



MacroMedics® HXP Baseplates

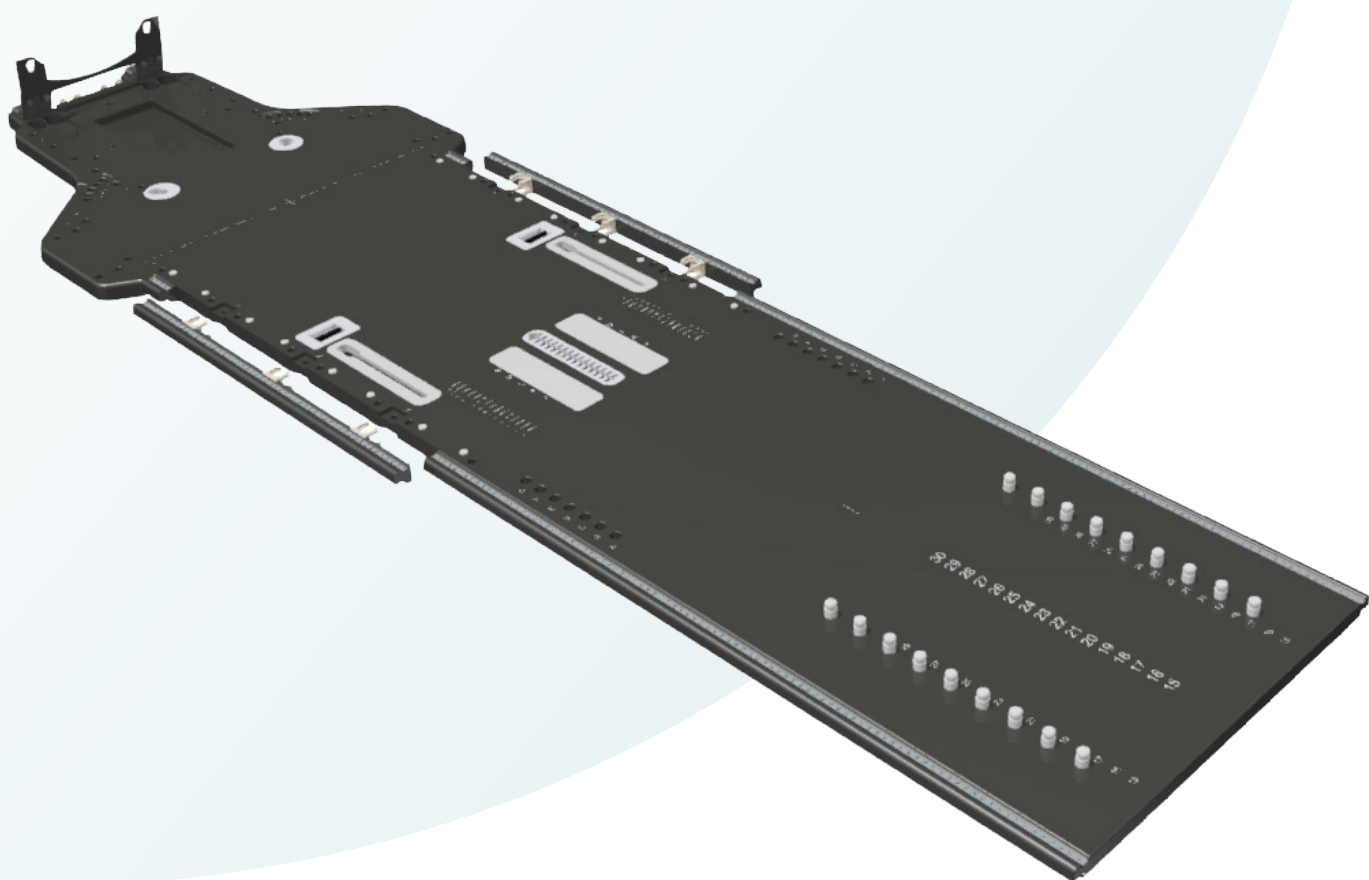


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1. Warnings



- 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.
- Ensure that the baseplate is correctly secured to the couch prior to use.
- Take extra care when securing the baseplate to the couch to not damage the products.
- Instruct the user not to lean on the OMB HXP Rail System.
- Do not exceed an equally distributed load of 200 kg on the baseplate.
- If the cranial end of the board is extended past the couch, do not exceed a load of 15 kg in this area.
- Rulers used on the devices are only intended for reference of the device positioning of accessories. Rulers shall not replace patient position verification.
- 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:

- 126110 OmniBoard™ HXP Base, EXF
- 125410 MultiBoard™ base ExaFix HexaPod
- 125420 MultiBoard™ base Type-O HexaPod
- 125450 MB HXP Rail System, set/2
- 174910 OmniBoard™ 2.0 HXP base, RE
- 175130 OmniBoard™ HXP Base, S-Type
- 175160L OMB HXP Rail System left
- 175160R OMB HXP Rail System right



3. Intended Use

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

4. Installation Instructions

4.1 SECURING THE OB HEXAPOD TO THE COUCH

I. Placing the CouchStrips

Place an indexing CouchStrip towards the cranial end on the couch at the desired longitudinal position.
Place a sliding CouchStrip towards the caudal end.
For additional information, refer to IFU147100 - CouchStrips & Sidepieces.

II. Placing the OmniBoard

Carefully align the OmniBoard with the CouchStrips and gently slot it in place.
Ensure that there is no play between the baseplate and the couch.

4.2 ATTACHING AND DETACHING THE OMNIBOARD HXP RAIL SYSTEM

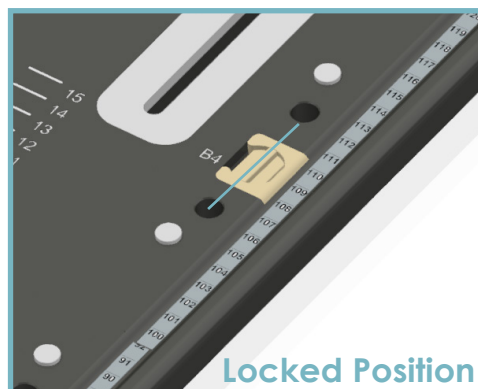
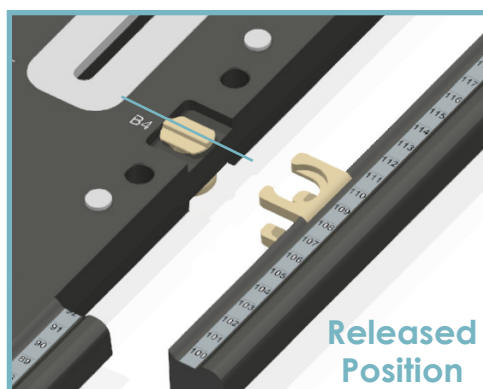
OMB HXP Rail System consists of a right and left rail that can be attached to either side of the OmniBoard HXP baseplate.

To attach the rail:

Ensure that the locking mechanism on both sides of the OmniBoard HXP baseplate is in the released position, as shown on the image below. Ensuring that the rulers are facing up, carefully slide the rails' hooks onto the baseplate's locking mechanism. Turn the knobs 90 degrees to secure the rails in place.

To detach the rail:

Rotate all of the locking mechanism 90 degrees to the released position. Gently pull on the rail to separate it from the baseplate.



4.3 SECURING THE MULTIBOARD HEXAPOD TO THE COUCH

I. Placing the CouchStrips

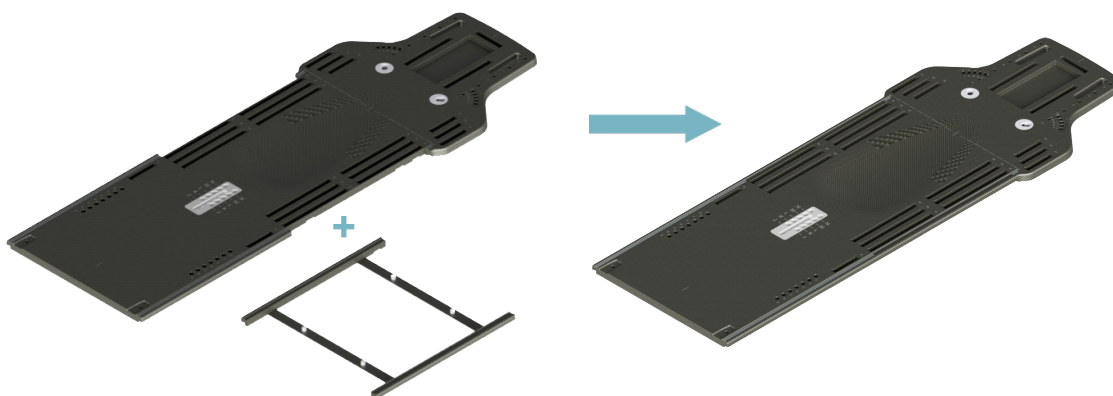
Place an indexing CouchStrip towards the cranial end on the couch at the desired longitudinal position.
Place a sliding CouchStrip towards the caudal end.
For additional information, refer to IFU147100 - CouchStrips & Sidepieces.

II. Placing the MultiBoard

Carefully align the MultiBoard with the CouchStrips and gently slot it in place.

4.4 ATTACHING AND DETACHING THE MULTIBOARD HXP RAIL SYSTEM

The MultiBoard HXP Rail System can be attached to the MultiBoard HXP baseplate. Carefully align the bottom of the MultiBoard HXP baseplate with the rail system and gently slot it in place.

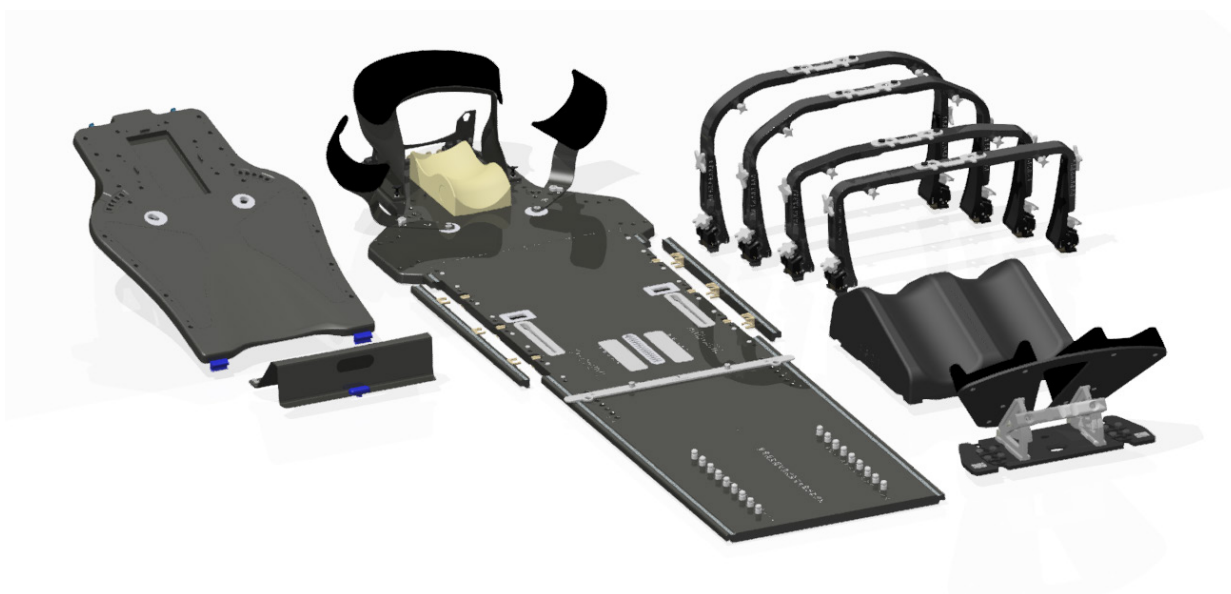


4.5 PATIENT POSITIONING

Follow the department protocol and the Instructions for Use of the individual accessories for patient set-up.

4.6 PLACING THE ACCESSORIES

Attach the required accessories following their instructions for use. Please check the latest MacroMedics' catalogue or contact your distributor for further information on available accessories.



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: (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 which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.



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SOLUTIONS IN RADIOTHERAPY

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