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SOLUTIONS IN RADIOTHERAPY

MacroMedics ® FluxBoard

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 15112021V9IFU164100

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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.
- Secure the device properly before positioning the patient.
- Do not place any other weight on the extended part other than the patient's head and shoulders.
- Rulers used on the devices, are only intended for reference of the device positioning of accessories. Rulers shall not replace patient position verification.
- Do not exceed an equally distributed load of 200 kg on the FluxBoard System.

- Prevent the formation of closed-loops as they can lead to MRI burns.
  Use an isolator between the patient's arms to avoid skin-to-skin contact.

- In the USA, federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
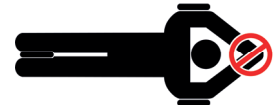
2. MRI Safety Information

2.1   MR CONDITIONAL
The following devices are MR conditional:

- 164120   MRIdian FluxBoard Thorax Plate

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 G²/cm (50 T²/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:

- 164110   MRIdian FluxBoard Base
- 164140   The FluxBoard mirrorflex
- 164220   MRIdian H&N mattress
- 164230   MRIdian H&N Base
- 164210   MRIdian Padding
- 164190   MRIdian U-Grip
- 125310   Rigid UAS MR set/2
- 122860   T-Grip for EagleBoard MR
- 122740   ArmCup for Handgrips set/2
- 173540   Low Bridge Support RE, MR
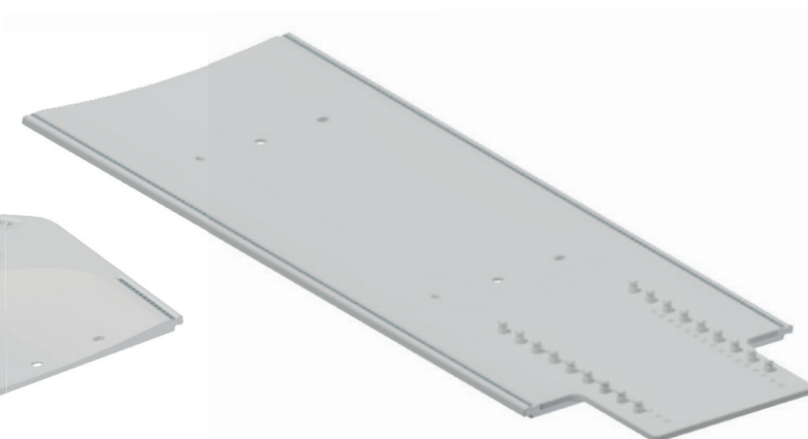- 112850   SSPS © Cradle-FB MR

3. Intended Use

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

4. Installation Instructions

The FluxBoard consists of two separate modules. The Thorax Module and the Treatment Base. Combined, they form the FluxBoard baseplate and can be attached to a CouchTop with the use of CouchStrips.
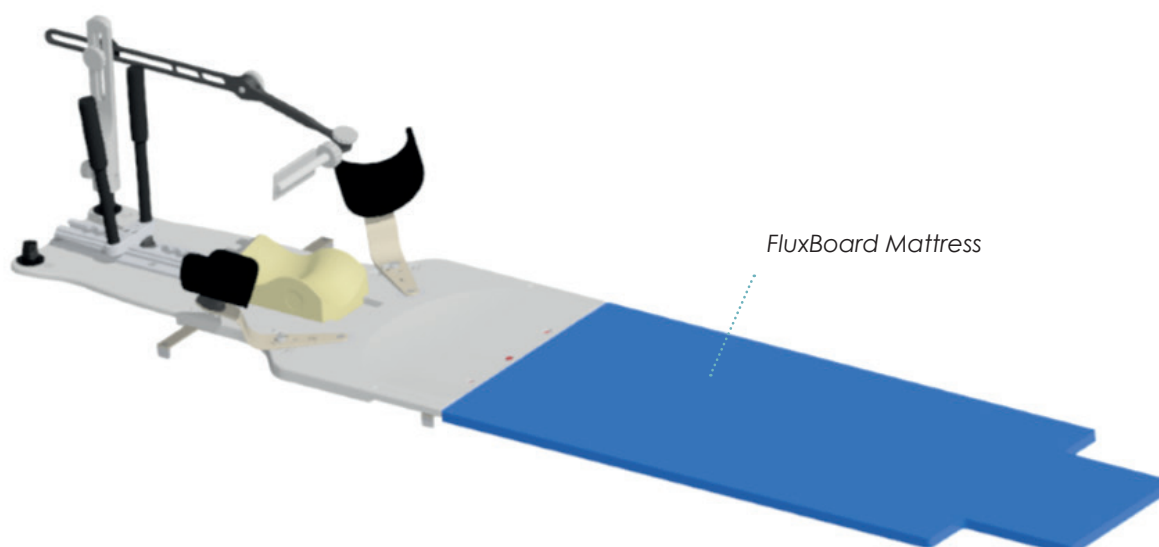
*164120 FluxBoard Thorax Module*   *164110 FluxBoard treatment base*

When the FluxBoard treatment Base (164110) is not used, the FluxBoard Mattress can be used instead for patient comfort.

FluxBoard Mattress

4.1   PLACE THE COUCHSTRIPS

Place the CouchStrips on the couchtop in designated indexed positions. Place the FluxBoard on the CouchStrips. If desired, the CouchStrip can be mounted on the baseplate with screws.
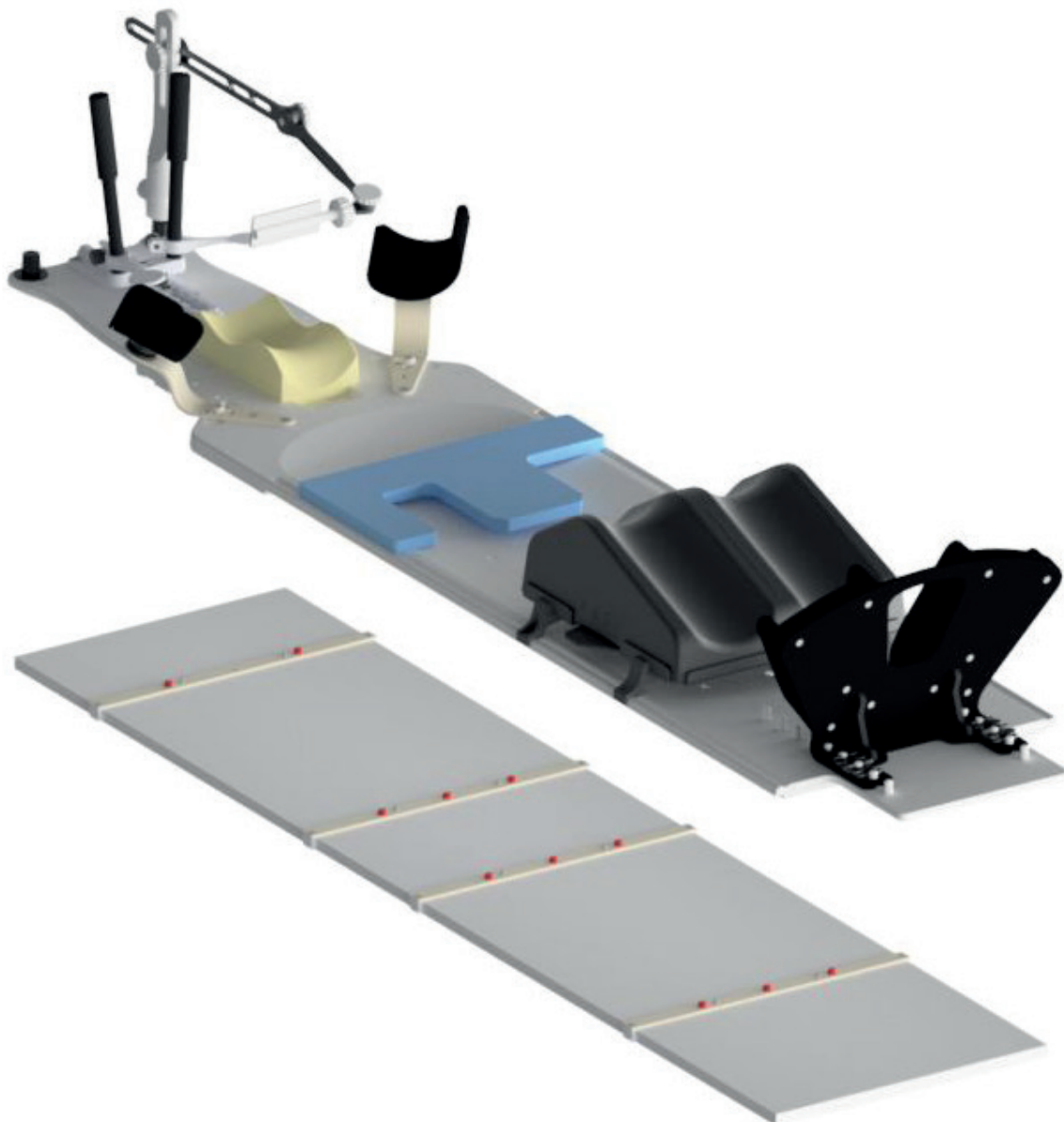
4.3 PLACE THE FLUXBOARD COMPONENTS

I. FLUXBOARD PADDING

The FluxBoard padding is designed to surround the coil to provide more comfort to the patient during treatment.

II. MAXSUPPORT 1 - HEADSUPPORT

The MaxSupport 1 supports the patients head during treatment. Move the patient cranial or caudal by using the indexation for the MaxSupport. Non-slip foil on the bottom of the MaxSupport 1 retains it in the selected position.

MaxSupport

FluxBoard Padding
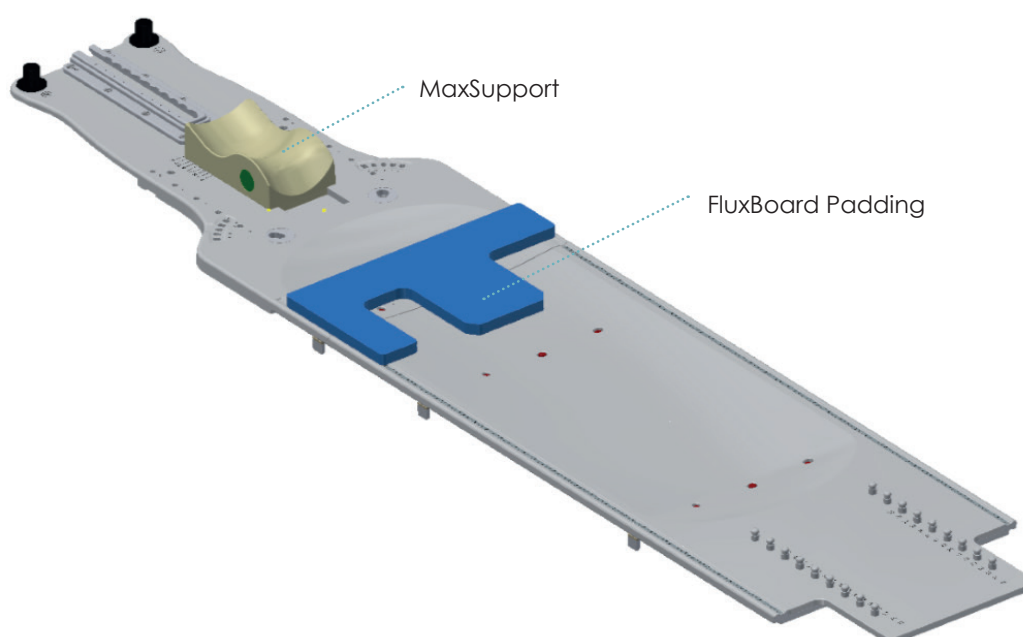
III. RIGID ADJUSTABLE ARMSUPPORTS

These can be used on the thorax module to support the upper arms. Use the white knob (circled in blue) to lock or release the arm support and put it in one of the five positions.
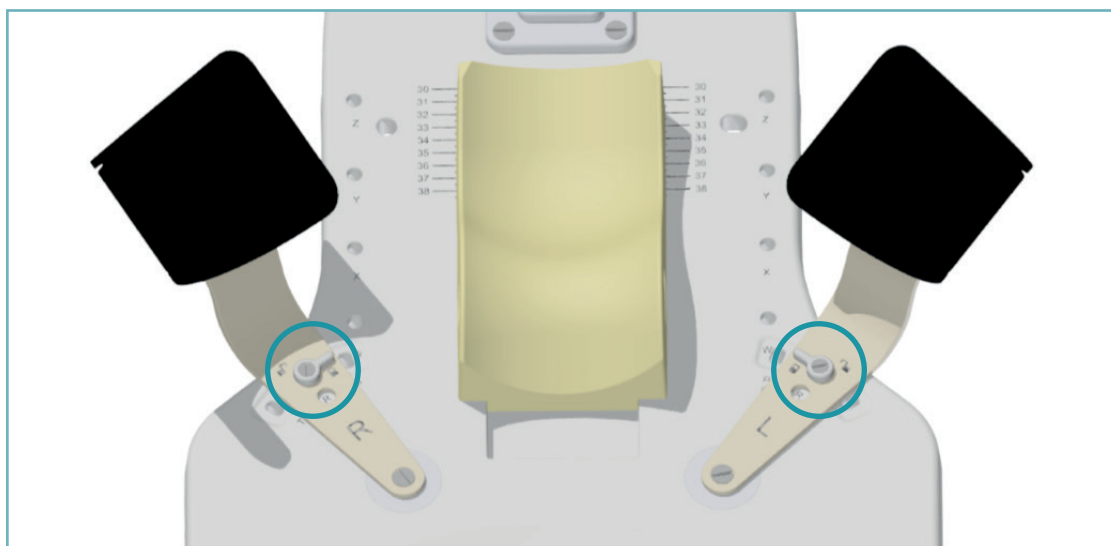
IV.   FluxBoard U-Grip

The U-grip can be placed onto the FluxBoard by sliding it into the holder. Make sure that the A and B side are corresponding to the A and B on the holder. When positioned in the other direction, it is the responsibility of the user to note the correct position. The black knob needs to be vertical (in "open" position) to slide in. After positioning rotate the black knob to horizontal position to lock. Refer to the Set-Up sheet for position documentation.
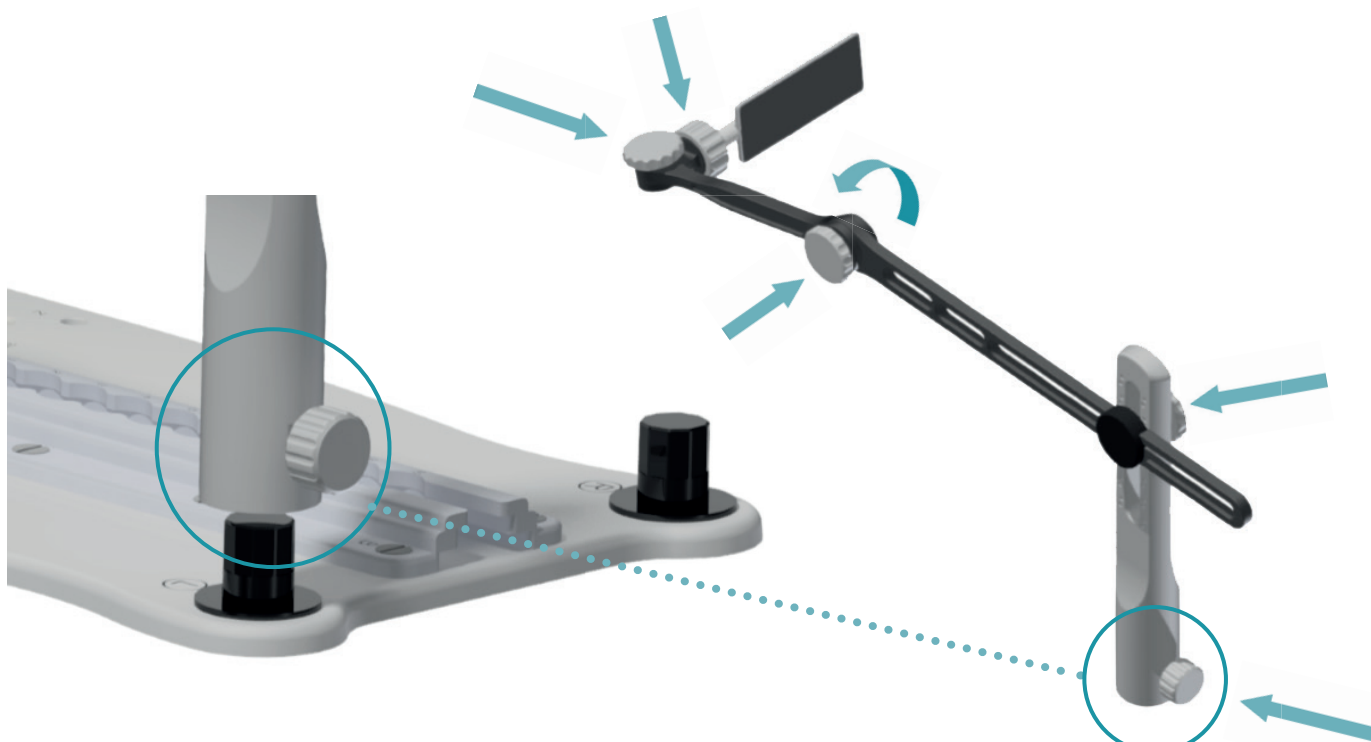

Open

Closed

Slide U-Grip into FluxBoard holder

A & B
Corresponding
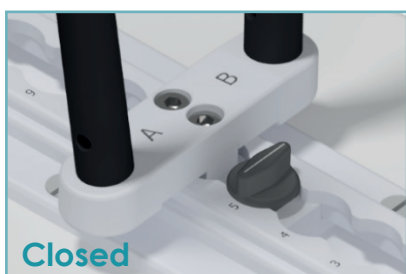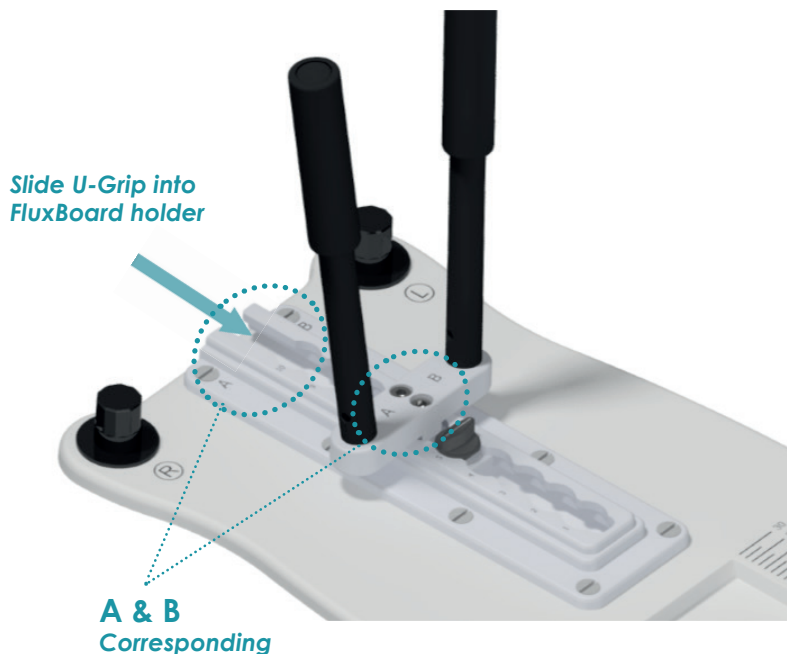
V.   FLUXBOARD MIRRORFLEX - (NOT INCLUDED IN CT VERSION)

Place the mirror over the black stud and thighten it with the white knob. The mirror can be placed on the right or left side of the baseplate. By unscrewing the white knobs on the mirror arm, the position of the mirror can be set in every desired position.

VI.   FLUXBOARD KNEESUPPORT BRIDGE

Place the KneeSupport onto the FluxBoard and read the ruler for its position. Refer to the Set-Up sheet for position documentation.
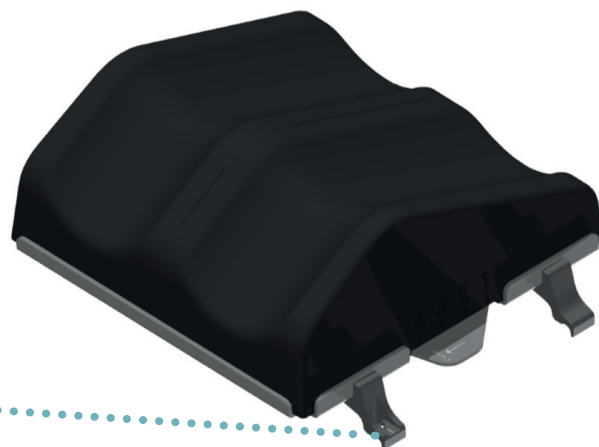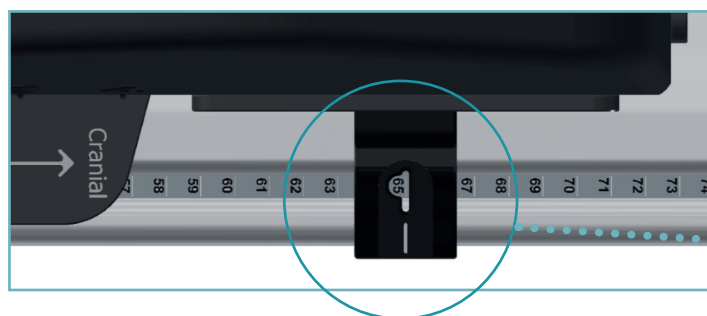
VII.   FLUXBOARD FEETSUPPORT

Before placing the FeetSupport onto the baseplate, push the locking plates cranial to unlock the holes. The locking plates are found on the base of the feetsupport. Place the FeetSupport over the pins on the baseplate. Once in position, pull the locking plates caudal to lock the FeetSupport to the baseplate. Refer to the Set-Up sheet for position documentation.

Cranial

Caudal

Locking Plates
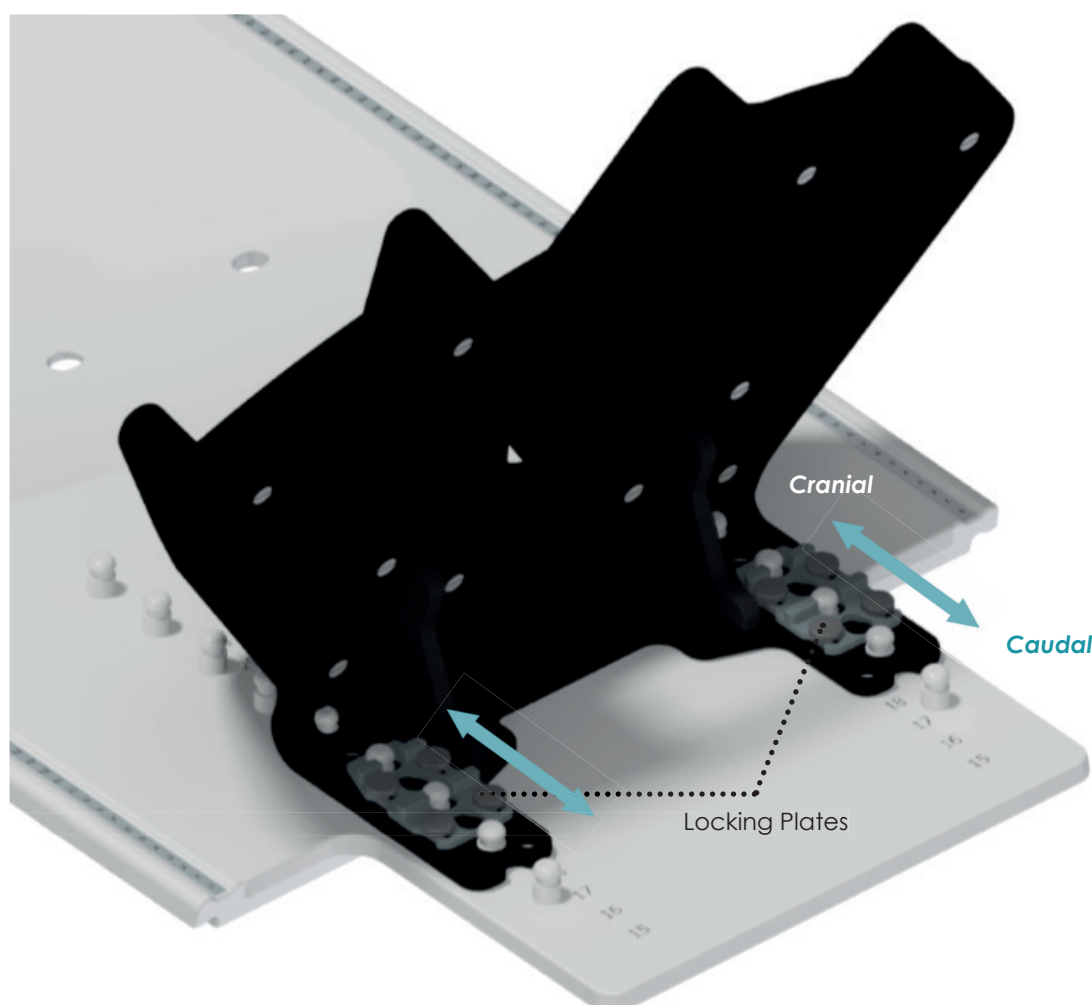
4.4   PLACE THE FLUXBOARD OPTIONAL ACCESSORIES

I.   FLUXBOARD HEAD & NECK MODULE

The FluxBoard Head & Neck Module can be placed instead of the FluxBoard Thorax Module and is designed for the usage of the Head & Neck Cradle.


II.   FLUXBOARD HEAD & NECK CRADLE

This Cradle can only be used on the Fluxboard Head & Neck Module. The Cradle can be locked with plungers, as shown in the images below.

The cradle can be used in combination with Double Shell masks.
Refer to IFU112100 for instructions on how to mould Double Shell masks.


Unlocked

Locked
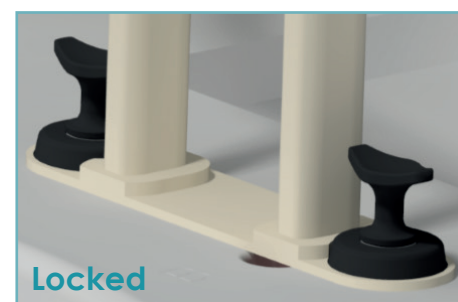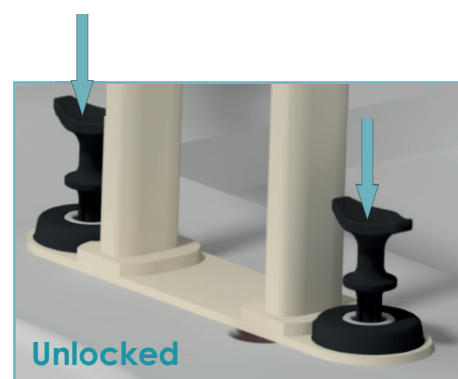
III.   WRIST SUPPORT - ACCESSORY OF THE U-GRIP

Unscrew the handles on the U-Grip to mount the wrist supports. Place them over the bars of the U-Grip and tighten them with the black turning knob. Screw the handles back on.

handles

U-Grip bars

Black turning knobs
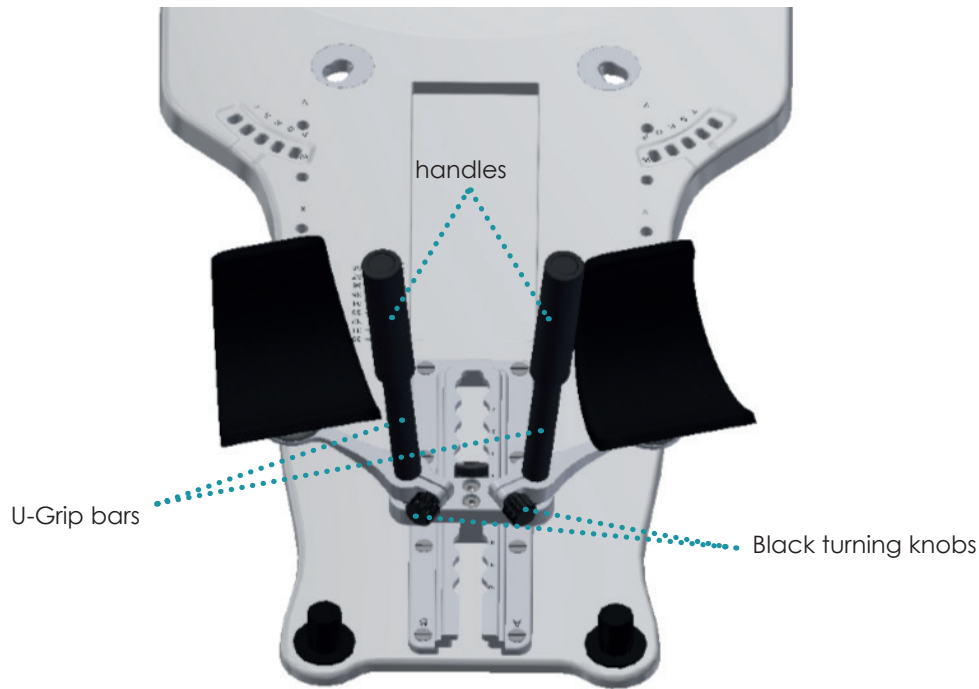
IV.   T-GRIP

The T-grip allows height-adjustment in six different positions. The T-grip can be placed by sliding it into the holder. Make sure that the A and B side are corresponding to the A and B on the holder. The black knob must be "Open" (in vertical position) to slide into the holder of the FluxBoard. After positioning rotate the black knob to a horizontal position to lock.

Corresponding letter A

Open

Closed
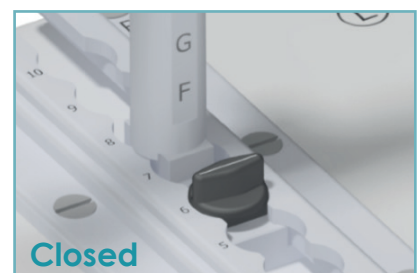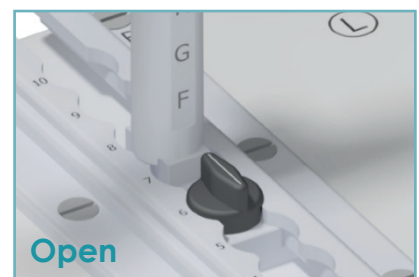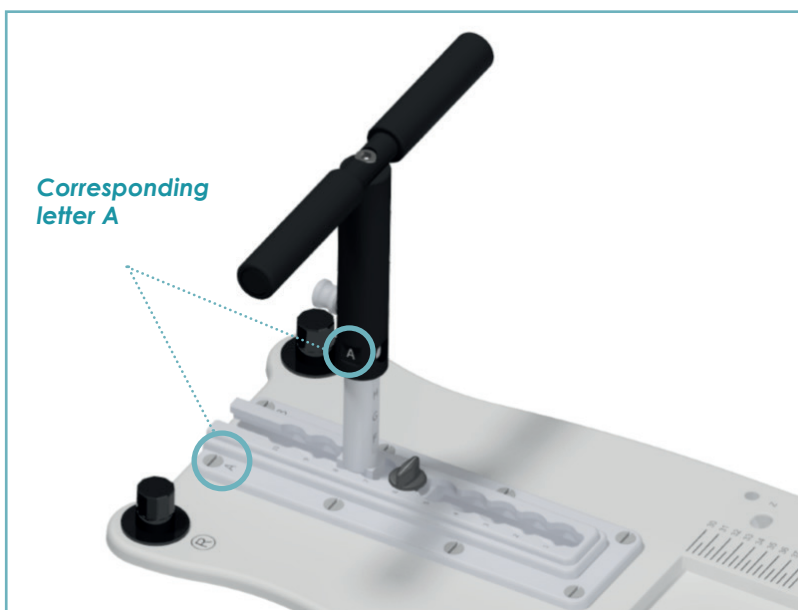
5. Cleaning, Storage and Disposal

- 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
CE	European Conformity	EC declaration of conformity by manufacturer.
(factory symbol)	Manufacturer	Indicates the medical device manufacturer.
REF	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT GS1 Code: (10)	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
SN GS1 Code: (21)	Serial Number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
(book symbol)	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	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\	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions.
(key symbol)	Prevent Closed Loops	Prevent the formation of closed-loops as they can lead to MRI burns. Use an isolator between the patient's arms to avoid skin-to-skin contact.

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