



ORFIT Industries

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2110 Wijnegem, Belgium

ORFIT® ECO BLACK NS

INSTRUCTIONS FOR USE

A. GENERAL PRODUCT INFORMATION

ORFIT® ECO BLACK NS is a coated low temperature thermoplastic sheet material for the fabrication of orthoses, external immobilization devices and rehabilitation aids.

ORFIT® ECO BLACK NS is applied directly to the patient once it is activated.

! ***ORFIT® ECO BLACK is not suitable for internal use. This product may not be used on open wounds or in the mouth.***

B. PRODUCT RANGE

ORFIT® ECO BLACK NS is available in sheets of different sizes, thicknesses and types of perforation:

Art.no.	Thickness in mm	Sizes in mm	Perforation type
8938Z.1/NS	2.4	600 x 450	non perforated
8938Z.4/NS	2.4	600 x 450	mini perforated
8934Z.1/NS	3.2	600 x 450	non perforated
8934Z.4/NS	3.2	600 x 450	mini perforated
8954Z.1/NS	3.2	600 x 900	non perforated
8954Z.4/NS	3.2	600 x 900	mini perforated

C. PRECAUTIONS BEFORE USE

1. Make sure the workplace is well-ventilated to avoid overheating.
2. The necessary tools should in no way put the operator at risk.
3. Position the patient comfortably and ensure that you have easy access to the involved body part.

D. ACTIVATION TECHNIQUE

1. ORFIT® ECO BLACK NS is activated by heating at a minimum temperature of 65°C (149°F). Possible activation sources are: suspan water bath, dry heater, heat gun, heating plate, hot air oven. The activation time depends on the heat source and varies from 2 to 5 minutes.
2. When using a suspan water bath, it is recommended to use distilled water or to soften the water by adding a spoonful of liquid soap, although this is not required. When using a heat gun, do not exceed 250 °C (482°F) to avoid breakdown of the material.
- !** 3. ***Please note: temperatures of 65°C (149°F) or more can also be reached in the patient's daily life. Think of a closed car in the summer, the surface of a hot radiator, a sauna or the proximity of an open fireplace.***

4. High temperatures up to a maximum of 120°C (248°F) do not damage ORFIT® ECO BLACK NS, but are not user-friendly. High temperatures are allowed provided that the activation time is reduced accordingly and that the product is sufficiently rubbed with talcum powder. Wear insulating gloves and do not apply ORFIT® Eco Back NS directly on the patient at these high activation temperatures.

! **5. Never use an open flame to activate ORFIT® ECO BLACK NS.**

E. WORKING PROPERTIES

Cutting:

1. Draw the orthosis pattern on the ORFIT® ECO BLACK NS sheet using a marker.
2. Cut the pattern out roughly with a suitable pair of scissors or use a cutter. When using a cutter, carve a straight line and break the sheet into smaller pieces for easier handling.

! ***Be careful of possible cuts when using a cutter, always keep the assisting hand away from the cutting line.***

3. Heat the ORFIT® ECO BLACK NS sheet until it is slightly softened and cut out the precise orthosis pattern with of a pair of scissors.

Applying:

1. Activate the ORFIT® ECO BLACK NS pattern until it becomes completely mouldable and stretchable. Take it out of the water and let its surface cool and dry on a towel for a few seconds. **Make sure that the temperature of the activated material will not burn the patient.**

ORFIT® ECO BLACK NS is:

- not adhesive at all when wet heated.
- slightly adhesive when dry heated at a low temperature.
- fully adhesive when dry heated at high temperature

2. Several application techniques are possible:

Use gravity technique to assist in moulding or mould the material circumferentially around the extremity and stick edges together. Utilise the stretch, elastic and self-adhesive properties of ORFIT® ECO BLACK NS to facilitate conformability. It is also possible to secure the orthosis in place on the body part by means of a non-adhesive bandage.

As with all thermoplastics, take advantage of the stretch and the elasticity of ORFIT® ECO BLACK NS while moulding but be aware that it may tear if overstretched.

3. In case of accidental bonding, let ORFIT® ECO BLACK NS harden completely so that parts that are stuck can be separated. Reactivation in hot water is then safe again.
4. Remove the orthosis from the patient when ORFIT® ECO BLACK NS is sufficiently hardened to maintain its shape. Excessive material can be trimmed before complete hardening. To do so, use a suitable pair of bandage scissors.
The cooling time can be shortened by means of cold air, a cold bandage or a cold spray.
5. To attach fastening straps and secure hinges, outriggers or other accessories to the orthosis, the NS film must be REMOVED locally. It can be scratched off with a knife, sandpaper or with a grinding tool. Use dry heat to make the spots sticky and press both sides together firmly to secure the bonding.

F. FINISHING

There are several ways to give the edges of an ORFIT ECO BLACK NS orthosis a smooth and even finish:

- local reheating and rubbing with the finger,
- after hardening, edge finishing can be done by means of a deburring knife,
- grinding by using a suitable grinding tool at a low turning speed.

G. MAINTENANCE AND WASTE MANAGEMENT

Orthoses made of ORFIT® ECO BLACK NS should be cleaned daily. Use lukewarm water and liquid soap, biological detergent, toothpaste or pre-moistened isopropanol wipes. Rinse well and dry thoroughly.

! Never use solvents. Avoid acid detergents.

Sterilization of ORFIT® ECO BLACK NS in an autoclave is impossible.

Disinfection is possible with alcohol, quaternary ammonium or a solution of commercial disinfecting soaps (HAC®, Hibiscrub, Sterilium®, etc.).

! Avoid prolonged contact with detergents and acids which may affect the NS film.

After use, an orthosis can be disposed of with normal household waste without harming the environment. ORFIT® ECO BLACK NS is biodegradable.

H. STORAGE

- ORFIT® ECO BLACK NS can be stored vertically, if supported and horizontally if not.
- Storage must be in a dark, cool, dry place at a temperature of min. 10°C (50°F) and max. 30°C (86°F) and in the original packaging.
- Once removed from the packaging, the left-overs should be placed back in the packaging for storage to avoid adhesion of the NS film and 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 relation to storage circumstances. When aged, the material may become brittle and soft when activated.

I. GENERAL SAFETY ADVICE

- ! * ORFIT® ECO BLACK NS 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 ORFIT® ECO BLACK.**
- ! * To make orthoses and rehabilitation aids, ORFIT® ECO BLACK NS may only be used by qualified health professionals.**
- ! * Give the patient sufficient information about the exact use, wearing schedule and maintenance of the orthosis.**

J. ADDITIONAL INFORMATION

For additional information such as product brochures, instructional movies, Safety Data Sheets and regulatory information, please visit our website www.orfit.com.

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 N.V.

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