



positioning
patients for life.®

PRODUCT GUIDE & USER MANUAL


RT-4551KV10

kVue™ Brachy Insert

for kVue Couch Top





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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.

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.

LOAD RATING

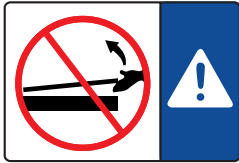
DO NOT exceed 200 kg (440 lbs) uniformly distributed load or maximum working load of couch base, whichever is less.

! 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.

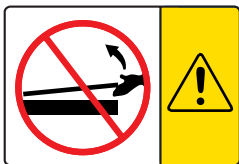
GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS

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



OR

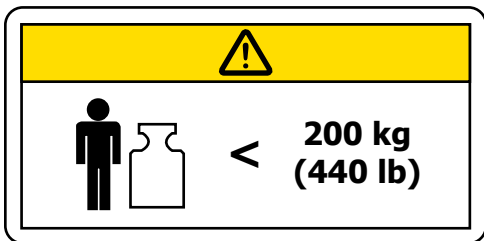


KVUE INSERT INSTALLATION AND REMOVAL

! NEVER LIFT THE END OF THE KVUE INSERT !

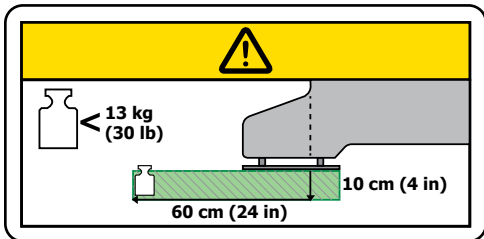
The mating pins may bend or break, rendering the kVue unusable.

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



LOAD RATING

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



LOAD RATING

Do NOT exceed 13 kg at 10 cm (30 lb at 4 in) laterally from the accessory rail, and 61 cm (24 in) superiorly from the perennial cut out.



TRAPPING ZONE

Use caution when moving the kVue to avoid patient injury. A trapping zone may occur between the kVue Insert and the support beams.

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.

OPERATING INSTRUCTIONS

INSTALLATION

KVUE INSTALLATION

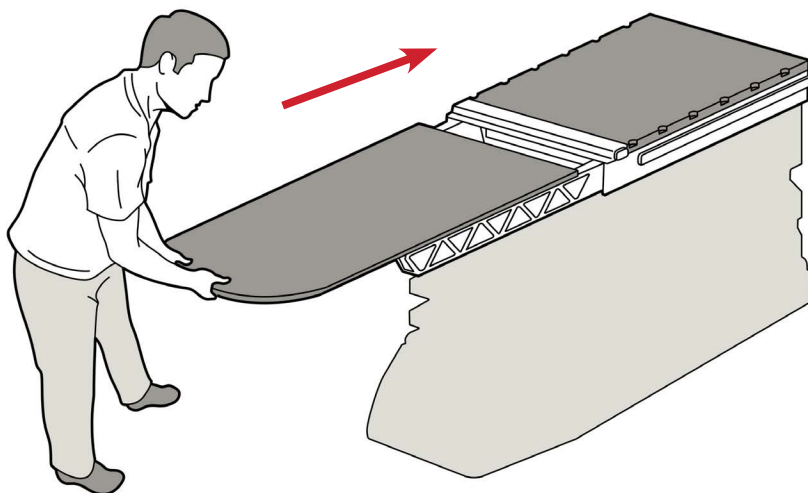
The kVue is designed to fit all major radiotherapy treatment systems. Quick installation minimizes linear accelerator downtime during installation. Refer to the kVue Couch Top Installation Manual for specific installation information.

! 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 Brachy Insert directly into the receiving holes.

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



kVue with Standard Insert

OPERATING INSTRUCTIONS

SET-UP

PERINEAL FILLER AND PADS

1. Once Brachy Insert is installed onto the kVue, insert the Perineal Filler in place, if needed. (Fig. 1)
2. Place Brachy Insert Pad over the Brachy Insert and kVue Back Panel. (Fig. 2)
3. Place Perineal Pad onto the Perineal Filler, if needed. (Fig. 3 & 4)



OPERATING INSTRUCTIONS

REMOVAL

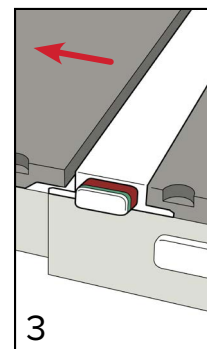
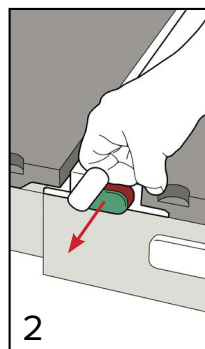
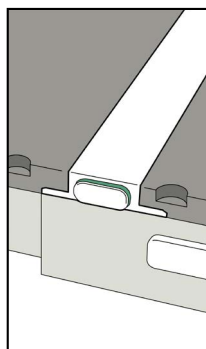
PERINEAL FILLER AND PADS

1. Remove Perineal Pad from the Perineal Filler, by pulling upward.
2. Remove Brachy Insert Pad from the Brachy Insert and kVue Back Panel, by pulling upward. This pad may be folded in half and stored.
3. Remove the Perineal Filler, by pulling upward.

KVUE INSERT REMOVAL

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

1. Rotate Lever counter-clockwise.
2. Pull the rotated Lever from one side of the kVue until the kVue Insert is released.
3. Slide the kVue Insert away from the kVue.



MAINTENANCE

CLEANING THE SYSTEM

The device can be cleaned with a mild, non-abrasive cleaning or disinfecting solution. Do not spray or pour liquids onto the kVue surface as they may flow into the OneTouch Latch or mechanisms within the couch base. 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 kVue and Brachy Insert surfaces. To disinfect the Brachy Insert surface, refer to specific instructions from the cleaning agent manufacturer.

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

DO NOT spray directly onto the kVue or Brachy Insert or allow to flow into the Baseframe.

DO NOT place sharp objects on the kVue or Brachy Insert.

SPECIFICATIONS

LENGTH (RT-4551KV10): 1042 mm

ALUMINUM EQUIVALENCE: ~0.5 mm @ 100 kVp

WATER EQUIVALENCE: 6 mm @ 6 MV

WEIGHT LIMIT: 200 kg (440 lb) Uniformly Distributed Load

SETUP SHEET

RT-4551KV10 – KVUE BRACHY INSERT

Patient Name:

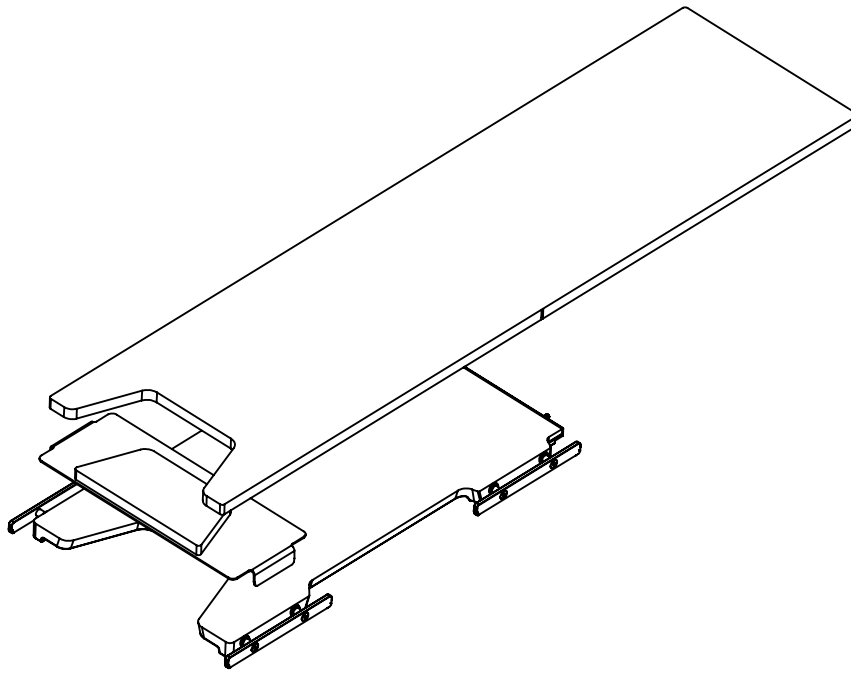
Patient ID #:

Setup by:

Physician:

Date:

Comments:




Moving Rails Location:


Perineal Filler Used: **YES** **NO**

Notes:



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