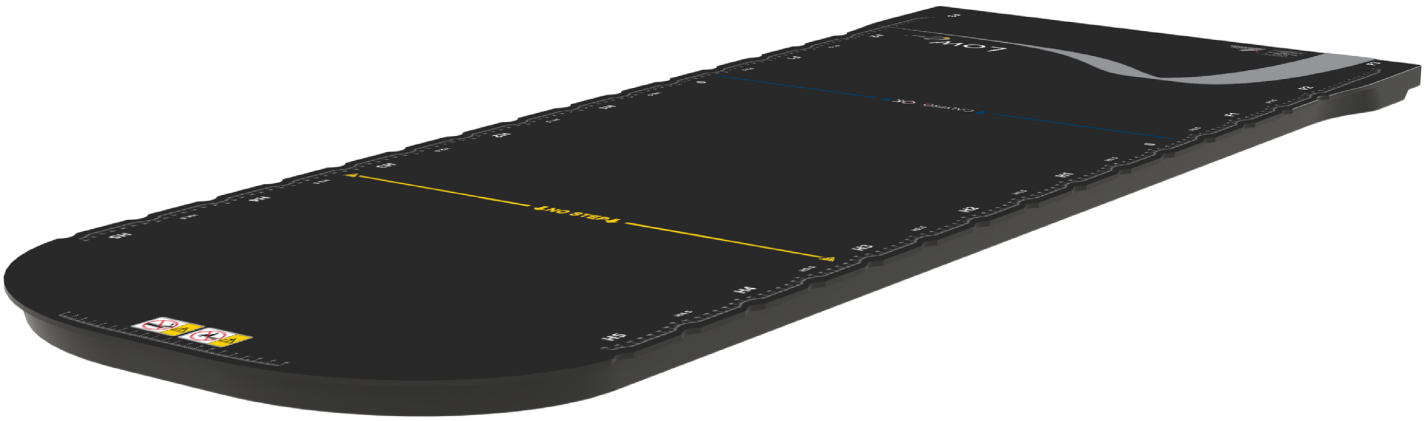
positioning
patients for life.®

PRODUCT GUIDE & USER MANUAL

RT-4551KV19

kVue™ Low-e™ Standard Insert



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CE

EC REP	Advena Limited Tower Business Centre, 2nd Flr Tower Street, Swatar, BKR 4013 Malta	Made in the USA Qfix 440 Church Rd, Avondale, Pennsylvania, USA +1 610-268-0585 www.Qfix.com

! NOTE ! THROUGHOUT THIS IFU "KVUE COUCH TOP" REFERS TO ALL KVUE COUCH TOPS, INCLUDING THE KVUE CALYPSO®, THE KVUE EDGE™, THE KVUE PRO, THE KVUE ONE, AND THE KVUE COUCH TOP.

! NOTE ! THROUGHOUT THIS IFU "KVUE INSERT" REFERS TO ALL KVUE INSERTS, INCLUDING THE LOW-E™ STANDARD INSERT.

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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.

TREATMENT BEAM ATTENUATION

The Low-e Standard Insert (RT-4551KV19) has a lower water equivalence than the Standard Insert (RT-4551KV1) and most kVue Inserts. Actual attenuation based on specific setups 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.

INFERIOR ISOCENTER LINE

The Low-e™ Standard Insert is marked with a blue line that represents the furthest proximal location for the isocenter when using the kVue Couch Top. Contact Varian Medical Systems or refer to Calypso® System User's Manual for more specific information about the importance of this line.

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 249 kg (550 lb) uniformly distributed load or maximum safe 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.

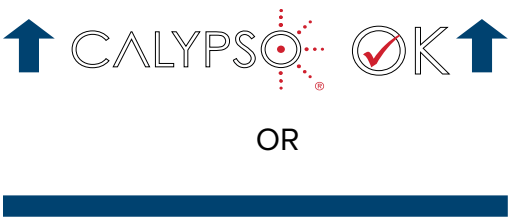
GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS

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

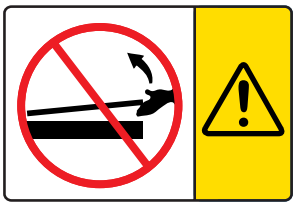
CALYPSO® SYSTEM COMPATIBLE

Indicates Calypso® compatible when used with the kVue Calypso®, the kVue Pro, the kVue One, or kVue EDGE™.



BLUE INFERIOR ISOCENTER LINE

The kVue Calypso® Insert is marked with a blue line that represents the furthest proximal location for the isocenter when using the Calypso® System. Contact your Varian Medical Systems Representative or refer to Calypso® System User's Manual for more specific information about the importance of this line.



KVUE INSERT INSTALLATION & REMOVAL

! WARNING ! NEVER LIFT THE END OF THE KVUE INSERT

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

"NO STEP" LINE

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 or lower torso; it is NOT designed to support the entire patient load.

Standing or sitting on the kVue Insert beyond the "No Step" line may damage the kVue Insert or cause 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.

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OPERATING INSTRUCTIONS

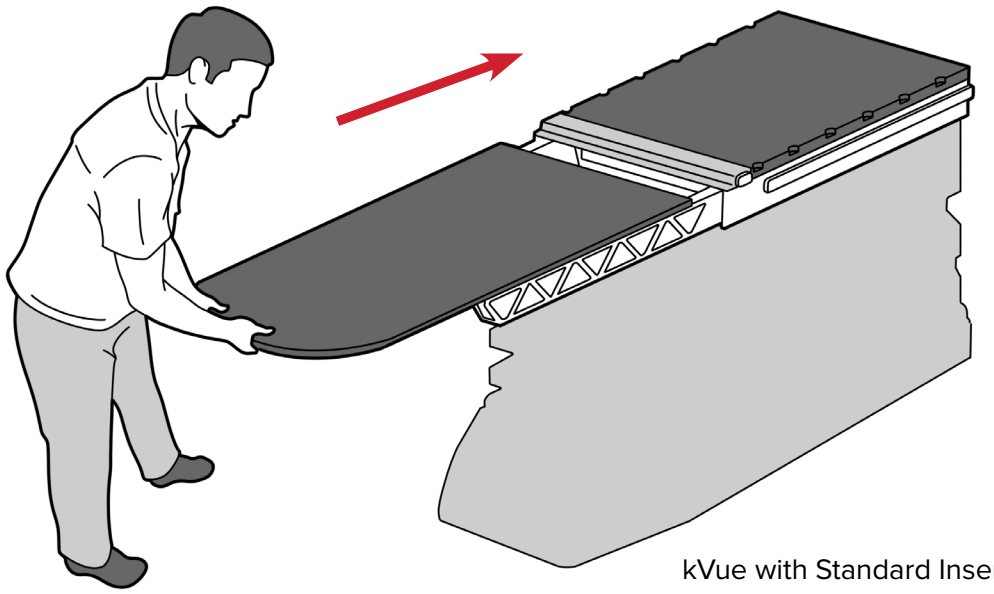
INSTALLATION

KVUE INSERT INSTALLATION

1. Place the kVue 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 kVue Insert directly into the receiving holes.

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

3. Verify insert is fully engaged by gently pulling it backwards, away from OneTouch Latch, to ensure it does not come out of receiving holes. Repeat this step during patient setup, even if insert has previously been installed.



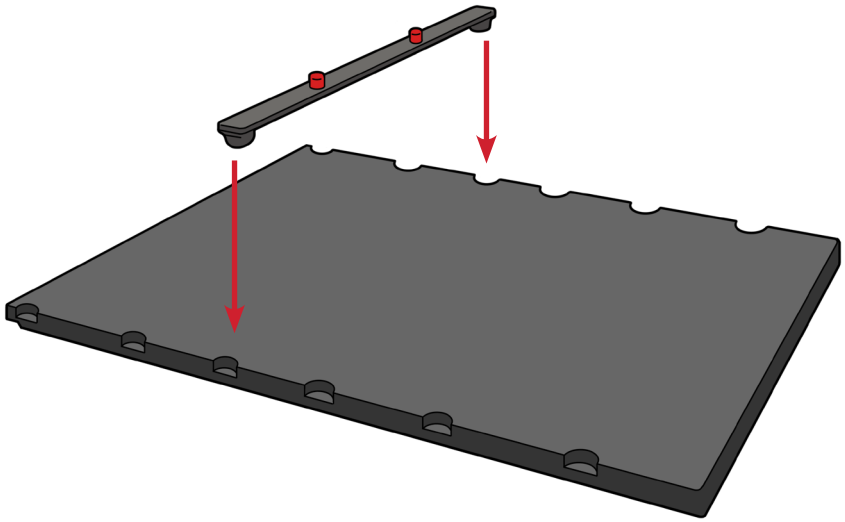
kVue with Standard Insert

OPERATING INSTRUCTIONS

SET-UP

LOCATING BAR INSTALLATION

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. When using the Calypso® System, use only Calypso compatible accessories.



OPERATING INSTRUCTIONS

REMOVAL

LOCATING BAR REMOVAL

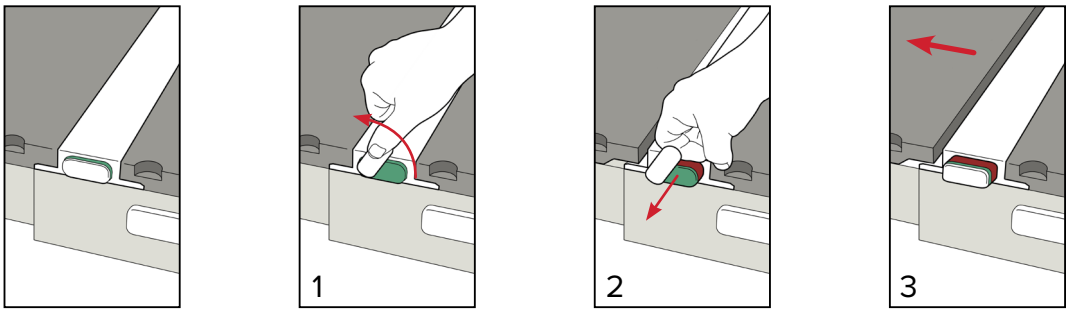
Pull up on either end of the Locating Bar.

KVUE INSERT REMOVAL

! NOTE ! The images shown below are of a standard kVue Couch Top. kVue Insert removal is the same for all versions of the kVue

! WARNING ! 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

! NOTE ! DO NOT spray or pour liquids onto the surface of the device as they may flow into the mechanisms within the baseframe.

! NOTE ! DO NOT place sharp objects on the device.

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.

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SPECIFICATIONS

LENGTH

1325 mm

WEIGHT LIMIT

249 kg (550 lb) uniformly distributed load or maximum safe working load of couch base, whichever is less.

LOCATION OF INFERIOR ISOCENTER LINE

420 mm from Inferior End of Insert

ALUMINUM EQUIVALENCE

The performance of the kVue with all kVue Inserts meets or exceeds x-ray attenuation specifications of CDRH 21 CFR 1020.30 and IEC 60601-1-3.

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SETUP SHEET

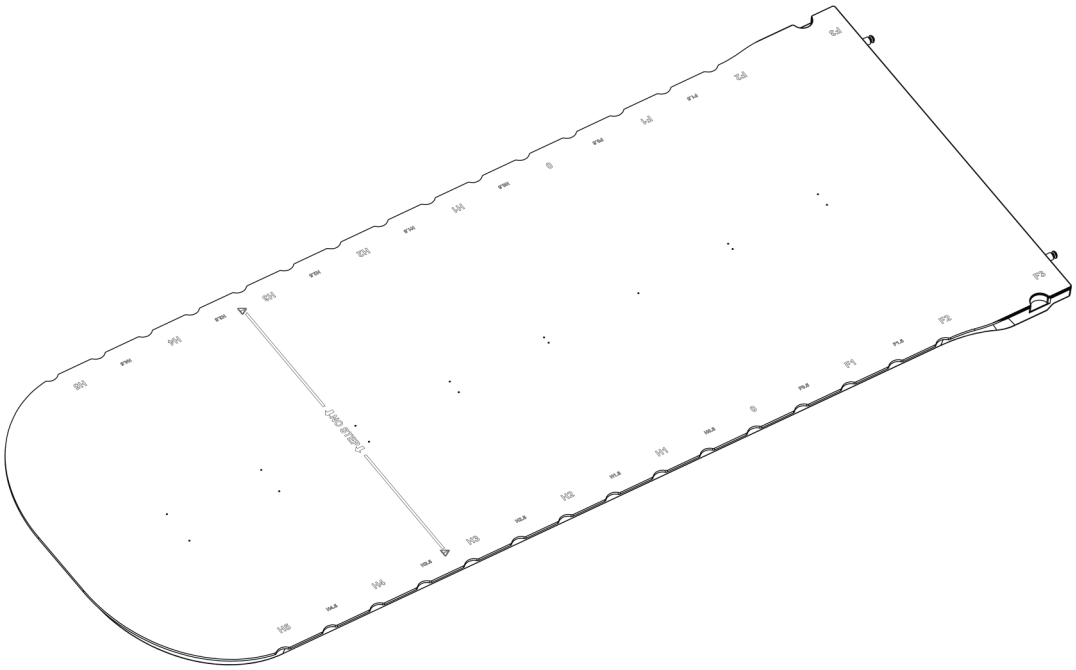
KVUE LOW-E™ STANDARD INSERT – RT-4551KV19

Patient Name:

Patient ID #: Setup by:

Physician: Date:

Comments:



Moving Rails Location:

Notes:

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