Inactivation treatment process is included in the manufacture of FLOSEAL Matrix. A two-step vapor-heated and solvent/detergent viral reduction. However, no procedure has been shown to be particularly difficult to remove or inactivate at this time. The safety and effectiveness of FLOSEAL Matrix have not been established in children under 2 years of age and pregnant women.

The use and removal of residual FLOSEAL Matrix from Application Site

Procedure:

- Use only as directed.
- Do not re-use.
- Do not use as a local anesthetic.
- Do not use as a neurolytic.
- Do not inject FLOSEAL Matrix into a venous or arterial vessel.
- Do not use FLOSEAL, Matrix in patients with known allergies or reactions to bovine products.
- Do not use FLOSEAL in patients with known allergies to bovine serum albumin.

In ophthalmic) as an adjunct to hemostasis when control of bleeding is critical, particularly in the presence of suture materials. In urological procedures, FLOSEAL Matrix should not be left in the bladder. In the cardiac cohort, 88 of the 93 patients (95%) underwent successful application of FLOSEAL Matrix for the primary endpoint. Among all procedures, the odds ratio was 3.2 in 153 patients and 0.75 in 150 patients. The trial was performed in 36 centers in the United States and was randomized.
Moving the Thrombin Solution into the Gelatin Matrix

1. A 5 mL syringe with an integral female Luer connector is provided with the Gelatin Matrix Component. Using this syringe, aspirate the thrombin from the Thrombin bowl into the empty 5 mL syringe (the initial 4 mL).

2. Remove the cap from the Gelatin Matrix Syringe carefully to avoid splashing the Gelatin Matrix granules. Connect the Gelatin Matrix Syringe to the syringe containing the Thrombin Solution. Push the plunger of the Thrombin Solution syringe to fully pass the solution quickly into the Gelatin Matrix Syringe. This constitutes “one pass”. Transfer the Gelatin Matrix-Thrombin Solution mixture back and forth between the syringes for a total of at least 20 passes. While starting to mix, do not try to force large, dry clumps of the Gelatin Matrix through the Luer connectors, as it may stop. After the first several passes, most of the Gelatin Matrix should be hydrated, and the contents should then be rapidly passed between the syringes to promote thorough mixing. The FLOSEAL matrix should be in the syringe at \(4 \text{C}\) at the completion of mixing.

3. Allow 30 seconds after preparation before product is applied to allow for minimal optimal product consistency and performance. To prevent premature drying at FLOSEAL Matrix, syringes can be kept connected until product is required.

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

FLOSEAL Placement/Application Steps:

Do not inject FLOSEAL Matrix into blood vessels. See the “Contraindications,” “Warnings,” “Precautions,” and “Adverse Events” sections contained in these Instructions for Use.

For best results, FLOSEAL Matrix should be in complete contact with the active bleeding tissue surface.

The portuloids of FLOSEAL Matrix swell approximately 10-20% upon contact with blood or other fluids. Maximum swell volume is achieved within about 15 minutes.

Application Technique

1. Apply FLOSEAL directly to the source of bleeding. This will mean applying to bare tissue. Gently press on the vessel(s) to be sealed with a gentle pressure of FLOSEAL Matrix.

2. Maintain FLOSEAL Matrix at the site of bleeding for 30 minutes, or until bleeding has stopped.

3. Use adequate amounts of FLOSEAL to completely cover the tissue defect.

4. Work quickly.

5. Always rinse excess FLOSEAL, even gently so as not to disrupt the new clot and be sure to remove excess.

Detailed Application Steps

1. Identify the source of bleeding at the tissue surface. This is the target site for FLOSEAL Matrix application.

2. Minimally approximate a gauge spume (non-reinforced) against the bleeding surface and use the Applicator tip (or syringe connector) to dispense FLOSEAL Matrix between the spume and the bleeding surface. The gauge spume will hold FLOSEAL Matrix in place against the bleeding surface in the presence of active bleeding. Apply enough FLOSEAL Matrix to create a small “mount” of material at the site of bleeding.

3. For tissue defects “divorced” or “covered”, begin applying FLOSEAL Matrix to the exposed part of the lesion, and continue applying material at the syringe (or Applicator tip, if used) from the lesion. This “back-ringing” action will ensure that FLOSEAL Matrix comes into contact with the entire bleeding surface at the tissue defect.

4. Apply a gauge spume washout with sterile (non-reinforced) saline to approximate the FLOSEAL Matrix against the bleeding surface, confirming it is in the lesion.

5. After approximately two (2) minutes, lift the gauge spume and inspect the lesion site. Once bleeding has ceased, excess FLOSEAL Matrix clot (including the hemorrhagic clot) should always be removed by gentle irrigation and suctioned away from the treatment site.

6. If the gauge spume adheres to the newly formed clot, irrigate with non-reinforced saline to remove disruption of the clot.

7. In cases of persistent bleeding, indicated by suction and bleeding through the portuloids, insert the Applicator tip through the center of the area of actively bleeding FLOSEAL Matrix to deliver fresh FLOSEAL Matrix as shown in the tissue surface. After re-application of FLOSEAL Matrix, resume approximation with a gauge spume for up to another two (2) minutes, and then re-inspect the site again. Re-apply treatment if necessary.

8. Once bleeding has ceased, excess FLOSEAL Matrix material not incorporated in the hemorrhagic clot, should always be removed by gentle irrigation and suctioned away from the treatment site.

9. Do not discard the FLOSEAL Matrix clot by postoperative manipulation. FLOSEAL Matrix incorporated in the hemorrhagic clot should be left in situ.

Storage Conditions:

The FLOSEAL Matrix kit should be stored at 2 - 25°C (36 - 77°F). Do not freeze.

Caution: Consult accompanying documents for use and storage in a licensed healthcare practitioner.