

May 22, 2017



Open letter to Medical Device Industry

Subject: Tyvek® Medical Packaging Transition Project (MPTP) – Global Supply Update

Along with our sterile packaging manufacturers and industry partners we have together helped medical device companies around the world prove functional equivalence of Legacy and Transition Tyvek® in their applications. We especially appreciate the many companies who have worked to ensure success of this important project around the globe.

We have determined that retaining flexibility to supply both Transition and Legacy Tyvek® 1059B and 1073B styles into the medical market is necessary in 2017 and 2018. Most 1073B and 1059B Tyvek® purchased outside of North America from DuPont is supplied as Transition Tyvek®. In North America, we will continue to fill orders to converters with a combination of Transition and Legacy Tyvek® to ensure the market volume needs.

While most device companies have tested and/or accepted the use of Transition Tyvek® and confirmed that it is interchangeable with Legacy Tyvek®, some have not. If you have qualified new devices or validated new processes or equipment only using Transition Tyvek® and would like to be able to accept Legacy Tyvek®, please review your change control procedures and evaluate the impact of this change on packaging and sterilization according to the Quality System Regulation and ISO 13485. For additional information or to consult with our technical and regulatory team, please contact your DuPont representative.

We will conduct a further webinar providing the most up to date information from our MPTP project including a review of the latest Technical Reference Guide and an update on the status of Legacy Tyvek® to the medical device industry in July. We recommend that you direct all inquiries related to supply strategies to your sterile packaging manufacturer who each have their own inventory management system.

Thank you for your continued support of our MPTP program. Our goal is to ensure supply to best meet the needs of the medical device industry.

Regards,

A handwritten signature in blue ink that reads "Margaret Pyers". The signature is written in a cursive, flowing style.

Margaret Pyers
Global Marketing Manager, Medical & Pharmaceutical Protection
DuPont Protection Solutions