



Production Order: **500000066052**

Material: **SA0254-06** Rev G

Material Type: ZFRT Description: Printed Shaft 144C Prox End Color B CMDR

Production Version: 8000

Plant / Business Unit: 1213 / AC5

Order Type: ZSTD

Project Phase:

Opn No.	Planned WorkCenter Description	Operation Details			Scrap Qty & Desc.	Date Comp.	Initials
		Comp. Qty	Comp. Qty	Comp. Qty			
50	CATASY04	Prepare Materials MPI0398 Rev. U			0	09Jan21	LY
	Catheter Assembly 4	Line Clearance MPI0230 Rev. E					
	Count: Yes	By: LY Date: 09Jan21					
		Prepare Materials					
		Confirmation Rreqd(Milestone)					
100	CATASY04	Straighten First Jacket MPI0398 Rev. U					
	Catheter						

Notes: DA: 1738 DA 1787

Date Printed: 09.01.2021 / 16:31:30

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Production Order: 500000066052

Production Order Document
Production Order Qty: 500
PC

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Opn No.	Planned Work Center Description	Operation Details						Comp. Qty & Desc.	Scrap Qty & Desc.	Date Comp.	Initials
		Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.				
	Assembly 4							500	0	09Jan21	LY
	Straighten First Jacket										
	Confirmation Rreqd(Milestone)										
MM0187-01	E	E	PC	1	0000064857	500					
					111						
150	CATASY04	Positioning Braid Over First Jacket						209	0	09Jan21	VY MS
	Catheter Assembly 4	MP0398 Rev. A						291	0	11Jan21	SC SP BK VLA VHLJ
	Positioning Braid Over First Jacket										
	Confirmation Rreqd(Milestone)										
MM0189-01	D	D	PC	500	0000064995	396					
					0000064796	100					

Notes:	

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Opt No.	Planned Work Center Description	Operation Details						Initiator
		Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Comments			
200	CATASY04 Catheter Assembly 4 	192	0 N/A	09Jan21	N/A			
	Strain Relief Reflow MPI0398 Rev. U							
	Temp = 420°F 5°F Air Flow = 60 SCFH							
	Strain Relief Reflow	Component Number	Req'd Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	
	Confirmation Rreqd(Milestone)	MM0527-01	B B	PC	500	0000058371	500	
		RM0096-01	F F	PC	125	27698	150	
250	CATASY04 Catheter Assembly 4 	107	2 - Too Tight 0 N/A	09Jan21	VX MC SC SP BK JK			
	Position Tubing For Reflow MPI0398 Rev. U							
	Notes:							

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Opn No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		Number	Rev	Used	No.	Qty Used					
	Position Tubing for Reflow	MM0186-00	D	D	PC	500	Pos-061101	450			
		MM0523-03	C	C	PC	500	000059871	500			
		MM0524-01	B	B	PC	500	0000058676	500			
		MM0530-01	B	B	PC	500	02000059064	500			
		RM7586-02	D	D	PC	500	25632	250			
		RM8745-01	B	B	PC	500	25632	250			
		MM0185-01	I	I	PC	500	0000064121	500			

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CV 11 Jan 21
CV 11 Jan 21
CV 11 Jan 21

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Op No.	Planned WorkCenter Description	Operation Details						Comp. Qty	Scrap Qty & Desc.	Date Comp.	Initials
		A	A	PC	500	0000063081	500				
	MM1540-01	A	A	PC	500	0000063081	500				
	MM1539-01	A	A	PC	500	0000061041	500				
	RM016101-MED	F	F	PC	46	0000061041	46				
						25704	100				
300	CATASY04 Catheter Assembly 4	Reflow MPI0398 Rev. M				72	0	09Jan21 12Jan21 1/1/2021 AS KS	AO VNUJ		
350	CATASY04 Catheter Assembly 4	Skive Heat Shrink MPI0398 Rev. M				277	0	11Jan21 12Jan21 1/1/2021 KK	PY YK		

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PC

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Opn No.	Planned Work Center Description	Operation Details			
		Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initiator
400	CATASY04 Skive Heat Shrink				
450	CATASY04 Catheter Assembly 4 Count: Yes In Process Inspection	272 214	3 Disc 2 EW 4 EW 1 AB 1 FM 1 DS	11Jan21 12Jan21	Puy YK Trencl YKA
	In-Process Inspection (Visual Inspection) MPI0398 Rev. <u>U</u> FM5104693 (Rework if needed. Use FM5104983)				
	Anneal Shaft MPI0398 Rev. <u>U</u> FM5104692 Anneal Shaft	203 283	0 0	11Jan21 12Jan21	Puy YK

Notes:	<i>6/1/21</i>
	<i>6/1/21</i>
	<i>6/1/21</i>

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Opn No.	Planned WorkCenter Description	Operation Details				Comp. Qty	Scrap Qty & Desc.	Date Comp.	Initiator
		Opn No.	WorkCenter	Opn Desc.	Opn Type				
500	CATASY04 Catheter Assembly 4	Leak Test/Prox Cut/Ring Gage-Dim 13/21 MPI0398 Rev. <u>G</u>				49	4 Fail DD 13 11 Jan 21 D Fail 12 Jan 21 CKY	11 Jan 21	NYC
		FM5104694 FM5104695				492			
	Leak Test/Prox Cut/Ring Gage-Dim 13/21	(Rework if needed - Use FM5104983)							
550	CATASY04 Catheter Assembly 4	Distal Cut MPI0398 Rev. <u>U</u> Line Closure MPI0230 Rev. <u>E</u> By: <u>C K Y</u> Date: <u>12 Jan 21</u>				49	D	11 Jan 21 D fail 12 Jan 21 CKY	MW
		Distal Cut				422	O		
600	PADPRIN1 Pad Print	Pad Print Set Up MPI0276 Rev. <u>D</u>				471	O	12 Jan 21	KWJ
	Count: Yes	Line Clearance MPI0230 Rev. <u>E</u>							
	Notes:	<u>✓/A</u>							

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Opn No.	Planned WorkCenter Description	Operation Details			
		Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Pad Print Setup	By: <u>KUT</u> Date: <u>12 Jan 21</u>			
		TMI0503 (circle TMI used) Cliché - TL0525 Ink # RM7407-01 Thinner - RM7408-01 Hardener - RM7409-01 Customized Measuring Equipment - Caliper Inspection Gauge TMI0843 Setup Rod # TL0815 Program - #10 Ink Viscosity (REF) -5 to 6 Pad - TL0545 or equivalent Fence - TL0538 Drying Oven - TMI0643 Drying Racks-TL0531, TL0532	Cliché - TL0567 Ink - RM7407-01 Thinner - RM7408-01 Hardener - RM7409-01 Customized Measuring Equipment - Caliper Inspection Gauge TMI0843 Setup Rod # TL0815 Program - #10 Ink Viscosity (REF) -5 to 6 Pad - TL0545 or equivalent Fence - TL0569 Drying Oven - TMI0643 Drying Racks-TL0531, TL0532	N/A	

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Opn No.	Planned WorkCenter Description	Operation Details				Comp. Qty & Desc.	Scrap Qty & Desc.	Date Comp.	Initials
		Opn	Tool	UOM	Qty.				
650	PADPRIN1 Pad Print 	Verification MPI0276 Rev. <u>D</u> Section 15.0		L	0.050	471	0	12/Jan/21	KUT
		Verification							

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KUT 12.Jan.21
KUT 12.Jan.21

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Opn No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		B	L	0.005	1P53072	0.005	N/A				
	RM7408-01	B	B	0.010	26264	0.010	N/A				
	RM7409-01	B	B	0.010	26264	0.010	N/A				
700	PADPRIN1 Pad Print  Prepare Surface for Ink	MPI0276 Rev. D Section 15.5 Polynit wipes 99% IPA					7471	0	12/Jan/21	KuT	
750	PADPRIN1 Pad Print  Print Parts	MPI0276 Rev. D Section 20.0 Inspection gauge TMI0843					471	0	12/Jan/21	KuT	

N/H

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KuT 12/Jan/21
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Opn No.	Planned WorkCenter Description	Operation Details					
		Comp. Qty	Scrap Qty	Qty Desc.	Date Comp.	Initiator	Comments
800	PADPRIN1 Pad Print 	In-Process Inspection and Rework MPI0276 Rev. <u>D</u> Section 30.0 Polynit Wipes 99% IPA Mag Light	471	0	12Jan21	KWJ	
850	PADPRIN1 Pad Print 	Curing Oven MPI0340 Rev. <u>E</u> Section 35.0 Curing Oven Confirmation Reqd(Milestone)	471	0	12Jan21	KWJ	
900	PADPRIN1 Pad Print 	Transfer Parts to Production MPI0276 Rev. <u>D</u> Section 40.0				N/A	
Notes:							

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Opn No.	Planned WorkCenter Description	Operation Details			
		Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initiator
	Transfer parts to Production	Transfer Parts to Line	5:30 pm		
		Time: <u>4:45 pm</u>	By: <u>DX</u> Date: <u>13 Jan 21</u>		
950	PADPRIN1	Cleaning MP0276 Rev. <u>D</u> Section 50.0		471	0
		Line Clearance MP0230 Rev. <u>E</u>			12 Jan 21, <u>DX</u>
		By: <u>KUT</u> Date: <u>12 Jan 21</u>			
1000	CATASY04	In-Process Dimensional Inspection		N/A	N/A
				N/A	N/A

Notes:	<u>N/A</u>
	<u>N/A</u>
	<u>N/A</u>

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Opn No.	Planned WorkCenter Description	Operation Details			
		Comp. Qty	Scrap Qty & Desc.	Date Comp.	Initiator
	Catheter Assembly 4	MPI0398 Rev. <u>U</u> FM5104662 FM5104696	50 446	15.00 FAH 25.00 21 Jan 21	20 Jan 21 21 Jan 21 ASD
	In-Process Dimensional Inspection	(No Rework can be done at this OP) Line Closure MPI0230 Rev. <u>E</u> By: <u>ASD</u> Date: <u>21 Jan 21</u>			NY
1050	QUALITY1	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	380 379	10 - TT 18 - OD/OS 12 - SL/OS 6 - IB 11 - ID/OS 1 - FB 2 - AB 2 - SCR 1 - PM 2 - WT 2 - DS	18 Feb 21
	Quality Inspection & Review				
	Quality Inspection & Review				
	Confirmation Rreqd(Milestone)				

Notes:	ASD 21 Jan 21

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Opn No.	Planned WorkCenter Description	Operation Details			
		Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initiators
	Confirmation Rreqd(Milestone)			2014	
1100	PACKINT1	Packaging Instructions SP10087 REV. <u>H</u>		376 0 30PES 21 AP	
	Packing assembly		Packing Instructions		
			Confirmation Rreqd(Milestone)		

Notes:

N/A

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PC
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Material: SA0254-06 Rev G

Batch Number: 00xx066052

By: AP

Date: 20 Feb 21

Reviewed By: Mosher

Date: 25 Feb 21

Notes:
N/A

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Document No: FM5104983

Rev: B Document Type: Manufacturing Form
Title: SA0254 Cause of Rework Form

PRODUCTION ORDER# 66052

Attachment B: Cause of Rework.

OPER 400.0

Date	Initial	AB (Prox)	AB (Distal)	DF	DS	EW	FM	Disc	SCR	SKV	VD
11 Jan 21	Puy	o	2	o	o	o	4	o	o	o	o
12 Jan 21	YK	/	8	o	o	/	3	o	o	o	/

Attachment B: Cause of Rework

OPER 500.0

Date	Initial	Dim 13 (Go Gauge)	Dim 21 (Go gauge)
12 Jan 21	Vc	0	55

PRODUCTION ORDER# 66052

OPER 400.0

In-Process Inspection

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
Using a magnification light, visually inspect the entire length of the shafts.	N/A	100%	2.85x Mag. Light		498	0	JK 12 Jan 21
Metallic Foreign Material: No embedded metallic and foreign material is allowed along the length of the shaft.	N/A	100%	2.85x Mag. Light		498	0	
All other Foreign Material:				Tappi Chart and 2.85x Mag. Light	498	0	
Particle Size Area: mm ²	Acceptable Limits per Part	See Table					
< 0.05 mm ²	No Limit						
0.05 mm ² ≤ Area < 0.25 mm ²	3						
0.25 mm ² ≤ Area < 0.80 mm ²	2						
0.80 mm ² ≤ Area ≤ 1.5 mm ²	1						
> 1.5 mm ²	0						
No surface damage to the shafts such as voids pits or cuts. (interior surface of distal end not included)	N/A	100%	2.85x Mag. Light		498	0	
No bumps, lumps, or protrusions along the shaft that will compromise the OD. Verify all protrusions to make sure the OD is still within specification.	N/A	100%	2.85x Mag. Light		498	0	
No flat spots, kinks, delamination, gaps between material transitions and material transitions should not exhibit cracking, no exposed or apparent braid.	N/A	100%	2.85x Mag. Light		486	12	
Verify all ODs along the entire length of shaft are within specification according to print/drawing requirements.	See QA Inspection Requirement	100%	See QA Inspection Equipment		486	0	JK 12 Jan 21



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Document No: FM5104692

Rev: B

Document Type: Manufacturing Form
Title: SA0254 Annealing Oven Log Form

66052

PRODUCTION ORDER#

OPER 450.0

Annealing Log Sheet

PRODUCTION ORDER# 500000046052

OPER 500.0

▲13 & ▲21 Max OD Gauge Check for the manufacturing lot PRIOR TO AND AFTER Inspection

Before & After Inspecting Parts	Dimension ## Gauge Check	TMI##XX (Ex. TMI0748AC or TMI0747AD)	Initials	Date	Time
Before	Dimension 13	TMI 0748AN	LY	11 Jan 21	12:30AM
Before	Dimension 21	TMI 0747U	LY	11 Jan 21	12:30AM
After	Dimension 13	TMI 0748AN	CL	12 Jan 21	2:00PM
After	Dimension 21	TMI 0747U	CL	12 Jan 21	2:00PM

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OPER 500.0

Pressure Decay Testing

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
Air Leak Test GN 15	N/A	100%	Issac Pressure Decay Tester	TMU 0747B	480	0	CKU 12 Jan 21
Outer Diameter ▲ 13 MAX OD at Pad Printed Area Drop Go Gauge from proximal end of shaft. Pass if ring stops at stop sleeve shoulder. Fail if gauge stops above or falls past stop sleeve shoulder.	0.145" +0.002"/- 0.004" (≤0.147")	100%	Ring Gauge TMI0748 or equivalent	TMU 0748 AND 471		15	CKU 12 Jan 21 OD fail
Outer Diameter ▲ 21 MAX OD Drop Go Gauge from stop sleeve shoulder. Pass if ring does not stop. Fail if ring stops less than 4" distal above stop sleeve shoulder.	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TMI0747 or equivalent	TMU 0747W	471	0	CKU 12 Jan 21

PRODUCTION ORDER# 66052

OP 1000.0 ▲13, ▲21 Max OD Gauge Check for the manufacturing lot **PRIOR TO AND AFTER** Inspection

Before & After Inspecting Parts	Dimension ## Gauge Check	TMI##XX (Ex. TMI0748AC or TMI0747AD)	Initials	Date	Time
Before	Dimension 13	TMI 0748 AM	CV	20 Jan 21	9:30 AM
Before	Dimension 21	TMI 0747 T	CV	20 Jan 21	9:30 AM
After	Dimension 13		CL		
After	Dimension 21	TMI 0748 AM	CL	21 Jan 21	6:00 AM
		TMI 0747 T		21 Jan 21	6:00 AM



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Document No: FM5104696

Rev: B Document Type: Manufacturing Form
Title: SA0254 In-Process Inspection Form

66052

PRODUCTION ORDER#

OP 1000.0

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
Outer Diameter ▲13 MAX OD at Pad Printed Area Drop Go Gauge from proximal end of shaft. Pass if ring stops at stop sleeve shoulder. Fail if gauge stops above or falls past stop sleeve shoulder.	0.145" +0.002"/-0.004" (≤0.147")	100%	Ring Gauge TMI0748 or equivalent	TM10748 100% 1/10/21	468	3	ASD NT 20 Jan 21 CKY 21 Jan 21
Outer Diameter ▲21 MAX OD Drop Go Gauge from stop sleeve shoulder. Pass if ring does not stop. Fail if ring stops less than 4" distal above stop sleeve shoulder.	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TMI0747 or equivalent	TM10747 100% 1/10/21	455	13	ASD NT 20 Jan 21 CKY 21 Jan 21
Outer Diameter ▲12 MAX OD Go-gauge: Measure from distal end to minimum 1.7" from tip. Gravity force only.	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0967, or equivalent	TM10967 100% 1/10/21	449	6	ASD NT 20 Jan 21 CKY 21 Jan 21
Outer Diameter ▲12 MIN OD No-go gauge: End must not pass through	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0968, or equivalent	TM10968 100% 1/10/21	449	0	ASD NT 20 Jan 21 CKY 21 Jan 21
Outer Diameter ▲18 MAX OD Measure from proximal end of shaft to the material transition.	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TM11 50049 100% 1/10/21	446	3	ASD NT 20 Jan 21 CKY 21 Jan 21
Outer Diameter ▲18 MIN OD Measure from proximal end of shaft to the material transition.	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TM11 50049 100% 1/10/21	446	0	ASD NT 20 Jan 21 CKY 21 Jan 21

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Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
Outer Diameter ▲3 AVG OD at Pad Printed Area Measure from distal end of material transition to stop sleeve shoulder NOTE: Measure AVG OD and record results	0.145 +0.002"/-0.004" (0.141"-0.147")	100%	Two Axis Laser Micrometer	TMI 50049	446	0	CKY 20 Jan 21 ASD 21 Jan 21
Outer Diameter ▲21 AVG OD Measure from stop sleeve shoulder to 4" distal of stop sleeve shoulder. NOTE: Measure AVG OD and record results	0.157" ± 0.003" (0.154"-0.160")	100%	Two Axis Laser Micrometer	TMI 50049	446	0	CKY 20 Jan 21 ASD 21 Jan 21
Outer Diameter ▲17 AVG OD Measure 4" distal the stop sleeve shoulder to the braid termination. NOTE: Measure and Record results	0.157" ± 0.003" (0.154"-0.160")	100%	Two Axis Laser Micrometer	TMI 50049	446	0	CKY 20 Jan 21 ASD 21 Jan 21
Outer Diameter ▲2 MAX OD Measure distally from the braid termination to the all the way distal end of the shaft.	0.142" ± 0.002" (0.140"-0.144")	100%	Two Axis Laser Micrometer	TMI 50049	446	0	CKY 20 Jan 21 ASD 21 Jan 21
Outer Diameter ▲2 MIN OD Measure distally from the braid termination to the all the way distal end of the shaft.	0.142" ± 0.002" (0.140"-0.144")	100%	Two Axis Laser Micrometer	TMI 50049	446	0	CKY 20 Jan 21 ASD 21 Jan 21



Document No: FM5104983

Rev: B

Document Type: Manufacturing Form

Title: SA0254 Cause of Rework Form

PRODUCTION ORDER# 66052

OPER 1050.0

Date	Initial	AB	DISC	DF	DS	EW	FM	OD	SCR	SKV	VD	OTHER
13 Feb 21	N/A	O	O	O	O	O	O	O	10	O	O	O

Record total quantity reworked:

10

Quantity Passed after Rework:

10

Rework Performed by: VC Date: 19 Feb 21 Rework Performed by: N/A Date: N/A

Re-Inspection Performed by: AP Date: 19 Feb 21

Maximum Force Reached During Tensile Test
 (10 samples accepted from final inspection for each lot shall be randomly selected
 and tensile tested)

Sample # →	1	2	3	4	5	6	7	8	9	10	Avg	St Dev	K	Calculated Lower Bound	Min Spec	Pass / Fail
Seg 1	27.24	26.3	28.11	26.15	31.64	26.88	26.15	26.69	37.48	28.13	28.477	3.561473	4.378	12.88487116	8.542	PASS
Seg B	22.12	21.89	21.65	22.1	21.82	21.24	21.9	22.22	26.17	25.58	22.669	1.7177857	4.378	15.14853412	8.542	PASS
Seg C	52.66	54.16	51.64	47.86	48.75	50.04	55.43	51.46	53.02	61.4	52.642	3.8601923	4.378	35.74207819	8.542	PASS

All Force Values are recorded in Pound-Force and Distance is in Inches
 Specification for lower bound is 38N was converted to 8.542lbf
 First Peak Force was collected during test and has been included in the raw data file. This information will not be captured/summarized in the DA due to it not being required for DA acceptance.

Kochyu Lee

24 JAN 21

LOT #: EDW50000066052
 Date: 24 JAN 2021
 Inspector Name: KOCK YU LEE
 Equipment ID: TM10311B
 Cal Due Date: 02 OCT 2021

**EDW Commander Balloon - Bend and
 Tensile Strength Testing**

TEST DATA SHEET

Sample	Dim 12 (Max) 0.142" +/- 0.002	Dim 12 min 0.142" +0.002	N/A	Dim 13 Avg 0.145" +0.002" -0.004"	Dim 13 Max 0.145" +0.002" -0.004"	Comments: N/A
1	0.1423	0.1405		0.1446	0.1457	
2	0.1431	0.1423		0.1452	0.1458	
3	0.1426	0.1417		0.1445	0.1454	
4	0.1425	0.1417		0.1445	0.1452	
5	0.1429	0.1421		0.1446	0.1455	
6	0.1428	0.1420		0.1444	0.1452	
7	0.1434	0.1426		0.1448	0.1458	
8	0.1436	0.1428		0.1446	0.1452	
9	0.1424	0.1416		0.1447	0.1457	
10	0.1430	0.1422		0.1448	0.1461	
11						
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Test Description: Dim 12 and 13 variable data recording

Lot Number: 502200066052

Tested by:

C Ky

Date: 20 Jan 21

Part Number: SA0254-xx 06

REQUESTOR Name: Saroenu Chhunm			
Document Number Affected			
Revision			
2100586			
Deviation From:			
100% Inspections at Final Inspection (Do <input type="checkbox"/> Not) Require SmartSolve Notification to be issued).			
For products listed below, SmartSolve Notification is not required for any sum of scraps at final inspection: SA0286-01 & -02; SA0254-04, -05 & -06; SA0155-01			
The following rules apply to these product families: If there is a characteristic that is 100% inspected at Final Inspection, and this product is an Edwards product line there is a 35% allowance to scrap at final inspection.			
All lots undergo 100% visual inspection; therefore, there is no risk to the customer for lots released without documenting in the SmartSolve notification.			
Justification:			
Part Number Affected			
SA0286-01 07 SA0286-02 07 SA0254-04 G SA0254-05 G SA0254-06 G SA0155-01 F			
Revision			
SA0286-01 07 SA0286-02 07 SA0254-04 G SA0254-05 G SA0254-06 G SA0155-01 F			
Start Date: End Date: Lot Number: 15Jan2021 22Jan2021 N/A			
Risk Assessment: Is there any potential risk(s) that may occur as a result of the proposed deviation including the following: Control Plans <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No FMEA's <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Validations <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Details (if any): If yes to any above, what controls are being put in place to mitigate the risk: N/A			
Corrective Action Required: If no, explain: No correction is required, SAP will address all lot manufactured in the new system.			
Training Required: If yes <input type="checkbox"/> No <input checked="" type="checkbox"/> If no, explain:			
Title Approval Name Approval Signature Date Quality Director Jeff Pumper Zach Nelson 15 Jan 2021 OPS Manager Jeff Pumper Zach Nelson 15 Jan 2021 Staff Engineer Vick Banegaswami PG22 15 Jan 2021 Deviation Authorization FM0002.REV.F			