

## 8 Things to Know About Why Biocompatible Materials are Important in a Medical Device

1. A common dictionary definition of BIOCOMPATIBILITY is “the quality of being compatible with living tissue or a living system by not being toxic or injurious and not causing immunological rejection”. Therefore, biocompatibility is important because a medical device (or component materials) should not harm the patient.
2. In a regulatory sense, biocompatibility is testing to determine potential toxicity resulting from contact with a material or medical device. Testing is performed to evaluate local and systemic reactions. Biocompatibility is important because systemic toxicity impairs an entire biological system such as the nervous or immune system. Furthermore, a systemic reaction is generally distant from the point of contact of the medical device. Therefore, the patient or doctor may not realize that a medical device is the source of a toxic reaction.
3. Two types of biocompatibility tests for allergic reactions are irritation and sensitization. An irritation reaction is immediate after a single exposure. Another characteristic of a sensitization reaction is that the toxic reaction is independent of dose. Therefore, the slightest exposure may cause a severe or possibly lethal toxic reaction. A sensitization reaction is delayed after repeated or prolonged exposure. Also, a sensitization reaction may not be localized. The delayed and non-localized nature of a sensitization reaction may prevent the patient or doctor from realizing the source of a toxic reaction.
4. Biocompatibility testing is important because the presence of extractable chemical compounds and agents from processing may influence biocompatibility. For example, the polymer itself used in a medical device may be biocompatible. However, addition of a plasticizer or other additive to the polymer may cause a toxic reaction. Cytotoxicity is the most sensitive of the biocompatibility tests and is useful for evaluating these types of harmful reactions.
5. Material interactions may cause a medical device to fail biocompatibility testing. The individual materials used to make a medical device may be biocompatible in part, but the combination of various materials may cause a toxic reaction. Therefore, the complete device requires biocompatibility testing.
6. Biocompatibility of a medical device is different than sterility (absence of microbes). However, sterility and cleanliness may influence biocompatibility. Therefore, a medical device should be cleaned and/or sterilized with the same method as planned for production.
7. Biocompatibility testing is an important part of obtaining the U.S. FDA’s approval to market a medical device. Biocompatibility is important even for Class I Devices (lowest risk) that are 510(k) application exempt. In order to avoid the need for test data from clinical trials, companies

try to convince the FDA that the medical device is substantially equivalent to a type of device on the market day. Biocompatibility testing may support a claim of equivalence with the FDA.

8. Biocompatibility is an important part of complying with standards of the United States Pharmacopeia (USP) and the International Organization for Standardization (ISO). USP is an independent, non-governmental, science-based organization that promotes the public health by establishing testing standards that ensure the quality of medicines and other health care technologies. USP standards are updated in official monographs, and these standards are enforceable by the U.S. FDA. ISO was established to determine uniform, worldwide standards. It is a non-governmental network of national standards institutes of 162 countries, and forms a bridge between private and public sectors. ISO 10993, published in 1995, is a series of standards for biological evaluation of medical devices and dental materials.