

Pharma



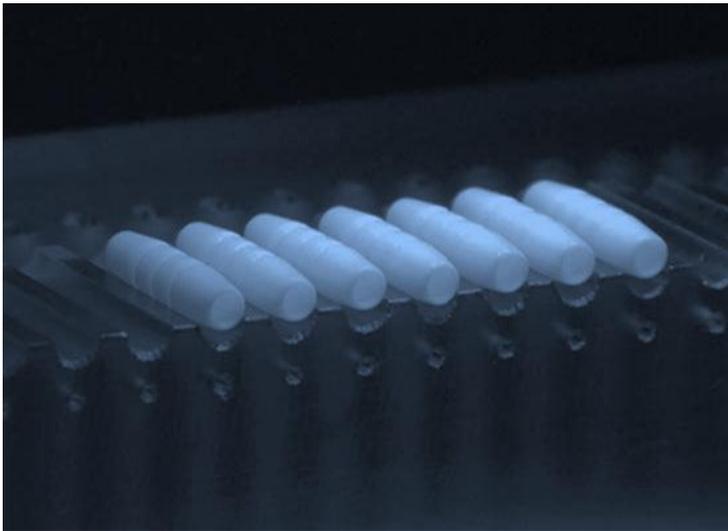
Pharma

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The ProMed Pharma Story

For over 20 years, ProMed Molded Products has specialized in the molding of small, intricately designed silicone components and sub-assemblies. In 2006, ProMed Pharma leveraged this expertise to begin production of polymer-based drug releasing implants and combination device components. Working with both established and early-stage medical device and pharmaceutical companies, we develop robust manufacturing processes and platforms for controlled release of drugs from a variety of materials.

Markets and Applications

Key markets for our services include cardiovascular, neurology, and orthopedics. Representative drug-device applications include steroid-eluting pacing and defibrillation leads, drug eluting stents and balloons, antimicrobial catheters, and wound or joint spacers. ProMed also supports pharmaceutical companies developing extended release formulations utilizing subcutaneous implants, intrauterine devices, intravaginal rings, and ophthalmic implants.

Drug Product Capabilities and Facilities

- Silicone molding - transfer, liquid injection, insert and compression molding
- Plastic injection molding - bio-material options such as ethylene vinyl acetate (EVA), polysulfone (PSU), polyether ether ketone (PEEK), and poly (lactide co-glycolide) (PLGA)
- Experience with steroids, hormones, anti-proliferatives, and microbicides
- Micro molding of parts as small as .001g, minimum shot size of .05g
- Design assistance, tooling, molding and assembly
- Dedicated presses and mixing equipment for pharmaceutical products
- Class 10,000 clean rooms, Class 5 isolators
- More than 10,000 square feet of available manufacturing space for new pharma operations



Quality Assurance

ProMed utilizes both in-house testing and partnerships with state-of-the-art analytical facilities to ensure that drug content, drug elution, purity, mechanical strength, and dimensional specifications are consistently met. ProMed Pharma's Quality Assurance is dedicated to delivering drug eluting components of the highest quality that can be used in implantable pharmaceutical products and/or life sustaining medical devices. The Quality System is compliant to 21 CFR 820, applicable sections of 21 CFR 210 & 211, and is ISO13485 certified. ProMed Pharma is registered with the FDA, and has an exceptional inspection history.