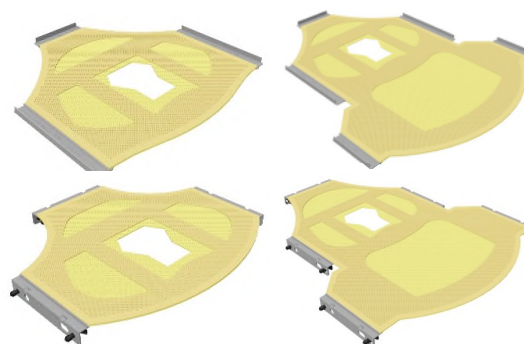


RAYCAST® HIGH PRECISION THERMOPLASTIC MATERIAL FOR PATIENT IMMOBILISATION 3- AND 5-POINTS OPEN FACE HYBRID MASK

Open Face Mask with HP Profiles
3-points and 5-points
Adult and Paediatric

Open Face Mask with Push-Pin Profiles
3-points and 5-points
Adult and Paediatric



A. GENERAL PRODUCT INFORMATION

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

B. PRODUCT DESCRIPTION

The open face hybrid mask leaves eyes, nose and mouth exposed. It is the ideal immobilization solution for brain and head & neck patients who suffer from claustrophobia. It is also compatible with modern motion management systems (F. Vision RT Compatible).

To create extra stability the mask is designed with 2 layers of thermoplastic material. The first layer is made from EFFICAST and the second layer from NANOR. These materials are specially formulated low melting temperature thermoplastics for patient immobilization in radiation oncology applications and they therefore have controlled performance characteristics.

They are easy to mould and use and 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 immobilization mask.

These thermoplastic pre-cuts have an innovative non-stick surface coating with antibacterial properties. The coating is applied on both sides of the mask surface and contains nano-silver particles that stop 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.

There are different mask designs.

Open Face Mask with HP Profiles Nanor reinforcement:

Article No.	Description
33759/16MI/12MI+N	3-pts HP mask
33782/16MI/12MI+N	3-pts HP Paediatric mask – Small
33783/16MI/12MI+N	3-pts HP Paediatric mask – Medium
33733/16MI/12MI+N	5-pts HP mask
33785/16MI/12MI+N	5-pts HP Paediatric mask – Small
33787/16MI/12MI+N	5-pts HP Paediatric mask – Medium
33735/16MI/12MI+N	5-pts HP Open Face and Neck mask
33796/16MI/12MI+N	3-pts HP Open Face mask for SRS
33798/16MI/12MI+N	5-pts HP Open Face mask for SRS
33800/16MI/12MI+N	3-pts HP open face mask with small aperture
33801/16MI/12MI+N	5-pts HP open face mask with small aperture

Open Face Mask with Push-Pin Profiles Nanor reinforcement:

Article No.	Description
33780/16MI/12MI+N	3-pts Push-Pin mask

33784/16MI/12MI+N	3-pts Push-Pin Paediatric mask – Small
33781/16MI/12MI+N	5-pts Push-Pin mask
33786/16MI/12MI+N	5-pts Push-Pin Paediatric mask – Small
33797/16MI/12MI+N	3-pts Push-Pin Open Face mask for SRS
33802/16MI/12MI+N	3-pts Push-Pin Open Face mask with small aperture
33803/16MI/12MI+N	5-pts Push-Pin Open Face mask with small aperture

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 an oven is used, the temperature should be 75 °C (167 °F).
4. When refitting a mask for each fraction, always verify that the devices are positioned correctly on the hardware parts.
5. Check the temperature of a mask before moulding it on a patient.
6. These thermoplastic masks are for single patient use only.
7. It is a product available on prescription only.

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) or an oven at a temperature of 75 °C (167°F). These are the ideal softening temperatures. Respect the minimum heating time of **4 minutes in the water bath and 11 minutes in the oven** to obtain ideal working properties.
Use a timer to check the above heating times.
For an open face mask with Nanor reinforcement, the Nanor reinforcement should be facing **upwards** in the water bath.
Do not heat the mask above 80°C (176°F). Do not heat it 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 mask
2. Place the patient in the correct treatment position on the suitable positioning devices (base plate, head supports, blocks, wedges, cushions, etc.).
3. When completely soft, take the open face mask out of the water and dry it on a towel.

Work swiftly. The time between taking the mask out of the water bath and placing it on the patient should not exceed 15 seconds.

4. Apply the mask on the patient. Use the forehead and chin as reference points. For the masks with small aperture, use the forehead and nose as reference points.



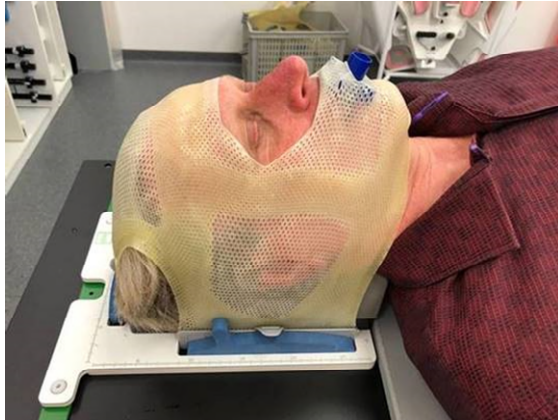
5. Insert the cranial flap while holding one hand gently on the forehead to prevent the mask from slipping backwards.



6. 2 other persons stand on each side of the patient and insert the lateral flaps while holding one hand gently on the reinforcement strip. This prevents the face opening from stretching too wide. Make sure the forehead part does not slide backwards while doing this.



7. For the open face SRS masks (33796/16MI/12MI+N, 33797/16MI/12MI+N & 33798/16MI/12MI+N), the hole for BiteFix bite block should be positioned over the protruding part of the BiteFix. Do not apply pressure on the bite block to avoid discomfort and pain on the teeth.



- For the 5-points masks, attach the shoulder profiles and make sure the mask covers the shoulders well.



- Mould the mask around the patient's chin, while holding one hand gently on the forehead. For the 5-points masks, mould the neck part gently with the back of your hand and push the shoulders down.



- 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.
- Leave the mask on the patient for another 10 minutes** to allow it to harden completely. **When using BiteFix, leave the mask on the patient for 15 minutes** to avoid discomfort when refitting the mask. 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).

- 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

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

Type	Attenuation (± 0.15%)		SBU (± 0.1 mm)
	6 MV	15 MV	mm H ₂ O equiv.
Mask with Nanor reinforcement	0.68 %	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. VISION RT COMPATIBLE

The Orfit Open Face Hybrid Masks are compatible for use with Vision RT products.



Vision RT recommends following guidelines regarding the opening size of the open face mask: It is important to use anatomical landmarks of the patient to ensure the opening size is ideal. For real-time tracking, including the cheeks, cheekbones and as much data possible down the hairline within the mask opening is ideal. The region of interest (ROI) should extend as laterally as possible to the anterior of the tragus (ear) and also include the brows and cheeks.

Please note following statements from Vision RT:

- Vision RT is unable to comment on, nor make claims, about the immobilization rigidity or patient alignment reproducibility when using this mask.
- Compatibility is subject to users following Orfit guidelines for forming open masks in conjunction with Surface Guided Radiotherapy Systems, and subject to users following Vision RT's guidelines for drawing Regions of Interest for use in SRS with Open Masks.
- The mask vendor is responsible for ensuring that users are in receipt of guidelines for forming masks for use in conjunction with Surface Guided Radiotherapy Systems. Vendors may change their guidelines from time to time without reviewing these changes with Vision RT. Vision RT is not liable for misuse of masks.
- Vision RT makes no comment on, and is not liable for, suitability or otherwise of masks for SRS or any other procedure.
- Purchasers are responsible for making their own choices as to the masks selected by them.

Visit the [website](#) for more information about Vision RT.

G. STORAGE

Always store the pre-cuts and finished masks in a dry place at a temperature of min. 10°C (50°F) and max. 30°C (86°F).

Sheets and pre-cuts must be stored in their original packaging.

H. 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.

The thermoplastic material is biodegradable. Contact your distributor if there are any questions or concerns.

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
 Activation temperature: between 65°C and 70°C (between 149°F and 158°F)		 Activation temperature: between 65°C and 70°C (between 149°F and 158°F)
 Heating time min. 3 minutes max. 30 minutes		 Heating time min. 4 minutes max. 30 minutes
 Drying: max. 10 seconds		 Drying: max. 10 seconds
 Modelling time: 1 to 1.5 minutes		 Modelling time: 1 to 1.5 minutes
 Hardening time: minimum 10 minutes		 Hardening time: minimum 10 minutes

Note:

33759/16MI/12MI+N
USA: UZ D704,3385
EU: 001322515-0001
CN: ZL201230491612.7

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