

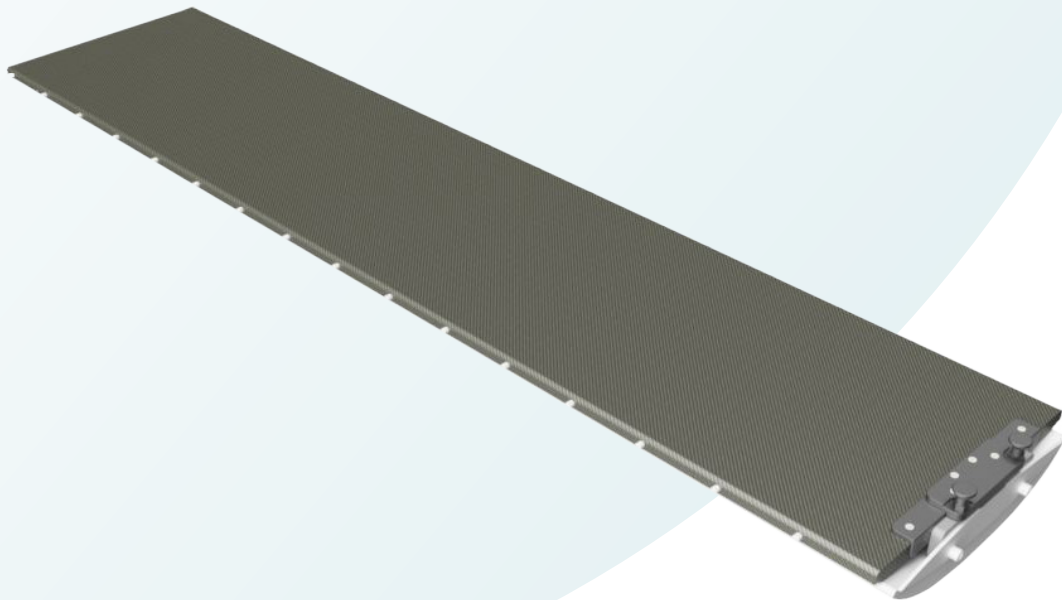


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SOLUTIONS IN RADIOTHERAPY

MANUAL 143000
Instructions for use
English Instructions

MacroMedics® CT CouchTops for Canon cradles



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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.
- Place and fix the device properly before positioning the patient. Only position the patient if the CouchTop is locked properly.
- Make sure that the patient lays down calmly.
- Prevent the surface from damaging and scratching.
- Do not sit at the cranial side of the CouchTop.
- Only unlock the CouchTop from the cradle when the CouchTop is unloaded.
- 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:

- 143100 CT Couchtop, CT143100
- 143120 CT Couchtop, CT143120
- 143140 CT Couchtop, CT143140
- 143330 CT CouchTop, CT143330



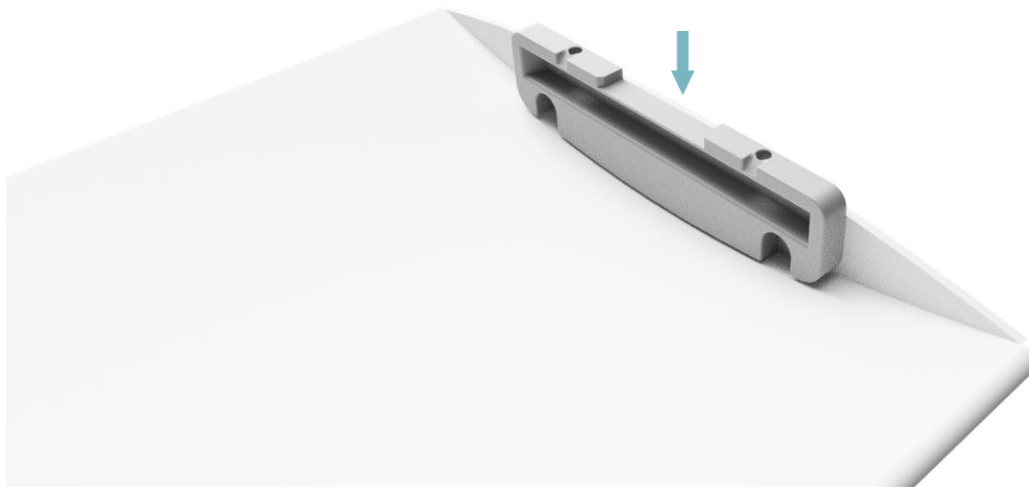
3. Intended Use

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

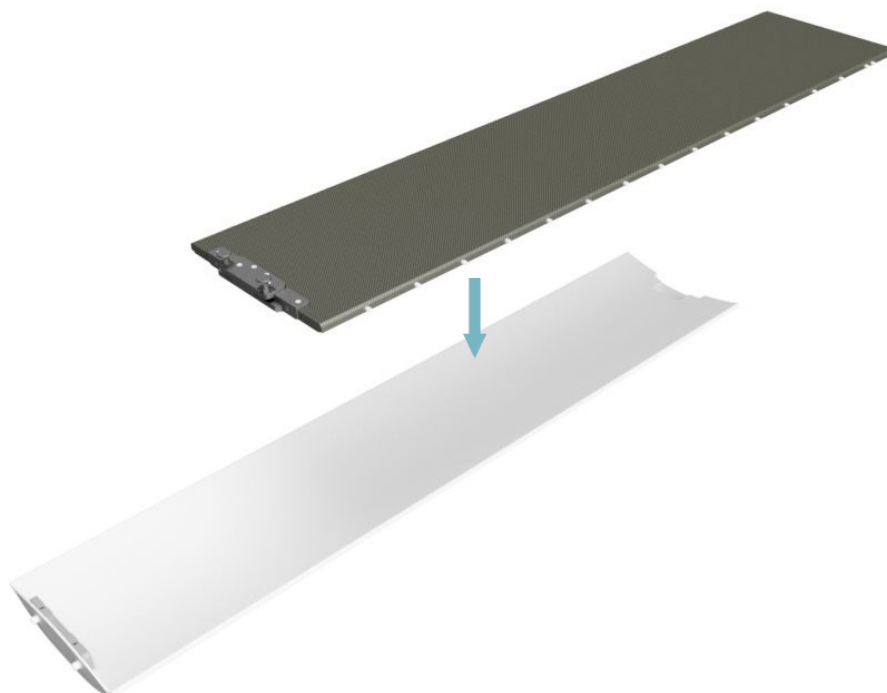
4. Installation Instructions

CouchTop installation for the **Canon Aquilion cradle**.
(CouchTops 143100, 143120, 143140 & 143330)

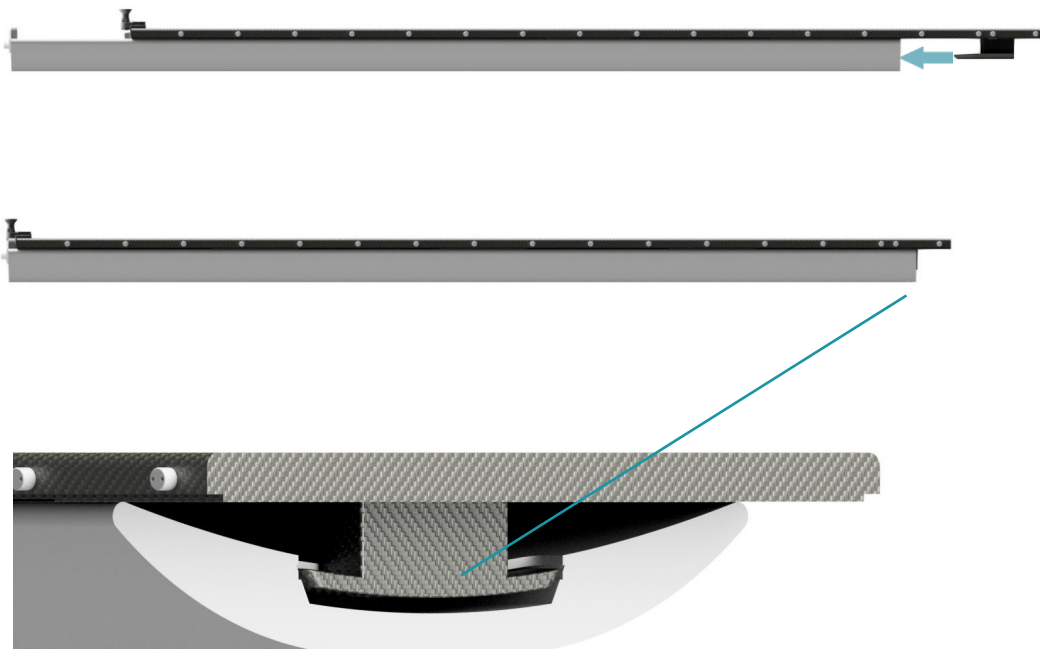
- I. Screw the caudal plate on the caudal side of the cradle with the original screws. If needed, adjust the caudal plate in height.



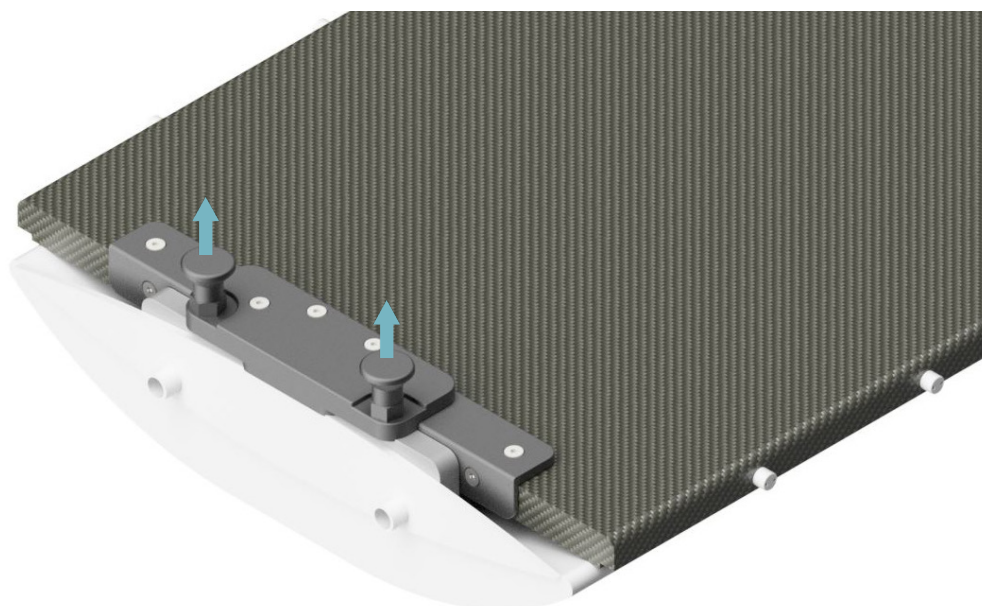
- II. Position the CouchTop above the cradle and place it carefully on the cradle.



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



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



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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