



GRAHAM ENGINEERING

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PROCESSING AND WORKPLACE SAFETY TIPS FOR FLUOROPOLYMER MEDICAL TUBING

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Recently Graham Engineering Corporation has received a number of inquiries from medical tubing processors with an interest in venturing into the world of fluoropolymers. Materials such as FEP, PFA, PVDF and ETFE are known for their excellent physical properties and hold promise for many medical applications, such as micro tubing for intravenous (IV) catheters and insulin infusion, single lumen and multi-lumen tubing for endoscopy and cardiology devices, and heat shrink tubing used as a manufacturing aid for catheter reflow purposes. Our American Kuhne extrusion systems have been employed for such applications.



Graham Engineering Corporation's Steve Maxson

Here are some important considerations that we have identified regarding extrusion equipment and safety related to processing fluoropolymers:

Components that come in contact with molten resin such as the die head, tooling, adapter, breaker plate, and screw should be made of corrosion-resistant metals with high nickel content like Inconel 625 or Hastelloy C276. For corrosion protection of the extruder barrel, I recommend a tungsten carbide/nickel-based bimetallic barrel liner such as X800[®]. For small medical extruders, 1.25-inch (32 mm) and smaller, the entire backing material of the bimetallic barrel is solid Inconel and the liner material is X800[®].



FEP intravenous catheter tubing

The typical fluoropolymer screw is a single-flight design with a 3:1 compression ratio. In some cases a low-shear Saxton-type distributive mixer is included at the end of the screw. Although Inconel and Hastelloy are corrosion resistant, these specialty metals have low torsional strength compared to common screws that are made of 4140 or 4340 heat-treated steel. For instance, Hastelloy 625 has a yield strength of approximately 52,000 psi (359 MPa), about half that of 4140 steel at 28-32 Rc. Inconel 625 is a little stronger than Hastelloy C276 but is not as corrosion resistant. Care must be taken to avoid screw breakage when using an Inconel or Hastelloy screw while processing other high temperature polymers that are not corrosive such as PEEK, Polysulfone (PSU), and Polyetherimide (PEI). For example,



a 1-in. (25mm) extruder with a 5HP motor geared for 100RPM screw speed is very likely to snap a screw made from Hastelloy 625 during a cold start situation.

Fluoropolymers have high melting points. For instance, PFA has a melting point at about 305°C (581°F). The barrel set points for FEP are in the 600-740°F range; therefore the extruder barrel heaters should be made from cast bronze and rated up to 480°C (900°F). Due to the high operating temperatures, a special dual-layer barrel safety shroud should be used over the barrel to protect the operator from burns.

Fluoropolymers are also highly susceptible to melt fracture (“shark skin” appearance) on the surface of tubing, caused by excessive shear in the die tooling gaps as output rates are increased. The typical approach to avoiding melt fracture is to utilize larger tooling gaps, which means making the tubing with a larger drawdown. Tooling drawdowns of 3:1 to 20:1 are common for many polymers, whereas processors of fluoropolymers have used drawdowns of 50:1 or greater.



Magnified view of melt-fractured surface

Proper safety measures are important to consider when processing fluoropolymers. According to the [“Guide to the Safe Handling of Fluoropolymer Resins,”](#) published by the Fluoropolymers Division of the Plastics Industry Association (formerly SPI), gases, vapors and fumes released during the extrusion of fluoropolymers may be harmful to human health.

Vapors and fumes released during extrusion and while cleaning the die head can cause flu-like symptoms (chills, headaches, fever) that typically pass within 24 to 48 hours. The corrosive gases should be captured immediately and removed with an exhaust ventilation system that includes extraction hoods, ducting, and a fan. Extraction hoods should be placed above the die head and, for large-diameter tubing, an additional extraction hood over the area where the tubing is cut to length. Sealed packages of fluoropolymer resins should only be opened in well ventilated areas. Consult the resin supplier’s MSDS for specific recommendations.

If you would like more information about processing fluoropolymers please contact me at smaxson@grahamengineering.com or visit our exhibit at MD&M West (Booth 1933), where we will have a compact modular American Kuhne extruder on display with two barrel modules including a high temperature corrosion resistant 1.0” barrel.

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