



macromedics

SOLUTIONS IN RADIOTHERAPY

MANUAL 153100
Instructions for use
English Instructions

MacroMedics® Bolus Material



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1. Warnings



- Inspect the product prior to use. Do not use the product when damage is detected.
- Do not expose the product to UV rays, direct or indirect sunlight.
- The 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.
- After heating, test the temperature of the bolus material before placing it on the patient.
- Ensure that the thermoplastic material is not too hot for skin contact before placing it on the patient.
- Do not remove the thermoplastic material from the patient until the material has cooled completely. Removing the Thermoplastic material before it has set may result in material 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

The following devices are MR Safe:

- 153210 MacroCast non-perfo Bolus 3,2 mm
- 153220 MacroCast non-perfo Bolus 4,8 mm



3. Intended Use

The Bolus material is intended for use in radiotherapy as a flexible, tissue-equivalent thermoplastic sheet to conform to patient contours.

4. Non-Perfo Thermoplastic Bolus Material

- This thermoplastic Bolus material is ideal for hard-to-bolus areas and any irregular surfaced anatomical features, softening when heated and becoming moldable for a perfect fit.
- To create thicker layers of Bolus, different layers of heated (sticky) thermoplastic Bolus can be placed on top of each other. Material can be cut when soft. Use plastic wrap (or equivalent) between the thermoplastic layers to avoid sticking to each other.
- Ensure to dry the material thoroughly with towels after it comes out of the water bath.
- Use a hairnet (or equivalent) on the patient's hair to avoid sticking.

4.1 TECHNICAL PROPERTIES AND PROCESSING REQUIREMENTS

Thickness:	3.2 mm	4.8 mm
Colour	Orange	Orange
Waterbath or oven temperature:	65-70 degrees Celsius.	65-70 degrees Celsius.
Time in the waterbath:	3 minutes	6 minutes
Time in the oven:	10 minutes	16 minutes
Cool down time:	10-12 minutes	10-12 minutes

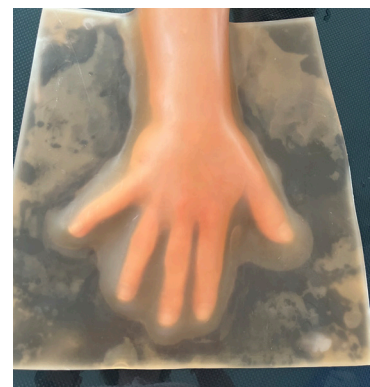
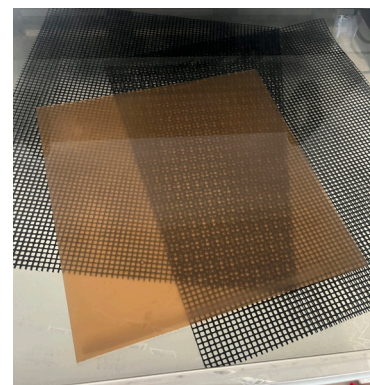
Indication for attenuation:

- 0,5% absorption per mm Bolus at 6MV
- 0,35% absorption per mm Bolus at 10MV

4.2 USAGE INSTRUCTIONS



1. Warm the Bolus to the specified temperature for the recommended duration. Watch for an even change in color, and ensure it reaches a transparent state.
2. Ensure to dry the material thoroughly with towels after it comes out of the waterbath and before skin application to avoid skin burns. Excess moisture can create airbubbles, so be sure the area is free from water. After heating, test the temperature of the Bolus material before placing it on the patient. Ensure the product is not too hot to burn the skin when coming out of the oven or waterbath.
3. Gently mold the Bolus; gravity will assist in the molding process.
4. The material will cool and harden gradually due to its thickness. Cool packs might cause deformation of the Bolus material when used to speed up the cooling process.



5. Cleaning, Storage and Disposal

5.1 CLEANING INSTRUCTIONS FOR NON-PERFO THERMOPLASTIC BOLUS MATERIAL

- 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.
- 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 products left on the device prior to use.
- The devices are not suitable for sterilization or thermal disinfection. Dry properly.

5.2 STORAGE

- Products should be stored in a clean, dry environment protected from direct sunlight exposure.
- Products are best stored flat. Avoid stacking and mounting in piles whenever possible.
- Prevent storing products where contact with sharp objects, edges or other items is likely to occur.

5.3 DISPOSAL

- Use before date specified on the packaging.
- Bolus material shall be disposed after the patient's treatment.
- Dispose of the product in accordance with the local laws and regulations applicable to your country.

6. 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.

7. 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.

8. 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.
	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.
	Medical device	Indicates the item is a medical device.
	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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