

Production Order: 500000295737



Production Order Document
Production Order Qty: 500

PC

Sheet: 1 of 1

Material: SA0155-01 Rev F

Material Type:	ZFRT	Description: Edwards Flex Shaft Commander 155885	Order Type: ZSTD
Production Version:	7988		Project Phase:
Plant / Business Unit:	1213 / AC5		

Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials																								
50	KITTING3 Kitting Devices  Kitting Devices	<p>Kitting Devices</p> <p>Perform Order Kitting, Load Minor Mandrels, Dry Extrusions, and Cut FEP</p> <p>Record Time Extrusions Enter Dryer (Initial/Time/Date): <u>KP02 6:00am 16 Jan 24</u></p> <p>Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>KP02 9:30pm 16 Jan 24</u></p> <p>Record Dryer Shelf #: <u>N/A</u></p>																												
		<table border="1"> <thead> <tr> <th>Component Number</th> <th>Req'd Rev Rev Used</th> <th>UOM</th> <th>Qty.</th> <th>Batch No.</th> <th>Actual Qty Used</th> </tr> </thead> <tbody> <tr> <td>1000-2053-01</td> <td>A <u>A</u></td> <td>PC</td> <td>500</td> <td><u>0000278860</u></td> <td><u>500</u></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td><u>0000268040</u></td> <td><u>50</u></td> </tr> <tr> <td>MM1537-02</td> <td>A <u>A</u></td> <td>PC</td> <td>500</td> <td><u>0000276175</u></td> <td><u>500</u></td> </tr> </tbody> </table>	Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	1000-2053-01	A <u>A</u>	PC	500	<u>0000278860</u>	<u>500</u>					<u>0000268040</u>	<u>50</u>	MM1537-02	A <u>A</u>	PC	500	<u>0000276175</u>	<u>500</u>	N/A	N/A	BZnZd DKW	
Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																									
1000-2053-01	A <u>A</u>	PC	500	<u>0000278860</u>	<u>500</u>																									
				<u>0000268040</u>	<u>50</u>																									
MM1537-02	A <u>A</u>	PC	500	<u>0000276175</u>	<u>500</u>																									

Notes: DA 2564 , 2484

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details					Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		RM0158-01	E	<u>E</u>	PC	200	<u>N/A</u>	<u>N/A</u>		
							<u>58497</u>	<u>150</u>		
		TL0167-02	E	<u>E</u>	PC	70	<u>N/A</u>	<u>N/A</u>		
							<u>N/A</u>	<u>Bulk</u>		
		TL0165-05	J	<u>J</u>	PC	5	<u>N/A</u>	<u>Bulk</u>		
							<u>N/A</u>	<u>Bulk</u>		
		TL0165-03	J	<u>J</u>	PC	5	<u>N/A</u>	<u>Bulk</u>		
							<u>N/A</u>	<u>Bulk</u>		
		141967-01	02	<u>02</u>	PC	500	<u>85500</u>	<u>56</u>	<u>N/A</u>	<u>N/A</u>
							<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
		RM7349-02	C	<u>C</u>	PC	543	<u>① 82568 N/A</u> <u>82858</u> <u>82855, 82734</u>	<u>N/A</u> <u>200</u> <u>200, 146</u>		
		RM7348-01	C	<u>C</u>	PC	500	<u>78688</u>	<u>550</u>		
							<u>N/A</u>	<u>N/A</u>		

Notes:

N/A

N/A
N/A

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Opr No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	RM4001-01	B	<u>B</u>	PC	125	<u>82435</u>	<u>200</u>				
		D	<u>D</u>	PC	56	<u>74663</u>	<u>63</u>				
		C	<u>C</u>	PC	500	<u>0000275490</u>	<u>489</u>				
		E	<u>E</u>	PC	594	<u>77866</u>	<u>600</u>				
		I	<u>I</u>	PC	1	<u>82971</u>	<u>Bulk</u>	N/A	N/A	N/A	N/A
		I	<u>I</u>	PC	1	<u>82971</u>	<u>Bulk</u>				
		A	<u>A</u>	PC	500	<u>0000278970</u>	<u>500</u>				
		A	<u>A</u>	PC	1000	<u>0000284209</u>	<u>1000</u>				

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details					Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		MM1536-01	B	<u>B</u>	PC	500	<u>0000281413</u>	<u>60</u>		
							<u>0000281412</u>	<u>500</u>		
		MM0180-01	E	<u>E</u>	PC	500	<u>0000263145</u>	<u>80</u>		
							<u>0000282489</u>	<u>400</u>		
		MM0179-01	D	<u>D</u>	PC	500	<u>0000275691</u>	<u>100</u>		
							<u>0000276172</u>	<u>500</u>		
		MM0178-01	E	<u>E</u>	PC	500	<u>0000272345</u>	<u>80</u>		
							<u>0000276174</u>	<u>500</u>	<u>N/A</u>	<u>N/A</u>
		MM0177-01	C	<u>C</u>	PC	500	<u>0000265872</u>	<u>40</u>		
							<u>0000278966</u>	<u>500</u>		
		MM0176-01	D	<u>D</u>	PC	500	<u>N/A</u>	<u>N/A</u>		
							<u>0000281411</u>	<u>500</u>		
		MM0074-01	G	<u>G</u>	PC	500	<u>N/A</u>	<u>N/A</u>		
							<u>0000291638</u>	<u>517</u>		
								<u>60</u>		

Notes:

N/A

N/A

N/A

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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
100	CATASY01 Catheter Assembly 1 	Line Clearance Perform Line Clearance and Heat Gun Setting	500	0	17 Jan 24	V078
	Line Clearance					
	Confirmation Reqd(Milestone)					
150	CATASY01 Catheter Assembly 1 	Major and Minor Mandrel Assembly	500	0	17 Jan 24	AS 31 JY90 PM 96
	Major and Minor Mandrel Assembly					
Notes:						
N/A						
N/A						
N/A						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
M1	Confirmation Reqd(Milestone)		N/A	N/A	N/A	N/A
200	CATASY01 Catheter Assembly 1  Loading Braid Stock Confirmation Reqd(Milestone)	Loading Braid Stock	500	0	17 Jun 24	cp32 y014
250	CATASY01 Catheter Assembly 1  Trim Braid Wire at Proximal End		500	0	17 Jun 24	CL30 ny35

Notes:

N/A

N/A

N/A

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Opn No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Trim Braid Wire at Proximal End Confirmation Reqd(Milestone)	MIA	MIA	MIA	MIA	MIA
300	CATASY01 Catheter Assembly 1 	Insert Cut Hypo Tube Insert Cut Hypo Tube Confirmation Reqd(Milestone)	500	0	17 Jan 24	SH23 G522
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0	17 Jan 24	ST96 V078

Notes:

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Op. No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Load Tubing					
400	CATASY01 Catheter Assembly 1 	Reflow	500	0	SH85 V078 Pm96 17 Jun 24	
450	CATASY01 Catheter	FEP Removal	500	0	A139 SG88 Pm96 17 Jun 24	
Notes:						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
550	CATASY01 Catheter Assembly 1 Remove Heat Shrink & Mandrel Confirmation Reqd(Milestone)	Remove Heat Shrink & Mandrel	475	0	17 Jan 24	SV46 VA96 LL61 FB01 D429 TRN K155 RS23
600	CATASY01 Catheter Assembly 1 Distal Tip Assembly Confirmation	Distal Tip Assembly	475	0	17 Jan 24	ML60 VA96 FB01 RS23

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
650	CATASY01 Catheter Assembly 1 	Loading Heat Shrink	475	0	ML38 17/05/24	
	Loading Heat Shrink					
	Confirmation Reqd(Milestone)					
700	CATASY01 Catheter Assembly 1 	Tipping Record Tipping Oven Information: TMI: 0521 Cal Due: 31 May 24 TMI: 2083C Cal Due: 31 May 24 TMI: 0386 Cal Due: 31 May 24 TMI: 0936A Cal Due: 31 May 24	475	0	ML38 STR48 17/05/24	
	Tipping					
Notes:						
N/A						
N/A						
N/A						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Major Mandrel Removal MA Confirmation Reqd(Milestone)	n/a	n/a	n/a	n/a	n/a
850	CATASY01 Catheter Assembly 1 	Cut to Length Record DIM05 gage result for the first 5 parts at the start of operation: 1. <u>passed</u> 2. <u>passed</u> 3. <u>passed</u> 4. <u>passed</u> 5. <u>passed</u>	467	SKV-1 SL-1 ②	SS52 17 Jan 24	
900	QUALITY1 Quality Inspection & Review	Quality Inspection and Review Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	n/a	n/a	n/a	n/a
Notes:						
<i>n/a</i>						
<i>n/a</i>						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Quality Inspection & Review  Confirmation Reqd(Milestone) <i>N/A</i> Re-Inspect after re-work. Required Inspection Visual/OD Inspection Record Inspection Data in SAP ROS Record Laser Micrometer Information: TMI: <u>0700-01</u> Cal Due: <u>31 May 24</u> TMI: <u>N/A</u> Cal Due: <u>N/A</u> TMI: <u>N/A</u> Cal Due: <u>N/A</u> Material Consumed: Part #: <u>PN4001-01</u> Batch #: <u>82435</u> Qty: <u>18</u> Part #: <u>1000-153-01</u> Batch #: <u>87106</u> Qty: <u>15</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u>	<i>#67</i> <i>419</i>	<i>FM-1</i> <i>DIS-4H 4H</i> <i>4H 1H</i> <i>DEL-4H</i> <i>ACD-1</i> <i>(1)</i> <i>FM-1H</i> <i>EW-LHM 11</i> <i>WIK-1H</i> <i>#SUS-11</i> <i>#GUS-11</i> <i>SCR-1</i> <i>(48)</i>	<i>17 Jan 24</i>	<i>P146</i> <i>KT217</i> <i>DY201</i> <i>K155</i>	
950	QUALITY1 Quality Inspection & Review Quality Inspection & Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information: TMI: <u>N/A</u> Cal Due: <u>N/A</u> Record Caliper Information:	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>

Notes:

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	 Quality Inspection & Review  <i>MIA</i>	TMI: <u>n/a</u> Cal Due: <u>n/a</u> Record DIM02 Go/No-Go Gage Information: TMI: <u>0691</u> Cal Due: <u>30sep25</u> TMI: <u>0692</u> Cal Due: <u>30sep25</u> Record DIM02 Inspection Results N = 54: Pass: <u>54</u> Fail: <u>0</u>	<i>380</i>	Dis-HH-LHT LHT-LHT-I(II) (SP) SFP-I(II) DeL-LHT LHT-(JT) <i>(39)</i>	<i>17Jan24</i>	0521 SS44 TRN
1000	QUALITY1  Quality Inspection & Review  Quality Inspection & Review  <i>MIA</i>	Quality Inspection & Review Leak Test Record Inspection Data in SAP ROS Record Leak Tester Information: TMI: <u>1056</u> Cal Due: <u>31may24</u> Record Length Gage Information: TMI: <u>08890</u> Cal Due: <u>30sep24</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30sep24</u>	<i>364</i>	LT-HH-LHT LHT-I <i>(16)</i>	<i>0</i> <i>17Jan24</i>	SS44

Notes:

*n/a**n/a**n/a*

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N/A	Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
1150	PACKINT1 Packing assembly  Package Confirmation Reqd(Milestone)	Package Package, Label, and Ship Finished Parts	334	0	19 Jan 24 AP10	AP10

Notes:

N/A AP10 19 Jan 24

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Batch Number: 0000295737

By: AP10

Date: 19 Jan 24

Reviewed By:

RB29

Date:

19 JAH24

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u/a AP10 19 Jan 24

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PO #: 500000295737

OP #: 900 Shift #: 1st

Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):

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Status CURRENT Effective 5/8/2023



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FM5104665 Rev: C
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OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10942	44	9:05pm	429	V078	16Jan24	9:17pm	415	SH85	16Jan24	16
Tm10942	44	9:37pm	430	SH85	16Jan24	9:49pm	415	SH85	16Jan24	16
Tm10942	44	10:17pm	430	SH85	16Jan24	10:29pm	415	SH85	16Jan24	16
Tm10942	44	10:52pm	428	V078	16Jan24	11:04pm	415	V078	16Jan24	16
Tm10942	44	11:50pm	430	SH85	16Jan24	12:02am	415	SH85	17Jan24	16
Tm10942	44	12:45AM	429	V078	17Jan24	12:57AM	415	V078	17Jan24	16
Tm10942	44	1:23AM	430	V078	17Jan24	1:35AM	415	V078	17Jan24	16
Tm10942	44	1:57AM	430	SH85	17Jan24	2:09AM	415	A739	17Jan24	8
Tm10942	44	5:35am	430	AX05	17Jan24	5:47am	415	AX05	17Jan24	16
Tm10942	44	5:55am	429	AX05	17Jan24	6:07am	415	KL95	17Jan24	16
Tm10942	44	6:14am	427	AX05	17Jan24	6:26am	415	KL95	17Jan24	16
Tm10942	44	6:40am	429	AX05	17Jan24	6:52am	415	OS21	17Jan24	16

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correction for SH 85



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OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10745	44	9:35 pm	430	SH85	16 Jan 24	9:37 pm	415	SH85	16 Jan 24	16
Tm10745	44	10:00pm	430	V078	16 Jan 24	10:12pm	415	SH85	16 Jan 24	16
Tm10745	44	10:33pm	430	SH85	16 Jan 24	10:45pm	415	SH85	16 Jan 24	16
Tm10745	44	11:18pm	430	V078	16 Jan 24	11:30pm	415	SH85	16 Jan 24	16
Tm10745	44	12:12AM	430	V078	17 Jan 24	12:24AM	415	V078	17 Jan 24	16
Tm10745	44	12:30AM	429	V078	17 Jan 24	12:42AM	415	V078	17 Jan 24	16
Tm10745	44	1:06AM	430	V078	17 Jan 24	1:18AM	415	V078	17 Jan 24	16
Tm10745	44	1:45AM	429	V078	17 Jan 24	1:57AM	415	A139	17 Jan 24	16
Tm10745	44	5:13am	430	AX05	17 Jan 24	5:25am	415	AX05	17 Jan 24	16
Tm10745	44	5:45am	429	AX05	17 Jan 24	5:57am	415	KL95	17 Jan 24	16
Tm10745	44	6:25am	430	AX05	17 Jan 24	6:37am	415	0521	17 Jan 24	16
Tm10745	44	6:48am	430	AX05	17 Jan 24	7:00am	415	0521	17 Jan 24	16



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OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10409	N/A	1:00AM	190°F	AT39	17 Jan 24	2:10AM	190°F	AT39	17 Jan 24	29
TM10409	N/A	4:30 am	190°F	KLSS	17 Jan 24	5:40am	190°F	KLSS	17 Jan 24	27
TM10409	N/A	5:35am	190°F	SSH44	17 Jan 24	6:45am	190°F	SSH44	17 Jan 24	33
TM12036	N/A	6:05am	190°F	SSH44	17 Jan 24	7:15am	190°F	SSH44	17 Jan 24	34
TM10409	N/A	6:50am	190°F	SSH44	17 Jan 24	8:00am	190°F	SSH44	17 Jan 24	51
TM10409	N/A	8:05am	190°F	SSH44	17 Jan 24	9:15am	190°F	SSH44	17 Jan 24	31
TM12036	N/A	8:40am	190°F	SSH44	17 Jan 24	9:50am	190°F	SSH44	17 Jan 24	50
TM10409	N/A	9:30am	190°F	SSH44	17 Jan 24	10:40am	190°F	KLSS	17 Jan 24	59
TM12036	N/A	10:15am	190°F	KLSS	17 Jan 24	11:20 am	190°F	KLSS	17 Jan 24	41
TM10409	N/A	1:20am	190°F	KLSS	17 Jan 24	12:30pm	190°F	KLSS	17 Jan 24	38
TM12036	N/A	12:00pm	190°F	KLSS	17 Jan 24	1:10pm	190°F	KLSS	17 Jan 24	42
TM10409	N/A	12:30pm	190°F	KLSS	17 Jan 24	1:40pm	190°F	KLSS	17 Jan 24	34
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

① SSH44 17 Jan 24

Page 1 of 1

Status CURRENT Effective 5/8/2023



Document No: 5106073
Rev: E
Document Type: Manufacturing Form
Title: SA0155-01 Visual Rework Form

PO #: 500000295737 OP #: 500 Shift #: 2nd

Total Parts Reworked:		20	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	n/a	n/a
EH	Exposed Hypotube	n/a	n/a
EW	Exposed Wire		5
MP	Micropores	n/a	n/a
SCR	Scratch	///	3
SKV	Skive Marks	n/a	n/a
VD	Voids		3
n/a	n/a	n/a	n/a
Inspected By (Sign and Date):		Vanneej. Lor 16 Jan 24	

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only.

Data Uploaded for Engineering Review (Check):



Document No: 5106073
Rev: E
Document Type: Manufacturing Form
Title: SA0155-01 Visual Rework Form

PO #: 500000295737

OP #: 500 Shift #: 2nd

Total Parts Reworked:		12	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	N/A	N/A
EW	Exposed Wire		8
MP	Micropores	N/A	N/A
SCR	Scratch		2
SKV	Skive Marks		1
VD	Voids		1
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		Cheng Ior 16 Jan 24	

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only.

Data Uploaded for Engineering Review (Check):



Document No: 6102646
Rev: A
Document Type: Manufacturing Form
Title: SA0155-01 Tipping Rework Form

PO #: 500000295737 OP #: 750 Shift #: 2nd.

Total Parts Reworked:		37	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		37
DIM07 US / WC	DIM07 Undersized (Window Closed)	N/A	N/A
EH	Exposed Hypotube	N/A	N/A
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		Mm02	16 Jan 24

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):



Document No: 6102646
Rev: A
Document Type: Manufacturing Form
Title: SA0155-01 Tipping Rework Form

PO #: 500000295737 OP #: 750 Shift #: 1st

Total Parts Reworked:		125	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		28
DIM07 US / WC	DIM07 Undersized (Window Closed)		15
EH	Exposed Hypotube		37
N/A	Glue, Stopper		45
Inspected By (Sign and Date):		STR 48	17 Jan 24

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):



Document No: 5106073
Rev: E
Document Type: Manufacturing Form
Title: SA0155-01 Visual Rework Form

PO #: 500000295737 OP #: 500 Shift #: 1st

Total Parts Reworked:		158	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube		16
EW	Exposed Wire		104
MP	Micropores	N/A	N/A
SCR	Scratch		3
SKV	Skive Marks		16
VD	Voids		19
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		LL61, TA36, CB81, VC09 17Jan24	

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only.

Data Uploaded for Engineering Review (Check):



Document No: 5106073
Rev: E
Document Type: Manufacturing Form
Title: SA0155-01 Visual Rework Form

PO #: 50000 295737 OP #: 500 Shift #: 2

Total Parts Reworked:		13	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube	N/A	0
EW	Exposed Wire		10
MP	Micropores		2
SCR	Scratch		1
SKV	Skive Marks	N/A	0
VD	Voids	N/A	0
N/A	N/A	N/A	0

Inspected By (Sign and Date): DX35 16 Jan 24

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only.

Data Uploaded for Engineering Review (Check):

Table 4 Δ ΔG° (kJ/mol) at 298 K

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CONTROL

DEVIATION FORM Extension to 23 Oct 2023 JZK
See attached email extension to 24 SEP 2023
TSL
24 AUG 23

CONTROLLED COPY DEVIATION AUTHORIZATION NUMBER: 2484

APPLICATION FORM B7Bn3 to 23 OCT 2023
See attached email extract
1521
24 AUG 23
J2C
21523

Ennis

Requestor Name: Uddesh Kanadnis

Requestor Name: Udhesh Kapadnis	Document Number Affected	Revision
	3107610	L

Deviation From:	<p>QIP3107610, Section 8.0 Inspection Requirements (Supplemental Visual Inspection) OP 1050:</p> <p>Current QIP3107610 does not state to inspect for the correct extrusion configuration.</p>
Deviation To:	<p>This DA allows addition inspection for correct assembly of extrusion material MM0179-01 and MM1536-01 during performing QIP3107610, Section 8.0 Inspection Requirements (Supplemental Visual Inspection) OP 1050.</p> <p>See instructions attached to this DA.</p>

Deviation From:

QNP3107610, Section 8.0 Inspection Requirements
(Supplemental Visual Inspection) OP 1050:
Current QNP3107610 does not state to inspect for the
correct extrusion configuration.

The diagram illustrates the physical assembly of a pre-relay component. It features a central vertical blue column representing the relay core. To the left of this core, there is a white rectangular area containing a black 'DIGITAL' label at the bottom and a yellow 'Hybrid Stock' label above it. A red line labeled 'Wire Out Hole' extends from the top of this area. To the right of the core, several blue rectangular blocks of decreasing size are stacked vertically, each labeled with a part number: 'MMA0176-01', 'MMA0177-01', 'MMA0178-01', 'MMA0179-01', 'MMA0180-01', 'MMA0181-01', 'MMA0182-01', 'MMA0183-01', 'MMA0184-01', and 'MMA0185-01'. The entire assembly is mounted on a light blue printed circuit board.

Deviation To:

This DA allows addition inspection for correct assembly of extrusion material MM0179-01 and MM1536-01 during performing QIP3107610, Section 8.0 Inspection Requirements (Supplemental Visual Inspection) OP 1050. See instructions attached to this DA.

Justification: Recently it has been found that operators are incorrectly assembling MM0179-01 and MM1536-01. The event documents in NC-26390, and NC-26426. Only few of experienced inspectors can detect finished unit that contains incorrect extrusion configuration, and inexperienced inspectors may not which potential non-conformance unit sent to customer. Interim correction action has been implemented at OP 250, 300, 350 to detect unit built with out of oriented extrusions. This DA is adding another layer of inspection at final QC inspection to avoid incorrect assembly defects.

Part Number Affected	Revision	
SA0155-01	H	
Start Date:	End Date:	Lot Number:
26 Jul 2023	25 Aug 2023	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: No corrective action is required for this event as there are no changes to the current process.

consumption of material, or how the product is produced. This added inspection guidelines are to avoid incorrect extrusion assembly defects.

Training Required: Yes No **If no, explain:**

① UK55, 23 JU 2023

CREGANNA MEDICAL is part of	DA	2484 2468
TE		①

Description/Objectives of Training:

DA- Inspection at final QC, Op#1050.

Procedure:

- 100% inspection at Op#1050 per the instructions below.
- Inspect 1 part at a time.
- Inspection is focused on the correct MM0179-01 and MM1536-01 assembly.
- Use the example MM0179-01 and ~~MM1536-02~~ fixture for inspection. (See image 1)
① MM01536-01 type correction T512 10AUG-23

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Image- 1

Step 1:

- Visually locate the MM0180-01 (Vestamid) transition to MM0179-01 on the completed part approximately 9.75" from the distal end using magnification light 2.25X minimum.
- Align the fixture MM0179-01 extrusion proximal end to the Vestamid transition on completed part.
(See image 2)



Image- 2

- Visually verify the MM0179-01 distal end of the fixture is approximately at the same location on the completed part. (See image 3)

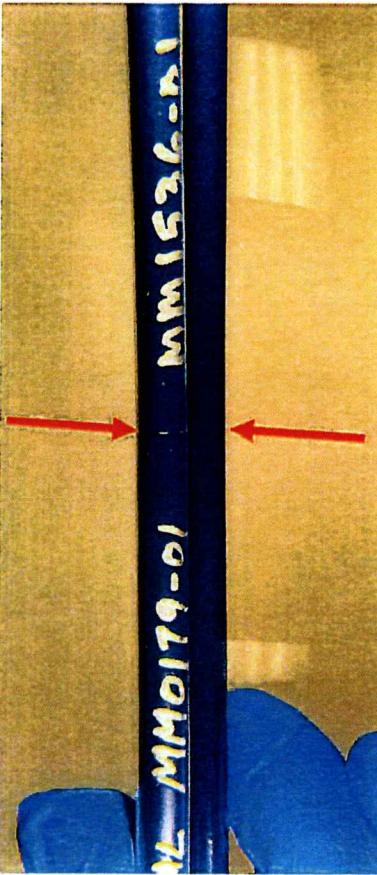


Image- 3

- Scrap the part if the transition is not approximately aligned. Save the scrapped parts for Engineer review.
- If the part transition is aligned, move to Step 2.

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Step 2:

- Visually verify the MM1536-01 distal end of the fixture is approximately at the same location on the completed part. (See image 4)

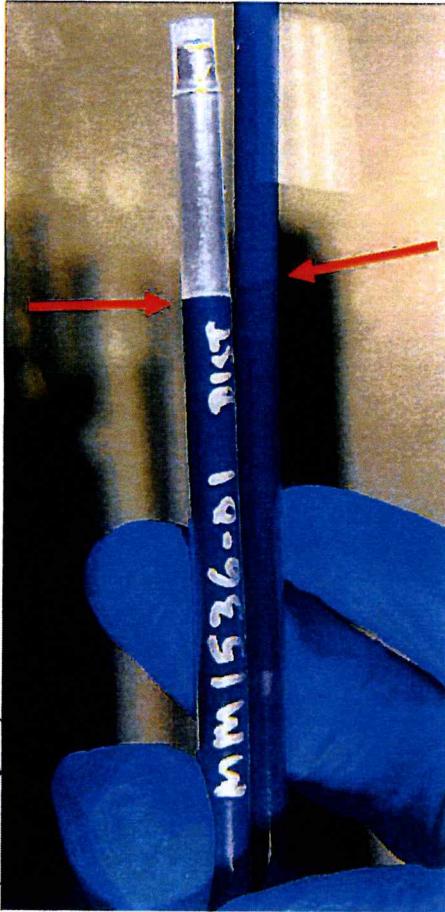


Image- 4

- Scrap the part if the transition is not approximately aligned. Save the scrapped parts for Engineer review.
- If the part transition is aligned, the part passes inspection.
- Use Image 5 as a guide for GOOD and BAD extrusion transition alignment.

1	MM0179-01 GOOD PART	MM1536-01
2	MM1536-01	MM0179-01 MM0179-01 and MM1536-01 Wrong Order - BAD PART
3	MM0179-01	MM0179-01 Two MM0179-01 - BAD PART
4	MM1536-01	MM1536-01 Two MM1536-01 - BAD PART

Image - 5

Title	Approval Name	Approval Signature	Date
Mgr. Quality Engineering	Hai Nguyen		25 Jul 2023
Mgr. Manufacturing Engineering	Jake Stanislawski		25 JUL 2023
Mgr. Operations	Matthew Benson		25 Jul 2023

FM0002.RevF Deviation Authorization

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Entered to MANDATORY 3228 12/15/2023
Entered to 13 February 2024 3228 V4/5/24

CONTROLLED COPY DEVIATION AUTHORIZATION NUMBER: DA2564

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DEVIATION AUTHORIZATION FORM

Requestor Name: Krishna Selvaraj	
Document Number Affected	Revision
Doc #3005206 (MPI0238)	BP
Deviation From:	Deviation To:
Doc #3005206 (Flex Commander MPI0238): OPER850.11: Using a laser micrometer, check the DIM06 outer diameter. Position the laser indicator as close to the distal edge as possible. Start the measurement, then slowly move the part through the laser micrometer until reaching the lower edge of the shoulder.	Doc #3005206 (Flex Commander MPI0238): OPER850.11: Using a laser micrometer at OPER900 (TMI0700-01) , check the DIM06 outer diameter. Position the laser indicator as close to the distal edge as possible. Start the measurement, then slowly move the part through the laser micrometer until reaching the lower edge of the shoulder.

Justification:

TMI0602 lasermic which is currently used in SA0155-01 Flex commander product at OPER850 for Dim 6 inspection has mechanical failure and confirmed as not usable.

TMI0700-01 lasermic is used at OPER900 for 100% inspection for Dim 1, Dim 6 and Dim 9. Since TMI0700-01 is already qualified to inspect Dim 6 per ES0647: Laser micrometer equivalency test, there is no additional risk in using TMI0700-01 for OPER850 Dim 6 inspection till TMI0602 issue is resolved.

Part Number Affected	Revision	
SA0155-01	H	
Start Date:	End Date:	Lot Number:
16 Nov 23	15 DEC 23	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 <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		
If yes to any of the above, what controls are being put in place to mitigate the risk – N/A		
Corrective Action Required: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
If no, explain: This is a temporary change to use TMI0700-01. DA will be removed once the lasermic TMI0602 issues are resolved and accepted for usage.		
Training Required: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If no, explain: N/A		
Title	Approval Name	Approval Signature
Engineering Manager	Jake Stanislowski	
Quality Manager	Jay Zabel	
Operations Manager	Matthew Benson	
		Date
		16 Nov 2023
		16 Nov 2023
		16 Nov 2023

Maximum Force Reached During Tensile Test (10 samples accepted from final inspection for each lot shall be 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 A	28.17	27.51	29.18	29.66	25.82	26.55	27.55	24.94	25.69	25.73	27.08	1.593842	4.378	20.1021583	8.542	PASS
Seg B	59.52	55.4	57.56	56.14	57	59.13	57.53	60.57	57.23	59.8	57.988	1.68845	3.981	51.2662819	8.542	PASS
Seg C	80.05	81.74	79.77	85.36	83.43	77.95	80.56	80.17	79.44	80.28	80.875	2.130682	2.911	74.6725849	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 is not required to used for DA acceptance.

17 jan 24 J00