

PRESCRIBING INFORMATION
FLOSEAL Hemostatic Matrix

INDICATIONS: FLOSEAL Matrix is indicated in surgical procedures (other than in ophthalmic) 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 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 occur. To avoid a risk of allergic-anaphylactoid reaction and/or thromboembolic events, which may be life-threatening, do not inject FLOSEAL Matrix into a vessel or tissue. Do not use FLOSEAL Matrix in the closure of skin incisions because it may interfere with the healing of the skin edges due to mechanical interposition of gelatin. Do not use FLOSEAL Matrix in patients with known allergies to materials of bovine origin.

WARNINGS: FLOSEAL is 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 be removed from the site of application using gentle irrigation. The maximum swell volume of 20% is achieved within about 10 minutes. FLOSEAL should not be used for controlling intrauterine post-partum bleeding or menorrhagia. FLOSEAL should not be used in the presence of infection. The safety and effectiveness of FLOSEAL has not been established in children and pregnant women. Do not use air to remove residual FLOSEAL Matrix from Applicator tip. FLOSEAL should not be used in conjunction with methylmethacrylate or other acrylic adhesives.

FOR MORE INFORMATION: Please consult the Instructions for Use at http://www.baxter.ca/en_CA/assets/downloads/monographs/Floseal%20FinalArtwork_0726933_23FEB2015_footer%20removed.pdf for important information relating to indications for use warnings, precautions, adverse events and directions for use which have not been discussed in this piece. The Instructions for Use is also available by calling us at 1-888-719-9955.
