

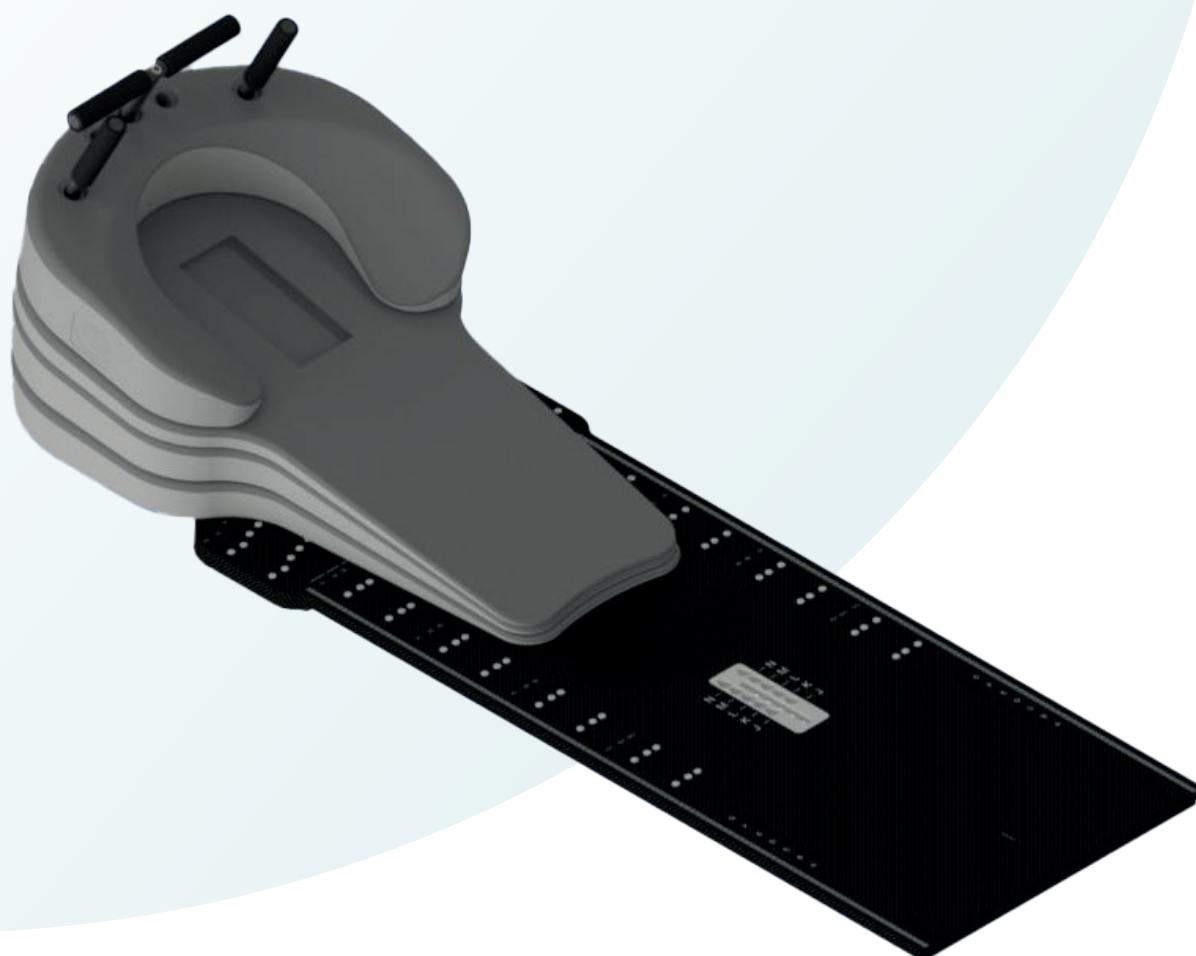


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SOLUTIONS IN RADIOTHERAPY

MANUAL 115420
Instructions for use
English Instructions

MacroMedics® ThoraxTilt



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1. Warnings



- Inspect the device thoroughly before use. Do not use the device if damaged.
- Check individual components on MR-safety when used together in a patient positioning system.
- Ensure that the device is secured before positioning the patient.
- The device should not overhang past the baseplate.
- Do not exceed an equally distributed load of 75 kilograms.
- Instruct the patient not to reposition themselves after set-up.
- 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 SAFE

The following devices are MR Safe:

- 115430 Thoraxtilt PRO 5 Wedge
- 115440 Thoraxtilt PRO 2.5 Wedge
- 115450 Thoraxtilt PRO 5 Wedge Stand Alone
- 115460 Thoraxtilt PRO Armsupport
- 115470 ThoraxTilt PRO for MultiBoard/OmniBoard
- 115480 ThoraxTilt PRO Stand Alone



3. Intended Use

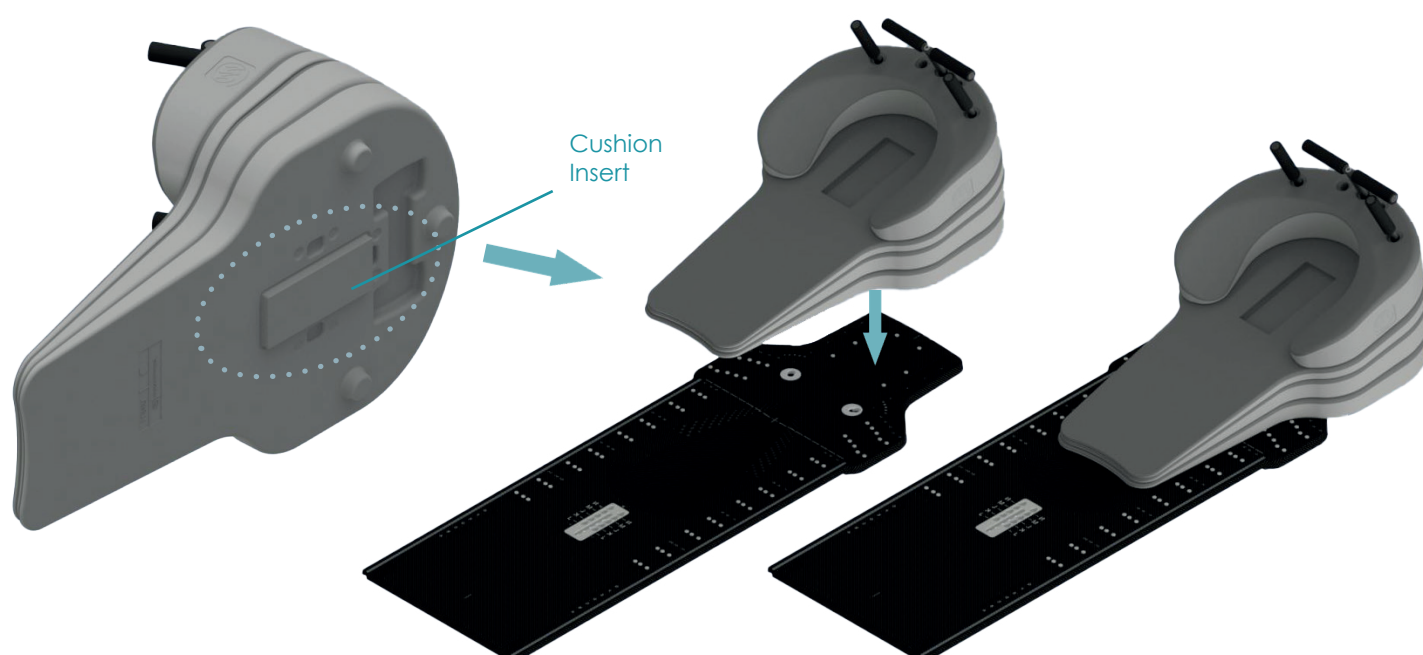
Positioning of the patient during radiotherapy and radiodiagnostics, including MR where indicated.

4. Use Instructions

The ThoraxTilt is made up of three stackable layers and an arm support. There are two versions available: a standalone version and a version which can be used with the MultiBoard or OmniBoard.

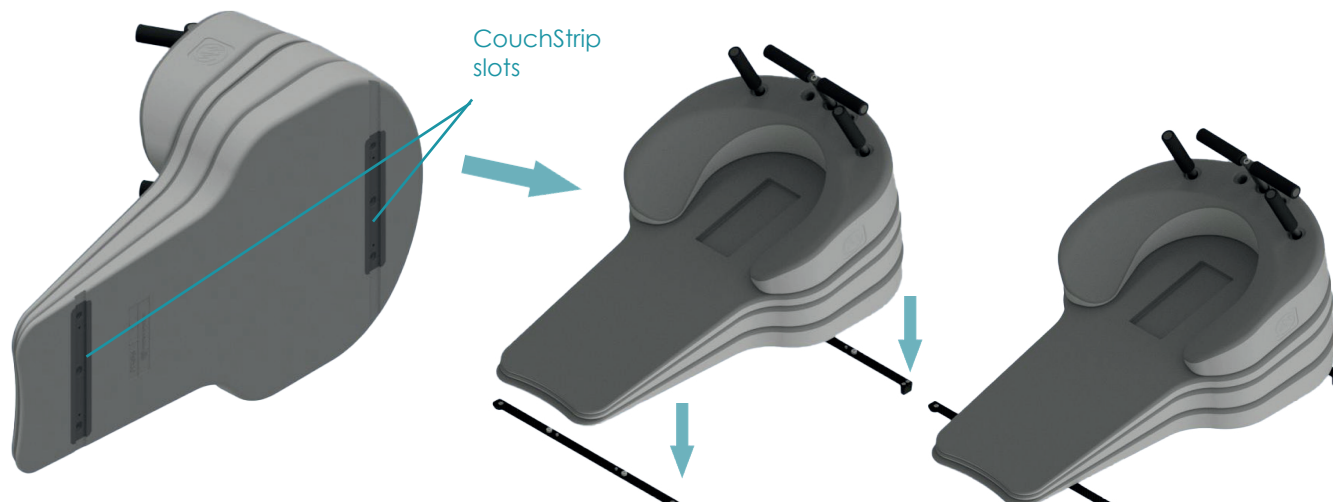
4.1 Using the ThoraxTilt with the MultiBoard or OmniBoard.

- Locate the cushion insert at the bottom of the ThoraxTilt.
- Align this insert with the corresponding Cushion slot on the MultiBoard or OmniBoard.
- Carefully press the ThoraxTilt down until it clicks into place, ensuring it is securely attached to the baseplate.



4.2 Using the standalone ThoraxTilt.

- Place the CouchStrips on the treatment couch in the designated, indexed positions.
- Align the slots on the underside of the ThoraxTilt with the CouchStrips.
- Lower the ThoraxTilt onto the CouchStrips until it is securely placed.



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.
- 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.
- The devices are not suitable for sterilization or thermal disinfection.
- Store the device in a clean, ventilated environment. Store the device in a separate area and do not place any accessories on it which could harm the device.
- 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.
	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.
	Keep Dry	Indicates a medical device that needs to be protected from moisture.
	Keep Away from Sunlight	Indicates a medical device that needs protection from light and heat sources.
	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.



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