Floseal
HEMOSTATIC MATRIX

FLOSEAL with RECOTHROM Preparation Instructions

1 PREPARING THE THROMBIN SOLUTION

Inside the sterile field

1

Open the vial adapter packaging. Remove the luer cap from the pre-filled sodium chloride solution syringe.

2

Attach the pre-filled sodium chloride solution syringe to the luer connector of the vial adapter.

3

Remove the plastic cap from the thrombin vial. While holding the vial adapter, pierce the rubber stopper of the thrombin vial. Transfer the entire contents of the sodium chloride solution into the thrombin vial.

NOTE: If necessary, the vacuum in the vial can be released. Loosen the syringe connection one quarter turn, then retighten. Ensure all the thrombin is completely dissolved. Gently swirl the vial, if necessary.

4

Once reconstituted, the thrombin solution can be used to prepare FLOSEAL Matrix immediately or may be stored in the vial up to four (4) hours.

NOTE: For FLOSEAL 5mL kit, draw 4mL thrombin solution into the syringe. For FLOSEAL 10mL kit, draw 8mL thrombin solution into the syringe.

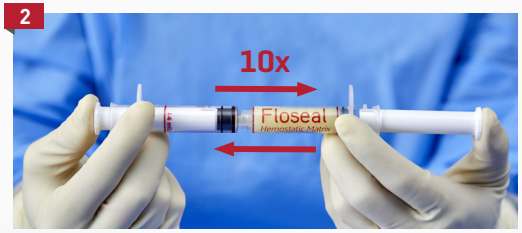
2 MIXING THE THROMBIN SOLUTION INTO THE GELATIN MATRIX

Inside the sterile field

1

Remove the luer cap from the FLOSEAL Gelatin Matrix syringe. Connect this syringe to the syringe containing the thrombin solution.

2



Quickly push the thrombin solution into the gelatin matrix. Transfer the mixture between syringes for a total of 10 back-and-forth passes, making sure the FLOSEAL material ends in the syringe labeled FLOSEAL.

Allow 30 seconds after preparation before FLOSEAL Matrix is applied to help ensure optimal product consistency. Keep syringes connected until ready to use. FLOSEAL Matrix may be used up to 8 hours after mixing with the thrombin solution.

3

FLOSEAL Matrix may be extruded directly from the syringe. If desired, connect an applicator tip to the FLOSEAL Matrix syringe.

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.
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