

Production Order: 500000066053



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>CL</u> Date: <u>11 Jan 21</u>	500	0	11 Jan 21 CL	
100	CATASY04 Catheter	Straighten First Jacket MPI0398 Rev. <u>u</u>		N/A		

Notes: DA : 1738 DA1787

N/A

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19 Feb 21 CL

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Opr No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used				
N/A	Assembly 4											
	Straighten First Jacket	MM0187-01	E	<u>E</u>	PC	1	<u>0000064857</u>	<u>500</u>	500	0	11 Jan 21	KS
	Confirmation Reqd(Milestone)						<u>N/A</u>	<u>N/A</u>				
150	CATASY04	Positioning Braid Over First Jacket MPI0398 Rev. <u>u</u>							326	0	t-11-21 11 Jan 21 <u>NY</u>	N.V
	Catheter Assembly 4	Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used				
	Positioning Braid Over First Jacket	MM0189-01	D	<u>D</u>	PC	500	<u>0000064796</u> <u>0000064797</u> <u>0000064994</u>	<u>300</u> <u>84</u> <u>84</u>	174	0	11 Jan 21	MT
	Confirmation Reqd(Milestone)						<u>0000064994</u>	<u>32</u>				
							<u>0000064796</u>	<u>32</u>				

Notes:

N/A

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11 Jan 21 NV
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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																																			
200	CATASY04 Catheter Assembly 4 	<p>Strain Relief Reflow MPI0398 Rev. <u>1A</u></p> <p>Temp = 420°F 5°F Air Flow = 60 SCFH</p> <table border="1"> <thead> <tr> <th>Component Number</th> <th>Req'd Rev</th> <th>Rev Used</th> <th>UOM</th> <th>Qty.</th> <th>Batch No.</th> <th>Actual Qty Used</th> </tr> </thead> <tbody> <tr> <td>MM0527-01</td> <td>B</td> <td><u>B</u></td> <td>PC</td> <td>500</td> <td><u>0000058674</u></td> <td><u>500</u></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td><u>0000058371</u></td> <td><u>50</u></td> </tr> <tr> <td>RM0096-01</td> <td>F</td> <td><u>F</u></td> <td>PC</td> <td>125</td> <td><u>27976</u></td> <td><u>191</u></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td><u>N/A</u></td> <td><u>N/A</u></td> </tr> </tbody> </table>	Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	MM0527-01	B	<u>B</u>	PC	500	<u>0000058674</u>	<u>500</u>						<u>0000058371</u>	<u>50</u>	RM0096-01	F	<u>F</u>	PC	125	<u>27976</u>	<u>191</u>						<u>N/A</u>	<u>N/A</u>	312 188	0 0	11Jan21 11Jan21	AN AD
Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																																			
MM0527-01	B	<u>B</u>	PC	500	<u>0000058674</u>	<u>500</u>																																			
					<u>0000058371</u>	<u>50</u>																																			
RM0096-01	F	<u>F</u>	PC	125	<u>27976</u>	<u>191</u>																																			
					<u>N/A</u>	<u>N/A</u>																																			
250	CATASY04 Catheter Assembly 4 	<p>Position Tubing For Reflow MPI0398 Rev. <u>u</u></p> <table border="1"> <thead> <tr> <th>Component</th> <th>Req'd</th> <th>Rev</th> <th>UOM</th> <th>Qty.</th> <th>Batch</th> <th>Actual</th> </tr> </thead> </table>	Component	Req'd	Rev	UOM	Qty.	Batch	Actual	270 230	0 0	11Jan21 11Jan21	SC WKA SP VWJ BK VXMS																												
Component	Req'd	Rev	UOM	Qty.	Batch	Actual																																			

Notes:

N/A

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AN 11 Jan 21



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Opn No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
Position Tubing for Reflow	Number	Rev	Used		No.	Qty	Used					
	MM0186-00	D	<u>D</u>	PC	500	<u>P08-061101</u>	<u>350</u>					
						<u>P08-061101</u>	<u>150</u>					
	MM0523-03	C	<u>C</u>	PC	500	<u>0000059871</u>	<u>500</u>					
						<u>N/A</u>	<u>N/A</u>					
	MM0524-01	B	<u>B</u>	PC	500	<u>0000058676</u>	<u>500</u>					
						<u>N/A</u>	<u>N/A</u>					
	MM0530-01	B	<u>B</u>	PC	500	<u>00000059064</u>	<u>500</u>					
						<u>0000059064</u>	<u>70</u>					
	RM7586-02	D	<u>D</u>	PC	500	<u>25632</u>	<u>465</u>					
						<u>TP64459</u>	<u>35</u>					
	RM8745-01	B	<u>B</u>	PC	500	<u>27440</u>	<u>200</u>					
						<u>27613</u>	<u>135</u>					
						<u>27613</u>	<u>165</u>					
	MM0185-01	I	<u>I</u>	PC	500	<u>0000058372</u>	<u>465</u>					
						<u>P01-090901</u>	<u>35</u>					

Notes:

N/A



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Opn No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		MM1540-01 A <u>A</u> PC 500					<u>0000063081</u>	<u>500</u>			
		MM1539-01 A <u>A</u> PC 500					<u>0000061041</u>	<u>465</u>		<u>N/A</u>	
		RM016101-MED <u>N/A</u> F <u>F</u> PC 46					<u>0000061041</u>	<u>35</u>			
							<u>25104</u>	<u>20</u>			
							<u>TP65405</u>	<u>100</u>			
300	CATASY04 Catheter Assembly 4 	Reflow MPI0398 Rev. <u>U</u> Temp = 415°F (+/- 15 °F) Speed = 4.5 in/min (+/- 0.5 in/min)					<u>160</u>	<u>0</u>	<u>11Jan21</u>	<u>KS</u>	
350	CATASY04 Catheter Assembly 4	Skive Heat Shrink MPI0398 Rev. <u>U</u>					<u>340</u>	<u>0</u>	<u>11Jan21</u>	<u>BA.</u>	
Notes:											
<u>N/A</u>											

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N/A	Skive Heat Shrink	N/A				
400	CATASY04 Catheter Assembly 4 Count: Yes In Process Inspection	In-Process Inspection (Visual Inspection) MPI0398 Rev. <u>u</u> FM5104693 (Rework if needed. Use FM5104983)	490	6EW 2DF 2DS	12 Jan 21	YK Trn CL VKA
450	CATASY04 Catheter Assembly 4 Anneal Shaft	Anneal Shaft MPI0398 Rev. <u>u</u> FM5104692	490	0	12 Jan 21	YK

Notes:

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
500	CATASY04 Catheter Assembly 4 	Leak Test/Prox Cut/Ring Gage-Dim 13/21 MPI0398 Rev. <u>U</u> FM5104694 FM5104695 Leak Test/Prox Cut/Ring Gage-Dim 13/21 (Rework if needed - Use FM5104983)	175 289	102 Fail 12 OP Fail 14 OP Fail	12 Jan 21 12 Jan 21	CKY NYL
550	CATASY04 Catheter Assembly 4 	Distal Cut MPI0398 Rev. <u>U</u> Line Closure MPI0230 Rev. <u>E</u> By: <u>MCL</u> Date: <u>12 Jan 21</u>	175 289	0 0	12 Jan 21 12 Jan 21	CKY ML
600	PADPRIN1 Pad Print Count: Yes 	Pad Print Set Up MPI0276 Rev. <u>D</u> Line Clearance MPI0230 Rev. <u>E</u>	464	0	13 Jan 21	PK (TRN) DX

Notes:

N/A

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CKY 12 Jan 21

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Opr. No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Pad Print Setup	By: PK (TRN) (DX) Date: 13 Jan 21 TMI0503 (circle TMI used) 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	TMI0735 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			N/A

Notes:

N/A

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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 	<p>Verification MPI0276 Rev. <u>D</u> Section 15.0</p> <table border="1"> <thead> <tr> <th>Component Number</th> <th>Req'd Rev</th> <th>Rev Used</th> <th>UOM</th> <th>Qty.</th> <th>Batch No.</th> <th>Actual Qty Used</th> </tr> </thead> <tbody> <tr> <td>RM7407-01</td> <td>B</td> <td><u>B</u></td> <td>L</td> <td>0.050</td> <td><u>25658</u></td> <td><u>0.040</u></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td><u>N/A</u></td> <td><u>N/A</u></td> </tr> </tbody> </table>	Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	RM7407-01	B	<u>B</u>	L	0.050	<u>25658</u>	<u>0.040</u>						<u>N/A</u>	<u>N/A</u>	464	O 13Jan21 (TRN D)	PK
Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																				
RM7407-01	B	<u>B</u>	L	0.050	<u>25658</u>	<u>0.040</u>																				
					<u>N/A</u>	<u>N/A</u>																				

Notes:

N/A

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Opr No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	N/A	RM7408-01	B	<u>B</u>	L	0.005	TP53072	0.005				
		RM7409-01	B	<u>B</u>	L	0.010	26764	0.010			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 Prepare Surface for Ink						464	0	13 Jan 21	PK (TPN)	
750	PADPRIN1 Pad Print Print Parts	Print Parts MPI0276 Rev. <u>D</u> Section 20.0 Inspection gauge TMI0843						464	0	13 Jan 21	PK (TPN) (D)	

Notes:

N/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	464	0	13 Jan 21	PK (TPN DL)
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>3:55 PM</u> By: <u>PK</u> Date: <u>13 Jan 21</u>	464	0	13 Jan 21	PK (TPN DL)
900	PADPRIN1 Pad Print	Transfer Parts to Production MPI0276 Rev. <u>D</u> Section 40.0	464	0	14 Jan 21	PK

Notes:

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	<p>Transfer parts to Production</p> <p>Confirmation Reqd(Milestone)</p>	<p>Transfer Parts to Line</p> <p>Time: 5:30 AM</p> <p>By: PK Date: 14 Jan 21</p>				N A
950	<p>PADPRIN1</p> <p>Pad Print</p> <p>Count: Yes</p> <p>Cleaning</p> <p>Confirmation Reqd(Milestone)</p>	<p>Cleaning MPI0276 Rev. D Section 50.0</p> <p>Line Clearance MPI0230 Rev. E</p> <p>By: PK (TPN/DX) Date: 13 Jan 21</p>	464	0	13 Jan 21	PK (TPN) DX
1000	CATASY04	In-Process Dimensional Inspection				N/A

Notes:

N/A

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Op. No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	<p>Catheter Assembly 4 </p> <p>In-Process Dimensional Inspection </p>	<p>MPI0398 Rev. <u>4</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>	427 432	370 Fail 320 Fail	23 Jan 21	Pny MLI
1050	<p>QUALITY1 Quality Inspection & Review </p> <p>Quality Inspection & Review </p> <p>Confirmation Reqd(Milestone)</p>	<p>Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan</p>	372	(60) 43.00/OS#18 1-SL/over 2-WT 1-PRT 2-DISC 1-VD 10-TT	19 Feb 21	DX

Notes:

N/A

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by 10 Feb 21
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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 MPI0398 Rev. <u>u</u> Material consumed Material RM8745-01 Batch 28340 Rev B Qty 13 Material _____ Batch _____ Rev _____ Qty _____ Material _____ Batch _____ Rev _____ Qty _____ Material _____ Batch _____ Rev _____ Qty _____ Material _____ Batch _____ Rev _____ Qty _____	371	1SL	19 Feb 21	VC
1090	QUALITY1 Quality Inspection & Review Quality Inspection & Review	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	371	0	19 Feb 21	DX
Notes: <i>N/A</i>						

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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	N/A	N/A
1100	PACKINT1 Packing assembly Packing Instructions Confirmation Reqd(Milestone)	Packaging Instructions SPI0087 REV. <u>H</u>	371	0	19 Feb 21 AP	

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Batch Number: 0000006053

By: AP

Date: 19 Feb 21

Reviewed By:

Date: 19 Feb 21

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Document No: FM5104983

Rev. B

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

PRODUCTION ORDER# 50000066053

Attachment B: Cause of Rework.

OPER 400.0

Date	Initial	AB (Prox)	AB (Distal)	DF	DS	EW	FM	Disc	SCR	SKV	VD
12 Jan 21	√c yk	o	58	o	o	/	19	o	9	/	o

Attachment B: Cause of Rework

OPER 500.0

Date	Initial	Dim 13 (Go Gauge)	Dim 21 (Go gauge)
11 Jan 21	✓	0	6
12 Jan 21	MC	0	97

PRODUCTION ORDER# 50000000 66053

OPER 500.0

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

Before & After Inspecting Parts	Dimension ## Gauge Check	TMI###XX (Ex. TMI0748AC or TMI0747AD)	Initials	Date	Time
Before	Dimension 13				
Before	Dimension 21	TMI0748 AN CL	12 Jan 21	10:50 AM	
After	Dimension 13	TMI0747 u CL	12 Jan 21	10:50 AM	
After	Dimension 21	TMI0748AN LY	12 Jan 21	9:00 PM	
		TMI0747u LY	12 Jan 21	9:00PM	

PRODUCTION ORDER# 500000660653 66053

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	TM10791 U9D	0	0	MUL 12 Jan 21			
Outer Diameter ▲ 13 MAX OD at Pad Printed Area	0.145" +0.002"/- 0.004" (≤0.147")	100%	Ring Gauge TM10748 U6U	11612	26	0	MUL 12 Jan 21			
Outer Diameter ▲ 21 MAX OD	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TM10747	1164	0	0	MUL 12 Jan 21			



Document No: FM5104662

Rev: B

Document Type: Manufacturing Form

Title: SA0254 Max OD Form

PRODUCTION ORDER# 500000066053

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 KJL		25 Jan 21	5:10 A.M
Before	Dimension 21	TMI 0747 T KJL		25 Jan 21	5:10 A.M
After	Dimension 13	TMI 0748 AM MV		23 Jan 21	7:30 P.m
After	Dimension 21	TMI 0747 T MV		23 Jan 21	7:30 P.m

PRODUCTION ORDER# 50000066053

OP 1000.0

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
Outer Diameter ▲13 MAX OD at Pad Printed Area Drop Go Gauge from proximal end of shaft. Pass if ring stops at stop sleeve shoulder. Fail if gauge stops above or falls past stop sleeve shoulder.	0.145" +0.002"/- 0.004" (≤0.147")	100%	Ring Gauge TMI0748 or equivalent	TMI 0748 459	459	5	xx 23 Jan 21
Outer Diameter ▲21 MAX OD Drop Go Gauge from stop sleeve shoulder. Pass if ring does not stop. Fail if ring stops less than 4" distal above stop sleeve shoulder.	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TMI 0747 or equivalent	TMI 0747 444	444	15	xx 23 Jan 21
Outer Diameter ▲2 MAX OD Go-gauge: Measure from distal end to minimum 1.7" from tip. Gravity force only.	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0967, or equivalent	TMI 0967 427	432	12	xx 23 Jan 21
Outer Diameter ▲2 MIN OD No-go gauge: End must not pass through	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0968, or equivalent	TMI 0968 427	432	0	xx 23 Jan 21
Outer Diameter ▲8 MAX OD Measure from proximal end of shaft to the material transition.	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI 50049 427	432	0	pm/ 23 Jan 21
Outer Diameter ▲8 MIN OD Measure from proximal end of shaft to the material transition.	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI 50049 427	432	0	pm/ 23 Jan 21

pm/ 23 Jan 21
L4 10 Feb 21
L4 10 Feb 21
L4 10 Feb 21

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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	TMI50049 427 432	0	0	Puy 23 Jan 21
Outer Diameter ▲21 AVG OD Measure from stop sleeve shoulder to 4" distal of stop sleeve shoulder. NOTE: Measure AVG OD and record results	0.157" ± 0.003" (0.154"-0.160")	100%	Two Axis Laser Micrometer	TMI50049 427 432	0	0	Puy 23 Jan 21
Outer Diameter ▲17 AVG OD Measure 4" distal the stop sleeve shoulder to the braid termination. NOTE: Measure and Record results	0.157" ± 0.003" (0.154"-0.160")	100%	Two Axis Laser Micrometer	TMI50049 427 432	0	0	Puy 23 Jan 21
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	TMI50049 427 432	0	0	Puy 23 Jan 21
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	TMI50049 427 432	0	0	Puy 23 Jan 21

L4 10 Feb 21
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L4 10 Feb 21
L4 10 Feb 21

Document No: FM5104983

Rev: B

Document Type: Manufacturing Form

Title: SA0254 Cause of Rework Form

PRODUCTION ORDER# 5000006053

OPER 1050.0

Date	Initial	AB	DISC	DF	DS	EW	FM	OD	SCR	SKV	VD	OTHER
19 Feb 21	DR	O	O	O	O	O	O	O	10	O	O	4-DSU
					N/A							

Record total quantity reworked:

14

Quantity Passed after Rework:

13

Rework Performed by: VC Date: 19 Feb 21 Rework Performed by: NIA Date: NIA

Re-Inspection Performed by: DR Date: 19 Feb 21

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0125-2014

Title	Approval Name	Approval Signature	Date
Mfg Engineering manager	Renata Holahan		08DEC20
Quality Manager QPS mgmt	Steve Julie MO 10DEC20		08DEC20
Operation Manager #1	Wich-Opatz		09AEE2020

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

It h_0 , explain: Deviation talks about recording the variable data at a operation where we are already checking for the dimension.

Yes No **Co-Effective Action Required:**

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

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

Risk Assessment

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

SA0254-04/05/06	(5)	Part Number Affected
N/A	(5)	Revision

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

Deviation Form:	Currentiy at "inline dimensional inspection operation" operators 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.
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Document Number Affected	Revision	MP10398	U	N/A

Requestor Name: Govind Sharma

DEVIATION AUTHORIZATION FORM

DEVIATION AND HORIZONTION NUMBER: DA1738



CREGANNA
MEDICAL
is part of

TEST DATA SHEET

Sample	Dim 12 (Max) 0.142" +/- 0.002	Dim 12 min 0.142" +/- 0.002	Dim 13 Avg N/A	Dim 13 Max 0.145" +0.002" -0.004"	Dim 13 Max 0.145" +0.002" -0.004"	Comments: N/A
1	0.1432	0.1424	N/A	0.1449	0.1456	
2	0.1439	0.1436	N/A	0.1444	0.1460	
3	0.1427	0.1424	N/A	0.1452	0.1462	
4	0.1434	0.1428	N/A	0.1438	0.1477	
5	0.1430	0.1427	N/A	0.1445	0.1454	
6	0.1431	0.1426	N/A	0.1446	0.1453	
7	0.1430	0.1423	N/A	0.1449	0.1456	
8	0.1427	0.1418	N/A	0.1450	0.1459	
9	0.1426	0.1420	N/A	0.1442	0.1447	
10	0.1431	0.1429	N/A	0.1445	0.1454	
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Test Description: Dim 12 and 13 variable data recording

Tested by: Puy

Lot Number: 500000066053

Part Number: SA0254-xx 06

Date: 23 Jan 21

Maximum Force Reached During Tensile Test
 (10 samples accepted from final inspection for each lot shall be randomly selected
 and tensile tested)

Sample # →	1	2	3	4	5	6	7	8	9	10	Avg	St Dev	K	Calculated Lower bound	Min Spec	Pass / Fail
Seg 1	29.12	27.44	26.49	28.14	26.56	27.87	26.64	27.08	25.82	26.29	27.145	1.0011355	4.378	22.76202893	8.542	PASS
Seg B	23.5	23.02	21.14	22.82	21.75	22.17	22.18	22.51	23.08	23.03	22.52	0.715666	4.378	19.38681439	8.542	PASS
Seg C	48.62	65.44	46.98	65.56	59.94	48.24	53.4	66.14	48.9	52.44	55.566	7.9081733	4.378	20.94401743	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.

Kochhy Lee

19 Feb 21



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 PETZL 15 JAN 2021		15 JAN 2021