



Polycast® Medical Grade PMMA

(formerly Glasflex)

IMPLANTABLES

- Biocompatible (USP Class VI)*
- Proven lot traceability
- Polycast® provides clarity for better placement of implant
- Custom manufacturing
- FDA masterfile on all medical materials
- Meets requirements of USP Class VI Plastics for systemic toxicity, 4 week intramuscular implantation test and intracutaneous reactivity tests.

APPLICATIONS

- Orthopedic implants
- Craniomaxillofacial (CMF) implants
- Distal Centralizers
- Implantable sensors for CGM (continuous glucose monitor)
- Intraocular lens implants

INTRAOCULAR
LENS IMPLANT



CAST ACRYLIC SHEET, RODS & TUBES

- PMMA products for medical applications and devices
- Acrylic suitable for high precision machining**

APPLICATIONS

- Custom Orthotics (POLYDOR®)
- Reservoirs for medical devices and imaging machines
- Fluidic manifolds used for diagnostics and analytical instruments

* Based on biocompatibility test results, PMMA MEDICAL GRADE ROD & SHEET, as supplied, is suitable for manufacturing medical devices certifiable according to requirements of U.S. Pharmacopeial Convention (USP) Class VI.

** FDA: Food and Drug Administration's regulations concerning food contact applications as described in 21 CFR 177.1010 for all food types, including alcoholic beverages in room temperature or refrigerated applications.

Summary of Typical Properties of PMMA Sheet & Rod

| PROPERTY | TEST METHODS | POLYCAST FDA GRADE | UVA 400 | UVA 400-NCL | UVA 400-LCL | PMMA MEDICAL ROD #2 | PMMA MEDICAL ROD #3 |
|---|---------------------------------------|--------------------|----------------------|------------------------|------------------------|----------------------|----------------------|
| Monomer Content | Gas Chromatography | – | No Greater Than 0.8% | No Greater Than 0.8% | No Greater Than 0.8% | No Greater Than 0.8% | No Greater Than 0.8% |
| Refractive Index | ASTM D542 | 1.49 | 1.49 | 1.49 | 1.49 | 1.49 | 1.49 |
| Specific Gravity | ASTM D792 | 1.19 | 1.19 | 1.19 | 1.19 | 1.19 | 1.19 |
| Rockwell Hardness | ASTM D785 | M-98 | M-94 | M-94 | M-94 | M-94 | M-94 |
| Tensile Strength (Rupture) | ASTM D638 | 11,250 PSI | 9,000 PSI | 9,000 PSI | 9,000 PSI | 9,000 PSI | 9,000 PSI |
| Flexural Strength (Rupture) | ASTM D790 | 15,000 PSI | 15,000 PSI | 15,000 PSI | 15,000 PSI | 15,000 PSI | 15,000 PSI |
| Compression Strength (Yield) | ASTM D695 | 18,000 PSI | 18,000 PSI | 18,000 PSI | 18,000 PSI | 18,000 PSI | 18,200 PSI |
| Impact Strength (Izod Unnotched – ft. lbs./in.) | ASTM D256 | 0.375 | 4.2 | 4.2 | 4.2 | 4.2 | 4.2 |
| Haze | ASTM D1003 | Less Than 0.5% | Less Than 0.5% | Less Than 0.5% | Less Than 0.5% | Less Than 0.5% | Less Than 0.5% |
| UV Transmission | | 0% @ 320 nm | 10% @ 370 nm | Less Than 10% @ 400 nm | Less Than 10% @ 400 nm | 10% @ 370 nm | 85% @ 370 nm |
| Visible Light Transmission | ASTM D1003 | 92% | 92% | 92% | 92% | 92% | 92% |
| Molecular Weight | | – | 2 Million | Greater Than 2 Million | Infinite | Infinite | 2 Million |
| Solvent Resistance | Weight gain in acetone (24 hours/22") | – | 2% | 170% | 19% | 2% | 170% |
| Water Absorption | ASTM D570 | 0.35% | 0.35% | 0.35% | 0.35% | 0.35% | 0.35% |

Spartech Polycast manufactures medical grade PMMA cast acrylic products for the medical device community using Good Manufacturing Practice (GMP). Intended applications include implantable intraocular lenses and cement spacers for orthopedic prostheses.

Biocompatibility studies were performed by an independent laboratory using Good Laboratory Practice (GLP) regulations. This information is supported by certified results of extensive clinical scientific data. All information is included in our FDA Master File # MAF-300, which is held under the custodianship of the FDA and authorization can be granted upon request.

The following clinical tests were performed to establish the biocompatibility of these materials, as outlined by the FDA.

- Hemolysis test by Extraction Method
- Hemolysis test by Direct Contact
- Salmonella/Mammalian Mutagenicity Test
- Cytotoxicity test using the Agarose Overland Method
- Guinea Pig Maximization test of Biomaterial Extracts (Magnusson and Kligman) with added positive controls
- USP Systemic Toxicity Study in Mice
- USP Intracutaneous Toxicity test in the Rabbit
- Inhibition of Cell Growth, 9 Point Assay
- Accelerated Extractables
- Physicochemical - USP tests
- Residual Monomer GC
- Infrared Analysis
- Ultraviolet and UV Visible Spectra
- Gel Permeation HPLC (Molecular Dispersion)

Biocompatibility (USP Class VI)*

| TEST | METHOD | RESULT |
|--|--|---|
| 1. Cytocompatibility Study | (MEM) (L-929) / 72 Hrs. (SC) (AS) + (cso) / 24Hrs. (SC) (AS) (CSOO + extracts for Acute systemic toxicity) | No Lysis or Cytotoxicity Effect No Cell Lysis No Toxicity |
| a. Extract | | |
| b. Direct Contact Saline-blood Mixture | Direct Contact with Lysis | No Blood Cell |
| c. Cell Attachment | L-929 | Non Toxic |
| 2. Mutagenicity | AMES (Vitro) | Not Mutagenic |
| 3. Systemic Toxicity Extract in Mouse | USP-TUO12-500 | No Considerable Toxicity |
| 4. Rabbit Intradermal Injection of Extract | Erythema Edema | None None |
| 5. Sensitization | By DNCB | Good Sensitization |
| 6. Implantation Test | | No Reaction |
| a. Intramuscular | | |
| b. Implantation Test 4-Week | | |
| 7. Equivalence Evaluation and Toxicological Risk Assessment | USP and ISO 10993 Guidelines | Demonstrated chemical and toxicological equivalence among all UVA 400 materials |



Only Polycast sheet products are ISO certified.



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