

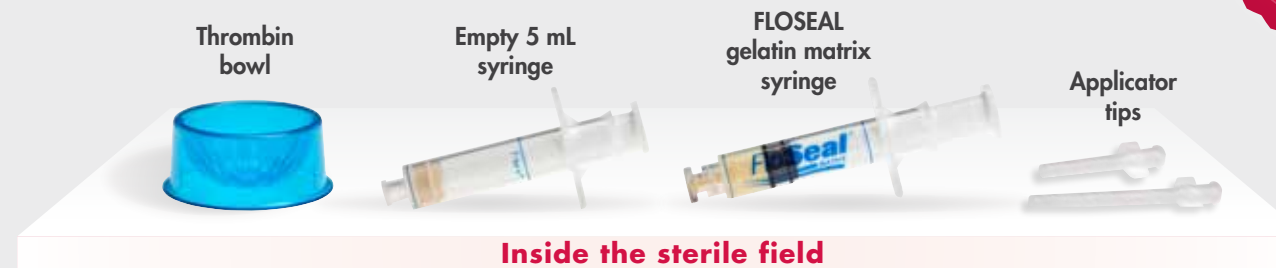
Same great performance with needle-free simplicity in preparation



**NOW
NEEDLE-FREE**

FLOSEAL Hemostatic Matrix Preparation Instructions (5 mL)

Separate the package elements and place the sealed gelatin matrix components in a **sterile field**.



FLOSEAL Hemostatic Matrix Indication

FLOSEAL is indicated in surgical procedures (other than in 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 inject or compress FLOSEAL into blood vessels. Do not apply FLOSEAL 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 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 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 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.

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

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

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

Caution: Federal Law (United States) restricts this device to sale by or on the order of a licensed healthcare practitioner.

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1 Preparing the Thrombin Solution

Outside the sterile field



- Remove the Luer cap from the pre-filled sodium chloride solution syringe.
- Remove the plastic flip-off cap from the thrombin vial.



- Open the vial adapter packaging.
- Attach the pre-filled sodium chloride solution syringe to the Luer connector of the vial adapter.



- 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.



- Leave the syringe attached to the vial adapter and affix the "Thrombin" sticker to it.
- If you have any concern regarding maintaining aseptic technique, please note the option of using a separate sterile syringe that has a standard male Luer connection rather than reattaching the pre-filled sodium chloride solution syringe. Affix the "Thrombin" label to it.*



- Gently swirl the thrombin vial with the syringe still attached until the thrombin is completely dissolved.
- Loosening the syringe from the vial adapter releases the pressure in the vial and speeds reconstitution of the Thrombin Solution.



- Aspirate the Thrombin Solution into the syringe now labeled "Thrombin."
- Loosen the syringe connection a quarter (1/4) turn then re-tighten. Ensure that the syringe and vial adapter are firmly connected prior to drawing the solution into the syringe.

Once mixed, the Thrombin Solution can be used immediately or may be stored in the vial up to **4 hours**.

Additional Tip: Disconnect the syringe from the vial and pull air into the empty syringe and then reattach. Inject air into the vial in order to make withdrawing all of the liquid feasible. The addition of air into the vial after the solution is dissolved allows ease of drawing up any solution.

2 Mixing the components

Inside the sterile field



- Place the thrombin bowl onto the sterile field and apply the "Thrombin" sticker to it.
- Transfer the Thrombin Solution into the bowl.



- Using the empty 5 mL syringe aspirate the Thrombin Solution to the indicated mark (4 mL).



- Remove the Luer cap from the FLOSEAL gelatin matrix syringe.
- Connect this syringe to the syringe containing the Thrombin Solution.



- Push the Thrombin Solution quickly into the gelatin matrix.
- Transfer the mixture back and forth at least 20 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 **2 hours** after mixing with the Thrombin Solution.



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

For more information or a demonstration of the new FLOSEAL Hemostatic Matrix Kit with needle-free adapter, please see your Baxter Sales Representative.

To order FLOSEAL, call 1-800-423-2090

FLOSEAL Hemostatic Matrix

5 mL (with needle-free adapter)

Ordering code

1503350



Same great performance with needle-free simplicity in preparation



**NOW
NEEDLE-FREE**

FLOSEAL Hemostatic Matrix Preparation Instructions (10 mL)

Separate the package elements and place the sealed gelatin matrix components in a **sterile field**.



FLOSEAL Hemostatic Matrix Indication

FLOSEAL is indicated in surgical procedures (other than in 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 inject or compress FLOSEAL into blood vessels. Do not apply FLOSEAL 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 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 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 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.

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

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

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

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1 Preparing the Thrombin Solution

Outside the sterile field



- Remove the Luer cap from the pre-filled sodium chloride solution syringe.
- Remove the plastic flip-off cap from the thrombin vial.



- Open the vial adapter packaging.
- Attach the pre-filled sodium chloride solution syringe to the Luer connector of the vial adapter.



- 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.



- Leave the syringe attached to the vial adapter and affix the "Thrombin" sticker to it.
- If you have any concern regarding maintaining aseptic technique, please note the option of using a separate sterile syringe that has a standard male Luer connection rather than reattaching the pre-filled sodium chloride solution syringe. Affix the "Thrombin" label to it.*



- Gently swirl the thrombin vial with the syringe still attached until the thrombin is completely dissolved.
- Loosening the syringe from the vial adapter releases the pressure in the vial and speeds reconstitution of the Thrombin Solution.



- Aspirate the Thrombin Solution into the syringe now labeled "Thrombin."
- Loosen the syringe connection a quarter (1/4) turn then re-tighten. Ensure that the syringe and vial adapter are firmly connected prior to drawing the solution into the syringe.

Once mixed, the Thrombin Solution can be used immediately or may be stored in the vial up to **4 hours**.

Additional Tip: Disconnect the syringe from the vial and pull air into the empty syringe and then reattach. Inject air into the vial in order to make withdrawing all of the liquid feasible. The addition of air into the vial after the solution is dissolved allows ease of drawing up any solution.

2 Mixing the components

Inside the sterile field



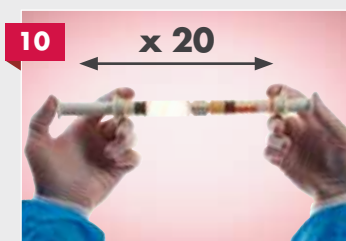
- Place the thrombin bowl onto the sterile field and apply the "Thrombin" sticker to it.
- Transfer the Thrombin Solution into the bowl.



- Attach the Luer connector to the empty 10 mL syringe and aspirate the Thrombin Solution to the indicated mark (8 mL).



- Remove the Luer cap from the FLOSEAL gelatin matrix syringe.
- Connect this syringe to the syringe containing the Thrombin Solution.



- Push the Thrombin Solution quickly into the gelatin matrix.
- Transfer the mixture back and forth at least 20 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 **2 hours** after mixing with the Thrombin Solution.



- FLOSEAL may be extruded directly from the syringe. However, if desired, connect an applicator tip.
- If the malleable tip is selected, form the tip as necessary after it is attached. Flush with saline, if needed.

For more information or a demonstration of the new FLOSEAL Hemostatic Matrix Kit with needle-free adapter, please see your Baxter Sales Representative.

To order FLOSEAL, call 1-800-423-2090

FLOSEAL Hemostatic Matrix	Ordering code
10 mL (with needle-free adapter)	1503352

