

## Absorbable Haemostatic Matrix for Surgical and Topical Use

### Composition, Function

BloodSTOP® iX Absorbable Haemostat is woven matrix of fibres consisting of watersoluble, oxidized-etherified regenerated cellulose derivatives.

Upon contact with blood or fluids, BloodSTOP® iX transforms into an a transparent, adherent gel matrix, rapidly sealing the wound and activating the intrinsic coagulation pathway.

BloodSTOP® iX conforms and adheres to any wound or injury.

BloodSTOP® iX is fully biocompatible, pH neutral, non-irritant and displays minimal expansion.

BloodSTOP® iX is soluble in saline, it 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.

### Instructions For Use

#### Indications

BloodSTOP® iX is used adjunctively in surgical procedures to assist in the control of capillary, venous and small arterial haemorrhage when surgical haemostasis is inadequate or impractical.

Class III EC Certification - Internal use, wholly absorbable, for the control of bleeding during and after surgery.

BloodSTOP® iX 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 in exodontia and oral surgery

Surgical applications include: Neurosurgery, Vascular Surgery, Thoracic Surgery, Abdominal and Gastrointestinal surgery.

BloodSTOP® iX is indicated for emergency topical use to control haemorrhage and to manage wounds when a moist environment is needed. Irrigation with saline facilitates dressing changes without disturbing the wound bed or clot.

Topical applications include, acute and chronic wounds including reconstructive surgical procedures and with Negative Pressure Wound Therapy.

For burns BloodSTOP® iX can be used as an initial protective dressing and for subsequent dressing changes.

#### IMPORTANT

**ENSURE THAT DRY GLOVES AND INSTRUMENTS ARE USED TO PLACE THE DRESSING AND TO APPLY THE NECESSARY PRESSURE TO ALLOW THE DRESSING TO SEAL THE WOUND AND ACHIEVE HAEMOSTASIS**

**FAILURE TO DO SO WILL RESULT IN DRESSING STICKING TO INSTRUMENTS/GLOVES. ONCE THE DRESSING IS GELLED DO NOT TOUCH / MANIPULATE IT!!**

**IF ADDITIONAL HAEMOSTASIS IS REQUIRED, APPLY ADDITIONAL LAYERS USING DRY INSTRUMENTS**

### Instructions for Surgical Application

Using sterile technique, and dry gloves or instruments, tear open the sealed package and removing the “silk like” sheet of BloodSTOP® iX Absorbable Haemostat Matrix. Cut, fold or roll sufficient sized pieces to fit over the specific area of bleeding.

Using dry gloves or instruments place the BloodSTOP® iX onto/ into the wound applying appropriate pressure with a rolling action until adhered or secured in place.

BloodSTOP® iX will transform to a sticky transparent gel. Once gelled avoid any further manipulation.

If bleeding persists through the gel, additional dry layers of BloodSTOP® iX may be placed until stable haemostasis is achieved. Again use dry instruments and take care when applying to avoid disrupting the initial layers.

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 result in re-bleeding. Excess fluid should be evacuated at once if possible. Additional BloodSTOP® iX may be needed in order to mitigate risks for re-bleeding.

### Precautions and Warnings

BloodSTOP® iX Absorbable Haemostat 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 Absorbable Haemostat is not intended as a substitute for the proper use of sutures and ligatures. It 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, grafting material(s) or implants as it may interfere with fusion.

BloodSTOP® iX exhibits a mass-dependent, minor expansion. For small cavity haemostasis, room must be allowed for this slight expansion of BloodSTOP iX. When used in areas of bony confine or the spinal cord, where any additional pressure generated by the expansion cannot be relieved by the gel escaping and could cause pressure damage or occlusion of underlying structures, BloodSTOP iX must be removed after hemostasis is achieved.

Special care must be taken, regardless of the type of surgical procedure, to consider the advisability of removing excess BloodSTOP® iX Absorbable Haemostat after haemostasis is achieved. No more than the necessary quantity should be used and excess material should be removed before surgical closure.

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

BloodSTOP® iX must not be allowed to enter into the flow of blood vessels, lymphatic vessels or cerebrospinal fluid as it may result in embolization or occlusion.

## Instructions for Dental Application

### Dental Extraction

Select appropriate size of BloodSTOP® iX gauze, such as a 1.3x5cm dressing.

Use a DRY instrument to press the BloodSTOP® iX dressing into the middle of the socket. If doing a primary closure, suture as required.

**Other intra-oral Surface Bleeding** (eg. Biopsy, periodontal surgical wounds)

Cut BloodStop iX to the appropriate size and apply directly to the bleeding surface. Apply a second piece if additional protection is desired. Rinse away with saline once bleeding has stopped.

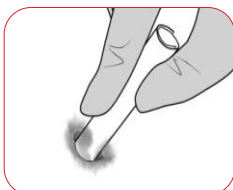
## Instructions for Emergency Use in Topical Wounds

### For lacerations and Abrasions

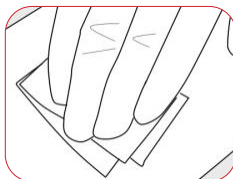
Place 2 or more layers of BloodSTOP® iX directly onto/into wound with dry or gloved hand and provide pressure.



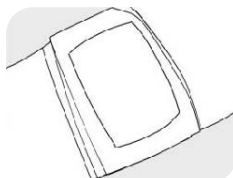
**For Puncture Wounds** roll and place into wound. Apply pressure.



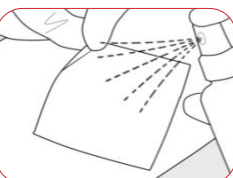
BloodSTOP® iX will absorb blood and turn into an adhesive gel to seal the wound. As the sticky gel may adhere to gloves during application, be careful when removing hand. Rolling fingers against one another can help.



Cover and apply continuous pressure for about 2-3 minutes. Wrap and tie bandage to maintain compression.



To remove, wet BloodSTOP® iX with saline, and irrigate without disturbing the clot(s).



## Instructions for Topical Application

**For Wound Healing** when a moist environment is needed including burns

Following lavage and debridement, apply one or more layers to wound with dry instruments or gloves. BloodSTOP® iX will adhere and conform to any wound. Apply continuous pressure until bleeding stops completely.

Cover with additional secondary absorbant layer to maintain moist environment.

To change dressing, saturate with sterile saline and gentle wipe away the gel.

## Shelf Life and Storage

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

BloodSTOP® iX packages must be stored dry, in controlled room temperature.

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



Single use

Company Address



Use by date

Do not use if package is damaged



Reference number

Method of Sterilization : Irradiation



Batch number

CE Mark and identification



Instructions for use

Do Not Resterilize



**LifeScience PLUS**  
REVOLUTIONARY WOUND CARE

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