

ORFIBRACE™ NS

INSTRUCTIONS FOR USE

A. GENERAL PRODUCT INFORMATION

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

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

B. PRODUCT RANGE

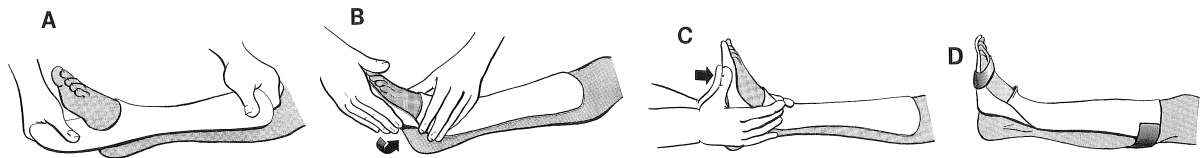
ORFIBRACE™ NS is available in sheets and pre-cut forms of 3 mm thickness.

Sheets:

Art. No.	Size in mm	Perforation type
8854.1/NS	600 x 900 x 3	non perforated
8854.6/NS	600 x 900 x 3	macro perforated

Pre-cuts for Ankle-Foot Orthosis (3 mm non perforated):

Art. no.	Size
35981/OB/NS	x-small
35982/OB/NS	small
35983/OB/NS	medium
35984/OB/NS	large



! This precut pattern is not suitable for the following applications:

- fractures (scaphoide)
- acute de Quervain tendinitis
- first webspace contractures

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. Make sure that the temperature of the activated material will not burn the patient.

D. ACTIVATION TECHNIQUE

1. ORFIBRACE™ NS is activated by heating at a temperature of min. 65°C (149°F) and max. 160°C (325°F). Possible activation sources are: water bath, heat gun, heating plate, hot air oven and microwave oven.

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

activation source	temperature	activation time
water bath	65°C (149°F)	2 minutes
heating plate	160°C (320°F)	1 minute
hot air oven	160°C (320°F)	1 minute
microwave oven		1 to 5 minutes

2. When dry heating ORFIBRACE™ NS at temperatures above 120°C (248°F), it is recommended to rub both sides of the material with talcum powder before activation. The oven plate must also be covered with a Teflon film.

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 120°C (248°F), extra attention must be given to:
 1. the heating time: do not overheat ORFIBRACE™ NS .
 2. cooling the material sufficiently before applying it to the patient.**! Wear gloves when removing ORFIBRACE™ 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. Never use an open flame to activate ORFIBRACE™ NS .

E. WORKING PROPERTIES

Cutting

1. Draw the brace pattern on the ORFIBRACE™ 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 ORFIBRACE™ 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 ORFIBRACE™ NS pattern until it becomes soft and stretchable. Remove from the heat source and let cool sufficiently before applying to the patient.

2. Several application techniques are possible:
 - manual moulding: moulding by manual stretching and holding.
 - closed technique: circumferential moulding with overlapping of the edges.
 - bandaging technique: secure the splint by means of a bandage.Use the stretch and elastic properties of ORFIBRACE™ NS as much as possible.
3. ORFIBRACE™ NS is self-adhesive when briefly heated at a high temperature (100°C - 212°F). Permanent adhesions can be achieved by firm pressure. ORFIBRACE™ NS does not stick to other products such as fixation straps or metal outriggers unless ORFIT® Classic is used in between. Both material surfaces need to be DRY heated and firmly pressed together.
4. Do not remove the brace from the patient before ORFIBRACE™ NS is sufficiently hard. ORFIBRACE™ NS sets relatively quickly and therefore the excessive material should be trimmed before complete hardening. 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 give the edges of an ORFIBRACE™ NS brace a smooth and even finish:

- 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 ORFIBRACE™ 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 ORFIBRACE™ 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 off with normal household waste without harming the environment. ORFIBRACE™ 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

- ORFIBRACE™ NS can be stored vertically, if supported, or horizontally.
- 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

- ! * **ORFIBRACE™ 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 ORFIBRACE™ NS .**
- ! * **To make orthoses and rehabilitation aids, ORFIBRACE™ 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.

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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