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Sterilization 101

Medical Materials & Technologies

1 How sterilization impacts medical device design

Sterilization is an incredibly important factor to consider when designing medical devices. Just like the design process itself – sterilization is like putting together a puzzle. You need to make sure all the pieces, the components, fit.

Sterilization directly effects device design. Some sterilization methods may alter certain material properties. For example, gamma radiation causes most polypropylenes to stiffen and degrade. Because of its influence, the sterilization method can define which materials to use in some projects. If that is the case, be sure to use a sterilization mode compatible with the material.

As you design the sterilization process to meet your needs, consider the temperature range, duration and whether the device will be sterilized in its package – and the impact that can have on the device components. Some materials may not pose any issues before sterilization, but with it, they can unintentionally interact with other materials. Anticipating the results will help you identify how your device will perform after sterilization. If you find your device requires sterilization, but a compatible method is not available, you may need to redesign, ultimately influencing how the device will be manufactured.

2 What are sterilization non-negotiables?

When thinking about sterilization, consider these non-negotiables: What components of the device cannot be modified in terms of device integrity? If the device has a pharmaceutical component, like a drug-eluting stent, the sterilization process may alter the drug, and, subsequently, its efficacy. A drug is an active component and possible degradation could occur from high-energy or high-temperature sterilization methods. Gamma radiation and eBeam and steam processes could also cause potential damage to electronics.

Also consider your packaging. Some sterilization methods can cause packaging to yellow or wrap, which may negatively impact the device's appeal. Because sterilization can impact items such as packaging and processes, as well as pharmaceutical and mechanical components, it's important to explore different sterilization methods early in the design process.

3 Cost considerations

As with any device design project, cost is important. Sterilization, when performed at scale, can directly impact the manufacturing and distribution processes, while still needing to ensure sterility of the product. One of the best ways to plan for success is to sterilize the device during or directly after the prototype phase. It allows for trial and error and the ability to test for potential pitfalls. When the device is submitted for FDA approval, it will have already undergone sterilization and be approved within the desired parameters.

4 Types of sterilization

There are three main types of sterilization: steam heat, high energy and chemical – all of which inactivate microorganisms.

Heat sterilization: heats devices to inactivate bacteria. Hospitals often use high-temperature moist-heat (steam) or dry-heat sterilization to clean surgical instruments.

High-energy sterilization: disrupts biological processes of bacteria. The amount of energy needed to sterilize will be determined by device geometry and the density of materials. These sterilization methods include the following:

- **Gamma radiation:** Photons released during the degradation of radioactive material inactivates all bacteria.
- **Ultraviolet radiation:** Ultra-short wavelengths of light [UVC] are used to inactivate bacteria
- **Electron beam (e-Beam) radiation:** Electrons accelerated to high velocities inactivate bacteria.

Chemical sterilization: Ethylene oxide (EO) gas inactivates microorganisms and bacteria. EO gas permeates packaging to ensure the entire device is sterilized. Other forms of chemical sterilization such as nitrogen dioxide or hydrogen peroxide can also be effective forms of chemical sterilization.

5 How do you decide which sterilization process is best for your device?

Choosing the best sterilization process will require an analysis of many components. As formerly outlined – device integrity, materials, pharmaceutical components, packaging and processes all play a part.

Types of devices:

Single-use devices require a sterilization method that can penetrate products sealed in their final packaging.

Combination devices pair tissue or pharmaceutical or another component, such as a drug-eluting stent, so the sterilization method must ensure both the device's sterility and retain functionality.

Implantable devices include heart valves, stents, knee replacements and more. Most implantable devices, like orthopedics, need sterilization to ensure a high level of safety for the patient.

Pharmaceuticals have active drug components that need to maintain efficacy, so they need a sterilization method that will maintain efficacy if required.

6 A closer look at adhesives

Sterilization affects individual adhesives, as well as combinations of adhesives. Scientists ask how sterilization might impact:

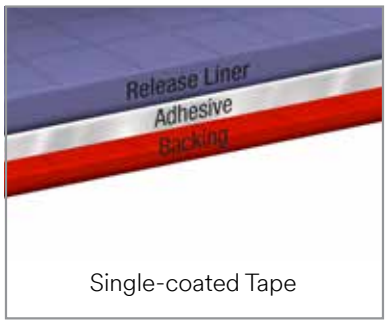
- Tack: how quickly the adhesive bonds to a surface
- Peel: force required to remove the adhesive from a surface
- Shear: the ability of the adhesive to resist forces applied parallel to the substrate
- Liner release: force required to remove the liner from the adhesive
- Backing tensile strength: how easily the backing breaks
- Flexibility: how the product conforms to a substrate, such as skin
- Wear time: how long the adhesive will adhere to a substrate, such as skin
- Shelf life: confidence in the efficacy of an adhesive after a period of time stored under ambient conditions

Exposure to high energy radiation can cause adhesives to stiffen or soften. A stiff adhesive might not adhere properly, whereas a soft adhesive may ooze at the edges. It's clear that considering all components of a device – including adhesives – is paramount when it comes to sterilization.

For these reasons, it's important to consider the impact of sterilization on tape construction and material components including adhesive type and release liner chemistry.

Examples of tape constructions

Double-coated Tape



Single-coated Tape

Transfer Adhesive

7 Sterilization moving forward

As the medical device industry continues to evolve and grow – sterilization will, too. Already, leaders in sterilization are looking for radiation alternatives, most notably X-ray, due to a growing shortage of cobalt rods used for gamma radiation. This changing landscape indicates why including sterilization early in your design conversations is crucial. The sooner you can anticipate changes and challenges, the better off you'll be.

See 3M technical data sheets for specific product sterilization information.

If you'd like to learn more about our adhesive capabilities and how sterilization plays a role, contact your 3M representative.

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