

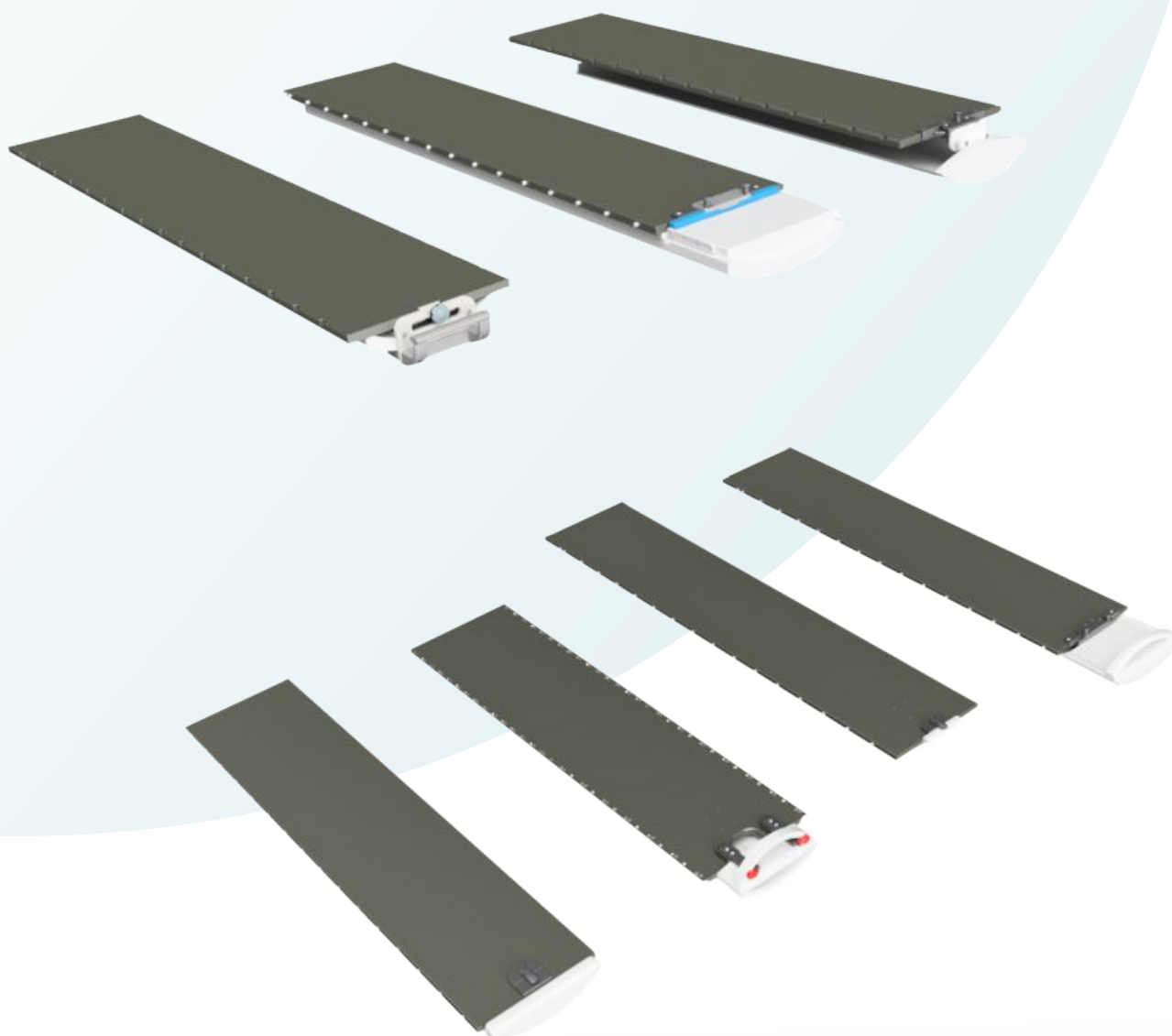


macromedics

SOLUTIONS IN RADIOTHERAPY

MANUAL 140000
Instructions for use
English Instructions

MacroMedics® CT CouchTops for Siemens cradles



MacroMedics BV

Oostbaan 670
2841ML Moordrecht
The Netherlands
+31(0)182-389777

info@macromedics.com
www.macromedics.com

Table of Contents

1. Warnings.....	3
2. MRI Safety Information.....	3
3. Intended Use.....	3
4. Installation Instructions.....	4
5. Cleaning, Storage and Disposal.....	18
6. Warranty.....	18
7. Notices.....	18
8. Glossary of Symbols.....	19

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 Siemens 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:

- 140100 CT Couchtop, CT140100
- 140120 CT Couchtop, CT140120
- 140150 CT Couchtop, CT140150
- 140170 CT Couchtop, CT140170
- 140220 CT Couchtop, CT140220
- 140250 CT Couchtop, CT140250
- 140260 CT Couchtop, CT140260
- 140270 CT Couchtop, CT140270
- 140280 CT Couchtop, CT140280
- 140290 CT Couchtop, CT140290
- 140300 CT Couchtop, CT140300
- 140340 CT Couchtop, CT140340
- 140350 CT Couchtop, CT140350
- 140450 CT Couchtop, CT140450
- 140470 CT Couchtop, CT140470
- 140490 CT Couchtop, CT140490



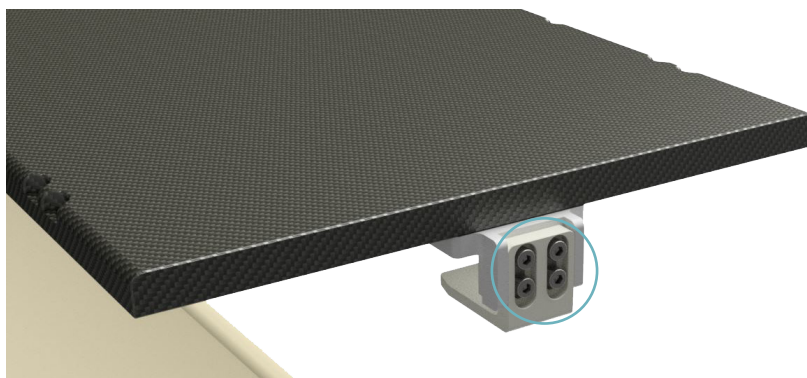
3. Intended Use

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

4. Installation Instructions

4.1 CouchTop installation for the **Siemens Sensation** cradles. (CouchTop 140100 & 140120)

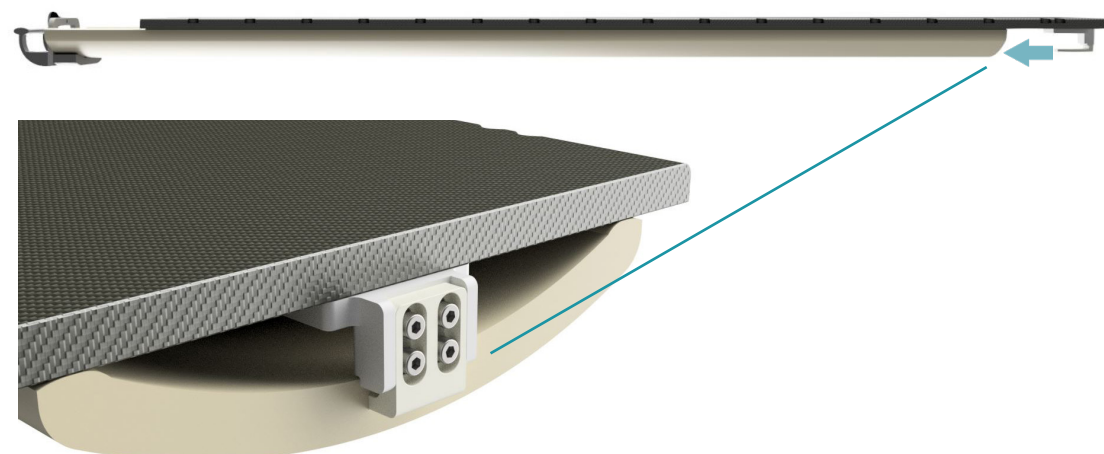
- I. At the cranial end of the CouchTop, loosen the four screws of the spoon (circled) with an Allen key and position the CouchTop above the cradle.



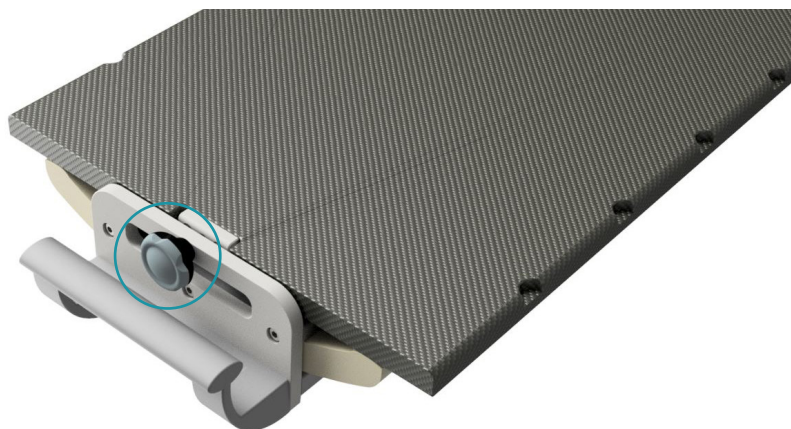
- II. Carefully place the CouchTop on the cradle as shown below.



- III. Slide the CouchTop towards the caudal end. Make sure that the CouchTops' spoon, at the cranial end, slides into the designated hole in the cradle.



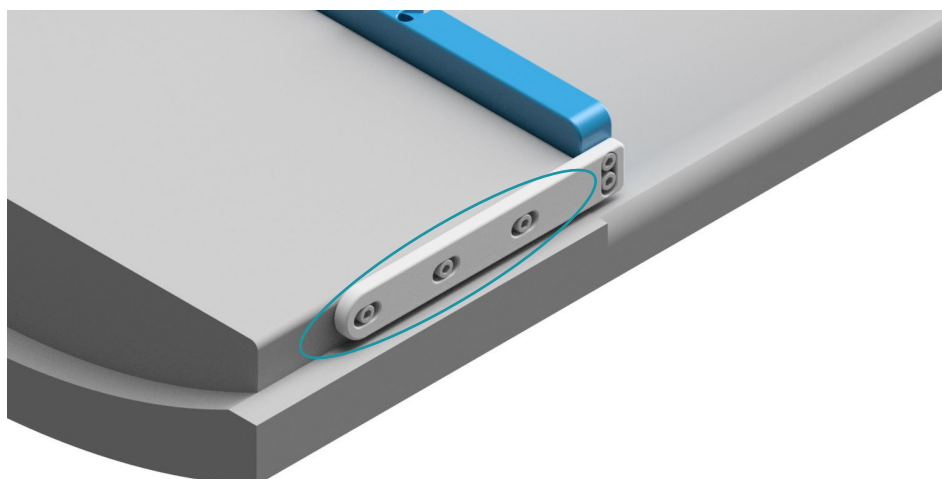
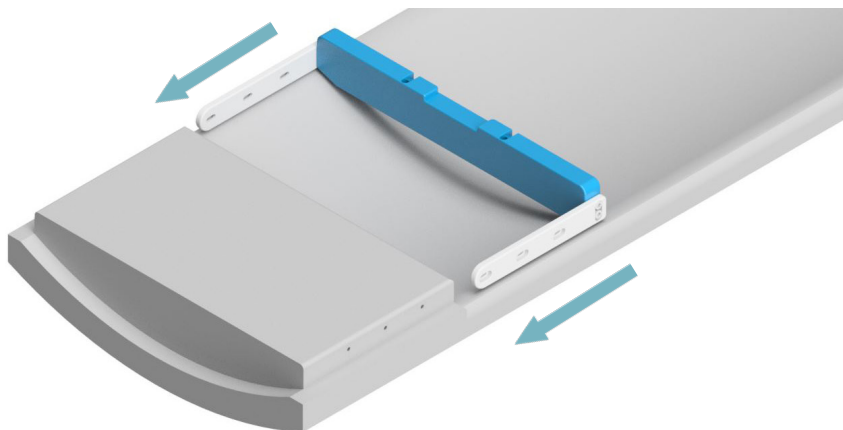
- IV. Check if the indexing plunger, at the caudal end, has correctly slid into the designated hole in the CouchTop.



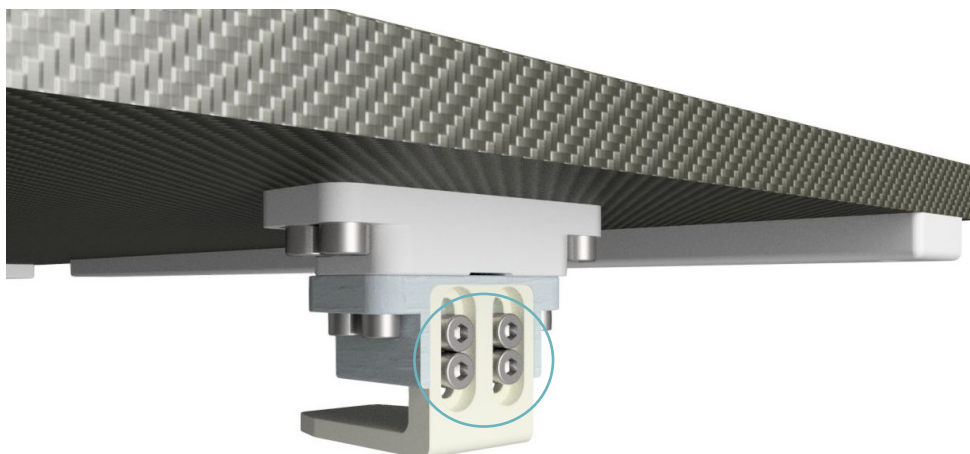
- V. Tighten the four screws from step one.

4.2 CouchTop installations for the **Siemens Somatom Definition cradles.** (CouchTop 140150 & 140170)

- I. Place the fixation strip on the caudal side of the cradle and tighten the screws (circled) on both sides.



- II. At the cranial end of the CouchTop, loosen the four screws of the spoon (circled) with an Allen key.



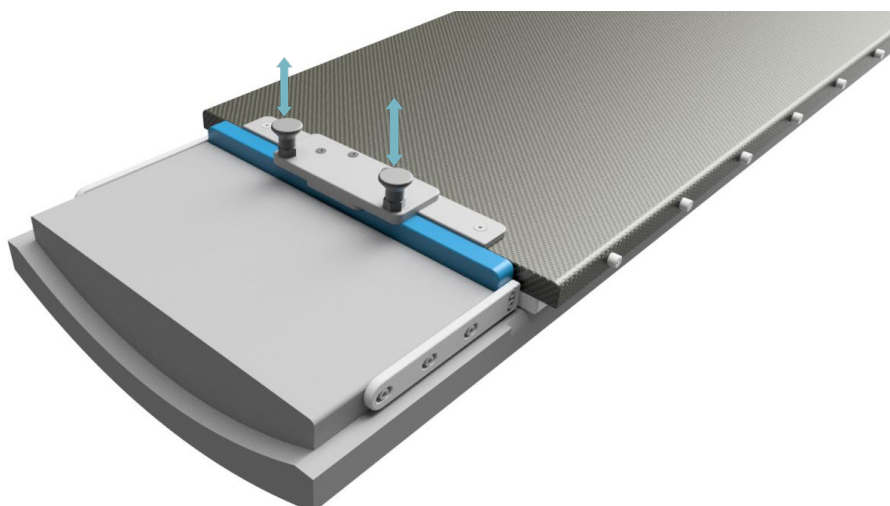
- III. Position the CouchTop above the cradle and carefully place the CouchTop on the cradle.



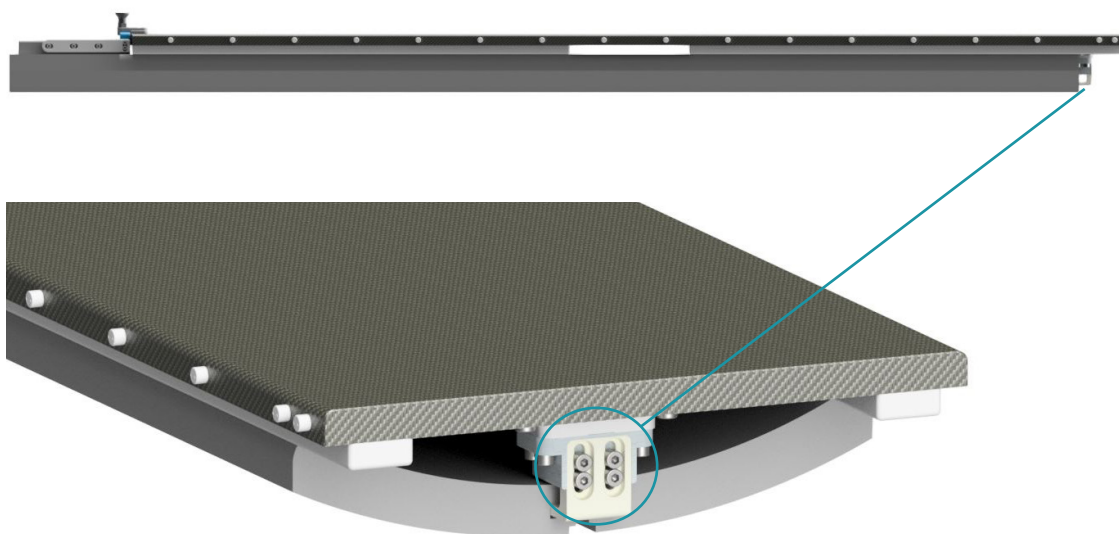
- IV. Slide the CouchTop towards the caudal end of the cradle.



Now that the caudal strip is approaching, pull the indexing plunger knobs and place the CouchTop against the caudal strip. After placing the CouchTop, release the indexing plunger knobs to fix the CouchTop to the cradle.



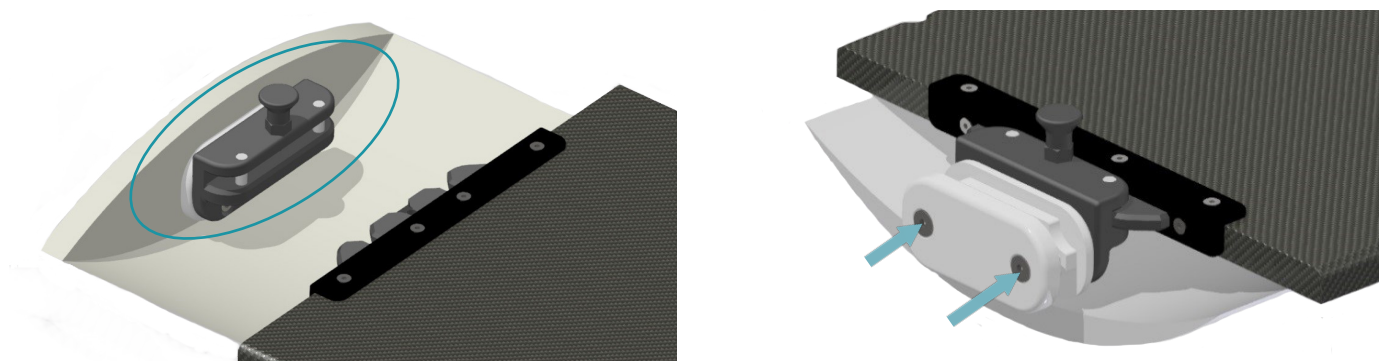
- V. Make sure that the CouchTops' spoon, at the cranial end (circled), slides into the designated hole in the cradle.



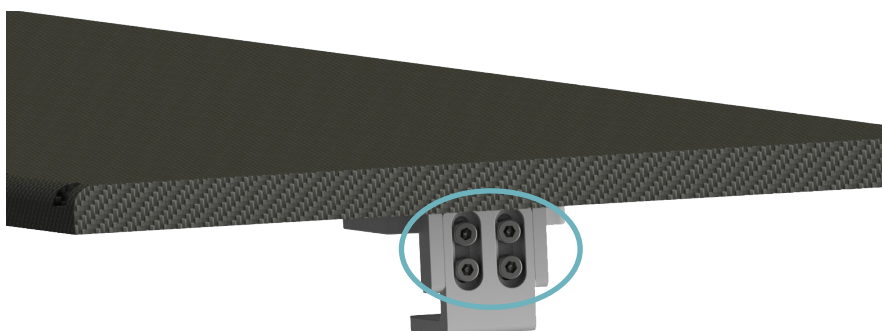
- VI. Tighten the four screws from step two.

4.3 CouchTop installation for the **Siemens Somatom Emotion** cradle. (CouchTop 140220)

- I. Mount the caudal block to the the cradle as shown below:

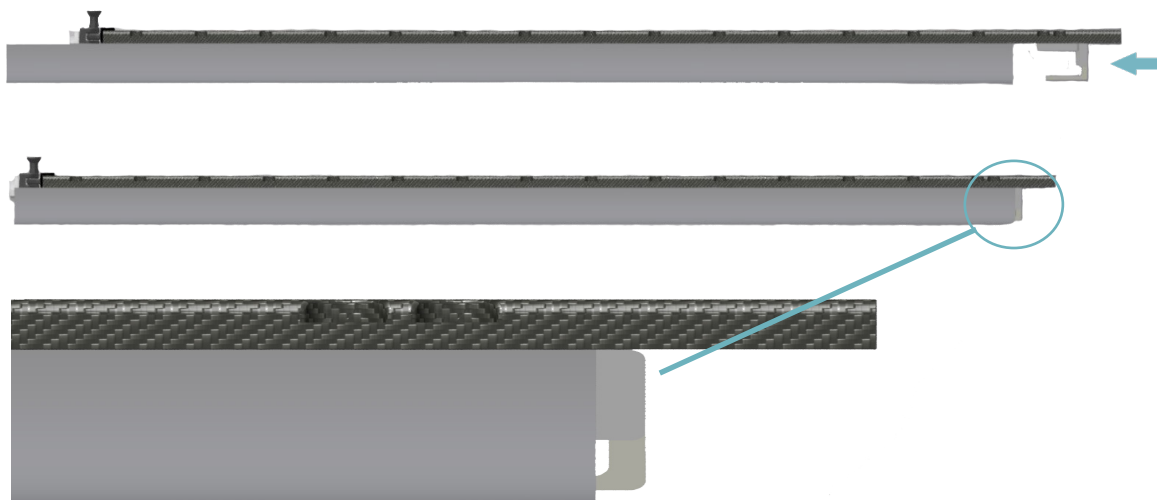


- II. At the cranial end of the CouchTop, loosen the four screws of the spoon (circled) with an Allen key.

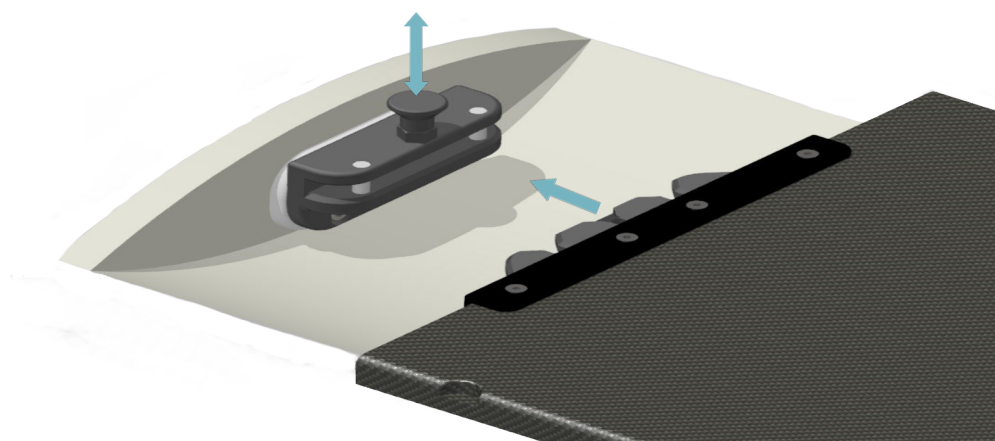


- III. Position the CouchTop above the cradle and carefully place the CouchTop on the cradle. Slide the CouchTop towards the caudal end of the cradle.

Make sure that the CouchTops' spoon, at cranial end (circled), slides into the designated hole in the cradle.



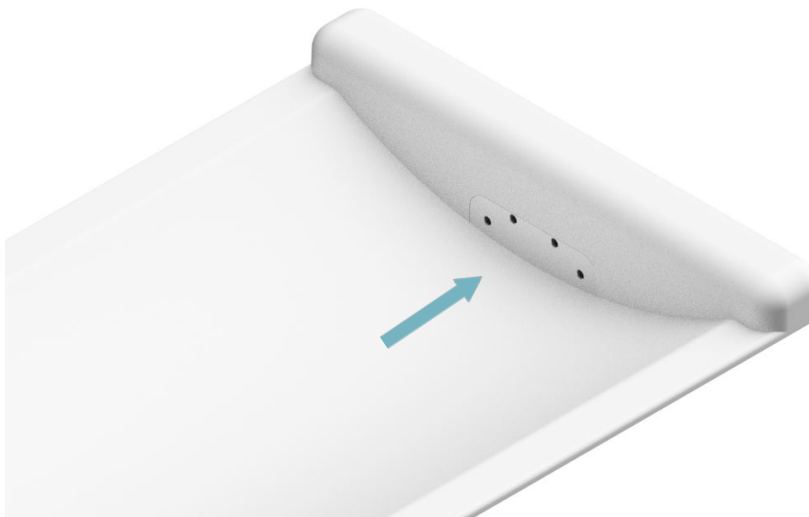
- IV. Now that the caudal end is approaching the caudal block, pull the indexing plunger knob and push the CouchTop against the caudal block. Once in place, release the indexing plunger knob to secure the CouchTop to the cradle.



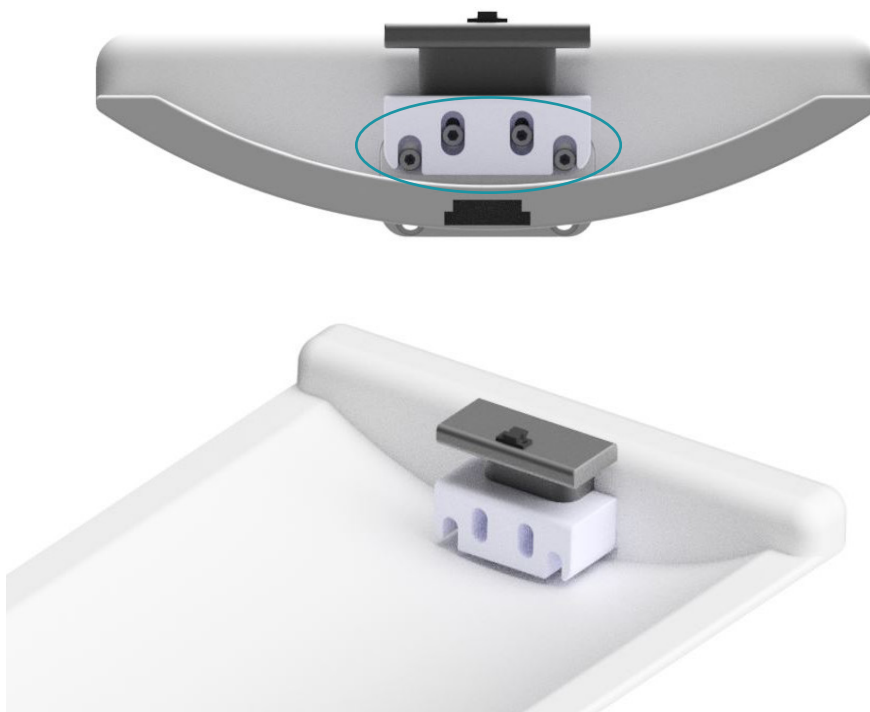
- V. Tighten the four screws from step two, located at the cranial side.

4.4 CouchTop Installation for the **Siemens Biograph mCT New Couch.** (CouchTop 140250, 140260, 140270, 140280 & 140290)

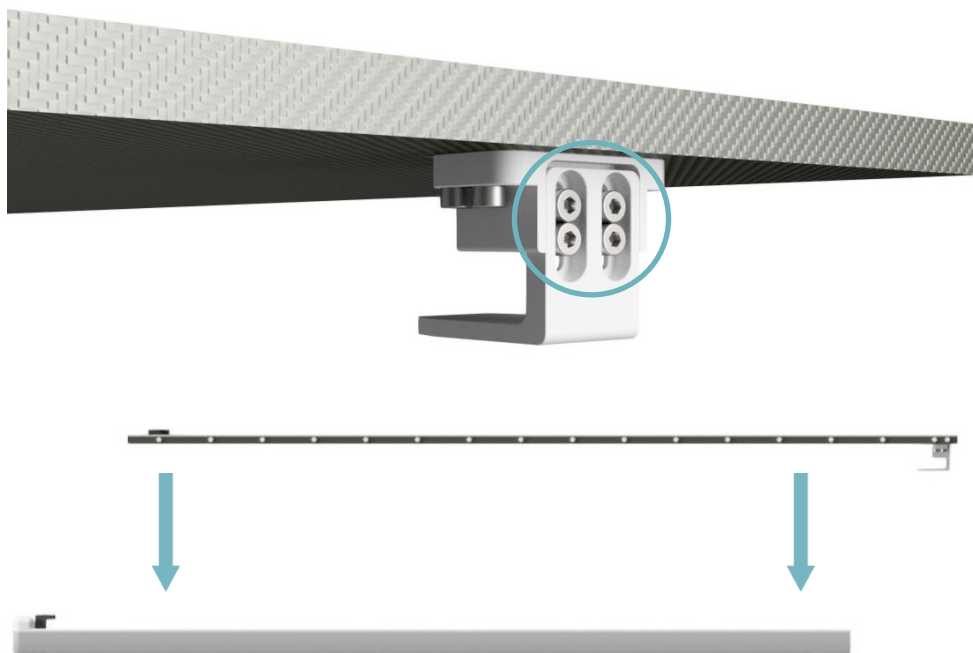
- I. Open the cradle cover and place the metal cradle plate, with the use of the original screws.



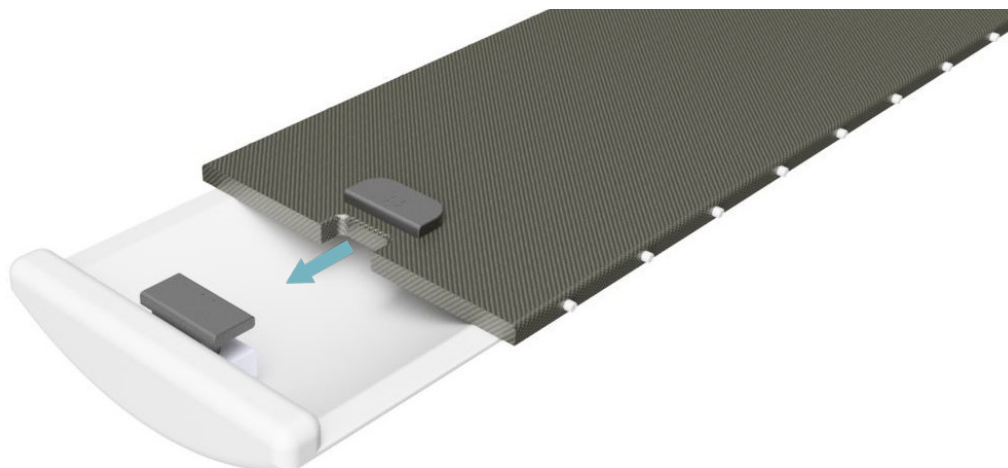
- II. Place the holding block on the metal cradle plate. Adjust the height if necessary and tighten the screws (circled) with an Allen key.



- III. At the cranial end of the CouchTop, loosen the four screws of the spoon (circled) with an Allen key and position the CouchTop above the cradle.



- IV. Slide the CouchTop towards the caudal end of the cradle. Take care that the CouchTop aperture fits the holding block.



- V. Make sure that the CouchTops' spoon, at cranial end (circled), slides into the designated hole in the cradle.



- VI. Lock the caudal side of the CouchTop by turning the knob of the latch in caudal direction.



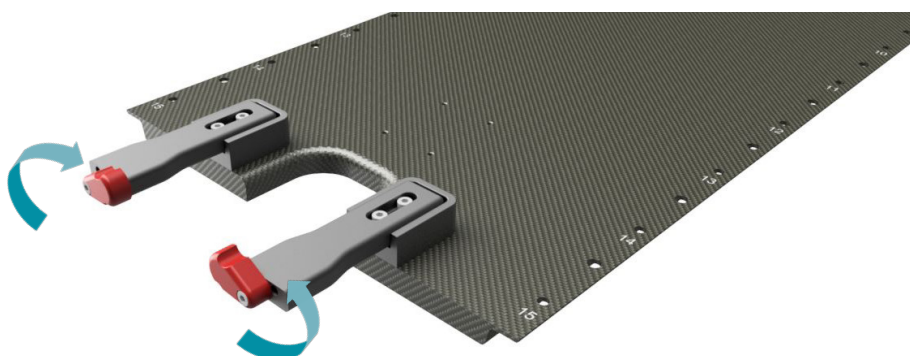
- VII. Tighten the four screws from step three, located at the cranial side.

4.5 CouchTop installation for the **Siemens Gammacamera & Symbia** cradles. (CouchTops 140300 & 140340)

- I. At the cranial end of the CouchTop, loosen the four screws of the spoon (circled) with an Allen key and position the CouchTop above the cradle.



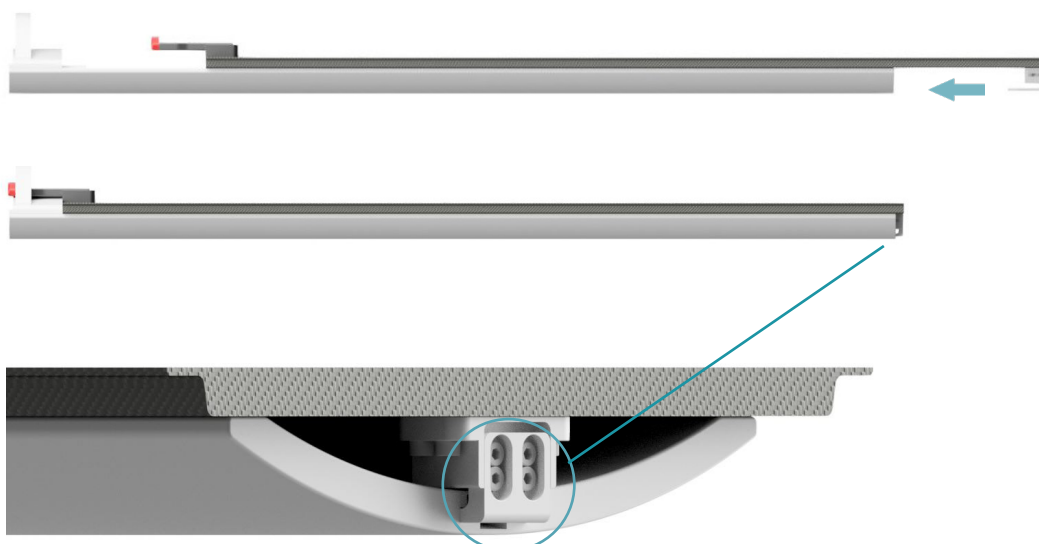
- II. Loosen the four CT locker screws with an Allen key at the caudal side of the CouchTop and turn the clamps to medial.



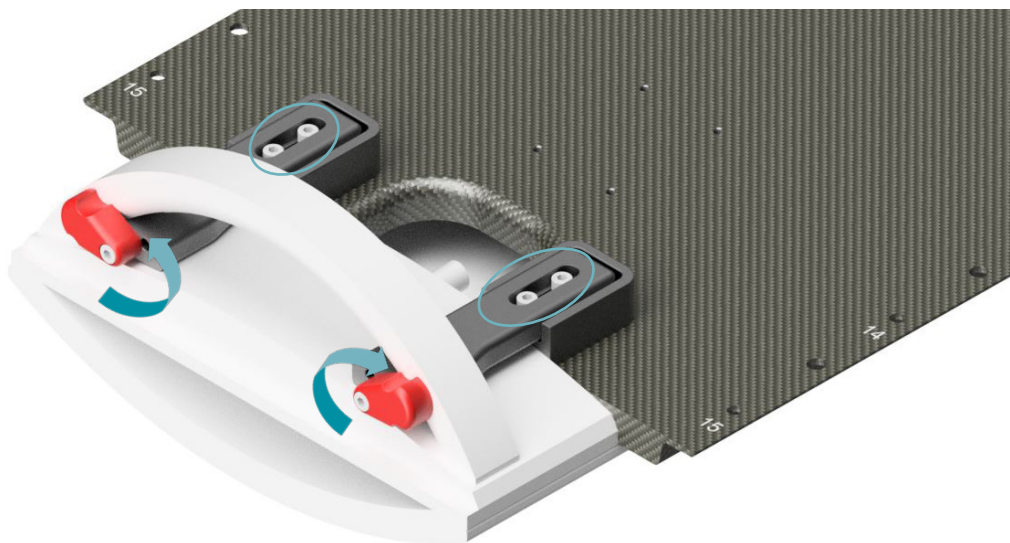
- III. Position the CouchTop above the cradle and carefully place the CouchTop onto the cradle.



- IV. Slide the CouchTop towards the caudal end of the cradle. Make sure that the CouchTops' spoon, at cranial end (circled), slides into the designated hole in the cradle and that the CouchTop lays flat against the caudal part of the cradle.



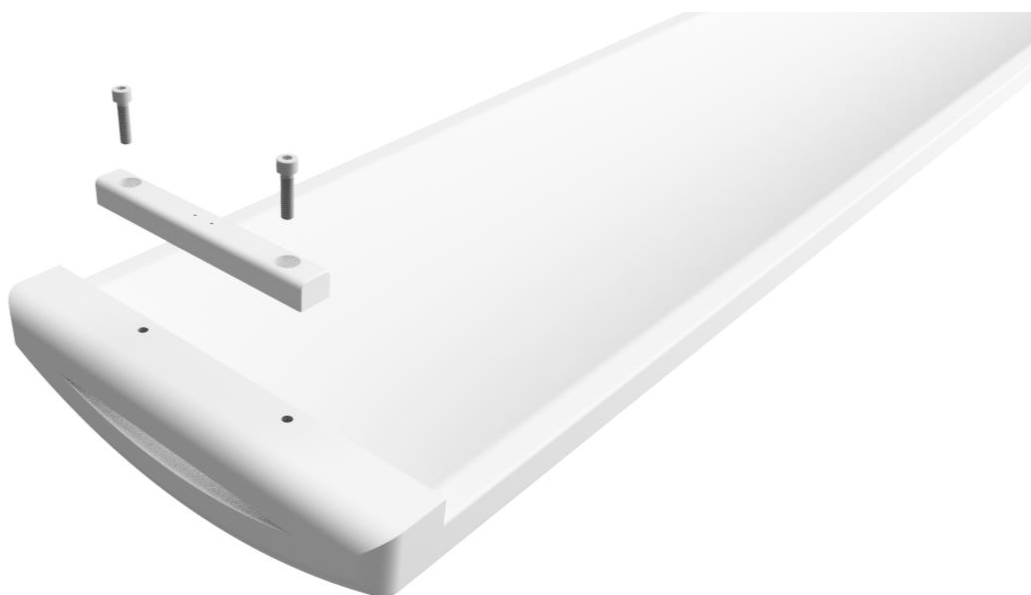
- V. If needed, adjust the CT lockers to eliminate play in longitudinal direction. Turn the clamps lateral, place them against the caudal arch and tighten the screws.



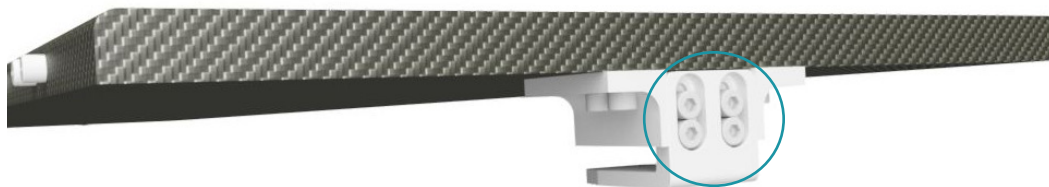
- VI. Tighten the four screws from step one.

4.6 CouchTop installation for the **Siemens Biograph mCT old Couch.** (CouchTop 140350, 140370 & 140390)

- I. Screw the caudal block on the caudal side of the cradle using the original screws. Place shims if necessary.



- II. At the cranial end of the CouchTop, loosen the four screws of the spoon (circled) with an Allen key.



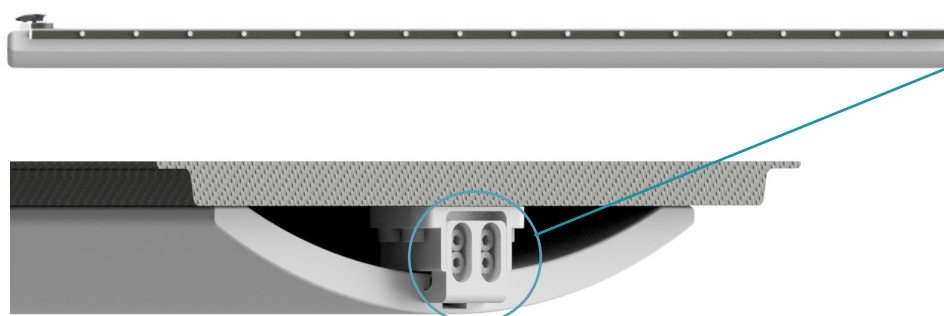
- III. Position the CouchTop above the cradle and carefully place the CouchTop on the cradle.



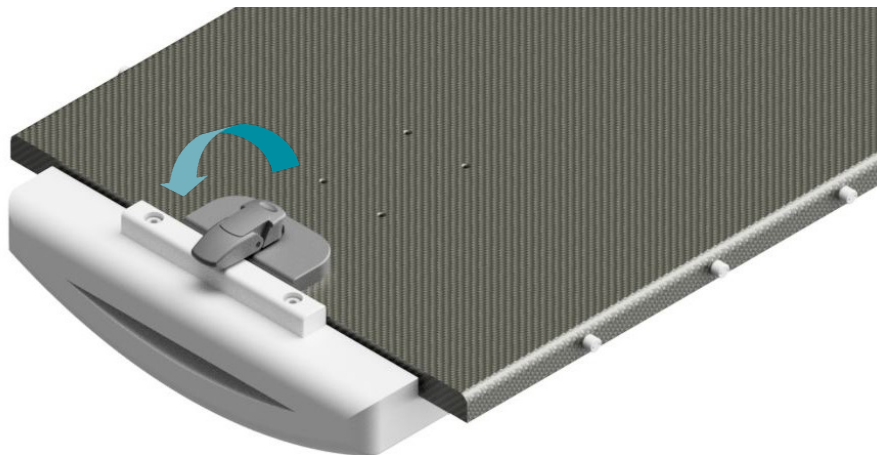
- IV. Slide the CouchTop towards the caudal end of the cradle.



- V. Make sure that the CouchTops' spoon, at cranial end (circled), slides into the designated hole in the cradle and that the CouchTop lays flat against the caudal part of the cradle.



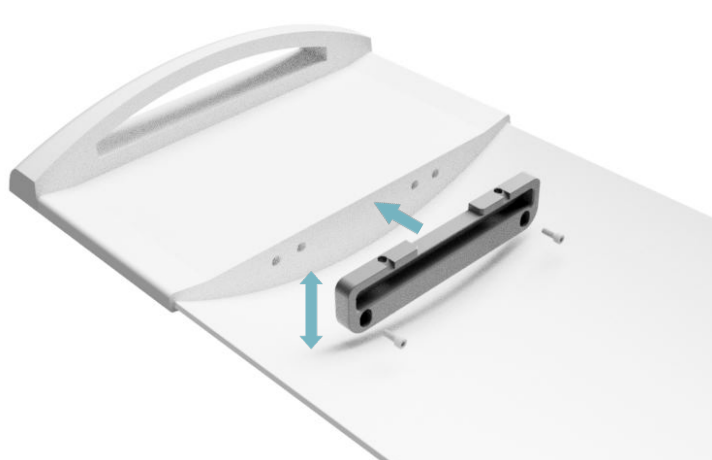
- VI. Turn the latch caudal to lock the CouchTop in longitudinal direction. Check if the latch can close properly without any play in longitudinal direction after locking. If necessary, the latch block can be adjusted in longitudinal position to remove any longitudinal play.



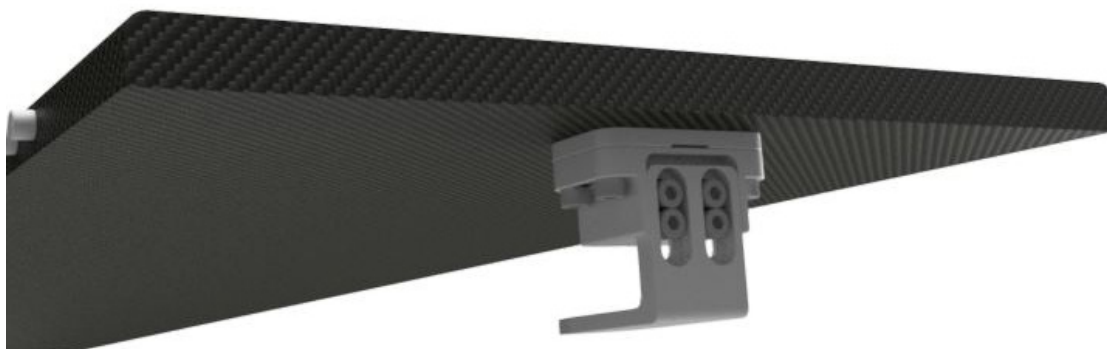
- VII. Tighten the four screws from step two, located on the spoon at the cranial side.

4.7 CouchTop installation for the **Siemens Somatom Definition AS cradles.** (CouchTops 140450, 140470 & 140490)

- I. Attach the caudal block with the delivered screws and use an Allen key to tighten them. If needed, the caudal block can slightly be adjusted in height.



- II. Loosen the screws of the CouchTops' spoon with an Allen key at the cranial side of the CouchTop.



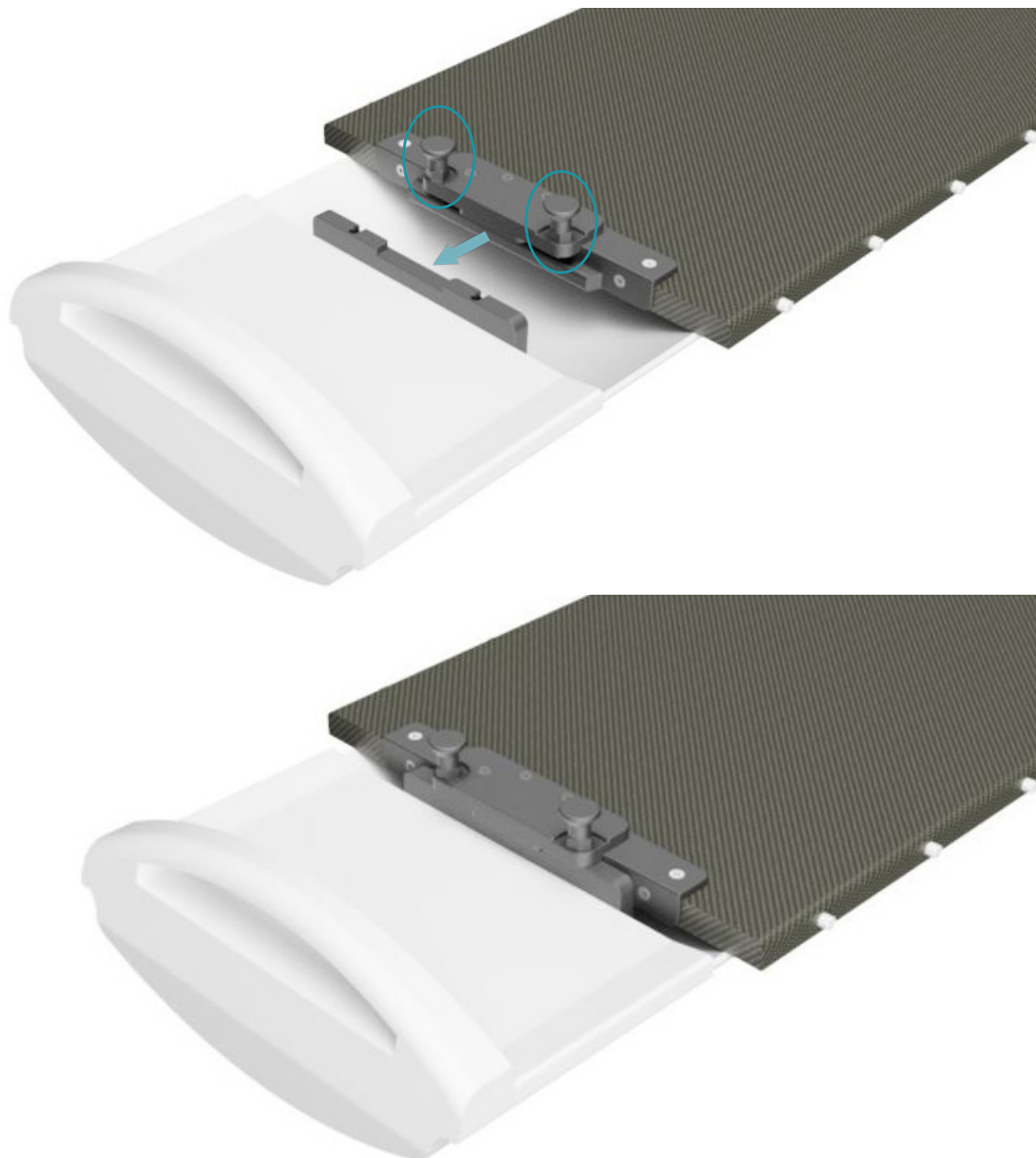
- III. Position the CouchTop above the cradle and place the CouchTop carefully on the cradle.



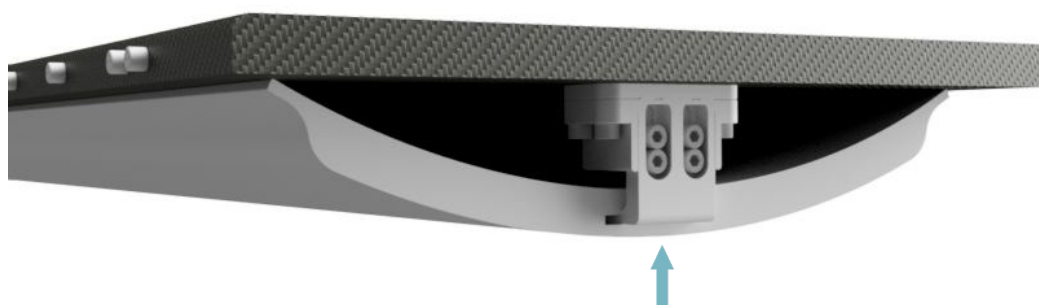
- IV. Slide the CouchTop towards caudal.



- V. As the CouchTop approaches the caudal block of the cradle, pull the two indexing plunger knobs and place the CouchTop flat against the caudal block. When the couchtop is in place, release the indexing plunger knobs to secure the couchtop to the cradle.



- VI. Make sure that the CouchTop spoon slides in the cradle and tighten the screws.



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.



macromedics

SOLUTIONS IN RADIOTHERAPY

MacroMedics BV

Oostbaan 670
2841 ML Moordrecht
The Netherlands



+31 (0) 182 38 97 77

info@macromedics.com
www.macromedics.com

(Visit www.macromedics.com for a digital copy of this manual)



26042021V4IFU140000