

Production Order: 500000307851



Production Order Document
Production Order Qty: 500

PC

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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
		Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used				
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): <i>Am 68 4:30pm 15Feb24</i> Record Time Extrusions First Exit Dryer (Initial/Time/Date): <i>Am 68 5:00pm 18Feb24</i> Record Dryer Shelf #: <i>N/A</i>						N/A	N/A	<i>14Feb24 TRD</i>
		Kitting Devices	MM0179-01	D <i>D</i>	PC	500	<i>0000293119</i>	<i>500</i>	<i>N/A</i>	<i>N/A</i>	
			MM1536-01	B <i>B</i>	PC	500	<i>0000290560</i>	<i>500</i>			

Notes: DA 2564, 2484

N/A

N/A

Date Printed: 02/14/2024 / 17:32:03

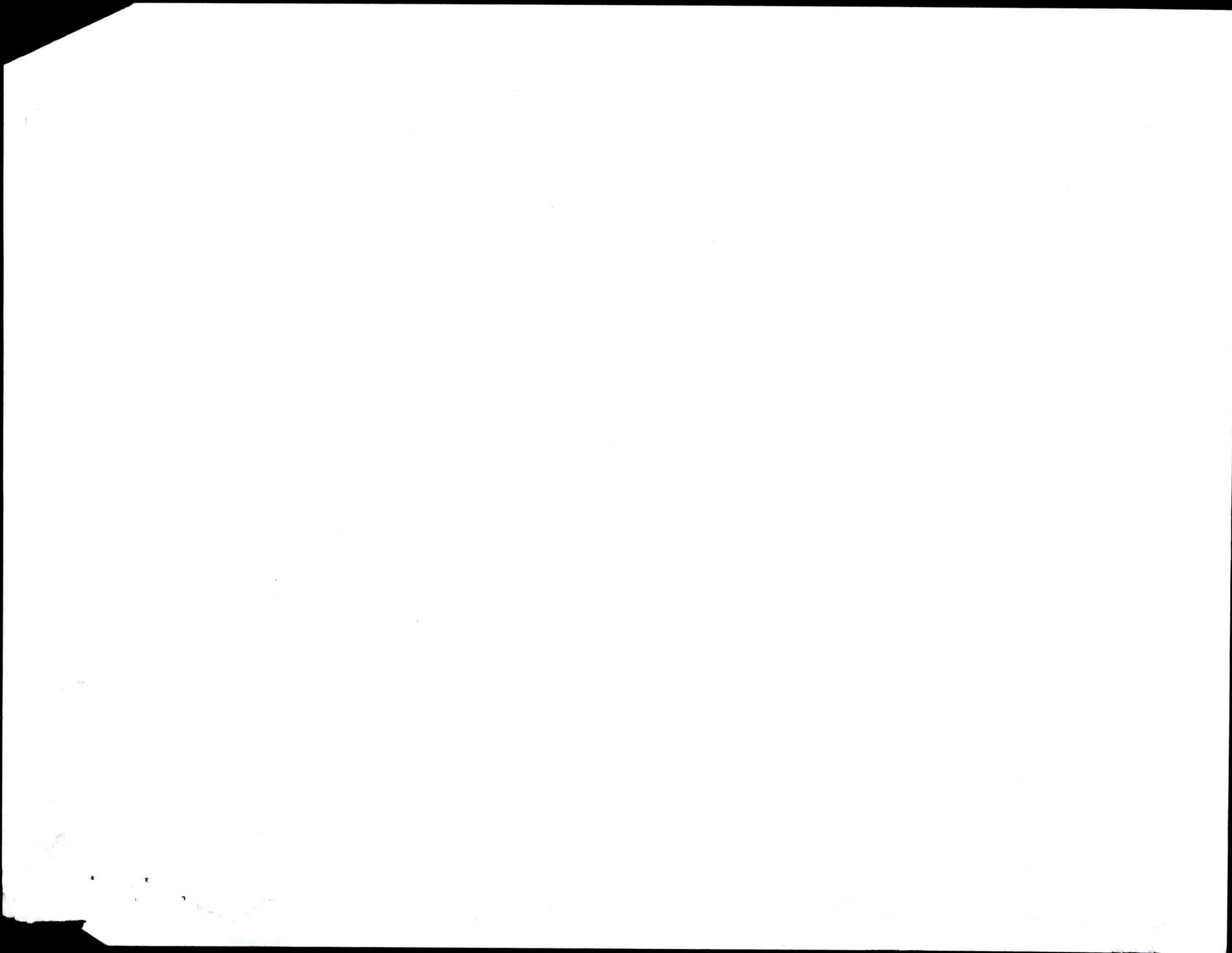
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N/A	N/A	RM0158-01	E	<u>E</u>	PC	200	<u>31054</u>	<u>N/A</u>	<u>N/A</u>	
		1000-1153-01	A	<u>A</u>	PC	594	<u>88368</u> <u>88349</u> <u>88370</u>	<u>200</u> <u>200</u> <u>200</u>		
		1000-2053-01	A	<u>A</u>	PC	500	<u>0000387943</u>	<u>500</u>	<u>N/A</u>	
		MM1537-02	A	<u>A</u>	PC	500	<u>0000290571</u> <u>0000288401</u>	<u>500</u> <u>120</u>		
		TL0167-02	E	<u>E</u>	PC	70	<u>N/A</u>	<u>Bulk</u>	<u>N/A</u>	<u>N/A</u>
		TL0165-05	J	<u>J</u>	PC	5	<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>			

Notes:

N/A

N/A

N/A

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N/A	N/A	141967-01	02	<u>02</u>	PC	500	<u>85678</u>	<u>525</u>		
		RM7349-02	C	<u>C</u>	PC	543	<u>89195</u>	<u>N/A</u>		
		RM7348-01	C	<u>C</u>	PC	500	<u>88491</u>	<u>600</u>		
		RM4001-01	B	<u>B</u>	PC	125	<u>82810</u>	<u>500</u>		
		RM0607-01	D	<u>D</u>	PC	56	<u>74063</u>	<u>100</u>		
		RM0498-01	C	<u>C</u>	PC	500	<u>000275493</u>	<u>200</u>		
		RM0009-04	I	<u>I</u>	PC	1	<u>88993</u>	<u>N/A</u>		
		RM0009-04	I	<u>I</u>	PC	1	<u>88993</u>	<u>N/A</u>		

Notes:

N/A

N/A

N/A

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N/A	N/A	MM1538-01	A	<u>A</u>	PC	500	<u>0000290562</u>	<u>500</u>	<u>Bulk</u>	
							<u>0000278970</u>	<u>80</u>		
		MM1537-01	A	<u>A</u>	PC	1000	<u>0000294701</u>	<u>1060</u>		
							<u>N/A</u>	<u>N/A</u>		
		MM0177-01	C	<u>C</u>	PC	500	<u>0000294697</u>	<u>500</u>		
							<u>0000252923</u>	<u>80</u>		
		MM0180-01	E	<u>E</u>	PC	500	<u>0000294374</u>	<u>400</u>		
							<u>0000295974</u>	<u>100</u>	N/A	N/A
		MM0178-01	E	<u>E</u>	PC	500	<u>0000290565</u>	<u>500</u>		
							<u>N/A</u>	<u>N/A</u>		
		MM0176-01	D	<u>D</u>	PC	500	<u>0000288413</u>	<u>500</u>		
							<u>N/A</u>	<u>N/A</u>		
		MM0074-01	G	<u>G</u>	PC	500	<u>0000303770</u>	<u>516</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	N/A	N/A	N/A	N/A	N/A	N/A
100	CATASY01 Catheter Assembly 1  Line Clearance Confirmation Reqd(Milestone)	Line Clearance Perform Line Clearance and Heat Gun Setting	500	0	19Feb24	PY46
150	CATASY01 Catheter Assembly 1  Major and Minor Mandrel Assembly	Major and Minor Mandrel Assembly	500	0	19Feb24	JG92 PM96 NK62 SY47 JY90

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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	19 Feb 24	LH45 MY450 NY35 Y014
250	CATASY01 Catheter Assembly 1  Trim Braid Wire at Proximal End		500	0	19 Feb 24	VP62 V078 CP32

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 Confirmation Reqd(Milestone)	Insert Cut Hypo Tube	500	0	19Feb24 AL42 PC22 TRV BD64 VV25 OS31 GS22	
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0	19Feb24 AL65 AL34 CL05	
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	19Feb24 SN607 PL22 TRN SD34 PM76 NK62 TA36 CL30 ST85	
450	CATASY01 Catheter	FEP Removal	500	0	19Feb24 PM96 SX60	

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
	Assembly 1 FEP Removal Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
500	CATASY01 Catheter Assembly 1 In-process Inspection and Rework Material Consumed: Part #: 100-1153-01 Batch #: 88369 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	In-process Inspection and Rework Material Consumed: Part #: 100-1153-01 Batch #: 88369 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	493	EW - III DF - IIII 19Feb24 7	LL61 VC09 CB81 R66 VLC91 TD45	
N/A	N/A	N/A	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
550	CATASY01 Catheter Assembly 1  Remove Heat Shrink & Mandrel Remove Heat Shrink & Mandrel Confirmation Reqd(Milestone)	Remove Heat Shrink & Mandrel	493	0	19Feb24	AX82 VA96 FB01 RS 23 DX35 SV46
600	CATASY01 Catheter Assembly 1  Distal Tip Assembly Distal Tip Assembly Confirmation	Distal Tip Assembly	485	8	19Feb24	DL - 1111 MAH - 1111 D1/30 MU78 ML60

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	485	0	11Feb24	AX82 UA96 F801 PP40
	Loading Heat Shrink					
	Confirmation Reqd(Milestone)					
700	CATASY01 Catheter Assembly 1 	Tipping Record Tipping Oven Information: TMI: <u>0386</u> Cal Due: <u>31 MAY 24</u> TMI: <u>0521</u> Cal Due: <u>31 MAY 24</u> TMI: <u>20836</u> Cal Due: <u>31 MAY 24</u> TMI: <u>09361</u> Cal Due: <u>31 MAY 24</u> Tipping	485	0	① 11Feb24 19Feb24	RS23
Notes:						
N/A						
N/A						
N/A						

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① mm02 19Feb24



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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 	<p>Tip Inspection/ Flash Removal Material Consumed:</p> <table> <tr> <td>Part #: <u>2m4001-01</u></td> <td>Batch #: <u>82810</u></td> <td>Qty: <u>N/A</u></td> </tr> <tr> <td>Part #: <u>200-153-01</u></td> <td>Batch #: <u>88369</u></td> <td>Qty: <u>N/A</u></td> </tr> <tr> <td>Part #: <u>N/A</u></td> <td>Batch #: <u>N/A</u></td> <td>Qty: <u>N/A</u></td> </tr> <tr> <td>Part #: <u>N/A</u></td> <td>Batch #: <u>N/A</u></td> <td>Qty: <u>N/A</u></td> </tr> <tr> <td>Part #: <u>N/A</u></td> <td>Batch #: <u>N/A</u></td> <td>Qty: <u>N/A</u></td> </tr> </table> <p>Tip Inspection/ Flash Removal Confirmation Reqd(Milestone)</p>	Part #: <u>2m4001-01</u>	Batch #: <u>82810</u>	Qty: <u>N/A</u>	Part #: <u>200-153-01</u>	Batch #: <u>88369</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>	Part #: <u>N/A</u>	Batch #: <u>N/A</u>	Qty: <u>N/A</u>	484	EH-1 ①	HV36 STX48 mn02 19Feb24
Part #: <u>2m4001-01</u>	Batch #: <u>82810</u>	Qty: <u>N/A</u>																		
Part #: <u>200-153-01</u>	Batch #: <u>88369</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>																		
Part #: <u>N/A</u>	Batch #: <u>N/A</u>	Qty: <u>N/A</u>																		
800	CATASY01 Catheter Assembly 1 	Major Mandrel Removal	479	ACD-44 ⑤	SS52 KT26 19Feb24															

Notes:

N/A
N/A
N/A

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N/A	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. <u>passed</u> 2. <u>passed</u> 3. <u>passed</u> 4. <u>passed</u> 5. <u>passed</u>	477	SKV-11	19feb24	SS52 M15
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	SH04 HTB MV33 PL66
Notes:						
N/A						
N/A						
N/A						

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900	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:</p> <p>TMI: <u>0700-01</u> Cal Due: <u>31 May 24</u></p> <p>TMI: <u>N/A</u> Cal Due: <u>N/A</u></p> <p>Material Consumed:</p> <p>Part #: <u>1000-115301</u> Batch #: <u>E8369</u> Qty: <u>N/A</u></p> <p>Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u></p>	450	D1S-4H1 HHT W1K-1 EH-111 EW-1 MAH-1 #6US-1 #6OS-1 #7OS-1111 21	19 Feb 24	D424 P746 K155 Y936
950	QUALITY1 Quality Inspection & Review	<p>Quality Inspection & Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information:</p> <p>TMI: <u>50713B</u> Cal Due: <u>12 APR 24</u></p> <p>Record Caliper Information:</p>	N/A	N/A	N/A	N/A

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
950	Quality Inspection & Review Confirmation Reqd(Milestone)	TMI: <u>7033</u> Cal Due: <u>30 Apr 24</u> Record DIM02 Go/No-Go Gage Information: TMI: <u>0691</u> Cal Due: <u>30 Sep 25</u> TMI: <u>0692</u> Cal Due: <u>30 Sep 25</u> Record DIM02 Inspection Results N = 54: Pass: <u>54</u> Fail: <u>0</u>	409	DIS(SP) HHH DIS - HHHHH HHH 1 WK - 11 SAR - HHHHH HHH 111	19 Feb 24 19 Feb 24 19 Feb 24 19 Feb 24 19 Feb 24	Y936 Y936 Y936 Y936 Y936
1000	QUALITY1 Quality Inspection & Review 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>31 May 24</u> Record Length Gage Information: TMI: <u>08891</u> Cal Due: <u>30 Sep 24</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30 Sep 24</u>	400	LT - HHHHH	19 Feb 24	CB81 Y936 SG88

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N/A	N/A	N/A	N/A	N/A	N/A	N/A
1050	QUALITY1 Quality Inspection & Review  Quality Inspection & Review Confirmation Reqd(Milestone)	Required Inspection Visual Final Inspection Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	316	Fm-M11(11) D15-111 MEx-11 eH-1 ew-1 VD-1 SCR-1 RDG-1 GN11-1 CRK-1 Fm-11 ②4	20 Feb 24	Zey50 SV43
1100	CATASY01 Catheter Assembly 1  Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initials/Date): <u>GS85 20 Feb 24</u>	N/A	N/A	20 Feb 24	GS85
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
1100	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	376	0 20 Feb 24	APW 20 Feb 24	ABW 20 Feb 24

Notes:

N/A ABW 20 Feb 24

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Batch Number: 0000307851

By: APW

Date: 20 Feb 24

Reviewed By:

RB29

Date:

20 feb 24

Notes:

N/A APW 20 Feb 24

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OP 400

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

① V078 19 Feb 24



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

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Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10745	44	6:14pm	430	SD34	18Feb24	6:26pm	415	SD34	18Feb24	16
TM10745	44	5:35am	430	PM96	19Feb24	5:47am	415	PM96	19Feb24	16
TM10745	44	6:05am	430	TA36	19 Feb 24	6:17am	415	TA36	19 Feb 24	16
TM10745	44	7:10am	430	0521	19 Feb 24	7:22am	415	0521	19 Feb 24	16
TM10745	44	8:05am	430	0521	19 Feb 24	8:17am	415	0521	19 Feb 24	16
TM10745	44	8:40am	430	0521	19 Feb 24	8:52am	415	0521	19 Feb 24	16
TM10745	44	9:48am	430	0521	19 Feb 24	10:03am	415	0521	19 Feb 24	16
TM10745	44	10:50am	430	0521	19 Feb 24	11:02am	415	0521	19 Feb 24	16
TM10745	44	11:40am	430	0521	19 Feb 24	11:52am	415	0521	19 Feb 24	16
TM10745	44	12:20pm	430	0521	19 Feb 24	12:32pm	415	0521	19 Feb 24	16
TM10745	44	1:52pm	430	PM96	19 Feb 24	2:04pm	415	PM96	19 Feb 24	16
TM10745	44	2:48pm	430	0521	19 Feb 24	3:00pm	415	0521	19 Feb 24	16



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

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① 0521 19 Feb 24
② V078 19 Feb 24



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OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TMI0942	44	5:14 AM	430	PM 96	19 Feb 24	5:26 AM	415	PM 96	19 Feb 24	16
TMI0942	44	5:55 AM	430	TA 36	19 Feb 24	6:07 AM	415	TA 36	19 Feb 24	16
TMI0942	44	6:30 AM	430	OS 21	19 Feb 24	6:42 AM	415	OS 21	19 Feb 24	16
TMI0942	44	7:46 AM	430	PM 96	19 Feb 24	7:58 AM	415	PM 96	19 Feb 24	16
TMI0942	44	8:14 AM	430	PM 96	19 Feb 24	8:26 AM	415	PM 96	19 Feb 24	16
TMI0942	44	8:48 AM	430	OS 21	19 Feb 24	9:00 AM	415	OS 21	19 Feb 24	16
TMI0942	44	9:35 AM	430	TA 36	19 Feb 24	9:47 AM	415	TA 36	19 Feb 24	16
TMI0942	44	11:20 AM	430	OS 21	19 Feb 24	11:32 AM	415	OS 21	19 Feb 24	16
TMI0942	44	12:00 PM	430	TA 36	19 Feb 24	12:12 PM	415	TA 36	19 Feb 24	16
TMI0942	44	12:35 PM	430	OS 21	19 Feb 24	12:47 PM	415	OS 21	19 Feb 24	16
TMI0942	44	1:35 PM	430	OS 21	19 Feb 24	1:47 PM	415	OS 21	19 Feb 24	16
TMI0942	44	2:25 PM	430	TA 36	19 Feb 24	2:37 PM	415	TA 36	19 Feb 24	16



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

PO #: 500000 307851 OP #: 500 Shift #: 2nd

Total Parts Reworked:		17	
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	11111	8
MP	Micropores	N/A	N/A
SCR	Scratch	///	3
SKV	Skive Marks	N/A	N/A
VD	Voids	1111	6
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		Vammeej. Lor 18 Feb 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 #: 500000301851

OP #: 500 Shift #: 1st

Total Parts Reworked:		157	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube		26
EW	Exposed Wire		91
MP	Micropores	N/A	N/A
SCR	Scratch		5
SKV	Skive Marks		1
VD	Voids		34
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		CB81, LL61, VC09	19 Feb 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 #: 500000307851 OP #: 500 Shift #: 2

Total Parts Reworked:		15	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	/	1
EH	Exposed Hypotube	N/A	0
EW	Exposed Wire		12
MP	Micropores	N/A	0
SCR	Scratch	N/A	0
SKV	Skive Marks	N/A	0
VD	Voids	//	2
N/A	N/A	N/A	0

Inspected By (Sign and Date):

DX35 19 Feb 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):

DX35 19 Feb 24



Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

PO #: 500000307851OP #: 750 Shift #: 1st

Total Parts Reworked:		57	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		18
DIM07 US / WC	DIM07 Undersized (Window Closed)		5
EH	Exposed Hypotube		7
N/A	Glue , stopper		27
Inspected By (Sign and Date):		Hv36 19 Feb 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 #: 50000307851 OP #: 750 Shift #: 2nd.

Total Parts Reworked:		35	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		25
DIM07 US / WC	DIM07 Undersized (Window Closed)	N/A	N/A
EH	Exposed Hypotube		10
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		MM02	19Feb24

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):

PRODUCTION ORDER# 500000307851

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10409	N/A	10:10am	190°F	0521	19Feb24	11:20am	190°F	0521	19Feb24	62
Tm10409	N/A	11:35am	190°F	SSHH	19 Feb 24	12:45pm	190°F	SSHH	19 Feb 24	47
Tm12036	N/A	12:05pm	190°F	SSHH	19 Feb 24	1:15pm	190°F	SSHH	19 Feb 24	43
Tm10409	N/A	1:45pm	190°F	SSHH	19 Feb 24	2:55pm	190°F	SSHH	19 Feb 24	43
Tm10409	N/A	2:55pm	190°F	SSHH	19 Feb 24	4:05 pm	190°F	SSHH	19 Feb 24	56
Tm10409	N/A	4:27pm	190°F	KT26	19 Feb 24	5:37pm	190°F	KT26	19 Feb 24	32
Tm12036	N/A	4:56pm	190°F	KT26	19 Feb 24	6:06pm	190°F	KT26	19 Feb 24	217
Tm10409	N/A	6:08pm	190°F	KT26	19 Feb 24	7:18pm	190°F	KT26	19 Feb 24	34
Tm12036	N/A	6:53pm	190°F	KT26	19 Feb 24	8:03pm	190°F	KT26	19 Feb 24	30
Tm10409	N/A	7:27pm	190°F	KT26	19 Feb 24	8:37pm	190°F	KT26	19 Feb 24	32
Tm12036	N/A	8:04pm	190°F	KT26	19 Feb 24	9:14pm	190°F	KT26	19 Feb 24	23
Tm10409	N/A	9:11pm	190°F	KT26	19 Feb 24	10:21pm	190°F	KT26	19 Feb 24	30
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

① SSHH 19 Feb 24

② KT26 19 Feb 24



Document No: 6102619
Rev: B
Document Type: Manufacturing Form
Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 500000307851 OP #: 900 Shift #: 1st

Total Parts Reworked:		36	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		1
EH	Exposed Hypotube		2
EW	Exposed Wire		6
MP	Micropores	n/a	n/a
SCR	Scratch		5
SKV	Skive Marks	n/a	n/a
VD	Voids		5
DIM01 US	DIM01 OD Undersized	n/a	n/a
DIM06 US	DIM06 OD Undersized	n/a	n/a
DIM06 OS	DIM06 OD Oversized	n/a	n/a
DIM09 US	DIM09 OD Undersized	n/a	n/a
Inspected By (Sign and Date):		P146 19 Feb 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: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 500000307851OP #: 900 Shift #: 2nd

Total Parts Reworked:		57	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube		2
EW	Exposed Wire		6
MP	Micropores	N/A	0
SCR	Scratch		22
SKV	Skive Marks	N/A	0
VD	Voids		3
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized		36
DIM06 OS	DIM06 OD Oversized		3
DIM09 US	DIM09 OD Undersized	N/A	0
Inspected By (Sign and Date):		See H 19 Feb 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: 6102619
Rev: B
Document Type: Manufacturing Form
Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 50000307851 OP #: 900 Shift #: 2

Total Parts Reworked:		56	
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		11
MP	Micropores	N/A	0
SCR	Scratch		50
SKV	Skive Marks	N/A	0
VD	Voids	/	7
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized	N/A	0
DIM06 OS	DIM06 OD Oversized	N/A	0
DIM09 US	DIM09 OD Undersized	N/A	0
Inspected By (Sign and Date):		① <u>Craig</u> <u>18 Feb 24</u>	<u>19 Feb 24</u>

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 D66 19 Feb 24



PO #: 500000307851 **OP #:** 900 **Shift #:** 2

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):

- CONFIDENTIAL -

Page 1 of 1

Status CURRENT Effective 5/8/2023

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	31.7	28.32	24.42	25.84	35.17	33.89	25.67	25.4	27.74	29.08	28.723	3.7352824	4.378	12.3699337	8.542	PASS
Seg B	75.68	70.93	77.34	67.2	75.11	74.17	67.11	72.51	69.5	70.72	72.027	3.5383174	3.981	57.9409584	8.542	PASS
Seg C	80.26	90.71	82.61	89.44	80.87	91.03	91.73	82.07	90.28	82.72	86.172	4.7973831	2.911	72.2068178	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 #: 500000307851

Date: 20FEB2024

Inspector Name: AUGUSTINE JAH

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24



20 FEB 2024

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CREGANNA MEDICAL

* See attached email extension to 24 SEP 23
TS2
24 AUG 23

REGANNA MEDICAL is part of **TECHNICON**

DEVIATION AUTHORIZATION NUMBER: 2484
See attached email extension to 24SEP23

CONTROLLED COPY

Requestor Name: Udhesh Kanadnis
Request ID: 3228-11272023

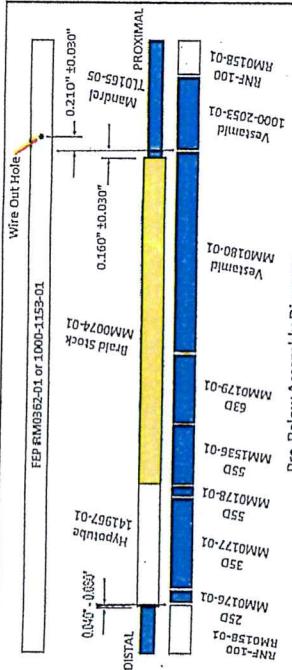
Document Number Affected	Revision
3107610	L

Deviation From:

QIP3107610, Section 8.0 Inspection Requirements (Supplemental Visual Inspection) OP 1050:

Current QIP3107610 does not state to inspect for the correct extrusion configuration

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.



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 one of the event documents in NC-26390, and NC-26426 contains incorrect extrusion configuration, and interim unit sent to customer. Interim correction action has been put out of oriented extrusions. This DA is adding another

are incorrectly assembling MM0179-01 and MM1536-01. A new of experienced inspectors can detect finished unit that used inspectors may not which potential non-conformance implemented at OP 250, 300, 350 to detect unit built with of inspection at final OC inspection to avoid incorrect

Part Number Affected	Revision	
SA0155-01	H	
Start Date:	End Date:	Lot Number:
26 Jul 2023	25 Aug 2023	N/A

Piers Assessment

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.		

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

CONTROLLED COPY

① UK55, 23JW 2023

CREGANNA
MEDICAL
is part of
TE

DA | 2484
2468-
①

Description/Objectives of Training:
DA- Inspection at final QC, Op#1050.

Group Training Record

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 MM1536-01 fixture for inspection. (See image 1)
①MM1536-01 Type connection TS12 16AUG23



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)

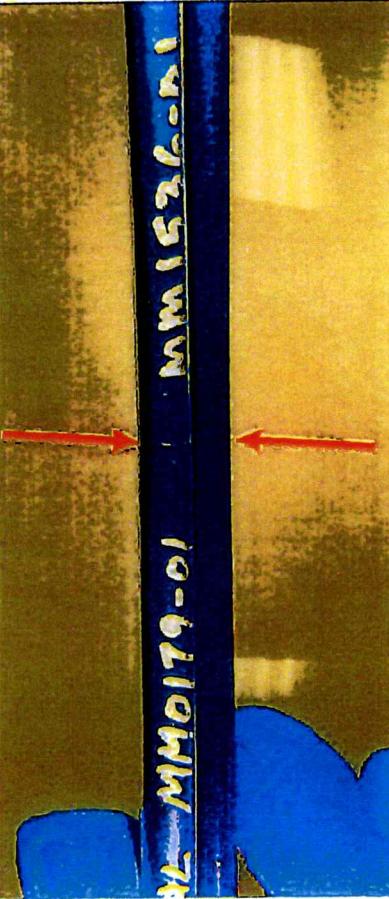


Image- 3

- 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.

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)

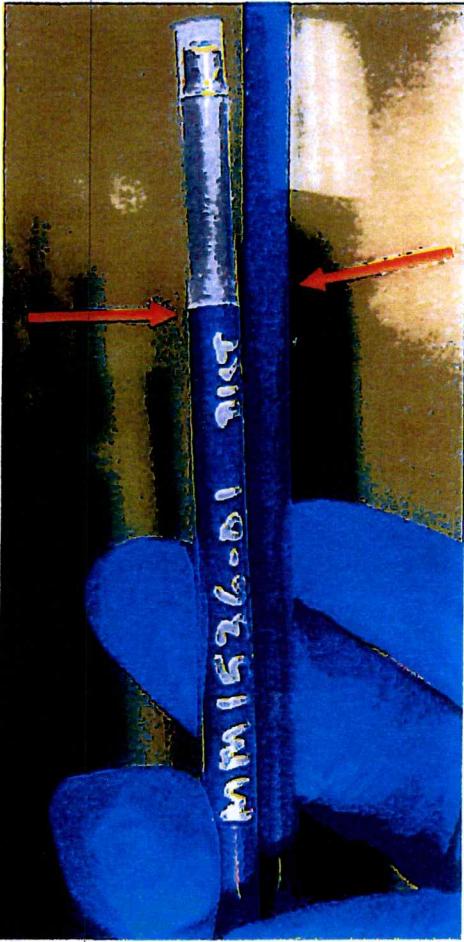


Image- 4

- 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



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:	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:	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 FMEAs <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