flow control solutions

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Synthetic Polysioprene (IR) For Medical Products

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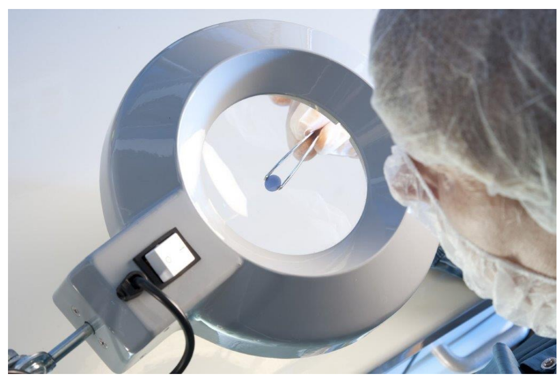
Synthetic polyisoprene has become an important polymer for medical fluid control components

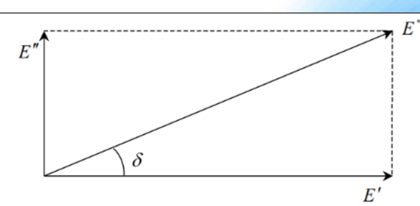
Natural Polyisoprene (NR) and Synthetic Polyisoprene (IR) are rubber thermoset materials, which have properties that are very useful in many applications, especially medical fluid control components and device assemblies. These material properties include extremely high elongation, high values of tensile and tear resistance while also exhibiting excellent resilience, or the ability to quickly return or recover to the original shape after deformation.
Such properties make the use of Synthetic Polyisoprene (IR) ideal in medical applications requiring the prevention of fluid leakage around surgical instruments, fluid control valves re-sealing against a seat or interface, and pressure regulating membranes;

- Catheter valves and seals
- Laparoscopic introducer valves (trocars, sheath seals)
- Diagnostic slit septum valves
- Ventilator flapper disc valves
- Guidewire seals
- Non-return pressure regulating diaphragms
- Needless injection site valves



One may notice that all of these applications combine dynamic and static sealing requirements. In addition to all the typical material properties, Vernay Scientists realized they needed to look deeper. Resilience is a good example, which is actually a dynamic material characteristic. In evaluating and measuring the dynamic characteristics of materials, we frequently use a Dynamic Mechanical Analyzer (DMA) to quantify dynamic properties and compare different rubber recipes in effof rubber thermoset materials orts to optimize characteristics of resilience. Using the DMA, we can quantify the dynamic complex modulus, the storage modulus and the loss modulus. Through years of research, we have observed that maximizing the storage modulus and minimizing the loss modulus results in a more resilient recipe with reduced hysteresis. Think of the storage modulus as the spring component of the complex modulus, in some applications, it is preferred that the rubber part exhibits characteristics like an ideal

E'	Storage modulus
E''	Loss modulus
$E^{*}=\sqrt{(E')^{2}+(E'')^{2}}$	Complex modulus
$\tan\delta=\frac{E''}{E'}$	Mechanical damping



spring – quick to respond and returning nearly all the energy (not absorbing or dampening energy). The characteristics of the rubber recipe are adjusted using various polymers, fillers, plasticizers and other ingredients, specifically to adjust the ratio of elastic vs loss modulae. This allows Vernay Chemists to match the resulting rubber material properties specifically to the application and part criteria.
In addition to the physical characteristics of the IR formulation, meeting specific industry regulations for medical applications is critical. These regulatory aspects include, but are not limited to; biocompatibility (USP Class VI and ISO10993), low extractable pharmaceutical and in some cases white listed materials (FDA 21CFR177.2600). Within these regulations are strict limitations on performance characteristics and laboratory tests that the materials must meet in areas such as; cytotoxicity, hemolysis, mutation, sensitization, limitations on maximum ingredient ratios, restricted ingredients, etc. Translating these requirements into the science and chemistry requires further consideration of impacts to material viscosity, rheology and resulting physical properties like modulus, resilience and chemical compatibility. It's a delicate balance.

Material formulation and properties are important but they are not the only factor. The elastomeric materials and molded parts are dependent upon a balance of 3 critical technical aspects; 1) formulamedical tion material properties, 2) part/tooling geometry and 3) the molding process. We refer to these as the development "trifecta" because each one is dependent upon the others. Changes to any one will have impacts on the remaining two. Although Synthetic Polyisoprene (IR) exhibits many beneficial material properties and characteristics, the part geometry and molding process needs to be considered and balanced together in order to produce a successful product meeting all of the application criteria.

Glossary of Compounding Terminology

Aging
The irreversible change of material properties after exposure to an enviroment for an interval of time.

Compression Set
The deformation that remains in rubber after it has been subjected to and released from a specific compressive for a definitve period of time at a prescribed temperature.

Duromoter (hardness)
An arbitrary numerical value that measures the resistance to indentation of the blunt indenter point of durometer. Value may be taken immediately or after a very short specified time.

Elastomer
A polymeric material which, at room temperature can be deformed, and upon removal of the deforming foce, recover substantially in size and shape.

Elongation
The increase in length of a material while under tensile stress. Elongation is expressed numerically as a fraction or percentage of the initial lenght.

Glass Transition
The change in an amorphus region of a partially crystalline polymer from a viscous or rubbery condition to a hard and relatively brittle one; usually brought by changing the temperature.

Microhardness
TA way of measuring the rubber hardness of thin or complex sections.

Modulus
In the physical testing of rubber, the force in pounds per square inch of Newtons per square meter of initial cross-sectional area necessary to produce a stated percentage of elongation.

Resilience
The ability of a strained elastomeric body, by virtue of high yield strength and low elastic modulus, to recover its size and form after deformation.

Rheology
The study of the deformation and flow of materials in terms of stress, strain and time.

Specific Gravity
The ratio of the weight of a given substance to the weight of an equal volume of water at a specified temperature.

Tear Resistance
The force per unit of thickness required to initiate tearing in the direction of the stress.

Tensile Strength
IThe maximum stress applied during stretching of a specimen to rupture.

Volume Change
The increase or decrease in volume of a specifime after immersion in a liquid or exposure to a vapor at a predetermined temperature and time.

Wear Resistance
Sometimes considered as the ability of a material to withstand the cumulative and iintegrated actions of all the deletirous influences (especially abrasion) encountered in use, which tends to impair its serviceability.

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Bob Ferguson is the VP of Global Research & Development for Vernay Laboratories. Bob is a researcher at heart with a passion for scientific discovery and advancing technical boundaries via experimentation in the laboratory. Bob's expertise lies in rubber material formulation development, nanoparticles as additives, magnetic and electro-rheologic materials.