

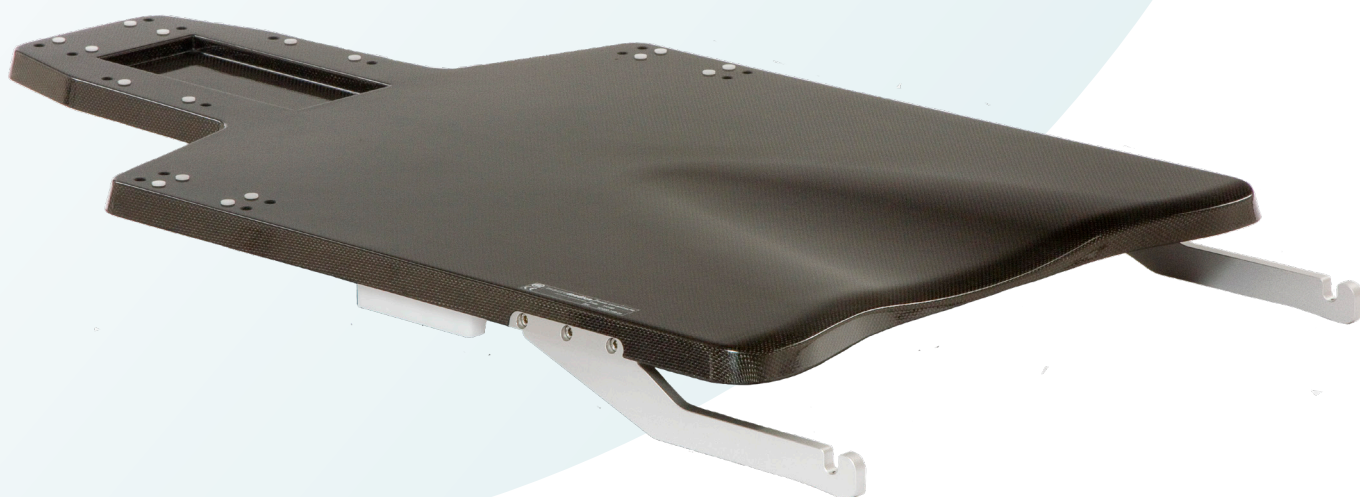


**macromedics**

SOLUTIONS IN RADIOTHERAPY

MANUAL 168100  
Instructions for use  
English Instructions

## MacroMedics® IMRT Baseplates



**MacroMedics BV**

Oostbaan 670  
2841ML Moordrecht  
The Netherlands  
+31(0)182 389 777

[info@macromedics.com](mailto:info@macromedics.com)  
[www.macromedics.com](http://www.macromedics.com)



**[ This page is intentionally left blank ]**

## Table of Contents

1. Warnings.....	4
2. MRI Safety Information.....	4
3. Intended Use.....	4
4. Installation Instructions.....	5
5. Cleaning, Storage and Disposal.....	13
6. Warranty.....	13
7. Notices.....	13
8. Glossary of Symbols.....	14

## 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.
- Place the patient carefully on the device and make sure they lie calmly. Instruct the patient not to reposition themselves after set-up.
- If the cranial end of the board is extended past the couch, do not exceed a load of 15 kg in this area.
- 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:

- 110110 ExaFix™ IMRT, VAIGRT
- 110130 ExaFix™-IMRT, VAEX
- 110180 ExaFix™ IMRT, ElektaIB
- 110190 ExaFix™ IMRT, ElektaPR
- 111130 ExaFix™ IMRT, VAEXEX
- 111330 RealEase IMRT, VAIGRT
- 111430 S-Type IMRT, VAIGRT



## 3. Intended Use

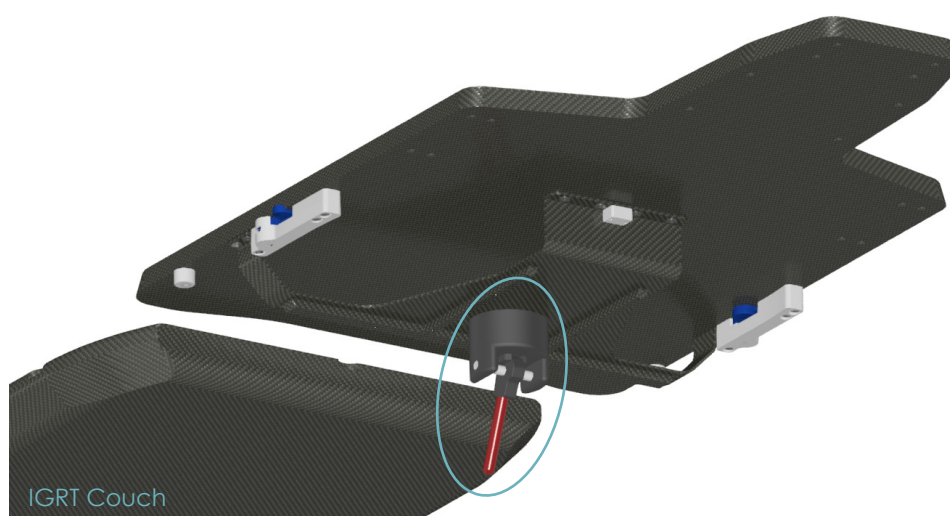
Positioning of the patient during radiotherapy and radiodiagnostics, including MR where indicated.

## 4. Installation Instructions

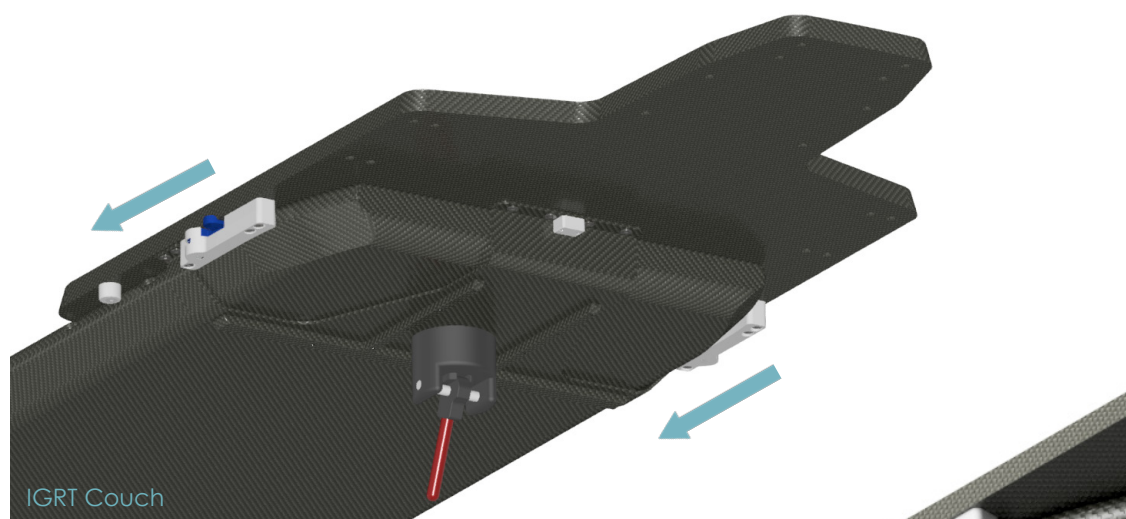
### 4.1 ASSEMBLY OF THE IMRT BASEPLATE FIT FOR **VARIAN IGRT COUCH**

[ 110110 EXAFIX™ IMRT, VAIGRT / 111330 RealEase IMRT, VAIGRT / 111430 S-Type IMRT, VAIGRT ]

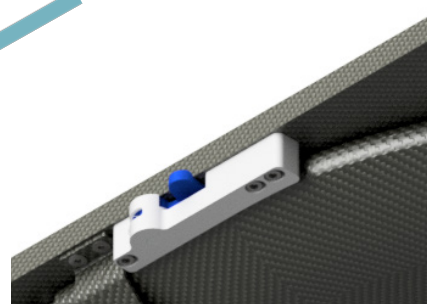
- I. Release the clamping mechanism by pulling on the red handle, pointing downwards and facing the ground.



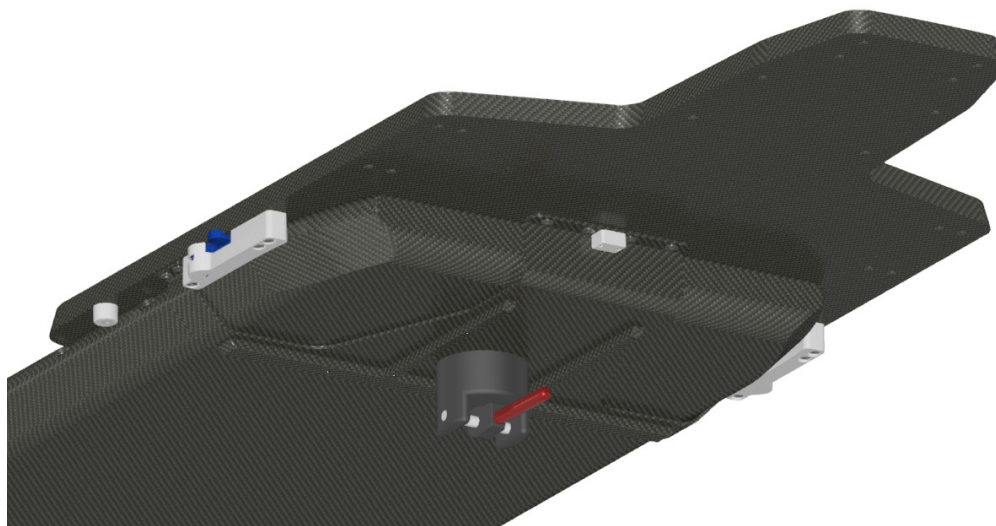
- II. Slide the IMRT baseplate over the cranial end of the IGRT couch.



- III. On both sides, the Blue clamps will position themselves into the Exact indexing slots. In the middle, The white Block will position itself into the center Exact indexing slot.

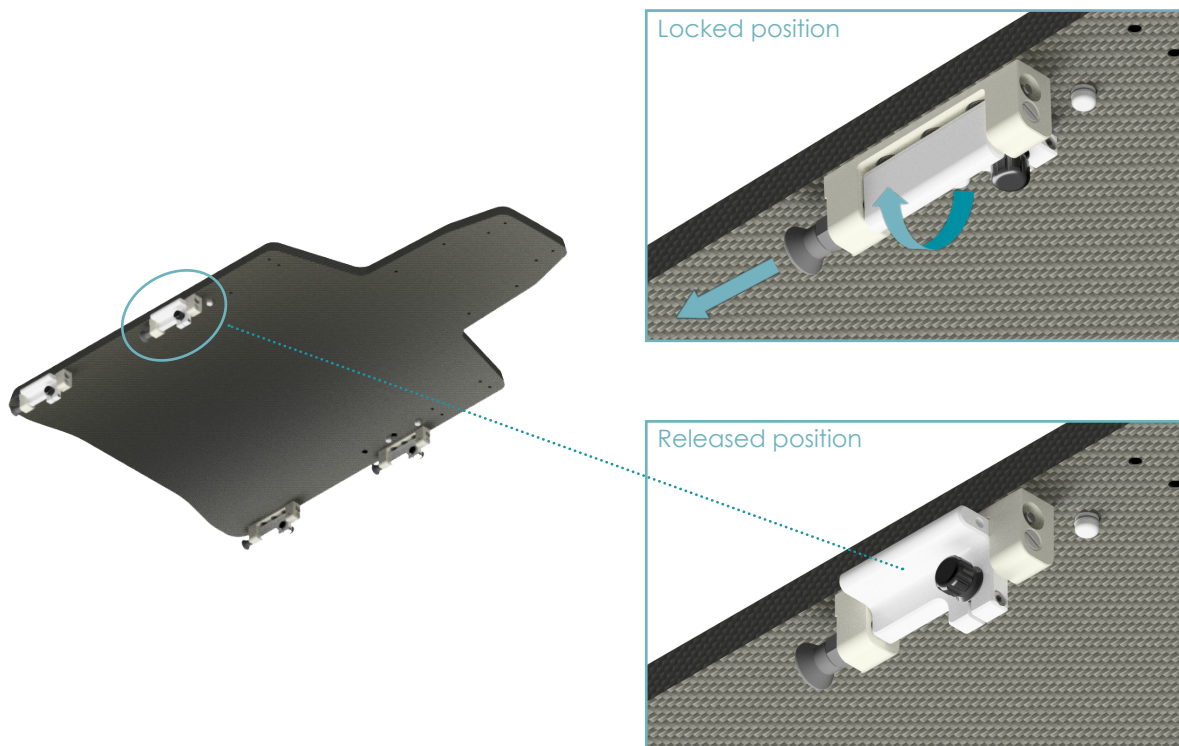


- IV. When the baseplate is positioned correctly onto the couch, pull the red handle towards the cranial end of the baseplate. It is now fixed in position.

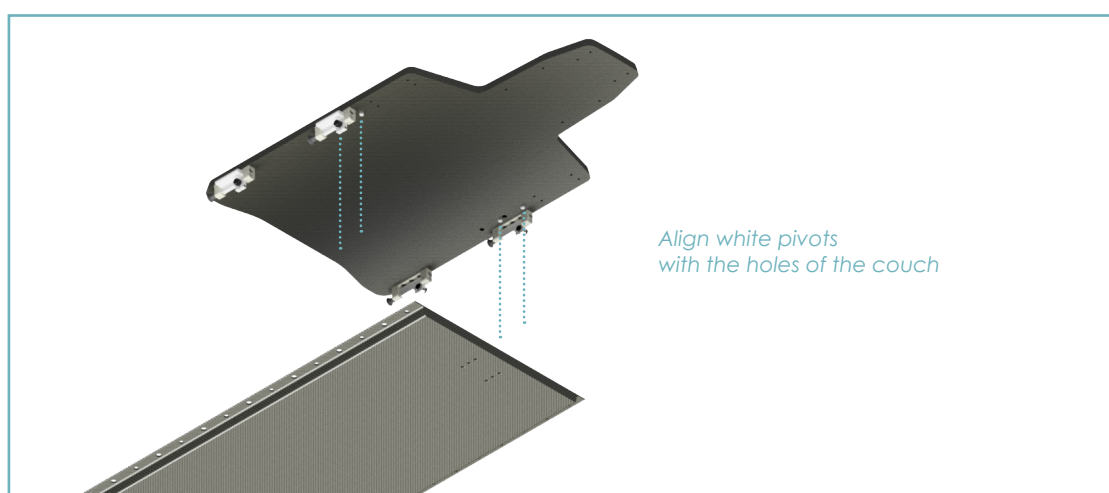


## 4.2 ASSEMBLY OF THE EXAFIX IMRT BASEPLATE FIT FOR ELEKTA IBEAM EVO COUCHTOP [ 110180 ExaFix™-IMRT ElektaIB ]

- I. To release the locking mechanism, pull the spring-pin and tilt the clamps outward.

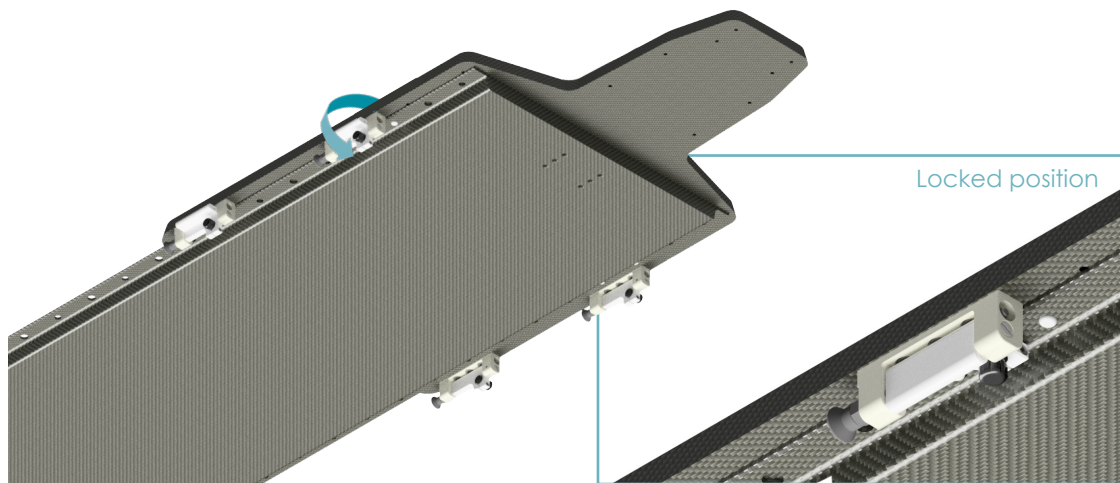


- II. Align the four white baseplate pivots with the corresponding holes on the couch.
- III. Place the baseplate carefully onto the couch.

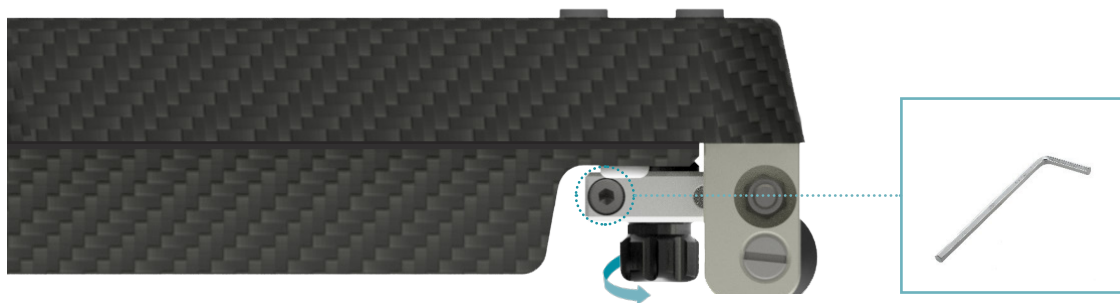




- IV. Rotate the locking mechanism until the spring-pins lock into place.



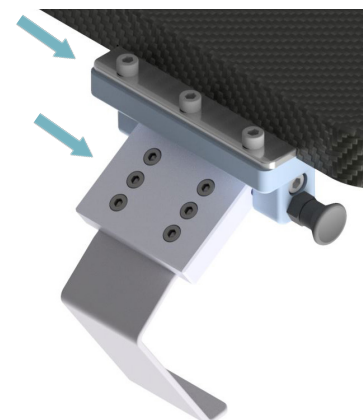
- V. Tighten the black adjusting knobs to fix the couch. With the Allen key, turn the M4 bolts to lock the black adjusting knobs.



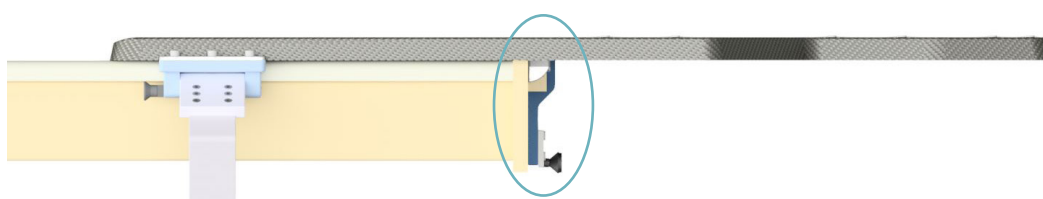
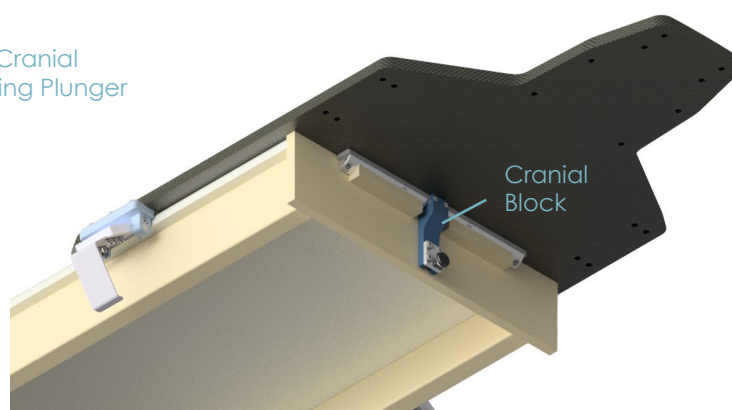
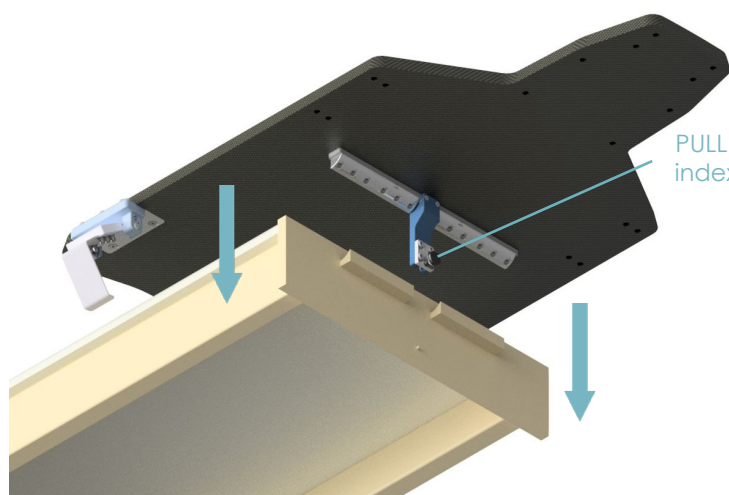


### 4.3 ASSEMBLY OF THE EXAFIX IMRT BASEPLATE FIT FOR **VARIAN EXACT COUCH, LONG** [ 111130-Exafix-IMRT/VAEX ]

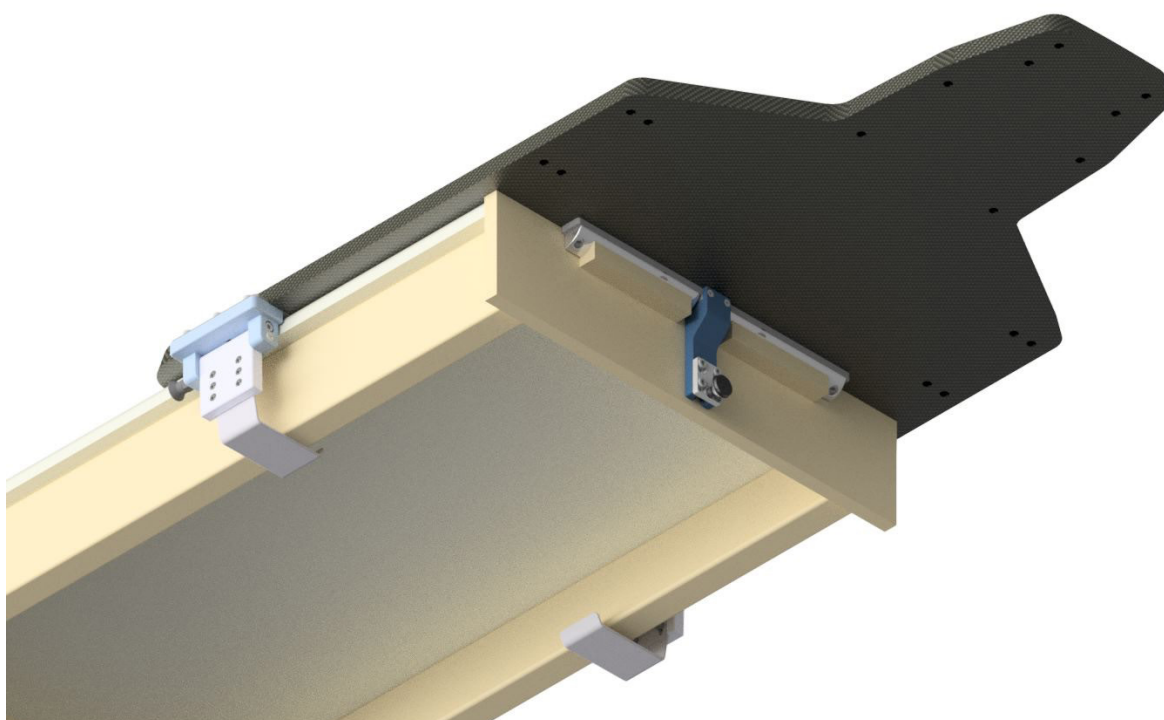
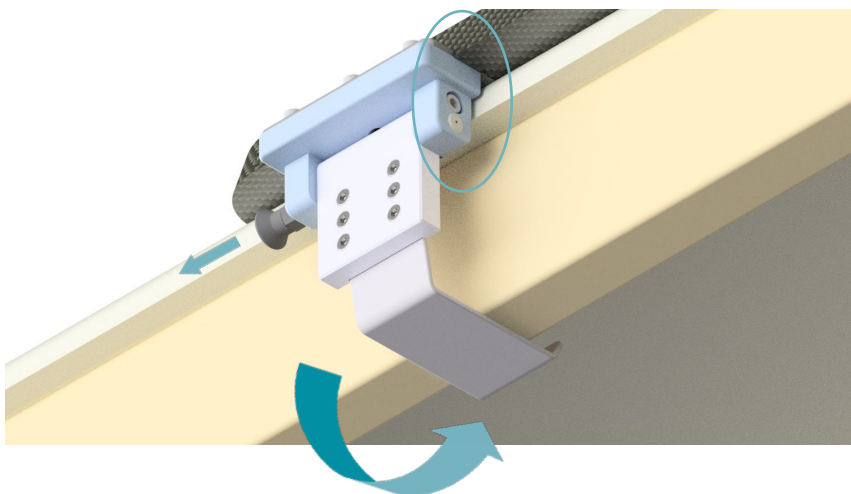
- I. Loosen the nine screws positioned on the clamp mechanism. Use an Allen key (4 mm). Do this on both sides.
- II. Pull the caudal indexing plunger on both sides, to unlock the clamps and turn both clamps outwards.



- III. Position the baseplate above the couch. Pull the cranial indexing plunger as you position the baseplate carefully on the couch. Make sure that the cranial block lays smoothly against the cranial side of the couch. Release the cranial indexing plunger to secure the baseplate to the couch. (If needed place shim (168125) under the cranial block, circled below).



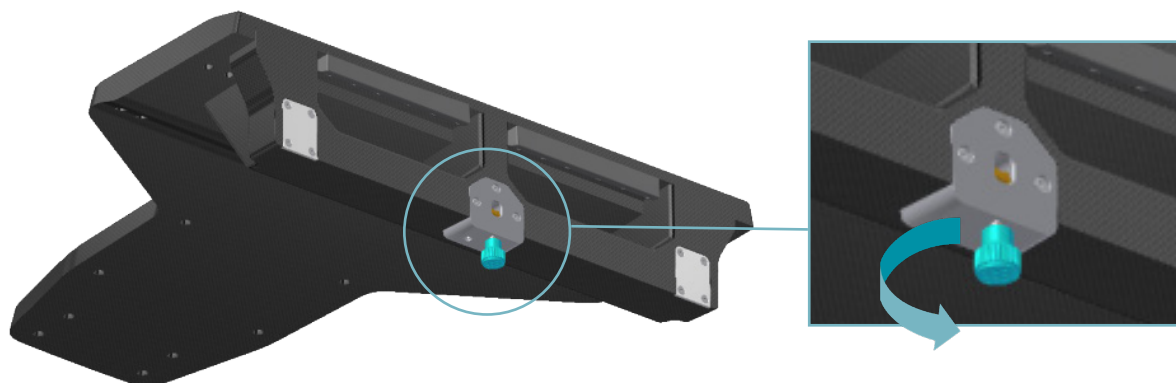
- V. Pull the caudal indexing plungers and turn the clamps inwards. Make sure that the sides of the clamps are laying flat against the couch, as circled below. Fasten the nine screws on both sides of the clamping mechanism.



#### 4.4 ASSEMBLY OF THE EXAFIX IMRT BASEPLATE, FIT FOR **VARIAN EXACT COUCHTOP**

[ 110130 ExaFix™-IMRT, VAEX]

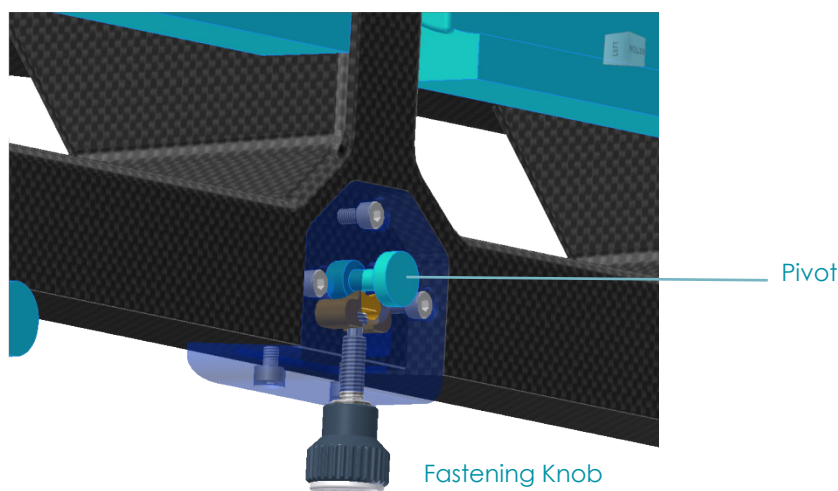
- I. **Opening the lock.**  
Rotate the black knob (highlighted blue in the image) counterclockwise to open the lock.



- II. **Hook the IMRT baseplate onto the Couch.**  
Make sure that the plastic blocks (blue in the picture) on the IMRT baseplate fall in the metal hooks on the couch.

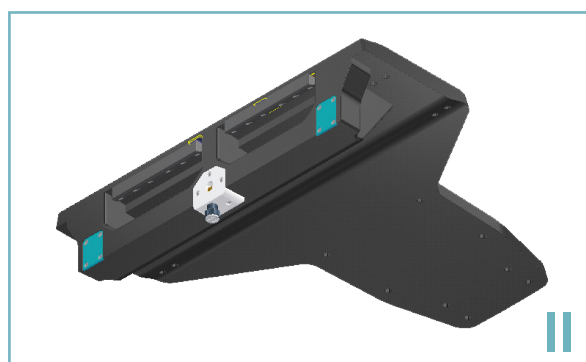
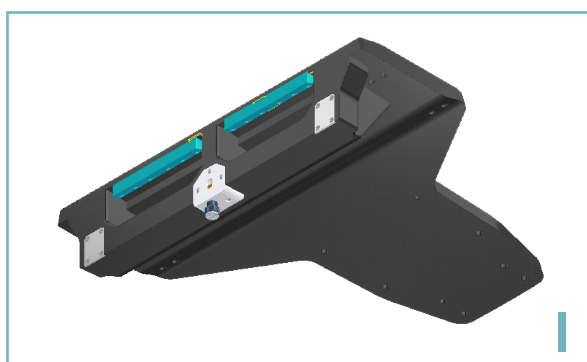


- III. **Position the pivot and lock it.**  
Position the metal pivot in the hole of the IMRT baseplate.  
To lock the IMRT baseplate, rotate the knob clockwise so it fastens the metal pivot on the frontside of the couch.



#### LINING OUT THE BASEPLATE

- IV. **To lift or lower the baseplate**  
Place shims no: 168125 under the plastic mounting blocks (blue)
- V. **To adjust the baseplate along its symmetry-axis**  
Place shims no: 168114 under the metal plates (blue)



#### VI. PLACE ACCESSORIES

Place the HeadSupport and Mask. For more information on masks and mask moulding, refer to IFU117000 Manual - Thermoplastic Masks.  
For more information on head support, blocks and wedges, refer to IFU117100 Manual - HeadSupports, Blocks and Wedges.

## 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.
<b>Rx ONLY</b>	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, non-metallic, and nonmagnetic.
	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

**[ This page is intentionally left blank ]**





**macromedics**

SOLUTIONS IN RADIOTHERAPY

**MacroMedics BV**

Oostbaan 670  
2841 ML Moordrecht  
The Netherlands



+31 (0) 182 389 777

[info@macromedics.com](mailto:info@macromedics.com)  
[www.macromedics.com](http://www.macromedics.com)

(Visit [www.macromedics.com](http://www.macromedics.com) for a digital copy of this manual)



26042021V16IFU168100