

Klarity® O-type Masks 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

Klarity® Thermoplastic Masks are specially formulated for enhanced molding capabilities to ensure minimal shrinkage, resulting in optimal patient comfort. They can be closely molded to a patient's anatomy, providing strong support, comfort, and accurate reproducibility. 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 waterbath to 165°F (73°C).
2. Fit the baseplate to the treatment table and prepare proper head and neck support.
3. Determine where the mask will fit into your baseplate to ensure efficient alignment when molding the mask.
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 3-10 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. Slightly pre-stretch the mask laterally before applying.
8. Position the mask over the patient's face and place the pre-cut hole at the tip of the nose.
9. Gently and steadily pull the thermoplastic down at the sides, inserting the lateral profiles into the receiving slots.
10. Lock the lateral profiles in place with the locking bars or wedges.
11. Hold the thermoplastic at the bridge of the nose and pull the top cranial profile down over the patient's head. Lock the cranial profile in place with locking bar or wedge.
12. With your fingers, gently and quickly mold the thermoplastic to the contours of the patient (nose, cheeks, shoulder, etc.), advising patient to keep eyes closed.
13. Leave the mask on the patient until it cools completely and rests for at least 10 minutes. The thermoplastic will shrink slightly during the cooling process.

Removing:

14. Ensure the mask has cooled completely. Removing the mask too soon may result in excess shrinkage and patient discomfort when refitting.
15. Release profiles from baseplate by removing locking bars or wedges and remove the mask from the patient.
16. 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-011



Keep in a
cool and dry
environment



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