

Klarity® Elekta HeadStep Masks for Radiation Therapy INSTRUCTIONS FOR USE

GENERAL INFORMATION

Klarity Thermoplastic Masks are medical devices used to ensure precise positioning and immobilization of patients undergoing radiation 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 determine the angle of the baseplate.
3. Position the patient's head in the head support.

Heating:

4. 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 waterbath and shake off the excess water.

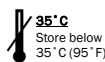
Molding:

5. Feel the thermoplastic to make sure it is not too hot to come in contact with the patient's skin.
6. Position the mask over the patient's face.
7. Tilting slightly downward at the chin, gently press the mask over the patient's face until the outer frame touches the baseplate.
8. Snap the frame ends into the baseplate and lock it at the back.
9. With your fingers, gently and quickly mold the thermoplastic to the contours of the patient, paying close attention to the nose bridge.
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. Remove the mask from the patient.
13. 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-016



EC REP

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