

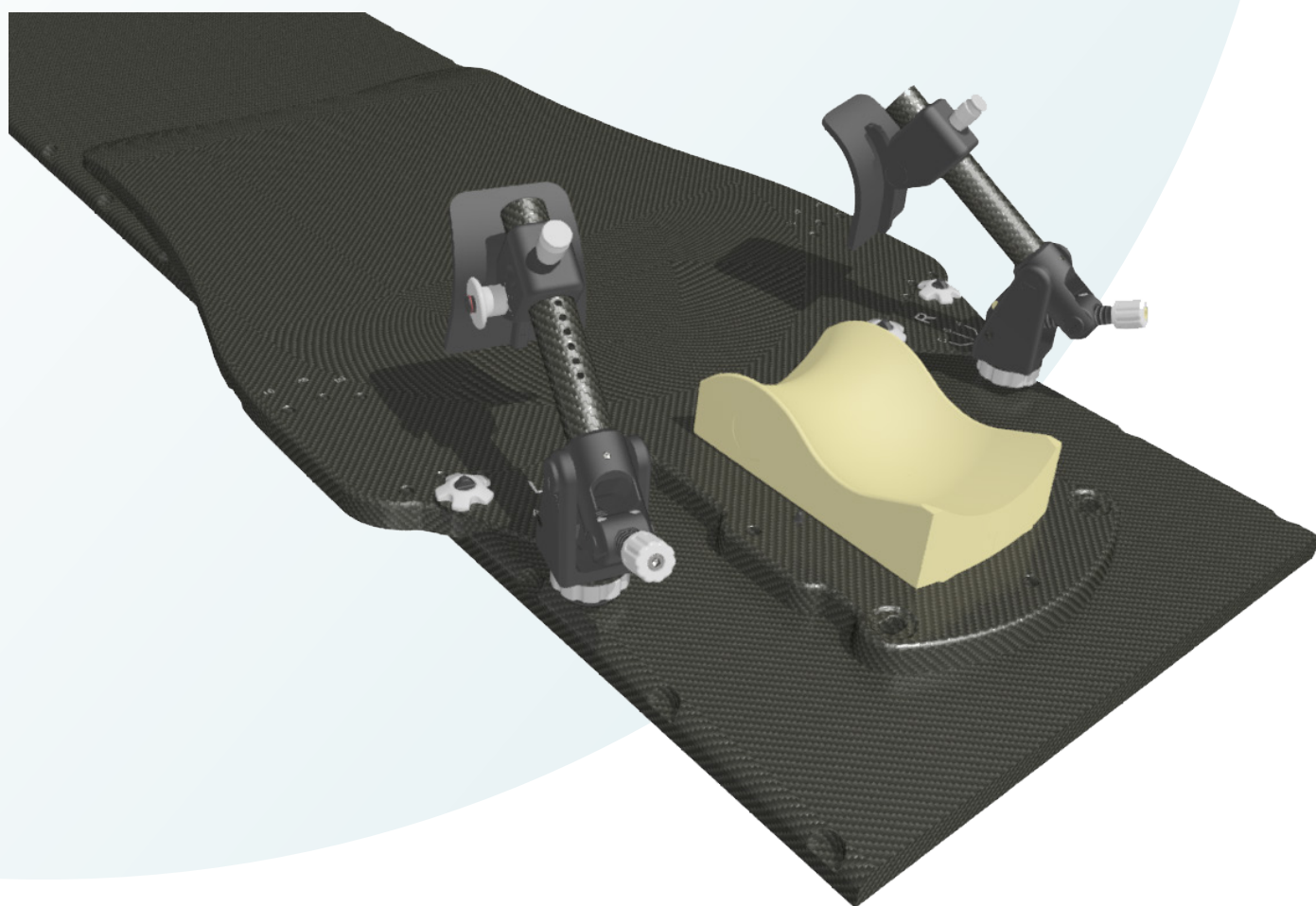


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SOLUTIONS IN RADIOTHERAPY

MANUAL 111250
Instructions for use
English Instructions

MacroMedics ® Shoulder Depressor



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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 Shoulder Depressor to the baseplate and retract it before positioning the patient.
- Ensure that all locking mechanisms are activated before starting treatment.
- 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 products are MR unsafe:

- 111250 Shoulder Depressor, set/2



2.2 MR CONDITIONAL

The following products are MR conditional:

- 111290 Shoulder depressor MRC, set/2



A patient with this device can be safely scanned in an 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 (25 T/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.

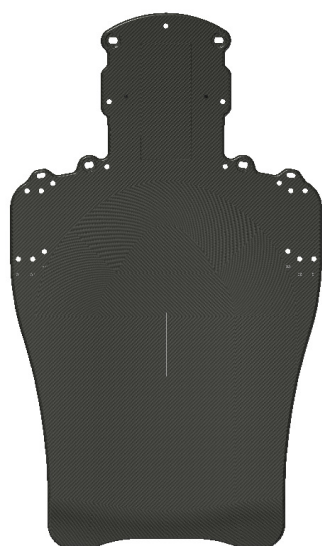
3. Intended Use

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

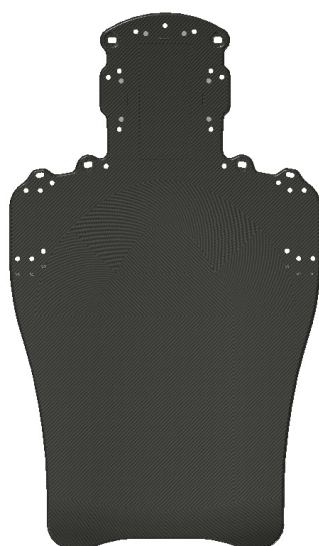
4. Installation Instructions

4.1 USE A CORRECT BASEPLATE

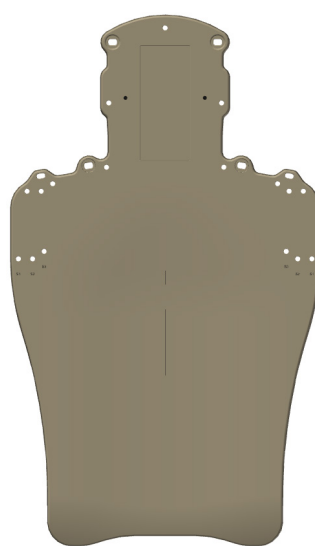
Ensure that a compatible MacroMedics baseplate is used.



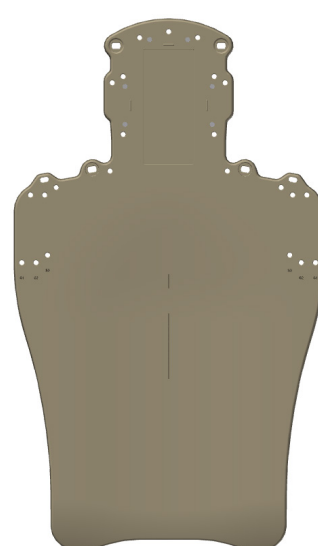
111400
S-Type Baseplate



111300
RealEase Baseplate



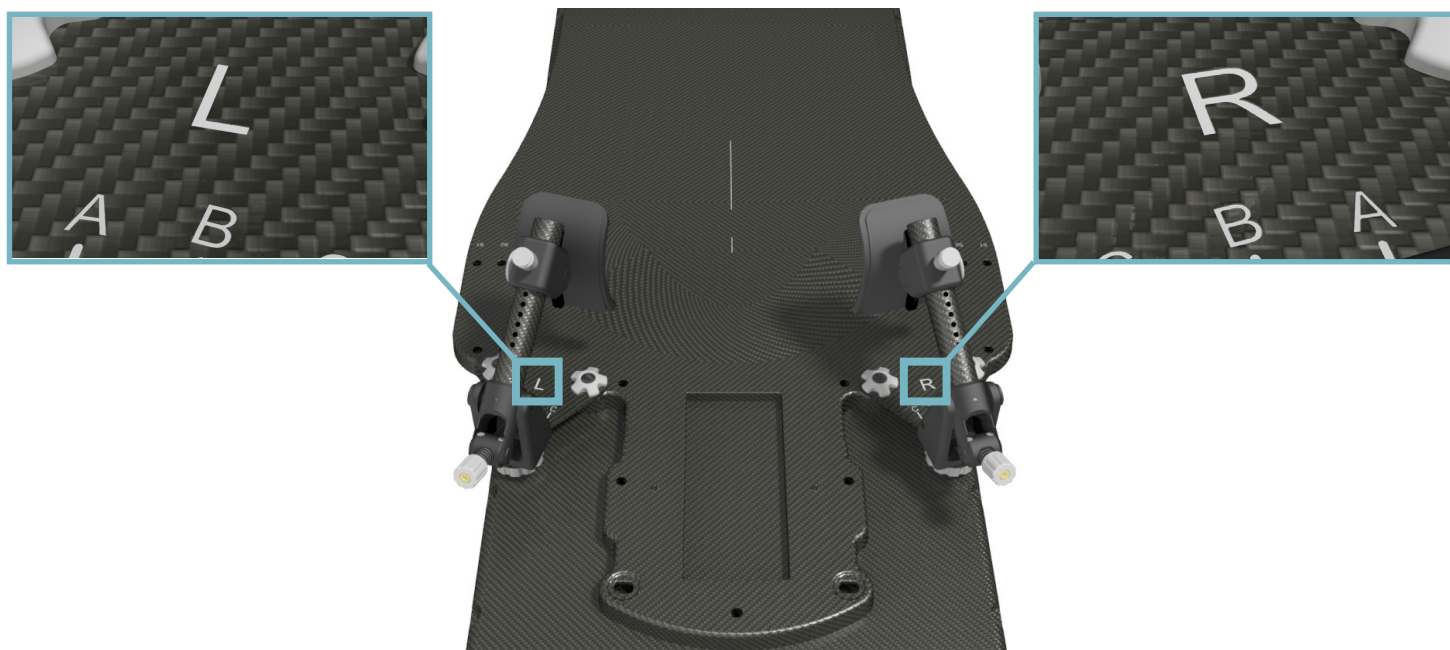
111450
S-Type Baseplate, MR



111350
RealEase Baseplate, MR

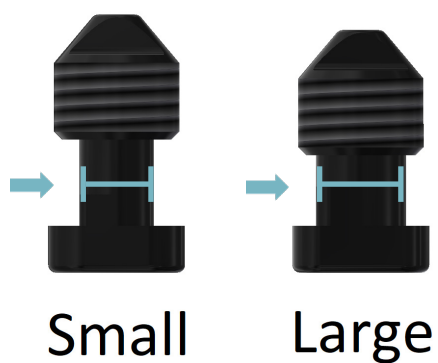
4.2 HOW TO ATTACH THE SHOULDER DEPRESSORS TO THE BASEPLATE

Align the left Shoulder Depressor (indicated with an 'L') on the left side of the baseplate and the right Shoulder Depressor (indicated with an 'R') on the right side of the baseplate.

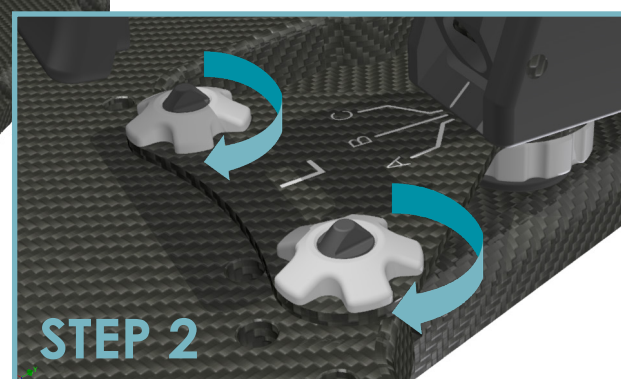
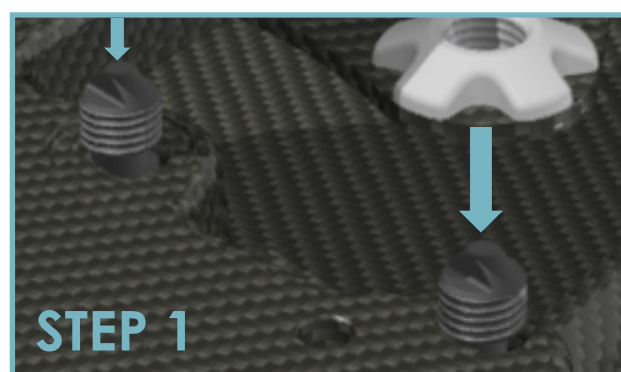
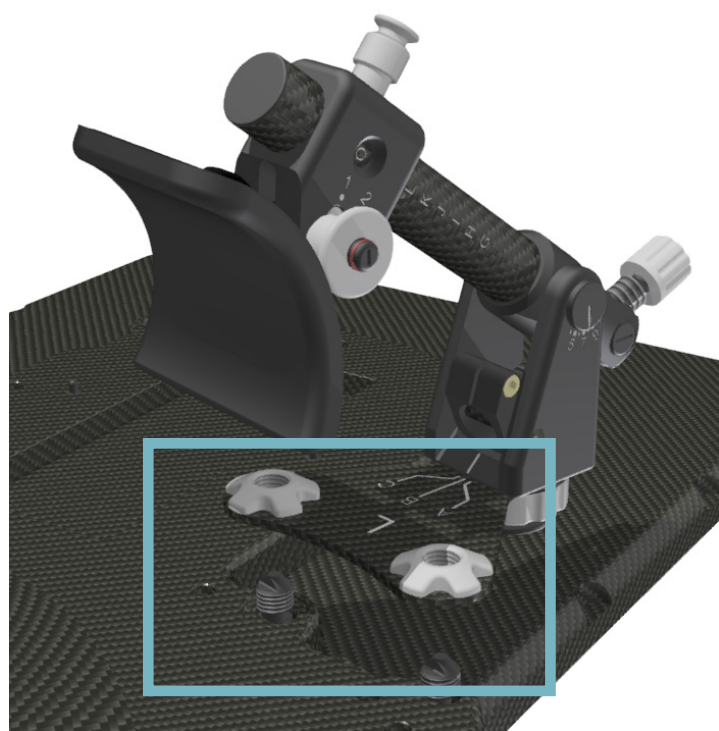


To attach the Shoulder Depressors to the baseplate:

- I. Insert the included small and large black pins into the corresponding holes of the baseplate.

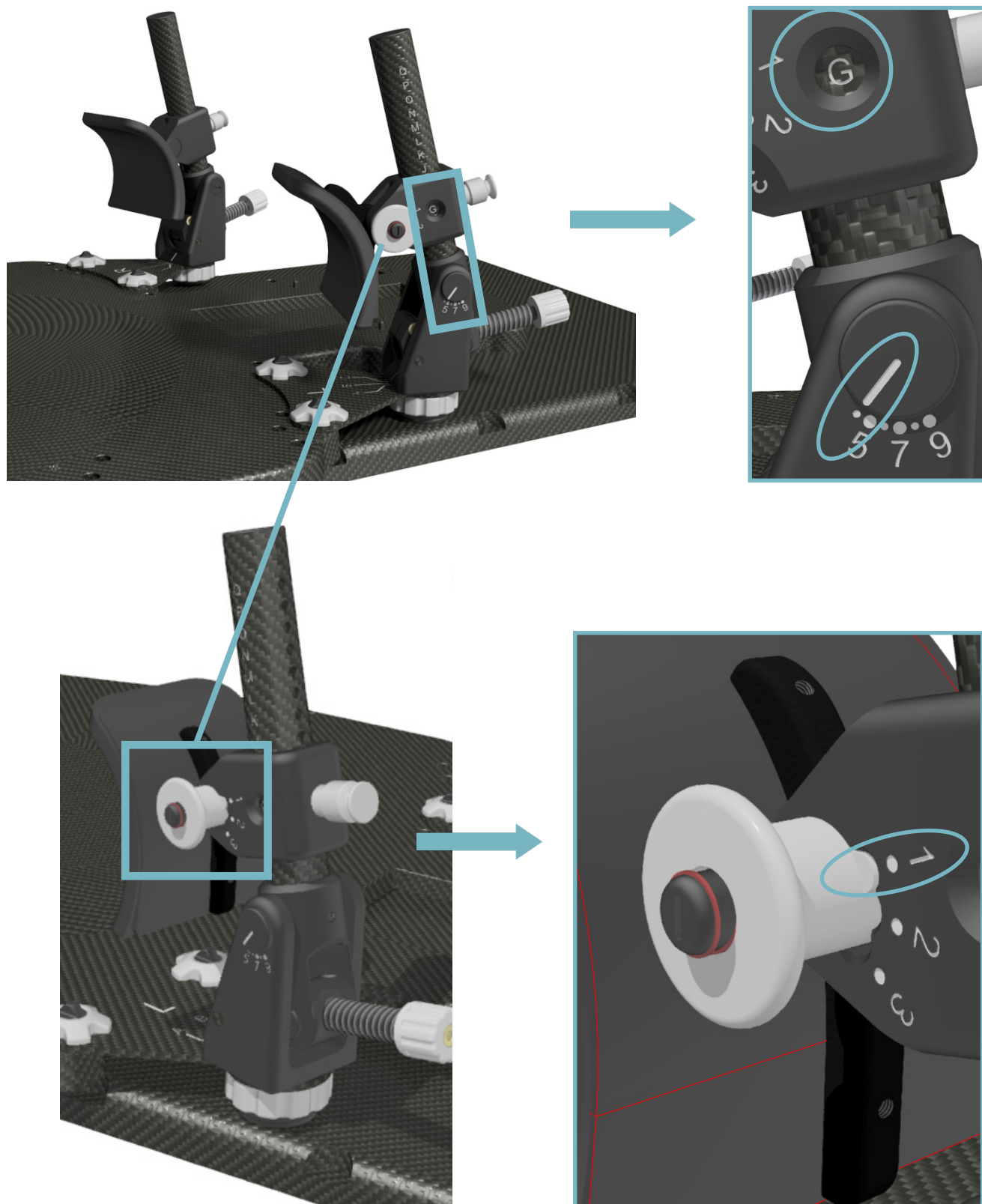


- II. Position the two holes in the base of the Shoulder Depressor above the two black pins and lower the Shoulder Depressor onto the baseplate. Turn the white star-shaped knobs clockwise to secure the Shoulder Depressors in place.



4.3 POSITION THE SHOULDER DEPRESSORS IN THEIR INDEXED POSITIONS.

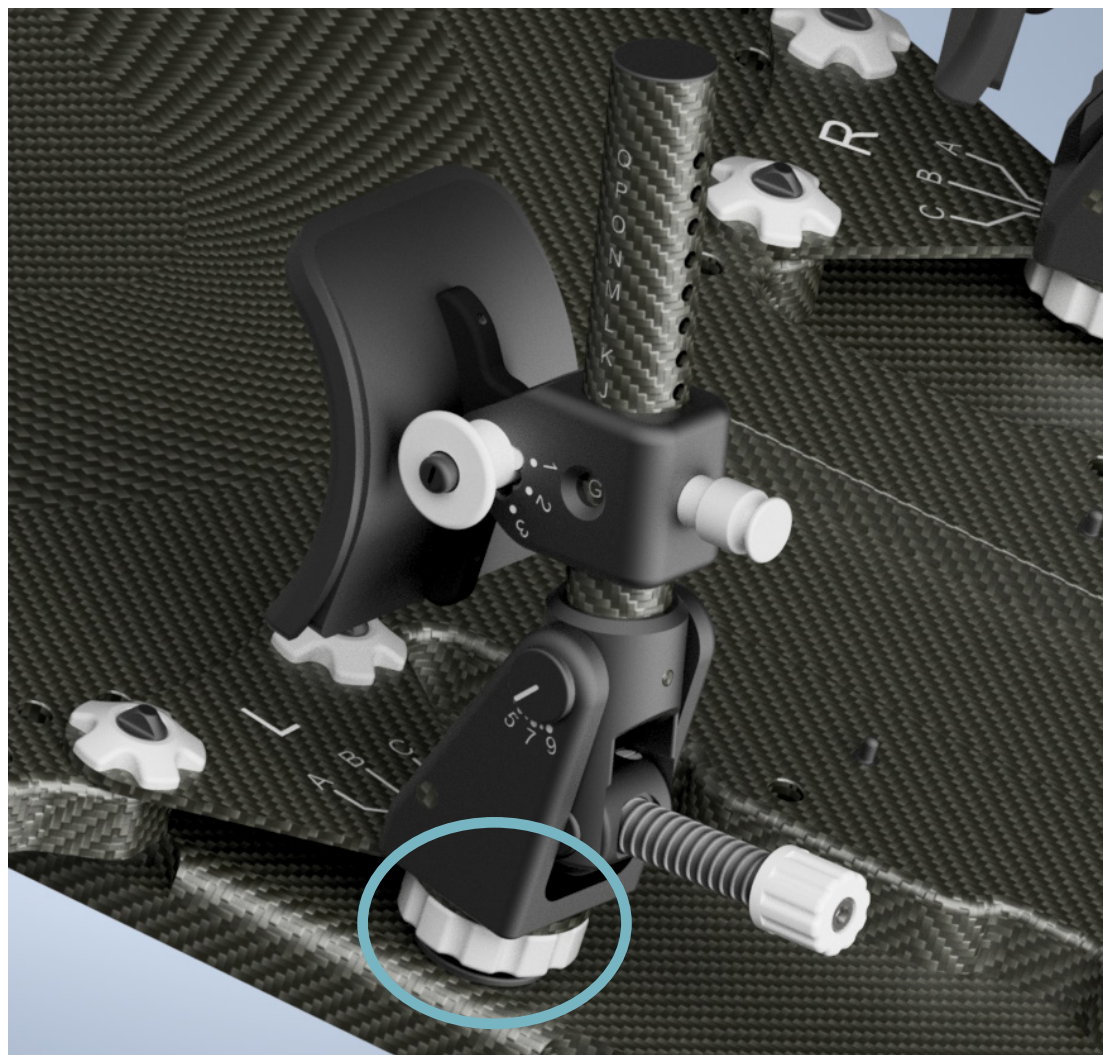
Prior to positioning the patient on top of the baseplate, make sure that the Shoulder Depressors are retracted in the indexed positions: G, 4 and 1.



4.4 ADJUST THE POSITION OF THE SHOULDER DEPRESSORS TO THAT OF THE PATIENT.

After the patient has laid down on the baseplate, position the shoulder cup against the patient's shoulder and move it to the desired position.

To optimise the position of the cup, the rotation of the Shoulder Depressor can be adjusted. Turn the white knob highlighted below counterclockwise and swivel the Shoulder Depressor into the desired indexed position (A, B or C). Once the Shoulder Depressor is in the desired position, turn the white knob clockwise to secure it in place.



White ribbed knob

4.5 AFTER TREATMENT RETURN THE SHOULDER DEPRESSORS TO INDEXED POSITIONS.

After treatment, before lifting the patient off the baseplate, set the Shoulder Depressors to the indexed position indicated in step 4.3.

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 detailed on the bottle 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.
- 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

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
	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.
Rx ONLY	Prescription Only	Devices for sale to physicians or trained healthcare providers only.
	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions.
	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.



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