ORFICAST® THERMOPLASTIC TAPE

A. GENERAL PRODUCT INFORMATION

ORFICAST Thermoplastic Tape is a low temperature thermoplastic material, with a textile-like feel, used for the fabrication of small immobilization orthoses.

ORFICAST Thermoplastic Tape is applied directly to the patient after it is activated.

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

B. PRODUCT RANGE

ORFICAST Thermoplastic Tape is available in rolls of ± 300 cm length, widths of 3 and 6 cm in 2 colours. The thickness of the material is 1.3 mm (1/20").

The density of the material is about 20 g/m.
<table>
<thead>
<tr>
<th>Art. no.</th>
<th>Description</th>
<th>Colour</th>
</tr>
</thead>
<tbody>
<tr>
<td>4030</td>
<td>1 roll – width: 3 cm</td>
<td>Blue</td>
</tr>
<tr>
<td>4030Z</td>
<td>1 roll – width: 3 cm</td>
<td>Black</td>
</tr>
<tr>
<td>4031</td>
<td>box with 12 rolls – width: 3 cm</td>
<td>Blue</td>
</tr>
<tr>
<td>4031Z</td>
<td>box with 12 rolls – width: 3 cm</td>
<td>Black</td>
</tr>
<tr>
<td>4032</td>
<td>1 roll – width: 6 cm</td>
<td>Blue</td>
</tr>
<tr>
<td>4032Z</td>
<td>1 roll – width: 6 cm</td>
<td>Black</td>
</tr>
<tr>
<td>4033</td>
<td>box with 6 rolls – width: 6 cm</td>
<td>Blue</td>
</tr>
<tr>
<td>4033Z</td>
<td>box with 6 rolls – width: 6 cm</td>
<td>Black</td>
</tr>
</tbody>
</table>

**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 ORFICAST Thermoplastic Tape will not burn the patient.**

**D. ACTIVATION TECHNIQUE**

1. ORFICAST Thermoplastic Tape is softened by heating at a minimum temperature of 65°C (149°F). Possible activation sources are: Suspan water bath, dry heater, heating plate, microwave oven and heat gun. The activation time depends on the heat source and the product size, and varies from 30 seconds to 5 minutes:

   2. Dry heater or heating plate: 1-5 min
   3. Microwave oven: 500W: 2–2,5 min (first heat sufficient amount of water in the microwave and afterwards activate the ORFICAST Thermoplastic Tape by steeping it into this hot water)
   4. Heat gun: 1-4 seconds: only use the heat gun to locally (re)activate the ORFICAST Thermoplastic Tape in order to make small corrections to the shape of the orthosis or to attach hook and loop tape. The heat gun is not meant to be used as heat source to activate the total length of the ORFICAST Thermoplastic Tape before moulding it onto the patient.

2. When activated on a heating plate, ORFICAST Thermoplastic Tape should be placed on a silicone or Teflon sheet to prevent it from adhering to the plate. When using a heat gun, it should be set at a minimum airflow and the temperature should not exceed 250°C (482°F) to avoid breakdown of the material.

! **3. Be careful: 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.**

4. Temperatures up to a maximum of 100°C (212°F) do not damage ORFICAST Thermoplastic Tape, but are not user-friendly. Higher temperatures are allowed on the condition that the activation time is reduced accordingly.

! **5. Never use an open flame to activate ORFICAST Thermoplastic Tape.**

**E. WORKING PROPERTIES**

**Applying:**

1. Various application techniques are possible:

   - Wrapping technique: identical to the application of plaster bandages.
- Strips can be sewn together to make specific patterns.
- Manual moulding of the ORFICAST Thermoplastic Tape strip [or several layers together].

Use the stretch and elastic properties of ORFICAST Thermoplastic Tape but avoid compression of the skin.

2. ORFICAST Thermoplastic Tape sticks to itself and to all porous surfaces very easily. In case of accidental bonding, keep it activated and gently pull the layers apart.

To obtain a homogeneous orthosis, ORFICAST Thermoplastic Tape must be applied while hot. When completed, firmly press to enhance adhesion of all layers.

Straps, orthosis accessories or reinforcements can also be stuck to the orthosis using the self-adhesive properties of ORFICAST Thermoplastic Tape. First re activate the ORFICAST orthosis locally using the heat gun until the material becomes brilliant and sticky. Afterwards glue the desired materials onto the surface of the orthosis and press firmly to secure the bonding.

3. ORFICAST Thermoplastic Tape has low to moderate memory. The material can be reactivated and unwrapped if not totally pressed together. This allows you to make small corrections to the orthosis if necessary.

F. FINISHING

! In order to assure the strength of the adhesion, the ORFICAST Thermoplastic Tape surface should BRIEFLY be DRY heated at HIGH temperature.

1. Do not remove ORFICAST Thermoplastic Tape from the patient before the orthosis is sufficiently hard.
2. If the orthosis must be cut to be removed, use a suitable pair of bandage scissors and do not wait until the product is completely hard.
3. The cooling time can be shortened by means of cold air, a cold bandage or a cold spray.

G. MAINTENENCE AND WASTE MANAGEMENT

To clean the ORFICAST Thermoplastic Tape, use lukewarm water and soap. Rinse locally and dry with a hairdryer on a cool setting to avoid prolonged skin maceration. Do not put the entire orthosis into water as this might cause loss of the shape.

! Never use solvents, avoid acid detergents.

Sterilization of ORFICAST Thermoplastic Tape orthosis in an autoclave is impossible.

ORFICAST Thermoplastic Tape can be disinfected with alcohol, quaternary ammonium or a solution of commercial disinfecting soaps (HAC®, Sterilium®, etc.). Rinse well after treatment. After use, an orthosis can be disposed of with normal household waste without harming the environment. ORFICAST Thermoplastic Tape is biodegradable.

H. ADVICE FOR THE PATIENT

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

I. STORAGE

- It is advised to store to ORFICAST Thermoplastic Tape 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-over material 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.

J. GENERAL SAFETY ADVICE

! * ORFICAST Thermoplastic Tape 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 ORFICAST Thermoplastic Tape.

ORFICAST Thermoplastic Tape may only be used by qualified health professionals for the fabrication of orthoses.

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.

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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