



macromedics

SOLUTIONS IN RADIOTHERAPY

MANUAL 156100
Instructions for use
English Instructions

MacroMedics® Vacuum Positioning Cushions



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1. Warnings



- Inspect the device thoroughly before use. Do not use the device if damaged or if missing parts.
- Check individual components on MR-Safety when used together in a patient positioning system.
- Keep the Cushion valve out of the radiation treatment path.
- Verify the device's attenuation characteristics before clinical use when the device is intended to be in the incoming radiation treatment-beam pathway.
- Do not inflate the Vacuum Positioning Cushion above 100 Mbar.
- Please be aware not to deform the cushion whilst the patient is being (re)positioned.
- In the USA, federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

2. MRI Safety Information

2.1 MR SAFE

- 155900 Quick inflation connector



2.2 MR CONDITIONAL

- 156610 Vacuum Positioning Cushion EagleBoard-2
- 156110 Abdominal Vacuum Positioning Cushion, size S
- 156120 Abdominal Vacuum Positioning Cushion, size XL
- 156130 Vacuum Positioning Cushion, head support, 30x40cm, 3L
- 156140 Vacuum Positioning Cushion, head support, 25x50cm, 3L
- 156150 Vacuum Positioning Cushion, head & shoulder support, T-shape, 50x70cm, 5L
- 156160 Vacuum Positioning Cushion, breast support, 50x70cm, 8L
- 156170 Vacuum Positioning Cushion, pelvic support, 65x65cm, 13L
- 156180 Vacuum Positioning Cushion, body support, 100x70cm, 30L
- 156190 Vacuum Positioning Cushion, body support, 100x80cm, 36L
- 156210 Vacuum Positioning Cushion, body support, 120x80cm, 36L
- 156220 Vacuum Positioning Cushion, body support, 100x150cm, 51L
- 156230 Vacuum Positioning Cushion, body support, 200x100cm, 85L
- 156240 Vacuum Positioning Cushion, body support, T-shape 120x120cm



A patient with the above devices can be safely scanned in an MR system meeting the following the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla, with
- Maximum spatial field gradient of 2,500 G/cm (25 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Due to the size and location of the metallic parts, no clinically significant RF heating is expected. It is the responsibility of the user to ensure that these conditions are met.

2.3 MR UNSAFE

- 155920 Quick inflation connector with 2m tube + CPC connector to vacuum machine





3. Intended Use

Positioning of the patient during radiotherapy and radio diagnostics, including MR where indicated.

4. Proton Use

Use of the Vacuum Positioning Cushions for patients receiving proton therapy has not been investigated.

5. Instructions for Use

5.1 Inflation/deflation of the Vacuum Positioning Cushions and patient Positioning.

- I. Flatten out the Vacuum Positioning Cushion and make sure that the filling is evenly distributed.
- II. Position the patient on the Vacuum Positioning Cushion.
- III. Connect the Vacuum Positioning Cushion to the pump. If necessary, use a Quick Inflation Connector as shown in the image below:



Accessories:

- 155900 VQIC2 quick inflation connector with 2m tube
- 155920 VQIC2CPC quick inflation connector with 2m tube + CPC connector to vacuum machine

- IV. Start the vacuum pump and generate a slight vacuum, then stop the pump.
- V. Start molding the Vacuum Positioning Cushion around the patient's body/region of interest. Build an adequate rim around the body to ensure precise positioning for future use with that patient.



- VI. Once the desired hardness has been achieved, stop the vacuum pump and detach it from the Vacuum Positioning Cushion. If using the Quick Inflation Connectors, press the blue buttons on either side of the part to detach it from the Vacuum Positioning Cushions' valve.
- VII. Remember to keep the Vacuum Positioning Cushions' valve out of the radiation treatment path.

5.2 Attaching the Vacuum Positioning Cushion to the SBRT Secure Arches.

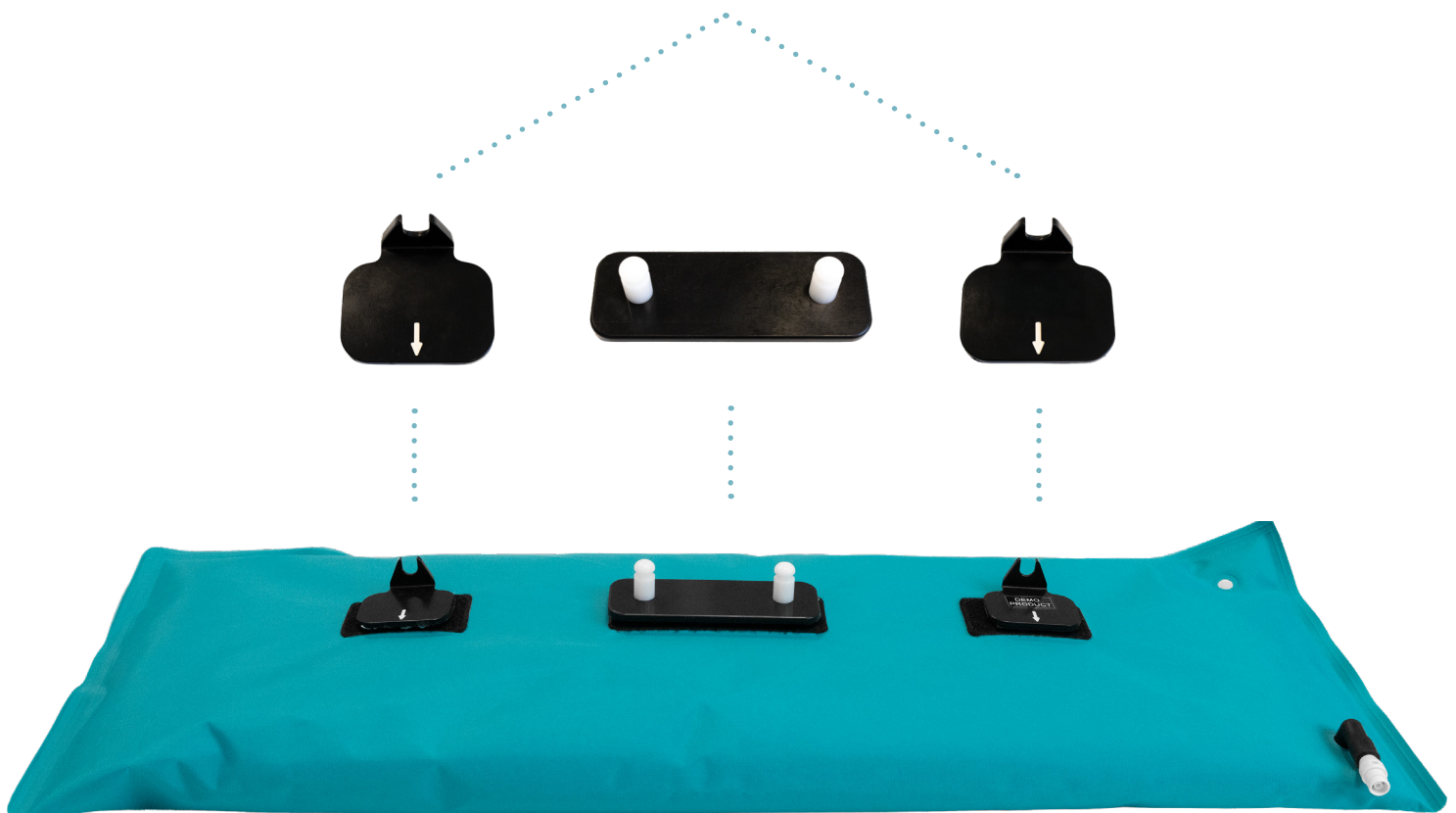
The instructions on this page and the next only apply to the following Vacuum Positioning Cushions:

- 156110 Abdominal Vacuum Positioning Cushion, size S
- 156120 Abdominal Vacuum Positioning Cushion, size XL

Dedicated plastic parts are required for attaching the Vacuum Positioning Cushions to the SBRT Secure Arch. These plastic parts can be connected to the Vacuum Positioning Cushion by using velcro pads, as shown in underneath image.

- I. Before attaching the Vacuum Positioning Cushion to the Secure Arch, check the orientation of the indication arrows, as shown in the image below:

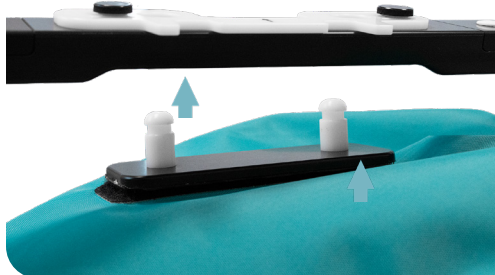
The orientation is correct when the arrows point in the same direction.



- II. Attach the Vacuum Positioning Cushion, one side at a time, to the Secure Arch. Once the first side is in position, lock it by turning the white star shaped knob clockwise, as shown in the image below:



- III. Continue with the plastic part in the middle and stick the two white pins through the holes in the Secure Arch. Slide the white locking plate to the right side to secure the Vacuum Positioning Cushion, as shown in the images below.



Note: If the white locking plate moves with too much resistance, release the black ribbed knobs until the resistance reaches an acceptable level. Be careful not to unscrew them too much.

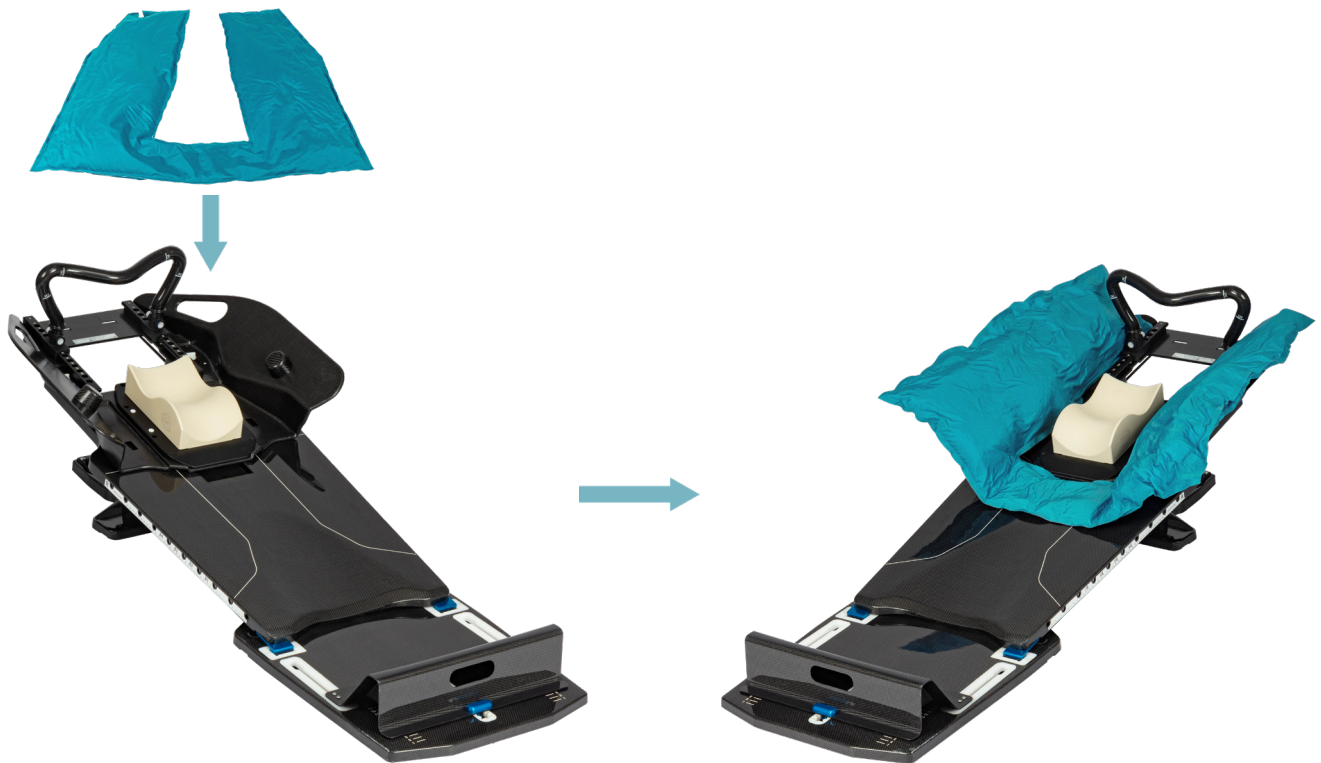


- IV. Repeat step two for attaching the last side.

- V. After treatment, detach the Vacuum Positioning Cushion from the Secure Arch by sliding the white locking plate to the left and turn the aforementioned star shaped locking knobs counterclockwise.

5.3 Placing the U-shaped vacuum Positioning Cushion on the EagleBoard-2.

- I. Position the U-shaped Vacuum Positioning Cushion on the EagleBoard-2 with the two ends of the Vacuum Positioning Cushion facing upwards, as shown below:



- II. Flatten out the Vacuum Positioning Cushion and distribute the filling roughly as desired. Mould the cushion around the Vacuum Cushion positioning knobs on the wings of the EagleBoard-2 to hold the Vacuum Positioning Cushion in place.
- III. Position the patient.
- IV. Start deflating the Vacuum Positioning Cushion as described in chapter 5.1 - 'Inflation/deflation of the Vacuum Positioning Cushion'.

6. Cleaning, Storage and Disposal

- Clean the device before and after every use with 70% Isopropanol or soapy water, applied with a soft cloth. Rinse with water and dry properly. Follow the cleaning precautions detailed on the bottle of the cleaning agent.
- Having cleaned the device, perform a visual inspection of the device to ensure that it is thoroughly clean. If it is not, either repeat the cleaning process described above until the device is thoroughly clean upon visual inspection or dispose of the device to prevent the use of a soiled device.
- If unsure about the cleaning fluid, do not use it. Never use Ethanol (Ethyl alcohol), aerosol sprays, corrosive cleaning agents, solvents or abrasive detergents.
- The devices are not suitable for sterilization or thermal disinfection.
- Store the device in a clean, ventilated environment.
- Dispose of the device in accordance with the local laws and regulations applicable to your country.

7. Warranty

The MacroMedics products are warranted to be free from defects in manufacturing, material and construction. The warranty is for 1 year starting from the date of delivery.










Product warranties remain valid provided the product was installed and/or used according to the instructions. Defects, malfunctions or failures caused by nature, misuse, abuse and unauthorised alteration or repair are not warranted.

This warranty is limited to the repair and/or replacement at the sole discretion of MacroMedics.

8. Notices

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user or patient is established.

9. Glossary of Symbols

Symbol	Symbol Name	Description of Symbol
	CE Mark	CE marking of conformity
	Manufacturer	Indicates the medical device manufacturer.
	Medical Device	Indicates the item is a medical device
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
 GS1 Code: (10)	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Consult Instruction for Use	Indicates the need for the user to consult the instructions for use.
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
Rx ONLY	Prescription Only	Devices for sale to physicians or trained healthcare providers only.
	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 nonconductive, nonmetallic, and nonmagnetic.
	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions.



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