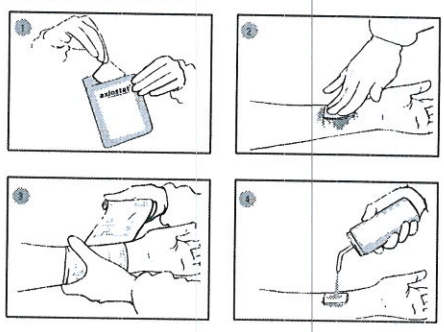
For Femoral Access			
Sheath Size	Heparin Dosage	Time to apply pressure to ensure Haemostasis	Time to remove secondary dressings
6-8Fr Diagnostic Procedure	5000 to 7000 units/mL	Approx. 5 minutes	Not before 360 minutes
9-12Fr Diagnostic Procedure	7500 to 12000 units/mL	Approx. 8 minutes	Not before 360 minutes
6-12Fr PCI (Percutaneous Coronary Intervention) or above	6000 to 12000 units/mL	Approx. 10 minutes	Not before 360 minutes

HOW SUPPLIED:
Axiostat® Chitosan Haemostatic Dressing is supplied in the following sizes:

10 cm x 10 cm	8 cm x 20 cm	8 cm x 12 cm
8 cm x 8 cm	8 cm x 5 cm	7.5 cm x 150 cm
5 cm x 5 cm	3.5 cm x 3.5 cm	2 cm x 2 cm
1 cm x 8 cm	1 cm x 4 cm	1 cm x 1 cm

STORAGE:
Store at 20 to 35°C. Avoid direct sunlight, heat and moisture.

DIRECTIONS FOR USING AXIOSTAT® CHITOSAN HAEMOSTATIC DRESSING:



1. Open the pack and remove Axiostat® from it.
2. Place Axiostat® such that it covers the entire bleeding site. Apply uniform pressure until Axiostat® sticks to the wound.
3. Apply a secondary dressing if required to make sure Axiostat® remains dry and in position.
4. Removal: Irrigate Axiostat® with plenty of water or saline and gently peel it off. Do not remove/peel open Axiostat® without medical supervision.

CE 2460 STERILE R ISO 13485

EC REP

IFUA.04.12.18.Rev00

axiostat®

Chitosan Haemostatic Dressing
(Non-absorbable Haemostat)

INSTRUCTIONS FOR USE

AXIO

Manufactured by:
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Регистрация МИ в Росздравнадзоре
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AXIOSTAT®
Chitosan Haemostatic Dressing
(Non-absorbable Haemostat)

DESCRIPTION:
Axiostat® Chitosan Haemostatic Dressing belongs to an advanced class of wound dressing that stops bleeding within few minutes of application by providing an active mechanical barrier. Axiostat® acts as a barrier against bacteria. Axiostat® can be kept on the wound site up to 24 hours.

COMPOSITION:
Axiostat® is made up of 100% chitosan extracted from shell fish. Natural material tends to change color. Efficacy remains unchanged.

ACTIONS:
Axiostat® when applied to the wound site with compression, the pressure constricts the wound along with the blood vessel and the surrounding tissue, this creates a mechanical barrier that temporarily stops the bleeding. Axiostat® adheres to the wound and creates a mechanical seal around the bleeding site thereby promoting the haemostasis.

INDICATIONS:
Axiostat® Chitosan Haemostatic dressing is a sterile, single-use, non-absorbable haemostatic dressing intended to be used to control bleeding for the following indications:
- To stop moderate to severe bleeding due to cuts, abrasions, lacerations, punctures, venous or arterial bleeding.
- Haemodialysis, vascular access sites while reducing ambulation time in patients who have undergone diagnostics or interventional endovascular procedure utilizing procedural sheath.
- To stop moderate to severe bleeding during surgical procedures, dental procedures and trauma injuries.

WARNINGS:
Axiostat® Chitosan Haemostatic Dressing is a non-absorbable dressing made up of 100% chitosan and may break down into glucosamine if left inside the body for more than 24 hours. However it is not recommended to be implanted. Contains chitosan extracted from Shellfish. Do not use Axiostat® if package is damaged or contents are wet. Do not re-sterilize Axiostat®. Axiostat® is recommended for single-use only. Functionality is not guaranteed and risk of contamination if reused.

Axiostat® when used in vascular or surgical procedures, must be under the supervision of a trained healthcare professional. Observe sterile techniques at all times when using Axiostat® in vascular and surgical application. Recommend sterile gauze usage to apply uniform pressure and to hold Axiostat® in position during vascular and surgical procedures. Continuous flow of blood from the puncture site is a medical emergency, hence seek immediate medical attention. Axiostat® when used in Dental procedures, ensure that the device is not swallowed by the patient. Axiostat® could result in hematoma if incorrectly used at puncture sites.

PRECAUTIONS:
Employ appropriate groin management post procedure and post hospital discharge to prevent infection when Axiostat® is used during vascular procedures. The use of Axiostat® may result in nerve compression if large sizes are used in small wounds.

Notify physician if any of the following occur:
- Bleeding or significant drainage from the puncture site.
- Swelling, redness or warmth around the puncture site.
- Increased tenderness, numbness or cold sensation around the puncture site.

The safety and effectiveness of the Axiostat® dressing has not been evaluated in the following patient populations:
- Patients with uncontrolled hypertension (>180 mm Hg systolic).
- Patients with bleeding disorders such as Thrombocytopenia (<100,000 platelet count), thrombasthenia, von Wille Brand's disease, or anaemia (Hgb<10 mg/dl, Hct<30).
- Patients receiving glycoprotein IIb/IIIa inhibitors before, during, or after the catheterization procedure.
- Patients with bleeding diathesis or coagulopathy.
- Patients already having hematoma/pseudoaneurysm.
- Patients having ACT (Activated Clotting Time) > 180 sec.
- Patients undergoing therapeutic thrombolysis.
- Patients with auto-immune disorder and on medications for treating the same.

Refer the below tables for the duration of use of Axiostat® during Vascular puncture procedures:

For Radial Access			
Sheath Size	Heparin Dosage	Time to apply pressure to ensure Haemostasis	Time to remove secondary dressings
6-8Fr Diagnostic Procedure	5000 to 7000 units/mL	Approx. 3 minutes	Not before 45 minutes
6-8Fr PCI (Percutaneous Coronary Intervention)	7500 to 9000 units/mL	Approx. 5 minutes	Not before 90 minutes
6-8Fr PCI (Percutaneous Coronary Intervention) or above	Above 9000 units/mL	Approx. 8 minutes	Not before 180 minutes

RAMYA KRISHNADAS
RA - MANAGER

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