DUPONT™ TYVEK® 40L FAQS — APRIL 2018

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DuPont™ Tyvek® 40L FAQs

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EXECUTIVE SUMMARY

DuPont has a long-standing and ongoing commitment to the medical and pharmaceutical packaging industry that began in 1972 when Tyvek® was first used for sterile packaging. Since that time, Tyvek® has been used in virtually every form of sterile medical packaging for a wide variety of products, including: cardiovascular catheters, sutures, endoscopic instrumentation, surgical preparation kits, injection systems, electrosurgical accessories and implantable devices, just to name a few.

Its unique balance of properties, which includes outstanding resistance to microbial penetration while maintaining breathability; puncture resistance; protection during distribution; and compatibility with a wide range of sterilization methods, has enabled sterility maintenance of medical devices to protect the health of literally millions of patients worldwide.

In 2014, DuPont interviewed many medical device manufacturers (MDMs) to gain a better understanding of their medical packaging innovation needs. These interviews highlighted the need for a better material to package low-cost and lightweight Class I and IIa devices, especially in the emerging Asian markets. To meet the unique needs of these applications and markets, DuPont developed Tyvek® 40L, an outstanding value proposition for the protection of lightweight, low-risk devices.

Like all other Tyvek® styles for medical and pharmaceutical packaging applications, Tyvek® 40L is flash-spun virgin high-density polyethylene (HDPE), spun on the same assets as those used for the current medical packaging styles. A different bonding process is used to create the unique balance of properties and visuals of this new lightweight product. Tyvek® 40L is slit on assets that are qualified for medical and pharmaceutical packaging styles. Building on well-established Tyvek® technologies, the new product's properties include low-linting, excellent moisture resistance and broad sterilization compatibility. When compared to even reinforced, heavy basis weight papers, Tyvek® 40L shows better strength (tear and puncture) and far superior breathability. Tyvek® 40L also peels cleanly when opening the package, even if it is uncoated and sealed to a peelable film. With its very low basis weight, Tyvek® 40L provides excellent value and packaging source reduction opportunities to support sustainability efforts.

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TYVEK® PORTFOLIO

1. What is Tyvek® 40L?

DuPont is introducing Tyvek® 40L, a new class of Tyvek® for medical packaging applications that provides a cost-effective option for protecting lightweight, low-risk devices as an alternative to high-end medical papers. Tyvek® 40L was unveiled at MEDTEC 2017 in Shanghai, China. Commercial sales of Tyvek® 40L have begun in China and there are plans for global availability in mid-2018. Samples are currently available for evaluation.

Tyvek® 40L features many of the same benefits that have made Tyvek® a standard of excellence for medical packaging since 1972, including:

- maintaining sterility until point of use—even under rigorous conditions;
- low particulate generation;
- clean peel;
- puncture and tear resistance during handling and transportation—even in high humidity; and
- compatibility with most major sterilization methods and excellent performance with ethylene oxide (EO) and gamma radiation sterilization

Tyvek® 40L can be readily distinguished by its embossed, linen-like appearance. Tyvek® 40L provides excellent value and expands the DuPont portfolio in the medical packaging market to serve a broader set of needs.

2. Will Tyvek® 40L replace Tyvek® 2FS™?

Tyvek® 40L was developed to address demand for an alternative option in the most cost-sensitive and low-risk medical devices. It provides a unique balance of properties compared to the other Tyvek® styles for medical packaging and has improved features compared to medical-grade papers. Customers will be able to choose among the Tyvek® styles according to their own company preferences and needs for product protection.

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PRODUCT SPECIFICATIONS

3. What is Mullen Burst?

Mullen Burst on Tyvek® 40L is measured following ISO 2758 Standard "Paper—Determination of bursting strength." Burst strength is a commonly used test for measuring the strength of nonwovens and papers. The test specimen is held between annular clamps and subjected to an increasing pressure from a rubber diaphragm pressed against it by hydraulic pressure. The pressure is increased at a controlled rate until the specimen bursts. The burst strength is the maximum pressure up to the point of the burst.

4. Why isn't delamination a specification property/ miscellaneous property?

Due to the unique bonding technique, a delamination test cannot be conducted on a Tyvek® 40L sample because the sheet cannot be separated.

5. I thought DuPont measures peel performance through Tyvek® delamination. Because you don't measure delamination on Tyvek® 40L, which property will now represent this performance?

The bonded sheet structure—not a delamination value—is what controls peel performance. For our existing medical styles, the delamination specification ensures consistent bonding performance. For Tyvek® 40L, because delamination is "Not Applicable," Mullen Burst was selected to ensure consistent bonding performance.

6. Why are product specifications called preliminary while product is commercially available?

Tyvek® 40L product specifications are called preliminary product specifications because even if they are based on multiple manufacturing production runs, they are not representative of process long-term variability. Final product specifications will be issued mid-2018.

7. Does the higher porosity have an impact on the microbial barrier performance?

With Tyvek® 40L, we achieve higher porosity than many porous medical packaging materials while still maintaining a microbial barrier that is as good as or better than many of the competitive medical papers that have much lower porosities. This is achieved through a unique structure that has a minimum impediment to air flow while having good microbial barrier.

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PROCESSING/PRINTING

8. Does DuPont recommend any inks to be used on Tyvek® 40L?

We recommend contacting our printing experts to discuss your needs and obtain best guidance. Depending on the printing technology, we can help you find the resources to work with (e.g., printing machine manufacturers). Also, DuPont is conducting some printing tests (ink jet, thermal transfer). The outcome of this study can also help you define an appropriate printing solution.

9. Has the printing performance of Tyvek® 40L been evaluated?

DuPont is conducting some printing tests (ink jet, thermal transfer). The outcome of this study can help you define an appropriate printing solution. In the meantime, please consult with your local DuPont representative.

10. It appears there are pinholes in the sheet of Tyvek® 40L when it is held against the light. Are these actual holes?

The visible pattern of Tyvek® 40L, which allows light to be transmitted, are actually areas where the polyethylene (PE) has been bonded and melted into a "solid" PE area that becomes translucent. Although light can be transmitted, these are not holes but a film-like area.

11. Tyvek® 40L is so thin; how do you ensure that printing is not transferring to the other side?

A limited number of printing trials (flexographic printing) at customer locations has shown good printing quality and no ink transfer to the other side of Tyvek® 40L. Each type of ink, as well as applications, must be evaluated. Tyvek® 40L has a different look than the other styles of Tyvek® which results in a certain light see-through of the printed layout. DuPont will continue gathering feedback from customers about printing on Tyvek® 40L.

12. Does the embossing pattern impact the printability of Tyvek® 40L?

Initial printing tests of Tyvek® 40L are suggesting that C grading can be achieved (ISO 15415 and ISO 15416), depending on the printing technology, inks and settings. DuPont will publish more information soon. In the meantime, please consult with your local DuPont representative.

REGULATORY

13. Biocompatibility, toxicological attributes and chemical characterization are only presented pre-sterilized; would we get them post-sterile as well?

Only PRE-sterilization data will be available for your validation.

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PACKAGING PERFORMANCE

14. Where can I find sealing window range for Tyvek® 40L sealed to typical films?

Sealing guidance for flexible blister application is provided in Section 4 of the "Preliminary Technical Documentation and ISO 11607 Compliance" document.

15. What about skirted packages?

Tyvek® should not be sealed all the way to its edge because this could allow adhesive to flow around the edge of the bonded Tyvek® surface and attach to individual filaments. This attachment to individual filaments, as opposed to the bonded Tyvek® surface, could cause fiber tear during peeling.

When forming multiple pouches across the web, tooling should be designed so that an unsealed area of at least 1 mm resides between adjacent pouches, also known as a "skirt." Singularizing pouches across the web should be performed in unsealed areas between pouches.

Tooling for blisters should be designed in a way that an unsealed area or "skirt" of at least 1 mm resides between adjacent trays.

16. What packaging formats has DuPont tested successfully?

Based on numerous preliminary testing with customers, DuPont experienced an excellent performance of Tyvek® 40L in flexible form-fill-seal blister applications. Sterile packaging manufacturers (SPMs) are currently evaluating the performance of Tyvek® 40L in pouch applications.

17. Is there any difference in performing dye penetration test and related performance with Tyvek® 40L compared to other Tyvek® styles?

One should follow the recommendations outlined in ASTM F1929-15. If dye is left too long in the packaging made with Tyvek®, the dye begins to wick through the material. After having introduced the dye, one should immediately observe the seal area for penetration of the dye solution across the seal width. Channels in the seal will be readily detected. One should use 5 seconds per side max as a guide for a 4-sided package (total time less than or equal to 20 seconds). An optical device may help for detailed examination in the case of any doubts.

18. When opening an uncoated package made with Tyvek® 40L post manufacturing for quality evaluation, is there anything different I should expect from a seal visual perspective, especially when inspecting the white mark on the peel film side?

The "white mark," which is visible on the film side when opening a sealed package may look different compared to packages made with other Tyvek® styles for medical and pharmaceutical packaging applications due to the different bonding pattern (linen embossing) on Tyvek® 40L. This "structure" does not influence seal integrity performance but must be considered when establishing seal quality assessment acceptance criteria. Of course, the sealing process must be properly validated and seal integrity must be demonstrated per applicable regulatory requirements.

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19. Which coatings can be used with Tyvek® 40L?

Tyvek® 40L peels cleanly when opening a package when it is coated or uncoated and sealed to a peelable film. Tyvek® 40L is available coated and uncoated, depending on the application. DuPont does not apply any coatings. For guidance on coated product, please contact your supplier or sterile packaging manufacturer (SPM).

20. Which films can be used with Tyvek® 40L?

Sealing guidance for flexible blister applications is provided in Section 4 of the "Preliminary Technical Documentation and ISO 11607 Compliance" document. In this guidance, some typical film types are listed. For additional guidance, please contact your local DuPont representative.

21. What are the typical seal strength values that DuPont observed during package testing?

During Tyvek® 40L development stages, packaging created with the collaboration of selected medical device manufacturers (MDMs) has demonstrated fiber tear free opening for seal strength values up to 1.5 lb_f/in. (in form-fill-seal application with regular thermo-formable peelable films).

Tyvek® 40L is a lightweight, thin and very flexible material. It is in a new class of lightweight materials that behave slightly differently from stiffer materials seen in this industry. When compared to a stiffer material sealed to the same film, it is possible that the "measured" seal strength will be lower for the same sealing protection (seal adhesion), particularly when testing via ASTM F88–Technique A: Unsupported/ Free Tail. With the high flexibility of Tyvek® 40L, it is recommended to consider the ASTM F88 techniques (tail holding methods).

Depending on the selected method, seal strength results can vary. Sealing guidance for flexible blister application is provided in Section 4 of the "Preliminary Technical Documentation and ISO 11607 Compliance" document.

DuPont does not recommend any specific seal strength values because DuPont does not supply packaging. This is the responsibility of the MDM to define seal strength value meeting their sterilization and distribution challenges, as well as allowing aseptic presentation of the devices.

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PRODUCT COMMERCIALIZATION

22. When will Tyvek® 40L be available in my region?

Tyvek® 40L is currently available in Asia. In mid-2018, product will become commercially available in EU and in NA. Samples are available in these regions now. Please contact your local DuPont representative or sterile packaging manufacturer (SPM) for samples.

23. What widths of Tyvek® 40L are available in my region?

Available widths for Asia: 420 mm, 620 mm, 860 mm, 1010 mm and 1524 mm. Please contact your local DuPont representative for product availability in your region.

24. Tyvek® 40L will be available globally in mid-2018. Why is the global availability planned so much later?

New Tyvek® 40L was first launched in Asia because it was specifically designed for that market. DuPont will be ramping up the commercial production to offer this new product in EU and NA. Currently, product samples are available in all regions for trials. We are excited to see the global interest in this new offering. Tyvek® 40L will broaden the existing Tyvek® portfolio to address packaging needs for lightweight, price-competitive medical devices.

25. How can I access a sample of Tyvek® 40L?

Tyvek® 40L is available through authorized Tyvek® suppliers and their customers. Please contact your SPM or local DuPont representative for additional guidance.

STERILIZATION

26. Can STERRAD®, VHP or similar sterilization be used for Tyvek® 40L?

DuPont has not demonstrated the compatibility of Tyvek® 40L with low-temperature oxidative plasma sterilization methods like STERRAD® or VHP, but only with the most common sterilization methods (EO, electron beam, gamma) used with low-risk, lightweight devices. Medical device manufacturers (MDMs) are responsible to assess and validate their own sterilization cycles and to check the compatibility of their device and packaging with their selected sterilization.

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LINEN EMBOSSING

27. How do I recognize the smooth side and the rough side?

The smooth side of Tyvek® 40L is the flat side of the sheet while the rough side is the linen embossed side.

28. Can we use the linen embossing pattern to recognize the machine direction (MD)/cross direction (CD) of Tyvek® 40L?

Yes. Although not "obvious" to a casual observer, the embossing pattern is not symmetrical in the MD and CD direction.