

# Production Order: 500000301657



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		
* 24Jan2024 - For ES0703 per DA2594 JSR			① JD58 31JAN24

Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials																								
50	KITTING3  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>XC31 5:30AM 29JAN24</u></p> <p>Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>KC31 10:30AM 29JAN24</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>0000278880</u></td> <td><u>400</u></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td><u>0000287543</u></td> <td><u>100</u></td> </tr> <tr> <td>MM1537-02</td> <td>A <u>A</u></td> <td>PC</td> <td>500</td> <td><u>0000288401</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>0000278880</u>	<u>400</u>					<u>0000287543</u>	<u>100</u>	MM1537-02	A <u>A</u>	PC	500	<u>0000288401</u>	<u>500</u>	N/A	N/A	① JD58 27Jan24	DK00
Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																									
1000-2053-01	A <u>A</u>	PC	500	<u>0000278880</u>	<u>400</u>																									
				<u>0000287543</u>	<u>100</u>																									
MM1537-02	A <u>A</u>	PC	500	<u>0000288401</u>	<u>500</u>																									

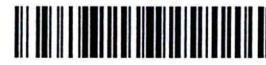
Notes: DA 2484, 2564 ① JD58 31JAN24 WO NOT USED FOR ES0703 PER DA2594

N/A

N/A

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① GSG531 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	RM0158-01	E	<u>E</u>	PC	200	N/A 58497	N/A 200		
		TL0167-02	E	<u>E</u>	PC	70	N/A	N/A	Bulk	
		TL0165-05	J	<u>J</u>	PC	5	N/A	N/A	Bulk	
		TL0165-03	J	<u>J</u>	PC	5	N/A	N/A	Bulk	
		141967-01	02	<u>02</u>	PC	500	85502	514	N/A	N/A
		RM7349-02	C	<u>C</u>	PC	543	82835 82863	500 100		
		RM7348-01	C	<u>C</u>	PC	500	82885 82886	450 50		

### 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
<i>N/A</i>	<i>N/A</i>	RM4001-01	B	<u>B</u>	PC	125	<u>82457</u>	<u>100</u>			
		RM0607-01	D	<u>D</u>	PC	56	<u>74662</u>	<u>167</u>			
		RM0498-01	C	<u>C</u>	PC	500	<u>0000287644</u> <u>0000275492</u> <u>0000287642</u>	<u>304</u> <u>99</u> <u>59</u>			
		RM0362-01	E	<u>E</u>	PC	594	<u>78864</u>	<u>600</u>			
		RM0009-04	I	<u>I</u>	PC	1	<u>79170</u>	<u>Bulk</u>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>
		RM0009-04	I	<u>I</u>	PC	1	<u>79170</u>	<u>Bulk</u>			
		MM1538-01	A	<u>A</u>	PC	500	<u>0000278970</u>	<u>500</u>			
		MM1537-01	A	<u>A</u>	PC	1000	<u>0000384709</u>	<u>1000</u>			

Notes:

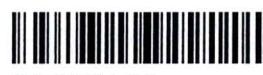
*N/A*

*N/A*

*N/A*

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N/A	N/A	MM1536-01	B	<u>B</u>	PC	500	<u>0000281412</u>	N/A		
		MM0180-01	E	<u>E</u>	PC	500	<u>0000282490</u>	N/A		
		MM0179-01	D	<u>D</u>	PC	500	<u>0000276172</u>	500		
		MM0178-01	E	<u>E</u>	PC	500	<u>0000276174</u>	500	N/A	N/A
		MM0177-01	C	<u>C</u>	PC	500	<u>0000284208</u>	40		
		MM0176-01	D	<u>D</u>	PC	500	<u>0000288413</u>	500		
		MM0074-01	G	<u>G</u>	PC	500	<u>0000245168</u>	499		
							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
NA	NA	MA	NA	NA	NA	NA
100	CATASY01  Catheter Assembly 1  	Line Clearance Perform Line Clearance and Heat Gun Setting	500	0 30 Jan 24	Y078	
150	CATASY01  Catheter Assembly 1  	Major and Minor Mandrel Assembly	500	0 30 Jan 24	Y014 CP32 JY90 PM96 NK6	Y014 CP32 JY90 PM96 NK6

Notes:

MA
MA
MA

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① Y014 29 JAN 24

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
NP	Confirmation Reqd(Milestone )	MA	MA	MA	MA	MA
200	CATASY01 Catheter Assembly 1 	Loading Braid Stock	500	0	30Jan24	NY35 DX35 VP62
250	CATASY01 Catheter Assembly 1 	Trim Braid Wire at Proximal End	500	0	30Jan24	ST96 DX35 MY50
<b>Notes:</b>						MA MA MA

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Trim Braid Wire at Proximal End  NP Confirmation Reqd(Milestone )	MA	MA	MA	MA	MA
300	CATASY01 Catheter Assembly 1   Insert Cut Hypo Tube  Insert Cut Hypo Tube  Confirmation Reqd(Milestone )	Insert Cut Hypo Tube	500	0	30 Jan 24	0531 GS22 DV39
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0	30 Jan 24	CL05 SH23 VV25 CY97
<b>Notes:</b>						MA
						MA
						MA

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	Load Tubing  Confirmation Reqd(Milestone )		MA	MA	MA	MA
400	CATASY01  Catheter Assembly 1  Reflow  Confirmation Reqd(Milestone )	Reflow	500	0	30 Jan 24	V078 pm 96 NR62 AL34 AX05
450	CATASY01  Catheter	FEP Removal	500	0	30 Jan 24	JY90 pm 96
Notes:		MA MA MA				

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	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  Confirmation Reqd(Milestone )	In-process Inspection and Rework  Material Consumed: Part #: 1000-1153-0 Batch #: 88728 Qty: 10 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 Part #: N/A Batch #: N/A Qty: N/A	475	EN-HHT OF-HHT HHT HHT III (25) 305mm	M002 R66 LL61 VC09 CB81	
			N/A	N/A	N/A	M2
	Notes:			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	475	0	30 Jan 24	OH59 RS23 FB01 AX82 VA96 MV78
	Remove Heat Shrink & Mandrel					
	Confirmation Reqd(Milestone )					
600	CATASY01  Catheter Assembly 1  	Distal Tip Assembly	453	DL - 111 111 MAH - 111 111 11 (22)	30 Jan 24	PH59 FB01 AX82 VA96
	Distal Tip Assembly					
	Confirmation					

**Notes:**

N/A

MA

N/A

MA

N/A

MA

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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  Loading Heat Shrink  Confirmation Reqd(Milestone )	450	DL-111  ③	PHH9 FB01 AX82 VA96 ML38  30 Jan 24	
700	CATASY01  Catheter Assembly 1  	Tipping  Record Tipping Oven Information: TMI: 0386 Cal Due: 31may24 TMI: 0936A Cal Due: 31may24 TMI: 20831 Cal Due: 31may24 TMI: 0521 Cal Due: 31may24  Tipping	450	○	Hv36 ML38  30 Jan 24	

Notes:

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  	<p>Tip Inspection/ Flash Removal</p> <p>Material Consumed:</p> <table border="1"> <tr> <td>Part #:</td> <td>RM4001-01</td> <td>Batch #:</td> <td>82957</td> <td>Qty:</td> <td>4</td> </tr> <tr> <td>Part #:</td> <td>RM0607-01</td> <td>Batch #:</td> <td>74662</td> <td>Qty:</td> <td>5</td> </tr> <tr> <td>Part #:</td> <td>N/A</td> <td>Batch #:</td> <td>N/A</td> <td>Qty:</td> <td>N/A</td> </tr> <tr> <td>Part #:</td> <td>N/A</td> <td>Batch #:</td> <td>N/A</td> <td>Qty:</td> <td>N/A</td> </tr> <tr> <td>Part #:</td> <td>N/A</td> <td>Batch #:</td> <td>N/A</td> <td>Qty:</td> <td>N/A</td> </tr> </table>	Part #:	RM4001-01	Batch #:	82957	Qty:	4	Part #:	RM0607-01	Batch #:	74662	Qty:	5	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	445	EH-III  5  P/Tan 24	STX48 Hv36 MM02 SV46
Part #:	RM4001-01	Batch #:	82957	Qty:	4																														
Part #:	RM0607-01	Batch #:	74662	Qty:	5																														
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																														
800	CATASY01  Catheter Assembly 1  	Major Mandrel Removal	441	ACD-III ① 0 III ACD-III ② ACD - IIII	30 Jan 24 SS44 SS52 XL91																														

Notes:

N/A

N/A

N/A

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① PY46 30 Jan 24      ② XL91 30 Jan 24

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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Major Mandrel Removal  Confirmation Rreqd(Milestone )	N/A	N/A	N/A	N/A	S ①
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>	441	0	30Jan24	SS52 ML65 TRN KL67
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	SHaf ML46 MV33 ML65
Notes:						
N/A						
N/A						
N/A						

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① XL91 30Jan24



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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:</p> <p>TMI: 0700-01 Cal Due: 31 May 24</p> <p>TMI: N/A Cal Due: N/A</p> <p>Material Consumed:</p> <p>Part #: RM14001-01 Batch #: 82457 Qty: N/A</p> <p>Part #: RM0158-01 Batch #: 58497 Qty: N/A</p> <p>Part #: RM0607-01 Batch #: 74662 Qty: N/A</p> <p>Part #: 100-1153-01 Batch #: 88728 Qty: N/A</p> <p>Part #: N/A Batch #: N/A Qty: N/A</p>	392	DIS-IHT-IHT IHT-IHT-IHT MAR-IHT ACD-II Scr-1 #SUS-II #BOS-II #TOS-IHT III #QUS-II #GOS-II	30Jan24	XL91 KL67 P66 HT72
950	QUALITY1  Quality Inspection & Review	<p>Quality Inspection &amp; Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information:</p> <p>TMI: N/A Cal Due: N/A</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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N/A	 <b>Quality Inspection &amp; Review</b> <b>Confirmation Reqd(Milestone )</b>	<p>TMI: <u>N/A</u> Cal Due: <u>N/A</u></p> <p>Record DIM02 Go/No-Go Gage Information:</p> <p>TMI: <u>0691</u> Cal Due: <u>30Sep25</u></p> <p>TMI: <u>0692</u> Cal Due: <u>30Sep25</u></p> <p>Record DIM02 Inspection Results N = 54: Pass: <u>157</u> Fail: <u>0</u></p>	<span style="font-size: 2em;">366</span> <span style="font-size: 1.5em;">26<sup>(2)</sup></span>	DEK(TT)HHH DIS(SP)HHH WK-II STR-II DIS - LHHII	<span style="font-size: 2em;">20Jan24</span>	XL91 KL67
1000	 <b>Quality Inspection &amp; Review</b>  <b>Quality Inspection &amp; Review</b> <b>Confirmation Reqd(Milestone )</b>	<p>Quality Inspection &amp; Review</p> <p>Leak Test</p> <p>Record Inspection Data in SAP ROS</p> <p>Record Leak Tester Information:</p> <p>TMI: <u>1056</u> Cal Due: <u>31 May 24</u></p> <p>Record Length Gage Information:</p> <p>TMI: <u>0889D</u> Cal Due: <u>30Sep24</u></p> <p>Record Calibrated Ruler Information:</p> <p>TMI: <u>0629</u> Cal Due: <u>30Sep24</u></p>	<span style="font-size: 2em;">363</span> <span style="font-size: 1.5em;">3<sup>(3)</sup></span>	OAL-1 LT-1 #S1US-1	<span style="font-size: 2em;">20Jan24</span>	XL91 KL67

Notes:

N/A  
N/A  
N/A

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① XL91 30Jan24  
② KL67 30Jan24

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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	341	ND - 111 DIS - 111 SCR - 111 SKV - 111 Del - 11 GNI - 11 DNT - 1 FB - 1 ET - 1  <span style="border: 1px solid black; border-radius: 50%; padding: 2px;">22</span>	31 Jan 24	XN26 SV43 YK95
1100	CATASY01  Catheter Assembly 1    Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initials/Date): <u>KP02 31 Jan 24</u>	N/A	N/A	31 Jan 24	KP02

Notes:

N/A

N/A

N/A

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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	341	0	31Jan24  B#11	

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Batch Number: 0000301657

By: BA71

Date: 31 Jan 24

Reviewed By:

RB29

Date:

02 feb 24

Notes:

MH  
NL  
JK

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Dates to 2024 3228 1/6/23  
 Expiry to 19 Feb 2024 3228 1/6/23  
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 is part of  
 Extend to 2025 3228 1/6/23  
 Dates to 2023 3228 1/6/23



CREGANNA MEDICAL

DEVIATION AUTHORIZATION NUMBER: 2484  
 \* See attached email extension to 24SEPT23  
 TSIS  
 24AUG23 3228 1/6/23

## CONTROLLED COPY

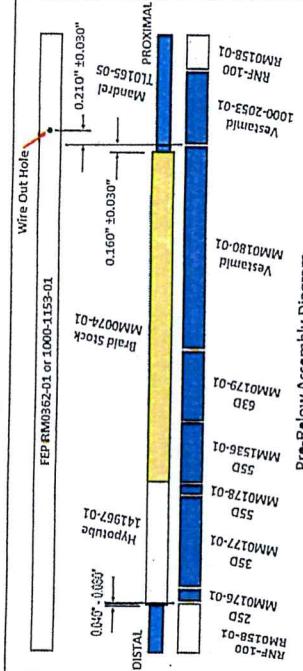
### **DEVIATION AUTHORIZATION FORM**

**Requestor Name:** Udhesh Kapadnis

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.



#### **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	End Date:	Revision
SA0155-01	25 Aug 2023	H

**Start Date:** 26 Jul 2023      **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  Yes  No   FMEAs  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:**

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

FM0002.RevF Deviation Authorization

**CONTROLLED COPY**

① UK55, 23JW 2023



DA | 2484.  
①  
DA | 2468.

**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 MM1536-02 fixture for inspection. (See image 1)  
① **MM0179-01** **MM1536-02** **typo correction TS2 10AUG23**

#### CONTROLLED COPY

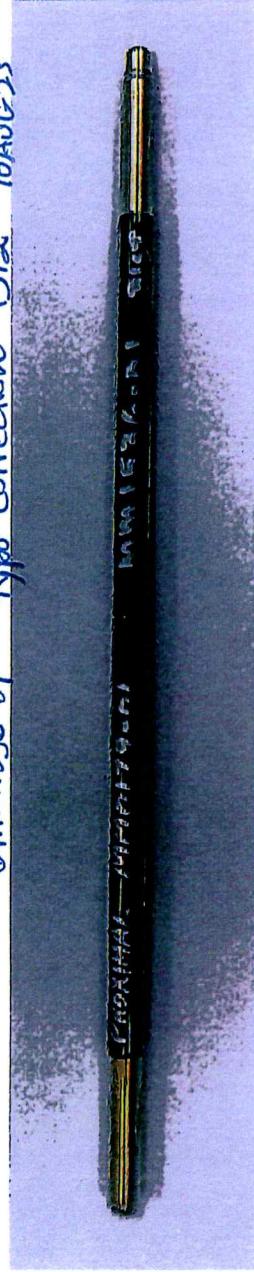


Image-1

#### 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)

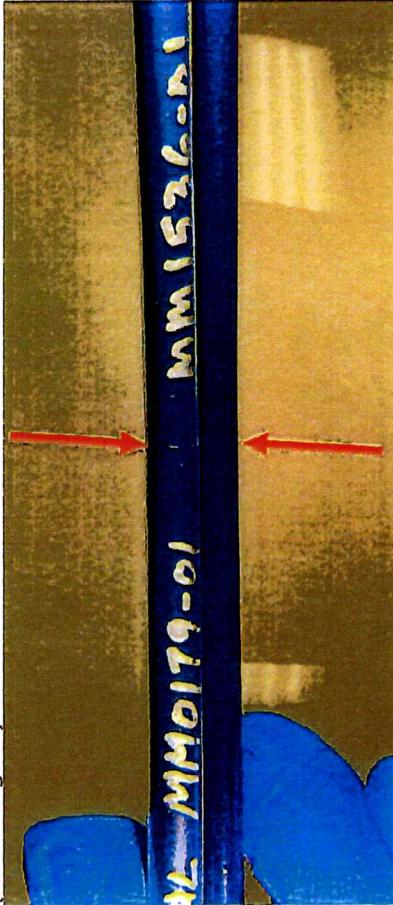


Image-3

- 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)

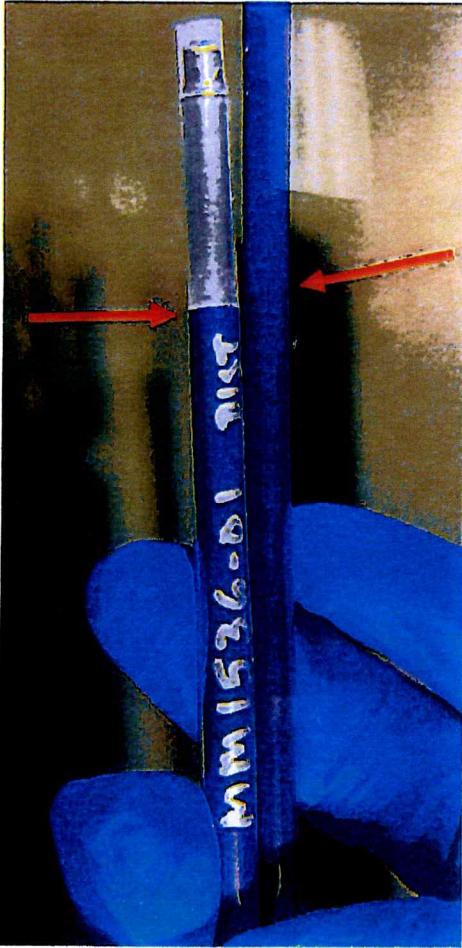


Image- 4  
Scrap the part if the transition is not approximately aligned. Save the scrapped parts for Engineer review.

- If the part transition is aligned, the part passes inspection.
- Use Image 5 as a guide for GOOD and BAD extrusion transition alignment.

<b>1</b>	MM0179-01 <b>GOOD PART</b>	MM1536-01
<b>2</b>	MM1536-01	MM0179-01 <b>MM0179-01 and MM1536-01 Wrong Order - BAD PART</b>
<b>3</b>	MM0179-01 <b>Two MM0179-01 - BAD PART</b>	MM0179-01
<b>4</b>	MM1536-01 <b>Two MM1536-01 - BAD PART</b>	MM1536-01

Image - 5

Entered to Hansa J228 11/16/2023  
Entered to 13 Feb 2024 J228 1/9/2024

**CONTROLLED COPY** DEVIATION AUTHORIZATION NUMBER: DA2564

CREGANNA  
MEDICAL  
is part of



## DEVIATION AUTHORIZATION FORM

Requestor Name: Krishna Selvaraj			
Document Number Affected	Revision		
Doc #3005206 (MPI0238)	BP		
Deviation From:	Deviation To:		
<b>Doc #3005206 (Flex Commander MPI0238): OPER850.11:</b> 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.	<b>Doc #3005206 (Flex Commander MPI0238): OPER850.11:</b> Using a laser micrometer at <b>OPER900 (TMI0700-01)</b> , 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.		
<b>Justification:</b> 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	
<b>Risk Assessment:</b> 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			
<b>Corrective Action Required:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No			
<b>If no, explain:</b> This is a temporary change to use TMI0700-01. DA will be removed once the lasermic TMI0602 issues are resolved and accepted for usage.			
<b>Training Required:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <b>If no, explain:</b> 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



Document No: 5105589

FM5104665 Rev: C

Document Type: Manufacturing Form

Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000301657

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10745	44	12:00AM	430	V078	30Jan24	12:24AM	415	JY90	30Jan24	16
Tm10745	44	12:30AM	430	V078	30Jan24	12:42AM	415	JY90	30Jan24	16
Tm10745	44	1:13 AM	430	V078	30Jan24	1:25 AM	415	JY90	30Jan24	16
Tm10745	44	1:45AM	429	JY90	30Jan24	1:57AM	415	JY90	30Jan24	16
Tm10745	44	5:15am	430	NK62	30Jan24	5:27am	415	NK62	30Jan24	16
Tm10745	44	5:55AM	430	NK62	30Jan24	6:17AM	415	NK62	30Jan24	16
Tm10745	44	6:15AM	430	NKL2	30Jan24	6:27AM	415	NKL2	30Jan24	16
Tm10745	44	6:35am	430	NK62	30Jan24	6:47AM	415	NK62	30Jan24	16
Tm10745	44	7:50am	430	NK62	30Jan24	8:02am	415	NK62	30Jan24	16
Tm10745	44	8:20am	430	AX05	30Jan24	8:32am	415	AX05	30Jan24	16
Tm10745	44	8:45am	429	AX05	30Jan24	8:57am	415	AX05	30Jan24	16
Tm10745	44	9:16am	430	AX05	30Jan24	9:26am	415	AX05	30Jan24	16

① P416 31 Jan 24 correction for NK662  
①



Document No: 5105589

FM5104665 Rev: C

Document Type: Manufacturing Form

Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000301657

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10745	44	9:40am	429	AX05	30Jan24	9:52am	415	AX05	30Jan24	16
TM10745	44	11:15am	430	OS21	30Jan24	11:27am	415	OS21	30Jan24	16
TM10745	44	11:35am	430	TA36	30Jan24	11:47am	415	TA36	30Jan24	15
				N/A						
				0521	30 Jan 24					



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

PRODUCTION ORDER# 500000301657

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10942	44	12:17 AM	430	JY90	30Jan24	12:29 AM	415	JY90	30Jan24	16
TM10942	44	12:52 AM	430	V078	30Jan24	1:04 AM	415	V078	30Jan24	16
TM10942	44	1:28 AM	430	V078	30Jan24	1:40 AM	415	V078	30Jan24	16
TM10942	44	1:55 AM	430	V078	30Jan24	2:07 AM	415	V078	30Jan24	11
TM10942	44	5:48 AM	430	NK62	30Jan24	5:52 AM	415	NK62	30Jan24	16
TM10942	44	6:05 AM	429	NK62	30Jan24	6:17 AM	415	NK62	30Jan24	16
TM10942	44	6:25 AM	429	NK62	30Jan24	6:37 AM	415	NK62	30Jan24	16
TM10942	44	6:55 AM	430	NK62	30Jan24	7:07 AM	415	NK62	30Jan24	16
TM10942	44	7:35 AM	430	NK62	30Jan24	7:47 AM	415	NK62	30Jan24	16
TM10942	44	7:59 AM	428	Ax05	30Jan24	8:11 AM	415	Ax05	30Jan24	16
TM10942	44	8:30 AM	430	Ax05	30Jan24	8:42 AM	415	Ax05	30Jan24	16
TM10942	44	8:59 AM	428	Ax05	30Jan24	9:11 AM	415	Ax05	30Jan24	16





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

PO #: 50000301657

OP #: 500 Shift #: 2

Total Parts Reworked:		<u>10</u>	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	<u>n/a</u>	<u>0</u>
EH	Exposed Hypotube	<u>11</u>	<u>2</u>
EW	Exposed Wire	<u>HH 11</u>	<u>7</u>
MP	Micropores	<u>n/a</u>	<u>0</u>
SCR	Scratch	<u>n/a</u>	<u>0</u>
SKV	Skive Marks	<u>111</u>	<u>3</u>
VD	Voids	<u>n/a</u>	<u>0</u>
<u>n/a</u>	<u>n/a</u>	<u>n/a</u>	<u>0</u>

Inspected By (Sign and Date):

29 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 #: 500000301657

OP #: 500

Shift #:

1ST

Total Parts Reworked:

170

Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	1	1
EH	Exposed Hypotube		70
EW	Exposed Wire		85
MP	Micropores	1	1
SCR	Scratch		4
SKV	Skive Marks		2
VD	Voids		24
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		CB81, LL61, VC09, TA36	30 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):

PO #: 50000301657OP #: 750 Shift #: 1st

Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

Total Parts Reworked:		157	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		40
DIM07 US / WC	DIM07 Undersized (Window Closed)		11
EH	Exposed Hypotube		32
N/A	Glue, Stopper		74
Inspected By (Sign and Date):		Hv36 30 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):

PO #: 500000301657OP #: 750 Shift #: 2nd

Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

Total Parts Reworked:		31	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		13
DIM07 US / WC	DIM07 Undersized (Window Closed)		8
EH	Exposed Hypotube		10
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		Mmo2	30Jan24

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# 500000301657

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10409	N/A	7:40am	190°F	k155	30Jan24	8:50AM	190°F	k155	30Jan24	36
Tm12036	N/A	8:15am	190°F	k155	30Jan24	9:25am	190°F	k155	30Jan24	32
Tm10409	N/A	9:00am	190°F	k155	30Jan24	10:10am	190°F	k155	30Jan24	52
Tm12036	N/A	9:50am	190°F	k155	30Jan24	11:00am	190°F	k15	30Jan24	51
Tm10409	N/A	11:10 am	190°F	k155	30Jan24	12:20 PM	190°F	k155	30Jan24	50
Tm12036	N/A	11:45am	190°F	SS44	30Jan24	12:55pm	190°F	SS44	30Jan24	42
Tm10409	N/A	1:35PM	190°F	SS44	30Jan24	2:45PM	190°F	SS44	30Jan24	52
Tm10409	N/A	3:00 pm	190°F	KT27	30Jan24	4:10 pm	190°F	SG88	30Jan24	77
Tm10409	N/A	4:53PM	190°F	SG88	30Jan24	6:08PM	190°F	SG88	30Jan24	49
① Tm12036	N/A	5:32PM	190°F	XL91	30Jan24	6:42PM	190°F	N/A	N/A	41
			N/A							
			5688	30Jan24						

① 5688 30Jan24

PO #: 500000301657OP #: 900 Shift #: 2nd

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

Total Parts Reworked:		53	
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		3
MP	Micropores	N/A	0
SCR	Scratch		12
SKV	Skive Marks	N/A	0
VD	Voids		1
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized		42
DIM06 OS	DIM06 OD Oversized		2
DIM09 US	DIM09 OD Undersized	0 N/A SH 04 30 Jan 24	0
Inspected By (Sign and Date):		SH 04 30 Jan 24 Sree H - 30 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.

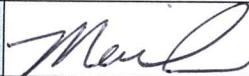
Data Uploaded for Engineering Review (Check):

SH 04 30 Jan 24



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

PO #: 500000301657 OP #: 900 Shift #: 2nd

Total Parts Reworked:		82	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	NA	NA
EH	Exposed Hypotube	NA	NA
EW	Exposed Wire		2
MP	Micropores		1
SCR	Scratch		53
SKV	Skive Marks		5
VD	Voids		8
DIM01 US	DIM01 OD Undersized	NA	NA
DIM06 US	DIM06 OD Undersized		28
DIM06 OS	DIM06 OD Oversized	NA	NA
DIM09 US	DIM09 OD Undersized	NA	NA
Inspected By (Sign and Date):			30 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: 6102619  
Rev: B  
Document Type: Manufacturing Form  
Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 500000301657 OP #: 900 Shift #: 2

Total Parts Reworked:		49	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube		3
EW	Exposed Wire		6
MP	Micropores	N/A	N/A
SCR	Scratch		62
SKV	Skive Marks		
VD	Voids		
DIM01 US	DIM01 OD Undersized		
DIM06 US	DIM06 OD Undersized		
DIM06 OS	DIM06 OD Oversized		
DIM09 US	DIM09 OD Undersized		
Inspected By (Sign and Date):		HT72 30 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: 6102619  
Rev: B  
Document Type: Manufacturing Form  
Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 50000301657 OP #: 900 Shift #: 2

Total Parts Reworked:		<u>16</u>	
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	N/A	0
MP	Micropores	N/A	0
SCR	Scratch		16
SKV	Skive Marks	N/A	0
VD	Voids		2
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):		<u>Candy</u> <u>30 Jan 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):

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	29.97	32.97	23.33	32.03	29.7	29.13	27.46	29.76	27.72	29.71	29.178	2.6523231	4.378	17.5661295	8.542	PASS
Seg B	73.28	70.6	75.83	76.3	71.73	68.62	71.02	67.94	76.83	77.78	72.993	3.5367187	3.981	58.913323	8.542	PASS
Seg C	83.86	76.49	86.79	86.67	80.71	84.17	75.49	75.5	83.15	85.37	81.82	4.4960625	2.911	68.7319621	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

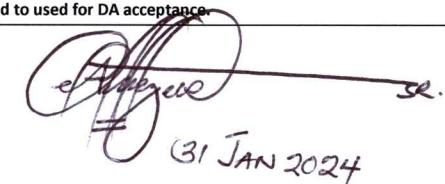
LOT #: 500000301657

Date: 31JAN2024

Inspector Name: AUGUSTINE JAH

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24



(31 JAN 2024)