



**macromedics**

SOLUTIONS IN RADIOTHERAPY

MANUAL 155100  
Instructions for use  
English Instructions

## MacroMedics ® Vacuum 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.
- Do not inflate the Vacuum 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

- |                                |                                  |
|--------------------------------|----------------------------------|
| • 155110 VacuumCushion 30x40   | • 155430 VacuumCushion 120x80    |
| • 155140 VacuumCushion 25x50   | • 155450 VacuumCushion 100x150   |
| • 155150 VacuumCushion 50x70 T | • 155510 VacuumCushion 200x100   |
| • 155210 VacuumCushion 50x70   | • 155520 VacuumCushion 120x120 T |
| • 155300 VacuumCushion 65x65   | • 155610 VacuumCushion EB-2      |
| • 155400 VacuumCushion 100x70  | • 123450 VacuumCushion, abdom.S  |
| • 155410 VacuumCushion 100x80  | • 123470 VacuumCushion, abdom.XL |

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.



## 3. Intended Use

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

## 4. Proton Use

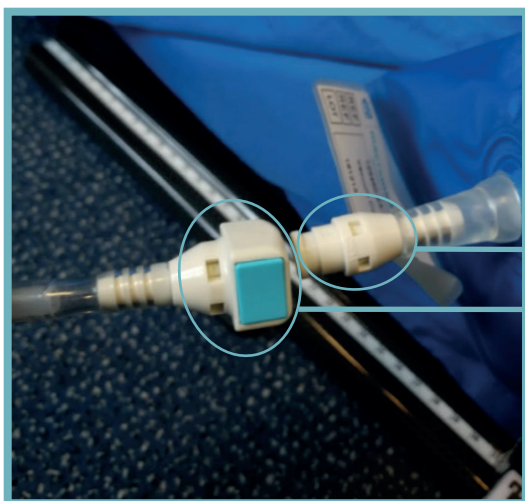
Use of the VacuumCushions for patients receiving proton therapy has not been investigated.

## 5. Instructions for Use



### 5.1 INFLATION/DEFLATION OF THE VACUUM CUSHIONS AND PATIENT POSITIONING.

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



Quick inflation connector, male part

Quick inflation connector, female part

- IV. Start the vacuum pump and generate a slight vacuum, then stop the pump.
- V. Start molding the Vacuum 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 Cushion. If using the Quick Inflation Connectors, press the blue buttons on either side of the part to detach it from the Vacuum Cushions' valve.
- VII. Remember to keep the Vacuum Cushions' valve out of the radiation treatment path.

## 5.2 ATTACHING THE VACUUM CUSHION TO THE SBRT SECURE ARCHES.

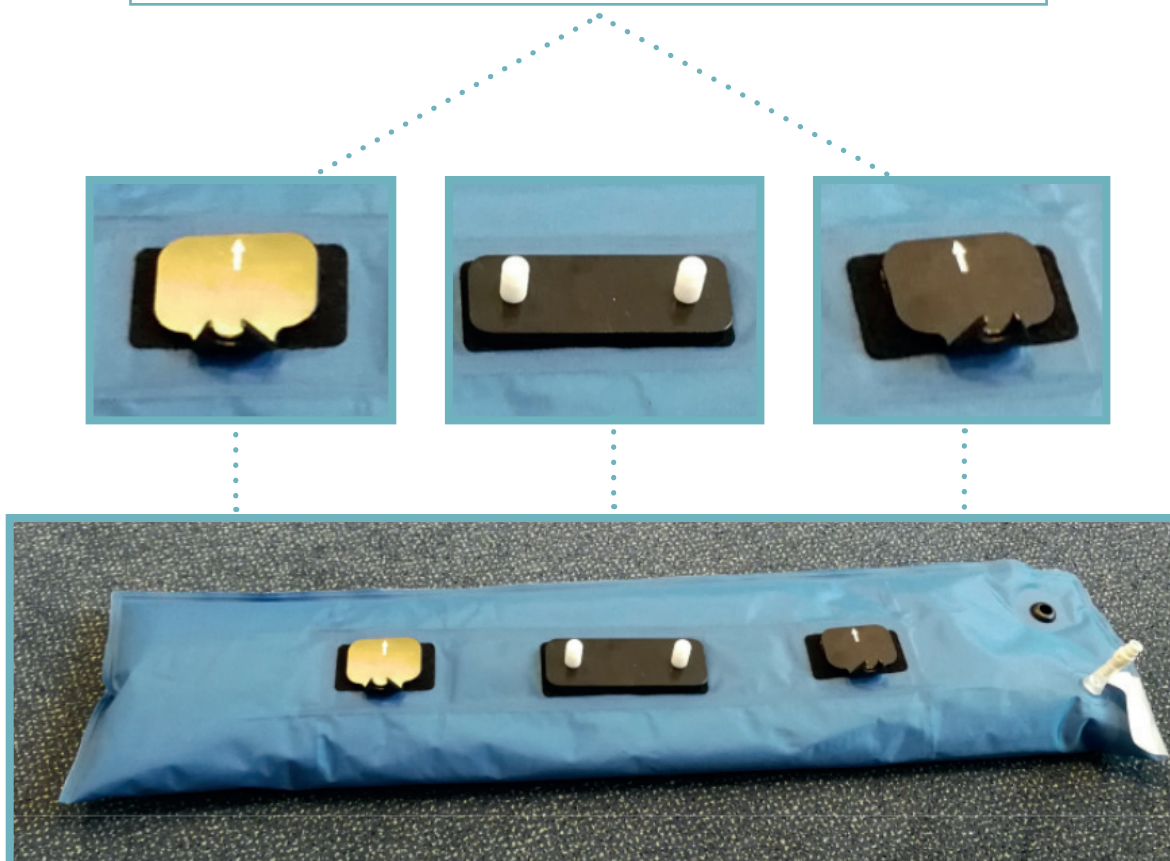
The instructions on this page and the next only apply to the following Vacuum Cushions:

- 123450 VacuumCushion, abdom.S
- 123470 VacuumCushion, abdom.XL

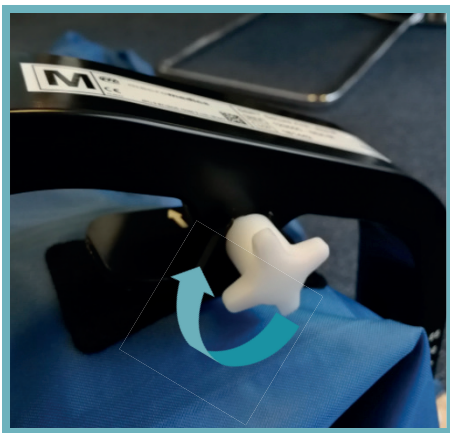
Dedicated plastic parts are required for attaching the Vacuum Cushions to the SBRT Secure Arch. These plastic parts can be connected to the Vacuum Cushion by using Velcro pads, as shown in underneath image.

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

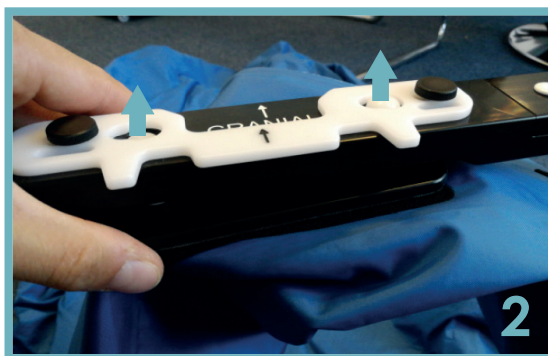
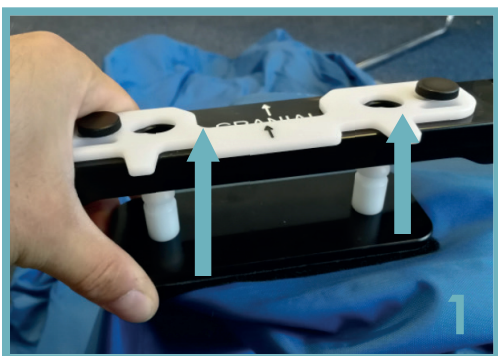
The orientation is correct when the arrows point in the same direction.



- II. Attach the Vacuum 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. Slide the white locking plate to the right side to secure the Vacuum 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.



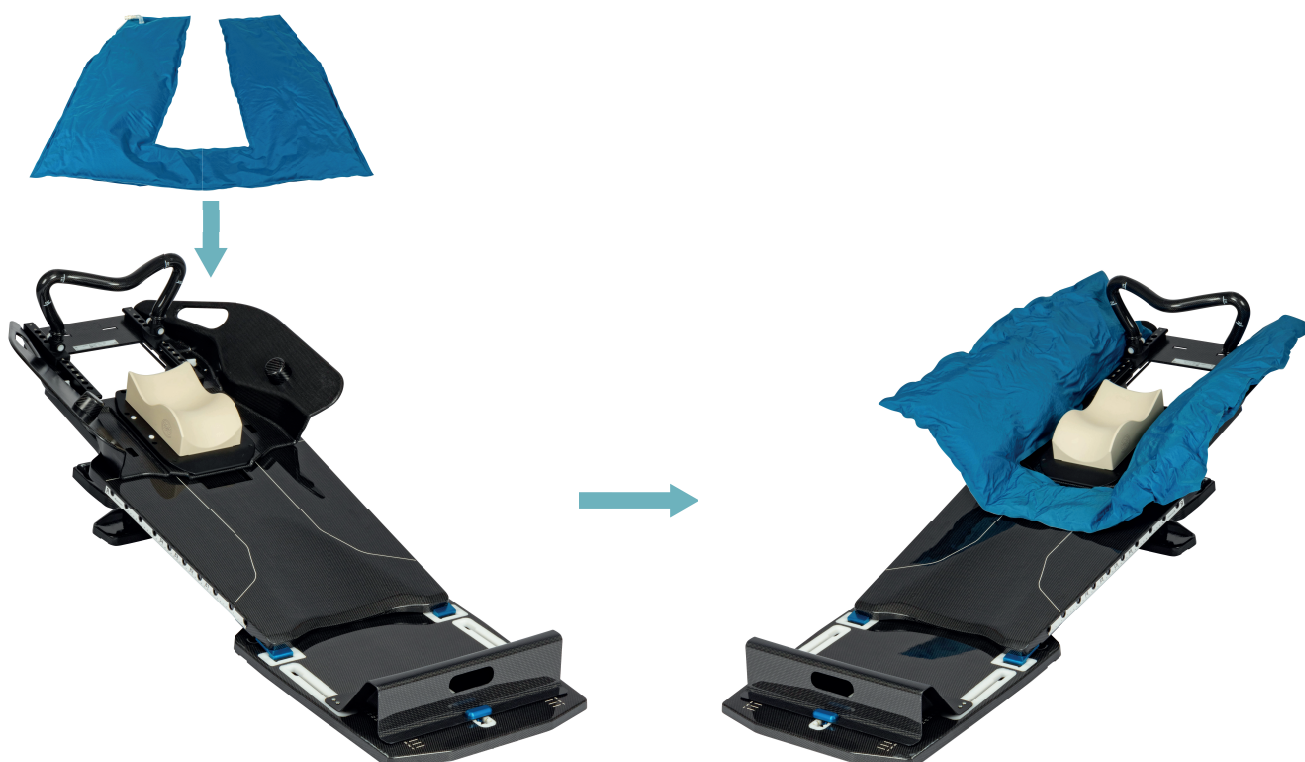
- IV. Repeat step two for attaching the last side.



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

### 5.3 PLACING THE U-SHAPED VACUUM CUSHION ON THE EAGLEBOARD-2.

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





- II. Flatten out the Vacuum 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 Cushion in place.
- III. Position the patient.
- IV. Start deflating the Vacuum Cushion as described in chapter 4.1 - 'Inflation/deflation of the Vacuum Cushion'.



## 6. Cleaning, Storage and Disposal

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- Clean the device before and after every use with mild soap and luke-warm water or alcohol-based disinfectant applied with a soft cloth. Rinse with water and dry properly. Avoid aerosol sprays, bleach, 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

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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

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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
	European Conformity	EC declaration of conformity by manufacturer.
	Manufacturer	Indicates the medical device manufacturer.
	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.
<b>Rx ONLY</b>	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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