

KEPITAL MX25LF01

**(Silicone-modified and medium-low viscosity
grade for medical application)**

R&D Center

1. Characteristics

KEPITAL MX25LF01 adds a special type of silicone and has a very high level of friction and wear resistance. It exhibits a tremendous reduction of friction and wear properties while in contact with POM or other resins under load.

KEPITAL MX25LF01 has passed the biocompatibility assessments ISO 10993-5 and USP Class 6. As such, it is suitable for medical device parts when friction and wear resistance required without sacrificing mechanical properties compared to the standard medical grade.

- (1) Good mechanical properties
- (2) Good sliding performance
- (3) Excellent long-term dimensional stability
- (4) High resistance to chemicals
- (5) Low tendency for creep and fatigue
- (6) Food contact compliance to FDA & 10/2011 EC
- (7) Passed ISO 10993-5 & USP Class 6

2. Available applications

Key Properties	Applications
<ul style="list-style-type: none">■ Good mechanical properties■ Resistance to alcohols, esters, ketones, aliphatic and aromatic hydrocarbons■ High wear resistance from naturally high lubricity■ Excellent long-term dimensional stability■ High creep and fatigue resistance	<p>Suitable for medical applications requiring good sliding performance and high dimensional precision</p> <ul style="list-style-type: none">■ Disposable pens (Insulin pens)■ Nasal sprays■ Surgical guns■ Catheters, etc.

3. General properties

Property	Test method	Unit	KEPITAL MX25BT01	KEPITAL MX25LF01
Density	ISO 1183	g/cm ³	1.41	1.39
Melt flow rate	ISO 1133	g/10 min	13	28
Tensile modulus	ISO 527-2	MPa	2,750	2,300
Tensile strength		MPa	65	55
Yield strain		%	9	8
Nominal strain at break		%	30	30
Flexural strength	ISO 178	MPa	90	75
Flexural modulus	ISO 178	MPa	2,600	2,430
Charpy notched impact strength (23 °C)	ISO 179-1e/A	kJ/m ²	6.0	5.5
Charpy notched impact strength (-30 °C)		kJ/m ²	5.0	4.0
Heat deflection temperature (1.8 MPa)	ISO 75	°C	100	95
CLTE	ISO 11359	X 10 ⁵ /°C	12	13
Mold shrinkage (flow direction)	ISO 294-4	%	2.0	2.0

4. Biocompatibility assessments

ISO 10993-5 is a test for in vitro cytotoxicity. In addition, USP Class 6 is about biological reactivity test class 6 of the US Pharmacopeia Convention.

KEPITAL MX25LF01 has passed the biocompatibility assessments ISO 10993-5 and USP Class 6. As such, KEP can provide biocompatibility assurance prior to complete product testing.

Test method	Item	Result	Remark
ISO 10993-5	Cytotoxicity	Pass	PBL Pacific (USA)
USP <88> Class VI	Systemic Injection	Pass	
	Intracutaneous	Pass	
	Implantation	Pass	

5. Friction and wear resistance

A unique characteristic of KEPITAL MX25LF01 are its good friction and wear properties which far surpass other medical grades. KEPITAL MX25LF01 has a low friction coefficient in the engaging parts and represents a smaller abrasion loss than other resins.

The test method is a Ring-on-Ring type (rotation type). Two ring-type specimens are contacting each other. Then, one specimen is fixed and the other specimen is rotating.

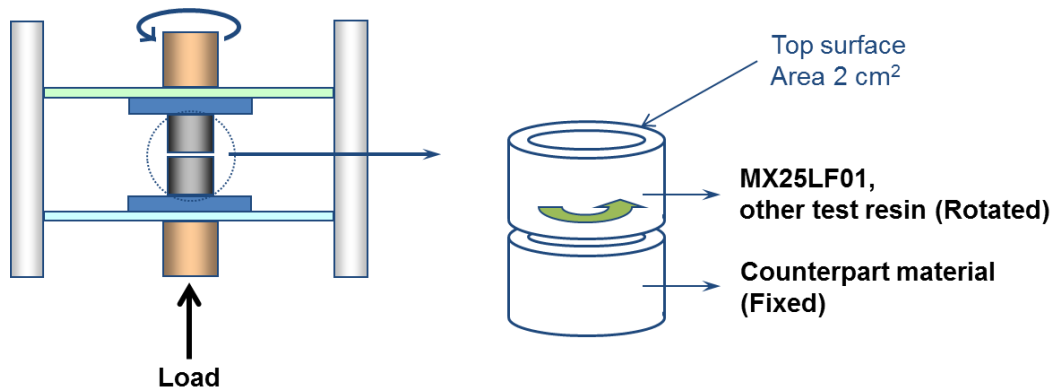
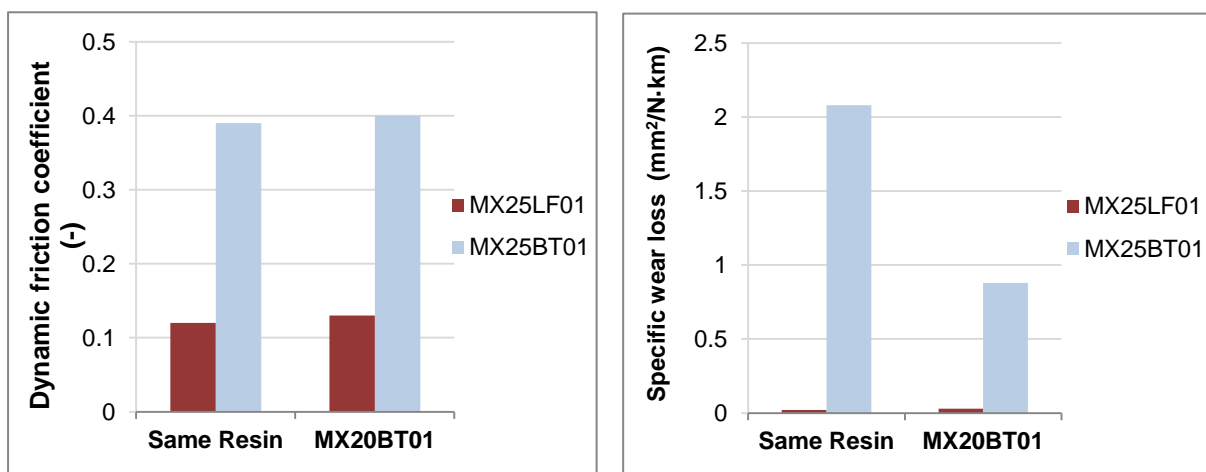


Figure 1. The friction and wear test method

(1) vs. KEPITAL medical grades

KEPITAL MX25LF01 has superior sliding performance compared to medical unfilled grade (KEPITAL MX20BT01, MX25BT01). It has a very low dynamic friction coefficient and specific wear values compared to MX25BT01.

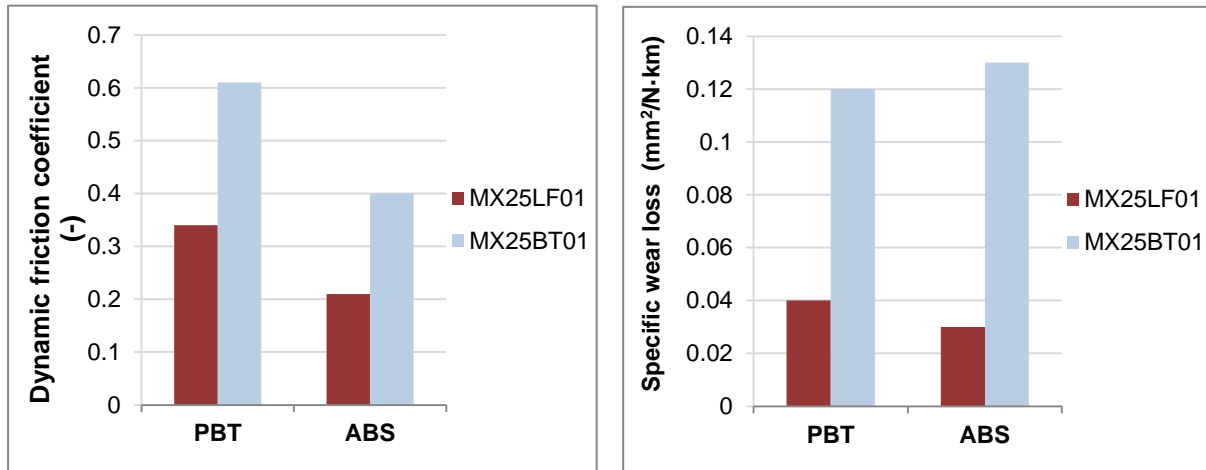


Test conditions are load 70 N, speed 100 mm/s and running time 2 h

Figure 2. The friction and wear resistance contact with POM

(2) vs. other resins

In addition, KEPITAL MX25LF01 has excellent sliding performance contacted with PBT and ABS. It has low dynamic friction coefficient and specific wear values compared to MX25BT01.



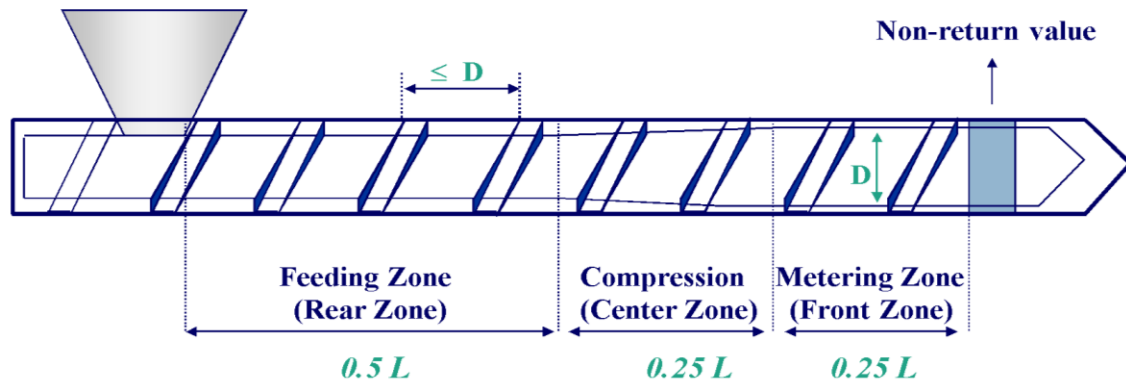
Test conditions are load 30 N, speed 100 mm/s and running time 2 h

Figure 3. The friction and wear resistance contact with PBT & ABS

6. Advantages of KEP medical grade

- (1) Consistent product quality from the designated production line
- (2) Supply assurance with independent production lines and production capability
- (3) Product availability and local tech service in EU, USA, and China
- (4) Quality assurance with expanded analytical control per batch
- (5) Long-term availability of product
- (6) 2-year advanced customer notification of discontinuation of product or formulation changes to customer
- (7) Experience with new medical device development in cooperation with customers

7. Injection Molding Conditions



Classification		Celsius	Fahrenheit
Pry-drying		80 ~ 100 °C (3~4 h)	175 ~ 212 °F (3~4 h)
Cylinder Temperature	Rear	170 °C	337 °F
	Center	190 °C	374 °F
	Front	190 ~200 °C	374 ~ 392 °F
	Nozzle	180 ~210 °C	356 ~ 410 °F
Mold Temperature		60 ~ 80 °C	160 ~ 175 °F

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