

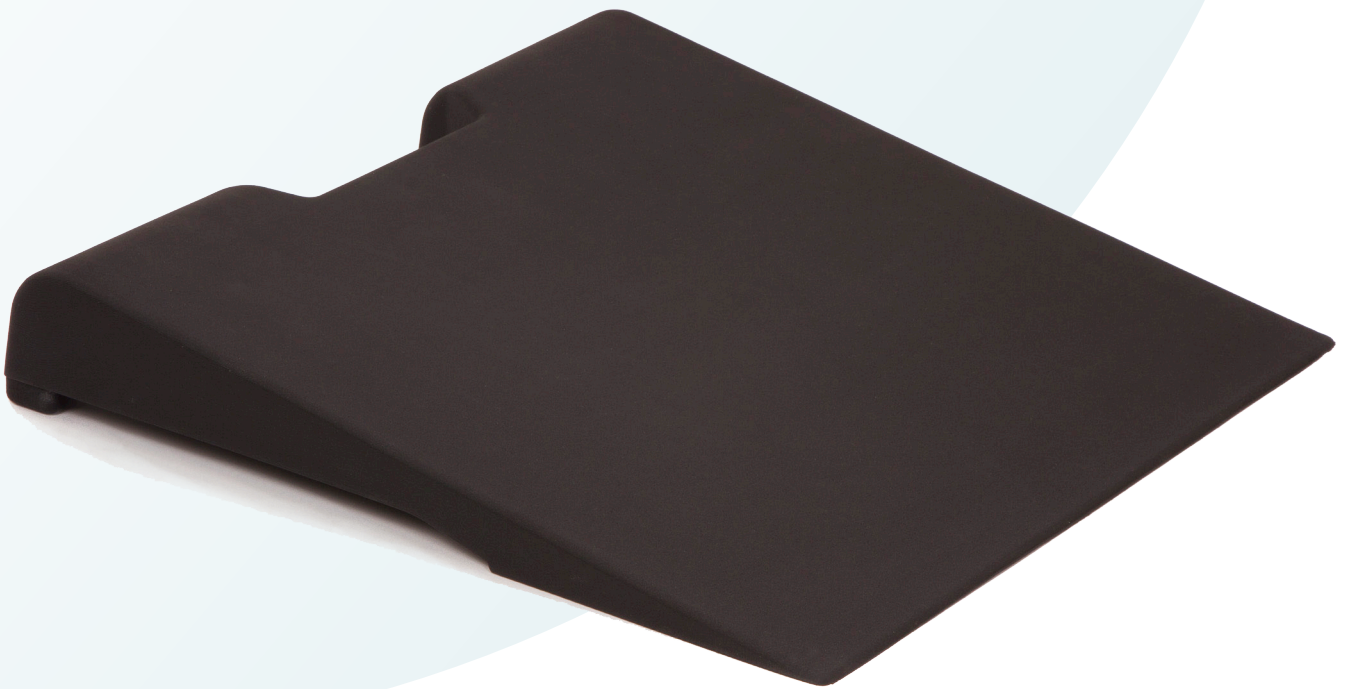


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SOLUTIONS IN RADIOTHERAPY

MANUAL 115100
Instructions for use
English Instructions

MacroMedics® Support 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.
- Do not use MR unsafe items in an MR environment.
- Secure the device properly before positioning the patient.
- Make sure that the patient lays down calmly.
- Do not exceed an equally distributed load of 200 kg on 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:

- 115100 ShoulderCus. ExaFix™-5
- 115150 ShoulderCushion IMRT
- 115160 ShoulderCushion DSCP/SSPS
- 115200 Mattress
- 115250 Mattress Short



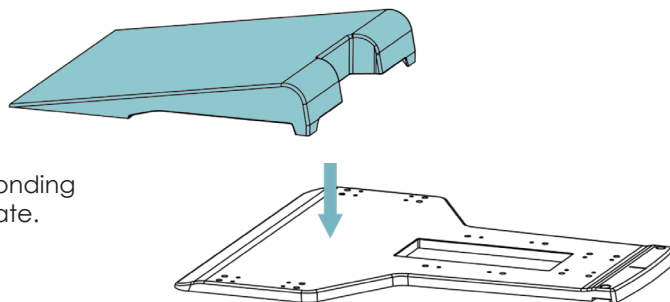
3. Intended Use

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

4. Installation Instructions

CHOOSE THE CORRECT SUPPORT CUSHION

Choose the correct Support Cushion with the corresponding Baseplate and place the cushion on top of the baseplate.

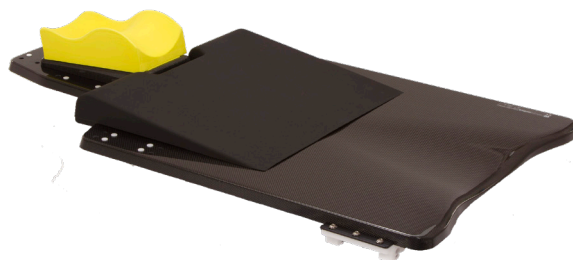


The Support Cushions are each compatible with a certain type of Baseplate. See below:

- **115100 Shouldercushion:** Intended for use with ExaFix baseplates.
- **115150 Shouldercushion:** Intended for use with IMRT baseplates.



[115100]
Shoulder Cushion with ExaFix Baseplate



[115150]
Shoulder Cushion with IMRT Baseplate

- **115200 Mattress:** Intended for use with ExaFix-baseplates.
- **115250 Mattress:** Intended for use with ExaFix-baseplates short version, 460x460x15mm.



[115200]
Mattress for ExaFit Baseplate

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.
- Make sure that there is no residue of the cleaning agent left on the device prior to use.
- 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.

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.
	Keep Dry	Indicates a medical device that needs to be protected from moisture.
	Keep Away from Sunlight	Indicates a medical device that needs protection from light sources.
	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.



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