

Klarity® Blue U-Frame 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 Klarity Blue thermoplastic material used in these 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. 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

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. Position the patient on the baseplate.

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 10 minutes).
 - The thermoplastic will be soft and pliable 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 3 minutes).
- The thermoplastic will be soft and pliable when ready.
- Lift the mask from the bath and shake off the excess water.

Molding:

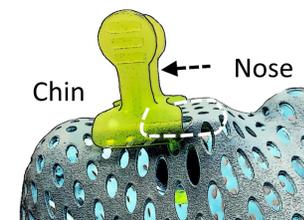
5. Feel the thermoplastic to make sure it is not too hot to come in contact with the patient's skin.
6. Position the mask over the patient's face.
7. Gently and steadily press the thermoplastic down until the frame touches the baseplate.
8. Align the frame holes with the baseplate pins and lock the frame with the swivel clamps.
9. With your fingers, gently and quickly mold the thermoplastic to the contours of the patient.
10. Leave the mask on the patient until it cools completely. The set up time is very quick, between 1-5 minutes..

Removing:

11. Ensure that the mask is rigid and has cooled completely.
12. Release the swivel clamps.
13. Remove the mask from the patient.

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.



To be used by a qualified medical professional
IFU-M-008



Keep in a cool and dry environment



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