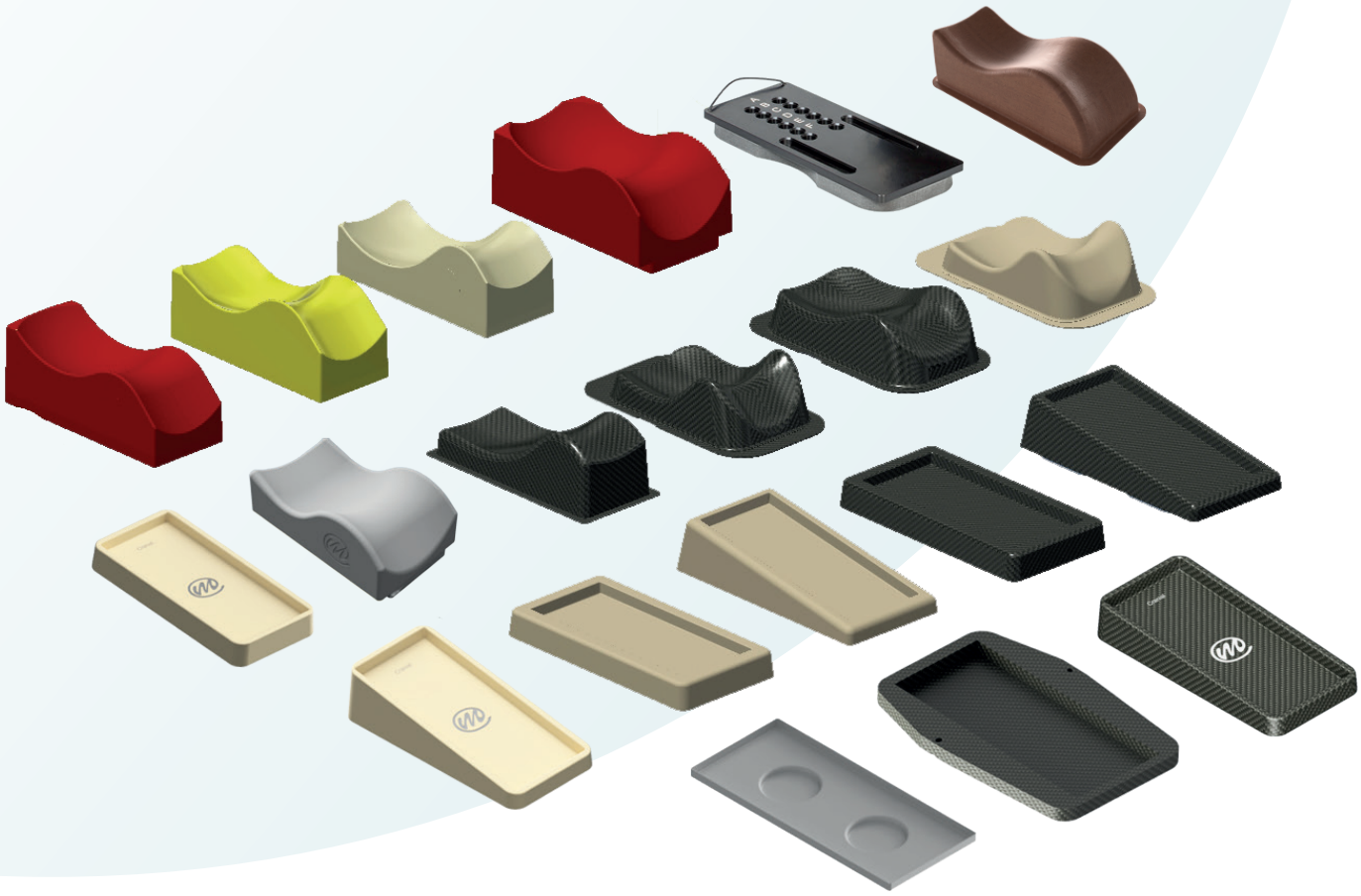
macromedics
SOLUTIONS IN RADIOTHERAPY

MANUAL 117100
Instructions for use
English Instructions

MacroMedics® MaxSupport™

HeadSupports, Blocks, Wedges, Shims & Extender



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1. Warnings



- Inspect the device thoroughly before use. Do not use the device if damaged or incomplete.
- Check individual components on MR-safety when used together in a patient positioning system.
- Do not use MR Unsafe items in an MR environment.
- Verify the device's attenuation characteristics before clinical use when the device is intended to be in the incoming radiation treatment-beam pathway.
- Secure the device properly before positioning the patient.
- Make sure that the patient lays down calmly and instruct the patient not to reposition themself after set-up.
- Use the appropriate number of shims to avoid inaccuracies. It is the customer's responsibility to determine the appropriate number of shims.
- 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 UNSAFE

The following devices are labelled MR Unsafe:



- All black, carbon fiber HeadSupports, blocks and wedges, marked MR Unsafe
- 110650 - Adaptor head support on baseplates Type-S

2.2 MR SAFE

The following devices are labelled MR Safe:



- All soft foam head supports
- All white, glass fiber HeadSupports, blocks and wedges, marked MR Safe
- All brown, natural fiber HeadSupports marked MR Safe

3. Intended Use

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

4. Product Codes

MaxSupports:

117110	MaxSupport™ 1
117120	MaxSupport™ 2
117130	MaxSupport™ 3
117140	MaxSupport™ 4
117100	MaxSupport™ set/3
117150	MaxSupport™ 5
117160	MaxSupport™ 6
117170	MaxSupport™ 7
117000	MaxSupport™ wide set/3
117125	MaxSupport™ 25 CF
117135	MaxSupport™ 35 CF
117145	MaxSupport™ 45 CF
117105	MaxSupport™ CF set/3
116225	MaxSupport™ 25 MR
116235	MaxSupport™ 35 MR
116245	MaxSupport™ 45 MR
116205	MaxSupport™ MR set/3
116940	MaxSupport™ Prone
116950	MaxSupport™ PedSupine
110600	Adaptor MaxSupport™ TO
110650	Adaptor MaxSupport™ TS
116300	MaxSupport™ S-A
116310	MaxSupport™ S-B
116320	MaxSupport™ S-C
116330	MaxSupport™ S-D
116350	MaxSupport™ S-Line set/4
116360	MaxSupport™ S-E
116370	MaxSupport™ S-F
116380	MaxSupport™ S-Line set/6
116400	MaxSupport™ S-A MR
116410	MaxSupport™ S-B MR
116420	MaxSupport™ S-C MR
116430	MaxSupport™ S-D MR
116450	MaxSupport™ S-Line MR set/4
116460	MaxSupport™ S-E MR
116470	MaxSupport™ S-F MR
116480	MaxSupport™ S-Line MR set/6
116500	MaxSupport™ S-BA
116510	MaxSupport™ S-BB
116520	MaxSupport™ S-BC
116530	MaxSupport™ S-BD
116550	MaxSupport™ S-Line set/4
116560	MaxSupport™ S-BE
116570	MaxSupport™ S-BF
116580	MaxSupport™ S-Line B set/6
117180	MaxSupport™ I
117190	MaxSupport™ II
117230	MaxSupport™ III
117240	MaxSupport™ IV
117210	MaxSupport™ SSPS Galaxy
117220	MaxSupport™ SSPS SupeRay-AimRay
117320	MaxSupport 25 Natural Fibers
117330	MaxSupport 35 Natural Fibers
117340	MaxSupport 45 Natural Fibers

Blocks/Wedges for ExaFix Systems:

110510	Block low CF ExaFix™
110520	Block high CF ExaFix™
110580	Elev.Blocks ExaFix™ set/2
110530	Wedge 5 CF ExaFix™
110540	Wedge 7 CF ExaFix™
110550	Wedge 10 CF ExaFix™
110560	Wedge 15 CF ExaFix™
110500	Wedges, CF, ExaFix™set/3
110410	Block low ExaFix™ MR
110420	Block high ExaFix™ MR
110480	Elev. Blocks set/2 MR
110430	Wedge 5 ExaFix™ MR
110440	Wedge 7 ExaFix™ MR
110450	Wedge 10 ExaFix™ MR
110460	Wedge 15 ExaFix™ MR
110400	Wedges, set/3, MR

Blocks/Wedges:

110710	Block 1
110720	Block 2
110780	Elevation Blocks, set/2
110730	Wedge 1
110740	Wedge 4
110750	Wedge 2
110760	Wedge 3
110700	Wedges, CF, set/3
110810	Block 1 MR
110820	Block 2 MR
110880	Elevation Blocks, set/2 MR
110830	Wedge 1 MR
110840	Wedge 4 MR
110850	Wedge 2 MR
110860	Wedge 3 MR
110800	Wedges, set/3, MR

Blocks/Wedges for OmniBoard, MultiBoard & RealEase Systems:

171610	Block low CF RE
171620	Block high CF RE
171680	Elevation blocks RE set/2
171630	Wedge 5 CF, RE
171640	Wedge 7, CF, RE, HE
171650	Wedge 10 CF, RE
171660	Wedge 15 CF, RE
171600	Wedges, RE, set/3
171710	Block low MR RE
171720	Block high MR RE
171780	Elevation blocks RE MR set/2
171730	Wedge 5, RE, MR
171740	Wedge 7, RE, MR
171750	Wedge 10, RE, MR
171760	Wedge 15, RE, MR
171700	Wedges, RE, MR, set/3

MaxSupport Extender:

121180	MaxSupport™ Extender

MaxSupport Shims:

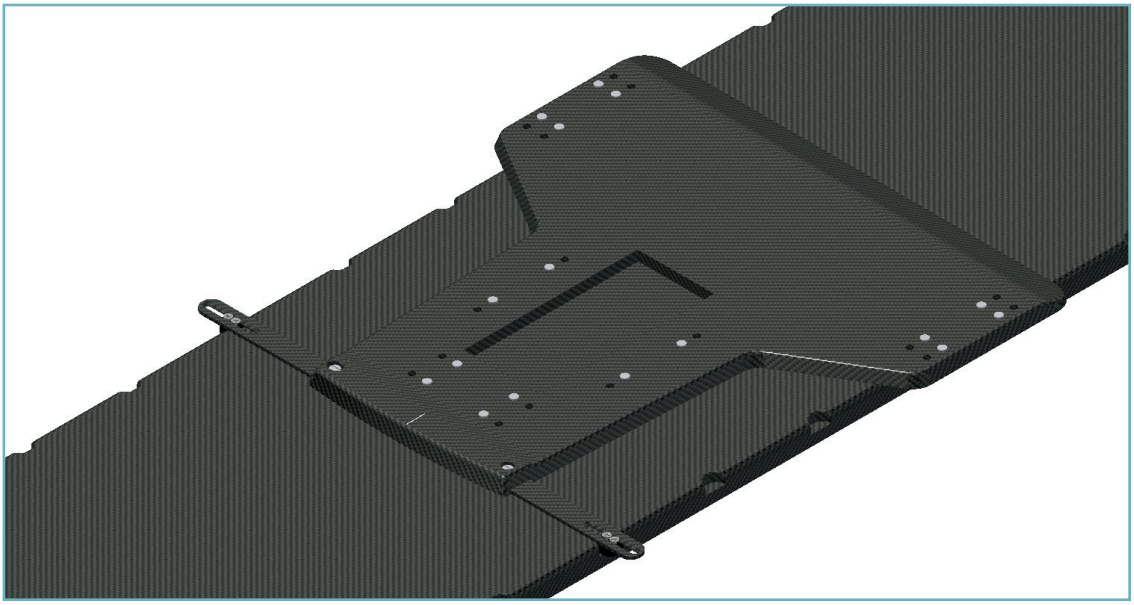
117200	MaxSupport™ Shim set/3

5. Use Instructions for the MaxSupport

5.1 GENERAL INSTRUCTIONS

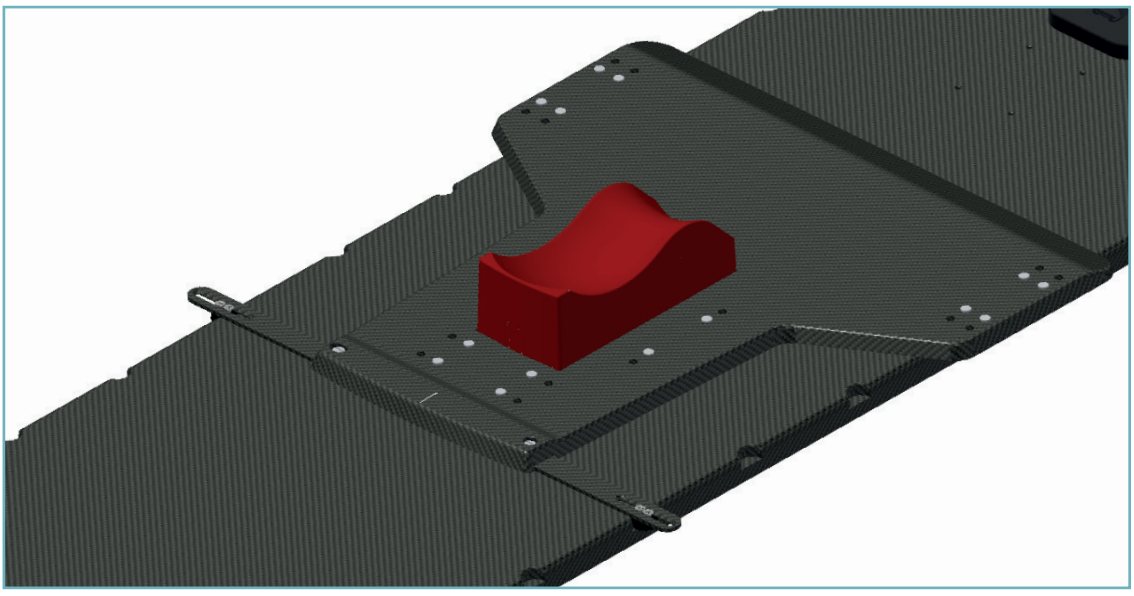
I. Place the CouchStrips and attach the baseplate.

Place the CouchStrip in the correct position on the couch and attach the baseplate.
For more information, refer to *IFU147100 Manual - CouchStrips & Sidepieces*.



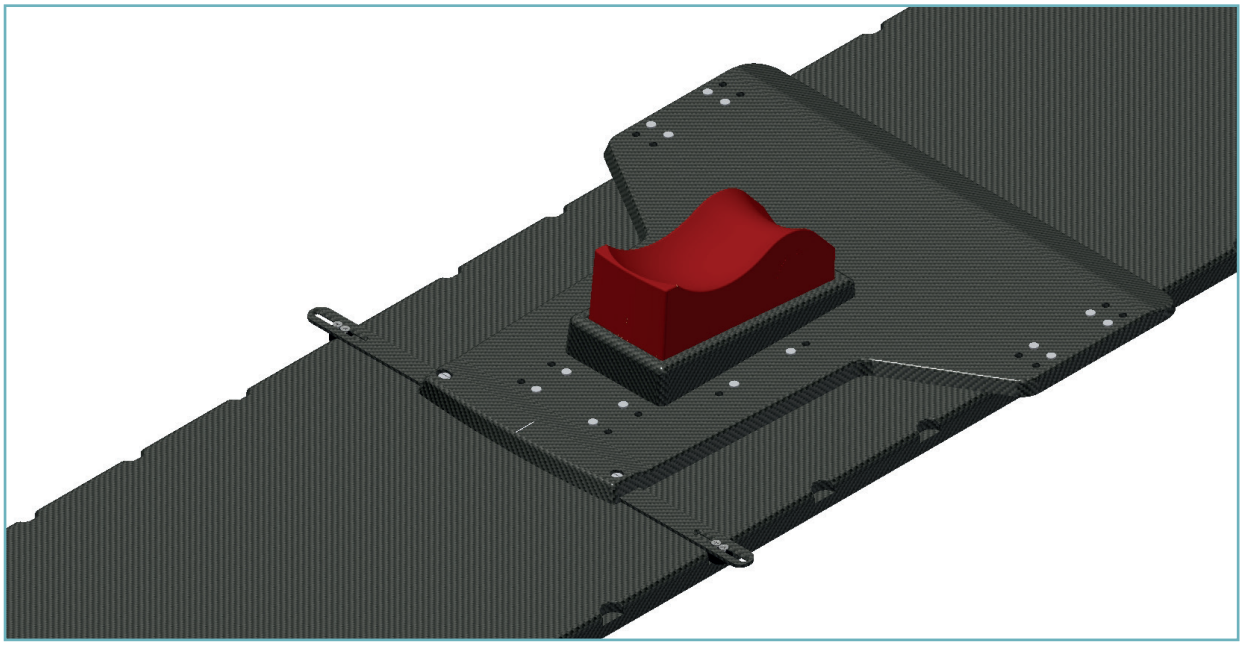
II. Place the HeadSupport.

Place the HeadSupport in the cushion aperture on the baseplate. Make sure that there is no air under the HeadSupport.



III. Elevate or tilt the HeadSupport.

Place Blocks or Wedges under the HeadSupport to elevate or tilt the head. MacroMedics recommends not to use more than two Wedges or Blocks in one set-up.
For more extreme tilting or inclination, use a tilting baseplate (ExaTilt, HeadTilt).



5.2 INSTRUCTIONS FOR OMNIBOARD REALEASE, MULTIBOARD REALEASE & REALEASE BASEPLATES

The RealEase Blocks and Wedges have a different position on the baseplate than standard MacroMedics Blocks and Wedges. These are positioned more to the caudal direction to fit with masks on the OmniBoard, MultiBoard and RealEase baseplates.

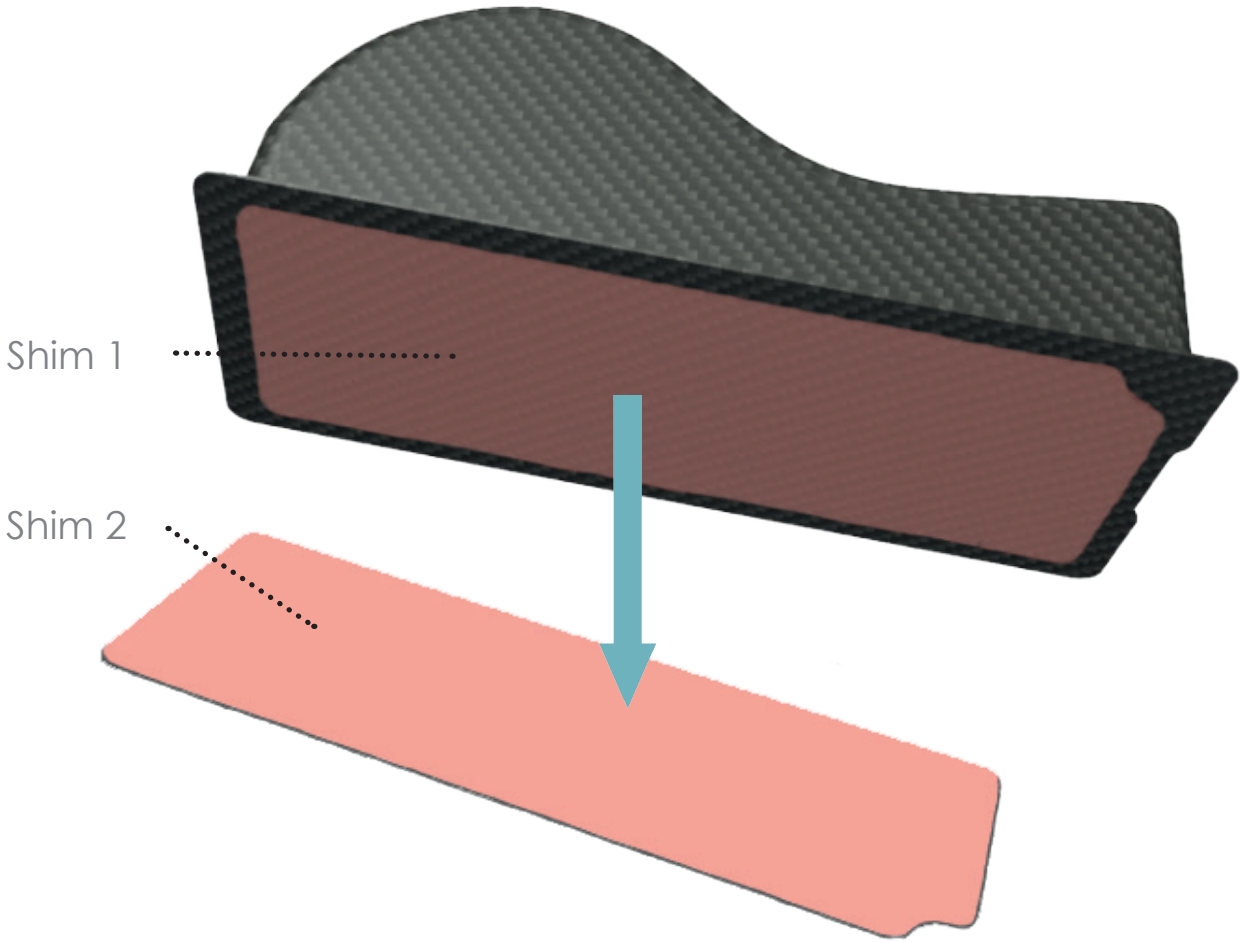
6. Use Instructions for the Shims

During mask moulding, shims are placed under the HeadSupport. MacroMedics recommends to use maximum 3 shims (1 shim = 1 mm, 3 shims = 3 mm). It is the customer's responsibility to determine the appropriate number of shims. This may be based on expected swelling.

[For more information on moulding MacroMedics Masks, refer to *IFU117000 Manual - Thermoplastic Masks.*]

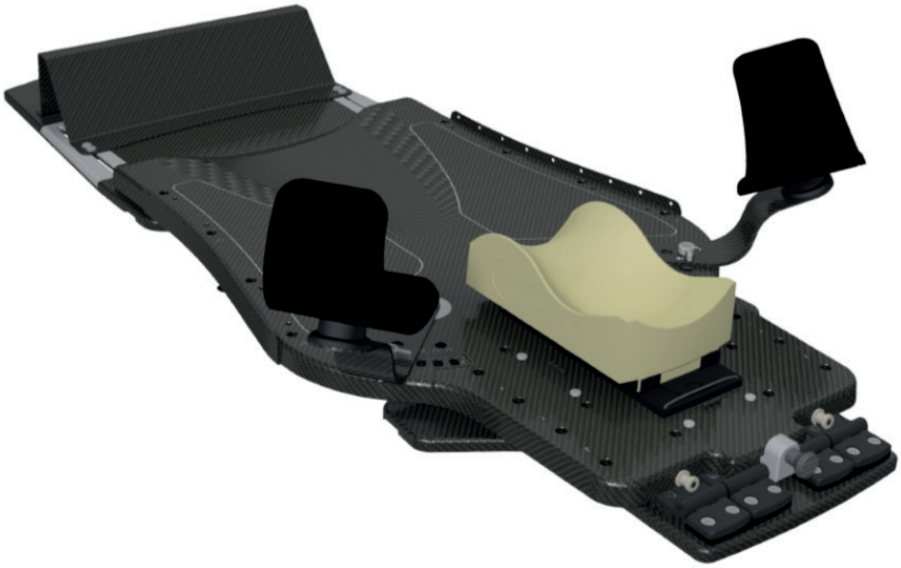
If the mask is too tight for the treatment, remove one or more shims to create more space under the mask.

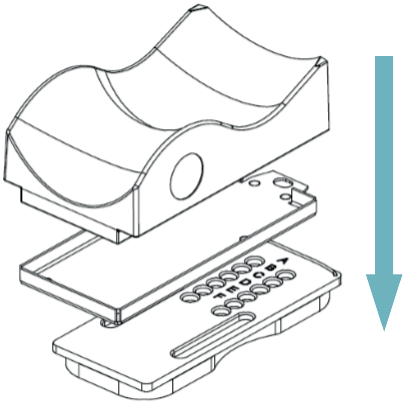
The following image shows two shims placed underneath a carbon fiber HeadSupport. This adds 2 mm to the height of the HeadSupport.



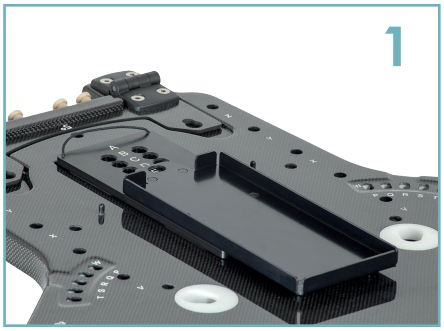
7. Use Instructions for the Extender

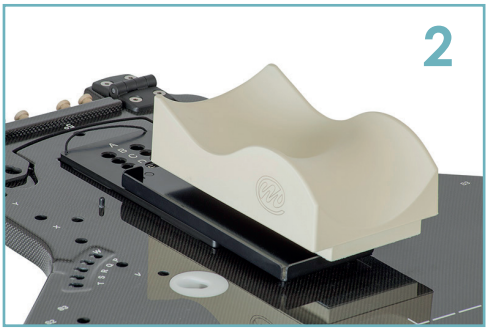
Use the MaxSupport Extender with any of the MacroMedics MaxSupports and in combination with a BreastBoard SX or OmniBoard Breast Treatment Module.

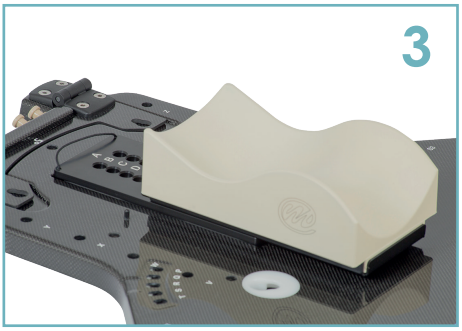




Place a MaxSupport into the MaxSupport Extender. It has six discrete positions:
A, B, C, D, E, and F, which enables the user to move the device five centimeters up or down.







8. 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 provided by the manufacturer of the cleaning agent.
- 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 thoroughy clean upon visual inspection or dispose of the device to prevent the use of a soiled device.
- 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.
- Make sure to store the products so that no mechanical pressure is applied to them.
- Make sure to store the foam products in a dry environment, away from direct sunlight and heat sources.
- Dispose of the device in accordance with the local laws and regulations applicable to your country.

9. 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.

10. 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.

11. Glossary of Symbols

Symbol	Symbol Name	Description of Symbol
CE	CE Mark	CE marking of conformity.
MD	Medical Device	Indicates the medical device manufacturer.
	Manufacturer	Indicates the medical device manufacturer.
REF	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
LOT GS1 Code: (10)	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
SN 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.
	Keep Away from Sunlight	Indicates a medical device that needs protection from light sources.
MR	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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