

# Engineering Plastic Solutions for Life Science Industry



## INCREASED SECURITY

- ❖ Biocompatibility tested and certified Life Science Grades portfolio
- ❖ Resistance to most common cleaning and sterilisation methods
- ❖ Full traceability from raw material to stock shape
- ❖ Colour coding possibilities

## REDUCE TIME TO MARKET

- ❖ Certification according to regulatory standards saves time for testing
- ❖ Extensive technical knowhow and support from development to market

## COST REDUCTION

- ❖ Improved wear performance in unlubricated conditions
- ❖ Lower weight which leads to lower inertia forces
- ❖ Higher output
- ❖ Lower in-use noise level versus metals



# Engineering Plastic Solutions Stock Shapes for Life Sciences

The Life Science Grades (LSG) are designed specifically for the Medical, Pharmaceutical and Biotechnology markets. They save OEMs the time and costs associated with biocompatibility testing and regulatory approvals. Key benefits of the Life Science Grades are:

## PERFORMANCE

Using the cutting edge material, will replace existing solutions made of stainless steel, titanium and glass or ceramics due to combination of properties like weight reduction, resistance to commonly used sterilisation methods, X-ray transparency, design flexibility, anti-static performance and resistance to high energetic radiation.

## BIOCOMPATIBILITY

The LSG portfolio includes plastics which comply with FDA, ISO 10993 and USP guidelines for biocompatibility testing of materials.

## FULL TRACEABILITY

Our partner Quadrant provides OEMs with the assurance of full traceability for its comprehensive LSG product portfolio.



## Dental Instruments



- ❖ Dental instruments and grips
- ❖ Dental drilling and suction equipment
- ❖ Isolating parts
- ❖ Healing caps
- ❖ Temporary abutments

## Surgical Instruments & Supplies



- ❖ Fixator equipment
- ❖ Surgical grips
- ❖ Targeting devices
- ❖ Isolating parts
- ❖ Endoscopic equipment
- ❖ Minimal invasive products

## Pharmaceutical Processing & Packaging



- ❖ Applications for tablet production
- ❖ Sliding and wear parts for pharmaceutical handling and packaging
- ❖ Filling and dosing equipment for pharmaceuticals
- ❖ Sealing and handling for blister packaging
- ❖ Mixing equipment for creams and ointments

## Analytical and Diagnostic Equipment



- ❖ Trays
- ❖ Centrifuges
- ❖ DNA probe analyser
- ❖ Transport and sliding parts
- ❖ Mass spectrometers
- ❖ Radiation equipment
- ❖ Ultrasound equipment
- ❖ X-ray and MRI devices

## Biotechnology and Laboratory Equipment



- ❖ Fermentation of microorganism
- ❖ Screening process
- ❖ Bio reactors
- ❖ Nozzles, adaptors, caps
- ❖ Optics and lenses

MATERIALS	TESTS (1)(2)								USP Class VI (conclusion from tests 3, 4 and 5)
	1. Cytotoxicity Ref.: ISO 10993-5 and USP <87> Biological Reactivity Tests, In Vitro Elution Test	2. Sensitisation Ref.: ISO 10993-10, Magnusson & Kjellman Neutralisation 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 <861> 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-AES	
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	✓	✓	✓	✓	✓	✓	✓	✓	✓
PSU LSG natural	✓	✓	✓	✓	✓	✓	✓	✓	✓
PC LSG natural	✓	✓	✓	✓	✓	✓	✓	✓	✓
ACETRON® LSG	✓	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).

## Compatible with common 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	+	++ / +	++	+	+
PSU LSG natural	+	++ / +	+	+	+
PC LSG natural	+	- / --	--	+	+
ACETRON® LSG	+	+ / -	--	+	--

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

## YOU INSPIRE...

Our best successes come from close working relationships with our customers – but not just on solving application problems with our material properties. The more we understand about what's important to your company, what it takes to compete, what determines your success and value with customers for your equipment.

Let's work together on your ideas and these success factors, where our materials can help you better compete in your industry.

REGULATION APPLIANCE    LOW SYSTEM COST    BIOCOMPATIBILITY  
RELIABILITY YIELD    CONFIDENCE    OUTPUT    TRACEABILITY  
COMPETITIVENESS    CONSISTENCY    PRODUCTIVITY  
SERVICE    LOW MAINTENANCE    ELECTRICAL INSULATION  
ANTI-STATIC PERFORMANCE

Challenge us with your application requirements. Tell us what it takes for you to compete and deliver value in your industry. That gives us the opportunity to work with your engineers to provide the best combination of technical support, material and finished part performance for your equipment – within your overall cost targets.

STERILISATION RESISTANCY    X-RAY TRANSPARENCY    LSG PORTFOLIO  
CERTIFICATION    LONG WEAR LIFE    USP AND ISO 10993 TESTING  
STATIC MANAGEMENT    RELIABLE AND APPROVED QUALITIES    IONIC  
FULL TRACEABILITY    HIGH QUALITY RESINS    PREDICTABLE  
DIMENSIONS    TECHNICAL AND LOGISTICAL SERVICES  
SELF-LUBRICATING