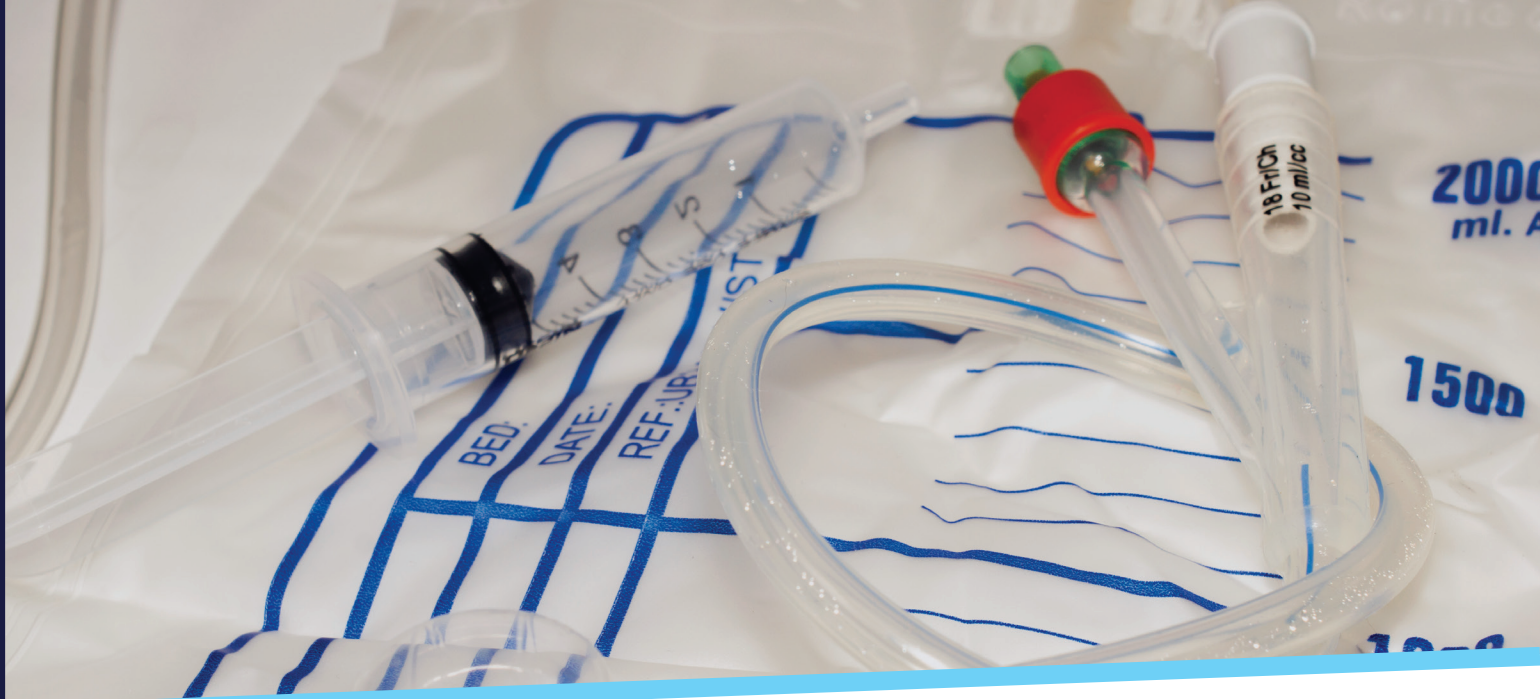




Seal of Disapproval

How TekniPlex Healthcare helped a leading supplier of urinary catheters correct a recall-inducing sterility seal failure.



PROBLEM

One of the world's top three manufacturers of urinary catheters had a legacy packaging process. In a sector where product protection is paramount and sterility is mission-critical, the company created sterile blister cavities for its catheters on a reliable form-fill-seal (FFS) thermoforming machine.

With urinary catheters, packages must not only perform but reassure: when a nurse or other caregiving professional opens the packaging immediately prior to catheterization, they commonly look for a telltale, efficacy-attesting trace. This intentional indication helps verify that a proper, sterile seal has been maintained up to that point – a medical device must called “seal transfer.”

Catheter packaging typically involves two materials: a top and bottom web. The company was utilizing a bottom web comprised of ethylene-vinyl acetate (EVA), Ionomer, and a second layer of EVA. Its top web was 1059 DuPont™ Tyvek® – a sturdy structure comprised of spun-bound polyolefin.

Unfortunately, it wasn't quite sturdy enough. Packaged catheters in the field were discovered with open seals, a sterility breach that led to a costly recall, production line stoppage and temporary inability to serve its customers.

Recalls are never welcome news, but recalls in the medical device sector can be particularly devastating.

The first reason, of course, is the potential for adverse patient health events; catheters must be sterile, without exception.

The business side of a recall is no less enviable. Not only must resources be spent retrieving defective products from warehouses, distributors and even hospitals and nursing homes, but often a recall's impetus – in this case, a packaging design flaw – cannot be expediently remedied. This is because any significant changes to the packaging process must be approved by regulatory governing bodies around the world, a re-validation process that could mean up to a full year of lost revenue and forfeited market share.

In this scenario, the company would use valuable resources collecting defective products, invest heavily in the package's re-engineering... then hurry up and wait while the new design underwent the understandably rigorous regulatory approval process. Then, additional equipment and manpower would be needed to make up for lost production time – or, even worse, the lost market share would make such catch-up measures moot.

The company needed a solution in a few weeks, not 12 months. So it turned to TekniPlex Healthcare.

SOLUTION

The reason for the recall was an insufficient seal between the top and bottom webs, resulting in a weak seal. While the flaw was slight, close most certainly doesn't count when it comes to sterility. The problem needed to be comprehensively addressed as quickly as possible.

There are several possible causes for poor transfer seals, including an inadequate initial thermoforming machine seal, damage during transportation, and small-but-critical seal breaches during a specialized sterilization step: air evacuation in an ethylene oxide (ETO) chamber. Of these, the customer's engineering team suspected that the ETO chamber process was the likeliest culprit, as this was where the blister cavity was subjected to the most stress.

The TekniPlex Healthcare team set to work finding a solution that would stand up to the stress test. Ultimately, their proposed solution comprised a similar Tyvek® substrate, albeit one with a high-performance coating that produces stronger seal strengths in the finished package. The substrate was called 2FS Tyvek®, and the coating was specifically designed for strenuous ETO cycles.

Notably, TekniPlex Healthcare's proprietary coating had shown impressive durability in high heat and humidity, as well as the ability to maintain exemplary seal transfer despite the powerful gas purge washes common in ETO cycles. The coating would help the customer's blister package keep an intact sterile barrier in the most stressful testing and real-world scenarios.

Incorporating TekniPlex Healthcare's heat seal coated 2FS Tyvek® material provided the fastest-possible path back to safe, sterile mass production of its customer's urinary catheters.

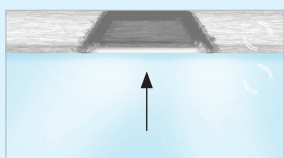
Crucially, the employment of pre-validated substrates shaved commercial production downtime from upwards of a full year to just two months.

Thanks to TekniPlex Healthcare's extensive materials coating expertise, any blow to the company's reputation will be far less severe. In an industry where recalls entail not only product returns but mandatory public reporting, the company's various existing and potential catheter customers can now see for themselves how thoroughly and expeditiously the problem was solved.

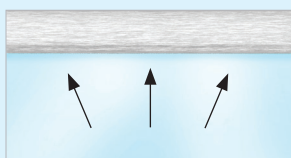
The catheter company even got an unintended bonus: materials savings, achieved because the heat seal coated 2FS Tyvek® was less expensive than its less effective predecessor. A feat exceedingly rare in the medical device sector, TekniPlex Healthcare helped its customer save face and save money – all in a substantially tightened time frame.

By working with a proven solutions provider employing a proven heat coated material, the catheter company turned a potential worst-case scenario into a minimal disruption whose alleviation saved both materials expenses and high-leverage customers.

80%
REDUCTION
IN COMMERCIAL
PRODUCTION
DOWNTIME
WITH THE TEKNIPLIX
HEALTHCARE SOLUTION



Unacceptable seal transfer.
Voids within the seal.



Proper seal transfer.
Consistent seal pattern.

Compromised seals were caused by using inferior materials. TekniPlex Healthcare's heat seal coated 2FS Tyvek® **proved more effective...and affordable!**

BENEFIT

- A Tyvek® 2FS substrate with a high-performance coating was used, to create stronger seals.
- The improved package seal showed **improved durability in high heat and humidity, and during gas purge washes.**
- The 2FS Tyvek® **provided the fastest path back to safe, sterile mass production.**
- **Impact to the company's reputation was limited.**
- The company's customers saw for themselves how **thoroughly and expeditiously the problem was solved.**
- New process **proved to be less expensive.**



A legacy packaging process led to unreliable product sealing, sterility breach, and production stoppage. TekniPlex Healthcare offered a **coated product which kept disruption to a minimum.**

ABOUT TEKNIPLIX HEALTHCARE

TekniPlex Healthcare deploys world-class material science expertise to deliver value in creating products for medical devices, diagnostics, and drug delivery. With a deep understanding of the needs of end-users, our offerings ensure we provide innovative solutions at the point of patient care. For more information about TekniPlex Healthcare and our solutions, visit www.Tekni-Plex.com/healthcare.