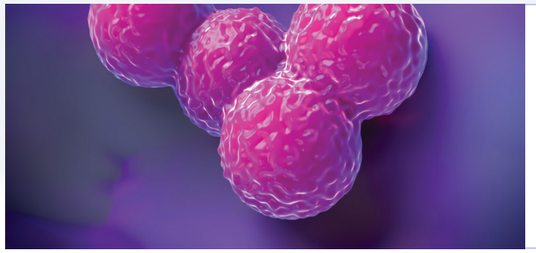
Hospital Acquired Infections

Polymer Technologies to Manage Risk

HOSPITAL ACQUIRED INFECTIONS

According to the Center for Disease Control (CDC), 4% of inpatients in U.S. acute care hospitals contract health care associated infection. Of these, one in every four is associated with a medical device. In-dwelling devices, such as central venous and urinary catheters, are particularly susceptible to bacterial infection. Increasingly, medical device companies are considering technologies to reduce device associated infections.

Microorganisms that can cause infection include bacteria, fungi/mold, and algae. Of these, bacteria pose the greatest threat to patients treated with medical devices. Of greatest concern are devices adjacent to the body surface, particularly those entering through a natural orifice or incision, and left in place for three or more days. This allows time for microorganisms outside the body to attach to the surface of the device and begin colonization. Mature colonies form biofilms that can detach from the surface and enter the body, causing infection. Risk of infection increases duration of device use.



Common Devices Associated with HAI

Indwelling vascular catheters

Urinary access devices

Masks and airway devices

Wound care dressings

Beds, trays, other durable goods

STERILIZATION

Sterilization techniques are designed to kill microorganisms/pathogens that may cause infections. Effectiveness depends on the process, as well as type and quantity of microorganism present. Common medical device sterilization methods include radiation (gamma and electron beam), ethylene oxide gas (EtO), and steam.

Gamma Sterilization

Uses gamma radiation to kill microorganisms. Because it is clean, induces no heat, and leaves no chemical residue, gamma sterilization has become an industry standard. Gamma sterilization is compatible with most plastics; however, the dosage rate must be limited according to the material. Amorphous polymers are more radiation resistant than semi-crystalline, and aromatic polymers are more radiation resistant than aliphatic.

Electron beam (E-Beam)

Uses a concentrated, highly charged stream of electrons to kill microorganisms. Dosage rates are high and penetration is low, potentially requiring multiple passes from different directions for complex medical devices. Absorbed energy from the electron beam can alter polymer properties and color; however, there is generally less degradation than occurs with gamma sterilization.

Ethylene oxide (EtO)

Uses a colorless, flammable, poison gas to kills micro-organisms. This low temperature process is highly compatible with most plastics and widely used for disposable devices. However, gas residuals post-sterilization are of concern for devices in contact with skin, mucous and short-term implants; and exposure to high levels of EtO is considered a health hazard.

Steam

Uses moist heat to kill microorganisms, and is commonly used for reusable metallic devices. Most plastics cannot withstand repeated high temperature steam sterilization cycles (121° C for 30 minutes, or 134° C for 20 minutes). Autoclave steam sterilization is performed in a pressurized vessel.

Solvay's medical grade Radel® PPSU and Udel® PSU are rigid, high-strength, transparent polymers that offers higher heat resistance and excellent hydrolytic stability. These polymers retain mechanical properties when exposed to as much as 1,000 cycles of steam sterilization and are frequently used for durable instrument trays and surgical handles.

COMPARISON OF STERILIZATION METHODS

METHOD	ETHYLENE OXIDE (EtO)	GAMMA	AUTOCLAVE
METHOD OF ACTION	Toxic gas	Radiation	High temperature steam
POLYMER COMPATIBILITY	Suitable for most polymers	May cause discoloration and degradation of properties	Only for high temperature, moisture resistant polymers
COMMON APPLICATIONS	Blood and renal care components, devices w/ embedded electronics	Fluid delivery devices, pre-packaged components	Lab ware, surgical instruments and trays

POLYMER MODIFICATIONS TO FIGHT INFECTIONS

ANTIMICROBIALS

Antimicrobials are substances used to kill (biocidal) or prevent reproduction and colonization (biostatic) of harmful microorganisms. Antimicrobial options for medical device components include surface coating components or functionalizing polymers used to manufacture components. Surface coating can be highly effective for single use devices; however, treatments can be wiped off during cleaning. Antimicrobial additives that are blended into polymers are permanent.

Antimicrobial additives for plastics can be organic or inorganic. Organic additives are small molecules, incompatible with the polymer matrix, that migrate to the surface of the polymer where they have a have a biostatic effect on microorganisms. Organic additives, such as silane, can be economical and fast-acting against bacteria, fungi and algae. However, lack of biocompatibility data for some organic antimicrobial additives in polymers has limited use in medical device applications.

Inorganic additives are based on unreactive metal ions that release to the surface of the polymer over time. At the surface, these ions react with moisture, causing biocidal and biostatic effects on microorganisms. Silver ions, the by-product of silver oxidation, are well recognized antimicrobial additives. These are typically bound to ceramic glass, titanium dioxides, or zeolites to regulate release rates and duration of action. Silver ion formulations are generally resistant to most plastic processing temperatures.

Combat™ antimicrobial compounds incorporate silver ion technology into the polymer matrix to attack microbes and prevent colonization of harmful bacteria. These ions are formulated with additional additives to control release rates in the finished device.

COMBAT™ ANTIMICROBIAL POLYMER TECHNOLOGY

SURFACE ENGINEERING

Infection is the result of bacteria attaching and colonizing on the surface of a medical device. Reduced adhesion properties of device surfaces can deter anchoring of harmful microorganisms. Materials with high surface energy are more prone to adherence than those with low surface energy. In general, plastics have low surface energy properties compared to metal and ceramics. However, some have considerably lower surface energy than others. These polymers tend to also be recognized for low coefficient of friction properties as well. These include polyethylene, polypropylene, polytetrafluoroethylene (PTFE), and acetal. High surface energy polymers include thermoplastic polyurethane (TPU), thermoplastic polyesters, acrylonitrile butadiene styrene (ABS), polycarbonate, and acrylic. Surface energy and coefficient of friction can be modified by incorporating organic or inorganic additives into the polymer. For example, PTFE is commonly used as an additive in other polymers to enhance lubricity.

ProPell™ low friction compounds use a proprietary, non-migratory additive that enhances the surface of parts without substantially altering the physical properties of the polymer. Tests show that parts produced from ProPell 80A thermoplastic polyurethane (TPU) reduce coefficient of friction by 66% reduction compared to the unmodified TPU polymer. Parts made from Propell 35D polyether block amide (PEBA) have dry coefficient of frictions 84% lower than the unmodified polymer.

FOSTER

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