

# Production Order: 500000292876



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	Order Type: ZSTD
Production Version:	7999		Project Phase:
Plant / Business Unit:	1213 / AC5		

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. <u>AH</u>  Line Clearance MPI0230 Rev. <u>F</u>  By: <u>NT35</u> Date: <u>03 Jan 24</u>	500	0	03 Jan 24	NT35
100	CATASY04	Straighten First Jacket MPI0398 Rev. <u>AH</u>	N/A	N/A	N/A	N/A

Notes: DA2581

N/A

N/A

Date Printed: 03.01.2024 / 02:07:23

Page: 1 of 17



SA0254-06

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000292876



Production Order Document  
Production Order Qty: 500

PC

Sheet: 1 of 1

## Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Catheter Assembly 4										
N/A	Straighten First Jacket	Component Number	Req'd Rev Rev	UOM	Qty.	Batch No.	Actual Qty Used	500	0	03 Jan 24	AQH
		1000-1190-01	A A	FT	2708.350	0000289946	3,108.360				
	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: 0000286458	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					500	0	03 Jan 24	SP63 VJ06 CX32 CL94
	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.									
Notes:											
N/A											
N/A											
N/A											

Date Printed: 03.01.2024 / 02:07:23

Page: 2 of 17



SA0254-06

CREGANNA MEDICAL  
is part of



## Production Order: 500000292876



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

Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details					Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials											
		Braid Production Lot No: 0000286480	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	N/A	03 Jan 24	① ADLZ	
		Component Number	Req'd Rev	UOM	Qty.	Batch No.	Actual Qty Used														
		MM0189-01	D	D	PC	500	0000286458	262	0000286480	268	RM0096-01	F	F	PC	34	82176	34	N/A	N/A	03 Jan 24	① NY45

Notes:

N/A

N/A

N/A

Date Printed: 03.01.2024 / 02:07:23

Page: 3 of 17



SA0254-06

① NY45 03 Jan 24  
CREGANNA MEDICAL  
is part of



# Production Order: 500000292876



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

## Material: SA0254-06 Rev G

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				
N/A	Strain Relief Reflow  Confirmation Reqd(Milestone )	RM0096-01	F <u>F</u>	PC	167	82176	164				
		MM0527-01	C <u>C</u>	PC	500	0000276169	500	N/A	N/A	03Jan23	
250	CATASY04  Catheter Assembly 4  Position Tubing for Reflow	Position Tubing For Reflow MPI0398 Rev. <u>AH</u>						500	0	03Jan23	SP63 VJ06 CX32
		Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used				
		MM0186-00	D <u>D</u>	PC	500	0000275689	18				
						0000282491	482				
		MM0523-03	C <u>C</u>	PC	500	0000244863	500	N/A	N/A		

Notes:

N/A

N/A

N/A

Date Printed: 03.01.2024 / 02:07:23

Page: 4 of 17



SA0254-06

CREGANNA MEDICAL  
is part of



# Production Order: 500000292876



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

## Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details						Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	MM0524-01	B	<u>B</u>	PC	500	0000273850	500	N/A		
		MM0530-01	B	<u>B</u>	PC	500	0000247129	500	N/A		
		RM7586-02	D	<u>D</u>	PC	500	83420	250			
							82839	250			
		MM0185-01	I	<u>I</u>	PC	500	0000281409	500	N/A		
		MM1539-01	A	<u>A</u>	PC	500	0000278949	500	N/A		
		TL5909-01	B	<u>N/A</u>	PC	5	N/A		N/A		
		RM016101-MED	F	<u>E</u>	PC	125	82407	125	N/A		
		MM1540-01	B	<u>B</u>	PC	500	0000278958	500	N/A		

Notes:

N/A

N/A

N/A

Date Printed: 03.01.2024 / 02:07:23

Page: 5 of 17



SA0254-06

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000292876



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

## Material: SA0254-06 Rev G

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
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	03 Jan 24	EELST
	Reflow	Component Number Req'd Rev Rev Used UOM Qty. Batch No. Actual Qty Used	1000-1154-01 A    A PC    500 86146    300 86147    200 86115    11			
350	CATASY04 Catheter Assembly 4 	Skive Heat Shrink MPI0398 Rev. AH	500	0	04 Jan 24	M106 VX41 AN00
	Skive Heat					

Notes:

N/A

N/A

N/A

Date Printed: 03.01.2024 / 02:07:23

Page: 6 of 17



SA0254-06

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000292876



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

## Material: SA0254-06 Rev G

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
400	CATHASY04  Catheter Assembly 4  Count: Yes  In Process Inspection	In-Process Inspection (Visual Inspection) MPI0398 Rev. AH  FM5104693  (Rework if needed. Use FM5104983)	495	EW-III BS - 1 ⑤	04-Jan-24	VX41 AN00
450	CATHASY04  Catheter Assembly 4	Anneal Shaft MPI0398 Rev. AH FM5104692	495	0	04-Jan-24	VX41 AN00
Notes:						
N/A						
N/A						
N/A						

Date Printed: 03.01.2024 / 02:07:23

Page: 7 of 17



SA0254-06

CREGANNA MEDICAL  
is part of



**Production Order: 500000292876**

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

**Material: SA0254-06 Rev G**

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Anneal Shaft	MIA	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)	493	OP13-11 04Jan24 ②	S286 mp06	
550	CATASY04  Catheter Assembly 4  	Distal Cut MPI0398 Rev. AH Line Closure MPI0230 Rev. F By: mp06 Date: 04 Jan 24  Distal Cut	493	0 04Jan24	M106 MB23	
600	PADPRIN1  Pad Print  	Pad Print Set Up MPI0276 Rev. F	493	0 04Jan24	PK15	

**Notes:**

N/A

N/A

N/A

Date Printed: 03.01.2024 / 02:07:23

Page: 8 of 17



SA0254-06

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000292876



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

## Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details	Comp Cty.	Scrap Qty & Desc	Date Comp.	Initials
N/A	Count: Yes  Pad Print Setup	Line Clearance MPI0230 Rev. <u>F</u> By: <u>PK15</u> Date: <u>04 Jan 24</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	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	N/A	N/A	N/A

Notes:

N/A

N/A

N/A

Date Printed: 03.01.2024 / 02:07:23

Page: 9 of 17



SA0254-06

CREGANNA MEDICAL  
is part of



Production Order: 500000292876



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

Material: SA0254-06 Rev G

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
650	PADPRIN1 Pad Print  Verification	Verification MPI0276 Rev. <u>F</u> Section 15.0	493	0	04Jan24 PK15	

Notes:

N/A

N/A

N/A

Date Printed: 03.01.2024 / 02:07:23

Page: 10 of 17



SA0254-06

CREGANNA MEDICAL  
is part of



**Production Order: 500000292876**

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

**Material: SA0254-06 Rev G**

Opr No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	RM7408-01	B	<u>B</u>	L	0.005	<u>66780</u> N/A	<u>0.005</u> N/A	N/A	N/A	N/A
		RM7409-01	B	<u>B</u>	L	0.010	<u>85169</u> N/A	<u>0.010</u> N/A			
700	PADPRIN1  Pad Print  	Prepare Surface for Ink MPI0276 Rev. <u>F</u> Section 15.5 Polynit wipes 99% IPA						493	0	04Jan24	PK15
750	PADPRIN1  Pad Print  	Print Parts MPI0276 Rev. <u>F</u> Section 20.0 Inspection gauge TMI0843						493	0	04Jan24	PK15
	Print Parts										

**Notes:**

N/A

N/A

N/A

Date Printed: 03.01.2024 / 02:07:23

Page: 11 of 17



SA0254-06

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000292876



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

## Material: SA0254-06 Rev G

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	493	0	04Jan24	PK15
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>12:42 PM</u> By: <u>PK15</u> Date: <u>04 Jan 24</u>	493	0	04Jan24	PK15
900	PADPRIN1 Pad Print	Transfer Parts to Quality MPI0276 Rev. <u>F</u> Section 40.0	493	0	04JAN24	LVO4 TRN GL42
Notes:  <u>N/A</u>  <u>N/A</u>  <u>N/A</u>						

Date Printed: 03.01.2024 / 02:07:23

Page: 12 of 17



SA0254-06

CREGANNA MEDICAL  
is part of



# Production Order: 500000292876



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

## Material: SA0254-06 Rev G

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: <u>9:15 PM</u> By: <u>LV04</u> Date: <u>04 JAN 24</u>  TRN GL42	N/A	N/A	N/A	N/A
950	PADPRIN1  Pad Print  Count: Yes  Line Clearance MPI0230 Rev. <u>F</u>	Cleaning MPI0276 Rev. <u>F</u> Section 50.0  Line Clearance MPI0230 Rev. <u>F</u>  By: <u>LV04</u> Date: <u>04 JAN 24</u>  TRN GL42	493	0	04JAN24	LV04 TRN GL42
1050	QUALITY1	Required Inspection	N/A	N/A	N/A	N/A

Notes:

N/A

N/A

N/A

Date Printed: 03.01.2024 / 02:07:23

Page: 13 of 17



SA0254-06

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000292876



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

## Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
10500	Quality Inspection & Review 	Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	459	4-IB 6-SLNG 2-000912 8-SCR 5-VB 5-TT 2-DSE 1-EW 1-FM	05Jan24	AT87 SB08 KL45 XXC6 CN70 LTO3 AT74 YK95
1070	CATASY04 Catheter Assembly 4  Rework Process Confirmation	Rework MPI0398 Rev. <u>N/A</u>  Material consumed Material _____ Batch _____ Rev _____ Qty _____ Material _____ Batch _____ Rev _____ Qty _____	459	0	05JAN24	LTO3

Notes:

N/A

N/A

N/A

Date Printed: 03.01.2024 / 02:07:23

Page: 14 of 17



SA0254-06

CREGANNA  
MEDICAL  
is part of



**Production Order: 500000292876**



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

**Material: SA0254-06 Rev G**

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	459	0	05 JAN 24	LTO3
1100	PACKINT1  Packing assembly  	Packaging Instructions SPI0087 REV. 0	459	0	08 Jan 24	ABTU

**Notes:**

N/A AD10 08 Jan 24

Date Printed: 03.01.2024 / 02:07:23

Page: 15 of 17



SA0254-06

CREGANNA MEDICAL  
is part of



**Production Order: 500000292876**



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

**Material: SA0254-06 Rev G**

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Packing Instructions					
	Confirmation Reqd(Milestone )	N/A AB10 08 Jan 24				

**Notes:**

N/A AB10 08 Jan 24

Date Printed: 03.01.2024 / 02:07:23

Page: 16 of 17



SA0254-06

**CREGANNA MEDICAL**  
is part of



**Production Order: 500000292876**



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

**Material: SA0254-06 Rev G**

**Batch Number:** 0000292876

**By:** A810

**Date:** 08 Jan 24

**Reviewed By:**

RB29

**Date:**

08 JAN 24

**Notes:**

N/A A810 08 Jan 24

Date Printed: 03.01.2024 / 02:07:23

Page: 17 of 17



SA0254-06

CREGANNA  
MEDICAL  
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## DEVIATION AUTHORIZATION FORM

Requestor Name: Geoffrey Dybicz

Document Number Affected	Revision
3107613	I

## Deviation From:

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  $2.0" \pm 0.3"$  100% TM10724 + TM10724 + 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.

**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	End Date:	Revision
SA0254 – All Tabs	31Jan2024	F

Start Date:	End Date:	Lot Number:
20Dec2023		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  Yes  No FMEA's  Yes  No Validations  Yes  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 checked="" type="checkbox"/> No	Change plan to follow for Document update
If no, explain:			Tsia 21DEC23

Training Required:	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	If no, explain:
Manager, Manufacturing Engineering			
Quality Manager			
Manager, Operations			

Deviation Authorization 2581 Secondary Inspection Record			
100% GNG Inspection #1	100% GNG Inspection #2	Inspector Initials	Inspector Initials
05/20/24	05/20/24	AJTH	AJTH
Date Completed	Date Completed	05/20/24	05/20/24
Time Completed	Time Completed	1:45 PM	1:45 PM
Units Passing	Units Passing	487	487
Units Failed	Units Failed	0	0

Note: 100% GNG 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 engineer immediately if the second inspector rejects any units.

PRODUCTION ORDER# 50000292876

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

**OPER 400.0**

**In-Process Inspection (Visual Inspection)**

<b>Test/Specification</b>	<b>Dimensions</b>	<b>Sample Plan</b>	<b>Equipment</b>	<b>TMI/TL</b>	# <b>Pass</b>	# <b>Fail</b>	<b>Initial/Date</b>												
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 04 Jan 24												
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:																			
<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th><b>Particle Size</b> Area: mm<sup>2</sup></th> <th><b>Acceptable Limits per Part</b></th> </tr> </thead> <tbody> <tr> <td>&lt; 0.05 mm<sup>2</sup></td> <td>No Limit</td> </tr> <tr> <td>0.05 mm<sup>2</sup> ≤ Area &lt; 0.25 mm<sup>2</sup></td> <td>3</td> </tr> <tr> <td>0.25 mm<sup>2</sup> ≤ Area &lt; 0.80 mm<sup>2</sup></td> <td>2</td> </tr> <tr> <td>0.80 mm<sup>2</sup> ≤ Area ≤ 1.5 mm<sup>2</sup></td> <td>1</td> </tr> <tr> <td>&gt; 1.5 mm<sup>2</sup></td> <td>0</td> </tr> </tbody> </table>	<b>Particle Size</b> Area: mm <sup>2</sup>	<b>Acceptable Limits per Part</b>	< 0.05 mm <sup>2</sup>	No Limit	0.05 mm <sup>2</sup> ≤ Area < 0.25 mm <sup>2</sup>	3	0.25 mm <sup>2</sup> ≤ Area < 0.80 mm <sup>2</sup>	2	0.80 mm <sup>2</sup> ≤ Area ≤ 1.5 mm <sup>2</sup>	1	> 1.5 mm <sup>2</sup>	0	See Table	100%	Use a calibrated Tappi Chart and Inspect at a minimum of 2.85x magnification		500	0	
<b>Particle Size</b> Area: mm <sup>2</sup>	<b>Acceptable Limits per Part</b>																		
< 0.05 mm <sup>2</sup>	No Limit																		
0.05 mm <sup>2</sup> ≤ Area < 0.25 mm <sup>2</sup>	3																		
0.25 mm <sup>2</sup> ≤ Area < 0.80 mm <sup>2</sup>	2																		
0.80 mm <sup>2</sup> ≤ Area ≤ 1.5 mm <sup>2</sup>	1																		
> 1.5 mm <sup>2</sup>	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		500	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%	Inspect at a minimum of 2.85x magnification		500	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		495	5													
Measured material overflow on proximal end of stop sleeve must be ≤0.02" (i.e., 0.2 mm <sup>2</sup> dot on Tappi chart).	≤0.2 mm <sup>2</sup>	100%	Use a calibrated Tappi Chart and Inspect at a minimum of 2.85x magnification	N/A	495	0	AN00 04 Jan 24												





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

PRODUCTION ORDER# 500000292876

**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	M/28	04 Jan 24	12:30AM
Before	Dimension 21	TMI0747X	M/28	04 Jan 24	12:30AM
After	Dimension 13	TMI0748AM	1Y45	04 Jan 24	10:00AM
After	Dimension 21	TMI0747X	1Y45	04 Jan 24	10:00AM

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

PRODUCTION ORDER# 500000292876

**OPER 500.0**

**Pressure Decay Testing**

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
<b>Air Leak Test GN 15</b>	N/A	100%	Issac Pressure Decay Tester	TMI 0797B	495	0	MP06 04Jan24
<b>Outer Diameter ▲13 MAX OD at Pad Printed Area</b>  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	TMI 0748AM	493	2	MP06 04Jan24
<b>Outer Diameter ▲ 21 MAX OD</b>  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	TMI 0747X	493	0	MP06 04Jan24

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: \_\_\_\_\_

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	28.7	22.57	28.6	22.72	26.53	23.25	22.34	26.83	25.6	24.02	25.116	2.4668252	4.378	14.31623919	8.542	PASS
Seg B	21	21.72	24.51	20.76	21.56	20.99	21.13	20.23	19.87	21.37	21.314	1.2581927	4.378	15.80563233	8.542	PASS
Seg C	50.8	51.01	49.09	47.66	46.07	49.61	51.9	46.4	45.28	49.55	48.737	2.2769378	4.378	38.76856649	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.  
KINK TEST AND BEND TEST PERFORMED .

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

LOT #: 500000292876

Date:05JAN24

Inspector Name:Andrew Wipf

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 2024


05Jan24