positioning
patients for life.®

PRODUCT GUIDE & USER MANUAL

Aquaplast RT™ Custom Thermoplastic

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Registro Anvisa No: 81300160001

AQUAPLAST RT™ CUSTOM THERMOPLASTIC

INTENDED USE

Aquaplast RT is intended to immobilize, position, and reposition patients undergoing radiation therapy.

! NOTE ! United States Federal law restricts this device to sale by or on the order of a physician.

PATIENT TARGET GROUPS

Patients undergoing radiation therapy or diagnostic imaging procedures.

INTENDED USERS

The intended user for the products is a person qualified in accordance with the requirements of the regulatory region.

PRECAUTIONS FOR USE

- The use of this device may cause mild sensitization upon contact with the skin of individuals.
- Aquaplast RT thermoplastic is supplied for single patient use only and is not sterile.
- Custom Thermoplastic will attenuate a radiotherapy beam and increase skin dose. Attenuation and increased skin dose should be taken into account during planning and treatment.
- Refer to Qfix.com for a listing of symbols and their definitions.
- A shower cap may be used to cover the patient's hair during mask fabrication. In its softened state, masks may stick to hair that has been sprayed with hair spray.
- Any open wound or lesion should be covered with a dressing or plastic wrap according to hospital protocol prior to molding the mask.

! WARNING ! VERIFICATION OF PATIENT POSITION MUST BE COMPLETED DURING PLANNING AND TREATMENT IN A RADIOTHERAPY ENVIRONMENT. FOLLOW STANDARDIZED SETUP VERIFICATION PROTOCOLS TO VERIFY PATIENT POSITION PRIOR TO TREATMENT BEING ADMINISTERED.

! WARNING ! DOSE DEPTH, DEPOSITION, AND TRANSITION AREA EFFECTS MUST BE EVALUATED DURING PLANNING AND TREATMENT WITHIN A PROTON THERAPY ENVIRONMENT.

SERIOUS INCIDENTS

Please report any serious incidents (e.g. incidents which result in or have the potential to result in death or serious injury) to both Qfix and your country's Competent Authority.

MR SAFETY INFORMATION

MR Non-clinical testing has demonstrated **Aquaplast RT Custom Thermoplastic** is MR Safe. The **Aquaplast RT Custom Thermoplastic** may be used in an MR environment.

SOFTENING THE AQUAPLAST RT™ CUSTOM THERMOPLASTIC

Water Bath

! WARNING ! FOLLOW ALL WARNINGS, PRECAUTIONS, AND INSTRUCTIONS FOR USE CONTAINED WITHIN THE PRODUCT GUIDE AND USER MANUAL FOR THE WATER BATH.

! WARNING ! DO NOT LEAVE THE THERMOPLASTIC IN THE WATER BATH BEYOND 30 MINUTES.

! WARNING ! THE THERMOPLASTIC MATERIAL MAY BE HOT! HANDLE WITH CARE. ALLOW TO COOL SLIGHTLY PRIOR TO PATIENT CONTACT TO AVOID PATIENT INJURY.

1. Place the supplied nylon mesh in the bottom of a shallow water bath, and then a large unfolded paper towel on top of the mesh in the bath, pre-heated to approximately 75°C (165°F).
2. Place desired size of Aquaplast RT™ Custom Thermoplastic into the hot water and allow it to turn clear, with no whiteness/opacity to the material. Once clear, remove the thermoplastic by the ends of the mesh and allow the excess water to pour off the thermoplastic material into the bath. Next, lay the thermoplastic material on a flat clean surface (mesh side down) to check the temperature (there are several minutes of working time). Check the temperature by placing the inside of your wrist on the material, making sure it is not too hot for the patient.

Recommended Heating Times and Temperatures for Qfix Custom Thermoplastic

Thermoplastic	Heat Until	Heating Temperature
Aquaplast RT™ Custom Thermoplastic	4–6 minutes or until thermoplastic material turns clear	70°–75°C (160°–170°F).

RapidHeat™ Oven

! WARNING ! FOLLOW ALL WARNINGS, PRECAUTIONS, AND INSTRUCTIONS FOR USE CONTAINED WITHIN THE PRODUCT GUIDE AND USER MANUAL FOR THE RAPIDHEAT™ OVEN.

! WARNING ! THE OVEN RACKS MAY BE HOT! HANDLE WITH CARE. USE HAND PROTECTION WHEN HANDLING.

Prior to taking the patient into the simulation room, turn on the RapidHeat™ Oven by pressing the power button.

Manual Mode

1. When the Program Indicator (P01, P02, etc.) stops flashing, press the INCREASE or DECREASE button to set the desired temperature. The light will flash next to the small TEMPERATURE icon. Refer to table below.
2. Press the TIMER button. The light will flash next to the small TIMER icon. Press the INCREASE or DECREASE button to set desired heating time.
3. Press START/STOP to begin the preheat cycle. The display will flash “PrH” for PREHEATING. Jump to “Heating the thermoplastic material” section.

! NOTE ! When changing the temperature, verify the light next to the small TEMPERATURE icon is flashing. When changing the heating time, verify the light next to the small TIMER icon is flashing.

Program Mode

1. While the Program Indicator (P01, P02, etc.) ***is flashing***, press the INCREASE or DECREASE button until the desired Program is selected.
2. Press START/STOP to begin the preheat cycle.

! NOTE ! The display will indicate the last memorized program by flashing P01 (Program 1), P02 (Program 2), etc. If the display stops flashing before the desired program has been selected, press the P button and press the INCREASE or DECREASE button until the desired program has been selected.

Heating the Thermoplastic Material

1. The oven will beep and the display will indicate PrH READY when the oven has completed the pre-heating cycle and is ready to heat the thermoplastic material.
2. Place the Aquaplast RT™ Custom Thermoplastic on top of the mesh liner.
3. Using the mesh liner as a transfer sheet, place the mesh liner onto the oven rack.
4. When the oven door is shut, press START/STOP and the timer will begin counting down.
   - During the softening cycle, the actual temperature of the oven chamber can be observed by pressing the TEMPERATURE button once.
   - To increase or decrease the oven temperature, press the INCREASE or DECREASE button until the desired temperature is reached.
   - To increase or decrease the countdown timer, press the TIMER button followed by the INCREASE or DECREASE buttons to re-set desired heating time.
   - Press the LAMP button to illuminate the oven interior. The light will remain on for 60 seconds.
   - Opening the oven door during the softening process will pause the timer. The timer will resume the countdown when the oven door is shut.
5. When the timer reaches zero, the oven will beep three times and then once every 60 seconds indicating the softening cycle has been completed. The display will indicate READY. Using the mesh liner as a transfer sheet, remove the thermoplastic material from the oven rack.
6. Ensure the thermoplastic material is cool enough for patient comfort prior to patient contact.

NOTE: Allow the thermoplastic material to turn clear, with no whiteness/opacity to the material. Once clear, remove the thermoplastic material by the ends of the mesh. Next, lay the thermoplastic material on a flat clean surface (mesh side down) to check the temperature (there are several minutes of working time). Check the temperature by placing the inside of your wrist on the material, making sure it is not too hot for the patient.

Recommended Heating Times and Temperatures for Qfix Custom Thermoplastic

Thermoplastic	Heat Until	Heating Temperature
Aquaplast RT™ Custom Thermoplastic	6–12 minutes or until thermoplastic material turns clear	74°C (165°F)

! WARNING ! DO NOT HEAT THE THERMOPLASTIC MATERIAL BEYOND 30 MINUTES.

FORMING AQUAPLAST RT™ CUSTOM THERMOPLASTIC

Step 1
Moisten the area of the patient's skin surface for application during simulation by wetting the target area with hand lotion, a water atomizer, or mineral oil using a paper towel. Moistening the skin makes for easy application and removal. This step is only necessary during the forming process. If the thermoplastic material is to be placed over a patient's hair, a non-stick barrier such as plastic wrap should be used to prevent adhesion.

Step 2
Remove the Aquaplast RT™ Custom Thermoplastic from the water bath or oven by lifting the mesh (and paper towel if using water bath) by the far corners to prevent stretching.

Step 3
Allow the material to cool to a comfortable temperature, turn the material upside down on the area to be formed with thermoplastic, being careful not to stretch it. Peel off the layer of mesh and then the paper towel. Mold the material using only light pressure to match the contours of the patient's anatomy and hold until the material stiffens.

Step 4
Speed up the cooling process by fanning the material. Once the material becomes slightly opaque/white, carefully lift the material to allow air to flow to the bottom side of the thermoplastic material. Proper airflow allows the material to cool evenly and prevent excess air gaps.

Step 5
Once the Aquaplast RT Custom Thermoplastic is white and opaque, if desired, information such as the region of interest, patient information, or other items as may be appropriate may be marked on the surface of the thermoplastic material with a permanent marker.

Step 6
The thermoplastic material is fully set once it is as white as it was prior to forming and is cool to the touch.

! NOTE ! Removing the thermoplastic material fully from the patient while still warm may cause it to warp and may cause an incorrect fit for treatment.

PARTS LIST

! NOTE ! Qfix offers custom thermoplastic material in a variety of sizes and thicknesses. Your physics department should determine which product is suitable for a given application.

Product Code	Description	Quantity Per Package
RT-1910-4	Aquaplast RT™ Thermoplastic Sheet, 4.8 mm, 20 cm x 23 cm	5
RT-1913-2	Aquaplast RT™ Thermoplastic Sheet, 2.4 mm, 30 cm x 30 cm	5
RT-1913-3	Aquaplast RT™ Thermoplastic Sheet, 3.2 mm, 30 cm x 30 cm	5
RT-1913-4	Aquaplast RT™ Thermoplastic Sheet, 4.8 mm, 30 cm x 30 cm	5
RT-1922	Aquaplast RT™ Thermoplastic Sheet, 4.8 mm, 45 cm x 60 cm	5
RT-1931-4	Aquaplast RT™ Thermoplastic Sheet, 4.8 mm, 30 cm x 45 cm	5
RT-7001	Adapt-It Thermoplastic Pellets, 1lbs	1
RT-7003	Adapt-It Thermoplastic Pellets, 3lbs	1

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