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# PRODUCT GUIDE & USER MANUAL

RT-4544KV & RT-4544KV-10


kVue Access 360™ &

kVue Access 360™ G2

Prone Breast Couch Top Insert  
*with Supraclavicular Access*





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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.**

**! 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.**

**! WARNING ! SCALES ON THE KVUE ACCESS 360™ & KVUE ACCESS 360™ G2 ARE FOR REFERENCE USE ONLY.**

## 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

- The Dual Hand Grips and Hand Grip Posts are not designed to support the patient's weight: **DO NOT** use handles to position the patient. **DO NOT** use handles to get on or off of the device.
- Patients may need assistance getting on and off of the device.
- Due to the length of the device it is recommended to have two people handle the device during installation and removal.
- **DO NOT** use more than 3 stacked CT Shims at one time. Doing so may cause device to be unstable.

## TREATMENT BEAM ATTENUATION

The structural regions of the kVue Access 360™ and the kVue Access 360™ G2 Couch Top Insert will attenuate a photon beam. Actual attenuation based on setup should be verified with your particular equipment. Treatment through any device, even one constructed of composite material will lead to an increased skin dose.

## LOAD RATING

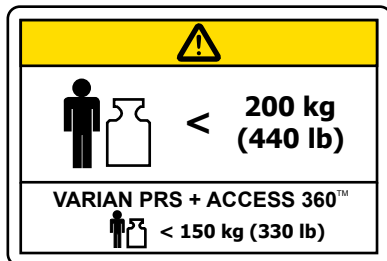
DO NOT exceed 200 kg (440 lbs) uniformly distributed load or maximum working load of couch base, whichever is less.

**! 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.

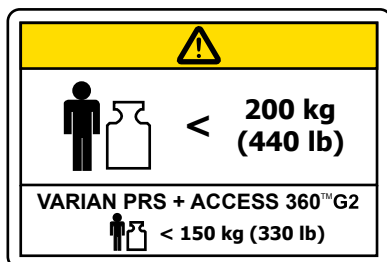
# GENERAL PRECAUTIONS

## WARNING LABELS & DESCRIPTIONS

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



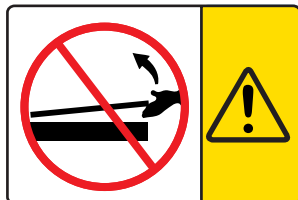
OR



### LOAD RATING

DO NOT exceed 200 kg (440 lb) uniformly distributed load or maximum safe working load of kVue Insert, or couch base, whichever is less.

DO NOT exceed 150 kg (330 lb) uniformly distributed load when used in combination with Varian PRS.



### DO NOT LIFT

**! WARNING ! NEVER LIFT THE END OF THE COUCH TOP INSERT.**

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



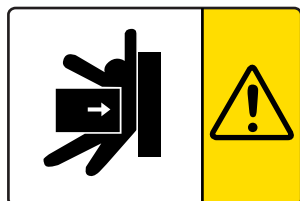
### “NO STEP” LINE

The area beyond the breast cut out has been designed and tested to support the patient's upper torso; it is NOT designed to support the entire patient load.

Standing or sitting on the Couch Top Insert beyond the breast cut out may damage the Couch Top Insert or cause injury.

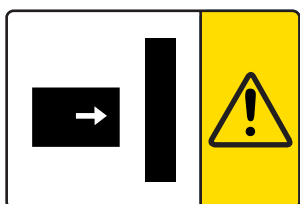
# GENERAL PRECAUTIONS

## WARNING LABELS & DESCRIPTIONS



### POTENTIAL INJURY

There is potential for injury between the Couch Top Insert and other equipment in the treatment suite. Use caution when moving the Couch Top to avoid injury.



### GANTRY COLLISION

The wide variety of motions obtainable by couch bases and treatment heads may present situations where the Couch Top Insert can collide with other items, including the gantry. Use caution when moving the couch or gantry to avoid equipment damage or patient injury.

# 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

## DESCRIPTION

The kVue™ Access 360™ & kVue Access 360™ G2 are designed to allow breast cancer treatment for both left and right breast, including whole breast, partial breast and accelerated breast treatments. Placing the patient in prone position helps increase separation of the breast from critical organs at risk. Exposure to the heart, lung and surrounding healthy tissue may be minimized, while providing the potential for:

- More uniform dose delivery
- Less skin toxicity
- Reduced respiratory motion

The sleek, cantilever design provides both oblique and non-coplanar access, potentially enabling higher dose per fraction. Since the beam path is primarily through the breast with minimal Couch Top interference, artifact and scattering may be minimized.

The Access Prone G2 (RT-4544-01) can be used as a CT/MR simulation device for the Access 360™ G2 (RT-4544KV-10).

**! WARNING ! THE ACCESS 360 (RT-4544KV) CANNOT BE USED AS A SIMULATION DEVICE FOR ANY PRODUCT, OTHER THAN ITSELF OR OTHER ACCESS 360 (RT-4544KV) DEVICES.**

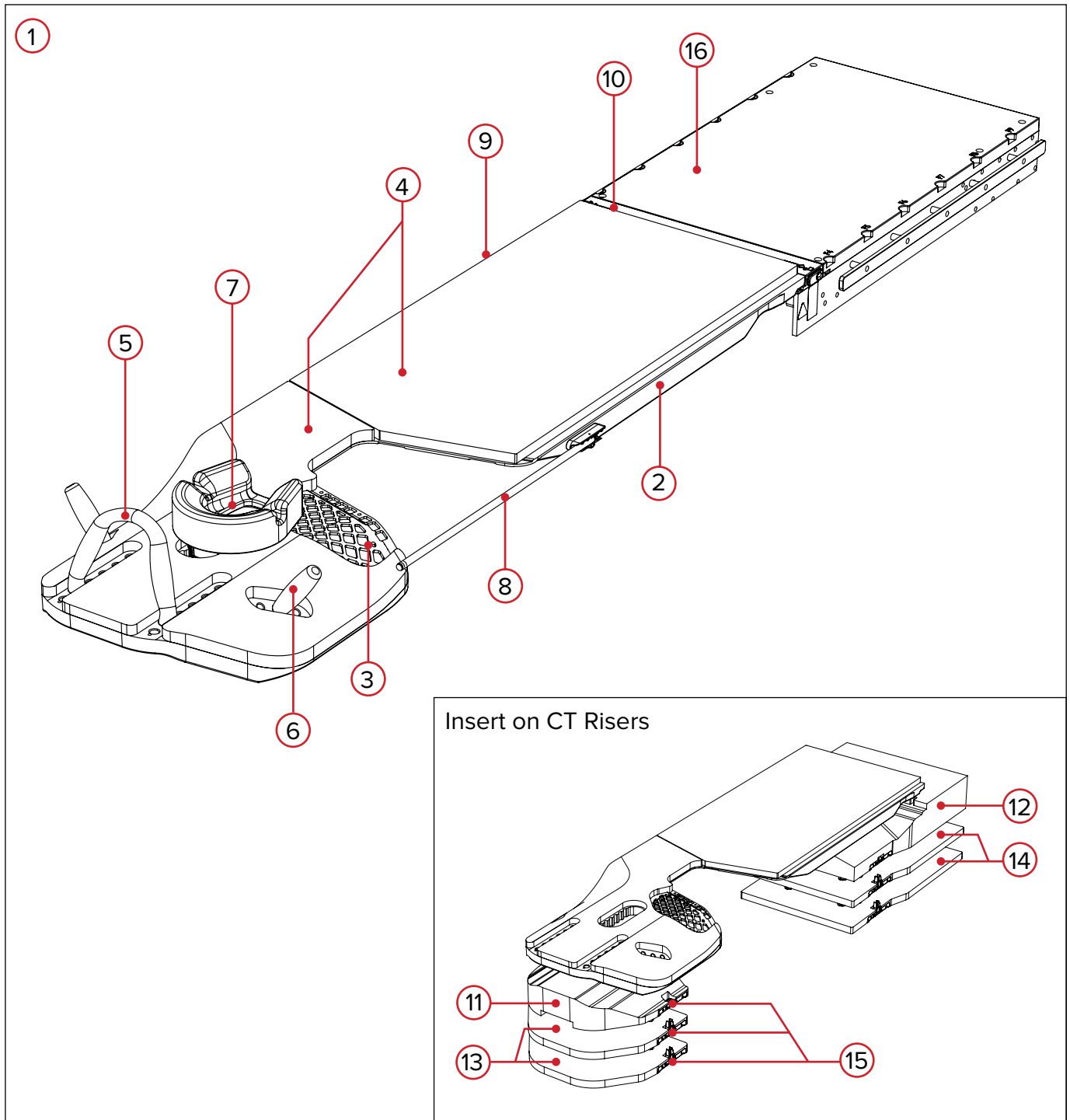
## REQUIRED ACCESSORIES

CT Risers (for Simulation)



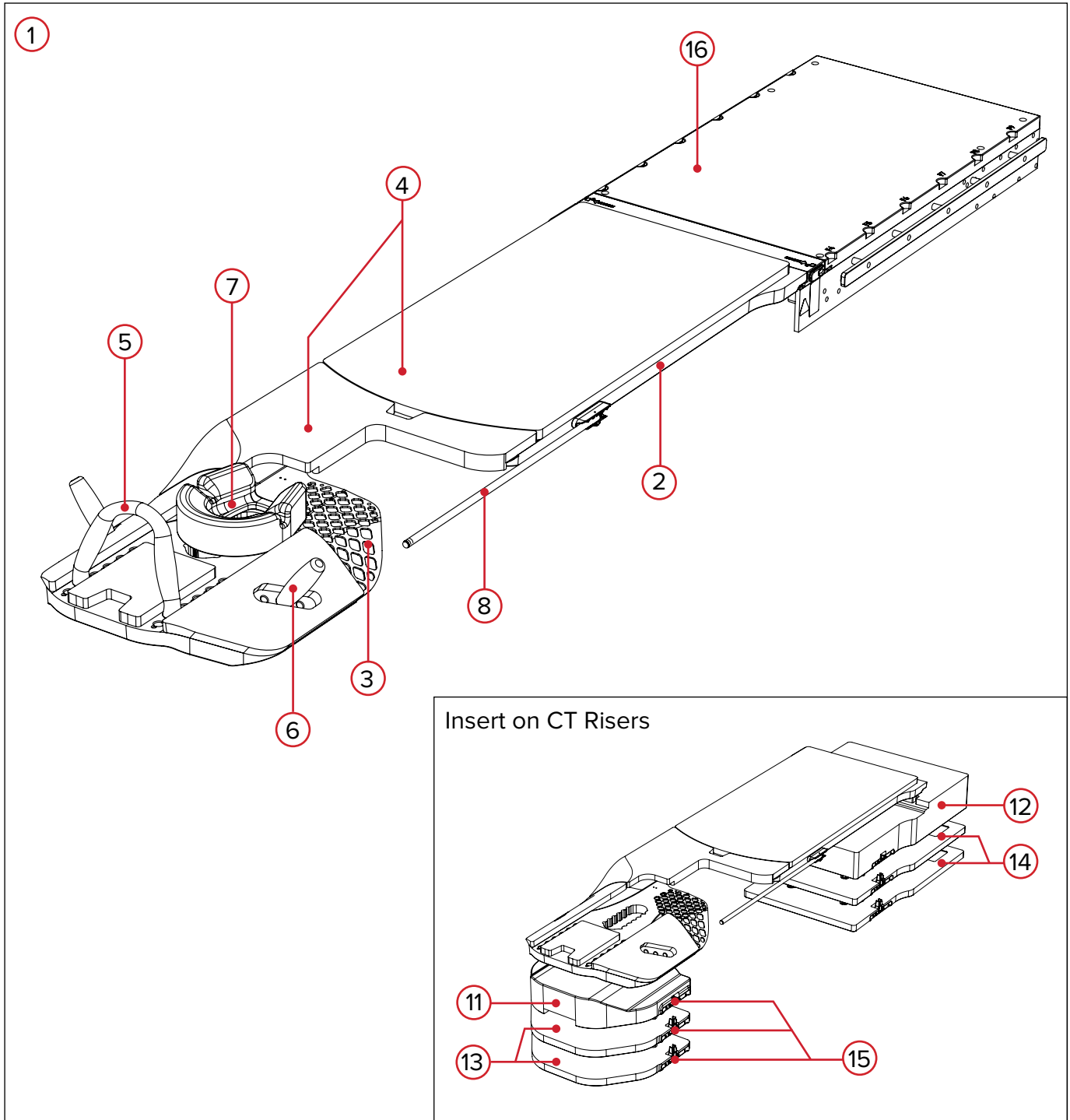
# FEATURES

## KVUE™ ACCESS 360™ COMPONENTS



# FEATURES

## KVUE™ ACCESS 360™ G2 COMPONENTS



# FEATURES

## COMPONENTS

### 1. KVUE™ ACCESS 360™ & KVUE™ ACCESS 360™ G2 PRONE BREAST COUCH TOP INSERT SYSTEM

The Access 360™ & Access 360™ G2 are used to aid in the positioning and setup of patients undergoing radiotherapy of the breast and clavicle region in the prone position.

### 2. KVUE™ ACCESS 360™ & KVUE™ ACCESS 360™ G2 PRONE BREAST COUCH TOP INSERT

The kVue system allows for quick and easy interchanging between the right and left Access 360™ & Access 360™ G2 as well as other kVue Couch top Inserts. The Insert includes a grid to allow for treatment to the clavicle region.

### 3. SUPRACLAVICULAR GRID

The supraclavicular grid allows for treatment to the clavicle region with low attenuation.

### 4. CUSHIONS

The cushions are for patient comfort, however they can be removed and vacuum cushions may be used. The cushions also have additional patient positioning graphics.

### 5. DUAL HAND GRIP

The Dual Hand Grip is ergonomically designed to reduce strain on the patient's wrist, unlike a standard post that is used with other devices.

### 6. HAND GRIP POST

The Hand Grip Posts offer a grip for patients with limited mobility.

### 7. HEADRESTS

The system comes with a Prone and Contour Headrest. Either can be used depending on the preference of set-up. They can be indexed to the Insert in multiple locations depending on the patient's height.

### 8. IPSILATERAL SCALE

The Ipsilateral Scale swings and snaps superiorly for setup, and swings back inferiorly for treatment and storage. The scale may be used as an alignment aid. It's accuracy is  $\pm 1$  mm.

### 9. CONTRALATERAL SCALE

**Access 360™:** The Contralateral Scale is located along the contralateral side of the Insert and may be used as an alignment aid. The scale's accuracy is  $\pm 1$  mm. (Available on Access 360 only)

**Access 360™ G2:** Additional Ipsilateral scales are available for use on the contralateral side. (Access 360 G2 only)

### 10. INFERIOR SCALE

The Inferior Scale is located below the Knee Markings on the Insert and may be used as an alignment aid. The scale's accuracy is  $\pm 1$  mm. (Available on Access 360 only)

# FEATURES

## COMPONENTS

### 11. SUPERIOR CT RISER

The Superior CT Riser indexes to the CT Overlay by using a Locating Bar. It raises the superior end of the Insert 13 cm, and is used in conjunction with the Inferior CT Riser during simulation.

### 12. INFERIOR CT RISER

The Inferior CT Riser indexes to the CT Overlay by using a Locating Bar. It raises the inferior end of the Insert 13 cm, and is used in conjunction with the Superior CT Riser during simulation.

### 13. SUPERIOR CT RISER SHIM

The CT Riser Shim indexes to a Locating Bar and raises the Superior CT Riser in increments of 2.5 cm. This shim can snap to another Superior CT Riser Shim, as well as the Superior CT Riser.

### 14. INFERIOR CT RISER SHIM

The CT Riser Shim indexes to a Locating Bar and raises the Inferior CT Riser in increments of 2.5 cm. This shim can snap to another Inferior CT Riser Shim, and can be screwed into the Inferior CT Riser.

### 15. INDEXING PLATE

The CT Risers contain Indexing Plates, which locate the CT Risers to the Couch Top using a Locating Bar. The Indexing Plates on the CT Risers, snap into the Indexing Plates on the CT Shims for height adjustment.

### 16. kVUE™ COUCH TOP

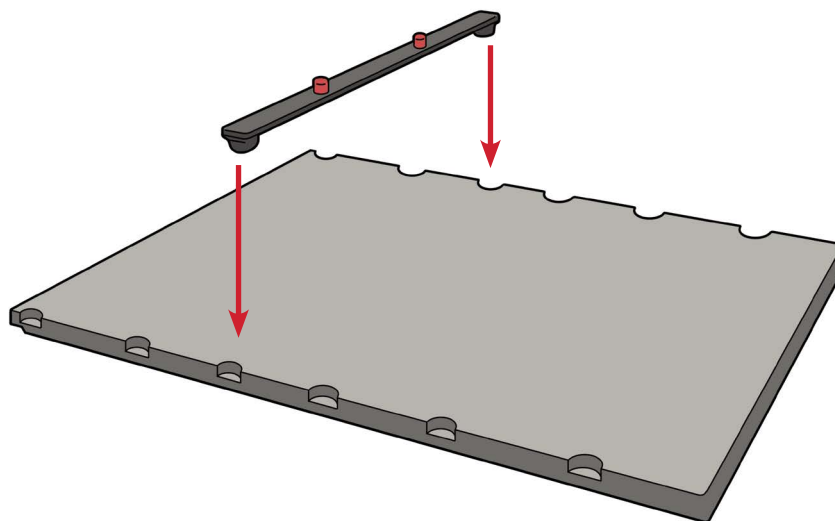
The kVue Couch Top is the complete patient support system, excluding the original equipment couch base. It consists of the Baseframe (including support beams), the Interface Plate (if required), and the appropriate kVue Couch Top Insert. (For more information refer to the kVue Installation and User Manual)

# OPERATING INSTRUCTIONS

## SET-UP

### LOCATING BAR

The Locating Bar has two locating pins that match most standard positioning accessories. To attach, place either end of the Locating Bar in the appropriate Varian Exact® compatible index notches and snap in place. To remove or reposition, pull up on either end of the bar.



# OPERATING INSTRUCTIONS

**! NOTE !** Due to the length of the device it is recommended to have two people handle the device during installation and removal.

## ATTACHING THE CT RISERS AND CT SHIMS TO THE OVERLAY

1. Attach 2 Locating Bars 1260 mm (typically 9 index notches) apart and snap into place (Fig. 1 & 2).

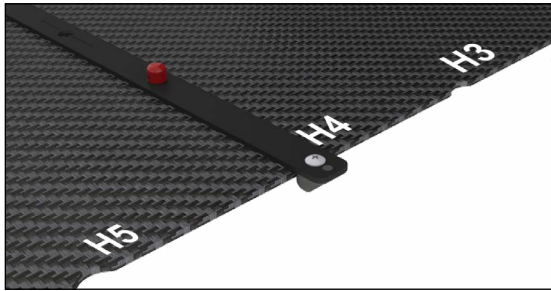


Fig. 1

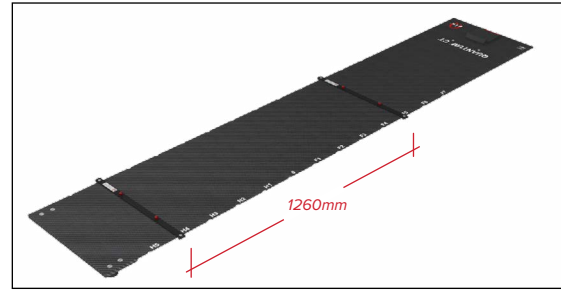


Fig. 2

2. Place the CT Risers and CT shims, depending on your intended setup, onto the Locating Bars (Fig. 3 & 4). Be sure to index the CT Risers and CT Shims using the same locations on both the Inferior and Superior CT Riser A, B, C, or D (Fig. 5, 6 & 7). Shims may be stacked on each other to increase the height by 2.5 cm increments.

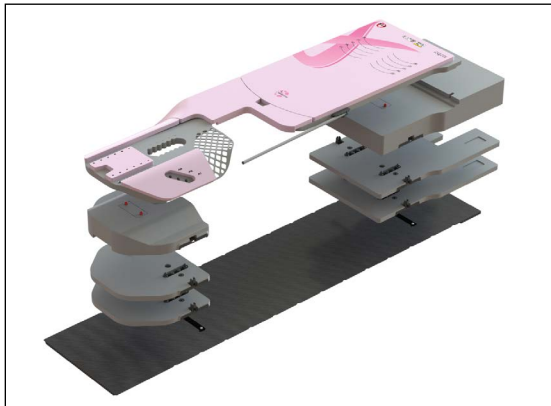


Fig. 3

OR

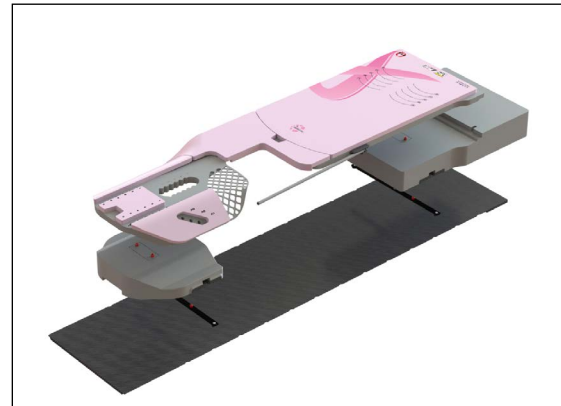


Fig. 4

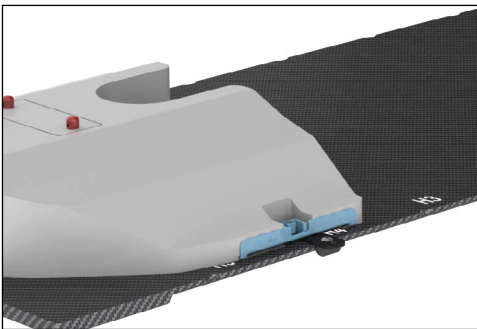


Fig. 5

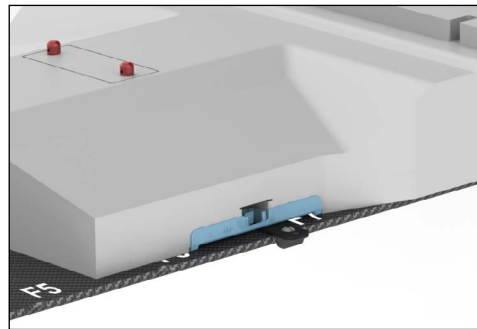


Fig. 6

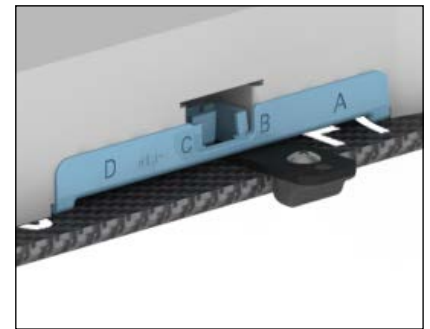


Fig. 7

# OPERATING INSTRUCTIONS

3. To decrease the height of the device or remove CT Risers and Shims, remove the Access 360™ or Access 360™ G2. While pressing the release buttons on each side of the indexing plate lift the CT Riser or CT Shim off the CT Shim below and remove (Fig. 8).

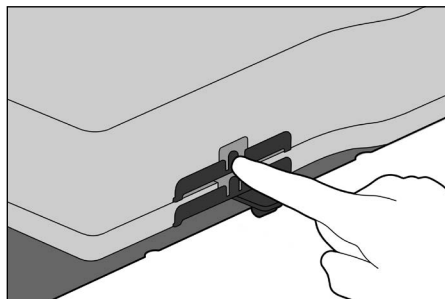


Fig. 8

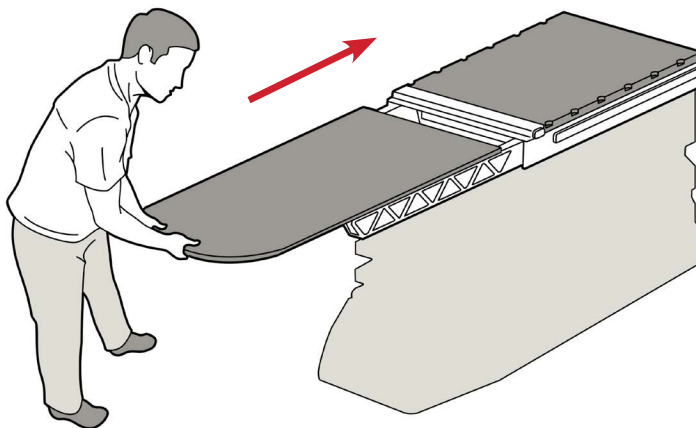
# OPERATING INSTRUCTIONS

## INSTALLATION

**! NOTE !** Due to the length of the device, it is recommended to have two people handle the device during installation and removal.

### COUCH TOP INSERT INSTALLATION

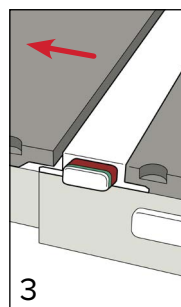
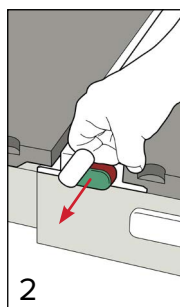
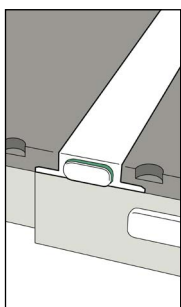
1. Place the kVue Couch Top Insert on top of the support beams and align the two mating pins with the receiving holes in the OneTouch Latch.
2. From the head end of the kVue Couch Top, slide the Couch Top Insert directly into the receiving holes. You will hear a click when the Couch Top Insert is locked into place. **ONLY** the green button surface will be visible when properly installed.



### COUCH TOP INSERT REMOVAL

**! NEVER LIFT THE END OF THE COUCH TOP INSERT ! ALTHOUGH THE MECHANISM IS VERY ROBUST, THE MATING PINS MAY BEND OR BREAK, RENDERING THE COUCH TOP UNUSABLE.**

1. Rotate Lever counter-clockwise.
2. Pull the rotated Lever from one side of the Couch Top until the Couch Top Insert is released. This can be accomplished with one hand.
3. Slide the Couch Top Insert away from the Couch Top.





# OPERATING INSTRUCTIONS

## SET-UP

### HEADREST

1. Choose either the Prone Headrest or Contour headrest to use for patient. (Prone Headrest shown below)
2. Insert the plastic alignment piece into the appropriate slot (A, B, C, D, E, F) at the superior end of the device (Fig. 9 & 10).
3. To remove or reposition pull the headrest upward away from the Insert.

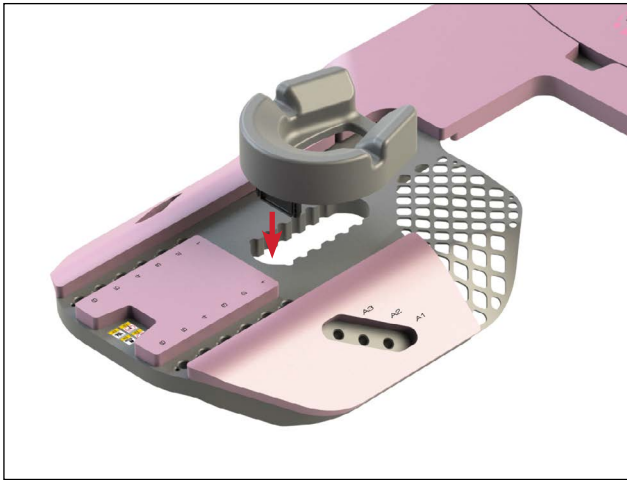


Fig. 9

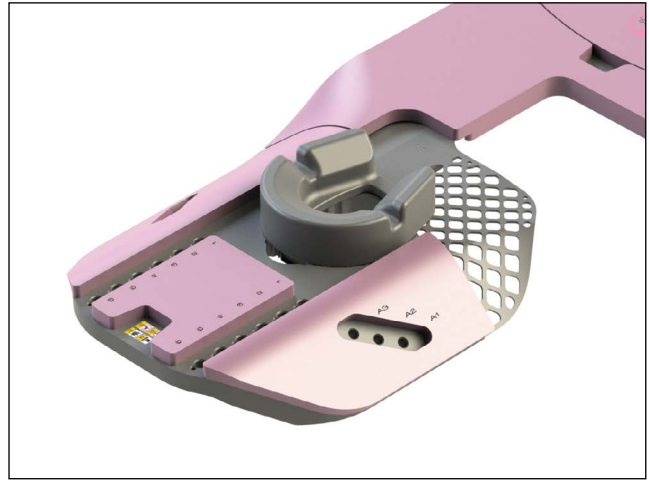


Fig. 10

# OPERATING INSTRUCTIONS

## SET-UP

### DUAL HAND GRIP

**! CAUTION ! THE DUAL HAND GRIP AND HAND GRIP POSTS ARE NOT DESIGNED TO SUPPORT A PATIENT'S WEIGHT:**

- **DO NOT** use handles to position the patient.
- **DO NOT** use handles to get on or off of the device.

1. Align ends of the Dual Hand Grip with corresponding holes (1, 2, 3, 4, 5, 6) at the superior end of the Insert.
2. Push down on the Dual Hand Grip into the holes (Fig. 11 & 12).

**! NOTE !** The Dual Hand Grip should be arched back towards the patient as shown in the image below (Fig. 10).

3. To remove or reposition the Dual Hand Grip, pull upward until it snaps out of the holes (Fig. 11 & 13).

**! NOTE !** Pressure should be applied to the top of the Insert when removing handles so it does NOT lift upward; although the mechanism is very robust, the mating pins may bend or break, rendering the Couch Top unusable.

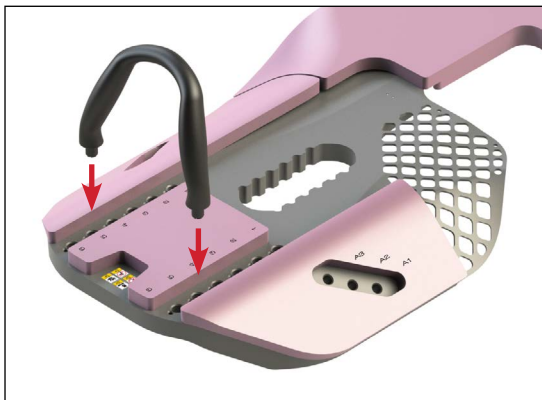


Fig. 11

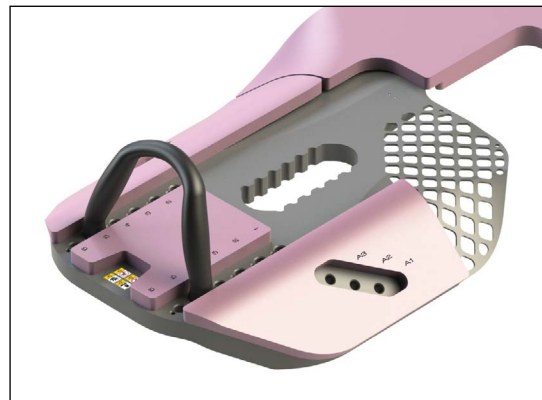


Fig. 12

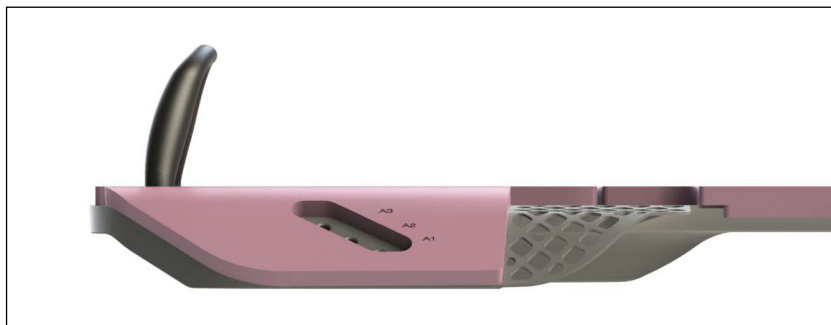


Fig. 13

# OPERATING INSTRUCTIONS

## SET-UP

### HAND GRIP POSTS

1. Insert the Hand Grip Posts into the appropriate hole (A1, A2, A3) at the superior end of the Insert (Fig. 14).
2. Turn the Hand Grip Posts either direction until handle tightens in the hole and locks into place (Fig. 15).
3. To remove the Hand Grip Posts turn the opposite direction of installation until the handle loosens, then pull straight out (Fig. 14 & 15).

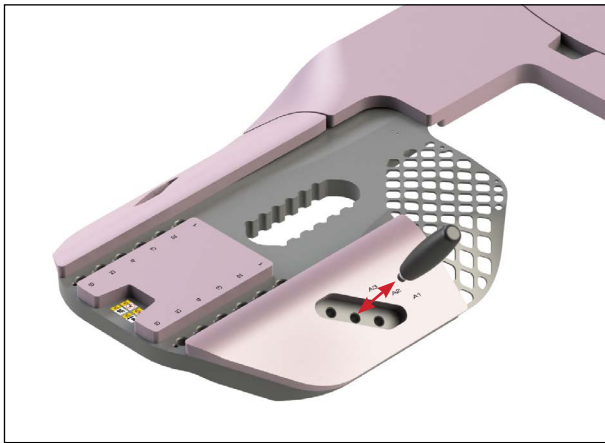


Fig. 14

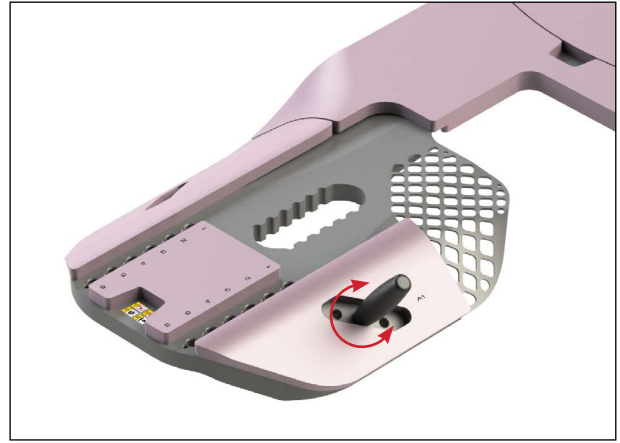


Fig. 15

# OPERATING INSTRUCTIONS

## PATIENT POSITIONING

**! NOTE !** Patients may need assistance getting on and off of the device. The instructions below are our suggested technique, but may vary for each clinic.

### HOW TO GET ON AND OFF THE ACCESS 360™ & ACCESS 360™ G2

1. Lower the Couch or use a step stool to assist the patient in getting onto the Insert.
2. Once the patient is on the insert, line up their knees with the proper markings on the foam.
3. Have the patient use their hands or elbows to move their upper body into position.
4. Have the patient slowly lower into position.
5. Once in position, place the patients head onto the head rest and have them grab the hand grips.
6. To get off of the Insert, follow steps in reverse.

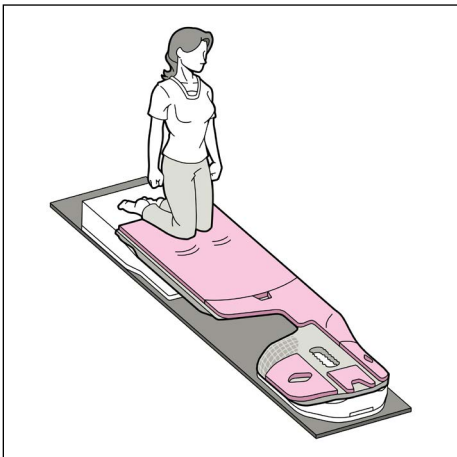


Fig. 16

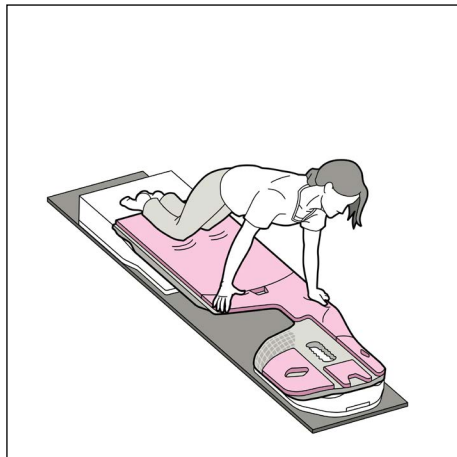


Fig. 17

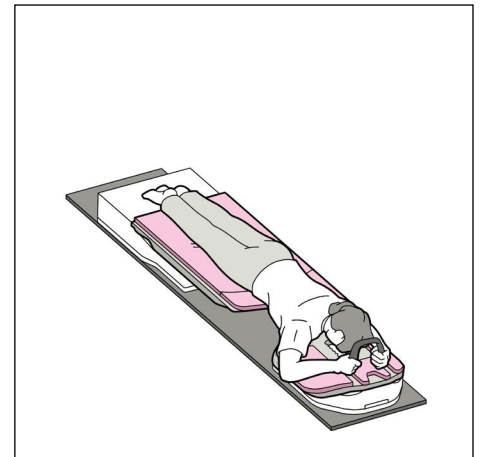


Fig. 18

# OPERATING INSTRUCTIONS

## SET-UP

### IPSILATERAL SCALE

**! CAUTION ! THE IPSILATERAL SCALE IS NOT DESIGNED TO SUPPORT A PATIENT'S WEIGHT.**

1. Once patient is in place, swing Ipsilateral scale superiorly until it locks into place (Fig. 20).
2. Align the patient.

**! NOTE !** The scales are present as an alignment aid; it is the user's responsibility to confirm the position of the patient.

**! NOTE !** The scales accuracy are tested to  $\pm 1$  mm.

3. Swing the Ipsilateral Scale inferiorly, into it's storage position, prior to treatment and/or storage (Fig. 19 & 20).



Fig. 19: Storage Position



Fig. 20

# 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. 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.

- Water
- Soap and Water

## DISINFECTING THE SYSTEM

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

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

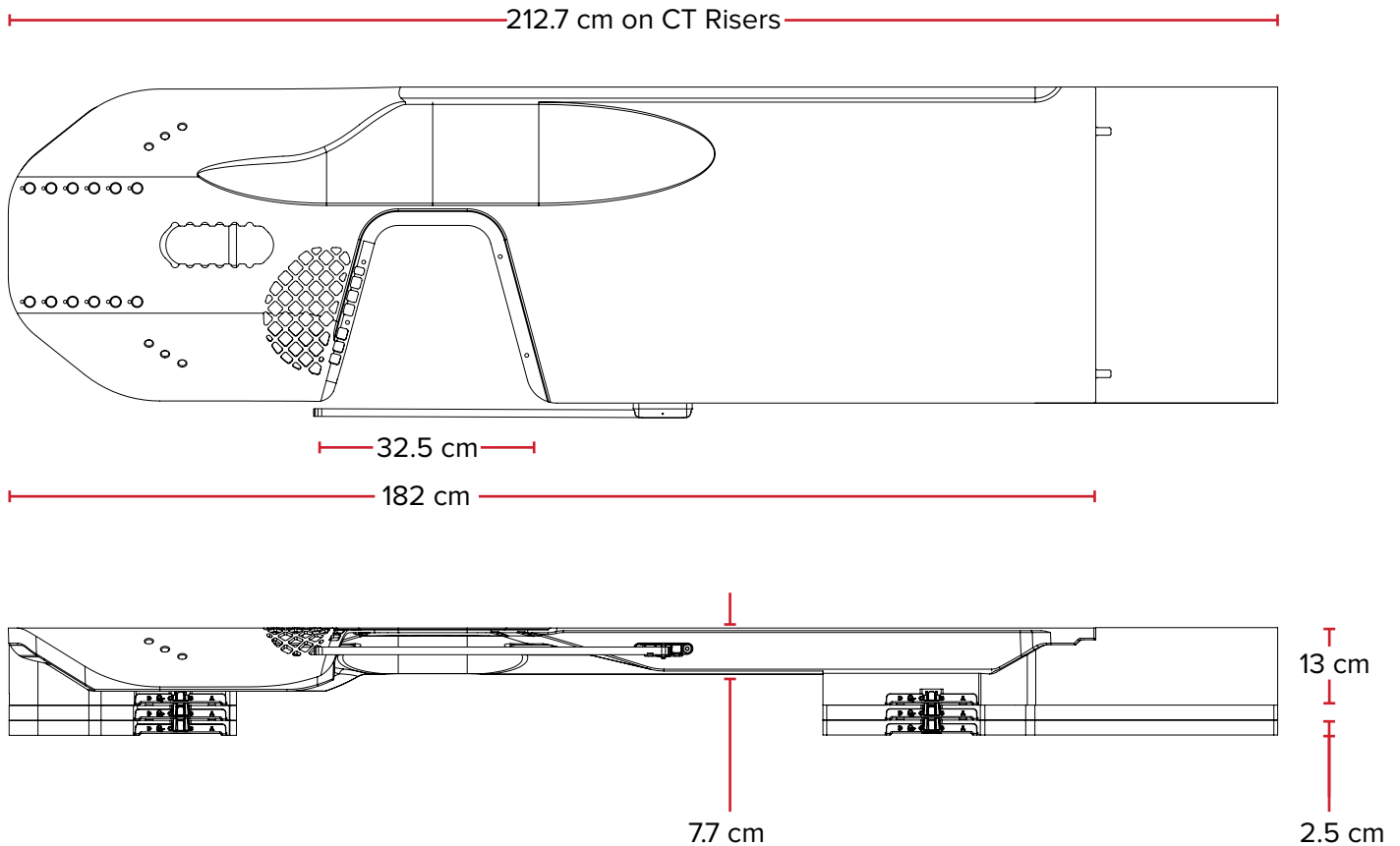
DO NOT spray directly onto the Couch Top or Couch Top Insert or allow to flow into the Baseframe.

DO NOT place sharp objects on the Couch Top or Couch Top Insert.

# SPECIFICATIONS

## ACCESS 360™

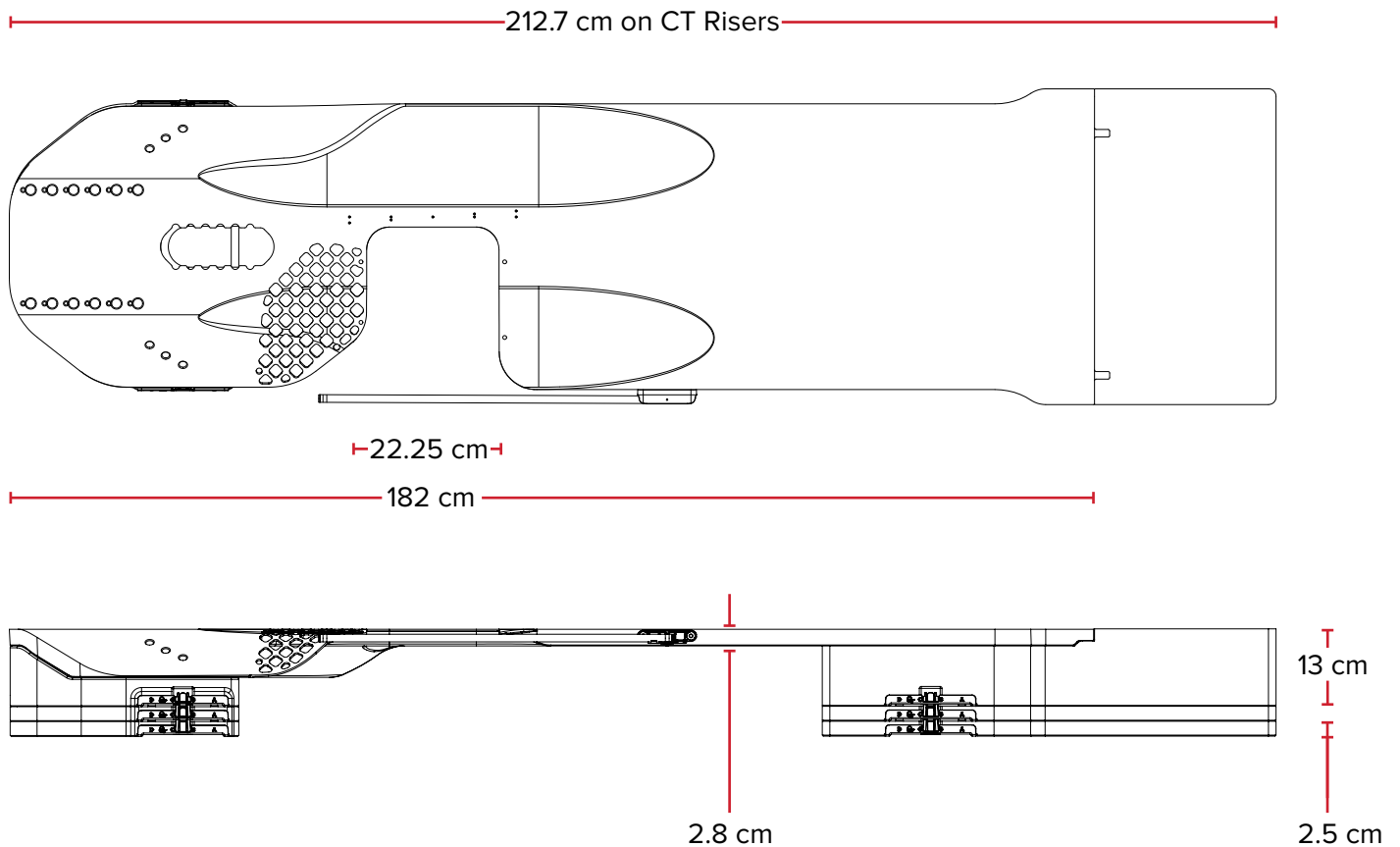
**Weight Limit:** 200 kg (440 lb) for a uniformly distributed load.



# SPECIFICATIONS

## ACCESS 360™ G2

**Weight Limit:** 200 kg (440 lb) for a uniformly distributed load.





# PATIENT SETUP

## KVUE™ ACCESS 360™ COUCH TOP INSERT

Patient Name:

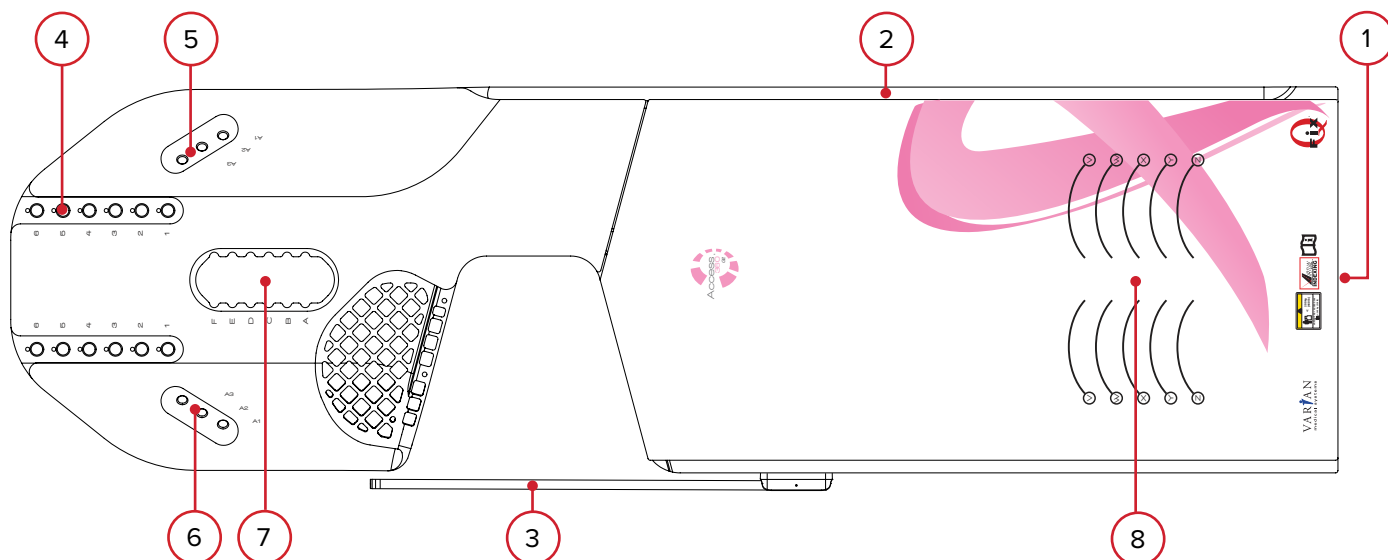
Patient ID #:

Setup by:

Physician:

Date:

Comments:



Left Insert

Right Insert

**! NOTE ! Left insert is shown above.**

1. Inferior Alignment:

2. Contralateral Scale:

3. Ipsilateral Scale:

4. Dual Hand Grip Location (select one): **1** **2** **3** **4** **5** **6** **N/A**

5. Hand Grip Post, Patient Right (select one): **A1** **A2** **A3** **N/A**

6. Hand Grip Post, Patient Left (select one): **A1** **A2** **A3** **N/A**

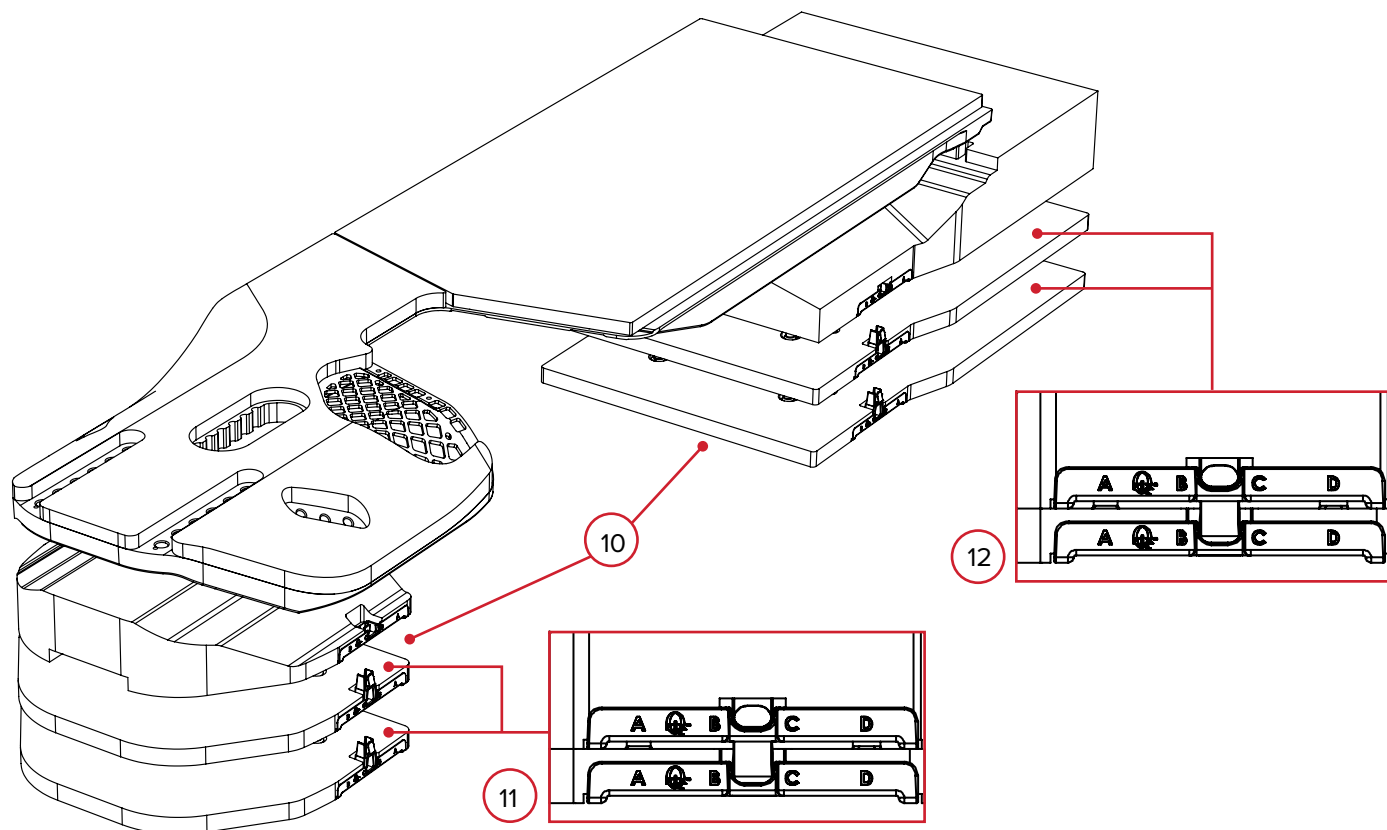
7. Headrest used: **None** **Prone** **Contour** Location (select one): **A** **B** **C** **D** **F**

8. Knee Location (select one): **V** **W** **X** **Y** **Z**

9. Additional Notes:

# PATIENT SETUP

## KVUE™ ACCESS 360™ COUCH TOP INSERT (CONTINUED)



**! NOTE !** Left insert is shown above.

### CT Risers and Shims

10. How many sets of CT Riser Shims are being used (select one): **0**    **1**    **2**    **3**

11. Superior CT Riser – Location on Locating Bar (select one): **A**    **B**    **C**    **D**

11a) Indexing Bar location on Couch Top:

12. Inferior CT Riser – Location on Locating Bar (select one): **A**    **B**    **C**    **D**

12a) Indexing Bar location on Couch Top:

13. Additional Notes:

# PATIENT SETUP

## KVUE™ ACCESS 360™ G2 COUCH TOP INSERT

Patient Name:

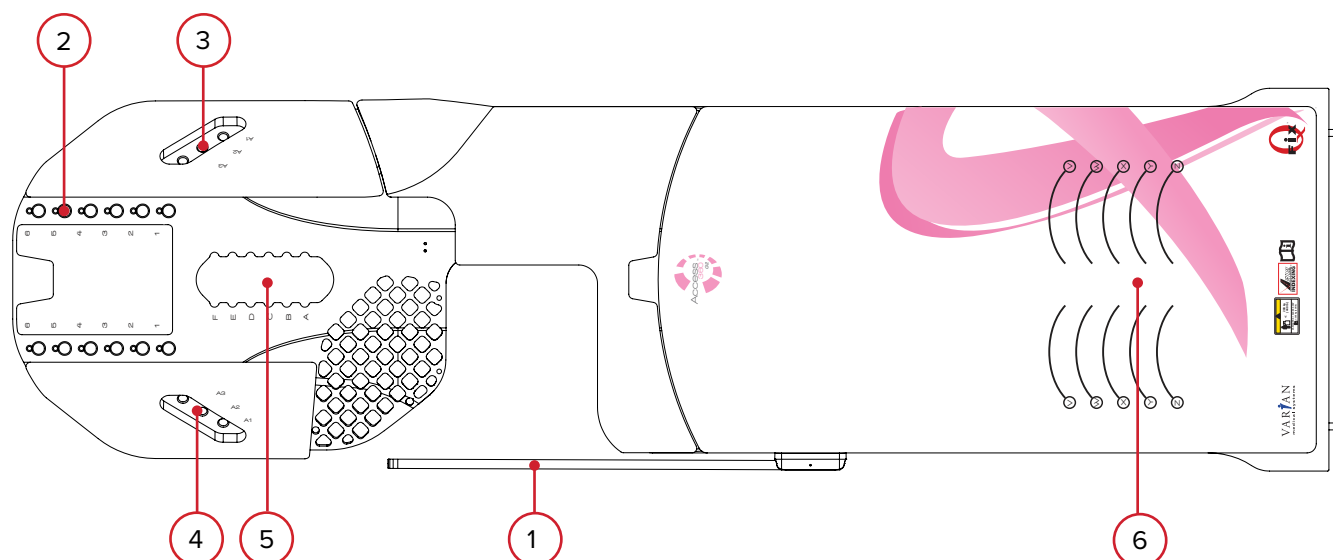
Patient ID #:

Setup by:

Physician:

Date:

Comments:



Left Insert

Right Insert

**! NOTE ! Left insert is shown above.**

1. Ipsilateral Scale:

2. Dual Hand Grip Location (select one): **1**    **2**    **3**    **4**    **5**    **6**    **N/A**

3. Hand Grip Post, Patient Right (select one): **A1**    **A2**    **A3**    **N/A**

4. Hand Grip Post, Patient Left (select one): **A1**    **A2**    **A3**    **N/A**

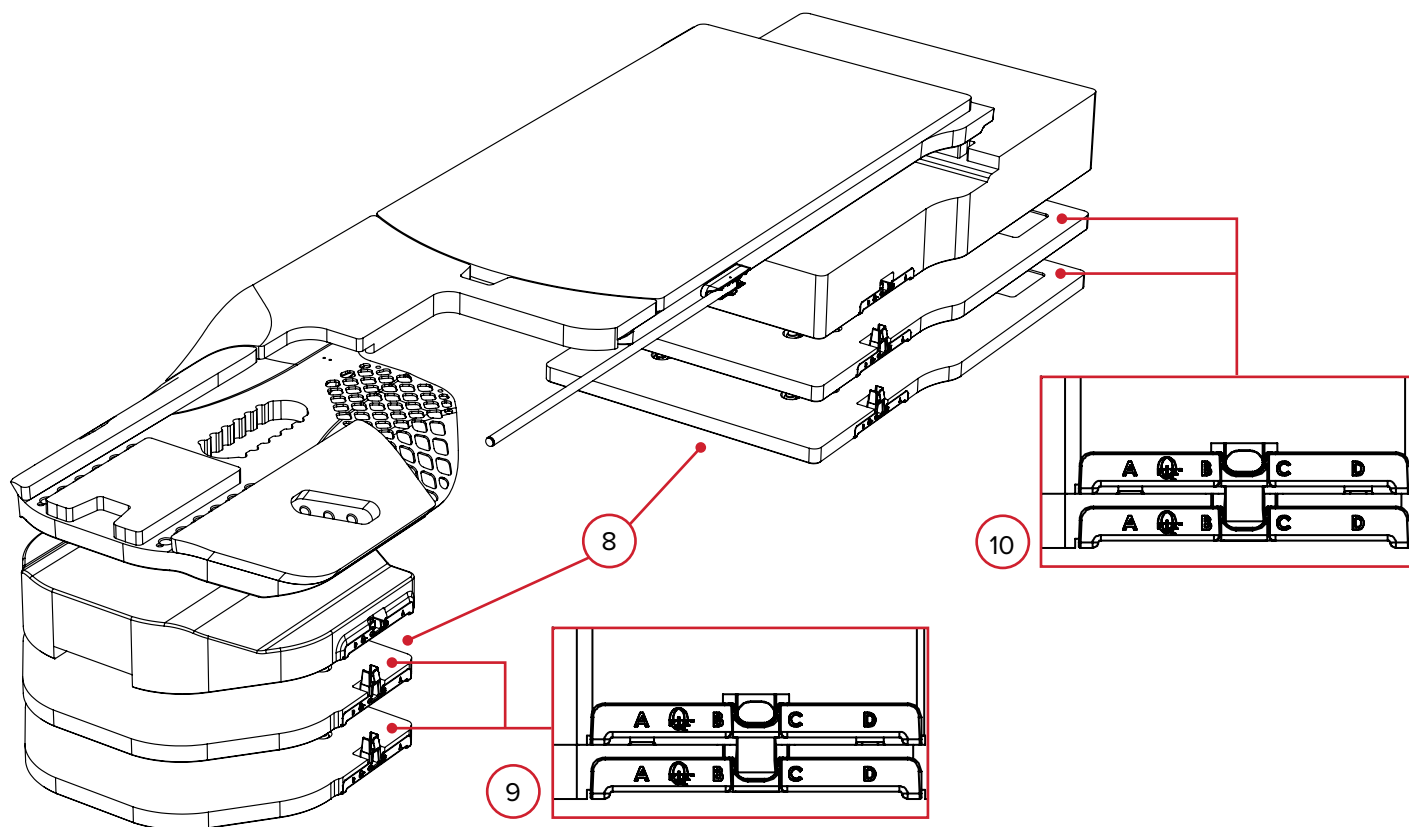
5. Headrest used: **None**    **Prone**    **Contour**    Location (select one): **A**    **B**    **C**    **D**    **F**

6. Knee Location (select one): **V**    **W**    **X**    **Y**    **Z**

7. Additional Notes:

# PATIENT SETUP

## KVUE™ ACCESS 360™ G2 COUCH TOP INSERT (CONTINUED)



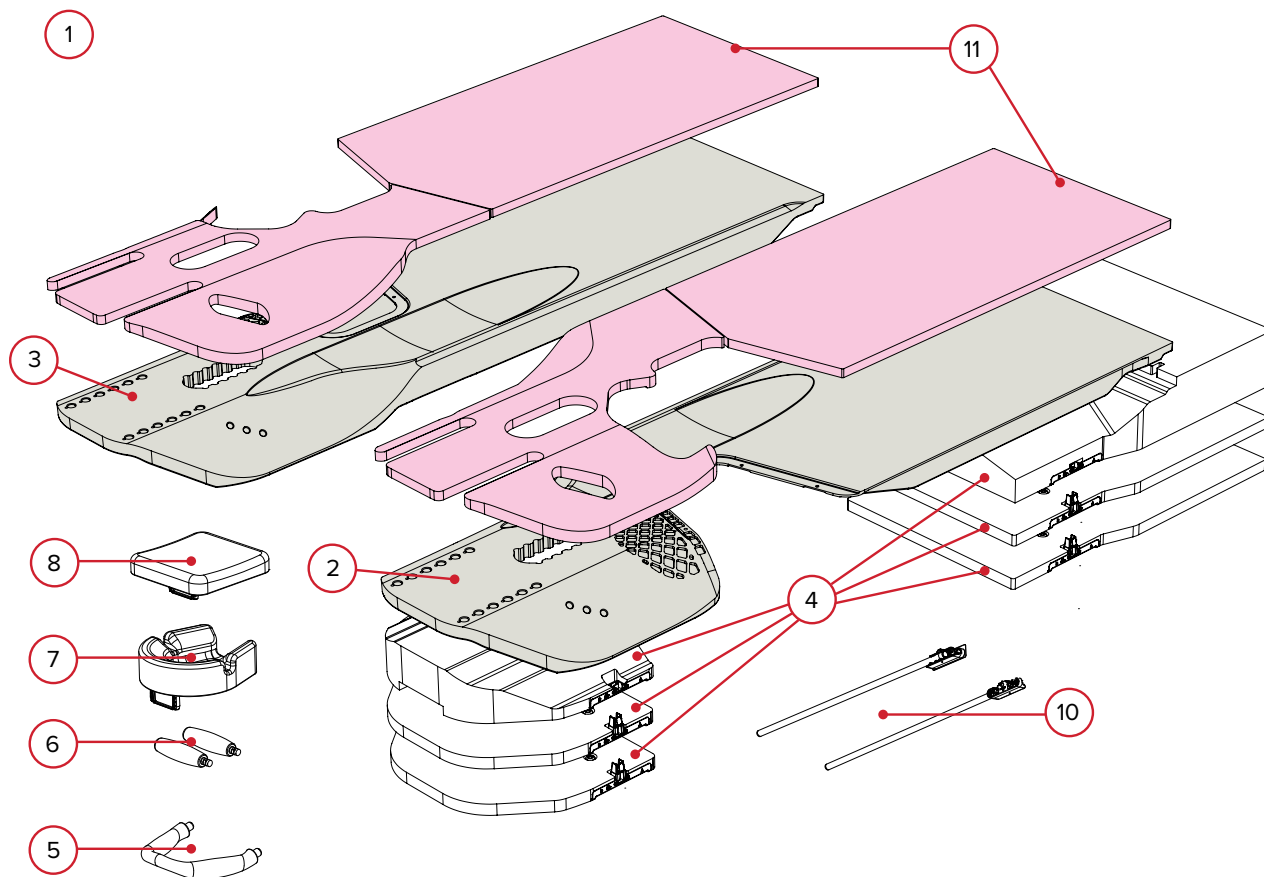
**! NOTE !** Left insert is shown above.

### CT Risers and Shims

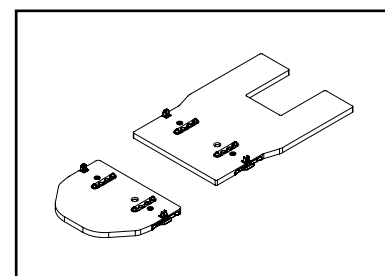
8. How many sets of CT Riser Shims are being used (circle one): **0**    **1**    **2**    **3**
9. Superior CT Riser – Location on Locating Bar (circle one): **A**    **B**    **C**    **D**  
9a) Indexing Bar location on Couch Top:
10. Inferior CT Riser – Location on Locating Bar (circle one): **A**    **B**    **C**    **D**  
10a) Indexing Bar location on Couch Top:
11. Additional Notes:

# PARTS LIST

## KVUE™ ACCESS 360™ COUCH TOP INSERTS



1. RT-4544KV – kVue Access 360 Package
2. RT-4544KV-01 – kVue Access 360 Couch Top Insert, Left Breast
3. RT-4544KV-02 – kVue Access 360 Couch Top Insert, Right Breast
4. RT-4544KV-03 – kVue Access 360 CT Riser Set
5. RT-4544KV-04 – Dual Grip Handle
6. RT-4544KV-05 – Hand Grip Post
7. RT-4544KV-06 – Prone Headrest
8. RT-4544KV-07 – Contour Headrest
9. RT-4551CART – Storage Cart (not shown in diagram)
10. 8001846 – Ipsilateral Scale
11. 8001946 – Access 360 Pad Set

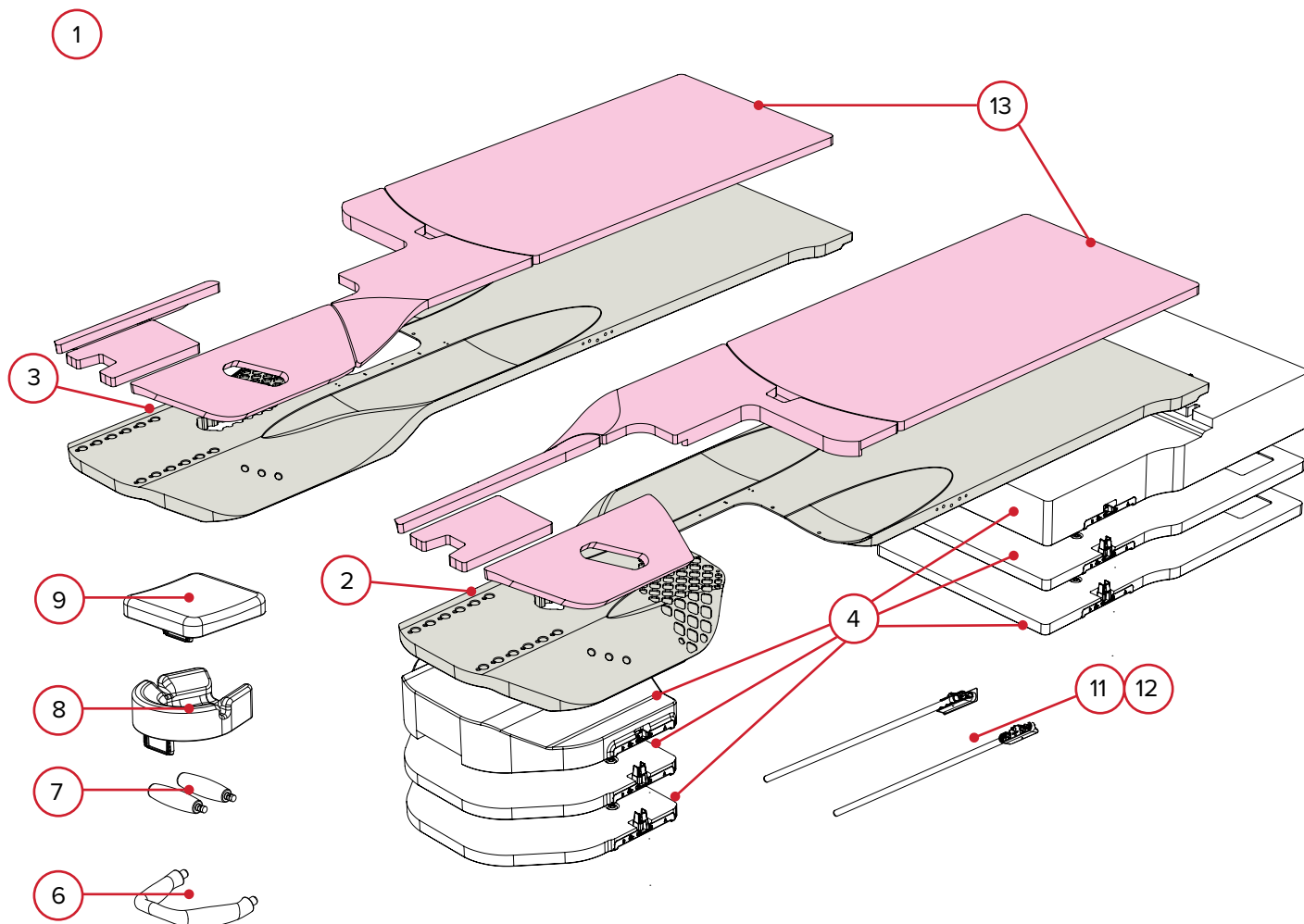


RT-4544KV-03A

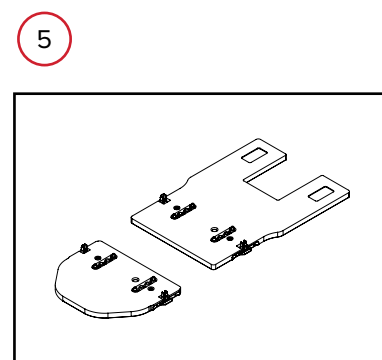
kVue™ Access 360™ Shim Set  
(Sold Separately)

# PARTS LIST

## KVUE™ ACCESS 360™ G2 COUCH TOP INSERTS



1. RT-4544KV-10 – kVue Access 360 G2 Package
2. RT-4544KV-11 – kVue Access 360 G2 Couch Top Insert, Left Breast
3. RT-4544KV-12 – kVue Access 360 G2 Couch Top Insert, Right Breast
4. 8002581 – kVue Access 360 G2 CT Riser Set
5. 8002579 – kVue Access 360 G2 Shim Set
6. RT-4544KV-04 – Dual Grip Handle
7. RT-4544KV-05 – Hand Grip Post
8. RT-4544KV-06 – Prone Headrest
9. RT-4544KV-07 – Contour Headrest
10. RT-4551CART – Storage Cart (not shown in diagram)
11. 8002601 – 40 cm Ipsilateral Scale (Replacement)
12. 8002602 – 48 cm Ipsilateral Scale (Accessory)
13. 8003038 – Access 360 G2 Pad Set



8002579

kVue™ Access 360™ G2 Shim Set  
(Sold Separately)





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