

Life Science Grades for Medical & Bioprocessing needs

A broad range of thermoplastic materials, pre-assessed
for biocompatibility as per USP class VI and ISO 10993

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1. Introduction

Raising the bar for Medical and Bioprocessing materials

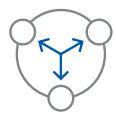
Selecting the right materials for your medical and bioprocessing applications can be a challenge. It is a complex global market, testing is expensive, and you've got strict regulatory, compliance and sterilization requirements. On top of this, you also have supply chain risks, sustainability and even more to consider.

In order to master such complex challenges, the Engineering Shapes & Solutions Division of Mitsubishi Chemical Group (MCG) is the ideal partner by your side. Our comprehensive portfolio of Life Science Grades (LSG) raises the bar again and supports you in meeting your requirements. As they are already pre-assessed for biocompatibility, our LSG high-performance thermoplastic stock shapes are designed to help you meet the stringent demands of these markets.

This guide introduces you to the wide range of our innovative LSG polymer solutions and applications that expand your own possibilities. MCG supports you throughout your entire project to help ensure ongoing success. You will find answers to your most frequent questions and will have access to our expert teams who are available to provide additional information and support.

2. Processing selection

The MCG difference



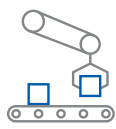
From product development to delivery, the right partner for your needs

Because you require a partner who is well acquainted with the complexities of the Healthcare and Bioprocessing markets, and can help you navigate your product journey successfully, MCG adds value at every step.

We offer expert support through your material selection and your regulatory assessment processes — and can assist in managing the inevitable changes as they occur.

Take advantage of our industry know-how and expertise in medical plastics processing. Our deep insight in available medical resins, our own conversion methods, post-machining, assembly and testing can help you to reduce cost and speed up your market introduction.

Because MCG is vertically integrated, product availability risks are reduced, and supply more secure. On top of this, our material experts are by your side any time you need support in your decisions regarding design, manufacture or compliance.



The benefits of manufacturing with LSG materials

When you manufacture your products with LSG materials, you can expect a variety of benefits over traditional materials. LSG materials are pre-assessed for biocompatibility – not only on resin, but on shape as well. You'll get a high level of quality assurance and have full traceability on your materials from resin to stock shape/machined parts. MCG's global footprint also means global production capabilities and warehousing, thereby increasing availability of materials. These advantages enable you to get your product to market faster and reduce costs thanks to the wide variety of available stock shapes.

2. Processing selection

The MCG difference



Pre-assessed through the value chain

Production of LSG materials begins with teaming up with our resin suppliers. Resins, sourced from A-class manufacturers, are pre-assessed for biocompatibility in alignment with the intended use of the product. To create stability within the supply chain, the Engineering Shapes & Solutions Division of MCG also requires Management of Change (MoC) from their suppliers. This creates a very predictable, stable system where medical requirements are safeguarded throughout the supply chain and product changes are minimized.

You need to rely on international quality standards and so the production of LSG shapes and machined components is undertaken within our Global ISO 13485 certified quality management systems.

Although it is common market practice to rely solely on the pre-assessment testing of the resin, this poses a compliance risk, as this fails to consider the potential impact of the conversion process on biological safety. Therefore, we add another level of assessment by testing the converted stock shapes on biocompatibility and so extending the compliance to include the conversion and even machining operations. For the OEM, this brings the pre-assessment testing closer to the final component, increasing the chance of a successful project.

LSG stock shapes are globally stocked and supplied with traceability and biocompatibility pre-assessment certificates. Material and process selection assistance is included, so your engineers can consult with our technical staff to design the best parts out of the most compliant materials – improving time-to-market while reducing costs.

By the end of 2028, medical device manufacturers placing finished medical devices in the European market must comply with the newly updated European Medical Device Regulations. MCG's Life Science Grade materials and documentation are well-suited to provide medical device manufacturers with a stable, secure supply of pre-assessed semifinished materials that will assist with their transition to the more rigorous requirements of the MDR.

2. Processing selection

The MCG difference



MCG's unique range of processing capabilities

- **Production of semi-finished stock shapes**
 - by extrusion
 - by compression molding
- **Production of Near Net Shapes**
 - saves material and machining time, and therefore cost
- **Production of molded shapes**
 - by injection molding
- **Production of final components**
 - by machining, assembly, and testing
- **Machined parts for manufacturing, polishing, assembly, testing, cleaning and packaging**

Contact us

Want to find out more about how you can get the most out of our compliant materials, with on-hand support for your application creation?

Get in touch with our expert teams today by filling in the contact form here: <https://www.mcam.com/en/contact>

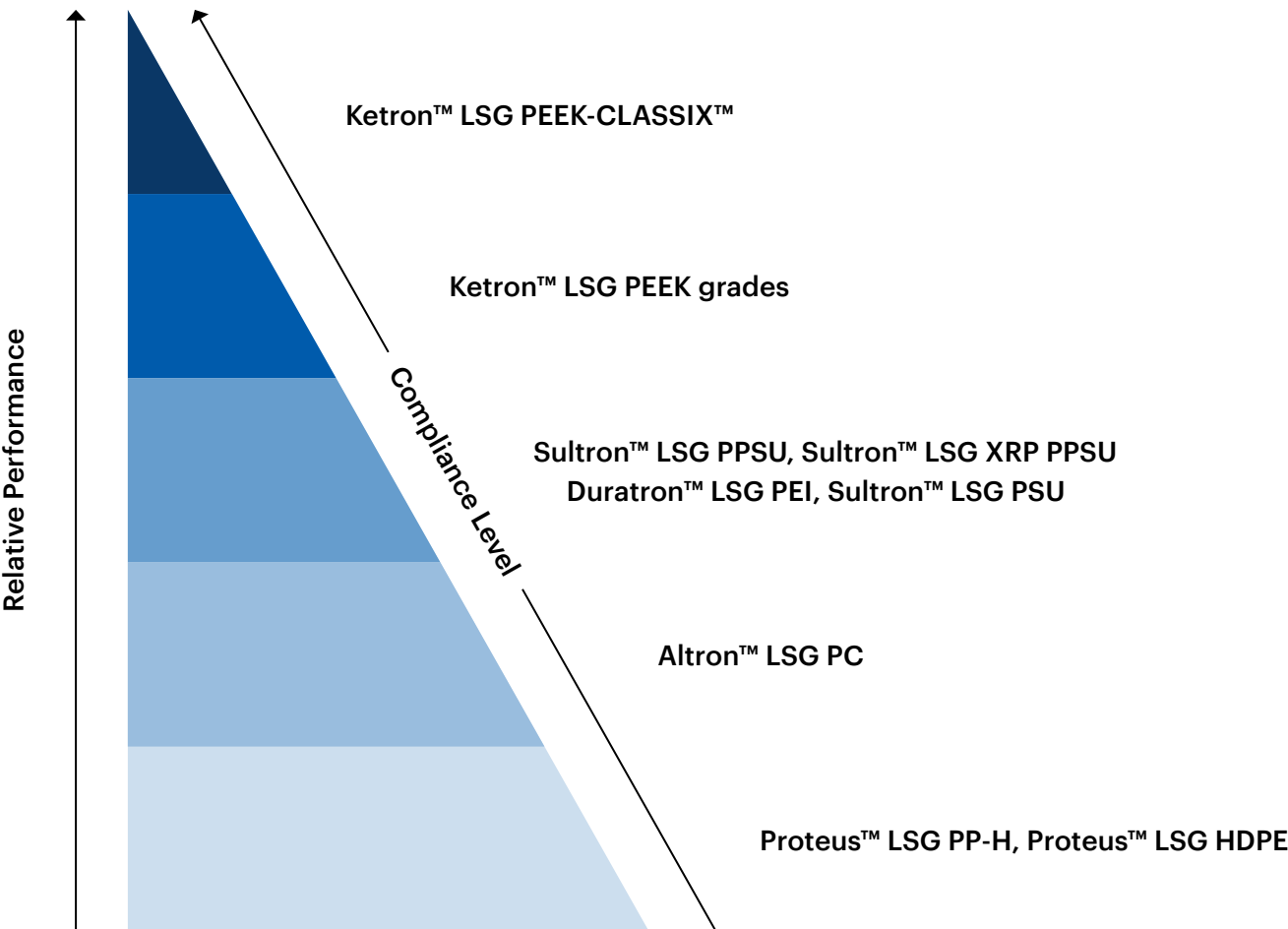
3. Life Science Grades

LSG portfolio

When selecting a Life Science Grade material for your project, we recommend you start by gathering the specific requirements of your application: both in terms of compliance and performance.

The LSG portfolio of thermoplastic shapes encompasses a wide range of materials with different levels of performance properties relevant to medical and bioprocessing applications, including stiffness, temperature resistance, dimensional stability, impact strength, sterilizability, chemical resistance, and gamma radiation resistance. The LSG portfolio also spans an array of different compliance levels for different intended uses in the medical and bioprocessing fields.

The following chart gives an at-a-glance overview of the relative performance and compliance levels of the LSG portfolio.



Note: The full portfolio listing can be found in the biocompatibility table on page. 16 & 17.

Materials portfolio

Ketron™ LSG PEEK-CLASSIX™

Made from Invibo PEEK-CLASSIX™ resin (see page. 26). Exhibits high mechanical strength and stiffness, excellent resistance to chemicals and repeated sterilization via all current methods in commercial use. Pre-assessed for biocompatibility on both resin and shape, according to USP Class VI and ISO 10993 for up to 30 days contact with body tissue.

- **Excellent sterilization resistance via steam, dry heat, Ethylene Oxide (EtO), plasma, and gamma or x-ray irradiation**
- **Enhanced mechanical properties and chemical resistance**
- **White color to match teeth in dental applications**

Intended use/applications:

Those in which the duration of contact with human body tissue is limited up to 30 days*. This includes: air delivery, drug delivery, blood management, temporary dental abutments.

*** Note:** LSG materials are not intended for use in the manufacture of medical devices that will be permanently implanted in the body, nor are they intended for use in life-sustaining medical devices.



Materials portfolio

Ketron™ LSG PEEK, Ketron™ LSG FG PEEK

(FG = Food Grade)

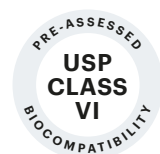
Two options – Life Science Grade and Life Science Grade + Food Grade (FG). Exhibits high stiffness and mechanical strength. Components are also sterilizable by means of steam (autoclave), dry heat, EtO, plasma, and gamma- & x-ray irradiation. Pre-assessed for biocompatibility on both resin and shape for up to 24 hours contact with body tissue according to USP VI and ISO 10993, as well as wetted contact in bioprocessing. Standard food approvals include FDA 21 CFR § 177.2415, while the FG type also includes Regulation (EU) No. 10/2011 food contact approval (based on food related migration tests).

- Excellent sterilization resistance via steam, dry heat, Ethylene Oxide, plasma, gamma and x-ray
- Unfilled PEEK base for high mechanical strength and chemical resistance
- Exceptional heat resistance

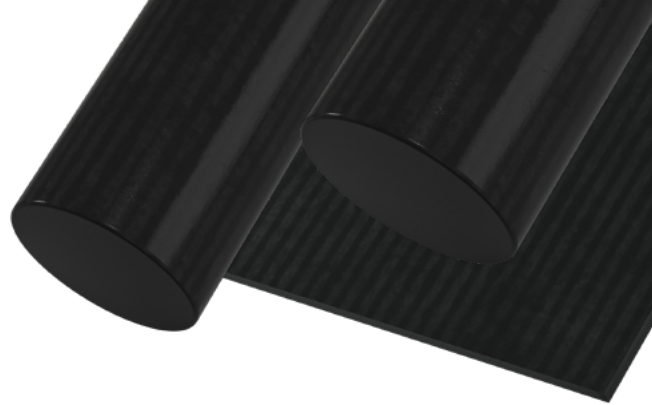
Intended use/applications:

Those in which the duration of contact with human body tissue is limited up to 24 hours*, as well as wetted contact in bioprocessing. This material is an excellent candidate for applications in the medical and bioprocessing fields, such as endoscopes/laparoscopes, manifolds, valves, connectors, lids, and adapters.

* **Note:** LSG materials are not intended for use in the manufacture of medical devices that will be permanently implanted in the body, nor are they intended for use in life-sustaining medical devices.



Materials portfolio



Ketron™ LSG CA30 PEEK

Excellent mechanical strength, stiffness, resistance to chemicals and repeated sterilization via all current methods. Pre-assessed for biocompatibility on both resin & stock shape (USP VI & ISO 10993) for up to 24 hours contact.

- **Excellent sterilization resistance via steam, dry heat, Ethylene Oxide, plasma, gamma and x-ray**
- **Exceptional resistance to heat and chemicals**
- **30% carbon fiber reinforced for exceptional mechanical properties**

Intended use/applications:

Those in which the duration of contact with human body tissue is limited up to 24 hours*
Potential applications for this material include nailing target devices, grips, adapters, and washers.

*** Note:** LSG materials are not intended for use in the manufacture of medical devices that will be permanently implanted in the body, nor are they intended for use in life-sustaining medical devices.



Materials portfolio

Sultron™ LSG PPSU, Sultron™ LSG FG PPSU, Sultron™ LSG XRP PPSU

(FG = Food Grade, XRP = X-ray RadioPaque)

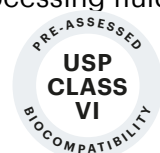
Superior hydrolysis resistance makes this Radel® PPSU base for biocompatibility on resin material highly suitable for repeated steam autoclaving and hot washing cycles. Exhibits resistance to common acids and bases over a broad temperature range, such as commercial washing solutions. Pre-assessed for biocompatibility for up to 24 hours contact with body and tissue according to USP VI and ISO 10993, as well as wetted contact in bioprocessing. Standard food approvals include FDA 21 CFR & 177.2500, while the FG (Food Grade) type also includes Regulation (EU) No. 10/2011 food contact approval (which is based on food-related extractable & leaching tests). With the XRP grade, addition of the x-ray image contrast agent Barium Sulphate allows for visibility under x-ray.

- Excellent sterilization resistance via steam, dry heat, Ethylene Oxide, plasma, gamma and x-ray
 - Superior ductility and hydrolysis resistance for autoclaving and hot washing
 - XRP grade delivers improved visibility for x-ray radiography
 - Wide array of color options
- Intended use/applications:** Those in which the duration of contact with human body tissue is limited up to 24 hours*, as well as wetted contact in bioprocessing. Including trial implants, sterilization trays, dental and surgical instrument handles, brachytherapy applicators, bioprocessing fluid handling caps, couplings, and fittings

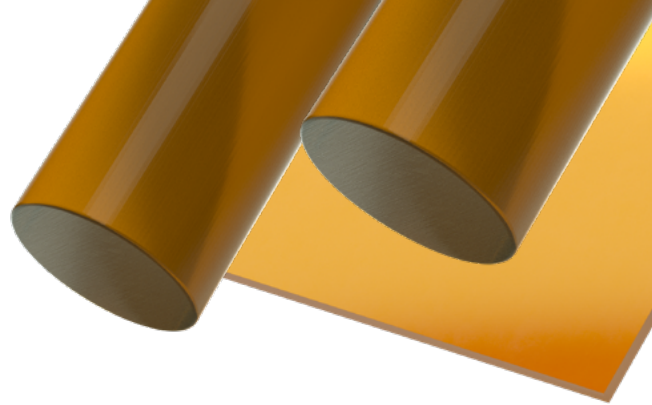
Intended use/applications:

Those in which the duration of contact with human body tissue is limited up to 24 hours*, as well as wetted contact in bioprocessing. Including trial implants, sterilization trays, dental and surgical instrument handles, brachytherapy applicators, bioprocessing fluid

*** Note:** LSG materials are not intended for use in the manufacture of medical devices that will be permanently implanted in the body, nor are they intended for use in life-sustaining medical devices.



Materials portfolio



Duratron™ LSG PEI

Stock shapes made from unfilled ULTEM™ PEI resin, with outstanding mechanical, thermal, and electrical performance, plus very good chemical and hydrolysis resistance. Pre-assessed for biocompatibility on both resin and shape for up to 24 hours contact with body tissue according to USP VI and ISO 10993, as well as wetted contact in bioprocessing.

- **Excellent sterilization resistance via steam, dry heat, Ethylene Oxide, plasma, and gamma or x-ray irradiation**
- **Excellent resistance to hydrolysis and chemicals**
- **Excellent dimensional stability**

Intended use/applications:

Those in which the duration of contact with human body tissue is limited up to 24 hours*, as well as wetted contact in bioprocessing. This includes: endoscopy/laparoscopy, dental and surgical handles and tools.

Sultron™ LSG PSU

Stock shapes made from unfilled Udel® PSU resin, exhibiting great mechanical, thermal, and electrical properties. Pre-assessed for biocompatibility on both resin and shape for up to 24 hours contact with body tissue according to USP VI and ISO 10993, as well as wetted contact in bioprocessing.

- **Excellent sterilization resistance via steam, dry heat, Ethylene Oxide, plasma, and gamma or x-ray irradiation**
- **Good hydrolysis resistance**
- **Great mechanical, thermal, & electrical properties**
- **Great visual transparency**

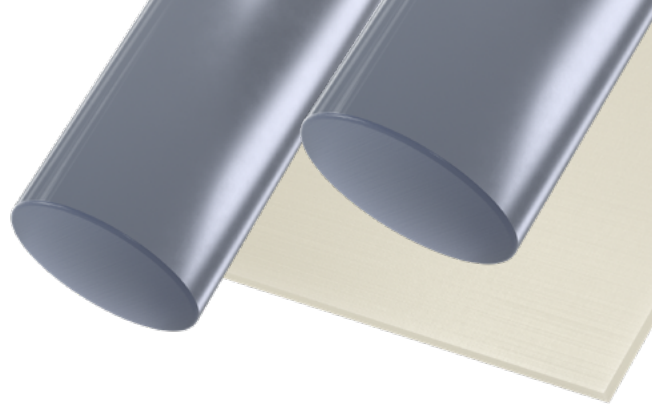
Intended use/applications:

Those in which the duration of contact with human body tissue is limited up to 24 hours*, as well as wetted contact in bioprocessing. Because of the above properties, as well as the material's visual transparency, Sultron™ LSG PSU components are great candidates for applications in the medical and bioprocessing fields such as applicators, manifolds, steam cleaning equipment inserts, and valves.

* **Note:** LSG materials are not intended for use in the manufacture of medical devices that will be permanently implanted in the body, nor are they intended for use in life-sustaining medical devices.



Materials portfolio



Altron™ LSG PC

Stock shapes offering outstanding impact resistance, toughness, and dielectric properties, as well as very good mechanical and thermal properties. Pre-assessed for biocompatibility on both resin and shape, according to USP Class VI and ISO 10993 for up to 30 days contact with body tissue, as well as wetted contact in bioprocessing.

- **Sterilization via Ethylene Oxide, plasma, gamma and x-ray**
(note: will discolor after gamma)
- **Not suitable for steam sterilization and dry heat**

Intended use/applications:

Those in which the duration of contact with human body tissue is limited up to 30 days*, as well as wetted contact in bioprocessing. This includes medical device housings, analyzers, and bioreactor equipment.

Proteus™ LSG HP PP-H

Stock shapes are made from High Purity homopolymer polypropylene resin that has undergone additional filtration to remove the last remaining black particles, thus increasing purity. Pre-assessed for biocompatibility at the stock shape level for wetted contact applications in bioprocessing according to USP VI and ISO 10993.

- **Sterilization via Ethylene Oxide, plasma, gamma and x-ray**
- **Excellent resistance to chemical cleaning agents**
- **Zero moisture absorption**
- **Low levels of extractables and leachables**

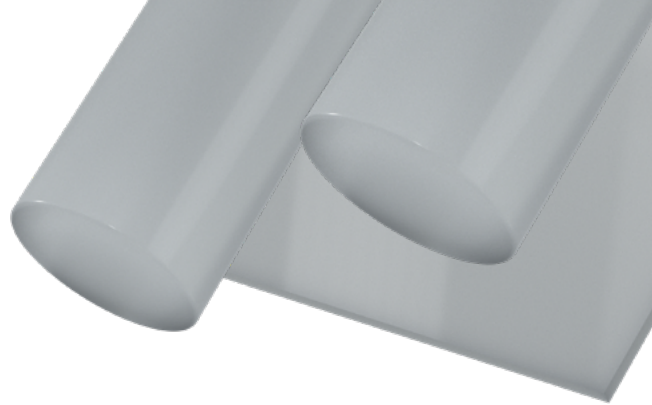
Intended use/applications:

Bioprocessing wetted contact applications (not intended for applications involving body contact)*. This includes upstream applications in bioreactors (valves, mixers/impellers), downstream applications in chromatography (fluid distribution plates), and filtration plates.

* **Note:** LSG materials are not intended for use in the manufacture of medical devices that will be permanently implanted in the body, nor are they intended for use in life-sustaining medical devices.



Materials portfolio



Proteus™ LSG HS PP-H

Heat Stabilized PP-H stock shapes, made from high purity homopolymer polypropylene resin, exhibiting superior resistance to steam sterilization, cleaning agents, and disinfectants with improved dimensional stability. Pre-assessed for biocompatibility at the stock shape level (ISO 10993) and supported for use in non-body contact medical applications.

- Sterilization by steam, Ethylene Oxide, plasma, gamma and x-ray
- Higher dimensional stability than Proteus™ LSG HP PP-H
- Heat stabilized recipe
- Zero moisture absorption

Intended use/applications:

Medical applications in which there is no direct body contact*, such as surgical trays, caddies, and device housing components.

Proteus™ LSG HDPE

Exhibits low extractables and leaching, low moisture absorption, and great resistance to chemical cleaning agents, allowing parts to retain excellent impact resistance and tensile strength throughout repeated use. Pre-assessed for biocompatibility on both resin and stock shape for up to 24 hours body contact according to USP VI and ISO 10993, as well as wetted contact in bioprocessing.

- Sterilization by Ethylene Oxide, plasma, gamma and x-ray
- Great chemical resistance
- Extractable and Leachable testing performed according to ISO 10993-18
- Excellent impact resistance and tensile strength

Intended use/applications:

Those in which the duration of contact with human body tissue is limited up to 24 hours* as well as wetted contact in upstream applications in bioreactors (valves, mixers/impellers), downstream applications in chromatography (fluid distribution plates), and filtration plates.

* **Note:** LSG materials are not intended for use in the manufacture of medical devices that will be permanently implanted in the body, nor are they intended for use in life-sustaining medical devices.



4. LSG material selection

Selecting the right materials for your application

What is unique about your material needs? How can our LSG portfolio make your product a success? Let our 360-degree knowledge of medical devices and bioprocessing applications guide you.

The first step is identifying the best material for your needs.

Material selection criteria

The best way to design new applications is to follow our material selection guideline. It starts with gathering specific requirements about your application and guides you through all the critical properties. Our materials experts are available to support your engineers validate their approach.

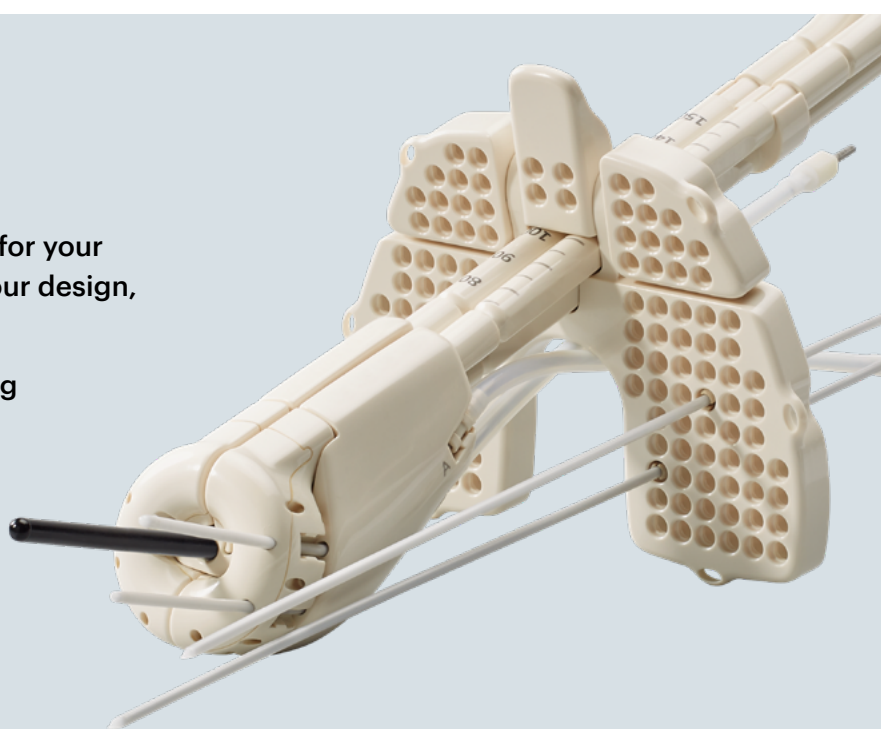
The first step is determining medical and/or bioprocessing criteria specific to your product. From there, assessing a variety of characteristics of your application – including stiffness, temperature resistance, dimensional stability, impact strength, sterilizability and chemical resistance, gamma radiation resistance – will further narrow the options among our pre-assessed materials. Machinability needs of your product will also help determine which is the recommended material or shape to start with.

Contact us

For support in selecting the best materials for your application, and validating them against your design, our expert teams are available to help.

Get in touch with a specialist today by filling in the contact form here:

<https://www.mcam.com/en/contact>



Credit: Photo courtesy of Nucletron Operations B.V. / Elekta

4. LSG material selection

Biocompatibility pre-assessment table – Medical

Materials	Tests / Compliance								Body Contact Duration Intended applications of which the duration of contact with human body tissue is limited to
	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 Pure Water extract, 70°C/24h	USP Class VI Conclusion from tests 3, 4 and 5	
Ketron™ LSG PEEK grades									
Ketron™ LSG PEEK-CLASSIX™ white	●	●	●	●	●	●	●	●	< 30d
Ketron™ LSG PEEK natural, black	●	●	●	●	●	●	●	●	≤ 24h
Ketron™ LSG FG PEEK natural, black	●	●	●	●	●	●	●	●	≤ 24h
Ketron™ LSG PEEK red	●	○	●	●	●	○	●	●	≤ 24h
Ketron™ LSG PEEK blue	●	○	●	●	●	○	●	●	≤ 24h
Ketron™ LSG PEEK green	●	○	●	●	●	○	●	●	≤ 24h
Ketron™ LSG PEEK yellow	●	○	●	●	●	○	●	●	≤ 24h
Ketron™ LSG CA30 PEEK	●	●	●	●	●	●	●	●	≤ 24h
Sultron™ LSG PPSU grades									
Sultron™ LSG R5100 PPSU black BK937	●	●	●	●	●	●	●	●	≤ 24h
Sultron™ LSG R5500 PPSU black BK937	●	○	●	●	●	○	●	●	≤ 24h
Sultron™ LSG FG R5100 PPSU black BK937	●	●	●	●	●	●	●	●	≤ 24h
Sultron™ LSG R5100 PPSU bone NT15	●	○	●	●	●	○	●	●	≤ 24h
Sultron™ LSG R5500 PPSU bone NT15	●	○	●	●	●	○	●	●	≤ 24h
Sultron™ LSG R5500 PPSU blue BU1027	●	○	●	●	●	○	●	●	≤ 24h
Sultron™ LSG R5500 PPSU brown BN1164	●	○	●	●	●	○	●	●	≤ 24h
Sultron™ LSG R5500 PPSU green GN1007	●	○	●	●	●	○	●	●	≤ 24h
Sultron™ LSG R5500 PPSU light grey GY1037	●	○	●	●	●	○	●	●	≤ 24h
Sultron™ LSG R5500 PPSU orange OR1145	●	○	●	●	●	○	●	●	≤ 24h
Sultron™ LSG R5500 PPSU red RD1018	●	○	●	●	●	○	●	●	≤ 24h
Sultron™ LSG R5500 PPSU violet VT2582	●	○	●	●	●	○	●	●	≤ 24h
Sultron™ LSG R5500 PPSU yellow YL1337	●	○	●	●	●	○	●	●	≤ 24h
Sultron™ LSG R5500 XRP PPSU									
Sultron™ LSG R5500 PPSU XRP blue BL2935CX6	●	○	●	●	●	○	●	●	≤ 24h
Sultron™ LSG R5500 PPSU XRP black BLK7547CX6	●	○	●	●	●	○	●	●	≤ 24h
Sultron™ LSG R5500 PPSU XRP dark green DGN3415CX6	●	○	●	●	●	○	●	●	≤ 24h
Sultron™ LSG R5500 PPSU XRP grey GRY403CX6	●	○	●	●	●	○	●	●	≤ 24h
Duratron™ LSG grades									
Duratron™ LSG PEI natural	●	●	●	●	●	●	●	●	≤ 24h
Duratron™ LSG PEI black	●	○	●	●	●	○	●	●	≤ 24h
Duratron™ LSG PEI blue	●	○	●	●	○	○	●	○	≤ 24h
Sultron™ LSG PSU grades									
Sultron™ LSG PSU natural NT	●	●	●	●	●	●	●	●	≤ 24h
Altron™ LSG PC grades									
Altron™ LSG PC	●	○	●	●	●	○	●	●	< 30d
Proteus™ LSG PP grades									
Proteus™ LSG HP PP-H	●	○	●	●	●	○	●	●	None
Proteus™ LSG HS PP-H white, black	●	○	○	○	○	○	●	○	None
Proteus™ LSG HDPE grades									
Proteus™ LSG HDPE	●	○	●	●	●	○	●	●	< 30d
Note: To see the disclaimer, please see page. 26.									
● Shape tested (incl pre-assessment of resin) ○ Raw material tested d Days									
● Shape testing pending/planned ○ Not tested h Hours									

Note: To see the disclaimer, please see page. 26.

● Shape tested (incl pre-assessment of resin)
● Shape testing pending/planned

○ Raw material tested
○ Not tested

d Days
h Hours

4. LSG material selection

Biocompatibility pre-assessment table – Bioprocessing

Materials	Tests / Compliance	USP Class VI Conclusion from tests 3, 4 and 5	Animal Free Origin (AFO) or TSE/ BSE Ref.: Note for Guidance EMA/410/01 Rev.3	Food Contact – FDA Ref.: USA FDA 21 CFR 177 and 178	Food Contact – EU Ref.: Commission Regulation (EU) No 10/2011
Ketron™ LSG PEEK grades					
Ketron™ LSG PEEK-CLASSIX™ white		●	■	◆	◆
Ketron™ LSG PEEK natural, black		●	■	◆	◆
Ketron™ LSG FG PEEK natural, black		●	■	◆	◆
Ketron™ LSG PEEK red		●	■	◆	◆
Ketron™ LSG PEEK blue		●	■	◆	◆
Ketron™ LSG PEEK green		●	■	◆	◆
Ketron™ LSG PEEK yellow		●	■	◆	◆
Ketron™ LSG CA30 PEEK		●	■	◆	◆
Sultron™ LSG PPSU grades					
Sultron™ LSG R5100 PPSU black BK937		●	■	◆	◆
Sultron™ LSG R5500 PPSU black BK937		●	■	◆	◆
Sultron™ LSG FG R5100 PPSU black BK937		●	■	◆	◆
Sultron™ LSG R5100 PPSU bone NT15		●	■	◆	◆
Sultron™ LSG R5500 PPSU bone NT15		●	■	◆	◆
Sultron™ LSG R5500 PPSU blue BU1027		●	■	◆	◆
Sultron™ LSG R5500 PPSU brown BN1164		●	■	◆	◆
Sultron™ LSG R5500 PPSU green GN1007		●	■	◆	◆
Sultron™ LSG R5500 PPSU light grey GY1037		●	■	◆	◆
Sultron™ LSG R5500 PPSU orange OR1145		●	■	◆	◆
Sultron™ LSG R5500 PPSU red RD1018		●	■	◆	◆
Sultron™ LSG R5500 PPSU violet VT2582		●	■	◆	◆
Sultron™ LSG R5500 PPSU yellow YL1337		●	■	◆	◆
Sultron™ LSG R5500 XRP PPSU					
Sultron™ LSG R5500 PPSU XRP blue BL2935CX6		○	■	◆	◆
Sultron™ LSG R5500 PPSU XRP black BLK7547CX6		○	■	◆	◆
Sultron™ LSG R5500 PPSU XRP dark green DGN3415CX6		○	■	◆	◆
Sultron™ LSG R5500 PPSU XRP grey GRY403CX6		○	■	◆	◆
Duratron™ LSG grades					
Duratron™ LSG PEI natural		●	■	◆	◆
Duratron™ LSG PEI black		●	■	◆	◆
Duratron™ LSG PEI blue		●	■	◆	◆
Sultron™ LSG PSU grades					
Sultron™ LSG PSU natural NT		●	■	◆	◆
Altron™ LSG PC grades					
Altron™ LSG PC		●	■	◆	◆
Proteus™ LSG PP grades					
Proteus™ LSG HP PP-H		●	■	◆	◆
Proteus™ LSG HS PP-H white, black		○	■	◆	◆
Proteus™ LSG HDPE grades					
Proteus™ LSG HDPE		●	■	◆	◆

Note: To see the disclaimer, please see page. 26.

- Shape tested (incl pre-assessment of resin)
- Shape testing pending/planned
- Raw material tested
- Not tested

- Animal Free Origin (AFO)
- Absence TSE/BSE
- Not compliant

- ◆ Shape compliant
- ◆ Raw material compliant
- ◆ Not compliant

4. LSG material selection

Sterilization resistance

Various sterilization methods are used in the medical industry to kill all viable micro-organisms on a part or device before use. Given their intended use in applications involving direct or indirect contact with human body tissue, the Life Science Grades were designed to be compatible with modern sterilization techniques such as EtO (ethylene oxide gas), autoclave (steam), dry heat, plasma, and irradiation by gamma or X-ray.

Explore the sterilization compatibility table below to evaluate which thermoplastic materials may be good candidates for your application.

Life Science Grades	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**	G	G
Duratron™ LSG PEI	G	VG / G	VG	G	G	G
Sultron™ LSG PSU	G	VG / G	G	G	G	G
Altron™ LSG PC	G	P / NS	NS	G	G	G
Proteus™ LSG HP PP-H*	G	G / P	P	G	P	G
Proteus™ LSG HS PP-H*	G	VG / G	P	G	P	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.

** not suited for continuous cycles without intervening cleaning

X-rays have an energy range of 100eV to 100keV. Gamma rays cover the EM spectrum with energy levels above 100keV. This makes gamma rays more powerful than X-rays therefore assumed at least same level of compatibility as to Gamma irradiation

4. LSG material selection

Chemical resistance

The Life Science Grades are resilient against many chemicals commonly found in healthcare applications. Review the plastic/chemical compatibility chart below as a rough guideline to understanding which thermoplastic material will resist the chemicals relevant to your application.

Chemical Resistance	Weak (dilute) acids	Strong acids	Oxidising chemicals	Weak (dilute) alkalis	Strong alkalis	Hot water (* 80°C)	Steam	Esters (e.g. ethyl acetate)	Ketones (e.g. acetone)	Aromatic hydrocarbons (e.g. benzene, toluene)	Aliphatic hydrocarbons (e.g. hexane, octane)
Ketron™ LSG PEEK-CLASSIX™	●	◐	◐	●	●	●	●	●	●	●	●
Ketron™ LSG PEEK	●	◐	◐	●	●	●	●	●	●	●	●
Ketron™ LSG CA30 PEEK	●	◐	◐	●	●	●	●	●	●	●	●
Sultron™ PPSU	●	◐	◐	●	●	●	●	◐	○	◐	●
Duratron™ LSG PEI	●	○	○	●	○	●	●	◐	○	○	●
Sultron™ PSU	●	○	○	●	◐	◐	○	○	○	○	●
Altron™ LSG PC	●	○	○	◐	○	◐	○	○	○	○	●
Proteus™ LSG HP PP-H	●	◐	○	●	●	●	●	●	●	◐	●
Proteus™ LSG HS PP-H	●	◐	○	●	●	●	●	●	●	◐	●
Proteus™ LSG HDPE	●	●	○	●	●	◐	○	●	●	◐	●

● Resistant – In general acceptable service life ◐ Partially resistant – Limited service life ○ Non-resistant

Please visit our website for detailed chemical resistance info: <https://www.mcam.com/en/support/chemical-resistance-information>

The following list of statements relating to the Life Science Grade portfolio is available via our web site (<https://www.mcam.com/en/support/regulatory-information>):

- Substances of Very High Concern (SVHC)
- Restriction of Hazardous Substances (RoHS)
- Per- and Polyfluoroalkyl Substances (PFAS)
- TSCA Persistent, Bioaccumulative, and Toxic (PBT) substances
- Biocides
- Latex
- Nanomaterials

- Phthalates
- Radioactive substances
- TSE/BSE (animal origin)
- Conflict minerals
- Persistent organic pollutants (POP)

In addition to the above, the following are also available via the web site for specific products:

- Safety Data Sheets (SDS)
- Product Handling Information Sheets (PHIS)
- FDA food contact statements
- Declarations of Compliance (DoC)

4. LSG material selection

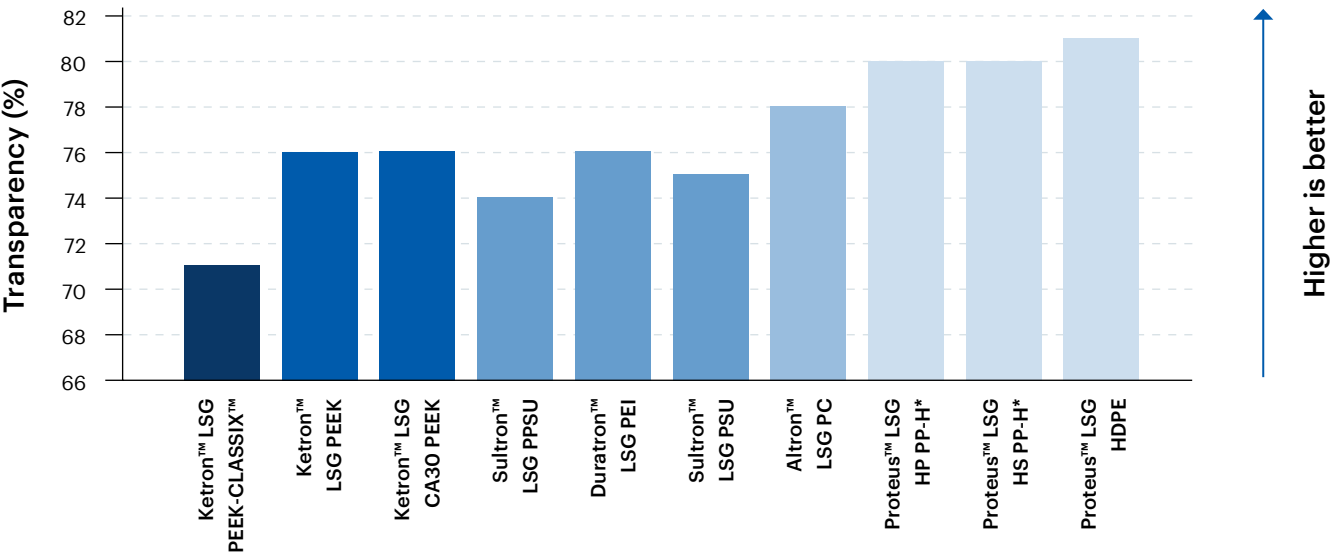
X-ray transparency

The transparency of a plastic material to high-energy radiation is a highly relevant attribute in the material selection process for medical applications, especially those involving medical imaging or radiation therapy. Thermoplastic materials used in these applications must allow x-rays and/or gamma rays to pass through them without significant attenuation in order to enable clarity and accuracy.

The Life Science Grades from Mitsubishi Chemical Group exhibit transparency levels between 71% and 81%, making them excellent candidates for components in the fields of medical imaging, radiation therapy, or dosimetry.

Transparency of the life science grades to high energy radiation

(Measured at 23°C on 12 mm thick test plates, applying radiation with an energy level of 59keV)



* Material not tested ; estimated value based on known material composition and/or miscellaneous literature data.

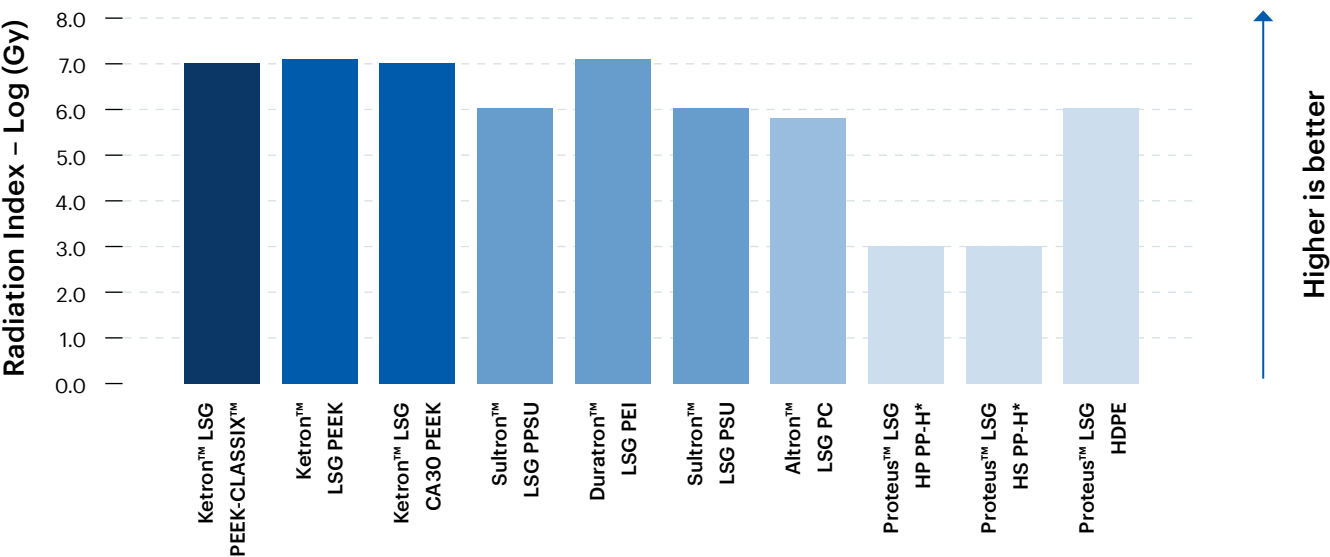
4. LSG material selection

Radiation resistance

The level of resistance exhibited by a plastic material to gamma radiation is a crucial consideration in medical, life science, and bioprocessing applications. Adequate gamma radiation resistance helps to ensure effective sterilization, maintain product integrity and safety, and the support long-term performance of components and devices.

Given their intended use in medical, life science, and bioprocessing applications, the Life Science Grades from Mitsubishi Chemical Group are designed to exhibit high levels of resistance to gamma radiation.

Resistance of the life science grades to gamma radiation

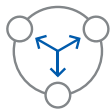


Index 6 = 10⁶Gy / 1MGy = 10⁶Gy / 1 Gy = 100rad / 100rad = 1J/kg / 1J/kg = 6.24.10¹²MeV/kg
X-rays energy ranging from 100eV to 100keV. Gamma radiation have energy greater than 100keV.
* Material not tested ; estimated value based on known material composition and/or miscellaneous literature data.

The Radiation Index (RI) is defined as the logarith, base 10, of the absorbed dose in Mega grays at which the flexural stress at break or flexural strain at break of the tested material is reduced to 50% of its original value, under specified conditions of irradiation (the most radiation-sensitive of these two properties is chosen as the reference critical property).

5. Ordering & delivery

Ease of business



A partnership dedicated to mutual long-term success

Have you experienced frustrations in having your products delivered, or difficulty contacting your supplier to answer questions after delivery? At MCG Engineering Shapes & Solutions Division, we view our business relationships as partnerships – we're in it for your long-term success. That means an ease of doing business you may not have had before.

We'll provide detailed and complete regulatory statements, including our own material test results on samples, machined from our stock-shape – to bring biocompatibility as close to your final application as possible. We'll bring full traceability and document retention, and make management of change transparent, simple and straightforward.

Finally, we could take back your post-industrial waste and reprocess them into less critical industrial products. Our Life Science Grades are always made from virgin resins.



Traceability and document retention

Our attention to traceability includes a commitment to document retention. This spans the resin batches, our own conversion into semi-finished shapes, quality and certification of LSG products; well beyond regulatory requirements after final product release.

5. Ordering & delivery

Ease of business



Change management

Obviously MCG strives to keep materials unchanged as long as possible. However, in some rare cases, changes are inevitable. In order to manage this, we have set a strict policy about Management of Change.

Our strict change management policy requires LSG grade resin suppliers to provide notification of changes at any time. By this we make sure that changes that could affect the performance or biological safety of the product are being approved by us prior to implementing the change.

Furthermore, for the Life Science Grades we now offer change notification provisions with sufficient lead time to allow for your approval, or for you to collaborate with us to source suitable alternatives.

Key benefits of manufacturing with LSG materials

- Materials pre-assessed for biocompatibility (USP Class VI & ISO 10993)
- Quality assurance through ISO 13485
- Traceability from resin to stock shape / machined part
- Global availability
- Reduced time to market
- Design flexibility within a broad variety of available stock shapes and customized near net shape

6. Mitsubishi Chemical Group overview

Global leadership



Proprietary solutions for the Medical and Bioprocessing industries

Mitsubishi Chemical Group (MCG) has dedicated Healthcare teams around the world. Our customers benefit from the globally integrated MCG portfolio for Life Science Grade and Bioprocessing applications. It includes proprietary technologies and services for the Medical and Bioprocessing industries and offers diverse solutions from raw materials to finished products. Our unique portfolio of high-performance thermoplastics, composites, fibers, bio-based materials, and resins offers customers better access to sustainable materials and systems that help reduce their carbon footprint without compromising on performance.



6. Mitsubishi Chemical Group overview

Global leadership



A network of expertise and innovation

As the world's leading manufacturer of pre-assessed high-performance materials for a wide range of requirements and applications in the healthcare industry, we help to bring ambitious engineering ideas to life globally.

The Mitsubishi Chemical Group (MCG) is a global network of experts, innovative technologies, and comprehensive material solutions headquartered in Tokyo, Japan.

The Engineering Shapes & Solutions Division is part of MCG's Specialty Materials Business Group, and specializes in the development, processing, manufacture and application of advanced and innovative high-performance thermoplastics and composites. Headquartered in Lenzburg/Switzerland, MCG's Engineering Shapes & Solutions Division spans 44 locations in 20 countries and has more than 3,000 employees who support you and drive the development of new products and applications for you.



Our KAITEKI philosophy

Everything we do as a company, as a partner, and as an industry leader is guided by the principles of KAITEKI – the vision of our holding company Mitsubishi Chemical Group Corporation (MCGC): "The sustainable wellbeing of people and the planet" – KAITEKI.

More than ever before, we believe achieving excellence means taking decisive action in the present to lay the groundwork for an equally beneficial future. Realizing KAITEKI means achieving a balance between environment, society, technology, and business needs. It relates directly to sustainable development: we're meeting our own needs without compromising the ability of future generations to meet theirs.

This is the commitment that drives us to address social and environmental demands while also creating new and sustainable value for our stakeholders.

Disclaimers & Credits

Disclaimers

Pre-assessment test results are for informational purposes only and are not guaranteed for any particular application. Mitsubishi Chemical Advanced Materials (MCAM) does not assume liability for the accuracy and completeness of the information and expressly disclaims any liability warranties of any kind, either express or implied, including the warranties of merchantability and fitness for a particular purpose, are made concerning the information and the products. Mitsubishi Chemical Group (MCG) Engineering Shapes & Solutions Division will undertake applications for Life Science Grades, which will consider the type of body tissue contact and the duration in line with the intended use of the products.

The information is intended for use by technically skilled persons at their own discretion and risk to facilitate an initial assessment of the biocompatibility of the material for a finished device. The customer is solely responsible for testing and assessing the customer's intended application, processes, and uses. The products of Mitsubishi Chemical Advanced Materials should not be used for applications involving medical devices that are intended to remain implanted in the human body for a period are intended to remain in contact with internal human tissue or bodily fluids for more than 24 hours (30 days*); or as critical components of medical devices that are essential to the continuation of human life. *30 days applies to Ketron™ LSG PEEK-CLASSIX™ white only.

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Credits

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Get in touch

General inquiries

Contact.

contact.mcam@mcgc.com

<https://www.mcam.com/en/contact>

Visit.

<http://www.mcam.com/en/industries/healthcare>

Europe

Mitsubishi Chemical
Advanced Materials NV

Galgenveldstraat 12
8700 Tielt,
Belgium

Tel: +32 51 42 35 11

North America

Mitsubishi Chemical
Advanced Materials Inc.

2120 Fairmont Avenue
PO Box 14235 — Reading,
PA 19612-4235

Tel: +1 610 320 6600

Asia-Pacific

Mitsubishi Chemical
Advanced Materials Asia Pacific Ltd.

Unit 7B, 35/F, Cable TV Tower,
9 Hoi Shing Road,
Tsuen Wan, Hong Kong

Tel: +852 2470 26 83

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