

HEMOBLAST ISI

HEMOBLAST™ Bellows is indicated in surgical procedures as an adjunct to hemostasis when control of minimal, mild, and moderate bleeding by conventional procedures is ineffective or impractical, except in neurosurgical, ophthalmic, and urologic procedures.

Important Risk Information for HEMOBLAST™ Bellows:

1. Do not inject HEMOBLAST™ Bellows into a vessel or tissue. There is a risk of allergic-anaphylactoid reaction and/or thromboembolic events, which may be life-threatening.
2. Do not apply HEMOBLAST™ Bellows in the absence of active blood flow, e.g., while the vessel is clamped or bypassed. Extensive intravascular clotting and even death may result.
3. Do not administer to patients with known allergies or hypersensitivity to materials of porcine or bovine origin.
4. Because HEMOBLAST™ Bellows is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.
5. HEMOBLAST™ Bellows contains chondroitin sulfate from bovine origin which is associated with a remote risk for Transmissible Spongiform Encephalopathies (TSE), which has been minimized in accordance with regulatory guidelines by a manufacturing process with demonstrated TSE inactivation capacity.
6. When applied to a bleeding site, HEMOBLAST™ Bellows swells up to 60% within about 5 minutes.
7. Do not attempt to trim the applicator tip.
8. HEMOBLAST™ Bellows should not be used at the site of a valve replacement or repair as valvular dysfunction could occur.
9. HEMOBLAST™ Bellows should not be applied at the site of a synthetic graft or patch implant due to potential for decreased effectiveness.
10. The product should not be in contact with circulating cerebrospinal fluid (CSF).
11. The material has not been tested on children and pregnant or lactating women.

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