



**macromedics**

SOLUTIONS IN RADIOTHERAPY

MANUAL 130500  
Instructions for use  
English Instructions

## MacroMedics® Pelvic Prone Board



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# 1. Warnings



- Inspect the device thoroughly before use. Do not use the device if damaged or incomplete.
- Prevent the surface from damage and scratching.
- Check individual components on MR-Safety when used together in a patient positioning system.
- Do not use MR Unsafe items in an MR environment.
- Take extra care when securing the baseplate to the couch to not damage the products.
- Do not use the Prone Cushions for head & neck radiation.
- Secure the device properly before positioning the patient.
- The device shall not extend from the cranial side of the couch.
- Do not exceed an equally distributed load of 200 kg on the device.
- Instruct the patient to lay down calmly and not to reposition themselves after set-up.
- Rulers used on the devices are only intended for reference of the device positioning of accessories. They shall not replace patient position verification.
- Remove all accessory devices before moving or storing the Pelvic Prone Board, as otherwise they may fall and become damaged.
- 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:

- 130650 Pelvic Prone Board, glass fiber with small prone cushion
- 116800 Pron Pillo
- 116850 Indexable Pron Pillo for Pelvic Prone Board

## 2.2 MR UNSAFE

The following devices are MR Unsafe:

- 130600 Pelvic Prone Board, carbon fiber, with small prone cushion



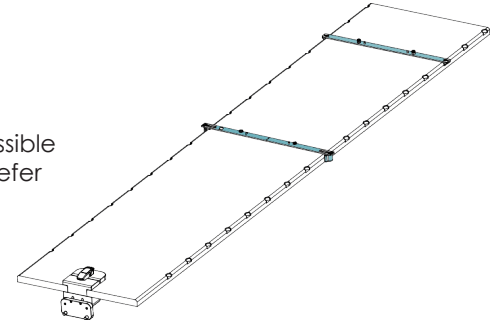
# 3. Intended Use

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

## 4. Installation Instructions - placing the devices

### 4.1 PLACING THE COUCHSTRIP

- I. Place an indexing CouchStrip at the cranial end of the CouchTop.
- II. Place a sliding CouchStrip on the caudal end.
- III. Fasten the CouchStrip properly. Make sure that no movement is possible between the couchtop and 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 PELVIC PRONE BOARD

- I. Carefully align the Pelvic Prone Board with the CouchStrips and gently slot into place.
- II. Ensure that no movement is possible between the Pelvic Prone Board and the Couchtop.
- III. If applicable, place the Pron Pillo on the device in the correct position.



### 4.3 PLACING THE PATIENT

- I. Position the patient on the device with their body shifted towards the cranial end of the device so that the patient can slide in caudal direction into the fixed apertures on the Pelvic Prone Board.
- II. Consequently, the stomach will automatically be pushed in cranial direction over the lower rim of the abdomen opening. This step is very important, it will minimise the volume of the small bowel in the treatment area by pushing it up and letting it fall down into the abdomen aperture.
- III. The patient should be face down in the head support, arms raised with hands clasped together above the head support.
- IV. Ensure that the patient's face is comfortably positioned inside the hole of the head support. Breathing should not be restricted and the neck should be straight and comfortable. Twisting the neck sideways reduces the reproducibility of daily positioning.
- V. Place the patient's lower leg on a rotated KneeSupport, ankles on the higher end of the KneeSupport for improved reproducibility.
- VI. Optional: Reference marks or tattoos can be used for accurate repositioning.
- VII. Use your preferred imaging protocol.

## 5. Cleaning, Storage and Disposal

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- 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 product.
- 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

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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

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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.
 GSI 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.
	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 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.
	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.



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