



ORFIT Industries

Vosveld 9a
2110 Wijnegem, Belgium



INSTRUCTIONS FOR USE

A. GENERAL PRODUCT INFORMATION

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

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

B. PRODUCT RANGE

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

Art. no.	Type	Thickness in mm	Sizes in mm	Perforation type
8332.SO1/NS 8332.SO2/NS	soft	1.6	450 x 600	non perforated micro
8333.SO1/NS 8333.SO2/NS 8333.SO2+/NS 8333.SO3/NS 8333.SO4/NS	soft	2.0	450 x 600	non perforated micro micro plus maxi mini
8338.SO1/NS 8338.SO2/NS	soft	2.5	450 x 600	non perforated micro
8334.SO1/NS 8334.SO3/NS 8334.SO4/NS 8354.SO1/NS 8354.SO3/NS 8354.SO4/NS 8334.ST1/NS 8334.ST4/NS 8354.ST1/NS 8354.ST4/NS	soft stiff	3.2	450 x 600 600 x 900 450 x 600 600 x 900	non perforated maxi mini non perforated maxi mini non perforated mini non perforated mini
8355.SO1/NS 8355.SO4/NS 8355.ST1/NS 8355.ST4/NS	soft stiff	4.2	600 x 900	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. Make sure that the temperature of the activated material will not burn the patient.**

D. ACTIVATION TECHNIQUE

1. ORFIT® NS is softened by heating at a minimum temperature of 65°C (149°F). Possible activation sources are: water bath, 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 recommended to soften the water by adding a teaspoon of liquid soap.
! **When using a heat gun, do not exceed the temperature of 250°C (482°F) to avoid thermal breakdown of the material.**
! **When using a heating plate or an oven, the hot plate must be covered with a Teflon film and the surface of the thermoplastic material must be rubbed with talcum powder.**
Temperatures to 160°C (320°F) are allowed on the condition that the proper heating time is not exceeded (see table below).
3. ORFIT® NS becomes transparent at the softening temperature. This is a perfect indicator that the material has reached its proper moulding temperature.

Activation time:

Sheet thickness	At 80°C (176°F)	At 160°C (320°F)
1,6 mm	± 4 min.	± 1 min
2,0 mm	± 5 min 30 sec.	± 1 min 30 sec
3,2 mm	± 9 min	± 2 min
4,2 mm	± 16 min	± 2 min 30 sec

! **Caution: do not heat the material longer than necessary at very high temperatures. The thermoplastic will become fluid and unusable.**

! **Wear insulating gloves and do not apply the thermoplastic to the patient's skin before cooling sufficiently.**

! **4. Beware: temperatures of 65°C (149°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.**

! **5. Never use an open flame to activate ORFIT® NS.**

E. WORKING PROPERTIES

Cutting

1. Draw the splint pattern on the ORFIT® NS sheet by means of a 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. Heat the ORFIT® NS sheet until it is formable but not yet stretchable and cut the precise splint pattern with a pair of scissors.

Applying

1. Activate the ORFIT® NS pattern until it is completely transparent. Take it out of the water and let its surface cool or dry on a towel for a few seconds.

! **ORFIT® NS is:**

- ***not adhesive when wet heated, or when dry heated and powdered with talcum.***
- ***a little adhesive when wet heated, towelled and pressed together when dry heated at low temperature (between 65°C (149°F) and 80°C (176°F)).***
- ***adhesive when dry heated at high temperature (between 120°C (248°F) and 160°C (320°F)). However the bonding is never permanent and will be detached once hardened.***

2. Several application techniques are possible:
 - gravity technique: the material forms itself under gravity.
 - closed technique: mould the material around the extremity and overlap the edges.
 - bandaging technique: secure the splint by means of a bandage.

Utilise the stretch and elastic properties of ORFIT® NS as much as possible.

3. In case of accidental bonding, let ORFIT® NS harden completely so that the parts that are stuck can be separated. Reactivation in hot water is then safe again.
4. Do not remove the splint from the patient before ORFIT® NS has become completely opaque. Excessive material can be trimmed before complete hardening. To do so, use a suitable pair of bandage scissors.
The cooling time can be shortened by means of cold air, a cold bandage or a cold spray.
5. To attach fastening straps and secure hinges, outriggers or other accessories to the splint, the NS film must be REMOVED locally. This can be done by spot heating the surface and by tearing the film, applying vigorous pressure with twist movements. The film can also be scratched off with a knife or with rough sandpaper or with a grinding tool. Do not encrust the film into the splinting material by back and forth movements. The film can also be softened with acetone or rubbing alcohol and then wiped off.

F. FINISHING

There are several ways to give the edges of an ORFIT® NS splint a smooth and even finish:

- local reheating and rubbing with a wet finger,
- after hardening, edge finishing can be done with a deburring knife,
- grinding by using a suitable grinding tool at a low turning speed.

G. MAINTENANCE AND WASTE MANAGEMENT

Orthoses made of ORFIT® NS 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® NS orthoses in an autoclave is impossible.

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

! **Avoid prolonged contact with detergents and acids which may affect the NS film.**

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

H. ADVICE FOR THE PATIENT

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

I. STORAGE

- ORFIT® NS can be stored vertically, if supported, or horizontally.
- ORFIT® NS must be stored in its original packaging 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, the left-overs should be stored back in the packaging to avoid adhesion of the NS film and 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.

J. GENERAL SAFETY ADVICE

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

K. ADDITIONAL INFORMATION

For additional information such as distributor contact information, 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.

ORFIT® is a registered trademark of ORFIT INDUSTRIES N.V.



© ORFIT INDUSTRIES N.V.
Ref.: 31010 – VERSION 8
LAST UPDATE: 04/02/2016 - REVISION DATE: 04/02/2018