

RediFoam™

INSTRUCTIONS FOR USE (IFU)



INTENDED USE

Device is intended to aid in patient positioning and immobilization.

CAUTION

Federal (United States) law restricts this device to sale by or on the order of a physician.

WARNING

- Do not use before reading material data safety sheet.
- Do not use if integrity of packaging is compromised or expiration date has passed.
- Users of this product have an obligation and responsibility to provide the highest degree of safety hazard control to co-workers and themselves. To avoid safety hazards, wear all recommended protective equipment and follow safety control policies established by your facility.
- Device should be used for a single patient throughout setup and treatment cycle.
- Device, if improperly used, may explode.

USING REDIFOAM™

WARNING

- Ensure bottle cap is directed away from people while shaking.

1. Place positioning forms on table, if desired. Cover surfaces with plastic sheet.
2. Place appropriate plastic bag (*provided*) on table or in forms. Smooth folds from bag.
3. Wear appropriate personal protective equipment (PPE) per SDS. At a minimum, this should include chemical resistant gloves, chemical resistant long sleeve clothing and eye protection.
4. Ensure contents of both bottles are between 60-80°F.

WARNING

- Using below 60°F will cause decreased foaming, using above 80°F may cause excessive foaming and possible rupture of container and using outside the 60-80°F range will cause more variance of foam density.

5. Shake Part A until components are uniform in color.
6. Shake Part B until components are uniform in color.
7. Pour contents of Part A bottle into Part B bottle.
8. Immediately securely recap Part B bottle and shake vigorously for *only* 10 seconds.
9. Immediately remove cap from Part B bottle and discard cap.
10. Immediately empty ENTIRE contents of bottle into plastic bag and discard UNCAPPED bottle.

WARNING

- Do not recap bottles after emptying; recapping bottles may cause rupture of bottles.

11. Smooth plastic bag contents to distribute evenly. Roll open end and hold up to avoid foam leakage.
12. Place patient on bag and mold foam.

NOTE: Heat will radiate through bag to patient.

13. Allow foam to harden before removing patient (*approximately 15 minutes*).

REPROCESSING

WARNING

- *Users of this product have an obligation and responsibility to provide the highest degree of infection control to patients, co-workers and themselves. To avoid cross-contamination, follow infection control policies established by your facility.*

1. Clean surface of device by removing visual contaminants with common germicidal or antiseptic wipe, such as alcohol. If visual contamination cannot be removed, repeat cleaning steps and if necessary, discontinue use.

MAINTENANCE

NOTE: Inspect device prior to use for signs of damage and general wear.

DISPOSAL

- NOTE:
- If foam leakage occurs, place into plastic bag. Dispose of contents and begin process again.
 - If expiration date has passed, expand foam in plastic bag and dispose.



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