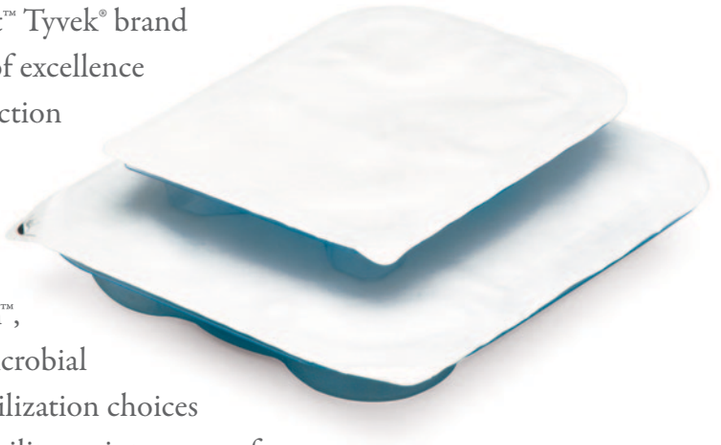
DUPONT
Tyvek.

DUPONT™ TYVEK® PROVIDES PROTECTION FOR YOUR PRODUCTS WHEN IT MATTERS MOST.

DUPONT™ TYVEK® FOR MEDICAL AND PHARMACEUTICAL PACKAGING DELIVERS TRUSTED PROTECTION

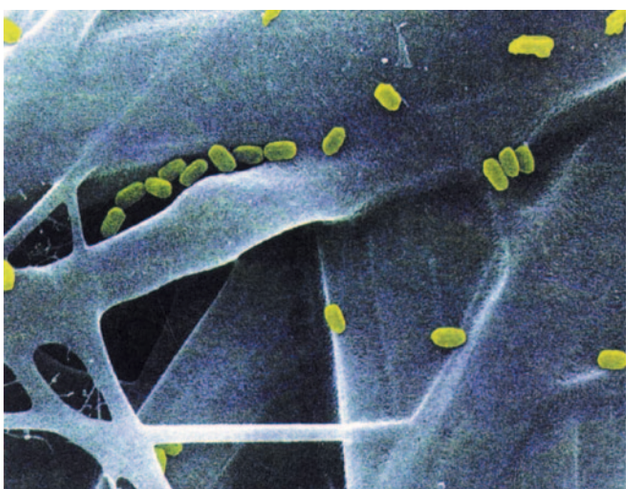
Since its introduction to the industry in 1972, DuPont™ Tyvek® brand protective material has been recognized as a standard of excellence for sterile medical packaging. Tyvek® earned this distinction because it provides a higher degree of protection for medical devices and supplies than any other porous material used for sterile packaging applications.



Available in four styles—Tyvek® 1073B, Tyvek® Asuron™, Tyvek® 1059B and Tyvek® 2FS™—these outstanding microbial barrier products have expanded the packaging and sterilization choices available to medical device manufacturers, enabling sterility maintenance of medical devices to help protect the health of literally millions of patients worldwide.

Used in virtually every form of sterile medical packaging, Tyvek® is the material of choice for pouches, lid stock, breather patches and headers for bags. A wide variety of products are packaged in Tyvek®, including: sutures; cardiovascular catheters; endoscopic instrumentation; surgical preparation kits; injection systems; electrosurgical accessories; and implantable devices, just to name a few.

In test after test, Tyvek® consistently outperforms other commercially available porous packaging materials, including medical-grade papers. For an in-depth report of property comparison tests, including tables and figures, visit www.MedicalPackaging.DuPont.com and review the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging.*



Microbes trapped on fiber surfaces of DuPont™ Tyvek® (500x magnification).

Cross-sectional view of DuPont™ Tyvek® (500x magnification).

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

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

DUPONT™ TYVEK® HAS INHERENT ADVANTAGES OVER OTHER MATERIALS

Made of high-density polyethylene (HDPE), Tyvek® is vapor permeable, yet water- and chemical-resistant. Tyvek® offers an optimum balance of microbial penetration resistance, tear strength, puncture resistance and clean peel.

Specifically, Tyvek® offers outstanding resistance to microbial penetration, significantly reduced risk of package failure, compatibility with a broad range of sterilization methods, and low risk of device contamination.

OUTSTANDING RESISTANCE 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 it is opened for the product to be used.

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. *(See Figures 2 and 3.)*

In addition, comprehensive shelf-life studies have shown that Tyvek® can maintain sterility for at least five years if package integrity is not compromised.

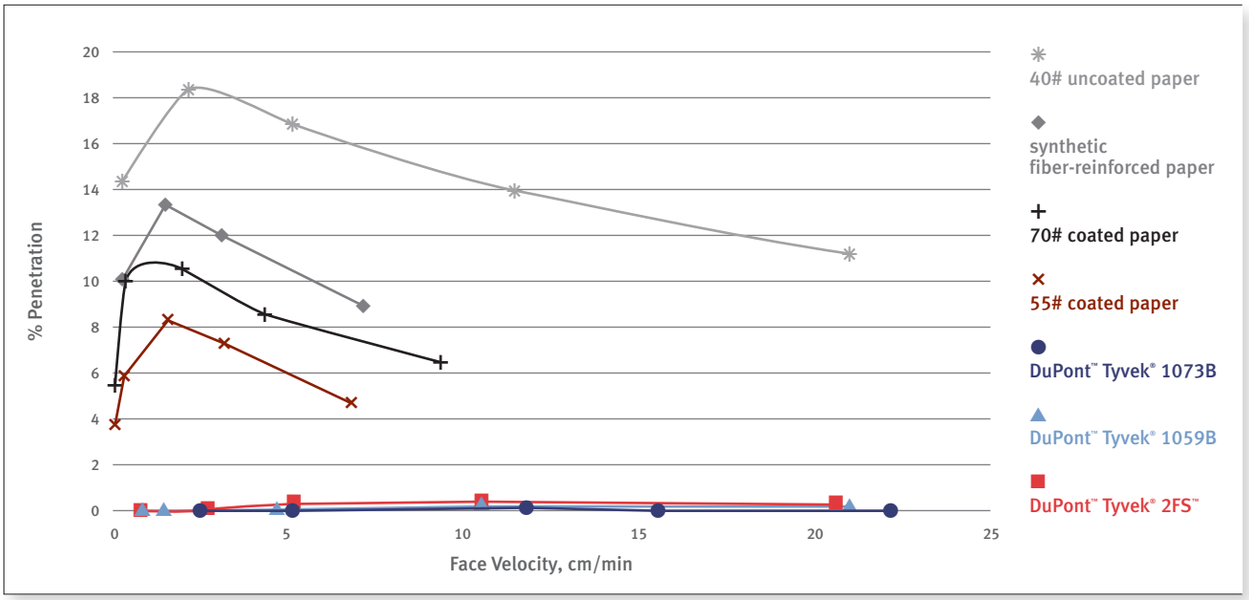


Figure 2. Particle penetration of porous sterile barrier materials per ASTM F2638.

This test measures the ability of a porous substrate to prevent particle penetration, which is 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.

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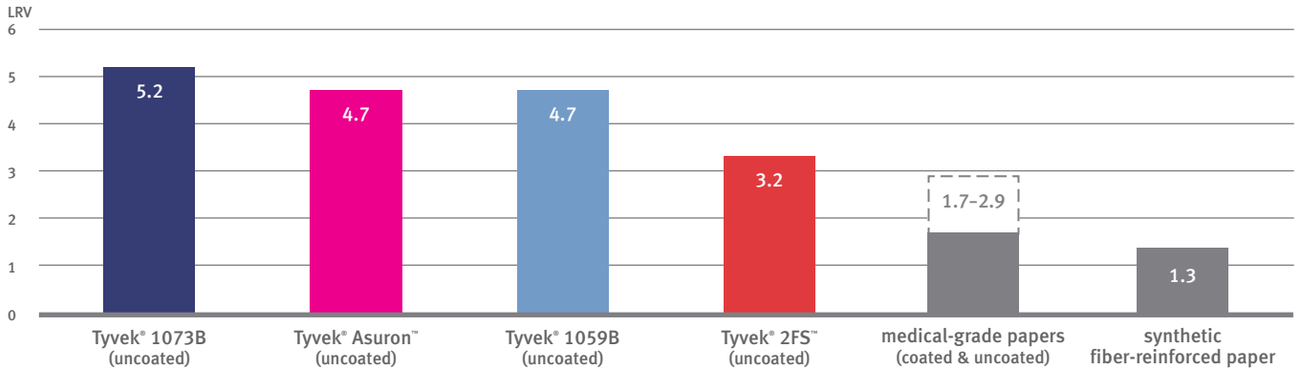

Figure 3. Microbiological barrier testing of sterile barrier materials (ASTM F1608).

This test measures the ability of porous sterile barrier materials to prevent bacterial spore penetration. The higher the log reduction value (LRV), the more resistant the packaging is to microorganisms.

SIGNIFICANTLY REDUCED RISK OF PACKAGE FAILURE

The tough, continuous fibers of Tyvek® help protect package integrity from both product breakthrough inside and rough handling outside. What's more, because it is breathable, Tyvek® minimizes the formation of condensation due to temperature extremes that can occur during transport.

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. *(See Figures 4 and 5.)*

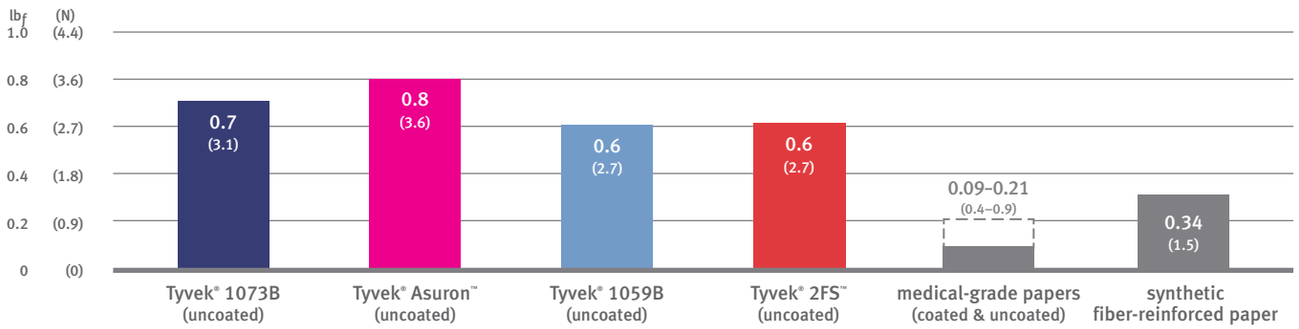

Figure 4. Elmendorf tear (MD) properties of DuPont™ Tyvek® styles and medical-grade papers (ASTM D1424 and EN 21974).

This test 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.

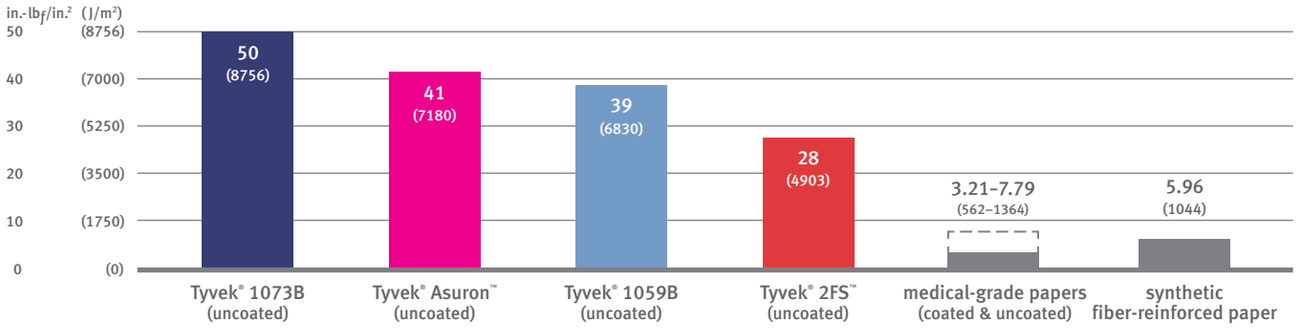

Figure 5. Spencer Puncture properties of DuPont™ Tyvek® styles and medical-grade papers (ASTM D3420, procedure B).

This test determines the impact resistance of plastic films and packaging materials under conditions that closely approximate the strain rate that these materials are subject to in the healthcare industry. These results were obtained using a modified Spencer Puncture test apparatus that features a 9/16-in. (14.3-mm) diameter hemispheric-shaped probe tip and a 6,400-gram pendulum, which is necessary to puncture tough materials like Tyvek®. Results using different test apparatus are not comparable.

COMPATIBILITY WITH A BROAD RANGE OF STERILIZATION METHODS

Unlike medical-grade papers and films, Tyvek® is compatible with all of the most commonly used sterilization methods, including: ethylene oxide (EO), gamma, electron-beam, steam (under controlled conditions), and low-temperature oxidative sterilization processes (e.g., STERRAD® Sterilization System). *(See Table I.)* That's because Tyvek® is made from 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. No matter which of these sterilization methods is used, Tyvek® will retain its superior protective properties of microbial barrier and strength.

Table I. Material compatibility with various sterilization methods

	DuPont™ Tyvek®	Coated, Latex-saturated Medical-grade Paper	Medical Film
Ethylene Oxide (EO)	Yes	Yes	No
Gamma Radiation	Yes	Yes	Yes
Electron-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.

LOW RISK OF DEVICE CONTAMINATION

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 either the medical device or the sterile field.

DUPONT MEDICAL AND PHARMACEUTICAL PROTECTION— AN INDUSTRY AND TECHNOLOGY LEADER

The DuPont Medical and Pharmaceutical Protection Team, backed by the vast resources of DuPont, offers unique, highly engineered materials that deliver trusted protection. But our contribution to the medical and pharmaceutical packaging industries goes far beyond our product offering.

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.

HELPING SPEED UP YOUR COMPLIANCE PROCESS

To help you meet worldwide regulations and packaging standards, while accelerating your product regulatory submissions and certifications, the DuPont network of regulatory affairs experts has compiled extensive compliance data and created the *DuPont Technical Reference Guide for Medical and Pharmaceutical Packaging*. The information in this guide will help you develop and validate the most appropriate solutions with DuPont™ Tyvek®.

And, to help you comply with ISO 11607-1:2006, our experts have compiled documentation that demonstrates the compliance of Tyvek® with the materials portion of the standard. The result is a comprehensive compliance guidebook for Tyvek® that enables medical device manufacturers and sterile packaging manufacturers to focus on the package material production, final package design qualification and the device package process validation portions of the standard, thus saving time and money.

Compliance of Tyvek® to the ISO 11607-1:2006 standard is supported by a number of DuPont Technical Information Documents (TIDs), which contain the necessary experimental data to demonstrate compliance. The compliance guidebook describes the TIDs and explains their applicability to the various sections of ISO 11607-1:2006.

For a downloadable copy of the guidebook *DuPont™ Tyvek® Compliance to ISO 11607-1:2006,* visit www.MedicalPackaging.DuPont.com.

PARTICIPATING IN INDUSTRY STANDARDS ORGANIZATIONS

Members of the DuPont Medical and Pharmaceutical Protection Team regularly participate in many industry standards organizations, including:

- 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)

PROVIDING PACKAGING SCIENCE SUPPORT

DuPont packaging engineers are available globally to share their knowledge about materials, package design and processing to help you optimize package performance and total cost, while easing implementation.

CONDUCTING EDUCATIONAL SEMINARS

Experts from the DuPont Medical and Pharmaceutical Protection Team conduct educational seminars that cover a variety of important topics, such as: sterilization science; industry regulations; and package engineering and design. These seminars are designed to help you stay up to date and to give you the information you need to help you better meet your customers' needs.

Our commitment to the medical and pharmaceutical packaging industries is unwavering and these are just some of the ways that we are putting our commitment into action.

Tyvek®

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, call us today at 1.800.44.TYVEK or visit us at www.MedicalPackaging.DuPont.com

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