How to Choose the Ideal Ultra Engineering Polymer for Your Extruded Medical Application

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There has been a profound shift in the medical industry where procedures have aimed to become more minimally invasive, quicker and more effective. The goal of this shift is to minimize patient recovery times, reduce the size of access incisions and to provide better patient outcomes through advanced medical procedures. These new methods necessitate new medical devices that tend to be more demanding of their components than in devices past. This requires medical devices and their components to use updated and advanced polymers. Many of these advanced materials fall under the general description of high heat polymers. We will refer to the high heat polymers discussed here as "ultra-engineering polymers" to identify that they reside at the pinnacle of performance within the engineering polymer designation. There are a wide range of these ultra-engineering high heat polymers but many of them are somewhat new to the plastics industry and some are relatively uncommon. Unfamiliarity with ultra-engineering polymers can prove challenging in choosing the ideal material for today's demanding and cutting-edge medical devices and components. I will identify several of the more common ultra-engineering polymers, potential applications, their general properties and their positive aspects and limitations. This white paper aims to inform all those responsible for choosing and specifying materials for devices and extruded components about the variety of ultra-engineering polymers that are available, so the ideal material can be chosen for your device.

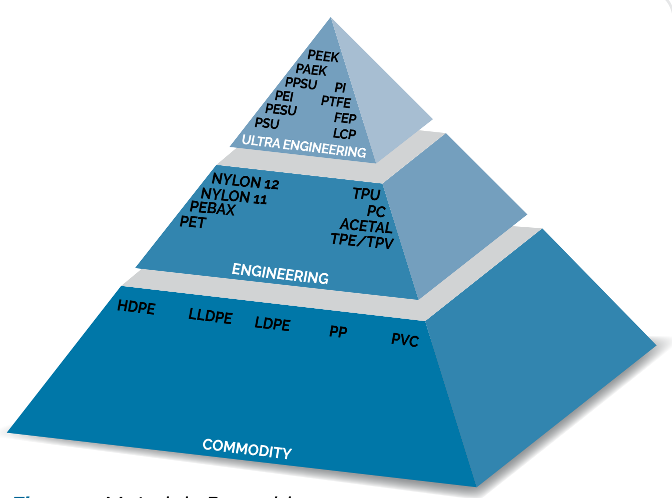

Figure 1. *Materials Pyramid*

Ultra-engineering polymers fall under the general classification of engineered polymers yet they are at the pinnacle of performance for all thermoplastics (**Figure 1**). Ultra-engineering polymers bridge the performance gap between standard engineering polymers, such as nylon and polycarbonate; and metals, composite materials and thermoset plastics like polyimide. Their description of "high heat polymer" indicates not only that these materials are processed at higher temperatures, typically between 600˚ F and 750˚ F +, but that they subsequently, also have high continuous operating temperatures, most well over 300˚ F. Ultra-engineering polymers have very good chemical resistance which makes them ideal for the hospital environment and the many harsh chemicals and drugs that plastics can be exposed to. The physical properties of ultra-engineering polymers also out perform all other standard engineered polymers in the areas of tensile strength, flexural strength and impact resistance. Additionally, these materials have good dielectric properties and have some level of inherent flame resistance without additives. All the materials to be discussed in this white paper have USP Class VI and ISO 10993 approvals and some have permanent implant approved grades as well as MAF support.

Polymer Common Properties

The materials discussed here have some common properties and abilities as well drawbacks that will be touched on here with material specific properties being addressed in their section. High heat polymers can be extruded into large diameter and micro-bore tubing configurations, thin walls, multi-lumens, solid rods/mandrels, complex profiles and filament. High heat polymers can be colored and compounded with additives such as radiopacifiers, electrically and thermally conductive additives and various types of physical reinforcements. They can also be thermally formed and reflowed for catheter applications as well as RF welded providing for easier assembly and connection methods than stainless steel.

High heat polymers are more expensive than most standard engineering materials and even more expensive than commodity materials. Implant grades of these materials can be exponentially more expensive than their standard, medical grade versions. When high heat materials are compounded, their costs can double or triple, further increasing material costs. Because of their high processing temperatures, some colorant components and additives can be limited because some of those constituents cannot withstand the elevated processing temps therefore limiting the number of possible colors and PMS matching. Several of these high heat polymers do not have neutral natural colors which will also affect color matching.

PEEK

Currently the "buzz" material for high requirement plastic medical applications is PEEK (polyetheretherketone). PEEK is the highest performing, commercial polymer, it is no wonder that it is specified in so many high requirement applications. There are many aspects of PEEK that make it the ideal choice for some applications. PEEK is a semi-crystalline material which contributes to some of its best in class properties, its properties are also optimized in its semi-crystalline state. Semi-crystalline polymers, like PEEK, have a portion of their molecules align and form crystals during proper processing. PEEK has some of the highest tensile and flexural strength of all commercial, non-reinforced thermoplastics. This translates to great push-ability and torque functionality in catheter components and access devices. PEEK also has very low elongation and great compressive strength, as well as excellent chemical resistance to hospital solvents, wipe down chemicals (Solvay Specialty Polymers 2015), and harsh drugs. PEEK has good dielectric and insulative properties as well as a high continuous operating temperature of 465° F or more which makes it a great choice for ablation procedures. Its low surface energy finish and hardness makes PEEK a good choice for artherectomy devices. PEEK is fairly inert and bio-stable which can reduce the possibility of negative patient reactions. PEEK is unique in that it has similar physical properties and density to cortical bone (Solvay Specialty Polymers 2015). It also doesn't have degradation or sensitivity issues like that of titanium as well as not having reactivity to MRI procedures which makes PEEK ideal for bone and dental permanent implants (Solvay Specialty Polymers 2015); permanent implant grades of PEEK are available for these types of applications but require an intensive approval process for their use and come with extremely high costs. PEEK has excellent resistance to all major sterilization techniques in 100 cycles or more and 1000 + cycles of steam sterilization (Solvay Specialty Polymers 2015). All these properties combined allow PEEK to occupy a unique position as a material suitable for one time use devices but also for durable devices that will be reused multiple times.

There is no such thing as a perfect or universal polymer, so PEEK does have some restrictions to keep in mind while considering it in your next device. PEEK is the highest cost raw material of all the materials discussed here, with implant grades being many times more expensive. PEEK has an opaque beige appearance which may not be aesthetically pleasing for some users. This opaque beige color also can limit how well it can be colored, especially light colors, and how vibrant bright colors may appear. PEEK requires special surface preparation prior to printing, usually plasma. Reflow processes with PEEK can be more difficult than other materials because of the high processing temperature and high crystallinity. While PEEK is extremely strong, it is not as "tough" and ductile as other high heat polymers.

PAEK

There is another high heat, semi-crystalline polymer in the PEEK family called PAEK (polyaryletherketone). This material can be utilized as an alternative to PEEK with an approximate 20% to 30% raw material cost savings. PAEK has similar physical, thermal and chemical properties (Solvay Specialty Polymers 2016) as PEEK but with improved toughness and ductility (Solvay Specialty Polymers 2015—**Figure 2**). PAEK also has similar restrictions as PEEK.

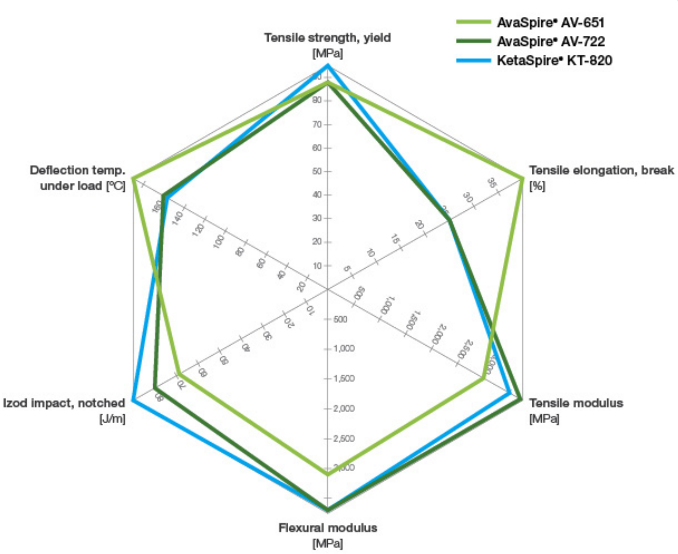

Figure 2. *Ultra-Polymers PAEK comparison PEEK*

Amorphous Polymers

The remainder of the ultra-engineering polymers to be discussed are all amorphous and range from transparent to clear in appearance (**Figure 3**). An amorphous polymer does not have a distinct melting point and no crystalline structure. The amorphous ultra-engineering polymers to be discussed are PPSU, PSU, PESU and PEI (Solvay Specialty Polymers 2016).

PPSU

PPSU (polyphenylsulfone) has the highest heat resistance of all the sulfones and PEI (polyetherimide). PPSU has a continuous operating temperature of about 400˚ F, which allows it to handle some of the same high heat applications as PEEK. PPSU is very hydrolytically stable which enables it to excel in high heat and humidity environments. PPSU is

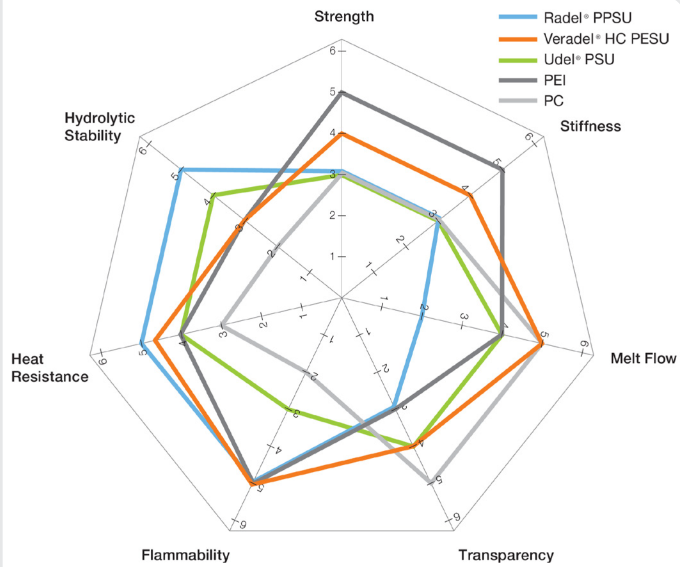

Figure 3. *Transparent Polymer Comparison*

highly chemical resistant to all hospital solvents and wipe down chemicals (Solvay Specialty Polymers 2015) and also can withstand 100 or more cycles of all sterilization methods as well as 1000 + cycles of steam sterilization (Solvay Specialty Polymers 2015). These properties along with its transparency allows this material to also bridge the gap between one time use and durable devices where the ability to see the placement or position of catheters or endoscopy tools, or the flow of fluids is critical to the functionality of the device and procedure. PPSU has very high ductility which is quantified by the lowest tensile and flexural strengths of all the materials discussed here. This high ductility positions this material as a candidate for steerable catheters and catheters that need to follow torturous paths through the body while still having need of high heat and chemical resistance. Permanent implant grades of PPSU are available for applications such as wire lead coatings, fluid transfer and orthopedics (Solvay Specialty Polymers 2015).

PPSU has the highest raw material costs of these amorphous materials but it is still less expensive than PEEK. PPSU has a transparent amber appearance which may not be aesthetically pleasing for some users. However, the amber color appears less pronounced in thin wall and micro-bore configurations. This transparent amber color can limit how well it can be colored, especially light colors, and may affect how vibrant bright colors may appear.

PSU

The strength and toughness of the amorphous materials start to increase from this point forward. PSU (polysulfone) is a high strength sulfone material with greatly improved clarity over PPSU. PSU has the lowest continuous operating temperature of all these high heat polymers at about 340˚ F, but it is still considerably higher than other common engineered polymers. PSU has good chemical resistance to many hospital chemicals (Solvay Specialty Polymers 2015) and is hydrolytically stable for hot and humid environments (Solvay Specialty Polymers 2015). It can withstand 40 kGy of Gamma and up to 100 cycles of all other sterilization methods (Solvay Specialty Polymers 2015). PSU can be a choice for a durable component but doesn't have as long of a life span in some environments as the other materials covered here. PSU's properties position it as a great, higher end replacement for polycarbonate. PSU has better chemical resistance, higher hydrolytic stability, and much higher temperature resistance than polycarbonate (Solvay Specialty Polymers 2015). Even though PSU can have a slight yellowish tint to it, PSU still has good clarity while most grades of medical polycarbonate need to have a noticeable purplish tint to them to compensate for color shifts during Gamma sterilization. PSU has good ductility and better toughness. PSU is a good option for dental tools and components because of its toughness and hydrolytic stability. PSU comes in permanent implant grades that are not suitable for structural components but can be used in applications where ductility, strength, toughness and clarity are necessary.

PSU has good clarity, so it can be colored to transparent and opaque colors and be more accurately color matched, provided color constituents can withstand processing temperatures. Raw material prices for PSU are moderate, about 50% to 75% higher than polycarbonate and similar to prices for PEI and PESU.

Some of the limitations of PSU are: it does have decreased sterilization and chemical resistance compared to the other ultra-engineering polymers that are discussed here. PSU also has lower tensile and flexural properties than PESU and PEI but are higher than PPSU.

PESU

Another member of the sulfone family that has high potential for use in medical applications is PESU (polyether sulfone). PESU has the highest tensile and flexural strength of the sulfones listed here as well as excellent clarity. PESU has better chemical resistance to hospital solvents and disinfectants and has good hydrolytic stability (Solvay Specialty Polymers 2014). In combination with PESU's continuous operating temperature of about 390˚ F, these properties make it a good candidate for harsh applications where high strength and clarity are needed. Applications such as sight windows and patient access components where being able to see fluid movement, and device location and position are necessary. Because of the stiffness and hardness of PESU it has good pushability and torque properties that can potentially eliminate braiding and other reinforcement methods in some applications. PESU has just slightly decreased physical and thermal properties compared to PEI which makes it a good option for replacement of PEI while adding greatly improved clarity. PESU is also an option as a much higher performing alternative to polycarbonate with greater physical, thermal, and chemical properties and with only the slightest yellowish tint. But as stated earlier, polycarbonate needs to be tinted noticeably purplish to compensate for color shifts during Gamma sterilization while PESU does not, retaining its clarity during all sterilization methods.

PESU has excellent clarity, especially in thinner wall configurations, so it can be colored to transparent and opaque colors and be more accurately color matched, provided color constituents can withstand processing temperatures. Raw material prices for PESU are moderate, and similar to prices for PEI and PSU. PESU can withstand 4 megarads of Gamma, greater than 1000 steam sterilization cycles and 100 or more cycles of the other major sterilization methods (Solvay Specialty Polymers 2016).

PESU is susceptible to environmental stress cracking due to exposure to certain families of solvents that can be present in the hospital environment (Solvay Specialty Polymers 2016). PESU has slightly lower tensile and flexural properties than PEI but are close enough that PESU can be a replacement for PEI in many applications.

PEI

PEI (polyetherimide) is the final ultra-engineering material we will be discussing here. PEI is commonly known by the brand name Ultem. PEI is the highest strength of the amorphous materials we have covered with higher tensile strength, flexural strength and hardness than all the sulfones. PEI's continuous operating temperature is about 390˚ F (Saudi Basic Industries Corporation (SABIC) 2016) and is hydrolytically stable, as well as having better chemical resistance to many hospital solvents and disinfectants (Saudi Basic Industries Corporation (SABIC) 2014). These properties allow PEI to be used in durable products such as device sheaths, access devices and sterilization tray dividers and supports. Because of PEI's strength and durability, it is also suitable for dental tool parts and fixtures. PEI can withstand greater than 1000 steam sterilization cycles, and is suitable for Gamma, EtO and vaporized hydrogen peroxide sterilization processes (Saudi Basic Industries Corporation (SABIC) 2014). PEI also has excellent color stability through hundreds of sterilization cycles (Saudi Basic Industries Corporation (SABIC) 2014).

PEI has good transparency, so it can be colored to transparent and opaque colors. Raw material prices for PEI are moderate, and similar to prices for PSU and PESU.

PEI has a transparent amber appearance which may not be aesthetically pleasing for some users. This transparent amber color can limit how well it can be colored, especially light colors, and may affect how vibrant bright colors may appear. PEI is attacked by some solvents which can be present in the hospital environment, this attack can be exhibited by environmental stress cracking.

Other Ultra-Engineering Polymers

There are a variety of families of ultra-engineering polymers beyond those discussed in this white paper. These other high heat polymers tend to fall in similar property ranges as those defined by PEEK, PPSU, PSU, PESU and PEI. Most of these other polymer families will have extrusion grades or grades suitable for extrusion. These other materials are sometimes formulated for very specific application types or targeted for certain physical, chemical or thermal properties and can subsequently have notable processing limitations that can dictate what types of parts and configurations are possible and the types of equipment that are necessary to process them. That is not to say ultra-engineering polymers other than those listed here should be avoided by any means, because they can fill in and extend the performance gaps of the materials discussed here. Utilizing a processor with experience and knowledge of these other families of materials will be key to the success of devices specifying other ultra-engineering polymers.

Conclusion

The materials that we identified here are some of the major players in the growth of advanced material usage in medical devices and their components. PEEK, PPSU, PSU, PESU and PEI have added a level of performance to plastics that was relatively unknown until not that long ago. Navigating the properties and differences between them require those in development and specification roles to gain a new knowledge set. The goal of this white paper was to provide a high-level overview of these materials to quickly help designers gain awareness of the many ultra-engineering material options available to them. Knowledge of the variety of ultra-engineering polymers, their properties and positive and limiting aspects is the solution to unfamiliarity with these advanced materials and will enable ideal material selections for medical applications. An additional requirement for specifying an ultra-engineering material is to find a processor that has the knowledge, skills, and experience necessary for converting them to extruded components. All of these ultra-engineering materials require specialized extrusion equipment, purpose designed tooling and the knowledge of unique processing methods that relatively few extruders have. Apollo Medical Extrusion Technologies has the experience and techniques necessary to manufacture complex, high requirement medical device components utilizing ultra-engineering materials. Being able to specify the ideal ultra-engineering polymer for your extruded medical component and having a skilled processor to manufacture it will open up a brave new world of medical devices.

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Based in Alpharetta, Georgia with multiple plants across the United States, Mexico, Costa Rica, Ireland, and Malaysia, Spectrum Plastics Group is a North American leader in the development and manufacture of custom and specialty plastics products and components for the medical device industry. Spectrum Plastics offers a full range of custom design, engineering and fabrication services, as well as meet the requirements of ISO 9001, ISO 13485, and operates multiple Class 7 & Class 8 clean rooms.

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