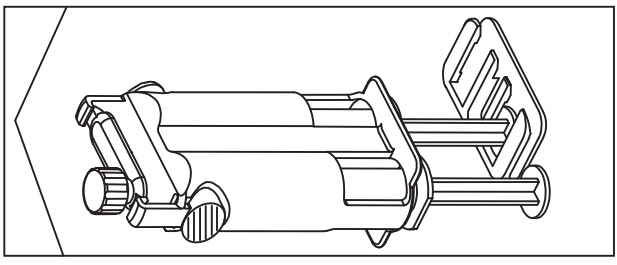
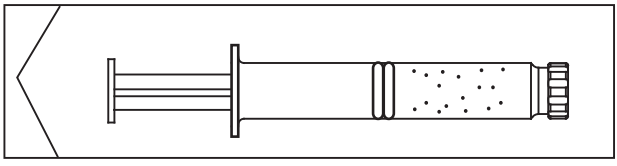
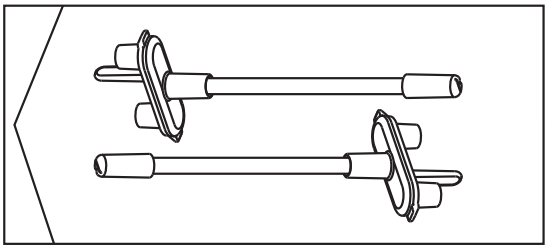
Baxter

COSEAL Surgical Sealant







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COSEAL Surgical Sealant

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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 gynecologic 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.

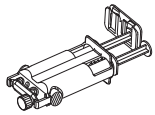
These components come in a kit that includes an applicator(s). At the time of administration, the mixed PEGs and solutions form a hydrogel that adheres to tissue, synthetic graft materials and covalently bonds to itself.

Preclinical studies suggested resorption in 7-30 days. The rate of resorption can differ as it is dependent on several factors, including the amount of product applied in situ and the site of use.

The COSEAL kit includes:

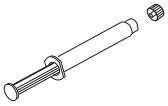
LIQUID COMPONENTS POUCH

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 laparotomic or laparoscopic gynecological surgery as an adjunct to good surgical technique intended to reduce the incidence, severity and extent of post surgical adhesion formation.

INTENDED USE

COSEAL is intended for sealing and prevention or reduction of 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^2).

> 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.

COSEAL should be used with caution in contaminated areas of the body. Specifically, 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 the 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 and lactating 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^2).

ADVERSE EVENTS
During the European and US COSEAL sealing clinical studies, there were three adverse events attributed 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, inflammation, foreign body reaction, allergic reaction, pneumoperitoneum complications, increase in adhesions, and transient compromised kidney function.

Post market surveillance showed a cumulative incidence of adverse events possibly attributed to the use of COSEAL below 0.1%. This includes rare reports of surgical site infections (SSI) possibly related to use of COSEAL, occlusion of ventricular assist devices or superior vena cava and in pediatric patients, cardiac tamponade due to swelling of the product. As with other sealants anastomotic leakage or postoperative bleeding are rare adverse incidents. In the 2020 Post Market Clinical Follow-Up User Survey, incidence of adverse events of 0.16% to 0.27%, such as inflammation and seroma, was reported. Warnings and precautionary statements are included in the respective sections of the IFU.

ADVERSE EVENTS REPORTING: For a user and/or patient if, during the use of this device, or as a result of its use, a serious incident has occurred, please report this incident to the manufacturer, and/or its authorized representative, and to the competent authority of the Member State in which the user and/or patient is established.

Directions for Use
HOW SUPPLIED

COSEAL and its accessories are Latex-Free.

COSEAL is supplied as a sterile single use only unit.

Do not re-sterilize any components.

COSEAL has a slight sulfurous odor that does not affect its acceptability for use.

Applicators, **COSEAL Spray Set, and other COSEAL- compatible spray devices** may be purchased separately.

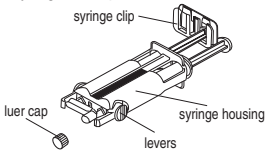
Do not use if pouches, syringes or Luer lock caps are damaged or opened.

Dispose of device following local regulations on disposal of medical waste.

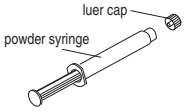
STORAGE CONDITIONS
Store at 2°C to 25°C.

MIXING INSTRUCTIONS
- Use COSEAL within 2 hours of preparation. Do not remove the syringe clip.
- Using aseptic technique, open each pouch and transfer contents into the sterile field. In the sterile field, prepare the liquid and powder components as described below.

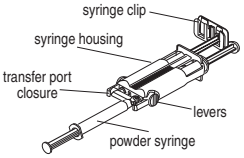
1. Remove the Luer cap on the transfer port closure. Do not remove the syringe clip. Rotate the syringe clip away from the other syringe plunger. This will allow ease of transfer between liquid syringe and powder syringe in step 3.



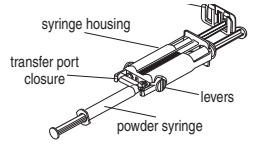
2. Remove the Luer cap from the powder syringe.



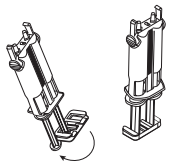
3. Connect the powder syringe to the opening on the transfer port closure. Transfer the liquid into powder by forcefully depressing the plunger. Mix contents back and forth between the syringes until the solid is completely dissolved (at least 20 times). Push entire contents into the syringe contained in the syringe housing.



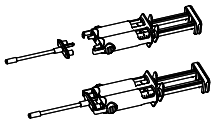
4. Disengage the powder syringe by detaching the transfer port closure as follows:
   - Grasp the powder syringe barrel
   - Press the levers on the syringe housing
   - Pull both the empty powder syringe and transfer port closure from the housing.



5. Holding the syringe tips up, level syringe plungers and rotate the syringe clip to connect to other plunger. Hold the syringe upright and expel all air.



6. Snap the applicator onto the end of the syringe housing. COSEAL is now ready to use.



Application Methods

1. Using Standard Applicator (supplied with kit)

2. COSEAL Spray Set or other COSEAL-compatible spray device (sold as an accessory)

APPLICATION using the Standard Applicator

Note: For peripheral vascular graft procedures, restore blood circulation to the surgical site to expand the graft. Reclamp to stop circulation.

1. Aspirate excess blood and blot or air-dry all surfaces prior to application.
2. Hold the applicator approximately 3 cm from the site (touching the site or holding more than 6 cm from the site is not recommended). Apply sealant forcibly to enhance mixing, moving quickly along the anastomotic site. Avoid direct contact with tissue or with gel.
3. If COSEAL is to be applied to another site several minutes after first application, replace the applicator tip.
4. Apply a uniform layer of sealant to the treatment site. If necessary, rotate the site and bend the applicator to facilitate exposure of all surfaces. Overlap the application slightly to ensure complete coverage of the treatment site. Following application wait at least 60 seconds before restoring circulation, applying irrigation, blotting with gauze, or touching the sealant.
5. If the material remains "watery" and does not gel within approximately 30 seconds, flush the site with saline, and aspirate the material.
6. If the treated site fails to seal, dry the surface. Reclamping the vessel may be required to dry the field for reapplication of COSEAL. Reapply sealant. Do not disturb the sealant. If the sealant does not seal, flush the site with saline, aspirate and use standard treatment.
7. If the applicator becomes clogged, replace it with a new applicator as follows: Press the ribbed surface of levers on the syringe housing and remove the clogged applicator. Attach the new applicator.

APPLICATION using COSEAL Spray Set or other COSEAL-compatible Spray Device

Note: For use in adhesion prevention, use a spray accessory device. For assembly, follow the Instructions for Use provided with the accessory spray device. The recommended application dosage for adhesion prevention is 1 mm thick layer (1 mL per 10 cm^2)

1. Adjust the pressure according to the pressure ranges indicated in the applicator's Instructions for Use. Note: To prevent clogging, airflow should always precede and follow product application.
2. Aspirate excess blood and blot or air dry all surfaces prior to application.
3. To provide a uniform layer to the treatment site, hold the spray applicator 5-10 cm from the site, keep constant pressure on the syringes, and spray with a sweeping motion. Overlap the application slightly to ensure complete coverage of the treatment site. Following application, wait at least 60 seconds before disturbing the site. To reduce the likelihood of unintended adherence of the applied COSEAL to tissues near the application site, it is important to avoid contact between the applied COSEAL layer from neighboring tissue for at least 60 seconds after application, and to rinse the exposed surface of the applied COSEAL with saline at the end of the 60-second waiting period.
4. If COSEAL fails to gel, flush the site with saline, aspirate and repeat application steps above or use standard treatment.

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