

ORFIT® ECO

A. GENERAL PRODUCT INFORMATION

ORFIT ECO is a low temperature thermoplastic sheet material for the fabrication of orthoses, external immobilisation devices and rehabilitation aids.

ORFIT ECO is applied directly to the patient after it is activated.

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

B. PRODUCT RANGE

ORFIT ECO is available in sheets of different thicknesses, sizes and types of perforation.

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

C. PRECAUTIONS BEFORE USE

1. The workplace must be well ventilated to avoid overheating.
2. The necessary tools should in no way put the patient at risk.
3. Encourage the patient to assume a comfortable position and ensure that you yourself are in an easy working position.
4. Rub the orthosis with talcum powder before applying to the patient.
- ! **5. Make sure that the temperature of the activated material will not burn the patient.**

D. ACTIVATION TECHNIQUE

1. ORFIT ECO is softened by heating at a minimum temperature of 60°C (140°F). Possible activation sources are: Suspan water baths, 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 recommendable to soften the water by adding a teaspoon of liquid soap.
When dry heating ORFIT ECO, both sides of the material have to be rubbed with talcum powder before activation.
When using a heating plate or an oven, the hot surface must be covered with a Teflon film.
When using a heat gun, do not exceed the temperature of 250°C (482°F) to avoid breakdown of the material.
- ! **3. Be careful: temperatures of 60°C (140°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, but are not user-friendly. Even higher temperatures are allowed for activation on the condition however that the material is removed from the heat source as soon it is soft. Wear gloves and do not apply ORFIT ECO immediately to the patient's skin at these high activation temperatures.
- ! **5. Never use an open flame to activate ORFIT ECO.**

E. WORKING PROPERTIES

Cutting

1. Draw the brace pattern on the ORFIT ECO sheet by means of an Orfit marker
2. 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 of possible cuts when using a cutter; always keep the assisting hand away from the cutting line.**
3. For a precise pattern, heat the ORFIT ECO sheet until it is formable but not yet stretchable and cut the pattern by means of a pair of scissors.

Applying

1. Activate the ORFIT ECO pattern until it becomes soft and stretchable. Remove from the heat source and let cool sufficiently before applying to the patient.
2. Several application techniques are possible:
 - manual moulding: moulding by manual stretching and holding.
 - closed technique: circumferential moulding with overlapping of the edges.
 - bandaging technique: secure the orthosis by means of a bandage.
Use the stretch and elastic properties of ORFIT ECO as much as possible.
3. ORFIT ECO easily sticks to itself and to all porous surfaces. In case of accidental bonding, the 2 parts that are stuck can be taken apart when completely reactivated.
Permanent adhesion to attach fixation straps and orthosis accessories is possible with dry heat.

! **In order to ensure that the material is well-adhered, both surfaces should be BRIEFLY DRY heated at high temperature (max. 250°C – 482°F).**

4. Do not remove the orthosis from the patient before ORFIT ECO is sufficiently hard. ORFIT ECO sets relatively quickly and therefore the excessive material should be trimmed before complete hardening. The setting time can be shortened by means of cold air, a cold bandage or a cold spray.

F. FINISHING

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

- local reheating and rubbing with a wet 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 should be cleaned daily. Use lukewarm water and liquid soap, biological detergent or toothpaste, and rinse well.

Never use solvents. Avoid acid detergents.

Sterilization of ORFIT ECO orthoses in an autoclave is impossible.

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

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

H. ADVICE FOR THE PATIENT

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

I. STORAGE

- ORFIT ECO can be stored vertically, if supported, or horizontally.
- It must be stored 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 stored back in the 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 relation to storage circumstances. When too old, it becomes brittle and soft when activated.

J. GENERAL SAFETY ADVICE

! * **ORFIT ECO 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.**

! * **To make orthoses and rehabilitation aids, ORFIT ECO 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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