



1 Preparing the Thrombin Solution

Inside the sterile field



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



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



- 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.



- Facilitate reconstitution of the thrombin by holding the vial and gently swirling it with the syringe still attached until the Thrombin is completely dissolved.

**If necessary, the vacuum in the vial can be released. Loosen the syringe connection one quarter (1/4) turn then re-tighten*



- 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:
FLOSEAL Matrix 5mL KIT:
Draw 4mL Thrombin solution

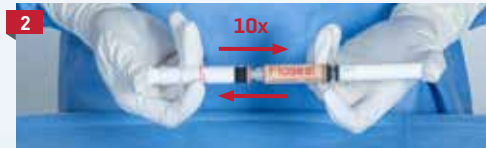
FLOSEAL Matrix 10mL KIT:
Draw 8mL Thrombin solution

2 Mixing the Thrombin Solution into the Gelatin Matrix

Inside the sterile field



- Remove the luer cap from the FLOSEAL Gelatin Matrix Syringe. Connect this syringe to the syringe containing the Thrombin Solution.



- 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 mixed FLOSEAL material ends in the FLOSEAL Matrix syringe.
- 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.



- 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 for FLOSEAL Matrix

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 use FLOSEAL Matrix in the closure of skin incisions because it may interfere with the healing of the skin edges.

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

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

FLOSEAL Matrix swells by approximately 10% to 20% after product is applied. Maximum swell volume is achieved within about 10 minutes.

The safety and effectiveness of FLOSEAL Matrix has not been established in children under 2 years of age and pregnant women.

Do not use air to remove residual FLOSEAL Matrix from Applicator tip. The Applicator tips should not be cut. 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.

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

ITEM

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| FLOSEAL Fast Prep 5ml | case of 6 | ADS201844 |
| FLOSEAL Fast Prep 10ml | case of 6 | ADS201845 |
| Disposable Curved Applicator | pack of 10 | ADS201815 |
| 13cm Malleable Applicator | pack of 6 | ADS201816 |
| Endoscopic Applicator [41cm] | case of 6 | 0600125 |
| Endoscopic Applicator with Malleable Tip | case of 6 | 0600127 |

For questions or ordering information, please contact your Baxter representative or call 888-229-0001
<https://advancedsurgery.baxter.com>

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