

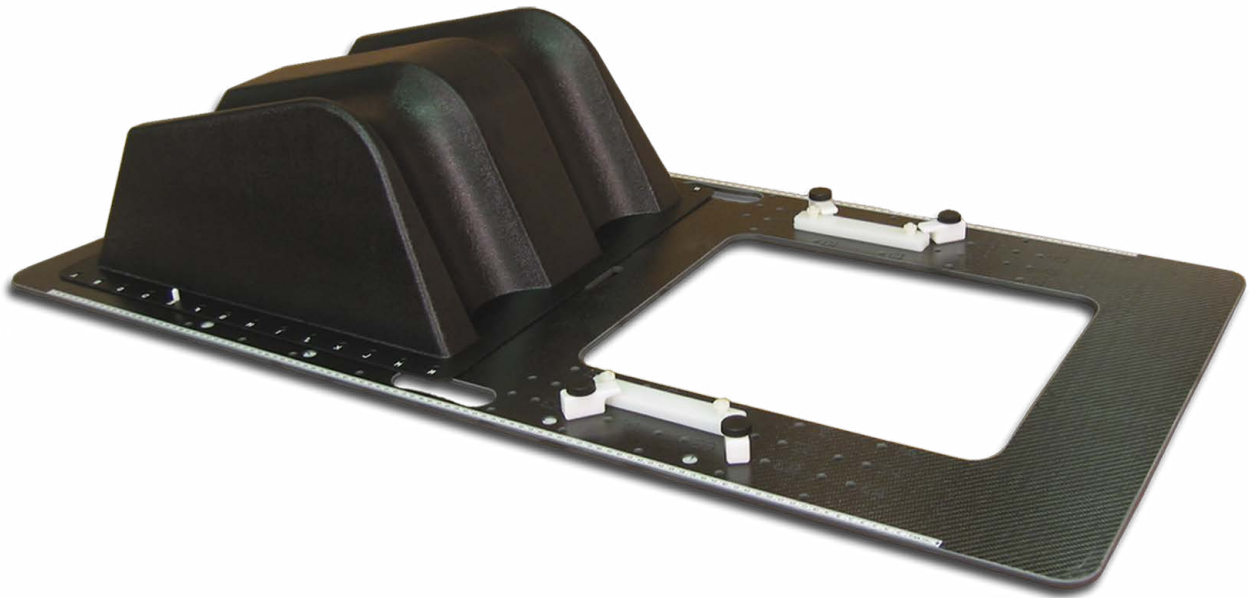


positioning  
patients for life.®


# PRODUCT GUIDE & USER MANUAL

RT-4526S

Qfix® Carbon Fiber Pelvis System





|    |     |   |  |
|----|-----|---|--|
| EC | REP | Advena Limited<br>Tower Business Centre, 2nd Flr<br>Tower Street, Swatar, BKR 4013<br>Malta |  Made in the USA by<br>Qfix<br>440 Church Rd, Avondale, Pennsylvania, USA<br>+1 610-268-0585 <a href="http://www.Qfix.com">www.Qfix.com</a> |
|----|-----|---|--|

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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 ! DO NOT CANTILEVER DEVICE ON COUCH TOP.**

## 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.

## 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.

## LOAD RATING

DO NOT exceed 225 kg (500 lb) uniformly distributed load or maximum working load of couch base, whichever is less.

## WARNING LABELS & DESCRIPTIONS

Refer to [Qfix.com](http://Qfix.com) for a listing of symbols and their definitions.

# INTENDED USE

This device 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**

Patient's 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

**! NOTE !** Refer to the **Product Guide and User Manual for the Pelvis & Extremities Thermoplastics (P/N 2008084)** for operating instructions, product features, specifications, warnings, cautions, and other general precautions related to the use of Pelvis & Extremities Thermoplastics.

1. Position the patient by aligning the treatment region over the open treatment panel of the Qfix Pelvis Immobilization Board (RT-4526S).
2. An Adapter, RT-4526EXA, may be used to index the Qfix Pelvis Immobilization Board to the Varian Exact® Couch and Exact® Compatible CT Overlays.
3. Qfix Opti-Handles secure Aquaplast RT™ and Fibreplast Pelvis Precut, Aqua-Brief, and Aqua-Belt Thermoplastic to the Qfix Pelvis Immobilization Board.
4. The positioning of the patient, the Opti-Handles, and the associated swivel locks should be considered before softening the thermoplastic. Use of the Indexed Knee Wedge or an Aquaplast mould with a bonded Groin Lock should also be considered prior to softening the thermoplastic.
5. Record the board's setup parameters, including the location of the Opti-Handles, Groin Lock, and Indexed Knee Wedge on the supplied patient setup record.
6. Once the patient is positioned on the Qfix Carbon Fiber Pelvis Board, the appropriate thermoplastic may be applied.

**! NOTE !** Refer to the **Product Guide and User Manual for the Pelvis & Extremities Thermoplastics (P/N 2008084)** or instructions for softening the thermoplastic in either the **RapidHeat™ Oven** or a **Water Bath**.

# OPERATING INSTRUCTIONS

## MOLDING INSTRUCTIONS FOR THE AQUA-BRIEF™, AQUA-BELT™, AND AQUAPLAST RT™ & FIBREPLAST® PELVIS PRECUT

1. Position patient on the Carbon Fiber Pelvis Board.

**! NOTE !** Ensure an 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.
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, at least 10–15 minutes, before removing. If possible, begin simulation as the thermoplastic cools without removing the thermoplastic until simulation is completed.

# OPERATING INSTRUCTIONS

## 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).

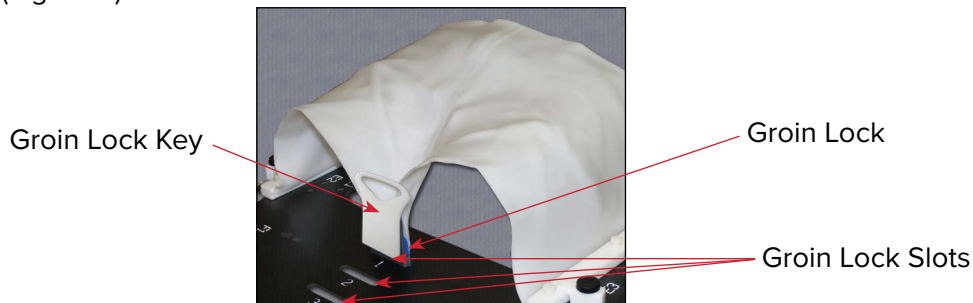


Fig. 2

# MAINTENANCE

## CLEANING THE SYSTEM

The device can be cleaned with a mild, non-abrasive cleaning or disinfecting solution. To clean, apply solution to clean cloth and wipe the surface.

## DISINFECTING THE SYSTEM

The following cleaning materials have been tested and found to be appropriate for cleaning the device surfaces. To disinfect the device surfaces, refer to specific instructions from the cleaning agent manufacturer.

- Water
- Isopropyl Alcohol
- Soap and Water

DO NOT spray directly onto the device.

DO NOT place sharp objects on the device.

# PARTS LIST

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

| Product Code | Description  |
|--------------|--|
| RT-4526S     | Qfix Pelvis Immobilization Board (includes integrated indexed knee wedge)          |
| RT-4526EXA   | Adapter to index RT-4526S to Varian Exact® Couch and Exact® Compatible CT Overlays |
| RT-4454      | Opti-Handles, 30 cm (12 in) for use with Aqua-Brief                                |
| RT-4456      | Opti-Handles, 15 cm (6 in) for use with Aqua-Belt                                  |
| RT-4458      | Opti-Handles, 60 cm (24 in)  |
| RT-4457      | Opti-Handles, 45 cm (18 in)  |

| Product Code | Description  | Quantity Per Package |
|--------------|--|----------------------|
| RT-1848      | Aquaplast RT Pelvis, 30 cm x 60 cm, 3.2 mm   | 5                    |
| RT-1849      | Aquaplast RT Pelvis, 15 cm x 60 cm, 3.2 mm   | 5                    |
| RT-1883P12A  | Aquaplast RT Pelvis, 30 cm x 45 cm, 3.2 mm   | 5                    |
| RT-1823P12A  | Aquaplast RT, 30 cm x 45 cm (12" x 18") solid with bonded Groin Lock (pre-punched) | 5                    |
| RT-1848      | Aquaplast RT Pelvis, 30 cm x 60 cm, 3.2 mm   | 5                    |
| RT-1882P18A  | Aquaplast RT Pelvis, 45 cm x 60 cm, 3.2 mm   | 5                    |
| RT-1883P12A  | Aquaplast RT Pelvis, 30 cm x 45 cm, 3.2 mm   | 5                    |
| RT-1823P12A  | Aquaplast RT, 30 cm x 45 cm (12" x 18") solid with bonded Groin Lock (pre-punched) | 5                    |
| RT-1883KP12A | Fibreplast Pelvis, 30 cm x 45 cm, 3.2 mm   | 5                    |
| RT-1822P18A  | Aquaplast RT Pelvis, 45 cm x 60 cm, 3.2 mm   | 5                    |
| RT-1849      | Aquaplast RT Pelvis, 15 cm x 60 cm, 3.2 mm   | 5                    |

# SETUP SHEET

## RT-4526S – QFIX CARBON FIBER PELVIS SYSTEM

Patient Name:

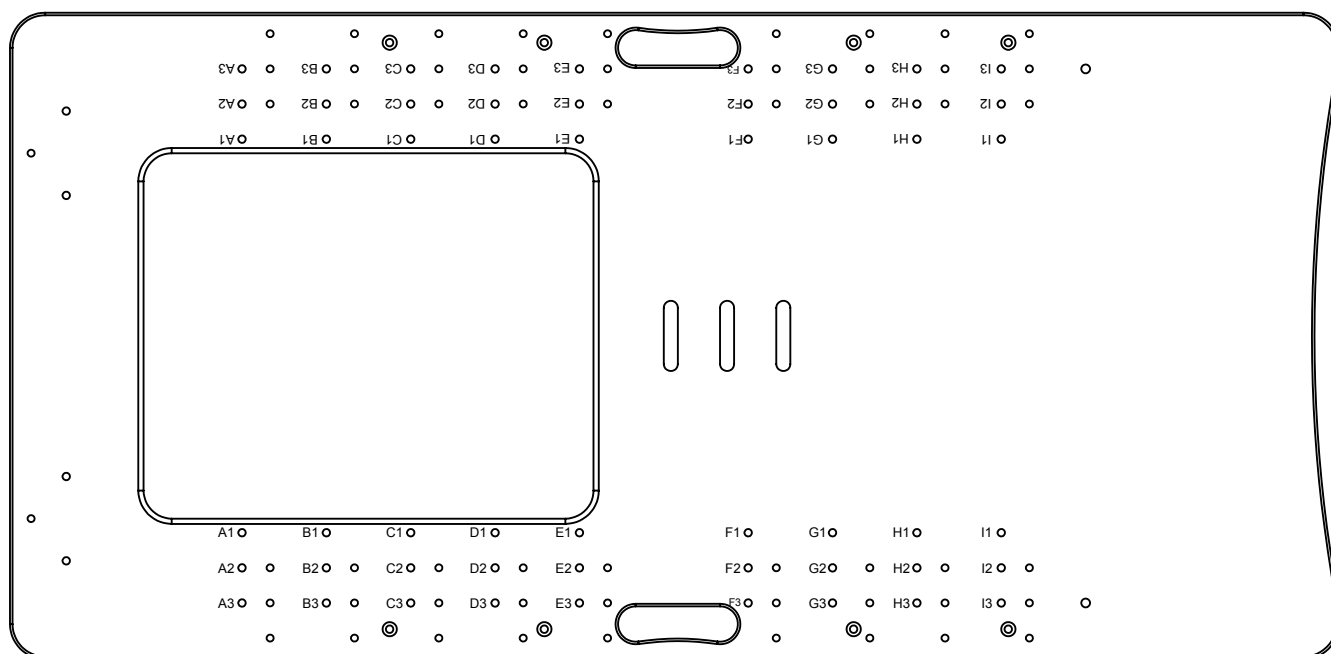
Patient ID #:

Setup by:

Physician:

Date:


Comments:




1. Length of Opti-Handles Used (select one): **6"**    **12"**    **18"**    **24"**    **27"**
2. Size of Aquaplast RT sheet used:
3. Width position (row) of Opti-Handles (select one): **1**    **2**    **3**
4. Length position (column) of Opti-Handle Positioning Pegs—must pick two sequential letters (select two):  
**A**    **B**    **C**    **D**    **E**    **F**    **G**    **H**    **I**
5. Position of Leg Wedge (select one): **A**    **B**    **C**    **D**    **E**    **F**    **G**    **H**    **I**    **J**    **K**  
**L**    **M**    **N**    **O**    **Not used**
6. Positioning of blue Groin Lock (select one): **1**    **2**    **3**    **Not used**



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