

ACETAL COPOLYMER

**KEPITAL®**



**KEPITAL MX Series**  
Solutions for component  
of medical device

## **KEPITAL® MX series for medical application**

As the life expectancy increases, more people concern about the health and are interested in the healthcare devices. It is also affected by the phenomenon that more people become exposed to so-called lifestyle diseases such as diabetes, asthma, respiratory disease and so on. This leads more demands for the insulin pen, blood glucose measuring kit, nasal spray, inhaler and so on. Those healthcare applications require every single components to be reliable in terms of the quality and the regulatory affairs.

KEPITAL MX series is newly positioned POM copolymer for the healthcare and medical applications by KOREA ENGINEERING PLASTICS CO.,LTD.(hereinafter referred to as KEP) in order to live up to those customers' increasing needs. This could be realized based on intensive experience which KEP has had so far from the material selection up to the processing optimization in the medical business.

As with any industry, KEP distinguishes itself by providing customized support in the medical industry. Besides the compliances to the food contact regulatory requirements in Europe and US market, MX series passed the biocompatibility test. In addition, production of MX series under stringent quality guideline and tightly controlled process makes itself pure and reliable.

### **Key features of KEPITAL MX series**

- Consistency of product quality
- Quality assurance under tight and extensive inspection
- Long-term product availability
- No changes of formulation

## Compliance to regulatory affairs

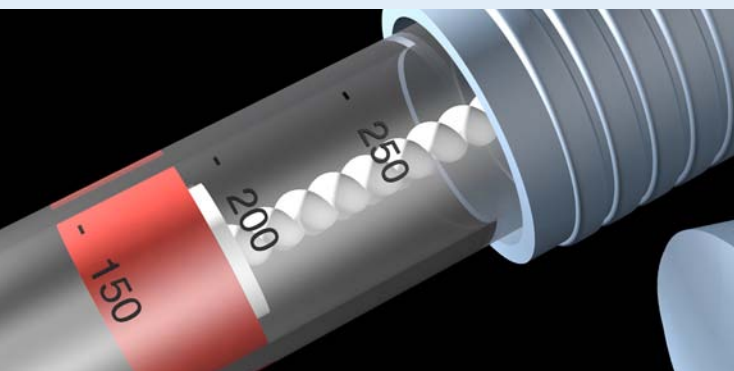
- Biocompatibility (USP Class 6, ISO 10993-5)
- Food contact compliance
- Drug Master File(DMF)
- General regulations for restricted substances  
"Substance of Very High Concern under REACH EC 1907/2006"  
"EU Decision 2001/2/EC : TSE, BSE, Animal origin"

## Key properties of MX Series

- High stiffness and rigidity with good resilience
- Low tendency to creep and fatigue
- Excellent long-term dimensional stability
- High resistance to chemicals
- Good sliding performance

Property	Test method	Unit	KEPITAL MX20BT01	KEPITAL MX25BT01	KEPITAL MX30BT01
<b>Physical properties</b>					
Density	ISO 1183	g/cm <sup>3</sup>	1.41	1.41	1.41
Melt flow rate	ISO 1133	g/10 min	9	13	27
Water absorption saturated in water at 23 °C	ISO 62	%	0.6	0.6	0.6
<b>Mechanical properties</b>					
Tensile modulus	ISO 527-1/-2	MPa	2700	2800	2900
Tensile stress at yield	ISO 527-1/-2	MPa	64	64	65
Strain at yield	ISO 527-1/-2	%	9	9	8
Nominal strain at break	ISO 178	MPa	32	30	18
Charpy notched impact strength	ISO 179/1Eu	kJ/m <sup>2</sup>	6.5	6.5	5.0
<b>Thermal properties</b>					
HDT A (1.80 MPA)	ISO 75-1/-2	°C	100	100	100
Vicat softening temperature (50 N)	ISO 306	°C	150	150	150
Coefficient of linear thermal expansion, longitudinal (23-55 °C)	ISO 1359-1/-2	x 10 <sup>5</sup> /°C	12	12	12
<b>Conformances-food</b>					
European food contact regulation			Yes	Yes	Yes
US FDA Regulation			Yes	Yes	Yes
<b>Conformances-pharmaceuticals</b>					
USP class 6			Yes	Yes	Yes
Cytotoxicity	ISO 10993-5		Yes	Yes	Yes
Drug Master File (DMF)			Yes	Yes	Yes

## Examples of typical applications



# 한국엔지니어링플라스틱(주) KOREA ENGINEERING PLASTICS CO.,LTD.

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## Notification to user

DO NOT USE KEPITAL IN MEDICAL APPLICATION FOR ANY CASE OF IMPLANTATION IN HUMAN BODY OR CONTACT WITH BODY TISSUE OR BLOOD.

KOREA ENGINEERING PLASTICS CO., LTD. ASSUMES NO WARRANTY OR LIABILITY OF KEPITAL FOR CONFORMANCES OF USP CLASS 6 OR ISO 10993-5 BUT PROVIDE CONFORMANCES BASED ON THE TEST RESULT FROM 3RD PARTY INSTITUTION. KOREA ENGINEERING PLASTICS CO., LTD HOLDS NO WARRANTY OR LIABILITY OF SUITABILITY OF PARTICULAR APPLICATIONS WITH CONFORMANCES OF KEPITAL TO FOOD OR PHARMACEUTICALS INFORMED TO USER.

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