



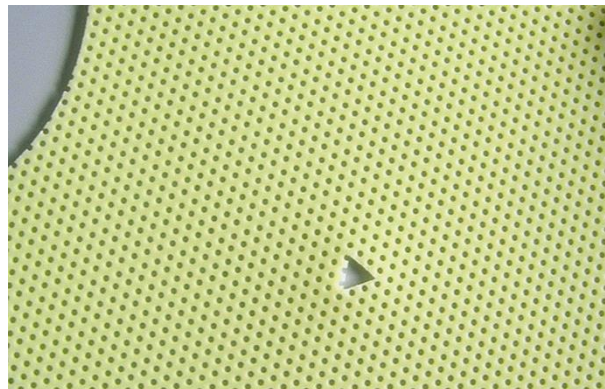
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RAYCAST® HIGH PRECISION EFFICAST® AND PELVICAST™ THERMOPLASTIC MATERIAL FOR PATIENT IMMOBILISATION

INSTRUCTIONS FOR USE

EFFICAST®/PELVICAST™

THERMOPLASTIC MATERIAL
 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 EFFICAST/PELVICAST.

B. PRODUCT DESCRIPTION

EFFICAST/PELVICAST 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. These thermoplastic pre-cuts have a new and innovative non-stick surface coating with antibacterial properties. The coating is applied on both sides of the mask surface and contains nano-silver particles that stop bacteria from growing on the plastic material. As such the masks have an inherent property that can play an important role in reducing the spread of harmful microbes in a hospital environment. EFFICAST/PELVICAST are 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 between 65°C and 70°C (149°F and 158°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 EFFICAST/PELVICAST in a water bath at a temperature between 65°C and 70°C (149 °F and 158°F). This is the ideal softening temperature.
Do not heat EFFICAST/PELVICAST above 80°C (176°F). Do not heat EFFICAST/PELVICAST longer than 30 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 EFFICAST/PELVICAST.
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:

EFFICAST 1.6 mm	3 minutes
EFFICAST 2.0 mm	3 minutes
EFFICAST 2.4 mm	4 minutes
EFFICAST 3.2 mm	4 minutes
HYBRID	4 minutes
PELVICAST	4 minutes

Use a timer to check the above heating time.

3. Observe the heating time closely, then take the EFFICAST/PELVICAST out of the water and dry it on a towel. Work swiftly. The time between taking EFFICAST/PELVICAST out of the water bath and placing it on the patient should not exceed 15 seconds.
4. Apply EFFICAST/PELVICAST 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.

- Mould the EFFICAST/PELVICAST 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. When moulding an 'open face hybrid' mask hold one hand gently on the forehead to prevent the mask from slipping backwards.
- Continue moulding until the EFFICAST/PELVICAST has regained its original colour and becomes firm. This takes from 1 to 2 minutes, depending on the temperature in the room.
- Leave the EFFICAST mask on the patient for minimum 10 minutes and the PELVICAST mask for minimum 15 minutes** to allow it to harden completely. Then remove it and store it in a safe place until needed for treatment.
- Make sure the mask contains the identification details of the patient (name of the patient, type of head support and type of block and wedge).
- 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.
- 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 coloured tape (1.5 mm) can also be used.

E. DOSIMETRIC PROPERTIES

The EFFICAST/PELVICAST thermoplastics are materials with a density of 1.13 g/cm³.

Attenuation (at 6 and 15 MV) and skin build up (SBU) values:

Type	Attenuation (± 0.15%)		SBU (± 0.1 mm) mm H ₂ O equiv.
	6 MV	15 MV	
1.6 mm micro	0.40 %	0.20 %	1.7
2.0 mm maxi	0.40 %	0.20 %	1.7
2.0 mm micro	0.45 %	0.25 %	2.2
2.4 mm maxi	0.50 %	0.35 %	2.3
3.2 mm maxi	0.70 %	0.45 %	2.9
Hybrid	0.65 %	0.45 %	3.0

The L-shaped profiles used to attach the mask to the base plates have the following dosimetric properties:

Attenuation factor (± 0.13 %)	
6 MV	0,73 %
15 MV	0,53 %
Skin Dose	2,4 mm H ₂ O equivalence

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

F. STORAGE

Always store the EFFICAST/PELVICAST 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). The humidity should be maximum 70 %. Sheets and pre-cuts must be stored in their original packaging.

G. MAINTENANCE AND WASTE MANAGEMENT

These products can be cleaned and disinfected by means of soapy water or an isopropanol or ethanol 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.**

Cleaning the pre-cuts on a regular base will also remove the layer of dead bacteria that may have formed on the surface of the mask. This will expose fresh surface with a renewed anti-bacterial activity.

The products can be disposed of with household waste.

EFFICAST/PELVICAST is biodegradable.

Contact your distributor if there are any questions or concerns.

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.

The instructions were written in accordance with the European Directive 93/42/EEC for Medical Devices. It is prohibited to make alterations to this text without prior approval from ORFIT Industries.

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Listed with



THERMOPLASTIC ACTIVATION

Thickness: 1.2 mm, 1.6 mm & 2.0 mm masks		Thickness: 2.4 mm, 3.2 mm & hybrid masks
 Activation temperature: between 65°C and 70°C (between 149°F and 158°F)	 Activation temperature: between 65°C and 70°C (between 149°F and 158°F)	 Activation temperature: between 65°C and 70°C (between 149°F and 158°F)
 Heating time: min. 3 minutes max. 30 minutes	 Heating time: min. 3 minutes max. 30 minutes	 Heating time: min. 4 minutes max. 30 minutes
 Drying: max. 10 seconds	 Drying: max. 10 seconds	 Drying: max. 10 seconds
 Modelling time: 1 to 1.5 minutes	 Modelling time: 1 to 1.5 minutes	 Modelling time: 1 to 1.5 minutes
 Hardening time: minimum 10 minutes	 Hardening time: minimum 10 minutes	 Hardening time: minimum 10 minutes