DuPont™ Tyvek® Medical Packaging Transition Project

Pre-Sterilization and Post-Sterilization Industry Summary Report

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EXECUTIVE SUMMARY

Pre-sterilization and Post-sterilization package testing results for the 78 cells in the Medical Packaging Transition Project ("**MPTP**") by third-party Nelson Laboratories indicate **Functional Equivalence** between current Tyvek® styles 1073B and 1059B and Transition Protocol material styles 1073B and 1059B. Specific test data to support this conclusion includes:

- Seal Strength (ASTM F88): 479 out of 480 instances of **Functional Equivalence**
- Microbial Barrier (ASTM F2638): 156 out of 156 instances of **Non-Inferiority**
- Package Integrity (ASTM F1929): 8,424 out of 8,424 instances of **No Dye Penetration**
- Visual Inspection (ASTM F1886M): 114,726 out of 114,729 instances of **No Material Defects**

Additional details are provided in the Tables and Figures that follow, including those in Appendix A, where results are presented by category.

MEDICAL PACKAGING TRANSITION PROJECT ("MPTP") OVERVIEW

MPTP is a plan to transition production of DuPont™ Tyvek® styles 1073B and 1059B to the latest flash-spinning technology and equipment. The project includes a systematic method for generating data at Nelson Laboratories, a third-party test laboratory, to prove that Tyvek® produced on newer lines (known as Transition Protocol material) is functionally equivalent to current Tyvek®. The study was initiated to help mitigate requalification and ensure the continuity and flexibility of future supply. In this context, **Functional Equivalence** means that attributes of Transition Protocol material meet functional and performance requirements. Positive outcomes from Functional Equivalence testing ensure that Transition Protocol material behaves similarly to current Tyvek® in various downstream processes and applications, even if some attribute data may not be identical. Transition Protocol material produced on the newer manufacturing lines is

projected to become commercially available around the globe in the third quarter of 2015 and includes product from two locations—Richmond, VA, USA and Contern, Luxembourg—with two polymer supply sources for the United States and two polymer supply sources for Luxembourg.

There are three MPTP study components to demonstrate that all six possible line/polymer combinations are interchangeable for both Tyvek® 1073B and Tyvek® 1059B, two of which involve the production and testing of sterilized medical device packages. Those two components are:

1. **U.S. FDA Transition Protocol** – a study plan based on sound principles of experimental design and statistical analysis for generating data to prove Functional Equivalence by comparing Transition Protocol material and current Tyvek® using 60 different device/package combinations ("**cells**") with a validated design and a validated forming, sealing and assembly process. The plan has been reviewed and accepted by the Center for Devices and Radiological Health ("**CDRH**") at the U.S. FDA. Over the course of protocol implementation, CDRH will review DuPont analysis of the third-party test laboratory data to determine Functional Equivalence. If CDRH agrees with DuPont's analysis and conclusions regarding Functional Equivalence, then it will issue guidance indicating that Medical Device Manufacturers ("**MDMs**") would not routinely be required to file amended 510(k)s or PMAs for existing devices because the transition represents a merge, or lot, change.

2. **Phantom Protocol** – creation and testing of 18 additional sterilized medical device/ package combinations ("**cells**") that are outside the scope of the U.S. FDA Transition Protocol but have been requested by the industry to support risk assessments.

The third study component is Biocompatibility, Food Contact and Pharmacopoeia testing.

In the U.S. FDA Transition Protocol, more than 70,000 packages of various sizes and constructions were made with three lots of current Tyvek® and three lots of material from all line/polymer combinations of Transition Protocol material using a wide variety of representative coatings and bottom webs available globally in the trade. The packages for the 60 different cells were manufactured through established supply chains by 40+ different MDMs from all over the world and included pouches, bags, form-fill-seal and rigid tray applications. For each cell, a total of approximately 1,200 packages were produced, 600 packages with current Tyvek® and 600 with Transition Protocol material, using the respective validated lower, nominal and upper sealing conditions for each cell to characterize performance over the manufacturer's range of operability. (It is important to note that no sealing window details were requested to preserve participant confidentiality.) The packages were Ethylene Oxide (**"EO"**), gamma or electron-beam irradiation sterilized using validated sterilization processes in accordance with the manufacturer's requirements and standards. For EO sterilization, residuals were tested for acceptability. Table 1 summarizes all 60 U.S. FDA Transition Protocol cells.

Table 1. Sixty Cell U.S. FDA Transition Protocol Matrix

		Style	Pouches and Bags						Form-Fill-Seal						Rigid Trays								
EO	Coated	1073B	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
EO	Uncoated	1073B	22	23	24	25	26	27															
Gamma	Coated	1073B	28		29		30		31		32		33		34		35		36		37		38	39
Gamma	Uncoated	1073B	40		41		42																
Electron-beam	Coated	1073B							43		44		45										
Electron-beam	Uncoated	1073B	46		47		48																
EO	Coated	1059B							49		50		51										
EO	Uncoated	1059B	52	53	54	55	56	57	58		59		60										

Representative grouping of ALL six line/polymer combinations

All six line/polymer combinations were distributed as equally as possible across sterilization condition and style, coating, and package type within the constraints of the number of cells in a category. Care was taken to ensure that no line/polymer combination would bias results for any category.

In the Phantom Protocol, more than 20,000 packages were made with three lots of current Tyvek® and three lots of material from various line/polymer combinations of Transition Protocol material. Package creation and number of packages for each of the 18 cells were similar to that of the U.S. FDA Transition Protocol and involved MDMs from the U.S. FDA Transition Protocol plus 11 MDMs from all over the world who are not participating in the U.S. FDA Transition Protocol. Packages included pouches, bags, form-fill-seal and rigid tray applications and sterilization methods included EO, gamma & electron-beam irradiation, steam, dry heat, low temperature H_2O_2 and low temperature $C_2H_4O_3$. Table 2 summarizes all 18 Phantom Protocol cells.

Table 2. Eighteen Cell Phantom Protocol Matrix

		Style	Pouches and Bags		Form-Fill-Seal	Rigid Trays		
EO	Coated	1073B	x74		X75	X71	X78	
EO	Uncoated	1073B	X61					
Gamma	Coated	1073B				X62	X63	
Gamma	Uncoated	1073B						
Electron-beam	Coated	1073B						
Electron-beam	Uncoated	1073B						
EO	Coated	1059B						
EO	Uncoated	1059B	X77					
Steam	Coated	1073B				X65	X66	X67
Steam	Uncoated	1073B	X69	X70				
Dry Heat	Coated	1073B				X68		
Low Temp. H_2O_2	Coated	1073B	X76					
Low Temp. $C_2H_4O_3$	Coated	1073B				X64		
Gamma	Coated	1059B			X72			
Electron-beam	Coated	1059B			X73			

Detailed descriptions of the range of package construction materials and the sterilization process parameters can be found using the **MPTP Cell Descriptor Selector Tool** on the www.areyouready.tyvek.com website. This tool allows MDMs to determine if their package configuration(s) and specific sterilization dose(s) or challenge(s) are within the study scope as they perform risk assessments and apply change control procedures. (Note: Data for Transition Protocol material vs. current Tyvek® material can also be found on the website to aid risk assessments. The data includes: specification and miscellaneous properties; biocompatibility, food contact and pharmacopeia results; and sterilization effects on physical, mechanical, thermal and microbial barrier performance.)

All U.S. FDA Transition Protocol and Phantom Protocol cells will be tested in the following four test environments:

- Pre-sterilization
- Post-sterilization
- Accelerated aging (1, 3, and 5 years) at nominal conditions of 50 °C and 23% RH
- Real-time aging (1, 3, and 5 years) at nominal conditions of 25 °C and monitored ambient RH

Packages from select U.S. FDA Transition Protocol and Phantom Protocol cells will also be subjected to 7-year and 10-year accelerated aging and 10-year real-time aging.

Paired data sets (Transition Protocol material vs. current Tyvek®) for each test environment for each cell are being generated and analyzed from the following tests:

- Seal Strength: ASTM F88
- Microbial Barrier: ASTM F2638
- Package Integrity: ASTM F1929
- Visual Inspection: ASTM F1886M

Finally, the MPTP study is designed to show Functional Equivalence in terms of sealing process performance, package stability and sterilization compatibility by testing seal integrity and strength as well as microbial barrier properties. The MPTP is an interconnected body of data, representing significantly more than the sum of all cells while individual cells cannot be considered in isolation. Indeed, the study considers many factors of potential variability (e.g. material, process) to prove Functional Equivalence and Interchangeability using an unparalleled amount of data based on a large industry-wide sample. In addition, the collaboration of various industry participants has made it possible to generate more data than any single company could have generated individually.

The MPTP study seeks to demonstrate Functional Equivalence, not to revalidate all possible industry package configurations. It would be unrealistic and cost prohibitive to test every bottom web and/or coating combination used in the industry. Package types can primarily be classified into three basic categories: 1) pouches & bags; 2) form-fill-seal applications; and 3) rigid trays & lids. EO, gamma and electron-beam are the most commonly used sterilization methods. The power of the MPTP study is in the test plan, which incorporates these basic package types and sterilization methods (and other types/methods), through broad, representative cross-sections of materials, sterilization cycles, package designs and manufacturing processes.

This Industry Summary Report summarizes pre-sterilization and post-sterilization data for all 78 cells. Industry Summary Reports for the other test environments will be published as data generation and analysis are completed. More detailed and comprehensive reports than Industry Summary Reports will be prepared and submitted to the U.S. FDA and other regulatory bodies under Confidentiality Agreements. After submission of the 1-year real-time aging report to the U.S. FDA, a letter affirming Functional Equivalence is expected (~3Q2015).

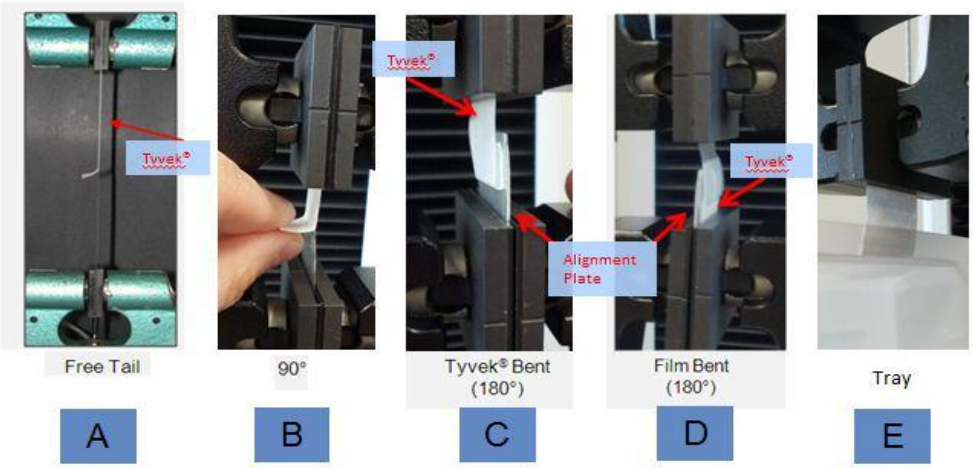
TESTING and RESULTS OVERVIEW

Data were analyzed for the four different attributes detailed in the approved study design: seal strength, microbial barrier, package integrity, and visual inspection. In the following sections, a brief overview of the study design and associated statistical methods is provided, followed by a high-level summary of the results for the Pre-sterilization and Post-sterilization study time points. Subsequent reports will contain additional time points when testing and analysis are completed.

Seal Strength (ASTM F88)

Seal strength was assessed via ASTM F88 in accordance with metric details specified by the MDMs. These metric details include a designation of either Maximum Load or Average Load as the response, as well as the testing apparatus/material orientation used. See Figure 1 for a visual description of the different seal strength methods/techniques employed in the study.

Figure 1. Description of Seal Strength Methods/Techniques



Technique	Tail Holding
A	Unsupported ("Free Tail"), angle can vary throughout test)
B	Supported 90° (Fixed angle by hand or other)
C	Tyvek® Bent (Supported 180°) "TYVEK UPPER"
D	Film Bent (Supported 180°) "TYVEK LOWER"
E	Free Tail Tyvek® Upper Bent 180°

For the Pre-sterilization and Post-sterilization time points, three sealing conditions across the sealing window were tested for both the Test Material (also called Test or Transition Protocol material) and the Control Material (also called Control or Current Tyvek®). These three sealing conditions are denoted by Lower, Nominal, and Upper sealing conditions. At each of the sealing conditions, 48 samples were tested. For most cells, this consisted of 4 test strips cut from each of 12 packages. However, some packages were too small to obtain 4 samples per package so either 1 or 2 test strips were cut per package resulting in a total of either 48 or 24 packages per condition, respectively.

Functional Equivalence was assessed by calculating the appropriate 90% confidence interval on the Difference in Means (Test-Control) for each cell at each sealing condition. If this interval was contained within the Functional Equivalence bounds, then the seal strength was declared Functionally Equivalent. While the Transition Protocol material must satisfy the Functional Equivalence criteria, Transition Protocol material

packages must also meet or exceed Current Tyvek® package performance with respect to achieving minimum seal strength requirements, as defined by the MDMs.

In the two figures that follow, the average Percent Change in Seal Strength relative to the Control is calculated and presented in Figure 2 for all cells designated as Maximum Load. Figure 3 details the results for Average Load cells. Note this average Percent Change is computed by calculating individual cell percent changes:

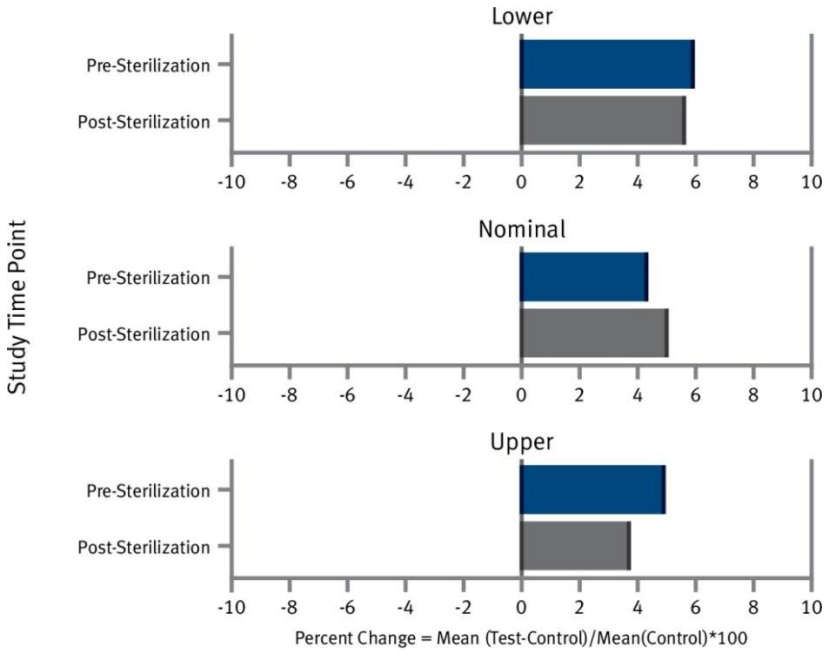
Percent Change = Mean (Test-Control)/Mean (Control)*100

and then taking the average of the individual cell percent change values.

It should be noted that packages from three cells in the study contained non-peelable seals due to their constructions as either vent, Kwikbreathe™ True Header, or weld seal bags. Because non-peelable seals were outside the scope of the study, these packages were not included in the Percent Change calculations. It should also be noted that in creating the Maximum and Average Load Figures, five cells were double packages and both the inner and outer seal strength data were included. (N=58 + N=22 totals N=80, determined from 78 cells – 3 cells + 5 cells = 80 cell data points.)

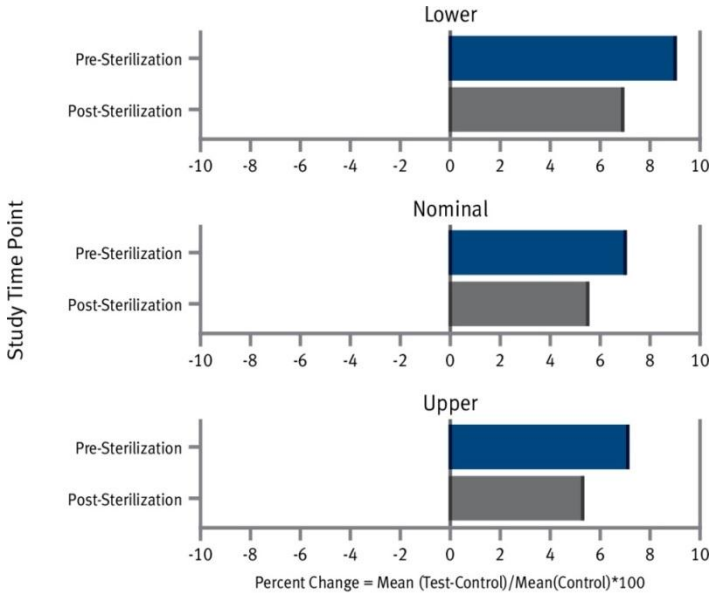
There are 479 instances of Functional Equivalence for Pre-sterilization and Post-sterilization. All cells pass Functional Equivalence criteria with the exception of one uncoated 1059B FFS package at the Upper sealing condition in the Pre-sterilization phase of the study. The cell failed the Functional Equivalence criteria by 0.05 lb/in. on the upper side of the criteria, indicating the Transition Protocol material produced higher seal strength than the Control. This package, a Sterile Fluid Path product, was formed on equipment comprised of multiple cavities. A Root Cause Failure Analysis ("**RCFA**") identified potential causes related to unequal sampling among the cavities and/or execution errors in package labeling/testing; however, these causes could not be eliminated or assigned. Note that this same anomaly was not observed in the Post-sterilization phase. Also note a retest was performed using sample retains on both the Pre-sterilization and Post-sterilization packages with as much equal representation from cavities as possible. Twice the number of data points were tested on the Upper sealing condition to gain a better understanding of package sealing behavior. The anomaly was not replicated in the retest; the Test and Control material were found to be equivalent.

Figure 2. Avg. Percent Change in Mean Seal Strength (Test-Control) for Maximum Load Cells; N=58



Test=Transition Protocol Material
Control=Current Tyvek®

Figure 3. Avg. Percent Change in Mean Seal Strength (Test-Control) for Average Load Cells; N=22



Test=Transition Protocol Material
Control=Current Tyvek®

A high level summary of the results tested for each package configuration, material, and sterilization combination is shown in Table 3.

Table 3. Summary of Seal Strength Functional Equivalence Results*

Industry Summary: MPTP Test Results at Pre- & Post-Sterilization, Pass/Fail Summary for Seal Strength* — ASTM F88

Tyvek® Style	Coating Type	Sterilization Type	Pouches and Bags		Form-Fill-Seal		Rigid Trays	
			Pass	Fail	Pass	Fail	Pass	Fail
1073B	Coated	Pre-Sterilization	11	0	13	0	24	0
		EO	7	0	7	0	11	0
		Gamma	3	0	3	0	8	0
		Electron-beam			3	0		
		Steam					3	0
		Dry Heat					1	0
		Low Temp. H_2O_2	1	0				
		Low Temp. $C_2H_4O_3$					1	0
	Uncoated	Pre-Sterilization	14	0				
		EO	7	0				
		Gamma	3	0				
		Electron-beam	3	0				
		Steam	1	0				
1059B	Coated	Pre-Sterilization			5	0		
		EO			3	0		
		Gamma			1	0		
		Electron-beam			1	0		
	Uncoated	Pre-Sterilization	5	0	2	1**		
		EO	5	0	3	0		

There are no cells in the MPTP for this category

*Vent bag, Kwikbreathe™ True Header bag and weld seal bag seal strengths are not included; the failure modes were non-peelable seals.

A high sealing condition for one package configuration exceeded the high end of the equivalence limit by 0.05 lb/in., implying that the Transition Protocol material seal strength was stronger than the current material. ***This anomaly was not duplicated with post-sterilization data.*

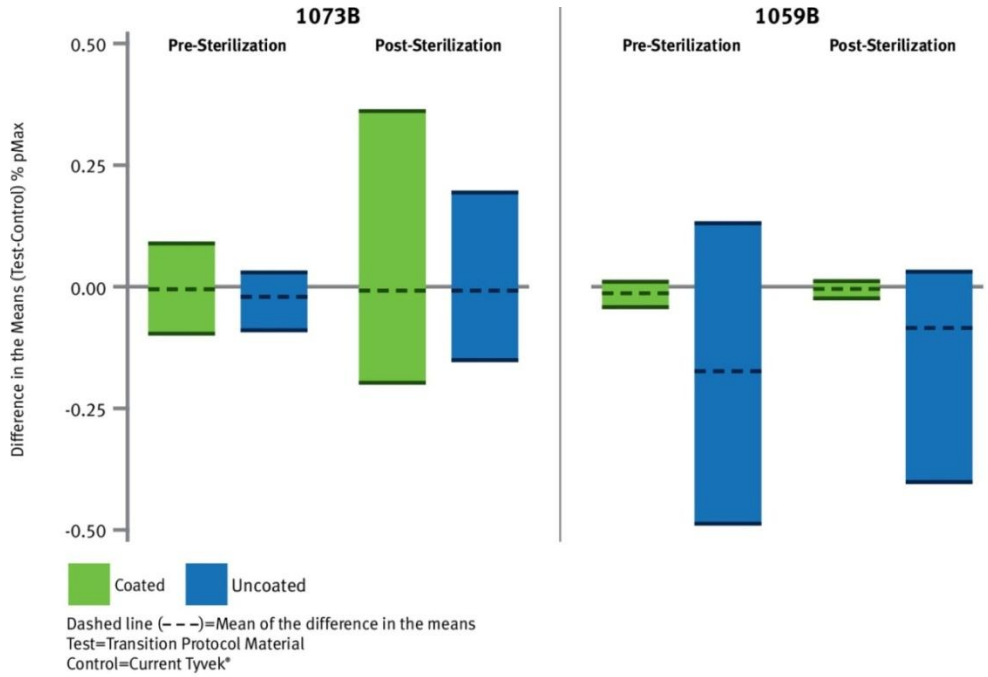
Microbial Barrier (ASTM F2638)

Microbial barrier performance was tested using ASTM F2638. The % pMax value for three Test samples and three Control samples from each cell was determined; a **lower/smaller** % pMax value indicates better microbial barrier performance. A statistical test of non-inferiority was performed to indicate the Test material does not underperform Control material. A 95% student's t upper confidence bound was calculated and compared to the pre-established non-inferiority criteria from the study design.

The difference in the Means (Test-Control) for % pMax was calculated for each cell. These differences were then sorted according to Tyvek® style (1059B or 1073B) and coating status (coated or uncoated). The **endpoints** of each of the bars shown in Figure 4 represent the highest and the lowest difference in the Means (Test-Control) observed for % pMax. A **0.00** value for the difference in the Means indicates that the Transition Protocol material Mean and the Current Tyvek® Mean are the same. The **dashed line** in each bar represents the Mean of the difference in the Means for each group. **Dashed lines** which fall below **0.00** (i.e. negative values) indicate the Transition Protocol material had a lower/smaller Mean than Control material (and thus better barrier). All cells pass the Microbial Barrier Non-Inferiority Criteria, representing 156 instances.

It should be noted that the vertical scale in Figure 4, as well as vertical scales on microbial barrier graphs in the Appendix, are very small numbers and represent minimal differences in the Means. Moreover, due to the outstanding microbial barrier performance of Tyvek®, **individual** % pMax values used in calculating differences were very small as well.

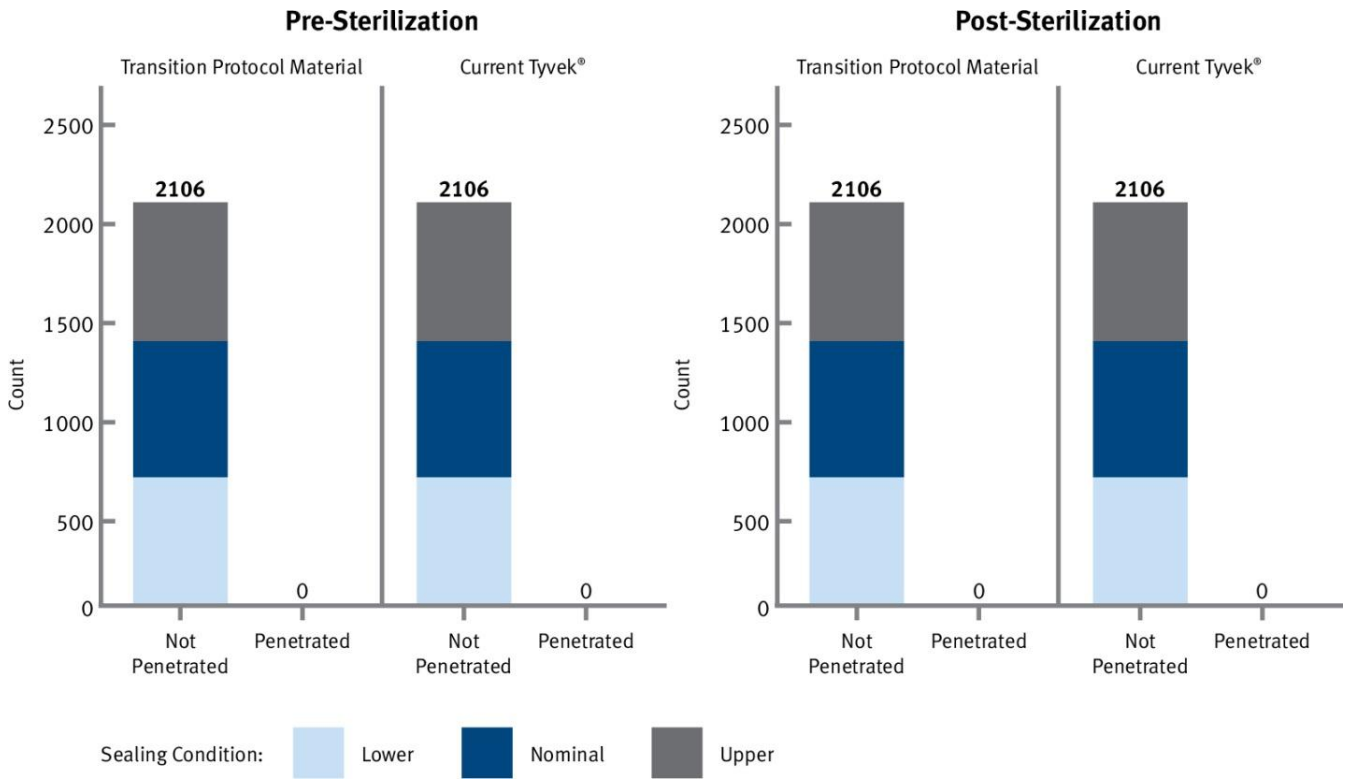
Figure 4. Range of Differences in % pMax Mean (Test-Control) for All Cells by Tyvek® Style, Time Point, and Coating Status



Package Integrity Testing (ASTM F1929)

ASTM F1929 was applied to assess package integrity via a dye penetration test. In the Pre-sterilization and Post-sterilization phases of the study, package integrity testing was performed at the Lower, Nominal, and Upper sealing conditions. Nine packages from each condition were tested. Figure 5 shows a summary of the data. No package failed the dye penetration test due to a material defect in Tyvek®; there are 4,212 instances of no dye penetration in Transition Protocol material and 4,212 instances of no dye penetration in Current Tyvek® for a total of 8,424 instances of no dye penetration. Due to the discrete nature of this data, the pass/fail criteria for package integrity will be assessed at the conclusion of the study.

Figure 5. Package Integrity Testing Summary

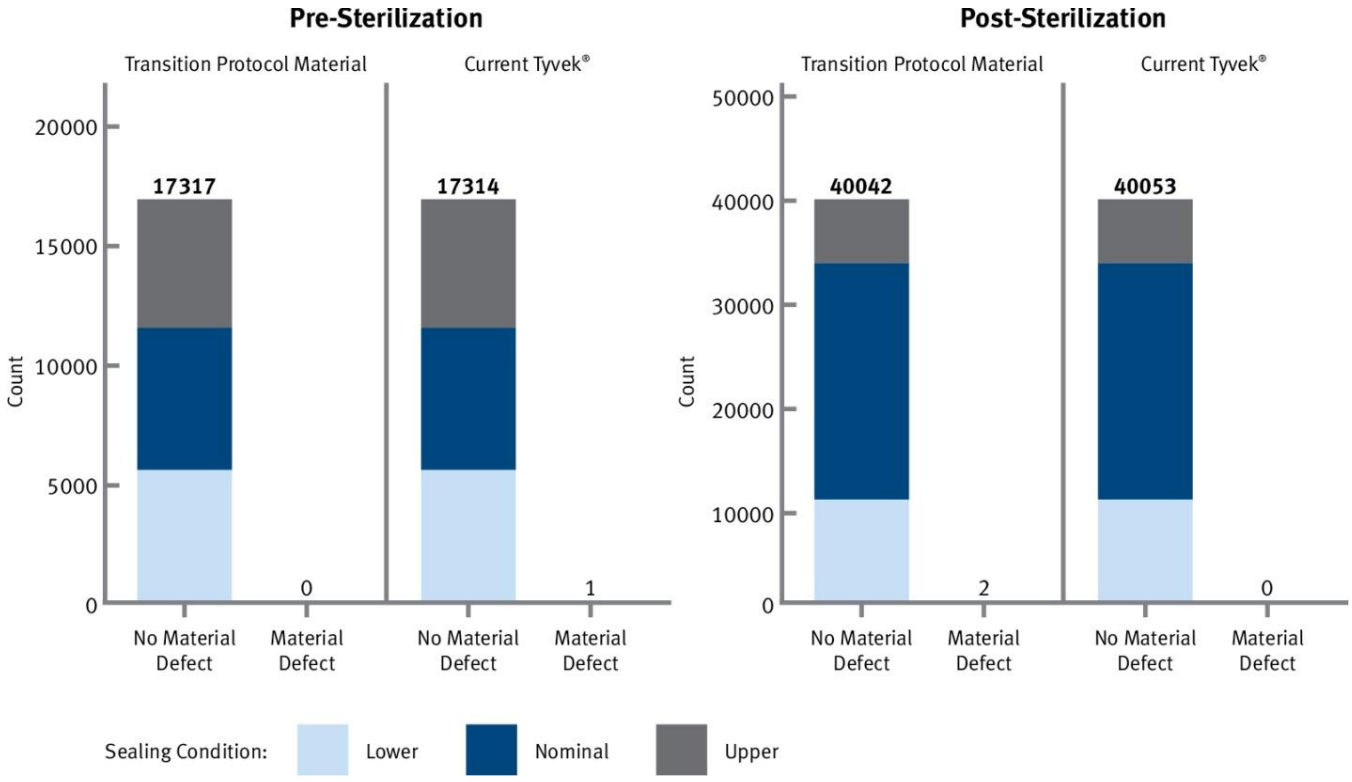


Visual Inspection (ASTM F1886M)

All packages in the Pre-sterilization and Post-sterilization time points were visually inspected as per ASTM F1886M. A material related defect is defined in the Protocol as an anomaly in Tyvek® extending 50% or more across the width of the seal; the 50% criteria was established for the purposes of an operational definition. Note however that the presence of a defect such as this does not necessarily affect seal integrity. Figure 6 depicts 114,726 instances of no material defects, and only one material related defect in Current Tyvek® and two material related defects in Transition Protocol material. This is well within the established pass/fail criteria of the study. The defects were veins or raised areas in the material that extended more than 50% across the width of the seal, defects that did not appear to affect the integrity of the package (per the Package

Integrity results). **Visual Inspection is considered Functionally Equivalent because it passes the criteria set forth in the study design.**

Figure 6. Visual Inspection Summary



CONCLUSIONS

In summary, Pre-sterilization and Post-sterilization testing indicates:

- 479 out of 480 instances of seal strength Functional Equivalence
- 156 out of 156 instances of microbial barrier Non-Inferiority
- 8,424 out of 8,424 instances of no dye penetration
- 1 Control and 2 Test material related defects out of 114,729 visually inspected packages

Results from the Pre-sterilization and Post-sterilization study time points indicate Functional Equivalence for seal strength, microbial barrier, and visual inspection. The one sealing condition for one cell which did not meet the Functional Equivalence criteria is an anomaly due to either unrepresentative sampling, possible execution errors in labeling or testing, and/or product type. Data from a structured retest of this cell indicated Functional Equivalence. Package integrity results will be assessed at the conclusion of the study but show no material related defects thus far. It should be noted that all EO residual determinations met MDM requirements according to documentation provided by MDMs.

APPENDIX A: CATEGORY RESULTS

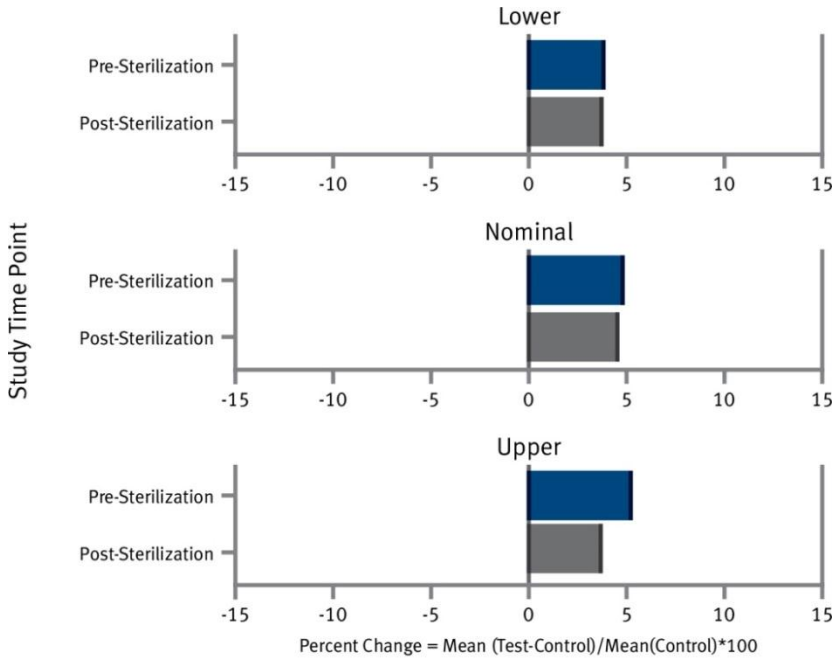
Overall results were presented in the previous section. Appendix A presents the data in a different format, i.e. by category, where it is broken down in further detail to help facilitate industry risk assessments. As evaluations are done, be cognizant of the number of cells represented by each Figure.

A set of Seal Strength, Microbial Barrier, Package Integrity, and Visual Inspection results are shown for each of the following categories:

- **Coated 1073B Pouches/Bags**
- **Coated 1073B Form-Fill-Seal**
- **Coated 1073B Lids/Rigid Trays**
- **Uncoated 1073B Pouches/Bags**
- **Coated 1059B Form-Fill-Seal**
- **Uncoated 1059B Pouches/Bags**
- **Uncoated 1059B Form-Fill-Seal**

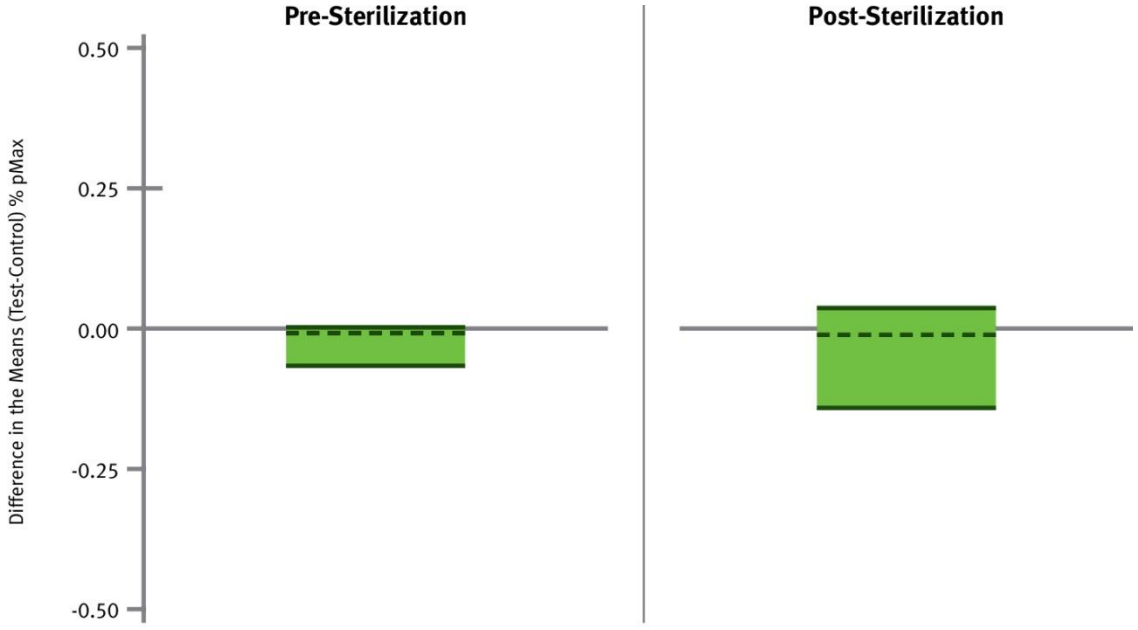
Coated 1073B Pouches/Bags

Figure A1. Avg. Percent Change in Mean Seal Strength (Test-Control) for Coated 1073B Pouches/Bags



Test=Transition Protocol Material
Control=Current Tyvek®

Figure A2. Range of Differences in % pMax Mean (Test-Control) for Coated 1073B Pouches/Bags



Dashed line (– – –)=Mean of the difference in the means
Test=Transition Protocol Material
Control=Current Tyvek®

Figure A3. Package Integrity Summary for Coated 1073B Pouches/Bags

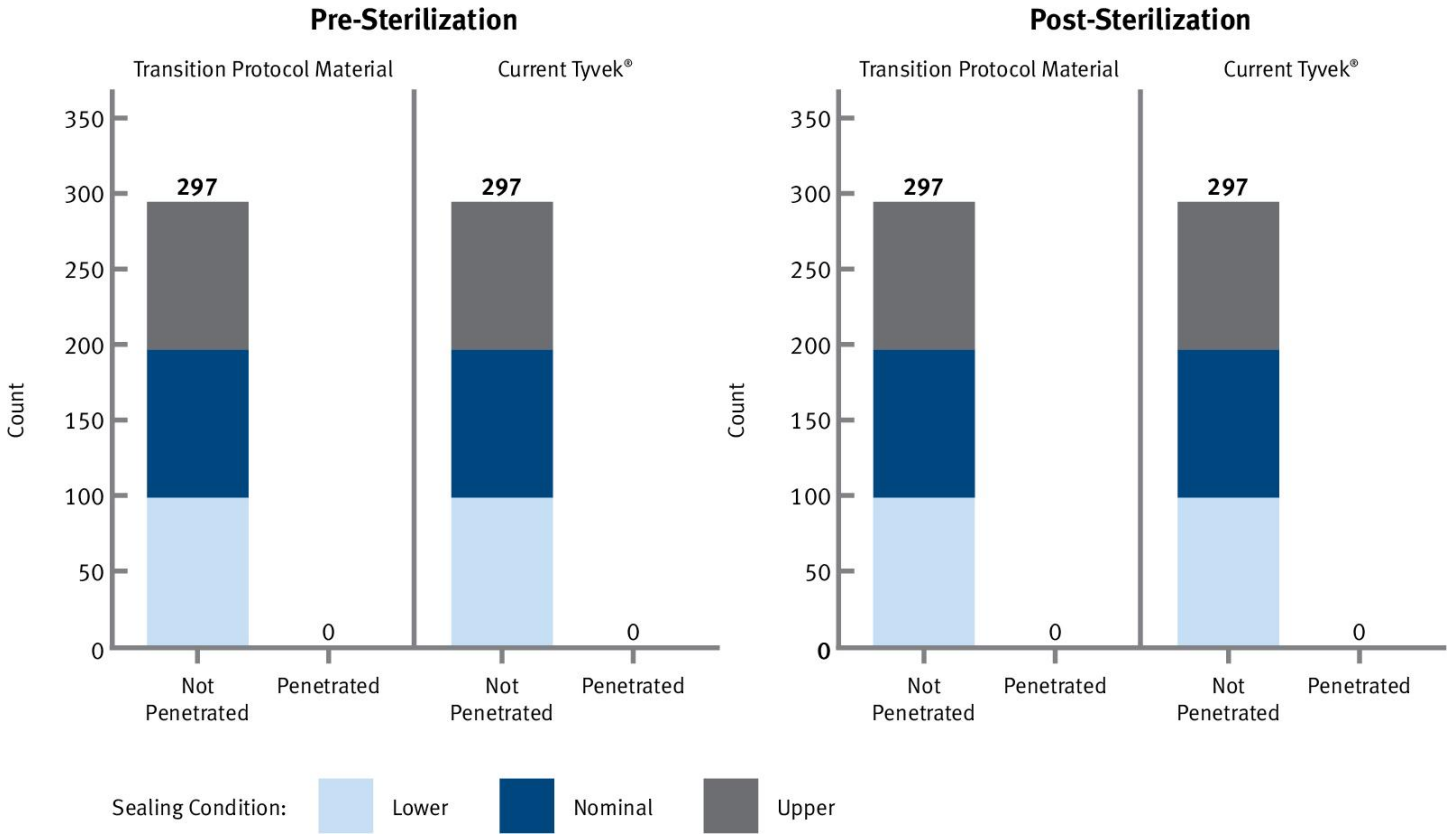
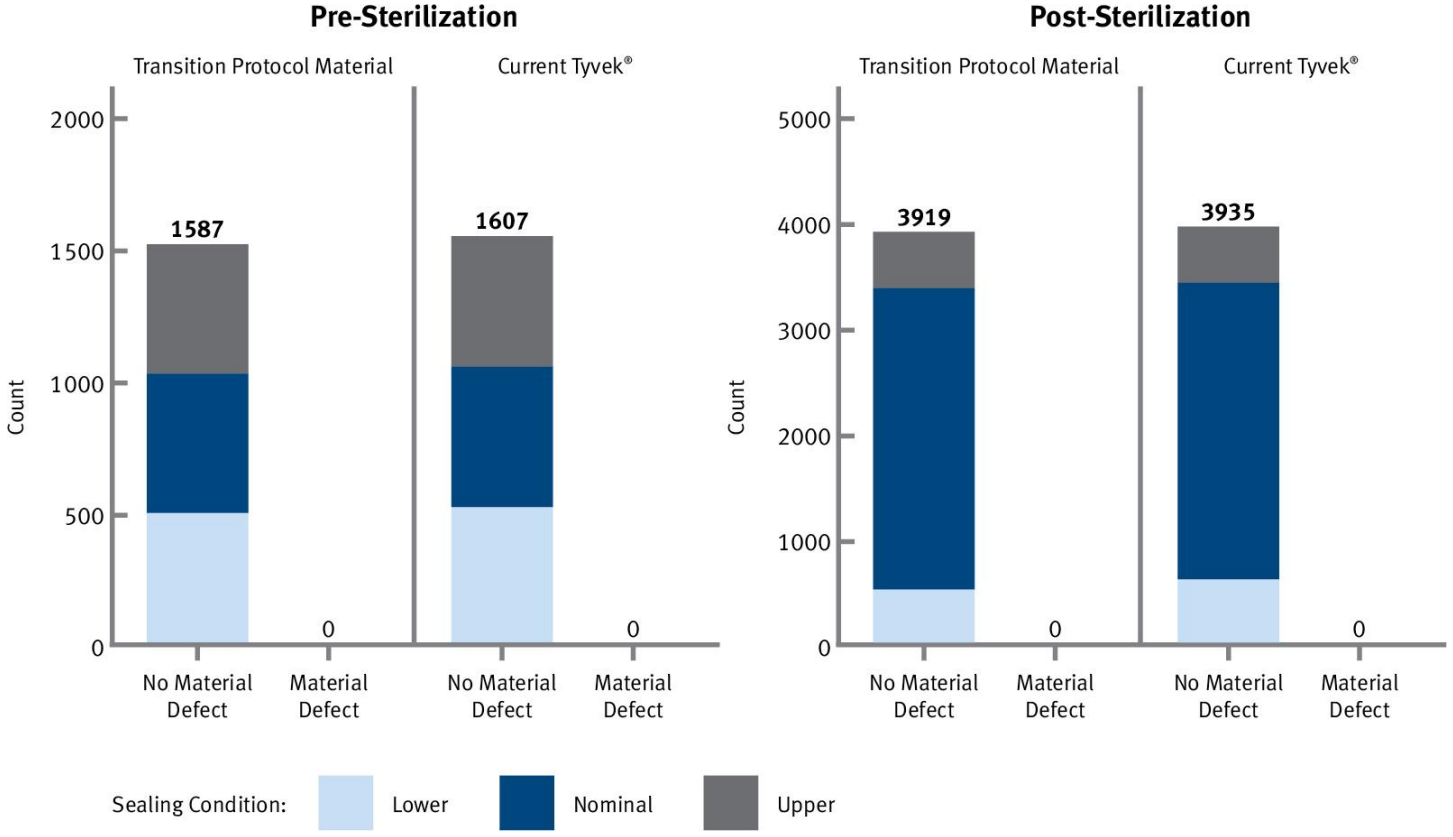
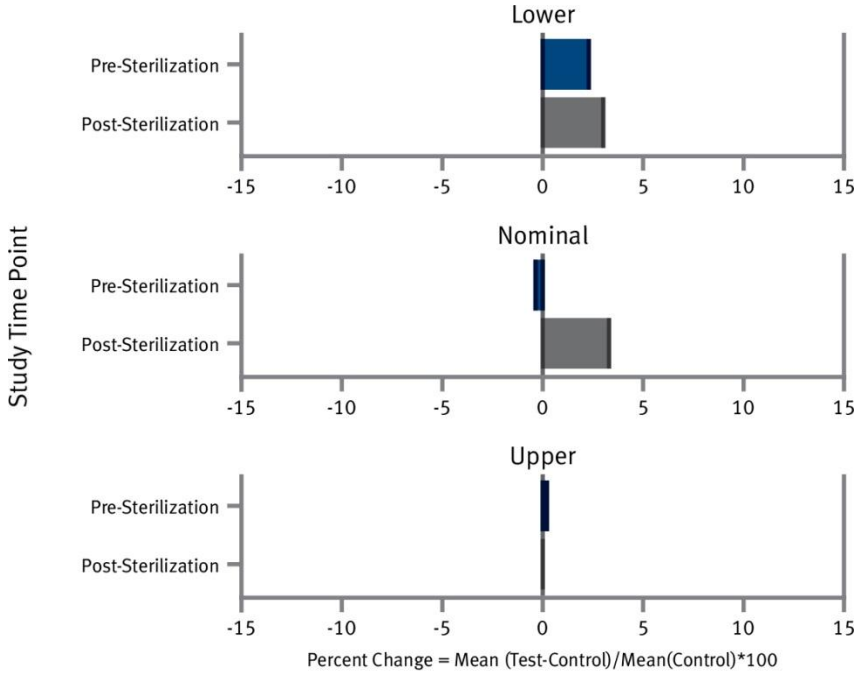


Figure A4. Visual Inspection Summary for Coated 1073B Pouches/Bags



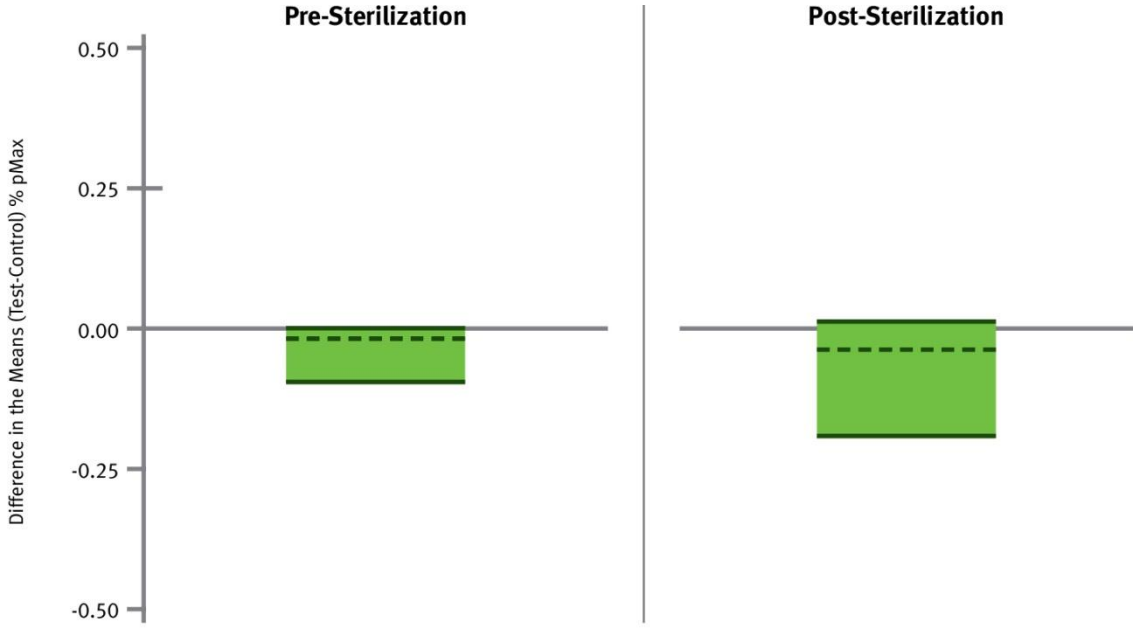
Coated 1073B Form-Fill-Seal

Figure A5. Avg. Percent Change in Mean Seal Strength (Test-Control) for Coated 1073B Form-Fill-Seal



Test=Transition Protocol Material
Control=Current Tyvek®

Figure A6. Range of Differences in % pMax Mean (Test-Control) for Coated 1073B Form-Fill-Seal



Dashed line (– – –)=Mean of the difference in the means
Test=Transition Protocol Material
Control=Current Tyvek®

Figure A7. Package Integrity Summary for Coated 1073B Form-Fill-Seal

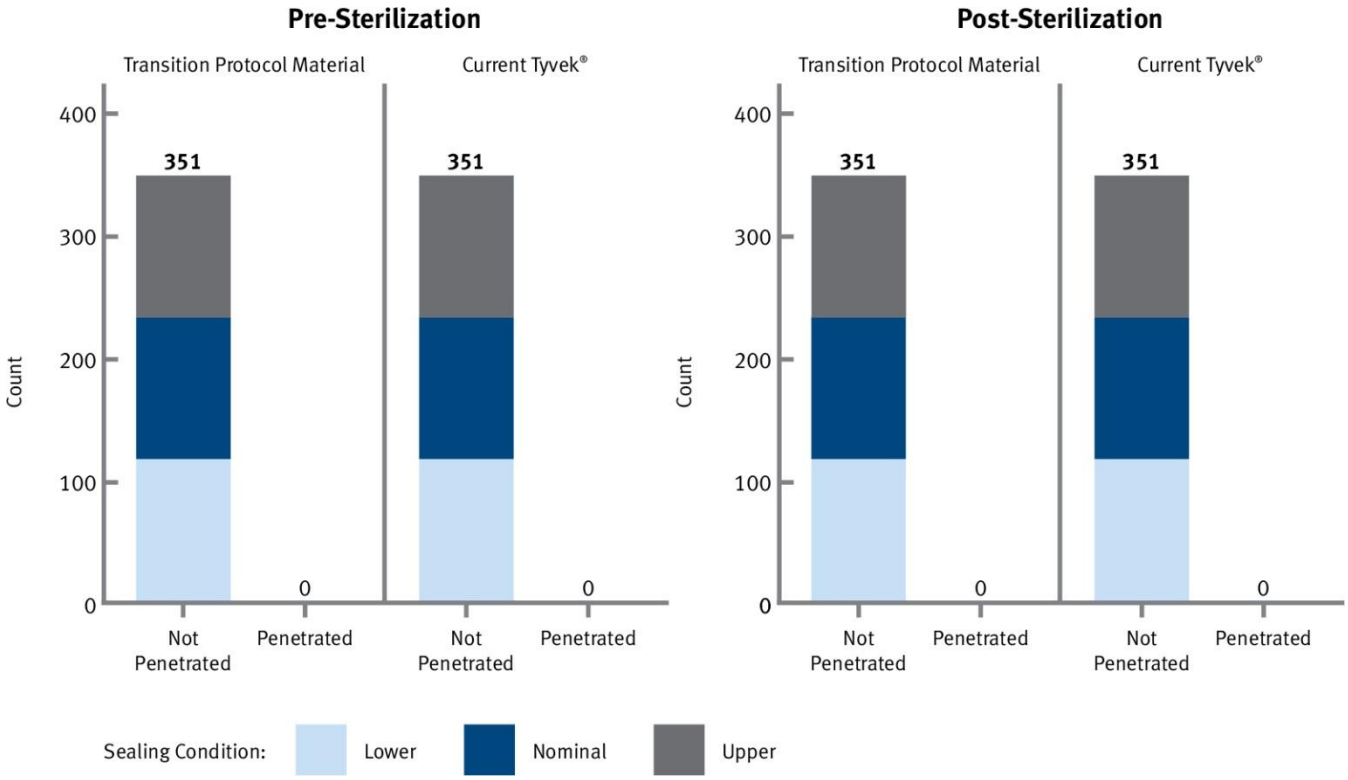
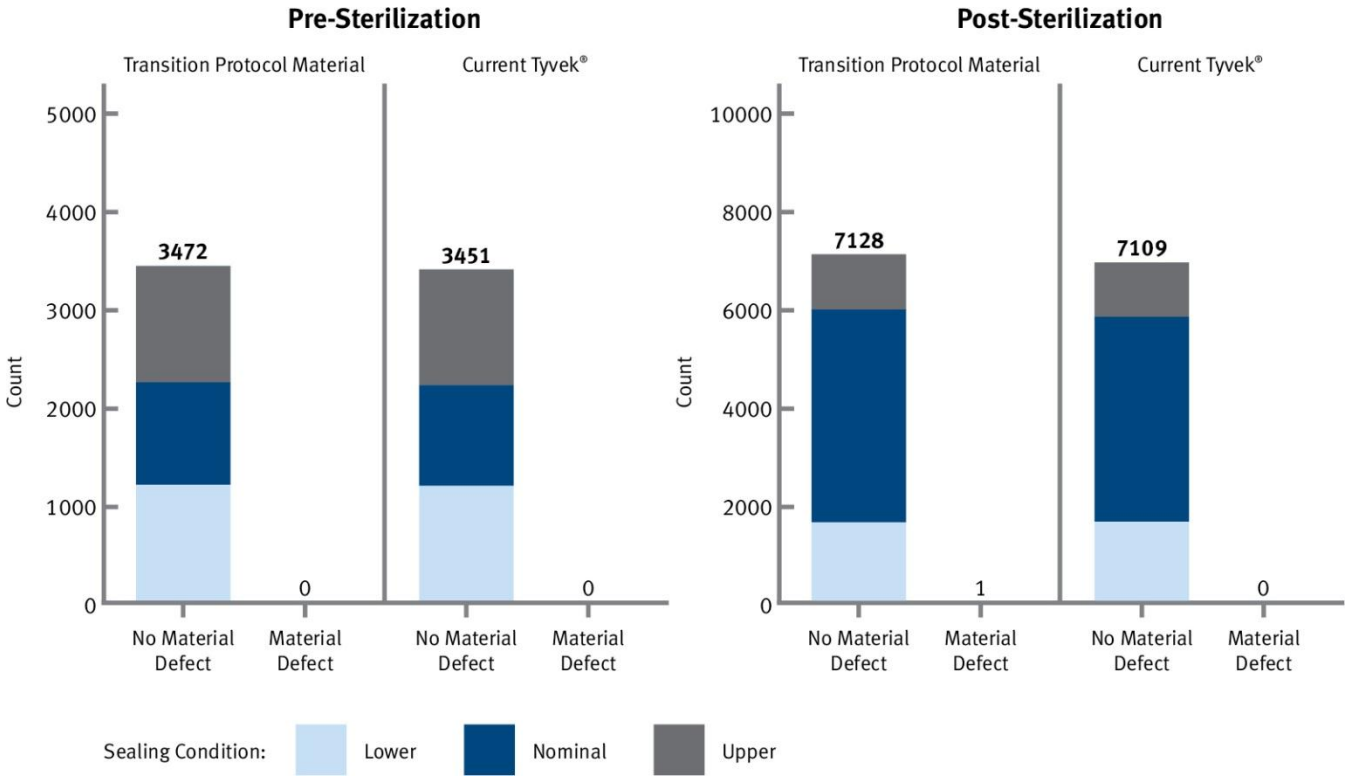
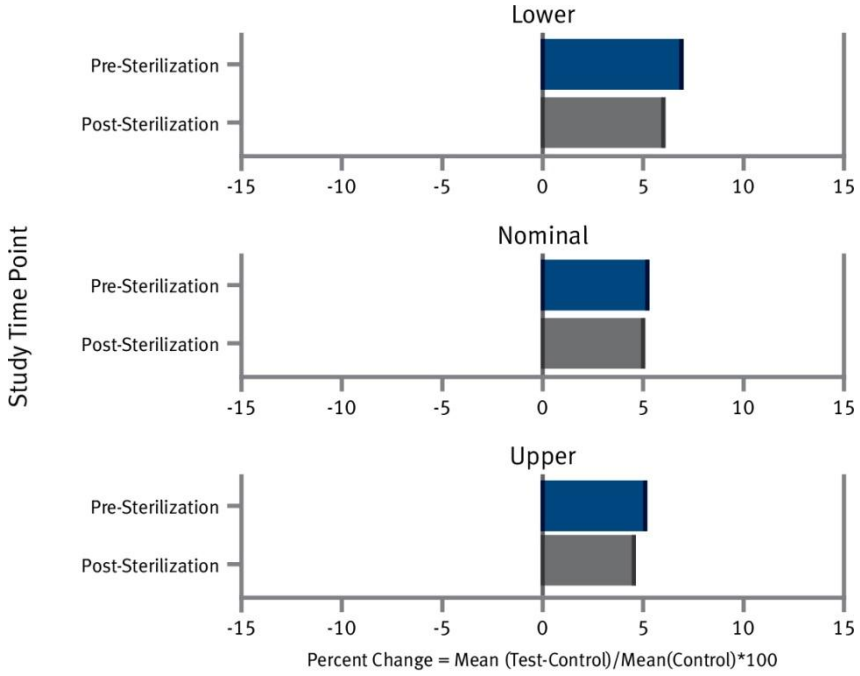


Figure A8. Visual Inspection Summary for Coated 1073B Form-Fill-Seal



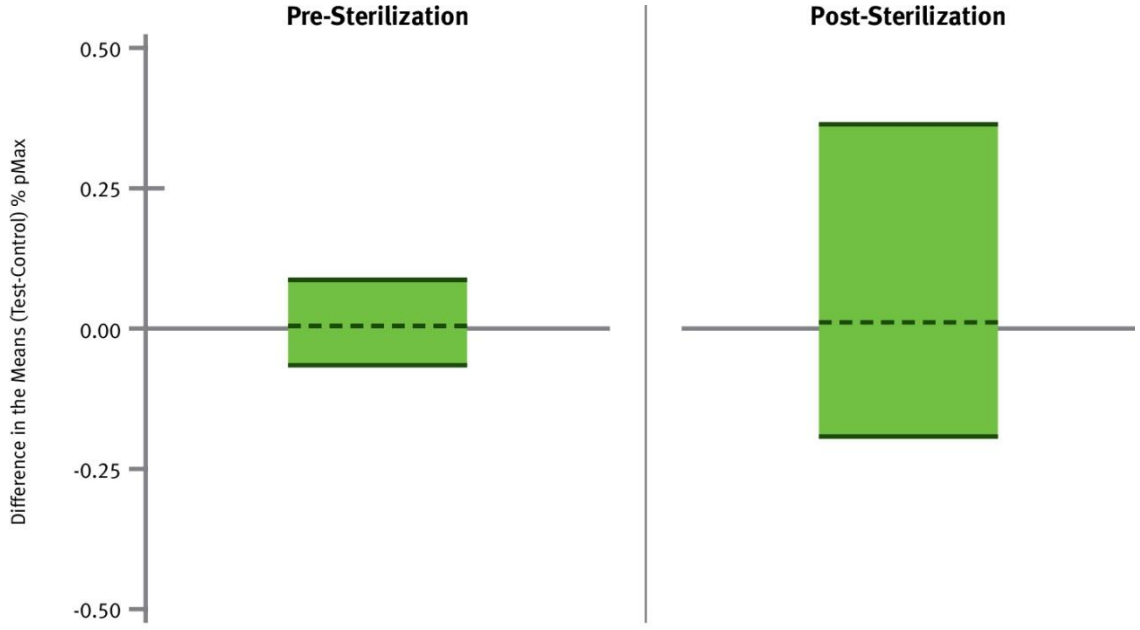
Coated 1073B Lids/Rigid Trays

Figure A9. Avg. Percent Change in Mean Seal Strength (Test-Control) for Coated 1073B Lids/Rigid Trays



Test=Transition Protocol Material
Control=Current Tyvek®

Figure A10. Range of Differences in % pMax Mean (Test-Control) for Coated 1073B Lids/Rigid Trays



Dashed line (– – –)=Mean of the difference in the means
Test=Transition Protocol Material
Control=Current Tyvek®

Figure A11. Package Integrity Summary for Coated 1073B Lids/Rigid Trays

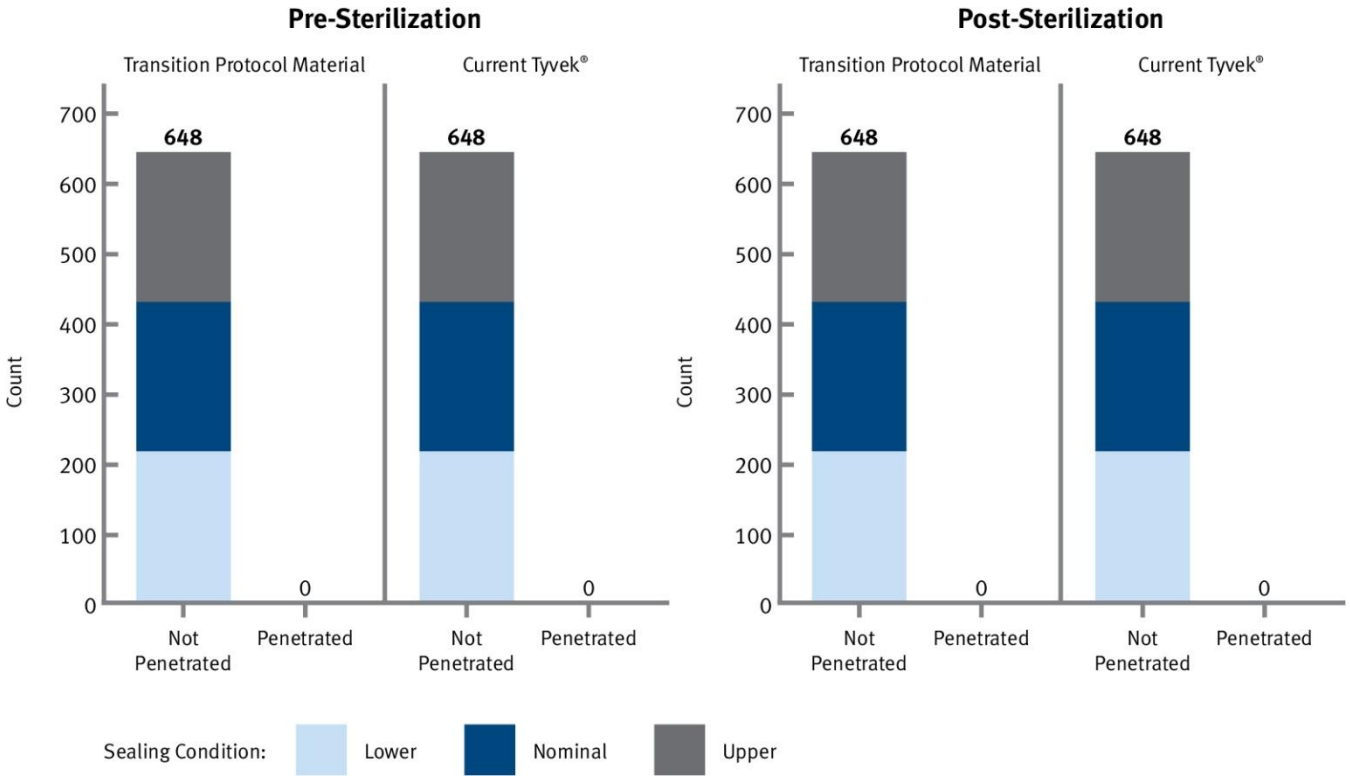
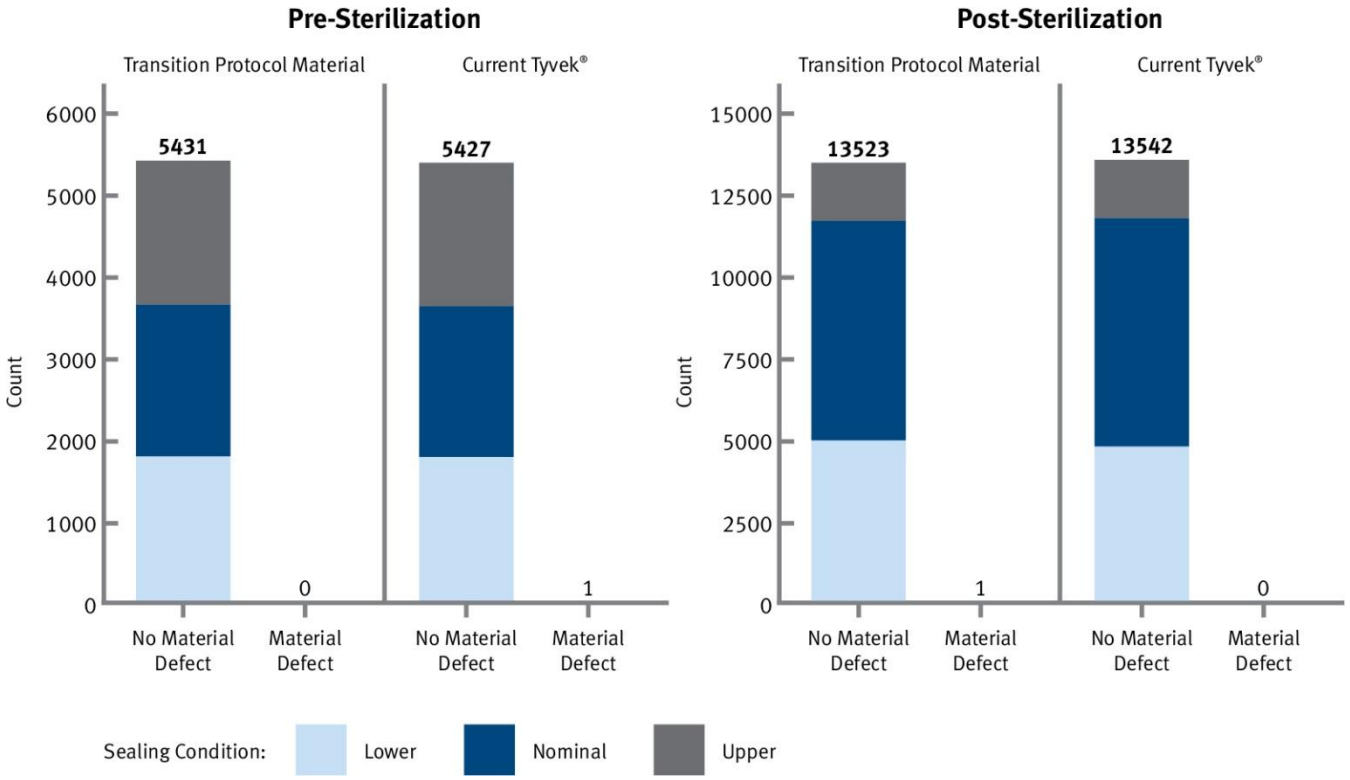
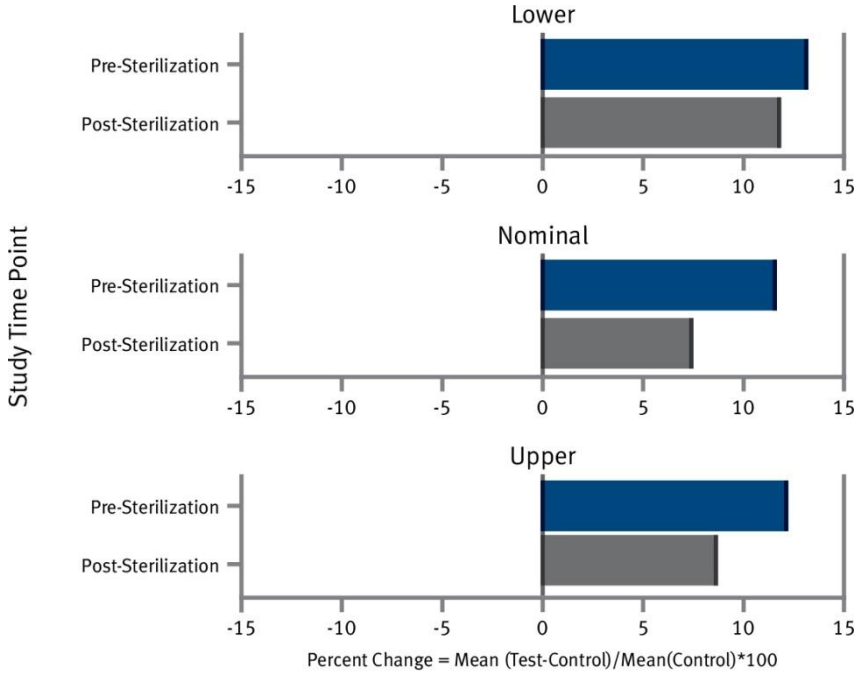


Figure A12. Visual Inspection Summary for Coated 1073B Lids/Rigid Trays



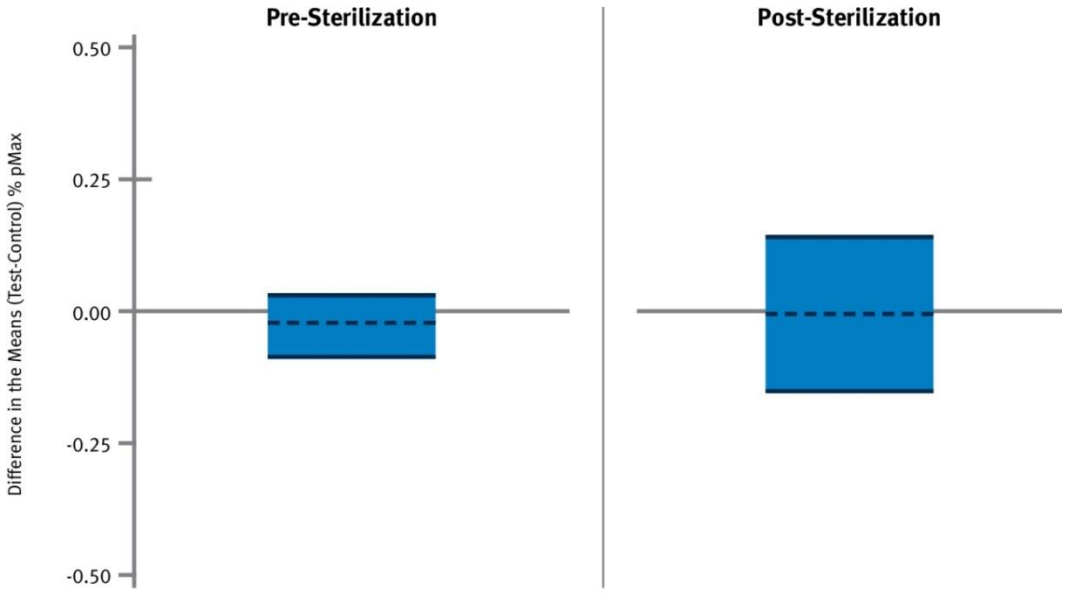
Uncoated 1073B Pouches/Bags

Figure A13. Avg. Percent Change in Mean Seal Strength (Test-Control) for Uncoated 1073B Pouches/Bags



Test=Transition Protocol Material
Control=Current Tyvek®

Figure A14. Range of Differences in % pMax Mean (Test-Control) for Uncoated 1073B Pouches/Bags



Dashed line (– – –)=Mean of the difference in the means
Test=Transition Protocol Material
Control=Current Tyvek®

Figure A15. Package Integrity Summary for Uncoated 1073B Pouches/Bags

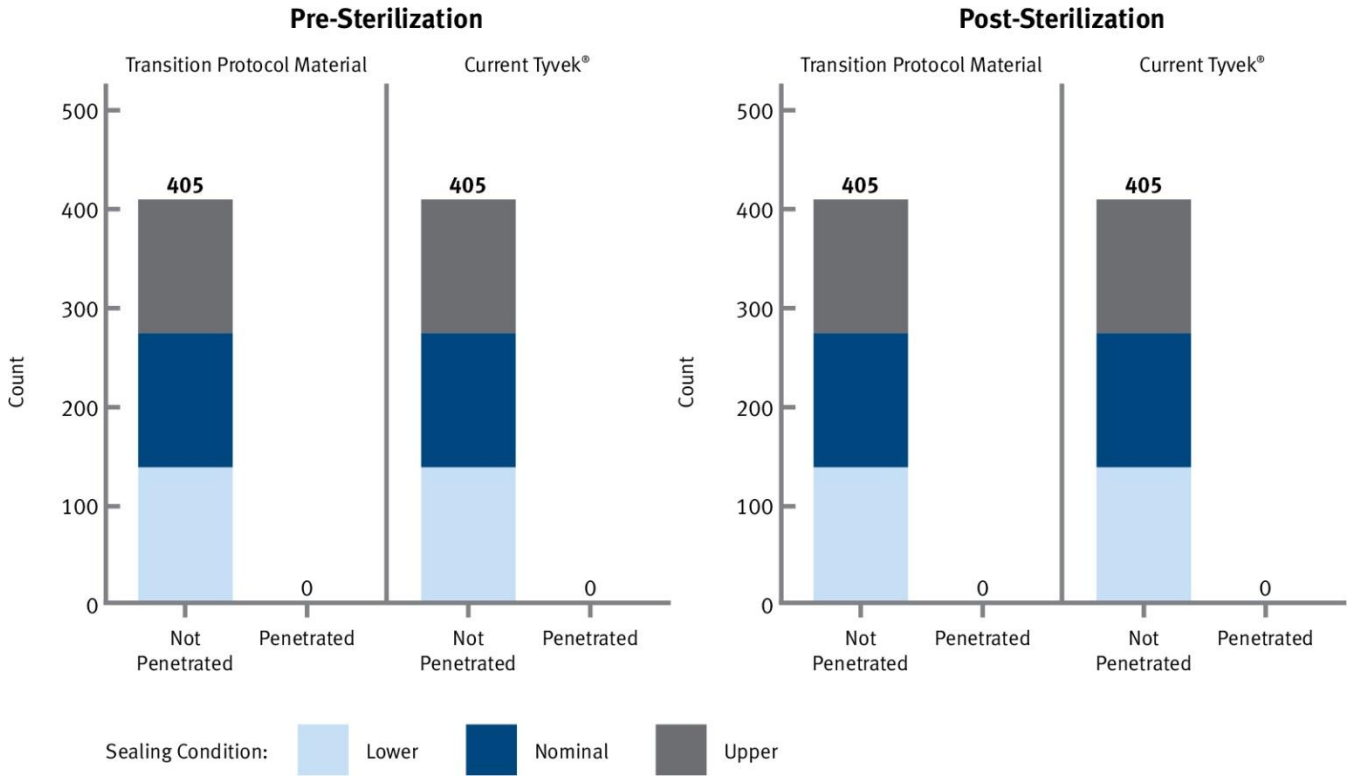
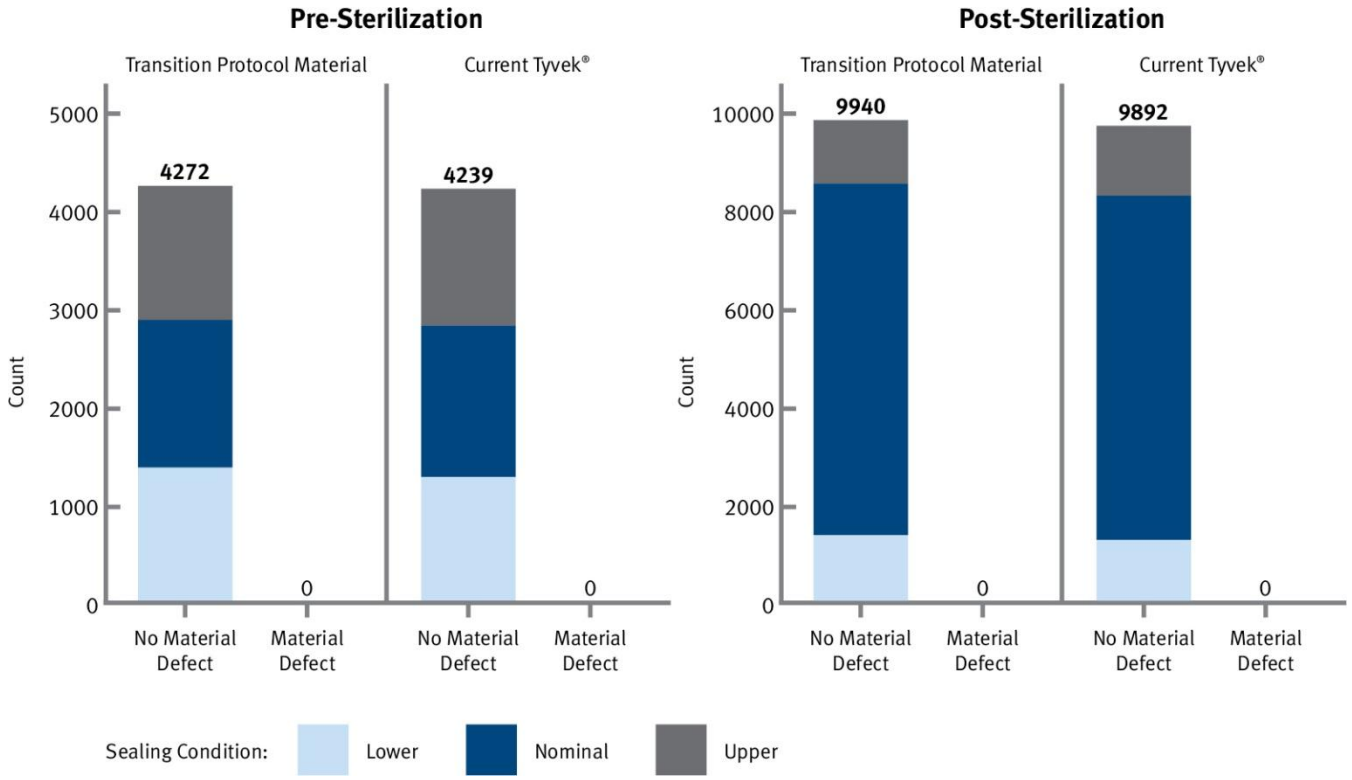
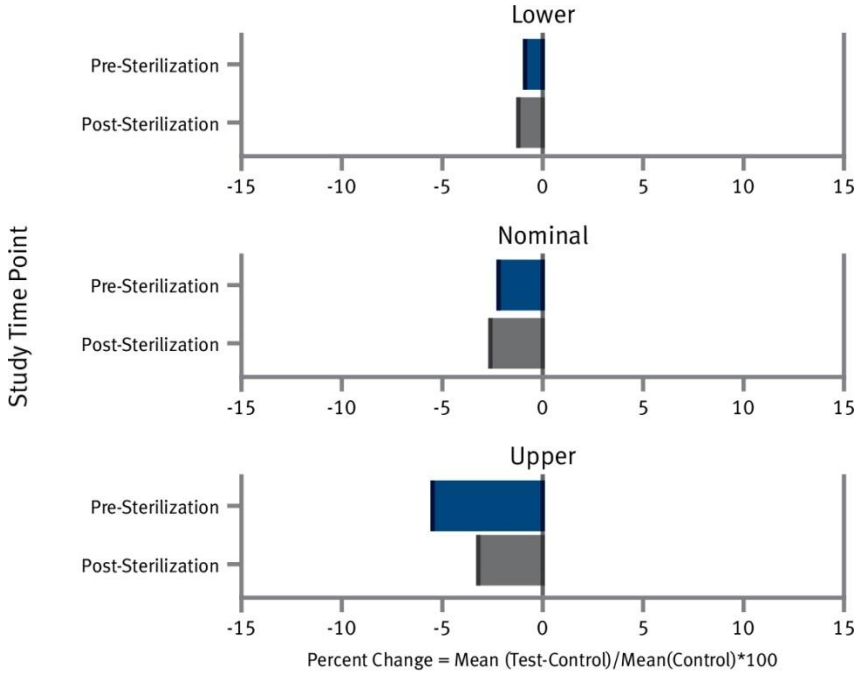


Figure A16. Visual Inspection Summary for Uncoated 1073B Pouches/Bags



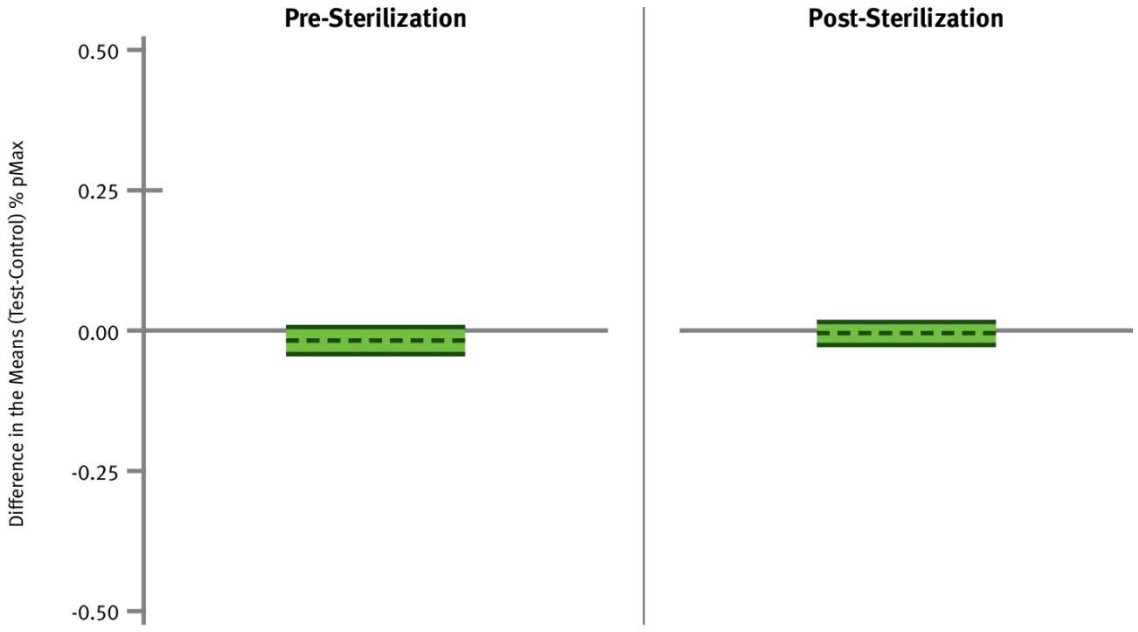
Coated 1059B Form-Fill-Seal

Figure A17. Avg. Percent Change in Mean Seal Strength (Test-Control) for Coated 1059B Form-Fill-Seal



Test=Transition Protocol Material
Control=Current Tyvek®

Figure A18. Range of Differences in % pMax Mean (Test-Control) for Coated 1059B Form-Fill-Seal



Dashed line (– – –)=Mean of the difference in the means
Test=Transition Protocol Material
Control=Current Tyvek®

Figure A19. Package Integrity Summary for Coated 1059B Form-Fill-Seal

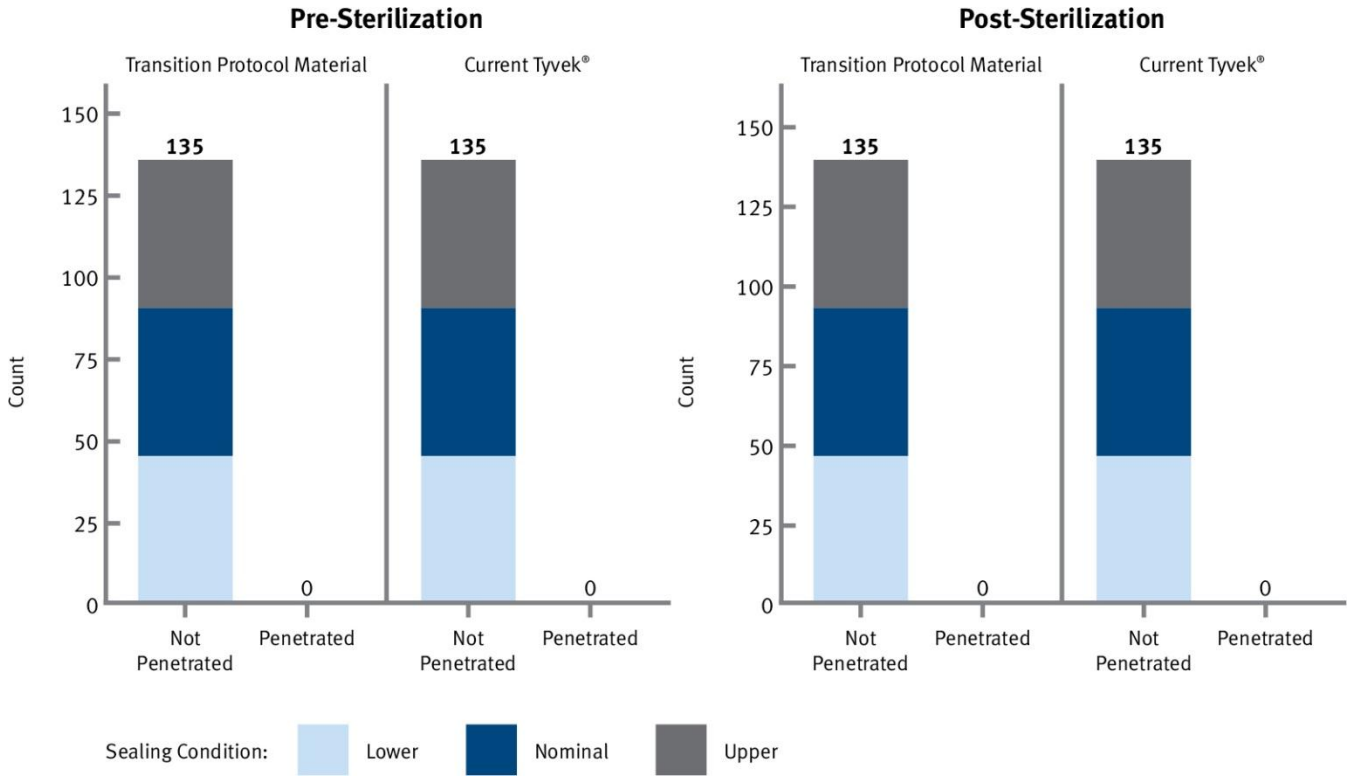
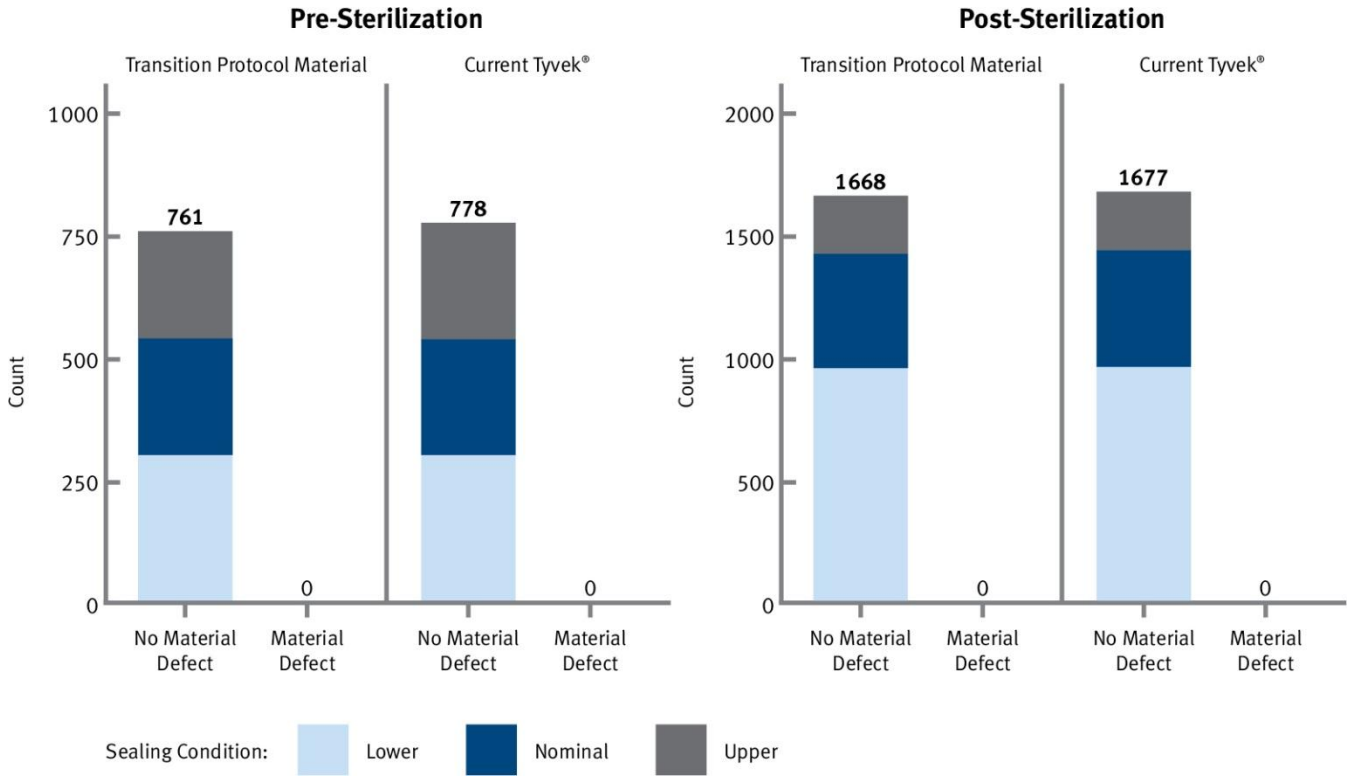
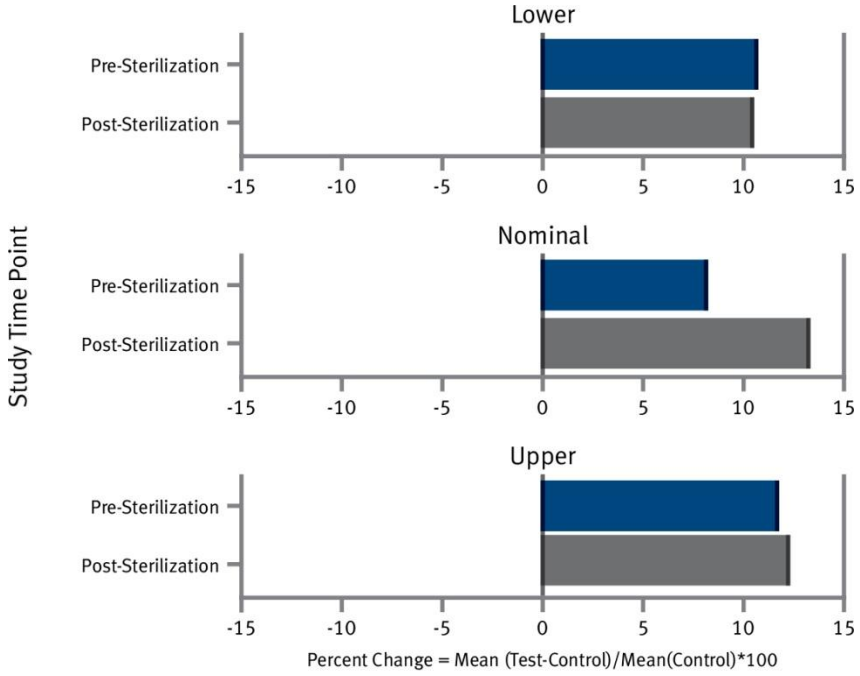


Figure A20. Visual Inspection Summary for Coated 1059B Form-Fill-Seal



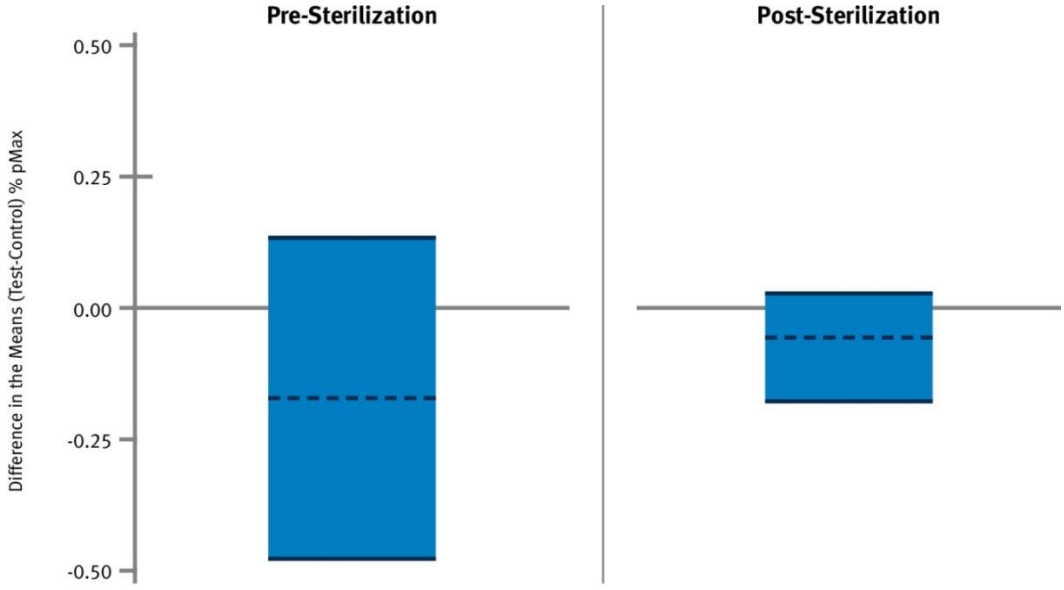
Uncoated 1059B Pouches/Bags

Figure A21. Avg. Percent Change in Mean Seal Strength (Test-Control) for Uncoated 1059B Pouches/Bags



Test=Transition Protocol Material
Control=Current Tyvek®

Figure A22. Range of Differences in % pMax Mean (Test-Control) for Uncoated 1059B Pouches/Bags



Dashed line (– – –)=Mean of the difference in the means
Test=Transition Protocol Material
Control=Current Tyvek®

Figure A23. Package Integrity Summary for Uncoated 1059B Pouches/Bags

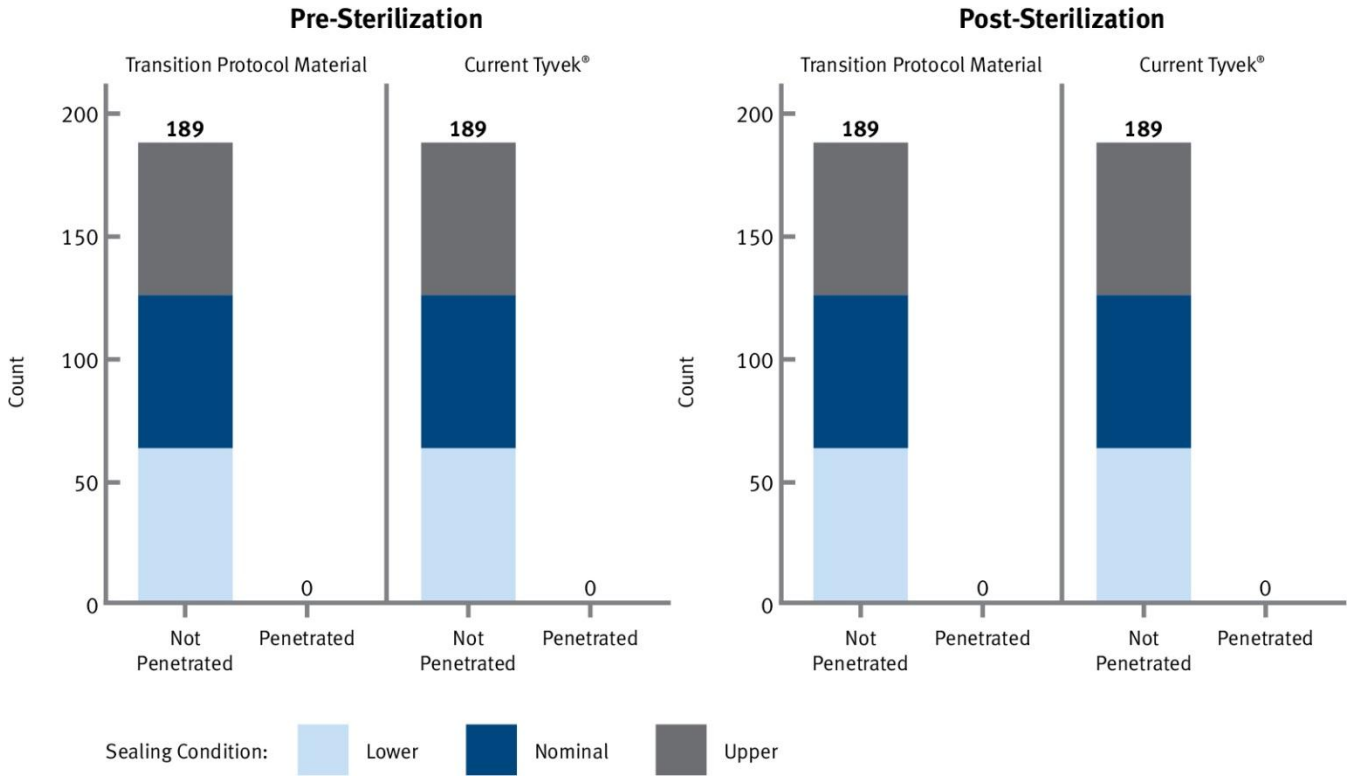
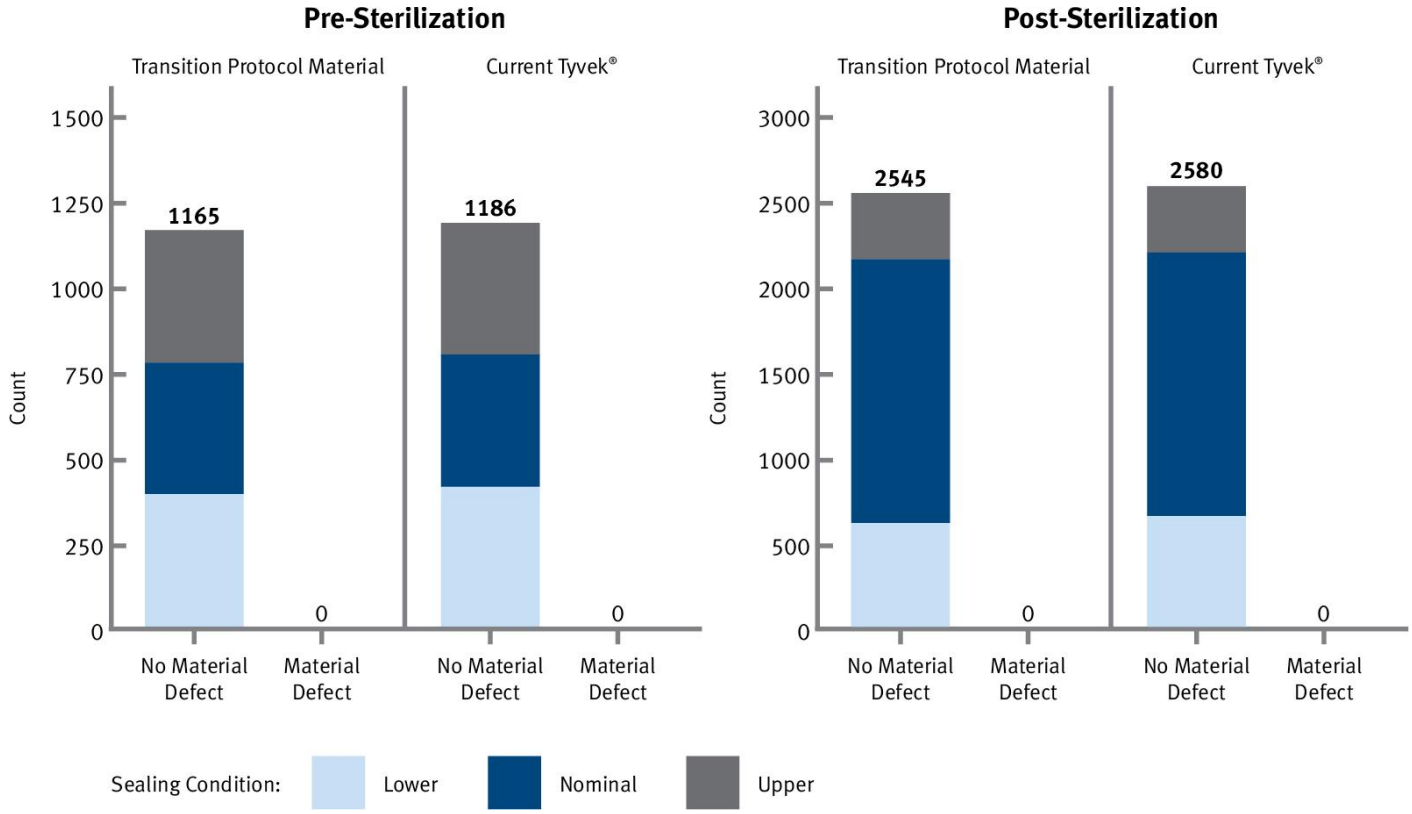
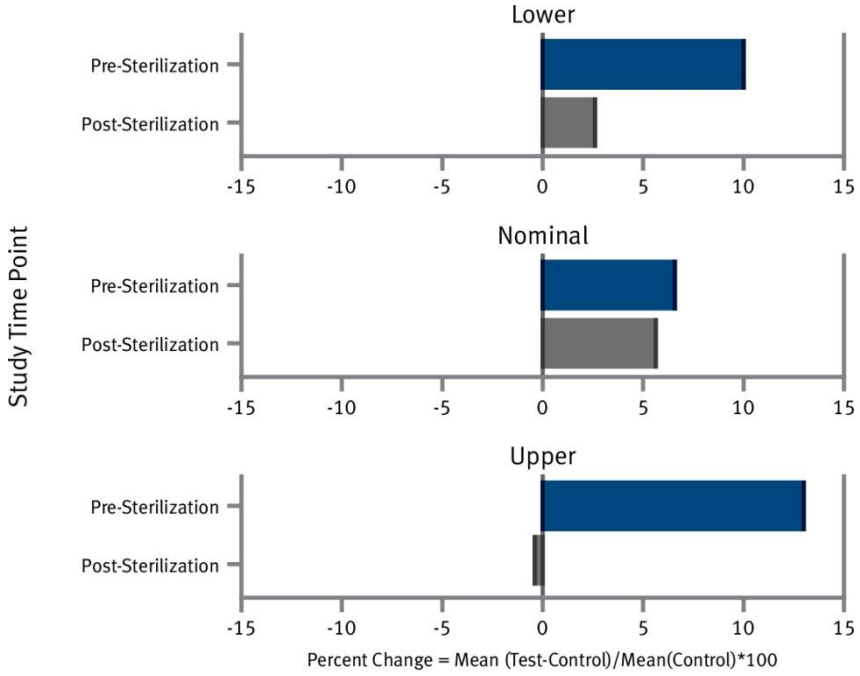


Figure A24. Visual Inspection Summary for Uncoated 1059B Pouches/Bags



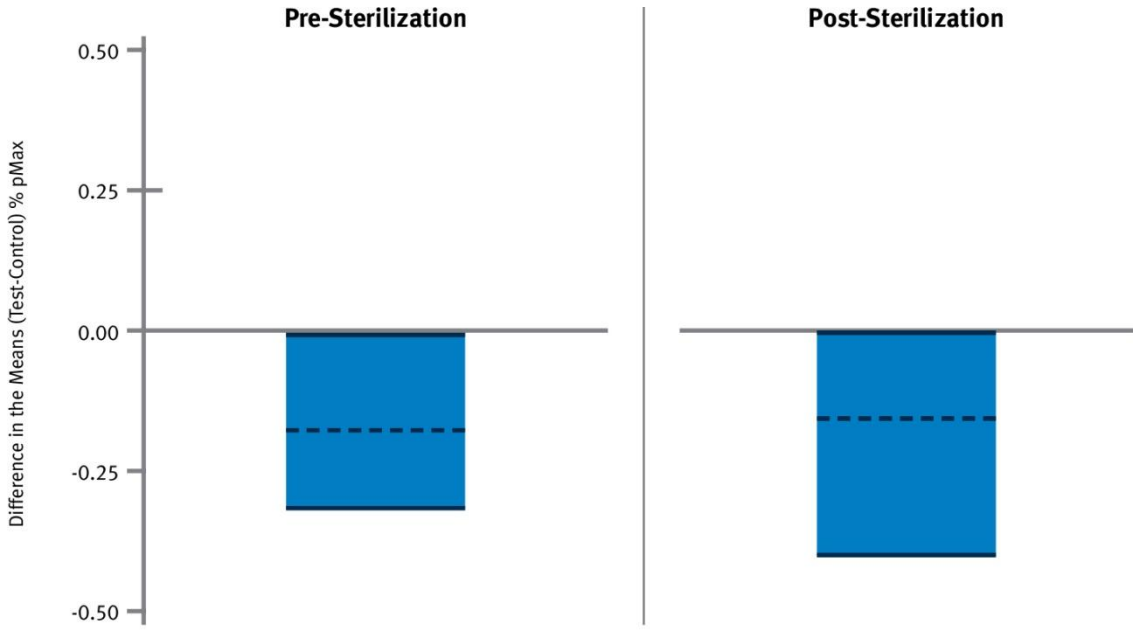
Uncoated 1059B Form-Fill-Seal

Figure A25. Avg. Percent Change in Mean Seal Strength (Test-Control) for Uncoated 1059B Form-Fill-Seal



Test=Transition Protocol Material
Control=Current Tyvek®

Figure A26. Range of Differences in % pMax Mean (Test-Control) for Uncoated 1059B Form-Fill-Seal



Dashed line (– – –)=Mean of the difference in the means
Test=Transition Protocol Material
Control=Current Tyvek®

Figure A27. Package Integrity Summary for Uncoated 1059B Form-Fill-Seal

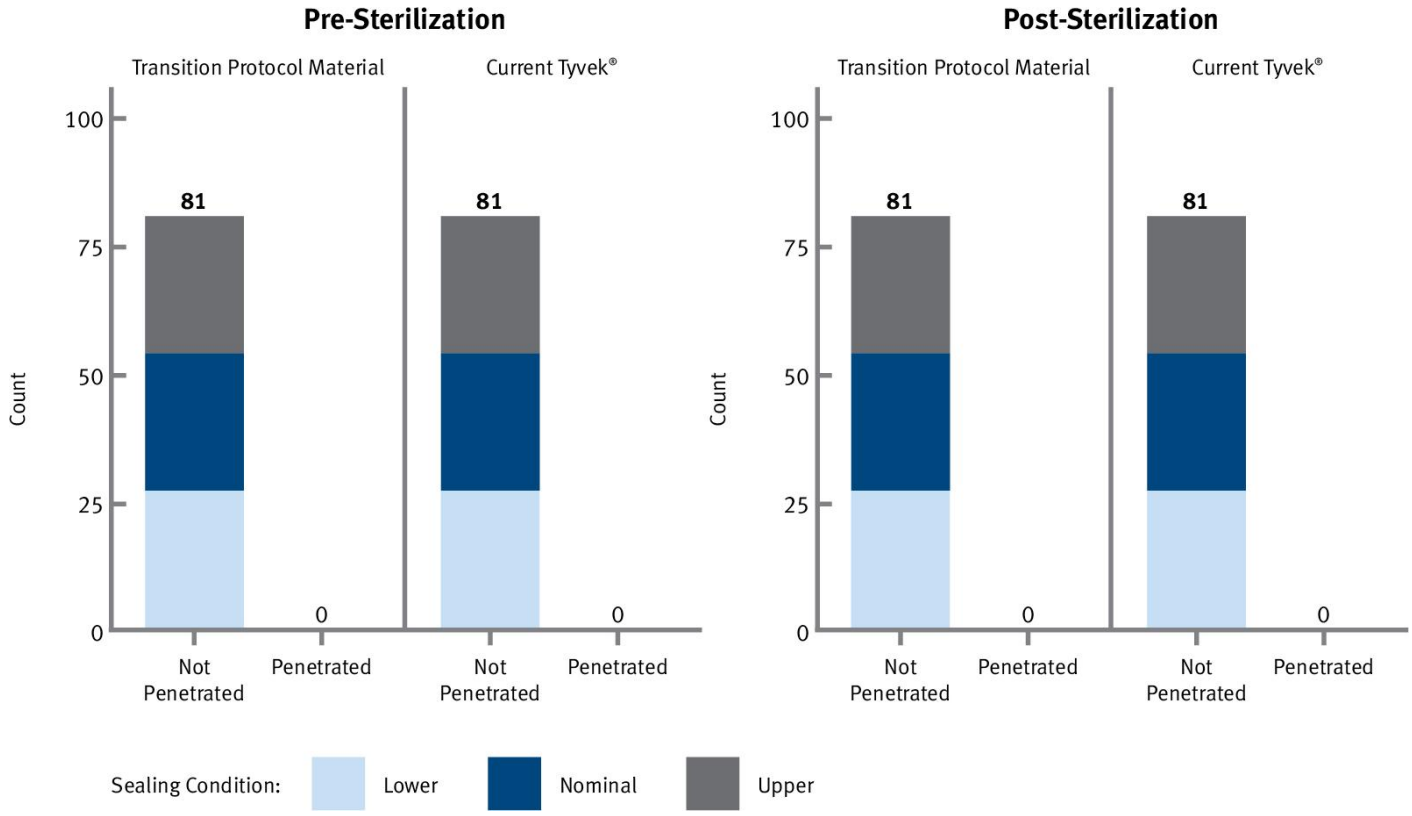


Figure A28. Visual Inspection Summary for Uncoated 1059B Form-Fill-Seal