

## ORFITRANS®

### A. GENERAL PRODUCT INFORMATION

ORFITRANS is a high melting temperature thermoplastic material for the production of external orthoses and prosthetic check and inner sockets.

- \* ORFITRANS PETG is the most rigid and crystal clear material for short term check sockets.
- \* ORFITRANS Stiff is a very stiff clear material with high impact resistance for check sockets.
- \* ORFITRANS Stiff Protect is a very stiff clear material with high impact resistance for check sockets and antibacterial properties.
- \* ORFITRANS Medium Soft is semi-transparent material with slightly flexible properties.
- \* ORFITRANS Medium Soft Protect is semi-transparent material with slightly flexible and antibacterial properties.
- \* ORFITRANS Medium Soft Beige is a slightly flexible material in beige colour.
- \* ORFITRANS Medium Soft Beige Protect is a slightly flexible material with antibacterial properties in beige colour.
- \* ORFITRANS Excel is a semi-transparent PE-copolymer for flexible sockets.
- \* ORFITRANS Excel Black is a black PE-copolymer for flexible sockets.
- \* ORFITRANS Extra Soft is a semi-transparent and flexible material.
- \* ORFITRANS Extra Soft Beige is a flexible material in beige colour.
- \* ORFITRANS Extra Soft Silicone is a white, flexible material.
- \* ORFITRANS Supra Soft is a semi-transparent material, the most flexible of our range.

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

### B. PRODUCT RANGE

ORFITRANS is available in sheets of different thicknesses and sizes. For a product overview: see last pages of these IFU.

### C. PRECAUTIONS BEFORE USE

1. The workplace must be well-ventilated to avoid overheating. However, there should be no draughts to avoid unequal cooling of the activated material.
2. Ensure that all necessary tools are within reach to be able to work quickly and efficiently.
3. Check the sheet for any damages or non-conformities before use. In case of any damage, do not use the item.
- !** 4. ***Wear suitable clothing (long sleeves), and avoid contact with the materials at very high temperatures. Always wear proper isolating gloves.***

### D. ACTIVATION TECHNIQUE

1. ORFITRANS is preferably activated in a convection oven or an infrared oven. A heating plate, or a plate oven can also be used.
2. Each ORFITRANS material has its own optimum activation temperature and activation time depending on the type of oven and the thickness of the sheet. These activation times are guidelines only. The activation time in a convection or infrared oven depends on the material and the thickness of the sheet.

Product	Optimum activation temperature		Thickness		Average activation time in a convection oven (minutes)	Average activation time in an infrared oven (minutes)
	160°C	320°F				
ORFITRANS PETG			8 mm	5/16"	15m30	8
			10 mm	3/8"	20m30	9m30
			12 mm	1/2"	24m30	12
			15 mm	19/32"	30	15m30

ORFITRANS Stiff	160°C	320°F	8 mm 10 mm 12 mm 15 mm	5/16" 3/8" 1/2" 19/32"	25 33 36 49	27 32 34 45
ORFITRANS Stiff Protect	160°C	320°F	8 mm 10 mm 12 mm 15 mm	5/16" 3/8" 1/2" 19/32"	25 33 36 49	27 32 34 45
ORFITRANS Medium Soft	150°C	302°F	8 mm 10 mm 12 mm 15 mm	5/16" 3/8" 1/2" 19/32"	17 18 21 25	8m30 10 12 16
ORFITRANS Medium Soft Protect	150°C	302°F	8 mm 10 mm 12 mm 15 mm	5/16" 3/8" 1/2" 19/32"	17 18 21 25	8m30 10 12 16
ORFITRANS Medium Soft Beige	150°C	302°F	8 mm 10 mm 12 mm 15 mm	5/16" 3/8" 1/2" 19/32"	17 18 21 25	8m30 10 12 16
ORFITRANS Medium Soft Beige Protect	150°C	302°F	8 mm 10 mm 12 mm 15 mm	5/16" 3/8" 1/2" 19/32"	17 18 21 25	8m30 10 12 16
ORFITRANS Excel	130°C	266°F	3 mm 4 mm 5 mm 8 mm 10 mm 12 mm 15 mm	1/8" 5/32" 13/64" 5/16" 3/8" 1/2" 19/32"	5 6 7 13 16 19 21	2m30 3m30 4 7 9 11 14
ORFITRANS Excel Black	130°C	266°F	8 mm 10 mm 12 mm 15 mm	5/16" 3/8" 1/2" 19/32"	13 16 19 21	7 9 11 14
ORFITRANS Extra Soft	150°C	302°F	9 mm 12 mm	23/64" 1/2"	11 14	7 9
ORFITRANS Extra Soft Beige	150°C	302°F	5 mm 9 mm 12 mm	13/64" 23/64" 1/2"	10 11 14	4m30 7 9m30
ORFITRANS Extra Soft Silicone	150°C	302°F	9 mm 12 mm 15 mm	23/64" 1/2" 19/32"	11 14 23	7 10 12m30
ORFITRANS Supra Soft	150°C	302°F	8 mm 10 mm 12 mm 15 mm	5/16" 3/8" 1/2" 19/32"	16 18 20 24	7m30 9 10 12

Make sure the temperature gauge of the oven is working properly and has been correctly adjusted (it is possible to calibrate this with a glass thermometer). ORFITRANS is not mouldable enough at temperatures below the indicated activation temperatures and will flow abundantly at excessively high temperatures.

3. When using a sheet oven, the oven plate must be covered with a Teflon-film and check if both items are clean.
4. Remove the protective film from both sides of ORFITRANS.
5. For moulding a prosthetic socket, the ORFITRANS sheet is locked in a frame and heated so that the plastic gradually sags and forms a drop-like bubble. When the length of this bubble has reached approximately 2/3 of the length of the positive (plaster) mould (minimum 15 cm), ORFITRANS is ready to be formed.

! **7. Never use an open flame for the activation of the plastic because of risk of fire.**

#### E. WORKING PROPERTIES

##### Forming

1. The positive (plaster) mould has to be dry and must have a smooth and dust free surface. Preheating the cast to 60°C (140°F) which allows for more working time. If you use a foam positive, don't use too much grease.
2. Take the activated material out of the oven with isolating gloves. Turn the "drop" upside down and pull it slowly along the length of the plaster mould until the frame covers the basic platform.
3. Turn on the vacuum pump very gently to work away wrinkles in the plastic before the vacuum is completed.

##### Cooling

1. The cooling process must occur over a long period of time and at room temperature.
2. Leave ORFITRANS on the (plaster) mould until it is fully cooled to avoid internal stresses that may alter the shape.
3. Remove frame and trim excess material using saw or knife. Remove from positive mould or brake the positive mould.

! **Wear protective clothing and gloves when using a saw or knife.**

#### F. FINISHING

The edges of ORFITRANS are finished by grinding and polishing using adapted wheels and at a speed according the ORFITRANS material.

! **Pay attention to security measures when using grinding and polishing machines.**

#### G. MAINTENANCE AND WASTE MANAGEMENT

1. Prostheses and orthoses made of ORFITRANS must be cleaned daily. Use lukewarm water and soap or a biological detergent, and rinse well.

! **Never use solvents.**

2. Disinfection of prosthetic sockets and orthoses is possible with alcohol, quaternary ammonium or a solution of commercial disinfecting soaps (HAC®, Sterilium®, etc.).
3. After use, prosthetic sockets and orthoses can be disposed of with normal household waste without harming the environment.

Degradation temperature of ORFITRANS:

	Degradation temperature
ORFITRANS PETG	+300°C (+572°F)
ORFITRANS Stiff	300°C (572°F)
ORFITRANS Stiff Protect	300°C (572°F)
ORFITRANS Medium Soft	200°C (392°F)
ORFITRANS Medium Soft Beige	200°C (392°F)
ORFITRANS Medium Soft Protect	200°C (392°F)
ORIFTRANS Medium Soft Beige Protect	200°C (392°F)

ORFITRANS Excel ORFITRANS Excel Black	300°C (572°F) 300°C (572°F)
ORFITRANS Extra Soft ORFITRANS Extra Soft Beige ORFITRANS Extra Soft Silicone	230°C (446°F) 230°C (446°F) 230°C (446°F)
ORFITRANS Supra Soft	230°C (446°F)

#### H. ADVICE FOR THE PATIENT

! **Give the patient sufficient information about the exact use and maintenance of the orthosis or the prosthetic socket.**

#### I. STORAGE

Plastics must be stored in their original packaging and in a dry room at a temperature of min. 10°C (50°F) and max. 30°C (86°F). Avoid exposure to light.

#### J. GENERAL SAFETY ADVICE

- ! \* **ORFITRANS 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 ORFITRANS.**
- ! \* **To make orthoses and prosthesis, ORFITRANS 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)

		PRODUCT						
Thickness	Sheet size in mm	ORFITRANS PETG	ORFITRANS Stiff	ORFITRANS Stiff Protect	ORFITRANS Medium Soft	ORFITRANS Medium Soft Protect	ORFITRANS Medium Soft Beige	ORFITRANS Medium Soft Beige Protect
6 mm	400 x 400						37SS/4460B	37SS/AB/4460B
8 mm	400 x 400	37PETG/4480	37ST/4480	37ST/AB/4480	37SS/4480	37SS/AB/4480	37SS/4480B	37SS/AB/4480B
10 mm	400 x 400	37PETG/44100	37ST/44100	37ST/AB/44100	37SS/44100	37SS/AB/44100	37SS/44100B	37SS/AB/44100B
12 mm	400 x 400	37PETG/44120	37ST/44120	37ST/AB/44120	37SS/44120	37SS/AB/44120	37SS/44120B	37SS/AB/44120B
15 mm	400 x 400	37PETG/44150	37ST/44150	37ST/AB/44150	37SS/44150	37SS/AB/44150		
8 mm	1225 x 1225	37PETG/1225122580						
10 mm	1225 x 1225	37PETG/12251225100						
12 mm	1225 x 1225	37PETG/12251225120						
15 mm	1225 x 1225	37PETG/12251225150						

		PRODUCT					
Thickness	Sheet size in mm	ORFITRANS Excel	ORFITRANS Excel Black	ORFITRANS Extra Soft	ORFITRANS Extra Soft Beige	ORFITRANS Extra Soft Silicone	ORFITRANS Supra Soft
3 mm	1225 x 1225	37SS42/1225122530					
4 mm	1225 x 1225	37SS42/1225122540					
5 mm	1225 x 1225	37SS42/1225122550					
5 mm	400 x 400				37SS62/4450B		
8 mm	400 x 400	37SS42/4480	37SS42/4480Z				37SS32/4480
9 mm	400 x 400			37SS62/4490	37SS62/4490B	37SIL/4490	
10 mm	400 x 400	37SS42/44100	37SS42/44100Z				37SS32/44100
12 mm	400 x 400	37SS42/44120	37SS42/44120Z	37SS62/44120	37SS62/44120B	37SIL/44120	37SS32/44120
15 mm	400 x 400	37SS42/44150	37SS42/44150Z				37SS32/44150

**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. ORFITRANS® is a registered trademark of ORFIT INDUSTRIES N.V.



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