

**ORFIT Industries**Vosveld 9a  
2110 Wijnegem, Belgium**ORFILIGHT® BLACK NS****INSTRUCTIONS FOR USE****A. GENERAL PRODUCT INFORMATION**

ORFILIGHT® BLACK NS is a low temperature thermoplastic sheet material with an extra low weight. It is used for the fabrication of orthoses, for external immobilisation devices and rehabilitation aids.

ORFILIGHT® BLACK NS is applied directly to the patient after it is activated.

! **ORFILIGHT® is not suitable for internal use. It may not be used on open wounds or in the mouth.**

**B. PRODUCT RANGE**

ORFILIGHT® BLACK NS is available in sheets of different thicknesses and types of perforation as well as in pre-cut blanks.

Sheets:

Art. no.	Thickness in mm	Size in mm	Perforation type
8332Z.2/L/NS	1.6	450 x 600	micro perforated
8338Z.2/L/NS	2.5		micro perforated
8334Z.1/L/NS	3.2		non perforated
8334Z.4/L/NS	3.2		mini perforated

Pre-cuts:

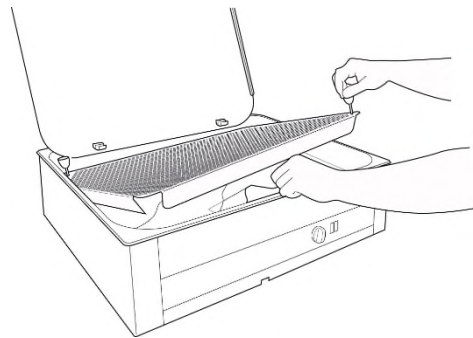
Art. no.	Size	Description	Material
35810Z/L/NS	S	Thumb post splint	1.6 mm micro perforated
35811Z/L/NS	M		
35812Z/L/NS	L		
35814Z/L/NS	S	Wrist + thumb splint	2.5 mm micro perforated
35815Z/L/NS	M		
35816Z/L/NS	L		
35820Z/L/NS	S	Dorsal wrist cock-up splint	3.2 mm non perforated
35821Z/L/NS	M		
35822Z/L/NS	L		

## C. PRECAUTIONS BEFORE USE

! **Make sure that the temperature of the activated material will not burn the patient.**

## D. ACTIVATION TECHNIQUE

1. ORFILIGHT® BLACK NS is activated by heating it at a temperature of 65°C (149°F). Possible activation sources are: Suspan water bath, heat gun or heating plate. The activation time depends on the heat source and varies from 30 seconds to 3 minutes. (e.g. at 65° C, 1,6 mm : 30 sec., 2,5 mm : 2 min., 3,2 mm : 3 min.)
2. When using a Suspan water bath, it is recommended to soften the water by adding a teaspoon of liquid soap. ORFILIGHT® BLACK NS can be towelled. Accidental bonding can be undone by continuous gentle traction.
3. Since ORFILIGHT® BLACK NS floats, it must be kept under water by placing it under the Suspan grill, or the net that is supplied with the Suspan (see picture).
4. ORFILIGHT® BLACK NS is coated with a non-sticky film. However, ORFILIGHT® BLACK NS has a gentle controlled stickiness. This controlled stickiness will help you moulding a splint, a third hand.



When using a heating plate, the hot surface must be covered with a Teflon film.

**! Watch out, ORFILIGHT® BLACK NS scalds at 150°C (300°F).**

5. **Beware: Temperatures of 65°C (149°F) or more can 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.**
6. High temperatures up to a maximum of 120°C (248°F) do not damage ORFILIGHT®, but are not user-friendly. Even higher activation temperatures are allowed on the condition that the activation time is reduced accordingly. Wear gloves and do not apply ORFILIGHT® BLACK NS directly to the patient's skin at these high activation temperatures.
7. **Never use an open flame to activate ORFILIGHT® BLACK NS.**

## E. WORKING PROPERTIES

### Cutting

1. Draw the splint pattern on the ORFILIGHT® BLACK NS sheet by means of a marker.
2. With thick sheets cut the pattern roughly with a suitable pair of scissors or use a cutter. When using a cutter, carve a straight line and break the sheet in two.

! **Be careful when using a cutter; always keep the assisting hand away from the cutting line.**

3. To cut the precise splint contour in thick sheets with a pair of scissors, heat ORFILIGHT® BLACK NS until it is formable but not yet stretchable.

### Applying

1. Activate the ORFILIGHT® BLACK NS pattern until it is completely soft. The activation time depends on the material thickness: 1,6 mm = 1 min. / 2,5 mm = 2 min. / 3,2 mm = 3 min. Take the pattern out of the water and allow the surfaces to cool or dry on a towel for a few seconds.

2. Several application techniques are possible:
  - Gravity technique: the material forms itself under gravity.
  - Closed technique: form the material around the limb and stick the edges together.
  - Bandaging technique: secure the splint by means of a Latex bandage.Use the benefit of stretch and elastic properties of ORFILIGHT® BLACK NS to a maximum.
3. In case of accidental bonding, the 2 parts that are stuck can be taken apart when completely reactivated. Permanent adhesion of fixation straps and splint 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 both ORFILIGHT® surfaces are BRIEFLY DRY heated at high temperature (max. 250°C – 482°F).***

4. Do not remove the splint from the patient before ORFILIGHT® BLACK NS 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.

## G. MAINTENANCE AND WASTE MANAGEMENT

Orthoses made of ORFILIGHT® BLACK NS should be cleaned daily. Use lukewarm water and liquid soap or biological detergent, and rinse well.

! ***Never use solvents. Avoid acid detergents.***

Sterilisation of ORFILIGHT® BLACK NS orthoses in an autoclave is impossible. Sterilisation by means of gas treatment is possible.  
Disinfection is possible with alcohol, quaternary ammonium or a solution of commercial disinfecting soaps (HAC®, Sterilium®, etc.).

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

## H. ADVICE FOR THE PATIENT

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

## I. STORAGE

- ORFILIGHT® BLACK NS 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

- ! \* ***ORFILIGHT® 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 ORFILIGHT® BLACK NS.***
- ! \* ***To make orthoses and rehabilitation aids, ORFILIGHT® BLACK NS may only be used by qualified health professionals.***

#### K. ADDITIONAL INFORMATION

For additional information such as product brochures, Safety Data Sheets and regulatory information, please visit our website [www.orfit.com](http://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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