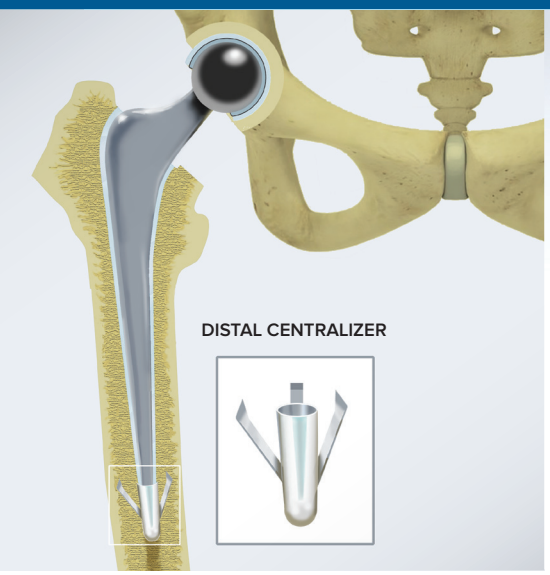
POLYCAST®
PRODUCT BULLETIN

SPARTECH®



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.

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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 date. 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		
a. Extract	(MEM) (L-929) / 72 Hrs. (SC) (AS) + (cso) / 24Hrs. (SC) (AS) (CSO0 + extracts for Acute systemic toxicity	No Lysis or Cytotoxicity Effect No Cell Lysis No Toxicity
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	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

ISO 9001:2015

Only Polycast sheet products are ISO certified.

MADE IN USA

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