterilized?**

A: Yes. The NewGen Surgical Needle Counters maintain their performance, shape, strength, and sterility with ethylene oxide (EO) sterilization.

**Q: Is there any difference in the use of this product in the O.R.?**

A: No. The Needle Counters were designed with the O.R. staff in mind to provide clinical performance and functionality that is similar to the current plastic product.

**Q: Can the Needle Counters get wet?**

A: To ensure that the Needle Counters function properly, care should be taken to keep them dry. The NewGen Surgical Needle Counters are treated with a biodegradable water-resistant coating and can tolerate limited exposure to fluids in the normal course of surgery. However, they were not designed to be used as a fluid reservoir nor should they be submerged in water or other fluids.

**Q: Are the Needle Counters puncture-resistant?**

A: Yes, the needle counter complies with ASTM F2132, which is an international standard for the puncture resistance requirements of materials used in containers for discarded medical needles and other sharps. However, do not use excessive force that could compromise the integrity of the needle counter box.

In addition, the needle counters support OSHA recommendations for safe sharps handling and sharps protocol, which should be followed at the respective facility.

## **Product Waste and Disposal**

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**Q: How is the NewGen Surgical Needle Counter disposed of?**

A: There should be no change in the disposal method between existing single-use plastic needle counters and the NewGen Surgical Needle Counters. The protocol of most hospitals is to place used skin staplers in the sharps bin, where they are then processed to be non-infectious and non-sharp for incineration or landfill.

**Q: If the NewGen Surgical Needle Counter disposal method follows the same path as the current needle counters, what is the difference in waste?**

A: Conventional plastic needle counters are made from high-intensity polystyrene (HIPS) plastic and are not eligible for recycling in this application. HIPS do not readily biodegrade in a landfill. In a landfill, plastic does not readily biodegrade and accumulates over decades in the natural environment. If incinerated, plastic can emit harmful pollutants such as bisphenols and phthalates into the air and environment.

NewGen Surgical's bagasse Needle Counter boxes are made from renewable resources and are free of toxins and chemicals of concern. During decomposition and/or incineration, bagasse is not harmful to human or planetary health unlike conventional plastics.

**Q: Are the NewGen Surgical Needle Counters biodegradable or compostable?**

A: The NewGen Surgical Needle Counter box is biodegradable and compostable. NewGen Surgical's bagasse Needle Counters box will decompose over time. With the renewable properties of sugarcane, the environmental benefits of using an upcycled feedstock, and the ability of bagasse to decompose, NewGen Surgical's Needle Counters minimize the environmental impacts through the entire life cycle of the product. Bagasse is a natural biodegradable plant material.

**Product Compliance and Certifications**

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**Q: Are the NewGen Surgical Needle Counters FDA-approved?**

A: Needle Counters are classified as Class 1 devices and as with all Class 1 devices, they do not require 510(k) clearance. NewGen Surgical and all products of NewGen Surgical are registered with the FDA.

**Q: Is NewGen Surgical Inc. ISO 13485 certified?**

A: Yes, we are ISO 13485:2016 certified for the design and manufacture of surgical and medical devices for operating room accessories, patient care, and surgical packaging, including skin staplers, needle counters, basins, and bowls.

**Q: Are the NewGen Surgical Needle Counters CE Marked?**

A: Yes, the Needle Counters have the CE marking, which is a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European market.