

INSTRUCTIONS FOR USE

DESCRIPTION:

The Merit Medical Clo-Sur P.A.D.™ is a soft, non-woven hydrophilic wound dressing. Clo-Sur P.A.D.™ is packed in a foil pouch and sterilized by E-beam radiation.

INDICATIONS:

The Merit Medical Clo-Sur P.A.D.™ is intended for use in the local management of bleeding wounds such as vascular access sites, percutaneous catheters or tubes, and the promotion of rapid control of bleeding in patients following hemodialysis and in patients on anticoagulation therapy.

CONTRAINDICATIONS:

- No known contraindications.

WARNINGS:

READ ALL INSTRUCTIONS PRIOR TO USE. OBSERVE ALL WARNINGS AND PRECAUTIONS NOTED THROUGHOUT THESE INSTRUCTIONS. FAILURE TO DO SO MAY RESULT IN COMPLICATIONS.

- Do not reuse. Discard after one procedure.
- Product reuse is not feasible and could be unsafe due to risk of cross-infection. The pad material dissolves once it comes in contact with bodily fluids. The product cannot be effectively cleaned, decontaminated, or reprocessed into its original form after a single application.
- For external use only.

PRECAUTIONS:

- Do not use open or damaged packages.
- Product is water soluble. Do not autoclave.
- Do not expose to organic solvents.

STORAGE INFORMATION:

- Store in a temperature controlled environment (15° - 30° C)
- Keep dry, protect from light, and avoid prolonged exposure to high temperatures.

COMPLICATIONS:

Some of the complications are, but not limited to bleeding, hematomas, pseudoaneurysm, rash and swelling.

PROCEDURE:

1. Apply pressure proximal to treatment area.
2. Verify treatment area is dry.
3. Apply the Clo-Sur P.A.D.™ over the treatment area and place a clean, sterile gauze pad over the Clo-Sur P.A.D.™
4. Apply firm pressure over the treatment area and slowly release proximal pressure to permit blood to contact the Clo-Sur P.A.D.™.
5. Hold continuous pressure over the treatment area for a minimum of ten minutes, then slowly release.
6. Verify hemostasis; secure the treatment area with the Clo-Sur P.A.D.™ left in place using a dry adhesive dressing.

POST PROCEDURE INSTRUCTIONS FOR Clo-Sur P.A.D.

1. After 24 hours, remove dressing, wet Clo-Sur P.A.D.™ with water and allow it to dissolve and remove slowly.
2. Do not bathe or swim for 5 days following procedure.
3. Avoid any strenuous activity for at least 72 hours. This includes but is not limited to jogging, bicycling, climbing stairs, walking long distances or lifting heavy objects.
4. Observe treatment area for any signs of infection, including drainage, swelling, redness, increased pain etc. Watch for signs of hematoma development, which will be a hard painful bruise at the treatment area.
5. If a hematoma or bleeding develops, hold pressure at the site, call your doctor immediately or go to the emergency room.
6. Call your physician's office if you have any problems or concerns..

There is no expressed or implied warranty, including merchantability and fitness for a particular purpose for the Clo-Sur P.A.D. Under no circumstances shall Merit Medical be liable for any direct, incidental or consequential damages other than as expressly provided by specific law. No person has the authority to bind Merit Medical to any representation or warranty except as specifically set forth herein. Descriptions or specifications are meant to generally describe the Clo-Sur P.A.D. and related procedures, and do not constitute any expressed warranties or practice.

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