BloodSTOP® iX

CONTROLS BLEEDING FAST

Absorbable Hemostat

(100% purified, water soluble, etherified sodium carboxymethyl cellulose)

Instructions for Surgical Use Indication

Class III EC Certification

Intended Use: Implant surgical use, wholly absorbable, for the control of bleeding during and after surgery.

Intended User: Intended to be used by trained medical professionals in clinical settings (e.g., surgical suites in hospitals, clinics, ambulances).

Intended Population: for the general population and for patients on anticoagulation medication.

Indications

BloodSTOP® iX Advanced Hemostat (100% purified, water soluble, etherified sodium carboxymethyl cellulose) is used adjunctively in surgical procedures to assist in the control of capillary, venous, and small arterial hemorrhage when surgical hemostasis is inadequate or impractical. It is used to control diffuse bleeding from:

- Cut surfaces of solid organs
- Peritoneal or pleural surfaces
- Bleeding near nerves – where there is risk for cautery-induced injury
- Bleeding near any vital structures at risk for cautery-induced injury
- Bleeding from vascular structures and grafts due to suture holes
- Bleeding in exodontia and oral surgery
- Traumatic surgeries
- Bleeding after surgical debridement of burns and other wounds

Clinical Benefits: Fast and effective hemostasis.

Composition, Function

BloodSTOP iX is a woven matrix of fibers consisting of 100% purified, water soluble, etherified sodium carboxymethyl cellulose.

BloodSTOP iX, upon contact with blood, transforms into a sticky, translucent gel that slows further diffusion of liquid molecules.

BloodSTOP iX gel exerts a pro-coagulant activity and activates the intrinsic coagulation pathway. It seals the wound, minimizes blood loss and saves operation time. The translucent gel allows doctor to easily monitor the wound. It also creates a natural autologous moist healing environment.

It is fully biocompatible and is broken down and completely absorbed by the body at rates that depend on the amount(s) placed and the availability of fluid(s) in the area(s) where it has been applied.

Its complete absorbability facilitates imaging studies later, where it can no longer be confused with normal or pathological tissue.

Techniques for application

Cut, fold, or roll sufficient sized pieces to fit over and adhere to the specific areas of bleeding. Apply appropriate pressure and/or secure the material in place for each wound configuration until stable hemostasis is achieved.

BloodSTOP iX transforms to a sticky gel when wet. Use additional dry layers of matrix, dry instruments and rolling motions as needed not to interfere with the efficient placement of the material and to avoid accidental removal.

It is advisable to consider how much material must be deployed and left in specific areas where additional peritoneal fluid and exudates are present. Excess fluid may lead to accelerated dissolution of BloodSTOP iX and causes re-bleeding. Therefore, excess fluid should be evacuated at once if possible. Additional BloodSTOP iX may be needed in order to mitigate risks for re-bleeding.

Additional layers of BloodSTOP iX or longer compression times may be required, particularly for patients who are on anticoagulants.

To remove excess product once hemostasis is achieved, rinse with sterile water or sterile saline, wiping gently if necessary.

Contraindications

BloodSTOP iX is not intended as substitute for systemically administered antimicrobial agents to control or prevent post-operative infections. Contaminated and potentially contaminated areas have to be treated as such and provided with adequate drainage.

BloodSTOP iX is not intended as a substitute for the proper use of sutures and ligatures.

BloodSTOP iX should not be used as the primary source of hemostasis to control hemorrhage from large arteries, but may be used adjunctively.

BloodSTOP iX should not come in contact with broken bone surfaces, seeding material(s) or implants as it may interfere with fusion.

Do not use BloodSTOP iX in conjunction with blood salvage systems as some absorbable hemostatic materials have been reported to fragment and pass through the filters of blood salvage systems, occluding the system and/or the patient's vasculature.

Do not use in conjunction with methyl-methacrylate adhesives as some absorbable hemostatic materials have been reported to interfere with these adhesives used to fixate orthopedic prosthetic devices to bone.

BloodSTOP iX is not compatible with peritoneal dialysis as it may occlude catheters and filters.

BloodSTOP iX is not compatible with drainages into the peritoneal or other cavities. Care must be taken not to contaminate such drainage spaces.

BloodSTOP iX is not for use on chemical burns resulting from strong acids or bases.

BloodSTOP iX is not for use on patient with known cellulose allergy.

Precautions/Warnings

BloodSTOP iX exhibits a mass-dependent, minor expansion. For small cavity hemostasis, room must be allowed for this slight expansion of BloodSTOP iX. When BloodSTOP iX is used to help achieve hemostasis in, around, or in proximity to bony confine or the spinal cord, it must always be removed after hemostasis is achieved since it may swell and exert unwanted pressure.

Special care must be taken, regardless of the type of surgical procedure, to consider the advisability of removing excess BloodSTOP iX after hemostasis is achieved. No more than the necessary quantity of BloodSTOP iX should be used. In all cases, no more than 100 in^2 (645 cm^2) of BloodSTOP iX should be used on adults (≥70 kg), and no more than 14 in^2 (90 cm^2) of BloodSTOP iX should be used on children (≥10 kg) or adults <70kg. Do not use BloodSTOP iX on children weighing <10kg. Excess product that has not changed to gel should be removed before closure.

BloodSTOP iX may persist for longer periods of time in areas where there is limited access to fluid. Granuloma formation is possible.

BloodSTOP iX may be visible on imaging until absorbed. If imaging is performed during this period, inform the interpreting clinician that BloodSTOP iX was used.

Hematoma may occur if hemostasis is not fully achieved.

BloodSTOP iX must not be allowed to enter into the flow of blood vessels, lymphatic vessels, cerebrospinal fluid, nor cochlear fluid, as it may result in embolization or occlusion.

In case of redness, fever, inflammation, or any other sign of adverse or allergic reaction, or infection; discontinue use.

Do not reuse, as device will no longer be sterile after initial use, and could result in infection.

Do not resterilize, as package testing for double sterilization has not yet been performed.

Disposal Instructions

Wearing appropriate personal protective equipment (PPE), dispose of any used dressings or dressings that made patient contact but were not ultimately used in biohazard waste containers provided by clinical setting.

Shelf Life and Storage

BloodSTOP iX is supplied sterile in a single sealed, waterproof individual package.

For maximum shelf life, store at room temperature/20–25°C(68-77°F), with excursions permitted to 15–30°C (59-86°F).

The expiration date of BloodSTOP iX is printed on the pack. Do not use after this date.

Symbols Used On Labeling

MD	Medical device	UDI	Unique device identifier
	Single use		Company address
	Use by date		Do not use if package is damaged or open
REF	Reference number		Double sterile barrier system
LOT	Batch number	STERILE R	Method of sterilization: irradiation
	See instructions for use		
EU REP	WellKang Ltd. Enterprise Hub, NW Business Complex, 1 Beraghmore Rd. Derry, BT48 8SE, Northern Ireland, UK	CE 2460	CE Mark and identification number of notified body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC as amended by 2007/47/EEC.
20 °C 25 °C	Temperature Limits		
	Importer		Do not resterilize

A Summary of Safety and Clinical Performance (SSCP) will be available in the Eudamed database on medical devices, https://ec.europa.eu/tools/eudamed, searchable by BloodSTOP iX Basic UDI-DI code, 08507440018SIXIIBB. Until that time, the SSCP is available upon request to ra@lifesciencepplus.com.

Please report all side effects, complications and adverse events to LifeScience PLUS, Inc. and Competent Authority in the member state of occurrence.

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