orfit The personal fit

TECHNICAL DATA SHEET

TECNOFIT™ 2.5 mm (3/32”)

Thickness	mm (inches)	2.5 (3/32)	2.5 (3/32)	2.5 (3/32)
Perforation	% (type)	0 (non perfo)	3.5 (mini)	25 (maxi)
Thermoforming conditions				
Optimum activation temperature (in water bath)	°C (°F)	65 (149)	65 (149)	65 (149)
Activation time (in water bath)	minutes	3 - 4	3 - 4	3 - 4
Transparent when activated		yes	yes	yes
Working time	minutes	2 ¼ - 2 ¾	2 - 2 ½	1 - 1 ½
Hardening time	minutes	5 ¼ - 5 ¾	4 ¾ - 5 ¼	2 ½ - 3
Time to completion	minutes	22 - 23	19 - 20	10 - 11
Resistance to stretch		high	high	high
Drape		high	high	high
Memory (after 200 % elongation)		full	full	full
Maximum elongation when activated	%	440	365	285
Memory (after maximum elongation)		full	full	full
Sticks to itself when activated and wet		temporarily	temporarily	temporarily
Sticks to itself when activated, after drying		reliable under low stress	reliable under low stress	reliable under low stress
Adhesion (velcro strip) using heat gun		yes	yes	yes
Mechanical properties at 21°C				
Flexural modulus	MPa	445	325	290
Elastic modulus	MPa	235	200	145
Tensile strength	MPa	18.5	14.0	10.0
Strain at break	%	no break	no break	110
General properties				
Density	g cm^{-3}	1.14	1.14	1.14
Hardness (shore D)		57	57	57
Surface feeling		smooth	smooth	smooth
Color		natural	natural	natural
Odor		none	none	none
Fatigue	cycles	> 10000	> 10000	> 10000
Biocompatible		yes	yes	yes

TECNOFIT™ 3.2 mm (1/8”)

Thickness	mm (inches)	3.2 (1/8)	3.2 (1/8)	3.2 (1/8)
Perforation	% (type)	0 (non perfo)	3.5 (mini)	25 (maxi)
Thermoforming conditions				
Optimum activation temperature (in water bath)	°C (°F)	65 (149)	65 (149)	65 (149)
Activation time (in water bath)	minutes	3 - 4	3 - 4	3 - 4
Transparent when activated		yes	yes	yes
Working time	minutes	2 ¾ - 3 ¼	2 ½ - 3	2 – 2 ½
Hardening time	minutes	7 ¾ - 8 ¼	6 ½ - 7	5 ½ - 6
Time to completion	minutes	21 - 22	18 - 19	16 – 17
Resistance to stretch		high	high	high
Drape		high	high	high
Memory (after 200 % elongation)		full	full	full
Maximum elongation when activated	%	400	300	250
Memory (after maximum elongation)		full	full	full
Sticks to itself when activated and wet		temporarily	temporarily	temporarily
Sticks to itself when activated, after drying		reliable under low stress	reliable under low stress	reliable under low stress
Adhesion (velcro strip) using heat gun		yes	yes	yes
Mechanical properties at 21°C				
Flexural modulus	MPa	445	345	250
Elastic modulus	MPa	235	205	185
Tensile strength	MPa	18.5	14.5	10
Strain at break	%	no break	no break	no break
General properties				
Density	g cm^{-3}	1.14	1.14	1.14
Hardness (shore D)		57	57	57
Surface feeling		smooth	smooth	smooth
Color		natural	natural	natural
Odor		none	none	none
Fatigue	cycles	> 10000	> 10000	> 10000
Biocompatible		yes	yes	yes

INFORMATION

The hardening time indicates the time period during which the material remains flexible, but no longer mouldable.

The time to completion indicates the length of time until the orthosis is finished and can be worn by the patient.

The memory indicates the ability of the material to regain its original shape after reheating.

The flexural modulus indicates the resistance of the material to a force causing it to bend.

The elastic modulus defines the ratio of the applied tensile stress to the change in shape of the material.

The tensile strength is the pulling force required to break the material.

The strain at break is the length increase of the material when stretched until failure.

The hardness indicates the resistance of the material to compression.

Fatigue indicates the minimum number of stress cycles the material sustains when bending over 90 degrees without failure.

The biocompatibility is studied according the guidelines of the International Organization for Standardization 10993 – Biological Evaluation of Medical Devices:

- Primary skin irritation study.
- Delayed dermal contact sensitization study.
- Cytotoxicity study.

Note:

Belgium T +32 (0)3 326 20 26
America T 516-935-8500

Ref.: 80016 – TECNOFIT.docx
VERSION 4

LAST UPDATE: 08/07/2022