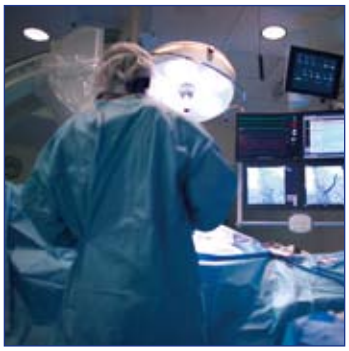
Engineering Plastics for Short-term Body Contact in the Life Science Industry



Quadrant Life Science Grades (LSG) are designed specifically for the medical, pharmaceutical and biotechnology markets. They help OEMs to save time and costs associated with biocompatibility testing and regulatory approvals.

KEY BENEFITS OF QUADRANT LIFE SCIENCE GRADES

PERFORMANCE

Using the cutting edge material portfolio from Quadrant will replace existing solutions made of stainless steel, Titanium and glass or ceramics. Quadrant Life Science Grades offer a unique combination of properties like weight reduction, resistance to commonly used sterilisation methods, X-ray transparency, design flexibility, colour coding possibilities, resistance to high energetic radiation and antistatic performance.

All Quadrant Life Science Grades are certified for body contact of up to 24 hours. Ketron® PEEK-Classix™ is even approved for body contact up to 30 days.

BIOCOMPATIBILITY

The LSG portfolio includes plastics which comply with ISO 10993 and USP guidelines for biocompatibility testing of materials. Certification according regulatory standards safes time before testing.

FULL TRACEABILITY

Quadrant provides OEMs with assurance of full traceability for its comprehensive LSG product porfolio from raw material to stock shape.

GLOBAL AVAILABILITY

With production facilities in Europe, North America and Asia, and a presence in 27 countries through its select distribution network, Quadrant guarantees the consistent quality and availability of its products worldwide.

QUALITY ASSURANCE

In line with its ISO 9001:2000 certified Quality Assurance System, Quadrant thorougly monitors and controls the entire manufacturing process of its Life Science Grades.

QUADRANT

You inspire … we materialize®

BIOCOMPATIBILITY TESTING

MATERIALS / TESTS (1) (2)	1. Cytotoxicity Ref.: ISO 10993-5 and USP <87> Biological Reactivity Tests, In Vitro Elution Test	2. Sensitisation 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. 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 Test for Plastics Ref.: USP <661> Containers, Ultra Pure Water Extract, 70° C/24h	8. Heavy metal content (mg/kg) Testing the content of cadmium, chromium, lead and mercury by means of ICP-MS	USP Class VI (conclusion from tests 3, 4 and 5)
Ketron® PEEK-Classix™ LSG white	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ketron® PEEK-CA30 LSG	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ketron® PEEK-GF30 LSG blue (RAL 5019)	✓	✓	✓	✓	✓	✓	✓	✓	✓
Ketron® PEEK LSG natural/black	✓	✓	✓	✓	✓	✓	✓	✓	✓
Quadrant® LSG PPSU black	✓	✓	✓	✓	✓	✓	✓	✓	✓
Quadrant® LSG PPSU colours (red, yellow, grey, brown, blue, green)	✓	NT	NT	NT	NT	NT	✓	✓	NT (3)
Duratron® LSG PEI natural	✓	✓	✓	✓	✓	✓	✓	✓	✓
Quadrant® LSG PSU natural	✓	✓	✓	✓	✓	✓	✓	✓	✓
Quadrant® LSG PC natural	✓	✓	✓	✓	✓	✓	✓	✓	✓
Acetron® LSG natural/black	✓	NT	NT	NT	NT	NT	✓	✓	NT (3)

✓ This test was carried out and the material passed the test
NT Not tested

(1) All tests were run on test specimens machined from rod diameter 50 mm shortly after manufacture.

(2) Quadrant EPP 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. Quadrant EPP 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** specific medical, pharmaceutical, or biotechnological applications. **It remains the customer's sole responsibility to test and assess the suitability of Quadrant's Life Science Grades for its intended applications, processes and uses.**

(3) Please note that the virgin, natural coloured POM Copolymer resins used in the manufacture of all Acetron® LSG stock shapes meet the requirements of USP Class VI (according to biocompatibility tests carried out on behalf of the resin suppliers), and that active Drug Master Files (DMF) on these resins are filed in the DMF-Database of the American Food and Drug Administration (FDA).



STERILISATION METHODS

LIFE SCIENCE GRADES	Ethylene oxide gas	Steam 121°C/134°C	Dry heat 160°C	Plasma	Gamma irradiation
Ketron® PEEK-Classix™ LSG white	++	++ / ++	++	++	++
Ketron® PEEK-CA30 LSG	++	++ / ++	++	++	++
Ketron® PEEK-GF30 LSG blue (RAL 5019)	++	++ / ++	++	++	++
Ketron® PEEK LSG natural/black	++	++ / ++	++	++	++
Quadrant® LSG PPSU black	++	++ / ++	++	++	+
Duratron® LSG PEI natural	+	++ / +	++	+	+
Quadrant® LSG PSU natural	+	++ / +	+	+	+
Quadrant® LSG PC natural	+	- / --	--	+	+
Acetron® LSG natural/black	+	+ / -	--	+	--

++ very good + good - poor -- not suited

APPLICATION EXAMPLES

- Trial implants
- Medical instruments
- Endoscopic equipment
- Radiation therapy and brachytherapy components
- Trays for trauma products
- Biotechnology and laboratory equipment
- Analytical and diagnostic equipment

This brochure and any data and specifications presented on our website shall provide promotional and general information about the Engineering Plastic Products (the «Products») manufactured and offered by Quadrant Engineering Plastic Products («Quadrant») and shall serve as a preliminary guide. All data and descriptions relating to the Products are of an indicative nature only. Neither this brochure nor any data and specifications presented on our website shall create or be implied to create any legal or contractual obligation.

Any illustration of the possible fields of application of the Products shall merely demonstrate the potential of these Products, but any such description does not constitute any kind of covenant whatsoever. Irrespective of any tests that Quadrant may have carried out with respect to any Product, Quadrant does not possess expertise in evaluating the suitability of its materials or Products for use in specific applications or products manufactured or offered by the customer respectively. The choice of the most suitable plastics material depends on available chemical resistance data and practical experience, but often preliminary testing of the finished plastics part under actual service conditions (right chemical, concentration, temperature and contact time, as well as other conditions) is required to assess its final suitability for the given application. It thus remains the customer's sole responsibility to test and assess the suitability and compatibility of Quadrant's Products for its intended applications, processes and uses, and to choose those Products which according to its assessment meet the requirements applicable to the specific use of the finished product. The customer undertakes all liability in respect of the application, processing or use of the aforementioned information or product, or any consequence thereof, and shall verify its quality and other properties.

Quadrant 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.

Quadrant's Products 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 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® PEEK-Classix™ LSG white only.

Learn more online at
www.quadrantplastics.com

Quadrant has extensive product and machining resources available online. Our website is a portal to a wealth of technical data and the easiest way to engage our application specialists. Our team stands ready to help offer solutions to your toughest problems.

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