

INSTRUCTIONS FOR USE

A. GENERAL PRODUCT INFORMATION

ORFIT[®] ORTHO is a rubber feeling low temperature thermoplastic sheet material based on polyester instead of polyisoprene. It is designed for the fabrication of orthopaedic braces, orthoses, external immobilisation devices and rehabilitation aids.

ORFIT[®] ORTHO is applied directly to the patient after it is activated unless higher temperatures are used and the patient is protected by a stockinette.

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

B. PRODUCT RANGE

ORFIT[®] ORTHO is available in sheets of different sizes and types of perforation.

ART. NO.	SIZES in mm	PERFORATION
16310.1	450 x 600 x 2.7	non perfo
16310.6	450 x 600 x 2.7	macro perfo
1634.1	450 x 600 x 3.2	non perfo
1634.6	450 x 600 x 3.2	macro perfo
1654.1	600 x 900 x 3.2	non perfo
1654.6	600 x 900 x 3.2	macro perfo

C. PRECAUTIONS BEFORE USE

1. The workplace must be well-ventilated.
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. *ORFIT[®] ORTHO tends to feel hot when just activated. Wait long enough and make sure that the temperature is not uncomfortable for the patient and that it does not cause any burns.*

D. ACTIVATION TECHNIQUE

1. ORFIT[®] ORTHO is activated by heating at a temperature of min. 75°C (167°F) and preferably not more than 100°C (212°F). Possible activation sources are: water bath Suspan no. 1 (art. no. 35096), Suspan no. 2 (art. no. 32500) heat gun (art. no. 35351), heating plate and hot air oven.

The activation time depends on the heat source and the temperature.

activation source	temperature	activation time
water bath	75°C (167°F)	1'30" (2.7 mm) - 2'00" (3.2 mm)
heating plate	100°C (212°F)	1'30" (2.7 mm) - 2'30" (3.2 mm)
hot air oven	160°C (320°F)	2'00" (2.7 mm) - 2'30" (3.2 mm)

2. When dry heating ORFIT[®] ORTHO at temperatures above 80°C (176°F), it is necessary to rub both sides of the material with talcum powder before activation. The oven plate must also be covered with Teflon.

When using a heat gun, do not exceed the temperatures of 250°C (482°F) to avoid breakdown of the material.

3. With activation temperatures higher than 100°C (212°F), extra attention must be given to:

1. the heating **time**: do not overheat ORFIT[®] ORTHO - it then becomes very drapy and sticky.
2. cool the material sufficiently before applying it to the patient.

! Wear gloves when removing ORFIT[®] ORTHO from the heat source and check the temperature before applying it to the patient.

4. Be careful: temperatures of 80°C (176°F) or more can also occur in a patient's daily life, e.g. a closed car in the summer, the surface of a hot radiator, a sauna or the proximity of a fireplace.

! 5. Do not use an open flame to activate ORFIT[®] ORTHO.

E. WORKING PROPERTIES

Cutting

1. Draw the brace pattern on the ORFIT[®] ORTHO sheet by means of an ORFIT[®] marker (art. no. 35003Z (black)). The drawing resists water but can be whipped off with water.
2. Cut the pattern roughly with a suitable pair of scissors (art. no. 35065 or 35064), or cutter. With 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 exact contours, heat the ORFIT[®] ORTHO sheet until it is pliable, and cut the pattern by means of a pair of regular scissors.

Applying

1. Activate the ORFIT[®] ORTHO pattern until it becomes soft and slightly stretchable. Remove from the heat source and let cool sufficiently before applying to the patient. Towelling is recommended.
2. Several application techniques are possible:
 - manual moulding by stretching and stroking
 - closed technique: circumferential moulding with overlapping of the edges.
 - bandaging technique: secure the splint by means of a bandage.
3. ORFIT[®] ORTHO is self-adhesive when briefly heated at a high temperature (100°C - 212°F or higher) but no permanent bonding can be achieved. ORFIT[®] ORTHO does not stick to other products such as fixation straps or metal outriggers.
4. Do not remove the brace from the patient before ORFIT[®] ORTHO is sufficiently hard (3-5 minutes). Trimming with scissors results in nice smooth edges. To do so, use a suitable pair of bandage scissors (art. no. 35063).

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 extra smooth the edges of ORFIT[®] ORTHO :

- local reheating and rubbing with a wet finger,
- after hardening, edge finishing can be done by means of a deburring knife (art. no. 35307),
- grinding by using a suitable grinding tool at a low turning speed.

G. MAINTENANCE AND WASTE MANAGEMENT

Orthoses made of ORFIT[®] ORTHO should be cleaned daily. Use lukewarm water and liquid soap, biological detergent or toothpaste, and rinse well.

! ***Do not use solvents. Avoid acid detergents.***

Sterilization of ORFIT[®] ORTHO orthoses in an autoclave is impossible. Sterilization by means of gas treatment is possible but expensive.

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

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

H. ADVICE FOR THE PATIENT

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

I. STORAGE

- If supported, ORFIT[®] ORTHO can be stored vertically. If not, horizontally is recommended..
- 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[®] ORTHO 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[®] ORTHO.***
- ! * ***To make orthoses and rehabilitation aids, ORFIT[®] ORTHO 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.

These 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.

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