

ORFIGUARD

Orfit Colors Dominant Black NS 2mm Micro-Perforated Article Number: 35903Z/NS

A. GENERAL PRODUCT INFORMATION

The ORFIGUARD is designed to provide immediate facial protection during sports activities and following facial injuries, ensuring comprehensive protection for the nose, nose bridge, eye sockets, and surrounding tissues. This mask is ideal for athletes, as it helps prevent new injuries and provides instant support for existing facial injuries. Once applied, athletes can safely and confidently continue playing with the mask, ensuring continued protection.

Additionally, the ORFIGUARD is effective in protecting the nose, eye sockets, and surrounding tissues following facial surgeries, contributing to enhanced recovery post-surgery.

B. PRODUCT DESCRIPTION

The ORFIGUARD precut is a specially formulated thermoplastic made of Orfit Colors Dominant Black NS 2mm micro-perforated. With its low melting temperature, the ORFIGUARD precut offers controlled performance characteristics, ensuring ease of use, precise molding, and patient comfort.

Key Product Features:

- ❖ **Universal Fit:** The ORFIGUARD is designed to fit all face sizes (one-size-fits-all), without the need for specific measurements.
- ❖ **Durable Material:** made from top-quality materials
- ❖ **Comprehensive protection:** Covers nose, nose bridge, eye sockets, and surrounding tissues
- ❖ **Immediate Application:** Ready for activation and fitting, providing quick protection after molding.
- ❖ **Excellent Conformability and Precise Fitting:** Easily molded around the facial features for a perfect fit, yet can be remolded as needed.
- ❖ **Customizable:** Can be tailored to fit individual anatomical features perfectly.
- ❖ **Post-Operative Use:** Effective after facial surgeries, aiding post-operative protection and recovery.
- ❖ **Excellent Reproducibility:** Consistently provides reliable protection with each use.
- ❖ **Breathable Design:** Features micro-perforations for enhanced airflow and comfort.
- ❖ **Superior Comfort:** Designed to mold closely to the face, providing maximum comfort during wear.
- ❖ **Enhanced Stability:** Upgraded head strap design ensures a stronger, secure, and comfortable fit.
- ❖ **User-Friendly:** Simple to apply and adjust as needed.
- ❖ **Biocompatible:** Allergy-free, safe for skin contact, with a non-sticky and non-irritating surface
- ❖ **Portable:** Lightweight and easy to carry, making it convenient for on-the-go use.

ORFIGUARD Pack Contents:

1. **Thermoplastic Precut:**
One piece of precut made of
Orfit Colors Dominant Black NS 2mm Micro-perforated
2. **Soft Foam Pieces (Luxofoam):**
One piece (7cm x 7cm) for nose
Four pieces (3cm x 4cm) for cheek and forehead
3. **Headband:**
Five double-sided loop straps with hook closures
Back piece with the Orfit logo printed on it
4. **Instructions For Use**



! Please note that the mask comes in a flat shape which is thermoformable and must be heated and molded to fit the face.

C. PRECAUTIONS BEFORE USE

1. The workplace must be well-ventilated.
2. A water bath or other source of heated water is filled with water and set at the right temperature of 65 - 67°C (149 - 153°F).
3. Check the temperature of a mask before molding it on a patient.

D. ACTIVATION TECHNIQUE

Put the precut in the pre-heated water (65 - 67°C) and wait for **3 minutes** until it feels moldable.

- ! **The water temperature should be 65 - 67°C (149 - 153°F).**
- ! **The minimum heating time is 3 minutes.**
- ! **Do not heat the precut longer than 20 minutes.**
- ! **Never use an open flame to activate the precut.**

E. WORKING PROPERTIES

Applying

1. Trim the edges of the nose foam with scissors and shape it to fit.
2. Remove the back cover of the foam and stick it on the nose. (the self-adhesive side should stick to the nose)

Tip: To remove or reduce the adhesiveness, apply a bit of water to the surface of the foam.



3. Put the precut in the pre-heated water (65 - 67°C) and wait for **3 minutes** until it feels moldable.

Tip: Add some soap to the water to prevent the precut from sticking to the metal grid in the water bath.

4. Take the activated precut out of the water and let the surfaces cool or dry on a towel for a few seconds.
! **Before applying the mask, check the temperature of the mask in order not to burn the patient.**
5. Mold the mask around the patient's face and make sure to conform the nose part properly as it is the most important part of the Orfiguard providing rigidity and stability.



6. Continue molding until the mask becomes firm. This takes 1 to 2 minutes, depending on the temperature in the room.

Leave the mask on the patient for another 5 minutes to allow it to harden completely.

7. Mark the redundant parts that you need to cut off with a pen or marker.



8. Remove the mask from the face.

9. Remove the nose foam from the mask.



10. Trim the redundant parts as marked.



11. Smooth out the trimmed edges using a heat gun or by dipping in the 65°C water, if needed.
! Be careful not to overheat the material as it may lose its shape.

12. Stick the foam pieces inside the molded mask.



13. Apply the 5 connection straps to the mask.



14. Place the mask with straps attached to the face.

15. Place the back piece of the headband with the Orfit logo on the back of the head and attach the straps to the back piece.



16. Ensure that the mask, straps, and back piece fit the face snugly but not too tightly. Then, cut off any excess strap material.



F. MAINTENANCE AND WASTE MANAGEMENT

This product can be cleaned and disinfected using soapy water or an isopropanol-based disinfectant, applied with a soft cloth. If unsure about the cleaning fluid, do not use it. Never use aerosol sprays, corrosive cleaning agents, solvents, or abrasive detergents. Cleaning the ORFIGUARD regularly 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.

G. ADVICE FOR THE PATIENT

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

H. STORAGE

- ORFIGUARD should be stored in its original packaging before use.
- Storage must be in a dark, cool, dry place at a temperature of min. 10°C (50°F) and max. 30°C (86°F).

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 thermoplastic material ages in direct relation to storage conditions. When too old, thermoplastic materials become brittle and too soft when activated. When too warm, thermoplastic materials get soft and deform.

I. 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.

J. ADDITIONAL INFORMATION

For additional information such as distributor contact information, product brochures, safety and technical data sheets, and regulatory information, please visit our website www.orfit.com

Note:

The instructions were written in accordance with the Medical Devices Regulation (EU) 2017/745. It is prohibited to make alterations to this text without prior approval from Orfit Industries.
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