

Choose the Right Rubber Material & Process for Your Medical Parts



WHITEPAPER



Introduction

When it's time to design and develop a new medical device that calls for an elastomer component, there are a number of material options and manufacturing processes to consider. The long list of material properties impacting performance includes your prospective polymer's end-use environment, chemical compatibility, hardness, compression set, tensile properties and manufacturability, to name a few. Although the selection process may appear daunting, understanding your application, the physical and mechanical properties of your material options and the interaction with mating components will

go a long way. These key attributes in conjunction with understanding volume ramp schedules will drive the proper manufacturing processes to ensure a successful product launch.

This article will walk you through some of the factors and trade-offs you'll need to address when selecting a polymer for your medical component. It will also describe some of the capabilities that rubber and plastic specialists can provide you to enhance your product development.

AN IMPROVEMENT IN		USUALLY IMPROVES		BUT SACRIFICES
Abrasion Resistance	→	Hardness/Elongation	→	Resilience
Impact Resistance	→	Elongation	→	Modulus
Creep Resistance	→	Resilience	→	Flex Resistance
Oil Resistance	→	Tear Resilience	→	Low Temperature Flex
Resilience	→	Creep Resilience	→	Tear Resistance
Tensile Strength	→	Modulus	→	Elongation
Vibration Damping	→	Impact Resistance	→	Structural Integrity

Choosing the correct material always involves trade-offs in performance. Create a chart to help determine your part's most critical performance characteristics.



Cleanliness and Safety Drive Material Needs for Medical Parts

Begin your material selection process by reviewing the product's design intent, including clinical operation requirements. With any medical part, patient safety and cleanliness play a critical role in the material you choose. Assess where and how your part will be used, as well as any sterilization processes it may encounter.

For instance, molded rubber seals are widely used in medical equipment, including implantable devices. Accordingly, you'll need to know the following about your material:

Biocompatibility.

Will the material make contact with skin? Will the product be blood or sterile fluid contacting? Is it intended for either temporary or permanent implantation, the latter of which is considered 10 years or more? Rubber specialists can offer materials that meet USP Class VI standards and materials that comply with ISO 10993 biocompatibility standards.

Sterilization needs.

It isn't enough to ask yourself whether your part will be sterilized. Some materials can't survive high-temperature steam sterilization and instead undergo ethylene oxide (EtO) sterilization, while others are more suited for the deep penetration of gamma radiation. In addition, chemicals and solvents used for cleaning can cause a part to shrink.

Physical and mechanical properties.

As with any rubber part application, you must consider temperature extremes, as well as the stresses your material will undergo that may cause it to stretch, deform or compress.

Liquid Silicone Rubber (LSR) is often selected for medical device products, but in many applications, High Consistency Rubber (HCR) has been proven to be a better choice that can drive down overall part cost and reduce time to market.



Understand Your Material's Physical Properties

Hardness

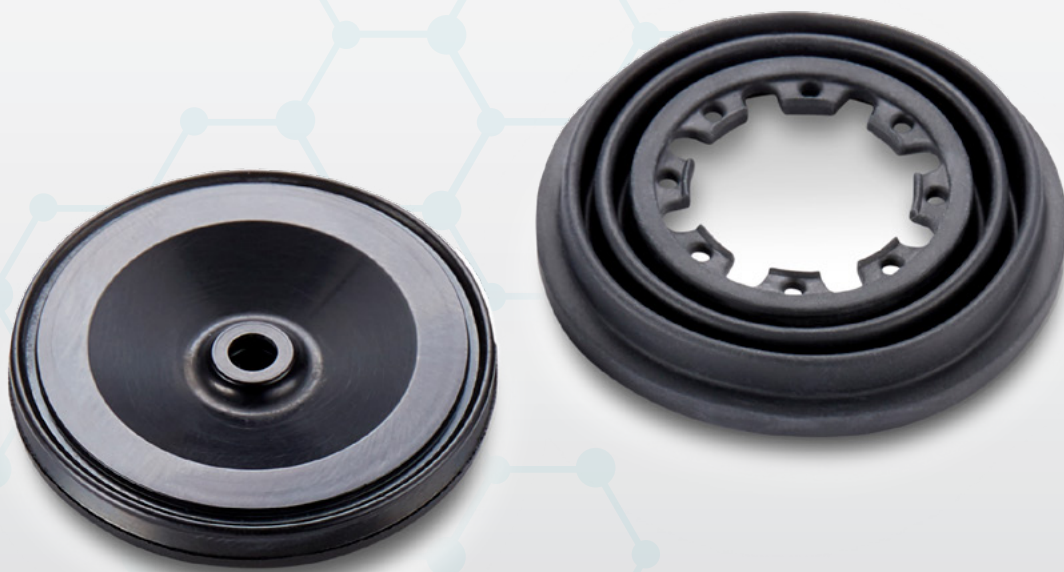
Hardness is defined as the rubber's resistance to indentation by a harder object and is an important consideration for critical medical components and seals. Rubber hardness is measured using a Shore durometer — according to ASTM D2240 — and the values are expressed in Shore hardness scale units. Hardness of thermoset rubbers range from 20 Shore A to 90 Shore A, and harder thermoplastic elastomers are categorized as Shore D. However, the most common hardness range is 50 Shore A to 80 Shore A.

Your application needs will dictate your required material hardness. For example, sealing products typically use materials with a hardness of

approximately 70 Shore A. If your parts will have complex geometries or require deep undercuts, look for a material hardness between 30 Shore A and 80 Shore A.

Material Permeability

When it comes to medical components, a gas or other medium's ability to penetrate rubber is an important factor in material selection. Components that endure sterilization are vulnerable to moisture incursion, so the material's permeability must be as low as possible. A material's molecular size and polarity, the filler material in your compound, your application's temperature and other factors will determine permeability.



Mechanical Properties: Testing and Evaluation

Tensile Strength

Material specialists like Trelleborg will analyze a rubber to see how it will behave under extension following ASTM D624 or ASTM D412 specifications. In a typical tensile strength test, gradually heavier loads are applied to a material sample, stretching the material to various lengths. This data is plotted graphically to create a stress-strain curve on an X-Y axis, with:

Y axis = stress (MPa, force per unit area)

X axis = deformation of the material
(elongation length)

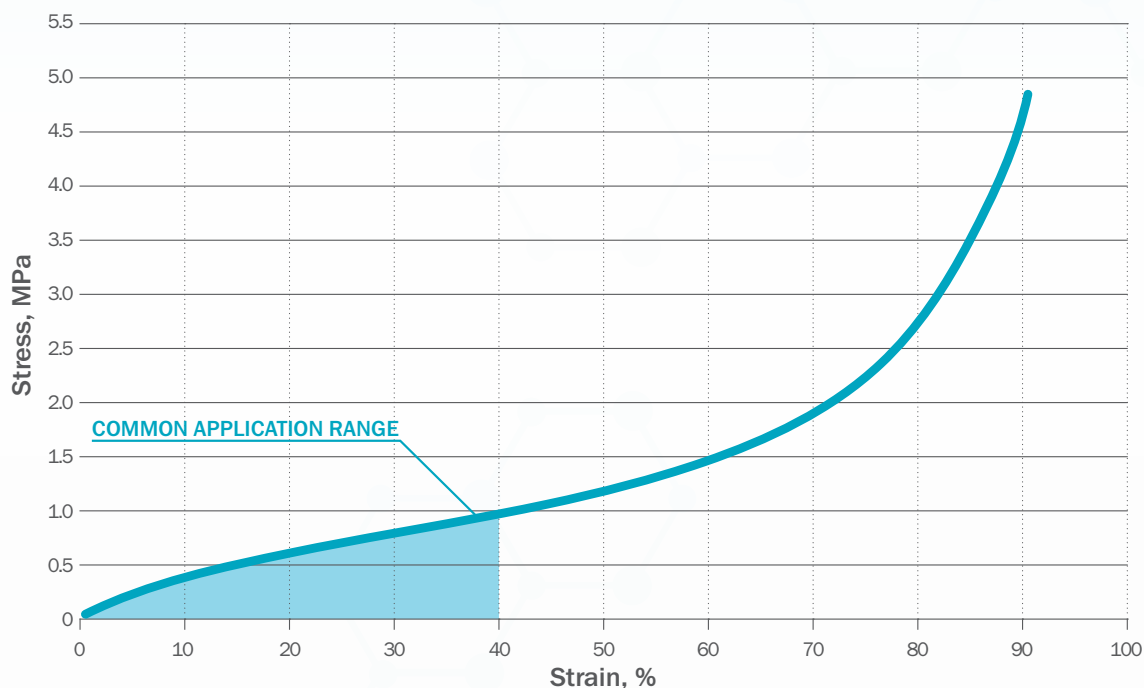
The material's performance can be seen in different regions of the stress-strain curve:

- **Elastic modulus:** Part of the elastic region, elastic modulus is the initial slope in a stress-strain curve where deformation can be reversed when stress is removed.
- **Yield stress:** The peak stress, just before fracturing occurs.
- **Necking:** Following the yield stress point, a small region of the polymer sample experiences a large amount of nominal strain.
- **Cold drawing:** The process whereby the neck extends with the direction of the applied stress as polymer chains break down. This linear region of the graph is ideal for product design.
- **Strain hardening:** The slope in which the material is permanently strained to increase its peak stress.
- **Fracture:** The polymer chains fail.

If you require a stiff, rugged rubber, a steep curve will indicate a tough material that offers good resistance to deformation caused by elongation. A more gradual curve means the material deforms more easily



Typical Shore A EP Rubber Tension Data



Simple tension summary data, room temperature (23 °C).

Ultimate Elongation / Elongation at Break (Eb)

Ultimate Elongation is the percentage of the increased length to which the elastomer can be stretched (strained) to the break point and is measured against the original length of the specimen. Tensile stress is usually measured and reported at predetermined strains — 50, 100 and 300 percent — before the break occurs. The tensile values at different strains are reported as moduli.

Compression Set Resistance

Rubber deforms under compressive load and rarely returns completely to its original dimensions when the load is removed. The

difference between the original and final dimensions, expressed as a percentage, is known as the compression set. Compression set measurements are usually performed following ASTM D 395 Method B (compression under constant deflection). This property is one of the most important aged properties, as it describes the ability of a molded article to maintain a seal under a compressive force. As many molded rubber articles are used in compression, the ability to define sealability is most easily done by measuring compression set resistance.



Manufacturing Process Considerations

In addition to matching your application's criteria with a material's physical and mechanical properties, manufacturing processes and their volumes will impact your choice of material and the unit price of your part. Manufacturing processes present cost trade-offs, and certain processes may not be ideal for some materials. The most common rubber manufacturing process options include:

Injection molding

In this process, uncured rubber is fed into vessels for heating. When the rubber reaches the desired temperature, the material is extruded into a mold cavity where it hardens and cures. Taking the geometric factors involved with tooling into consideration, injection molding is the most efficient manufacturing process. Its high precision also makes it suitable for custom projects or parts that have complex shapes. Injection molding can effectively handle volumes as high as tens of millions of units, and it has the added benefit of generating little material waste.

Transfer molding

Another popular method used with complex designs, transfer molding is well-suited for parts requiring multiple cavities. Here, material is preheated and preformed for placement into a pot located between a closed mold system's top plate and plunger. The material is pushed out of the pot through sprues and into the mold cavity where it is heated and pressurized. This process is often used for colored rubber parts.

Compression molding

Known for its simplicity, this method involves placing a preformed, uncured rubber compound directly into a heated mold cavity. Once in the cavity, the compound is compressed into its final shape by the mold closure. Compression molding is inexpensive and fast, and it can be used for most materials.

Each process involves trade-offs when it comes to achieving certain characteristics. Flash is one example. This condition can be defined as excess material that protrudes from a molded part's surface at its parting lines. A combination of factors play into whether the flash has a permissible thickness. Eliminating the extraneous rubber from a part will change the tooling geometry to achieve the desired precision. Because the tooling is more delicate, tooling life diminishes and the cost of the reduced tooling life can influence your choice of manufacturing method.

In addition, certain materials are harder to process, which can lead to damaged parts. Due to this combination of material and process factors, consult with your rubber parts specialist to understand all the options involved with selecting the right rubber compound and manufacturing process to best achieve your goals.

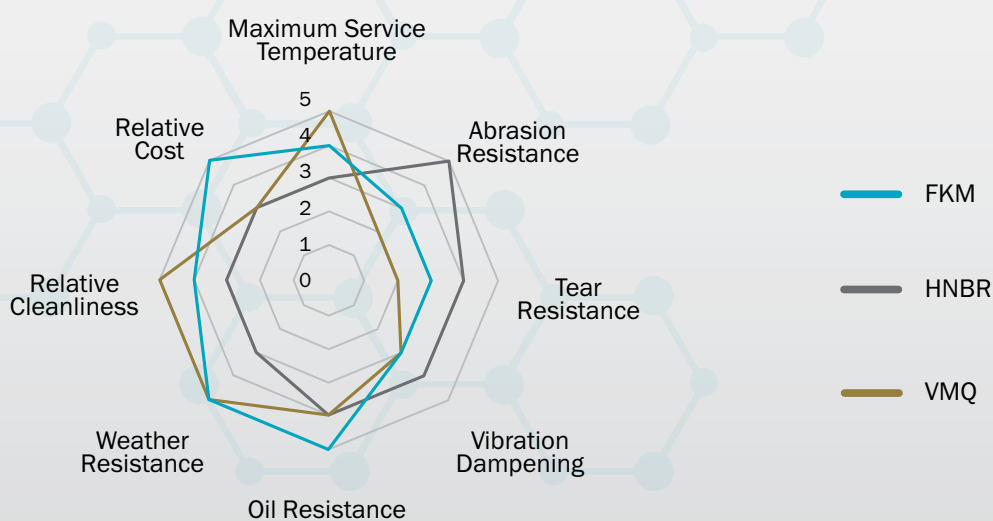
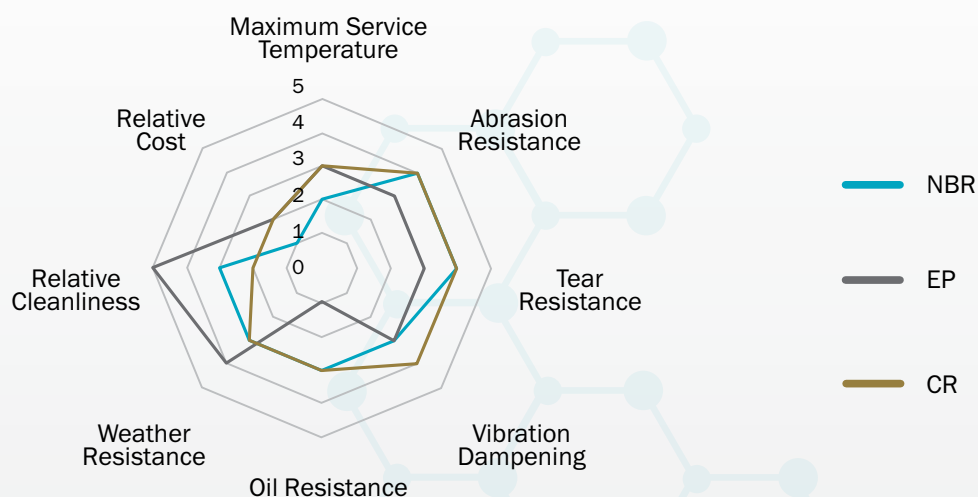


Narrowing Your Selection

Once you have determined all of your desired properties and characteristics, you can identify your potential material and manufacturing options with the help of your rubber expert and

their information library. Our team will create a chart that allows you to cross-reference your criteria with the materials.

Rubber Design Characteristics



For example, if you require a silicone, your Trelleborg material science partner will list the compound numbers that match your needs for biocompatibility, sterilization, insulin capability, temperatures or any other criteria you require.

Customize a Compound

Although there are many standard materials to choose from, no two applications are alike. For applications with specific needs that a standard material may not be able to satisfy, it pays to choose a rubber specialist that has the capability and expertise to create a custom formulation that can best match your requirements.

To help determine whether a custom formulation is more suitable for the application than a standard material, Trelleborg applies many different test methods and devices to measure the material's physical and mechanical properties. Using a process called compounding, we can enhance materials with additives to boost a property or make it more suitable for a specific manufacturing method. Still, compounding often creates more trade-offs. By enhancing one property, another may diminish. Your rubber specialist can walk you through the trade-offs to make sure you get the best performing material for the application.

Trelleborg has a proven history of helping medical OEMs design high-performance molded parts, and we also have the capability and expertise to develop the best-performing elastomeric for the application. From silicone molding, rubber

to thermoplastic elastomer (TPE) conversion, cleanroom assembly or compounds that comply with ISO 10993, USP Class VI and FDA standards, we can solve your rubber parts design, development or manufacturing challenges no matter the volume. Application examples include insulin and glucose monitoring instruments for diabetes, POC diagnostics testing, delivery systems for transcatheter aortic valve replacement and other cardiovascular tools and surgical instruments.

We also provide a wide variety of design tools and resources at www.trelleborg.com/en/healthcare to help designers navigate the material selection and product development process.



Explore Your Options With a Rubber Material Expert

Creating a medical component with a rubber material requires careful attention to various factors that will affect performance and manufacturability. Material choices and manufacturing options present many trade-offs. Be sure to understand your options and work with

a rubber specialist that has the capabilities and expertise to design, formulate and test materials to help you make the best choices to achieve quality, reliable rubber parts for your medical application.



For more information and to access Trelleborg's engineering tools for medical device design visit
www.trelleborg.com/healthcare/tools-and-media



Understanding Industry Test Methodologies



U.S. FOOD & DRUG
ADMINISTRATION

Rubber Industry

- ASTM vol 9.01 Rubber, Natural and Synthetic, General Test Methods
- ASTM vol 9.02 Rubber Products, Specifications and Related Test Methods

Medical Industry Standards

- ISO 13485
- ISO 10993
- USP Class VI
- EU Pharmacopeia 3.1.9

Overview of Test Methods and Industry Standards

Material testing is critical for selecting the right rubber for your medical application. That's why ASTM International, formerly known as American Society for Testing and Materials, has established test methods for determining mechanical properties of materials. Medical standards organizations have likewise established tests to ensure patient safety when they come into contact with medical devices.

Here's an overview of both ASTM and medical industry testing standards that engineers should be aware of when developing medical parts and devices made with molded rubber:

ASTM Test Standards

ASTM D412. A primary tensile test method for thermoset rubber and thermoplastic elastomers.

ASTM D623. A test method used to determine the tear strength of thermoset rubbers, thermoplastic elastomers and silicones, categorized by different sample material shapes.

ASTM D2240. This test method measures rubber hardness using a durometer. The rubber material is penetrated by a specified indenter under certain force and time conditions.

Medical Industry Test Standards

ISO 13485:2016. Organizations involved in medical device design, production and installation that achieve this certification have demonstrated that they have met the standard's

strict requirements for quality management and best practices in place.

USP Class VI; ISO 10993 biocompatibility compliance. USP Class VI is the U.S. Pharmacopeial Convention's most stringent protocol for testing plastics and ensuring materials used in a medical device are safe for contact with human tissue.

ISO 10993. This biocompatibility test is more stringent than USP Class VI and includes more extensive toxicity and hemocompatibility tests. ISO 10993 testing is more rigorous because it is intended for medical devices that will be implanted permanently or semi-permanently. It also divides medical devices into three categories — surface, implant and external communicating — plus three subcategories — limited, prolonged and permanent. Review your application carefully to be sure your material is tested to its proper category.

FDA Establishment Registration. Establishments used for the production and distribution of medical devices used in the U.S. must register with the FDA each year.

Standards for Referencing

ASTM International also publishes various standards to help make rubber-related nomenclatures and terminology easy to understand:

ASTM D1418. A general classification system for rubber and rubber latices.

ASTM D1566. A glossary of technical terms used in the rubber industry.



Trelleborg is a world leader in engineered polymer solutions that seal, damp and protect critical applications in demanding environments. Its innovative solutions accelerate performance for customers in a sustainable way.

Trelleborg Healthcare & Medical develops, manufactures and supplies innovative engineered solutions for demanding medical, biotech and pharmaceutical applications in thermoplastics, silicone and other elastomers. We focus on meeting the most demanding needs of Healthcare & Medical customers with innovative solutions.

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