

Klarity® Open Face and Open Eye & Mouth S-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

The proprietary Klarity thermoplastic material used in these S-type masks 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. R461-8STF and R461-8SHTF Klarity Open Face masks are compatible with the Vision RT System.

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

It is recommended that two medical professionals take part in molding the open face head masks, and three medical professionals take part in molding the open face head and shoulder masks.

Preparation:

1. Preheat oven or water bath to 165°F (73°C).
2. Fit the baseplate to the treatment table and prepare the proper head and neck support.
3. Insert the sleeves into the holes on the frame. Insert pins into the sleeves. Determine where the pins on the frame snap into your baseplate to ensure efficient mask molding.
4. Check that each pin is in the up position.
5. Position the patient on the baseplate.

To be used by a qualified medical professional
IFU-M-004



Keep in a
cool and dry
environment



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Heating:

6. Heat mask (two methods):

Convection Oven Method:

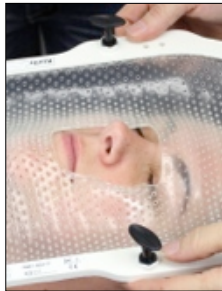
- Remove the mask from the sealed plastic pouch.
- Place the mask on the rack in the oven.
- Heat the mask for 3 to 10 minutes, depending on the oven model (do not exceed 30 minutes).
- The thermoplastic will be translucent when ready.
- Retrieve the mask from the oven.

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:

7. Feel the thermoplastic to make sure it is not too hot to come in contact with the patient's skin.
8. (Therapist A) Position the mask over the patient's face, lining up the openings with the patient's eyes and mouth.
9. (Therapist B) Place your hands on the forehead and chin of the mask to keep the mask in the desired position.



10. (Therapist A) Gently and steadily press the thermoplastic down until the outer frame touches the baseplate, with the pins aligned to the holes in the baseplate. If molding a head & shoulder mask, have Therapist C pull down from the bottom to keep the mask smooth.
11. Press each pin until it clicks into the baseplate.
12. With your fingers, gently and quickly mold the thermoplastic to the contours of the patient.
13. 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:

14. 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.
15. Release the pins from the baseplate by pulling them up.
16. Remove the mask from the patient.
17. If desired, treatment portals can be cut into the mask using heavy shears or a cast cutter.

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35°C Store below 35°C (95°F)



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