CASE STUDY

Packaging Failure: Discovery, Investigation & Resolution

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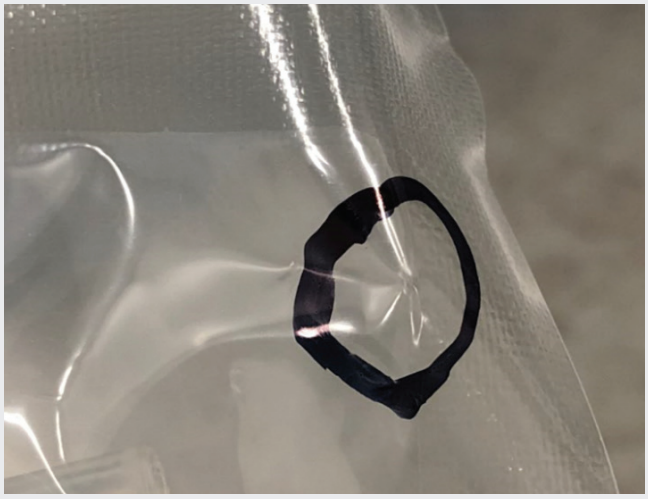
HEALTHCARE PACKAGING

CUSTOMER CHALLENGE

The product that came to the lab for testing was a surgical kit, wrapped in CSR wrap, with a header bag serving as the sterile barrier with five sterile barrier systems placed directly into a box. There were no cartons, dividers or other protection provided. This is a relatively large and bulky product packaging system with a nominal box weight of approximately 15 lbs.

Initial integrity testing showed a high failure rate of approximately 50%, presenting as pinholes in the corners of the header bag. Time was of the essence to gain necessary approvals and meet project parameters.

View of sterile barriers inside the box



Closeup view, example of pinholes in corner of bags

INVESTIGATION

Our team conducted an initial visual observation of the pinholes for characterization and to determine potential causes.

Our immediate takeaways:

- ☑ The pinholes were consistent with one another—it was clear that we were dealing with one failure mode, not multiple failure modes.
- ☑ There were no obvious sources of puncture, whether from the outside in or the inside out.
- ☑ The bag material became “bunched up” in the corners of the bags when loaded into the box. In other words, there was excess or loose bag material with nowhere to go, making it crinkled and creased when the bags were loaded.

Next, we performed a series of microscope imaging captures to yield new information. Starting from high magnification and incrementally backing out, microscope analysis corroborated our initial visual assessment that puncture was not to blame.

However, the microscope analysis did reveal tell-tale characteristics of flex cracking:

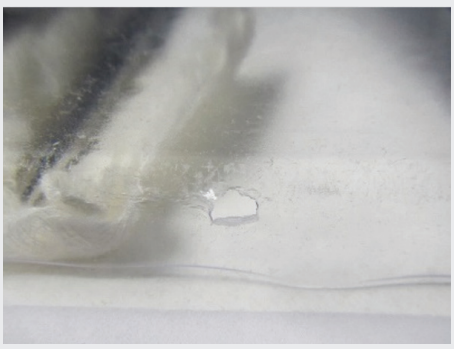
- ☑ Edges of the pinhole, and material immediately surrounding the pinhole, showed white stress marks (sometimes called "witness marks"), which is indicative of flex cracking.
- ☑ Edges of the pinhole were relatively clean, not 'stringy' or 'stretched out' as might happen with a hole created by a puncture or snag.
- ☑ Pinholes were clearly located along creases / folds of the bag material.

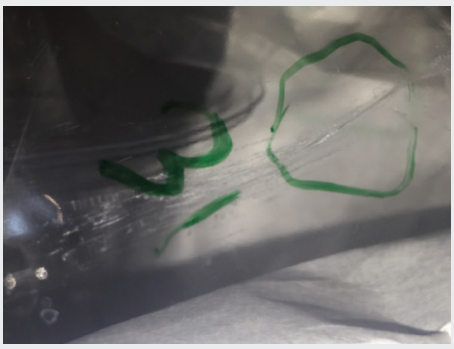
Severe flex marks were observed at several magnification levels. Flex cracking was confirmed.

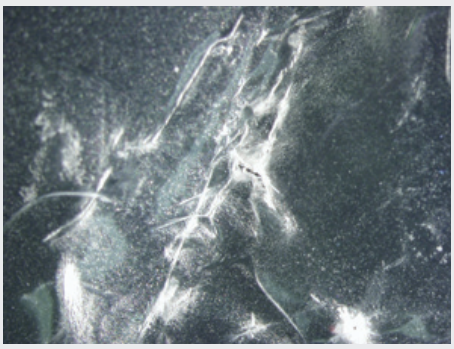
The various magnified images showed different markings that occur with flexing. There was no evidence of any type of damage inconsistent with flex cracking, supporting the hypothesis. From there, our focus shifted to the next question: what condition(s) existed that produced favorable flex cracking conditions?

The entire packaging system from medical device to shipper was analyzed. The combined physical characteristics of the device and the overall packaging system underscored the critical nature of holistic analysis. Of equal significance is how individual selections behave among compounding layers that are intended to protect the units during transit. Even a single aspect overlooked can increase the risk for damage. Essentially, the process was to reverse engineer from the outside in to determine what led to the failure. These results would inform the mitigation protocols. Here is what we found:

- ☑ Cutting away to view the contents within the shipper box showed that excess film from the taped header bag was getting bunched in the offending corner.
- ☑ The headspace of the shipping carton created an environment that allowed product to bounce around. This led to flex cracking.







These magnified images show severe film flex marks, confirming the source of pinhole to be flex cracking.

MITIGATION

The findings of the transit tests that were run on this packaging system led us to look at material selection, header bag and shipper carton. These resulted in a two-pronged approach to mitigation:

Material Selection

Testing the properties of the selected film was critical. Different materials have different flex crack resistive properties. It is important to review and understand how good a material is at resisting flex cracking. The ASTM F392-392M test (Flex Durability of Flexible Barrier Materials or Gelbo) is a good method of ranking films. It is perhaps counterintuitive, but thicker films don't necessarily mean better flex crack resistance!

Redesign of Pouch

We eliminated the header bag and re-engineered a pouch. The new design used double layers of material to reinforce problematic areas by adding extra strips of Tyvek & film. In testing performance of 48/92-gauge polyester vs. 48/96-gauge, more pinholes occurred in the thicker 48/92 version. We also tested and ultimately selected a nylon pouch. Nylon typically demonstrates better flex resistance than polyester. The new packaging system allowed the client to get back on track without packaging fails, ensuring sterility of the surgical kit to the end use.

CONCLUSION

Material selection, medical device characteristics and rigorous testing of each packaging layer—both as a standalone and as part of an overall system—add up to a safe, effective system. While no system is guaranteed to perform perfectly, even with consideration to every detail, a properly engineered system and early testing can help every launch avoid serious setbacks.

Packaging Compliance Labs, in Grand Rapids, Michigan, conducts a wide range of packaging tests for the medical device market. What our clients see on an individual basis, and what we see on a larger scale is that package testing is often conducted in the eleventh hour of a launch timeline. If a failure is found, (we estimate in 30-percent or more cases) time and cost constraints compound an already concerning situation.

For questions or concerns, please contact us.

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