

Preparation Instructions (5 mL)

FLOSEAL Hemostatic Matrix



1 Open all packages and place the components in a sterile field.



1 Inspect the integrity of the contents of the FLOSEAL Kit. If the packaging or vial has been damaged or opened, do not use.



2 Open the package containing the ampoule and deliver the ampoule to the sterile field.



3 Open the outer pouch of the thrombin component and deliver the inner pouch to the sterile field. Once placed in the sterile field, the inner package may be opened at any time.



4 Open the outer pouch of the gelatin matrix component and deliver the inner pouch to the sterile field. Once placed in the sterile field, the inner package may be opened at any time.

Needle-free simplicity in preparation

2 Preparing the Thrombin Solution

Once mixed, the Thrombin Solution can be used immediately or may be stored at 2-25°C in the vial up to 4 hours.

Components:



5 Remove the Tyvek lid from the vial adapter packaging.



6 Remove twist-off cap from the Sodium Chloride ampoule.



7 While gripping the vial adapter packaging, attach the pre-filled Sodium Chloride ampoule to the luer connector of the vial adapter and remove from remaining packaging.



8 Remove the plastic flip-off cap from the Thrombin vial.



9 While holding the vial adapter, pierce the rubber stopper of the Thrombin vial.

Transfer the entire contents of the Sodium Chloride ampoule into the Thrombin vial.



10 Gently swirl the Thrombin vial with vial adapter and ampoule attached until the Thrombin is completely dissolved.



3 Mixing the components

Components:



11 Remove ampoule.



12 Attach empty 5 mL syringe with female luer connector to the vial adapter and draw the thrombin solution from the vial to the indicated mark (4 mL).

Discard the empty Thrombin vial and the vial adapter appropriately.



13 Remove the luer cap from the FLOSEAL gelatin matrix syringe.

Connect this syringe to the syringe containing the Thrombin Solution.



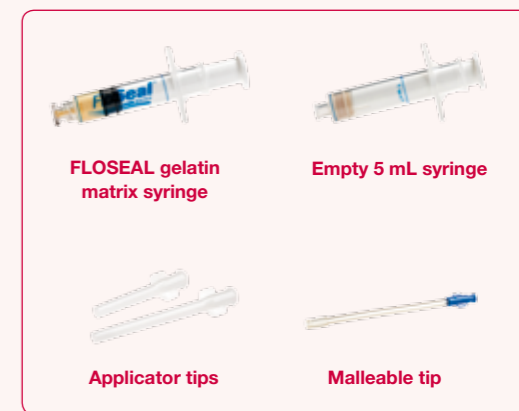
14 Push the Thrombin Solution quickly into the gelatin matrix.

Transfer the mixture back and forth at least 10 times, making sure the mixed FLOSEAL material ends up in the FLOSEAL syringe.

Allow 30 seconds after preparation before FLOSEAL is applied to ensure optimal product consistency. FLOSEAL may be used up to 8 hours after mixing with the Thrombin Solution.



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



FLOSEAL Hemostatic Matrix Indication

FLOSEAL is indicated in surgical procedures as an adjunct to hemostasis when control of bleeding, ranging from oozing to spurting, by ligature or conventional procedures is ineffective or impractical.

Contraindications

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

Warnings

Do not inject or compress FLOSEAL into blood vessels. For a complete list of all warnings please refer to your IFU.

Ordering Information

Product	Ordering code
Flo seal Hemostatic Matrix 5 mL (with needle-free adapter), 6 pack	1503353
Endoscopic Applicator, 6 pack	060012

For detailed information please contact your local representative:

www.baxterbiosurgery.com