

Production Order: 500000292875



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. AH Line Clearance MPI0230 Rev. F By: CV 40 Date: 02 Jan 24	500	0	03 Jan 23	CV 40
100	CATASY04	Straighten First Jacket MPI0398 Rev. AH	N/A	N/A	N/A	N/A

Notes: DA 2581

N/A

N/A

Date Printed: 02.01.2024 / 15:17:38

Page: 1 of 17



SA0254-06

CREGANNA
MEDICAL
is part of



Production Order: 500000292875



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

Material: SA0254-06 Rev G

Opn No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Catheter Assembly 4 Straighten First Jacket Confirmation Reqd(Milestone)	Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	500	0	03JAN24	XD12
		1000-1190-01	A A	FT	2708.350	0000289941	2,510				
						0000289946	598.350				
150	CATASY04 Catheter Assembly 4 Positioning Braid Over First Jacket Confirmation Reqd(Milestone)	Positioning Braid Over First Jacket MPI0398 Rev. AH Record Braid Pic Count for 15 parts below: Braid Production Lot No: 0000286459 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	W84 SS79 CL94 CX316 CX32	

Notes:

H/A

H/A

H/A

Date Printed: 02.01.2024 / 15:17:38

Page: 2 of 17



SA0254-06

(CX3203JAN24

CREGANNA
MEDICAL
is part of



Production Order: 500000292875



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: <u>0000286458</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>	
	N/A	Component Number	Req'd Rev	UOM	Qty.	Batch No.	Actual Qty Used			
		MM0189-01	D <u>D</u>	PC	500	<u>0000286459</u>	<u>278</u>			
						<u>0000286458</u>	<u>222</u>			
		RM0096-01	F <u>F</u>	PC	34	<u>84676</u>	<u>34</u>			
						<u>N/A</u>	<u>N/A</u>			
200	CATASY04 Catheter Assembly 4	Strain Relief Reflow MPI0398 Rev. <u>A4</u> Temp = 420°F 5°F Air Flow = 60 SCFH						500	0	BD64 NT35 SF35 03Jan24

Notes:

N/A

N/A

N/A

Date Printed: 02.01.2024 / 15:17:38

Page: 3 of 17



SA0254-06

CREGANNA
MEDICAL
is part of



(1) NY45 03Jan24

Production Order: 500000292875



Production Order Document
Production Order Qty: 500

PC

Sheet: 1 of 1

Material: SA0254-06 Rev G

Op. 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	84674	166				
		MM0527-01	C <u>C</u>	PC	500	0000276169	500				
250	CATASY04 Catheter Assembly 4 Position Tubing for Reflow	MM0186-00	D <u>D</u>	PC	500	0000275689	500	500	0	03 Jan 24	VX41 SX6G SPZ3 VJ06 CX32
		MM0523-03	C <u>C</u>	PC	500	0000276167	500	N/A			

Notes:

N/A

N/A

N/A

Date Printed: 02.01.2024 / 15:17:38

Page: 4 of 17



SA0254-06

CREGANNA
MEDICAL
is part of



Production Order: 500000292875



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		MM0524-01	B	<u>B</u>	PC	500	<u>0000273850</u>	<u>500</u>	<u>N/A</u>	<u>N/A</u>	
		MM0530-01	B	<u>B</u>	PC	500	<u>0000247129</u>	<u>500</u>	<u>N/A</u>	<u>N/A</u>	
		RM7586-02	D	<u>D</u>	PC	500	<u>83420</u>	<u>500</u>	<u>82839</u>	<u>62</u>	
		MM0185-01	I	<u>I</u>	PC	500	<u>0000281409</u>	<u>500</u>	<u>N/A</u>	<u>N/A</u>	
		MM1539-01	A	<u>A</u>	PC	500	<u>0000273841</u>	<u>500</u>	<u>N/A</u>	<u>N/A</u>	
		TL5909-01	B	<u>N/A</u>	PC	5	<u>N/A</u>	<u>Bulk</u>	<u>N/A</u>	<u>Bulk</u>	
		RM016101-MED	F	<u>F</u>	PC	125	<u>82407</u>	<u>125</u>	<u>N/A</u>	<u>N/A</u>	
		MM1540-01	B	<u>B</u>	PC	500	<u>0000278958</u>	<u>500</u>			

Notes:

N/A

N/A

N/A

Date Printed: 02.01.2024 / 15:17:38

Page: 5 of 17



SA0254-06

① NT35 02 Jan 24

CREGANNA
MEDICAL
is part of



Production Order: 500000292875



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	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	SS29 MHID EE65
	Reflow	Component Number Req'd Rev Rev Used UOM Qty. Batch No. Actual Qty Used	1000-1154-01 A A PC 500 86145 500 960115 10			
350	CATASY04 Catheter Assembly 4 	Skive Heat Shrink MPI0398 Rev. AH	500	0	03Jan24	Ay69 AN00 VX41 M66
	Skive Heat					

Notes:

N/A

N/A

N/A

Date Printed: 02.01.2024 / 15:17:38

Page: 6 of 17



SA0254-06

CREGANNA
MEDICAL
is part of



Production Order: 500000292875



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	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)	494	EW-III ① DSS-II BIM-1	03Jan24	ANOD VX41
450	CATASY04 Catheter Assembly 4 	Anneal Shaft MPI0398 Rev. AH FM5104692	494	0	03Jan24	ANOD VX41
Notes:						
N/A						
N/A						
N/A						

Date Printed: 02.01.2024 / 15:17:38

Page: 7 of 17



SA0254-06

CREGANNA
MEDICAL
is part of



① VX41 03Jan24

Production Order: 500000292875



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	Anneal Shaft	H/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 H1 H1T11 03 Jan 24		5086
550	CATASY04 Catheter Assembly 4 	Distal Cut MPI0398 Rev. AH Line Closure MPI0230 Rev. F By: M106 Date: 03 Jan 24	482	0	03 Jan 24	M106
600	PADPRIN1 Pad Print	Pad Print Set Up MPI0276 Rev. F	N/A	N/A	N/A	N/A

Notes:

N/A

N/A

N/A

Date Printed: 02.01.2024 / 15:17:38

Page: 8 of 17



SA0254-06

CREGANNA
MEDICAL
is part of



Production Order: 500000292875



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	<p>Count: Yes </p> <p>Pad Print Setup</p> <p>Line Clearance MPI0230 Rev. <u>F</u> By: <u>LV04 TRN</u> Date: <u>03 JAN 24</u> <u>GL42</u></p> <p><u>TMI0503</u> (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><u>TMI0735</u> 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>	482	0	03JAN24	LV04 TRN GL42	

Notes:

N/A

N/A

N/A

Date Printed: 02.01.2024 / 15:17:38

Page: 9 of 17



SA0254-06

CREGANNA MEDICAL
is part of



Production Order: 500000292875



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 LV04 03JAN24				
650	PADPRIN1 Pad Print 	Verification MPI0276 Rev. F Section 15.0	482	0	03JAN24 TRN GL42	LV04

Notes:

N/A

N/A

N/A

Date Printed: 02.01.2024 / 15:17:38

Page: 10 of 17



SA0254-06

CREGANNA
MEDICAL
is part of



Production Order: 500000292875



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	RM7408-01	B	<u>B</u>	L	0.005	<u>66780</u>	<u>0.005</u>	<u>N/A</u>	<u>N/A</u>	N/A
	N/A	RM7409-01	B	<u>B</u>	L	0.010	<u>85169</u>	<u>0.010</u>	<u>N/A</u>	<u>N/A</u>	N/A
700	PADPRIN1 Pad Print 	Prepare Surface for Ink MPI0276 Rev. <u>F</u> Section 15.5 Polynit wipes 99% IPA					482	0	03JAN24	LN04 TRN GL42	
750	PADPRIN1 Pad Print 	Print Parts MPI0276 Rev. <u>F</u> Section 20.0 Inspection gauge TMI0843					482	0	03JAN24	LN04 TRN GL42	
	Print Parts										

Notes:

N/A

N/A

N/A

Date Printed: 02.01.2024 / 15:17:38

Page: 11 of 17



SA0254-06

CREGANNA
MEDICAL
is part of



Production Order: 500000292875



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 MPI0276 Rev. <u>F</u> Section 30.0 Polynit Wipes 99% IPA Mag Light In-process Inspection and Rework	482	0	03Jan24	LV04 TRN GL42
850	PADPRIN1 Pad Print 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>6:35 AM</u> By: <u>PK15</u> Date: <u>04 Jan 24</u> Confirmation Reqd(Milestone)		350 132	0 0	03Jan24 04Jan24	LV04 TRN GL42 PK15
900	PADPRIN1 Pad Print	Transfer Parts to Quality MPI0276 Rev. <u>F</u> Section 40.0	482	0	04Jan24	PK15
Notes:		N/A N/A N/A				

Date Printed: 02.01.2024 / 15:17:38

Page: 12 of 17



SA0254-06

CREGANNA
MEDICAL
is part of



Production Order: 500000292875

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>2:35 PM</u> By: <u>PK15</u> Date: <u>04 Jan 24</u>	N/A	N/A	N/A	N/A
950	PADPRIN1 Pad Print Count: Yes  Cleaning MPI0276 Rev. <u>F</u> Section 50.0 Line Clearance MPI0230 Rev. <u>F</u> Cleaning Confirmation Reqd(Milestone)	Cleaning MPI0276 Rev. <u>F</u> Section 50.0 Line Clearance MPI0230 Rev. <u>F</u> By: <u>PK15</u> Date: <u>04 Jan 24</u>	482	0	04Jan24	PK15
1050	QUALITY1	Required Inspection	N/A	N/A	N/A	N/A

Notes:

N/A
N/A
N/A

Date Printed: 02.01.2024 / 15:17:38

Page: 13 of 17



SA0254-06

CREGANNA MEDICAL
is part of

Production Order: 500000292875



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
1050	Quality Inspection & Review 	Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	444	4-IB 4-SL/GNS 1-ODOS/12 9-SCR 6-VD 5-TT 3-PRT 3-FM 1-EW 1-SKV 1-SP	05Jan24	CN70 SB08 LT03 AJ74 J001 KLUS
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 _____	444	0	05JAN24	LT03

Notes:

N/A

N/A

N/A

Date Printed: 02.01.2024 / 15:17:38

Page: 14 of 17



SA0254-06

CREGANNA
MEDICAL
is part of



Production Order: 500000292875



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  Confirmation Reqd(Milestone)	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	444	0	05JAN24	LTO3
1100	PACKINT1 Packing assembly 	Packaging Instructions SPI0087 REV. O	444	0	08Jan24	A010

Notes:

N/A A010 08 Jan 24

Date Printed: 02.01.2024 / 15:17:38

Page: 15 of 17



SA0254-06

CREGANNA MEDICAL
is part of



Production Order: 500000292875



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)	<i>N/A APR 08 Jan 24</i>				

Notes:	<i>N/A APR 08 Jan 24</i>

Date Printed: 02.01.2024 / 15:17:38

Page: 16 of 17



SA0254-06

CREGANNA
MEDICAL
is part of



Production Order: 500000292875



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

Material: SA0254-06 Rev G

Batch Number: 0000292875

By: AB10

Date: 08 Jan 24

Reviewed By:

RB29

Date:

08 JAN 24

Notes:

N/A AB10 08/01/24 08 Jan 24

Date Printed: 02.01.2024 / 15:17:38

DA010 08 Jan 24
Page: 17 of 17



SA0254-06

CREGANNA MEDICAL
is part of



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% TMI0724 + 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.

Deviation To:

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 $2.0'' \pm 0.3''$ 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.

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: 20Dec2023	End Date: 31Jan2024

Lot Number: 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: Yes No *Change plan to follow for Document update*
If no, explain: *Tsix 21 Dec 23*

Training Required: Yes 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% GNE Inspection #1	100% GNE Inspection #2	Inspector Initials	Inspector Initials
Date Completed	05/Jan/24	Date Completed	05/Jan/24
Time Completed	04:30 AM	Time Completed	04:00 AM
Units Passing	478	Units Passing	478
Units Failing	A	Units Failing	C

- Note: 100% GNE 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.

PRODUCTION ORDER# 5000002912875

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													
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"> <thead> <tr> <th>Particle Size Area: mm²</th> <th>Acceptable Limits per Part</th> </tr> </thead> <tbody> <tr> <td>< 0.05 mm²</td> <td>No Limit</td> </tr> <tr> <td>0.05 mm² ≤ Area < 0.25 mm²</td> <td>3</td> </tr> <tr> <td>0.25 mm² ≤ Area < 0.80 mm²</td> <td>2</td> </tr> <tr> <td>0.80 mm² ≤ Area ≤ 1.5 mm²</td> <td>1</td> </tr> <tr> <td>> 1.5 mm²</td> <td>0</td> </tr> </tbody> </table>	Particle Size Area: mm ²	Acceptable Limits per Part	< 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	See Table	100%	Use a calibrated Tappi Chart and Inspect at a minimum of 2.85x magnification		500	0	VX4103Jan24
Particle Size Area: mm ²	Acceptable Limits per Part																		
< 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%	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		494	6													
Measured material overflow on proximal end of stop sleeve must be ≤0.02" (i.e., 0.2 mm ² dot on Tappi chart).	≤0.2 mm ²	100%	Use a calibrated Tappi Chart and Inspect at a minimum of 2.85x magnification	N/A	494	0	VX4103Jan24												

PRODUCTION ORDER# 500000292875

Attachment B: Cause of Rework.

OPER 400.0

Date	Initial	AB (Prox)	AB (Distal)	DF	DS	EW	FM	Disc	SCR	SKV	VD
03 Jan 24	AN00	0	0	0	0	0	2	0	0	0	0
03 Jan 24	VX41	0	0	0	0	0	18	0	2	0	0
				N/A	VX41 03 Jan 24						

Attachment B: Cause of Rework

OPER 500.0

Date	Initial	Dim 13 (Go Gauge)	Dim 21 (Go gauge)
03 Jan 24	M106	0	7

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

PRODUCTION ORDER# 500000292875

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	TM10748 AM	M/28	03Jan24	6:00 PM
Before	Dimension 21	TM10747 X	M/28	03Jan24	6:00 PM
After	Dimension 13	TM10748 AM	M/28	03Jan24	12: 40 AM
After	Dimension 21	TM10747 X	M/28	03Jan24	12: 40 AM

PRODUCTION ORDER# 500000292875

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	TMI 0797B	494	0	M106 03Jan24
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	TMI 0748AM	482	12	M106 03Jan24
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	TMI 0747X	482	0	M106 03Jan24

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	EDW Commander Balloon - Bend and Tensile Strength Testing
Seg 1	25.4	24.1	26.82	28.21	27.78	32.69	27.74	24.67	25.8	30.44	27.365	2.6534851	4.378	15.7480421	8.542	PASS	LOT #: 500000292875 Date:05JAN24 Inspector Name:Andrew Wipf Equipment ID: TMI0311B Cal Due Date: 27 OCT 2024
Seg B	20.87	21.18	21.17	21.05	21.9	25.39	20.54	20.69	23.07	23.64	21.95	1.5881506	4.378	14.99707682	8.542	PASS	
Seg C	47.64	45.92	41.4	47.09	49.23	53.67	36.18	33.26	47.49	51.37	45.325	6.4939857	4.378	16.8943307	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 .



OSJan 24