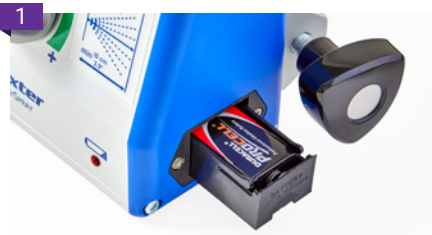


Coseal Surgical Sealant and EasySpray Pressure Regulator Preparation Instructions

Baxter

Circulator Nurse | EasySpray Regulator Setup



FIRST TIME USE: Open the battery compartment with the aid of a coin or screwdriver and insert a standard 9 Volt battery.

NOTE:
DO NOT use rechargeable batteries.

The **EasySpray** Pressure Regulator should be visually inspected at regular intervals.

If the low-battery indicator light is illuminated (only lights up when gas flow is activated), change the battery immediately.



Put the **EasySpray** Pressure Regulator on a plain and stable surface or use the clamp on the back side of the **EasySpray** Pressure Regulator to mount the device on an IV-pole or suitable rail. Firmly set screws to assure stable connection to either the IV-pole or rail.

When mounting the **EasySpray** Pressure Regulator to an IV pole, observe the following conditions:
Use stable IV poles with a five-wheel base greater than or equal to 58 cm in diameter and with pole diameter lesser than or equal to 4 cm.



Connect the **EasySpray** Pressure Regulator device with pressurized air, nitrogen or medical grade CO₂ in the OR.*

CAUTION:
DO NOT connect to an oxygen source.

NOTE: Gas adapter connector and cable may look different depending on your facility.

CAUTION: Pressurized air supply must be between 3.5 and 7.0 bar (50 - 100 psi).



Connect the transparent filter of the spray set pressure line to the male luer connector on the **EasySpray** Pressure Regulator.

Connect the blue filter of the spray set sensor line to the blue marked female luer connector on the **EasySpray** Pressure Regulator.

NOTE: Follow instructions for use for **Coseal** Surgical Sealant and **Coseal** Spray Set preparation.



Turn the switch on the front side of the **EasySpray** Pressure Regulator to the ON-position (I).



Adjust the pressure on the **EasySpray** Pressure Regulator according to the specifications in the spray set instructions for use by turning the regulator knob in the appropriate direction.

FOR BAXTER SPRAY SET: appropriate pressure range of 1.5 - 2.0 bar (21.8 - 29.0 psi).

The quantity of product applied is controlled by the product application system but not by the gas released.



When spraying **Coseal** Surgical Sealant has been completed or the **EasySpray** Pressure Regulator is no longer in use, turn the switch on the front side to the OFF-position (O).

Carefully read the **Coseal** Spray Set Instructions for Use for the spray set you are using (compatible with the **EasySpray** Pressure Regulator). These instructions provide the recommended spraying distance, gas pressure, and application details.

TIPS

The **EasySpray** Pressure Regulator 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.

Selected Important Risk Information

Life-threatening/fatal air or gas embolism has occurred with the use of spray devices employing a pressure regulator to administer fibrin sealants. This event appears to be related to the use of the spray device at higher than recommended pressures and/or in close proximity to the tissue surface. The risk appears to be higher when fibrin sealants are sprayed with air, as compared to CO₂ and therefore cannot be excluded with **Coseal** Surgical Sealant when sprayed in open wound surgery.

When applying product using a spray device, be sure to use a pressure within the pressure range recommended by the spray device manufacturer.

*The **EasySpray** Pressure Regulator has no adapter installed from the factory due to multiple possible configurations, and should be installed by the hospital's biomedical engineering dept.

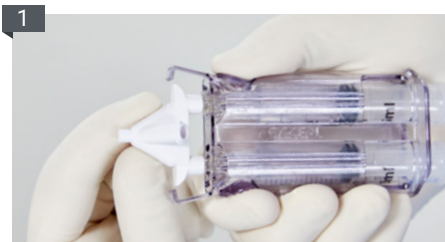
Coseal Surgical Sealant and EasySpray Pressure Regulator

Preparation and Application Instructions

Baxter

Scrub Nurse | Coseal Spray Set Setup

1



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

2



Attach clear connector to the Luer-lock connector on the underside of the spray head.

3



Remove the standard plunger clip on the **Coseal** Surgical Sealant unit.

4



Attach the spray set clip by sliding it onto the syringe plungers.

There are two rows of slots on the clip. The first row is for the 4 mL and 8 mL kits, and the second row is for the 2 mL kits.

Surgeon | Application

1



Spray from a distance of 10 - 15 cm for optimum results.

2



To activate the flow of gas, cover the opening in the clip center with thumb. To begin application, gently depress the syringe plunger.

The **EasySpray** Regulator 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.

3



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

In order to ensure optimal safe use of Coseal Surgical Sealant by spray application, the following recommendations should be followed:	Applicator tip to be used	Pressure regulator to be used	Gas to be used	Recommended distance from target tissue	Recommended spray pressure / Gas flow rate
	Coseal Spray Set	EasySpray Pressure Regulator	CO ₂ * Medical Air or Nitrogen	10 - 15 cm	1.5 - 2.0 bar (21.8 - 29.0 psi)
* CO ₂ is the preferred gas for application, however Medical Air or Nitrogen are acceptable gasses for administration of Coseal Surgical Sealant in open surgery.					

The information presented here is based on the **Coseal** Surgical Sealant Instructions for Use, the **Coseal** Spray Set Instructions for Use, and the **EasySpray** Pressure Regulator Instructions for Use. Baxter, Coseal and EasySpray are trademarks of Baxter International Inc. or its subsidiaries.
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