



NeoMend Inc. "ProGEL™ Surgical Sealant"

Caution: Federal Law restricts this device to sale by or on the order of a physician

Composition

NeoMend Inc. "ProGEL™ Surgical Sealant" is a two component hydrogel sealant, consisting of the following substances:

- 1.) Human Serum Albumin solution (HSA).
 - 2.) Poly (ethylene glycol) di-succinimidyl succinate (PEGSS2), a dried powder reconstituted with sterile water.
- Mixed at the time of application, the liquid components quickly cure in situ to form a flexible patch for sealing and/or reducing air leaks in the lung. After application, the body resorbs the patch material within 28 days.

Intended Use/ Indications

NeoMend Inc. "ProGEL™ Surgical Sealant" is intended as an adjunct to standard tissue closure techniques for sealing or reducing air leaks (ALs) incurred during pulmonary surgery:

Individualization of Treatment / Dose

- The amount of NeoMend Inc. "ProGEL™ Surgical Sealant" solution required depends upon the surface area to be sealed.
- Applied as a spray, a 4.2mL NeoMend Inc. "ProGEL™ Surgical Sealant" applicator will normally cover an area 40 sq cm (6 sq in) when applied 1 mm thick.

Contraindications

- Do not use the Sealant in patients who have a history of an allergic reaction to Human Serum Albumin.

Warnings

- The safety and effectiveness of the Sealant has not been evaluated in humans less than 18 years of age, nor in pregnant or nursing women.

Precautions

- Ventilation of the target area should be stopped temporarily if possible to reduce air leakage from the targeted sites and to minimize tissue movement during sealant application. If the patient needs ventilation, a reduced tidal volume is recommended.
- Sealant use has not been studied with other sealants or hemostatic materials.
- Use of additives (e.g., antibiotics) with the Sealant has not been studied.
- The safety of the Sealant has not been evaluated in patients receiving more than 30 mL of the Sealant.
- Keep the applicator tip approximately 5 cm (2 in) away from target area to avoid creating bubbles in the sealant material during application. Bubbles may compromise the adherence and/or mechanical properties of the Sealant.
- Do not use rehydrated cross-linker after 20 minutes, as the performance of the Sealant may be compromised.
- The Sealant is intended for single use only. Do not resterilize or reuse.
- Inspect sterile package and seal prior to use. Do not use if sterile package or seal are damaged or open. Discard unused material.

Storage

- NeoMend Inc. "ProGEL™ Surgical Sealant" should be stored at 35°F to 45°F (2° to 8° C).
- Do not freeze.

Maintaining the Device Effectiveness

- Sealant should be used within 20 minutes after dissolving the white powdered PEGSS2 in water

Patient Counseling Information

The HSA component of NeoMend Inc. "ProGEL™ Surgical Sealant" is prepared from pooled human venous plasma. The plasma is derived from blood collected from volunteer donors. Precautions are taken to assure the blood products viral safety, including the screening of blood donors and testing of each donated unit for viruses. In addition, a validated viral inactivation step is implemented in the processing of all HSA product. Because of albumin's unusual stability compared to other human blood products, it is possible to heat treat (pasteurize) the protein. This routine processing for ten hours at 60°C has been shown to effectively eradicate known viral pathogens (*Erstad, BL, Pharmacother, 1996, 16:996-1001*)

How Supplied

NeoMend Inc. "ProGEL™ Surgical Sealant" is supplied sterile and is intended for single use only.

Each kit contains:

One each - 2.5mL B-D plastic syringe with 0.5 in 26 ga needle.

One each - 5mL Vial of USP sterile water for injection
(Used for reconstitution of the PEGSS2)

One each - pre-loaded cartridge containing 2.1mL Human Serum Albumin solution

One each - pre-loaded cartridge containing 275 mg Poly (ethylene glycol) di-succinimidyl succinate (PEGSS2) as a dried white powder

One each - Applicator assembly

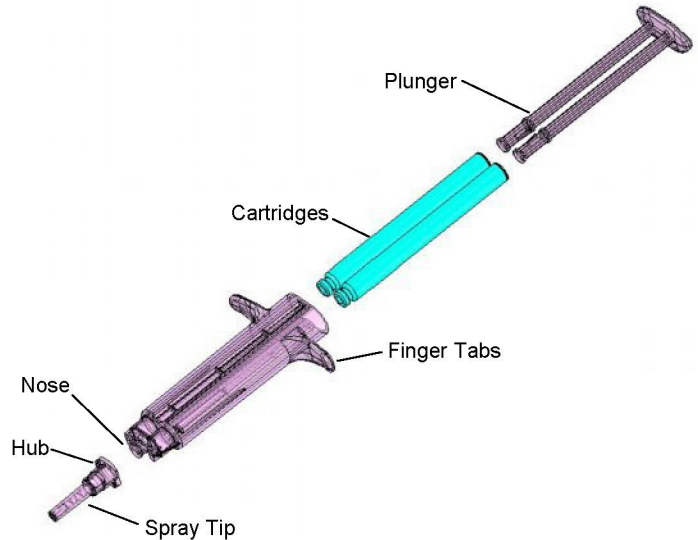
Two each - Spray tips

Instructions for Use

A. Sealant Preparation

Practicing aseptic technique, open the sterile pack and pass its contents into the sterile field.

1. Using the 2.5mL syringe provided, draw 2mL of sterile water into the syringe and express any air in the syringe.
2. Inject the 2mL of sterile water into the cartridge containing the white powder (PEGSS2).
3. Mix the cartridge contents by gently rocking the cartridge end to end. The solution is ready for use when it is clear and contains no un-dissolved powder.
4. With the nose of the applicator pointed up, load both cartridges into the twin-chambered applicator housing (without spray tip attached). Gently press the cartridges to seat them into place.
5. Insert the push rod assembly into the openings in the rear of the cartridges.
6. With the nose of the applicator pointed up, briskly flick it to free any air bubbles. Express the air by gently but firmly pushing up on the plunger. Take care to express as little fluid as possible during this process.
7. Wipe the nosepiece with a clean gauze to remove any liquid that may have been expressed with the air. Avoid mixing of components by not wiping from one aperture across the other.
8. Place a spray tip on the nose of the applicator and rotate clockwise about 1/4 turn until locked.
9. Apply Sealant. Refer to section B, Sealant Application, for detailed information.



B. Sealant Application

Note: The unique design of the spray tip allows for sealant application as a spray or as a stream. Firm steady pressure on the plunger will yield a spray, while gentle pressure will yield a stream of sealant. Interruption of the application for approximately 10 seconds may result in occlusion of the spray tip. If occlusion occurs remove the spray tip, wipe the end of the applicator to remove any fluid and attach a new spray tip (provided) onto the end of the applicator as before.

1. Select the tissue surface to be sealed. (Note: Each 4.2mL applicator will supply enough sealant to cover an area 40 cm² (6 sq in) 1 mm thick.
2. Irrigate the area to be sealed with saline to remove any pooled blood or blood clots. Evacuate irrigation solution with suction or sponge prior to sealant application.
3. Ventilation to the affected area should be stopped. If ventilation needs to be maintained, reducing the tidal volume is recommended to minimize air leakage and lung movement during application of the sealant.
4. Hold the spray tip approximately 2 inches (5 cm) from the tissue to be sealed, and apply firm, steady pressure to the plunger.
5. Maintain a firm pressure on the plunger and move the spray tip from side to side along a line from the distal to the proximal margin of the tissue surface to be sealed.
6. The sealant cures in 20-30 seconds, forming a flexible patch. The patch can be tested 2 minutes after application. Sealant application may be repeated if necessary. Repeat applications will require replacing the previously used Spray Tip with the additional tip provided in the kit.
7. If the applicators contents are not entirely used in the first application, immediately remove the spray tip and wipe the nosepiece clean to prevent the remaining material from activating. A new spray tip can then be attached and the remaining material applied.
8. If more than one kit is needed to seal a defect, additional kits should be prepared and applied as required.

