




positioning
patients for life.®

PRODUCT GUIDE & USER MANUAL

RT-4558-B1 & RT-4558-B2
kVue™ SBRT Bridges





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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.

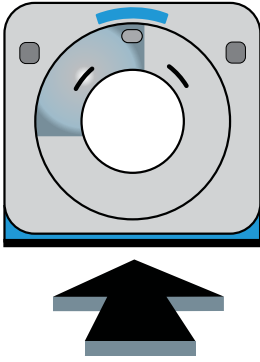
SAFETY INFORMATION

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

WARNING LABELS & DESCRIPTIONS

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

GENERAL PRECAUTIONS



TOWARDS GANTRY

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

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

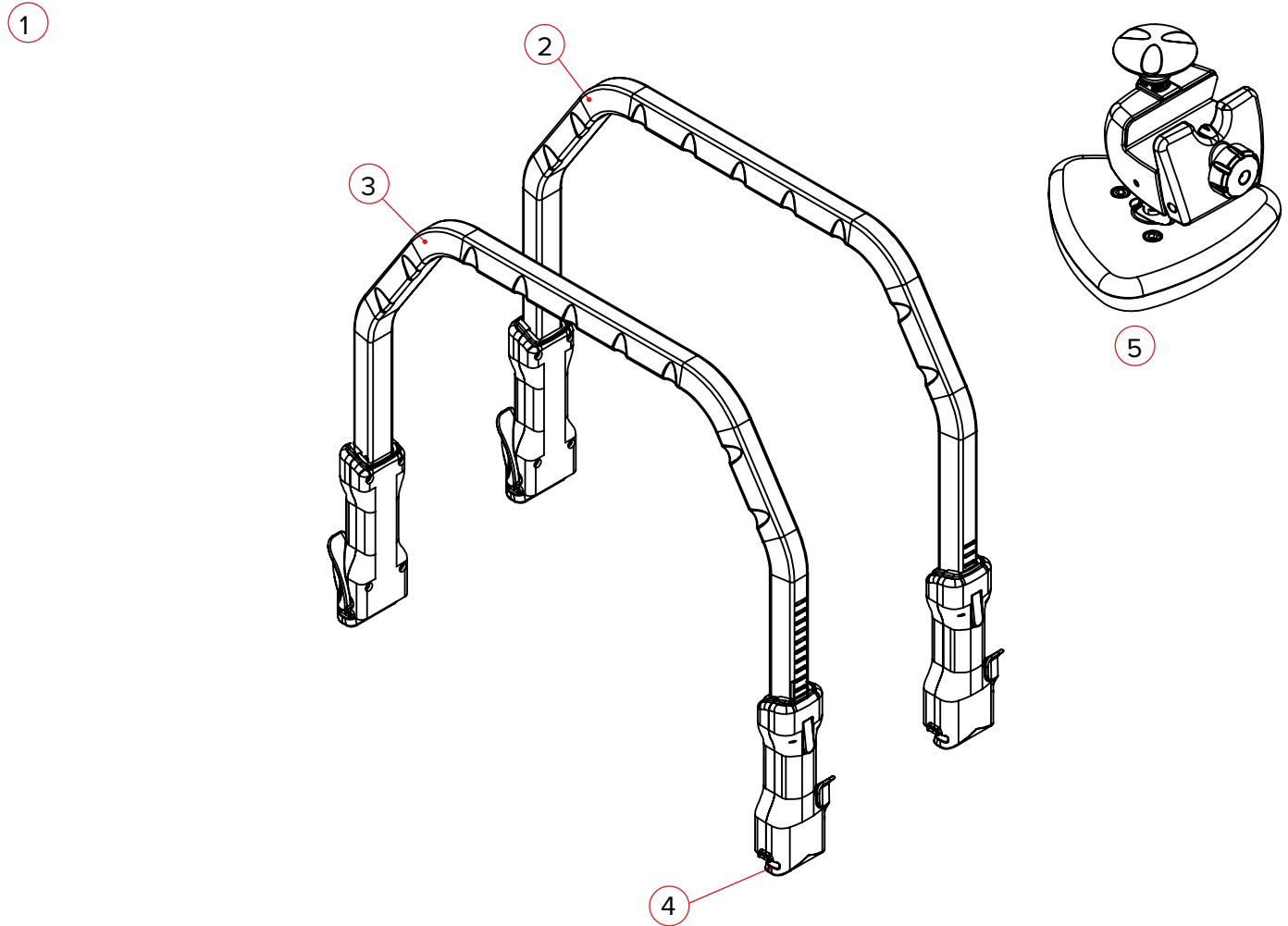
Patients undergoing radiation therapy or diagnostic imaging procedures.

INTENDED USERS

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

FEATURES

COMPONENTS



FEATURES

COMPONENTS

1. KVUE™ SBRT BRIDGES

The kVue Bridges come in multiple sizes. They are adjustable in height, include an easy single motion lever, horizontal scales, and indexing notches for VacQfix™ cushions. The bridges have a low attenuation coefficient, which enables treatment through the kVue Bridges, however it is not recommended.

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 kVue Bridges to the treatment surface. The clamp indexes to the treatment device by aligning white markings on the clamps with the scales on the treatment device.

5. COMPRESSION PADDLE & CLAMP

The compression paddle clamps onto the kVue Bridge and includes a safety release button, tactile compression, and increment 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 kVue 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. Using the scale on the device, align the bridge clamps directly across from each other.
3. Lock down both bridge clamps by pushing up on the locking lever until the bridge clamps are secure. (Fig. 2)

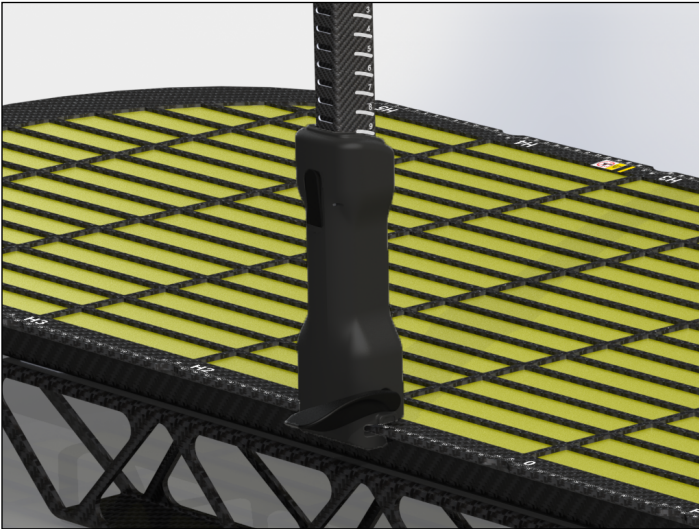


Fig. 1

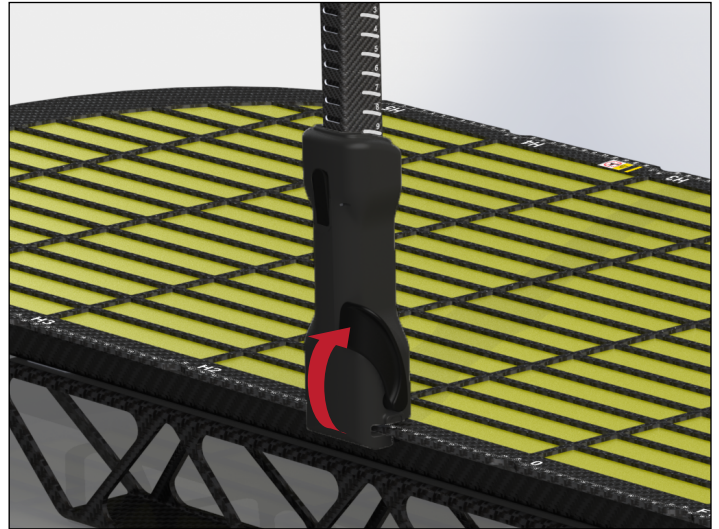


Fig. 2

COMPRESSION PADDLE INSTALLATION

1. Unscrew locking knob and tilt back front plate of the compression clamp until it fits around the bridge. (Fig. 3 & 4)
2. Lock down the compression clamp by turning the locking knob until the clamp is secured. (Fig. 5)



Fig. 3



Fig. 4



Fig. 5

OPERATING INSTRUCTIONS

INSTALLATION

VACQFIX™ CUSHION CLIP INSTALLATION

Align the VacQfix cushion clip to the desired location on the kVue™ Bridge and push them around the kVue Bridge until they snap into place. (Fig. 6 & 7)



Fig. 6



Fig. 7

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. (Fig. 8)
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. 9, 10 & 11)

! NOTE ! The white marking on the clamp indicates the position on the device. (Fig. 12)

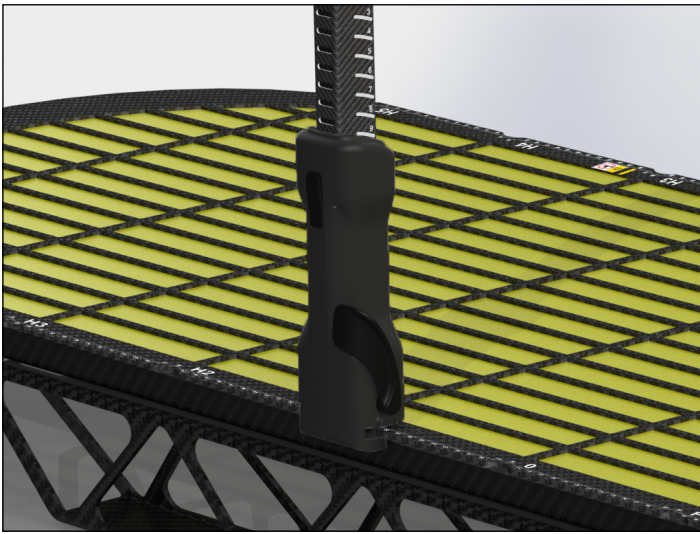


Fig. 8



Fig. 9

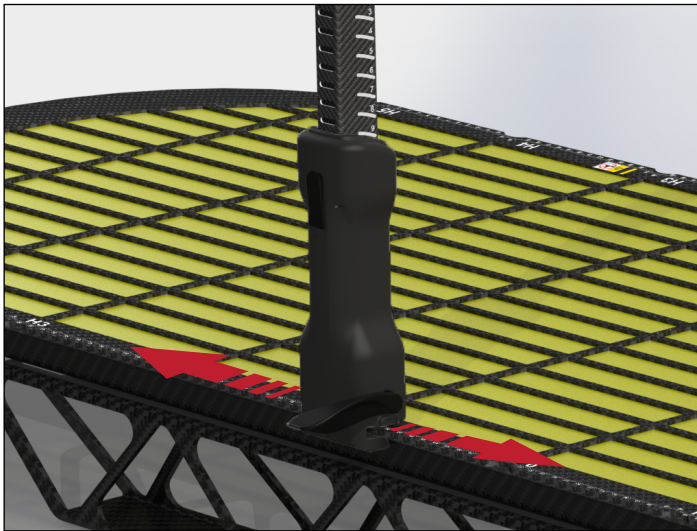


Fig. 10



Fig. 11

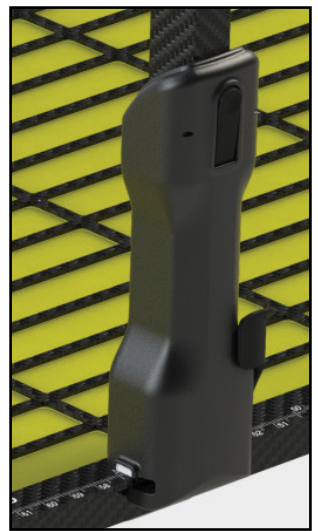


Fig. 12

OPERATING INSTRUCTIONS

SET UP

COMPRESSION CLAMP ADJUSTMENT

1. To adjust the lateral location of the compression clamp, loosen the locking knob on the back side of the clamp. (Fig. 13)
2. Slide the compression clamp to the desired location and secure by tightening locking knob. (Fig. 13 & 14)
3. 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. 15)

! 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. 16)



Fig. 13



Fig. 14

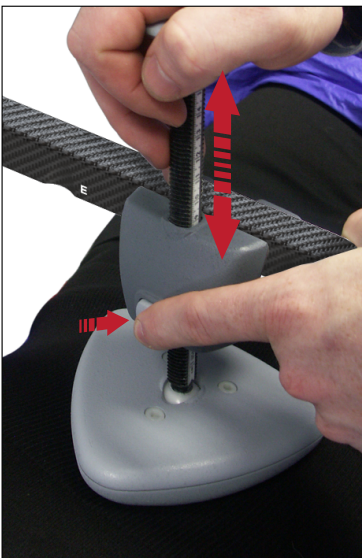


Fig. 15



Fig. 16

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 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 surfaces. To disinfect the surfaces, refer to specific instructions from the cleaning agent manufacturer.

- 10% Clorox® Bleach Solution
- Isopropyl Alcohol
- Cidex® 2.4% Activated Dialdehyde Solution
- Soap and Water

DO NOT place sharp objects on the device.

Periodically check all fasteners for tightness.

SPECIFICATIONS

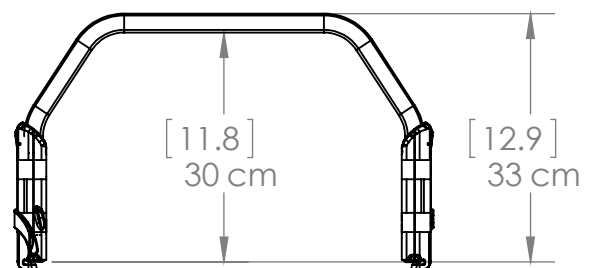
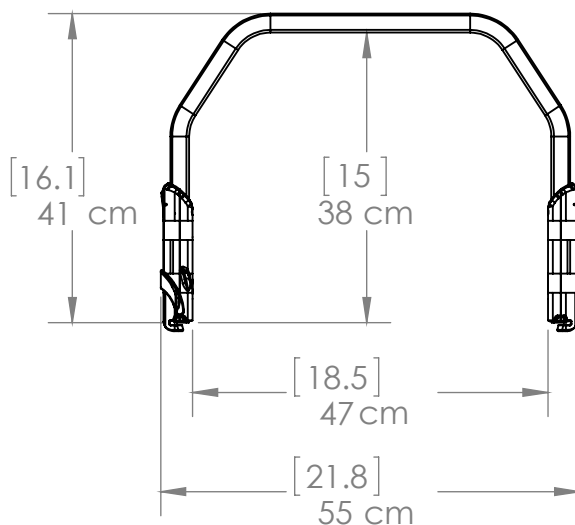
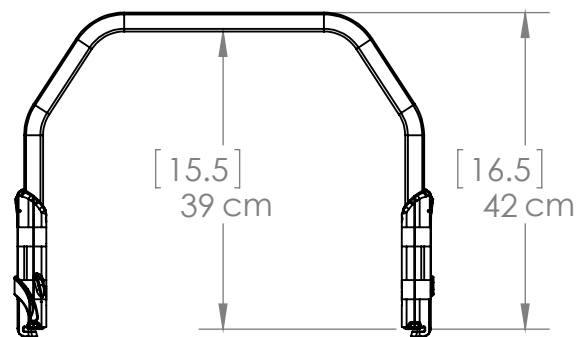
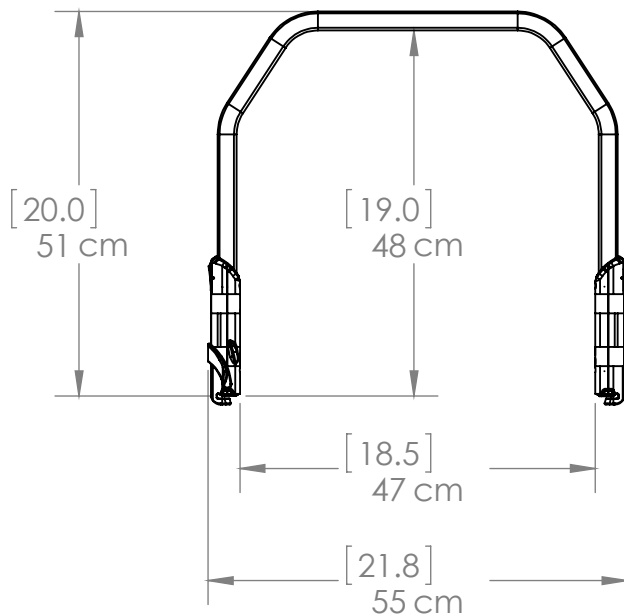
WIDTH

55 cm

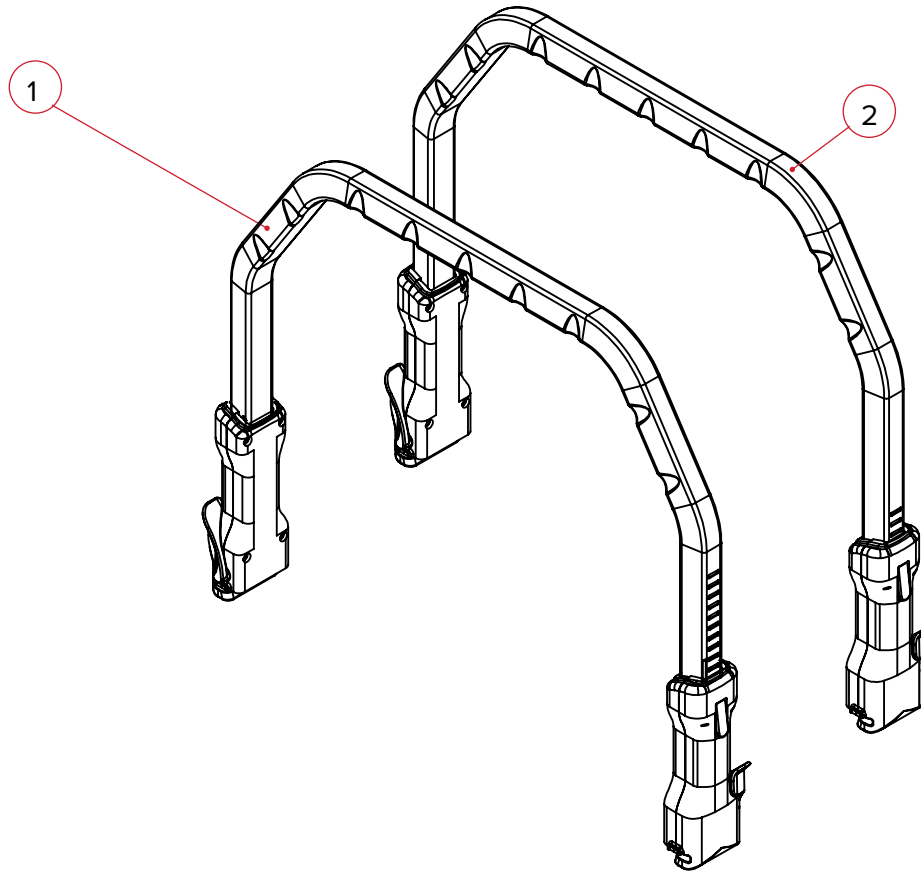
HEIGHT

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. 2004528 — Small kVue Bridge
2. 2004529 — Large kVue Bridge

PATIENT SETUP

KVUE™ SBRT BRIDGES – RT-4558-B1 & RT-4558-B2

Patient Name:

Patient ID #:

Setup by:

Physician:

Date:

Comments:

Kvue Bridge Setup (each bridge should have its own setup record)

Bridge used: **Small** **Large**

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

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

Notes:

Compression Paddle (fill out if accessory was used)

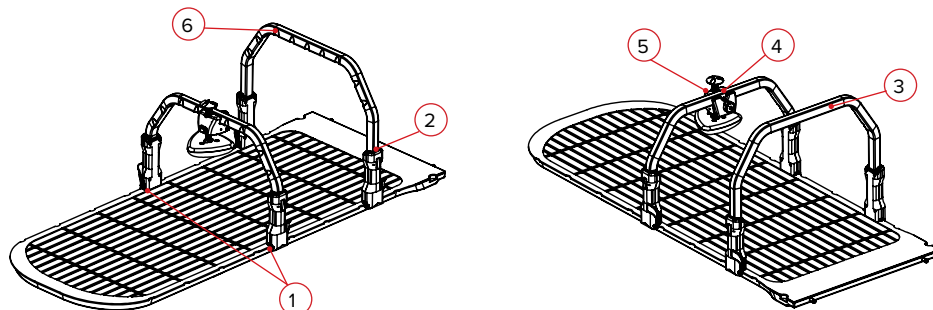
4. Location of Accessory on Bridge: _____ cm
5. Height of Compression Paddle _____ cm

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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