ORFIT® FLEX NS

INSTRUCTIONS FOR USE

A. GENERAL PRODUCT INFORMATION

ORFIT® FLEX NS is a low temperature thermoplastic sheet material for the fabrication of orthopaedic braces, orthoses, external immobilisation devices and rehabilitation aids.
ORFIT® FLEX NS is applied directly to the patient after it is activated.

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

B. PRODUCT RANGE

ORFIT® FLEX NS is available in sheets of different sizes, sizes and types of perforation.

Art. No.	Size in mm	Perforation type
1338.1/NS	450 x 600 x 2.4	non perforated
1338.6/NS	450 x 600 x 2.4	macro perforated
1334.1/NS	450 x 600 x 3.2	non perforated
1334.6/NS	450 x 600 x 3.2	macro perforated
1354.1/NS	600 x 900 x 3.2	non perforated
1354.6/NS	600 x 900 x 3.2	macro perforated

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® FLEX NS tends to feel hot when activated. Make sure that this temperature is not uncomfortable for the patient.***

D. ACTIVATION TECHNIQUE

1. ORFIT® FLEX NS is activated by heating it at a temperature of min. 65°C (149°F) and max. 80°C (176°F). Possible activation sources are: water bath, heat gun, heating plate and hot air oven.
   The activation time depends on the heat source and the temperature.

activation source	temperature	activation time	
		2.4 mm	3.2 mm
water bath	65°C (149°F)	3'00"	3'00"
heating plate	80°C (176°F)	3'00"	3'00"

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2. When dry heating ORFIT® FLEX NS at temperatures above 80°C (176°F), it is recommended 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 80°C (176°F), extra attention must be given to:
   1. the heating **time**: do not overheat ORFIT® FLEX NS.
   2. cool the material sufficiently before applying it to the patient.
   ! Wear gloves when removing ORFIT® FLEX NS from the heat source and check the temperature before applying it to the patient.

4. Be careful: temperatures of 65°C (149°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 an open fireplace.

! *5. Do not use an open flame to activate ORFIT® FLEX NS.*

E. WORKING PROPERTIES

Cutting

1. Draw the brace pattern on the ORFIT® FLEX NS sheet by means of a marker.
2. Cut the pattern roughly with a suitable pair of scissors 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® FLEX NS sheet until it is pliable, yet not stretchable and cut the pattern by means of a pair of regular scissors.

Applying

1. Activate the ORFIT® FLEX NS pattern until it becomes soft and 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: moulding by manual stretching and holding.
   - bandaging technique: secure the splint by means of a bandage.

   Use the stretch properties of ORFIT® FLEX NS as much as needed.
3. ORFIT® FLEX NS is self-adhesive when briefly dry heated at a high temperature (80°C - 176°F or higher). Permanent bounding can be achieved by dry heating (both surfaces) and firm pressure. ORFIT® FLEX NS does not stick permanently to other products such as fixation straps or metal outriggers.
4. Do not remove the brace from the patient before ORFIT® FLEX NS is sufficiently hard (3-5 minutes). Trimming with scissors results in nice smooth edges. To do so, use a suitable pair of bandage scissors. 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 an ORFIT® FLEX NS:
- 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® FLEX NS should be cleaned daily. Use lukewarm water and disinfecting soap or pre-moistened isopropanol wipes. Rinse well.

! *Never use solvents. Avoid acid detergents.*

Sterilization of ORFIT® FLEX NS 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 orthosis can be disposed of with normal household waste without harming the environment.

ORFIT® FLEX NS 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® FLEX NS 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 too soft when activated.

J. GENERAL SAFETY ADVICE

! * ***ORFIT® FLEX 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® FLEX NS .***
! * ***To make orthoses and rehabilitation aids, ORFIT® FLEX NS 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.

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Listed with

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