HEMOBLAST™ Bellows

35 cm Nozzle Extension

Caution: Federal law restricts this device to sale on or by the order of a physician.

This device is intended for use with HEMOBLAST™ Bellows. Refer to HEMOBLAST™ Bellows Instructions for Use for complete information.

Manufacturer

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1. Device Description

The HEMOBLAST™ Bellows 35 cm Nozzle Extension is a sterile, single-use applicator device. The HEMOBLAST™ Bellows 35 cm Nozzle Extension is designed to be used with HEMOBLAST™ Bellows to deliver the hemostatic powder during laparoscopic surgical procedures or any procedures when additional applicator length is needed. The Nozzle Extension is 35 cm in length.
HEMOBLAST™ Bellows is available separately. Please see the HEMOBLAST™ Bellows Instruction for Use for complete information on the hemostatic agent.

2. How Supplied

The HEMOBLAST™ Bellows 35 cm Nozzle Extension is supplied sterile in double packaging. One (1) box contains six (6) individually packaged Applicators.

3. Indications

The HEMOBLAST™ Bellows 35 cm Nozzle Extension is indicated for use in delivering HEMOBLAST™ Bellows hemostatic powder to bleeding surgical sites through a 5 mm or larger diameter trocar as well as solely as an extension without the use of a trocar.

4. Warnings and precautions

- Do not use the Nozzle Extension to manipulate or retract organs or tissue.
- To prevent product contamination prior to application, always follow aseptic techniques.
- The product must be manipulated and used by qualified personnel according to the general principles of sterility and pre-medication.
- The tip of the Nozzle Extension must be directly visualized at all times to minimize potential for unintended contact with tissue, organs, or blood as well as any possible unintended spillage of residual powder.
- The nozzle extension should not be bent over (>) 65° to avoid any kinking risk.
- The safety and effectiveness of the combined use of the Nozzle Extension with other hemostatic agents has not been evaluated and is therefore not recommended.
- The nozzle extension should not be used during transperitoneal laparoscopic or transthoracic thoracoscopic approaches to the anterior spine.
- Ensure all gauze and other accessories placed in the body are removed after use.

5. Directions for use

Applicator Assembly

1. Inspect the integrity of the product and its packaging prior to use. Do not use if damaged.
2. Peel open the bags to remove the Nozzle Extension from its packaging with attention to sterile procedures.
3. Ensure that both edges of the Nozzle Extension are tip formed are rounded and not sharp.
4. Remove the HEMOBLAST™ Bellows from its packaging and remove its cap using a twisting motion. Discard cap.
5. Firmly insert the Nozzle Extension into the nozzle of HEMOBLAST™ Bellows until resistance can be felt and a firm connection is observed. Either end of the Nozzle Extension can be inserted into the HEMOBLAST ™ Bellows nozzle.
6. The assembled device can then be used.

Laparoscopic Application

1. Prepare the application site as outlined in the HEMOBLAST™ Bellows Instruction for Use (IFU).
2. Place one or more dry gauze in close proximity of the target bleeding site using laparoscopic forceps.
3. Place one or more saline-soaked gauze(s) in close proximity of the target bleeding site using laparoscopic forceps (avoid contact with blood) prior to applying HEMOBLAST™ Bellows hemostatic powder on the wound.
4. Gently insert the Nozzle Extension through a 5 mm or larger diameter trocar.
5. Avoid applying excessive bending forces on the Nozzle Extension to avoid kinking. If kinking occurs, do not use the Nozzle Extension; remove it and replace with a new Nozzle Extension.
6. Avoid direct contact between the Nozzle Extension tip and blood at the surgical site to minimize the potential for clogging the tip during HEMOBLAST™ Bellows application.
7. If the Nozzle Extension becomes occluded/clogged during use, replace with a new Nozzle Extension. Do not cut the Nozzle Extension to remove the occlusion.
8. Use dry gauze to blot excess blood from the target bleeding site so the hemostatic powder may be applied directly to the source of bleeding. The wound surface should be as dry as possible before application of HEMOBLAST™ Bellows hemostatic powder.
9. Immediately position the Nozzle Extension approximately 2-3 cm from the site of bleeding. Laparoscopic graspers may be used to facilitate precise application.
10. Apply the HEMOBLAST™ Bellows powder as directed in the HEMOBLAST™ Bellows IFU.
11. When applied with the Nozzle Extension tip 2-3 cm from the target bleeding site, HEMOBLAST™ Bellows can treat a surface area up to 50 cm^2.
12. Immediately use a saline-soaked gauze to hold the hemostatic powder in contact with the bleeding area as directed in the HEMOBLAST™ Bellows IFU.
13. Gently remove the laparoscopic applicator through the trocar.

Open Application

For use in open procedures refer to the HEMOBLAST™ Bellows IFU.

6. Storage and Handling

- The product is sterile unless the package has been opened, damaged, or otherwise contaminated.
- For single-use only.
- Do not reuse or resterilize. Reuse of single-use device creates a potential risk of patient or user infections.
- Do not use after the expiration date indicated on the package.
- Product must be stored in a dry environment at room temperature.
- The product must be discarded after use according to the institutional policy for medical devices.

7. Sterilization

HEMOBLAST™ Bellows 35 cm Nozzle Extension is sterilized by gamma irradiation.

For any additional information, please contact the manufacturer.

8. Symbols

Symbol	Standard	Reference #	Title	Definition
	ISO 15223-1	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 15223-1	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 15223-1	5.2.6	Do not resterilize	Indicates a medical device that is not to be resterilized.
	ISO 15223-1	5.2.8	Do not use if package is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	ISO 15223-1	5.4.2	Do not re-use	Indicates a medical device that is intended for one single use only.
	ISO 15223-1	5.4.3	Consult the instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 15223-1	5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	ISO 15223-1	5.2.12	Double sterile barrier system	Indicates two sterile barrier system
	ISO 15223-1	5.6.3	Non-Pyrogenic	Indicates a medical device that is non-pyrogenic.
	FDA Guidance "Alternative to Certain Prescription Device Labeling Requirements", issued 1/21/2000	N/A	Caution : Federal law restricts this device to sale on or by the order of a physician	Requires prescription in the United States.
	ISO 15223-1	5.1.1	Manufacturer	Indicates the medical device manufacturer.
	N/A	N/A	Contents	Numeral represents quantity of units inside the packaging.

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