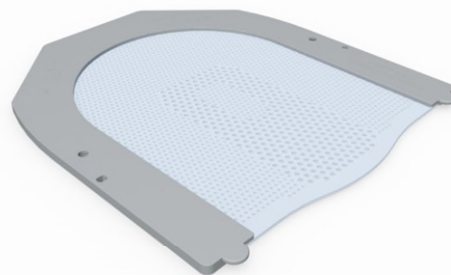


## UON® HEAD MASKS THERMOPLASTIC MASKS FOR PATIENT IMMOBILISATION IN RADIATION ONCOLOGY



### 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 UON.

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™ 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 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.

The UON® Head Mask is available in different thermoplastic configurations: the thickness, perforation style and length of the thermoplastic material differ. See our brochures or website for more information on the types 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.

### D. HOW TO USE THE UON®-FRAME

1. Place the 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 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 the thermoplastic material.**
2. Place the patient in the correct treatment position on the suitable positioning devices (base plate, head supports, blocks, wedges, cushions, etc.). Make sure that all four locking levers of the base plate are in the open position. Observe the following minimum heating times to obtain ideal working properties:

|            | Water bath | Dry heat oven |
|------------|------------|---------------|
| UON 2.4 mm | 3 minutes  | 13 minutes    |
| UON 3.2 mm | 4 minutes  | 14 minutes    |
| UON hybrid | 4 minutes  | 15 minutes    |

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

Observe the heating time closely, then take the UON® out of the water and dry it on a towel. Work Swiftly. The time between taking UON® 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 UON® 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.

3. Stand behind the patient and centre the UON®-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.
4. Hold the UON®-frame with U-PLAST™ in position whilst locking the four levers. The slanting edges, which are an integral part of the specific design of the UON®-frame, enable the smooth swivelling of the 4 locking levers over the frame.
5. After the UON®-frame with U-PLAST™ has been fixed onto the base plate, and during the hardening process of the thermoplastic, gently mould the softened 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.

6. Continue moulding until the U-PLAST™ 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 UON® 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 U-PLAST™ 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<br>(± 0.15 %) |        | SBU<br>(± 0.1 mm)          |
|-------------|---------------------------|--------|----------------------------|
|             | 6 MV                      | 15 MV  | mm H <sub>2</sub> O equiv. |
| 2.4 mm maxi | 0.50 %                    | 0.35 % | 2.30                       |

|             |        |        |      |
|-------------|--------|--------|------|
| 3.2 mm maxi | 0.70 % | 0.45 % | 2.90 |
|-------------|--------|--------|------|

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

#### F. STORAGE

Always store the UON® 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 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.

The UON®-frame is 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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