CONTENT BRIEF

Biomaterial Basics: An Introduction to Biocompatibility and Biostability

Choosing the right polymers for your medical device is a complex process, including testing, quality control and compliance decisions. During material selection, one of the more common considerations original equipment manufacturers (OEMs) will encounter is the performance of the polymer in a biological environment. When selecting a material, two properties of a polymer that are sometimes misunderstood but critical to the performance of the device are biocompatibility and biostability. In this overview, we'll define biocompatibility and biostability, explain why they both matter to patient health and comfort, and provide examples of how performance properties of commonly used polymers determine what devices in which they may successfully be used.

HEALTH

BIOCOMPATIBILITY AND BIOSTABILITY AT ITS SURFACE

In simple terms, biocompatibility is the effect of a material on its host, while biostability is the effect of the host on the material. The biocompatibility and biostability performance of a material should be considered within the context of the biological environment and intended exposure time for the device. A device with a material that does not have the appropriate biocompatibility profile could elicit an unwanted host response, e.g., blood clotting, while insufficient biostability could result in premature degradation or loss of key properties that could result in failure of the device.

It's important for an OEM to have a trusted partner that can provide guidance on material selection considering the specific biocompatibility and biostability requirements of the finished device. This guidance helps them develop medical devices that not only mitigate the risks of adverse reactions, but also reduce hospital associated infections, shorten patient recovery times, and improve the patient's overall experience with the device. Beyond commercially available materials, an innovative partner will also consider development of materials that have enhanced biocompatibility and biostability that will allow the development of more effective medical devices.

Formulation of materials to address the biological considerations of innovative medical devices while enhancing physical and other performance characteristics requires a versatile chemistry. Thermoplastic polyurethanes (TPU) can be tailored by modifying their chemical building blocks to achieve application specific biostability without sacrificing other critical material properties. In addition, because TPU performance is modulated by modifying the type and ratios of its chemical components, rather than by adding plasticizers, TPUs tend to exhibit inherent biocompatibility in a number of applications. To learn more, watch our on-demand webinar, Materials for Implantable Devices Decoding Thermoplastic Polyurethanes.

BIOSTABILITY

The ability of a material to maintain its key performance characteristics throughout the lifetime of the medical device in which it is used.

BIOCOMPATIBILITY

The ability of a material to interact with a host without generating a response that would negatively impact its performance.

THE FUTURE OF BIOCOMPATIBILITY AND BIOSTABILITY

While no synthetic polymer can be considered completely biocompatible or biostable for all medical device applications, Lubrizol is committed to continuing to innovate to enhance these properties in TPUs. We are invested in developing materials to broaden the design space to enable the creation of the next generation of medical devices.

With regards to specific biostability considerations, the following general guidance can be helpful for selecting a sub-set of polyurethanes that may be suitable for an application. However, the ultimate selection of a material depends on application-specific performance criteria that should be confirmed by the medical device designer's own testing:

- **Consider polycarbonate-based polyurethanes for:**
  - Superior resistance to hydrolysis and oxidative pressure of long-term blood contact applications, especially where softness and flexibility are required.
- **Consider polyether-based polyurethanes for:**
  - Excellent hydrolysis resistance at low pH, such as in long-term gastric contact.
  - Good oxidative resistance at higher durometer (Shore 55D and harder) in long term blood contacting applications.

The biocompatibility and biostability properties of TPUs make them an excellent candidate for a wide variety of medical device applications, including:

- Short- and long-term infusion catheters
- Interventional catheters
- Structural heart applications
- Pacing and neuromodulation applications
- Dental and orthodontic devices

Lubrizol's wide selection of TPU materials offers solutions for all these options. To see a full list of Lubrizol's medical device polymers, click here.

PARTNERS FOR BETTER POLYMER PERFORMANCE

Lubrizol is committed to developing materials for the medical device industry that provide exceptional performance in applications requiring special consideration around biocompatibility and biostability.

In our next brief on this topic, we discuss some of the most common biocompatibility and biostability factors that can impact the success of a medical device. Click here to learn more.

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