

ORFICAST™ THERMOPLASTIC TAPE

INSTRUCTIONS FOR USE

ACTIVATION
TEMPERATURE:
65°C (149°F)



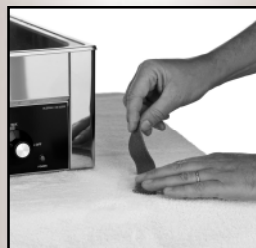
MINIMUM
ACTIVATION TIME:
1 minute



MAXIMUM
ACTIVATION TIME:
30 minutes



DRYING TIME:
max 10 seconds



MOULDING TIME:
1 minute



HARDENING TIME:
Minimum 5 minutes



A. GENERAL PRODUCT INFORMATION

ORFICAST™ Thermoplastic Tape is a low temperature thermoplastic knitted textile material for the fabrication of small splints and casts for immobilization.

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 and widths of 3 and 6 cm. The thickness of the material is 1.3 mm (1/20"). The density of the material is about 20 g/m.

| Art. no. | Sizes in cm | Description |
|----------|------------------------------------|-------------------|
| 4030 | width: 3 cm – length: ± 300 cm | 1 roll |
| 4031 | width: 3 cm – length: ± 300 cm | 12 rolls in 1 box |
| 4032 | width: 6 cm – length: ± 300 cm | 1 roll |
| 4033 | width: 6 cm – length: ± 300 cm | 6 rolls in 1 box |

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.

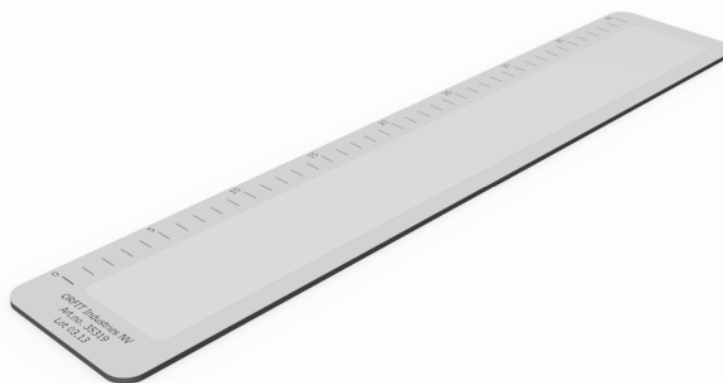
D. ACTIVATION TECHNIQUE

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.
 1. Water bath: 65°C (149°F): 1 min.
 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 cast 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 molding it onto the patient.

2. When activated on a heating plate, ORFICAST™ Thermoplastic Tape should be placed on 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

Before activating ORFICAST™ Thermoplastic Tape, use the accompanying ORFICAST™ ruler (ref. 35319) as follows:



1. Place and attach one end of the ORFICAST™ Thermoplastic Tape roll at the “0” mark of the fixation strip on the ORFICAST™ ruler. Press this end firmly to attach it on the fixation strip.
2. Move the ORFICAST™ Thermoplastic Tape roll to the opposite side of the ORFICAST™ ruler while unrolling and pressing the ORFICAST™ Tape onto the fixation strip
3. Stop unrolling the ORFICAST™ Thermoplastic Tape at one of the numbered marks (0-40) when reaching the sufficient length of tape for making the desired splint.
4. Cut the ORFICAST™ Thermoplastic Tape at this length and press the loose end also firmly to attach to the fixation strip.

Note: the engraved head marks (0-40) and the marks in between them indicate the total length of the ORFICAST™ Thermoplastic Tape in cm's (inches). These marks allow you to precisely choose and cut the correct length of ORFICAST™ Thermoplastic Tape for your desired splint and avoid any waste of product. The ORFICAST™ ruler can also be used to easily measure and pre-cut several pieces or samples in advance of serial splinting.

5. Once the full length of the ORFICAST™ Thermoplastic Tape is well attached to the ORFICAST™ ruler, you can start the activation process by choosing one of the

activation techniques earlier mentioned in point D.

6. Make sure the ORFICAST™ Thermoplastic Tape is completely activated (soft and sticky) before unstrapping it from the ORFICAST™ ruler.

Note: when activating the ORFICAST™ Thermoplastic Tape by means of hot water (in suspan or microwave), first take the ORFICAST™ ruler out of the hot water with a spatula and place it on a towel. Unstrap the ORFICAST™ Thermoplastic Tape from the fixation strip and remove excess water by pressing the full length with the palm of the hand onto the towel.

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 cast, ORFICAST™ Thermoplastic Tape must be applied while hot. When completed, firmly press to enhance adhesion of all layers. Straps, splint accessories or reinforcements can also be stuck to the cast using the self-adhesive properties of ORFICAST™ Thermoplastic Tape. First reactivate the ORFICAST™ splint locally using the heat gun until the material becomes brilliant and sticky. Afterwards glue the desired materials onto the surface of the splint and press firmly to secure the bonding.
3. ORFICAST™ Thermoplastic Tape has perfect memory. The material can be reactivated and unwrapped if not totally pressed together. This allows you to make small corrections to the splint 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 cast is sufficiently hard.
2. If the cast 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. MAINTENANCE AND WASTE MANAGEMENT

To clean the ORFICAST™ Thermoplastic Tape cast, 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 splint or cast into water as this might cause loss of the shape.

! Never use solvents, avoid acid detergents.

Sterilization of ORFICAST™ Thermoplastic Tape splints and removable casts 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, a splint 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 cast or splint and about the possible constraints.

I. STORAGE

- It is advised to store the 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 ADVICES

- ! * 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 casts, and splints.**

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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