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EXTRUSION

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Plastic extrusion is a steady-state process for converting a thermoplastic raw material to a finished or near-finished product. The raw material is usually in the form of plastic pellets or powder. The conversion takes place by forming a homogeneous molten mass in the extruder and forcing it through a die orifice that defines the shape of the product's cross section. The formed material, or extrudate, is cooled and drawn away from the die exit. The extrudate can then be wound on a spool or cut to a specified length.

By contrast with injection molding, which is a cyclic process, extrusion is a steady-state process. Extruded products are long and continuous, and have a cross section that is usually constant with respect to the axis or direction of production. Injection-molded products are discrete items with varying cross sections in each axis.

Equipment. The major components of an extruding system are the drive, hopper, feed screw, die system, and heating and cooling elements. The drive consists of a motor or belt drive, which should be linked to the extruder through a double reduction gearbox; such an arrangement helps to transform the high speed of the motor into the lower speed and high torque required for the extruder. The hopper should hold enough resin pellets or granules to last at least two to three hours; when medical products are being extruded, the hopper's flow restrictors should be left fully open for "flood feeding," which ensures adequate flow of material to the screw.

The feed screw delivers a homogeneous flow of material to the die assembly at a constant melt pressure and temperature. Screw speed is the strongest contributor to raised melt process temperatures, which can result in a weakened extrudate. To ensure good material performance, screw speed should be monitored to keep temperatures as low as possible.

Several types of dies are used in medical product manufacturing, including sheet dies, profile dies, tubing dies, and coating dies. In-line dies (parallel to the extruder path) are commonly used for sheets, profiles, and tubing; cross-head dies (90° to the extruder path) are used for tubing and coating; angle dies (any setting other than 90°) are used when more than one extruder is being employed to make a single product (such as striped or multilayer tubing).

Cooling of the extrudate is most often accomplished through the use of an open cooling trough or a vacuum sizer. Other equipment options include the use of an extrudate puller, which can help the manufacturer control the tolerances of completed products; this can be an important factor in medical device manufacturing.

Materials. Extrusion techniques can be used to process most thermoplastics and some thermoset plastics. The resins most commonly extruded for medical applications include polyethylene, polypropylene, polyurethane, polystyrene, fluoropolymers, polyamide, polyester, and flexible polyvinyl chloride. A characteristic that often differentiates extruded from injection-molded plastics is the viscosity of the plastic at normal processing temperatures. Extruded plastics often have a higher melt viscosity, which allows the extrudate to retain the shape imparted to it by the die while the extrudate is in the quenching stages.

Combinations of various resins can be used to gain special physical, biological, or chemical properties. Many additives can be used during the extrusion process to enhance processing characteristics of the polymer or to alter product properties. Such additives include lubricants, thermal stabilizers, antioxidants, radiopacifying agents, and colorants.

Processing Parameters. The parameters important to extrusion processing are similar to those of injection molding processes. Resin temperature, resin pressure, resin moisture content, screw speed, and screw motor amperage are usually controlled or monitored to provide a homogeneous melt at a controlled volumetric rate. Quenching temperature and the rate at which the extrudate is drawn are controlled or monitored to provide a controlled product size. Dimension measurements, using a variety of gauging methods, can be taken of the extrudate as it is produced. In contrast to injection molding, extrusion can vary the size of the final product without changing the die tooling. Common extrusion production tolerances are within 1% of the nominal measured value.

Design Considerations. Extruded medical products fall readily into two categories: those having just one resin in the product cross section, and those having more than one. The first category includes tubing with single- or multilumen profiles, films for product packaging, and sheets that can be postformed into fluid containers. The second category includes catheter tubing with encapsulated striping, and multilayer tubing, films, and sheets.

Various materials can also be encapsulated within the extrudate to provide additional properties. Fibers can be braided in to increase burst strength. Stainless-steel wires can be added to improve kink resistance or to provide electrical conductivity. Fiber-optic bundles can carry images or illumination. Each of these techniques has potential for use in medical device manufacturing.