

Production Order: 500000292546



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:	7987		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 Perform Order Kitting, Load Minor Mandrels, Dry Extrusions, and Cut FEP Record Time Extrusions Enter Dryer (Initial/Time/Date): <u>Am 68 10:00</u> ^{03 JAN 24} _{m 37 min} Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>Am 68 11:00</u> ^{05 JAN 24} _{03 JAN 24} Record Dryer Shelf #: <u>N/A</u>																												
	Kitting Devices	<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>MM0179-01</td> <td>D <u>D</u></td> <td>PC</td> <td>500</td> <td><u>0000276172</u></td> <td><u>500</u></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td><u>N/A</u></td> <td><u>N/A</u></td> </tr> <tr> <td>MM1536-01</td> <td>B <u>B</u></td> <td>PC</td> <td>500</td> <td><u>0006271063</u></td> <td><u>500</u></td> </tr> </tbody> </table>	Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	MM0179-01	D <u>D</u>	PC	500	<u>0000276172</u>	<u>500</u>					<u>N/A</u>	<u>N/A</u>	MM1536-01	B <u>B</u>	PC	500	<u>0006271063</u>	<u>500</u>	N/A	N/A	032024 TRD	
Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																									
MM0179-01	D <u>D</u>	PC	500	<u>0000276172</u>	<u>500</u>																									
				<u>N/A</u>	<u>N/A</u>																									
MM1536-01	B <u>B</u>	PC	500	<u>0006271063</u>	<u>500</u>																									

Notes: DA 2564, 2484

N/A

N/A

Date Printed: 01/03/2024 / 17:44:54

Am 68 03 JAN 24

Am 68 03 JAN 24

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CREGANNA MEDICAL
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Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details					Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	RM0158-01	E	<u>E</u>	PC	200	<u>N/A</u> <u>98497</u>	<u>N/A</u> <u>200</u>		
		1000-1153-01	A	<u>A</u>	PC	594	<u>N/A</u> <u>86522</u> <u>86526</u> <u>86748</u>	<u>N/A</u> <u>200</u> <u>200</u> <u>200</u>		
		1000-2053-01	A	<u>A</u>	PC	500	<u>00002168040</u> <u>0000278880</u>	<u>400</u> <u>100</u>		
		MM1537-02	A	<u>A</u>	PC	500	<u>0000276175</u> <u>0000271023</u>	<u>500</u> <u>60</u>	<u>N/A</u>	<u>N/A</u>
		TL0167-02	E	<u>E</u>	PC	70	<u>N/A</u> <u>N/A</u>	<u>Bulk</u> <u>Bulk</u>		
		TL0165-05	J	<u>J</u>	PC	5	<u>N/A</u> <u>N/A</u>	<u>Bulk</u> <u>Bulk</u>		
		TL0165-03	J	<u>J</u>	PC	5	<u>N/A</u> <u>N/A</u>	<u>Bulk</u> <u>Bulk</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	141967-01	02	D	PC	500	① 82899 000282899	500			
		RM7349-02	C	C	PC	543	82852	600	N/A		
		RM7348-01	C	C	PC	500	82882	450	N/A		
		RM4001-01	B	B	PC	125	82095 82098	N/A 100	N/A	N/A	N/A
		RM0607-01	D	D	PC	56	71864	101			
		RM0498-01	C	C	PC	500	000287518	500	N/A		
		RM0009-04	I	I	PC	1	82971	Bulk			
		RM0009-04	I	I	PC	1	82971	Bulk			

Notes:

N/A

N/A

N/A

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① GS8509 Jan 24

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Opr No.	Planned WorkCenter Description	Operation Details					Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	MM1538-01	A	A	PC	500	N/A	Bulk		
							0000271052	500		
							0000265874			
							0000268	40		
		MM1537-01	A	A	PC	1000	0000281413	1120		
							N/A	N/A		
		MM0177-01	C	C	PC	500	0000278960	500		
							N/A	N/A	N/A	N/A
		MM0180-01	E	E	PC	500	0000275691	500		
							0000295690	60		
		MM0178-01	E	E	PC	500	0000271050	500		
							N/A	N/A		
		MM0176-01	D	D	PC	500	0000281411	500		
							N/A	N/A		
		MM0074-01	G	G	PC	500	0000285432	514		
							0000286923	44		

Notes:

N/A

N/A

N/A

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(1) GSCS 08 Jan 24

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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	06Jan24 OB58	
	Line Clearance Confirmation Reqd(Milestone)					
150	CATASY01 Catheter Assembly 1 	Major and Minor Mandrel Assembly	500	0	06Jan24 YK40	SD67 SD34 AM47
	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
N/A	Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
200	CATASY01 Catheter Assembly 1  Loading Braid Stock Confirmation Reqd(Milestone)	Loading Braid Stock	500	0	06Jan24	SC10 MC11
250	CATASY01 Catheter Assembly 1  Trim Braid Wire at Proximal End		500	0	06Jan24	AIGS PY67
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	Trim Braid Wire at Proximal End Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
300	CATASY01 Catheter Assembly 1  Insert Cut Hypo Tube Insert Cut Hypo Tube Confirmation Reqd(Milestone)	Insert Cut Hypo Tube	500	0	06Jan24	RW47 PL22
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0	06Jan24	CXG3.124 BD64
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	Load Tubing Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
400	CATASY01 Catheter Assembly 1  Reflow Confirmation Reqd(Milestone)	Reflow	500	0	06Jan24	CDP AL67
450	CATASY01 Catheter	FEP Removal	500	0	06Jan24	SD34 YK40
Notes:						
N/A						
N/A						

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Assembly 1 	N/A	N/A	N/A	N/A	N/A
N/A	FEP Removal					
	Confirmation Reqd(Milestone)					
500	CATASY01 Catheter Assembly 1 	In-process Inspection and Rework Material Consumed: Part #: 1000-153-0 Batch #: 86526 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	491	VP-111 EW-1411 9	06Jan24	LS46 AR02 YK95
N/A	In-process Inspection and Rework					
	Confirmation Reqd(Milestone)					
N/A	N/A	N/A	N/A	N/A	N/A	N/A
Notes:						
		N/A	N/A	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
550	CATASY01 Catheter Assembly 1 	Remove Heat Shrink & Mandrel Remove Heat Shrink & Mandrel Confirmation Reqd(Milestone)	487	MAH-III DL-1 4	06Jan24	MH10 PT09 YK95
600	CATASY01 Catheter Assembly 1 Distal Tip Assembly Confirmation	Distal Tip Assembly	487	0	06Jan24	PT09 YK95

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
N/A	Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
650	CATASY01 Catheter Assembly 1 	Loading Heat Shrink	487	0	06Jan24 LH45	PT09
	Loading Heat Shrink					
	Confirmation Reqd(Milestone)					
700	CATASY01 Catheter Assembly 1 	Tipping Record Tipping Oven Information: TMI: 0386 Cal Due: 31 May 2024 TMI: 0521 Cal Due: 31 May 2024 TMI: 0521 Cal Due: 31 May 2024 TMI: 2083C Cal Due: 31 May 2024 Tipping	487	0	06Jan24	YK40
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	Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
750	CATASY01 Catheter Assembly 1 	Tip Inspection/ Flash Removal Material Consumed: Part #: RM4001-0 Batch #: 82095 Qty: N/A Part #: RM0607-0 Batch #: 71864 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	484	EH-111 (3)	06Jan24	B160
800	CATASY01 Catheter Assembly 1 	Major Mandrel Removal	484	0	06Jan24	YK40 BD64 KL45 TRN SN67
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 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. Pass 2. Pass 3. Pass 4. Pass 5. Pass	484	O	07Jan24	KL45 AL42 TRN
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:						
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	Quality Inspection & Review Confirmation Reqd(Milestone)	<p>Re-Inspect after re-work.</p> <p>Required Inspection Visual/OD Inspection Record Inspection Data in SAP ROS Record Laser Micrometer Information: TMI: 0700-01 Cal Due: 31 MAY 2024 TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A Material Consumed: Part #: RM4001-01 Batch #: 82098 Qty: N/A Part #: RM0607-01 Batch #: 71864 Qty: N/A Part #: RM0158-01 Batch #: 58497 Qty: N/A Part #: 1000-153-01 Batch #: 86522 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A</p>	467	DEL-HH(SP) DEL-HH(DX (TT)) SCR-1 #10S-1 17	07Jan24	PZ22 TK95 LS46 KX54
950	QUALITY1 Quality Inspection & Review	<p>Quality Inspection & Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information: TMI: N/A Cal Due: N/A Record Caliper Information:</p>	N/A	N/A	N/A	N/A

Notes:

N/A
N/A
N/A

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Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	 N/A Quality Inspection & Review Confirmation Reqd(Milestone)	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>30Sep2025</u> TMI: <u>0692</u> Cal Due: <u>30Sep2025</u> Record DIM02 Inspection Results N = 54: Pass: <u>54</u> Fail: <u>0</u>		465 (2)	07Jan24	PL22 Q1b
1000	 QUALITY1 Quality Inspection & Review N/A Quality Inspection & Review Confirmation Reqd(Milestone)	Quality Inspection & Review Leak Test Record Inspection Data in SAP ROS Record Leak Tester Information: TMI: <u>1056</u> Cal Due: <u>31May2024</u> Record Length Gage Information: TMI: <u>0889</u> Cal Due: <u>30Sep2024</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30Sep2024</u>	465	0	07Jan24	CB58

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
1050	QUALITY1 Quality Inspection & Review 	Required Inspection Visual Final Inspection Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS Quality Inspection & Review Confirmation Reqd(Milestone)	u/l	• SCR-HI / • SKV-VM • DL-III • VD-II • EW-II • DNT-I • EH-I • DIS-I • STN-I • CRK-I • FB-I 24	SV43 08 Jan 24	
1100	CATASY01 Catheter Assembly 1 	Line Closure Perform Line Closure Settle materials issued to production order (Initial/Date): <u>G585 08 Jun 24</u> Line Closure	n/a	n/a	08 Jan 24 G585	
Notes:						
<u>N/A</u>						
<u>N/A</u>						

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① G585 08 Jun 24

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
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	441	O	DAJANAU AP10	AP10

Notes:

N/A AP10 09 Jan 24

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Batch Number: 0000292546

By: AP10

Date: 09 Jan 24

Reviewed By:

RB29

Date:

09 JAN 24

Notes:

N/A AP10 09 Jan 24 /

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SA0155-01

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Document No: 5106073

Rev: E

Document Type: Manufacturing Form

Title: SA0155-01 Visual Rework Form

PO #: 50000292546OP #: 500 Shift #: 3 AM 3

(2)

PO #: 50000292831

Total Parts Reworked:		(1) 123 124	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		5
EH	Exposed Hypotube		15
EW	Exposed Wire		70
MP	Micropores	N/A	N/A
SCR	Scratch		8
SKV	Skive Marks		(1) 11 12
VD	Voids		14
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		1246 . RA 02	06 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):

(1) CB58 06 Jan 24

(2) KL45 08 JAN 24



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

PO #: 500000 292546

OP #: 500 Shift #: 3sh 3

Total Parts Reworked:		67	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		3
EH	Exposed Hypotube		17
EW	Exposed Wire		30
MP	Micropores	N/A	N/A
SCR	Scratch		10
SKV	Skive Marks		3
VD	Voids		4
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		LS46 .AR02	05 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):

① KL4S 08JAN24



Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

PO #: 500000292546

OP #: 750 Shift #: 3RD

Total Parts Reworked:		203	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		46
DIM07 US / WC	DIM07 Undersized (Window Closed)		36
EH	Exposed Hypotube		70
GD/AB	Glue Damage / Air Bubbles		51
Inspected By (Sign and Date):		BI60 06 Jan 24	06 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):

① CB58 06 Jan 24



Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 500000292546

OP #: 900 Shift #: 3

Total Parts Reworked:		261	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		3
EH	Exposed Hypotube		12
EW	Exposed Wire		79
MP	Micropores	N/A	N/A
SCR	Scratch		68
SKV	Skive Marks		41
VD	Voids		23
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized		19
DIM06 OS	DIM06 OD Oversized		16
DIM09 US	DIM09 OD Undersized	N/A	N/A
Inspected By (Sign and Date):		LS46, V435, KX54	07JAN24

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: 5105589
FM5104665 Rev: C
Document Type: Manufacturing Form
Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000292546

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10745	44	12:05pm	430	cm99	05Jan24	12:17pm	415	cm99	05Jan24	16
TM10745	44	12:24pm	430	cm99	05Jan24	12:36pm	415	cm99	05Jan24	16
TM10745	44	1:23pm	430	SD34	05Jan24	1:35pm	415	SD34	05Jan24	16
TM10745	44	1:45pm	430	cm99	05Jan24	1:57pm	415	cm99	05Jan24	16
TM10745	44	2:04pm	430	RL47	05Jan24	2:16pm	415	RL47	05Jan24	16
TM10745	44	2:39pm	430	SD34	05Jan24	2:51pm	415	SD34	05Jan24	16
TM10745	44	4:08pm	430	RL47	05Jan24 05Jan24 ①	4:20pm	415	RL47	05Jan24	16
TM10745	44	4:48pm	430	RL47	05Jan24	5:00pm	415	RL47	05Jan24	16
TM10745	44	5:24pm	430	cm99	05Jan24	5:36pm	415	cm99	05Jan24	16
TM10745	44	6:05pm	430	CD19	05Jan24	6:17pm	415	CD19	05Jan24	16
TM10745	44	6:19pm	430	SD34	05Jan24	6:31pm	415	SD34	05Jan24	16
TM10745	44	7:10AM	430	AL42	06JAN24	7:22AM	415	AL42	06JAN24	16

① CD19 05Jan24
① CB58 06Jan24





Document No: 5105589
FM5104665 Rev: C
Document Type: Manufacturing Form
Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000292546

OP 400

① CB58 06Jan24



PRODUCTION ORDER# 500000292546

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10409	N/A	6:30AM	190F	SN67	06JAN24	7:40AM	190F	SN67	06JAN24	21
Tm12036	N/A	7:15AM	190F	SN67	06JAN24	8:25AM	190F	SN67	06JAN24	30
Tm10409	N/A	8:05AM	190F	SN67	06JAN24	9:15AM	190F	SN67	06JAN24	33
Tm10409	N/A	9:30AM	190F	SN67	06JAN24	10:40AM	190F	SN67	06JAN24	37
Tm12036	N/A	10:30AM	190F	SN67	06JAN24	11:40AM	190F	SN67	06JAN24	41
Tm10409	N/A	11:15AM	190F	PL22	06JAN24	12:25PM	190F	PL22	06JAN24	39
Tm12036	N/A	12:04PM	190F	YK40	06 Jan 24	1:14PM	190F	YK40	06 Jan 24	42
Tm10409	N/A	1:35PM	190F	BD64	06Jan24	2:45PM	190F	BD64	06Jan24	40
Tm12036	N/A	2:200PM	190F	BD64	06Jan24	3:10PM	190F	BD64	06Jan24	28
Tm10409	N/A	3:10PM	190F	BD64	06Jan24	4:20PM	190F	BD64	06Jan24	52
Tm10409	N/A	4:45PM	190F	BD64	06Jan24	5:55PM	190F	BD64	06Jan24	40
Tm10409	N/A	5:00 AM	190F	KL45	07JAN24	6:10AM	190F	KL45	07JAN24	81
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

① BD64 06Jan24



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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:	<p>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.</p>		

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:		
16 Nov 23	15 DEC 23		
Lot Number:			
N/A			
Risk Assessment:			
Is there any potential risk(s) that may occur as a result of the proposed deviation including the following: Control Plans <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	Date
Engineering Manager	Jake Stanislowski		16 Nov 2023
Quality Manager	Jay Zabel		16 Nov 2023
Operations Manager	Matthew Benson		16 Nov 2023



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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	11:46AM	430	SN67	05Jan24 ②05Jan24	11:58AM	415	SN67	05Jan24	16
TM10942	44	12:14PM	430	cm99	05Jan24	12:26PM	415	cm99	05Jan24	16
TM10942	44	1:37PM	430	SD34	05Jan24 ①05Jan24	1:49PM	415	SD34	05Jan24	16
TM10942	44	2:25PM	430	SD34	05Jan24	2:37PM	415	SD34	05Jan24 ②05Jan24	16
TM10942	44	2:50PM	430	cm99	05Jan24	3:02PM	415	cm99	05Jan24	16
TM10942	44	3:11PM	430	SD34	05Jan24	3:23PM	415	SD34	05Jan24	16
TM10942	44	4:27PM	430	SN67	05Jan24	4:39PM	415	SN67	05Jan24	16
TM10942	44	5:06PM	430	SD34	05Jan24	5:18PM	415	SD34	05Jan24	16
TM10942	44	5:42PM	430	SN67	05Jan24	5:54PM	415	SN67	05Jan24	16
TM10942	44	6:25PM	430	SD34	05Jan24	6:37PM	415	SD34	05Jan24	10
TM10942	44	6:52AM	430	AL42	06JAN24	7:04AM	415	AL42	06JAN24	16
TM10942	44	7:23AM	430	AL42	06JAN24	7:40AM	415	AL42	06JAN24	16

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① SD34
05Jan24



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OP 400

① AL42 06JAN24

② PLZ22 ObJan24

Bethel & Doss 3228 11/21/23



CREGANNA
MEDICAL

15 Part of

IS PART OF **DEVIATION A**
Extends to 22-Nov-2023 328 FOR 33

Requestor Name: Udhesh Kanadnis

CONTROLLED COPY DEVIATION AUTHORIZATION NUMBER: 2484

NOTIFICATION FORM Extension to 23 Oct 2023 215
* See attached email extension to 24 SEP 2023
1512 24 AUG 23 215

Requestor Name: Udhesh Kapadnis	
Document Number Affected	Revision
3107610	L

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): NA

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

Corrective Action Required:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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, 23JW 2023

DA	2484
2468	①



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is part of

Group Training Record

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)
①MM0179-01 **②MM1536-01** **type Connection TS12** **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)

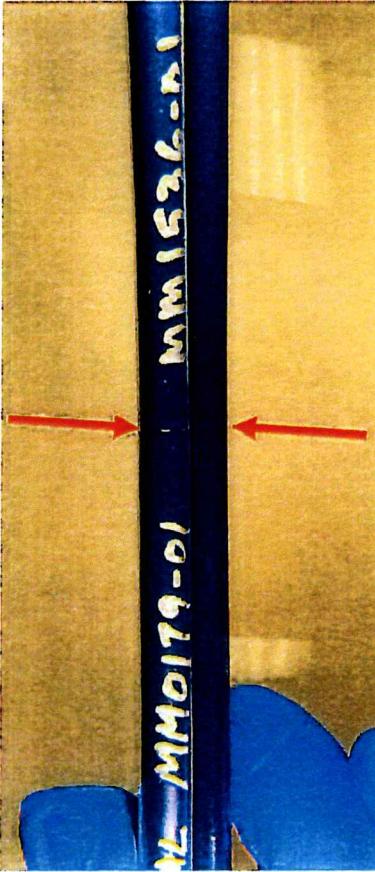


Image- 3

- 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)

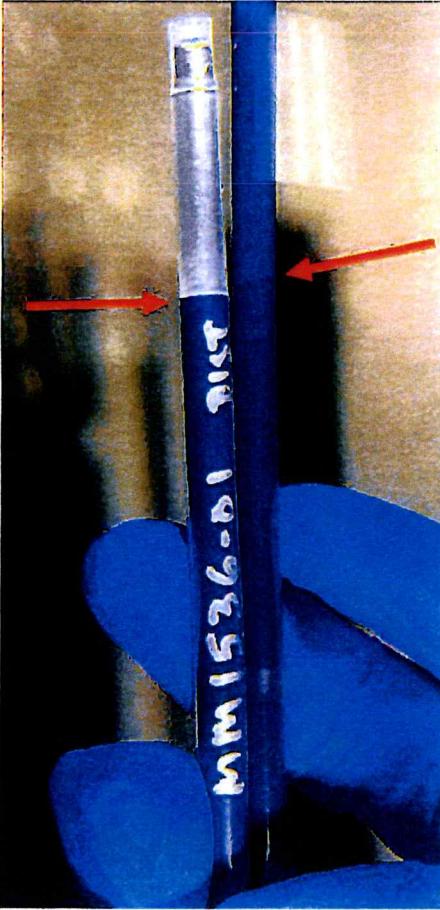


Image- 4

- 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 Two MM0179-01 - BAD PART	MM0179-01
4	MM1536-01 Two MM1536-01 - BAD PART	MM1536-01

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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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	21.95	25.37	28.17	25.02	23.56	24.13	28.12	26.65	29.47	26.11	25.855	2.3256743	4.378	15.6731978	8.542	PASS
Seg B	59.53	57.64	54.09	58.82	59.18	58.49	59.76	60.82	59.66	60.12	58.811	1.879311	3.981	51.3294627	8.542	PASS
Seg C	76.56	75.86	76.96	76.2	79.88	78.24	74.05	75.64	74.97	76.25	76.461	1.6430693	2.911	71.6780253	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.

EDW Commander Flex - Bend and Tensile Strength Testing

LOT #: 500000292546

Date: 08 JAN 2024

Inspector Name: KOCK YU LEE

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24

KockYulLee,

08JAN24