

Production Order: 500000164476Production Order Document
Production Order Qty: 500

PC

Sheet: 1 of 1

Material: SA0254-06 Rev G

Material Type: ZFRT

Description: Printed Shaft 144C Prox End Color
B CMDR

Order Type: ZSTD

Production Version: 7999

Project Phase:

Plant / Business Unit: 1213 / AC5

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty	Scrap Qty & Desc.	Date Comp.	Initials
50	CATASY04 Catheter Assembly 4 Count: Yes  Prepare Materials MPI0398 Rev. <u>A0</u> Line Clearance MPI0230 Rev. <u>E</u> By: <u>M28</u> Date: <u>28 Jul 22</u> Prepare Materials Confirmation Reqd(Milestone)		500	0	01Aug22/M28	
100	CATASY04 Catheter	Straighten First Jacket MPI0398 Rev. <u>A0</u>	N/A	N/A	N/A	N/A

Notes: DA2233, DA2262

N/A
N/A

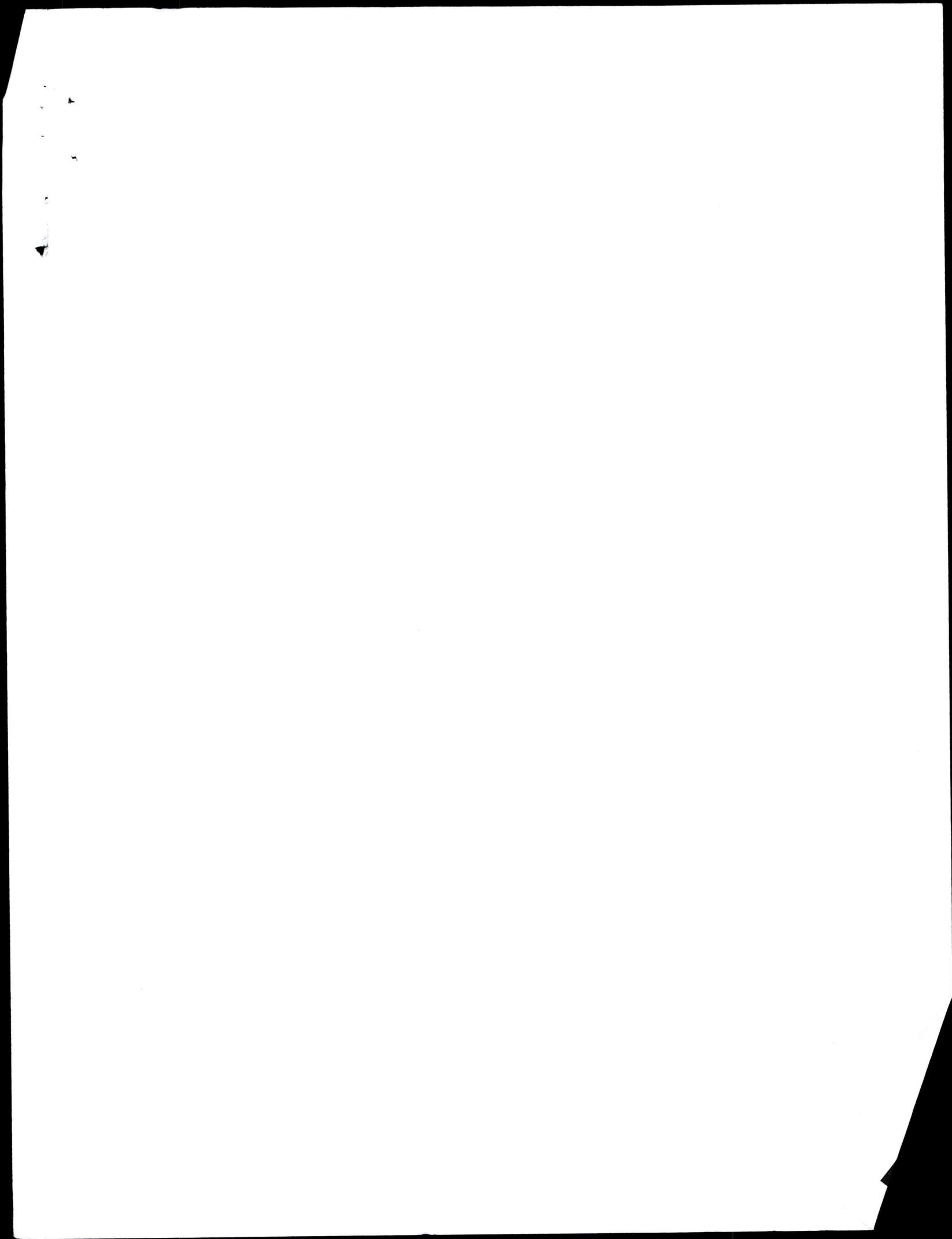
Date Printed: 28.07.2022 / 22:25:54

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Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details						Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Assembly 4 							500	0	01Aug22	AD4Z
	Straighten First Jacket 	Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.	Actual Qty Used				
	Confirmation Reqd(Milestone)	1000-1190-01	A <u>A</u>	FT	2708.350	<u>0000152198</u>	<u>2,708.350</u>				
150	CATASY04 Catheter Assembly 4 Positioning Braid Over First Jacket Confirmation Reqd(Milestone)	Positioning Braid Over First Jacket MPI0398 Rev. <u>AD</u> Record Braid Pic Count for 15 parts below: Braid Production Lot No: <u>0000162121</u> 1. <u>40</u> 2. <u>40</u> 3. <u>40</u> 4. <u>40</u> 5. <u>40</u> 6. <u>40</u> 7. <u>40</u> 8. <u>40</u> 9. <u>40</u> 10. <u>40</u> 11. <u>40</u> 12. <u>40</u> 13. <u>40</u> 14. <u>40</u> 15. <u>40</u> If more than braid production lot is used for The build, record the braid pic count for 15 parts for the second braid production lot below. Enter N/A if only one braid production lot is used for the build. Braid Production Lot No: <u>0000160921</u>						500	0	01 Aug 22	TX64 MH1D TRNC27 SV09 VV84 VJ06 AY69 SP63

Notes:

N/A

N/A

N/A

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Production Order: 500000164476

A standard linear barcode is positioned vertically on the right side of the page, consisting of vertical black bars of varying widths.

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Production Order: 500000164476

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PC

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Production Order: 500000164476



Material: SA0254-06 Rev G

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Opn No.	Planned Work Center Description	Operation Details				Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		B	<u>B</u>	PC	500	<u>0000148246</u>	<u>500</u>		<u>N/A</u>
MM0524-01		B	<u>B</u>	PC	500	<u>0000137442</u>	<u>440</u>		<u>N/A</u>
MM0530-01		B	<u>B</u>	PC	500	<u>0000131738</u>	<u>60</u>		<u>N/A</u>
RM7586-02		D	<u>D</u>	PC	500	<u>48360</u>	<u>250</u>		<u>N/A</u>
MM0185-01		I	<u>I</u>	PC	500	<u>0000143341</u>	<u>500</u>		<u>N/A</u>
MM1539-01		A	<u>A</u>	PC	500	<u>0000145509</u>	<u>500</u>		<u>N/A</u>
TL5909-01		B	<u>N/A</u>	PC	5	<u>N/A</u>	<u>N/A</u>		<u>N/A</u>
RM016101-MED		F	<u>F</u>	PC	125	<u>53186</u>	<u>125</u>		<u>N/A</u>
MM1540-01		B	<u>B</u>	PC	500	<u>0000158323</u>	<u>500</u>		<u>N/A</u>
Notes:									
<u>N/A</u>									
<u>N/A</u>									
<u>N/A</u>									

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Material: SA0254-06 Rev G

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Opn No.	Planned WorkCenter Description	Operation Details				Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
300	CATASY04 Catheter Assembly 4	N/A	N/A	N/A	N/A	500	0	01Aug22 MS41EE65	N/A
		Reflow MPI0398 Rev. A0							
		Temp = 415°F (+/- 15 °F)							
		Speed = 4.5 in/min (+/- 0.5 in/min)							
Reflow	Component Number	Req'd Rev	UOM	Qty.	Batch No.				
		Rev Used							
1000-1154-01	A	A	PC	500	52191,53449	195,95			
					52525,55036	200,10			
350	CATASY04 Catheter Assembly 4	Skive Heat Shrink MPI0398 Rev. A0							
	Skive Heat								

Notes:

N/A
N/A
N/A

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01Aug22

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Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	N/A					
400	<p>Shrink</p> <p>CATHETER ASSEMBLY 4</p> <p>Count: Yes</p> <p>In Process Inspection</p>	<p>N/A</p> <p>In-Process Inspection (Visual Inspection) MPI0398 Rev. AD</p> <p>FM5104693</p> <p>(Rework if needed. Use FM5104983)</p>	<p>N/A</p> <p>EW IIII</p> <p>DISC II</p> <p>491</p> <p>AB III</p>	<p>N/A</p> <p>01Aug22</p>	<p>N/A</p> <p>AN002</p> <p>Mlob</p>	
450	<p>CATHETER ASSEMBLY 4</p>	<p>Anneal Shaft</p> <p>MPI0398 Rev. AD</p> <p>FM5104692</p>				
	Notes:	N/A N/A N/A				

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Opr. No.	Planned WorkCenter Description	Operation Details				Comp. Qty.	Scrap Offy & Desc.	Date Comp.	Initials
500	CATASY04 Catheter Assembly 4 	Leak Test/Prox Cut/Ring Gage-Dim 13/21 MPI0398 Rev. <u>D</u>	N/A	N/A	N/A	356	OD18 MM MM MM MM MM MM MM MM 131 OD 13 111 4	01 AUG 22 MP06 PVL62	N/A
550	CATASY04 Catheter Assembly 4 	Distal Cut MPI0398 Rev. <u>A</u> Line Closure MPI0230 Rev. <u>E</u> By: _____ Date: <u>01 Aug 22</u>	356	0	01 AUG 22 MP06 PVL62				
600	PADPRIN1 Pad Print 	Pad Print Set Up MPI0276 Rev. <u>E</u>	138	0	02 AUG 22 BB49				

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Material: SA0254-06 Rev G

Opn No.	Planned Work Center Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
Count: Yes	Line Clearance MP10230 Rev. E	By: GL42 Date: 02 Aug 22	218	0	02 Aug 22 GL42	
Pad Print Setup	TMI0503 (circle TMI used) Cliché - TL0525 Ink # RM7407-01 Thinner - RM7408-01 Hardener - RM7409-01 Customized Measuring Equipment - Calliper Inspection Gauge TMI0843 Setup Rod # TL0815 Program - #10 Ink Viscosity (REF) -5 to 6 Pad - TL0545 or equivalent Fence - TL0538 Drying Oven - TMI0643 Drying Racks-TL0531, TL0532	TMI0735 Cliché - TL0567 Ink - RM7407-01 Thinner - RM7408-01 Hardener - RM7409-01 Customized Measuring Equipment - Calliper Inspection Gauge TMI0843 Setup Rod # TL0815 Program - #10 Ink Viscosity (REF) -5 to 6 Pad - TL0545 or equivalent Fence - TL0569 Drying Oven - TMI0643 Drying Racks-TL0531, TL0532				
Notes:	N/A N/A N/A					
Date Printed:	28.07.2022 / 22:25:54					

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Material: SA0254-06 Rev G

Opr No.	Planned Work Center Description	Operation Details				Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
650	PADPRIN1 Pad Print 	Verification MPI0276 Rev. <u>E</u> Section 15.0				138	0	02 Aug 22	BRH
	Verification					218	0	02 Aug 22	GL42
	Component Number	Req'd Rev Rev Used	UOM	Qty.	Batch No.				
RM7407-01	B	<u>B</u>	L	0.050	<u>55227</u>				
	Notes:	N/A	N/A	N/A	N/A				

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Material: SA0254-06 Rev G

Opn No.	Planned Work Center Description	Operation Details					Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
		B	R	L	0.005	54359				
700	PADPRIN1	Pad Print				RM7408-01	B	N/A	0.DID	N/A
						RM7409-01	B	54358	0.020	N/A
								N/A		
750	PADPRIN1	Print Parts				Print Parts	0	138	02Aug22 GL42	N/A
		MPI0276 Rev. E				MPI0276 Rev. E	0	218	02Aug22 GL42	N/A
		Section 20.0				Section 20.0				
		Inspection gauge TMI0843				Inspection gauge TMI0843				
		Print Parts				Print Parts				

Notes:

N/A

N/A

N/A

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Material: SA0254-06 Rev G

Opr No.	Planned Work Center Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
800	PADPRIN1	In-Process Inspection and Rework MPI0276 Rev. <u>E</u> Section 30.0 Polynit Wipes 99% IPA Mag Light	138	0	02 Aug 22 31048	
		In-process Inspection and Rework	218	0	02 Aug 22 GL42	
850	PADPRIN1	Curing Oven MPI0340 Rev. <u>B</u> Section 35.0 Curing oven for 120 +30/-15 minutes Parts sit for 8 hours minimum after curing oven Lot Completion time: <u>3:16 AM</u> By: <u>GL42</u> Date: <u>03 Aug 22</u>	138	0	02 Aug 22 B1H49	
		Curing Oven Confirmation Rqrd(Milestone)	218	0	02 Aug 22 GL42	
900	PADPRIN1	Transfer Parts to Production MPI0276 Rev. <u>E</u> Section 40.0	N/A	N/A	N/A	N/A
		Notes:	N/A	N/A	N/A	N/A

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Material: SA0254-06 Rev G

Opn No.	Planned Work Center Description	Operation Details		Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
950	PADPRIN1 Pad Print Count: Yes 	Cleaning MPI0276 Rev. <u>E</u> Section 50.0 Line Clearance MPI0230 Rev. <u>E</u> Cleaning By: <u>BH48</u> Date: <u>03 Aug 22</u>		356	0	03AUG22 BH48	
1000	CATASY04 Confirmation Reqd(Milestone))	In-Process Dimensional Inspection		N/A	N/A	N/A	N/A
Notes:							
<u>N/A</u>							
<u>N/A</u>							
<u>N/A</u>							

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Material: SA0254-06 Rev G

Op'r No.	Planned Work Center Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Catheter Assembly 4	MPI0398 Rev. <u>A</u> FM5104662 FM5104696 (No Rework can be done at this OP) Line Closure MPI0230 Rev. <u>E</u>				
1050	QUALITY1 Quality Inspection & Review	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	350	0D12 0D21 1	03 Aug 22	M106
	Quality Inspection & Review			7-IB 3-S46N6 32- castles	04 Aug 22	N/A
	Confirmation Reqd(Milestone)			3-VJ 2-FM 1-AB 5-SCR 309 290	04 Aug 22 11L. 72.	N/A
	Notes:			3-DSR 4-JSC 11-000518 7-SCR		N/A

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L703 04 AUG 22
L703 04 AUG 22
L703 04 AUG 22

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Material: EΛΩΣΕΙ ΟΣ

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Material: SA0254-06 Rev G

Opn No.	Planned WorkCenter Description	Operation Details		Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
1100	PACKINT1 Packing assembly 	Packaging Instructions SPI0087 REV. <u>M</u>	N/A	N/A	N/A	N/A	N/A
	Packing Instructions Confirmation Reqd(Milestone)	309 0 04AUG12 RATI TRUAF10					

Notes:

N/A N/A
N/A

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Material: SA0254-06 Rev G

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Batch Number: 0000164476

By: TRN API

Date: 04 AUG 22

Reviewed By:

WJ32

Date:

05 Aug 22

Notes:

N/A

N/A

N/A

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PRODUCTION ORDER# 500000164476

OPER 400.0

Document No: FM5104693
Rev: C
Document Type: Manufacturing Form
Title: SA0254 In-Process Inspection Form

In-Process Inspection (Visual Inspection)

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	# Initial/Date
Using a magnification light, visually inspect the entire length of the shafts.	N/A	100%	Inspect at a minimum of 2.85x magnification	500	0	0	M106 01 Aug 22
Metallic Foreign Material: No embedded metallic and foreign material is allowed along the length of the shaft.	N/A	100%	Inspect at a minimum of 2.85x magnification	500	0	0	
All other Foreign Material:							
Particle Size Area: mm ²	Acceptable Limits per Part						
< 0.05 mm ²	No Limit	See Table	100%	Use a calibrated Tappi Chart and Inspect at a minimum of 2.85x magnification	500	0	
0.05 mm ² ≤ Area < 0.25 mm ²	3						
0.25 mm ² ≤ Area < 0.80 mm ²	2						
0.80 mm ² ≤ Area ≤ 1.5 mm ²	1						
> 1.5 mm ²	0						
No surface damage to the shafts such as voids pits or cuts. (interior surface of distal end not included)	N/A	100%	Inspect at a minimum of 2.85x magnification	500	0	0	
No bumps, lumps, or protrusions along the shaft that will compromise the OD. Verify all protrusions to make sure the OD is still within specification.	N/A	100%	Inspect at a minimum of 2.85x magnification	500	0	0	
No flat spots, kinks, delamination, gaps between material transitions and material transitions should no exhibit cracking, no exposed or apparent braid.	N/A	100%	Inspect at a minimum of 2.85x magnification	491	9	0	
Measured material overflow on proximal end of stop sleeve must be ≤0.02" (i.e., 0.2 mm ² dot on Tappi chart).	≤0.2 mm ²	100%	Use a calibrated Tappi Chart and Inspect at a minimum of 2.85x magnification	N/A	491	0	M106 01 Aug 22

M106
01 Aug 22



PRODUCTION ORDER# 500000164476

Attachment B: Cause of Rework.

OPER 400.0

Attachment B: Cause of Rework

OPER 500.0



OPER 450.0 PRODUCTION ORDER# 500000164476

Annealing Log Sheet



Document No: FM5104694
Rev: B

Document Type: Manufacturing Form
Title: SA0254 Max OD Gauge Check Form

PRODUCTION ORDER# 5000001b4476

OPER 500.0

▲13 & ▲21 Max OD Gauge Check for the manufacturing lot PRIOR TO AND AFTER Inspection

Before & After Inspecting Parts	Dimension ## Gauge Check (Ex. TMI0748AC or TMI0747AD)	TMI####XX (Ex. TMI0748AC or TMI0747AD)	Initials	Date	Time
Before	Dimension 13	TMI0748AC	CL27	01 Aug 22	11:00 AM
After	Dimension 21	TMI0747X	CL27	01 Aug 22	11:00 AM



Document No: FM5104695
Rev: C

Document Type: Manufacturing Form
Title: SA0254 Pressure Decay Testing Form

PRODUCTION ORDER# 500000164476

OPER 500.0

Pressure Decay Testing							
Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
Air Leak Test GN 15	N/A	100%	Issac Pressure Decay Tester	TMI 0747B	491	0	PV62 01 Aug 22
Outer Diameter ▲ 21 MAX OD at Pad Printed Area Drop Go Gauge from proximal end of shaft. Pass if ring stops at stop sleeve shoulder. Fail if gauge stops above or fails past stop sleeve shoulder.	0.145" +0.002"/- 0.004" (≤0.147")	100%	Ring Gauge TMI0748	TMI 0748	356	135	PV62 01 Aug 22
Outer Diameter ▲ 21 MAX OD Drop Go Gauge from stop sleeve shoulder. Pass if ring does not stop. Fail if ring stops less than 4" distal from stop sleeve shoulder.	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TMI0747	TMI 0747	356	0	PV62 01 Aug 22

Document No: FM5104662

Rev: B

Document Type: Manufacturing Form

Title: SA0254 Max OD Form

PRODUCTION ORDER# 500000164476

OP 1000.0 ▲13, ▲21 Max OD Gauge Check for the manufacturing lot PRIOR TO AND AFTER Inspection

Before & After Inspecting Parts	Dimension ## Gauge Check	TMID##XX (Ex. TMI0748AC or TMI0747AD)	Initials	Date	Time
Before	Dimension 13	TMI0748AM	CL27	03Aug22	10:40AM
Before	Dimension 21	TMI0747W	CL27	03Aug22	10:40AM
After	Dimension 13	TMI0748AM	CL27	03Aug22	2:06PM
After	Dimension 21	TMI0747W	CL27	03Aug22	2:06PM

PRODUCTION ORDER# 500000164476

OP 1000.0

In-process Dimensional Inspection (OD Inspection)

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
Outer Diameter $\Delta 13$ MAX OD at Pad Printed Area Drop Go Gauge from proximal end of shaft. Pass if ring stops at stop sleeve shoulder. Fail if gauge stops above or falls past stop sleeve shoulder.	0.145" +0.002"/- 0.004" (≤0.147")	100%	Ring Gauge TMI0748	TMI 0748Am	356	0	W435 03 Aug 22
Outer Diameter $\Delta 21$ MAX OD Drop Go Gauge from stop sleeve shoulder. Pass if ring does not stop. Fail if ring stops less than 4" distal from stop sleeve shoulder.	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TMI0747	TMI 0747W	355	1	W435 03 Aug 22
Outer Diameter $\Delta 2$ MAX OD Go-gauge: Measure from distal end to minimum 1.7" from tip. Gravity force only.	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0967 Ring Gauge Helper TL0980	TMI 0967m	351	4	W435 03 Aug 22
Outer Diameter $\Delta 2$ MIN OD No-go gauge: End must not pass through	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0968	TMI 0968E	351	0	W435 03 Aug 22
Outer Diameter $\Delta 8$ MAX OD Measure from proximal end of shaft to the material transition.	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI 50049	351	0	W435 M10b 03 Aug 22
Outer Diameter $\Delta 8$ MIN OD Measure from proximal end of shaft to the material transition.	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI 50049	351	0	W435 M10b 03 Aug 22

PRODUCTION ORDER# 500000164476

OP 1000.0

In-process Dimensional Inspection (OD Inspection)

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
Outer Diameter $\Delta 13$ MAX OD at Pad Printed Area	0.145" +0.002"/- 0.004" (≤0.147")	100%	Ring Gauge TMI0748	TMI 50049	351	0	M435 M106 03 Aug 22
Outer Diameter $\Delta 21$ MAX OD	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TMI0747	TMI 50049	351	0	M435 M106 03 Aug 22
Outer Diameter $\Delta 12$ MAX OD	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0967 Ring Gauge Helper TL0980	TMI 50049	350	1	M435 M106 03 Aug 22
Outer Diameter $\Delta 2$ MIN OD	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0968	TMI 50049	350	0	M435 M106 03 Aug 22
Outer Diameter $\Delta 18$ MAX OD	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI 50049	350	0	M435 M106 03 Aug 22
Outer Diameter $\Delta 18$ MIN OD	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI 50049	350	0	M435 M106 03 Aug 22

Document No: FM5104983
Rev: B
Document Type: Manufacturing Form
Title: SA0254 Cause of Rework Form

PRODUCTION ORDER# 500000 164476

OPER 1050.0

Date	Initial	AB	DISC	DF	DS	EW	FM	OD	SCR	SKV	VD	OTHER

Record total quantity reworked:

Quantity Passed after Rework:

VFD3 OK M/C 12

Rework Performed by: _____ Date: _____

Rework Performed by: _____ Date: _____

Re-Inspection Performed by: _____ Date: _____

* EXTENDED TILL 12 AUG 2022 THRU 13 JUL 2022

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DEVIATION AUTHORIZATION NUMBER: DA2233

DEVIATION AUTHORIZATION FORM

Requestor Name: Sagar Alahari

Document Number Affected	Revision
3107613	F
N/A	N/A

Deviation From:

At Final inspection i.e., OPER1050, use TMI084X (where X is 1 if inspecting -04, 2 if inspecting -05, or 3 if inspecting -06) to inspect Dimension 19 on LTPD 15 % of production lot and at Reinspection i.e., OPER1090, inspect 100% of the production lot (if applicable).

Deviation To:

At Final inspection i.e., OPER1050, use a ruler (with 100THS place side) to inspect Dimension 19 (Pad print/Marker bands) on sample of 75 pcs from a production lot and at Reinspection i.e., OPER1090, inspect 100% of the lot (if applicable) for SA0254-TAB.

Record the results on attachment.

Justification:

During Edwards SIP, it was discovered that TMI0841, TMI0842, and TMI0843 fixtures at TE were not inspecting to print. This is continuation of DA2085 (Expired on 14 MAY 22).

Part Number Affected	Revision
SA0254-TAB	G
N/A	N/A

Start Date:	End Date:	Lot Number:
16 MAY 2022	15 JUN 2021	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

15 JUN 2022 SA08 19 May 2022

* EXTENDED TO 14 JUL 2022 ON 14 JUN 2022 THRU

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

If no, explain: Gauges and documentation will be updated once customer approval is received.

Training Required: Yes No **If no, explain:** N/A

Title	Approval Name	Approval Signature	Date
Quality Manager	Tafzeelur Rahaman		16 MAY 2022
Manf. Engineering Manager	Jared Smith		16 MAY 2022
Operations Manager	Matthew Benson		16 May 2022

Attachment for Deviation: DA 2233 ON 16 MAY 22

CONTROLLED COPY

	Dim 19				
Specification	3.5" ± 0.1"				
Upper	3.6"				
Lower	3.4"				
Sample Plan	75 Pcs				
TMI#	0614				
Sample #	N/A	Sample #	N/A	Sample #	N/A
1	3.52	26	3.52	51	3.52
2	3.52	27	3.52	52	3.52
3	3.52	28	3.51	53	3.51
4	3.52	29	3.52	54	3.52
5	3.51	30	3.52	55	3.52
6	3.52	31	3.52	56	3.52
7	3.52	32	3.52	57	3.51
8	3.52	33	3.51	58	3.52
9	3.51	34	3.52	59	3.52
10	3.52	35	3.52	60	3.52
11	3.52	36	3.52	61	3.52
12	3.52	37	3.52	62	3.52
13	3.52	38	3.52	63	3.52
14	3.52	39	3.52	64	3.52
15	3.52	40	3.51	65	3.52
16	3.52	41	3.52	66	3.52
17	3.52	42	3.52	67	3.51
18	3.52	43	3.52	68	3.52
19	3.52	44	3.52	69	3.52
20	3.51	45	3.52	70	3.52
21	3.52	46	3.52	71	3.52
22	3.52	47	3.51	72	3.52
23	3.52	48	3.52	73	3.52
24	3.52	49	3.52	74	3.52
25	3.51	50	3.52	75	3.52
Initial/Date	LTO3 04 Aug 22	N/A	N/A	N/A	N/A

① EXTENDED TILL 22 AUG 2022 TR14 22 JUL 2022

DEVIATION AUTHORIZATION NUMBER: DA2262

CREGANNA
MEDICAL
is part of



DEVIATION AUTHORIZATION FORM

Requestor Name: Sagar Alahari

Document Number Affected	Revision
3005617/MPI0398	AD
N/A	N/A

Deviation From:

Normal Production process per MPI0398.

Deviation To:

AT OPER500 -

- Normal OP500 per MPI0398.
- Perform Ring gauge inspection of Dim 18 OD Max and Min. Save the rejects for Engineering review, and record as scrap in SAP router and DA attachment.

At OPER1000-

- Use Laser Mic to inspect and record Dim 18 AVG OD on 57 parts per production lot.

Note: Follow Appendix C in MPI0398 for Laser Mic Data Recording Procedure

Justification:

During Final QC inspection, a very high fallout rate was observed for Dimension 18 OD Max Ring gauge inspection. Deviation is for data collection between In-line operations for root cause investigation documented in NC-20477 & NC-21443.

Part Number Affected	Revision
SA0254-04/05/06	G
N/A	N/A

Start Date:	End Date:	Lot Number:
24-JUN-2022	23-JUL-2022	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):

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

Corrective Action Required: Yes No

If no, explain: Deviation for data collection only. Corrective action is not required.

Training Required: Yes No **If no, explain:** N/A

Title	Approval Name	Approval Signature	Date
Quality Manager	Tafzeelur Rahaman		24 JUN 2022
Manufacturing Manager	Jake Stanislowski		24 JUN 2022
Operations Manager	Dan Anderson		24 JUN 2022

Inspection for DA2262

Inspection instructions:

DIM 18 OD MAX:

Drop a drop ring gauge (TMI0966) from the proximal end of the shaft. Place the ring gauge helper (TL0981) gently over the end of the part such that it rests on the go ring gauge but does not advance the ring further.

Pass if the shaft end is visible above the surface of the ring gauge helper.

Fail if the shaft end is not visible above the surface of the ring gauge helper.

Fail if the shaft end is even with the surface of the ring gauge helper.

Fail if the ring gauge stops prior to the full inspection length and ring gauge helper is not required.

DIM 18 OD MIN:

Load ring gauge (TMI0965) on distal end of the shaft.

Pass if the shaft end does not pass through ring gauge.

Fail if the shaft end passes through ring gauge and visible on the other end.

NOTE:

- No rework will be performed on DIM 18 MAX rejected parts.
- Record the scrap on SAP router and the table below.
- Save the rejected parts for Engineering review, if necessary.

Inspection Form (Fill below for each lot)

Product	SA0254-06
Production Lot Number	500000/64476

Operation	Test/Specification	Dimension	Sample Plan	Equipment	TMI#	#PASS	#FAIL	Initial and Inspection Date
OPER 500: LEAK TEST/ PROXIMAL CUT/ RING GAUGE- DIM 13/21	▲ 18 Proximal Outer Diameter MAX (0.138"-0.142")	0.140" ± 0.002" 100%	Ring gauge TMI0966	TMI0966 ①49+	131	PV6201Aug22		
	▲ 18 Proximal Outer Diameter MIN		Ring gauge TMI0965	TMI0965 360	0			PV6201Aug22

① PV6201Aug22

Maximum Force Reached During Tensile Test
 (10 samples accepted from final inspection for each lot shall be randomly 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 1	30.48	27.96	34.08	26.74	26.36	36.22	27.2	24.38	36.29	25.52	29.523	4.4769485	4.378	9.922919513	8.542	PASS
Seg B	20.7	20.82	21.16	20	24.02	22.28	21.54	21.5	21.5	23.53	21.705	1.2529543	4.378	16.21956613	8.542	PASS
Seg C	65.36	50.16	63.06	52.66	52.1	48	66.6	49.9	47.58	53.86	54.928	7.2684903	4.378	23.10654951	8.542	PASS

All Force Values are recorded in Pound-Force and Distance is in Inches

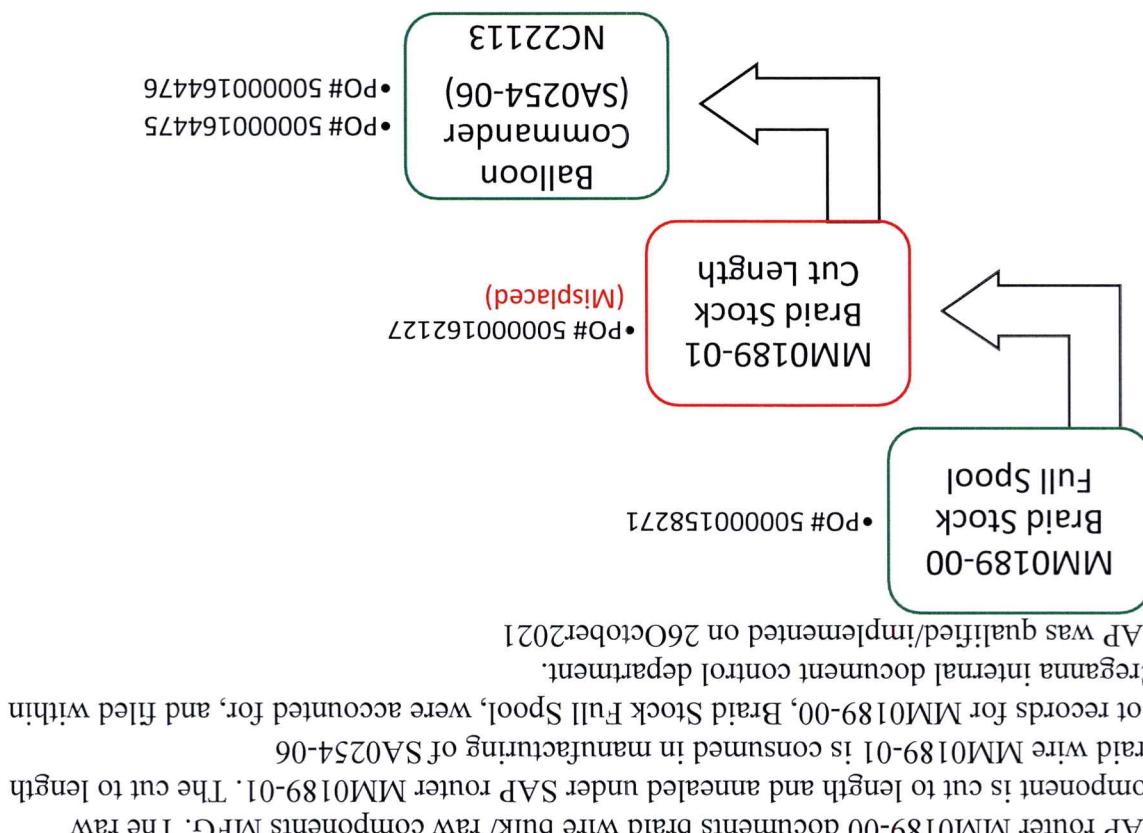
Specification for lower bound is 38N was converted to 8.542lbf

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 not being required for DA acceptance.
KINK TEST AND BEND TEST PERFORMED.

EDW Commander Balloon - Bend and Tensile Strength Testing
 LOT #: EDW500000164476
 Date: 04 AUG 22
 Inspector Name: LUKASZ C. TSHISHIMBI
 Equipment ID: TM10311B
 Cal Due Date: 31 OCT 2022

04 AUG 22

Braiding process flow in brief



Notes:

be shipped based on SAP ERP records.

furnished assembly SA0254-06 lots 500000164475, 500000164476 met customer requirements or can

the Braided Stock Cut Length production order 500000162127 met cut to length requirements and

the order was completed and confirmed on 19th July 2022. This memo provides the justification that

production order 500000162127 could not be located/misplaced while SAP ERP system shows that

Stock Cut Length w/ production order 500000162127, MM0189-01. The braid wire subassembly

On 17th Aug 2022, NC-22113 has been initiated for 2 balloon commander lots that consumed Braided

This memo pertains to Balloon Commander (SA0254-06) production orders included in NC-22113.

Purpose:**Subject:** NC-22113

DATE: 13 SEP 2022

Misplaced Annealing Production Orders

- SAP ERP records show order 500000162126 and before 500000162128. Please refer to the above SAP image.
- The lot records of 500000162126 and 500000162128 were reviewed, revealing lots were built with certified operators (1st and 2nd shift), the cut to length and annealing was done with released SAP process MP10288 Rev.J and MP10094 Rev.R, and assigned instructions within the manufacturing process MP10288 Rev.J and MP10094 Rev.R, and assigned instructions within the released SAP router M01189-01 during MFG. SAP records show that the operators completed the manufacturing process on 20July2022.
- Refer to attachment 1 for bradiing operators hourly production tracker and attachment 2 for individual training records of operators that worked on Lot# 500000162127. During training record review

Order No	Customer Name	Conf. No.	Work Order No	Entered Date	Entered By	Unit Conf.	Unit Count	Unit Conf. of Milestone	Oper./Act.	SubOp.	Created On
S00000162126	S001328540	500	PC	0	PC	ANNEAL01	TE439430	X	0050	19.07.2022	
S00000162127	S001328541	500	PC	0	PC	ANNEAL01	TE439430	X	0100	19.07.2022	
S00000162128	S001328542	500	PC	0	PC	ANNEAL01	TE439430	X	0150	19.07.2022	
S00000162129	S001328543	500	PC	0	PC	ANNEAL01	TE439430	X	0200	19.07.2022	
S00000162130	S001328544	500	PC	0	PC	ANNEAL01	TE439430	X	0200	19.07.2022	
S00000162131	S001328545	500	PC	0	PC	ANNEAL01	TE439430	X	0050	20.07.2022	
S00000162132	S001328546	400	PC	0	PC	ANNEAL01	TE276229	X	0100	20.07.2022	
S00000162133	S001328547	500	PC	0	PC	ANNEAL01	TE276518	X	0200	20.07.2022	
S00000162134	S001328548	500	PC	0	PC	ANNEAL01	TE439430	X	0050	20.07.2022	
S00000162135	S001328549	500	PC	0	PC	ANNEAL01	TE439430	X	0100	21.07.2022	
S00000162136	S001328550	500	PC	0	PC	ANNEAL01	TE439430	X	0150	21.07.2022	
S00000162137	S001328551	500	PC	0	PC	ANNEAL01	TE439430	X	0200	21.07.2022	

1. SAP router for MM0189-00, order 500000158271 shows that the braiding operation is performed per MPI0110. Also The following inspection is performed per MPI0110

a. Verify Pic per inch (PPI) with minimum 10x magnification

b. Braided pattern justification:



Casey O'Callahan, Sr. Operations Manager

22 SEP 2022

114867

Hope Przybilla, Sr. Quality Manager

22 SEP 2022

Hope Przybilla

Approvers:

Sagar Alahari, Quality Engineer

Sagar Alahari

Originator:

Based on above provided information, no impact to form, fit and function of produced product (Balloon Commander SA0254-06). The lot build records can be obtained from SAP ERP system, individual training records of operators worked for order 50000162127 can be seen in the attachment; with that component can be consumed to Balloon commander assembly level. Produced Balloon Commander SA0254-06 can progress as normal process. The approved memo is to be attached to NC-22113 for record.

Hour	FC Output	BC Output	Steering Output	TFR Output	SFR Output	AFR Output	Pascal Output	Stretching	Stretching	Reason for not meeting Target	OT	Total	160/288	/286	/285	/280	/450
1	/21	/19	/25	/33	/33	/22	/22	100	100	RC 162127	OT						
2	/37	/31	/100	/131	/195	/88	/88	100	100	RC 162127	OT						
3	/31	/31	/75	/98	/146	/66	/66	100	100	RC 162127	OT						
4	/37	/37	/100	/131	/195	/88	/88	100	100	RC 162127	OT						
5	/37	/37	/100	/131	/195	/88	/88	100	100	RC 162127	OT						
6	/21	/19	/50	/66	/98	/44	/44	100	100	RC 162127	OT						
7	/37	/37	/100	/131	/195	/88	/88	100	100	RC 162127	OT						
8	/31	/31	/75	/98	/146	/66	/66	100	100	RC 162127	OT						
9	/36	/37	/100	/131	/195	/88	/88	100	100	RC 162127	OT						
10											Regular Time						

Date: 18.Jul.2018
FKA/ML

Shift (circle one): 1 2 3 8 hr Days

Hourly Production Tracker

Line:

Quality Department
5905 Trenton Lane North
Plymouth MN 55442 USA



Attachment 1: Hourly Production Trackers - Lot#50000162127

Hour	FC Output	Screening Output	LCG Output	7FR Output	8FR Output	AFR Output	Pascal Output	Scanning	Tip Cutting	Reason for not meeting Target	Line: <u>Ammealine</u>
OT											
1	72	19	75	75	33	33	73	72	124	38	162125. all Shuttle BC
2	72	37	100	100	195	195	88	88	206	56	Shuttle SFE
3	72	31	146	146	198	198	75	75	206	49	151887
4	72	37	131	131	195	195	100	100	206	49	
5	72	37	131	131	195	195	100	100	206	56	
6	72	19	50	50	86	86	44	44	124	38	
7	72	37	100	100	195	195	88	88	206	56	Shuttle BC
8	31	31	100	100	146	146	66	66	206	49	162127
9	36	37	100	100	163	163	73	73	165	52	
OT											
Total	/288	/286	275	709	/1366	/1366	/623	500	/450		

Hourly Production Tracker
Shift (circle one): 1 2 3
Date: 19 JUL 22
8 hrs Days flowgely flowing flowing
Line: Ammealine

Quality Department
5905 Trenton Lane North
Plymouth MN 55442 USA



te.com

	Hour	FC Output	Seeding Output	BC Output	TR Output	SFR Output	AFR Output	Pascal Output	Stretching	TIP Cutting	Reason for not meeting Target
OT											
	1	/21	/19	/75	/33	/33	/22	100/24	/38	PC 142107	
	2	/37	/37	/100	/131	/195	/66	800/206	/56	PC 142107	
	3	/31	/31	/75	/98	/246	/66	800/206	/49	PC 142107	
	4	/37	/37	/100	/131	/195	/88	800/206	/56	PC 142107	
	5	/37	/37	/100	/131	/195	/88	800/206	/56	PC 142107	
	6	/21	/19	/50	/56	/98	/44	100/24	/38	BC 142127	
	7	/37	/37	/100	/131	/195	/88	800/206	/56	BC 142108	
	8	/31	/31	/75	/98	/246	/66	800/206	/49	PC 142108	
	9	/36	/37	/75	/110	/153	100/153	100/153	/52	PC 142108	
OT											

Line: Annealing
Shift (circle one): 1 2 3
8 hr Days

19 JUL 22

date:

NDL504 Nylabond

Quality Department
5905 Trenton Lane North
Plymouth MN 55442 USA



affinealing by C = 300

Hourly Production Tracker
shift (select one) 2 3
8 hr Days

Date: 10 Jul 23

Folache | 50/50

Plymouth MN 55442 USA
5905 Trenton Lane North
Quality Department



Hourly Production Tracker
Shift (circle one): 1 2 3 Line: Annelling

Cap. 10

say's

Plymouth MN 55442 USA
5905 Trenton Lane North
Quality Department



$$008 = 78$$

Date: 26 July 22

34 days

hourly production tracker

Plymouth MN 55442 USA
5905 Trenton Lane North
Quality Department



300

 BC → 28000016212 → 100
 PC → 38000061563 → 280

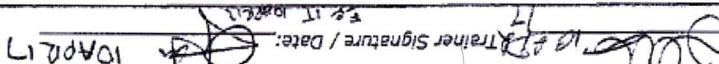
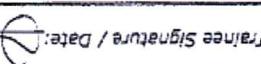
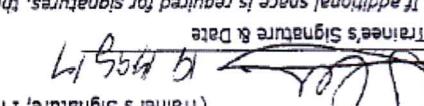
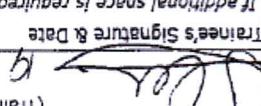
		Total	/288	/286	/79	/929	/1366	/623	/1550	/450
	OT									
9		/36	/36	/37	/75	/98	/110	/163	/163	/52
8		/31	/31	/31	/75	/98	/110	/163	/163	/52
7		/37	/37	/37	/100	/131	/131	/195	/195	/56
6		/21	/19	/50	/66	/98	/98	/206	/206	/38
5		/37	/37	/100	/131	/131	/195	/195	/195	/56
4		/37	/37	/100	/131	/131	/195	/195	/195	/56
3		/31	/31	/100	/131	/131	/195	/195	/195	/49
2		/37	/37	/100	/131	/131	/195	/195	/195	/56
1		/21	/19	/25	/33	/33	/33	/126	/126	/38
	OT									
		Hour	FC Output	Steering Output	BC Output	TFR Output	SFR Output	Pascal Output	Stretching	Trip Cutting
										Reason for not meeting Target

Line: Announcing
 Shift (circle one): 1 2 3 8 hr Days
 Date: 20 Jul 22.

Desp - Crl

Quality Department
 5905 Trenton Lane North
 Plymouth MN 55442 USA

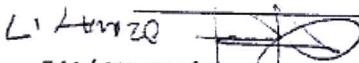
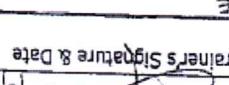
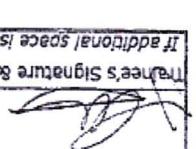


TRAINEE NAME: (Please Print): THOMAS PHOUMLIVONG Employee Number: 0094						
Individual Training Record						
CREGANNA MEDICAL						
Description of Training to be performed: DECALIVE, AUREAL, ERAL, TELEPERATION						
For Manufacturing Training, complete the following prior to starting hands on training: Reviewed MP: <input checked="" type="checkbox"/> Reviewed LHR <input checked="" type="checkbox"/> Reviewed tooling/equipment <input checked="" type="checkbox"/> Reviewed Safety Hazards / PPE						
Trainee Signature / Date:  10APR17						
Trainer Signature / Date:  10APR17						
Document all Training						
Part Number	Lot Number	Revision	Accepted	Rejected	Comments	Trainer Date/Initials
1. MNG043-01	1W15178-17	I	300	0		IT 10 APR 17
2. MNG057-01	C042310-17	I	QAM	0		IT 24 APR 17
3. MNG057-01	C042483-17	I	SGS	1		IT 24 APR 17
4. LMW0189-01	EON24162-17	I	427	0		IT 25 APR 17
5. LMW0077-01	CEY2444-17	I	242	0		IT 26 APR 17
6. LMW0078-01	CEV2304-17	I	337	0		IT 27 APR 17
(Trainer's Signature, I hereby certify that the training given was accurate and complete.)						
Trainee's Signature & Date:  14 MAY 17						
Name of Trainer: ANU TALENTINO						
Trainee's Signature & Date:  14 MAY 17						
If additional space is required for signatures, the reverse side of this form may be used.						

Quality Department
5905 Trenton Lane North
Plymouth MN 55442 USA

Attachment 2: Individual training records



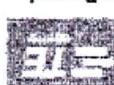
INDIVIDUAL TRAINING RECORD						
CRREGANNA MEDICAL						
Employee Name: (Please Print): THOMAS PHOENIX						
Employee Number: 0094						
MPI/MM/LHR/SPI/SOP/Other:						
Description of Training to be performed: DEFENSE, ANNUAL FLAID, HAZARD						
For Manufacturing Training, complete the following prior to starting hands on training:						
Reviewed MPI <input checked="" type="checkbox"/> Reviewed LHR <input checked="" type="checkbox"/> Reviewed tooling/equipment <input checked="" type="checkbox"/> Reviewed Safety Hazards / PPE						
Product Line: AEREAIR						
Operational(s): 10. 20. 30.						
Trainee Signature / Date:  02/14/17						
Trainer Signature / Date:  02/14/17						
Documentation all Training						
Part Number	Lot Number	Revision	Accepted	Rejected	Comments	Trainer
1. MM000000-01	102081-17	E	901	O		27APR17
2. MM0010-01	102040-17	E	677	2		27APR17
3. VM00077-01	CET2563-17	T	500	O	QA APR 17	27APR17
4. VM00077-01	CET2567-17	T	531	O	QA APR 17	27APR17
5. MM0003-01	1022575-17	I	254	O	QA APR 17	27APR17
6. MM00077-01	CET2515-17	I	545	O	QA APR 17	27APR17
(Trainers Signature, I hereby certify that the training given was accurate and complete.)						
Trainee Signature & Date:  19-May-17 UTM TOLENTINO						
Trainer's Signature & Date:  19-May-17						
If additional space is required for signatures, the reverse side of this form may be used.						
Name of Trainer						
Page 4 of 6						

- CONFIDENTIAL -

FM0402 Rev. A

* Fill out a separate training form per MPI/MM/LHR/SPI/SOP

If additional space is required, the reverse side of this form may be used.

Trainee's Signature & Date: <u>Nelson Nyangwono</u>						Trainer's Signature & Date: <u>A. CANAGAY</u>
(Trainer's Signature, I hereby certify that the training given was accurate and complete.)						
Part Number	Lot Number	Revision	Accepted	Rejected	Comments	Trainer Date/Initial
1. MM 0189-01	50000119763	R	550	0	Good	16 Nov 2021 GCAZ
2. MM 0189-01	50000120170	R	475	0	Good	17 Nov 2021 GCAZ
3. MM 0189-01	50000120685	R	575	0	Good	18 Nov 2021 GCAZ
4. MM 0189-01	50000121162	R	550	0	Good	20 Nov 2021 GCAZ
5. MM 0189-01	50000121163	R	550	0	Good	22 Nov 2021 GCAZ
6. MM 0189-01	50000121377	R	350	0	Good	22 Dec 2021 GCAZ
Document all Training						
Trainee Signature / Date: <u>Nelson Nyangwono</u>			Trainer Signature / Date: <u>A. CANAGAY</u>			
<input checked="" type="checkbox"/> Reviewed MPI <input checked="" type="checkbox"/> Reviewed LHR <input checked="" type="checkbox"/> Reviewed tooling/equipment <input checked="" type="checkbox"/> Reviewed Safety Hazards / PPE For Manufacturing Training, complete the following prior to starting hands on training: Annnalizing fluid (faster cannaclor)						
Product Line: <u>Cannula Line</u> Operation(s): <u>150-C</u> Employee #: <u>0094</u> *Document #: <u>MM / MPI / LHR / SPI / SOP / Other:</u>						
Trainee NAME: (Please Print): <u>Nelson Nyangwono</u> Employee #: <u>EXPRESS-180</u> Individual Training Record 						

Operator: Nelson Nyangwono

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FM0402 Rev. A

* Fill out a separate training form per MPI/HM/LHR/SPI/SOP

If additional space is required, the reverse side of this form may be used.

Part Number	Lot Number	Revision	Accepted	Rejected	Comments	Trainer Date/Initials		Trainer's Signature & Date
						Name of Trainer	Trainee's Signature & Date	
1.M10189-01	500000118227	R	570	0	Good	04-Nov-21	GLORIA A. CAMAGAY	<i>[Signature]</i> 12-Nov-2021
2.M00074-01	500000117977	R	225	0	Good	04-Nov-21	GLORIA	<i>[Signature]</i> 04-Nov-2021
3.M10189-01	500000118518	R	520	0	Good	08-Nov-21	GLORIA	<i>[Signature]</i> 08-Nov-2021
4.M10189-01	500000119736	R	570	0	Good	11-Nov-21	GLORIA	<i>[Signature]</i> 11-Nov-2021
5.MN0380-01	500000119568	R	355	0	Good	11-Nov-21	GLORIA	<i>[Signature]</i> 11-Nov-2021
6.M10189-01	500000119569	R	520	0	Good	11-Nov-21	GLORIA	<i>[Signature]</i> 11-Nov-2021

(Trainer certifies that the training given was accurate and complete.)

Document all Training

Trainee Signature / Date: *[Signature]* 04-Nov-2021 Trainer Signature / Date: *[Signature]* 04-Nov-2021

Reviewed MPI Reviewed LHR Reviewed tooling/equipment Reviewed Safety Hazards / PPE

For Manufacturing Training, complete the following prior to starting hands-on training:

Product Line: *ConnexLink*

Description(s) of training to be performed: *Cat 8 Etching (Baculum Components)*

Operation(s): *100.0*

*Document #: (MPI) MM / LHR / SPI / SOP / Other: *0094*

TRAINEE NAME: (Please Print): *WELSAN NYANGWAN* Employee #: *EKFRA655-180*

Individual Training Record



CRGCANNA MEDICAL

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FM0402 Rev. B

INDIVIDUAL TRAINING RECORD						
Trainee's Name: KA Varag Employee #: TE508593 Document Revision: J						
Description(s) of Training to be performed: Cutting Board (FLEX Communication/Edition Committee)						
Product Line: Dining						
For Managers/Coordinators: Completes the following prior to starting hands-on training:						
Reviewed LHR Reviewed tooling/equipment Reviewed Safety Hazards / PPE						
Trainee Signature / Date: 28-Feb-2022						
Document all Training						
Part Number	Lot Number	Part # Revision	Accepted	Rejected	Comments	Trainee Date/Initials
JMM0014-01	500000 136988	G	500	0	N/A	28-Feb-2022 GCA
JMM0014-01	500000 136989	G	500	0	N/A	28-Feb-2022 GCA
JMM0189-01	500000 137080	D	500	0	N/A	28-Feb-2022 GCA
JMM0189-01	500000 137081	D	500	0	N/A	28-Feb-2022 GCA
JMM0189-01	500000 137325	A	150	0	N/A	28-Feb-2022 GCA
(Trainee's signature, I hereby certify that the training given was accurate and complete)						
Trainer's Signature & Date: 14-Feb-2022 GCA						
Name of Trainer: GCA						
Trainer's Signature & Date: 15-Feb-22						
Supervisor / Lead / Designee Signature and Date:						
Form has been verified for date accuracy and completion: <i>[Signature]</i>						
Fill out a separate training form per MPI/MHR/SPP/SDP. If additional space is required, the reverse side of this form may be used.						

Operator: Ka Vang

- CONFIDENTIAL -

Individual Training Record						
Trainee NAME: K.A. Vargy Employee No: TEE508593 Document Revision: 004/4						
Description(s) of Training to be performed: Type Cutting blade (Balloons (Cannulae)) Product Line: Cannula						
For Manufacturer Training, complete the following prior to starting hands on training: <input checked="" type="checkbox"/> Reviewed MPF <input checked="" type="checkbox"/> Reviewed LHR <input checked="" type="checkbox"/> Reviewed tooling/equipment <input checked="" type="checkbox"/> Reviewed Safety Hazards / PPE						
Trainee Signature / Date: 01 Mar 2022						
Document all Training <input checked="" type="checkbox"/> Trainer Signature / Date: 01 Mar 2022						
Part Number Lot Number Part # Revision Accepted Rejected Comments Trainer Date/Initials						
1. MW 0189-01	500000136984	③	325	0	N/A	01/03/2022 GCG
2. MW 0189-01	500000136985	③	375	0	N/A	02/03/2022 GCG
3. MW 0189-01	500000137083	③	250	0	N/A	03/03/2022 GCG
4. MM 0189-01	500000137512	③	150	0	N/A	03/03/2022 GCG
5. N/A	N/A	N/A	N/A	N/A	N/A	N/A
(Trainer's Signature), hereby certify that the training given was accurate and complete.						
Trainee's Signature & Date: 01 Mar 2022						
Trainer's Signature & Date: 01 Mar 2022						
Supervisor / Lead / Designer Signature and Date: 15 Mar 2022						
Form has been verified for date accuracy and completion:						
Additional space is required, the reverse side of this form may be used.						
Fill out a separate training form per MP/MW/LHR/SOP						

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FM0402 Rev. B																							
<input type="checkbox"/> If additional space is required, the reverse side of this form may be used. <input checked="" type="checkbox"/> Fill out a separate training form per MPI/MIM/UHR/SPI/SDP																							
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2" style="text-align: center; padding: 5px;">Trainee's Signature & Date:</td> <td colspan="2" style="text-align: center; padding: 5px;">Trainer's Signature & Date:</td> <td colspan="2" style="text-align: center; padding: 5px;">Supervisor / Lead / Designee Signature and Date:</td> </tr> <tr> <td colspan="2" style="text-align: center; padding: 5px;"><i>15/11/22</i></td> <td colspan="2" style="text-align: center; padding: 5px;"><i>14/11/22</i></td> <td colspan="2" style="text-align: center; padding: 5px;"><i>14/11/22</i></td> </tr> <tr> <td colspan="6" style="text-align: center; padding: 5px;">Form has been verified for date accuracy and completeness:</td> </tr> </table>						Trainee's Signature & Date:		Trainer's Signature & Date:		Supervisor / Lead / Designee Signature and Date:		<i>15/11/22</i>		<i>14/11/22</i>		<i>14/11/22</i>		Form has been verified for date accuracy and completeness:					
Trainee's Signature & Date:		Trainer's Signature & Date:		Supervisor / Lead / Designee Signature and Date:																			
<i>15/11/22</i>		<i>14/11/22</i>		<i>14/11/22</i>																			
Form has been verified for date accuracy and completeness:																							
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Trainee's Signature, I hereby certify that the training given was accurate and complete.																							
<i>15/11/22</i>																							
Part Number:	Lot Number:	Part # Revision:	Accepted:	Rejected:	Comments:																		
JMWI189-01	500000135773	D	275	0	N/A																		
JMWI189-01	500000135775	D	400	0	N/A																		
JMWI189-01	500000135776	D	400	0	22 Feb 2022 GCR																		
JMWI189-01	500000135777	D	275	0	N/A																		
JMWI189-01	500000135779	D	500	0	N/A																		
JMWI189-01	500000135781	D	400	0	23 Feb 2022 GCR																		
JMWI189-01	500000135782	D	400	0	N/A																		
JMWI189-01	500000135783	D	400	0	23 Feb 2022 GCR																		
JMWI189-01	500000135785	D	400	0	N/A																		
JMWI189-01	500000135787	D	400	0	N/A																		
JMWI189-01	500000135789	D	400	0	N/A																		
Trainee's Signature & Date:																							
<i>15/11/22</i>																							
Trainer's Signature & Date:																							
<i>14/11/22</i>																							
Document all Training:																							
<i>15/11/22</i>																							
For Manufacturer Training, complete the following prior to starting hands on training:																							
<input checked="" type="checkbox"/> Reviewed MPI <input type="checkbox"/> Reviewed LHR <input type="checkbox"/> Reviewed tooling/equipment <input type="checkbox"/> Reviewed Safety Hazards / PPE																							
Product Line:																							
<i>Crucible</i>																							
Description(s) of Training to be performed:																							
<i>Crucible Crucible Crucible (bottom line)</i>																							
Operational:																							
<i>150</i>																							
Employee #: <i>150</i>																							
Employee Name: <i>AL Vaca</i>																							
Employee #: <i>150</i>																							
Employee Name: <i>AL Vaca</i>																							
Document Revision:																							
<i>R</i>																							
Document #: <i>0094</i>																							
Employee #: <i>150</i>																							
Individual Training Record																							
 CREGANNA <small>MEDICAL</small>																							

Quality Department
5905 Trenton Lane North
Plymouth MN 55442 USA



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FMO402 Rev. B

Operator: Thomasina K Williams

Plymouth MN 55442 USA
5905 Trenton Lane North
Quality Department



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FMO402 Rev. B

INDIVIDUAL TRAINING RECORD					
TRAINEE NAME: HOMELING K WILLIAMS					
EMPLOYEE #: TWD42-TE521540	DOCUMENT #: MWI/44-0288	DOCUMENT REVISION #: Q	DESCRIPTION(S) OF TRAINING TO BE PERFORMED:	PRODUCT LINE: E&I CABLES	
FOR MANUFACTURING TRAINING, COMPLETE THE FOLLOWING PRIOR TO STARTING HANDS ON TRAINING:					
<input type="checkbox"/> REVIEWED MP <input type="checkbox"/> REVIEWED LHR <input type="checkbox"/> REVIEWED TOOLING/EQUIPMENT <input type="checkbox"/> REVIEWED SAFETY HAZARDS / PPE					
DOCUMENTS ATTACHED TO TRAINING:					
Part Number	Lot Number	Part # Revision	Accepted	Rejected	Comments
1. 120000004-01	50000000163818	J	500	0	28 JUL 22 (EB29)
2. 120000004-01	50000000163818	J	90	0	27 JUL 22 (EB29)
3. 120000004-01	50000000163818	J	100	0	26 JUL 22 (EB29)
4. MM0118-01	50000000163818	J	100	0	25 JUL 22 (EB29)
5. MM0118-01	50000000163818	J	500	0	28 JUL 22 (EB29)
(Trainee's Signature, I hereby certify that the training given was accurate and complete)					
Trainee's Signature & Date: <u>TWD42</u> 28 JUL 22 Name of Trainer: <u>K. Williams</u> Date: <u>28 JUL 22</u> Supervisor / Lead / Designer Signature & Date: <u>B. B. B.</u> 28 JUL 22					
Form has been verified for date accuracy and completion. * Fill out a separate training form per MPI/MM/LHR/SPI/SP/OP if additional space is required, the reverse side of this form may be used.					

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Quality Department



Status CURRENT Effective 12/8/2023

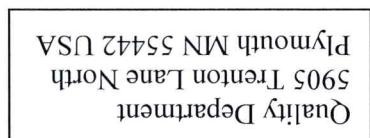
- CONCLUDING -

HMO142 REV. B

* Fill out a separate training form per MPI/MM/LHR/SPI/SOP

INDIVIDUAL TRAINING RECORD						
TRAINEE NAME: CRB/CANNA MEDICAL INC. DOCUMENT #:						
EMPLOYEE #: TE 487750						
OPERATOR(S): 150						
DESCRIPTION(S) OF TRAINING TO BE PERFORMED: Broad Type Cutting/Fix Commanders & Follow Commanders						
PRODUCT LINE: Gunning Decoartment						
FOR INDIVIDUALIZING TRAINING, COMPLETE THE FOLLOWING PRIOR TO STARTING HANDS ON TRAINING:						
REVIEWED TAILING/EQUIPMENT						
REVIEWED PPE						
REVIEWED LHR						
DOCUMENT ALL TRAINING						
Part Number	Lot Number	Part Revision	Accepted	Rejected	Comments	Trainer Date/Initials
1. M10074-01	50000148543	G	100	0	N/A	04 May 22
2. MM0074-01	50000148640	G	100	0	N/A	04 May 22
3. M10074-01	50000149176	G	300	0	N/A	08 May 22
4. M10074-01	50000149347	G	300	0	N/A	12 May 22
5. M10074-01	50000150339	G	300	0	N/A	13 May 22
(Trainee's Signature), I hereby certify that the training given was accurate and complete.						
Trainee's Signature & Date: 13 May 22						
Name of Trainer: P. Name & Date: 17 May 22						
Trainer's Signature & Date:						
Form has been verified for date accuracy and completeness.						
Signature / Lead / Designee Signature and Date:						
If all the spaces in required, the reverse side of this form may be used.						

Operator: Francella Kyne



Status CURRENT Effective 12/8/2021

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FM0402 REV. B

Individual Training Record						
Trainee NAME:	RAChel DOL					
Employee #:	489188					
Document Revision #:	MPL0049 Mpl0094					
Product Line:	Decommissioning / Strengthening					
For Manufacturer Training, complete the following prior to starting hands on training:						
<input checked="" type="checkbox"/> Reviewed MPI <input checked="" type="checkbox"/> Reviewed LHR <input checked="" type="checkbox"/> Reviewed tooling/equipment <input checked="" type="checkbox"/> Reviewed Safety Hazards / PPE		Dокумент all Training				
Part Number:	Lot Number	Part # Revision	Rejected	Accepted	Comments	Trainer Date/Initials
1. MMD189-C1	SD000014595	D	5C	0	_____	01Aug22
2. MM1029-C1	SD00000163823	A	17D	5	5DB	01Aug22
3. MM1029-C1	SD00000163824	A	199	1	1BD	01Aug22
4.						
(Trainer's Signature, hereby certify that the training given was accurate and complete)						
Name of Trainer: <i>Rachael Dol</i> Trainer's Signature & Date: <i>01Aug22</i> Supervisor / Lead / Designee Signature and Date: <i>Rachael Dol</i> Form has been verified for date accuracy and completion: <i>Rachael Dol</i> <i>01Aug22</i>						
<small>If additional space is required, the reverse side of this form may be used.</small> <small>Fill out a separate training form per MPI/MAM/HR/SOP</small>						

Operator: Rachel Dol



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FMO402 Rev. A

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1202CEC2021 08DEC2021

- * Fill out a separate training form per MPI/MM/LHR/SPI/SOP

102

Name of Trainer

re

Part Number	Lot Number	Revision	Accepted	Rejected	Comments	Trainer Date/Initials
1. M47101189-01	500000123827	R	100	0	" "	07DEC21 / EBS25
2. M47101189-01	500000123588	R	100	0	" "	07DEC21 / EBS25
3. M47101189-01	500000123589	R	100	0	" "	07DEC21 / EBS25
4. M47101189-01	5000000124145	R	350	0	" "	08DEC21 / EBS23
5. M47101189-01	5000000124145	R	150	0	" "	08DEC21 / EBS23
6. M47101189-01	5000000124145	R	250	0	" "	10DEC21 / EBS24

Trainee Signature / Date: 07 DEC 2021 Trainer Signature / Date: 07 DEC 2021

Reviewed LHR Reviewed MP1 Reviewed Safety Hazards / PPE

After manufacturing, reworking, complete the following prior to starting hands on training:

Product Line: Penning

Tip Cutting Broad wire (Rallion commander) Description(s) of Training to be performed:

150-6 Operations(s):

4600 er:

EMPLOYEE #: 1E5D0311 **TRAINEE NAME: (Please Print):** JOSÉ EDUARDO LALAKE

THIRTEEN TRADING RECORDS

CHEQUAN
MEDICAL
is part of

Operator: Josephine Clarke

Quality Department
5905 Trenton Lane North
Plymouth MN 55442 USA

MO402 REV. A

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PLG 29 14 DEC 2021
PLG 29 13 DEC 2021

* Fill out a separate training form per MPI/MM/LHR/SPI/SOP

If additional space is required, the reverse side of this form may be used.

Part Number	Lot Number	Revision	Accepted	Rejected	Comments	Trainer Date/Initial		Trainee Signature & Date	Trainer's Signature & Date
						Trainee's Signature	Date		
1. MM0189-01	500010125007	R	325	0		PLG 29 13 DEC 2021	PLG 29 13 DEC 2021	PLG 29 13 DEC 2021	PLG 29 13 DEC 2021
2. MM0189-01	50000125009	R	25	0		PLG 29 13 DEC 2021	PLG 29 13 DEC 2021	PLG 29 13 DEC 2021	PLG 29 13 DEC 2021
3. MM0189-01	50000125363	R	44045	0	HIA	PLG 29 13 DEC 2021	PLG 29 13 DEC 2021	PLG 29 13 DEC 2021	PLG 29 13 DEC 2021
4. MM0189-01	50000125464	R	500	0		PLG 29 13 DEC 21	PLG 29 13 DEC 21	PLG 29 13 DEC 21	PLG 29 13 DEC 21
5. MM0189-01	50000125465	R	280	0		PLG 29 13 DEC 21	PLG 29 13 DEC 21	PLG 29 13 DEC 21	PLG 29 13 DEC 21
6. MM0189-01	50000125765	R	300	0		PLG 29 13 DEC 21	PLG 29 13 DEC 21	PLG 29 13 DEC 21	PLG 29 13 DEC 21

(Trainee's Signature, I hereby certify that the training given was accurate and complete.)

PLG 29 13 DEC 2021

Trainee Signature / Date: *PLG 29 13 DEC 2021* Trainer Signature / Date: *PLG 29 13 DEC 2021*

For Manufacturing Training, complete the following prior to starting hands on training:

Reviewed MPI Reviewed LHR Reviewed tooling/equipment Reviewed Safety Hazards / PPE

Product Line: *Manufacturing* Description(s) of Training to be performed: *Tip - Cutting Steel Wire*

Operation(s): *150-6* *Document #: *MPI/MM/LHR/SPI/SOP/Other: 0094*

Employee #: *TE500311* Trainee NAME: (Please Print): *Josephine Clarke*

Individual Training Record

CRGANNA MEDICAL SYSTEMS

TE

TECNA MEDICAL INDUSTRIAL TRAINING RECORD Employee #: TE 500311 Trainee NAME: JOSPEH INC CLARK Document #: MP1 0041 Document Revision: R Employee #: TE 500311 Individual Training Record (Please Print) MP/UR/SP/AR Document #: MP1 0041 Document Revision: R Product Line: ANNEALING For Manufacturing Training, complete the following prior to starting hands-on training: <input type="checkbox"/> Reviewed MP <input type="checkbox"/> Reviewed LHR <input type="checkbox"/> Reviewed tooling/equipment <input type="checkbox"/> Reviewed Safety Hazards / PPE Trainee Signature / Date: <i>J. Clark</i> 27 Apr 22 Trainer Signature / Date: <i>Maurizio</i> 27 Apr 22 Document all Training Part Number Lot Number Part # Revision Accepted Rejected Comments Trainer Date/Initials						
1. MM0074	SM0000146467	5	100	0	N/A	ML18 27 Apr 22
2. MM0074	SM0000146468	6	100	0	N/A	ML18 27 Apr 22
3. MM0074	SM0000146470	7	100	0	N/A	ML18 27 Apr 22
4.						
5.						
(Trainee's Signature, I hereby certify that the training given was accurate and complete) Name of Trainer Name of Trainee Trainer's Signature & Date Trainee's Signature & Date Form has been verified for date accuracy and completion: <i>S. Clark</i> 28 Apr 22 Supervisor / Lead / Designer Signature and Date If additional space is required, the reverse side of this form may be used. Fill out a separate training form MP/MI/LHR/SOP FM0402 Rev. B						

Document Number Affected	Revision
SPI0005(3005409);	REV P;
SPI0006(3005410);	REV K;
SPI0012(3005425);	REV 15;
SPI0003(3005408);	REV H;
SPI0087(3005625);	REV M;
SPI0256(3106848);	REV 05;
SPI0129(3005834);	REV 07;
SPI0250(3006245);	REV E;
SPI0261(3106823);	REV D;
SPI0255(3106838);	REV 04;
SPI0259(3107348);	REV 02;
SPI0260(3106847);	REV 01;
SPI0155(3005973);	REV 05;
SPI0262(3106992);	REV A;
SPI0274(3107960);	REV 03

Requestor Name: Saketh Tharumtreeddy (TE471240)

DEVIATION AUTHORIZATION FORM

DEVIATION AUTHORIZATION NUMBER: DA 2263



is part of
CRG ANNNA
MEDICAL

① EXPIRED TIL 02 AUG 2022 TE14 22 GLL2022

Part Number Affected	Revision
SA0155 - 01	F
SA0286 - 01 & SA0286 - 02	07
SA0285 - 01	08
SA0067 - TAB	J
SA00621-01	4
SA0613-01	A
SA0608-01	A
SA0604-01	A

Justification: The following DA is an interim containment action for CAPA-11585/SCAR-001716. The DA will act as a checklist for shipping personnel to verify approved suppliers of individual Raw Materials from certifications against Raw Material - Approved Supplier Matrix (DA Attachment) for specific part number (SAXXXX-XX). The action will help the TE prevent shipping of product(s) built with unapproved suppliers.

- **Note - Perform the DA instructions specific to product line, for more details refer to DA attachment and perform 8.0.
- Per SPI0005 after step 4.3.1 proceed to 4.4.
 - Per SPI0006 after step 4.3.1 complete the review per DA attachment and proceed to 4.4.
 - Per SPI0003 after step 4.3.2 complete the review per DA attachment and proceed 4.4.
 - Per SPI0003 after step 4.3.1 proceed 4.4.
 - Per SPI0007 after step 4.3.2 complete the review per DA attachment and perform 4.3.3.
 - Per SPI0256 after step 6.3.2 complete the review per DA attachment and perform 6.4.
 - Per SPI0250 after step 5.3.3 complete the review per DA attachment and perform 5.4.
 - Per SPI0259 after step 5.2.3 proceed 5.2.4
 - Per SPI0260 after step 5.3.1 proceed 5.3.2
 - Per SPI0255 after step 5.3.1 proceed 5.3.2
 - Per SPI0269 after step 4.3.1 complete the review per DA attachment and perform 4.4.
 - Per SPI0269 after step 4.3.1 complete the review per DA attachment and perform 4.4.
 - Per SPI0271 after step 7.3.1 complete the review per DA attachment and perform 7.4.
 - Per SPI0269 after step 4.3.1 proceed 4.4.
 - Per SPI0261 after step 5.3.1 proceed 5.3.2
 - Per SPI0255 after step 5.3.1 proceed 5.3.2
 - Per SPI0260 after step 5.3.1 proceed 5.3.2
 - Per SPI0255 after step 5.3.1 proceed 5.3.2
 - Per SPI0262 after step 6.3.1 proceed 6.4
 - Per SPI0274 after step 7.1.1 proceed 8.0
 - Per SPI0262 after step 6.3.1, complete the review per DA attachment and perform 6.4.
 - Per SPI0262 after step 6.3.1, complete the review per DA attachment and perform 5.3.2
 - Per SPI0255 after step 5.3.1, complete the review per DA attachment and perform 5.4.
 - Per SPI0259 after step 5.2.3 proceed 5.2.4
 - Per SPI0260 after step 5.3.1 proceed 8.0
 - Per SPI0255 after step 5.3.1 proceed 5.3.2
 - Per SPI0262 after step 6.3.1 proceed 6.4
 - Per SPI0274 after step 7.1.1 proceed 8.0

Deviation To:

Deviation From:

ST40 27 JUN 2022

INFORMATION.

*4. REFER TO THE CURRENT SPI AND PRODUCT ITEM
 REVISION. SEE ATTACHED MEMO FOR MORE

Title				Approval Name	Approval Signature	Date														
				Tafzeelur Rahaman		24 JUN 2022														
				Matthew Benson		24 JUN 2022														
				Jared Smith		24 JUN 2022														
				(DOL of Operations)①	(MOLSES AUTHORITY)②	24 JUN 2022														
				Manufacturing Engine Manager	Quality Control Manager	24 JUN 2022														
DEV: UN68 J7 JUN 2022																				
FM002.REV.F Deviation Authorization																				
If no, explain: The corrective action will be housed under CAPA 11585																				
Corrective Action Required: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If no, explain: N/A																				
Training Required: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If no, explain: N/A																				
<table border="1"> <tr> <td colspan="2">Control Plans</td> <td><input type="checkbox"/> Yes</td> <td><input checked="" type="checkbox"/> No</td> <td>FMEA's</td> <td><input type="checkbox"/> Yes</td> <td><input checked="" type="checkbox"/> No</td> </tr> <tr> <td colspan="2">Validations</td> <td><input type="checkbox"/> Yes</td> <td><input checked="" type="checkbox"/> No</td> <td colspan="3">Details (if any): N/A</td> </tr> </table>							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		
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																
<table border="1"> <tr> <td colspan="2">Risk Assessment:</td> <td colspan="5">Is there any potential risk(s) that may occur as a result of the proposed deviation including the following: There is no observed risk to the product and process.</td> </tr> <tr> <td colspan="2"></td> <td colspan="5"></td> </tr> </table>							Risk Assessment:		Is there any potential risk(s) that may occur as a result of the proposed deviation including the following: There is no observed risk to the product and process.											
Risk Assessment:		Is there any potential risk(s) that may occur as a result of the proposed deviation including the following: There is no observed risk to the product and process.																		

Start Date:	End Date:	Lot Number:	
SA0603-01	SA0602-01	04	05
SA0601-01	SA0598-01	03	05
SA0579-01	SA0474-01	A	A
SA0473-01			

CONTROLLED COPY

- o Edwards approved NOC 20022-SP-1595 for the use of PTFE Liner for SA0343-01 only (10016327001) sourced from Optinova 1000-2727-01 (alternate source RM7591-01) PTFE Liner 0.168" ID x 0.002" W and 1000-2726-01 (alternate source for RM7538-02) PTFE Liner 0.030" ID x 0.0015" W.

1) New Additions of Raw materials to DA 2263

Risk Assessment: The risk assessment will be based on all the updates, removal, and/or addition of raw materials to the (Raw material-approved supplier matrix as part of deviation). Following are the changes captured between the transition of DA2245 to DA2263.

- After the implementation of DA 2245, it was identified that the product lines (SA0343-01) Pascal Steerable Gen 1C and SA0598-01(DDS 18FT Steering Shaft v1.5) had approved NOCs from Edwards to use alternative raw materials. These approved raw materials were initially not part of DA 2245. Additionally, after reviewing the DA 2245 data, it was identified that some raw materials needed to be updated, removed, and/or added to (Raw material- approved supplier matrix).

- DA2245 was implemented as a Downstream interim action for SCAR001716/CAPA-11585. The purpose of the downstream deviation is to verify if all the raw materials that were consumed to manufacture Edwards lots are from approved suppliers. The raw material- approved supplier matrix (as an attachment to DA 2263) provides the list of approved suppliers for their respective product raw materials.

This memo documents the rationale for closing out the previous Deviation 2245 and opening a new deviation 2263 to continue downstream interim action. The memo also analyzes the risk associated with the update, addition, and/or removal of raw materials from the raw material-approved supplier with the new DA2263.

Background:

SCAR-1716 / CAPA-11585
Subject: Closure of Deviation 2245 and opening a new Deviation 2263 as part of interim action for

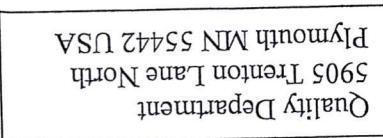
FROM: Saketh Reddy Thauvetteddy, Quality Engineer

DATE: 06/28/2022

MEMO



Quality Department
5905 Trenton Lane North
Plymouth MI 44223 USA



- o There is no risk to the initial containment as these are new addition / approved suppliers by Edwards as part of NOC's.

These FEP are used for the following processes:

1. As an aid for protecting the exterior surface of features of the shaft from damage, foreign material, etc. (Temporary protective jacket)
2. As an aid for protecting restacking or isolating loose components/features of the shaft (no bonding involved)
3. As an aid for controlling the flow of polymer in a restraint or define local features
4. As an aid for controlling the flow of polymer in a restraint or define local features (not used establishing the tip bond which occurs through an ID and butt joint via main reflow)

Table 2

Part Number	RM0567	RM0357	Current	Proposed	FEP Supplier	Zeus	Fluorinated Ethylene Propylene	All applications outlined below except tipping below excluding tipping	All applications outlined below except tipping below including tipping	Only to be used in tipping if RM0357 runs out	Process used	All applications outlined below except tipping	All applications outlined below except tipping	Wall thickness (ref.)	.010" ± .002"	Same
Recovered ID	.210" min	.240" min	.230" min	.250" min	Recovered ID	.131" max	.150" max	.144" max	.156" max	.156" min	Recovered ID	.210" max	.131" max	Recovered ID	.010" ± .002"	Same
Material	Zeus	Zeus	Same	Same	Material	Fluorinated Ethylene Propylene	Same	Same	Same	Same	Material	Fluorinated Ethylene Propylene	Same	Wall thickness (ref.)	.010" ± .002"	Same
FEP Supplier	RM0567	RM0357	Proposed	Proposed	FEP Supplier	RM4001	RM7648	Proposed	Proposed	Proposed	FEP Supplier	RM4001	RM7648	Recovered ID	.210" max	.131" max

composition.

- o Edwards approved NOC 20022-SP-1729 for the use of RM4001-01 & RM7648-01 for SA0598-01. The line currently utilizes FEP (PNS RM4001 and RM7648 only to be used in tipping if proposed/approved FEP (PNS RM4001 and RM7648 only to be used in tipping if RM0357 runs out)) are all sourced from Zeus and are of the same material.

Table 1

CURRENT MATERIAL APPROVED MATERIAL DESCRIPTION																	
RM7538-02	ZEUS	PTFE ESI	1000-2726-	PTFE Exit Tech	0.030 ID x 0.0015 W	0.0015 W	TE Brooklyn Park, (Optimova)	ZEUS	Industrial Tubing	0.030 ID x 0.0015 W	0.0015 W	TE Brooklyn Park, (Optimova)	ZEUS	Industrial Tubing	0.030 ID x 0.0015 W	0.0015 W	TE Brooklyn Park, (Optimova)
RM7591-01	ZEUS	PTFE 1.168ID	1000-2727-	PTFE Liner	0.168 ID x 0.02W 60L	0.002 Wall x 60	PTFE Free	ZEUS	Industrial Tubing	0.168 ID x 0.02W 60L	0.002 Wall x 60	PTFE Free	ZEUS	Industrial Tubing	0.168 ID x 0.02W 60L	0.002 Wall x 60	PTFE Free

MATERIAL NUMBER	MATERIAL DESCRIPTION	PRODUCT no	REASON FOR ADDITION	SA0473-01	R-Pebax 3533 SA01 25% Panton 289C	SA0473-01	R-M8313-01
RM7655-01	FEP Limet Ext Sub-Lite-Wall Tech 60L	SA0474-01	Bypassed during matrix compilation	SA0474-01	FEP Limet Ext Sub-Lite-Wall Tech 60L	SA0474-01	RM7655-01

3) Addition of Raw materials to the raw material-approved supplier matrix in DA 2263

- o The above materials inadvertently got into the matrix. Removing these RMs does not pose any risk to the interim containment as they are currently not used on the product.

Table 3

MATERIAL NUMBER	MATERIAL DESCRIPTION	PRODUCT no	REASON FOR REMOVAL	PRODUCt	NUMBER	MATERIAL DESCRIPTION	PRODUCT no	REASON FOR REMOVAL	PRODUCt	NUMBER	MATERIAL DESCRIPTION	PRODUCT no	REASON FOR REMOVAL	PRODUCt
TL0971-01	Stepped Mandrel Short Sheath	SA0608-01	Non-Consumable part, the part does not ship to the customer											
RM8203-01	103-0340 PET Shrink Tube	SA0579-01	The part was previously introduced using DA 2112. Not required anymore.											
RM7534-02	FEP HS 64L 270Exp ID .010W 1.6-1	SA0473-01	Not part of DA 2112. Not part of 0.400" MIN.1DX0.250"MAX.0DX20"1											
RM4004-02	FEP HS	SA0473-01	Not part of 0.400" MIN.1DX0.250"MAX.0DX20"1											
RM7838-02	MB .1805ID .1835OD .0015W .050L	SA0254	Not part of SA0254 BOM											

2) Removal of raw materials from the raw material-approved supplier matrix from DA2245

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Table 4

TL1019-01	Main shipping Mandrel	SA0579-01	Bypassed during matrix compilation	SA0579-01	Small shipping Mandrel	SA0579-01	Bypassed during matrix compilation	SA0579-01	FE P HS .188 Exp ID 1.6-1 Shrink R	SA0579-01	FE P Heat Shrink, 0.150" Expanded ID, 1.6:1 Shrink Ratio	SA0579-01	FE P Heat Shrink, 0.150" Expanded ID, 1.6:1 Shrink Ratio	SA0579-01	FE P Heat Shrink, 0.150" Expanded ID, 1.6:1 Shrink Ratio	SA0579-01	FE P Heat Shrink, 0.150" Expanded ID, 1.6:1 Shrink Ratio	SA0579-01	PET Tubing Heat Shrink, Avg. ID 0.064", Avg. Wall 0.0010"	SA0579-01	PET Tubing Heat Shrink, Avg. ID 0.064", Avg. Wall 0.0010"	SA0579-01	PET Tubing Heat Shrink, Avg. ID 0.064", Avg. Wall 0.0010"	SA0579-01	0.064", Avg. Wall 0.0010"
TL1021-02																									
RM4004-02																									
RM0138-01	BW 304SS .003 Single Lead min.	SA0613-01	Bypassed during matrix compilation	SA0613-01	0.400" MIN.IDX0.250" MAX.ODX20" L	SA0613-01	Bypassed during matrix compilation	SA0613-01	FE P HS .003 Single Lead min.	SA0613-01	FE P Heat Shrink, 0.150" MAX.ODX20" L	SA0613-01	FE P Heat Shrink, 0.150" MAX.ODX20" L	SA0613-01	FE P Heat Shrink, 0.150" MAX.ODX20" L	SA0613-01	FE P Heat Shrink, 0.150" MAX.ODX20" L	SA0613-01	300kpsi	SA0613-01	300kpsi	SA0613-01	300kpsi		
RM0305-04																									
RM0380-02																									
RM0380-03																									
RM8581-02																									
RM8581-03																									

- *2 RM0305-01 has been removed from the DA2263 as a GDP correction. RM0305-01 is not used on SA0579-01 and an alternative RM0305-02 is currently being used on SA0579-01.

CC: DA 2263

Tafzeelur Rahaman, Quality and Reliability Engineering Manager

Saketh Reddy Thauwreddy
28 JUN 2022

Saketh Reddy Thauwreddy, Quality Engineer

Saketh Reddy
28 JUN 2022

- Based on the above risk assessment and review of all the updates, removal, and/or addition of Raw materials to the (Raw material-approved supplier matrix as part of downstream stream deviation), there is no risk of interim containment action. Therefore DA 2245 is closed, and new DA 2263 is opened to continue carrying out the downstream interim action,
- Raw materials, as part of SCAR001716 and CAPA-11585.

Conclusion:

- Added Appendix A, which needs to be filled out whenever there is a new approved supplier for raw material from Edwards.
- Detailed instructions were added to the new DA 2263 to improve the effectiveness of the review.
- Detailed instructions were added to the new DA 2263 to improve the effectiveness of the numbers, they were confirmed to have been manufactured with approved raw materials.
- From table 4 were from the approved suppliers. After reviewing all the affected Edwards part all the lots manufactured with raw materials that were initially missing as part of DA2245 between June 7th and June 24th2022 (DA 2245 active date). The review was done to ensure LHS / Routers specific to the affected product numbers was performed for the date range the initial containment carried out as part of SCAR 001716/CAPA 11585. A review of all the items as part of table 4 are single-sourced RMs. Therefore, there is no risk to part of DA 2263 attachment.
- All the above items as part of table 4 additions of new RM's/RM approved suppliers will be filled out in appendix A as additions of new RM's/RM approved suppliers for their respective product raw materials. Any the list of approved suppliers for their respective product raw materials. Any raw material-approved supplier matrix (as an attachment to DA 2263) provides the raw materials consumed to manufacture the Edwards lots are from approved suppliers. affect the scope of the DA, as the purpose of the DA is to verify if all the raw materials consumed to manufacture the Edwards lots are from approved suppliers.
- *1 Refer to current SPI and product item revision. A change in the revision doesn't affect the scope of the DA, as the purpose of the DA is to verify if all the raw materials consumed to manufacture the Edwards lots are from approved suppliers.

4) SA/SPI Revisions

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Edwards Product's Raw Material – Supplier Matrix (INSTRUCTIONS)

1) Verify all the approved raw material supplier's names as provided in the DA attachment (Raw material- approved supplier matrix) against name of the supplier provided in their respective raw material certifications. **The DA attachment provides the list of approved suppliers for their respective raw material of the product.**

- 2) Identify the batch number of the raw material used in the respective lot of the product. The batch number of the raw material can be found in LHR/Router.

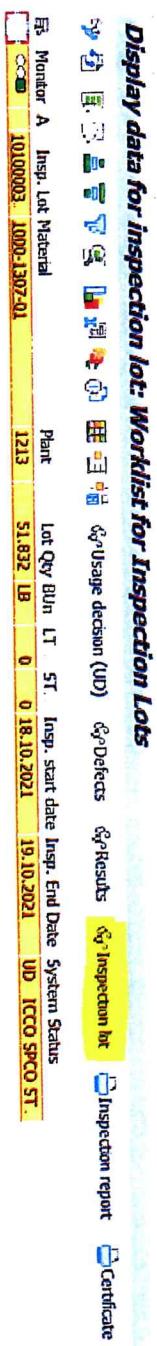
- 3) How to find Certification(s) in SAP-ERP System:

Login to SAP PRM portal.

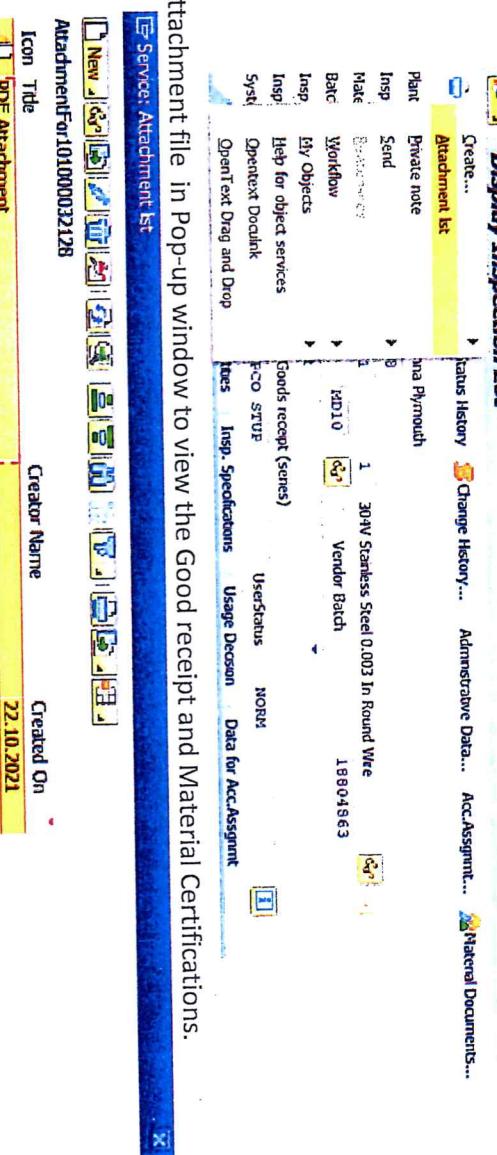
Go to "Inspection Lot Selection" using QA33 Transaction code.

Remove the lot creation dates. Type Plant as "1213" and Batch number as needed for Raw Material. Click "Execute" or Hit F8.

Select the inspection lot row and click on "Inspection lot" just below header.



Click on the arrow shown in image below and select "Attachment list"



Double-click on the PDF Attachment file in Pop-up window to view the Good receipt and Material Certifications.

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DA(2263) ATTACHMENT

- 4) Once Certification has been found verify that supplier on the certification matches with the approved raw material supplier from DA attachment. If the supplier's name matches, sign off the space dedicated to the individual raw material by entering your initials and date.
- 5) If the supplier's name in raw materials certification do not match with the list of approved suppliers per DA attachment, quarantine the lot and contact the respective Quality Engineer for further instructions.
- 6) Some of the Raw materials may not be identified in LHR/Router and/or parent level BOM(SAP) because they have been used on the MM/Sub-assembly level. In such cases, locate the scanned copy of MM level batch number in the respective LHR of the product from shared drive and identify the RM P/N and its Batch number used.
 - 7) Go to shared drive using pathway(s):
\\USCM5FS100\Data\Shares\Class II\Shared\Completed SAP Production Orders\Edwards\\USCM5FS100\Data\Shares\Class II\Shared\Completed LHR's AKA Quality2\Edwards (EDW)
 - 8) If the Raw material has not been used the lot of the product per LHR/Router and SAP and in some cases sub-assemblies, DA trained personnel is to "N/A" the space dedicated for that raw material.
 - 9) Fill up table 1 to capture the details of the lot without fail
 - 10) Type "N/A" for all blank sections in the DA attachment.
 - 11) After completing all the above steps, attach the DA and DA attachment to the respective LHRs without fail.
 - 12) Refer to Appendix-A, if there is any addition approved supplier for raw material with respect to a product line.

SA PART NUMBER	PRODUCT DESCRIPTION	LOT NO.	VERIFICATION INITIAL & DATE
SA0254-06	Printed Shaft 144C PROX End color.	500000164476	ex46 05 Aug 22

Table 1

1) SA0067-01 (9Fr Balloon Shaft)

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM0142-01 Used in MM0118-00	BW .0015 .007 Sgl Ld min 300kpsi Grn Bob	Ulbrich	N/A	
RM0380-01	FEP HS 68L .150min Exp ID .094mx Rec	Zeus Industrial Tubing Products	TE - Guaymus	
RM7346-01 Used in 1000-1299-01	PTFE Core .098 PFOA free	Zeus Industrial Tubing Products	N/A	

2) SA0155-01 (Flex Commander)

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM0498-01	SS Pullwire Assembly Notched	TE-Metals	N/A	
*1000-1153-01	FEP HS .260 Expanded ID	TE - Guaymus	N/A	
141967-01	Edwards Commander Cut Hypotube	TE connectivity medical-Galway A.K.A. Creganna Medical-Galway Parkmore West Galway, Ireland	N/A	
RM0096-01 Used in MM1537-01	FEP HS .165mn Exp ID .103mx Rec 48ml	TE - Wilsonville	N/A	
RM0138-01 Used in MM0074-01	BW 304SS .003 Single Lead min. 300kpsi	Ulbrich	N/A	
RM0158-01	12L RNF 100 Heatshrink 3-16	Lapp Tannehill	N/A	
*RM0362-01	FEP HS 0.270"MIN.IDX0.169"MAX.ODX54" L	Zeus Industrial Tubing Products	N/A	
RM0607-01	FEP HS .240 Exp ID 1.3-1 Shrink Ratio	Zeus Industrial Tubing Products	N/A	
RM4001-01	FEP HS 0.230 Min ID x .010 Wall x 36L	Zeus Industrial Tubing Products	TE - Guaymus	

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RM7348-01	PTFE Liner .0155ID .0015W 57L PFOA Free	Zeus Industrial Tubing Products	N/A	N/A
RM7349-02	PTFE Liner .0025W .172ID 54L PFOA Free	Zeus Industrial Tubing Products	N/A	N/A

*Indicates Alternate Raw Material, either RM0362-01 or 1000-1153-01

3) SA0254-04, -05, -06 (Balloon Commander Shaft-Pink, -Blue, -Orange)

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM0096-01	FEP HS .165mn Exp ID .103mx Rec 48minL	TE-Wilsonville	N/A	Cx46 05 Aug 22
* 1000-1154-01	FEP HS .168 Exp ID	TE - Guaymus	N/A	Cx46 05 Aug 22
(Used in RM0189-01)	BW .002 .006 Sgl Ld min. 300kpsi Brn Bob	Ulbrich	Fort Wayne Metals Research Prod.	Cx46 05 Aug 22
RM016101-MED	RNF 100 HS 18 Clear 12 Length	Lapp Tannehill	N/A	Cx46 05 Aug 22
RM7407-01	TPU 970-1L Marabu Ink White Tampapur	Pad Print Machinery of Vermont	N/A	Cx46 05 Aug 22
RM7408-01	TPV- Thinner Marabu Thinner (Ink) TPV	Pad Print Machinery of Vermont	N/A	Cx46 05 Aug 22
RM7409-01	H1-100ml Hardener Marabu Hardener (Ink)	Pad Print Machinery of Vermont	N/A	Cx46 05 Aug 22
RM7586-02	Stop Sleeve L Shldr .500 304 SS 80 grit	TE - Wilsonville	N/A	Cx46 05 Aug 22
*RM8745-01	FEP HS .168 Exp ID	TE - Carrollton	N/A	N/A

* Indicates Alternate Raw Material, either RM8745-01 or 1000-1154-01

4) SA0285-01 (Steering Tubing)

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM0144-01 Used in MM0215-00	BW .001 .005 Single Lead 300kpsi Pur Bob	Ulbrich	N/A	
RM0158-01	12L RNF 100 Heatshrink 3-16	Lapp Tannehill	N/A	
RM4001-01	FEP HS 0.230 Min ID x .010 Wall x 36L	Zeus Industrial Tubing Solutions	TE - Guaymus.	
RW7374-01	PULL RING SUBASSEMBLY	TE Metals	N/A	
RW7375-01	PTFE Liner ESL .015ID .0015W 32minL	Zeus Industrial Tubing Products	N/A	
RM7376-02	PTFE Liner .0035 ESL	Zeus Industrial Tubing Products	N/A	
RM7876-01 Used in MM0213-01	FEP Heat Shrink 0.125 x 48L	Zeus Industrial Tubing Products	N/A	

5) SA0286-01, -02 (Sheath Tubing - Certitude 18Fr, 21Fr)

SA0286-01 (Sheath Tubing - Certitude 18Fr) Material List

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM0162-01	RNF 100 HS 1/4" ID X 12" L, CLEAR	Lapp Tannehill	N/A	
RM0384-01	PET HS 0.280" ID X 0.001" WALL X 50"MIN.L	Nordson MEDICAL, (NH) Inc. (U.S.)	N/A	
RM0385-01	RNF 100 HS 3/8" ID X 12" MIN. L, NATURAL	Lapp Tannehill	N/A	
RM3004-01	Coil Sheath .2655 ID Marker Band	Lake Region Medical	N/A	

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RM6012-01	PTFE HS Liner ESLW 0.291" MIN. Exp. ID	Zeus Industrial Tubing Products	N/A	
RM7337-01	Coil Wire 304V SS 0.005"X0.015"Flat Wire	Fort Wayne Metals Research Prod.	N/A	
RM7407-01	TPU 970-1L Marabu Ink White Tampapur	Pad Print Machinery of Vermont	N/A	
RM7408-01	TPV- Thinner Marabu Thinner (Ink) TPV	Pad Print Machinery of Vermont	N/A	
RM7409-01	H1-100ml Hardener Marabu Hardener (Ink)	Pad Print Machinery of Vermont	N/A	
RM7417-01	FEP HS 0.370"MIN.IDX0.010"WALLX20"MIN.L	Zeus Industrial Tubing Products	N/A	

SA0286-02 (Sheath Tubing - Certificate 21Fr) Material List

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM0385-01	RNF 100 HS 3/8" ID X 12" MIN. L, NATURAL	Lapp Tannehill	N/A	
RM0550-01	PET Heat shrink 0.320 ID x 0.0005 Wall	Nordson MEDICAL, (NH), Inc. (U.S.)	N/A	
RM3005-01	Coil Sheath .2985" ID Marker Band	Lake Region Medical	N/A	
RM4004-02	FEP HS 0.400"MIN.IDX0.250"MAX.0DX20"L	Zeus Industrial Tubing Products	N/A	
RM6011-02	PTFE H-S Liner .329" ID Sub-Lite Etched	Zeus Industrial Tubing Products	N/A	
RM7337-01	Coil Wire 304V SS 0.005"X0.015"Flat Wire	Fort Wayne Metals Research Prod.	N/A	
RM7407-01	TPU 970-1L Marabu Ink White Tampapur	Pad Print Machinery of Vermont	N/A	
RM7408-01	TPV- Thinner Marabu Thinner (Ink) TPV	Pad Print Machinery of Vermont	N/A	

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6) SA0343-01 (Pascal Steerable Gen 1C)

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM7805-01	Anchor Ring Assembly	TE - Metals	N/A	
RM7695-01	Asm Compression Coil with Hypotube	TE - Metals	N/A	
RM0162-01	RNF 100 HS 1/4" ID X 12" L, CLEAR	Lapp Tannehill	N/A	
RM0163-01	RNF 100 HS .0625 12L	Lapp Tannehill	N/A	
RM0459-01	Braidwire 304SS .002 x .008 160-220 kpsi	Ulbrich	N/A	
RM0565-01	PET HS .230 ExplD .0005Wall	Nordson MEDICAL, (NH), Inc. (U.S.)	N/A	
RM7534-02	FEP HS 64L .270Exp ID .010W 1.6-1	TE - Carrollton	N/A	
*RM7538-02	62L PTFE ESL 0.030ID x 0.0015W	Zeus Industrial Tubing Products	N/A	
*1000-2726-01	PTFE Ext Etch 0.030 ID x 0.0015 W	TE Brooklyn Park a.k.a Optinova	N/A	
^RM7591-01	PTFE .168ID .002W 60L PFOA Free ESL	Zeus Industrial Tubing Products	N/A	
^1000-2727-01	TFE Liner 0.168 ID x 0.002 Wall x 60 L" W	TE Brooklyn Park a.k.a Optinova	N/A	
RM7648-01	FEP HS 65L .250Exp ID .010W 1.6:1 SR	Zeus Industrial Tubing Products	N/A	

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RM7662-03	MB Slot .070 PT IR 0.080 L	Lake Region Medical	N/A	
RM7884-01	FEP Heat Shrink AWG 9 x 48L	Zeus Industrial Tubing Products	N/A	
RM7943-01	Flex Tube	Resonetics	N/A	
RM8241-02	20.0L Ext Tube Protector	Fluortek	N/A	
RM8271-01	Hypotube Stop, Anchor Ring	MicroGroup Inc	N/A	
RM8361-01	Asm Crowned Pull Ring .080 Weld Slot	TE – Metals	N/A	

* Indicates Alternate Raw Material, either RM7538-02 or 1000-2726-01

Λ Indicates Alternate Raw Material, either RM7591-01 or 1000-2727-01

7) SA0473-01 (Alterra Inner Shaft Gen 3)

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM0096-01	FEP HS .165mn Exp ID .103mx Rec 48minL	TE - Wilsonville	N/A	
RM0099-01	FEP HS .075mn Exp .047mx Rec 65.5L Natl	TE - Wilsonville	N/A	
RM0140-01 Used in MM0543-01	BW .002 .006 Sgl Ld min. 300kpsi Brn Bob	Fort Wayne Metals Research Prod.	Ulbrich	
RM0164-01	RNF-100 Heatshrink 3/32", 12" Length	Lapp Tannehill	N/A	
RM0338-01 Used in MM0543-00	Celcon Core 0D .049" +/- .0005"	Dunn Industries	N/A	
RM0367-01	FEP Heat Shrink .100"	Zeus Industrial Tubing Products	N/A	
RM0380-01	FEP HS 68L .150min Exp ID .094mx Rec	Zeus Industrial Tubing Products	TE - Guaymus	

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RM0617-01	0.037 Shipping Mandrel	Tega (formerly NEPG)	N/A	
RM7347-01	PTFE Ext Special .110OD .025W PFOA free	Zeus Industrial Tubing Products	N/A	
RM7648-01	FEP HS 65L .250Exp ID .010W 1.6:1 SR	Zeus Industrial Tubing Products	N/A	
RM7653-02	1in Gritblast prox end, Inner Shaft tube	Resonetics	N/A	
RM8319-01	Stent Connector w-Dovetail	Azure MicroDynamics, Inc.	N/A	
RM8313-01	R-Pebax 3533 SA01 25% Pantone 289C	Compounding solution, LLC	N/A	

8) SA0474-01 (Alterra Soft Tip Outer Shaft Gen 3)

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM0138-01	BW 304SS .003 Single Lead min. 300kpsi	Ulbrich	N/A	
RM0158-01	12L RNF 100 Heatshrink 3-16	Lapp Tannehill	N/A	
RM7617-01	Fluoro PEELZ Heat Shrink, 0.230" ID	Zeus Industrial Tubing Products	N/A	
RM7648-01	FEP HS 65L .250Exp ID .010W 1.6:1 SR	Zeus Industrial Tubing Products	N/A	
RM7659-02	0.235" L Outer Shaft Proximal Hypotube	Resonetics	N/A	
RM7681-01	PET HS .250ID x .001W	Nordson MEDICAL, (NH), Inc. (U.S.)	N/A	
RM7816-01	FEP Heat Shrink .290 Exp ID, 1.6-1 62'L	TE - Carrollton	N/A	

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RM8166-01	FEP HS Liner Sub-Lite Wall ID0.178 x 55L	Zeus Industrial Tubing Products	N/A
RM8714-01	MB PTFE IR .222 ID x .040L	Lake Region Medical.	N/A
RM7655-01	FEP Liner Ext Sub-Lite-Wall Etch 60L	Zeus Industrial Tubing Products	N/A

9) SA0526-01 (Pascal Steerable Gen 2)

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM7805-01	Anchor Ring Assembly	TE - Metals	N/A	
RM7695-01	Asm Compression Coil with Hypotube	TE - Metals	N/A	
RM0162-01	RNF 100 HS 1/4" ID X 12" L, CLEAR	Lapp Tannehill	N/A	
RM0163-01	RNF 100 HS .0625 12L	Lapp Tannehill	N/A	
RM0459-01	Braidwire 304SS .002 x .008 160-220 kpsi	Ulbrich	N/A	
RM7534-02	FEP HS 64L.270Exp ID .010W 1.6-1	TE - Carrollton	N/A	
RM7538-02	62L PTFE ESL 0.030ID x 0.0015W	Zeus Industrial Tubing Products	N/A	
RM7591-01	PTFE .168ID .002W 60L PFOA Free ESL	Zeus Industrial Tubing Products	N/A	
RM7648-01	FEP HS 65L.250Exp ID .010W 1.6:1 SR	Zeus Industrial Tubing Products	N/A	

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RM7662-03	MB Slot .070 PT IR 0.080 L	Lake Region Medical	N/A
RM7943-01	Flex Tube	Resonetics	N/A
RM8241-02	20.0L Ext Tube Protector	Fluortek	N/A
RM8361-01	Asm Crowned Pull Ring .080 Weld Slot	TE - Metals	N/A
RM8742-02	FEP HS.240 Exp ID 10L	TE - Carrollton	N/A
RM8772-01	ProximalLaser Cut Hypotub	Creganna Medical Ireland Limited	N/A
RM8772-02	Proximallaser Cut Hypotub	Resonetics	N/A

10) SA0579-01 (Pascal Implant Shaft Gen 2)

Material	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
1000-1307-01 /RM8561-01	304V Stainless Steel 0.003 In Round Wire	Fort Wayne Metals Research Prod.	N/A	
RM0102-01	FEP HS 64L .070 Exp ID Natural	Zeus Industrial Tubing Products	N/A	
RM0105-01	FEP HS 64L .115 Exp ID Natural	TE - Carrollton	N/A	
RM0158-01	12L RNF 100 Heatshrink 3-16	Lapp Tannehill	N/A	
RM0305-02	FEP HS 60L .188 Exp ID 1.6-1 Shrink R	TE - Wilsonville	N/A	
* RM0305-04	FEP HS 60L .188 Exp ID 1.6-1 Shrink R	TE - Wilsonville	N/A	

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SEE ATTACHED MEMO FOR MORE INFORMATION

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RM0305-04	FEP HS 60L .188 Exp ID 1.6-1 Shrink R	TE - Wilsonville	N/A	
RM0380-01	FEP HS 68L .150min Exp ID .094mx Rec	TE - Guaymus	N/A	
RM0380-02	FEP HS 68L .150min Exp ID .094mx Rec	TE - Guaymus	N/A	
RM0380-03	FEP HS 68L .150min Exp ID .094mx Rec	TE - Guaymus	N/A	
RM4400140	Peek HPC Masking Plug	MedFab	N/A	
RM8157-01	FEP Heat Shrink, 65inL, 0.255in ID min	TE - Carrollton	N/A	
RM8544-01	Attachment Fingers	ADMEDES	N/A	
RM8545-01	Implant Shaft Central Lumen	MicroLumen	N/A	
RM8546-01	Ring Implant Shaft Distal	Resonetics	N/A	
RM8548-01	PTFE Liner, PFOA FREE, .0285ID	Zeus Industrial Tubing Products	N/A	
RM8572-01	5 Lumen Ext, 10L Pebax 55D	Dunn Industries	N/A	
RM8581-01	PET HS .064ExpID 50LMin, Clear	Nordson MEDICAL, (NH), Inc. (U.S.)	N/A	
RM8581-02	PET HS .064ExpID 50LMin, Clear	Nordson MEDICAL, (NH), Inc. (U.S.)	N/A	
RM8581-03	PET HS .064ExpID 50LMin, Clear	Nordson MEDICAL, (NH), Inc. (U.S.)	N/A	
*RM8748-01	Implant Shaft Gen II HypoTube	Creganna Medical Ireland Limited	N/A	
*RM8748-02	Implant Shaft Gen II HypoTube	Resonetics	N/A	
RW8786-01	FEP HS .165 ID 70 L	TE - Carrollton	N/A	

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TL1019-01	Main shipping Mandrel	Xylem	N/A	
TL1021-02	Small shipping Mandrel	Xylem	N/A	

* Indicates Alternate Raw Material, either RM8748-01 or RM8748-02

11) SA0598-01 (DDS 18Fr Steering Shaft v1.5)

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM0138-01	BW 304SS .003 Single Lead min. 300kpsi	Ulbrich	N/A	
RM0158-01	12L RNF 100 Heatshrink 3-16	Lapp Tannehill	N/A	
RM0162-01	RNF 100 HS 1/4" ID X 12" L, CLEAR	Lapp Tannehill	N/A	
RM0163-01	RNF 100 HS .0625 12L	Lapp Tannehill	N/A	
RM0273-01	FEP H-S .320in min ID x 56in min Length	TE - Carrollton	N/A	
*RM0357-01	FEP H-Shrink .240" ID 27in min Length	Zeus Industrial Tubing Products	N/A	
*RM4001-01	FEP H-Shrink 0.230" Min ID x 0.010" Wall x 36" long			
RM0565-01	PET HS .230 ExplD .0005Wall	Nordson MEDICAL, (NH), Inc. (U.S.)	N/A	
ARM0567-01	48" L, FEP H-S, 0.210" ID, 1.6-1 Ratio	Zeus Industrial Tubing Products	N/A	

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^RM4001-01	FEP H-Shrink 0.230" Min ID x 0.010" Wall x 36" long		
RM7695-01	Asm Compression Coil with Hypotube	TE - Metals	N/A
RM7648-01 (Used at tipping OP only, if run out of RM0357- 01 per QE)	FEP H-Shrink 0.250" Expanded ID, 1.6:1 Shrink Ratio.	Zeus Industrial Tubing Products	N/A
RM8157-01	FEP Heat Shrink, 65inL, 0.255in ID min	TE - Carrollton	N/A
RM8407-00	PTFE Ext..901Sub-Lite-Wall Etch .03ID	Zeus Industrial Tubing Products	N/A
RM8432-01	Distal Pull Ring Assembly	TE - Metals	N/A
RM8433-01	Middle Anchor Pull Ring Assembly	TE - Metals	N/A
RM8434-01	Proximal Anchor Ring Assembly	TE - Metals	N/A
RM8439-01	FEP H-S 0.280 Min:D x 0.175 x 64L	TE - Carrollton	N/A
RM8767-01	PTFE Liner 0.169"ID x 0.0035"Wall	TE - Carrollton	N/A
RM8784-02	Protective Extruded Tubing 0.370ID 24L	Fluortek	N/A
RM8784-03	Protective Extr Tubing, 0.370" ID, 6" L	Fluortek	N/A

* Indicates Alternate Raw Material, either RM0357-01 or RM4001-01

^ Indicates Alternate Raw Material, either RM0567-01 or RM4001-01

12) SA0601-01 (Cardioband GC 2.0 Guide Catheter)

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Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM8756-01	Anchor Ring Ass'y – Dual Hypotube, Guide Catheter	TE - Metals	N/A	
1000-1094-01	LCHT, distal flex, dual pull wire (assembly)	TE - Metals	N/A	
1000-1100-01	Liner-PTFE Etched 0.222Dx0.003 wallx60L	TE - Brooklyn Park (Optinova)	N/A	
RM8286-01	Braid Wire, 304V Stainless Steel, 0.004 x 0.008"	Fort Wayne Metals Research Prod.	N/A	
RM0384-01	PET Heat shrink .280" \pm .014" ID x .001" \pm .0002" W x 50" L MIN	Nordson MEDICAL, (NH), Inc. (U.S.)	N/A	
1000-1117-01	CB-GC-0.004x016-wire-comp-coil-stopper-assy	TE - Metals	N/A	
1000-1119-01	CB-GC-004x016-wire-comp-coil-stopper-assy	TE - Metals	N/A	
1000-1115-01	PTFE Liner, 0.027" ID x 0.003" W x 62" L	TE - Brooklyn Park (Optinova)	N/A	
1000-1101-01	PTFE Liner, 0.025" ID x 0.003" W x 62" L	TE - Brooklyn Park (Optinova)	N/A	
RM8742-01	FEP Heat Shrink; 0.240" Expanded ID, 1.6:1	TE - Carrollton	N/A	
RM0273-01	FEP Heat Shrink; 0.320" Expanded ID, 1.6:1 Shrink Ratio	TE - Carrollton	N/A	

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13) SA0602-01 (Cardioband TSS 2.0 Guide Sheath)

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
1000-1137-01	CB-TSS-LCHT, distal flex, dual pull wire	TE - Metals	N/A	
1000-1378-01	CB-TSS-LCHT, Prox	TE - Metals	N/A	
1000-1116-01	Liner-PTFE Etched 0.308ODx0.003 wallx60L	Zeus Industrial Tubing Products	N/A	
RM7769-01	FEP Heat Shrink; 0.400" Expanded ID, 1.6:1	Zeus Industrial Tubing Products	N/A	
RM8286-01	Braid Wire, 304V Stainless Steel, 0.004 x 0.008"	Fort Wayne Metals Research Prod.	N/A	
*1000-1490-01	.003 x .022 SS-DR-952 SET up Wire	Fort Wayne metals (Xylem company)	N/A	
RM7797-01	FEP Heat Shrink, .420" Exp ID, 1.6-1 65" L	Zeus Industrial Tubing Products	N/A	
RM7417-01	FEP Heat Shrink; 0.370" Expanded ID, 1.6:1 Shrink Ratio	Zeus Industrial Tubing Products	N/A	
1000-1386-01	PTFE Liner, 0.030" ID x 0.003" Wall x 62" L	TE - Brooklyn Park (Optinova)	N/A	
RM7341-01	PET Heat Shrink, 0.390" ID x 0.001" Wall x 50" L	Nordson MEDICAL, (NHH), Inc. (U.S.)	N/A	

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RM0385-01	RNF 100 Heat Shrink 3/8"	Lapp Tannehill	N/A	
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*Reach out to the QE (NHA ROPER) for certification of the material

14) SA0603-01 (Liner Shaft 23Fr Guide Sheath)

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM0385-01	RNF 100 HS 3/8" ID X 12" MIN. L, NATURAL	Lapp Tannehill	N/A	
RM7341-01	PET HS 0.390" IDX0.0010" WALLX50"MIN.L	Nordson MEDICAL, (NH), Inc. (U.S.)	N/A	
RM7348-01	PTFE Liner .0155ID .0015W 57L PFOA Free	Zeus Industrial Tubing Products	N/A	
RM7769-01	FEP HS .400 Exp ID 1.6-1 65L	Zeus Industrial Tubing Products	N/A	
RM7797-01	FEP HS 0.420MIN.ID X 0.260MAX.OD X 65L	Zeus Industrial Tubing Products	N/A	
RM8007-01	FEP HS 3/8X 48L	Zeus Industrial Tubing Products	N/A	
RM8286-01	Braid Wire, 304V Stainless Steel, 0.004 x 0.008"	Fort Wayne Metals Research Prod.	N/A	
RM8347-01	Co-Extrusion	Dunn Industries	N/A	
RM8353-01	Pull Ring Assembly, SS	Resonetics	N/A	
RM8513-01	PET HS .360 ID X .003 Wall	Nordson MEDICAL, (NH), Inc. (U.S.)	N/A	

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15) SA0608-01 (Pulmonic 18 Fr Inline Sheath)

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM0384-01	PET HS 0.280" ID X 0.001" WALL X 50" MIN. L.	Nordson MEDICAL,(NH) Inc. (U.S.)	N/A	
RM0385-01	RNF 100 HS 3/8" ID X 12" MIN. L, NATURAL	Lapp Tannehill	N/A	
RM6012-01	PTFE HS Liner ESLW 0.291" MIN. Exp. ID	Zeus Industrial Tubing Products	N/A	
RM7337-01	Coil Wire 304V SS 0.005"X0.015"Flat Wire	Fort Wayne Metals Research Prod.	N/A	
RM7417-01	FEP HS 0.370"MIN.IDX0.010" WALLX20"MIN.L	Zeus Industrial Tubing Products	N/A	

16) SA0613-01 (Pulmonic Outer 29mm)

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM0162-01	RNF 100 HS 1/4" ID X 12" L, CLEAR	Lapp Tannehill	N/A	
RM0362-01	FEP HS 0.270"MIN.IDX0.169"MAX.ODX54" L	Zeus Industrial Tubing Products	N/A	
RM0385-01	RNF 100 HS 3/8" ID X 12" MIN. L, NATURAL	Lapp Tannehill	N/A	

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Part Number	Description	Supplier	Lead Time	Comments
RM4400142-01	FEP HS 0.38"MIN.IDX0.217"MAX.ODX52"MIN.L	Zeus Industrial Tubing Products	N/A	
RM7341-01	PET HS 0.390" IDX0.0010" WALLX50"MIN.L	Nordson MEDICAL, (NH), Inc. (U.S.)	N/A	
RM7550-01	PET HS 0.220" IDX0.0010" WALLX50"MIN.L	Nordson MEDICAL, (NH), Inc. (U.S.)	N/A	
RM7648-01	FEP HS 65L .250Exp ID .010W 1.6:1 SR	Zeus/Creganna Ireland	N/A	
RM7797-01	FEP HS 0.420MIN.ID X 0.260MAX.OD X 65L	Zeus Industrial Tubing Products	N/A	
RM7858-01	Push-on Round FDA Cap .243ID White	Protective Industries, Inc-Capplugs	N/A	
RM8319-01	Stent Connector w-Dovetail	Azure MicroDynamics, Inc.	N/A	
RM8341-01	PTFE HS Liner ESLW 0.330MIN.Exp.ID X 60L	Zeus Industrial Tubing Products	N/A	
RM8405-01	Cut SS HY 0.218ID X 0.238OD X 0.400L	MicroGroup Inc	N/A	
RM8489-01	Braid Wire, 0.008 Dia, 304V SS	Fort Wayne Metals Research Prod.	N/A	
RM4004-02	FEP HS 0.400"MIN.IDX0.250"MAX.ODX20" L	Zeus Industrial Tubing Products	N/A	
RM0138-01	BW 304SS .003 Single Lead min. 300kpsi	Ulbrich	N/A	

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Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM0140-01	Braidstock, Annealed, 0.120"ID, .002x.006"	Fort Wayne Metals Research Prod.	Ulbrich	
RM8805-01	FEP Etched Liner	TE - Brooklyn Park (Optinova)	N/A	
RM8745-01	FEP Heat Shrink 0.168 Exp ID 63" L	TE - Carrollton	N/A	
1000-1220-01	PTFE, Ext. tubing, Natural, 0.120"x0.151", 20" Length	Zeus Industrial Tubing Products	N/A	
RM7320-02	FEP Heat Shrink 0.140" Exp. ID 80"L	Zeus Industrial Tubing Products	N/A	
1000-2492-01	Alternate for RM7320-CTL FEP Heat Shrink 0.139 Exp ID	Optinova Americas Inc.	N/A	

18) SA0621-01 (Commander X)

Material Number	Material Description	Approved Supplier 1	Approved Supplier 2	Verified by & Date
RM8805-01	PTFE Liner, Etched PTFE Liner 0.109" ID x 0.0020"Wall, 68"Length	TE - Brooklyn Park (Optinova)	N/A	
*RM7320-02	FEP Heat Shrink 0.140" Exp ID 1.6-1 Shrink Ratio, 80"Length	Zeus Industrial Tubing Products	N/A	
*1000-2492-01	Alternative for RM7320-02 FEP HS 0.139 Exp ID 71" L	Optinova Americas Inc.	N/A	
RM0305-02	FEP Heat Shrink 0.188" Exp ID 60"	TE - Wilsonville	N/A	

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1000-1220-01	PTFE ext. tubing, natural, 0.120 x 0.151" 20.0" L	Zeus Industrial Tubing Products	N/A
RM8149-01	Annealed Braid, 1 st layer (.002x.012)52" L	Ulbrich specialty wire product LLC	N/A
RM8149-01	Annealed Braid, 2 nd layer (.002x.012)30" L	Ulbrich specialty wire product LLC	N/A

*Indicates alternate Raw Material, either RM7320-02 or 1000-2492-01

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N/A
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Name/ signature/ date Issued by (DA Admin)	
Name/ signature/ date Approved By (VS Quality Manager)	
Name/ signature/ date Updated by:	
Notification date: NOC# (if any):	
Supplier site:	
Part#:	Supplier Name:
SA#	Product Name:

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Name/ signature/ date Issued by (DA Admin)	
Name/ signature/ date Approved By (VS Quality Manager)	
Name/ signature/ date Updated by:	
Notification date: NOC# (if any):	
Supplier site:	
Part#:	Supplier Name:
SA#	Product Name:

- a. The form is to be filled by Value stream Quality Engineer and is approved by responsible value stream Quality Manager and issued by DA 2263 admin
- b. The form needs to be legible
- c. The form needs to be filled after formal approval from the customer
- d. Ensure all the people who have completed the DA 2263 have been notified of the new material or source update

DA Appendix A Instruction-

APPENDIX A

		Issued by (DA Admin)	
		Name/Signature/date	
		Approved By (VS Quality Manager)	
		Name/Signature/date	
		Updated by:	
		Name/Signature/date	
		Notification date:	
		NOC# (if any):	
		Supplier site:	
		Supplier Name:	Part#:
		Product Name:	SA#

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		Issued by (DA Admin)	
		Name/Signature/date	
		Approved By (VS Quality Manager)	
		Name/Signature/date	
		Updated by:	
		Name/Signature/date	
		NOC# (if any):	Notification date:
		Supplier site:	
		Supplier Name:	Part#:
		Product Name:	SA#