

Klarity HipFix Masks

Compatible with Klarity PelvicFix and Civco HipFix Baseplates

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 HipFix masks utilize a single sheet of thermoplastic over the abdomen and pelvis for accurate reproducibility. The Klarity thermoplastic material used in these masks has been specially designed to ensure minimal shrinkage and superior fixation and has a non-stick coating.

Klarity masks are available in a variety of sizes and perforation patterns. Please consult www.klaritymedical.com for a complete selection.

MAINTENANCE AND DISPOSAL

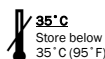
Klarity Thermoplastic Masks must be stored in a dry, clean place at a temperature between 50-95°F (10-35°C). Dispose of masks with normal facility waste.

INSTRUCTIONS FOR USE

Preparation:

1. Attach the thermoplastic sheet to the handles, per manufacturer's instructions.
2. Preheat oven or water bath to 165°F (73°C).
3. Fit the baseplate to the treatment table and prepare suitable body support.
4. Determine where the handle holes fit the baseplate to ensure efficient mask molding.
5. Position the patient on the baseplate.

To be used by a qualified medical professional
IFU-M-017



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

Heating:

6. 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 30 minutes).
- The thermoplastic will be clear 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 clear when ready.
- Lift the mask from the bath and shake off the excess water.

Molding:

7. Position the mask over the patient's torso, aligning the holes of the handles with the pins of the baseplate.
8. Gently and steadily press the thermoplastic down until the outer frame touches the baseplate, with all pins entering the correct holes.
9. Push the slider bars forward to lock the handles to the baseplate.



10. With your fingers, gently and quickly mold the thermoplastic to the contours of the patient.
11. Leave the mask on the patient until it cools completely, for at least ten minutes. The thermoplastic will shrink slightly during the cooling process.

Removing:

12. 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.
13. Release the pins from the baseplate by pulling the slider bars back.
14. Remove the mask from the patient.
15. If desired, treatment portals can be cut into the mask using heavy shears or a cast cutter.



To be used by a qualified medical professional
IFU-M-017



Keep in a cool and dry environment



35°C Store below 35°C (95°F)



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