



positioning
patients for life.®


PRODUCT GUIDE & USER MANUAL

RT-1778PR2DC

Aquaplast RT™ 20 cm Chin Strap for the
Portrait™ Head Only Mask Adapter





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Fibreplast® is registered trademark of Qfix.

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GENERAL PRECAUTIONS

WARNING STATEMENTS

! WARNING ! NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED. IF ANY PART OF THIS DEVICE EXPERIENCES A CATASTROPHIC LOAD, APPEARS DAMAGED OR FUNCTIONS IMPROPERLY, DISCONTINUE USE IMMEDIATELY AND CONTACT QFIX AT +1 484-720-6054 OR TECHSUPPORT@QFIX.COM.

! 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.

PRECAUTIONS FOR USE

- The use of this device may cause mild sensitization upon contact with the skin of individuals.
- Aquaplast RT™ thermoplastics are supplied for single patient use only and are not sterile.
- 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.

TREATMENT BEAM ATTENUATION

Treatment through any device will lead to an increase in skin dose. Thermoplastic masks will attenuate a radiotherapy beam and increase skin dose. Attenuation and increased skin dose should be taken into account during planning and treatment.

GENERAL PRECAUTIONS

MR SAFETY INFORMATION

 The **Aquaplast RT™ 20 cm Chin Strap for the Portrait™ Head Only Mask Adapter, RT-1778PR2DC**, is MR Safe.

- The **Aquaplast RT™ 20 cm Chin Strap** must be used with the **Portrait™ Head Only Mask Adapter for Access™ Supine Breast Device, RT-4546-03**, and the **MR Safe version of the Access™ Supine (RT-4546MRI)** both clearly labeled with the following symbol prior to MR scanning:



 The **Portrait™ Head Only Mask Adapter for Access™ Supine Breast Device, RT-4546-03**, is MR Safe.

 The **Access™ Supine Breast Device, RT-4546MRI**, is MR Safe.

WARNING LABELS & DESCRIPTIONS

Refer to Qfix.com for a listing of symbols and their definitions.



MR SAFE

An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically non-conductive, nonmetallic and nonmagnetic.

INTENDED USE

Aquaplast RT™ and Fibreplast® are 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.

OPERATING INSTRUCTIONS

SET UP

1. Attach RT-4546-03 Portrait™ Head Only Mask Adapter for Access™ Supine Breast Device to the Access Supine Breast Device.

! NOTE ! Refer to the Product Guide and User Manual for Portrait™ Head Only Mask Adapter for Access™ Supine Breast Device, RT-4546-03 (P/N 2008021) for instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of the Portrait™ Head Only Mask Adapter for Access™ Supine Breast Device.

2. Position the patient on the Access™ Supine Breast Device using a headrest if desired.

! NOTE ! Refer to the Product Guide and User Manual for Access™ Supine Breast Device (P/N 2004394) for instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of the Access™ Supine Breast Device.

3. Ensure the pin inside the PR Clip (blue plastic edge of the Chin Strap) is located on the inside half of the of the hole towards the opposite pin (Fig. 1).

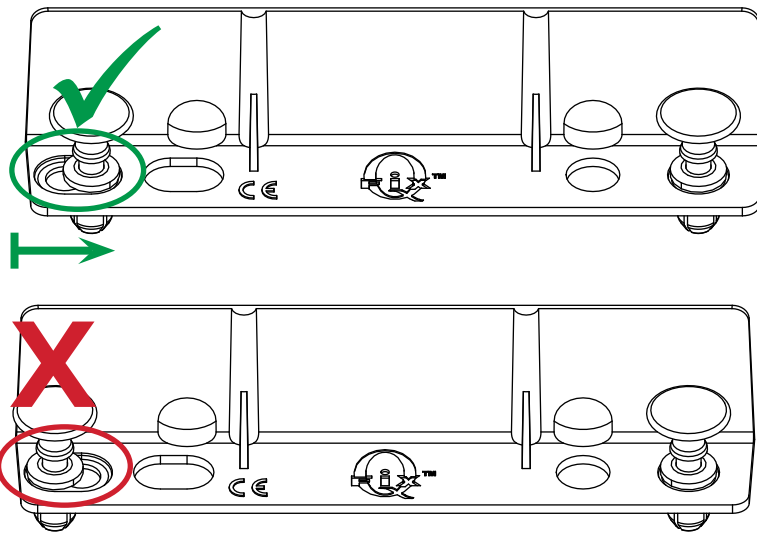


Figure 1

! NOTE ! Refer to the Product Guide and User Manual for Aquaplast RT™ & Fibreplast® (P/N 2002890) for instructions for heating and softening the thermoplastic, product features, specifications, warnings, cautions, and other general precautions related to the use of Aquaplast RT™ thermoplastic material.

OPERATING INSTRUCTIONS

4. When the Aquaplast RT™ 20 cm Chin Strap for the Portrait™ Head Only Mask Adapter is ready for molding, attach one side of the Chin Strap to the Portrait Head Only Mask Adapter. Align the slot and hole on the PR Clip on the Chin Strap to the slot and hole on the Portrait Head Only Mask Adapter (Fig. 2).
5. Fully depress the Pins on the Chin Strap into the Portrait Head Only Mask Adapter (Fig 2).

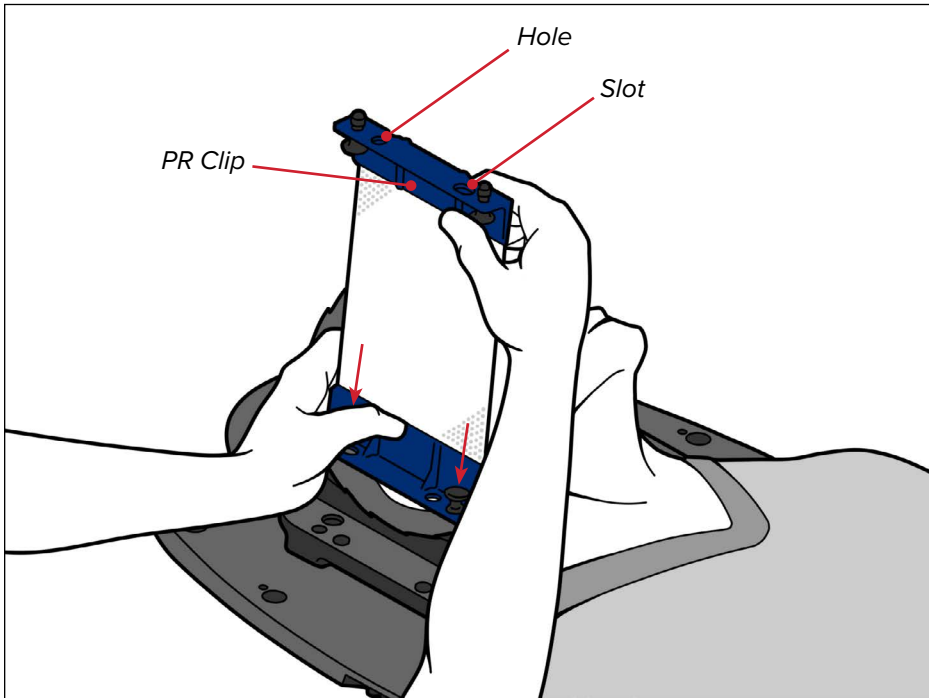


Figure 2

OPERATING INSTRUCTIONS

6. Repeat with the opposite side of the Aquaplast RT™ 20 cm Chin Strap. Stretch the thermoplastic over the patient's mouth and chin. Ensure the thermoplastic is not covering the nose. Bottom of chin strap should cover underside of chin (Fig. 3).

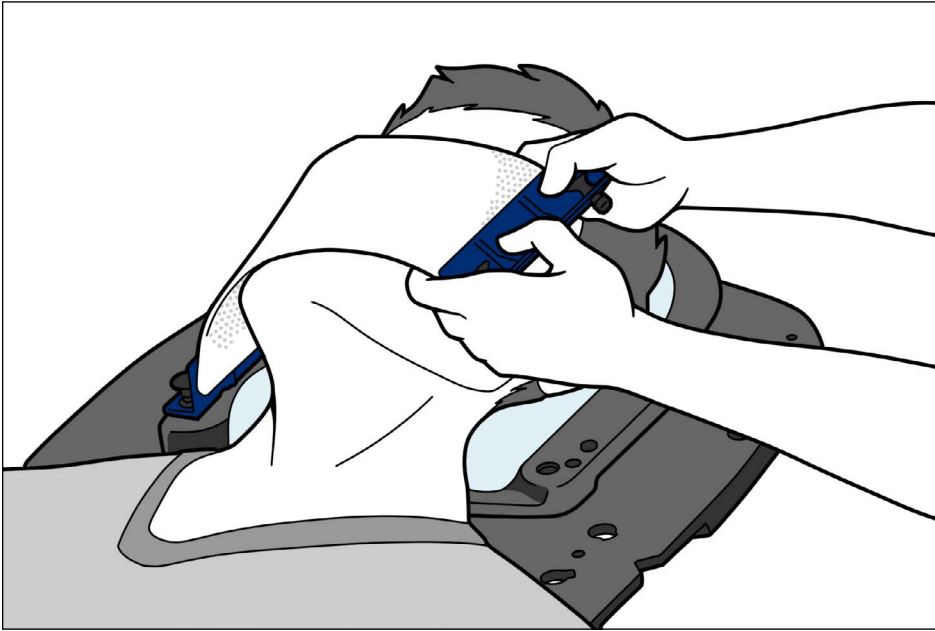


Figure 3

! NOTE ! Fold excess thermoplastic back over itself to avoid covering the nose and laryngeal prominence (commonly known as the Adam's Apple).

! CAUTION ! IF THE THERMOPLASTIC IS POSITIONED TOO LOW OVER MOUTH AND CHIN, THE CHIN STRAP MAY NOT FULLY IMMOBILIZE THE PATIENT.


! CAUTION ! DO NOT COVER PATIENT'S NOSE OR LARYNGEAL PROMINENCE DURING MOLDING PROCESS. ONCE HARDENED, THE THERMOPLASTIC MAY CAUSE PATIENT DISCOMFORT.


REMOVAL

1. Pull up on each pin on the Aquaplast RT 20 cm Chin Strap.
2. Remove the Aquaplast RT 20 cm Chin Strap from the patient and from the Portrait Head Only Mask Adapter.



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