



Quality Your Products Depend On

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September 24, 2014

To our valued customer:

As DuPont has announced in June 2011, DuPont™ will be transitioning Tyvek® 1073B and Tyvek® 1059B to newer production lines that utilize their latest flash-spinning technology. Please visit www.transition.tyvek.com for additional information and updates concerning the transition.

As your packaging supplier, Technipaq is writing to update you on the progress of the pending change to the 1073B and 1059B grades of DuPont Tyvek®. Please carefully review the following points below.

- DuPont's transition project is a very comprehensive, systematic approach that will take several years to complete. DuPont has scheduled the transition protocol timeline in an 8 phase plan (the first 4 of which are already complete). The US FDA Transition Protocol will officially conclude in 2018.
- Commercial launch of Tyvek® 1073B and Tyvek® 1059B from the new lines is targeted to occur in late 2015. At that time, the Transition Protocol material will become interchangeable with current Tyvek®. DuPont will formally issue a change notification letter to Technipaq at least 180 days prior to commercially introducing Tyvek® 1073B and Tyvek® 1059B produced on the newer lines. Technipaq will notify our customers upon receipt of this communication.
- DuPont's Medical Packaging Transition Project ("MPTP") is intended to prove that the Tyvek® produced with the latest flash-spinning technology is functionally equivalent in performance to the Tyvek® you use today.
- For more detailed information about DuPont's testing plan, progress and recommendations and guidance, please visit DuPont's website at http://www2.dupont.com/Medical_Packaging/en_US/news_events/mptp_data_documents.html.
- DuPont has allowed Technipaq to acquire Tyvek® 1073B and Tyvek® 1059B produced on the newer lines (control sales material) via a controlled sales program. Therefore, Technipaq has the control sales material available for sample orders.
 - We recommend that you begin your internal testing as determined by your risk assessments and discuss your plan and forecasted needs with us as soon as possible. We further encourage you to submit orders for the control sales material if you need to conduct internal risk assessments, including validating material for new or existing device packaging and/or need to perform additional testing.
 - If you are interested in having Technipaq run trials of the controlled sales material, or if you would like Technipaq to perform validation runs on your existing product using the new material, please contact us for a quote.
 - If you are planning to introduce a new product that requires full validation in the near future, you may want to consider validating based on the new material.
- Technipaq has completed pre-sterilization qualifications that will serve as a supplement to the qualifications already included in DuPont's Transition Protocol and Phantom Protocol. These qualification reports are now available upon request for uncoated Tyvek® 1073B and Tyvek® 1059B transition material.
- As stated above, Technipaq is currently accepting orders from its customer for the controlled sales Tyvek®. This material is only to be used for testing and/or for qualification purposes for new product development activities and is not intended for packaging of existing commercial devices until applicable regulations in the country of sale are met.

ARE YOU READY? Visit WWW.TRANSITION.TYVEK.COM for the latest information and updates concerning the transition.

Sincerely,

David J Turner

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