



macromedics

SOLUTIONS IN RADIOTHERAPY

MANUAL 161100
Instructions for use
English Instructions

MacroMedics® OmniCouch™



MacroMedics BV

Oostbaan 670
2841ML Moordrecht
The Netherlands
+31(0)182 389 777

info@macromedics.com
www.macromedics.com

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1. Warnings



- Inspect the device prior to use and do not use the product when damage is detected.
- Rulers on the device cannot be used as a measurement tool but only for reference for the positioning of accessories.
- Ensure that the device is properly secured before use.
- Ensure there is no possibility for collision between gantry and device.
- When positioning the patient, take into account any deflection/sagging of the treatment table, as this may cause the patient's actual position to deviate from the planned treatment position of the patient.
- Ensure that the patient's hands, arms and limbs do not hang over the side of the couchtop to avoid potential pinch points.
- Keep hands clear of the locking mechanism when moving the OmniCouch between longitudinal positions P1 and P2 to avoid injury.
- In the USA, federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

2. MRI Safety Information

MR UNSAFE

The following devices are MR Unsafe:

- 161100 OmniCouch, Couchtop for Elekta Versa HD
- 161310 OmniBoard H&N base CyberKnife RE
- 161330 OmniCouch H&N base CyberKnife RE KS
- 161410 OmniCouch CT CouchTop for Siemens SOMATOM Confidence (RealEase)
- 161610 OmniCouch PET/CT RE
- 161710 OmniCouch CT CouchTop for Canon LB Exceed (RealEase)
- 161720 OmniCouch CT CouchTop Siemens Somatom Go Open Pro (RealEase)
- 161730 OmniCouch CT GE Omni Legend model for Erasmus Medical Center



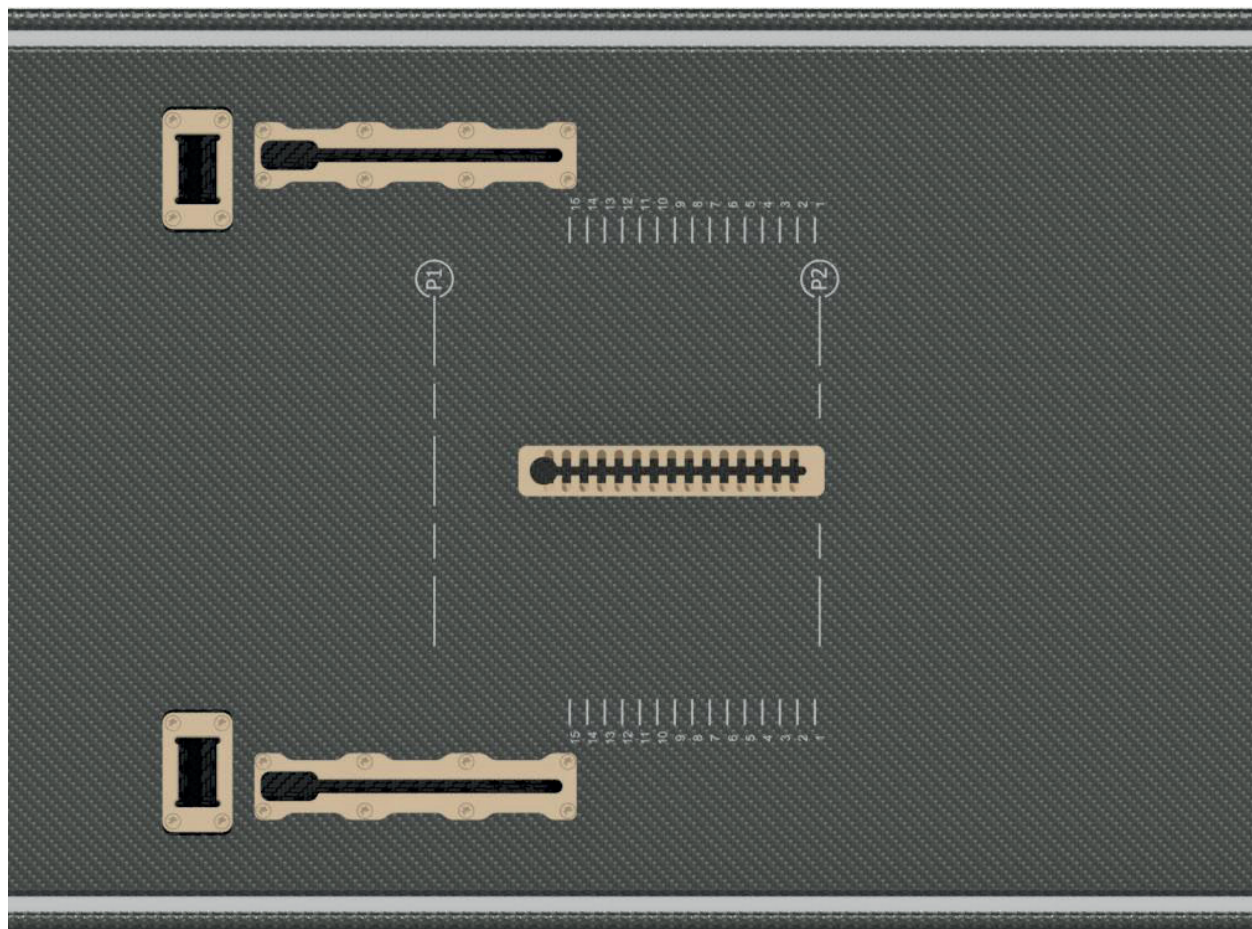
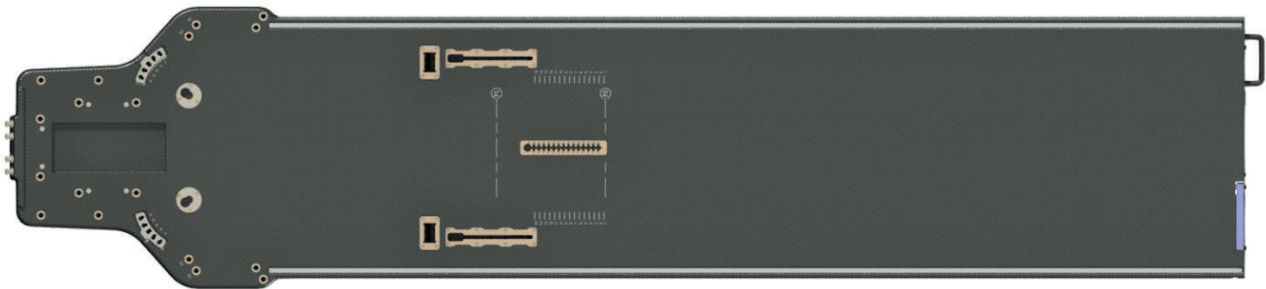
3. Intended Use

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

4. Use Instructions

4.1 OmniCouch 161100 - Couchtop for Elekta Versa HD

- I. The OmniCouch offers a wide range of treatment area with its integrated travel range system. The following instructions explain how range is achieved by moving the OmniCouch couchtop in two discrete positions, P1 or P2.



- II. It is possible to read the active position on the top surface and on the side of the OmniCouch. See the figures below:



In position P1, an optimal travel range is offered towards the cranial section of the radio translucent part of the OmniCouch Couchtop. In position P2, an optimal travel range is provided towards the caudal section of the radio translucent part of the OmniCouch couchtop.

There are two operating instruments located at the caudal side of the OmniCouch. To move the OmniCouch couchtap from position P1 to position P2 or vice versa, complete the following steps:

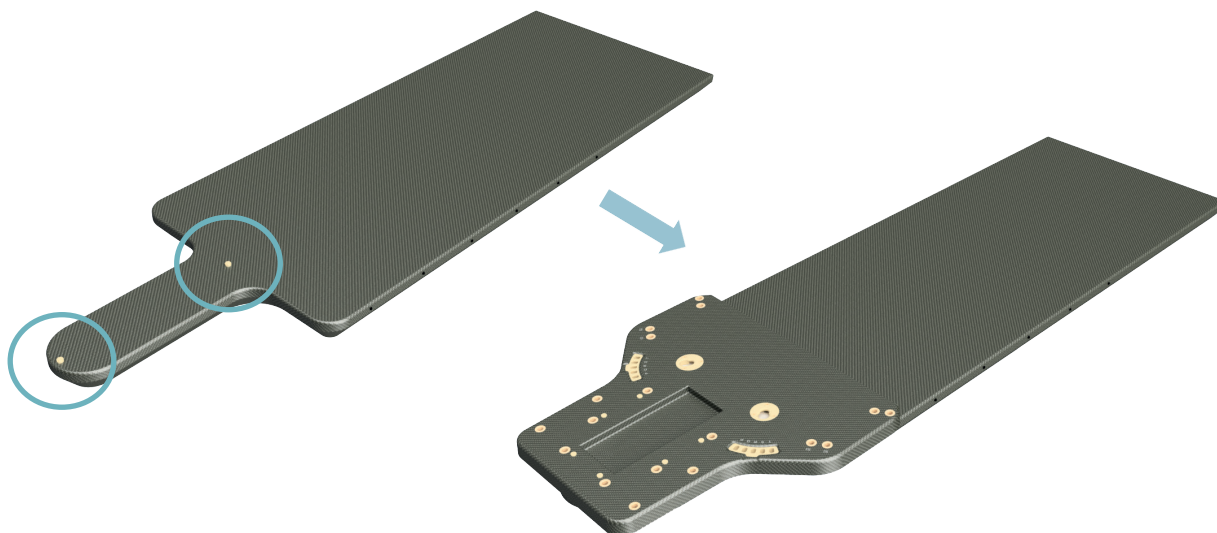
- To unlock the Couchtop from its locked position, raise the blue handle upwards.
- To move the OmniCouch, press the blue round button. This releases the second locking mechanism.
- To move the OmniCouch into the desired position, push or pull the black handle. In the newly set position, the blue locking handle will automatically spring back into its closed position and the blue round button should be released. Please see the following images.

The transfer of the OmniCouch couchtap to the desired discrete position can only be achieved with proper operation.



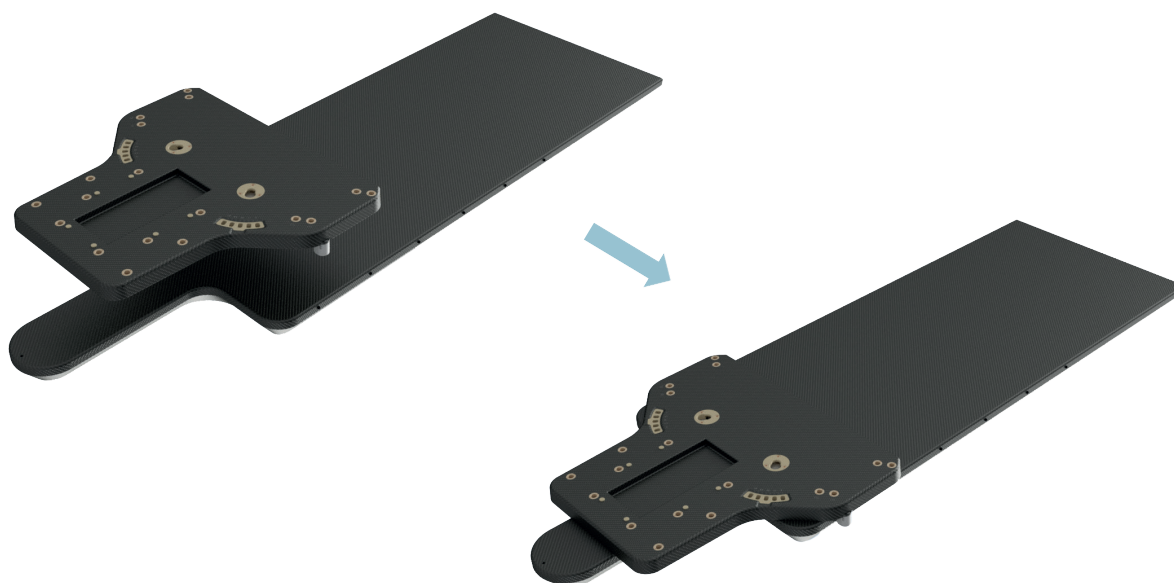
4.2 OmniCouch 161310 - OmniBoard H&N base CyberKnife RE

- I. Place the Peek positioning pivots in the Cyberknife tabletop.
- II. Position the baseplate on the CyberKnife tabletop.



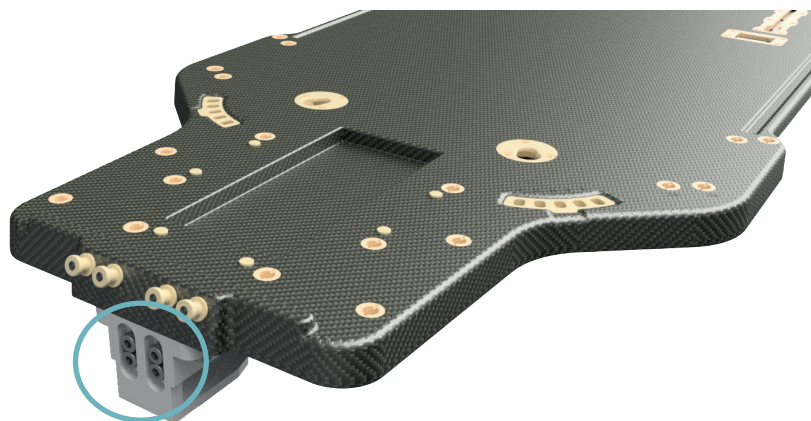
4.3 OmniCouch 161330 - OMC H&N base CyberKnife RE KS

- I. Align the device and the designated couchstrip above the CyberKnife tabletop.
- II. Place the baseplate on the cyberknife tabletop.

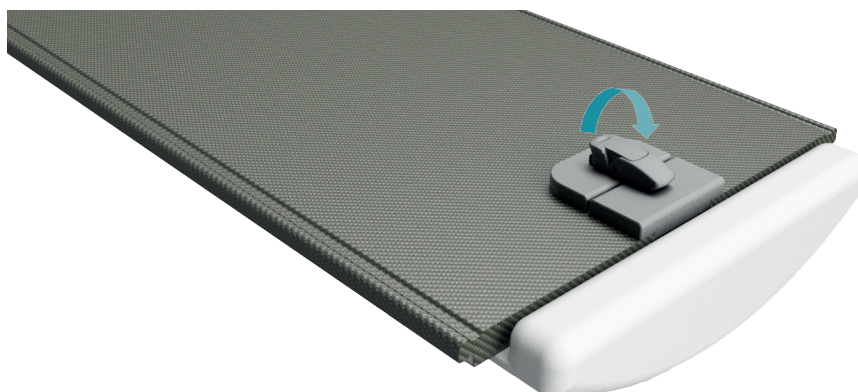


4.4 161410 - OmniCouch CT CouchTop for Siemens SOMATOM Confidence (RealEase) 161610 - OmniCouch PET/CT RE

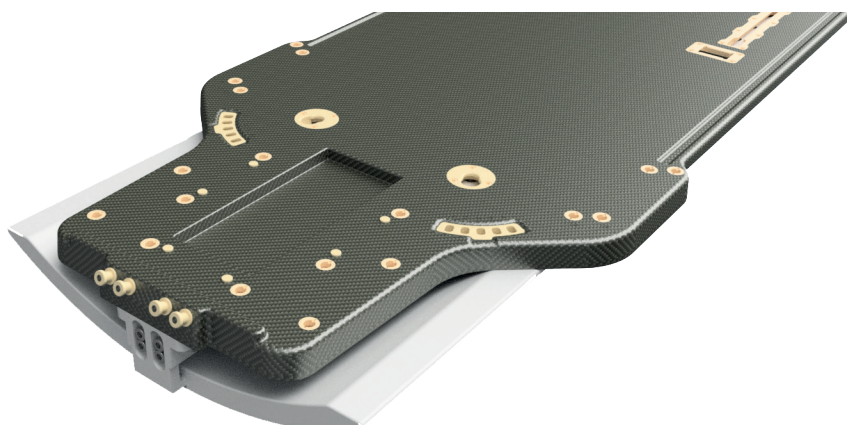
- I. Open the cradle cover and place the metal cradle plate at the caudal end of the cradle, with the use of the original screws.
- II. At the cranial end of the OmniCouch, loosen the four screws of the spoon (circled) with an Allen key and position the OmniCouch above the cradle.



- III. Slide the OmniCouch towards the caudal end of the cradle. Take care that the OmniCouch aperture fits the holding block.
- IV. Lock the caudal side of the OmniCouch by turning the knob of the latch in caudal direction.



- V. Tighten the four screws from step two, located at the cranial side.



4.5 161710 - OmniCouch CT CouchTop for Canon LB Exceed (RealEase)

- I. Screw the caudal plate on the caudal side of the cradle with the original screws. If needed, adjust the caudal plate in height.



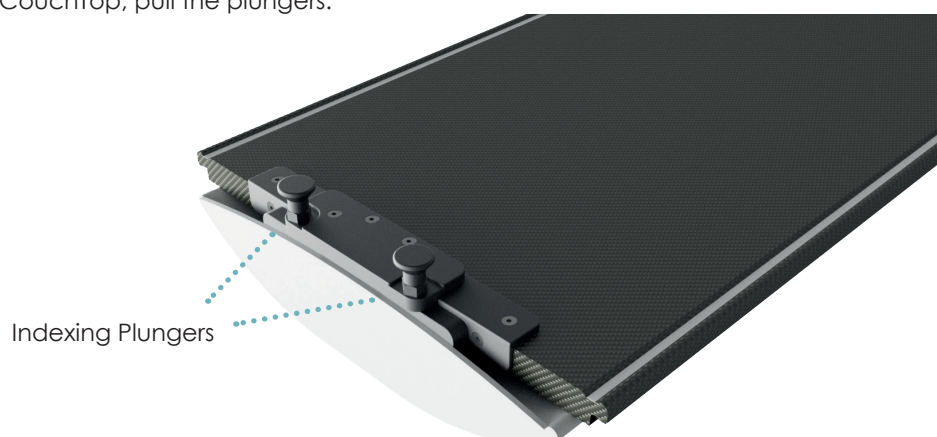
- II. Position the OmniCouch above the cradle and place it carefully on the cradle.



- III. Slide the OmniCouch in caudal direction and make sure that the OmniCouch's spoon slides into the cradle.

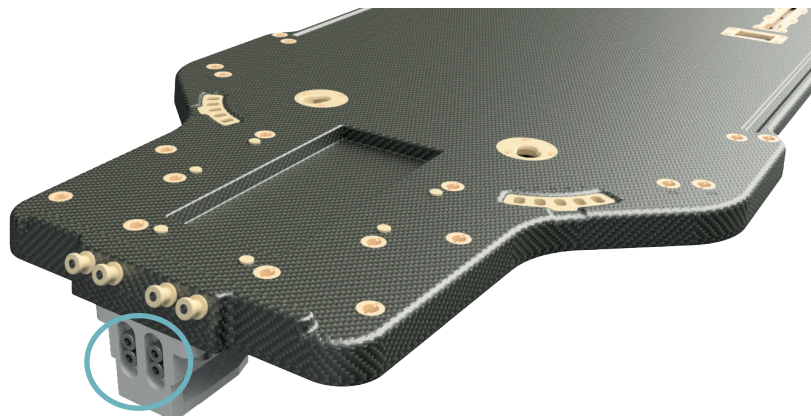


- III. Check if the indexing plungers are seated in the corresponding holes of the caudal plate. To release the CouchTop, pull the plungers.

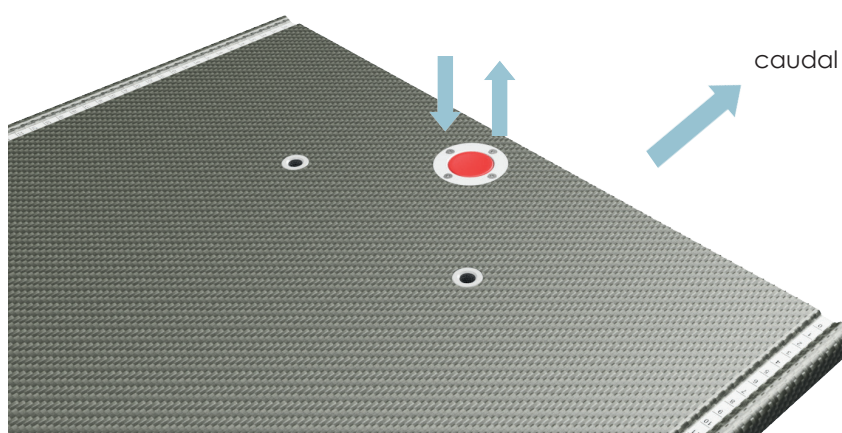


4.6 161720 - OmniCouch CT CouchTop Siemens Somatom Go Open Pro (RealEase)

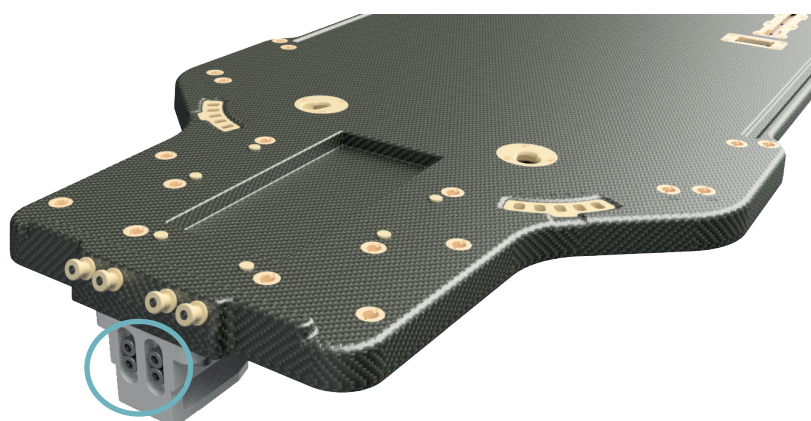
- I. At the cranial end of the OmniCouch, loosen the four screws of the spoon (circled) with an Allen key and position the OmniCouch above the cradle



- II. Position the OmniCouch above the cradle and place it carefully on the cradle.
- III. Slide it in caudal direction whilst pushing the red knob at the caudal end in the OmniCouch. Stop with sliding it when you hear a clicking noise and the knob is flush with the surface of the OmniCouch.

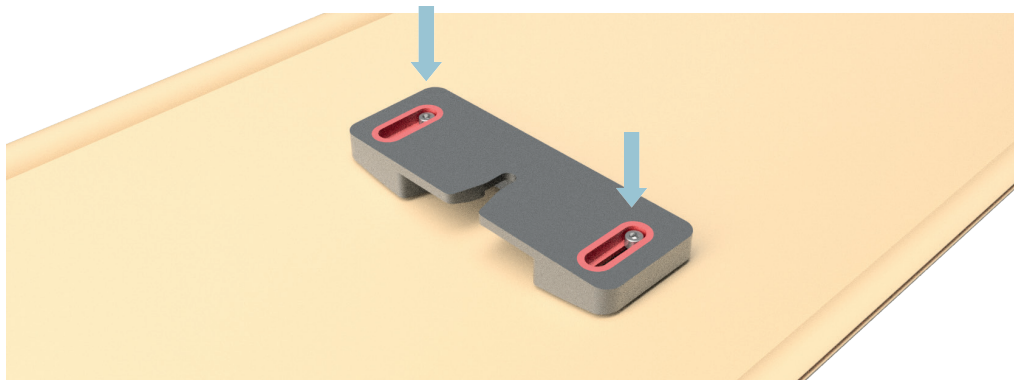


- IV. Tighten the four screws from step one, located at the cranial side.



4.7 161730 - OmniCouch CT GE Omni Legend model for Erasmus Medical Center

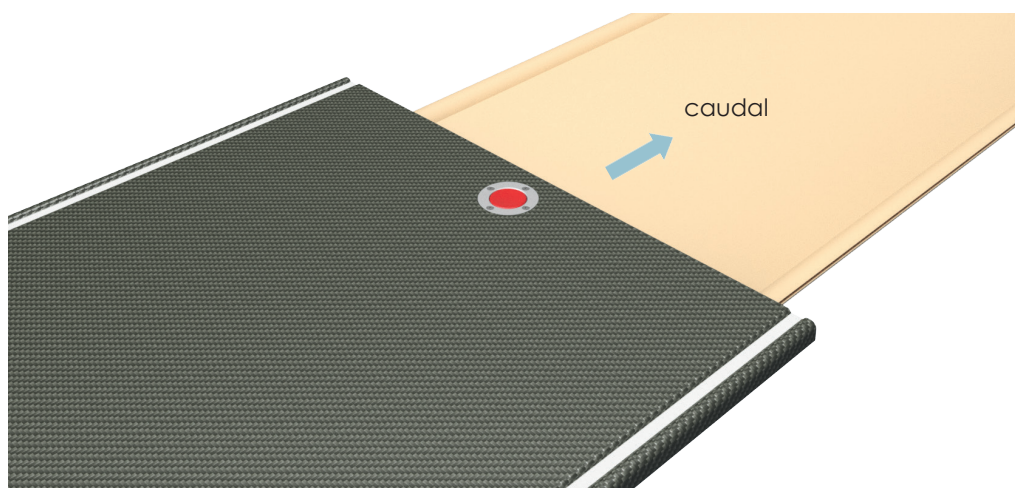
- I. Mount the caudal block on to the cradle with the two included M6 Bolts.



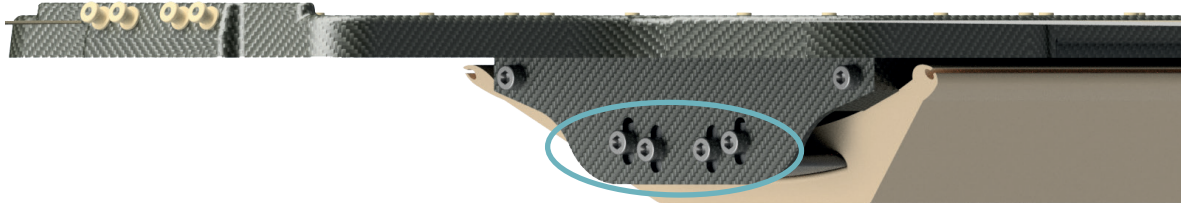
- II. At the cranial end of the OmniCouch, loosen the four screws of the spoon (circled) with an Allen key and position the OmniCouch above the cradle.



- III. Position the OmniCouch above the cradle and place it carefully on the cradle.
- IV. Slide it in caudal direction whilst pushing the red knob at the caudal end in the OmniCouch. Stop with sliding it when you hear a clicking noise and the knob is flush with the surface of the OmniCouch.



Check if the spoon is correctly positioned in the cradle.



- IV. Tighten the four screws from step one, located at the cranial side.

5. Cleaning, Storage and Disposal

- The devices are not suitable for sterilization or thermal disinfection.
- Inspect for damage or wear before every use. Do not use when damaged.
- Store the device in a flat position in a safe place.
- Dispose of the device in accordance with the local laws and regulations applicable to your country.

Regularly Clean:

- 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.
- Having cleaned the device, perform a visual inspection of the device to ensure that it is thoroughly clean. If it is not, either repeat the cleaning process described above until the device is thoroughly clean upon visual inspection or dispose of the device to prevent the use of a soiled device.
- If unsure about the cleaning fluid, do not use it. Never use Ethanol (Ethyl alcohol), aerosol sprays, corrosive cleaning agents, solvents or abrasive detergents.

Periodically Clean:

- Plastic PEEK parts and apertures.
- To clean the PEEK plastic parts and underlying apertures, remove the PEEK parts and use a clean cloth and soap to wipe clean the part and apertures.
- Carbon fiber surfaces.
- Use a clean cloth and soap to wipe clean the carbon fibre surfaces.
- Metal components.
- Use a clean cloth and soap to wipe clean the aluminium parts on the cranial side of the OmniCouch.
- Having cleaned the device, perform a visual inspection of the device to ensure that it is thoroughly clean. If it is not, either repeat the cleaning process described above until the device is thoroughly clean upon visual inspection or dispose of the device to prevent the use of a soiled device.

6. Warranty

The MacroMedics products are warranted to be free from defects in manufacturing, material and construction. The standard warranty is for 1 year starting from the date of delivery.








Product warranties remain valid provided the product was installed and used in conformance with the instructions. Defects, malfunctions or failures caused by nature, misuse, abuse and unauthorized 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 Mark	CE marking of conformity
	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 Unsafe	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.

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