

**Description**

QuikClot Radial consists of a roll dressing and an adhesive bandage. The roll is a soft, white, sterile, hydrophilic hemostatic dressing. This product contains kaolin.

Indications

QuikClot Radial is applied topically as an adjunct to manual compression and is indicated for the local management and control of surface bleeding from vascular access sites, percutaneous catheters or tubes utilizing introducer sheaths up to 12 Fr. or up to 7 Fr. for patients on drug/induced anti-coagulation treatment.

Contraindications

QuikClot Radial has not been tested on patients with bleeding disorders due to underlying disease (liver, kidney, or others) and is not indicated for these populations.

Warnings

QuikClot Radial has been tested in clinical trials and its efficacy has been shown only in patients treated with anticoagulation medications: heparin, clopidogrel bisulfate and warfarin. The efficacy of QuikClot Radial in the presence of other anticoagulation medications is not known.

Precautions

- For external use only
- Sterility not guaranteed if package is damaged or opened
- Discard if package is damaged
- Avoid contact with eyes
- Use aseptic techniques
- Do not re-sterilize
- Reuse will cause risk of infection and loss of efficacy
- Longer compression time may be required for patients who are hypertensive, obese, or on drug-induced anticoagulant therapies
- The adhesive bandage is not intended for use on fragile or compromised skin unless used in conjunction with protective films
- Do not use when an individual is sensitive to any of the components in the adhesive bandage
- In patients with either very large or very small wrists, where adequate pressure cannot be achieved by the adhesive bandage, other means such as medical tape or manual compression should be used to maintain firm pressure on the dressing
- If insufficient pressure is applied over the puncture site, bleeding may not be controlled

Storage Conditions

Keep dry. Keep from heat (including storage in direct sunlight or in direct contact with heat sources). Store at temperatures of 77°F (25°C) or less.

Instructions for use

1. Remove hemostatic roll from package. Place roll into sterile field using aseptic technique. Do not wet the roll with saline before using it
2. Remove the adhesive bandage from package. Grasp the two edges of the bandage and pull to break the release liner. Remove release liner from bandage.
3. Place the roll on the puncture site. Apply manual compression on the roll while the introducer is removed. To maintain manual compression on the roll, Step 4 may require assistance from a second health care provider.

4. DO NOT MOVE OR LIFT THE ROLL. Center the adhesive bandage over the roll. Maintain manual compression on the roll. Stretch bandage around wrist until the adhesive edges overlap, adhering the tan colored tab to the patient's skin and overlapping the white tab to adhere on top of the tan tab. Note: Arterial punctures using large dilators will require longer manual compression time. Proceed to Step 5.
5. The adhesive bandage should be left in place for at least 30 minutes. Compression on the roll should then be gradually released by cutting every other elastic band on both sides over the next 30 minutes.
6. The adhesive bandage's pressure should be completely released at one hour after application. To complete the pressure release, cut all the remaining elastic bands.
7. The hemostatic roll may be left in place for up to 24 hours. NOTE: Health care providers are encouraged to continue to use the standard of care at their Institution. The standard of care includes manual compression at the puncture site, time to ambulation, and time to patient discharge.