HaemoCer™
HaemoCer™ PLUS

Powder for Haemostasis and Adhesion Prevention Barrier

Instructions for use

PLANT BASED
100 % ABSORBABLE

BioCer

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These instructions for use apply to both HaemoCer and HaemoCer PLUS.

HaemoCer is not made with natural rubber latex.

Federal law (USA) restricts this device to sale by or on the order of a physician.

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Content

Dispenser bottle with haemostatic powder / powder for adhesion prevention and applicator

Description

HaemoCer is intended for use as an absorbable haemostatic agent to stop bleeding during surgical procedures. In addition, HaemoCer serves as an adhesion-preventing barrier after procedures in cavities covered by mesothelium, except in newborns and infants due to reduced amylase activity. HaemoCer contains no animal or human components. It is a biocompatible, sterile, white powder that is non-pyrogenic. HaemoCer is typically absorbed within several days completely. HaemoCer PLUS is a further development of HaemoCer and demonstrates a comparatively increased suction effect.
Sterilization is performed by irradiation.

Action

HaemoCer consists of hydrophilic particles that rapidly absorb water from the blood and initiate a dehydration process. Blood solids (platelets, blood cells) and blood proteins are concentrated so that natural haemostasis is accelerated.
In contact to blood, the haemostatic powder forms a gel matrix that acts as an instant barrier against further bleeding, independent of the patients clotting status.
For adhesion prophylaxis, HaemoCer is applied as a powder and transformed into a gel by moistening with sterile saline or sterile water. This acts as a temporary mechanical barrier to prevent postoperative adhesions.
Absorption normally requires several days and depends amongst others on the amount applied and the site of use.

Intended purpose

HaemoCer is used as powder for haemostasis and adhesion prevention barrier.

Indications

HaemoCer is an adjunct haemostatic agent for use in surgical procedures, when control of bleeding from capillary, venous, or arteriolar vessels by pressure, ligature and other conventional procedures is either ineffective or impractical.
HaemoCer is also indicated when the formation of postoperative adhesions is to be prevented following surgical interventions in cavities with a mesothelial lining.

Contraindications

HaemoCer must not be used for injection into blood vessels, because extensive intravascular coagulation may occur.
HaemoCer must not be used for controlling post-partum bleeding or menorrhagia.
HaemoCer must not be used for injection into bladder or ureteral lumen.
HaemoCer must not be used for injection into the eyes.
HaemoCer is contraindicated in patients who are sensitive to starch or starch-derived materials.

Patient target group

The patient target group includes all patients of all age groups. HaemoCer has not been investigated in children or pregnant women. In neonates up to ten months of age, amylase activity may be reduced, so the rate of absorption of products such as HaemoCer may be diminished.

Intended user

This device is to be used only by physicians familiar with the relevant surgical techniques. The surgeon bears the responsibility for the application.

Clinical benefit

HaemoCer reduces postoperative complications, blood transfusions, time spent in the operating room and the use of hospital resources through both haemostasis and adhesion prevention.

Material composition

HaemoCer is a plant-based medical product obtained from purified plant starch.

Instructions for use

Before use, inspect the packaging of HaemoCer on its integrity. If the package has either been opened before or damaged, discard and replace with a new package.
Unpack the dispenser and the applicator from the sterile packaging and check both items for damage whilst at the same time checking whether there are any clumps in the haemostatic powder. Do not use if you notice any abnormalities.
Remove the screw cap by turning counter-clockwise and connect the applicator firmly to the dispenser.
For maximum effect of HaemoCer the following technique is recommended:

Haemostasis:

1. Remove all excess blood by blotting, wiping, or suctioning at the intended site and identify the source of bleeding. It is important to remove excess blood so that the haemostatic particles of HaemoCer may be immediately and directly applied to the site of active bleeding.
2. Immediately apply a liberal amount of HaemoCer directly to the source of bleeding, completely covering the wound. Where possible, contact between the applicator and blood or tissue should be avoided, so in order to prevent blockage of the applicator.
3. Immediately apply appropriate direct pressure on the treated site by using a dry, non-adhering substrate (gauze). Amount and duration of the pressure are dependent on the wound. For more profuse bleeding, pressure should be maintained longer.
4. Before removing the gauze carefully or in case of adhering gloves, instruments etc. irrigation with saline is recommended, to dissolve the adhesions.
5. If bleeding continues after the application, remove excess HaemoCer material and reapply.
6. Once haemostasis is achieved, completely remove excess HaemoCer powder carefully by irrigation and aspiration. This is particularly important in newborns and infants with reduced amylase activity.

Adhesion prevention:

The procedure described below is merely the recommended procedure for using HaemoCer to achieve adhesion prevention. Therefore, these instructions cannot replace medical experience and judgement in the treatment of specific surgical situations.

1. To achieve the best results with HaemoCer, first remove any excess blood from the area of use by suctioning, wiping or dabbing.
2. Generously apply HaemoCer powder to the entire mesothelial defect and wound surfaces. HaemoCer powder that is administered to non-traumatized mesothelial surfaces has no negative effects. Where possible, contact between the applicator and blood or tissue should be avoided, in order to prevent blockage of the applicator.
3. After the complete administration of HaemoCer all the powder applied is moistened with sterile saline solution or sterile water until the powder is completely converted into a gel covering the affected surface.

Further applicators are available for the use of HaemoCer for deeper-lying or difficult to access sources of bleeding, as well as for endoscopic and laparoscopic procedures where the applicator provided is not sufficient or is impracticable:
- HaemoCer Universal Applicator
- HaemoCer FlexApplicator
- HaemoCer Endoscopic Applicator

Detailed information on the additional applicators, their usage and combination with HaemoCer, can be found in the respective instructions for use.

Warnings

HaemoCer is not intended as a substitute for a good surgical practice and, in particular, the proper use of conventional procedures for haemostasis (e.g. ligature).
HaemoCer is supplied as a sterile product. It cannot be resterilized. Unused, open systems have to be discarded.
Reusing single-use devices can lead to potentially serious health problems for the patient and malfunction of the product.
HaemoCer is not recommended when an infection is suspected and should, therefore, be used with caution in contaminated areas.
Combined use of HaemoCer with other topical haemostatic agents has not been studied in clinical trials and is, therefore, not recommended.
Once haemostasis is achieved, excess HaemoCer particles should be removed from the site of application by irrigation and aspiration. This is particularly important in case of an application in and around the spinal cord, the foramina of the bone, and/or the optic nerve and chiasm. HaemoCer swells immediately to its maximum volume upon contact with blood or fluids. The possibility of compression necrosis of surrounding tissue due to swelling is eliminated by removal of excess haemostatic material.

Precautions

When HaemoCer is used in conjunction with an autologous blood salvage circuit or an extracorporeal cardiopulmonary bypass circuit, care must be exercised to prevent a possible particle entry into the bypass circuit. Entry is prevented by using a 40µ cardiotomy reservoir, cell washing, and 40µ transfusion filter, such as LipiGuard™.
HaemoCer is intended to be used in dry state. Contact to fluids (saline or antibiotic solutions) prior to application will result in loss of haemostatic properties.
HaemoCer is not recommended for the primary treatment of coagulation disorders.
No testing has been performed on the use of HaemoCer on bone surfaces to which prosthetic materials are to be attached with adhesives. To avoid possible strength reduction of methyl methacrylate adhesives used to attach prosthetics, excess HaemoCer material should be fully removed from bony surfaces by irrigation prior to the adhesive use.
An effect on blood glucose level due to use of HaemoCer is conceivable, but has not yet been observed. We recommend that patients with diabetes use no more than 15g of HaemoCer. In patients not affected by diabetes, single doses of up to 50g are considered safe.
It has been reported in the literature that the presence of residual haemostatic agent may lead to confusion in diagnostic imaging, as it may be difficult to distinguish between residual haemostatic agent and a tumor or abscess.

Side effects

None known as yet for HaemoCer. Side effects described from other haemostatic products include a short-term increase of inflammatory parameters, local inflammation and foreign body reactions, granuloma formation, pleural effusion and fever.
Post-operative adhesions may occur even if HaemoCer is used. Possible causes include insufficient haemostasis or improper application, such as incomplete wound coverage with gel or insufficient conversion of powder to gel barrier with liquid.

Storage

HaemoCer should be stored at room temperature in the original packaging away from light. Protect product from moisture.

Disposal

All components supplied with the device, as well as any unused powder, should be handled and safely disposed of in accordance with local and regional laws and regulations and with the hospital's standard procedures. Components supplied with the device may include, for example, packaging and instructions for use. For infectious waste, the special requirements for hazardous waste must be observed.

Information to be provided to the patient

Traceability labels are affixed to each package, indicating the device type, expiry date and batch number. A label should be placed in the patient's permanent record to uniquely identify the device used.
The summary of safety and clinical performance (SSCP) for this device can be found at http://www.biocer-gmbh.de/sscp.

Incident reporting

Users and/or patients should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the country in which the user and/or patient is established.