



**macromedics**

SOLUTIONS IN RADIOTHERAPY

MANUAL 130250  
Instructions for use  
English Instructions

## MacroMedics® FeetSupport™



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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 the products outside of the prescribed MRI Safety conditions.
- Place the FeetSupport carefully on the pins of the baseplate.
- Take care not to damage the baseplate when positioning the FeetSupport.
- The product contains metal parts. The metal parts in the FeetSupport can affect the CT image quality.
- Make sure that the patient removes their footwear before using the product.
- Ensure that the FeetSupport is secured to the baseplate before positioning the patient.
- Do not place extremities between the rotating mechanism of the rotatable FeetSupport.
- 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 CONDITIONAL

The following devices are MR Conditional:

- 130250 FeetSupport™, fixed
- 130260 FeetSupport™, rotatable
- 130450 FeetSupport™ 2.0, fixed
- 130490 FeetSupport™ 2.1, rotatable
- 164130 MRidian fixed FeetSupport™



The devices labelled as MR Conditional can be safely used in a MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla, **with**
- Maximum spatial field gradient of 2,500 G/cm (25T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Due to the size and location of the metallic parts, no clinically significant RF heating is expected.

## 3. Intended Use

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

## 4. Types of FeetSupport



130260 – FeetSupport™, rotatable



130250 – FeetSupport™, fixed



130450 – FeetSupport™ 2.0, fixed



130490 – FeetSupport™ 2.1, rotatable



164130 – MRIdian FeetSupport™, fixed

## 5. Installation Instructions

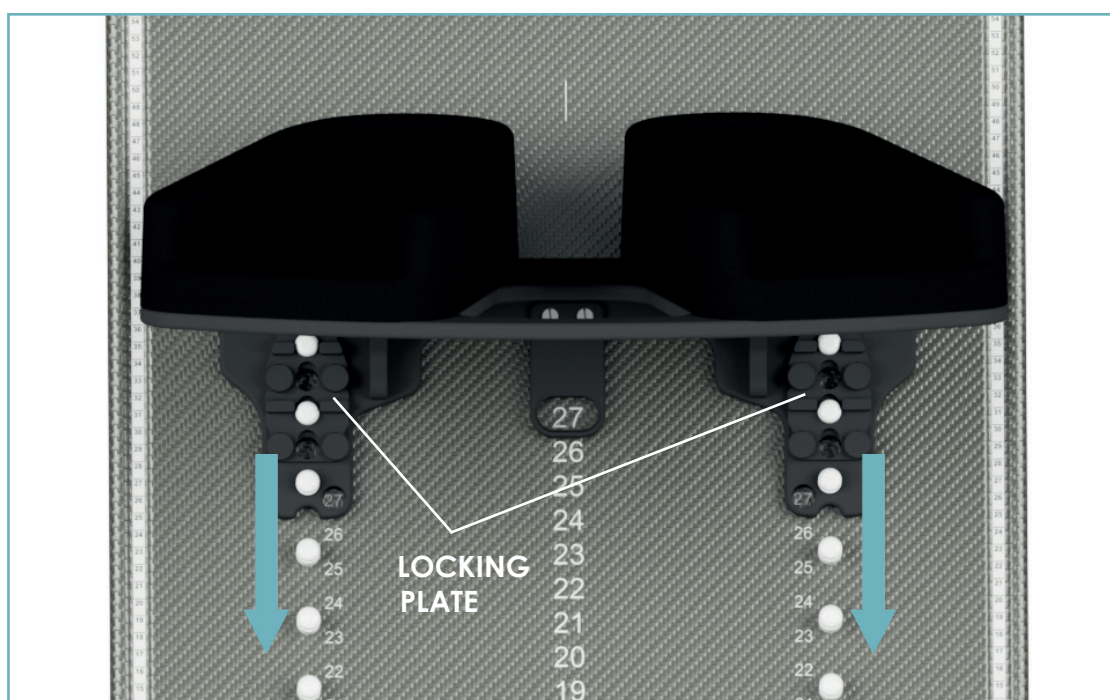
### 5.1 ATTACHING THE FIXED FEETSUPPORT TO A CORRESPONDING BASEPLATE

*(Applicable to the following FeetSupport models: 130260/130250/164130)*

Before placing the FeetSupport onto the baseplate, push the locking plates in the cranial direction to unlock the holes. The locking plates can be found on the base of the FeetSupport. The slots are open and the FeetSupport can be placed over the pins on the baseplate.



Pull the black locking plates in the caudal direction to lock the FeetSupport to the baseplate. Read the position index on the baseplate for patient repositioning.

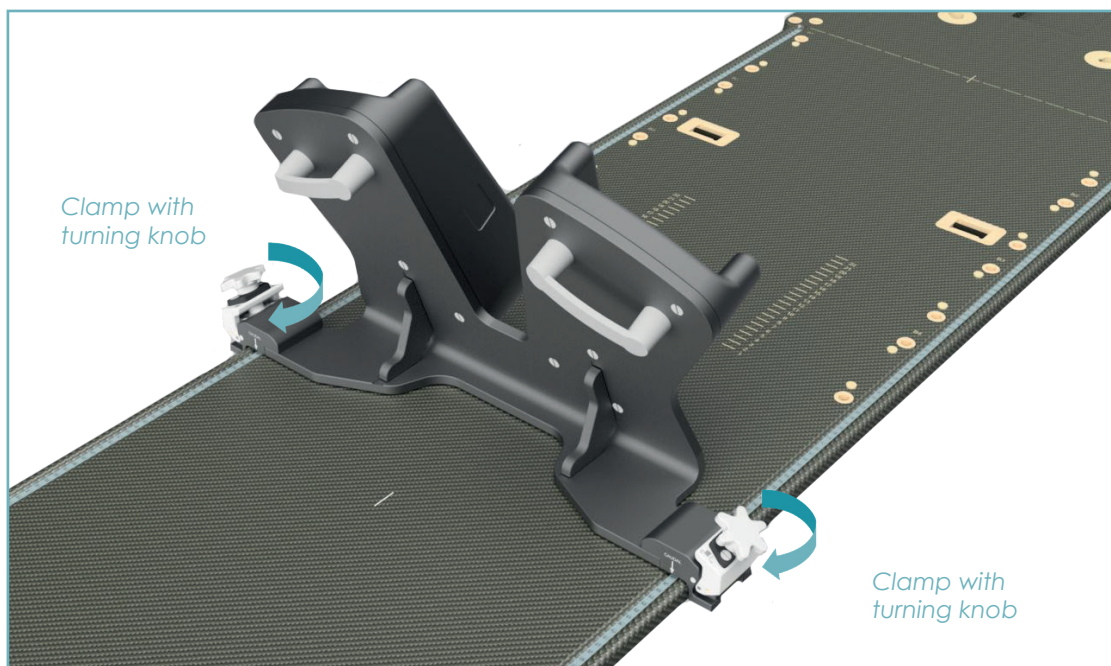




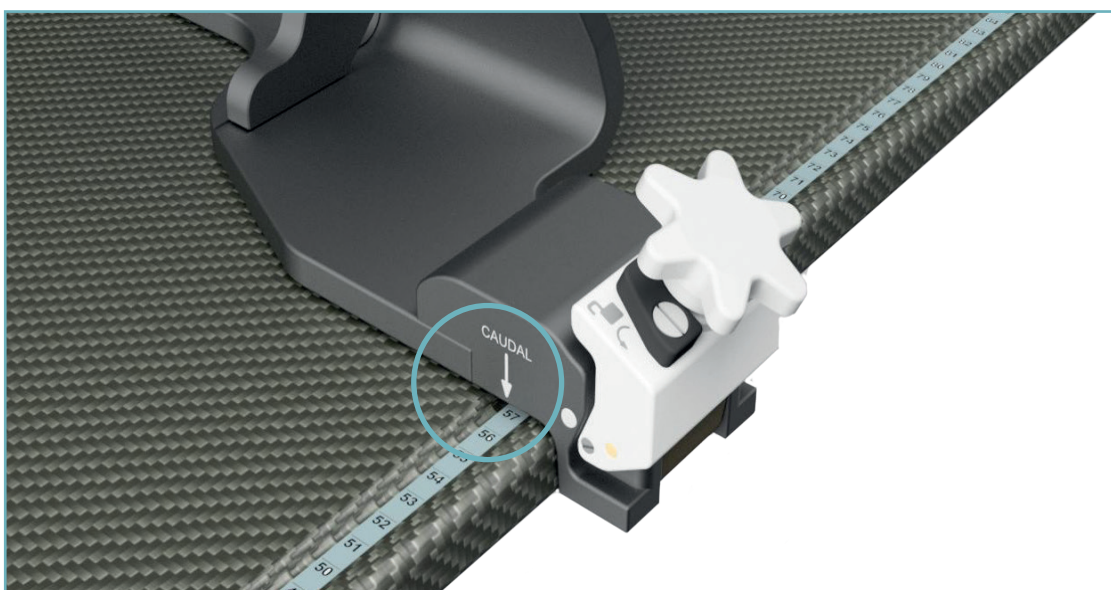
## 5.2 ATTACHING THE SLIDING FEET SUPPORT TO THE OMNIBOARD AND OMNICOUCH. (Applicable to the following FeetSupport models: 130450/130460)

Place the FeetSupport at the caudal side of the OmniBoard (2.0 & 3.0) or OmniCouch and locate the clamps on the sides of the baseplate.

Rotate and hand-tighten the knobs on each side of the FeetSupport until it is properly fastened onto the baseplate. Do not apply too much force as this may cause damage.

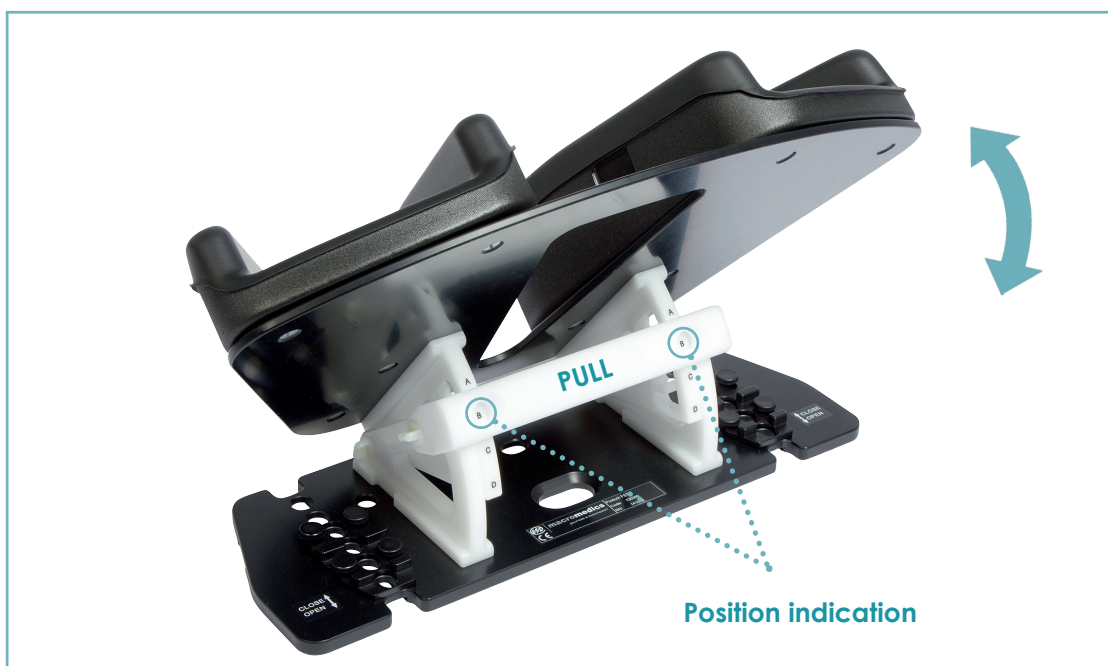


Read the position index on the ruler of the Omnicouch for patient positioning.



### 5.3 CHANGING THE ANGLE OF THE ROTATABLE FEETSUPPORT

Pull the white horizontal rail to unlock the rotating mechanism and change the angle of the FeetSupport by moving it up or down. Push back the rail to lock the FeetSupport in the chosen position. The position is indicated on both sides of the rail of the rotating mechanism.





## 6. 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 bottle of the cleaning agent.
- Do not 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 FeetSupport in the upright position, in a dry environment away from direct sunlight.
- Dispose of the device in accordance with the local laws and regulations applicable to your country.

## 7. 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.

## 8. 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.

## 9. 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.
<b>Rx ONLY</b>	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 Conditional	An item with demonstrated safety in the MR environment within defined conditions.

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