Absorbable Hemostat for Surgical Use
(100% purified, water soluble, etherified sodium carboxymethyl 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 (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

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 doctors 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 Absorbable Hemostat transforms to a sticky gel when wet. Use additional dry layers of matrix, dry instruments and rolling motions as needed 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.

Contraindications

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.

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.
Symbols Used On Labeling

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tbody>
<tr>
<td>X</td>
<td>Single use</td>
</tr>
<tr>
<td>REF</td>
<td>Use by date</td>
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<tr>
<td>LOT</td>
<td>Reference number</td>
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<tr>
<td>B</td>
<td>Batch number</td>
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<tr>
<td>S</td>
<td>See instructions for use</td>
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<tr>
<td>WC</td>
<td>WellKang Ltd.</td>
</tr>
<tr>
<td>K</td>
<td>The Black Church</td>
</tr>
<tr>
<td>P</td>
<td>St. Mary's Place</td>
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<td>D</td>
<td>Dublin 7, D07 P4AX, Ireland</td>
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<tr>
<td>℃</td>
<td>Temperature Limits</td>
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<tr>
<td>2460</td>
<td>CE Mark and identification number of notified body</td>
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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 Absorbable Hemostat after hemostasis is achieved. No more than the necessary quantity of BloodSTOP® iX Absorbable Hemostat should be used. In all cases, no more than 100 in² (645 cm²) of BloodSTOP® iX should be used on adults, and no more than 14 in² (90 cm²) of BloodSTOP® iX should be used on children. 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.

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, or 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.

Shelf Life and Storage

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

For maximum shelf life, storage temperature of 15-30 °C (59-86 °F) is recommended.

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

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

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Manufactured in the USA

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Under issued Patents: US 7,262,381; PCT/CA07/00681; WO02/087643

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