



## INTEGRITY TESTING OF POROUS PACKAGING FOR MEDICAL/PHARMACEUTICAL PACKAGING

By: Donald Barcan

*Special thanks to Steve Franks of TM Electronics for loaning me the MDT-500 Pressure Decay Test equipment and Restraining Plate fixture and to Jan Gates of Abbott Vascular for obtaining the SEM photographs.*

A porous package is defined as a package that contains at least one web which consists of a material (or part thereof) that is permeable. ANSI/AAMI/ISO 11607:1, in Appendix C, states that a material is considered impermeable if “after not less than 1 hour of testing per ISO 5635-5 there shall be no visible movement of the cylinder, within the tolerance of  $\pm 1$  mm”. Examples of materials which are permeable are paper and spun-bonded polyolefin (Tyvek™).

Currently, testing porous packages for either seal integrity or package integrity usually involves using dye testing or underwater bubble testing<sup>1,2</sup> or some variation of these tests. These tests are messy and are limited as to the size of defect that can be detected and also rely on good operator technique. One major problem with the tests are the results are qualitative not quantitative. There are other test methods for package and seal integrity, as described in ASTM F2228 & F2338<sup>3,4</sup>, but these tests require expensive test equipment and use a removable mask (tape) to eliminate the porosity of the permeable side of the package.

Medical Device Packaging Consultant and inventor Donald Barcan has developed an application to enhance the testing of POROUS medical device packages. He calls the material “**WholeSeal® Brand of Laboratory Non-Porous Coating**”. The process is described in a recently awarded US Patent<sup>8</sup>. The coating is applied to the exterior of the porous side of the package. **WholeSeal® Brand** is an aqueous polyurethane emulsion which can be applied by brush or roller and air dries to an impervious thin film. It is the forming of this flexible, continuous, and virtually impervious film that is at the heart of the process. This coating is effective when applied to a spun-bonded polyolefin or paper or many other commercially available porous materials. Upon drying, the porous package becomes non-porous to allow for testing the package for



seal integrity or for integrity defects on the uncoated side of the package, such as pinholes. Drying **WholeSeal<sup>®</sup> Brand** can be speeded up by using an air dryer or low temperature oven.

Once dry, the coated package can be tested for leaks using current pressure decay technology such as ASTM F2095<sup>5</sup>. The process has been tested and shown to detect imperfections below 25 $\mu$  in size but limited to the sensitivity of the test equipment. The application of **WholeSeal<sup>®</sup> Brand** is not removable so its application renders the package non salable. Specifications can be written around a specific quantitative leak rate, exceeding which could be considered a package failure. This coating will also extend the time available to do dye testing because the dye will not penetrate the coated side as quickly as the uncoated porous material.

A major application of this technology is to assist in the evaluation of packages created on form/fill/seal packaging machines where the formed side of the package is a flexible film. There is always an opportunity for significant cost reduction by either changing the film construction or gage and changing the forming plug/tool. Using **WholeSeal<sup>®</sup> Brand** and ASTM F2095<sup>5</sup>, the user will be able to quantitatively measure whether the changes are acceptable or not, particularly after handling and distribution testing.

At ASTM, ASTM F-2095<sup>5</sup> has been modified to include the application of a film forming coating to the permeable side of the package in order to facilitate pressure decay testing. One of the major concerns, as part of the evaluation, was to determine if the coating penetrate through the permeable material? If it did, one could assume that the coating could fill any seal imperfections, such as channels, and thereby invalidate the results of the pressure decay testing for seal integrity. This phenomenon could be called wicking through the material. The attached SEM photographs show that wicking through the porous material did not occur.

Coatings, in general, are not designed to prevent wicking through the permeable materials. **WholeSeal<sup>®</sup> Brand** is a film forming coating which is designed to prevent complete wicking through most medical packaging materials. To verify that this is true, Jan Gates, Principal Packaging Engineer at Abbott Vascular, arranged for Scanning Electronic Microscope (SEM) photos be taken of typical medical device porous materials which were flood coated with **WholeSeal<sup>®</sup> Brand**. Several materials were evaluated. They were: Ovantex<sup>™</sup>, 50# Latex Reinforced Paper, 2FS Tyvek<sup>™</sup>, 30# MG Paper, 1073B Tyvek<sup>™</sup>, 1059B Tyvek<sup>™</sup>, 42# Surgical Paper, & Coated 1073B Tyvek<sup>™</sup>. The results of these SEM images are shown in the Appendix.

The use of ASTM F-2095<sup>5</sup> and **WholeSeal<sup>®</sup> Brand** for pressure decay testing, still requires the test user to insure the coating does NOT penetrate the material under test. This could involve SEM or any other method which gives the test user verifiable evidence that the coating does not wick through their material. Independently satisfying this requirement is key to utilizing a film former, such as **WholeSeal<sup>®</sup> Brand**, to test for seal integrity. On the other hand, for evaluating pinholes in flexible formed materials, the

only requirement should be insuring the uniform & complete application of the porous web to insure that web is no longer porous to the sensitivity the test requires.

Another application for **WholeSeal<sup>®</sup> Brand** is with ASTM-1140<sup>6</sup>, and F-2054<sup>7</sup>. Where the porous side of the package becomes to large (surface area) for the internal pressurization to overcome the loss through the permeable material, the use of **WholeSeal<sup>®</sup> Brand** can seal-off the porosity to enable accurate and repeatable burst test data. Additionally, **WholeSeal<sup>®</sup> Brand** has been used in conjunction with ASTM-1929<sup>9</sup> to increase the amount of test time when doing dye testing for seal integrity. The issues of accuracy & repeatability have not been determined at this time.

**WholeSeal<sup>®</sup> Brand** is available from DBI, Inc. (Donbar Industries, Inc.), [www.2dbi.com](http://www.2dbi.com)

## REFERENCES

<sup>1</sup> ASTM F1929-Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

<sup>2</sup> ASTM F2096-Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test).

<sup>3</sup> ASTM F2228-Standard Test Method for Non-Destructive Detection of Leaks in Medical Packaging which Incorporates Porous Barrier Material by CO2 Tracer Gas Method.

<sup>4</sup> ASTM F2338-Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method.

<sup>5</sup> ASTM F2095-Standard Test Method for Pressure Decay Leak Test for Nonporous Flexible Packages with and without Restraining Plates.

<sup>6</sup> ASTM F-1140, Standard Test Method for Internal Pressurization Failure Resistance of Unrestrained Packages for Medical Applications

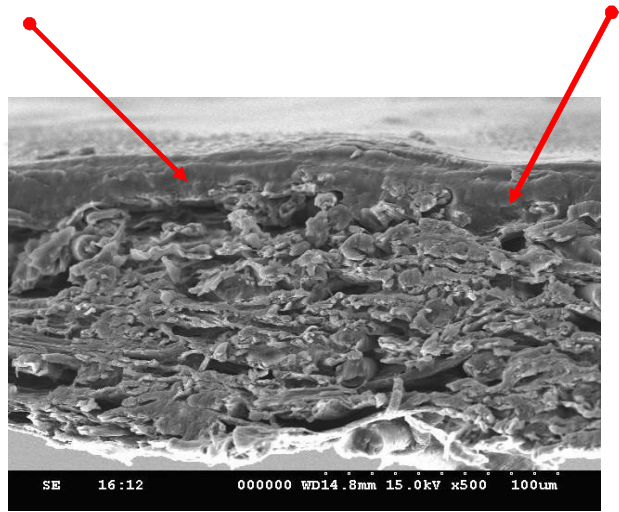
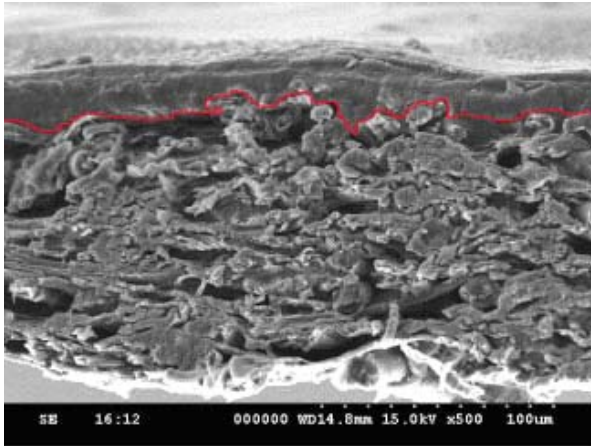
<sup>7</sup> ASTM F-2054, Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization within Restraining Plates.

<sup>8</sup> U.S. Patent No: 7,565,828 B2, Systems and Methods for Testing Packaging.

<sup>9</sup> ASTM F-1929, Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.

## APPENDIX

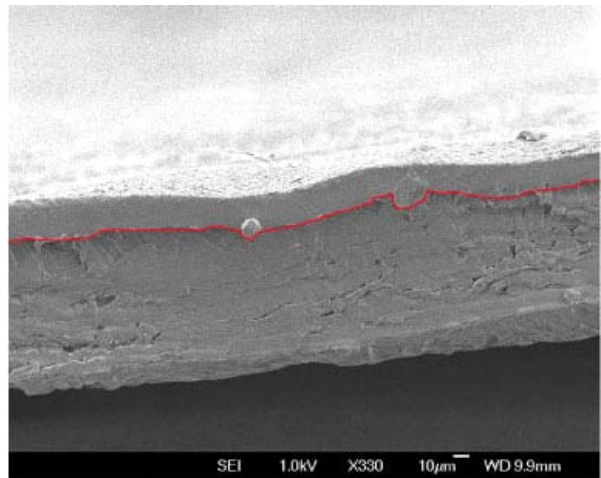
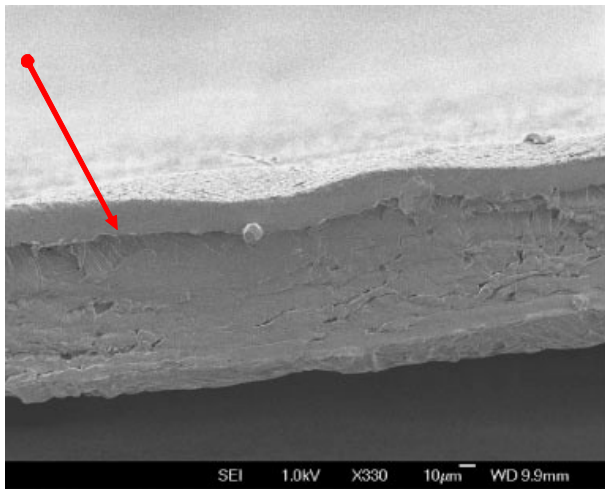
Material Shown: Ovantex  
Magnification: 615 X



WholeSeal<sup>®</sup> Coated, arrow or line shows contact area

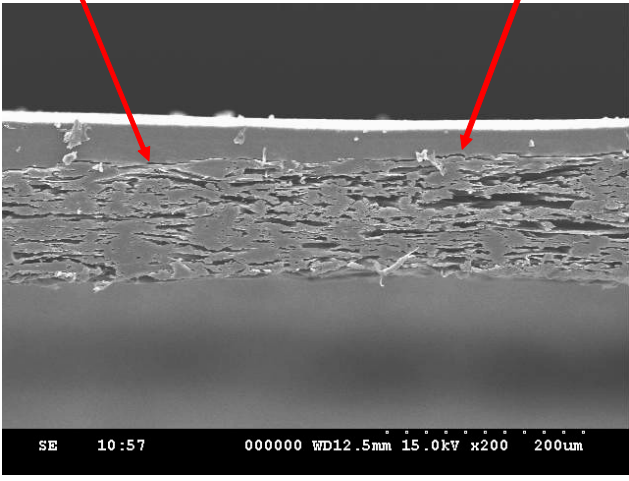
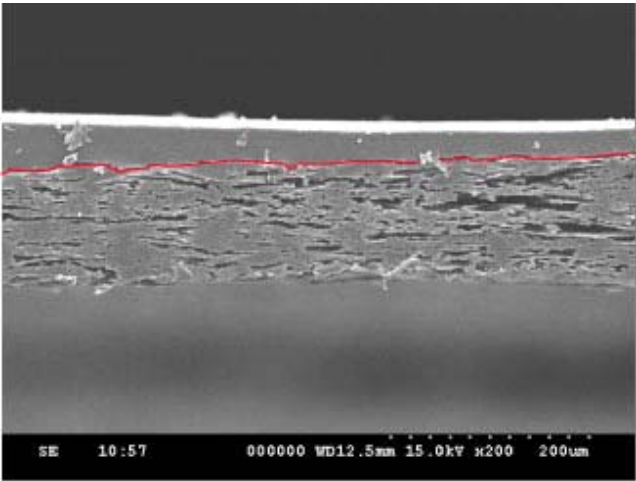
Material Shown: 50# Latex Reinforced Paper

Magnification: 330 X



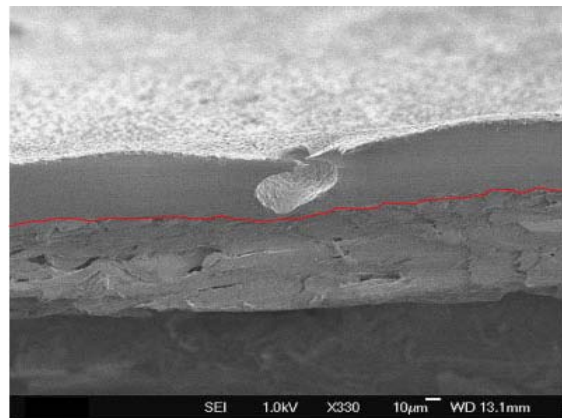
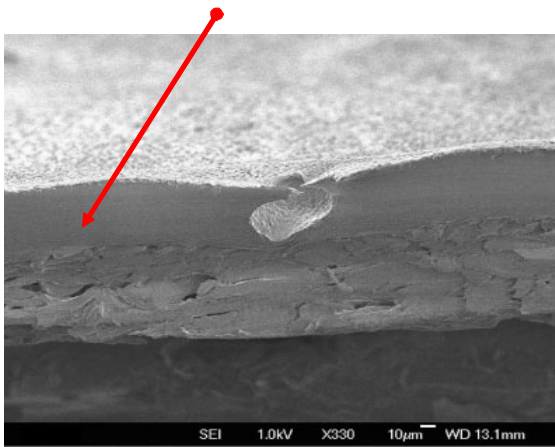
WholeSeal<sup>®</sup> Coated, arrow or line shows contact area

Material Shown: Tyvek® 2FS  
Magnification: 246 X



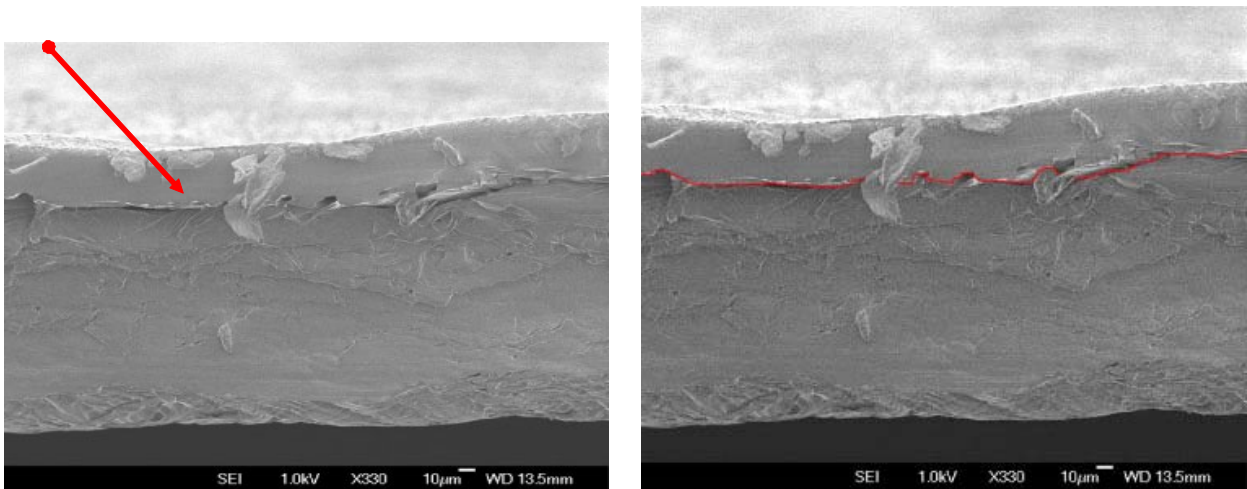
WholeSeal® Coated, arrow or line shows contact area

Material Shown: 30# MG Paper  
Magnification: 431 X



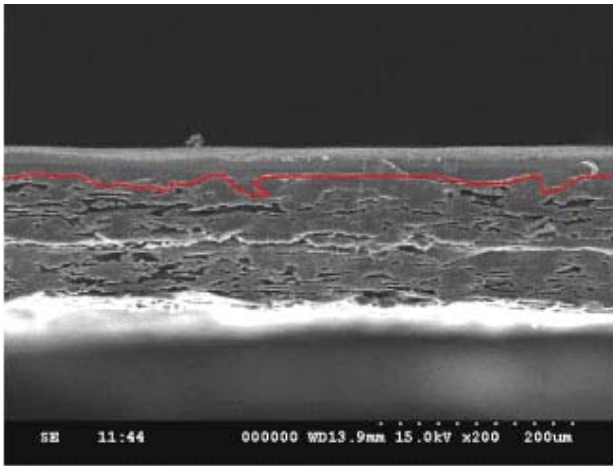
WholeSeal<sup>®</sup> Coated, arrow or line shows contact area

Material Shown: Tyvek® 1073B  
Magnification: 330 X



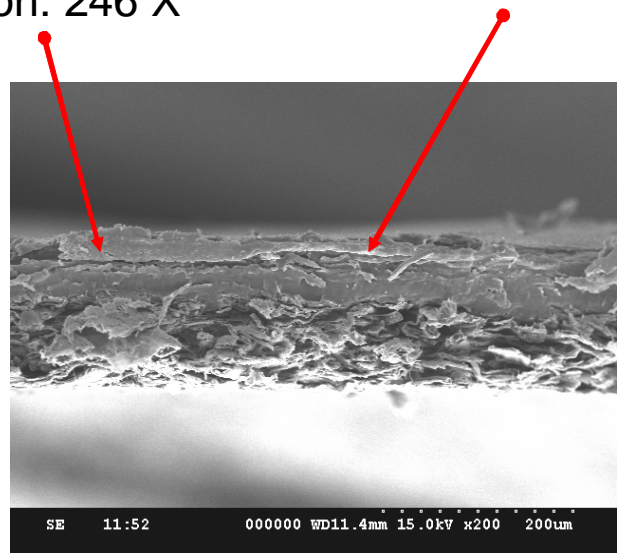
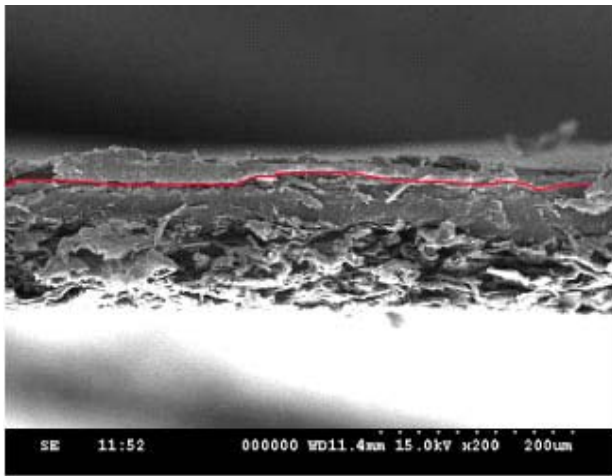
WholeSeal® Coated, arrow or line shows contact area

Material Shown: Tyvek® 1059B  
Magnification: 246 X



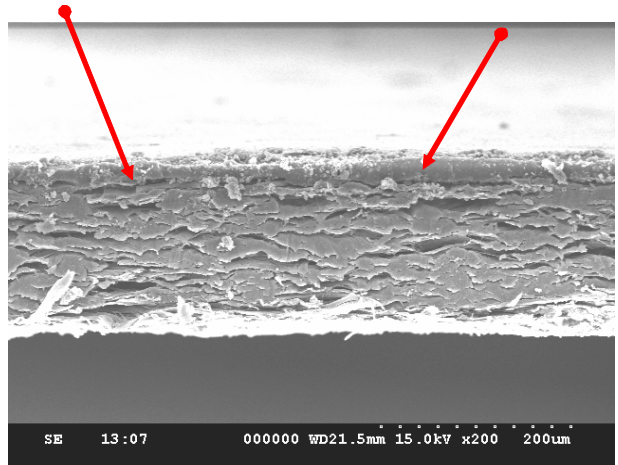
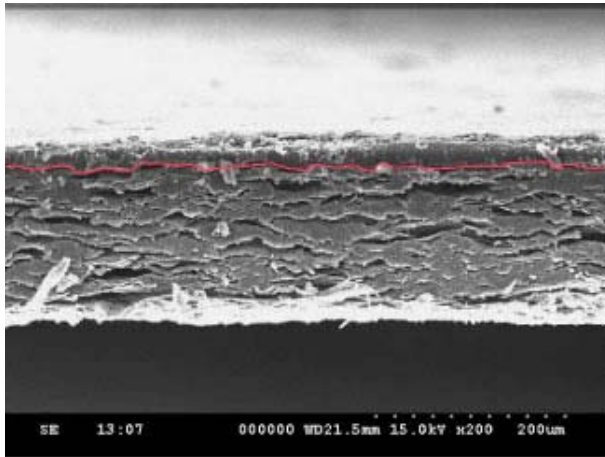
WholeSeal® Coated, arrow or line shows contact area

Material Shown: 42# Surgical Paper  
Magnification: 246 X



WholeSeal<sup>®</sup> Coated, arrow or line shows contact area

Material Shown: Tyvek® 1073B - coated  
Magnification: 246 X



WholeSeal® Coated, arrow or line shows contact area