HaemoCer™
Endoscopic Applicator

Operating instructions

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The HaemoCer™ Endoscopic Applicator is not made from natural rubber latex.

Under (US) federal law, this device may only be sold by a physician or under prescription.

BioCer and HaemoCer™ are brands of BioCer Entwicklungs-GmbH in Bayreuth, Germany.

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CE 0197

HRD144EN.01/2024-05

ENGLISH

Content

HaemoCer™ Endoscopic Applicator

Description

The HaemoCer™ Endoscopic Applicator is a flexible, manually operated single-use device used to deliver the resorbable haemostatic powder HaemoCer™/ HaemoCer™ PLUS during endoscopic examinations through natural body orifices. The HaemoCer™ Endoscopic Applicator has a tube length of 2400 mm, an outer tube diameter of 2.5 mm and a pump ball as a source of compressed air. Additionally, it has a built-in HEPA (High Efficiency Particulate Air) filter for filtering ambient air before it enters the applicator and the tube. **Full information on the surgical haemostatic powders can be found in the operating instructions of HaemoCer™/ HaemoCer™ PLUS respectively.**

Indication

The HaemoCer™ Endoscopic Applicator is intended for short-term application of HaemoCer™/ HaemoCer™ PLUS haemostatic powders through natural body orifices in the context of various endoscopic examinations.

Preparation

- Prior to using the HaemoCer™ Endoscopic Applicator, check the sterile packaging is intact. If the sterile packaging has been either opened or damaged, discard it and replace it with a new product.
- Remove the applicator from the sterile packaging and check the applicator is also intact.
- Screw the pump ball onto the Luer Lock connection at the filter end of the applicator **(Fig. 1)**.
- Use your thumbs to close the screw attachment for the HaemoCer™ bottle on the Y piece **(Fig. 2)** and feed the tube of the HaemoCer™ Endoscopic Applicator all the way into the instrument channel of the endoscope, until the applicator tip can be seen through the camera.
- Note: Make sure the Y piece is kept firmly closed while the applicator is being inserted and under no circumstances actuate the endoscope's suction or flush functions.
- Recommendation: While the applicator is being inserted, the pump ball should also be used occasionally to drain any fluid that may have entered the applicator.
- Once the applicator is positioned correctly in the instrument channel, keep pumping the pump ball **(Fig. 3)** quickly and firmly while still holding the Y piece closed with your thumb, in order to remove any fluid that may have entered the applicator. Pump approx. 8–10 times or until no more fluid comes out of the applicator tip.
- Now lift your thumb off the opening and screw the HaemoCer™/ HaemoCer™ PLUS bellows bottle onto the corresponding thread as tightly as possible **(Fig. 4)**.
- Caution: To do this, bring the HaemoCer™ Endoscopic Applicator into an upright position, so that the **opening** of the bellows bottle **faces upwards** when it is screwed on.

Application

- Prepare the HaemoCer™ Endoscopic Applicator as described above.
- Turn the applicator through 180° so that the **opening** of the bellows bottle **faces downwards (Fig. 5)**. The HaemoCer™ Endoscopic Applicator is now ready for operation **(Fig. 6)**.
- Position the tube tip as close to the site of bleeding as possible.
- Note: Avoid contact between the applicator tip and the blood to minimize the risk of the supply becoming blocked.
- Note: Maintain a sufficient distance from the endoscope tip during application to prevent clogging of the work channel/lens of the endoscope.
- Begin administering the powder via the HaemoCer™ Endoscopic Applicator by pumping the pump ball several times **(Fig. 7)**. Pumping consistently with the pump ball prevents the tip from becoming blocked. If, however, the tube tip does become blocked, it can simply be trimmed using sharp scissors.
- When the bleeding is under control, remove the HaemoCer™ Endoscopic Applicator from the endoscope.
- If another unit of haemostatic powder is needed, position the applicator upright **(Fig. 4)**, remove the empty bellows bottle and tightly screw in the new unit, as described above. The tube can remain in the endoscope while this is done. Once the bellows bottle is attached, turn the applicator through 180° so that the bellows bottle faces upwards **(Fig. 5)**. The HaemoCer™ Endoscopic Applicator is now ready for operation with a new unit of HaemoCer™/ HaemoCer™ PLUS **(Fig. 6)**.

Contraindications

- HaemoCer™/ HaemoCer™ PLUS must not be used for injection into blood vessels, because this poses the risk of extensive intravascular coagulation.
- HaemoCer™/ HaemoCer™ PLUS must not be used to control postpartum bleeding or menorrhagia.
- HaemoCer™/ HaemoCer™ PLUS must not be used for injection into the bladder or urethra.
- HaemoCer™/ HaemoCer™ PLUS must not be used for injection into the eyes.
- HaemoCer™/ HaemoCer™ PLUS is not suitable for patients with an intolerance to starches or starch products.
- HaemoCer™/ HaemoCer™ PLUS must not be used with the HaemoCer™ Endoscopic Applicator for injection into the bile duct or pancreatic duct.

Warnings

HaemoCer™/ HaemoCer™ PLUS in conjunction with the HaemoCer™ Endoscopic Applicator is not intended as a substitute for suitable surgical methods, including proper application of conventional haemostatic techniques (e.g. ligation).
The HaemoCer™ Endoscopic Applicator is supplied as a sterile product and cannot be resterilised. Unused, opened products must be discarded.
Reusing single-use medical devices can lead to potentially serious health problems for the patient and to a malfunction of the product.

Precautions

This product should only be used by physicians who are familiar with endoscopic techniques. The physician is responsible for the application.

Side effects

None reported to date.

Storage

The HaemoCer™ Endoscopic Applicator should be stored at room temperature in its original packaging away from light. Protect product from moisture.

Fig. 1

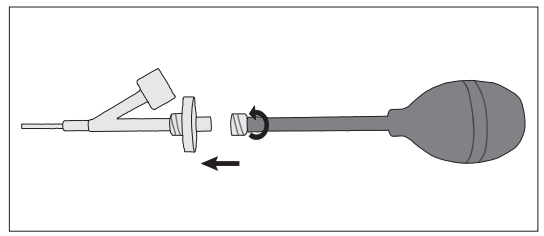

Fig. 2

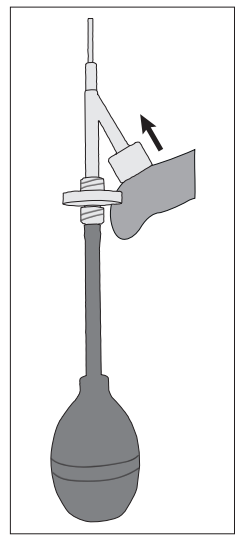

Fig. 3

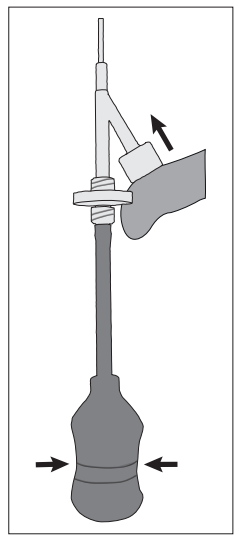

Fig. 4

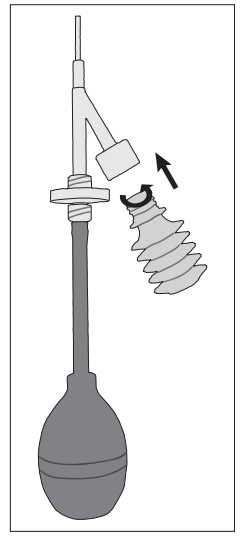

Fig. 5

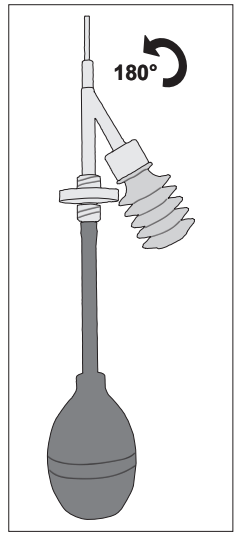

Fig. 6

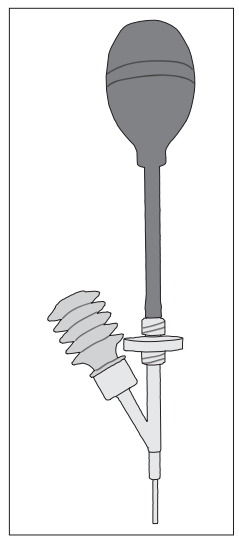
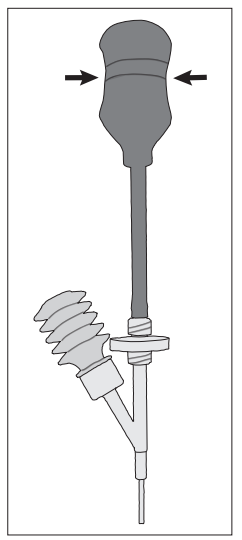
Fig. 7