

ORFIGUARD

Orfit Colors Black NS

Article no 35903Z/NS

A. GENERAL PRODUCT INFORMATION

The product referred to in these instructions is a medical device, used for protection after a facial injury, fracture or other conditions which would require a protection of the nose, nose bridge or eye sockets. It is specifically suited to protect the nose bridge and surrounding tissues. The ORFIGUARD is a one-size-fits-all complete set, no specific measurements need to be taken for sizing.

B. PRODUCT DESCRIPTION

The ORFIGUARD is a specially formulated low melting temperature thermoplastic for facial protection during physical activity 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 protection mask. These thermoplastic pre-cuts have a new and innovative non-stick surface coating. The ORFIGUARD is available in a mask form. The mask consists of Orfit Colors Black NS.

C. PRECAUTIONS BEFORE USE

1. The workplace must be well-ventilated.
2. A water bath is filled with water and set at the right temperature of 65-70°C (169 - 176°F). A small amount of liquid soap can be added in order to soften the water.
3. Check the temperature of a mask before moulding it on a patient.

D. ACTIVATION TECHNIQUE

1. Place the ORFIGUARD in a water bath at a temperature of 65 - 70°C (169 - 176°F). This is the ideal softening temperature.
Do not heat the ORFIGUARD longer than 20 minutes.
Never use an open flame to activate the ORFIGUARD
2. Place the patient in a correct treatment position. Ideally this is the supine position for best access by the clinician. Observe the following minimum heating time to obtain ideal working properties:

ORFIGUARD	3 minutes
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Use a timer to check the above heating time.

3. Observe the heating time closely, then take the ORFIGUARD out of the water and dry it on a towel. Let the mask cool during 10 seconds.
4. Before applying the ORFIGUARD, check the temperature of the mask in order not to burn the patient. If needed, you can use the supplied Luxofoam as a spacer to generate enough space between nose and the medical device (thermoplastic material).
5. Mould the ORFIGUARD around the patient's contours and try to incorporate as many hard body points in the mask as possible as these are the ideal reference points during the application of the mask.
6. Continue moulding until the ORFIGUARD becomes firm. This takes 1 to 2 minutes, depending on the temperature in the room.
7. Leave the ORFIGUARD on the patient for another 5 minutes to allow it to harden completely. Then remove it and apply the connection strips (hook & loop tape) and store it in a safe place until needed for treatment.

E. WORKING PROPERTIES

Applying

1. Activate the ORFIGUARD until it is completely soft. Take the pattern out of the water and allow the surfaces to cool or dry on a towel for a few seconds.
Use the benefit of stretch and elastic properties of to a maximum.
2. Permanent adhesion of fixation straps and orthotic accessories is possible by dry heating the surface and by attaching under high pressure.

! In order to secure a self-adhesive bond, it is paramount that the self-adhesive glue and the thermoplastic masks are BRIEFLY DRY heated at high temperature (max. 250°C – 482°F).

3. Do not remove the orthosis from the patient before it is sufficiently hardened.
Excessive material should be trimmed before complete hardening. To do so, use a suitable pair of scissors.
The cooling time can be shortened by means of cold air, a cold bandage or a cold spray.

F. FINISHING

Trimming edges whilst the material is still relatively soft results in sealed edges. It is also possible to grind and polish the edges by using a coated abrasive wheel at low speed.

Attach Hook and loop straps according to the patient's anatomy and activity level. In case of pressure points, these can be treated by spot-heating the pressure area with a heat gun and by then pushing the material outward. Self-adhesive padding may also be applied on the inside of the ORFIGUARD.

G. MAINTENANCE AND WASTE MANAGEMENT

This product can be cleaned and disinfected by means of soapy water or 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 the pre-cuts on a regular basis will also remove the layer of dead bacteria that may have formed on the surface of the mask. Contact your distributor if there are any questions or concerns. The product can be disposed of with household waste.

H. ADVICE FOR THE PATIENT

! **Give the patient sufficient information about the exact use and possible constraints of the ORFIGUARD.**

I. STORAGE

- ORFIGUARD should be stored in its original packaging.
- Storage must be in a dark, cool, dry place at a temperature of min. 10°C (50°F) and max. 30°C (86°F).
- Once removed from the packaging, leftover materials must be put back in the original packaging to avoid biodegradation.

Low temperature thermoplastics can only be kept for a limited period of time and must be protected as much as possible from light, heat and humidity. The material ages in direct relation to storage conditions. When too old, materials become brittle and too soft when activated.

J. GENERAL SAFETY ADVICE

- ! * **ORFIGUARD is not suitable for internal use. It may not be used on open wounds or in the mouth.**
- ! * **Never use an open flame to activate ORFIGUARD.**
- ! * **ORFIGUARD may only be used by qualified health professionals.**

K. 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.

Note:

The instructions were written in accordance with the European Directive 93/42/EEC for Medical Devices. It is prohibited to make alterations to this text without prior approval from Orfit Industries. ORFIT® is a registered trademark of ORFIT INDUSTRIES N.V.



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