

CLOSE DRY
STAY DRY

ACHIEVE HEMOSTASIS
FAST & EASY

UNDERSTAND YOUR OPTIONS

Each of these products offers distinctive features that make it especially appropriate for particular bleeding scenarios that you may encounter.



Coseal
Surgical Sealant



Flexible Synthetic Sealant



TISSEEL
[Fibrin Sealant]



Sprayable Fibrin Sealant



TachoSil[®]
[Absorbable Fibrin Sealant Patch]



Fibrin Sealant Patch



Flo seal
Hemostatic Matrix



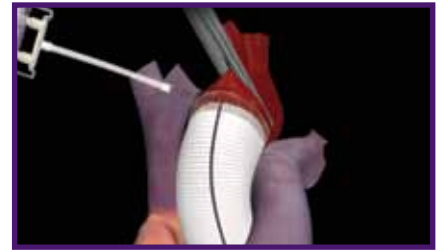
Flowable Hemostatic Matrix

Please see the tabbed sections for the Indication and detailed Important Risk Information for each product.

OPTIMIZE YOUR CONTROL

Baxter's BioSurgery is committed to providing you with clinically based guidance on selecting the most effective adjunctive solutions for specific bleeding situations.

For complex aortic repair involving tissue to tissue or tissue to graft anastomosis



For broad, raw, oozing surfaces in surgeries involving cardiopulmonary bypass



For Topical Use Only

For mild to moderate bleeds in cardiovascular surgery¹



For aggressive bleeding, wet field application^{2,3}



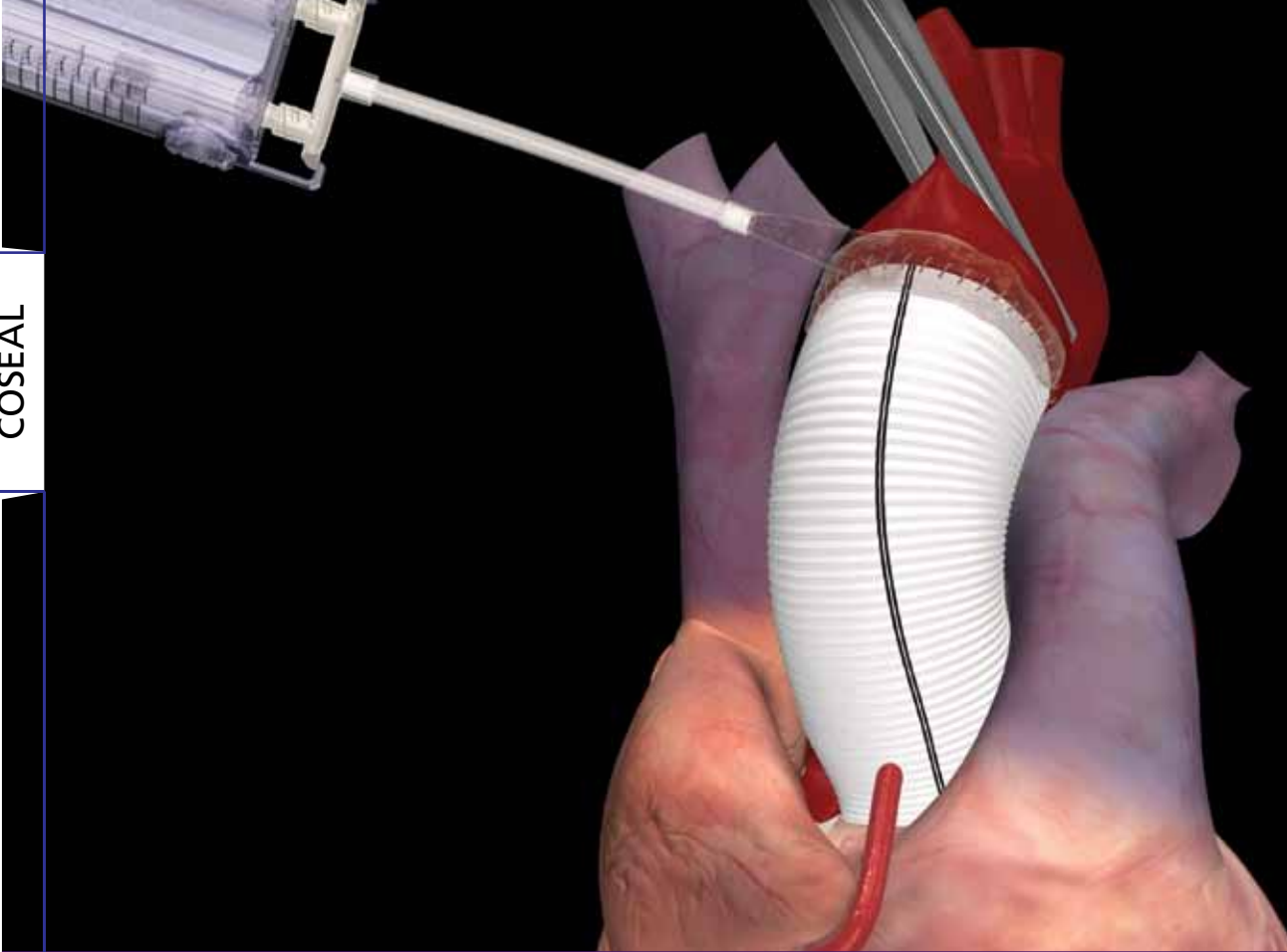
COSEAL

Please see the enclosed Prescribing Information and Instructions for Use for full details.

PROACTIVE BLEEDING CONTROL AND POSTOPERATIVE LEAKAGE PROTECTION*

*COSEAL controls and protects against bleeding by providing an adjunctive mechanical barrier during vascular reconstructions

COSEAL



Coseal
Surgical Sealant

COSEAL is a completely synthetic sealant.⁴ Applied to high-pressure suture lines and synthetic grafts, it provides an effective mechanical seal for reinforcement and adjunctive hemostasis.^{5,6}

Why COSEAL Surgical Sealant ?

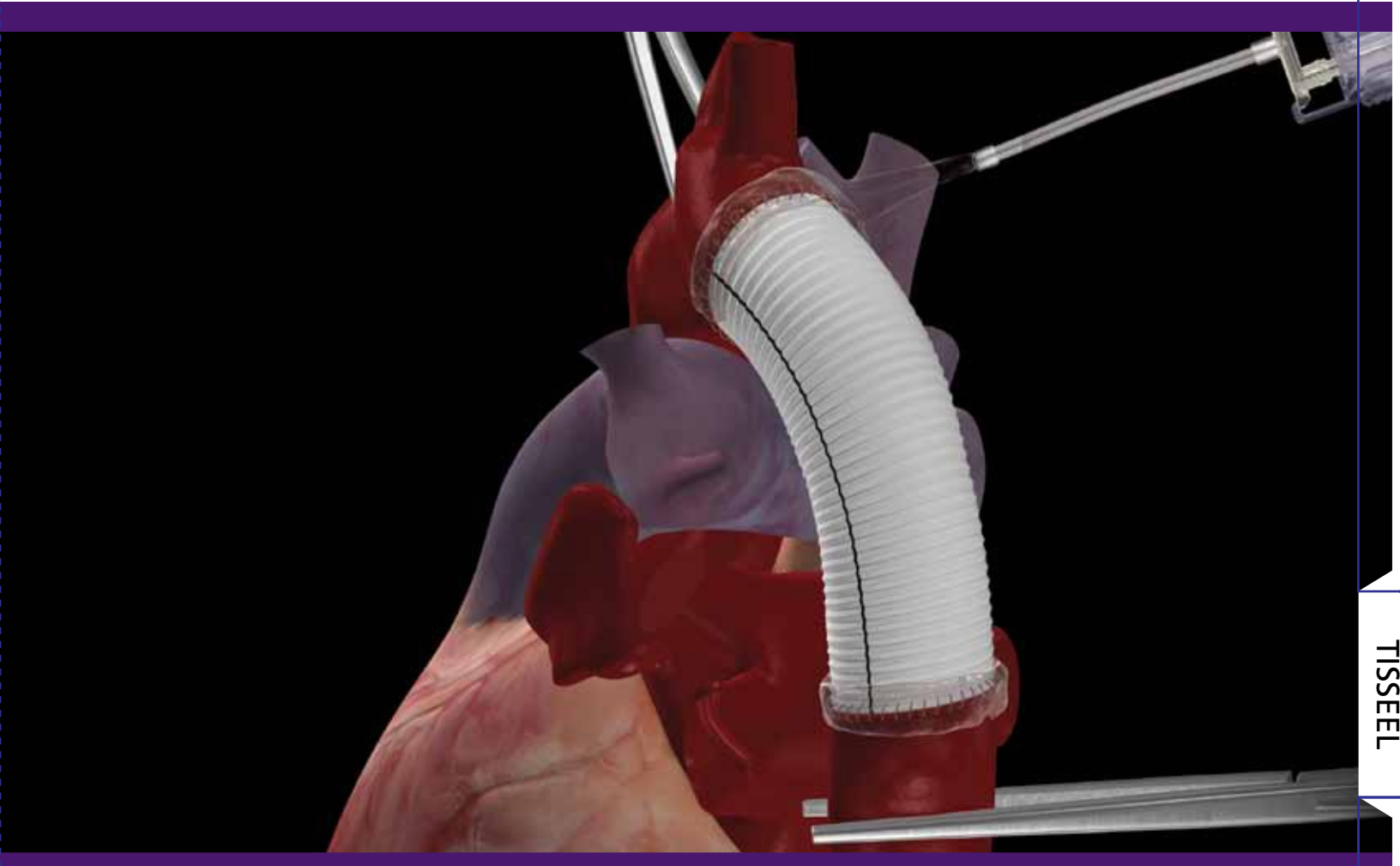
Strong Adherence to native tissue and synthetic graft material^{4,5,6}

Elasticity to allow normal dilatation during the wound healing process^{7,8}

Demonstrated burst strength to withstand pressure spikes up to 660 [+/- 150] mmHg (in vitro burst test for closure of puncture defects 0.6-0.9 mm diameter, n=4) in porcine carotid artery⁹



Coseal
Surgical Sealant



TISSUEEL

COSEAL [Surgical Sealant] Indications

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.

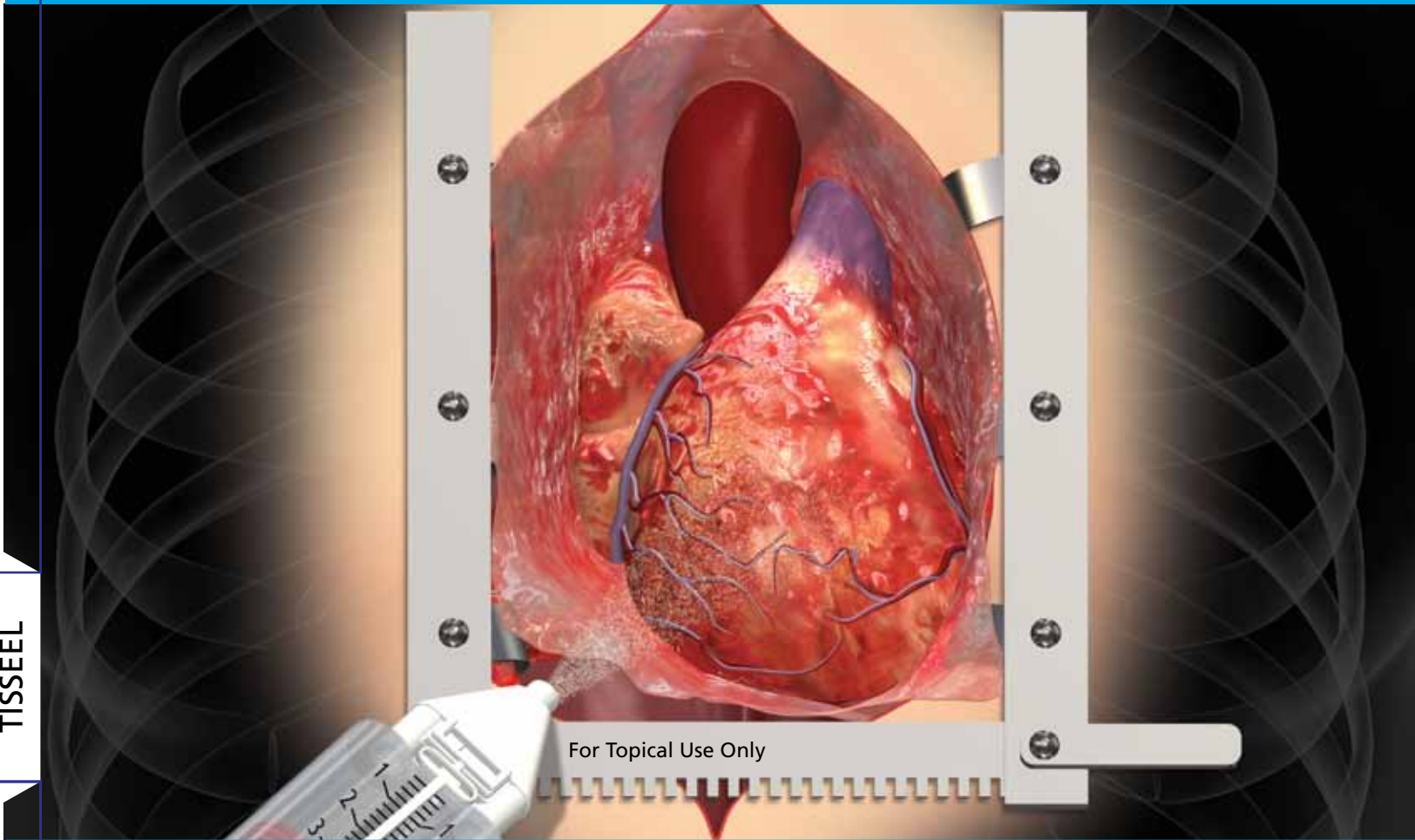
Do not inject COSEAL into vessels.

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.

DIFFUSE OOZING ACROSS BROAD, RAW SURFACES

TISSEEL



TISSEEL provides effective adjunctive hemostasis with sprayable application across broad, raw, oozing surfaces in surgeries involving cardiopulmonary bypass.

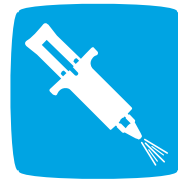
Why TISSEEL [Fibrin Sealant] ?

Clinically proven efficacy in challenging cardiovascular reoperations^{10,11}

Spray application option for even distribution across broad surfaces

Pre-filled syringe eliminates mixing and reconstitution

Satisfactory hemostatic agent in fully heparinized patients undergoing cardiopulmonary bypass¹⁰



TISSEEL

[Fibrin Sealant]

TISSEEL [Fibrin Sealant] Indications

Hemostasis: TISSEEL is a fibrin sealant indicated for use as an adjunct to hemostasis in surgeries involving cardiopulmonary bypass and treatment of blunt or penetrating splenic injuries when control of bleeding by conventional surgical techniques, including suture, ligature, and cautery, is ineffective or impractical. TISSEEL is a hemostatic agent that may be used in fully heparinized patients undergoing cardiopulmonary bypass.

Sealing: TISSEEL is a fibrin sealant indicated as an adjunct to standard surgical techniques (such as suture and ligature) to prevent leakage from colonic anastomoses following the reversal of temporary colostomies.

Important Risk Information for TISSEEL

For Topical Use Only. Do not inject TISSEEL directly into the circulatory system or into highly vascularized tissue. Intravascular application of TISSEEL can lead to intravascular coagulation, may result in life-threatening thromboembolic events, and may increase the likelihood and severity of acute hypersensitivity reactions in susceptible patients. Caution should be exercised to minimize the risk of inadvertent intravascular application in cardiopulmonary bypass surgeries.

Do not use TISSEEL in individuals with a known hypersensitivity to aprotinin.

Do not use TISSEEL for the treatment of severe or brisk arterial or venous bleeding. In these situations, TISSEEL will be washed away in the flow of blood before hemostasis can be attained.

Hypersensitivity or allergic/anaphylactoid reactions may occur with the use of TISSEEL. In specific cases, these reactions have progressed to severe anaphylaxis. Cases (less than one out of 10,000) have been reported in post marketing experience with TISSEEL. Such reactions may especially be seen if TISSEEL is applied repeatedly over time or in the same setting, or if systemic aprotinin has been administered previously. Even if the first treatment was well tolerated, this may not exclude the occurrence of an allergic reaction after a subsequent administration of TISSEEL or systemic aprotinin. Observed symptoms associated with allergic anaphylactic reactions to TISSEEL have included: bradycardia, tachycardia, hypotension, flushing, bronchospasm, wheezing, dyspnea, nausea, urticaria, angioedema, pruritus, erythema and paresthesia.

Aprotinin is known to be associated with anaphylactic reactions. Even in the case of strict local application of aprotinin, there is a risk of anaphylactic reactions to aprotinin, particularly in the case of previous exposure.

Discontinue administration of TISSEEL in the event of hypersensitivity reactions. Remove remaining product from the application site.

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 use of the spray device at higher than recommended pressures and in close proximity to the tissue surface.

When applying TISSEEL using a spray device, be sure to use the pressure within the pressure range recommended by the spray device manufacturer. In the absence of a specific recommendation avoid using pressure above 20-25 psi. Do not spray closer than the distance recommended by the spray device manufacturer. In the absence of a specific recommendation avoid spraying closer than 10-15 cm from the surface of the tissue. When spraying TISSEEL, changes in blood pressure, pulse, oxygen saturation and end tidal CO₂ should be monitored because of the possibility of occurrence of air or gas embolism. When using the EASYSPRAY device, or an equivalent spray device for open surgical procedures cleared by FDA, TISSEEL must not be sprayed in enclosed body areas and must be sprayed onto only visible application sites.

Exposure to solutions containing alcohol, iodine or heavy metals may cause TISSEEL to be denatured. If any of these substances have been used to clean the wound area, the area must be thoroughly rinsed before the application of TISSEEL.

Apply TISSEEL as a thin layer. Excess clot thickness may delay the natural wound healing process.

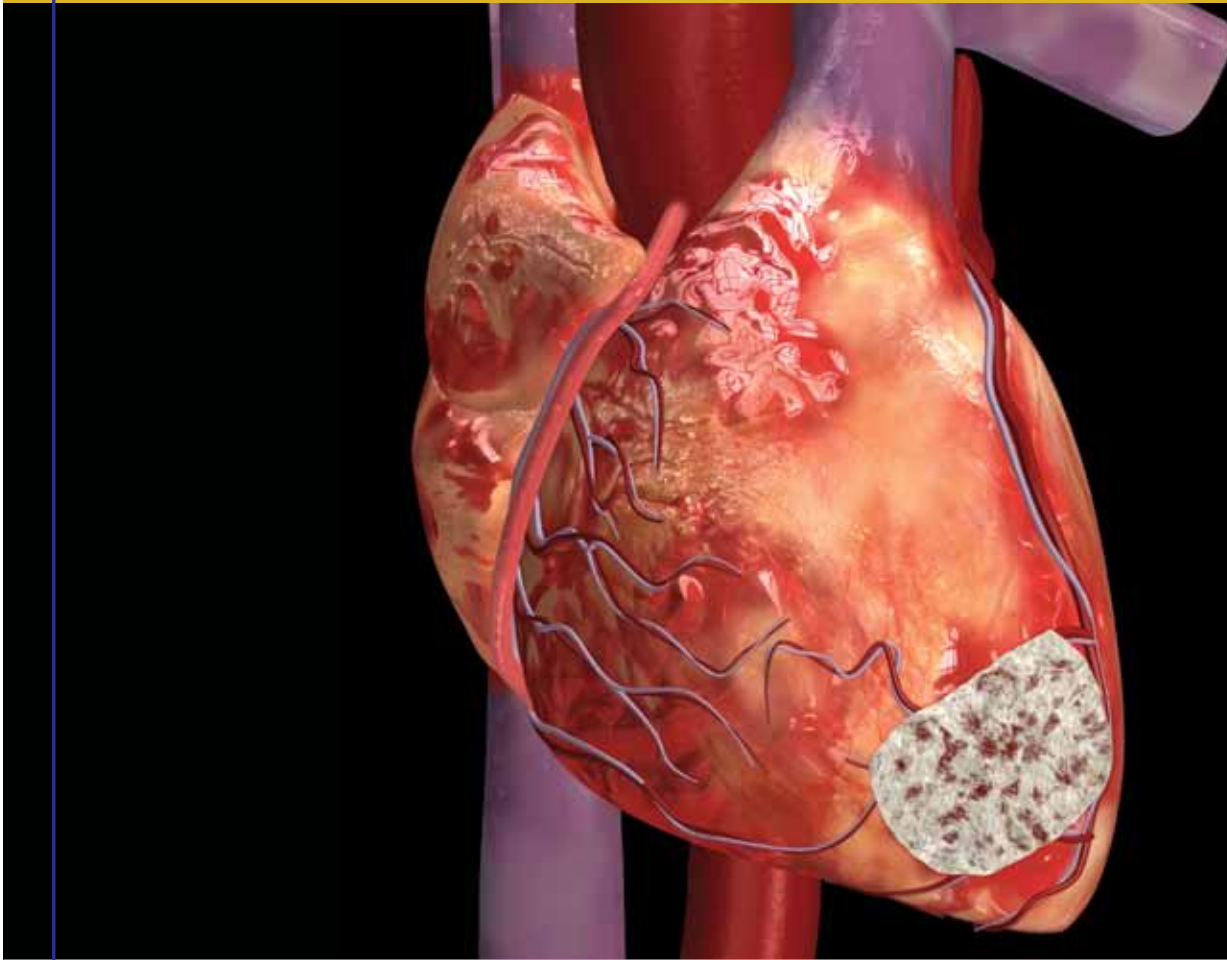
The safety and effectiveness of the combined use of TISSEEL with other biocompatible materials has not been evaluated in controlled clinical trials. The safety and effectiveness of TISSEEL used alone or in combination with biocompatible carriers in neurosurgical procedures or other surgeries involving confined spaces have not been evaluated; its use in this setting is not FDA approved.

TISSEEL is made from human plasma. It may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

There have been reports of serious adverse events such as paralysis and other compressive complications possibly related to the use of fibrin sealant in combination with resorbable hemostatic agents.

Please see accompanying full Prescribing Information.

MILD-TO-MODERATE BLEEDING IN DISCRETE LOCATIONS



TachoSil® is the only ready-to-use absorbable fibrin sealant patch.¹ TachoSil® combines a collagen matrix with the human coagulation factors.¹ TachoSil® can be applied directly to the bleeding area¹ in the open-heart cavity.

Why TachoSil® [Absorbable Fibrin Sealant Patch] ?

Active adjunctive hemostasis supported by the **structure of a collagen patch**¹

Wet or dry field application with precise coverage¹

Ready-to-use¹, package-to-patient

TachoSil[®] [Absorbable Fibrin Sealant Patch] Indications

TachoSil[®] is indicated as an adjunct to hemostasis for use in cardiovascular surgery when control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

Do not use TachoSil[®] in renal pelvis or ureter procedures.

Do not use TachoSil[®] in the closure of skin incisions.

Do not use TachoSil[®] in neurosurgical procedures.

Important Risk Information for TachoSil[®]

Apply on the surface of tissue only. Do not apply TachoSil[®] intravascularly. Intravascular application may result in life-threatening thromboembolic events.

Do not use TachoSil[®] in individuals known to have anaphylactic or severe systemic reaction to human blood products or horse proteins.

Do not use TachoSil[®] for the treatment of severe or brisk arterial bleeding.

Do not use TachoSil[®] as the primary mode to control hemostasis. TachoSil[®] is not intended as a substitute for meticulous surgical technique and the proper application of suture, ligature or other conventional procedures for hemostasis.

Hypersensitivity or allergic/anaphylactoid reactions may occur with TachoSil[®]. Symptoms associated with allergic anaphylactic reactions include: flush, urticaria, pruritus, nausea, drop in blood pressure, tachycardia or bradycardia, dyspnea, severe hypotension and anaphylactic shock. These reactions may occur in patients receiving TachoSil[®] for the first time or may increase with repetitive applications of TachoSil[®].

In the event of hypersensitivity reactions, discontinue administration of TachoSil[®].

Do not leave TachoSil[®] in an infected or contaminated space.

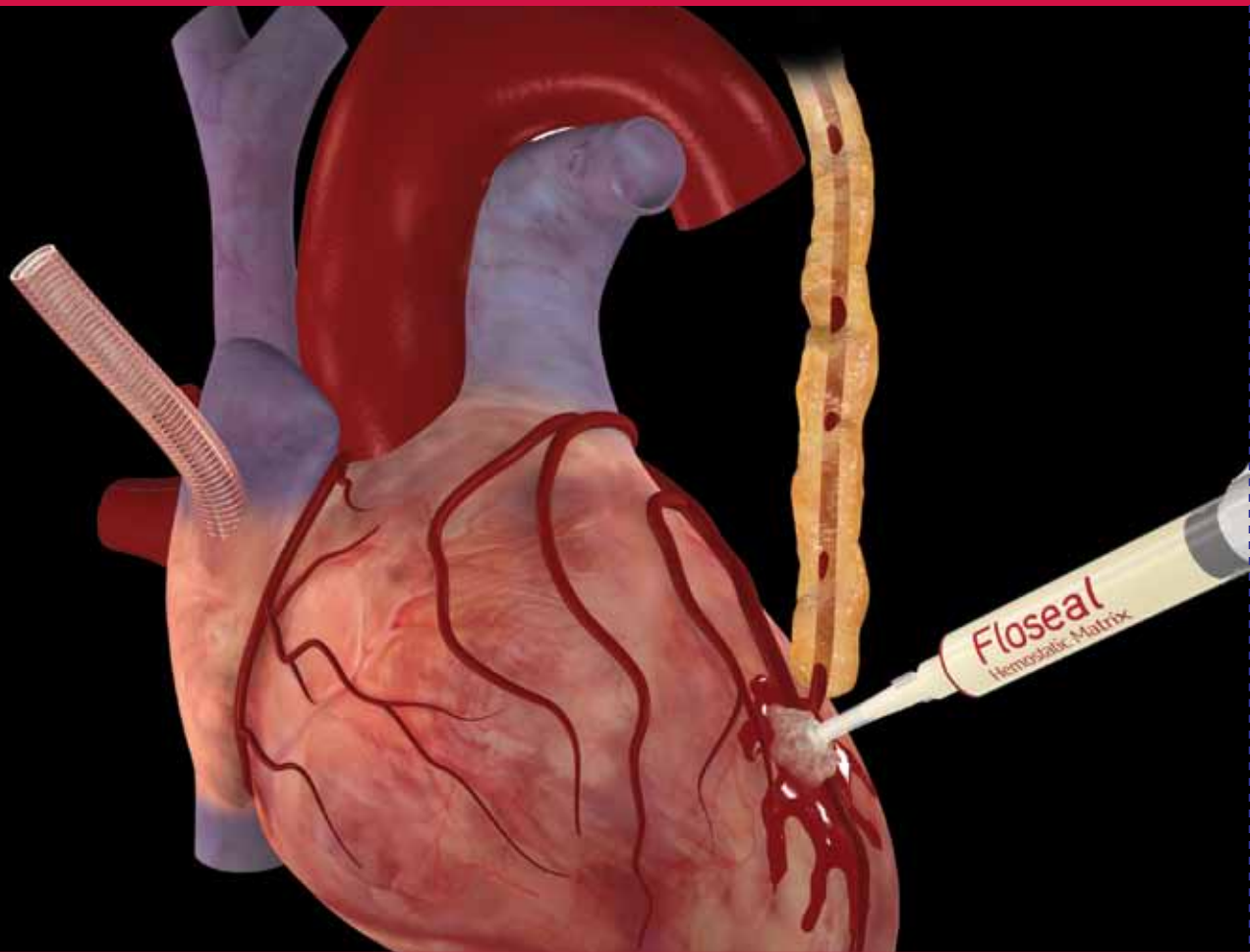
When placing TachoSil[®] into cavities or closed spaces, avoid overpacking. Use only the minimum amount of TachoSil[®] patches necessary to achieve hemostasis.

The active substances of TachoSil[®] are made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, that can cause disease.

In the cardiovascular study the most frequently reported adverse reactions were atrial fibrillation (18 patients [29.0%] in the TachoSil[®] group and 14 patients [24.6%] in the comparator group) and pleural effusion (14 patients [22.6%] in the TachoSil[®] group and 11 patients [19.3%] in the comparator group).

Please see accompanying full Prescribing Information.

AGGRESSIVE BLEEDING WET FIELD APPLICATION



FLOSEAL provides effective, flowable, adjunctive hemostasis clinically proven to stop aggressive bleeds in cardiovascular surgery.² FLOSEAL can be applied on irregular surfaces³ such as the sternum and bleeding anastomoses.

Why FLOSEAL Hemostatic Matrix ?

Efficacy in active bleeding sites including wounds submerged in pooled blood²

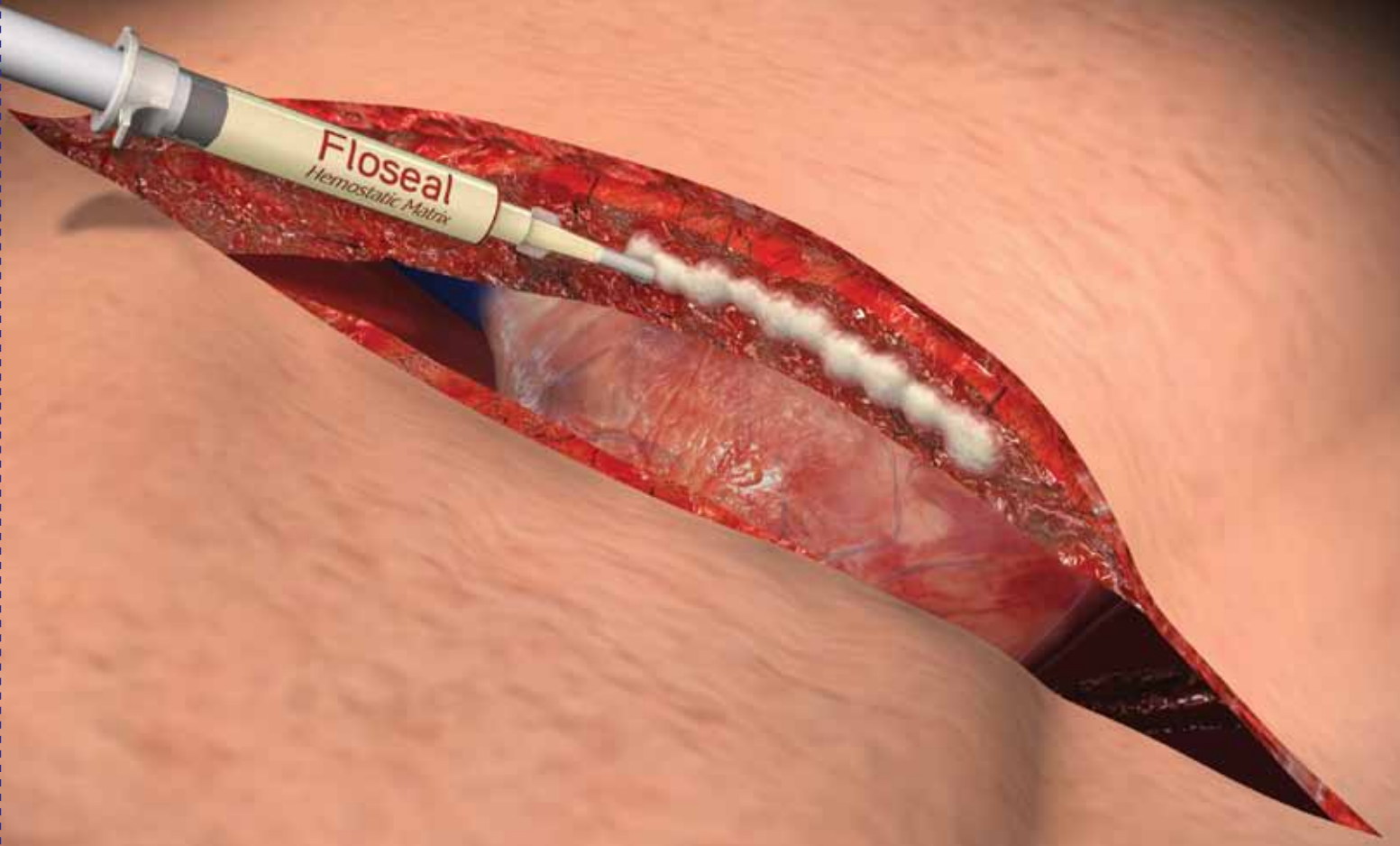
Conformability for precise application on irregular surfaces¹²

Speed to hemostasis: Median time to hemostasis: 2 minutes²

Effective hemostasis: Stops bleeding 89% of the time in fully heparinized patients²



Floseal
Hemostatic Matrix



FLOSEAL Hemostatic Matrix Indications

FLOSEAL is indicated in surgical procedures (other than ophthalmic) as an adjunct to hemostasis when control of bleeding by ligation or conventional procedures is ineffective or impractical.

Important Risk Information for FLOSEAL

Do not use FLOSEAL in patients with known allergies to materials of bovine origin.

Do not use FLOSEAL in the closure of skin incisions because it may interfere with the healing of the skin edges.

FLOSEAL must not be injected into blood vessels, or allowed to enter blood vessels. Do not apply in the absence of active bleeding. Extensive intravascular clotting and even death may result.

FLOSEAL is made from human plasma. It may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.

FLOSEAL is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for hemostasis.

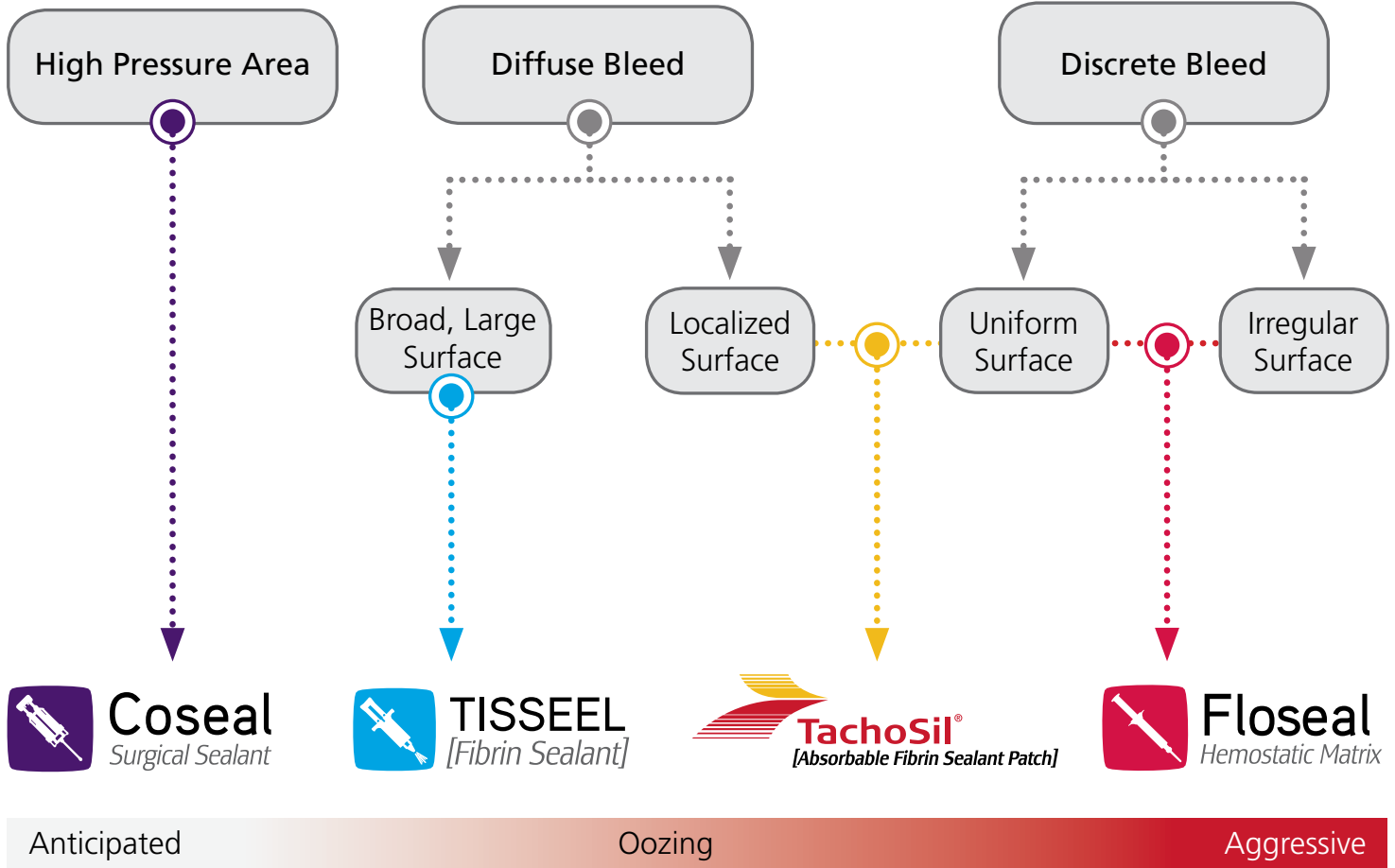
Excess FLOSEAL (material not incorporated in the hemostatic clot) should always be removed by gentle irrigation from the site of application.

The maximum swell volume of approximately 20% is achieved within about 10 minutes.

FLOSEAL should not be used in conjunction with methylmethacrylate or other acrylic adhesives. Do not use FLOSEAL on bone surfaces where adhesives will be required to attach a prosthetic device.

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

Selecting the Optimal Adjunctive Hemostatic Agent or Sealant in Cardiovascular Surgery Bleeding Scenarios



www.baxterbiosurgery.com

For more information, contact your local sales representative or call 1-800-423-2090

References

1. TachoSil® [Absorbable Fibrin Sealant Patch] full Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; 2010.
2. FLOSEAL Hemostatic Matrix Instructions for Use. Hayward, CA: Baxter Healthcare Corporation. 0710217. Rev. 2. February 2010.
3. Oz MC, Delos MC, Badduke BR, et al. Controlled clinical trial of a novel hemostatic agent in cardiac surgery. *Ann Thorac Surg* 2000;69:1376-1382.
4. COSEAL Surgical Sealant Instructions For Use, Hayward, CA: Baxter Healthcare Corporation. March 2009.
5. Glickman M, Gheissari A, Money S, et al. A polymeric sealant inhibits anastomotic suture hold bleeding more rapidly than Gelfoam/Thrombin. *Arch Surg* 2002;137:326-331.
6. 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.
7. 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.
8. 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.
9. Wallace DG, Cruise GM, Rhee WM, et al. A tissue sealant based on reactive multifunctional polyethylene glycol. *J Biomed* 2001;58:545-555.
10. TISSEEL [Fibrin Sealant] full Prescribing Information, 10/2010.
11. Rousou J, Gonzalez-Lavin L, Cosgrove D, et al. Randomized clinical trial of fibrin sealant in patients undergoing re-sternotomy or reoperation after cardiac operations. *J Thorac Cardiovasc Surg* 1989;97:194-203.
12. Renkens KL Jr., Payner TD, Leipzig TJ, et al. A multicenter, prospective, randomized trial evaluating a new hemostatic agent for spinal surgery. *Spine* 2001;26:1645-1650.

Please see product ordering information included in the pocket.

Baxter, Coseal, Floseal and Tisseel are registered trademarks of Baxter International Inc. TachoSil® is a registered trademark of Nycomed Pharma AS, used under license.



Baxter

Baxter International Inc.
One Baxter Parkway
Deerfield, Illinois 60015

www.baxter.com