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# **Polyacetal Resin for Medical Solutions**

## **KEPITAL<sup>®</sup> MX Series**

**R&D Center**

**KOREA ENGINEERING PLASTICS CO.,LTD.**

## KEPITAL MX Series, Polyacetal Resin for Medical Applications

### Our Focus on POM Production Permits KEP to Deliver Maximum Product and Economic Value to Medical Customers

KOREA ENGINEERING PLASTICS CO.,LTD (KEP) offers polyacetal resin (Polyoxymethylene, POM), co-polymer. KEP takes pride in its flagship KEPITAL co-polymer, further enhancing our offerings with the KEPITAL MX Series, developed to address unique customer demands in the medical field through our sophisticated capabilities.

The growing medical market demands nuanced material solutions that are not only harmless to the human body, but also easy to process and made with long-term usability in mind. The KEPITAL MX Series proves itself a peerless choice when the situation calls for sliding performance and dimensional stability.

Plastics from the KEPITAL MX Series are very easy to handle and exhibit excellent sliding performance thanks to naturally high lubricity retaining long-term dimensional stability in sophisticated medical applications. KEP collaborates with OEMs, CAE programmers and other medical professionals to solve and even exceed difficult design and developmental challenges.



## **Compliance with Global Regulations**

All materials used in medical applications must meet following regulations as a matter of law:

### **Medical Applications**

- (1) Biocompatibility
  - 1) ISO 10993-5 (Test for In vitro cytotoxicity)
  - 2) USP Class VI (US Pharmacopeia convention, biological reactivity test class VI)
- (2) Drug Master File (DMF) Listing

### **Food Contact Applications**

- (1) EU Regulation No. 10/2011
  - Monomers and additives listed on EU No. 10/2011 on plastics materials and articles intended to come into contact with food
- (2) EU Regulation No. 2023/2006 of GMP
  - Good Manufacturing Practice for materials and articles intended to come into contact with food
- (3) FDA Title 21 177.2470 for "Polyoxymethylene copolymer"

### **Other Applications**

- (1) "Substance of Very High Concern under REACH EC 1907/2006"
- (2) "Europe Decision 2001/2/EC : TSE, BSE – No Animal Origin"
  - no risk materials are used in the production, monomers / ingredients are of petro-chemical origin, additives from animal origin
- (3) "Phthalates, Latex, Bisphenol A" free

As KEP is a trusted and reliable development partner to the medical industry, we offer biocompatibility-assurance prior to complete product testing. We dedicate our best efforts to achieve full legal and customer approval with all of our material solutions.

## KEPITAL MX Series portfolio

Our KEPITAL MX Series are produced in various grades with different viscosities.

Table 1. General description of KEPITAL MX Series

Grade		MFR (g/10 min)	Characteristics
General types	MX20BT01	9	<ul style="list-style-type: none"> <li>General grade</li> <li>Medium-viscosity grade for injection molding</li> </ul>
	MX25BT01	13	<ul style="list-style-type: none"> <li>General grade</li> <li>Medium-low viscosity grade for injection molding</li> </ul>
	MX30BT01	27	<ul style="list-style-type: none"> <li>Low-viscosity grade for injection molding</li> <li>Suitable for multi-cavity molds and thin-walled part</li> </ul>
Specialized types	MX25BT03	13	<ul style="list-style-type: none"> <li>Medium-low viscosity grade for injection molding.</li> <li>Featuring greater stiffness</li> </ul>
	MX25LF01	28	<ul style="list-style-type: none"> <li>Low-viscosity grade for injection molding.</li> <li>Silicone-modified wear-resistance grade</li> </ul>

Individual properties differ according to flow behavior. The KEPITAL MX Series can be divided into the following sections:

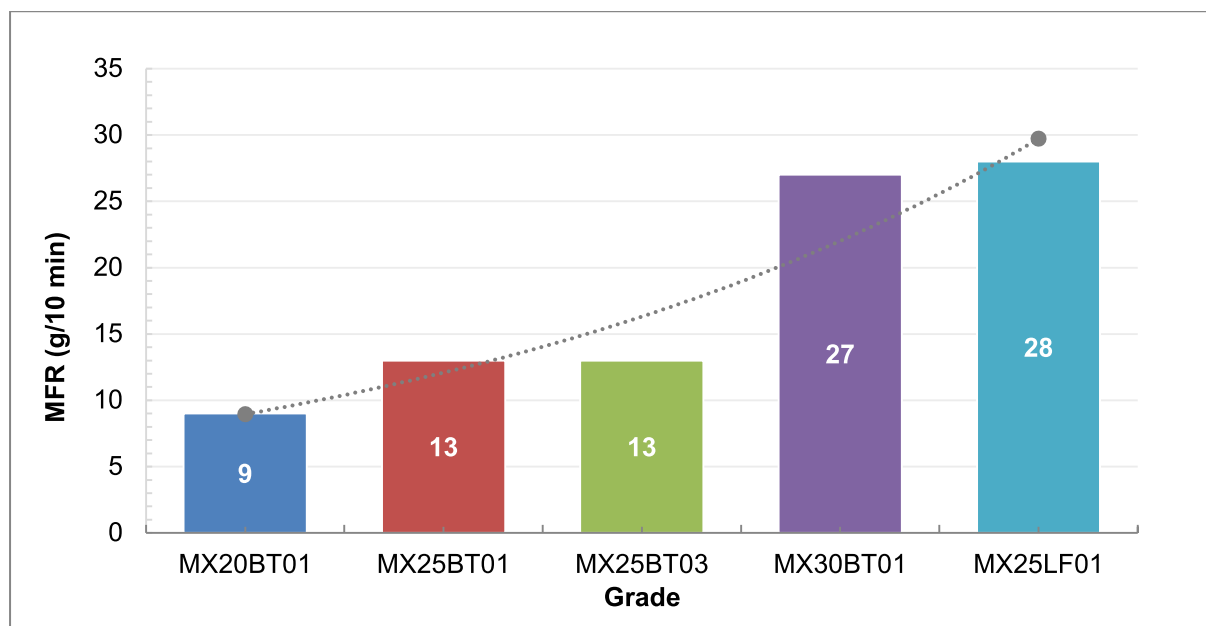


Figure 1. Flowability of KEPITAL MX Series for a variety of applications

## Mechanical Properties

Table 2. Mechanical properties of MX Series

Property		Standard	Unit	Grade				
				General			High stiffness	Silicone modified
				MX20BT01	MX25BT01	MX30BT01	MX25BT03	MX25LF01
General information	Polymer abbreviation	ISO 1043	-	POM	POM	POM	POM	POM
Rheological properties	Melt mass-flow rate	ISO 1133	g/10 min	9	13	27	13	28
Mechanical properties	Tensile modulus	ISO 527-2	MPa	2,700	2,750	2,850	2,850	2,300
	Tensile stress		MPa	64	65	63	68	55
	Yield strain		%	10	9	8	10	8
	Nominal strain at break		%	32	30	25	30	30
	Flexural modulus	ISO 178	MPa	2,550	2,600	2,600	2,800	2,430
	Flexural strength		MPa	87	90	90	93	75
	Charpy notched impact strength (23 °C)	ISO 179-1	kJ/m <sup>2</sup>	6.5	6.0	5.0	6.0	5.5
	Charpy notched impact strength (-30 °C)	ISO 179-1	kJ/m <sup>2</sup>	5.5	5.0	4.0	5.5	4.0
Thermal properties	Melting temperature	ISO 3146	°C	165	165	165	168	165
	Temperature of deflection under Load	ISO 75-2	°C	100	100	98	101	95
	Coefficient of linear thermal expansion	ISO 11359-2	10 <sup>-5</sup> / °C	12	12	12	12	12
Other properties	Water absorption	ISO 62	%	0.2	0.2	0.2	0.2	0.2
	Density	ISO 1183	g/cm <sup>3</sup>	1.41	1.41	1.41	1.41	1.39
	Molding shrinkage	ISO 294-4	%	2.0	2.0	2.0	2.0	2.0



## Sliding Performance

The demand for longer lifetime and cost-effective products has recently increased; it has brought up the importance of and interest in friction and wear characteristics, particularly for self-lubricating products.

The KEPITAL MX Series has been widely used in sliding parts because of its inherent lubricity. Moreover, the MX25LF01 (silicone-modified grade) has been developed for more finely-turned applications which require superior wear resistance.

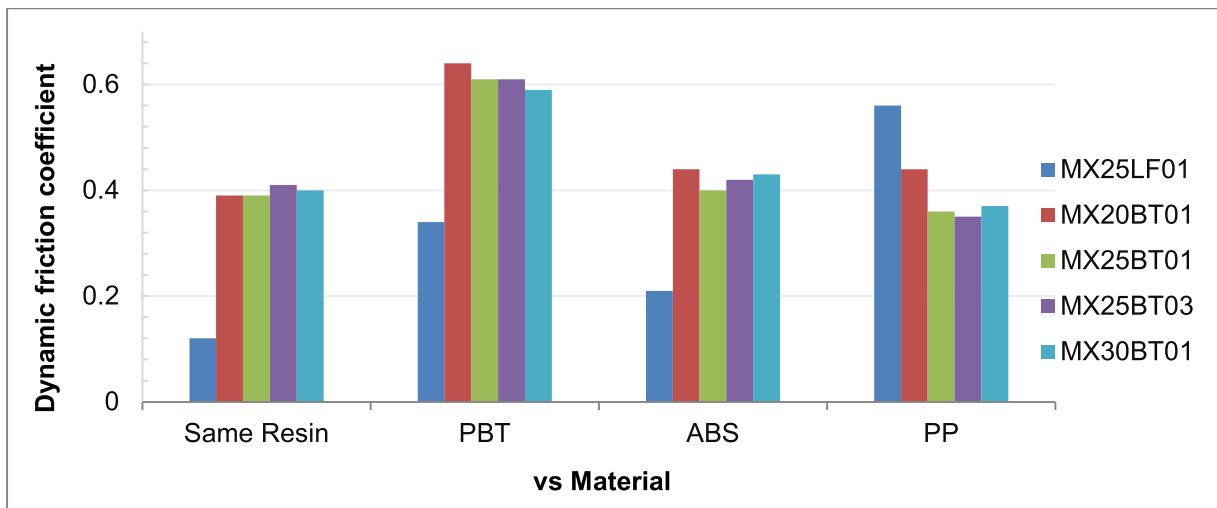


Figure 2. Dynamic friction coefficients of MX Series

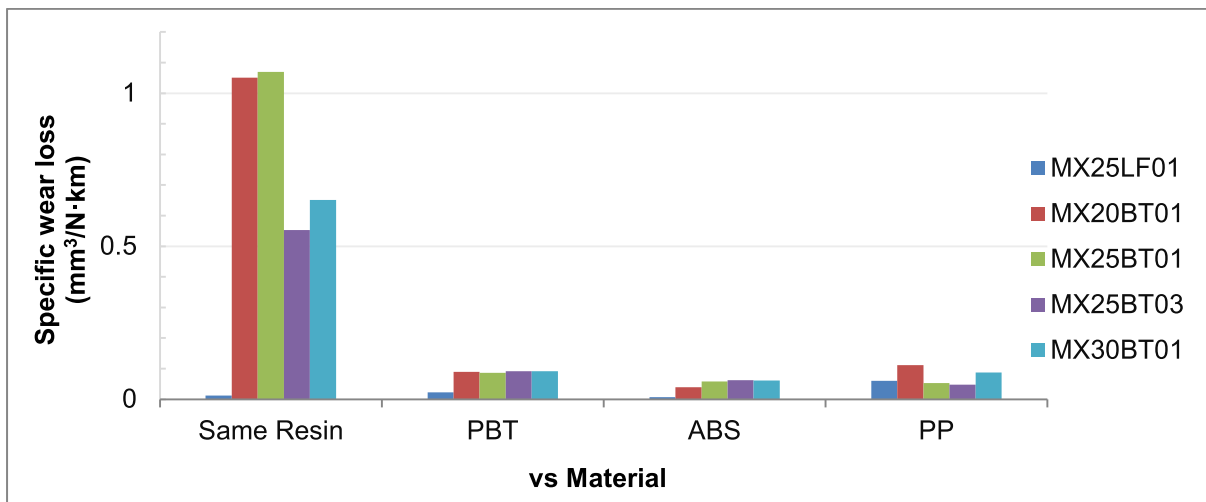


Figure 3. Specific wear loss of MX Series

## Chemical Properties

### Sterilization Suitability

Table 3. Resistance to sterilization of KEPITAL MX Series

Product	Sterilization Process			
	Autoclave	EtO	Gamma	E-beam
KEPITAL® MX Series(POM)	+	++	x	x (assumption)

\*Legend :

++	Excellent performance
+	Good performance (some considerations)
x	Not recommended

**1. Good performance (some considerations):** MX Series shows good autoclave sterilization behavior until 25 cycles under the conditions:

- Equipment : Tuttnauer 3850EL-D
- Temperature : 134 °C
- Pressure : 29.4 psig
- Sterilization time : 3 min
- Waiting time : 30 min
- Total time (1 cycle) : 57 min

**2. Excellent performance:** Properties of MX Series are retained after EtO sterilization under the conditions:

- Regulation : ISO 11135-1
- Gas : 30 % ethylene oxide + 70 % CO<sub>2</sub>
- Temperature : 52 ~ 58 °C
- Humidity : 90 ± 10 % R.H.
- Exposure time : 6 h

**3. Not recommended:** Properties of MX Series are **not retained** after gamma ray sterilization under the conditions:

- Regulation : ISO 11137; Sterilization of health care product package
- Dose rate : 10 kGy, 20 kGy, 30 kGy



## Chemical Resistance

KEPITAL exhibits good resistance to the following chemicals;

Table 4. Long-term resistance to various chemicals of the KEPITAL MX Series

Product	Alcohol	Ester	Ketone	Aliphatic hydrocarbon	Aromatic hydrocarbon	Acid
KEPITAL® MX Series(POM)	++	++	++	++	++	x

\*Legend:

++	Excellent performance
+	Good performance (some considerations)
x	Not recommended

However, strong acids, oxidizing agents and halogens are strongly recommended to be kept away from KEPITAL as they break down the plastic's chemical structure. The changes in physical properties to various chemicals are illustrated in the following table.

Table 5. Chemical resistance of KEPITAL after immersion in various chemicals

Chemicals	Immersion time (h)	Temperature (°C)	Measurements		
			Retention rate (%)		
			Tensile strength	Weight	Length
Iso-octane	19,680	23	97	100	100
Gasoline	1,000	65	92	101	100
Diesel	1,000	90	100	100	100
Methanol	8,760	50	88	102	101
Ethanol	8,760	50	89	102	101
Acetone	8,760	23	83	104	102
Toluene	8,760	50	90	103	102
Benzene	6,600	60	90	104	102
Carbon tetrachloride	8,760	23	98	102	100
Ethylene glycol (100 %)	480	120	89	-	-
Acetic acid 1 %	8,760	23	101	100	100
Sulfuric acid 1 %	4,320	23	100	100	100
Hydrochloric acid 10 %	960	40	100	99	100
Sodium hydroxide 10 %	552	23	102	100	100
Sodium hypochlorite (effective chlorine 3 ppm)	552	23	100	100	-
One-Luber No. 2	2,400	100	105	100	100
Hot water	1,000	85	103	100	100
Please consider making practical tests with applications under real circumstances to make sure the part will last for a certain period without failure as the above results will change according to testing conditions, unexpected effects, etc.					



## Special Offers That KEP Provides

- Adhering to strict medical industry standards, KEP invested in a designated line to produce the MX Series.
- By maintaining the long-term capacity to produce medical grade polymers, KEP demonstrates its deep commitment to the medical market
- Globally available, the KEPITAL MX Series is bolstered by local technical support in the USA, Europe, Korea and China.
- Enhanced quality control is performed on every MX polymer batch.
- Two years advanced notification will be provided to customers in the case of an MX Series product formulation change.
- KEP supports the MX Series with CAE, mold flow, molding analysis, design and other related technical services upon request.

## Available Applications in Medical Fields

Table 6. Various merits and applicable medical products requiring sliding performance

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

## A Neighbor to Our Customers

KEP operates a number of sites in Korea, including its headquarters in Seoul, a research center in Gunpo and manufacturing plants in Ulsan and Pyeongtaek.

As KEPITAL evolved into a global brand, we systematically developed our own distribution organizations. KEP always seeks close proximity to its customers to guarantee comprehensive technical support and reliable logistic services.

In 2002, KEP Americas, LLC was formed and customers are served from its offices.

In 2003, KEP Europe GmbH was founded in Wiesbaden, Germany. Based in the heart of Europe and Germany, our staff manages the comprehensive distribution network to serve customers in virtually all European countries, the Middle East and Africa.

In 2004, we set up our KEP China sales organization based in Shanghai to gain closer proximity to our customers in this emerging market.



**HQ**

Mapo-daero 119 (Gongdeok-dong) Hyeoseong Bldg.  
Mapo-gu, Seoul, Korea  
Tel 82-2-707-6840 ~ 8, Telefax 82-2-714-9235

**KEP Americas**

106 North Denton Tap Road Suite 210-202 Coppel,  
TX 75019, USA  
Tel +1 888 KEPITAL, Telefax +1 888 537-3291

**KEP Europe GmbH**

Rheingaustrasse 190-196 D-65203 Wiesbaden, Germany  
Tel +49 (0)611 962-7381, Telefax +49 (0)611 962-9132

**KEP China**

A1905, HongQiao Nanfeng Plaza, 100 Zunyi Road,  
Shanghai, China  
Tel +86 21 6237-1972, Telefax +86 21 6237-1803

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Disclaimer: The information contained in this data sheet is based on our current knowledge and experience, so it may change as new knowledge and experience becomes available. This information is based on only above-mentioned product produced in Korea Engineering Plastics Co., Ltd. ("KEP") through relevant test methods and conditions and doesn't relate to any products made of this product with the inclusion of other additives, such as processing aids or colorants. This information should not be construed as a promise or guarantee of specific properties of this product described or its suitability for a particular application, so users make their own determination as to its suitability to their purposes prior to use this product. It is the sole responsibility of the users to investigate whether any existing patents are infringed by the use of this product. This product is not intended for use in medical and dental implants and users should meet all safety and health standards. KEP makes no warranty and assumes no liability in connection with any use of this information.