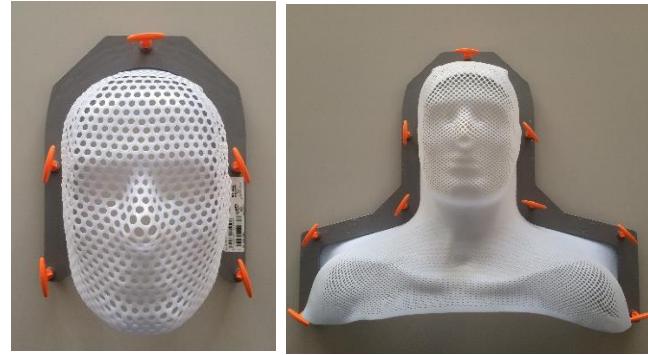




The  
precision  
expert

# INSTRUCTIONS FOR USE

## RAYCAST® DUON® HEAD AND HEAD, NECK AND SHOULDER MASKS THERMOPLASTIC MASKS 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 DUON.

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™, the material used for DUON immobilisation masks, 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.

This thermoplastic material has an innovative non-stick surface coating with antibacterial properties. The coating is applied on both sides of the mask surface and stops 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.

DUON masks are available with thermoplastics of different thicknesses and types of perforation. It comes in Head only formats but also in Head, Neck and Shoulder versions. Please consult our catalogue for a complete overview of all masks 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.  
When using a dry heat oven, preheat the oven to 75°C (167°F).
3. Check the temperature of a mask before moulding it on a patient.
4. 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.

6. The grey inserts in the frame that accept the orange T-shaped pins to fix a mask to the base plate, are pre-mounted. The orange T-shaped pins itself still need to be inserted. Every mask is provided with a bag of T-shaped pins. Insert the T-shaped pins for all holes in the frame.



#### Important!

Check if all the T-shaped pins are in the 'up' position (unlocked) before mounting to the base plate.

If an insert or peg should break, it can be replaced. First remove the peg. You might have to open up the lips of the insert slightly. Next push the two lips that have a barb (indicated by the red arrow) inwards and remove the insert.



#### D. HOW TO USE THE DUON®-FRAME

1. Place the DUON mask in a water bath at a temperature between 65°C and 70°C (149 °F and 158°F). This is the ideal softening temperature.  
Place the DUON mask in the dry heat oven at 75°C (167°F). **Do not heat the mask above 80°C (176°F). Do not heat the mask 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 DUON.**
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:

	Water bath	Dry heat oven
DUON 2.4 mm	3 minutes	13 minutes
DUON Head 3.2 mm	4 minutes	14 minutes
DUON HNS 3.2 mm	4 minutes	16 minutes
DUON Hybrid	4 minutes	15 minutes

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

3. Observe the heating time closely, then take the DUON mask out of the water and dry it on a towel. Work Swiftly. The time between taking DUON out of the water bath and placing it on the patient should not exceed 10 seconds since the material will start cooling and hardening.  
When taking DUON masks out of a dry heat oven, the mask can be placed directly on to the patient, but make sure the mask is not too warm.
4. Stand behind the patient and centre the DUON-frame over the patient's face. Starting under the chin, gently pull the frame towards you over the face and head of the patient and down to the base plate. Make sure all the pins are properly inserted in the base plate.
5. Mould the DUON 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.
6. Continue moulding until the DUON has regained its original colour and becomes firm. This takes from 1 to 2 minutes when using a water bath and 4 to 6 minutes

when using a dry heat oven, depending on the temperature in the room.

7. **Leave the DUON mask on the patient for minimum 10 minutes** to allow it to harden completely. Hardening of 10 minutes is necessary, irrespective of heating method. Then remove the mask and store it in a safe place until needed for treatment.
8. 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).
9. 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 DUON thermoplastics are materials with a density of 1.13 g/cm<sup>3</sup>.

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

Type	Attenuation ( $\pm 0.15\%$ )		SBU ( $\pm 0.1\text{ mm}$ ) mm H <sub>2</sub> O equiv.
	6 MV	15 MV	
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 DUON pre-cuts and finished masks in a dark and dry place at a temperature of min. 10°C (50°F) and max. 30°C (86°F). The humidity should be maximum 70%. Pre-cuts must be stored in their original packaging.

#### G. MAINTENANCE AND WASTE MANAGEMENT

These products can be cleaned and disinfected by means of 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. DUON is biodegradable.

The DUON-frames 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 distributors contact information, product brochures, Safety Data Sheets and regulatory information, please visit our website [www.orfit.com](http://www.orfit.com).

##### Note:

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