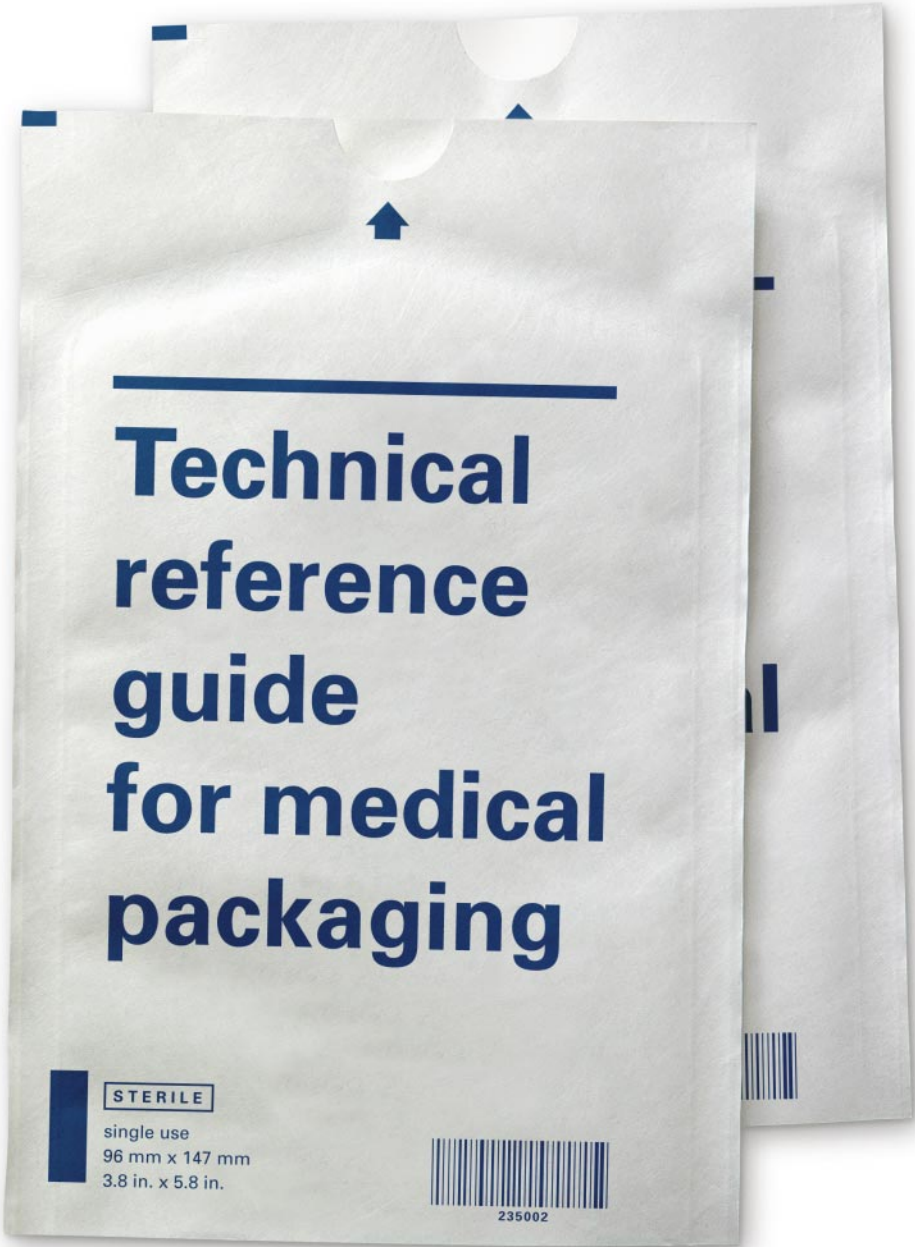


DuPont Medical Packaging



The miracles of science™

Technical reference guide for medical packaging

3 Introduction

5 Why Tyvek® is unique

7 Tyvek® vs. medical-grade papers: a comparison of properties

12 Compatibility with sterilization methods

18 Aging studies

24 Guidelines for printing on Tyvek®

27 Processing/troubleshooting guidelines

31 Glossary of medical packaging terms

35 Guide to some common industry acronyms

Introduction

DuPont™ Tyvek® for medical packaging delivers trusted protection

Since its introduction to the industry more than 30 years ago, DuPont™ Tyvek® brand protective material has been recognized as a standard of excellence for medical packaging. Tyvek® earned this distinction because it provides a higher degree of protection for medical devices and supplies than any other porous material used for sterile packaging applications.

The unique structure of Tyvek® gives it inherent advantages over other materials. Specifically, Tyvek® offers:

Outstanding resistance to microbial penetration

In test after test, Tyvek® held out bacterial spores and test particles better than other porous packaging materials — even under the most rigorous conditions. What's more, 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 here illustrate how bacteria are trapped on the fiber surfaces of Tyvek®.

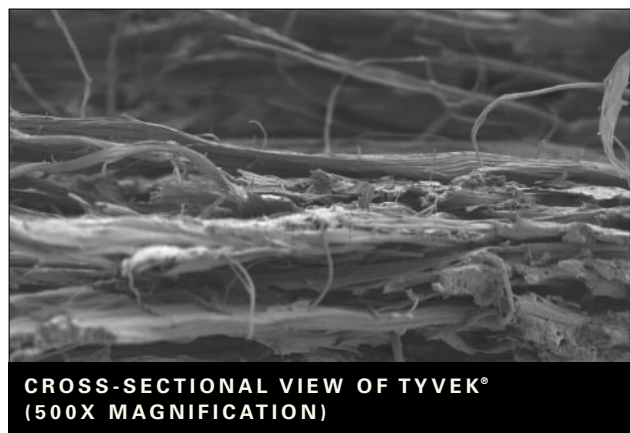
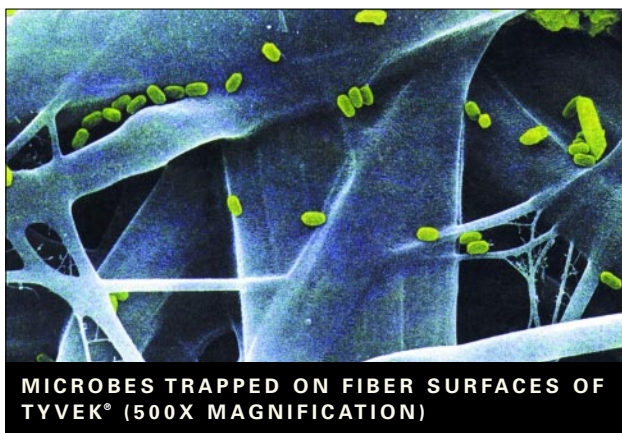


Figure 1. Scanning electron micrographs (SEMs) of Tyvek®.

The unique structure of Tyvek®, which creates a tortuous path with substantial lateral movement, results in superior microbial barrier properties.

Superior tear strength and puncture resistance

The tough, continuous fibers of Tyvek® 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.



Clean peel

Because the structure of Tyvek® makes it low linting, virtually no airborne particles are generated when packages are opened. This clean peel minimizes the risk of introducing particulates into a clean environment.

Compatibility with a broad range of sterilization methods

Only Tyvek® is compatible with all of the most commonly used sterilization methods. No matter which process you use: ethylene oxide (EtO), gamma, electron-beam, steam (under controlled conditions) or newer methods, such as the STERRAD® Sterilization System, Tyvek® will retain its protective properties, color and flexibility.

Bioburden

The process of manufacturing Tyvek® allows only short periods of time when the sheet is subject to airborne particulates and microbes; therefore, the bioburden on the surface of Tyvek® is very low. This low bioburden does not add significantly to the required sterilization time. Measured as colony forming units (cfu) per ft², the typical bioburden for Tyvek® 2FS™ is 62; for Tyvek® 1059B is 93; and for Tyvek® 1073B is 80.

Ideal fit with environmental goals

As for ecological responsibility, Tyvek® is an excellent choice. This lightweight, durable material is an effective way to conserve resources and demonstrate environmental stewardship. It is lightweight for the performance delivered and is recyclable. It can also be cleanly incinerated or easily landfilled. Due to its porous structure, if compressed, Tyvek® would have less than half its thickness. In the United States, Tyvek® can be recycled at more than 70 facilities nationwide that accept flexible high-density polyethylene (HDPE) with the SPI #2 symbol. In Europe, Tyvek® is produced on a site under verified environmental management policy according to ISO 14000 (EMAS). It can be recycled at local recycling facilities that accept polyethylene waste according to local legislation. The items sent for recycling must not have been in contact with any hazardous substance. There are also several facilities in Asia Pacific that will accept Tyvek® for recycling. For more information, visit www.MedicalPackaging.dupont.com. Visit www.MSDS.dupont.com for a copy of the Material Safety Data Sheet (MSDS).

An industry and technology leader

The DuPont Medical Packaging Team, backed by the vast resources of DuPont, is committed to developing new, cost-effective solutions and providing the support you need to ensure that end-users receive the highest quality medical packaging available. 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 developed a seminar series to help the industry stay on top of standards, regulations and new technologies. In addition, members of our team regularly participate on American Society for Testing and Materials (ASTM-International), International Organization for Standardization (ISO), European Committee for Standardization (CEN), as well as in industry activities, such as the Sterile Barrier Association (SBA, formerly known as ESPA), Association of periOperative Registered Nurses (AORN) Congress, Institute of Packaging Professionals (IoPP), European Medical Devices and Technology Industry Association (EUCOMED) and International Safe Transit Association (ISTA). And, because we want to help future packaging engineers, we established a scholarship program at some of the top packaging science schools.

Why Tyvek® is unique

2

Made of 100 percent high-density polyethylene, Tyvek® brand protective material offers all the best characteristics of paper, film and fabric in one material. This unique balance of properties, which cannot be found in any other material, makes Tyvek® lightweight yet strong; vapor-permeable, yet water- and chemical-resistant, as well as puncture-, tear- and abrasion-resistant. Tyvek® is also low-linting, smooth and opaque. Table I lists specification and other properties of styles of Tyvek® for medical packaging applications. It is important to note that these properties are representative for uncoated Tyvek® as sold by DuPont. Any downstream operations, such as coatings applied by sterile packaging manufacturers, may change these values.

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.

Flash-spinning and bonding process

Tyvek® is formed by a fully integrated process using continuous and very fine fibers (having an average diameter of 4 micrometers) of 100 percent high-density polyethylene that are randomly distributed and nondirectional. (For purposes of comparison, a human hair is approximately 75 micrometers in cross section.) These fibers are first flashspun, then laid as a web on a moving belt before being bonded together using only heat and pressure. By varying both the lay-down speed and the bonding conditions, DuPont technicians can engineer the flashspun sheet to meet market needs, such as Tyvek® in soft and hard structure.

Tyvek® soft and hard structure

Tyvek® soft structure is designed specifically for those textile applications where drape, hand and soft feel are of prime importance, such as limited-use protective garments. Tyvek® hard structure can supplant traditional paper by offering superior tear-resistance and lighter weight. It is ideal for envelopes and graphics applications. A variety of finishing techniques, including embossing, corona treatment (to improve adhesion of printing inks and coatings), anti-static treatment and softening for drapability, allow the product to be fine-tuned to the specific needs of end-users.

Tyvek® for medical packaging applications is not corona treated nor anti-stat treated because these treatments may compromise the barrier characteristics of Tyvek®. The only styles of Tyvek® designed for use in medical packaging applications are: 1073B, 1059B and Tyvek® 2FS™. These styles are manufactured to rigorous quality standards to meet the unique requirements of the medical packaging industry.

Table I. Specification and other properties of styles of Tyvek® for medical packaging

Property	Test Method	Units	Tyvek® 1073B	Tyvek® 1059B	Tyvek® 2FS™
SPECIFICATION PROPERTIES *					
Basis Weight*	ASTM D3776 ¹ DIN EN ISO 536 ¹	oz/yd ² (g/m ²)	2.20 (74.6)	1.90 (64.4)	1.76 (59.5)
Delamination*	ASTM D2724 ²	lb/in. (N/2.54 cm)	0.52 (2.3)	0.50 (2.2)	0.61 (2.7)
Gurley Hill Porosity*	TAPPI T460 ISO 5636-5	sec/100 cc	22	22	22
OTHER PROPERTIES					
Microbial Barrier	ASTM F1608	Log Reduction Value (LRV)	5.2	4.7	3.2
Bendtsen Air Permeability	ISO 5636-3 ³	mL/min	609	638	520
Moisture Vapor Transmission Rate	TAPPI T523 ⁴	g/m ² /24 hr	1615	1640	>1500
Hydrostatic Head	AATCC TM 127 DIN EN 20811 ⁵	in. H ₂ O (cm H ₂ O)	59 (150)	56 (142)	57 (145)
Tensile Strength, MD	ASTM D5035 ⁶ DIN EN ISO 1924-2 ⁶	lb/in. (N/2.54 cm)	43.4 (193)	36.6 (163)	35.1 (156)
Tensile Strength, CD	ASTM D5035 ⁶ DIN EN ISO 1924-2 ⁶	lb/in. (N/2.54 cm)	46.8 (208)	39.2 (174)	35.3 (157)
Elongation, MD	ASTM D5035 ⁶ DIN EN ISO 1924-2 ⁶	%	22	21	23
Elongation, CD	ASTM D5035 ⁶ DIN EN ISO 1924-2 ⁶	%	26	26	28
Elmendorf Tear, MD	ASTM D1424 DIN EN 21974	lb (N)	0.77 (3425)	0.67 (2980)	0.63 (2.8)
Elmendorf Tear, CD	ASTM D1424 DIN EN 21974	lb (N)	0.79 (3514)	0.72 (3203)	0.83 (3.7)
Mullen Burst	ASTM D774 ISO 2758	psi (kPa)	178 (1227)	153 (1055)	134 (925)
Thickness	ASTM D1777 ⁷ DIN EN 20534 ⁸	mils (µm)	7.3 (185)	6.5 (165)	6.11 (155)
Thickness Range	ASTM D1777 ⁷ DIN EN 20534 ⁸	mils (4 sigma) (µm) (4 sigma)	3.5-11.1 (89-282)	2.9-10.1 (74-257)	2.8-9.1 (70-230)
Opacity	TAPPI T425 ISO 2471 ⁹	%	92.4	90.7	94.3

*Specification property (controlled to aim and released within specifications). The customer is responsible for determining that Tyvek® is suitable for the intended application.

Notes: All properties are typical values based on roll averages, with samples taken uniformly across the sheet. Customers must conduct their own tests to ensure suitability for the intended application. These properties are representative for uncoated Tyvek® as sold by DuPont. Any downstream operations, such as coatings applied by sterile packaging manufacturers (SPMs), may change these values.

MD = machine direction; CD = cross direction.

1. Modified sample size.
2. For Tyvek® 2FS™, test was modified for speed and gauge length.
3. ΔP = 0.22 psi (1.5 kPa), area 10 cm².
4. Test conditions: 73°F (23°C)/85% relative humidity.
5. Rate of use: 60 cm H₂O/min.
6. Modified for speed and gauge length.
7. 7.15 psi, 0.625-in. diameter presser foot.
8. Surface 2 cm², pressure 14.5 psi (100 kPa).
9. Modified for different backing standards, area and illumination.

Tyvek® vs. medical-grade papers: a comparison of properties



Tyvek® brand protective material offers an optimum balance of microbial penetration resistance, tear strength, puncture resistance and clean peel, as well as compatibility with existing and new methods of sterilization. The secret to the superior performance of Tyvek® is that it's not a paper, but rather a sheet of flashspun and bonded high-density polyethylene (HDPE) fibers. Continuous strands of very fine, interconnected fibers are randomly 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.

Figures 1 through 6 show that Tyvek® consistently outperforms medical-grade papers in test after test.

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 bacteria spores and other contaminating microorganisms. Bacteriological tests clearly demonstrate that Tyvek® outperforms other commercially available porous packaging materials, including medical-grade papers. Comprehensive shelf-life studies have shown that Tyvek® can maintain sterility for at least five years if package integrity is not compromised. (See **Aging studies**, section 5, for details.)

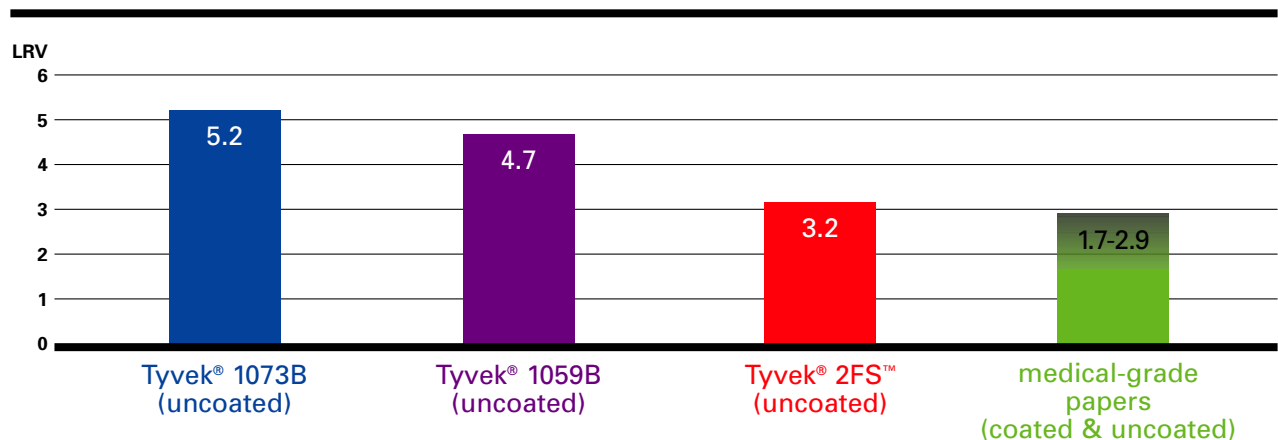


Figure 1. Microbial barrier test results.

Per ASTM F1608. Microbial barrier is the measure of the ability of a porous substrate to prevent bacteria penetration. A completely impermeable control sample (microbial penetration is zero) is challenged with one million or 10^6 colony forming units (cfu). The number of cfu 10^6 has a \log_{10} 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 bacteria and microorganisms.

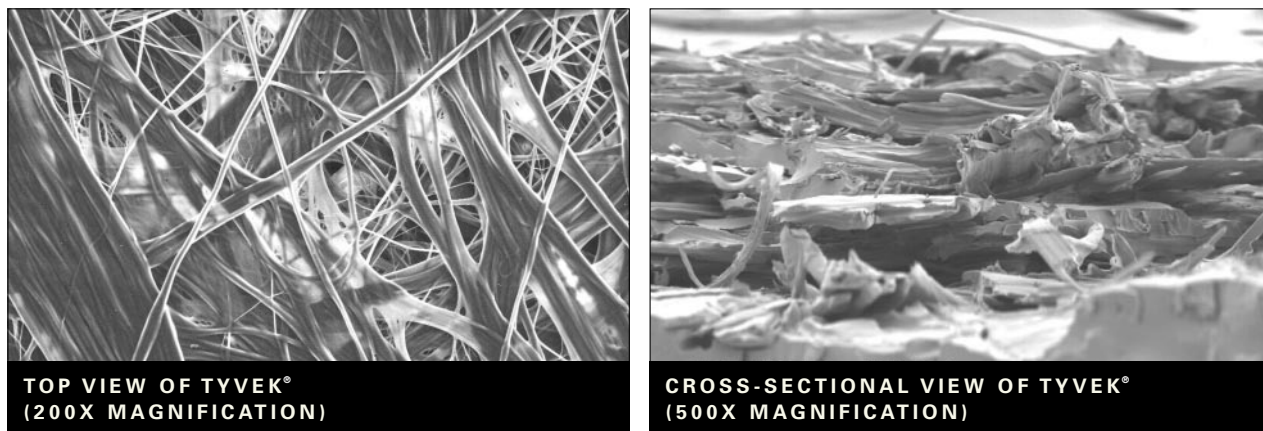


Figure 2. Scanning electron micrographs (SEMs) of Tyvek®
 The unique structure of Tyvek®, which creates a tortuous path with substantial lateral movement, results in superior microbial barrier properties.

Superior tear strength and puncture resistance

The tough, continuous fibers of Tyvek® protect package integrity from product breakthrough and also from penetration by an object outside the packaging during rough handling. Compared to 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.

Tyvek® is up to eight times stronger than medical-grade papers of equal or greater basis weight, so it resists punctures — even from the irregular or sharp edges of many surgical devices. In contrast, one small tear in a package made of medical-grade paper can contaminate a sterilized device and compromise the entire sterile field.

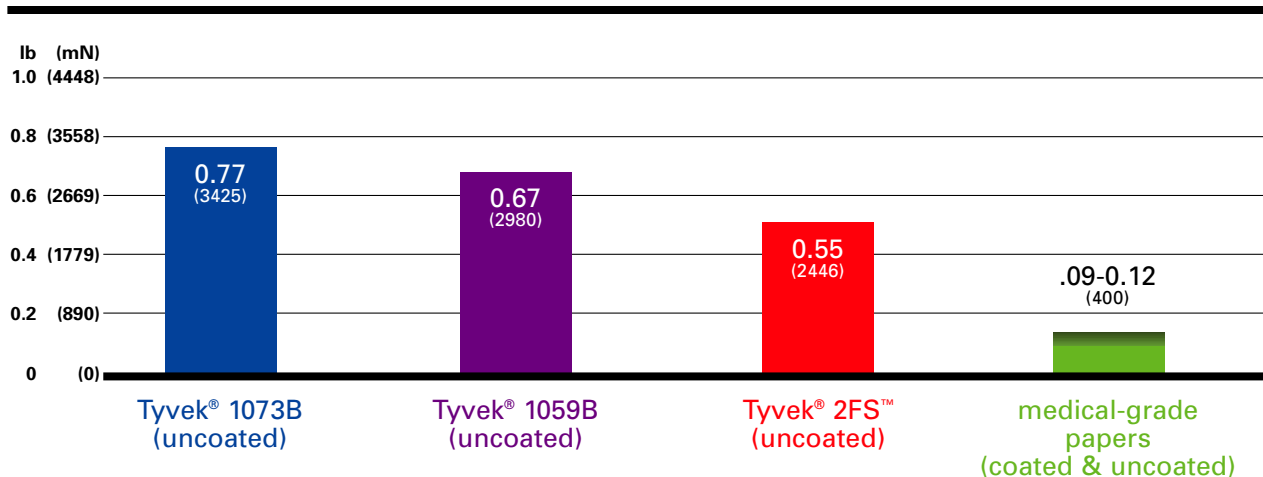


Figure 3. Elmendorf Tear (MD) test results.
 Per ASTM D1424 and DIN EN 21974. Elmendorf Tear measures the force required to propagate an initiated tear from a cut or a nick. MD signifies machine direction. The higher the value, the less likely a material will tear under force.

Exceptional resistance to breakage

Tyvek® is an extremely flexible packaging material that won't break or tear as easily as medical-grade papers. This resiliency, combined with the inherent strength of Tyvek®, ensures that form/fill/seal packaging lines run smoothly, without significant downtime due to material failures.

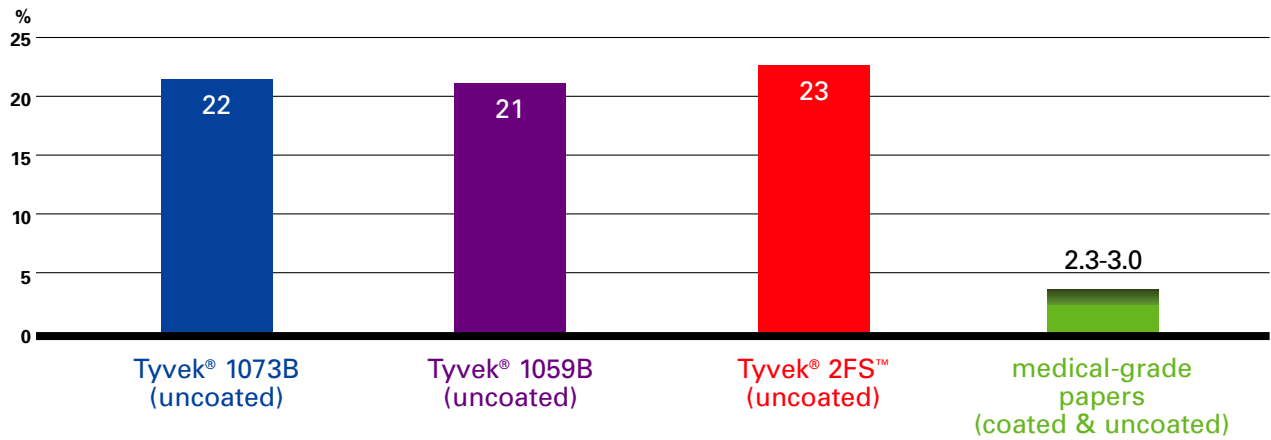


Figure 4. Elongation (MD) test results.

Per ASTM D5035 and DIN EN ISO 1924-2. Sample length 5 in. (13 cm), rate of extension (ROE) 2 in./min (5 cm/min). Elongation is the measure of the extent a substrate will stretch before it breaks. MD signifies machine direction. The higher the value, the more a package will stretch before it breaks.

Clean peel

Unlike paper, which can release a significant number of particulates when a package is opened, Tyvek® is known for its clean peel and low-linting features. Particulate generation tests comparing Tyvek® to medical-grade papers provide conclusive evidence that Tyvek® generates far fewer airborne particulates that could contaminate the medical device or the wound site.

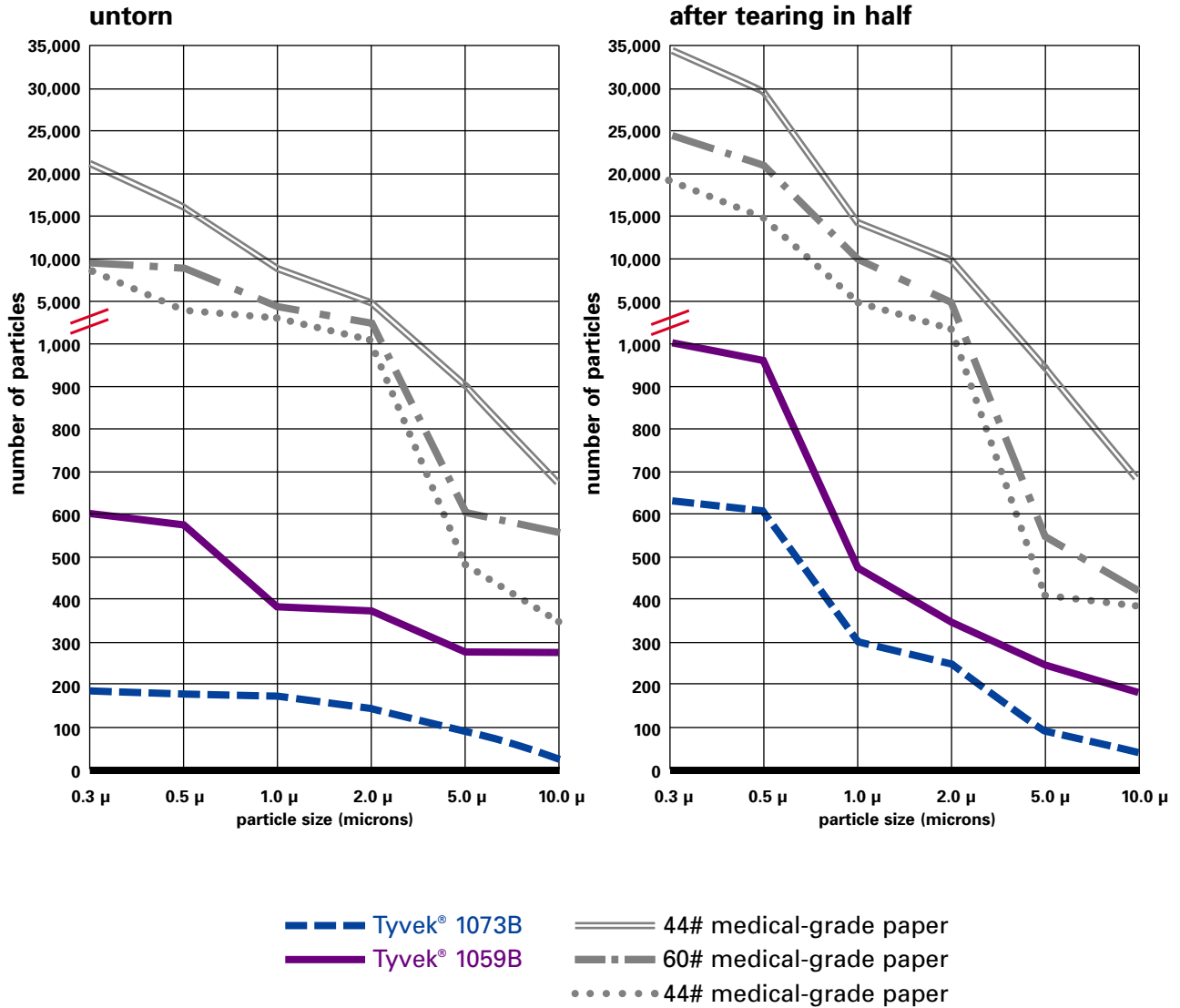


Figure 5. Particle generation test results.

As tested by an internal DuPont protocol. For the particulate generation testing, samples (medical-grade papers, as well as Tyvek® 1073B and Tyvek® 1059B) were tumbled in a tumbling drum. The drum was housed in a HEPA filter lab bench. The lab bench air was filtered with two prefilters and one HEPA filter. Air was supplied by a blower with a pressure drop across the filters of 0.5 in. (1.3 cm) of water. Sampling was done with a cleanroom monitor coupled to a paper tape printer. All of the equipment was housed in a temperature-controlled, HEPA-filtered-air cleanroom that had full air exchange approximately every minute.

Outstanding water resistance

Tyvek® is highly resistant to penetration by water and other liquids. In fact, water in contact with Tyvek® does not “wet” its surface, which means that water does not spread but remains as droplets on the surface of Tyvek®. Even in the event of accidental laboratory or operating room spills, Tyvek® protects the integrity and sterility of packaged medical devices. Unlike medical-grade papers, Tyvek® maintains its strength, both wet and dry. Because Tyvek® does not get wet by water, it will not absorb water and, therefore, contamination of the product by waterborne organisms is highly unlikely.

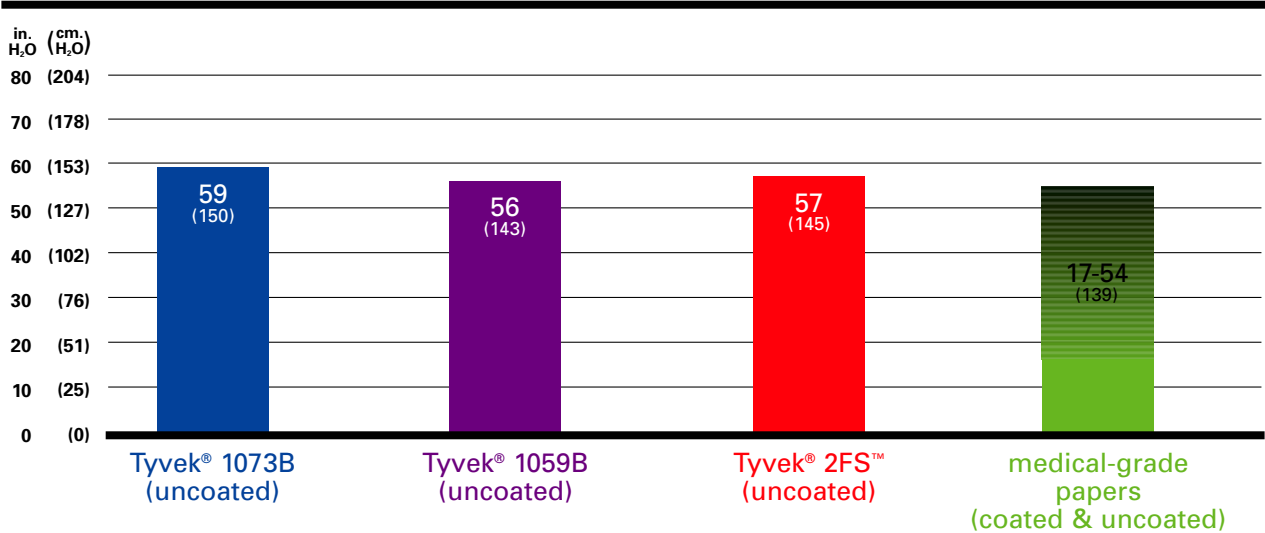


Figure 6. Hydrostatic head test results.

Per AATCC™ 127 and DIN EN 20811 (rate of use: 60 cm H₂O/min). 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.

Compatibility with sterilization methods

Unlike medical-grade papers and films, Tyvek® brand protective material is compatible with all of the most commonly used sterilization methods, including: ethylene oxide (EtO), gamma, electron-beam, steam (under controlled conditions), as well as with new methods such as plasma/hydrogen peroxide (e.g., STERRAD® Sterilization System). That's because Tyvek® is made from high-density polyethylene, 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. No matter which sterilization method is used, Tyvek® will retain its superior protective properties of bacterial barrier and strength.

Table I. Material compatibility with various sterilization methods

	Tyvek®	Coated, Latex-Saturated Medical-Grade Paper	Medical Film
Ethylene Oxide (EtO)	Yes	Yes	No
Gamma Radiation	Yes	Yes	Yes
E-beam Radiation	Yes	Yes	Yes
Steam	Yes ¹	Yes ²	No
STERRAD®	Yes	No	No

1. Under controlled conditions (250°F to 260°F [121°C to 127°C] at 30 psi for 30 minutes.
2. May become brittle.

Ethylene oxide (EtO)

Ethylene oxide (EtO) does not adsorb well on Tyvek®; thus, it desorbs completely within six minutes, leaving no residues on Tyvek®. In contrast, it takes 105 minutes for EtO to desorb completely from paper. Table II shows the results from tests comparing the strength and barrier of medical-grade styles of Tyvek® both before and after sterilization with EtO. Refer to **Aging studies**, section 5, Table I, for a listing of physical properties before and after a five-year shelf-life test for Tyvek® sterilized by EtO.

Table II. Strength and barrier properties before and after EtO sterilization

	Tensile Strength, MD ¹ lb/in. (N/2.54 cm)	Microbial Barrier, LRV ²
Tyvek® 1073B		
unsterilized	44 (196)	5.2
sterilized	46 (205)	5.3
Tyvek® 1059B		
unsterilized	37 (165)	4.7
sterilized	35 (156)	4.7
Tyvek® 2FS™		
unsterilized	31 (138)	3.6
sterilized	33 (147)	3.3

1. Per ASTM D5035 and DIN EN ISO 1924-2; modified for speed and gauge length.

2. Log Reduction Value as tested per ASTM F1608.

Radiation

Under radiation sterilization doses typically used in the industry, Tyvek® maintains excellent microbial barrier properties and experiences only slight changes in tensile strength, elongation and color. Unlike other porous 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 pass through. Nonporous materials can trap these odors inside the packaging. It's important to note that although Tyvek® can easily withstand re-sterilization with either gamma or electron beam (E-beam), the device itself may not. If re-sterilization is required, gas sterilization can be performed. Tyvek® will remain flexible after re-sterilization and will continue to provide an excellent microbial barrier.

Per ANSI/AAMI/ISO 11607 section 4.2.1.2: "In specific cases where multiple sterilization cycles are required, the performance of the packaging materials shall be evaluated to ensure that the material's performance remains within specified limits. This shall be the responsibility of the manufacturer." In this standard, the manufacturer is defined as the medical device manufacturer.

Gamma

Table III provides results from tests comparing the strength and barrier of medical-grade styles of Tyvek® both before and after gamma radiation at various doses. Refer to **Aging studies**, section 5, Tables IV and V, for real-time and accelerated aging test results for medical-grade styles of Tyvek® both before and after sterilization with gamma radiation.

Table III. Results from tests comparing strength and microbial barrier of medical-grade Styles of Tyvek® both before and after gamma radiation at various doses*

	Tensile Strength, MD ¹ lb/in. (N/2.54 cm)	Microbial Barrier, LRV ²
Tyvek® 1073B		
unsterilized	42.0 (187)	5.2
sterilized		
25 kGy	39.1 (174)	5.2
30 kGy	—	5.3
50 kGy	35.8 (159)	5.2
60 kGy	—	5.4
100 kGy	23.1 (103)	5.1
Tyvek® 1059B		
unsterilized	36.7 (163)	4.7
sterilized		
25 kGy	28.9 (128)	4.7
30 kGy	—	5.1
50 kGy	26.5 (118)	4.1
60 kGy	—	4.5
100 kGy	19.1(85)	4.2
Tyvek® 2FS™		
unsterilized	30.8 (137)	3.6
sterilized		
30 kGy	25.1 (112)	3.6
60 kGy	21.2 (94)	3.4

*25 kGy and 30 kGy were single doses; all others were cumulative amounts from double doses (i.e., 50 kGy represents a double dose of 25 kGy, etc.).

1. ASTM D5035 and DIN EN ISO 1924-2; modified for speed and gauge length.
2. Log Reduction Value as tested per ASTM F1608.

Electron beam

Table IV provides results from tests comparing the strength and microbial barrier of medical-grade styles of Tyvek® both before and after electron beam sterilization at various doses. Refer to **Aging studies**, section 5, Table IV, for real-time aging test results for medical-grade styles of Tyvek® both before and after sterilization with electron beam.

Table IV. Results from tests comparing strength and microbial barrier of medical-grade styles of Tyvek® both before and after electron beam sterilization at various doses*

	Tensile Strength, MD ¹ lb/in. (N/2.54 cm)	Microbial Barrier, LRV ²
Tyvek® 1073B		
unsterilized	42.0 (187)	5.2
sterilized		
50 kGy	35.8 (159)	5.2
100 kGy	21.5 (96)	5.2
Tyvek® 1059B		
unsterilized	36.7 (163)	4.7
sterilized		
50 kGy	30.4 (135)	4.9
100 kGy	21.2 (94)	4.3

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

1. ASTM D5035 and DIN EN ISO 1924-2; modified for speed and gauge length.
2. Log Reduction Value as tested per ASTM F1608.

Steam

Tyvek® has been shown to meet packaging criteria for steam sterilization under controlled conditions (250°F to 260°F [121°C to 127°C] at 30 psi for 30 minutes). Packaging programs using Tyvek® for steam sterilization are now commercial at several medical device and pharmaceutical manufacturers.

Research has shown that Tyvek® continues to be superior to medical-grade paper when strong, lint-free, steam-sterilizable lidding is required. In fact, Tyvek® retains its dimensional stability and integrity at 250°F to 260°F (121°C to 127°C) at 30 psi for 30 minutes with no discoloration. Rigid or semi-rigid trays restrict potential shrinkage and wrinkling, which can result in a smoother/tighter lid.

Table V provides results from tests comparing physical properties of medical-grade styles of Tyvek® both before and after steam sterilization at various temperatures. Figure 1 shows the results of shrinkage tests on Tyvek® 1059B and Tyvek® 1073B after steam sterilization.

Table V. Physical properties of medical-grade styles of Tyvek® both before and after steam sterilization

	Tensile Strength, MD ¹ lb/in. (N/2.54 cm)	Microbial Barrier, LRV ²	Shrinkage Autoclave, %	Gurley Hill ³ sec/100 cc
Tyvek® 1073B				
unsterilized	41.9 (186)	5.2	—	24.3
sterilized 30 min				
250°F (121°C)	43.1 (192)	4.8	0.5	24.0
255°F (124°C)	48.4 (215)	4.75	0.3	25.5
260°F (127°C)	48.2 (214)	5.2	1.4	24.9
Tyvek® 1059B				
unsterilized	35.2 (157)	4.7	—	18.7
sterilized 30 min				
250°F (121°C)	36.0 (160)	4.0	1.0	20.7
255°F (124°C)	38.7 (172)	3.8	0.5	34.1
260°F (127°C)	40.2 (179)	3.8	1.5	22.6
Tyvek® 2FS™				
unsterilized	27.8 (124)	3.6	—	18.3
sterilized 30 min				
250°F (121°C)	26.7 (119)	3.1	0.8	20.1
255°F (124°C)	28.5 (127)	3.1	0.3	19.6
260°F (127°C)	29.1 (129)	3.3	0.9	17.3

1. ASTM D5035 and DIN EN ISO 1924-2; modified for speed and gauge length.
2. Log Reduction Value as tested per ASTM F1608.
3. TAPPIT460 and ISO 5636-5.

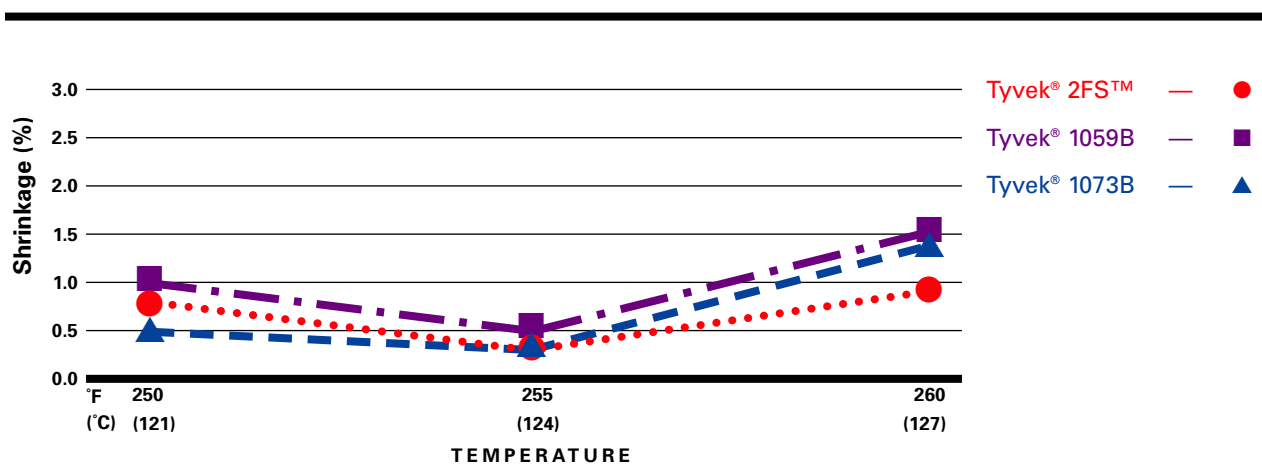


Figure 1. Results of shrinkage tests conducted on Tyvek® 2FS™, Tyvek® 1059B and Tyvek® 1073B after steam sterilization.

Plasma/hydrogen peroxide

Tyvek® is suitable for use with the STERRAD® Sterilization System from Advanced Sterilization Products, a Johnson & Johnson company. This environmentally safe sterilization alternative uses low-temperature gas plasma to avoid the degrading effects of steam or the residues of ethylene oxide (EtO). Medical-grade papers, including autoclave paper pouches, are NOT acceptable for use with the STERRAD® System because cellulosic materials neutralize the sterilizing agent. For more information about STERRAD® Sterilization System, contact Advanced Sterilization Products at (++1) 800-595-0200 or (++1) 949-581-5799 in the U.S. Or at (++41) 56-417-3333 in Europe. Additional information may also be found under www.sterrad.com

Sterilization Pouches and Rolls

Advanced Sterilization Products (ASP), a Johnson & Johnson company, has developed a complete range of sterilization pouches and rolls — using DuPont™ Tyvek® 4057B brand protective material – suitable for the STERRAD® Sterilization process. Made of tough, continuous fibers of 100 percent high-density polyethylene, Tyvek® provides a higher degree of protection for medical devices and supplies than any other porous material used for sterile packaging applications.

Specifically, Tyvek® offers outstanding resistance to microbial penetration; features superior tear strength and puncture resistance; and is low linting. Tyvek® resists penetration by objects outside the package as well as product breakthrough from irregular edges of many surgical devices. Tyvek® is also known for its clean peel, opening easily without generating dust or particles in the OR. ASP also prints a STERRAD® Chemical Indicator on their 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, please contact ASP at 1.888.STERRAD or visit their website at www.sterrad.com.



Biocompatibility

Biocompatibility testing using industry accepted test methods was performed on samples of Tyvek® 1073B, 1059B and 2FS™ before and after exposure to sterilization. Methods included: ethylene oxide (EtO), gamma irradiation, electron beam irradiation and STERRAD®. The results of the testing indicate that all of the styles of Tyvek® are biocompatible.

Sample Exposure Results for Tyvek® 1073B, 1059B and 2FS™

Test Performed	Unexposed	Ethylene Oxide (EtO)	Gamma Irradiation (25 & 50 kGy)	Electron Beam (25 & 50 kGy)	STERRAD®
Determination of Extractives from Olefin Polymers ³	Below maximum allowable percentage				
Hemolysis-Rabbit Blood-ISO ^{2,4}	Non-hemolytic				
L929 MEM Elution Test-USP ⁸	Non-cytotoxic				
ISO-Rabbit Pyrogen Test (Material Mediated) ^{1,2}	Non-pyrogenic				
Kligman Maximization Test-ISO (CSO and NaCl extracts) ^{2,7}	Non-allergenic				
Systemic Injection Test-ISO ^{1,2}	No biological reaction				
Primary Skin Irritation Test-ISO ⁷	Non-irritant				
Short Term Intramuscular Implantation Test-ISO (14 and 28 days) ^{5,6}	Non-irritant				
USP Class VI Test ⁹	0% sensitization				

Tests were based on the following references:

1. Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity, EN/ISO 10993-1995
2. Biological Evaluation of medical Devices-Part 12: Sample Preparation and Reference Materials, EN/ISO 10993-12, 1997
3. 21 CFR 177. 1520, Olefin Polymers, Federal Register, Title 21, Chapter 1, 1997.
4. Biological Evaluation of Medical Devices-Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4, 1992
5. Biological Evaluation of Medical Devices-Part 6: Tests for Local Effects After Implantation, ISO 10993-6, 1995
6. ASTM Section 13, Volume 13.01 medical Devices, Designation: F 981-93, 1994
7. Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Sensitization, EN/ISO 10993-10, 1996.
8. United States Pharmacopoeia 25, National Formulary 20, 2002, <87> Biological Reactivity Tests, In Vitro.
9. United States Pharmacopoeia 25, National Formulary 20, 2002, <88> Biological Reactivity Tests, In Vivo.

STERRAD® is a registered trademark of Advanced Sterilization Products, a Johnson & Johnson company.

Aging studies

Tyvek® provides long-term sterility of packaged medical devices

In test after test, the long-term effectiveness of Tyvek® brand protective material in keeping medical devices sterile during storage has been conclusively demonstrated. Test methods used to evaluate the microbial barrier properties of Tyvek® include the Barrier Test Consortium (BTC) method, ASTM method F1608, DuPont Bacterial Test Chamber and a host of others. Results from both material-based and whole package shelf-life studies show:

- Tyvek® holds out bacterial spores, even under the most rigorous conditions.
- Bacteriological studies clearly prove the outstanding efficacy of Tyvek® as a bacterial barrier, even after repeated challenges.
- Tyvek® maintains sterility even after five years of exposure to environments contaminated with microorganisms.

The first shelf-life studies of Tyvek® were initiated in 1972. Conducted at S.G.S. U.S. Testing Company's Laboratories, Fairfield, NJ, the studies 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® 1059B and Tyvek® 1073B in 1978. The study was conducted at DuPont Stine Haskell Laboratories. 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 be more severe 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.



Why Tyvek® works so well

Tyvek® inherently resists penetration by microorganisms better than any other porous packaging material because of its unique structure. Tyvek® is a sheet structure formed from continuous strands of very fine, interconnected fibers of high-density polyethylene. These fibers are randomly 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 and other liquids; low linting; puncture resistance; and air permeability.



MICROBES TRAPPED ON FIBER SURFACES OF TYVEK® (500X MAGNIFICATION)

Five-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 (EtO). Each package consisted of a lid of Tyvek® sealed to poly-Mylar® film. To ensure that the petri dish was sterile prior to long-term shelf storage, samples were randomly tested following the United States Pharmacopoeia (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 ensured that the density of spores was consistently maintained over the many years of the test.

Five-year shelf-life test results

All results shown in the following tables (I through V) are for uncoated samples of Tyvek® as supplied by DuPont. It is important to note that any downstream operations, such as coatings applied by sterile packaging manufacturers (SPMs), may affect the properties.

Table I. Physical properties of Tyvek® sterilized by ethylene oxide (EtO) before and after five-year shelf-life test

Property	Test Method	Units	Tyvek® 1059B		Tyvek® 1073B	
			Initial	After 5 Yrs	Initial	After 5 Yrs
Delamination	ASTM D2724	lb/in. (N/2.54 cm)	0.45 (2)	0.49 (2)	0.47 (2)	0.44 (2)
Gurley Hill Porosity	TAPPIT460 ISO 5636-5	sec/100 cc	29.8	27.9	37.4	36.8
Microbial Barrier	Internal DuPont	Log Reduction Value (LRV)	4.7 ¹	unchanged	5.2 ¹	unchanged
Hydrostatic Head	AATCC TM 127 DIN EN 20811 ²	in. H ₂ O (cm H ₂ O)	59+ (150+)	59+ (150+)	59+ (150+)	59+ (150+)
Tensile Strength, MD	ASTM D5035 ³ DIN EN ISO 1924-2 ³	lb/in. (N/2.54 cm)	36.7 (163)	35.9 (160)	44.0 (196)	45.1 (201)
Spencer Puncture	ASTM D3420 ⁴	psi (kPa)	51 (352)	52 (359)	77 (531)	77 (531)
Seal Strength	⁵	lb/in. (N/2.54 cm)	1.33 (6)	1.44 (6)	1.53 (7)	1.57 (7)

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. Modified for ⁹/₁₆-in. (14.28-mm) diameter probe.
5. Sealing conditions: temperature — 290°F (143°C); dwell time — 1 second; pressure (seal through the film) — 90 psi (621 kPa).

Accelerated aging test protocol

Samples of Tyvek® 1059B and Tyvek® 1073B were aged using the accelerated conditions listed below. Samples were rotated through the following cycle six times, which is equivalent to six years of aging.

- Two weeks at 130°F (54°C) with a relative humidity equal to 17%
- Two days at -4°F (-20°C)
- Two weeks at 130°F (54°C) with a relative humidity between 70% and 80%

After the accelerated aging, the samples were stored for five years at ambient temperature and humidity.



Table II. Accelerated aging test results for Tyvek® 1059B and Tyvek® 1073B

Property	Test Method	Units	Tyvek® 1059B			Tyvek® 1073B		
			Initial	After		Initial	After	
				6 cycles	5 years		6 cycles	5 years
Tensile Strength, MD	ASTM D5035 ¹ DIN EN ISO 1924-2 ¹	lb/in. (N/2.54 cm)	37 (165)	39 (174)	39 (174)	42 (187)	42 (187)	40 (178)
Microbial Barrier	ASTM F1608	Log Reduction Value (LRV)	4.7 ²	unchanged		5.2 ²	unchanged	

1. Modified for speed and gauge length.
2. Typical value.

At the time the accelerated aging test described above was conducted, Tyvek® 2FS™ had not yet been introduced. A different aging test was performed on samples of Tyvek® 2FS™. In this test, the samples were aged at 138°F (55°C) and 75% relative humidity. The results of that test are shown in Table III.

Table III. Accelerated aging test results for Tyvek® 2FS™

Property	Test Method	Units	Tyvek® 2FS™	
			Initial	After 36.5 weeks
Tensile Strength, MD	ASTM D5035 ¹ DIN EN ISO 1924-2 ¹	lb/in. (N/2.54 cm)	30.8 (137)	30.8 (137)
Elongation, MD	ASTM D5035 ¹ DIN EN ISO 1924-2 ¹	%	17	17
Microbial Barrier	ASTM F1608	Log Reduction Value (LRV)	3.1	unchanged

1. Modified for speed and gauge length.



Real-time aging test protocol

Samples of Tyvek® 1059B and Tyvek® 1073B were sterilized using gamma and electron beam (E-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 also noted.

Table IV. Real-time aging test results for Tyvek® 1059B and Tyvek® 1073B

	Tensile Strength, ¹ lb/in. (N/2.54 cm)		Microbial Barrier, LRV ²
	MD	CD	
Gamma Radiation 50 kGy*			
Tyvek® 1059B			
Original ³	36.6 (163)	40.1 (178)	4.7 ⁴
Initial	27.5 (122)	31.0 (138)	—
After 7 years	26.5 (118)	28.6 (127)	4.1
Tyvek® 1073B			
Original ³	42.0 (187)	47.9 (213)	5.2 ⁴
Initial	33.0 (147)	39.3 (175)	—
After 7 years	32.0 (142)	33.3 (148)	5.2
Gamma Radiation 100 kGy*			
Tyvek® 1059B			
Original ³	36.6 (163)	40.1 (178)	4.7 ⁴
After 7 years	19.1 (85)	22.2 (99)	4.2
Tyvek® 1073B			
Original ³	42.0 (187)	47.9 (213)	5.2 ⁴
After 7 years	23.1 (103)	29.2 (130)	5.1
E-Beam Radiation 50 kGy*			
Tyvek® 1059B			
Original ³	36.6 (163)	40.1 (178)	4.7 ⁴
Initial	32.1 (143)	32.7 (145)	—
After 7 years	30.4 (135)	27.8 (124)	4.9
Tyvek® 1073B			
Original ³	42.0 (187)	47.9 (213)	5.2 ⁴
Initial	36.9 (164)	35.4 (157)	—
After 7 years	35.8 (159)	32.5 (145)	5.2
E-Beam Radiation 100 kGy*			
Tyvek® 1059B			
Original ³	36.6 (163)	40.1 (178)	4.7 ⁴
Initial	23.9 (106)	27.1 (121)	—
After 7 years	21.2 (94)	21.0 (93)	4.3
Tyvek® 1073B			
Original ³	42.0 (187)	47.9 (213)	5.2 ⁴
Initial	27.0 (120)	27.0 (120)	—
After 7 years	21.5 (96)	25.3 (113)	5.2

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

1. ASTM D5035 and DIN EN ISO 1924-2; modified for speed and gauge length.
2. Log Reduction Value 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. Prior to sterilization.
4. Typical values. ASTM F1608 was not available in 1990 when the test was initiated.

Accelerated and real-time aging test after gamma sterilization

Pouches of Tyvek® 1073B and 2.5-mil polyester/polyethylene were stored at 131°F (55°C) and ambient relative humidity for a period of 10 weeks, followed by storage at ambient conditions for five years. The effect of aging on seal strength is shown in Table V.

Table V. Accelerated and real-time aging test results for Tyvek® 1073B

	Seal Strength ¹ lb/in. (N/2.54 cm)
Original	0.915 (4)
Sterilized with 30 kGy Gamma	0.949 (4)
Accelerated Aging	
2 weeks	0.931 (4)
4 weeks	0.856 (4)
6 weeks	0.953 (4)
8 weeks	0.887 (4)
10 weeks	0.848 (4)
Real-Time Aging	
3 years	0.778 (3)
5 years	0.853 (4)

1. ASTM D903.

Guidelines for printing on Tyvek®

Styles of Tyvek® for medical packaging — 1059B, 1073B and Tyvek® 2FS™ — can be printed in much the same way as paper, using standard commercial printing equipment. However, because of the unique requirements of the medical packaging industry, these styles have no antistatic coating and are not corona-treated. When used for lidding, they are often treated with a heat seal adhesive coating. Because these factors may adversely affect automatic sheet feeding and ink adhesion, special steps must be taken to obtain optimum printing results. When printing on styles of Tyvek® for medical packaging, we recommend testing before proceeding with production operations. It is also important to establish the suitability of the ink in those applications where direct contact with the medical device is likely.

Flexographic printing guidelines

Flexography is the recommended technique for printing on medical-grade styles of Tyvek®. 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. With Tyvek® 2FS™, it is more difficult to feel the difference between the two sides. To help you determine the rough from the smooth side, a simple six-step procedure has been developed. For details, refer to **Processing/Troubleshooting guidelines**, section 7. Other important recommendations are listed here.

Press conditions

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. (1.3 N/cm) of width.
- *Temperatures* — Maintain web temperatures below 175°F (79°C).
- *Chilled Rolls* — Use chilled rolls before windup.

Printing plates

Selecting the appropriate type of printing plate to use will depend on the nature of the job.

- *For overall print uniformity (even with type as small as 4 points and medium-density bar codes)* — Use DuPont™ Cyrel® photopolymer plates with a 50 Durometer hardness (Shore A) mounted with 15 mil to 20 mil (0.38 mm to 0.51 mm) of sticky-back, closed-cell foam.
- *For fine-line reverses greater than 13 mil (0.33 mm)* — Use soft natural rubber plates with a 30 Durometer hardness (Shore A) backed up with 15 mil to 20 mil (0.38 mm to 0.51 mm) of sticky-back, closed-cell foam.

Inks

Using the proper ink is important for achieving high-quality results.

- *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 help users remain in compliance with state environmental regulations while achieving high-quality results.

A list of ink manufacturers familiar with the unique requirements of printing on medical-grade styles of Tyvek® can be obtained by calling 1-800-44-TYVEK®; outside the United States, call the regional contact (see back cover for a complete listing).

Lithographic printing guidelines

Although flexography is the recommended method for printing on medical-grade styles of Tyvek®, offset lithography can produce acceptable print quality. For best results, use the smooth side of the sheet. Although either side prints well, the smooth side, with a slight downward curl at the edges, is preferred because it makes sheet feeding slightly easier. 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. With Tyvek® 2FS™, it is more difficult to feel the difference between the two sides. To help you determine the rough from the smooth side, a simple six-step procedure has been developed. For details, refer to **Processing/Troubleshooting guidelines**, section 7. Other important recommendations are listed here.

Offset blankets

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

Applying an additional 3 mil to 4 mil (0.08 mm to 0.10 mm) 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

Using the proper ink and following these specific recommendations are important for achieving high-quality results.

- *Low-solvent-content inks* — Use inks with <3% volatile solvent because hydrocarbon solvents found in many litho inks tend to swell and distort Tyvek®. Using low-solvent-content inks also benefits the environment because these materials release fewer volatile organic compounds (VOCs) than traditional offset inks.
- *Extra strong colors* — Use extra strong colors to keep ink film thickness to a minimum (<0.3 mil [0.008 mm]). 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. If your images appear dull or washed out, reduce the amount of dampening solution in the fountain; do not increase the ink volume.

- *Drying* — Because litho inks dry more slowly on Tyvek® than they do on paper, be sure that pile height does not exceed 20 in. (0.5 m). Winding the sheets and maintaining the fountain solution at a pH between 4 and 5 will also accelerate drying.

A list of ink manufacturers familiar with the unique requirements of printing on medical-grade styles of Tyvek® can be obtained by calling 1-800-44-TYVEK®; outside the United States, call the regional contact (see back cover for a complete listing).

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. Medical-grade styles of Tyvek® 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. For medical-grade styles of Tyvek®, which are not corona treated, wax ribbons give the best results. 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. However, because of the inherent thickness variability of Tyvek®, low- or medium-density bar codes can be printed to a D-C ANSI bar code quality using the thermal transfer process. Because Tyvek® 2FS™ has a higher contrast, bar codes with a consistent C rating can be printed. If a high-density bar code is needed, or a higher quality rating is specified, then a label should be used.

Ink jet printing

Medical-grade styles of Tyvek® have been printed successfully using continuous and drop-on-demand ink jet printers. However, because Tyvek® is made of high-density polyethylene and does not absorb water, solvent-based inks must be used. Most 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. The new 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 the ink jet or thermal transfer printers.



Processing/troubleshooting guidelines

Setting sealing parameters

The seal strength developed during a heat sealing process depends upon several factors, including:

- The sealing dwell time;
- The sealing temperature;
- The sealing pressure;
- The characteristics of the sealant; and
- The test method used to determine the seal strength.

If the objective is to simply make the permanent closure seal on a pre-formed pouch, careful control of the sealing time and temperature is not necessary. However, creating a peelable seal that will withstand shipping loads is quite a different matter.

Sealing dwell time refers to the clamp closed time during which the interface between the two webs is raised to a temperature that is high enough to either melt or activate the sealant. When sealing thin webs, such as polyester/polyethylene laminates used in medical pouches, the interface reaches the activation temperature approximately 0.5 seconds after the sealing mechanism closes. Some manufacturers operate at very high platen temperatures to achieve a clamp closed time of 0.75 seconds, which leaves only 0.25 seconds for the seal to form. If reaching the initiation temperature is retarded by only 0.05 seconds, that is 20% of the sealing time, and it will have a measurable effect on seal strength. With that short of a sealing time, anything that can affect the rate of temperature increase at the sealing surface can have a significant effect. Common factors include:

- Variation in platen temperature;
- Non-uniform heat transfer due to uneven contact or pressure (platen warpage or misalignment); and
- Material thickness.

Therefore, high platen temperatures and short clamp closed times can produce significant variability in seal strength. Longer clamp closed times and lower platen temperatures will produce more uniform seal strengths.

Avoiding fold problems

A sheet of Tyvek® is heat treated on both sides. This treatment makes the exterior less flexible than the interior of the structure. 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 fiber structure holding the two layers together will fail and the inner surface will buckle inward.



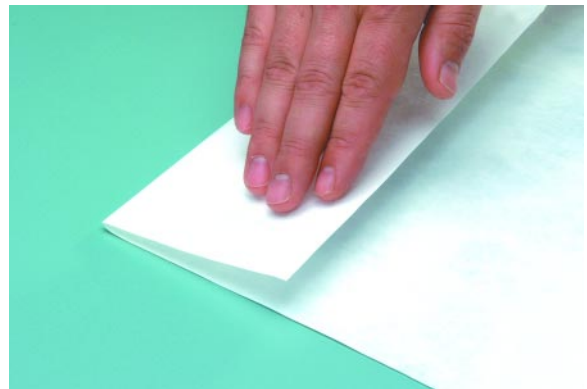
The result will be the formation of a delaminated area along the centerline of the sheet of Tyvek®. This is commonly seen when the flexible edge of a pouch seal is bent or folded to fit into a cardboard shelf package. With the polyester film on the outside of the bend, all of the force to make the fold is converted to compression loads on the inner surface of the sheet of Tyvek®, which may lead to delamination. 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 microbial barrier test. No reduction in Log Reduction Values (LRV) was observed.

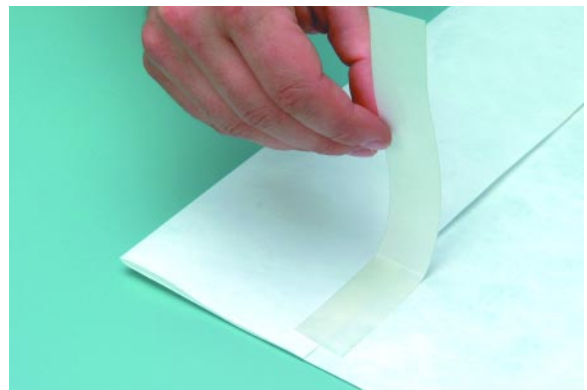
Determining the rough vs. smooth side of Tyvek® 2FS™

When sealing to Tyvek® 2FS™, it is important to always seal to the rough side. Sealing to the smooth side will result in fiber tear/delamination. Typically, rolls of Tyvek® 2FS™ are wound smooth side out when they are shipped. However, the following steps can be used to verify which way the roll is wound.

1. Fold back the edge of the Tyvek® approximately 6 in. (15 cm) and crease flat. NOTE: If the roll is wound correctly with the smooth side out, the folded area will be the rough side.



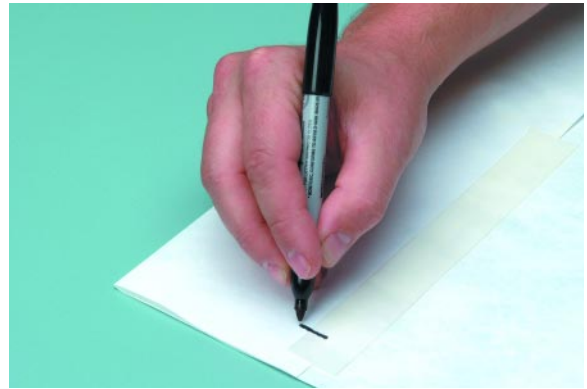
2. Cut a strip of 1-in. (2.5-cm) wide Arclad® AR-516 tape approximately 8 in. (20 cm) long. Place it on the "seam" so that approximately 1/2 in. (1 cm) is on the smooth side and 1/2 in. (1 cm) is on the rough side.



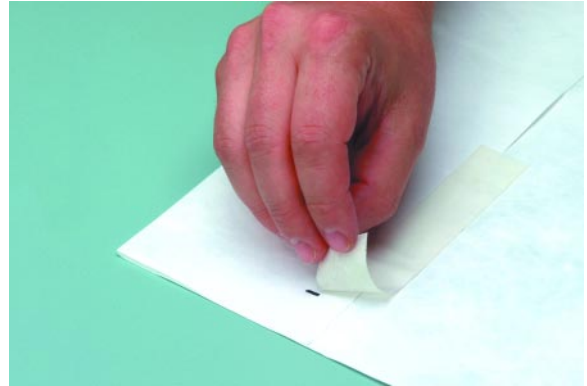
3. Smooth the tape down by running your finger along the "seam" one or two times. Use moderate pressure.



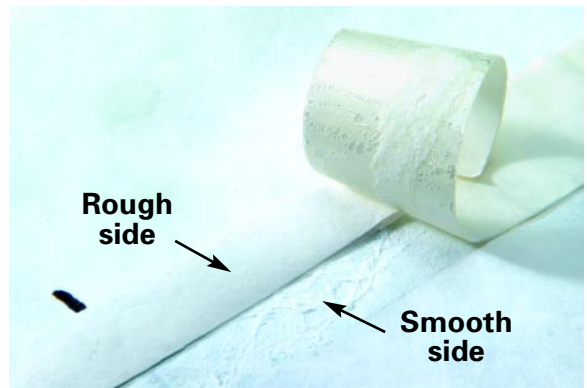
4. Using a felt tip pen or marker, draw a line on one side of the tape, extending the line onto the Tyvek® for easy identification.



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. (5 cm) to create a new "seam." Then, repeat steps 2 through 6.



Fiber tear

Fiber tear results from a delamination of the sheet of Tyvek®, which is caused by a sharp bend of the Tyvek® as it is being peeled from the film web. 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 the 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 less tendency to delaminate.

Cutting and Slitting Tyvek®

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

When forming pouches

The Tyvek® web should not be sealed all the way to its edge. This could allow adhesive to flow around the edge of the bonded Tyvek® surface and attach to individual fibers. This attachment to individual fibers 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.

Any edge trim removed from outside pouches on the web after sealing should be cut off in an unsealed area.

Sealing Lids to Trays

The Tyvek® web should not be sealed all the way to its edge. This could allow adhesive to flow around the edge of the bonded Tyvek® surface and attach to individual fibers. This attachment to individual fibers as opposed to the bonded Tyvek® surface could cause fiber tear and/or delamination during peeling.

When forming multiple trays across the web, tooling should be designed so that an unsealed area of at least 1 mm resides between adjacent trays.

Singularizing trays across the web should be performed in unsealed areas between trays.

Any edge trim removed from outside trays on the web after sealing should be cut off in an unsealed area.



Glossary of medical packaging terms

Basis weight

The measure of the weight per unit of area of the sheet. This is typically expressed in oz/yd², g/m², or lb/3,000 ft² ream. For example, Tyvek® style 1073B has a basis weight of 2.20 oz/yd², 74.6 g/m² or 45.8 lb/ream.

Reference standards: ASTM D3776 and DIN EN ISO 536 (both modified sample size).

Coefficient of friction

The measure of how slippery the surfaces of a substrate are relative to itself or to some other surface, typically wood or metal. Tyvek® has a low Coefficient of Friction. This means that sheets of Tyvek® slide easily over one another and on other surfaces. This is important when reams of cut sheets are moved, because a sudden stop or turn can cause the stack to slide and the ream to collapse. It is also critical when processing Tyvek® on a Form/Fill/Seal (FFS) machine. DuPont does not typically measure the Coefficient of Friction of Tyvek®. We use a slide angle instrument to measure the angle at which a sample with a 1-lb (0.45-kg) weight will start sliding. For Tyvek®, this is approximately 18 to 20 degrees. Paper has a 30-degree slide angle.

Delamination

The measure of the internal bonding level of a given substrate. For Tyvek®, it is the weakest point of the substrate, which is almost exactly in the middle. To perform the measurement, a split is initiated in a 1-in. (2.5-cm) wide sample. This split is the starting point to peel the layers apart. The average force to continue the peel is measured using an Instron. The results are given as lb/in. or N/2.54 cm. Medical grades of Tyvek® are among the most highly bonded styles of Tyvek®. This property is very important for medical packaging.

Reference standard: ASTM D2724.

Elongation

The measure of the extent a substrate will stretch before it breaks. The units are percentage (%) of sample length. Thus, a 10-in. (25-cm) sample of a substrate that has 20% Elongation will stretch 2 in. (5 cm) before breaking. Two aspects of Elongation are important: one is the total Elongation, which relates to how much energy the substrate can absorb (i.e., resiliency); and the other is the initial slope of the stress-strain curve, which relates to how rapidly the substrate elongates when initial forces are applied. This property is referred to as the Initial Modulus of the material. Both are important in medical packaging because the first relates to the protective nature of the material and the second relates to how a package distorts as pressures are applied. In web fed equipment, the Initial Modulus also relates to how much the material resists loss of registration. Elongation is measured by taking a 1 in. x 8 in. (2.5 cm x 20 cm) strip of product, clamping it so that 5 in. to 6 in. (13 cm to 15 cm) are between the jaws of an Instron, and then applying force to the ends until the sample breaks.

Reference standards: ASTM D5035 and DIN EN ISO 1924-2 (both modified for speed and gauge length).



Hydrostatic head

The measure of the pressure required to force three drops of water through a substrate. It is converted to the height of a column of water, which corresponds to the pressure. The units are typically inches (in.) or centimeters (cm). This property is determined by the largest pore size and the affinity of water for the substrate. For medical grades of Tyvek®, the largest pore size is approximately 20 µm and the surface energy is 32 dynes/cm to 25 dynes/cm.

Reference standards: AATCTM 127 and DIN EN 20811 (rate of use: 60 cm H₂O).

Microbial barrier

The measure of the ability of a porous substrate to prevent bacteria penetration. The standard test method that is used is ASTM F1608. This test measures the “filtration” efficiency of a substrate to remove spores from an aerosol that is being forced through the substrate in an air stream. The test uses a flow rate of 2.8 L/min and a spore concentration of 1×10^6 colony forming units (cfu)/sample port. The measure of barrier is the Log Reduction Value (LRV), which is the difference of the Log¹⁰ of the sample and the control. The initial control sample is close to the inoculum concentration (i.e., the log is ~6.0). If the control port has a Log of 6.0 and a test material allowed 10 spores to pass through, the corresponding LRV is 5.0 (6.0-1.0 = 5.0). Tyvek® 1073B has an LRV of 5.2 and is the best permeable substrate available for medical packaging.

There are two disadvantages associated with this test method. The first is that it takes a long time to incubate the spores to get a count of how many spores penetrated the test material. The second is that the test method incorporates a relatively high flow rate. This is a flow rate never seen by a medical device package except during rapid evacuation or depressurization in an autoclave or ethylene oxide (EtO) sterilizer. A test method in development by the Barrier Test Consortium* eliminates both problems. The test method functions by counting inert particles (that are approximately the size of a bacterial spore) as they penetrate the barrier material at velocities close to those experienced during transportation. This method also varies the flow rate and thereby generates a penetration curve. On this penetration curve, most substrates tested have a maximum. Therefore, it is possible to report a P_{MAX} , which is the maximum penetration for the given substrate. The flow rate at which the maximum occurs depends on the mass and fiber diameter of the substrate. The Barrier Test Consortium is now actively promoting this test to the various Standards organizations as the appropriate standard for evaluating barrier instead of the current ASTM standard.

Reference standard: ASTM F1608.

*Members of the Barrier Test Consortium Ltd are: Henry Cooke, Kimberly-Clark, Oliver Products, Perfecseal, Rexam Medical Packaging, Westfield Medical and DuPont Nonwovens. For more information, visit the web site at www.sterilebarrier.org or send an email to the Secretary-General of the Sterile Barrier Association (SBA, formerly known as ESPA) at secretary@sterilebarrier.org.

Moisture vapor transmission rate (MVTR)

The measure of the rate at which moisture vapor is transmitted through a sample. The test is conducted by putting the sample, which is mounted over a cup of distilled water, in a controlled humidity chamber and measuring the change in weight over a period of time. It is measured in g/m²/24 hr. There are several different manufacturers of MVTR equipment. It is important to note that MVTR results are highly dependent on the test method used and the material type. Important variables between test methods include: pressure gradient; volume of air space between liquid and sheet sample; temperature; air flow speed over the sample; and test procedure. Therefore, the results are not comparable from one company to another, nor between different pieces of equipment.

Reference standard: TAPPI T523 (test conditions: 23°C [73°F]/85% relative humidity)



Mullen burst

The measure of the ability of a substrate to resist forces applied uniformly throughout the substrate. It is measured by clamping a sample in a ring stand and expanding a diaphragm under the sample until the sample ruptures in the weakest spot. The pressure in the diaphragm (psi or kPa) is recorded. Because Tyvek® is isotropic (exhibits the same value when measured along axes in all directions), it has a very high Mullen Burst for a low weight material. Mullen Burst is proportional to the Basis Weight of the material, the bonding level, and to some extent, the Elongation. The Mullen Burst value increases as these three property values increase. This property indicates how a package 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.

Reference standards: ASTM D774 and ISO 2758.

Opacity

The measure of how much light passes through a substrate. It is a ratio of the reflected light through a sample with a white and a black background. If the reflected light is the same from both backgrounds, then the opacity is 100%. A white background without any sample reflects 100% of light. A black background has zero reflectance. Opacity depends on the Basis Weight and bonding level of Tyvek®. Because medical grade Tyvek® is highly bonded, the Opacity is relatively low. For the lower Basis Weight styles, the variation in visual appearance is more evident. Opacifiers, such as TiO₂ used in Tyvek® 2FS™, improve visual appearance and barcode readability.

Reference standards: TAPPI T425 and ISO 2471 (modified for different backing standards, area and illumination).

Porosity

The measure of the ability of a substrate to permit flow of air at a given pressure differential. Two methods are used: Gurley Hill Porosity in the United States and Bendtsen Air Permeability in Europe and most of the rest of the world. The Gurley Hill method measures the time to pass 100 cc of air through 1 in.² (6.45 cm²) of sample at a pressure of approximately 5 in. (13 cm) of water. The Bendtsen method measures the actual flow rate of air in mL/min through a 10-cm² sample at a pressure differential of 1.5 kPa (6 in. of water). Porosity is important for gas sterilization processes to ensure that a sufficient amount of sterilant saturates the package in a short time and that the subsequent flushing and aeration of any residuals of the sterilant are efficient. Porosity also allows the packages to equilibrate rapidly from the pressure changes that occur in sterilization, shipping and storage environments. If any material in the device develops an odor after gamma radiation, the porous material allows the odor to vent so that none is evident when the package is opened.

Reference standards: Gurley Hill Porosity: TAPPI T460 and ISO 5636-5; Bendtsen Air Permeability: ISO 5636-3 ($\Delta P = 0.22$ psi, [1.5 kPa], area 10 cm²).

Specification vs. other properties

Specification properties are controlled to aim and released within specifications. The values for other properties are typical but carry no warranty, express or implied. For medical packaging, specification properties are Basis Weight, Gurley Hill Porosity and Delamination. Basis Weight is measured by a beta gauge as the product is spun. The closed loop control of the belt speed, as well as the Tuning algorithm, ensures that the sheet of Tyvek® meets the specification. The measurement is verified by the gravimetric method of six 1-ft²- (0.093-m²-) samples from the roll. Gurley Hill Porosity is controlled by monitored and recorded process conditions and then verified by measurement after bonding. Delamination is controlled by the Opacity measurement after bonding and the closed loop control of the steam drum temperature to keep it on aim. This is verified by the Delamination measurement after bonding. All other properties are the result of keeping the three specification properties on aim.



Spencer puncture

The measure of the ability of a substrate to resist puncture by impact using a hemispheric-shaped probe. The units are psi (kPa). As used with Tyvek®, the probe is $\frac{9}{16}$ in. (14.3 mm) in diameter. Results with different sized probes are not comparable. As was true for the Mullen Burst values, Basis Weight, bonding level and Elongation determine the Spencer Puncture. This property indicates how a package will perform if an object falls on the package or if an object in the package strikes the lid.

Reference standard: ASTM D3420.

Tear

The measure of the ability of a substrate to resist tearing when a highly localized force is applied. Elmendorf Tear measures the energy required to propagate an initiated tear for a unit distance. The units are lb or Newtons. This property is important because nicks and cuts may occur at the edge of the Tyvek® and could affect the clean peel of the lid. Tear strength is mainly dependent on the bonding level in Tyvek®. The higher the bonding level, the lower the tear. The tear strength of Tyvek® is significantly higher than that of medical-grade paper.

Reference standards: ASTM D1424 and DIN EN 21974.

Tensile strength

The measure of the ability of a substrate to resist loads in the plane of the sheet. The units are lb/in. or N/2.54 cm. Along with Elongation, Tensile determines the ability of a material to absorb energy before failure. Tensile is directly proportional to the Basis Weight, bonding level, tenacity and orientation of individual fibers. Tensile is measured by taking a 1 in. x 8 in. (2.5 cm x 20 cm) strip of product, clamping it so that 6 in. (15 cm) are between the jaws of an Instron, and then applying force to the ends until the sample breaks.

Reference standards: ASTM D5035 and DIN EN ISO 1924-2 (both modified for speed and gauge length).

Thickness

The measure of the distance between the upper and lower surfaces of a substrate. The units of measure are usually mils, μm or mm. Thickness is measured by placing the material on a hard, flat surface and then determining the distance from the base by using a presser foot that is parallel to the base and applied to the top surface of the material. The presser foot is normally circular and the pressure applied to the foot depends on the material measured. For Tyvek®, the pressure is 1 psi to 10 psi (7 kPa to 69 kPa). Because there is little compaction at this low pressure, the measurement corresponds to the highest spot in the area covered by the presser foot. Thus, the larger the cross-sectional area of the presser foot, the greater the chance to pick the highest spots on the sheet. For this reason, the average thickness value measured for a sheet is lower as the area of the presser foot decreases.

Reference standards: ASTM D1777 (7.15 psi, 0.625-in. diameter presser foot) and DIN EN 20534 (surface 2 cm², pressure 14.5 psi [100 kPa]).



Guide to some common industry acronyms

AATCC — American Association of Textile Chemists and Colorists

AdvaMed — Advanced Medical Technology Association (formerly HIMA, Health Industry Manufacturers Association)

ANSI — American National Standards Institute

AORN — Association of periOperative Registered Nurses

ASQ — American Society for Quality

ASTM INTERNATIONAL — American Society for Testing and Materials International

CD — Cross Direction

CEN — European Committee for Standardization

DIN — Deutsches Institut für Normung (German standards organization)

EDANA — European Disposables and Nonwovens Association

EDMA — European Diagnostic Manufacturers Association

EN — European Norm

EUROMED — European Medical Devices and Technology Industry Association

FDA — Food and Drug Administration

IoPP — Institute of Packaging Professionals

ISO — International Organization for Standardization

ISTA — International Safe Transit Association

LRV — Log Reduction Value

MD — Machine Direction

MDD — Medical Device Directive

MDM — Medical Device Manufacturer

MDMA — Medical Device Manufacturers Association

MEDEC — Medical Devices Canada

SAL — Sterility Assurance Level

SBA — Sterile Barrier Association (formerly ESPA, European Sterilization Packaging Association)

SEM — Scanning Electron Micrograph

SPM — Sterile Packaging Manufacturer

TAG — Technical Advisory Group

TAPPI — Technical Association of the Pulp and Paper Industry

USP — United States Pharmacopoeia

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