PHARMACEUTICAL & MEDICAL Packaging NEWS
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Materials

Tamper-Evident Thermoformed Packaging

by Pete Colburn, technical manager, Cyro Industries (Rockaway, NJ)

Users can reap the benefits of tamper-evident packaging without compromising sterilization quality.

Medical device manufacturers can incur significant costs due to package failure. Additional loss is incurred when someone other than the intended user opens packaging to illegally retrieve valuable medical products.

Such tampering is not always apparent. External seals can be opened, removed, and discarded without trace evidence. Some materials can be cut open or punctured with little noticeable evidence of failure. As a result, tamper-evident packaging has become an important component of the medical and pharmaceutical industries.

SUPPLYING TAMPER EVIDENCE

Alexis Swan, corporate contract coordinator for Yale–New Haven Hospital in New Haven, CT, deals with packaging-integrity issues with medical and surgical supplies. "One of the biggest issues of healthcare providers is the ability and need to maintain a sterile field," she says. "You want to be able to open a package and introduce the product into a sterile field, making sterilization reliability very important. We assume that the package has an appropriate level of integrity, so it is important that if a package fails, the failure is obvious. The people handling packages in a hospital inspect them to ensure that the sterile barrier in the package has not been compromised. We must be able to see any type of failure in the package immediately."

There are materials available that have been designed to show evidence of failure instantly, so that the judgment of sterile reliability can be made quickly and easily. Engineered compounds such as some acrylic-based multipolymer extrusion compounds are formulated to show that tampering with the rigid package is readily apparent.

Such compounds present strong evidence of tampering in two ways. First, if the rigid tray itself is tampered with, by tearing or cutting into it with a knife or even by sticking a needle through the sidewall, the material turns from a transparent blue tint to a highly visible, opaque white where the breach occurred. Second, once sealed, if the lidding stock is separated from the tray, the optical properties of the thermoformed compound make that seal separation evident by an apparent color change, even with the lidding stock laying against the tray edge. This is because the seal provides a certain amount of color depth when viewed through a specialized packaging compound.

Questions have been raised about whether such tamper-evident features could lead to packages being falsely identified as having had their integrity compromised, for

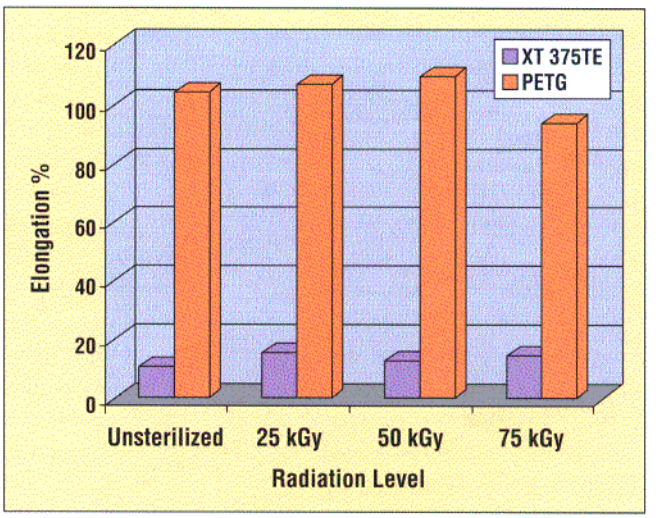

Figure 1. Tensile elongation after E-beam sterilization.

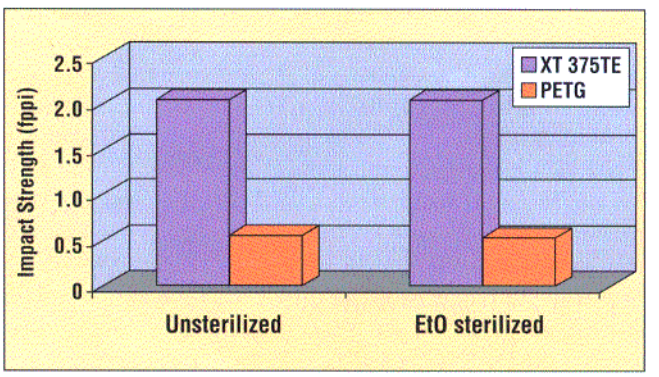

Figure 2. Notched izod impact strength after EtO sterilization.

example, after being knocked around during shipping. This is unlikely to happen. To activate the tamper-evident features, the package must be struck fairly hard. And if they are triggered, this should be a signal to check the package, not to dismiss it automatically as compromised.

Heat sealing forms strong visible bonds with rigid tamper-evident acrylic-based trays. A range of lid-stock substrates can be used to seal the trays, including coated Tyvek, manufactured by DuPont Medical Packaging (Wilmington, DE). The adhesive used with coated Tyvek is activated at 250°–265°F. When sealing with coated Tyvek, it is important to use a rigid material, such as a tamper-evident acrylic-based compound, with a thermoforming temperature well below this.

STREAMLINED STERILIZATION

Packaging materials should not yellow or become brittle after the sterilization process. Some materials may show some yellowing depending on thickness. Tamper-evident acrylic-based compounds may slightly yellow in packages 0.040 in. thick, but thinner gauges that are typical for packages (0.010–0.020 in.) will show very little color change, if any.

Ethylene oxide (EtO) sterilization temperatures can deform the shape of some packages but will not warp acrylic-based thermoformed trays. Acrylic-based products such as XT polymer can be used in packaging applications that are EtO sterilized without concern about package deformation due to the temperatures used in that process. EtO sterilization is generally done at temperatures in the range of 145°–165°F. With a DTL (deflection temperature under load) of 192°F, XT polymer is not affected by EtO sterilization temperatures. PETG products, however, have DTL values in the range of 145°–149°F, and can therefore become deformed in the sterilization process if the temperature exceeds the DTL value.

Radiation sterilization can affect the mechanical properties of plastic compounds, but again, acrylic compounds exhibit no changes in mechanical properties up to 5 Mrd or 50 kGy of radiation. With gamma radiation, a material is considered to be significantly affected when it loses about 25% of its tensile elongation. This will occur with XT 375TE, the tamper-evident brand of XT polymer, at about 7 Mrd of radiation. Typical sterilization levels are 2.5 to 5 Mrd. When subjected to E-beam radiation, XT polymer retains its strength properties at radiation levels up to 75 kGy (Figure 1).

XT polymer shows significant impact strength and resistance to crack initiation and propagation both before and after EtO and E-beam sterilization. This resistance to cracking further demonstrates the ability of acrylic-based materials to maintain the integrity of the package when impacted in handling. While PETG materials exhibit high tensile elongation properties, their resistance to cracking is about 25% of that of XT polymer before and after EtO sterilization (Figure 2), and about 30% of XT polymer's impact strength after high E-beam sterilization doses of 75 kGy.

An additional benefit associated with tamper-evident acrylic-based compounds is postpackaging sterilization. Once thermoformed, acrylic-based polymer trays can be filled and sealed before final sterilization of the contents and the package. A sealed acrylic-based package can be sterilized using gamma, E-beam, or EtO sterilization methods. This method of sealed-package sterilization ensures both the contents and the packaging are free of contamination, and avoids numerous component sterilizations and the need for a sterile packaging line. Final validation testing is required to ensure the medical components are sterilized effectively inside the package. Manufacturers looking to streamline their packaging operation and provide effective tamper-evident packaging can take advantage of this.

IMPROVING PACKAGE DESIGN

The ability of some compounds to be thermoformed over a wide temperature range allows the flexibility to use higher temperatures in order to obtain good definition on intricate parts without losing melt strength. Thermoformed rigid trays with deep-draw designs require a material with relatively high melt strength. Where deep draws can be limited with polyesters or crystalline materials due to their low melt strength, tamper-evident acrylic-based compounds can easily be thermoformed to draw ratios of 7:1 with good quality.

Package decoration can be an important component of design and validation. Decorating techniques can be used for a number of identification, information, or instructional purposes on thermoformed trays. Some thermoforming compounds contain lubricants that may interfere with decorating processes. Compounds such as acrylic possess excellent denesting properties and will not require silicone or lubricants to denest trays and prevent blocking. So lubricant interference with the decorating process is not a factor. Standard pad printing, screen-printing, and hot stamping techniques can be used with many extruded plastics. Acrylic-based inks are recommended for sharp graphics and vibrant color printing on acrylic-based substrates. Manufacturers seeking brand distinction or eye appeal in consumer arenas can use foil embossing decorating methods with rigid packaging trays.

A major trend that has taken root in the medical device and pharmaceutical industries is brand distinction. Acrylic-based thermoformed compounds offer manufacturers the advantage of embossing an anticounterfeiting holographic stamp into the packaging. The holographic embossing offers a clear visual anticounterfeiting validation for medical and pharmaceutical devices without adversely affecting the material's tamper-evident or sterilization properties.

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