



Coseal
Surgical Sealant

Preparation Instructions

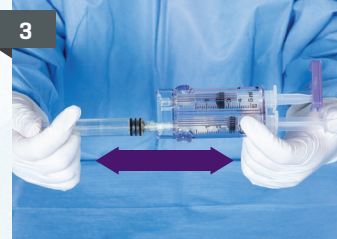
Preparation



1 Open pouches and transfer the COSEAL components into the sterile field.



2 In sterile field, attach powder syringe to transfer port on syringe housing. Ensure purple syringe clip attached to syringe housing is rotated away from the free plunger.



3 Transfer the liquid into the powder syringe by forcefully depressing the free plunger on the syringe housing. Mix contents back and forth, at least 20 times, until all powder is completely dissolved. End with entire contents in the syringe housing.



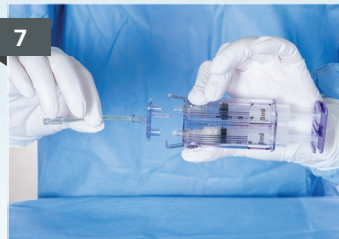
4 Disengage the powder syringe and transfer port together by depressing levers on the side of syringe housing.



5 Holding the syringe tips up, level the plungers and rotate the syringe clip to connect the other plunger.

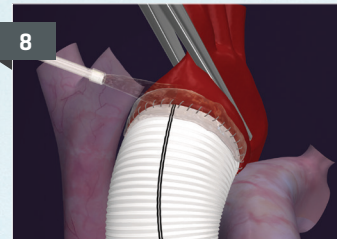


6 Hold the assembly upright and expel all the air from both syringes.



7 Attach applicator tip. DO NOT PRIME the applicator tip.

Use COSEAL Sealant within 2 hours of preparation.



8 The application pattern depends on the rate and force with which the plunger is depressed. As the force increases, the application pattern will become broader.



9 Allow at least 60 seconds after application, before touching or laying any object(s) on top of the COSEAL Sealant.

For spray application, please see instructions for EASYSpray Regulator (open application) or DUPLOSPRAY Regulator (laparoscopic application).

Please see Indication and Detailed Important Risk Information on the reverse side.



COSEAL [Surgical Sealant] Indication and Important Risk Information

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 cm²).

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

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.

For safe and proper use of this device, please refer to full device Instructions for Use.

ITEM NUMBER

PRODUCT DESCRIPTION

934073	COSEAL Surgical Sealant, 2 mL
934074	COSEAL Surgical Sealant, 4 mL
934075	COSEAL Surgical Sealant, 8 mL

For questions or ordering information, please contact your Baxter representative

Advancing the art of healing