



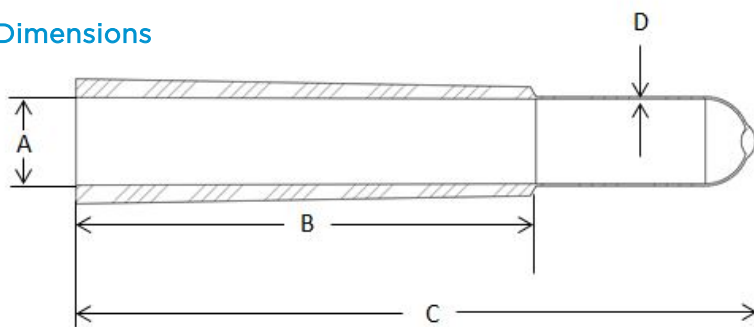
Silicone Test Chambers

for Ophthalmic Medical Device Manufacturers

Silicone Test Chambers

The Test Chamber product is a USP <88>, Plastic Class VI, silicone molded component manufactured exclusively for Medical Device Manufacturers for the ophthalmic surgical market. It is molded from 40 durometer silicone raw material and is typically used to test the pressure of the hand piece of a Medical Device Manufacturer's phacoemulsification system prior to the start of a procedure. In addition to our standard product, Saint-Gobain can also manufacture to your custom designed print and specification.

Critical Dimensions



Critical Dimension	Nominal Dimension		Tolerance	
	Inches	Millimeters	Inches	Millimeters
A	0.310	7.87	+/-0.005	+/-0.13
B	1.630	41.40	+/-0.050	+/-1.27
C	2.380	60.45	+/-0.050	+/-1.27
D	0.008	0.20	+/-0.003	+/-0.08

Documentation

Supporting documentation for this product (Item Number 160-104542) is available upon request including a Validation Summary Report and Raw Material Datasheet. Contact your sales representative for more information.

To find out more about how Saint-Gobain can meet your medical manufacturing needs, call (800) 236-7600 or email at medical@saint-gobain.com

ON THE WEB AT: www.medical.saint-gobain.com

Key Characteristics

- ISO Class 8 Cleanroom Manufacturing
- Meets USP <88>, Plastic Class VI Criteria
- 40 Durometer
- Facility's QMS is ISO 13485 Certified
- Facility's QMS is held to the requirements outlined in 21 CFR 820

IMPORTANT: "This Saint-Gobain product is manufactured in the United States and is meeting the FDA definition of a finished device [21CFR820.3(l)] made on behalf of medical device manufacturers [21 CFR 807.20(a)(2)] under contract-manufacturing agreement. In accordance with the United States' jurisdiction, Saint-Gobain complies with the FDA's requirements for contract manufacturers of finished devices. Please refer to our Medical Products Disclaimer at www.medical.saint-gobain.com/resources/regulatory-and-quality/medical-product-disclaimer.

Caution: For manufacturing, processing or repacking"

IMPORTANT: It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics products for all intended uses and that the materials to be used comply with all applicable medical regulatory requirements. Saint-Gobain Performance Plastics assumes no responsibility for any product failures that occur due to misuse of the materials it provides arising out of the design, fabrication or application of the products into which the materials are incorporated.

WARRANTY: For a period of 12 months from the date of first sale, Saint-Gobain Performance Plastics warrants this product to be free of defects in materials and workmanship. Our only obligation will be to replace any portion proving defective, or at our option, to refund the purchase price thereof.

