

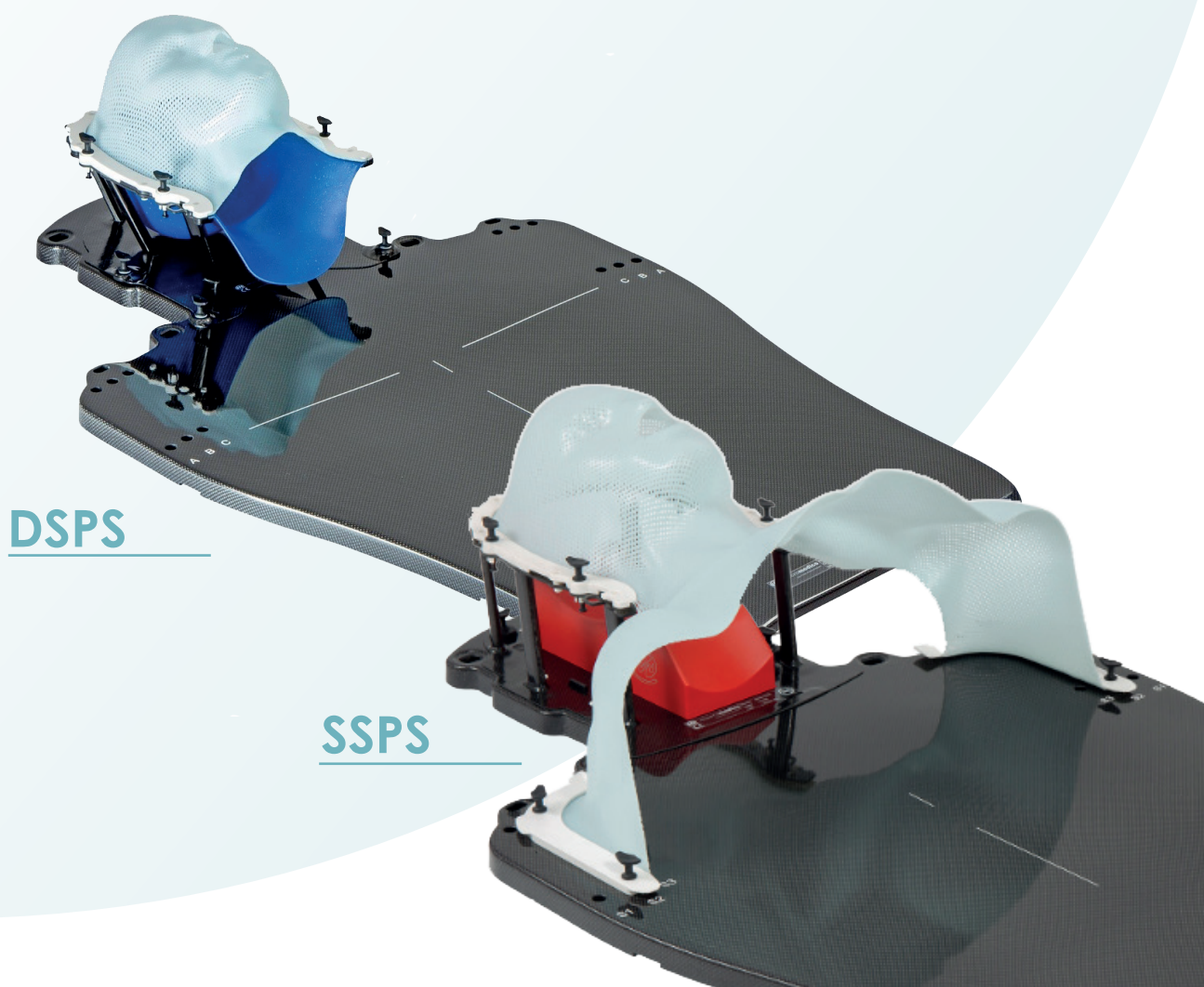


macromedics

SOLUTIONS IN RADIOTHERAPY

MANUAL 112100
Instructions for use
English Instructions

DSPS® Double Shell Positioning System & SSPS® Single Shell Positioning System



DSPS

SSPS



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1. Warnings



- Inspect the device thoroughly before use. Do not use the device if damaged.
- 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.
- Make sure that the device is securely fixed before positioning the patient.
- When using a Type-I cradle, ensure that there is no clearance between the cradle and the baseplate.
- 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.
- Ensure that the mask is not too hot for skin contact before placing it on the patient.
- Do not remove the mask from the patient until the material cools completely. Removing the thermoplastic mask before it has set may result in the mask's 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:

- | | |
|----------------------------------|---------------------------------|
| • 111220 SSPS® Cradle RE MR | • 115520M Mask SSPS®-FS |
| • 111530 SSPS® Cradle S-Type, MR | • 115560M Mask SSPS®-FL |
| • 111610 SSPS® Cradle Type-O, MR | • 115570M Mask SSPS®-FSL |
| • 111650 SSPS® Cradle ExaFix™ MR | • 115620M Mask SSPS®-FSO |
| • 112640 DSPS® Shim set | • 115670M Mask SSPS®-FSOL |
| • 112850 SSPS® Cradle-FB MR | • 115720M Mask SSPS®-FSS |
| • 112910 DSPS® Cradle-MEXF H MR | • 115770M Mask SSPS®-FSSL |
| • 112920 DSPS® Cradle-O H MR | • 115810M Mask SSPS®-FVR |
| • 112930 DSPS® Cradle-S H MR | • 115820M Mask SSPS®-FSVRS |
| • 114500M Mask SSPS®-FN | • 115860M Mask SSPS®-FVRL |
| • 114530M Mask UMCN | • 115870M Mask SSPS®-FSVRS� |
| • 114550M Mask DSPS®-OS | • 171250 DSPS® Cradle-M H RE MR |
| • 115510M Mask SSPS®-F | |



2.2 MR UNSAFE:

- | | |
|-------------------------------|---------------------------------|
| • 111110 SSPS® Cradle Type-I | • 112730 DSPS® Cradle-S H |
| • 111120 SSPS® Cradle RE | • 112740 DSPS® Cradle-VRT H |
| • 111520 SSPS® Cradle S-Type | • 112750 DSPS® Cradle-B H |
| • 111600 SSPS® Cradle Type-O | • 112760 DSPS® Cradle-I H |
| • 111620 SSPS® Cradle ExaFix™ | • 112770 DSPS® Cradle-U H |
| • 111630 SSPS® Cradle U | • 112780 DSPS® Cradle-V H |
| • 112710 DSPS® Cradle-MEXF H | • 112790 DSPS® Cradle-QA H |
| • 112720 DSPS® Cradle-O H | • 171210 DSPS® Cradle-MEXF H RE |




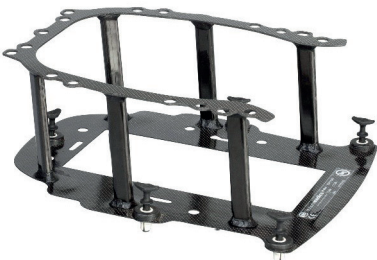
3. Intended Use

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

4. Positioning Options

- **Double Shell Positioning System (DSPS®)** uses two thermoplastic masks and a cradle to support the patient's head.
- **Single Shell Positioning System (SSPS®)** uses a head support, a cradle, and one thermoplastic mask to support the patient's head.

The following tables provide details on the treatment positioning options possible with each mask and cradle type.

Cradle		Positioning Options
<p style="text-align: center;">DSPS® Cradle</p>  <p> 112710 DSPS® Cradle-MEXF H 112780 DSPS® Cradle-V H 112720 DSPS® Cradle-O H 112790 DSPS® Cradle-QA H 112730 DSPS® Cradle-S H 112910 DSPS® Cradle-MEXF H MR 112740 DSPS® Cradle-VRT H 112920 DSPS® Cradle-O H MR 112750 DSPS® Cradle-B H 112930 DSPS® Cradle-S H MR 112760 DSPS® Cradle-I H 171210 DSPS® Cradle-MEXF H RE 112770 DSPS® Cradle-U H 171250 DSPS® Cradle-M H RE MR </p>		Supine and Prone DSPS®
<p style="text-align: center;">SSPS® Cradle</p>  <p> 111110 SSPS® Cradle Type-I 111610 SSPS® Cradle Type-O, MR 111120 SSPS® Cradle RE 111620 SSPS® Cradle ExaFix™ 111220 SSPS® Cradle RE MR 111650 SSPS® Cradle ExaFix™ MR 111520 SSPS® Cradle S-Type 111630 SSPS® Cradle U 111530 SSPS® Cradle S-Type, MR 112850 SSPS® Cradle-FB MR 111600 SSPS® Cradle Type-O </p>		Supine and Prone DSPS® and SSPS®

	Mask Options for Supine Treatment	Mask options for Prone treatment
DSPS and SSPS	114550M Mask DSPS®-OS 115510M Mask SSPS®-F 115520M Mask SSPS®-FS 115560M Mask SSPS®-FL 115570M Mask SSPS®-FSL 115620M Mask SSPS®-FSO 115670M Mask SSPS®-FSOL 115720M Mask SSPS®-FSS 115770M Mask SSPS®-FSSL 115810M Mask SSPS®-FVR 115820M Mask SSPS®-FSVRS 115860M Mask SSPS®-FVRL 115870M Mask SSPS®-FSVRS�	114500M Mask SSPS®-FN
DSPS ONLY	114550M Mask DSPS®-OS	114530M Mask UMCN

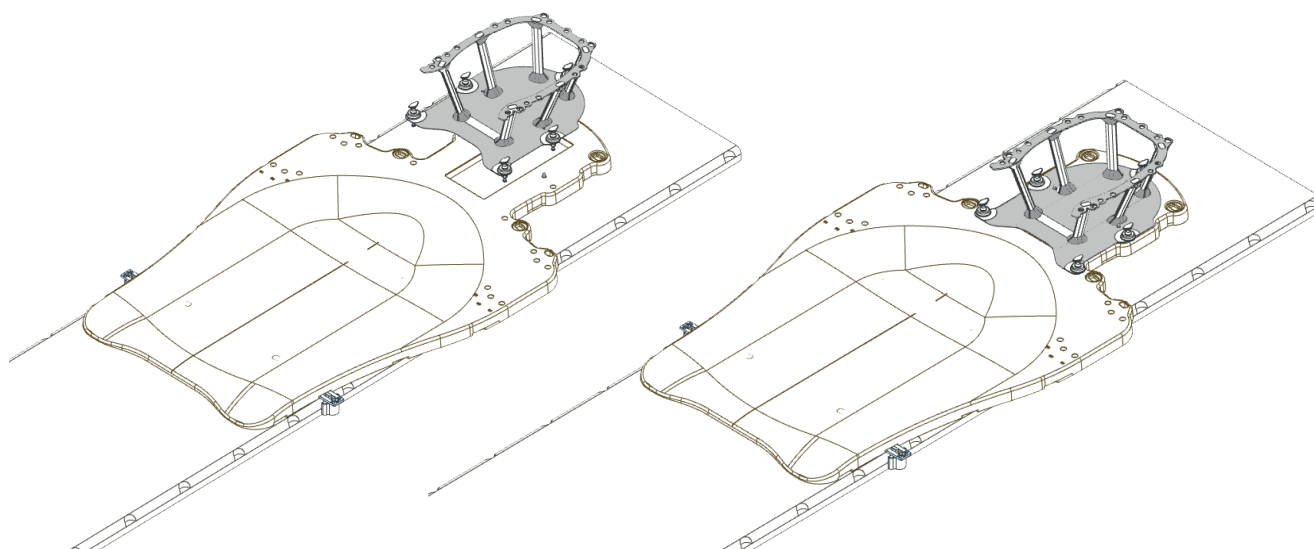
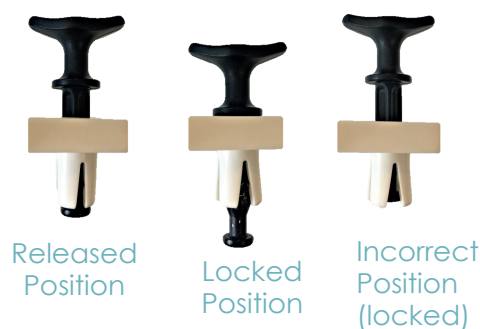
Note: MacroMedics offers thermoplastic masks with special cut-outs for patients with long hair and for treatments using surface guided radiotherapy systems.

5. Cradle Set-Up

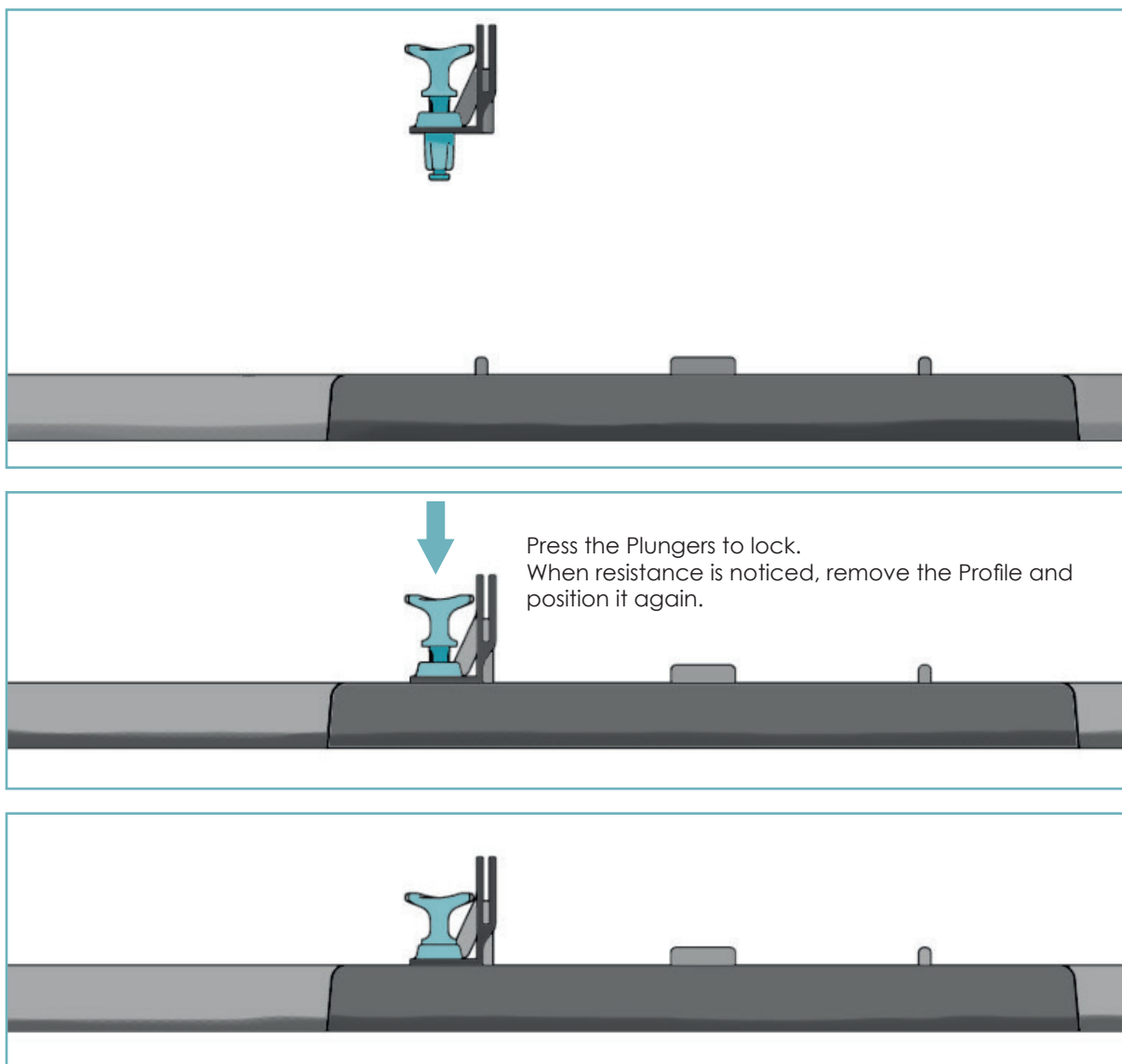
For optimum set-up stability, MacroMedics recommends using a baseplate which is secured to the couchtop.

5.1 CRADLES WITH PLUNGERS AND QUICKFASTENERS

- I. Ensure that the plungers or quickfasteners are in the released position in the cradle rim.
- II. Align and slot the cradle onto the baseplate.



III. Lock the cradle in place by pressing down on the plungers or quickfasteners.



IV. After use, the cradle can be detached

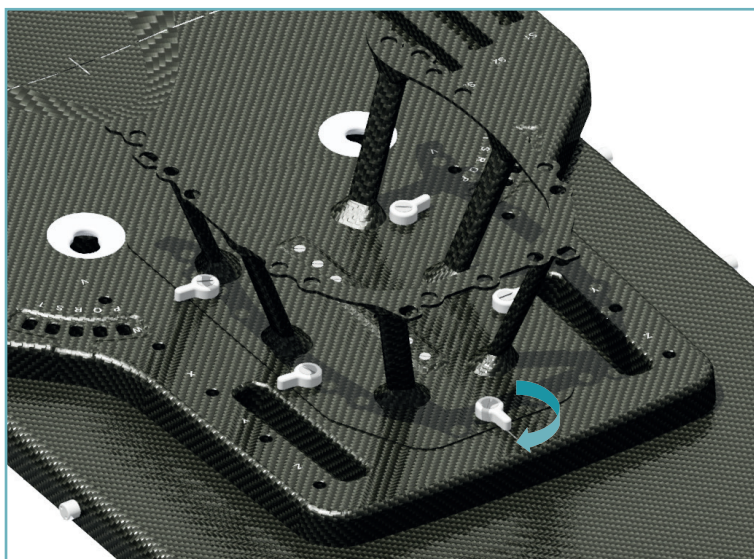
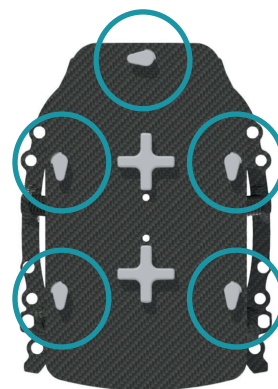
- Press on the cradle rim.
- Use your other hand to release all Plungers. Do not pull too hard! This will lock the Profile.
- Set the plungers back in released position during storage.

When removing the cradle becomes difficult:

- Clean the baseplate holes with a cotton bud.
- Spray Teflon spray in the hole.
- Remove residual teflon spray from the hole.

5.2 TYPE - O CRADLES

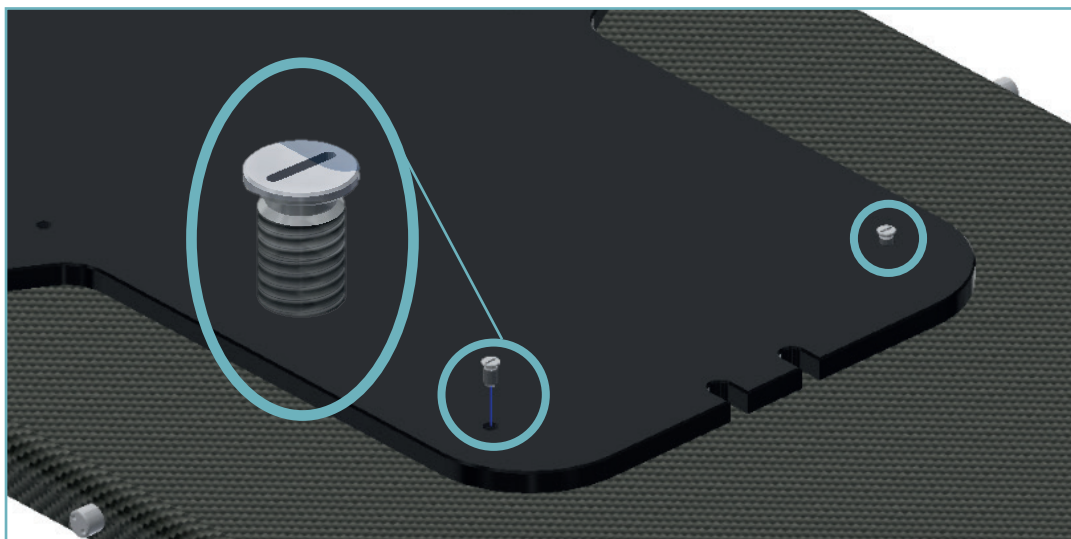
- I. Ensure that the locking knobs are in the released position.
- II. Align and slot the cradle onto the baseplate.
- III. Lock the cradle in place by rotating the locking knobs 90 degrees so the knobs are pointing outwards.



- IV. After use, the cradle can be detached by returning the locking knobs to the released position.

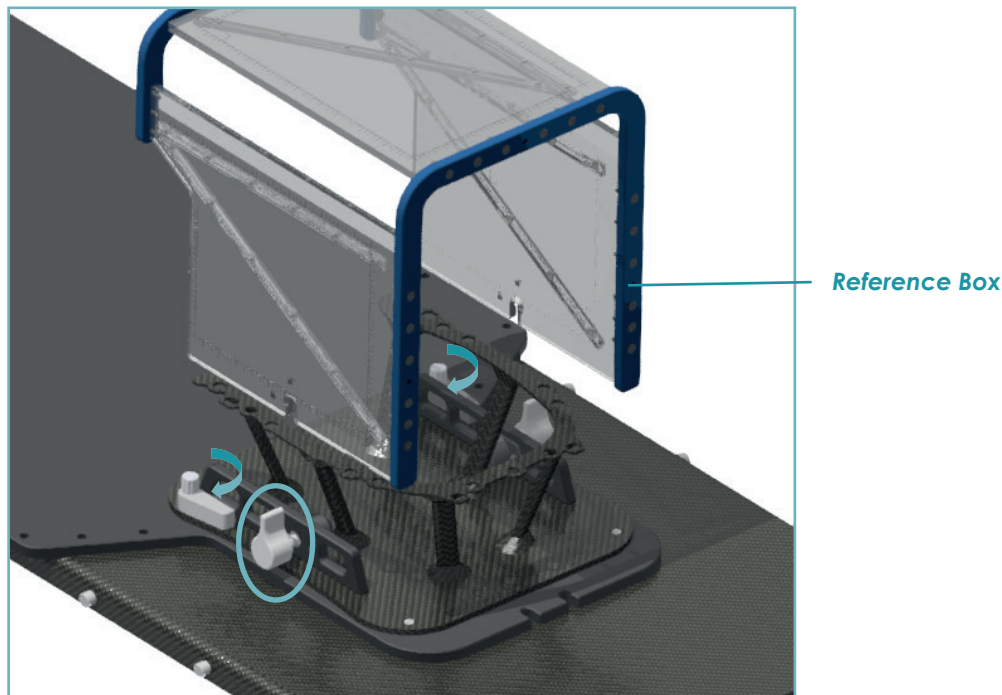
5.3 TYPE - B CRADLES

- I. Attach the two pivots to the baseplate by screwing them into place. Align and slot the cradle onto the baseplate.

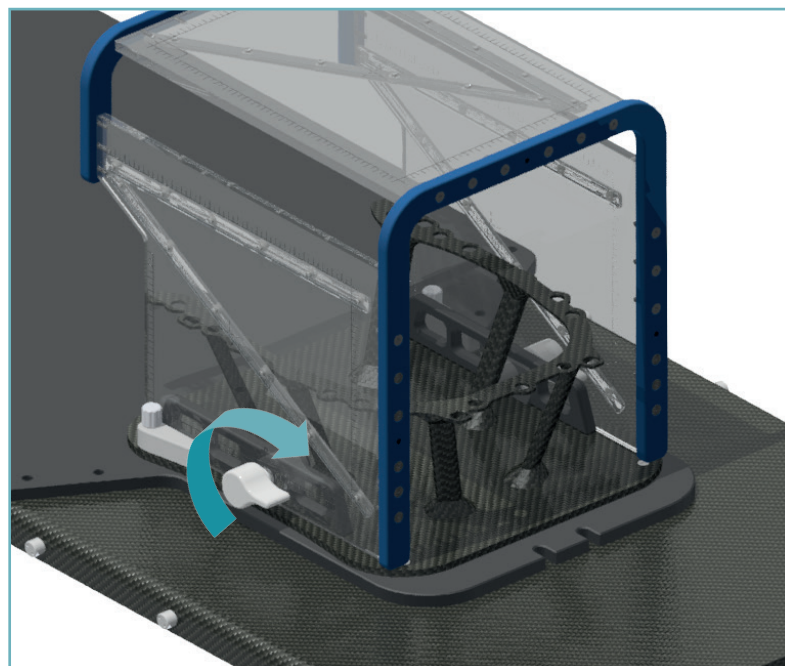


- II. Secure the cradle in place by tightening the white knobs at both side of the cradle.

Ensure that the locking knobs (circled) are in the released position to be able to place the reference box over the cradle.



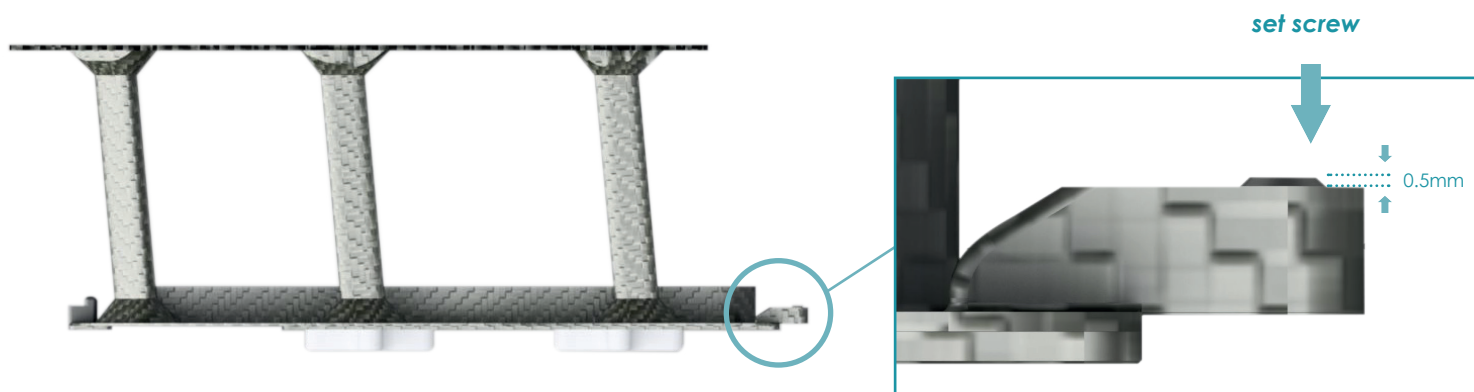
- III. When using the reference cradle, place the reference box over the cradle, as shown below. Secure it in place by rotating the locking knobs 90 degrees so the knob is pointing towards the cranial end of the board.



- IV. After use, the cradle and reference box can be detached by returning the locking knob to the released position and loosening the white knobs.

5.4 TYPE-I CRADLES

Place the Type-I cradle on the baseplate. The two set screws on the caudal side of the cradle base extend 0.5mm to prevent any movement when slotted into the baseplate. If some clearance is encountered between the cradle and baseplate, adjust the set screw in height by turning it in clockwise direction. If the set screw is positioned too high and prevents the cradle from being slotted into the baseplate, rotate it in counter-clockwise direction to lower it.



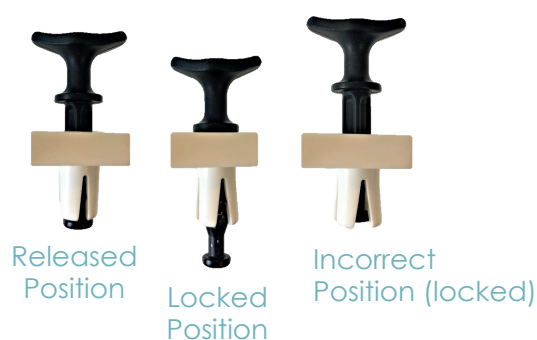
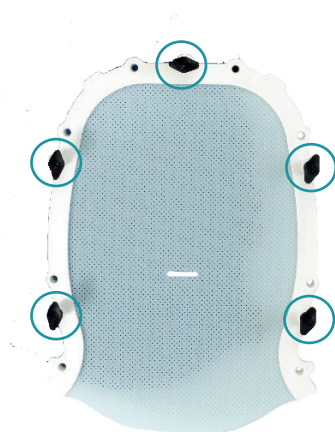
5.5 OTHER CRADLES

Other cradles are aligned and slotted into the baseplate and are subsequently fixed in place using the third-party baseplate's clamping mechanisms or locks. Refer to the corresponding Instructions for Use for further details.

6. Mask Set-Up

The masks are packaged without the plungers inserted. Prior to mask usage, insert the supplied plungers into the plunger holders (holes) in the white frame of the mask. Gently push them through until they are in released position.

For fastening the masks to the cradle with the plungers, please see the instructions as described in chapter 5.1.3.



7. 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 the head on the head support.
- When using a mask on a patient with long hair, place the hair in ponytail on the top left side of the patient's head.

8. Supine Treatment



*Double Shell Positioning System (DSPS®)
for supine treatment*

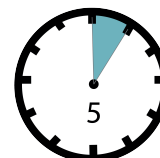


*Single Shell Positioning System (SSPS®)
for supine treatment*

8.1 MOULDING A SUPINE OCCIPITAL MASK [DSPS® ONLY]

1. Take a new supine occipital mask (dark blue RayOC thermoplastic mask with the 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 15 to 20 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.
4. Place the black frame onto the DSPS® cradle, with the MacroMedics logo facing upwards.
5. Ensure that all of the frame's plungers are pushed properly into the holes in the cradle rim.
6. Place the patient's head on the occipital mask and gently position the patient's head on top of the mask in the desired position for treatment.
7. The mask will sink in 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 hands on the patient's forehead 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.

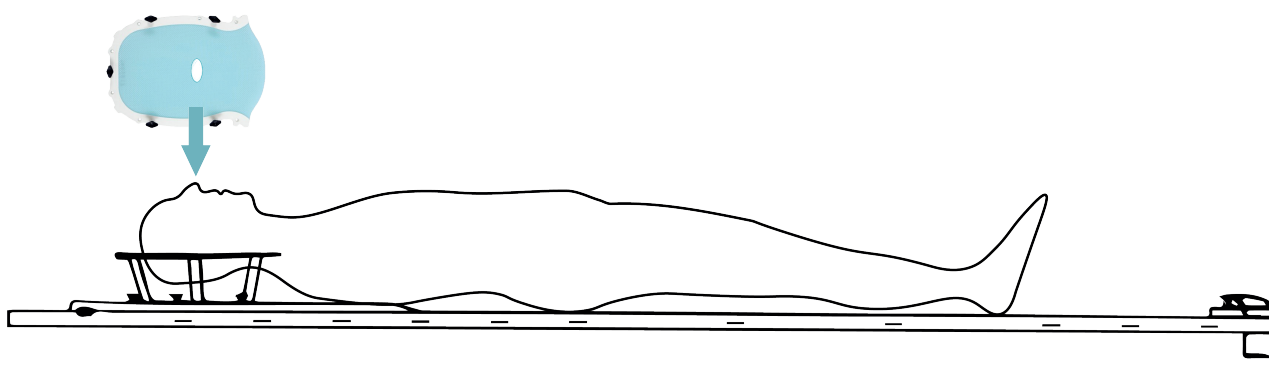
8. Use your hands to mould the mask to the side of the neck and the cranial area, including occipital bone. The ventral inferior line of the base of skull is an optimal landmark to mould. Hold the mask in position for 10-20 seconds to ensure an impression is formed.
9. When the mask material starts to harden, you can use cold packs or cold wet towels to cool the mask and speed up the setting process.
10. Keeping the patient in the same position, let the mask cool and set for at least 5 minutes.
11. After 5 minutes, the mask should have fully set.



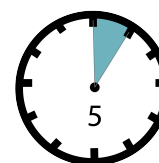
8.2 MOULDING A SUPINE FACIAL MASK [DSPS® AND SSPS®]

1. Lay the patient in the supine position with the head resting on the occipital mask for DSPS® or supine head support for SSPS®.
2. Take a new supine facial mask (Perforated RayPRO 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 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 MacroMedics' logo facing upwards.
6. The nose hole should be positioned on the superior tip of the nose first. Stretch the mask down to the cradle rim in a smooth, continuous movement for even stretch of the material.

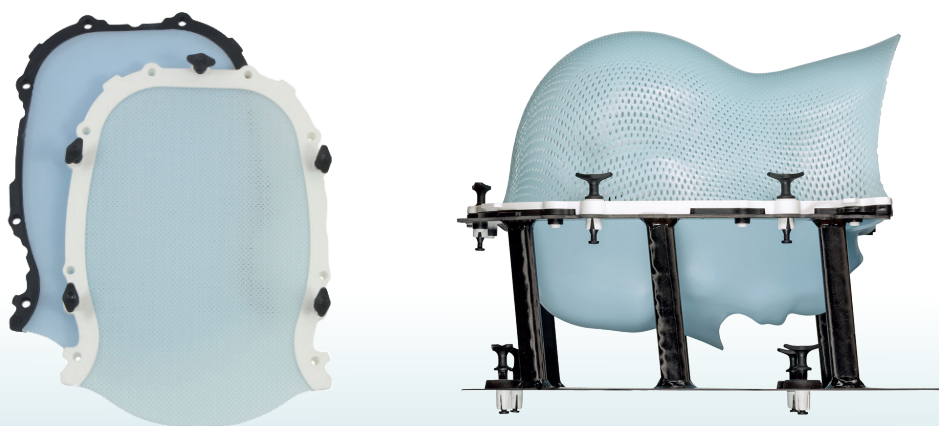
Nose hole first



7. When using a mask on a patient with long hair, place the opening in the frame around the ponytail.
8. Place 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 structures of the face like the nose bone, orbitae, chin, and forehead.
10. If applicable, after moulding the facial region of the mask, proceed with moulding the mask around the neck and shoulders.
11. To speed up the setting process, you can use cold packs or cold, wet towels to cool the mask.
12. Cure and cool the mask for at least 5 minutes.
13. Release the plungers and remove the mask(s) carefully.
14. Label the mask(s) with the patient's name/ identifier.



9. Prone Treatment



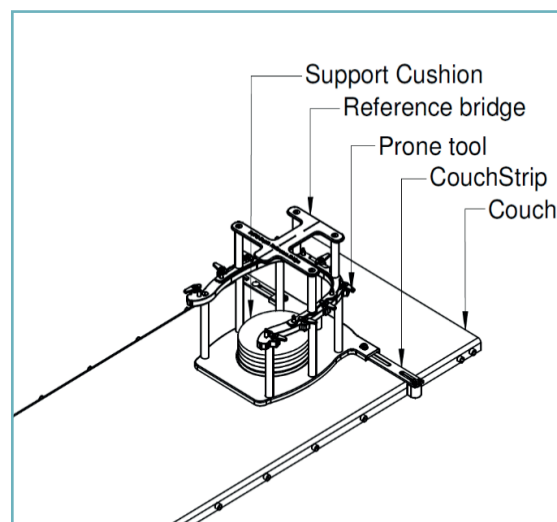
Double Shell Positioning System (DSPS®) for prone treatment

9.1 MOULDING A PRONE FACIAL MASK [DSPS® ONLY; REQUIRES PRONE TOOL SET]

1. Secure the Prone Tool to the couch top or treatment board using a CouchStrip or similar.



Prone Tool Set

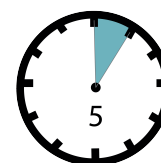


2. Lay the patient in the supine position with the head resting on the Support Cushions.
3. Place the Reference Bridge on the Prone Tool to determine if the position of the patient's head is at the correct height. The tip of the nose should touch the reference tool to ensure that there will be enough distance between the bottom of the cradle and the patient's head when the facial prone mask is placed on the cradle. Add or remove Support Cushions to achieve the desired height.
4. Once the patient's head is at the correct height, remove the Reference Bridge.
5. Take a new prone facial mask (Non-perforated MacroCast thermoplastic mask with the black frame).
- 6.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 2 to 4 minutes 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.
- 6.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 7 minutes and 30 seconds to 8 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.
7. Position the mask above the patient's face, with the MacroMedics logo facing downwards.
8. The nose hole should be positioned on the superior tip of the nose first. Stretch the mask down to the Prone Tool rim in a smooth, continuous movement for even stretch of the material.
9. Lock the mask in place using the swivel clamps on the prone tool.

10. Use both hands to mould the structures of the face like nose bone, orbitae, chin, and forehead.

For male patients, it is highly recommended to fold up the mask material in the neck section to avoid pressure in the region when the patient is lying in the prone position.

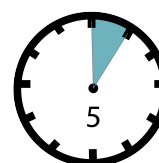
11. To speed up the setting process, you can use cold packs or cold, wet towels to cool the mask.
12. Cure and cool the mask for at least 5 minutes. Ensure that this mask has fully set prior to moulding the occipital mask as the weight of the patient could otherwise cause it to stretch.
13. Release the plungers and remove the mask carefully.
14. Replace the Prone Tool with an appropriate cradle.
15. Place the prone mask, face down on the cradle.



9.2 MOULDING A PRONE OCCIPITAL MASK [DSPS® AND SSPS®]

1. Lay the patient in the supine position with the head resting on the occipital mask for DSPS® or prone head support for SSPS®.
2. Take a new prone occipital mask (Perforated RayPRO 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 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 head with MacroMedics' logo facing upwards.

6. Stretch the mask down to the cradle rim in a smooth, continuous movement for even stretch of the material.
7. Secure the mask in place by pressing down the plungers. Be careful not to pinch the patient's ears or skin around the neck.
8. Use your hands to mould the mask to the side of the neck and the cranial area, including occipital bones. The ventral inferior line of the base of skull is a particularly optimal landmark to mould.
9. To speed up the setting process, you can use cold packs or cold, wet towels to cool the mask.
10. Cure and cool the mask for at least 5 minutes.
11. Release the plungers and remove the masks carefully.
12. Label the mask(s) with the patient's name/ identifier.



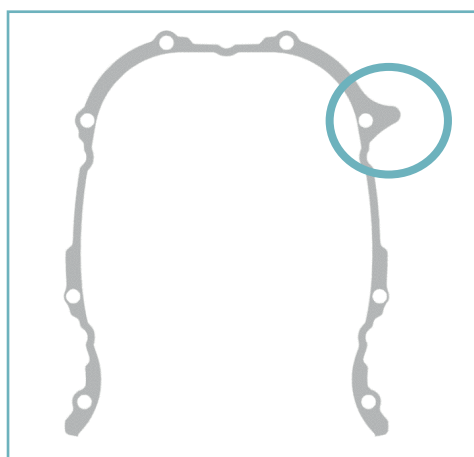
10. Using shims

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. The shims can be used for both supine and prone position. An example of a shim used as part of the DSPS supine set-up can be seen below.

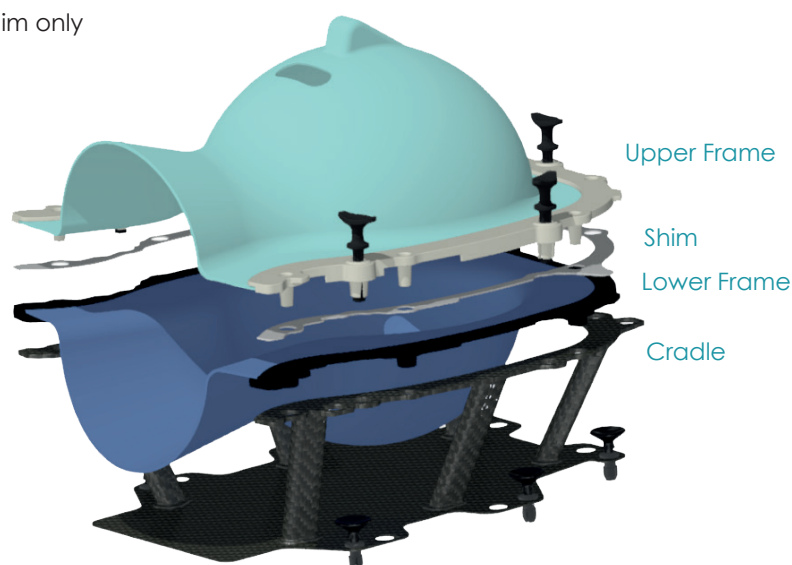
Check the tab of the shim (the tab is circled in blue below) to identify whether it is a 1.0 mm Shim or a 0.5 mm Shim.

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 only



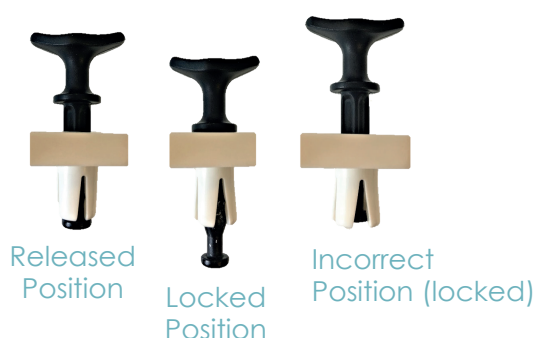
Shim with the tab highlighted.



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

11. 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.
- Store the thermoplastic Masks in a dry place away from direct sunlight.
- Store the products with the Quickfasteners in the released position to prevent grommet deformation. See the image below.
- Dispose of the device in accordance with the local laws and regulations applicable to your country.



12. 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.

13. 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.

14. 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: (10)	Batch Code	Indicates the manufacturer's batch code so that the batch or lot 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.
	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.
 GS1 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 GS1 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, nonmetallic, and nonmagnetic.
	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
	Single patient multiple use	To indicate that the medical device may be used multiple times (multiple procedures) on a single patient.



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