

## Choosing the Right Plastic Resin for Your Medical Product

Do you know which plastic resin to choose for your medical product? Teel has a team of engineers experienced with a variety of materials to help medical device manufacturers make the right choice.

To determine resin options, we assess the following:

1. Product performance requirements.
2. Regulatory requirements.
3. Resin availability.

### Performance Requirements

Teel NPPD Director Bruce Martin-Wright explains that, in the initial stages of choosing a resin, “We try to find out from a performance standpoint what the part needs to do.” This involves determining the intended function and environment of the product, including factors such as the level of heat exposure, abrasion, sterilization, degree of contact with the human body, and whether the product will be bent or formed into a shape. “That usually guides us to a family of polymers,” says Bruce.

Resins used in medical products come in all kinds, including options from medical-grade versions of common commodity resins, such as PVC, to medical grades of higher performance engineering plastics. Manufacturers of medical-grade resins must follow stricter, defined procedures in the production process to avoid contamination.

Teel works to determine the medical grade resin best suited for a product’s exact needs. While resin must be up to the task of the intended product, Bruce explains that “you don’t want to overbuild the part with a bunch of attributes it doesn’t need because all those attributes come with a cost.”

### Regulatory Requirements

Critically important for the medical market, the next step is to assess what regulatory standards the product must meet for its intended use. Medical products typically must adhere to certain sterilization requirements and avoid or limit the use of certain substances in their manufacture that are deemed harmful.

Some commonly applicable regulatory requirements include FDA GRAS substance regulations, 510(k), EU10/2011, USP Class, and IQ/OQ/PQ validation. Other more specific requirements may be needed based on the end-use of the product that further determine acceptable resin options.



*Teel works with an array of medical-grade resins every year to process extruded and injection molded diagnostic and medical disposable products.*



Because plastic medical device manufacturers must complete detailed and time-consuming validation processes to bring their products to market, medical-grade manufacturers must commit to supplying a resin to a medical customer long term, generally providing three-years' notice regarding any change to a resin's ingredients. This allows time for a medical device manufacturer to validate a new material. These regulations make resin availability another key factor in choosing the right one.

### Resin Availability

Bruce points out that resin availability, especially recently, is another important factor Teel considers in recommending a resin. For example, "If you get stuck with a resin that's only available in Asia or Europe," says Bruce, "shipping becomes a constraint." Device manufacturers then do not have the ability to react expeditiously to changes in market demand. "You either can't produce product because you can't produce material fast enough, or you're sitting on a lot of expensive inventory, and nobody wants that either," he says.

Teel maintains strong relationships with partner vendors to stay informed about resin availability. In deciding on a resin to use for a product, Bruce says, "Once we've got the scope narrowed down a little bit, then we reach out to our partner vendors." Bruce says that Teel works with several vendors with a wide breadth of products and a depth of knowledge that allows them to suggest a suite of available options after they receive initial information from the Teel team.

Teel's experience processing a wide selection of materials becomes important when options may be limited. "We've got a history with a lot of materials," says Bruce. Teel processes more than 60 different polymers per year. If possible, Bruce and his team typically try to find one of the many resins they have a history with for medical products. "It speeds up the development process for us to both get the part out for validation but also get material in here to validate," says Bruce.

### Conclusion

Choosing the right plastic resin for medical products can be a complex process involving multiple levels of assessment. We use our engineering, materials, and regulatory knowledge along with our strong industry connections to help take the pressure off our customers who are in the midst of time-consuming validation processes.