



macromedics

SOLUTIONS IN RADIOTHERAPY

MANUAL 110100
Instructions for use
English Instructions

MacroMedics® Head & Neck Baseplates



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1. Warnings



- Inspect the device thoroughly before use. Do not use the device when 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.
- Prevent the surface from damage and scratching.
- Ensure that the baseplate is correctly secured to the couch prior to use.
- Ensure to not extend the baseplate any further than the dotted line in relation to the cranial end of the couchtop.
- Place the patient carefully on the device and make sure that they lie down calmly. Instruct the patient to not reposition themselves after set-up.
- Place and fix the device properly before positioning the patient.
- The baseplate shall not extend from the cranial side of the couch.
- The maximum patient weight is 200 kg. Make sure that the load is equally distributed.
- 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:

- 110100 ExaFix™-5
- 110120 ExaFix™-3
- 110250 ExaFix™-5P, pediatric
- 110280 ExaFix™-IMRT, 2P CF
- 111230 Handgrips RE or TS
- 111300 RealEase baseplate
- 111400 S-Type baseplate
- 111760 RealEase baseplate
- 111730 Handgrips HNS



2.2 MR SAFE

The following devices are MR Safe:

- 110140 ExaFix™-5A
- 110160 ExaFix™-3A
- 110290 ExaFix™-IMRT, 3P MR
- 111350 RealEase baseplate, MR
- 111450 S-Type baseplate, MR
- 111770 RealEase baseplate, MR
- 111830 Handgrips HNS, MR



2.3 MR CONDITIONAL

The following devices are MR Conditional:

- 111280 Handgrips RE or TS, 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 (25T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Due to the size and location of the metallic parts, no clinically significant RF heating is expected.

3. Intended Use

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

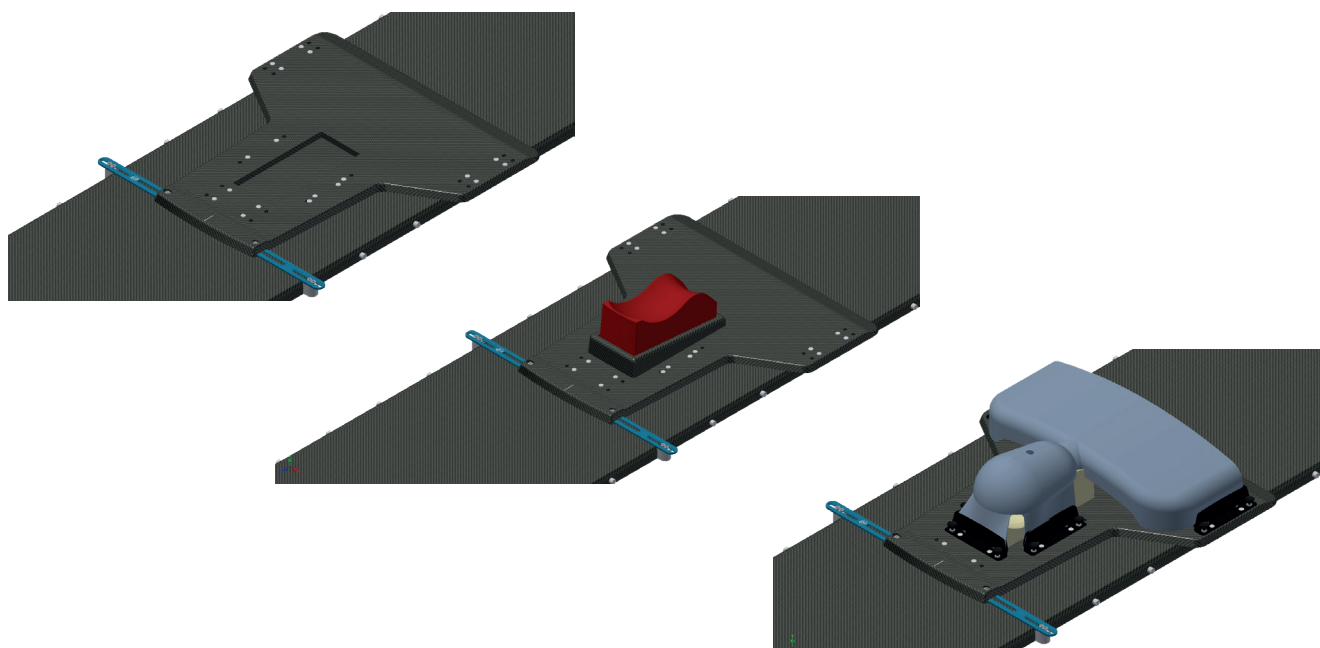
4. Installation Instructions

4.1 PLACING THE COUCHSTRIPS

- I Place the indexing CouchStrip at the cranial end of the CouchTop.
- II Place the sliding CouchStrip on the caudal end (not applicable if handgrips are used).
- III Fasten the CouchStrip. For more information, refer to IFU147100 - CouchStrips and Sidepieces.
- IV For use in MR, use a glass fiber, MR safe 3-Pin CouchStrip.

4.2 PLACING THE HEAD & NECK BASEPLATE, WITHOUT HANDGRIPS

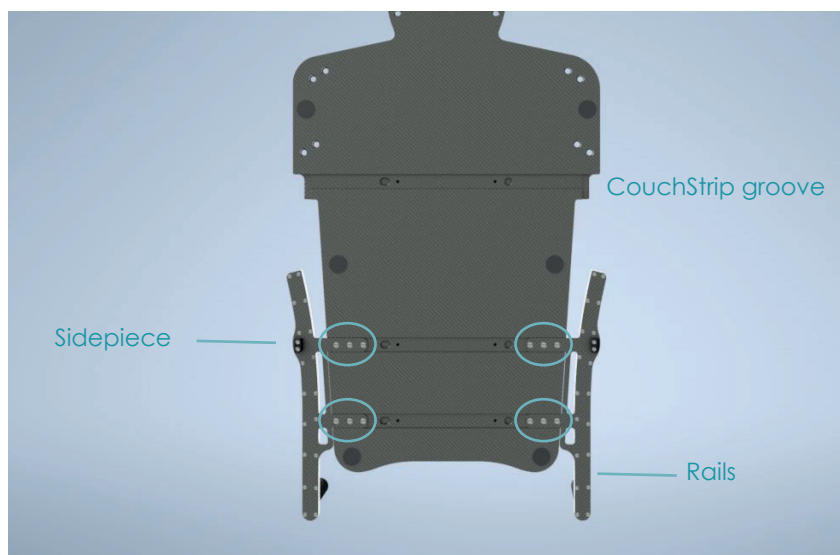
- I Carefully align the Head & Neck Baseplate with the CouchStrip and gently slot into place.
- II Place the HeadSupport.
- III Position the Patient.
- IV Place the Thermoplastic Mask.



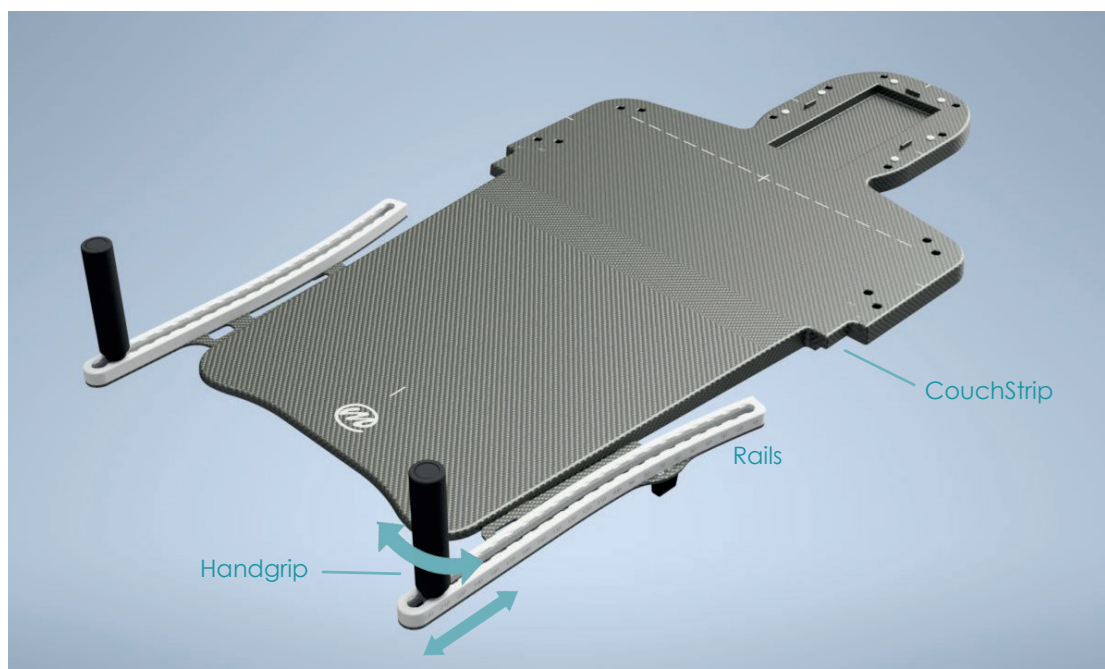
4.3 PLACING THE HEAD AND NECK BASEPLATE, WITH HANDGRIPS

The handgrips are optional and are compatible with RealEase and S-Type baseplates.

- I Screw the rails to the bottom of the Head and Neck Baseplate. Make sure that all 12 screws are tightened.



- II Carefully align the Head and Neck Baseplate with the CouchStrip and gently slot into place.
- III Place the handgrips into the rails and slide the them into the required position. Turn the handgrips clockwise to tighten them and counterclockwise to loosen them.



- IV Place the HeadSupport.
- V Position the Patient.
- VI Place the Thermoplastic Mask.

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.
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 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.



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