## "Zelas"" Medical Grade Coumpounds

### New silicone modified polypropylene resin Zelas<sup>™</sup> SMP

**Properties functionalized by by silicone** modification

High sliding performance Water and oil repellency

Unlike conventional silicone MB, not by blending silicone but chemically bonding it to PP.



#### **Friction properties**

- No bleeding-out, Low extractables
- Thermal fusion with PP
- Excellent heat sealing

Static friction coefficient Dynamic friction coefficient

### Low protein adsorption · Low protein adsorption & Good adhesion "Zelas™ CP"





- Good Adhesion with heat (<60°C)
- High transparency
- Low autofluorescence
- Low protein absorption
- **Good gamma radiation resistance USP ClassVI**, Japanese Pharmacopoeia dissolution test compatibility

Microfluidic (channel side)		CP208 (2mmt, 40µm channel)			
Microfluidic Lid		CP208 (2mmt)	CP211 (2mmt)		
	85	poor	Good		
C C	90	fair	Good		
dr	95	fair	Good		
ter	100	Good	Good		
ess	105	Good	Good		
Pre	110	Good	Good		
Hot	115	partially deformed	partially deformed		
	125	deformed	deformed		

### **Medical Grade TPU**

### High sliding capability elastomer "ChronoSil™"



- Low coefficient of friction
- Biocompatible
- Long term implantable



### Lubricious hydrophilic urethane coating "Hydromed™"



### Low adsorption elastomer "Zelas<sup>™</sup> AMP/TPU" (under development)

- Low serum protein adsorption performanceGood antithrombotic
- Coating free. Processable via injection and extrusion
- Zelas<sup>™</sup> AMP has effective to PVC and other materials.



# Contract production of medical injection molding parts

### **Our Business and Capability**

MCC Advanced Moldings utilizes a wide range of injection molding technologies as well as post-processing (assembly, filling, etc.) to provide products that meet a wide variety of needs.







Dental Containers (Molding & Assembly) Single use parts (Molding)

### Flow of Solution Provision



No need to prepare design and drawings when communicating your requirements. Please just tell us what you would like to achieve. We will make a drawing of the specific shape and propose it to you.

In addition, the Tsukuba Plant manufactures all products in a clean environment suitable for their intended use, based on a quality control system compliant with ISO13485/ISO9001.

Our advantage is the ability to provide consistent services from development to mass production on consignment is a key advantage of our company.



Sanitary Inspection Containers (Liquid preparation, molding, filling, and assembly)

## Freeform Injection Molding (FIM)

- New injection molding technology using a special 3D printer.
- Complex and unique shapes not possible with conventional technology.
- Quickly evaluate the usability of various shapes in a variety of materials, from soft to high-strength and fiber-reinforced plastics.



### **Flow of Solution Provision**



### Example of molding applying compliant mechanism<sup>\*1</sup> design

Cooperate with Functional Design Laboratory, Science & Innovation Center, Mitsubishi Chemical Corporation.

#### pinch by pressing pinch by pulling the tab the tab

### Integrated switch mechanism

#### negative Poisson's ratio

\*The diameter increases by pulling.









\*1 What's a compliant mechanism.

Mechanism that transmits force/displacement using flexibility and elasticity in an integrated resin structure.

# Stock Shape Portfolio for Medical & Pharmaceutical



### **Industrial Grade**

\*MediTECH<sup>®</sup> and LSG are the only materials that can be used for body contact purposes.

### **MediTECH**<sup>®</sup> **Implantable Polymers**

Chirulen<sup>™</sup> / Extrulen<sup>™</sup> UHMW-PE

- · 1020
- 1020X
- 1020E
- 1020EX
- · 1050

### Life Science Grade

Body contact up to 30days

Ketron<sup>™</sup> LSG PEEK-CLASSIX<sup>™</sup>

**Body contact up to 24hours** 

- Ketron<sup>™</sup> LSG CA30 PEEK
- Ketron<sup>™</sup> LSG PEEK
- Duratron<sup>™</sup> LSG PEI

- · 1050X
- X : Cross-Linked
- E : Vitamin E Blended

Zeniva<sup>®</sup> PEEK • Zeniva<sup>®</sup> ZA-500

- Sultron<sup>™</sup> LSG PPSU
- Sultron<sup>™</sup> LSG PSU
- Proteus<sup>™</sup> LSG PP
- Altron<sup>™</sup> LSG PC
- Proteus<sup>™</sup> LSG HP PP
- Proteus<sup>™</sup> LSG HDPE

No body contact

• Proteus<sup>™</sup> LSG HS PP

Zeniva<sup>®</sup> is a registered trademark of Syensqo. PEEK-CLASSIX<sup>™</sup> is a trademark of Vixtrex.

## Meditech<sup>®</sup> Medical PolyMers

### **Plastic Materials for Implantable Medical Devices**



### Chirulen<sup>™</sup> & Extrulen<sup>™</sup> UHMW-PE

Ultra-high molecular weight polyethylene has excellent machinability and wear resistance. We have over



Zeniva® PEEK is a high-performance material with high mechanical properties and excellent biocompatibility. Zeniva® PEEK has excellent fatigue and creep

30-years-experience of application to artificial joint parts and various medical device parts.

### Vitamin E added grade

Vitamin E is used to suppress free radicals generated during cross-link processing, and is expected to reduce oxidation and wear particles in the body.

### **Cross-Linking process**

By modifying the polyethylene molecular chain into a cross-linked structure, it is expected that the wear suppression effect can be improved.

resistance. Since Zeniva® PEEK has similar modulus of human cortical bone, it contributes to reducing stress shielding.

Zeniva® PEEK does not cause heavy metal allergies or metal ion erosion, does not interfere with X-rays or CT scans, and does not cause halation.

Zeniva® PEEK has high strength and stiffness, fatigue resistance, and excellent dimensional stability. Ideal for machining that requires high precision and prototyping of injection molded parts.

## Life Science Grade

Mitsubishi Chemical Group (MCG) provides biocompatible material portfolio "Life Science Grade (LSG)" for the medical device and pharmaceutical industries.

LSG can be used to replace stainless steel, titanium, glass, or ceramic.

LSG also offers a variety of benefits and possibilities, including light weight, resistance to commonly used sterilization processes, x-ray permeability, design flexibility, antistatic performance, and resistance to high-energy radiation.

### **Biological safety**

Most of LSG materials have been pre-evaluated in ac-

### **Biocompatibility pre-assessment table**

Tests / Compliance	1. Cytotoxicity Ref.: ISO 10993-5 and USP <87> Biological Reactivity Tests, In Vitro Elution Test	2. Sensitization Ref.: ISO 10993-10, Magnusson & Kligman Maximization Method	3. Intracutaneous Reactivity Ref.: ISO 10993-10 and USP <88> Biological Reactivity Tests, In Vivo – Intracutaneous test	4. Acute Systemic Toxicity Ref.: ISO 10993-11 and USP <88> Biological Reactivity Tests, In Vivo – Systemic Injection Test	5. Implantation Test Ref.: USP <88> Biological Reactivity Tests, In Vivo – Implantation Test ( 7 days)	6. Human blood compatibility Ref.: ISO 10993-4, Indirect Hemolysis (in vitro)	7. USP-Physicochemical Tests for Plastics Ref.: USP < 661> Containers, Ultra Water extract, 70°C/24h	USP Class VI Conclusion from tests 3, 4 and 5	Body Contact Duration Intended applications of which the duration of Contact with human body tissue is limited to.
Ketron <sup>™</sup> LSG PEEK Grade									
Ketron <sup>™</sup> LSG PEEK-CLASSIX <sup>™</sup> white	•	•	•	•	•	•		•	≤ 30d
Ketron™ LSG PEEK natural, black	•	•	•	•	•	•	•	•	≤ 24h
Ketron™ LSG Food Grade PEEK natural	•	•	•	•	•	•	•	•	≤ 24h
Ketron <sup>™</sup> LSG PEEK red /blue/green/yellow	•	0	$\bigtriangleup$	$\bigtriangleup$	$\bigtriangleup$	$\bigcirc$	•	$\bigtriangleup$	≤ 24h
Ketron™ LSG CA30 PEEK	•	•	•	•	•	•	•	•	≤ 24h
Sultron <sup>™</sup> LSG PPSU Grade									
Sultron <sup>™</sup> LSG R5100 PPSU black BK937	•	•	•	•	•	•	•	•	≤ 24h
Sultron™ LSG R5500 PPSU black BK937	•	0	$\bigtriangleup$	$\bigtriangleup$	$\triangle$	0	•	$\bigtriangleup$	≤ 24h
Sultron <sup>™</sup> LSG R5500 PPSU blue/brown/green/orange/red/yellow/grey	•	0	$\bigtriangleup$	$\bigtriangleup$	$\bigtriangleup$	$\bigcirc$	•	$\bigtriangleup$	≤ 24h
Duratron <sup>™</sup> LSG PEI Grade									
Duratron <sup>™</sup> LSG PEI natural	•	•	•	•	•	•	•	•	≤ 24h
Duratron™ LSG PEI black	•	0	•	•	•	0	•	•	≤ 24h
Sultron <sup>™</sup> LSG PSU Grade									
Sultron™ LSG PSU natural	•	•	•	•	•	•	•	•	≤ 24h
Altron <sup>™</sup> LSG PCGrade									
Altron™ LSG PC	•	•	•	•	•	$\bigcirc$	•	•	≤ 24h
Proteus <sup>™</sup> LSG PP Grade									
Proteus <sup>™</sup> LSG HP PP-H None	•	0	•	•	•	0	$\bigtriangleup$	•	None
Proteus™ LSG HS PP-H white, black	•	0	$\bigcirc$	$\bigcirc$	0	0	•	$\bigcirc$	None
Proteus <sup>™</sup> LSG HDPE Grade									
Proteus™ LSG HDPE	•	$\bigtriangleup$	•	•	•	0	●	•	≤ 24h
	•:9 ():N	Shape teste Not tested	ed (incl. rav	w materials	<ul> <li>Shape tested (incl. raw materials)</li> <li>Not tested</li> <li>Not tested</li> </ul>				

cordance with the US Pharmacopeia (USP) and ISO 10993 biocompatibility guidelines and can be used in medical devices that come in contact with the human body and animals within 30 days\* or 24 hours. LSG is also resistant to various types of sterilization and can be used not only for single use but also for repeated use, contributing to environmental friendliness and cost reduction.

\*Ketron<sup>™</sup> PEEK-CLASSIX<sup>™</sup> LSG white only

### **Our global operations**

MCG has manufacturing facilities in Europe, North America, and Asia, all with certified quality control systems to support product purchases worldwide. In addition to materials, we can offer total solutions for semi-finished products, processed products, sterilization, and packaging.

### **Traceability and quality assurance**

LSG can be tracked lot information from the master

### **Sterilization resistance**

batch of raw materials to the molded materials. It is monitored and controlled throughout the manufacturing process through quality management systems, including ISO13485.

### **Applications**

 Medical devices Sterilization cases •Diagnosis equipment parts •Bio process equipment parts Surgical equipment and devices •Laboratory equipment

Compatibility with some commonly used sterilization methods

	Ethylene Oxide gas	Wet heat (steam) 21°C/134°C	Dry heat 160°C	Plasma	Gamma irradiation	X-ray irradiation
Ketron <sup>™</sup> LSG PEEK-CLASSIX™	VG	VG/VG	VG	VG	VG	VG
Ketron <sup>™</sup> LSG PEEK	VG	VG/VG	VG	VG	VG	VG
Ketron <sup>™</sup> LSG CA30 PEEK	VG	VG/VG	VG	VG	VG	VG
Sultron™ LSG PPSU	VG	VG/VG	VG	<b>G</b> (1)	G	G
Duratron <sup>™</sup> LSG PEI	G	VG/G	G	G	G	G
Sultron™ LSG PSU	G	VG/G	NS	G	G	G
Altron <sup>™</sup> LSG PC	G	P/NS	Р	G	G	G
Proteus <sup>™</sup> LSG HP PP-H	G	G/P	Р	G	G	G
Proteus <sup>™</sup> LSG HDPE	G	P/NS	NS	G	G	G

VG Very Good / G Good / P Poor / NS Not Suited

\*Material not tested ; estimated value based on known material composition and/or miscellaneous literature data. ① Not suited for continuous cycles without intervening cleaning

### Polyethylene (PE)hollow fiber membrane STERAPORE™

STERAPORE<sup>™</sup> is a hollow fiber membrane (HFM) made of PE, which has excellent flexibility and durability, and enables thoughtful equipment design.











### Membrane filter

(1) Volumetric efficiency(2) Long life(3) High flow rate



### Polyethylene (PE)hollow fiber membrane STERAPORE<sup>TM</sup>

### **Our HFM Position**

Size	Objects	Separation Method and applications			
lon-Low lon-Low O.2nm Jouenar weight O.2nm	H <sub>2</sub> O Na <sup>+</sup> Ca <sup>2+</sup> Cl <sup>-</sup> OH <sup>-</sup>	Seawater desalination Ultrapure water production			
e 2nm	Sucrose	Food industry			
$ \begin{array}{c}       5nm \\       0.01 \mu m \\       0.02 \mu m \\       0.05 \mu m \\       0.1 \mu m \\       0.2 \mu m \\       0.4 \mu m \end{array} $	Lysozyme serum albumin γ • globulin polio virus, Japanese encephalitisPseudomonas diminuta	Particulate removal RO, UF pre-processing Ion exchange pre-processing Chlorella concentrate			
O.5μm 1μm 2μmJuge batticle 2μmJuge batticle 2μm	Latex emulsion Vibrio cholerae, Salmonella typhi Escherichia coli Staphylococcus Cryptosporidium Giardia Echinococcus	Sterile water production General filtration			

### Applications Water treatment filter for medical and dental equipment





#### Dental unit etc.

Endoscope cleaning equipment, Medical hand wash equipment etc.

### We also have products for air filtration and degassing modules.