



Production Order: 500000066052



Production Order Document
Production Order Qty: 500
PC

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Material: SA0254-06 Rev G

Material Type:	ZFRT	Description: Printed Shaft 144C Prox End Color B CMDR	Order Type: ZSTD
Production Version:	8000	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>U</u> Line Clearance MPI0230 Rev. <u>E</u> By: <u>LY</u> Date: <u>09Jan21</u>		500	0	09Jan21	LY
100	CATASY04 Catheter	Straighten First Jacket MPI0398 Rev. <u>U</u>				N/A

Notes: DA: 1738 DA 1787

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Op. No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Assembly 4 Straighten First Jacket Confirmation Reqd(Milestone)							500	0	09Jan21	LY
		Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used			
		MM0187-01	E	E	PC	1	0000064857	500			
							NIA	NIA			
150	CATASY04 Catheter Assembly 4 Positioning Braid Over First Jacket Confirmation Reqd(Milestone)	Positioning Braid Over First Jacket MPI0398 Rev. NIA						209 291	0 0	09Jan21 11Jan21	VY MS SC SP BK VKA VWJ
		Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used			
		MM0189-01	D	D	PC	500	0000064995	396			
							0000064796	100			

Notes:

NIA

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Opn 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																					
200	CATASY04 Catheter Assembly 4 	<p>Strain Relief Reflow MPI0398 Rev. U</p> <p>Temp = 420°F 5°F Air Flow = 60 SCFH</p> <table border="1"> <thead> <tr> <th>Component Number</th> <th>Req'd Rev</th> <th>Rev Used</th> <th>UOM</th> <th>Qty.</th> <th>Batch No.</th> <th>Actual Qty Used</th> </tr> </thead> <tbody> <tr> <td>MM0527-01</td> <td>B</td> <td>B</td> <td>PC</td> <td>500</td> <td>0000058371</td> <td>500</td> </tr> <tr> <td>RM0096-01</td> <td>F</td> <td>F</td> <td>PC</td> <td>125</td> <td>27698</td> <td>150</td> </tr> </tbody> </table>	Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	MM0527-01	B	B	PC	500	0000058371	500	RM0096-01	F	F	PC	125	27698	150	192 308	0 0	09Jan21 15Jan21	NH AY AN
Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																					
MM0527-01	B	B	PC	500	0000058371	500																					
RM0096-01	F	F	PC	125	27698	150																					
250	CATASY04 Catheter Assembly 4 	<p>Position Tubing For Reflow MPI0398 Rev. U</p> <table border="1"> <thead> <tr> <th>Component</th> <th>Req'd</th> <th>Rev</th> <th>UOM</th> <th>Qty.</th> <th>Batch</th> <th>Actual</th> </tr> </thead> </table>	Component	Req'd	Rev	UOM	Qty.	Batch	Actual	107 391	2 - Too Tight 0	09Jan21 11Jan21	VX MCU SC SP BK VKA														
Component	Req'd	Rev	UOM	Qty.	Batch	Actual																					

Notes:

N/A

N/A

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Opn No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
<i>NIA</i>	Position Tubing for Reflow	Number	Rev	Used		No.	Qty	Used				
		MM0186-00	D	<u>D</u>	PC	500	<u>P08-061101</u>	<u>450</u>				
							<u>P08-061101</u>	<u>50</u>				
		MM0523-03	C	<u>C</u>	PC	500	<u>0000059871</u>	<u>500</u>				
							<u>NIA</u>	<u>NIA</u>				
		MM0524-01	B	<u>B</u>	PC	500	<u>0000058676</u>	<u>500</u>				
							<u>NIA</u>	<u>NIA</u>				
		MM0530-01	B	<u>B</u>	PC	500	<u>0000059064</u>	<u>500</u>				
							<u>NIA</u>	<u>NIA</u>				
		RM7586-02	D	<u>D</u>	PC	500	<u>25632</u>	<u>250</u>				
							<u>25632</u>	<u>250</u>				
		RM8745-01	B	<u>B</u>	PC	500	<u>27613</u>	<u>200</u>				
							<u>25632</u>	<u>27598</u>				
		MM0185-01	I	<u>I</u>	PC	500	<u>0000064121</u>	<u>500</u>				
							<u>NIA</u>	<u>NIA</u>				

Notes:

*NIA**NIA*

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CV 11 Jan 21
CV 11 Jan 21
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Opn No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		MM1540-01 A <u>A</u> PC 500	<u>0000063081</u>	<u>500</u>								
		MM1539-01 A <u>A</u> PC 500	<u>0000061041</u>	<u>500</u>								
		RM016101-MED <u>NIA</u> F <u>F</u> PC 46	<u>NIA</u>	<u>NIA</u>	<u>46</u>	<u>NIA</u>	<u>25704</u>	<u>100</u>				
300	CATASY04 Catheter Assembly 4 	Reflow MPI0398 Rev. <u>U</u> Temp = 415°F (+/- 15 °F) Speed = 4.5 in/min (+/- 0.5 in/min)						72 428 426	0	09Jan21 12Jan21 11Jan21 450 AD VWJ KS	AD VWJ KS	
350	CATASY04 Catheter Assembly 4	Skive Heat Shrink MPI0398 Rev. <u>U</u>						277 221	0 0	11Jan21 12Jan21	Pny YK	
Notes:												
<u>NIA</u>												
<u>NIA</u>												

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

Notes:

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
500	CATASY04 Catheter Assembly 4 Leak Test/Prox Cut/Ring Gage-Dim 13/21	Leak Test/Prox Cut/Ring Gage-Dim 13/21 MPI0398 Rev. <u>4</u> FM5104694 FM5104695 (Rework if needed - Use FM5104983)	49 492	4 Fail OP 13 11 Jan 21 11 80 Fail	11 Jan 21 12 Jan 21 CKY	NYC
550	CATASY04 Catheter Assembly 4 Distal Cut	Distal Cut MPI0398 Rev. <u>4</u> Line Closure MPI0230 Rev. <u>E</u> By: <u>CKY</u> Date: <u>12 Jan 21</u>	49 422	0	11 Jan 21 12 Jan 21	ML ADD
600	PADPRIN1 Pad Print Count: Yes 	Pad Print Set Up MPI0276 Rev. <u>D</u> Line Clearance MPI0230 Rev. <u>E</u>	471	0	12 Jan 21	KWJ

Notes:

✓/A

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Opn No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Pad Print Setup	By: <u>KUT</u> Date: <u>12 Jan 21</u> TMI0503 (circle TMI used) <u>TMI0735</u> Cliché - TL0525 Cliché - TL0567 Ink # RM7407-01 Ink - RM7407-01 Thinner - RM7408-01 Thinner - RM7408-01 Hardener - RM7409-01 Hardener - RM7409-01 Customized Measuring Equipment - Caliper Customized Measuring Equipment - Caliper Inspection Gauge TMI0843 Inspection Gauge TMI0843 Setup Rod # TL0815 Setup Rod # TL0815 Program - #10 Program - #10 Ink Viscosity (REF) -5 to 6 Ink Viscosity (REF) -5 to 6 Pad - TL0545 or equivalent Pad - TL0545 or equivalent Fence - TL0538 Fence - TL0569 Drying Oven - TMI0643 Drying Oven - TMI0643 Drying Racks-TL0531, TL0532 Drying Racks-TL0531, TL0532			N/A	

Notes:

N/A





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Opn No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials																				
		N/A																								
650	PADPRIN1 Pad Print 	<p>Verification MPI0276 Rev. <u>D</u> Section 15.0</p> <table border="1"> <thead> <tr> <th>Component Number</th> <th>Req'd Rev</th> <th>Rev Used</th> <th>UOM</th> <th>Qty.</th> <th>Batch No.</th> <th>Actual Qty Used</th> </tr> </thead> <tbody> <tr> <td>RM7407-01</td> <td>B</td> <td><u>B</u></td> <td>L</td> <td>0.050</td> <td><u>25382 25658</u></td> <td><u>0.040</u></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td>N/A</td> <td>N/A</td> </tr> </tbody> </table>	Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	RM7407-01	B	<u>B</u>	L	0.050	<u>25382 25658</u>	<u>0.040</u>						N/A	N/A	471	0	12Jan21 KNT
Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																				
RM7407-01	B	<u>B</u>	L	0.050	<u>25382 25658</u>	<u>0.040</u>																				
					N/A	N/A																				

Notes:

KNT 12 Jan 21

KNT 12 Jan 21

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Opn 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>TP53072</u> <u>0.005</u> RM7409-01 B <u>B</u> L 0.010 <u>26764</u> <u>0.010</u> <u>NA</u> <u>NA</u>				
700	PADPRIN1 Pad Print  Prepare Surface for Ink	Prepare Surface for Ink MPI0276 Rev. <u>D</u> Section 15.5 Polynit wipes 99% IPA	7471	0	12Jan21	KUT
750	PADPRIN1 Pad Print  Print Parts	Print Parts MPI0276 Rev. <u>D</u> Section 20.0 Inspection gauge TMI0843	471	0	12Jan21	KUT
Notes: <u>N/A</u>						

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Opn 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>D</u> Section 30.0 Polynit Wipes 99% IPA Mag Light	471	0	12Jan21	KWJ
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>9:25 AM</u> By: <u>PK</u> Date: <u>13Jan21</u>	471	0	12Jan21	KWJ
900	PADPRIN1 Pad Print	Transfer Parts to Production MPI0276 Rev. <u>D</u> Section 40.0				

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Opn No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Transfer parts to Production	Transfer Parts to Line Time: <u>4:15 pm</u> 5:30 pm By: <u>DX</u> Date: <u>13 Jan 21</u>	471	0	13 Jan 21	DX
950	PADPRIN1 Pad Print Count: Yes	Cleaning MPI0276 Rev. <u>D</u> Section 50.0 Line Clearance MPI0230 Rev. <u>E</u> By: <u>kut</u> Date: <u>12 Jan 21</u>	471	0	12 Jan 21	KUT
1000	CATASY04	In-Process Dimensional Inspection	N/A	N/A	N/A	N/A

Notes:

N/A

N/A

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Op No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Catheter Assembly 4 In-Process Dimensional Inspection	MPI0398 Rev. <u>U</u> FM5104662 FM5104696 (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>	50 446	1800 FAILED 25 OD	20 Jan 21 21 Jan 21	CRW ASD
1050	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	380 379	ID - TT 18 - OD/BS/OS 12 - SL/OS 6 - IB 11 - ID/OS 1 - FIB 2 - AB 2 - SCR 1 - PM 2 - WT 2 - DS 2 - DS	18 Feb 21	NY

Notes:

ASD 21 Jan 21

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AP 19 FEB 21
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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
1070	CATHASY04 Catheter Assembly 4 Rework Process Confirmation Reqd(Milestone)	Rework MPI0398 Rev. <u>U</u> Material consumed Material RM 8745-01 Batch 28340 Rev B Qty 10 Material _____ Batch _____ Rev _____ Qty _____ Material _____ Batch _____ Rev _____ Qty _____ Material _____ Batch _____ Rev _____ Qty _____ Material _____ Batch _____ Rev _____ Qty _____	N/A 379	0	19Feb21	VC
1090	QUALITY1 Quality Inspection & Review Quality Inspection & Review	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	376	SCR - 2 #180D-1	19FEB21	AP

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Confirmation Reqd(Milestone)	N/A		N/A		
1100	PACKINT1 Packing assembly  Packing Instructions Confirmation Reqd(Milestone)	Packaging Instructions SPI0087 REV. H	376	0	20 Feb 21 AP	

Notes:

N/A

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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#

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Attachment B: Cause of Rework.

OPER 400.0

Attachment B: Cause of Rework

OPER 500.0

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 Jun 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 Jun 21



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Document No: FM5104692

Rev: B

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

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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

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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

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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**

Comments:

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TEST DATA SHEET

Date:

Part Number: SA0254-xx 06

Sample	Dim 12 (Max)	Dim 12 min	N/A	Dim 13 Avg	Dim 13 Max
1	0.1423	0.1405	0.1446	0.1457	0.1458
2	0.1431	0.1423	0.1452	0.1417	0.1426
3	0.1454	0.1425	0.1445	0.1417	0.1426
4	0.1452	0.1425	0.1445	0.1417	0.1425
5	0.1429	0.1421	0.1446	0.1421	0.1455
6	0.1428	0.1420	0.1444	0.1420	0.1452
7	0.1434	0.1426	0.1448	0.1426	0.1458
8	0.1436	0.1428	0.1446	0.1428	0.1452
9	0.1424	0.1416	0.1447	0.1416	0.1457
10	0.1430	0.1422	0.1448	0.1422	0.1461
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CONTROLLED COPY

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			