

## Production Order: 500000294404



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	<p>Kitting Devices            Perform Order Kitting, Load Minor Mandrels, Dry Extrusions, and Cut FEP            Record Time Extrusions Enter Dryer (Initial/Time/Date): <u>Xc31 7:00AM 09JAN24</u>            Record Time Extrusions First Exit Dryer (Initial/Time/Date):  <u>Xc31 10:00PM 09JAN24</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>0000276172</u></td> <td><u>500</u></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td><u>0000272345</u></td> <td><u>25</u></td> </tr> <tr> <td>MM1536-01</td> <td>B <u>B</u></td> <td>PC</td> <td>500</td> <td><u>0000281412</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>0000276172</u>	<u>500</u>					<u>0000272345</u>	<u>25</u>	MM1536-01	B <u>B</u>	PC	500	<u>0000281412</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>0000276172</u>	<u>500</u>																								
				<u>0000272345</u>	<u>25</u>																								
MM1536-01	B <u>B</u>	PC	500	<u>0000281412</u>	<u>500</u>																								

Notes: DA2484, 2564

N/A

N/A

Date Printed: 01/08/2024 / 12:15:12

Page: 1 of 18



SA0155-01

0685 11 Jan 24

CREGANNA MEDICAL  
is part of



## Production Order: 500000294404

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
MP  N/A		RM0158-01	E	<u>E</u>	PC	200	0000263145 58497 81054	40 50 100		
		1000-1153-01	A	<u>A</u>	PC	594	87098/87103 87104	200/200 200		
		1000-2053-01	A	<u>A</u>	PC	500	0000278880 0000268040	500 20		
		MM1537-02	A	<u>A</u>	PC	500	0000276175 N/A	500 N/A		
		TL0167-02	E	<u>E</u>	PC	70	N/A N/A	Bulk Bulk	N/A N/A	N/A
		TL0165-05	J	<u>J</u>	PC	5	N/A N/A	Bulk Bulk		N/A
		TL0165-03	J	<u>J</u>	PC	5	N/A N/A	Bulk Bulk		

Notes:

N/A

N/A  
N/A

Date Printed: 01/08/2024 / 12:15:12

Page: 2 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of

## Production Order: 500000294404



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
MD N/A		141967-01	02	02	PC	500	86568/82898 82899	21/45 434			
		RM7349-02	C	C	PC	543	82836 82851	245 306			
		RM7348-01	C	C	PC	500	78686/78687 82881/82883	150/150 150/100			
		RM4001-01	B	B	PC	125	82103 82818	N/A 64			
		RM0607-01	D	D	PC	56	78845 ① 0000275485 ② 0000275489 N/A ③ 0000282541 0000285399	106 ② 330 ③ 43 ④ 12 N/A	N/A	N/A	N/A
		RM0498-01	C	C	PC	500	① 0000281518 ② 0000287514 0000275485 0000275489 0000282571	25 54 11 330 12			
		RM0009-04	I	I	PC	1	82991 N/A	Bulk Bulk			
		RM0009-04	I	I	PC	1	82991	Bulk			

Notes:

N/A

N/A

N/A

Date Printed: 01/08/2024 / 12:15:12 ① KL27 11 JAN 24  
 ① KL27 08 JAN 24 0000275485  
 0000282571 0000287518  
 0000285399 0000287519  
 0000275489

Page: 3 of 18  
 ② GS85 11 Jan 24



SA0155-01

CREGANNA  
MEDICAL  
is part of



## Production Order: 500000294404



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	MM1538-01	A	<u>A</u>	PC	500	0000278970	Bulk			
						N/A	500			
	MM1537-01	A	<u>A</u>	PC	1000	0000281413	1103			
						N/A	N/A			
	MM0177-01	C	<u>C</u>	PC	500	0000278966	500			
						N/A	N/A			
	MM0180-01	E	<u>E</u>	PC	500	0000282489	200	500	① N/A	N/A
						0000275691	300			
	MM0178-01	E	<u>E</u>	PC	500	0000276174	500		N/A	N/A
						N/A	N/A			
	MM0176-01	D	<u>D</u>	PC	500	0000281411	500			
						0000271036	40			
	MM0074-01	G	<u>G</u>	PC	500	0000291661	520			
						N/A	N/A			

Notes:

N/A

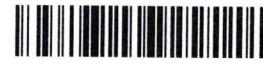
N/A

N/A

Date Printed: 01/08/2024 / 12:15:12

(1) G885 11 Jan 24

Page: 4 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



**Production Order: 500000294404**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 Confirmation Req'd(Milestone )	Line Clearance Perform Line Clearance and Heat Gun Setting	500	0	105 <sup>m<sup>24</sup></sup>	V078
150	CATASY01 Catheter Assembly 1  Major and Minor Mandrel Assembly	Major and Minor Mandrel Assembly	500	0	105 <sup>m<sup>24</sup></sup>	SX60 PM96 NK62 AF54 AX05

**Notes:**

N/A

N/A

N/A

Date Printed: 01/08/2024 / 12:15:12

Page: 5 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of

**Production Order: 500000294404**



Production Order Document  
Production Order Qty: 500

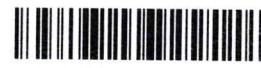
PC  
Sheet: 1 of 1

**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
200	CATASY01 Catheter Assembly 1 	Loading Braid Stock	500	0	10 Jun 24	CP32 Y014 MV5D SXII VP62
	Loading Braid Stock					
	Confirmation Reqd(Milestone )					
250	CATASY01 Catheter Assembly 1 	Trim Braid Wire at Proximal End	500	0	10 Jun 24	CL30 CX05 PL34 SXII
<b>Notes:</b>						
N/A						
N/A						
N/A						

Date Printed: 01/08/2024 / 12:15:12

Page: 6 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



**Production Order: 500000294404**



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  N/A Confirmation Reqd(Milestone )	N/A	N/A	N/A	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 105cm <sup>24</sup>	ST23 GS22 W25	
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0 105cm <sup>24</sup>	ST96 NY35 CY67 CT86	

**Notes:**

N/A  
N/A  
N/A

Date Printed: 01/08/2024 / 12:15:12

Page: 7 of 18



SA0155-01

**CREGANNA MEDICAL**  
is part of



**Production Order: 500000294404**

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
400	<b>CATASY01</b> Catheter Assembly 1  Reflow  Confirmation Reqd(Milestone)	Reflow	500	0	105cm <sup>2</sup>	SH85 NY95 V078 PM96 NK62 RN21 AF54
450	<b>CATASY01</b> Catheter	FEP Removal	500	0	105cm <sup>2</sup>	SG88 JY90 PM96 AP34
Notes:						

Date Printed: 01/08/2024 / 12:15:12

Page: 8 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000294404



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 )	N/A	N/A	N/A	N/A	N/A
500	CATASY01  Catheter Assembly 1  In-process Inspection and Rework  Confirmation Reqd(Milestone )	In-process Inspection and Rework Material Consumed: Part #: <u>1000-1153-01</u> Batch #: <u>N/A</u> Qty: <u>N/A</u> Part #: <u>1000-1153-01</u> Batch #: <u>87106</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> AT39 09 Jan 24	486	SKN-1 OF-1H1 EN-1H1 BP-11  10 Jan 24  14	10 Jan 24  14	1266 HT72 TD45 CB81 LL61 VC09 TA36
			N/A	N/A	N/A	N/A
			N/A	N/A	N/A	N/A
			N/A	N/A	N/A	N/A
			N/A	N/A	N/A	N/A
			N/A	N/A	N/A	N/A
			N/A	N/A	N/A	N/A

Date Printed: 01/08/2024 / 12:15:12

Page: 9 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



**Production Order: 500000294404**



**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 Confirmation Reqd(Milestone )	Remove Heat Shrink & Mandrel	486	0	10 Jan 24	ML38 MM02 RS23 FBO1 AX82
600	CATASY01 Catheter Assembly 1  Distal Tip Assembly Confirmation	Distal Tip Assembly	468	OF-1 IDB-1 DS-1 DL-HTT1 MAH-HTT 1111 (18)	10 Jan 24	DX35 RS23 FBO1 DV39 VA98 AX82

**Notes:**

11

NIA

via

Date Printed: 01/08/2024 / 12:15:12



SA0155-01

**CREGANNA  
MEDICAL**  
is part of



# Production Order: 500000294404



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	468	0	SV46 FBO VA96 105cm <sup>24</sup> 4X82	
	Loading Heat Shrink					
	Confirmation Reqd(Milestone )					
700	CATASY01 Catheter Assembly 1 	Tipping Record Tipping Oven Information: TMI: <u>0386</u> Cal Due: <u>31 May 24</u> TMI: <u>0521</u> Cal Due: <u>31 May 24</u> TMI: <u>2083C</u> Cal Due: <u>31 May 24</u> TMI: <u>0936A</u> Cal Due: <u>31 May 24</u> Tipping	468	0	SV46 STX48 105cm <sup>24</sup>	
Notes:						

Date Printed: 01/08/2024 / 12:15:12

Page: 11 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000294404



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 #: 82103 Qty: N/A Part #: RM058-00 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	Tip Inspection/ Flash Removal  Material Consumed: Part #: RM4001-01 Batch #: 82103 Qty: N/A Part #: RM058-00 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	468	0  <i>10 Jan 24</i>	PP40  S1X48 Hv36	
800	CATASY01  Catheter Assembly 1    Major Mandrel Removal	Major Mandrel Removal	466	ACD-11  <i>10 Jan 24</i>	SSH44  SS52 Pm96	

Notes:

N/A

N/A

N/A

Date Printed: 01/08/2024 / 12:15:12

Page: 12 of 18



SA0155-01

(1) KLS 10 Jan 24

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000294404



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
	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>	465	SKV-1	105cm	SS52
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						
① N/A						
N/A						

Date Printed: 01/08/2024 / 12:15:12

Page: 13 of 18



SA0155-01

01/08/2024  
10 Jan 24

CREGANNA  
MEDICAL  
is part of



## Production Order: 500000294404

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	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: 31May24 TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A Material Consumed: Part #: RM4001-0 Batch #: 82103 Qty: 10 Part #: N/A Batch #: N/A Qty: N/A Part #: 10200-153-0 Batch #: 87103 Qty: 15 Part #: RM0607-01 Batch #: 13845 Qty: 10 Part #: RM0716-01 Batch #: N/A Qty: N/A RM0158-01 Batch# 58497 Qty: 7</p>	439	EW-III WK-HH I DIS-II #6US-III #60S-III #SUS-III EH-I #90S-II #10S-I	10Jan24	KT217 XL91 P246 ML46 SH04 MV33 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

Date Printed: 01/08/2024 / 12:15:12

① MV18 10Jan24

Page: 14 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of

# Production Order: 500000294404



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>	<p>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>30Sep24</u> 30Sep25 XL91 10Jan24          TMI: <u>0692</u> Cal Due: <u>30Sep25</u>          Record DIM02 Inspection Results N = 54:          Pass: <u>54</u> Fail: <u>0</u></p>	409	<u>DIS(HH) HHT</u> <u>DEL(7)</u> <u>HHT HH</u> <u>DIS-HH HHT</u> <u>STR- HHT</u>	10Jan24	XL91 KL67
1000	<b>QUALITY1</b>   <b>Quality Inspection &amp; Review</b>   <b>Confirmation Reqd(Milestone )</b>	<p>Quality Inspection &amp; 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></p>	385	<u>LT-HH HHT</u> <u>HHT HHT</u> <u>HH</u>	10Jan24	SS44 KL67

Notes:

N/A

N/A

N/A

Date Printed: 01/08/2024 / 12:15:12

Page: 15 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



Production Order: 500000294404



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

**Material: SA0155-01** Rev E

Date Printed: 01/08/2024 / 12:15:12



SA0155-01

**CREGANNA  
MEDICAL**  
is part of



**Production Order: 500000294404**



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	354	0 12 Jan 24	AP10	

Notes:

N/A AP10 12 Jan 24 /

Date Printed: 01/08/2024 / 12:15:12

Page: 17 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



Production Order: 500000294404



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

Material: SA0155-01 Rev F

Batch Number: 0000294404

By: AP10

Date: 12 Jan 24

Reviewed By:

RB29

Date:

12 JAN 24

Notes:

N/A AP10 12 Jan 24 /

Date Printed: 01/08/2024 / 12:15:12

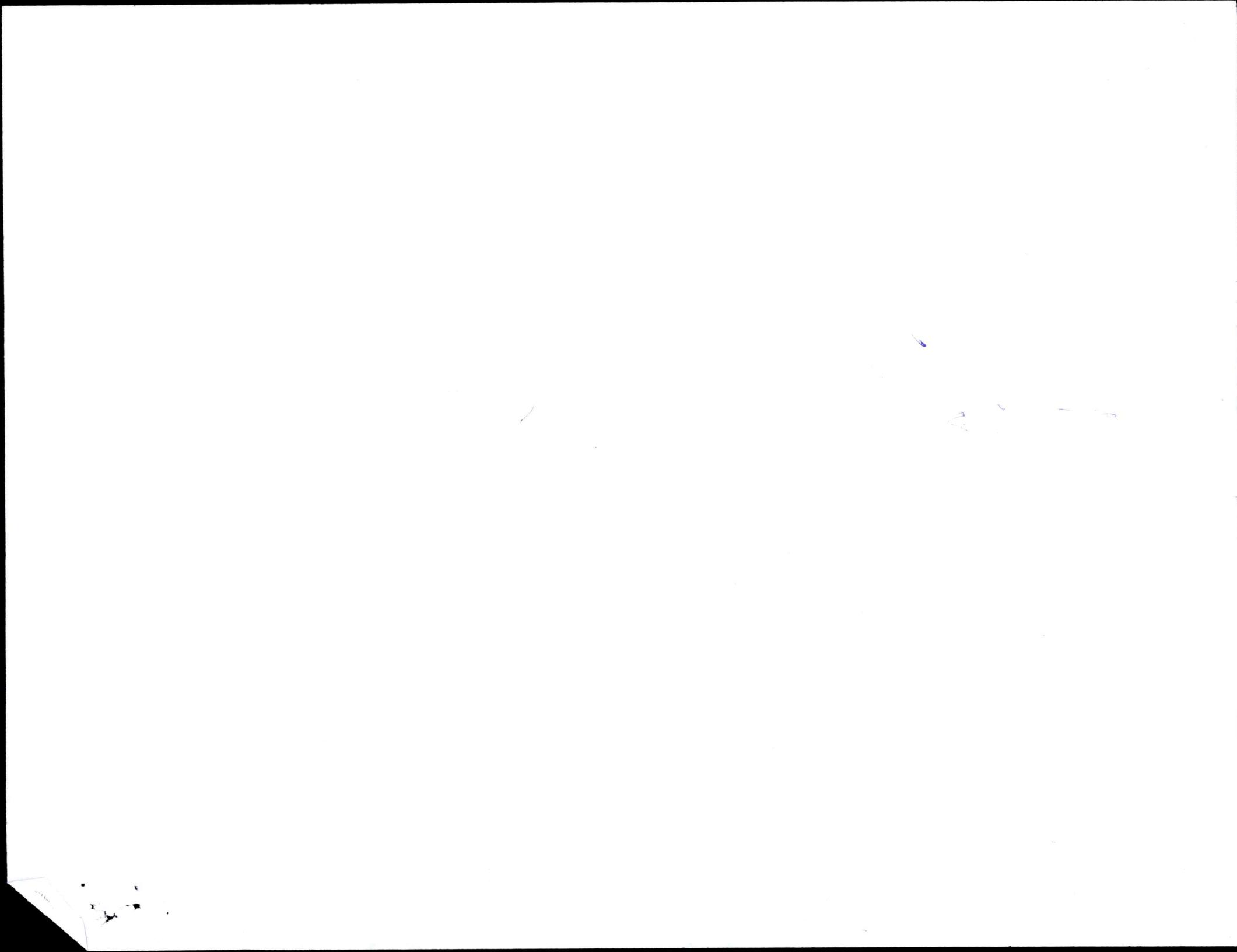
Page: 18 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of







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 MM0179-01  
10AUG23

#### CONTROLLED COPY

#### 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- 1



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)

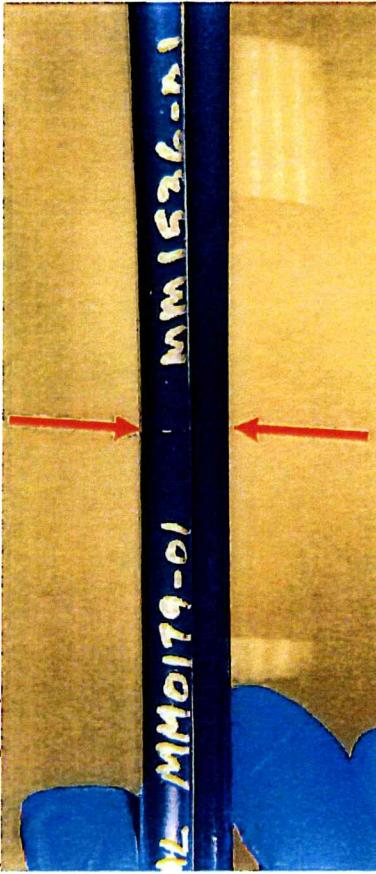


Image- 3

- 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)

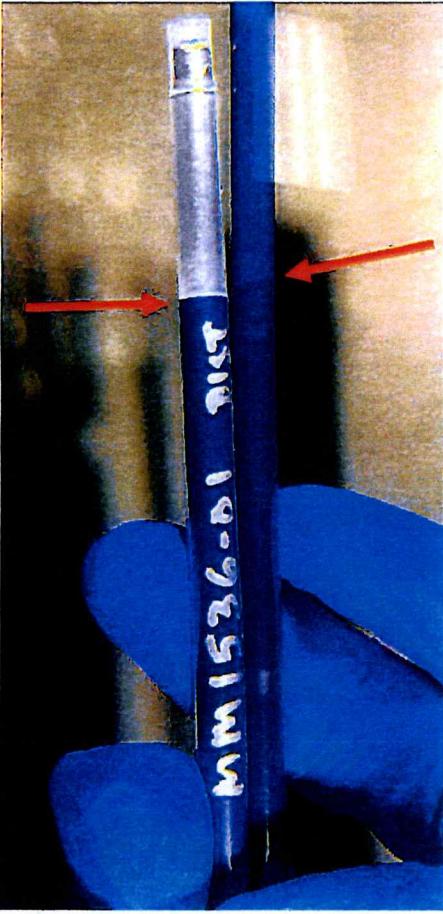


Image- 4

- 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

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

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

**Justification:**

TMI0602 lasermic which is currently used in SA0155-01 Flex commander product at OPER850 for Dim 6 inspection has mechanical failure and confirmed as not usable.

TM10700-01 lasermic is used at OPER900 for 100% inspection for Dim 1, Dim 6 and Dim 9. Since TM10700-01 is already qualified to inspect Dim 6 per ES0647: Laser micrometer equivalency test, there is no additional risk in using TM10700-01 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>	<b>Lot Number:</b>
16 Nov 23	15 DEC 23	N/A
<b>Risk Assessment:</b>		
Is there any potential risk(s) that may occur as a result of the proposed deviation including the following: Control Plans <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No FMEA's <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Validations <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Details (if any): N/A		
If yes to any of the above, what controls are being put in place to mitigate the risk – N/A		
<b>Corrective Action Required:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
<b>If no, explain:</b> This is a temporary change to use TM10700-01. 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>
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# 500000294404

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10942	44	11:48pm	430	SH85	09Jan24	11:58pm	415	SH85	09Jan24	16
Tm10942	44	12:11 Am	430	V078	10Jan24	12:23 AM	415	V078	10Jan24	16
Tm10942	44	12:30 AM	427	SH85	10Jan24	12:45 AM	415	SH85	10Jan24	16
Tm10942	44	12:57 AM	430	SG88	10Jan24	1:09 AM	415	SG88	10Jan24	16
Tm10942	44	1:24 AM	429	SH85	10Jan24	1:36 AM	415	SH85	10Jan24	16
Tm10942	44	1:54 AM	429	SH85	10Jan24	2:06 AM	415	SH85	10Jan24	16
Tm10942	44	5:19 AM	430	PM96	10Jan24	5:31 AM	415	PM96	10Jan24	16
Tm10942	44	5:30 AM	427	AX05	10Jan24	5:48 AM	415	AX05	10Jan24	16
Tm10942	44	6:10 AM	430	OS21	10Jan24	6:22 AM	415	OS21	10Jan24	16
Tm10942	44	6:30 AM	428	AX05	10Jan24	6:42 AM	415	AX05	10Jan24	16
Tm10942	44	6:49 AM	427	NK62	10Jan24	6:51 AM	415	NK62	10Jan24	16
Tm10942	44	7:37 AM	430	RN27	10Jan24	7:49 AM	415	RN27	10Jan24	16

① NK62 10Jan24



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

**PRODUCTION ORDER#** 500000294404

OP 400



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

PRODUCTION ORDER# 500000294404

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10745	44	10:53pm	428	SH85	09Jan24	11:05PM	415	SH85	09Jan24	16
Tm10745	44	11:54pm	430	V078	09Jan24	12:06AM	415	V078	10Jan24	16
Tm10745	44	12:20AM	429	JY90	10Jan24	12:32AM	415	SH85	10Jan24	16
Tm10745	44	12:42AM	428	SH85	10Jan24	12:54AM	415	SH85	10Jan24	16
Tm10745	44	1:12AM	430	JY90	10Jan24	1:24AM	415	JY90	10Jan24	16
Tm10745	44	1:41AM	429	SG88	10Jan24	1:53AM	415	SG88	10Jan24	16
Tm10745	44	5:10am	430	AX05	10Jan24	5:22am	415	AX05	10Jan24	16
Tm10745	44	5:26AM	429	PM96	10Jan24	5:38AM	415	PM96	10Jan24	16
Tm10745	44	5:44AM	429	NK62	10Jan24	5:56AM	415	NK62	10Jan24	16
Tm10745	44	6:20AM	430	AX05	10Jan24	6:32AM	415	AX05	10Jan24	16
Tm10745	44	6:40AM	428	AX05	10Jan24	6:52AM	415	AX05	10Jan24	16
Tm10745	44	7:48AM	430	OS21	10Jan24	8:00AM	415	OS21	10Jan24	16

① NK62 10Jan24



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

PRODUCTION ORDER# 50000294404

OP 400



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

PO #: 500000294404 OP #: 500 Shift #: 2

Total Parts Reworked:		12	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube		2
EW	Exposed Wire		9
MP	Micropores	N/A	N/A
SCR	Scratch	N/A	N/A
SKV	Skive Marks	N/A	N/A
VD	Voids		1
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		HT72 09 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 #:** 500000294404      **OP #:** 500    **Shift #:** 2

Total Parts Reworked:		4	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	MIA	0
EH	Exposed Hypotube	II	2
EW	Exposed Wire	II	2
MP	Micropores	MIA	0
SCR	Scratch	MIA	0
SKV	Skive Marks	MIA	0
VD	Voids	MIA	0
MIA	MIA	MIA	0

**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 #:** 500000294404

OP #: 500 Shift #: 1

**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 #: 500000294404 OP #: 750 Shift #: 1st

Total Parts Reworked:		125	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		28
DIM07 US / WC	DIM07 Undersized (Window Closed)		18
EH	Exposed Hypotube		31
N/A	Glue, Stopper		48
Inspected By (Sign and Date):		STR 48	10 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):

PRODUCTION ORDER# 500000294404

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10409	N/A	Hi55am	190°F	SS44	10Jan24	6:05AM	190°F	SS44	10Jan24	23
TM12036	N/A	5:30am	190°F	SS44	10Jan24	6:10am	190°F	SS44	10Jan24	38
TM10409	N/A	6:10am	190°F	SS44	10Jan24	7:20am	190°F	SS44	10Jan24	40
TM12036	N/A	6:35am	190°F	SS44	10Jan24	7:45am	190°F	SS44	10Jan24	34
TM10409	N/A	8:00am	190°F	SS44	10Jan24	9:10am	190°F	KL95	10Jan24	43
TM12036	N/A	9:00am	190°F	SS44	10Jan24	10:10am	190°F	KL95	10Jan24	43
TM10409	N/A	10:00am	190°F	KL95	10Jan24	11:10am	190°F	KL95	10Jan24	51
TM12036	N/A	11:15am	190°F	KL95	10Jan24	12:25PM	190°F	PM96	10Jan24	42
TM10409	N/A	11:40am	190°F	PM96	10Jan24	12:50pm	190°F	Hv36	10Jan24	24
TM12036	N/A	12:30 PM	190°F	PM96	10Jan24	1:40 PM	190°F	PM96	10Jan24	75
TM10409	N/A	1:00pm	190°F	Hv36	10Jan24	2:16PM	190°F	PM96	10Jan24	53
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

①PM 96 10 Jan 24

PM96 10 Jan 24



**PO #:** 500006294404

OP #: 900 Shift #: 1st

Document No: 6102619

Rev: B

**Document Type: Manufacturing Form**

**Title: SA0155-01 Dimensional/Visual Rework Form**

Total Parts Reworked:			
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	11	2
EW	Exposed Wire		41
MP	Micropores	N/A	N/A
SCR	Scratch		52
SKV	Skive Marks	N/A	N/A
VD	Voids		17
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized		71
DIM06 OS	DIM06 OD Oversized	N/A	N/A
DIM09 US	DIM09 OD Undersized	N/A	N/A
Inspected By (Sign and Date):		KT47	PY46 10 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



PO #: 500000294404 OP #: 900 Shift #: 2nd

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

Total Parts Reworked:		47	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles		1
EH	Exposed Hypotube		5
EW	Exposed Wire		3
MP	Micropores	N/A	0
SCR	Scratch		36
SKV	Skive Marks		1
VD	Voids		4
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized		12
DIM06 OS	DIM06 OD Oversized	N/A	0
DIM09 US	DIM09 OD Undersized	N/A	0
Inspected By (Sign and Date):		Deeby Maitra 10 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	27.32	27.05	26.66	25.22	27.63	28.18	25.87	25.67	25.82	25.41	26.483	1.025866	4.378	21.9917585	8.542	PASS
Seg B	61.64	61.21	58.51	61.94	60.24	61.38	59.61	69.36	62.53	60.58	61.7	2.9382232	3.981	50.0029335	8.542	PASS
Seg C	78.61	78.32	77.85	74.68	76.15	74.7	76.9	75.41	75.86	76.37	76.485	1.4155584	2.911	72.3643095	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 #: 500000294404

Date: 11 JAN 24

Inspector Name: Andrew Wipf

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24


11 Jan 24