

Production Order: 500000303482



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>AL71 5:30pm 04Feb24</u> Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>K002 11:30am 05Feb24</u> Xc31 05FEB24 Xc31 10:30pm 05FEB24 Record Dryer Shelf #: <u>N/A</u></p>				KL27 01Feb24

Notes: DA2564, 2484, DA2594

N/A

N/A

Date Printed: 02/01/2024 / 14:07:41

Page: 1 of 18



SA0155-01

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Production Order: 500000303482



Production Order Document

Production Order Qty: 500

PC
Sheet: 1 of 1

Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details						Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	RM0158-01	E	<u>E</u>	PC	200	0000271063 58497	40 50			
		1000-1153-01	A	<u>A</u>	PC	594	81054 87657 87661 87669 87668	100 100 100 200 200			
		1000-2053-01	A	<u>A</u>	PC	500	0000287543 0000248640	300 200			
		MM1537-02	A	<u>A</u>	PC	500	0000288401	500	N/A	N/A	N/A
		TL0167-02	E	<u>E</u>	PC	70	N/A	Bulk			
		TL0165-05	J	<u>J</u>	PC	5	N/A	Bulk			
		TL0165-03	J	<u>J</u>	PC	5	N/A	Bulk			
							N/A	Bulk			

Notes:

NIA

N/A

N

Date Printed: 02/01/2024 / 14:07:41

Page: 2 of 18



SA0155-01

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Production Order: 500000303482



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
		141967-01	02	02	PC	500	85502	500		
							N/A	N/A		
		RM7349-02	C	C	PC	543	82857	500		
							82861	100		
		RM7348-01	C	C	PC	500	84588	400		
							① 85428	100		
		RM4001-01	B	B	PC	125	82434	20		
							82457	100		
		RM0607-01	D	D	PC	56	74663	60		
							N/A	N/A		
		RM0498-01	C	C	PC	500	0000287643 0000287644	59 398		
							0000287645	26		
		RM0009-04	I	I	PC	1	88992	Bulk		
							N/A	Bulk		
		RM0009-04	I	I	PC	1	88992	Bulk		

Notes:

N/A

N/A

N/A

Date Printed: 02/01/2024 / 14:07:41

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Page: 3 of 18



SA0155-01

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Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	MM1538-01	A	A	PC	500	0000290562	N/A	Bulk		
		MM1537-01	A	A	PC	1000	0000290561	N/A			
		MM0177-01	C	C	PC	500	0000284208	N/A			
		MM0180-01	E	E	PC	500	0000282490	500			
		MM0178-01	E	E	PC	500	0000276174	N/A			
		MM0176-01	D	D	PC	500	0000271050	500			
		MM0074-01	G	G	PC	500	0000288411	40			
							0000281411	40			
							0000297032	519			
							N/A	N/A			

Notes:

N/A

N/A

N/A

Date Printed: 02/01/2024 / 14:07:41

Page: 4 of 18



SA0155-01

CREGANNA
MEDICAL
is part of

Production Order: 500000303482



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	P/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	06Feb24	KL95 N078
	Line Clearance					
	Confirmation Reqd(Milestone)					
150	CATASY01 Catheter Assembly 1 	Major and Minor Mandrel Assembly	500	0	06Feb24	AF54 JY90 SH23 pm 96
	Major and Minor Mandrel Assembly					
Notes:						
N/A						
N/A						
N/A						

Date Printed: 02/01/2024 / 14:07:41

Page: 5 of 18



SA0155-01

CREGANNA
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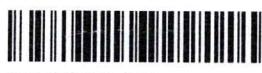
Material: SA0155-01 Rev F

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
200	CATASY01 Catheter Assembly 1 	Loading Braid Stock Loading Braid Stock Confirmation Reqd(Milestone)	500	0	06Feb24 VPC2 SX11 CP22 DY35	
250	CATASY01 Catheter Assembly 1 	Trim Braid Wire at Proximal End	500	0	06Feb24 MV50 SX11 CLOS NY35	

Notes:
 N/A
 N/A
 N/A

Date Printed: 02/01/2024 / 14:07:41

Page: 6 of 18



SA0155-01

CREGANNA
MEDICAL
is part of

Production Order: 500000303482



Production Order Document
Production Order Qty: 500

PC

Sheet: 1 of 1

Material: SA0155-01 Rev F

Opn No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Trim Braid Wire at Proximal End Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
300	CATASY01 Catheter Assembly 1  Insert Cut Hypo Tube Insert Cut Hypo Tube Confirmation Reqd(Milestone)	Insert Cut Hypo Tube	500	0	06Feb24	VU25 LM WB AS31 GS22 ST96
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0	06Feb24	C497 DY29 SK11 Trn SH23 GS22

Notes:

N/A

N/A

N/A

Date Printed: 02/01/2024 / 14:07:41

Page: 7 of 18



SA0155-01

CREGANNA
MEDICAL
is part of



Production Order: 500000303482



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)	N/A	N/A	N/A	N/A	N/A
400	CATASY01 Catheter Assembly 1 Reflow Confirmation Reqd(Milestone)	Reflow	500	0	06Feb24 NK62 SX11 SY47 V078 SH85 Pm 96	
450	CATASY01 Catheter	FEP Removal	500	0	06Feb24 V291 TRW A139 JY90 PM 96	

Notes:

N/A
N/A
N/A

Date Printed: 02/01/2024 / 14:07:41

Page: 8 of 18



SA0155-01

CREGANNA
MEDICAL
is part of



Production Order: 500000303482



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 Material Consumed: Part # 1000-1153 Batch #: 87661 Qty: 10 Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A Part #: N/A Batch #: N/A Qty: N/A		483	EW-447 1/1 WT-1 OF-441 1/1	06 Feb 24 LL61 VCO9 TA36	V291 P260
	In-process Inspection and Rework Confirmation Reqd(Milestone)	N/A	N/A	N/A	N/A	N/A
	Notes:					

Date Printed: 02/01/2024 / 14:07:41



SA0155-01

Production Order: 500000303482



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	472	MAH - HTT DL - 1 HTT ⑪	06 Feb 24	ML38 Y936 (TRN) MU78 VA96 AX82 DY29 FB01 RS23
600	CATASY01 Catheter Assembly 1 Distal Tip Assembly Confirmation	Distal Tip Assembly	472	○	06 Feb 24	ML60 VA96 AX82 PH59 FB01

Notes:

n/a

n/a

n/a

Date Printed: 02/01/2024 / 14:07:41

Page: 10 of 18



SA0155-01

CREGANNA MEDICAL
is part of



Production Order: 500000303482



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	Reqd(Milestone)		MA	MA	MA	MA
650	CATASY01 Catheter Assembly 1 	Loading Heat Shrink	472	0	06 Feb 24	PP40 AX82 PH59 FB01
	Loading Heat Shrink					
	Confirmation Reqd(Milestone)					
700	CATASY01 Catheter Assembly 1 	Tipping Record Tipping Oven Information: TMI: <u>10521</u> Cal Due: <u>31 MAY 24</u> TMI: <u>10524</u> Cal Due: <u>31 MAY 24</u> TMI: <u>1053C</u> Cal Due: <u>31 MAY 24</u> TMI: <u>0386</u> Cal Due: <u>31 May 24</u> Tipping	472	0	06 Feb 24	PP40 STX48 HV36 RS 23
Notes:						
<i>MA</i>						
<i>MA</i>						
<i>MA</i>						

Date Printed: 02/01/2024 / 14:07:41

① TM10936 A
AT39 06 Feb 24

Page: 11 of 18



CREGANNA MEDICAL
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Material: SA0155-01 Rev F

PC
Sheet: 1 of 1

Cpr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
P/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 #: 82457 Qty: N/A Part #: RM6007-01 Batch #: 74663 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	471	EH-1	mm02 SV46 STX48 Hv36 06 Feb 2024	
800	CATASY01 Catheter Assembly 1 	Major Mandrel Removal	459	ACD-LH11 44	SG88 SS44 5552 06 Feb 2024	
Notes:						
<i>N/A</i>						
<i>N/A</i>						

Date Printed: 02/01/2024 / 14:07:41

Page: 12 of 18



SA0155-01

CREGANNA
MEDICAL
is part of

Production Order: 500000303482



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	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>	458	SKU -1	06Feb24	SS52 ML65
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	MV33 HT72 ST04
Notes:						
N/A						
N/A						
N/A						

Date Printed: 02/01/2024 / 14:07:41

Page: 13 of 18



SA0155-01

CREGANNA
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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:</p> <p>TMI: <u>0700-01</u> Cal Due: <u>N/A</u></p> <p>TMI: <u>0700-01</u> Cal Due: <u>31 May 24</u></p> <p>TMI: <u>N/A</u> Cal Due: <u>N/A</u></p> <p>Material Consumed:</p> <p>Part #: <u>Part#000-01</u> Batch #: <u>82434</u> Qty: <u>N/A</u></p> <p>Part #: <u>1000-1153-01</u> Batch #: <u>87668</u> Qty: <u>N/A</u></p> <p>Part #: <u>RM0607-01</u> Batch #: <u>74663</u> Qty: <u>N/A</u></p> <p>Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u></p> <p>Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u></p>	413	<p>DIS-4H II EW-4H ①</p> <p>EW-1H #70S-4H #90S-1H</p> <p>DL-1H</p> <p>DEL-1H</p> <p>WT-1H</p> <p>#5US-4H</p> <p>#6US-4H</p> <p>#6US-4H</p>	06Feb24	DY29 KT29 XL91 KL67
950	QUALITY1 Quality Inspection & Review	<p>Quality Inspection & Review Borescope Inspection Record Inspection Data in SAP ROS Record Tip Gage Information:</p> <p>TMI: <u>50713-B</u> Cal Due: <u>12 Apr 24</u></p> <p>Record Caliper Information:</p>	N/A	N/A	N/A	N/A

Notes:

N/A

N/A

N/A

Date Printed: 02/01/2024 / 14:07:41

Page: 14 of 18



SA0155-01

OP146 06 Feb 24

CREGANNA
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Production Order: 500000303482

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)	TMI: 50317 Cal Due: 31 Aug 24 Record DIM02 Go/No-Go Gage Information: TMI: 0691 Cal Due: 30 Sep 25 TMI: 0692 Cal Due: 30 Sep 25 Record DIM02 Inspection Results N = 54: Pass: 54 Fail: 0	398	DIS - HTT (x2) HTT ST2-111 DIS-1	06 Feb 24	OS21 XL91 KL67
1000	QUALITY1 Quality Inspection & Review Confirmation Reqd(Milestone)	Quality Inspection & Review Leak Test Record Inspection Data in SAP ROS Record Leak Tester Information: TMI: 1056 Cal Due: 30 May 24 Record Length Gage Information: TMI: 08896 Cal Due: 31 Sep 24 Record Calibrated Ruler Information: TMI: 0629 Cal Due: 30 Sep 24	388	LT-HTT HTT	06 Feb 24	SSH4 XL91 KL67

Notes:

N/A

N/A

N/A

Date Printed: 02/01/2024 / 14:07:41

Page: 15 of 18

OPX46 06 Feb 24



SA0155-01

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Production Order: 500000303482



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	350	SCR - HN (H161) VD - HN (1) DIS - H11 Mar - 11 DISC - 11 KNK - 11 RDG - 1 Del - 1 DL - 1 Fm - 1	07Feb24 (30)	SV43 XN26 TRAD (TRN) KY88
1100	CATASY01 Catheter Assembly 1  Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initials/Date): KP02 07Feb24	N/A	N/A	07Feb24	KP02
Notes:						
<i>N/A</i>						
<i>N/A</i>						
<i>N/A</i>						

Date Printed: 02/01/2024 / 14:07:41

Page: 16 of 18



SA0155-01

① XN26 06Feb24

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Production Order: 500000303482



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	358	0	07Feb24	mmvjt

Notes:

N/A

N/A

N/A

Date Printed: 02/01/2024 / 14:07:41

Page: 17 of 18



SA0155-01

CREGANNA
MEDICAL
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Production Order: 500000303482



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

Material: SA0155-01 Rev F

Batch Number: 0000303482

By: MMY7

Date: 07Feb24

Reviewed By:

RB29

Date:

09Feb24

Notes:

N/A

N/A

N/A

Date Printed: 02/01/2024 / 14:07:41

Page: 18 of 18



SA0155-01

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EX-102 BULLDOGS + DOGS 28 19 Feb 1984 RECEIVED BY
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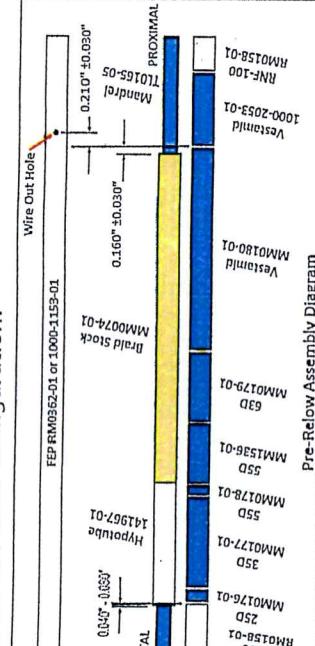
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DEVIATION AUTHORIZATION NUMBER: 2484
K See attached email extension to 2481

TSU
24 AUG 23
to 23 OCT 23

CONTROLLED COPY

Requestor Name: Udhesh Kanadnis

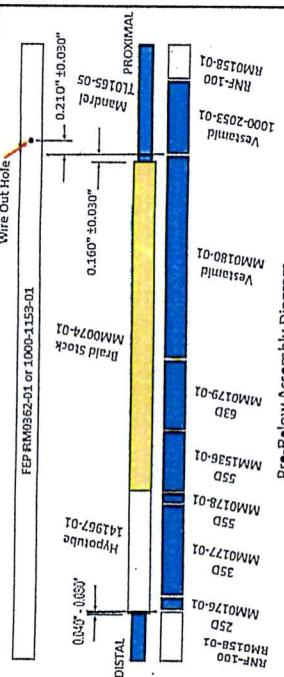
Requestor Name:	Udhesha Kapadnis		
Document Number Affected	3107610	Revision	L
Deviation From:			
<p>QIP3107610, Section 8.0 Inspection Requirements (Supplemental Visual Inspection) OP 1050:</p> <p>Current QIP3107610 does not state to inspect for the correct extrusion configuration.</p>			
Deviation To:			
<p>This DA allows addition inspection for correct assembly of extrusion material MM0179-01 and MM1536-01 during performing QIP3107610, Section 8.0 Inspection Requirements (Supplemental Visual Inspection) OP 1050.</p> <p>See instructions attached to this DA.</p>			
			

Deviation From:

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

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

See instructions attached to this DA
Regulations (Supplemental Visual)



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) QD 1050

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

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 OC inspection to avoid incorrect

Part Number Affected	Revision	
SA0155-01	H	
Start Date:	End Date:	Lot Number:
26 Jul 2023	25 Aug 2023	N/A

Simpler Accounts - 1

Risk Assessment: Is there any potential risk(s) that may occur as a result of the proposed deviation including the following:
 Control Plans Yes No FMEA's Yes No Validations Yes No
Details (if any): N/A

If yes to any of the above what controls are being put in place to mitigate?

Corrective Action Baseline: Yes No

f no, explain: No corrective action is required for this event as there are no changes to the current process, consumption of material, or how the product is produced. This added inspection guidelines are to avoid incorrect

Training Required: Yes No **If no available:**

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

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① UK55, 23JW 2023

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DA

2484
2468

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** **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)

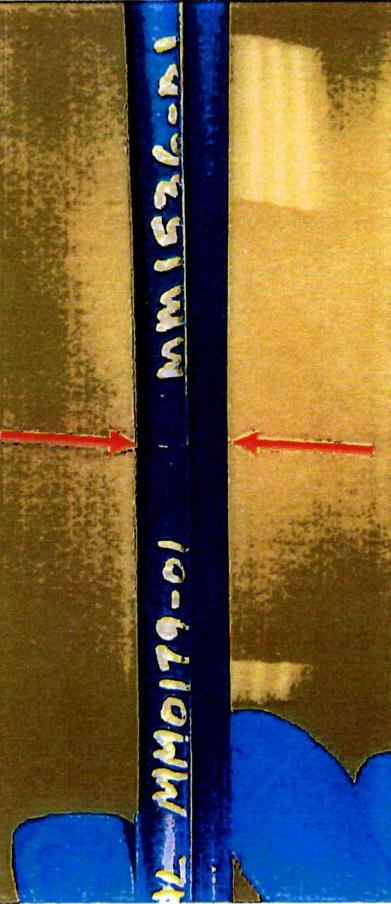


Image- 3

- 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.

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

Image - 5

Beta to Hemant 328 1/1/2023
Beta to 13 Feb 2024 328 1/4/2024

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DEVIATION AUTHORIZATION FORM

Requestor Name:	Krishna Selvaraj		
Document Number Affected	Revision	Revision	
Doc #3005206 (MPI0238)	BP	BP	
Deviation From:	Deviation To:		
Doc #3005206 (Flex Commander MPI0238): OPER850.11: Using a laser micrometer, check the DIM06 outer diameter. Position the laser indicator as close to the distal edge as possible. Start the measurement, then slowly move the part through the laser micrometer until reaching the lower edge of the shoulder.	Doc #3005206 (Flex Commander MPI0238): OPER850.11: Using a laser micrometer at OPER900 (TMI0700-01) , check the DIM06 outer diameter. Position the laser indicator as close to the distal edge as possible. Start the measurement, then slowly move the part through the laser micrometer until reaching the lower edge of the shoulder.		
Justification: TMI0602 lasermic which is currently used in SA0155-01 Flex commander product at OPER850 for Dim 6 inspection has mechanical failure and confirmed as not usable. TMI0700-01 lasermic is used at OPER900 for 100% inspection for Dim 1, Dim 6 and Dim 9. Since TMI0700-01 is already qualified to inspect Dim 6 per ES0647: Laser micrometer equivalency test, there is no additional risk in using TMI0700-01 for OPER850 Dim 6 inspection till TMI0602 issue is resolved.			
Part Number Affected	Revision	Revision	
SA0155-01	H	H	
Start Date:	End Date:	Lot Number:	
16 Nov 23	15 DEC 23	N/A	
Risk Assessment: Is there any potential risk(s) that may occur as a result of the proposed deviation including the following: Control Plans <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No FMEA's <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Validations <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Details (if any): N/A If yes to any of the above, what controls are being put in place to mitigate the risk – N/A			
Corrective Action Required: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No			
If no, explain: This is a temporary change to use TMI0700-01. DA will be removed once the lasermic TMI0602 issues are resolved and accepted for usage.			
Training Required: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If no, explain: N/A			
Title	Approval Name	Approval Signature	Date
Engineering Manager	Jake Stanislowski		16 Nov 2023
Quality Manager	Jay Zabel		16 Nov 2023
Operations Manager	Matthew Benson		16 Nov 2023

DEVIATION AUTHORIZATION FORM

Requestor Name: Udhesh Kapadnis

Document Number Affected	Revision
3005206 (MPI0238)	BQ
SA0155-01 Router	F
QIP3107610	N

Deviation From:

- Move SA0155-01 assemblies to OP900 for visual inspection and Rework after completing process at OP850-Cut to length.
- Perform visual inspection and rework at Op900 as per QIP3107610 Rev N.

Deviation To:

- Move SA0155-01 assemblies to off-line 360° inspection system (TMI2434A) for visual inspection after completing process at OP850-Cut to Length.
- Perform visual inspection by using off-line 360° inspection system (TMI2434A) and verify defects per attached inspection instructions. Move SA0155-01 assemblies to OP900 for visual defect rework and 100% visual inspection per QIP3107610 Rev N.

Justification:

The purpose of this deviation is to collect the inspection data for only 3 standard production lots of SA0155-01 assemblies by using off-line 360° inspection system (TMI2434A). Data collected will be used to access 360° inspection system (TMI2434A) in-line implementation. See attached inspection instructions.
Use of 360° Inspection system (TMI2434A) has very low risk to finished goods quality based on the 3108296 evaluations.

Part Number Affected	Revision	
SA0155-01	F	
Start Date:	End Date:	Lot Number:
12 Jan 2024	11 Feb 2024	N/A

Risk Assessment:

Is there any potential risk(s) that may occur as a result of the proposed deviation including the following:
Control Plans Yes No FMEA's Yes No Validations Yes No
Details (if any):
N/A

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

Corrective Action Required:

Yes No N/A

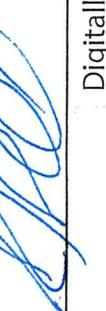
If no, explain:

SA0155-01 lots run with DA for off-line use will provide data to assess 360° Inspection in-line use. Corrective action will be needed when 360° Inspection in-line is approved.

Training Required:

Yes No If no, explain: N/A

CONTROLLED COPY

Title	Approval Name	Approval Signature	Date
Quality Manager	Jay Zabel		12 Jan 2024
Operations Manager	Matt Benson		18 Jan 2024
Engineering Manager	Jake Stanislawski		12 JAN 2024
Edwards Supplier Quality Engineer	Spencer Reynolds	Digitally signed by Spencer Reynolds DN: cn=Spencer Reynolds, email=Spencer_Reynolds@edwards.com Reason: I am approving this document Date: 2024.01.23 10:43:18 -07'00'	

Inspection Procedure

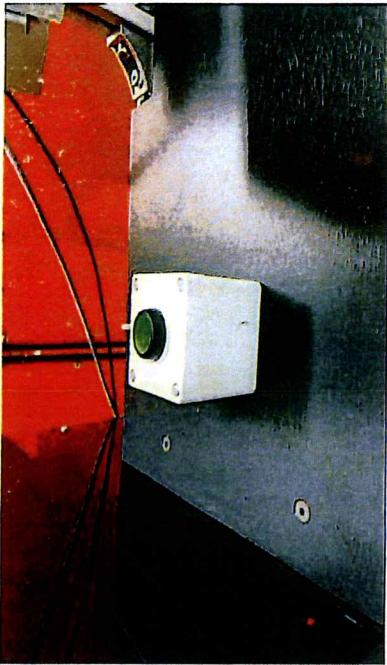
CONTROLLED COPY

Step#	Written Instructions
1.	Get a clean wipe and fold in half. Apply adequate amount (wet enough to wipe the stent area smoothly) of IPA on the top of the wipe.
2.	Wrap the wet wipe around the distal end. Make sure there is no gap between the parts and the wipe.
3.	Wipe the part from the distal end to the end of stent area. Rewrap the part using the dry area on the wipe.
4.	Loads and aligns catheter with stop fixture on load station with the pull wire facing Upward direction.

CONTROLLED COPY

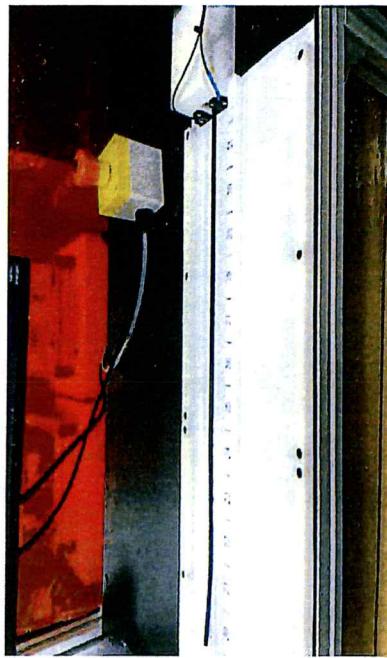
Press the green start button. Machine indexes catheter and inspects for defects.

5.



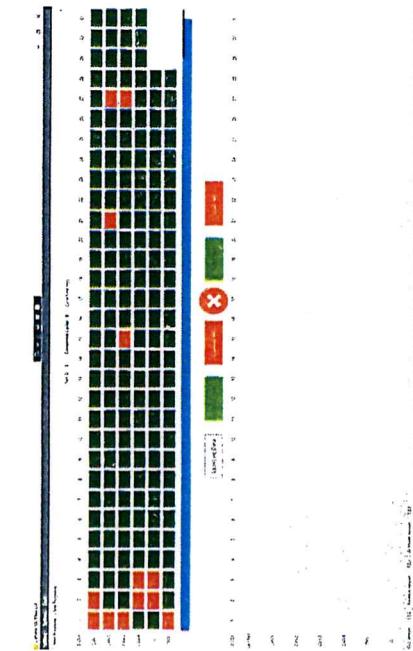
Unload the catheter from unloading station.

6.



Inspection results are displayed on the GUI monitor. Place inspected catheter on index fixture to align GUI defect results.

7.



After aligning GUI defect result with index fixture, inspect defects per 3107610 SA0155-01 QIP for acceptance.

8.
 - Take no action for result determined acceptable.
 - Use cleanroom tape to identify result determined rework.
 - Scrap catheter determined scrap.



Document No: 5105589

FM5104665 Rev: C

Document Type: Manufacturing Form

Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000303482

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10942	44	11:45pm	430	JY90	05 Feb 24	11:57pm	415	JY90	05 Feb 24	16
TM10942	44	12:20AM	430	AT39	06 Feb 24	12:32AM	415	AT39	06 Feb 24	16
TM10942	44	12:45AM	427	Y014	06 Feb 24	12:57AM	415	Y014	06 Feb 24	16
TM10942	44	1:15AM	428	Y014	06 Feb 24	1:27PM	415	SH85	06 Feb 24	16
TM10942	44	1:45AM	430	CL30	06 Feb 24	1:57pm	415	JY47	06 Feb 24	16
TM10942	44	5:15am	430	AX05	06 Feb 24	5:27am	415	AX05	06 Feb 24	16
TM10942	44	5:40am	430	AX05	06 Feb 24	5:52am	415	AX05	06 Feb 24	16
TM10942	44	6:12am	429	KL95	06 Feb 24	6:24am	415	KL95	06 Feb 24	16
TM10942	44	7:45am	430	TA36	06 Feb 24	7:57am	415	TA36	06 Feb 24	16
TM10942	44	8:00am	430	TA36	06 Feb 24	8:12am	415	TA36	06 Feb 24	16
TM10942	44	8:20am	430	KL95	06 Feb 24	8:32am	415	KL95	06 Feb 24	16
TM10942	44	8:48am	430	OS21	06 Feb 24	9:00am	415	OS21	06 Feb 24	16



PRODUCTION ORDER# 500000303482

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10745	44	11:35pm	430	JY90	05 Feb 24	11:47pm	415	JY90	05 Feb 24	16
Tm10745	44	11:55pm	429	JY90	05 Feb 24	12:07AM	415	JY90	06 Feb 24	16
Tm10745	44	12:12AM	428	JY90	06 Feb 24	12:24 AM	415	JY90	06 Feb 24	16
Tm10745	44	12:35AM	428	AT39	06 Feb 24	12:47AM	415	AT39	06 Feb 24	16
Tm10745	44	12:57AM	429	Y014	06 Feb 24	1:09AM	415	SH85	06 Feb 24	16
Tm10745	44	1:30AM	429	SH85	06 Feb 24	1:42AM	415	SH85	06 Feb 24	16
Tm10745	44	1:53AM	429	Sy47	06 Feb 24	2:05AM	415	V078	06 Feb 24	10
Tm10745	44	5:30am	430	AX05	06 Feb 24	5:42am	415	AX05	06 Feb 24	16
Tm10745	44	5:58am	427	AX05	06 Feb 24	6:10am	415	AX05	06 Feb 24	16
Tm10745	44	6:25am	430	AX05	06 Feb 24	6:37am	415	AX05	06 Feb 24	16
Tm10745	44	7:52am	430	KL95	06 Feb 24	8:04am	415	KL95	06 Feb 24	16
Tm10745	44	8:30am	430	0521	06 Feb 24	8:42am	415	0521	06 Feb 24	16

① JY90 06 Feb 24

② P44607 Feb 24



Document No: 5105589

FM5104665 Rev: C

Document Type: Manufacturing Form

Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000303482

OP 400



Document No: 5105589

FM5104665 Rev: C

Document Type: Manufacturing Form

Title: SA0155-01 Reflow Log Sheet Form

PRODUCTION ORDER# 500000303482

OP 400



PO #: 500000303482

OP #: 500 Shift #: 1st

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

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

Data Uploaded for Engineering Review (Check):



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

PO #: 500000303482

OP #: 500 Shift #: 2nd

Total Parts Reworked:		14	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	n/a	n/a
EH	Exposed Hypotube	n/a	n/a
EW	Exposed Wire	1111	7
MP	Micropores	n/a	n/a
SCR	Scratch	111	3
SKV	Skive Marks	n/a	n/a
VD	Voids	1111	4
n/a	n/a	n/a	n/a
Inspected By (Sign and Date):		Varneeg Lor 05 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 #: 50000303482

OP #: 500 Shift #: 2

Total Parts Reworked:		<u>10</u>	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	<u>1</u>	<u>1</u>
EH	Exposed Hypotube	<u>11</u>	<u>2</u>
EW	Exposed Wire	<u> </u>	<u>8</u>
MP	Micropores	<u>N/A</u>	<u>0</u>
SCR	Scratch	<u>N/A</u>	<u>0</u>
SKV	Skive Marks	<u>N/A</u>	<u>0</u>
VD	Voids	<u>N/A</u>	<u>0</u>
<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>0</u>
Inspected By (Sign and Date):		<u>Amber</u> 05 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: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

PO #: 500000303482OP #: 750 Shift #: 2nd

Total Parts Reworked:		8	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		3
DIM07 US / WC	DIM07 Undersized (Window Closed)		3
EH	Exposed Hypotube		2
N/A	N/A	N/A	N/A
Inspected By (Sign and Date):		SV46 05 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):



PO #: 500000303482

OP #: 750 Shift #: 1st

Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

Total Parts Reworked:		138	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		18
DIM07 US / WC	DIM07 Undersized (Window Closed)		20
EH	Exposed Hypotube		48
N/A	Glue - stopper		52
Inspected By (Sign and Date):		Hv 36 06 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# 500000303482

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10409	N/A	4:15am	190°F	K155	06 Feb 24	5:25am	190°F	K155	06 Feb 24	40
TM10409	N/A	5:45am	190°F	K155	06 Feb 24	6:55am	190°F	K155	06 Feb 24	50
TM12036	N/A	6:30am	190°F	K155	06 Feb 24	7:40 am	190°F	K155	06 Feb 24	37
TM10409	N/A	8:10am	190°F	SS44	06 Feb 24	9:20 am	190°F	SS44	06 Feb 24	30
TM12036	N/A	8:50am	190°F	SS44	06 Feb 24	10:00am	190°F	SS44	06 Feb 24	36
TM10409	N/A	9:40am	190°F	SS44	06 Feb 24	10:50am	190°F	SS44	06 Feb 24	40
TM10409	N/A	11:20 am	190°F	K155	06 Feb 24	12:30pm	190°F	K155	06 Feb 24	40
TM12036	N/A	11:55am	190°F	SS44	06 Feb 24	1:05 pm	190°F	SS44	06 Feb 24	37
TM10409	N/A	12:35pm	190°F	0521	06 Feb 24	1:45 pm	190°F	SS44	06 Feb 24	40
TM10409	N/A	2:20 PM	190°F	PM96	06 Feb 24	3:30 pm	190°F	PM96	06 Feb 24	46
TM10409	N/A	3:44 Pm	190°F	SG88	06 Feb 24	4:54pm	190°F	SG88	06 Feb 24	28
TM12036	N/A	4:16pm	190°F	SG88	06 Feb 24	5:26pm	190°F	SG88	06 Feb 24	35
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A



Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 500000303482

OP #: 900 Shift #: 15+

Total Parts Reworked:		110	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	1	1
EW	Exposed Wire		48
MP	Micropores	N/A	N/A
SCR	Scratch		52
SKV	Skive Marks	1	1
VD	Voids		14
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized		19
DIM06 OS	DIM06 OD Oversized	N/A	N/A
DIM09 US	DIM09 OD Undersized	N/A	N/A
Inspected By (Sign and Date):		DY29 P146 KTH7	06 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 #: 50000303482OP #: 900 Shift #: 2nd

Total Parts Reworked:		55	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube		2
EW	Exposed Wire		2
MP	Micropores	N/A	0
SCR	Scratch		13
SKV	Skive Marks	N/A	0
VD	Voids		2
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized		51
DIM06 OS	DIM06 OD Oversized	N/A	0
DIM09 US	DIM09 OD Undersized	N/A	0
Inspected By (Sign and Date):		See H 06 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 #: B00000303482

OP #: 900 Shift #: 2

Total Parts Reworked:		<u>61</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>1</u>	<u>1</u>
EW	Exposed Wire	<u> </u>	<u>13</u>
MP	Micropores	<u>N/A</u>	<u>N/A</u>
SCR	Scratch	<u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u> <u> </u>	<u>68</u>
SKV	Skive Marks	<u>N/A</u>	<u>N/A</u>
VD	Voids	<u> </u>	<u>5</u>
DIM01 US	DIM01 OD Undersized		
DIM06 US	DIM06 OD Undersized		
DIM06 OS	DIM06 OD Oversized		
DIM09 US	DIM09 OD Undersized		
Inspected By (Sign and Date):		<u>HT72 06Feb24</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):

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	26.08	26.98	25.48	28.14	25.76	26.2	25.69	26.89	27.86	29.58	26.866	1.3156764	4.378	21.1059686	8.542	PASS
Seg B	60.93	71.72	61.86	62.47	65.4	65.29	63.44	66.25	63.34	62.82	64.352	3.082801	3.981	52.0793691	8.542	PASS
Seg C	80.47	80.87	80.77	80.37	77.09	72.05	73.9	77.66	76.65	78.55	77.838	3.0303348	2.911	69.0166955	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 #: 500000303482

Date: 07 FEB 24

Inspector Name: LUKASU C. TSHISHIMBI

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24

07 Feb 24
