

## TECNOFIT™

### A. GENERAL PRODUCT INFORMATION

TECNOFIT is a low temperature thermoplastic sheet material for the fabrication of orthotics, external immobilization devices and rehabilitation aids.

TECNOFIT is applied directly to the patient after it is activated.

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

### B. PRODUCT RANGE

TECNOFIT is available in sheets of different thicknesses, sizes and types of perforation.

Art. no.	Thickness in mm	Sizes in mm	Perforation type
8738.1 8738.4 8738.3	2.5	450 x 600	non-perforated mini maxi
8734.1 8734.4 8754.1 8754.4	3.2	450 x 600 600 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. Rub the orthosis with talcum powder before applying to the patient.

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

### D. ACTIVATION TECHNIQUE

1. TECNOFIT is softened by heating at a minimum temperature of 60°C (140°F). Possible activation sources are: Suspan 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 dry heating TECNOFIT, both sides of the material have to be rubbed with talcum powder before activation. 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 temperature of 250°C (482°F) to avoid breakdown of the material.
3. TECNOFIT becomes transparent at the softening temperature. This is a perfect indicator that the right temperature has been reached in the material.

! **4. 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.**

5. High temperatures up to a maximum of 120°C (248°F) do not damage TECNOFIT, but are not user-friendly. Higher temperatures are allowed on the condition that the activation time is reduced accordingly and that the product is sufficiently rubbed with talcum powder. Wear gloves and do not apply TECNOFIT directly to the patient's skin at these high activation temperatures.

! **6. Never use an open flame to activate TECNOFIT.**

### E. WORKING PROPERTIES

#### Cutting

1. Draw the orthotic pattern on the TECNOFIT 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 TECNOFIT sheet until it is formable but not yet stretchable and cut the precise orthotic pattern by means of a pair of scissors.

#### Applying

1. Activate the TECNOFIT 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. Several application techniques are possible:
  - gravity technique: the material forms itself under gravity.
  - closed technique: form the material around the extremity and stick the edges together.

- bandaging techniques: secure the orthosis by means of a bandage.  
Utilise the stretch and elastic properties of TECNOFIT as much as possible.

3. TECNOFIT easily sticks to itself and to all porous surfaces. In case of accidental bonding, take the two parts apart after reactivation. Permanent adhesion to attach fixation straps and orthosis accessories is possible with dry heat.

! **In order to assure the strength of the adhesion, both surfaces should be briefly DRY heated at high temperature (max. 250°C-482°F).**

4. Do not remove the orthosis from the patient before TECNOFIT has become completely opaque.  
You may cut the excessive material away 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.

#### F. FINISHING

1. There are several ways to give the edges of a TECNOFIT orthosis 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 (art. no. 35307),
  - grinding by using a suitable grinding tool at a low turning speed.
2. The surface of TECNOFIT® orthoses is usually dull after application. It can be given a nice smooth finish by heating it with a heat gun for a few seconds and not touching it until it has hardened.

#### G. MAINTENANCE AND WASTE MANAGEMENT

Orthoses made of TECNOFIT must be cleaned daily. Use lukewarm water and liquid soap, biological detergent or toothpaste, and rinse well.

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

Sterilization of TECNOFIT 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 of with normal household waste without harming the environment. TECNOFIT 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 orthosis.**

#### I. STORAGE

- TECNOFIT 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 too soft when activated.

#### J. GENERAL SAFETY ADVICE

- ! \* **TECNOFIT 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 TECNOFIT.**  
! \* **To make orthoses and rehabilitation aids, TECNOFIT 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](http://www.orfit.com).

#### Note:

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.  
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