


HaemoCer™

FlexApplicator

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™ FlexApplicator

Description

A single use, flexible, manual apparatus, the HaemoCer™ FlexApplicator is designed to deliver the absorbable haemostatic powder HaemoCer™ / HaemoCer™ PLUS. The usable tube length of the HaemoCer™ FlexApplicator is 14 cm. The integrated wire enables the HaemoCer™ FlexApplicator to be bend while retaining its curved form. **Please see the Instructions for Use for HaemoCer™ / HaemoCer™ PLUS for complete information on the surgical haemostatic powder.**

Indications

The HaemoCer™ FlexApplicator 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™ FlexApplicator 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.
- Press the applicator 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.
- Form the HaemoCer™ FlexApplicator as required for access to the surgical site.
- Position the HaemoCer™ FlexApplicator tip at the site of bleeding as close as possible.
- Begin delivering HaemoCer™ 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.



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™ FlexApplicator is not intended as a substitute for suitable surgical technique and particularly appropriate practice of conventionally haemostatic technique (e.g. ligation).

HaemoCer™ FlexApplicator 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. HaemoCer™ FlexApplicator may not be trimmed.

Adverse Events

Not reported to date.

Storage

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

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