

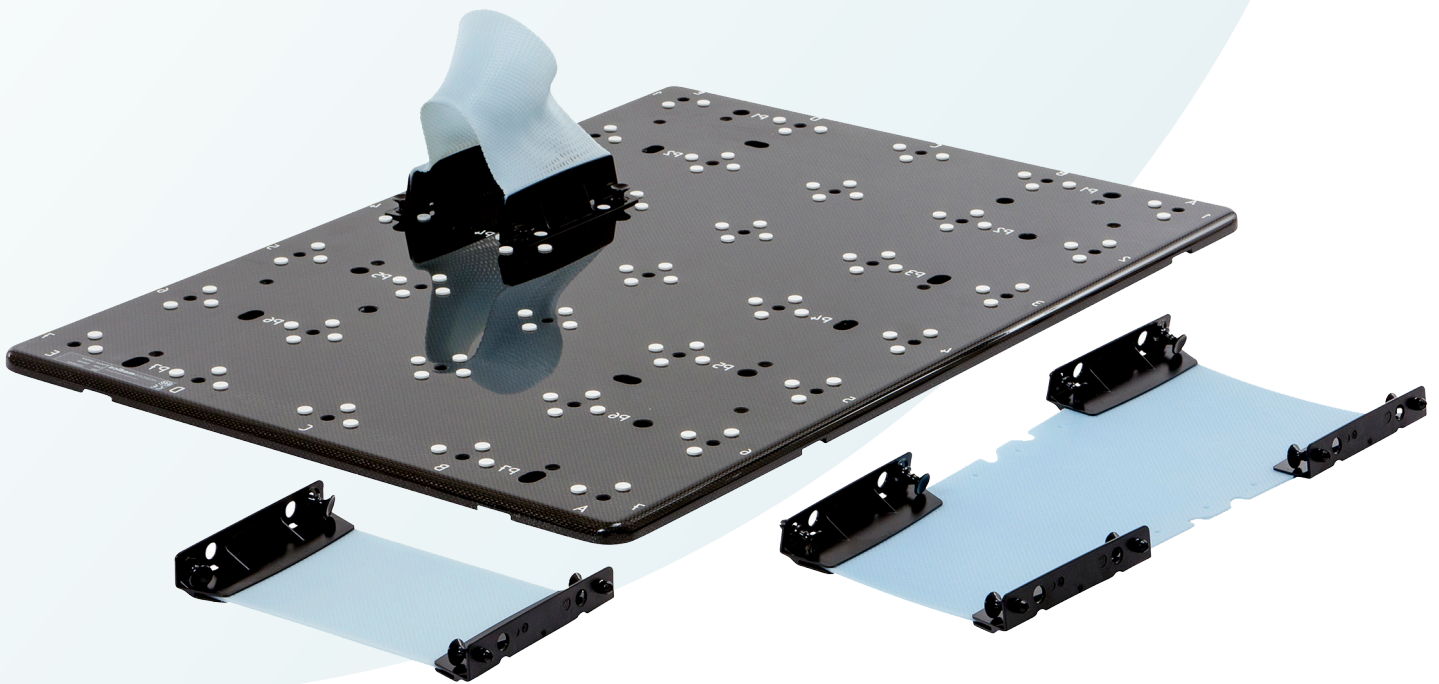


**macromedics**

SOLUTIONS IN RADIOTHERAPY

MANUAL 135100  
Instructions for use  
English Instructions

## MacroMedics® UniqFix



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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.
- 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 UNSAFE

The following devices are MR unsafe:

- 135100 UniqFix



## 2.2 MR SAFE

The following devices are MR safe:

- 135150 UniqFix MR



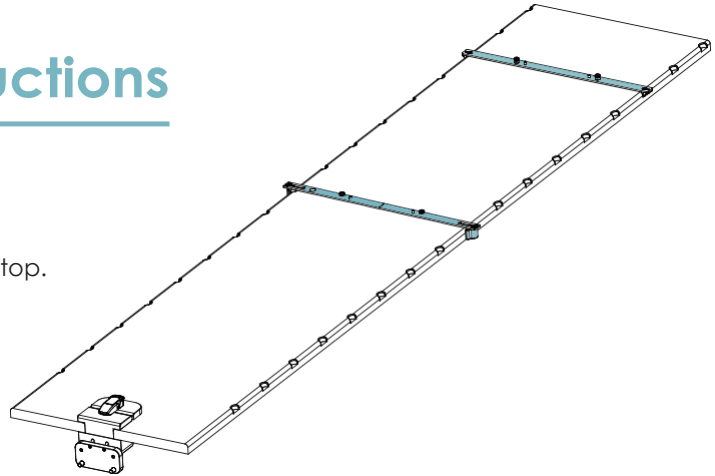
# 3. Intended Use

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

## 4. Installation Instructions

### I. PLACE THE COUCHSTRIPS

Place the couchstrips onto the couchtop.



### II. PLACE THE UNIQFIX

Place the UniqFix onto the couchstrips. Make sure that there is no movement between the baseplate and the couch.

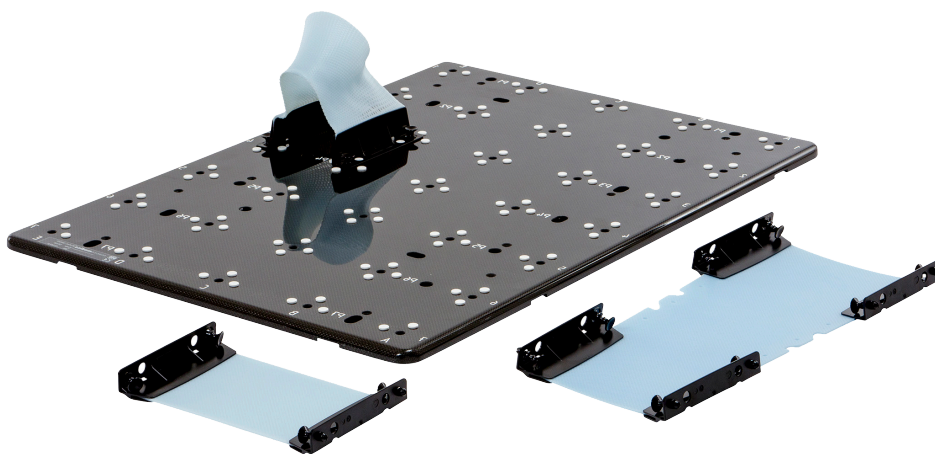
### III. POSITIONING THE PATIENT

Place the affected body part onto the UniqFix.

Lift the body part with a cushion if necessary.

Mould a Mask around the body part, referring to IFU117000 - Thermoplastic Masks.

Record the position of the Mask Profiles on the UniqFix Set-Up sheet.



## 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.
 GS1 Code: (21)	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 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 Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.



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