



**macromedics**

SOLUTIONS IN RADIOTHERAPY

MANUAL 122500  
Instructions for use  
English Instructions

## MacroMedics® BreastBoards & ThoraxSupports



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# 1. Warnings



- Inspect the device thoroughly before use. Do not use the device if damaged or incomplete.
- Check individual components on MR-Safety when used together in a patient positioning system.
- Do not use MR Unsafe items in an MR environment.
- Prevent the surface from damage and scratching.
- Secure the device properly before positioning the patient.
- The device shall not extend from the cranial side of the couch.
- Do not exceed the allowable maximum patient weight of 150 kilograms.
- Rulers on the devices are only intended for reference of the device positioning of accessories. Rulers shall not replace patient position verification.
- Instruct the patient to lay down calmly and not to reposition themselves after set-up.
- 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.
- When used for proton treatment, ensure that the devices are not in the incoming radiation-treatment-beam pathway.
- 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



• 121160	BreastBoard SX 5 Degree Adapter	• 122500	BreastBoardLX™
• 122100	ThoraxSupport™	• 122590	BottomStop Adaption
• 122300	Upper AS TS/MBLX, set/2	• 126140	OmniBoard™ BTM-SX-EX
• 122320	Rotatable armrest LV, set/2	• 126160	OmniBoard™ bottomstop
• 122330	Cranial AS for BBLX/TS, set/2	• 172400	BreastBoardSX™, RAS
• 122380	Profiles LB1, set/10	• 172410	BreastBoard SX™
• 122390	Profiles LB1, set/2	• 172420	Profiles BreastBoardSX™, set/2
• 122520	WedgeThoraxSupport™	• 172450	BreastBoardSX™, HAS
• 122540	HighBridgeSupp. TS/MBLX	• 172110	FlexBoard™ base
• 122610	ThoraxSupport™ complete	• 172120	FlexBoard™ BTM-EX
• 122650	ThoraxSupport™ short	• 172130	OmniBoard™ BTM-EX
• 122670	90D ArmSupports TS	• 173600	OmniBoard™ BTM-LX
• 122730	Handpole MBLX-LB1	• 173660	FlexBoard™ BTM-LX
• 122760	Handpoles with armcup	• 174540	OmniBoard™ BTM-SX-RE
• 122350	Profiles BreastBoardLX™ set/10	• 174630	FlexBoard™ BTM-SX
• 122360	Profiles BreastBoardLX™, set/2	• 175010	OmniBoard™ BTM-SX-S

## 2.2 MR CONDITIONAL



• 122150	ThoraxSupport™, MRC	• 122740	Armcup for handpoles, set/2
• 122310	Upper AS TS/MBLX, MRC, set/2	• 122750	BreastBoard LX™, MRC
• 122340	Cranial AS for BBLX/TS MRC, set/2	• 126190	OmniBoard™ bottomstop MRC
• 122660	ThoraxSupport™, short MRC	• 174590	OmniBoard™ BTM-SX-RE, MRC
• 122710	Rotatable AS LV MRC, set/2	• 175060	OmniBoard™ BTM-SX-S, MRC

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. It is the responsibility of the user to ensure that these conditions are met.

## 2.3 MR SAFE

- 122530 WedgeThoraxSupport™, MR



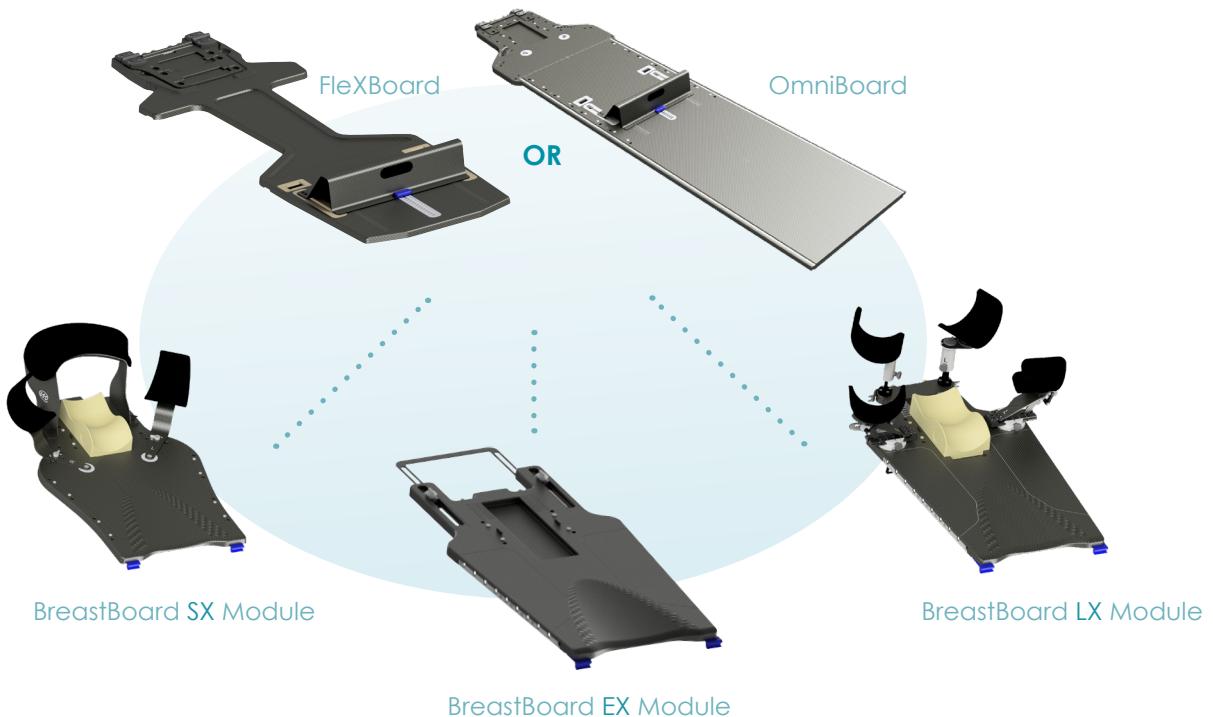
# 3. Intended Use and Indications for Use

**Intended Use:** Positioning of the patient during radiotherapy and radiodiagnostics, including MR where indicated.

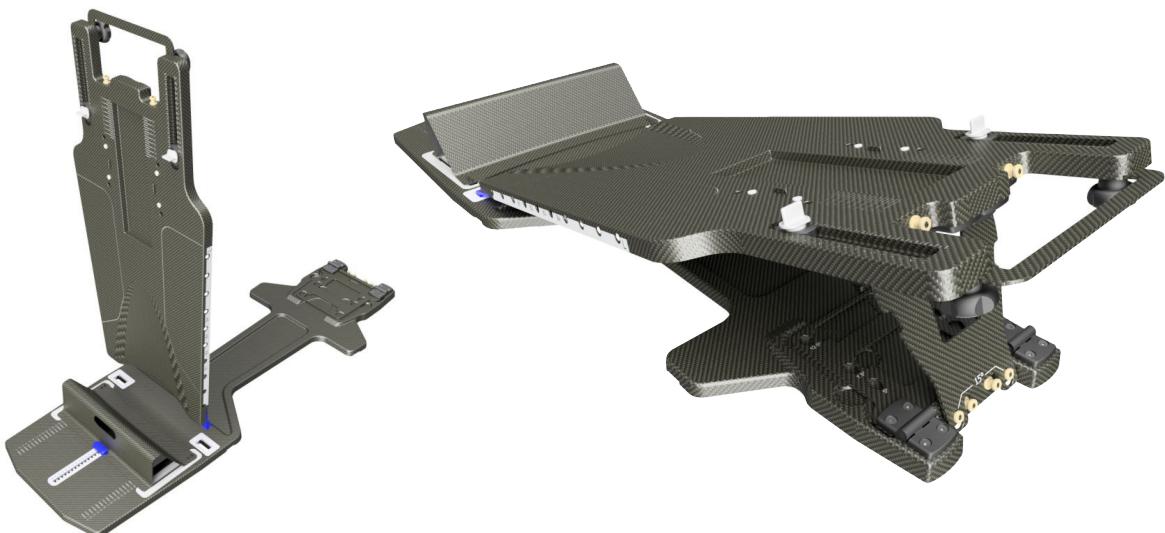
**Indications for Use:** To aid in the positioning of patients 18 and older undergoing radiation therapy of the breast and chest region, including photon, proton, and electron treatments. The devices are also used to position the patient during image acquisition to support treatment planning including in Computed Tomography (CT) imaging systems.

## 4. Installation Instructions

- I. Instructions for placing the **BreastBoard SX Module**, **BreastBoard LX Module** & **BreastBoard EX Module** on an **OmniBoard** or **FlexBoard**:



Lift the BreastBoard Module and position it vertically above the predestined board. Align the hinge plates at the caudal end of the BreastBoard Module with the slots in the predestined board and slide the BreastBoard in the slots. Carefully lower the Cranial end of the BreastBoard towards the OmniBoard/FlexBoard and the BreastBoard will lock itself. Fix the BreastBoard at an angle using the Angled plates.



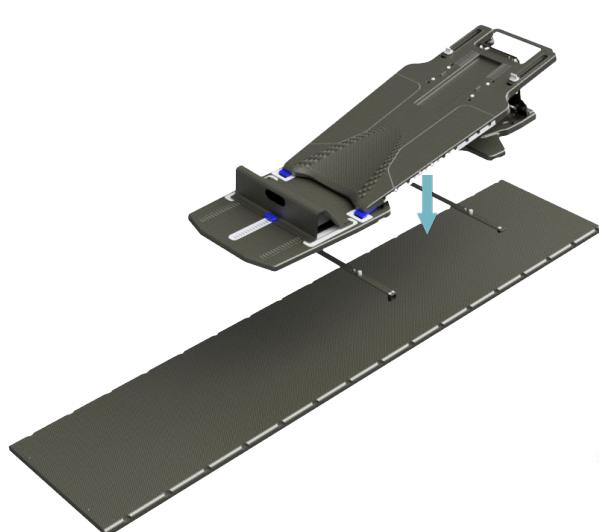
*The images above show the attachment of the BreastBoard EX to the FlexBoard. The procedure is the same for attaching the BreastBoard Modules to the OmniBoard.*

II. Instructions for placing the **FleXBoard with BreastBoard Module SX, LX & EX**, the **BreastBoard SX & LX** and the **ThoraxSupport** on a **CouchTop**:

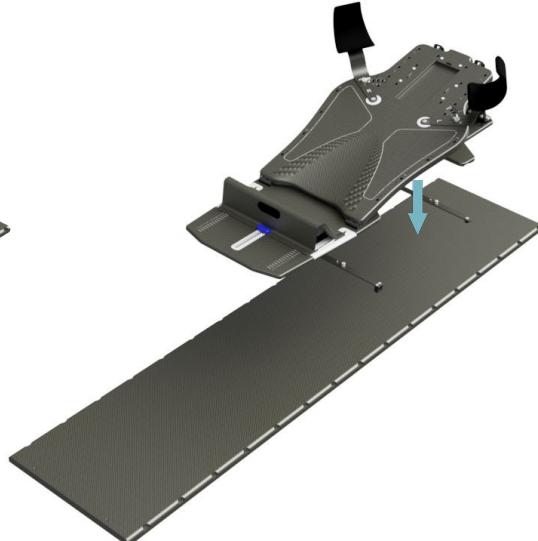
Place the correct Couchstrips on the Couch in indexed positions. Fasten the CouchStrip and make sure that no movement is possible between the CouchStrip and the couch. For more information, refer to IFU147100 - CouchStrips and Sidepieces. The CouchStrips can be screwed onto the baseplate for convenience. (For the usage in a MR environment, use the glass fiber, MR-Safe 3-Pin CouchStrip).

Position the BreastBoard or ThoraxSupport above the Couchtop, align the slots at the bottom of the module with the CouchStrips and carefully place it on the Couchtop.

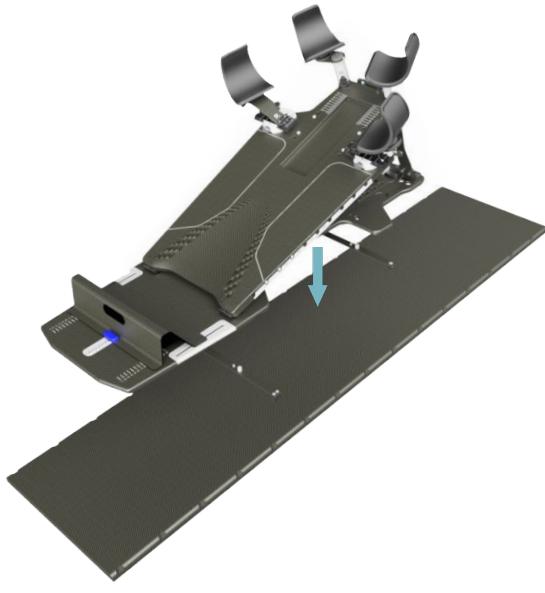
BreastBoard EX on FleXBoard



BreastBoard SX



BreastBoard LX



ThoraxSupport



### III. Adjusting the components of the BreastBoards & ThoraxSupports

Adjust the components of the BreastBoards and ThoraxSupports for accurate patient positioning and record the positions in the corresponding Set-Up sheet.

#### The Armsupports

The armsupports can be adjusted in one direction.



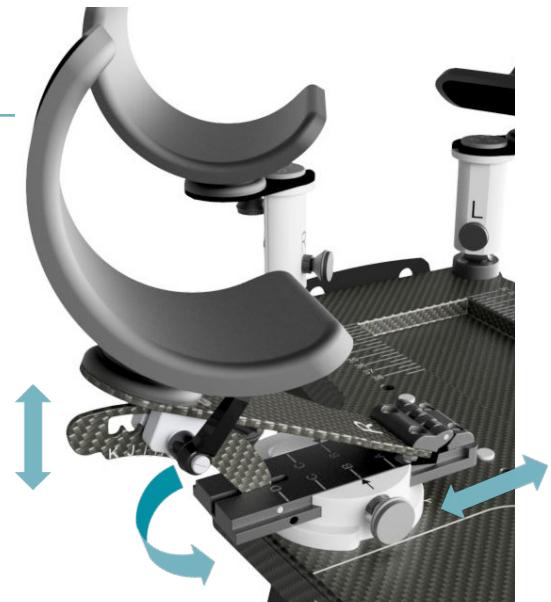
#### The Upper Armsupports

The upper arm supports can be adjusted in three directions with pushpins.



#### The Cranial Armsupports

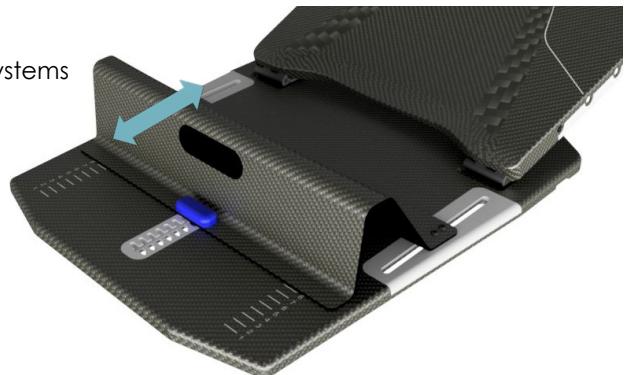
The Cranial Arm Supports can be adjusted in two directions.



### The BottomStop

Lift the bottomstop on the grip aperture, slide into the desired position and lower into the middle strip.

For the installation instructions of the BottomStop Sliding (174230), please refer to IFU123100 - SBRT Systems

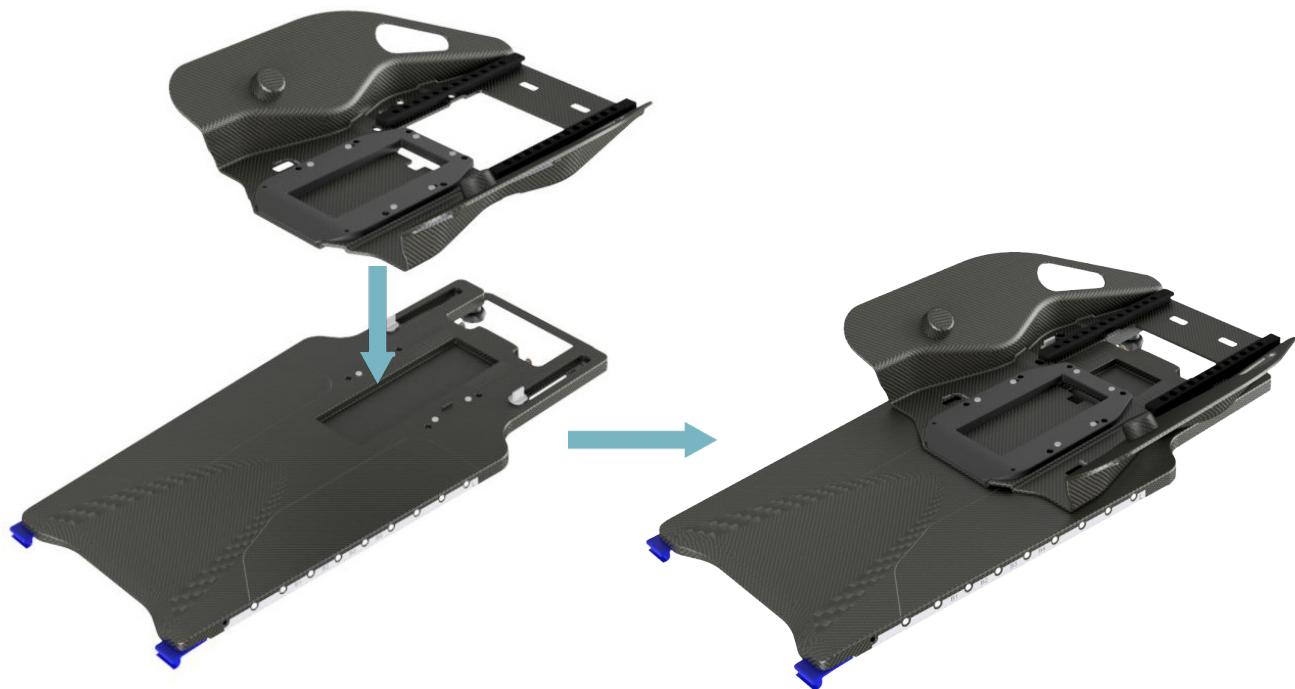


### Carbon Fiber L-Profiles

Place the carbon fiber profiles for the Breast Mask in the desired position on the sides of the BreastBoard and lock them with Quickfasteners. Refer to the *Thermoplastic Masks IFU117000* for instructions on profile assembly and Mask heating.

#### IV. Installation of the EagleBoard 2 on the BreastBoard EX

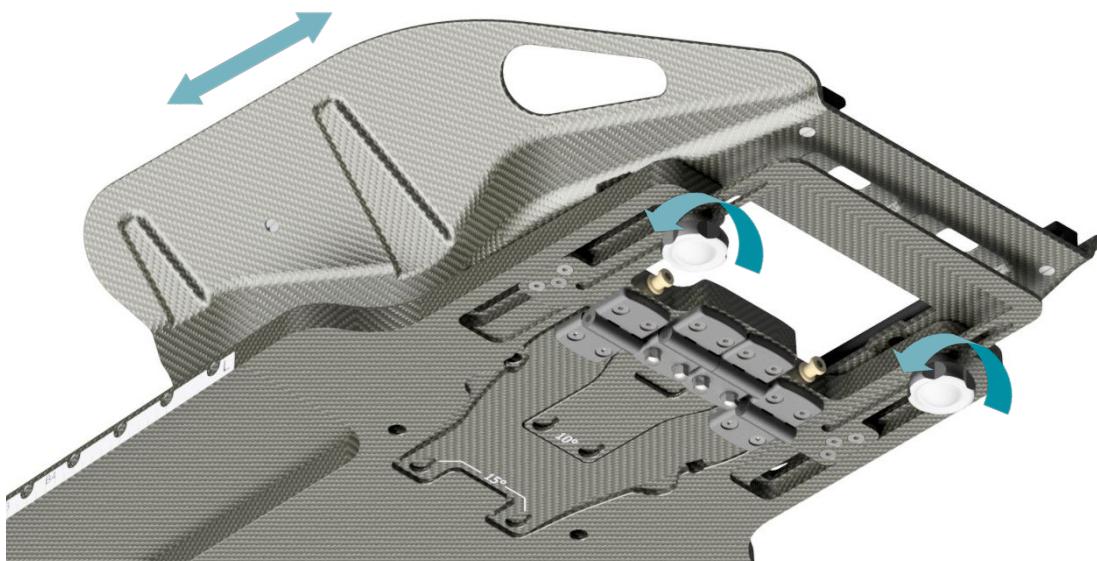
Position the EagleBoard 2 above the BreastBoard EX, align its holes at the bottom with the knobs on the BreastBoard EX and place it carefully on the BreastBoard.



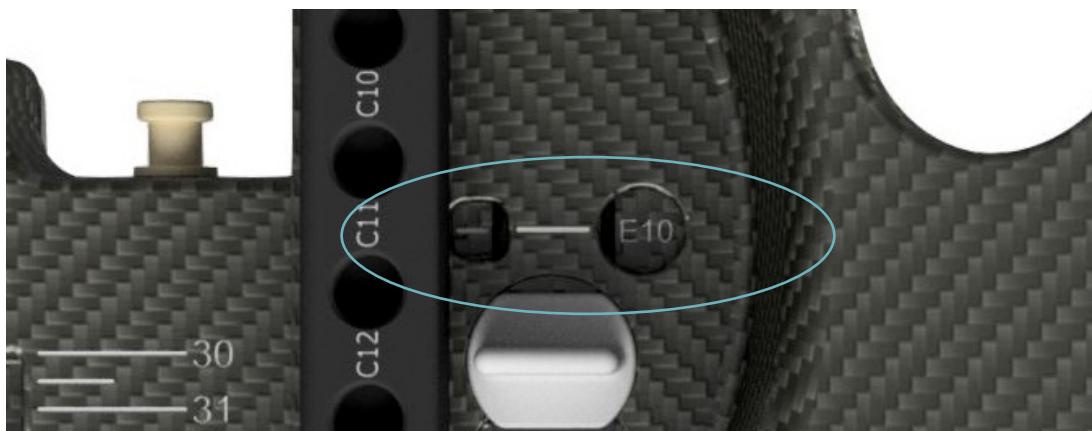
Slide the EagleBoard 2 towards the caudal side and lock it by turning the lock knobs counterclockwise. Turn the lock knobs back in clockwise direction to loosen.



For adjustment of the EagleBoard 2 in longitudinal direction, loosen both of the grip knobs at the dorsal side of the BreastBoard EX.



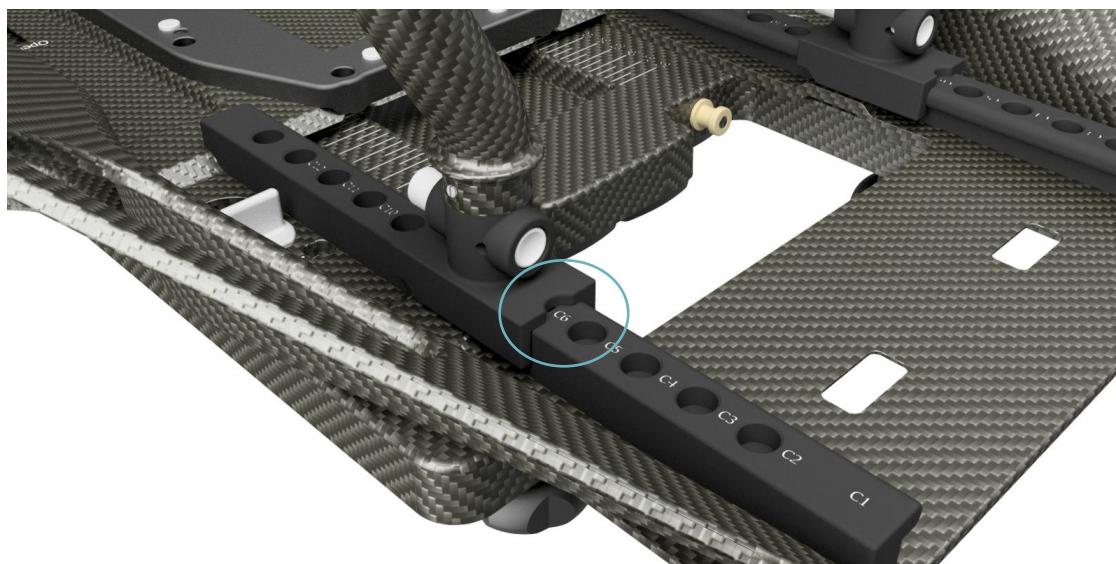
Turn the grip knobs clockwise to lock the EagleBoard 2 on the desired indexed position.



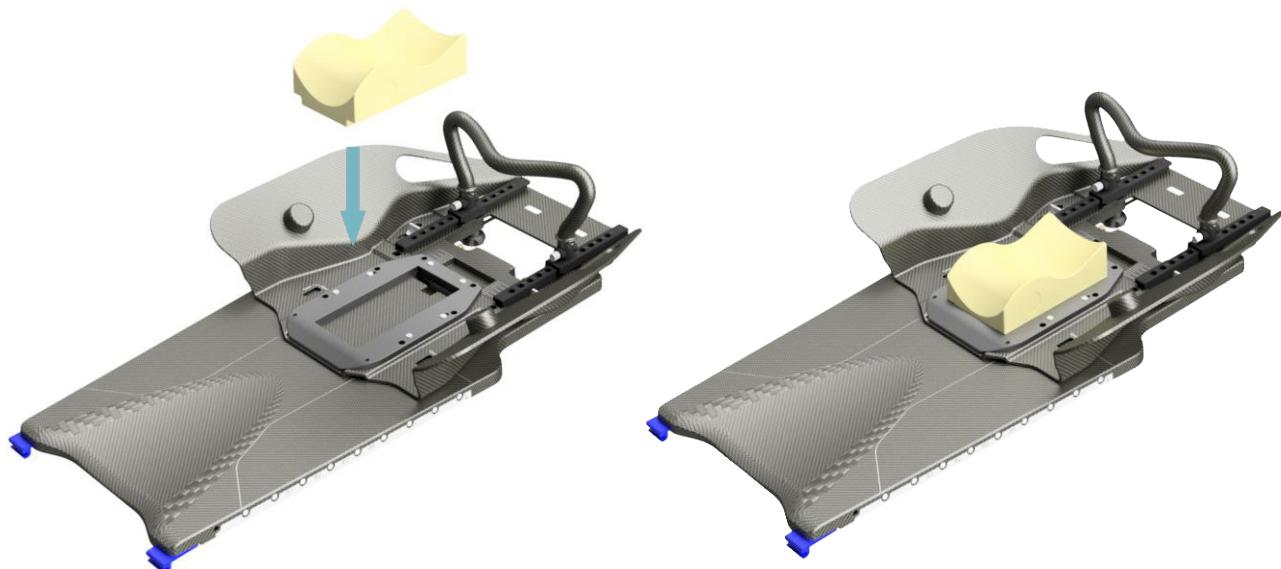
Align the M-Grip with the rails on the EagleBoard 2.  
Push the white lock knobs on the M-Grip and  
slide it onto the rails.



Place the M-Grip on the desired indexed position and release the lock knobs to fix the M-Grip to the rails of the OmniBoard EX.



Place the HeadSupport in the HeadSupport adaptor.

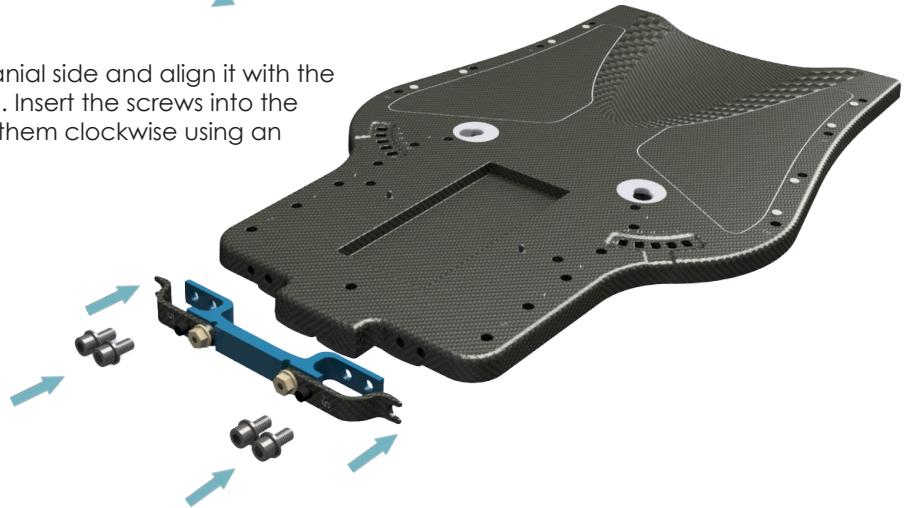


V. Installation of the 121160 BreastBoard SX 5 degree Adapter

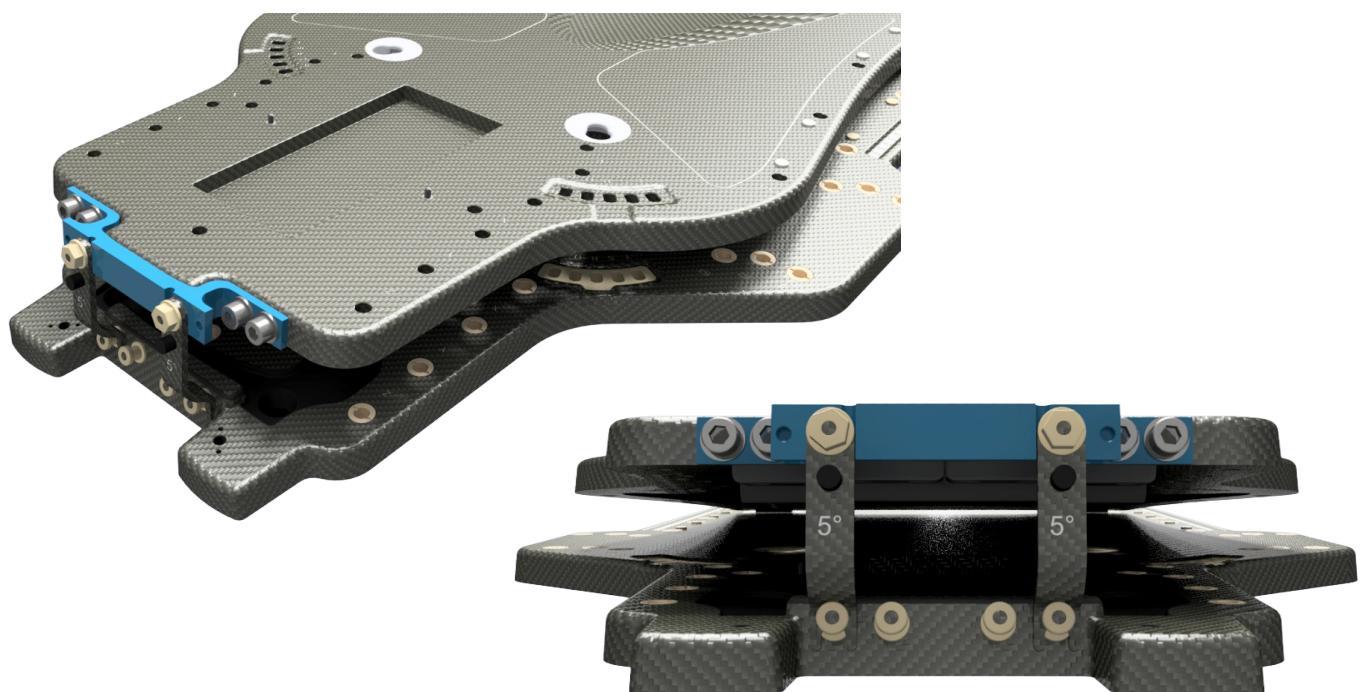
Remove the blue pivots by rotating them counterclockwise. If the pivots cannot be loosened by hand, use a rubber strip to increase grip.



Position the bracket on the cranial side and align it with the corresponding mounting holes. Insert the screws into the designated holes and tighten them clockwise using an 8 mm Allen key.



Ensure that the adapter is correctly positioned and that all screws are securely tightened. The BreastBoard can now be mounted onto the MacroMedics baseplate and positioned at an inclination angle of 5°.



## 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: (10)	Batch Code	Indicates the manufacturer's batch code so that the batch or lot 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.
<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, non-metallic, and nonmagnetic.
	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.
	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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