

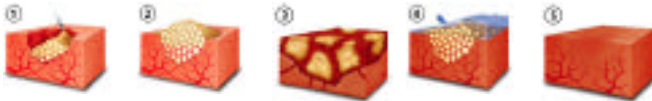
FloSeal Matrix Hemostatic Sealant

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Technology and medical advances have led to new and improved surgical techniques which allow us to help fight disease and recover from injuries faster. We see these advances in all surgical disciplines from vascular and cardiac to orthopedic and general surgery to even office based outpatient surgery.



In all surgical procedures blood loss will occur. The amount of blood loss depends on several factors including the type of surgery, medications administered, and the method of hemostasis (method to stop bleeding). Not all products work the same and many topical products are not effective on anti-coagulated patients. Staples and sutures have been the most common method for closing surgical wounds but they have numerous limitations including the fact that they have inherent sealing capabilities. Over the years numerous materials have been used to achieve hemostasis such as sponges, topical hemostats (like gelatin sponge), thrombin, fibrin glue and other types of surgical sealants.

FloSeal Matrix is an extremely versatile collagen- derived material with numerous potential applications in the surgical field including bleeding control and adhesion prevention. FloSeal is indicated in surgical procedures (other than ophthalmic and urological) as an adjunct to hemostasis when control of bleeding by ligatur or conventional procedures becomes ineffective or impractical.



FloSeal comes packages as a kit with two sterile components: 1.) a gelatin matrix component with a granular physical structure, and 2.) a thrombin component. Thrombin is a commercially available clotting enzyme.

When mixed the thrombin coats the gelatin matrix and they act together to promote hemostasis. The mixture's granular nature allows it to conform to irregular wound geometries.

How It Works:

1. FloSeal is applied to the tissue surface at the base of the lesion. Its granules fill the wound and conform to the shape.
2. The granules swell by 10-20% upon contact with blood creating a dam at the site of bleeding.
3. Thrombin converts fibrinogen to a fibrin polymer forming a clot around the stable matrix.
4. Excess granules not incorporated in the clot are gently irrigated away without disruption of the seal.
5. Finally FloSeal is reabsorbed by the body within 6-8 weeks, consistent with the time frame of normal wound healing.

Clinical Trials: In a clinical study performed in 1998 FloSeal Matrix successfully stopped bleeding in 72 of 74 (97%) discrete applications. The 20 different types of surgeries in this series encompassed several procedures ranging from endarterectomies (surgical cleaning of the carotid arteries) to pediatric heart reconstruction to spinal discectomies – all indicative of FloSeals broad potential.

Advantages: FloSeal is a flowable gel that can be delivered to any bleeding surface. It remains in place on irregular anatomy and can be irrigated away if needed without disrupting the clot. Its application does not require a dry field and it can be used on brisk or profuse arterial bleeding. FloSeal is effective on heparinized patients and can be stored at room temperature. There is no complex mixing involved, as the solution can be prepared in approximately 2 minutes and it is delivered in a single syringe. FloSeal is competitively priced and significantly less expensive than some other hemostatic sealants.