positioning
patients for life.®

PRODUCT GUIDE & USER MANUAL

Pelvis, Breast, & Extremities Thermoplastics

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Registro Anvisa No: 81300160001

AQUAPLAST RT™ & FIBREPLAST® THERMOPLASTICS

INTENDED USE

Aquaplast RT and Fibreplast 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 and Fibreplast thermoplastics are supplied for single patient use only and are not sterile.
- Thermoplastic material 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.

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

! 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.

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 & Fibreplast Thermoplastics** are MR Safe. The **Aquaplast RT & Fibreplast Thermoplastics** may be used in an MR environment.

MR Non-clinical testing has demonstrated **Opti-Handles**™ are MR Safe. The **Opti-Handles** may be used in an MR environment.

INFORMATION & HELPFUL HINTS

- Aquaplast RT and Fibreplast are available in a variety of sizes and thicknesses. Please see the Qfix catalog or visit www.Qfix.com for a complete selection of thermoplastics and more information.
- Aquaplast RT and Fibreplast thermoplastics can be adapted to be used with commercially available immobilizing and positioning devices such as foaming agents and vacuum cushions.
- For optimal fit and patient comfort a 10 x 10 cm (4 x 4 in) gauze pad can be placed over bony prominences to alleviate potential pressure points.
- Any open wound or lesion should be covered with a dressing or plastic wrap according to hospital protocol prior to molding the thermoplastic.
- When not in use, keep thermoplastic away from heat and direct sunlight.
- Aquaplast RT & Fibreplast should be disposed of according to hospital protocol.

SOFTENING THE THERMOPLASTIC

! 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.
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” 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.

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Heating the Thermoplastic

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.
2. Attach the Opti-Handle or similar accessory to the Aquaplast RT or Fibreplast thermoplastic if needed.
3. Place thermoplastic on top of the mesh liner.
4. Using the mesh liner as a transfer sheet, place the mesh liner onto the oven rack.
5. 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.
6. 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 from the oven rack.
7. Ensure the thermoplastic is cool enough for patient comfort prior to patient contact.

Recommended Heating Times and Temperatures for Qfix Thermoplastics

Thermoplastic	Heating Time	Heating Temperature
Aquaplast RT & Fibreplast	8–20 minutes	74°C (165°F)

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

SOFTENING THE THERMOPLASTIC

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

1. Prior to taking the patient into the simulation room, turn on the water bath, checking for sufficient water to cover the thermoplastic.
2. Attach the Opti-Handle or similar accessory (if required) to the Aquaplast RT or Fibreplast thermoplastic.
3. Place the mesh liner in the hot water and place the thermoplastic on top of the mesh liner.

Recommended Heating Times and Temperatures for Qfix Thermoplastics

Thermoplastic	Heating Time	Heating Temperature
Aquaplast RT	4 minutes	70°–75°C (160°–170°F)
Fibreplast	4 minutes	75°–80°C (165°–175°F)

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

4. Using the mesh liner as a transfer sheet, remove the thermoplastic from the water and blot off excess water with a dry towel. Ensure the thermoplastic is dry and cool enough for patient comfort.

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

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MOLDING INSTRUCTIONS FOR AQUA-BRIEF™

1. Position patient on the Carbon Fiber Pelvis Board.

! NOTE ! Refer to the Product Guide and User Manual for the Qfix Carbon Fiber Pelvis System (P/N 2005114) for operating instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of the Qfix Carbon Fiber Pelvis System.

! NOTE ! Ensure the Opti-Handle or similar accessory is attached to the thermoplastic prior to softening the thermoplastic.

2. Prior to placing the softened thermoplastic over the patient, verify the thermoplastic is cool enough for patient comfort.
3. Use appropriate knee wedge positioner, however if using the Groin Lock, a knee wedge positioner is not typically used.

! NOTE ! If using the Groin Lock, refer to the section, “Instructions for Using the Groin Lock”.

4. Attach one Opti-Handle to the Carbon Fiber Pelvis Board. Mold the thermoplastic over the patient securing the opposite Opti-Handle to the Carbon Fiber Pelvis Board.
5. Continue molding the thermoplastic with gentle finger pressure until desired contour has been achieved (Figure 1).

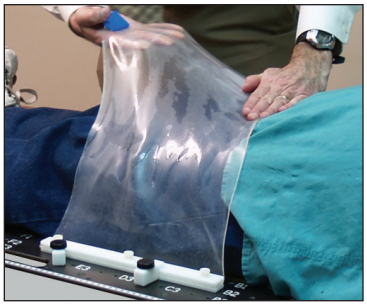


Fig. 1

6. Allow the thermoplastic to cool completely to the touch before removing. If possible, begin simulation as the thermoplastic cools without removing the thermoplastic until simulation is completed.

MOLDING INSTRUCTIONS FOR THE AQUAPLAST RT™ AND FIBREPLAST® PELVIS PRECUT

1. Use appropriate positioning devices, depending on the device used.

! NOTE ! Ensure the Opti-Handle or similar accessory is attached to the thermoplastic prior to softening the thermoplastic.

2. Prior to placing the softened thermoplastic over the patient, verify the thermoplastic is cool enough for patient comfort.
3. Use appropriate wedge positioners, however if using the Groin Lock, a knee wedge positioner is not typically used.
4. Attach one Opti-Handle to the device. Mold the thermoplastic over the patient securing the opposite Opti-Handle to the device.

! NOTE ! Securing the thermoplastic will vary depending on type of device being used.

5. Continue molding the thermoplastic with gentle finger pressure until desired contour has been achieved.
6. Allow the thermoplastic to cool completely to the touch before removing. If possible, begin simulation as the thermoplastic cools without removing the thermoplastic until simulation is completed.

INSTRUCTIONS FOR USING THE GROIN LOCK

! NOTE ! Use only Aquaplast RT™ and Fibreplast® Thermoplastics with a bonded Groin Lock.

1. Insert Groin Lock into appropriate Groin Lock Slot on the device (Figure 2).
2. Place the Groin Lock Key behind the Groin Lock to prevent the Groin Lock from slipping out of the device (Figure 2).

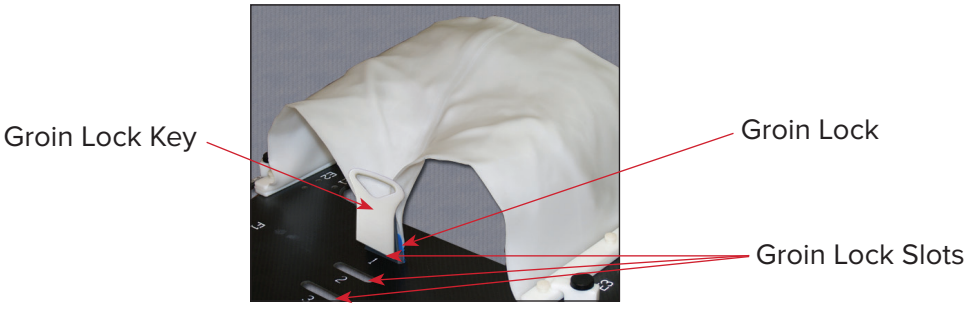
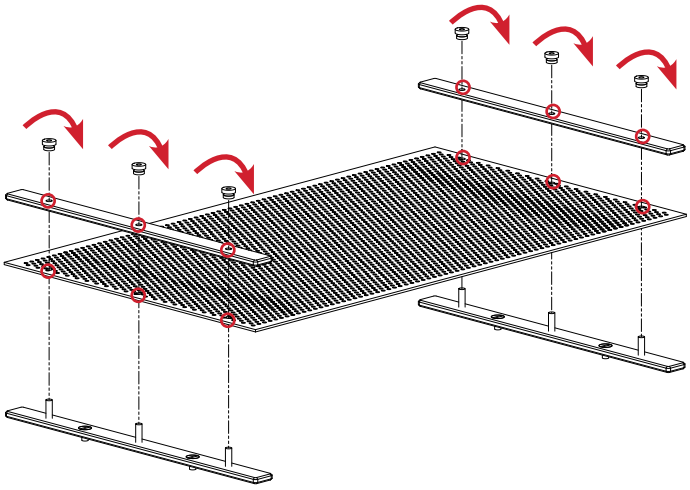


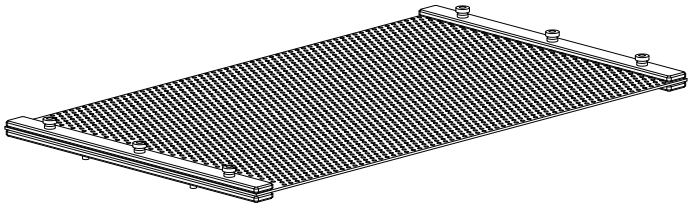
Fig. 2

OPTI-HANDLE THERMOPLASTIC ACCESSORY

SET UP

Opti-Handle™ Thermoplastic Accessory





PARTS LIST

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

Product Code	Description	Quantity Per Package
RT-1722	Aquaplast RT Sheet, 18" x 24", 2.4 mm, Solid	5
RT-1722P24	Aquaplast RT Sheet, 2.4 mm, 18" x 24", Solid	5
RT-1778	Aquaplast RT Sheet, 2.4 mm, 18" x 24", Microperf	5
RT-1782	Aquaplast RT Sheet, 18" x 24", 2.4 mm, Perf	5
RT-1783P3	Aquaplast 30 cm x 45 cm x 2.4 mm 12” x 18” Standard Perf	5
RT-1821KP	Fibreplast Pelvis Precut for MT 3-point Hip System, 3.2 mm, Solid	10
RT-1821P	Aquaplast RT Pelvis Precut for MT 3-point Hip System, 3.2 mm, Solid	10
RT-1822P18A	Aquaplast 45 cm x 60 cm x 3.2 mm 18" x 24" Solid with bonded Groin Lock (pre-punched for 45 cm handles)	5
RT-1823P12A	Aquaplast 30 cm x 45 cm x 3.2 mm 12" x 18" Solid with bonded Groin Lock (pre-punched for 30 cm handles	5
RT-1848	Aquaplast 30 cm x 60 cm x 3.2 mm 12" x 24" Solid with bonded Groin Lock (pre-punched for 30 cm handles)	5
RT-1882KP	Fibreplast Pelvis Precut for MT 3-point Hip System, 3.2 mm, Standard Perf	5
RT-1882ORFPLV4	Aquaplast RT Pelvis Precut with pre-bonded disposable handles for ORF 4-point system, 3.2mm, Standard Perf	10
RT-1882P	Aquaplast RT Pelvis Precut for MT 3-point Hip System, 3.2 mm, Standard Perf	5
RT-1882P18A	Aquaplast 45 cm x 60 cm x 3.2 mm 18" x 24" Standard Perf with bonded Groin Lock (pre-punched for 45 cm handles)	5
RT-1883P	Aquaplast RT Sheet, 12” x 18”, 3.2 mm, Perf	5
RT-1883P12A	Aquaplast 30 cm x 45 cm x 3.2 mm 12" x 18" Standard Perf with bonded Groin Lock (pre-punched for 30 cm handles)	5
RT-1892	Aquaplast RT Sheet, 3.2 mm 40%, 18" x 24"	5

RT-4454	Opti-Handles, 30 cm (12 in.) for use with Aqua-Brief
RT-4456	Opti-Handles, 15 cm (6 in.)
RT-4457	Opti-Handles, 60 cm (24 in.)
RT-4458	Opti-Handles, 45 cm (18 in.) for use with Aqua-Brief

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