Silicone Rubber

Material Benefits and Fabrication Advantages
Selecting a high-quality elastomer for critical applications, particularly medical devices, can be a challenge. Designers, engineers and managers must carefully evaluate a wide array of material properties and processing possibilities in order to meet demanding performance specifications and budget requirements, so the performance criteria must be clearly defined. For example, durometer, elongation, modulus and tear must be determined to specify the correct material. With so many materials and fabrication methods available today, it is often difficult to recognize the optimum solution. Further, the implications of selecting an inferior material may cause a project to fail.

To make the most informed decision, it is helpful to gather as much data as you can about each material. This white paper is intended to provide you with factual information on silicone rubber elastomers, their properties, fabrication methods and advantages.

Silicones: Their History and Definition

Since the 1960s, silicone rubber has found widespread use in medical, aerospace, electrical, construction and industrial applications. Flexibility over wide temperature ranges, good resistance to compression set, a wide range of durometer selections, and inert and stable compounds are some of the reasons for its use.

Silicone rubbers are synthetic polymers with an unusual molecular structure — a giant backbone of alternating silicon and oxygen atoms. This linkage is similar to the linkage found in quartz, thus silicones have superior heat resistance compared to other elastomers. There are two popular catalyst systems used to cross-link silicon polymers: the platinum (addition cure) systems and peroxide (free radical).

Properties of Silicone Rubber

The strong silicon-oxygen chemical structure of silicone gives the elastomer its unique performance properties. Examples include:

**Temperature Resistance**
Silicones withstand a wider range of temperature extremes than nearly all other elastomers, remaining stable through a range of -75°F to 500°F. They may be sterilized by ethylene oxide (ETO), gamma, e-beam, steam autoclaving and various other methods.

**Mechanical Properties**
Silicone rubbers have high tear and tensile strength, good elongation, great flexibility and a durometer range of 5 to 80 Shore A. The softest durometers available are reinforced gels.

**Electrical Properties**
Silicones exceed all comparable materials in their insulating properties as well as flexibility in electrical applications. They are nonconductive and maintain dielectric strength in temperature extremes far higher or lower than those in which conventional insulating materials are able to perform.

**Biocompatibility**
In extensive tests, silicone rubbers have exhibited superior compatibility with human tissue and body fluids, and an extremely low tissue response when implanted, compared to other elastomers. They do not support bacteria growth and will not stain or corrode other materials. Silicones are odorless, tasteless and are often formulated to comply with biocompatibility guidelines for medical products.

**Chemical Resistance**
Silicones resist water, oxidation and many chemicals, including some acids and alkali solutions. Concentrated acids, solvents, oils and fuels have a negative effect on silicone rubber and should not be used with silicone.
Silicone elastomers are typically molded by three main methods: liquid injection molding (LIM), transfer molding and compression molding. The injection molding process, an excellent choice for high-volume applications, employs lower pressures and higher temperatures than the other molding methods — 250 to 2,000 psi injection pressure and temperatures of 245°F to 485°F. By contrast, transfer and compression molding operate at pressures of 2,000 to 8,000 psi and temperatures of 200°F to 370°F. In designing for the molding process, designers should take into account the material shrinkage rate, which can range from 2% to 4%, depending on the material.

During molding, the three variables that must be controlled are temperature, pressure and time. The temperature must be optimized to ensure sufficient crosslinking in a minimum cure time but low enough to prevent scorching the elastomer. The pressure must allow complete filling, maintain dimensional stability in the part, prevent voids and flash. Timing of all functions is critical for the production of consistently acceptable, fully cured parts.

**Liquid Injection Molding (LIM)**

Liquid injection molding has many benefits in the fabrication of silicone rubber, including cleanliness and speed. In the LIM process, pumping systems deliver the two-part liquid silicone (catalyst and crosslinker) directly into a mixer for homogenization, then directly into the mold cavity in a completely closed process. Molding and vulcanization (curing) occur rapidly within the mold cavity at a range of temperatures.

Overall, injection can take as little as .05 to 10 seconds, while molding and vulcanization take 10 to 90 seconds or more, depending upon shot weight and cross-section thickness.

**Transfer and Compression Molding Using High-Consistency Rubber (HCR) Silicones**

Transfer and compression molding are widely accepted and are in use today. Unlike the LIM process, transfer and compression molding require separate pre-mixing of the HCR silicone rubber on a two-roll mill. The material is then cut into predetermined shot size and fed into the tool via transfer or a stuffer box.

These processes must be operated at lower temperatures, requiring longer operating cycles. This is why it’s not uncommon to see large molds with 100 cavities or more on diaphragm, bottle closure, O-ring seal and many other applications.

When transfer molding, a hydraulic ram displaces HCR silicone through the sprues and gates into the cavities. Compression molding differs. The HCR silicone is manually placed into the cavities, and it is compressed in the mold to complete the fill during the closing action of the press.

**Overall Benefits of Silicone Rubber**

Silicone rubbers are unmatched by other elastomers in many important specification categories.

Outstanding benefits of silicone include:
- Unsurpassed biocompatibility
- Ability to be sterilized by many methods
- Low compression set
- High tear strength
- High elongation
- Natural translucence or high clarity
- Ability to be pigmented and radiopacity
- Ability to retain softness indefinitely
- Long shelf life
- Processing versatility
- UV, moisture and steam resistance
- Ease of cleaning

**Fabricating Silicone Rubber**

**Molding**

Liquid injection molding, due to its closed process, minimizes contamination. Additionally, because it employs a single automated step, it provides consistent part quality with less chance for material mix variation.

The principal advantages of LIM include:
- Cleanliness
- No material preparation labor
- Lower injection pressure
- Faster cycle rates
- Availability of fully automated systems

**LIM Steps:**

1. **Meter Mixing**

2. **Mold Forming and Vulcanization**

3. **Final Part**
Extrusion

The HCR silicone extrusion process yields a broad range of tubing and profiles. The extrusion process begins with the two-part HCR silicone (catalyst and crosslinker) being blended on a two-roll mill. The blending yields a homogeneous compound that is formed into strips and fed continuously into the extruder. A feed screw maintains proper pressure at the pin and die. Once extruded, the tubing passes through hot-air vulcanization ovens (HAVs), where radiant heat cures the product. During the extrusion process, laser micrometer checks are performed to continuously ensure proper dimensional control.

The extrusion process is able to produce single-lumen, multilumen and coextruded tubing in a variety of properties and diameters. Other extrusions include:

- Profiles or non-round cross-sections, for such applications as instrument stands, clips, gaskets, seals, ties and markers
- X-ray opacity in stripe or opaque form to provide the doctor with a visual aid
- Reinforced tubing to provide added strength, electrical conductivity, kink resistance or stretch resistance

Examples of extruded silicone products include catheters, drain and fluid path tubes, gasketing, ribbon, sheathing, balloon cuffs and coextruded electrical conductors, with fluid path lumens.

Assembly

There is almost no limit to the configurations in which two or more silicone rubber components may be joined to create assemblies for special functions.

Some silicone fabricators can provide the assembly of silicone subcomponents in special environments, such as clean rooms and HEPA filtered facilities, to meet OEM cleanliness requirements.

The most common assembly methods for joining multiple silicone rubber subcomponents include insert molding and bonding. The insert molding process involves injection-molding liquid silicone around an existing part or parts. The bonding process entails joining one or more silicone components together with silicone adhesives.

Secondary Operations

Full-service silicone fabricators provide a range of secondary operations to satisfy specialized product requirements:

- Silk screening
- Slitting
- Punching
- Beveling
- Bundling
- Functional testing

Examples of extruded silicone products include catheters, drain and fluid path tubes, gasketing, ribbon, sheathing, balloon cuffs and coextruded electrical conductors, with fluid path lumens.

A multi-component assembly — This catheter began with a molded or extruded tube, internally reinforced with a stainless steel spiral wire. The wire, specified by the customer to provide kink resistance, was inserted into the mainshaft I.D. and then encapsulated. Next, a molded balloon was bonded onto the distal end. The tip of the mainshaft was beveled and coated for ease of insertion. The check valve assembly was then attached through bonding for cuff inflation. The assembly also has several secondary processes, including holes pierced in the sidewalls for drainage and printing on the side for identification.
## Applications

Silicone rubber components and assemblies are employed in a wide range of applications, including:

- Airway, endotracheal tubes, with and without cuffs
- Drainage catheters, with and without balloons
- Compression clips and standoffs
- Delivery catheters with and without cuffs
- Drainage tubes, all shapes and sizes
- Ear plugs/hearing aids
- Electrosurgical handpieces
- Feeding devices and tubing
- Wire/fluid path coextrusions
- Power supply cables
- Infusion sleeves/test chambers
- Introducer tips/flexible sheaths

## Commonly Fabricated Parts

<table>
<thead>
<tr>
<th>Part</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pilot Balloon</td>
<td><img src="pilot_balloon.jpg" alt="Pilot Balloon" /></td>
</tr>
<tr>
<td>Reinforced Tube</td>
<td><img src="reinforced_tube.jpg" alt="Reinforced Tube" /></td>
</tr>
<tr>
<td>Bolster</td>
<td><img src="bolster.jpg" alt="Bolster" /></td>
</tr>
<tr>
<td>3-Lumen Catheter</td>
<td><img src="3_lumen_catheter.jpg" alt="3-Lumen Catheter" /></td>
</tr>
<tr>
<td>Flat Drain</td>
<td><img src="flat_drain.jpg" alt="Flat Drain" /></td>
</tr>
<tr>
<td>Bellows</td>
<td><img src="bellows.jpg" alt="Bellows" /></td>
</tr>
<tr>
<td>Precision Pump Tube</td>
<td><img src="precision_pumpTube.jpg" alt="Precision Pump Tube" /></td>
</tr>
<tr>
<td>Shunt</td>
<td><img src="shunt.jpg" alt="Shunt" /></td>
</tr>
</tbody>
</table>

## Silicone Rubber Comparative Analysis

<table>
<thead>
<tr>
<th>When Compared To...</th>
<th>Silicone Material Delivers...</th>
</tr>
</thead>
</table>
| Latex               | • Lot-to-lot consistency due to controlled synthetic process, vs. organic lot-to-lot variations  
                        • Superior biocompatibility  
                        • Higher clarity  
                        • Better electrical insulation properties  
                        • Stability over a broader temperature range |
| PVCs                | • Inertness and absence of leachable additives  
                        • Superior biocompatibility  
                        • Stability over a broader temperature range  
                        • Superior sterilization properties |
| Polyurethanes and Vinlys | • Plasticizer- and toxin-free  
                             • Superior biocompatibility  
                             • Broader temperature stability  
                             • Lower compression set  
                             • Better clarity  
                             • Greater softness |
| TPEs                | • Superior biocompatibility  
                        • Superior chemical resistance  
                        • Lower durometer  
                        • Lower compression set |
Making the Decision

When evaluating silicone rubber as a potential material for your part, consider your possible need for design assistance, prototyping, cost effectiveness and testing requirements. While silicone rubber may have a higher per-pound cost than other common elastomers, consider the superior end results along with tooling, prototyping and manufacturing efficiencies that can help you realize substantial savings. Once you determine that silicone rubber is the right material for your part and select a fabrication process, consider the following qualifications when choosing a silicone fabricator:

**Engineering and Design**
Is the potential fabricator well-staffed with experienced engineers who can help you refine your concepts and design the custom tools to produce them? What prototyping methods are available? Are they able to do the secondary operations required?

**Materials Expertise**
Does the fabricator have the expertise and experience to help you choose the proper silicone compound for your application? Are engineers available to help you evaluate the physical specifications of your product and determine the optimum process parameters? Are they able to supply the proper grade silicones for your application?

**Manufacturing Capabilities**
Does the fabricator maintain QSR-controlled manufacturing facilities? Is the fabricator equipped for short or long runs, low or high volumes? Does the fabricator have advanced molding and extrusion equipment, including LIM and HCR equipment? Do they offer assembly, secondary, wash and packaging operations? If cleanliness is an important specification for your part, does the vendor have a controlled environment for its manufacturing area?

**Quality**
Does the supplier practice audited quality control production? Maintain advanced inspection equipment such as video microscopes and laser micrometers? Perform raw material testing, in-process inspection, SPC and end product testing? Provide 100% inspection when specified?

About Vesta, Inc.

Vesta is an ISO 13485 certified contract manufacturer providing molding, extrusion and assembly services to support the global medical device industry. Vesta is recognized for its expertise in design assistance, material selection and compliance to quality standards. Molding capabilities include liquid injection, transfer and insert molding of medical grade silicone. Vesta’s ExtruMed™ precision solutions utilize thermoplastics and silicone for a wide range of tubing and tight-tolerance extrusion applications, with special capabilities in braiding, balloon blowing and PEEK extrusion. Vesta capitalizes on 40 years of experience in helping the top medical device companies launch their products with success. Find more information about Vesta’s complete solutions at www.vestainc.com