

Finding Balanced Solutions for Medical-Grade Materials » » »

When medical device and diagnostics manufacturers work through material selection for their products, polymers such as polycarbonate (PC), polyethylene terephthalate (PET), and poly-vinyl chloride (PVC) are commonly used materials that first come to mind. Some of these established grades are used because they meet certain basic needs required for various healthcare applications. When selecting the right material for a specific application, it is common for designers to focus on attributes such as impact performance, clarity, chemical, and/or heat resistance. Designers often have to evaluate the advantages and disadvantages associated with each resin type. Products may have a benefit in terms of a single physical or chemical attribute, which can be offset with a shortcoming in another area. For example, a product may offer excellent clarity or toughness, but may be difficult to process. Other products may offer good chemical resistance, but are costly to procure.

Many of these traditional raw materials have been designed to address one or two desired traits – even excelling well beyond the necessary design criteria. However, these materials may not meet the end user's desire to have a product that is well-balanced along a breadth of various characteristics. Over the years, there have been advances in various material technologies that have resulted in alternate grades being made available in the market which can offer a better balance of product characteristics

ONE A Solution with Balanced Characteristics

Zylar and Clearblend, two products offered by INEOS Styrolution, provide a balance of the key physical characteristics sought by medical device manu-

facturers. Both transparent products have physical and chemical performance characteristics that address the requirements for manufacturing a variety of medical devices. Furthermore, these materials have demonstrated measurable advantages in production efficiency and electricity consumption.

Zylar is a methylmethacrylate butadiene styrene polymer, which is a clear and tough material made by modifying a styrene acrylic copolymer (SMMA) with an impact modifier. It is also referred to as an MBS or terpolymer, or an impact modified copolymer. Clearblend is made with the same ingredients as Zylar but the material is blended rather than fully compounded. Both materials are clear, and they can be colored easily through the addition of concentrates or liquid colors.

Zylar Properties at a Glance

Property	Unit	Zylar 650	Zylar 670	Zylar 960
MFR, 200/5.0	g/10 min	4	6	6
Tensile Strength at Yield	psi	3800	4000	3400
Tensile Modulus	Kpsi	310	265	250

Elongation at break	%	40	42	70
IZOD notched	ft-lb/in	3	2	11
Vicat softening temperature	°F	210	208	201
Haze	%	2	2	2

Clearblend Properties at a Glance

Property	Unit	Clearblend 145	Clearblend 155	Clearblend 165
MFR, 200/5.0	g/10 min	3.5	6	5
Tensile strength at yield	psi	4000	4000	3000
Specific gravity		1.04	1.04	1.04
Elongation at break	%	40	40	50
IZOD notched	ft-lb/in	1	2	5
Vicat softening temperature	°F	208	208	201
Water absorption	% (24 hrs)	0.1	0.1	0.1
Haze	%	2	2.5	2

TWO Advantages of Zylar and Clearblend

Zylar and Clearblend demonstrate their advantages in the production process. Zylar is easy to process, offering excellent flow properties. The material's molding behavior is comparable to high-impact polystyrene (HIPS). In spiral flow tests, both Zylar and Clearblend resins flowed the same distance as polycarbonate, but they did so at much lower temperatures. That capability enables manufacturers to use these materials in high cavity molds and achieve greater productivity while consuming less energy. Zylar also has a 14-30% density advantage compared to other transparent resins, which directly translates into 20-25% less Zylar being required to produce the same number

of parts produced from another material.

In addition to faster cycle times and lower processing temperatures, Zylar has been known to result in fewer rejected parts because fewer black specks are generated in finished parts. The material needs little to no drying because it is inherently hydrophobic. Furthermore, Zylar is neither corrosive nor abrasive, which leads to less wear and tear on production tools.

Zylar and Clearblend exhibit notable advantages for medical products. Both materials retain their properties after undergoing gaseous sterilization methods, such as ethylene oxide and nitrogen oxide. Zylar and Clearblend also hold up well under electron beam or gamma ray sterilization methods

often used for medical devices. While traditional materials can also be sterilized by irradiation, these methods can cause materials to show significant visible changes in the product, such as yellowing. Additives and tints can be added in the production process to improve the color-correction capabilities of the material, but this option adds cost.

Zylar and Clearblend can undergo sterilization by E-beam or gamma radiation methods with limited to no discoloration of the material. Unlike the color changes observed in traditional materials, Zylar and Clearblend resist the yellowing caused by high-energy sterilization methods. These materials also undergo little change in color in dark storage. Color steadfastness is important for medical devices because medical products that develop a yellow tint are not aesthetically pleasing, nor do they convey the sense of confidence and cleanliness required of equipment for the healthcare industry.

THREE Applications of Zylar and Clearblend

Zylar and Clearblend are suitable for a wide range of applications. Within the healthcare market, their use includes but is not limited to the following applications: transparent reservoirs, housings, syringe bodies, connectors, urine collectors, and mouth pieces. The material is resistant to common household chemicals and commercial

cleaners and compliant with US and EU food contact regulations, which enables its use in a wide range of applications.

Zylar offers good lipid and alcohol resistance and bonds well with various tubing materials, making it an excellent choice for IV system applications.

These grades are also offered to the market with INEOS Styrolution's "Essential HD Package." This service package includes:

- Fixed resin formulation as defined by the Drug Master File (DMF) filed with the FDA with a notification of change commitment up to 12 months in conjunction with a long term supply contract.
- Various compliance certifications such as USP Class VI, ISO-10993-4, ISO-10993-5, EU and FDA Food contact statements, and various pharmacopoeia compliance.

FOUR Conclusion

Zylar and Clearblend meet many of the requirements for medical products while also providing density and processing advantages when compared to many other transparent grade materials that have historically been used in this industry. These processing advantages lead to savings that can offset validation costs. Both Zylar and Clearblend are produced and supported by INEOS Styrolution, a leading company providing styrenic polymers to the global medical industry.

Zylar® and Clearblend® - Clear alternatives to Polycarbonate

Zylar



Clearblend

