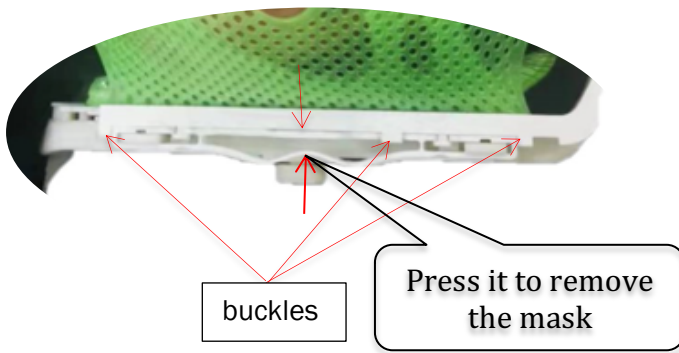


Removing the Mask

16. Let the mask harden for at least 30 minutes.
17. When mask is fully cool, press the edge strip of the middle mask to unlock the mask and remove the top and middle mask.

Tightening the Mask

18. The mask can be tightened if necessary (for example, if the patient has lost weight) by using the height adjustment knob on the baseplate.



**Klarity® Dynamic Masks
for BrainLab Systems**

INSTRUCTIONS FOR USE

GENERAL INFORMATION

Klarity Thermoplastic Masks are medical devices used to ensure precise positioning and immobilization of patients undergoing radiation therapy treatment. Klarity Dynamic Masks are compatible with BrainLab systems.

PRODUCT DESCRIPTION

The proprietary Klarity thermoplastic material used in our 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. 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.

PARTS INCLUDED

For masks R408A-1 and RG408A-1

Klarity Dynamic Masks for BrainLab Systems	Each Set Includes:
	Front Mask
	Rear Mask
	Middle Mask
	Package of Loose Pellets

To be used by a qualified medical professional
IFU-M-020



Keep in a cool and dry environment



Store below 35°C (95°F)



EC REP

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INSTRUCTIONS FOR USE

Preparation:

1. Preheat oven or water bath to 165°F (73°C).
2. Place the patient's head in the mask ring and attach to the baseplate table in a comfortable position.
3. Ensure that the vertical posts are positioned at ear height.

Heating:

4. Heat mask elements (two methods):

Convection Oven Method:

- a. Remove the mask elements from the sealed plastic pouch.
- b. Place the mask elements on the rack in the oven. All mask pieces can be placed in the oven at once. Loose pellets can be placed in a silicone cup in the oven.
- c. Heat the thermoplastic for 3 to 10 minutes, depending on the oven model (do not exceed 30 minutes).
- d. The thermoplastic will be translucent when ready and can be removed from oven.

Water Bath Method:

- e. Remove the mask elements from the sealed plastic pouch.
- f. Place the mask elements in the water bath one at a time.
- g. Heat the thermoplastic for 1 to 2 minutes (do not exceed 5 minutes).
- h. The thermoplastic will be translucent when ready.
- i. Lift the thermoplastic from the waterbath and shake off the excess water.

Molding:

Rear Mask

5. Lift the patient's head and snap the rear mask into the vertical strut
6. Lower the patient's head onto the rear mask.
7. Gently mold the material to the contours of the patient. Take special care to make sure the ears are in a comfortable position.

Middle Mask

8. Ensure that the base is adjusted to the proper height.
9. Place the middle mask on the center of the patient's face. Push both sides down onto the vertical column.

Nose Bridge

10. Take the prepared loose pellets and roll them in your hand to create a T-shape.
11. Place the pellet-T on the bridge of the patient's nose and gently mold it toward the strip on the forehead and down toward the eyes, getting no closer than 3mm to the eyes.
12. For the best connection, it is best to do this while the middle mask is still slightly translucent.
13. Let the middle mask and nose bridge harden completely.

Front Mask

14. Place the prepared front mask centrally over the patient's face with the window opening over the patient's eyes.
15. Align the positioning cylinders of the front mask with the slot of the middle mask, and press the six buckles on both sides of the front mask down to assemble the front mask and the middle mask together.

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