

How to select the optimal plastics for medical devices

Selecting the optimal materials is a vital step during the development of a medical device.

Rushing, or overlooking a rigorous selection process can lead to unknowns in the performance of materials, and ultimately risks to patient health. Corrective measures once a product is in production are very complex, and often expensive.

Smithers experts explore why plastics are used in medical devices, and how your team can ensure confidence in the materials you select for new designs.

Why plastics for medical devices?

- Plastics are often a cheaper alternative to other materials
- They utilize well-known manufacturing techniques
- Plastics typically have a longer shelf life than many other materials

However, these are all only true if the right plastic material types are being used in the first place.

Considerations for optimal materials

The material selection process should take into account a full suite of different considerations in order to consider your materials as being 'optimal'.

It starts with long- and short-term mechanical, physical and environmental conditions that may be experienced by the medical device during processing, assembly, storage, transport and service.

Considerations must then also focus on compliance with medical device regulations, characteristics of the product, how it's handled by the end user and how it will be cleaned.

Finally, cost and ease of material supply are critical to a successful polymer selection. A lack of supply of your chosen materials may require production to be stopped, or even changes made to the design midway through manufacture.

These must all be addressed before making a final decision on the materials that will be used to manufacture the medical device.

Reducing risk

When selecting plastics, you and your team will want to ensure that your materials will not be the cause of a product failure. Verification and validation is a key component of this, on top of taking an approach of due diligence when deciding between different polymers.

Part of this is ensuring compliance with legislation such as medical device regulation (MDR) and other European directives. These ensure that patient health is not compromised, and that devices perform as required. A materials expert can help guide you through this.

Future of material selection in medical devices

We are seeing a drive towards medical devices designed to be self-administered at home by the patient. This will require extra considerations around suitable materials due to the changing usage profiles and functionality requirements.

Medical device regulations can change – any time this happens a rethinking around material usage is often required.

Finally, innovation by medical device producers continues to accelerate. Plastic materials have a unique and important role to play in the medical field and with appropriate material selection, will continue to be used for the next generation of medical devices.

How Smithers can help

Smithers polymer experts have decades of experience, working in industry and supporting clients solve complex material challenges. Their design-stage support includes:

- Optimizing material selection, including assistance with material replacement
- Formulating cost reduction strategies for your product or material
- Advice on sustainability initiatives, the use of recycled materials, and post-consumer recycling (PCR) options
- Independent material specification development
- Material reviews and benchmarking to ensure peak performance
- Formulation ingredient evaluations
- Providing assurance of material quality
- Advising how to prevent premature product failure
- Performing failure analysis on existing products
- Advising on how aspects of product design and manufacturing can affect performance.

For more information and to get in touch with an expert:

[smithers.com/polymer-consulting](https://www.smithers.com/polymer-consulting)

