



positioning
patients for life.®

PRODUCT GUIDE & USER MANUAL

VacQfix™ Cushion





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VacQfix is a trademark of Qfix.

Exact® is a registered trademark of Varian Medical Systems.

Cidex® is a registered trademark of Johnson & Johnson.

Clorox® is a registered trademark of The Clorox Company.

Virox® is a registered trademark of Virox Technologies Inc.

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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 ! DO NOT USE A PEN OR OTHER OBJECTS TO DEFLATE/INFLATE THE VACUUM CUSHION! WE STRONGLY RECOMMEND USING A QFIX APPROVED VACUUM PUMP TO DEFLATE/INFLATE THE CUSHION.

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.

MRI SAFETY INFORMATION



Non-clinical testing has demonstrated the **VacQfix Cushions** are MR Conditional. This device may be used in an MR system meeting the following conditions:

- **Static magnetic field of 1.5T or less.**
- **The VacQfix valve stem must remain outside the plane of imaging.**



Non-clinical testing has demonstrated the **VacQfix Indexer** is MR Safe. Once the conditions for the **VacQfix Cushions** are met, the **VacQfix Indexer** may be used in an MR environment.

GENERAL PRECAUTIONS

WARNING LABELS & DESCRIPTIONS

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



MR CONDITIONAL

An item with demonstrated safety in the MR environment within defined conditions.

These conditions are defined on page 4 in the MRI Safety Information section.



MR SAFE

An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically non-conductive, nonmetallic and nonmagnetic.

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

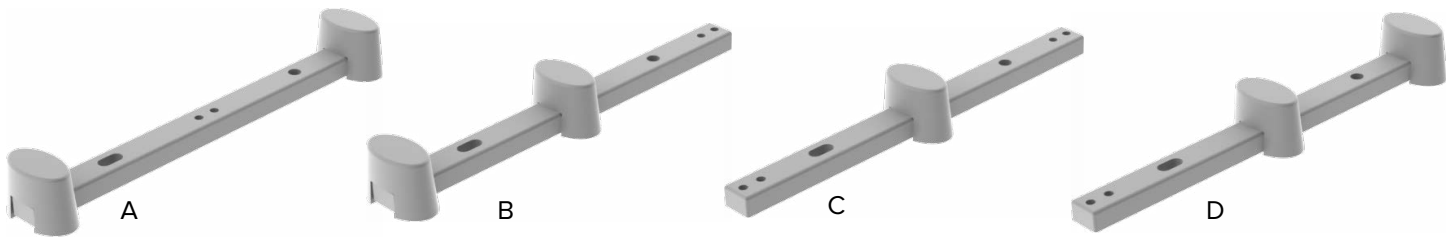
The intended user for the products is a person qualified in accordance with the requirements of the regulatory region.

OPERATING INSTRUCTIONS

INSTALLATION

ADJUSTING THE INDEXER

The VacQfix indexer may be set up in the following combinations:



To adjust the location of the indexing blocks, remove the nylon screw using a 6 mm Hex Key, turning it counter-clockwise. Move the indexing block to the desired location and retighten the screws, turning clockwise (Fig. 1 & 2).

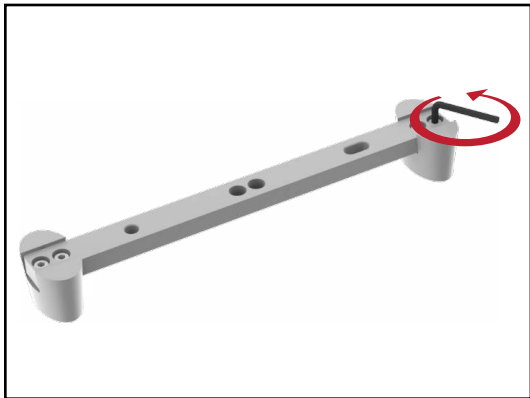


Fig. 1

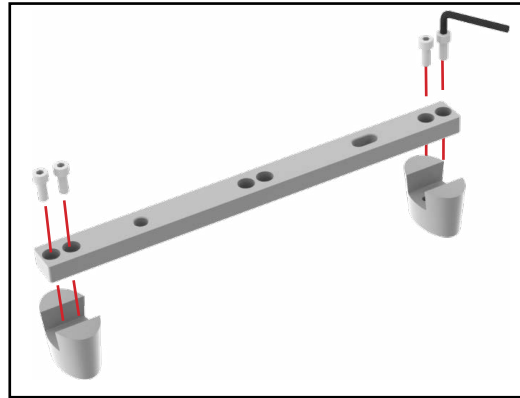


Fig. 2

OPERATING INSTRUCTIONS

INSTALLATION

ATTACHING THE OPTIONAL VACQFIX INDEXER

! NOTE ! A single Indexer may be used on any one cushion. An additional Indexer may be used as required for increased repositioning accuracy on longer cushions.

1. Attach one Locating Bar for every indexer being used onto the kVue or kVue Insert surface. To attach, place either end of the Locating Bar in the appropriate Varian Exact® compatible index notches and snap in place (Fig. 3).

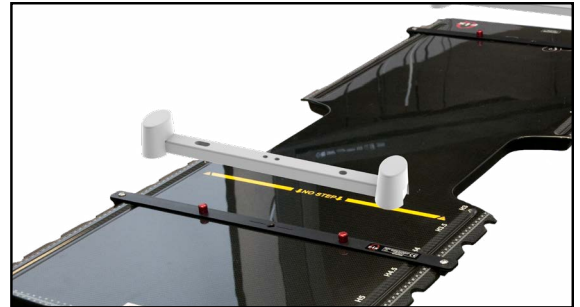


Fig. 3

2. Locate the Indexer(s) onto the Locating Bar(s) by lining up the red indexing pins to the hole and slot in the indexer(s) (Fig. 4 & 5).



Fig. 4

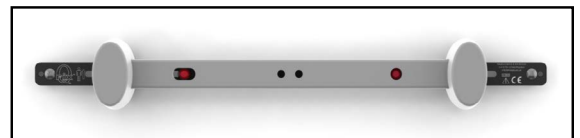


Fig. 5

3. Fill the cushion with enough air so that the folds and creases are eliminated. Then, place the cushion over the indexer(s) (Fig. 6).

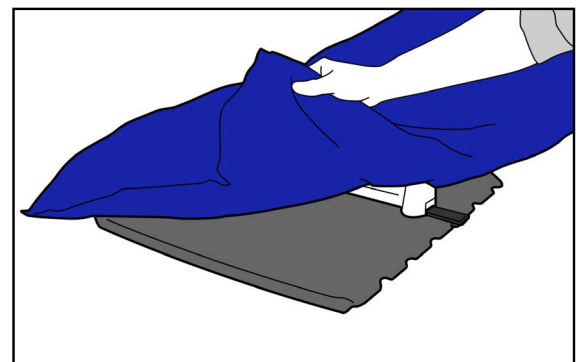


Fig. 6

OPERATING INSTRUCTIONS

SET-UP

1. Attach the vacuum hose to the valve. When you hear an audible 'click', this will ensure that a proper connection has been made and the hose and valve have been fitted properly (Fig. 7).

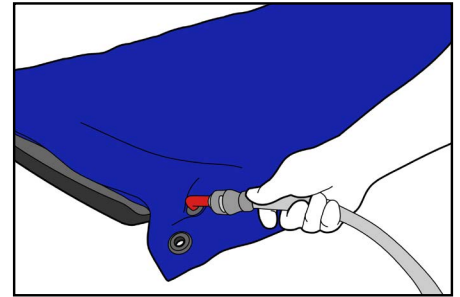


Fig. 7

2. Fill the cushion with enough air so the folds and creases are eliminated. Before the patient is positioned, pre-mold the cushion to ensure that the filling is in the proper place. A stiff but relatively moldable vacuum level is needed to ensure proper patient positioning. You can test the stiffness of the cushion by pressing with 2 fingers (Fig. 8).

! NOTE ! DO NOT overfill the cushion.

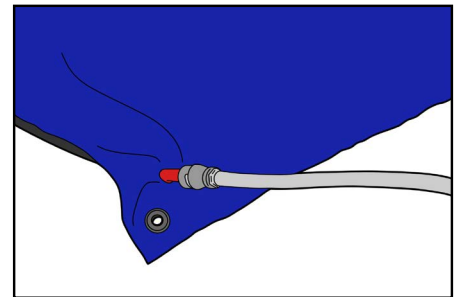


Fig. 8

3. Place the patient onto the cushion and begin to vacuum out the air. Shape the cushion around the patient as needed. The cushion must still be moldable but relatively hard (Fig. 9).
4. Continue to vacuum out the air until the cushion becomes firm around the patient. To ensure maximum vacuum is achieved, continue to operate the vacuum pump for an additional 5 minutes until the cushion is completely hard to ensure proper positioning.

! NOTE ! The cushion may need to be vacuumed more or less than 5 minutes depending on the size of the cushion and the vacuum pump.

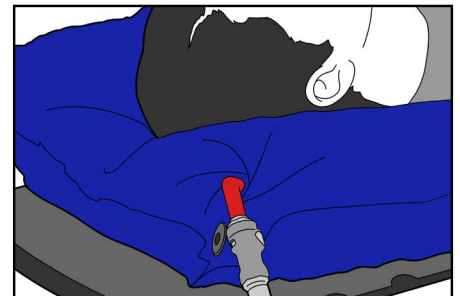


Fig. 9

OPERATING INSTRUCTIONS

INSTRUCTIONS FOR VACUUM PUMP

TO EVACUATE CUSHION

1. Connect pump to mains.
2. Connect hose to vacuum port of the pump, if pump has vacuum and air ports.
3. Turn on vacuum, using switch or foot pedal.

TO INFLATE CUSHION

1. Connect pump to mains.
2. Connect hose to air port of the pump, if pump has vacuum and air ports.
3. Turn on air, using switch or foot pedal.

MAINTENANCE

CLEANING THE VACQFIX™ CUSHIONS

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 VACQFIX™ CUSHIONS

To disinfect the device, use one of the following disinfectants according to the manufacturer's instructions.

- 10% Clorox® Bleach Solution
- Cidex® 2.4% activated dialdehyde disinfecting Solution
- Virox® .5% Accelerated Hydrogen Peroxide Solution
- Isopropyl Alcohol

Do not use other solvents to clean vacuum cushions.

STORAGE

1. VacQfix Cushions should be completely evacuated.
2. Properly store cushions on storage rack in a cool dry location, away from exposure to potential puncture and direct sunlight during course of treatment and after use.

If other vacuum adapters are required, RT-PUMP-KIT is available.

PARTS LIST

This Instructions for Use leaflet applies to the following part numbers:

Product Code	Description
RT-4517-0002	VacQfix Cushion, 160 cm x 120 cm/80 cm, 2 Chambers
RT-4517-0002M	VacQfix Cushion, 165 cm x 130 cm, 2 Tapered (Economy valve)
RT-4517-0003	VacQfix Cushion, 230 cm x 120 cm/80 cm, 3 Chambers
RT-4517-0003M	VacQfix Cushion, 230 cm x 120 cm/80 cm, 3 Chambers
RT-4517-100100F30	VacQfix Cushion, 100 cm x 100 cm, 30L fill
RT-4517-100100F30M	VacQfix Cushion, 100 cm x 100 cm, 30L fill
RT-4517-100100F40	VacQfix Cushion, 100 cm x 100 cm, 40L fill
RT-4517-100100F40M	VacQfix Cushion, 100 cm x 100 cm, 40L fill
RT-4517-100100TRAPF35	VacQfix Cushion, 100 cm x 100 cm, TRAP, 35L fill
RT-4517-100130PENF45	VacQfix Cushion, 100 cm x 130 cm, PEN, 45L fill
RT-4517-100130PENF45M	VacQfix Cushion, 100 cm x 130 cm, PEN, 45L fill
RT-4517-100150F70	VacQfix Cushion, 100 cm x 150 cm, 70L fill
RT-4517-100150F70M	VacQfix Cushion, 100 cm x 150 cm, 70L fill
RT-4517-100220F120	VacQfix Cushion, 100 cm x 220 cm, 120L fill
RT-4517-100220F120M	VacQfix Cushion, 100 cm x 220 cm, 120L fill
RT-4517-10070F30	VacQfix Cushion, 100 cm x 70 cm, 30L fill
RT-4517-10070F30M	VacQfix Cushion, 100 cm x 70 cm, 30L fill
RT-4517-10070F35	VacQfix Cushion, 100 cm x 70 cm, 35 liter fill
RT-4517-10070F35M	VacQfix Cushion, 100 cm x 70 cm, 35 liter fill
RT-4517-10070F40	VacQfix Cushion, 100 cm x 70 cm, 40L fill
RT-4517-10070F40M	VacQfix Cushion, 100 cm x 70 cm, 40L fill
RT-4517-12075F35	VacQfix Cushion, 120 cm x 75 cm, 35L fill
RT-4517-230120T80F90	VacQfix Cushion, 120 cm/80 cm x 230 cm, 90L fill
RT-4517-230120T80F90M	VacQfix Cushion, 120 cm/20 cm x 230 cm, 90L fill
RT-4517-4079VF15	VacQfix Cushion, 40 cm x 79 cm, 15L fill
RT-4517-4079VF15M	VacQfix Cushion, 40 cm x 80 cm, 15L fill
RT-4517-4080F15	VacQfix Cushion, 40 cm x 80 cm, 15L fill
RT-4517-4080F15M	VacQfix Cushion, 40 cm x 80 cm, 15L fill
RT-4517-5070F15	VacQfix Cushion, 50 cm x 70 cm, 15L fill
RT-4517-5070F15M	VacQfix Cushion, 50 cm x 70 cm, 15L fill
RT-4517-70120F40	VacQfix Cushion, 120 cm x 70 cm, 40L Fill Gen.II
RT-4517-70150F60	VacQfix Cushion, 70 cm x 150 cm, 60L fill

PARTS LIST

Product Code	Description
RT-4517-70150F60M	VacQfix Cushion, 70 cm x 150 cm, 60L
RT-4517-7070F20	VacQfix Cushion, 70 cm x 70 cm, 20L fill
RT-4517-7070F20M	VacQfix Cushion, 70 cm x 70 cm, 20L fill
RT-4517-80150F65	VacQfix Cushion, 150 cm x 80 cm, 65L fill
RT-4517-80150F65M	VacQfix Cushion, 150 cm x 80 cm, 65L fill
RT-4517-IND01	VacQfix Indexer
RT-4517-PB1	VacQfix Cushion, Prone Breast Cushion w/Contralateral Breast Support
RT-4517-PB3	VacQfix Cushion, 96 cm x 55 cm, 12L fill
RT-4517-PB3M	VacQfix Cushion, 96 cm x 55 cm, 12L fill
RT-4517-PB4	VacQfix Cushion, 96 cm x 55 cm, 15L fill
RT-4517-PB4M	VacQfix Cushion, 96 cm x 55 cm, 15L fill
RT-4517-T6565F7	VacQfix Cushion, 65 cm x 65 cm, T-Shaped, 7L fill
RT-4517-T6565F7M	VacQfix Cushion, 65 cm x 65 cm, T-Shaped, 7L fill
RT-4517-T7993F20	VacQfix Cushion, 79 cm x 93 cm, 20L fill
RT-4517-T7993F20M	VacQfix Cushion, 79 cm x 93 cm, 20L fill



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