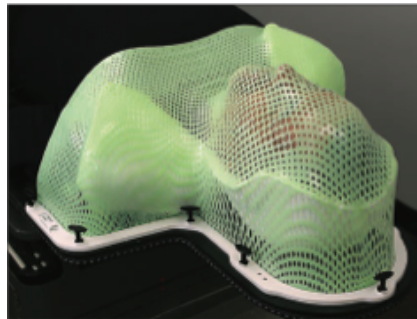
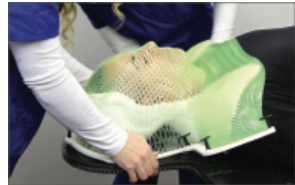


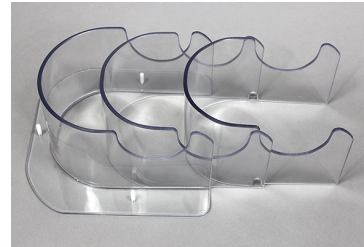
11. Once the neck and shoulder straps are in place, you can make any final positioning adjustments to the cushion. Take special care to keep the cushion out of the path of the mask, especially around the edge of the face, and the tops of the shoulders.
12. The Klarity Cushion™ will begin to set after 2-4 minutes, and it will become fully rigid in 5-7 minutes. Leave the straps in place until the cushion has cooled completely.
13. Once the cushion is fully hard, remove the straps and shell mold.
14. Prepare your thermoplastic mask per the manufacturer's instructions.
15. The thermoplastic mask should come down around the patient's face and cushion, creating a fully encompassing shell around the patient's head and shoulders.
16. If additional adjustments are needed, you can reheat a small area of the cushion with a heat gun or hair dryer for spot treatment, or you can place the cushion back in the oven to completely remold the cushion (one per patient).



Klarity® Shell System INSTRUCTIONS FOR USE

GENERAL INFORMATION

The Klarity Shell System is an advanced indexing tool that provides secure, customized head and neck support for patients undergoing radiation therapy.



PRODUCT DESCRIPTION

The Klarity Shell System is a unique method of high-precision positioning and immobilization for head and neck treatments. An acrylic shell is used to hold a moldable Klarity Cushion™* around the posterior side of the patient's head. Straps assist with molding the cushion. After the cushion cools, the shell is removed, and a thermoplastic mask is formed over the patient and cushion to secure the patient to the treatment table. This method holds all sides of the head comfortable and provides significantly increased support, stability, and repositioning accuracy. Please note that there is some natural color variation in the fabric material of the product. This is considered normal and has no impact on the product performance. Klarity Cushions™ for the Shell System are available in a variety of sizes. Please consult our catalog or www.klaritymedical.com for a complete selection.

MAINTENANCE AND DISPOSAL

Store Klarity Cushions™ in a dry, clean place at temperatures between 50–95°F (10–35 °C). Avoid direct sunlight. Dispose of Klarity Cushions™ with normal facility waste after patient's treatment cycle is completed. The Shell molds and straps can be cleaned and re-used.

**Patent Pending*

To be used by a qualified medical professional
IFU-C-004



Keep in a cool and dry environment



35°C Store below 35°C (95°F)



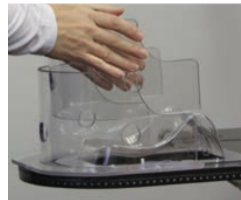
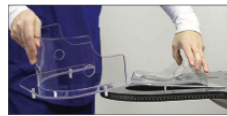
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INSTRUCTIONS FOR USE

Patient Set-Up

1. Secure one self-adhesive Velcro strip to each side of the treatment couch (may be reused after initial setup).
2. Place the outer Shell Mold on the baseplate with the alignment pins in the corresponding holes of the baseplate.
3. Position your patient on the table so their head is in the center of the shell mold and the back of their skull rests comfortably on the headrest. Check that the holes for the mask pins are accessible around the patient's head and shoulders. Adjust patient accordingly.
4. Check the space between the patient's head and the outer shell mold. Ideally, there should be 1-2cm of empty space between the top of the patient's head and the outer shell. If there is more than 2cm of empty space, add 1 or 2 of the inner shell molds to obtain proper spacing.
5. Direct the patient to sit up.



Heating the Klarity Cushion™

There are two methods for heating Klarity Cushions™. The convection oven method is strongly recommended.

Convection Oven Method:

- Preheat oven to 165°F (73°C).
- Remove the cushion from the sealed plastic pouch.
- Place the cushion on the oven rack. The cushion will become moldable in 10–12 minutes, depending on the oven model (do not exceed 1 hour).
- Remove the cushion from the oven.

Water Bath Method:

- Preheat water bath to 165°F (73°C).
- Keep the cushion sealed in its plastic pouch and place it in the water bath.

- After five minutes, flip the cushion and continue heating until it becomes soft and pliable (about 10 minutes total). It helps to keep the lid closed and use a timer for the 5-minute intervals.
- Remove the cushion from the water bath and take it out of its pouch.

Molding the Klarity Cushion™:

6. Place the heated cushion directly above the outer shell mold. Make sure there is approximately 1 inch overhand over the top and sides of the outer shell.
7. While firmly holding on the to the top of the cushion, direct the patient to lie back and slowly press their head into the shell cushion until it is comfortably resting on the headrest (if using), or baseplate.
8. If adjustments are needed, have the patient sit up, relocate the cushion to the desired position, and repeat the process.
9. Attach the 2-inch neck strap to the underside of the Klarity Cushion™, below the patient's ear. Draw the strap across the patient's torso, pull tight, and attach the other end of the strap to the Velcro on the treatment couch. Repeat on the other side, creating an X over the patient.
10. Take the 6-inch shoulder strap and attach the Velcro end to the underside of the patient's shoulder, just above their shoulder blade. Draw the strap over the shoulder and across their torso, following the patch of the previously placed neck strap. Pull tight and attach to the Velcro on the treatment table. Repeat on the other side.



*Patent Pending

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