

BIOPOLYMER BASED HAEMOSTATIC SPONGE

PRODUCT DESCRIPTION:

AcuClot is an advanced Haemostatic Sponge designed to stop surgical and superficial bleeding. Its composition and structure accelerate the blood coagulation cascade, resulting in faster bleeding control. The sponge is based on ActClot Technology (Activated Clotting Mechanism) that enhances blood coagulation through charge-based platelet aggregation. Due to this cationic nature, the sponge is bioadhesive and creates a mechanical seal at the wound, accelerating the natural process of blood clotting. The sponge's microporous honeycomb structure enables rapid absorption of liquid is up to 40 times its weight and its ability to absorb blood is about 15-20 times its weight. Moreover, AcuClot is based on a biopolymer, making it completely biodegradable.

COMPOSITION:

AcuClot is composed of Chitosan and Alginate. Natural materials tend to change colour over time. The effectiveness remains the same.

ACTION:

AcuClot acts as a haemostatic agent by inhibiting fibrinolysis and promoting platelet and erythrocyte aggregation. It enhances platelet aggregation by electrostatically interacting with negatively charged molecules on activated platelets and by increasing the expression of GPIIb-IIIa. The sponge also promotes erythrocyte aggregation by electrostatically interacting with negatively charged molecules on erythrocytes and forming a 3D network to capture them. Additionally, AcuClot inhibits fibrinolysis by suppressing the secretion of plasminogen activator.

INDICATIONS:

AcuClot Biopolymer Based Haemostatic Sponge is a sterile, single-use, non-absorbable haemostatic sponge used for controlling bleeding in the following circumstances:

- In order to stop moderate to severe bleeding caused by cuts, abrasions, lacerations, punctures and venous or arterial bleeding.
- Haemodialysis, vascular access sites and ambulation time reduction in patients with diagnostic or interventional endovascular procedures.
- In surgical procedures, dental procedures and trauma injuries, to control moderate to severe bleeding.

WARNINGS:

In the absence of oxygen, AcuClot Biopolymer Based Haemostatic sponge may break down into glucosamine if left inside the body. However, it is not advised to have it implanted.

AcuClot should not be used if the package is damaged or the contents are wet. Do not re-sterilize AcuClot. AcuClot should only be used once. Its functionality is not guranteed and there is a risk of contamination if it is reused.

AcuClot must be used under the supervision of a trained healthcare professional when used in vascular or surgical procedures. When using AcuClot in vascular and surgical applications, always use sterile techniques. Use sterile gauze to apply uniform pressure and keep AcuClot in place during vascular and surgical procedures. A continuous flow of blood from the puncture site is a medical emergency, so seek medical attention right away.

AcuClot when used in dental procedures, ensure that the device is not swallowed by the patient.

If AcuClot is used incorrectly at puncture sites, it can cause haematoma.

PRECAUTIONS:

When AcuClot is used during vascular procedures, employ appropriate groin management post procedure and post hospital discharge to prevent infection. If large sizes of AcuClot are used in small wounds, it may cause nerve compression.

Sterilization method VDmax 15 Dose Range: 15 ± 2 KGy

Should any of these occur, notify your physician:

- numbness or cold sensations.

AcuClot haemostatic sponge's safety and efficacy have not been studied in the following patient populations:

- 180 mm Hg).
- catheterization.

Keep in position for few minutes.

ADVERSE EFFCTS:

Very rare case of skin irritations or allergies may occur.

Significant drainage or bleeding from the puncture site.

Redness, swelling or warmth around the puncture site.

Around the puncture site, there may be increased tenderness,

Patients with uncontrolled hypertension (systolic blood pressure more than

 Patients with thrombocytopenia like bleeding disorders (100,000 platelet count), thrombasthenia, Von Willebrand's disease or anaemia (Hgb10 mg/dl, Het30). Patients who are using glycoprotein IIb/Illa inhibitors before, during or after

Patients suffering from bleeding diathesis or coagulopathy.

Patients who already have a haematoma or a pseudoneurysm.

Patients with an ACT (Active Clotting Time) of more than 180 seconds.

Patients who have an auto-immune illness and are taking drugs to treat it.

GUIDELINES FOR USING ACUCLOT BIOPOLYMER BASED HAEMOSTATIC SPONGE:



Open the pack and take out AcuClot.



Apply AcuClot to the bleeding site so that it completely covers it. Apply consistent pressure until AcuClot adheres to it.



If necessary, use a secondary dressing to keep AcuClot in place.



Removal: Irrigate **AcuClot** thoroughly with water or saline and gently pull it away.

STERIE R	Sterilized using irradiation.	Ż
20°C - 25 C	Temperature limit.	
	Do not use if package is damaged.	
STERLIZE	Do not re-sterilize.	
2	Do not re-use.	
	Keep dry.	

HOW SUPPLIED:

AcuClot Biopolymer Based Haemostatic Sponge is supplied in the following sizes:

APPLICATION	PRODUCT CODE	SIZES(cm)
Dental	ACT0101	1x1
Dialysis	ACT0303	3x3
Vascular/Surgical	ACT5555	5.5x5.5
Emergency/Trauma	ACT0808	8x8
Military	ACT1010	10x10



STORAGE:



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Store at ambient temperature. Avoid direct sunlight, heat and moisture.