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Medical Design TECHNOLOGY

EMPHASIS ON THERMOPLASTICS

Medical device designers are expanding their knowledge of new thermoplastic technologies and exploring how to apply these materials in unique applications.

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MATERIAL & COMPONENT REVIEW

By thinking about customization in terms of the steps outlined in this article, manufacturers can determine if a custom temperature controller makes sense for their products.

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CASE IN POINT: CATHETER TIPPING

An automated system is introduced to resolve inconsistency and waste issues associated with a manual tipping method.

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REGULATORY REPORT

A merging of device and pharma companies is unlikely to become the trend according *The Gray Sheet.*

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Electrostatic Dissipation

Finding materials that dispel static charges has become key as inhalation devices are expanding into new treatment areas

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Cover Story

Electrostatic Dissipation

Doctors are now experimenting with inhalation therapies for conditions other than respiratory ailments. As a result, drug delivery devices need to become more sophisticated and effective. This exclusive report examines a new family of acrylics that promises to improve the clinical effectiveness of drug delivery cost-effectively. ▶ *By Peter D. Colburn*

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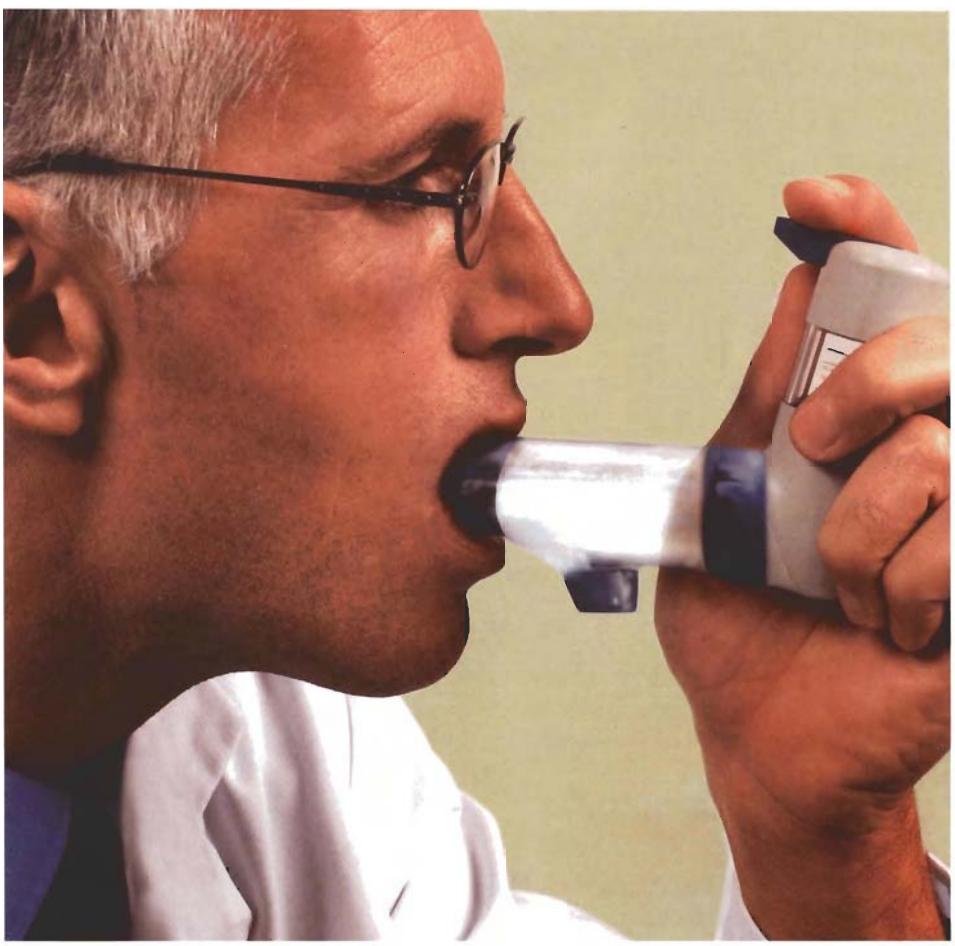
On the cover: Acrylic resins used in brachytherapy applications are tested for reliable electrostatic dissipative (ESD) properties. Brachytherapy is a cancer treatment in which radioactive material is placed directly into or near a tumor. The delivery device is crucial. A device made from materials that provide reliable ESD protection can help guarantee delivery of appropriate radiation dosages.

AT A GLANCE

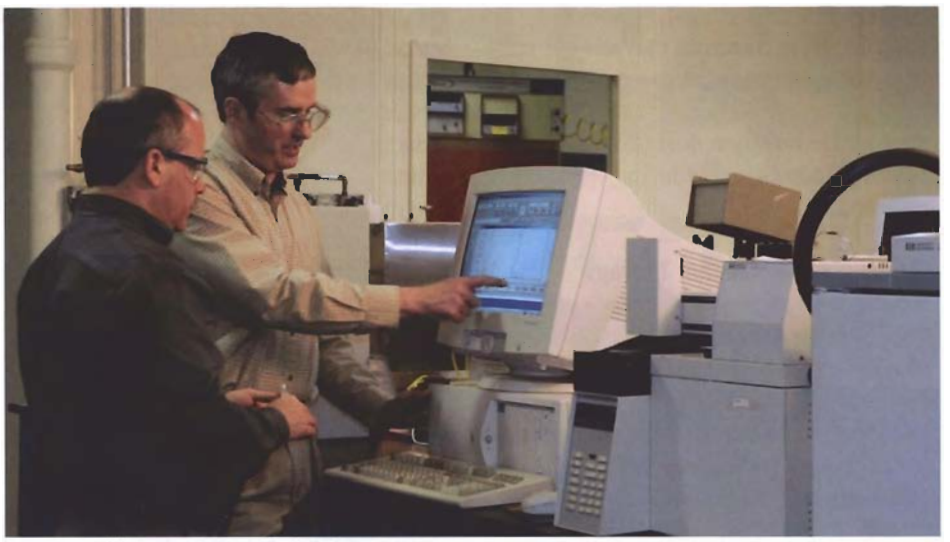
- New chemistries offered
- Test results and conclusions
- Problems with additives
- Real-world options

The invisible forces of static can be the enemy of delicate medical procedures. Static charges created through friction can, for example, hinder radioactive seeds from reaching malignant tumors in cancer treatment, or it can prevent powdered pharmaceuticals from reaching the lungs in inhalation therapies. Most medical devices rely on topical coatings or additives to dispel static charges, but these coatings fail in low humidity levels and degrade or leach out over time.

Recently researchers have employed an alloy process to create materials that have inherent electrostatic dissipative (ESD) properties. These new materials—transparent multipolymer acrylics—have been shown to consistently and efficiently dispel static charges. In addition, unlike materials that use coatings to dispel static, they retain their ESD properties at varying humidity levels and after repeated



Static charges can make inhalation therapy treatment less effective. Researchers have employed an alloy process to create materials with inherent electrostatic dissipative properties that dispel static charges.



A composition analysis of Vu-Stat static dissipative acrylic multipolymer compound used for brachytherapy is performed to ensure that it will improve the efficiency of the procedure.

Studies show that particle delivery can increase by as much as 70 to 144 percent with the use of an anti-static device.

washings. This combination of powerful anti-static protection, optical clarity, and durability makes these acrylics an ideal foundation for medical devices.

Primary opportunities for use of these materials include brachytherapy (a type of radiation treatment) and inhalation therapy. Their enhanced ESD performance could add value to these and other medical applications to enhance health benefits, make treatment more cost-effective, and lengthen the shelf life of medical devices.

Source of Stability

It is well known that polymerization processes can be used to engineer materials with highly consistent and stable properties. Developers of new acrylic compounds have followed the premise that materials will dispel static more effectively if their anti-static component is a stable polymer compatible with base components and capable of transferring a charge through the material or along its surface—in other words, if the ESD properties are part and parcel of the material as a whole. To test this theory, they have combined an acrylic-based terpolymer with an ESD polymer and evaluated its performance at five different humidity levels. (Specifically, a terpolymer of ethyl acrylate, methylmethacrylate, and styrene was blended with a polymeric ESD component.)

The results were impressive: in all five tests, the material demonstrated improved anti-static performance with increasing levels of the ESD component. In particular, developers examined the material's surface resistivity, or resistance to the flow of electrical current over its surface, as well as the volume resistivity, or resistance to the flow of current through the three-dimensional volume of a sample. They also considered the static decay properties, or the ability of the ESD material to release an applied static charge. This battery of tests showed that high ESD performance can be consistently created by adding a minimum of 15 percent polymeric ESD component.

Atmospheric Conditions

Most medical materials on the market use additives, such as quaternary amines, to dispel static charges. These coatings rely on the presence of moisture to transfer electrostatic charges along the surface of materials, drawing moisture to the surface of the part. This means they perform well at high levels of humidity but their ESD performance becomes less and less effective as relative humidity levels drop. In fact, they lose most of their effectiveness as humidity drops below 60 percent and can be ineffective in humidity levels as high as 85 percent.

It is possible to improve ESD performance in medical devices by increasing the content of quaternary amine coatings. Yet experience shows that coating content at levels higher than 3 percent can create problems during manufacture. Significant amounts of the liquid additive ooze out of the material during the molding process, leaving residue on the mold and on the surface of molded articles.

In order to be considered inherently anti-static, materials should not require additives or coatings. This new family of ESD acrylics does not rely on the presence of moisture or moisture absorption to work, making it reliable in a variety of atmospheric conditions. Notably, it performs well at lower humidity levels when static charges are most likely to be generated. Even at zero percent relative humidity, the material still demonstrates good ESD performance.

Durability and Transparency

With medical devices that rely on coatings to dissipate static, the scratches and wear and tear that come with repeated use can cause the devices to become less static resistant. Likewise, additives such as quaternary amines can leach out through the surface over time or during washing, reducing the efficacy of the device. One of the comparative benefits of an inherently ESD product is that its performance does not degrade over time. It provides lasting protection from static even after repeated sterilization and use.

In addition, the material maintains a high level of transparency: 85.1 percent as measured by a Byk-Gardner spectrophotometer on a 3.2 mm thick plaque. This means that clinicians can see that the device is properly cleaned and can easily read any dosage-counting display within the treatment vehicle.

Example #1: Brachytherapy

Transparency, durability, and permanent ESD characteristics make this new high-performing ESD material a good foundation for a variety of medical devices. The

material was developed to improve the efficiency of procedures that rely on precise localized treatment, specifically brachytherapy and inhalation therapy. Its use has the potential to enhance the clinical effectiveness and potential health benefits of these and other treatments while at the same time lowering costs by reducing pharmaceutical waste.

Brachytherapy is an advanced cancer treatment in which radioactive material, typically a "seed," is placed directly into or near a tumor. (A "seed" is radioactive material encased in a metal tube smaller than a rice grain.) This method enables oncologists to deliver a high dosage of radiation to the malignant tumor while reducing exposure to the patient's surrounding healthy tissues. Increased radiation dosages have been shown in many situations to provide good health outcomes by improving local tumor control.

The term "brachy" is Greek for "short distance," indicating that the treatment is precise and localized. This method of treatment can be used to combat cancer of the prostate, cervix, lung, esophagus, and breast, among others, and is often administered on an outpatient basis with a patient under local anesthesia.

Typically, the radioactive seeds are delivered to the tumor by pushing them through a tube using a wire device. Experience shows that this process generates static charges, causing seeds to become stuck inside the tube. In some cases, seeds may be inadvertently removed when the tube is withdrawn from the patient.

For brachytherapy, in particular, the delivery device is crucial. A device designed from materials that provide reliable ESD protection under any atmospheric condition can help guarantee delivery of appropriate radiation dosages, maximizing health outcomes and reducing waste of the radioactive source.

Example #2: Inhalation Therapy

Inhalation therapies are another common type of clinical treatment in which static charges can make treatment less effective. For patients with chronic respiratory conditions, such as asthma or respiratory ailments associated with cystic fibrosis, inhalation devices deliver drug therapies directly to the bronchioles or lungs, where it can have maximum effect.

The main advantage of inhalation therapies is that they enable clinicians to deliver drugs directly to the lung area, without exposing the rest of the body to potentially harmful effects. For example, swallowing steroid pills or undergoing steroid injections—methods of controlling asthma or treating an asthma attack—can have unhealthful side effects such as bone loss, sleeping disorders, confusion, or even psychosis. This is because the drug must travel through the blood stream and be carried throughout the body to work. To avoid unwanted effects from steroids and other types of drugs, doctors generally recommend inhalation therapy. Inhalation devices can deliver a steroid directly into the lungs to reduce inflammation in the airways and improve breathing.

Inhalation therapies rely on plastic devices to deliver powdered pharmaceuticals. Some devices, such as metered dose inhalers, propel the drugs forward using a spacer or tube that modulates the delivery of medication. Static charges cause the powder to stick to the walls of the device, reducing the intended dosage to the patient's lungs. Several studies have shown that dissipating the static charge can significantly increase the flow of pharmaceutical particles through the plastic inhalers and spacer units. In fact, these studies show that particle delivery can increase by as much as 70 to 144 percent with the use of an anti-static device.

With a static-free mouthpiece and spacer, much more of the drug is delivered to the patient the first time. This can make inhalation therapies more beneficial as well as more cost-effective.

The demand for high-performing ESD medical devices may grow as inhalation therapies become more common. Doctors are now experimenting with inhalation therapies for conditions other than respiratory ailments. For example, protein-based medicines such as insulin cannot be given orally because they are digested before they can be effective. Typically, such medicines have been injected, but doctors are now experimenting with delivering such drugs directly to the lungs through inhalation therapy. This could improve their effectiveness and avoid the need for repeated injections.

These examples make clear that the reliability and performance of drug delivery devices will only become more important as medical treatments become more sophisticated. As health care costs continue to rise, the efficiency of medical devices will become more crucial as well. The medical design industry can look to this new family of ESD materials for ESD protection and good return on investment.

The Properties and Benefits of Inherently ESD Materials

Properties
- Transparency: 85 percent at 3.2 mm
- Durability: Maintains ESD properties after repeated washings
- Reliability: Works at any humidity level or atmospheric condition
- Efficacy: Provides permanent ESD protection

Benefits
- Improves efficiency in drug delivery
- Maximizes potential health benefits
- Makes clinical treatments more cost-efficient
- Increases shelf life of medical devices

ONLINE

For additional information on the technologies discussed in this article, see *Medical Design Technology* online at www.mdtmag.com or CYRO Industries at www.cyro.com.