Shaping the future with engineering plastics

by Tim Brown

The demand for plastics in the medical industry in the United States will reach US$6.5 billion in 2012, mainly due to heightened concerns over infection control and increased use of disposable products. Packaging will clearly remain the largest market; however, lower volume engineering plastics are expected to significantly outpace commodity plastics.

The physical properties of engineering and high-performance plastics such as impact resistance, dimensional stability and resistance to autoclaving has enabled new and improved designs for medical devices and components. They offer color coding options, lighter weight and are easy to machine in comparison to commonly used metals such as stainless steel.

When referring to medical grade plastics, numerous requirements must be considered in choosing the correct plastic for an application. The technical requirements must always be evaluated, but often it is necessary to ensure the material is compatible with the human body. Simply asking the question, "Does this application require the plastic to be biocompatible?" will start you in the decision making process. If so, further questions are needed to determine the type and level of biocompatibility.

Instrument handles machined from Sustason PPSU MG (Radel®)

Primary considerations in choosing the type of plastic for Life Science applications are:

Will the plastic be in contact with the human body?

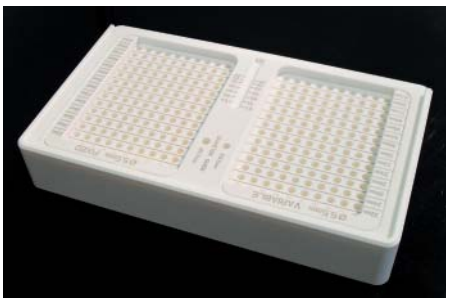
The chief basic regulations for biological testing and assessment of materials are ISO 10993 and USP VI. These include a series of tests for evaluating biocompatibility of a medical device prior to a clinical trial. For non-implant applications, compliance to ISO 10993-5 (in vitro cytotoxicity) is typically the most requested.

What are the structural requirements?

These factors help determine if an engineering or high performance plastic is needed. Engineering plastics are among the most common and useful thermoplastics and typically exhibit good mechanical properties. High performance plastics are generally defined by their ability to maintain their physical properties under thermal, chemical or electrical stress, while operating at elevated temperatures above 300°F/148.9°C. Amorphous thermoplastics are mostly transparent and their mechanical properties are almost unchanged over a wide temperature range, frequently right up to their continuous operating temperature. They include PPSU, PEI, PC and PPO. Partially crystalline thermoplastics are usually opaque, exhibit good strength, toughness and hardness and a great resistance to stress cracks. They include acetal, PP and PEEK.

Will sterilization be used and what type?

An essential aspect of selecting a suitable plastic in a medical application is also the requirement for repeated sterilization and disinfection of the product. The cleaning process typically occurs in autoclaving devices at elevated temperatures (greater than 250°F/121°C with steam or suitable disinfectants. The resistance of the polymer should be checked in each case. The most common type of sterilization is with steam (autoclaving) but there are other methods including hot air, ethylene oxide, plasma and gamma rays.



Medical tray machined from Polystone® P MG White

Regarding engineering and high performance plastics, the most commonly used in the medical and life science industries are:

PPSU: incredible toughness, high resistance to sterilization
PEEK: superior physical properties including high temperature stability
PEI: high heat resistance, high strength and broad chemical resistance
PSU: good chemical and repeated hot steam resistance
Acetal: excellent wear properties and very dimensionally stable
PP: easily machined and dimensionally stable when heat stabilized
PPO: excellent impact properties and stability
PC: high impact strength and transparent

To reiterate, finished products machined from plastics are used in a host of medical device and instrument applications. For those applications that come into contact with the human body, they require biocompatibility, and for those that do not come into direct contact, standard plastics are usually suitable. In many cases, the type of plastic and

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even the specific brand of raw material is listed in the specification from the OEM. Common medical and life science applications include:

- Surgical handles and grips for instrumentation
- Sizing trials for knee and hip replacements
- Fixations devices
- Endoscopic housings and eyepieces
- Sterilization trays and caddies
- Parts for X-ray and MRI devices
- Blocks and housings for dialysis machines
- Supports and adaptors for respiratory units
- Grips and handles for dental instruments
- Wear parts for pharmaceutical pill and tablet production
- Valve housings and nozzles for fluid distribution

Another important standard in the medical and life science industries is the Medical Device Standard of ISO 13485. Published in 2003, it represents the requirements for a comprehensive management system for the design and manufacturing of medical devices. Critical elements include controls to ensure product safety, risk management activities, inspection and traceability, documentation and validation of processes and verification of the effectiveness of corrective and preventive actions. For medical device OEMs, certification to this standard by their suppliers is becoming increasingly more important and, in some cases, required. ■

Röchling is ISO 13485 certified — Medical Grade Rods

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