

6 Defects to Avoid by Rightsizing Your Medical Packaging

When it comes to medical packaging, sizing is crucial. Packages that are undersized or oversized are more likely to become damaged or have a breach in the sterile barrier; costing you time and money and compromising patient safety. However, packages that are properly sized will do just the opposite; better protect your device, maintain the sterile barrier, and get your product to market quickly.

Below, our experts walk through potential defects that could occur with a pouch that is not sized appropriately.

1. Seal Creep

The first defect that could occur when a pouch is undersized is seal creep. For example, when a bulky device is packed too tightly in a pouch, the device can put stress on the seal and cause the materials to pull apart. When there is increased stress on the seal, it can cause seal creep to occur.

Seal creep can also occur during high-temperature and/or high-vacuum situations, such as during an Ethylene Oxide sterilization cycle or high-altitude transportation, such as air shipments or ground shipments in mountainous terrain. The high temperature could cause the sealant layers to re-activate unintentionally and the vacuum could cause the package to expand. This combination could result in a seal creep defect in your sterile barrier package.

TIP: Conducting a dye penetration test can be a good way to detect seal creep in a test environment. Along with rightsizing your package, selecting the proper packaging materials and appropriate sealant layer technology in your sterile barrier system is a good way to avoid seal creep.

2. Channels in the Seal

A second defect is channels in the seal area, typically caused by wrinkled materials during the sealing process. Like most defects, there are a variety of reasons wrinkles can occur.

For example, if a large device does not allow the pouch materials to lie flat during the sealing process, wrinkles may form and ultimately cause a channel in the seal. Another reason might be that there is not enough material at the end of the pouch to handle during the sealing process. If the space between the device and the end of the pouch is too short, the sealing process may be affected.

TIP: Designing a pouch with ample room between the device and the end of the pouch will help the sealing area lay flat and minimize the chance of wrinkles.

3. Punctures

Punctures are arguably the most common defect to occur when a package is undersized. For example, if an injection molded plastic device is tightly packed in a flexible sterile barrier system, small areas of flash (also known as excess material) could create a sharp edge that forces its way through the packaging. Or perhaps the device has a sharp point that repeatedly pushes against the material during simulated or actual transportation testing. When a package is undersized, there is typically more concentrated force on the material, increasing the risk of puncture.

TIP: It's important to remember, there can be different types of causes that result in the same type of defect. Therefore, determining the root cause of the pinhole is vital.

4. Flex Cracking

Flex cracking is a defect that can be easily overlooked. It occurs when a flexible material is repeatedly flexed in a concentrated area, most commonly during the vibration cycle of simulated and actual distribution. With repeated flexing, stress marks tend to show up, and they may turn slightly white. Those marks could eventually contain pinholes.

TIP: Proper material selection for your pouch can help to reduce defects due to flex cracking. Some flexible materials are more malleable, therefore more forgiving than others. Thicker material is not always better for your package!

5. Abrasion

Another defect that can occur because of an undersized pouch is abrasion. For example, when an area of film within a DuPont™ Tyvek® to film pouch gets wrinkled and comes to a point, that point can rub up against a shipping container or a shelf carton during the vibration cycle of simulated and actual distribution. This abrasion force can eventually lead to a pinhole.

TIP: When packaging a device, try to minimize the amount of material tenting. If it is unavoidable, find a way to reduce the amount of interaction between the sterile barrier system and the shipping container.

6. Device Damage

Device damage is one of the biggest risks to an improperly sized sterile barrier system and/or protective packaging. It can occur when a package is too large or too small. When a package is too large, there can be unintended movement within the package causing the device to shift excessively during transportation, risking device damage. When the package is too small, the device is more tightly pressed against the package and is prone to damage from external forces.

With these potential defects in mind, it's important for medical device companies to continually evaluate the packaging for each project and device. Each package should be properly sized to avoid these defects and ensure your product gets to market safely.