Why Medical Equipment Housings are Cracking and How Material Selection Can Help Prevent It
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By

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THE PROBLEM

A growing concern with medical devices is the cracking of polymer housings for electrical equipment used in the healthcare environment. In some cases, the cracking can occur within three to four months of initial use in a healthcare environment. Cracked polymer housings can lead to several problems for patients, healthcare providers, and medical equipment manufacturers. Most importantly, the medical equipment may malfunction, leading to patient injury or even death. Equipment failures also generate extra costs and resource time for the medical equipment manufacturer associated with service calls, product returns, and warranty claims. If a particular housing failure becomes widespread, it could lead to a product recall which not only has a large financial implication but can also damage the brand.

A search of United States Food and Drug Administration (FDA) medical device recalls indicates this phenomenon is not new. For example, a hemodialysis instrument was recalled in 2006 because polymer components “may become cracked due to mechanical and thermal stress.” In 2009, a surgical light was recalled because “cracks may form around the screw connections.” Twenty seven medical equipment manufacturers were interviewed at the National Teaching Institute & Critical Care Exposition in Boston, MA in May 2013. Of those interviewed, 13 reported having cracking problems with polymer housings and five of those indicated the problem was severe. During these interviews, it was found the problem is primarily in emergency rooms, exam rooms, and ambulances. There does not seem to be a problem with medical equipment used in the home. In separate interviews, it was also discovered that dental equipment manufacturers are seeing a polymer cracking problem as well.

Metal has long been the material of choice and is commonly found in heavy duty or high pressure applications such as oxygen tanks. However, polymers have replaced metal as the predominant material in medical equipment housings because they give product designers greater freedom to design complex shapes or consolidate components. Polymers are also used due to their low cost, light weight, aesthetics, and corrosion resistance. Therefore reverting to metal is not a realistic option for medical equipment manufacturers experiencing cracking problems with polymeric housings.
HEALTHCARE-ASSOCIATED INFECTIONS

The incidence of healthcare-associated infections (HAI’s) such as methicillin-resistant staphylococcus aureus (MRSA) and vancomycic-resistant enterococci (VRE) has increased approximately 36% in the last 20 years and today causes nearly 100,000 deaths yearly. In 2009, Medicare decided it would no longer cover the costs associated with treating patients who develop HAI’s. Their rationale is they should not be financially responsible for a healthcare facility mistake. The financial burden, estimated at $14,000 per infection, thus falls on the patient or healthcare facility.

There are different methods and treatments to sterilize medical devices to eliminate the threat microorganisms can pose to patients. These include autoclaving (steam), ethylene oxide, gas plasma, and e-beam or gamma irradiation. Most medical equipment housings are not currently designed to withstand these methods and so the primary approach to kill microorganisms is to use chemical disinfectants.

Most HAI organisms can live on medical device surfaces for months and certain “super bugs”, like MRSA and VRE, are resistant to traditional cleansers. To cope with this challenge, healthcare facilities are cleaning medical equipment more frequently and with more powerful disinfectants than ever before. According to Centers for Disease Control and Prevention guidelines, “Medical equipment surfaces…can become contaminated with infectious agents and contribute to the spread of HAI’s…Ensure that at a minimum, noncritical patient-care devices are disinfected…after use on each patient.” Disinfectants found to be effective in the fight against MRSA and VRE are T-Spray™, CIDEXPLUS®, and CaviCide®. A recent Mayo Clinic study confirmed that the increased frequency of disinfection of hospital surfaces substantially reduces infection rates.

Examples of durable medical equipment that are likely to require chemical disinfection include patient monitoring devices (blood pressure monitors and bedside electrocardiogram monitors), infusion devices (insulin pumps, infusion pumps, and injection pens), dialysis equipment, respiratory devices (ventilators, nebulizers and continuous positive airway pressure machines), defibrillators, and handheld devices (barcode scanners).
HOW CAN THESE DISINFECTANTS AFFECT POLYMERS?

Some polymers can become prematurely brittle when they contact chemicals while under stress – a concept known as environmental stress cracking. An example of stress on a polymer is when a screw is tightened to connect two components of a housing. Once embrittled, polymers can develop small micro-fractures or crazing. This crazing can propagate into larger cracks and eventually fracture. Different chemicals can affect a polymer in different ways. A polymer can be resistant (e.g. no property loss or discoloration) to one chemical but easily crack when exposed to another chemical.

This phenomenon can occur when medical equipment is repeatedly wiped down by disinfectants such as T-Spray™, CIDEXPLUS®, and CaviCide®. These powerful chemicals are causing environmental stress cracking in the medical equipment housings. Evidence of this was seen with the recalled surgical light mentioned earlier. The recall notice indicated “cracking is significantly influenced by the use of certain disinfectants containing alcohol.” As further evidence, an Adverse Event Report to the FDA in 2004 noted use of a particular disinfectant solution resulted in “an increase in the number of devices showing signs of chemical attack of the plastic parts.” Therefore, choosing a polymer that resists cracking from disinfectants can eliminate the growing number of cracked polymer housings seen with medical equipment.
**Which Polymers Resist Cracking from Disinfectants?**

A common polymer laboratory test for environmental stress cracking was used to determine which polymers resist the typical chemical disinfectants that are frequently used to sterilize medical device housings. ASTM D543 Standard Practices for Evaluating the Resistance of Plastics to Chemical Reagents is a test often used to determine the resistance of polymers to chemicals. Figure 1 shows the apparatus used for the study. Tensile bars are bent in the apparatus to create stress in the middle of the bar. The disinfectant being evaluated is placed on a porous cloth and remains in contact with the tensile bar for three days. The tensile properties of the polymer are tested before and after exposure to the disinfectants. Polymers with greater retention of tensile properties after three days of exposure are seen as more resistant to the disinfectant. To more easily group the results, polymers with 90-100% property retention were classified as “Acceptable”, 50-90% as “Marginal”, and less than 50% as “Poor”. Polymer samples that cracked before the three day testing period was completed were also identified.

Five polymers were tested in this study. Four are currently used in the manufacture of medical equipment housings – flame retardant acrylonitrile butadiene styrene (FR ABS), polycarbonate-acrylonitrile butadiene styrene blend (PC+ABS), polycarbonate-polyethylene terephthalate blend (PC+PET), and polycarbonate-polybutylene terephthalate blend (PC+PBT). These materials are all flame resistant grades (UL 94 V-0 or 5VA) because the medical equipment housings enclose an electrical energy source and thus require a flame resistance polymer. The fifth polymer studied was rigid vinyl. Rigid vinyl is a polymer known to have excellent chemical resistance as well as flame resistance.

The three disinfectants tested were T-Spray™, CaviCide®, CIDEXPLUS®.

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<tr>
<th>Polymers Tested</th>
<th>Disinfectants Tested</th>
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<tbody>
<tr>
<td>FR ABS</td>
<td>T-Spray™ (quaternary ammonium)</td>
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<tr>
<td>PC+ABS</td>
<td>CaviCide® (isopropanol)</td>
</tr>
<tr>
<td>PC+PET</td>
<td>CIDEXPLUS® (glutaraldehyde)</td>
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<td>Rigid Vinyl</td>
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Table 2 shows the results of the study and indicate that only rigid vinyl performed as “Acceptable” for all three disinfectants. PC+PBT performed as “Marginal” for the three disinfectants. FR ABS, PC+ABS, and PC+PET performance ranged from “Cracked” to “Marginal”. Of the three disinfectants trialed, T-Spray™ appears to be the harshest on polymers while CaviCide® appears to be the mildest, only having a significant affect on FR ABS.

Therefore it can be concluded that a polymer’s chemistry plays a significant role in determining its resistance to chemical disinfectants. The chemical structure of rigid vinyl is inherently resistant to chemicals. This is evidenced by rigid vinyl’s extensive use in consumer appliances (resistant to laundry detergents and stain removers), fluid handling (resistance to water treatment chemicals and industrial chemicals), and packaging (resistant to automotive fuel additives). A polymer like polycarbonate has inherently poor chemical resistance in its chemical structure and therefore needs to be modified to improve its performance.

Other factors such as temperature and level of stress applied to the polymer can also influence environmental stress cracking. Therefore, it is important to test polymers side-by-side under the same conditions to get more meaningful results. Finally, it is also important to keep in mind this testing was conducted in a laboratory environment under controlled conditions using tensile bars. While this test can be an effective screening method to provide a relative indicator of performance, end use testing on actual parts is critical to determining ultimate performance in the field.

**SUMMARY**

Cracking of polymer housings for medical equipment is a growing concern. The primary cause of this problem is environmental stress cracking caused by repeated use of chemical disinfectants used to clean the polymers to help prevent healthcare-associated infections.
Choosing a polymer that is resistant to these powerful disinfectants is key to reducing or eliminating the cracking problem. A laboratory study was conducted to determine how various polymers would stand up to common disinfectants. The results showed that rigid vinyl consistently outperformed FR ABS, PC+ABS, PC+PET, and PC+PBT. Medical equipment manufacturers should consider rigid vinyl as a material of construction if polymer cracking is a concern in the application.

For additional information on Geon™ HC solutions for healthcare from PolyOne, please visit www.polyone.com/GeonHC.

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9 T-Spray™ is a trademark of Pharmaceutical Innovations, Inc. CIDEXPLUS® is a registered trademark of Advanced Sterilization Products Division of Ethicon. CaviCide® is a registered trademark of Metrex.