



positioning  
patients for life.®

# PRODUCT GUIDE & USER MANUAL


RT-4800-B1

RT-4800-B2

InfinityLock™ SBRT Compression Bridges





<div><div>EC</div><div>REP</div></div>		<div>Advena Limited</div> <div>Tower Business Centre, 2nd Flr</div> <div>Tower Street, Swatar, BKR 4013</div> <div>Malta</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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# 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.

## SAFETY INFORMATION

To ensure safe use of the SBRT Compression Bridges, it is recommended that the user is educated and trained on the safe operation of the system prior to use.

In order to use the SBRT Compression Bridges accurately and safely, the user must have the necessary expertise in a hospital setting.

Ensure SBRT Compression Bridges are securely locked to the patient support surface and verify setup is correct prior to initiation of treatment.

To ensure optimal reproducibility, it is recommended that the SBRT Compression Bridges are used in conjunction with patient support surfaces with indexing reference scales.

## MRI SAFETY INFORMATION

 Non-clinical testing has demonstrated the **SBRT Compression Bridges** are MR Safe. These devices may be used in an MR system.

 **! WARNING ! THE USE OF QFIX REPLACEMENT PARTS ARE 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

Use only proven MR Safe or MR Conditional accessories, tested and approved for your MR system.

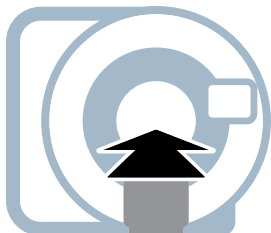
Consider the MR compatibility of accessories prior to use on your MR system.

 **! WARNING ! MAINTENANCE AND OTHER SERVICE OF PRODUCTS SHOULD NEVER BE PERFORMED IN AN MR ENVIRONMENT.**

# GENERAL PRECAUTIONS

## WARNING LABELS & DESCRIPTIONS

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



### TOWARDS GANTRY

Orientation of the Bridges. During setup of the Bridges make sure that the arrow is pointing towards the Gantry.



### 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

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**

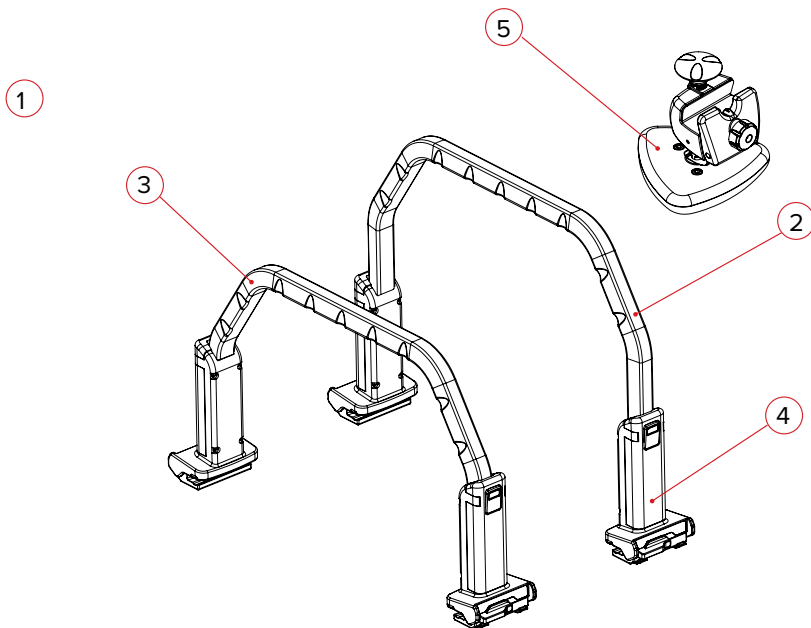
Patients undergoing radiation therapy or diagnostic imaging procedures.

## **INTENDED USERS**

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

# FEATURES

## COMPONENTS



### 1. INFINITYLOCK SBRT COMPRESSION BRIDGES

The InfinityLock SBRT Compression Bridges come in multiple sizes. They are adjustable in height, include an easy single motion lever, horizontal scales, and indexing notches for VacQfix™ cushions.

### 2. LARGE BRIDGE

The large bridge may be adjusted vertically from 39 cm to 48 cm (measurement is from the treatment surface to the underside of the bridge).

### 3. SMALL BRIDGE

The small bridge may be adjusted vertically from 30 cm to 38 cm (measurement is from the treatment surface to the underside of the bridge).

### 4. BRIDGE CLAMP

The bridge clamp securely locks the InfinityLock SBRT Compression Bridges to the InfinityEdge™ of the treatment surface. The clamp indexes to the treatment device by aligning blue indicators on the clamps with the scales on the treatment device.

### 5. COMPRESSION PADDLE & CLAMP

The compression paddle clamps onto the InfinityLock SBRT Compression Bridge and includes a safety release button, tactile compression, and incremented lateral placement along the bridge.

### 6. THIGH COMPRESSION VACQFIX CUSHION (not shown in diagram)

The thigh compression VacQfix cushion offers complete leg immobilization. The cushion is adjustable along the InfinityLock SBRT Compression Bridge with snap on VacQfix cushion clips, and includes the One-Step™ valve.

# OPERATING INSTRUCTIONS

## INSTALLATION

### BRIDGE CLAMP TO INSERT INSTALLATION

1. With locking lever in the unlocked position, attach a bridge clamp to each side of the device. (Fig. 1)
2. Firmly slide both clamps onto the InfinityEdge of the device until clamps are fully seated.
3. Using the scale on the device, align the bridge clamps directly across from each other.
4. Lock down both bridge clamps by rotating the locking lever until the bridge clamps are secure. (Fig. 2)

**! NOTE ! Do not rotate lever to the locked position unless bridge clamp is fully engaged on edge of device. Do not store bridge with the lever in a locked position.**

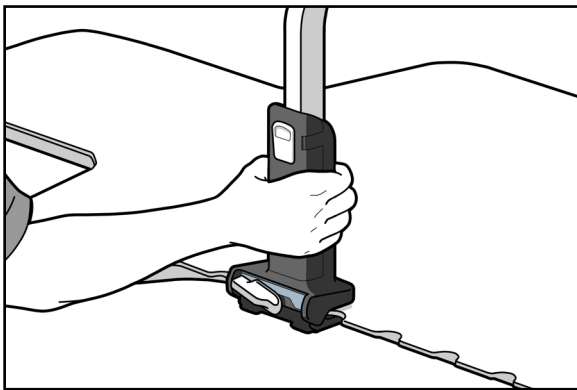


Fig. 1

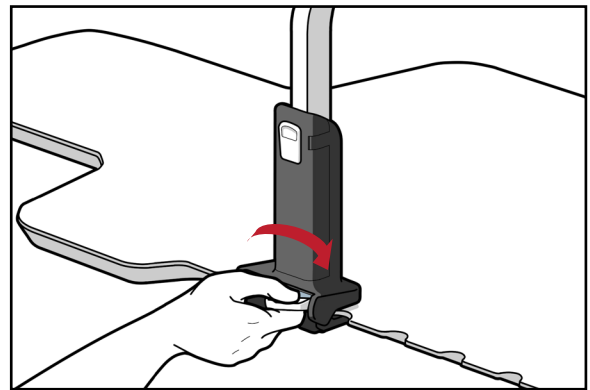


Fig. 2

### COMPRESSION PADDLE INSTALLATION

1. Unscrew locking knob and tilt back front plate of the compression clamp until it fits around the bridge. (Fig. 3)
2. Lock down the compression clamp by turning the locking knob until the clamp is secured. (Fig. 4)

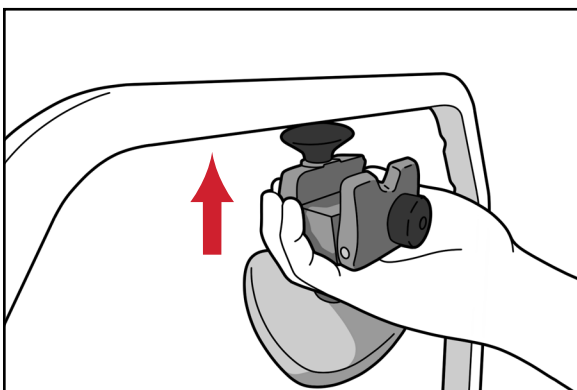


Fig. 3

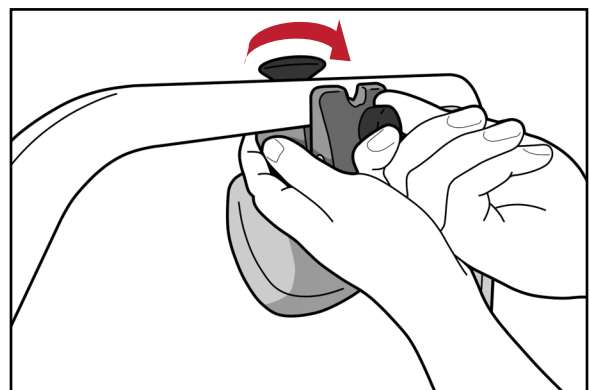


Fig. 4



# OPERATING INSTRUCTIONS

## INSTALLATION

### VACQFIX™ CUSHION CLIP INSTALLATION

Align the VacQfix cushion clip to the desired location on the InfinityLock SBRT Compression Bridge and push them around the InfinityLock SBRT Compression Bridge until they snap into place. (Fig. 5 & 6)

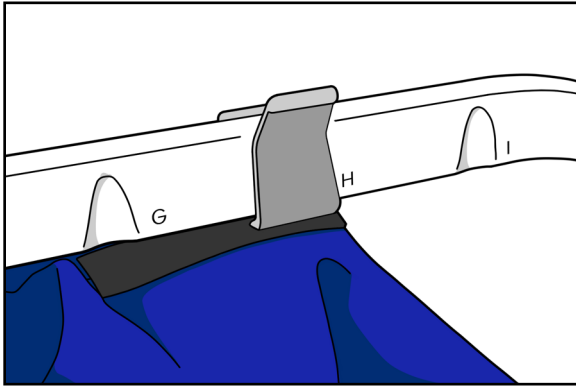


Fig. 5

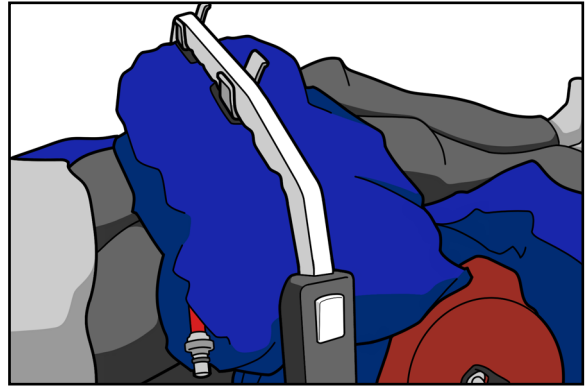


Fig. 6

# OPERATING INSTRUCTIONS

## SET UP

### BRIDGE ADJUSTMENT

1. For vertical adjustment, while pushing and holding in the release button, raise or lower the bridge to the desired height. Verify height is locked into a position as indicated on bridge. (Fig. 7)
2. For horizontal adjustment, unlock each bridge clamp, slide the bridge to the desired location on the device, and then lock the bridge clamp back into place. (Fig. 8 & 9)

**! NOTE !** The blue indicator on the clamp indicates the position on the device. (Fig. 10)

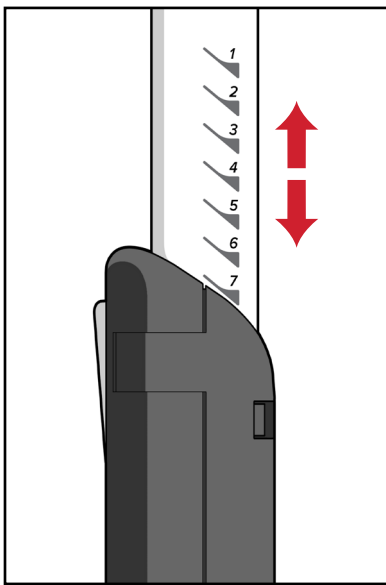


Fig. 7

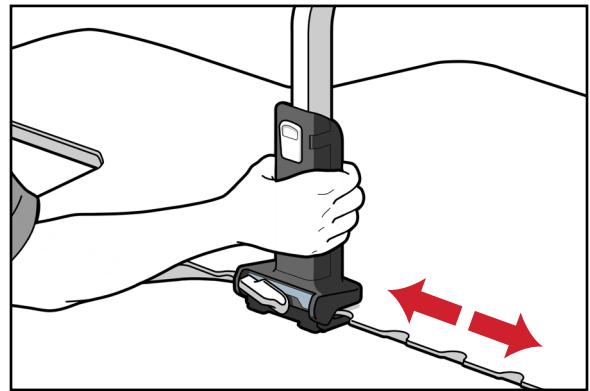


Fig. 8

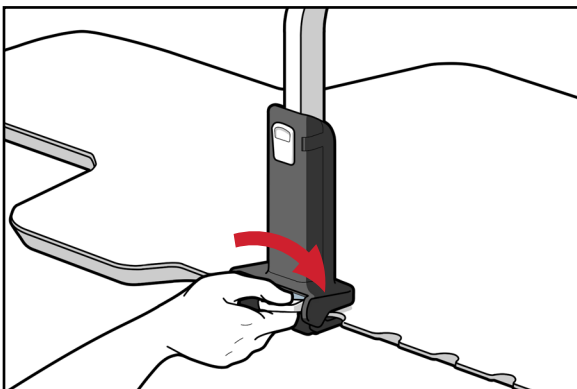


Fig. 9

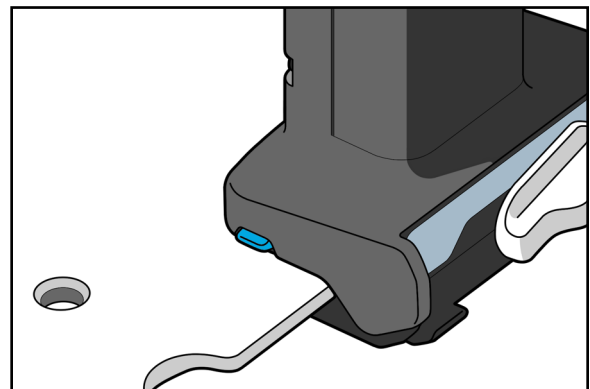


Fig. 10

# OPERATING INSTRUCTIONS

## SET UP

### COMPRESSION CLAMP ADJUSTMENT

1. With the locking knob loose, slide the compression clamp to the desired location and secure by tightening locking knob. (Fig. 11)
2. Once the patient is in position, the compression paddle can be lowered into their diaphragm by pushing in on the release button and pushing down on the shaft. (Fig. 12)

**! NOTE !** In the event of an emergency, the compression clamp works as a safety release. By pushing in on the release button, the compression paddle will release off of the patient. (Fig. 13)

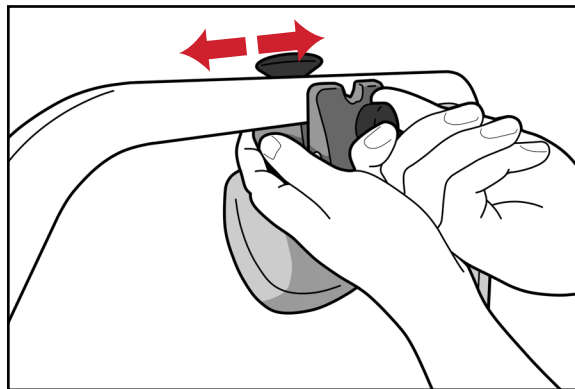


Fig. 11

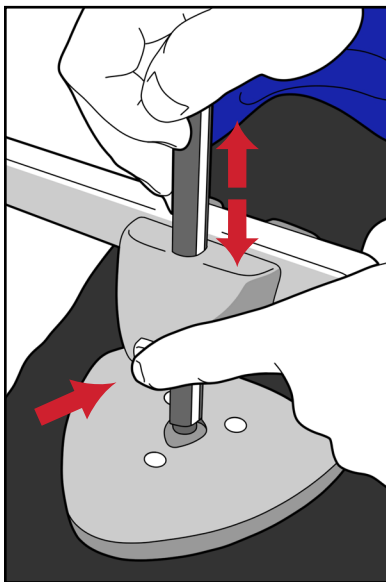


Fig. 12

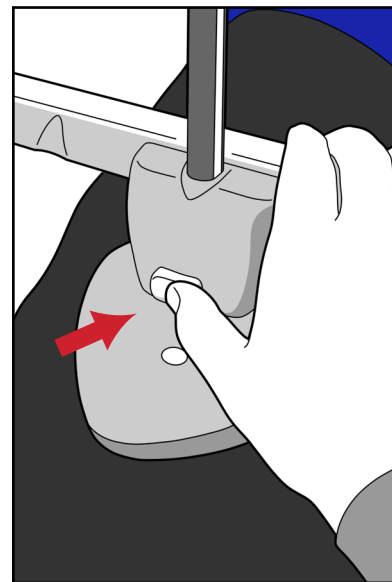


Fig. 13

# OPERATING INSTRUCTIONS

## REMOVAL

### DEVICE REMOVAL

1. To remove VacQfix cushion clips, spread apart clips so they open and pull away from the bridge.
2. To remove Compression Clamp, loosen screw until the clamp can be pulled away from the bridge.
3. To remove bridge, unlock both bridge clamps and pull each clamp away from the sides of the device.

# MAINTENANCE

## CLEANING THE SYSTEM

The device can be cleaned with a mild, non-abrasive cleaning solution. To clean, apply solution to clean cloth and wipe the surface. Visually inspect the device, if it is not clean, repeat the previous cleaning steps until visually clean. Use a clean cloth moistened with water to wipe the device to remove any cleaning agent residue. To dry, wipe the device with a clean, dry cloth. The following cleaning material has been tested and found to be appropriate for cleaning the device.

- 10% Clorox® Bleach Solution

## DISINFECTING THE SYSTEM

To disinfect the device, use an alcohol or Super Sani-Cloth® wipe. Wipe the surface of the device with the cloth and allow the device to dry before use.

DO NOT place sharp objects on the device.

Periodically check all fasteners for tightness.

# SPECIFICATIONS

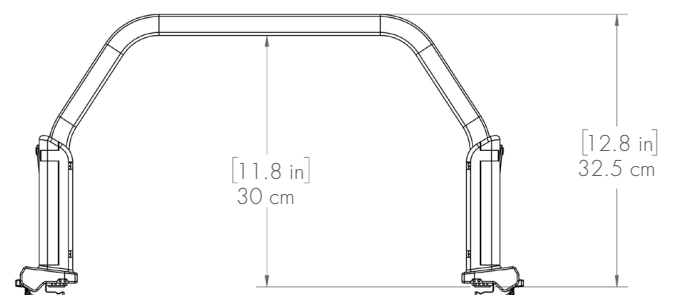
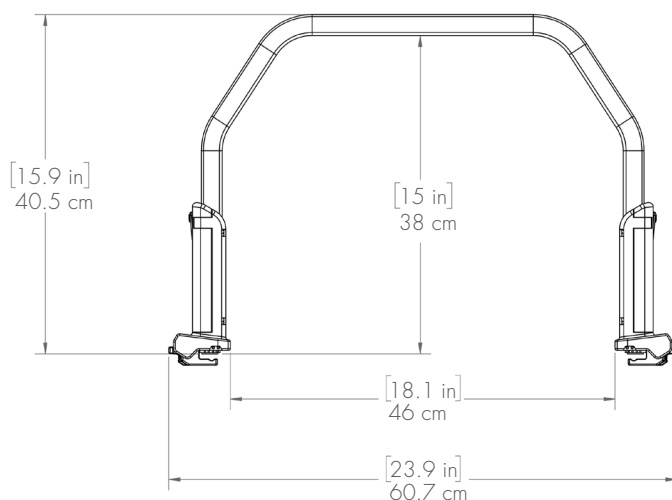
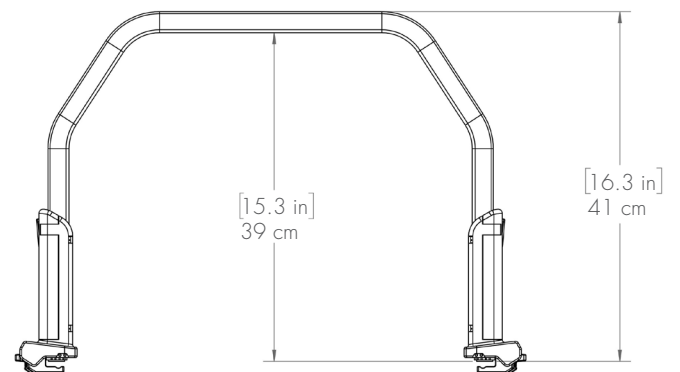
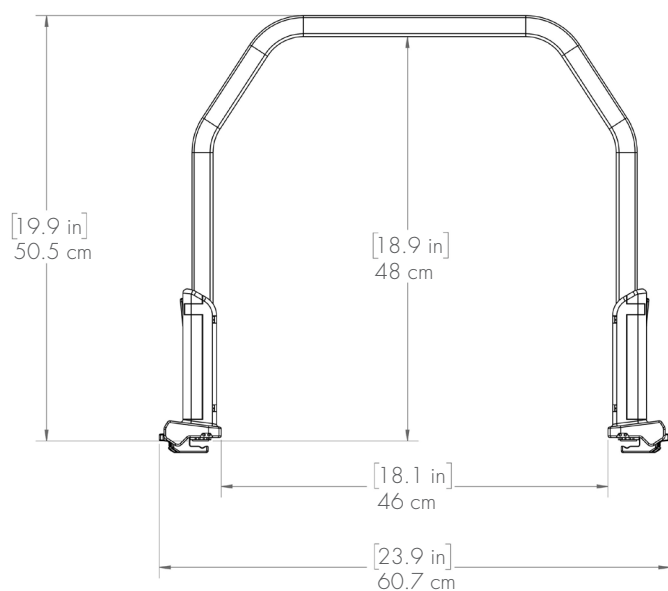
## WIDTH

60.7 cm

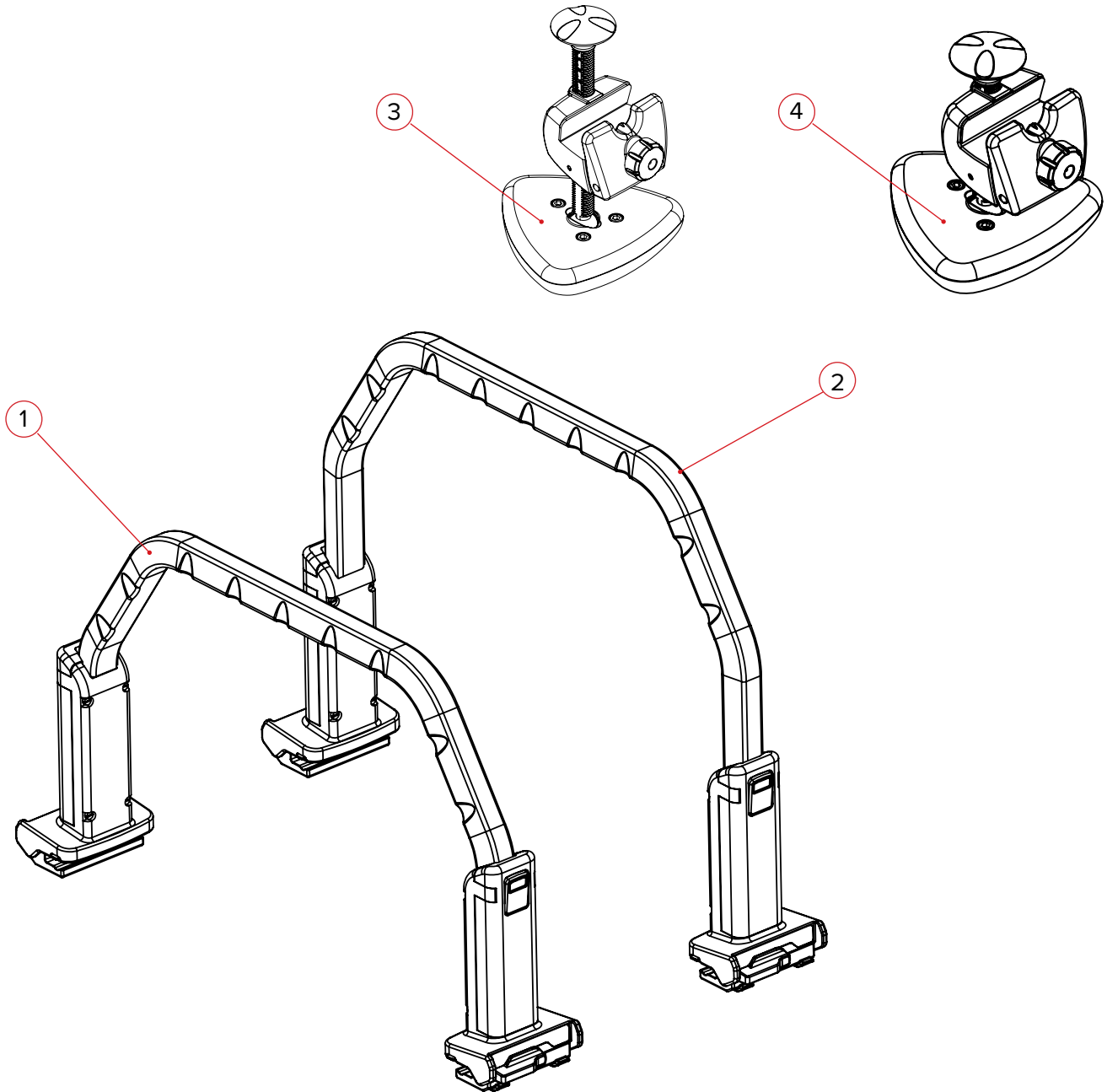
## HEIGHT

Large Bridge = 48 cm at Max Height, 39 cm at Min Height

Small Bridge = 38 cm at Max Height, 30 cm at Min Height



# PARTS LIST



1. RT-4800-B1 — InfinityLock SBRT Compression Bridge, Small
2. RT4800-B2 — InfinityLock SBRT Compression Bridge, Large
3. RT-4558KV4 — Compression Paddle (Standard)
4. RT-4558KV4-01 — Compression Paddle (Low Profile)
5. 2001944 — SBRT Lockable VacQfix Cushion Clip (Long) (Not pictured)
6. 2001945 — SBRT Lockable VacQfix Cushion Clip (Short) (Not pictured)

# PATIENT SETUP

## INFINITYLOCK SBRT COMPRESSION BRIDGE & PADDLE – RT-4800-B1, RT-4800-B2

Patient Name:

Patient ID #:

Setup by:

Physician:

Date:

Comments:

### InfinityLock SBRT Compression Bridge Setup (each bridge should have it's own setup record)

Bridge used: **Small**      **Large**

Accessory used: **Compression Paddle**      **Thigh Compression Cushion**

1. Location on Device:      mm (should be same location on both Patient Left and Right)
2. Height of Bridge: (1–19)
3. Laser Alignment:      mm

Notes:

### Compression Paddle (fill out if accessory was used)

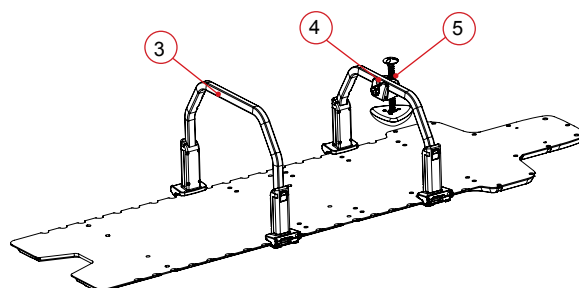
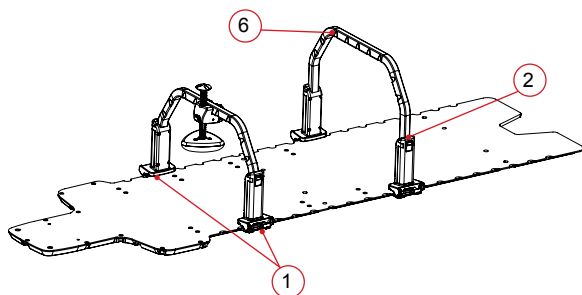
4. Location of Accessory on Bridge:      mm
5. Height of Compression Paddle      mm

Notes:

### Thigh Compression VacQfix Cushion (fill out if accessory was used)

6. Location of Accessory on Bridge:  
Large Clip Only: (mark A through I)

Notes:













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