Molding Bioresorbable Materials for Medical Devices and Components

Taking full advantage of bioresorbable materials in medtech requires an understanding of each material’s strengths, production challenges, and ideal applications.
Bioresorbable materials, which dissolve and are absorbed into the body, represent the cutting edge in medical device performance. From load-bearing applications to drug delivery, 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 — as well as dispelling misconceptions surrounding the use of injection-molded bioresorbable products because of costly and inconsistent parts produced using improper practices — allows device manufacturers to take full advantage of the utility offered by such materials. Equally vital is identifying a molding partner experienced with bioresorbable materials, who can work with a manufacturer to develop a process that minimizes waste and delivers consistently high product quality.

**Bioresorbable Material Use In Medtech Is Expanding**

Implantable bioresorbable materials have been in use for more than 25 years. Most products made from such materials are standalone components (i.e., they are not integrated into a larger device or assembly). A common application is bioresorbable sutures, used to tie skin together following surgery or some other wound. Metal staples have been (and still are) used, but dissolvable staples give healthcare providers an option that does not need to be removed from the body once the wound has adequately healed. In neurology, tiny iterations of these bioresorbable staples are trusted with the delicate task of binding together brain tissue.

Bioresorbable screws used in orthopedic applications and bioresorbable cardiac stents operate under the same principle. Dissolvable screws support tissue growth and, as the patient’s condition improves, they are absorbed into the body — 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 in popularity in combination product applications because of the efficiency they can provide. For example, when a patient takes a tablet orally, only a low percent of the therapeutic is absorbed by the body because of the inherent inefficiencies of that delivery system. When the drug is embedded in a bioresorbable material, the manufacturer is able to precisely control its rate of release, and none of the drug is wasted, making bioresorbables a more efficient and dependable delivery system.

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

**Bioresorbable Product Manufacturing Considerations**

Bioresorbable materials are generally composed of either polylactide (PLA), polyglycolide (PGA), or polycaprolactone (PCL), as well as formulations that combine those materials in differing amounts. For example, a polylactide-polyglycolide co-polymer can be formulated in different ratios, such as an 85:15 PLA/PGA combination or a 70:30 PLA/PGA combination.

Formulation usually is determined by the manufacturer and depends on how long the material is intended to stay inside the body — PLA generally survives longer in the body (i.e., dissolves at a slower rate) while PGA is absorbed more quickly — or by the 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. Thus, it is critical to maintain precise formulation and a consistent manufacturing process. Beyond formulation, the capability to mold a bioresorbable component depends on material availability, adaptability, and reproducibility, as well as material and manufacturing costs.

Availability, once the principal concern when only one or two suppliers globally existed for some materials, is less worrisome today. Not only do numerous suppliers now exist for most materials, but OEMs often compound their own materials to avoid issues associated with non-availability or shipping.

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 (that do not degrade the material or introduce variation).

Cost, in this context, 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. Further, in some cases, a
contract manufacturer cannot buy certain grades of material directly from the supplier, meaning the OEM may need to provide materials to the CM.

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. Conversely, Donatelle uses micro systems that minimize material use when molding small parts, and thus do not waste valuable material.

How Donatelle Ensures Consistent Bioresorbable Product Quality

When Donatelle creates a manufacturing process for a bioresorbable product, we develop the molding process in conjunction with our customers so they can perform testing after the part is molded. Once that part and process are approved, we 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. Donatelle has nearly 50 years’ experience manufacturing implantable components for the medical device industry, experience that has optimized our ability to handle various materials, minimize waste, develop the manufacturing process, and ensure we have in place consistent, robust validation practices for that manufacturing process.

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. Thus, it is imperative to meticulously collect and document information during the development and manufacturing processes, allowing for traceability and investigation after the fact. This documentation also aids in maintaining systems and the validation process.

Donatelle boasts manufacturing knowledge for a multitude of materials, but when customers approach us with a new formulation or part design, we need to discover its moldability by putting it through the manufacturing process. We may find out a certain part cannot be molded as intended (e.g., a particularly thin section or long section does not fill in properly). In such cases, we explain the issue to the customer and then collaborate to determine whether the solution is to alter the material composition or part design. OEMs often have difficulty finding a vendor who can provide these services consistently. Donatelle’s experience empowers us to understand the rigors of the device industry, as well as implantable device and component manufacturing, whether for novel products or customers already producing implantable components who wish to advance their product lines with bioresorbable products.

Finally, consider that every secondary operation undertaken at another location introduces risk for something adverse to happen to a part. Donatelle offers bioresorbable component customers a vertically integrated facility, receiving raw materials and performing all activities in one location before sending the finished product out for sterilization — ensuring complete control of the manufacturing process. To learn more, contact the author or visit us at https://www.donatellemedical.com/capabilities/bioresorbable/.
ABOUT DONATELLE

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.

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Raghu Vadlamudi is the chief research and technology director at Donatelle, located in New Brighton, MN. He has more than 20 years of experience in the medical device manufacturing industry, managing process development groups, and directing and coordinating process validation activities utilizing knowledge-based manufacturing practices. Vadlamudi is an ASQ-certified medical device auditor, certified metal cutting professional, certified medical device compliance professional, and certified process validation professional. He also co-authored a chapter titled “Process Troubleshooting” in an Injection Molding Handbook published by Hanser Publishing Company, Germany. Vadlamudi currently serves as a Plastics Engineering Advisory Board member at University of Wisconsin-Stout.

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