Duplospray Quick Setup Guide

Coseal Surgical Sealant

Instructions for Scout Nurse – Duplospray Mis Regulator

Position DUPLOSPRAY System so the foot switch is placed next to the surgeon's foot at time of application.

Attach the supply hose located at the back of the regulator to a source of medical grade CO_2.

While depressing the foot switch, adjust the gas flow to 1.0-2.0 litres per minute. Check the gas flow by noting the height of the ball in the gas gauge while stepping on foot switch.

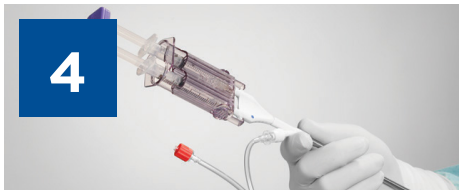
Attach the spray set to the DUPLOSPRAY. Connect the clear hooded luer connector on the tubing set to the male clear gas port on the regulator. Connect the blue male luer connector on the tubing set to the female luer blue vent port on the regulator.

Instructions for Scrub Nurse – Duplospray Mis Applicator

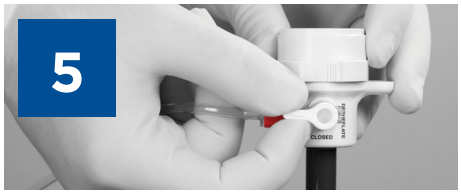
Prepare COSEAL Surgical Sealant according to the instructions in the package insert.

Firmly snap the spray head onto the nozzles of the Coseal syringes.

Attach gas supply line (clear luer connector) to sterile applicator. Turn white locking collar to secure connection.



Pass assembled syringe and spray applicator to surgeon for spray application.



Attach patient vent line (red luer connector) to available female luer on trocar vent valve. Ensure vent valve is fully open.

Important Points

- **Depress foot pedal to start gas flow** prior to applying COSEAL Surgical Sealant. Circulating nurse checks gas flow gauge on regulator before surgeon inserts applicator. If flow level ball does not move when foot pedal is depressed, the applicator is occluded and should be replaced.
- Ensure gas supply line (clear luer connector) has no kinks
- While activating the footswitch dispense COSEAL Surgical Sealant through the applicator tip by slowly depressing the plungers at a recommended spraying distance of **3cm**. The recommended minimum spraying distance of **2cm** (optimal work distance of **3cm**). To stop spray delivery release pressure on plungers while maintaining gas flow by holding down foot pedal for an additional **3-5** seconds to clear applicator.

Tips

The patient vent line attached to the trocar cannula vent valve will only vent gas out when foot pedal is depressed. After connection to trocar cannula, ensure vent valve is fully open on trocar cannula prior to spray application. The twin-tube assembly can be easily separated as necessary to allow freedom of movement.

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Coseal [Surgical Sealant]

Instructions for use

Product Description

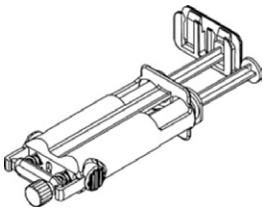
Coseal Surgical Sealant (Coseal) is a synthetic hydrogel designed to act as a sealant around a sutured site in cardiovascular and thoracic surgery and in patients undergoing cardiac or abdomino-pelvic surgery to prevent or reduce the incidence, severity and extent of postsurgical adhesion formation. Coseal is composed of two synthetic polyethylene glycols (PEGs), a dilute hydrogen chloride solution and a sodium phosphate/sodium carbonate solution.

These components come in a kit that includes an applicator(s). At the time of administration, the mixed PEGs and solutions form a hydrogel that adheres to tissue, synthetic graft materials and covalently bonds to itself.

The Coseal kit includes:

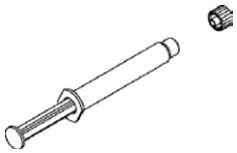
Liquid Components Pouch

The Liquid Components Pouch consists of two syringes, containing solutions, which are preassembled into a housing. A transfer port closure is attached to the housing assembly to allow mixing of the PEG powders into the correct syringe. A clip is attached to the plunger rod of the syringe that does not require mixing with the PEG powders.



Powder Component Pouch

The Powder Component Pouch consists of a syringe containing two PEG powders and a desiccant packet.



Applicator Pouch

Each applicator pouch contains two applicators.

Indications

Coseal is indicated for:

- Sealing suture lines along arterial and venous reconstructions.
- Enforcement of suture and staple lines in lung resection procedures.
- Patients undergoing cardiac surgery to prevent or reduce the incidence, severity and extent of post surgical adhesion formation.
- Patients undergoing laparotomy or laparoscopic abdomino-pelvic surgery as an adjunct to good surgical technique intended to reduce the incidence, severity and extent of post surgical adhesion formation.

Contraindications

Do not use Coseal as a bronchial stump sealant, during bronchial sleeve resections, or for sealing decorticated lung areas.

Do not use Coseal in procedures in which pleural adhesions are desired.

Warnings

Application involving the use of pressurized gas may be associated with potential risks of air embolism, tissue rupture, or gas entrapment with compression, that may be life-threatening. To minimize these risks control the maximum pressure as indicated in the applicator instructions for use.

Do not inject Coseal into vessels.

Do not use in place of sutures, staples or mechanical closure.

To prevent any compressive effects, in compression-sensitive cavities or in patients with an increased risk of compression (e.g. neonatal cardiac procedures), application of a thin layer of product is recommended (1 mL per 10 cm).

Coseal swells up to four times its volume within 24 hours of application and additional swelling occurs as the gel resorbs. Therefore, surgeons should consider the maximum swell volume and its possible effect on surrounding anatomic structures potentially sensitive to compression.

Do not use Coseal in contaminated or “dirty” pulmonary resection cases.

Precautions

To prevent any lines, catheters or pacing wires from being sealed onto the surface of moving organs, (heart, lung or bowel) either place these after the application of Coseal or lift the device to allow application of Coseal directly onto the tissue surface. Allow 60 seconds of polymerization time prior to laying to implant on top of the polymerized Coseal.

To apply Coseal for adhesion prevention, use the Coseal Spray Set or other Coseal-compatible spray device. Hold the spray set 5-10 cm from the site to provide a uniform layer to the treatment site.

The safety and performance of Coseal have not been established in pregnant women.

In vivo testing demonstrated a mild skin sensitization response in an animal model. Similar testing in humans has not been conducted.

During clinical investigations, the volume of Coseal used per patient ranged from 2 mL to 24 mL. The maximum volume of Coseal to be used per patient will be based upon the surgical procedure. The safety of Coseal has not been evaluated in patients receiving more than 24 mL of Coseal.

Do not apply Coseal over any devices or objects that will need to be removed. Coseal must not be used as a mechanism of adherence, even temporarily, for any object.

Always apply a thin, continuous layer of Coseal on large surfaces or in compression-sensitive areas using spray application. The application of excess product can be avoided by applying a minimal amount of Coseal to achieve proper sealing. A thin layer can be achieved by spraying a thickness of approximately 1 mm of product (1 mL per 10 cm).

Adverse Events

During the European and US Coseal sealing clinical studies, there were three adverse events attribute d by investigators to Coseal (one fever, one hematoma and one infection). No other adverse events reported in the multicenter clinical studies were attributed to Coseal.

During the manufacturing sponsored European adhesion prevention clinical studies, no adverse events were attributed to Coseal. No increase in frequency of adverse events has been noted with the use of Coseal in adhesion prevention procedures compared with surgery alone, however, as with any surgically implanted biomaterials there may be the potential for adverse reactions, including infection, foreign body reaction, allergic reaction, pneumoperitoneum complications, increase in adhesions, and transient compromised kidney function.

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PBS Information: This product is not listed on the PBS

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