



## Platinum-Cured Silicone Tubing | mitos-R

- Reinforced platinum-cured silicone tubing
- Withstands high pressure, resists kinking

mitos-R is a platinum-cured silicone hose with polyester fiber braid reinforcement structure to maintain flexibility, withstand high pressure and resist kinking.

This hose can be molded with other silicones into manifold assemblies with molded tri-clamp, creating seamless and crevice-free fittings. It can also be used in radially-crimped hose assemblies.

### Features and Benefits

- Lot number and customized information directly on hose with CLEAR-mark® label\*
- Can be molded with other silicones into manifold assemblies (Ts, Ys, crosses, elbows and reducers)
- Animal derived component free
- Certificate of conformance with each order
- Manufactured in ISO Class 7 clean room
- Can be chemically or mechanically cleaned and can be sterilized by chemicals, autoclave or gamma-irradiation
- SIP / CIP capable
- Available with internal diameter up to 1 inch

\*CLEAR-mark® is a registered trademark of Integra Companies.



### Molded silicone fittings

Molded silicone fittings are the ideal option when there is need for an easily cleanable assembly, or to reduce the risk of cross-contamination. In each molded fitting, the elastomer chains of the platinum-cured silicone are cross-linked to create a permanent molecular bond to the tubing. A special feature of our molded tri-clamp is an integrated gasket that, when connected to another fitting, eliminates 50% of the sealing faces creating seamless and crevice-free fittings. For extra support, we offer a full stainless steel or polysulfone back-up cup on the outside of each molded fitting. Our plastic back-up cups have a unique wrap around design that fully encases the tri-clamp mold.



### Applications

Molded manifold assemblies
High pressure transfer lines
Single-use applications
Radially-crimped hose assemblies

## Specifications

### Materials of Construction

- Material: Platinum-cured silicone with fiber braid reinforcement

### Available Fittings

- Molded tri-clamp
- Radially-crimped 316L stainless steel
- All industry standard connections

### Sterilization

- Gamma Irradiation: Maximum of 50 kGy
- Autoclave: 1 bar (14.5 psi) @ 121°C (250°F)

### Physical Properties

- Elongation at break (%): ASTM D-412 425%
- Shore hardness: ASTM D-2240 60 Shore A
- Tear strength: ASTM D-412 100 die B (PPI)
- Tensile strength: 1200 psi
- General temperature range: -100°F (-73.3°C) to 302°F (150°C)
- Brittle temperature: -100°F (-73.3°C)
- Max. operating temperature: 400°F (204.4°C)

### Certified Standard of Compliance

- FDA CFR 177.2600
- USP Class VI
- European Pharmacopoeia 3.1.9
- ISO 10993
- Additional validation testing performed, see validation guide for details

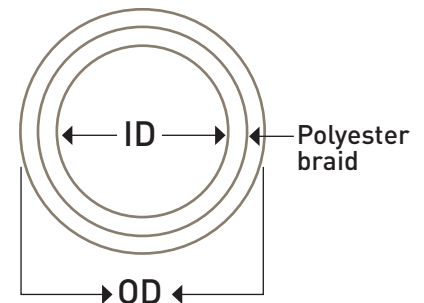
### mitos-R biocompatibility, physicochemical and particulate test results

Test Description	Test Reference	Results	Details
<b>Biocompatibility tests</b>			
Salmonella typimurium and E. coli Reverse Mutation Assay	ISO 10993-3	Pass	Test article is considered nonmutagenic.
Hemocompatibility (Hemolysis Test)	ISO 10993-4	Pass	The test article is considered nonhemolytic under the experimental conditions employed.
MEM Elution Test	ISO 10993-5, 1999 USP <87>	Pass	The test article is considered noncytotoxic.
Intramuscular Implantation	ISO 10993-6, 1995 ASTM F981-93	Pass	Test article considered non-toxic.
Intracutaneous Injection	ISO 10993-10	Pass	The test article is considered a negligible irritant.
Kligman Maximization	ISO 10993-10	Pass	The skin treated with the test article extracts exhibited no reaction to the challenge (0% sensitization).
Rabbit Pyrogen Test	ISO 10993-11	Pass	The test article is considered nonpyrogenic.
Class VI Test	USP <88>	Pass	Test article meets USP guidelines for Class VI Plastics - 70°C.
<b>Physicochemical tests</b>			
European Pharmacopoeia Ch. 3.1.9: Silicone Elastomer for Closures & Tubing	EP 4, 2002 Ch. 3.1.9	Pass	N/A
Inhibition and Enhancement Testing	USP <85>	Pass	Test article didn't inhibit or enhance LAL Endotoxin Test, Gel Clot Method.
Rubber Articles Intended for Repeated Use	21 CFR 177.2600	Pass	Meets requirements
Elastomeric Closures for Injections - USP	USP <381>	Pass	"WFI Extract - Turbidity: 0.05 NTU - Reducing Agents: 0.1 mL - pH Change: 0.36 - Total Extractables: 0.0 mg IPA Extract - Turbidity: 0 NTU - Total Extractables: 45.0 mg"

## Sizes

Part Number	ID (in.)	OD (in.)	*Recommended working pressure (psi) @ 68 °F	Minimum burst pressure (psi) @ 68 °F
02-MITOS-R	1/8	3/8	175	700
03-MITOS-R	3/16	0.462	170	650
04-MITOS-R	1/4	1/2	160	575
06-MITOS-R	3/8	5/8	150	550
08-MITOS-R	1/2	7/8	140	420
10-MITOS-R	5/8	1	115	400
12-MITOS-R	3/4	1 1/8	90	350
16-MITOS-R	1	1 3/8	60	225

\* Note: If part of a molded assembly, maximum operating pressure would change.



Parker technologies can be combined to produce integrated solutions that will speed up development times, increase efficiency and safety, and guarantee reproducible product quality.



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