

# Selection of Materials for Medical Applications

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# Selection of Materials for Medical Applications

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**Abstract** – *Applications in the healthcare industry, and medical devices in particular, have some demanding requirements for thermoplastic materials that are unique to this arena. While polymers have been used in the healthcare industry for decades, it has only been in the last several years that designers have begun to discover the benefits of using specialty compounds in medical applications. Unique technologies relating to anti-static, wear resistant, and elastomeric compounds that have been useful in other industries are just now finding their way into medical devices. This paper presents an overview of the material selection process from the viewpoint of a specialty compounder with specific emphasis on the unique requirements for medical applications.*

## I. INTRODUCTION

Material selection is often one of the most intimidating and confusing hurdles encountered by medical device designers. What material will have the required chemical resistance? There seem to be hundreds of polymers to choose from – where do I start? What suppliers support applications with internal body tissue or body fluid contact?

On the other hand, healthcare applications can be equally intimidating and mysterious for material suppliers. What does the customer expect from a material supplier? What type of information do we need to generate? What risks are involved in supplying medical applications?

For this reason, direct communication between the designer and the material supplier is imperative for optimum medical device design. Early dialogue allows the designer to clearly state the device's goals and requirements. The material supplier also has the opportunity to share new technologies available in thermoplastic compounds and discuss which technologies have the most applicability in the current application.

The material selection process requires a preliminary understanding of polymers, additives, and their properties. Of primary importance is a basic understanding of polymer morphology and the properties different

morphologies bring. Thoroughly defined application requirements are then needed in order to select appropriate candidate materials. Besides what can be considered “traditional” material requirements like strength, stiffness, or impact resistance, medical applications often have special requirements unique to the healthcare industry. We will divide application requirements into two parts – environmental exposure and property requirements. Within each part we will discuss candidate polymers and additives, as well as those materials to be avoided.

For the purposes of this paper we will use a broad definition of the term “medical” when discussing device design. Medical devices may include surgical tools and catheters that require body tissue or fluid contact, diagnostic devices that use thermoplastic compounds for housings and internal components, or pharmaceutical applications where drug flow path is a concern.

## II. POLYMER PROPERTIES

A basic understanding of what is meant by polymer *morphology* will be helpful in breaking down the material options when selecting materials for a device. The general term morphology is used to define structure – in this case the structure of the polymer chains at a molecular level. A thermoplastic resin will be categorized as one of two types of morphology: amorphous or semi-crystalline.

Amorphous materials (Fig. 1) have a completely random orientation of the polymer chains. This orientation results in relatively low, uniform shrinkage, good dimensional stability, and low warpage. In general, amorphous materials have better overall toughness and creep resistance than semi-crystalline materials [1]. Examples of amorphous materials that are commonly used in the healthcare industry include Acrylic, ABS, polycarbonate, polysulfone, polyethersulfone (PES), and polyphenylsulfone (PPSU).

In semi-crystalline materials (Fig. 2) you will find ordered, *crystalline* regions amongst the random polymer chains. The formation of these regions during processing, called *crystallization*, increases polymer shrinkage. It also causes the shrinkage to be less uniform, resulting in potential warping of a molded part. However, these negatives can be outweighed by superior chemical resistance, wear resistance, and excellent response to reinforcement [1]. Fiber reinforced semi-crystalline materials generally offer very high overall strength and stiffness. Semi-crystalline polymers that are commonly used in the healthcare industry include polypropylene, polyethylene, nylon and polyetheretherketone (PEEK).



Fig. 1 Amorphous

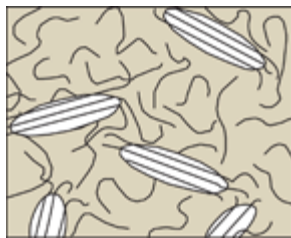


Fig. 2 Semi-crystalline

### III. APPLICATION REQUIREMENTS

As we consider the topics that arise during the evaluation of the application's requirements, we will divide them into two parts – typical requirements and medical requirements. By typical, we mean the types of requirements that often come up when considering thermoplastic materials for an application. Since the focus of the paper, however, is selection of materials for medical applications, we will spend the majority of the time on the requirements that are specific to the healthcare industry (medical requirements).

#### 1.) ENVIRONMENTAL EXPOSURE

By *environmental exposure*, we are really asking the question, “What conditions must the material survive, and what must survive around the material?” Typical requirements would include chemical resistance, temperature, and humidity. Specific chemical resistance guidelines can narrow down your material selection relatively quickly. Temperature and humidity are usually not much of a concern for medical applications due to the controlled environment in which most devices and applications are used. An exception, as we will discuss later in this section, would be materials that need to be steam sterilized.

There are a few environmental exposures that are specific to medical applications. The most common areas of concern are in parts that will need to be *sterilized*, parts that require internal *body tissue or fluid contact*, and applications requiring materials within a device to be in the *drug flow path*.

Let us first consider sterilization as an environmental exposure. The three most common types of sterilization are *radiation*, *ethylene oxide*, and *autoclave (steam)*.

Radiation can be divided into two main types, gamma and electron beam (e-beam). Gamma is the more common of the two and the energy produced from gamma radiation penetrates deeply through assemblies or packaging [2]. E-beam requires a higher dosage due to its lower penetration [3]. Radiation typically damages polymers via either chain scission (reduction of molecular weight) or crosslinking [2]. There are some antioxidant packages that can be used to improve the radiation stability of certain polymers, but the best course of action is to select polymers that are known to perform well. It is also important to note that multiple exposures to radiation are cumulative. A part that receives two separate 20 kiloGray (kGy) doses of gamma radiation will have undergone the same amount of damage as a part that receives one 40 kGy dose.

Styrenic thermoplastics, including ABS, show very good resistance to radiation sterilization techniques. Other inherently radiation-resistant

thermoplastics include polysulfone, PPSU, and PES. In terms of mechanical performance polycarbonate is generally resistant to radiation, but it will discolor (yellow) with radiation exposure [4]. Pigments can be used to mask this color change. Polypropylene is often used for applications utilizing radiation sterilization, but does require additional antioxidant stabilization in order to be able to expose it to more than one sterilization cycle.

Ethylene oxide sterilization (EtO) uses toxic ethylene oxide gas to kill unwanted cells on medical devices. As such, the main concern with using EtO sterilization is chemical resistance to the toxic gas. The majority of thermoplastic polymers can handle exposure to EtO without significant changes in properties or color [2].

Autoclaving, or steam sterilization, is the last of the three main sterilization methods. Autoclaving uses the combination of heat and moisture to kill microorganisms. Temperatures are typically 121°C (250°F) to 134°C (273°F) and exposure times vary from 3 minutes up to 15 minutes or more [5]. Typically, the lower the temperature, the longer the time needed to sterilize the part. The concern when selecting thermoplastic materials for parts that may be exposed to steam sterilization is the ability to tolerate repeated cycles of the moisture/temperature combination. Also, parts that are molded with high residual stress levels may begin to see some stress relaxation (annealing) and therefore change dimension or warp when exposed to these temperatures.

Materials that have resistance to the harsh combination of heat and moisture can be autoclaved successfully. Materials like polypropylene, polyamides, polycarbonate and polysulfone can be used, but care must be taken to how many autoclaving cycles they are exposed to. The best polymers for resistance to autoclaving are PPSU and PEEK, with both polymers able to handle exposure to thousands of cycles. Some polyethylene can be autoclaved, but only at lower temperatures and for limited lengths of time due to its low resistance to temperature. Families of polymers like styrenics (ABS, polystyrene) and polyesters (PBT or PET) are poor candidates for

autoclaving due to poor resistance to the heat/moisture environment. Polyesters and some styrenics can embrittle with prolonged exposure to steam. [6]

The next type of environmental exposure unique to materials in healthcare applications is exposure to internal body tissues and fluids. In most cases, concerns over environmental exposure leads us to consider how the material will be affected by the environment that it is in. In this case, however, the major concern is how the compound affects its environment – namely internal body tissues and fluids. Biocompatibility testing via ISO 10993 series of standards is the most commonly accepted method of determining suitability for use in such exposures.

It is important to note, however, that the material of manufacture is just one consideration when it comes to biocompatibility. ISO 10993-1 specifies that process contaminants, residues, and degradation products be taken into account when doing biocompatibility testing [7]. What this means to device designers is that using “ISO 10993-compliant” or “USP Class VI-compliant” materials doesn’t really shorten the amount of testing required in the development of a medical device. The entire manufacturing process really needs to be evaluated. Knowing that an “ISO 10993-compliant” material is being used adds an extra layer of security that the compound will likely pass future testing, but an overall biological evaluation of the final product will still need to be completed.

The nature of the specialty compounding market does not lend itself to have dozens of off-the-shelf, already biocompatibility-tested materials developed for medical device applications. It is far more common for the specialty compounder to draw on past experience and the information available from raw material suppliers when formulating compounds intended for uses that will require biocompatibility testing. Since plastics additives themselves are rarely tested for biocompatibility, the use of non-migratory FDA compliant ingredients can be used as a first step of formulating products for these types of applications.

It is vitally important for the specialty compounder to learn early during application development of the need for passing biocompatibility testing. Many polymer manufacturers and raw material suppliers have put limitations on the use of their products in applications that require tissue or fluid contact. Steps can be taken at the beginning of development to identify potential raw material candidates that have a high likelihood of passing biocompatibility and also to setup the formula such that alternative raw material substitutes are restricted.

The final type of environmental exposure we will consider is when the material is in direct contact with the flow of drugs through a device. The concerns for this situation are similar to the tissue/fluid contact concerns mentioned previously, except we now need to look at the effect that the material has on drugs as opposed to the body.

Again chemical resistance is important, as we do not want the drugs to promote material degradation. It is also undesirable to have the potency of the drug affected by the thermoplastic compound it is in contact with - either via extraction of additives and monomers or via chemical reactivity between the drug and the polymer. Extraction and biocompatibility data are often reviewed in such cases, and a drug master file (DMF) may be utilized to convey important confidential information to the FDA on the material(s) for the application.

## 2.) PROPERTY REQUIREMENTS

By *property requirements*, we are asking the question, "What other properties does the material bring to the table?" Typical types include tensile, flexural, and impact properties. It may also include long-term tests like fatigue or fatigue resistance. Fatigue resistance measures the ability of a material to resist exposure to repeated stress. Creep measures the deflection of a material against a constant load over long periods of time. A device designer may also need to consider post-molding assembly methods (like ultrasonic welding, heat staking, or the use of adhesives) during the material selection stage.



Fig. 3 Heart valve repair tool with radiopaque polymers.

More important to this discussion, however, are the properties that new thermoplastic formulation technologies can bring to the healthcare industry. The four main areas of interest for different aspects of this industry are: radiopacity, conductivity, wear resistance/lubricity, and laser markability.

Certain additives can be used to make a polymer radiopaque, that is, able to be seen by still X-ray imaging or fluoroscopy. This is useful in surgical instruments, catheters, and other items that need to be seen during surgery. Barium sulfate is the most common additive used to obtain radiopacity. This technology is applicable to most polymers; however, barium sulfate does cause degradation in many polycarbonate resins, resulting in embrittlement. Tungsten can also be used as a radiopacifier. In fact, high loading levels of tungsten (over 90% by weight) can be used to impart some X-ray shielding characteristics; however, the high cost of tungsten has limited its use in this industry over the last three years. Bismuth-based minerals like bismuth subcarbonate or bismuth trioxide can also be used, though they also are a generally higher cost option as compared to barium sulfate.

Over the last 10 years, conductive thermoplastics have started making their way into applications in the healthcare industry. In some dry-powder drug delivery applications, static build-up on the surface of the thermoplastic part can attract the drug and cause incorrect dosages [8]. The use of permanently antistatic compounds in these applications reduces or eliminates static build-up and allows for accurate dosing. Compounds based on acrylic (PMMA), polypropylene, and PC/ABS

are commonly used in these types of devices. Permanently antistatic acrylic compounds can even maintain a high level of transparency. Higher levels of conductivity may be required in some applications, notably pipette tips and EKG sensors [9]. These applications may utilize carbon black or carbon fiber to obtain these higher levels of conductivity.

Medical devices that have any plastic-on-metal or plastic-on-plastic sliding parts may be candidates for utilizing technologies that improve the wear resistance of those parts of the device. Gears inside pumps, sliding covers, and other internal device components are all examples of applications that have used wear resistant technologies. Additives like PTFE and silicone are commonly used to improve the lubricity and wear resistance of a material. A classic example of how lubricated materials can improve product performance is in a blood glucose meter housing (Fig. 4). An unmodified polycarbonate showed significant wear and abrasion at the interface of the cover and the housing. Utilizing a wear resistant additive package in the compound increased product life and eliminated squeaking that occurred when the lid was opened and closed.



Fig. 4 Glucose meter containing wear resistant compounds.

The final material technology that we will discuss in this section is laser-markability. A laser-markable compound may be more desirable than traditional hot stamping or pad printing because the mark is more solvent resistant and more permanent [9]. Additives can be incorporated into some thermoplastic

compounds that cause a photochemical reaction on the surface of the part when exposed to the laser beam. Laser marking can be used to incorporate serial numbers, logos, and even dosage markers on some drug delivery devices.

### 3.) OTHER CONSIDERATIONS

In today's healthcare industry, there is a growing trend toward home healthcare devices including glucometers, insulin delivery devices, and even kidney dialysis units. Because it needs to appeal to the home consumer, aesthetics and product differentiation are becoming increasingly important [10]. Two thermoplastic technologies specifically address this growing trend: *color* and *elastomers*.

Color has long been incorporated into materials for product differentiation. Color technologies can be used to convert medical devices into consumer-friendly products that don't look like medical devices. By gaining consumer acceptability, the devices are much more likely to be used in public and may increase patient medication compliance [9]. Color technologies like chroma-shift, metallic, and even glow-in-the-dark can add a perceived value that is beyond their cost [9].

Elastomeric materials are also being used for product differentiation in the marketplace. Beyond more functional applications like gaskets and liners for sound damping, elastomers can be used to give the product a "soft-touch" feel to again enhance perceived value. Many of the technologies that are available in rigid thermoplastic materials – color, radiopacity, and conductivity, to name a few – are also available for use in elastomeric compounds. This opens up an interesting design window for today's medical device designers. Elastomers can be used to give a non-slip "grip" for surgical tools [8]. Overmolding elastomers around edges and corners of a device can create a more rugged look and can improve the actual or perceived life of a device. Today's elastomer compounds have an increased level of compatibility for overmolding onto a variety of rigid substrates, creating a seemingly endless supply of material combinations for devices in the healthcare industry.

## IV. CONCLUSION

This is an exciting time to be involved in the development of medical devices. Proven thermoplastic compound technologies are opening up new performance capabilities for today's medical device. Material selection does not have to be an intimidating process. With early communication of application requirements and material capabilities, today's specialty compounder is well equipped to service the development of new devices.

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## ABOUT THE AUTHOR

Karl Hoppe graduated in 1998 from Winona State University with a Bachelors of Engineering in Composite Materials Engineering. He joined RTP Company that same year and is the lead development engineer for RTP Company's structural materials. His responsibilities include long fiber compound development, high specific gravity compound development, and general structural materials development. He has authored one patent related to thermoplastic material formulations. Along with these responsibilities he has been the main R&D contact for medical applications since 2000.

## ABOUT RTP COMPANY

RTP Company is a privately owned specialty compounder, creating thousands of custom formulations each year from a variety of thermoplastic resins, additives, and fillers. Offering worldwide manufacturing and distribution, the company employs more than 800 employees at eight plant locations. Its primary customers include injection molders/extruders, original equipment manufacturers, and contract manufacturing customers.

Headquartered in Winona, Minnesota, the company also operates manufacturing facilities at Sauk Rapids, Minnesota; South Boston, Virginia; Fort Worth, Texas; Indianapolis, Indiana; Beaune, France; Singapore; and Suzhou, China. Each facility houses complete manufacturing, product development, color lab, and technical services.

RTP Company specialty compounds are used in a variety of industries, including electronics, business machines, automotive, medical, appliance, consumer, industrial, and fluid handling. Product development is customer-driven, with made-to-order formulas that meet customer specifications for conductivity, wear resistance, color, flame retardance, structural, and high temperature performance.