BloodSTOP® iX

CONTROLS BLEEDING FAST

Absorbable Haemostatic Matrix for Surgical and Topical Use

Composition, Function

BloodSTOP® iX is a woven matrix of fibres consisting of water soluble, oxidized-etherified regenerated cellulose derivatives.

Upon contact with blood or fluids, BloodSTOP® iX 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 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.

Instructions For Use

Indication

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

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. 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

For wound management including burns when a moist environment is needed. Can be used with Negative Pressure Wound Therapy.

IMPORTANT

PLEASE PLACE DRESSING INTO THE SITE DRY. FAILURE TO DO SO WILL RESULT IN DRESSING STICKING TO INSTRUMENTS/GLOVES

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

ONCE THE DRESSING IS GELLED DO NOT TOUCH/MANIPULATE IT!!

IF ADDITIONAL HAEMOSTASIS IS REQUIRED, APPLY AN ADDITIONAL DRESSING USING DRY INSTRUMENTS

Instructions for Surgical 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 haemostasis is achieved.

BloodSTOP iX Absorbable Haemostat transforms to a sticky gel when wet. Use additional dry layers of matrix,using dry instruments and rolling motions as needed so as 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.

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.

BloodSTOP® iX Absorbable Haemostat 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 1.3 x 5cm 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.

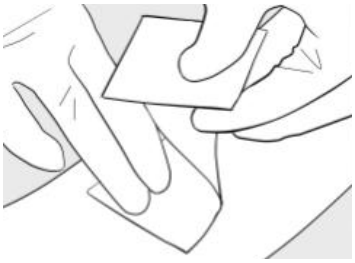
Other intra-oral Surface Bleeding (e.g. Biopsy, periodontal surgical wounds)

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

Instructions for Topical Application

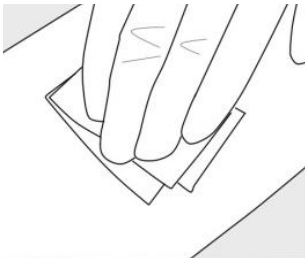
For Emergency Use in Traumatic Wounds.

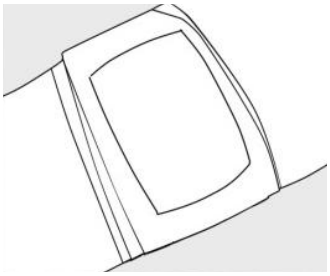
Place 2 or more layers of BloodSTOP® iX directly onto/into wound with dry or gloved hand and provide pressure.



For puncture wounds roll and place into wound. Apply pressure.

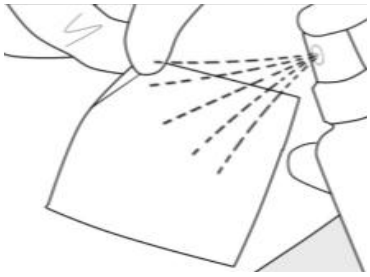
BloodSTOP® iX will absorb blood and turn into an adhesive gel to seal the wound. As the sticky gel may adhere to gloves during application, be careful when removing hand. Rolling fingers against one another can help.





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).



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, it will 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	
REF	Reference number	Method of Sterilization : Irradiation	STERILE R
LOT	Batch number	CE Mark and idenfication of number of notified body	CE 0434
	Instructions for use	Do Not Resterilize	2 STERILIZE

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LifeScience PLUS
REVOLUTIONARY WOUND CARE