

# Klarity® P-Type 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. 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 handles fit into the baseplate pins to ensure efficient mask molding.
- 4. Check that all pins are in the up (unlocked) position.
- 5. Position the patient on the baseplate.

## **Heating:**

- 6. 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).

To be used by a qualified medical professional IFU-M-013











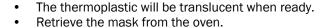












#### Water Bath Method:

- 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:

- 7. Feel the thermoplastic to make sure it is not too hot to come in contact with the patient's skin.
- 8. Position the mask over the patient's face.
- 9. Gently and steadily pull the thermoplastic down at the sides, inserting the side profiles into the receiving slots and pressing the pins into place.
- 10. Gently pull the top cranial profile down and lock into place.
- 11. With your fingers, gently and quickly mold the thermoplastic to the contours of the patient.
- 12. 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:

- 13. 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.
- 14. Release handles from baseplate by lifting the locking pins.
- 15. Remove the mask from the patient.
- 16. If desired, treatment portals can be cut into the mask using heavy shears or a cast cutter.

EC REP

Lotus NL B.V Koningin Julianaplein 10, le Verd, 2595AA The Hague, Netherlands T: +31645171879 (English) T: +31626669008 (Dutch)

Klarity Medical Products, LLC 600 Industrial Parkway Heath, OH 43056 T: 740.788.8107 F: 740-788-8109 info@klaritymedical.com www.klaritymedical.com