orfit The precision expert

THERMOPLASTIC MATERIAL FOR PATIENT IMMOBILISATION HP PRO® SOLUTION

Head masks

Article Nos. **25100/16MI+N**
25100/16MI+N/NH
25100/2MI+
25100/2MI+/NH
25101/16MI+N
25101/16MI+N/NH
25103/16MI+N/NH

Head, Neck and Shoulder Masks

Article Nos. **25105/2MI+N**
25105/2MI+N/NH
25105/2MI+
25105/2MI+/NH
25106/2MI+N
25106/2MI+N/NH
25107/2MI+N/NH

A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices, used for patient positioning and immobilisation in radiation therapy. The Efficast® and Nanor® thermoplastic masks for the HP PRO Solution are used to retain and reproduce a patient's position during 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

Efficast and Nanor are specially formulated extra thin low melting temperature thermoplastic materials 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 a comfortable patient immobilisation mask.
These thermoplastic pre-cuts have an innovative non-stick surface coating.
The masks for the HP PRO Solution are available in different thicknesses and types of perforation. Please consult our catalogue or website for a complete overview of all pre-cuts 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 the mask before moulding it on a patient.
5. These thermoplastic masks are for single patient use only.
6. It is a product available on prescription only.
7. If the patient has medium to long hair it is helpful to add a hair cover. This will automatically clear the areas where the mask profiles must be attached. It provides more time to mould the mask and prevents hair getting stuck in between the mask profile connection.

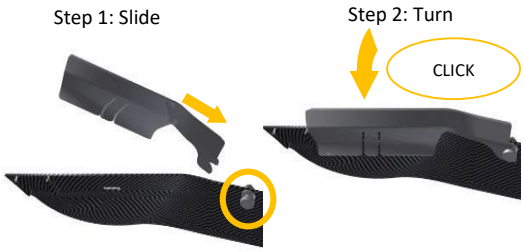
D. METHOD OF ACTIVATION AND APPLICATION

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.
   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 material.
2. Place the patient in the correct treatment position on the suitable positioning devices (base plate, head supports, cushions, etc.).
   Observe the following minimum heating times to obtain ideal working properties:

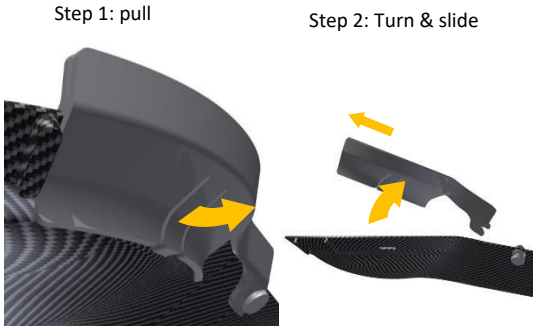
NANOR 1.6 mm	3 minutes
NANOR 2 mm	3 minutes
EFFICAST 2.0 mm	3 minutes

   Use a timer to check the above heating time.
3. Observe the heating time closely, then take the mask out of the water and dry it on a towel. Work swiftly. The time between taking the thermoplastic material out of the water bath and placing it on the patient should not exceed 15 seconds.
4. Apply the mask 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 e.g. cushions) 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. To secure the mask to the base plate you have to work in a few steps. First slide the caudal side of the lateral profiles next to the head over the indexing pin and secondly swivel the profile inwards until it clicks over the base plate.



6. Then attach the cranial profile by sliding it over the cranial end of the base plate until it clicks over the base plate.
7. When moulding a 5-points mask, secure the 2 shoulder profiles after you have secured the cranial profile, be sliding them over the base plate until they click into it.
8. Mould the mask around the patient's contours and try to incorporate the hard body points, such as the nose bridge and chin, in the mask as these are the ideal reference points during the application of the mask.
9. Continue moulding until the mask has regained its original colour and becomes firm. This takes from 1 to 2 minutes, depending on the temperature in the room.
10. **Leave the 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.
11. To remove the mask you will have to work in steps again. First remove the cranial and shoulder profiles by pulling the handles of the profile out of the base plate and sliding them of the base plate.
    Then remove the lateral profiles by pulling the handle upwards and turning the profile outwards of the base plate, then you can slide the profile of the indexing pin.



12. 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).
13. 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.
14. 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 thermoplastics are materials with a density of 1.13 g/cm³. The Nanor thermoplastics are materials with a density of 1.17 g/cm³.

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

Type	Attenuation (± 0.15 %)		mm H_2O equiv.
	6 MV	15 MV	(± 0.1 mm)
Nanor 1.6 mm micro+	0.46 %	0.32 %	1.56
Efficast 2.0 mm micro	0.45 %	0.25 %	2.2

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

F. STORAGE

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

G. MAINTENANCE AND WASTE MANAGEMENT

These products can be cleaned by means of water 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 is recommended when contamination can be seen on the mask.
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.
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.

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