

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

Page: 1 of 16



SA0254-06

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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

Page: 3 of 16

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)

Material: SA0254-06 Rev G
Sheet: 1 of 1
Production Order Document
Production Order Qty: 500
PC



Production Order: 500000066049

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SA0254-06

Page: 5 of 16

Date Printed: 08.01.2021 / 17:00:37

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SA0254-06



Page: 6 of 16

Date Printed: 08.01.2021 / 17:00:37

Opn.	Planned WorkCentre	Description	Operation Details				Comp. Qty	Scrap Qty	8. Descri.	Date	Comp.	Initials
400	CATASY04	In-Process Inspection (Visual Inspection)	2E/W	5E/W	2E/W	5E/W	266	0	1AB	11 Jun 21	PNY	N/A
400	CATASY04	In-Process Inspection (Visual Inspection)	1DF	2FM	1AB	2E/W	266	0	3DS	11 Jun 21	PNY	N/A
450	CATASY04	In-Process Inspection (Visual Inspection)	1DF	2FM	1AB	2E/W	266	0	2DISC	11 Jun 21	PNY	N/A

Production Order Document
Production Order Qty: 500
PC



Production Order: 500000066049

Material: SA0254-06 Rev G

Sheet: 1 of 1

Production Order Document Order Qty: 500
PC

Sheet: 1 of 1

Page: 6 of 16

Page: 6 of 16



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Op#	Planned WorkCentre	Description	Operation Details	Comp. Qty.	Scrap Qty.	8-hr Descr.	Date	Initials
500	CATASY04	Leak Test/Prox Cut/Ring Gage-Dim 13/21	MP10398 Rev. U	4	0	90	6503 Fault	09 Jan 21 NYL
500	CATASY04	Leak Test/Prox Cut/Ring Gage-Dim 13/21	FM5104694	0	0	90	6503 Fault	11 Jan 21 NYL
550	CATASY04	Catheter Assembly 4	MP10398 Rev. U	4	0	322	0	09 Jan 21 NYL
550	CATASY04	Catheter Cut	MP10230 Rev. E	0	0	40	0	11 Jan 21 NYL
600	PADDPRIN1	Catheter Assembly 4	MP10276 Rev. D	0	0	210	0	11 Jan 21 GL
600	PADDPRIN1	Pad Print Set Up	MP10230 Rev. E	0	0	176	0	12 Jan 21 PK

Production Order Document
Production Order Qty: 500
PC



Production Order: 500000066049

Sheet: 1 of 1

Material: SA0254-06 Rev G



SA0254-06

Page: 7 of 16

Date Printed: 08.01.2021 / 17:00:37

N/A

Notes:



QTY.	Part Number	Description	Work Center	Planned Date	By:	Date:
Operation Details						
0	TM10503	(circle TMI used)	Cliche - TL0567	Link # RM7407-01	Thinner - RM7408-01	Hardener - RM7409-01
0	TM10735		Cliche - TL0567	Link - RM7407-01	Thinner - RM7408-01	Hardener - RM7409-01
0	TM10503		Customized Measuring	Equipment - Caliper	Inspection Gauge TM10843	Setup Rod # TL0815
0	TM10735		Setup Rod # TL0815	Program - #10	Ink Viscosity (REF) - 5 to 6	Pad - TL0545 or equivalent
0	TM10503		Ink Setup Rod # TL0815	Fence - TL0569	Fence - TL0569	Fence - TL0538
0	TM10735		Program - #10	Drying Oven - TM10643	Drying Oven - TM10643	Drying Ovens-TL0531, TL0532
0	TM10503		Ink Viscosity (REF) - 5 to 6	Pad - TL0545 or equivalent	Ink Viscosity (REF) - 5 to 6	Drying Racks-TL0531, TL0532
0	TM10735		Pad - TL0545 or equivalent	Drying Racks-TL0531, TL0532	Drying Racks-TL0531, TL0532	Drying Racks-TL0531, TL0532
0	TM10503		Drying Racks-TL0531, TL0532	Drying Racks-TL0531, TL0532	Drying Racks-TL0531, TL0532	Drying Racks-TL0531, TL0532





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SA0254-06



Page: 9 of 16

Date Printed: 08.01.2021 / 17:00:37

Op.	Planned WorkCentre	Description	Operation Details						Verification						Verification						Notes:	
No.	WorkCentre	Description	Comp.	Scrap Qty.	Qty.	Comp.	Scrap Qty.	Qty.	UOM	Batch No.	Rev	Req'd	Component Number	Actual Qty Used	Qty Used	Rev	Req'd	Component Number	Actual Qty Used	Qty Used	Notes:	
650	PADPRINT1	Pad Print											MPI0276 Rev. 1D	Section 15.0								Verifications

Production Order Document
Production Order Qty: 500
PC



Production Order: 500000066049

Sheet: 1 of 1

Material: SA0254-06 Rev G



Production Order: 500000066049

Material: SA0254-06 Rev G

Sheet: 1 of 1

Qpt	Planned Workcenter	Description	Operation Details	Compl.	Scrap Qty	8 Descc.	Comp.	Intials
	RMT408-01	B	L 0.005 TPS3072 - 0.005	N/A	N/A	N/A	N/A	N/A
	RMT409-01	B	L 0.010 TPS3634 - 0.010	N/A	N/A	N/A	N/A	N/A
	700 PADPRIN1	Pad Print Surface for link MP10276 Rev. D	Section 15.5 Polyurethane Wipes 99% IPA	0	240	0	11/Jan/21	GL PK

	750 PADPRIN1	Pad Print Parts MP10276 Rev. D	Section 20.0 Inspection 20.0. Inspection gauge TM10843	0	176	0	11/Jan/21	GL PK

Notes:	
<i>N/A</i>	

Page: 10 of 16

Date Printed: 08.01.2021 / 17:00:37

SA0254-06



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SA0254-06

Page: 11 of 16

Date Printed: 08.01.2021 / 17:00:37

Op.	Planned WorkCentre	Description	Operation Details				Comp.	Scrap Qty	Qty.	Comp.	Scrap Descr.	Qty.	Comp.	Scrap Qty	Op.	
800	PADPRIN1	In-Process Inspection and Rework	MP10276 Rev. D	Section 30.0	99% IPA	Polyunit Wipes	0	0	176	0	11 Jan 21	GK	0	0	11 Jan 21	800
850	PADPRIN1	Curing Oven	MP10340 Rev. B	Section 35.0			0	0	416	0	12 Jan 21	GK	0	0	12 Jan 21	850
900	PADPRIN1	Pad Print	Transfer Parts to Production	MP10276 Rev. D	Section 40.0	Section 40.0	0	0	416	0	13 Jan 21	Ty	0	0	13 Jan 21	900
<p>N/A</p>																

Production Order Document
Production Order Qty: 500
PC



Production Order: 500000066049

Material: SA0254-06 Rev G

Sheet: 1 of 1

Production Order Document Order Qty: 500
PC

Op.	Planned WorkCentre	Description	Operation Details					
No.			Comp. Qty.	Scrap Qty.	% Defec.	Date	Initials	
950	PADPRIN1	Transfer Parts to Line	5:30 am	By: <u>Ty</u>	Date: <u>13 Jan 21</u>			
		to Production						
		Confirmation Redd(Milestone)						
1000	CATASY04	In-Process Dimensional Inspection	416	0	12 Jan 21	PK	N/A	
		Confirmation Redd(Milestone)						
		Completion Date:	12 Jan 21					
		Line Clearance E						
		Count: Yes						
		Pad Print MPI0276 Rev. D						
		Section 50.0						
		Line Clearance MPI0230 Rev. E						
		Cleaning						
		Confirmation Redd(Milestone)						
		Completion Date:	12 Jan 21					
		Line Clearance MPI0230 Rev. E						
		Count: Yes						
		Pad Print MPI0276 Rev. D						
		Section 50.0						
		Line Clearance MPI0230 Rev. E						
		Cleaning						
		Confirmation Redd(Milestone)						
		Completion Date:	12 Jan 21					
		In-Process Dimensional Inspection						

Production Order Document
Production Order Qty: 500
PC

Material: SA0254-06 Rev G
Sheet: 1 of 1



Production Order: 50000066049



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SA0254-06

Page: 12 of 16

Date Printed: 08.01.2021 / 17:00:37

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AP 19 JAN 21
AP 19 JAN 21
AP 19 JAN 21
AP 19 JAN 21
AP 19 JAN 21
AP 19 JAN 21

Opn.	Planned WorkCentre	WorkCentre Description	Operation Details				Initials	Comments	Scrap Qty.	Comp. Qty.	Qty.	Operation Details	Line Closure	In-Process Dimensional Inspection	Quality Inspection & Review	Quality Inspection & Review	Record Data in SAP Inspection Plan	Required Inspection	Quality Inspection & Review	Confirmation & Milestone Review	Notes:
1050	QUALITY1																				





Opn	Planned Workcenter	Operation Description	Qty.	Scrap Qty	& Descr.	Date	Initials
Material: SA0254-06 Rev G							
1070	CATASY04	Rework Assembly 4					
		MP10398 Rev. M					
		Material consumed					
		Process					
		Confirmation of Milestone					
1090	QUALITY1	Required Inspection					
		Perform Quality Inspection per QIP Document #3107613					
		Record Data in SAP Inspection Plan					
		Review Quality Inspection & Inspection Review					
		Notes:					





Opn.	Planned Workcenter	Description	Operation Details					
Qty.	Comp. Date	Start Date	Qty.	Scrap Qty	Qty.	Comp.	Initials	
1100	PACKINT1	Packaging Instructions SP10087 REV. H						





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SA0254-06

Page: 16 of 16

Date Printed: 08.01.2021 / 17:00:37

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
PC



Production Order: 500000066049

Material: SA0254-06 Rev G

Sheet: 1 of 1

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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Before & After	Dimension #	Gauge	TM###XX	Initials	Date	Time	Inspecting Parts
Before	Dimension 13	TMI0748AN	MU	09 Jan 21	9:00pm		
After	Dimension 21	TMI0747TU	MU	09 Jan 21	9:00pm		
Before	Dimension 13	TMI0748AN	MU	09 Jan 21	9:00pm		
After	Dimension 13	TMI0748AN	MU	11 Jan 21	6:30pm		
Before	Dimension 21	TMI0747TU	MU	09 Jan 21	9:00pm		
After	Dimension 21	TMI0747TU	MU	11 Jan 21	6:30pm		
Before	Dimension 13	TMI0748AN	MU	09 Jan 21	9:00pm		
After	Dimension 21	TMI0747TU	MU	11 Jan 21	6:30pm		
Before	Dimension 13	TMI0748AN	MU	09 Jan 21	9:00pm		
After	Dimension 21	TMI0747TU	MU	11 Jan 21	6:30pm		

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

OPER 500.0

PRODUCTION ORDER# 50000066049

Title: SA0254 Max OD Gauge Check Form

Document Type: Manufacturing Form

Rev: B

Document No: FM5104694



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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		0	0	WU 115 Jun 21
Outer Diameter A 13 MAX OD at Pad Printed Area		Ring Gauge equivalent TM10748 or +/- 0.004"	100%	0.145" +0.002/-	65	65	WU 115 Jun 21
Outer Diameter A 21 MAX OD		Ring Gauge equivalent TM10747 or +/- 0.003"	100%	0.157" ± 0.003"	0	0	WU 115 Jun 21

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			PRODUCTION ORDER# 66099
Outer Diameter A21 MAX OD				
Outer Diameter A2 MAX OD				
Outer Diameter A2 MIN OD	0.142" ± 0.002"	100%	Ring Gauges TM10967, or equivalent	UT
No-go gauge: End must not pass through	(0.140"-0.144")	0.948E	370	0
Go-gauge: Measure from digital end to minimum 1.7"	(0.140"-0.144")	0.967J3	370	39
from tip. Gravity force only.				15 Jan 21
Outer Diameter A2 MIN OD	0.142" ± 0.002"	100%	Ring Gauges TM10968, or equivalent	UT
No-go gauge: End must not pass through	(0.140"-0.144")	0.948E	370	0
Go-gauge: Measure from proximal end to the material transition.	(0.138"-0.142")	0.967J3	370	39
Outer Diameter A2 MAX OD	0.142" ± 0.002"	100%	Ring Gauges TM10967, or equivalent	UT
No-go gauge: End must not pass through	(0.140"-0.144")	0.948E	370	0
Go-gauge: Measure from proximal end to the material transition.	(0.138"-0.142")	0.967J3	370	39
Outer Diameter A12 MAX OD	0.142" ± 0.002"	100%	Ring Gauges TM10968, or equivalent	UT
No-go gauge: End must not pass through	(0.140"-0.144")	0.948E	370	0
Go-gauge: Measure from digital end to minimum 1.7"	(0.140"-0.144")	0.967J3	370	39
from tip. Gravity force only.				15 Jan 21
Outer Diameter A12 MIN OD	0.142" ± 0.002"	100%	Ring Gauges TM10968, or equivalent	UT
No-go gauge: End must not pass through	(0.140"-0.144")	0.948E	370	0
Go-gauge: Measure from proximal end to the material transition.	(0.138"-0.142")	0.967J3	370	39
Outer Diameter A12 MAX OD	0.142" ± 0.002"	100%	Ring Gauges TM10967, or equivalent	UT
No-go gauge: End must not pass through	(0.140"-0.144")	0.948E	370	0
Go-gauge: Measure from proximal end to the material transition.	(0.138"-0.142")	0.967J3	370	39
Outer Diameter A12 MIN OD	0.142" ± 0.002"	100%	Ring Gauges TM10968, or equivalent	UT
No-go gauge: End must not pass through	(0.140"-0.144")	0.948E	370	0
Go-gauge: Measure from proximal end to the material transition.	(0.138"-0.142")	0.967J3	370	39
Outer Diameter A18 MAX OD	0.140" ± 0.002"	100%	Two Axis Laser Micrometer	UT
Measure from proximal end of shaft to the material transition.	(0.138"-0.142")	5C049	346	0
Outer Diameter A18 MIN OD	0.140" ± 0.002"	100%	Two Axis Laser Micrometer	UT
Measure from proximal end of shaft to the material transition.	(0.138"-0.142")	5C049	346	0
Outer Diameter A18 MAX OD	0.140" ± 0.002"	100%	Two Axis Laser Micrometer	UT
Measure from proximal end of shaft to the material transition.	(0.138"-0.142")	5C049	346	0
Outer Diameter A18 MIN OD	0.140" ± 0.002"	100%	Two Axis Laser Micrometer	UT
Measure from proximal end of shaft to the material transition.	(0.138"-0.142")	5C049	346	0

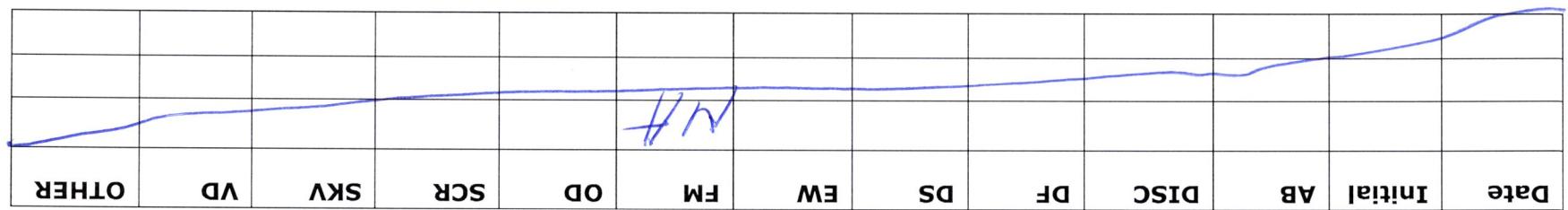


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Test/Specification	Document No:	Rev: B	Title: SA0254 In-Process Inspection Form Document Type: Manufacturing Form	PRODUCTION ORDER#
Outer Diameter A3 AVG OD at Pad Printed Area	FM5104696			60049
Outer Diameter A21 AVG OD				
15 Jan 21	NT	0	Measure from stop 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.

Page 1 of 2
Printed On: 12/8/2020 4:36:00 PM



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.

Deviation To:

100% Inspections at Final Inspection (Do 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

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:

15Jan2021

End Date:

22Jan2021

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):

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:

Yes No **If no, explain:**

Title	Approval Name	Approval Signature	Date
Quality Director	Jeff Pumper		15 JAN 2021
OPS Manager	Zach Nelson		15 JAN 2021
Staff Engineer	Vivek Rangaswami <i>15 Jan 2021</i>		15 JAN 2021

FMM002.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
EDW Commander Balloon - Bend and Tensile Strength Testing											
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	22.259
Seg C	53.5	54.26	67.22	49.9	54.21	52.88	67.58	60.58	50.06	50.67	6.6999655

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
 Kocayule