



macromedics

SOLUTIONS IN RADIOTHERAPY

MANUAL 132100
Instructions for use
English Instructions

MacroMedics® LEX-Ultra



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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.
- The baseplate shall be correctly secured to the couch prior to use.
- The device shall be secured before positioning the patient.
- Instruct the patient to not reposition themselves after set-up.
- Ensure there is no possibility for collision between gantry and device.
- Be careful to ensure that patient's skin does not become caught when adjusting the device (moving leg supports).
- 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:

- 132100 LEX Ultra



2.2 MR SAFE

The following devices are MR Safe:

- 132150 LEX-Ultra MR



3. Intended Use

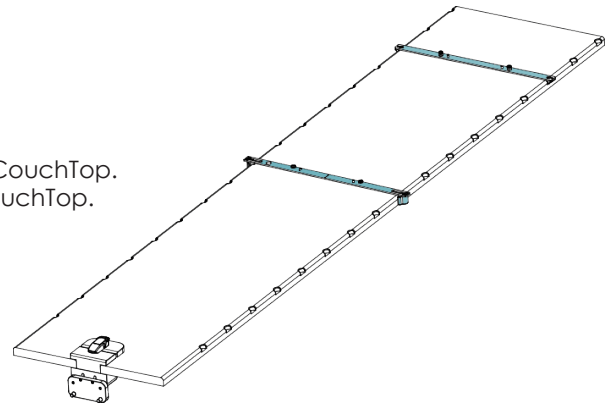
Positioning of the patient during radiotherapy and radiodiagnostics, including MR where indicated.

4. Use Instructions

4.1 PLACE THE COUCHSTRIPS

Place the indexing CouchStrip at the cranial end of the CouchTop.
Place the sliding CouchStrip at the caudal end of the CouchTop.

Optional: Screw the fixed CouchStrips onto the device using 2x Countersunk M6x20 Polyamide screws.

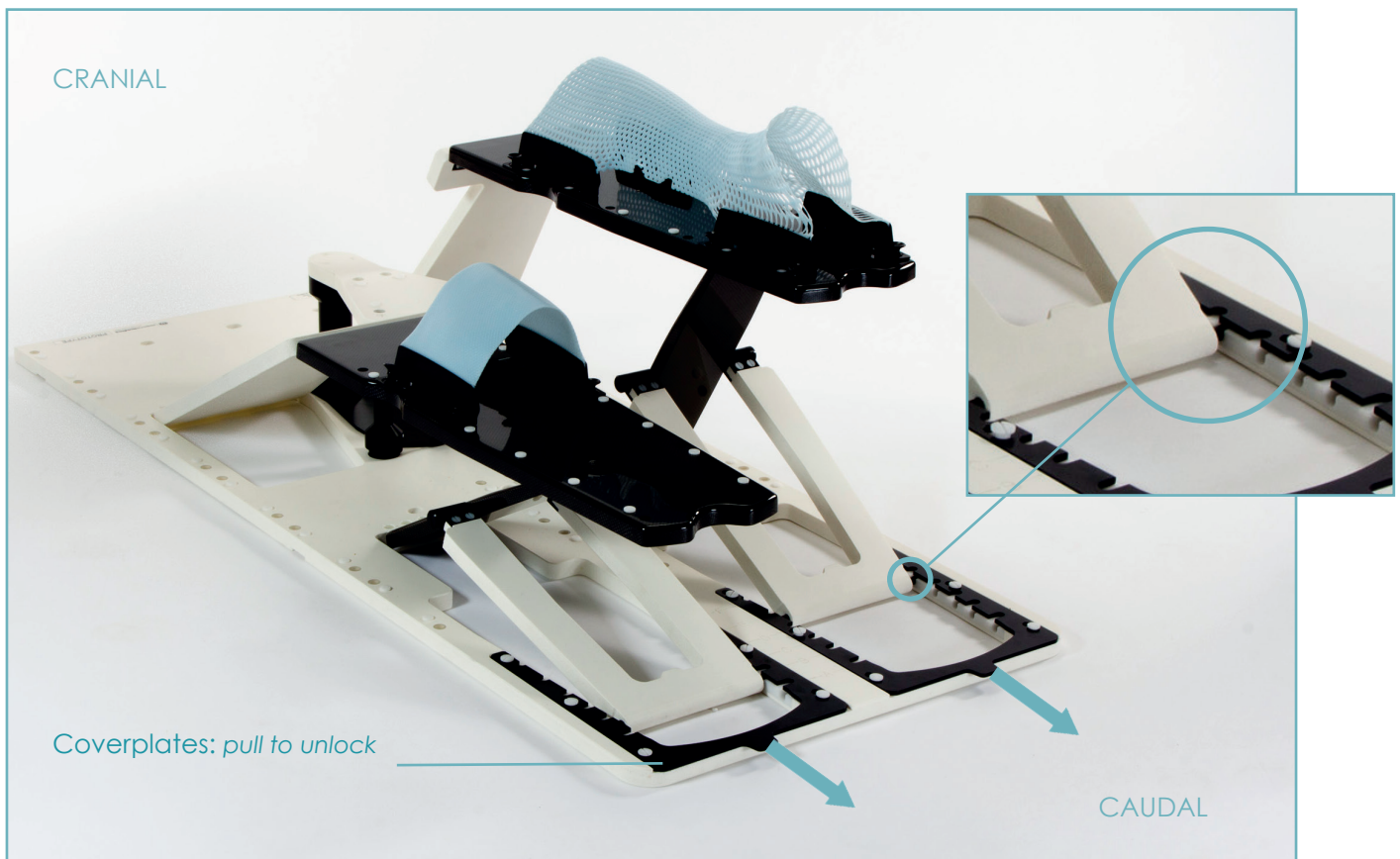


4.2 PLACE THE LEX-ULTRA

Carefully align the LEX-Ultra with the CouchStrips and gently slot into place.

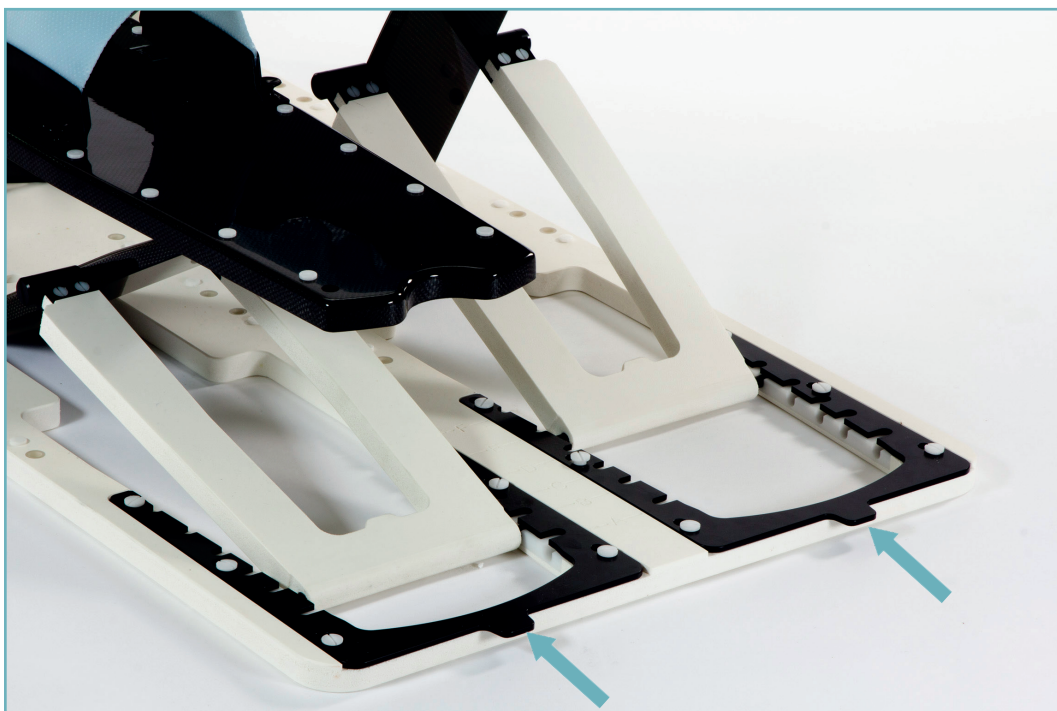
4.3 CHANGING THE TILTING POSITION OF THE LEG SUPPORT

Open the locking mechanism by pulling the coverplate towards caudal direction, allowing the pins of the leg supports to fall into the indents in the base.



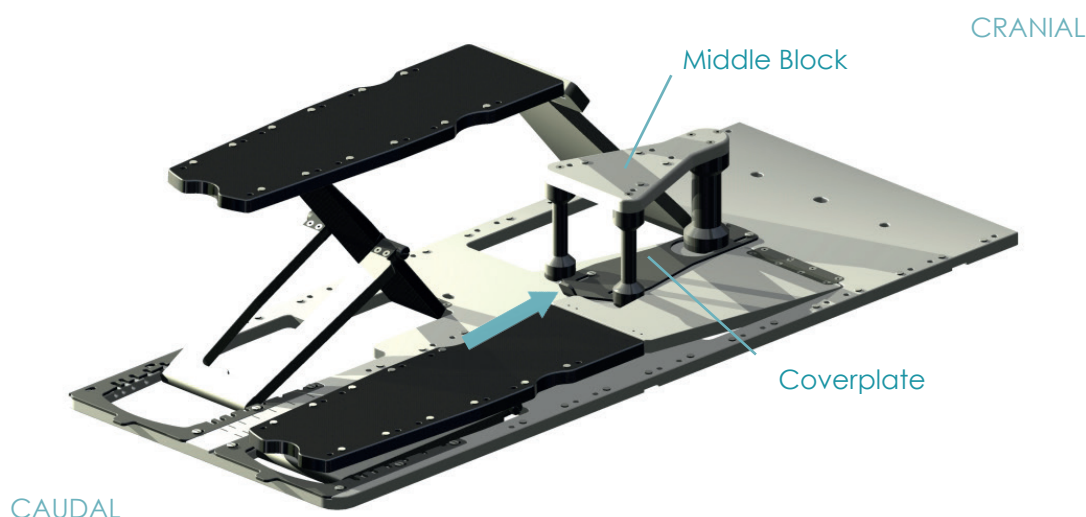
4.4 LOCKING THE LEG SUPPORTS IN THE CORRECT POSITION

Close the locking mechanism by pushing the coverplate towards cranial direction.



4.5 REMOVING THE MIDDLE BLOCK (OPTIONAL)

Remove the middle block by pushing the coverplate towards cranial direction, unlocking the locking mechanism, and then lift the middle block.



4.6 IMMOBILIZING THE PATIENT

Use an Extremity Mask or Pelvic Mask to immobilize the lower extremities or the pelvic area. For Mask moulding instructions, refer to the instructions for use; IFU117000 - Thermoplastic Masks.

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 provided by the manufacturer 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: (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.
Rx ONLY	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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