

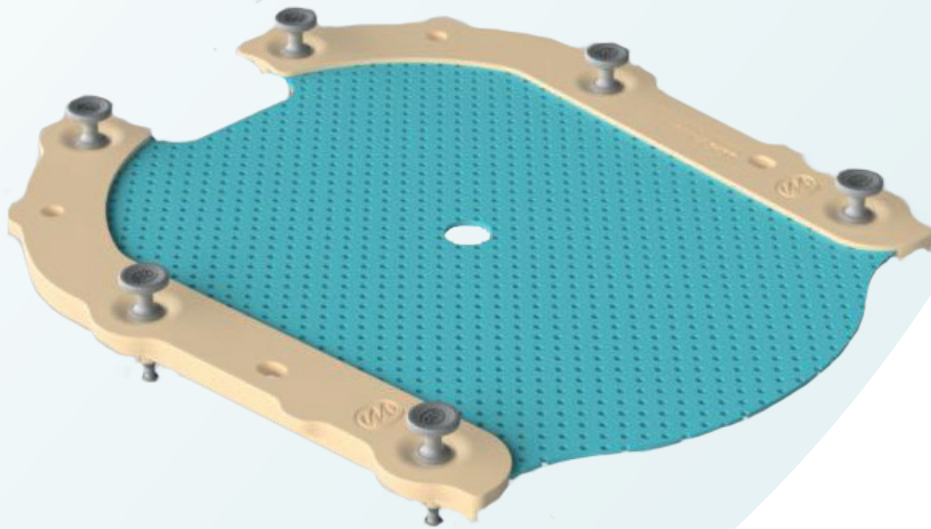


macromedics

SOLUTIONS IN RADIOTHERAPY

MANUAL 114730
Instructions for use
English Instructions

MacroMedics® D^{SPS} Environ®



MacroMedics BV
Oostbaan 670
2841ML Moordrecht
The Netherlands
+31(0)182-389777
info@macromedics.com
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. Supine Treatment.....	5
6. Using shims.....	7
7. Cleaning, Storage and Disposal.....	8
8. Warranty.....	8
9. Notices.....	8
10. Glossary of Symbols.....	9

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.
- Do not use the thermoplastic mask after its expiry date.
- The thermoplastic masks are for single patient use.
- Ensure that the thermoplastic mask is not too hot for skin contact before placing it on the patient.
- The mask heating times for an oven are recommendations only as the appropriate times depend on the individual oven. It is the user's responsibility to determine the appropriate heating times.
- Do not remove the thermoplastic mask from the patient until the material has cooled completely.
- Removing the thermoplastic before it has set may result in mask deformation.
- If using more than one shim, do not exceed a thickness of 1.5 mm.
- 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:

- 114710 DSPS® EVR Shim Set
- 114730M Mask SSPS™-FEVR
- 114740M Mask DSPS®-OSEVR
- 114760M Mask SSPS™-FEVRO
- 114790M Mask SSPS™-FEVRONE



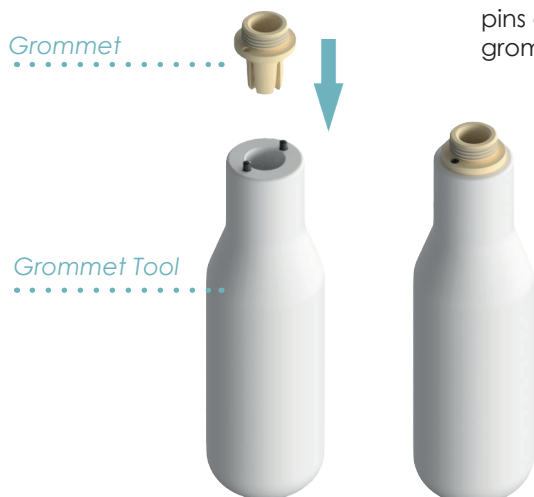
3. Intended Use

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

4. Installation Instructions

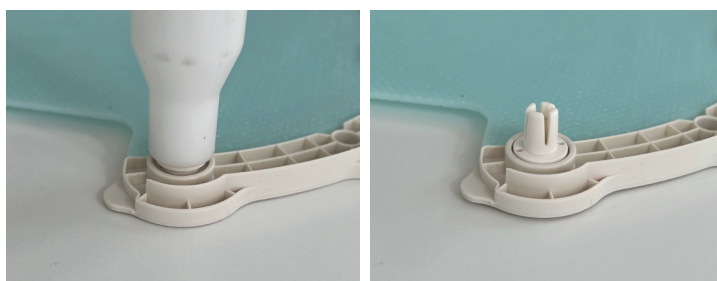
4.1 MASK SET-UP

The masks are packaged without the grommets and plungers inserted. Prior to mask usage, firstly, insert the supplied grommets with the Grommet Tool as shown below.

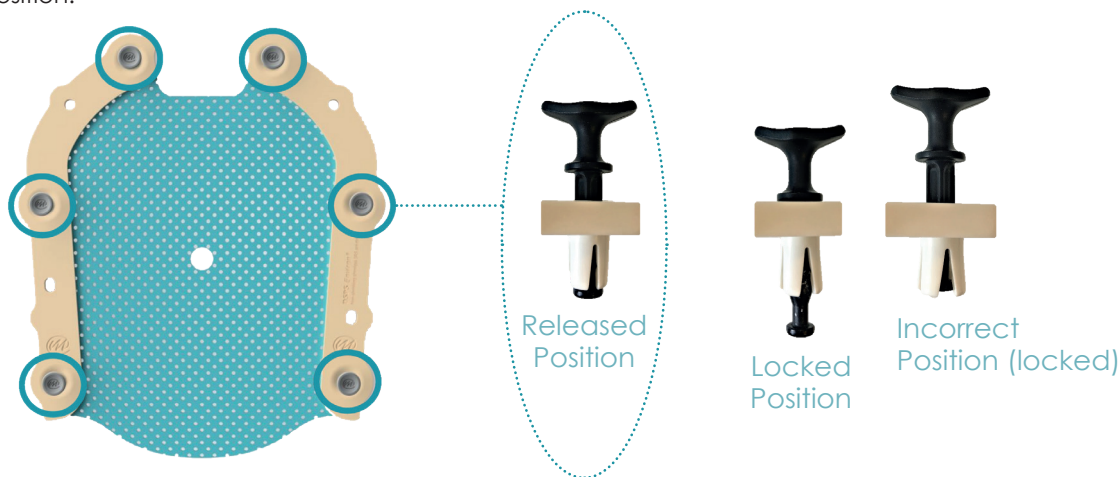


Place the grommet on the MacroMedics Grommet Tool. Align the two pins of the Grommet Tool with the two holes in the grommet. Push the grommet into the hole of the Grommet Tool.

Place the grommet into the designated hole of the device. Turn clockwise to tighten and counterclockwise to loosen.



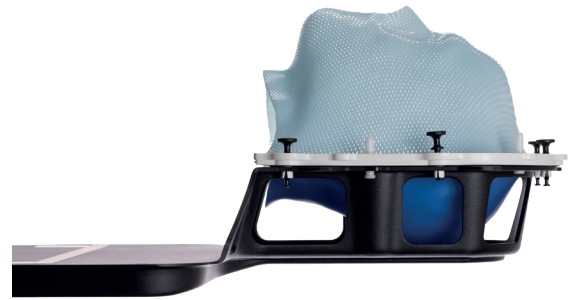
Secondly, insert the plungers into the grommets. Gently push them through until they are in released position.



4.2 PATIENT SET-UP

Follow your department's patient positioning protocol for head and neck patients. For DSPS treatments, there should be approximately 1 finger width in between the cradle rim and the top on the patient's head. For SSPS treatments, position the patient by letting them lay down with their head on the head support. When using a mask on a patient with long hair, place the hair in ponytail on the cranial side of the patient's head.

5. Supine Treatment



5.1 MOULDING A SUPINE OCCIPITAL MASK [DSPS ONLY]

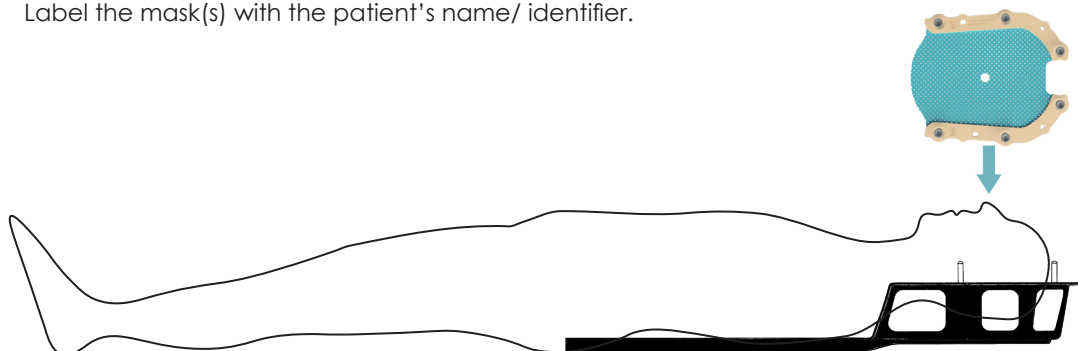
1. Take a new RayOC supine occipital mask (dark blue thermoplastic mask with black frame).
- 2.a **When using a Waterbath** to heat the mask, set the water temperature between 68°C and 70°C (154.4°F and 158°F). Leave the mask in the water for approximately 8 to 12 seconds until it becomes sufficiently pliable. Take the mask out of the waterbath and dry it between two towels. Check the temperature of the mask before skin contact.
- 2.b **When using an Oven** to heat the mask, set the oven temperature between 68°C and 70°C (154.4°F and 158°F). Leave the mask in the oven for approximately 2 minutes and 50 seconds to 3 minutes, until it becomes sufficiently pliable. Take the mask out of the oven and check the temperature of the mask before skin contact. If the mask is too warm, cool it down before placing it on the patient.
3. Lift the patient's head or ask the patient to sit up and place the black frame onto the system, with the MacroMedics logo facing upwards.
4. Ensure that the frame is pushed properly over the position pins on the system.
5. Place the patient's head on the occipital mask. The mask will sink due to the weight of the head. If the depth of the impression is not deep enough, gently apply pressure with the palm of your hand on the patient's forehead. However, the mask should never touch the cradle base.
6. To achieve the prescribed position and depth for the mask, we recommend an impression depth of approximately 1 cm above the cradle's base. Different positions may be preferred depending on the target area.
7. Use your hands to mould the mask to the side of the neck and the cranial area, including the occipital bone. The ventral inferior line of the base of the skull is an optimal landmark to mould. Hold the mask in position for 10 - 20 seconds to ensure an impression is formed.
8. After 5 minutes, the mask should have fully set.



5.2 MOULDING A SUPINE FACIAL MASK [DSPS ONLY]

1. Lay the patient in supine position with the head resting on the occipital mask for DSPS.
2. Take a new RayPRO supine facial mask (Perforated thermoplastic mask with the white frame).
3. Make sure that all 5 black plungers are in the released position.
- 4.a **When using a Waterbath** to heat the mask, set the water temperature between 68°C and 70°C (154.4°F and 158°F). Leave the mask in the water for approximately 1 to 2 minutes and until it becomes sufficiently pliable. Take the mask out of the waterbath and dry it between two towels. Check the temperature of the mask before skin contact.
- 4.b **When using an Oven** to heat the mask, set the oven temperature between 68°C and 70°C (154.4°F and 158°F). Leave the mask in the oven for approximately 4 minutes to 4 minutes and 30 seconds, until it becomes sufficiently pliable. Take the mask out of the oven and check the temperature of the mask before skin contact. If the mask is too warm, cool it down before placing it on the patient.
5. Position the mask above the patient's face, with the MacroMedics' logo facing upwards.
6. Firstly, the nose hole should be positioned on the superior tip of the nose. Stretch the mask down to the cradle rim in a smooth, continuous movement for even stretch of the material.
7. When using a mask on a patient with long hair, place the opening in the frame around the ponytail.
8. Push the white frame slowly onto the black frame and secure the mask in place by pressing down the plungers. Be careful not to pinch the patient's ears or skin around the neck.
9. Use both hands to mould the the mask to the structures of the face such as the nose bone, orbitae, chin, and forehead.

10. To speed up the setting process, you can use cold packs or cold, wet towels to cool the mask.
11. Cure and cool the mask for at least 5 minutes.
12. Release the plungers and remove the mask(s) carefully.
13. Label the mask(s) with the patient's name/ identifier.



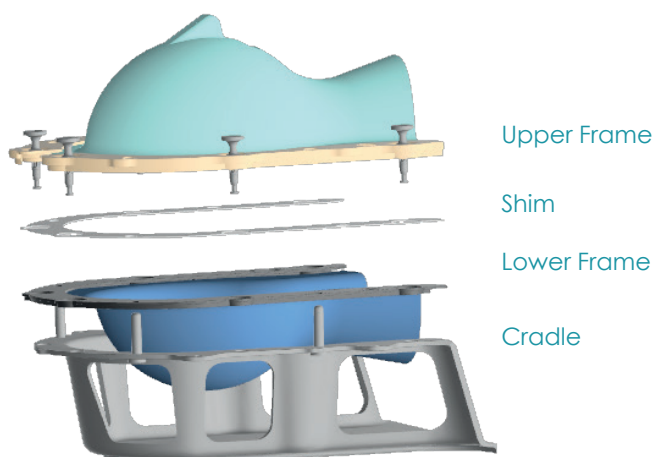
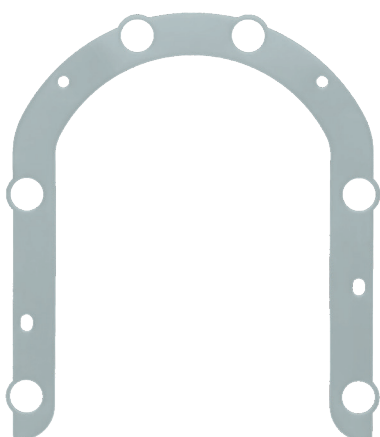
6. Using shims

For DSPS treatments, to maintain patient comfort in the case of facial swelling, the separation between the lower and upper masks may be increased by placing one or two shims between the masks. Shims are available in 1.0 mm and 0.5 mm thicknesses. An example of a shim used as part of the DSPS supine set-up can be seen below.

Check the label on the shim to identify whether it is a 1.0 mm Shim or a 0.5 mm Shim.

Shims can be used in the following combinations:

- One 0.5 mm Shim only
- One 1.0 mm Shim only
- One 0.5 mm Shim and one 1.0 mm Shim



Example of a Shim being used as part of a DSPS-Environ supine set-up

7. 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.
- Store the thermoplastic Masks in a dry place away from direct sunlight.
- Store the products with the plungers in the released position to prevent grommet deformation. Refer to the image in chapter 4.1.
- Dispose of the device in accordance with the local laws and regulations applicable to your country.

8. 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.

9. 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.

10. 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: (10)	Batch Code	Indicates the manufacturer's batch code so that the batch or lot 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 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.
 GSI Code: (17)	Use-by Date	Indicates the date after which the medical device is not to be used. When the graphical symbol is used, the date is expressed in the format: YYYY-MM-DD. On the other hand, when expressed next to the GSI Code (17), the date is in the format: YYMMDD.
	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.
	Single Patient Multiple Use	To indicate that the medical device may be used multiple times (multiple procedures) on a single patient.



[This page is intentionally left blank]



[This page is intentionally left blank]



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)



10012024V5IFU114730