

Klarity Blue™ Open Face 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 Klarity Blue thermoplastic material used in these S-type masks 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. The thermoplastic cools quickly for a more efficient set-up.

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.

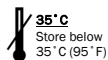
Preparation:

1. Preheat oven or water bath to 165°F (73°C).
2. Insert the sleeves into the holes on the frame. Insert pins into the sleeves.
3. Check that each pin is in the disengaged position.
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.

To be used by a qualified medical professional
IFU-M-005



EC REP

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- Heat the mask for 3 to 10 minutes, depending on the oven model. If using the Klarity AirFlow oven, heat the mask for 3-6 minutes (do not exceed 10 minutes).
- The thermoplastic will be soft 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 soft when ready.
- Lift the mask from the bath and shake off the excess water.

Molding:

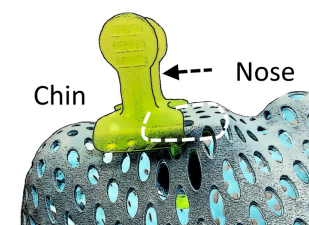
6. Feel the thermoplastic to make sure it is not too hot to come in contact with the patient's skin.
7. (Therapist A) Position the mask over the patient's face, lining up the openings with the patient's eyes and mouth.
8. (Therapist B) Place your hands on the forehead and chin of the mask to keep the mask in the desired position.
9. (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.
10. Press each pin until it clicks into the baseplate.
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. The set up time is very quick, between 1-5 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 the pins from the baseplate by pulling them up.
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.

Extra Strong Thermoplastics and the Klarity BiteLok®:

1. When using a strong thermoplastic mask, there are 2 options for using the QuickFit™ tool.
 - a. Option 1 - While the mask is still warm, pinch the two QuickFit tool handles together, place the QuickFit tool over the BiteLok and release. Allow mask to fully cool. **Please note: When using the BiteLok with stronger thermoplastic masks, take extra care when removing the mask. You will not be able to remove the BiteLok from the mask.**
 - b. Option 2 – While the mask is still warm, pinch the two handles together and align the QuickFit™ tool with the lower part of the BiteLok mouthpiece, toward the chin. You will only lock in the bottom half of the BiteLok. This will still allow you to reindex the BiteLok to the mask, while still being able to remove it for cleaning.



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