



Molded silicone manifolds

- Permanent connection prevents product loss
- Seamless, crevice-free, eliminates entrapment areas

With custom-designed manifolds, Parker domnick hunter molds imagination into reality. Whether a foot-long piece of tubing with sanitary ends or a manifold with over 100 junctions, Parker domnick hunter can mold single- or multi-use systems tailored to your application.

Our proprietary overmolding technology allows for any configuration of Ys, Ts, crosses, reducers, elbows and molded tri-clamps with unlimited lengths between molds. Inside diameters are available from 1/8" to 1".

Each mold is molecularly bonded to the tubing by cross-linking of the elastomer chains. This permanent connection prevents product loss and contamination commonly experienced with hose barb failures. Internally, molds are seamless and crevice-free to eliminate entrapment areas and potential contamination.

Molded silicone manifolds can be created out of mitos-P or mitos-R tubing. Parker domnick hunter molded manifolds are fully validated and delivered with a certificate of conformance.

Features and Benefits

- Stronger, seamless molded junctions eliminate entrapment areas
- Configured for your requirements
- All materials used in the manufacture of the single manifolds are fully traceable
- Molded silicone manifolds are manufactured free from known animal components
- Single manifolds can be gamma irradiated
- Storing at room temperature (-65-70 °F) is recommended for silicone manifolds. Shelf-life: physical property test data is available for product stored after irradiation
- Manufactured in a Class 7 (10,000) cleanroom



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 wraparound design that fully encases the tri-clamp mold.

Cross Mold



Y Mold



T Mold



Silicone Molded Stopper



Reducer Mold



Specifications

Mechanical properties of mitos-P tubing:

- Elongation at break: ASTM D-412 550-1500%
- Shore hardness: ASTM D-2240 55-57 Shore A
- Specific gravity: ASTM D-792 1.135-2.37
- Compression set: 5.0 - 42.5%
- Tear strength: die B (PPI) ASTM D-412 200-500

mitos-P biocompatibility, physicochemical and particulate test results

| Test Description | Test Reference | Results | Details |
|--|-----------------------------------|---------|---|
| Biocompatibility tests | | | |
| Biological reactivity test, <i>in vivo</i> Class VI | USP <88> | Pass | Extraction conditions 70 °C |
| Hemolysis test | ISO 10993-4 ASTM F756-00 | Pass | The test article is considered non-hemolytic under the experimental conditions employed |
| Cytotoxicity | ISO 10993-5 | Pass | Test item considered non-cytotoxic |
| Implantation test | ISO 10993-6 | Pass | Did not produce a biological response |
| Irritation & sanitization | ISO 10993-10 | Pass | The skin treated with the test article extracts exhibited no reaction to the challenge [0% sensitization] |
| Acute systemic toxicity test | ISO 10993-11 | Pass | Extraction conditions 70 °C ± 2 °C for 24 hrs |
| Physicochemical tests | | | |
| Test for plastics; Silicone elastomer | EU PH 6 th 2009, 3.1.9 | Pass | N/A |
| Bacterial Endotoxins - LAL test | USP <85> | Report | 100 cm ² of the test article contains 0.6505 EU (0.0121 EU/ml) |
| TOC analysis | USP 32, NF 27, 2009 <643> | Report | 1.992 mg C/L |
| USP particulate / microscopic particulate count | USP 32, NF 27, 2009 <788> | Report | 5 particulates / mL with size ≥ 25 µm |

Summary of extractables results for gamma-irradiated platinum-cured silicone manifold*

| | Volatile Extractables | Semi-Volatile & Non-Volatile Extractables | Acetate & Formate |
|-------------|--|--|------------------------------------|
| Water | Trimethyl silanol: 0.7 ppm Low molecular weight alcohol residues: 8ppm, e.g. ethanol, IPA | • Plasticizers / residues: 1.1 ppm | Formate: 19 ppm Acetate: 9 ppm |
| PBS, pH 3 | Trimethyl silanol: 0.5 ppm Low molecular weight alcohol residues: 8ppm | • Plasticizers: 1ppm | Formate: 19 ppm Acetate: 35 ppm |
| PBS, pH 10 | Trimethyl silanol: 0.7 ppm Low molecular weight alcohol residues: 6ppm | • Plasticizers / residues: 2.2 ppm • Fatty acid slip agents: 5.9 ppm | Formate: 28 ppm Acetate: 11 ppm |
| 20% Ethanol | None detected | • Plasticizers / residues: 12.6 ppm • Paraffin oils: 0.8 ppm • Residual solvent: 0.8 ppm | Formate: 18 ppm Acetate: 9 ppm |

* The data below is derived from a gamma irradiated, complete molded tubing system, including representative junctions and fittings. Extraction volume: 100 mL. Surface area: 930 cm². Extractions were conducted under accelerated conditions for 3 days at 40 °C with water; PBS, pH3; PBS, pH 10; or 20% ethanol, to simulate 24 day exposure. Please note, that although values are quantitative, they are meant to be qualitative as a starting point for customer leachables studies.

Detailed data and testing are available upon request. Please contact your local Parker domnick hunter representative.

Services

Samples and prototypes of silicone manifolds to fit your application are available upon request.

Open Architecture allows us to work with existing specifications or upgrade to fit your application needs.

Regulatory statements

| Statement Available | Result |
|---|--------|
| REACH Compliant | Yes |
| RoHS Compliant | Yes |
| Drug Master File (Listing numbers available) | Yes |
| Latex | No |
| Phthalates | No |
| PVC | No |

Parker domnick hunter technologies can be combined to produce integrated solutions that will speed up development times, increase efficiency and safety, and guarantee reproducible product quality. Visit www.parker.com/dhsingleuse

