macromedics

SOLUTIONS IN RADIOTHERAPY

MacroMedics® Thermoplastic Masks

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1. Warnings

- Inspect the device thoroughly before use. Do not use the device if damaged or if 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.
- Fix the Thermoplastic mask properly before treatment.
- The Thermoplastic masks are for single patient use.
- 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 Thermoplastic mask is not too hot for skin contact before placing it on the patient.
- Do not remove the Thermoplastic mask from the patient until the material has cooled completely. Removing the Thermoplastic mask before it has set may result in mask deformation.
- Store the 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

2.1 MR UNSAFE:

MacroMedics Thermoplastic masks with Carbon Fiber Profiles are MR Unsafe.

2.2 MR SAFE:

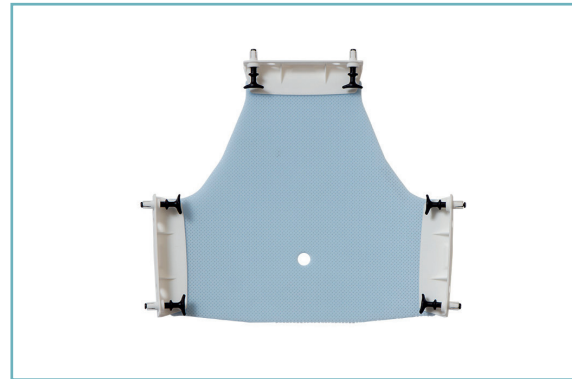All MacroMedics Thermoplastic masks with plastic Profiles are MR Safe.

3. Intended Use

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

4. Types of Mask Profiles
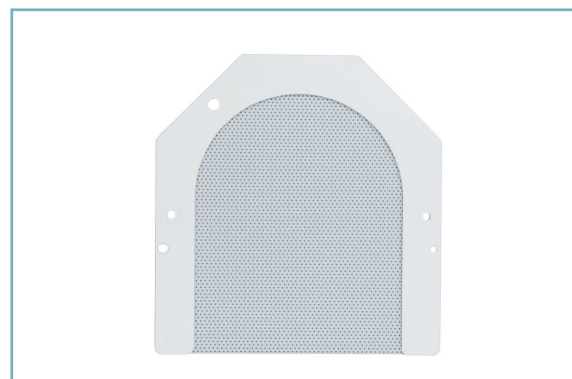

Mask with L-Profiles

Mask with RealEase Profiles

Mask with O-Profiles

Mask with S-Type Profile

Mask with Carbon Fiber (CF) Profiles

U-frame mask standard perforation

5. Installation Instructions

5.1   ASSEMBLY OF THE CARBON FIBER PROFILES

Attach the Thermoplastic Mask to the Carbon Fiber Profiles by screwing the bolts and nuts into each other as shown below. Make sure that the Quickfasteners in the Profiles are set to their released position when the mask is stored.

Released Position   **Locked Position**   **Incorrect Position (locked)**
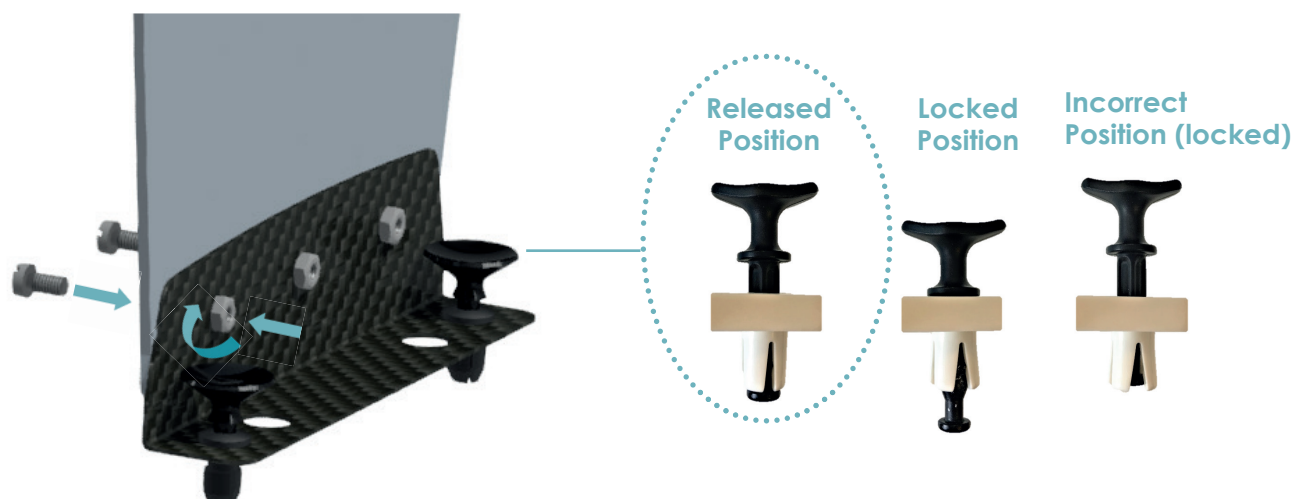
5.2   HOW TO MAKE THERMOPLASTIC MASKS FLEXIBLE

Different types of Thermoplastic masks require different heating times in the water bath. The appropriate times and temperatures are presented in the table below.

Ensure that the material has turned completely from opaque to translucent before removing it from the water.

	Perforated MacroCast Thermoplastics	**Non-perforated** MacroCast Thermoplastics	**Selective perforated** Thermoplastics (S-Type & U-Frame)	**MacroCast Posi** Thermoplastics
Time of immersion in the waterbath	45 - 60 s	2 - 4 min	2.3 mm = 2 min 3.0 mm = 4 min	1 min
Temperature of the waterbath	68°C - 70°C (154.4°F -158°F)	68°C - 70°C (154.4°F -158°F)	68°C - 70°C (154.4°F -158°F)	70°C - (158°F)
Time in oven	4 - 8 min	4 - 8 min	4 - 8 min	5 - 9 min
Temperature of the oven	68°C - 70°C (154.4°F -158°F)	68°C - 70°C (154.4°F -158°F)	68°C - 70°C (154.4°F -158°F)	75°C - (165°F)

Check the temperature of the mask before skin contact. If the mask is too warm, cool it down before placing it on the patient.

Keep the Carbon Fiber Profiles out of the water!
Do not use the oven for masks with Carbon Fiber Profiles!

The above images portray the process of submerging a mask into a waterbath to make it flexible for use.

### **5.4** MOULDING THE THERMOPLASTIC MASK

(Recommended to mould with two persons)

1. When the mask comes out of the waterbath, dry the mask with a towel.

⚠️ 2. Check if the temperature of the mask is not too hot to touch the patients' skin.

3. Position the mask above the patients' face. Align the nose hole of the mask with the nose of the patient.

4. Carefully pull the Profiles towards the baseplate so that the mask forms around the patients' face.

5. First secure the profiles which are located on both sides of the head to the baseplate. Then lock the most Cranial Profile. Lastly, secure the Shoulder Profiles if applicable.

6. Mould the mask precisely around the nose bridge, chin and eye sockets of the patient.

7. When the facial features have been precisely moulded into the mask, start cooling down the mask. Cold-packs can be used to speed up the cooling process.
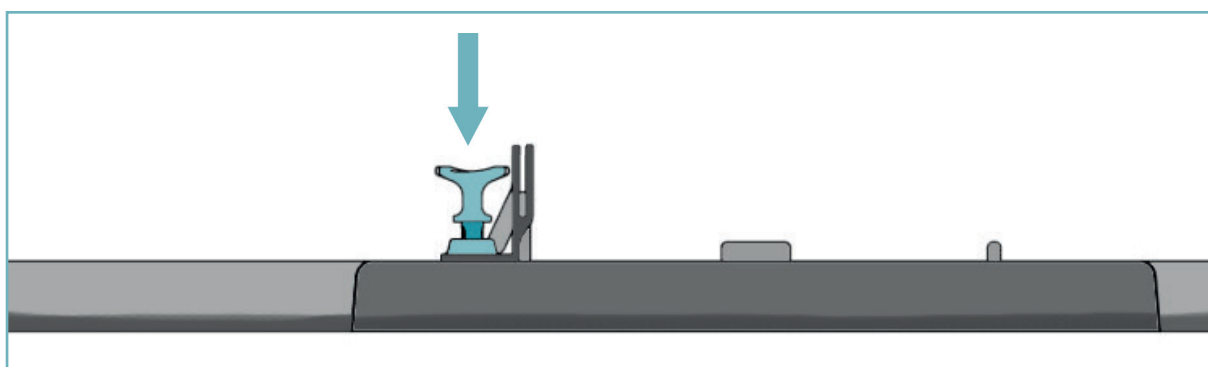
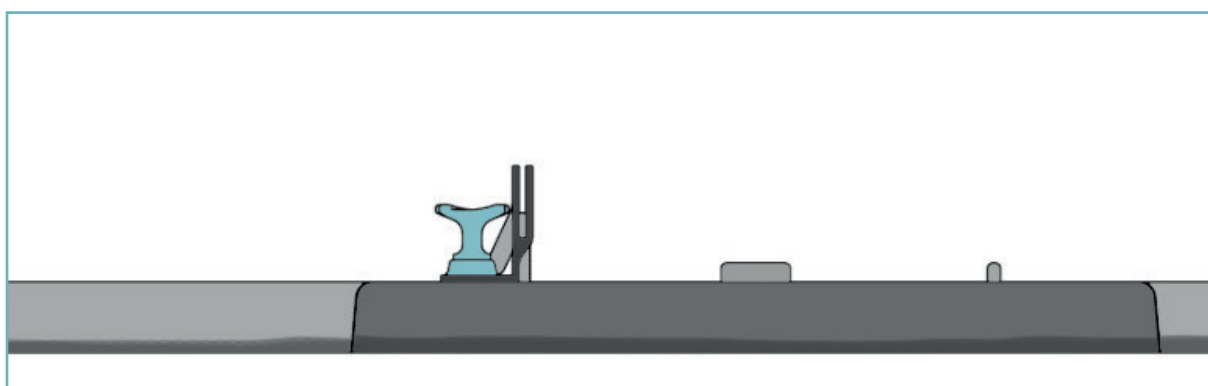8. When completely cooled, remove the mask.

5.5 FASTENING THE PROFILES

I. Place the Profile perpendicular to the baseplate and align the Plungers with the holes in the baseplate.
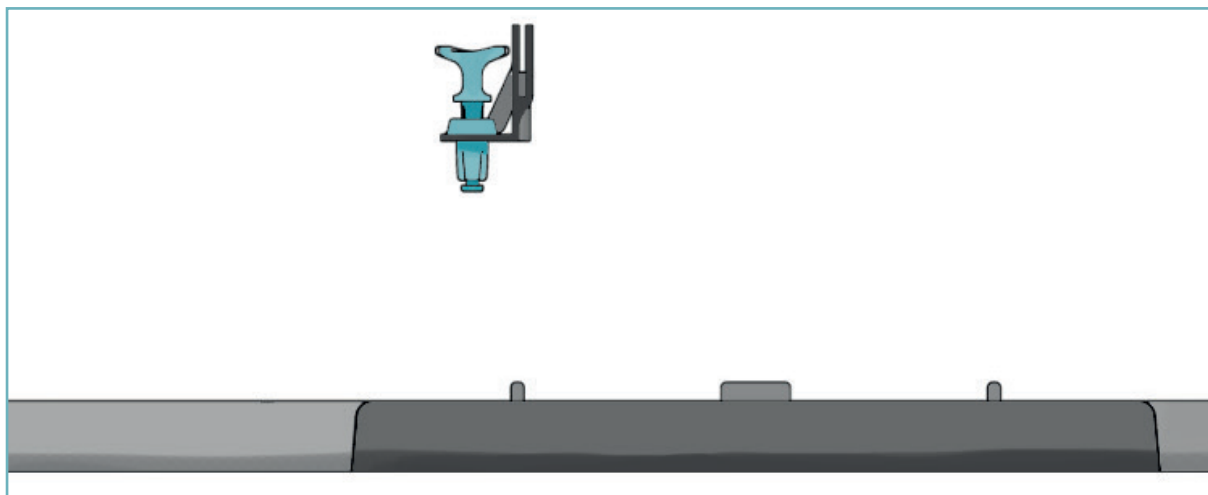

II. Place the Plungers in the holes.

III. Press the Plungers to lock.
When resistance is noticed, remove the Profile and position it again.

5.6   Removing the Profiles

I.   Always start with the head Profiles, then the shoulders.

II.   Press on the middle of the Profile.

III.   Use your other hand to release all Plungers.
Do not pull too hard! This will lock the Profile.

IV.   Set the plungers in released position during storage.

Released Position   **Locked Position**   **Incorrect Position (locked)**
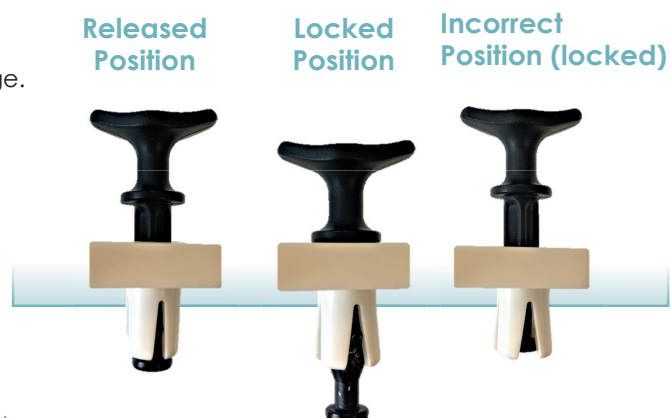
When removing the profiles becomes difficult:

• Clean the baseplate holes with a cotton bud.

• Spray Teflon spray in the hole.

• Remove residual teflon spray from the hole.

PULL   PUSH   PULL
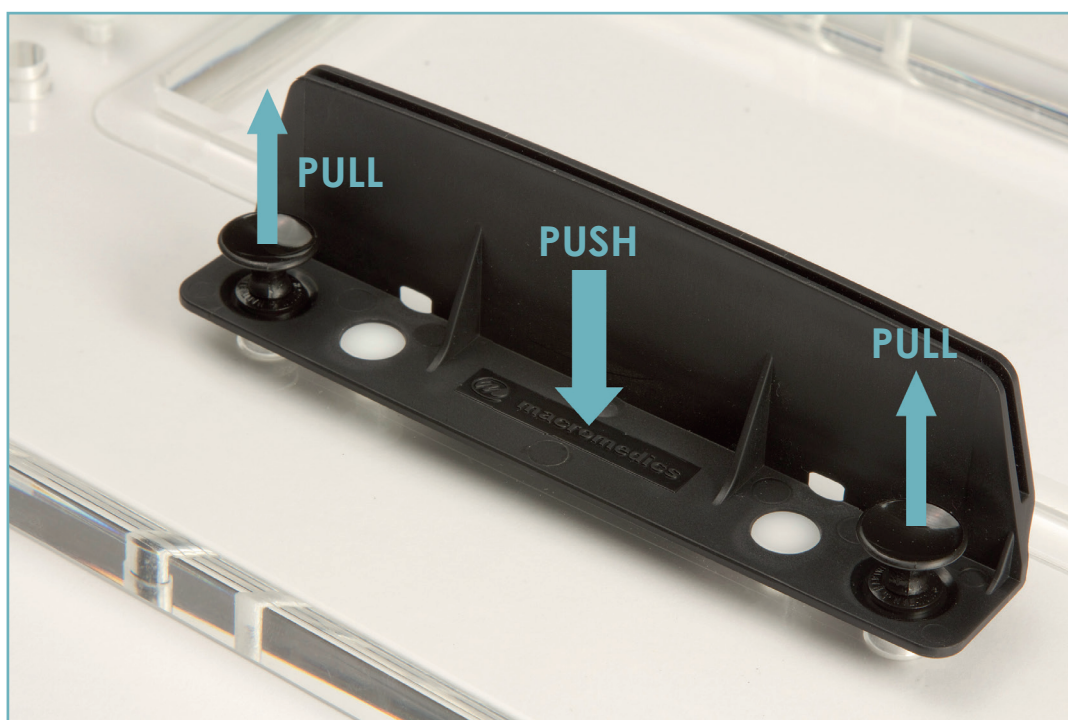
6. Cleaning, Storage and Disposal

- 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.
- Make sure that there is no residue of the cleaning agent left on the device prior to use.
- 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 Plunger image on page 9).
- Dispose of the device in accordance with the local laws and regulations applicable to your country.

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
CE	European Conformity	EC declaration of conformity by manufacturer.
(factory symbol)	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.
(booklet symbol)	Consult Instruction for Use	Indicates the need for the user to consult the instructions for use.
(triangle warning symbol)	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.
(umbrella symbol)	Keep Dry	Indicates a medical device that needs to be protected from moisture.
(sun symbol)	Keep Away from Sunlight	Indicates a medical device that needs protection from light sources.
(hourglass symbol) 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	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 crossed out symbol)	MR Unsafe	An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
(single patient multiple use symbol)	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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