



positioning  
patients for life.®


# PRODUCT GUIDE & USER MANUAL

RT-4558CB01

Stradivarius™ Compression Belt  
*150 cm & 115 cm Long*





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

Cidex® is a registered trademark of Johnson and Johnson.

Virox® is a registered trademark of Virox Technologies Inc.

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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.**

## 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.

## 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 assist with immobilization, positioning and repositioning of patients undergoing radiation therapy.

The Stradivarius Compression Belt is intended to be used for patients undergoing SBRT treatment of the lung.

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

**! NOTE ! During normal operation, fluctuation of 15–20 mmHg, as displayed on manometer, can be expected.**

**! 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

## INSTALLATION

### INITIAL ASSEMBLY

1. Insert connector from air bladder with a firm twist into the top of the manometer. When properly attached, less than 1/16" of connector shaft will remain visible (Fig. 1).



Fig. 1

2. Line up hook and loop in order to attach the compression board to the air bladder. Once lined up, press the compression board down onto the bladder (Fig. 2).



Fig. 2

# OPERATING INSTRUCTIONS

## SET UP

### POSITIONING ON PATIENT

1. Insert one of the ends of the belt into one of the slots, keeping the numbers facing upwards (Fig. 3).



Fig. 3

2. With patient standing or sitting upright, wrap the opposite end of the belt around the back of the patient and then back through the open slot (Fig. 4).



Fig. 4

3. Adjust the Compression Belt to the desired position and then pull each side of the strap tight, towards the patients' back. The strap will attach to itself with the hook and loop (Fig. 5).



Fig. 5

# OPERATING INSTRUCTIONS

## SET UP

### INFLATING/DEFLATING BLADDER

4. To inflate the bladder, first close the valve by pushing up on the tripper to move outward (Fig. 6).



Fig. 6

5. Inflate the bladder by squeezing the bulb rapidly (Fig. 7).

**! NOTE ! Record manometer readout (Fig. 8).**



Fig. 7



Fig. 8

6. To deflate the bladder, open the valve by squeezing on the trigger (Fig. 9).



Fig. 9



# MAINTENANCE

The Compression Belt 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
- Virox® 0.5% accelerated hydrogen peroxide solution

DO NOT use alcohol or other solvents to clean the accessory.

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

# SETUP SHEET

## Stradivarius™ Compression Belt – RT-4558CB01

Patient Name:

Patient ID #:

Setup by:

Physician:

Date:

Comments:



Belt used: 150 cm 115 cm

1. Location for "A":

2. Location for "B":

3. Manometer readout: mmHg (FOR REFERENCE ONLY) (Pressure fluctuation of 15–20 mmHg is normal)

Notes:





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