



macromedics

SOLUTIONS IN RADIOTHERAPY

MANUAL 176010
Instructions for use
English Instructions

MacroMedics® MR Body Coil Holder Secure Arch



MacroMedics BV
Oostbaan 670
2841ML Moordrecht
The Netherlands
+31(0)182 389 777
info@macromedics.com
www.macromedics.com



Table of Contents

1. Warnings.....	3
2. MRI Safety Information.....	3
3. Intended Use.....	3
4. Installation Instructions.....	4
5. Cleaning, Storage and Disposal.....	6
6. Warranty.....	6
7. Notices.....	6
8. Glossary of Symbols.....	7

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.
- Secure the device properly before positioning the patient.
- Any rulers used on the device are only intended for reference of the device position. Rulers shall not replace patient position verification.
- It is the user's responsibility to ensure that collision does not occur between the CT and the device.
- In the USA, federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

2. MRI Safety Information

MR SAFE

The following devices are MR safe:

- 176010 Secure Arch for Coil Holder



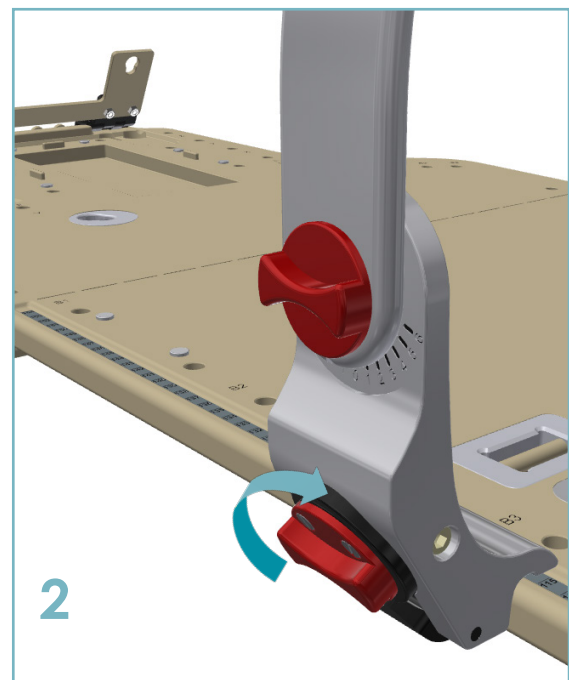
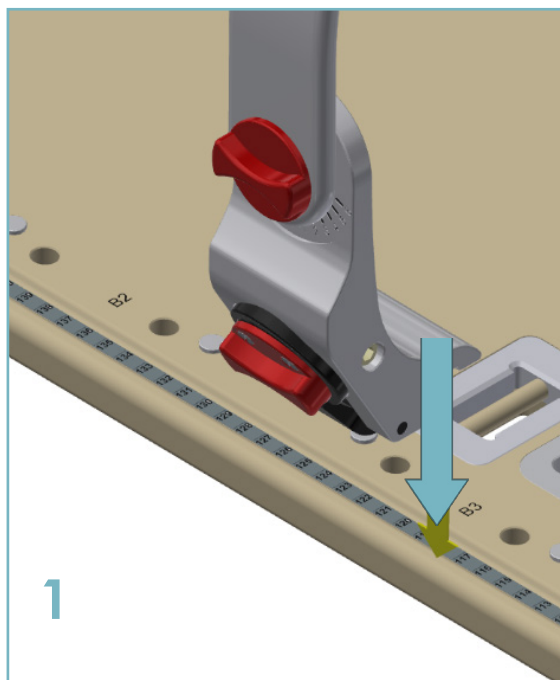
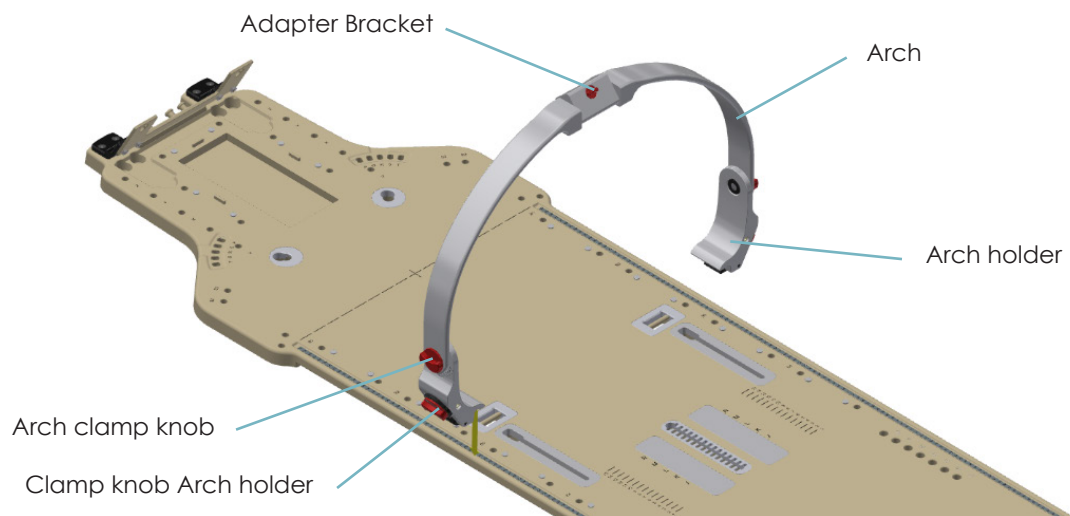
3. Intended Use

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

4. Installation Instructions

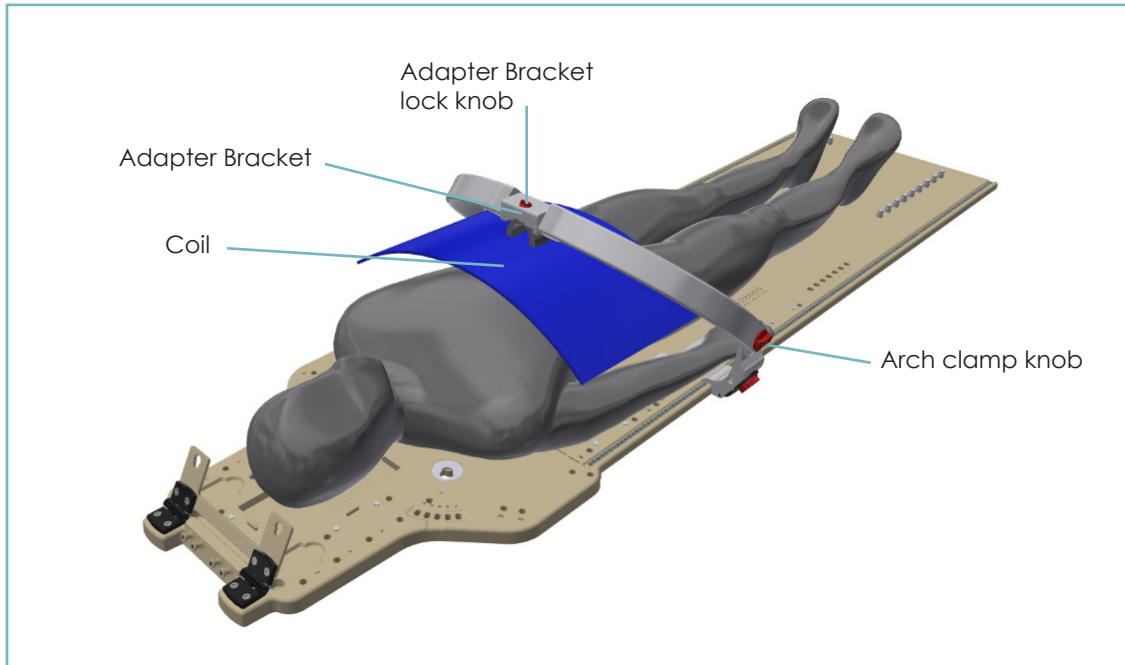
4.1 PLACING THE ARCH HOLDERS

Place the Arch Holders carefully over the patient onto the OmniBoard baseplate rails. Turn the red clamp knobs on the Arch Holders, at both ends of the Arch, clockwise until the Arch Holders are fixed to the rails.



4.2 ATTACHING THE COIL ADAPTER TO THE ADAPTER BRACKET

Slide the adapter of the Coil in the Adapter Bracket, then turn the Adapter Bracket lock knob to secure it in position.



4.3 ADJUSTING THE CRANIAL/CAUDAL ANGLE OF THE ARCH

On both sides, turn the red Arch clamp knob counterclockwise to release the Arch and push the Arch to the Cranial or Caudal side. Then turn it clockwise to secure it in position.



5. 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 product.
- 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.
- Make sure that there is no residue of the cleaning agent left on the device prior to use.
- Store the device in a clean, ventilated environment.
- Dispose of the device in accordance with the local laws and regulations applicable to your country.

6. 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.

7. 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.

8. 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.
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.



macromedics

SOLUTIONS IN RADIOTHERAPY

MacroMedics BV

Oostbaan 670
2841 ML Moordrecht
The Netherlands



+31 (0) 182 389 777

info@macromedics.com
www.macromedics.com

(Visit www.macromedics.com for a digital copy of this manual)



26042021V5IFU176010