**Requirements of Biomaterials:**

Biomaterials must have special properties that can be tailored to meet the  
needs of a particular application - this is an important concept to bear in  
mind. For example, a biomaterial must be biocompatible, non-carcinogenic, corrosion-resistant, and has low toxicity and wear . However, depending on the application, differing requirements may arise. Sometimes these requirements can be completely opposite. In tissue engineering of the bone, for instance, the polymeric scaffold needs to be biodegradable so that as the cells generate their own extracellular matrices, the polymeric biomaterial will be completely replaced over time with the patient's own tissue. In the case of mechanical heart valves, on the other hand, we need materials that are biostable, wear-resistant, and which do not degrade with time. Materials such as pyrolytic carbon leaflet and titanium housing are used because they can last at least 20 years or more.

Generally, the requirements of biomaterials can he grouped into four broad categories:

1**-Biocompatibility:**

Biocompatibility involves the acceptance of an artificial implant by the surrounding tissues and by the body as a whole. Biocompatible materials do not irritate the surrounding structures, do not provoke an abnormal inflammatory response, do not incite allergic or immunologic reactions, and do not cause cancer. Other compatibility characteristics that may be important in the function of an implant device made of biomaterials include (1) adequate mechanical properties such as strength, stiffness, and fatigue properties; (2) appropriate optical properties if the material is to be used in the eye, skin, or tooth; and (3) appropriate density. Sterilizability, manufacturability, long-term storage, and appropriate engineering design are also to be considered.

The failure modes may differ in importance as time passes following the implant surgery. For example, consider the case of a total joint replacement in which infection is most likely soon after surgery, while loosening and implant fracture become progressively more important as time goes on. Failure modes also depend on the type of implant and its location and function in the body. For example, an artificial blood

vessel is more likely to cause problems by inducing a clot or becoming clogged with thrombus than by breaking or tearing mechanically.

**2-Sterilizability:**

The material must be able to undergo sterilization. Sterilization techniques include dry heat, gamma, gas (ethylene oxide (ETO)) and steam autoclaving. Some polymers such as polyacetal will depolymerize and give off the toxic gas formaldehyde when subjected under high energy radiation by gamma. These polymers are thus best sterilized by ETO.

Sterilizability of biomedical polymers is an important aspect of the properties because polymers have lower thermal and chemical stability than other materials such as ceramics and metals; consequently, they are also more difficult to sterilize using conventional techniques.

In dry heat sterilization, the temperature varies between 160 and 190°C. This is above the melting and softening temperatures of many linear polymers such as polyethylene and PMMA. In the case of polyamide (nylon), oxidation will occur at the dry sterilization temperature although this is below its melting temperature. The only polymers which can safely be dry sterilized are PTFE and silicone rubber.

Steam sterilization (autoclaving) is performed under high steam pressure at relatively low temperature (125–130°C). However, if the polymer is subjected to attack by water vapor, this method cannot be employed. PVC, polyacetals, PE (low-density variety), and polyamides belong to this category.

Chemical agents such as ethylene and propylene oxide gases and phenolic and hypochloride solutions are widely used for sterilizing polymers since they can be used at low temperatures. Chemical agents sometimes cause polymer deterioration even when sterilization takes place at room temperature. However, the time of exposure is relatively short (overnight), and most polymeric implants can be sterilized with this method.

Radiation sterilization using the isotopic 60Co can also deteriorate polymers since at high dosage the polymer chains can be dissociated or cross-linked according to the characteristics of the chemical structures, as shown in Table 1 In the case of PE, at high dosage (above 106 Gy) it becomes a brittle and hard material. This is due to a combination of random chain scission cross-linking. PP articles will often discolor during irradiation giving the product an undesirable color tint but the more severe problem is the embrittlement resulting in flange breakage, Luer cracking, and tip breakage. The physical properties continue to deteriorate with time, following irradiation. These problems of coloration and changing physical properties are best resolved by avoiding the use of any additives that discolor at the sterilizing dose of radiation.

**TABLE 1** Effect of Gamma Irradiation on Polymers That Could Be Cross-Linked or Degraded.

|  |  |
| --- | --- |
| **Cross-Linking Polymers** | **Degradable Polymers** |
| Polyethylene  Polypropylene  Polystyrene  Polyarylates  Polyacrylamide  Polyvinylchloride  Polyamides  Polyesters  Polyvinylpyrrolidone  Polymethacrylamide  Rubbers  Polysiloxanes  Polyvinylalcohol  Polyacroleine | Polyisobutylene  Poly-α−methylstyrene  Polymethylmetacrylate  Polymethacrylamide  Polyvinylidenechloride  Cellulose and derivatives  Polytetrafluoroethylene  Polytrifluorochloroethylene |