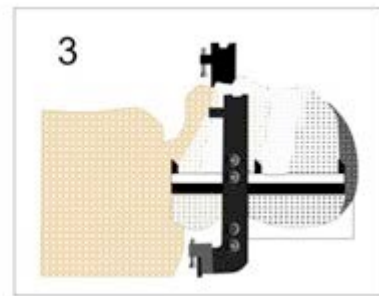
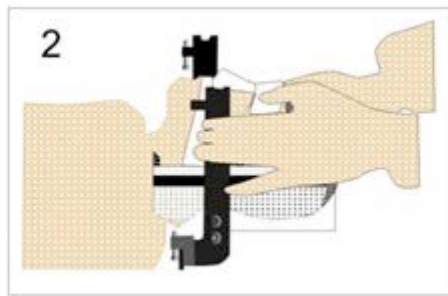
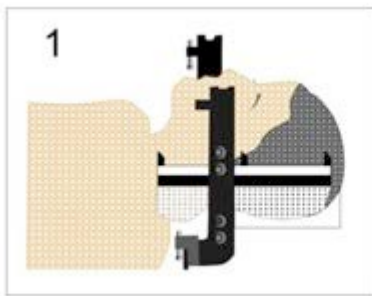
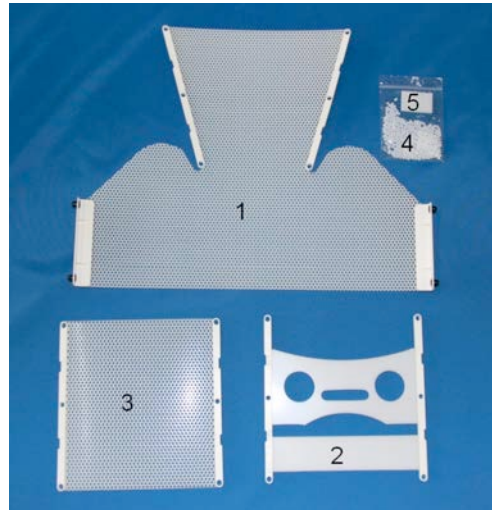


### INSTRUCTIONS FOR USE

CE Product: R408-2

One package of KLARITY R408-2 Mask Set, containing

- 1 Top Mask (1)
- 1 Middle Mask (2)
- 1 Rear Mask (3)
- 1 Package of loose pellets (4)
- 1 Dental support stripe (5)



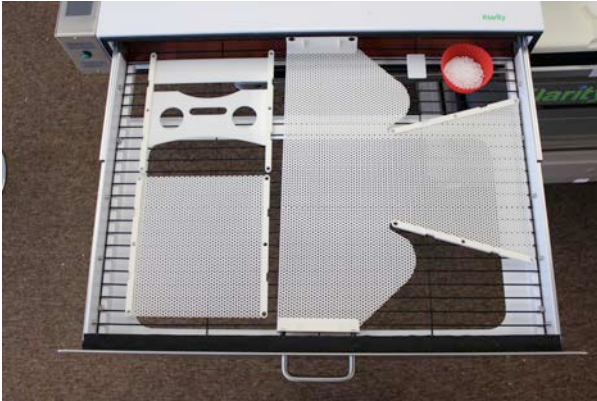
### Preparation

The following items are necessary to mold a Frameless Radiosurgery mask:

- Water bath or dry heat oven at 70 to 80 degrees C (158 to 176 degrees F).
- Mask set for single patient, containing:
  1. Top Mask
  2. Middle Mask
  3. Rear Mask
  4. One package of loose pellets
  5. Dental support strip
- Clips and spacers for mask accessories.

### Oven Heating Method

- Set temperature to 74 degrees C (165 degrees F)
- Place mask contents on the oven rack as shown: (All parts can be placed in the oven at the same time.)



- Keep non-perforated items and pellets toward the back of the oven rack. (If your oven was purchased from Klarity Medical Products, LLC, a silicone cup may have been included with the oven.) Use the silicone cup to heat up the pellets. (A large silicone muffin cup or mini non-stick pan can be used- the wider the base, the faster the pellets will heat up).
- Set timer for 15 minutes. The masks and pellets will be ready when heated in an oven for 15 minutes. Keep drawer/door closed the entire time.

### Patient positioning

To position the patient properly, place the patient's head within the CFK Base plate and onto the H&N Support. Finally, position the patient so that the base plate is adjacent to the patient's shoulder and the occiput is resting comfortably on the H&N Support.

### Molding the Rear Mask

- **Water Bath** - Place the Rear Mask into the heated water bath, and leave it there until it becomes translucent.
- Remove the sheet from the water bath and dry it or remove it from the oven.
- Lift the patient's head and mount the Rear Mask onto the Base plate.
- Lower the patient's head onto the mask.
- Gently mold the material to the contour of the patient's head as the mask material is hardening.

**Warning:** Test the temperature of the softened mask material for patient comfort.

*The use of the mask material may cause mild irritation to patients with sensitive skin. If lesions or open wounds are present in the face of the patient, they must be covered before you mold the mask using plastic wrap or adequate dressings.*

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### **Molding the Middle Mask**

- **Water Bath** -Place the Middle Mask into the water bath. It may take a little longer to become translucent.
- Place the 2 mm spacer bars onto the CFK Base plate. Make sure the indentation is on the outside.
- Remove the translucent mask from the water bath and dry it or remove it from the oven.
- Position the solid strip just above the patient's eyebrows.
- The strip with the three holes is placed beneath patient's nose closely covering the patient's chin and the middle hole leaving the patient's mouth.
- Mount the Middle Mask to the CFK Base Plate and secure the mask using the 2mm manufacturing clips.
- Gently mold the material to the contour of the patient's head as the mask material is hardening.

### **Molding the Nose Bridge**

- **Water Bath** - Place the loose pellets onto the mesh sheet supplied with the H&N Mask Set and place them into the water bath. If using dry heat, remove pellets from silicone cup.
- After the pellets have become transparent, roll them in your hand to create a T-shaped form.
- Place it on the bridge of the patient's nose and gently mold it toward the strip on the forehead and down toward the eyes, going no closer than 3mm to the eyes.
- For the best connection, the Middle Mask should still be translucent when molding.
- Let both the Middle Mask and Nose Bridge completely harden.

### **Molding the Top Mask**

- **Water Bath** - Place the Top Mask into the water bath until it becomes transparent.
- Remove the clips from the CFK Base Plate.
- Remove the mask from the water bath and dry it or remove it from the oven.
- Then pull the mask over the patient's face, starting with the narrow part in the middle of the mask, which is placed at the chin, and go on with molding the mask to the patient's forehead.
- Clip the 2mm spacer clips on each side of the CFK Base Plate.
- Pull the over the patient's shoulders and attach the lateral bars to the Frameless Radiosurgery Imaging Support or the Imaging couch Top by pushing the rapid fasteners.
- Gently mold the material to the contour of the patient's face as the mask material is hardening.
- Let the mask harden at least 30 min.

### **Removing the Mask**

After the mask is completely hardened, first open the clips and remove the Top and the Middle Mask.

### **Tightening the Masks**

The mask can be tightened if necessary, e.g. if the patient has lost weight:

- Remove the 2mm clips and the Top and the Middle Mask.
- Replace the 2mm spacer bar with the 1mm spacer bar.
- Place the mask back in their former position and secure with 1mm clips.
- If the mask needs to be tightened even further, remove the 1mm spacer bar and replace the clips with the clips without marking.

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## *Thermoplastic for Radiation Therapy*

**Warning:** Be sure to record the appropriate size of the spacer bar and clips, and attach the patient identification to the mask. Store the mask at room temperature (24 degrees C/ 75 degrees F) and do not reheat.

### **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. The density is approximately 1.15 g/cm<sup>3</sup> at room temperature and 1.06g/cm<sup>3</sup> at body temperature, making it essentially tissue equivalent. 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 suggest either cut windows or avoid the double-layer areas of the mask for your beam path when skin-breakdown starts to occur. The mask sets required per patient treatment are also provided non-sterile and are for single patient use only.

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