TACHOSIL® (Absorbable Fibrin Sealant Patch)

TACHOSIL is indicated as an adjunct to hemostasis for use in cardiovascular surgery when control of bleeding by standard surgical techniques (such as suture, ligature or cautery) is ineffective or impractical.

Do not use TACHOSIL in renal pelvis or ureter procedures.

Do not use TACHOSIL in the closure of skin incisions.

Do not use TACHOSIL in neurosurgical procedures.

Important Risk Information for TACHOSIL

Apply on the surface of tissue only. Do not apply TACHOSIL intravascularly. Intravascular application may result in life-threatening thromboembolic events.

Do not use TACHOSIL in individuals known to have anaphylactic or severe systemic reaction to human blood products or horse proteins.

Do not use TACHOSIL for the treatment of severe or brisk arterial bleeding.

Do not use TACHOSIL as the primary mode to control hemostasis. TACHOSIL is not intended as a substitute for meticulous surgical technique and the proper application of suture, ligature or other conventional procedures for hemostasis.

Hypersensitivity or allergic/anaphylactoid reactions may occur with TACHOSIL. Symptoms associated with allergic anaphylactic reactions include: flush, urticaria, pruritus, nausea, drop in blood pressure, tachycardia or bradycardia, dyspnea, severe hypotension and anaphylactic shock. These reactions may occur in patients receiving TACHOSIL for the first time or may increase with repetitive applications of TACHOSIL.

In the event of hypersensitivity reactions, discontinue administration of TACHOSIL.

Do not leave TACHOSIL in an infected or contaminated space.

When placing TACHOSIL into cavities or closed spaces, avoid overpacking. Use only the minimum amount of TACHOSIL patches necessary to achieve hemostasis.

The active substances of TACHOSIL are made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, that can cause disease.
In the cardiovascular study the most frequently reported adverse reactions were atrial fibrillation (18 patients [29.0%] in the TACHOSIL group and 14 patients [24.6%] in the comparator group) and pleural effusion (14 patients [22.6%] in the TACHOSIL group and 11 patients [19.3%] in the comparator group).

Please see accompanying full Prescribing Information.