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This document is not intended for use in the People’s Republic of China.
This Technical Reference Guide is applicable to DuPont™ Transition Tyvek® 1073B and Transition Tyvek® 1059B, as well as Tyvek® 2FS™. In some cases, information based on data that was generated on Legacy Tyvek® is presented. In those cases, this distinction is clearly indicated. Transition Tyvek® has been proven to be functionally equivalent to Legacy Tyvek®. Legacy Tyvek® is either Tyvek® 1073B or Tyvek® 1059B produced on the original manufacturing lines. Transition Tyvek® is either Tyvek® 1073B or Tyvek® 1059B produced on the newer manufacturing lines.

NOTE: There is a tremendous amount of data and information referenced in this document that can be viewed and downloaded by clicking on the supplied links. Therefore, it is important to use this document while on a computer with access to the internet.
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Why is DuPont™ Tyvek® the preferred choice for sterile barrier systems?

**DuPont™ Tyvek® for medical and pharmaceutical packaging delivers trusted protection**

Since its introduction to the industry in 1972, Tyvek® brand protective material has been recognized as a standard of excellence for sterile medical packaging. Tyvek® earned this distinction because it provides a high degree of microbial barrier in combination with excellent porosity and puncture protection for sterile packaging of medical devices and supplies.

**Helping speed up your compliance process**

In this guide you will find extensive compliance data established by our network of regulatory affairs and technical experts to help you develop, validate and document the most appropriate solutions for your applications with Tyvek®. This will help you to meet worldwide regulations and packaging standards, while accelerating your product regulatory submissions and certifications.

A separate document, MPTP Styles 1073B and 1059B Compliance to EN ISO 11607, describes the compliance of Transition Tyvek® 1073B and Transition Tyvek® 1059B with the materials portion of the EN ISO 11607-1 standard.


**Providing packaging science support**

DuPont Packaging Engineers are available globally to support you with knowledge about materials, packaging design and processing to help optimize performance and total cost, as well as to ease implementation.

**LEARN MORE ABOUT THE SCIENCE OF PROTECTION WITH DUPONT™ TYVEK®**

The unique flashspun structure of Tyvek® gives it inherent advantages, including:

**Outstanding resistance to microbial penetration**

Microbial barrier test data consistently prove that Tyvek® holds out microbes and particles better than other porous packaging materials—even under the most rigorous conditions. Aging studies have proven that Tyvek® can maintain its properties for at least seven to 10 years. In addition, a long-term shelf-life study proved conclusively that Tyvek® can maintain sterility for at least five years if package integrity is not compromised. The photomicrographs shown in Figure 1 illustrate how bacteria are trapped on the filament surfaces of Tyvek®.

**Significantly reduced risk of package failure**

The tough, continuous filaments of Tyvek® help protect package integrity from both product breakthrough inside and rough handling outside. Tyvek® is so tough, it resists punctures—even from the irregular or sharp edges of many surgical devices. Compared to medical-grade papers, Tyvek® has superior tear strength and puncture resistance.

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**Figure 1. Scanning electron micrographs (SEMs) of DuPont™ Tyvek®.**

The unique structure of Tyvek®, which creates a tortuous path with substantial lateral movement, results in superior microbial barrier protection.
Why is DuPont™ Tyvek® the preferred choice for sterile barrier systems?

What’s more, because it is breathable, Tyvek® minimizes the formation of condensation due to temperature extremes that can occur during transport. This breathability also allows medical packages made with Tyvek® to equilibrate rapidly from the pressure changes that occur not only during shipping and in storage environments, but also during sterilization. This helps alleviate stress on the seals.

**Low risk of device contamination**

The unique structure of Tyvek® generates very few airborne particles when packages are opened or handled. This clean peel minimizes the risk of introducing particulates into highly controlled environments such as operating rooms, cleanrooms and aseptic filling processes, helping to address increasingly stringent industry and regulatory requirements.

**Biocompatibility, food contact and pharmacopeia**

Tyvek® styles for medical and pharmaceutical packaging applications are manufactured to rigorous quality standards to meet the unique requirements of these highly regulated industries. They meet all the acceptable performance criteria for biocompatibility—even after sterilization—when tested according to ISO 10993 and United States Pharmacopeia (USP). In addition, all styles meet the extractable or composition requirements of various food contact regulations, such as 21 CFR 177.1520 and Commission Regulation (EU) No 10/2011; and all styles other than Tyvek® 2FS™ meet the requirements of pharmacopeia regulations such as European Pharmacopeia, Section 3.1.5. For the applicable revision dates of the different test standards, please refer to Section 3, “Biocompatibility, food contact, pharmacopeia and bioburden.”

**Compatibility with a broad range of sterilization modalities**

Only Tyvek® is compatible with the most commonly used sterilization modalities: ethylene oxide (EO), gamma, electron-beam, steam or dry heat (under controlled conditions) or low-temperature oxidative sterilization processes. Results from testing of Tyvek® exposed to each of these modalities show it retained its protective properties of microbial barrier and strength, as well as its color and flexibility.

**Helps you meet your environmental goals**

As for ecological responsibility, Tyvek® is an excellent choice because it is made of virgin high-density polyethylene (HDPE). This lightweight, durable material is an effective way to conserve resources and demonstrate environmental stewardship. Tyvek® is produced under verified environmental management policy according to ISO 14001.

If the Tyvek® has not been in contact with any hazardous substance, it can be recycled at local recycling facilities that accept HDPE waste according to local legislation.

DuPont and other leading companies in the healthcare, recycling and waste management industries have come together to form the Healthcare Plastics Recycling Council (HPRC). The technical coalition is working to inspire and enable sustainable, cost-effective recycling solutions for plastic products and materials used in the delivery of healthcare. For more information, visit the HPRC website.

**TYVEK®—ORIGINS AND HOW IT IS MADE**

**A miracle of science from DuPont**

The discovery of Tyvek® was a chance occurrence by a DuPont researcher, Jim White, who in 1955 noticed white polyethylene fluff coming out of a pipe in a DuPont experimental lab. After examining this material, it was found that it had some very interesting properties. A program to develop the new material was set up, and a year later DuPont submitted a patent proposal for strong yarn linear polyethylene.

The proprietary flash-spinning technology, which is the basis for what was to become a new engineered sheet structure from DuPont, took several more years to perfect. In 1959, a pilot facility was established for trial applications such as book covers, tags, labels and certain garments. In 1965, the new engineered sheet structure was registered under the trademark name Tyvek®, but it was not until April 1967 that commercial production of Tyvek® started. In 1972, the first styles of Tyvek® designed for use in medical and pharmaceutical packaging applications were developed.

**Flash-spinning and bonding process**

Tyvek® is formed by a fully integrated process using continuous and very fine filaments (having an average diameter of 4 μ) of HDPE that are randomly distributed and multi-directional. (For purposes of comparison, a human hair is approximately 75 μ in cross section.) These filaments are first flashspun, then laid as a web on a moving belt before being bonded together. By varying the flash-spinning and bonding process conditions, DuPont can engineer the sheet properties to meet specific market needs.

Tyvek® for medical and pharmaceutical packaging applications is neither corona treated nor anti-static treated because these treatments may compromise the barrier characteristics of Tyvek®. The styles of Tyvek® designed for use in medical and pharmaceutical packaging applications are: Tyvek® 1073B, Tyvek® 1059B and Tyvek® 2FS™. These styles are manufactured to rigorous quality standards to address the
Why is DuPont™ Tyvek® the preferred choice for sterile barrier systems?

unique requirements for medical and pharmaceutical packaging applications, according to good manufacturing practices (Commission Regulation [EU] № 2023/2006).

**Dual sourcing**

Transition Tyvek® 1073B and Transition Tyvek® 1059B are manufactured in two different locations—Richmond, VA in the United States and in Luxembourg in Europe. This provides greater long-term continuity and flexibility of Tyvek® supply. Tyvek® 2FS™ is produced in Luxembourg. Legacy Tyvek® 1073B and Legacy Tyvek® 1059B are produced in Richmond, VA.

**AT THE FOREFRONT OF TECHNOLOGICAL AND REGULATORY DEVELOPMENT**

An industry and technology leader

As leaders in the industry, we are dedicated to sharing information and expertise on topics ranging from industry standards and regulatory compliance to technical issues and quality. We develop and participate in conferences to help the industry stay at the forefront of standards, regulations and new technologies. In addition, members of our team regularly participate on activities within:

- ASTM International
- International Organization for Standardization (ISO)
- European Committee for Standardization (CEN)
- Association for the Advancement of Medical Instrumentation (AAMI)
- Standardization Administration of the People’s Republic of China (SAC)
- Japanese Standards Association (JSA)
- Sterile Barrier Association (SBA)
- Parenteral Drug Association (PDA)
- Healthcare Plastics Recycling Council (HPRC)

**Contact our experts**

If you have questions or need additional support with submission challenges, troubleshooting, analytical services, as well as packaging and regulatory compliance, contact your local DuPont representative.
Why is DuPont™ Tyvek® the preferred choice for sterile barrier systems?

STERILE BARRIER SYSTEMS (SBS) MADE OF DUPONT™ TYVEK®

Packaging for terminally sterilized medical devices, also defined as sterile barrier system (SBS) in ISO 11607, serves different key functions. The first is to allow for sterilization. The second is to maintain sterility and package integrity throughout all steps of the value chain until the point of use by providing an appropriate microbial barrier, as well as physical protection against damage, while not interacting with the packaged devices. At the healthcare setting, medical professionals should be able to open the SBS smoothly while ensuring an aseptic presentation of the packaged product. Identification of the product must be printed on either the package or on a label.

The following porous SBS can be made with Tyvek® to optimally serve all the functions previously described:
- Pouches (peelable): Top web Tyvek®; bottom web film
- Sterilization bags (non-peelable, therefore transparent seals can be created): Top web Tyvek®; bottom web film
- Header bags/vented bags: Film or aluminum-based bag with Tyvek® window or vent
- Flexible or rigid trays—Form-Fill-Seal (FFS): Top web Tyvek®; bottom web film
- Rigid trays—preformed from film: Top web Tyvek®; bottom web film
- Nested tubs: Top web Tyvek®; inner layer sheet Tyvek®; bottom web film (the entire system is then packed in one to three pouches or header bags)
- Others (four-side-seal pouches; gusseted pouches; pouch reels; flow packs; etc.)

Figure 2. Pouches made with DuPont™ Tyvek®.

Figure 3. Sterilization bag made with DuPont™ Tyvek®.

Figure 4. Header bag made with DuPont™ Tyvek®.

Figure 5. Flexible and rigid trays made with DuPont™ Tyvek®.

Figure 6. Nested tub made with DuPont™ Tyvek®.
Why is DuPont™ Tyvek® the preferred choice for sterile barrier systems?

**DUPONT™ TYVEK® VS. MEDICAL-GRADE PAPERS: A COMPARISON OF PROPERTIES**

Tyvek® offers an optimum balance of microbial penetration resistance, tear strength, puncture resistance and low linting features (for clean peel and low particulate), as well as compatibility with the most commonly used sterilization modalities, including: EO, gamma, electron-beam, steam or dry heat (under controlled conditions) and low-temperature oxidative sterilization processes.

The secret to the superior performance of Tyvek® is that it is not made of cellulosic fibers, but rather a sheet of flashspun and bonded HDPE filaments. Continuous strands of very fine, interconnected filaments are multi-directionally oriented and bonded together by heat and pressure during manufacture. The result is a tough, durable sheet structure that provides a unique combination of physical properties that no other sterile packaging material can match.

Tyvek® has become a standard of excellence against which other sterile packaging materials are judged. When tested against other porous packaging materials, data from Tyvek® shows it consistently performs excellently in tests for microbial barrier; tear; puncture and burst strength; resistance to breakage; liquid resistance; EO desorbance; and particle generation.

Figure 7 provides an overview showing various physical properties of Tyvek® compared to medical-grade papers.

**Figure 7. DuPont™ Tyvek® vs. medical-grade papers: a comparison of properties—microbial barrier (ASTM F2638), Mullen burst (ISO 2758), Elmendorf tear (ASTM 1424 and EN 21974), elongation (EN ISO 1924-2) and hydrostatic head (AATCC TM 127 and EN 20811).**

Due to the smaller sampling populations used for these material comparisons, the Tyvek® data presented in this section may differ slightly from the specification and miscellaneous properties tables.
Why is DuPont™ Tyvek® the preferred choice for sterile barrier systems?

Excellent barrier to microbial penetration

The number-one priority in selecting packaging materials for medical devices is the ability of the package to maintain sterility from the point of sterilization until the product is opened for use. Even under the most rigorous conditions in highly contaminated environments, Tyvek® is highly resistant to penetration by bacterial spores and other contaminating microorganisms.

Particulate and bacteriological tests clearly demonstrate that Tyvek® outperforms other commercially available porous packaging materials, including medical-grade papers (Figure 8). Aging studies have proven that Tyvek® can maintain its properties for at least seven to 10 years. In addition, a long-term shelf-life study proved conclusively that Tyvek® can maintain sterility for at least five years if package integrity is not compromised. See Section 5, “Stability Testing” for details.

ASTM F2638 Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier measures the ability of a porous substrate to prevent particle penetration. All materials have a face velocity where maximum percent particle penetration occurs (% pMax). The lower the percent penetration, the better the performance.

ASTM F2638 testing of Tyvek® 1073B, Tyvek® 1059B and Tyvek® 2FS™ demonstrates that these Tyvek® medical and pharmaceutical packaging styles all have a pMax around 0.5%.

The pMax of the other tested porous sterile barrier materials ranges from approximately 4.0% to 14.0%.

Tyvek® is exceptional at maintaining microbial barrier throughout product distribution. A study compared Legacy Tyvek® 1073B and Tyvek® 2FS™ to four different medical-grade papers in standard chevron pouches. Microbial barrier testing was conducted according to ASTM F2638, before and after sterilization (EO, gamma) and subsequent transportation testing.

The study showed that three of the four types of medical-grade paper showed a significant decrease in microbial barrier performance after gamma sterilization and after environmental conditioning and transportation testing compared to pre-sterilization. This decrease in microbial barrier performance was mainly linked to creases and punctures in the material. The same three medical-grade paper types had the poorest microbial barrier performance overall, including pre-sterilization. Legacy Tyvek® 1073B and Tyvek® 2FS™ showed the best barrier performance overall compared to the four medical-grade paper types.

Details are contained in the white paper titled “Medical Packaging Study—The Impact of Sterilization and Transportation Testing on the Microbial Barrier of Different Materials.”

Figure 8. Particle penetration of porous sterile barrier materials (ASTM F2638—in % pMax with a particle size of 1 µm, face velocity max 25 cm/min or flow max 1.5 or 2 L/min).

ASTM F2638, Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier, measures the ability of a porous substrate to prevent particle penetration, which is highly correlated to microbiological spore penetration. All materials have a face velocity where maximum percent particle penetration occurs (% pMax). The lower the percent penetration, the better the performance. For more information, see “Microbial Barrier Properties of Porous Sterile Barrier Systems: Does Selection of Packaging Material Matter?” in our Medical Packaging Knowledge Center.
Superior tear strength, puncture resistance and burst strength

The tough, continuous filaments of Tyvek® protect your package from product breakthrough (Figure 9) and also from penetration by an object outside the packaging during rough handling. Compared to many commonly used medical-grade papers, Tyvek® provides superior puncture resistance and tear strength, which means that Tyvek® does not puncture easily and tears do not readily propagate if a package is nicked (Figure 10).

**Figure 9.** Mullen burst properties of DuPont™ Tyvek® styles and medical-grade papers (ISO 2758—in psi).

This test measures the ability of a substrate to resist forces applied uniformly throughout the substrate. This property indicates how a material may perform in environments where pressure changes take place and the package balloons or where a force is applied over a relatively large area, such as when a heavy object is placed on top of a lidded tray.

**Figure 10.** Elmendorf tear (MD) properties of DuPont™ Tyvek® styles and medical-grade papers (ASTM D1424 and EN 21974—in lbf).

MD = machine direction

This test measures the ability of a substrate to resist tearing when a highly localized force is applied. Elmendorf tear measures the force required to propagate an initiated tear for a unit distance. The unit is lb. The higher the value, the less likely a material will tear under force. This property is important because nicks and cuts may occur at the edge of a lid and could affect its clean peel. The tear strength of Tyvek® is significantly higher than that of medical-grade paper.
Why is DuPont™ Tyvek® the preferred choice for sterile barrier systems?

**Exceptional flexibility to prevent breakage**

Tyvek® is an extremely flexible packaging material that will not break or tear as easily as commonly used medical-grade papers (Figure 11). This resiliency, combined with the inherent strength of Tyvek®, offers the opportunity for form-fill-seal packaging lines to run smoothly and without significant downtime due to material web breaks, and helps packages resist damage during handling, distribution and storage.

To demonstrate that Tyvek® can withstand very high environmental challenges, DuPont conducted an extensive performance testing study to evaluate the performance of standard chevron pouches made with either Legacy Tyvek® 1073B, Tyvek® 2FS™ or one of five different medical-grade papers. Seal strength and package integrity were measured after sterilization (EO, gamma), after accelerated aging and after conditioning and subsequent transportation testing.

The study showed that none of the pouches made with Legacy Tyvek® 1073B or Tyvek® 2FS™ showed loss of integrity after transportation testing. On the other hand, loss of integrity was reported for three of the five types of medical-grade paper that were evaluated in this study. The integrity failures, which were observed after gamma sterilization, were all linked to punctures and/or creases in the paper.

Complete details about the scope of the study and the materials tested can be found in the white paper titled “Medical Packaging Study—Reducing the Risk of Failure through Performance Testing of Packaging Made from Various Materials.”

**Outstanding moisture resistance and moisture vapor transmission**

Tyvek® has outstanding moisture resistance, unlike medical-grade paper. In fact, water in contact with Tyvek® does not wet its surface or spread; it simply remains as droplets on the surface. That’s because Tyvek® is hydrophobic and does not absorb moisture, giving it distinct advantages compared to medical-grade paper (Figure 12).

For example, when medical-grade paper absorbs moisture, its strength and puncture resistance are reduced. This can greatly influence package performance, especially during distribution. In sharp contrast to medical-grade paper, Tyvek® maintains its superior strength both wet and dry, and it does not swell.

In addition to its outstanding moisture resistance, another advantage of Tyvek® is that a high moisture vapor transmission rate (MVTR) can be achieved. This is particularly important for the EO sterilization process where water is introduced as a vapor because moisture enhances the effectiveness of EO as a sterilant. Likewise, high MVTR is also essential for effective and productive steam sterilization processes.

Occasionally, medical device and pharmaceutical packages are subjected to adverse conditions that allow them to get wet, such as rain on a loading dock or flooding. When this occurs, the time of exposure and severity are not typically known. Because most device manufacturers label their packages as “sterile unless opened or damaged,” we believe water exposure under these types of scenarios would constitute damage.

---

**Figure 11. Elongation (MD) properties of DuPont™ Tyvek® styles and medical-grade papers (EN ISO 1924-2—in % with a modified speed, sample width and gauge length). MD = machine direction**

Elongation is the measure of the extent a substrate will stretch before it breaks. The higher the value, the more a package will stretch before it breaks.
Why is DuPont™ Tyvek® the preferred choice for sterile barrier systems?

Figure 12. Hydrostatic head properties of DuPont™ Tyvek® styles and medical-grade papers (AATCC TM 127 and EN 20811—in in. H₂O with a rate of use of 24 in. H₂O/min). Hydrohead values may differ slightly after hydrogen peroxide gas plasma sterilization; for more details, see Section 4. “Sterilization Compatibility.”

Hydrostatic head is the measure of the pressure required to force three drops of water through a substrate. The higher the value, the more resistant the package is to water penetration.
Why is DuPont™ Tyvek® the preferred choice for sterile barrier systems?

Compatibility with a broad range of sterilization modalities

Only Tyvek® is compatible with the most commonly used sterilization modalities. No matter which method you use: EO, gamma, electron-beam, steam or dry heat (under controlled conditions) or low-temperature oxidative sterilization, Tyvek® will retain its protective properties of microbial barrier and strength, as well as its color and flexibility. Low-temperature oxidative sterilization processes, such as hydrogen peroxide gas plasma, cannot be used with cellulosic materials such as medical-grade paper.

In addition, medical-grade papers may change color when sterilized with gamma radiation; however, Tyvek® will not. DuPont performed an extensive study to evaluate the performance of standard chevron pouches made with either Legacy Tyvek® 1073B, Tyvek® 2FS® or one of five different medical-grade papers. Tyvek® remained unchanged, while all five medical-grade paper pouches showed some visible color change post gamma sterilization.

To learn more, download the white paper titled “Medical Packaging Study—Reducing the Risk of Failure through Performance Testing of Packaging Made from Various Materials.”

Rapid EO desorption*

EO does not readily adsorb on Tyvek® and is released more rapidly than from cellulosic materials such as medical-grade papers, including synthetic fiber-reinforced paper (Figure 13).

Figure 13. Ethylene oxide (EO) residual concentration in porous sterile barrier materials after sterilization and aeration for 6, 12, 24 and 48 hours. The residual analysis was conducted according to ISO 10993-7.

*Based on data generated on Legacy Tyvek®. Transition Tyvek® has been proven to be functionally equivalent. Legacy Tyvek® is either Tyvek® 1073B or Tyvek® 1059B produced on the original manufacturing lines. Transition Tyvek® is either Tyvek® 1073B or Tyvek® 1059B produced on the newer manufacturing lines.
Why is DuPont™ Tyvek® the preferred choice for sterile barrier systems?

**Low linting**

Unlike medical-grade paper, which can release a significant number of particulates when a package is opened, the unique continuous filament structure of Tyvek® results in clean peel and low lint features that help minimize the risk of device contamination when packages are opened or handled. Therefore, Tyvek® is also an excellent choice as a sterile packaging material for use in very sensitive processing environments, such as aseptic filling operations in pharmaceutical applications.

Tests were conducted to measure the quantity and size of particles generated by Tyvek® and medical-grade papers after twisting and compression of the material. A standard test method for determining lint and other particles generated in the dry state (Gelbo Flex) was used. The method was designed to comply with the intent of ISO 9073-10.

The material samples were subjected to a combined twisting and compression action in a test chamber. During the flexing, air was withdrawn from the chamber and the particles generated were enumerated and sized using a laser particle counter. Both sides of each material were tested and the average number of particles per size was reported.

Data showed that the Tyvek® samples generated fewer particles than the medical-grade papers across the entire size range, from 0.3 µm to 25.0 µm (Figure 14). The medical-grade papers tested in this study generated up to 180,000 particles while Tyvek® generated less than 50. This study shows that Tyvek® generates significantly fewer airborne particulates that could contaminate either the medical device or the sterile field.

![Number of Particles](image)

**Figure 14.** Particles generated by Transition Tyvek® 1073B, Transition Tyvek® 1059B and two commonly used medical-grade papers (Gelbo Flex testing method, ISO 9073-10).
**DuPont™ Tyvek®—Properties**

The unique structure of DuPont™ Tyvek®—tough, continuous filaments—creates both a tortuous path for superior microbial barrier and excellent strength properties. Made of high-density polyethylene (HDPE), Tyvek® offers the best characteristics for packaging in one material. This unique balance of properties, which cannot be found in any other material, makes Tyvek® lightweight yet strong; vapor-permeable and yet moisture-resistant; as well as puncture-, tear- and abrasion-resistant. Tyvek® is also low-linting, smooth and opaque with a white surface that can be printed using standard commercial printing equipment.

**SPECIFICATION AND MISCELLANEOUS PROPERTIES OF TYVEK®**

Specification properties of Tyvek® styles for medical and pharmaceutical packaging applications can be found at the following links.

- Specification Properties of Transition Tyvek® 1073B and 1059B
- Specification Properties of Tyvek® 2FS™

Miscellaneous properties of Tyvek® styles for medical and pharmaceutical packaging applications can be found at the following links.

- Miscellaneous Properties of Transition Tyvek® 1073B and 1059B
- Miscellaneous Properties of Tyvek® 2FS™

It is important to note that these specification and miscellaneous properties are for uncoated Tyvek® as sold by DuPont. Any downstream operations, such as coatings applied by sterile packaging manufacturers (SPMs), may change these values. A description of the test methods used for these specification and miscellaneous properties can be found in "Aligned Test Methods and Sampling Plans for DuPont™ Tyvek® Medical and Pharmaceutical Packaging Styles."

**Specification vs. miscellaneous properties**

Specification properties are based on roll averages, with samples taken uniformly across the sheet. Specification properties are controlled to a nominal value and released within release specifications. The values for miscellaneous properties are typical but carry no warranty, expressed or implied. For medical and pharmaceutical packaging, specification properties are basis weight, Gurley Hill porosity and delamination.

Miscellaneous properties are the result of keeping the three specification properties on aim. Sampling plans for both specification properties and for miscellaneous properties are described in "Aligned Test Methods and Sampling Plans for DuPont™ Tyvek® Medical and Pharmaceutical Packaging Styles."
DIFFERENTIAL SCANNING CALORIMETRY (DSC) AND INFRARED SPECTRUM “FINGERPRINTING” VIA ATR-FTIR

Tyvek® is made of virgin high-density polyethylene (HDPE) with its typical characteristics. DuPont generated differential scanning calorimetry (DSC), as well as infrared spectrum curves as a reference.

Figure 15. DSC curves for Transition Tyvek® 1073B and Transition Tyvek® 1059B Individual DSC plots—offset for clarity.
Note: Slight differences in crystallinity are consistent with normal DSC sampling and lot-to-lot variability.

Figure 16. DSC curves for DuPont™ Tyvek® 2FS™.
Note: Slight differences in crystallinity are consistent with normal DSC sampling and lot-to-lot variability.
Figure 17. IR curves for Transition Tyvek® 1073B and Transition Tyvek® 1059B (including all line/polymer combinations). Sheet samples analyzed using Attenuated Total Reflectance (ATR)–Fourier Transform Infrared Spectroscopy (FTIR).

Figure 18. IR curves for DuPont™ Tyvek® 2FS™. Sheet samples analyzed using Attenuated Total Reflectance (ATR)–Fourier Transform Infrared Spectroscopy (FTIR).
TYVEK® TEMPERATURE RESISTANCE

To demonstrate the temperature stability of Tyvek®, DuPont performed an extensive dimensional stability study on Transition Tyvek® 1073B and Transition Tyvek® 1059B. Each material passed through the following steps:

- steam (261°F, 30 minute exposure, 30 minute drying)
- freeze (-112°F, minimum 24 hours)
- thaw (minimum 24 hours)
- freeze (-112°F, minimum 24 hours)
- thaw (minimum 24 hours)

After each cycle, each material was evaluated and % shrinkage in area was calculated. After the last cycle, physical properties, such as tensile and puncture strength, as well as microbial barrier, were measured.

This study showed that Transition Tyvek® 1073B and Transition Tyvek® 1059B retain their toughness and flexibility down to -112°F. When exposed to heat, Tyvek® melts at approximately 275°F. Under actual processing conditions, the temperature can influence the handling of the web. The range of exposures should be controlled or validated. During roll processing, it is recommended that the web temperature should not exceed 175°F and web tension should remain below 0.75 lb/in.

![Figure 19. Dimensional study for Transition Tyvek® 1073B and Transition Tyvek® 1059B.](image-url)
CHEMICAL RESISTANCE

Because Tyvek® is made of HDPE, it is relatively chemically inert.

We do not recommend Tyvek® coming into contact with liquid chemicals in medical packaging applications. The chemical substances may permeate or may react with the material. Each such application will need to be validated.

A number of adhesives can be used to glue Tyvek®, either to itself or to other substrates. Water-based synthetic adhesives, such as ethylene/vinyl acetate adhesives, and the acrylic pressure-sensitive adhesives work well with Tyvek®. The synthetic adhesives that contain low-molecular weight materials can act like solvents at elevated temperatures, absorbing into the filaments (or polymer) and causing swelling and wrinkling.

Polyurethane adhesives provide optimum adhesion, flexibility and water resistance for adhering Tyvek® to itself and to a variety of substrates. Hot melt polyamide adhesives form good bonds to Tyvek® with a variety of materials.

The first step in choosing an adhesive is to verify if any of the components may interact with Tyvek®. Consultation with the adhesive manufacturer is recommended.

---

### Table I. Coefficient of Friction (COF)—Static/Dynamic—Transition Tyvek® 1073B, Transition Tyvek® 1059B and Tyvek® 2FS™ against 316 stainless steel (ASTM D1894)

<table>
<thead>
<tr>
<th></th>
<th>TRANSITION TYVEK® 1073B</th>
<th>TRANSITION TYVEK® 1059B</th>
<th>TYVEK® 2FS™</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Static COF</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rough, MD</td>
<td>0.167</td>
<td>0.197</td>
<td>0.120</td>
</tr>
<tr>
<td>Rough, CD</td>
<td>0.207</td>
<td>0.191</td>
<td>0.115</td>
</tr>
<tr>
<td>Smooth, MD</td>
<td>0.197</td>
<td>0.212</td>
<td>0.149</td>
</tr>
<tr>
<td>Smooth, CD</td>
<td>0.203</td>
<td>0.185</td>
<td>0.167</td>
</tr>
<tr>
<td><strong>Dynamic COF</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rough, MD</td>
<td>0.099</td>
<td>0.103</td>
<td>0.090</td>
</tr>
<tr>
<td>Rough, CD</td>
<td>0.101</td>
<td>0.101</td>
<td>0.086</td>
</tr>
<tr>
<td>Smooth, MD</td>
<td>0.106</td>
<td>0.103</td>
<td>0.093</td>
</tr>
<tr>
<td>Smooth, CD</td>
<td>0.103</td>
<td>0.104</td>
<td>0.097</td>
</tr>
</tbody>
</table>

MD = machine direction; CD = cross direction
Biocompatibility, food contact, pharmacopeia and bioburden

Biological evaluation of Transition Tyvek® 1073B and Transition Tyvek® 1059B for medical and pharmaceutical packaging was performed using testing methodologies according to ISO 10993 and United States Pharmacopeia (USP). Tyvek® styles have also been tested for U.S. Food Contact 21 CFR 177.1520 and European Food Contact EC No 10/2011. Further testing has been performed according to U.S. Pharmacopeia USP <88> Class VI, USP <661> and <661.1> and to European Pharmacopeia EP 3.1.5 and EP 3.1.3, as well as Bioburden, which has been determined per testing requirements of ISO 11737-1:2006/R2011. Transition Tyvek® 1073B and Transition Tyvek® 1059B meet the performance criteria.

Some critical tests such as extractables and leachables have also been performed on samples of Transition Tyvek® after exposure to sterilization by ethylene oxide (EO), gamma, electron-beam, low-temperature oxidative (STERRAD® 100S, vaporized hydrogen peroxide) and steam sterilization processes and proved that Transition Tyvek® 1073B and Transition Tyvek® 1059B meet the performance criteria after sterilization (Table II).

Biological evaluation of DuPont™ Tyvek® 2FS™ was performed using testing methodologies according to ISO 10993 and United States Pharmacopeia (USP) and meets the performance criteria for these tests (Table III). Tyvek® 2FS™ does not meet European Pharmacopeia requirements.

Additional information can be obtained by contacting your local DuPont representative.
### Table II. Biocompatibility, food contact, pharmacopeia and bioburden testing results for Transition Tyvek® 1073B and Transition Tyvek® 1059B

#### BIOCOMPATIBILITY

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Results</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytotoxicity (ISO 10993-5:2009)</td>
<td>PASS:</td>
<td>Pre-sterilization and 5- and 10-year accelerated aging (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vaporized hydrogen peroxide, steam)</td>
</tr>
<tr>
<td>Cytotoxicity (USP &lt;87&gt;)</td>
<td>PASS (pre-sterilization)</td>
<td></td>
</tr>
<tr>
<td>USP &lt;88&gt; Class VI Biological Reactivity Tests, in vivo</td>
<td>PASS (pre-sterilization)</td>
<td></td>
</tr>
<tr>
<td>Skin irritation and sensitization (ISO 10993-10:2010)</td>
<td>PASS (pre-sterilization)</td>
<td></td>
</tr>
<tr>
<td>Extractables and leachables (ISO 10993-18:2005: Infrared spectroscopy; ICP-MS; GC-MS; UPLC-MS)</td>
<td>Pre-sterilization:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>No major bands of interest (Infrared spectroscopy)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No quantifiable extractables above a concentration of 1.0 µg/mL detected by ICP-MS; GC-MS; UPLC-MS</td>
</tr>
<tr>
<td></td>
<td>Post-sterilization (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vaporized hydrogen peroxide, steam):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>No major bands of interest (Infrared spectroscopy)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No quantifiable extractables above a concentration of 1.0 µg/mL detected by ICP-MS; GC-MS; UPLC-MS</td>
</tr>
<tr>
<td></td>
<td></td>
<td>UPLC-MS testing—see*</td>
</tr>
</tbody>
</table>

#### ENDOTOXINS

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Results</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endotoxins (USP &lt;85&gt;)</td>
<td>PASS (pre-sterilization)</td>
<td></td>
</tr>
</tbody>
</table>

#### BIOBURDEN

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Results</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bioburden (ISO 11737-1:2006)</td>
<td>&lt;100 cfu/ft**</td>
<td></td>
</tr>
</tbody>
</table>

#### U.S. FOOD CONTACT

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Results</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 CFR 177.1520</td>
<td>PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vaporized hydrogen peroxide, steam)</td>
<td></td>
</tr>
</tbody>
</table>

#### U.S. PHARMACOPEIA

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Results</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>USP &lt;661&gt;</td>
<td>PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vaporized hydrogen peroxide, steam)</td>
<td></td>
</tr>
<tr>
<td>USP &lt;661.1&gt;</td>
<td>PASS (pre-sterilization)</td>
<td></td>
</tr>
</tbody>
</table>

#### EUROPEAN FOOD CONTACT

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Results</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU N° 10/2011 and EC N° 2023/2006</td>
<td>PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, steam)</td>
<td></td>
</tr>
</tbody>
</table>

#### EUROPEAN PHARMACOPEIA

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Results</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>EP 3.1.5 and EP 3.1.3 (8th edition of European Pharmacopeia)</td>
<td>Meets the compositional and extractable requirements (pre-sterilization)</td>
<td></td>
</tr>
</tbody>
</table>
| Selected Testing: | PASS (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vaporized hydrogen peroxide, steam) | (1) Identification A:
IR Spectrometry (2) Hexane Solubility |

#### JAPANESE FOOD SANITATION LAW

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Results</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specifications and Standards for foods, food additives and other materials (Notification No. 370 of MHLW III-D-2)</td>
<td>PASS (pre-sterilization)</td>
<td></td>
</tr>
</tbody>
</table>
### Biocompatibility, food contact, pharmacopeia and bioburden

#### Table III. Biocompatibility, food contact, pharmacopeia and bioburden testing results for DuPont™ Tyvek® 2FS™

<table>
<thead>
<tr>
<th><strong>BIOCOMPATIBILITY</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytotoxicity (ISO 10993-5:2009)</td>
<td>PASS (pre-sterilization)</td>
</tr>
<tr>
<td>USP &lt;88&gt; Class VI Biological Reactivity Tests, in vivo</td>
<td>PASS (pre-sterilization)</td>
</tr>
<tr>
<td>Skin irritation and sensitization (ISO 10993-10:2010)</td>
<td>PASS (pre-sterilization)</td>
</tr>
<tr>
<td>Extractables and leachables (ISO 10993-18:2005: Infrared spectroscopy; ICP-MS; GC-MS; UPLC-MS)</td>
<td>Pre-sterilization:</td>
</tr>
<tr>
<td></td>
<td>• No major bands of interest (Infrared spectroscopy)</td>
</tr>
<tr>
<td></td>
<td>• No quantifiable extractables above a concentration of 1.0 µg/mL detected by ICP-MS; GC-MS; UPLC-MS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>BIOBURDEN</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bioburden (ISO 11737-1:2006)</td>
<td>&lt;100 cfu/ft²*</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>U.S. FOOD CONTACT</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>21 CFR 177.1520</td>
<td>PASS (pre-sterilization)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>EUROPEAN FOOD CONTACT</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>EU N° 10/2011 and EC N° 2023/2006</td>
<td>PASS (pre-sterilization)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>JAPANESE FOOD SANITATION LAW</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Specifications and Standards for foods, food additives and other materials (Notification No. 370 of MHLW III-D-2)</td>
<td>PASS (pre-sterilization)</td>
</tr>
</tbody>
</table>

Note: Please reference the listed standards to obtain explanations for the definition of "PASS".

* Determined per testing requirement of ISO 11737-1:2006/R2011. This indication is based on a limited number of tests.
Sterilization compatibility

Unlike medical-grade papers and films, DuPont™ Tyvek® offers sterilization compatibility with the most commonly used modalities for sterilizing medical devices. These include: ethylene oxide (EO), gamma, electron-beam, steam or dry heat (under controlled conditions) and low-temperature oxidative sterilization processes (e.g., STERRAD® or vaporized hydrogen peroxide). That's because Tyvek® is made of 100% high-density polyethylene (HDPE), which is extremely stable when exposed to sterilant gases and high-energy sterilization processes. In addition, Tyvek® is specially engineered to enable sterilant gases and steam to penetrate and escape quickly. For the sterilization modality you choose, Tyvek® can retain its superior protective properties of microbial barrier and strength, as well as its color and flexibility.

Table IV. Material compatibility with various sterilization modalities

<table>
<thead>
<tr>
<th>Material Compatibility</th>
<th>DUPONT™ TYVEK®</th>
<th>MEDICAL-GRADE PAPER</th>
<th>ALL FILM PACKAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylene Oxide (EO)</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Gamma Radiation</td>
<td>Yes</td>
<td>Yes(^1)</td>
<td>Yes(^1,2)</td>
</tr>
<tr>
<td>Electron-beam Radiation</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Steam</td>
<td>Yes(^3)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Dry Heat</td>
<td>Yes(^4)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>STERRAD(^*)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Vaporized Hydrogen Peroxide</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

1. May become brittle.
2. May entrap undesirable odors inside the package.
3. Under controlled conditions (250°F at 30 psi for 30 minutes with temperatures up to 260°F).
4. Under controlled conditions (250°F); cycle time to be validated.

Table V. Ethylene oxide (EO) sterilization details for DuPont™ Tyvek® sterilization compatibility testing

<table>
<thead>
<tr>
<th>STERILIZATION TYPE</th>
<th>DOSAGE</th>
<th>DETAILS</th>
</tr>
</thead>
</table>
| Ethylene Oxide (EO)| 2X cycles | Total time per cycle (excluding pre- and post-conditioning): 8 hours and 10 minutes
|                    |        | EO exposure time per cycle: 8 hours and 0 minutes
|                    |        | EO concentration: 725 ppm
|                    |        | Maximum temperature: 131°F (55°C)
|                    |        | Maximum relative humidity: 60%
|                    |        | Maximum pressure rate change: 25 psi/min |
RADIATION

Tyvek® maintains excellent microbial barrier properties and experiences usually only slight changes in tensile strength, elongation, microbial barrier and color when exposed to radiation doses typically used in the medical device industry. Unlike several other materials, Tyvek® resists post-sterilization brittleness and when packages are opened, Tyvek® maintains its low-linting performance.

Because Tyvek® is porous, undesirable odors produced by radiation sterilization can be aerated out of the package. Nonporous materials can trap these odors inside the packaging. Furthermore, Tyvek® minimizes the formation of condensation due to temperature extremes that can occur during transport.

The breathability also allows medical packages made with Tyvek® to equilibrate rapidly from the pressure changes that can occur in shipping and in storage environments. This helps alleviate stress on the seals.

**Gamma and electron-beam**

After exposure to gamma or electron-beam radiation up to 100 kGy, Tyvek® maintains its superior microbial barrier and the impact on strength properties is limited. See Tables VI and VII and Figures 21-28 for details and data on sterilization compatibility of Tyvek®.

These properties are also maintained after irradiation followed by exposure to accelerated and real-time aging. Refer to Section 5, “Stability Testing” for test results after aging.

<table>
<thead>
<tr>
<th>Table VI. Gamma radiation sterilization details for DuPont™ Tyvek® sterilization compatibility testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>STERILIZATION TYPE</td>
</tr>
<tr>
<td>--------------------</td>
</tr>
<tr>
<td>Gamma</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table VII. Electron-beam sterilization details for DuPont™ Tyvek® sterilization compatibility testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>STERILIZATION TYPE</td>
</tr>
<tr>
<td>--------------------</td>
</tr>
<tr>
<td>Electron-beam</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
Sterilization compatibility

STEAM

Tyvek® has been shown to meet packaging criteria for steam sterilization under controlled conditions (250°F at 30 psi for 30 minutes with temperatures up to 260°F). An advantage of the porous nature of Tyvek® is that a high MVTR can be achieved. Packaging using Tyvek® for steam sterilization is commercial at medical device and pharmaceutical manufacturers. Another advantage of Tyvek® 1073B and Tyvek® 1059B is that they meet the requirements of European Pharmacopeia, Section 3.1.5. Tyvek® continues to provide superior performance compared to medical-grade paper when strong, low-linting packaging is required. Tyvek® retains its dimensional stability and integrity—with no discoloration—when steam sterilized under controlled conditions (250°F at 30 psi for 30 minutes with temperatures up to 260°F).

Tensile strength, elongation, puncture resistance, microbial barrier and Gurley Hill porosity of Tyvek® are maintained after steam sterilization under controlled conditions for 30 minutes at temperatures up to 260°F. See Table VIII and Figures 21-28 for details and data on sterilization compatibility of Tyvek®. Rigid or semi-rigid trays restrict potential shrinkage and wrinkling, which can result in a smoother/tighter lid. Shrinkage of Transition Tyvek® after steam sterilization is less than 4% and Gurley Hill porosity is maintained (Figure 20). Refer to Section 5, “Stability Testing,” for test results after aging.

Table VIII. Steam sterilization details for DuPont™ Tyvek® sterilization compatibility testing

<table>
<thead>
<tr>
<th>STEERILIZATION TYPE</th>
<th>DOSAGE</th>
<th>DETAILS</th>
</tr>
</thead>
</table>
| Steam               | 1X cycle | Total time per cycle: 1 hour and 0 minutes  
Steam exposure per cycle: 0 hours and 30 minutes  
Maximum temperature: 261°F (127°C)  
Maximum pressure: 40 psia |

Figure 20. Results of shrinkage tests and Gurley Hill porosity measurements conducted on Transition Tyvek® 1073B and Transition Tyvek® 1059B after steam sterilization.
LOW-TEMPERATURE OXIDATIVE (STERRAD®, VAPORIZED HYDROGEN PEROXIDE)

Transition Tyvek® 1073B and Transition Tyvek® 1059B maintain superior strength and microbial barrier after STERRAD® or vaporized hydrogen peroxide sterilization. See Table IX and Figures 21-28 for details and data on sterilization compatibility of Tyvek®. Refer to Section 5, “Stability Testing,” for test results after aging.

Based on test data and extensive long-term use, it is clear that Tyvek® is well-suited for use with the STERRAD® Sterilization System from Advanced Sterilization Products (ASP), Division of Ethicon Inc., a Johnson & Johnson company. This sterilization modality uses low-temperature hydrogen peroxide gas plasma to enable sterilization of heat-labile devices.

Low-temperature oxidative sterilization processes should not be used with cellulosic materials such as medical-grade paper because these materials rapidly interact with the oxidizing agent and its superoxide radicals. This can result in an aborted cycle due to inadequate sterilant concentration. Tyvek® is made of HDPE and allows for an effective sterilant concentration to be achieved.

Table IX. Low-temperature oxidative sterilization details for DuPont™ Tyvek® sterilization compatibility testing

<table>
<thead>
<tr>
<th>STERILIZATION TYPE</th>
<th>DOSAGE</th>
<th>DETAILS</th>
</tr>
</thead>
</table>
| Low-temperature Oxidative: STERRAD® 100S | 1X cycle | Total time per cycle: 0 hours and 55 minutes  
H₂O₂ exposure time per cycle: 0 hours and 28 minutes  
Sterilant concentration: 58%  
Maximum temperature: 131°F (55°C) |
| Low-temperature Oxidative: Vaporized Hydrogen Peroxide | 1X cycle | Total time per cycle: 1 hour and 40 minutes  
H₂O₂ exposure time per cycle: 0 hours and 40 minutes  
Sterilant concentration: 35%  
Maximum temperature: 122°F (50°C) |
Although Tyvek® interacts only slightly with these types of sterilants, the surface energy may be increased with some methods such as STERRAD®. This can cause a lowering of the hydrostatic head (Table X). The performance of Tyvek® as a sterile barrier is not affected (Figure 26) but the liquid test methods for assessing package integrity (such as dye penetration and water immersion) can produce results that are different from untreated material. The data in Table X demonstrates that the hydrostatic head is not affected by vaporized hydrogen peroxide sterilization.

### Sterilization pouches and rolls intended for the healthcare sterilization market

Advanced Sterilization Products (ASP), Division of Ethicon Inc., a Johnson & Johnson company, has developed a complete range of self-seal pouches, heat-seal pouches and heat-seal rolls made with Tyvek® for use in the STERRAD® System. ASP also prints a STERRAD® Chemical Indicator on its pouches and rolls to simplify the identification of processed packages. The STERRAD® Sterilization process is also used for industrial device sterilization with common package configurations using Tyvek® protective material. For information about the STERRAD® System, including cycle time and performance details, visit the ASP website.

### Table X. Effect of low-temperature oxidative sterilization on hydrostatic head and surface energy—Transition Tyvek® 1073B and Transition Tyvek® 1059B

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>COMPARABLE TEST METHOD(S)</th>
<th>UNITS</th>
<th>TRANSITION TYVEK® 1073B</th>
<th>TRANSITION TYVEK® 1059B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrostatic Head</td>
<td>AATCC TM 127 EN 20811*</td>
<td>in. H₂O</td>
<td>63</td>
<td>62</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>33</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>65</td>
<td>64</td>
</tr>
<tr>
<td>Surface Energy–Contact Angle, Rough Side</td>
<td>ASTM D5946</td>
<td>degrees</td>
<td>97</td>
<td>96</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>68</td>
<td>62</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>96</td>
<td>93</td>
</tr>
<tr>
<td>Surface Energy–Contact Angle, Smooth Side</td>
<td>ASTM D5946</td>
<td>degrees</td>
<td>94</td>
<td>93</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>61</td>
<td>59</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>94</td>
<td>91</td>
</tr>
</tbody>
</table>

*Rate of use: 60 cm H₂O/min.
RE-STERILIZATION

It is important to note that although Tyvek® may withstand re-sterilization with either gamma or electron-beam, the device itself may not. If re-sterilization is required, gas sterilization can also be performed. Tyvek® will remain flexible after re-sterilization and will continue to provide an excellent microbial barrier. Customers must conduct their own tests to ensure suitability for the intended application.

DUPONT™ TYVEK® STERILIZATION COMPATIBILITY—TEST RESULTS

Figure 21. Effects of sterilization on material tensile strength (MD) for Transition Tyvek® 1073B, Transition Tyvek® 1059B and Tyvek® 2FS™ (ASTM D5034—in lbf/4 in.). MD = machine direction

*No results available for Tyvek® 2FS™.
Sterilization compatibility

Figure 22. Effects of sterilization on material tensile strength (CD) for Transition Tyvek® 1073B, Transition Tyvek® 1059B and Tyvek® 2FS™ (ASTM D5034—in lbf/4 in.). CD = cross direction.
*No results available for Tyvek® 2FS™.

Figure 23. Effects of sterilization on material elongation (MD) for Transition Tyvek® 1073B, Transition Tyvek® 1059B and Tyvek® 2FS™ (ASTM D5034—in %). MD = machine direction.
*No results available for Tyvek® 2FS™.
Sterilization compatibility

Figure 24. Effects of sterilization on material elongation (CD) for Transition Tyvek® 1073B, Transition Tyvek® 1059B and Tyvek® 2FS™ (ASTM D5034—in %). CD = cross direction. *No results available for Tyvek® 2FS™.

Figure 25. Effects of sterilization on material puncture strength for Transition Tyvek® 1073B, Transition Tyvek® 1059B and Tyvek® 2FS™ (ASTM F1342—in lbf). *No results available for Tyvek® 2FS™.
Figure 26. Effects of sterilization on material microbial barrier for Transition Tyvek® 1073B, Transition Tyvek® 1059B and Tyvek® 2FS™ (ASTM F2638—in % pMax with a particle size of 1 µm, flow max 2 L/min).

ASTM F2638, *Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier*, measures the ability of a porous substrate to prevent particle penetration, which is highly correlated to microbiological spore penetration. All materials have a face velocity where maximum percent particle penetration occurs (% pMax). The lower the percent penetration, the better the performance. Please note that the scale of the Y axis has been magnified (compared to Figure 8) to show detail. It is important to note that all Tyvek® styles have a low pMax in all conditions tested.

*No results available for Tyvek® 2FS™.

Figure 27. Effects of sterilization on material microbial barrier for Transition Tyvek® 1073B and Transition Tyvek® 1059B (ASTM F1608—in LRV).

ASTM F1608, *Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)*, measures the ability of porous sterile barrier materials to prevent bacterial spore penetration. A completely impermeable control sample (microbial penetration is zero) is challenged with one million or 10⁶ colony forming units (cfu). The number of cfu 10⁶ has a log₁₀ value of 6. If a sample challenged in the same way as the control allows 10 cfu (log 10=1) to penetrate, then its log reduction value (LRV) is 5 (6–1=5). Therefore, the higher the LRV, the more resistant the packaging is to microorganisms.
**Figure 28. Effects of sterilization on material color \((L,a,b)\) for Transition Tyvek® 1073B and Transition Tyvek® 1059B.**

*These values were obtained using a handheld X-Rite® 500 Series Spectrodensitometer, with a white copier-grade backdrop and the following instrument settings: an observer angle of 2° and illuminant type = D65 (representative of 6500 K daylight).

\[
\Delta E_{ab} = \sqrt{(L_2 - L_1)^2 + (a_2 - a_1)^2 + (b_2 - b_1)^2}
\]

where 2 = Pre-sterilization and 1 = Post-sterilization.

A \(\Delta E_{ab}\) value of ~2.3 corresponds to “a just noticeable difference.”
PERFORMANCE OF DUPONT™ TYVEK® AFTER AGING

Tyvek® inherently resists penetration by microorganisms better than any other porous medical packaging material because of its unique structure. Tyvek® is a sheet structure formed from continuous strands of very fine, interconnected filaments of high-density polyethylene (HDPE). These filaments are multi-directionally oriented and bonded together by heat and pressure. This structure also imparts other important properties for medical packaging, including: strength; resistance to penetration by water; low linting; puncture resistance; and air permeability.

Tyvek® can provide long-term sterility maintenance of sterilized and packaged medical devices. The effectiveness of Tyvek® in keeping medical devices sterile during storage has been conclusively demonstrated both by aging studies and by all of the medical devices in the market with five-year—or longer—expiry dates.

Test methods used to evaluate the microbial barrier properties of Tyvek® include ASTM F2638, ASTM F1608 and the DuPont Bacterial Test Chamber. Results from both material-based and whole-package shelf-life studies show:

• Tyvek® holds out bacterial spores, even under the most rigorous conditions.
• The outstanding efficacy of Tyvek® as a bacterial barrier, even after repeated challenges.
• Tyvek® maintains sterility even after at least five years of exposure to environments contaminated with microorganisms.

The first DuPont shelf-life studies of Tyvek® were initiated in 1972 and demonstrated that Tyvek® resisted spore penetration for at least one year under normal conditions.

To extend that investigation, DuPont initiated a long-term shelf-life study of Tyvek® 1073B and Tyvek® 1059B in 1978. The study was conducted at the DuPont Haskell Laboratory for Toxicology. The objective of this program was to see how well these styles of Tyvek® would resist penetration by airborne bacterial spores. This test was designed to have a more severe microbial challenge than typical real-world conditions. The samples were challenged repeatedly with high bio-contamination levels (at ambient temperature and pressure) for months and years at a time.

The results of this study showed that Tyvek® is a remarkably reliable microbial barrier. Tyvek® can maintain sterility for at least five years, providing package integrity is maintained.

Newly generated accelerated and/or real-time aging studies show that Tyvek® 1073B and Tyvek® 1059B can maintain physical and microbial barrier properties for at least seven to 10 years and Tyvek® 2FS™ for at least five years.

Please note: The data shown in Tables XI through XIII are for uncoated samples of Tyvek®. It is important to note that any downstream operations, such as coatings applied by sterile packaging manufacturers (SPMs), may affect the properties. Some of the data in this Section has been generated with Legacy Tyvek® and some data has been generated with Transition Tyvek®. Transition Tyvek® is either Tyvek® 1073B or Tyvek® 1059B produced on the original manufacturing lines. Transition Tyvek® is either Tyvek® 1073B or Tyvek® 1059B produced on the newer manufacturing lines. Additional real-time aging study results will be added to this Technical Reference Guide as they become available.

SUMMARY OF THE 5-YEAR SHELF-LIFE TEST PROTOCOL

1. Contents of packages tested for initial sterility

Open petri dishes were sealed in special packages, 4.25 in. x 6.75 in. (10.8 cm x 17.1 cm), designed to simulate actual disposable medical devices sealed in packages. The package and contents were then sterilized using ethylene oxide (EO). Each package consisted of a lid of Tyvek® sealed to poly-PET film. To ensure that the petri dish was sterile prior to long-term shelf storage, samples were randomly tested following the United States Pharmacopeia (USP) methods for both anaerobic and aerobic bacteria. An anaerobic chamber was used to test for anaerobic microbial contamination. The petri dish was removed from the opened package and placed in a sterile bag containing either fluid thioglycolate culture medium or soybean casein digest broth. This tested the sterility of the packaged “device” before the multi-year shelf-life study was started.

2. Stored packages heavily dosed with bacterial spores

Packages containing sterile petri dishes were stored on shelves in cabinets protected from outside contamination and stored under controlled temperature and relative humidity. Every four months throughout the entire five years of testing, each package was sprayed with a uniform, massive dose of Bacillus circulans spores. Actual counts indicated 4,000 to 5,000 spores on each package.
3. Package sterility checked periodically
To check sterility, 10 packages were withdrawn randomly from the storage shelves every six months and the outside surface of the poly-Mylar® was disinfected. A small hole was then made through the poly-Mylar® film and the petri dish with a hot, pencil-tip soldering iron. Then, 15 mL of sterile nutrient agar were injected into the petri dish and the entry hole was covered with biocidal tape. If any spores had penetrated the lid of Tyvek®, they would have grown on the culture medium after incubation. No spores were detected on any samples during the study.

4. Tyvek® is inspected for possible bacteria growth
The final part of the test procedure determined that the packages were indeed challenged with the bacterial spores on the outside of the lid of Tyvek®. A small swatch of Tyvek® from the package lid was cut out and placed on an agar medium. After evidence of bacteria growth, the swatches were examined under a microscope and colonies of B. circulans were counted. This acted as a check for the number of viable spores that were actually on the surface of Tyvek®. It also concluded that the density of spores was consistently maintained over the many years of the test.

RESULTS OF 5-YEAR REAL-TIME AGING STUDY AFTER EO STERILIZATION
Tyvek® retains its physical properties over time, allowing a package to maintain integrity.

Table XI shows the physical properties before and after 5-year real-time aging of Legacy Tyvek® 1073B and Legacy Tyvek® 1059B sterilized by EO. Tyvek® 1073B is the reference product providing the highest level of protection for all demanding applications and Tyvek® 1059B is the product providing robust protection for medium-risk applications.

Table XI. Physical properties of Legacy Tyvek® sterilized by ethylene oxide (EO) before and after 5-year real-time aging*

<table>
<thead>
<tr>
<th>PROPERTY</th>
<th>TEST METHOD</th>
<th>UNITS</th>
<th>LEGACY TYVEK® 1073B INITIAL</th>
<th>LEGACY TYVEK® 1073B AFTER 5 YEARS</th>
<th>LEGACY TYVEK® 1059B INITIAL</th>
<th>LEGACY TYVEK® 1059B AFTER 5 YEARS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delamination</td>
<td>ASTM D2724</td>
<td>lb/in.</td>
<td>0.47</td>
<td>0.44</td>
<td>0.45</td>
<td>0.49</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(N/2.54 cm)</td>
<td>(2)</td>
<td>(2)</td>
<td>(2)</td>
<td>(2)</td>
</tr>
<tr>
<td>Gurley Hill Porosity</td>
<td>TAPPI T460</td>
<td>sec/100 cc</td>
<td>37</td>
<td>37</td>
<td>30</td>
<td>28</td>
</tr>
<tr>
<td>Microbial Barrier</td>
<td>Internal DuPont</td>
<td>Log Reduction Value (LRV)</td>
<td>5.2*</td>
<td>unchanged</td>
<td>4.7*</td>
<td>unchanged</td>
</tr>
<tr>
<td>Hydrostatic Head</td>
<td>AATCC TM 127 EN 20811*</td>
<td>in. H₂O (cm H₂O)</td>
<td>59+ (150+)</td>
<td>59+ (150+)</td>
<td>59+ (150+)</td>
<td>59+ (150+)</td>
</tr>
<tr>
<td>Tensile Strength, MD</td>
<td>ASTM D5035* EN ISO 1924-2*</td>
<td>lb/in. (N/2.54 cm)</td>
<td>44.0 (196)</td>
<td>45.1 (201)</td>
<td>36.7 (163)</td>
<td>35.9 (160)</td>
</tr>
<tr>
<td>Seal Strength</td>
<td>ASTM F88*</td>
<td>lb/in.</td>
<td>1.53</td>
<td>1.57</td>
<td>1.33</td>
<td>1.44</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(N/2.54 cm)</td>
<td>(7)</td>
<td>(7)</td>
<td>(6)</td>
<td>(6)</td>
</tr>
</tbody>
</table>

*Based on data generated on Legacy Tyvek®. Transition Tyvek® has been proven to be functionally equivalent. Legacy Tyvek® is either Tyvek® 1073B or Tyvek® 1059B produced on the original manufacturing lines. Transition Tyvek® is either Tyvek® 1073B or Tyvek® 1059B produced on the newer manufacturing lines.

1. Typical values. ASTM F1608 Standard did not exist so barrier was tested by internal DuPont method similar to the current Standard. Property remained unchanged after five years.
2. Rate of use: 60 cm H₂O/min.
3. Modified for speed and gauge length.
4. Sealing conditions: temperature—290°F (143°C); dwell time—1 second; pressure (seal through the film)—90 psi (621 kPa).

RESULTS OF 1- AND 7-YEAR REAL-TIME AGING STUDY AFTER GAMMA AND ELECTRON BEAM
Samples of Legacy Tyvek® 1073B and Legacy Tyvek® 1059B were sterilized using gamma and electron beam and then aged at room temperature for seven years. Both tensile strength and microbial barrier were tested before and after aging. Original properties prior to sterilization are shown to demonstrate the radiation stability of Legacy Tyvek® (Table XII). Other polymeric materials that are not radiation stable are subject to chain scission reactions, which greatly reduce physical properties.
### Table XII. Real-time aging test results for Legacy Tyvek® 1073B and Legacy Tyvek® 1059B*

<table>
<thead>
<tr>
<th></th>
<th>TENSILE STRENGTH¹, MD</th>
<th>TENSILE STRENGTH¹, CD</th>
<th>MICROBIAL BARRIER, LRV²</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>lb</td>
<td>N</td>
<td>lb</td>
</tr>
<tr>
<td><strong>Gamma Radiation 50 kGy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Legacy Tyvek® 1073B</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-sterilization</td>
<td>42</td>
<td>187</td>
<td>48</td>
</tr>
<tr>
<td>Post-sterilization</td>
<td>33</td>
<td>147</td>
<td>39</td>
</tr>
<tr>
<td>After 7 years</td>
<td>32</td>
<td>142</td>
<td>33</td>
</tr>
<tr>
<td><strong>Legacy Tyvek® 1059B</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-sterilization</td>
<td>37</td>
<td>163</td>
<td>40</td>
</tr>
<tr>
<td>Post-sterilization</td>
<td>28</td>
<td>122</td>
<td>31</td>
</tr>
<tr>
<td>After 7 years</td>
<td>27</td>
<td>118</td>
<td>29</td>
</tr>
<tr>
<td><strong>Gamma Radiation 100 kGy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Legacy Tyvek® 1073B</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-sterilization</td>
<td>42</td>
<td>187</td>
<td>48</td>
</tr>
<tr>
<td>After 7 years</td>
<td>23</td>
<td>103</td>
<td>29</td>
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<tr>
<td><strong>Legacy Tyvek® 1059B</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Pre-sterilization</td>
<td>37</td>
<td>163</td>
<td>40</td>
</tr>
<tr>
<td>After 7 years</td>
<td>19</td>
<td>85</td>
<td>22</td>
</tr>
<tr>
<td><strong>Electron-beam Radiation 50 kGy</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Legacy Tyvek® 1073B</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-sterilization</td>
<td>42</td>
<td>187</td>
<td>48</td>
</tr>
<tr>
<td>Post-sterilization</td>
<td>37</td>
<td>164</td>
<td>35</td>
</tr>
<tr>
<td>After 7 years</td>
<td>36</td>
<td>159</td>
<td>33</td>
</tr>
<tr>
<td><strong>Legacy Tyvek® 1059B</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-sterilization</td>
<td>37</td>
<td>163</td>
<td>40</td>
</tr>
<tr>
<td>Post-sterilization</td>
<td>32</td>
<td>143</td>
<td>33</td>
</tr>
<tr>
<td>After 7 years</td>
<td>30</td>
<td>135</td>
<td>28</td>
</tr>
<tr>
<td><strong>Electron-beam Radiation 100 kGy</strong></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Legacy Tyvek® 1073B</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-sterilization</td>
<td>42</td>
<td>187</td>
<td>48</td>
</tr>
<tr>
<td>Post-sterilization</td>
<td>27</td>
<td>120</td>
<td>27</td>
</tr>
<tr>
<td>After 7 years</td>
<td>22</td>
<td>96</td>
<td>25</td>
</tr>
<tr>
<td><strong>Legacy Tyvek® 1059B</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-sterilization</td>
<td>37</td>
<td>163</td>
<td>40</td>
</tr>
<tr>
<td>Post-sterilization</td>
<td>24</td>
<td>106</td>
<td>27</td>
</tr>
<tr>
<td>After 7 years</td>
<td>21</td>
<td>94</td>
<td>21</td>
</tr>
</tbody>
</table>

*Based on data generated on Legacy Tyvek®. Transition Tyvek® has been proven to be functionally equivalent. Legacy Tyvek® is either Tyvek® 1073B or Tyvek® 1059B produced on the original manufacturing lines. Transition Tyvek® is either Tyvek® 1073B or Tyvek® 1059B produced on the newer manufacturing lines.

**50 kGy was a single dose; 100 kGy was a cumulative amount, representing a double dose of 50 kGy.

1. ASTM D5035 and EN ISO 1924-2; modified for speed, sample width (1 in. [2.54 cm]) and gauge length.
2. Log Reduction Value (LRV) as tested per ASTM F1608. Note that ASTM F1608 Standard did not exist when the test was initiated, so barrier for the original value was tested by an internal DuPont method similar to the current Standard.
3. Typical values. ASTM F1608 was not available in 1990 when the test was initiated.
RESULTS OF 1-, 3-, 5-, 7- AND 10-YEAR ACCELERATED AGING STUDY AFTER DIFFERENT STERILIZATION MODALITIES

Samples of Transition Tyvek® 1073B and Transition Tyvek® 1059B were aged according to the standard ASTM F1980 using the following accelerated conditions:

- Accelerated aging (1, 3, 5, 7 and 10 years) at nominal conditions of 122°F and 23% relative humidity (RH), assuming an ambient temperature of 77°F.

Samples of Tyvek® 2FS™ were aged according to the standard ASTM F1980 using the following accelerated conditions:

- Accelerated aging (1, 3 and 5 years) at 140°F and ambient RH, assuming an ambient temperature of 77°F.

**Figure 29. Effects of sterilization and accelerated aging on material tensile strength (MD) for Transition Tyvek® 1073B, Transition Tyvek® 1059B and Tyvek® 2FS™ (ASTM D5034—in lbf/4 in.). MD = machine direction
*No results available for Tyvek® 2FS™.**

**Figure 30. Effects of sterilization and accelerated aging on material tensile strength (CD) for Transition Tyvek® 1073B, Transition Tyvek® 1059B and Tyvek® 2FS™ (ASTM D5034—in lbf/4 in.). CD = cross direction
*No results available for Tyvek® 2FS™.**
### Stability testing

#### Figure 31. Effects of sterilization and accelerated aging on material elongation (MD) for Transition Tyvek® 1073B, Transition Tyvek® 1059B and Tyvek® 2FS™ (ASTM D5034—in %). MD = machine direction.

*No results available for Tyvek® 2FS™.

#### Figure 32. Effects of sterilization and accelerated aging on material elongation (CD) for Transition Tyvek® 1073B, Transition Tyvek® 1059B and Tyvek® 2FS™ (ASTM D5034—in %). CD = cross direction.

*No results available for Tyvek® 2FS™.
Figure 33. Effects of sterilization and accelerated aging on material puncture strength for Transition Tyvek® 1073B, Transition Tyvek® 1059B and Tyvek® 2FS™ (ASTM F1342—in lb f). *No results available for Tyvek® 2FS™.

Figure 34. Effects of sterilization and accelerated aging on material microbial barrier for Transition Tyvek® 1073B, Transition Tyvek® 1059B and Tyvek® 2FS™ (ASTM F2638—in % pMax with a particle size of 1 µm, flow max 2 L/min). The lower the % pMax, the better the performance.

ASTM F2638, Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier, measures the ability of a porous substrate to prevent particle penetration, which is highly correlated to microbiological spore penetration. All materials have a face velocity where maximum percent particle penetration occurs (% pMax). The lower the percent penetration, the better the performance.

*No results available for Tyvek® 2FS™.
RESULTS OF 1-YEAR REAL-TIME AGING STUDY AFTER DIFFERENT STERILIZATION MODALITIES

Samples of Transition Tyvek® 1073B and Transition Tyvek® 1059B were sterilized using various sterilization modalities and aged using the conditions listed here:

- Real-time aging (1 year) at nominal conditions of 77°F and monitored ambient RH.

For sterilization details, see Section 4, "Sterilization Compatibility."

Figure 35. Effects of sterilization and 1-year real-time aging on material tensile strength (MD) for Transition Tyvek® 1073B and Transition Tyvek® 1059B (ASTM D5034—in lbf/4 in.). MD = machine direction

Figure 36. Effects of sterilization and 1-year real-time aging on material tensile strength (CD) for Transition Tyvek® 1073B and Transition Tyvek® 1059B (ASTM D5034—in lbf/4 in.). CD = cross direction
Figure 37. Effects of sterilization and 1-year real-time aging on material elongation (MD) for Transition Tyvek® 1073B and Transition Tyvek® 1059B (ASTM D5034—in %). MD = machine direction

Figure 38. Effects of sterilization and 1-year real-time aging on material elongation (CD) for Transition Tyvek® 1073B and Transition Tyvek® 1059B (ASTM D5034—in %). CD = cross direction
Figure 39. Effects of sterilization and 1-year real-time aging on puncture strength for Transition Tyvek® 1073B and Transition Tyvek® 1059B (ASTM F1342—in lbf).

Figure 40. Effects of sterilization and 1-year real-time aging on material microbial barrier for Transition Tyvek® 1073B and Transition Tyvek® 1059B (ASTM F2638—in % pMax with a particle size of 1 µm, flow max 2 L/min). The lower the % pMax, the better the performance.

ASTM F2638, *Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier*, measures the ability of a porous substrate to prevent particle penetration, which is highly correlated to microbiological spore penetration. All materials have a face velocity where maximum percent particle penetration occurs (% pMax). The lower the percent penetration, the better the performance.
RESULTS OF COMBINED ACCELERATED AND REAL-TIME AGING TEST AFTER GAMMA STERILIZATION (SEAL STRENGTH)

The effect of gamma sterilization and aging on seal strength is negligible (Table XIII). Pouches of Legacy Tyvek® 1073B and 2.5-mil polyester/polyethylene were gamma irradiated (30 kGy) and then stored at 131°F and ambient RH for a period of 10 weeks, followed by storage at ambient conditions for three years and then assessed for seal strength according to ASTM F88.

DuPont performed an extensive study to evaluate the performance of standard chevron pouches made with either Legacy Tyvek® 1073B, Tyvek® 2FS™ or one of five different medical-grade papers. Tests performed were seal strength and package integrity after sterilization (EO, gamma), after accelerated aging and after conditioning and subsequent transportation testing.

To learn more about the effect of EO, gamma sterilization and accelerated aging on seal strength, download the white paper titled “Medical Packaging Study—Reducing the Risk of Failure through Performance Testing of Packaging Made from Various Materials.”

Table XIII. Seal strength of DuPont™ Tyvek® 1073B after gamma sterilization following accelerated and real-time aging*,**

<table>
<thead>
<tr>
<th></th>
<th>Seal Strength lb/in. (N/2.54 cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-sterilization</td>
<td>0.915 (4.07)</td>
</tr>
<tr>
<td>Sterilized with 30 kGy Gamma</td>
<td>0.949 (4.22)</td>
</tr>
<tr>
<td>Accelerated Aging</td>
<td></td>
</tr>
<tr>
<td>2 weeks</td>
<td>0.931 (4.14)</td>
</tr>
<tr>
<td>4 weeks</td>
<td>0.856 (3.85)</td>
</tr>
<tr>
<td>6 weeks</td>
<td>0.953 (4.24)</td>
</tr>
<tr>
<td>8 weeks</td>
<td>0.887 (3.95)</td>
</tr>
<tr>
<td>10 weeks</td>
<td>0.848 (3.77)</td>
</tr>
<tr>
<td>Real-Time Aging</td>
<td></td>
</tr>
<tr>
<td>3 Years</td>
<td>0.778 (3.46)</td>
</tr>
</tbody>
</table>

*Based on data generated on Legacy Tyvek® 1073B. Transition Tyvek® 1073B has been proven to be functionally equivalent. Legacy Tyvek® is either Tyvek® 1073B or Tyvek® 1059B produced on the original manufacturing lines. Transition Tyvek® is either Tyvek® 1073B or Tyvek® 1059B produced on the newer manufacturing lines.

**This data is an example based on one possible packaging material configuration. Other material combinations may behave differently.
MECHANICAL PROPERTIES
A sterile barrier system must withstand many challenges during sterilization, handling, storage and distribution. Physical properties provide an important indication of the probability that the material, as part of the packaging, can stay intact throughout the life cycle.

See Section 5, “Stability Testing” for additional information on the effects of sterilization and accelerated/1-year real-time aging on material tear strength, elongation and puncture strength for Transition Tyvek® 1073B, Transition Tyvek® 1059B and ‘Tyvek® 2FS™.

TRANSPORT SIMULATION AND SUBSEQUENT TESTING
To demonstrate that ‘Tyvek’ can withstand very high environmental challenges, DuPont conducted an extensive performance testing study to evaluate the performance of standard chevron pouches made with either Legacy Tyvek® 1073B, ‘Tyvek® 2FS™ or one of five different medical-grade papers. Seal strength and package integrity tests were done after sterilization (ethylene oxide [EO], gamma), after accelerated aging and after conditioning and subsequent transportation testing.

The study showed that loss of integrity after transportation testing was reported for three of the five types of medical-grade paper that were evaluated in this study. The integrity failures, which were only observed after gamma sterilization, were all linked to punctures and/or creases in the paper. All pouches made with Legacy Tyvek® 1073B or ‘Tyvek® 2FS™ maintained integrity.

Complete details about the scope of the study and the materials tested can be found in the white paper titled “Medical Packaging Study—Reducing the Risk of Failure through Performance Testing of Packaging Made from Various Materials.”

To demonstrate that ‘Tyvek’ keeps its microbial barrier even under rigorous conditions such as transport, microbial barrier testing was conducted according to ASTM F2638, before and after sterilization (EO, gamma) and subsequent transportation testing.

As shown by the data, Legacy Tyvek® 1073B and ‘Tyvek® 2FS™ showed the best microbial barrier performance. On the other hand, three of the four types of medical-grade paper showed a significant decrease in microbial barrier performance after gamma sterilization, environmental conditioning and transportation testing compared to pre-sterilization. This decrease in microbial barrier performance was mainly linked to creases and punctures in the material. Details are contained in the white paper titled “Medical Packaging Study—The Impact of Sterilization and Transportation Testing on the Microbial Barrier of Different Materials.”

STORAGE REQUIREMENTS
Because Tyvek® is made of high-density polyethylene (HDPE) filaments, it is not affected by climatic changes in humidity, temperature or atmospheric pressure. Exposure to UV light should be limited to less than one month. Normal shipping, handling and storage conditions should be used.

PACKAGING EXPOSED TO LIQUID
When medical-grade paper absorbs moisture, its strength and puncture resistance are reduced. This can greatly influence package performance, especially during distribution. In sharp contrast to medical-grade paper, ‘Tyvek’ maintains its superior strength both wet and dry.

‘Tyvek’ has the advantage because it is hydrophobic and holds out water until a fairly high pressure (see Figure 12 in Section 1, “Why is DuPont™ Tyvek® the preferred choice for sterile barrier systems?”). Occasionally, medical device and pharmaceutical packages are subjected to adverse conditions that allow them to get wet, such as rain on a loading dock or flooding. When this occurs, the time of exposure and severity are not typically known, nor has such exposure been tested during package design. We believe water exposure under these types of scenarios would constitute damage relative to the typical manufacturer labeling “sterile unless opened or damaged.” Each device manufacturer must determine based on individual risks and requirements if such wetted packages are still fit for use.
GUIDELINES FOR PRINTING

Styles of Tyvek® for medical and pharmaceutical packaging can be printed using standard commercial printing equipment and suitable inks. Because of the unique requirements for medical and pharmaceutical packaging, these styles have no antistatic coating and are not corona treated. Therefore, special steps must be taken to obtain optimum printing results. When printing on Tyvek® medical and pharmaceutical packaging styles, we recommend testing before proceeding with production operations.

For additional information about printing on Tyvek®, refer to the DuPont™ Tyvek® Users Manual and the DuPont™ Tyvek® for Graphics website.

Flexographic printing guidelines

Flexography is the recommended technique for printing on Tyvek® medical and pharmaceutical packaging styles. For best results, use the smooth side of the sheet. The difference between the rough (“wire”) side and the smooth side is minor, but can usually be felt. Rolls supplied directly from DuPont are wound smooth side out. Rolls supplied from a sterile packaging manufacturer (SPM) may be wound differently. Be sure to check with your SPM or supplier to determine how your rolls are wound.

To help you determine the rough from the smooth side, a simple six-step procedure has been developed. For details, see “Determining the rough vs. smooth side of Tyvek®.” Other important recommendations are listed here.

Press conditions for flexography

Ensuring optimum press conditions will help prevent sheet distortion, registration problems in multi-color work, softening of adhesives and ink pick-off.

- Tensions—Keep tensions below 0.75 lb/in. of width.
- Temperatures—Maintain web temperatures below 175°F.
- Chilled rolls—Use chilled rolls before windup.
- Reduce the web temperature prior to wind-up on a chill roller. This helps to prevent blocking and minimizes distortion, and is essential for printing on Tyvek® medical and pharmaceutical packaging styles.

Printing plates for flexography

Selecting the appropriate type of printing plate is dependent upon the nature of the printing job. General printing best practices should be followed to optimize the conditions of the pressroom for ultimate performance. Printing variables include the plate, cushion, ink and anilox. As always, it is best to clean the printing plate with 100% alcohol prior to inking to enhance ink transfer.

For printing solids, type and other fine detail-oriented images, it is best to use a medium durometer plate mounted on a medium firm cushion tape. For images that include fine line screens with dots, it is best to use a higher durometer plate. This should be mounted on a medium firm cushion tape.

For both, anilox selection should be based on a line screen volume that does not over-ink the plate. Please seek manufacturer’s guidelines for viscosity, pH and other transfer properties that are dependent on your ink application and resistance properties.

Recommended printing plates:
- Digital Solvent—use DuPont™ Cyrel® EASY ESX or Cyrel® EASY EPR
- Digital FAST—use Cyrel® EASY EFX or Cyrel® DFP
- Analog—use Cyrel® NOWS or Cyrel® EXL

Inks for flexography

It is important to not only choose the proper ink for the process, but to verify the suitability of the ink in applications where direct contact with the medical device is likely.

- Alcohol-based polyamide inks—These solvent-based inks typically provide the best adhesion and rub resistance. Adding microcrystalline wax will reduce the offsetting.
- Water-based inks—These inks make it possible to achieve high-quality results while complying with environmental regulations.
Lithographic printing guidelines

Although flexography is the recommended method for printing on Tyvek® medical and pharmaceutical packaging styles, offset lithography can produce acceptable print quality. For best results, use the smooth side of the sheet. The difference between the rough (“wire”) side and the smooth side is minor, but can usually be felt. For details, see “Determining the rough vs. smooth side of Tyvek®.”

Rolls supplied directly from DuPont are wound smooth side out. Rolls supplied from an SPM may be wound differently. Be sure to check with your SPM or supplier to determine how your rolls are wound.

Offset blankets for lithography

Selecting the appropriate type of blanket to use will depend on whether or not the Tyvek® is coated.

- For adhesive-coated Tyvek®—Use conventional offset blankets of medium hardness.
- For uncoated Tyvek®—Use compressible offset blankets.

Squeeze recommendation for lithography

Applying an additional 3 mil to 4 mil of squeeze between the blanket and back cylinder is required compared to that used for paper of equivalent average thickness. This additional impression, coupled with the compressibility of Tyvek®, compensates for possible thickness variations of Tyvek®.

Inks for lithography

It is important to not only choose the proper ink for the process, but to verify the suitability of the ink in applications where direct contact with the medical device is likely. In addition, follow these specific recommendations for printing on Tyvek® medical and pharmaceutical packaging styles.

- Low-solvent-content inks—Use inks with <3% volatile solvent because hydrocarbon solvents found in many litho inks tend to swell and distort Tyvek®. These inks also release fewer volatile organic compounds (VOCs) compared to traditional offset inks.
- Extra-strong colors—Use extra-strong colors to keep ink film thickness to a minimum (<0.3 mil). This will help minimize sheet distortion and dot gain.
- Tint creation—Use opaque white rather than an extender when creating tints to minimize the appearance of fiber swirl.
- Fountain solution—Maintain fountain solution at a minimum level. Either conventional water or alcohol/water dampening systems can be used. Alcohol substitutes also work well. Do not increase the ink volume if your images appear dull or washed out. Instead, reduce the amount of dampening solution in the fountain.
- Drying—Litho inks dry more slowly on Tyvek® than they do on paper, so be sure that pile height does not exceed 20 in. Winding the sheets and maintaining the fountain solution at a pH between 4 and 5 can accelerate drying.

More information about ink and printing machine manufacturers familiar with the unique requirements of printing on Tyvek® medical and pharmaceutical packaging styles can be obtained by contacting your local DuPont representative.

Special notes for adhesive-coated Tyvek®

When selecting offset inks, it is important to advise the ink supplier if the Tyvek® has an adhesive coating because special ink formulations may be required to prevent ink set-off to the coated surface. In some cases, printing is done on the adhesive side. This also should be discussed with the ink supplier to ensure optimum compatibility between the ink and the coating.
Variable information printing
The need to print variable information on packages has resulted in an increased use of electronically controlled printing processes. These electronic devices can output variable information such as: lot, production date, sequential numbering, product codes and bar codes. Tyvek® medical and pharmaceutical packaging styles are compatible with some of these processes.

Thermal transfer printing
The most common process for printing variable information is thermal transfer. This process uses heated pins to activate a pigmented wax, resin or wax/resin blend that is carried on a ribbon. The image is created when the molten ink transfers to the substrate.

Wax ribbons give the best results for Tyvek® medical and pharmaceutical packaging styles (which are not corona treated). The image durability is marginal. If more durability is required, a wax/resin blend ribbon should be used. A 90/10 wax/resin blend ribbon yields good results. This blend ribbon may need to be custom manufactured because many ribbon manufacturers only stock 50/50 blend ribbons.

Excellent results in printing alpha-numeric information have been achieved using 300- to 600-dpi printers. Because of the inherent thickness variability of Tyvek®, thermal transfer printing on Tyvek® tends to produce D-C ANSI bar code quality. If a high-density bar code is needed, or a higher-quality bar-code rating is specified, a label should be used.

Ink jet printing
Tyvek® medical and pharmaceutical packaging styles have been printed successfully using continuous and drop-on-demand ink jet printers. However, because Tyvek® is made of high-density polyethylene (HDPE) and does not absorb moisture, solvent-based inks are preferred. Some water-based inks are slower drying and tend to feather on Tyvek®, resulting in a blurry image. Acceptable results have also been achieved with ultraviolet (UV) and change-of-phase inks, which cure almost instantly. Typically, 200- to 300-dpi print heads are used.

Laser (electrostatic) printing
Conventional laser printing is not recommended for Tyvek® because the high temperatures used to set the toner distort the Tyvek® during normal printing and will melt the Tyvek® if a jam occurs. Cool-process (flash-fusion) laser printers are compatible with Tyvek®; however, the toner transfer efficiency is marginal and the printed image is not as sharp as it is with thermal transfer or ink jet printers.
Printing assessment—Barcode readability tests

Unique device identification (UDI) requires the printing of complex barcodes. DuPont conducted barcode readability tests to demonstrate that the printing of barcodes directly on Tyvek® shows good results. Please note that results may vary when using different printing equipment or other barcode readers than those used in this study.

Both flexography and thermal transfer printing technologies were assessed on Transition Tyvek® 1073B. The samples were printed on versatile test equipment, which can be switched from one printing technology to another in a few minutes by simply changing the printing modules.

For the barcode readability test, three different types of barcode readers were used:

- Regular 1D laser scanner—A standard range laser barcode scanner can only be used for reading 1D barcodes by pointing the laser beam over the barcode horizontally.*
- 2D barcode imager—A 2D barcode imager operates as a camera with barcode decoding capabilities. An illuminated square indicates the area where it reads. The 2D imager can read both 1D and 2D codes.*
- 2D DPM reader (Direct Part Marking)—The core of a DPM reader is the same as a regular 2D imager. The differences are found in the reader’s optics, decoding software and illumination, which are altered specifically for DPM codes to read contrast on these difficult materials. DPM codes are often applied on reflective surfaces such as metal and plastic.*

*Information supplied courtesy of OPAL Associates B.V.

Barcode readability test details:

- Result is a pass (= readable) or a fail (= not readable)
- Four different barcodes have been tested
- The barcodes have been selected according to GS1 standards; size and details are listed in Figure 41
- Six samples per barcode type have been scanned
- 6P/6 means: Six Pass for six scanned barcodes
- 0P/6 means: Zero Pass for six scanned barcodes

<table>
<thead>
<tr>
<th>FLEXOGRAPHIC PRINTING</th>
<th>EAN 13</th>
<th>GS1 128</th>
<th>GS1 DATAMATRIX</th>
<th>GS1 DATAMATRIX</th>
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<tr>
<td>1D Barcode</td>
<td></td>
<td></td>
<td>2D Barcode</td>
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</tr>
<tr>
<td>Size: 21 x 8 mm</td>
<td></td>
<td></td>
<td>Symbol size: 18 x 18</td>
<td></td>
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<tr>
<td>Barcode readability with handheld barcode scanner</td>
<td>Transition Tyvek® 1073B</td>
<td>Transition Tyvek® 1073B</td>
<td>Transition Tyvek® 1073B</td>
<td></td>
</tr>
<tr>
<td>Regular 1D laser scanner</td>
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<td>0P/6</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>2D barcode imager</td>
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<td>5P/6</td>
<td>6P/6</td>
<td>5P/6</td>
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<tr>
<td>2D DPM reader</td>
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<tr>
<th>THERMAL TRANSFER PRINTING</th>
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<th>GS1 DATAMATRIX</th>
<th>GS1 DATAMATRIX</th>
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<tr>
<td>1D Barcode</td>
<td></td>
<td>2D Barcode</td>
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<tr>
<td>Size: 55 x 12 mm</td>
<td></td>
<td>Symbol size: 12 x 12</td>
<td></td>
</tr>
<tr>
<td>Barcode readability with handheld barcode scanner</td>
<td>Transition Tyvek® 1073B</td>
<td>Transition Tyvek® 1073B</td>
<td></td>
</tr>
<tr>
<td>Regular 1D laser scanner</td>
<td>6P/6</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>2D barcode imager</td>
<td>6P/6</td>
<td>6P/6</td>
<td></td>
</tr>
<tr>
<td>2D DPM reader</td>
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</tbody>
</table>

Figure 41. Barcode readability results for Transition Tyvek® 1073B.
**Application guidance**

**LABELING**
A number of adhesives can be used to glue spunbonded olefin, either to itself or to other substrates.

Water-based synthetic adhesives, such as ethylene/vinyl acetate adhesives and the acrylic pressure-sensitive adhesives, work well with Tyvek®. The synthetic adhesives that contain low-molecular weight materials can act as solvents at elevated temperatures, causing swelling and wrinkling.

Polyurethane adhesives provide optimum adhesion, flexibility and water resistance for adhering Tyvek® to itself and to a variety of substrates. Hot melt polyamide adhesives form good bonds to Tyvek® with a variety of materials.

The first step in choosing an adhesive is to verify if any of the components may interact with Tyvek®. Consultation with the adhesive manufacturer is recommended.

For optimized performance during gas sterilization, it is important to keep enough uncovered porous area to allow for the sterilization gases to enter the package and escape.

For additional information, see “Chemical resistance” in Section 2, “DuPont™ Tyvek™—Properties.”

**HEAT SEALING GUIDELINES**

The resultant material bond and seal strength of a heat seal packaging process depends on several factors, including: sealing temperature, sealing dwell time, sealing pressure, characteristics of the sealant, the sealing machine and even the test method used to measure the seal strength.

Seals must be strong enough to withstand the rigors of shipping, handling and storage, yet at the same time facilitate easy access for the end-user to open the sterile package using aseptic presentation techniques. Optimizing the heat sealing process and consistently producing packages with the appropriate seal strength is of critical importance because it can have a direct impact on product efficacy and patient safety.

The primary heat seal factors of temperature, time and pressure are interactive. A change or tweak in one typically requires a change or tweak in one or more of the other factors. A balance between time, temperature and pressure must be met to achieve the desired seal strength, seal integrity, visual seal transfer and desired opening behavior.

It is recommended to optimize the heat sealing process using tools such as Design of Experiments and the evaluation of heat seal curves, depending on the complexity of the process and parameters. The objective is to define an operating (sealing) window with validated minimum, nominal and maximum sealing conditions. This not only results in a heat sealing process that consistently produces acceptable seals, but also can optimize energy output and operational throughput and efficiencies.

**Sealing temperature**

The heat sealing process, as previously described, marries two materials and creates a bond. To achieve this bond, one of the materials typically carries a surface sealant layer. The heating elements of heat seal packaging equipment are raised to a temperature high enough to either melt or activate the sealant.

In the case of packaging made of Tyvek® and film, the sealant is either on the Tyvek® side in the form of a heat seal coating or on the film side. It is important to ensure that the respective coating, film and sealant are compatible with the chosen sterilization method. There are different types of coatings and films with sealant available on the market that work well with Tyvek®. Contact your local DuPont representative to learn more about potential suppliers.

Temperatures must be high enough to activate the sealant layer, while not overheating the surface of the material and inducing extreme transparentization. The actual temperature, as well as the distribution of the temperature should be verified using sensor paper or more sophisticated electronic sensor technologies.

Depending on the activation temperature of the sealant, raising the temperature and lowering the dwell time or lowering the temperature and raising the dwell time could produce more consistent seals without transparentizing the Tyvek®.

**Sealing dwell time**

Sealing dwell time refers to the time the heating elements of a packaging process (clamps, plates, bars, etc.) are in direct contact with the substrate(s). It can be either one-sided or two-sided heating. The two materials come together to form a bond or seal. It is important to understand how the equipment measures the dwell time to determine “true dwell time,” which is when the webs are actually pressed together. That’s because controls for heat sealing equipment vary and cycle time may or may not include travel time for the machine to engage into its final closed position. Any variation in the rates of materials reaching their seal initiation temperature, even by fractions of a second, can have a measureable effect on seal strength.

**Sealing pressure**

The third key factor of heat sealing is the pressure at which the equipment brings together and holds the two materials together to form the seal. It is important to know the actual pressure the substrates are exposed to because this value is often not equivalent to the input pressure or the set point on the machine controls. There are many techniques to measure...
sealing pressure—from sensor paper to more sophisticated electronic sensor technologies.

For most heat seal materials, studies have shown that pressure is the least significant of the three factors required to make a heat seal. Pressure must be sufficient to ensure proper contact area between the materials. If pressure is too high while reaching the sealant’s melting point, outward flow of the sealant may occur and affect the package’s opening behavior.

Other factors
The three main factors for heat sealing—temperature, dwell time and pressure—can produce significant variability in seal strength. However, there are other factors related to time, temperature and pressure that can also affect heat seals. Some common factors include:

- Variation in platen temperature—“hot spots” or “cold spots”
- Non-uniform heat transfer due to uneven contact or pressure caused by a warped or misaligned platen
- Pressure not defined or adjusted in relation to seal surface when switching seal designs (applied pressure changes based on the amount of seal surface)
- Material thickness or variation

Sensor paper or more sophisticated electronic sensor technologies can be used to detect variations in platen temperature or uneven pressure.

To produce uniform seal strengths resulting in clean, pealable seals that are strong enough to withstand the rigors encountered during shipping, handling and storage, it is important to develop a robust heat sealing process by optimizing the temperature, dwell time and pressure for specific material combinations. An operating (sealing) window must be properly defined and validated.

THE UNIQUE STRUCTURE OF TYVEK®

The DuPont™ Tyvek® Medical Packaging Transition Project (MPTP) testing and global market feedback have shown that sealing performance is exceptional using properly validated processes. It is recommended to run three different lots of material for validation purposes.

The seal strength distribution graph (Figure 42) demonstrates an equal temperature transfer. This example is based on one material combination (uncoated Transition Tyvek® 1073B sealed to a 100-gauge bi-axial nylon with HDPE film). The seal strength has been tested according to the ASTM F88 free tail method and averages have been calculated from more than 500 data points.

**Figure 42.** Pouch seal strength distribution for uncoated Transition Tyvek® 1073B sealed to a 100-gauge bi-axial nylon with high-density polyethylene (HDPE) film (ASTM F88).

**Figure 43.** Microscopic view of DuPont™ Tyvek® (200x magnification).*
DETERMINING THE ROUGH VS. SMOOTH SIDE OF TYVEK®

Tyvek® material has two sides; one is called the “smooth” side and the other is called the “rough” side. When looking at the two sides, a difference in structure can be perceived. The rough side comes into contact with the belt during the spinning process and, therefore, shows a pattern. See Figures 44 and 45 for microscopic photos showing the difference between the smooth vs. rough side of (uncoated) Tyvek®.

Figure 44. Microscopic view of the smooth side of DuPont™ Tyvek® (25x magnification).

Figure 45. Microscopic view of the rough side of DuPont™ Tyvek® (25x magnification).
When sealing Tyvek®, it is important to always seal to the rough side. Sealing to the smooth side may result in fiber tear. Typically, rolls of Tyvek® are wound smooth side out when they are shipped.

If needed, the following steps can be used to verify which way the roll is wound:

Tyvek® can also be supplied in coated form from SPMs. The coating is usually applied on the rough side of Tyvek®. Please ask your supplier for more information.

1. Fold back the edge of the Tyvek® approximately 6 in. and crease flat. NOTE: If the roll is wound correctly with the smooth side out, the folded area will be the rough side.

2. Cut a strip of 1 in. wide ARclad® AR-516 tape approximately 8 in. long. Place it on the “seam” so that approximately ½ in. is on the smooth side and ½ in. is on the rough side.

3. Smooth the tape down by running your finger along the “seam” one or two times. Use moderate pressure.

4. Using a felt tip pen or marker, draw a line on one side of the tape, extending the line onto the Tyvek® for easy identification.

5. Peel off the strip of tape.

6. Look at the adhesive side of the tape and note which half shows evidence of fiber tear. This will be the smooth side. NOTE: If you have any doubt, take the existing flap and fold it back on itself approximately 2 in. to create a new “seam.” Then, repeat steps 2 through 6.
**PACKAGE QUALITY EVALUATION**

The most important requirement for a medical package is to maintain sterility until the point of use. It must be demonstrated that a sterile barrier system (SBS) can keep its integrity through all the steps of the value chain. The base condition is a validated packaging process that produces a good quality seal and thus allows for barrier performance against the migration of microorganisms.

There are different test methods used for package quality evaluation on the market. Below are a few examples. These and more test methods are listed in Annex B of ISO 11607 Standard Packaging for terminally sterilized medical devices. For additional information, consult the ASTM F2097 Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products.

**Strength of package closures:**
- ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1140 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages

**Seal integrity:**
- ASTM F1886 Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection
- ASTM F1929 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
- ASTM F2096 Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)
- ASTM F2228 Standard Test Method for Non-Destructive Detection of Leaks in Packaging Which Incorporates Porous Barrier Material by CO₂ Tracer Gas Method (Porous materials to be covered)
- ASTM F2338 Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method (Porous materials to be covered)
- ASTM F3004 Standard Test Method for Evaluation of Seal Quality and Integrity Using Airborne Ultrasound

**Microbial barrier:**
- ASTM F2638 Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier

A well-defined testing strategy is the basis for the qualification of a safe and reliable SBS.

DuPont conducted an extensive study to evaluate the performance of standard chevron pouches made with either Legacy Tyvek® 1073B, Tyvek® 2FS™ or one of five different medical-grade papers. Tests performed were seal strength and package integrity after sterilization (EO, gamma), after accelerated aging and after conditioning and subsequent transportation testing.

In a second study, microbial barrier testing was conducted before and after sterilization (EO, gamma) and subsequent transportation testing.

To learn more, download the white papers titled "Medical Packaging Study—Reducing the Risk of Failure through Performance Testing of Packaging Made from Various Materials" and “Medical Packaging Study—The Impact of Sterilization and Transportation Testing on the Microbial Barrier of Different Materials” found at our Medical Packaging Knowledge Center.
SLITTING OF TYVEK®

Tyvek® filaments are very strong. When slitting Tyvek®, all cutting parts should be kept clean and sharp, with true, well-supported, nick-free edges to obtain a clean cut.

To reduce the buildup of static, antistatic equipment, such as ionizers to control static charges on the material, can be used.

There are different slitting methods and knives used to cut Tyvek®:

- Crush cutting—A steel knife with a sharp, slightly rounded edge lasts longer than one with a pointed edge
- Other slitting methods—A sharp edge is recommended:
  - Shear cut—steel blades such as those used in automated form-fill-seal machines
  - Razor cut—steel, ceramic or tungsten carbide blades
  - Die-cut—steel rule or male/female dies

Because Tyvek® 2FS™ contains TiO₂ opacifier, it may wear slitting blades faster than other Tyvek® medical and pharmaceutical packaging styles. Ceramic blades can be used to slit Tyvek® 2FS™.

PROCESSING/TROUBLESHOOTING GUIDELINES

Avoiding fold problems

A sheet of Tyvek® is a monolayer material that is heat treated or bonded on both sides. This treatment makes the exterior less flexible than the interior of the structure and allows the monolayer material to perform more closely to a multilayer structure (Figure 46).

When any sheet structure is bent, the outer surface is placed in tension while the inner surface is placed in compression. The tighter the bend, the greater these forces become. If these loads become excessive, the filament structure holding the two layers together will succumb to the forces and the inner surface will buckle inward (Figure 47).

Figure 46. Pictorial representation of DuPont™ Tyvek® during package opening.

Tyvek®, a monolayer material, acts like a multilayer material represented by the green/yellow/green layers.

Figure 47. Pictorial representation of DuPont™ Tyvek® during opening at an extreme angle.

An extreme fold or bend puts the exterior surface in tension and the interior surface in compression, causing the interior of the sheet to buckle.
The result will be the formation of a delaminated area along the center line of the sheet of Tyvek®. This is commonly seen when the flexible edge of the pouch seal is bent or folded to fit into a shelf carton. With the pouch film on the outside of the bend, all of the force to make the fold is converted to compression loads on the inner surface of the sheet of Tyvek®, which may lead to separation within the interior of the sheet, commonly referred to as sheet separation (Figure 48). However, it has been demonstrated that this phenomenon does not compromise the integrity of the package.

Specifically, samples were designed that would allow a microbial aerosol challenge to be applied to both the sheet of Tyvek® and the seal section containing the delaminated area. The samples were placed in the apparatus used in the ASTM F1608 and ASTM F2638 microbial barrier tests. No reduction in Log Reduction Values (LRV) for ASTM F1608 or percent penetration rates for ASTM F2638 was observed.

Sheet separation is typically encountered during the qualification phase of package testing. During underwater bubble leak testing (ASTM F2096:2002) a pouch with sheet separation will produce a stream of air bubbles that appear to be a channel in the seal. This result requires additional lab testing to determine if there is truly a channel in the seal or if sheet separation has produced a false positive.

A dye penetration test (ASTM F1929:2003) is used to differentiate a channel (Figure 49) from sheet separation. Lab technicians must follow the ASTM protocol when performing the test to ensure “wicking” is not produced.

If dye is left too long in the pouch made with Tyvek®, the dye begins to wick through the material (Figure 50).

Figure 48. Micrograph of folded DuPont™ Tyvek® showing sheet separation, a phenomenon that does not compromise the integrity of the package.

Figure 49. Channel in seal determined during dye penetration testing (ASTM F1929:2003).

Figure 50. Wicking occurs when dye is left too long in the pouch during ASTM F1929:2003 testing.
Another way to confirm sheet separation vs. a channel is to reserve the pouches after dye testing, wait until the residual dye has dried and then peel the pouch open to reveal either dye in the sealed area, indicating a channel in the seal, or no dye, indicating sheet separation. In addition to the possible phenomena of internal sheet separation, there is another point to consider when folding Tyvek® sterile barrier systems (SBS): the edge of the fold may be in direct contact with the secondary packaging (shelf carton) and result in severe abrasion points. Although Tyvek® resists abrasion better than other porous materials, severe abrasion can cause holes in any material.

One example is a pouch folded over the edge of a “sharp” tray in a shelf carton exposed to vibrations during transport (Figure 51).

Figure 51. Pouch folded over the edge of a rigid tray.

The best way to avoid sheet separation, false positives and abrasion points is to avoid folding pouches. However, if the package fold is necessary, opt for a gentle curl instead of a true fold.

For more information, read “Porous Sterile Barrier Integrity Testing: Failure Anomalies,” an article that was published in the January 2006 issue of *MD&DI* magazine. This article can be found in the magazine’s online archive.

Over sealing or no seal transfer

Over sealing or insufficient seal transfer may occasionally occur. A proper investigation is important.

How can this be avoided?

- Choose the right sealant (either on the film or on the Tyvek® side)
- Adjust the sealing parameters
- Add a sheet of Teflon® to the top of the heat platen
- Control the pressure and temperature distribution on the sealing platen (sensor paper or more sophisticated electronic sensor technologies can be used)
- Check for contamination on the sealing platen
- Check the condition of the sealing platen and sealing rubber
- Select an appropriate durometer/stiffness of the sealing rubber (talk to the supplier of your packaging machine)

Seal integrity testing will help to assess the risk linked to any seal issues.

Fiber tear

Even though Tyvek® is much stronger than most other porous materials, fiber tear and/or delamination may occasionally occur. A sharp bend of Tyvek® as it is being peeled from the film web, rough cut edges, high sealing temperatures and other factors can lead to fiber tear, which usually results in a partial delamination of the Tyvek® sheet. (See “Avoiding Fold Problems” for a description of how this delamination occurs.)

To eliminate fiber tear, the first option is to reduce the seal strength. If this does not produce the desired result, you can consider either of the following possible solutions:

- Use a more flexible film that will not force Tyvek® to bend as much when the seal is opened.

OR

- Use a heavier basis weight of Tyvek® that has a greater bend radius and a lower tendency to delaminate.

AND

- Ensure that you use an appropriate sealant either on the Tyvek® or on the film side to allow for good peel functionality.

Cutting and slitting Tyvek®

Blades, cutting wheels and dies need to be maintained so they are sharp and free of nicks and other imperfections that could cause rough, irregular cuts. Irregular edge cuts could enable films or foils to adhere to filaments from the center region of the Tyvek® sheet during heat sealing. This attachment to individual filaments, as opposed to the bonded Tyvek® surface, could cause fiber tear and/or delamination during peeling.
Application guidance

Forming pouches
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 and/or delamination 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. Singularizing pouches across the web should be performed in unsealed areas between pouches.

Sealing lids to trays and form-fill-seal (FFS) packaging
Several factors cause or greatly increase the occurrence of fiber tear when opening lids sealed to either rigid or flexible thermoformed trays. Eliminating these factors can greatly reduce the probability of fiber tear and allow for a clean peel opening.

Figure 53 demonstrates various lid placements on a tray and the predicted result after peeling. A leading cause of fiber tear is improper lid placement and/or improper lid size.

Any edge trim removed from outside pouches on the web after sealing should be cut off in an unsealed area.
Lids should not be sealed all the way to the edge of the tray (Figure 52). 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 and/or delamination during peeling.

Additionally, if the edge of the lid has a microscopic nick or rough cut edge, this can act as an initiation point for a tear when the lid is peeled. Tooling should be designed so that an unsealed area of at least 1 mm resides between adjacent trays in the case of FFS packaging, also known as a “skirt” (Figure 54), or in the case of an individual thermoformed tray, the lid overhangs the outer tray edge by at least 1 mm.

Figure 54. Multiple cavity thermoform with “skirt” seal or gap between sealed areas. Unsealed gap avoids the risk of delamination.
In an experiment conducted by DuPont, lid placement was a strong predictor of whether or not the lid would experience fiber tear during opening (Figures 55 and 56). The physics of peeling open a lid from a tray requires an adhesive break of the bond between the heat seal coating and the tray. A proper adhesive break leaves the heat seal coating on the tray (white witness mark) and allows the lid to peel cleanly away from the tray. An oversized lid allows for clean initiation of the peel.

**Figure 55.** DuPont sealing experiment to test the effect of lid placement on fiber tear.
Proper lid placement with minimum of 1-mm lid overhang all the way around the tray. All 32 samples showed consistent seal area and no delamination during opening.

**Figure 56.** Results of improper lid placement during DuPont sealing experiment.
There was no overhang; lid length and width dimensions were equal to the tray seal area dimensions. A total of 26 out of 32 samples experienced fiber tear ranging from minimal to extreme.
Summary—How to reduce the risk of fiber tear and/or delamination

- Use a more flexible film or a heavier basis weight of Tyvek®
- Choose the right sealant (on the Tyvek® or the film)
- Avoid over sealing; adjust the sealing parameters (seal strength)
- Use only sharp, nick-free knives for cutting
- Do not cut through the seal; place the lid accordingly on the tray

CONTROLLING STATIC CHARGES DURING CONVERTING OPERATIONS

Static electricity is an accumulation of electrical charges on a surface (positive or negative). There can be an overabundance of electrons (negative charges) or a deficiency of electrons (positive charges) on the surface of an insulating material such as nonwoven material or plastic film. A charge can also accumulate on a conductor, such as a metal roll, machine part or the human body, if it is isolated from electrical ground. Tyvek® for medical and pharmaceutical packaging applications does not have an antistatic treatment applied. When converting Tyvek® on processing equipment (such as a lid cutting machine), static charge occurs.

Therefore, it is strongly recommended to install appropriate antistatic equipment such as ionizers to control static charges on the material. There are specialized companies that can provide support in helping you to define the correct measures. Additional information can be obtained by contacting your local DuPont representative.

RECYCLING OF TYVEK®

As for ecological responsibility, Tyvek® is an excellent choice. This lightweight, durable material can be an effective way to conserve resources and demonstrate environmental stewardship. Tyvek® is produced under verified environmental management policy according to ISO 14001.

Tyvek® can be recycled at local recycling facilities that accept flexible HDPE waste according to local legislation. The items sent for recycling must not have been in contact with any hazardous substance.

DuPont and other leading companies in the healthcare, recycling and waste management industries have come together to form the Healthcare Plastics Recycling Council (HPRC). The technical coalition is working to inspire and enable sustainable, cost-effective recycling solutions for plastic products and materials used in the delivery of healthcare. Visit the HPRC website for more information.

Mechanical recycling

Tyvek® or products made from Tyvek® can be mechanically recycled into products such as underground cable protection piping, automotive parts, blown film, packaging cores and trays. Products made from Tyvek® that are printed, glued, welded or sewn can also be recycled, as can Tyvek® that has been extrusion coated or laminated with an item from the same polymer family.

Chemical feedstock recycling

Tyvek®, together with other synthetic waste, can be processed through chemical feedstock recycling. The chemical components are separated and these basic raw materials are recovered for reuse, thus reducing consumption of new oil resources.
### Test methods and standards

#### Table XIV. Test methods and standards

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## Test methods and standards

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Methods for measuring properties

Aligned Test Methods and Sampling Plans for DuPont™ Tyvek®
Medical and Pharmaceutical Packaging Styles
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<td>CFU</td>
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<td>Coefficient of Friction</td>
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<td>FTIR</td>
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<td>Log Reduction Value</td>
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# Guide to some common industry acronyms

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<td>Moisture Vapor Transmission Rate</td>
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<td>PDA</td>
<td>Parenteral Drug Association</td>
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<td>pMax.</td>
<td>Maximum Particle Penetration</td>
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<td>RH</td>
<td>Relative Humidity</td>
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<td>SAC</td>
<td>Standardization Administration of the People’s Republic of China</td>
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<td>SAL</td>
<td>Sterility Assurance Level</td>
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<td>SBA</td>
<td>Sterile Barrier Association (formerly ESPA, European Sterilization Packaging Association)</td>
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<td>SBS</td>
<td>Sterile Barrier System</td>
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<td>SEM</td>
<td>Scanning Electron Micrograph</td>
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<td>SPM</td>
<td>Sterile Packaging Manufacturer</td>
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<td>TAG</td>
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</tr>
<tr>
<td>UDI</td>
<td>Unique Device Identification</td>
</tr>
<tr>
<td>USP</td>
<td>United States Pharmacopeia</td>
</tr>
<tr>
<td>UV</td>
<td>Ultraviolet</td>
</tr>
<tr>
<td>VH202</td>
<td>Vaporized hydrogen peroxide</td>
</tr>
<tr>
<td>VOCs</td>
<td>Volatile Organic Compounds</td>
</tr>
</tbody>
</table>
References


Tyvek™ for Medical and Pharmaceutical Packaging Reference Library.

For more information about DuPont® Tyvek® for medical and pharmaceutical packaging and to find out how we can help you with packaging and regulatory compliance, visit us at www.MedicalPackaging.DuPont.com.

You can also find links to other resources in your country and information in other languages at this website.

This document is not intended for use in the People’s Republic of China.

This Technical Reference Guide is applicable to DuPont™ Transition Tyvek® 1073B and Transition Tyvek® 1059B, as well as Tyvek® 2FS™. In some cases, information based on data that was generated on Legacy Tyvek® is presented. In those cases, this distinction is clearly indicated. Transition Tyvek® has been proven to be functionally equivalent to Legacy Tyvek®. Legacy Tyvek® is either Tyvek® 1073B or Tyvek® 1059B produced on the original manufacturing lines. Transition Tyvek® is either Tyvek® 1073B or Tyvek® 1059B produced on the newer manufacturing lines. This Document is published in October 2017 in addition to the June 2017 Amended version, which is applicable to Legacy Tyvek® 1073B, Legacy Tyvek® 1059B and Tyvek® 2FS™.