BloodSTOP® iX

CONTROLS BLEEDING FAST

Absorbable Hemostat for Surgical Use

(Water-soluble, oxidized-etherified regenerated cellulose)

Instructions for Surgical Use

Indication

Class III EC Certification

Internal use, wholly absorbable, for the control of bleeding during and after surgery, for the general population and for those on anticoagulation medication.

BloodSTOP iX Absorbable Hemostat (water-soluble, oxidized-etherified regenerated 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

Composition, Function

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

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 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 Absorbable Hemostat 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.

Precautions and Warnings

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

BloodSTOP ®iX Absorbable Hemostat 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.

BloodSTOP ®IX exhibits a mass-dependent, minor expansion. For small cavity hemostasis, 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 Hemostat after hemostasis is achieved. No more than the necessary quantity of BloodSTOP iX Absorbable Hemostat should be used. 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, cerebrospinal fluid, nor cochlear fluid, as it may result in embolization or occlusion.

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.

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 Hemostat is printed on the pack. Do not use after this date.

Symbols Used on Labeling


Single use


Use by date

Reference number

Batch number


See instructions for use

Welkang Ltd
Suite B, 29 Harley Street
LONDON, W1G 9QR, U.K.


Company Address


Do not use if package is damaged

Method of sterilization: irradiation

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.

Do not resterilize

Please report all side effects, complications and adverse events to LifeScience PLUS, Inc.

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