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MATERIALS

# Selecting the Right Polymer

**Choosing the correct polymer for a medical device requires a comprehensive look at many aspects of performance and economy. This decision-making process is illustrated here with approaches to choosing materials for an injection moulded steam sterilisation tray for surgical instruments and goods.**

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## Diverse requirements

Aesthetics, strength and chemical resistance, which include sterilisation methods, are important aspects designers need to understand when determining the best material for a medical device, taking into account its intended purpose. Factors such as whether the design will be manufacturable in a reliable way, avoiding the potential for catastrophic failure and protecting the safety of patient and clinician must be considered. This article discusses approaches to choosing materials for an injection moulded steam sterilisation tray for surgical instruments and goods.

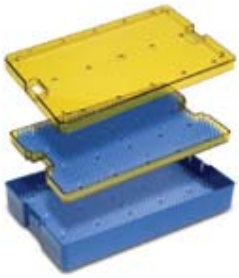

**Figure 1: Sterilisation box with removable centre tray and transparent lid for viewing contents. Tray and base are lined with silicone rubber mats (blue) for arranging small components.**

With the advent of steam-resistant high performance plastics, lighter weight and transparency have become obtainable. Sterilisation trays provide a simple solution whereby instruments are placed in the base and enclosed with a one-piece lid. The basic geometric design is a shallow five-sided box with a detachable lid. The injection moulded trays used today typically comprise a base pan and a transparent lid to enable the clinician to view the contents. Base pans are sometimes equipped with silicone rubber brackets or mats for holding instruments in place and may also contain one or more "shelf" trays inside that hold smaller items (Figures 1 and 2).

## Determining performance requirements

**Figure 2: This sterilisation box is designed to hold instruments such as scopes or other long-aspect ratio parts. The transparent lid allows the clinician to readily view the contents without opening and thus breaking the sterile field.**

The first step in designing any product is to define its end-use requirements. This is particularly challenging in a hospital setting. The product and its constituents must be as inherently safe as possible and provide the desired benefits to the user. In effect, the product must "do no harm." Designers must first consider materials that best comply with the appropriate regulatory statutes. For example, materials recognised as compliant with Food and Drug Administration (FDA) regulations are subjected to a variety of tests to demonstrate that they are not inherently harmful to human life and do not leach out or decompose into any harmful components.

Because the application requires repeated immersion in a steam autoclave, the technical data supplied by the resin manufacturer must be reviewed to determine whether the material is affected by the conditions found in the sterilisation process. These conditions include saturated steam; chemicals such as boiler additives (typically, highly reactive amine-based oxygen scavengers added to a steam generator's feed water to retard corrosion); and sanitising chemicals. The maximum temperature resistance is also crucial, because steam autoclave sterilisation cycles range from 121 °C (250 °F) saturated steam ("Gravity" cycle) to 140 °C (285 °F) ("Flash" cycle).[1] Some engineering materials that may perform well at 121 °C saturated steam, may not fare as well at 132 °C (270 °F) or higher because of inherent limitations in the thermoplastic softening point of the plastic.

The designer must also consider the physical demands required of the assembly: strength, stiffness under load and resistance to impact. Design considerations will integrate other aspects such as snap fits and supplementary hardware. Is visual transparency required? Will graphics such as a logo, operating instructions or cautionary statements be needed? If so, can the graphics withstand the sterilisation environment? Finally, can the moulding resin be tooled for reliable injection moulding?

## The end use environment

All applications should undergo a thorough review of the end-use environment to determine if there are unknown factors that could affect the performance of the product. The most important factors affecting thermoplastics include temperature, chemical exposure and loads. Temperature and chemicals will affect the polymer structure, whereas impact, vibration and cyclical loads

may affect the mechanical performance. For thermoplastic materials, temperature is the first checkpoint; they will soften with heat and lose properties such as strength. The cleaning and sterilisation process combines both heat and chemicals and these are the primary focus here.

Steam sterilisation is well understood for surgical instruments; operating room supplies and other sterilisation techniques can be radically different. Some are suitable for different types of materials such as paper and packaging for disposable items. The designer must evaluate the performance expectations of the end product in its environment and determine whether the product being designed needs to work with all methods of sterilisation. Steam sterilisation is the oldest and most common method of sterilising surgical instruments, but other methods such as ethylene oxide (EtO) gas and plasma sterilisation are also being used for delicate instruments that cannot tolerate steam temperatures. See Table I for a comparison of sterilisation methods.

Table I: Relative comparison of thermoplastic moulding resins for steam autoclave trays. Rating scale: 1 = least suitable; 5 = most suitable.

In addition to the sterilisation methods, there may be other factors that could affect the performance of the tray. For example, how much load must it carry? Will the tray be subject to precleaning or soaking in a strong solvent or cleaning agent? How often will the tray be cycled: once per day or ten times per day? Asking those questions during the design phase will reduce the chance of unexpected problems for the finished product.

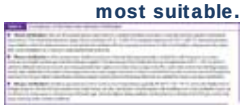

Table II: A comparison of the three main methods of sterilisation.

**Selection resources**

Selecting the right material can be puzzling. Often a search may yield many types of resins that seem similar, but in fact they may have important characteristics that are missing for a given application. Some have properties that are not needed. A good place to begin is by accessing a materials database and searching for resins that possess the critical properties that are required. There are many good websites for learning about the properties of injection moulding resins, among them are:

IDES is a materials information database company that gathers property data from most resin manufacturers and provides search tools to query the database by inclusion or exclusion of critical properties.[2]

MatWeb is a materials database that includes metals.[3]

CAMPUS (Computer Aided Materials Preselection by Uniform Standards) was initiated in 1988 for the purpose of uniform testing and reporting of material property data for global use.[4] This type of data allows engineers to make a more objective selection between competing resin producers when choosing a similar grade of material. As suitable candidate grades of resin are found, the designer can go directly to the resin manufacturer for more detailed information. Many resin companies conduct application specific testing that shows the performance of its product in environments such as steam, hot water or chemicals. The following is a basic framework of the selection steps that will help designers create a successful product.

**Decision-making steps**

Step 1: Property selection. A designer must first create a list of important properties for the application and divide it into "must have" and "nice to have." Once this is done, one or more databases can be queried to generate a list of candidate resins. A hierarchy of (property) importance should be established and the materials ranked accordingly. When selecting grades for the sterilisation tray, all candidate resin grades must be processable by injection moulding. The major properties can be ranked in the following order: FDA-compliant, steam and chemical resistant, stiffness and impact strength. Transparency may also be considered for the cover lid assembly.

Step 2: Economics and availability. The cost of materials varies by grade and the quantity purchased, therefore, the designer must obtain pricing from the resin suppliers to add to the property matrix. Resin price will be the largest percentage of cost for what may be an all-plastic tray and high performance resins command a premium price. A realistic determination of material usage must be made to obtain the best price possible. The designer should work with resin suppliers or their authorised distributors to be sure of getting the best quality product. Material "certs," a document issued by the resin manufacturer that is lot traceable, should be obtained.

Availability of materials is also important to consider. Are the best candidate materials available in the manufacturing location? For example, it can be difficult to find high performance resins in developing countries; also, materials can go out of production as a result of disruptions caused by plant expansions or catastrophic events. Are there any import tariffs or restrictions? Can more than one grade be specified or is the material produced by only one supplier? What is the alternative to a shortage or supply disruption? Where possible, it is good practice to specify more than one supplier or type of resin to avoid these pitfalls.

Step 3: Product design. The design of the product is important from the functional aspect and for manufacturability. The tray will be injection moulded, therefore, gating and material flow will be critical. Sterilisation of the contents depends on admission of steam, therefore the walls will need permeations. The box will need rigidity, thus stiffening ribs may be desired in the bottom or sides. How will the lid be attached? Interlocking snap-fit tabs is one option, or a spring-loaded stainless steel clip may offer greater durability. Much of today's three-dimensional modelling software can create part models to be interpolated to show the strength of the tray design in a given material.

Step 4: Tooling and moulding. Essential to any successful application is the ability to mould a good part, and good moulding starts with good tooling. It has often been said that the cheapest mould is the one that works. Make sure that the toolmaker is

experienced and has a proven record for making high quality moulds. Skimping on the tool quality is likely to lead to problems with the moulded parts. When selecting a high performance polymer, keep in mind that these materials require good heat management to ensure low stress and dimensionally stable parts. Wall thickness and gating must be considered to ensure optimum material flow. Filling of the mould can be through a direct sprue gate or a hot-tip bushing. Mould filling analysis software can be run once the parts are designed to guide this choice. This will also point out areas of high stress and suggest ways to reduce it to acceptable levels.

Step 5: Material selection. After evaluating the cost and benefits of several materials, preferred choices will emerge. In this example, there are a limited number of materials that best meet the criteria for a steam sterilisation tray. These materials are from two families of amorphous thermoplastics: sulphone polymers and polyetherimide polymers. These materials have good resistance to steam and sterilising chemicals and also exhibit good mechanical strength without the use of fibre reinforcement. Both can be obtained in a transparent amber colour and are easily pigmented within a limited range of colour (because of the inherent yellow hue and limited range of heat stable pigments).

Further investigation of best practices and prior art will reveal whether a certain material is being used successfully in a similar application. This can give the designer added confidence in his final selection. For example, a search will reveal that crystalline polymers such as polyetheretherketone or liquid crystalline polymers have greater chemical resistance and may be more suited to plasma sterilisation. The amorphous polymers are transparent and have greater toughness without the reinforcement.

Step 6: Testing and validation. Once the parts are moulded and assembled, the trays should be put through end-use tests to determine how well they perform. The trays should be subjected to repeated sterilisation and observed for breakage, cracks or discolouration. Other tests for this application can include drop impact, cleanliness, transparency or any other desired property. In addition, it is suggested that the user submit the trays to a third party testing house to evaluate sterilisation efficacy. Table II shows a relative cost and performance overview comparing the suitability of several high performance thermoplastic resins for use in repeat sterilisation environments.

### Achieving product success

Choosing the correct plastic resin for any application is a balance between cost and performance. Many types of materials may perform well, but it is the responsibility of the manufacturer to determine what level of performance is required to provide a safe product that meets customer expectations. Talking with the resin suppliers to obtain supplementary, application specific data and validating the design by end-use testing can save time and resources. Taking these steps as a basic framework will enable the designer to make an informed decision and increase the chance for a successful product launch the first time out.

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