ORFIT® NS

A. GENERAL PRODUCT INFORMATION

ORFIT NS is a low temperature thermoplastic sheet material for the fabrication of orthoses, external immobilisation 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.SO2/NS	soft	2.5	450 x 600	micro
8334.SO1/NS 8334.SO3/NS 8334.SO4/NS	soft	3.2	450 x 600	non-perforated maxi mini
8354.SO1/NS 8354.SO3/NS 8354.SO4/NS			600 x 900	non-perforated maxi mini
8334.ST1/NS 8334.ST4/NS	stiff		450 x 600	non-perforated mini
8354.ST1/NS 8354.ST4/NS			600 x 900	non-perforated mini
8355.SO1/NS 8355.SO4/NS	soft	4.2	600 x 900	non-perforated mini
8355.ST1/NS 8355.ST4/NS	stiff			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 ORFI® NS.***

E. WORKING PROPERTIES

Cutting

1. Draw the orthotic 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 orthotic 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.
2.

! ***ORFIT NS is:***
- ***<u>not adhesive</u> when wet heated, or when dry heated and powdered with talcum.***
- ***<u>a little adhesive</u> when wet heated, towelled and pressed together when dry heated at low temperature (between 65°C (149°F) and 80°C (176°F)).***
- ***<u>adhesive</u> 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.***

3. 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 orthosis by means of a bandage.

   Utilise the stretch and elastic properties of ORFIT NS as much as possible.
4. 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.
5. Do not remove the orthosis 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.

6. The cooling time can be shortened by means of cold air, a cold bandage or a cold spray.
7. To attach fastening straps and secure hinges, outriggers or other accessories to the orthosis, 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 orthotic fabrication 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 orthosis 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, Safety Data Sheets and regulatory information, please visit our website www.orfit.com.

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