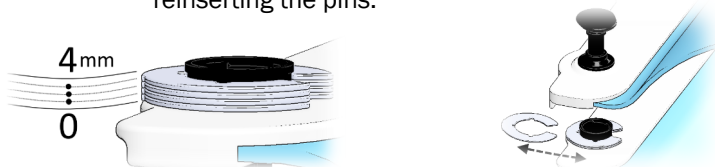


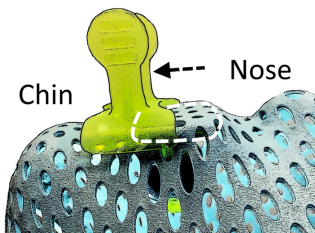
Using the Simple Shim™ System

1. Adding/Removing Shims:
 - a. Shims can be added or removed to adjust the height of the top mask. Each shim is 1mm thick. Height can be adjusted from 0.0mm (no shims) up to 4.0mm (4 shims).
 - b. Sleeves must be securely pressed into position before reinserting the pins.



Extra Strong Thermoplastics and the Klarity BiteLok®:

1. Form the upper mask according to the manufacturer's instructions, placing the mask over the BiteLok.
2. 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.



Klarity® Simple Shim™ SRS* 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 Simple Shim™ SRS masks offer an extra strong thermoplastic mask set with non-stick coating, with adjusting shims at each pin location to maximize treatment accuracy and patient comfort.

PRODUCT DESCRIPTION

The Klarity Simple Shim SRS mask is specifically designed to help achieve precise treatment accuracy for Stereotactic Radiosurgery. The two-piece system allows for both anterior and posterior support, while providing a 0.0mm-4.0mm range of adjustment at each pin location. Our new Klarity Blue™ thermoplastic, included in both the anterior and posterior masks, creates a stronger, more rigid mask with increased stability for the most precise treatment setups.

MAINTENANCE AND DISPOSAL

All 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

- Two-piece Mask Set with upper and lower sleeves pre-inserted (1)
- 1.0mm shims (24)
- Mask Pins (7)
- Extra Top Sleeve (1)
- Extra Bottom Sleeve (1)

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 the proper head and neck support.

To used by a qualified medical professional
IFU-M-010



Keep in a cool and dry environment



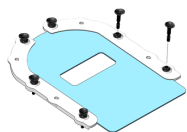
Store below 35°C (95°F)



EC REP

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3. Insert the sleeves (if necessary) into the holes on the upper and lower frames. The sleeves should always be firmly pressed into the frames before inserting pins.
4. Insert 6 pins into the top mask. When inserted properly, the pin will be retained inside the mask frame. Lift pins upward to the disengaged position.

Heating and Molding the Lower Mask:

1. Heating the mask (two methods):

Convection Oven Method:

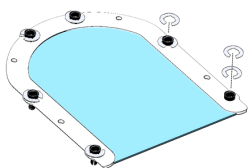
- a. Place the lower mask on the rack in the oven.
- b. Heat the mask for 3 to 10 minutes, depending on the oven model. If using the Klarity AirFlow oven, heat the mask for 3-6 minutes (do not exceed 10 minutes).
- c. The thermoplastic will be soft when ready.
- d. Retrieve the mask from the oven.

Water Bath Method:

- a. Place the lower mask in the water bath.
- b. Heat the mask for 1 to 2 minutes (do not exceed 5 minutes).
- c. The thermoplastic will be soft when ready.
- d. Lift the mask from the bath and shake off the excess water.

2. Molding the Lower Mask:

- a. Feel the thermoplastic to make sure it is not too hot to come in contact with the patient's skin.
- b. Line the mask up with the baseplate. Have the patient lie down into the mask and rest the back of their head on the chosen head support.
- c. Form the mask around the back of the head and behind the neck and ears as desired.
- d. Allow the mask to cool completely before making the upper mask.
- e. Cooling time for the mask is 3-5 minutes.
- f. Place desired number of shims onto the lower mask. It is recommended that you place 2 shims per pin location. This will give flexibility to increase the shims up to four (4mm) or decrease down to zero (0mm).



To used by a qualified medical professional
IFU-M-010



Keep in a
cool and dry
environment



35°C
Store below
35°C (95°F)



Heating and Molding the Upper Mask:

1. Heat the mask (two methods):

Convection Oven Method:

- a. Place the upper mask on the rack into the oven.
- b. Heat the mask for 3 to 10 minutes, depending on the oven model. If using the Klarity AirFlow oven, heat the mask for 3-6 minutes (do not exceed 10 minutes).
- c. The thermoplastic will be soft when ready.
- d. Retrieve the mask from the oven.

Water Bath Method:

- a. Place the upper mask in the water bath.
- b. Heat the mask for 1 to 2 minutes (do not exceed 5 minutes).
- c. The thermoplastic will be soft when ready.
- d. Retrieve the mask from the oven.
- e. Feel the thermoplastic to make sure it is not too hot to come in contact with the patient's skin

2. Molding the Upper Mask:

- a. Verify pins are not in the engaged position.
- b. Align the upper mask with the sleeves on the lower mask and press the mask down over the patient's face.
- c. Make sure the upper frame is pressed firmly into the lower frame and engage the pins.
- d. Form the mask around the patient's face and chin as desired
- e. Allow the mask to cool completely
- f. Cooling time for the mask is 3-5 minutes.

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