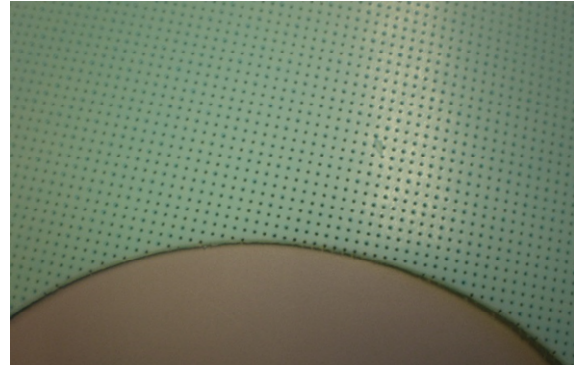


HIGH PRECISION ORFIT® OCEAN GREEN THERMOPLASTIC MATERIAL FOR PATIENT IMMOBILIZATION

ORFIT® OCEAN GREEN

THERMOPLASTIC MATERIAL
WITH ANTIBACTERIAL COATING
FOR PATIENT IMMOBILISATION
IN RADIATION ONCOLOGY



A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices, used for patient positioning and immobilisation in radiation therapy.

These instructions apply for all the products that carry the brand name ORFIT OCEAN GREEN.

B. PRODUCT DESCRIPTION

ORFIT OCEAN GREEN is a specially formulated low melting temperature thermoplastic for patient immobilisation in radiation oncology applications and it therefore has controlled performance characteristics. It is easy to mould and use and it can be shaped very closely to the patient's anatomy, providing excellent reproducibility and patient comfort. This results in a high precision and comfortable patient immobilisation mask. It exhibits a controlled stretch, that provides for fixation force. ORFIT OCEAN GREEN has a non-stick antibacterial coating to prevent sticking to the patient's hair and skin. It is available in pre-cuts and sheets of different thicknesses and types of perforation. Please consult our catalogue for a complete overview of all pre-cuts and sheets available.

C. PRECAUTIONS FOR USE

1. The workplace must be well-ventilated.
2. A water bath is filled with water and set at the right temperature of 65°C (149°F). A small amount of liquid soap can be added in order to soften the water.
3. When refitting a mask for each fraction, always verify that the devices are positioned correctly on the hardware parts.
4. Check the temperature of a mask before moulding it on a patient.

D. METHOD OF ACTIVATION AND APPLICATION

1. Place ORFIT OCEAN GREEN in a water bath at a temperature of 65°C (149 °F). This is the ideal softening temperature. **Do not heat ORFIT OCEAN GREEN above 80°C (176°F). Do not heat ORFIT OCEAN GREEN longer than 20 minutes. When using a heat gun, do not exceed the temperature of 250°C (482°F) to avoid breakdown of the material. Never use an open flame to activate ORFIT OCEAN GREEN.**
2. Place the patient in the correct treatment position on the suitable positioning devices (base plate, head supports, blocks, wedges, cushions, etc.).
Observe the following minimum heating times to obtain ideal working properties:

ORFIT OCEAN GREEN 1.6 mm	3 minutes
ORFIT OCEAN GREEN 2.0 mm	3 minutes
ORFIT OCEAN GREEN 3.2 mm	4 minutes

Use a timer to check the above heating time.

3. Observe the heating time closely, then take the ORFIT OCEAN GREEN out of the water and dry it on a towel. Work swiftly. The time between taking ORFIT OCEAN GREEN out of the water bath and placing it on the patient should not exceed 15 seconds.
4. Apply ORFIT OCEAN GREEN on the patient. Pre-stretch both lateral sides of the mask slightly above the patient (depending on the size of the patient and the used positioning tools like blocks, wedges, cushions, etc.) before securing it to the base plate. This will result in an even stretch of the mask material and hence a higher stability of the mask.
5. Mould the ORFIT OCEAN GREEN around the patient's contours and try to incorporate as many hard body points (nose bridge, chin, hip bone, etc.) in the mask as these are the ideal reference points during the application of the mask.
6. Continue moulding until the ORFIT OCEAN GREEN has regained its original color and becomes firm. This takes from 1 to 2 minutes, depending on the temperature in the room.
7. **Leave the ORFIT OCEAN GREEN mask on the patient for another 5 minutes to allow it to harden completely.** Then remove it and store it in a safe place until needed for treatment.
8. If necessary, holes can be made for the eyes, the nose and the mouth and the indicated irradiation fields. Use a pair of scissors or a knife.
9. Treatment fields can be indicated on the mask by sticking pieces of tape on the mask and by drawing lines with a marker. A narrow piece of colored tape (1.5 mm) can also be used.

E. STORAGE

Always store the ORFIT OCEAN GREEN sheets, pre-cuts and finished masks in a dry place at a temperature of min. 10°C (50°F) and max. 30°C (86°F).
Sheets and pre-cuts must be stored in their original packaging.

F. DOSIMETRIC PROPERTIES

The ORFIT OCEAN GREEN thermoplastics are materials with a density of 1.13 g/cm³.

Attenuation (at 6 and 10 MV) and skin build-up (SBU) values:

Type	Attenuation ($\pm 0.15\%$)		SBU ($\pm 0.1\text{ mm}$)
	6 MV	10 MV	mm H ₂ O equiv.
1.6 mm micro	0.40 %	0.20 %	1.7
2.0 mm maxi	0.40 %	0.10 %	1.7
2.0 mm micro	0.40 %	0.20 %	2.2
3.2 mm maxi	0.90 %	0.25 %	2.9

Note: Use these numbers as a guidance only. Perform the measurements again in your department to verify these results.

G. MAINTENANCE AND WASTE MANAGEMENT

These products can be cleaned and disinfected by means of soapy water or an isopropanol based disinfectant, applied with a soft cloth. If unsure about the cleaning fluid, do not use. **Never use aerosol sprays, corrosive cleaning agents, solvents or abrasive detergents.**

Contact your distributor if there are any questions or concerns. The products can be disposed of with household waste. ORFIT OCEAN GREEN is biodegradable.

H. ADDITIONAL INFORMATION

For additional information such as distributor contact information, product brochures, Safety Data Sheets and regulatory information, please visit our website www.orfit.com.

Note:

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ORFIT INDUSTRIES
Vosveld 9A | B-2110 Wijnegem | Belgium
T (+32) (0)3 326 20 26
welcome@orfit.com

www.orfit.com



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