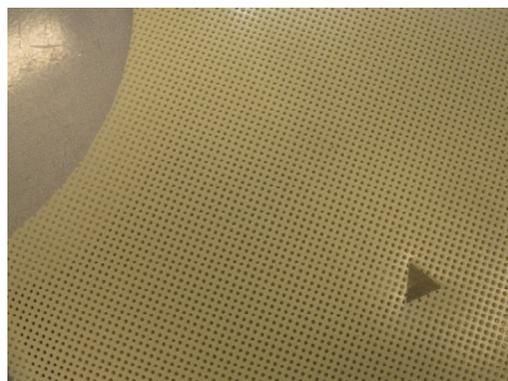


NANOR® THERMOPLASTIC MATERIAL FOR PATIENT IMMOBILISATION

NANOR MASK & HYBRID MASK WITH NANOR



A. GENERAL PRODUCT INFORMATION

The products referred to in these instructions are medical devices, used for patient positioning and immobilisation in radiation therapy. The NANOR thermoplastic material is used to retain and reproduce a patient's position during radiation therapy.

These instructions apply for all the products that carry the brand name NANOR.

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

NANOR is a specially formulated extra thin low melting temperature thermoplastic for patient immobilisation in radiation oncology applications and it therefore has controlled performance characteristics. The material is reinforced with nano-particles, which gives it a high stability even for the very thin masks. 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. NANOR is available in pre-cuts and sheets of different thicknesses and types of perforation. Hybrid masks that consist out of an Efficast pre-cut with a Nanor reinforcement laser welded to it, are also available. Please consult our catalogue or website 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. When using an oven, the temperature should be set at 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. It is a product available on prescription only.

D. HOW TO USE NANOR

1. Place NANOR in a water bath at a temperature between 65°C and 70°C (149 °F and 158°F) or in an oven at a temperature of 75 °C (167 °F). These are the ideal softening temperatures.

When heating a Nanor Hybrid mask in a water bath, make sure that the Nanor part is facing upwards. Do not heat NANOR above 80°C (176°F). Do not heat NANOR 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 NANOR.

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	
NANOR 1.2 mm	3 minutes
NANOR 1.6 mm	3 minutes
NANOR 2.0 mm	3 minutes
NANOR 2.4 mm	3 minutes
Hybrid (Efficast 16MI or 2MA + NANOR 12MI+)	4 minutes
Oven	
NANOR 1.6 mm	8 minutes
NANOR 2.0 mm	8 minutes
NANOR 2.4 mm	9 minutes
Hybrid (Efficast 16MI + NANOR 12MI+)	11 minutes
Hybrid (Efficast 2MA + NANOR 12MI+)	13 minutes

Use a timer to check the above heating time.

3. Observe the heating time closely, then take the NANOR mask out of the water and or oven. Towel dry the mask when using a water bath. 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 since the material will start cooling and hardening. When using an oven, first check the temperature before applying the mask on the patient's face.
4. Apply the NANOR 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 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.
5. Mould the NANOR 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.

6. Continue moulding until the mask has regained its original colour and becomes firm. This takes from 1 to 3 minutes, depending on the heating device and the temperature in the room.
7. **Leave the NANOR 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.
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

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 ₂ O equiv. (± 0.1 mm)
	6 MV	15 MV	
1.2 mm micro+	0.32 %	0.25 %	1.24
1.6 mm micro+	0.46 %	0.32 %	1.56
Hybrid (Efficast 16MI, NANOR 12MI+)	0.54 %	0.34 %	2.1

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 NANOR 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 an isopropanol 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 is recommended when contamination can be seen on the mask.

The products can be disposed of with household waste. NANOR is biodegradable.

All profiles are made of material that can be recycled. Contact your distributor if there are any questions or concerns.

H. PACKAGES

Mask 33792/2MA/12MI+N/NH is part of following SRS-Fix packages:

- 36403: SRS-Fix Consumable Package 1 – HP Profiles
- 36404: SRS-Fix Consumable Package 2 – HP Profiles

Mask 33793/2MA/12MI+N/NH is part of following SRS-Fix packages:

- 36405: SRS-Fix Consumable Package 3 – Push-pin Profiles
- 36406: SRS-Fix Consumable Package 4 – Push-pin Profiles

I. 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.

THERMOPLASTIC ACTIVATION TECHNIQUE

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

Note:

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