Indication
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 urological procedures

Important Risk Information for HEMOBLAST™ Bellows

- 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.
- 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.
- Do not use the HEMOBLAST™ Bellows for treatment of severe or extreme bleeding.
- Do not administer to patients with known allergies or hypersensitivity to materials of porcine or bovine origin.
- Do not use in the closure of skin incisions because it may interfere with the healing of the skin edges due to mechanical interposition of the powder.
- 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.
- 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.
- HEMOBLAST™ Bellows is not intended as a substitute for meticulous surgical technique and the proper application of ligatures or other conventional procedures for hemostasis.
- When applied to a bleeding site, HEMOBLAST™ Bellows swells up to 60% within about 5 minutes. Caution should be used when applying HEMOBLAST™ Bellows in any cavities or closed spaces due to the swelling of the device.
- Do not attempt to trim the applicator tip.
- HEMOBLAST™ Bellows should not be used at the site of a valve replacement or repair as valvular dysfunction could occur.
- HEMOBLAST™ Bellows should not be applied at the site of a synthetic graft or patch implant due to potential for decreased effectiveness.
- The product should not be in contact with circulating cerebrospinal fluid (CSF).
- Do not implant in an infected or necrotic site or one that is likely to develop an infection.
- The safety and effectiveness of the combined use of the hemostatic agent with other devices has not been evaluated in controlled clinical trials.
- 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.