

## Patient Information Leaflet

### HaemoCer™ Haemostatic Powder

Product Code	Description	Product Code	Description
HFP102	HaemoCer™ 2g	HFP201	HaemoCer™ PLUS 1g
HFP103	HaemoCer™ 3g	HFP203	HaemoCer™ PLUS 3g
HFP105	HaemoCer™ 5g	HFP205	HaemoCer™ PLUS 5g

#### **What is in this leaflet?**

This leaflet answers some common questions about HaemoCer™ Haemostatic Powder. All medical devices and implants have risks and benefits. Your surgeon has weighed the risks of using HaemoCer™ Haemostatic Powder against the benefits that are expected. This leaflet does not contain all the available information about HaemoCer™ Haemostatic Powder and it does not take the place of talking to your surgeon. Your surgeon has been provided additional information and can answer any questions you may have. Follow your surgeon's advice even if it differs from what is in this leaflet. Please read this leaflet carefully and keep it in a safe place so you may refer to it in future if needed.

#### **What is HaemoCer™ Haemostatic Powder?**

HaemoCer™ is a plant based medical device derived from purified plant starch for the use as an absorbable hemostatic agent to control bleedings during surgical procedures. HaemoCer™ contains no animal or human components. It is a biocompatible, sterile, white powder that is nonpyrogenic. HaemoCer™ is typically absorbed within few days completely.

#### **What is HaemoCer™ Haemostatic Powder used for?**

HaemoCer™ is an adjunct hemostatic 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.

#### **How is HaemoCer™ Haemostatic Powder used?**

HaemoCer™ Haemostatic Powder can only be used surgically, by a qualified surgeon.

#### **When must HaemoCer™ Haemostatic Powder not be used?**

HaemoCer™ shall not be used for injection into blood vessels, because extensive intravascular coagulation may occur.

HaemoCer™ shall not be used for controlling post-partum bleeding or menorrhagia.

HaemoCer™ shall not be used for injection into bladder or ureteral lumen.

HaemoCer™ shall not be used for injection into the eyes.

HaemoCer™ is contraindicated in patients who are sensitive to starch or starch derived materials.

#### **What to do after HaemoCer™ Haemostatic Powder has been used?**

There have been no reported Adverse Events for HaemoCer™ Haemostatic Powder to date.

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.

#### **Reporting adverse effects**

If you wish to report any adverse effects you believe are a result of HaemoCer™ Haemostatic Powder, please talk with your surgeon.

Please report any serious device related incident to the manufacturer, and the Therapeutic Goods Administration (TGA) using the following contact links:

BioCer Entwicklungs-GmbH Germany via:

Email: [info@biocer-gmbh.de](mailto:info@biocer-gmbh.de)

or

BioCer Entwicklungs-GmbH  
Ludwig-Thoma-Str. 36c  
95447 Bayreuth  
Germany

Therapeutic Goods Administration via their website:

[www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems)