

## Klarity Blue™ Proton Therapy Masks for Qfix BoS™ INSTRUCTIONS FOR USE

### GENERAL INFORMATION

Klarity Thermoplastic Masks are medical devices used to ensure precise positioning and immobilization of patients undergoing proton therapy treatment.

### PRODUCT DESCRIPTION

The Klarity Blue thermoplastic material 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.

### 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. Determine where the holes fit into the pins on the underside of the baseplate.
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.
- 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:

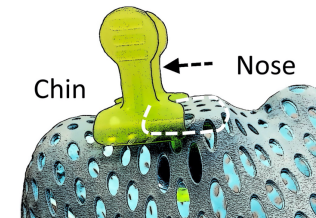
6. Feel the thermoplastic to make sure it is not too hot to come in contact with the patient's skin.
7. Position the mask over the patient's face.
8. Gently and steadily wrap the mask around the head (or head & shoulders) of the patient and attach the handles to the pins on the underside of the baseplate.
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. The thermoplastic will shrink slightly during the cooling process.

#### Removing:

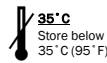
11. Ensure that the mask is rigid and has cooled completely.
12. Release the mask by pulling the handles off the pins on the underside of the baseplate.
13. Remove the mask from the patient.

#### 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-018



EC REP

Lotus NL B.V.  
Koningin Julianaplein 10, le Verd, 2595AA  
The Hague, Netherlands  
T: +31645171879 (English)  
T: +31626669008 (Dutch)

Klarity Medical Products, LLC  
600 Industrial Parkway  
Heath, OH 43056  
T: 740.788.8107 F: 740-788-8109  
info@klaritymedical.com  
www.klaritymedical.com