


COSEAL is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage¹

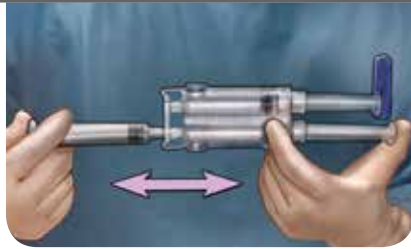
Preparation instructions¹ for Scrub Nurse (Use Aseptic Technique)

1




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

2




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 dissolved. End with entire contents in the syringe housing.

3



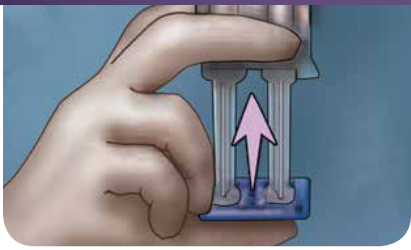
Disengage the powder syringe and transfer port together by depressing levers on the side of syringe housing.

4




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

5



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


6



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

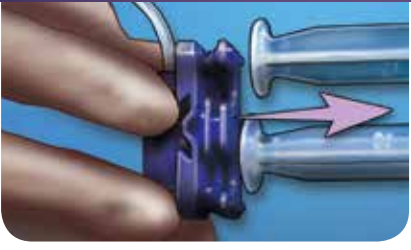
- Pass applicator to surgeon for focal application —OR— Continue to Step 7 if surgeon is using EASYSpray.
- Use COSEAL within 2 hours of preparation.

7



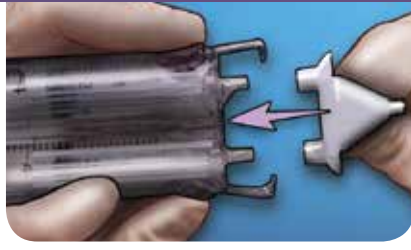
• If surgeon is using EASYSpray: Remove the standard plunger clip on the COSEAL unit and obtain the COSEAL clip provided in the EASYSpray sprayset packaging.

8




Attach the EASYSpray clip to the back of the syringe plungers. There are two rows of slots on the clip. The first row of slots is for the 4/8 mL kits, and the second row is for the 2 mL kits.

9




Obtain spray head from sprayset packaging. Firmly attach the spray head to the hubs of the syringes, ensuring the clips lock on both sides.

10



Fit the spray tubing of the sprayset onto the Luer-lock connection on the underside of the sprayhead.


11



- Pass the assembled COSEAL unit to the surgeon for spray application.
- Pass the end of the spray tube with the sterile filters to the circulating nurse.


EASYSpray Instructions² for Circulating Nurse


1




Insert 9V battery into the EASYSpray pressure regulator device. Connect EASYSpray device to IV pole or cart rail using the clamps on the back of the device.
Do not use rechargeable batteries.

2




Connect the black tube, located at the side of the EASYSpray device, to a propellant gas source. Use compressed medical air or nitrogen only.  **Do not connect to an oxygen source.**

3



Set wall unit pressure between 3.5 and 7 bar (51-100 psi).


4



- Accept the sprayset filters passed from the scrub nurse.


Connect sprayset filters to EASYSpray device. Connect the clear filter to the male luer connector and the blue filter to the blue female luer connector.

5




Turn the on/off switch on the front side of the EASYSpray to the ON position. The low-battery indicator light will only illuminate when the battery is weak and the gas flow is activated at the same time.

6



Check the gauge on the EASYSpray device for the appropriate pressure range of 1.0-2.0 bars. Adjust pressure setting by turning the black pressure control knob.⁴

Instructions for Surgeon



- To activate the flow of gas, occlude the opening in the clip center with thumb. To begin application, gently depress the COSEAL plungers. Apply only to dry fields in a thin layer.²
- The EASYSpray device will continue to emit gas for a brief period after the thumb is removed from the clip/plunger. This delay helps to avoid clogging of the spray head.²
- Allow at least 60 seconds after application, and before touching or laying any object on top of the Coseal.¹
- Spray from a distance of 10-15 cm for optimum results. For a distance of less than 10 cm, the pressure must be adjusted accordingly. Avoid spraying from a distance of less than 5 cm.²
See table below for adjustment settings.

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Please see Warnings and Precautions, Indications and Important Risk Information on the reverse side.

| Distance | 5 cm | 10 cm | 15 cm |
|----------|--------------|----------------|--------------|
| Pressure | 1 bar/15 psi | 1.5 bar/22 psi | 2 bar/29 psi |



Coseal
Surgical Sealant

EASYSpray Warnings and Precautions

Caution: Pressurized gas supply must be between 3.5 and 7 bar (51-100 psi).

Caution: DO NOT connect to an oxygen source. Failure to follow these instructions can lead to explosion, which could result in serious injury or death.

Prior to operation, make sure that the pressure range of the device is adjusted to the range specified in the appropriate sprayset Instructions For Use.

Caution: Any application of pressurized gas may be associated with a potential risk of gas embolism, tissue rupture or gas entrapment with compression, which may be life threatening. Be sure to take appropriate measures to address these risks by observing the recommended minimum spraying distance and the maximum pressure provided in the appropriate sprayset Instructions For Use.

Caution: Spraying into enclosed body cavities requires appropriate safety measures to make sure that the above mentioned risks will be avoided.

NOTE: Do not use with rechargeable batteries.

The use of accessories of other manufacturers is not permitted.



Do not connect to an oxygen source.

Do not use rechargeable batteries.

COSEAL [Surgical Sealant] Indication and Important Risk Information

Indication

COSEAL is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.

Important Risk Information for COSEAL

COSEAL is not to be used in place of sutures, staples, or mechanical closure.

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.

Apply only as a thin layer.

Use caution when applying with pressurized gas.

Do not place devices or other objects on top of tissue where COSEAL has been applied, until the material is fully polymerized (non-tacky).

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.

Do not inject COSEAL into vessels.

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

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

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REFERENCES

1 COSEAL Surgical Sealant Instructions for Use, Hayward, CA: Baxter Healthcare Corporation. March 2009. 2 EASYSpray Pressure Regulator Instructions for Use, 6299610EH04. 3 Coseal Spray Set Instructions for Use Baxter AG, 1221 Vienna, Austria Ref 0600021 December 2010.

Baxter

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