



TekniPlex Healthcare reduces costs by \$200K annually, solves quality/lead time issues for a medical device OEM

Changing the forming web to an easily recyclable material and eliminating lidding particulate significantly improves both cost and quality issues.

PROBLEM

A company that produces medical device components was experiencing challenges with two different package types.

First package: Deep-draw form-fill-seal (FFS) tray made from PETG that housed multiple components sealed to coated Tyvek® lidding. The tray would occasionally warp after being subjected to EtO sterilization.

Second package: Flexible FFS package that contained a single medical device component. The FFS package was made from EVA/Surlyn/EVA forming film, with gridcoated paper lidding. Particulate from the paper would flake off and find its way onto the product and package. Further complicating supply issues was that the coated paper was being shipped from a European manufacturer. Additionally, periodic skips in the coating pattern were causing weak and/or open seals.

Additionally, the issues resulted in customer complaints. Further, internal rejections required the company to open multiple Corrective Action/Preventative Action (CAPA) projects that consumed valuable engineering, quality and operations resources.

CAUSE

First package: The PETG resin grade used for the application was causing the trays to warp, creating another set of issues. Also, PETG is not recyclable in the readily available #1 waste stream.

Second package: Paper particulate can be generated by the cutting operation on the FFS packaging equipment and from the paper flexing in distribution. This caused the particulate to get on the product when the package was opened. Also, the paper's grid pattern heat seal coating had periodic skips resulting in non-conforming open and/or weak seals that were found during in-process inspections.

SOLUTION

First package after: TekniPlex Healthcare recommended that the tray be made from its PX material. After customer testing, it was noted that PX was more rigid than PETG, allowing the company to downgauge the material from 30 to 25 mil and reduce material cost. Further, PX is recyclable in the #1 stream which enabled the company to get closer to meeting its sustainability goals. TekniPlex Healthcare also manufactures coated Tyvek®, so it was able to produce the lidding material for this package.

Second package after: For the second package, TekniPlex Healthcare also provided a total solution. It kept the tray structure the same, but substituted low-linting coated Tyvek® for the coated paper that had been problematic. The heat seal coating is formulated with a higher seal strength for stronger package seals. The coating is applied as an air knife flood coat so there is less chance of missing coverage compared to the current process. The coating is also more porous and reduced the risk of open seals in sterilization and distribution.

Because TekniPlex Healthcare has a global manufacturing footprint, including the United States, it was able to eliminate the freight/time issues that were in play with the European coated paper supplier. The TekniPlex Healthcare solution eliminated the quality issues, significantly improved lead times and enabled freight cost reduction.

BENEFIT

By switching both of its packages to TekniPlex Healthcare materials, the company realized significant annual benefits and savings.

- Material cost reduction: **9.25% overall or \$150K**
- Lead time reduction: **4 weeks**
- Supplier consolidation: **four suppliers to one**
- Wasted material due to open or weak seals: **\$15K**
- CAPA-compliant savings: **\$20K (cost associated with paperwork eliminated)**
- Freight savings: **\$10.8K**



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ABOUT TEKNIPLEX 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.TekniPlexHealthcare.com/healthcare.