



June 25, 2007

**Launch Properties
Test Details for DuPont™ Tyvek® Asuron™**

To Whom It May Concern;

This document contains technical information concerning DuPont™ Tyvek® Asuron™ (Style Number 4070B). Tyvek® Asuron™ is a new Tyvek® product for the medical packaging industry. The intent of this document is to share technical information about Tyvek® Asuron™. This document replaces customer data package release #1 and #2, containing the same data plus additional data for 5 year and 10 year accelerated aging studies. More data packages will be released as the real time aged material becomes available and is tested. One (1) year real time data should be available late 2007. The remaining real time aged material should be available in 2009, 2011, and 2016.

If you have any further questions please do not hesitate to contact your Account Manager or myself directly.

Sincerely,

Wanita Hlavaty
E. I. DuPont de Nemours
P.O Box 27001
Richmond, Virginia 23261
(804) 383-3666

The DuPont Oval Logo, DuPont™ and Tyvek® are trademarks or registered trademarks of E I du Pont de Nemours and Company, or its affiliates.

6/25/2007 7:52:49 AM

Page 1 / 29

(Customer Data Package Release 3)

Table of Contents

Introduction:	3
Physical Property Analysis:	7
General Product Information:	9
Contact Angle	9
Parker Smoothness	9
Color	10
DSC and IR Scanning	10
Sheet Stability	11
Biocompatibility	11
Primary Skin Irritation	12
FDA Extractables	12
Bioburden	12
Unique Performance Characteristics	13
Printability	13
Thermal Transfer	13
Flexographic Printing	14
Homogeneous Appearance	15
Improved Seal Appearance at Higher Temperatures	16
Sterilization and Aging:	17
Post Sterilization - Specification Physical Properties (English Units)	18
Post Sterilization - Other Physical Properties (English Units)	19
Post Sterilization - Specification Physical Properties (International Units)	22
Post Sterilization - Other Physical Properties (International Units)	23
Barrier Properties	26
Operational Data:	27
Seal Curves	27
Blade Wear	28
Ultraviolet Light Filtering	29

Launch Properties

Test Details for Tyvek® Asuron™

Introduction:

This data package is divided into five (5) sections: Specifications, General Product Information, Unique Performance Characteristics, Sterilization and Aging, and Sample Seal Curves.

Validation procedures:

Three (3) sample sets were created from both Tyvek® Asuron™ and Tyvek® 1073B material. Samples drawn for Tyvek® Asuron™ contain product from three (3) spin lines. To capture examples at the extremes of the specification, samples include product that has porosity values close to the high specification limits and delamination values close to the low specification limits. Samples drawn for 1073B contain randomly selected product from three (3) separate runs. This 1073B product meets all property and manufacturing limits. 1073B is used as a comparison for all testing.

For most testing sample sizes range from six (6) to fifteen (15) per sample set. For the product comparison, this then equals between eighteen (18) and forty-five (45) samples per product (1073B versus Tyvek® Asuron™). Sample sizes will be identified in each section.

Specifications and Physical Properties

Specification values are based on over 15 development runs of Tyvek® Asuron™. Specifications may be adjusted in the future as larger commercial runs are produced. This section also includes an evaluation of roll to roll property variability between 1073B and Tyvek® Asuron™.

General Product Information:

Several tests were run to characterize Tyvek® Asuron™. In most cases, these test results were identical to Tyvek® 1073B, since Tyvek® Asuron™ compares closely with Tyvek® 1073B. This section includes these tests, as well as product safety testing.

Unique Performance Characteristics:

Tyvek® Asuron™ has several characteristics that differentiate it from the standard medical packaging style 1073B. These include more homogeneous appearance, improved printability, and improve visual seal characteristics at higher sealing temperatures. Since Tyvek® Asuron™ is manufactured both in the United States and in Luxembourg, a fourth improvement is expanded fulfillment capacity for improved service and contingency planning.

Sterilization and Aging:

To perform the sterilization study, each validation sample set was sheeted and sterilized. A validation sample set is defined as a set of samples from one of the three (3) validation materials. There are three (3) sample sets for Tyvek® Asuron™ and three (3) sample sets for 1073B comparison. Six (6) types of sterilization were performed, ethylene oxide (EtO), gamma radiation at 25 & 50 kGy, electron beam radiation at 25 & 50 kGy, and Steam or autoclave. One set was left unsterilized to act as a control. For each sample set, six (6) results were obtained for physical properties and barrier properties (LRV). Aging studies will include 1, 3, 5, and 10 year accelerated aging as well as 1, 3, 5, and 10 year real time aging.

At this time, post sterilization and accelerated aging data is available. Data from real time aging studies will be issued as they are completed.

Operational Data:

Operational data contains information developed that may give insight into how Tyvek® Asuron™ may perform in the trade. This involves information about seal curves, blade wear, and light transmittance.

OTHER PROPERTIES
DuPont Nonwovens

Features: No Antistat, No Corona Product: Tyvek® Asuron™
 Style: 4070B 2.0 oz/yd²
 Customer Use/End Use: _____ Customer Delivery Unit: Roll
Medical Packaging Product Unit: Mill Roll Merge: _____
 Use Exception: _____ Effective Date: December 2005 Last Reviewed: December 2005

The following data is supplied for information:

<u>Other Properties</u>	<u>99.994% Range (Roll Ave.)</u>						<u>Test Method</u>	
	<u>-----US Units-----</u>			<u>--International Units--</u>			<u>DuPont</u>	<u>Comparable Test Methods</u>
	<u>Nominal</u>	<u>Low</u>	<u>High</u>	<u>Nominal</u>	<u>Low</u>	<u>High</u>		
Hydrostatic Head US - in H ₂ O Int'l - cm H ₂ O	61	45	78	155	114	198	0056-00	AATCC TM 127 DIN EN 20811 ²
Thickness (Indiv. Test) US - mils Int'l - μm	7.1	3.2	10.9	180	81	277	0027-96	ASTM D1777 ³ DIN EN 20534 ⁴
Tensile (MD) US - lb/in Int'l - N/2.54cm	38.1	28.7	47.6	170	128	212	0041-96	ASTM D5035 ⁵ DIN EN ISO 1924-2 ⁵
Tensile (CD) US - lb/in Int'l - N/2.54cm	44.4	32.3	56.5	198	144	251	0041-96	ASTM D5035 ⁵ DIN EN ISO 1924-2 ⁵
Elmendorf Tear (MD) US - lb Int'l - mN	0.87	0.51	1.26	3872	2270	5607	0007-96	ASTM D1424 DIN EN 21974
Elmendorf Tear (CD) US - lb Int'l - mN	0.99	0.69	1.36	4406	3070	6052	0007-96	ASTM D1424 DIN EN 21974
Opacity US - % Int'l - %	96.9	93.8	99.0	96.9	93.8	99.0	0020-96	TAPPI T 425 ISO 2471 ⁶
Bendtsen Air Perm. US - ml/min Int'l - ml/min	575	377	1133	575	377	1133		ISO 5636/3 ⁷
Mullen Burst US - psi Int'l - kPa	153	115	191	1054	792	1316	0014-96	ASTM D774 ISO 2758

All properties are typical values based on roll averages, with samples taken uniformly across the sheet.

Other properties are the result of controlling the specification properties to an aim. The values shown for other properties are typical but carry no warranty, expressed or implied. The customer is responsible for determining that Tyvek® is suitable for the intended application.

² Rate of use: 60 cm H₂O/min

³ 7.15 psi, 0.625-inch diameter presser foot

⁴ Surface 2 cm², pressure 100 kPa

6/25/2007 7:52:49 AM

⁵ Modified for speed and gauge length

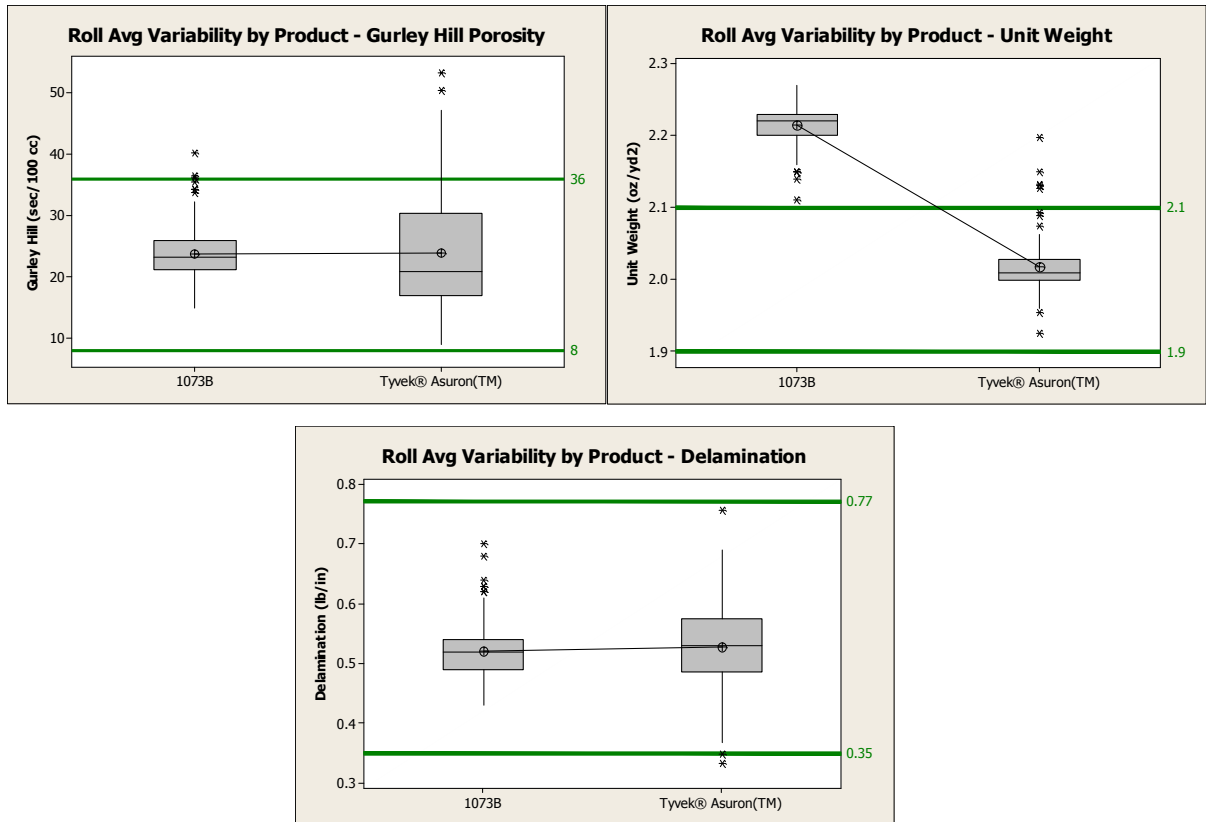
⁶ Modified for different backing stds, area & illumination

⁷ ΔP = 1.5 kPa, area 10 cm²

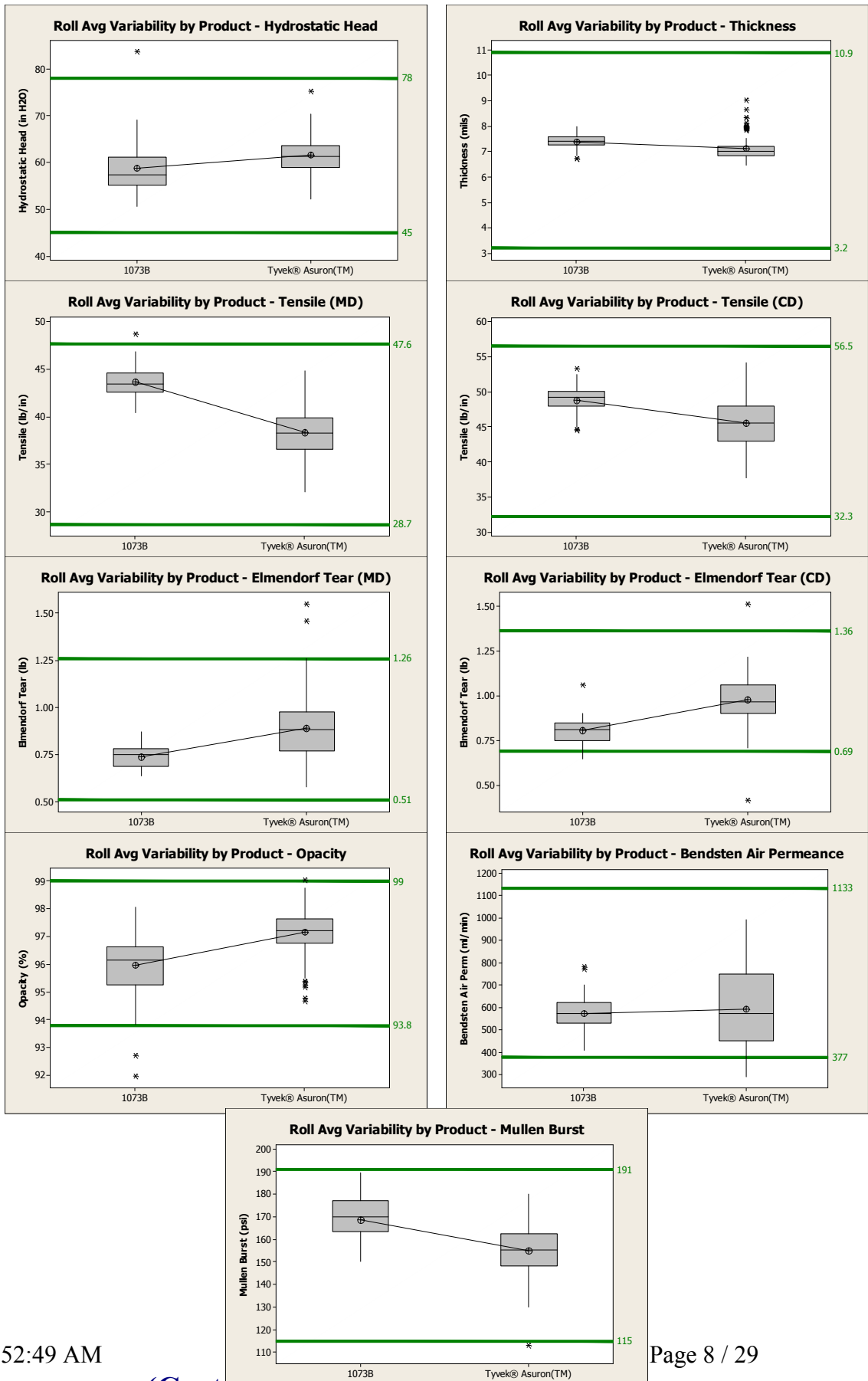
Physical Property Analysis:

Physical property variability was compared to 1073B historical data. Sixty (60) production days of 1073B compared with the fifteen (15) production runs of Tyvek® Asuron™. Since the product runs of Tyvek® Asuron™ were small, and process conditions were changed to identify the process window, the variability of the Tyvek® Asuron™ is higher than the 1073B. This variability is expected to reduce close to the same level as 1073B as we develop more experience and have longer production runs.

Specification Properties:



Other Properties:



General Product Information:

General information was gathered about Tyvek® Asuron™ using the validation sample sets.

Contact Angle

Contact angle was measured using a Contact Angle Meter (Model CAM-FILM-Ton) per DuPont test method TM-1003-96. Six (6) samples for each validation sample set, giving 18 total samples per product, were analyzed.

Contact angle measurements of liquid droplets on substrate surfaces are used to characterize surface wettability. The contact angle is defined as the angle between the substrate support surface and the tangent line at the point of contact of the liquid droplet with the substrate. This value is related by Young's equation to the surface energy of the substrate. The value of the contact angle of the liquid droplet will depend upon the surface energy of the substrate and the surface tension of the liquid. Glass and metals are examples of high energy surfaces over which most liquids spread spontaneously, with the angle tending to zero. In contrast, plastic materials are typical low energy surfaces such that liquids placed on these surfaces remain in the form of drops having finite contact angles so long as the surface energy of the substrate is less than the surface tension of the liquid.

	Smooth Side	Rough Side
1073B	97.7	101.1
Tyvek® Asuron™	113.3	114.6

Parker Smoothness

Smoothness affects the printability of the surface. Parker Smoothness follows TAPPI Test Method T 555 om-04 "Roughness of Paper and Paperboard (Print Surf Method)". It measures the roughness of paper and paperboard under conditions intended to simulate the nip pressures and backing substrates found in printing processes. It is applicable to coated and uncoated papers and paperboards which are intended to be printed by contacting printing processes. The tester determines the resistance to flow or air between the test surface and a metal band in contact with it.

	Smooth Side (μm)	Rough Side (μm)
1073B	6.0	7.2
Tyvek® Asuron™	4.7	6.4

Color

Specimens of Tyvek® were subjected to a controlled light source. The light rays which are reflected from the specimens were picked up by photo-detectors and broken down and reported in Hunter 'L', 'a', and 'b' color values. 'L' value is a measure of lightness and varies from 100 for perfect white to zero for black, approximately as the eye would evaluate it. 'a' value is a measure of redness when plus, gray when zero, and greenness when minus. 'b' value is a measure of yellowness when plus, gray when zero, and blueness when minus.

	"L"	"a"	"b"
1073B	97.01	-.50	-.11
Tyvek® Asuron™	97.81	-.60	-.50

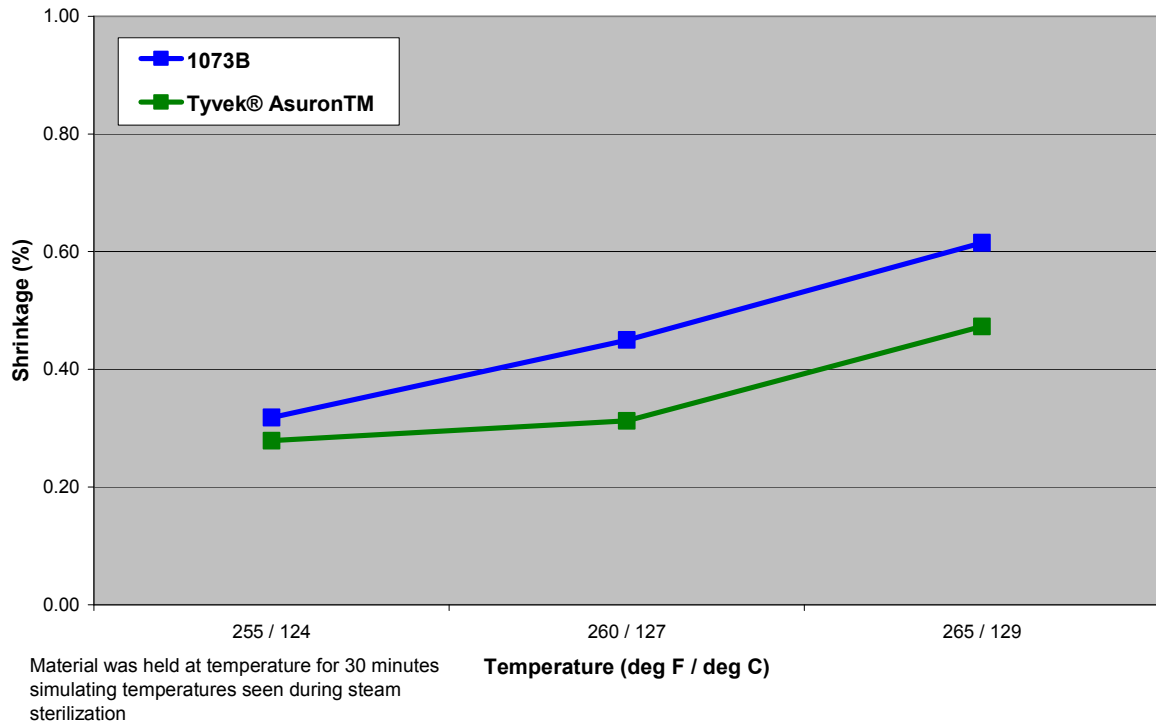
DSC and IR Scanning

DSC and IR are used to determine any shift in material structure. This include crystallinity as well as additives. DSC and IR scanning were performed on each validation sample set. DSC, differential scanning calorimetry, measures the melting point and heat of melting of a material. Results between Tyvek® Asuron™ samples and 1073B samples, as well as between styles, were equivalent. IR measures the amount of surface reflectance per differing wavelengths. Results between Tyvek® Asuron™ samples and 1073B samples were equivalent. Results between styles differed slightly at the short wavelengths. This difference is attributed to the TiO2 addition. Copies of the DSC and IR results are available on request.

Sheet Stability

Sheet stability becomes important during steam sterilization since sterilization occurs at temperatures near the melting temperature of Tyvek®. To simulate sheet stability during steam sterilization, six (6) nominal eight (8) inch strips were cut from each validation sample set, providing 18 samples per type. Each strip was pre-measured using instrumentation with precision to 0.0001. Samples were then heated for 30 minutes at determined temperatures. The samples were then allowed to cool and were re-measured. There is no statistical difference between Tyvek® Asuron™ shrinkage and 1073B shrinkage.

Shrinkage versus Temperature



Biocompatibility

Test Performed	Product Type	Unexposed	Ethylene Oxide (EtO)	Gamma Irradiation (25 & 50 kGy)	Electron Beam (25 & 50 kGy)	Steam
L929 MEM Elution Cytotoxicity Test – USP (Ref CYT-001)	1073B	Non-cytotoxic				
L929 MEM Elution Cytotoxicity Test – USP (Ref CYT-001)	Tyvek® Asuron™	Non-cytotoxic				

Primary Skin Irritation

Each validation lot was evaluated for its potential to product Primary Dermal Irritation after a single topical 4 hour application to the skin of New Zealand White rabbits. For all samples, no signs of erythema or edema were noted at any observation period. Based on the criteria of the protocol, each sample was considered a negligible irritant.

Testing was conducted in compliance with U.S. Food and Drug Administration regulations set forth in 21 CFR, Part 58. The sections of the regulations not performed included characterization and stability of the test article and its mixture with carriers, 21 CFR, Parts 58.105 and 58.113. All three samples used 1073B as a control. Hard copy results are available upon request.

FDA Extractables

% Hexane extractable analysis (Maximum extractable fraction in n-Hexane) was completed according to 21CFR 177.1520 (d) (3) (ii) (i) Option1. % Xylene extractable analysis (Maximum soluble fraction in Xylene) was completed according to 21CFR 177.1520 (d) (4) (ii). Per specifications under 21CFR 177.1520, all samples were below limits both for articles that contact food as well as articles for packing and holding food during cooking.

Bioburden

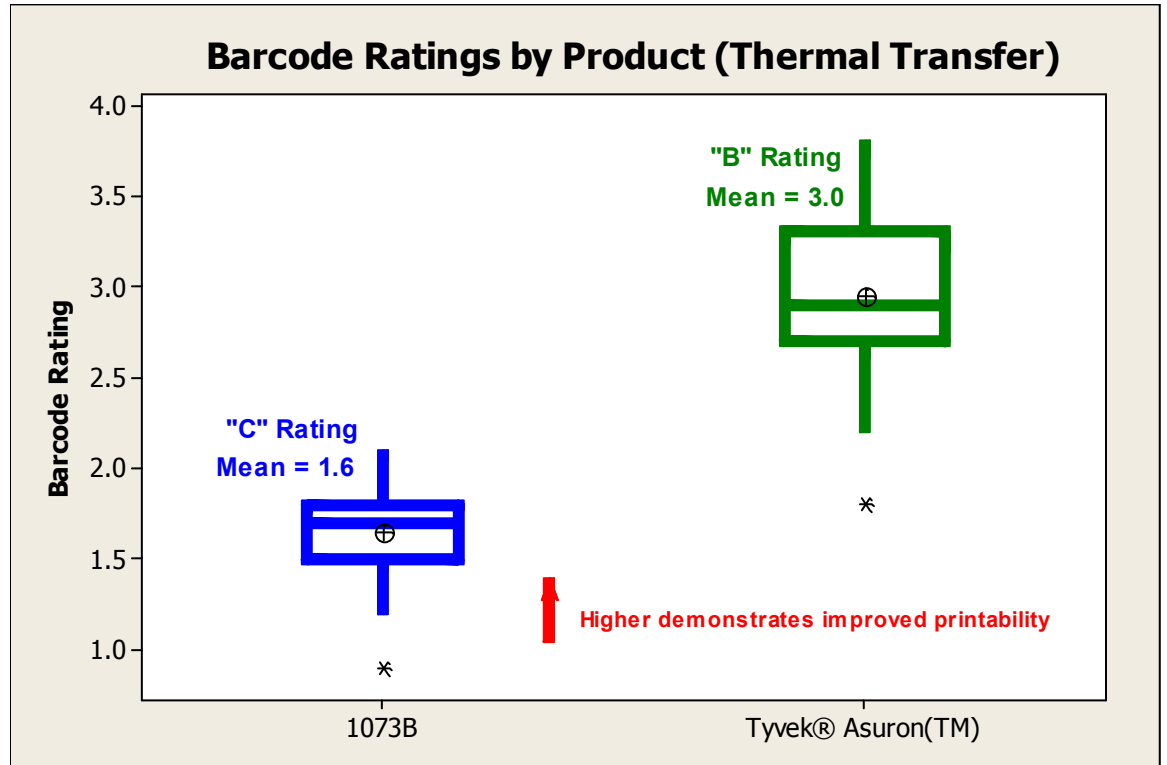
Analysis tested for routine aerobic, aerobic spore, and yeast/mold bioburden in accordance with ANSI/AAMI/ISO 11737-1 1995 Sterilization of Medical Devices Microbiological Methods – Part 1: Estimation of the Population of Microorganisms on Products. Five (5) samples were tested for each validation sample set. All results for both 1073B and Tyvek® Asuron™ populations were below 2.0 on a log scale.

Unique Performance Characteristics

Printability

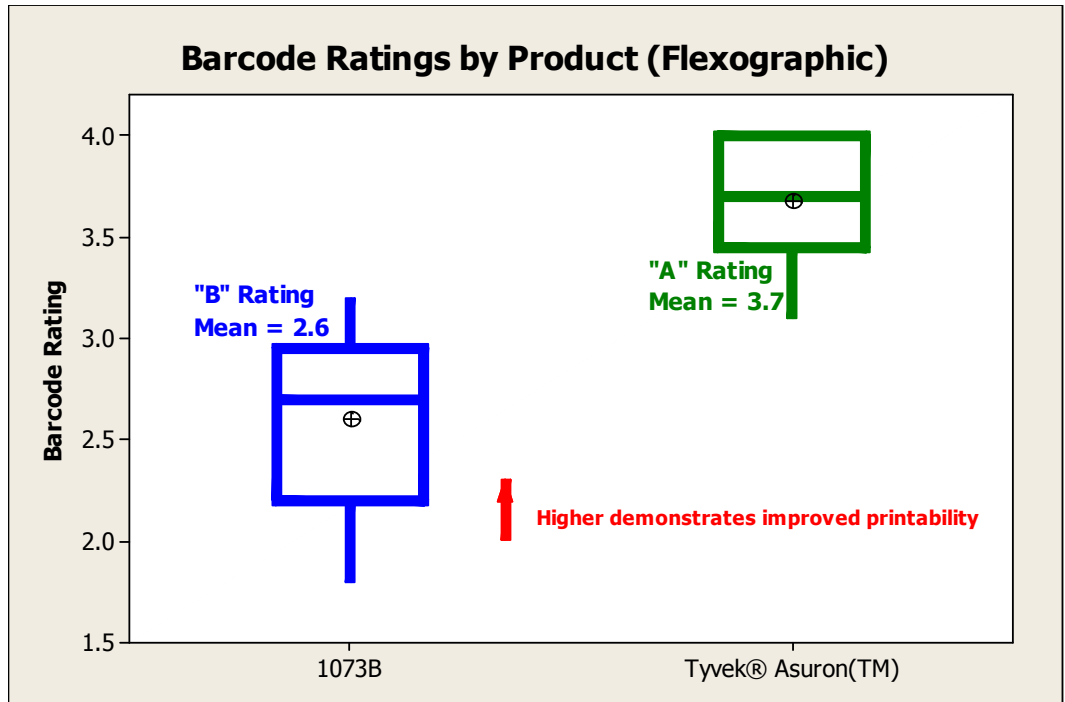
Thermal Transfer

Barcode analysis was completed using thermal transfer printing. Forty-one (41) samples were printed of 1073B and forty-seven (47) samples were printed on Tyvek® Asuron™. Results show Tyvek® Asuron™ a complete grade level better than 1073B.



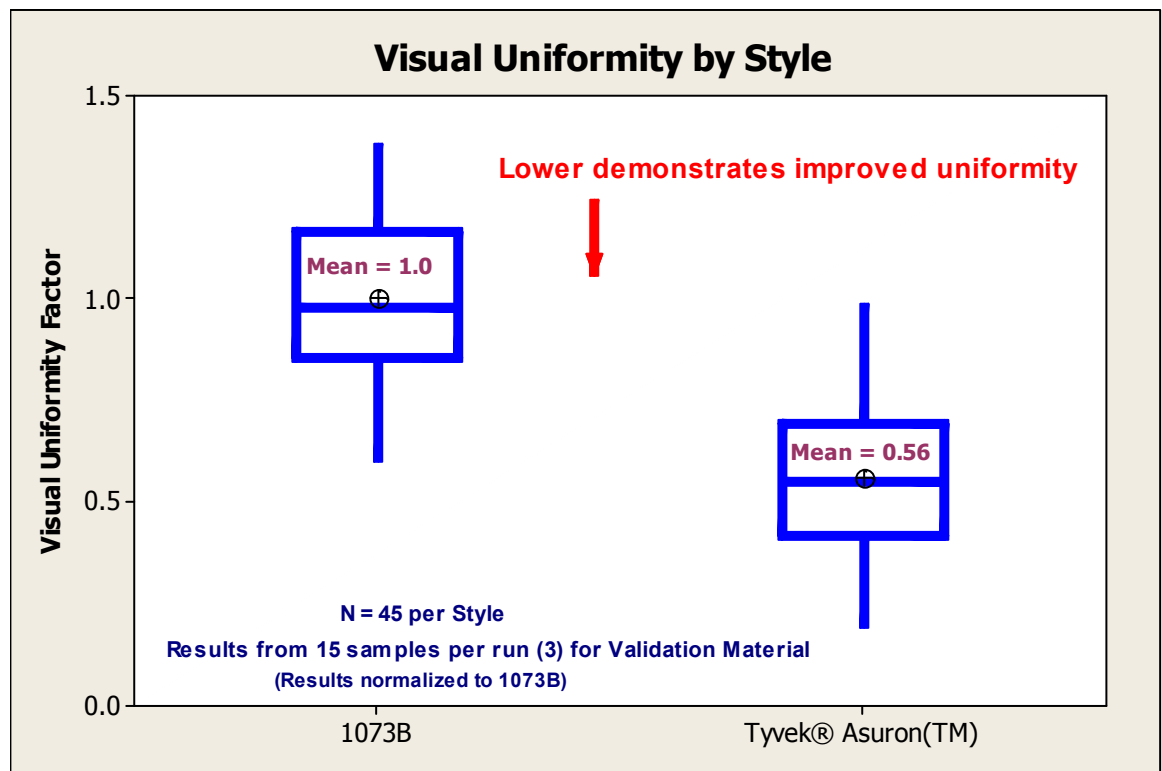
Flexographic Printing

Barcode analysis was completed using flexographic printing. Printing was completed on a Mark Andy LP 3000 printer using black water graphics ink and a 300 count analox roll. Fifteen (15) samples were printed from each of the validation materials, giving a total of forty-five (45) samples each for 1073B and Tyvek® Asuron™. Results show Tyvek® Asuron™ a complete grade level better than 1073B.



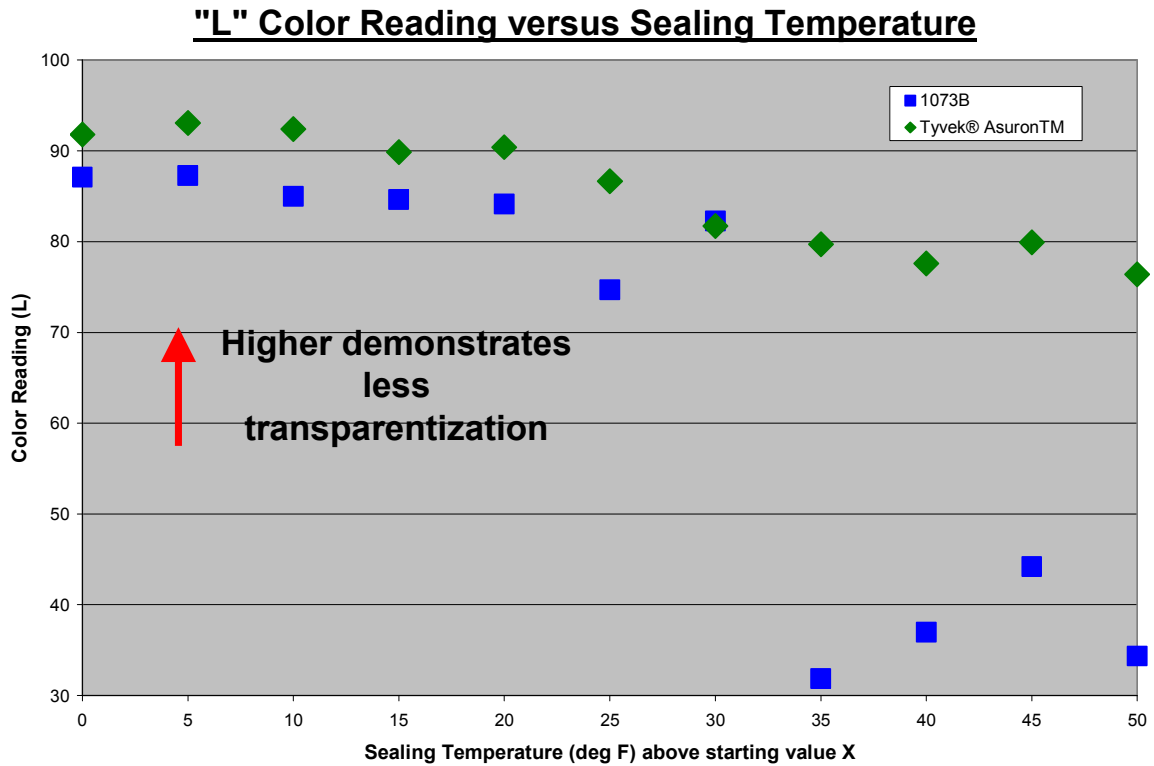
Homogeneous Appearance

Tyvek® Asuron™ is more uniform than 1073B. This is measured using a visual system. Since no standard exists for measuring visual uniformity, a technique used by the paper industry to determine mottle was employed. This technique is based on a technical paper by Roy R. Rosenberger, “Stochastic Frequency Distribution Analysis as Applied to Mottle Measurement”. This system uses a digital camera to capture infrared light transmitted through the Tyvek® sample. The pixels from the digital picture are then converted to grey scale and analyzed for variability. The variability is determined by dividing the matrix of grey scale values into equal sub-matrices. The standard deviation of each sub-matrix is calculated. The result is then the multiplication of the average standard deviation of the sub-matrices, the standard deviation of the sub-matrices’ standard deviations, the standard deviation of the total population, and a scaling factor. Since light intensity can affect the results, results were normalized against 1073B as a control.



Improved Seal Appearance at Higher Temperatures

Some Tyvek® can become transparent at high temperatures. Visual transparentization analysis was completed using validation material. Two samples for each validation sample set were “sealed” on a bar sealer, mounted against a black background, and measured for “L” color. L’ color is a measure of lightness and varies from 100 for perfect white to zero (0) for black, approximately as the eye would evaluate it.



Sterilization and Aging:

To perform the sterilization study, each validation sample set was sheeted and sterilized. A validation sample set is defined as a set of samples from one of the three (3) validation materials. There are three (3) sample sets for Tyvek® Asuron™ and three (3) samples sets for 1073B comparison. Six (6) types of sterilization were performed, ethylene oxide (EtO), gamma radiation at 25 & 50 kGy, electron beam radiation at 25 & 50 kGy, and Steam or autoclave. One set was left unsterilized to act as a control. For each sample set, six (6) results were obtained for physical properties and barrier properties (LVR). Conditions for each type of sterilization are below:

1. EtO
EtO sterilization was performed after 8 hours of preconditioning. Cycle exposure included an exposure temperature of 37 °C and relative humidity of 60%. Exposure dwell was 600 minutes.
2. Gamma 25 kGy
3. Gamma 50 kGy
4. E-Beam 25 kGy
5. E-Beam 50 kGy
6. Steam
Thirty (30) minute sterilization at 124 °C with a 20 minute exhaust time.

Per ISO 11607, real-time aging is the required test used to demonstrate the ability of a sterile barrier system to maintain integrity over time. Accelerated aging was utilized, in addition to real time tests, to demonstrate aging stability in order to provide more rapid results. This does not preclude the requirement to perform real-time aging tests. It is generally accepted theory that elevated temperatures will increase chemical reactions, thereby simulating the effects of natural aging. More precisely, Von't Hoff's rule states that a rise in temperature of 10°C above ambient will double the rate of a chemical reaction. ASTM International F1980-99e1 *Standard Guide for Accelerated Aging of Sterile Medical Device Packages* and AAMI TIR No.17, *Radiation Sterilization – Material Qualification* uses this theory to establish Aging Factor (AF) estimates. These documents define the Aging Factor as a ratio of time between T_{RT} (Real time aging temperature) and T_{AA} (Accelerated Aging temperature) that is estimated or calculated to achieve the same level of functional degradation of the healthcare product in real time, as that observed under accelerated aging. The formula used to calculate an AF for temperature ranges greater than 10°C:

$$AF = Q_{10} \exp[(T_{AA} - T_{RT})/10]$$

If $Q_{10} = 2$, $T_{AA} = 57^{\circ}\text{C}$, $T_{RT} = 20^{\circ}\text{C}$, then AF, using the formula above $AF = 13$. The aging factor is then applied to calculate the time required for the sample to be held in accelerated aging conditions (t_{AA}) by means of the following equation:

$$t_{AA} = \frac{RTE}{AF}$$

Where RTE (Real Time Equivalent) is the desired time interval for testing. An example of one year testing interval is calculated below.

Accelerated Aging Time (t_{AA}) – 1 Year Aging (52 weeks)

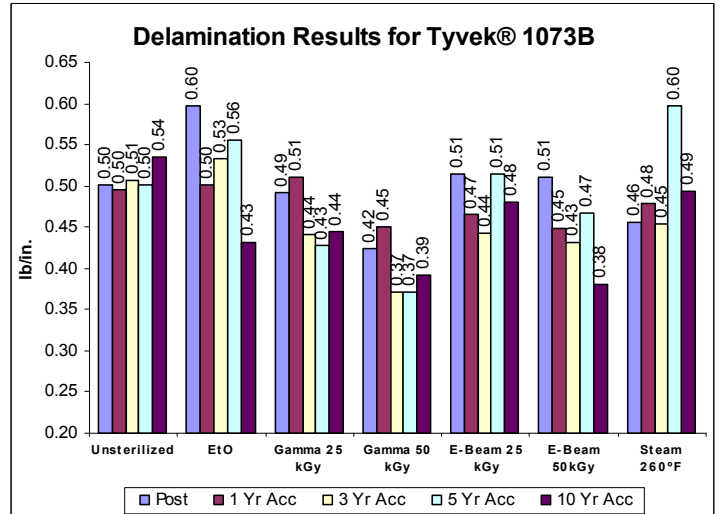
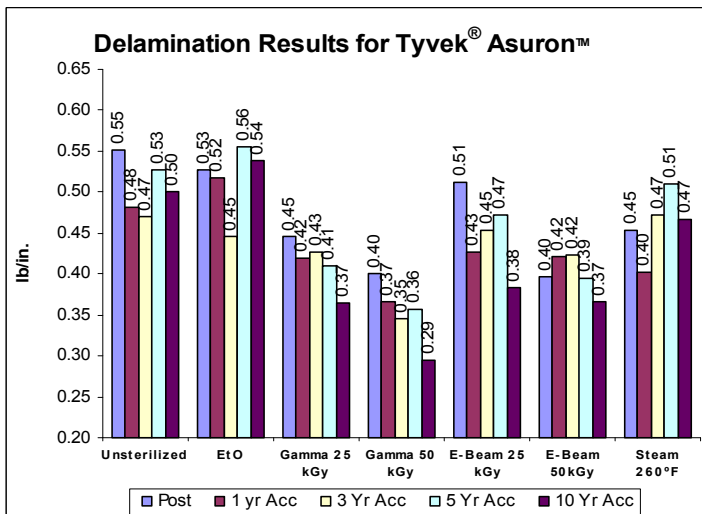
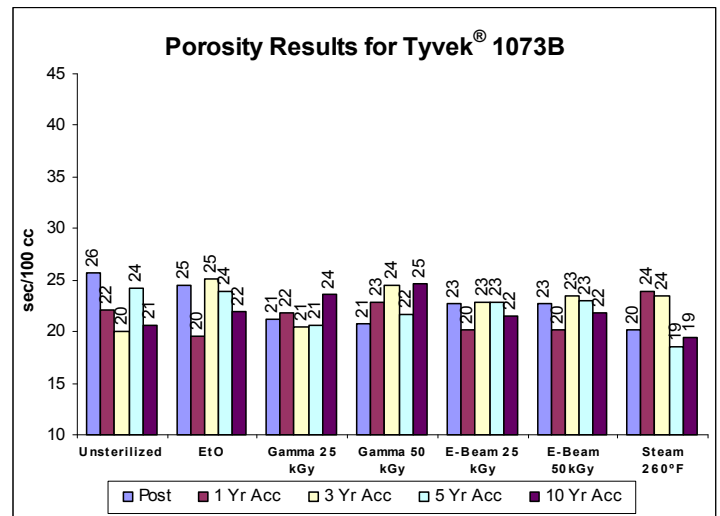
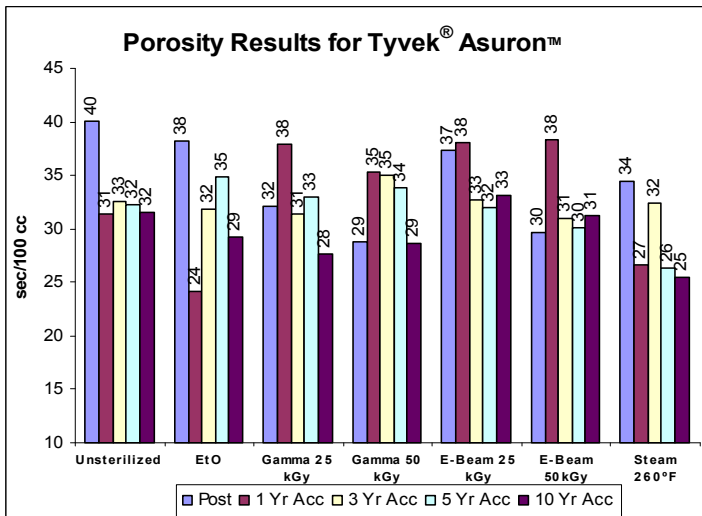
$$t_{AA} = \frac{52 \text{ weeks}}{13}$$

$$t_{AA} = 4 \text{ weeks}$$

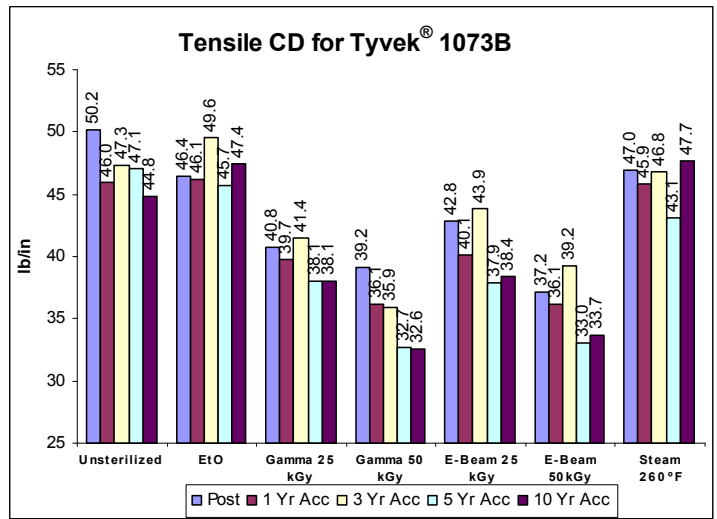
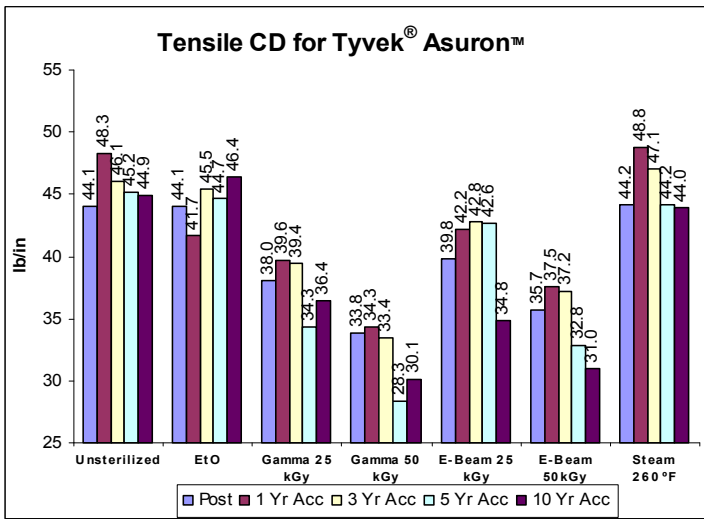
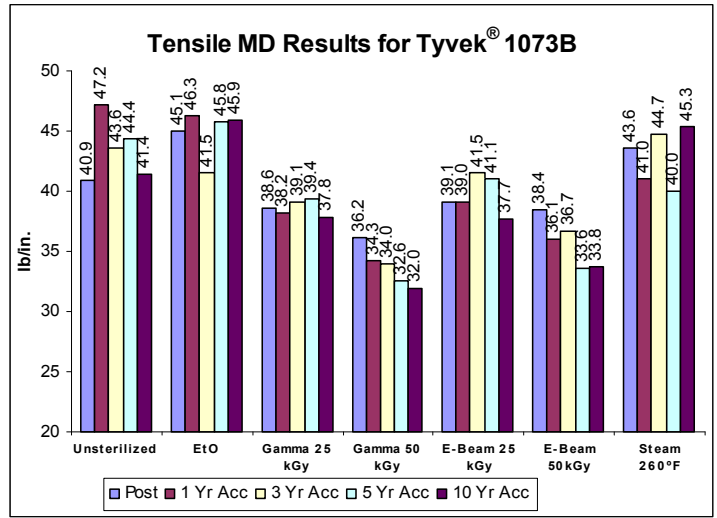
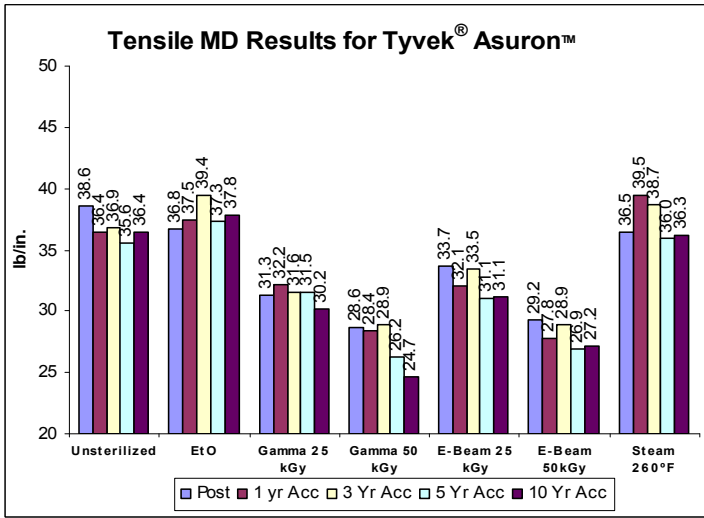
Post Sterilization - Specification Physical Properties (English Units)

To more clearly understand the affects of sterilization and aging, the results have been displayed in graphical format. Each graph contains data available for post sterilization and accelerated aging. Graphs are shared for DuPont™ Tyvek® Asuron™ and 1073B for comparison. Graphs are shown with English units. Metric units follow in the next section.

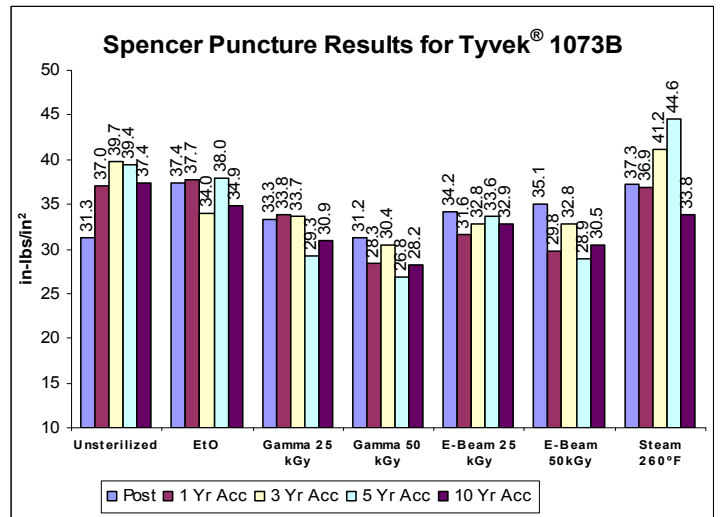
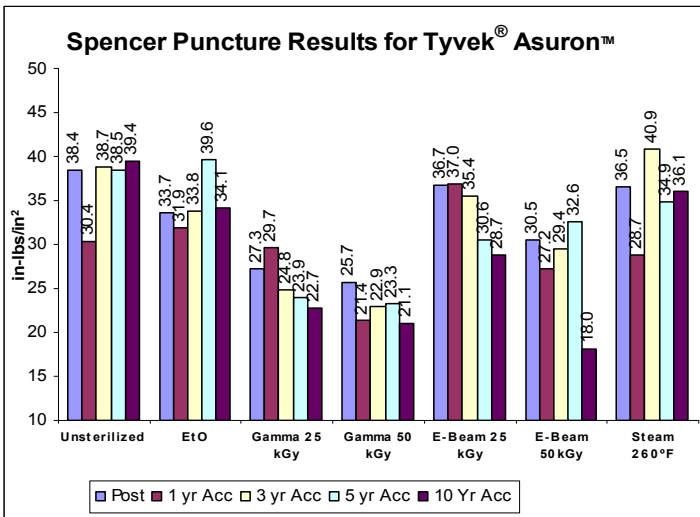
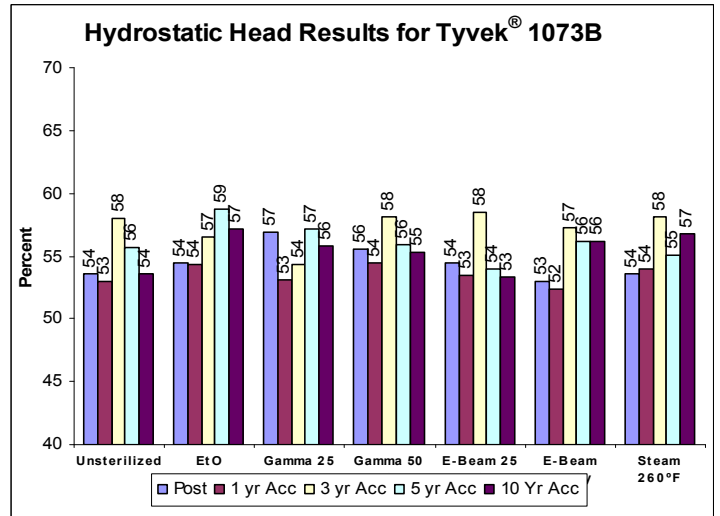
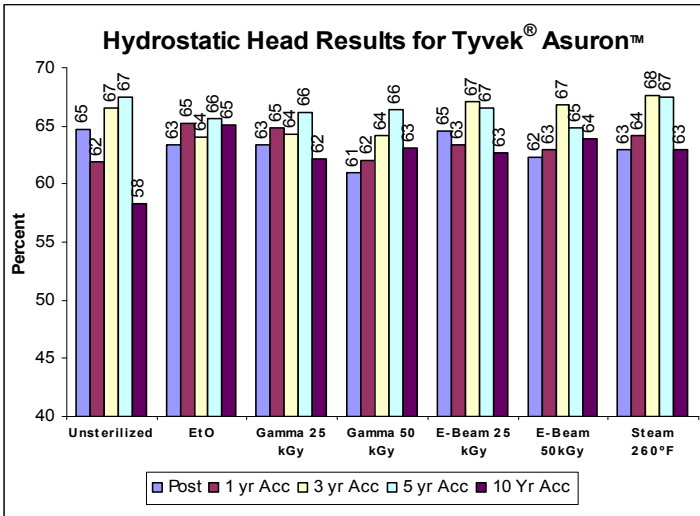
Spencer Puncture is measured per ASTM D3420, except the probe diameter is 9/16 inch (14.3 mm). Because of this difference in probe diameter, results are reported in in-lbf/in² or J/m².



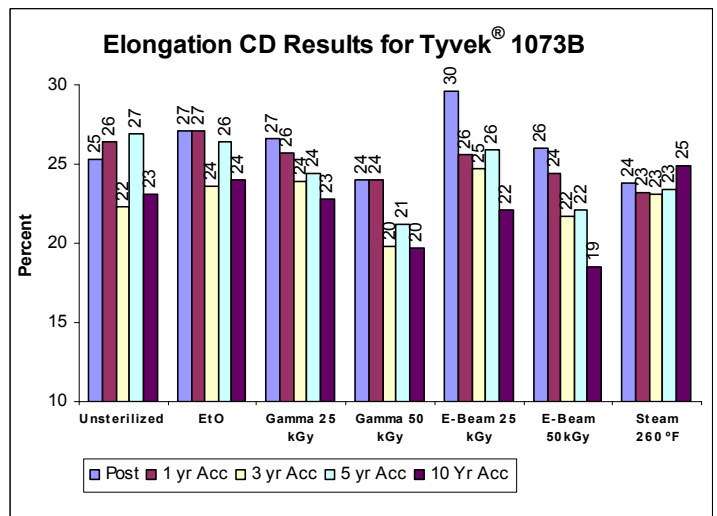
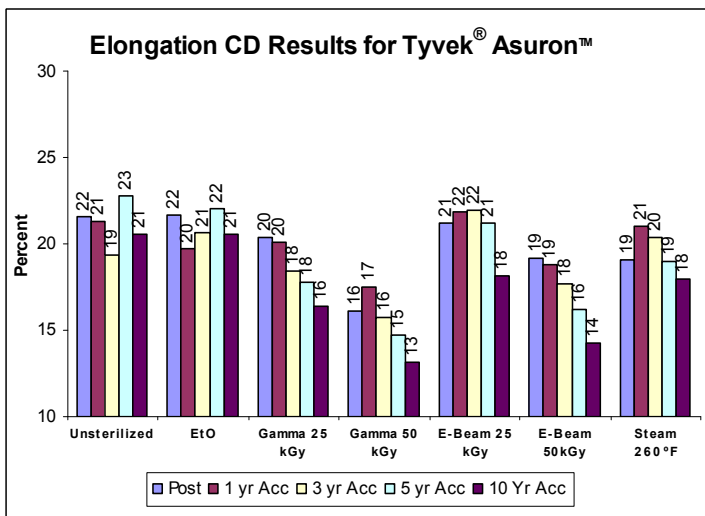
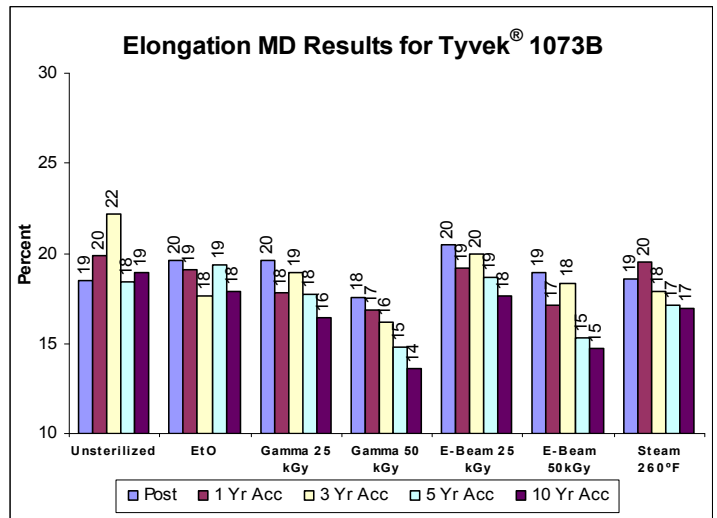
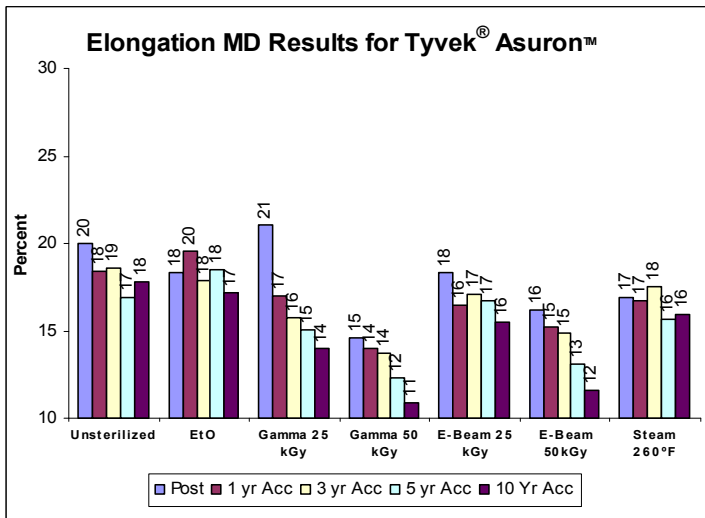
Post Sterilization - Other Physical Properties (English Units)



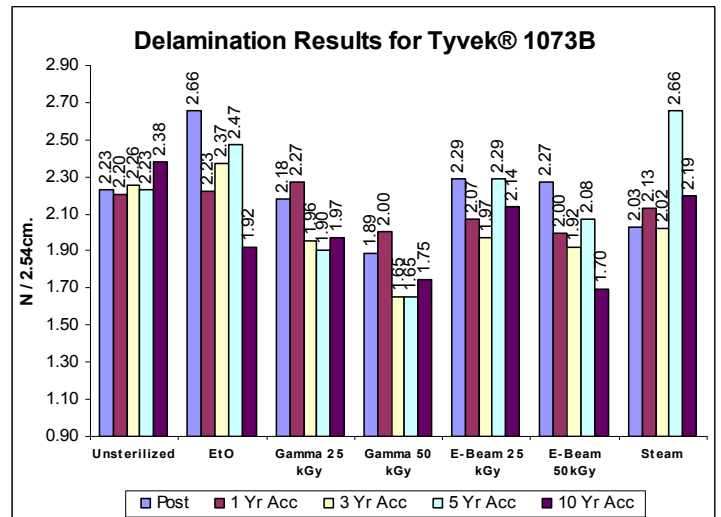
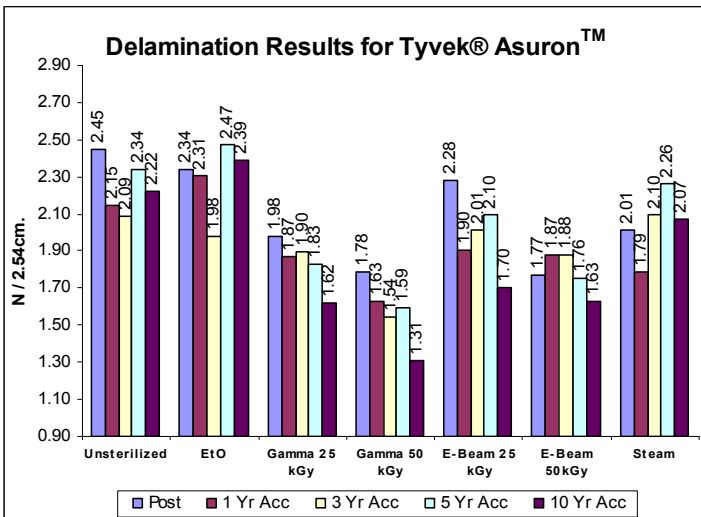
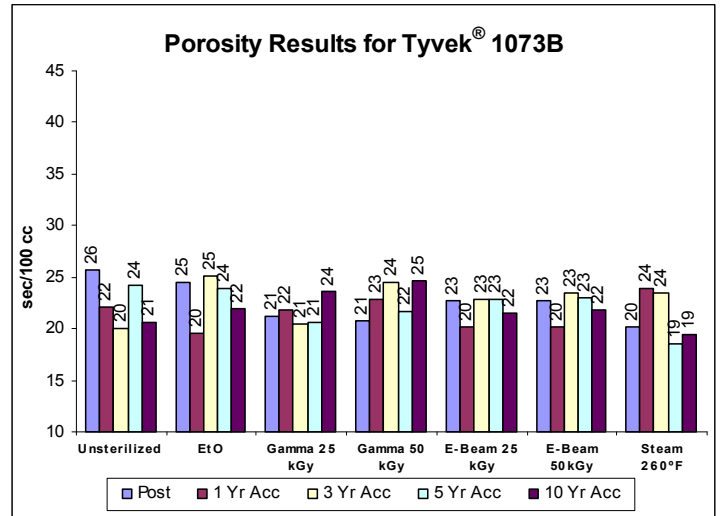
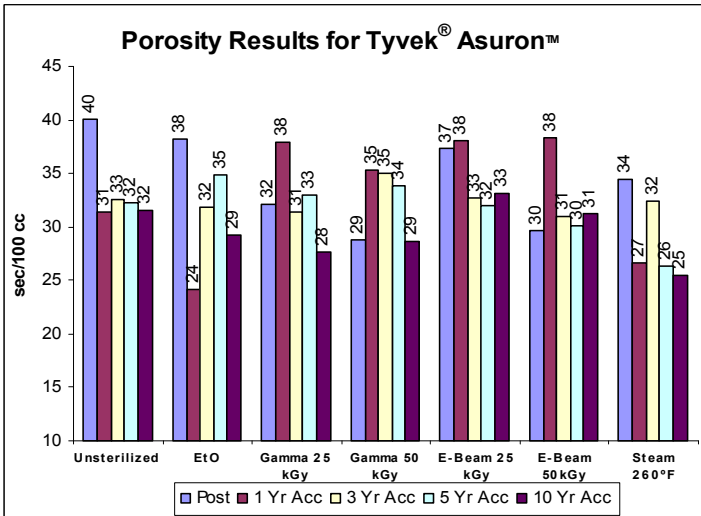
Post Sterilization - Other Physical Properties – continued (English Units)



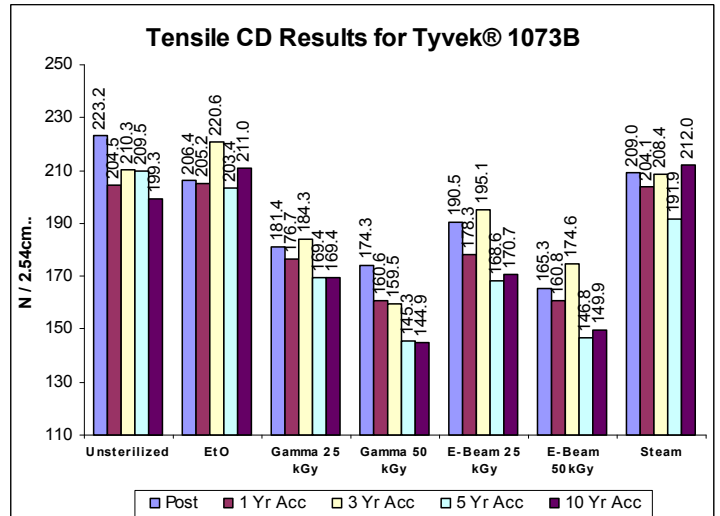
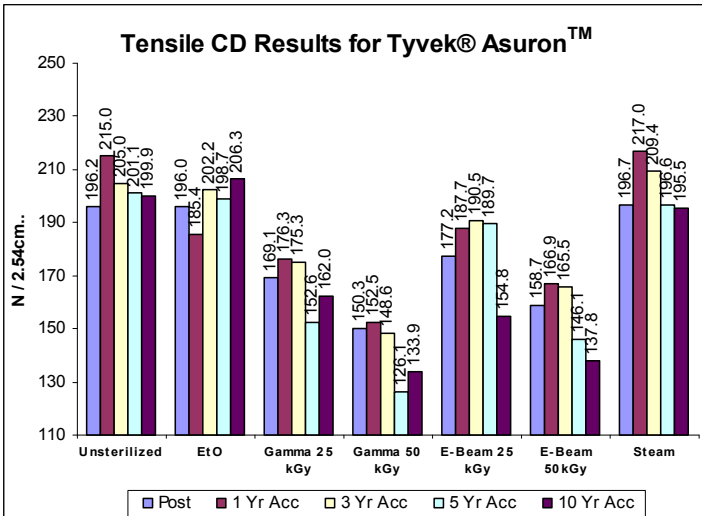
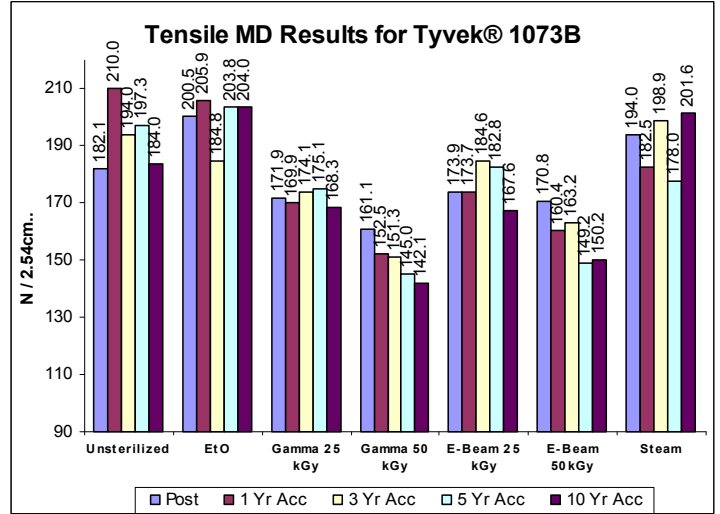
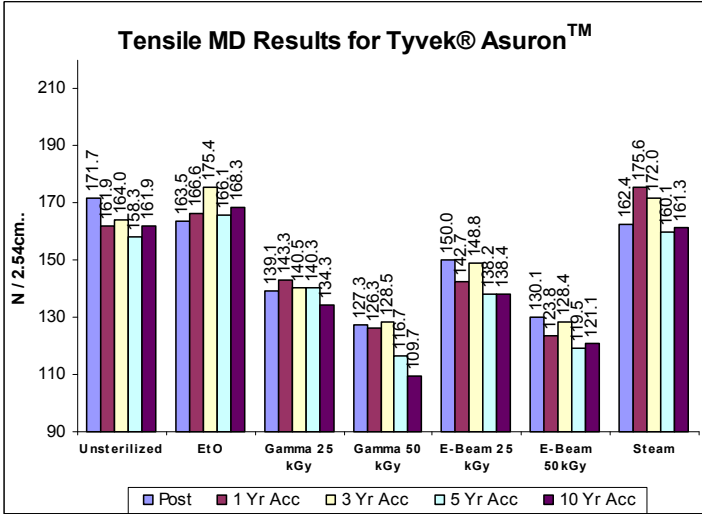
Post Sterilization - Other Physical Properties – continued (English Units)



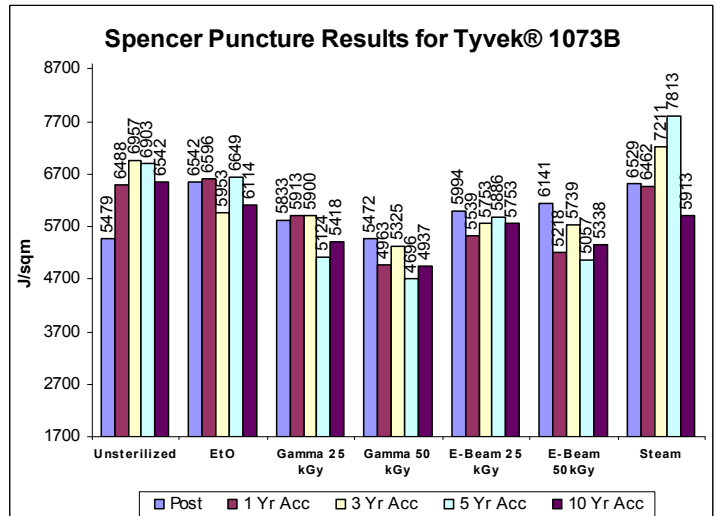
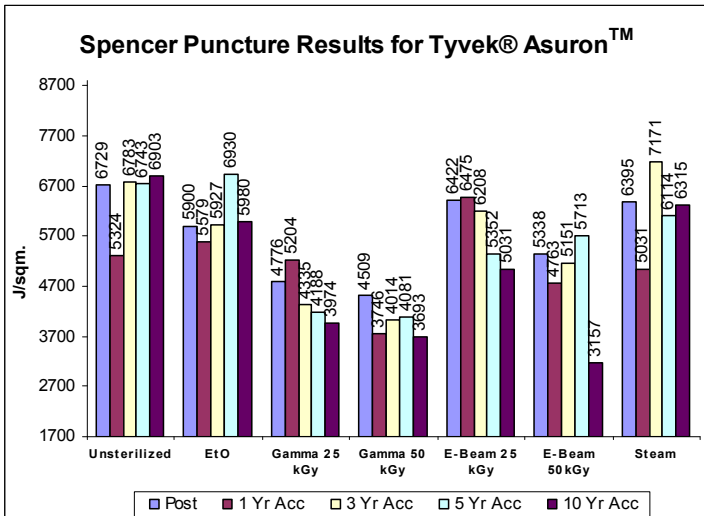
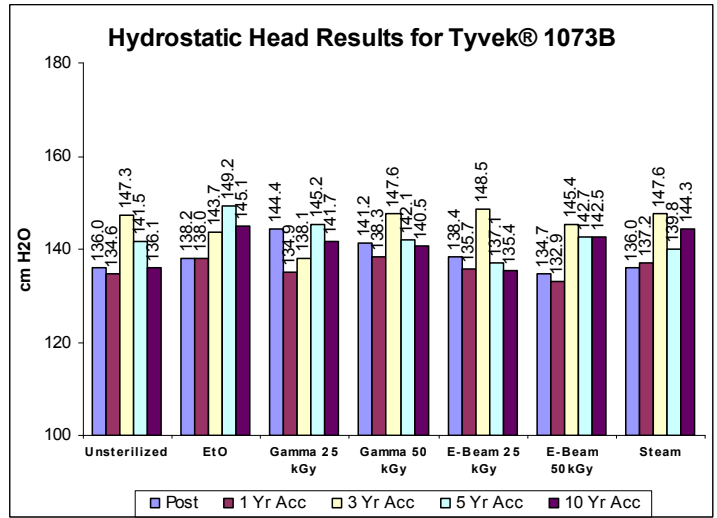
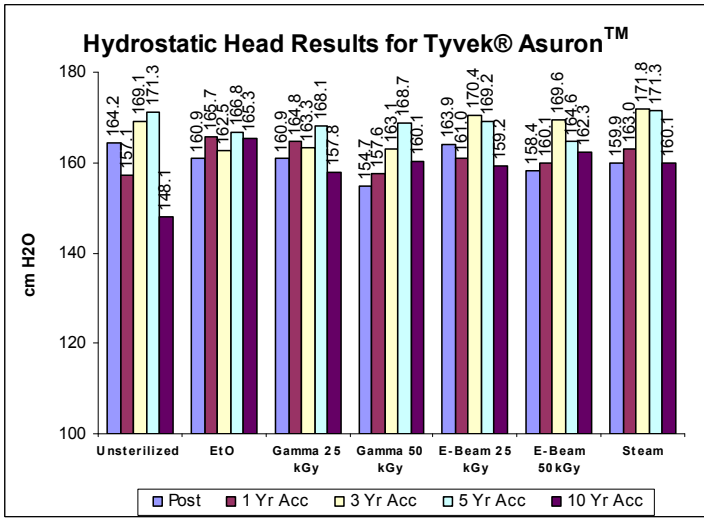
Post Sterilization - Specification Physical Properties (International Units)



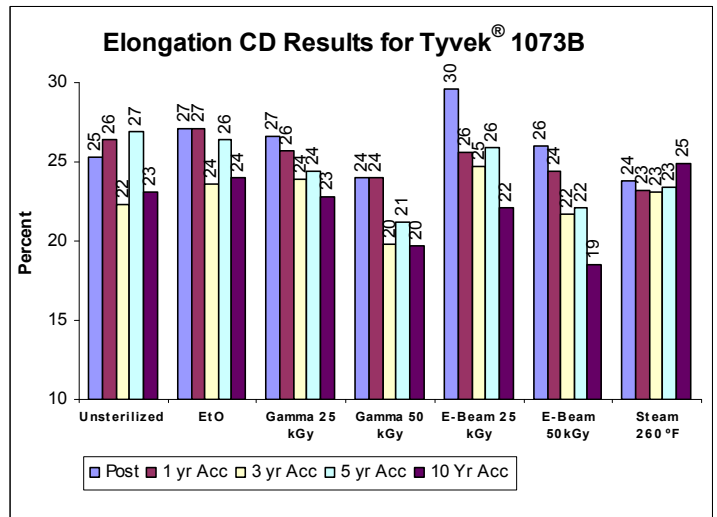
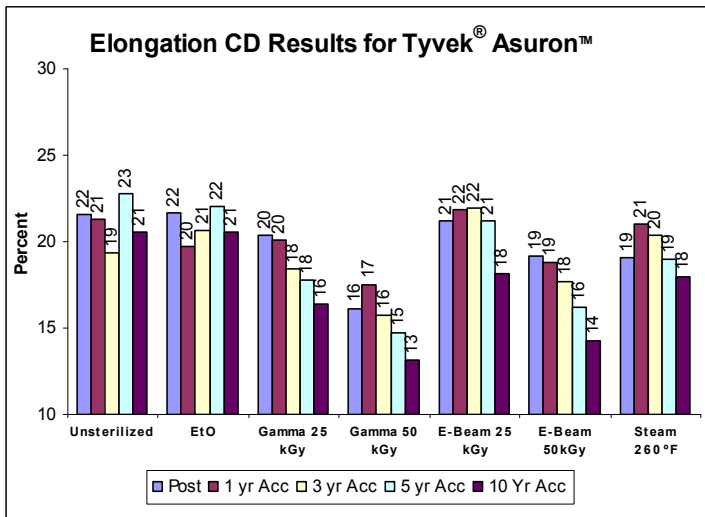
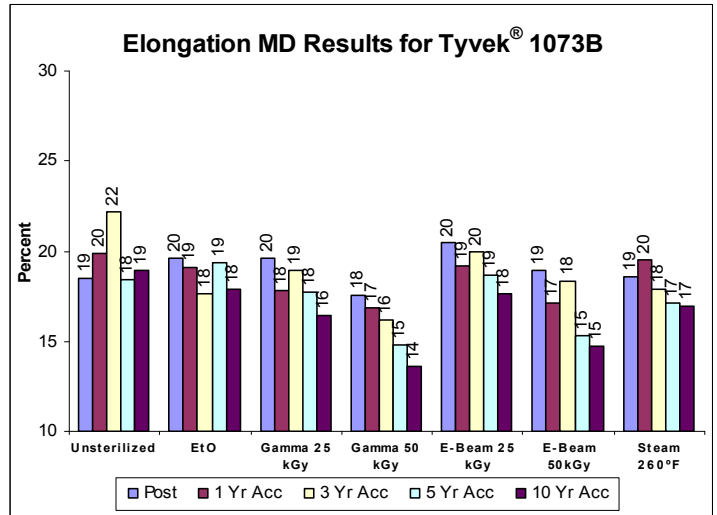
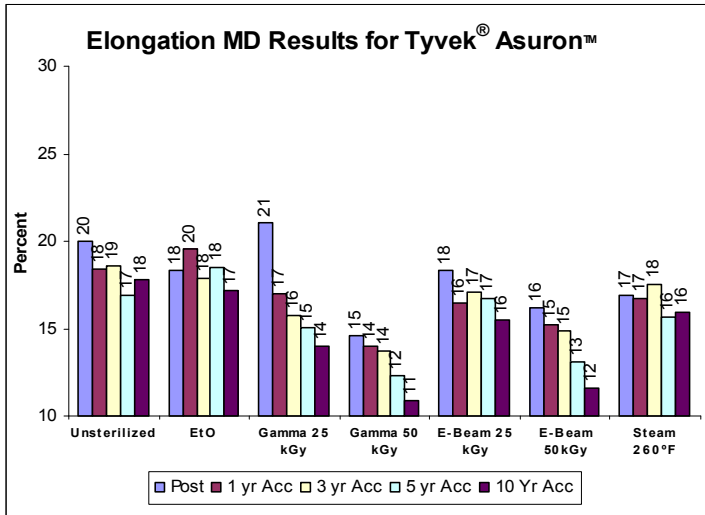
Post Sterilization - Other Physical Properties (International Units)



Post Sterilization - Other Physical Properties - Continued (International Units)

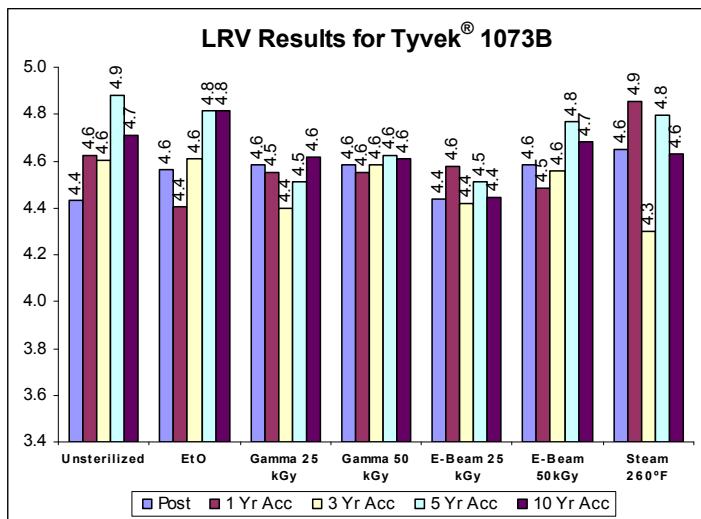
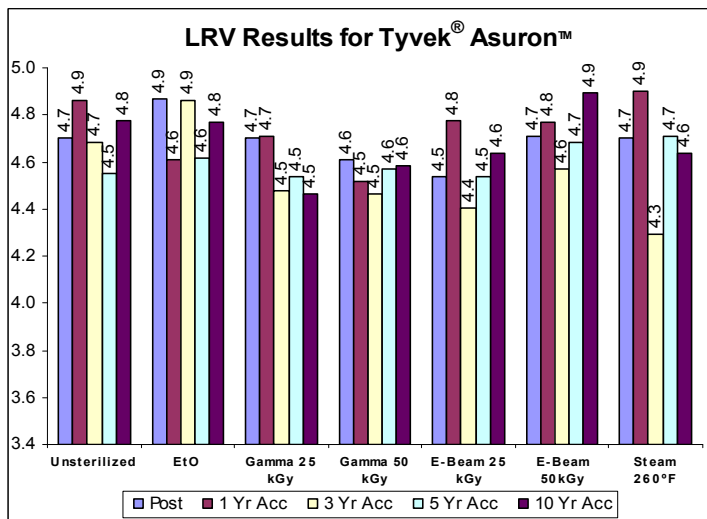


Post Sterilization - Other Physical Properties - Continued (International Units)



Barrier Properties

Barrier properties were tested per *ASTM F1608-00, Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)*. The negative control and samples were plated directly.



Operational Data:

Seal Curves

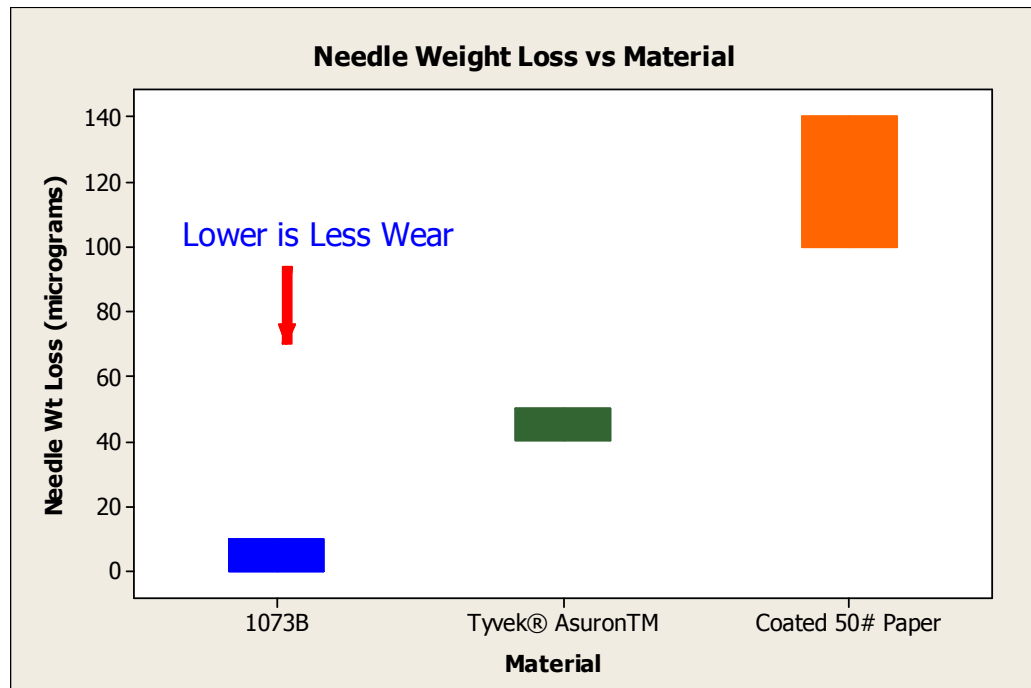
Seal curve experience is still being developed. Based on preliminary results, Tyvek® Asuron™ performs similar to 1073B in peel strength performance. Starting at nominal 1073B conditions will provide seal strengths similar to 1073B.

Blade Wear

TiO₂ is a natural abrasive. This means that blade management, specifically stationary blade (razor slitting), will be important when operating with Tyvek® Asuron™. Blade wear can be overcome by changing to carbide blades. Blade problems were not seen when the material was die cut with a rotary die or cut with a guillotine blade.

To provide some comparison around potential blade wear, a needle abrasion test was conducted. The needle abrasion test compares the weight of a brass needle before and after penetrating a pad of 600g/m² basis weight 10,000 times. For more information on the test method used please look at the website of the Georgia Tech Institute of Paper Science Technology. Samples of Tyvek® Asuron™ (contains Titanium Dioxide), 1073B (no Titanium Dioxide), and coated 50# paper were submitted for comparison. The two Tyvek® samples were repeated three times and the paper was repeated twice. According to the change in needle weight, 1073B is the least abrasive material, followed by Tyvek® Asuron™, and coated 50# paper is the most abrasive material. The average results are:

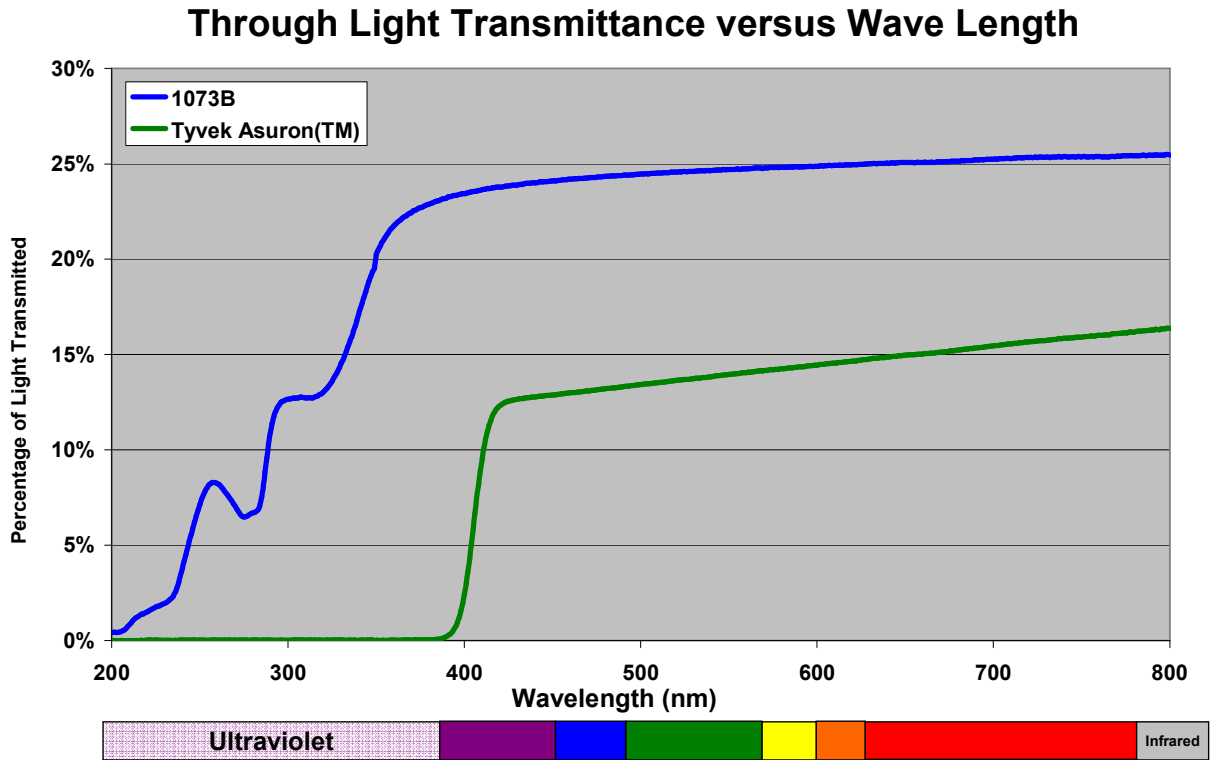
Sample	Needle Penetrations	Needle Weight before (micrograms)	Needle Weight After (micrograms)	Delta Needle Weight (micrograms)
Tyvek® Asuron™	10,002	535,397	535,350	47
1073B	10,004	531,837	531,833	4
Coated 50# Paper	10,006	542,155	542,035	120



Note: This data was developed during initial product testing, and was not repeated with validation material.

Ultraviolet Light Filtering

Although not normally required in the medical packaging field, Tyvek® Asuron™ has the unique ability to filter ultraviolet light. This is due to the TiO₂ addition. Tyvek® Asuron™ blocks low wavelength light in the ultraviolet range. Once the wavelengths increases close to visible light, Tyvek® Asuron™ allows through transmittance. Below is a graph comparing the through light transmittance for 1073B and Tyvek® Asuron™.



Note: This data was developed during initial product testing, and was not repeated with validation material.