

Production Order: 500000292877



Production Order Document
Production Order Qty: 500
PC
Sheet: 1 of 1

Material: SA0254-06 Rev G

Material Type: ZFRT Description: Printed Shaft 144C Prox End Color B CMDR
Production Version: 7999
Plant / Business Unit: 1213 / AC5

Order Type: ZSTD

Project Phase:

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
50	CATASY04 Catheter Assembly 4 Count: Yes 	Prepare Materials ·MPI0398 Rev. AH Line Clearance ·MPI0230 Rev. F By: CV 40 Date: 03 Jan 24	500	0	03Jan24	CV40
100	CATASY04	Straighten First Jacket MPI0398 Rev. AH	N/A	N/A	N/A	N/A

Notes: DA 2581.

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details						Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used				
150	Catheter Assembly 4										
	Straighten First Jacket	1000-1190-01	A A	FT	2708.350	0000289940	2,808.350			03Jan24	BK05
	Confirmation Reqd(Milestone)						N/A	N/A			
150	CATASY04 Catheter Assembly 4	Positioning Braid Over First Jacket MPI0398 Rev. AH Record Braid Pic Count for 15 parts below: Braid Production Lot No: 0000284480	1. 40 2. 40 3. 40 4. 40 5. 40 6. 40 7. 40 8. 40 9. 40 10. 40 11. 40 12. 40 13. 40 14. 40 15. 40							03Jan24	SP63 VV84 VJ06 M106 MY71 (TRN) NT35
	Positioning Braid Over First Jacket	If more than braid production lot is used for The build, record the braid pic count for 15 parts for the second braid production lot below. Enter N/A if only one braid production lot is used for the build.									
	Confirmation Reqd(Milestone)										

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details					Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
)	Braid Production Lot No: <u>0000286483</u>	1. <u>40</u>	2. <u>40</u>	3. <u>40</u>	4. <u>40</u>	5. <u>40</u>	6. <u>40</u>	7. <u>40</u>	8. <u>40</u>
			9. <u>40</u>	10. <u>40</u>	11. <u>40</u>	12. <u>40</u>	13. <u>40</u>	14. <u>40</u>	15. <u>40</u>	
		Component Number	Req'd Rev	UOM	Qty.	Batch No.	Actual Qty Used			
		MM0189-01	D <u>D</u>	PC	500	<u>0000286480</u>	<u>221</u>	N/A	N/A	N/A
						<u>0000286483</u>	<u>295</u>			
		RM0096-01	F <u>E</u>	PC	34	<u>84673</u>	<u>34</u>	N/A	N/A	
200	CATASY04 Catheter Assembly 4	Strain Relief Reflow MPI0398 Rev. <u>AH</u> Temp = 420°F 5°F Air Flow = 60 SCFH						500	0	03Jan24 SF35 16126 TRN M/28 NT35

Notes:

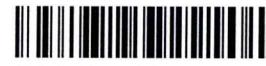
N/A

N/A

N/A

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		Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used				
	Strain Relief Reflow n/a Confirmation Reqd(Milestone)	RM0096-01	F F	PC	167	84673 82176	66 100	n/a	n/a	n/a	
		MM0527-01	C C	PC	500	0000276169	500	n/a	n/a	n/a	
250	CATASY04 Catheter Assembly 4 Position Tubing for Reflow	Position Tubing For Reflow MPI0398 Rev. AH						500	0	03Jan24	CX32 CL94 SX66 MY34
		Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used				
	Position Tubing for Reflow	MM0186-00	D D	PC	500	0000282491	500 n/a n/a				
		MM0523-03	C C	PC	500	0000244863	500 n/a n/a				

Notes:

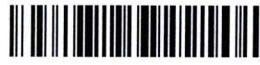
n/a

n/a

n/a

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Opr No.	Planned WorkCenter Description	Operation Details						Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
R N/A	MM0524-01	B	<u>B</u>	PC	500	0000265904	500				
	MM0530-01	B	<u>B</u>	PC	500	0000276170	500				
	RM7586-02	D	<u>D</u>	PC	500	83420	500				
	MM0185-01	I	<u>I</u>	PC	500	82839	91				
	MM1539-01	A	<u>A</u>	PC	500	0000281409	500	N/A	N/A	N/A	N/A
	TL5909-01	B	<u>N/A</u>	PC	5	0000278969	500				
	RM016101-MED	F	<u>E</u>	PC	125	82407	125				
	MM1540-01	B	<u>B</u>	PC	500	0000278958	500				

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	N/A N/A	N/A	N/A	N/A	N/A
300	CATASY04 Catheter Assembly 4 	Reflow MPI0398 Rev. AH Temp = 415°F (+/- 15 °F) Speed = 4.5 in/min (+/- 0.5 in/min)	500	0	03Jan24 EE65 SS79	
	Reflow	Component Number Req'd Rev Rev Used UOM Qty. Batch No. Actual Qty Used				
		1000-1154-01 A A PC 500 860147 200 860144, 860146 200, 100				
350	CATASY04 Catheter Assembly 4 	Skive Heat Shrink MPI0398 Rev. AH	500	0	04Jan23 AD00	
	Skive Heat					

Notes: N/A
N/A
N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Shrink	N/A	N/A	N/A	N/A	N/A
400	CATASY04 Catheter Assembly 4 Count: Yes 	In-Process Inspection (Visual Inspection) MPI0398 Rev. AH FM5104693 (Rework if needed. Use FM5104983)	497	EW-1 DF-11 ③	O4 Jan 23	AN00
450	CATASY04 Catheter Assembly 4 	Anneal Shaft MPI0398 Rev. AH FM5104692	497	D	O4 Jan 23	AN00
Notes: N/A						
N/A						
N/A						

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N/A	Anneal Shaft	N/A	N/A	N/A	N/A	N/A
500	CATASY04 Catheter Assembly 4 	Leak Test/Prox Cut/Ring Gage-Dim 13/21 MPI0398 Rev. AH FM5104694 FM5104695 Leak Test/Prox Cut/Ring Gage-Dim 13/21 (Rework if needed - Use FM5104983)	482	0 D13 777 777 1111 LT-1	04 Jan 23	MP06 S886
550	CATASY04 Catheter Assembly 4 	Distal Cut MPI0398 Rev. AH Line Closure MPI0230 Rev. F By: _____ Date: 04 Jan 23	482	0	04 Jan 23	MB23 PK15 VX41
600	PADPRIN1 Pad Print 	Pad Print Set Up MPI0276 Rev. F	250	0	04 Jan 24	PK15

Notes:

N/A

N/A

N/A

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Op No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	<p>Count: Yes </p> <p>Pad Print Setup <i>N/A</i></p>	<p>Line Clearance MPI0230 Rev. <u>F</u></p> <p>By: <u>LW04 TRN</u> Date: <u>04JAN24</u></p> <p><i>GL42</i></p> <p>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</p> <p>TMI0735 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</p>	<i>482</i>	<i>0</i>	<i>04JAN24</i>	<i>LW04 TRN GL42</i>

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		<i>N/A GL42 TRN LV04 04JAN24</i>				
650	PADPRIN1 Pad Print  Verification	Verification MPI0276 Rev. <u>F</u> Section 15.0	250 232	0 0	04Jan24 04JAN24	PK15 LV04 TRN GL42

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details						Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
MA	N/A	RM7408-01	B	<u>B</u>	L	0.005	<u>66780</u>	<u>0.010</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
		RM7409-01	B	<u>B</u>	L	0.010	<u>85169</u>	<u>0.020</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
700	PADPRIN1 Pad Print 	Prepare Surface for Ink MPI0276 Rev. <u>F</u> Section 15.5 Polynit wipes 99% IPA					250	0	04Jan24	PK15	
	Prepare Surface for Ink						232	0	04JAN24	LW04 TRN GL42	
750	PADPRIN1 Pad Print 	Print Parts MPI0276 Rev. <u>F</u> Section 20.0 Inspection gauge TMI0843					250	0	04Jan24	PK15	
	Print Parts						232	0	04Jan24	LW04 TRN GL42	

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty	Scrap Qty & Desc.	Date Comp.	Initials
800	PADPRIN1 Pad Print  In-process Inspection and Rework	In-Process Inspection and Rework MPI0276 Rev. <u>F</u> Section 30.0 Polynit Wipes 99% IPA Mag Light	250 232	0 0	04Jan24 04JAN24	PK15 LV04 TRN GL42
850	PADPRIN1 Pad Print  Curing Oven Confirmation Reqd(Milestone)	Curing Oven MPI0340 Rev. <u>B</u> Section 35.0 Curing oven for 120 +30/-15 minutes Parts sit for 8 hours minimum after curing oven Lot Completion time: <u>11:30PM</u> By: <u>LV04</u> Date: <u>04-Jan-24</u> TRN GL42	250 232	0 0	04Jan24 04JAN24	PK15 LV04 TRN GL42
900	PADPRIN1 Pad Print	Transfer Parts to Quality MPI0276 Rev. <u>F</u> Section 40.0	482	0	05Jan24	PK15
Notes: N/A N/A N/A						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Transfer parts to QA Confirmation Reqd(Milestone)	Transfer Parts to Line Time: 7:30 AM By: PK15 Date: 05 Jan 24	N/A	N/A	N/A	N/A
950	PADPRIN1 Pad Print Count: Yes Confirmation Reqd(Milestone)	Cleaning MPI0276 Rev. F Section 50.0 Line Clearance MPI0230 Rev. F By: PK15 Date: 05 Jan 24	482	0	05 Jan 24	PK15
1050	QUALITY1	Required Inspection	N/A	N/A	N/A	N/A

Notes:
N/A
N/A
N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty	Scrap Qty & Desc.	Date Comp.	Initials
1050	Quality Inspection & Review 	Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	457	11-OD/13 3-SL/GN6 1-IB 4-SCR 2-FIB 2-TT 1-FM 1-DS	06 JAN 24	AT87 KL45 XX66 mY28 YK95 AJ74 LT03
1070	CATASY04 Catheter Assembly 4 Rework Process Confirmation	Rework MPI0398 Rev. _____ Material consumed Material _____ AJ74 Batch Rev _____ Qty _____ Material _____ AJ74 Batch Rev _____ Qty _____ 06 Jan 2024	457	0	06 JAN 24	AJ74

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
1090	QUALITY1 Quality Inspection & Review  Quality Inspection & Review Confirmation Reqd(Milestone)	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	457	0	06 Jan 24	Aj74 L103
1100	PACKINT1 Packing assembly 	Packaging Instructions SPI0087 REV. O	457	0	08 Jan 24	AB10

Notes:

N/A AB10 08 Jan 24

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① Aj74 06 Jan 24

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty	Scrap Qty & Desc.	Date Comp.	Initials
	Packing Instructions					
	Confirmation Reqd(Milestone)	<i>U/A AF10 08 Jan 24</i>				

Notes:

U/A AF10 08 Jan 24

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Batch Number: 0000292877

By: AB10

Date: 08 Jan 24

Reviewed By:

RB29

Date:

08 JAM 24

Notes:

N/A AB10 08 Jan 24

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DEVIATION AUTHORIZATION FORM

Requestor Name:	Geoffrey Dybicz		
Document Number Affected	Revision		
3107613	I		
Deviation From: <p>MIC # Test/Specification Dimensions Sampling Equipment US100585 Distal Segment without Braid GN 6 View perpendicular to table. Pass if braid ends in "Acceptable Braid" region. Fail if braid ends in "No Braid Area" or "Must Have Braid" region. Record Summary PASS/FAIL 2.0" ± 0.3" 100% TMI0724 + TMI0724 + Fiber Optic Light.</p>	Deviation To: <p>MIC # Test/Specification Dimensions Sampling Equipment US100585 Distal Segment without Braid GN 6 View perpendicular to table. Pass if braid ends in "Acceptable Braid" region. Fail if braid ends in "No Braid Area" or "Must Have Braid" region. Record Summary PASS/FAIL 2.0" ± 0.3" 200% TMI0724 + Fiber Optic Light. A different inspector must perform the second round of inspections. The second inspector should only inspect parts that passed the first round of inspections. Use attached form to record the results of both inspections. Notify engineering immediately if the second inspector rejects any parts.</p>		

Justification: Edwards has initiated SCAR-001909 as a result of three escapes for GN6. They are now 100% inspecting for this feature, instead of AQL. In order to successfully close the SCAR, we need to eliminate any additional escapes. This deviation will be used to catch any potential escapes while permanent corrective actions are implemented.

Part Number Affected	Revision		
SA0254 - All Tabs	F		
Start Date:	End Date:	Lot Number:	
20Dec2023	31Jan2024	All Lots	
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 of the above, what controls are being put in place to mitigate the risk			
Corrective Action Required: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Change plan to follow for Document update		
If no, explain:			
Training Required: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If no, explain:		
Title	Approval Name	Approval Signature	Date
Manager, Manufacturing Engineering	Jake Stanislowski		20 Dec 2023
Quality Manager	Jay Zabel		20 Dec 2023
Manager, Operations	Matthew Benson		20 Dec 2023

Deviation Authorization 2581 Secondary Inspection Record

100% GN6 Inspection #1		100% GN6 Inspection #2	
Inspector Initials	YK95	Inspector Initials	XX66
Date Completed	05 Jan 24	Date Completed	05 Jan 24
Time Completed	2 Hr 30 Min	Time Completed	2 hrs 15 min
Units Passing	247 + 468	Units Passing	468
Units Failing	3	Units Failing	0

Note: 100% GN6 inspection must be performed twice.

Note: The second round of inspections must be completed by a different inspector.

Inspections may not occur concurrently.

Note: Notify engineering immediately if the second inspector rejects any units.

① YK95 05 Jan 24

PRODUCTION ORDER# 500000292877

Document No: FM5104693
Rev: C
Document Type: Manufacturing Form
Title: SA0254 In-Process Inspection Form

OPER 400.0

In-Process Inspection (Visual 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%	Inspect at a minimum of 2.85x magnification		500	0	AN00 04Jan23
Metallic Foreign Material: No embedded metallic and foreign material is allowed along the length of the shaft.	N/A	100%	Inspect at a minimum of 2.85x magnification		500	0	
All other Foreign Material:	See Table	100%	Use a calibrated Tappi Chart and Inspect at a minimum of 2.85x magnification		500	0	
No surface damage to the shafts such as voids pits or cuts. (interior surface of distal end not included)	N/A	100%	Inspect at a minimum of 2.85x magnification		498	2	
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%	Inspect at a minimum of 2.85x magnification		498	0	
No flat spots, kinks, delamination, gaps between material transitions and material transitions should no exhibit cracking, no exposed or apparent braid.	N/A	100%	Inspect at a minimum of 2.85x magnification		497	1	
Measured material overflow on proximal end of stop sleeve must be $\leq 0.02"$ (i.e., 0.2 mm ² dot on Tappi chart).	$\leq 0.2 \text{ mm}^2$	100%	Use a calibrated Tappi Chart and Inspect at a minimum of 2.85x magnification	N/A	497	0	AN00 04Jan23

PRODUCTION ORDER# 50000292877

Attachment B: Cause of Rework.

OPER 400.0

Date	Initial	AB (Prox)	AB (Distal)	DF	DS	EW	FM	Disc	SCR	SKV	VD
04Jan24	AN00	○	○	○	○	○	6	○	○	○	○

N/A AN00 04 Jan 24

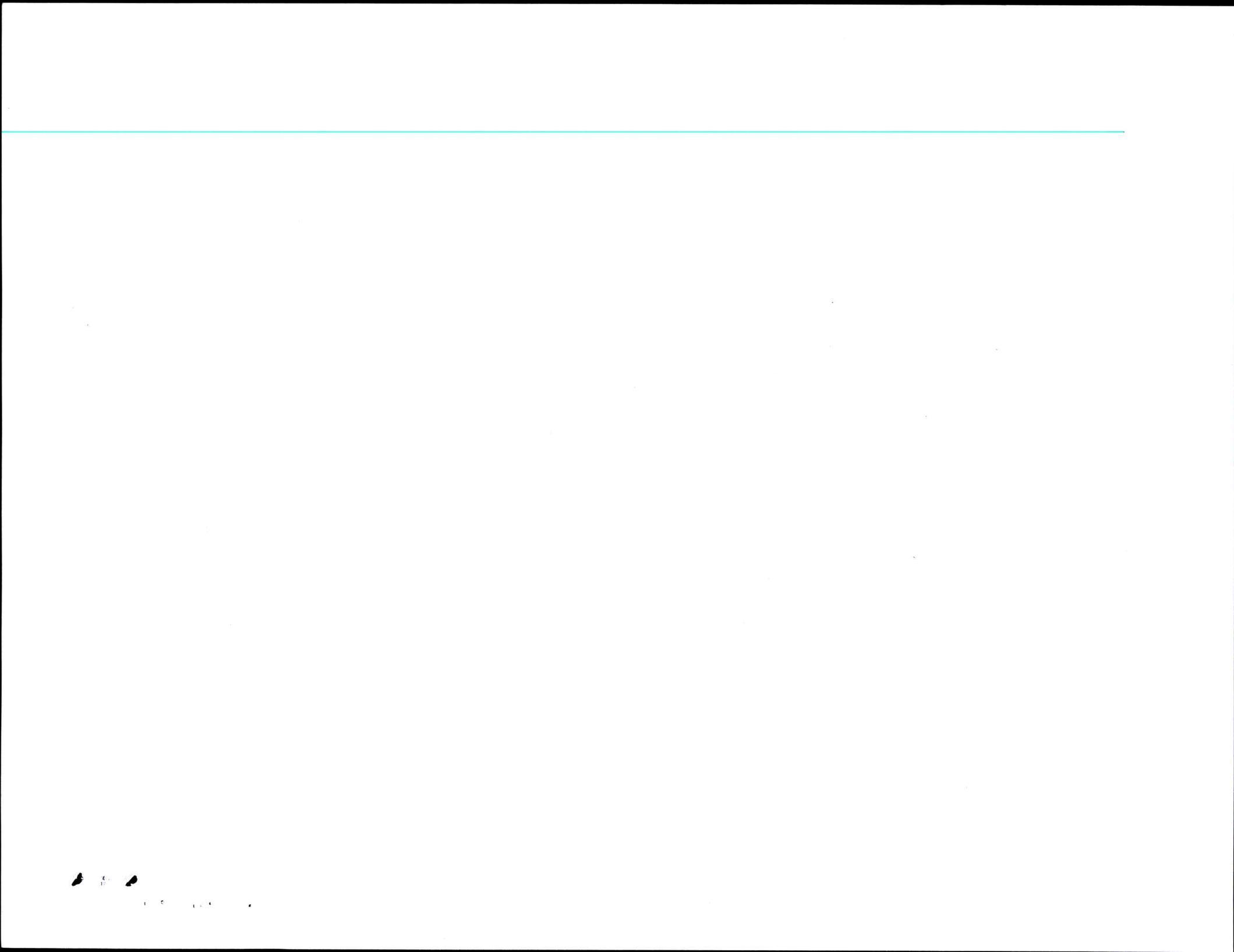
Attachment B: Cause of Rework

OPER 500.0

Date	Initial	Dim 13 (Go Gauge)	Dim 21 (Go gauge)

N/A SQ86 ① 04Jan24 ①
 ② 04Jan25

① 1445 08Jan24



Document No: FM5104694
 Rev: B
 Document Type: Manufacturing Form
 Title: SA0254 Max OD Gauge Check Form

① 500000292877
 PRODUCTION ORDER# 50000028

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	TMI0748AM	1445	04Jan24	10:30 AM
Before	Dimension 21	TMI0747X	1445	04Jan24	10:30 AM
After	Dimension 13	TMI0748AM	NT35	① 04Jan24 04Jan23	07:15PM
After	Dimension 21	TMI0747X	NT35	① 04Jan24 04Jan23	07:15PM

① MP06 04 Jan 24

Document No: FM5104695
 Rev: C
 Document Type: Manufacturing Form
 Title: SA0254 Pressure Decay Testing Form

PRODUCTION ORDER# SC0000292877

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	TMI0797B	1	496	SP86 ① 04 Jan 23 04Jan24
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	TMI0748TM	14	482	SP86 ① 04 Jan 24 04 Jan 23
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 from stop sleeve shoulder.	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TMI0747	TMI0747X	0	482	SP86 ① 04 Jan 23 04Jan24

① 1445 08 Jan 24

Document No: FM5104983
Rev: B
Document Type: Manufacturing Form
Title: SA0254 Cause of Rework Form

PRODUCTION ORDER# _____

OPER 1050.0

Date	Initial	AB	DISC	DF	DS	EW	FM	OD	SCR	SKV	VD	OTHER

Record total quantity reworked:

Quantity Passed after Rework:

Rework Performed by: _____ Date: _____ Rework Performed by: _____ Date: _____

Re-Inspection Performed by: _____ Date: _____

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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	EDW Commander Balloon - Bend and Tensile Strength Testing		
Seg 1	28.73	26.53	29.46	30.44	26.85	26.25	28.81	25.84	26.6	31.04	28.055	1.8754866	4.378	19.84411965	8.542	PASS	LOT #: 500000 292877		
Seg B	22.01	23.17	24.24	22.68	22.76	20.78	21.95	20.49	21.07	20.97	22.012	1.2074749	4.378	16.72567503	8.542	PASS	Date: 08 JAN 2024		
Seg C	51.54	48.41	49.8	49.36	52.69	53.54	50.06	52.48	54.19	54.77	51.684	2.1914338	4.378	42.0899027	8.542	PASS	Inspector Name: KOCK YU LEE		
																Equipment ID: TMI0311B			
																Cal Due Date: 27 OCT 2024			

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.

KINK TEST AND BEND TEST PERFORMED .

Kochyong Lee

08JAN24