

Klarity Bolus™ INSTRUCTIONS FOR USE

GENERAL INFORMATION

Klarity Bolus™ is a tissue equivalent bolus material and is sufficiently flexible to conform to the patient's surface.

PRODUCT DESCRIPTION

Klarity Bolus is indicated for radiation therapy clinical treatments as a tissue equivalent aid to correct for anatomical irregularities and deliver a prescribed dose to the skin and underlying tissue. Target population is Adult, Child and Infant, and Federal (USA) law restricts this device to sale by, or on the order of a physician.

Klarity Bolus™ features a slightly tacky surface for excellent conformity. It can be cut with scissors to any desired shape and can be layered as needed to increase thickness. It is made of a silicone gel that incorporates a thin polyester mesh netting to provide dimensional stability.

Klarity Bolus has been tested for tissue equivalency at 6 MV and 10 MV photon and at 6 MeV and 12 MeV electron energy levels. Further testing will be required to confirm performance with proton therapy systems.

MAINTENANCE AND DISPOSAL

Klarity Bolus™ should be stored in a dry, clean place. Gloves should be worn when working with bolus for cleanliness.

To clean Klarity Bolus, it should be washed with mild soap or detergent in warm water. Thoroughly rinse, and dry product between use. Allow to air dry in a clean, dust-free environment.

Avoid alcohol-based cleaners or other harsh or abrasive chemicals. Do not soak product in any type of disinfectant and do not autoclave or gas sterilize product. Bolus should not be machine washed or dried.

Klarity Bolus is for single patient use only and can be discarded with normal hospital waste

To be used by a qualified medical professional
IFU-A-010



INSTRUCTIONS FOR USE

1. Select appropriate thickness and cut to size or shape with scissors.
2. Under the guidance of a medical professional, mold the material to the target area, allowing it to adhere to the skin.

Product ID's	
RKB-3003	Klarity Bolus™ .3 cm thickness 30x30 cm
RKB-3005	Klarity Bolus™ .5 cm thickness 30x30 cm
RKB-3010	Klarity Bolus™ 1 cm thickness 30x30 cm



EC REP

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