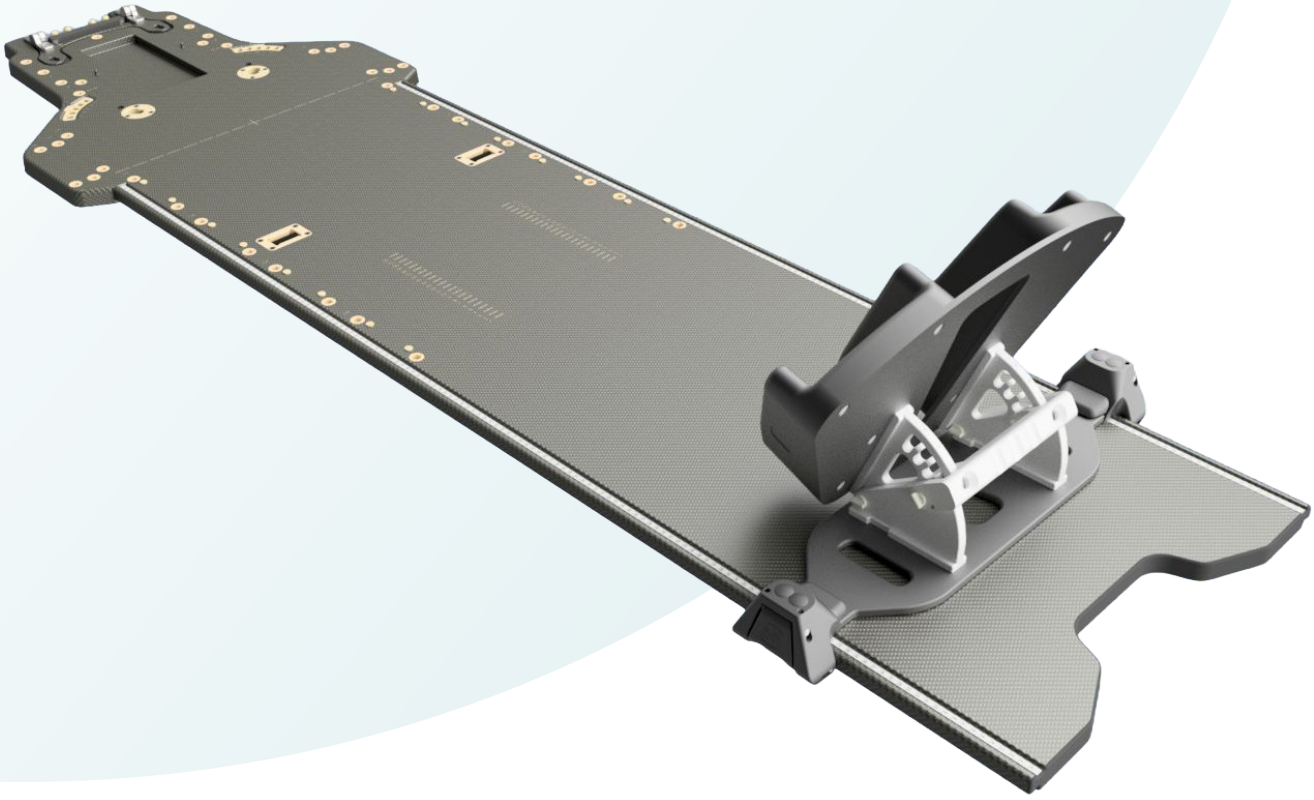
macromedics
SOLUTIONS IN RADIOTHERAPY

MANUAL 130250
Instructions for use
English Instructions

MacroMedics® FeetSupport™



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1. Warnings



- Inspect the device prior to use and to not use the product when damage is detected.
- 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.
- Do not slide the FeetSupport while the clamps are in the locked position. Trying to slide the FeetSupport when clamps are locked may cause device damage.
- 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.

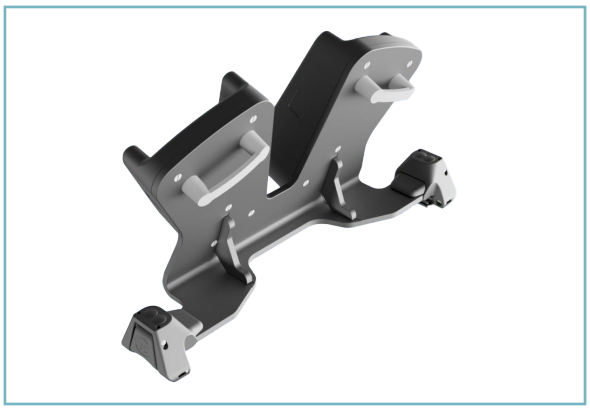
4. Types of FeetSupport



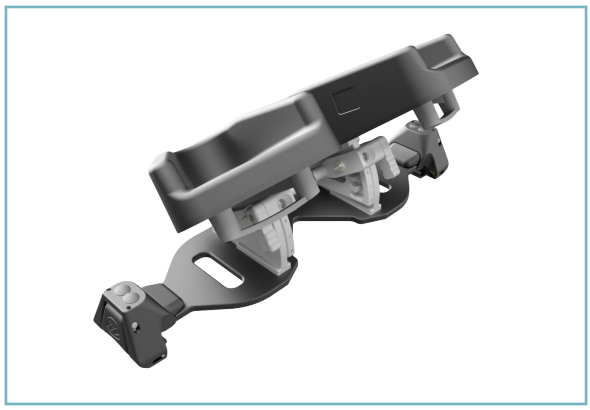
130260 – FeetSupport™, rotatable



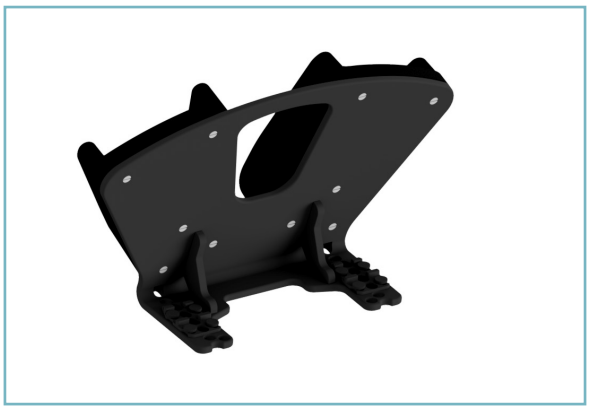
130250 – FeetSupport™, fixed



130450 – FeetSupport™ 2.0, fixed



130490 – FeetSupport™ 2.1, rotatable



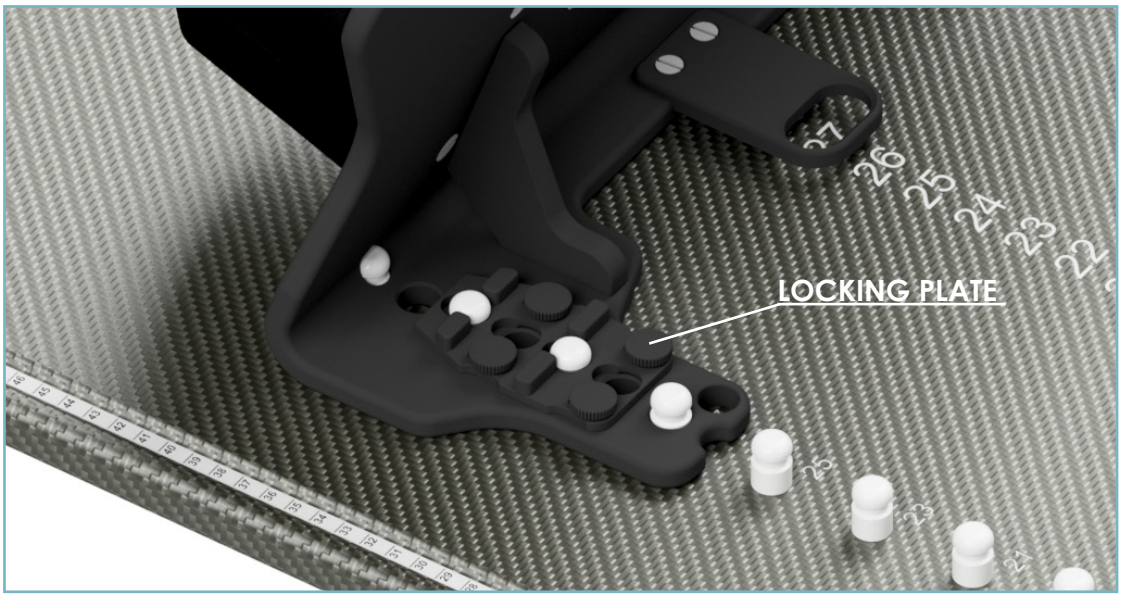
164130 – MRIdian FeetSupport ™, fixed

5. Use Instructions

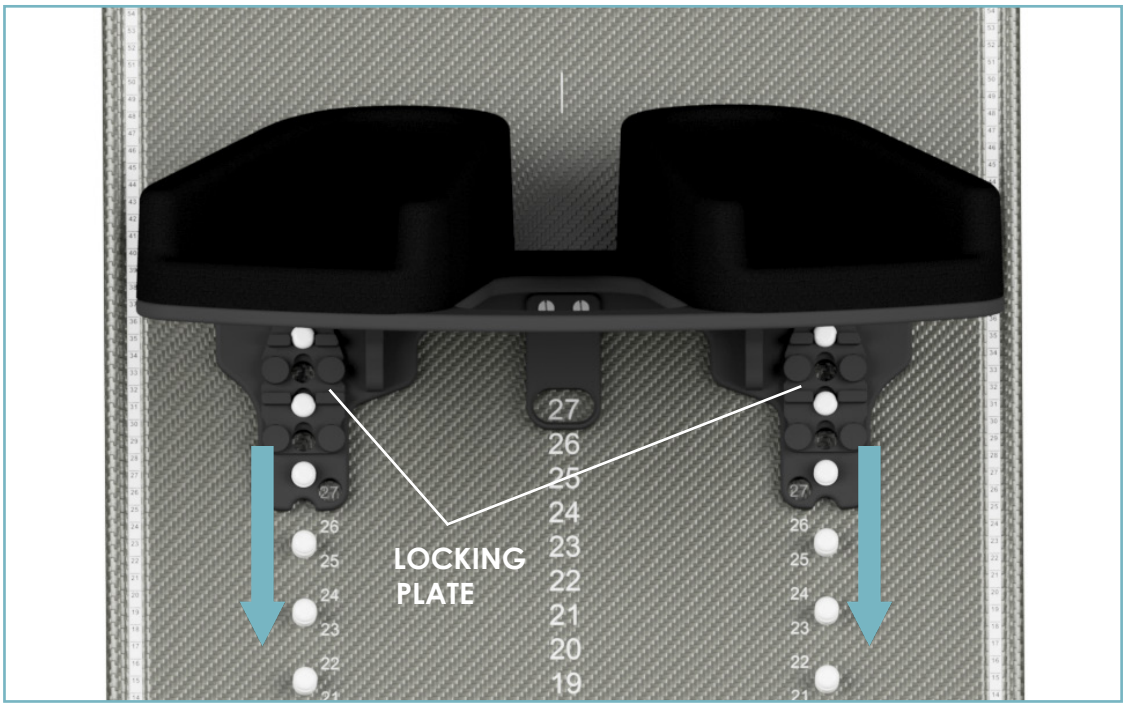
5.1 Attaching the fixed FeetSupport to a corresponding baseplate

(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 baselate.



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.

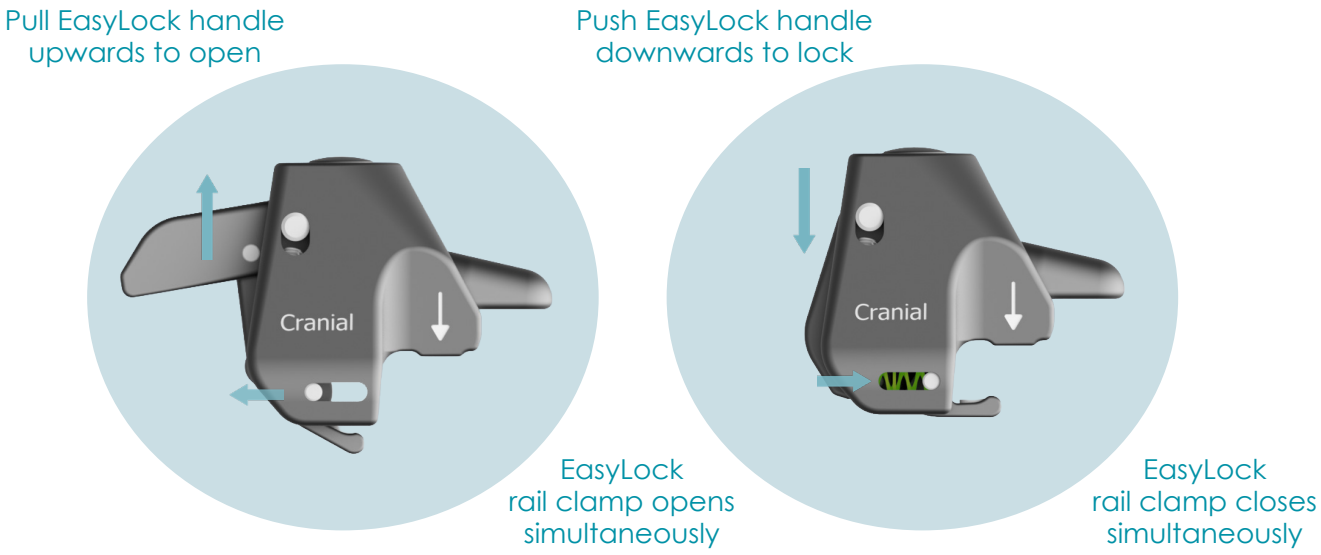


5.2 Attaching the sliding FeetSupport to the OmniBoard and OmniCouch.

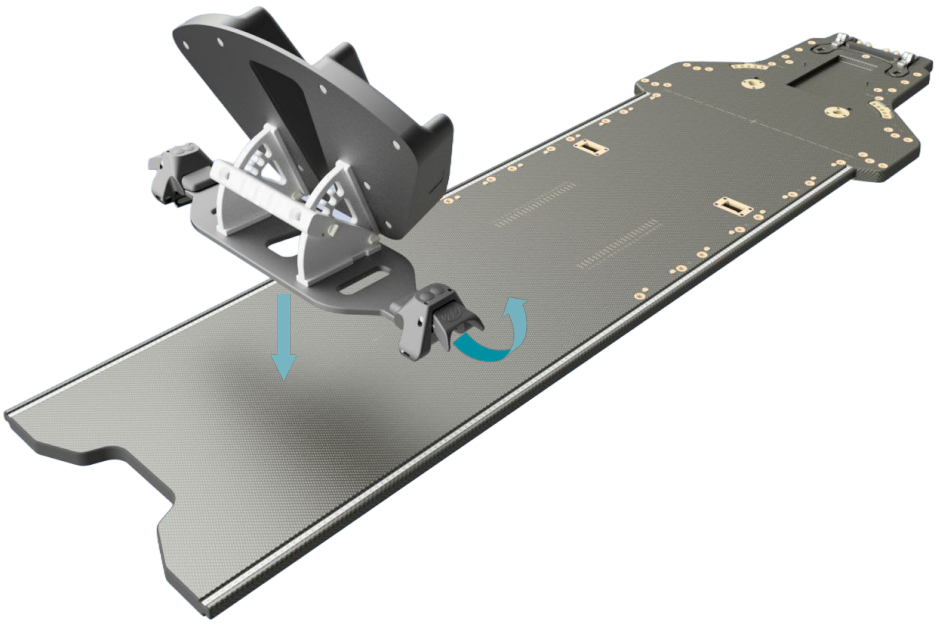
(Applicable to the following FeetSupport models: 130450/130460)

I. Place the FeetSupport at the caudal side of the OmniBoard (2.0 & 3.0) or the OmniCouch. Locate the EasyLock clamps on both sides of the baseplate.

If a clamp is in the locked or partially open positon, pull the EasyLock handle fully upwards until it reaches its upper end position and the EasyLock rail clamp opens up fully.

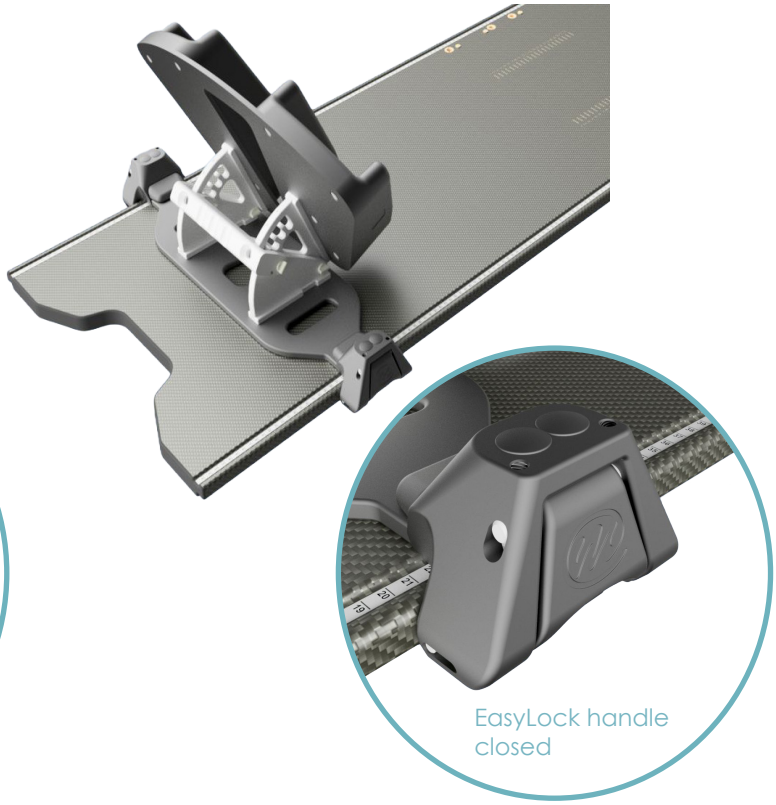


With both EasyLock rail clamps fully open, align the FeetSupport with the OmniBoard rails. Slide the BottomStop along the rail into the desired longitudinal position for the patient.



II. Once the BottomStop is correctly positioned, push both the EasyLock clamp handles downwards to lock the BottomStop securely onto the OmniBoard.

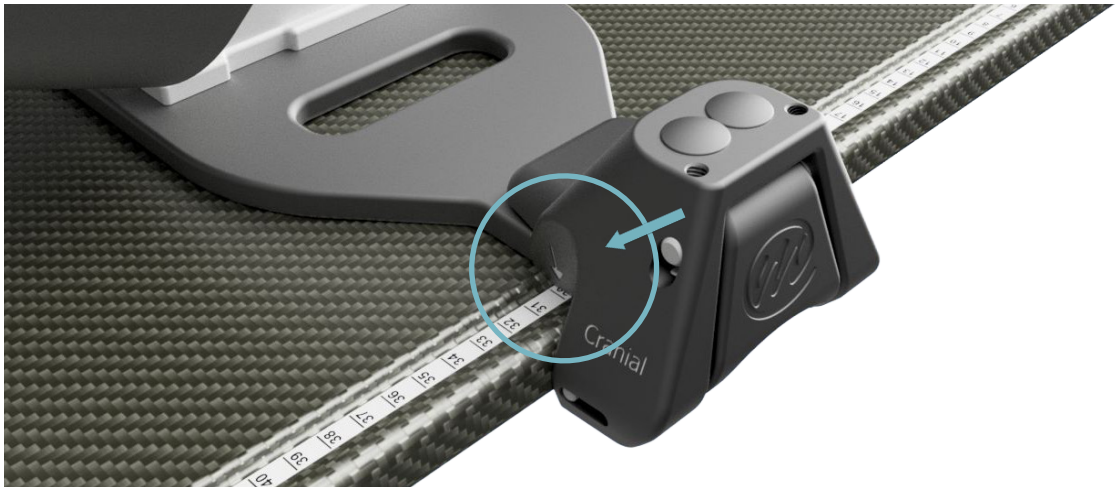




After locking the clamps, perform a functional check to verify that the clamp fixation is secure and functioning correctly, and do not use the device if the clamp fixation is found to be loose, damaged, or otherwise not functioning as intended.

Always ensure the clamps are unlocked before sliding the BottomStop.

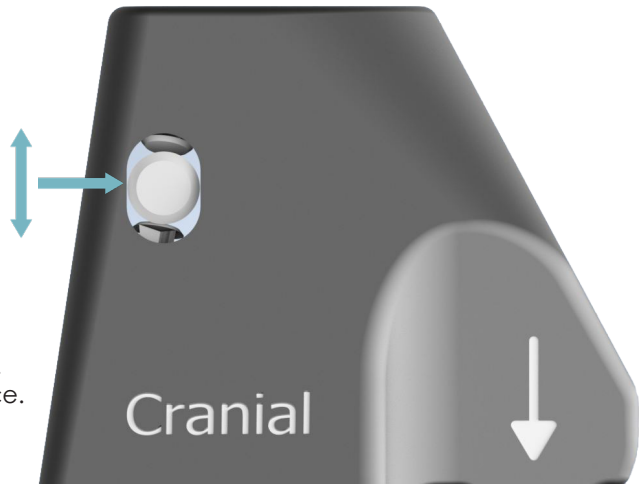
III. Read the position index on the ruler of the OmniBoard to record the longitudinal position for patient repositioning.



IV. Adjusting the clamp

If excessive force is required to close the clamp, or if the clamp does not secure firmly onto the OmniBoard, adjust the height of the clamping axis. Each clamp has two set screws on each side (four in total) that allow adjustment of the clamping force. A flat-head screwdriver with a maximum blade thickness of 5 mm is required. Ensure that adjustments are performed symmetrically on both sides to maintain correct clamping alignment.

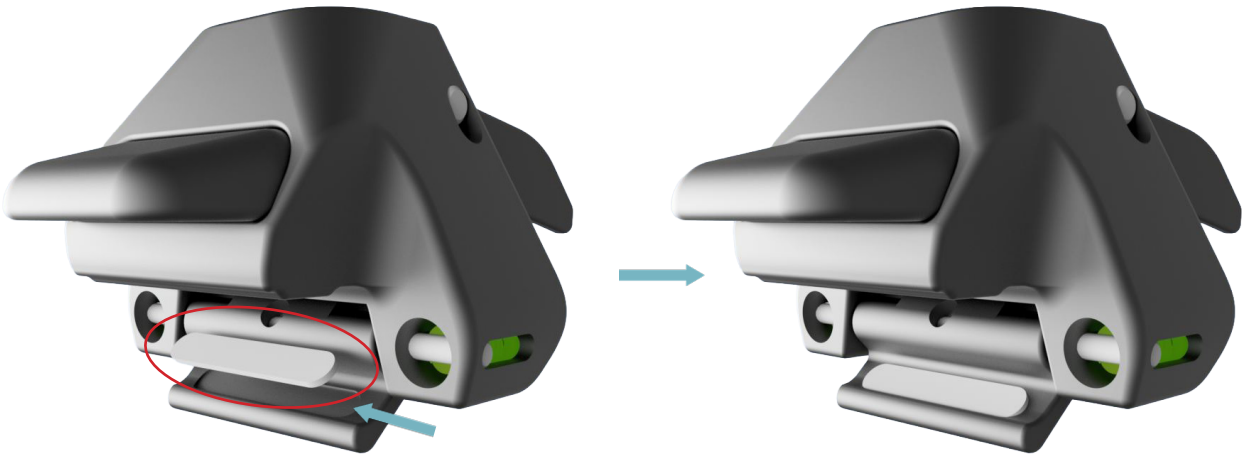
- Moving the axis upwards will decrease the clamping force.
- Moving the axis downwards will increase the clamping force.



V. Replacing the rubber strips

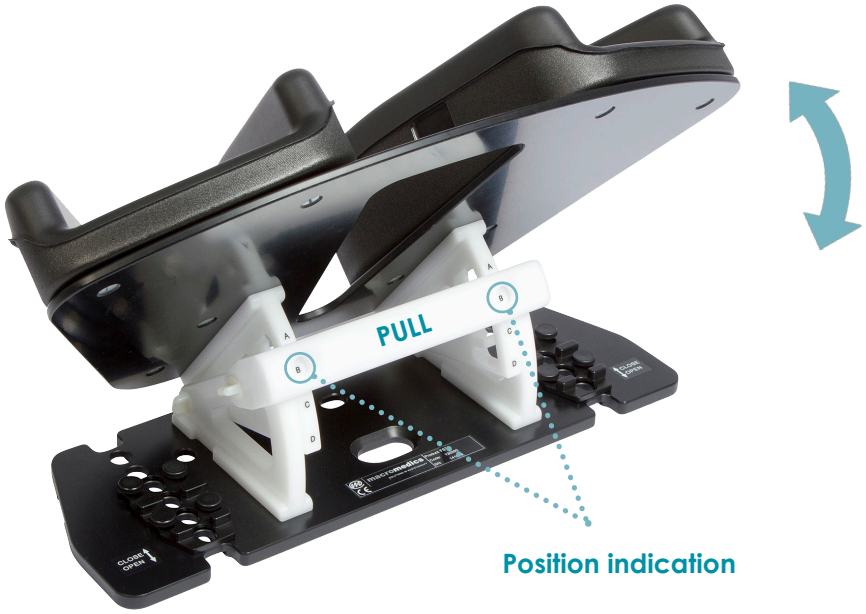
If adequate clamp fixation cannot be achieved after adjusting the clamping axis, the rubber clamping strip (indicated by the red circled area) may need to be replaced.

Remove the rubber clamping strip and ensure that no strip material or adhesive residue remains on the surface of the clamp. Clean the indicated surface (blue arrowed) with 70% isopropyl alcohol and allow it to dry completely. Apply an adequate amount of cyanoacrylate adhesive to the surface and carefully place the new rubber clamping strip. Allow the adhesive to cure fully, then re-adjust the clamping axis (step IV) to set the correct clamping force.



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 FeetSuport in the chosen position. The position is indicated on both sides of the rail of the rotating mechanism.



6. 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.
- 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.
- 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 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

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

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
CE	CE Mark	CE marking of conformity.
	Manufacturer	Indicates the medical device manufacturer.
REF	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
SN 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.
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 Conditional	An item with demonstrated safety in the MR environment within defined conditions.

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