

Klarity® Proton Therapy Masks for Qfix BoS™ INSTRUCTIONS FOR USE

GENERAL INFORMATION

Klarity Thermoplastic Masks are medical devices used to ensure precise positioning and immobilization of patients undergoing proton therapy treatment.

PRODUCT DESCRIPTION

The proprietary Klarity thermoplastic material has been specially designed to ensure minimal shrinkage and superior fixation and has a non-stick coating. The result is a mask that molds closely to the patient's contours to provide accurate reproducibility and optimal patient comfort. Klarity masks are available in a variety of sizes and perforation patterns. Please consult www.klaritymedical.com for a complete selection.

MAINTENANCE AND DISPOSAL

Klarity Thermoplastic Masks must be stored in a dry, clean place at a temperature between 50-95 °F (10-35 °C). Dispose of masks with normal facility waste.

INSTRUCTIONS FOR USE

Preparation:

1. Preheat oven or water bath to 165°F (73°C).
2. Fit the baseplate to the treatment table and prepare proper head and neck support.
3. Determine where the holes fit into the pins on the underside of the baseplate to ensure efficient mask molding.
4. Position the patient on the baseplate.

Heating:

5. Heat mask (two methods):
Convection Oven Method:
 - Remove the mask from the sealed plastic pouch.
 - Place the mask on the rack in the oven.
 - Heat the mask for 3 to 10 minutes, depending on the oven model (do not exceed 30 minutes).
 - The thermoplastic will be translucent when ready.
 - Retrieve the mask from the oven.

Water Bath Method:

- Remove the mask from the sealed plastic pouch.
- Place the mask in the water bath.
- Heat the mask for 1 to 2 minutes (do not exceed 5 minutes).
- The thermoplastic will be translucent when ready.
- Lift the mask from the bath and shake off the excess water.

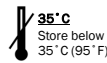
Molding:

6. Feel the thermoplastic to make sure it is not too hot to come in contact with the patient's skin.
7. Position the mask over the patient's face.
8. Gently and steadily wrap the mask around the head (or head & shoulders) of the patient and attach the handles to the pins on the underside of the baseplate.
9. With your fingers, gently and quickly mold the thermoplastic to the contours of the patient.
10. Leave the mask on the patient until it cools completely, for at least ten minutes. The thermoplastic will shrink slightly during the cooling process.

Removing:

11. Ensure that the mask is rigid and has cooled completely. Removing the mask too soon may result in excess shrinkage and patient discomfort when refitting.
12. Release the mask by pulling the handles off the pins on the underside of the baseplate.
13. Remove the mask from the patient.
14. If desired, treatment portals can be cut into the mask using heavy shears or a cast cutter.

To be used by a qualified medical professional
IFU-M-019



EC REP

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