GELFOAM PLUS Hemostasis Kit Indications

GELFOAM PLUS is intended as a hemostatic device for surgical procedures when control of capillary, venous, and arteriolar bleeding by pressure, ligature, and other conventional procedures is either ineffective or impractical.

Thrombin (Human) used without the Gelfoam Sterile Sponge is not indicated for hemostasis.

Important Risk Information for GELFOAM PLUS

GELFOAM PLUS is not recommended for use other than an adjunct for hemostasis.

GELFOAM PLUS should not be used in closure of skin incisions, because it may interfere with the healing of the skin edges.

GELFOAM PLUS should not be placed intravascularly, because of the risk of embolization.

Do not use GELFOAM Sterile Sponge in patients with known allergies to porcine collagen or Human Thrombin.

GELFOAM PLUS contains thrombin, which is made from human plasma. It may carry the risk of transmitting infectious agents, e.g., viruses, and theoretically the Creutzfeldt-Jakob disease (CJD) agent.

GELFOAM PLUS is not recommended in the presence of infection. There have been reports of fever associated with the use of Gelfoam Sterile Sponge, without demonstrable infection.

While packing a cavity for hemostasis is sometimes surgically indicated, GELFOAM PLUS should not be used in this manner unless excess product not needed to maintain hemostasis is removed. Whenever possible, GELFOAM PLUS should be removed after use in laminectomy procedures and from foramina in bone, once hemostasis is achieved. This is because GELFOAM Plus may swell to its original size on absorbing fluids, and produce nerve damage by pressure within confined bony spaces.

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