PATIENT INFORMATION LEAFLET

Medical device: HEMOBLAST™ Bellows

Hemostatic agent – Reference : BQF02-AU

Please contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed

Any serious incident occurring related to HEMOBLAST™ Bellows should be reported with no delay to the distributor or manufacturer of the device and the Therapeutic Goods Administration. *Please refer to page 4 for contact details.*

E-mail address for any serious incident related to HEMOBLAST™ Bellows: complaint@biomup.com

INTENDED PURPOSE

Name of the Device: HEMOBLAST™ Bellows

Model Number : BQF02-AU

Intended purpose:

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. HEMOBLAST™ Bellows is also indicated in laparoscopic surgical procedures in the following specialties: Vascular, Abdominal, Gynecology and Head and Neck surgeries.

INTENDED POPULATION

Kind of patient on whom the device is intended to be used: The product is intended for adult population. It has not been tested on children, pregnant or, lactating women.

SAFE USE OF THE DEVICE

Intended performance of the device:

The HEMOBLAST™ Bellows is indicated as an adjuvant to hemostasis. The clinical benefits are :

- HEMOBLAST™ Bellows can be applied on focal and large diffuse bleeding surfaces (up to 50 cm²) for effective hemostasis.
- The human thrombin in HEMOBLAST™ Bellows has an adjunctive role and stimulates the coagulation pathway
- Effective hemostasis during surgical procedures is a key parameter in reducing the potential need of blood transfusion administration; and
- Immediately ready for use

Undesirable side effects that could be caused by use of the device:

Hypersensitivity or allergic/anaphylactoid reactions may occur with HEMOBLAST™ Bellows. Symptoms associated with such reactions include:

- Redness of the skin (flush),
- Hives (urticaria),
- Itchy areas of the skin (pruritus),
- Stomach discomfort and the sensation of wanting to vomit (nausea),
- Drop in blood pressure,
- Increased or decreased of heart pulse rate (tachycardia or bradycardia),
- Difficulty in breathing (dyspnea),
- Severe low blood pressure (severe hypotension), and
- Acute, severe, allergic reaction (anaphylactic shock).

These reactions may occur in patients exposed to the product for the first time or may increase with repetitive applications of the product.

In the event of hypersensitivity reactions, the use of HEMOBLAST™ Bellows should be permanently interrupted. Mild reactions can be managed with antihistamines. Severe hypotensive reactions require immediate intervention using current principles of shock therapy.

The most likely adverse reactions expected after application of hemostatic agents are:

- Low red blood cell count (anemia),
- Quivering or irregular heartbeat (atrial fibrillation),
- Infection,
- Scar formation (adhesion formation),
- Small bowel blockage (obstruction),
- Foreign body reaction with formation of inflammatory cells (giant cell granuloma),
- Serious bleeding (hemorrhage),
- Pain,
- Abscess and small nodule (granuloma) formation,
- Mild post-operative bleeding, and
- Local inflammation.

Residual risks that could arise due to any shortcomings of the protection measures:

The product must be stored between 2°C and 25°C (36 – 77° F) in a dry place away from humidity. In case storage conditions are not met, the powder contained in HEMOBLAST™ Bellows might be altered.

Warnings that could arise from the interaction of the device with other equipment:

- Exposure to solutions containing alcohol, iodine or heavy metals may cause the product to be inactivated. Avoid any contact of the product with non-physiological product.
- The safety and effectiveness of the combined use of HEMOBLAST™ Bellows with other biocompatible materials has not been evaluated.
- The product does not interfere with Magnetic Resonance (MR) environment and apparatus.

Precautions and other measures that should be taken by the patient or health professional because of the risks previously quoted:

The product must be stored between 2°C and 25°C (36 – 77° F) in a dry place away from humidity

Nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken: N/A

Symptoms of the device that could indicate that the device is malfunctioning:

If the powder of HEMOBLAST™ Bellows doesn't flow outside of the device, the device is malfunctioning.

Precautions and other measures that should be taken by the patient if the performance of the device changes or the patient experiences any of the symptoms mentioned previously:

Please contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed

Expected device lifetime:

HEMOBLAST™ Bellows is resorbable within 4 weeks. The shelf-life of the device is 36 months.

Measures that could shorten or lengthen device lifetime:

The product must be stored between 2°C and 25°C (36 – 77° F) in a dry place away from humidity. In case storage conditions are not met, the powder contained in HEMOBLAST™ Bellows and shelf-life might be altered.

Precautions and other measures that should be taken at, or near, the end of the expected device lifetime: N/A

Other circumstances in which the patient should contact a health professional in relation to the operation of the device:

Please contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed

DEVICE COMPOSITION

Materials and substances included in the device:

HEMOBLAST™ Bellows is a single use, sterile medical device containing a hemostatic powder comprised of collagen, chondroitin sulfate, and thrombin. The powder is dry, sterilized, compatible with the human body (biocompatible), and does not produce fever (non-pyrogenic). No preparation, mixing or heating is required. HEMOBLAST™ Bellows is composed predominantly of highly purified porcine collagen with smaller amounts of bovine chondroitin sulfate and human derived thrombin. Each device (bellows) contains 1500 IU of thrombin.

- Porcine collagen: is a common protein derived from pig, particularly the bones and skin. Collagen is used to start the process of stopping the bleeding
- Bovine chondroitin sulfate: is a sugar derived from the smooth elastic tissue, rubber like padding that covers and protects the ends of bones (cartilage). This material can also be found as part of nose, ears and many other body parts. Biom'Up collects this product from cow windpipe. This component is used to make sure the blood clot stays stable.
- Thrombin is a protein already present in the body and is obtained from volunteer blood donors. Thrombin is an enzyme that stimulates the coagulation of blood clot formation.

Plasma donations are from US plasma centers only. All individual donations of the plasma were tested for Hepatitis B virus surface antigen (HBsAg), human immunodeficiency viruses (HIV1/-HIV2) and hepatitis C virus (HCV) and found to be negative. The plasma pools were tested and found to be non-reactive for HCV RNA, HBV DNA and HIV1 RNA as determined by Polymerase Chain Reaction Nucleic Acid Test. The product complies with the specifications of the manufacturer and World Health Organization. The manufacturing procedures for the HEMOBLAST™ Bellows include processing steps designed to reduce the risk of viral transmission

Manufacturing residuals:

Thrombin contained in HEMOBLAST™ Bellows is made from human plasma. Standard measures to prevent infections resulting from the use of medicinal products or medical devices containing derivatives from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection, and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products or medical devices containing derivatives from human blood or plasma are administered/used, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV), and for the non-enveloped hepatitis A virus. The measures

taken may be of limited value against non-enveloped viruses such as parvovirus B19. Parvovirus B19 infection may be serious for pregnant women (fetal infection) and for individuals with immune-deficiency or increased erythropoiesis (e.g., hemolytic anemia). It is strongly recommended that every time that HEMOBLAST™ Bellows is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product. Appropriate vaccination (against hepatitis A and B) should be considered for patients in regular/repeated receipt of human plasma-derived thrombin.

Chondroitin sulfate contained in HEMOBLAST™ Bellows is from bovine origin. The risk with respect to transmissible Spongiform Encephalopathies (TSE) has been minimized in accordance with regulatory guidelines by a manufacturing process with demonstrated TSE inactivation capacity.

In case of hypersensitivity or allergic/anaphylactoid reactions due to the porcine and bovine origin of some HEMOBLAST™ Bellows components, the use of HEMOBLAST™ Bellows should be permanently interrupted.

CONTACT

- **Australian Health Authority : Therapeutic Goods Administration TGA, PO Box 100, Woden ACT 2606, Australia, www.tga.gov.au**
- **Distributor : Life Healthcare, Level 8, 15 Talavera Rd, North Ryde NSW 2113, https://www.lifehealthcare.com.au/**
- **Manufacturer : Biom'Up France SAS, 8 Allée Irène Joliot Curie, 69800 Saint-Priest, France, www.biomup.com**