

#### Saint-Gobain Life Sciences – Medical Components



## Saint-Gobain

### **Medical Market Capabilities**

A world leader with unparalleled material expertise in silicone, thermoplastic elastomers and fluoropolymers, Saint-Gobain is the processing expert in molding, extrusion and allencompassing custom fabrication for medical OEMs, contract manufacturers and design houses. Our tradition of excellence goes back more than 300 years through our parent company, Compagnie de Saint-Gobain, one of the world's top 100 industrial corporations, with operations in more than 60 countries. We leverage our global technology to provide worldwide advanced materials research, polymer processing and manufacturing support unmatched by any competitor.

Our company offers ISO Class 7 and 8 cleanrooms for medical device component manufacturing as well as compliance to many ISO regulations. In addition to molding and extrusion, Saint-Gobain supports customers through value-added services and supply chain solutions that may include assembly operations and kanban systems.

Leading the way through our global resources and technological expertise, we are committed to providing you with outstanding quality and exceptional value by developing innovative, high-performance solutions for your medical device needs.

Our engineers stand ready to partner with you throughout the entire life cycle of your product - from design and development to prototype and tool build into full production.

#### Who We Are

Saint-Gobain specializes in fluid management solutions including components and tubing for medical device manufacturers. Through our expertise in silicone, thermoplastic elastomers and fluoropolymers, we produce high quality products such as TYGON® tubing, Bio-Sil® tubing, and custom fabricated parts such as filters, seals, gaskets, valves and other fluid management components.

#### **Market Segments**

- Cardiology
- Ophthalmology
- Wound Therapy
- Diagnostics
- Minimally Invasive Surgery
- Nutrition
- IV Delivery
- Endoscopy
- Disposables
- Renal Dialysis
- Advanced Drug Delivery

\*Please contact us if you do not see the market you are looking for, we can help you.



#### **Advanced Molding** and Fabrication

Saint-Gobain is a global leader in silicone molding and custom silicone fabrication. Based on the design, material and cost requirements for your medical device component, our design and project engineers will work with you to determine the optimal molding process for your particular application.

#### Silicone Micromolding

- Liquid injection molding
- High consistency molding
- Insert molding
- Transfer molding
- High volume molding

#### Silicone Micromolding

- Complex part geometries
- Parts as small as 0.001g
- Mold tolerances as low as 0.0001"
- Part tolerances as low as 0.001"
- Hole sizes as small as 0.003"
- Thin wall sections to 0.0015"
- Undercuts, threads, blind shutoffs

#### Two-Shot Silicone + **Thermoplastic Molding**

- Reduced part cost
- Greater design freedom
- Elimination of assembly
- Improved performance & quality
- Increased bond strength
- Reduced handling & validation costs
- Product to the market faster

#### **Global Presence, Local Resource**

#### State-of-the-Art Extrusion

#### Silicones, Thermoplastic Elastomers & Fluoropolymers

Saint-Gobain is the world's leading producer of engineered, highperformance polymer extrusion products. Our core competency lies in our process technologies that transform difficult-to-process materials into useful extrusion products for medical OEMs, contract manufacturers and design houses. These materials include fluoropolymers (PTFE, PFA and FEP), silicone rubber and a range of other high-performance engineered polymers.

Tapes

Custom formulations

- Single and multi-lumen tubing
- Paratubing
- Round or profile tubing
- Microbore tubing
- Coextrusions up to five layers

#### Prototyping & Tooling

With our in-house tooling design and build services for extrusion and silicone molding, Saint-Gobain improves your control over the prototyping and production processes. Our dedicated development center partners with you throughout the design and development phase to provide a manufacturable design and material that meets your device requirements, delivering a functional and affordable silicone component as quickly as possible.

#### Custom Compounding

Saint-Gobain specializes in custom material blending and compounding, including high & low durometer formulations, color matching, and more, all designed to meet your specific material requirements. Our highly skilled team of applications engineers, process engineers and chemists are available to assist you in developing and commercializing new products. Each of our manufacturing sites is equipped with a material testing lab to ensure that raw materials, in-process, and finished products meet design specifications and the highest quality levels.

#### On the web at:

#### www.medical.saint-gobain.com

To find out more about how Saint-Gobain can meet your medical manufacturing needs, call (800) 236-7600 or email us at medical@saint-gobain.com Follow us on Twitter @SG\_LifeSciences Follow us on LinkedIn Saint-Gobain Life Sciences

Radiopaque and corrugated tubing

Custom lengths and packaging

Important: "Please refer to our Medical Products Disclaimer at www.medical.saint-gobain.com/resources/regulatory-and-quality/ medical-product-disclaimer. Saint-Gobain's medical products offer covers:

- Medical Components [21 CFR 820.3(c)], intended for processing or use in the manufacture or assembly of medical devices before the finished medical device is packaged/labeled; Medical Components are intended to be included as part of the finished, packaged, and labeled device [21CFR820.3(c)].

Finished Devices [21CFR820.3(I)] made on behalf of medical device manufacturers [21 CFR 807.20(a)(2)] under contract-manufacturing agreement. In accordance with the United States' jurisdiction, Saint-Gobain complies with the FDA's requirements for contract manufacturers of finished devices

**IMPORTANT:** It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Performance Plastics tubing for all intended uses. Laboratory and clinical tests must be conducted in accordance with applicable regulatory requirements in order to determine the safety and effectiveness for use of medical products in any particular application.

For a period of 6 months from the date of first sale, Saint-Gobain Performance Plastics Corporation warrants this product to be free from defects in materials and workmanship. Our only obligation will be to replace any portion proving defective, or at our option, to refund the purchase price thereof. User assumes all other risk, if any, including the risk of injury, loss or damage, direct or consequential, arising out of the use, misuse, or inability to use, this product. THIS WARRANTY IS IN LIEU OF THE WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, AND ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. No deviation is authorized.

Saint-Gobain Performance Plastics Corporation assumes no obligations or liability for any advice furnished by it, or for results obtained with respect to those products. All such advice is given and accepted at the buyer's risk.

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