

E-Beam Sterilizes the Industry

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Introduction

When an engineer packages for medical industries, there are many issues to put into perspective. The first issue that comes into most people's minds is sterilization. In many recent cases, medical devices have not been properly sterilized, which has led to the death and illness of many patients. This, in turn, could possibly result in lawsuits. There are many ways that medical device manufacturers sterilize their packages and products.

Although great amounts of package testing are done after the sterilization process, problems still arise when the product hits the market. All sterilization processes have their own adverse effects. One main issue that arises frequently is the seal integrity on medical packaging pouches. A two-polymer bond, or a polymer and Tyvek, bond create the seal. Sometimes these bonds are weakened or broken down by the most commonly used sterilization method today, ethylene oxide. This leads to an open environment and entrance for microorganisms and bacteria. Other aspects such as breakdown in strength of packaging components and aesthetic appeal also occur through many other processes.

These major concerns have prompted companies to look into electronic-beam sterilization, more commonly known as e-beam. Positive issues such as cost/time, atmospheric effects, and material effects to packaging will result in a change.

E-beam sterilization is a rapid-growing process being used in the medical industries. New technology and the ability to control the energy level within the beam are reasons the process is being used more often. The first work with ionizing irradiation took place in 1895; the process was patented in 1921. In 1965, the Surgeon General stated the e-beam process was safe to use on medical device packaging. Since then, the process has increased in popularity. Now, we have materials compatible with e-beam technology. Other uses for e-beam have also become popular, such as strengthening certain materials, irradiating mail, and most importantly, keeping medical products safe. E-beam is being used more often today because the technology is advancing rapidly.

The Electron-Beam Linear Accelerator, (E-beam) works similar to a television tube. Instead of electrons being widely dispersed and hitting a phosphorescent screen at low energy levels, they are concentrated and accelerated close to the speed of light. This produces very quick reactions on molecules within the product. A conveyer or cart system moves the product to be sterilized under the e-beam at a predetermined speed to obtain the desired electron dosage. Products move in and out of the irradiation area continuously. Product thickness depends on density and electron energy.

Sterilization Methods

There are many different processes used for sterilization. Methods such as e- beam, gamma, and ethylene oxide (ETO) are most common. While e-beam and gamma are very similar, ETO is a drastically different process.

ETO sterilization is completed while packaging is in its final configuration. The process ends by placing the packaging and the product into a large chamber. Gas is pumped into the chamber and then vacuumed out continuously for up to 14 days.

Time Advantage

Time can be a major issue when it comes to sterilization processes, especially when a customer needs the product immediately. The three main types of sterilization used on medical packaging vary in time. According to a Steris, contract sterilizer, ETO sterilization can take up to 14 days on certain cycles. (Steris Representative, 2003). Many major medical companies are now contracting the ETO process to an outsource company, such as Steris or Cosmed,. As one can see this would be very time consuming. The company must first send the packaged product to the sterilizer by truck or air before the process can start. The next reason is that this process requires time for the ethylene oxide to permeate through the package and chamber size is limited. Most ETO chambers can hold between 6 and 10 pallets of product. If the company has more product than this, the process will not begin on the next four to six pallets until the first batch is done. Once this is completed, the pallet must then be loaded onto a truck and shipped back to the medical company, or to its distribution center.

With e-beam sterilization, time issues can easily be eliminated. They can be decreased to a point that is not even comparable to ETO. E-beam sterilization can be fast enough to implement at the end of the production packaging line. With this advantage, no other form of sterilization can match e-beam. At most, e-beam would take one minute per package. This time would be far less than any other process. Gamma irradiation can take 4 to 6 hours, while ETO can take up to 14 days.

Cost

Cost issues also give e-beam the advantage over other processes. As described in the above section, e-beam is a major time saver, and time is money. E-beam also can be added into the production line, which cuts down the distribution costs, amount of handling, and its inherent risk. According to a Titan representative, the initial cost to implement the system into the line is minimal compared to the cost of having contract sterilizer bills and added distribution costs (Titan scan rep, 2003).

There is also a cost savings over the ETO process due to the elimination of an expensive packaging component. With e-beam, there is no need for Tyvek or any other type of porous material on the sterile barrier. The need for porous materials is eliminated (Allen, 1998).

Effects of Processes

As previously discussed, all forms of sterilization have negative effects to a wide variety of packaging materials. These effects can vary from material to material and between the different packaging components. Sterilization can affect polymers, seal strength, label and box adhesion, corrugated and paperboard strength, and material color. E-beam and ETO do have some similar effects, but ETO has more adverse effects in the long run.

The major issue with ETO has to do with medical pouches. Both polyethylene-polyethylene bags and polyethylene-Tyvek bags can be affected. Major pressure changes within the sterilization chambers. During the ETO process, gas is flushed throughout the chamber and enters the packaging through a Tyvek portion. For this process to work, the packaging must have a porous material so the gas can get through the packaging and onto the product. The gas, accompanied by heat, enters the chamber several times. Every time the gas enters the chamber it must also leave. These chambers have vacuums that suck the gas out of the chamber, and also out of the packaging. This pressure change can drastically reduce seal strength and in some cases burst the pouch, resulting in catastrophic consequences. If the seal strength is weakened, or the bag bursts, the sterile environment is lost and the product could be exposed to bacteria. These bacteria could often lead to problems mentioned earlier.

Another downfall to ETO sterilization is the effects heat can induce on packaging materials. This heat can exceed 150 degrees F. Many polymers tend to distort or melt at these extreme temperatures (Device Link, 1997). The heat within these chambers can fluctuate 15 degrees above or below the intended temperature. This heat can also reduce the strength of polyethylene-Tyvek seals by greater than 55 percent. In turn, this decrease in strength can lead to a non-sterile environment and negative effects.

Another negative effect that ETO has on packaging is the decrease in strength of corrugated and paperboard materials. This decrease in strength can lead to distribution and handling problems during post-sterilization. Why do these materials get affected? This decrease in strength does not occur during the actual process, it occurs when the product leaves the sterilization chambers. After having been in extreme heat for up to 14 days on and off, the product and packaging absorb a great amount of heat (as discussed in the previous paragraph). After the process, the product is immediately removed and put on the shipping docks to be distributed to the customers. This is an uncontrolled environmental situation. When this product gets moved into the distribution cycle, there is a high risk of damage.

Effects of Irradiation

Radiation can cause the breakdown of packaging materials at high energy levels, but the level to decontaminate a product through medical packaging is low. The problem with this breakdown is the creation of free radicals from polymers. This can lead to the material becoming part of the product. The creation of free radicals is known as chain scissioning (RDI Services, 2003).

Chain scissioning occurs when a substance/polymer is exposed to an excess of radiation. The carbon-carbon bonds that connect atoms can become detached and possibly destroyed. This problem can lead to decreased tensile strength within a polymer. This problem can easily be avoided as new polymers are being created that have longer chains and will not detach. Such polymers as EVOH are unaffected. EVOH contains five chains, and e-beam has only slight breakdown of one of these chains (Greenburg, 2000).

On the opposite side of the spectrum, e-beam can be advantageous to use with some polymers. A phenomenon called cross-linking can take place within certain packaging polymers used in the medical field. Cross-linking occurs when the beam hits the material and allows the molecules to slip and slide over each other. The molecules intertwine and create many benefits. Some of the benefits include increased tensile strength, increased form stability, resistance to deformation, resistance to solvents, shrink memory, and the resistance to stress cracking.

Polyethylene is one polymer that can benefit from e-beam sterilization. Certain studies have been done to even benefit non-packaging materials (RDI services, 2003).

Although there are a few exceptions, most polyolefin materials will cross-link. With some simple engineering in materials, packaging configurations can benefit from the e-beam sterilization method. E-beam is the only process that will benefit certain polymers, and shows little effects to fibrous materials, such as corrugated and paperboard.

Atmosphere

The next point is the effect on the atmosphere around the sterilization process. This also seems to be an area where all processes have their downfalls. E-beam again leads in this area with the minimal amount of effects.

E-beam only creates one problem for the atmosphere. During the process, small amounts of ozone are released and exhausted into the air, however, this is the only effect to the environment. The possibility of a person coming in contact with the beam is the only other problem, and workers in the area must wear protective vests.

ETO has major issues and atmospheric effects. ETO gas is considered highly flammable, a toxin, reactive, and a carcinogen. Long time users that have come into contact with the gas may have neurological and respiratory damage (No Harm Org, 2003).

Conclusion

There are wide arrays of disadvantages to packaging sterilization processes. Sterilization methods are very important priorities when engineering medical device packaging. One must take this into consideration as lives could depend on package design. The advantages of material issues, time and cost savings, and the effects on the atmosphere it is clear to say that e-beam has a bright future. More and more companies are converting to e-beam sterilization as the material compatibilities are increasing at an incredible rate to suit the

needs of the method. E-beam can save lives, money, and time for the packaging of medical devices.

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