FOSTER

Foster Corporation

Polymer Compounding & Services for Medical Device Manufacturing

POLYMER SOLUTIONS

that enable medical device technologies and improve the quality of life

The building blocks of advanced medical devices are polymers tailored to achieve specific performance properties. For more than three decades, Foster Corporation has been a leading supplier of these custom compounds for medical applications, blending standard polymers with performance additives or other polymers to achieve properties specific to each device. Our services support projects from formulation development, to prototype and development, through to production scale up.

SERVICES

Formulation Development

Our Medical Plastics Innovation Center includes a wide range of capabilities for comprehensive material development, including twin screw extrusion, injection molding, film extrusion, tubing extrusion, polymer testing and characterization.

Color Matching

Our color matching capabilities cover thousands of PMS color specifications and countless custom shades. Biocompatible organic and inorganic pigments can be added to unmodified polymers or custom compounds.

Custom Melt Compounding

Our biomedical polymer manufacturing operations include co-rotating twin screw extruders ranging in size from 27-53 mm. A range of pre and post extrusion equipment maximizes quality, consistency and throughput.

Clean Room Compounding

A class 10,000 cGMP clean room is equipped with GMP compliant designed extrusion equipment, highly accurate feeders, and fully integrated computer process controls and monitoring systems for manufacturing of implantable materials.

Dry Blending

Dry blends are prepared without the presence of heat, thereby reducing the potential for thermal degradation. Dry blending is an economical and practical process method for those applications with less rigorous performance or appearance requirements and a greater emphasis on cost.

Toll Compounding

Toll compounding services are available for material manufacturers or other customers who have developed a compound formulation and require our compounding expertise.

Testing Services

In addition to our standard tests performed on each lot of material, we offer a range of additional tests for Foster products on a contract basis, including viscosity, ASTM standards, Fourier Transform Infrared (FTIR), Thermal Gravimetric Analysis (TGA), Differential Scanning Calorimetry (DSC) and more.

Regulatory Support

The Foster Regulatory Department is available to assist with regulatory compliance, testing and FDA submission, including but not limited to Safety Data Sheets (SDS), REACH, ROHS, Conflict Minerals, Latex, BPA, Phthalates, Animal Origin, and FDA 21 CFR.

POLYMER EXPERTISE

Elastometric Compounds

As a leader in polymer compounds used for minimally invasive devices, including diagnostic and therapeutic catheters, Foster has developed a core competency in the custom compounding of thermoplastic elastomers.

- Thermoplastic Olefins (TPO)
- Thermoplastic Vulcanizates (TPV)
- Copolyester Elastomers (COPE)
- Styrenic Block Copolymers (SBC)
- Thermoplastic Urethanes (TPU)
- Polyether Block Amides (PEBA)

Fluoropolymer Compounds

All our fluoropolymer compounds are manufactured using a twin screw extruder with corrosion resistant Hastelloy metal coating on all contact surfaces. Multiple and down-stream feed ports allow for inputting raw materials at the appropriate stage in the extrusion process.

- Fluorinated ethylene propylene (FEP)
- Perfluoroalkoxy (PFA)
- Polyvinylidene fluoride (PVDF)
- Polyethylenetetrafluoroethylene (ETFE)
- Polychlorotrifluoroethylene (PCTFE)
- Polyethylenechlorotrifluoroethylene (ECTFE)

High Performance Polymers

Since inception we have focused on blending performance materials for critical applications. Our range of precision, twin-screw compounding equipment makes us ideally suited for custom compounding high performance thermoplastics.

- Polyetheretherketone (PEEK)
- Polyphenylsulfone (PPSU)
- Polysulfone (PSU)
- Polyetherimide (PEI)
- Polyethersulfone (PESU)

Bioresorbable Polymers

Foster Corporation specializes in melt extrusion blending and forming. Compounds formulated with these bioresorbable polymers are manufactured in a cGMP clean room production facility using twin screw extruders that incorporate cGMP design for medical applications.

- –Polymers - Polylactide (PLA), polyglycolide (PGA) and copolymers of PLA/PGA tailored to meet mechanical performance and resorption rates required
- –Bone growth additives - Tricalcium phosphate (TCP), Hydroxyapatite (HA)

MARKETS

General Medical
including disposable medical products and single use devices

Minimally Invasive
Including catheters and surgical instruments

Implants
Including permanent and bioresorbable devices

Non-Medical
Applications in semiconductor, aerospace, military and other markets

ADVANCED TECHNOLOGIES

Radiopacity– Additives that provide visibility of polymers under x-ray and fluoroscopy for device used in interventional cardiology and radiology, neurology and implants. Additives include barium sulfate, bismuth subcarbonate, bismuth oxychloride, bismuth trioxide, tungsten, and LoPro® Compounds.

Lubricity– Additives that reduce coefficient of friction of the base polymer, improving functionality of contacting surfaces such as minimally invasive catheters, handle triggers, buttons and gears. These include polytetrafluoroethylene (PTFE), fluorinated oil, Propell™ surface modification additives and PureEase™ process modification additives.

Antimicrobial– Additives that help to reduce the risk of infection for applications that contact the body for extended periods of time, such as including catheters, wound dressings, hospital bedding, surgical drapes, and hospital gowns. These include Combat™ silver-based antimicrobial additives.

Colors– Custom pigmenting of polymers for functional or aesthetic purposes in a wide range of medical applications. For devices in contact with the human body, pigments include those listed under Title 21 of the Code of Federal Regulations (CFR) Parts 73 & 74, Subpart D which are certified by the FDA and exempt from batch certification. Color options include pre-colored formulations and Medi-Batch™ color concentrates.

Reinforcements– Additives that enhance the structural performance of medical polymers while maintaining flexibility, ductility and surface finish. These blends are well suited for catheter shafts and balloons. These include Nanomed® and Nanomed MAX® compounds.

Selective Enhancements– Additives that retain properties of the formulation through exposure to heat, light, oxygen or other manufacturing or environmental conditions. These include heat and UV light stabilizers like HLS™, hydrophilic additives, antioxidant additives, and processing aids.

MEDICAL PLASTICS INNOVATION CENTER

Twin Screw Compounding–
Sample Development

Extrusion Line–
Process Evaluation

Injection Molding–
Test Samples

Mechanical Property Testing

Environmental Chamber

PROPRIETARY TECHNOLOGY	DESCRIPTION	BENEFIT
LoPro™ radiopaque compounds	*Radiopaque fillers for thin wall devices, such as catheters*	*Consistent imaging performance*
Propell™ surface modification	*Additives that reduce friction and tackiness of low durometer polymers*	*Improves component functionality* *May eliminate additional processes*
PureEase™ process modification	*Additives that improve processing and handling of TPUs*	*Improves process handling* *Improves yields*
Medi-Batch™ color concentrates	*Pigments certified to FDA 21 CFR 73 Subpart D*	*Economical alternative to pre-coloring* *Expedites regulatory approval process*
Nanomed™ reinforcement	*Nanoparticle reinforcement additive for thin wall devices*	*Improves strength and retains flexibility* *Enhances barrier properties*
HLS™ stabilization	*Heat and UV light stabilizer additives*	*Retains properties after processing* *Extends shelf life of components*

QUALITY

Our mission is to remain the industry leader in the design and manufacture of critical polymers and compounds by providing our customers with defect-free, cost-effective, highly-engineered materials in a timely manner. We accomplish this through innovative development of new materials, employment of advanced manufacturing processes, employment of a dedicated staff trained in excellence at all levels, maintaining our customer-oriented focus, and adherence to rigorous quality, safety, and environmental standards.

The Foster Quality Management System is registered to ISO 13485: 2016.

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