



MEDICAL  
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SA0254-06

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Date Printed: 08.01.2021 / 17:00:37

								Notes: DA:1738, DA1787

Op#	Planned WorkCentre	Description	Operation Details			Comp.	Scrap Qty	Qty.	Inittials
50	CATASY04	Prepare Materials	MP10398 Rev. L	Line Clearance	MP10230 Rev. E	By:	08Jan21	Date:	LJ
100	CATASY04	Assembly 4	Prepare Materials	MP10398 Rev. L	Line Clearance	MP10230 Rev. E	By:	08Jan21	LJ

Material Type:	ZFR	Description: Printed Shaft 144C Prox End Color B CMDR	Order Type: ZSTD	Project Phase:	Version:	Plant / Business Unit:	Produced:	Planned WorkCentre	No.
Material:	SA0254-06	Rev G	Sheet: 1 of 1	PC	PC	Product Document Order Qty: 500	Production Order Document	Product Order Qty: 500	Prod

# Production Order: 500000066049

Production Order Document  
Production Order Qty: 500  
PC

## Material: SA0254-06 Rev G

Sheet: 1 of 1

Opn No.	Planned WorkCenter Description	Operation Details						Comp. Qty	Scrap Qty & Desc.	Date Comp.	Initiator
		Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.				
	Assembly 4							500	0	08 Jan 21	14
	Straighten First Jacket	MM0187-01	E	E	PC	1	0000064857	500		09 Jan 21	SP (LA AN)
	Confirmation Rreqd(Milestone )			N/A				164	0	08 Jan 21	BA : SP (LA AN)
150	CATASY04 Catheter Assembly 4	MM0189-01	D	D	PC	500	0000064795	359		08 Jan 21	BA : SP (LA AN)
	Positioning Braid Over First Jacket	MM0189-01	D	D	PC	500	0000064993	94		08 Jan 21	BA : SP (LA AN)
	Confirmation Rreqd(Milestone )						0000064796	50			

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SA0254-06

**Production Order:** 500000066049

Production Order Document  
Production Order Qty: 500

Material: SA0254-06 Rev G

## Observation Details

## Notes:

Date Printed: 08.01.2021 / 17:00:37

Date: 2 af 1

A standard linear barcode consisting of vertical black bars of varying widths on a white background.

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# Production Order: 5000000066049

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Production Order Qty: 500  
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## Material: SA0254-06 Rev G

Opn No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Intrans.
		Number	Rev	Used	No.	Qty Used					
	Position Tubing for Reflow	MM0186-00	D	D	PC	500	P08-061101	250			
		MM0523-03	C	C	PC	500	0000058407	250			
		MM0524-01	B	B	PC	500	0000059871	100			
		MM0530-01	B	B	PC	500	0000059872	500			
		RM7586-02	D	D	PC	500	0000057812	N/A			
		RM8745-01	B	B	PC	500	25469	500			
		MM0185-01	I	I	PC	500	0000064121	500			

Notes:

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09 Jan 21 CL  
09 Jan 21 CL  
09 Jan 21 CL

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Material: SA0254-06 Rev G

## Notes:

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A standard linear barcode consisting of vertical black bars of varying widths on a white background.

VNU 09 Jan 21



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## Material: SA0254-06 Rev G

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Opn No.	Planned WorkCenter Description	Operation Details					
		Comp. Qty & Desc.	Scrap Qty & Desc.	Date Comp.	Initiat		
400	CATASY04 Skive Heat Shrink	N/A					
400	CATASY04 Catheter Assembly 4 Count: Yes	In-Process Inspection (Visual Inspection) MPI0398 Rev. U FM5104693 In Process Inspection	215 266 1 AB 2 FM 1 DF 3 DS 2 DISC (Rework if needed. Use FM5104983)	5 EW 2 EW 1 AB 2 FM 1 DF 3 DS 2 DISC	09Jan21 11 Jan 21	Pny TRWL JK	
450	CATASY04 Catheter Assembly 4	Anneal Shaft MPI0398 Rev. U FM5104692	150 331 0	09Jan21 11 Jan 21	Pny TRWL JK		
		Anneal Shaft					

Notes:

N/A

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Op# No.	Planned WorkCenter Description	Operation Details					
		Comp. Qty	Scrap Qty & Desc.	Date Comp.	Initiat		
500	CATASY04  Catheter Assembly 4	Leak Test/Prox Cut/Ring Gage-Dim 13/21  MPI0398 Rev. <u>H</u>	0 6500 Fail 90 0	09 Jan 21 NYL 11 Jan 21 CKY 11 Jan 21 NYT	09 Jan 21 NYL 11 Jan 21 CKY 11 Jan 21 NYT		
	Leak Test/Prox Cut/Ring Gage-Dim 13/21	(Rework if needed - Use FM5104983)					
550	CATASY04  Catheter Assembly 4	Distal Cut MPI0398 Rev. <u>H</u> Line Closure <u>L</u> MPI0230 Rev. <u>F</u> By: <u>WU</u>	0 322 0 90 0	09 Jan 21 NYL 11 Jan 21 CKY 11 Jan 21 NYT	09 Jan 21 NYL 11 Jan 21 CKY 11 Jan 21 NYT		
	Distal Cut	Date: 11 Jan 21					
600	PADPRIN1  Pad Print Count: Yes	Pad Print Set Up MPI0276 Rev. <u>D</u> Line Clearance <u>E</u> MPI0230 Rev. <u>E</u>	0 240 0 176 0	11 Jan 21 CK 12 Jan 21 PK	11 Jan 21 CK 12 Jan 21 PK		
	Notes:	W/A					

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Opn Nb.	Planned WorkCenter Description	Operation Details			
Opn Nb.	Planned WorkCenter Description	By:	Date:	Comp. Qty. City.	Scrap Qty. & Desc.
	Pad Print Setup	TM0503 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	TM0735 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		

Notes:	N/A	

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Material: SA0254-06 Rev G



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Opr No.	Planned WorkCenter Description	Operation Details					Initials
		Comp. Qty. Qty.	Scrap Qty. & Desc.	Date Comp.			
650	PADPRIN1  Verification	240	0	11 Jan 21	GJ		
		176	0	12 Jan 21	PK		
RM7407-01	B  Pad Print  Verification	0.050	TP 25383	0.050	N/A		

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Opn No.	Planned WorkCenter Description	Operation Details						Comp. Scrap Qty & Desc.	Date Comp.	Initials
		Opn No.	WorkCenter	Tool	Unit	Qty	Opn Desc.			
	N/A	RM7408-01	B	B	L	0.005	TP53072	0.005		
		RM7409-01	B	B	L	0.010	TP25634	0.00		
700	PADPRIN1	Pad Print					Prepare Surface for Ink MPI0276 Rev. D Section 15.5 Polynit wipes 99% IPA	240 176	0 0	11Jan21 GL 12Jan21 PK
							Prepare Surface for Ink			
750	PADPRIN1	Pad Print					Print Parts MPI0276 Rev. D Section 20.0 Inspection gauge TMI0843	240 176	0 0	11Jan21 GL 12Jan21 PK
							Print Parts			

Notes:

N/A

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Op. No.	Planned WorkCenter Description		Operation Details			
			Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initiator
800	PADPRIN1	In-Process Inspection and Rework MP10276 Rev. <u>D</u> Section 30.0 Polynit Wipes 99% IPA Mag Light	240 176	0 0	11 Jan 21 12 Jan 21	CZ PK
850	PADPRIN1	Curing Oven MP10340 Rev. <u>B</u> Section 35.0  Curing oven for 120 +30/-15 minutes Parts sit for 8 hours minimum after curing oven By: <u>PK</u> Lot Completion time: <u>12:50 PM</u> Date: <u>12 Jan 21</u> Curing Oven Confirmation Reqd(Milestone )	416	0	12 Jan 21	PK
900	PADPRIN1	Transfer Parts to Production MP10276 Rev. <u>D</u> Section 40.0	416	0	13 Jan 21	TW
		Notes:				

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## Operation Details

Opn No.	Planned WorkCenter Description	Operation Details			
		Comp. Qty	Scrap Qty	Date Comp.	Initials
	 Transfer parts to Production Confirmation Reqd(Milestone )	Transfer Parts to Line Time: <u>5:20 am</u> By: <u>Ty</u> Date: <u>13 Jan 21</u>			V A
950	 PADPRIN1 Pad Print Count: Yes Cleaning Confirmation Reqd(Milestone )	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>	416	0	12 Jan 21 PK
1000	CATASY04	In-Process Dimensional Inspection			N/A

Notes

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A standard linear barcode is positioned vertically on the left side of the page. To its right, the number '800251 06' is printed in a large, bold, black font.

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# Production Order: 500000066049

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Production Order Qty: 500  
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## Material: SA0254-06 Rev G

Opn No.	Planned WorkCenter Description	Operation Details					
		Comp. Qty	Scrap Qty & Desc.	Date Comp.	Initials	Comp.	
	Catheter Assembly 4	MPI0398 Rev. <u>1A</u> FM5104662 FM5104696  (No Rework can be done at this OP)	346	70 DD FA 1 15 Jun 21	NT		
	In-Process Dimensional Inspection	Line Closure MPI0230 Rev. <u>E</u>  By: <u>NT</u> Date: <u>15 Jun 21</u>					
1050	QUALITY	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	FF 10 HO 07/08/21 246	16 JUN 21 19 JUN 21 PRT - 11 IB - 8 AB - 1 FM - 1 TT - 10 SCR - 1	AP AP		
		Quality Inspection & Review					
		Quality Inspection & Review					
		Confirmation Reqd(Milestone )					
		Notes:					

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## Material: SA0254-06 Rev G

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

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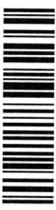
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Opn No.	Planned WorkCenter Description	Operation Details			
		Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Confirmation Rqd(Milestone )				✓/A
1100	PACKINT1	Packing Instructions SPI0087 REV. H	246	21/San 21 AF	
	Packing assembly				
	Packing Instructions				
	Confirmation Rqd(Milestone )				

Notes:


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**Production Order:** 500000066049



Production Order Document  
Production Order Qty: 500  
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**Material:** SA0254-06 Rev G

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**Batch Number:** 0000066049

By: AF

Date: 21 Jan 21

**Reviewed By:** maf

Date: 23 Jan 21

**Notes:**

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Document No: FM5104983

Page D

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

PRODUCTION ORDER# 666049

## **Attachment B: Cause of Rework.**

OPER 400.0

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

## **Attachment B: Cause of Rework**

OPERA 500-0

Date	Initial	Dim 13 (Go Gauge)	Dim 21 (Go gauge)
11 Jan 21	✓	0	109
11 Jan 21	✓	0	90
11 Jan 21			N/A

Status CURRENT Effective 10/27/2020



PRODUCTION ORDER# 06049

**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	491	0	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	491	0	0	
All other Foreign Material:			Tappi Chart and 2.85x Mag. Light	491	0	0	
Particle Size Area: mm <sup>2</sup>	Acceptable Limits per Part	See Table					
< 0.05 mm <sup>2</sup>	No Limit						
0.05 mm <sup>2</sup> ≤ Area < 0.25 mm <sup>2</sup>	3						
0.25 mm <sup>2</sup> ≤ Area < 0.80 mm <sup>2</sup>	2						
0.80 mm <sup>2</sup> ≤ Area ≤ 1.5 mm <sup>2</sup>	1						
> 1.5 mm <sup>2</sup>	0						
No surface damage to the shafts such as voids pits or cuts. (interior surface of distal end not included)	N/A	100%	2.85x Mag. Light	491	0	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	491	0	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	481	16	0	
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	481	0	0	YK 11 Jan 21



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Document No: EM5104692

Down D

Rev. B

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

6049

**PRODUCTION ORDER#** \_\_\_\_\_

OPER 450.0

## Annealing Log Sheet



PRODUCTION ORDER# 50000066049

**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  (Ex. TMI0748AC or TMI0747AD)	TMI##XX	Initials	Date	Time
Before	Dimension 13	TMI0748AN	MJ	09 Jan 21	9:00pm
Before	Dimension 21	TMI0747U	MW	09 Jan 21	9:00PM
After	Dimension 13	TMI0748AN	LJ	11 Jan 21	6:30 pm
After	Dimension 21	TMI0747U	LJ	11 Jan 21	6:30 PM

PRODUCTION ORDER# 66019

OPER 500.0							Pressure Decay Testing			
Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date			
<b>Air Leak Test GN 15</b>	N/A	100% Issac Pressure Decay Tester	TM10747	481	0		<u>MCL 11 Jan 21</u>			
<b>Outer Diameter ▲ 13 MAX OD at Pad Printed Area</b>	0.145" +0.002"/- 0.004" (≤0.147")	100%	Ring Gauge TM10748 or equivalent	TM10748	416	65				
<b>Outer Diameter ▲ 21 MAX OD</b>	Drop Go Gauge from proximal end of shaft. Pass if ring stops at stop sleeve shoulder. Fail if gauge stops above or falls past stop sleeve shoulder.	0.157" ± 0.003" (≤0.160")	100% Ring Gauge TM10747 or equivalent	TM10747	416	0	<u>MCL 11 Jan 21</u>			

PRODUCTION ORDER# 66049

**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	CL	15-Jan-21	5:15 AM
Before	Dimension 21	TMI 0747T	CL	15-Jan-21	5:15 AM
After	Dimension 13	TMI 0748 AM	CL	15-Jan-21	12:30 pm
After	Dimension 21	TMI 0747T	CL	15-Jan-21	12:30 pm

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
<b>Outer Diameter ▲3 MAX OD at Pad Printed Area</b>	0.145" +0.002"/- 0.004" (≤0.147")	100%	Ring Gauge TMI0748 or equivalent	TMI 0748Rm	415	1	NT 15 Jan 21
<b>Outer Diameter ▲21 MAX OD</b>	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TMI0747 or equivalent	TMI 0747T	409	4	NT 15 Jan 21
<b>Outer Diameter ▲2 MAX OD</b>	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0967, or equivalent	TMI 0967J	370	39	NT 15 Jan 21
<b>Outer Diameter ▲2 MIN OD</b>	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0968, or equivalent	TMI 0968E	370	0	NT 15 Jan 21
<b>Outer Diameter ▲18 MAX OD</b>	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI 50049	344	24	NT 15 Jan 21
<b>Outer Diameter ▲18 MIN OD</b>	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI 50049	344	0	NT 15 Jan 21

PRODUCTION ORDER# 66049

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
<b>Outer Diameter ▲3 AVG OD at Pad Printed Area</b>  Measure from distal end of material transition to stop sleeve shoulder  <b>NOTE:</b> Measure Avg OD and record results	0.145 +0.002"/-0.004" (0.141"-0.147")	100%	Two Axis Laser Micrometer	TMI 50049	344	0	NT 15 Jan 21
<b>Outer Diameter ▲21 AVG OD</b>  Measure from stop sleeve shoulder to 4" distal of stop sleeve shoulder.  <b>NOTE:</b> Measure Avg OD and record results	0.157" ± 0.003" (0.154"-0.160")	100%	Two Axis Laser Micrometer	TMI 50049	344	0	NT 15 Jan 21
<b>Outer Diameter ▲7 AVG OD</b>  Measure 4" distal the stop sleeve shoulder to the braid termination.  <b>NOTE:</b> Measure and Record results	0.157" ± 0.003" (0.154"-0.160")	100%	Two Axis Laser Micrometer	TMI 50049	344	0	NT 15 Jan 21
<b>Outer Diameter ▲2 MAX OD</b>  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	344	0	NT 15 Jan 21
<b>Outer Diameter ▲2 MIN OD</b>  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	344	0	NT 15 Jan 21

PRODUCTION ORDER# 66049

OPER 1050.0

Date	Initial	AB	DISC	DF	DS	EW	FM	OD	SCR	SKV	VD	OTHER

Record total quantity reworked:

NA

Quantity Passed after Rework:

NA

Rework Performed by: NA Date: NA Rework Performed by: NA Date: NA

Re-Inspection Performed by: NA Date: NA

## DEVIATION AUTHORIZATION FORM

**Requestor Name:** Govind Sharma

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

<b>Deviation From:</b>	<b>Deviation To:</b>
Currently at "Inline dimensional inspection operation" operators just check the dimension using laser mic and ring gauges and do not record any variable data.	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.

<b>Justification:</b>	
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	G1
N/A	N/A

Start Date:	End Date:	Lot Number:
12/9/2020	1/9/2021	N/A

Risk Assessment:
Extend to 08 Feb 21. AT 08 Feb 21   08 Jan 21

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 <sup>Mo 9 Dec 20</sup> <del>OPS Mgr</del>	Steve Julie <sup>Mo 9 Dec 20</sup> <del>Mirin Opaz</del>		08 DEC 20
Operation Manager <sup>*0</sup>	Mitch.Opaz <sup>*0</sup>		09 DEC 2020

Govind Sharma

Steve Julie

\*05 J 09 DEC 2020

FM0002.RevF

10/30/2015

Deviation Authorization

# TEST DATA SHEET

Part Number: SA0254-xx 06

Date: 15 Jan 21

Lot Number: 66049

Tested by: NT

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	0.1452
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	0.1426		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	0.1426	0.1421		0.1445	0.1455
11					
12					
13					
14					
15					
16			NA		
17					
18					
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Comments: \_\_\_\_\_

FM0015

Rev A

Effectivity Date: October 9, 2008

TACPRO, INC.

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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:	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:**  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 PETR <small>15 JAN 2021</small>		15 JAN 2021

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	31.14	28.01	30.12	27.34	26.31	28.11	31.4	32.01	33.2	29.84	29.748	2.240252	4.378	19.94017688	8.542	PASS
Seg B	23.44	22.36	20.94	23.88	19.16	21	23.85	21.18	24.56	22.22	22.259	1.6981326	4.378	14.82457533	8.542	PASS
Seg C	53.5	54.26	67.22	49.9	54.21	52.88	67.58	60.58	50.06	50.67	56.086	6.6999655	4.378	26.75355102	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 8.5421bf

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.

Korhynlop

20 JAN 21