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## 3 Plastics Used in Medical Devices

Laurence W. McKeen, PhD

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Medical devices range from simple devices, to test equipment, to implants. Plastics are used more and more in these devices, for weight, cost, and performance purposes. Examples of medical devices include surgical instruments, catheters, coronary stents, pacemakers, magnetic resonance imaging (MRI) machines, X-ray machines, prosthetic limbs, artificial hips/knees, surgical gloves, and bandages.

This chapter will discuss plastics used in the construction of medical devices in three sections. The first section will review the general composition of plastic materials which will include the materials added to the basic polymers. The second section will discuss many factors that contribute to the plastic selection. The final section will review the chemistry, the response to sterilization

processes, and the application of most common plastic materials in medical products.

## 3.1 Plastic Compositions

The basic components of plastic and elastomer materials are polymers. The word polymer is derived from the Greek term for “many parts.” Polymers are large molecules comprised of many repeat units, called monomers, that have been chemically bonded into long chains. There are thousands of commercially available polymers that are the basis of plastics. While some plastics are neat polymers, more often than not they are formulated products containing a blend of ingredients each added for a purpose.

### 3.1.1 Polymer Properties

For any given polymer type, there can be hundreds of grades manufactured by multiple resin manufacturers with distinctly different properties. Some of these grades include variations of the basic polymer: its size or its structure. Other variations are the added ingredients (or additives) which may be incorporated to modify performance, appearance, or other purposes. Variations in the polymer structure are discussed in the next section.

#### 3.1.1.1 Linear, Branched, and Cross-linked Polymers

Some polymers are linear, a long chain of connected monomers. Polyethylene, polyvinyl chloride (PVC), Nylon 66, and polymethyl methacrylate (PMMA) are some linear commercial examples found in this chapter. Branched polymers can be visualized as a linear polymer with side chains of the same polymer attached to the main chain. While the branches may themselves be further branched, the secondary branches do not connect to another polymer chain. The ends of the branches are not connected to any other chemical structure. Special types of branched polymers include star polymers, comb polymers, brush polymers, dendronized polymers [1], ladders, and dendrimers. Cross-linked polymers, sometimes called network polymers, are characterized by connection of different chains. The branches are essentially connected to different polymer chains

on the ends. These three polymer structures are shown in Figure 3.1.

#### 3.1.1.2 Isomers

Isomers (from Greek *isomerēs*, *isos* = “equal,” *méros* = “part”) are compounds with the same molecular formula but a different arrangement of atoms. There are many kinds of isomers and the properties can differ widely or almost not at all.

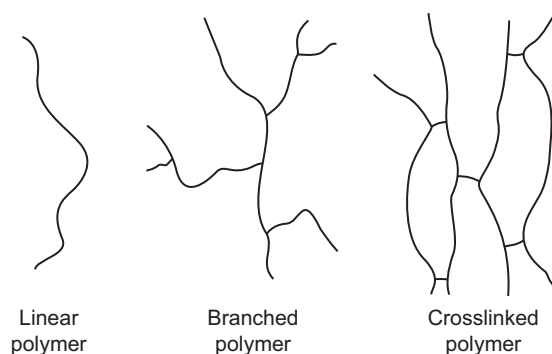
##### Structural Isomers

Structural isomers have the atoms arranged in a completely different order as shown in Figure 3.2. Here both polymer repeating groups have the same formula,  $-C_4H_8-$ , but the atoms are arranged differently. The properties of structural isomers may be very different from each other.

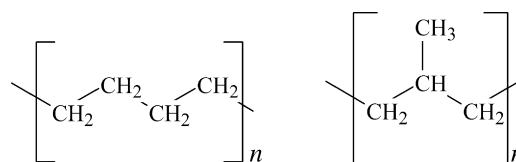
Often the repeating group in a polymer has exactly the same formula, but the repeating group is flipped over as shown in Figure 3.3. If one views the repeating group as having a head and a tail, then the different ways to connect neighboring repeating units is head–tail, head–head, and tail–tail.

##### Geometric Isomers

When there is a carbon–carbon double bond in a molecule, there may also be two ways to arrange the groups attached to the double bonds. This is



**Figure 3.1** Linear, branched, and cross-linked polymers.



**Figure 3.2** Structural isomers.

best seen in side-by-side structures as shown in Figure 3.4.

These structures are called *geometric isomers* which owe their existence to hindered rotation about double bonds. If the substituents are on the same side of the double bond, then the isomer is referred to as *cis*- (Latin: on this side). If the substituents are on the opposite side of the double bond, these are referred to as *trans*- (Latin: across).

#### Stereoisomers—Syndiotactic, Isotactic, Atactic

Stereoisomerism occurs when two or more molecules have identical molecular formula and the same structural formula (i.e., the atoms are arranged in the same order). However, they differ in their two or three dimensional (spatial) arrangements of their bonds. This means distinct spatial arrangements of the atoms—even though they are bonded in the same order. The concept would best be understood by an example.

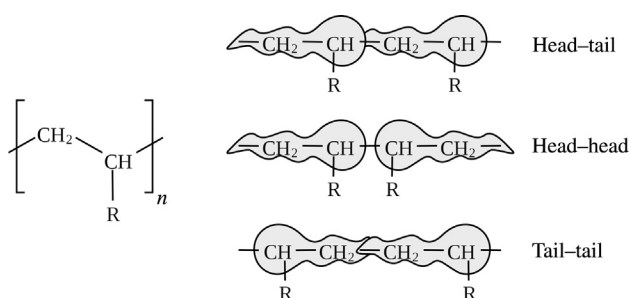


Figure 3.3 Head to tail isomers [2].

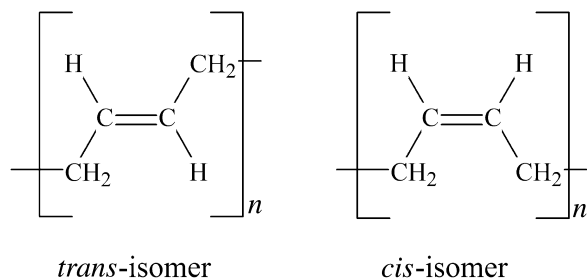


Figure 3.4 *cis*- and *trans*-isomers.

Polypropylenes (PPs) all have the same simplified structural polymer formula of polypropene as shown in Figure 3.5.

There are, however, subtle differences in the ways the polypropene structure can be arranged. Figure 3.6 shows a longer structure of polypropene, one that also shows some three-dimensional structure. This structure shows how some bonds (the dotted lines) are behind the plane of the paper while others stick out of the paper (the ones on the ends of the little triangular wedges). In this structure, some of the  $-\text{CH}_3$  groups are presented above the paper plane and others are behind the paper plane. This is called *atactic* polypropene.

Atactic polypropene has at random about 50% of hydrogen/methyl groups in the front and the back of the  $\text{C}-\text{C}-\text{C}$  chain viewing plane. This form of polypropene is amorphous (noncrystalline) and has an irregular structure due to the random arrangement of the methyl groups attached to the main carbon-carbon chain. It tends to be softer and more flexible than the other forms of this polymer which are described next.

In *isotactic* polypropene, all the methyl groups are positioned in front of the  $\text{C}-\text{C}-\text{C}$  chain viewing plane and all of the hydrogen atoms are at back, as shown in Figure 3.7. This stereoregular structure maximizes the intermolecular contacts and thus increases the intermolecular forces as compared to the atactic form. This regular structure is much stronger (than the atactic form) and is used in sheet and film form for packaging and carpet fibers.

*Syndiotactic* polypropene has a regular alternation of 50% of hydrogen/methyl groups in front/

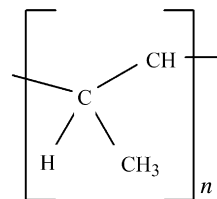


Figure 3.5 The structure of polypropene.

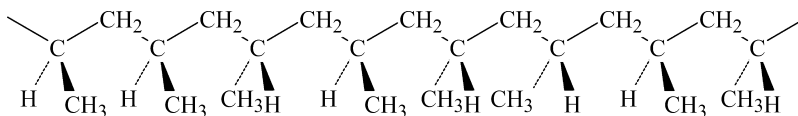
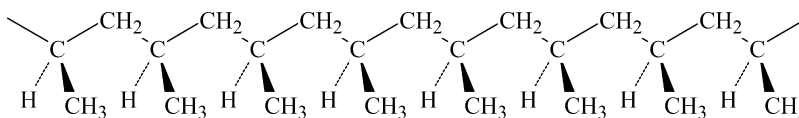
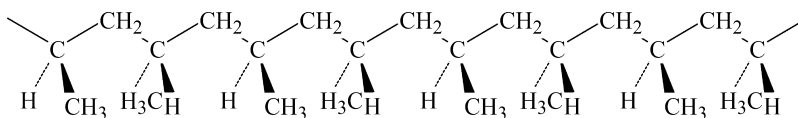


Figure 3.6 The structure of atactic polypropene.



**Figure 3.7** The structure of isotactic polypropylene.



**Figure 3.8** The structure of syndiotactic polypropylene.

back of the C—C—C chain viewing plane as shown in Figure 3.8. Its properties are similar to isotactic polypropylene rather than the atactic form, i.e., the regular polymer structure produces stronger intermolecular forces and a more crystalline form than the atactic polypropylene.

### 3.1.1.3 Molecular Weight

A polymer's molecular weight is the sum of the atomic weights of individual atoms that comprise a molecule. It indicates the *average* length of the bulk resin's polymer chains. All polymer molecules of a particular grade do not have the exact same molecular weight. There is a range or distribution of molecular weights. Another common means of expressing the length of a polymer chain is the *degree of polymerization*; this quantifies the average number of monomers incorporated into the polymer chain. The average molecular weight can be determined by several means, but this subject is beyond the scope of this book. Low molecular weight polyethylene chains have backbones as small as 1000 carbon atoms long. Ultrahigh molecular weight polyethylene (UHMWPE) chains can have 500,000 carbon atoms along their length.

Many plastics are available in a variety of chain lengths or different molecular weight grades. These resins can also be classified indirectly by a viscosity value or by a proxy parameter called *melt flow rate*, rather than molecular weight. Within a resin family, such as polycarbonate (PC), higher molecular weight grades have higher melt viscosities. For example, in the viscosity test for PC, the melt flow rate ranges from approximately 4 g/10 min for the highest molecular weight, standard grades to more than 60 g/10 min for lowest molecular weight, high-flow, specialty grades.

Molecular weight of the polymers that are used in medical plastics affects a number of their properties. While it is not always possible to quantify the molecular weights of plastics, as mentioned previously, higher flowing plastics of a given series of products generally have lower molecular weights.

### 3.1.2 Polymer Blends

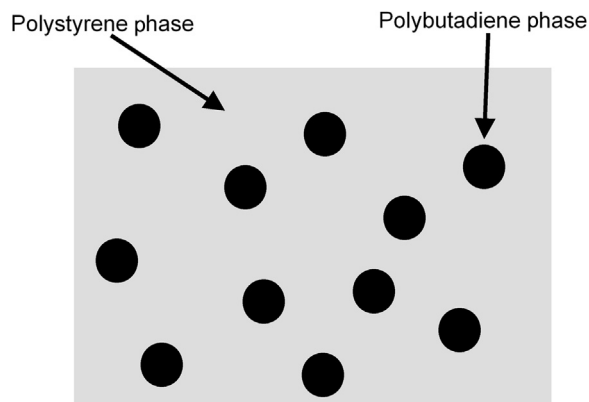
Polymers can often be blended. Occasionally, blended polymers have properties that exceed those of either of the constituents. For instance, blends of PC resin and PET polyester originally created to improve the chemical resistance of the PC actually have fatigue resistance and low-temperature impact resistance superior to either of the individual polymers.

Sometimes a material is needed that has some of the properties of one polymer and some of the properties of another. Instead of going back into the lab and trying to synthesize a brand-new polymer with all the desired properties, two polymers can be melted together to form a blend that possesses some of the properties of each constituent.

Two polymers that do actually mix well are polystyrene and polyphenylene oxide. Other examples of polymer pairs that form blends include:

- Polyethylene terephthalate (PET) with polybutylene terephthalate (PBT)
- PMMA with polyvinylidene fluoride.

Phase-separated mixtures are obtained when one tries to mix most polymers. But strangely enough, the phase-separated materials also turn out to be sometimes useful. They are called immiscible blends.



**Figure 3.9** An immiscible blend of polystyrene and polybutadiene.

Polystyrene and polybutadiene are immiscible. When polystyrene is mixed with a small amount of polybutadiene, the two polymers do not blend. Polybutadiene separates from the polystyrene into little spherical blobs. If this mixture is viewed under a high-power microscope, it resembles the picture shown in [Figure 3.9](#).

Multiphase polymer blends are of major economic importance in the polymer industry. The most common examples involve the impact modification of a thermoplastic by the microdispersion of a rubber into a brittle polymer matrix. Most commercial blends consist of two polymers combined with small amounts of a third compatibilizing polymer which typically consists of a block or graft copolymer. Multiphase polymer blends are often easier to process than a single polymer with similar properties.

Blending two or more polymers offers yet another method of tailoring resins to a specific application. Because blends are only physical mixtures, the resulting polymer usually has physical and mechanical properties that lie somewhere between the values of its constituent materials. Additional information on the subject of polymer blends is available in the literature [\[3–5\]](#).

### 3.1.3 Additives

The properties of neat polymers are often ideal neither for production nor for the end use. When this is the case, additives are added to the polymer to improve the performance shortfall. The additives can also improve the processing of polymers in addition to modifying its properties.

Additives encompass a wide range of substances that aid processing or add value to the final product [\[6,7\]](#). Found in virtually all plastics, most additives are incorporated into a resin family by the supplier as part of a proprietary package. For example, you can choose standard PC resin grades with additives for improved internal mold release, ultraviolet (UV) stabilization, and flame retardance; or nylon grades with additives to improve impact performance.

Additives often determine the success or failure of a resin or system in a particular application. Many common additives are discussed in the following sections. Except for reinforcement fillers, most additives are added in very small amounts.

#### 3.1.3.1 Fillers, Reinforcement, Composites

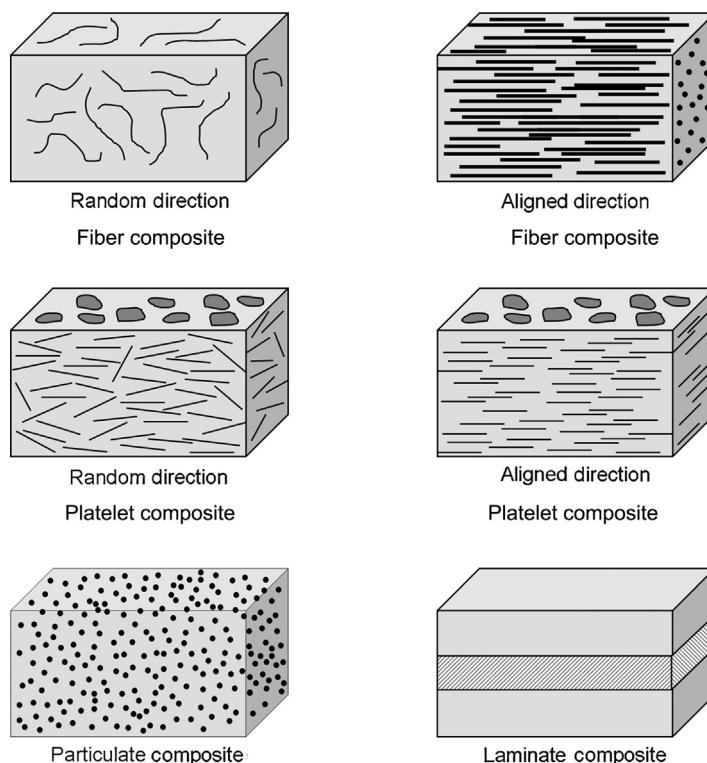
Reinforcing fillers can be added in large amounts. Some plastics may contain as much as 60% reinforcing fillers. Often, fibrous materials, such as glass or carbon, are added to resins to create reinforced grades with enhanced physical or mechanical properties. For example, adding 30% short glass fibers by weight to Nylon 6 improves creep resistance and increases stiffness by 300%. These glass-reinforced plastics usually suffer some loss of impact strength and ultimate elongation, and are more prone to warping because of the relatively large difference in mold shrinkage between the flow and cross flow directions.

Plastics with non-fibrous fillers such as glass spheres or mineral powders generally exhibit higher stiffness characteristics than unfilled resins, but not as high as fiber-reinforced grades. Resins with particulate fillers are less likely to warp and show a decrease in mold shrinkage. Particulate fillers typically reduce shrinkage by a percentage value roughly equal to the volume percentage of filler in the polymer, an advantage in tight tolerance molding.

Often reinforced plastics are called *composites*. The plastic/polymer material containing the reinforcement is referred to as the matrix. One can envision a number of ways different reinforcing materials might be arranged in a composite. Many of these arrangements are shown in [Figure 3.10](#).

Particulates, in the form of pigments, may be added to impart color. Occasionally particulates, called *extenders*, are added to reduce the amount of





**Figure 3.10** Several types of composite materials.

relatively expensive polymer used which reduces the overall cost.

Platelet additives may impart color and luster, metallic appearance, or a pearlescent effect, but they also can strongly affect permeation properties. Most of these additives have little or no permeation through themselves, so when a film contains particulate additives, the permeating molecule must follow a path around the particulate additive as shown in [Figure 3.11](#). This is called a *tortuous path effect*.

### 3.1.3.2 Release Agents

External release agents are lubricants, liquids, or powders, which coat a mold cavity to facilitate part removal. Internal release agents, which are part of the plastic formulation, can accomplish the same purpose. The identities of the release agents are rarely disclosed, but frequently they are fine fluoropolymer powders (called micropowders), silicone resins, or waxes.

### 3.1.3.3 Slip Additives/Internal Lubricants

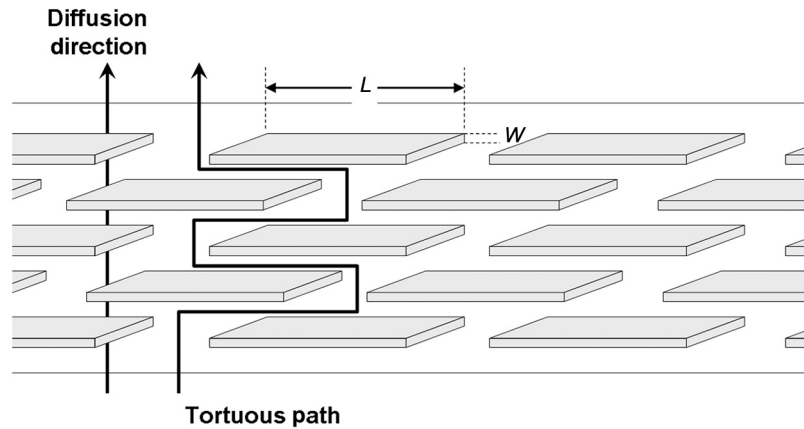
When polymeric films slide over each other, they encounter a resistance that is quantified in

terms of the coefficient of friction (COF). Plastic films with high COF tend to stick together instead of sliding over one another. Sticking makes the handling, use, and conversion of films difficult. To overcome sticking, slip agents are added.

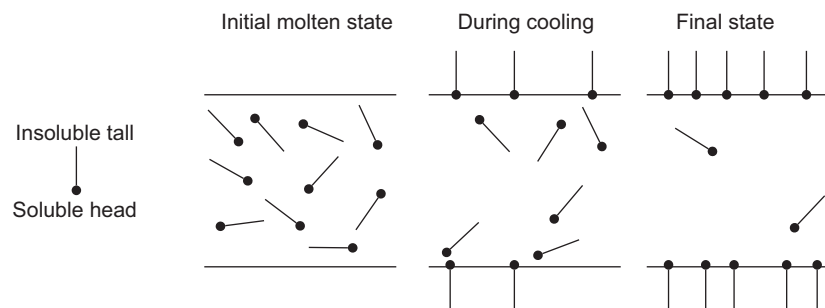
Slip additives are divided into two migrating and non-migrating types. Migrating slip additives are the most common class and they are used above their solubility limit in the polymer. These types of additives are molecules comprised of two distinct parts, typically pictured as a head and tail as shown in [Figure 3.12](#). One part of the molecule, usually the head, is designed to be soluble in the polymer (particularly when it is molten during processing) making up the plastic. The other part, the tail, is insoluble. As the plastic cools and solidifies from its molten state, these molecules migrate to the surface, where the insoluble end “sticks out” reducing the COF. This process is shown in [Figure 3.12](#). These additives are typically fatty acid amides.

Some common non-migrating slip additives are *dusted* on plastic surfaces. These include:

- PTFE (polytetrafluoroethylene) in micropowder form imparts the lowest COF of any internal



**Figure 3.11** Tortuous path of permeant molecule through a particulate containing film.



**Figure 3.12** Mode of action of a typical migrating slip additive.

lubricant. Manufacturers and suppliers are many, including DuPont™, Zonyl®, and 3 M Dyneon™.

- Molybdenum disulfide, commonly called “moly,” is a solid lubricant often used in bearing applications.
- Graphite is a solid lubricant used like molybdenum disulfide.

### 3.1.3.4 Catalysts

Catalysts, substances that initiate or change the rate of a chemical reaction, do not undergo a permanent change in composition or become part of the molecular structure of the final product. Occasionally they are used to describe a setting agent, hardener, curing agent, promoter, etc., and they are added in minute quantities, typically less than 1% usually to thermosetting plastics.

### 3.1.3.5 Impact Modifiers and Tougheners

Many plastics do not have sufficient impact resistance for the use for which they are intended. Rather than changing to a different type of plastic, they can be impact-modified in order to fulfill the performance in use requirements. Addition of modifiers called *impact modifiers* or *tougheners* significantly improves impact resistance. This is one of the most important additives. There are many suppliers and chemical types of these modifiers.

General-purpose impact modification is considered a low level of impact modification. It improves room temperature impact strength but does not take into account any requirements for low-temperature (<0°C) impact strength. For most of these types of applications, only low levels of impact modifier is required (<10%).

Low-temperature impact strength is required for applications that require a certain level of low-temperature flexibility and resistance to breakage. For example, this is the case for many applications in the appliances. For this purpose, modifier levels between 5% and 15% of mostly reactive modifiers are required. Reactive modifiers can bond chemically to the base polymer.

Super tough impact strength may be required for applications in which a part must not fail even if it is struck at low temperatures ( $-30^{\circ}\text{C}$  to  $-40^{\circ}\text{C}$ ) under high speed. This requirement can only be fulfilled with high levels (20–25%) of reactive impact modifier with low glass transition temperature.

### 3.1.3.6 Radiation Stabilizers

*Radiation stabilizers*, also referred to in the art as “antirads,” may be used to mitigate the detrimental effects of the gamma ray dose on plastics generally. Stabilizers like antioxidants and free radical scavengers can prevent degradation and cross-linking. In general, polymers that contain aromatic ring structures are more resistant to radiation effects compared to aliphatic polymers.

*UV stabilizers:* Another way plastics may degrade is by exposure to UV light. UV radiation can initiate oxidation in air. Plastics which are used outdoors or exposed to lamps emitting UV radiation are subject to photooxidative degradation. UV stabilizers are used to prevent and retard photooxidation. Pigments and dyes may also be used in applications not requiring transparency. Photooxidative degradation starts at the exposed surface and propagates throughout the material. Many UV stabilizers, like phenolics, hindered amine light stabilizers, and phosphates, may offer some protection against gamma and electron beam radiation.

### 3.1.3.7 Optical Brighteners

Many polymers have a slight yellowish color. They can be modified to appear whiter and brighter by increasing reflected bluish light (in the range of 400–600 nm). One way to accomplish this is by incorporating an additive that absorbs in the UV range but reemits the energy at higher wavelength in the visible range. This effect is called *fluorescence* and these types of additives are called optical brighteners or fluorescent whitening agents.

### 3.1.3.8 Plasticizers

Plasticizers are added to enhance and maintain flexibility in a plastic. Various phthalates are commonly used for this purpose. Since they are small molecules, they may extract or leach out of the plastic causing a loss of flexibility with time. Just as deliberately added, small molecules may leach out, and small molecules from the environment may be absorbed by the plastic and act like a plasticizer. The absorption of water by nylons (polyamides) is an example of this phenomenon.

### 3.1.3.9 Pigments, Extenders, Dyes, Mica

Pigments are added to impart color to a plastic, but they may also affect the physical properties. Extenders are usually cheap materials added to reduce the cost of a plastic resins. Dyes are colorants that are chemically different to pigments. Mica is a special pigment added to impact sparkle or metallic appearance.

### 3.1.3.10 Coupling Agents

The purpose of adding fillers is either to lower the cost of the polymer, make it tougher or stiffer, or make it flame retardant so that it does not burn when it is ignited. Often the addition of the filler will reduce the elongation at break, the flexibility, and in many cases the toughness of the polymer because the fillers are added at very high levels. One reason for the degradation of properties is that the fillers are not compatible with the polymers, thus form stress rises centers. The addition of coupling agents can improve the compatibility of the filler with the polymer. As a result, the polymer will like the filler more, the filler will adhere better to the polymer matrix, and the properties of the final mixture (e.g., elongation, flexibility) will be enhanced.

### 3.1.3.11 Thermal Stabilizers

One of the limiting factors in the use of plastics at high temperatures is their tendency not only to become softer but also to thermally degrade. Thermal degradation can present an upper limit to the service temperature of plastics. Thermal degradation can occur at temperatures much lower than those at which mechanical failure is likely to occur. Plastics can be protected from thermal degradation by incorporating stabilizers into them.



### 3.1.3.12 Antistats

Antistatic additives are capable of modifying properties of plastics in such a way that they become antistatic, conductive, and/or improve electromagnetic interference shielding (EMI). Carbon fibers, conductive carbon powders, and other electrically conductive materials are used for this purpose.

When two (organic) substrates rub against one other, electrostatic charges can build up. This is known as tribocharging. Electrostatic charges can impact plastic parts in several ways; one of the most annoying being the attraction of dust particles. One way to counter this effect is to use antistats (or antistatic additives). This effect is principally a surface effect, although one potential counter measure (conductive fillers) converts it into a bulk effect.

Tools that decrease electrostatic charges and hence increase the conductivity of an organic substrate can be classified as:

- external antistat (surface effect);
- conductive filler (bulk and surface effect);
- internal antistat (surface effect).

An external antistat is applied via a carrier medium to the surface of the plastic part. The same considerations and limitations apply as with non-migrating slip additives. Conductive filler is incorporated into the organic substrates and builds up a conductive network on a molecular level. While both approaches are used in organic substrates, they are not the most common.

An internal antistat is compounded into the organic substrate and migrates to the plastic part surface. The same principle considerations apply as for migrating slip additives (see [Figure 3.12](#)).

The need to protect sensitive electronic components and computer boards from electrostatic discharge during handling, shipping, and assembly has provided the driving force for development of a different class of antistatic packaging materials. These are sophisticated laminates with very thin metalized films.

There are other additives used in plastics, but the ones discussed above are the most common.

## 3.2 Medical Devices—Material Selection Process

In the United States, medical devices, whether they contain plastics or not, are regulated by the Food and

**Table 3.1** Examples of Medical Devices Associated with FDA Device Class

<b>Class I devices</b>	Tongue depressors
	Bandages
	Gloves
	Bedpans
	Simple surgical devices
<b>Class II devices</b>	Wheelchairs
	X-ray machines
	MRI machines
	Surgical needles
	Catheters
	Diagnostic equipment
<b>Class III devices</b>	Heart valves
	Stents
	Implanted pacemakers
	Silicone implants
	Hip and bone implants

Drug Administration (FDA). Devices are classified into three classes: Class I, Class II, and Class III depending upon their risk and criticality. [Table 3.1](#) provides a few examples of devices of each FDA class.

The United States Pharmacopoeia (USP) further classifies medical devices as given in [Table 3.2](#).

Each device class requires a different level of regulation and compliance. Certifying compliance can be a complex and expensive process.

When choosing a plastic for a medical device, design considerations are important. Materials selection, production process selection, and part geometry are interdependent. Usage conditions such as temperature, chemical contact and resistance, and applied stresses during use, are considered. Also, very important for medical devices is sterilization method compatibility including consideration of single vs. repeat sterilization. A summary of many of these considerations follows.

### 3.2.1 Physical and Mechanical Properties

Physical properties are important; one must know the dimensions, size, and weight requirements for the part or product. If used by a surgeon,

**Table 3.2** USP Classification of Medical Devices

Device Category	Contact	Exposure Time	USP Class
Surface device	Skin	Limited	USP Class I
		Prolonged	USP Class I
		Permanent	USP Class I
Mucosal surfaces	Limited	USP Class I	
		Prolonged	USP Class III
		Permanent	USP Class V
	Breached or compromised surfaces	Limited	USP Class III
		Prolonged	USP Class V
		Permanent	USP Class VI
External communicating devices	Blood path indirect	Limited	USP Class IV
		Prolonged	USP Class V
		Permanent	USP Class VI
	Tissue/bone/dentin communicating	Limited	USP Class IV
		Prolonged	USP Class VI
		Permanent	USP Class VI
	Circulating blood	Limited	USP Class IV
		Prolonged	USP Class VI
		Permanent	USP Class VI
Implant devices	Implant devices	Permanent	Class VI

it must be light enough to handle precisely. The design engineer must consider the loads, stresses, and impact that the product might see during its use. Other physical properties can be important including transparency/opacity, color (some items might use color to aid in identification), aesthetics, water

absorption, lubricity, and wear resistance. Important mechanical properties are tensile strength, tensile elongation, tensile modulus, impact resistance (all for toughness), and flexural modulus. Details on the importance of these properties and their measurement are available in the literature [8].

### 3.2.2 Thermal Properties

Thermal effects must be evaluated both during the production and use of the part or product. Molding temperatures seen during part production are typically much higher than end-use temperatures. Plastic material properties at melting temperatures, sterilization temperatures, and environmental conditions that include both temperature and humidity need to be characterized. Thermal properties of interest include melting point, processing temperatures, heat deflection (or distortion) temperature under load, glass transition temperature, continuous use temperature, and thermal conductivity.

### 3.2.3 Electrical Properties

Electrical and computer technology is an important part of modern medical treatments, so electrical properties such as conductivity and insulation properties must be considered. Some materials may need to dissipate accumulated static charge, whereas other materials might need electrical insulation properties. Electrical properties to consider are surface and volume conductivity or resistivity, dielectric strength, and comparative tracking index (CTI).

### 3.2.4 Chemical Resistance

Many medical devices may require chemical resistance to various types of oils, greases, processing aids, disinfectant, bleaches, and other hospital

chemicals. Chemical resistance must be considered for the product during production, use and cleaning, sterilizing or disinfecting.

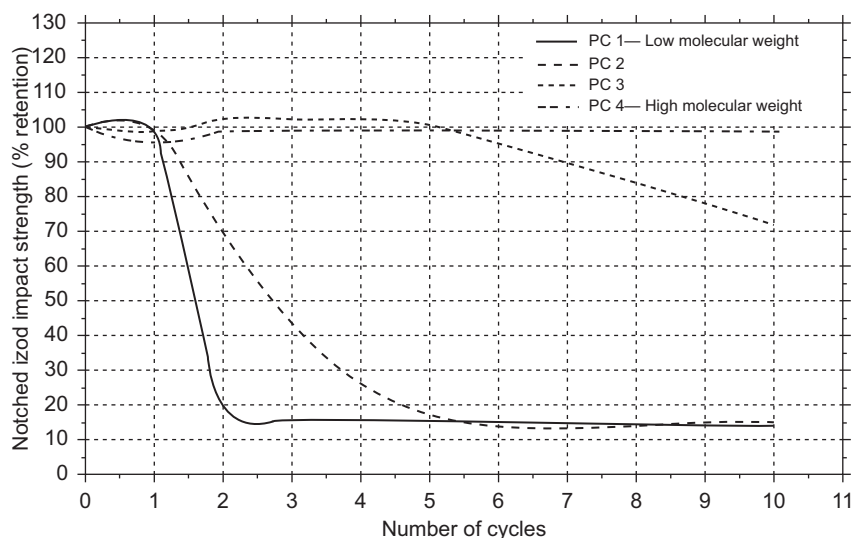
### 3.2.5 Sterilization Capability

Many reusable, disposable, implant, and packaging materials will need to be sterilized by various methods like steam, dry heat, ethylene oxide (EtO), electron beam, and gamma radiation. They must be able to withstand these conditions and still maintain their properties for the intended use. Of particular importance is hydrolytic stability for steam sterilization, thermal resistance to steam and autoclave conditions, chemical resistance to EtO, and resistance to high-energy radiation including electron beam, gamma, and UV. This is the subject of a reference work by this author [9].

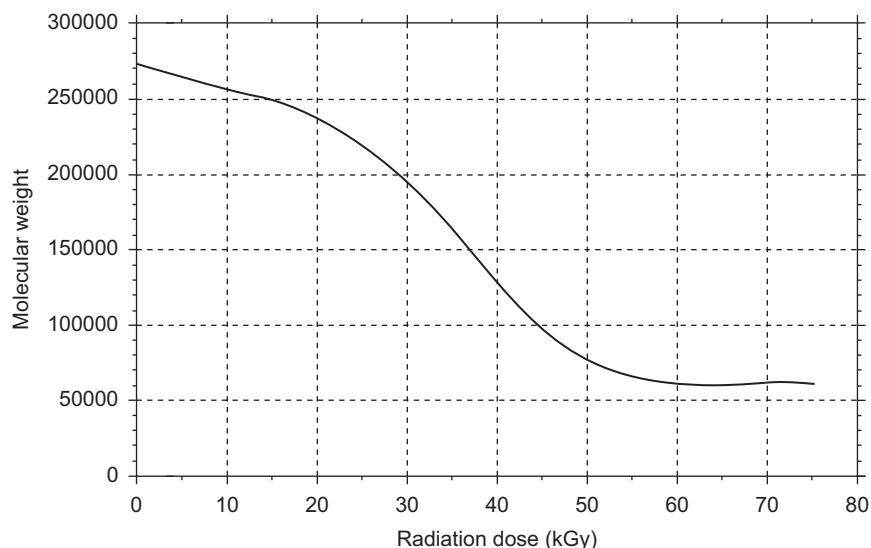
Examples of the effect of sterilization processes on plastics properties are found in [Figures 3.13–3.15](#).

### 3.2.6 Long-Term Durability

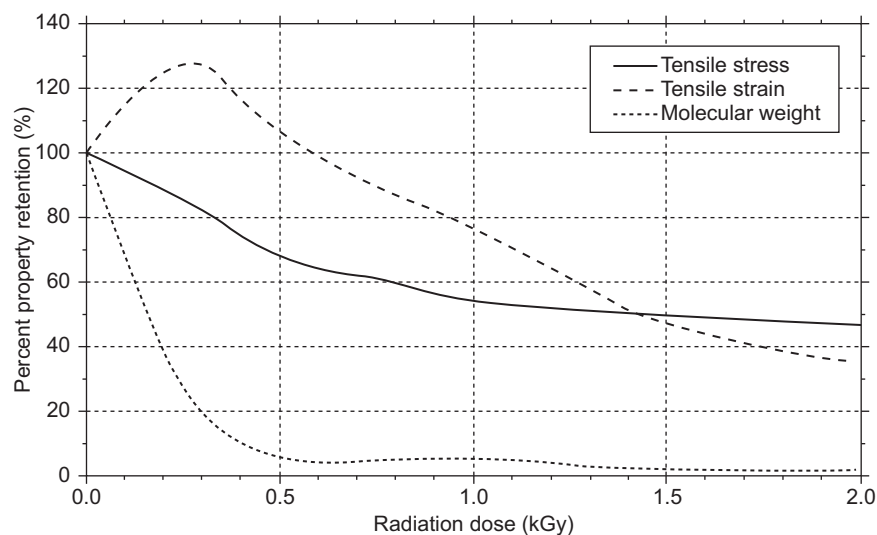
Devices may need to perform for a long period of time under various environmental and thermal conditions. Materials must be selected to meet these long-term aging needs. Instruments must have good ergonomics and functionality. Identification methods like the use of color are also gaining importance. Drug-delivery products comprise needles, tubing, bags, manifolds, Y-sites, clips, and connectors. These are mainly disposable products. Apart from cost, these parts must have excellent chemical and/or lipid



**Figure 3.13** The effect of steam sterilization on the impact strength of PCs [10].



**Figure 3.14** The effect of electron beam sterilization on the molecular weight of polylactic acid (PLA).



**Figure 3.15** Effect of gamma sterilization on some retention of properties of PTFE.

resistance, flexibility, transparency and clarity, sterilization resistance, toughness, tear and burst strength, softness, and no leachables and extractables (discussed in the next section). End-of-life and disposal requirements are also important. Endoscopy is one area that uses a lot of electronics and ancillary products like cameras, light sources, monitors, and recording equipment. Electric, power, and thermal management is very important, including material durability and toughness. Infection control products and devices include gloves, masks, drapes, and gowns. Apart from fit and comfort, materials for these

products must be nonirritating, chemically resistant, and stain resistant.

### 3.2.7 Leachables and Extractables

An important criterion for the use of plastics in medical device applications is quantifying the type and amount and identifying the material that is leached out or extracted from the plastic when in contact with chemicals, reagents, or bodily fluids during the end use. *Extractables* and *leachables* are

compounds that can be extracted from the elastomeric or plastic components, or coatings. This is commonly considered for containers and medical devices that come into contact with solvents such as alcohol at various temperatures of use and storage. The difference between extractables and leachables is slight; leachables is generally a more aggressive exposure that is meant to indicate a worst-case scenario.

Both extractables and leachables are affected by the type and amount of additives in the formulation of the plastic. They include plasticizers, antioxidants, stabilizers, pigments, lubricants, vulcanizers, catalysts, residual monomers and oligomers, residual solvents, and contaminants.

The extracts or leachants are often used for the further biological tests. *Cytotoxicity* is the assessment of the (toxic) effect of chemicals on cells. *Sensitization* tests determine the allergic or hypersensitivity reactions of skin and tissues when exposed to materials or their extracts for prolonged periods of time. *Irritation* tests determine whether the part, material, or extract causes local irritation on skin or mucous membranes via exposure through skin, eye, or mucosa. *Acute system toxicity* testing evaluates whether the extracts cause toxicity effects on various systems of the body when injected into the animal. *Subchronic toxicity* testing is used for all implants. The extract is injected intraperitoneally (in the abdomen walls) or intravenously (in the veins) and evaluated for system toxicity effects. *Genotoxicity* testing evaluates the genetic damage caused by the extracts. *Hemocompatibility* evaluates the compatibility of materials and their extracts with blood and blood components.

### 3.2.8 Supplemental Tests

Additional tests are occasionally required that may include:

- Carcinogenesis—Long-term tests for implants to test for formation of cancerous cells.
- Reproductive—Long-term test on the effects of the materials and extracts on the reproductive system.
- Biodegradation—Long-term evaluation of material degradation in the body.

### 3.2.9 Shelf Life and Aging

Accurate prediction of medical product shelf-life performance is critical. Fortunately, the majority of medical products are constructed from a limited number of polymers that have been well characterized in terms of change in their properties over extended-use periods. A procedure known as the simplified protocol for accelerated aging (also called the “10-degree rule”) is used. When applied to well-characterized polymer systems over moderate temperature ranges, the test results obtained can be within the required degree of accuracy [11].

### 3.2.10 Joining and Welding

Medical devices may have complex shapes that cannot be molded directly. In these cases, the plastic parts made need to be separately made and joined together with adhesives or by welding. A number of techniques are used for welding, including:

- Hot gas welding
- Speed tip welding
- Extrusion welding
- Contact welding
- Hot plate welding
- High-frequency welding
- Injection welding
- Ultrasonic welding
- Friction welding
- Spin welding
- Laser welding
- Solvent welding.

Changes in the plastics from welding processes must be considered as well as introduction of adhesives and the chemicals used in them.

### 3.2.11 Medical Grade Plastics

The effort to evaluate many of these factors can be reduced by using medical grades of the plastics of interest. The manufacturers of these plastics may have already had a significant number of the studies done thereby reducing the time and cost of commercialization.

### 3.3 Common Medical Device Polymers

This section covers many of the common plastics that are used in various medical devices. It is primarily focused on the polymers and has a chemistry focus. Included for each polymer are chemical structures, some sterilization guidance, and some example uses.

#### 3.3.1 Polyethylene

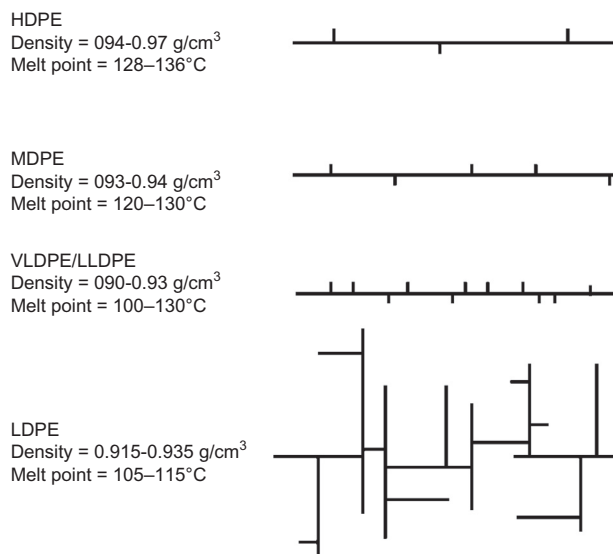
Polyethylene can be made in a number of ways. The way it is produced can affect its physical properties. It can also have very small amounts of comonomers, which will alter its structure and properties.

The basic types or classifications of polyethylene, according to the ASTM D1248, are:

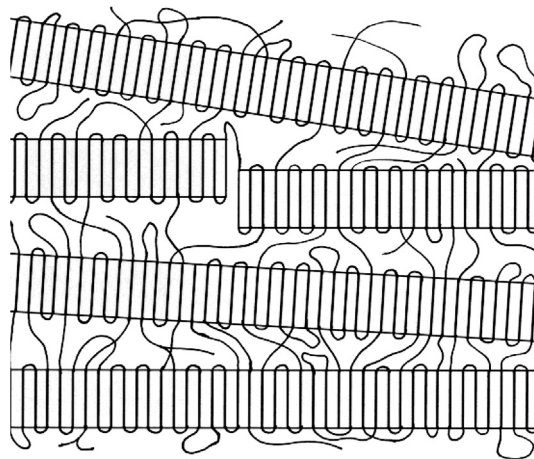
- Ultra-low-density polyethylene (ULDPE), polymers with densities ranging from 0.890 to 0.905 g/cm<sup>3</sup>, contains comonomer.
- Very-low-density polyethylene (VLDPE), polymers with densities ranging from 0.905 to 0.915 g/cm<sup>3</sup>, contains comonomer.
- Linear low-density polyethylene (LLDPE), polymers with densities ranging from 0.915 to 0.935 g/cm<sup>3</sup>, contains comonomer.
- Low-density polyethylene (LDPE), polymers with densities ranging from about 0.915 to 0.935 g/cm<sup>3</sup>.
- Medium density polyethylene (MDPE), polymers with densities ranging from 0.926 to 0.940 g/cm<sup>3</sup>, may or may not contain comonomer.
- High-density polyethylene (HDPE), polymers with densities ranging from 0.940 to 0.970 g/cm<sup>3</sup>, may or may not contain comonomer.

Figure 3.16 shows the differences graphically. The differences in the branches in terms of number and length affect the density and melting points of some of the types.

Branching affects the crystallinity. A diagram of a representation of the crystal structure of polyethylene is shown in Figure 3.17. One can imagine how branching in the polymer chain can disrupt the crystalline regions. The crystalline regions are the



**Figure 3.16** Graphical depictions of polyethylene types.



**Figure 3.17** Graphical diagram of polyethylene crystal structure.

highly ordered areas in the shaded rectangles of Figure 3.17. A high degree of branching would reduce the size of the crystalline regions, which leads to lower crystallinity.

#### *Sterilization:*

The low heat deflection temperatures of polyethylene plastics (30–50°C) make them unsuitable for steam and autoclave sterilization. The plastics would bend, warp, and deform under the temperatures (100–130°C) used in these sterilization methods. EtO, gamma radiation, and e-beam sterilization methods are suitable.



EtO has no effect on the properties of HDPE. Polyethylene will oxidize or cross-link under high-energy radiation and needs to be stabilized to reduce it. In some cases, UHMWPE is deliberately cross-linked with high-energy radiation to improve the wear behavior in the knee and hip implants. Radiation doses of 50–100 kGy are used for cross-linking and standard doses of 25–40 kGy (in an inert atmosphere) are used to sterilize the UHMWPE parts.

*Applications and uses:* Containers, packaging films, pouches, lidstock, breather patches, and headers for bags. UHMWPE is used as the wear-bearing surface of hip and knee arthroplasty and total joint replacement.

### 3.3.2 Polypropylene

The three main types of PP are generally available:

1. *Homopolymers* are made in a single reactor with propylene and catalyst. It is the stiffest of the three propylene types and has the highest tensile strength at yield. In the natural state (no colorant added), it is translucent and has excellent see-through or contact clarity with liquids. In comparison to the other two types, it has less impact resistance, especially below 0°C.
2. *Random copolymers* (homophasic copolymer) are made in a single reactor with a small amount of ethylene (<5%) added which disrupts the crystallinity of the polymer allowing this type to be the clearest. It is also the most flexible with the lowest tensile strength of the three. It has better room temperature impact than homopolymer but shares the same relatively poor impact resistance at low temperatures.
3. *Impact copolymers* (heterophasic copolymer), also known as block copolymers, are made in a two reactor system where the homopolymer matrix is made in the first reactor and then transferred to the second reactor where ethylene and propylene are polymerized to create ethylene propylene rubber (EPR) in the form of microscopic nodules dispersed in the homopolymer matrix phase. These nodules impart impact resistance both at ambient and

cold temperatures to the compound. This type has intermediate stiffness and tensile strength and is quite cloudy. In general, the more ethylene monomer added, the greater the impact resistance with correspondingly lower stiffness and tensile strength.

Oriented and multilayered films of PP are also common.

*Sterilization resistance:* The use of PP films in radiation-sterilized applications is somewhat limited. The high ratio of film surface area to mass, combined with the sensitivity of irradiated PP to oxygen-promoted degradation, causes them to be severely embrittled after normal sterilizing doses of radiation. Even resin formulations which yield highly radiation-resistant injection molded devices are badly degraded after irradiation in thin film form. Special formulations of medical PP are coming to market specifically to overcome this disadvantage. Blends of PP and metallocene-catalyzed, ethylene-based plastomers are particularly suited to the construction of highly radiation-resistant, thin-gauge medical device packages.

*Gamma radiation resistance:* Basell offers several grades which are specially formulated to minimize the effects after typical radiation sterilization dosages of up to 5 megarads, as tested by Basell protocol. Catastrophic failures have been reported in gamma-sterilized PP materials that experienced shelf-life storage. This was a result of long-term degradation. “Long-lived free radicals trapped in the crystalline domains migrated toward the crystalline/amorphous interface combining with available oxygen to form peroxy and hydroperoxy radicals that initiated degradation near the interface. As enough tie molecules between crystallites were cut through the chain scission process, significant reduction of PP’s elongation could occur which would lead to catastrophic failures” [12].

PP materials that are adequately stabilized can survive the radiation stabilization process with enough antioxidant remaining to protect the sterilized product from further degradation. The stability of sterilized PP depends on the supplier stabilizer system, and the stability of a radiation-sterilized PP can be simply and rapidly determined by oxygen induction testing (OIT) [13].

*Autoclave sterilization:* PP has a melting temperature high enough for autoclave application.

#### Applications and uses:

- Homopolymer: Thermoforming, slit film and oriented fibers, high clarity, syringes, and closures, sutures, drapes, and gowns.
- Random copolymer: Food, household chemicals, beauty aid products, clear containers, and hot fill applications.
- Impact copolymers: Film, sheet, profiles, high-pressure resistance, medical trays, and thin-wall parts.

### 3.3.3 Polystyrene

Polystyrene is the simplest plastic based on styrene. Its structure is shown in Figure 3.18. Pure solid polystyrene is a colorless, hard plastic with limited flexibility. Polystyrene can be transparent or can be made in various colors. It is economical and is used for producing plastic model assembly kits, plastic cutlery, CD “jewel” cases, and many other common objects where a fairly rigid, economical plastic is desired. There are numerous medical applications.

Three general polystyrene types are:

1. General purpose or crystal (PS or GPPS)
2. High impact (HIPS)
3. Syndiotactic (SPS).

#### Sterilization:

Polystyrene is not recommended for steam and autoclave sterilization. Its low heat distortion

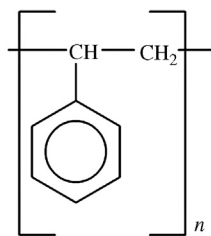


Figure 3.18 Chemical structure of polystyrene.

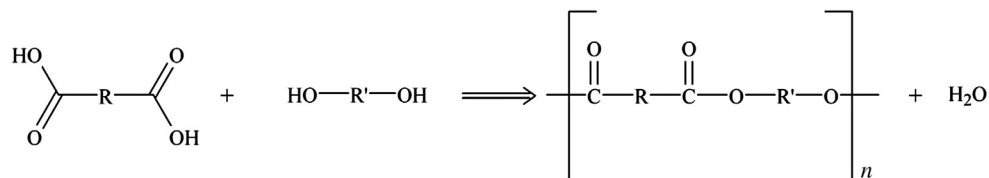


Figure 3.19 Chemical structure of polyester.

temperature will cause the parts to warp and disfigure. Polystyrene can be sterilized with EtO.

*EtO resistance:* Polystyrene resins retain their properties after exposure to one normal EtO sterilization cycle. Excessive or multiple exposures to EtO sterilization are not recommended because EtO can cause embrittlement and stress cracking of the polymer [13].

*Gamma and electron beam resistance:* Polystyrene is very stable to gamma radiation and electron beam due to its high aromatic content. Color changes are seen after e-beam sterilization [14].

*UV light sterilization resistance:* Styron is resistant to sterilization by UV light. This technology is based on a short wavelength of 254 nm during which the part-to-lamp distance is controlled [15].

#### Applications and uses:

- *General purpose:* Diagnostic instruments and disposable laboratory ware, Petri dishes, tissue culture components, flasks, and pipettes.
- *Oriented:* Oriented polystyrene films can be printed and laminated to foams for food service plates and trays offering improved esthetics. The films can also be used as a laminate to polystyrene sheet for a high-gloss shine.
- *High impact:* Laboratory ware and other medical devices.

### 3.3.4 Polyester

Polyesters are formed by a condensation reaction that is very similar to the reaction used to make polyamide or nylons. A diacid and dialcohol are reacted to form the polyester with the elimination of water as shown in Figure 3.19.

While the actual commercial route to making the polyesters may be more involved, the end result is the same polymeric structure. The diacid is usually aromatic. Polyester resins can be formulated to be brittle and hard, tough and resilient, or soft and

flexible. In combination with reinforcements such as glass fibers, they offer outstanding strength, a high strength-to-weight ratio, chemical resistance, and other excellent mechanical properties. The three dominant materials in this plastics family are PC, PET, and PBT. Liquid crystal polymers are also considered to be polyesters. Thermoplastic polyesters are similar in properties to Nylon 6 and Nylon 66, but have lower water absorption and higher dimensional stability than the nylons.

*Sterilization:*

*EtO Sterilization:*

Polyesters generally can be sterilized with EtO. Due to their low hydrolytic stability (i.e., the polymer chains can be cleaved by hydrolysis) and low glass transition temperatures, steam and higher heat autoclave sterilizations are not recommended. All polyesters based on terephthalic acid contain aromatic groups and hence can be sterilized with gamma and e-beam radiation.

*Gamma radiation resistance:* Ticona Vectra<sup>®</sup> liquid crystalline polymers (LCPs) have excellent resistance to gamma radiation.

*Steam sterilization resistance:* Ticona Vectra<sup>®</sup> LCP has good resistance to hydrolysis. Prolonged exposure to hot water and steam at high temperatures (121°C, 2 bar up to 1000 h) leads to hydrolytic degradation however. The glass-fiber-reinforced grades exhibit a more severe decline in mechanical properties, as do many other glass-fiber-reinforced polymers, owing to capillary action at the glass-fiber/polymer interface (wick effect). Ticona Vectra<sup>®</sup> A625 has particularly good resistance to hydrolysis. Under selected test conditions, virtually no change in tensile strength or elastic modulus occurred after 1000 h.

*PBT* can be sterilized by gamma ray or dry heat, up to about 180°C.

*Applications and uses:*

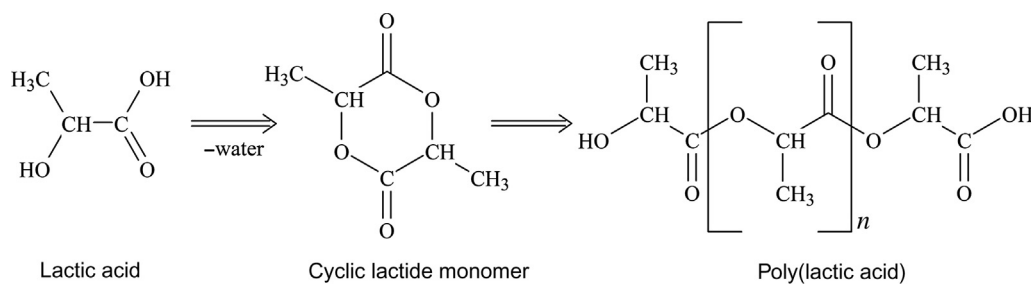
*Liquid crystalline polymer:* Sterilizable trays, dental tools, and surgical instruments, surgical device control cables, surgical tubing, cannulae, films.

*PBT:* Packaging, syringe pump component, dental instruments, miniature scalpel blade holders, melt blown for liquid filtration applications, high-temperature caps.

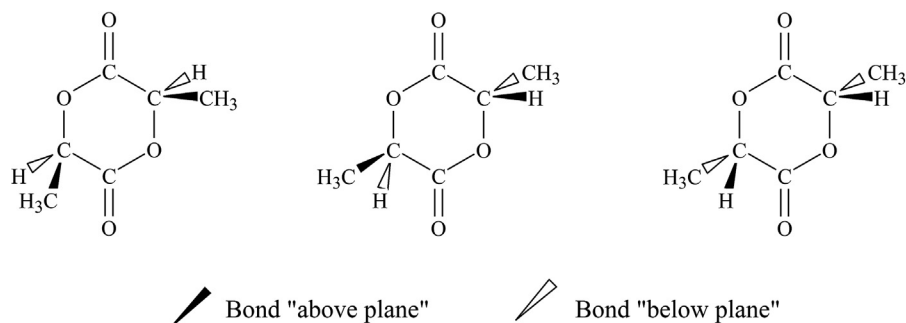
### 3.3.5 Polyester (PLA and Other Biosorbable Plastics)

Bioresorbable polymer implants are rapidly growing alternatives to traditional implants in many applications. These implants are only required to serve for a certain time period ranging from weeks to months. PLA is derived from renewable resources, such as corn starch or sugarcane. PLA polymers are considered biodegradable and compostable. PLA is a thermoplastic, high-strength, high-modulus polymer that can be made from annually renewable sources to yield articles for use in either the industrial packaging field or the biocompatible/bioabsorbable medical device market. Bacterial fermentation is used to make lactic acid, which is then converted to the lactide dimer to remove the water molecule which would otherwise limit the ability to make high molecular weight polymer. The lactide dimer, after the water is removed, can be polymerized without the production of the water. This process is shown in Figure 3.20.

The dimer can be isolated into three forms: the optically active L-lactide, the optically active D-lactide, and the optically inactive DL mixture DL-lactide. These stereoisomer structures are shown in Figure 3.21. The enantiomeric ratio of the dimer can be controlled. Fermentation-derived lactic acid is 95% L-isomer.



**Figure 3.20** Conversion of lactic acid to PLA.



**Figure 3.21** Stereoisomeric structures of the lactide dimer.

Polyhydroxyalkanoates (PHAs) are naturally produced and include poly-3-hydroxybutyrate (PHB or PH3B), polyhydroxyvalerate (PHV), and polyhydroxyhexanoate (PHH). A PHA copolymer called PHBV (poly(3-hydroxybutyrate-co-3-hydroxyvalerate)) is less stiff and tougher, and it may be used as packaging material. Chemical structures of some of these polymers are shown in [Figure 3.22](#).

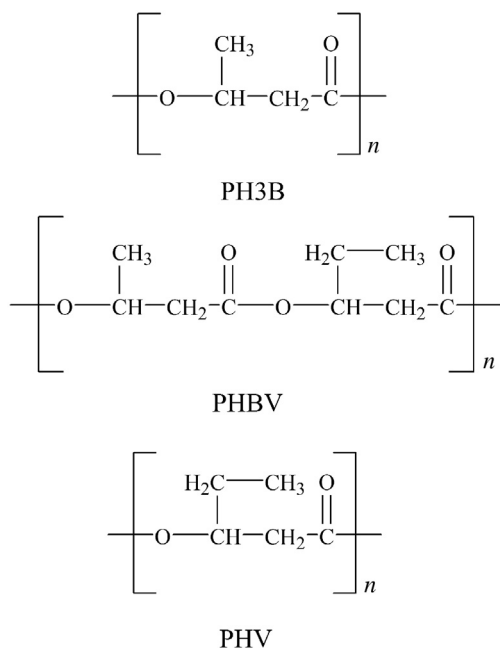
#### *Sterilization:*

*Autoclave* and *dry heat* is usually performed at temperatures equal to or higher than 121°C. PLA, PGA, and PLGA implants are susceptible to hydrolysis and their deformation at higher temperatures therefore precludes the use of these sterilization methods.

*EtO sterilization:* EtO is chemically highly reactive and acts as a plasticizer for PLA, PGA, and PLGA, which can lead to changes in the polymer structure. EtO sterilization is performed at temperatures of 50–60°C, which can lead to molecular weight loss. Therefore, EtO sterilization is not suggested.

*Radiation sterilization:* For the radiation sterilization of bioresorbable polymers, temperature and dose conditions need to be closely controlled to avoid significant degradation. Gamma sterilization at dry ice temperatures is preferred.

*Applications and uses:* Commercially available biodegradable devices are employed in sutures, orthopedic fixation devices, dental implants, ligature clips, tissue staples, and skin covering devices; stents, dialysis media, and drug-delivery devices. It is also being evaluated as a material for tissue engineering.



**Figure 3.22** Structures of several PHAs.

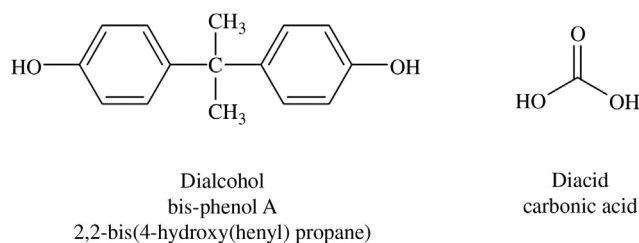
### 3.3.6 Polycarbonate

PC is a type of polyester but is being discussed separately. Theoretically, PC is formed from the reaction of bis-phenol A and carbonic acid. The structures of these two monomers are shown in [Figure 3.23](#).

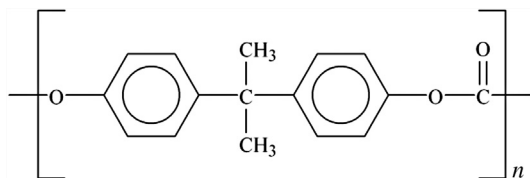
Commercially, different routes are used (different monomers), but the PC polymer of the structure shown in [Figure 3.24](#) is the result.

PC performance properties include:

- Very impact resistant, is virtually unbreakable and remains tough at low temperatures
- “Clear as glass” clarity
- High heat resistance
- Dimensional stability
- Resistant to UV light, allowing exterior use
- Flame retardant properties.



**Figure 3.23** Chemical structures of monomers used to make PC polyester.



**Figure 3.24** Chemical structure of PC polyester.

Typical application requirements include:

- Optical clarity: transparent and colorable
- Durability/impact resistance
- Ductility to withstand impact of rigorous use
- Biocompatible tested grades
- Sterilizable: gamma, EtO; limited autoclave
- Dimensional stability
- Ultrasonic weldable; bondable

#### *Sterilization:*

PCs can be sterilized by high-energy gamma and e-beam radiation but must be stabilized to prevent polymer degradation and discoloration.

**Gamma radiation resistance:** PC is much more resistant to gamma irradiation than most polymers. The primary effect of gamma irradiation on PC is chain scission (chain breakage). Fortunately, the high chain stiffness of PC makes it very difficult for the two ends of the chain to move apart. Therefore, many of the broken chains will recombine. In addition, the aromatic nature of the PC gives it other opportunities to absorb the energy from the gamma photon, rather than just breaking the polymer chain. From a retention of mechanical properties point of view, PC has always been

considered one of the most resistant materials for gamma irradiation [16]. Assuming that 28 kGy (2.8 megarads) of energy is required to sterilize PC, the resin can be sterilized 10–20 times before any appreciable reduction in mechanical strength occurs. PC does, however, become progressively more yellow with each sterilization. Special stabilizers can make them less susceptible to color changes.

**EtO resistance:** The properties of polystyrene resins are unchanged to 50 EtO sterilization cycles [17]. The temperature during sterilization should not exceed 65°C. Tests have shown that repeated sterilization can cause slight brittleness combined with crack formation. The impact strength of test specimens treated with pure EtO at 55°C for 50 cycles of 6 h each is unchanged in comparison with the starting level despite slight crack formation.

**Steam resistance:** After one to three autoclave cycles (Hi-Vac at 132°C), PC resins have limited utility [18]. Makrolon® DP 1-1262 and Makrolon® Rx-1805 can be sterilized by employing superheated steam (121°C) [18,19]. To prevent deformation of the molded parts, the sterilization temperature should not exceed 125°C. Care must also be taken to ensure that Makrolon parts are not damaged by substances added to the boiler feed water, such as alkaline corrosion inhibitors, and that the article is positioned in such a way that no condensation can accumulate inside it. As a rule, it is possible to sterilize molded parts made of Makrolon many times before gradual chemical decomposition reduces the mechanical strength to a level where it is no longer adequate for certain applications. Sterilization tests on test specimens have shown that even after 100 cycles of 30 min each at 120–125°C, the part still retains comparatively good impact strength. This also generally applies even if the material exhibits hairline cracks and the molded part appears slightly milky as a result of the high stresses imposed on the material by repeated sterilization.

**Sterilization with peracetic acid:** Makrolon can be sterilized with 2% concentration peracetic acid without suffering damage.

**Sterilization with hot air:** Sterilization with hot air plays only a minor role for molded parts in Makrolon, since temperatures of 180–200°C are generally used to save time. No problems are to be expected with molded parts of Makrolon up to a hot air temperature of 135°C.

*Applications and uses:* Medical apparatus (sterilizable), reservoirs, high-pressure syringes, artery cannulas, stopcocks, luers, centrifugal force separators, blood filter housings, dialyzer housings; glucose meters, pumps, insulin pens; surgical device handles and housings.

### 3.3.7 Polyvinyl Chloride

PVC is a flexible or rigid material that is chemically nonreactive. Rigid PVC is easily machined, heat formed, welded, and even solvent cemented. PVC can also be machined using standard metal working tools and finished to close tolerances and finishes without great difficulty. PVC resins are normally mixed with other additives such as impact modifiers and stabilizers, providing hundreds of PVC-based materials with a variety of engineering properties.

There are three broad classifications for rigid PVC compounds: Type I, Type II, and CPVC. Type II differs from Type I due to greater impact values, but lower chemical resistance. CPVC has greater high temperature resistance. These materials are considered “unplasticized,” because they are less flexible than the plasticized formulations. PVC has a broad range of applications, from high-volume construction-related products to simple electric wire insulation and coatings.

PVC is the most widely used plastic resin in medical devices. Approximately 25% of all plastic medical products are made of PVC, according to most market estimates. The main reason is the resin’s low cost, ease of processing, and the ability to tailor its properties to a wide range of applications. The following is a more thorough list of reasons for the popularity of PVC in medical devices:

- Used successfully for over 50 years in various medical devices with no known adverse or toxic effects.
- Plasticized PVC has good clarity and transparency retention so that tubes and other products allow for continual monitoring of fluid flow.
- PVC can be manufactured in a range of flexibilities and its resistance to kinking in tubing reduces the risk of fluid flow being interrupted.
- PVC can be used in a wide range of temperatures, and it retains its flexibility, strength, and durability at low temperatures.

- PVC formulations exhibit excellent strength and toughness.
- PVC exhibits very good chemical resistance and stability and is also biocompatible for applications in blood bags and drug delivery.
- Plasticized PVC maintains its product integrity under various sterilization environments like steam, radiation, and EtO.
- PVC can be easily welded to various other plastics by a wide range of methods.
- Its relatively lower cost and high-performance value maintains its position as the number one plastic used in medical devices.
- PVC has safety and cost advantages for a wide variety of medical applications, especially for single-use disposable devices.

A large number of plasticizers have been used with PVC to reduce rigidity, the most common family being the phthalates, especially, di(2-ethylhexyl) phthalate (DEHP). It is sometimes called dioctyl phthalate and abbreviated DOP. These plasticizers are incorporated in amounts ranging from 40% to 65%. There are many other plasticizers used in medical applications.

Heat stabilizers are typically used in medical grade PVC, to protect it against not only the high temperatures the resin might see during processing, but also the high heat it may encounter in storage or autoclaving. Barium–zinc additives are very effective heat stabilizers for PVC but are restricted for medical applications in some countries. Alternatives like calcium–zinc formulations are often used to stabilize medical-grade PVC. Heat stabilizers trap the hydrogen chloride that is generated when PVC decomposes at high temperatures. This prevents discoloration and degradation. Rigid PVC may contain up to 15% by weight of thermal stabilizers. Another additive, Tinuvin<sup>®</sup>–P, 2-(2H-benzotriazol-2-yl)-*p*-cresol, is used to provide stability from exposure to UV light.

#### *Sterilization:*

*Gamma radiation resistance:* Gamma-ray sterilization generally uses an energy dose of about 2.5 megarads. Sterilization at excessive dosage rates or with excessive sterilization times can result in discoloration or odor. Rigid PVC suffers more severe adverse effects than flexible PVC when inappropriate procedures of this type are used. Specific



gamma radiation-resistant PVC blends are commercially available [20]. PVC degrades by chain scission when exposed to high-energy radiation causing degradation or the radicals can react with oxygen to form oxidized products leading to discoloration.

**EtO resistance:** EtO sterilization is recommended for PVC. When choosing EtO gas sterilization, a 7- to 14-day quarantine period is necessary to assure that there is no EtO residue [10]. Sterilization using EtO gas is a method which has proven particularly useful for PVC products having a large number of cavities or capillaries [10].

**Autoclave sterilization:** Steam sterilization in autoclaves is conducted at temperatures from 121°C to 134°C. The temperature used is above the glass transition temperature of PVC. Rigid unplasticized PVC is unsuitable for use in steam and autoclave sterilizations as the material and parts will warp and distort when exposed to that temperature range. The temperature range poses no problem for flexible PVC, which is a rubbery material. Plasticized, flexible PVC can be sterilized using steam or autoclave. Low-temperature steam sterilization (conducted at 60–80°C) can be used for both rigid and flexible PVC.

**Low-temperature plasma sterilization:** PVC products can also be sterilized using newly developed low-temperature plasma technology (Sterrad® plasma sterilization) [10].

**Applications and uses:**

- Rigid PVC: luer connectors and Y-sites.
- Flexible PVC: secondary packaging, blister packs, solution containers, fluid transport tubes, drip chambers, diaphragms, pull rings, oxygen facemasks, and gloves.

### 3.3.8 Polyethersulfone

Polyethersulfone (PES) is an amorphous polymer and a high-temperature engineering thermoplastic. Even though PES has high-temperature performance, it can be processed on conventional plastics processing equipment. Its chemical structure is shown in Figure 3.25. PES has an outstanding ability to withstand exposure to elevated temperatures in air and water for prolonged periods.

Because PES is amorphous, mold shrinkage is low and is suitable for applications requiring close tolerances and little dimensional change over a wide temperature range. Its properties include:

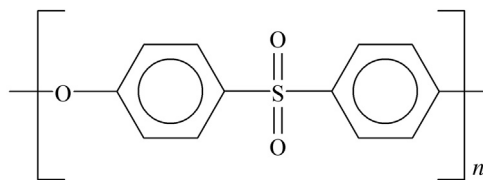


Figure 3.25 Structure of PES.

- Excellent thermal resistance— $T_g$  224°C
- Outstanding mechanical, electrical, flame, and chemical resistance
- Very good hydrolytic and sterilization resistance
- Good optical clarity

**Sterilization:**

**General sterilization resistance:** PES withstands cold sterilants, disinfectants, and germicides.

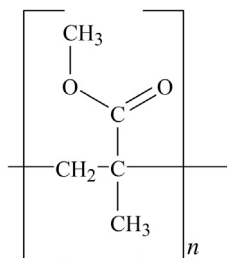
**Gamma and electron beam radiation resistance:** PES offers very high resistance to gamma radiation over the entire range of service temperatures. PES products exposed to high-energy radiation suffer a noticeable decrease in tensile strength at yield and a significant decrease in ultimate elongation. Gassing is very slight; transmittance for gamma rays is very high.

**Autoclave or steam sterilization resistance:** PES parts can be repeatedly sterilized in superheated steam. After more than 100 sterilization cycles, samples remain transparent and largely retain their high level of mechanical properties. PES absorbs more water and is thus suitable only for steam sterilization without a vacuum phase. In order to avoid environmental stress cracking, the level of molded in stress in parts should be as low as possible.

**Applications:** Medical equipment that requires repeated sterilization; fluid handling couplings/fittings.

### 3.3.9 Polyacrylate (Acrylic, PMMA)

While a large number of acrylic polymers are manufactured, PMMA is by far the most common. The structure of PMMA is shown in Figure 3.26. Nearly everyone has heard of Plexiglas®. PMMA has two very distinct properties that set the products apart from others. First, it is optically clear and colorless. It has a light transmission of 92%. The 4%



**Figure 3.26** Structure of PMMA.

reflection loss at each surface is unavoidable. Second, its surface is extremely hard. They are also highly weather resistant.

PMMA films show very good abrasion resistance, weather resistance (with a UV absorber), and are absolutely colorless.

Acrylic resins are available as homopolymer (primarily PMMA), copolymer, and terpolymer. Each of these is discussed separately in the following sections.

*Sterilization resistance:* Wet EtO and steam sterilization methods are not recommended for acrylic [21].

*Gamma radiation resistance:* Plexiglas SG-7 exposed to 5.0 megarads of gamma radiation experiences virtually no yellowing or discoloration. Properties such as impact, tensile, and flexural strength, modulus of elasticity, and percent elongation are constant [22]. Gamma sterilization has a tendency to yellow most acrylics. This yellowing is often temporary and recovery can be complete, with the parts retaining their original integrity. The higher the radiation dosage, the greater the yellowing, and the longer the required recovery time. Current techniques have cut recovery time to a week for some grades [22].

*E-beam radiation resistance:* Plexiglas maintains constant impact, tensile, and flexural strength, modulus of elasticity, and percent elongation properties [23].

*EtO resistance:* Acrylics and impact-modified acrylics are compatible with EtO gas and can be EtO sterilized without adversely affecting the medical device.

*Applications and uses:* Clear, disposable plastics—only glass transmits light as well; chest drainage units, medical spikes, breathing apparatus accessories, urological accessories, Y-sites, check valves, filter housings, IV adaptors, IV pump housings, medical cassettes, blood handling components, and catheter accessories.

### 3.3.10 Hydrogel (Acrylate)

Hydrogel is a special acrylic polymer or blend of acrylic and silicone polymers that is used in contact lenses. The acrylic is made from monomers that have hydroxyl (—OH) groups on them that “like” water. One such hydrophilic polymer is poly (hydroxyl ethyl acrylate) (or PHEA) or poly (hydroxyl ethyl methacrylate) (or PHEMA). Blends of a hydrophobic silicone with a hydrophilic PHEMA produce a lens material that has improved oxygen transmissibility.

The oxygen transmission is the difference between silicone hydrogel lenses and conventional hydrogel lenses.

Hydrogels used in dressings are also an important component in many different types of wound care. The hydrogel dressing is designed to hold moisture in the surface of the wound, providing the improved environment for both cleaning the wound, and allowing the body to rid itself of necrotic tissue. The moisture in the wound is also essential in pain management for the patient, and these dressings are very soothing and cooling.

*Sterilization:* Hydrogel contact lenses are generally chemically sterilized by soaking in solutions designed for that purpose.

*Applications and uses:* Soft contact lenses, wound dressings, drug delivery.

### 3.3.11 Polysulfone

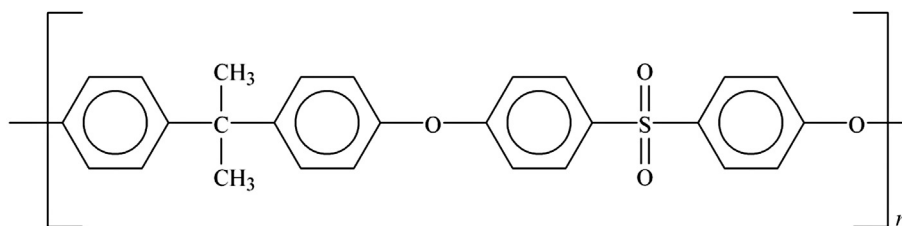
Polysulfone (PSU) is a rigid, strong, tough, high-temperature amorphous thermoplastic. The structure of PSU is shown in Figure 3.27.

Its properties are:

- High thermal stability
- High toughness and strength
- Good environmental stress crack resistance
- Inherent fire resistance
- Transparency.

*General sterilization resistance:* PSU maintains a high enough glass transition temperature to withstand different sterilization techniques including steam, EtO, and gamma and electron beam radiation.

*Gamma and electron beam radiation resistance:* PSUs are highly resistant to degradation by gamma



**Figure 3.27** Structure of PSU.

or electron beam radiation. There is no evidence of change in mechanical properties after irradiation at 2.5, 4, or 6 megarads. Tensile strength, elongation, modulus, and notched Izod impact values remain essentially unchanged. There is no significant change in chemical resistance following irradiation. PSU discolors during irradiation; the level of discoloration increases with the radiation dosage.

*EtO resistance:* MPU couplings can be EtO sterilized up to five cycles.

*Autoclave or steam sterilization resistance:* PSU can withstand greater than 1000 autoclave cycles at 140°C with no significant change in mechanical properties. Transparent PSU will retain its clarity during extended service life. PSU parts can be repeatedly sterilized in superheated steam. After more than 100 sterilization cycles, samples remain transparent and largely retain their high level of mechanical properties. MPU couplings can be autoclave sterilized at 121°C (270°F) for 60 min. The maximum number of cycles recommended is 25.

*Dry heat sterilization:* Products made from PSU can be dry heat sterilized at 140°C; recommended exposure is 6 h in dry 125°C heat.

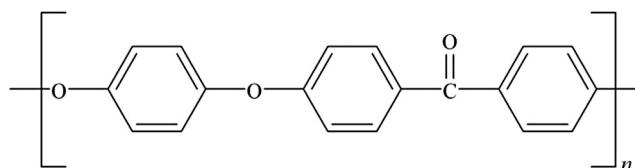
*Chemical sterilants:* PSU performs well, retaining its strength in a wide variety of aqueous disinfectants including buffered glutaraldehyde, phenol, quaternary ammonium, iodophor and formaldehyde types, and detergent germicide.

*Applications:* Membranes and fluid handling applications and MPU couplings.

### 3.3.12 Polyetheretherketone

Polyetheretherketones (PEEK) are also referred to as polyarylktones. The most common structure is given in [Figure 3.28](#).

PEEK is a thermoplastic with extraordinary mechanical properties. The Young's modulus of elasticity is 3.6 GPa and its tensile strength is 170 MPa. PEEK is partially crystalline, melts at around 350°C,



**Figure 3.28** Structure of PEEK.

and is highly resistant to thermal degradation. The material is also resistant to both organic and aqueous environments, and is used in bearings, piston parts, pumps, compressor plate valves, and cable insulation applications. It is one of the few plastics compatible with ultrahigh vacuum applications. In summary, the properties of PEEK include:

- Outstanding chemical resistance
- Outstanding wear resistance
- Outstanding resistance to hydrolysis
- Excellent mechanical properties
- Outstanding thermal properties
- Very good dielectric strength, volume resistivity, tracking resistance
- Excellent radiation resistance

*Gamma radiation resistance:* Victrex® PEEK shows excellent resistance to hard (gamma) irradiation, absorbing over 1000 megarads of radiation without suffering significant damage and showing no embrittlement of the polymer. It is believed that PEEK will resist dose levels of well over 10,000 megarads of particle (alpha or beta) irradiation without significant degradation of properties. Fiber-reinforced grades are expected to show even better performance than this.

*EtO resistance:* PEEK polymers can be sterilized by EtO methods.

*Steam sterilization resistance:* PEEK maintains high mechanical strength, stress cracking resistance, and hydrolytic stability in the presence of

pressurized steam (200°C, 14 bar), dry heat (170–180°C), hot water, solvents, and chemicals. PEEK can withstand high temperatures and pressures for extended periods of time.

*Applications and uses:* Reusable medical components including dental syringes and keyhole surgery devices, catheters, disposable surgical instruments.

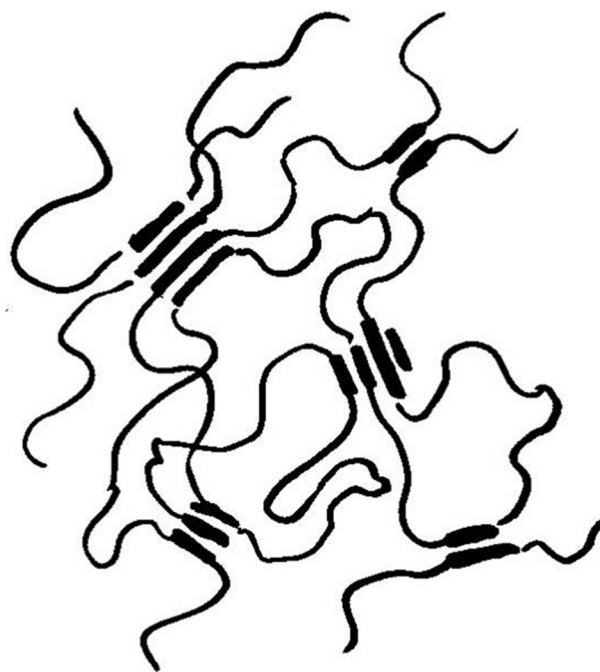
### 3.3.13 Thermoplastic Elastomers (TPE, TPU)

An elastomer is a polymer with the property of “elasticity,” generally having notably low Young’s modulus and high yield strain compared with other materials [23]. The term is often used interchangeably with the term rubber. Elastomers are amorphous polymers existing above their glass transition temperature, so that considerable segmental motion is possible, so it is expected that they would also be very permeable. At ambient temperatures, rubbers are thus relatively soft and deformable. Their primary uses are for seals, adhesives, and molded flexible parts. Elastomers may be thermosets (requiring vulcanization, a form of cross-linking) or thermoplastic, called thermoplastic elastomer or TPE.

TPEs have two big advantages over the conventional thermoset (vulcanized) elastomers. Those are ease and speed of processing. Other advantages of TPEs are the ability to recycle scrap, lower energy costs for processing, and the availability of standard, uniform grades (not generally available in thermosets).

TPEs are molded or extruded on standard plastics-processing equipment in considerably shorter cycle times than those required for compression or transfer molding of conventional rubbers. They are made by copolymerizing two or more monomers, using either the block or graft polymerization techniques. One of the monomers provides the hard, or crystalline, polymer segment that functions as a thermally stable component; the other monomer develops the soft or amorphous segment, which contributes the elastomeric or rubbery characteristic. This is shown in Figure 3.29 in which the hard crystalline parts of the molecule are the thick lined segments of the polymer chain. As shown, the hard segments can be aligned together forming crystalline regions.

Physical and chemical properties can be controlled by varying the ratio of the monomers and the length of the hard and soft segments. Block



**Figure 3.29** Schematic of the structure of a TPE.

techniques create long-chain molecules that have various or alternating hard and soft segments. Graft polymerization methods involve attaching one polymer chain to another as a branch. The properties that are affected by each phase can be generalized.

“Hard phase”—plastic properties:

1. Processing temperatures
2. Continuous use temperature
3. Tensile strength
4. Tear strength
5. Chemical and fluid resistance
6. Adhesion to inks, adhesives, and over-molding substrates.

“Soft phase”—elastomeric properties:

1. Lower service temperature limits
2. Hardness
3. Flexibility
4. Compression set and tensile set.

ISO 18064 [8] sets a standard nomenclature system for TPEs. Those having a prefix TP shall be followed by a letter representing each category of TPEs.

The categories are outlined below:

1. TPA—polyamide TPE, comprising a block copolymer of alternating hard and soft segments with amide chemical linkages in the hard blocks and ether and/or ester linkages in the soft blocks.
2. TPC—copolyester TPE, consisting of a block copolymer of alternating hard segments and soft segments, the chemical linkages in the main chain being ester and/or ether.
3. TPO—olefinic TPE, consisting of a blend of a polyolefin and a conventional rubber, the rubber phase in the blend having little or no cross-linking.
4. TPS—styrenic TPE, consisting of at least a triblock copolymer of styrene and a specific diene, where the two end blocks (hard blocks) are polystyrene and the internal block (soft block or blocks) is a polydiene or hydrogenated polydiene.
5. TPU—urethane TPE, consisting of a block copolymer of alternating hard and soft segments with urethane chemical linkages in the hard blocks and ether, ester or carbonate linkages or mixtures of them in the soft blocks.
6. TPV—thermoplastic rubber vulcanizate consisting of a blend of a thermoplastic material and a conventional rubber in which the rubber has been cross-linked by the process of dynamic vulcanization during the blending and mixing step.
7. TPZ—unclassified TPE comprising any composition or structure other than those grouped in TPA, TPC, TPO, TPS, TPU, and TPV.

Urethanes are a reaction product of a diisocyanate and long and short chain polyether, polyester, or caprolactone glycols. The polyols and the short chain diols react with the diisocyanates to form linear polyurethane molecules. This combination of diisocyanate and short chain diol produces the rigid or hard segment. The polyols form the flexible or soft segment of the final molecule. [Figure 3.30](#) shows the molecular structure in schematic form.

The properties of the resin depend on the nature of the raw materials, the reaction conditions, and the ratio of the starting raw materials. The polyols used have a significant influence on certain properties of the thermoplastic polyurethane. Polyether and polyester polyols are both used to produce many products.

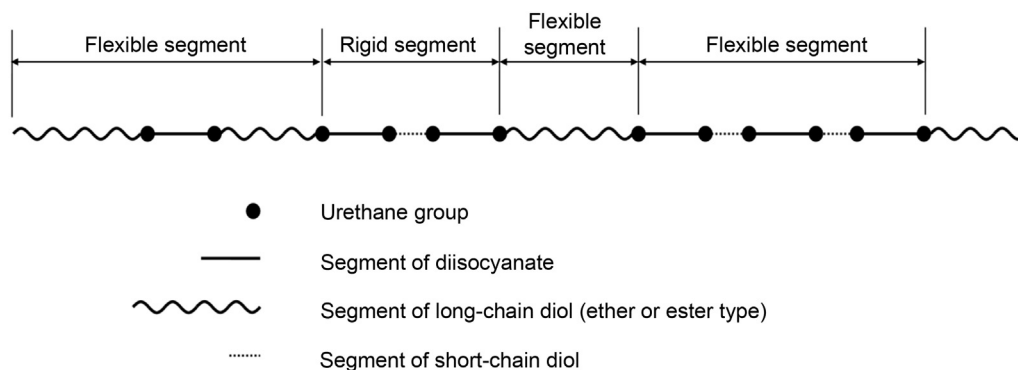
The polyester-based TPUs have the following characteristic features:

- Good oil/solvent resistance
- Good UV resistance
- Abrasion resistance
- Good heat resistance
- Mechanical properties.

The polyether-based TPUs have the following characteristic features:

- Fungus resistance
- Low-temperature flexibility
- Excellent hydrolytic stability
- Acid/base resistance.

In addition to the basic components described above, most resin formulations contain additives to facilitate production and processability.



**Figure 3.30** Molecular structure of a thermoplastic polyurethane elastomer.



The polyether types are slightly more expensive and have better hydrolytic stability and low-temperature flexibility than the polyester types.

**Gamma radiation resistance:** The physical properties of transparent rigid thermoplastic polyurethanes are not significantly affected by exposure to a maximum of 10 megarads of gamma radiation. Discoloration is dramatic upon exposure to gamma radiation. Yellowness index increases from 6.3 before exposure to 77.6 after exposure. The discoloration is permanent with minimal bleach-back.

**EtO resistance:** Transparent and opaque rigid thermoplastic polyurethanes are compatible with multiple cycles of EtO sterilization. They generally retain tensile strength and Izod impact properties after exposure to five cycles of EtO gas. Less than 300 ppm residual EtO was present on the first day following exposure with continued degassing over time.

**Applications and uses:** Catheters, valves, needleless syringes, surgical instruments, wound dressing and tape, shunts, drug patches, medical bags, and tubing.

### 3.3.14 Thermoset Elastomers— Silicone

One of the most important thermoset elastomers is silicone, also known as siloxane, polyorganosiloxane, or polysiloxane. Silicone rubber is a semi-organic synthetic. Its polymer backbone structure consists of a chain of silicon and oxygen atoms rather than carbon and hydrogen atoms, as in the case with other types of rubber. The molecular structure of silicone rubber results in a very flexible—but weak—chain. Silicones are very stable at low and high temperatures. Although fillers may improve properties somewhat, tear and tensile strengths remain relatively low. Figure 3.31 shows four of the primary groups that make up a typical polysiloxane. To simplify the discussion of polysiloxane composition, the monomers are identified by letters:

“M” stands for  $\text{Me}_3\text{SiO}$

“D” for  $\text{Me}_2\text{SiO}_2$

“T” for  $\text{MeSiO}_3$

“Q” for  $\text{SiO}_4$

“P” for replace Me with phenyl side groups

“V” for replace Me with vinyl side groups (typically <1%)

“F” for replace Me with fluorine.

Some common abbreviations for the polymers include MQ, VMQ, PMQ, PVMQ, PDMS poly(1-trimethylsilyl-1-propyne) or PTMSP.

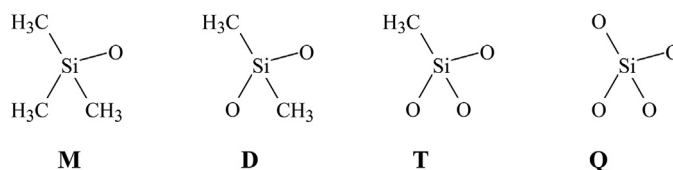
Because silicones, in general, are temperature and moisture resistant, they are typically not affected by most sterilization methods. The most common sterilization methods used for medical devices that contain silicone include dry heat, steam autoclaving, EtO, gamma radiation, and electron beam (e-beam) radiation.

**Dry heat or steam autoclaving** will most likely have little effect on silicone’s physical properties because of its moisture and heat resistance. The drawback to heat sterilization of silicone materials is that the high heat may cause the silicone to expand which must be taken into consideration how the device is configured and packaged.

**EtO sterilization:** Silicones generally have a high permeability to EtO molecules allowing the EtO to diffuse through the polymer network, inducing sterilization throughout the polymer matrix. The only precaution is to ensure that all of the EtO has been removed from the silicone device before it is used, which usually takes 24 h.

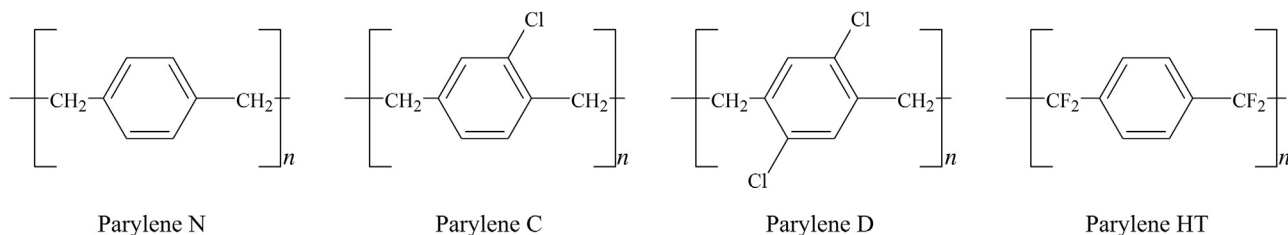
**Gamma and electron beam sterilization:** Radiation is known to induce changes in the molecular architecture of silicone rubber, increasing its molecular weight and decreasing elasticity.

**Applications and uses:** prostheses, artificial organs, facial reconstruction, catheters, artificial skin, contact lenses, drug-delivery systems, contact lenses.



**Figure 3.31** Structure of groups that make up polysiloxanes.





**Figure 3.32** Structures of the Parylene polymer molecules.

### 3.3.15 Poly-p-xylylene (Parylene)

Parylene is the generic name for members of a series of polymers. The basic member of the series, called Parylene N, is poly-para-xylylene, a completely linear, highly crystalline material. The structures of four Parylene types are shown in Figure 3.32.

Parylene polymers are not manufactured and sold directly. They are deposited from the vapor phase by a process which in some respects resembles vacuum metalizing. The Parylenes are formed at a pressure of about 0.1 torr from a reactive dimer in the gaseous or vapor state. Unlike vacuum metalizing, the deposition is not line of sight, and all sides of an object to be encapsulated are uniformly impinged by the gaseous monomer. Due to the uniqueness of the vapor phase deposition, the Parylene polymers can be formed as structurally continuous films from as thin as a fraction of a micrometer to as thick as several millimeters.

The first step is the vaporization of the solid dimer at approximately 150°C. The second step is the quantitative cleavage (pyrolysis) of the dimer vapor at the two methylene–methylene bonds at about 680°C to yield the stable monomeric diradical, para-xylylene. Finally, the monomeric vapor enters the room temperature deposition chamber where it spontaneously polymerizes on the substrate. The substrate temperature never rises more than a few degrees above ambient.

Parylene is used as a coating on medical devices ranging from silicone tubes to advanced coronary stents, synthetic rubber products ranging from medical grade silicone rubber to EPDM (ethylene propylene diene monomer rubber).

The manufacturer of coating equipment and starting materials is Para Tech Coating, Inc. They also offer coating services.

#### *Sterilization:*

Parylene coatings respond to these sterilization methods in a variety of ways (see summary of

responses in Table 3.3). With regard to tensile properties, Parylene N and C were largely unaffected by any of these sterilization techniques. Only steam appears to have had any effect, causing an annealing impact on samples coated with Parylene C, seen as an increase in film crystallinity with a slight change in the tensile properties. Similarly, the tensile modulus property of Parylene N exhibited a minor change.

*H<sub>2</sub>O<sub>2</sub> plasma sterilization* treatment appeared to alter dielectric strength, with a minimal change in Parylene C, and no change in Parylene N.

*Applications and uses:* Needles, prosthetic devices, implantable components, catheter, electrodes, stents, epidural probes, cannulae assemblies.

### 3.3.16 Fluoropolymers

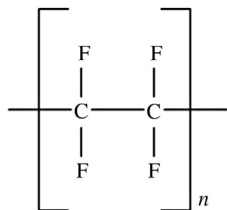
PTFE polymer is an example of a linear fluoropolymer. Its structure in simplistic form is shown in Figure 3.33.

Formed by the polymerization of tetrafluoroethylene (TFE), the (–CF<sub>2</sub>–CF<sub>2</sub>–) groups repeat many thousands of times. The fundamental properties of fluoropolymers evolve from the atomic structure of fluorine and carbon and their covalent bonding in specific chemical structures. The backbone is formed of carbon–carbon bonds and the pendant groups are carbon–fluorine bonds. Both are extremely strong bonds. The basic properties of PTFE stem from these two very strong chemical bonds. The size of the fluorine atom allows the formation of a uniform and continuous covering around the carbon–carbon bonds and protects them from chemical attack, thus imparting chemical resistance and stability to the molecule. PTFE is rated for use up to (260°C). PTFE does not dissolve in any known solvent. The fluorine sheath is also responsible for the low surface energy (18 dynes/cm) and low COF (0.05–0.8, static) of PTFE. Another attribute of the uniform fluorine sheath is the electrical inertness (or non-polarity) of the PTFE molecule. Electrical fields impart only slight polarization in

**Table 3.3** Effects of Various Sterilization Methods on Parylene [24]

Sterilization Method	Parylene N					Parylene C				
	Dielectric Strength	WVT	Tensile Strength	Tensile Modulus	COF	Dielectric Strength	WVT	Tensile Strength	Tensile Modulus	COF
Steam	None	Δ43%	None	Δ12%	Δ38%	None	Δ5*	Δ17%	Δ9%	None
EtO	None	Δ21%	None	None	Δ33%	None	8%	None	None	None
E-beam	NA	None	None	None	None	NA	None	None	None	None
H <sub>2</sub> O <sub>2</sub> plasma	None	None	None	None	Δ48%	Δ9%	None	None	None	Δ188%
Gamma	None	None	None	None	None	None	Δ5%	None	None	None

\*5% values are not likely to be statistically significant. NA = not applicable; COF = coefficient of friction; WVT = water vapor transmission.



**Figure 3.33** Chemical structure of PTFE.

this molecule, so volume and surface resistivities are high.

The PTFE molecule is simple and is quite ordered. PTFE can align itself with other molecules or other portions of the same molecule. Disordered regions are called *amorphous* regions. This is important because polymers with high crystallinity require more energy to melt. In other words, they have higher melting points. When this happens it forms what is called a crystalline region. Crystalline polymers have a substantial fraction of their mass in the form of parallel, closely packed molecules. High molecular weight PTFE resins have high crystallinity and therefore high melting points, typically as high as 320–342°C (608–648°F). The crystallinity of as-polymerized PTFE is typically 92–98%. Further, the viscosity in the molten state (called melt creep viscosity) is so high that high molecular weight PTFE particles do not flow even at temperatures above its melting point. They sinter much like powdered metals; they stick to each other at the contact points and combine into larger particles.

PTFE is called a *homopolymer*, a polymer made from a single monomer. Recently many PTFE manufacturers have added minute amounts of other monomers to their PTFE polymerizations to produce alternate grades of PTFE designed for specific applications. Fluoropolymer manufacturers continue to call these grades modified homopolymer at below 1% by weight of comonomer. These modified granular PTFE materials retain the exceptional chemical, thermal, antistick, and low-friction properties of conventional PTFE resin, but offer some improvements:

- Weldability
- Improved permeation resistance
- Less creep

- Smoother, less porous surfaces
- Better high-voltage insulation

The copolymers described in the next sections contain significantly more of the non-TFE monomers.

#### *Sterilization:*

Exposure to high-energy (ionizing) radiation, regardless of the source, degrades PTFE by breaking down the molecules and reducing its molecular weight, resulting in a marked decrease in melt viscosity. As in thermal degradation, radiation stability of PTFE is much better under vacuum compared to air.

*Applications and uses:* fittings, valves, pumps, tubing.

#### *Expanded PTFE*[25]:

One of the most unique and remarkable developments in the processing of homofluoropolymers is the expansion of the polymeric matrix without the use of soluble fillers, foaming agents, or chemical additives. This invention constitutes the physical inducement of billions of small pores in the structure of an article of PTFE resulting in new properties and significant savings in material consumption. W.L. Gore and Associates invented this technology in the early 1970s. The trademark Gore-Tex® is well known in lightweight waterproof and breathable fabrics, microfiltration membranes, medical implants, microwave carriers, industrial sealants, and high tensile fabrics.

*Applications and uses:* microfiltration membranes, medical implants.

#### *Fluorocoatings:*

Fluorocoatings are used in medical devices. They often provide dry lubrication, insulation, and nonstick properties. Coatings are used on catheter guide wires and on metered dose inhaler canisters and valves.

## 3.4 Summary

There are many more polymers used in medical device applications than those listed in this chapter and more are being developed and used all the time. There are also dozens of other ways to sterilize than the ones mentioned. Table 3.4 provides a basic summary of the performance of a wide range of polymers used in plastics when sterilized by the most common methods.

**Table 3.4** Sterilization Matrix of Plastics [26]

Polymer	Polymer Abbreviation	Steam	Dry Heat	Ethylene Oxide	Gamma Radiation	Electron Beam
<b>Polyolefins</b>						
High-density polyethylene	HDPE	Poor	Poor	Good	Good	Good
Low-density polyethylene	LDPE	Poor	Poor	Good	Good	Good
Ultrahigh molecular weight polyethylene	UHMWPE	Poor	Poor	Good	Good	Good
Polypropylene <sup>a</sup>	PP	Good	Fair	Good	Fair	Fair
Polypropylene copolymers		Good	Fair	Good	Fair	Fair
Cyclo olefin copolymer	COC	Fair	Fair	Good	Good	Good
Polyvinyl chloride plasticized <sup>a,b</sup>	PVC	Fair	Fair	Good	Good	Good
Polyvinyl chloride unplasticized <sup>a,b</sup>	PVC	Poor	Poor	Good	Fair	Fair
<b>Polystyrene/styrenics</b>						
Polystyrene	PS	Poor	Poor	Good	Good	Good
Acrylonitrile butadiene styrene copolymer (Abs)	ABS	Poor	Poor	Good	Good	Good
Styrene–acrylonitrile copolymer (San)	SAN	Poor	Poor	Good	Good	Good
Acrylonitrile styrene acrylate	ASA	Poor	Poor	Good	Good	Good
Methacrylate acrylonitrile butadiene styrene copolymer	MABS	Poor	Poor	Good	Good	Good
Styrene–butadiene copolymer	SBC	Poor	Poor	Good	Good	Good
Acrylics <sup>a,b</sup>		Poor	Poor	Good	Good	Good
Polycarbonates <sup>a,b</sup>		Fair	Fair	Good	Good	Good
High heat polycarbonates		Good	Good	Good	Good	Good
Polyurethanes		Poor	Poor	Good	Good	Good
Acetals	POM	Good	Good	Good	Poor	Poor
<b>Polyamides</b>						
Nylon 6, Nylon 66	PA6, PA66	Fair	Fair	Good	Fair	Fair
Aromatic		Good	Good	Good	Good	Good
Nylon 12, 6/12	PA12	Poor	Poor	Good	Fair	Fair

(Continued)

**Table 3.4** Sterilization Matrix of Plastics [26]—*Cont'd*

Polymer	Polymer Abbreviation	Steam	Dry Heat	Ethylene Oxide	Gamma Radiation	Electron Beam
<b>Polyesters</b>						
Poly butylene terephthalate	PBT	Fair	Fair	Good	Good	Good
Poly ethylene terephthalate	PET	Poor	Poor	Good	Good	Good
Copolyesters		Poor	Poor	Good	Good	Good
<b>High-temperature thermoplastics</b>						
Polysulfones	PSU	Good	Good	Good	Good	Good
Polyphenylene sulfide	PPS	Good	Good	Good	Good	Good
Liquid crystalline polymer	LCP	Good	Good	Good	Good	Good
Polyetherimide	PEI	Fair	Fair	Good	Good	Good
Polyamide–imide	PAI	Fair	Fair	Good	Good	Good
Polyetheretherketone	PEEK	Good	Good	Good	Good	Good
<b>Fluoropolymers</b>						
Polytetrafluoroethylene <sup>a</sup>	PTFE	Fair	Fair	Good	Poor	Poor
Fluorinated ethylene propylene	FEP	Good	Good	Good	Fair	Fair
Perfluoro alkoxy	PFA	Good	Good	Good	Good	Good
Ethylene chlorotrifluoroethylene	ECTFE	Good	Good	Good	Good	Good
Ethylene tetrafluoroethylene	ETFE	Good	Good	Good	Good	Good
Polyvinyl fluoride	PVF	Good	Good	Good	Good	Good
Polyvinylidene difluoride	PVF2	Good	Good	Good	Good	Good
<b>Elastomers</b>						
Silicones		Good	Good	Good	Good	Good
Urethane thermoplastic elastomer	TPU	Poor	Fair	Good	Good	Good
Copolyester thermoplastic elastomer	TPC	Poor	Good	Good	Good	Good
Polyamide thermoplastic elastomer	TPA	Poor	Poor	Good	Good	Good
Styrenic thermoplastic elastomer	TPS	Poor	Poor	Good	Good	Good
Olefinic thermoplastic elastomer	TPO	Poor	Fair	Good	Good	Good

(Continued)

**Table 3.4** Sterilization Matrix of Plastics [26]—*Cont'd*

Polymer	Polymer Abbreviation	Steam	Dry Heat	Ethylene Oxide	Gamma Radiation	Electron Beam
<b>Biopolymers</b>						
PLLA	PLLA	Fair	Good	Good	Good	Good
Poly(lactic acid)	PLA	Poor	Fair	Good	Good	Good
Poly(hydroxybutyrate)	PHB	Poor	Poor	Good	Fair	Fair
Poly(glycolic acid)	PGA	Good	Good	Good	Good	Good
Poly(lactic-co-glycolic acid)	PLGA	Poor	Poor	Good	Fair	Fair
Polycaprolactone	PCL	Fair	Good	Good	Good	Good

<sup>a</sup>Radiation stable grades should be considered for gamma and e-beam radiation sterilization.

<sup>b</sup>PVC, acrylics, PC—require corrective tint to compensate for discoloration.

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