

# Production Order: 500000307852



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 	<p>Kitting Devices                      Perform Order Kitting, Load Minor Mandrels, Dry Extrusions, and Cut FEP                      Record Time Extrusions Enter Dryer (Initial/Time/Date): <u>A171 2:15pm 13 Feb 24</u>                      Record Time Extrusions First Exit Dryer (Initial/Time/Date):  <u>Xc31 10:00pm 19 Feb 24</u>                      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>MM0179-01</td> <td>D <u>D</u></td> <td>PC</td> <td>500</td> <td><u>00002P14700</u> <u>XLS1</u> <u>20 Feb 24</u></td> <td><u>500</u> <u>80</u></td> </tr> <tr> <td>MM1536-01</td> <td>B <u>B</u></td> <td>PC</td> <td>500</td> <td><u>00002P10560</u></td> <td><u>500</u></td> </tr> </tbody> </table>	Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	MM0179-01	D <u>D</u>	PC	500	<u>00002P14700</u> <u>XLS1</u> <u>20 Feb 24</u>	<u>500</u> <u>80</u>	MM1536-01	B <u>B</u>	PC	500	<u>00002P10560</u>	<u>500</u>			
Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																		
MM0179-01	D <u>D</u>	PC	500	<u>00002P14700</u> <u>XLS1</u> <u>20 Feb 24</u>	<u>500</u> <u>80</u>																		
MM1536-01	B <u>B</u>	PC	500	<u>00002P10560</u>	<u>500</u>																		

Notes: DA 2484, 2564

N/A

N/A

Date Printed: 02/15/2024 / 15:52:55

Page: 1 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000307852



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
NP  MA	RM0158-01	E	<u>E</u>	PC	200	<u>0000281412</u>	<u>80</u>			
	1000-1153-01	A	<u>A</u>	PC	594	<u>88371</u> <u>88373</u> <u>88360</u>	<u>153</u> <u>200</u> <u>200</u> <u>200</u>	<u>N/A</u>		
	1000-2053-01	A	<u>A</u>	PC	500	<u>00002915775</u>	<u>500</u>	<u>N/A</u>		WGD
	MM1537-02	A	<u>A</u>	PC	500	<u>00002910571</u>	<u>500</u>	<u>N/A</u>	<u>NA</u>	<u>NA</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>			
	TL0165-03	J	<u>J</u>	PC	5	<u>N/A</u>	<u>Bulk</u>			
						<u>N/A</u>	<u>Bulk</u>			

Notes:

MA

MA

MA

Date Printed: 02/15/2024 / 15:52:55

Page: 2 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



## Production Order: 500000307852

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
MA MA		141967-01	02	02	PC	500	856e78	510			
		RM7349-02	C	C	PC	543	82862	N/A			
		RM7348-01	C	C	PC	500	82858	185			
		RM4001-01	B	B	PC	125	88490	315			
		RM0607-01	D	D	PC	56	90286	600	N/A	15feb24	4190
		RM0498-01	C	C	PC	500	74662	N/A			
		RM0009-04	I	I	PC	1	000275413	113			
		RM0009-04	I	I	PC	1	88993	N/A			
		RM0009-04	I	I	PC	1	88993	Bulk			

Notes:

MA

MA

MA

Date Printed: 02/15/2024 / 15:52:55

Page: 3 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of

## Production Order: 500000307852

Production Order Document  
Production Order Qty: 500

Material: SA0155-01 Rev F

PC  
Sheet: 1 of 1

Opr No.	Planned WorkCenter Description	Operation Details					Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	MM1538-01	A	P	PC	500	N/A <u>0000290562</u>	Bulk 500		
		MM1537-01	A	H	PC	1000	N/A <u>0000294761</u>	N/A 1,140		
		MM0177-01	C	C	PC	500	N/A <u>0000294697</u>	N/A 500	N/A	15feb24 V190
		MM0180-01	E	E	PC	500	N/A <u>0000294374</u>	N/A 500		
		MM0178-01	E	E	PC	500	N/A <u>0000290565</u>	N/A 500		
		MM0176-01	D	D	PC	500	N/A <u>0000288413</u>	N/A 500		
		MM0074-01	G	G	PC	500	N/A <u>0000306622</u>	N/A 522		

Notes:

N/A

N/A

N/A

Date Printed: 02/15/2024 / 15:52:55

Page: 4 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of

**Production Order: 500000307852**



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
MA	MA	MA	MA	MA	MA	MA
100	CATASY01  Catheter Assembly 1    Line Clearance  Confirmation Reqd(Milestone )	Line Clearance Perform Line Clearance and Heat Gun Setting	500	0	20Feb24	V078
150	CATASY01  Catheter Assembly 1    Major and Minor Mandrel Assembly	Major and Minor Mandrel Assembly	500	0	20Feb24	CL30 SH23 Y014 PM90

Notes:

N/A  
N/A  
N/A

Date Printed: 02/15/2024 / 15:52:55

Page: 5 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



## Production Order: 500000307852

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	500	0	20Feb24 ① NY35	ST96
	Loading Braid Stock					
	Confirmation Reqd(Milestone )					
250	CATASY01 Catheter Assembly 1 	Trim Braid Wire at Proximal End	500	0	20Feb24 ① NY35	CP32
Notes:						
			N/A			
			N/A			
			N/A			

Date Printed: 02/15/2024 / 15:52:55

① NY35 19 Feb 24

Page: 6 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of

**Production Order: 500000307852**



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
	Trim Braid Wire at Proximal End  Confirmation Reqd(Milestone )  N/A	N/A				
300	CATASY01  Catheter Assembly 1    Insert Cut Hypo Tube  Insert Cut Hypo Tube  Confirmation Reqd(Milestone )	Insert Cut Hypo Tube	500	0	20feb24 GS22	AS31
350	CATASY01  Catheter Assembly 1	Load Tubing	500	0	20Feb24 SY47 TKVVO78	CLO5 STH23

**Notes:**

N/A
N/A
N/A

Date Printed: 02/15/2024 / 15:52:55

Page: 7 of 18



SA0155-01

**CREGANNA MEDICAL**  
is part of



**Production Order: 500000307852**



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	 Load Tubing Confirmation Reqd(Milestone )					
400	<b>CATASY01</b> Catheter Assembly 1  Reflow Confirmation Reqd(Milestone )	Reflow	500	0	20Feb24	Sy47 STR5 PM96
450	<b>CATASY01</b> Catheter	FEP Removal	500	0	20Feb24	JY90 PM96

Notes:

N/A

N/A

N/A

Date Printed: 02/15/2024 / 15:52:55

Page: 8 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



## Production Order: 500000307852



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  					
	FEP Removal					
	Confirmation Reqd(Milestone )  <i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>
500	CATASY01  Catheter Assembly 1  	In-process Inspection and Rework Material Consumed: Part #: <u>10001153-0</u> Batch #: <u>88371</u> Qty: <u>N/A</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u>	498	DL-1 EW-1  <i>(2)</i>	20Feb24 Dx35 TD15 LL61 VC09 CB81	VL91
	In-process Inspection and Rework					
	Confirmation Reqd(Milestone )  <i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>
<b>Notes:</b>						
<i>N/A</i>						
<i>N/A</i>						

Date Printed: 02/15/2024 / 15:52:55

Page: 9 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



**Production Order: 500000307852**



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 )	493	MAH-1 EH-1 IDB-II DL-1  ⑤	20/Fe524	MM02 SV46 FBO) PHN9 AX82
600	CATASY01  Catheter Assembly 1  	Distal Tip Assembly    Distal Tip Assembly  Confirmation	493	0	20/Fe524	ML 60 FBO) PHN9 AX82

Notes:

N/A

N/A

N/A

Date Printed: 02/15/2024 / 15:52:55

Page: 10 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



## Production Order: 500000307852

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	Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
650	CATASY01  Catheter Assembly 1  	Loading Heat Shrink	493	0	20Feb24	PP40 F B01 PH59 AX82
	Loading Heat Shrink					
	Confirmation Reqd(Milestone )					
700	CATASY01  Catheter Assembly 1  	Tipping Record Tipping Oven Information: TMI: <u>0521</u> Cal Due: <u>31 May 2024</u> TMI: <u>2083C</u> Cal Due: <u>31 May 2024</u> TMI: <u>0936A</u> Cal Due: <u>31 May 2024</u> TMI: <u>0386</u> Cal Due: <u>31 May 2024</u>  Tipping	493	0	20Feb24	PP40 Hv36
<b>Notes:</b>						
N/A						
N/A						
N/A						

Date Printed: 02/15/2024 / 15:52:55

Page: 11 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of

## Production Order: 500000307852

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	Confirmation Reqd(Milestone )	N/A	N/A	N/A	N/A	N/A
750	CATASY01  Catheter Assembly 1  	<p>Tip Inspection/ Flash Removal Material Consumed:</p> <p>Part #: <u>Pm4001-01</u> Batch #: <u>98 N/A</u> Qty: <u>N/A</u>      Part #: <u>Pm4001-01</u> Batch #: <u>90286</u> Qty: <u>10</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></p> <p>PY46 20 Feb 24</p>	492	EH-1 ①	20Feb24 MV78 STX48 Hv36	
800	CATASY01  Catheter Assembly 1  	Major Mandrel Removal	487	ACD-HH ⑤	20Feb24 KT26 SSHH SS52	

Notes:

N/A

N/A

N/A

Date Printed: 02/15/2024 / 15:52:55

Page: 12 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	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>	487	0	LOFe <sup>n24</sup>	M165 5552
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	S H o 4 P 266 M V 33
<b>Notes:</b>						
N/A						
N/A						
N/A						

Date Printed: 02/15/2024 / 15:52:55

Page: 13 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of

## Production Order: 500000307852



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
	<b>Quality Inspection &amp; Review</b>  <b>Confirmation Reqd(Milestone )</b> <i>N/A</i>	Re-Inspect after re-work. 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 24</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>Pn4001-01</u> Batch #: <u>90286</u> Qty: <u>17</u> Part #: <u>1000-1153-01</u> Batch #: <u>855371</u> Qty: <u>N/A</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u>	461	DIS-HH111 MAR-1 TD-1 #70S-1 #60S-1 SKV-1 BW-1 #60S-11 FN-1 WK-111 EW-111 (26)	<i>20 Feb 24</i> <i>PY46</i>	<i>K155</i> <i>KT207</i>
950	<b>QUALITY1</b> <b>Quality Inspection &amp; Review</b>	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:	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>

Notes:

*N/A**N/A**N/A*

Date Printed: 02/15/2024 / 15:52:55

Page: 14 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000307852



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
	 <b>Quality Inspection &amp; Review</b>  <i>N/A</i>	TMI: <u>✓/A</u> Cal Due: <u>✓/A</u> Record DIM02 Go/No-Go Gage Information: TMI: <u>0691</u> Cal Due: <u>30 Sep 25</u> TMI: <u>0692</u> Cal Due: <u>30 Sep 25</u> Record DIM02 Inspection Results N = 54: Pass: <u>54</u> Fail: <u>0</u>		<i>DIS - VHT</i> <i>1</i> <i>STR - VHT</i> <i>111 (SP)</i> <i>WIL - 1</i> <i>(16)</i>	<i>20 Feb 24</i>	<i>7936</i>
1000	 <b>Quality Inspection &amp; Review</b>  <b>Quality Inspection &amp; Review</b>  <i>N/A</i>	Quality Inspection & Review Leak Test Record Inspection Data in SAP ROS Record Leak Tester Information: TMI: <u>1056</u> Cal Due: <u>31 May 24</u> Record Length Gage Information: TMI: <u>0889D</u> Cal Due: <u>30 Sep 24</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30 Sep 24</u>	433	<i>LT - VHT</i> <i>HHT/1</i> <i>(12)</i>	<i>20 Feb 24</i>	<i>7936</i> <i>SC88</i> <i>SSH4</i>

Notes:

*N/A*

*N/A*

*N/A*

Date Printed: 02/15/2024 / 15:52:55

Page: 15 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



## Production Order: 500000307852



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	405	Fm - 11 (TT) SCR - H11 III (TT) SCR - H11 EW - 111 PBC - 1 Fib - 1 Fm - 1 BP - 1 FL - 1 DL - 1 KUK - 1 CRK - 1 SKV - 1 GM1 - 1  28	20 FEB 24	KL45 SU3
1100	CATASY01  Catheter Assembly 1    Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initials/Date): XC31 20 FEB 24	N/A	N/A	20 FEB 24	XC31
Notes:						
N/A						
N/A						
N/A						

Date Printed: 02/15/2024 / 15:52:55

Page: 16 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



**Production Order: 500000307852**



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	405	0	21 Feb 24	BPA

Notes:

A  
N  
N

Date Printed: 02/15/2024 / 15:52:55

Page: 17 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



**Production Order: 500000307852**



Production Order Document  
Production Order Qty: 500

PC

Sheet: 1 of 1

**Material: SA0155-01 Rev F**

Batch Number: 0000301852

By: BMJ

Date: 21 Feb 24

Reviewed By:

RB29

Date:

23 Feb 24

Notes:

H  
M  
N

Date Printed: 02/15/2024 / 15:52:55

Page: 18 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of





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.RvF Deviation Authorization

**CONTROLLED COPY**

① UK55, 23JU 2023



2484  
DA | 2468  
①

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

### Group Training Record

#### Procedure:

- 100% inspection at Op#1050 per the instructions below.
- Inspect 1 part at a time.
- Inspection is focused on the correct MM0179-01 and MM1536-01 assembly.
- Use the example MM0179-01 and MM1536-01 fixture for inspection. (See image 1)  
**① MM1536-01 Type connection TS12 10AUG23**

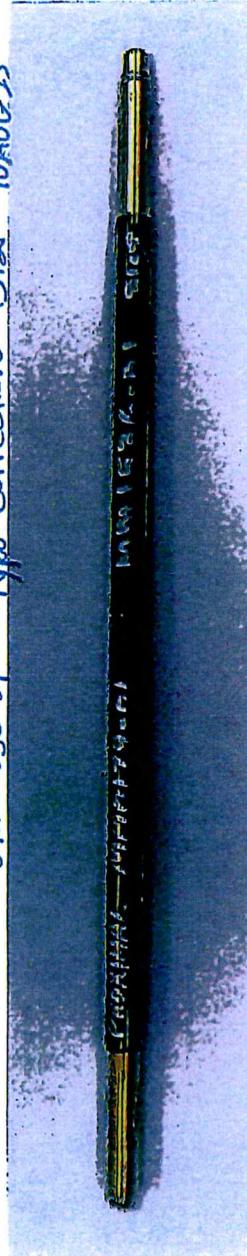


Image- 1

#### 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)

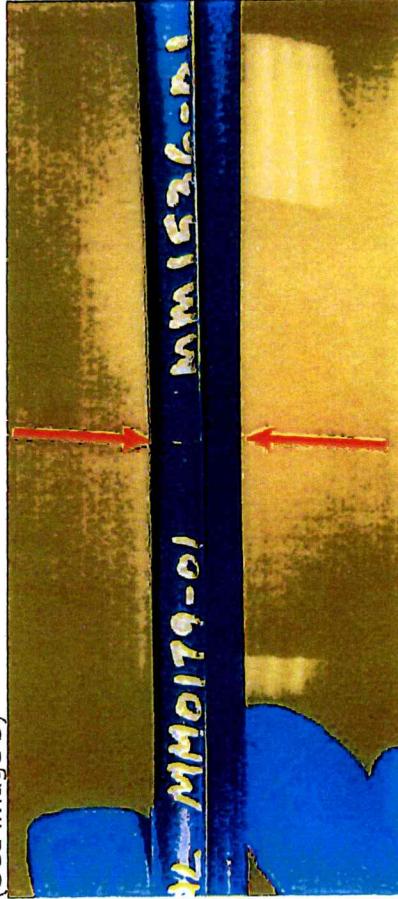
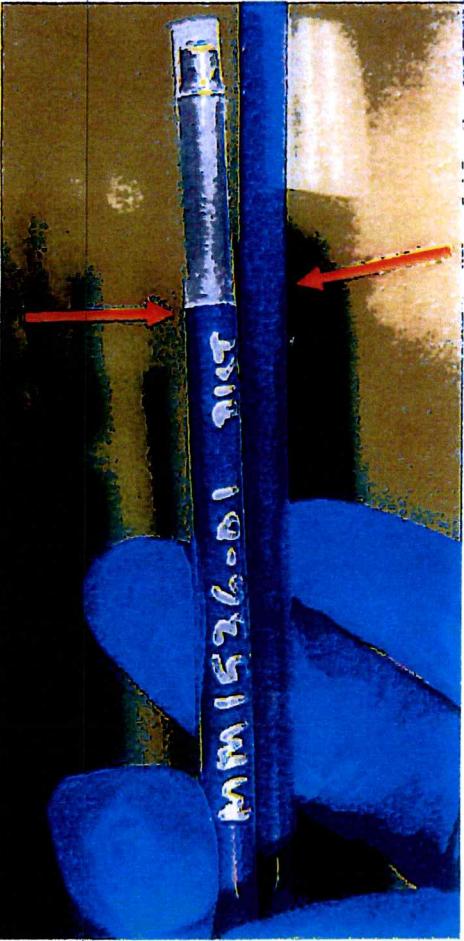


Image- 3

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

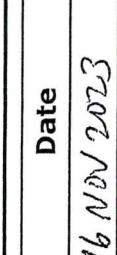
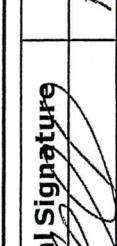
Image - 5

## DEVIATION AUTHORIZATION FORM

<b>Requestor Name:</b> Krishna Selvaraj	
<b>Document Number Affected</b>	<b>Revision</b>
Doc #3005206 (MPI0238)	BP
<b>Deviation From:</b>	
<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>Deviation To:</b>	
<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.	

### **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.

<b>Part Number Affected</b>	<b>Revision</b>		
SA0155-01	H		
<b>Start Date:</b>	<b>End Date:</b>		
16 Nov 23	15 DEC 23		
<b>Lot Number:</b>			
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 type="checkbox"/> Yes <input checked="" 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			
<b>Title</b>	<b>Approval Name</b>	<b>Approval Signature</b>	<b>Date</b>
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#: 500000307852

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10745	44	7:08pm	430	SH85	19 Feb 24	7:20pm	415	SH85	19 Feb 24	16
Tm10745	44	7:36pm	428	SH85	19 Feb 24	7:48pm	415	SH85	19 Feb 24	16
Tm10745	44	8:03pm	428	V078	19 Feb 24	8:15pm	415	JY90	19 Feb 24	8
Tm10745	44	9:15pm	430	JY90	19 Feb 24	9:27pm	415	JY90	19 Feb 24	16
Tm10745	44	9:45pm	430	CL30	19 Feb 24	9:57pm	415	CL30	19 Feb 24	16
Tm10745	44	10:26pm	430	CL30	19 Feb 24	10:38pm	415	CL30	19 Feb 24	16
Tm10745	44	10:55pm	429	SX60	19 Feb 24	11:07pm	415	SX60	19 Feb 24	16
Tm10745	44	11:46pm	430	JY90	19 Feb 24	11:58pm	415	SX60	19 Feb 24	16
Tm10745	44	12:14AM	429	SX60	20 Feb 24	12:26AM	415	SX60	20 Feb 24	16
Tm10745	44	12:46AM	429	Sy47	20 Feb 24	12:52AM	415	Sy47	20 Feb 24	16
Tm10745	44	1:05AM	429	Sy47	20 Feb 24	1:17AM	415	Sy47	20 Feb 24	16
Tm10745	44	1:39AM	429	Sy47	20 Feb 24	1:51AM	415	Sy47	20 Feb 24	16



Document No: 5105589

FM5104665 Rev: C

**Document Type: Manufacturing Form**

Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000307852

OP 400



Document No: 5105589

FM104665 Rev: C

Document Type: Manufacturing Form

Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000307852

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10942	44	6:54 PM	429	SH85	19 Feb 24	7:06 PM	415	SH85	19 Feb 24	16
Tm10942	44	7:26 PM	428	SH85	19 Feb 24	7:38 PM	415	SH85	19 Feb 24	16
Tm10942	44	7:52 PM	428	SH85	19 Feb 24	8:04 PM	415	SH85	19 Feb 24	16
Tm10942	44	8:56 pm	430	SX60	19 Feb 24	9:08 pm	415	SX60	19 Feb 24	16
Tm10942	44	9:29 pm	430	CL30	19 Feb 24	9:41 pm	415	CL30	19 Feb 24	16
Tm10942	44	10:01pm	429	SX60	19 Feb 24	10:13 pm	415	SX60	19 Feb 24	16
Tm10942	44	10:35pm	430	JY90	19 Feb 24	10:47pm	415	CL30	19 Feb 24	16
Tm10942	44	11:30 pm	430	Sy47	19 Feb 24	11:42 pm	415	Sy47	19 Feb 24	16
Tm10942	44	12:00 AM	428	Sy47	20 Feb 24	12:12 AM	415	Sy47	20 Feb 24	16
Tm10942	44	12:30AM	429	SH85	20 Feb 24	12:42 AM	415	SH85	20 Feb 24	16
Tm10942	44	1:00 AM	428	Sy47	20 Feb 24	1:12 AM	415	Sy47	20 Feb 24	16
Tm10942	44	1:24 AM	426	SX60	20 Feb 24	1:36 AM	415	SX60	20 Feb 24	16



PRODUCTION ORDER# 500000307852

OP 400

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

① PM 96 20 Feb 24



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

PO #: 500000307852

OP #: 500 Shift #: 2nd

Total Parts Reworked:		30	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		2
EH	Exposed Hypotube	n/a	n/a
EW	Exposed Wire		17
MP	Micropores	n/a	n/a
SCR	Scratch	///	3
SKV	Skive Marks	n/a	n/a
VD	Voids		10
n/a	n/a	n/a	n/a

Inspected By (Sign and Date):

Kamneet 019 Feb 24

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

Data Uploaded for Engineering Review (Check):

VL91 19 Feb 24



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

PO #: 500000307852

OP #: 500 Shift #: 2nd

Total Parts Reworked:		<u>33</u>	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	/	1
EH	Exposed Hypotube		4
EW	Exposed Wire		19
MP	Micropores	N/A	0
SCR	Scratch		6
SKV	Skive Marks	N/A	0
VD	Voids		3
N/A	N/A	N/A	0

**Inspected By (Sign and Date):** DX35 19 Feb 24

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

Data Uploaded for Engineering Review (Check):



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

**PO #:** 500000307852

**OP #:** 500    **Shift #:** 15+

Total Parts Reworked:		70	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		1
EH	Exposed Hypotube		16
EW	Exposed Wire		46
MP	Micropores	N/A	N/A
SCR	Scratch		1
SKV	Skive Marks	N/A	N/A
VD	Voids		8
N/A	N/A	N/A	N/A

**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 #: 50000307B52 OP #: 750 Shift #: 2nd

Total Parts Reworked:		21	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		10
DIM07 US / WC	DIM07 Undersized (Window Closed)		6
EH	Exposed Hypotube		5
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		mme2	19Feb24

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):



Document No: 6102646  
Rev: A  
Document Type: Manufacturing Form  
Title: SA0155-01 Tipping Rework Form

PO #: 500000307852 OP #: 750 Shift #: 1st

Total Parts Reworked:		51	
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)		6
EH	Exposed Hypotube		18
N/A	Glue - stopper		20
Inspected By (Sign and Date):		Hv36 20 Feb 24	

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):

**PRODUCTION ORDER#** 500000307852

**OP 800**

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm12036	N/A	9:51pm	190°F	KT26	19Feb24	11:01PM	190°F	KT26	19Feb24	35
Tm10409	N/A	10:30PM	190°F	KT26	19Feb24	11:40PM	190°F	KT26	19Feb24	38
Tm12036	N/A	10:57PM	190°F	KT26	19Feb24	12:07AM	190°F	KT26	20Feb24	25
Tm10409	N/A	11:59pm	190°F	KT26	19Feb24	1:09AM	190°F	KT26	20Feb24	36
Tm12036	N/A	12:49AM	190°F	KT26	20Feb24	2:09AM	190°F	KT26	20Feb24	33
Tm10409	N/A	4:30am	190°F	k155	20Feb24	5:40am	190°F	k155	20Feb24	52
Tm12036	N/A	5:20am	190°F	SSHH	20Feb24	6:30am	190°F	SSHH	20Feb24	36
Tm10409	N/A	5:50am	190°F	SSHH	20Feb24	7:00am	190°F	SSHH	20Feb24	35
Tm10409	N/A	7:15am	190°F	k155	20Feb24	8:25am	190°F	k155	20Feb24	21
Tm12036	N/A	8:00am	190°F	k155	20Feb24	9:10am	190°F	k155	20Feb24	33
Tm10409	N/A	8:50 am	190°F	k155	20Feb24	10:00am	190°F	k155	20Feb24	31
Tm12036	N/A	9:15 am	190°F	k155	20Feb24	10:25am	190°F	k155	20Feb24	31
Tm10409	N/A	10:15am	190°F	0521	20Feb24	11:25am	190°F	0521	20Feb24	81



Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 500000307852 OP #: 900 Shift #: 2nd

Total Parts Reworked:		8	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		
EH	Exposed Hypotube		
EW	Exposed Wire		
MP	Micropores		
SCR	Scratch	SH 04 19 Feb 24 N/A	
SKV	Skive Marks		
VD	Voids		
DIM01 US	DIM01 OD Undersized		
DIM06 US	DIM06 OD Undersized	HHH	10
DIM06 OS	DIM06 OD Oversized	HH	5
DIM09 US	DIM09 OD Undersized	N/A	0
Inspected By (Sign and Date):		See H 19 Feb 24	

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):



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

PO #: 50000307852 OP #: 900 Shift #: 2

Total Parts Reworked:		<u>32</u>	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	/	<u>1</u>
EH	Exposed Hypotube		<u>0</u>
EW	Exposed Wire	<u>     </u>	<u>12</u>
MP	Micropores		<u>0</u>
SCR	Scratch	<u>     </u>	<u>24</u>
SKV	Skive Marks		<u>0</u>
VD	Voids		<u>0</u>
DIM01 US	DIM01 OD Undersized		<u>0</u>
DIM06 US	DIM06 OD Undersized		<u>0</u>
DIM06 OS	DIM06 OD Oversized		<u>0</u>
DIM09 US	DIM09 OD Undersized		<u>0</u>
Inspected By (Sign and Date):		<u>Craig</u>	<u>19 Feb 24</u>

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):



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

PO #: 500000307852 OP #: 900 Shift #: 15F

Total Parts Reworked:		102	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		2
EH	Exposed Hypotube		4
EW	Exposed Wire		26
MP	Micropores		N/A
SCR	Scratch		51
SKV	Skive Marks		3
VD	Voids		22
DIM01 US	DIM01 OD Undersized		N/A
DIM06 US	DIM06 OD Undersized		13
DIM06 OS	DIM06 OD Oversized		N/A
DIM09 US	DIM09 OD Undersized		N/A
Inspected By (Sign and Date):		K155 PULC KTH1	20 Feb 24

Note: Indicate tally marks in groups of 5. Scrap is to be recorded on the SAP router; this form is for reworked parts only. DIM01 OS, DIM09 OS, Foreign Material, and Cracks are not reworkable per MPI0238.

Data Uploaded for Engineering Review (Check):

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	27.36	29.16	32.29	31.65	28.18	30.52	26.94	25.16	24.79	24.7	28.075	2.7926819	4.378	15.8486386	8.542	PASS
Seg B	75.54	75.36	68.78	68.34	70.83	75.17	69.97	67.72	70.26	73.64	71.561	3.0773779	3.981	59.3099588	8.542	PASS
Seg C	77.65	81.54	76.68	80.26	79.77	75.18	79.72	77.34	78.5	79.37	78.601	1.9002424	2.911	73.0693944	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.



20 FEB 2024