

# Production Order: 500000297267



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 Order Type: ZSTD  
 Plant / Business Unit: 1213 / AC5 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>XCS1 6:30PM 22JAN24</u>                      Record Time Extrusions First Exit Dryer (Initial/Time/Date):  <u>XCS1 2:30PM 23JAN24</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>1000-2053-01</td> <td>A <u>A</u></td> <td>PC</td> <td>500</td> <td><u>0000278838</u></td> <td><u>500</u></td> </tr> <tr> <td>MM1537-02</td> <td>A <u>A</u></td> <td>PC</td> <td>500</td> <td><u>0000288401</u></td> <td><u>500</u></td> </tr> </tbody> </table>	Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	1000-2053-01	A <u>A</u>	PC	500	<u>0000278838</u>	<u>500</u>	MM1537-02	A <u>A</u>	PC	500	<u>0000288401</u>	<u>500</u>	N/A	N/A	22JAN24 TDo
Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																		
1000-2053-01	A <u>A</u>	PC	500	<u>0000278838</u>	<u>500</u>																		
MM1537-02	A <u>A</u>	PC	500	<u>0000288401</u>	<u>500</u>																		

Notes: DA 2484, 2564

N/A

N/A

Date Printed: 01/22/2024 / 13:55:24

Page: 1 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



## Production Order: 500000297267



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		RM0158-01	E	<u>E</u>	PC	200	N/A <u>58497</u>	N/A 167		
		TL0167-02	E	<u>E</u>	PC	70	N/A <u>N/A</u>	N/A	Bulk	
		TL0165-05	J	<u>J</u>	PC	5	N/A <u>N/A</u>	N/A	Bulk	
		TL0165-03	J	<u>J</u>	PC	5	N/A <u>N/A</u>	N/A	Bulk	
		141967-01	02	<u>02</u>	PC	500	<u>85501</u> N/A	<u>525</u> N/A	N/A	N/A
		RM7349-02	C	<u>C</u>	PC	543	<u>82831</u> N/A	<u>598</u> N/A		
		RM7348-01	C	<u>C</u>	PC	500	<u>78690</u> N/A	<u>550</u> N/A		

Notes:

N/A

N/A

N/A

Date Printed: 01/22/2024 / 13:55:24

Page: 2 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



## Production Order: 500000297267

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	RM4001-01	B	<u>B</u>	PC	125	<u>82453</u>	100			
						N/A	N/A			
		D	<u>D</u>	PC	56	<u>74662</u>	56			
						N/A	N/A			
		C	<u>C</u>	PC	500	<u>0000287641</u>	500			
						N/A	N/A			
		E	<u>E</u>	PC	594	<u>80231</u>	600			
						N/A	N/A			
N/A	RM0009-04	I	<u>I</u>	PC	1	<u>82971</u>	Bulk	N/A	N/A	N/A
						N/A	Bulk			
	RM0009-04	I	<u>I</u>	PC	1	<u>82971</u>	Bulk			
						N/A	Bulk			
N/A	MM1538-01	A	<u>A</u>	PC	500	<u>000278970</u>	500			
						N/A	N/A			
N/A	MM1537-01	A	<u>A</u>	PC	1000	<u>000284209</u>	1066			
						N/A	N/A			

Notes:

Date Printed: 01/22/2024 / 13:55:24

Page: 3 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of

## Production Order: 500000297267

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
M/A N/A	MM1536-01	B	<u>B</u>	PC	500	<u>0000281412</u>	<u>N/A</u>	<u>N/A</u>		
	MM0180-01	E	<u>E</u>	PC	500	<u>0000282490</u>	<u>N/A</u>	<u>N/A</u>		
	MM0179-01	D	<u>D</u>	PC	500	<u>0000274172</u>	<u>N/A</u>	<u>N/A</u>		
	MM0178-01	E	<u>E</u>	PC	500	<u>0000276174</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
	MM0177-01	C	<u>C</u>	PC	500	<u>0000284208</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
	MM0176-01	D	<u>D</u>	PC	500	<u>0000281411</u>	<u>N/A</u>	<u>N/A</u>		
	MM0074-01	G	<u>G</u>	PC	500	<u>0000295125</u>	<u>N/A</u>	<u>N/A</u>		

Notes:

N/AN/AN/A

Date Printed: 01/22/2024 / 13:55:24

Page: 4 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of

**Production Order: 500000297267**



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
MB	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	24 Jan 24	PY46
150	CATASY01  Catheter Assembly 1    Major and Minor Mandrel Assembly	Major and Minor Mandrel Assembly	500	0	24 Jan 24	CL30 Y014 JY90

Notes:

N/A

N/A

N/A

Date Printed: 01/22/2024 / 13:55:24

Page: 5 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
MP	Confirmation Reqd(Milestone )		N/A	N/A	N/A	N/A
200	CATASY01  Catheter Assembly 1  	Loading Braid Stock  Loading Braid Stock  Confirmation Reqd(Milestone )	500	0	24Jan24	STCk nys5
250	CATASY01  Catheter Assembly 1  	Trim Braid Wire at Proximal End	500	0	24Jan24	AS31

Notes:

N/A  
N/A  
N/A

Date Printed: 01/22/2024 / 13:55:24

Page: 6 of 18



SA0155-01

CREGANNA MEDICAL  
is part of

**Production Order: 500000297267**



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
M18	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	O  24 Jun 24	CP32 GS22 V078	
350	CATASY01  Catheter Assembly 1	Load Tubing	500	O  24 Jun 24	CL05 GS22 V078	

Notes:

N/A

N/A

N/A

Date Printed: 01/22/2024 / 13:55:24

Page: 7 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



Production Order: 500000297267



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	CATASY01 Catheter Assembly 1  Reflow  Confirmation Reqd(Milestone)	Reflow	500	0	24JUN24	JY47 SH04
450	CATASY01 Catheter	FEP Removal	500	0	24JUN24	JY90 PM96

Notes:

Date Printed: 01/22/2024 / 13:55:24

Page: 8 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
	Assembly 1 					
	N/A FEP Removal Confirmation Reqd(Milestone )		N/A	N/A	N/A	N/A
500	CATASY01 Catheter Assembly 1 	In-process Inspection and Rework Material Consumed: Part #: 100-1153-01 Batch #: 87656 Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	494	DF-1 EH-1 EW-11 OF-11 ⑥	12/21 266 TD45 LL61 VC09 CB81 24 Jun 2024	V291 T P L V C B
	N/A In-process Inspection and Rework Confirmation Reqd(Milestone )		N/A	N/A	N/A	N/A
	N/A N/A		N/A	N/A	N/A	N/A
	Notes:			N/A	N/A	N/A
				N/A	N/A	N/A
				N/A	N/A	N/A

Date Printed: 01/22/2024 / 13:55:24

Page: 9 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of

# Production Order: 500000297267



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 )	490	SKV-1 DL-111 (4)	24 Jan 2024	HT72 MV78 VA96 FB01 AX82
600	CATASY01  Catheter Assembly 1    Distal Tip Assembly  Confirmation	Distal Tip Assembly	489	DL -1 (1)	24 Jan 2024	HT72 ML60 FB01 D429 AX82 RG23

Notes:

NA

NA

NA

Date Printed: 01/22/2024 / 13:55:24

Page: 10 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
M1P	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	24Jun24	ML38 AX82
700	CATASY01  Catheter Assembly 1    Tipping  Record Tipping Oven Information: TMI: 0521 Cal Due: 31 May 24 TMI: 2083C Cal Due: 31 May 24 TMI: 0386 Cal Due: 31 May 24 TMI: 0936A Cal Due: 31 May 24	Tipping  Record Tipping Oven Information: TMI: 0521 Cal Due: 31 May 24 TMI: 2083C Cal Due: 31 May 24 TMI: 0386 Cal Due: 31 May 24 TMI: 0936A Cal Due: 31 May 24	489	0	24Jun24	ML38 RS 23

Notes:

N/A	N/A	N/A
N/A	N/A	N/A

Date Printed: 01/22/2024 / 13:55:24

Page: 11 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
M1P	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 #: RMU001-01 Batch #: 82453 Qty: 10 Part #: RM0607-01 Batch #: 74662 Qty: 5 Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A	488	EH-1	DX35 mm02 STX48 Hr36  24Jun24		
800	CATASY01  Catheter Assembly 1    Major Mandrel Removal	480	ACD-HHHII	SG88 SS44  24Jun24		

Notes:

N/A

N/A

N/A

Date Printed: 01/22/2024 / 13:55:24

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
	Major Mandrel Removal  Confirmation Reqd(Milestone )	MA  MA	MA	MA	MA	MA
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. pass 2. pass 3. pass 4. pass 5. pass	480	0	24 Jan 24	Y936 SS52
900	QUALITY1  Quality Inspection & Review	Quality Inspection and Review Perform Quality Inspection per QIP Document #3107610 Record Data in SAP ROS	MA	MA	MA	SH04 ML65 ML46 MV33

Notes:

MA  
MA  
MA

Date Printed: 01/22/2024 / 13:55:24





Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Quality Inspection & Review  Confirmation Reqd(Milestone )	<p>Re-Inspect after re-work.</p> <p>Required Inspection Visual/OD Inspection Record Inspection Data in SAP ROS Record Laser Micrometer Information:</p> <p>TMI: 0700-01 Cal Due: N/A</p> <p>TMI: N/A Cal Due: N/A</p> <p>Material Consumed:</p> <p>Part #: 1000-1153-01 Batch #: 87656 Qty: N/A</p> <p>Part #: RMU001-01 Batch #: 32453 Qty: 16</p> <p>Part #: RMU0607-01 Batch #: 24662 Qty: 5</p> <p>Part #: RMU158-01 Batch #: 58497 Qty: 2</p> <p>Part #: N/A Batch #: N/A Qty: N/A</p>	① 3 433	ACD-1 MAR-1 DEL-HHHH DIS-HHHH #GUS-11 #60S-1 #70S-11 #90S-11 #5-4S-11 FH-1111 WK-1111 24Jan24	47	XLA1 KL67 L55 PY46
950	QUALITY1  Quality Inspection & Review	<p>Quality Inspection &amp; Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information:</p> <p>TMI: N/A Cal Due: N/A</p> <p>Record Caliper Information:</p>	N/A	N/A	N/A	N/A

Notes:

N/A

N/A

N/A

Date Printed: 01/22/2024 / 13:55:24

Page: 14 of 18



SA0155-01

① 6155 24Jan24  
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	 <b>Quality Inspection &amp; Review</b>   <b>Confirmation Reqd(Milestone )</b>	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>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>	411	DIS(P)HHH1 STR-HHHHH 111 DIS-111	24 Jan 24 (22)	XL91 KL67
1000	<b>QUALITY1</b>   <b>Quality Inspection &amp; Review</b>   <b>Confirmation Reqd(Milestone )</b>	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>0889 D</u> Cal Due: <u>30 SEP 24</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30 SEP 24</u>	394	LT - HHHHH 1111 OAL-111	24 Jan 24 (17)	XL91 KL67 SS44 LL61

Notes:

N/A

N/A

N/A

Date Printed: 01/22/2024 / 13:55:24

Page: 15 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	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	377	SCR-1 (T) DL-1 (T) FM-1 (T) DIS-1 (T) MP-1 EH-1 (17)	24 Jan 24	SV43 XN26
1100	CATASY01  Catheter Assembly 1    Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initials/Date): <u>KPZ</u> <u>24 Jan 24</u>	N/A	N/A	24 Jan 24 KPZ	
Notes:						
N/A						
N/A						
N/A						

Date Printed: 01/22/2024 / 13:55:24

Page: 16 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of

**Production Order: 500000297267**



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	377	0	25Jan24	M/28

Notes:

N/A

N/A

N/A

Date Printed: 01/22/2024 / 13:55:24

Page: 17 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



Production Order: 500000297267



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

Material: SA0155-01 Rev F

Batch Number: 0000297267

By: M/88

Date: 25 Jan 24

Reviewed By:

RB29

Date:

26 JAN 24

Notes:

N/A

N/A

N/A

Date Printed: 01/22/2024 / 13:55:24

Page: 18 of 18



SA0155-01

CREGANNA  
MEDICAL  
is part of



Batches to 2024 3228 U14533  
Expiry to 19 Feb 2024 3228 1/1/2024 3228  
CREGANNA MEDICAL is part of



Extend to 22 Nov 2023 3228 1/1/2023 3228  
Batches to 20 Dec 2023 3228 1/1/2023 3228

DEVIATION AUTHORIZATION NUMBER: 2484  
\* See attached email extension to 2484 STEPS  
TS12 24 AUG 23 J228

## DEVIATION AUTHORIZATION FORM ~~Expiry to 23 Oct 2023 3228~~ ~~1/1/2023 3228~~

Requestor Name: Udhesh Kapadnis

Document Number Affected	Revision
3107610	L

  
**Deviation From:**

QIP3107610, Section 8.0 Inspection Requirements (Supplemental Visual Inspection) OP 1050:  
Current QIP3107610 does not state to inspect for the correct extrusion configuration.

**Deviation To:**  
This DA allows addition inspection for correct assembly of extrusion material MM0179-01 and MM1536-01 during performing QIP3107610, Section 8.0 Inspection Requirements (Supplemental Visual Inspection) OP 1050.  
See instructions attached to this DA.

**Justification:** Recently it has been found that operators are incorrectly assembling MM0179-01 and MM1536-01. The event documents in NC-26390, and NC-26426. Only few of experienced inspectors can detect finished unit that contains incorrect extrusion configuration, and inexperienced inspectors may not which potential non-conformance unit sent to customer. Interim correction action has been implemented at OP 250, 300, 350 to detect unit built with out of oriented extrusions. This DA is adding another layer of inspection at final QC inspection to avoid incorrect assembly defects.

Part Number Affected	Revision
SA0155-01	H

  
**Start Date:** 26 Jul 2023    **End Date:** 25 Aug 2023    **Lot Number:** 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 FMEAs <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Validations <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Details (if any): N/A	<b>Corrective Action Required:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Training Required:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <b>If no, explain:</b>
If yes to any of the above, what controls are being put in place to mitigate the risk.		

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

FM0002.RevF

Deviation Authorization

**CONTROLLED COPY**

① UK55, 23JW 2023



Group Training Record

DA	2484 ①
----	-----------

DA	2468.
----	-------

#### 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 MM01536-01 type correction TS12 10AUG23

#### CONTROLLED COPY

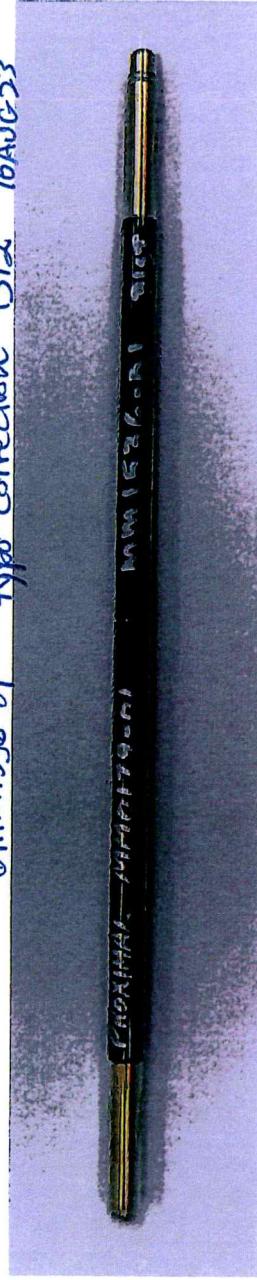


Image- 1

#### Step 1:

- Visually locate the MM0180-01 (Vestamid) transition to MM0179-01 on the completed part approximately 9.75" from the distal end using magnification light 2.25X minimum.
- Align the fixture MM0179-01 extrusion proximal end to the Vestamid transition on completed part. (See image 2)



Image- 2

- Visually verify the MM0179-01 distal end of the fixture is approximately at the same location on the completed part. (See image 3)

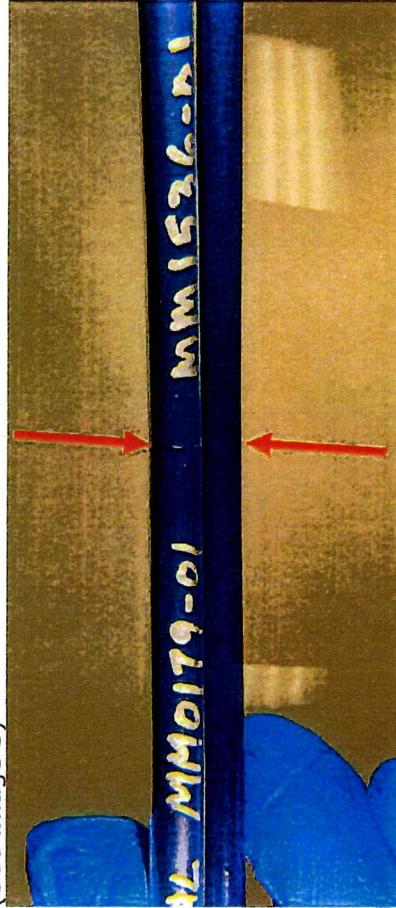
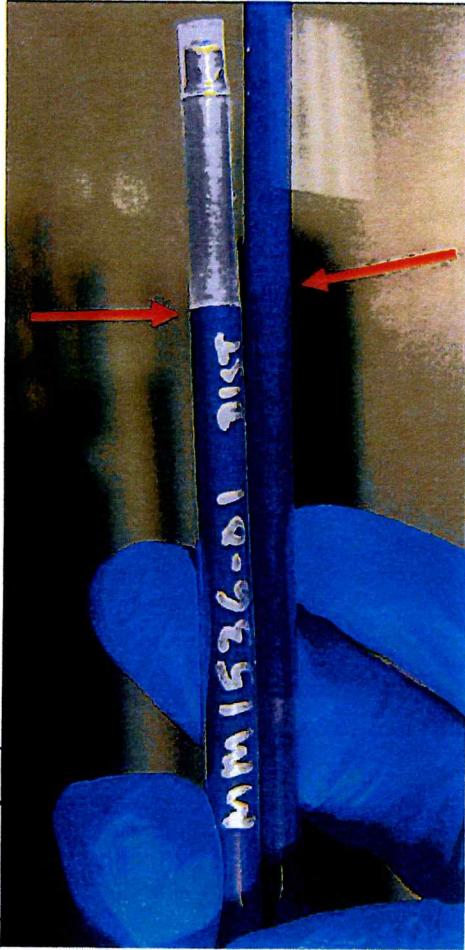


Image- 3

- Scrap the part if the transition is not approximately aligned. Save the scrapped parts for Engineer review.
- If the part transition is aligned, move to Step 2.

**Step 2:**

- Visually verify the MM1536-01 distal end of the fixture is approximately at the same location on the completed part. (See image 4)



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

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

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

Entered to HENNAH 3228 12/15/2023  
Entered to 13 Feb 2024 3228 V4/1/2024

**CONTROLLED COPY** DEVIATION AUTHORIZATION NUMBER: DA2564

**CREGANNA**  
MEDICAL  
is part of



## DEVIATION AUTHORIZATION FORM

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

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



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

PRODUCTION ORDER# 500000297267

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10942	44	4:14 pm	430	Sy47	23Jan24	4:26 pm	415	Sy47	23Jan24	16
Tm10942	44	4:45 pm	430	SH85	23Jan24	4:57 pm	415	SH85	23Jan24	16
Tm10942	44	6:14 pm	430	CL30	23Jan24	6:26 pm	415	SH85	23Jan24	16
Tm10942	44	6:46 pm	430	SH85	23Jan24	6:58 pm	415	SH85	23Jan24	16
Tm10942	44	7:15 pm	427	SH85	23Jan24	7:25 pm	415	SH85	23Jan24	16
Tm10942	44	7:44 pm	429	SH85	23Jan24	7:56 pm	415	SH85	23Jan24	16
Tm10942	44	8:47 pm	430	SH85	23Jan24	8:59 pm	415	SH85	23Jan24	16
Tm10942	44	9:25 pm	430	SH85	23Jan24	9:37 pm	415	SH85	23Jan24	16
Tm10942	44	9:54 pm	427	SH85	23Jan24	10:06 pm	415	SH85	23Jan24	16
Tm10942	44	10:23 pm	430	SH85	23Jan24	10:45 pm	415	SH85	23Jan24	16
① Tm10942	44	11:05 pm	428	SH85	23Jan24	11:17 pm	415	Sy47	23Jan24	16
Tm10942	44	11:40 pm	430	Sy47	23Jan24	11:52 pm	415	Sy47	23Jan24	16

① V078 23Jan24



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

**PRODUCTION ORDER#** 500000297267

OP 400



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

PRODUCTION ORDER# 500000297267

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10745	44	4:27pm	430	SH85	23Jan24	4:39pm	415	SH85	23Jan24	16
Tm10745	44	5:12pm	430	SH85	23Jan24	5:24pm	415	SH85	23Jan24	16
Tm10745	44	6:38pm	430	SH85	23Jan24	6:42pm	415	SH85	23Jan24	16
Tm10745	44	7:05pm	427	SH85	23Jan24	7:17pm	415	SH85	23Jan24	16
Tm10745	44	7:57pm	429	SH85	23Jan24	7:59pm	415	SH85	23Jan24	16
Tm10745	44	8:01pm	429	SH85	23Jan24	8:13pm	415	SH85	23Jan24	16
Tm10745	44	9:08pm	430	SH85	23Jan24	9:20pm	415	SH85	23Jan24	16
Tm10745	44	9:40pm	428	SH85	23Jan24	9:52pm	415	SH85	23Jan24	16
Tm10745	44	10:22pm	430	SH85	23Jan24	10:34pm	415	SH85	23Jan24	16
Tm10745	44	10:49pm	428	SH85	23Jan24	11:01pm	415	SH85	23Jan24	16
Tm10745	44	12:00Am	429	Sy47	24Jan24	12:12Am	415	Sy47	24Jan24	16
Tm10745	44	12:22Am	427	SH85	24Jan24	12:54Am	415	SH85	24Jan24	16

① AT39 23Jan24



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

**PRODUCTION ORDER#** 500000297267

OP 400



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

PO #: 50000297267 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	HHH HHH HHH	16
MP	Micropores	N/A	0
SCR	Scratch	N/A	0
SKV	Skive Marks	HHH//	8
VD	Voids	N/A	0
N/A	N/A	N/A	0
Inspected By (Sign and Date):		 23 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 #: 500000297267 OP #: 500 Shift #: 2nd

Total Parts Reworked:		<u>30</u>	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	<u>n/a</u>	<u>n/a</u>
EH	Exposed Hypotube	<u>n/a</u>	<u>n/a</u>
EW	Exposed Wire	<u>     </u>	<u>17</u>
MP	Micropores	<u>n/a</u>	<u>0</u> <del>+</del> <u>n/a</u>
SCR	Scratch	<u>///</u>	<u>3</u>
SKV	Skive Marks	<u>   </u>	<u>5</u>
VD	Voids	<u>   </u>	<u>7</u>
<u>n/a</u>	<u>n/a</u>	<u>n/a</u>	<u>n/a</u>
Inspected By (Sign and Date):		<u>Vanneej Lor</u> <u>23 Jan 24</u>	

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

Data Uploaded for Engineering Review (Check):  O v291 23 Jan 24



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

PO #: 500000297267 OP #: 500 Shift #: 1st

Total Parts Reworked:		52	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube		17
EW	Exposed Wire		30
MP	Micropores	N/A	N/A
SCR	Scratch	N/A	N/A
SKV	Skive Marks		2
VD	Voids		3
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		TA38, HL61, VC09 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.

Data Uploaded for Engineering Review (Check):

PO #: 50000297267OP #: 750 Shift #: 2

Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

Total Parts Reworked:		23	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		5
DIM07 US / WC	DIM07 Undersized (Window Closed)		2
EH	Exposed Hypotube		1
g d	glue damage		3
Inspected By (Sign and Date):		DX35 23 Jan 24	

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

Data Uploaded for Engineering Review (Check):



PO #: 50000297267 OP #: 750 Shift #: 2<sup>nd</sup>

Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

Total Parts Reworked:		50	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		43
DIM07 US / WC	DIM07 Undersized (Window Closed)		5
EH	Exposed Hypotube		2
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		Mmo 2	23 Jan 24

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

Data Uploaded for Engineering Review (Check):

PO #: 500000291261OP #: 750 Shift #: 1st

Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

Total Parts Reworked:		29	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		4
DIM07 US / WC	DIM07 Undersized (Window Closed)		5
EH	Exposed Hypotube		5
N/A	Glue , Stopper		15
Inspected By (Sign and Date):		STR48	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):

PRODUCTION ORDER# 500000297267

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM110409	N/A	9:14PM	190°F	SG88	23 Jan 24	10:24pm	190°F	SG88	23 Jan 24	55
TM12036	N/A	9:45pm	190°F	SG88	23 Jan 24	10:55pm	190°F	SG88	23 Jan 24	40
TM110409	N/A	10:22pm	190°F	SG88	23 Jan 24	11:32pm	190°F	SG88	23 Jan 24	48
TM12036	N/A	11:02pm	190°F	SG88	23 Jan 24	12:42AM	190°F	SG88	24 Jan 24	37
TM110409	N/A	12:16AM	190°F	SG88	24 Jan 24	1:26AM	190°F	SG88	24 Jan 24	53
TM12036	N/A	1:00AM	190°F	SG88	24 Jan 24	2:10AM	190°F	SG88	24 Jan 24	43
TM110409	N/A	4:30am	190°F	K155	24 Jan 24	5:40am	190°F	K155	24 Jan 24	36
TM12036	N/A	5:15am	190°F	SSH44	24 Jan 24	6:25am	190°F	SSH44	24 Jan 24	41
TM110409	N/A	5:50am	190°F	SSH44	24 Jan 24	7:00am	190°F	SSH44	24 Jan 24	33
TM12036	N/A	6:40am	190°F	SSH44	24 Jan 24	7:50am	190°F	SSH44	24 Jan 24	62
TM110409	N/A	7:10am	190°F	OS21	24 Jan 24	8:20am	190°F	OS21	24 Jan 24	32
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



PO #: 500000297267

OP #: 900 Shift #: 2nd

Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

Total Parts Reworked:		54	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	NA	NA
EH	Exposed Hypotube	11	2
EW	Exposed Wire	HH	5
MP	Micropores	NA	NA
SCR	Scratch	HHH HHH HHH HHH HHH HHH HHH HHH 11	42
SKV	Skive Marks	111	3
VD	Voids	HHH 1	6
DIM01 US	DIM01 OD Undersized	NA	NA
DIM06 US	DIM06 OD Undersized	HHH HHH 1	11
DIM06 OS	DIM06 OD Oversized	1	1
DIM09 US	DIM09 OD Undersized	NA	NA
Inspected By (Sign and Date):		Mil, See H	23 Jan 24

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

Data Uploaded for Engineering Review (Check):

PO #: 50000297267OP #: 900 Shift #: 2

Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

Total Parts Reworked:		18	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube	N/A	0
EW	Exposed Wire		8
MP	Micropores	N/A	0
SCR	Scratch		15
SKV	Skive Marks	N/A	0
VD	Voids	N/A	0
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized	N/A	0
DIM06 OS	DIM06 OD Oversized	N/A	0
DIM09 US	DIM09 OD Undersized	N/A	0
Inspected By (Sign and Date):		23 Jan 29	

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):



500000297267

**PO #:** 50002917267  
PY46 25 Jan 24

OP #: 900 Shift #: 1st

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):**

- 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	25.9	25.37	27.46	25.94	27.98	28.45	27.89	26.25	26.77	25.95	26.796	1.0728384	4.378	22.0991135	8.542	PASS
Seg B	61.93	58.59	64.8	64.92	63.68	61.69	64.08	61.07	62.2	62.77	62.573	1.9281197	3.981	54.8971555	8.542	PASS
Seg C	75.02	75.3	76.29	76.33	76.66	79.32	76.75	75.5	77.12	76.3	76.459	1.2088328	2.911	72.9400878	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 #: 500000297267

Date:25JAN24

Inspector Name:Andrew Wipf

Equipment ID: TMIO311B

Cal Due Date: 27 OCT 24


25Jan24