

# “Zelas™” Medical Grade Coumpounds

## New silicone modified polypropylene resin Zelas™ SMP

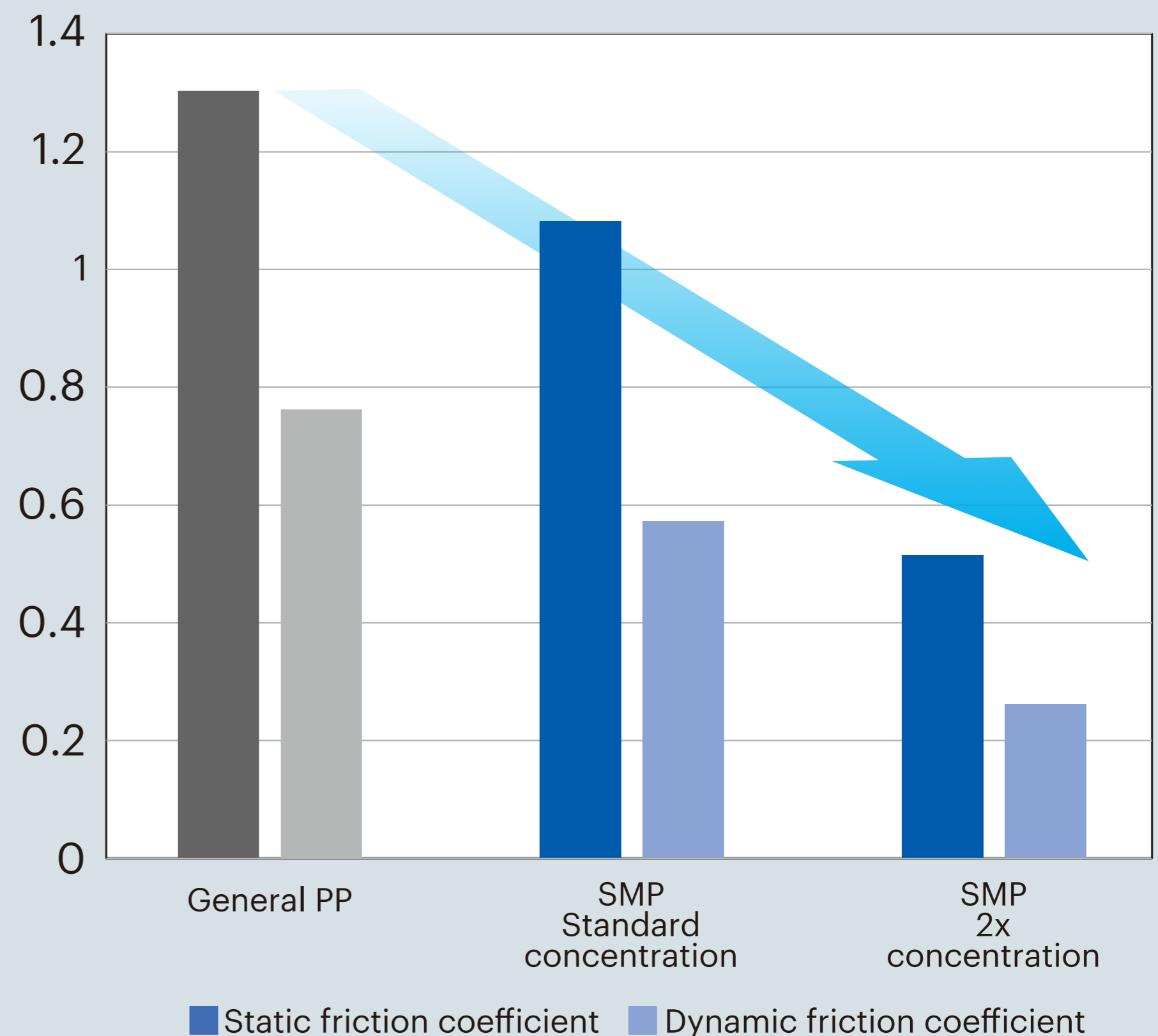
Properties functionalized by by silicone modification

- High sliding performance
- Water and oil repellency

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

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

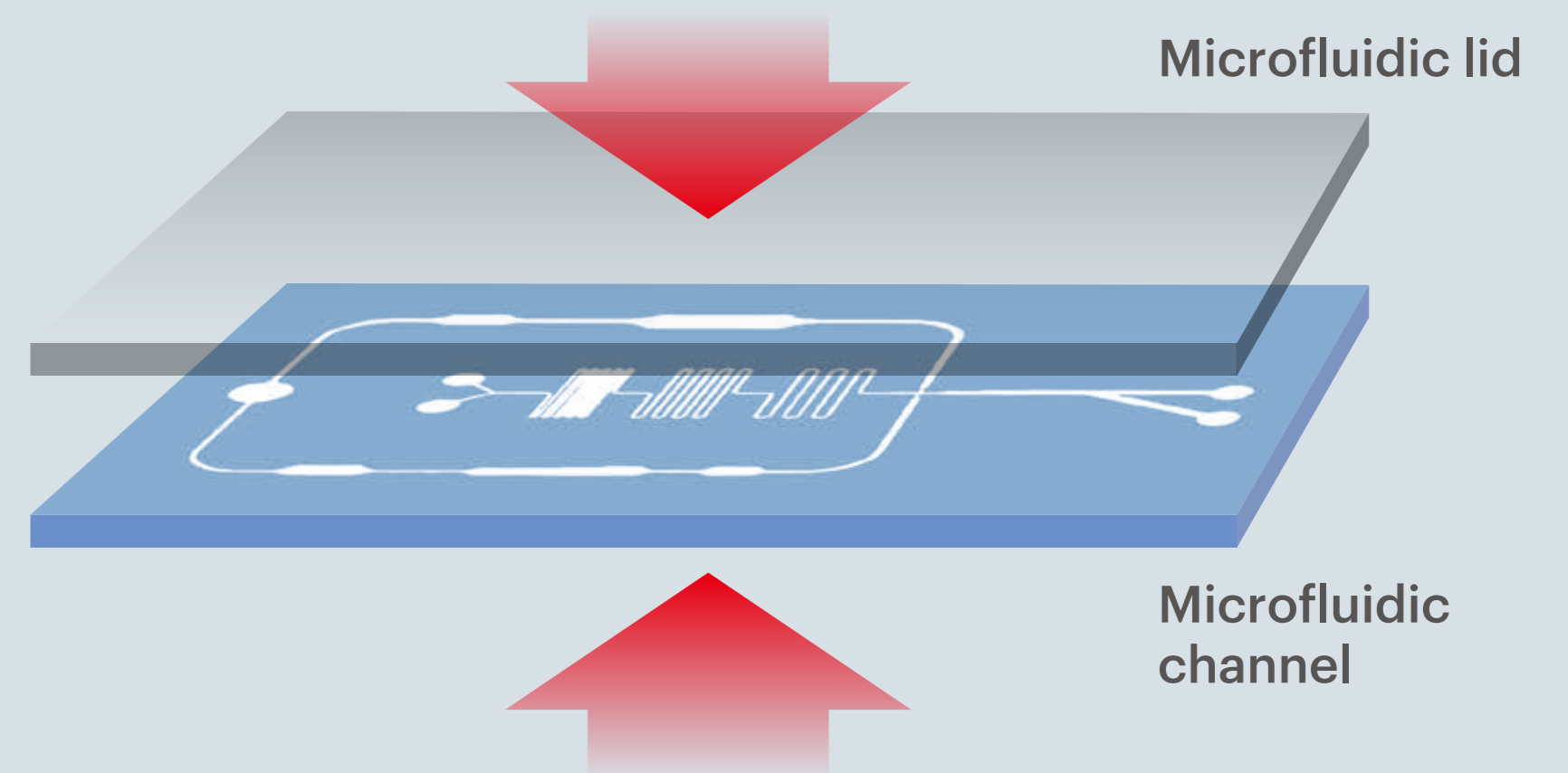
Friction properties



## Low protein adsorption • Low protein adsorption & Good adhesion “Zelas™ CP”



Hot heat press



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

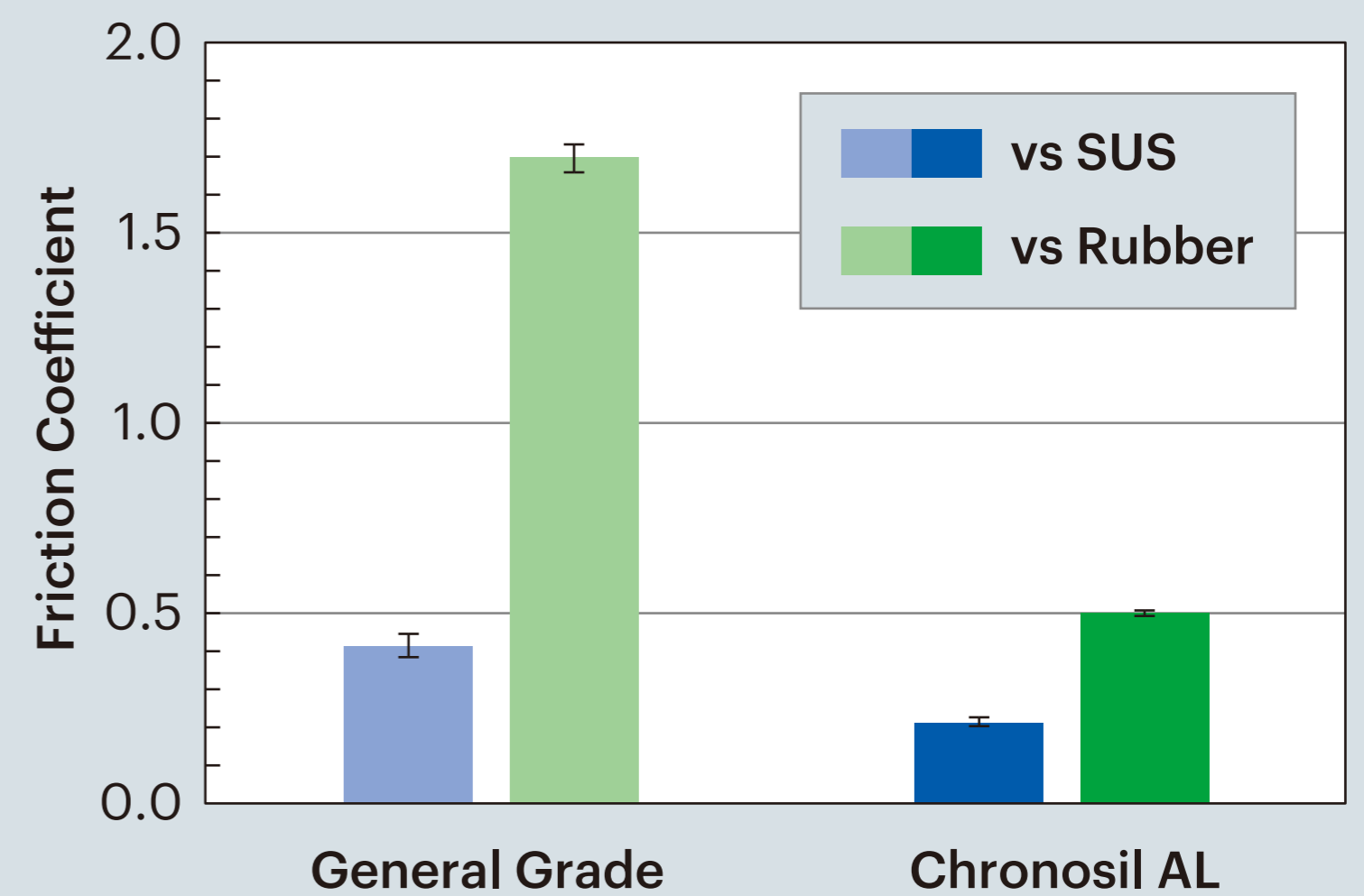
| Microfluidic (channel side) |     | CP208 (2mmt, 40µm channel) |                    |
|-----------------------------|-----|----------------------------|--------------------|
| Microfluidic Lid            |     | CP208 (2mmt)               | CP211 (2mmt)       |
| Hot Press temp (°C)         | 85  | poor                       | Good               |
|                             | 90  | fair                       | Good               |
|                             | 95  | fair                       | Good               |
|                             | 100 | Good                       | Good               |
|                             | 105 | Good                       | Good               |
|                             | 110 | Good                       | Good               |
|                             | 115 | partially deformed         | partially deformed |
|                             | 125 | deformed                   | deformed           |

# Medical Grade TPU

## High sliding capability elastomer “ChronoSil™”



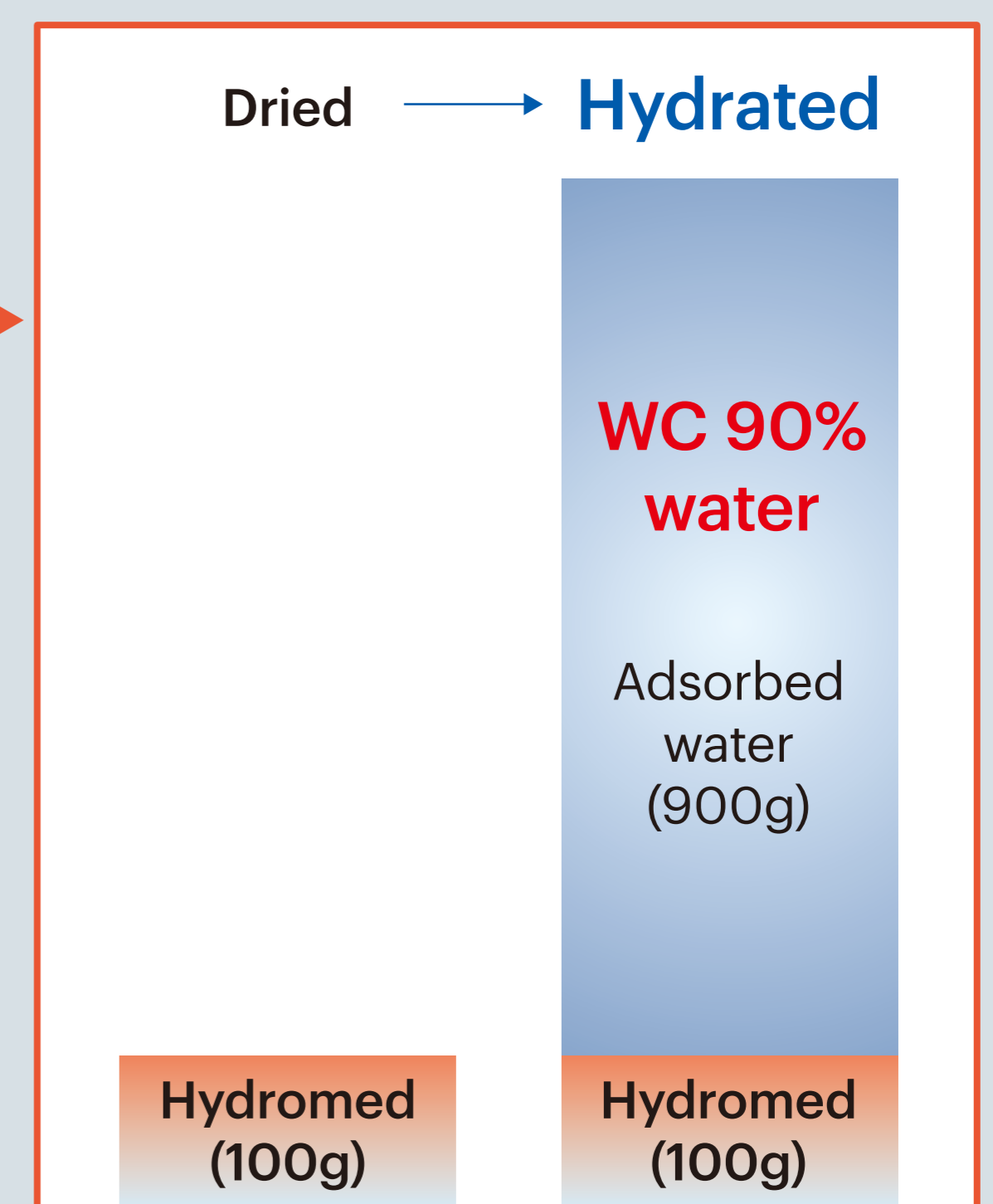
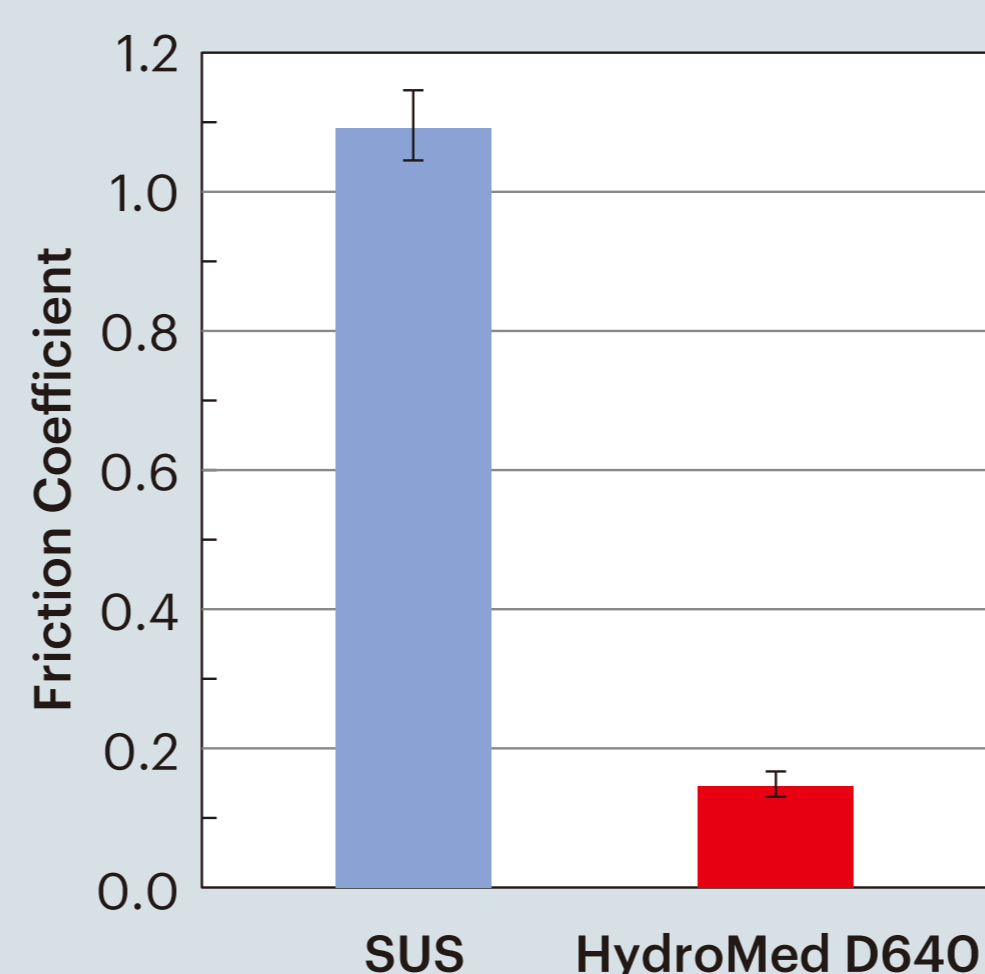
- Low coefficient of friction
- Biocompatible
- Long term implantable



## Lubricious hydrophilic urethane coating “Hydromed™”

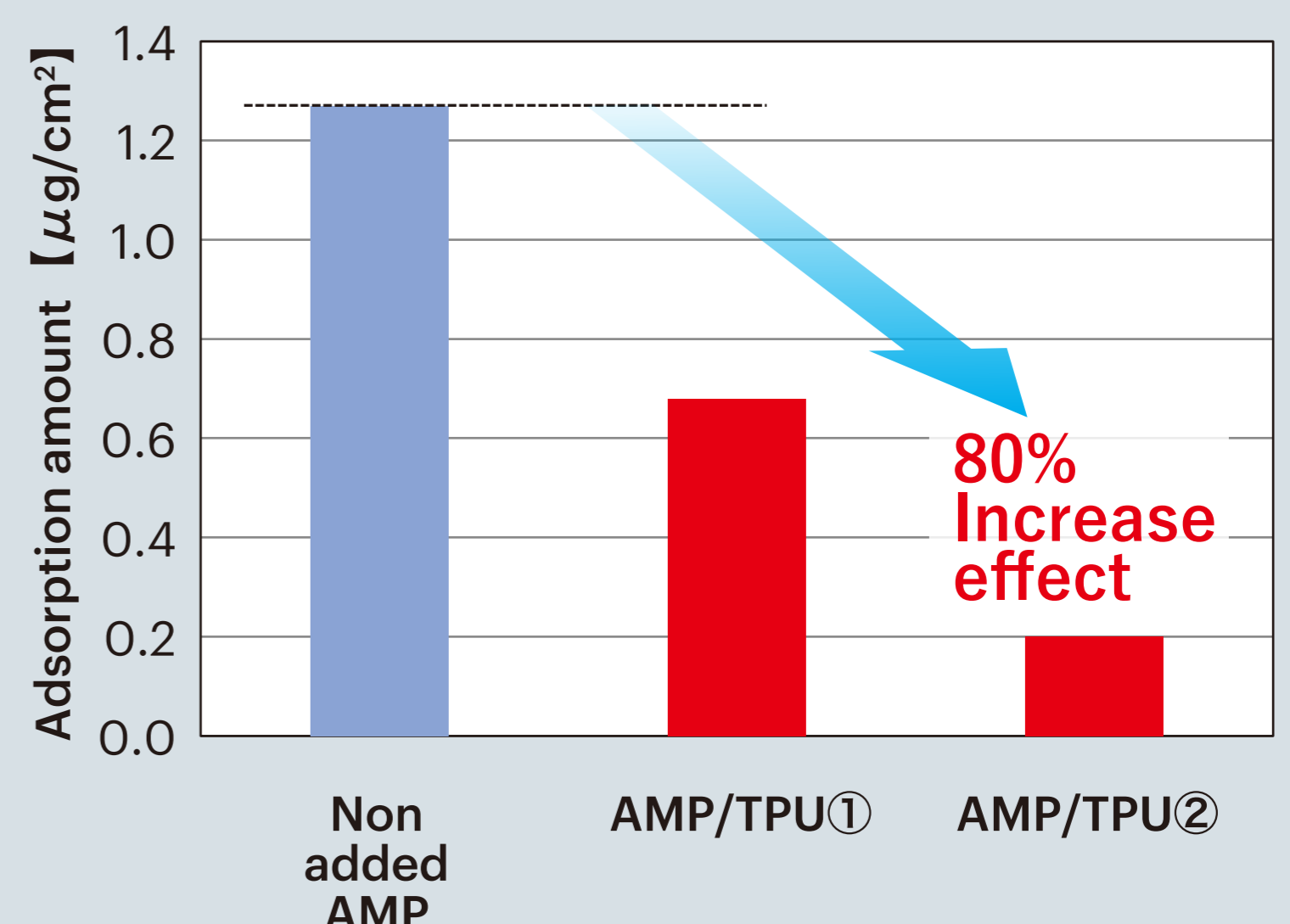
| Grade                   | D1 | D2 | D3 | D4 | D6 | D640 |
|-------------------------|----|----|----|----|----|------|
| Linear Expansion [%]    | 45 | 25 | 40 | 50 | 60 | 100  |
| Water content [%]       | 70 | 55 | 60 | 50 | 80 | 90   |
| Water contact angle [°] | 68 | 75 | 68 | 63 | 79 | 60   |

- Excellent lubricity
- High slip
- Solvent coating (low elution, UV irradiation free)



## Low adsorption elastomer “Zelas™ AMP/TPU” (under development)

- Low serum protein adsorption performance
- Good antithrombotic
- Coating free. Processable via injection and extrusion
- Zelas™ AMP has effective to PVC and other materials.



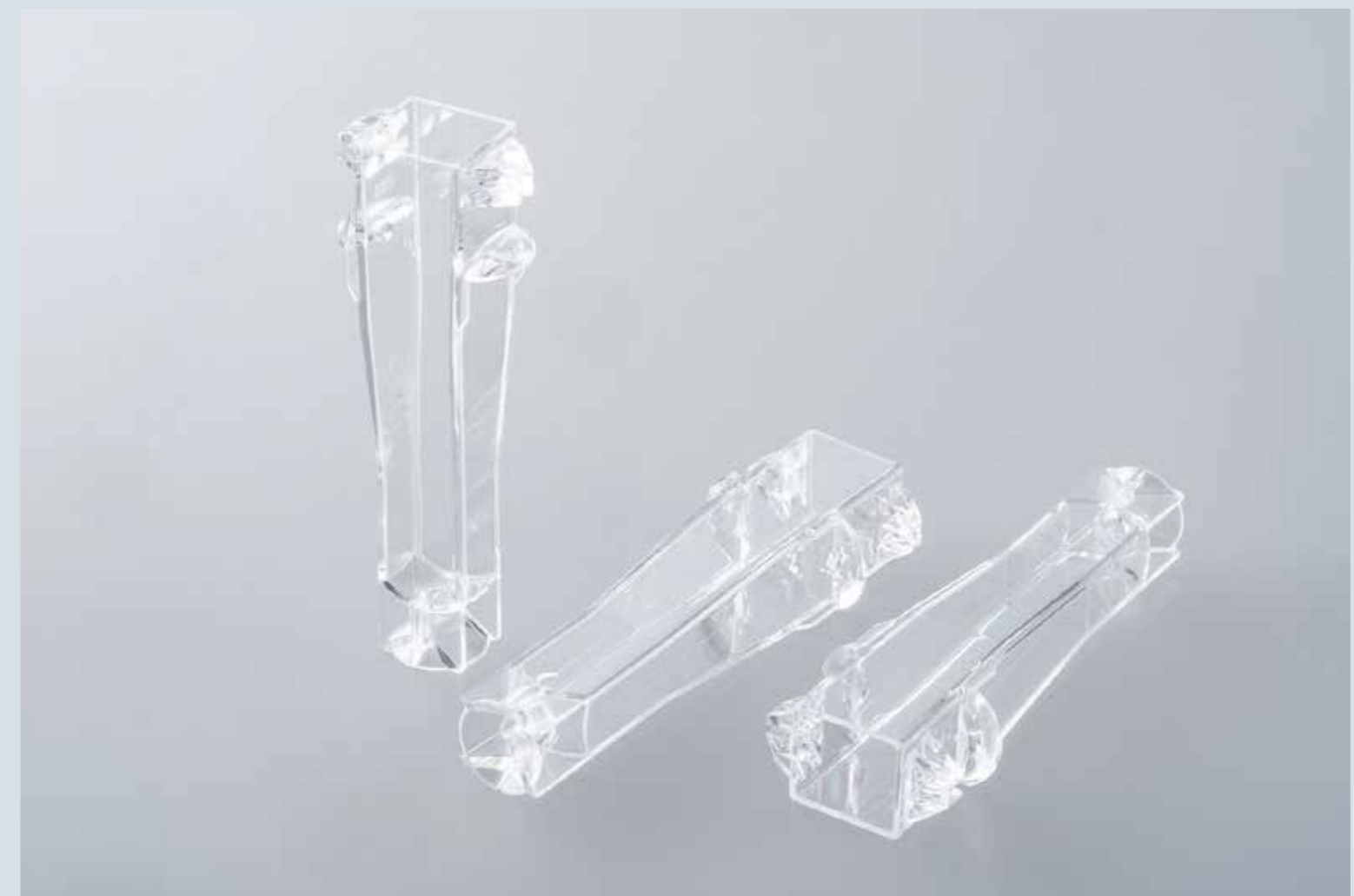
# Contract production of medical injection molding parts

## 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.

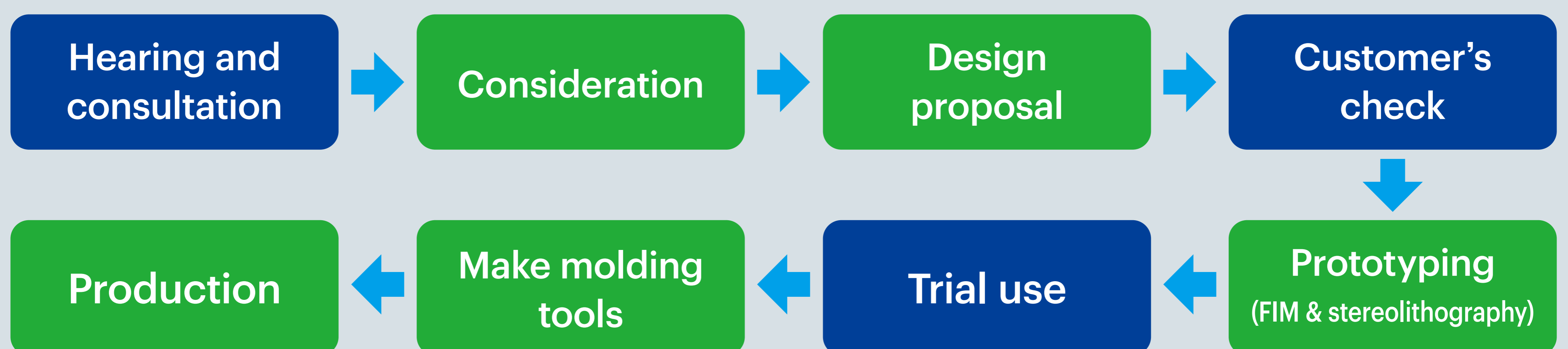


Dental Containers  
(Molding & Assembly)



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.



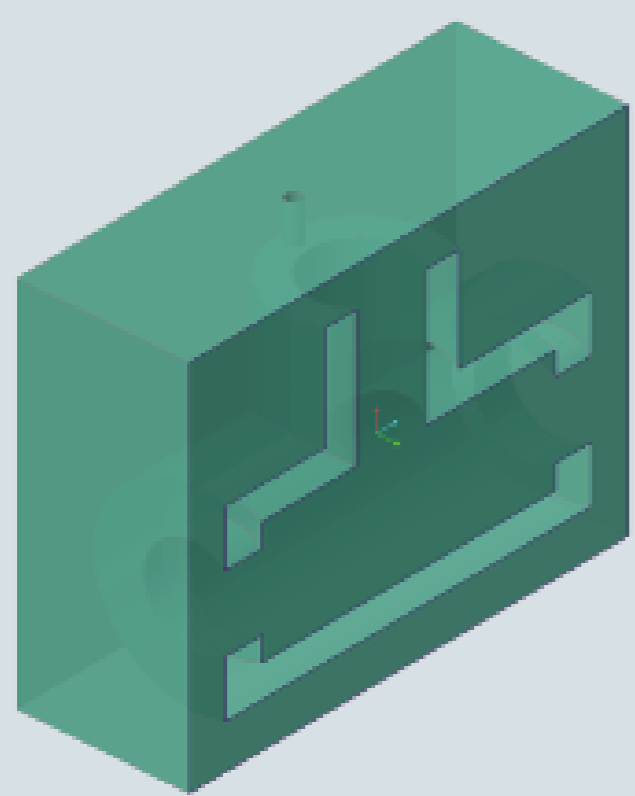
Sanitary Inspection Containers  
(Liquid preparation, molding, filling, and assembly)

# Freeform Injection Molding (FIM)

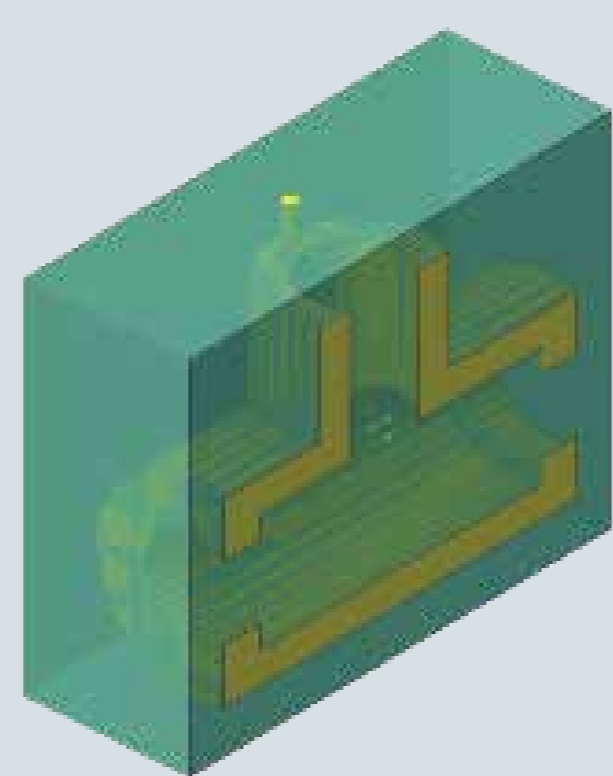
- New injection molding technology using a special 3D printer.
- Complex and unique shapes not possible with conventional technology.
- Quickly evaluate the usability of various shapes in a variety of materials, from soft to high-strength and fiber-reinforced plastics.

## FIM Process

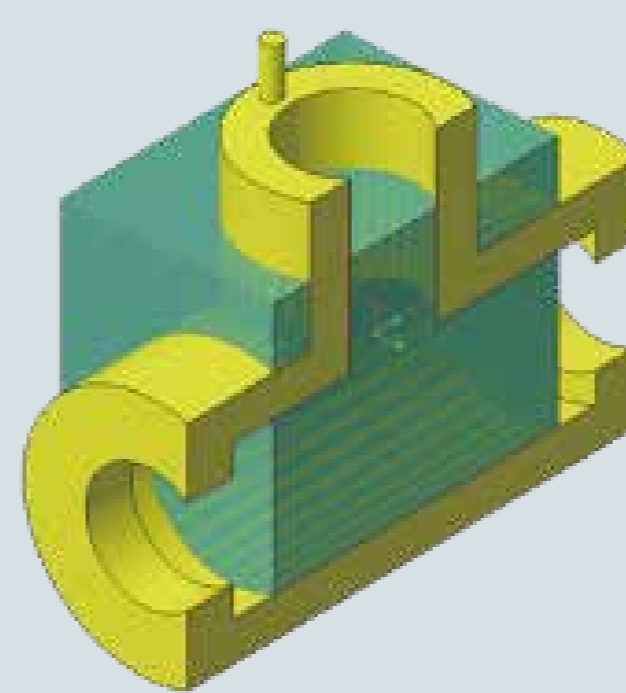
Resin mold  
(stereolithography)



Inject resin



Dissolve  
the mold



## 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  
the tab



pinch by pulling  
the tab

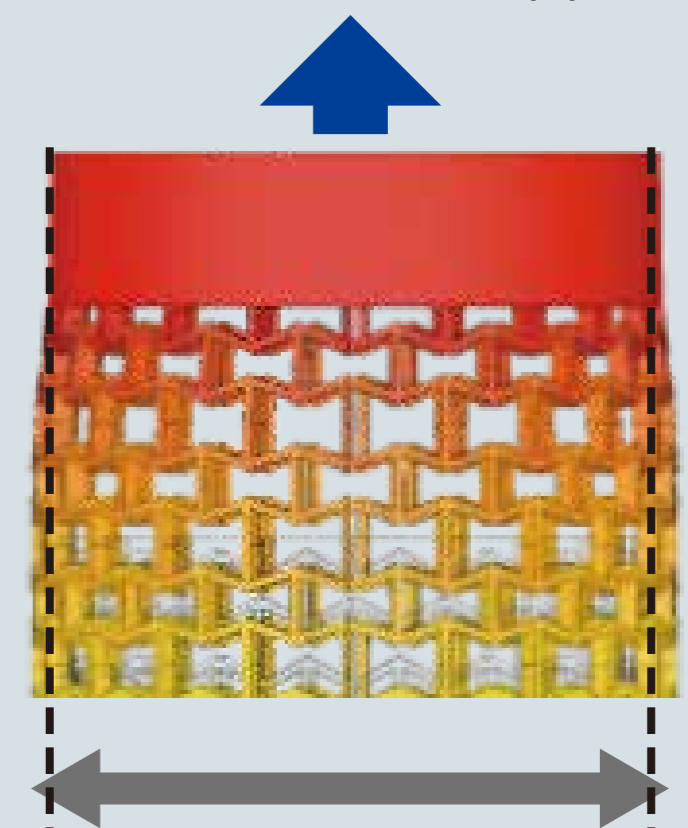


Integrated  
switch mechanism



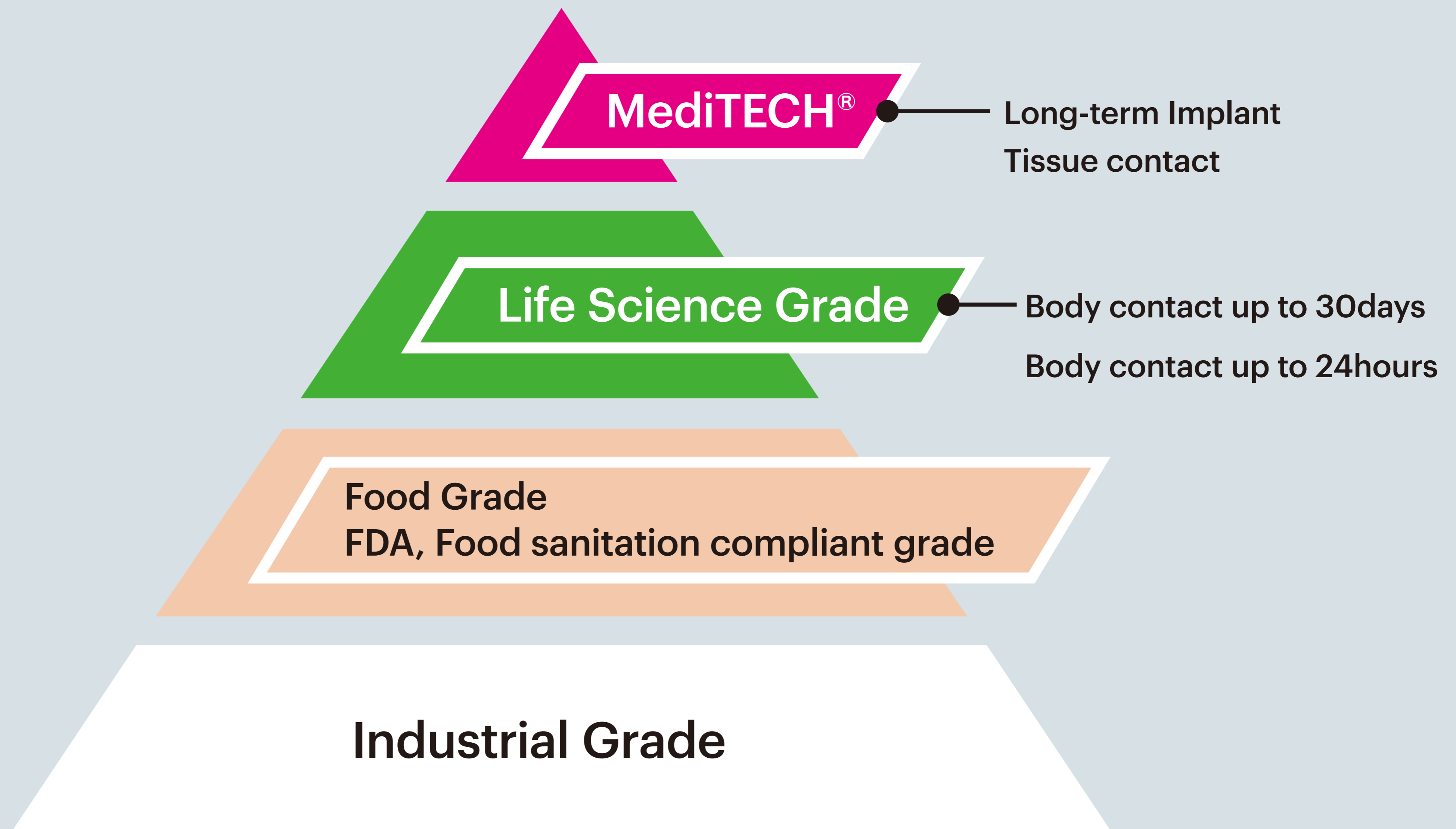
negative Poisson's ratio

※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



\*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
- 1050X

X : Cross-Linked

E : Vitamin E Blended

Zeniva<sup>®</sup> PEEK

- Zeniva<sup>®</sup> ZA-500

## 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
- 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

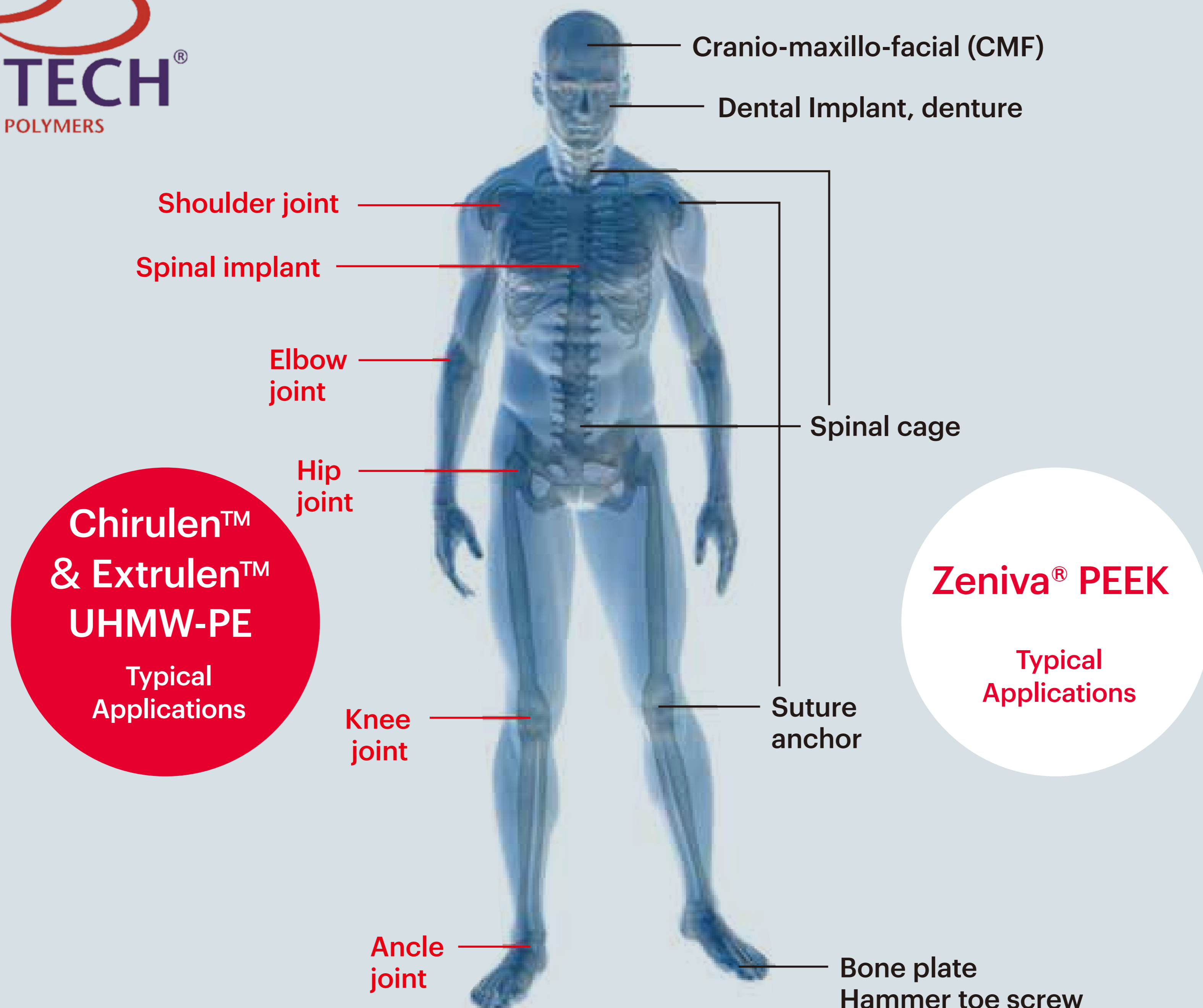
- Proteus<sup>™</sup> LSG HDPE

No body contact

- Proteus<sup>™</sup> LSG HS PP

# 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 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.

### Zeniva<sup>®</sup> PEEK

Zeniva<sup>®</sup> PEEK is a high-performance material with high mechanical properties and excellent biocompatibility. Zeniva<sup>®</sup> PEEK has excellent fatigue and creep resistance. Since Zeniva<sup>®</sup> PEEK has similar modulus of human cortical bone, it contributes to reducing stress shielding.

Zeniva<sup>®</sup> 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<sup>®</sup> 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 accordance 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™ PEEK-CLASSIX™ 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 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

## Biocompatibility pre-assessment table

| Tests / Compliance  | 1. Cytotoxicity<br>Ref.: ISO 10993-5 and USP <87> Biological Reactivity Tests, In Vitro Elution Test | 2. Sensitization<br>Ref.: ISO 10993-10, Magnusson & Kligman Maximization Method | 3. Intracutaneous Reactivity<br>Ref.: ISO 10993-10 and USP <88> Biological Reactivity Tests, In Vivo – Intracutaneous test | 4. Acute Systemic Toxicity<br>Ref.: ISO 10993-11 and USP <88> Biological Reactivity Tests, In Vivo – Systemic Injection Test | 5. Implantation Test<br>Ref.: USP <88> Biological Reactivity Tests, In Vivo – Implantation Test (7 days) | 6. Human blood compatibility<br>Ref.: ISO 10993-4, Indirect Hemolysis (in vitro) | 7. USP-Physicochemical Tests for Plastics<br>Ref.: USP <661> Containers, Ultra Water extract, 70°C/24h | USP Class VI<br>Conclusion from tests 3, 4 and 5 | Body Contact Duration<br>Intended applications of which the duration of Contact with human body tissue is limited to. |
|---|--|---|--|--|--|--|--|--|---|
| <b>Ketron™ LSG PEEK Grade</b>                                   |  |   |  |  |  |  |  |  |   |
| Ketron™ LSG PEEK-CLASSIX™ white                                 | ●  | ●   | ●  | ●  | ●  | ●  | ●  | ●  | ≤ 30d   |
| Ketron™ LSG PEEK natural, black                                 | ●  | ●   | ●  | ●  | ●  | ●  | ●  | ●  | ≤ 24h   |
| Ketron™ LSG Food Grade PEEK natural                             | ●  | ●   | ●  | ●  | ●  | ●  | ●  | ●  | ≤ 24h   |
| Ketron™ LSG PEEK red /blue/green/yellow                         | ●  | ○   | △  | △  | △  | ○  | ●  | △  | ≤ 24h   |
| Ketron™ LSG CA30 PEEK   | ●  | ●   | ●  | ●  | ●  | ●  | ●  | ●  | ≤ 24h   |
| <b>Sultron™ LSG PPSU Grade</b>                                  |  |   |  |  |  |  |  |  |   |
| Sultron™ LSG R5100 PPSU black BK937                             | ●  | ●   | ●  | ●  | ●  | ●  | ●  | ●  | ≤ 24h   |
| Sultron™ LSG R5500 PPSU black BK937                             | ●  | ○   | △  | △  | △  | ○  | ●  | △  | ≤ 24h   |
| Sultron™ LSG R5500 PPSU blue/brown/green/orange/red/yellow/grey | ●  | ○   | △  | △  | △  | ○  | ●  | △  | ≤ 24h   |
| <b>Duratron™ LSG PEI Grade</b>                                  |  |   |  |  |  |  |  |  |   |
| Duratron™ LSG PEI natural                                       | ●  | ●   | ●  | ●  | ●  | ●  | ●  | ●  | ≤ 24h   |
| Duratron™ LSG PEI black   | ●  | ○   | ●  | ●  | ●  | ○  | ●  | ●  | ≤ 24h   |
| <b>Sultron™ LSG PSU Grade</b>                                   |  |   |  |  |  |  |  |  |   |
| Sultron™ LSG PSU natural  | ●  | ●   | ●  | ●  | ●  | ●  | ●  | ●  | ≤ 24h   |
| <b>Altron™ LSG PCGrade</b>                                      |  |   |  |  |  |  |  |  |   |
| Altron™ LSG PC  | ●  | ●   | ●  | ●  | ●  | ○  | ●  | ●  | ≤ 24h   |
| <b>Proteus™ LSG PP Grade</b>                                    |  |   |  |  |  |  |  |  |   |
| Proteus™ LSG HP PP-H None                                       | ●  | ○   | ●  | ●  | ●  | ○  | △  | ●  | None  |
| Proteus™ LSG HS PP-H white, black                               | ●  | ○   | ○  | ○  | ○  | ○  | ●  | ○  | None  |
| <b>Proteus™ LSG HDPE Grade</b>                                  |  |   |  |  |  |  |  |  |   |
| Proteus™ LSG HDPE   | ●  | △   | ●  | ●  | ●  | ○  | ●  | ●  | ≤ 24h   |

● : Shape tested (incl. raw materials)    ▲ : Raw material tested    d : Days  
○ : Not tested    △ : Shape testing pending/planned    h : Hours

## Sterilization resistance

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™ LSG PEEK-CLASSIX™ | VG                 | VG/VG                       | VG             | VG     | VG                | VG                |
| Ketron™ LSG PEEK          | VG                 | VG/VG                       | VG             | VG     | VG                | VG                |
| Ketron™ LSG CA30 PEEK     | VG                 | VG/VG                       | VG             | VG     | VG                | VG                |
| Sultron™ LSG PPSU         | VG                 | VG/VG                       | VG             | G ①    | G                 | G                 |
| Duratron™ LSG PEI         | G                  | VG/G                        | G              | G      | G                 | G                 |
| Sultron™ LSG PSU          | G                  | VG/G                        | NS             | G      | G                 | G                 |
| Altron™ LSG PC            | G                  | P/NS                        | P              | G      | G                 | G                 |
| Proteus™ LSG HP PP-H      | G                  | G/P                         | P              | G      | G                 | G                 |
| Proteus™ 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

# New functional coating materials for medical devices (Newly developed)

## ① Anti-thrombogenic coating materials

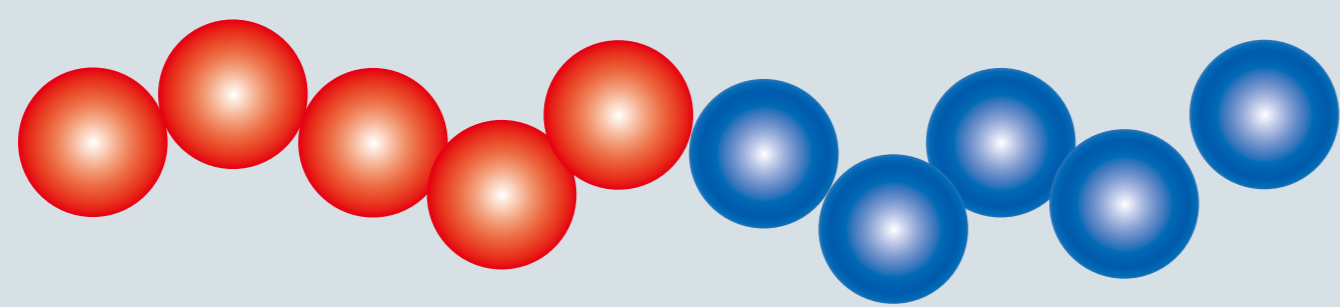
**Applications: Catheters, infusion bags, etc.**

A newly developed coating agent consisting of block polymers, which can be applied to medical components, excellent substrate adhesion and anti-thrombogenicity.

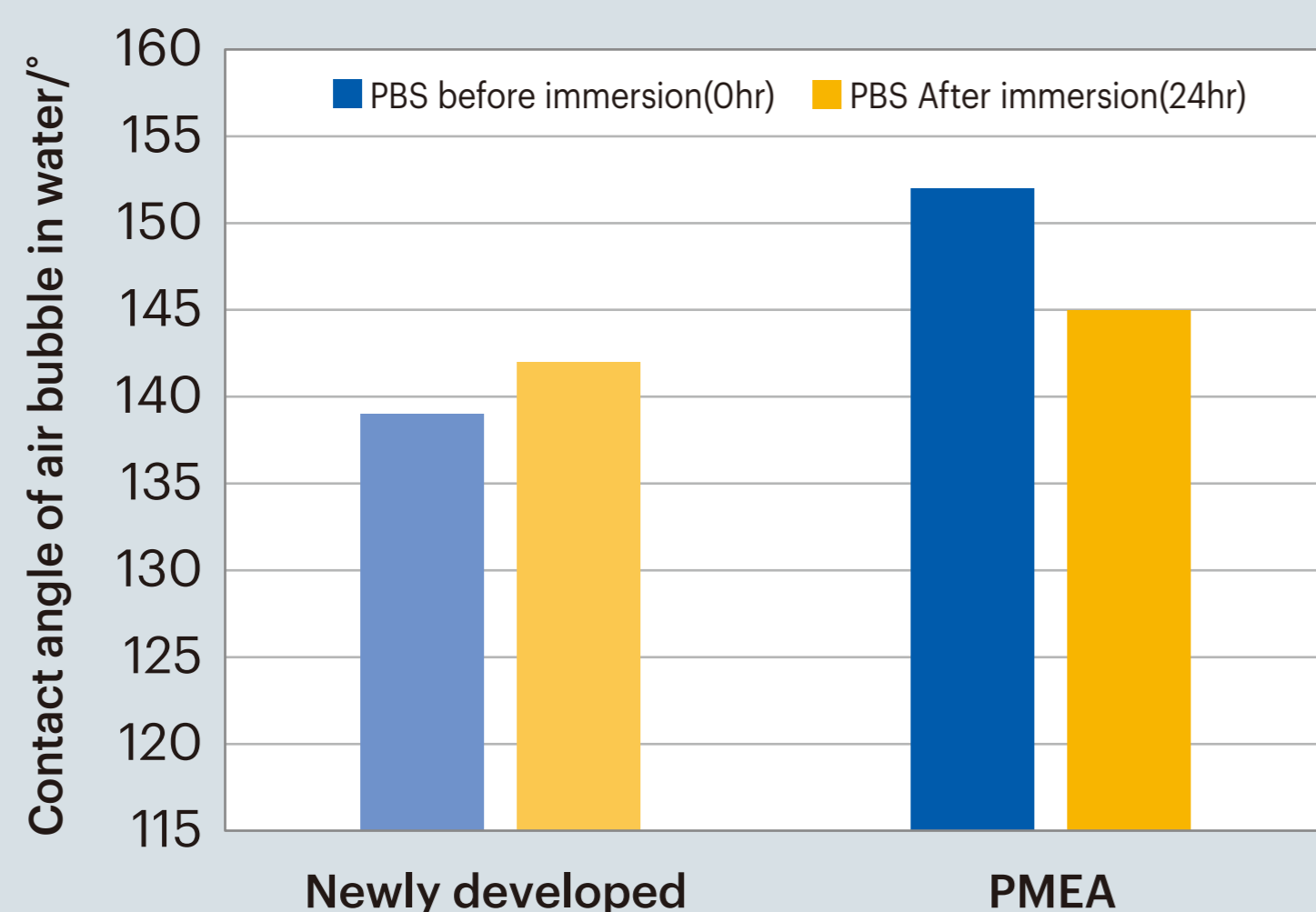


**Hydrophobic segment**  
Substrate adhesion,  
film formability

**Hydrophilic segment**  
Inhibition of protein  
adsorption



**Maintains coating film performance even after durability testing**

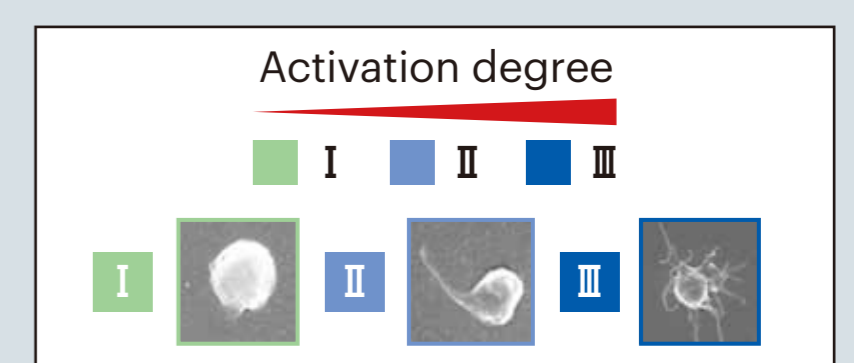
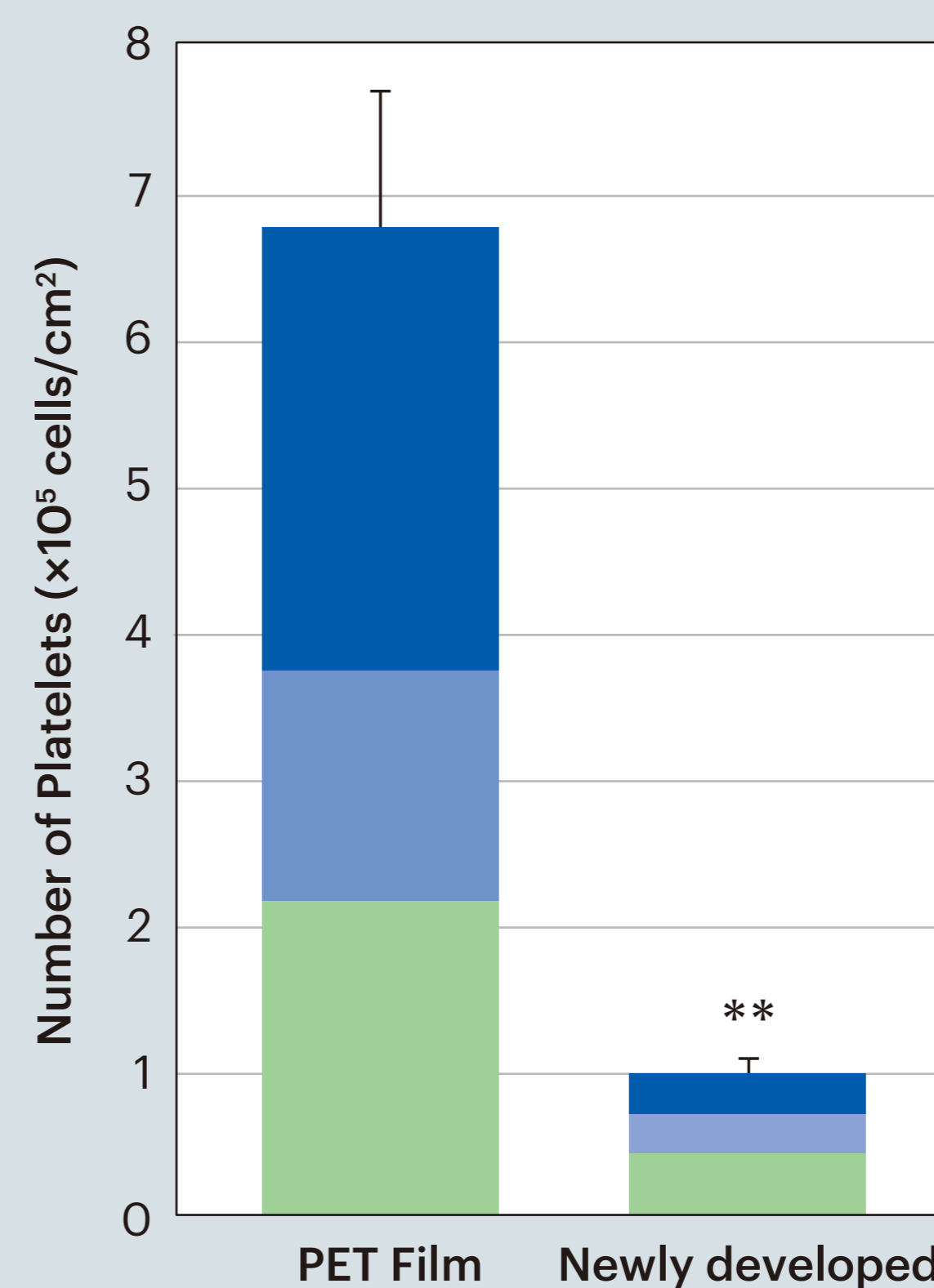


**Bio-compatibility**

**Anti-thrombotic**

**High-durability**

### Platelet Adhesion Test



\* P<0.05 (vsPET)  
\*\* P<0.01 (vsPET) mean±SD. n=15

□ Test method: A plasma solution containing 1x10<sup>5</sup> cells/μL of platelets was incubated at 37°C for 30min on samples. Subsequently, each sample was rinsed with PBS. The number and the degree of activation of the adhered platelets were determined through scanning SEM.

□ Cooperation: Tanaka Lab. Institute for Materials Chemistry and Engineering, Kyushu University

## ② Slide coating materials

**Applications: Prefillable syringes, catheters, etc.**

A silicone resin based thermoset coating. Provides high sliding properties to gaskets without silicone oil lubricants and inhibits agglomeration of biopharmaceuticals.

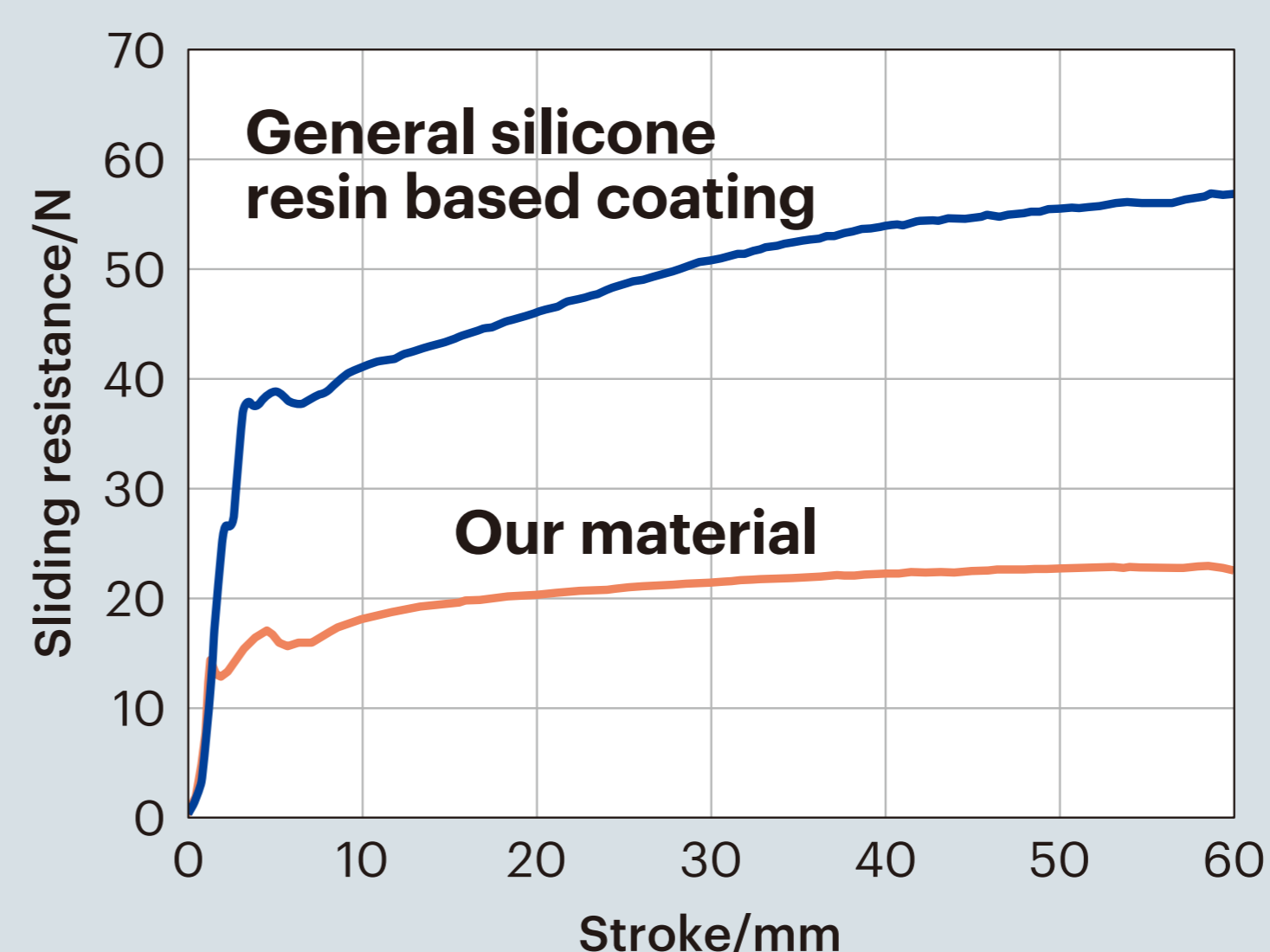


**Bio-compatibility**

**Low friction**

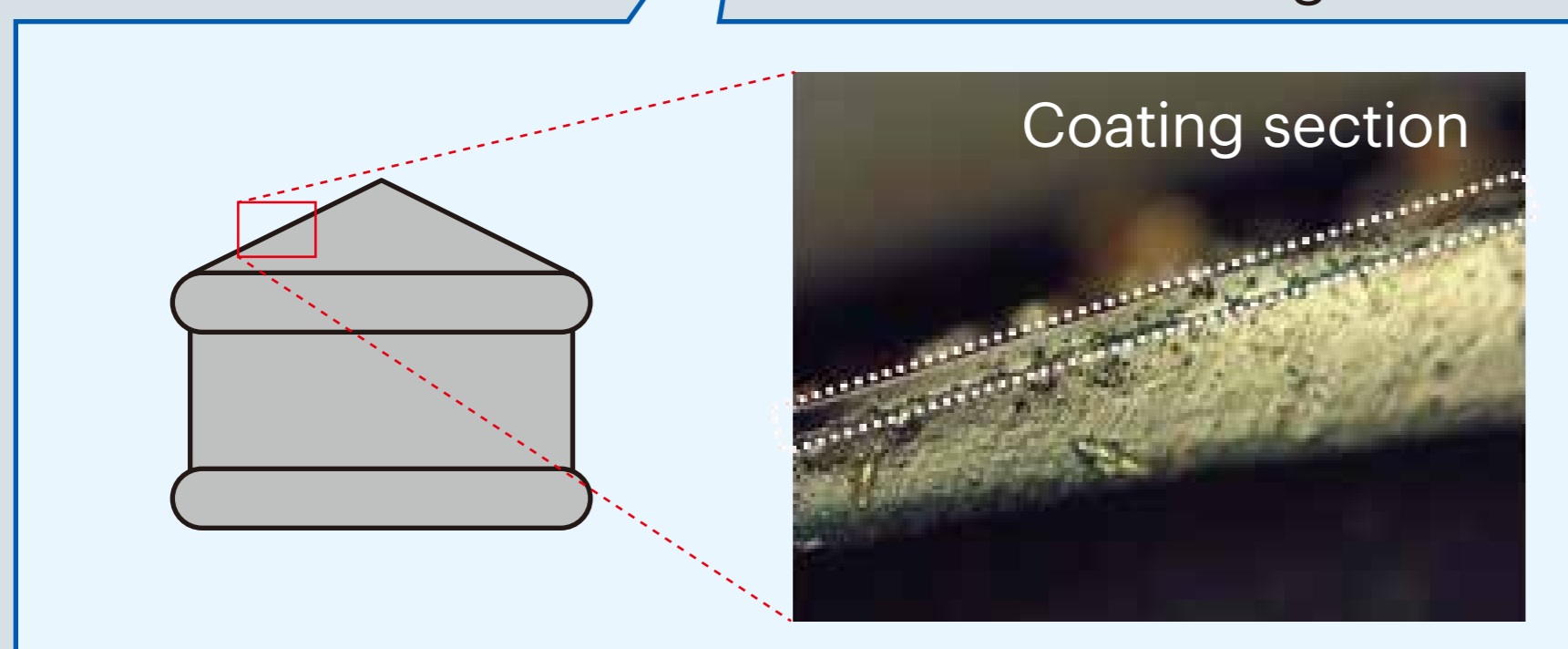
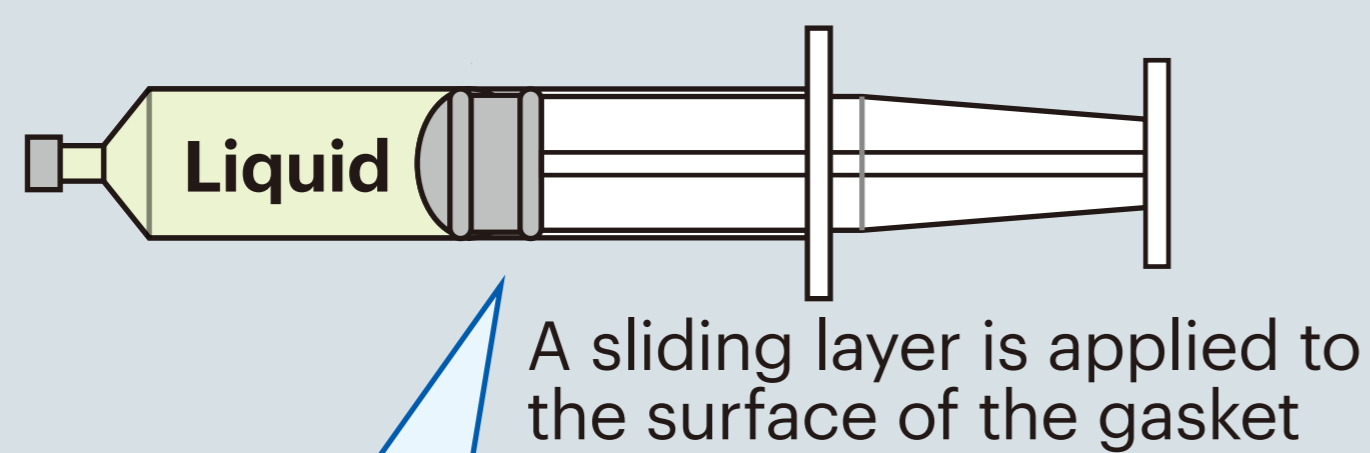
**Low elution**

### Coating improves syringe sliding properties



□ Test method  
Syringe: 20ml  
Barrel, plunger: PP  
Gasket: TPE  
Measurement temperature: room temperature  
Push-in speed: 100mm/min

\*The data are representative values and are not guaranteed.





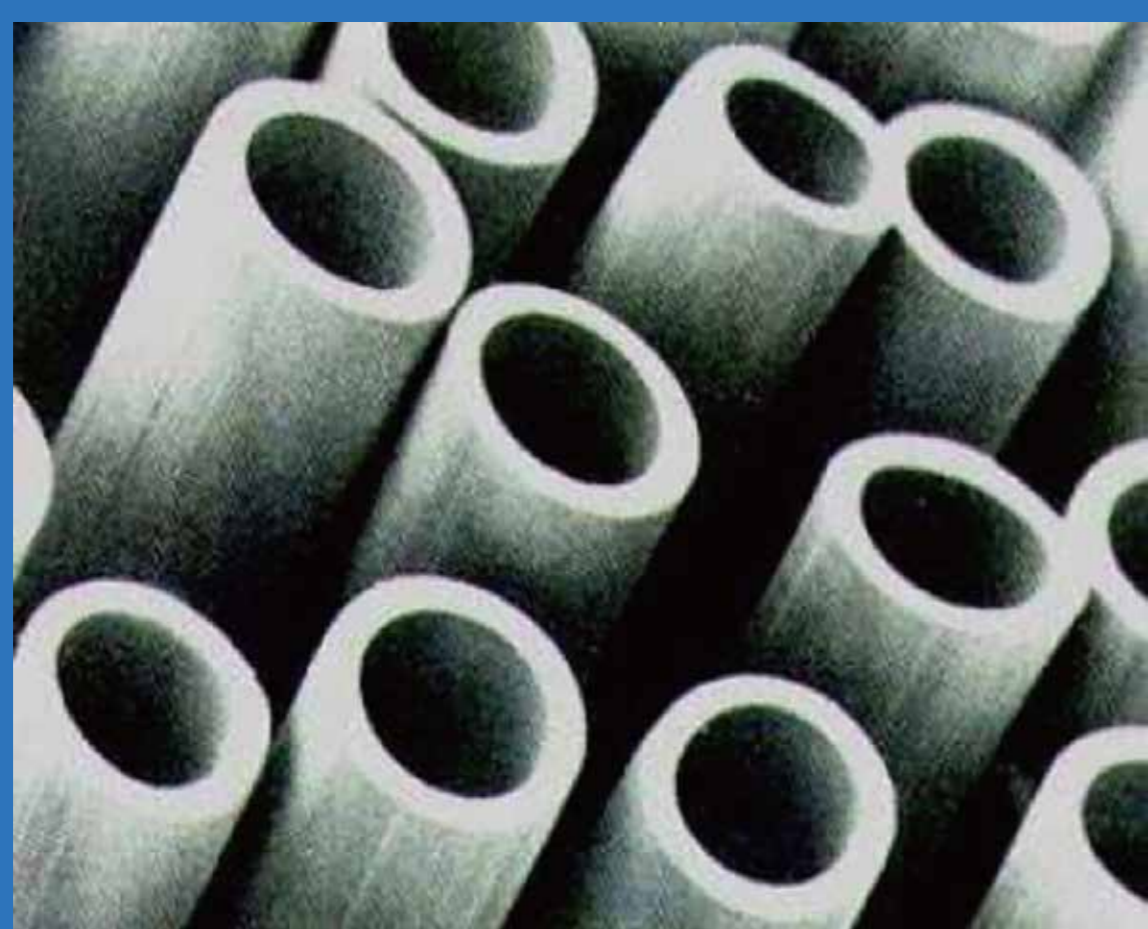
# Polyethylene (PE) hollow fiber membrane STERAPORE™

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



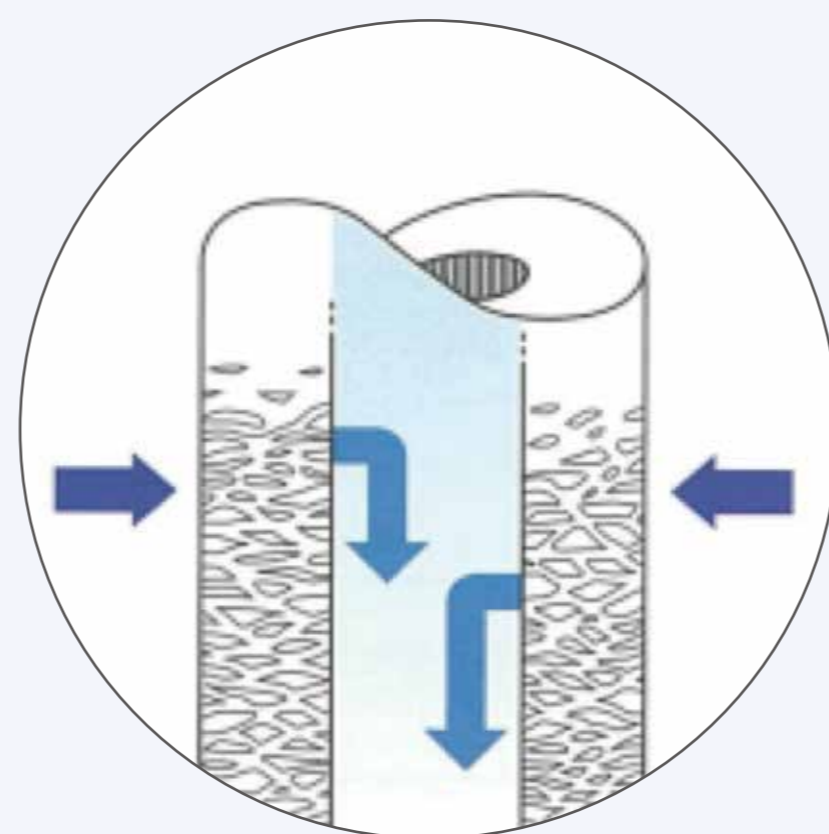
## Features

Image of HFM



300~500μm

Section Image



Surface Image



1μm

PE  
membrane

### Precise solid-liquid separation

: Captures fine particles with multiple structure

### Hygienic and safe membrane

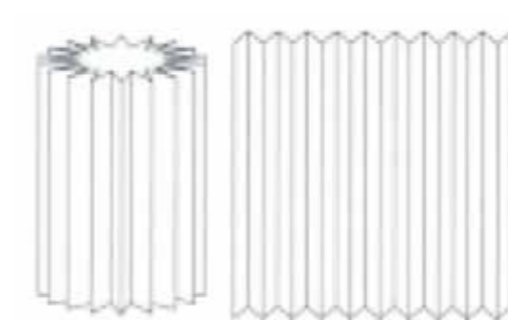
: High purity, 100% polyethylene

## Membrane filter

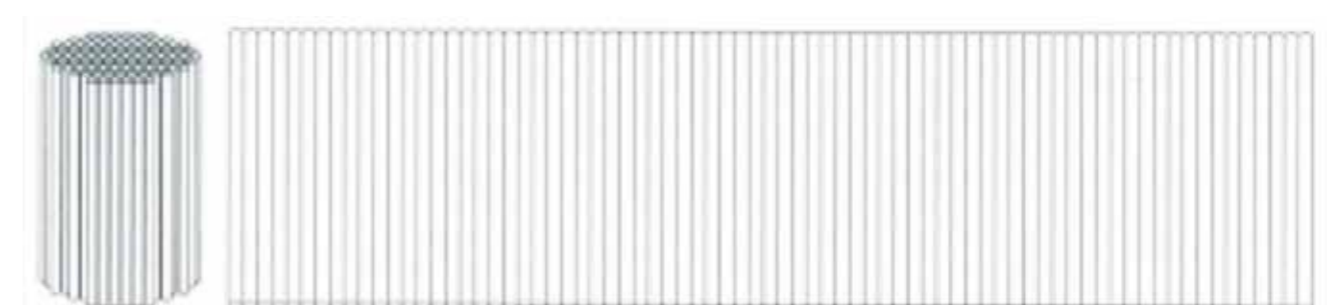
- (1) Volumetric efficiency
- (2) Long life
- (3) High flow rate



Flat filter



Hollow  
fiber  
membrane



# Polyethylene (PE) hollow fiber membrane STERAPORE™

## Our HFM Position

| Size  | Objects   | Separation Method and applications  |
|---|---|---|
| <b>Ion · Low molecular weight</b><br>0.1nm<br>0.2nm<br>0.5nm                          | H <sub>2</sub> O<br>Na <sup>+</sup><br>Ca <sup>2+</sup><br>Cl <sup>-</sup><br>OH <sup>-</sup><br>glutamic acid<br>Sucrose               | <b>Reverse osmosis RO</b><br>Seawater desalination<br>Ultrapure water production  |
| <b>Colloid</b><br>2nm<br>5nm<br>0.01μm<br>0.02μm<br>0.05μm<br>0.1μm<br>0.2μm<br>0.4μm | Lysozyme<br>serum albumin<br>γ · globulin<br>polio virus, Japanese encephalitis<br>Pseudomonas diminuta                                 | <b>Ultrafiltration UF</b><br>Food industry  |
| <b>Fine particle</b><br>0.5μm<br>1μm<br>2μm<br>5μm<br>10μm                            | Latex emulsion<br>Vibrio cholerae, Salmonella typhi<br>Escherichia coli<br>Staphylococcus<br>Cryptosporidium<br>Giardia<br>Echinococcus | <b>Our HMF position</b><br><b>confidential filtration MF</b><br>Particulate removal<br>RO, UF pre-processing<br>Ion exchange pre-processing<br>Chlorella concentrate<br>Sterile water production<br><b>General filtration</b> |

### 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**.