



positioning
patients for life.®

PRODUCT GUIDE & USER MANUAL


RT-4558KV & RT-4558KV1
kVue™ Stradivarius SBRT Insert

RT-4558-1 Stradivarius™ SBRT Overlay

RT-4558MRI Stradivarius™ SBRT Overlay-MR





<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> Made in the USA by</div> <div>Qfix</div> <div>440 Church Rd, Avondale, Pennsylvania, USA</div> <div>+1 610-268-0585 www.Qfix.com</div>
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Cidex® is a registered trademark of Johnson & Johnson.

TABLE OF CONTENTS

GENERAL PRECAUTIONS.....	4
WARNING STATEMENTS	4
SERIOUS INCIDENTS.....	4
ADDITIONAL WARNINGS	4
TREATMENT BEAM ATTENUATION	4
LOAD RATING	4
WARNING LABELS & DESCRIPTIONS.....	5
INTENDED USE.....	7
FEATURES.....	8
COMPONENTS.....	8
OPERATING INSTRUCTIONS.....	11
INSTALLATION.....	11
SET-UP	12
MAINTENANCE.....	16
CLEANING THE SYSTEM	16
DISINFECTING THE SYSTEM.....	16
SPECIFICATIONS.....	17
KVUE STRADIVARIUS SBRT INSERT	17
KVUE STRADIVARIUS SBRT OVERLAY & KVUE STRADIVARIUS SBRT OVERLAY-MR	18
SETUP SHEET	19
KVUE STRADIVARIUS SBRT INSERT—RT-4558KV & RT-4558KV1.....	19
STRADIVARIUS SBRT OVERLAY—RT-4558-1 & STRADIVARIUS SBRT OVERLAY-MR—RT-4558MRI	21

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 ! THE ONETOUCH™ IS A PRECISION MECHANISM AND IS ONLY FOR USE WITH APPROVED QFIX KVUE DEVICES. UNAPPROVED NON-QFIX DEVICES THAT HAVE NOT BEEN VALIDATED BY QFIX MAY NOT BE SAFE FOR USE AND WILL VOID WARRANTY IF USED.

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.

ADDITIONAL WARNINGS

- DO NOT carry a patient on SBRT Overlay-MR.
- DO NOT lift device from side edges. Hand holds are present on each end of the device on the bottom side to aid in lifting.

TREATMENT BEAM ATTENUATION

The kVue Stradivarius SBRT Insert and Stradivarius SBRT Overlay have a water equivalence of approximately 6 mm at 6 MV AP/PA photon beam. Kilovoltage x-ray attenuation is equivalent to about 0.5 mm aluminum at 100 kVp. Treatment through the composite support beams will increase the attenuation. Actual attenuation based on setup should be verified with your particular equipment. Treatment through any device, even one constructed of composite materials, will lead to an increase in skin dose.

LOAD RATING

SBRT Insert: DO NOT exceed 249 kg (550 lbs) uniformly distributed load or maximum working load of couch base, whichever is less.

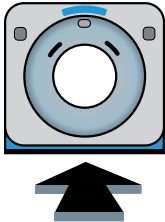
SBRT Overlay & SBRT Overlay-MR: DO NOT exceed 159 kg (350 lbs) uniformly distributed load or maximum working load of couch base, whichever is less.

! NOTE ! When combined with the OEM couch base, the load rating is the lower of the two safe working loads. The kVue Couch Top load should NOT exceed the original couch base manufacturer's specifications. Please refer to the product literature provided by the original manufacturer.

GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS

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



TOWARDS GANTRY

Locating on the Variable Height Bridges. During setup of the Bridges make sure that the arrow is pointing towards the Gantry.

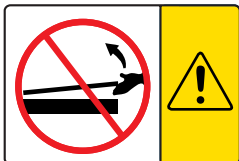


PINCH POINTS

Use caution when moving the Bridges vertically to avoid patient or personal injury.



OR



KVUE INSERT INSTALLATION AND REMOVAL

! WARNING ! NEVER LIFT THE END OF THE KVUE INSERT !

The mating pins may bend or break, rendering the kVue unusable.

Refer to the kVue Couch Top Installation Manual for kVue installation and removal instructions.

↓ NO STEP ↓

OR



“NO STEP” LINE (IF PRESENT)

The yellow line on the kVue Insert represents the end of the support beams. The area beyond the line has been designed and tested to support the patient's upper torso or lower body not exceeding the load rating.

Standing or sitting on the kVue Insert beyond the “No Step” line may damage the kVue Insert or cause injury.

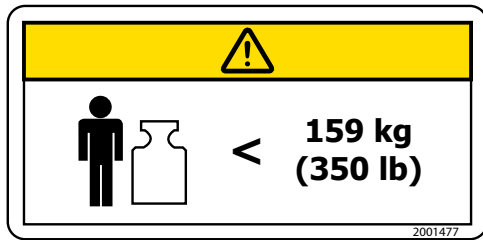


PINCH POINTS

Use caution when moving the kVue Moving Rails to avoid patient or personal injury.

GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS



LOAD RATING (SBRT OVERLAY & SBRT OVERLAY-MR)

DO NOT exceed 159 kg (350 lbs) uniformly distributed load when not on a couch base.

When on a couch base the maximum safe working load is that of the couch base.



MRI SAFE

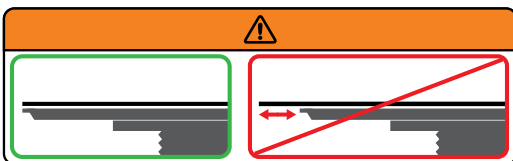
When present, item poses no known hazard in all MR environments. DO NOT use with any unapproved components or accessories. DO NOT use in conjunction with any ferromagnetic or conductive items.

! NOTE ! For RT-4558MRI only.



MRI SECURE

When present, this graphic indicates that the device or accessory is MRI safe, and may be used with other MR Secure or MR safe devices. DO NOT use in MRI if MR Secure accessory is being used with a MR Unsafe or NON-MR Secure Device.



DO NOT CANTILEVER

DO NOT cantilever the Overlay off the end of the couch top.

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

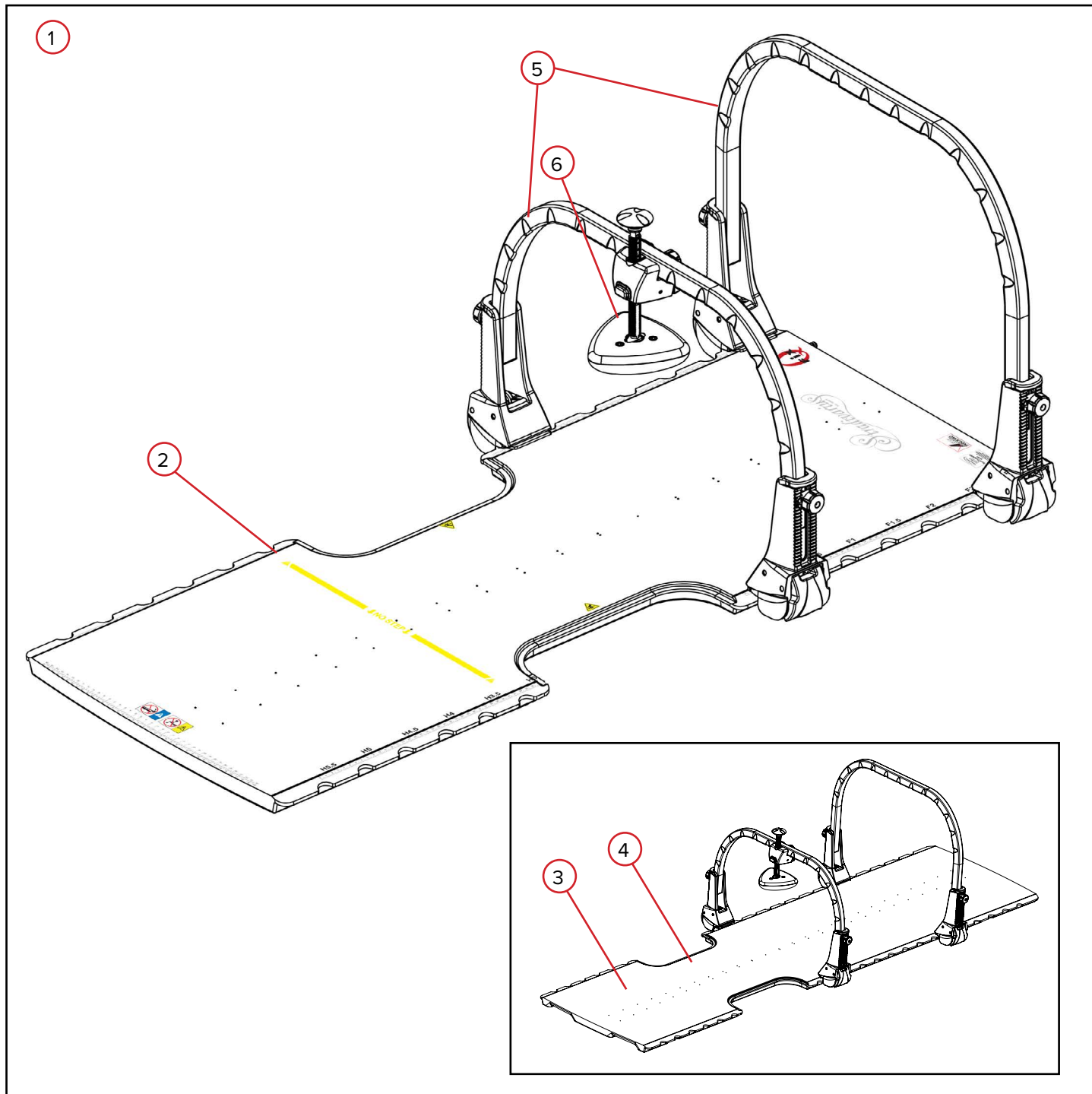
Patient's undergoing radiation therapy or diagnostic imaging procedures.

INTENDED USERS

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

FEATURES

COMPONENTS



FEATURES

COMPONENTS

1. KVUE™ STRADIVARIUS™ SBRT DEVICE

The kVue Stradivarius SBRT Device is designed for Hypofractionated Non-Coplanar Treatment.

2. KVUE STRADIVARIUS SBRT INSERT

The kVue Stradivarius SBRT Insert is compatible with the kVue and has indexing every 70 mm (double most other competitors), laser alignment scales, and central cut-outs for unobstructed treatment paths including non-coplanar fields.

3. KVUE STRADIVARIUS SBRT OVERLAY

The Stradivarius SBRT Overlay can be used as an overlay on most couch tops with two pin indexing. The device has indexing every 70 mm (double most other competitors), laser alignment scales and cut-outs for unobstructed treatment paths including non-coplanar fields.

4. KVUE STRADIVARIUS SBRT OVERLAY-MR

The Stradivarius SBRT Overlay can be used as an overlay on most couch tops with two pin indexing. The device has indexing every 70 mm (double most other competitors), laser alignment scales and cut-outs for unobstructed treatment paths including non-coplanar fields. This device is MRI safe, and may be used with other MR Secure or MR safe devices.

5. VARIABLE HEIGHT BRIDGES

The Variable Height Bridges come in multiple sizes. They are adjustable in height, include an easy single motion lever, horizontal and vertical laser alignment scales. The bridges have a low attenuation coefficient. This enables treatment through the Bridges, however it is not recommended. The Bridges are constructed to be MR safe.

6. COMPRESSION PADDLE

The Compression Paddle's features include a safety release button, tactile compression, and incriminated lateral placement along the Bridge. The Compression Paddle is also constructed to be MR safe.

7. WHOLE BODY VACQFIX™ CUSHION (NOT SHOWN IN DIAGRAM)

The Whole Body VacQfix Cushion is for complete body immobilization. Used in combination with the VacQfix Indexer, for accurate locating to the kVue Insert. The cushion features the One-Step™ Valve, and a flared top for arm immobilization.

FEATURES

COMPONENTS

8. THIGH COMPRESSION VACQFIX CUSHION (NOT SHOWN IN DIAGRAM)

The Thigh Compression VacQfix Cushion offers complete leg immobilization. The Cushion is adjustable along the Bridge with snap on attachments and includes the One-Step™ Valve.

9. SOFTOUCH KNEE WEDGE & FOOT BLOCK (NOT SHOWN IN DIAGRAM)

The SofTouch Knee Wedge and Foot Block are designed to provide precise, repeatable positioning and are contoured to relieve pressure point stress and improve patient comfort.

10. ARMSHUTTLE (NOT SHOWN IN DIAGRAM)

The Armshuttle is a versatile, patient friendly way to increase upper body setup repeatability when used in conjunction with the Stradivarius SBRT.

11. LOCATING BARS (NOT SHOWN IN DIAGRAM)

The Locating Bars are used to accurately locate accessories to the SBRT. The has Varian Exact® Indexing every 70 mm to locate accessories such as the ArmShuttle and VacQfix Cushions.

OPERATING INSTRUCTIONS

INSTALLATION

KVUE INSTALLATION

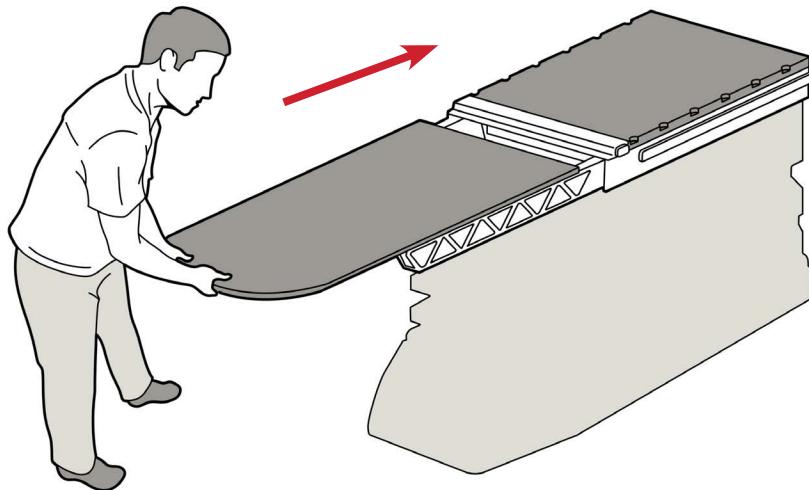
The kVue is designed to fit all major radiotherapy treatment systems. Quick installation minimizes linear accelerator downtime during installation. Refer to the kVue Couch Top Installation Manual for specific installation information.

! NOTE ! As detailed in the kVue Couch Top Installation Manual, the final height of the kVue surface may be different from the original system. Refer to the original system instructions to reset the system zero (origin) prior to initial use.

KVUE INSERT INSTALLATION

1. Place the Standard Insert on top of the support beams and align the two mating pins with the receiving holes in the OneTouch Latch.
2. From the head end of the kVue, slide the Standard Insert directly into the receiving holes.

You will hear a click when the Standard Insert is locked into place. ONLY the green button surface will be visible when properly installed.



kVue with Standard Insert

OPERATING INSTRUCTIONS

SET-UP

PATIENT POSITIONING

! NOTE ! The following instructions are general positioning instructions

1. Dock the SBRT Insert into the kVue or place SBRT Overlay on top of existing couch top using existing two pin indexing bars to align device.
2. Place ArmShuttle into correct position (if needed) onto the Stradivarius.
3. Place Whole Body VacQfix™ Cushion on the SBRT.
4. Place patient onto the cushion and position.
5. Place appropriate Knee Wedge & Foot Block into position
6. Attach Bridges into appropriate positioning and lock down to device, using palm of hand to push down clamp.
7. Apply vacuum to the Cushion and shape cushion around patient
8. Attach Bridge accessories, such as the Compression Paddle and Thigh Compression VacQfix Cushion, to each Bridge as needed.
9. Record all patient set-up data on provided Set-Up Sheet.

! NOTE ! Each patient may require their own unique set-up.

! NOTE ! The following pages go into further detail on the setup of each accessory.

OPERATING INSTRUCTIONS

SET-UP

ATTACHING VARIABLE HEIGHT BRIDGES

1. Attach the Bridges by pulling up on the clamp lever. Once the Bridge is in the correct position, using the palm of your hand, push the clamp lever down on both sides to lock the clamps in place (Fig. 1).

! NOTE ! Make sure Bridges are facing the correct direction. The arrow should be pointing towards the Gantry (Fig. 1a).

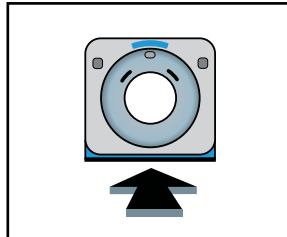


Fig. 1a



Fig. 1

2. To adjust the height of the Bridge, loosen the knob (turn counter-clockwise) until the Bridge slides freely. Once the Bridge is in the correct location, lock it in place by tightening the knob (turn clockwise) (Fig. 2).



Fig. 2

OPERATING INSTRUCTIONS

SET-UP

ATTACHING COMPRESSION PADDLE

3. Attach Compression Paddle horizontally along the Bridge by loosening the knob on the back side and sliding the paddle to the desired location (Fig. 3).

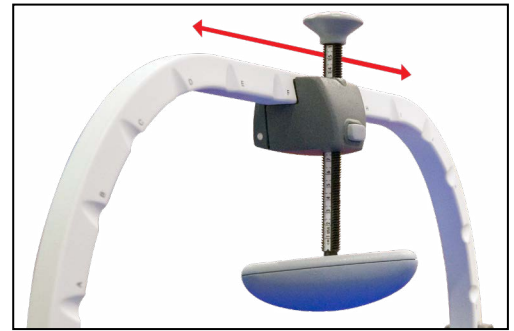


Fig. 3

4. Once the patient is in position, the Compression Paddle can be lowered into their diaphragm by pushing in on the Compression Paddle Button and pushing down on the shaft (Fig. 4).

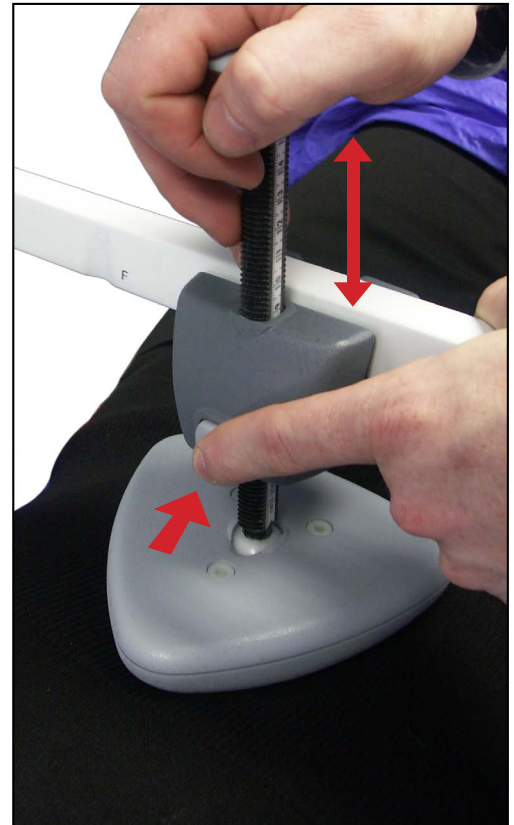


Fig. 4

! NOTE ! In the event of an emergency, the Compression Paddle works as a Safety Release. By pushing in on the Button, the Compression Paddle will release off of the patient (Fig. 5).



Fig. 5

OPERATING INSTRUCTIONS

SET-UP

ATTACHING VACQFIX CUSHIONS

1. With air in the Whole Body VacQfix Cushion, orient the patient in the correct position, then apply vacuum to the cushion to remove the air and harden the cushion (Fig. 6).



Fig. 6

2. With the patient in place, attach the Thigh Compression VacQfix Cushion to the Bridge using the supplied Snap on Attachment (Fig. 7). Once in place, apply vacuum to the cushion to remove the air and harden the cushion (Fig. 8).

! NOTE ! For further information on how to use the VacQfix Cushions, refer to the VacQfix Cushions User Manual.



Fig. 7



Fig. 8

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 SBRT Insert and SBRT Overlay surfaces. To disinfect the SBRT Insert and SBRT Overlay surfaces, refer to specific instructions from the cleaning agent manufacturer.

- A 10% Clorox® Bleach Solution
- Isopropyl Alcohol
- Cidex® 2.4% Activated Dialdehyde Solution

DO NOT place sharp objects on the SBRT Insert or SBRT Overlay.

SPECIFICATIONS

KVUE STRADIVARIUS SBRT INSERT

LENGTH: 1320 mm

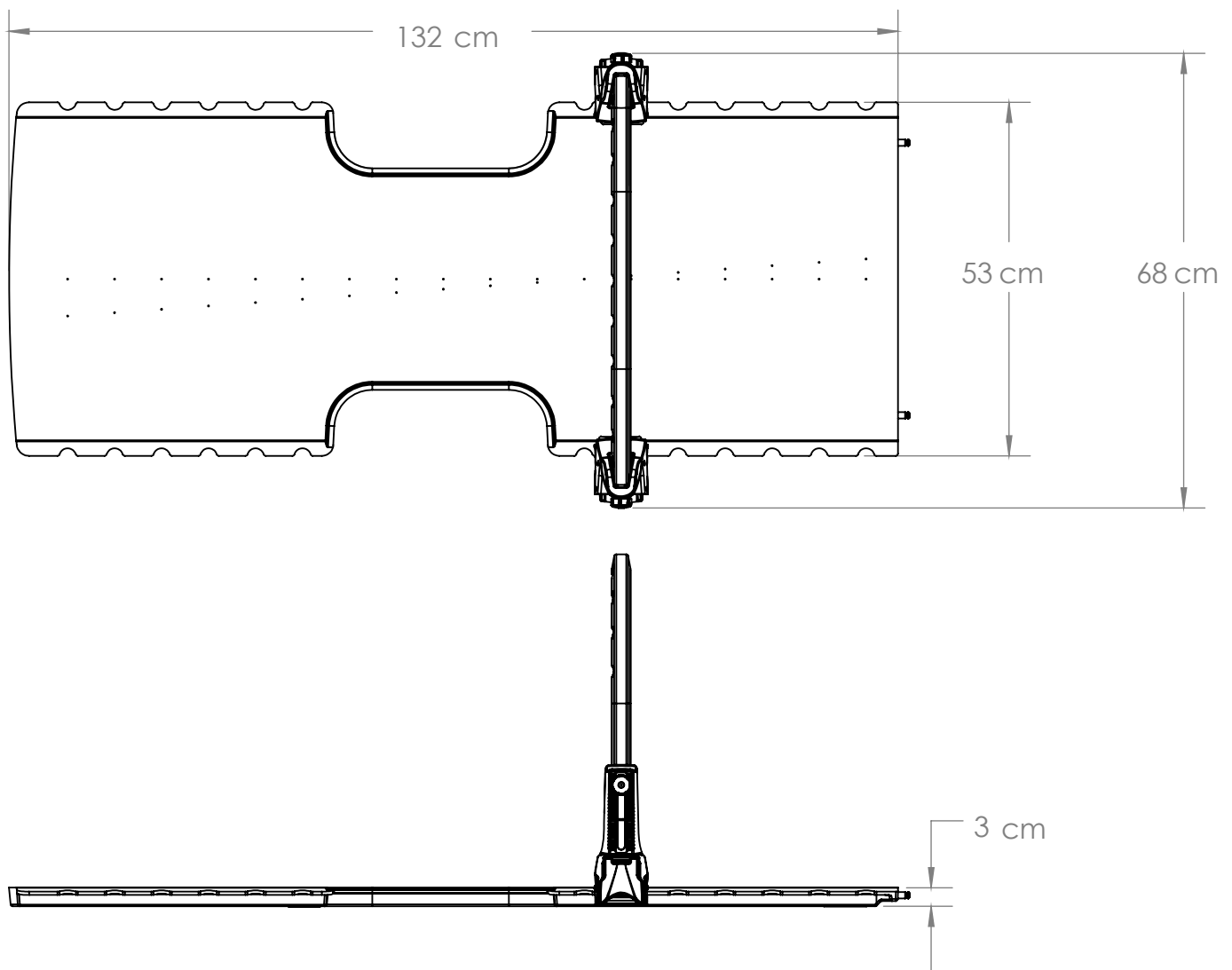
ALUMINUM EQUIVALENCE: ~0.6 mm @ 100 kVp

WATER EQUIVALENCE: 6 mm @ 6 MV

WEIGHT LIMIT: 249 kg (550 lb) Uniformly Distributed Load

HEIGHT:

- With Large Bridge = 50 cm at Max Height, 40 cm at Min Height
- With Small Bridge = 40 cm at Max Height, 30 cm at Min Height



SPECIFICATIONS

KVUE STRADIVARIUS SBRT OVERLAY & KVUE STRADIVARIUS SBRT OVERLAY-MR

LENGTH: 1950 mm

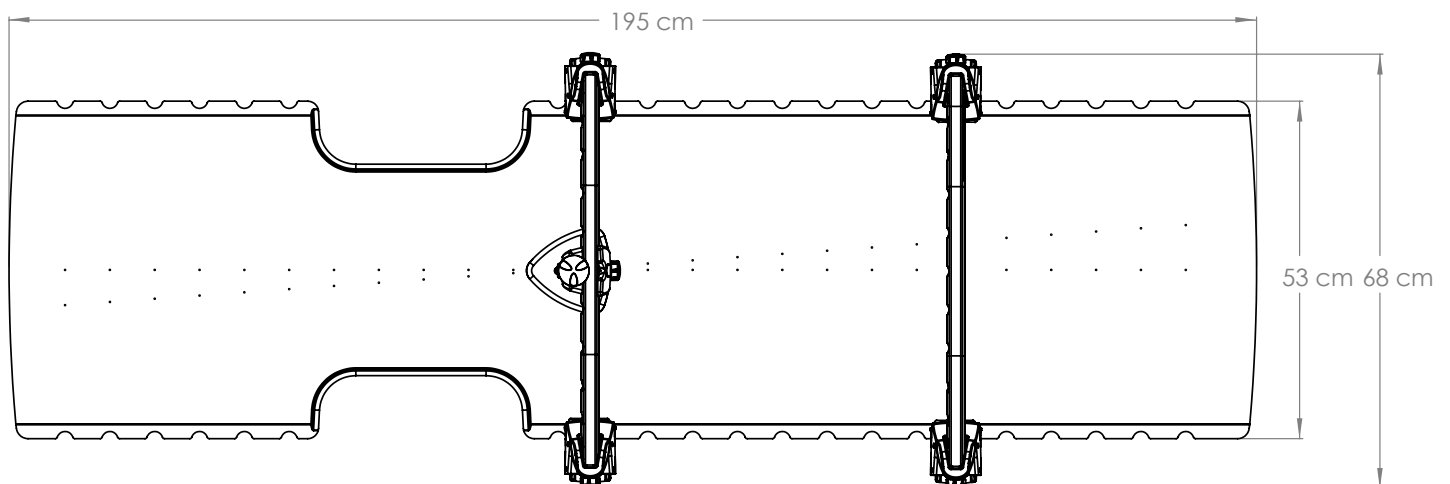
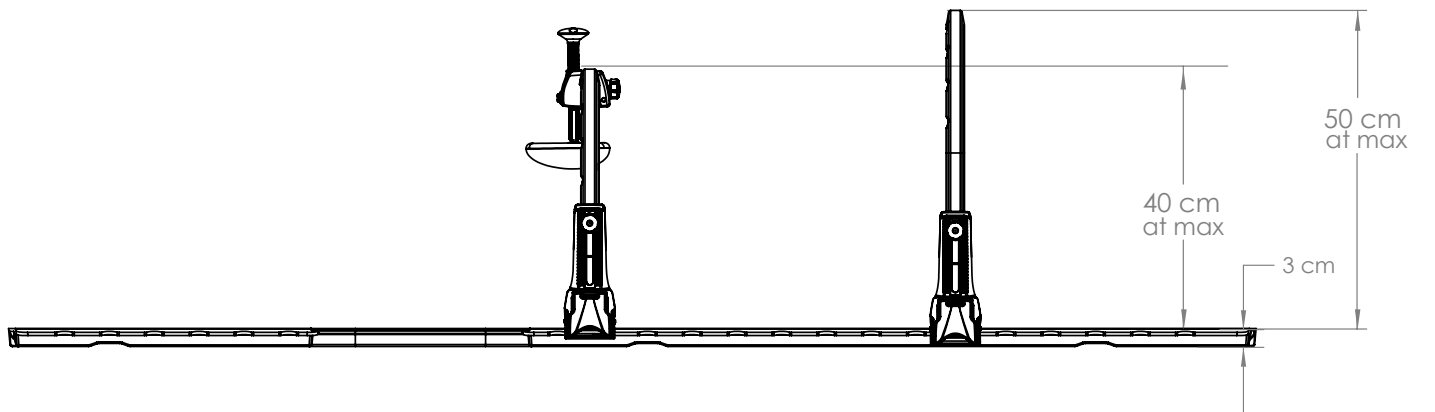
ALUMINUM EQUIVALENCE: ~0.6 mm @ 100 kVp

WATER EQUIVALENCE: 6 mm @ 6 MV

WEIGHT LIMIT: 159 kg (350 lb) Uniformly Distributed Load

HEIGHT:

- With Large Bridge = 50 cm at Max Height, 40 cm at Min Height
- With Small Bridge = 40 cm at Max Height, 30 cm at Min Height



SETUP SHEET

KVUE STRADIVARIUS SBRT INSERT—RT-4558KV & RT-4558KV1

Patient Name:

Patient ID #:

Setup by:

Physician:

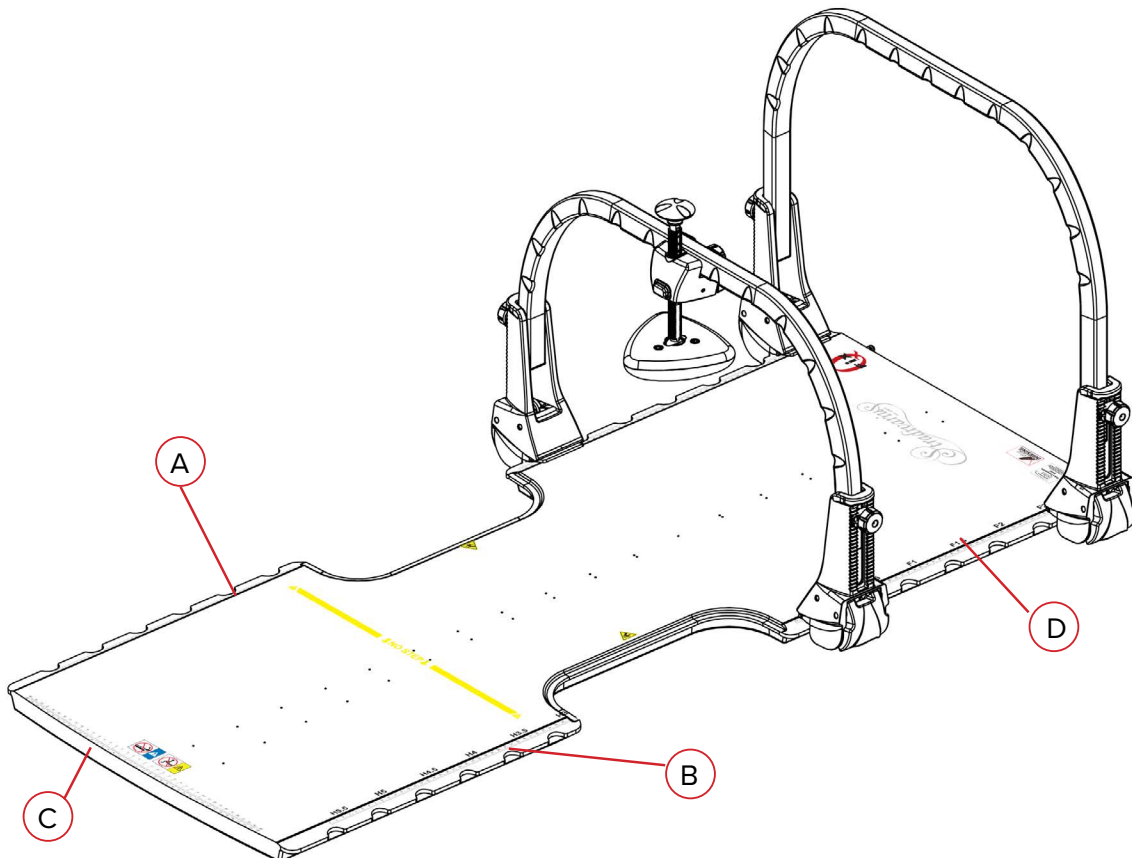
Date:

Comments:

kVue SBRT Couch Top Insert Setup

- A. Laser Alignment (Patient Left): mm
- B. Laser Alignment (Patient Right): mm
- C. Laser Alignment (Superior to Gantry): mm
- D. Qfix Locating Bar used? (Select one) **Y** **N** If Yes, what location(s)?

Notes:



SETUP SHEET

KVUE STRADIVARIUS SBRT INSERT—RT-4558KV & RT-4558KV1

Patient ID #:

Variable Height Bridges Setup (each bridge should have it's own setup record)

Bridge used: (Select one) **Small** **Large**

Accessory used: (Select one) **Compression Paddle** or **Thigh Compression Cushion**

1. Location on Device: mm (should be same location on both Patient Left and Right)
2. Height of Bridge: (Select one) **1** **2** **3** **4** **5** **6** **7** **8** **9** **10**
3. Laser Alignment: mm

Notes:

Compression Paddle (fill out if accessory was used)

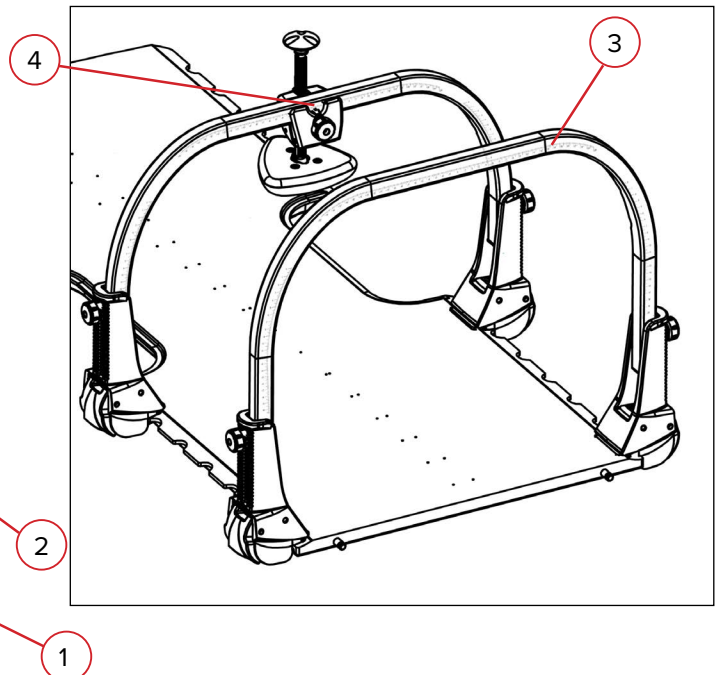
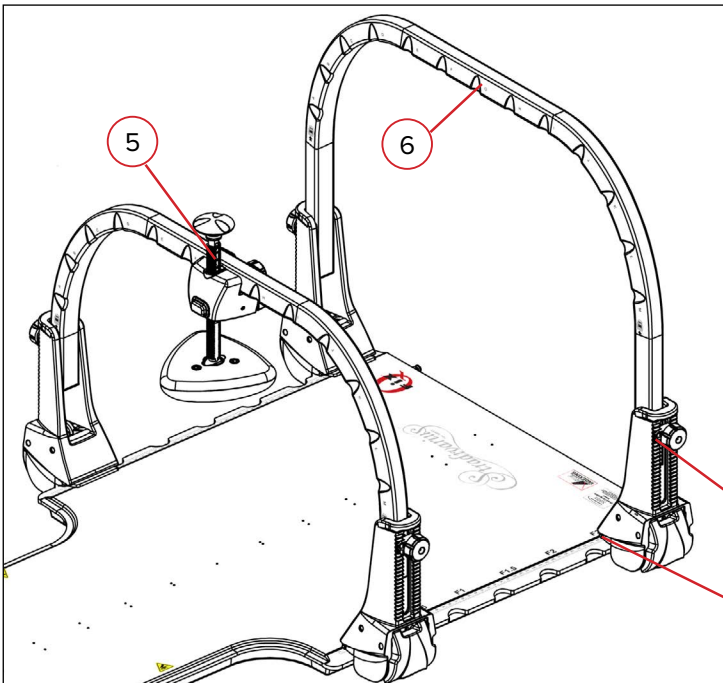
4. Location of Accessory on Bridge: mm
5. Height of Compression Paddle: mm

Notes:

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

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

Notes:



SETUP SHEET

STRADIVARIUS SBRT OVERLAY—RT-4558-1 & STRADIVARIUS SBRT OVERLAY—MR—RT-4558MRI

Patient Name:

Patient ID #:

Setup by:

Physician:

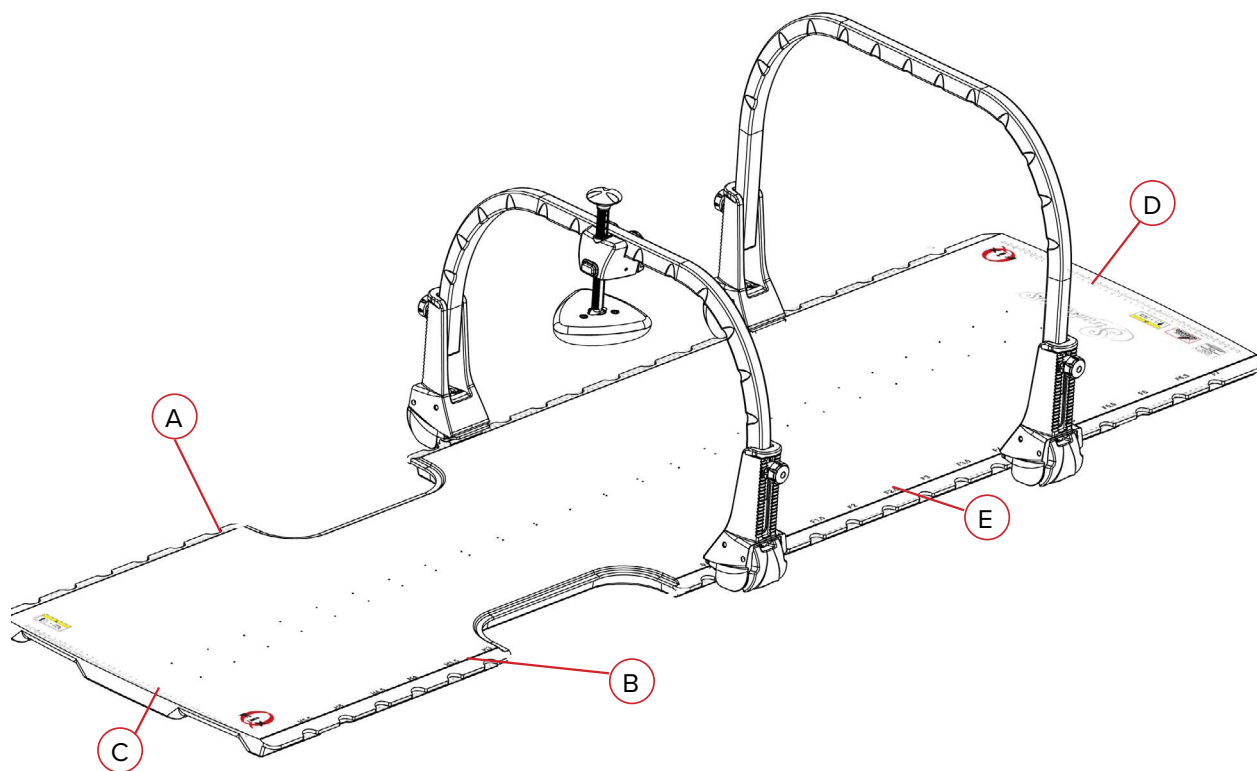
Date:

Comments:

kVue SBRT Couch Top Insert

- A. Laser Alignment (Patient Left): mm
- B. Laser Alignment (Patient Right): mm
- C. Laser Alignment (Superior to Gantry): mm
- D. Laser Alignment (Inferior to Gantry): mm
- E. Qfix Locating Bar used? (Select one) **Y** **N** If Yes, what location(s)?

Notes:



STRADIVARIUS SBRT OVERLAY—RT-4558-1 & STRADIVARIUS SBRT OVERLAY—MR—RT-4558MRI

Variable Height Bridges (each bridge should have it's own setup record)

Bridge used: (Select one) **Small** **Large**

Accessory used: (Select one) **Compression Paddle** or **Thigh Compression Cushion**

1. Location on Device: mm (should be same location on both Patient Left and Right)

2. Height of Bridge: (Select one) **1** **2** **3** **4** **5** **6** **7** **8** **9** **10**

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

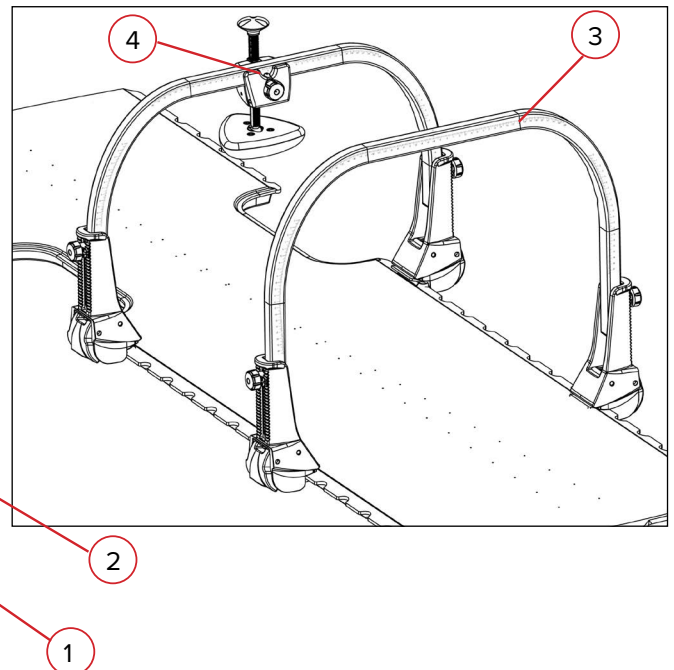
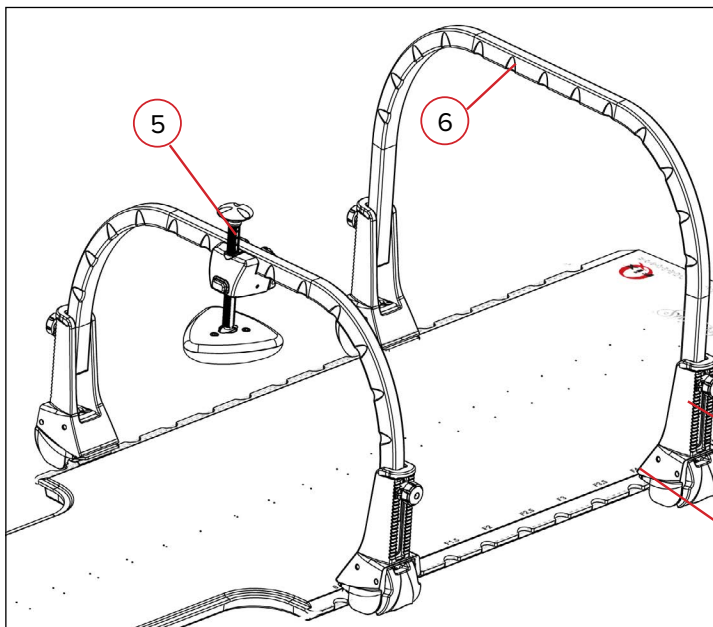
Notes:

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

6. Location of Accessory on Bridge:

Large Clip Only: (mark A through M):

Notes:





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