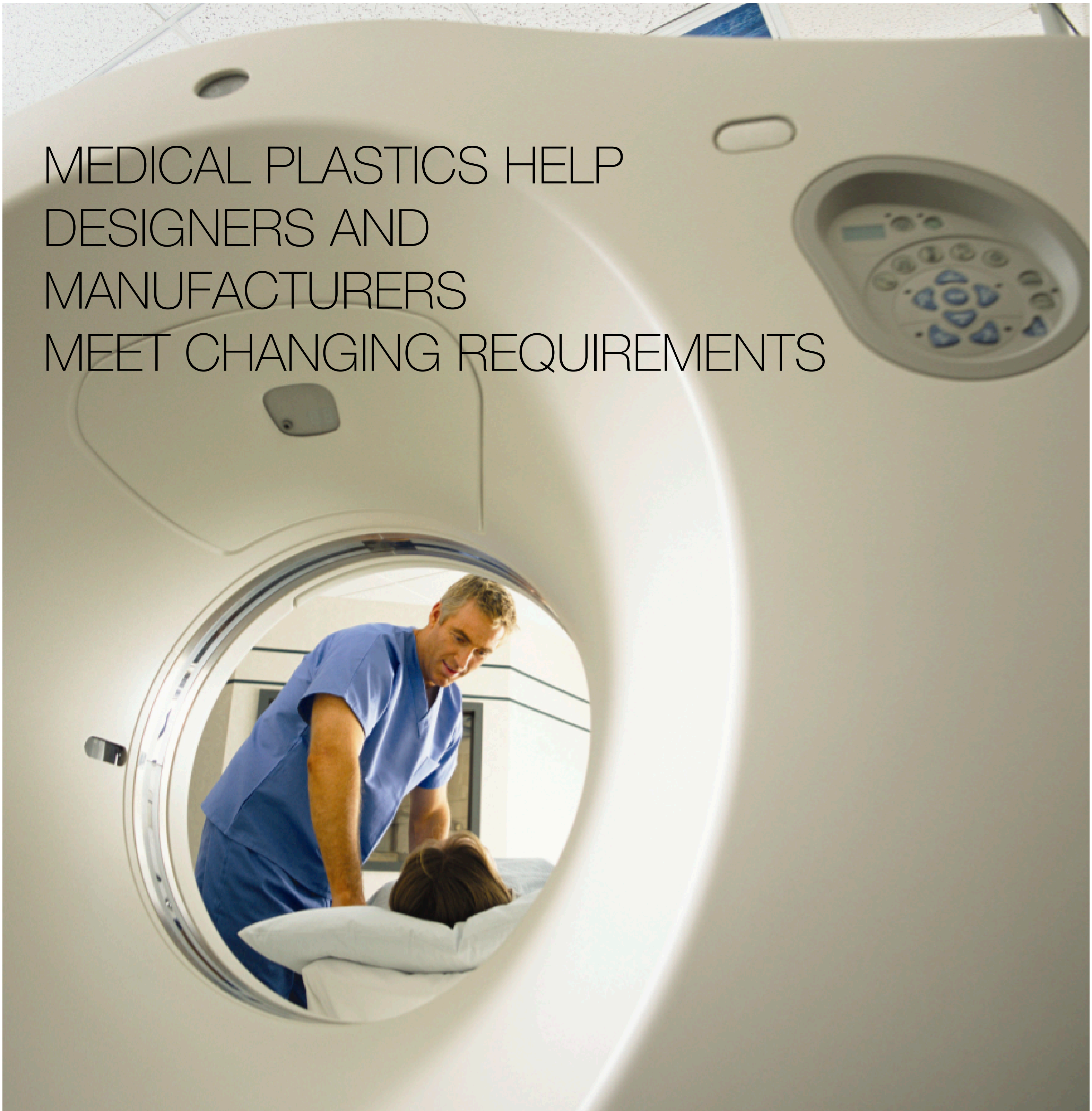
MEDICAL PLASTICS HELP DESIGNERS AND MANUFACTURERS MEET CHANGING REQUIREMENTS



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Today's medical device designers and OEMs are challenged to meet a wide, and sometimes conflicting, range of requirements. These targets stem not only from regulatory restrictions, but are equally likely to arise based on market perceptions, pressures to contain costs, and the changing materials supply landscape.

Specialty polymers designed for medical devices can provide solutions to these and other hurdles by supplying the optimum balance of properties, performance, and compliance for each application.

Current trends affecting medical device design

Regulatory compliance, while frustrating and challenging, is also creating new opportunities. In fact, designers can use this body of constraints as a means to drive positive change within their products. Remember that while a regulation may be in force in just one state, country or region, globalization means that it can have far-reaching impact.

With the increase in regulations governing plastics additives from flame retardants to plasticizers, opportunities can be found by anticipating new requirements and selecting compliant materials that speed the approval process.

Sometimes, there may not be an actual regulation in place, but consumer demand alone will force changes in material selection. One example is the current anxiety over bisphenol-A, or BPA. While there are no national laws restricting the use of BPA in medical or consumer applications, consumers want BPA-free baby and child products, and the market is responding.

Anticipating future regulations is also having an impact on device design. Trying to get ahead of future RoHS regulations that may ban the use of lead in medical devices, manufacturers and designers whose products generate radiation are looking for alternative materials that can provide the equivalent radiation shielding to lead.

Among material suppliers, consolidations are taking place to streamline production and improve efficiency. However, as grades are discontinued, OEMs need to substitute equivalent materials and requalify their products with the appropriate agencies.

Opportunities to improve designs with material solutions

Changing demographics are driving new opportunities for plastics in medical devices. The growing ranks of aging populations globally are having a significant impact on product design. Seniors are living longer and requiring more varied healthcare devices. They also want comfort and ergonomic design. Materials such as soft-touch TPEs and technologies such as overmolding can help meet these requirements.

Another impact of this demographic shift is increased demand for better healthcare services. Not only do older patients want improved hospital care, but active seniors are calling for increased medical home care, leading to requirements for consumer-friendly health equipment.

Plastics that can provide thin-wall molding capability, high performance and great appearance for home use will help designers to win in this market.

Finally, scientific breakthroughs in medicine continue to create the need for new materials. Non-invasive or less-invasive surgical techniques, for example, require miniaturized devices and specialized equipment. Plastics can offer the design freedom to create ultra-small devices with complex functionality. Endoscopic surgical instruments with soft-touch, over-molded handles, syringe components, gaskets, and seals are just a few examples.

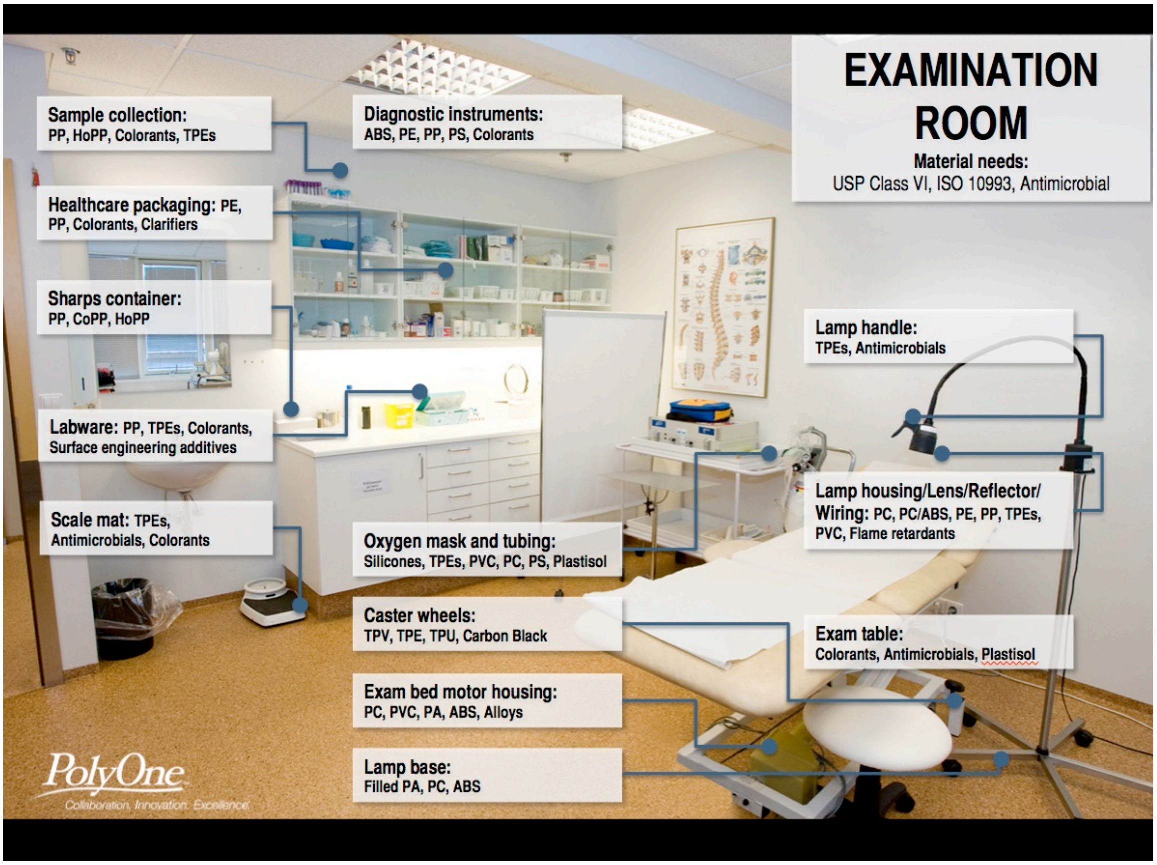
Minimally invasive medical devices tend to be recession-resistant, and are slated for 8 to 12 percent growth in the near term. In addition, demand is rising for radiopaque plastics used to make cardiac and urological catheters, further examples of the trend toward less invasive surgical procedures.

Antimicrobial polymers that resist bacteria, fungus, and algae are yet another tool for the designer's palette. As the death rate for hospital-born infections rises to roughly 100,000 per year in the U.S. and posts gains in other countries, hospitals are seeking to control the spread of infection and reduce their legal liability. This trend is driving growth, currently estimated at 15 percent for these materials. Application areas include bed rails, infusion sets, equipment housings, virtually any surface that the patient, doctor, or nurse might touch.

Material selection guidelines and suggestions

Specialized engineering thermoplastics, developed specifically for healthcare applications, can offer designers and OEMs a set of powerful tools for optimizing products, increasing speed to market, and improving product function. For example, today we have a multitude of options for flexible applications – traditional vinyl, nonphthalate vinyl, TPUs, TPEs, copolyesters, and EVA. In terms of innovation, OEMs and designers are now looking at biomaterials that now feature property enhancements unavailable in the past.

To help designers decide which materials are best for specific applications, this section follows various healthcare environments – from doctor's office and X-ray room to laboratory and operating room. Please note the accompanying table information, which provide greater detail for each environment.



Exam room: Patients first step onto a scale that is covered with a mat. These mats can be formulated to meet color and durability requirements, in part through the choice of a cross-linked thermoplastic vulcanizate or an elastomer based on styrenic block copolymers. There are now gel-soft TPE materials available as well. These materials can be formulated with anti-microbial additives to protect the surfaces from contamination.

Examination tables can consist of multiple polymer components. For instance, housings that cover motors can be molded from a flame retardant compound designed with vibration dampening characteristics to reduce noise. There are a variety of traditional and halogen-free alternative flame retardants depending on the resin system chosen.

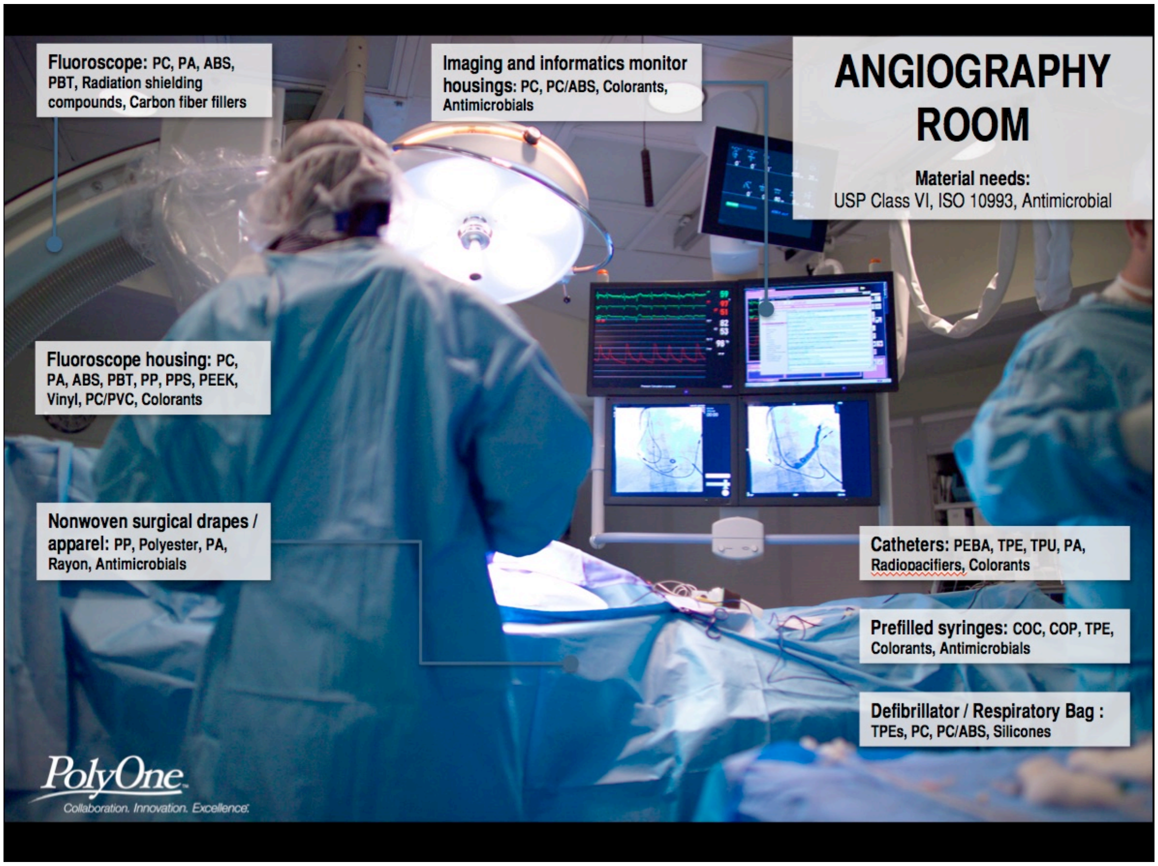
A housing for a light stand may be overmolded with a soft touch thermoplastic elastomer (TPE). TPEs offer a good balance of softness and bondability. Recent developments allow TPEs to bond to a variety of substrate plastics ranging from non-polar olefins to more polar materials like polyester or even nylon. The materials can be formulated to meet the desired softness rating, and provide both good wet grip and dry grip performance.

Some applications require USP Class VI rating. One example is an oxygen mask and tubing, where high performance vinyl or TPE compounds provide both economical and highly functional offerings. They are able to achieve required softness levels combined with resilience, high elongation and ease of manufacture.

A caster wheel represents traditional metal-to-plastic conversion where the primary driver is system economics. For the wheel hub, the plastic compound can be made from a variety of resins and filler systems. Moving from talc fillers to glass fibers to carbon fibers and even long glass and long carbon fibers provides increasing strength and practical impact performance.

For the wheels themselves, thermoplastic elastomers and especially thermoplastic vulcanizates can provide the good compression set performance required, and can be formulated with carbon black or other fillers and resins to provide electrostatic dissipation protection, tailoring the surface resistivity of the filled polymer system.

To create a material that is anti-static requires that reducing the surface resistivity of the polymer from 10^{12} or 10^{13} ohm/sq by a few orders of magnitude to 10^{10} to 10^{12}. If we now want these materials to dissipate static charge, we need to reduce this surface resistivity another couple of orders of magnitude to 10^{5} to 10^{12}. The most stringent requirements of conductivity and electromagnetic interference shielding must be down as low as 10 – 1000 ohm/sq.



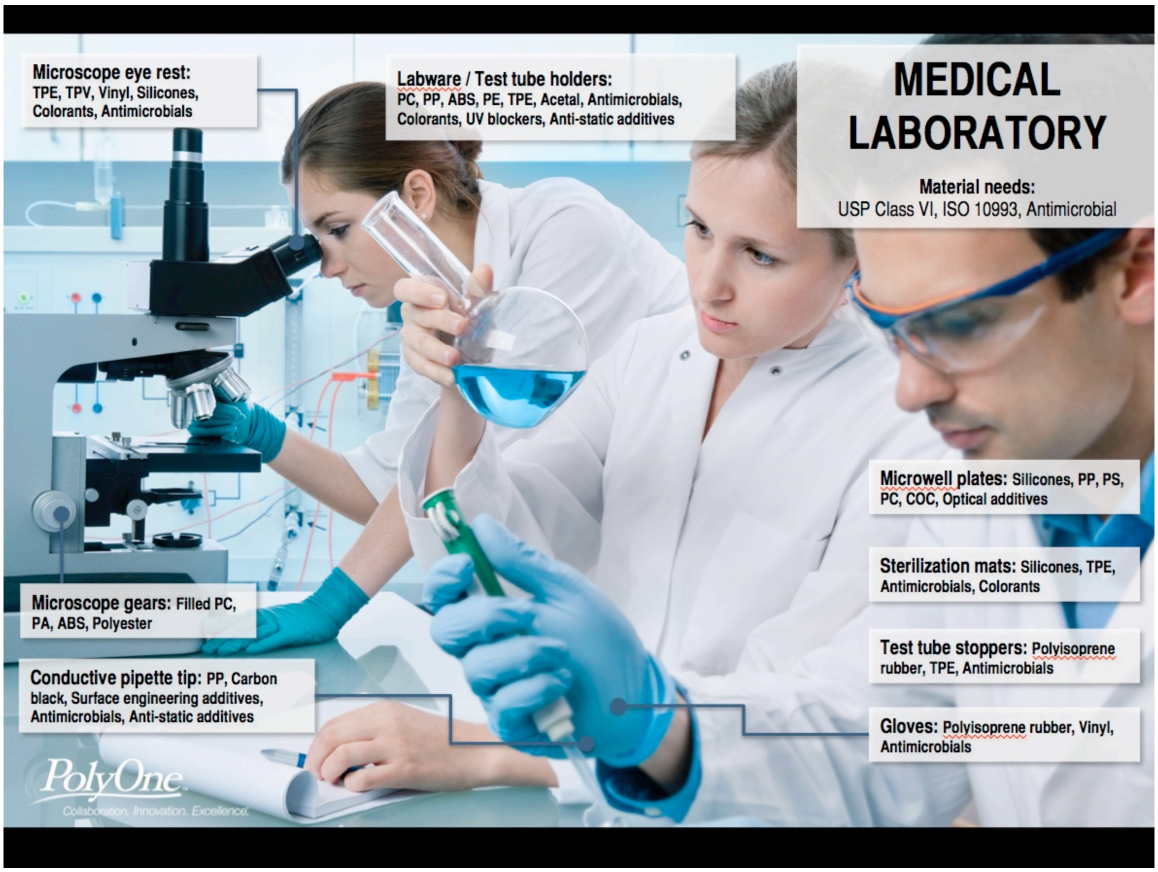
Angiography room: In a typical angiography room, comfort and reliability also apply, but material modifications bring specific benefits to equipment performance.

Electronic equipment gains functionality when the right polymeric material is selected. Plastics with high flow and high temperature resistance such as liquid crystal polymers and polyphenylene sulfide, traditionally used to mold connectors and other electrical devices, have enabled connectors to get smaller and more intricate. In addition, advancements in filler technology, including metal fillers and metal-coated fibers, allow compounding of electrically conductive materials that provide electromagnetic interference or EMI shielding performance.

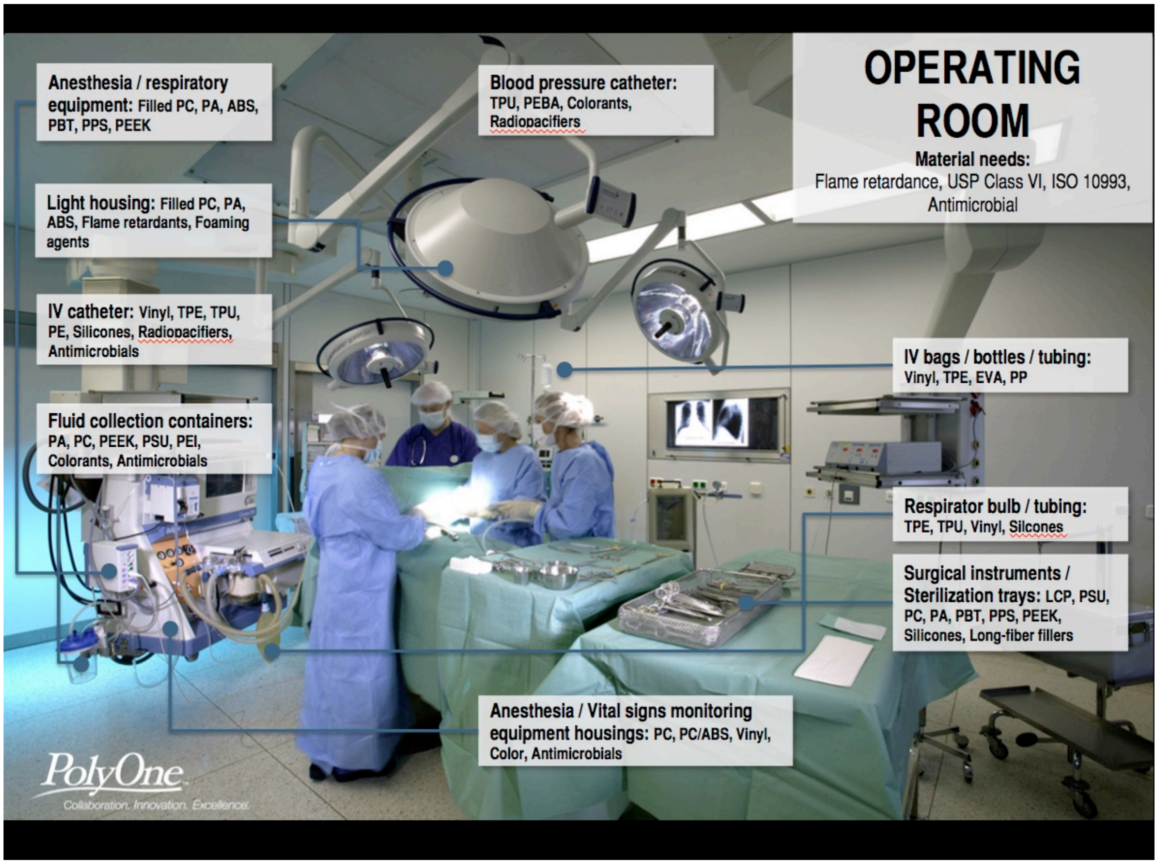
While this example refers X-ray electronics, these types of shielding connectors are used in a broad array of medical electronics, particularly as the device frequency increases or the device size decreases.

CT scanners and other X-ray generating equipment usually include components machined from lead or lead alloys that collimate, or guide, the X-ray photons. In addition, X-ray rooms are often lined with lead and the patient is draped in lead to minimize exposure to radiation.

Although the European Union's RoHS and WEEE directives currently exempt healthcare devices, tighter restrictions on the use of lead are expected in the future. Advances in polymer systems can provide an alternative. By using tungsten fillers, specific gravity of 11 can be achieved in a rigid nylon compound, reaching the same density as lead alloys. In comparison testing for shielding efficiency, these material show comparable performance to lead across a variety of radiation sources, including 100 and 125 kV X-rays. In testing for shielding efficiency, high specific gravity compounds showed equivalent performance to lead in shielding 35 keV gamma radiation from iodine-125 isotopes, 71keV gamma radiation from thallium-201 isotopes, and 152 keV gamma radiation from technecium-99m isotopes.



Laboratory: Pipette tips are used in conjunction with robotic pipettors for measuring and dispensing liquids in laboratory and production settings, with the goal of transferring a precise quantity of liquid. In situations where a robotic pipettor is used, the machine picks up a set of pipette tips, transfers a precise amount of liquid from one location to another, ejects the now used pipette tips, and begins the cycle again. The tips are often only once due to concerns that contamination may hinder measurement accuracy. In these automated systems, pipette tips are often made of conductive polymeric materials that enable the tip to sense the liquid and therefore accurately measure the correct amount of liquid being transferred. In certain applications, some amount of conductivity is required to avoid static build-up that could give an inaccurate transfer. Typical applications required surface resistivity values of less that 10^6 ohm/sq, and often as low as 10^4 ohm/sq and below.



Operating room: Respirator bulbs can be molded from vinyl, which still makes up a significant portion of medical plastics used today. Vinyl products display excellent clarity and chemical resistance, are easily processed, and can be formulated in a range of colors and durometers. They are sterilizable in steam, gamma radiation, and EtO and provide an economical option. For this reason, they are used in many fluid container applications, from IV and dialysis fluids to blood storage bags. In these bags, the low oxygen permeability and good clarity makes vinyl ideal. Medical vinyl compounds are also used in a broad range of tubing, such as wound and chest drainage tubes, catheters, and endotracheal tubing

In the OR, formulated polymer systems can be used in reusable versions of formerly disposable items. There are now materials that have the temperature and mechanical performance properties required for multiple uses and sterilizations. Materials such as polyphenylsulfone and PEEK can withstand over a thousand steam sterilization cycles, making them useful in surgical and dental instruments or in sterilization trays. Not only are these material resilient in steam sterilization, but their excellent chemical resistance extends to many common hospital disinfectants, giving longer life for these multiple use applications.

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