Coseal
Surgical Sealant

Reorder Number	Product Information
934070	COSEAL Surgical Sealant 2mL
934071	COSEAL Surgical Sealant 4 mL
934072	COSEAL Surgical Sealant 8 mL
934033	COSEAL Replacement Applicator (7 cm)
934034	COSEAL Extended Applicator (22 cm for MIS)
0600012	EASYSPRAY Regulator Unit
0600021	COSEAL SpraySet *(for use with EASYSPRAY Regulator Unit)*

COSEAL Surgical Sealant 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.

To order COSEAL Surgical Sealant call 1-800-423-2090
www.baxterbiosurgery.com

REFERENCES

1 Data on file, Baxter Healthcare. **2** COSEAL Surgical Sealant Instructions for Use, Hayward, CA: Baxter Healthcare Corporation. March 2009. **3** Hill A, Estridge TD,Maroney M, et al. Treatment of suture line bleeding with a novel synthetic surgical sealant in a canine iliac PTFE graft model. *J Biomed.* 2001;58: 308-312. **4** Hagberg RC, Safi HJ, Sabik J, et al. Improved intraoperative management of anastomotic bleeding during aortic reconstruction: Results of a randomized controlled trial. *Am Surg.* 2004;70: 307-311. **5** Glickman M, Gheissari A, Money S, et al. A polymeric sealant inhibits anastomotic suture hole bleeding more rapidly than Gelfoam/Thrombin. *Arch Surg.* 2002;137: 326-331. **6** DeAnda A, Jr., Elefteriades JA, Hasaniya NW, et al. Improving outcomes through the use of surgical sealants for anastomotic sealing during cardiovascular surgery. *J Card Surg*. 2009;24:325-333. **7** Wallace DG, Cruise GM, Rhee WM, et al. A tissue sealant based on reactive multifunctional polyetheylene glycol. *J Biomed.* 2001;58: 545-555. **8** Azadani AN, Matthews PB, Ge L, et al. Mechanical properties of surgical glues used in aortic root replacement. *Ann Thorac Surg*. 2009;87(4):1154-1160. **9** Haas CE, LeBlanc JM. Acute postoperative hypertension: A review of therapeutic options. *Am J Health-Syst Pharm*; 61:1661-1673.**10** Ferraris VA, Brown JR, Despotis GJ, et al. 2011 Update to The Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists Blood Conservation Clinical Practice Guidelines. *Ann Thorac Surg.* 2011;91:944-982.

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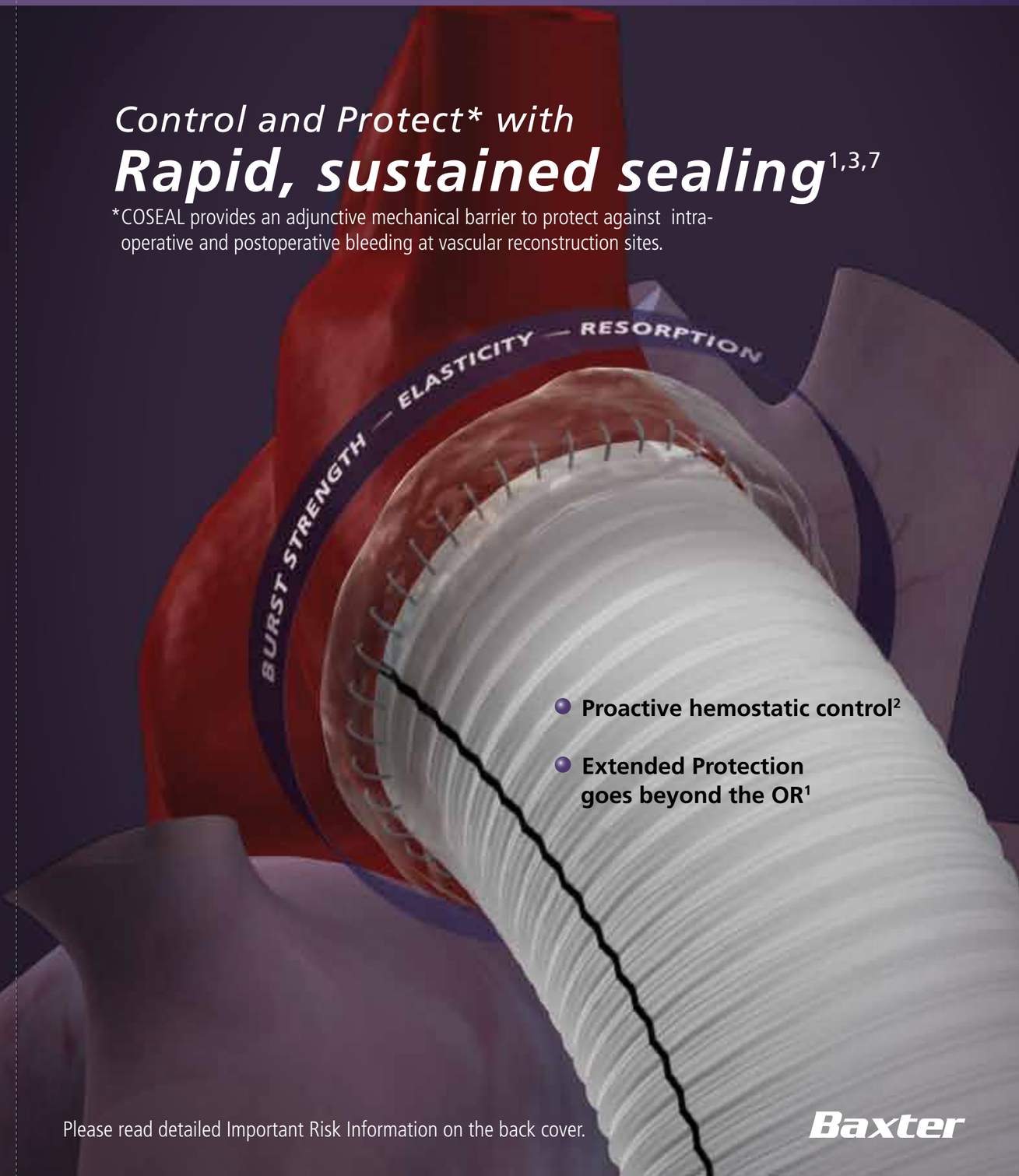
Coseal
Surgical Sealant

Control and Protect with*

Rapid, sustained sealing[1,3,7]

*COSEAL provides an adjunctive mechanical barrier to protect against intra-operative and postoperative bleeding at vascular reconstruction sites.



- **Proactive hemostatic control**[2]
- **Extended Protection goes beyond the OR**[1]

Please read detailed Important Risk Information on the back cover.

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Coseal
Surgical Sealant

Proactive patient protection

Extended protection against bleeding*
—from OR through recovery[1]

Rapid intraoperative control[2,3]

for aortic repairs and high pressure suture lines[4,5]

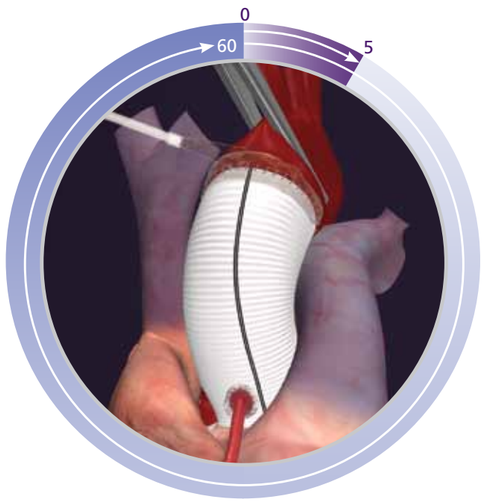
COSEAL Surgical Sealant is indicated for use in vascular reconstructions to achieve adjunctive hemostasis by mechanically sealing areas of leakage.[2]

- ***In the First 5 seconds:***
  COSEAL polymerizes to form a hydrogel[2,3]

Fast Gel Time	Adheres to tissue and graft material, reducing potential for inadvertent migration[2]

- ***At ~60 seconds:***
  COSEAL achieves a full mechanical seal to manage suture hole bleeding[2,3,4,5]

Wait at least 60 seconds post-application before applying irrigation, contacting the sealant, or restoring circulation and resuming procedure
COSEAL swells up to four times its volume within 24 hours of application and additional swelling occurs as the gel resorbs[2]



Apply only to dry fields in a thin layer[2]

- ***At 5 seconds— Gels and Adheres[2,3]***
- ***At ~60 seconds—Full Seal Achieved[2,3]***

- ***Works in tandem with your technique***
  - — Translucent seal helps to keep suture lines visible[3]
  - — Can be sutured through[6]
  - — Works independently of the coagulation cascade[4,5]
  - — Multiple application options: Focal, MIS, and Broad[2]
    - Use caution when applying with pressurized gas[2]

Please read detailed Important Risk Information on back cover

Elements of postoperative assurance

COSEAL provides a carefully balanced combination of properties to protect against bleeding without hindering the natural healing processes.[1] It is also completely free of glutaraldehyde and bovine components.[2]

*The mechanical seal provided by COSEAL remains beyond the intraoperative period for as long as 7 days[3]

BURST STRENGTH

Can withstand postoperative spikes over 5x normal systolic pressure[7]

660 [+/- 150] mmHg (in vitro burst test for closure of puncture defects 0.6-0.9 mm diameter, n=4) in porcine carotid artery

ELASTICITY

Thin, motion-responsive seal provides biomechanical compatibility[8]

Supports natural vascular dilation

RESORPTION

Resorbed within 30 days of application[3]

Remains at application site for up to 7 days

COSEAL supports the integrity of your work, providing postoperative protection at sites that may be at risk for increased bleeding due to:

- Coagulopathies[3,5]
- Acute postoperative hypertension[9]
  - — *Proven sealing of high-pressure sites*
- Friable vascular tissue[4,5]

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

COSEAL is included in the Blood Conservation Clinical Guidelines of the Society of Thoracic Surgeons[10]

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