



macromedics

SOLUTIONS IN RADIOTHERAPY

MANUAL 113000
Instructions for use
English Instructions

MacroMedics® DSPS-Prominent®



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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.
- Verify the device's attenuation characteristics before clinical use when the device is intended to be in the incoming radiation treatment-beam pathway.
- 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.
- For both user and patient, do not lean on the cranial side of the cradle.
- Be cautious not to apply excessive force on the cantilevered frame when moulding the masks.
- Do not exceed the allowable maximum patient weight of 150 kilograms.
- Ensure all the plungers are locked before use.
- Ensure all the sliding clamps are tightened before use.
- Do not try to remove the cradle from the baseplate/Omniboard when the sliding clamps/clips or quick fasteners/ plungers are in locked position.
- For the DSPS-Prominent® Cradles, ensure that there is sufficient clearance between the cradle clamps/ clips and the inside of the bore before use.
- Ensure that the patient's hands, arms and limbs do not hang over the side of the baseplate to avoid potential pinch.
- 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.
- Handle with care to prevent damage.
- Store the products with quickfasteners/ plungers in the released position to prevent grommet deformation.
- 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 SAFE

113820	DSPS-Prominent® baseplate, MR
113840	DSPS-Prominent® Cradle-I MR
113850	DSPS-Prominent® Cradle-II MR
113860	DSPS-Prominent® Cradle-V MR
113870	DSPS-Prominent® Cradle-III MR
113880	DSPS-Prominent® Cradle-IV MR
113890	Mask DSPS®-PROSHVRL set/5
113910	Mask DSPS®-PROSH set/5
113920	Mask DSPS®-PROSHL set/5
113930	Mask DSPS®-PROH, set/5
113940	Mask DSPS®-PROSHVR set/5
113950	Mask DSPS®-PROSVRL, set/5
113960	Mask DSPS®-PROS, set/5
113970	Mask DSPS®-PROSVR, set/5
113980	Mask DSPS®-PROSL, set/5
113990	Mask DSPS®-PRO, set/5

113760	Mask DSPS®-PROSCVRL set/5
113770	Mask DSPS®-PROSC set/5
113780	Mask DSPS®-PROSCVR set/5
113790	Mask DSPS®-PROSCL set/5



MR UNSAFE

113120	DSPS-Prominent® baseplate
113140	DSPS-Prominent® Cradle-I
113150	DSPS-Prominent® Cradle-II
113160	DSPS-Prominent® Cradle-III
113170	DSPS-Prominent® Cradle-IV
113180	DSPS-Prominent® Cradle-VI
113190	DSPS-Prominent® Cradle-V
113710	MLDRM tool



3. Intended Use/Indications for Use

Positioning and immobilization of the patient during radiotherapy. This includes positioning and immobilization of the patient during image acquisition to support treatment.

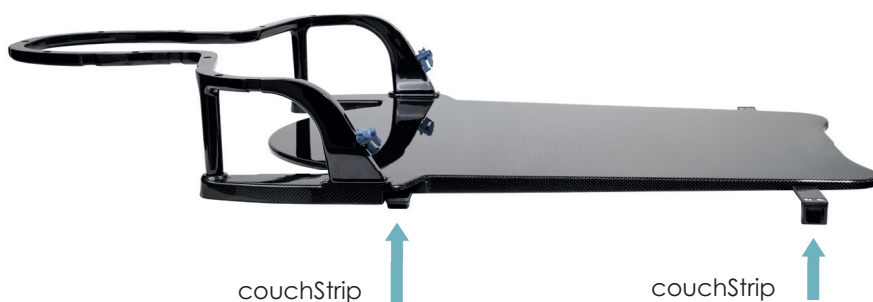
4. Baseplate and cradle set-up

4.1 SECURING THE DSPPS-PROMINENT® BASEPLATE TO THE COUCHTOP

- I. Position the two appropriate DSPPS-Prominent® couchstrips on the couchtop.

For more information, refer to IFU147100 - CouchStrips and Sidepieces.
For use in MR, use the dedicated glass fiber, MR Safe 3-Pin couchstrip.

- II. Position the DSPPS-Prominent® above the couchtop. Then, align the slots at the bottom of the baseplate with the two couchstrips and carefully place the baseplate on the couchstrips.

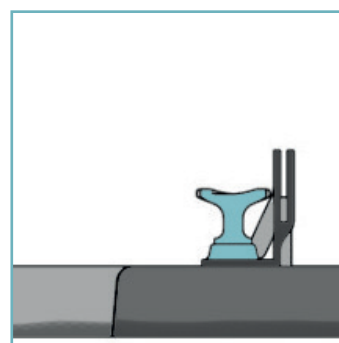
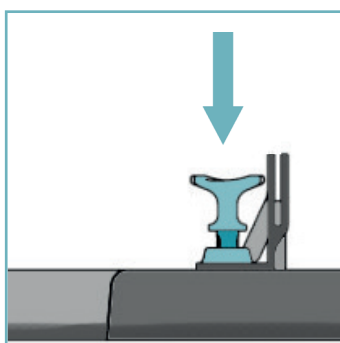


4.2 SECURING THE DSPPS-PROMINENT® CRADLE TO THE BASEPLATE

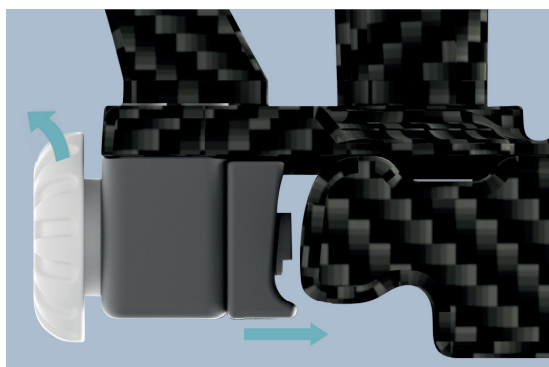
- I. Secure the Cradle with the Quickfasteners/Plungers.



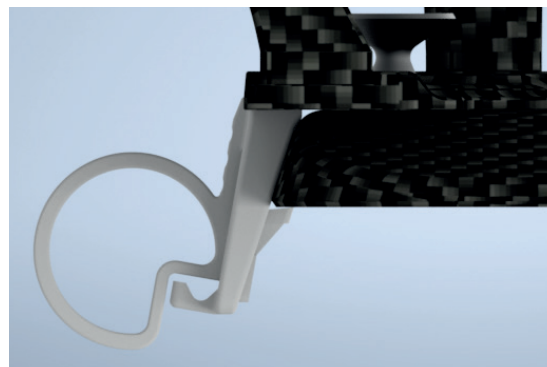
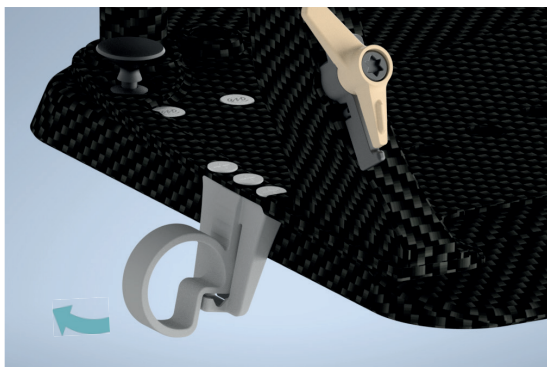
Place the Quickfasteners/Plungers in the holes
and press them down to lock.



- II. Securing the sliding clamps. Hand-tighten both turning knobs firmly until they securely lock onto the baseplate. Turn counter-clockwise to lock. (Not applicable for Cradle-V, see the following step)



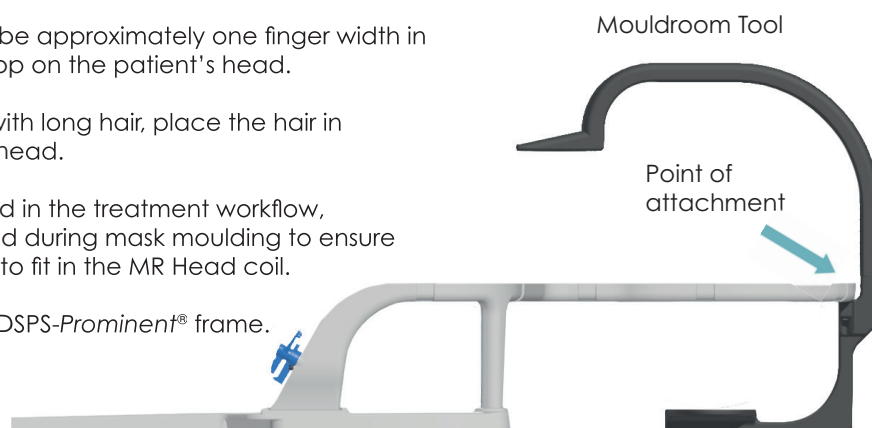
- III. The DSPProminent® Cradle-V can be locked to the sides of the baseplate by means of two clips. Carefully pull the clip away and slightly upwards from the Cradle and slowly release it so that it locks itself under the baseplate as shown below.



- III. Removing the DSPProminent® Cradle from the baseplate. First, release the Quickfasteners/Plungers by pulling them upwards. Do not pull too hard as this will lock the grommets (refer to section 6 for an illustration). Secondly, unlock the sliding clamps by turning the knob in clockwise direction. For Cradle-V, pull the clips away from the baseplate.

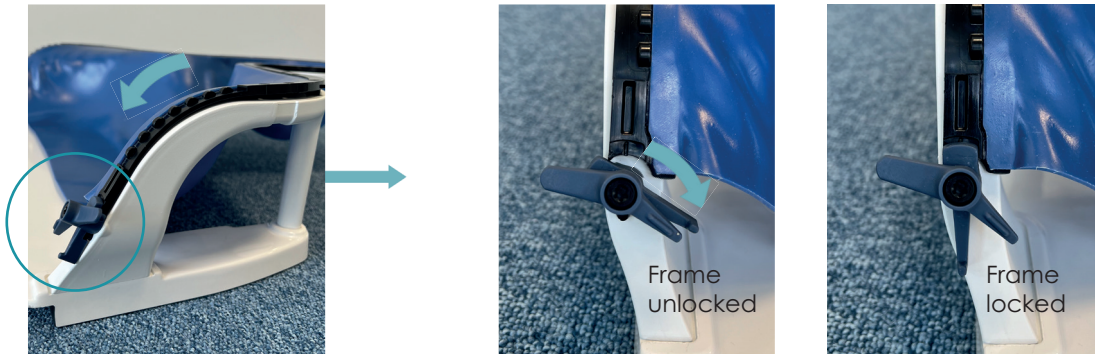
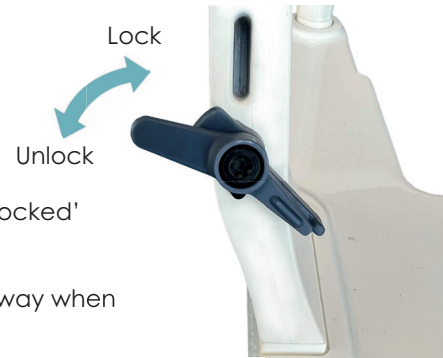
5. Mask set-up

- Follow your department's patient positioning protocol.
- For DSPS treatments, there should be approximately one finger width in between the cradle rim and the top on the patient's head.
- When using a mask on a patient with long hair, place the hair in a ponytail on top of the patient's head.
- When an MR Head coil will be used in the treatment workflow, the Mouldroom Tool should be used during mask moulding to ensure that the formed mask will be able to fit in the MR Head coil.
- Screw the Mouldroom Tool to the DSPProminent® frame.



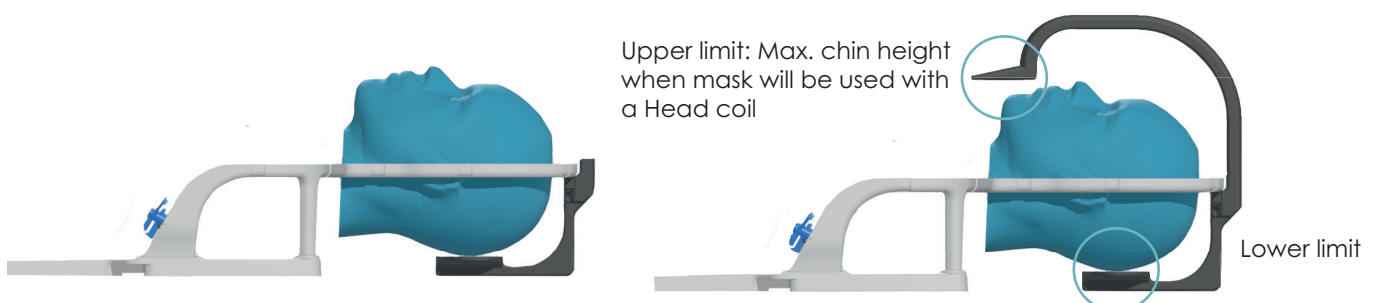
5.1 MOULDING THE OCCIPITAL MASK (Head only & Head, neck shoulder masks)

1. Make sure that the rotatable lock pawls on either side of the frame are in 'unlocked' positions - **Only applicable for the head, neck and shoulder masks.**
2. Rotate the top part of the Mouldroom Tool to one side so that it is not in the way when the patient has to lie down.
3. Take a new supine occipital mask (dark blue, RayOC thermoplastic mask with the black frame).
- 4.a **When using a Waterbath (for the head, neck & shoulder mask, we recommend using the MacroMedics MacroBath 4 or a bath with min. internal dimensions, in mm: 665w x 575d x 80h)** 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.
- 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 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, let it cool down before placing it on the patient.
5. Ask the patient to sit up in the desired position. Place the mask onto the DSPS-Prominent® cradle so that the pins at the bottom of the black frame fall into the designated holes of the cradle.
6. Bend both the ends of the frame (at shoulder height) along the slope of the cradle, lock the frame's ends with the rotatable lock pawl that is positioned closest to the frame by turning it until it is locked, as shown below - **Only applicable for the head, neck and shoulder masks.**



7. Ask the patient to gently lie down onto the mask. Gently position the patient's head on top of the mask in the desired position for treatment.

The mask will sink due to the weight of the patient. When an MR Head Coil will be used, the head should be positioned between the lower and upper limit of the Mouldroom Tool. The back of the head may touch the bottom of the Mouldroom Tool but should not rest on it. 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. Swing the top part of the Mouldroom Tool above the patient's head to check if the chin fits underneath it. If it does not, reposition the angle of the head slightly while the occipital mask is still mouldable. If the patient's chin exceeds the maximum height, the mask/ patient will not be able to fit in the Head coil.



8. 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.
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. While keeping the patient in the same position, let the mask cool and set for at least 5 minutes. After 5 minutes, the mask should have fully set.

CF DSPS-Prominent® Cradle with unmoulded Head Only Occipital Mask

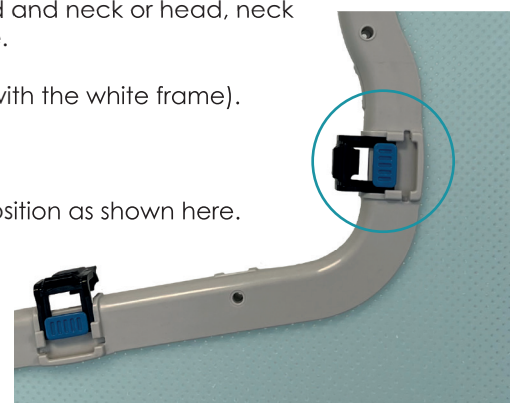


GF DSPS-Prominent® Baseplate with moulded Occipital Mask



5.2 MOULDING THE FACIAL MASK

1. Rotate the top part of the Mouldroom Tool to one side again so that it is not in the way when the patient has to lie down.
2. Instruct the patient to lie down in the supine position with the head and neck or head, neck and shoulders resting on the occipital DSPS mask, previously made.
3. Take a new facial mask (perforated RayPRO thermoplastic mask with the white frame).
4. Make sure that all the black sliding lock pawls are in 'unlocked' position as shown here.



- 5.a **When using a Waterbath (for the head, neck & shoulder mask, we recommend using the MacroMedics MacroBath 4 or a bath with min. internal dimensions, in mm: 665w x 575d x 80h)** 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.
- 5.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.
6. Position the mask above the patient's face, with the frame's logo facing upwards.
7. The nose hole should be positioned on the superior tip of the nose first. Stretch the mask down slowly to the cradle rim in a smooth, continuous movement for even stretch of the material.
8. When using a long hair mask, position the ponytail through the gap in the top of the frame of the mask.

9. Push the white frame slowly towards the black frame. Once both frames touch, secure the mask in place by pushing the sliding lock pawls into locked position. Be careful not to pinch the patient's ears or skin around the neck between the frames.

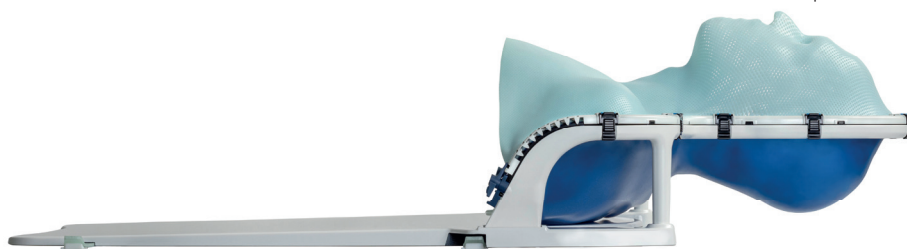


10. Now secure the ends of the upper frame to the cradle as well, just as described in step 6 of chapter 5.1, by locking the second rotatable lock pawl - **Only applicable for the head, neck and shoulder masks.**



11. Swing the top part of the Mouldroom Tool above the patient's head again to check if the chin still fits underneath it.
12. Use both hands to mould the structures of the face like the nose bone, orbitae, chin, and forehead.
13. After moulding the facial region of the mask, proceed with moulding the mask around the neck and shoulders - **Only applicable for the head, neck and shoulder masks.**
14. To speed up the setting process, you can use cold packs or cold, wet towels to cool the mask. Cure and cool the mask for at least 5 minutes.
15. Remove the Mouldroom Tool and label the mask(s) with the patient's name/ identifier.

GF DSPS-Prominent® Baseplate with moulded
Head, neck & shoulder Facial and Occipital Masks

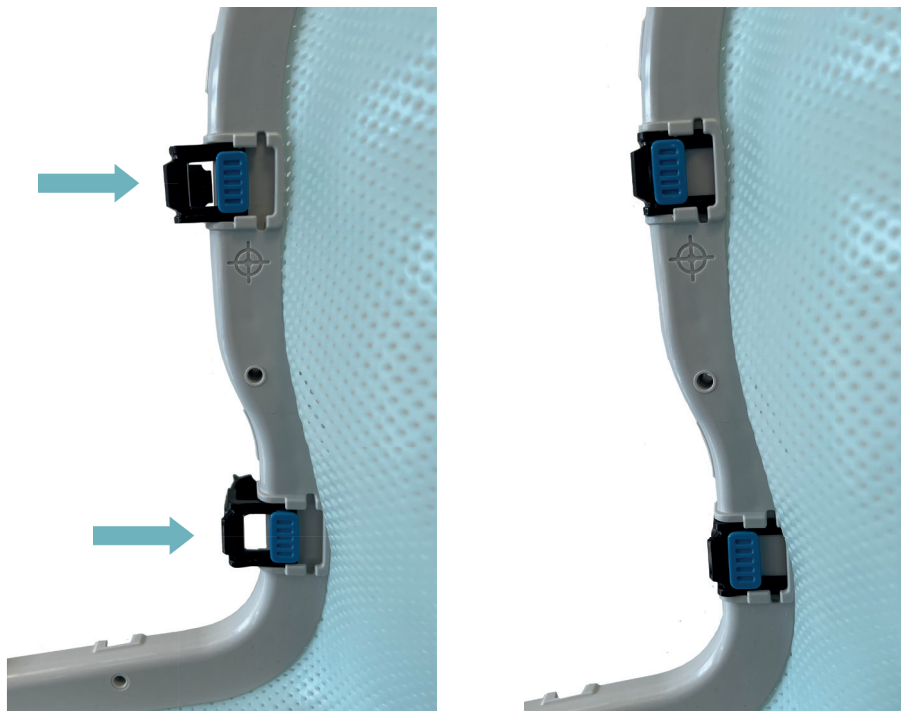


5.3 REMOVING THE FACIAL MASK

1. Unlock the two rotatable lock pawls at both sides of the frame - **Only applicable for the head, neck and shoulder masks.**
2. Unlock the black sliding lock pawls.
Place your thumb on top and your index finger at the bottom of the black lock pawl. With care, gently push a little upwards with your index finger to unlock it and then pull with both fingers in the horizontal direction, into unlocked position.

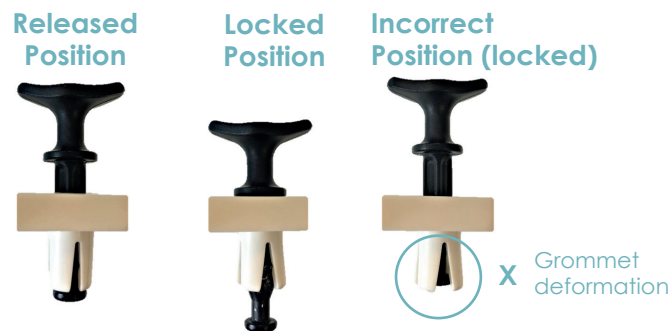


3. Remove the facial mask.
4. The patient can now get up.
5. Push the sliding lock pawls back into locked position for storage of the mask.



6. Cleaning, Storage and Disposal

- Clean the device thoroughly 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.
- 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 thoroughly 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.
- Store the thermoplastic masks in a dry place, away from direct sunlight.
- Store the products with the black sliding lock pawls in locked position.
- Dispose of the device in accordance with the local laws and regulations applicable to your country.
- Store the products with the Quickfasteners/Plungers in the released position to prevent grommet deformation.



7. 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.

8. 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.

9. 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, non-metallic, 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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