

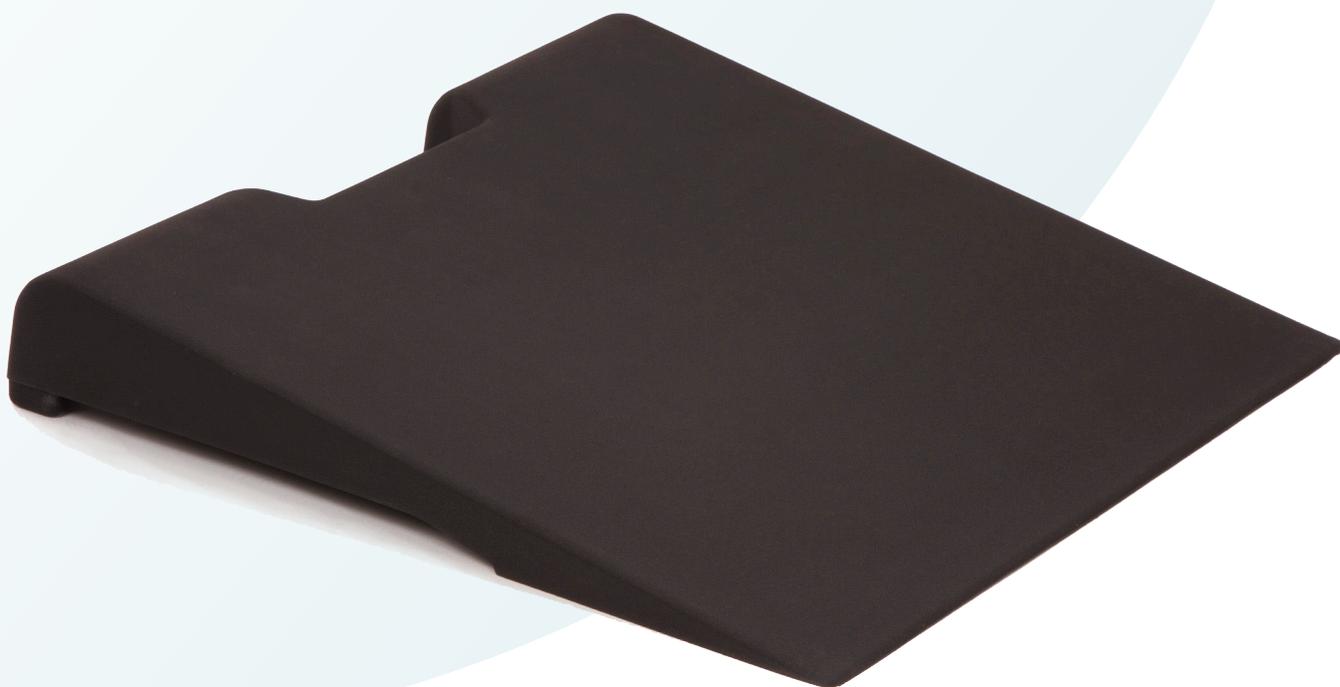


**macromedics**

SOLUTIONS IN RADIOTHERAPY

MANUAL 115100  
Instructions for use  
English Instructions

## MacroMedics® Support Cushions



**MacroMedics BV**  
Oostbaan 670  
2841ML Moordrecht  
The Netherlands  
+31(0)182 389 777  
[info@macromedics.com](mailto:info@macromedics.com)  
[www.macromedics.com](http://www.macromedics.com)



**[ This page is intentionally left blank ]**

## Table of Contents

1. Warnings.....	4
2. MRI Safety Information.....	4
3. Intended Use.....	4
4. Use Instructions.....	5
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.
- Do not use MR Unsafe items in an MR environment.
- Verify the device's attenuation characteristics before clinical use when the device is intended to be in the incoming radiation treatment-beam pathway.
- Secure the device properly before positioning the patient.
- Make sure that the patient lays down calmly and instruct the patient not to reposition themselves after set-up.
- 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 Shoulder Cushion ExaFix™-5
- 115150 Shoulder Cushion IMRT
- 115160 Shoulder Cushion DSCP/SSPS
- 115200 Mattress (non-medical device)
- 115250 Mattress Short (non-medical device)

# 3. Intended Use

## Intended use of the Shoulder Cushion:

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

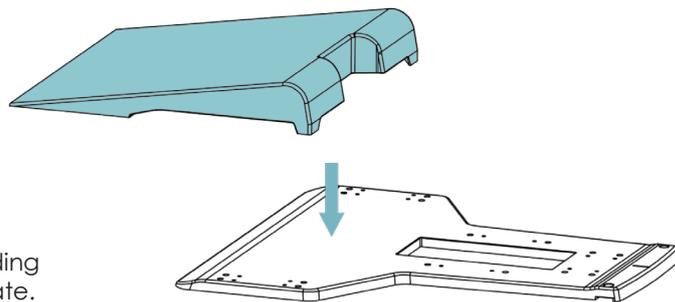
## Intended use of the Mattress:

Provide comfort.

## 4. Use Instructions

### CHOOSE THE CORRECT SUPPORT CUSHION

Choose the correct Support Cushion for 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 their compatibility outlined below:

- **115100 Shoulder Cushion:** Intended for use with ExaFix baseplates.
- **115150 Shoulder Cushion:** Intended for use with IMRT baseplates.
- **115160 Shoulder Cushion:** Intended for use with DSCP and SSPS 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 ExaFix Baseplate*

To remove the cushion, carefully lift it up from the 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 provided by the manufacturer of the cleaning agent.
- If unsure about the cleaning fluid, do not use it. Never use Ethanol (Ethyl alcohol), aerosol sprays, corrosive cleaning agents, solvents or abrasive detergents.
- 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.
- 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.
- Make sure to store the devices so that no mechanical pressure is applied to them.
- 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
	CE Mark	CE marking of conformity
	Manufacturer	Indicates the medical device manufacturer.
	Catalogue Number	Indicates the manufacturer's catalogue.
 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 product 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.



**macromedics**

SOLUTIONS IN RADIOTHERAPY

**MacroMedics BV**  
Oostbaan 670  
2841ML Moordrecht  
The Netherlands



+31 (0) 182 389 777  
info@macromedics.com

[www.macromedics.com](http://www.macromedics.com)

(Visit [www.macromedics.com](http://www.macromedics.com) for a digital copy of this manual)



05032026V15IFU115100