



Implantable Polymer Compounds

Custom Polymer Solutions for Implants

Delivery Science, a business unit of Foster Corporation, specializes in custom compounding polymers and additives used for human implants. Finished forms range from pellets for molding to extruded shapes. We offer prototype development through commercial production in an environmentally controlled clean room.



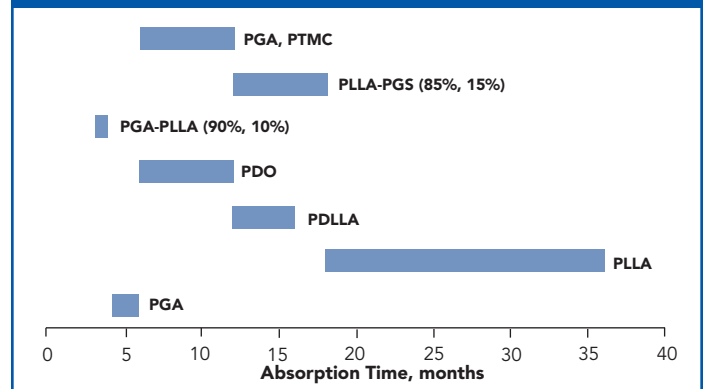
CUSTOM BLENDS & FORMS

POLYMERS

Polymers commonly used in implantable devices can be categorized based on anticipated duration of the polymer in the body ranging from long-term implantables, bioresorbable, to water soluble pharmaceutical polymers.

Long-Term Implantables – These include non-resorbable polymers such as polyethylene and polyurethane for combination medical devices and polyketones (e.g., PEEK) for spinal and orthopedic applications that require structural performance approximating bone.

LENGTH OF TIME BIORESORBABLES REMAIN IN THE BODY



PGA-PTMC = Polyglycolic Acid – Poly-Tri-Methylene-Carbonate
PLLA-PGS = Poly L- Lactide Acid/Poly Glycerol Sebacate
PGA- PLLA = Polyglycolic Acid/Poly L- Lactic Acid

PDO = Polydioxanone
PDLLA = Poly – DL- Lactic Acid
PLLA = Poly – L- Lactic Acid
PGA = Polyglycolic Acid

Bioresorbables – These include polylactide (PLA), polyglycolide (PGA) and copolymers of PLA/PGA which can be tailored to meet mechanical performance and resorption rates required for applications ranging from non-structural drug delivery applications to resorbable screws and anchors.

Pharmaceutical Polymers – These include polymers such as polyvinylpyrrolidone (PVP), polyethylene oxide (PEO), methacrylate and cellulose with applications ranging from soluble drug delivery film to coatings for increased lubricity.

ENHANCEMENTS

Biocompatible polymers can be enhanced to improve application performance such as visibility under x-ray, stimulation of bone growth, or local delivery of drugs to the therapeutic site.

Radiopaque – Polymers are inherently transparent to x-ray imaging and require specific additives to achieve visibility. Radiopaque fillers commonly blended with polymers for radiopacity include barium sulfate, bismuth subcarbonate, bismuth trioxide, bismuth oxychloride, and tungsten.

Bone Mineral – Phase pure β TCP (tricalcium phosphate) is an osteoconductive and biocompatible additive melt blended with bioresorbable polymers such as PLA for stimulation of bone growth in applications such as ACL screws. Alternatively, hydroxyapatite (HA) may be blended with bioresorbable polymers such as PLLA for interference screws for anterior cruciate ligament (ACL) reconstruction.

Active Pharmaceutical Ingredients (APIs) – Drug eluting implants may provide therapeutic benefits such as controlled release and local drug delivery. Selective APIs with suitable temperature profiles may be compatible with low melt temperature polymers for combination products.

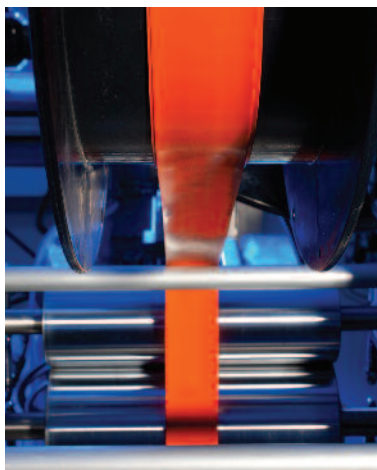
DELIVERY FORMS

Pellets – A wide range of pellet sizes can be achieved including micro-pellets (0.029in-0.047in/0.5mm-1.2mm) and traditional pellets (0.059in-0.118in/1.5mm-3.0mm) for capsule filling, implantable doses, or post processing structural parts.

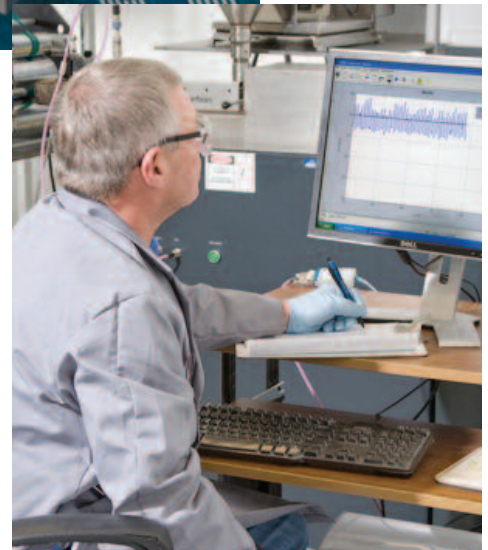
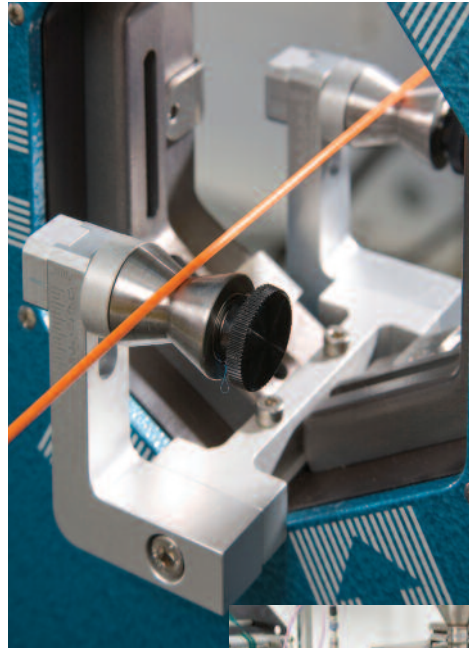


Fiber – Monofilament fibers are available with diameters ranging from 0.012in-0.028in (0.30mm-0.7mm) for sutures, woven structures and more. Tensile properties depend upon the material type and application requirements.

Film – Film sizes range from 1.969in-3.937in (50mm -100mm) wide with thickness of 0.0012in-0.0394in (0.03mm-1.00mm) for transdermal patches, bucal patches, implantable wraps and more.



Tubes – Implantable tubes can be made to meet specific application requirements. Single lumen, single materials are most common for implants with diameters as small as 0.0098in (0.25mm) with wall thicknesses as small as 0.0004in (0.01mm).



DEVELOPMENT SERVICES

Implants and drug delivery systems are the most highly regulated products in the medical market. Effective product development that can be validated and scaled to production is essential. We offer a complete range of services throughout the product life cycle.

- Formulation – Material Selection
- Feasibility – Small Batch Production
- Process Development – Non-GMP Process Definition
- GMP Trials – Clinical Supply
- Scale-Up – Maximization of Throughput
- Validation – Process & Test Methods
- Production – Implement Manufacturing Protocols



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