

Production Order: 500000292831



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: 7987
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>GS95 7:45 AM 04 Jun 24</u> Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>XC31 9:20 PM 04 JAN 24</u> Record Dryer Shelf #: <u>N/A</u>	N/A	N/A	03/2024	TPB

Notes: DA2484, 2564

N/A

N/A

Date Printed: 01/03/2024 / 17:45:13

Page: 1 of 18



SA0155-01

CREGANNA
MEDICAL
is part of



Production Order: 500000292831



Production Order Document
Production Order Qty: 500

PC
Sheet: 1 of 1

Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details					Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	RM0158-01	E	<u>E</u>	PC	200	<u>0000263145</u>	<u>40</u>		
		1000-1153-01	A	<u>A</u>	PC	594	<u>58497</u>	<u>200</u>		
		1000-2053-01	A	<u>A</u>	PC	500	<u>N/A</u>	<u>N/A</u>		
		MM1537-02	A	<u>A</u>	PC	500	<u>86749</u>	<u>200</u>		
		TL0167-02	E	<u>E</u>	PC	70	<u>86750</u>	<u>200</u>		
		TL0165-05	J	<u>J</u>	PC	5	<u>86751</u>	<u>200</u>		
		TL0165-03	J	<u>J</u>	PC	5	<u>0000268040</u>	<u>500</u>		
							<u>N/A</u>	<u>N/A</u>		

Notes:

N/A

N/A

N/A

Date Printed: 01/03/2024 / 17:45:13

Page: 2 of 18



SA0155-01

CREGANNA
MEDICAL
is part of





Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details						Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	141967-01	02	02	PC	500	82899	525			
							N/A	N/A			
		RM7349-02	C	C	PC	543	82853	600			
							N/A	N/A			
		RM7348-01	C	C	PC	500	82882	150			
							82883	300			
		RM4001-01	B	B	PC	125	82103	100	N/A	N/A	N/A
							① 82101 N/A	N/A			
		RM0607-01	D	D	PC	56	71864	125			
							N/A	N/A			
		RM0498-01	C	C	PC	500	0000287518	500			
							N/A	N/A			
		RM0009-04	I	I	PC	1	82971	Bulk			
							N/A	Bulk			
		RM0009-04	I	I	PC	1	82971	Bulk			

Notes:

N/A

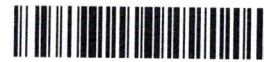
N/A

N/A

Date Printed: 01/03/2024 / 17:45:13

OKP02 08 Jan 24

Page: 3 of 18



SA0155-01

CREGANNA
MEDICAL
is part of

Production Order: 500000292831

Production Order Document
Production Order Qty: 500PC
Sheet: 1 of 1

Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details						Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	MM1538-01	A	A	PC	500	N/A	Bulk			
							0000271052	500			
		MM1537-01	A	A	PC	1000	N/A	N/A			
							0000281413	1000			
		MM0177-01	C	C	PC	500	N/A	N/A			
							0000278966	500			
		MM0180-01	E	E	PC	500	N/A	N/A			
							0000275691	400	N/A	N/A	N/A
		MM0178-01	E	E	PC	500	0000287541	100			
		MM0176-01	D	D	PC	500	0000271055	500			
		MM0074-01	G	G	PC	500	N/A	N/A			
							0000285433	517			
							N/A	N/A			

Notes:

N/A

N/A

N/A

Date Printed: 01/03/2024 / 17:45:13

Page: 4 of 18



SA0155-01

CREGANNA
MEDICAL
is part of

Production Order: 500000292831



Production Order Document
Production Order Qty: 500

PC

Sheet: 1 of 1

Material: SA0155-01 Rev F

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	05Jan24	V078
	Line Clearance					
	Confirmation Reqd(Milestone)					
150	CATASY01 Catheter Assembly 1 	Major and Minor Mandrel Assembly	500	0	05Jan24	Sy47 SH23 JY90 YLTHO SP34
	Major and Minor Mandrel Assembly					
Notes:						
N/A						
N/A						
N/A						

Date Printed: 01/03/2024 / 17:45:13

Page: 5 of 18



SA0155-01

CREGANNA MEDICAL
is part of



Production Order: 500000292831



Production Order Document
Production Order Qty: 500

PC
Sheet: 1 of 1

Material: SA0155-01 Rev F

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 Loading Braid Stock Confirmation Reqd(Milestone)	500	0	05Jan24 cp32 V078 SC00 AB65 MC17	
250	CATASY01 Catheter Assembly 1 	Trim Braid Wire at Proximal End	500	0	05Jan24 ny35 AS31 P167	

Notes: N/A
N/A
N/A

Date Printed: 01/03/2024 / 17:45:13

Page: 6 of 18



SA0155-01

CREGANNA MEDICAL
is part of



Production Order: 500000292831Production Order Document
Production Order Qty: 500

PC

Sheet: 1 of 1

Material: SA0155-01 Rev F

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	05Jan24	CL30 GS22 RL47 PL22
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0	05Jan24	ST96 SH23 CX637RN BD64
Notes:						
N/A						
N/A						
N/A						

Date Printed: 01/03/2024 / 17:45:13

Page: 7 of 18



SA0155-01

CREGANNA
MEDICAL
is part of

Production Order: 500000292831



Production Order Document
Production Order Qty: 500

PC

Sheet: 1 of 1

Material: SA0155-01 Rev F

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	N/A
400	 CATASY01 Catheter Assembly 1 Reflow Confirmation Reqd(Milestone)	Reflow	500	0	05Jan24	SX60 SH85 CD19 AL67
450	CATASY01 Catheter	FEP Removal	500	0	05Jan24	JY90 AM47 JC92
Notes:						
N/A						
N/A						
N/A						

Date Printed: 01/03/2024 / 17:45:13

Page: 8 of 18



SA0155-01

CREGANNA
MEDICAL
is part of



Production Order: 500000292831



Production Order Document
Production Order Qty: 500

PC
Sheet: 1 of 1

Material: SA0155-01 Rev F

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
	Confirmation Reqd(Milestone)					
500	CATASY01 Catheter Assembly 1 	In-process Inspection and Rework Material Consumed: Part #: 1000-1153-01 Batch #: 86751 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	478	EW - HLM BP-11 SKV-1 05Jan24 22	P66 DX35 MRO2 LS46 ARO2	
N/A	In-process Inspection and Rework					
	Confirmation Reqd(Milestone)					
N/A	N/A	N/A	N/A	N/A	N/A	N/A
Notes:						

Date Printed: 01/03/2024 / 17:45:13

Page: 9 of 18



SA0155-01

CREGANNA
MEDICAL
is part of



Production Order: 500000292831



Production Order Document
Production Order Qty: 500
PC
Sheet: 1 of 1

Material: SA0155-01 Rev F

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)	474	DL-11 IDB-11 	05Jan24	ML38 LH45 TRN MH1D
600	CATASY01 Catheter Assembly 1 Distal Tip Assembly Confirmation	Distal Tip Assembly	472	MAH-11 	05Jan24	CL03 KY94

Notes:

N/A

N/A

N/A

Date Printed: 01/03/2024 / 17:45:13

Page: 10 of 18



SA0155-01

CREGANNA
MEDICAL
is part of



Production Order: 500000292831

Production Order Document
Production Order Qty: 500

PC

Sheet: 1 of 1

Material: SA0155-01 Rev F

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	472	0	05Jan24	HL85 k797 pt09
	Loading Heat Shrink					
	Confirmation Reqd(Milestone)					
700	CATASY01 Catheter Assembly 1 	Tipping Record Tipping Oven Information: TMI: 0521 Cal Due: 31 May 24 TMI: 2083 C Cal Due: 31 May 24 TMI: 0386 Cal Due: 31 May 24 TMI: 0936 A Cal Due: 31 May 24 Tipping	472	0	05Jan24	HL85 B160
Notes:						
N/A						
N/A						
N/A						

Date Printed: 01/03/2024 / 17:45:13

Page: 11 of 18



SA0155-01

CREGANNA
MEDICAL
is part of

Production Order: 500000292831



Production Order Document
Production Order Qty: 500

PC
Sheet: 1 of 1

Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
750	CATASY01 Catheter Assembly 1 	Tip Inspection/ Flash Removal Material Consumed: Part #: RM4001-01 Batch #: 82101 Qty: N/A Part #: RM0607-01 Batch #: 71864 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	472	EH-L ① O	05Jan24	SV46 B160
800	CATASY01 Catheter Assembly 1 	Major Mandrel Removal	472	O	05Jan24	M165 KL45 TRN SN67 BD64 YR40
Notes:						
N/A						
N/A						
N/A						

Date Printed: 01/03/2024 / 17:45:13

Page: 12 of 18

①CB58 05Jan24



SA0155-01

CREGANNA
MEDICAL
is part of



Production Order: 500000292831Production Order Document
Production Order Qty: 500

PC

Sheet: 1 of 1

Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Major Mandrel Removal N/A Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
850	CATASY01 Catheter Assembly 1  Cut to Length Confirmation Reqd(Milestone)	Cut to Length Record DIM05 gage result for the first 5 parts at the start of operation: 1. <u>Pass</u> 2. <u>Pass</u> 3. <u>Pass</u> 4. <u>Pass</u> 5. <u>Pass</u> Cut to Length Confirmation Reqd(Milestone)	472	0	05Jan24	KL45
900	QUALITY1 Quality Inspection & Review	Quality Inspection and Review Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	N/A	N/A	N/A	N/A
Notes:						
N/A						
N/A						
N/A						

Date Printed: 01/03/2024 / 17:45:13

Page: 13 of 18



SA0155-01

CREGANNA
MEDICAL
is part of

Production Order: 500000292831



Production Order Document
Production Order Qty: 500

PC
Sheet: 1 of 1

Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Quality Inspection & Review Confirmation Reqd(Milestone)	<p>Re-Inspect after re-work.</p> <p>Required Inspection Visual/OD Inspection Record Inspection Data in SAP ROS Record Laser Micrometer Information: TMI: <u>0700-01</u> Cal Due: <u>31 May 2024</u> TMI: <u>N/A</u> Cal Due: <u>N/A</u> TMI: <u>N/A</u> Cal Due: <u>N/A</u> Material Consumed: Part #: <u>RM4001-01</u> Batch #: <u>82103</u> Qty: <u>N/A</u> Part #: <u>RM0607-01</u> Batch #: <u>71864</u> Qty: <u>N/A</u> Part #: <u>RM0158-01</u> Batch #: <u>58497</u> Qty: <u>N/A</u> Part #: <u>000-1153-01</u> Batch #: <u>86749</u> Qty: <u>N/A</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u></p>	448	24 DEL-1M1K (T1) DEL-1M(SP) DIS-111 EW-1111 #90S-1	05Jan24	KX54 DL07 PL22
950	QUALITY1 Quality Inspection & Review	<p>Quality Inspection & Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information: TMI: <u>N/A</u> Cal Due: <u>N/A</u> Record Caliper Information:</p>	N/A	N/A	N/A	N/A

Notes:

N/A

N/A

N/A

Date Printed: 01/03/2024 / 17:45:13

Page: 14 of 18



SA0155-01

CREGANNA
MEDICAL
is part of



Production Order: 500000292831



Production Order Document
Production Order Qty: 500

PC

Sheet: 1 of 1

Material: SA0155-01 Rev F

Op. No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Quality Inspection & Review Confirmation Reqd(Milestone)	TMI: <u>N/A</u> Cal Due: <u>N/A</u> Record DIM02 Go/No-Go Gage Information: TMI: <u>0691</u> Cal Due: <u>30Sep2025</u> TMI: <u>0692</u> Cal Due: <u>30Sep2025</u> Record DIM02 Inspection Results N = 54: Pass: <u>54</u> Fail: <u>0</u>	446	DIS-11 ②	05Jan24	DV10 PL22
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>31May2024</u> Record Length Gage Information: TMI: <u>0889</u> Cal Due: <u>30Sep2024</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30Sep2024</u>	444	LT-11 ②	05Jan24	CB58

Notes:

N/A

N/A

N/A

Date Printed: 01/03/2024 / 17:45:13

Page: 15 of 18



SA0155-01

CREGANNA
MEDICAL
is part of



Production Order: 500000292831



Production Order Document
Production Order Qty: 500

PC

Sheet: 1 of 1

Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	N/A	N/A	N/A	N/A	N/A
1050	QUALITY1 Quality Inspection & Review  Quality Inspection & Review Confirmation Reqd(Milestone) 	Required Inspection Visual Final Inspection Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	Y19	SCR - IIII FB - IIII DL - III DIS - II BP - II PBC - II EW - II ND - II DT - I EH - I GNII - I	06Jan24	SV43 <i>(25)</i>
1100	CATASY01 Catheter Assembly 1  Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initials/Date): <u>KP02</u> <u>08.Jan.24</u>	N/A	N/A	08Jan24	KP02

Notes:

N/A
N/A
N/A

Date Printed: 01/03/2024 / 17:45:13

Page: 16 of 18



SA0155-01

CREGANNA MEDICAL
is part of



Production Order: 500000292831



Production Order Document
Production Order Qty: 500

PC

Sheet: 1 of 1

Material: SA0155-01 Rev F

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	419	0 09 Jan 24	AP10	

Notes:

N/A AP10 09 Jan 24

Date Printed: 01/03/2024 / 17:45:13

Page: 17 of 18



SA0155-01

CREGANNA MEDICAL
is part of



Production Order: 500000292831



Production Order Document
Production Order Qty: 500

PC

Sheet: 1 of 1

Material: SA0155-01 Rev F

Batch Number: 0000292831

By: AP10

Date: 09 Jan 24

Reviewed By:

RB29

Date:

09 JAN 24

Notes:

N/A AP10 09 Jan 24

Date Printed: 01/03/2024 / 17:45:13

Page: 18 of 18



SA0155-01

CREGANNA MEDICAL
is part of



CREGANNA MEDICAL
is part of
TE

Extend to 2023-08-31
Due to 2023-08-31 DEVIATION AUTHORIZATION FORM Ext to 2023-08-31

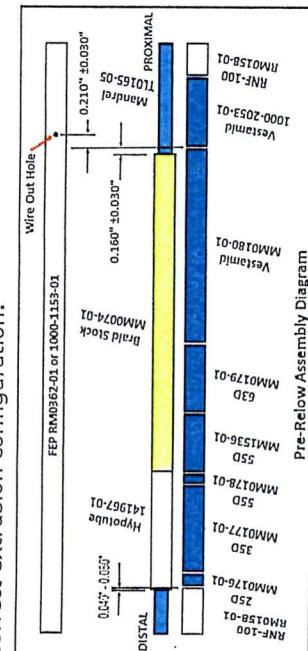
Requestor Name: Udhesh Kapadnis

CONTROLLED COPY DEVIATION AUTHORIZATION NUMBER: 2484
* See attached email extension to 24SEP23
TS2
24AUG23 3208-2023 24AUG23 3208-2023

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 FMEA's Yes No Validations Yes No
Details (if any): N/A

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

Corrective Action Required:	<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.	If no, explain:

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

① UK55, 23JW 2023

①	TE	DA	2484 2468
CREGANNA MEDICAL is part of			①

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

Procedure:

- 100% inspection at Op#1050 per the instructions below.
- Inspect 1 part at a time.
- Inspection is focused on the correct MM0179-01 and MM1536-01 assembly.
- Use the example MM0179-01 and ~~MM1536-02~~ fixture for inspection. (See image 1)
① MM0179-01 **10AUG-23** **TG2**



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)

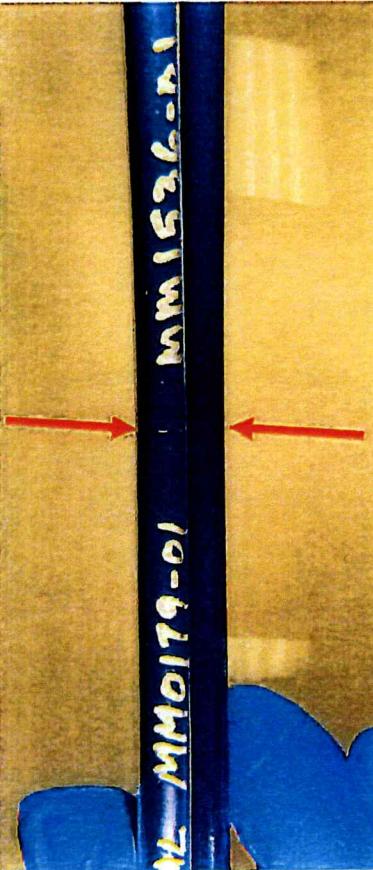


Image- 3

- 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.

CONTROLLED COPY

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)

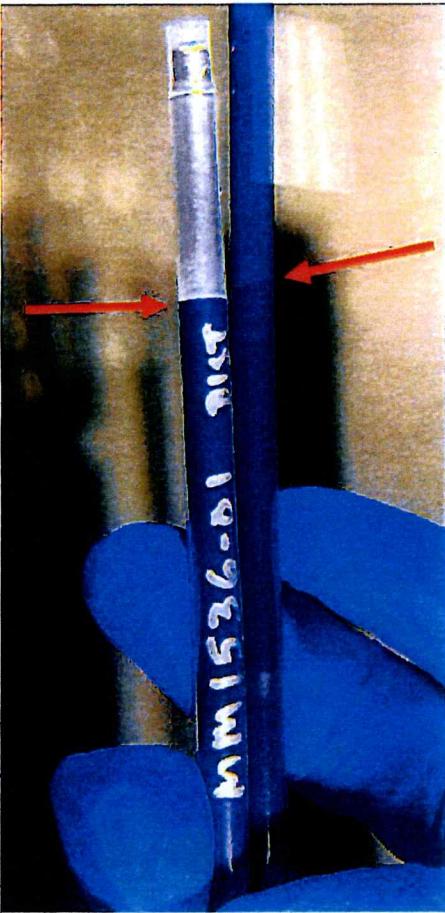


Image- 4

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

Image - 5

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

FM0002.RevF

Deviation Authorization

CONTROLLED COPY

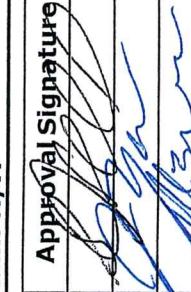
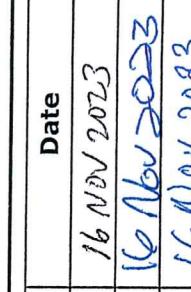
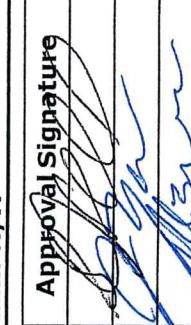
CONTROLLED COPY

DEVIATION AUTHORIZATION FORM

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

Justification:

TMI0602 lasermic which is currently used in SA0155-01 Flex commander product at OPER850 for Dim 6 inspection has mechanical failure and confirmed as not usable.
 TMI0700-01 lasermic is used at OPER900 for 100% inspection for Dim 1, Dim 6 and Dim 9. Since TMI0700-01 is already qualified to inspect Dim 6 per ES0647; Laser micrometer equivalency test, there is no additional risk in using TMI0700-01 for OPER850 Dim 6 inspection till TMI0602 issue is resolved.

Part Number Affected	Revision	
SA0155-01	H	
Start Date: 16 Nov 23	End Date: 15 DEC 23	Lot Number: N/A
Risk Assessment: Is there any potential risk(s) that may occur as a result of the proposed deviation including the following: Control Plans <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No FMEA's <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Validations <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Details (if any): N/A		
If yes to any of the above, what controls are being put in place to mitigate the risk – N/A		
Corrective Action Required: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
If no, explain: This is a temporary change to use TMI0700-01. DA will be removed once the lasermic TMI0602 issues are resolved and accepted for usage.		
Training Required: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If no, explain: N/A		
Title	Approval Name	Approval Signature
Engineering Manager	Jake Stanislowski	
Quality Manager	Jay Zabel	
Operations Manager	Matthew Benson	
Date		
16 Nov 2023		
16 Nov 2023		
16 Nov 2023		



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

PRODUCTION ORDER# 500000292831

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10745	44	9:58PM	428	SH85	04Jan24	10:10PM	415	SH85	04Jan24	16
Tm10745	44	10:37PM	430	SH85	04Jan24	10:49PM	415	SH85	04Jan24	16
Tm10745	44	11:29PM	430	SX60	04Jan24	11:41PM	415	SX60	04Jan24	16
Tm10745	44	12:00AM	428	SX60	05Jan24	12:12AM	415	SH85	05Jan24	16
Tm10745	44	12:39AM	429	SH85	05Jan24	12:46AM	415	SH85	05Jan24	16
Tm10745	44	1:07AM	430	SH85	05Jan24	1:19AM	415	SH85	05Jan24	16
Tm10745	44	1:34AM	428	SH85	05Jan24	1:46AM	415	SX60	05Jan24	16
Tm10745	44	7:01AM	430	Jc92	05Jan24	7:13AM	415	Jc92	05Jan24	16
Tm10745	44	7:30AM	430	CD19	05Jan24	7:42AM	415	CD19	05Jan24	16
Tm10745	44	7:58AM	430	CD19	05Jan24	8:10AM	415	CD19	05Jan24	16
Tm10745	44	8:18 AM	430	RV16	05Jan24	8:29 AM	415	RV16	05Jan24	16
Tm10745	44	9:10 AM	430	RV16	05Jan24	9:22 AM	415	RV16	05Jan24	16



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

PRODUCTION ORDER# 500000292831

OP 400

① CB58 05 Jan 24



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

PRODUCTION ORDER# 500000292831

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10942	44	10:13pm	430	SX60	04Jan24	10:25pm	415	SX60	04Jan24	16
TM10942	44	10:48pm	430	SX60	04Jan24	11:00pm	415	SX60	04Jan24	16
TM10942	44	11:45pm	430	SX60	04Jan24	11:57pm	415	SX60	04Jan24	16
TM10942	44	12:12Am	428	SH85	05Jan24	12:24Am	415	SH85	05Jan24	16
TM10942	44	12:48Am	430	SH85	05Jan24	1:00Am	415	SH85	05Jan24	16
TM10942	44	1:20Am	430	SH85	05Jan24	1:32Am	415	SH85	05Jan24	16
TM10942	44	1:53Am	430	SX60	05Jan24	2:05AM	415	SX60	05Jan24	16
TM10942	44	6:42 AM	430	RV16	05Jan24	6:54AM	415	RV16	05Jan24	16
TM10942	44	7:13AM	429	CD19	05Jan24	7:25AM	415	CD19	05Jan24	16
TM10942	44	7:49AM	430	RV16	05Jan24	8:01 AM	415	RV16	05Jan24	16
TM10942	44	8:28 AM	430	RV16	05Jan24	8:40 AM	415	RV16	05Jan24	16
TM10942	44	9:25AM	430	AM47	05JAN24	9:37 AM	415	AM47	05JAN24	16



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

PRODUCTION ORDER# 500000292831

OP 400

① Cm99 05Jan24



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

PO #: 50000 292831

OP #: 500 Shift #: 2

Total Parts Reworked:		20	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube	/	1
EW	Exposed Wire		5
MP	Micropores	N/A	0
SCR	Scratch	N/A	0
SKV	Skive Marks		2
VD	Voids	N/A	0
N/A	N/A	N/A	0
Inspected By (Sign and Date):		<u>Asif</u> DX35	04 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 #: 500000292831

OP #: 500 Shift #: 3rd

Total Parts Reworked:		103	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		4
EH	Exposed Hypotube		11
EW	Exposed Wire		65
MP	Micropores	N/A	N/A
SCR	Scratch		2
SKV	Skive Marks		11
VD	Voids		10
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		LS46, AR02	05 Jan 24

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

Data Uploaded for Engineering Review (Check):



Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

PO #: 50000292831

OP #: 750 Shift #: 3R

Total Parts Reworked:		470 180	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		81
DIM07 US / WC	DIM07 Undersized (Window Closed)		14
EH	Exposed Hypotube		52
GD / AB	Glue Damage/Air Bubbles		33
Inspected By (Sign and Date):		B160 05 Jan 2024	

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):

①CB58 05Jan24

PRODUCTION ORDER# 500000292831

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10409	N/A	1:00AM	190°F	AT39	05Jan24	2:10AM	190°F	AT39	05 Jan 24	34
Tm10409	N/A	4:40AM	190F	KL4S	05JAN24	5:50AM	190F	KL4S	05JAN24	44
Tm10409	N/A	6:58Am	190F	SN67	05 Jan 24 05 Jan 24	8:08AM	190F	SN67	05 Jan 24	19
Tm10409	N/A	8:10AM	190F	SN67	05Jan24	9:20AM	190F	SN67	05JAN24	28
Tm10409	N/A	9:30AM	190F	SN67	05Jan24	10:40AM	190F	SN67	05 Jan 24	31
Tm10409	N/A	10:40AM	190F	SN67	05Jan24	11:50AM	190F	SN67	05Jan24	49
Tm12036	N/A	11:40AM	190F	YK40	05Jan24	12:50PM	190F	YK40	05 Jan 24	30
Tm10409	N/A	12:17PM	190F	YK40	05Jan24	1:27PM	190F	YK40	05 Jan 24	37
Tm10409	N/A	1:36PM	190F	YK40	05.Jan24	2:46PM	190F	YK40	05Jan24	33
Tm12036	N/A	2:10PM	190F	BD64	05Jan24	3:20PM	190F	BD64	05Jan24	23
Tm10409	N/A	3:06PM	190F	BD64	05Jan24	4:16PM	190F	BD64	05Jan24	39
Tm10409	N/A	4:20PM	190F	BD64	05Jan24	5:30PM	190F	BD64	05Jan24	2632
Tm12036	N/A	4:50PM	190F	BD64	05Jan24	6:00PM	190F	BD64	05Jan24	25

① SN67 05Jan24

② BD64 05Jan24

PRODUCTION ORDER# 50000292831

OP 800



PO #: 500000292831

OP #: 900 Shift #: 3

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

Total Parts Reworked:		163	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		13
EH	Exposed Hypotube		21
EW	Exposed Wire		92
MP	Micropores	N/A	N/A
SCR	Scratch		61
SKV	Skive Marks		6
VD	Voids		28
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized		14
DIM06 OS	DIM06 OD Oversized		10
DIM09 US	DIM09 OD Undersized	N/A	N/A
Inspected By (Sign and Date):		D204, KX54	05.Jan.24

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. 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	30.2	27.07	26.33	25.56	25.4	28.73	24.22	24.8	25.72	25.95	26.398	1.825911	4.378	18.4041615	8.542	PASS
Seg B	58.19	58.64	58.89	61.13	59.03	59.29	58.18	56.83	55.94	63.32	58.944	2.0762049	3.981	50.6786284	8.542	PASS
Seg C	78.1	79.38	74.38	74.76	75.12	74.12	64.05	75.35	74.44	73.04	74.274	4.0679594	2.911	62.4321703	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 #: 500000292831

Date: 08 JAN 2024

Inspector Name: KOCK YU LEE

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24

Kockyulee

08 JAN 24