### INSTRUCTIONS FOR USE



## RAYCAST® HIGH PRECISION U-PLAST

# THERMOPLASTIC MATERIAL FOR PATIENT IMMOBILISATION



### A. GENERAL PRODUCT INFORMATION

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

The products may only be used in combination with positioning hardware produced by Orfit. Orfit prohibits the use of unauthorized third-party products in conjunction with its own products.

### B. PRODUCT DESCRIPTION

U-PLAST thermoplastic sheets are made from a specially formulated low melting temperature thermoplastic meant for patient immobilisation in radiation oncology applications and they therefore have 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 sheets have an innovative non-stick surface coating with antibacterial properties. The coating is applied on both sides of the sheet surface and contains Nanosilver particles that stop bacteria from growing on the plastic material

As such the sheets have an inherent property that can play an important role in reducing the spread of harmful microbes in a hospital environment.

U-PLAST 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

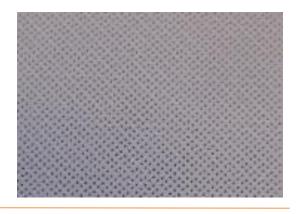
### C. PRECAUTIONS FOR USE

- 1. The workplace must be well-ventilated.
- 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.
- Check the temperature of a mask before moulding it on a patient.
- When refitting a mask for each fraction, always verify that the devices are positioned correctly on the hardware parts.
- 5. These thermoplastic masks are for single patient use only.

### D. HOW TO USE U-PLAST

 Place U-PLAST 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 U-PLAST above 80°C (176°F). Do not heat U-PLAST 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 the thermoplastic material.

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:

U-PLAST 2.4 mm	3 minutes	
U-PLAST 3.2 mm	4 minutes	

### Use a timer to check the above heating time.

- 3. Observe the heating time closely, then take the U-PLAST out of the water and dry it on a towel. Work swiftly. The time between taking U-PLAST out of the water bath and placing it on the patient should not exceed 15 seconds since the material will start cooling and hardening.
- 4. Apply U-PLAST 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 U-PLAST around the patient's contours and try to incorporate as many hard body points, such as the nose bridge and the chin, in the mask as these are the ideal reference points during the application of the mask.
- Continue moulding until the U-PLAST has regained its original colour and becomes firm. This takes from 1 to 2 minutes, depending on the temperature in the room.
- Leave the U-PLAST mask on the patient for another 10
  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.
- 10. 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 U-PLAST thermoplastics are materials with a density of 1.13  $\,\mathrm{g/cm^3}$ .

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

Туре -	Attenuation (± 0.15 %)		SBU (± 0.1 mm)
	6 MV	15 MV	mm H₂O equiv.
2.4 mm maxi	0.50 %	0.35 %	2.3
3.2 mm maxi	0.70 %	0.45 %	2.9

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

### F. STORAGE

Always store the U-PLAST sheets, pre-cuts and finished masks in a dry place at a temperature of min.  $10^{\circ}\text{C}$  ( $50^{\circ}\text{F}$ ) and max.  $30^{\circ}\text{C}$  ( $86^{\circ}\text{F}$ ). 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. U-PLAST is biodegradable.

All profiles are made of a material that can be recycled. 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 <a href="www.orfit.com">www.orfit.com</a>.

# 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) Heating time: min. 3 minutes max. 30 minutes Modelling time: 1 to 1.5 minutes Modelling time: 1 to 1.5 minutes Hardening time: minimum 10 minutes Minutes Markening time: minimum 10 minutes

### Note:

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