



**FOR TOPICAL USE ON ANIMALS**

**Product Description**

The active ingredients in SutureSeal are a proprietary formulation of Polyethylene glycol (PEG) formed by the reaction of multi-arm PEGylated compounds.

**Indication**

SutureSeal is a long lasting, liquid bandage product for clear, flexible coverage and protection of incision sites and wounds.

**Storage Information**

Store in a cool, dry place <8° C (<46° F), relative humidity below 70%. SutureSeal should be kept refrigerated or frozen to maximize shelf life. Room temperature is most ideal for standard application. Take out prior to use: 60 minutes if frozen and 30 minutes if refrigerated. Place back in cold storage if not used within 5 hours at room temperature.

**Directions for Use**

To ensure product integrity, inspect the packaging before use to confirm that the vacuum seal is intact. SutureSeal has been shown to remain on the application site up to two weeks. SutureSeal degrades and can be reapplied after a standard wound cleaning if needed.

1. Confirm the pouch has not been tampered with prior to opening. Open the pouch and remove syringes and brush tip. Discard the oxygen and freshness packets.
  2. Remove the brush from the brush holder.
  3. Remove the caps from both syringes and connect the syringes together.
  4. Mix the contents of the two syringes by vigorously pushing the plungers back and forth for 30 strokes or approximately 10-15 seconds. By this time the solid should be dissolved in the liquid. Small air bubbles are normal.
  5. Push all the liquid into the male syringe and disconnect the two syringes. Attach the brush tip to the syringe with the liquid polymer and discard the empty syringe.
- FROM THIS POINT YOU HAVE APPROXIMATELY 60 SECONDS TO APPLY THE POLYMER BEFORE IT BECOMES TOO VISCOUS.**
6. Push the plunger until the polymer dispenses into the brush tip. Brush the polymer onto the wound area evenly and completely.
  7. The liquid will turn into a gel and should stop flowing approximately 90 seconds after the mixing start time.\*



Please scan for instructional video

\*Note: A single SutureSeal packet contains enough polymer to cover a 15cm<sup>2</sup> wound area. You may observe runoff of excess polymer away from the application site but this is not detrimental to application or performance of the product.

**Mechanism of Action**

SutureSeal acts by forming a thin, flexible layer over the site or wound. SutureSeal is initially applied as a liquid and quickly gels into a flexible solid. The initial liquid phase of SutureSeal allows it to cover small and irregular spaces. The subsequent solid phase forms a barrier that protects and covers the incision site or wound.

**Contraindications**

SutureSeal is not intended as a wound or incision closure device and should not be used on wounds that are actively bleeding or seeping heavily.

**Precautions**

Ensure that the wound is clean and as dry as possible. The wound should be disinfected prior to applying this product.

**Human Warnings**

Not for human use. Keep out of reach of children. If contact with eyes or skin occurs, rinse with water and seek medical attention. If swallowed, get medical help or call a Poison Control Center right away. Avoid spilling on furniture or clothing. For medical emergencies, consult your physician.

**Adverse Reactions**

If ingested in the liquid form, the liquid is not expected to form a gel. If ingested in solid form, the gel is nontoxic and biodegradable. In studies to evaluate the safety of SutureSeal, there have been no adverse reactions to date.

**Animal Safety**

Safety studies have shown there is no inflammation or toxicity associated with the administration of SutureSeal. This polymer has passed in vitro cytotoxicity (ISO 10993-5) and hemolysis (ISO 10993-4) tests with no evidence of cytotoxicity or hemolysis. Preliminary safety studies in which the proprietary formulation was studied in animals have also shown no inflammation or toxicity.

**How Supplied**

SutureSeal is supplied in a foil package containing two syringes and one brush tip. Each kit has been processed through E-beam sterilization. One female syringe contains solid white powder and the male syringe contains phosphate buffer solution.

**SYMBOL DEFINITIONS**

- |                    |                                  |
|--------------------|----------------------------------|
| Lot Number         | See Instructions For Use         |
| Expiration Date    | Keep away from sunlight and heat |
| Do Not Reuse       | Do not use if package is damaged |
| Do Not Resterilize | Storage Temperature              |

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