

Production Order: 500000066049



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:	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>LJ</u> Date: <u>08Jan21</u>	500	0	08Jan21	LJ
100	CATASY04 Catheter	Straighten First Jacket MPI0398 Rev. <u>U</u>			NA	

Notes: DA1738, DA1787

Date Printed: 08.01.2021 / 17:00:37

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Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Assembly 4 							500	0	08Jan21	LY
PA	Straighten First Jacket	Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used			
	Confirmation Reqd(Milestone)	MM0187-01	E	<u>E</u>	PC	1	0000064857	500			
							N/A	N/A			
150	CATASY04 Catheter Assembly 4 	Positioning Braid Over First Jacket MPI0398 Rev. <u>U</u>						336	0	08 Jan21	BA - MIKY SP VICA AN
	Positioning Braid Over First Jacket	Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used			
	Confirmation Reqd(Milestone)	MM0189-01	D	<u>D</u>	PC	500	0000064795	359			
							0000064993	94			
							0'000064796	50			

Notes:

N/A





Material: SA0254-06 Rev G

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 	Strain Relief Reflow MPI0398 Rev. U Temp = 420°F 5°F Air Flow = 60 SCFH	275 225	0 0	08Jan21 09Jan21	A0 AY VKA
	Strain Relief Reflow Confirmation Rreqd(Milestone)	Component Number Req'd Rev Rev Used UOM Qty. Batch No. Actual Qty Used	MM0527-01 B B PC 500 0000058371 500 N/A N/A			
		RM0096-01 F F PC 125 27698 100 27976 26				
250	CATASY04 Catheter Assembly 4 	Position Tubing For Reflow MPI0398 Rev. U	220 277	3-Too Tight 0	08Jan21 09Jan21	VX MH BK SC SP AN

Notes:

N/A

Date Printed: 08.01.2021 / 17:00:37

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SP 09 Jan 21



SA0254-06

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Opn No.	Planned WorkCentre	WorkCentre	Operation Details						Initials
			Qty.	Comp. Qty	Scrap Qty	& Descc.	Date	Comp.	
M0186-00	for Reflow Soldering	D	PC	500	PO8-D61101	250			
M0523-03	Position Tubing	C	PC	500	0000058407	100			
M0524-01		B	PC	500	0000059871	400			
M0530-01		B	PC	500	0000057812	500			
RMT586-02		D	PC	500	25469	250			
RM8745-01		B	PC	500	27613	250			
MM0185-01		I	PC	500	0000064121	500			



Op#	Planned Workcenter	Description	Operation Details					
			Comp. Qty.	Scrap Qty.	% Descr.	Date	Comments	Materials
MM1540-01	A	PC	500	0000063081	500			MM1539-01 A PC 500 0000061041 500 25 25704 125 RM016101-MED N/A N/A N/A N/A N/A N/A N/A N/A N/A
300	CATASY04	Refilow Assembly 4	0	0	0	08Jan21	MS	Temp = 415°F (+/- 15°F) Speed = 4.5 in/min (+/- 0.5 in/min)
350	CATASY04	Refilow Assembly 4	0	0	0	08Jan21	VWT	Temp = 415°F (+/- 15°F) Speed = 4.5 in/min (+/- 0.5 in/min)

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WMT 09 Jan 21



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Opn No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	 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)	215 266	5 EW 2 EW 1 AB 2 FM 1 DF 3 DS 2 DISC	09 Jan 21 11 Jan 21	Pny YKA TRNCL YK
450	CATASY04 Catheter Assembly 4 Anneal Shaft	Anneal Shaft MPI0398 Rev. <u>u</u> FM5104692	150 331	0 0	09 Jan 21 11 Jan 21	Pny TRNCL YKA YK

Notes:

N/A

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Opn 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 MPI0398 Rev. <u>U</u> FM5104694 FM5104695 (Rework if needed - Use FM5104983)	4 322 90	0 6500 Fail 0	09 Jan 21 11 Jan 21 11 Jan 21	NYC CKY NYC
550	CATASY04 Catheter Assembly 4 	Distal Cut MPI0398 Rev. <u>U</u> Line Closure MPI0230 Rev. <u>E</u> By: <u>MU1</u> Date: <u>11 Jan 21</u>	4 322 90	0 0 0	09 Jan 21 11 Jan 21 11 Jan 21	NYC CKY XX MU1
600	PADPRIN1 Pad Print Count: Yes 	Pad Print Set Up MPI0276 Rev. <u>D</u> Line Clearance MPI0230 Rev. <u>E</u>	240 176	0 0	11 Jan 21 12 Jan 21	GL PK

Notes:

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
NR	Pad Print Setup	<p>By: <u>GL</u> Date: <u>11 Jan 21</u></p> <p>TMI0503 (circle TMI used) TMI0735 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</p>		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		N/A																							
650	PADPRIN1 Pad Print 	<p>Verification MPI0276 Rev. D 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>B</td> <td>L</td> <td>0.050</td> <td>TP253383</td> <td>0.050</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	B	L	0.050	TP253383	0.050						N/A	N/A	240 176	0 0	11Jan21 12Jan21	GL PK
Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																					
RM7407-01	B	B	L	0.050	TP253383	0.050																					
					N/A	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	N/A	RM7408-01 B <u>B</u> L 0.005 TP53072 0.005 RM7409-01 B <u>B</u> L 0.010 TP25634 0.010		N/A N/A N/A N/A	N/A	
700	PADPRIN1 Pad Print 	Prepare Surface for Ink MPI0276 Rev. <u>D</u> Section 15.5 Polynit wipes 99% IPA	240 176	0 0	11 Jan 21 GL 12 Jan 21 PK	
750	PADPRIN1 Pad Print 	Print Parts MPI0276 Rev. <u>D</u> Section 20.0 Inspection gauge TMI0843	240 176	0 0	11 Jan 21 GL 12 Jan 21 PK	
Notes:						
N/A						

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Op. 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	240 176	0 0	11 Jan 21 12 Jan 21	GR PK
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>12:50 PM</u> By: <u>PK</u> Date: <u>12 Jan 21</u>	416	0	12 Jan 21	PK
900	PADPRIN1 Pad Print	Transfer Parts to Production MPI0276 Rev. <u>D</u> Section 40.0	416	0	13 Jan 21	TY

Notes:

N/A





Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
NA	 Transfer parts to Production Confirmation Reqd(Milestone)	Transfer Parts to Line Time: <u>5:30 am</u> By: <u>TY</u> Date: <u>13 Jan 21</u>		NA		
950	PADPRIN1 Pad Print Count: Yes Cleaning MPI0276 Rev. <u>D</u> Section 50.0 Line Clearance MPI0230 Rev. <u>E</u> By: <u>PK</u> Date: <u>12 Jan 21</u> Confirmation Reqd(Milestone)		416	0	12Jan21	PK
1000	CATASY04	In-Process Dimensional Inspection	N/A	N/A	N/A	N/A

Notes:

N/A

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Material: SA0254-06 Rev G

Opr 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>A</u> FM5104662 FM5104696 (No Rework can be done at this OP) Line Closure MPI0230 Rev. <u>E</u> By: <u>NT</u> Date: <u>15 Jan 21</u>	346	70 O DFA	1 15 Jan 21	NT
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	246	FF-10 HO-OD/OS HIS-7 68 PRT-11 IB-8 AB-1 FM-1 TF-10 SCR-1	16 JAN 21 19 JAN 21	AP

Notes:

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~~AP 19 JAN 21~~
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Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
1070	CATASY04 Catheter Assembly 4 Rework Process Confirmation Reqd(Milestone)	Rework MPI0398 Rev. <u>M</u> Material consumed Material Batch Rev Qty Material Batch Rev Qty				
1090	QUALITY1 Quality Inspection & Review Quality Inspection & Review	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan				

Notes:

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Confirmation Reqd(Milestone)	N/A		N/A		
1100	PACKINT1 Packing assembly Packing Instructions Confirmation Reqd(Milestone)	Packaging Instructions SPI0087 REV. H	246	0	21 Jan 2021 AP	

Notes:

N/A

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Notes:	

	Review Date:	23/Jan/21
	Reviewed By:	mf

	Batch Number:	000006609
	By:	mf
	Date:	21/Jan/21

Production Order Document
Production Order Qty: 500
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Production Order: 500000066049

Material: SA0254-06 Rev G

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M115w21

N/A

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Date	Initial	Dim 13 (GO Gauge)	Dim 21 (GO Gauge)
11 Jan 21	VC	0	0

OPER 500.0

Attachment B: Cause of Rework

N/A

Date	Initial	AB (Prox)	AB (Distal)	DF	DS	EW	FM	DisC	SCR	SKV	VD
09 Jan 21	PW	0	6	0	0	0	6	0	0	0	0
11 Jan 21	YK	0	6	0	3	0	0	12	0	4	0

OPER 400.0

Attachment B: Cause of Rework.

60049

PRODUCTION ORDER#

Document No: FM5104983

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

Test/Specification	Dimensions	Sample Plan	Equipment	TM/TL	# Pass	# Fail	Initial/Date
Using a magnification light, visually inspect the entire length of the shafts.	N/A	100%	2.85X Mag.	Light	497	0	YK 11 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	497	0	YK 11 Jan 21
All other Foreign Material:	See Table						YK 11 Jan 21
Particulate Size	Acceptable Limits per Part	No Limit	2.85X Mag.	Light	497	0	YK 11 Jan 21
Area: mm ²	0.05 mm ² ≤ Area < 0.25 mm ²	0.05 mm ² ≤ Area < 0.25 mm ²	0.05 mm ² ≤ Area < 0.25 mm ²	2.85X Mag.	Light	497	0
	0.25 mm ² ≤ Area < 0.80 mm ²	0.25 mm ² ≤ Area < 0.80 mm ²	0.25 mm ² ≤ Area < 0.80 mm ²	2.85X Mag.	Light	497	0
	0.80 mm ² ≤ Area ≤ 1.5 mm ²	0.80 mm ² ≤ Area ≤ 1.5 mm ²	0.80 mm ² ≤ Area ≤ 1.5 mm ²	2.85X Mag.	Light	497	0
	> 1.5 mm ²	> 1.5 mm ²	> 1.5 mm ²	2.85X Mag.	Light	497	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	497	0	YK 11 Jan 21
No bumps, lumps, or protrusions along the shaft that will compromise the OD. Verily all protrusions to make sure the OD is still within specification.	N/A	100%	2.85X Mag.	Light	497	0	YK 11 Jan 21
No flat spots, kinks, delamination, gaps between material transitions and material transitions should no exhibit cracking, no exposed or apparent braid.	N/A	100%	2.85X Mag.	Light	497	0	YK 11 Jan 21
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 Requirement	NA	481	0	YK 11 Jan 21

In-Process Inspection

OPER 400.0

PRODUCTION ORDER# 06049

Title: SA0254 In-Process Inspection Form

Document Type: Manufacturing Form

Rev: B

Document No: FM5104693



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OPER 450.0

Annealing Log Sheet

PRODUCTION ORDER# 66649

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

Rev: B
 Document No: FM5104692

Oven #	Cycle #	Quantity	Time In	Temp. In (Actual)	Time Out	Temp. Out (Actual)	Initials	Date
Tm10943	NA	83	5 : 30 pm	190°F	6 : 30 pm	190°F	PWY	09 Jan 21
Tm10943	NA	67	8 : 00 pm	190°F	9 : 00 pm	190°F	PWY	09 Jan 21
Tm10943	NA	65	4 : 53 am	190°F	5 : 53 am	190°F	PWY	11 Jan 21
Tm10943	NA	150	7:00 am	190°F	8:00 am	190°F	PWY	11 Jan 21
Tm10943	NA	116	9:30 am	190°F	10:30 am	190°F	PWY	11 Jan 21
							N/A	

Status CURRENT Effective 10/27/2020

Before & After	Inspecting Parts	Dimension # # Gauge (Ex. TM10748AC or TM10747AAD)	Check Initials	Date	Time
Before	Dimension 13	TM10748AN	MV	09 Jan 21	9:00pm
After	Dimension 21	TM10747AN	MW	09 Jan 21	9:00pm
Before	Dimension 13	TM10748AN	MV	09 Jan 21	9:00pm
After	Dimension 21	TM10747AN	MW	09 Jan 21	9:00pm
Before	Dimension 21	TM10747AN	LJ	11 Jan 21	6:30pm
After	Dimension 21	TM10747AN	LJ	11 Jan 21	6:30pm

OPER 500.0 ▶ 13 & ▶ 21 Max OD Gauge Check for the manufacturing lot PRIOR TO AND AFTER Inspection

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

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OPER 500.0 Pressure Decay Testing							
Test/Specification	Dimensions	Equipment	Sample Plan	TM/TL	# Pass	# Fail	Initial/Date
Air Leak Test GN 15		Isaac Pressure Decay Tester	N/A	TM10747	481	0	W/L 115cm21
Outer Diameter A 13 MAX OD at Pad Printed Area		Ring Gauge	0.145" +0.002"/-	TM10748 or equivalent (≤0.147") 0.004"	65		W/L 115cm21
Outer Diameter A 21 MAX OD		Ring Gauge	0.157" ± 0.003"	TM10747 or equivalent (≤0.160") 100%	0		W/L 115cm21

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

PRODUCTION ORDER# 66049



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Before & After Parts	Dimension #	Gauge Check	Initials	Date	Time
Before	Dimension 13	TM1 Q748 AM (Ex. TM10748AC or TM10747AD)	CL	15Jan21	5:15AM
Before	Dimension 21	TM1 Q74747T (Ex. TM10747AD)	CL	15Jan21	5:15AM
After	Dimension 13	TM1 Q748 AM (Ex. TM10748AC or TM10747AD)	CL	15Jan21	13:30pm
After	Dimension 21	TM1 Q74747T (Ex. TM10747AD)	CL	15Jan21	13:30pm

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

66049

PRODUCTION ORDER#

Title: SA0254 Max OD Form

Document Type: Manufacturing Form

Rev: B

Document No: FM5104662



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Test/Specification	Document No:	Rev: B	Title: SA0254 In-Process Inspection Form Documentation Type: Manufacturing Form	OP 1000.0
Outer Diameter A3 MAX OD at Pad Printed Area	FM5104696			
Outer Diameter A21 MAX OD				
UT	15 Jan 21	1	Drop Go Gauge from proximal end of shaft. Pass if ring stops at sleeve shoulder. Fail if gauge stops above or falls past sleeve shoulder.	0.145" +0.002"/- 0.004" TMI 0748 or equivalent TM1
UT	15 Jan 21	1	Drop Go Gauge from proximal end of shaft. Pass if ring stops less than 4" digital above top sleeve shoulder.	0.157" ± 0.003" TMI 0747 or equivalent TM1
UT	15 Jan 21	4	Drop Go Gauge from proximal end of shaft. Pass if ring does not stop. Fail if ring stops less than 4" digital above top sleeve shoulder.	0.150" ± 0.003" TMI 0747 or equivalent TM1
Outer Diameter A2 MAX OD				
UT	15 Jan 21	39	Go-gauge: Measure from digital end to minimum 1.7" from tip. Gravity force only.	0.142" ± 0.002" TMI 0967 or equivalent TM1
Outer Diameter A2 MIN OD				
UT	15 Jan 21	0	No-go gauge: End must not pass through transition.	0.142" ± 0.002" TMI 0968, or equivalent TM1
Outer Diameter A18 MAX OD				
UT	15 Jan 21	34	Measure from proximal end of shaft to the material transition.	0.140" ± 0.002" (0.138"-0.142") TMI 1
Outer Diameter A18 MIN OD				
UT	15 Jan 21	0	Measure from proximal end of shaft to the material transition.	0.140" ± 0.002" (0.138"-0.142") TMI 1

PRODUCTION ORDER# 66099
Title: SA0254 In-Process Inspection Form

Rev: B
Document Type: Manufacturing Form

Document No: FM5104696

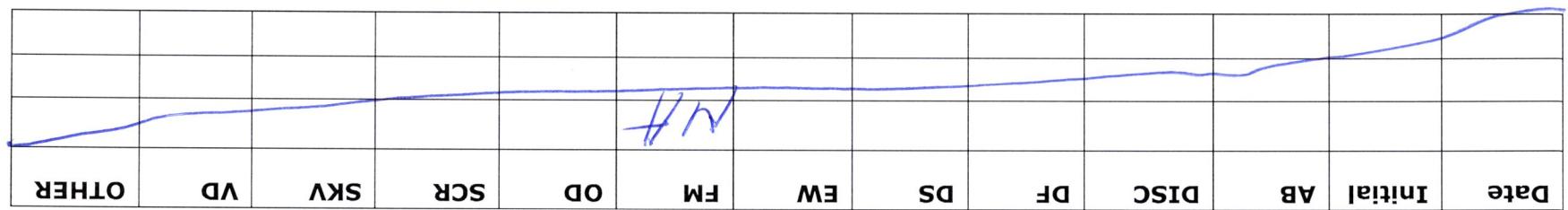


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Test/Specification	Document No:	Rev: B	Title: SA0254 In-Process Inspection Form Document Type: Manufacturing Form	PRODUCTION ORDER#
Outer Diameter A3 AVG OD at Pad Printed Area	FM5104696			60049
Outer Diameter A21 AVG OD				
15 Jan 21	NT	0	Measure sleeve shoulder to 4" distal of stop sleeve shoulder.	NOTE: Measure AVG OD and record results
15 Jan 21	NT	0	Measure from stop sleeve shoulder to 4" distal of stop sleeve shoulder to 4" distal of stop sleeve shoulder.	NOTE: Measure AVG OD and record results
Outer Diameter A17 AVG OD				
15 Jan 21	NT	0	Measure 4" distal the stop sleeve shoulder to the braid termination.	NOTE: Measure and Record results
Outer Diameter A12 MAX OD				
15 Jan 21	NT	0	Measure distally from the braid termination to the all the way distal end of the shaft.	NOTE: Measure and Record results
Outer Diameter A12 MIN OD				
15 Jan 21	NT	0	Measure distally from the braid termination to the all the way distal end of the shaft.	NOTE: Measure and Record results



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OPER 1050.0

PRODUCTION ORDER# 0049

Document No: FM5104983

Rev: B

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

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DEVIATION AUTHORIZATION FORM

Requestor Name: Govind Sharma

Document Number Affected	Revision
MPI0398	U
N/A	N/A

Deviation From:

Currently at "inline dimensional inspection operation" operators just check the dimension using laser mic and ring gauges and do not record any variable data.

Deviation To:

Record the variable data for Dim 12 and Dim 13. 10 samples from each lot. Variable data record form to be filled by ops department. ops lead to add to the excel file to monitor variable data behavior.

Justification:

As per the customer requirement we are starting to record the variable data for dimension 12 and 13 at "Inline dimensional inspection operation".

Part Number Affected	Revision
SA0254 - 04/05/06	61
N/A	N/A

Start Date:

12/9/2020

End Date:

1/9/2021

Lot Number:

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: Yes No **FMEA's:** Yes No **Validations:** Yes No

Details (if any): N/A

If yes to any of the above, what controls are being put in place to mitigate the risk?

Corrective Action Required: Yes No

If no, explain: Deviation talks about recording the variable data at a operation where we are already checking for the dimension.

Training Required: Yes No **If no, explain:** N/A

Title	Approval Name	Approval Signature	Date
Mfg Engineering manager	Renata Holahan		08 DEC 20
Quality Manager - Ops mgmt	Steve Julie		08 DEC 20
Operation Manager - OJ	Mitch Opatz		09 DEC 2020

TEST DATA SHEET

Part Number: SA0254-xx 04Date: 15 Jan 21Lot Number: 66049Tested by: HT

Test Description: Dim 12 and 13 variable data recording

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"
1	0.1437	0.1422		0.1441	0.1453
2	0.1432	0.1424		0.1441	0.1452
3	0.1443	0.1431		0.1445	0.1451
4	0.1436	0.1425		0.1445	0.1454
5	0.1436	0.1424		0.1446	0.1459
6	0.1434	0.1423		0.1448	0.1455
7	0.1424	0.1415		0.1445	0.1452
8	0.1431	0.1425		0.1448	0.1465
9	0.1430	0.1423		0.1450	0.1459
10	0.1424	0.1421		0.1445	0.1455
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Comments: _____

FM0015
Rev A
Effectivity Date: October 9, 2008

TACPRO, INC.

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DEVIATION AUTHORIZATION FORM

Requestor Name: Saroeun Chhum	
Document Number Affected	Revision
2100586	B

Deviation From:
100% Inspections at Final Inspection (Do not Require SmartSolve Notification to be issued).

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.

Justification:

All lots undergo 100% visual inspection; therefore, there is no risk to the customer for lots released without documenting in the Smartsolve notification.

Part Number Affected	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 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: N/A

Corrective Action Required:

Yes No

If no, explain:

No correction is required, SAP will address all lot manufactured in the new system.

Training Required:	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	If no, explain:
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Title	Approval Name	Approval Signature	Date
Quality Director	Jeff Pumper		15 JAN 2021
OPS Manager	Zach Nelson		15 JAN 2021
Staff Engineer	Vivek Rangaswami <small>15 JAN 2021</small>		15 JAN 2021

FM0002.RevF
Deviation Authorization

Maximum Force Reached During Tensile Test											
Sample #	(10 samples accepted from final inspection for each lot shall be randomly selected and tensile tested)										
	1	2	3	4	5	6	7	8	9	10	Pass/Fail
Seg 1	31.14	28.01	30.12	27.34	26.31	28.11	31.4	32.01	33.2	29.84	2.240252
Seg B	23.44	22.36	20.94	23.88	19.16	21	23.85	21.18	24.56	22.22	14.82457533
Seg C	53.5	54.26	67.22	49.9	54.21	52.88	67.58	60.58	50.06	50.67	26.75355102

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.

20 JAN 21
 Kocuk Yu Lee