



WoundHEAL[®]

Advanced Hemostat Instructions for Medical Professionals

BloodSTOP[®] iX is a surgical grade biocompatible hemostatic matrix made from 100% purified, water soluble, etherified natural sodium carboxymethyl cellulose. When BloodSTOP[®] iX comes in contact with blood or exudate, it quickly transforms into a translucent gel, 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 moist environment to promote healing.

Indications for Use:

- Emergency and therapeutic use in the control of bleeding from the skin and other surface wounds where temporary control of bleeding is required.
- For wound management when a moist environment is needed.
- For the general population and (EU countries only) for those on anticoagulant medications.

General Directions (e.g. Dialysis)

1. Fold BloodSTOP[®] iX in half to make two layers. Apply to the cleaned wound with dry instruments or gloves.
2. Apply pressure on the wound site.
3. Use additional layers of BloodSTOP[®] iX as needed. Moisten with sterile saline if necessary for adherence to the wound surface.
4. Combine with standard non-adherent wound dressings for further protection.
5. Should the bleeding recur, reapply pressure, use additional layers if necessary.
6. To remove excess BloodSTOP[®] iX material, rinse with sterile saline; wipe gently. Do not peel BloodSTOP[®] iX off.

Post-Op Nasal Packing

1. Select proper size of BloodSTOP[®] iX. Use dry forceps to pack BloodSTOP[®] iX into the nasal antrum. Apply pressure to affected arteries.
2. After the bleeding stops completely, BloodSTOP[®] iX gel will flow out with normal nasal drainage. If dry material remains, hydrate and flush out with sterile saline spray.

Dental Extraction

1. Select proper size of BloodSTOP[®] iX, such as a 0.5" x 2" strip.
2. Use a dry instrument to insert one or more pieces of the BloodSTOP[®] iX into the socket to cover the bleeding surface.
3. Moisten a regular gauze pad, two-inches in size (or larger, if necessary). Place it over the socket and have the patient gently bite down on it for 15-20 minutes. (Note: Dry gauze may pull the BloodSTOP[®] iX from the socket).
4. To remove, rinse out the socket.

For Moist Wound Management

1. Apply 1 or more layers to clean wound with dry or gloved hand. Apply continuous pressure until bleeding stops completely, usually 2-3 minutes. To avoid sticking to hand, roll fingers off of sticky gel.
2. Cover with non-adherent, occlusive dressing to maintain moist wound environment for the best healing.
3. Change within 24 hours. To remove, saturate with sterile water or sterile saline and gently wipe away the gel being careful not to disturb the clot. Repeat above steps until wound heals.

Other Intra-oral Surface Bleeding (e.g. biopsy, periodontal surgical wounds)

1. Cut BloodSTOP[®] iX to the appropriate size and apply directly to the bleeding surface.
2. Apply a second piece if additional protection is desired.
3. Rinse away with sterile saline once the bleeding has stopped.

Catheterization Lab/Interventional Radiology

1. Handle BloodSTOP® iX with dry gloves or dry instruments.
2. In accordance with hospital protocol for sheath/catheter removal, fold BloodSTOP® iX in half to make two layers and place on the puncture site, slowly removing sheath/catheter while maintaining direct and consistent pressure. Maintain pressure according to hospital protocol for positioning and hold times.
3. If bleeding persists, apply additional layers of BloodSTOP® iX and continue with direct, consistent pressure.
4. When the patient is stable, cover the wound with a non-adherent bandage to maintain visibility of the wound, and to keep BloodSTOP® iX from drying out.
5. Follow the hospital's standard protocol for time to patient movement, time to ambulation and time to patient discharge.
6. To remove, fully hydrate BloodSTOP® iX with sterile saline and wipe gently. Carefully blot the area, making sure not to disturb the clot.
7. If the patient will be removing BloodSTOP® iX at home, ensure he/she understands the importance of fully hydrating BloodSTOP® iX to soften it before gently washing off with sterile water. Instruct the patient to use caution upon removal to avoid disturbing the clot.

WARNINGS:

- BloodSTOP® iX is intended to assist in the control of wound surface bleeding in cases where hemostasis by clotting is indicated.
- BloodSTOP® iX is not intended as a substitute for the appropriate use of vascular closure devices when such devices are indicated.
- Longer compression times may be required for patients who are obese, hypertensive, or are on anticoagulants.
- When removing BloodSTOP® iX and/or any covering dressing, be careful not to disturb the clot.
- Never peel BloodSTOP® iX from a wound, as re-bleeding could occur. If BloodSTOP® iX dries out, soak thoroughly to rehydrate before removal.
- In case of swelling or redness, discontinue use.
- Do not reuse, as device will no longer be sterile after initial use, and could result in infection.
- For all uses, remove within 24 hours.
- Cover BloodSTOP® iX with a wrap or adhesive bandage to maintain pressure if the patient is to be moved.

STERILE: Sterility guaranteed unless individual wrapper is opened or damaged.

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

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Not made with natural rubber latex

Symbols Used on Labeling

	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 number of notified body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC as amended by 2007/47/EEC.
	See instructions for use		Do not resterilize
	WellKang Ltd. The Black Church St. Mary's Place Dublin 7, D07 P4AX, Ireland		
	Temperature Limits		

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LifeScience PLUS
REVOLUTIONARY WOUND CARE