

INSTRUCTIONS FOR USE

DESCRIPTION:

The Merit Medical Clo-SurPLUS P.A.D. is a soft, non-woven topical hemostasis pad. The Clo-SurPLUS P.A.D. is designed to provide a barrier to microbial penetration and has demonstrated in-vitro antibacterial activity that prevents colonization of the dressing. Clo-SurPLUS P.A.D. is packed in a foil pouch and sterilized by E-beam radiation.

INDICATIONS:

The Merit Medical Clo-SurPLUS P.A.D. is intended for use in the local management of bleeding wounds and to provide a barrier to bacterial penetration of the dressing in all patients and for the promotion of rapid control (hemostasis) of bleeding in patients following hemodialysis and for those on anticoagulation therapy. The dressing is indicated for the following wounds: skin puncture sites for vascular procedures, percutaneous catheters or tubes.

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 prior to applying the P.A.D.
3. Apply the Clo-SurPLUS P.A.D. over the treatment area and place a clean, sterile gauze pad over the Clo-SurPLUS P.A.D.
4. Gradually release proximal pressure to permit blood to contact the Clo-SurPLUS P.A.D.
5. Reapply proximal pressure, as required, to control bleeding.
6. Verify hemostasis by gradually releasing pressure and checking dressing for additional bleeding. Do not lift P.A.D. to verify.
7. Once hemostasis is achieved, secure the treatment area with the Clo-SurPLUS P.A.D. left in place using a dry adhesive dressing.

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

1. After 24 hours, remove dressing, wet Clo-SurPLUS P.A.D. with water and allow it to dissolve and remove slowly.
2. 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.
3. If a hematoma or bleeding develops, hold pressure at the site, call your physician immediately or go to the emergency room.
4. 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-SurPLUS 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-SurPLUS P.A.D. and related procedures, and do not constitute any expressed warranties or practice.

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