

Biocompatibility pre-assessment table

MATERIALS	TESTS (1)							
	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® PEEK-CLASSIX™ LSG 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	✓	✓	✓	NT	✓	✓
Duratron® LSG PEI blue	✓	NT	NT	NT	NT	NT	✓	NT
Sultron® LSG PSU natural	✓	✓	✓	✓	✓	✓	✓	✓

✓ The material passed the test performed under laboratory conditions on a representative specimen machined from stock shape. Tests are not performed for each material lot. Tests may be performed at initial sampling or periodically.

NT Not Tested

- (1) Pre-assessment test results are for informational purposes only and are not guaranteed for any particular application. MCAM does not assume liability for the accuracy and completeness of the information and expressly disclaims any liability concerning use of the information. No 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. 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 suitability of the products for 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 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.

Mitsubishi Chemical Group Advanced Materials will undertake a review process for all new 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.

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