

# USP CLASS VI GASKETS



**NEWMAN**  
SANITARY GASKET COMPANY

PRODUCTS OF INTEGRITY...FROM PEOPLE OF INTEGRITY



## USP Class VI Compliance Means Substantial Savings for You

Established in 1973 David Newman set out to create the only company in the country dedicated to manufacturing FDA compliant gaskets, "O"-rings and custom molded parts. Today, Newman continues to serve every element of the sanitary processing industries. Along with rubber-based compounds, we also produce Teflon® and Silicone components. With a 23,000 sq. ft. production facility, Newman has a full line of manufacturing equipment from transfer and compression presses, LIM injection molding and vertical injection presses, complete cleaning and finishing stations, inspection and shipping all under one roof for maximum efficiency.

### Meet Standards of Excellence in Every Way

Newman parts are traceable through our process and meet the standards of the FDA Code of Federal Regulations, Title 21, Paragraph 177.2600, and USP Class VI criteria. Our compounds are specifically formulated for companies requiring the highest sanitary standards and chemical purity. So you can be assured of the quality of each product's compound formulations. Our minimum standard has always been FDA specifications. Now the Company's goal for perfection brings USP Class VI compliance to Newman's impressive portfolio of compounds. Newman has five compounds that have been certified to USP Class VI requirements by Toxikon Laboratory in Woburn, Massachusetts, a federally bonded independent laboratory. These five compounds were found to be in compliance with the criteria of the U.S. Pharmacopoeia, Class VI, Section <88> Biological Reactivity Test, in Vivo.

Meeting both FDA and USP criteria guarantees that the elastomer is acceptable for sanitary process applications and the elastomers, or extracts from the elastomers, will not be harmful to human health.

**Providing FDA conformance with new, or replacement components is an imperative minimum requirement.**

**Newman Sanitary Gasket Company offers you the experience and dedication of personnel committed to the integrity of their products. Newman is prepared to meet all standard and custom rubber compound requirements of the pharmaceutical and biotech industries.**

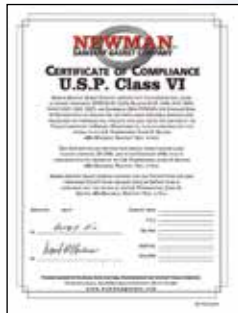




## Quality Assurance and Product Development

All Newman Class VI compliant components are shipped with a Newman Class VI certificate and are packaged and identified with a batch number and a cure date, making them 100% traceable. All parts are inspected and carefully packaged to assure you the highest quality part in the industry today. For sanitary process applications, it is also important that elastomers conform to FDA requirements and meet testing specifications of USP Class VI. Without these conditions, validation of the processing system and product would be in jeopardy. Engineers have a good understanding of metals, particularly stainless steel, which has a long history in sanitary processing. Most biotechnology, pharmaceuticals, food and beverage products that go from process to packaging run through stainless steel tubing and pipe. To ensure that the trip down these paths occurs lead-free, fittings, valves and pumps have specialized elastomer seals or gaskets. These special sealing devices have all been selected to perform under the process conditions, along with the characteristics of the process media and the effects of cleaning-in-place and sterilization clearly in mind.

The critical role played by elastomer components tends to be overlooked despite the risks of plant stoppages, or worse, product contamination, when seals are improperly specified. Elastomers are included in the wetted components of most process systems, which means they come directly into contact with line media. The same level of crucial consideration given to specifying appropriate piping material should also be applied to seals and gaskets. In fact, the ultimate safety, applicability and reliability of the total plant process system depend on the understanding of elastomers.



### Elastomer Use in Sanitary Process Applications

Material	Common Applications
Silicone	High purity. Temperatures service range to 450° F
Viton®	Resistant to chlorine cleaning agents, solvents and strong acids. Temperature service range to 400° F
EPDM	Pure waters, salts in water, dilute acids and alkalis low temp steam. Ozone resistant. Temperature service range to 275° F



Viton® is a registered trademark of DuPont



## Platinum Cured Silicone USP Class VI compliant "O"-Rings

Newman's USP Class VI compliant Platinum Cured Silicone "O"-Rings are complimented with our Class VI EPDM (black or white/peroxide cured) and Viton® (black or white/bisphenol cured). Each "O"-Ring is identified with a batch number and a cure date, making them 100% traceable and come packaged in heat-sealed bags.

Silicone material is known for its standard of purity and non-leaching characteristics. Its ability to withstand many chemicals and combination of chemicals is the reason it is so popular with the pharmaceutical industry. Silicone has excellent low temperature flexibility. Available in clear and red Silicone. Rated -80°F to 400°F.

## USP Class VI compliant Extrusions & Cord

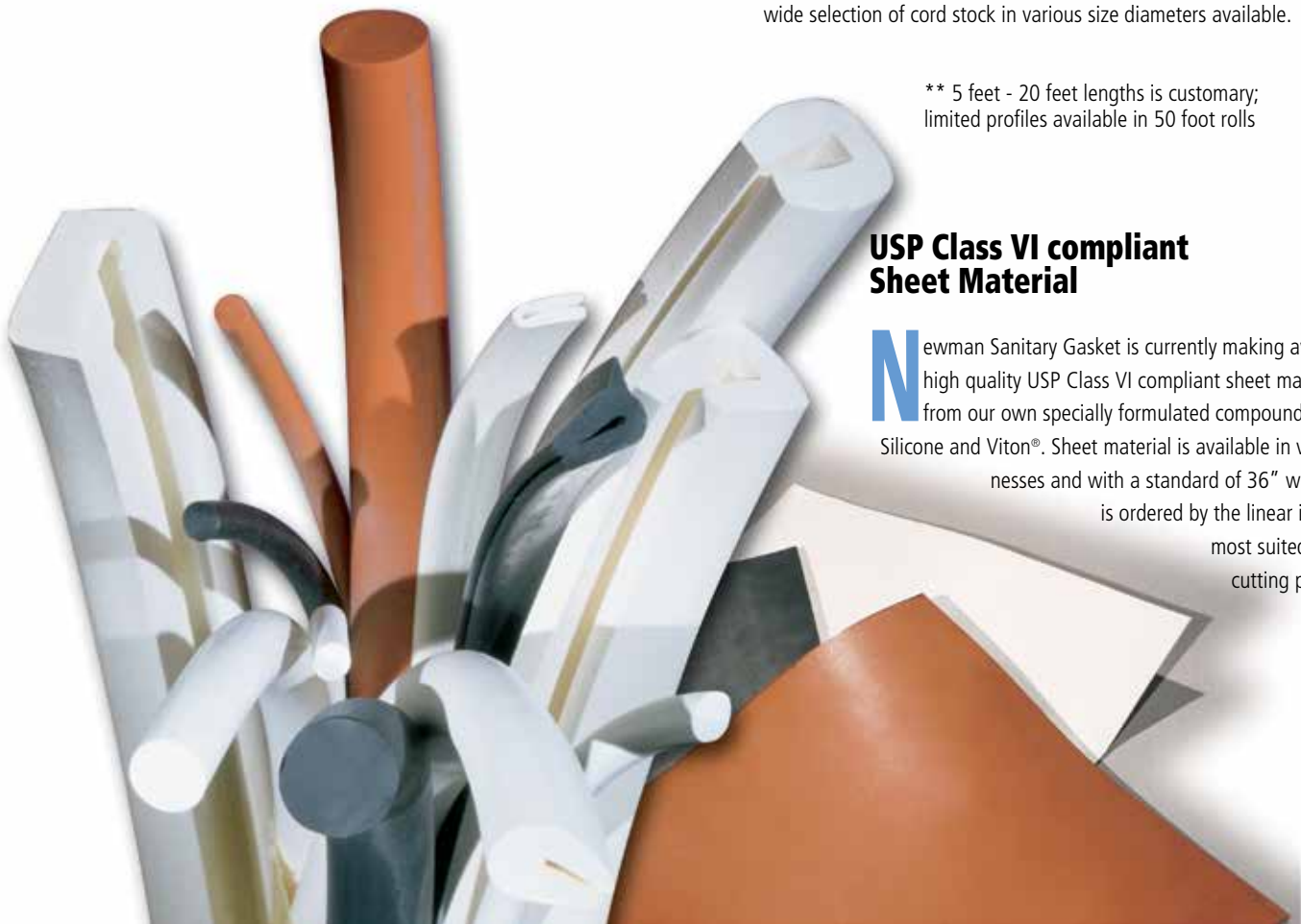
Newman's extrusion capabilities are available in straight lengths or in bonded shapes to form an endless component. Newman can extrude a custom profile (limited to 1" in diameter) from 2 feet to 50 feet\*\* in length from our Silicone, Viton®, or EPDM compounds.

Custom extrusions can be made to your specifications in compounds that meet FDA and USP Class VI requirements. Our specially formulated compounds make Newman your number one source for these superior FDA/USP compliant components. We currently have several standard extrusion molds available for your use. Along with our special extrusion profiles we also have a wide selection of cord stock in various size diameters available.

\*\* 5 feet - 20 feet lengths is customary;  
limited profiles available in 50 foot rolls

## USP Class VI compliant Sheet Material

Newman Sanitary Gasket is currently making available our high quality USP Class VI compliant sheet material made from our own specially formulated compounds: EPDM, red Silicone and Viton®. Sheet material is available in various thicknesses and with a standard of 36" width. Material is ordered by the linear inch and is most suited for die cutting parts.





## Custom Molding

Newman's custom molding group is able to develop and produce a broad range of products... products designed not only for the industries it now serves, but also for other sanitary applications.

Much of the custom molded work applies to processing systems and the manufacture of processing equipment. The materials used are much the same as the standard products which are Buna-N, Viton®, Silicon, EPDM and Teflon®.

All items are made to the customer's specifications by working closely with the customer to ensure proper fit and quality. Custom molding can vary from a small non-standard "O"-ring to a highly sophisticated rubber compound bonded to stainless steel, or a specific item needing just the right amount of resiliency to work efficiently on a given piece of equipment. Processing equipment manufacturers rely on Newman for their original and replacement rubber parts for countless uses in the pharmaceutical industry.

Each custom molded part is developed with your time-table in mind. With the highly skilled design engineer and the most efficient tooling costs, along with Newman's processing equipment experience working with FDA material where sanitary conditions are essential, the customer is assured the highest quality custom molded part in the industry today. Most importantly, it is provided at much less than the cost of other custom molders.

### USP Class VI Compliant Compounds for Custom Molders

Newman will provide its USP Class VI compliant compounds to qualified custom molders so you may upgrade to the highest standard of rubber compounds for your pharmaceutical customers and/or prospects. This is especially beneficial for pharmaceutical manufacturers already committed with tooling and who have long-standing business relationships with current suppliers.

### USP Class VI compliant "O"-Ring Kit for Glatt Nozzles

Newman "O"-Ring Kits for Glatt Nozzles are made from our exclusive USP Class VI compliant, EPDM or Viton® elastomers. Each "O"-Ring is hand finished and inspected to assure the finest in quality. Each "O"-Ring kit is identified with a batch number and a cure date, making them 100% traceable.

Newman has more than 30 years of expertise in the Pharmaceutical/ Medical rubber- manufacturing field. We will satisfy your most rigid requirements and deliver a high quality "O"-Ring kit to you at substantial savings.

Some parts shown are proprietary parts and are not available for resale.



Teflon® is a registered trademark of DuPont.  
Viton® is a registered trademark of DuPont

# NewFlo™ Replacement Diaphragms for ITT®, Saunders® and Gemü™ valves. New Dependability... New Performance... New Value... that you can count on!



Gemü™  
Valves



ITT®  
Valves



Saunders®  
Valves

Precision fit and designed for ITT®, Saunders® and Gemü™ valves, Newman NewFlo™ diaphragms deliver exceptional performance in today's demanding pharmaceutical processing environment. As always, you can count on Newman's reputation for excellence, success and expertise in the pharmaceutical industry.

### **Time-Tested Materials and Experience**

1. The elastomer backing is manufactured from Newman's famous polymer-rich 2107 EPDM compound.
2. The TFM™ facing of the diaphragm is made from time proven modified fluoropolymer, the choice of the diaphragm valve industry for pharmaceutical applications and validated for years. Manufacturer certified USP Class VI.
3. Mechanical testing by third party industry experts to 500 steam cycles and over 100,000 valve cycles has demonstrated exceptional steam resistance and long term durability. Newman's backings are shown to impart outstanding sealing properties at the lowest bonnet torque values.

### **Certified Peace of Mind**

1. Each diaphragm meets the requirements of FDA CFR Title 21 177.2600 (elastomers) and paragraph 177.1550 (perfluorocarbons) and USP Class VI.
2. Setting a new standard for traceability and causing a stir across the industry, every diaphragm is fully **batch** traceable at the **part level**, an exclusive in the industry (patent pending). This means that you will know the exact style, size, composition and provenance of every diaphragm in your system, simply by looking at the back of the diaphragm.
3. Each diaphragm is backed by Newman's unbeatable 35 year history in manufacturing of premium elastomer parts for the pharmaceutical industry.

Newman Diaphragms LLC (NDI) does not manufacture or sell ITT®, Saunders® or Gemü® OEM valves or diaphragms. NDI is not affiliated with any of these companies, nor is NDI or any of its products sponsored by or endorsed by any of these companies.

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