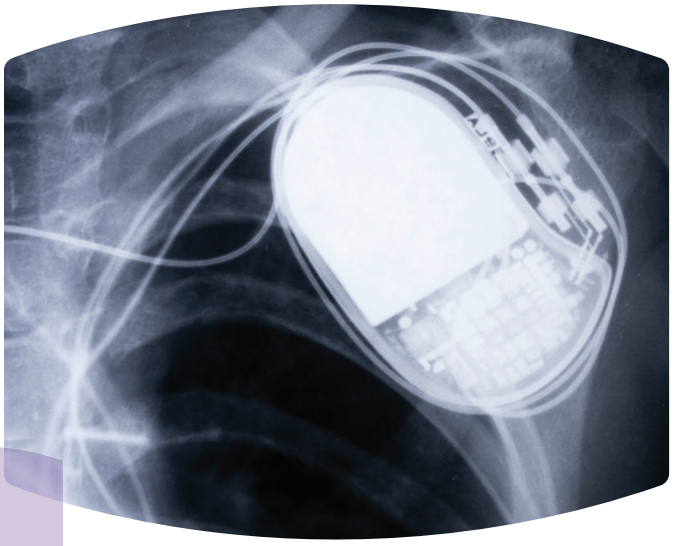
CONTENT BRIEF

The Biocompatibility and Biostability of the Materials Chosen for Your Device will Affect its Clinical Success.

A material's biocompatibility and biostability profile is a critical consideration in the development of your next medical device. The specific requirements of the medical device greatly influence the choice of appropriate material, as biocompatibility and biostability performance always need to be considered in the context of the end-use application.

HEALTH

To help ensure positive patient outcomes and mitigate potential risks when designing your device, your team should consider numerous factors that influence device biocompatibility and biostability during the material selection phase of development. In this overview, we will highlight the most important factors to help guide you to success in choosing the right polymer for your device.



THE MOST COMMON FACTORS AFFECTING BIOCOMPATIBILITY AND BIOSTABILITY

The biocompatibility and biostability requirements of a particular medical device are dependent upon its application-specific design and performance requirements. For example, the material utilized in a long-term cardiac implant has a stringent set of biocompatibility and biostability requirements designed and tested around extended blood and/or tissue contact. Conversely, a temporary surgical application may not consider biostability as a critical factor due to the limited duration of use. Below are key application-specific biocompatibility and biostability factors to consider.

Factor 1: DEVICE LOCATION

The location of use within the body determines the chemical environment that the material sees, which in turn influences the material performance requirements. For example, in direct blood contact, the body's immune response (via the white blood cells), can create a harsh oxidative environment at the material surface as the white blood cells try to phagocytize (consume) the foreign material. Therefore, devices in long-term direct blood contact generally need materials with excellent oxidative resistance. Conversely, devices in contact with skin may not experience the same level of oxidative pressure as in blood contact, so materials with resistance to hydrolysis (degradation by water) may be appropriate for construction. Furthermore, medical devices in contact with extreme pH environments, such as in the gastric system, require materials that can perform under chemically harsh environments.

BIOCOMPATIBILITY

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

BIOSTABILITY

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

Factor 2: DURATION OF DEVICE CONTACT

A device's duration of use determines biostability requirements and can dictate biocompatibility evaluation endpoints. For example, a short-term catheter that may only be in the body for several hours will not be subject to the same evaluation endpoints as an orthopedic implant designed to perform for years. From a biostability perspective, the chemical resistance required in an environment (as described above – oxidative, hydrolytic, extreme pH, etc.) is dependent on exposure time. Therefore, a device which needs to remain stable for hours may require different materials than a device used in the same environment that needs to remain stable for years.

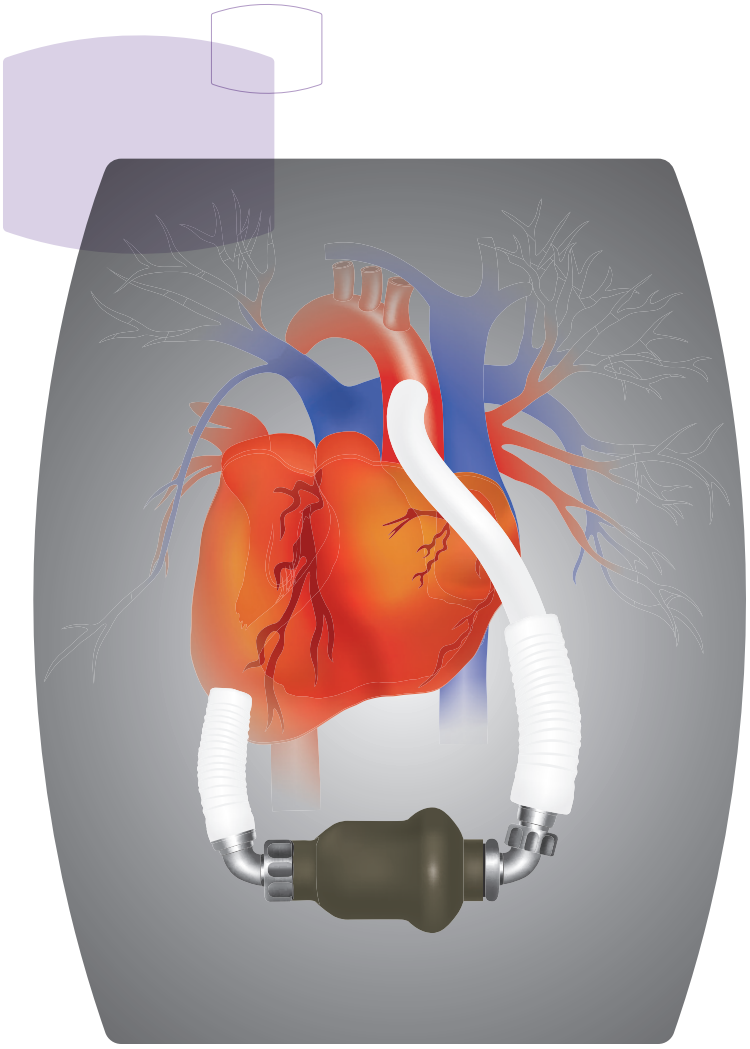
From a biocompatibility perspective, devices that are in contact with the body for an extended period will require different biocompatibility assessments including chronic toxicity, and genotoxicity. Additionally, potential degradation byproducts and extractables from the device materials may also need to be evaluated either via chemical or biological assessment.

Factor 3: MECHANICAL ACTIVITY AND REQUIREMENTS

The mechanical load to which a device component will be subjected during use (tension versus compression or static versus dynamic) can have significant implications on its biostability. Some polymers under constant or repetitive strain break down more quickly from biological conditions than unstrained polymers. For example, the mechanical requirements of an orthopedic implant are significantly different than material used in temporary drainage tubes. In this situation, additional polymer-specific considerations may need to be specified to ensure proper performance.

Factor 4: DEVICE CONTACT WITH DELICATE TISSUE

If the device is contacting delicate tissue, the mechanical action of the device against tissue can cause a physical biological response (i.e. swelling, tearing) that can impact the overall biocompatibility of the device. In this case, the mechanical properties of the material are as important as the chemical compatibility and should be considered during the initial phases of material selection for a device.



Factor 5: LOCAL EFFECTS AT THE BIOMATERIAL INTERFACE

Depending on a medical device's application, a determination needs to be made as to whether protein adsorption, fouling, and bacterial adhesion are a concern. These factors can significantly impact device performance, and material selection can be tailored based on the requirements at the biomaterial interface.

Factor 6: DEVICE STERILIZATION

Certain sterilization methods can change chemical and physical properties of device materials, potentially impacting their performance, including biocompatibility and biostability. Some thermoplastic polymers are negatively impacted by the heat, pressure, and humidity of autoclave (steam) sterilization methods. In extreme cases, autoclave sterilization can generate unwanted degradation byproducts in some polyurethanes. Other methods such as gamma or e-beam radiation are typically appropriate for thermoplastic polymers, but selecting an appropriate radiation dosage can be important to prevent chemical changes to the device materials. To learn more about proper sterilization, click here.

Factor 7: OVERALL DESIGN AND MANUFACTURING PROCESSES

Lastly, your team should holistically consider the design and manufacturing process of the device. What are the implications of other materials (i.e. conductive metals) contained in or in contact with the device? Will any additional chemical additives be required (i.e. plasticizers)? Will any coatings or textures be applied to the final version of the device? Will components be thick or thin walled? What processes will be utilized to manufacture the components? These design decisions can greatly impact biocompatibility and biostability of the final product, which is why it is important to partner with a trusted materials expert that can help guide you through these questions.

PARTNERS FOR BETTER POLYMER PERFORMANCE

Lubrizol is equipped with decades of knowledge and experience to provide OEMs with the insight to understand how device design and end use will determine component biocompatibility and biostability requirements and how this must drive material selection to create a clinically safe and effective device.

To learn more about how our team of medical polymers experts can support your medical device needs, contact us here.

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