

Production Order: 500000297268



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  
Production Version: 7988  
Plant / Business Unit: 1213 / AC5

Order Type: ZSTD

Project Phase:

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
50	KITTING3 Kitting Devices  Kitting Devices	Kitting Devices Perform Order Kitting, Load Minor Mandrels, Dry Extrusions, and Cut FEP Record Time Extrusions Enter Dryer (Initial/Time/Date): <u>XCB1 7:00PM 22Jan24</u> Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>PA2 4:35am 24Jan23</u> Record Dryer Shelf #: <u>N/A</u>				

Notes: DA 2564, 2484

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	RM0158-01	E	<u>E</u>	PC	200	<u>58497</u>	<u>N/A</u>	<u>150</u>		
							<u>N/A</u>	<u>N/A</u>		
	TL0167-02	E	<u>E</u>	PC	70	<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>N/A</u>
							<u>N/A</u>	<u>Bulk</u>		
	141967-01	02	<u>02</u>	PC	500	<u>85561</u>	<u>505</u>			
	RM7349-02	C	<u>C</u>	PC	543	<u>82852</u>	<u>N/A</u>	<u>93</u>		
						<u>82833</u>		<u>150</u>		
						<u>82854</u>		<u>73</u>		
						<u>82834</u>		<u>200</u>		
	RM7348-01	C	<u>C</u>	PC	500	<u>82885</u>	<u>300</u>			
						<u>78690</u>	<u>200</u>			

Notes:

N/A

N/A

N/A

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N/A	N/A	RM4001-01	B	<u>B</u>	PC	125	<u>82454</u>	<u>100</u>			
		RM0607-01	D	<u>D</u>	PC	56	<u>74662</u>	<u>56</u>			
		RM0498-01	C	<u>C</u>	PC	500	<u>0000287641</u>	<u>324</u>			
		RM0362-01	E	<u>E</u>	PC	594	<u>0000287642</u>	<u>184</u>			
		RM0009-04	I	<u>I</u>	PC	1	<u>82971</u>	<u>Bulk</u>	N/A	N/A	N/A
		RM0009-04	I	<u>I</u>	PC	1	<u>82971</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>0000284209</u>	<u>1060</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	MM1536-01	B	<u>B</u>	PC	500	<u>0000281412</u>	<u>N/A</u>		
		MM0180-01	E	<u>E</u>	PC	500	<u>0000282490</u>	<u>N/A</u>		
		MM0179-01	D	<u>D</u>	PC	500	<u>0000275691</u>	<u>20</u>		
		MM0178-01	E	<u>E</u>	PC	500	<u>0000276172</u>	<u>540</u>		
		MM0177-01	C	<u>C</u>	PC	500	<u>0000276174</u>	<u>500</u>	N/A	N/A
		MM0176-01	D	<u>D</u>	PC	500	<u>0000284208</u>	<u>N/A</u>	N/A	N/A
		MM0074-01	G	<u>G</u>	PC	500	<u>0000285406</u>	<u>77</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 24Jan24	KL95	
150	CATASY01  Catheter Assembly 1    Major and Minor Mandrel Assembly	Major and Minor Mandrel Assembly	500	0 24Jan24	Pm96 NK62 AF54 AX05	

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	n/a
200	CATASY01 Catheter Assembly 1  Loading Braid Stock  Loading Braid Stock  Confirmation Reqd(Milestone )	Loading Braid Stock	500	0	24 Jan 2024	MY50 PL34
250	CATASY01 Catheter Assembly 1  Trim Braid Wire at Proximal End	Trim Braid Wire at Proximal End	500	0	24 Jan 2024	VP62 5x11

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
	Trim Braid Wire at Proximal End  Confirmation Reqd(Milestone )		N/A	N/A	N/A	N/A
300	CATASY01  Catheter Assembly 1  	Insert Cut Hypo Tube  Insert Cut Hypo Tube  Confirmation Reqd(Milestone )	500	0	24JUN24	LM46 DV39
350	CATASY01  Catheter Assembly 1	Load Tubing	500	0	24JUN24	VV25 C497

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Load Tubing  Confirmation Reqd(Milestone )	N/A	N/A	N/A	N/A	MA
400	CATASY01  Catheter Assembly 1  Reflow  Confirmation Reqd(Milestone )	Reflow	500	0	24JUN24	Pm96 NK62 RN27 AF54
450	CATASY01  Catheter	FEP Removal	500	0	24JUN24	Pm96 AF54
Notes:						
MA						
MA 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	FEP Removal 	N/A	N/A	N/A	N/A	N/A
500	CATASY01 Catheter Assembly 1  In-process Inspection and Rework Material Consumed: Part #: <u>2001-01</u> Batch #: <u>82454</u> Qty: <u>205</u> Part #: <u>200153-01</u> Batch #: <u>87654</u> Qty: <u>20</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>	492 	OF - HHT EW - 111	24Jan24 LL61 VC09 C881		
N/A	In-process Inspection and Rework  Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
Notes:						
<u>N/A</u>						
<u>N/A</u>						
<u>N/A</u>						

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(1) V078 24Jan24

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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	492	0	24Jan24	RS 23 FB 01 VA 96 DV 39 AX 82 DX 35
600	CATASY01  Catheter Assembly 1    Distal Tip Assembly  Confirmation	Distal Tip Assembly	489	MAH ① HHT ② H ③ DL - 11 OF - 1 ④	24Jan24	FB 01 VA 96 AX 82 ML 60 PP 40 SV 46

Notes:

N/A

N/A

N/A

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① V678 24 Jan 24

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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  Confirmation Reqd(Milestone )	Loading Heat Shrink	489	0	24Jan24 AK82 ML38	F R01
700	CATASY01  Catheter Assembly 1    Tipping  Record Tipping Oven Information: TMI: 0386 Cal Due: 31may24 TMI: 2093C Cal Due: 31may24 TMI: 0521 Cal Due: 31may24 TMI: 0936A Cal Due: 31may24  Tipping	Tipping  Record Tipping Oven Information: TMI: 0386 Cal Due: 31may24 TMI: 2093C Cal Due: 31may24 TMI: 0521 Cal Due: 31may24 TMI: 0936A Cal Due: 31may24	489	0	24Jan24	PY46 ML38

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 #: Pm4001-01 Batch #: 82454 Qty: 5 Part #: Pmct607-01 Batch #: 74662 Qty: 4 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	489	0	24Jan24	STR48 Hv36 mm02 HT72
800	CATASY01 Catheter Assembly 1  	Major Mandrel Removal	489	0	24Jan24	SS44 SS52 pm 96 XL91 SG88

Notes:

N/A

N/A

N/A

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Opt No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
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>	489	0	24Jan24 5552 ML65 TRN K167 Y936	
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	SHat ML46 MV33
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
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: TMI: 0700-01 Cal Due: 31 May 24 TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A Material Consumed: Part #: Pm1001-01 Batch #: 82454 Qty: 17 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</p>	459	DIS-14A1H II EH-1 WK-11 PCL-24H II #905-11 #64S-1 ACD-1 MAR-1III	24Jan24	K155 KT267 PY446 XL91 KL67
950	QUALITY1  Quality Inspection & Review	<p>Quality Inspection &amp; 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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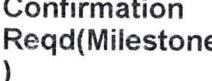


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Opn No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	 Quality Inspection & Review   Confirmation Reqd(Milestone)	TMI: <u>n/a</u> Cal Due: <u>n/a</u> Record DIM02 Go/No-Go Gage Information: TMI: <u>0691</u> Cal Due: <u>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>	432	DIS(SP)HH DELT)HH HH STR - III HH DIS - III	24Jun24	OS21 XL91 KL67
1000	 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>31may24</u> Record Length Gage Information: TMI: <u>0889D</u> Cal Due: <u>30SEP24</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30SEP24</u>	① 424 425	Lt - III I ① OAL + 425	24Jun24	LL41 XL91 KL67

Notes: n/an/an/a

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① KL67 24Jun24

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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	<b>QUALITY1</b> 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		SCR-111 VD-11 DIS-111 DL-11 FB-111 AB-1 Del-1 Mar-1 #50S-1 CRK-1 GMII-1 PBC-1 EW-1 SKV-1	401 25Jan24 24	XN26 SV43
1100	<b>CATASY01</b> Catheter Assembly 1  Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initials/Date): <u>KP02</u> <u>25Jan24</u>			N/A N/A 25Jan24 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	401	0	25 Jan 24	MJ/28

Notes:

N/A

N/A

N/A

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Batch Number:	0000297268
By:	MW8
Date:	25 Jan 24

Reviewed By:

RB29

Date:

26 JAN 24

Notes:

N/A

N/A

N/A

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**DEVIATION FORM** Entered to 23 Oct 2023  
See attached email extension to 24 SEP 2023  
1512 24 AUG 23 3152

**Requestor Name:** Udhesh Kapadnis  
**Requestor Address:** 104/1023, 32B, Sector 22, Noida-201303  
**Requestor Phone:** 9810233208  
**Requestor Email:** udheshkapadnis@gmail.com  
**Requestor Organization:** CREGANNA MEDICAL  
**Requestor Organization Address:** 104/1023, 32B, Sector 22, Noida-201303  
**Requestor Organization Phone:** 9810233208  
**Requestor Organization Email:** cregannamedical@gmail.com

**CREGANNA**  
MEDICAL

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Exhibit A to DEFENDANT'S MOTION FOR PRELIMINARY INJUNCTION  
Dated at DALLAS TEXAS this 22nd day of October, 1968.

Requestor Name: Uddhesh Kanadnis  
Extend to 2023-03-28 DEVIATION  
Due to 2023-03-28 [REDACTED]

Requestor Name: Udhesh Kapadnis		Document Number Affected	Revision
	3107610	L	
<b>Deviation From:</b>			
<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>			
<b>Deviation To:</b>			<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:

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

**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

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):**

**i** 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.

Decision Document 1

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

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① UK55, 23JW 2023



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 ~~MM1536-02~~ fixture for inspection. (See image 1)  
① **MM1536-01** *typo correction TS12 10AUG23*

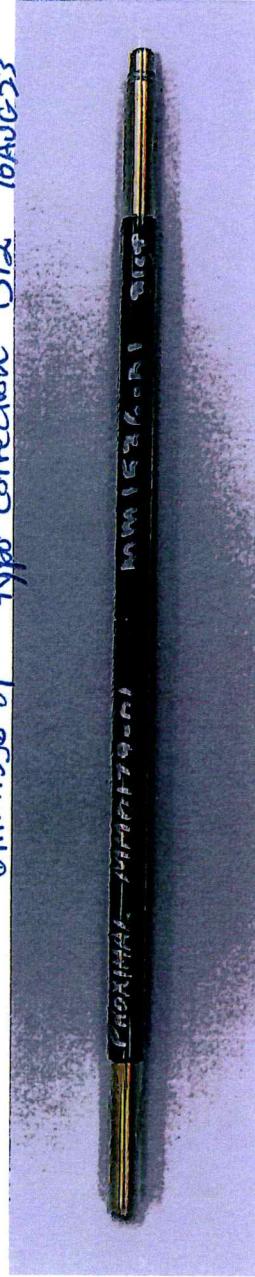


Image- 1

#### 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)

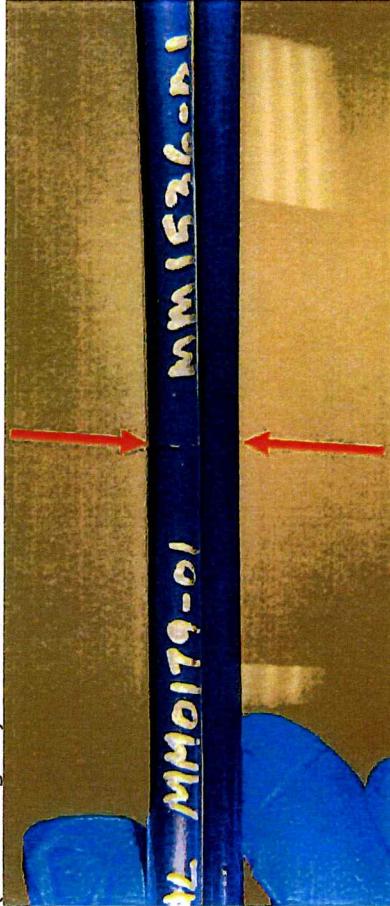
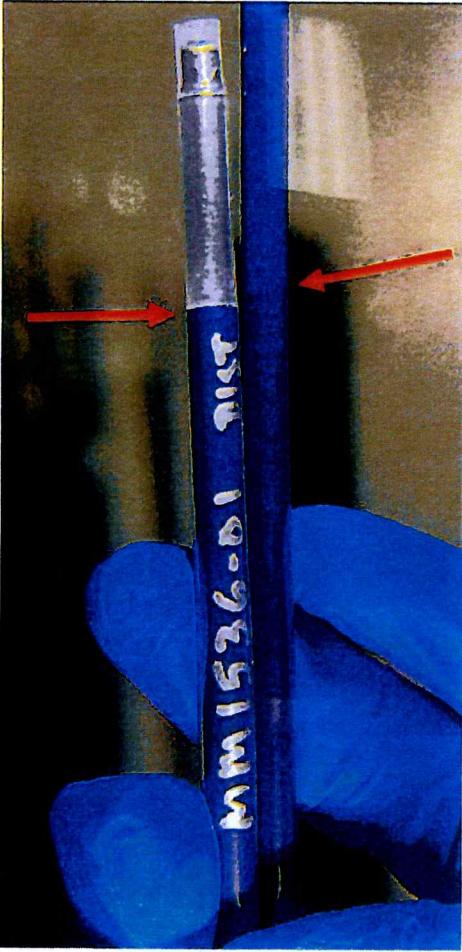


Image- 3

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

Image - 5

Entered to MANDY T228 12/15/2023  
Entered to 13 February 2023 1/6/2024

**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:	
<p><b>Doc #3005206 (Flex Commander MPI0238): OPER850.11:</b></p> <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>	<p><b>Doc #3005206 (Flex Commander MPI0238): OPER850.11:</b></p> <p>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.</p>	
<p><b>Justification:</b></p> <p>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.</p> <p>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.</p>		
Part Number Affected	Revision	
SA0155-01	H	
Start Date:	End Date:	Lot Number:
16 Nov 23	15 DEC 23	N/A
<p><b>Risk Assessment:</b></p> <p>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</p> <p>If yes to any of the above, what controls are being put in place to mitigate the risk – N/A</p>		
<p><b>Corrective Action Required:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><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.</p>		
<p><b>Training Required:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No   <b>If no, explain:</b> N/A</p>		
Title	Approval Name	Approval Signature
Engineering Manager	Jake Stanislowski	
Quality Manager	Jay Zabel	
Operations Manager	Matthew Benson	



Document No: 5105589

FM5104665 Rev: C

Document Type: Manufacturing Form

Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000297268

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
JM10942	44	5:25am	430	TA36	24Jan24	5:37am	415	TA36	24Jan24	16
JM10942	44	5:48am	430	OS21	24Jan24	6:00am	415	OS21	24Jan24	16
JM10942	44	6:10am	430	OS21	24Jan24	6:22am	415	OS21	24Jan24	16
JM10942	44	6:35am	429	OS21	24Jan24	6:47am	415	OS21	24Jan24	16
JM10942	44	7:45am	430	AX05	24Jan24	7:57am	415	AX05	24Jan24	16
JM10942	44	8:20am	430	AX05	24Jan24	8:32am	415	AX05	24Jan24	16
JM10942	44	8:44am	428	AX05	24Jan24	8:56am	415	AX05	24Jan24	16
JM10942	44	8:59am	427	KL95	24Jan24	9:11am	415	AX05	24Jan24	16
JM10942	44	9:30am	430	AX05	24Jan24	9:42am	415	AX05	24Jan24	16
JM10942	44	9:55am	428	AX05	24Jan24	10:07am	415	AX05	24Jan24	16
JM10942	44	11:00am	430	OS21	24Jan24	11:12am	415	OS21	24Jan24	16
JM10942	44	11:20am	430	OS21	24Jan24	11:32am	415	OS21	24Jan24	16

① 0521 25 Jan 24



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

PRODUCTION ORDER# 500000297268

OP 400



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

PRODUCTION ORDER# 500000297268

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10745	44	5:14 am	430	RN27	24Jan24	5:26 am	415	RN27	24Jan24	16
TM10745	44	5:35am	430	TB36	24Jan24	5:47am	415	TB36	24Jan24	16
TM10745	44	6:00am	430	OS21	24Jan24	6:12am	415	OS21	24Jan24	16
TM10745	44	6:20am	430	OS21	24Jan24	6:32am	415	OS21	24Jan24	16
TM10745	44	6:48am	430	OS21	24Jan24	7:00am	415	OS21	24Jan24	16
TM10745	44	7:59am	430	AX05	24Jan24	8:11am	① 415 44	AX05	24Jan24	16
TM10745	44	8:30am	430	AX05	24Jan24	8:42am	415	AX05	24Jan24	16
TM10745	44	8:55am	429	AX05	24Jan24	9:07am	415	AX05	24Jan24	16
TM10745	44	9:19am	430	KL95	24Jan24	9:31am	415	KL95	24Jan24	16
TM10745	44	9:42am	428	AX05	24Jan24	9:54am	415	AX05	24Jan24	16
TM10745	44	10:40am	430	OS21	24Jan24	10:52am	415	OS21	24Jan24	16
TM10745	44	11:10am	430	TB36	24Jan24	11:22am	415	TB36	24Jan24	16

① AX05 24Jan24



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

PRODUCTION ORDER# 500008297268

OP 400



**PO #:** 500000297268

OP #: 500

**Shift #:** 1

**Document No: 5106073**

Rev: E

**Document Type: Manufacturing Form**

## **Title: SA0155-01 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.

**Data Uploaded for Engineering Review (Check):**



**PO #:** 500000297268

OP #: 750 Shift #: 1st

Document No: 6102646

Rev: A

**Document Type: Manufacturing Form**

**Title: SA0155-01 Tipping Rework Form**

Total Parts Reworked:		118	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		12
DIM07 US / WC	DIM07 Undersized (Window Closed)		15
EH	Exposed Hypotube		23
N/A	Glue, Stopper		68
Inspected By (Sign and Date):		Hv36	24 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 #: 50000297268OP #: 750 Shift #: 2

Total Parts Reworked:		8	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)	N/A	N/A
DIM07 US / WC	DIM07 Undersized (Window Closed)		4
EH	Exposed Hypotube		4
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		HT72 24 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 #: 50000297268 OP #: 750 Shift #: 2<sup>nd</sup>

Total Parts Reworked:		11	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		7
DIM07 US / WC	DIM07 Undersized (Window Closed)		2
EH	Exposed Hypotube		2
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		MMO2	24Jan24

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# 500000297268

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM12036	N/A	8:15am	190°F	SSH44	24 Jan 24	9:25am	190°F	SSH44	24 Jan 24	30
TM10409	N/A	8:40am	190°F	SSH44	24 Jan 24	9:50am	190°F	SSH44	24 Jan 24	32
TM12036	N/A	9:30am	190°F	SSH44	24 Jan 24	10:40am	190°F	SSH44	24 Jan 24	53
TM10409	N/A	9:55am	190°F	SSH44	24 Jan 24	11:05am	190°F	SSH44	24 Jan 24	36
TM10409	N/A	11:15am	190°F	SSH44	24 Jan 24	12:25pm	190°F	SSH44	24 Jan 24	30
TM12036	N/A	11:55am	190°F	SSH44	24 Jan 24	1:05pm	190°F	SSH44	24 Jan 24	52
TM10409	N/A	12:30pm	190°F	K155	24 Jan 24	1:40pm	190°F	SSH44	24 Jan 24	33
TM10409	N/A	1:50pm	190°F	SSH44	24 Jan 24	3:00pm	190°F	SSH44	24 Jan 24	35
TM12036	N/A	2:30pm	190°F	SSH44	24 Jan 24	3:40pm	190°F	SSH44	24 Jan 24	43
TM10409	N/A	3:52pm	190°F	SG88	24 Jan 24	5:02pm	190°F	SG88	24 Jan 24	52
TM12036	N/A	4:28pm	190°F	SG88	24 Jan 24	5:38pm	190°F	SG88	24 Jan 24	35
TM10409	N/A	5:25pm	190°F	SG88	24 Jan 24	6:35pm	190°F	SG88	24 Jan 24	58
			N/A							
			SG88	24 Jan 24						

① SSH44 24 Jan 24

Status CURRENT Effective 5/8/2023



**PO #:** 500000-297268

OP #: 900 Shift #: 5

**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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Page 1 of 1

Status CURRENT Effective 5/8/2023



**PO #:** 500000297268

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):**

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Page 1 of 1

Status CURRENT Effective 5/8/2023



Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 500000297268

OP #: 900 Shift #: 2nd

Total Parts Reworked:		40	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube		4
EW	Exposed Wire		2
MP	Micropores	N/A	0
SCR	Scratch	/	22
SKV	Skive Marks	N/A	0
VD	Voids		7
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized		11
DIM06 OS	DIM06 OD Oversized	N/A	0
DIM09 US	DIM09 OD Undersized	N/A	0
Inspected By (Sign and Date):		Joe H 24 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, DIM06 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):



500000297268

PO #: 500000297268  
PY4625 Jan 24OP #: 900 Shift #: 2nd

Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

Total Parts Reworked:		46	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	NA	0
EH	Exposed Hypotube	NA	0
EW	Exposed Wire		8
MP	Micropores	NA	0
SCR	Scratch		32
SKV	Skive Marks		6
VD	Voids		2
DIM01 US	DIM01 OD Undersized	NA	0
DIM06 US	DIM06 OD Undersized		5
DIM06 OS	DIM06 OD Oversized	NA	0
DIM09 US	DIM09 OD Undersized	NA	0
Inspected By (Sign and Date):		<i>Mauri</i>	24 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):

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	25.26	24.26	27.53	24.45	25.47	25.42	25.94	25.57	25.09	25.43	25.442	0.8921734	4.378	21.536065	8.542	PASS
Seg B	65.08	59.89	60.63	63	65.14	65.66	61.92	62.11	65.64	64.14	63.321	2.1204792	3.981	54.8793721	8.542	PASS
Seg C	76.78	77.28	75.17	73.8	77.02	77.6	77.08	74.38	76.19	75.06	76.036	1.3363981	2.911	72.145745	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 #: 500000297268

Date: 25JAN24

Inspector Name: Andrew Wipf

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24


25 Jan 24