

Tyvek® Rx

A MEDICAL PACKAGING NEWSLETTER
FROM DUPONT

VOLUME 15 ISSUE 1 JANUARY 2006

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NEW AND IMPROVED

DuPont Medical Packaging will launch a new print advertising campaign in March 2006.

For more information:

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For Seminar Series information, visit our website:
www.MedicalPackaging.DuPont.com

The best just got better... Introducing new DuPont™ Tyvek® Asuron™

For more than 30 years, DuPont™ Tyvek® protective material for medical packaging has been recognized as a standard of excellence. Now, we are raising the bar even higher with the introduction of Tyvek® Asuron™ protective material.

Developed in response to input received from hundreds of medical device manufacturers (MDMs) during our extensive "voice of the customer" process, Tyvek® Asuron™ features the best physical properties of DuPont™ Tyvek® 1073B **plus** four significant improvements:

1. Better printability and bar code readability
2. More homogeneous appearance
3. Improved heat seal appearance at higher temperatures
4. Expanded fulfillment capacity for improved service and contingency planning

Better printability

Like the other styles of Tyvek® for medical packaging, Tyvek® Asuron™ can be printed in much the same way as paper, using standard commercial printing equipment. (Refer to the *Technical Reference Guide* for more information.) What sets Tyvek® Asuron™ apart is its improved printability. Small type and special characters are much sharper and easier to read when printed on Tyvek® Asuron™. Bar code readability is enhanced using flexography and thermal transfer printing, with Tyvek® Asuron™ earning a "B" verifiable barcode rating compared to Tyvek® 1073B earning a "C" verifiable barcode rating. (See Figure 1)

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The miracles of science™



By Michael H. Scholla, Ph.D.
Senior Consultant,
DuPont Medical Packaging and
DuPont Medical Fabrics

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information about**

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CEN:
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Regulatory update

Status of ISO/EN FDIS 11607-1 and ISO/EN FDIS 11607-2

At the April 2005 meeting of TC198/WG7 held in Sydney, Australia, all comments from the Draft International Standard (DIS) ballots were resolved and the documents were revised. These revised documents were sent to the International Organization for Standardization (ISO) Central Secretariat for editing and translation into German and French in preparation for the Final Draft International Standard (FDIS) ballots.

The good news is that the ISO editor's comments are relatively minor and mostly address formatting and style. (Some of you may remember that when the editor was finished revising the second edition of ISO 11607 a few years ago, major changes to the notes had been made and subsequently the original FDIS ballot resulted in a unanimous negative vote. After discussions with the editor, those notes were restored and the FDIS was successful.) The only points that I am trying to get restored to these revised documents are those places where the documents list items that are to be considered. The documents preface these lists with a statement that reads: "...these factors include, but are not limited to:" and then several items are listed. The editor wants to remove the "but are not limited to" phrase from these sentences.

From a purely editorial perspective, I agree with the comment to remove this phrase. However, as the convener (whose job it is to gain consensus), those five words mean a great deal. Whenever the committee lists items, it seems every member has something they want in that list. If left unchecked, the document could have more lists than anything else. As a committee, we solved this by inserting the statement "but are not limited to" and limiting the list to six to 10 items that we all agreed were the most important. I believe that once this is explained to the ISO editor, the statement will be restored.

Unfortunately, it has taken longer than expected to get the editorial review and translations completed.

I was probably being too optimistic with my original timeline and must remind myself that there were 19 documents from the TC 198 Sydney meeting that were sent to ISO for editing. Hopefully, the FDIS ballots will begin in early 2006. The FDIS ballot period lasts for two months and it is an up or down vote where only editorial comments are accepted.

AAMI packaging update

The Association for the Advancement of Medical Instrumentation (AAMI) packaging working group, co-chaired by Nick Fotis of Cardinal and John Spitzley of Medtronic, has already balloted the two standards for consideration as AAMI/ANSI/ISO standards. The ballot was approved and these documents are moving through the AAMI Standards Board and formal American National Standards Institute (ANSI) approval process. I would expect that by the second quarter of 2006, the standards will be available for purchase.

At the meeting of the group in November 2005, the draft of the Technical Information Report (TIR) was reviewed for technical content. Jan Gates from Guidant and Ram Singhal of the Flexible Packaging Association volunteered to take on responsibility as co-chairs of the task group. I would like to personally thank them for taking this task from me and know they will do an outstanding job.

John Spitzley announced that the November meeting was his last meeting representing Medtronic. As many of you know, John retired from Medtronic earlier last year. AAMI has requested nominations for a new co-chair of the packaging group to replace John. By the time you read this newsletter, the new co-chair may have already been appointed.

I would like to thank John (and acknowledge Medtronic's support of him) for his outstanding commitment and tireless efforts within AAMI, ISO and ASTM. John has been a major contributor to many important medical packaging standards and test methods. The good news for our industry is

Regulatory update

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that although he has retired from Medtronic, John will be working as a consultant and will remain involved in industry activities. All of us on the DuPont Medical Packaging Team wish John and his wife Judy all the best in their future endeavors.

CEN update

The European Committee for Standardization (CEN)/TC205/WG4 on medical packaging met in Berlin this past November to consider comments from the reaffirmation ballots for EN868 parts 2-10. Tim Galekop of Ahlstrom is the convener of this committee. As you may already know, CEN and ISO standards must be reviewed after five years. At that time, the committee can reaffirm, revise or withdraw the standard.

When ISO/EN FDIS 11607-1 and -2 are approved, these documents will replace EN868-1 as the normative standards in Europe. EN868-2 through -10 and application specific standards that are informative are up for the five-year review, prompting the ballot and meeting. While not personally in attendance, my understanding is that there were many comments and the group agreed to make changes to the documents for consideration at a subsequent meeting of the working group in Spring 2006.

Status of ISO/FDIS 15378

ISO/FDIS 15378: Primary packaging materials for medicinal products-Particular requirements for the application of ISO 9001:2000, with reference to Good Manufacturing Practice (GMP) was developed by TC76, transfusion, infusion and injection equipment for medical and pharmaceutical use. The FDIS ballot closed on December 17, 2005. The scope of this standard revolves around quality system and regulatory requirements for suppliers of primary packaging materials for medicinal products. The first time I became aware of this standard was when the FDIS ballot was announced.

The standard states the requirements from ISO 9001 and the QSR and adds specific requirements in reference to primary packaging materials. The way the standard is written, it is clearly intended for the applications within the scope of TC76. However, many of the definitions are not harmonized with ISO 11607 and the definition of a medicinal product is much further reaching than just transfusion, infusion and injection equipment. Clearly there are some issues to be resolved; however, if your company participates in these market segments, I would suggest you familiarize yourself with this standard.

Helping future packaging engineers

Five undergraduate students from the University of Wisconsin-Stout are among the latest recipients of the DuPont Medical Packaging Scholarship Program. Alicia Bush, Brianne Hartung, Laura Jacobsen, Christopher Newborg and Jim Persells were each awarded a \$1,000 scholarship.

The recipients are junior or senior packaging majors who have a career interest in the healthcare industry, particularly in medical devices. Three of them recently completed internships at medical device companies. Bush interned at Boston Scientific and both Jacobsen and Newborg interned at Medtronic.

The DuPont Medical Packaging Scholarship Program was established in 2001 to benefit the upcoming generation of packaging engineers. Through this program, DuPont Medical



DuPont Medical Packaging Scholarship winners at the UW-Stout Foundation Scholarship Award Ceremony 2005. *Left to right:* Christopher Newborg, Jim Persells, Brianne Hartung, Alicia Bush and Laura Jacobsen.

Packaging funds scholarships at three U.S. universities that are recognized for their outstanding packaging engineering programs. In addition to the University of Wisconsin-Stout, they are: Michigan State University and Rochester Institute of Technology. Each institution receives an annual \$5,000 donation to fund a scholarship program that best meets the needs of its packaging engineering students.

Introducing new DuPont™ Tyvek® Asuron™

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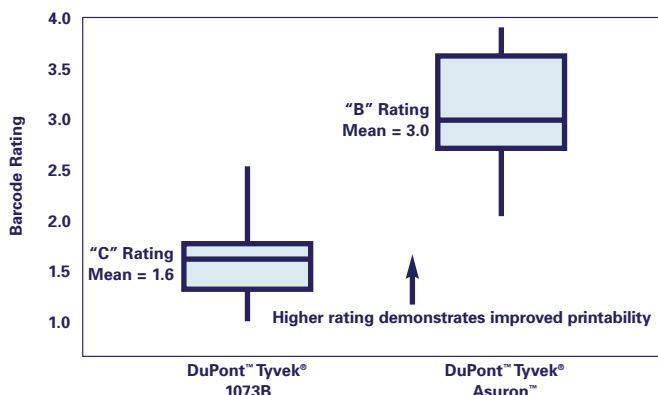


Figure 1. The enhanced barcode readability of DuPont™ Tyvek® Asuron™ is easy to see in this side-by-side comparison.

More homogeneous appearance

Tyvek® Asuron™ protective material features a much more homogeneous appearance than Tyvek® 1073B, as shown in Figure 2. This improved visual uniformity minimizes the appearance of inconsistent thicknesses throughout the sheet. With its better overall visual appearance, Tyvek® Asuron™ enhances the level of confidence and assurance that medical professionals have when handling a sterile package.

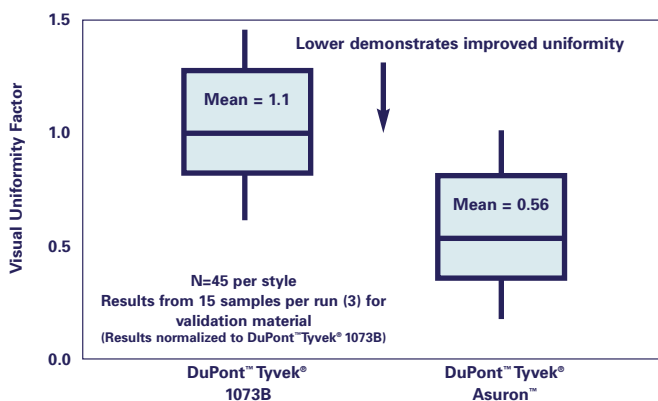


Figure 2. DuPont™ Tyvek® Asuron™ has greater visual uniformity than DuPont™ Tyvek® 1073B.

Improved heat seal appearance

Tyvek® Asuron™ has improved heat seal appearance at higher temperatures. That's because the addition of TiO₂ makes it less likely to show transparentization. This feature gives manufacturers greater flexibility when setting up heat sealing equipment and helps eliminate the appearance of transparentized seals.

Expanded fulfillment capacity

During our "voice of the customer" process, one of the most important issues we heard from MDMs was the need to have well-developed contingency plans in place. Specifically, many MDMs expressed concern about supply interruptions of the style of medical-grade DuPont™ Tyvek® they are using if a natural or man-made disaster struck the manufacturing facility where that style is currently being made.

To help eliminate this concern, Tyvek® Asuron™ will be produced at both of our manufacturing facilities—Richmond, Va., which is ISO 9002-registered, and Luxembourg, which is ISO 9001-registered. The ability to source from either of our manufacturing facilities will provide increased peace of mind for contingency planning and result in improved service.

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Introducing new DuPont™ Tyvek® Asuron™

Outstanding physical properties

Like other styles of medical-grade Tyvek® protective material, new Tyvek® Asuron™ has outstanding resistance to microbial penetration, is virtually non-linting and is compatible with all of the most commonly used sterilization methods. Table I provides a comparison of typical physical properties of Tyvek® Asuron™ vs. other styles of medical-grade Tyvek® and a 55# coated medical-grade paper.

Specify Tyvek® Asuron™ and see the difference

After reviewing the technical data presented here, it's easy to see that Tyvek® Asuron™ will be setting a new standard of excellence for sterile medical packaging. Start taking advantage of the significant improvements that Tyvek® Asuron™ has to offer. Specify this innovative packaging material and see the difference for yourself.

For more information about Tyvek® Asuron™, call 1-800-44-TYVEK®. To specify Tyvek® Asuron™ for your sterile medical packaging application, contact your sterile packaging manufacturer.

Property	Units		55# Paper (Coated)		DuPont™ Tyvek® 2FS™		DuPont™ Tyvek® 1059B		DuPont™ Tyvek® Asuron™		DuPont™ Tyvek® 1073B	
Delamination	lb/in	N/2.54 cm	—	—	0.61	2.70	0.50	2.22	0.56	2.31	0.52	2.31
Basis Weight	oz/yd ²	g/m ²	2.84	96.3	1.76	59.5	1.9	64.4	2.0	67.8	2.2	74.6
Porosity	sec	sec	66	66	22	22	22	22	22	22	22	22
Opacity	%	%	—	—	94.3	94.3	90.7	90.7	96.5	96.5	92.4	92.4
Thickness	mils	um	4.8	122	6.1	155	6.5	165	7.1	180	7.3	185
Spencer Puncture	in-lbf/in ²	J/m ²	10	1751	30	5254	35	6129	41	7180	42	7355
Mullen Burst	psi	kPa	—	—	134	925	153	1055	153	1054	178	1227
Hydrostatic Head	in H ₂ O	cm H ₂ O	18	46	57	145	56	142	61	155	59	150
Elmendorf Tear, XD	lb	mN	0.16	712	0.83	3694	0.72	3203	0.99	4406	0.79	3514
Elmendorf Tear, MD	lb	mN	0.16	712	0.63	2803	0.67	2980	0.87	3872	0.77	3425
Tensile Strength, XD	lb/in	N/2.54 cm	21.7	97	35.3	157	39.2	174	44.	198	46.8	208
Tensile Strength, MD	lb/in	N/2.54 cm	30.1	134	35.1	156	36.6	163	37.7	170	43.4	193

XD = cross direction / MD = machine direction

■ U.S. Units
■ International Units

Table I. Comparison of Typical Physical Properties

Sharing expertise at seminars in Asia

As leaders in the industry, DuPont is dedicated to providing information and sharing expertise to help medical device manufacturers (MDMs) and medical fabric distributors protect the health of patients around the world. As part of this commitment, experts from DuPont regularly conduct seminars in major cities throughout the United States, Europe and Asia.



Hosts and attendees of the seminar in Beijing included (from left to right): Michael Scholla, Ph. D, Park J. Qian, Zhigang Chen, George Menkle, Ichiro Ikeda, David Jiao, Liu Yi and Jingjun Mao.

Recently, Michael H. Scholla, Ph.D., Senior Consultant, DuPont Medical Packaging and DuPont Medical Fabrics, traveled to Asia to share his expertise on the regulatory framework of the medical device industry and international standards for sterilization and packaging. In some sessions, he also spoke about medical fabrics and discussed the benefits of single-use medical gowns and drapes.

DuPont teamed with Beijing Hua Guang Certification of Medical Devices, the China Association for Medical Devices Industry and Bemis Manufacturing Company's Health Care Products Group, to host a seminar in Beijing. Bemis also served as co-host of medical packaging seminars presented in Seoul, Korea, and in Penang, Malaysia.

In Shanghai, the focus of the seminars was on medical fabrics and protective apparel. Multigate, Australia's leading supplier of top quality hospital/surgical dressing and operating room apparel, served as co-host of these sessions.



Todd Apple speaks to seminar attendees in Beijing.

"We are very happy to share our experience and knowledge with local partners," said Todd Apple, Director, DuPont Nonwovens, Asia Pacific. "We hope we can add value so they can achieve the international standard and be competitive in the global market."

Editor's Note: The DuPont Medical Packaging Seminar Series is divided into six modules:

- Sterilization Technology
- Testing Packages & Materials
- ISO 11607 Packaging for Terminally Sterilized Medical Devices
- Printing on DuPont™ Tyvek®
- Brand Security
- DuPont™ Tyvek® Asuron™

DuPont technical experts will provide instruction for groups of employees at your site for whichever module(s) you select. Open-session seminars will also be held in U.S., European and Asian locations throughout the year. For more information, visit the website at www.MedicalPackaging.DuPont.com.

People on the move



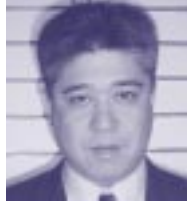
DuPont Medical Packaging wishes a fond farewell to **Eydie Triplett**, senior research engineer and certified Six Sigma Master Black Belt. Triplett has accepted an assignment with DuPont Advanced Fibers System. During her three years with the DuPont Medical Packaging Team, Triplett worked extensively with medical device manufacturers to obtain the “voice of the customer.” We thank her for all of her contributions and wish her well in her new assignment.



José Arévalo recently joined the DuPont Medical Packaging Team as the Business Development Manager for Latin America. Arévalo’s background includes extensive technical and marketing management experience. Before joining DuPont last year, he gained valuable experience working in the packaging, healthcare and pharmaceutical industries. Arévalo earned bachelor of science and master’s of science degrees in package engineering from RIT. He is fluent in Spanish and proficient in Latin American cultures.



Reema Badr is a new addition to the DuPont Medical Packaging Team assigned to product quality service. Badr has worked in various capacities in research laboratories for the past three years. She earned a bachelor’s degree in chemical engineering from Virginia Commonwealth University and is the recipient of the 2003 Philip Morris Entrepreneurial Business Plan Award.



Satoshi Hiraga is a Senior Marketing Specialist for the DuPont Medical Packaging Team in Japan. Hiraga worked in research and development roles for nearly 20 years before accepting this position at DuPont. He earned a bachelor’s degree in chemical engineering from Keio University in Tokyo.



Wanita Hlavaty has worked in the DuPont™ Tyvek® organization for more than half of her 23-year career at DuPont, but only recently began working with the DuPont Medical Packaging Team. Over the years, she has had a variety of assignments in plant support, process control, product development, robotics and R&D. Hlavaty has been temporarily assigned to the DuPont Medical Packaging Team to focus on the launch of Tyvek® Asuron™. Hlavaty earned a bachelor’s degree in mechanical engineering from Penn State University.



Patrick Young, Ph.D., joined the DuPont Medical Packaging Team as a Research Associate. He brings a wealth of research background in polymers, films, coatings and surface science, combined with more than 20 years of experience in product development, to his new assignment. Young earned his Ph.D. in chemistry from Ohio University. He holds four United States patents and is a certified ISO 9000 auditor. He also has extensive experience with ASTM, UL and FDA product compliance standards.

Calendar of events

Medical Device Technology 2006*

February 15-16, 2006
NEC, Birmingham, UK
DuPont Booth #219

Interphex 2006**

February 16-17, 2006
Puerto Rico Convention Center
San Juan, Puerto Rico
DuPont Booth #929

MEDTEC 2006*

March 7-9, 2006
Messe Stuttgart
Stuttgart, Germany
DuPont Booth #1311

HealthPack 2006***

March 14-15, 2006
Crowne Plaza Market Center Dallas Hotel
Dallas, TX
DuPont Booth #TBD

MD&M East Trade Show*

June 6-8, 2006
Jacob K. Javits Convention Center
New York, NY
DuPont Booth #2037

MEDTEC China*

June 21-23, 2006
Shanghai, China
DuPont Booth #TBD

MEDTEC China*

November 7-9, 2006
Guangzhou, China
DuPont Booth #TBD

MEDTEC Ireland*

September 20-21, 2006
Radisson SAS
Galway, Ireland
DuPont Booth #TBD

* For more information, contact Canon Communications at 310-445-4200 or visit www.devicelink.com/expo

** For more information, visit interphexpuertorico.com

*** For more information, visit www.healthpack.net

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