

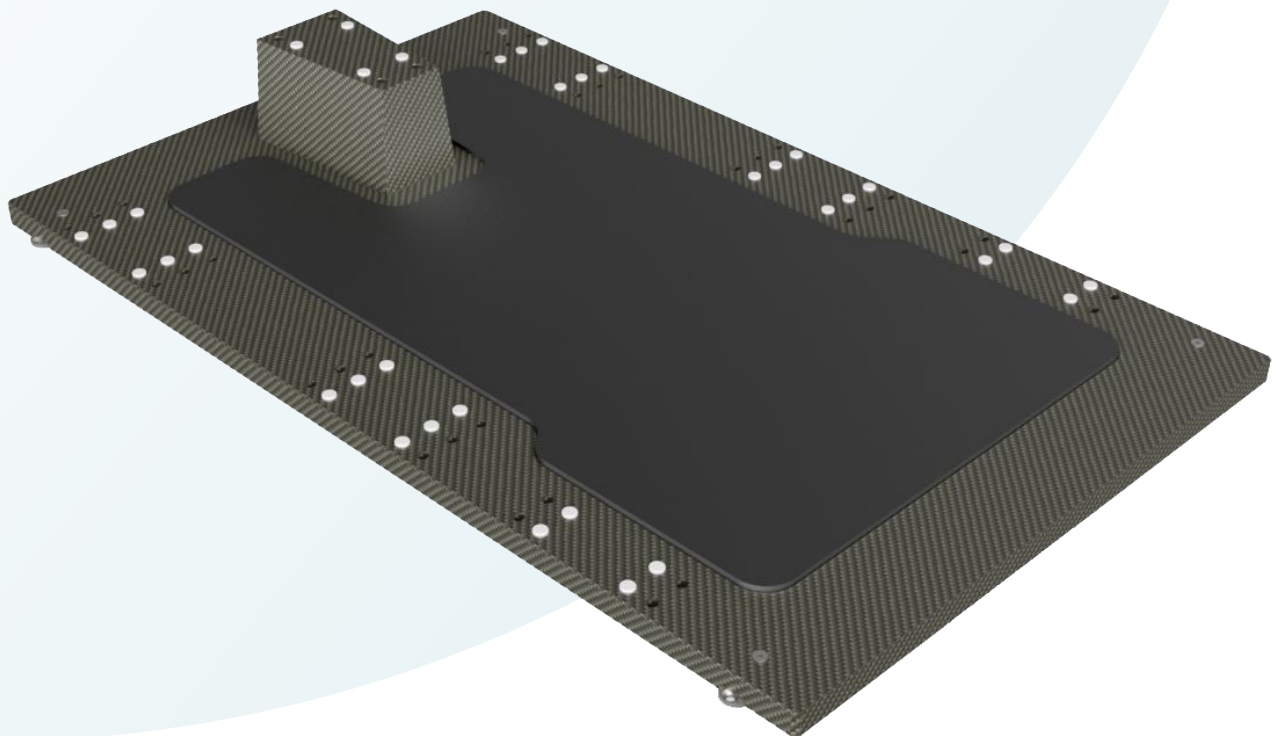


**macromedics**

SOLUTIONS IN RADIOTHERAPY

MANUAL 133100  
Instructions for use  
English Instructions

## MacroMedics® Pelvic Plate



**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)



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## 1. Warnings



- Inspect the device thoroughly before use. Do not use the device if damaged or incomplete.
- Check individual components on MR-safety when used together in a patient positioning system.
- Do not use MR unsafe items in an MR environment.
- Handle with care to prevent damage.
- Secure the device properly before positioning the patient.
- Do not exceed an equally distributed load of 200 kg on the baseplate.
- 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 UNSAFE:

The following devices are MR unsafe:

- 133100 Pelvic plate, CF



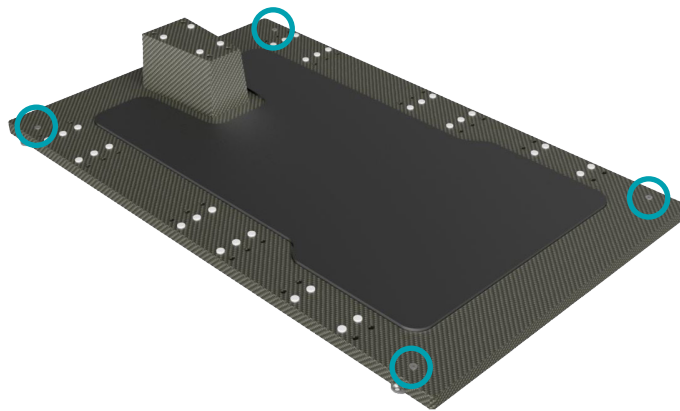
## 3. Intended Use

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

## 4. Installation Instructions

### I. PLACE THE BASEPLATE

The Pelvic Plate contains four strips on each bottom corner to position the Pelvic Plate on the Couch. Adjust their lateral position by loosening the screws (circled below) at the top of the Pelvic Plate, carefully move the strips to alter their lateral position. Tighten the screws again when the Pelvic Plate is positioned correctly.



### II. POSITION THE PATIENT

Position the patient on the Pelvic Plate and mould the pelvic Mask around the pelvic area of the patient. For more information on mask moulding, refer to IFU117000 - Thermoplastic Masks.



*Pelvic Mask*

## 5. Cleaning, Storage and Disposal

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- 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

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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.

## 7. 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.

## 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.
	Serial Number	Indicates the manufacturer's serial number so that a specific medical device 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 Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.



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