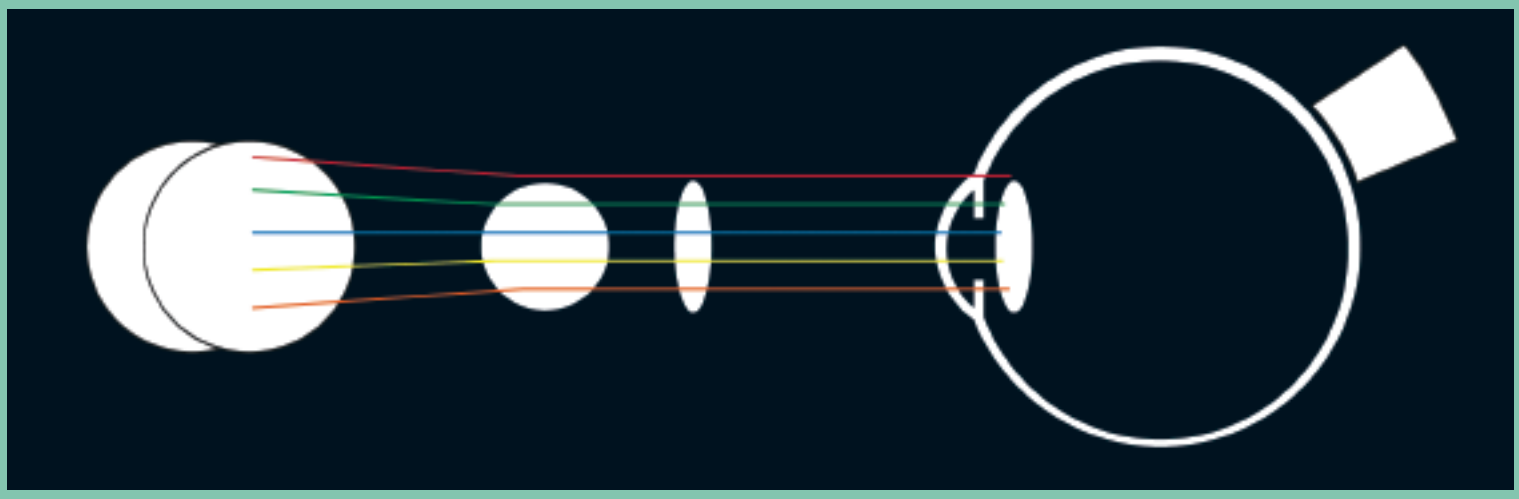
POLYCAST®

CELL CAST ACRYLIC

Medical Grade PMMA

(FormerlyGlasflex)



IOL

- **Biocompatible (USP *Class VI*)***
- **Proven lot traceability**
- **Proven market leader with over half a century of technical expertise in the polymerization and casting of medical grade PMMA**
- **Flexible custom manufacturing**
- **FDA masterfile on all medical materials**
- **Meets requirements of USP systemic toxicity and intracutaneous reactivity tests for *Class VI* plastics**
- **Medical grade implantable PMMA rod and sheet for:**
  - **— intraocular lenses, IOL**
  - **— orthopedic prostheses, cement spacers and anatomical implants**
- **PMMA products for other medical applications and devices including custom orthotics (POLYDOR®)**
- **Acrylic suitable for high precision machining and medical imaging markets**

Summary of Typical Properties

PROPERTY	TEST METHODS	PMMA SHEET & ROD AVERAGE VALUES				
		UVA 400	UVA 400-LCL	UVA 400-NCL	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 D 542	1.490	1.490	1.490	1.490	1.490
Specific Gravity	ASTM D 792	1.19	1.19	1.19	1.19	1.19
Rockwell Hardness	ASTM D 785	M-94	M-94	M-94	M-94	M-94
Tensile Strength (Rupture)	ASTM D 638	9,000 PSI	9,000 PSI	9,000 PSI	9,000 PSI	9,000 PSI
Flexural Strength (Rupture)	ASTM D 790	15,000 PSI	15,000 PSI	15,000 PSI	15,000 PSI	15,000 PSI
Compression Strength (Yield)	ASTM D 695	18,200 PSI	18,200 PSI	18,200 PSI	18,200 PSI	18,200 PSI
Impact Strength (IZOD Unnotched-ft. lbs./in.)	ASTM D 256	4.2	4.2	4.2	4.2	4.2
Haze	ASTM D 1003	Less Than 0.5%	Less Than 0.5%	Less Than 0.5%	Less Than 0.5%	Less Than 0.5%
UV Transmission		Less Than 10% @ 400nm	Less Than 10% @ 400nm	Less Than 10% @ 400nm	10% @ 370 nm	85% @ 370 nm
Visible Light Transmission	ASTM D 1003	92%	92%	92%	92%	92%
Molecular Weight		Infinite	Infinite	Greater Than 2 Million	Infinite	2 Million
Solvent Resistance	Weight gain in acetone (24 hours /22°)	2%	19%	170%	2%	170%
Water Absorption	ASTM D 570	0.35%	0.35%	0.35%	0.35%	0.35%

Biocompatibility (USP *Class VI*)*

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

- Hemolysis test by Extraction Method
- Hemolysis test by Direct Contact
- Salmonella/Mammalian Mutagenicity Test
- Cytotoxicity test of Sample Extract using the MEM Elution Method
- Cytotoxicity test using the Agarose Overlay 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 Extratables
- Physico-chemical - USP tests
- Residual Monomer GC
- Infrared Analysis
- Ultraviolet and UV Visible Spectra
- Gel Permeation HPLC (Molecular Dispersion)

	Method	Result
1. Cytocompatibility Study a. Extract b. Direct Contact Saline-blood Mixture c. Cell Attachment	(MEM) (L-929) / 72 Hrs. (SC) (AS) + (cso) / 24Hrs. (SC) (AS) (CSO0 + extracts for Acute systemic toxicity Direct Contact with Lysis L-929	No Lysis or Cytotoxicity Effect No Cell Lysis No Toxicity No Blood Cell Non Toxic
2. Mutagenicity	AMES (Vitro)	Not Mutagennic
3. Systemic Toxicity Extract in Mouse	USP-TUO12-500	No Considerable Toxicity
4. Rabbit Intradermal Injection of Extract	Erythmea Edema	None None
5. Sensitization	By DNCB	Good Sensitization
6. Implantation Test a. Intramuscular b. Implantation Test 4-Week		No Reaction
7. Equivalence Evaluation and Toxicological Risk Assessment	USP and ISO 10993 Guidelines	Demonstrated chemical and toxicological equivalence among all UVA 400 materials

QAS INTERNATIONAL ISO 9001:2008 REGISTERED FIRM

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