ORFIT® DRAPE NS

INSTRUCTIONS FOR USE

A. GENERAL PRODUCT INFORMATION

ORFIT® DRAPE NS is a non-sticky, low temperature thermoplastic splinting material for the fabrication of orthoses, external immobilisation devices and rehabilitation aids.
ORFIT® DRAPE NS is applied directly to the patient after it is activated.
ORFIT® DRAPE NS is designed for gravity moulding and is subsequently very drapy.

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

B. PRODUCT RANGE

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

Art. No.	Size in mm	Perforation type
1532.1/NS	450 x 600 x 1.6	non perforated
1532.6/NS	450 x 600 x 1.6	macro perforated
1534.1/NS	450 x 600 x 3.2	non perforated
1534.6/NS	450 x 600 x 3.2	macro perforated
1554.1/NS	600 x 900 x 3.2	non perforated
1554.6/NS	600 x 900 x 3.2	macro perforated

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 is comfortable for the patient and does not cause burns.***

D. ACTIVATION TECHNIQUE

1. ORFIT® DRAPE NS is softened by heating at a minimum temperature of 60°C (140°F). Possible activation sources are: Suspan water bath no. 1 (art. no. 35096), no. 2 (art. no. 32500), heat gun (art. no. 35351), 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 (but not mandatory) to clean the water by adding a teaspoon of disinfecting soap.
   When using a heat gun, do not exceed 250°C (482°F) to avoid breakdown of the material.

When using a heating plate or an oven, the hot surface must be covered with a Teflon film and the ORFIT® DRAPE NS rubbed with extra powder.

! ***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 100°C (212°F) do not damage ORFIT® DRAPE NS, but are not user-friendly. The activation time has to be reduced dramatically and the product must be sufficiently rubbed with talcum powder to avoid adhesion to the oven plate. Wear gloves and do not apply ORFIT® DRAPE NS directly to the patient's skin at these high activation temperatures.

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

E. WORKING PROPERTIES

Cutting

1. Draw the splint pattern on the ORFIT® DRAPE NS sheet by means of an ORFIT® marker (art. no. 35003G (yellow)).
2. Cut the pattern roughly with a suitable pair of scissors (art. no. 35065 or 35064), 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® DRAPE NS sheet until it is formable but not yet stretchable and cut the precise splint pattern with a pair of regular scissors.

Applying

1. Activate the ORFIT® DRAPE NS pattern until it is completely soft. Take it out of the water and let its surface cool and dry on a towel for a few seconds. Be aware that terry cloth may be tacky and leaves prints.

! ***ORFIT® DRAPE NS is coated with the intention to be :***
- ***<u>not adhesive</u> when wet heated, or dry heated and powdered with talcum.***
- ***<u>temporarily a little adhesive</u> when hot and dry, bud never permanently. Stuck material will detach once hardened.***

2. ORFIT® DRAPE NS is especially designed for the fabrication of splints made by gravity technique. Simply lay the splint pattern over the limb and let gravity do its work.
3. Do not remove the splint from the patient before ORFIT® DRAPE NS is completely hard.
   Excessive material can be trimmed before complete hardening. To do so, use a suitable pair of scissors (art. no. 35063).
   The cooling time can be shortened with cold air, cold spray or the use of a cold bandage.

F. FINISHING

There are several ways to give the edges of an ORFIT® DRAPE NS splint a smooth and even finish:
- local reheating and rubbing with a wet finger,
- grinding and polishing.

G. MAINTENANCE AND WASTE MANAGEMENT

Orthoses made of ORFIT® DRAPE NS should be cleaned daily. Use lukewarm water and disinfecting soap or pre-moistened isopropanol wipes. Rinse well.

! ***Never use solvents. Avoid acid detergents.***

Sterilisation of ORFIT® DRAPE NS orthoses in an autoclave is impossible. Sterilisation 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® DRAPE NS is biodegradable.

H. ADVICE FOR THE PATIENT

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

I. STORAGE

- ORFIT® DRAPE NS can be stored vertically if supported, or horizontally if not supported.
- 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 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 and soft when activated.

J. GENERAL SAFETY ADVICE

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