

axiostat[®] PATCH

VASCULAR CLOSURE PATCH

TECHNIQUE FOR USE Femoral Access

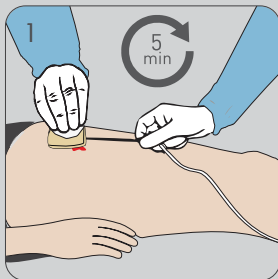


1. Gain control of the area above the Vascular Puncture Site, and pull out the sheath. (The sheath can be removed at an ACT of 180–230). Axiostat Patch can be used for sheath size of 6–12F.
2. Make sure the area surrounding the puncture site is DRY.
3. Take a gauze pad which is approximately the size of Axiostat Patch, and place over the Axiostat Patch (This process adds structure and prevents the Axiostat Patch from sticking to blood, if any, on the glove).
4. Place the Axiostat Patch over the Arterial or Venous puncture site using the 3-finger technique, then gently ease pressure allowing a small (dime size) amount of blood to flow from the site. (The Axiostat Patch’s “mechanism of action” is activated when it comes in contact with blood).
5. Re-establish proximal pressure above the puncture site and hold the Axiostat Patch firmly over the vascular closure. (Excessive pressure is not required).
6. Depending on the level of anticoagulation, begin releasing pressure over the artery after 4–6 minutes.

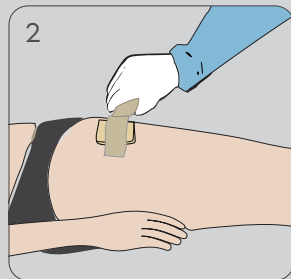
Observe for any bleeding. If bleeding continues, reapply pressure.

7. Do not move the Axiostat Patch after applying. Use another Axiostat Patch in case bleeding is not controlled or dressing is completely saturated with blood.
8. Carefully remove the gauze from the Axiostat Patch, leaving the Axiostat Patch in place over the puncture site. Apply a secondary dressing to ensure Axiostat Patch remains in position.
9. Remove Axiostat Patch within 24 hours by irrigating with plenty of sterile saline. When Axiostat Patch turns into a liquid gel, it can be easily and painlessly taken off. The time of removal should be according to the hospital protocols.
10. The patient’s head may be elevated 20 degrees after 20 minutes and 40 degrees after 40 minutes. “Time to ambulation” in a diagnostic procedure (DX) 60–75 minutes and 90–120 minutes in an interventional procedure (PCI).

How to Use—Femoral Closure

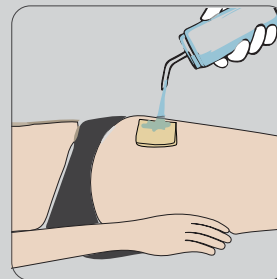


Remove Sheath carefully and use a gauze to apply Axiostat Patch above it. Hold pressure for at least 5 mins. Additional time may be required for certain patients.



Once applied, do not lift or remove Axiostat Patch, not even to check hemostasis. Apply secondary dressing to keep Axiostat Patch in position.

How to Remove—Femoral Closure



To remove Axiostat Patch, irrigate with sterile saline and gently peel it off.

VASCULAR CLOSURE PATCH

TECHNIQUE FOR USE—Femoral Access

Description:

The Axiostat Patch is a sterile, single use, non-absorbable hemostatic dressing. It is composed of Chitosan, a well-known natural polysaccharide generally derived from shellfish which has widely recognized hemostatic properties. The hemostatic dressing can be removed after the clotting has occurred but should not remain on for more than 24 hours. The hemostatic dressing is not intended to be implanted.

Composition:

Axiostat Patch is made up of chitosan extracted from shellfish. Natural material tends to change color. Hemostatic effectiveness remains unchanged.

Actions:

When applied with pressure, Axiostat Patch creates a mechanical barrier against bleeding.

Indications:

The Axiostat Patch is intended for local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing for patients and for the rapid control of moderate to severe bleeding. The dressing is indicated for the following wounds: lacerations, abrasions, surgical debridement sites, skin surface puncture sites, vascular procedure sites and sites involving percutaneous catheters, tubes and pins.

Warnings:

- Remove within 24 hours.
- It is a non-absorbable hemostatic dressing. Do not implant.
- Do not use if patient is allergic to shellfish.
- Do not use if package is damaged or contents are wet.
- For single use only. Do not re-use or re-sterilize.
- Axiostat Patch when used in vascular procedures, must be under the supervision of a trained healthcare professional. Observe sterile techniques at all times

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Before using, refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.

when using Axiostat Patch in vascular application. Recommend sterile gauze usage to apply uniform pressure and to hold Axiostat Patch in position during vascular procedures.

- After bleeding is controlled, do not remove Axiostat Patch immediately. Keep in position for at least 10 minutes.
- Axiostat Patch is intended for temporary control of bleeding only.

Precautions:

Employ appropriate groin management post procedure and post hospital discharge to prevent infection when Axiostat Patch is used during vascular procedures.

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 Patch 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, Het<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.

Storage:

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



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