

Baxter

Floseal

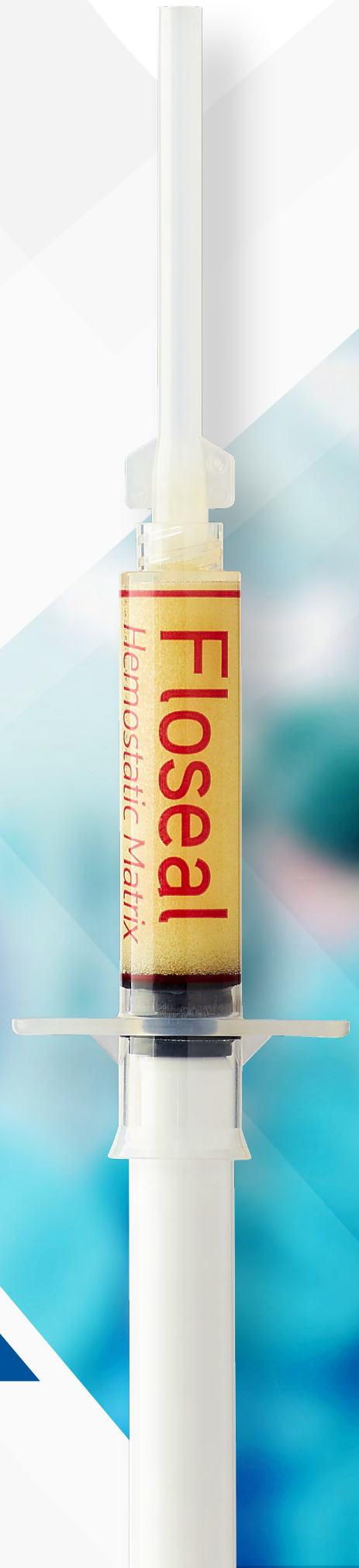
HEMOSTATIC MATRIX

FLOSEAL + RECOTHROM

UNMATCHED SPEED.
RELIABLE **HEMOSTASIS.**

THE **FIRST & ONLY** ACTIVE FLOWABLE HEMOSTAT
TO USE RECOMBINANT DNA TECHNOLOGY.

Please see the full indication and important risk information on back.



INNOVATING FLOSEAL WITH THE TECHNOLOGY OF **RECOTHROM**



FLOSEAL remains the same effective hemostat you've trusted for **20+ years**, innovated with the technology of **RECOTHROM** which allows for even faster product preparation.¹

THE BENEFITS OF **RECOTHROM**

RECOTHROM Thrombin Topical (Recombinant) is manufactured in a laboratory using recombinant DNA technology. The DNA sequence for human thrombin is isolated and replicated in a lab allowing RECOTHROM to provide the following benefits.²



No human blood components²

Manufactured using recombinant DNA technology²



Structurally similar to human thrombin²

Same amino acid sequence as human thrombin with reduced risk of viral or disease transmission²



Eliminate reliance on human blood donations²

Uses innovative technology to source thrombin²

THE ADVANTAGES OF FLOSEAL + RECOTHROM

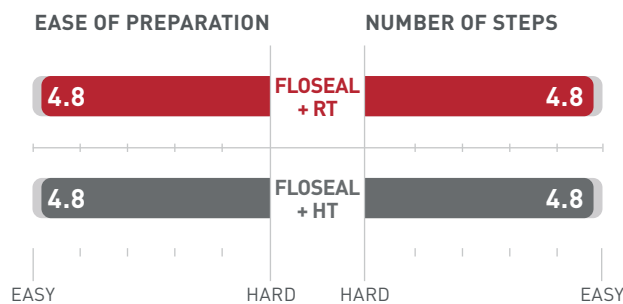


More than
1.5x
FASTER Prep Time

vs. FLOSEAL + Human Thrombin [HT]¹

Up to
78
SECONDS FASTER
Prep Time

vs. FLOSEAL + HT*¹



Comparison of technical characteristics, not clinical effectiveness.

SAME, EASY PREPARATION¹

FLOSEAL + RECOTHROM (RT) has the exact same preparation steps as FLOSEAL + HT.

MOST PREFERRED FLOWABLE HEMOSTAT¹

In a preparation comparison study, 30 surgical staff members prepared and evaluated thrombin reconstitution speed, total preparation time, and ease of preparation of FLOSEAL + RECOTHROM and FLOSEAL + Human Thrombin.



*FLOSEAL + RECOTHROM is faster to prepare than FLOSEAL + Human Thrombin. For 10 mL, FLOSEAL + RECOTHROM saved 78 seconds of preparation time. For 5 mL, FLOSEAL + RECOTHROM saved 41 seconds of preparation time.¹



Floseal

HEMOSTATIC MATRIX

FLOSEAL Hemostatic Matrix Indication

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

Important Risk Information

Do not inject intravascularly.

Do not inject or compress FLOSEAL Matrix into blood vessels.

Do not apply FLOSEAL Matrix in the absence of active blood flow, e.g., while the vessel is clamped or bypassed, as extensive intravascular clotting and even death may result.

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

Do not administer to patients with a history of hypersensitivity to RECOTHROM thrombin, any components of RECOTHROM, or hamster proteins. Hypersensitivity reactions, including anaphylaxis, may occur. RECOTHROM thrombin is produced in a genetically modified Chinese Hamster Ovary (CHO) cell line and may contain hamster or snake proteins.

Antibody formation to RECOTHROM occurred in <1% of patients. None of the antibodies detected neutralized native human thrombin.

Thrombin must be added to the Gelatin Matrix prior to use.

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

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

FLOSEAL Matrix should not be used for the primary treatment of coagulation disorders.

The safety and effectiveness for use in neurological and urological procedures has not been established through randomized clinical studies.

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

The particles of FLOSEAL Matrix swell approximately 10-20% upon contact with blood or other fluids creating a tamponade effect. Maximum swell volume is achieved within about 10 minutes.

It is not known whether FLOSEAL Matrix can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. FLOSEAL Matrix should be administered to a pregnant woman only if clearly needed.

The safety and effectiveness of the combined use of FLOSEAL Matrix with antibiotic solutions or powders has not been established.

Do not use air to remove residual FLOSEAL Matrix from Applicator tip. The Applicator tips should not be cut, as tissue injury from sharp edges may result.

Do not use FLOSEAL Matrix on bone surfaces where adhesives, such as methylmethacrylate or other acrylic adhesives, will be required to attach a prosthetic device.

As with other hemostatic agents, do not apply FLOSEAL Matrix to sites where there is negative peripheral venous pressure (e.g. due to patient positioning), as material may be drawn into the vascular system potentially resulting in life-threatening thromboembolic events.

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

ORDERING INFORMATION

DESCRIPTION	QUANTITY	ORDER NUMBER
FLOSEAL with RECOTHROM 5mL	case of 6	ADS202105
FLOSEAL with RECOTHROM 10mL	case of 6	ADS202110
Disposable Curved Applicator	pack of 10	ADS201815
13cm Malleable Applicator	pack of 6	ADS201816
Endoscopic Applicator (41cm)	case of 6	0600125



For questions or ordering information, please contact your Baxter representative or call 888-229-0001.

Visit advancedsurgery.baxter.com/floseal-recothrom for details.

ADVANCING THE ART OF HEALING

1. Baxter. Data on file.
2. Floseal with Recothrom IFU.

