

SecureFoam™

INSTRUCTIONS FOR USE (IFU)



SYMBOL GLOSSARY

(Note: All symbols may not be applicable to this product)

	Medical Device		Do Not Use if Package is Damaged
	Manufacturer		Do Not Reuse Single- Use Device
	Date of Manufacture		Single patient- multiple use
	Use- By Date		Consult Instructions For Use (IFU)
	Lot Code		Caution
	Reorder Number		Warning
	Serial Number		Authorized representative in the European Community
	Sterilized using irradiation		European Conformity
	Do not resterilize		Prescription Only or "For Use by or on the order of a licensed medical professional"
	Non- sterile		Temperature limitation
	Biological Risks		MR Safe
	European Conformity		

CAUTION:

Federal Law restricts this device to sale by or on the order of a licensed Physician or Radiation Therapist.

DEVICE DESCRIPTION

CQ Medical SecureFoam™ two part immobilization kit is a single patient use, customizable device intended to be used for the positioning and re-positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

PACKAGE CONTENTS

- (1) Bottle Part A foaming agent
- (1) Bottle Part B foaming agent
- (1) Large size plastic foaming bag

INDICATIONS

SecureFoam™ two part immobilization is a single patient use, reusable and customizable kit, intended to immobilize a patient undergoing a course of external beam radiation therapy treatment.

CONTRAINDICATIONS

No contraindications have been identified for the use of SecureFoam™ two part immobilization kit.

STORAGE

Store in a cool, dry environment. Do not expose to open flame or temperatures over 95 degrees Fahrenheit. Excessive heat can cause premature aging of components, resulting in a shorter shelf life.

ADVERSE REACTIONS

No adverse reactions have been identified for the use of SecureFoam™ two part immobilization kit.

DISCLAIMER

CQ Medical assumes no responsibility for injury to patients or personnel caused by negligent handling or misuse of this product.

ACTIONS FOR SPILLS/LEAKS

If a minor spill occurs involving either component A or component B, contain component with absorbent material and dispose. If spillage occurs of the mixed foaming agent, try to wipe up immediately with a dry disposable cloth or with acetone or a similar solvent. Once mixture is cured, removal may be difficult.

 WARNING

- Do NOT use SecureFoam™ two part immobilization kit if package is damaged or open.
- Do NOT recap Part B Bottle after mixing, contents remaining in bottle will expand.
- Do NOT expose uncovered skin to mixed chemicals. If an accident occurs, try to remove clumps from skin while still in viscous state. When remainder is dry, it must be mechanically removed, as foaming agent is chemically assistant. If liquid chemical comes in contact with skin, wipe thoroughly with a dry cloth, then rinse the area with water. Afterwards, wash with soap and water. If liquid chemical comes in contact with eyes, immediately flush with a large amount of water for at least 15 minutes and get medical assistance.
- This foaming agent should be used only by medical professionals. Use only in well-ventilated areas. Cover patient's to protect from accidental spillage of foaming agent. Wear gloves, eye protection and protective clothing when using. Read all instructions and safety information prior to using. Inform patients of what to expect during foam preparation. Patients must remain still during formation of mold. Foam will feel warm while expanding and hardening.

PRE-IMMOBILIZATION SET-UP

1. Place the plastic / foaming bag on the table under the area to be immobilized.
2. For extra patient protection, a patient comfort liner (available separately) can be placed over the foaming bag.
3. Place the patient on the table in position that has been instructed by the clinician.
4. If indicated, a breathing apparatus should be provided to the patient.

INSTRUCTIONS

1. Always wear chemical resistant gloves (latex, butyl rubber, nitrile rubber, polyvinyl chloride). Protective clothing, safety glasses and face shield.
2. Pour contents of bottle A into bottle B.
3. Recap bottle B securely.
4. With bottle pointing away from you, shake vigorously for 20 seconds.

**WARNING**

- *All folds / creases need to be removed before pouring foaming agent into liner. This ensures the integrity of the liner as the contents expand.*

5. Carefully remove cap and immediately pour entire contents into the plastic bag that is provided.

NOTE: Inspect plastic bag for possible tears or holes prior to patient use.

**WARNING**

- *DO NOT RECAP BOTTLE B after completing the preceding steps. Contents remaining in bottle will expand.*

6. Close and fold the opened end of the bag. Manipulate foam to desired location with your hands on top of the bag. Once the foam begins to rise up in the bag, you are ready to position the patient onto the bag. Use the patient comfort liner for extra protection against heat.
7. Allow 8 to 10 minutes for foam to cure after initial set. Patient should remain still this entire time. Once the foam has fully hardened, remove patient from form. The form is now customized to your patients anatomy and now ready for use. The customized form can be used throughout the patient's treatment cycle.

CLEANING INSTRUCTIONS

NOTE: It is the user's responsibility to clean products per hospital protocol / local regulations. Do not use alcohol-based cleaners on this product.

Recommended cleaning procedures include:

1. Wipe (blue bags) thoroughly with water-based antiseptic cleaner or foam.
2. Allow to dry before next patient use.

DISPOSAL INSTRUCTIONS

Dispose of properly in accordance with local regulations and standard or clinic procedures.



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