

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 & 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® CLASSIX™ LSG PEEK white	✓	✓	✓	✓	✓	✓	✓	✓
Ketron® LSG CA30 PEEK	✓	✓	✓	✓	✓	✓	✓	✓
Ketron® LSG GF30 PEEK blue (RAL 5019)	✓	✓	✓	✓	✓	✓	✓	✓
Ketron® LSG PEEK natural, black, red, blue, green	✓	✓	✓	✓	✓	✓	✓	✓
Sultron™ LSG PPSU black	✓	✓	✓	✓	✓	✓	✓	✓
Sultron™ LSG PPSU natural (ivory)	✓	NT	✓	✓	NT	NT	✓	✓
Sultron™ LSG PPSU blue, brown, green, grey, orange, red, yellow	✓	NT	NT	NT	NT	NT	✓	NT
Duratron® LSG PEI natural	✓	✓	✓	✓	✓	✓	✓	✓
Sultron™ LSG PSU natural	✓	✓	✓	✓	✓	✓	✓	✓
Altron™ LSG PC natural	✓	✓	✓	✓	✓	✓	✓	✓
Acetron® LSG natural & black	✓	NT	NT	NT	NT	NT	✓	NT (3)
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.

(3) Please note that the virgin, natural coloured POM Copolymer resins used in the manufacture of the Acetron® LSG natural & black stock shapes meet the requirements of USP Class VI (according to biocompatibility tests carried out on behalf of the resin suppliers).