

Mitsubishi Chemical Advanced Materials LIFE SCIENCE GRADE PORTFOLIO (LSG)



High-performance engineering plastic stock shapes used for VENTILATOR equipment

Mitsubishi Chemical Advanced Materials is providing a vital supply of manufactured materials for medical equipment to fight the COVID-19 crisis



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Medical grades for the fabrication of respiration and ventilator device components

Mitsubishi Chemical Advanced Materials offers specialty medical grades used for components in ventilators. To support the needs for machined parts used in ventilators and many other equipment in the medical and life science industry, Mitsubishi Chemical Advanced Materials offers the **largest stock of life science grade materials** in the world.

Our Life Science Grades portfolio consists of:

- Altron™ LSG PC
- Duratron® LSG PEI
- Ketron® LSG PEEK
- Proteus® LSG H PP
- Sultron™ LSG PPSU

Our Ketron® LSG PEEK, Altron® LSG PC, and Nylatron® PA materials have the strength, stiffness and dimensional stability needed for internal structural components and housings for respiratory equipment.



Biocompatible and compliant as per ISO 10993 and USP Class VI

Typical applications: piston end caps, distribution valves, oxygen concentrator components

Compatible with UV, ETO, Steam and other sterilization methods

Suitable for tissue and fluid contact up to 24 hours (Ketron® CLASSIX™ LSG PEEK: up to 30 days)

Product characteristics

- High strength, durability and impact strength
- Strong resistance to chemical cleaners and disinfectants
- Sterilizable by steam, hydrogen peroxide and gamma radiation
- Low creep under sustained loads at high temperatures
- Biocompatibility tested on shapes and full lot traceability

Products for the Life Science Industry

Mitsubishi Chemical Advanced Materials offers Life Science Grades that have been specifically developed for applications in the medical, pharmaceutical, and biotechnology industries. These products have been tested to ISO 10993 and USP guidelines for biocompatibility testing of materials while providing full traceability from raw material to stock shape.

Key benefits of the Life Science Grades:

Performance

Properties such as weight reduction, resistance to commonly used sterilization methods and design flexibility make LSG materials suitable for use in replacement of stainless steel, titanium, glass and ceramics applications.

Biocompatibility

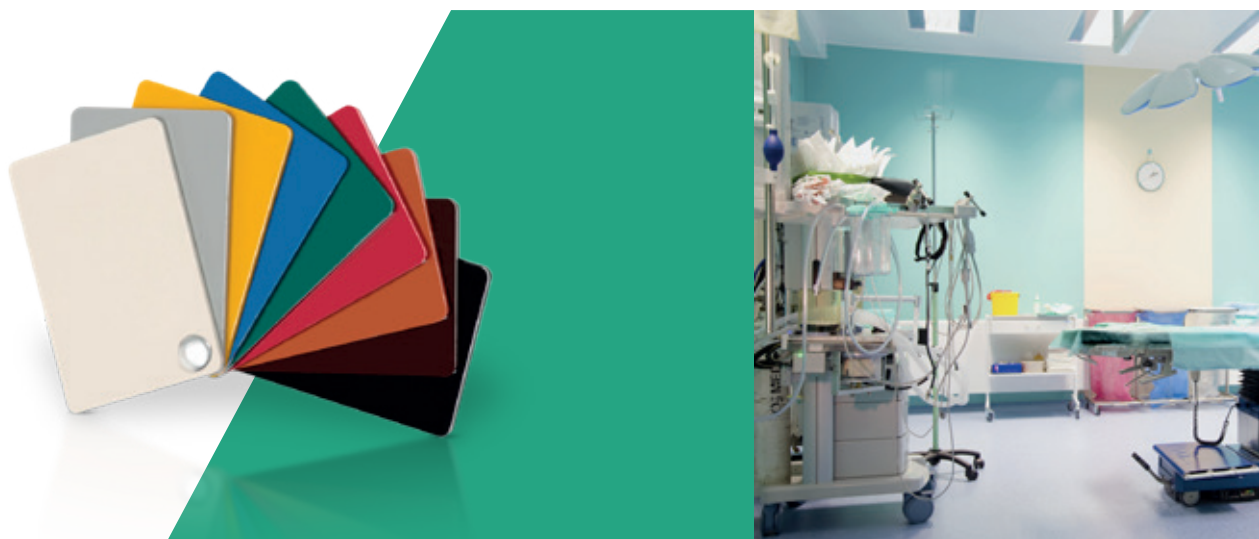
The LSG portfolio includes plastics which have been tested to ISO 10993 and USP guidelines for biocompatibility testing of materials.

Full traceability

Mitsubishi Chemical Advanced Materials provides OEMs with assurance of full traceability for its comprehensive LSG product portfolio.

Quality assurance

In line with its ISO 9001:2015 certified Quality Assurance System, Mitsubishi Chemical Advanced Materials thoroughly monitors and controls the entire manufacturing process of its Life Science Grades.



Products for the Life Science Industry



Within its portfolio of Life Science Grade Engineering Plastic Products - specifically developed for applications in the medical, pharmaceutical and biotechnology industries - Mitsubishi Chemical Advanced Materials offers the following biocompatible plastic stock shapes for machining with tested USP Class VI and ISO 10993 compliance:

Ketron® CLASSIX™ LSG PEEK [PEEK; for Life Science Applications; white]

Ketron® LSG CA30 PEEK [PEEK; for Life Science Applications; black]

Ketron® LSG PEEK [PEEK; for Life Science Applications; natural, black, red, blue, green]

Sultron™ LSG PPSU [PPSU; for Life Science Applications; black, red, yellow, grey, brown, blue, green, orange]

Duratron® LSG PEI [PEI; for Life Science Applications; natural]

Sultron™ LSG PSU [PSU; for Life Science Applications; natural]

Altron™ LSG PC [PC; for Life Science Applications; natural]

Proteus® LSG H PP [PP; for Life Science Applications; white]

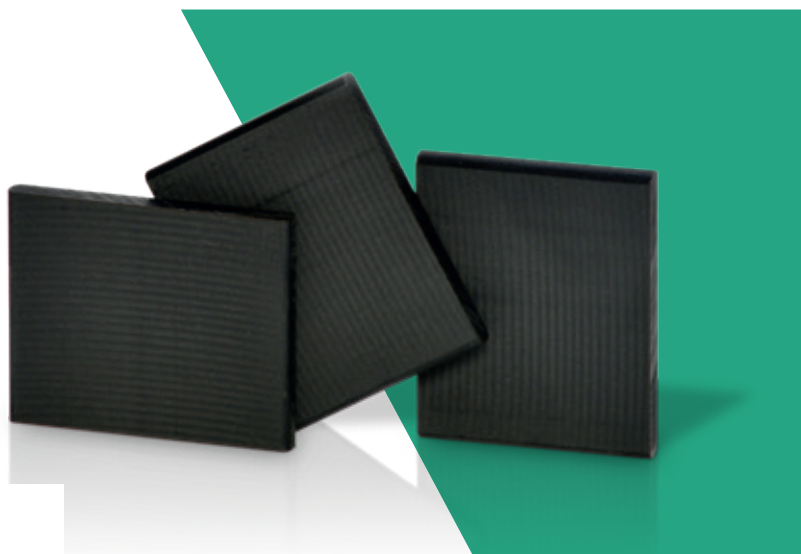
Products for the Life Science Industry

Biocompatibility Status USP and ISO 10993

A comprehensive biocompatibility type testing programme was run by an independent, internationally renowned and accredited testing organization on the Mitsubishi Chemical Advanced Materials LSG stock shapes in order to check their compliance with both United States Pharmacopeia [USP] and ISO 10993 guideline requirements for Biocompatibility Testing of Materials.

Application areas of MCAM's Life Science Grades in ventilator equipment:

- Structural components
- Valves
- Wear components
- Piston end caps



Mitsubishi Chemical Advanced Materials' LSG **Thermoplastic** Solutions have been found suitable for use in Ventilator components.

In Airpath Flow:

- Blowers
- Impellers
- Diaphragms
- Displacement chamber
- Compressor, concentrators
- Machined manifolds
- Cough valves and suction components
- Wear and friction components
- Nebulizers and humidity chambers

From Machine to Patient: Non-Invasive

- Y Fittings, tubing and connectors
- Face masks, connectors, clips and headbands
- Pneumatic connectors and valves

From Machine to Patient: Invasive

- Intubation and tracheal components

Biocompatibility Testing

MATERIALS	TESTS (1)(2)	1. Cytotoxicity Ref.: ISO 10993-5 and USP <87> Biological Reactivity Tests, In Vitro Elution Test	2. Sensitization Ref. ISO 10993-10, Magnusson & Klignan 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 Pure Water extract, 70°C/24h	USP Class VI (conclusion from tests 3, 4 and 5)
Ketron® CLASSIX™ LSG PEEK white		✓	✓	✓	✓	✓	✓	✓	✓
Ketron® LSG CA30 PEEK		✓	✓	✓	✓	✓	✓	✓	✓
Ketron® LSG PEEK natural, black		✓	✓	✓	✓	✓	✓	✓	✓
Ketron® LSG PEEK red, blue, green		✓	NT	NT	NT	NT	NT	✓	NT
Ketron® LSG Food Grade PEEK natural, black		✓	✓	✓	✓	✓	✓	✓	✓
Sultron™ LSG PPSU black		✓	✓	✓	✓	✓	✓	✓	✓
Sultron™ LSG Food Grade PPSU black		✓	✓	✓	✓	✓	✓	✓	✓
Sultron™ LSG PPSU natural (ivory)		✓	NT	✓	✓	NT	NT	✓	NT
Sultron™ LSG PPSU blue, brown, green, grey, orange, red, yellow		✓	NT	NT	NT	NT	NT	✓	NT
Duratron® LSG PEI natural		✓	✓	✓	✓	✓	✓	✓	✓
Duratron® LSG PEI black		✓	NT	in test	in test	in test	NT	✓	NT
Duratron® LSG PEI blue		✓	NT	NT	NT	NT	NT	✓	NT
Sultron™ LSG PSU natural		✓	✓	✓	✓	✓	✓	✓	✓
Altron™ LSG PC natural		✓	✓	✓	✓	✓	✓	✓	✓
Proteus® LSG H PP natural		✓	NT	NT	NT	NT	NT	✓	NT

✓ This test was carried out and the material passed the test.

NT Not Tested

(1) All tests were run on test specimens machined from stock shapes shortly after manufacture.

(2) Mitsubishi Chemical Advanced Materials performs testing on its Life Science Grades in order to facilitate evaluation by its customers of their biocompatibility with regard to the requirements applicable to the specific use of the finished product. Mitsubishi Chemical Advanced Materials does not possess expertise in evaluating the suitability of its tested materials for use in specific medical, pharmaceutical, or biotechnological applications. **It remains the customer's sole responsibility to test and assess the suitability of Mitsubishi Chemical Advanced Materials' Life Science Grades for its intended applications, processes and uses.** Mitsubishi Chemical Advanced Materials makes no warranties or representations whatsoever that its materials are manufactured in accordance with the quality standards appropriate and necessary for materials intended for use in implantable medical device applications and in applications that are essential to the restoration or continuation of a bodily function important to the continuation of human life.

Mitsubishi Chemical Advanced Materials' Life Science Grades should not be used for applications involving medical devices that are intended to remain implanted in the human body continuously for a period exceeding 24 hours (30 days*), or that are intended to remain in contact with internal human tissue or bodily fluids for more than 24 hours (30 days*). They should not be used either for the manufacture of critical components of medical devices that are essential to the continuation of human life.

*: '30 days' applies to Ketron® CLASSIX™ LSG PEEK white only.

Geometries of Stock Shapes

- **Sheets, Plates** 5 – 100 mm thickness
- **Rods** Diam. 5 – 200 mm

Mitsubishi Chemical Advanced Materials stocks many different dimensions of shapes for fast delivery!

Easy access to MCAM's Technical Resources

- Chemical Resistance Overview
 - Chemical Resistance Database on MCAM.com
- Sterilization Compatibility Overview
- Product Data Sheets
 - Find out more on MCAM.com – Life Science Grades

Compatibility with Sterilization methods

	Sultron™ LSG PPSU	Sultron™ LSG PSU	Ketron® LSG PEEK	Duratron® LSG PEI	Altron™ LSG PC
Steam 18 minutes at 134C	✓	✓	✓	✓	
> 10 cycles	✓	✓	✓	✓	
> 100 cycles	✓		✓	✓	
> 1000 cycles	✓	✓	✓		
Ethylene dOxide Gas 100 cycles	✓	✓	✓	✓	✓
Vaporized Hydrogen Peroxide 200 cycles	✓	✓	✓	✓	
High-Energy Gamma Radiation 40kGy	✓	✓	✓	✓	✓

Compatibility with Hospital Disinfectants

	Sultron™ LSG PPSU	Sultron™ LSG PSU	Ketron® LSG PEEK	Duratron® LSG PEI	Altron™ LSG PC
Aseptisol	Excellent	Excellent	Excellent	Poor	Poor
Bleach Solutions 10%	Excellent	Excellent	Excellent	Poor	Poor
Cavicide	Excellent	Excellent	Excellent	Excellent	Good
Cidex	Excellent	Excellent	Excellent		
Envirocide	Excellent	Excellent	Excellent	Excellent	Excellent
Grotanat	Excellent	Good	Excellent		
Hydrogen Peroxide, 3%	Excellent	Excellent	Excellent	Poor	Excellent
Isopropyl Alcohol, 70%	Excellent	Good	Excellent	Excellent	Good
Lysetol FF	Excellent	Good	Excellent		
Manu-Klenz	Excellent	Excellent	Excellent	Good	Good
Phenols, 2%	Excellent	Good	Excellent	Excellent	Excellent
Puristeril Plus	Excellent	Excellent	Excellent	Poor	Excellent
Quaternaries	Excellent	Good	Excellent	Poor	Poor
Sani-Cloth HB	Excellent	Excellent	Excellent	Good	Good
Sani-Cloth Plus	Excellent	Poor	Excellent	Good	Good
Sporotal 100	Excellent	Good	Excellent	Poor	Poor
Super Sani-Cloth	Excellent	Good	Excellent	Excellent	Good
Wex-Cide	Excellent	Poor	Excellent	Excellent	Good

Additive Manufacturing and Rapid Prototyping Opportunities for urgent Product Development

3D printing development has become a company's priority at Mitsubishi Chemical Advanced Materials. Our 3D Printing experts teams in the US and in Europe share knowledge and align our work in the 3D printing field between Mitsubishi Chemical Advanced Materials, and all our sister/parent companies to always find the best solution for our customers' needs.

3D Printing Capabilities

- Two designated 3D Printing labs
- One Global 3D Printing Industry Solution Team in the US and Europe
- A Global network through Mitsubishi Chemical Holdings Group, of sister companies who can provide design guidance, ensuring easy accessibility and a quick turnaround.

Design engineers benefit from MCAM's (in-house) Supply Chain Stewardship from single prototype through serial production, and including Rapid Prototyping Services as a service to compress product development time.

3D Printing Advantages

- Reduced part weight- parts can be hollow or honeycombed to save material and reduce weight.
- Decreased number of components needed- multiple components can be printed together.
- New design opportunities and capabilities that are not achievable with traditional machining.
- Significant reduction in development time (tooling, prototypes, design iterations) from weeks to mere hours.
- The more complex the geometry, the more beneficial 3D printing typically is.
- If tooling costs are a concern, or if there is a need for a small number of parts, 3D printing could be a more cost effective solution.

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