

Polyacetal (POM)

DURACON®

PM27S01N

WK2001

Medical

Introduction

DURACON® POM is widely used as a sliding component due to its excellent friction and wear characteristics. For even higher requirements, there are many grades suitable for specific applications which have been developed and are currently in use.

For many years the Polyplastics Group has served the medical and healthcare market with its high-purity material TOPAS® COC. Nowadays in these markets voices are being raised for other materials with high quality and high reliability. To meet such demands, we are adding the DURACON® POM PM Series to its medical portfolio.

The first to come out under the PM Series was the grade named "PM09S01N". With a standard viscosity it holds very standard mechanical properties and moldability of POM. In addition, the high-flow type grade named "PM27S01N" will contribute to wall-thinning, miniaturization and lightening of various medical devices that are becoming more and more complicated and highly-functional. These grades will hold features that meet medical device manufacturers' requirements as follows:

1. Agency Compliance

- ISO10993 and USP Class VI biocompatibility/cytotoxicity
- FDA Drug Master File (DMF) and Device Master File (MAF)
- EU 10/2011 and FDA food contact 21 CFR 177.2470

2. Quality Management System

- Conformity to VDI guideline "VDI 2017 Medical-grade Plastics"
- Full traceability of processes and products
- Production management based on GMP principle

3. Packaging

- For the first time among DURACON® POM grades, the materials are packaged in PE valve-type bags.

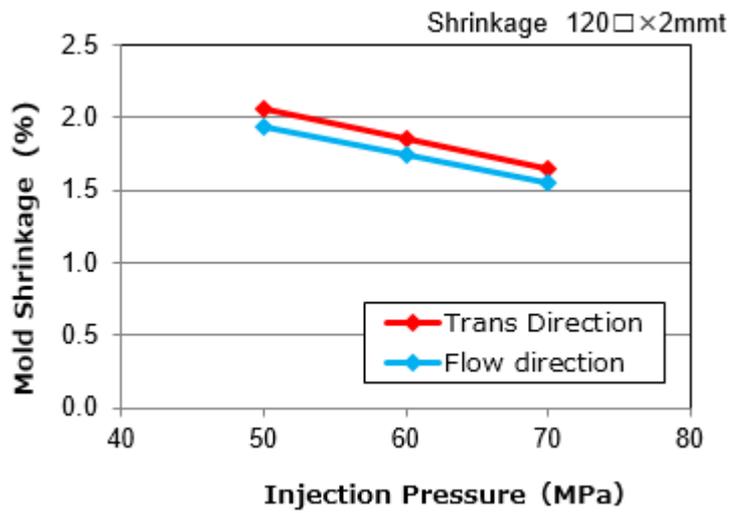
DISCLAIMER

- This material is not designed, developed or manufactured for any use in transplantation or implant.
- There is no evidence that this material functions well with sufficient quality and performance when it is used for any transplantation or implant.
- Polyplastics has never conducted appropriate studies or assessments as to the safety

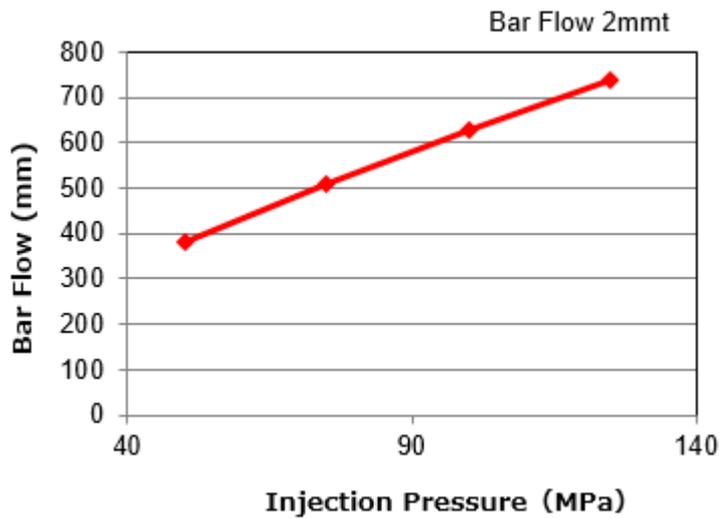
and suitability of this material for its use in any transplantation and implant.

Moldability

PM27S01N Mold Shrinkage



PM27S01N Flowability



General Properties of PM27S01N

table1-1 General Properties (ISO)

Item	Unit	Test Method	Medical
			PM27S01N
			High Flow, Fast Molding Cycle
Color			WK2001
ISO(JIS)quality-of-the-material display:		ISO11469 (JIS K6999)	>POM<
Density	g/cm ³	ISO 1183	1.41
Water absorption (23°C, 24hrs, 1mmt)	%	ISO 62	-
MFR (190°C, 2.16kg)	g/10min	ISO 1133	27
MVR (190°C, 2.16kg)	cm ³ /10min	ISO 1133	23
Tensile strength	MPa	ISO 527-1,2	66
Strain at break	%	ISO 527-1,2	20 ¹
Tensile modulus	MPa	ISO 527-1,2	2,900
Flexural strength	MPa	ISO 178	91
Flexural modulus	MPa	ISO 178	2,600
Charpy notched impact strength (23°C)	kJ/m ²	ISO 179/1eA	7
Temperature of deflection under load (1.8MPa)	°C	ISO 75-1,2	95
Coefficient of linear thermal expansion (23 - 55°C, Flow direction)	x10 ⁻⁵ /°C	Our standard	11
Coefficient of linear thermal expansion (23 - 55°C, Transverse direction)	x10 ⁻⁵ /°C	Our standard	11
Electric strength (3mmt)	kV/mm	IEC 60243-1	19
Volume resistivity	Ω·cm	IEC 60093	1 × 10 ¹⁴
Surface resistivity	Ω	IEC 60093	1 × 10 ¹⁶
Volume resistivity (Our standard)	Ω·cm		-
Surface resistivity (Our standard)	Ω		-
Mold Shrinkage (60×60×2mmt, Flow direction, Cavity Pressure 60 MPa)	%	ISO 294-4	2.1
Mold Shrinkage (60×60×2mmt, Transverse direction, Cavity Pressure 60 MPa)	%	ISO 294-4	2.2
Rockwell hardness	M(Scale)	ISO2039-2	88
Specific wear amount (Thrust, vs C-Steel, material side, pressure 0.49MPa, 30cm/s)	x10 ⁻³ mm ³ /(N·km)	JIS K7218	-
Specific wear amount (Thrust, vs C-Steel, steel side, pressure 0.49MPa, 30cm/s)	x10 ⁻³ mm ³ /(N·km)	JIS K7218	-
Coefficient of Dynamic Friction (Thrust, vs C-Steel, pressure 0.49MPa, 30cm/s)		JIS K7218	-

Item	Unit	Test Method	Medical
			PM27S01N
			High Flow, Fast Molding Cycle
Specific wear amount (Thrust, vs C-Steel, material side, pressure 0.98MPa, 30cm/s)	$\times 10^{-3} \text{mm}^3/(\text{N} \cdot \text{km})$	JIS K7218	1
Specific wear amount (Thrust, vs C-Steel, steel side, pressure 0.98MPa, 30cm/s)	$\times 10^{-3} \text{mm}^3/(\text{N} \cdot \text{km})$	JIS K7218	0.01>
Coefficient of Dynamic Friction (Thrust, vs C-Steel, pressure 0.98MPa, 30cm/s)		JIS K7218	0.4
Specific wear amount (Thrust, vs M90-44, material side, pressure 0.06MPa, 15cm/s)	$\times 10^{-3} \text{mm}^3/(\text{N} \cdot \text{km})$	JIS K7218	30
Specific wear amount (Thrust, vs M90-44, M90-44 side, pressure 0.06MPa, 15cm/s)	$\times 10^{-3} \text{mm}^3/(\text{N} \cdot \text{km})$	JIS K7218	60
Coefficient of Dynamic Friction (Thrust, vs M90-44, pressure 0.06MPa, 15cm/s)		JIS K7218	-
Flammability		UL94	-
The yellow card File No.			-
Appropriate List number of Ministerial Ordinance for Export Trade Control			Item 16 of Appendix -1

*1) Nominal strain at break

All figures in the table are the typical values of the material and not the minimum values of the material specifications.

NOTES TO USERS

- All property values shown in this brochure are the typical values obtained under conditions prescribed by applicable standards and test methods.
- This brochure has been prepared based on our own experiences and laboratory test data, and therefore all data shown here are not always applicable to parts used under different conditions. We do not guarantee that these data are directly applicable to the application conditions of users and we ask each user to make his own decision on the application.
- It is the users' responsibility to investigate patent rights, service life and potentiality of applications introduced in this brochure. Materials we supply are not intended for the implant applications in the medical and dental fields, and therefore are not recommended for such uses.
- For all works done properly, it is advised to refer to appropriate technical catalogs for specific material processing.
- For safe handling of materials we supply, it is advised to refer to the Safety Data Sheet "SDS" of the proper material.
- This brochure is edited based on reference literature, information and data available to us at the time of creation. The contents of this brochure are subject to change without notice upon achievement of new data.
- Please contact our office for any questions about products we supply, descriptive literatures or any description in this brochure.

DURACON® is a registered trademark of Polyplastics Co., Ltd. in Japan and other countries.

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