

**ORFIT Industries**

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ORFILIGHT®**INSTRUCTIONS FOR USE****A. GENERAL PRODUCT INFORMATION**

ORFILIGHT® 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® 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® 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
8332.2/L	1.6	450 x 600	micro
8338.2/L	2.5		micro
8334.1/L	3.2		non perforated
8334.4/L	3.2		mini

Pre-cuts:

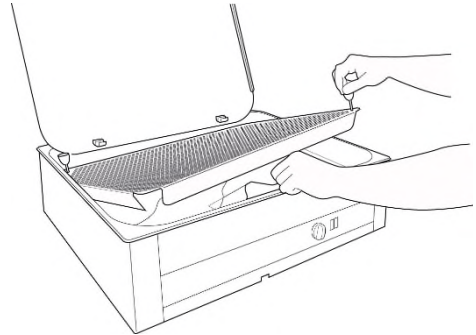
Art. no.	Size	Description	Material
35843/L	S	Flexor tendon gliding splint	2.5 mm micro perforated 3.2 mm mini perforated
35844/L	M		
35845/L	L		
35810/L	S	Thumb post splint	1.6 mm micro perforated
35811/L	M		
35812/L	L		
35818/L	XS	Dorsal wrist cock-up splint	3.2 mm non perforated
35820/L	S		
35821/L	M		
35822/L	L		

C. PRECAUTIONS BEFORE USE

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

D. ACTIVATION TECHNIQUE

1. ORFILIGHT® 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® can be towelled despite it is a sticky product.. Accidental bonding can be undone by continuous gentle traction.
3. Since ORFILIGHT® 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. When ORFILIGHT® is dry heated and adhesion is undesirable, both sides of the material must be rubbed with extra talcum powder before activation.



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

! Watch out, ORFILIGHT® scalds at 150°C (300°F). It then becomes yellowish and tears easily.

- ! **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 and that the product is sufficiently rubbed with talcum powder. Wear gloves and do not apply ORFILIGHT® directly to the patient's skin at these high activation temperatures.

- ! **7. Never use an open flame to activate ORFILIGHT®.**

E. WORKING PROPERTIES

Cutting

1. Draw the splint pattern on the ORFILIGHT® 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® until it is formable but not yet stretchable.

Applying

1. Activate the ORFILIGHT® 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® to a maximum.
3. ORFILIGHT® easily sticks to itself, less to porous surfaces. 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 an 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® 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® should be cleaned daily. Use lukewarm water and liquid soap, biological detergent or toothpaste, and rinse well.

! Never use solvents. Avoid acid detergents.

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

After use, an ORFILIGHT® 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® 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® 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®.***
- ! * ***To make orthoses and rehabilitation aids, ORFILIGHT® may only be used by qualified health professionals.***

K. ADDITIONAL INFORMATION

For additional information such as product brochures, Material 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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