Best practices for molding bioresorbable materials for medical devices

By Raghu Vadlamudi
Chief Research and Technology Director
Donatelle

Donatelle
Manufacturing that changes lives®

Best practices for molding bioresorbable materials for medical devices

By Raghu Vadlamudi
Chief Research and Technology Director, Donatelle

Bioresorbable materials, which dissolve and are absorbed into the body, represent the cutting edge in medical device performance. From drug delivery to load-bearing applications, bioresorbables give healthcare providers options beyond traditional implantable or biocompatible materials and allow for customization to meet the needs of nearly any patient.

Understanding possible bioresorbable material formulations and how they excel in particular applications allows device manufacturers to take full advantage of the utility such materials offer. Equally vital is developing a process that minimizes waste and delivers consistently high product quality.

Expanding use

Implantable bioresorbable materials have been in use for more than 25 years. Most products made from such materials are standalone components. For example, a common application is bioresorbable sutures, which are dissolvable stapes used to tie the skin together following surgery or some other wound.

Other examples include bioresorbable screws used in orthopedic applications and bioresorbable cardiac stents. Dissolvable screws support tissue growth and, as the patient's condition improves, the body absorbs them – versus stainless steel or titanium screws that remain implanted. Dissolvable stents can be infused with the same drugs used to coat metal mesh stents, releasing the drug as the stent is absorbed while bypassing risks associated with removing a metal stent from the body.

Bioresorbable materials are gaining popularity in combination product applications because of the efficiency they can provide. For example, when a patient takes a tablet orally, the body only absorbs a low percent[1] of the therapeutic, because of the inherent inefficiencies of that delivery system. When the drug is embedded in a bioresorbable material, the rate of release can be precisely controlled, making bioresorbables a more efficient and dependable delivery system.

In terms of regulation, bioresorbable products are similar to any implantable Class III medical device that has to go through testing for life cycle, transportation and shelf life. Bioresorbables also require some additional precautions relevant to their handling and molding.

Manufacturing considerations

Bioresorbable materials are generally composed of either polylactide (PLA), polyglycolide (PGA) or polycaprolactone (PCL), as well as formulations that combine those materials.

The manufacturer determines the formulation depending on how long the material is intended to stay inside the body or based on mechanical properties. Formulation also depends on the molding process. Consider a drug-delivery application wherein the material has to dissolve at a particular rate to facilitate controlled release of the therapeutic, but the material also has to endure the molding process without compromising the drug's efficacy. If material properties are altered to address processing issues, like temperature, pressure and moisture, that alters the absorbency rate in the human body.

Best practices for molding bioresorbable materials for medical devices

By Raghu Vadlamudi
Chief Research and Technology Director, Donatelle

Beyond formulation, the capability to mold a bioresorbable component depends on material availability, adaptability and reproducibility, as well as material and manufacturing costs. While numerous suppliers exist for most materials, many original equipment manufacturers (OEMs) compound their own materials to avoid potential availability issues and shipping costs.

Adaptability refers to a material's performance in a given use environment. For example, if a product will be used to screw bones together inside a leg, it will require a higher strength material or material grade compared to a surgical staple that does not require heavy load capacity. Custom formulation is used to adapt materials to their use cases.

Reproducibility defines how well a molder can consistently shape material into the desired forms with the necessary quality. As OEMs generally have a material formulation in mind when they design a product, the molder's responsibility is to ensure controls are in place that promote consistent process results.

Cost is associated with the manufacturing process, and not the material itself. However, it warrants mention that, like any implantable material, bioresorbable products must pass through significant testing to ensure their biocompatibility and the integrity of the production process.

Material cost does affect manufacturing cost when waste is figured in, though. Consider that conventional injection molding might require more material to fill a mold, even for a smaller part, because of the size of the machines being used. This could result in waste of up to 70 percent of the material in the sprues and runners used to feed material into the mold's part cavities. However, micro systems can be used that minimize material use when molding small parts.

Ensuring consistent product quality

Once a part and process are approved, the manufacturer must repeat and maintain the same process, replicating the exact in-process conditions for handling the materials and molding the part.

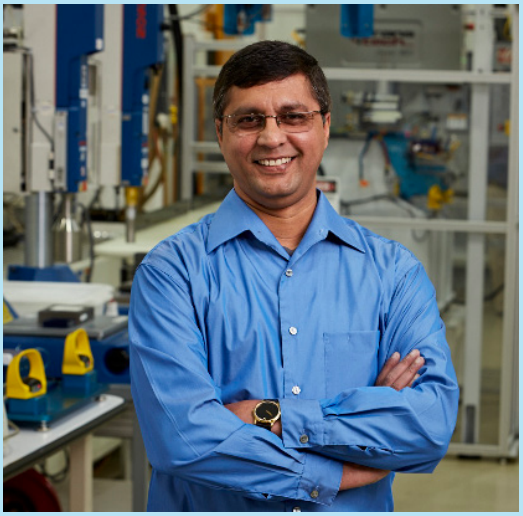
Deviating from that approach even slightly can lead to a change in degradation rate of the bioresorbable material, because it has been subjected to different heat, humidity or outside conditions, affecting its performance.

While materials like PEEK, titanium and stainless steel stay inside the body, bioresorbables are completely absorbed, meaning no evidence is left behind if an issue occurs or a device fails. Consequently, it is crucial to meticulously collect and document information during the development of manufacturing processes and during production runs, allowing for traceability and investigation after the fact. This documentation also aids in maintaining the validation state of the manufacturing processes.

[1] https://medicare-europe.co.uk/science-clinical-data/liquids-vs-pills.html

Best practices for molding bioresorbable materials for medical devices

By Raghu Vadlamudi
Chief Research and Technology Director, Donatelle



About the author

Raghu Vadlamudi is the Chief Research and Technology Director at Donatelle. He has more than 25 years of experience in the medical device manufacturing industry managing process development groups, directing and coordinating process validation activities utilizing knowledge-based manufacturing practices. Raghu is an ASQ certified Medical Device Auditor, Certified Metal Cutting Professional, Certified Medical Device Compliance Professional, and a Certified Process Validation Professional. Raghu also serves on the advisory board of Plastics Engineering Department at University of Wisconsin, Stout.

About Donatelle Plastics Inc.

At Donatelle, we make products that enhance – and save – lives. We manufacture complex medical devices and components for low- and high-volume needs. That's all we do. And we do it with the utmost precision, consistency, and rigor, because for you – and your customers – **quality is essential. Reliability is a must. And delivering on what's promised is vital.**

Learn more about how we can help bring your medical devices to market – with confidence.

Contact +1.651.633.4200
Visit donatellemedical.com

Donatelle
Manufacturing that changes lives®