

AQUAFIT[™] NS

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INSTRUCTIONS FOR USE

A. GENERAL PRODUCT INFORMATION

AQUAFIT[™] NS is a low temperature thermoplastic material with a non-stick (NS) coating which has unlimited potential for fabrication of very large to very small splints.

AQUAFIT^m NS is applied directly to the patient after it is activated.

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

B. PRODUCT RANGE

This product is available in sheets of different thicknesses and perforation types.

Article No.	Туре	Size in mm (inch)	Thickness in mm (inch)	Perforation
8632N.1/NS	soft	450 x 600 (17 11/16" x 23 9/16")	1.6 (1/16")	non perforated
8632N.2/NS	soft	450 x 600 (17 11/16" x 23 9/16")	1.6 (1/16")	micro
8639N.1/NS	soft	450 x 600 (17 11/16" x 23 9/16")	2.4 (3/32")	non perforated
8639N.2+/NS	soft	450 x 600 (17 11/16" x 23 9/16")	2.4 (3/32")	micro plus
8634N.1/NS	soft	450 x 600 (17 11/16" x 23 9/16")	3.2 (1/8")	non perforated
8634N.6/NS	soft	450 x 600 (17 11/16" x 23 9/16")	3.2 (1/8")	macro
8634N.3/NS	soft	450 x 600 (17 11/16" x 23 9/16")	3.2 (1/8")	maxi
8654N.1/NS	soft	600 x 900 (23 11/16" x 35 3/8")	3.2 (1/8")	non perforated
8654N.6/NS	soft	600 x 900 (23 11/16" x 35 3/8")	3.2 (1/8")	macro
8634N.ST1/NS	stiff	450 x 600 (17 11/16" x 23 9/16")	3.2 (1/8")	non perforated
8634N.ST6/NS	stiff	450 x 600 (17 11/16" x 23 9/16")	3.2 (1/8")	macro
8654N.ST1/NS	stiff	600 x 900 (23 11/16" x 35 3/8")	3.2 (1/8")	non perforated
8654N.ST6/NS	stiff	600 x 900 (23 11/16" x 35 3/8")	3.2 (1/8")	macro

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 make sure that you yourself are in an easy working position.

D. WORKING PROPERTIES

<u>Cutting</u>

Cutting to rough size is easiest by carving with a cutter, then breaking manually. Pattern cutting is done after semi-activation.

Activation

1. Activation in a water bath

AQUAFIT[™] NS is softened by heating at a temperature of **65°C (149°F)**. Possible activation source is a water bath.

Activation time: 3 min. at 65°C (149°F)

Take the material out of the water bath and dry quickly on a towel. Afterwards, apply the material to the patient.

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

2. Activation in an oven or dry heating device.

AQUAFIT[™] NS is softened by heating at a temperature of **75-90°C (176-194°F)**.

When using a heating plate or an oven, the hot surface must be covered with a Teflon film.

When using a heat gun, do not exceed the set temperature of $250^{\circ}C$ ($482^{\circ}F$) to avoid breakdown of the material.

High temperatures up to a maximum of 180°C (356°F) do not damage AQUAFIT[™] NS but are not userfriendly. Higher temperatures are allowed on the condition that the activation time is reduced accordingly.

! Wear gloves and do not apply AQUAFIT[™] NS directly to the patient's skin at high activation temperatures.

! Never use an open flame to activate AQUAFIT[™] NS.

Application

- 1. Let AQUAFIT[™] NS cool DOWN before application.
- ! AQUAFIT[™] NS is:
 - not adhesive when wet heated or when dry heated and powdered with talcum.
 - <u>a little adhesive</u> when wet heated, toweled and pressed together and when dry heated at low temperature (up to 80°C or 176°F).
 - <u>cohesive</u> when dry heated at high temperature (over 100°C or 212°F). However the bonding is not permanent and will pop once hardened.
 - 2. In case of accidental bonding, let AQUAFIT[™] NS harden completely and then pop apart. Reactivation in hot water or oven is possible.
 - 3. To attach fixation 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, by 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.

E. FINISHING

There are several ways to give the edges of an AQUAFIT[™] 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.

F. MAINTENANCE AND WASTE MANAGEMENT

! When cleaning AQUAFIT[™] NS, avoid prolonged contact with detergents and acids which may affect the NS film. Disinfection is possible with alcohol, quaternary ammonium or a solution of commercial disinfecting soaps (HAC[®], Sterilium[®], etc.)

After use, AQUAFIT[™] NS can be disposed of with normal household wast without harming the environment. AQUAFIT[™] NS is biodegradable.

G. STORAGE

AQUAFIT[™] NS sheets and leftovers must be stored individually in their original plastic packaging to avoid cohesion.

AQUAFIT[™] NS must be stored in a dark, cool, dry place at a temperature of min. 10°C (50°F) and max 30°C (86°F).

H. ADDITIONAL INFORMATION

For additional information such as distributor contact information, product brochures, Safety Data Sheets and regulatory information, please visit our website <u>www.orfit.com</u>.

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.

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