

Production Order: 500000066206



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>LY</u> Date: <u>12Jan21</u> Prepare Materials Confirmation Reqd(Milestone)		500	0	12Jan21	LY
100	CATASY04 Catheter	Straighten First Jacket MPI0398 Rev. <u>U</u>			N/A	

Notes: DA: 1738, DA1787 DA1787

N/A

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22 Feb 21 CL

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Material: SA0254-06 Rev G

Op No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Assembly 4 							500	0	12Jan21	LY
	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	<u>0000065532</u>	<u>500</u>	<u>N/A</u>		
150	CATASY04 	Positioning Braid Over First Jacket MPI0398 Rev. <u>4</u>						72	0	12Jan21	MH
N/A	Positioning Braid Over First Jacket	Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used		428	
	Confirmation Reqd(Milestone)	MM0189-01	D	<u>D</u>	PC	500	<u>0000065665</u>	<u>270</u>	<u>N/A</u>	<u>500</u>	<u>O</u>
							<u>0000064996</u>	<u>230</u>	<u>N/A</u>		

Notes:

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Production Order: 500000066206



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

Op 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>C</u> Temp = 420°F 5°F Air Flow = 60 SCFH						500	0	13Jan21	Ay
	Strain Relief Reflow	Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used			
	Confirmation Rreqd(Milestone)	MM0527-01	B	<u>B</u>	PC	500	<u>0000058674</u>	<u>500</u>			
							<u>NA</u>	<u>NA</u>			
		RM0096-01	F	<u>F</u>	PC	125	<u>27697</u>	<u>180</u>			
							<u>NA</u>	<u>NA</u>			
250	CATASY04 Catheter Assembly 4 	Position Tubing For Reflow MPI0398 Rev. <u>C</u>						500	0	13Jan21	SC BK SP AN
	Component	Req'd	Rev	UOM	Qty.	Batch	Actual				

Notes:

N/A

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Op. No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
WIA	Position Tubing for Reflow	Number	Rev	Used		No.	Qty	Used				
		MM0186-00	D	<u>D</u>	PC	500	<u>P08 - 061101</u>	<u>500</u>				
							<u>NA</u>	<u>NA</u>				
		MM0523-03	C	<u>C</u>	PC	500	<u>0000059871</u>	<u>500</u>				
							<u>NA</u>	<u>NA</u>				
		MM0524-01	B	<u>B</u>	PC	500	<u>0000058676</u>	<u>500</u>				
							<u>NA</u>	<u>NA</u>				
		MM0530-01	B	<u>B</u>	PC	500	<u>0000059064</u>	<u>500</u>				
							<u>NA</u>	<u>NA</u>				
		RM7586-02	D	<u>D</u>	PC	500	<u>25469</u>	<u>2500</u>				
							<u>25632</u>	<u>250</u>				
		RM8745-01	B	<u>B</u>	PC	500	<u>28195</u>	<u>400</u>				
							<u>26866</u>	<u>100</u>				
		MM0185-01	I	<u>I</u>	PC	500	<u>0000061042</u>	<u>500</u>				
							<u>NA</u>	<u>NA</u>				

Notes:

WIA

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CV 13 Jan 21



Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		MM1540-01 A <u>A</u> PC 500	<u>0000060069</u>	<u>500</u>	<u>NA</u>	<u>NA</u>						
		MM1539-01 A <u>A</u> PC 500	<u>0000061041</u>	<u>500</u>	<u>NA</u>	<u>NA</u>						
		RM016101-MED F <u>F</u> PC 46 <u>NA</u> <u>NA</u>		<u>26989</u>	<u>160</u>	<u>NA</u>						
300	CATASY04 Catheter Assembly 4 Reflow	Reflow MPI0398 Rev. <u>u</u> Temp = 415°F (+/- 15 °F) Speed = 4.5 in/min (+/- 0.5 in/min)					500	0	13Jan21	IW KS VWJ		
350	CATASY04 Catheter Assembly 4	Skive Heat Shrink MPI0398 Rev. <u>u</u>					500	0	13Jan21	px		

Notes:

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Material: SA0254-06 Rev G

Opn No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	 Skive Heat Shrink	<i>N/A</i>		<i>N/A</i>		
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)	489	6 EW 4 DISC 1 DF	13 Jan 21	Pny
450	CATASY04 Catheter Assembly 4 Anneal Shaft	Anneal Shaft MPI0398 Rev. <u>u</u> FM5104692	7 380 109	0 0	13 Jan 21 14 Jun 21	Pny YK

Notes:

N/A

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Pny 13 Jan 21

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Material: SA0254-06 Rev G

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)	257 220	8 Fail 300 Fail 400	13 Jan 21 14 Jan 21	NYL XX NT
550	CATASY04 Catheter Assembly 4 	Distal Cut MPI0398 Rev. <u>U</u> Line Closure MPI0230 Rev. <u>E</u> By: <u>NT</u> Date: <u>14 Jan 21</u> Distal Cut	257 220	0 0	13 Jan 21 14 Jan 21	MCG NT
600	PADPRIN1 Pad Print Count: Yes 	Pad Print Set Up MPI0276 Rev. <u>D</u> Line Clearance MPI0230 Rev. <u>E</u>	277 477	0	14 Jan 21	KUT

Notes:



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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Pad Print Setup	<p>By: <u>kut</u> Date: <u>14 Jan 21</u></p> <p>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 TMI0843C 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:





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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		N/A				
650	PADPRIN1 Pad Print Verification	Verification MPI0276 Rev. <u>D</u> Section 15.0	477	0	14Jan21	KUT

Notes:

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		RM7408-01	B	<u>B</u>	L	0.005	<u>IP55394</u>	<u>0.005</u>				
		RM7409-01	B	<u>B</u>	L	0.010	<u>26764</u>	<u>0.010</u>			<u>N/A</u>	
700	PADPRIN1 Pad Print 	Prepare Surface for Ink MPI0276 Rev. <u>D</u> Section 15.5 Polynit wipes 99% IPA						477	0	14Jan21	KUT	
750	PADPRIN1 Pad Print 	Print Parts MPI0276 Rev. <u>D</u> Section 20.0 Inspection gauge TMI0843						477	0	14Jan21	KUT	

Notes:

N/AN/A



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Opr 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	477	0	14Jan21	KUT
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>11:45 am</u> By: <u>Ty</u> Date: <u>15 Jan 21</u>	477	0	14Jan21	KUT
900	PADPRIN1 Pad Print	Transfer Parts to Production MPI0276 Rev. <u>D</u> Section 40.0		N/A		

Notes:



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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	 Transfer parts to Production Confirmation Reqd(Milestone)	Transfer Parts to Line Time: <u>11:30PM</u> By: <u>kut</u> Date: <u>15Jan21</u>	477	0	<u>15Jan21</u>	<u>kut</u>
950	PADPRIN1 Pad Print Count: Yes Line Clearance MPI0230 Rev. <u>B</u> Cleaning Confirmation Reqd(Milestone)	Cleaning MPI0276 Rev. <u>D</u> Section 50.0 Line Clearance MPI0230 Rev. <u>B</u> By: <u>kut</u> Date: <u>14Jan21</u>	477	0	<u>14Jan21</u>	<u>kut</u>
1000	CATASY04	In-Process Dimensional Inspection			<u>N/A</u>	

Notes:

N/AN/A

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Material: SA0254-06 Rev G

Op. No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	<p>Catheter Assembly 4 In-Process Dimensional Inspection </p> <p>MPI0398 Rev. <u>U</u> FM5104662 FM5104696</p> <p>(No Rework can be done at this OP)</p> <p>Line Closure MPI0230 Rev. <u>E</u></p> <p>By: <u>Pny</u> Date: <u>23 Jan 21</u></p>		474	30D Fail	23Jan21	CKY Pny ncl
1050	<p>QUALITY1 Quality Inspection & Review Quality Inspection & Review Confirmation Reqd(Milestone)</p>	<p>Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan</p>	370	#180D - 52 PRT - 33 TF - 10 SCR - 4 CEN - 3 VD - 1 FM - 1	20FEB21	AP

Notes:

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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	N/A	N/A	N/A	N/A	N/A	N/A
1070	CATASY04 Catheter Assembly 4 Rework Process Confirmation Reqd(Milestone)	Rework MPI0398 Rev. <u>1</u> Material consumed Material <u>N/A</u> Batch <u>N/A</u> Rev <u>N/A</u> Qty <u>N/A</u> Material <u>N/A</u> Batch <u>N/A</u> Rev <u>N/A</u> Qty <u>N/A</u>				
1090	QUALITY1 Quality Inspection & Review Quality Inspection & Review	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	370	0	Z 20FEB21 AP	
Notes:						
<i>N/A</i>						

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Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Confirmation Reqd(Milestone)	NA		NA		
1100	PACKINT1 Packing assembly  Packing Instructions Confirmation Reqd(Milestone)	Packaging Instructions SPI0087 REV. H	370	0	23Feb21	41

Notes:

NA

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Production Order: 5000000066206



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

Material: SA0254-06 Rev G

Batch Number:	0000066206
By:	YT
Date:	23 Feb 21

Reviewed By:	<i>Murder</i>
Date:	23 Feb 21

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

Date Printed: 11.01.2021 / 17:55:38

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PRODUCTION ORDER# 5000066206

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	500	0	0	PNY 13 Jan 2021
Metallic Foreign Material: No embedded metallic and foreign material is allowed along the length of the shaft.	N/A	100%	2.85x Mag. Light	500	0	0	
All other Foreign Material:			Tappi Chart and 2.85x Mag. Light	496	4		
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	496	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	496	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	489	7	7	
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	489	0	0	PNY 13 Jan 2021

PNY 13 Jan 2021



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Document No: FM5104983

Rev. B

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

PRODUCTION ORDER# 15000000-66206

Attachment B: Cause of Rework.

OPER 400.0

Date	Initial	AB (Prox)	AB (Distal)	DF	DS	EW	FM	Disc	SCR	SKV	VD
13 Jan 21	pny	o	8	o	o	o	2 2	o	o	o	o

Attachment B: Cause of Rework

OPER 500-0

Date	Initial	Dim 13 (Go Gauge)	Dim 21 (Go gauge)
14 Jan 21	VC	0	56 N/A



CREGANNA MEDICAL is part of

Document No: FM5104692
Rev: B
Document Type: Manufacturing Form
Title: SA0254 Annealing Oven Log Form

PRODUCTION ORDER# 500000066206

OPER 450.0

Annealing Log Sheet



PRODUCTION ORDER# 500000066906

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. TMI###XX TMI0748AC or TMI0747AD)	Initials	Date	Time
Before	Dimension 13	TMI 0748AN MW	13 Jan 21	10:05 pm
Before	Dimension 21	TMI 0747A MW	13 Jan 21	10:05 pm
After	Dimension 13	TMI 0748 AN CL	14 Jan 21	2:00 pm
After	Dimension 21	TMI 0747 U CL	14 Jan 21	2:00 pm

PRODUCTION ORDER# 4420450000066206

22 Feb 21 CL

OPER 500.0

Pressure Decay Testing

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
Air Leak Test GN 15	N/A	100%	Issac Pressure Decay Tester	TMI 0797B	489	0	NT 14 Jan 21
Outer Diameter ▲ 13 MAX OD at Pad Printed Area	0.145" +0.002"/- 0.004" (≤0.147")	100%	Ring Gauge TM10748 or equivalent	TMI 0748AN	477	12	NT 14 Jan 21
Outer Diameter ▲ 21 MAX OD 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	TMI 0747U	477	0	NT 14 Jan 21

22 Feb 21 CL

PRODUCTION ORDER# 442045cccc662c6

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 0746 AM	CL	21 Jan 21	6:20 AM
Before	Dimension 21				
		TMI 0747 TR	CL	21 Jan 21	6:20 AM
After	Dimension 13	TMI 0748 AM	CL	21 Jan 21	6:20 AM
After	Dimension 21	TMI 0747 TR	CL	21 Jan 21	8:40 AM

PRODUCTION ORDER# OP 1000.0 22 Feb 21 CL

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
Outer Diameter ▲13 MAX OD at Pad Printed Area	0.145" +0.002"/-0.004" (≤0.147")	100%	Ring Gauge TMI0748 or equivalent	TMI / 0748 #1	474	3	Cky 21 Jan 21
Outer Diameter ▲21 MAX OD	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TMI0747 or equivalent	TMI / 0747 T	474	0	Cky 21 Jan 21
Outer Diameter ▲22 MAX OD	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0967, or equivalent	TMI / 0967	474	0	Cky 21 Jan 21
Outer Diameter ▲2 MIN OD	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0968, or equivalent	TMI / 0968	474	0	Cky 21 Jan 21
Outer Diameter ▲8 MAX OD	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI / 50049	474	0	Pay 23 Jan 21
Outer Diameter ▲8 MIN OD	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI / 50049	474	0	Pay 23 Jan 21

PRODUCTION ORDER# 1042050006626
22-Feb-21 CL

Document No: FM5104696

Rev: B

Document Type: Manufacturing Form

Title: SA0254 In-Process Inspection Form

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
Outer Diameter ▲13 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	TM1 50049	474	0		PNY 23Jan21
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	TM1 50049	474	0		PNY 23Jan21
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	TM1 50049	474	0		PNY 23Jan21
Outer Diameter ▲12 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	TM1 50049	474	0		PNY 23Jan21
Outer Diameter ▲12 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	TM1 50049	474	0		PNY 23Jan21



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Document No: FM5104983

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

PRODUCTION ORDER# 1050-04 **OPER 1050-0**
DATE 22 Feb 2011

Record total quantity reworked:

NA

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

Re-Inspection Performed by: M/A Date: M/A

AK
Kette

Status CURRENT Effective 10/27/2020

Title	Approval Name	Approval Signature	Date
Mfg Engineering manager	Renate Holahan	RENE HOLAHAN	09/08/2020
Quality Manager Ops	Steve Julte	STEVE JULTE	08/08/2020
No QDCC20	Mo Tucci	MO TUCCI	08/08/2020
Operations Manager	Match Opatz	Match Opatz	09/08/2020

Training Required:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If no, explain: N/A
--------------------	---	---------------------

Corrective Action Required:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	If no, explain: Deviation talks about recording the variable data at a operation where we are already checking for the dimension.
-----------------------------	---	---

Risk Assessment:	If yes to any of the above, what controls are being put in place to mitigate the risk?	
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): N/A	Is there any potential risk(s) that may occur as a result of the proposed deviation including the following:	

Part Number Affected	SH0254-04/05/06	Revision: 5
Start Date:	12/9/2020	End Date: 1/9/2021
Lot Number:	N/A	At Orginal

Justification:		
As per the customer requirement we are starting to record the variable data for dimension 12 and 13 at "line dimension".		
Inspecction operation".		

Deviation From:	Currently at "line dimensional inspection operation" operators record the variable data for Dim 12 and Dim 13. 10 samples from each lot. Variable data using laser mic and ring gauges and do 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 recorded form to be filled by ops department ops lead to add to the excel file to monitor variable data behavior.	

Document Number Affected	MP10398	Revision: U
Requestor Name:	Govind Sharma	

Requestor Name:	Govind Sharma	
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DEVIATION AUTHORIZATION FORM



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Is part of
Gannett

30						
29						
28						
27						
26						
25						
24						
23						
22						
21						
20						
19						
18						
17						
16						
15						
14						
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12						
11						
10	0.1424	0.1419	NA	0.1442	0.1448	
9	0.1426	0.1423	NA	0.1435	0.1441	
8	0.1419	0.1416	NA	0.1444	0.1452	
7	0.1418	0.1415	NA	0.1445	0.1450	
6	0.1421	0.1418	NA	0.1439	0.1453	
5	0.1421	0.1415	NA	0.1434	0.1445	
4	0.1417	0.1415	NA	0.1442	0.1452	
3	0.1423	0.1416	NA	0.1442	0.1450	
2	0.1418	0.1417	NA	0.1446	0.1453	
1	0.1414 +/-0.021	0.1419	NA	0.1444	0.1450	

Test Description: Dim 12 and 13 variable data recording

Tested by: *PMT*Lot Number: *50000066206*Date: *23Jan21*Part Number: *SA0254-xx 06*

Sample	Dim 12 (Max) 0.142" +/-0.002	Dim 12 min 0.142" +/-0.002	Dim 13 Avg 0.145" +0.002"-0.004"	Dim 13 Max 0.145" +0.002"-0.004"	Dim 12 and 13 variable data recording	Comments:
1	0.1414 +/-0.021	0.1419	NA	0.1444	0.1450	
2	0.1418	0.1417	NA	0.1446	0.1453	
3	0.1423	0.1416	NA	0.1442	0.1450	
4	0.1417	0.1415	NA	0.1442	0.1452	
5	0.1421	0.1415	NA	0.1434	0.1445	
6	0.1421	0.1418	NA	0.1439	0.1453	
7	0.1418	0.1415	NA	0.1445	0.1450	
8	0.1419	0.1416	NA	0.1444	0.1452	
9	0.1426	0.1423	NA	0.1435	0.1441	
10	0.1424	0.1419	NA	0.1442	0.1448	
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TEST DATA SHEET

WKA2 Feb21

DEVIATION AUTHORIZATION FORM

DEVIATION AUTHORIZATION NUMBER: DA1787

Requestor Name: Saroenu Chhum		Deviation Form:	
Document Number Affected	Revision	Deviation To:	100% Inspections at Final Inspection (Do not require SmartSolve Notification to be issued).
2100586	B	SmartSolve Notification (Do not require 100% Inspections at Final Inspection (Do not require SmartSolve Notification to be issued)).	The following rules apply to these product families: If required for any sum of scraps at final inspection, 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 From:		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	Start Date:	End Date:
SAO286-01	07	SAO286-02	07
SAO286-04	07	SAO254-04	05
SAO254-05	G	SAO254-06	G
SAO254-06	F	SAO155-01	
SAO286-01	N/A	15Jan2021	22Jan2021
Risk Assessment: If yes to any of the above, what controls are being put in place to mitigate the risk: N/A Details (if any): 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			
Corrective Action Required: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes to any of the above, what controls are being put in place to mitigate the risk: 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: If no, explain: No correction is required, SAP will address all lot manufactured in the new system.			
Title Approval Name Approval Signature Date Quality Director Jeff Pumper Zach Nelson 15 JAD 2021 OPS Manager Zack Nelson 15 JAD 2021 Staff Engineer Vilek Rangaswami PTE 15 JAD 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	34.94	31.01	33.39	27.19	29.72	26.12	25.88	30.68	27.48	25.89	29.23	3.2437119	4.378	15.02902945	8.542	PASS
Seg B	23.18	22.5	20.87	22.14	23.34	20.95	21.56	22.78	20.55	21.61	21.948	0.992599	4.378	17.60257678	8.542	PASS
Seg C	47.71	66.11	51.46	50.08	67.52	49.68	47.94	46.44	46.88	51.67	52.549	7.7347232	4.378	18.68638173	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.

Kochyng Lee

22 Feb 21