

Production Order: 500000294400



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:

NC - 29096

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>Am 68 2:00PM 06 Jan 24</u> Record Time Extrusions First Exit Dryer (Initial/Time/Date): <u>Am 68 9:00AM 07 Jan 24</u> Record Dryer Shelf #: <u>n/a</u></p>																						
	Kitting Devices	<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>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>	MM1536-01	B <u>B</u>	PC	500	<u>0000281412</u>	<u>500</u>	N/A	N/A	04JAN24	KL27 27 04JAN24 KL27
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>																			
MM1536-01	B <u>B</u>	PC	500	<u>0000281412</u>	<u>500</u>																			

Notes: DA 2564, 2484

n/a

n/a

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NP N/A		RM0158-01	E	<u>E</u>	PC	200	<u>N/A</u> <u>58497</u>	<u>N/A</u> <u>203</u>			
		1000-1153-01	A	<u>A</u>	PC	594	<u>86759/86760</u>	<u>200/200</u>			
		1000-2053-01	A	<u>A</u>	PC	500	<u>0000268040</u> <u>86785</u>	<u>500</u> <u>200</u>			
		MM1537-02	A	<u>A</u>	PC	500	<u>0000276175</u> <u>N/A</u>	<u>500</u> <u>N/A</u>			
		TL0167-02	E	<u>E</u>	PC	70	<u>N/A</u>	<u>Bulk</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A N/A</u>
		TL0165-05	J	<u>J</u>	PC	5	<u>N/A</u> <u>N/A</u>	<u>Bulk</u>			
		TL0165-03	J	<u>J</u>	PC	5	<u>N/A</u> <u>N/A</u>	<u>Bulk</u>			

Notes:

N/A

N/A
N/A

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		141967-01	02 <u>D2</u>	PC	500	<u>80350/82898</u>	<u>11/68</u>				
						<u>82899</u>	<u>425</u>				
		RM7349-02	C <u>C</u>	PC	543	<u>82834/82835/82849</u>	<u>54/89/03</u>				
						<u>82728</u>	<u>69</u>				
		RM7348-01	C <u>C</u>	PC	500	<u>82851/82872</u>	<u>95/138</u>				
						<u>KL27 04 JAN 24</u>					
						<u>78687</u>	<u>500</u>				
		RM4001-01	B <u>B</u>	PC	125	<u>82104</u>	<u>N/A</u>				
						<u>82432</u>	<u>100</u>				
		RM0607-01	D <u>D</u>	PC	56	<u>71863</u>	<u>100</u>				
						<u>178</u>					
		RM0498-01	C <u>C</u>	PC	500	<u>N/A</u>	<u>N/A</u>				
						<u>0000176395</u>	<u>6</u>				
						<u>0000275488</u>	<u>244</u>				
						<u>0000282569</u>	<u>56</u>				
						<u>0000285399</u>	<u>86</u>				
						<u>0000285480</u>	<u>112</u>				
		RM0009-04	I <u>I</u>	PC	1	<u>82971</u>	<u>Bulk</u>				
						<u>N/A</u>	<u>Bulk</u>				
		RM0009-04	I <u>I</u>	PC	1	<u>82971</u>	<u>Bulk</u>				

Notes:

N/A

N/A

N/A

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0000176395
0000282569
0000285399
0000285480
0000285488

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Opt No.	Planned WorkCenter Description	Operation Details					Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		MM1538-01	A	<u>A</u>	PC	500	<u>0000271052</u>	<u>N/A</u>	<u>Bulk</u>	
		MM1537-01	A	<u>A</u>	PC	1000	<u>0000281413</u>	<u>N/A</u>	<u>N/A</u>	
		MM0177-01	C	<u>C</u>	PC	500	<u>0000278966</u>	<u>500</u>		
		MM0180-01	E	<u>E</u>	PC	500	<u>0000275691</u>	<u>N/A</u>	<u>N/A</u>	
		MM0178-01	E	<u>E</u>	PC	500	<u>0000271050</u>	<u>500</u>	<u>N/A</u>	<u>N/A</u>
		MM0176-01	D	<u>D</u>	PC	500	<u>0000281411</u> <u>0000260706</u> <u>0000271036</u>	<u>500</u> <u>40</u> <u>6</u>	<u>N/A</u>	
		MM0074-01	G	<u>G</u>	PC	500	<u>0000286930</u> <u>0000286923</u>	<u>513</u> <u>32</u>		

Notes:

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MA	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 Line Clearance Confirmation Reqd(Milestone)	500	0 ① 08 Jan 24		AB39
150	CATASY01 Catheter Assembly 1 	Major and Minor Mandrel Assembly Major and Minor Mandrel Assembly	500	0 ① 08 Jan 24		JG92 SD34 YK40 PM96
Notes:						
MA						
N/A						
N/A						

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①
OP446 088 08 Jan 24

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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	N/A
200	CATASY01 Catheter Assembly 1  Loading Braid Stock Loading Braid Stock Confirmation Reqd(Milestone)	Loading Braid Stock	500	0	08Jun24	PY67
250	CATASY01 Catheter Assembly 1  Trim Braid Wire at Proximal End	Trim Braid Wire at Proximal End	500	0	08Jun24	AIGS PL22 TRN RL47

Notes:

N/A

N/A

N/A

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Opn 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 08 Jan 24	ALG7 PL22 TRN BD64	
350	CATASY01 Catheter Assembly 1	Load Tubing	500	0 08 Jan 24	CX63 SN67	

Notes:

N/A

N/A

N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	 Load Tubing Confirmation Reqd(Milestone)					
400	 CATASY01 Catheter Assembly 1 Reflow Reflow Confirmation Reqd(Milestone)	Reflow	500	0	08 Jan 24	SNL67 AM47 TRN QW16 PM96 EN27
450	 CATASY01 Catheter	FEP Removal	500	0	08 Jan 24	SD34 PM 96

Notes:

		MA
		N/A
		N/A

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Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Assembly 1 					
	FEP Removal <i>N/A</i>			<i>N/A</i>	<i>N/A</i>	<i>N/A</i>
	Confirmation Reqd(Milestone)			<i>N/A</i>		
500	CATASY01 Catheter Assembly 1 	In-process Inspection and Rework Material Consumed: Part #: <u>100-1153-01</u> Batch #: <u>86760</u> Qty: <u>N/A</u> Part #: <u>N/A</u> Batch #: <u>N/A</u> Qty: <u>N/A</u>	487	EW - HII 11 TH ① OF - HII 1 <i>(13)</i>	08 Jan 24 <i>LL61 VC09 CB81 TA36</i>	
	In-process Inspection and Rework Confirmation Reqd(Milestone)					
<i>N/A</i>	<i>N/A</i>	<i>N/A</i> <i>N/A</i> <i>N/A</i> <i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>	<i>N/A</i>
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① ATB9 08 Jan 24
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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	487	0	08Jan24	RS 23 FB01 LL61
600	CATASY01 Catheter Assembly 1  Distal Tip Assembly Confirmation	Distal Tip Assembly	476	ELT - 11 DS - 11 IDB - 11 ① MAH MAH - HK DL - HK HK	08Jan24	RS 23 VA96 AX82 FB01

Notes:

101A

NA

N/A

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① LL61 08 Jan 24

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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 Loading Heat Shrink Confirmation Reqd(Milestone)	476	0	08Jan24	VA96 AX82 FB01
700	CATASY01 Catheter Assembly 1 	Tipping Record Tipping Oven Information: TMI: 10521 Cal Due: 31 May 24 TMI: 10386 Cal Due: 31 May 24 TMI: 0936A Cal Due: 31 May 24 TMI: 2083C Cal Due: 31 May 24	476	0	08Jan24	DY29
Notes:						
N/A						
N/A						
N/A						

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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 #: 82104 Qty: 15 Part #: RM4000-01 Batch #: 71863 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	476	0	08 Jan 24	Hv36 D429
	Tip Inspection/ Flash Removal					
	Confirmation Reqd(Milestone)					
800	CATASY01 Catheter Assembly 1 	Major Mandrel Removal	473	ACD-III	08 Jan 24	SS44 SS52
Notes:						
N/A						
N/A						
N/A						

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Opn 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>	① 1473 470	SKV-111	08Jan24	SS52 ML65 Yg36
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	LS46 AR02
Notes:						
N/A						
N/A						
N/A						

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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: 31 may 24 TMI: N/A Cal Due: N/A TMI: N/A Cal Due: N/A Material Consumed: Part #: 100-1153-01 Batch #: 86760 Qty: N/A Part #: RM400-01 Batch #: 82104 Qty: 15 Part #: RM0007-01 Batch #: 71863 Qty: 10 Part #: RM0158-01 Batch #: 58497 Qty: 10 Part #: N/A Batch #: N/A Qty: N/A</p>	451	DIS-III DEL-II FM-II EW-III MAR-1 #10S-III #5US-1 #6US-11 #90S-1	08Jan24	P146 SH09 HT72 ML46 KL67 ① MV33 Y936 MV33 TRN VX41
950	QUALITY1 Quality Inspection & Review	<p>Quality Inspection & 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

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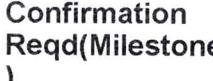
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① MV33 08Jan24



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Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	 Quality Inspection & Review  Confirmation Reqd(Milestone)	TMI: <u>N/A</u> Cal Due: <u>N/A</u> Record DIM02 Go/No-Go Gage Information: TMI: <u>0691</u> Cal Due: <u>30SEP25</u> TMI: <u>0692</u> Cal Due: <u>30SEP25</u> Record DIM02 Inspection Results N = 54: Pass: <u>54</u> Fail: <u>0</u>	405	STR - <u>1H</u> <u>1H</u> <u>1</u> DEL(CT) <u>1H</u> <u>1H</u> DIS(SP) <u>1H</u> DIS - <u>1H</u> <u>1H</u> <u>1H</u> <u>1H</u>	08Jan24	p146 OS21 KL67 1936
1000	QUALITY1  Quality Inspection & Review  Quality Inspection & Review  Confirmation Reqd(Milestone)	Quality Inspection & Review Leak Test Record Inspection Data in SAP ROS Record Leak Tester Information: TMI: <u>0691056</u> Cal Due: <u>3031May24</u> Record Length Gage Information: TMI: <u>06920</u> Cal Due: <u>30SEP24</u> Record Calibrated Ruler Information: TMI: <u>0629</u> Cal Due: <u>30SEP24</u>	391	OAL - <u>1</u> LT - <u>1H</u> <u>1H</u> <u>1H</u>	08Jan24	OS21 KL67 1936

Notes:

N/A

N/A

N/A

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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	335	SCR-HH1,HH2,HH3 EW-III TD-III DL- III ① DL- III III DNT-II DIS-II DISC-I SKV-I VD-HH1 FB-II AB-I FM-II PBC-I SKV-II BP-I STN-I	09Jan24	XN26 ZY50 SV43
1100	CATASY01 Catheter Assembly 1  Line Closure	Line Closure Perform Line Closure Settle materials issued to production order (Initial/Date): <u>KP02 09Jan24</u>	N/A	N/A	09Jan24	KP02
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① XN26 09 Jan 24

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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	335	0	10 Jan 24 BA71	

Notes:

N/A

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Batch Number: 0000294400

By: BA71

Date: 10 Jan 24

Reviewed By:

RB29

Date:

12 JAM 24

Notes:

N
N
A

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17/10/2008 at 10:45



CREGANNA
MEDICAL

CONTROLLED COPY DEVIATION AUTHORIZATION NUMBER: 2484
* See attached email extension to 2484

SCADA system
for water management

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.

This diagram illustrates the assembly sequence of a Pre-Relyow device. The components are arranged vertically along a central blue tube, which is labeled "RNF-100" at both ends. The assembly begins with a white rectangular component labeled "Wire Out Hole" at the top. Below it is a black rectangular component labeled "FEP RNM0362-01 or 1000-1155-01". A red arrow points from the "Wire Out Hole" label to the top edge of the black component. The next segment is a yellow component labeled "Hypolute" with a thickness of "0.155 - 0.050". Following this is a white component labeled "Hypodermic Slick" with a thickness of "0.160" to "0.030". Above this is a black component labeled "MNM0179-01". The next segment is a blue component labeled "350" with a thickness of "0.155 - 0.050". Below the "350" component is another blue component labeled "550" with a thickness of "0.155 - 0.050". The following blue component is labeled "630" with a thickness of "0.155 - 0.050". Above the "630" component is a black component labeled "MNM0179-01". The final visible component is a blue component labeled "Westmid 01" with a thickness of "0.160" to "0.030". At the very top of the assembly, a black component labeled "MNM0179-01" is shown with a thickness of "0.210" to "0.030". The word "PROXIMAL" is printed above the top-most blue component.

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.

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

Risk Assessment:

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

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

Corrective Action Required:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
If no, explain: No corrective action is required for this event as there are no changes to the current process, consumption of material, or how the product is produced. This added inspection guidelines are to avoid incorrect extrusion assembly defects.	

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

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

① UK55, 23JW 2023



DA 2484
2468 ①

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

Procedure:

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

① **MM0179-01** **MM1536-01** **10AUG-23**

Group Training Record

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)

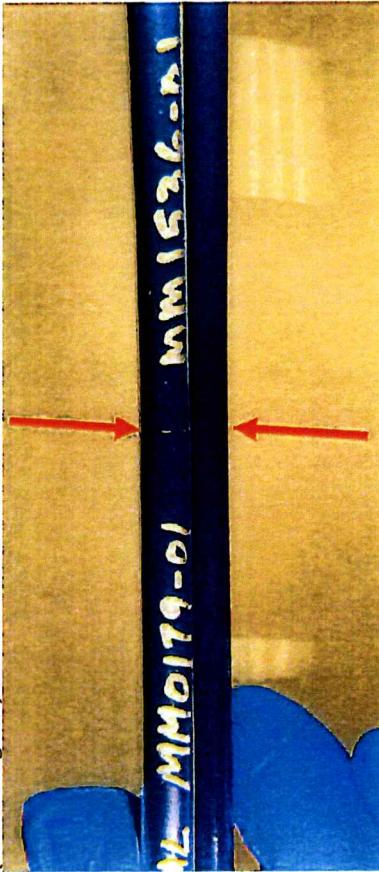


Image- 3

- 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.

CONTROLLED COPY

- Step 2:**
- Visually verify the MM1536-01 distal end of the fixture is approximately at the same location on the completed part. (See image 4)

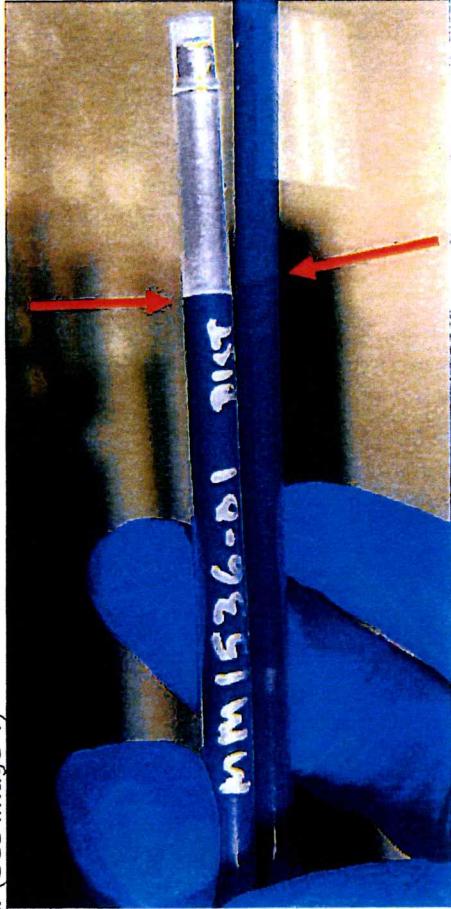


Image-4

- Scrap the part if the transition is not approximately aligned. Save the scrapped parts for Engineer review.
- If the part transition is aligned, the part passes inspection.
- Use Image 5 as a guide for GOOD and BAD extrusion transition alignment.

1	MM0179-01	MM1536-01	GOOD PART
2	MM0179-01	MM1536-01	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

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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Entered to Hanwha T228 12/12/2023

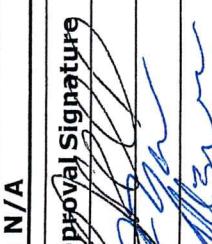
DEVIATION AUTHORIZATION FORM

Requestor Name: Krishna Selvaraj	
Document Number Affected	Revision
Doc #3005206 (MPI0238)	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.

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.

Part Number Affected	Revision	
SA0155-01	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
Engineering Manager	Jake Stanislowski	
Quality Manager	Jay Zabel	
Operations Manager	Matthew Benson	



PRODUCTION ORDER# 506000294400

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10745	44	10:16 AM	430	RJ16	07 Jan 24	10:28 AM	415	RJ16	07 Jan 24	16
TM10745	44	11:58 AM	430	SD34	07 Jan 24	12:10 PM	415	SD34	07 Jan 24	16
TM10745	44	2:04 PM	430	SD34	07 Jan 24	2:16 PM	415	SD34	07 Jan 24	16
TM10745	44	4:20 pm	430	SD34	07 Jan 24	4:32 pm	415	SD34	07 Jan 24	16
TM10745	44	6:23PM	430	SD34	07 Jan 24	6:35pm	415	SD34	07 Jan 24	4
TM10745	44	5:25 AM	430	PM 96	08 Jan 24 08 Jan 24 ①	5:37 AM	415	PM 96	08 Jan 24 08 Jan 24 ①	16
TM10745	44	5:54 AM	429	PM 96	08 Jan 24	6:06 AM	415	PM 96	08 Jan 24	16
TM10745	44	6:20 AM	429	PM 96	08 Jan 24 08 Jan 24 ①	6:32 AM	415	PM 96	08 Jan 24	16
TM10745	44	6:40 AM	430	DS21	08 Jan 24	6:52 AM	415	DS21	08 Jun 24	16
TM10745	44	7:45am	430	AX05	08 Jan 24	7:57am	415	AX05	08 Jan 24	16
TM10745	44	8:15am	430	AX05	08 Jan 24	8:27am	415	AX05	08 Jan 24	16
TM10745	44	8:40am	429	AX05	08 Jan 24	8:52am	415	AX05	08 Jan 24	16

② P146 09 Jan 24
correction for SD 34

① PM 96 08 Jan 24



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

PRODUCTION ORDER# 500000294400

OP 400

① 0521 08 Jan 24



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

PRODUCTION ORDER# 50000294400

OP 400

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
TM10942	44	11:03AM	① 430	SD34	07Jan24	11:15 AM	415	SD34	07Jan24	16
TM10942	44	11:30AM	430	SN67	07 Jan24	11:42AM	415	SN67	07 Jan24	16
TM10942	44	1:18PM	430	PY67	07 jan24	1:30PM	415	PY67	07 jan24	16
TM10942	44	2:38PM	430	SN67	07 Jan24	2:50PM	415	SN67	07 Jan24	16
TM10942	44	3:11PM	430	PY67	07 jan24	3:22PM	415	PY67	07 jan24	16
TM10942	44	5:00PM	430	Cm99	07Jan24	5:12pm	415	Cm99	07Jan24	① 16
TM10942	44	5:30pm	430	SD34	07Jan24	5:42pm	415	SD34	07Jan24	16
TM10942	44	6:05PM	430	SN67	07 Jan24	6:17PM	415	SN67	07 Jan24	16
TM10942	44	5:16 AM	430	PM96	08Jan24	5:22 AM	415	PM96	08 Jan 24	16
TM10942	44	5:37 AM	429	PM96	08 Jan 24	5:49 AM	415	PM96	08 Jan 24	16
TM10942	44	6:05am	430	OS21	08Jan24	6:17am	415	OS21	08Jan 24	16
TM10942	44	6:32 AM	429	PM96	08 Jan 24	6:44 AM	415	PM96	08 Jan 24	16

①CB58 07Jan24



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

PRODUCTION ORDER# 50000294400

OP 400



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

PO #: 500000294400

OP #: 500 Shift #: 3rd

Total Parts Reworked:		19	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	N/A
EH	Exposed Hypotube	111	5
EW	Exposed Wire	111 111	13
MP	Micropores	N/A	N/A
SCR	Scratch	N/A	N/A
SKV	Skive Marks	11	2
VD	Voids	N/A	N/A
N/A	N/A	N/A	N/A

Inspected By (Sign and Date): AR02 07 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):

① P14609Jan24

signed for AR02



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

PO #: 500000294400

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):

① PY46 09 Jan 24
signed for CB81



PO #: 500000294400

OP #: 750 Shift #: 1st

Document No: 6102646

Rev: A

Document Type: Manufacturing Form

Title: SA0155-01 Tipping Rework Form

Total Parts Reworked:		127	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)		15
DIM07 US / WC	DIM07 Undersized (Window Closed)		20
EH	Exposed Hypotube		42
N/A	Glue, Stopper		50
Inspected By (Sign and Date):		Hv36	08 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):



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

PO #: 500000294400

OP #: 750 Shift #: 2

Total Parts Reworked:		10	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
DIM07 OS / WO	DIM07 Oversized (Window Open)	III	5
DIM07 US / WC	DIM07 Undersized (Window Closed)	II	3
EH	Exposed Hypotube	II	2
N/A	N/A	N/A	N/A

Inspected By (Sign and Date):

MV 18 08 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# 500000 294400

OP 800

Oven #	Cycle #	Time In	Temp. In (Actual)	Initials	Date	Time Out	Temp. Out (Actual)	Initials	Date	Qty
Tm10943	N/A	7:15am	190F	SS44	08Jan24	8:25am	190F	SS44	08Jan24	40
Tm10409	N/A	8:00am	190F	SS44	08Jan24	9:10am	190F	SS44	08Jan24	20
Tm10286	N/A	8:30am	190F	SS44	08Jan24	9:40am	190F	SS44	08Jan24	43
Tm10409	N/A	9:15am	190F	SS44	08Jan24	10:25am	190F	SS44	08Jan24	44
Tm12036	N/A	9:50am	190F	SS44	08Jan24	11:00am	190F	SS44	08Jan24	30
Tm10409	N/A	11:00am	190F	SS44	08Jan24	12:10pm	190F	SS44	08Jan24	33
Tm12036	N/A	11:30am	190F	SS44	08Jan24	12:40pm	190F	SS44	08Jan24	41
Tm10409	N/A	12:15pm	190F	SS44	08Jan24	1:20pm	190F	SS44	08Jan24	54
Tm10409	N/A	1:50pm	190F	SS44	08Jan24	3:00pm	190F	SS44	08Jan24	36
Tm12036	N/A	2:25pm	190F	SS44	08Jan24	3:35pm	190F	SS44	08Jan24	34
Tm10409	N/A	3:40pm	190F	AT39	08Jan24	3:50pm	190F	AT39	08Jan24	22
Tm10409	N/A	4:54pm	190F	AT39 NEW 5988	08Jan24	5:04pm	190F	NEW AT39 5988	08Jan24	76
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

①AT39 08Jan24



Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 506000294400

OP #: 900 Shift #: 1st

Total Parts Reworked:		102	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	
EH	Exposed Hypotube	1	1
EW	Exposed Wire		26
MP	Micropores	N/A	N/A
SCR	Scratch		65
SKV	Skive Marks	N/A	N/A
VD	Voids		15
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized		10
DIM06 OS	DIM06 OD Oversized	N/A	N/A
DIM09 US	DIM09 OD Undersized	N/A	N/A
Inspected By (Sign and Date):		P/Y46 08 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 #: 500000294400OP #: 900 Shift #: 2nd

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

Total Parts Reworked:		43	
Router Code	Defect Failure Mode	Reworkable Defects (Tally)	Total Defects
AB	Air Bubbles	N/A	0
EH	Exposed Hypotube		5
EW	Exposed Wire		5
MP	Micropores	N/A	0
SCR	Scratch		33
SKV	Skive Marks		1
VD	Voids		1
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized		5
DIM06 OS	DIM06 OD Oversized	N/A	0
DIM09 US	DIM09 OD Undersized	N/A	0
Inspected By (Sign and Date):		See H 08 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):



Document No: 6102619

Rev: B

Document Type: Manufacturing Form

Title: SA0155-01 Dimensional/Visual Rework Form

PO #: 50000294400OP #: 900 Shift #: 2nd

Total Parts Reworked:		45	
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	1	21
MP	Micropores	N/A	N/A
SCR	Scratch		50
SKV	Skive Marks	/	1
VD	Voids	N/A	N/A
DIM01 US	DIM01 OD Undersized	N/A	N/A
DIM06 US	DIM06 OD Undersized	//	2
DIM06 OS	DIM06 OD Oversized	N/A	N/A
DIM09 US	DIM09 OD Undersized	N/A	N/A
Inspected By (Sign and Date):		PP40 HT72 08 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):



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

PO #: 500000294400 OP #: 900 Shift #: 2nd

Total Parts Reworked:		48	
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		10
MP	Micropores	N/A	0
SCR	Scratch		42
SKV	Skive Marks		3
VD	Voids		12
DIM01 US	DIM01 OD Undersized	N/A	0
DIM06 US	DIM06 OD Undersized		5
DIM06 OS	DIM06 OD Oversized	N/A	0
DIM09 US	DIM09 OD Undersized	N/A	0
Inspected By (Sign and Date):		<i>Meinhardt</i>	08 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	25.62	25.18	25.33	24.55	25	26.78	25.87	24.19	24.45	23.8	25.077	0.881464	4.378	21.2179503	8.542	PASS
Seg B	57.9	64.71	61.95	59.92	58	59.16	59.22	61.57	56.22	53.68	59.233	3.100713	3.981	46.8890601	8.542	PASS
Seg C	83.91	80.67	82.89	81.15	84.1	86.11	85.75	79.78	80.06	79.82	82.424	2.448193	2.911	75.2973102	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 #: 500000294400

Date: 09 JAN 24

Inspector Name: Javier Olivares

Equipment ID: TMI0311B

Cal Due Date: 27 OCT 24

J001 09 jan 24

TE MEDICAL REWORK/REINSPECTION WORK ORDER FORM

Customer: Edwards Lifesciences	PO No.: N/A
Description: Flex Commander	TE Medical Lot No.:294400
Customer P/N: 155885	Returned Quantity: 391
TE Medical P/N: SA0155-01	Other: N/A
RMA #:	NC or CAPA #: NC29096

Will the rework have adverse effects on the product? No Yes (Provide justification of rework and how it was concluded).

There will be no product rework allowed for this NC. There will be no adverse effect on the products as quality inspectors are certified to perform 100% visual inspection per existing Quality Inspection Plan (QIP3107610)

Special Instructions:

- QE/ Technician: to complete training per special instructions before sorting activity. Attach training record to NC before closing.
- Inspectors: to perform the line clearance per MPI0230 prior to re-inspection of each lot.
- Inspectors: to verify lot quantity prior to performing re-inspection of the affected lots. Contact Quality if count discrepancy found.
- Inspectors: to perform 100% dimensional inspection of Dim5 using calibrated Flex Shaft Tip Go/No Go gauge TM150713 and Vernier Caliper for DIM7. Defective units to be identified with defect type.
- DA Inspector: to perform 100% visual inspection using visual guideline doc # 3107585, before moving good units to Packaging. Contact Quality to remove hold in SAP.
- QC Operator: Confirm lots in SAP to reflect final accept/reject quantities from 200% inspection activities.
- Accepted units can be sent to Packaging and onward to Shipping.

Note: The scrap unit(s) will be documented within this Form and may be used for Engineering study (Quality Engineer is to collect scrapped parts)

Process	Qty	Initials	Equipment Number and Cal Due Date if applicable	Comments
Dimension inspection	391	SSH4	TM150713	N/A
Reworked (if necessary)	N/A	N/A	N/A	N/A
AQL Sampling	N/A	N/A	N/A	N/A
Total accepted	391	SSH4		N/A
Total failed / scrapped	0	SSH4		N/A
Other	/	N/A	N/A	N/A

REWORK/REINSPECTION WORK ORDER FORM

Note: Fill in the table below if components were replaced during the rework process. This form will be filed along with the original LHR.

Component(s) Used				Component(s) removed/scrapped			
P/N	Rev.	Lot No.	Qty.	P/N	Rev.	Lot No.	Qty.
A/A-SS144	09	Saw J4					

Process	Time	Hour(s)	Initials	Comments
Re-work hours (\pm .25 hrs)		≥ 7.5	SS14	N/A
Final Rework/Re-Inspection/Re-Test hours (\pm .25 hrs)		N/A	N/A	N/A

Re-work/Re-inspection/Re-Test Performed By: SS44 Date: 09 Jan 24

Final Rework/Re-inspection/Re-Test Reviewed By: N/A Date: N/A
Disposition of Reject Material (unit that does not meet the acceptance criteria after rework/inspection):

Scrap to Bin Scrap to R&D ENGINEERING AB
Scrap Disposition by (Name, Date & Sign): Alphonso Bahri dated 20/24/2024