Medical Device Sterilization: What Manufacturers Need to Know

Originally Published MDDI September 2002 STERILIZATION How do you decide on a sterilization procedure? What's new in sterilization? What's ahead? Seven experts provide answers. William Leventon

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STERILIZATION

How do you decide on a sterilization procedure? What's new in sterilization? What's ahead? Seven experts provide answers.

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Before you can sterilize a medical device, you have to figure out how you're going to do it. And before you can figure that out, you have to know your sterilization options. You should also get an update on what's new in the field, so your sterilization process can be as fast, effective, and inexpensive as possible.

Need help getting started? Read on and find out what seven experts have to say about some common sterilization methods. The experts also discuss a variety of new tools that could improve and shorten your sterilization process.

The Rhodotron TT300 electron-beam accelerator also produces x-rays, which penetrate more deeply than electron beams.

COMPATIBILITY CONSIDERATIONS

When deciding on a sterilization method, one of the first considerations should be product compatibility. "You have to eliminate methods that are incompatible," says Trabue Bryans, president of the Atlanta division of AppTec Laboratory Services (St. Paul, MN), which performs sterilization-related testing. For example, gamma irradiation may have to be ruled out because of adverse effects it may have on the product or packaging, even if it would be the most rapid sterilization modality.

Today, gamma compatibility is less of an issue than it was a decade ago, according to Ruth Brinston, director of marketing for MDS Nordion (Ottawa, ON, Canada), a maker of gamma sterilization equipment. She explains that, in the 1990s, suppliers introduced a variety of radiation-compatible materials that are now being specified by device manufacturers.

Nevertheless, gamma-related concerns remain. For instance, MDS Nordion generally recommends that gamma irradiation not be used on products made with Teflon, which can degrade under gamma exposure. But this isn't always the case. "I've seen gamma work just fine on filters with Teflon," says Brinston.

About 70% of products are compatible with electron-beam sterilization, according to Rod Wilson, vice president of sales and marketing for Biosterile Technology Inc. (Fort Wayne, IN), which makes in-line electron-beam sterilization systems. On the other hand, E-beam sterilization can be harmful to products containing batteries or

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electronic components. It can also degrade rubber and polypropylene, but these materials now come in grades that are E-beam compatible, Wilson notes. "Manufacturers are looking for alternatives to ethylene oxide and steam sterilization," he says. "So designers are trying to change materials in order to make devices radiation compatible."

Although it's a common sterilization technique, the use of ethylene oxide (EtO) can have a downside that must be considered. "Anything that goes through the process is going to absorb ethylene oxide," says John Walker, director of quality systems and regulatory compliance for Steris Corp. (Mentor, OH), which provides sterilization services and equipment.

Some materials absorb more EtO than others. Certain plastics, for example, absorb large amounts of the gas, while stainless steel absorbs almost none. "The more the product absorbs, the more EtO you have to get out of it prior to sale," Walker notes. This is done by aerating the product until its EtO content reaches the level specified in FDA-recognized standards.

The VHP M1000 system from Steris Corp. is designed for low-temperature biodecontamination of isolators, workstations, and filling lines. The VHP cycle operates in an open-loop configuration consisting of four phases: dehumidification, conditioning, decontamination, and aeration.

DESIGN ISSUES

In addition to materials, device designs can influence sterilization procedures. For instance, some devices can't be sterilized in their assembled form because a key component is sealed off from the sterilization process. These devices must be disassembled to expose all parts prior to sterilization, says Chris Dwyer, director of marketing and international sales for Raven Biological Laboratories (Omaha, NE), a manufacturer of biological indicators. (Biological indicators contain minute organisms and are placed in various locations on a product. Death of the organisms proves sterilization efficacy.)

Before deciding on a sterilization procedure, manufacturers should consider how the device is going to be used. This determines which parts will need to be sterile—and which will not. "We may look at a device and think we've got to get the whole thing sterilized," Bryans explains. "But then the manufacturer tells us, 'No, just this end will touch the patient. The rest of it won't.'"

Aside from outer surfaces, some less-obvious parts of a device may also require sterilization. "A lot of devices have motors inside," says Bryans. "A motor might not touch a patient, but it might generate air. What if bacteria get into that air? And what if that air is blown into a room?"

Complex device designs can pose problems for EtO processes because the gas must reach parts of the device that may have limited accessibility. When products have these types of features, manufacturers can opt for a "harsher" sterilization cycle, Walker notes. "You can pull a deeper vacuum, which creates more driving force for moisture and EtO to get into the device," he suggests. "Or you can increase the gas concentration in the sterilization chamber. You can also do something that helps move along a chemical process—like increasing the temperature."

When called on to sterilize a complex device, IBA Medical Sterilization & Analytical Labs (Oak Brook, IL) tailors a sterilization cycle for that product. These custom processes may include higher temperatures and longer gas dwell times, according to Patrick Hughes, vice president of sales and marketing for IBA, which offers electron-beam equipment and a variety of contract sterilization services. The company might also overpressurize the sterilization chamber with nitrogen to force the EtO into hard-to-reach areas. "You'd be surprised how EtO gets into nooks and crannies," Bryans says. "The process forces gas into a lot of the tough places."

No tough places can escape gamma irradiation, according to Brinston. "Gamma doesn't care about design configurations," she says. "It goes through everything."

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Electron beams aren't as certain to reach every crack and crevice in a device. So sterilizers put dosimeters in hard-to-reach areas to determine if the products have received a sufficient dose. If it is insufficient, says Wilson, the dose can be increased.

E-beam processes can also have trouble with "shadowing scenarios," Wilson explains. For example, the beam may not be able to reach a product stacked below another product. Sometimes, such a problem can be solved by changing one product's position. "You might put a product at an angle, turn it on its side, or turn it upside down," he says. "You have to figure out the best way to orient the product to the beam."

MATTERS OF DENSITY

In addition to orientation, E-beam users must be concerned with product density. "If a product is made of very dense material, an electron beam may not be able to penetrate it," Wilson says. The reason: the electrons in the beam are particles with mass. According to Hughes, this may limit the E-beam penetration distance to just half that of gamma radiation.

But there are ways around the penetration problem. "We can penetrate most products by giving them a double side of radiation," Wilson says. "We'll run a product through the beam, flip it, and run it back through." In addition, he notes that some products composed of superdense metals (such as orthopedic implants) only need surface sterilization, which the E-beam process can handle.

Package-related difficulties can also be surmounted. In most situations, Wilson says, E-beam sterilization is used for products in their final boxed form. If the packaging materials are too dense, however, the products can be removed from their containers before sterilization.

Nevertheless, Wilson concedes that product density can limit the effectiveness of electron-beam sterilization. "E-beam isn't a miracle cure," he says. "Some products will probably always need gamma or EtO sterilization."

EtO diffuses several millimeters into surfaces and penetrates all kinds of packaging, says Bryans. "But if something's really dense, it's not going to go through," she adds. "It won't go through half an inch of material. Only gamma radiation will get to enclosed places that need to be sterilized."

At IBA, pricing for radiation sterilization depends on product density, dose, and turnaround time requirements. The price of EtO sterilization also depends on product density and turnaround time, as well as design complexity and time in the sterilization chamber. When manufacturers choose a sterilization method, Hughes explains, cost considerations are normally secondary to such issues as material compatibility and how effective each method will be in sterilizing the product.

PARAMETRIC RELEASE

Beyond a choice of sterilization methods, contract firms offer a number of optional capabilities. Perhaps the most important of these is parametric release, which can dramatically speed up the sterilization process.

Following conventional EtO sterilization, product samples are sent to a laboratory for sterility testing, which shows whether the process has killed biological indicators that have been placed on the products. Sterility tests usually take two to seven days to complete.

Because parametric release relies on measurements of key sterilization variables, it eliminates the need for such sterility tests. If the measurements obtained in the chamber during processing meet specified requirements, products can be released to the market immediately following sterilization.

Cosmed Group Inc. (Queensbury, NY) offers parametric release as part of the company's contract EtO sterilization services. According to Clark Houghtling, Cosmed's vice president of technical affairs, parametric release requires three steps not required in conventional sterilization processes. These are direct measurements

of EtO concentration, relative humidity, and product temperature in the sterilizer chamber. In conventional processes, these values are determined by calculation. Direct measurement, however, "provides more-accurate data about what's going on inside the chamber," Houghtling says. "So parametric release gives you a higher level of confidence in the sterility of your product than release based on biological indicators."

On the downside, parametric release requires more-rigorous validation than methods that rely on sterility tests. Manufacturers using parametric release also need "state-of-the-art sterilizing equipment with all the bells and whistles for monitoring the process," Dwyer notes.

Although the extra validation requirements are expensive and time-consuming, "the payback is faster product turnaround," Houghtling says. Parametric release also eliminates costs associated with the use of biological indicators, Dwyer adds, as well as the expense of warehousing products while waiting for sterility test results.

EXPRESS SERVICE

Parametric release is part of Cosmed's new EOExpress EtO sterilization process. As the name suggests, EOExpress is fast. The entire process takes just one day, Houghtling claims, compared with three to five days for the typical radiation process. "It's a very powerful tool," he says.

To a large extent, EOExpress's rapid sterilization cycle is a result of so-called all-in-one processing. Years ago, Houghtling says, the entire sterilization process occurred in the sterilizer chamber. Over time, sterilizer equipment became more sophisticated—and more expensive. "That caused people to look for ways to get more out of this expensive asset," he says. "So the technology evolved in a way that moved parts of the process outside the sterilization chamber."

Today, EtO sterilization is normally done in three phases that take place in three different places. First is the preconditioning phase, which occurs in a large room that usually contains many different products. Here, the products are heated and humidified to reduce the amount of time they must be kept in the sterilizer. Next is sterilization, which takes place in the sterilizer chamber. Finally, the products are aerated in a room similar to the preconditioning room. Altogether, the three phases take two to three days. In addition, however, some products require as much as three weeks' extra aeration to reduce EtO residuals to acceptable levels.

In contrast, EOExpress uses the sterilizer chamber to accelerate both preconditioning and aeration. Inside the chamber, "you can do a more effective job in much less time because you can tailor the process to one product," Houghtling explains.

This isn't the case in preconditioning rooms, which might contain products from a dozen companies at the same time. These rooms can only be as warm as is allowed by the most temperature-sensitive product. "If one product can only handle a maximum temperature of 105°F, then the room temperature must be 105°F or lower," Houghtling notes.

In the sterilizer chamber, on the other hand, each product can be subjected to as much heat as it can handle. Products can also be heated more quickly and uniformly than they can in a large room. The chamber can also provide high-speed air recirculation that can't be produced in a preconditioning room, where "there are just a couple of ceiling fans blowing a little air around," Houghtling says.

In the aeration phase, the chamber heats products to their maximum temperature, quickly boiling off EtO. Meanwhile, high-speed air recirculation boosts airflow around the products to speed up the evaporation process. All this takes place during chamber evacuation, "so you're literally sucking EtO out of the products and packaging," Houghtling says. As a result, when products come out of the sterilizer chamber, they are already at or below government-required EtO residual levels. No additional hold time is required for EtO dissipation.

To perform all-in-one sterilization, a contractor needs many more sterilizers than companies that do out-of-sterilizer preconditioning and aeration. "It's a change for the sterilization industry to look at the all-in-one cycle as something beneficial," says Hughes, whose company also offers all-in-one EtO sterilization. "Does it take more time in our chambers? Yes, it does. But is it better for the customer? We believe it is."

EQUIPMENT ADVANCES

Another time-saving change in some plants is more-automated sterilization. Recently, MDS Nordion built what Brinston calls a fully automated irradiator for a medical customer. The machine features automated product loading and unloading, as well as a system that immediately reads dosimeters, which eliminates several-day waits for dosimetry readings from a laboratory.

During the sterilization process, some of MDS Nordion's customers now use the World Wide Web to check product status. The tracking system includes a bar code reader, which is used to enter product data. MDS Nordion provides the tracking equipment, while the customer provides the Web site used to access product information. "With this system, any sales rep can see where a product is in the process—in the sterilizer, out of the sterilizer, or at the shipping dock," Brinston says.

Also new from MDS Nordion is a batch gamma sterilizer. Smaller and less expensive than the company's other offerings, the machine is meant for customers who want to sterilize two or three pallet-loads of product at a time.

The new machine "gives you flexibility," Brinston says. "If you have a lot of different products, you can sterilize a low-density product in one batch and then do a very heavy product in the next batch. With a conventional sterilizer, it might be more difficult to schedule something like that."

Like MDS Nordion's batch unit, Biosterile's new E-beam sterilizer is smaller than other machines of its kind. For shielding purposes, large E-beam systems require stand-alone rooms with thick concrete or steel walls. Biosterile's small in-line unit, however, incorporates patented self-shielding that keeps radiation contained within the unit. This means users don't have to build special walls or make other facility modifications to isolate radiation from the sterilizer.

Wilson compares owning the compact E-beam sterilizer with owning an x-ray machine. Besides being simple to operate, he says, the machine lets manufacturers keep their sterilization processes in-house. This eliminates the necessity of shipping products to and from a contract sterilizer—reducing costs and turnaround time.

Another new system, this one from Steris, sterilizes products with vapor-phase hydrogen peroxide. According to Walker, vapor-phase hydrogen peroxide sterilization is a fairly gentle, low-temperature process that offers good material compatibility and does not leave harmful residuals. The process is well suited to metals and certain polymers.

COMING SOON

A number of other sterilization innovations are in development, but are not quite ready for the marketplace. One such product is IBA's x-ray sterilization system. Like E-beam radiation, the system's x-rays are generated by a machine rather than cobalt. Although x-ray sterilization isn't as fast as electron-beam processes, x-rays penetrate much more deeply than particle-based electron-beams, Hughes claims.

The system may cost a bit more than gamma processes; however, Hughes believes x-ray sterilization will be much faster than gamma, which will shorten turnaround times. X-rays also penetrate deeper than gamma radiation, and may be less harmful to some products owing to shorter exposure times. "The longer some plastics stay in front of radiation, the more likely it is that they'll turn yellow," Hughes explains.

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