

Market – Medical

From Implantable Devices to Disposable Items

Spectrum Plastics Group has the infrastructure, resources and expertise to handle a wide range of molding services for the medical marketplace. You handle product design and distribution and we will handle everything for you. We understand it is critical to develop processes capable of maintaining tight and repeatable outcomes in the molding and assembly of your components and devices. Spectrum Plastics Group understands the documentation requirements to serve this market.

Implantable Devices –

For 50+ years, Spectrum Plastics Group has been involved in the injection molding, assembly and supply base management of implantable devices. We are a major supplier to the orthopedic, dental, drug delivery, sport medicine, implantable component, and medical device market.

As a pioneer in the field of thermoplastic implantable components, we have continued to expand our capabilities to support the biomaterials sector. As new materials are developed and Device Master File (DMF) is filed, we are an early stage developer of production molding processes for new materials to bring your device to market. For many years, we have processed a variety of resins previously utilized in other industries. Some of these same resins are now available for implantable applications, making Spectrum Plastics Group highly experienced and qualified to efficiently support your implantable program.

Our medical contract manufacturing/molding experience ranges from all grades of bio-resorbable/bio-absorbable material, PEEK-OPTIMA®, polyurethane, liquid silicone rubber, polysulfone, polyphenylsulfone including Solviva™ Biomaterials with recent DMF's filings (Zeniva™ PEEK, Promiva™, Veriva™ PPSU, and Eviva™ PSU), which all can be used for implantable devices.

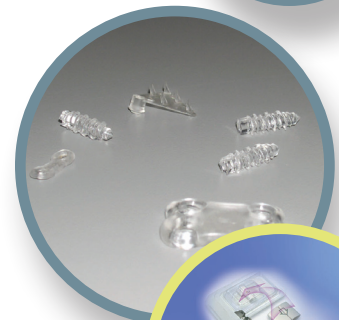
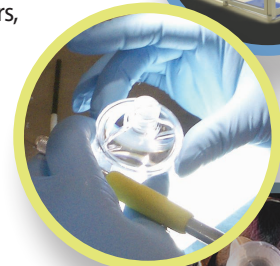
Medical Devices • Surgical Instruments • Dental Components –

Spectrum Plastics Group provides tight tolerance and cosmetic injection molding for numerous components. We insert mold (manual or automated insert loading), and over-mold (both over molded plastic components or Mylar™ strip) many engineered materials for disposable devices and medical instruments.

We mold a wide range of items for the laparoscopic, orthopedic and endoscopic medical market segments; from commodity to highly engineered resins, and simple to complex geometries. Items we have molded include precision molded knobs, handles, rack and pinions, covers, enclosures, medical staplers and insert molded needles. Spectrum Plastics Group also manufactures many disposable products such as dental vials, cervical scrapers, and packaging components.

We mold varying volumes of product and have developed molding cells and methods capable of supporting programs needing low, medium and high volume production. We have experience designing and developing molds from a single cavity with a simple sprue gate to 64 cavities with a complete custom built hot runner delivery system with valve gates.

Our medical contract manufacturing experience includes: assistance with part design, design for manufacturability and assembly, rapid prototyping, rapid tool development, Operational and Process Qualification development, production, medical packaging, and sterilization management.



Our full service capability acts as an extension of your current engineering and manufacturing by providing the following group of services:

Design & Engineering Services

- Rapid Prototyping (SLA, LS, RTV Castings, CNC Machining)
- Rapid Tooling (aluminum, P-20, or hardened steel)
- Product Design Support
- Design for Manufacturability and Assembly (DFM & DFA)
- MoldFlow Analysis
- Resins / Materials Expertise
- Tool Design and Build
- Molding Process (developed and validated utilizing decoupled/scientific molding methodology)
- Gage R & Rs
- Value Analysis / Cost Reduction
- Secured Electronic Communication

Manufacturing Services

- Injection Molding, Insert Molding, Over-Molding, Reel-to-Reel Molding, Micro Molding and Liquid Silicone Rubber (LSR) using Liquid Injection Molding (LIM) Technology (all available for low, medium and high volume production)
- Cell manufacturing technology utilizing automation and vision inspection
- Advanced CNC Plastic Machining (including tight tolerances, critical features and non-moldable geometries)
- Assembly & Sub-assembly (manual, semi-automated or automated)
- Stringent Process Qualification & Validation Methods (in process, on-going, and final testing as required)
- Molding Process (developed and validated utilizing decoupled/scientific molding methodology)

Value-Added Services

- Decoration (pad printing, hot stamping, screen printing, painting and decal application)
- Adhesive, Heat, Spin, Vibration, Solvent and Ultrasonic Welding
- Annealing
- EMI and RFI shielding
- Electro-less & Electrolytic Plating
- EM (Electro-mechanical) Assembly
- General Assembly (manual and semi-automated)
- Maintain Device History Records (as required)

Quality Registrations

- ISO 9001:2008
- ISO 13485:2003
- cGMP 21 CFR, Section 820 Compliant

To find out more, go to: www.spectrumplasticsgroup.com

Have a project you'd like to discuss?

Contact at us at sales@spectrumplasticsgroup.com

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One Stop...Taking Your Design from Prototype through Production

- Design & Engineering
- Design for Manufacturability
- Rapid Prototyping
- Rapid Tooling
- Tool Design & Build
- Injection Molding Technologies
- Value-Added Services
- Medical Packaging
- Sterilization Management

Certifications

- ISO 9001:2008
- ISO 13485:2003
- cGMP 21 CFR, Section 820 Compliant

