

ORFITRANS™

A. GENERAL PRODUCT INFORMATION

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

- * ORFITRANS Stiff is a very stiff clear material with high impact resistance for check sockets.
- * ORFITRANS Medium Soft is semi-transparent material with higher bending properties.
- * 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 with silicone is a milky, flexible material.

! 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 page 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. Wear suitable clothing 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)
	°C	°F	mm	inch		
ORFITRANS Stiff	160°C	320°F	8 mm	5/16"	25	27
			10 mm	3/8"	33	32
			12 mm	1/2"	36	34
			15 mm	19/32"	49	45
ORFITRANS Medium Soft	150°C	302°F	8 mm	5/16"	17	10.5
			10 mm	3/8"	18	13
			12 mm	1/2"	21	15
			15 mm	19/32"	25	17
ORFITRANS Excel	130°C	266°F	3 mm	1/8"	5	2.5
			4 mm	5/32"	6	3.5
			5 mm	13/64"	7	4
			8 mm	5/16"	13	7
			10 mm	3/8"	16	9
			15 mm	19/32"	21	11

ORFITRANS Excel Black	130°C	266°F	8 mm	5/16"	13	7
			10 mm	3/8"	16	9
			12 mm	1/2"	19	11
			15 mm	19/32"	21	14
ORFITRANS Extra Soft	150°C	302°F	9 mm	23/64"	11	7
			12 mm	1/2"	14	9
ORFITRANS Extra Soft Silicone	150°C	302°F	9 mm	23/64"	11	7
			12 mm	1/2"	14	10

3. 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.
4. When using a sheet oven, the oven plate must be covered with a Teflon-film and it is recommended to clean both ORFITRANS and the Teflon film with acetone before activation.
5. Remove the protective film from both sides of ORFITRANS.
6. For activating 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. It is preferably preheated to 60°C (140°F) which allows for more working time.
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 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. Cut the socket from the frame with a cutter and cut away the surplus of material.

! **Wear protective clothing and gloves when using a cutter.**

F. FINISHING

The edges of ORFITRANS are finished by grinding and polishing using adapted wheels and at a speed of 3000 rpm (grinding roll).

! **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 Stiff	300°C (572°F)
ORFITRANS Medium Soft	200°C (392°F)
ORFITRANS Excel ORFITRANS Excel Black	300°C (572°F)
ORFITRANS Extra Soft ORFITRANS Extra Soft with silicone	230°C (446°F) 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 rehabilitation aids, 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

		PRODUCT					
Thickness	Sheet size in mm	ORFITRANS Stiff	ORFITRANS Medium Soft	ORFITRANS Excel	ORFITRANS Excel Black	ORFITRANS Extra Soft	ORFITRANS Extra Soft Silicone
3 mm	1225 x 1225			37SS42/1225122530			
4 mm	1225 x 1225			37SS42/1225122540			
5 mm	1225 x 1225			37SS42/1225122550			
4.7 mm	400 x 400						
6.3 mm	400 x 400						
8 mm	400 x 400	37ST/4480	37SS/4480	37SS42/4480	37SS42/4480Z		
8.5 mm	400 x 400						
9 mm	400 x 400					37SS62/4490	37SIL/4490
10 mm	400 x 400	37ST/44100	37SS/44100	37SS42/44100	37SS42/44100Z		
11.5 mm	400 x 400						
12 mm	400 x 400	37ST/44120	37SS/44120	37SS42/44120	37SS42/44120Z	37SS62/44120	37SIL/44120
15 mm	400 x 400	37ST/44150	37SS/44150	37SS42/44150	37SS42/44150Z		

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 trademark of ORFIT INDUSTRIES N.V.



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