

LIQUID SILICONE RUBBER (LSR) IMPLANT GRADE 1:1 SYSTEMS 10-60 DUROMETER

PN 40023, 40024, 40025, 40026, 40027, 40028, 40071

DESCRIPTION

Applied Silicone Implant Grade Liquid Silicone Rubber (LSR) Systems are two part, 100% solids, pure dimethyl silicone elastomers, engineered for use in liquid injection molding (LIM) processes where high strength molded parts are desired for medical devices. Liquid Silicone Rubber (LSR) is a pumpable, colorless, translucent paste. When A and B components are mixed together in equal portions, the liquid will cure to a tough, rubbery elastomer via addition-cure chemistry. Custom formulation of radiopaque or color masterbatch is available upon request. This product is available in durometers of 10 to 60 Shore A. The LSR System is supplied as a two component kit consisting of equal amounts of Part A and Part B.

FEATURES

- Improved clarity
- Fast cure at elevated temperature
- No peroxide residue
- No volatile by-products
- Ideal for high production, automated LSR equipment
- Tested per ISO 10993 for long term implantation

TYPICAL PROPERTIES

These values are not intended for use in preparing specifications.

Test	Results						
	40023	40024	40025	40026	40027	40028	40071
APPEARANCE	Colorless Translucent Paste						
DUROMETER, SHORE A	12	20	30	40	50	60	70
TENSILE STRENGTH, psi	700	800	950	980	1000	1100	1100
ELONGATION, %	810	660	650	550	440	400	350
TEAR STRENGTH, ppi	100	120	130	170	200	220	200
SPECIFIC GRAVITY	1.11	1.10	1.12	1.12	1.13	1.13	1.14
COMPRESSION SET, %	55	55	55	55	55	55	n/a
With POSTCURE, %	20	20	20	20	15	15	n/a
LINEAR SHRINKAGE, %	2.0	2.0	2.0	2.0	2.0	2.0	2.0
EXTRUSION RATE, gr/min	250	225	150	130	125	120	110

NOTE: Test Cure Condition – compression molded 5 minutes @ 175°C
 Compression Set – 22 hrs @ 177°C
 Compression Set with Postcure – 4 Hr. @ 175°C
 Extrusion Rate – 90psi through 1/8" orifice @23-25°C

APPLICATIONS

Applied Implant Grade Liquid Silicone Rubber (LSR) Systems are designed to be mixed in equal parts using standard LIM processing equipment and techniques. Cure is typically achieved in 20 seconds at 160°C. Cure rate can be increased by increasing the temperature. Postcure is suggested to stabilize physical properties for implant applications. LSR is especially designed for manufacturing devices by either liquid injection molding or liquid extrusion. Some specific applications include:

- Precision molded parts
- Catheter strain relief junctions
- Insert molding
- Needle septum ports

BLENDING

Applied Liquid Silicone Rubber (LSR) Systems are supplied as A and B components which must be combined in equal portions prior to use. Airless mixing, metering, and dispensing equipment is recommended for production operations. Information is available from Applied Silicone Corporation on such systems.

PRECAUTIONS

Accurate measuring and complete mixing are important factors in obtaining consistent results. Special care must be taken to ensure clean molds and a clean work area. Contamination by trace amounts of various compounds can result in unreliable cure of the material. Avoid contact with amines, sulfur compounds, organotin compounds, peroxide catalyst residues, and organic rubbers, including latex gloves.

A Material Safety Data Sheet (MSDS) is supplied with each shipment. Avoid any contact with the eyes as this may cause temporary eye discomfort.

BIOCOMPATIBILITY

Applied Liquid Silicone Rubber (LSR) Systems are designed and tested to meet ISO 10993 requirements for long term implantation. A sample from each manufactured lot is subjected to MEM Tissue Culture testing.

Master Access Files, including formulation, manufacturing methods, testing, and toxicology have been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master Access Files must contact Applied Silicone Corporation. A compendium summary of testing is available.

LOT TESTING

Each production lot is certified as having specified physical properties and cytotoxicity screening. Additional testing is available upon request.

PACKAGING and STORAGE

Liquid Silicone Rubber is available in kits of 16, 80, and 800 pounds. Material should be stored in original, unopened containers below 30°C to maintain product integrity. Suggested retest date is six months from date of shipment. Retested conforming material can be used indefinitely if properly stored in clean containers.

DISCLAIMER

Applied Silicone Corporation warrants that this product meets applicable descriptions and specifications for a period of six months from shipment. No other warranties, expressed or implied, are intended. This product was designed for sophisticated users. The user must carefully review literature for uses where adverse effects are reported for certain applications of silicone in medical devices. The user of this material must independently determine that any product incorporating this material is safe and effective. The user of this material must thoroughly test any application consistent with industry requirements and/or standards. Applied Silicone Corporation disclaims any expressed or implied warranty against the infringement of any patent. Any suggestion of use by Applied Silicone should not be taken as inducement to infringe on any particular patent.

270 Quail Court • Santa Paula, CA 93060 USA

Tel: 805.525.5657 • Fax: 805.933.1675

www.appliedsilicone.com • siliconesales@appliedsilicone.com