


HaemoCer™

Universal Applicator

Instruction for Use

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

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Content

HaemoCer™ Universal Applicator

Description

A single use, flexible, manual apparatus, the HaemoCer™ Universal Applicator is designed to deliver the absorbable haemostatic powder HaemoCer™ / HaemoCer™ PLUS. HaemoCer™ Universal Applicator has a usable tube length of 38 cm. **Please see the IFU for HaemoCer™ / HaemoCer™ PLUS for complete information on the surgical haemostatic powder.**

Indications

The HaemoCer™ Universal Applicator is intended for the application of HaemoCer™ / HaemoCer™ PLUS onto surgical wound surfaces in different medical indication.

Preparation

- Before use, inspect the packaging of HaemoCer™ Universal Applicator on its integrity. If the package has either been opened before or damaged, discard and replace with a new package.
- Unpack the applicator from the sterile packaging and check that item is intact.
- Close the clip at the top of the applicator and press it onto the HaemoCer™ / HaemoCer™ PLUS applicator as shown below.

Instruction

- Prepare the application site as outlined in the Instructions for Use for HaemoCer™ / HaemoCer™ PLUS.
- Position the HaemoCer™ Universal Applicator tip at the site of bleeding as close as possible.
- Open the clip and begin delivering HaemoCer™ / HaemoCer™ PLUS by successively pumping the bellows flask.
- Avoid direct contact between the applicator tip and blood at the surgical site to minimize the potential for clotting the tip. If tip clotting occurs the HaemoCer™ Universal Applicator can be easily trimmed by a sharp scissors.



Contraindication

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

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

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

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

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

Warnings

HaemoCer™ / HaemoCer™ PLUS in conjunction with the HaemoCer™ Universal Applicator is not intended as a substitute for suitable surgical technique and particularly appropriate practice of conventionally haemostatic technique (e.g. ligation).

HaemoCer™ Universal Applicator is supplied as a sterile product and 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.

Precautions

This product should only be used by surgeons who are familiar with surgical techniques of this type. The surgeon bears the responsibility for the application.

Adverse Events

Not reported to date.

Storage

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

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