



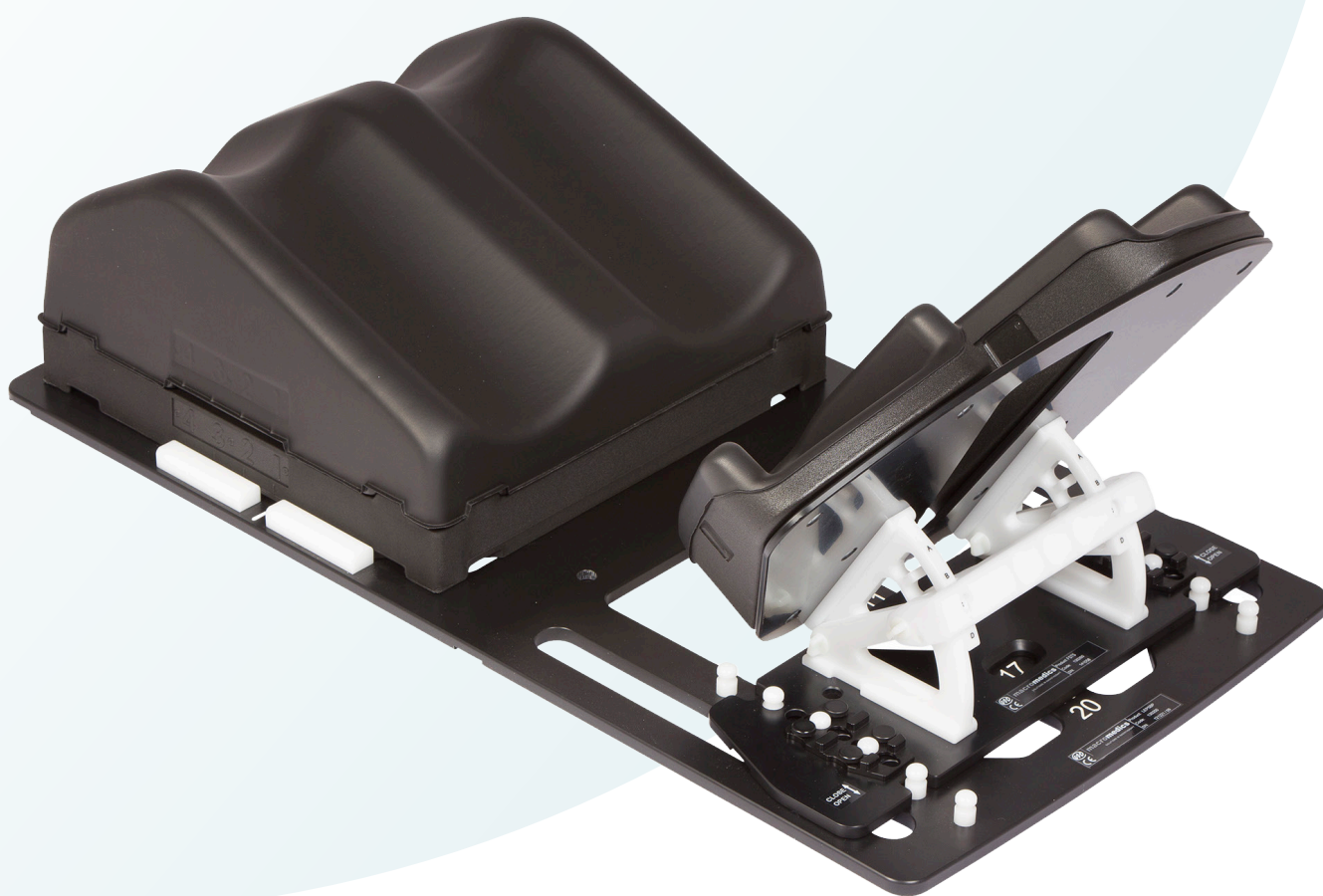
**macromedics**

SOLUTIONS IN RADIOTHERAPY

MANUAL 130300  
Instructions for use  
English Instructions

## MacroMedics® LEPS™

*Lower Extremity Positioning System*



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## Table of Contents

1. Warnings.....	4
2. MRI Safety Information.....	4
3. Intended Use.....	4
4. Installation Instructions.....	5
5. Cleaning, Storage & Disposal.....	12
6. Warranty.....	12
7. Notices.....	12
8. Glossary of Symbols.....	13

# 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.
- Secure the device properly before positioning the patient.
- Remove all accessory devices before moving or storing the LEPS baseplate, as otherwise they may fall and become damaged.
- 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 CONDITIONAL

The following devices are MR conditional:

- 130300 LEPS™, FeetSupport™, rot.
- 130310 LEPS™, FeetSupport™, fixed
- 130250 FeetSupport™, fixed
- 130260 FeetSupport™, rotatable



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 (25 T/m)
- Maximum force product of 50,000,000 G<sup>2</sup>/cm (50 T<sup>2</sup>/m)

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

## 2.2 MR SAFE

The following devices are MR safe:

- 130200 LEPS™ baseplate
- 130350 Shoulder retr. for LEPS™
- 130420 LEPS™ baseplate short
- 130100 KneeSupport™
- 130120 KneeSupport™ LiftBlock™
- 130130 KneeSupport™ low, plastic
- 130140 KneeSupport™, plastic



# 3. Intended Use

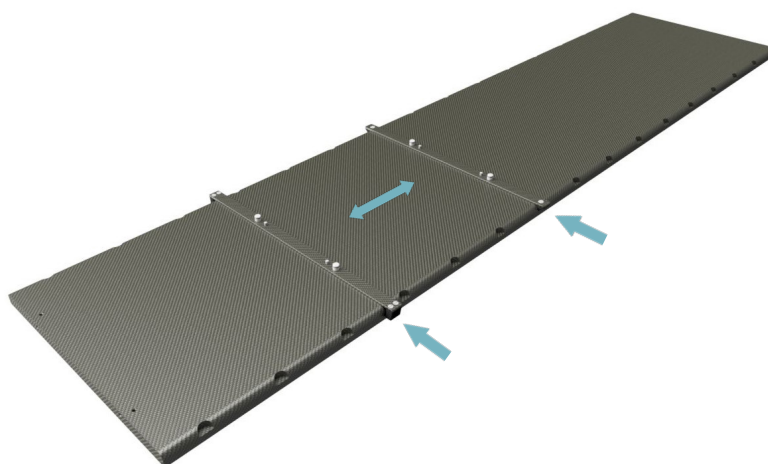
Positioning of the patient during radiotherapy and radiodiagnostics, including MR where indicated.

## 4. Installation Instructions

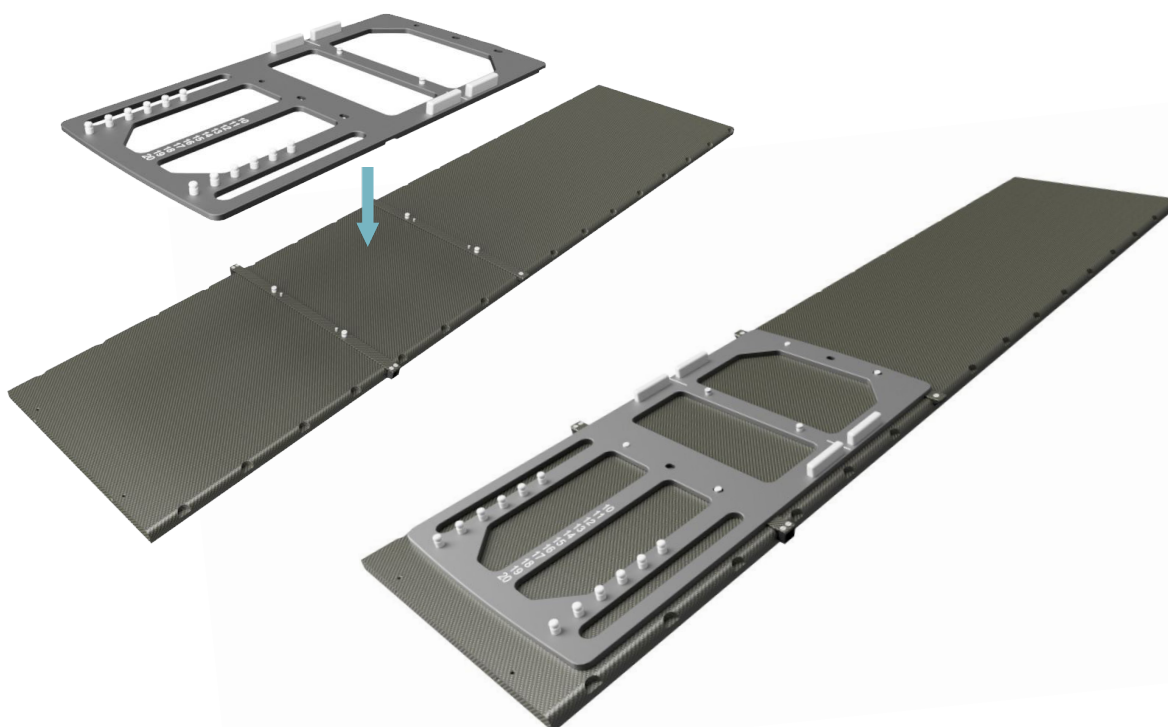
The LEPS supports the positioning of the patient's pelvic region and lower extremities. Shoulder Retractors can be optionally added to the system to enable the depression of the patient's shoulders.

### 4.1 PLACING THE LEPS.

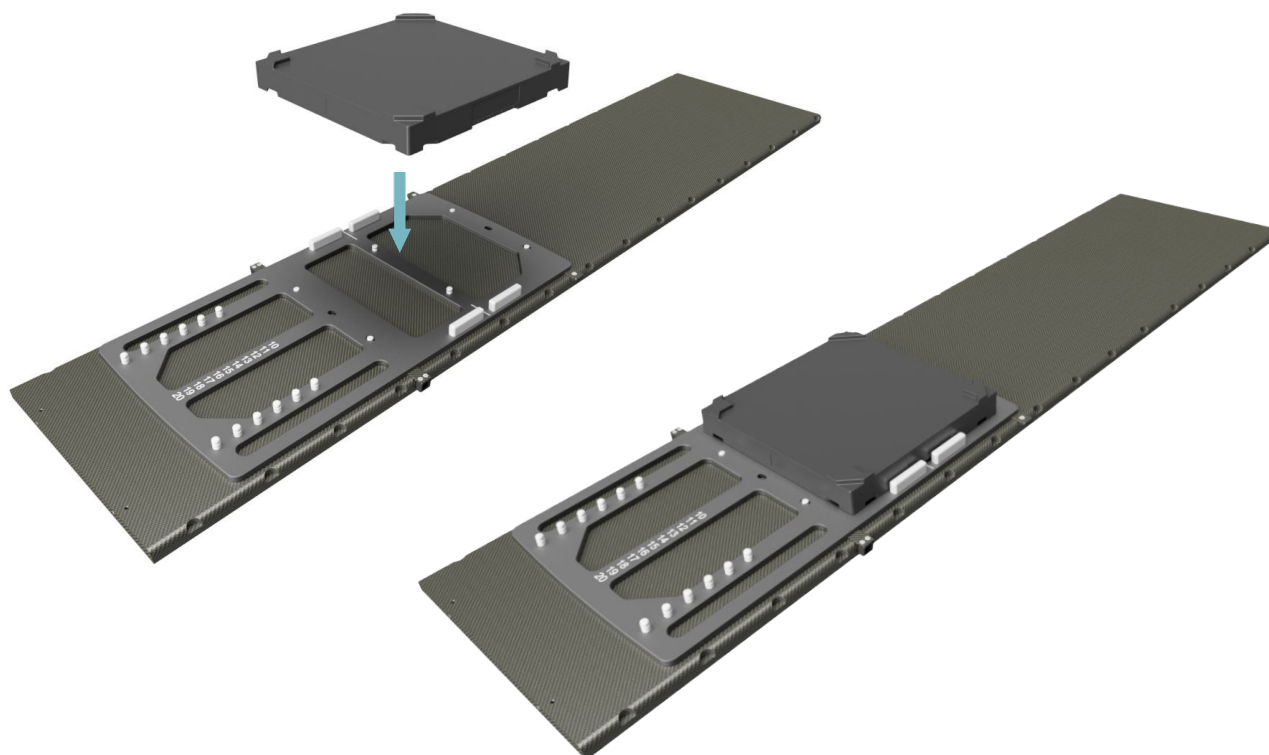
- I. Place the CouchStrips on a desired position on the CouchTop. Make sure that the distance between the Couchstrips align with the designated slots in the LEPS baseplate.



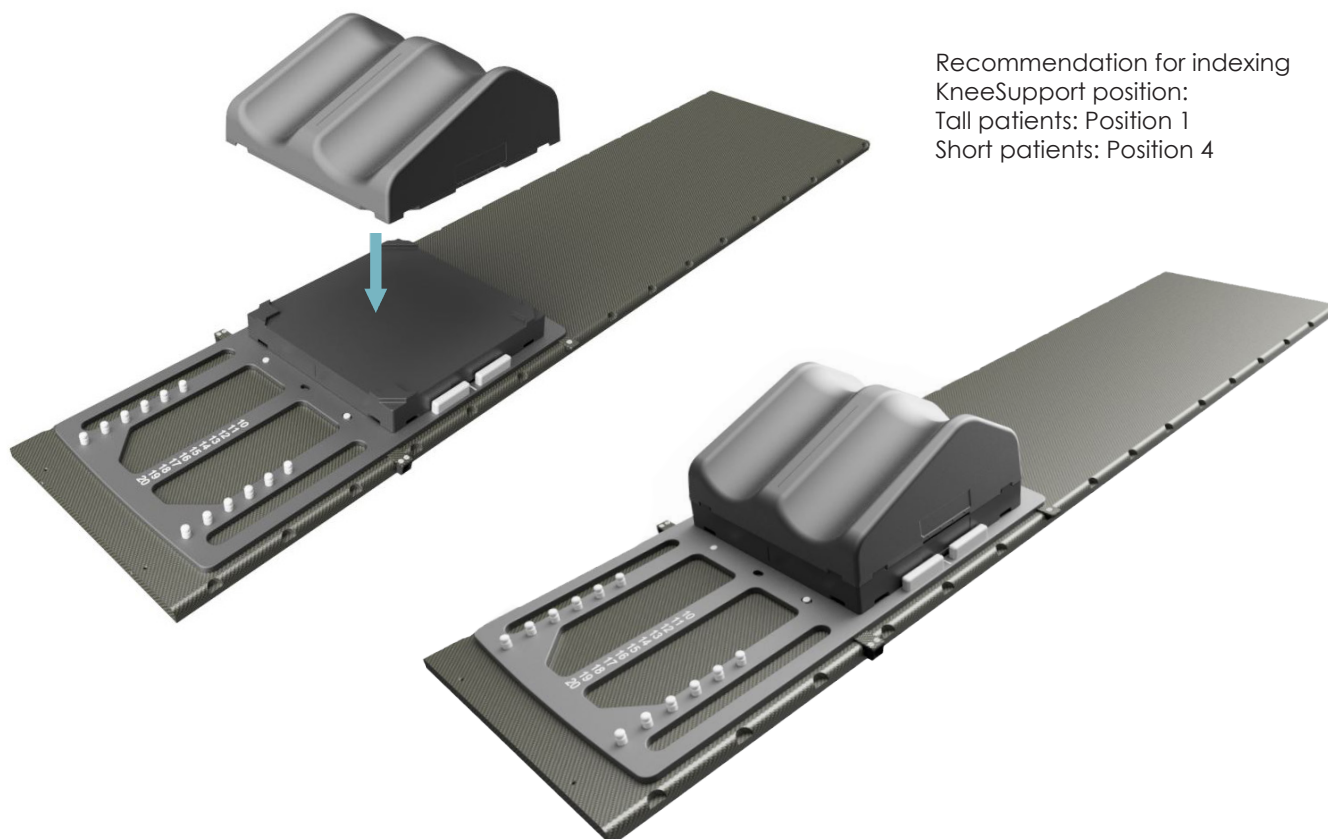
- II. Place the LEPS baseplate on the CouchStrips to secure it on the CouchTop.



- III. Place the LiftBlock on the LEPS baseplate.



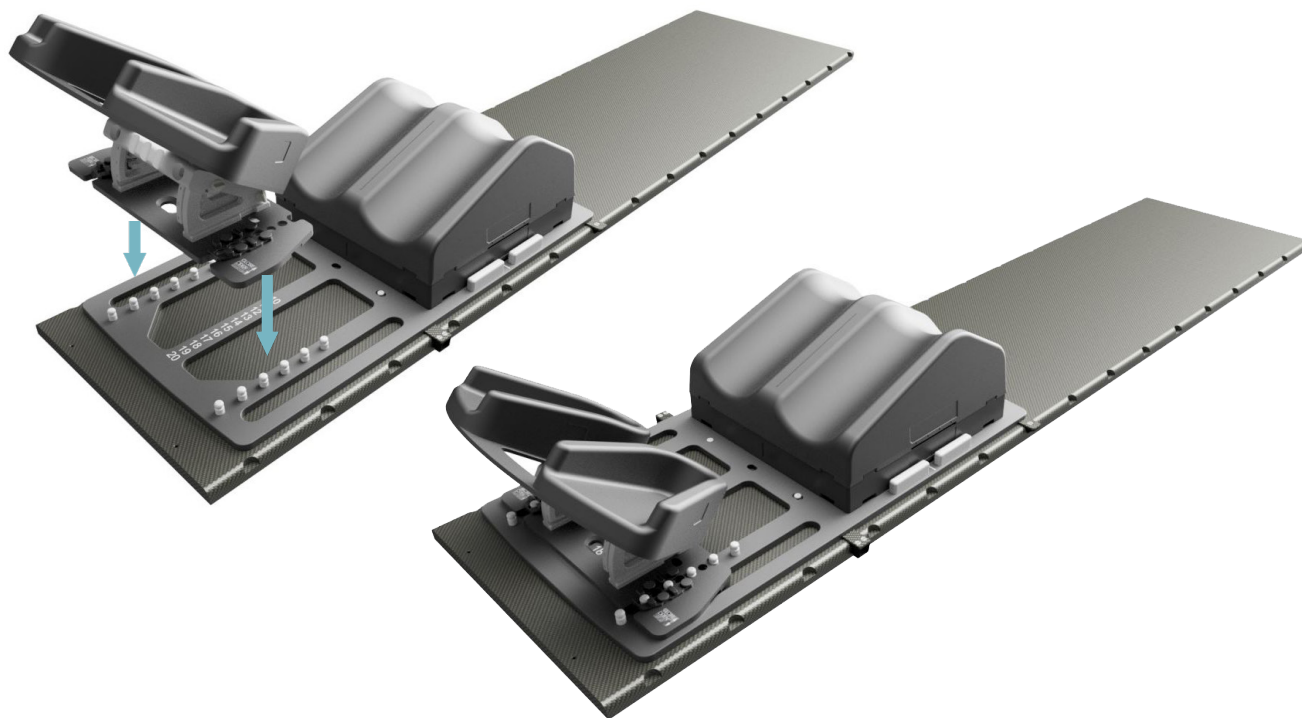
- IV. Place the KneeSupport on top of the LiftBlock. If needed, a KneeSupport can be placed without a LiftBlock.



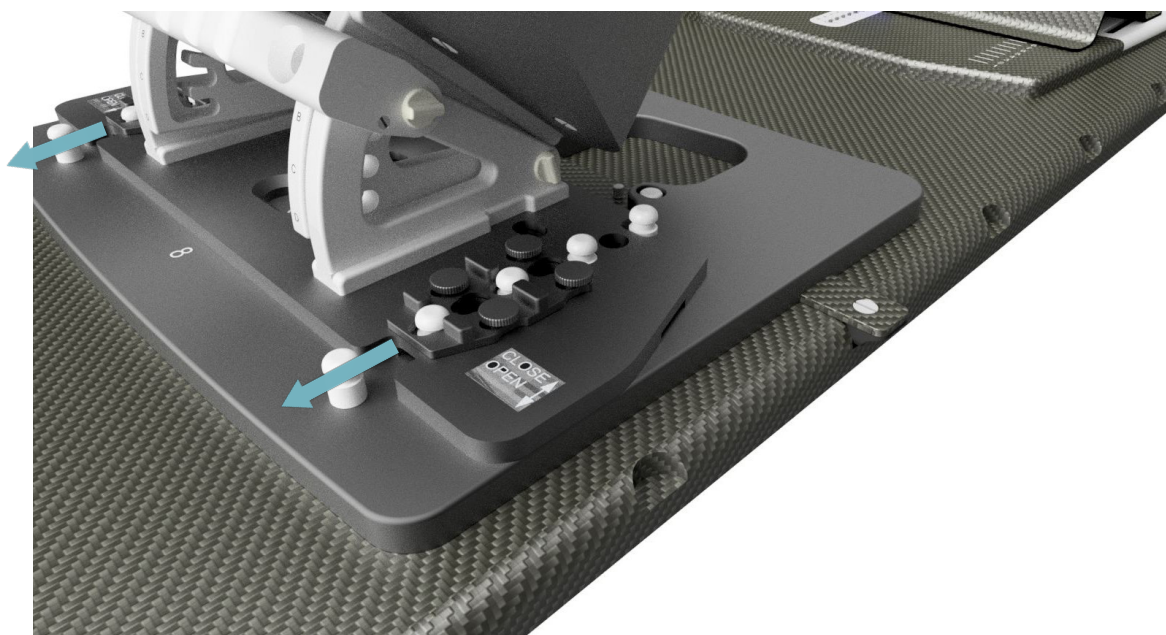
Recommendation for indexing  
KneeSupport position:  
Tall patients: Position 1  
Short patients: Position 4



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

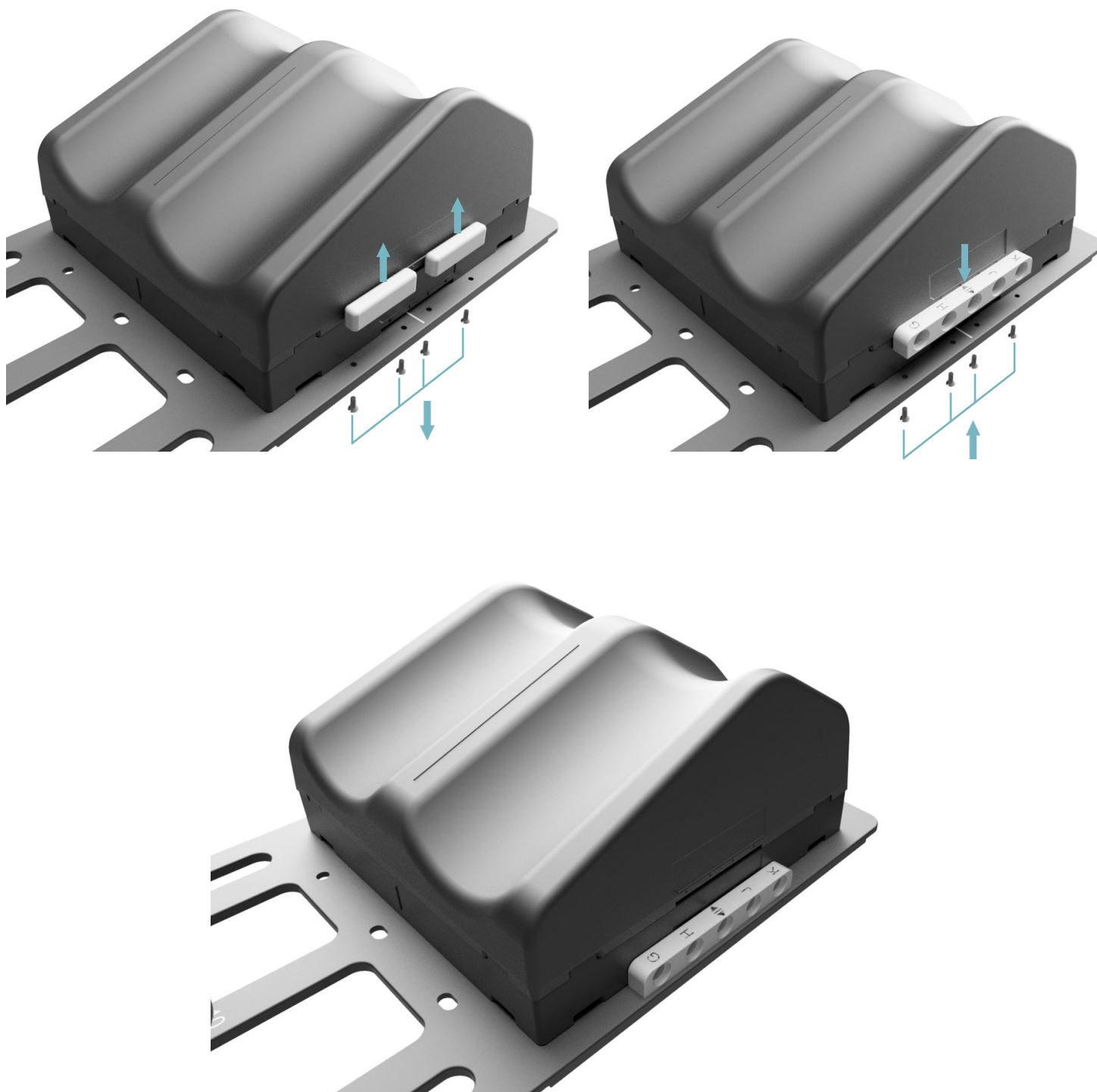


Pull the black locking plates in caudal direction to lock the FeetSupport to the baseplate.



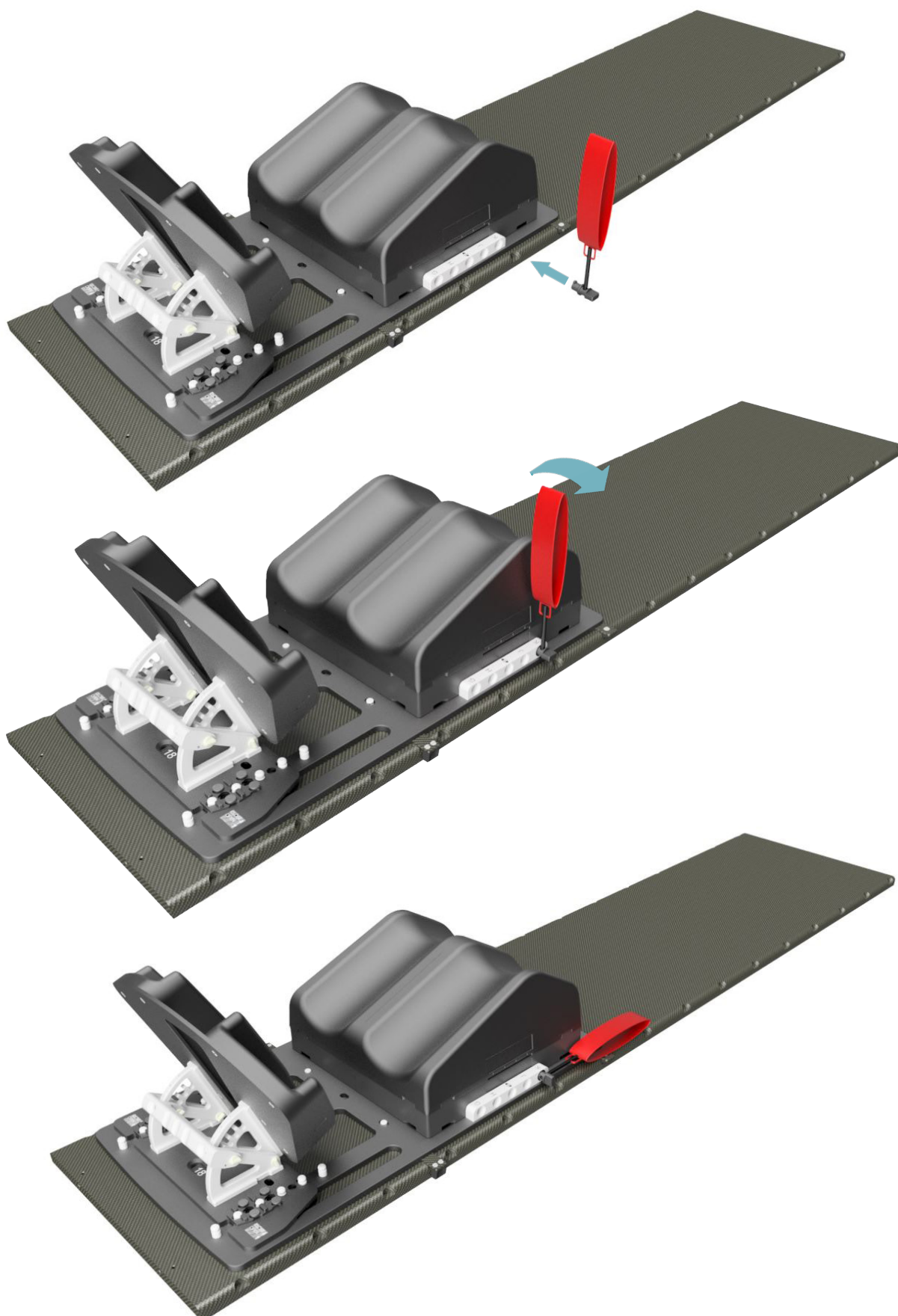
## 4.2 PLACING THE **SHOULDER RETRACTOR**.

- I. Unscrew the screws on both sides to remove the LEPS Side Strips from the LEPS baseplate. Place the Shoulder Retractor Side Strip on both sides of the LEPS baseplate. Use the same screws to secure them.





- II. Insert a Shoulder Retractor into each Shoulder Retractor Side Strip, with the wrist bands upwards, and turn it towards the cranial direction.



- III. Position the patient on the LEPS system. Place the patient's hand through the wrist bands and instruct the patient to hold tight. The more caudal the position of the Shoulder Retractor, the more the patient's shoulders are in a depressed position.



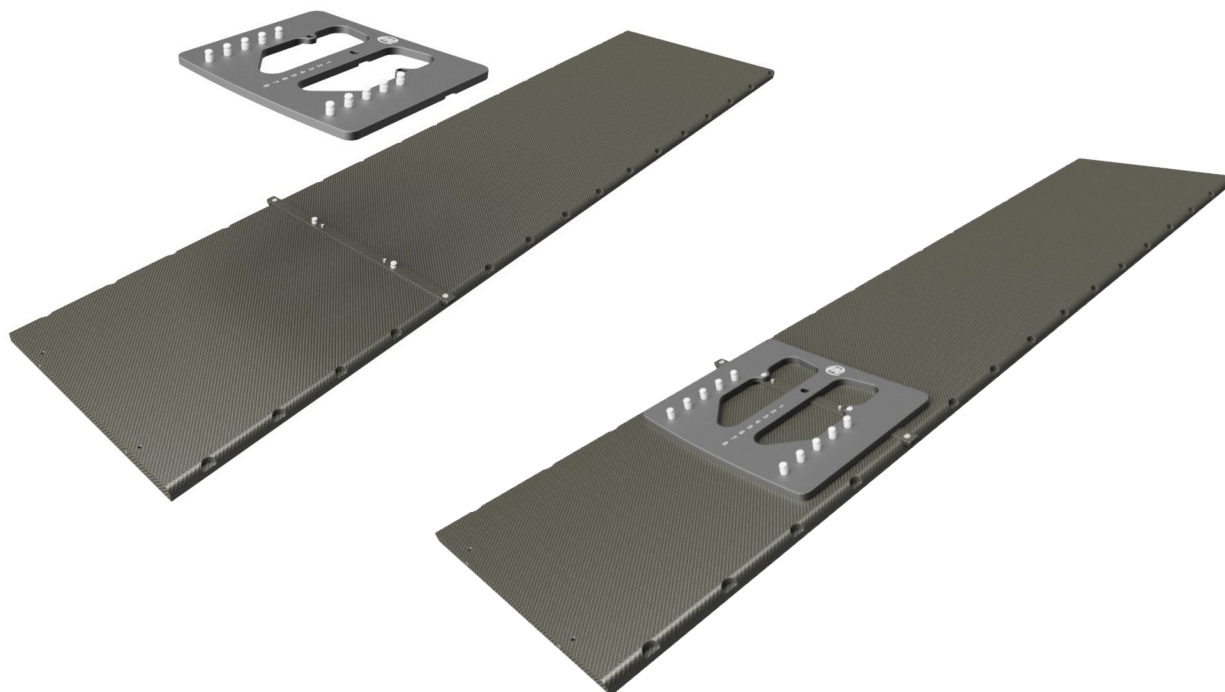
#### 4.3 PLACING THE LEPS SHORT

The LEPS Short baseplate can be used with a FeetSupport to position the patient's feet.

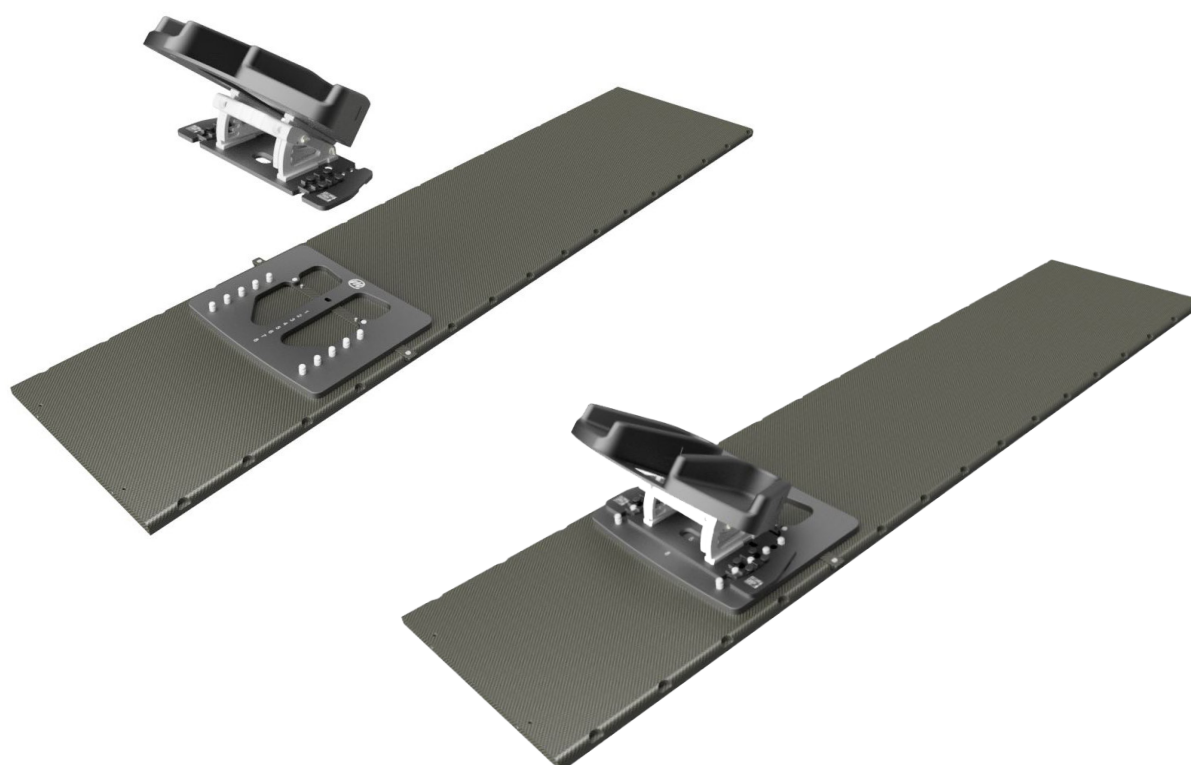
- I. Place one CouchStrip nearing the caudal end of the baseplate.



- II. Align the LEPS baseplate above the CouchTop. Make sure that the CouchStrip fall into the designated slot of the LEPS Short baseplate. Carefully place the LEPS Short baseplate.



- III. Place the FeetSupport on the LEPS baseplate short. Adjust its position. Lock it by pulling the locking plates at the base of the FeetSupport in caudal direction.



## 5. Cleaning, Storage & 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 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 LEPS in a upright position.
- 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: (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.
	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 Conditional	An item with demonstrated safety in the MR environment within defined conditions.



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