positioning
patients for life.®

PRODUCT GUIDE & USER MANUAL

RT-4558CB03
ZiFix Traverse™ Abdominal/Thoracic Motion Control System

Qfix | 440 Church Road | Avondale, Pennsylvania 19311 USA | +1 484-720-6053 | +1 610-268-0588 | www.Qfix.com

CE

EC REP	Advena Limited Tower Business Centre, 2nd Flr Tower Street, Swatar, BKR 4013 Malta	Made in the USA by Qfix 440 Church Rd, Avondale, Pennsylvania, USA +1 484-720-6053 www.Qfix.com

TABLE OF CONTENTS

Qfix | 440 Church Road | Avondale, Pennsylvania 19311 USA | +1 484-720-6053 | +1 610-268-0588 | www.Qfix.com

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 +1 484-720-6053 OR TECHSUPPORT@QFIX.COM.

! NOTE ! This device is to be used as reference only and should not be used in any other application.

! NOTE ! During normal operation, fluctuation of 10 mmHg, can be expected.

! NOTE ! It is recommended to re-inflate the bladder to its initial pressure after 2 minutes of initial inflation by opening the shutoff valve, squeezing the manometer bulb, and shutting the shutoff valve.

! NOTE ! Do not carry the device using the ZiFix Traverse Abdominal/Thoracic Motion Control System.

! NOTE ! Standing or sitting on the ZiFix Traverse Abdominal/Thoracic Motion Control System may damage the clamp or cause injury.

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.

SAFETY INFORMATION

In order to use the ZiFix Traverse Abdominal/Thoracic Motion Control System accurately and safely, the user must have the necessary expertise in a hospital setting.

To ensure safe use of the ZiFix Traverse Abdominal/Thoracic Motion Control System it is recommended that the users are educated and trained on the safe operation of the product prior to use.

TREATMENT BEAM ATTENUATION

The Qfix ZiFix Traverse Abdominal/Thoracic Motion Control System will attenuate a radiotherapy beam. Actual attenuation based on setup should be verified with your particular equipment. Attenuation and increased skin dose should be taken into account during planning and treatment.

GENERAL PRECAUTIONS

MRI SAFETY INFORMATION

! NOTE ! Refer to Features Section for MR configurations.

Non-clinical testing has demonstrated the **Manometer Pump** is MR Conditional. This device may be used in an MR system under the following conditions:

- **Static magnetic field of 3T or less.**
- **Disconnect the Manometer Pump from the device before scanning and remove the Manometer Pump from the patient table.**
- **Prior to scanning, move the manometer pump into gradient fields no greater than 200 mT (2000G), i.e. weaker gradient sections, of the magnetic field of the MRI scanner.**
- **If the magnetic field strength lines in the room configuration are not known, disconnect and remove the Manometer pump from the MR room prior to scanning. Consult the user manual for the MR system for information regarding magnetic field strength and spatial gradients for the system.**
- Once the above conditions are met, the ZiFix Traverse Abdominal/Thoracic Motion Control System and associated components may be used in an MR system meeting the following conditions outlined below.

Non-clinical testing has demonstrated the **Carrying Case** is MR Conditional. This device may be used in an MR system meeting the following conditions:

- **Static magnetic field of 3T or less.**
- **Prior to scanning, move the carrying case into gradient fields no greater than 200 mT (2000G), i.e. weaker gradient sections, of the magnetic field of the MRI scanner.**
- **If the magnetic field strength lines in the room configuration are not known, disconnect and remove the Carrying Case from the MR room prior to scanning. Consult the user manual for the MR system for information regarding magnetic field strength and spatial gradients for the system.**
- Once the above conditions are met, the **ZiFix Traverse Abdominal/Thoracic Motion Control System and associated components** may be used in an MR system meeting the following conditions outlined below.

Non-clinical testing has demonstrated the **ZiFix Traverse Abdominal/Thoracic Motion Control System** is MR Conditional. Once the conditions for the **Manometer Pump** and the **Carrying Case** are met, the **ZiFix Traverse Abdominal/Thoracic Motion Control System** may be used in an MR system meeting the following conditions:

- **Static magnetic field of 3T or less.**

GENERAL PRECAUTIONS

MRI SAFETY INFORMATION, CONTINUED

MR Non-clinical testing has demonstrated the **Compression Bladder Assemblies** are MR Safe. Once the conditions for the **Manometer Pump** and the **Carrying Case** are met, the **Compression Bladder Assemblies** may be used in an MR environment.

MR Non-clinical testing has demonstrated the **Compression Belt Straps** are MR Safe. Once the conditions for the **Manometer Pump** and the **Carrying Case** are met, the **Compression Belt Straps** may be used in an MR environment.

MR Non-clinical testing has demonstrated the **Compression Paddles** are MR Safe. Once the conditions for the **Manometer Pump** and the **Carrying Case** are met, the **Compression Paddles** may be used in an MR environment.

MR Non-clinical testing has demonstrated the **Compression Belt Clamps** are MR Safe. Once the conditions for the **Manometer Pump** and the **Carrying Case** are met, the **Compression Belt Clamp** may be used in an MR environment.

! WARNING ! THE USE OF QFIX REPLACEMENT PARTS IS RECOMMENDED TO ENSURE THE SAFETY, PERFORMANCE, AND MRI COMPATIBILITY OF THE PRODUCT(S), AS WELL AS TO MAINTAIN APPLICABLE WARRANTIES.

! WARNING ! USE OF UNAPPROVED MR ACCESSORIES MAY RESULT IN:

- **Injury to patient**
- **Damage to equipment**

Qfix | 440 Church Road | Avondale, Pennsylvania 19311 USA | +1 484-720-6053 | +1 610-268-0588 | www.Qfix.com

GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS

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

MR CONDITIONAL

An item with demonstrated safety in the MR environment within defined conditions.

These conditions are defined in the MRI Safety Information section.

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.

125 mmHg MAX

PRESSURE RATING

The maximum recommended pressure for the Compression Bladder is 125 mmHg. Refer to the Operating Instructions section of this IFU for bladder inflation directions. DO NOT exceed the maximum pressure rating.

INTENDED USE

The **ZiFix Traverse Abdominal/Thoracic Motion Control System** is intended to apply abdominal compression for managing internal body motion during respiration while maintaining maximum comfort to the patient. The **ZiFix Traverse Abdominal/Thoracic Motion Control System** is also intended to promote shallow breathing, in radiation therapy or radiology.

! 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

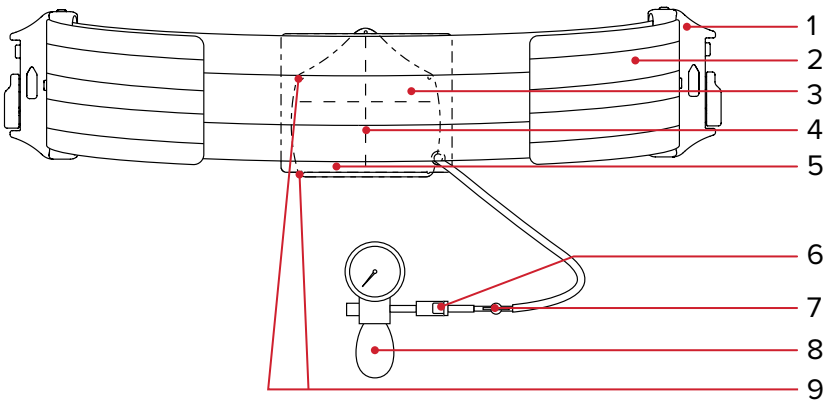
The intended user for the products is a person qualified in accordance with the requirements of the regulatory region.

Qfix | 440 Church Road | Avondale, Pennsylvania 19311 USA | +1 484-720-6053 | +1 610-268-0588 | www.Qfix.com

FEATURES

ZIFIX TRAVERSE ABDOMINAL/THORACIC MOTION CONTROL SYSTEM

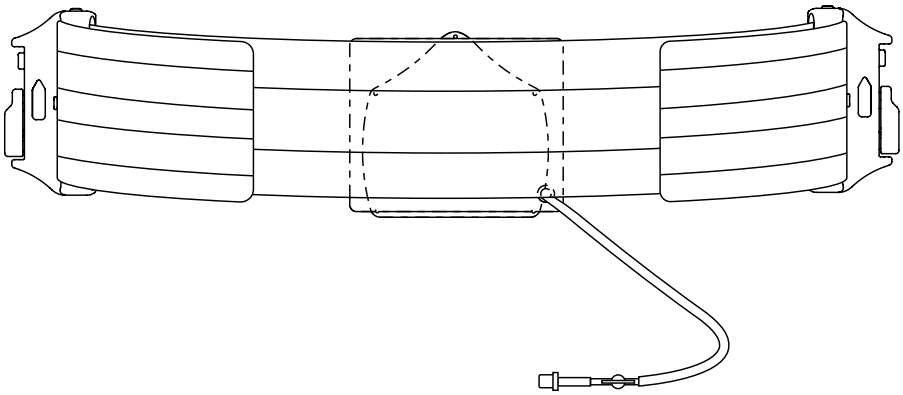
MR CONDITIONAL



1. **Compression Belt Clamps**
   - Right Clamp
   - Left Clamp
2. **Compression Belt Straps**
   - 130 cm x 13 cm
   - 170 cm x 13 cm
3. **Compression Bladder Assemblies**
   - 13 cm
4. **Alignment Lines**
5. **Compression Paddles**
   - 13 cm
6. **Quick Disconnect Fitting**
7. **Shutoff Valve**
8. **Manometer Pump**
9. **Virtual Indexing Marks**

ZIFIX TRAVERSE ABDOMINAL/THORACIC MOTION CONTROL SYSTEM WITH MANOMETER REMOVED

MR SAFE



OPERATING INSTRUCTIONS

SETUP

INITIAL ASSEMBLY

1. Ensure paddle is appropriately aligned for attachment to the bladder (Fig. 1). Align hook-and-loop fastener.

! NOTE ! If using the white alignment lines on the paddle, complete alignment prior to attaching bladder. The alignment lines are for reference use only.

! NOTE ! The virtual indexing marks may be used to verify location in imaging. The virtual indexing marks are for reference use only.

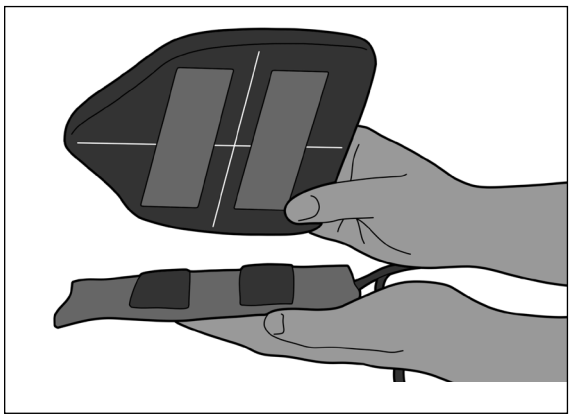


Fig. 1

2. Position belt with numbers facing down then feed the long end of belt through clamp (Fig. 2). Return the belt on itself ensuring the full length of the hook is engaged on the loop (Fig. 3).

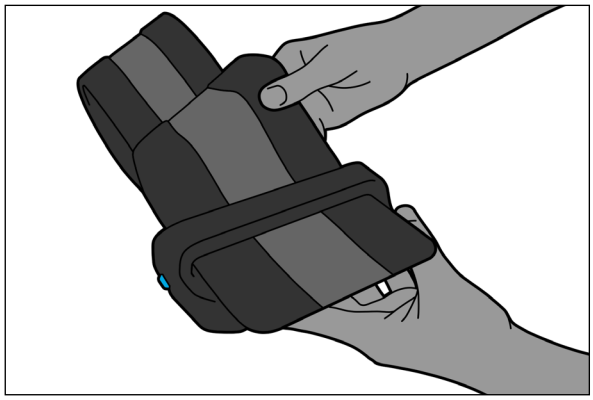


Fig. 2

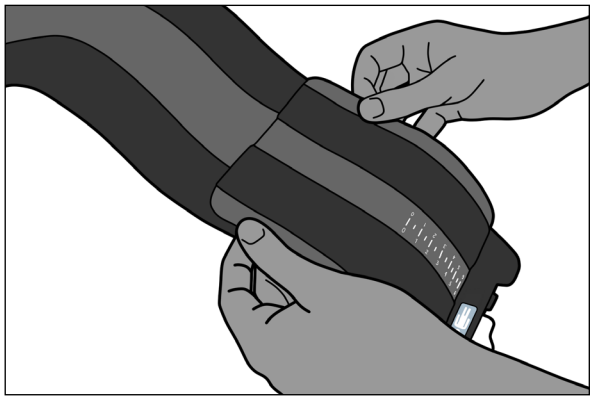


Fig. 3

Qfix | 440 Church Road | Avondale, Pennsylvania 19311 USA | +1 484-720-6053 | +1 610-268-0588 | www.Qfix.com

OPERATING INSTRUCTIONS

POSITIONING ON PATIENT

3. Position paddle and bladder on patient with the tip of the paddle aligned with the patient's sternum and below xiphoid process (Fig. 4).

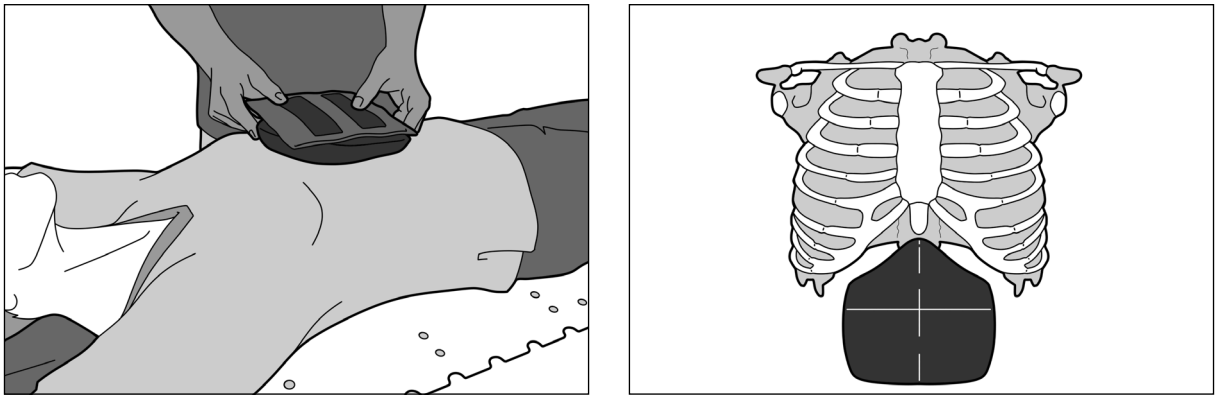
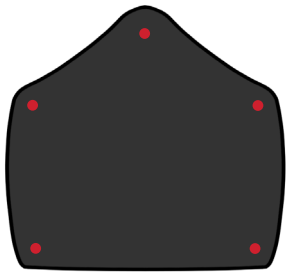


Fig. 4

! NOTE ! The five (5) fiducial markers located around the perimeter of the paddle may be used to aid in patient setup relative to patient anatomy under CT or X-ray imaging.



OPERATING INSTRUCTIONS

4. Ensure the Zifix Clamp lever is in the unlocked position and the clamp is in the correct orientation by matching the label direction with the patient superior and inferior direction (Fig. 5). Then firmly slide the clamp on to the device edge until completely seated (Fig. 6 & 7).

! NOTE ! Ensure there is no material between the clamp and device when installing.

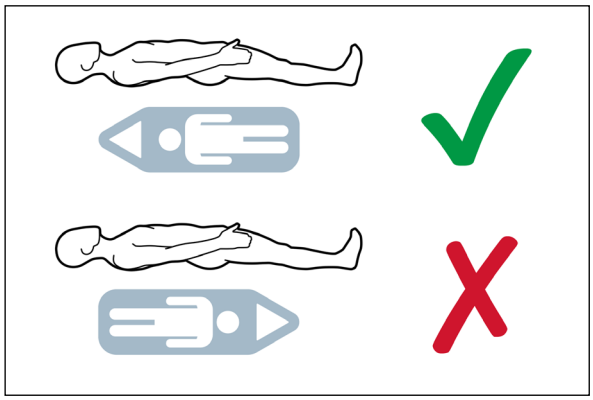


Fig. 5

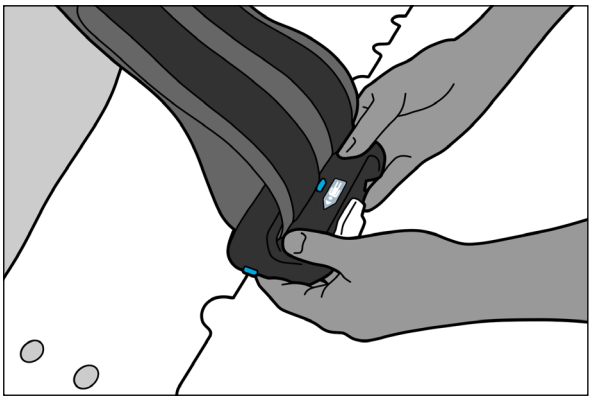


Fig. 6

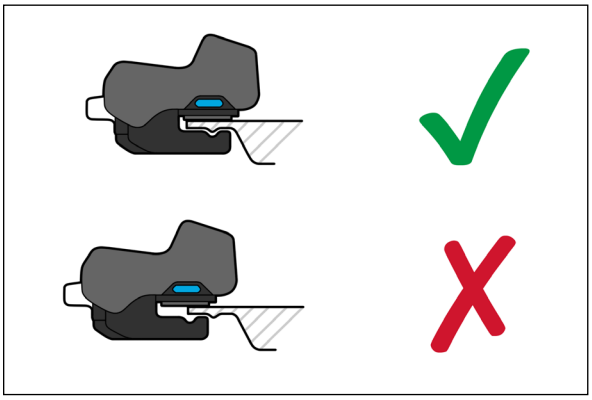


Fig. 7

Qfix | 440 Church Road | Avondale, Pennsylvania 19311 USA | +1 484-720-6053 | +1 610-268-0588 | www.Qfix.com

OPERATING INSTRUCTIONS

5. Rotate lever clockwise to lock clamp to device (Fig. 8).

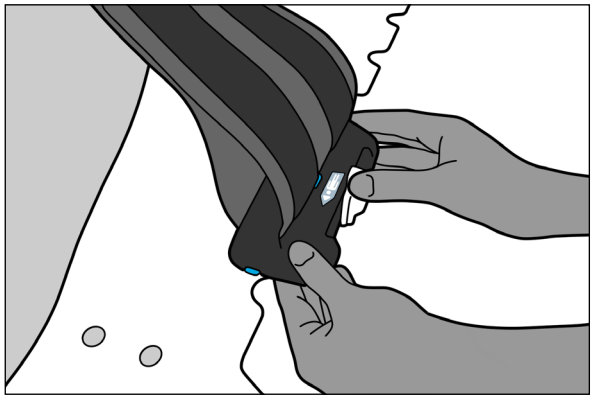


Fig. 8

6. Lay belt over patient, ensuring number side is facing down, attaching it to paddle and bladder. Ensure the loop on the belt aligns and engages with the hook on the bladder (Fig. 9).

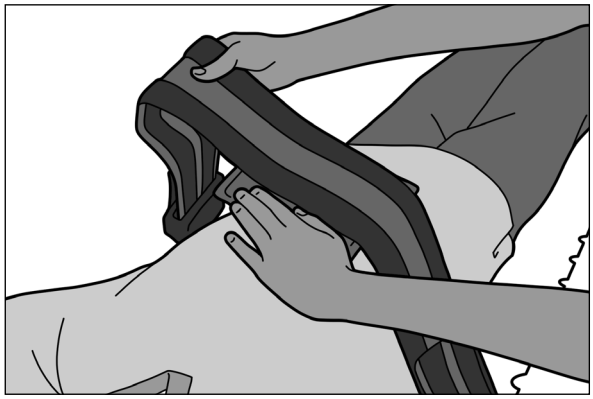


Fig. 9

7. Install other clamp on opposite device edge and lock clamp (Fig. 10).

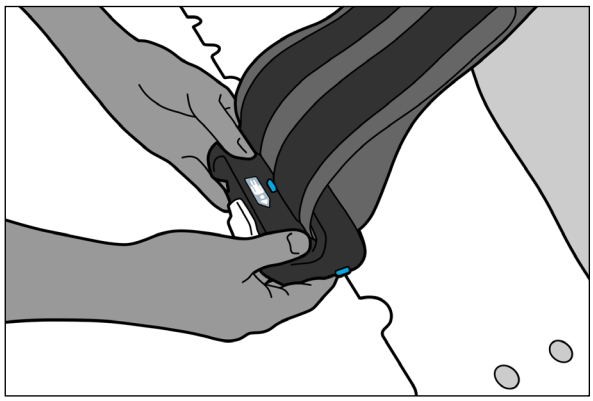


Fig. 10

OPERATING INSTRUCTIONS

8. Tighten belt as patient tolerance will allow (Fig. 11).

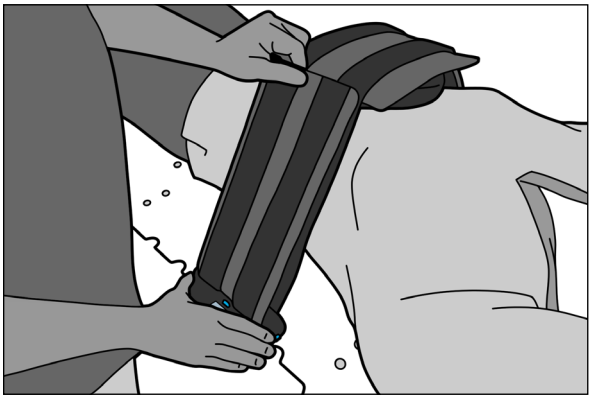


Fig. 11

! NOTE ! Ensure both clamps are fully locked before use.

9. Record clamp and belt scale positions (Fig. 12 & 13).

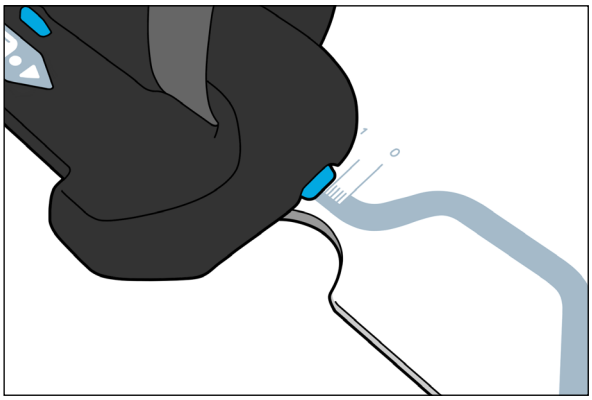


Fig. 12

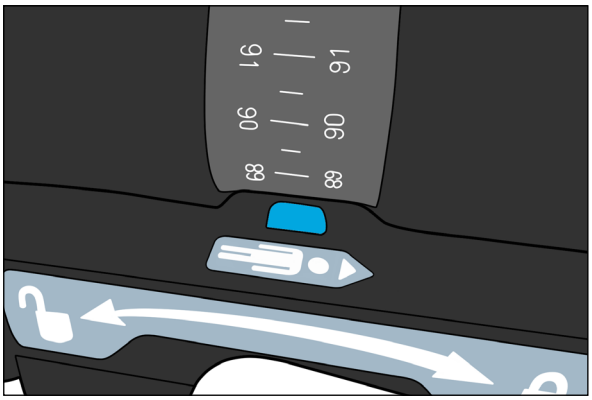


Fig. 13

Qfix | 440 Church Road | Avondale, Pennsylvania 19311 USA | +1 484-720-6053 | +1 610-268-0588 | www.Qfix.com

OPERATING INSTRUCTIONS

INFLATING BLADDER

1. First close the valve by rotating the knob towards you (Fig. 14).

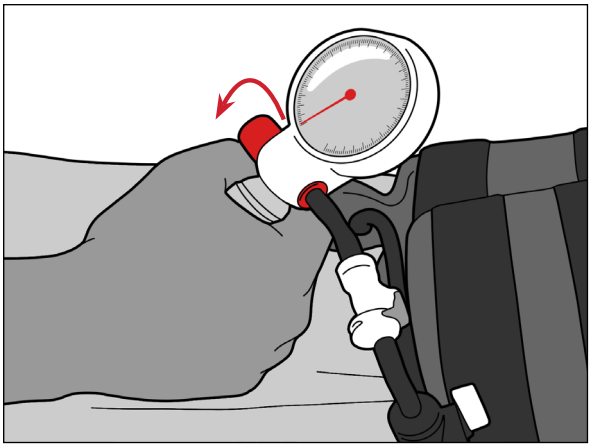


Fig. 14

2. Ensure that the shutoff valve is open. The valve handle should be in-line with tubing (Fig. 15).

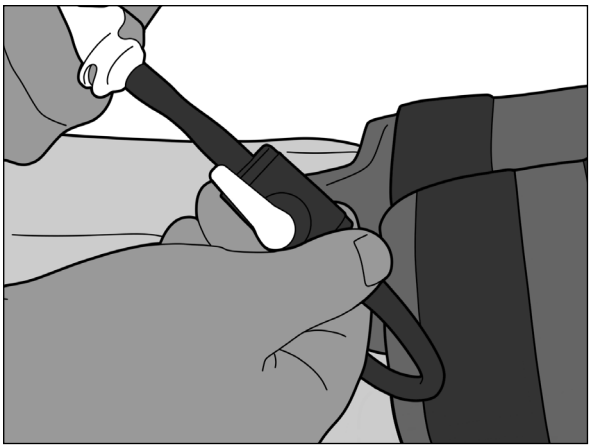


Fig. 15

OPERATING INSTRUCTIONS

3. Inflate the bladder to desired pressure by squeezing the bulb repeatedly (Fig. 16).

! WARNING ! DO NOT INFLATE BLADDER PRESSURE BEYOND 125 MMHG.

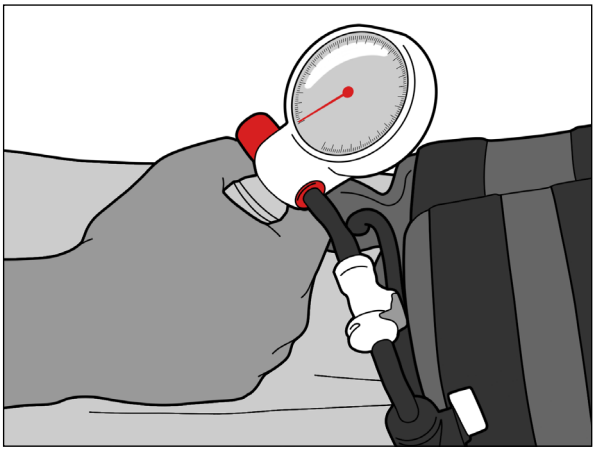
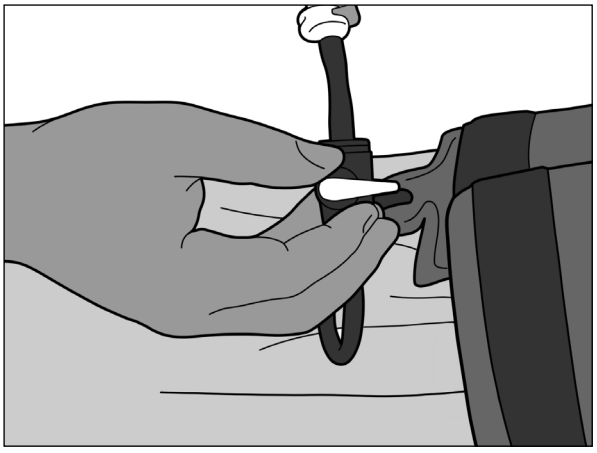


Fig. 16

4. Close the valve by turning the shutoff valve perpendicular to tubing. Wait 2 minutes (Fig. 17).

! NOTE ! It is recommended that the bladder is re-inflated to its initial pressure after 2 minutes of initial inflation.



2 minutes

Fig. 17

Qfix | 440 Church Road | Avondale, Pennsylvania 19311 USA | +1 484-720-6053 | +1 610-268-0588 | www.Qfix.com

OPERATING INSTRUCTIONS

5. After 2 minutes, open the valve by turning valve in-line with tubing (Fig. 18).

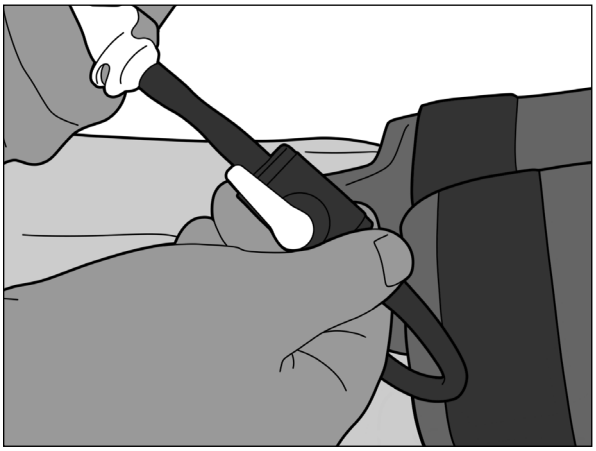


Fig. 18

6. Inflate the bladder to desired pressure by squeezing the bulb repeatedly (Fig. 19).

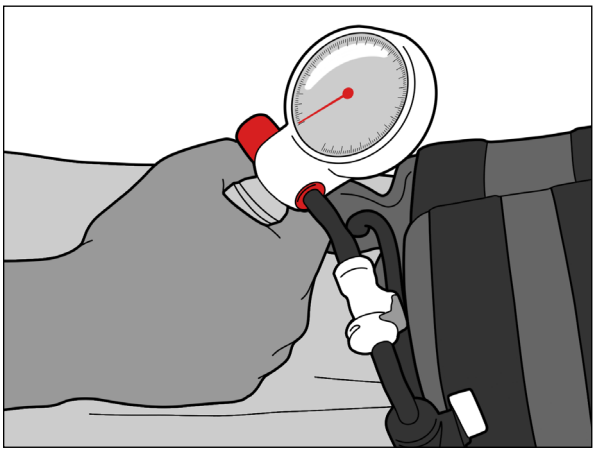


Fig. 19

7. Close the valve by turning the shutoff valve perpendicular to tubing (Fig. 17).

! NOTE ! Record manometer readout.

! WARNING ! MAX BLADDER PRESSURE IS 125 MMHG.

! WARNING ! THE PUMP MUST BE DISENGAGED VIA THE "QUICK DISCONNECT FITTING" AND REMOVED FROM THE PATIENT TABLE BEFORE SCANNING OR TREATMENT.

OPERATING INSTRUCTIONS

REMOVE PUMP FROM BLADDER

1. Verify shutoff valve is perpendicular to tubing (Fig. 20).

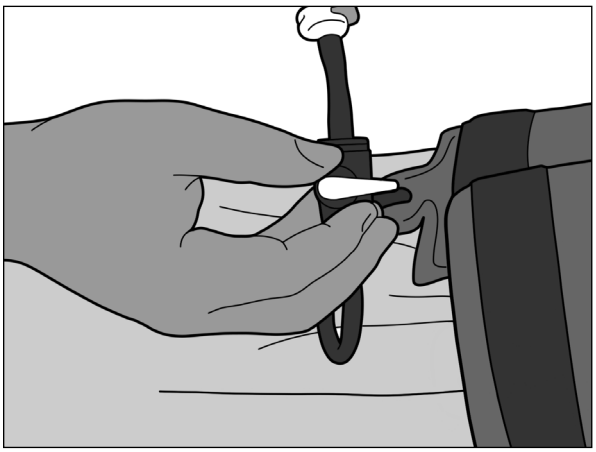


Fig. 20

2. Disconnect the Quick Disconnect Fitting by pressing the grey button on the Quick Disconnect Fitting (Fig. 21).

! NOTE ! Expect a small decrease in pressure if pump is reconnected and valve is reopened.

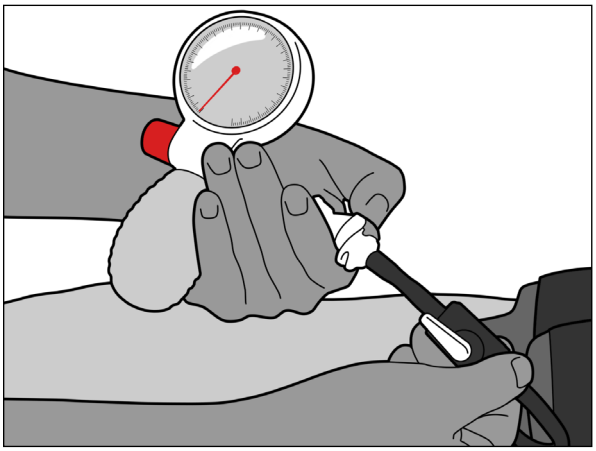


Fig. 21

OPERATING INSTRUCTIONS

REMOVAL

1. Disconnect Quick Disconnect Fitting. Open shutoff valve and release the air from the bladder (Fig. 22 & 23).

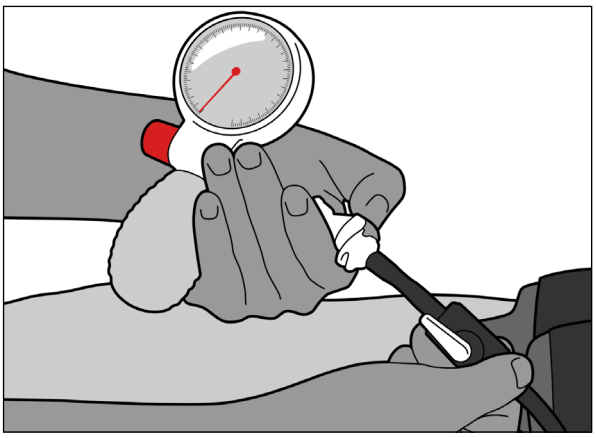


Fig. 22

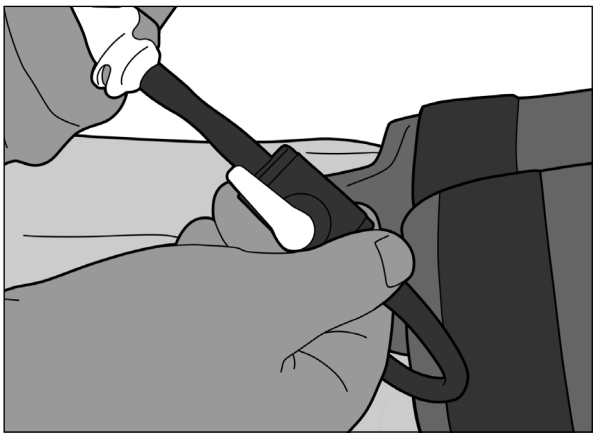


Fig. 23

—OR—

2. Rotate knob away from you (Fig. 24).

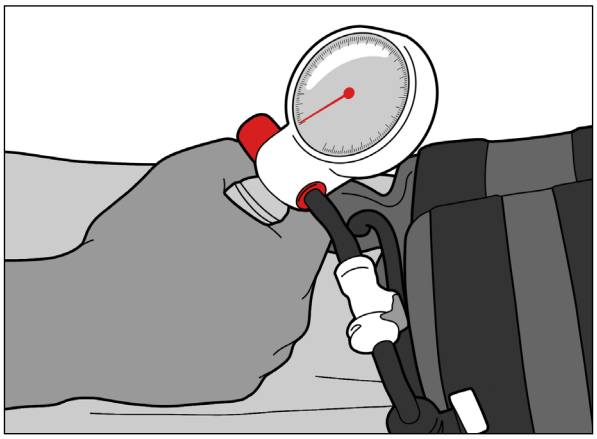


Fig. 24

3. Loosen belt as needed.
4. Unlock clamp and firmly slide off edge.
5. Assist patient in getting off table.

! NOTE ! The instructions listed above are the exemplary method. Other setup workflows may be acceptable in achieving the desired immobilization. Ensure all warning and precautions are observed. Always ensure appropriate alignment of the device and verify setup is correct prior to initiation of treatment.

Qfix | 440 Church Road | Avondale, Pennsylvania 19311 USA | +1 484-720-6053 | +1 610-268-0588 | www.Qfix.com

COMPATIBLE DEVICES

ZIFIX TRAVERSE COMPATIBILITY

The ZiFix Traverse Abdominal/Thoracic Motion Control System is compatible with devices featuring the InfinityEdge. The InfinityEdge is identified by the icon shown below.

The devices listed below are also compatible with **ZiFix Traverse Abdominal/Thoracic Motion Control System**. For the latest list of positioning and immobilization accessories please visit www.Qfix.com.

Product Code	Description	User Manual
RT-4551KV19	kVue™ Low-e™ Standard Insert	2007464

Qfix | 440 Church Road | Avondale, Pennsylvania 19311 USA | +1 484-720-6053 | +1 610-268-0588 | www.Qfix.com

MAINTENANCE

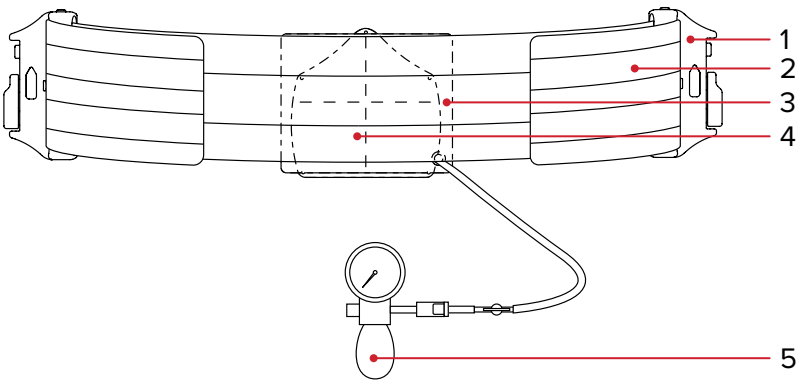
The **ZiFix Traverse Abdominal/Thoracic Motion Control System** can be cleaned using standard cleaning practices and common WATER-BASED hospital cleaning agents. The following cleaning materials have been tested and found to be appropriate:

- Cidex® 2.4% Activated Dialdehyde Disinfecting Solution
- Soap and Water
- Isopropyl Alcohol

DO NOT use other solvents to clean the device.

The gauge should be cleaned with a soft, dry cloth.

PARTS LIST



1. **Compression Belt Clamps**
   - Right Clamp – 2008707
   - Left Clamp – 2008680
2. **Compression Belt Straps**
   - 130 cm x 13 cm – 2007416
   - 170 cm x 13 cm – 2007263
3. **Compression Bladder Assemblies**
   - 13 cm – 2007544
4. **Compression Paddles**
   - 13 cm – 2007495
5. **Manometer Pump**
   - 2007700

SETUP SHEET

ZIFIX TRAVERSE ABDOMINAL/THORACIC MOTION CONTROL SYSTEM
RT-4558CB03

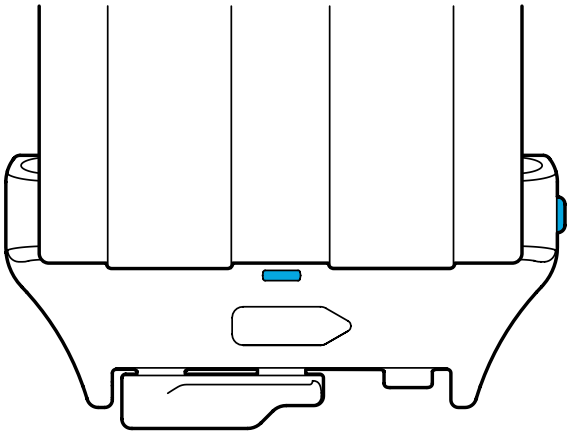
Patient Name:

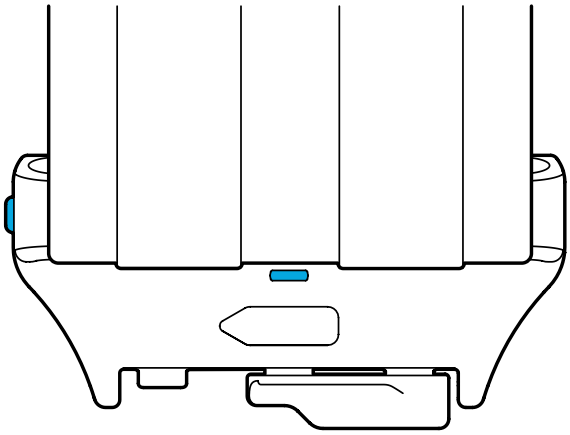
Patient ID #: Setup by:

Physician: Date:

Comments:

Belt used: ☐ 130 cm x 13 cm ☐ 170 cm x 13 cm





Left Clamp to Device Scale Location: Right Clamp to Device Scale Location:

Left Clamp to Belt Scale Location: Right Clamp to Belt Scale Location:

Manometer readout: mmHg (FOR REFERENCE ONLY) (Pressure fluctuation of about 10 mmHg is normal)

Notes:

440 Church Road
Avondale, PA 19311 USA
www.Qfix.com

+1 484.720.6053 / 800.526.5247

+1 610.268.0588 / 800.831.8174

sales@Qfix.com

2008703_EN_C
2021-12