

Removing the Mask

17. Let the mask harden for at least 30 minutes.
18. When mask is fully cool, first open the clips and remove the top and middle mask.
Never open the screws if the mask is on the patient and closed with clips. Never put the mask onto the patient without prior fixation of the vertical posts with the U-frame.

Tightening the Mask

19. The mask can be tightened if necessary if the patient has lost weight.
 - a. Remove the 2mm clips and the Front and Middle masks
 - b. Replace the 2mm spacer bar with the 1mm spacer bar.
 - c. Place the masks back into position and secure with the 1mm clips.
 - d. If the mask needs to be tightened further, remove the 1mm spacer bar and replace the clips with the unmarked clips.
 - e. Be sure to record the appropriate spacer bar and clip size and attach patient identification.

ADDITIONAL INFORMATION

The thickness of the material will vary depending on the size of the patient's head and the skill of the technician producing an evenly stretched mask. Treating through 3.2mm material with no less than 6 MeV can be done without significant loss of skin sparing. If treatment is performed with static fields rather than convergent arcs, we recommend cutting treatment portals or avoiding the double-layer areas of the mask for your beam path when skin-breakdown starts to occur.

Klarity® Stereotactic 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 Stereotactic masks are compatible with BrainLab masks systems.

PRODUCT DESCRIPTION

The proprietary Klarity thermoplastic material used in our 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. 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

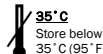
For masks: R406-1, RG406-4, R408, RG408-4AC, R408-2, RG408-2

Stereotactic Masks for BrainLab Systems	Each Set Includes:
	Front Mask
	Rear Mask
	Middle Mask
	Package of Loose Pellets
Dental Support Strip	

To be used by a qualified medical professional
IFU-M-014



Keep in a
cool and dry
environment



35°C
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:

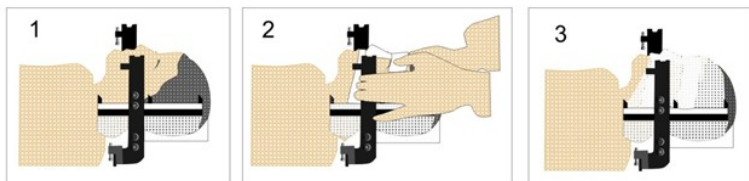
4. Heat mask elements (two methods):

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.



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Molding:

Rear Mask

5. Lift the patient's head and snap the mask into the vertical posts. For 2-pin masks, start at the upper side. For 3-pin masks, start at the lower side.
6. Lower the patient's head into the head rest.
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. Place the 2mm spacer bars onto the vertical posts.
9. Place the middle mask on the center of the patient's face. For Type A Masks, place the wider portion just above the patient's eyebrows with the other strip placed between the patient's nose and mouth. For Type B Masks, position the solid strip just above the patient's eyebrows. The strip with three holes is placed beneath the patient's nose, covering the chin with the middle hole leaving the mouth open.
10. Stretch the mask evenly towards the vertical posts. Snap onto the posts and secure the sheet with the S clips.

Nose Bridge

11. Take the prepared loose pellets and roll them in your hand to create a T-shape.
12. 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.
13. For the best connection, it is best to do this while the middle mask is still slightly translucent.
14. Let the middle mask and nose bridge harden completely.

Upper Mask

15. Remove the clips securing the middle mask.
16. Place the prepared upper mask centrally over the patient's face with the curve towards the patient's mouth.
17. Stretch the mask evenly toward the vertical posts, and snap into the posts. Secure with the 2mm clips.



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