FOR IMMEDIATE RELEASE

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Subject: Tyvek® Medical Packaging Transition Project

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. You may already have participated in one of the webinars DuPont hosted in June 2011 or/and attended the meetings held by DuPont™ in various cities throughout the world. If you were unable to participate in one of the webinars or meetings hosted by DuPont™, please visit **www.medicalpackaging.dupont.com** for additional information and updates concerning the transition. We are also enclosing for your information the follow-up letter received by Technipaq, Inc. from DuPont™ Medical Packaging.

As your packaging supplier, Technipaq is writing to formally notify you of the pending change to the 1073B and 1059B grades of DuPont Tyvek®. Please carefully review the following points detailed in the enclosed DuPont letter.

- 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 a 7 phase plan; the transition protocol will officially conclude in 2018 including launch of Tyvek® 1073B and Tyvek® 1059B from the new lines in 2014.
- DuPont's Transition Protocol is intended to prove that the Tyvek® produced with the latest flash-spinning technology is functionally equivalent in performance to the Tvyek® you use today.
- DuPont's testing plan of proving the performance for ETO, gamma and electron beam radiation has been reviewed and accepted by the CDRH (Center for Devices and Radiological Health) within the U.S. FDA.

- Contingent upon approval of DuPont's analysis and conclusions, CDRH would then issue guidance indicating that medical device manufacturers would not be required to file amended 510(k)s or PMAs for existing devices because the transition represents a merge, or lot change. Healthcare products regulated by the CDER (Center for Drug Evaluation and Research) and CBER (Centers for Biologics Evaluation and Research) are not within the scope of DuPont's Transition Protocol.
- DuPont will allow Technipaq to acquire Tyvek® 1073B and Tyvek® 1059B produced on the newer lines as early as 2013 via controlled sales for use in testing and qualification purposes for new product development activities only.
- 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.

Please visit **www.medicalpackaging.dupont.com** for additional information and updates concerning the transition. This information may also be accessed via link from **www.technipaq.com**.

DuPont Protection Technologies
Chestnut Run Plaza, Bldg. 728
4417 Lancaster Pike
Wilmington, DE 19805

DuPont Medical Packaging

March 27, 2012

Mr. Brian Rosenburg
Technipaq, Inc.
975 Lutter Drove
Crystal Lake, IL 60014

Dear Brian:

As we announced in June, DuPont will be transitioning Tyvek® 1073B and Tyvek® 1059B to manufacturing lines that use our latest flash-spinning technology to meet growing future demand. Additionally this will help ensure the continuity and flexibility of future supply by enabling production of these products in both our Richmond and Luxembourg manufacturing facilities using multiple polymer sources.

Realizing this change creates uncertainty for you and your customers, we have developed the *Transition Protocol*. This is a plan developed to transition Tyvek® 1073B and Tyvek® 1059B from the current to the latest flash-spinning technology and equipment. Based on sound principles of design and statistical analysis, the transition protocol is a systematic method for generating data to prove that the Tyvek® produced with the latest flash-spinning technology is functionally equivalent in performance to the Tyvek® you use today. This plan has been reviewed and accepted by the Center for Devices and Radiological Health (CDRH) within the U.S. FDA. It is important to note that this plan only covers devices regulated by CDRH and is limited to sterilization by ethylene oxide, gamma and electron beam radiation. We are currently working with regulatory bodies in Europe, China and Japan to offer guidance on the role of the *Transition Protocol* in these regulatory environments.

You will be able to obtain Tyvek® 1073B and Tyvek® 1059B produced on the newer lines in two ways. The first is by participating in the *Transition Protocol* testing matrix; we will supply your company with an adequate quantity of Tyvek® for you to manufacture the necessary sterile barrier systems for your Protocol partners. The second is by purchasing Tyvek® 1073B and Tyvek® 1059B through controlled sales (expected 2013).

There are several very important issues that must be considered concerning Tyvek® purchased under controlled sales. These are:

1. These materials will require evaluation and/or testing according to your company's and your customer's change control processes as well as the applicable regulations that apply based upon the point of sale of the device. This must be done prior to use in commercial medical devices for sale in the US until CDRH issues their letter of functional equivalency.

2. When CDRH issues their letter of functional equivalency, Tyvek® 1073B and Tyvek® 1059B produced on the newer lines can be used after documenting the change in each applicable device record, but without amending the respective 510 (k)s or PMAs. More information regarding the process to follow in other regions will be made available as soon as possible.

3. Medical products regulated by the Center for Drug Evaluation and Research (CDER) and the Centers for Biologics Evaluation and Research (CBER) are not within the scope of the protocol and will require evaluation and/or testing according to each company's change control process.

DuPont will formally issue a change notification letter to your company at least 180 days prior to commercially introducing Tyvek® 1073B and Tyvek® 1059B produced on the newer lines as replacements for material produced currently, if we have an executed change notification agreement in place with your company at that time.

You may have change notification agreements in place with your customers that have longer than 180 day notice requirements. You may attach this letter to your notification if desired.

Please visit our website www.medicalpackaging.dupont.com for additional information and updates concerning the transition or contact your account manager.

Sincerely,

Michael H. Scholla, Ph.D.
Global Director, Regulatory and Standards
DuPont Medical and Pharmaceutical Protection

cc: Pamela Langston-Vaughn
DuPont Protection Technologies
Wilmington, DE 19805