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PTFE Sub-Lite-Wall™ Tubing:
3M PTFE Fine Powder and Replacement PTFE Fine Powder Comparison Data

Background:
Zeus' supply chain is impacted by the recent announcement of 3M™ related to their exit from the fluorochemical business, which includes PTFE fine powders ("resin").

Purpose:

The purpose of this document is to describe Zeus' efforts to understand, investigate and replace impacted 3M raw materials with replacement raw materials. These evaluations of the material formulation, biocompatibility and performance criteria are provided as documentation and evidence to assist Zeus' customers in evaluating the risk of change in their specific applications. Zeus will continue to evaluate alternative resins and may use these resins when deemed appropriate, subject to applicable change control or notification requirements.

Abstract:

The evaluation of a replacement PTFE fine powder compared to the existing 3M PTFE fine powder was completed. Both the fine powder and PTFE extruded Sub-Lite-Wall™ tubing were assessed to identify any differences in properties or performance. The fine powder was compared based on the ASTM D4895 standard and CAS number assignation. The extruded tubing from the different resins were characterized to evaluate their composition via FTIR, biocompatibility via selected test methods outlined in USP Class VI, ISO-10993-4, and ISO-10993-5 documents, thermal properties, and mechanical properties. Because PTFE Sub-Lite-Wall™ tubing is known to be used as the liner in catheters, the etch ability and bondabililty of the tubing were assessed. This evaluation concludes that products manufactured using the replacement fine powder conform with all applicable chemical and dimensional specifications.

Contents:

I. ASTM D4895 Classification of PTFE Fine Powder:

The ASTM D4895 standard classifies PTFE fine powders based on their properties and performance. A copy of the standard may be obtained from WWW.ASTM.ORG.

Fine powders are characterized by:

Type: based on particle size
Grade: based upon specific gravity, thermal stability index, and stretch void index
Class: based upon extrusion pressure

General comparison process:

ASTM D4895			
Current 3M Resin	ASTM Type	ASTM Grade	ASTM Class
XX	I	1	C
YY	I	1	C

Replacement Fine Powder "Resin AA":

- Same ASTM Type
- Same ASTM Grade
- Same ASTM Class

II. Chemical Composition:

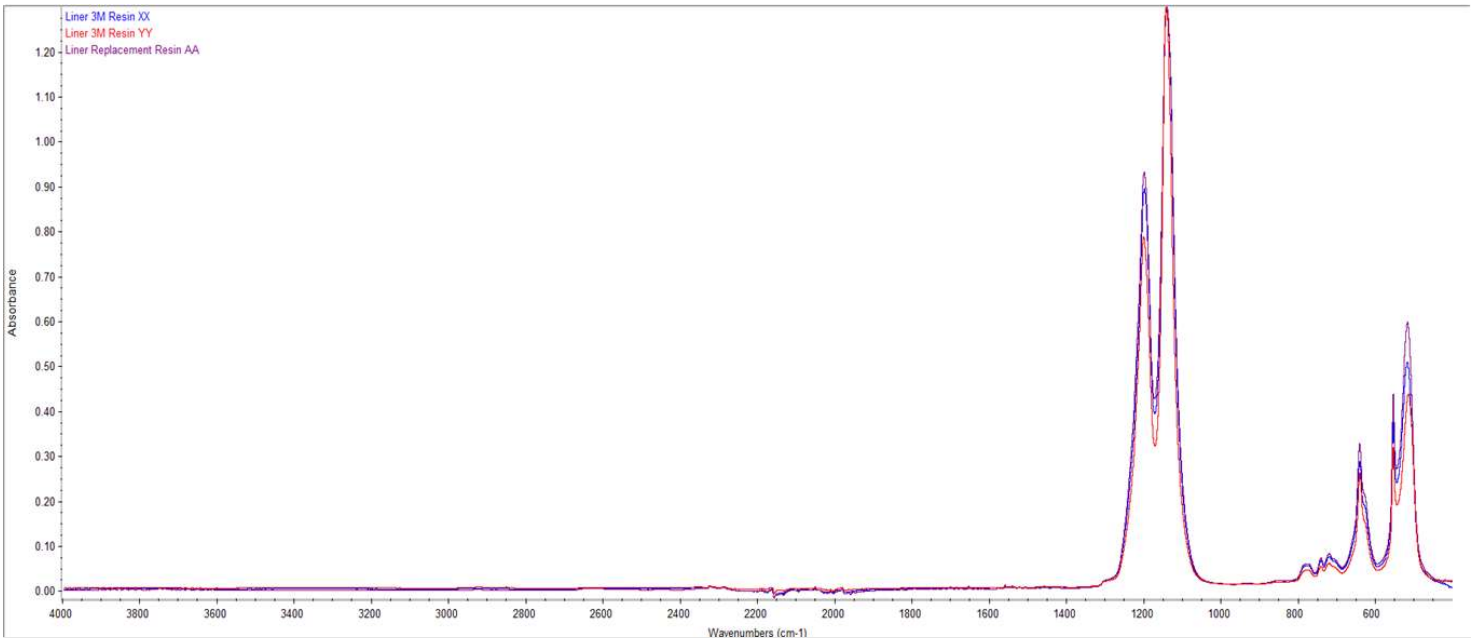
Both the 3M resins and the replacement resin have been assigned the same chemical identifier for PTFE, which is CAS Registry number 9002-84-0.

Liners produced from 3M and replacement fine powders were analyzed using ATR-FTIR. Zeus recommends evaluating the spectral overlay of the liners produced from replacement resin AA to liners produced from 3M resins, which is provided in the chart below.

The peaks present in the replacement resin overlay with the peaks from the other PTFE resins and align with the functional group vibrations for PTFE. There are no additional peaks present, which would indicate differences in material composition or contamination.

The slight differences in peak intensity are inherent to the test method and not attributed to material composition differences. Additionally, small fluctuations along the baseline, particularly between 1900 and 2600 cm^{-1} wavenumbers, are attributed to the test method and instrument configuration, not the material being tested.

Based on this analysis, the conclusion from the ATR-FTIR testing is that the liner produced from replacement resin is indistinguishable from liners produced from 3M resins.
The overlay below indicates that all the materials are PTFE.



III. Biocompatibility / Compliance:

All PTFE Fine powders used by Zeus are USP Class VI/ISO 10993 tested by independent laboratories. The biocompatibility tests in the table below were selected to verify that the change in PTFE resin did not alter the biocompatibility of the part. The test reports are enclosed.

The table below demonstrates biocompatibility comparison of 3M vs. Replacement Fine Powder:

Compliance	Tests Completed	Existing 3M Resins	Replacement Resin
USP Class VI	Acute Systemic Toxicity (Systemic Injection)	Pass	Pass
	Intracutaneous Test	Pass	Pass
	Implantation Test (11 day Surgical)	Pass	Pass
ISO 10993-4	ASTM F756-17 (Direct and Indirect)	Pass	Pass
ISO 10993-5	Test on extracts (MEM Elution)	Pass	Pass

Table # 1: Biocompatibility Comparison

Manufacturing Process:

The replacement resin is subject to the same quality system controls and manufacturing process and controls as the existing 3M resin, which is detailed in table # 2. The parts evaluated for this document are manufactured under these standard conditions.

Conditions	Replacement Resin vs Existing 3M Resins
Tooling	Same
Process	Same
Process Aids	Same
Equipment	Same
Control Plan	Same
Quality Procedure	Same
Quality Manual	Same
Supplier Controls	Same

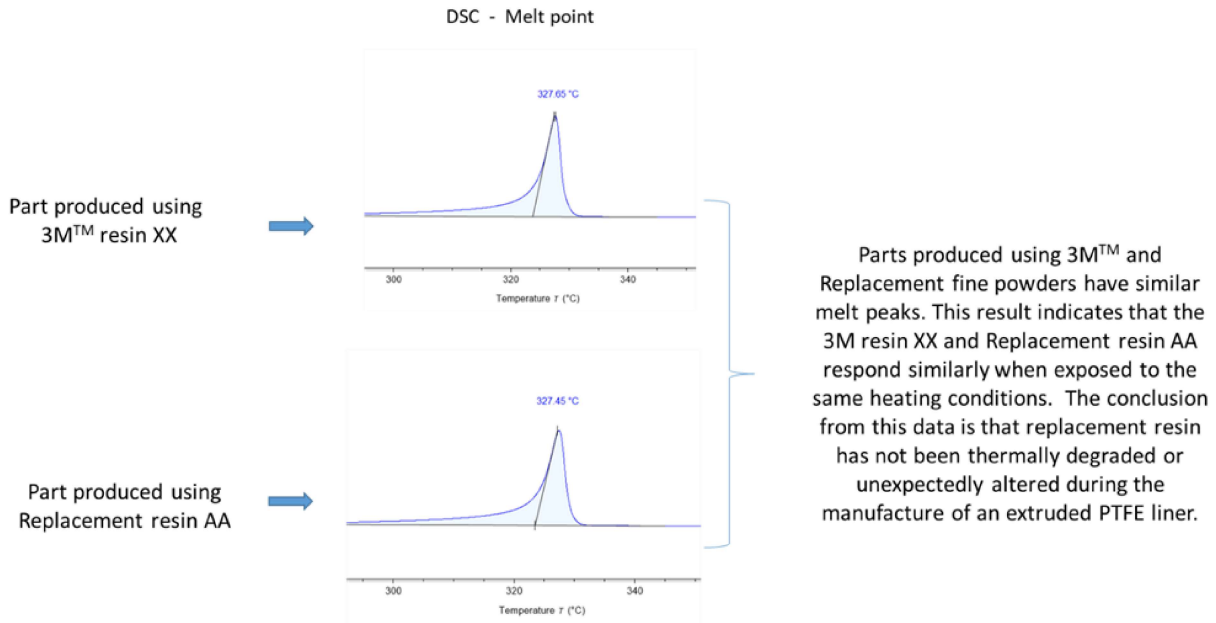
Table # 2: Quality System Controls & Manufacturing Controls Comparison for Existing 3M Resins and Replacement Resin

IV. Thermal Properties:

The thermal properties are the response of a material when heat is applied. In the manufacturing process of converting fine powder into extruded parts, such as liners, the material is exposed to heat. A comparison between the thermal responses of liners produced from the replacement resin versus the 3M resin will show if the replacement resin has a different response to standard processing conditions. For PTFE, the melting peak is thermal response of interest because it changes as the resin is converted from a fine powder to an extruded part. When comparing the thermograms shown below, both depict a similarly shaped melting curve with peak values of 327.05°C and 327.45°C. A difference of 0.4°C is not considered significant in this type of test. The second set of thermograms show the same result with a melt peak difference of 0.2°C. The conclusions from this data are that the thermal response from the liner made with 3M resin is the same as a liner made from the replacement resin, and the replacement resin has not been thermally degraded or unexpectedly altered during the manufacture of an extruded PTFE liner.

Part information:

Extruded etched PTFE Liner
Lots 172552978-1, 172551742-1
Inner Diameter: 0.097”
Wall Thickness: 0.0015”

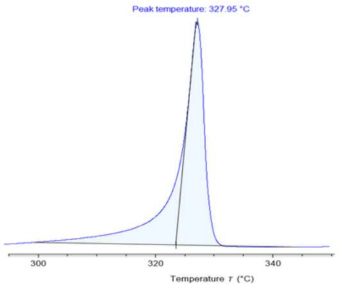


Part information:

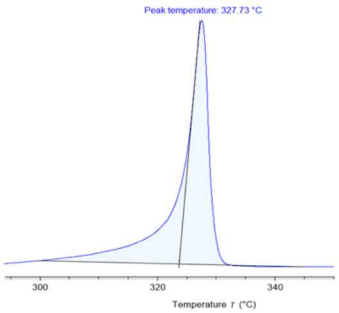
Extruded etched PTFE Liner
Lots: 20258101-1 and 202558105-1
Inner Diameter: 0.030” (nominal)
Wall Thickness: 0.002” (nominal)

DSC - Melt point

Part produced using 3M™ resin YY



Part produced using Replacement resin AA



Parts produced using 3M™ and Replacement fine powders have similar melt peaks. This result indicates that the 3M resin YY and Replacement resin AA respond similarly when exposed to the same heating conditions. The conclusion from this data is that replacement resin has not been thermally degraded or unexpectedly altered during the manufacture of an extruded PTFE liner.

V. Physical Dimensions of Liners:

Physical dimensions are measurements that define the part geometry. Three parts were selected to represent the product portfolio for PTFE Sub-Lite-Wall. The nominal dimensions of these parts are shown in the table below. Finished part dimensions meet the same specifications as parts produced from 3M fine powders.

Part	ID (Inches)	Wall (inches)
1	0.030”	0.002”
2	0.097”	0.0015”
3	0.302”	0.0035”

Table #3: Nominal Part Dimensions

VI. Mechanical Properties of Liners:

Mechanical properties describe how a material responds to an application of force. These properties are used to determine a material's suitability for use in an intended application. All mechanical properties as specified in existing part specifications will be maintained for the replacement resin. If during the production of a specific part, there are any dimensional or tensile related deviations required, notification will be provided, and path forward determined.

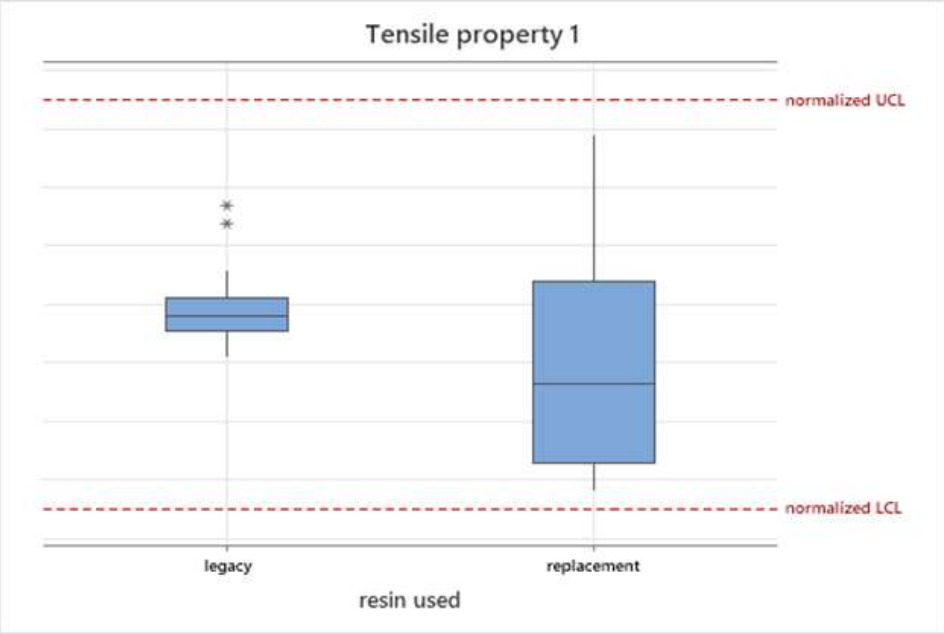
The replacement resin was evaluated against historical data on a part-to-part basis where available.

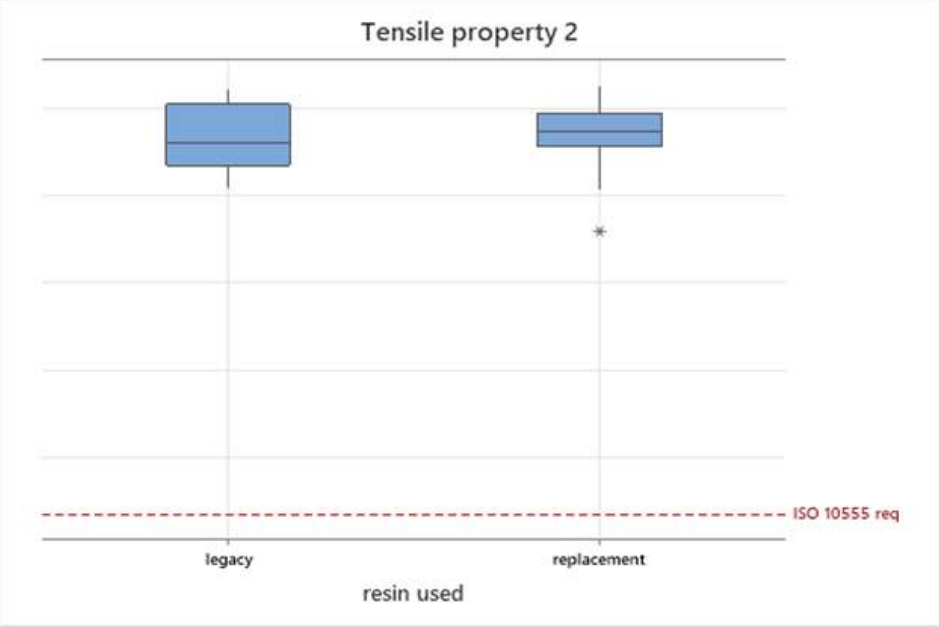
The mechanical property evaluations were completed on the same parts identified in table #3 above.

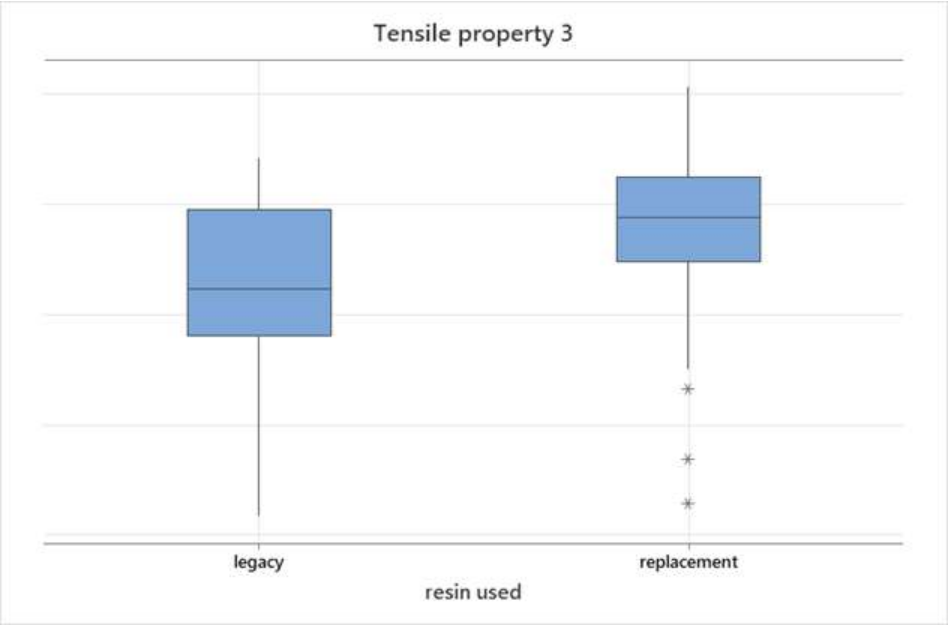
Tensile testing is used to obtain and compare the differences in the stress-strain response of materials. The following criteria, some of which are proprietary, were selected to show similarity between liners produced with existing 3M vs. replacement fine powder.

1. Tensile Property 1
2. Tensile Property 2
3. Tensile Property 3
4. Burst Test (subject to size)
5. Split test (pass/fail)

Tensile charts from Part 1 (ID 0.030”/Wall 0.002”) are shown below:



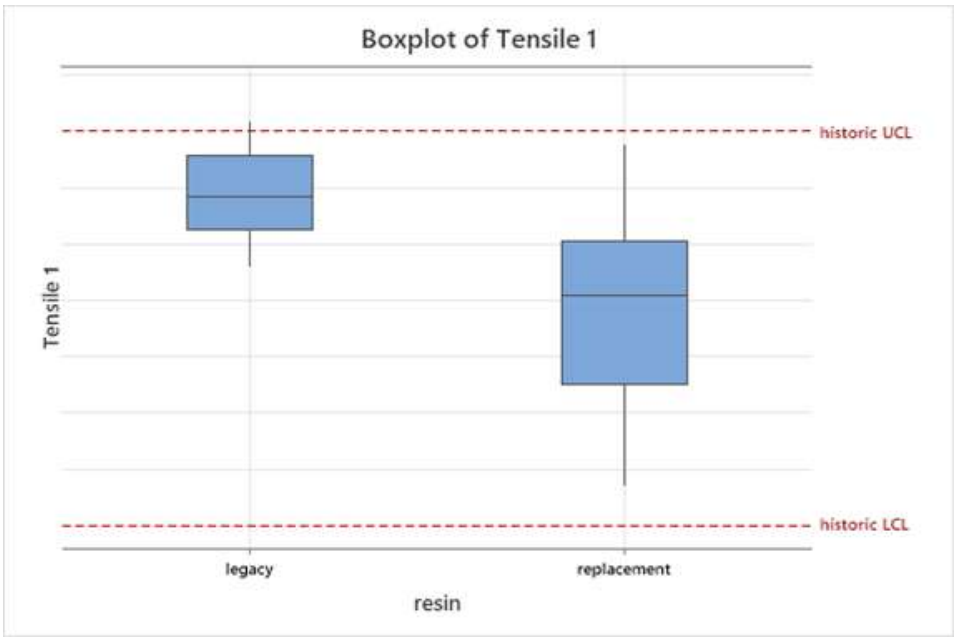


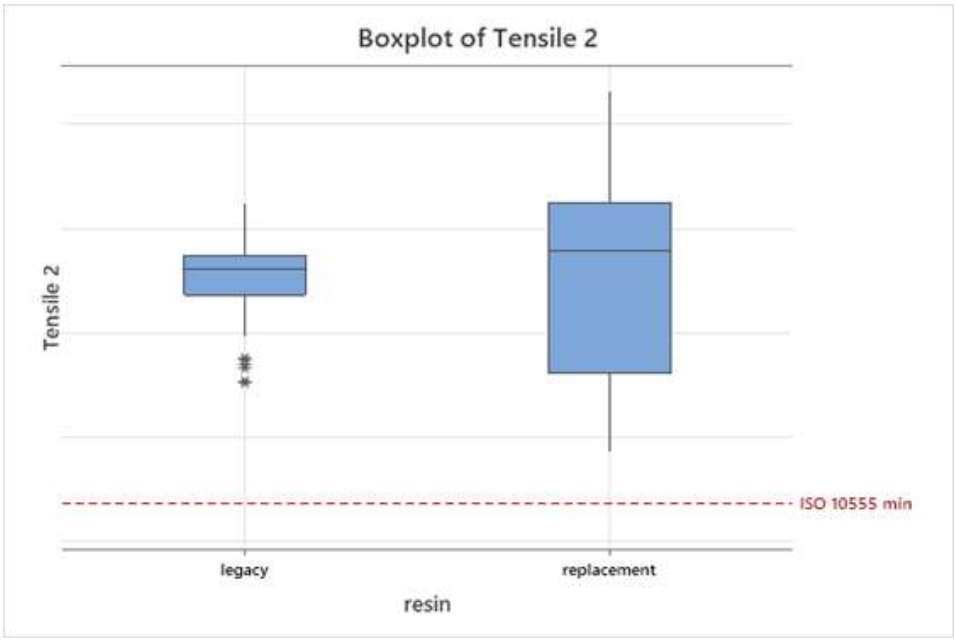


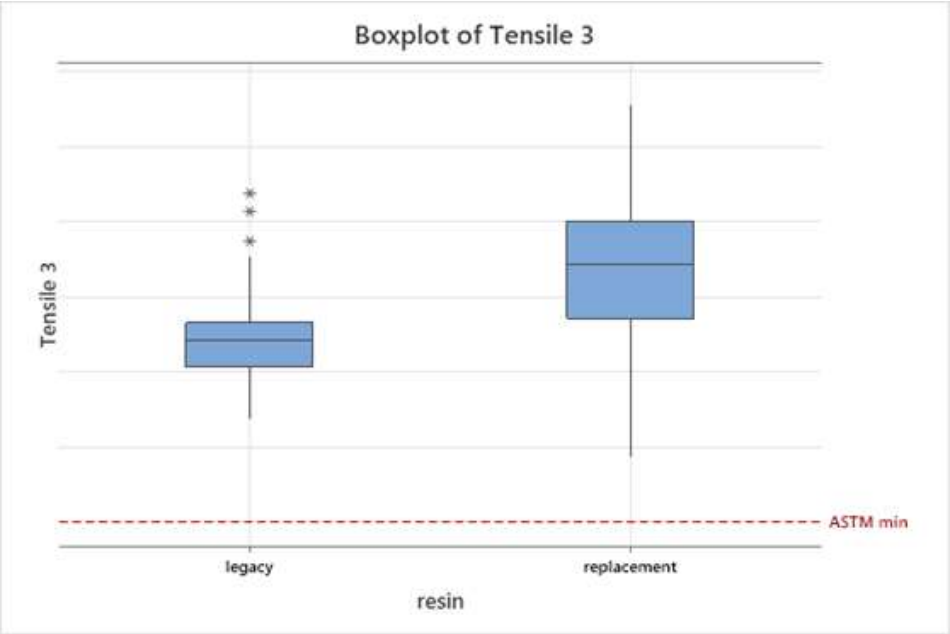
Property	Produced using 3M Grade	Produced using Alternate Grade
Split Test	PASS	PASS

Part 1 (ID 0.030”/Wall 0.002”) has similar tensile properties vs. the same part when run with legacy resin. Burst test was not performed on Part 1 due to size limitations.

Tensile charts from Part 2 (ID 0.097”/Wall 0.0015”) are shown below:

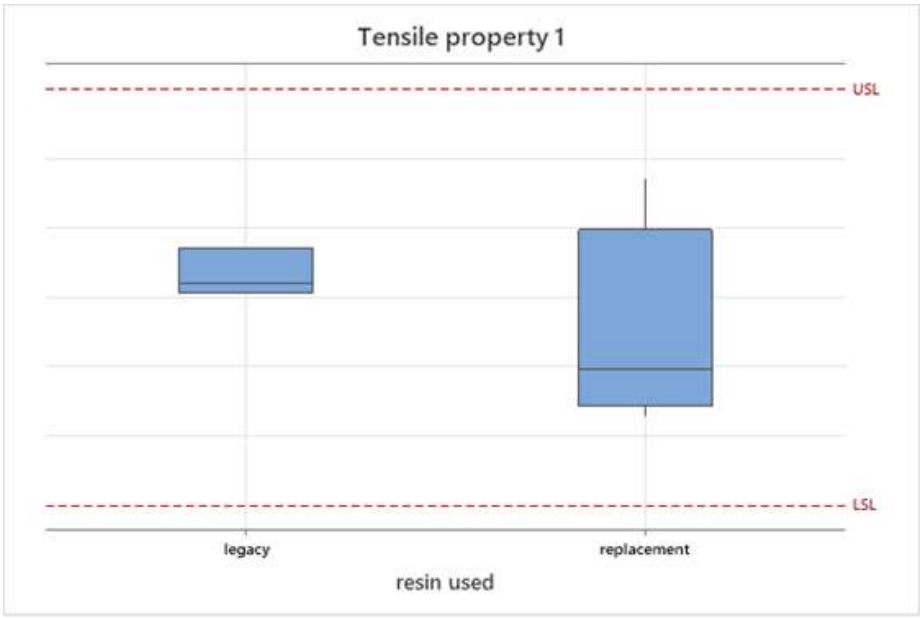


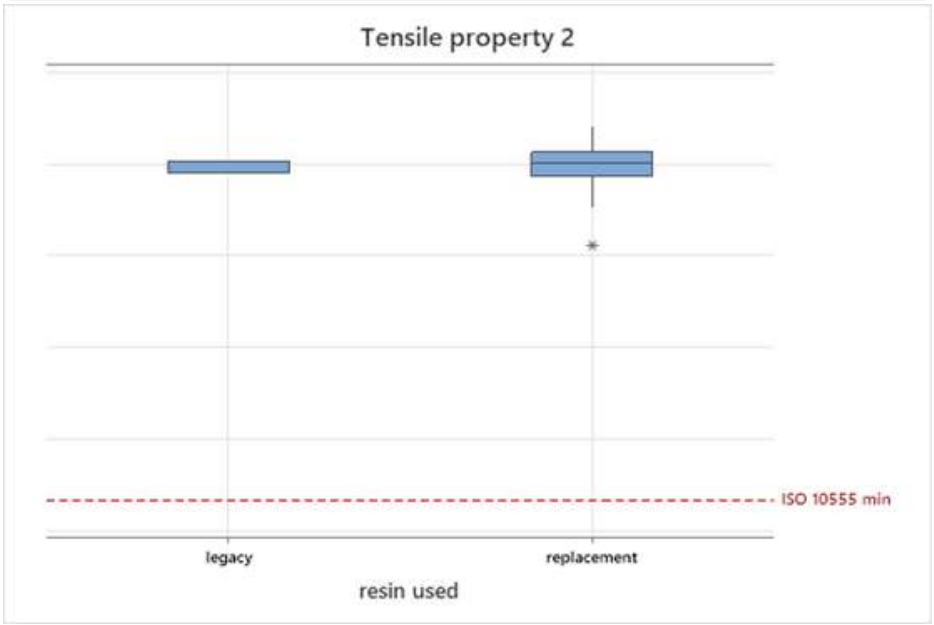


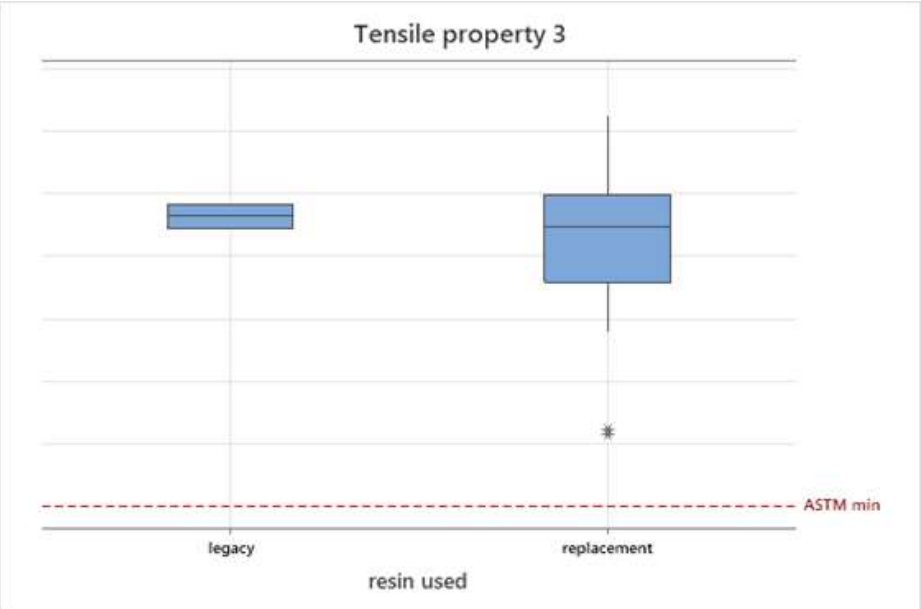


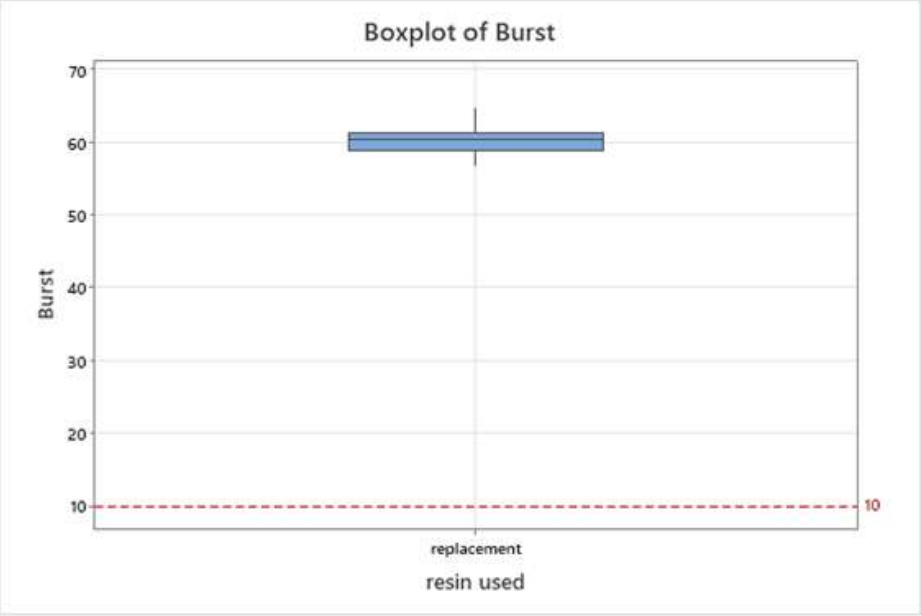
Part 2 (ID 0.097”/Wall 0.0015”) has similar tensile properties vs. the same part when run with the legacy resin. All burst values maxed out the text fixture at 99.9 PSI.

Tensile charts from Part 3 (ID 0.302”/Wall 0.0035”) are shown below:









Property	Produced using 3M Grade	Produced using Alternate Grade
Split Test	PASS	PASS

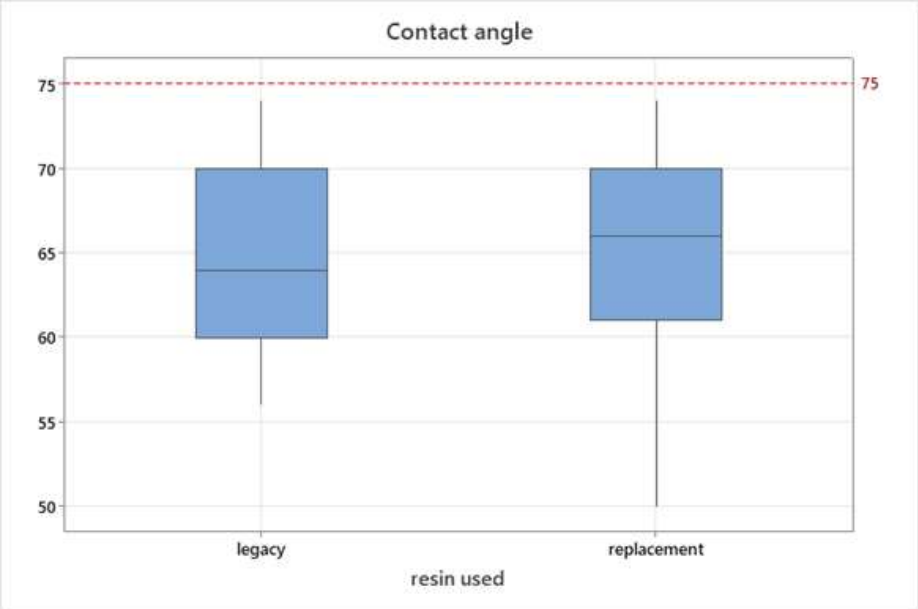
Part 3 (ID 0.302”/Wall 0.0035”) has similar tensile and burst properties vs. the same part when run with the legacy resin.

VII. Bondability:

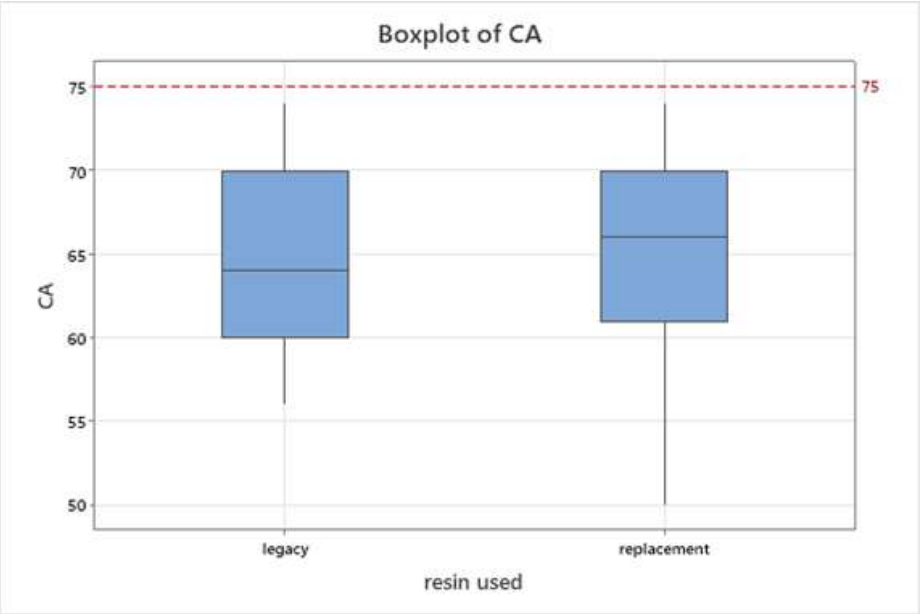
Etched PTFE liners are often used in applications that require adhesion between the liner and another material, such as nylon or poly(ether-block-amide). PTFE has a very low surface energy, which makes it difficult to adhere or bond to another material. The process of etching raises the surface energy to improve the bondability between the two materials. Contact angle is a method used to determine the surface energy of a material. Zeus has an internal specification set for contact angle that checks that the part has been etched. Contact angle is a standard release criterion for etched liners.

The contact angle results for three parts listed in table # 3 above are below:

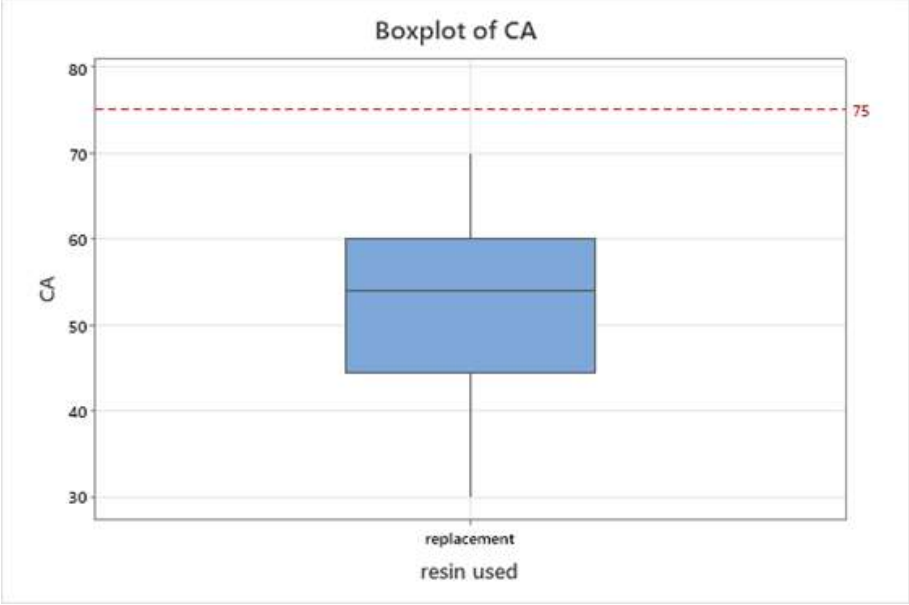
Part 1



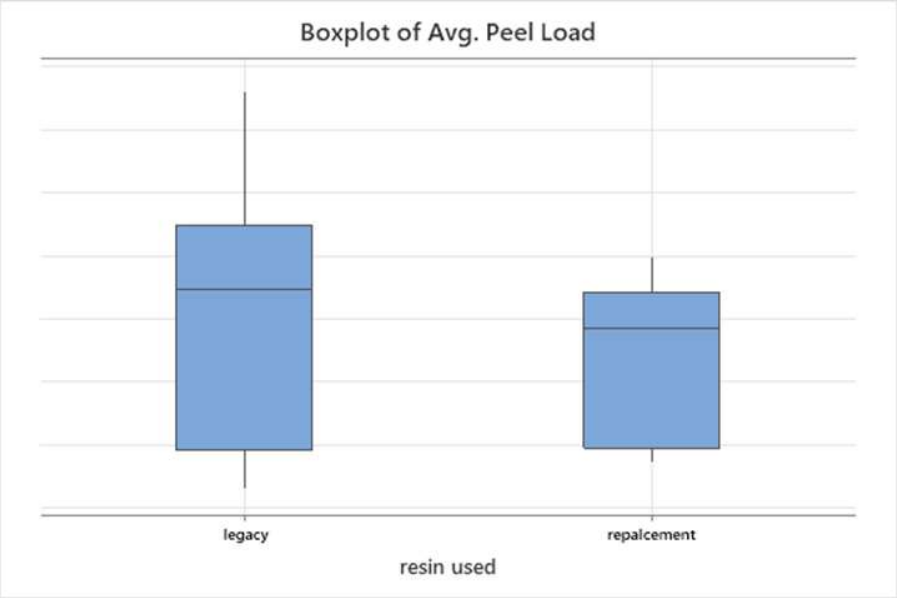
Part 2


Boxplot of CA
75
70
65
60
55
50
CA
75
legacy
replacement
resin used

Part 3


Boxplot of CA
80
70
60
50
40
30
CA
75
replacement
resin used

In addition to contact angle, Zeus measured the force required to separate Part 2 from a poly(ether-block-amide) jacket in a catheter. The process and materials used to construct the catheter were identical except for the fine powder PTFE used to produce the liner.



Testing demonstrated that replacement resins uphold existing contact angle requirements on all etched extrusions. The peel testing on Part 2 shows similar adhesion between the PTFE liner and the poly(ether-block-amide) outer jacket.

Conclusion:

The suitability of the replacement fine powder is evidenced by the FTIR, CAS number assignation, and identical classifications per the ASTM D4985 standard. To provide additional assurances that the change does not introduce biocompatibility risks, the replacement resin was assessed using methods outlined in USP Class VI, ISO 10993-4, and ISO 10993-5. The passing results support the conclusion that the replacement resin is unlikely to change the biocompatibility of Zeus' Sub-Lite-Wall tubing. Finally, the DSC, bondability, and mechanical property data indicate that the sub-lite-wall tubing made with the replacement resin meets all applicable chemical and dimensional product requirements for SLW tubing. Zeus will continue to evaluate alternative resins and may use these resins when deemed appropriate, subject to applicable change control or notification requirements.

PTFE Tubing and Value Add:
3M PTFE Fine Powder and Replacement PTFE Fine Powder Comparison Data

Background:

Zeus' supply chain is impacted by the recent announcement of 3M™ related to their exit from the fluorochemical business, which includes PTFE fine powders ("resin").

Purpose:

The purpose of this document is to describe Zeus' efforts to understand, investigate and replace impacted 3M raw materials with replacement raw materials. These evaluations of the material formulation, biocompatibility and dimensional criteria are provided as documentation and evidence to assist Zeus' customers in evaluating the risk of change in their specific applications. Zeus will continue to evaluate alternative resins and may use these resins when deemed appropriate, subject to applicable change control or notification requirements.

Abstract:

The evaluation of a replacement PTFE fine powder compared to the existing 3M PTFE fine powder was completed. Both the fine powder and PTFE extruded tubing were assessed to identify any differences in properties or performance. The fine powder was compared based on the ASTM D4895 standard and CAS number assignation. The extruded tubing from the different resins were characterized to evaluate their composition via FTIR and biocompatibility via selected test methods outlined in USP Class VI, and ISO-10993-4 and -5 documents, thermal properties, and physical dimensions. This evaluation concludes that products manufactured using the replacement fine powder conform with all applicable chemical and dimensional specifications.

Contents:

VIII. ASTM D4895 Classification of PTFE Fine Powder:

The ASTM D4895 standard classifies PTFE fine powders based on their properties and performance. A copy of the standard may be obtained from WWW.ASTM.ORG.

Fine powders are characterized by:

Type: based upon particle size
Grade: based upon specific gravity, thermal stability index and stretch void index
Class: based upon extrusion pressure

General comparison process:

ASTM D4895			
Current 3M Resin	ASTM Type	ASTM Grade	ASTM Class
XX	I	1	C
YY	I	1	C

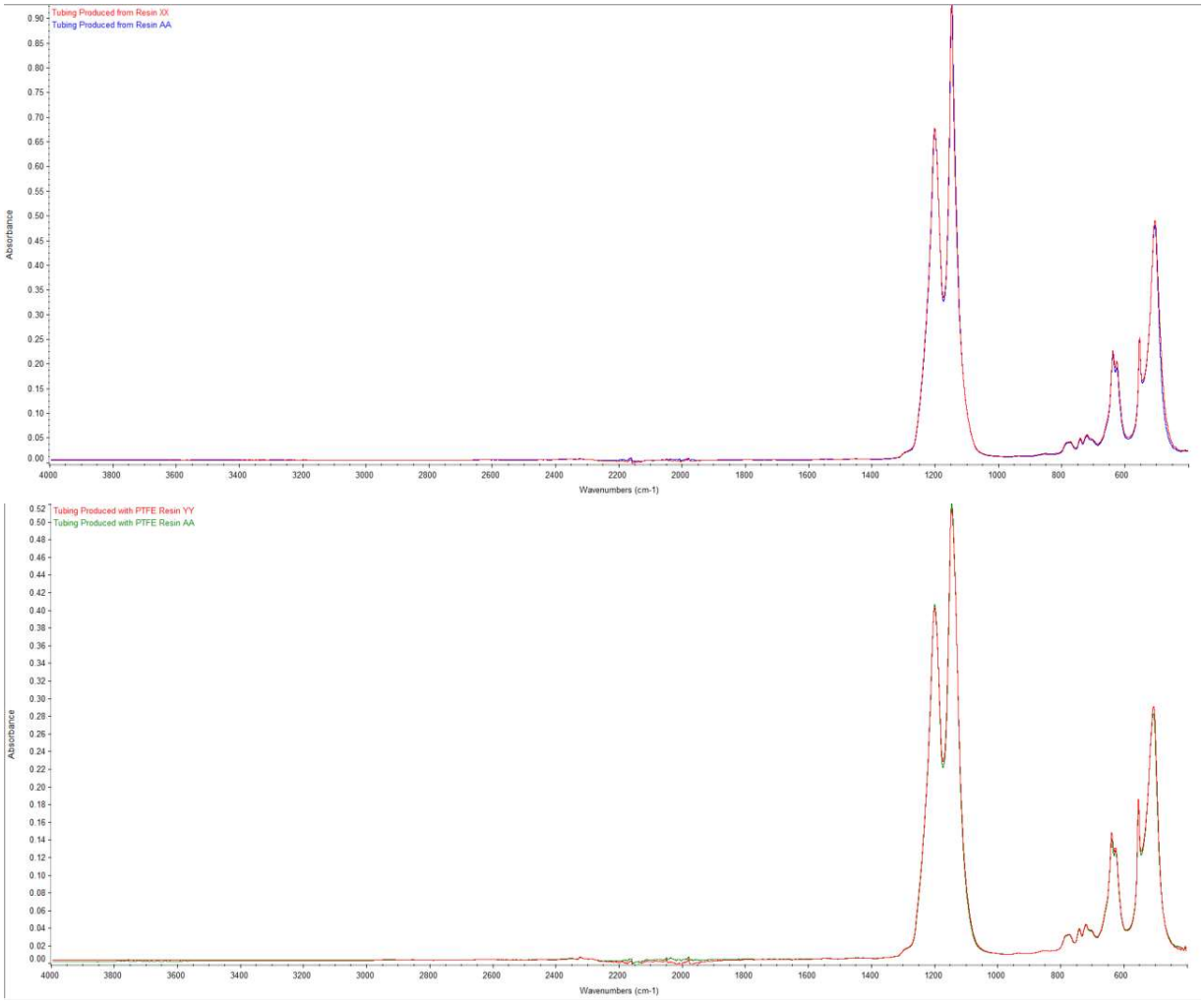
Replacement Fine Powder "Resin AA":

- Same ASTM Type
- Same ASTM Grade
- Same ASTM Class

IX. Chemical Composition:

Both the 3M resins and the replacement resin have been assigned the same chemical identifier for PTFE, which is CAS Registry number 9002-84-0.

PTFE tubing produced from 3M and replacement fine powders were analyzed using ATR-FTIR. Zeus recommends evaluating the spectral overlay of the tubes produced from replacement resin AA to tubes produced from 3M resins which is provided in the charts below.



The peaks present in the replacement resin overlay with the peaks from the other PTFE resins and align with the functional group vibrations for PTFE. There are no additional peaks present, which would indicate differences in material composition or contamination.

The slight differences in peak intensity are inherent to the test method and not attributed to material composition differences. Additionally, small fluctuations along the baseline, particularly between 1900 and 2600 cm^{-1} wavenumbers, are attributed to the test method and instrument configuration; not the material being tested.

Based on this analysis, the conclusion from the ATR-FTIR testing is that both tubes produced from the replacement resin are indistinguishable from tubes produced from 3M resins.

X. Biocompatibility / Compliance:

The 3M fine powder and the replacement PTFE fine powder used by Zeus are USP Class VI/ISO 10993 tested by independent laboratories. The biocompatibility tests in the table below were selected to verify that the change in PTFE resin did not alter the biocompatibility of the part. The test reports are enclosed.

The table below demonstrates biocompatibility comparison of 3M vs. Replacement Fine Powder:

Compliance	Tests Completed	Existing 3M Resins	Replacement Resin
USP Class VI	Acute Systemic Toxicity (Systemic Injection)	Pass	Pass
	• Intracutaneous Test	Pass	Pass
	• Implantation Test (11 day Surgical)	Pass	Pass
ISO 10993-4	ASTM F756-17 (Direct and Indirect)	Pass	Pass
ISO 10993-5	Test on extracts (MEM Elution)	Pass	Pass

Table # 1: Biocompatibility Comparison

Manufacturing Process:

The replacement resin is subject to the same quality system controls and manufacturing process and controls as the existing 3M resin, which is detailed in Table # 2. The parts evaluated for this document are manufactured under these standard conditions.

Conditions	Replacement Resin vs Existing 3M Resins
Tooling	Same
Process	Same
Process Aids	Same
Equipment	Same
Control Plan	Same
Quality Procedure	Same
Quality Manual	Same
Supplier Controls	Same

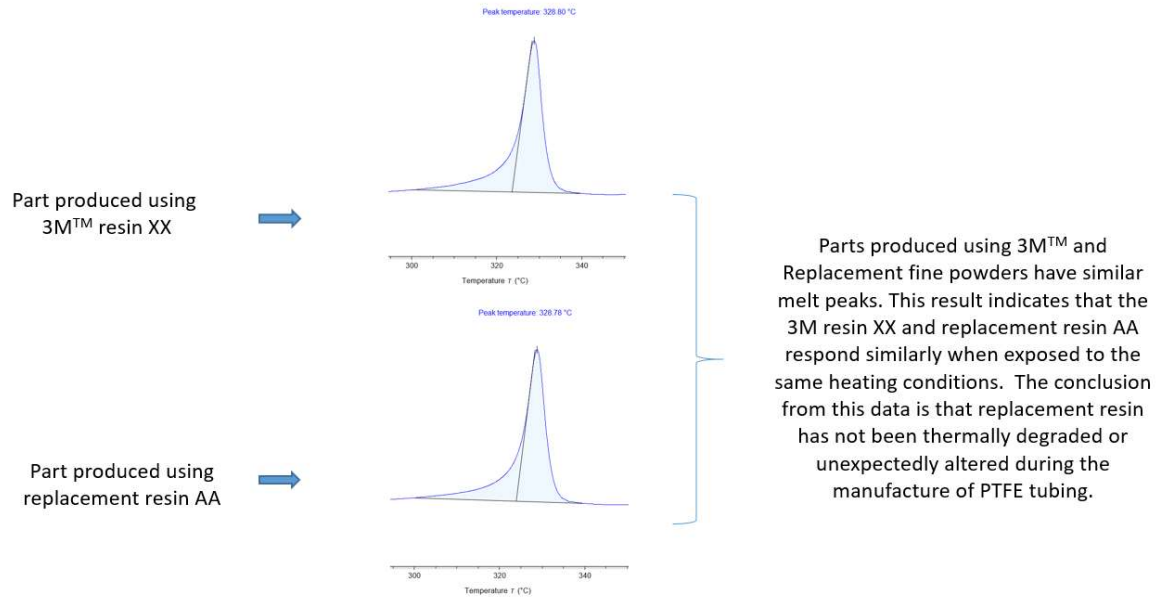
Table # 2: Quality System Controls & Manufacturing Controls Comparison for Existing 3M Resins and Replacement Resin

XI. Thermal Properties:

The thermal properties are the response of a material when heat is applied. In the manufacturing process of converting fine powder into extruded parts, such as liners, the material is exposed to heat. A comparison between the thermal responses of liners produced from the replacement resin versus the 3M resin will show if the replacement resin has a different response to standard processing conditions. For PTFE, the melting peak is the thermal response of interest because it changes as the resin is converted from a fine powder to an extruded part. When comparing the thermograms shown below, both depict a similarly shaped melting curve with peak values of 328.80°C and 328.78°C. This difference of 0.02°C is not significant in this type of test. The second set of thermograms shows a comparison of the flared section of the tubes made from each resin. The curves are similarly shaped with peak values of 327.61°C and 327.71°C. The additional value of this DSC is that it shows that even when exposed to additional processing steps, the replacement resin AA behaves the same as the 3M resins XX and YY. The conclusions from this data are that the thermal responses from parts made with 3M resins are the same as parts made from the replacement resin, and the replacement resin has not been thermally degraded or unexpectedly altered during the extrusion and secondary processes..

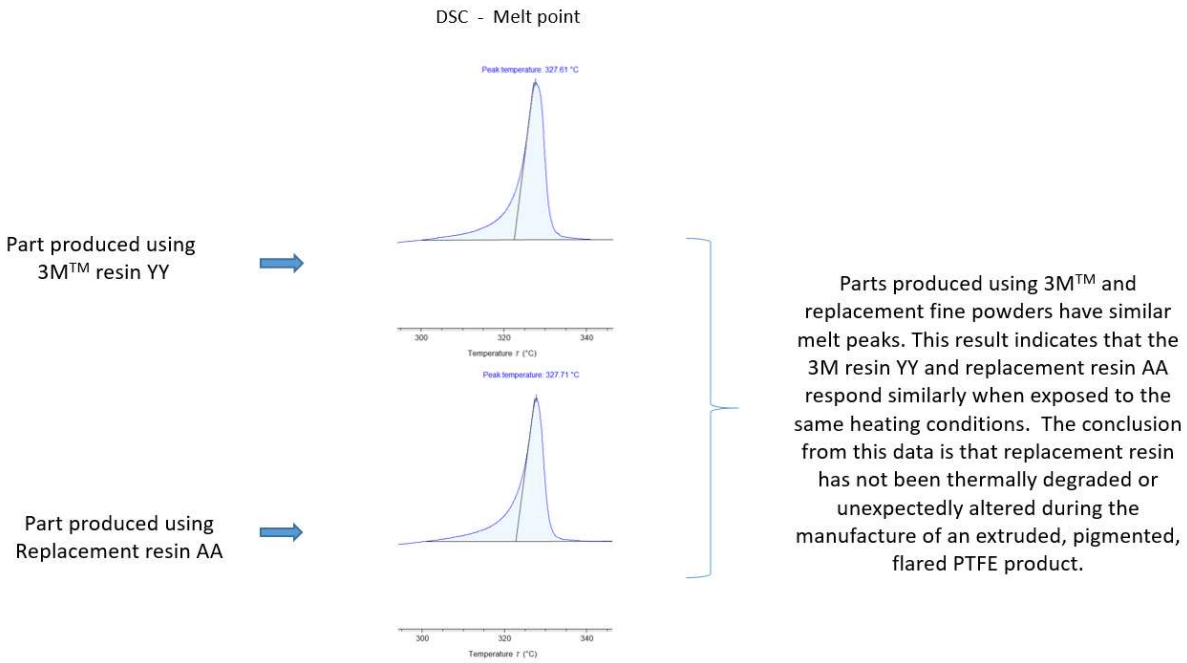
Part information:

AWG 9 Thin Wall
Inner Diameter: 0.118”
Wall Thickness: 0.015”



Part information:

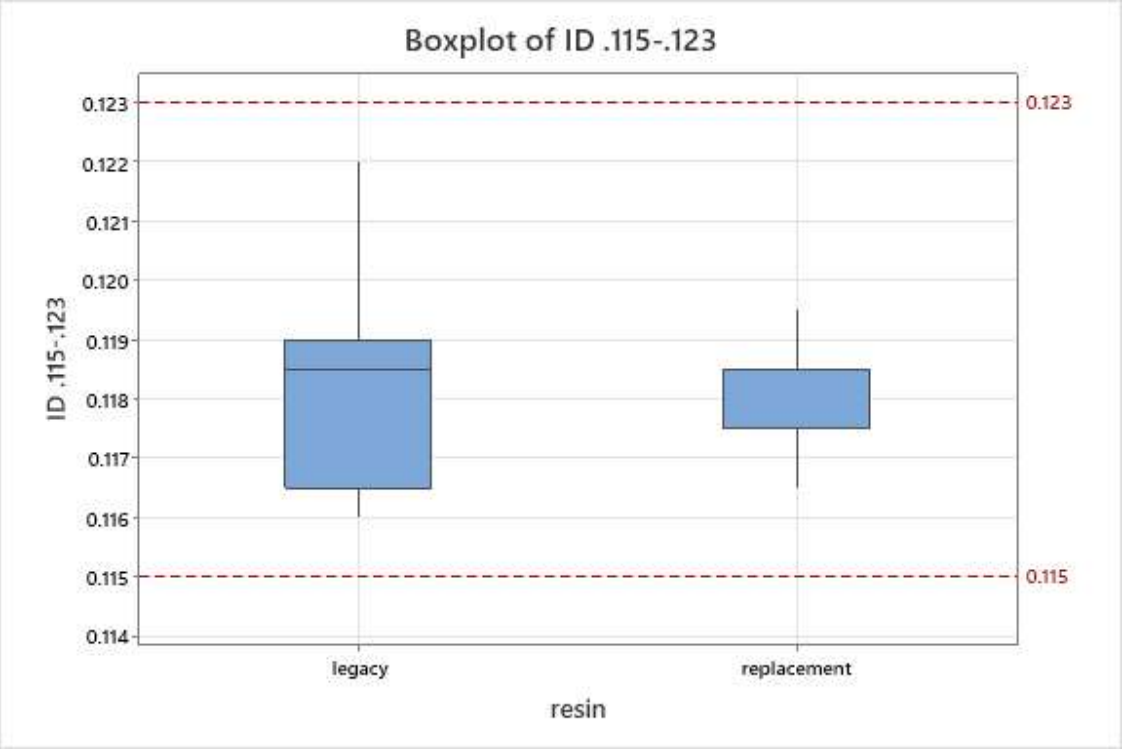
Blue Pigmented, Flared PTFE Tube
Inner Diameter: 0.028” (nominal)
Outer Diameter: 0.048” (nominal)
Flare: 0.077” with a 45° angle

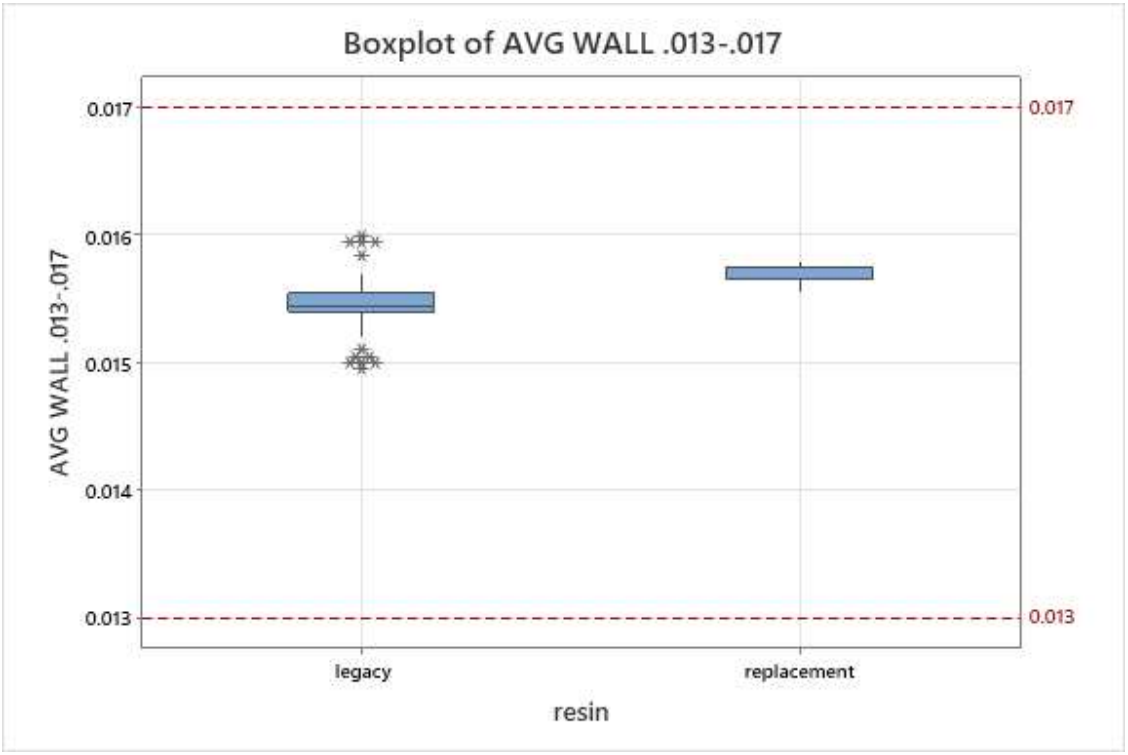


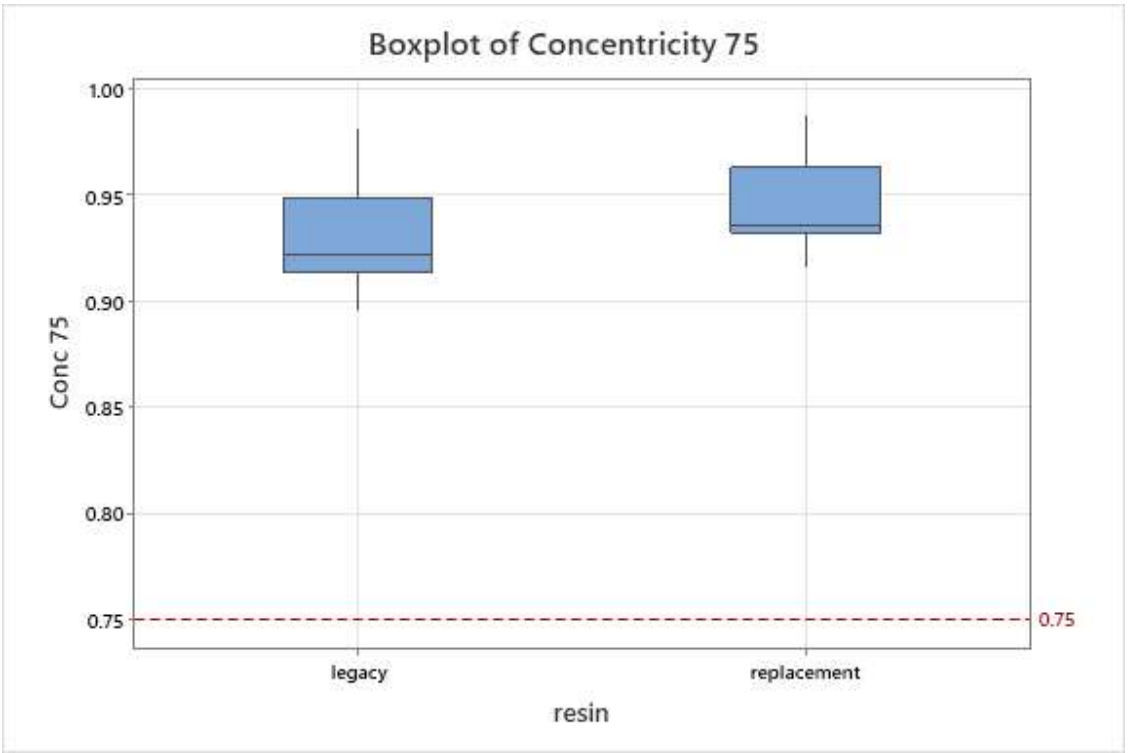
XII. Physical Dimensions of Tubing:

Physical dimensions are measurements that define the part geometry. Parts were selected to represent the product portfolio for PTFE Extruded Tubing and Value Add. The nominal dimensions of these parts are shown in the table below. Finished part dimensions meet the same specifications as parts produced from 3M fine powders.

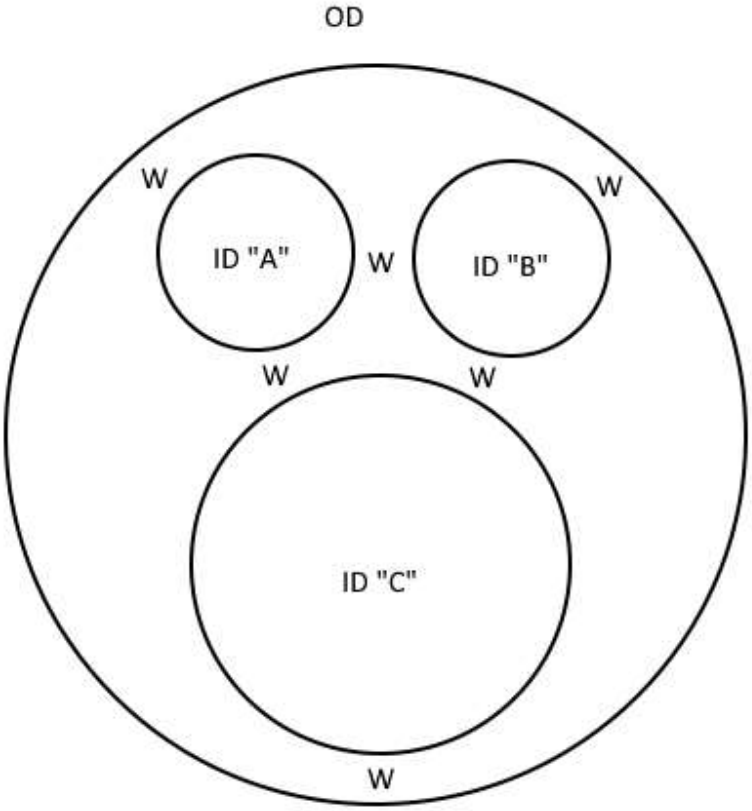
Part	Description	ID (Inches)	Wall (Inches)
1	AWG 9 Thin Wall	0.118”	0.015”

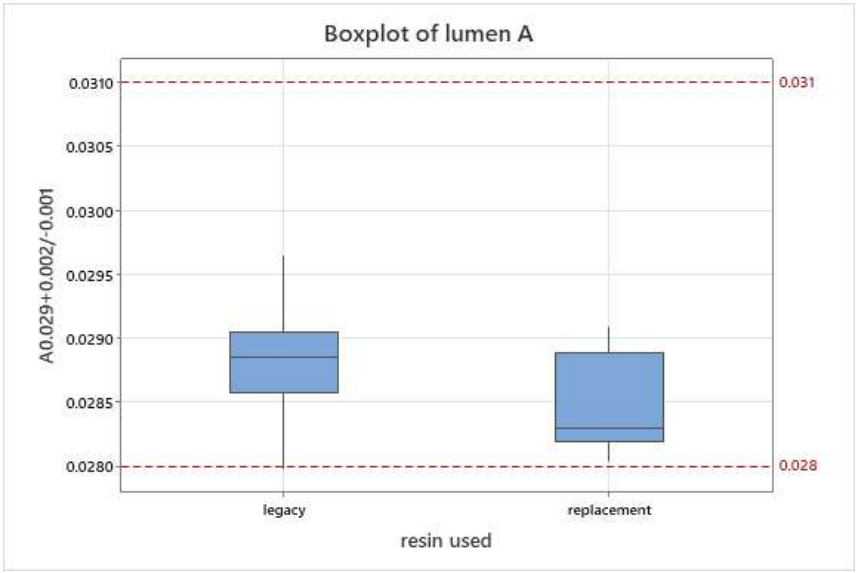


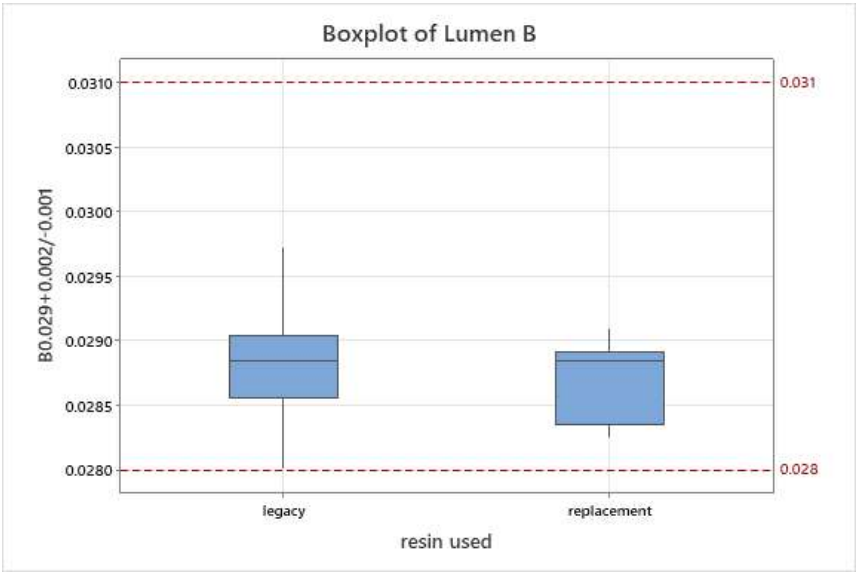


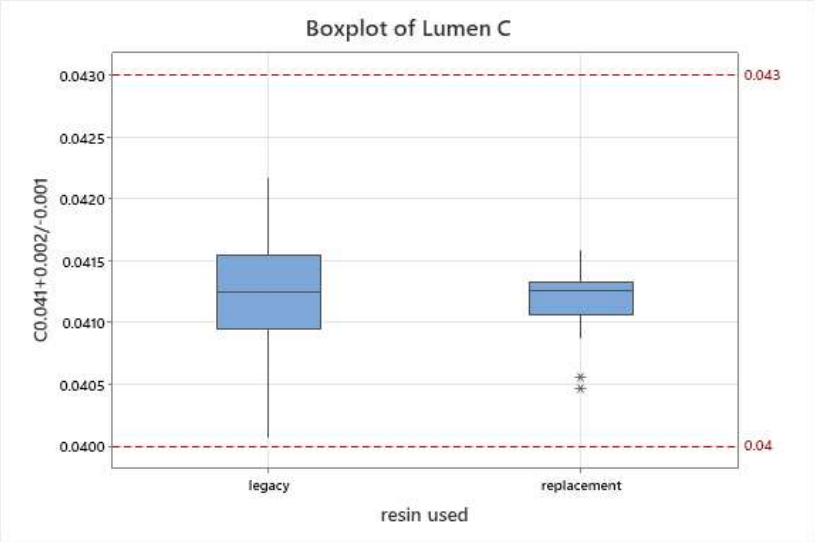


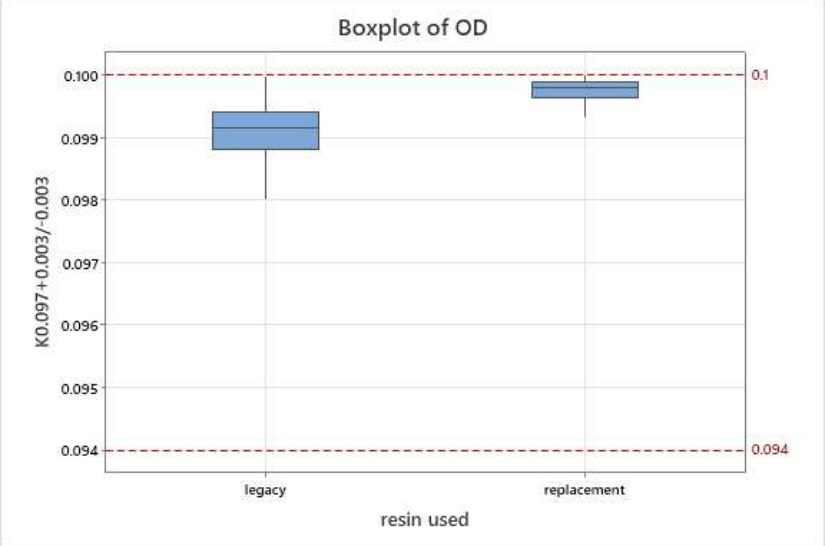
Part	Description	OD (Inches)	Lumen A (Inches)	Lumen B (Inches)	Lumen C (Inches)	Minimum Wall (Inches)
2	Multi-lumen	0.097+/-.003	0.029+.002/-.001	.029+.002/-.001	.041+.002/-.001	0.004 min

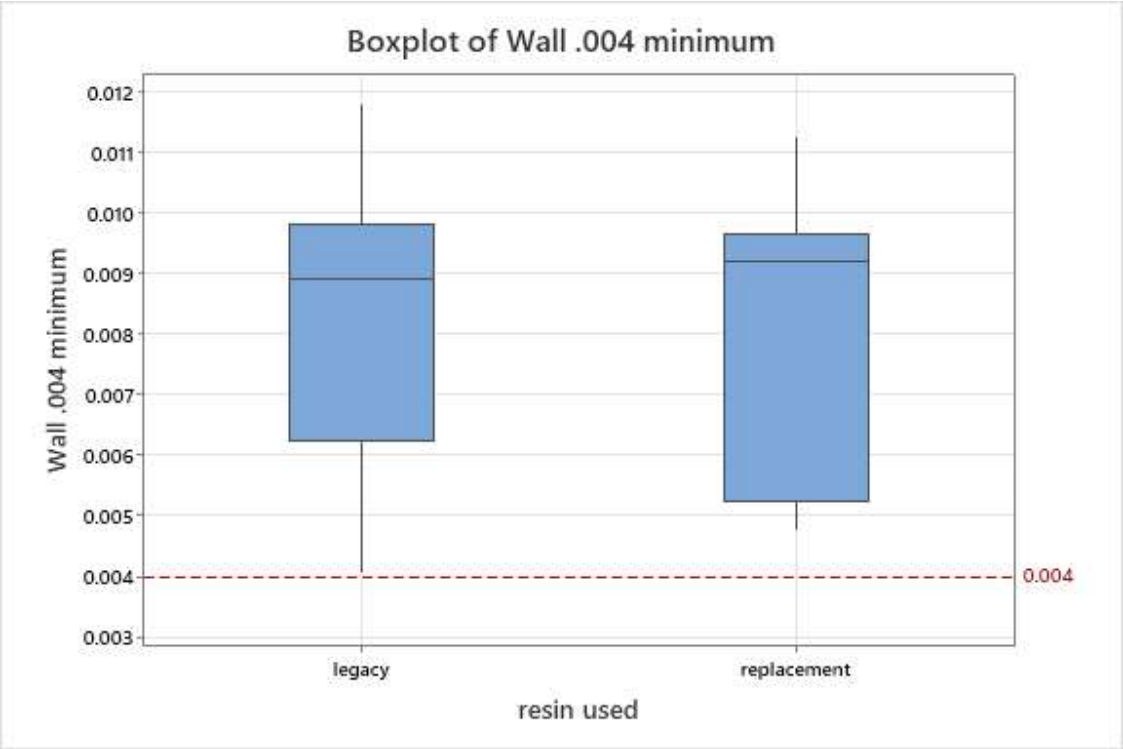








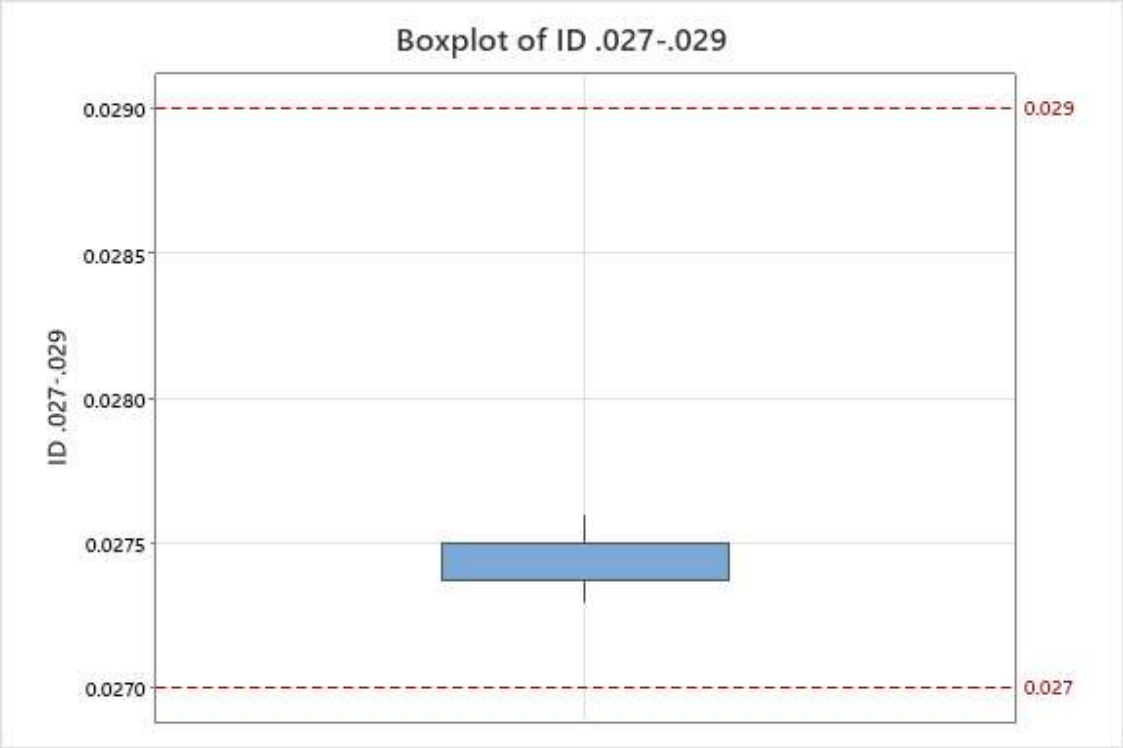


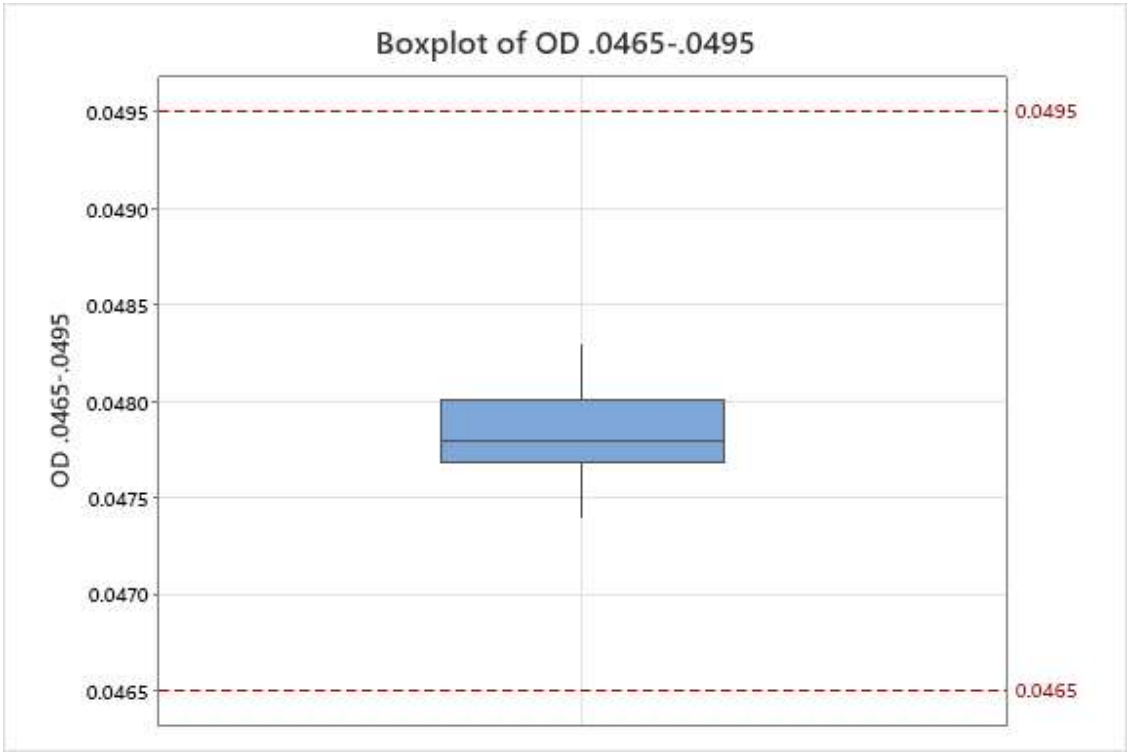


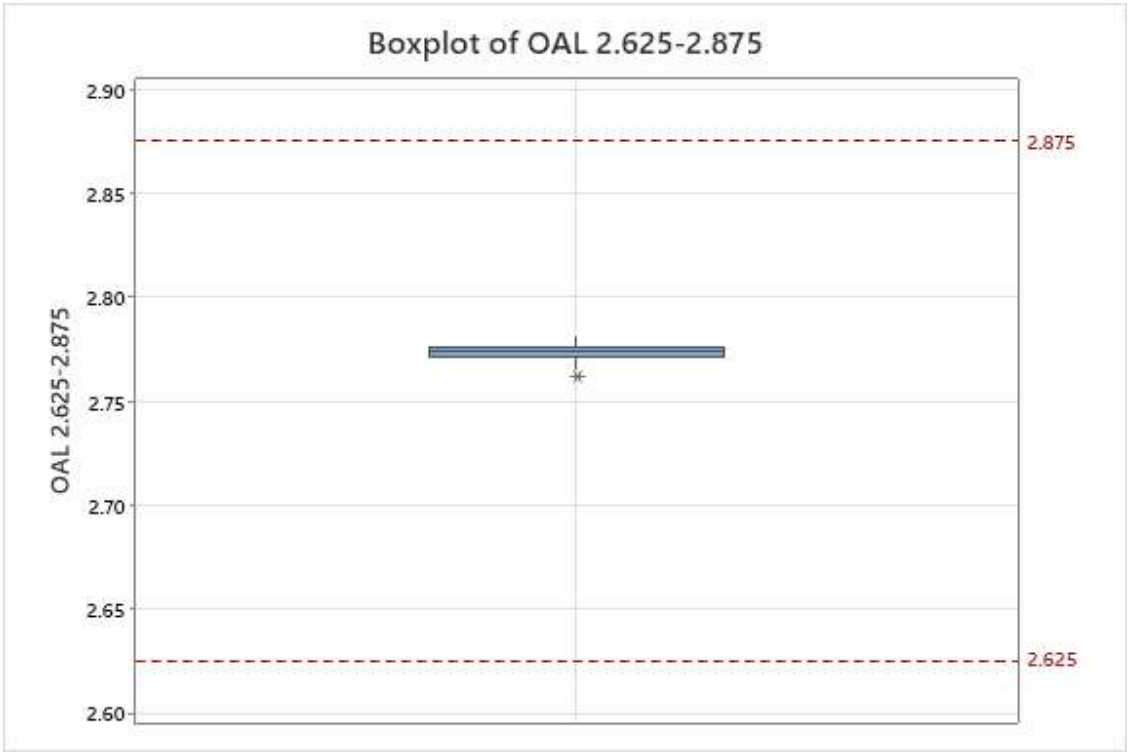
For this multi-lumen part, the ODs are extruded towards the upper specification limit and IDs towards the lower specification limit to maximize wall thickness at customer request. IDs are accepted on an attribute pass/fail basis.

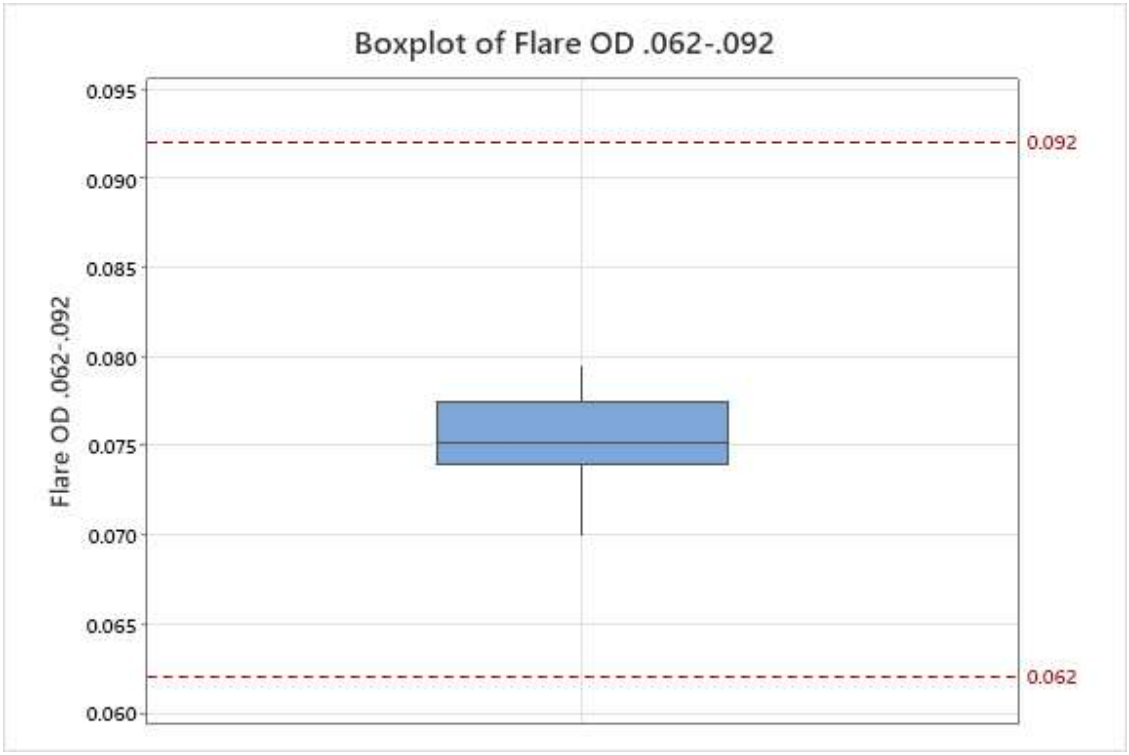
Part	Description	ID (Inches)	OD (Inches)	Flare OD (Inches)	Overall Length (degrees)
3	Flare	0.028”	0.048”	0.077”	2.625-2.875

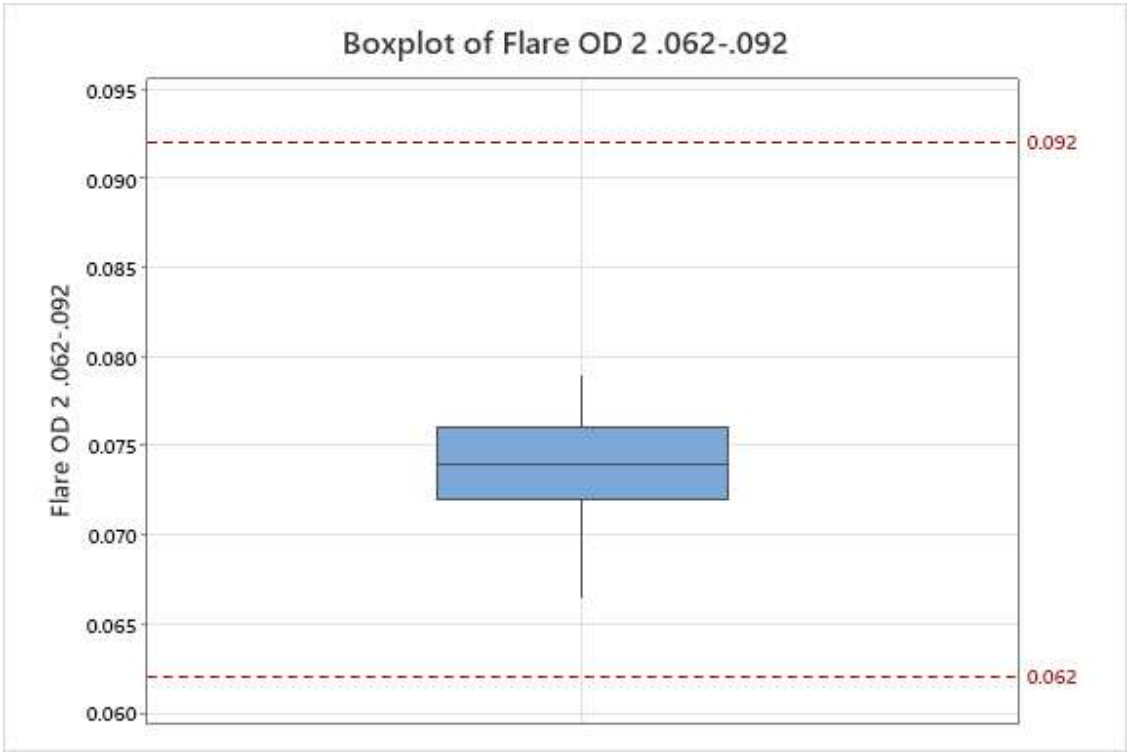
For this part, only replacement resin data was taken. Parts run with the legacy resin are accepted and reported on an attribute basis.



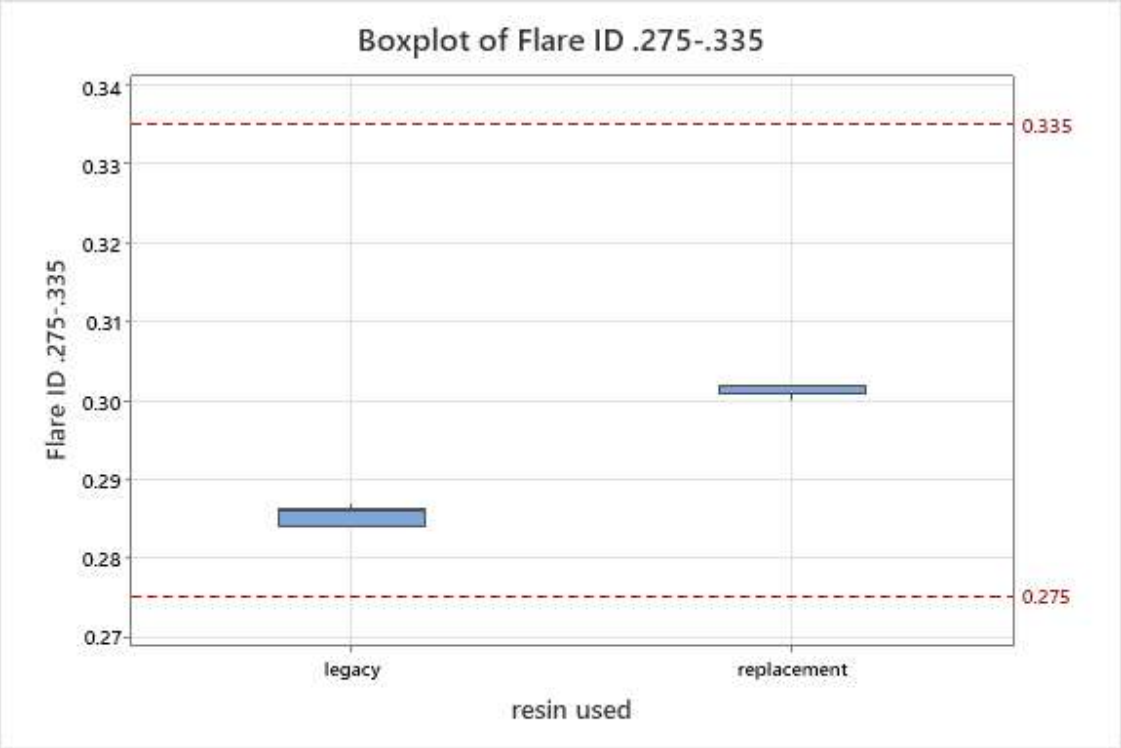


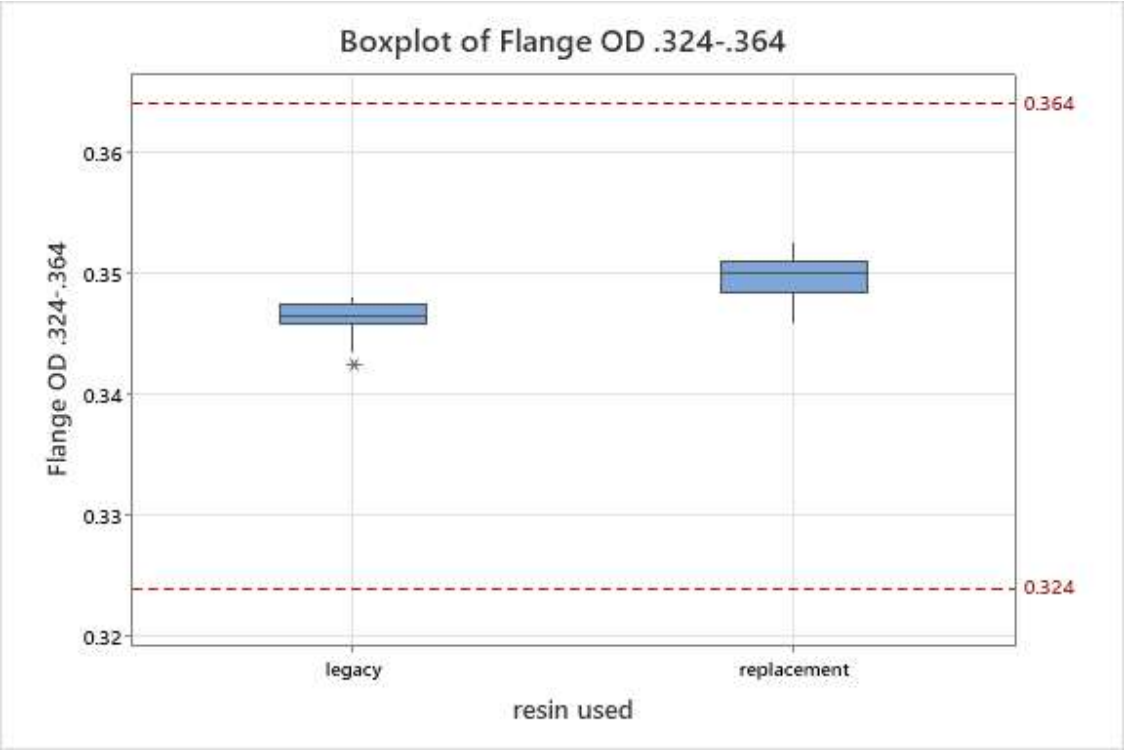


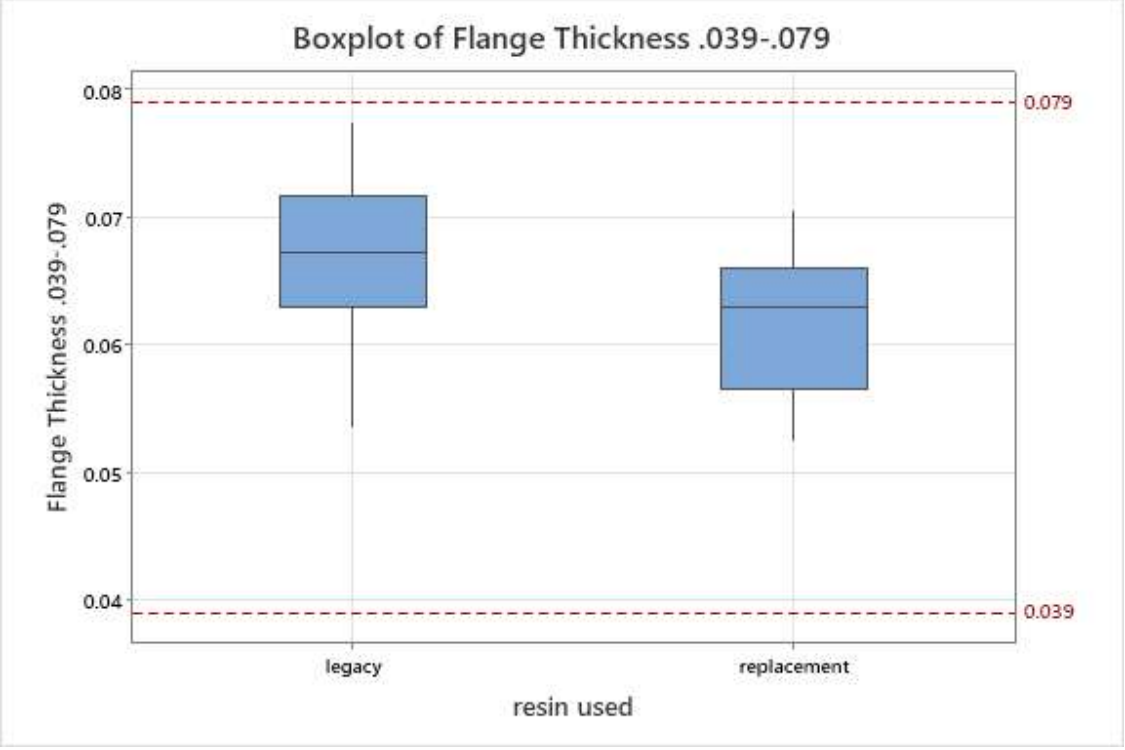

Boxplot of Flare OD .062-.092
Flare OD .062-.092
0.095
0.090
0.085
0.080
0.075
0.070
0.065
0.060
0.092
0.062

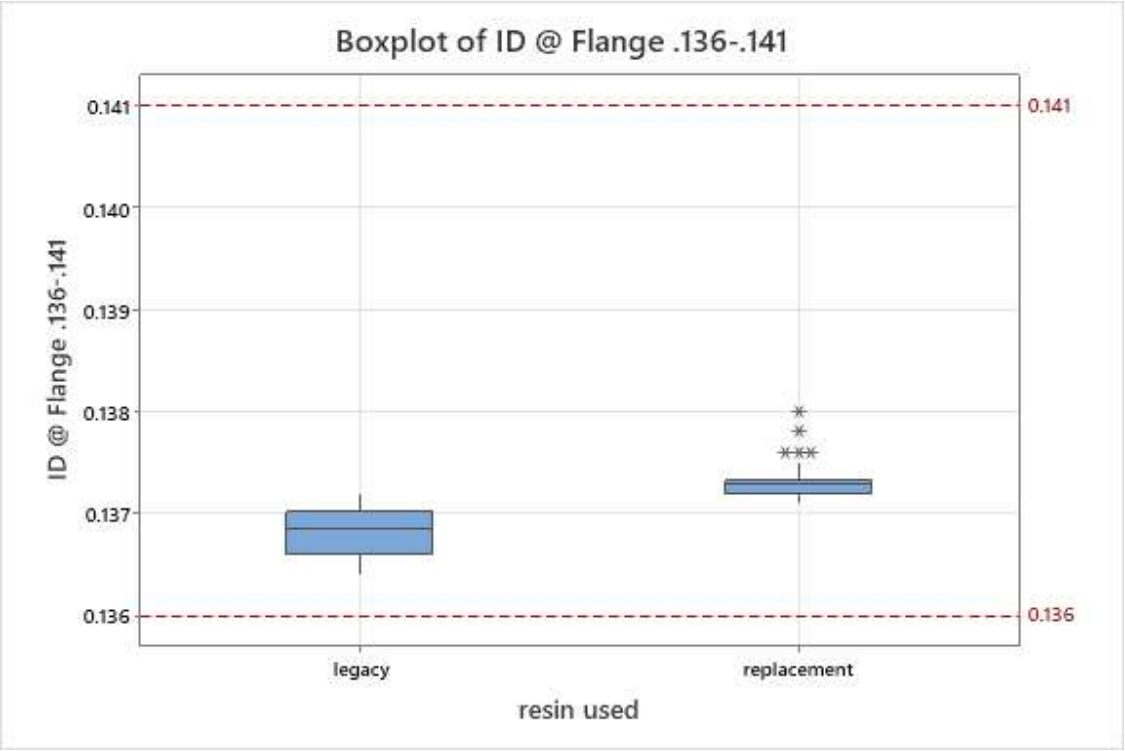

Boxplot of Flare OD 2 .062-.092
Flare OD 2 .062-.092
0.095
0.090
0.085
0.080
0.075
0.070
0.065
0.060
0.092
0.062

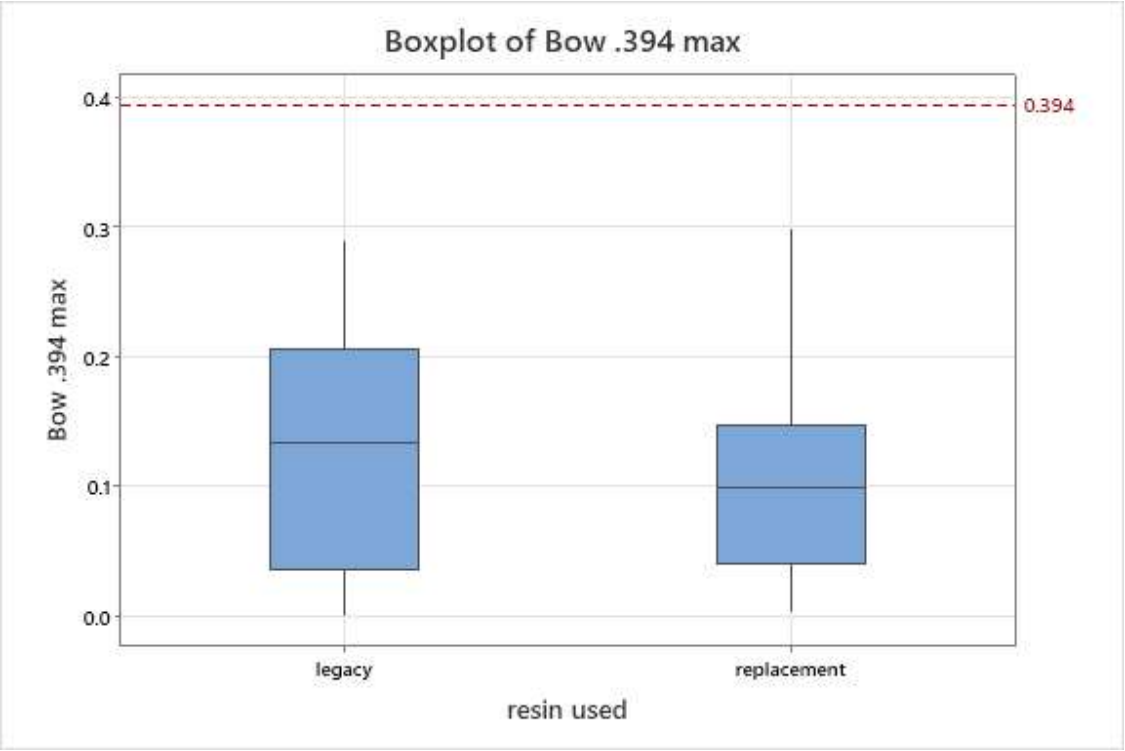
Part	Description	ID (Inches)	OD (Inches)	Flare ID (Inches)	Flange OD (Inches)	Flange Thickness (Inches)	Max Bow (Inches)	Overall Length (Inches)
4	Flare/ Flange	0.138”	0.197”	0.305”	0.344”	0.059”	0.394”	6.915”-7.415”

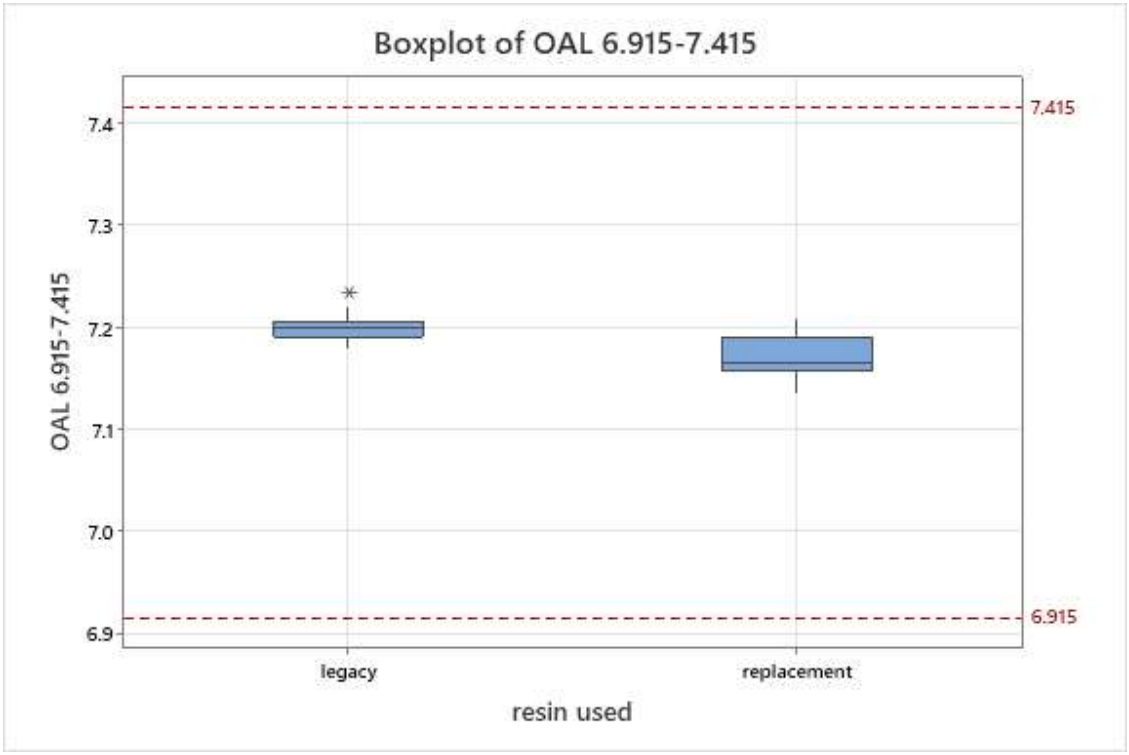


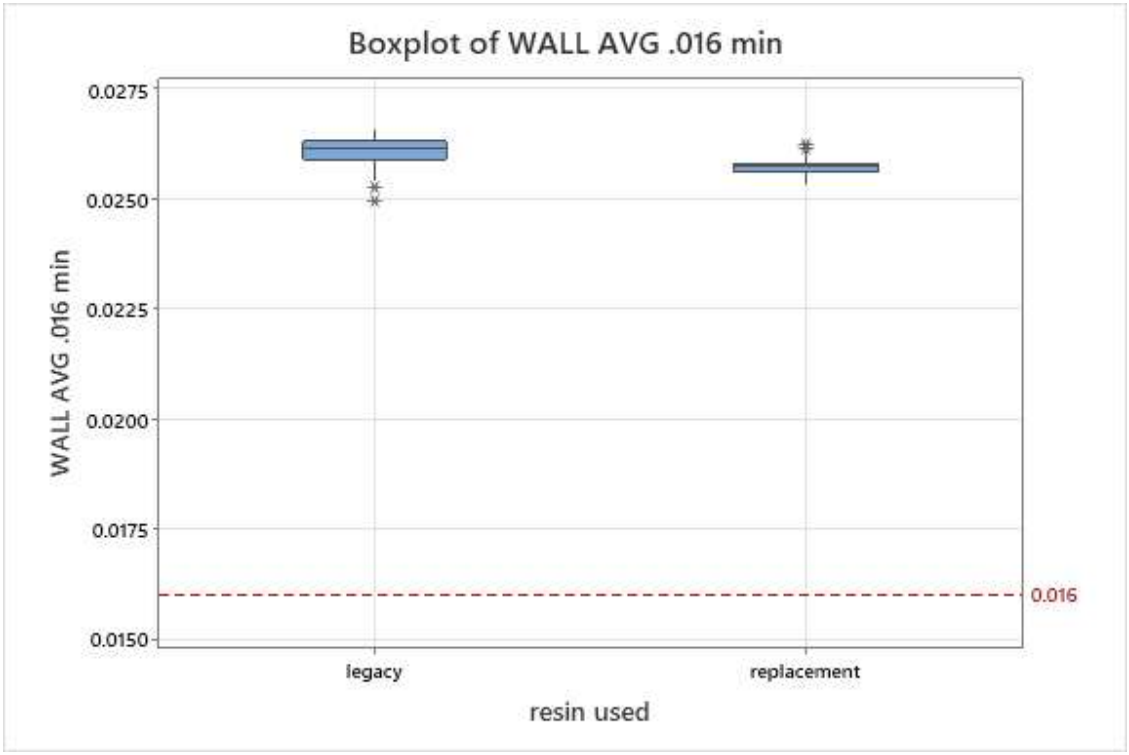




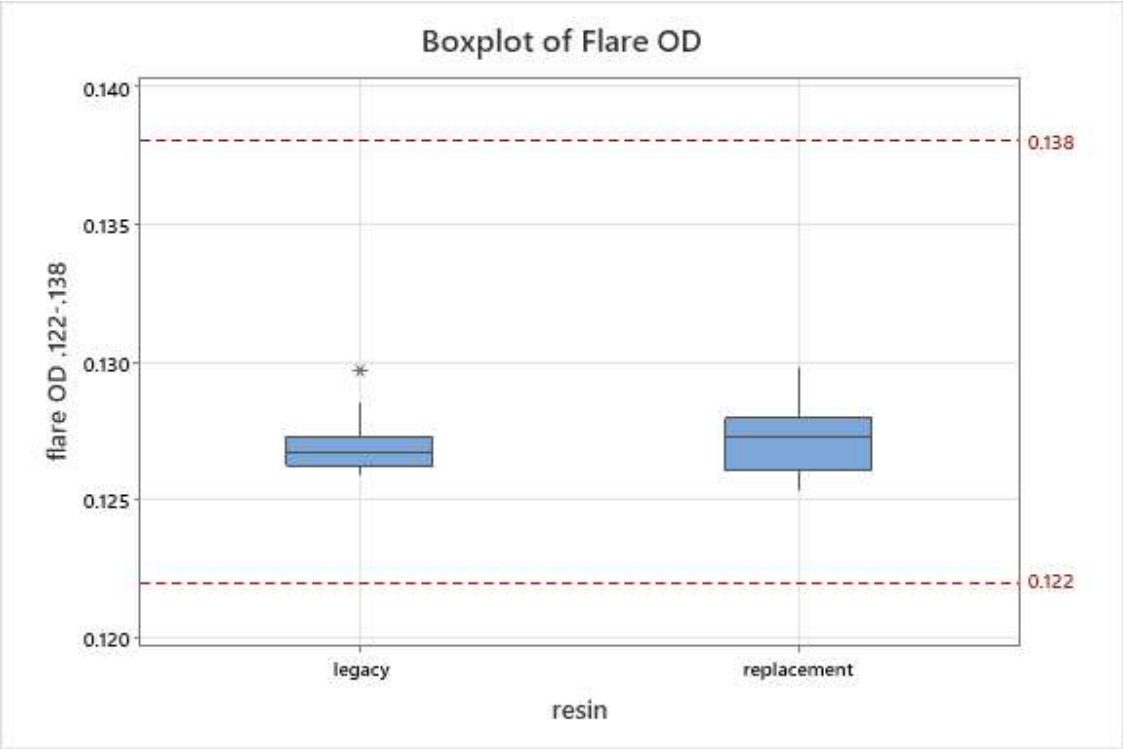


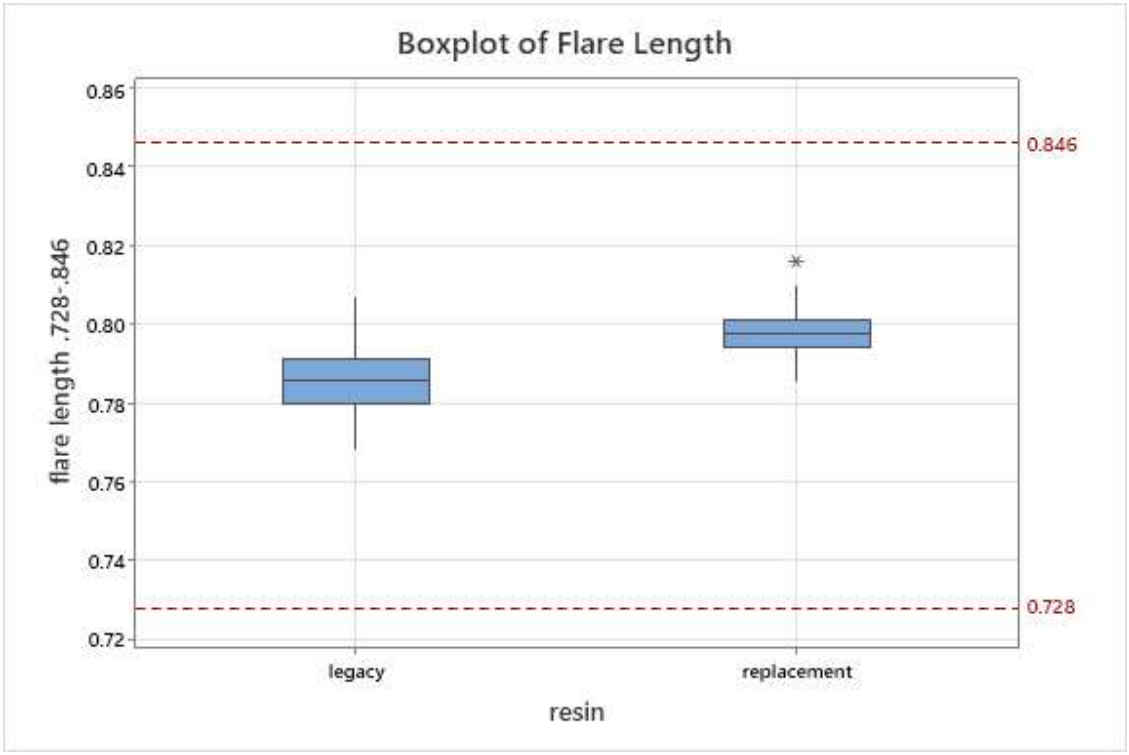


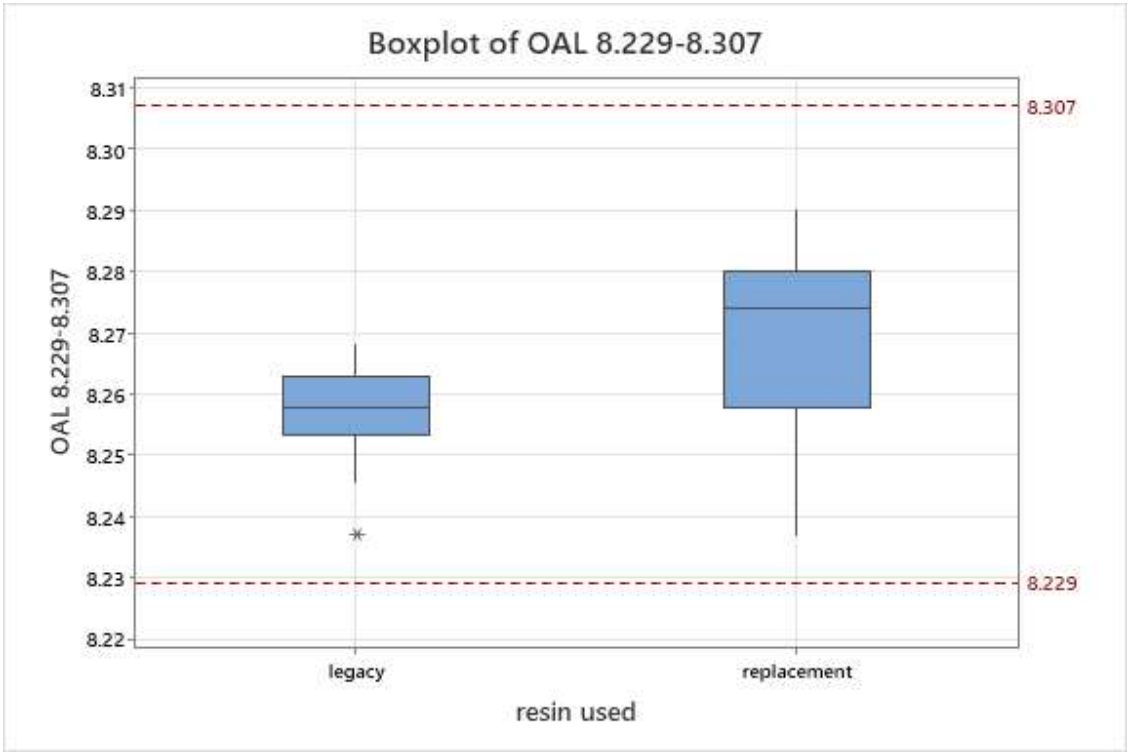


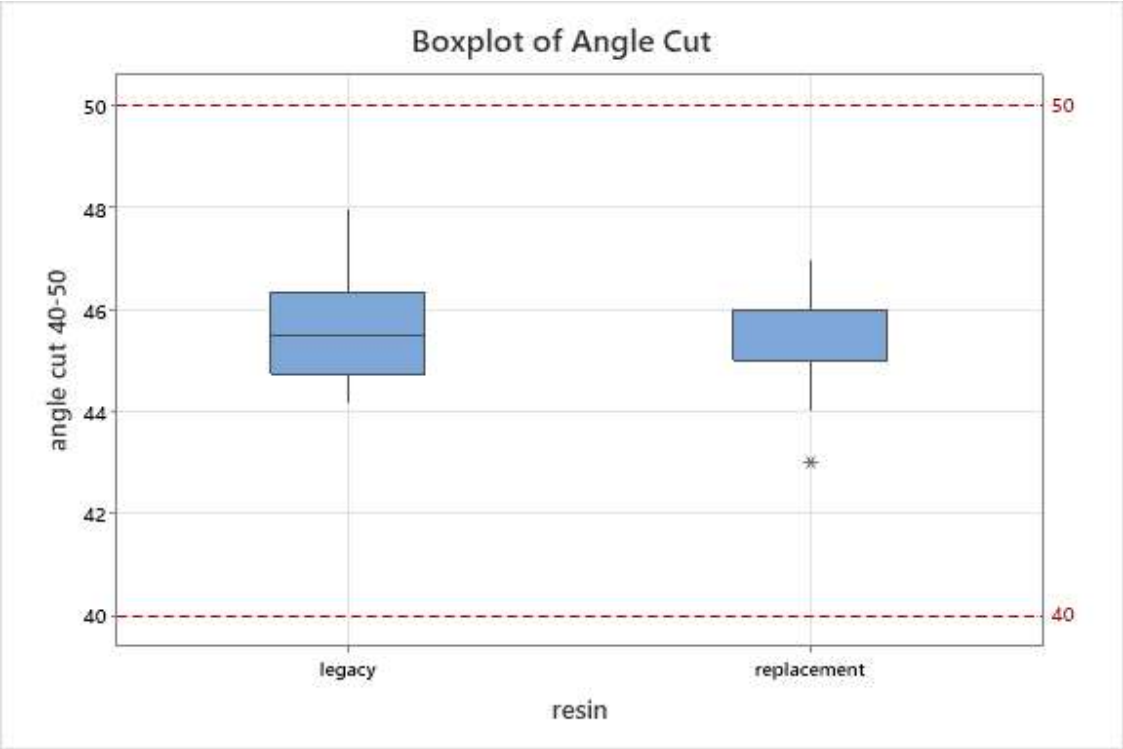


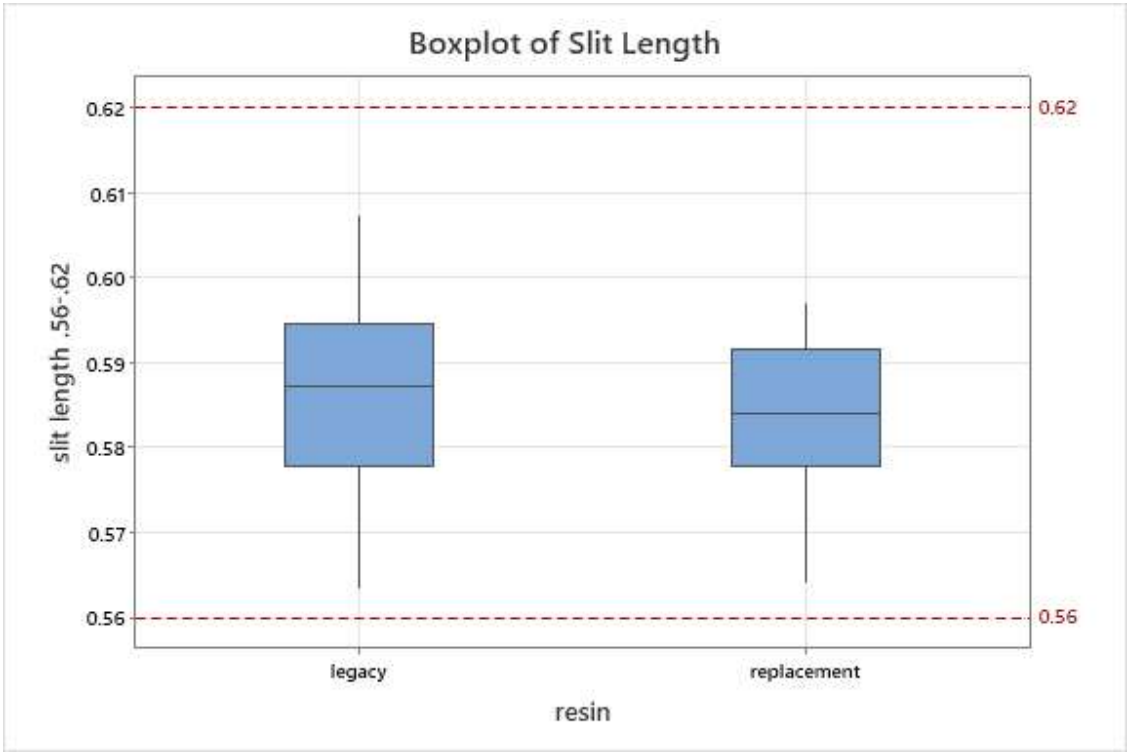
Part	Description	Flare ID (Inches)	Flare OD (Inches)	Flare Length (Inches)	Overall Length (Inches)
5	Flare	0.081+.001/-.002”	0.130+/-.008”	0.787”	8.229-.8.307

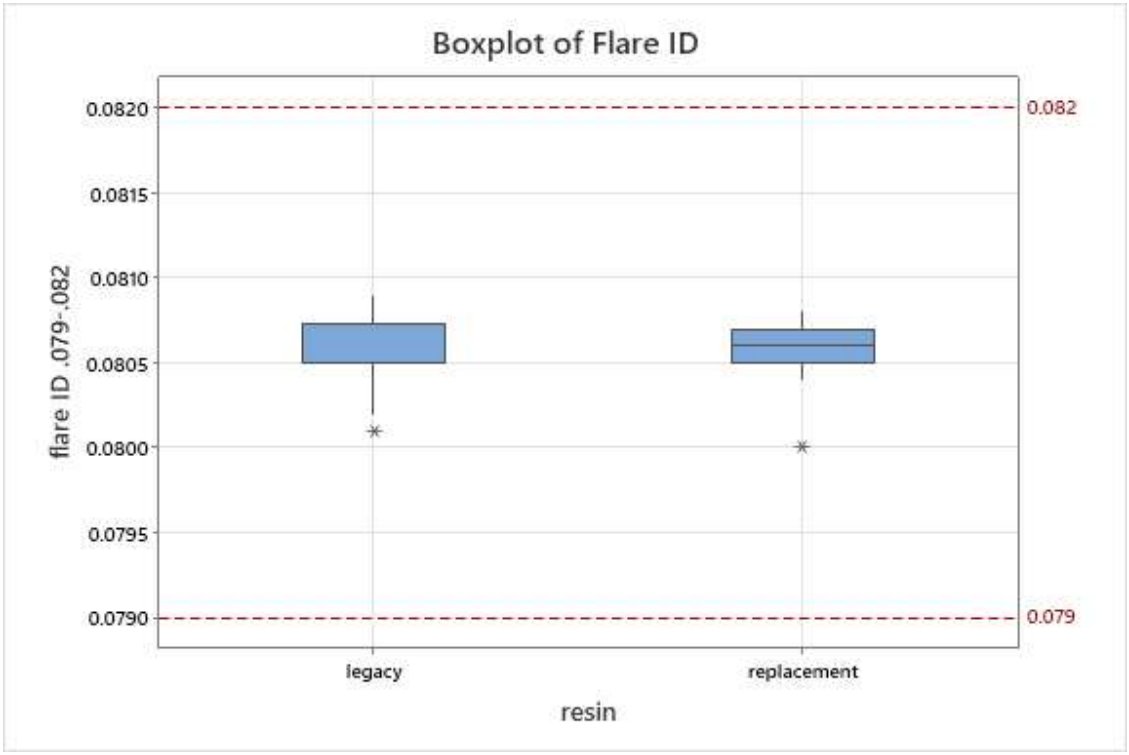












Conclusion:

The suitability of the replacement fine powder is evidenced by the FTIR, CAS number assignation, and identical classifications per the ASTM D4985 standard. To provide additional assurances that the change does not introduce biocompatibility risks, the replacement resin was assessed in methods outlined in USP Class VI and ISO 10993-4 and -5. The passing results support the conclusion that the replacement resin is unlikely to change the biocompatibility of Zeus' tubing. Finally, the DSC and dimensional data indicate that the tubing made with the replacement resin meets all applicable product requirements. Zeus will continue to evaluate alternative resins and may use these resins when deemed appropriate, subject to applicable change control or notification requirements.

PTFE Heat Shrink and Dual-Shrink™:
3M PTFE Fine Powder and Replacement PTFE Fine Powder Comparison Data

Background:

Zeus' supply chain is impacted by the recent announcement of 3M™ related to their exit from the fluorochemical business, which includes PTFE fine powders ("resin").

Purpose:

The purpose of this document is to describe Zeus' efforts to understand, investigate and replace impacted 3M raw materials with replacement raw materials. These evaluations of the material formulation, biocompatibility and dimensional criteria are provided as documentation and evidence to assist Zeus' customers in evaluating the risk of change in their specific applications. Zeus will continue to evaluate alternative resins and may use these resins when deemed appropriate, subject to applicable change control or notification requirements.

Abstract:

The evaluation of a replacement PTFE fine powder compared to the existing 3M PTFE fine powder was completed. The fine powder resins, PTFE Heat Shrink, and Dual-Shrink™ tubing were assessed to identify any differences in properties or performance. Dual-Shrink™ products contain two materials: PTFE and PFA or FEP. Only the PTFE component is affected by the 3M exit. The fine powder was compared based on the ASTM D4895 standard and CAS number assignation. The PTFE HeatShrink and the PTFE portion of the Dual-Shrink™ from the different resins were characterized to evaluate their composition via FTIR, biocompatibility via selected test methods outlined in USP Class VI, and ISO-10993-4 and -5 documents, thermal properties, and physical dimensions. This evaluation concludes that products manufactured using the replacement fine powder conform with all applicable chemical and dimensional specifications.

Contents:

XIII. ASTM D4895 Classification of PTFE Fine Powder:

The ASTM D4895 standard classifies PTFE fine powders based on their properties and performance. A copy of the standard may be obtained from WWW.ASTM.ORG.

Fine powders are characterized by:

Type: based upon particle size
Grade: based upon specific gravity, thermal stability index and stretch void index
Class: based upon extrusion pressure

General comparison process:

ASTM D4895			
Current 3M Resin	ASTM Type	ASTM Grade	ASTM Class
XX	I	1	C
YY	I	1	C

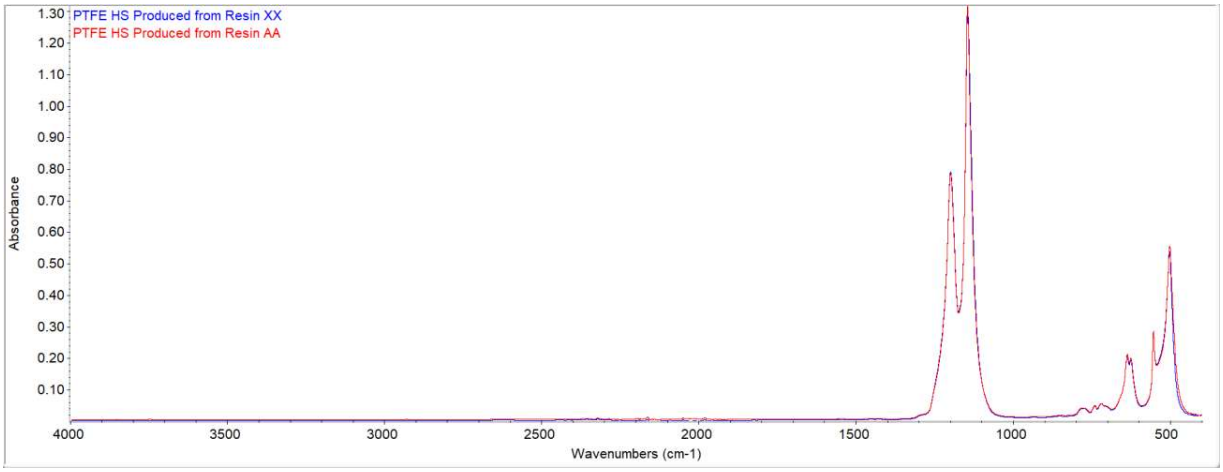
Replacement Fine Powder "Resin AA":

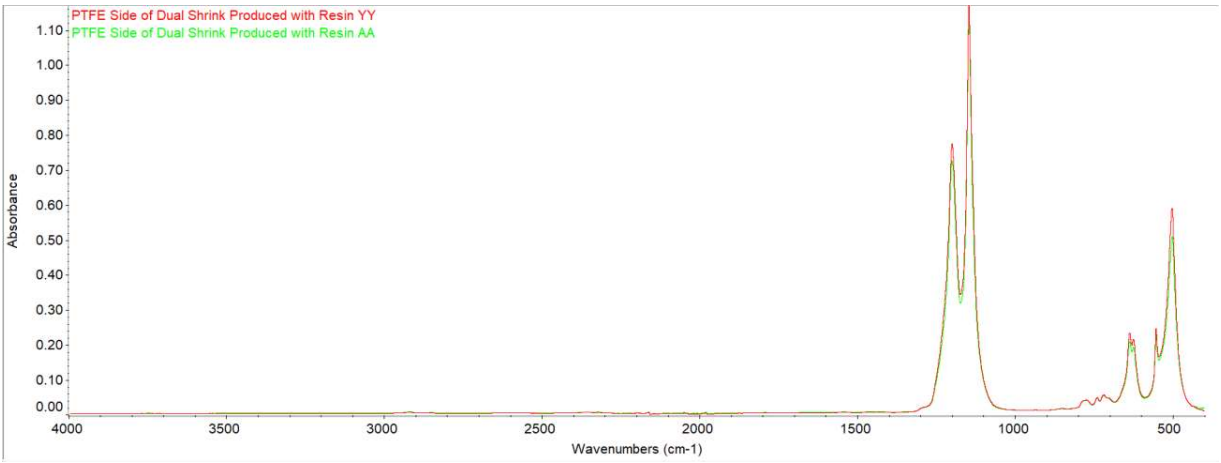
- Same ASTM Type
- Same ASTM Grade
- Same ASTM Class

XIV. Chemical Composition:

Both the 3M resins and the replacement resin have been assigned the same chemical identifier for PTFE, which is CAS Registry number 9002-84-0.

PTFE heat shrink and Dual-Shrink™ produced from 3M and replacement fine powders were analyzed using ATR-FTIR. Zeus recommends evaluating the spectral overlay of the heat shrink and Dual-Shrink™ produced from replacement resin AA to tubes produced from 3M resins which is provided in the charts below.





The peaks present in the replacement resin overlay with the peaks from the other PTFE resins and align with the functional group vibrations for PTFE. There are no additional peaks present, which would indicate differences in material composition or contamination.

The slight differences in peak intensity are inherent to the test method and not attributed to material composition differences. Additionally, small fluctuations along the baseline, particularly between 1900 and 2600 cm^{-1} wavenumbers, are attributed to the test method and instrument configuration; not the material being tested.

Based on this analysis, the conclusion from the ATR-FTIR testing is that tubes produced from the replacement resin are indistinguishable from tubes produced from 3M resins.

XV. Biocompatibility / Compliance:

The 3M fine powder and the replacement PTFE fine powder used by Zeus are USP Class VI/ ISO 10993 tested by independent laboratories. The biocompatibility tests in the table below were selected to verify that the change in PTFE resin did not alter the biocompatibility of the part. The test reports are enclosed.

The table below demonstrates biocompatibility comparison of 3M vs. Replacement Fine Powder:

Compliance	Tests Completed	Existing 3M Resins	Replacement Resin
USP Class VI	Acute Systemic Toxicity (Systemic Injection)	Pass	Pass
	• Intracutaneous Test	Pass	Pass
	• Implantation Test (11 day Surgical)	Pass	Pass
ISO 10993-4	ASTM F756-17 (Direct and Indirect)	Pass	Pass
ISO 10993-5	Test on extracts (MEM Elution)	Pass	Pass

Table # 1: Biocompatibility Comparison

Manufacturing Process:

The replacement resin is subject to the same quality system controls and manufacturing process and controls as the existing 3M resin, which is detailed in Table # 2. The parts evaluated for this document are manufactured under these standard conditions.

Conditions	Replacement Resin vs Existing 3M Resins
Tooling	Same
Process	Same
Process Aids	Same
Equipment	Same
Control Plan	Same
Quality Procedure	Same
Quality Manual	Same
Supplier Controls	Same

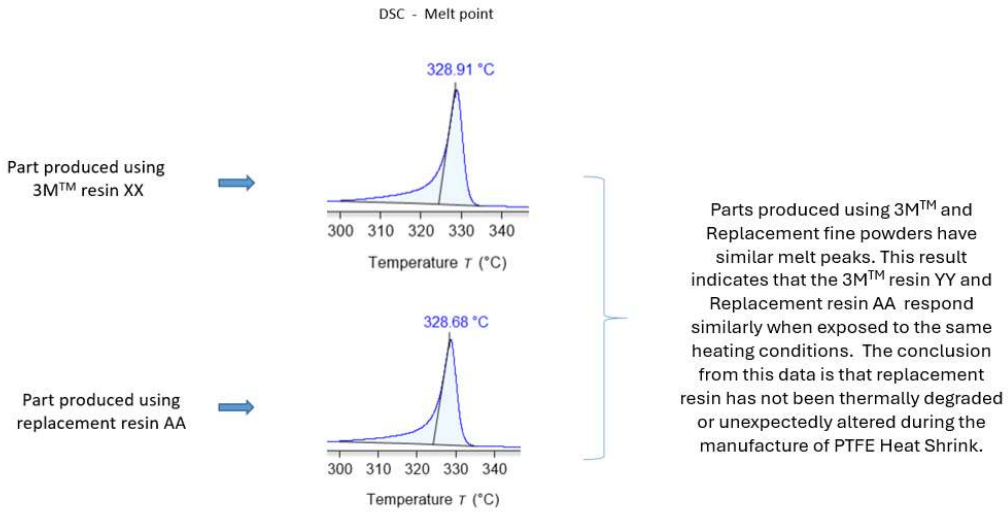
Table # 2: Quality System Controls & Manufacturing Controls Comparison for Existing 3M Resins and Replacement Resin

XVI. Thermal Properties:

The thermal properties are the response of a material when heat is applied. In the manufacturing process of converting fine powder into extruded parts and subsequent processing to Heat Shrink parts, the material is exposed to heat. A comparison between the thermal responses of parts produced from the replacement resin versus the 3M resin will show if the replacement resin has a different response to standard processing conditions. For PTFE, the melting peak is of interest because it changes as the resin is converted from a fine powder to a Heat Shrink/ Dual-Shrink™ part . The DSC thermograms below are taken from recovered parts because the thermogram is sensitive to part movement, which happens as the parts shrink. All samples were recovered under the same conditions. When comparing the first set of thermograms shown below, both depict a similarly shaped melting curve with peak values of 328.91°C and 328.68°C. The second set of thermograms shows a comparison of the PTFE portion of PTFE/FEP Dual-Shrink™ made from each resin. The curves are similarly shaped with peak values of 328.46°C and 327.89°C. The differences in melt peak of 0.23°C and 0.57°C are not significant in this type of test. The conclusions from this data are that the thermal responses from parts made with 3M resins are the same as parts made from the replacement resin, and the replacement resin has not been thermally degraded or unexpectedly altered during the extrusion and secondary processes.

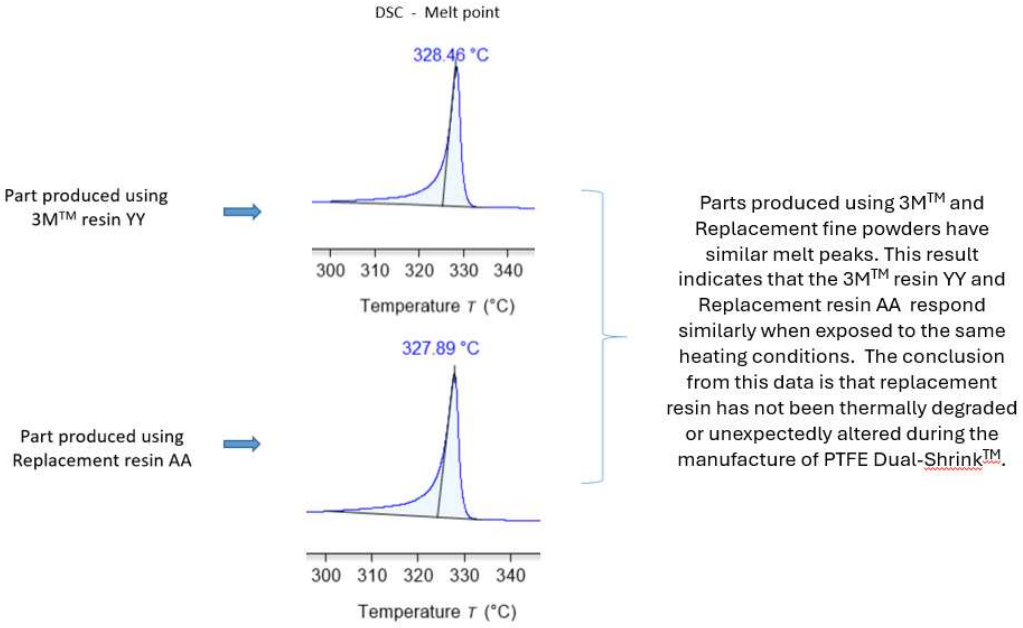
Part information:

PTFE Heat Shrink 4:1
Expanded ID max: 1.5”
Recovered ID min: 0.400”
Recovered Wall Thickness: 0.015”



Part information:

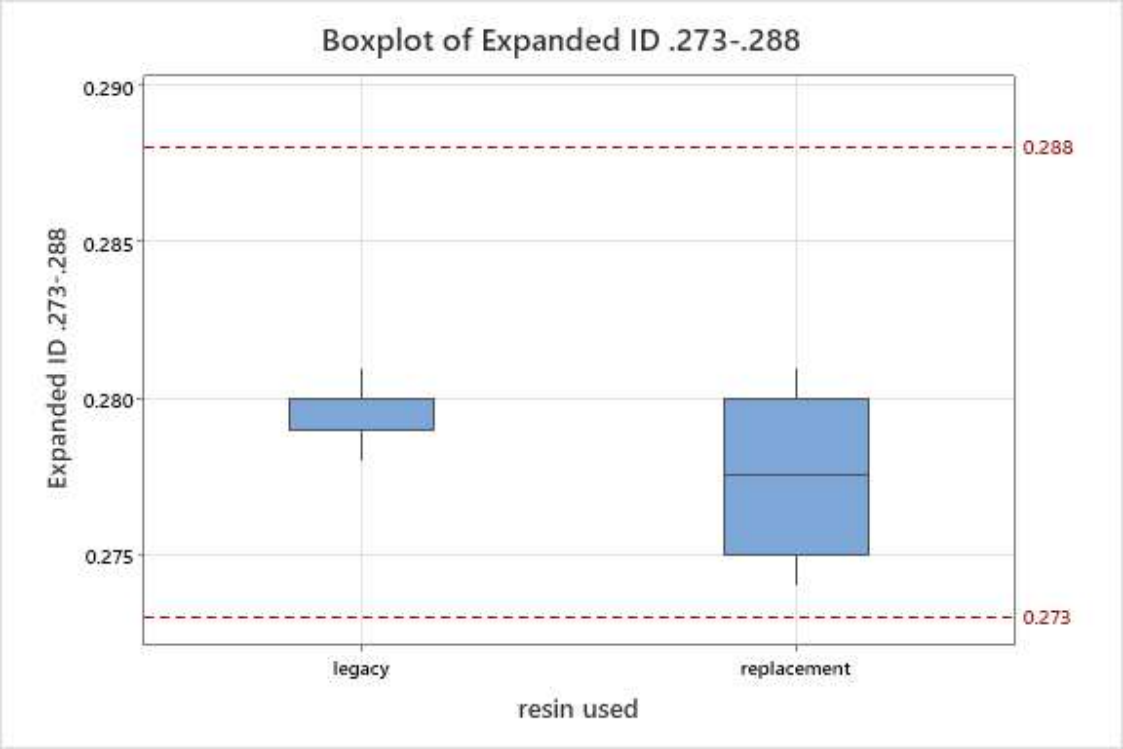
PTFE/ FEP Dual-Shrink™
Expanded ID min: 0.190”
Recovered ID max: 0.062”
Recovered Total Wall: 0.032”

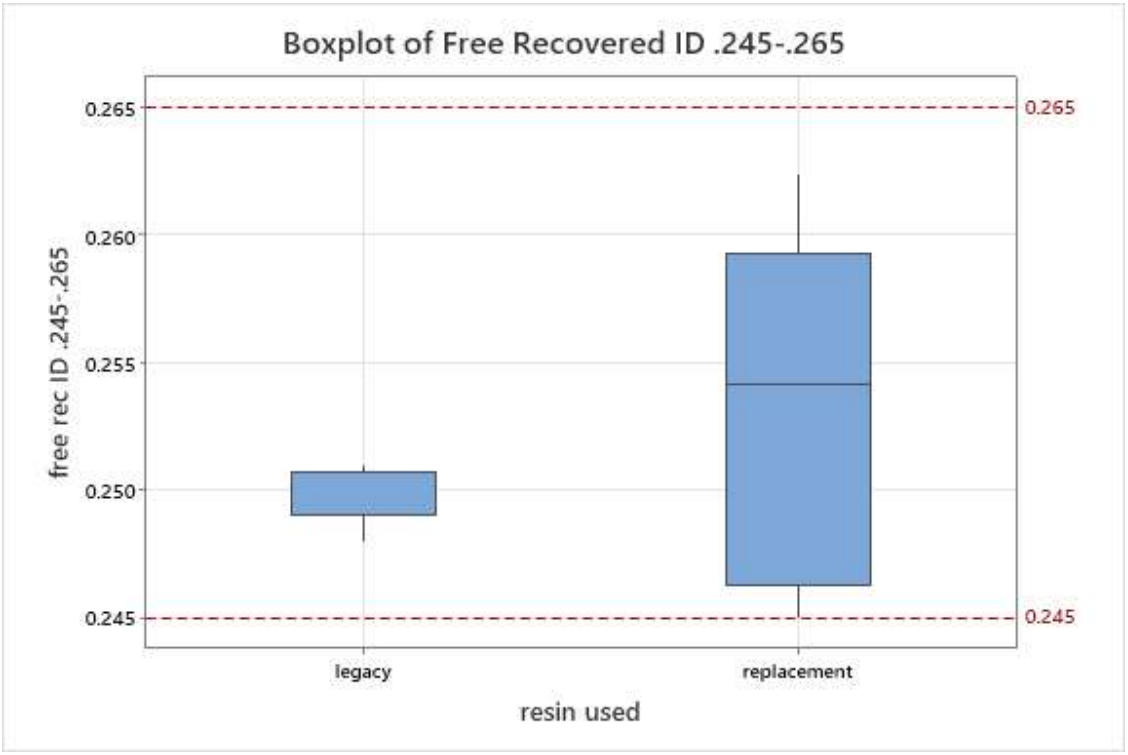


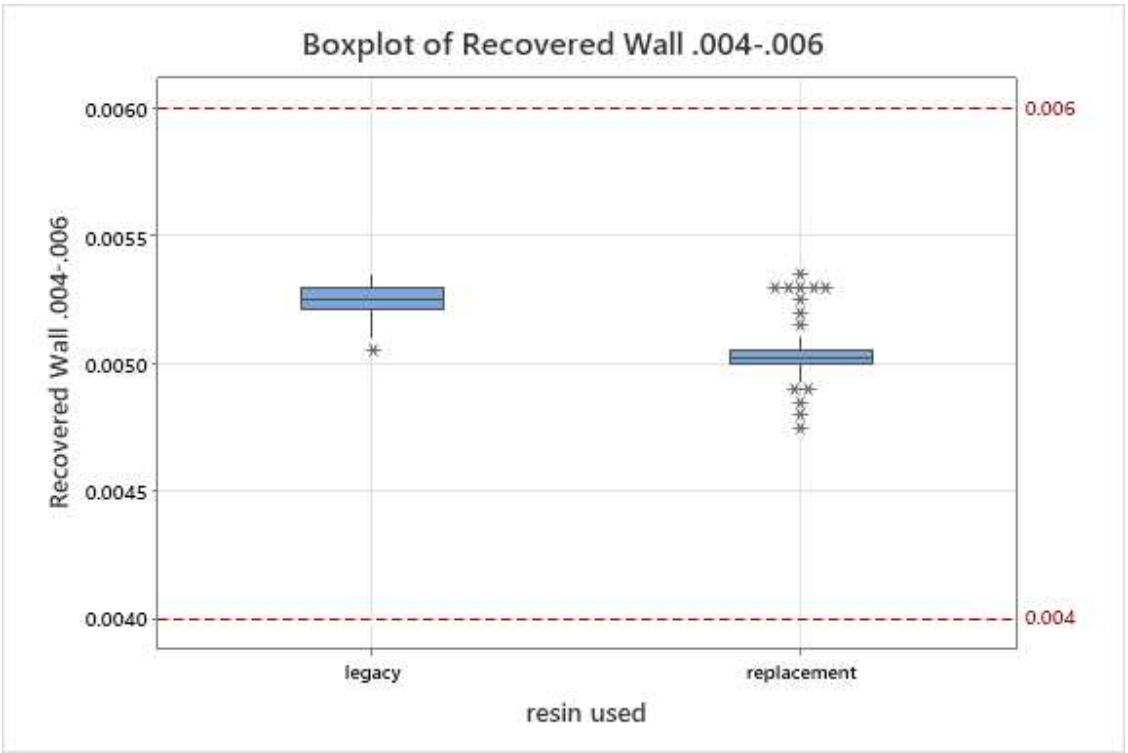
XVII. Physical Dimensions of Heat Shrink and Dual-Shrink™:

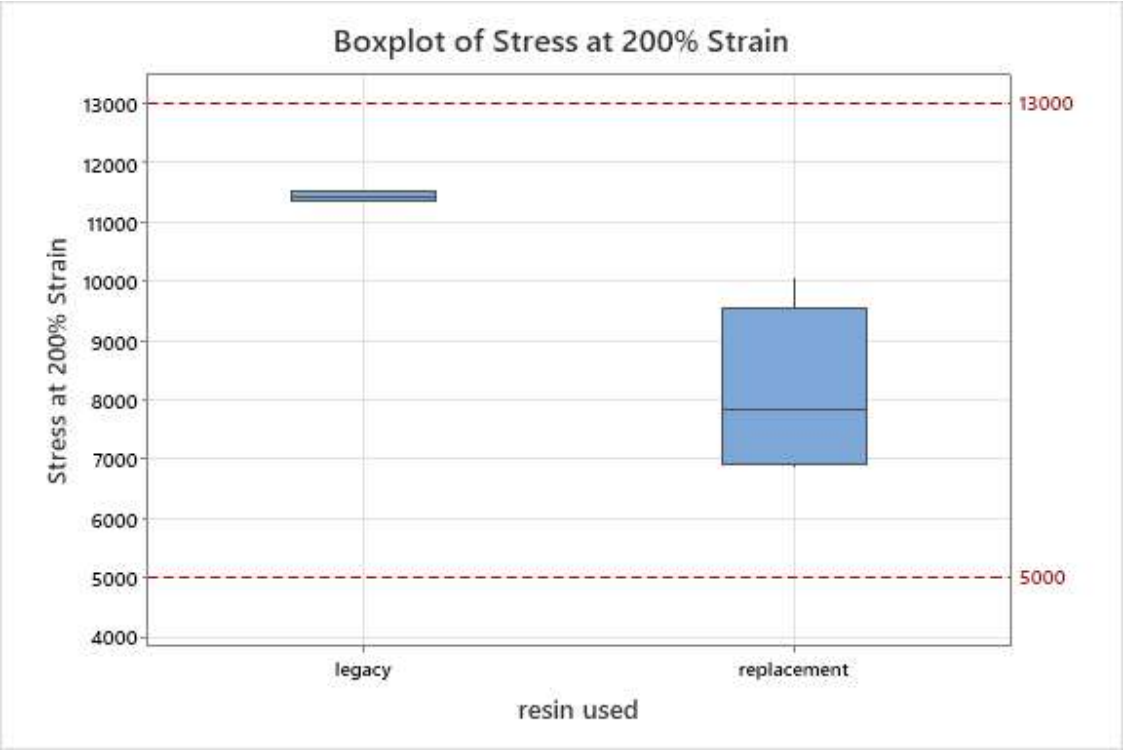
Physical dimensions are measurements that define the part geometry. Parts were selected to represent the product portfolio for PTFE Heat Shrink and PTFE Dual-Shrink™. The nominal dimensions of these parts are shown in the table below. Finished part dimensions meet the same specifications as parts produced from 3M fine powders.

Part	Description	Expanded ID (Inches)	Recovered ID (Inches)	Recovered Wall (Inches)	Tensile Stress at 200% Strain (PSI)
1	PTFE Heat Shrink Sub-Lite-Wall®	.273-.288	.245-.265	.004-.006	5000-13000

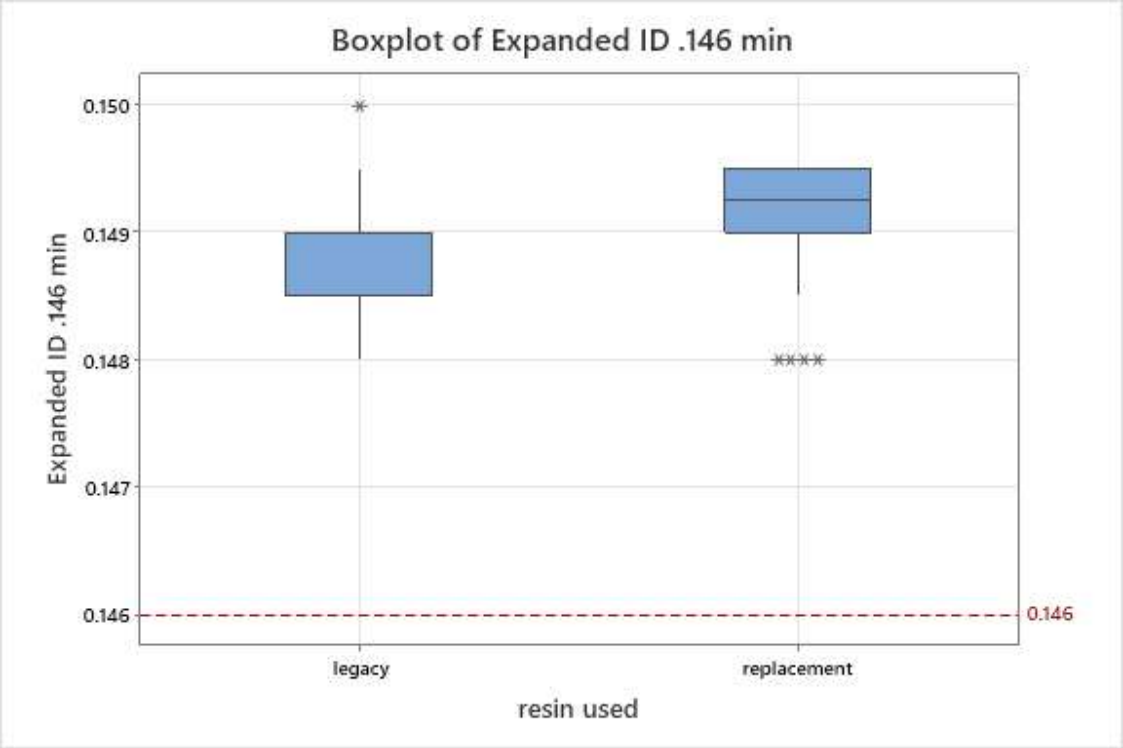


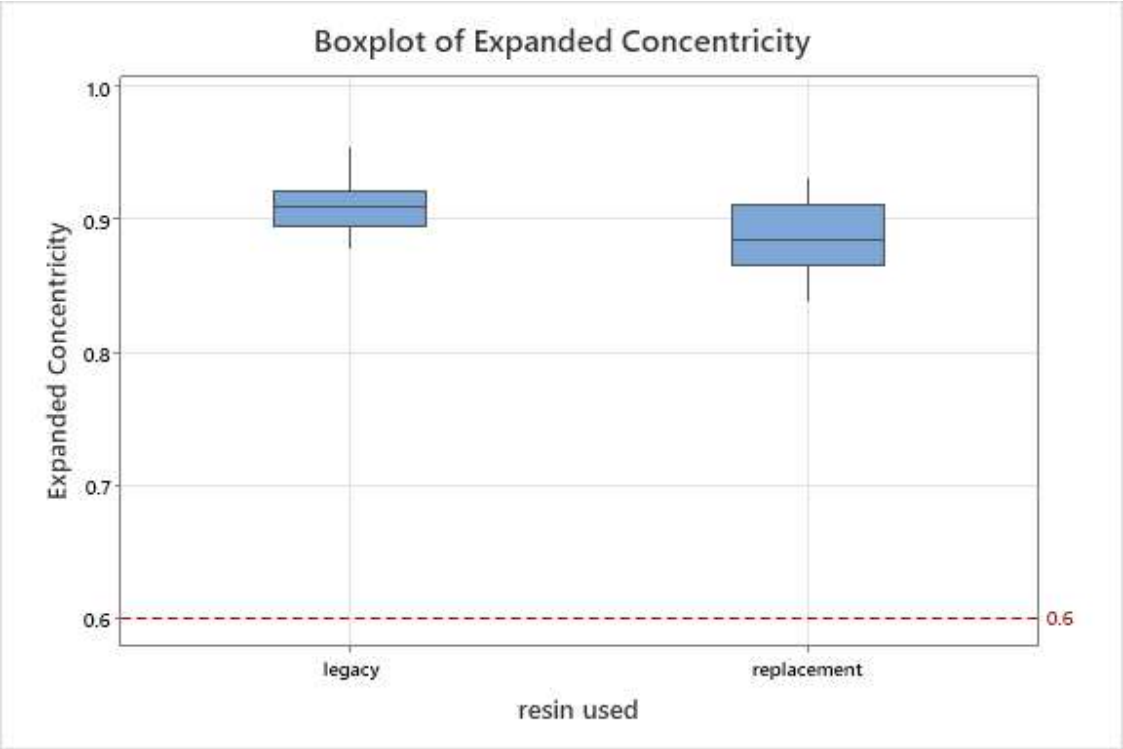


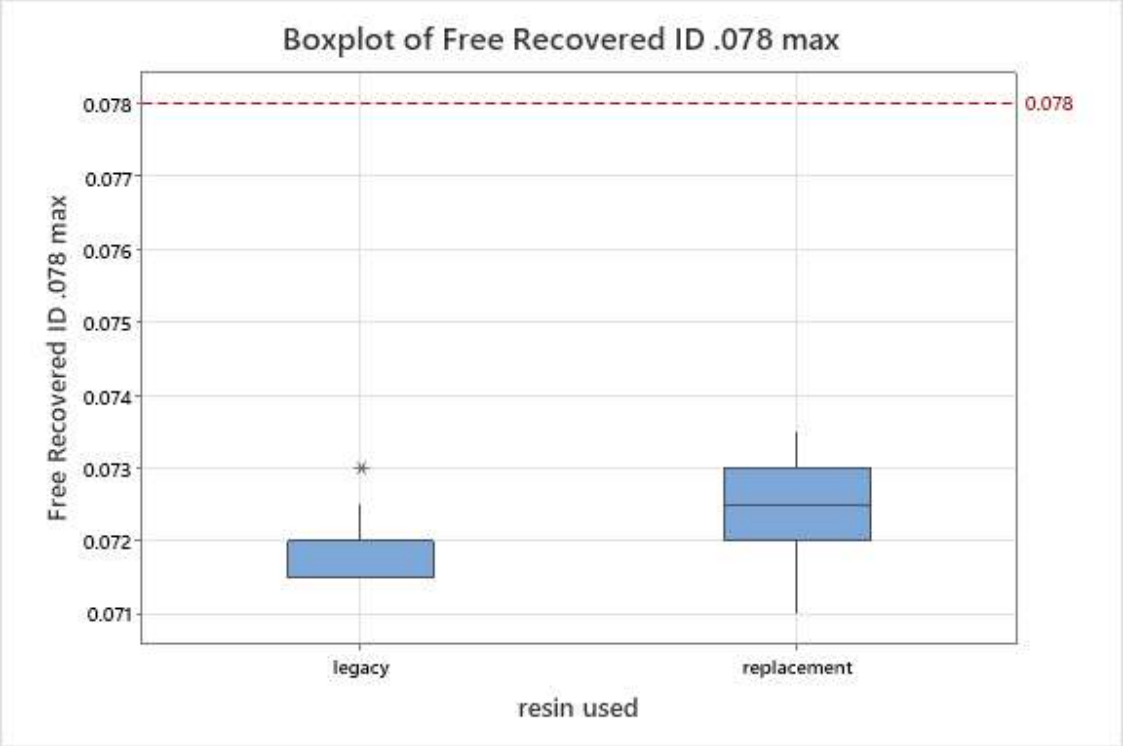


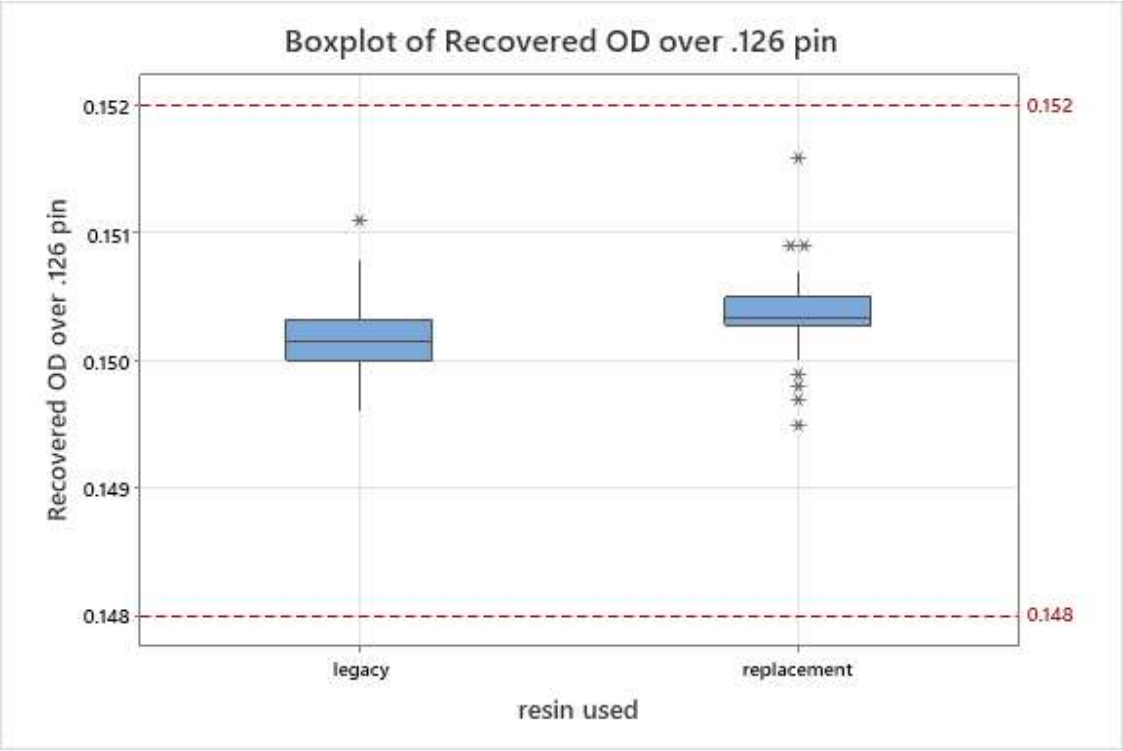


Part	Description	Expanded ID (Inches)	Expanded Concentricity (%)	Free Recovered ID (Inches)	Recovered OD over .126 mandrel
2	PTFE Heat Shrink Special	.146 minimum	60% minimum	.078 maximum	.148-.152

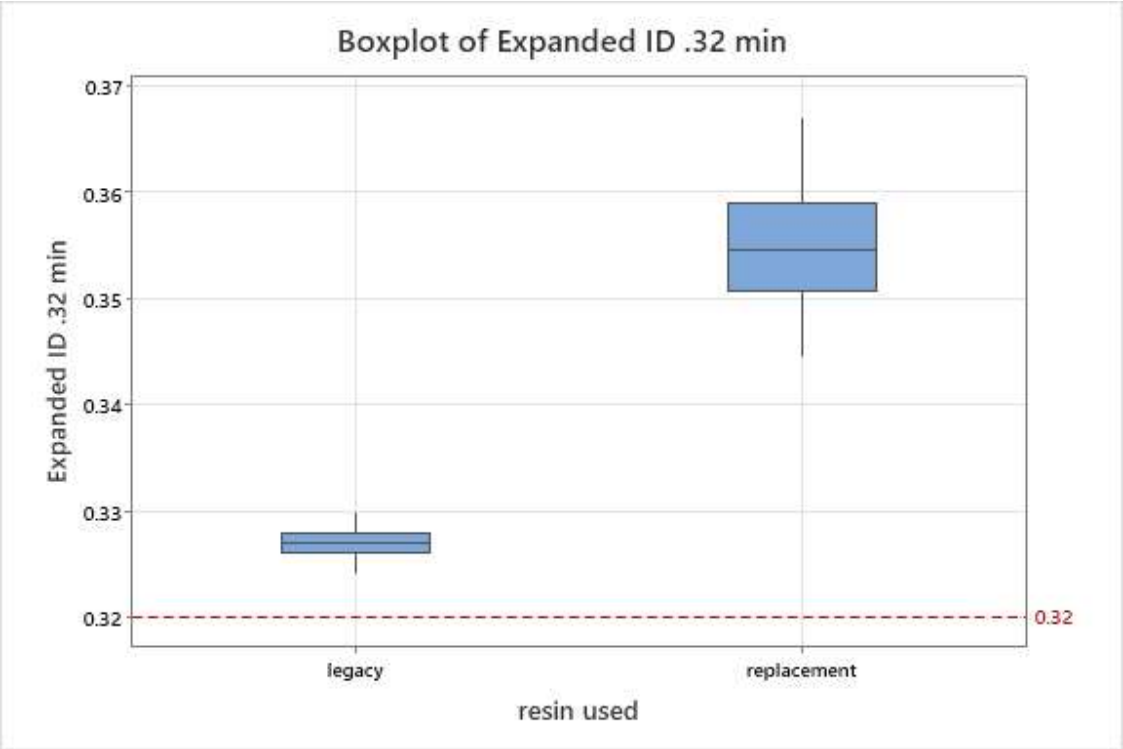


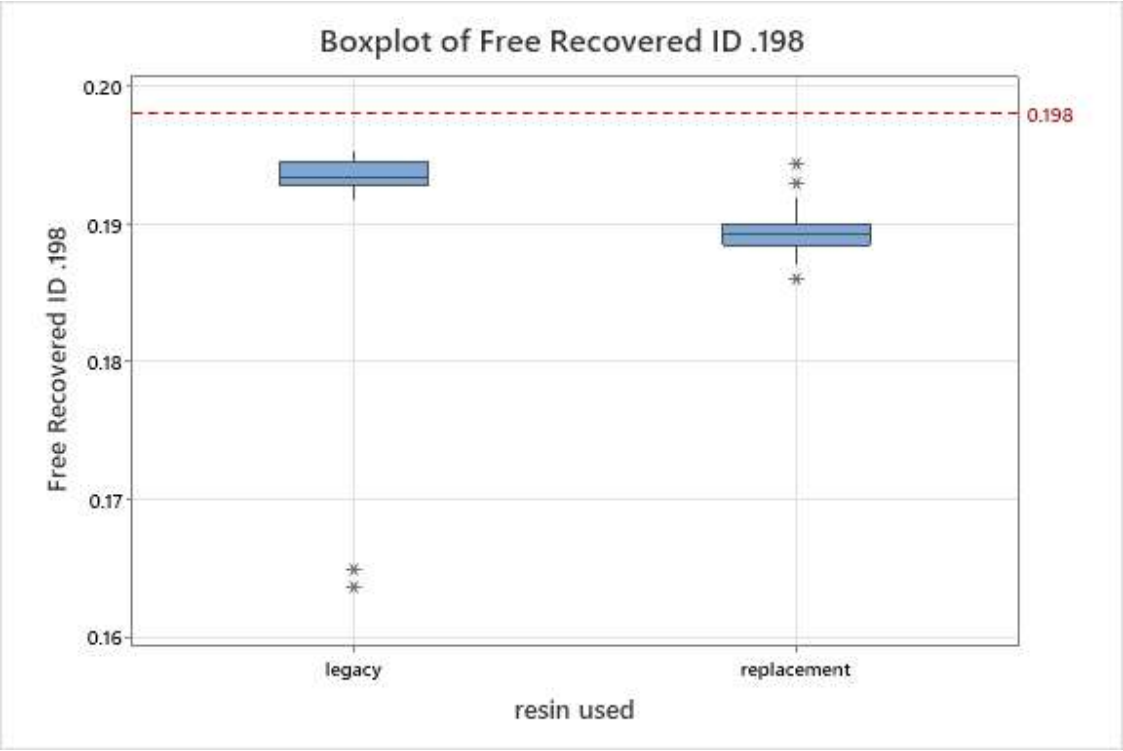

Boxplot of Expanded Concentricity
Expanded Concentricity
1.0
0.9
0.8
0.7
0.6
0.6
legacy
replacement
resin used

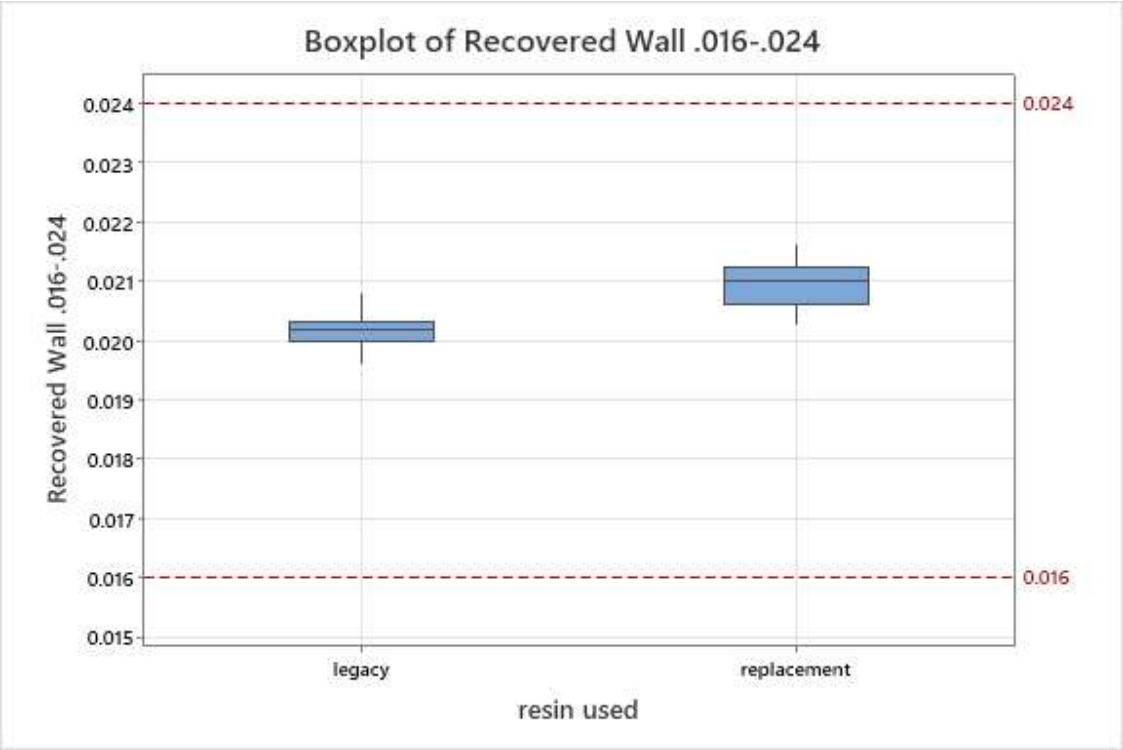

Boxplot of Free Recovered ID .078 max
Free Recovered ID .078 max
0.078
0.077
0.076
0.075
0.074
0.073
0.072
0.071
0.078
legacy
replacement
resin used

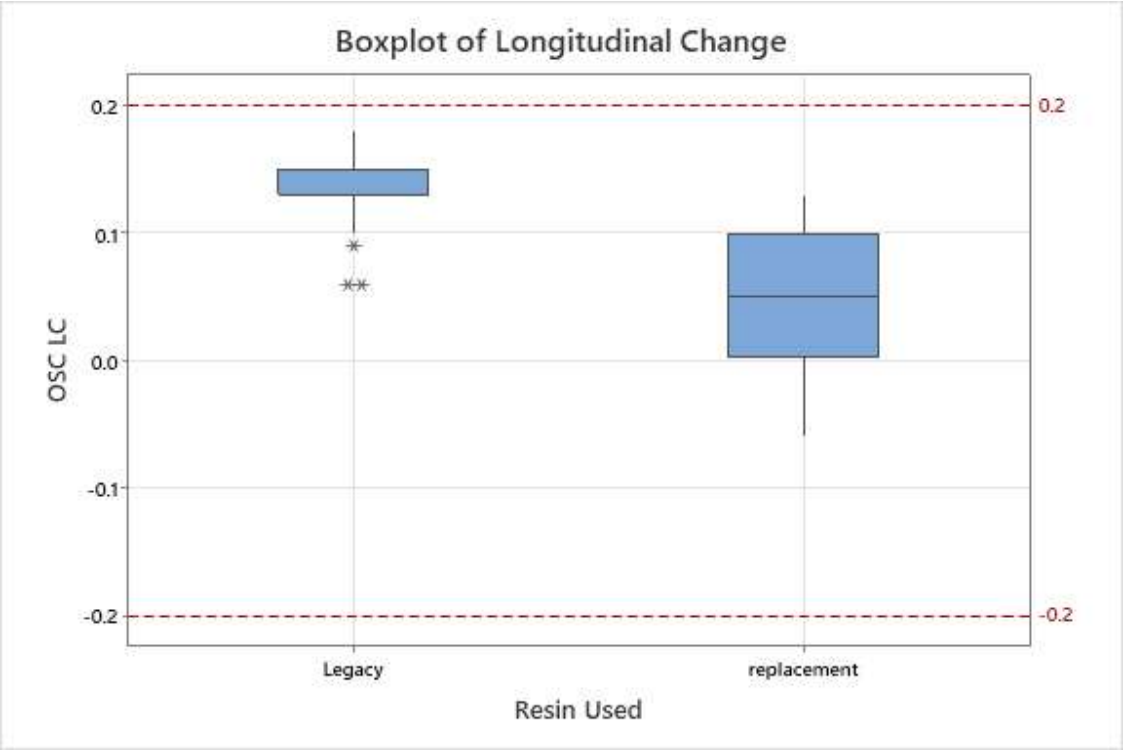

Boxplot of Recovered OD over .126 pin
0.152
0.151
0.150
0.149
0.148
Recovered OD over .126 pin
0.152
0.148
legacy
replacement
resin used

Part	Description	Expanded ID (Inches)	Free Recovered ID (Inches)	Recovered Wall (Inches)	Longitudinal change (%)
3	PTFE Heat Shrink Catalog AWG5 2:1	.320 minimum	.198 maximum	.016-.024	+/- 20%

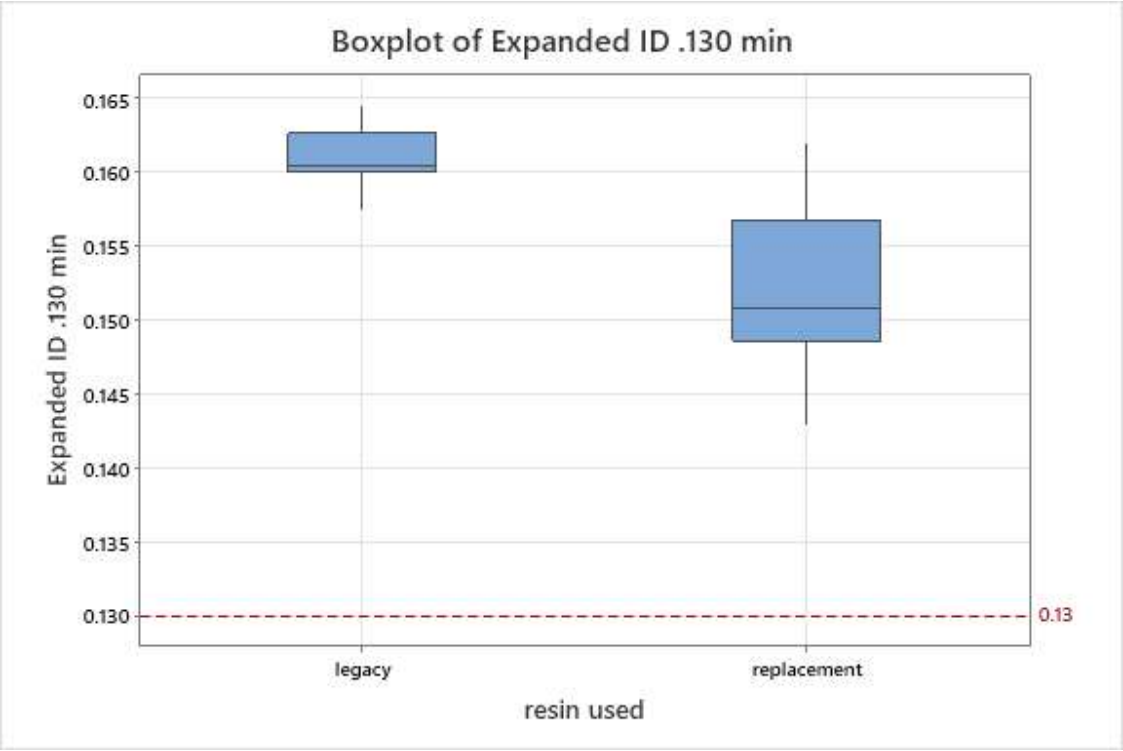



Boxplot of Free Recovered ID .198
Free Recovered ID .198
0.20
0.19
0.18
0.17
0.16
0.198
legacy
replacement
resin used

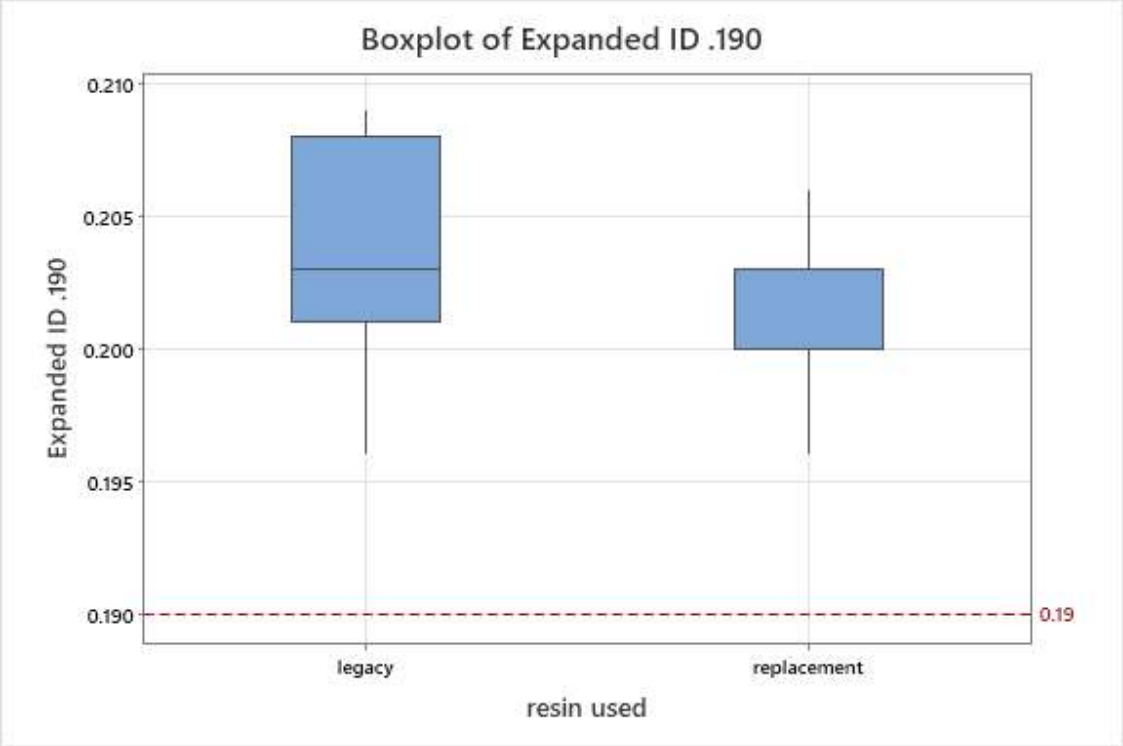

Boxplot of Recovered Wall .016-.024
Recovered Wall .016-.024
0.024
0.023
0.022
0.021
0.020
0.019
0.018
0.017
0.016
0.015
0.024
0.016
legacy
replacement
resin used

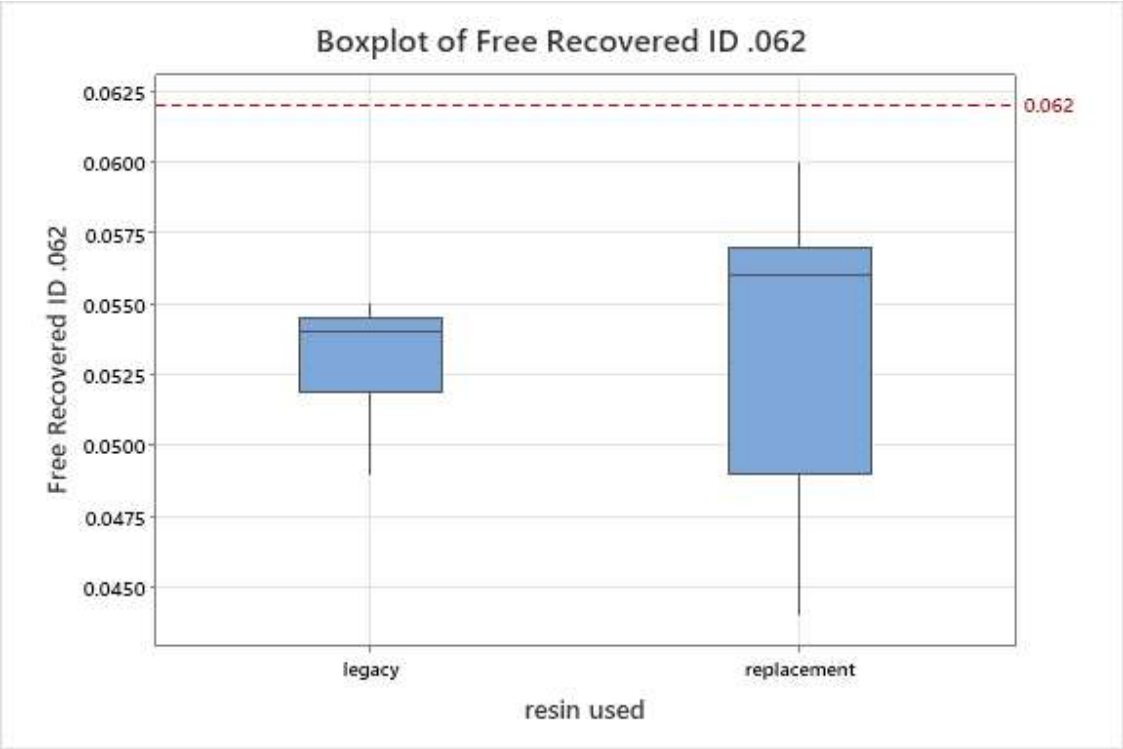

Boxplot of Longitudinal Change
0.2
0.1
0.0
-0.1
-0.2
OSC LC
0.2
-0.2
Legacy
replacement
Resin Used

Part	Description	Expanded ID (Inches)	Recovered ID (Inches)
4	PTFE/PFA Dual Shrink	.130 minimum	Recovers to solid rod, all parts passed

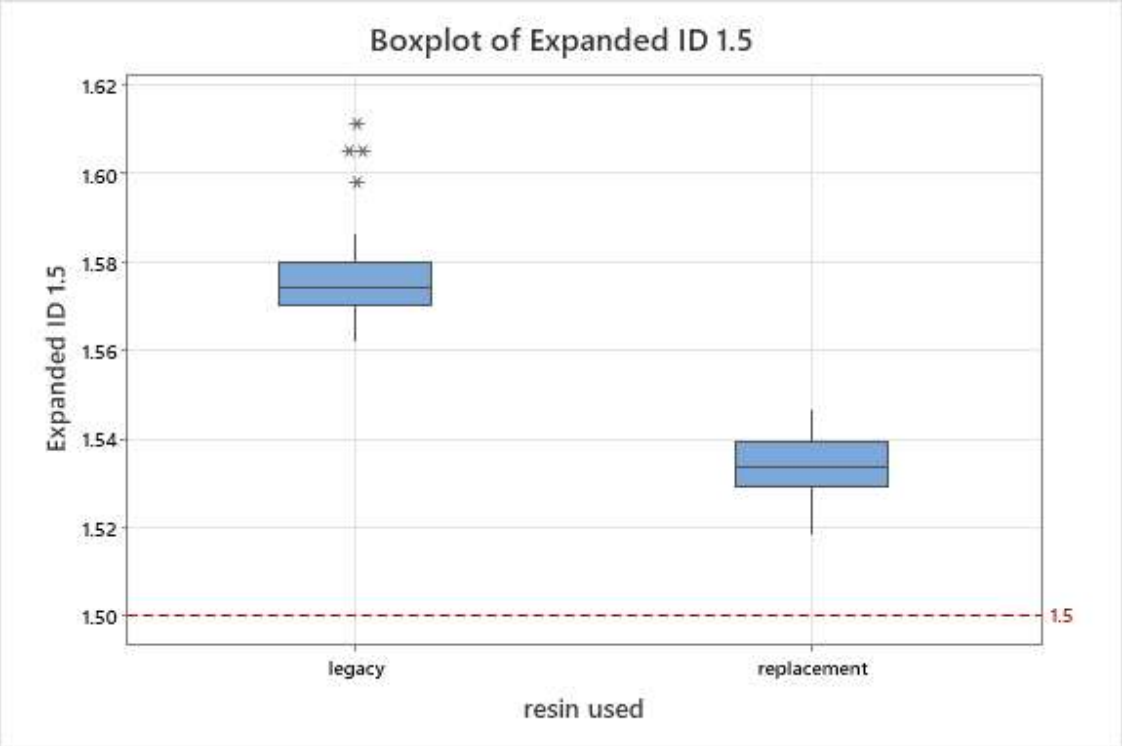


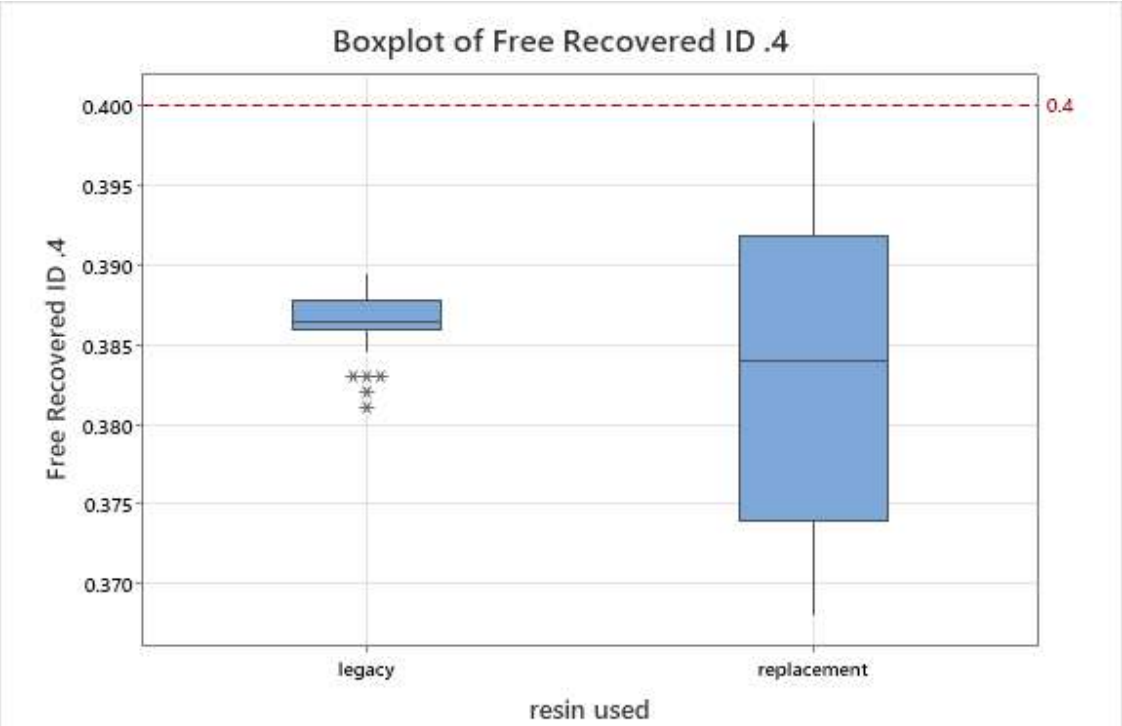
Part	Description	Expanded ID (EID, Inches)	Recovered ID (Inches)
5	PTFE/FEP Dual Shrink	.190 minimum	.062 maximum

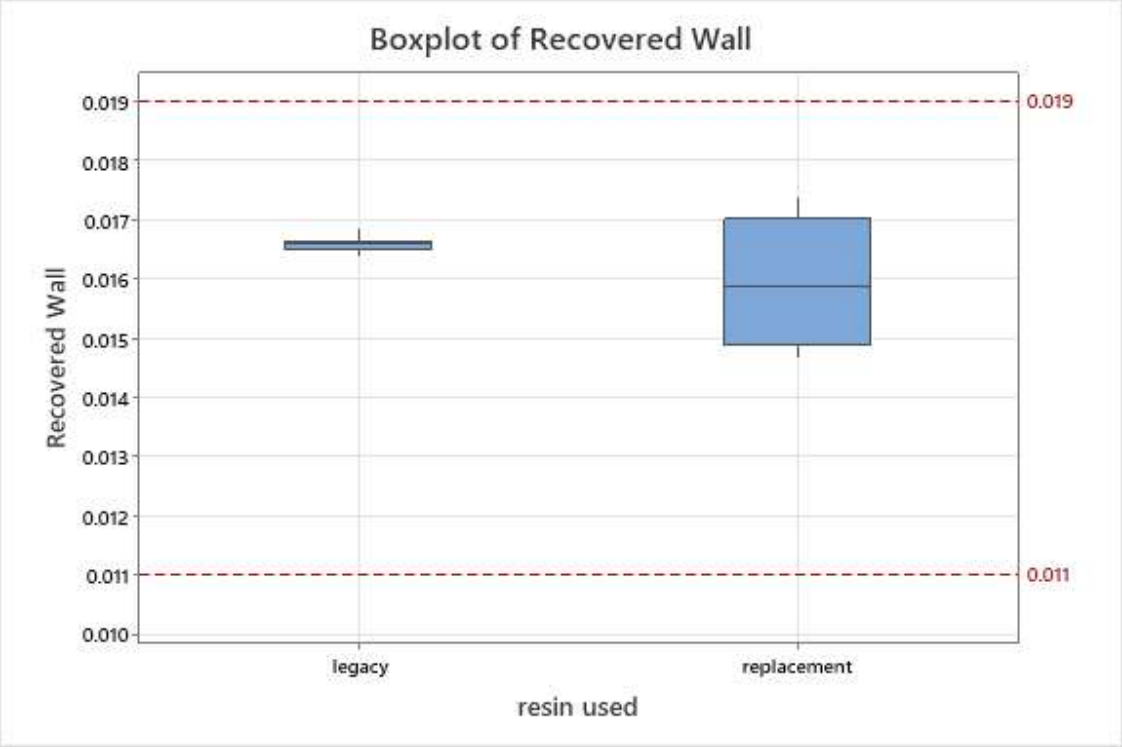


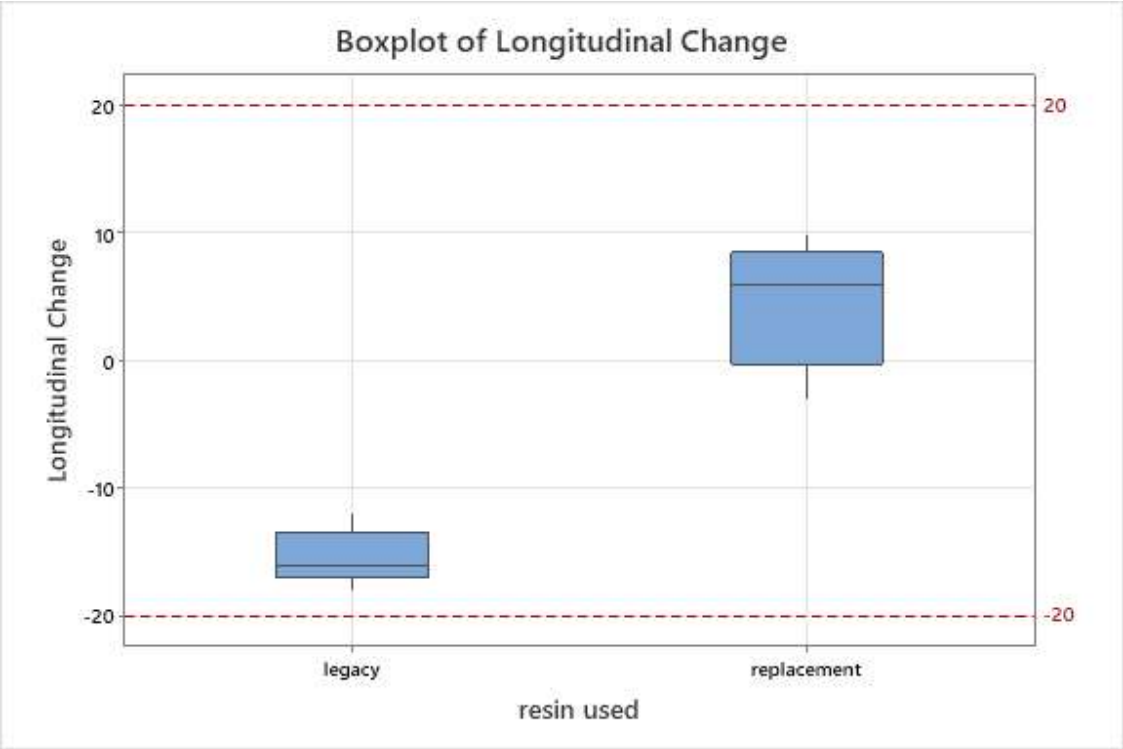


Part	Description	Expanded ID (Inches)	Recovered ID (Inches)	Recovered Wall (RW avg, Inches)	Longitudinal Change (LC, %)
6	PTFE Heat Shrink 4:1	1.5 minimum	.4 maximum	.011-.019	+/- 20%



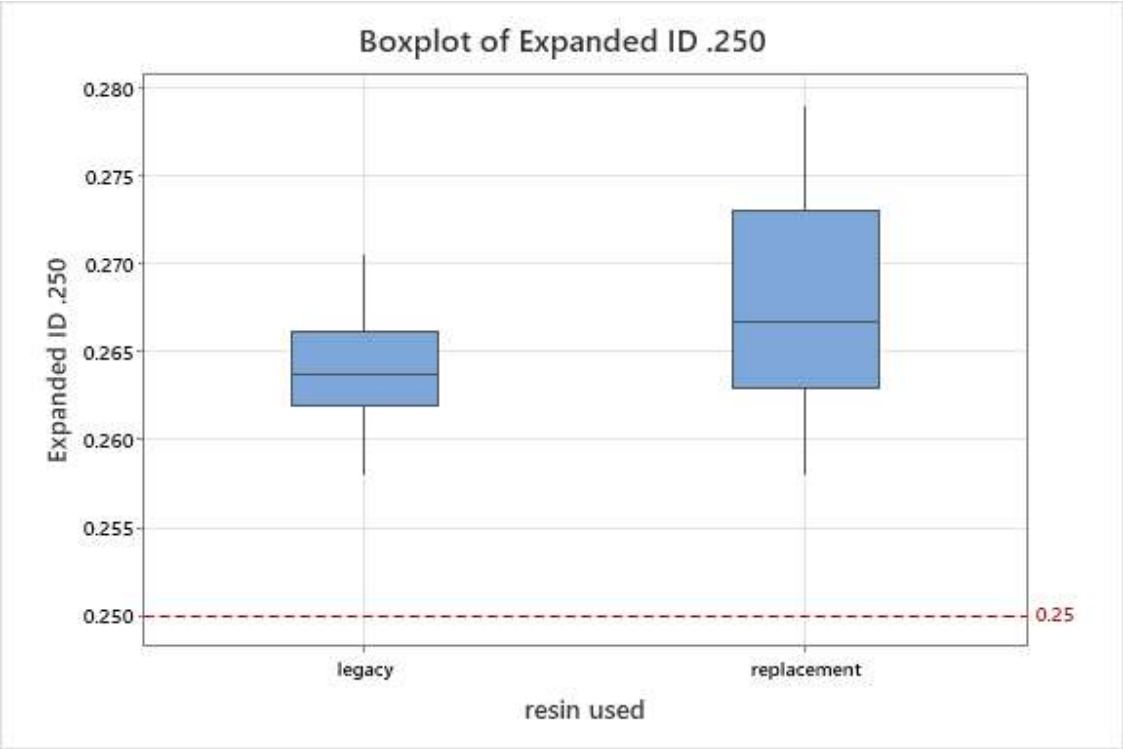

Boxplot of Free Recovered ID .4
0.400
0.395
0.390
0.385
0.380
0.375
0.370
0.4
Free Recovered ID .4
legacy
replacement
resin used

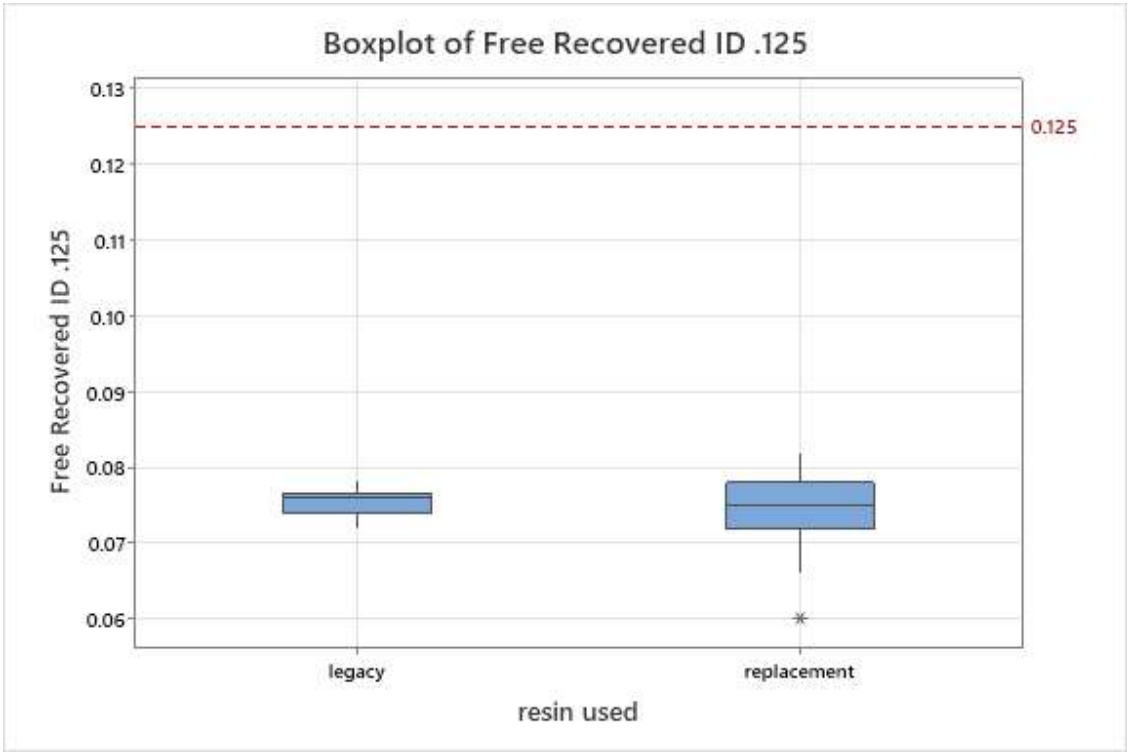

Boxplot of Recovered Wall
0.019
0.018
0.017
0.016
0.015
0.014
0.013
0.012
0.011
0.010
0.019
0.011
Recovered Wall
legacy
replacement
resin used

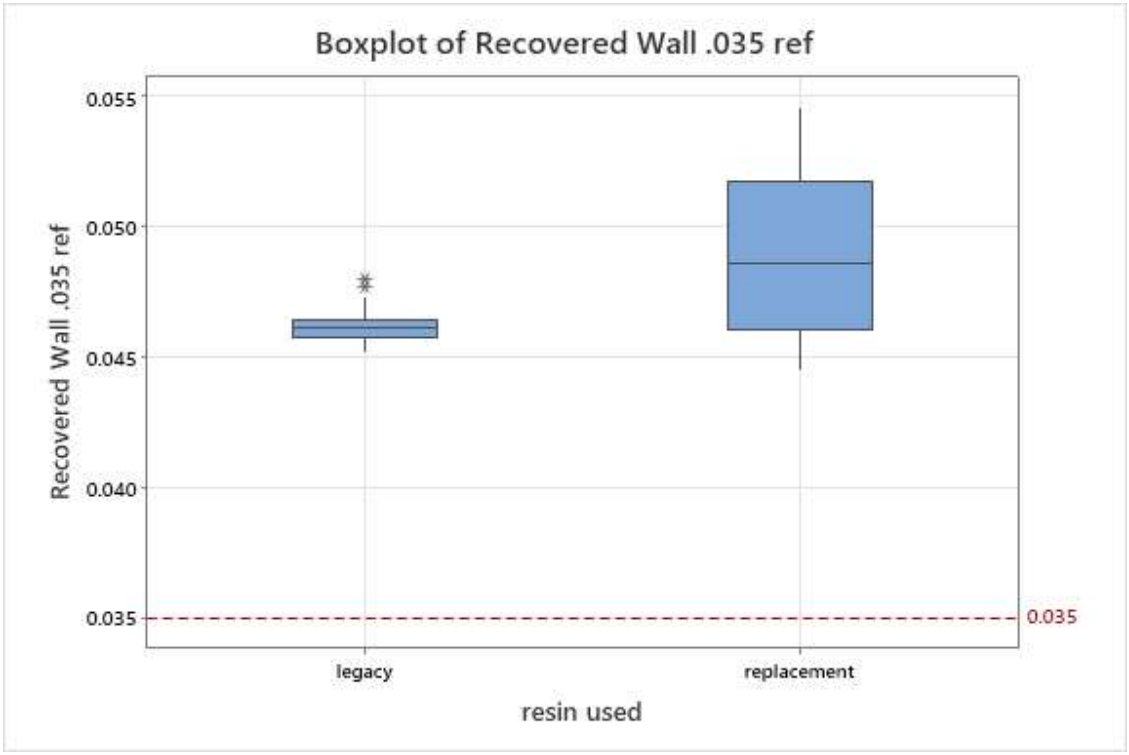


(n=5 for longitudinal change measurements)

Part	Description	Expanded ID (Inches)	Recovered ID (Inches)	Recovered Wall (RW REF, Inches)
7	PTFE/FEP Dual Shrink ZDS-250	.250 minimum	.125 maximum	.035 Reference Only







Conclusion:

The suitability of the replacement fine powder is evidenced by the FTIR, CAS number assignation, and identical classifications per the ASTM D4985 standard. To provide additional assurances that the change does not introduce biocompatibility risks, the replacement resin was assessed in methods outlined in USP Class VI and ISO 10993-4 and -5. The passing results support the conclusion that the replacement resin is unlikely to change the biocompatibility of Zeus' Heat Shrink and Dual-Shrink™. Finally, the DSC and dimensional data indicate that the heat shrink and Dual-Shrink™ made with the replacement resin meet all applicable chemical and dimensional product requirements. Zeus will continue to evaluate alternative resins and may use these resins when deemed appropriate, subject to applicable change control or notification requirements.