

**Production Order: 500000164476**Production 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

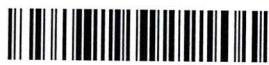
Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty	Scrap Qty & Desc.	Date Comp.	Initials
50	CATASY04  Catheter Assembly 4  Count: Yes    Prepare Materials MPI0398 Rev. <u>A0</u>  Line Clearance MPI0230 Rev. <u>E</u>  By: <u>M28</u> Date: <u>28 Jul 22</u>  Prepare Materials  Confirmation 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

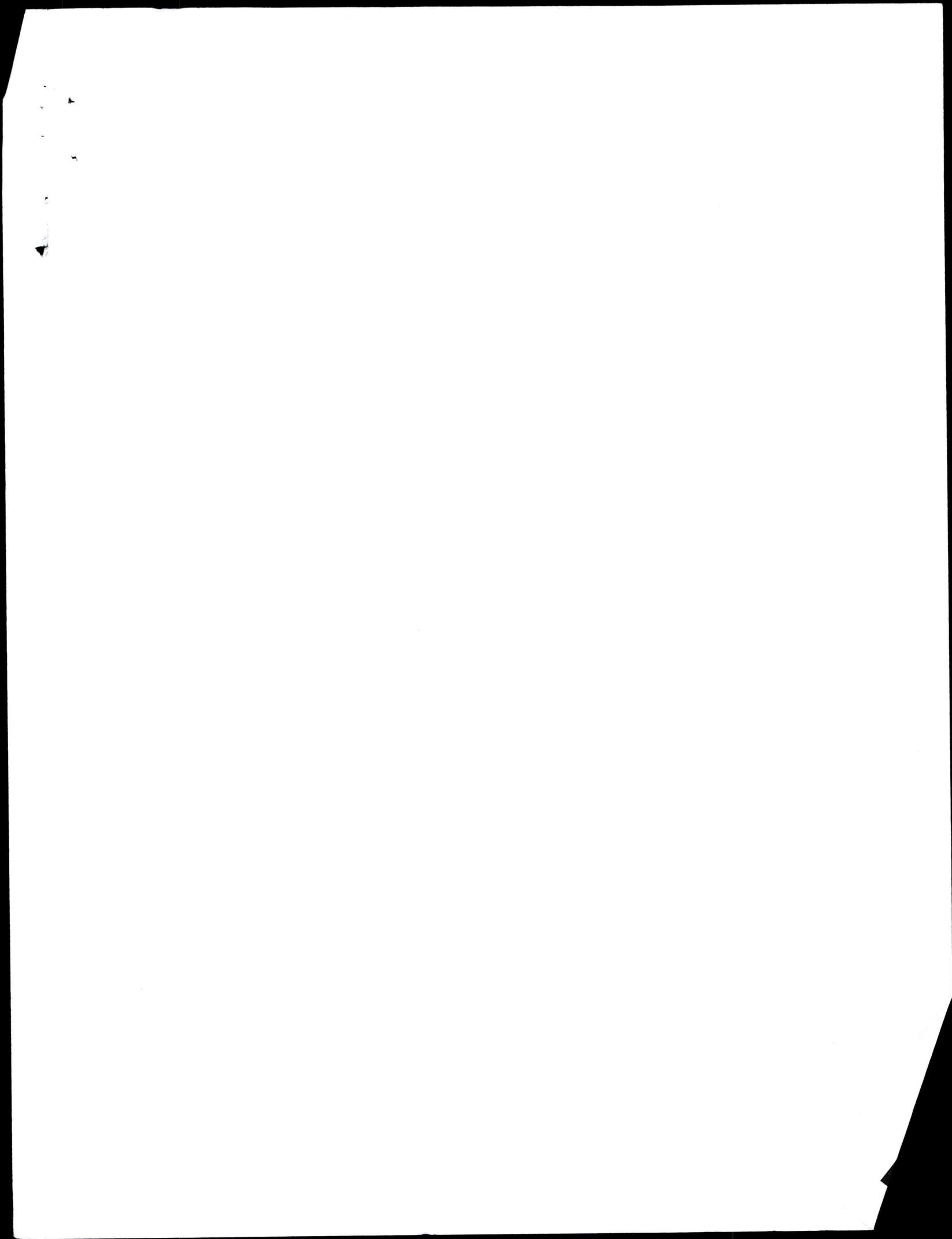
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Page: 1 of 17



SA0254-06

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# Production Order: 500000164476



Production Order Document  
Production Order Qty: 500

PC

Sheet: 1 of 1

## 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>2708.350</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

Date Printed: 28.07.2022 / 22:25:54

Page: 2 of 17



SA0254-06

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**Production Order:** 500000164476

A standard linear barcode is positioned vertically on the right side of the page.

Production Order Document  
Production Order Qty: 500  
PC

**Material:** SA0254-06 Rev G

Date Printed: 28.07.2022 / 22:25:54

Page: 3 of 17



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**Production Order:** 500000164476

A standard linear barcode consisting of vertical black bars of varying widths on a white background.

Production Order Document  
Production Order Qty: 500  
PC

**Material: SA0254-06** Rev G

Sheet: 1 of 1

Date Printed: 28.07.2022 / 22:25:54

Page: 4 of 17



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# Production Order: 500000164476



**Material: SA0254-06 Rev G**

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

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>
<b>Notes:</b>									
<u>N/A</u>									
<u>N/A</u>									
<u>N/A</u>									

Date Printed: 28.07.2022 / 22:25:54

Page: 5 of 17



CREGANNA  
MEDICAL

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# Production Order: 500000164476



**Material: SA0254-06 Rev G**

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

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	NIA
		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.		Actual Qty Used		
		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:

NIA  
NIA  
NIA

Date Printed: 28.07.2022 / 22:25:54

Page: 6 of 17



SA0254-06

01Aug22

CREGANNA MEDICAL

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# Production Order: 500000164476



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

## Material: SA0254-06 Rev G

Opn No.	Planned WorkCenter Description	Operation Details				Comp Qty.	Scrap Qty & Desc.	Date Corp.	Initials
400	Shrink					N/A	N/A	N/A	N/A
	CATHETER ASSEMBLY 4	In-Process Inspection (Visual Inspection) MPI0398 Rev. AD							
	Count: Yes								
		FM5104693							
		(Rework if needed. Use FM5104983)							
	In Process Inspection								
		Component Number	Req'd Rev Rev Used	UOM	Oty.	Batch No.		Actual Oty Used	
450	CATHETER ASSEMBLY 4	ANNEAL SHAFT MPI0398 Rev. AD	A	PC	5	55036	S	N/A	
		FM5104692							
	Notes:								
		N/A							
		N/A							
		N/A							

Date Printed: 28.07.2022 / 22:25:54

Page: 7 of 17



CREGANNA MEDICAL

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Production Order: 500000164476

A standard linear barcode consisting of vertical black bars of varying widths on a white background.

Production Order Document  
Production Order Qty: 500  
PC

**Material:** SA0254-06 Rev G

Sheet: 1 of 1

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**Notes:**

Date Printed: 28.07.2022 / 22:25:54

Page: 8 of 17



CREGANNA

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# Production Order: 500000164476



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

## 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					

Page: 9 of 17



CREGANNA MEDICAL  
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# Production Order: 500000164476



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

## 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				

Date Printed: 28.07.2022 / 22:25:54

Page: 10 of 17



CREGANNA  
MEDICAL

is part of



# Production Order: 500000164476



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

## 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

Date Printed: 28.07.2022 / 22:25:54

Page: 11 of 17



CREGANNA  
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# Production Order: 500000164476



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

## 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

Date Printed: 28.07.2022 / 22:25:54

Page: 12 of 17



SA0254-06

CREGANNA  
MEDICAL

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# Production Order: 500000164476



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

## 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	03 Aug 22	BH48		
1000	CATASY04 Confirmation Reqd(Milestone)	In-Process Dimensional Inspection	N/A	N/A	N/A	N/A		
	Notes:							

Date Printed: 28.07.2022 / 22:25:54

Page: 13 of 17



SA0254-06  
CREGANNA MEDICAL  
is part of



**Production Order:** 500000164476

A standard linear barcode consisting of vertical black bars of varying widths on a white background.

Production Order Document  
Production Order Qty: 500  
PC

**Material: SA0254-06 Rev G**

Opr No.	Planned WorkCenter Description	Operation Details				Date Comp:	Initials
		Comp Qty.	Scrap Qty & Desc.	Comp Qty.	Scrap Qty & Desc.	Date Comp:	Initials
1050	Catheter Assembly 4 In-Process Dimensional Inspection	350	0D12 AM 0D21	03 Aug 22	M106	W435	
	(No Rework can be done at this OP) Line Closure MPI0230 Rev. E By: M106 Date: 03 Aug 22						
1050	QUALITY1 Quality Inspection & Review	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	7-IB 3-SLGENG 32- <del>caste</del> 3-VJ 2-FM 1-AB 309 290 4-DSU 11-0005118 7-SCR	04 Aug 22	1t03 DA88 M106		
	Quality Inspection & Review						
	Confirmation Reqd(Milestone )						
	Notes:	N/A N/A N/A					

Date Printed: 28.07.2022 / 22:25:54

Page: 14 of 17



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L103 04 AUG 22  
L103 04 AUG 22  
L103 04 AUG 22

# Production Order: 500000164476



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

## Material: SA0254-06 Rev G

Opn No.	Planned Work Center Description	Operation Details		Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	N/A	N/A		N/A	N/A	N/A	N/A
1070	CATHETER ASSEMBLY 4	Rework MPI0398 Rev. _____		N/A	N/A	N/A	N/A
		Material consumed					
		Material	Batch		Rev	Qty	
		Material	Batch		Rev	Qty	
		Material	Batch		Rev	Qty	
		Material	Batch		Rev	Qty	
		Material	Batch		Rev	Qty	
1090	QUALITY1	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan					
		Quality Inspection & Review					
		Quality Inspection & Review					
	Notes:	N/A					
		N/A					
		N/A					
Date Printed: 28.07.2022 / 22:25:54							

Page: 15 of 17



SA0254-06 CREGANNA MEDICAL  
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L703 04AUG22  
L703 04AUG22

# Production Order: 500000164476



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

## 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 TRUAG10					

Notes:

N/A N/A

N/A

Date Printed: 28.07.2022 / 22:25:54

Page: 16 of 17



CREGANNA  
MEDICAL

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# Production Order: 500000164476



Material: SA0254-06 Rev G

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

Batch Number: 0000164476

TRUNARO

By: BATI

Date: 04 AUG 22

Reviewed By:

WJ32

Date:

05 Aug 22

Notes:

N/A

N/A

N/A

Date Printed: 28.07.2022 / 22:25:54

Page: 17 of 17



SA0254-06  
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PRODUCTION ORDER# 500000164476

## OPER 400.0

### 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 01Aug22
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:							
<b>Particle Size</b> Area: mm <sup>2</sup>	<b>Acceptable Limits</b> per Part						
< 0.05 mm <sup>2</sup>	No Limit	See Table	Use a calibrated Tappi Chart and Inspect at a minimum of 2.85x magnification	500	0	0	
0.05 mm <sup>2</sup> ≤ Area < 0.25 mm <sup>2</sup>	3	100%					
0.25 mm <sup>2</sup> ≤ Area < 0.80 mm <sup>2</sup>	2						
0.80 mm <sup>2</sup> ≤ Area ≤ 1.5 mm <sup>2</sup>	1						
> 1.5 mm <sup>2</sup>	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 <sup>2</sup> dot on Tappi chart).	≤0.2 mm <sup>2</sup>	100%	Use a calibrated Tappi Chart and Inspect at a minimum of 2.85x magnification	N/A	491	0	M106 01Aug22

M106  
01Aug22



PRODUCTION ORDER# 500000164476

## **Attachment B: Cause of Rework.**

OPER 400.0

## **Attachment B: Cause of Rework**

OPER 500.0



**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 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	Initials (Ex. TMI0748AC or TMI0747AD)	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	TM1/TL	# Pass	# Fail	Initial/Date
<b>Outer Diameter <math>\Delta 13</math> MAX OD at Pad Printed Area</b> 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 TM10748	TM1 0748Am	356	0	W435 03 Aug 22
<b>Outer Diameter <math>\Delta 21</math> MAX OD</b> 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 TM10747	TM1 0747W	355	1	W435 03 Aug 22
<b>Outer Diameter <math>\Delta 2</math> MAX OD</b> 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 TM10967 Ring Gauge Helper TL0980	TM1 0967m	351	4	W435 03 Aug 22
<b>Outer Diameter <math>\Delta 2</math> MIN OD</b> No-go gauge: End must not pass through	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TM10968	TM1 0968E	351	0	W435 03 Aug 22
<b>Outer Diameter <math>\Delta 8</math> MAX OD</b> Measure from proximal end of shaft to the material transition.	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TM1 50049	351	0	W435 M10b 03 Aug 22
<b>Outer Diameter <math>\Delta 8</math> MIN OD</b> Measure from proximal end of shaft to the material transition.	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TM1 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
<b>Outer Diameter <math>\Delta 13</math> MAX OD at Pad Printed Area</b>	0.145" +0.002"/- 0.004" (≤0.147")	100%	Ring Gauge TMI0748	TMI 50049	351	0	M435 M106 03 Aug 22
<b>Outer Diameter <math>\Delta 21</math> MAX OD</b>	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TMI0747	TMI 50049	351	0	M435 M106 03 Aug 22
<b>Outer Diameter <math>\Delta 12</math> MAX OD</b>	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
<b>Outer Diameter <math>\Delta 2</math> MIN OD</b>	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0968	TMI 50049	350	0	M435 M106 03 Aug 22
<b>Outer Diameter <math>\Delta 18</math> MAX OD</b>	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI 50049	350	0	M435 M106 03 Aug 22
<b>Outer Diameter <math>\Delta 18</math> MIN OD</b>	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

CREGANNA  
MEDICAL  
is part of



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:**

16 MAY 2022

**End Date:**

15 JUN 2021

**Lot Number:**

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

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)

<b>Product</b>	<b>SA0254-06</b>
<b>Production Lot Number</b>	<b>500000/64476</b>

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

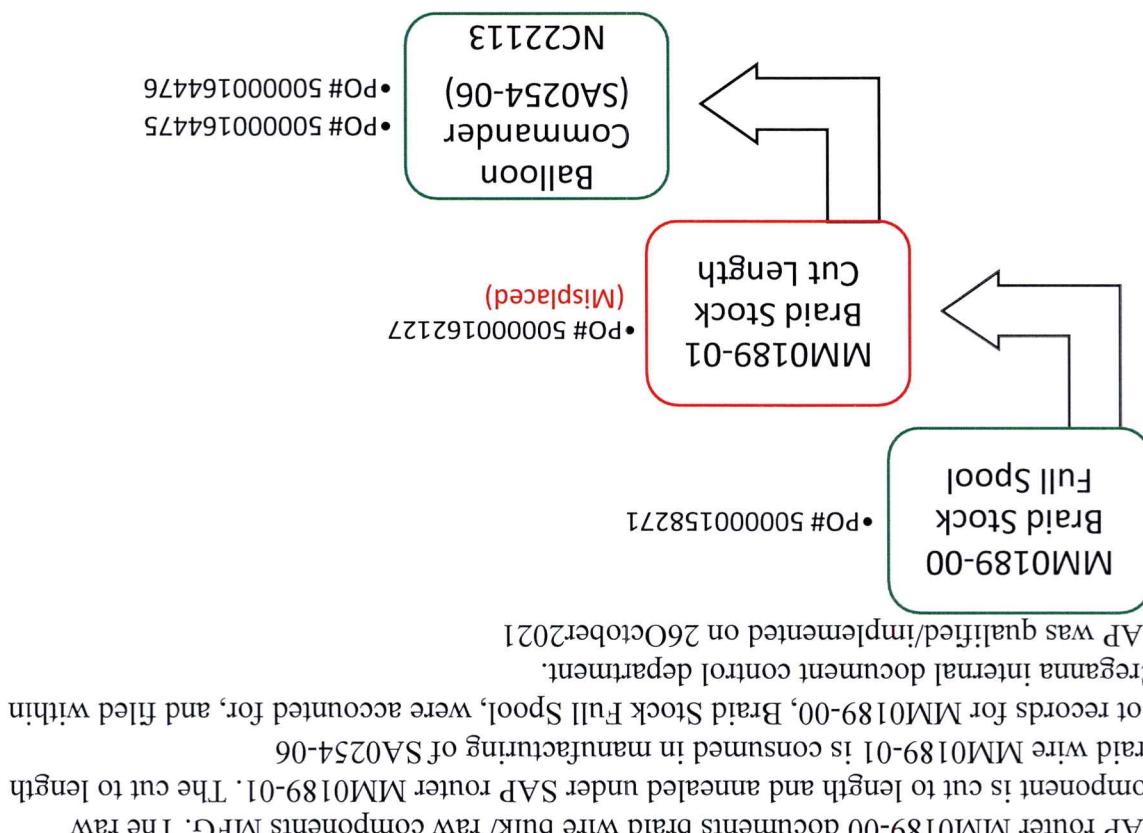
Specification for lower bound is 38N was converted to 8.542lbf

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.**

04 AUG 22

**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

Braiding process flow in brief



**Purpose:**

This memo pertains to Balloon Commander (SA0254-06) production orders included in NC-22113. On 17<sup>th</sup> Aug 2022, NC-22113 has been initiated for 2 balloon commander lots that consumed Braided Stock Cut Length w/ production order 500000162127, MM0189-01. The braid wire subassembly was completed and confirmed on 19<sup>th</sup> July 2022. This memo provides the justification that the order was completed and located/misplaced while SAP ERP system shows that production order 500000162127 could not be located/misplaced while SAP ERP system shows that the Braided Stock Cut Length production order 500000162127 met cut to length requirements and be shipped based on SAP ERP records.

Notes:

1. SAP router MM0189-00 documents braid wire bulk/ raw components MFG. The raw braid wire MM0189-01 is consumed in manufacturing of SA0254-06 component is cut to length and annealed under SAP router MM0189-01. The cut to length lot records for MM0189-00, Braided Stock Full Spool, were accounted for, and filed within Creagan internal document control department.
2. Lot records for MM0189-00, Braided Stock Full Spool, were accounted for, and filed within SAP was qualified/implemented on 26 October 2021

**Subject:** NC-22113**DATE:** 13 SEP 2022

## Misplaced Annealing Production Orders

4. Refer to attachment 1 for braiding operators hourly production tracker and attachment 2 for individual training records of operators that worked on Lot# 500000162127. During training record review process, one of the operator's July training record was not found. However, August training record is attached.
3. The lot records of 500000162126 and 500000162128 were reviewed, revealing lots were built with certified operators (1<sup>st</sup> and 2<sup>nd</sup> shift), the cut to length and annealing was done with released SAP router M0189-01 during MG. SAP records show that the operators completed the manufacturing process M0189 Rev.J and M010094 Rev.R, and assigned instructions within the manufacturing process M0189 Rev.J and M010094 Rev.R.
2. SAP ERP records show order 500000162127 for M0189-01 was built on 20July2022 after 500000162126 and before 500000162128. Please refer to the above SAP image.
4. Refer to attachment 1 for braiding operators hourly production tracker and attachment 2 for individual training records of operators that worked on Lot# 500000162127 has completed attached.
- c. Manufacturing inspection of annealed braid per MPI0094 is performed for b. Decorate, braid annealing operation per MPI0094
- a. Braid cutting operation per MPI0288
- SAP ERP record of M0189-01 shows that the order 500000162127 has completed attached.
- i. Kinks, necked and twisted braid  
ii. Broken wire  
iii. FM  
iv. Color  
v. Bend  
vi. Braided tip cut  
vii. presence of FEP over the annealed end of the braid

Order	Confirm. Yeld Unit	Scrap Count. Unit Conf.	Text Work Ctr	Entered	Final Conf/Milestone	Oper./Act.	Subop.	Created on
500000162126	0 PC	0 PC	ANNEAL01 TE439430 X	0050	19.07.2022	19.07.2022	5001328542 500 PC	0 PC
500000162127	0 PC	0 PC	ANNEAL01 TE439430 X	0100	19.07.2022	19.07.2022	5001328543 500 PC	0 PC
500000162128	0 PC	0 PC	ANNEAL01 TE276518 X	X	0200	20.07.2022	5001328544 500 PC	0 PC
	100 PC	0 PC	ANNEAL01 TE276518 X	0150	20.07.2022	20.07.2022	5001328545 500 PC	0 PC
	400 PC	0 PC	ANNEAL01 TE276229 X	0100	20.07.2022	20.07.2022	5001328546 400 PC	0 PC
	500000162127	0 PC	ANNEAL01 TE276229 X	0050	20.07.2022	20.07.2022	5001328547 500 PC	0 PC
	1000 PC	0 PC	ANNEAL01 TE276518 X	0200	20.07.2022	20.07.2022	5001328548 500 PC	0 PC
	500000162128	0 PC	ANNEAL01 TE276518 X	0050	20.07.2022	20.07.2022	5001328549 500 PC	0 PC
	5001328550 500 PC	0 PC	ANNEAL01 TE439430 X	0100	21.07.2022	21.07.2022	5001328551 500 PC	0 PC

1. SAP router for M0189-00, 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	/98	/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	/98	/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	/98	/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	FC Output	7FR Output	8FR Output	AFR Output	Pascal Output	Screening	Tip Cutting	Reason for not meeting Target	Line: <u>Ammealine</u>
OT											Date: <u>19 JUL 22</u>
1	72	19	75	75	33	33	73	72	124	38	<u>162125. all</u> <u>Shut+BC</u>
2	72	37	100	100	195	195	100	88	206	56	<u>Shut+5f-f</u>
3	72	31	100	100	146	146	146	75	206	49	<u>151887</u>
4	72	37	100	100	195	195	100	88	206	56	
5	72	37	100	100	195	195	100	88	206	56	
6	72	19	100	100	195	195	100	86	206	38	
7	72	37	100	100	195	195	100	86	206	56	<u>Shut+BC</u>
8	31	31	100	100	146	146	146	75	206	49	<u>162127</u>
9	36	37	100	100	195	195	100	86	206	52	
OT											Regime
Total	/288	/286	275	709	/1366	/1366	500	/623	/623	/450	

Quality Department  
5905 Trenton Lane North  
Plymouth MN 55442 USA



	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	/131	/63	100/155	/52	PC 142108	
OT											
	Total	/288	/286	/79	/929	/1366	/623	1500/1650	/450		

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

8 hr Days

Date: 19 JUL 22

Nodular  
Nodular

Final Culling % = 30%

	Hour	FC Output	Screening Output	BC Output	TR Output	SFR Output	AFR Output	Pascal Output	Stretching	TIP Cutting	Reason for not meeting Target	Line: Ammendaling
OT												
OT												
9		/36										
8		/31	/31	/37	/83	/110	/163	/163	/73	/165	/52	
7		/37	/31	/75	/98	/146	/146	/66	/206	/49		
6		/21	/19	/50	/66	/98	/98	/44	/224	/38		
5		/37	/100	/131	/195	/195	/88	/206	/56			
4		/37	/100	/131	/195	/195	/88	/206	/56			
3		/31	/31	/75	/98	/146	/146	/66	/206	/49		
2		/37	/37	/100	/131	/195	/195	/88	/206	/56		
1		/21	/19	/25	/33	/33	/22	/224	/38			
OT												

Hourly Production Tracker  
Shift (Grade one):  1 2 3  
Date: 16 Dec 22  
8 hr Days

Fracile | No|0

Quality Department  
5905 Trenton Lane North  
Plymouth MN 55442 USA



OT	OT	Hour	FC Output	Steering Output	BC Output	7FR Output	5FR Output	AFR Output	Pascal Output	Screching	Tip Cutting	Reason for not meeting Target	Total	/288	/286	/709	/925	/1366	/723	/1650	600 / 450
													Regular Time								
		9	/36	/37	/37	/110	/163	/163	/163	/73	/1650	162/28/B	OT								
		8	/32	/31	/75	/95	/46	/66	/206	87	/49										
		7	/37	/37	/100	/131	/135	/88	/206	87	/56										
		6	/72	/19	/66	/98	/44	/224	87	/38											
		5	/37	/37	/130	/131	/135	/88	/206	50	/56										
		4	/37	/37	/100	/131	/135	/88	/206	50	/56										
		3	/31	/31	/75	/98	/46	/206	50	/49											
		2	/37	/37	/100	/131	/135	/88	/206	50	/56										
		1	/22	/29	/25	/33	/33	/22	50	162/27/B											
OT	OT																				

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

Hourly Production Tracker Date: 20 Jul 22  
Shift (circle one): 1 (2) 3 Reason for not meeting Target

Hourly Production Tracker Date: 20 Jul 22 Reason for not meeting Target

Quality Department 5905 Trenton Lane North Plymouth MN 55442 USA



te.com

$BC = 300$   
 $FC = 100$

Hour	FC Output	Steaming Output	BC Output	TFR Output	SFR Output	AFR Output	Pascal Output	Stretching	Trip Cutting	Reason for not meeting Target	Line: Annealing	Shift (circle one): 1 2 3	8 hr Days	Comments
OT														
1	/21	/19	/25	/33	/33	/25	/22	/22	/124	/38				
2	/37	/37	/100	/131	/195	/195	/88	/88	/206	/56				
3	/31	/31	/75	/98	/146	/146	/55	/55	/206	/49				
4	/37	/37	/100	/131	/195	/195	/88	/88	/206	/56				
5	/37	/37	/100	/131	/195	/195	/88	/88	/206	/56				
6	/21	/21	/37	/37	/100	/131	/44	/44	/124	/38				
7	/37	/37	/100	/131	/195	/195	/88	/88	/206	/56				
8	/31	/31	/75	/98	/146	/146	/55	/55	/206	/49				
9	/35	/35	/100	/131	/195	/195	/88	/88	/206	/56				
OT														
														Regular Time

300  
        
 BC → 28000016212 → 100  
 PC → 38000061563 → 280

		Total	/288	/286	/79	/929	/1366	/623	/1650	/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.

October → Cello

Quality Department  
 5905 Trenton Lane North  
 Plymouth MN 55442 USA



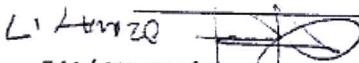
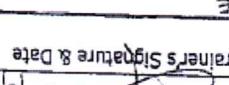
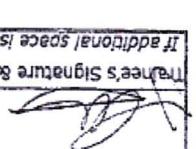
TRAINEE NAME: (Please Print): THOMAS PHOUMLIVONG Employee Number: 0094						
Individual Training Record						
CREGANNA MEDICAL						
Description of Training to be performed: DECALIVE, AUREAL, ERAL, TELPEREX						
For Manufacturing Training, complete the following prior to starting hands on training: 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: <i>10/02/17</i>						
Trainer Signature / Date: <i>10/02/17</i>						
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: <i>10/02/17</i>						
Name of Trainer: ANU TALENTINO						
Trainee's Signature & Date: <i>10/02/17</i>						
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

Operator: Thomsay Phoumlivong

Attachment 2: Individual training records



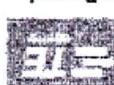
INDIVIDUAL TRAINING RECORD						
CRREGANNA MEDICAL						
Employee Name: (Please Print): THOMAS PHOENIX						
Employee Number: 0094						
MPI/MM/LHR/SPI/SOP/Other:						
Description of Training to be performed: DEFENSE, ANNUAL FLAID, HAZARD						
For Manufacturing Training, complete the following prior 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:  02/04/17						
Trainer Signature / Date:  02/04/17						
Document 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	677	O	QA APR 17	27APR17
5. MM0003-01	1022575-17	I	631	O	QA APR 17	27APR17
6. MM00077-01	CET2515-17	I	254	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.						

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\* 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/Initials
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: <b>Annnalizing Board (fallen componant)</b>						
Product Line: <u>Cannula</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> Individual Training Record 						

Operator: Nelson Nyangwono

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\* 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						
<p style="text-align: center;">Fill out a separate training form per MPI/MIN/HIR/SOP If additional space is required, the reverse side of this form may be used.</p>						
<p>Form has been verified for date accuracy and completion: <i>[Signature]</i> 15 Mar 22</p>						
<p>Trainee's Signature &amp; Date: <i>[Signature]</i> 14 Mar 2022</p>						
<p>Trainer's Signature &amp; Date: <i>[Signature]</i></p>						
<p>Trainee's Signature, I hereby certify that the training given was accurate and complete.</p>						
Part Number	Lot Number	Part # Revision	Accepted	Rejected	Comments	Trainer Date/Initials
1. MM0074-01	500000136988	G	500	0	N/A	28 Feb 2022 GCA
2. MM00074-01	500000136989	G	500	0	N/A	28 Feb 2022 GCA
3. MM0189-01	500000137080	D	500	0	N/A	28 Feb 2022 GCA
4. MM0189-01	500000137081	D	500	0	N/A	28 Feb 2022 GCA
5. MM0549-01	500000137325	A	150	0	N/A	28 Feb 2022 GCA
<p>Supervisor / Lead / Designee Signature and Date:</p>						
<p>Supervisor / Lead / Designee Signature and Date:</p>						
<p>Trainee's Signature &amp; Date:</p>						
<p>Trainee's Signature &amp; Date:</p>						
<p>For Manufacturing Training, complete the following prior to starting hands on training:</p>						
<p>Product Line: <i>Cannula</i> Description(s) of Training to be performed: <i>Cutting Build (FLEX Cannulae/Bolton Cannulae)</i></p>						
<p>Operations: <i>52</i> Reviewed MPI: <i>[Signature]</i> 28 Feb 2022</p>						
<p>Reviewed LHR: <i>[Signature]</i> 28 Feb 2022</p>						
<p>Reviewed Tools/Equipment: <i>[Signature]</i> 28 Feb 2022</p>						
<p>Reviewed Safety Hazards / PPE: <i>[Signature]</i> 28 Feb 2022</p>						
<p>Document all Training:</p>						
<p>Trainee Signature / Date: <i>[Signature]</i> 28 Feb 2022</p>						
<p>Trainer Signature / Date: <i>[Signature]</i> 28 Feb 2022</p>						
<p>Comments:</p>						

Operator: Ka Wang

## INDIVIDUAL TRAINING RECORD



Individual Training Record																																									
CRREGANNA MEDICAL																																									
Quality Department 5905 Trenton Lane North Plymouth MN 55442 USA																																									
te.com																																									
connectivity																																									
TE																																									
(any user/sr/af) Document #: TE508593 Employee #: 00041 Operation(s): 150.6.2 Description(s) of Training to be performed: Type Cutting blade (Balloons (Cannulae)) Product Line: Cannulae For Instructors Training, complete the following prior to starting hands on training: <input type="checkbox"/> Reviewed LHR <input type="checkbox"/> Reviewed tooling/equipment <input type="checkbox"/> Reviewed Safety Hazards / PPE Trainee Signature / Date: <i>Al by 01 March 2022</i> Trainer Signature / Date: <i>Al by 01 March 2022</i> Document Title Training Part Number    Lot Number    Part # Revision    Accepted    Rejected    Comments    Trainer Date/Initials <tr> <td>1. VM0189401</td> <td>500000136984</td> <td>①</td> <td>325</td> <td>0</td> <td>N/A</td> <td>01/10/2022 GCAZ</td> </tr> <tr> <td>2. VM0189401</td> <td>500000136985</td> <td>①</td> <td>375</td> <td>0</td> <td>N/A</td> <td>02/10/2022 GCAZ</td> </tr> <tr> <td>3. VM0189401</td> <td>500000137083</td> <td>①</td> <td>250</td> <td>0</td> <td>N/A</td> <td>03/10/2022 GCAZ</td> </tr> <tr> <td>4. VM0189401</td> <td>500000137512</td> <td>①</td> <td>150</td> <td>0</td> <td>N/A</td> <td>03/10/2022 GCAZ</td> </tr> <tr> <td>5. VM0189401</td> <td></td> <td></td> <td></td> <td></td> <td>N/A</td> <td>N/A</td> </tr>							1. VM0189401	500000136984	①	325	0	N/A	01/10/2022 GCAZ	2. VM0189401	500000136985	①	375	0	N/A	02/10/2022 GCAZ	3. VM0189401	500000137083	①	250	0	N/A	03/10/2022 GCAZ	4. VM0189401	500000137512	①	150	0	N/A	03/10/2022 GCAZ	5. VM0189401					N/A	N/A
1. VM0189401	500000136984	①	325	0	N/A	01/10/2022 GCAZ																																			
2. VM0189401	500000136985	①	375	0	N/A	02/10/2022 GCAZ																																			
3. VM0189401	500000137083	①	250	0	N/A	03/10/2022 GCAZ																																			
4. VM0189401	500000137512	①	150	0	N/A	03/10/2022 GCAZ																																			
5. VM0189401					N/A	N/A																																			

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FMG402 REV. B

" Fill out a separate training form per MP/IM/HR/Spi/SOP  
if additional space is required, the reverse side of this form may be used.

Supervisor / Lead / Designer Signature and Date:

Form has been verified for date accuracy and completion:

*ISAW/22*

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FM0402 Rev. B					
<p>Fill out a separate training form per MPI/MIM/UHR/SPI/SOP          If additional space is required, the reverse side of this form may be used.</p> <p>Form has been verified for date accuracy and completeness:</p> <p><i>[Handwritten Signature]</i></p> <p>Name of Trainer: <i>[Handwritten Signature]</i></p> <p>Supervisor / Lead / Designee Signature and Date: <i>[Handwritten Signature]</i></p> <p>Trainee's Signature &amp; Date: <i>[Handwritten Signature]</i></p> <p>Comments/Signature &amp; Date: <i>[Handwritten Signature]</i></p>					
<p>Trainee's Signature, I hereby certify that the training given was accurate and complete.</p> <p><i>[Handwritten Signature]</i></p> <p>Date: 14 March 2022</p> <p>Name of Trainer: <i>[Handwritten Signature]</i></p> <p>Comments/Signature &amp; Date: <i>[Handwritten Signature]</i></p>					
Part Number	Lot Number	Part # Revision	Accepted	Rejected	Comments
JM0189-01	500000135773	D	275	0	N/A
JM0189-01	500000135775	D	400	0	N/A
JM0189-01	500000135776	D	400	0	23 Feb 2022 GCR
JM0189-01	500000135777	D	275	0	N/A
JM0189-01	500000135778	D	175	0	23 Feb 2022 GCR
JM0189-01	500000135779	D	500	0	N/A
JM0189-01	500000135780	D	175	0	N/A
<p>Trainee's Signature &amp; Date: <i>[Handwritten Signature]</i></p> <p>Trainer Signature &amp; Date: <i>[Handwritten Signature]</i></p> <p>Comments all Training: <i>[Handwritten Signature]</i></p>					
<p>For Manufacturer Training, complete the following prior to starting hands on training:</p> <p><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</p> <p>Product Line: <i>Cannulae</i></p> <p>Description(s) of Training to be performed: <i>Cruciform Seal (Suture Cannulation)</i></p> <p>Operational(s): <i>150</i></p> <p>Employee #: <i>3503593</i></p> <p>Employee Name: <i>AL VAND</i></p> <p>Document #: <i>OC94</i></p> <p>Document Revision: <i>R</i></p> <p>Individual Training Record</p> <p>CRGANNA MEDICAL</p> <p>CONNECTIVITY</p>					
<p>Quality Department 5905 Trenton Lane North Plymouth MN 55442 USA</p>					



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FM10402 REV. B

Fill out a separate training form per MPI/MIN/LHR/SOP

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

Part Number	Lot Number	Part # Revision	Accepted	Rejected	Comments	Trainer Data/Minutes		
						Trainer's Signature & Date	Supervisor / Lead / Designer Signature & Date	Name of Trainer
5. MINIATURE-21	S000001C7650	R	300	0		30 JUN 22 / EFG29	30 JUN 22 / EFG29	30 JUN 22 / EFG29
4. MINIATURE-21	S000001C7652	L	241	0		28 JUN 22 / EFG28	28 JUN 22 / EFG28	28 JUN 22 / EFG28
3. MINIATURE-21	S000001C7654	C	173	6		26 JUN 22 / EFG26	26 JUN 22 / EFG26	26 JUN 22 / EFG26
2. MINIATURE-21	S000001C7655	R	264	0		27 JUN 22 / EFG27	27 JUN 22 / EFG27	27 JUN 22 / EFG27
1. MINIATURE-21	S000001C7653	R	194	0		27 JUN 22 / EFG27	27 JUN 22 / EFG27	27 JUN 22 / EFG27
							Trainer's Signature & Date: 30 Jun 22 Quality Gate 30 Jun 22	
							Trainee's Signature & Date: 30 Jun 22 Quality Gate 30 Jun 22	
							Supervisor / Lead / Designer Signature & Date: 30 Jun 22	
							Name of Trainer: 30 Jun 22	

Form has been verified for date accuracy and completion: *John Williams* 30 Jun 22

Trainer's Signature & Date: *John Williams* 30 Jun 22

Trainee's Signature & Date: *John Williams* 30 Jun 22

Supervisor / Lead / Designer Signature & Date: *John Williams* 30 Jun 22

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

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: *Automotive*Description(s) of Training to be performed: *Hand Tie Off*Documental Training: *Hand Tie Off*Operational(s): *130*Employee #: *777777*      \*Employee Revision: *E*\*Document #: *Q001/Q*      \*Document Revision: *E*\*Program #: *Q001/Q*      \*Program Revision: *E*Trainee Name: *CRIGANNA*

Individual Training Record

Quality Department  
5905 Trenton Lane North  
Plymouth MN 55442 USA

Operator: Thomasina K Williams



FM0402 Rev. B

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<p style="text-align: center;">Form has been verified for date accuracy and completion.</p> <p style="text-align: right;">Supervisor / Lead / Designee Signature and Date <i>[Signature]</i> 28 Jul 22</p>						
<p style="text-align: center;">Trainee's Signature &amp; Date <i>[Signature]</i> 28 Jul 22</p>						
<p style="text-align: center;">Name of Trainer <i>[Signature]</i> 28 Jul 22</p>						
<p style="text-align: center;">Trainer's Signature &amp; Date <i>[Signature]</i> 28 Jul 22</p>						
<p style="text-align: center;">Trainee's Signature, I hereby certify that the training given was accurate and complete!</p>						
Part Number	Lot Number	Part # Revision	Accepted	Rejected	Comments	Trainer Date/Initials
1. ZA00024-01	302-11163243	J	66	0		28 Jul 22 (EB29)
2. ZA00024-02	302-11163244	J	77	0		28 Jul 22 (EB29)
3. ZA00024-03	302-11163245	J	77	0		28 Jul 22 (EB29)
4. MM0118-01	50000016244	J	90	0		27 Jul 22 (EB29)
5. MM0118-01	500000163818	J	50	0		28 Jul 22 (EB29)
<p style="text-align: center;">*If additional space is required, the reverse side of this form may be used.</p>						
<p style="text-align: center;">*Fill out a separate training form per MPI/MR/SPI/SOP.</p>						

Status CURRENT Effective 12/8/2021

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FM4102 Rev. B

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

Form has been verified for date accuracy and completeness: <b>P</b> 17 May 22						
Trainer's Signature & Date: <b>P</b> 17 May 22 Trainee's Signature & Date: <b>F</b> 17 May 22						
Trainer's Signature, I hereby certify that the training given was accurate and complete.						
Part Number	Lot Number	Part Revision	Accepted	Rejected	Comments	Trainer Date/Initials
1. M11001401	50000 148543	G	100	0	N/A	04 May 22 GCR
2. M11001401	50000 148640	G	100	0	N/A	04 May 22 GCR
3. M11001401	50000 149176	G	300	0	N/A	08 May 22 GCR
4. M11001401	50000 149347	D	300	0	N/A	12 May 22 GCR
5. M11001401	50000 150399	D	300	0	N/A	13 May 22 GCR
Supervisor / Lead / Designee Signature and Date: <b>P</b> 17 May 22						
If additional space is required, the reverse side of this form may be used.						

Operator: Francella Kyrie



Status CURRENT Effective 12/8/2021

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FM402 Rev. B

<p style="text-align: right;">If additional space is required, the reverse side of this form may be used.</p> <p>Supervisor / Lead / Designer Signature and Date: <i>D. H. Miller 01Aug22</i></p> <p>Form has been verified for date accuracy and completeness:</p> <p><i>Roselouise Miller</i> <i>01Aug22</i></p> <p>Name of Trainer: <i>Roselouise Miller</i> <i>01Aug22</i></p> <p>Trainee's Signature &amp; Date: <i>Roselouise Miller</i> <i>01Aug22</i></p> <p>(Trainee's Signature, hereby certifies that the training given was accurate and complete)</p> <p>5. _____</p> <p>4. _____</p> <p>3. MM1029-01 500000163824 A 199 1 1BD 01Aug22</p> <p>2. MM1029-01 500000163823 A 17D 5 5DB 01Aug22</p> <p>1. MM0189-01 50000014595 D 5C 0 _____</p> <p>Part Number Lot Number Part # Revision Accepted Rejected Comments Trainer Date/Initials</p> <p>Document all Training</p> <p>Trainee Signature / Date: <i>Roselouise Miller</i> <i>01Aug22</i></p> <p>Trainer Signature / Date: <i>Roselouise Miller</i> <i>01Aug22</i></p> <p>For Manufacturer Training, complete the following prior to starting hands-on training:  <input checked="" type="checkbox"/> Reviewed LHR      <input checked="" type="checkbox"/> Reviewed Tools/equipment      <input checked="" type="checkbox"/> Reviewed Safety Hazards / PPE</p> <p>Product Line: <i>Decommissioning / Stripping</i></p> <p>Operations(s): <i>100</i></p> <p>Document Revision #: <i>01MPL0049 M010094</i></p> <p>Employee #: <i>489188</i></p> <p>Document #: <i>01MPL0049 M010094</i></p> <p>Document Revision #: <i>E</i></p> <p>MPN/Part #: <i>01MPL0049 M010094</i></p> <p>Product Name: <i>RACHEL DOL</i></p> <p>Individual Training Record</p> <p><b>CRB GANNAN MEDICAL</b></p> <p><small>is part of</small></p>						
---	--	--	--	--	--	--

*01Aug22*

Operator: Rachel Dol

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\* Fill out a separate training form per MPI/MHR/SPI/SOP  
FB24 08DEC2021

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		Trainee Signature & Date
						Name of Trainer	Trainee's Signature & Date	
1. M7M0189-01	500000123827	R	100	0	" "	07DEC21 / FB24	07DEC21 / FB24	
2. M7M0189-01	500000123828	R	100	0	" "	07DEC21 / FB24	07DEC21 / FB24	
3. M7M0189-01	500000124144	R	150	0	" "	08DEC21 / FB24	08DEC21 / FB24	
4. M7M0189-01	500000124145	R	150	0	" "	08DEC21 / FB24	08DEC21 / FB24	
5. M7M0189-01	500000124223	R	150	0	" "	08DEC21 / FB24	08DEC21 / FB24	
6. M7M0189-01	500000124564	R	250	0	" "	10DEC21 / FB24	10DEC21 / FB24	

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

*Jahat Edogun*

*Jahat Edogun*

Document all training

Trainee Signature / Date: 07DEC21 / JAHAT  
Trainer Signature / Date: 07DEC21 / JAHAT

Product Line: Annular

Operations: 150-6

Description(s) of Training to be performed: Tip cutting Braided wire (Annular communder)

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

Employee #: 1E500311

Trainee Name: (Please Print): Josepha Clark

Individual Training Record

CRGANTNA TEC MEDICAL CORPORATION

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 #: *MM0189-01* Employee #: *0094*

TRAINEE NAME: (Please Print): *Josephine Clarke* Individual Training Record

Employee #: *TE500311*

CRGANNA MEDICAL SYSTEMS  
is part of



<b>TECNA MEDICAL TRAINING CENTER</b> <b>Quality Department</b> <b>5905 Tremont Lane North</b> <b>Plymouth MN 55442 USA</b>						
<b>INDIVIDUAL TRAINING RECORD</b> <b>Employee #: TE 500311</b> <b>Document #: MP1 0041</b> <b>Document Revision:</b> <b>R</b> <b>(Please Print)</b> <b>TECNA MEDICAL</b>						
<b>TRAINEE NAME:</b> <b>Josephine Clark</b> <b>Individual Training Record</b>						
<b>Product Line:</b> <b>Annealing FC</b> <b>Description(s) of Training to be performed:</b> <b>For Manufacturing Training, complete the following prior to starting hands-on training:</b> <input type="checkbox"/> Reviewed MP <input type="checkbox"/> Reviewed tooling/equipment <input type="checkbox"/> Reviewed LHR <input type="checkbox"/> Reviewed Safety Hazards / PPE <b>Trainee Signature / Date:</b> <b>Mauro J. Lewis 27 Apr 22</b> <b>Trainer Signature / Date:</b> <b>Maria Luisa Lewis 28 Apr 22</b> <b>(Trainees Signature, I hereby certify that the training given was accurate and complete)</b> <b>Name of Trainer:</b> <b>Maria Luisa Lewis</b> <b>Trainee's Signature &amp; Date:</b> <b>Mauro J. Lewis 28 Apr 22</b> <b>Trainer's Signature &amp; Date:</b> <b>Maria Luisa Lewis 28 Apr 22</b> <b>Form has been verified for date accuracy and completion:</b> <b>Sig. Maria Luisa Lewis 28 Apr 22</b> <b>Supervisor / Lead / Designer Signature and Date</b> <b>If additional space is required, the reverse side of this form may be used.</b>						
<b>FM0402 Rev. B</b> <b>DATE: 11/22 FENT EFFECTIVE 12/8/2021</b> <b>-CONFIDENTIAL-</b> <b>Fill out a separate training form MP/MI/LHR/SOP</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:

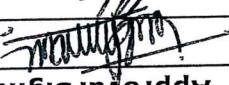
## Deviation From:

ST40

27 JUN 2022

## INFORMATION.

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

				FM002.REV.F Deviation Authorization
				QD@: UN68 27 JUN 2022
Title	Approval Name	Approval Signature	Date	Manufacturing Engine Manager (QD of Operations) <input checked="" type="checkbox"/> (Moldes autorizadas) <input type="checkbox"/> (QD de Fábrica) <input checked="" type="checkbox"/> (Moldes autorizadas now) 24 JUN 2022
Opertations Manager	Matthew Benson		24 JUN 2022	Jared Smith (QD de Fábrica) <input type="checkbox"/> 24 JUN 2022
Mgr Qlty & Reliability Engine	Tafzeelur Rahman		24 JUN 2022	
				If no, explain: N/A
				Training Required: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If no, explain:
				Corrective Action Required: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If no, explain: The corrective action will be housed under CAPA 11585
				If yes to any of the above, what controls are being put in place to mitigate the risk
				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
				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:

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			

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- 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:

### Purpose:

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

FROM: Saketh Reddy Thauvetteddy, Quality Engineer

DATE: 06/28/2022

MEMO



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Plymouth MN 55442 USA

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

main reason  
4. As an aid for polymer placement that itself acts to restrain the flow of polymer in a reflowed state (not used establishing the tip bond which occurs through an ID and butt joint via  
3. As an aid for component placement to define local features  
2. As an aid for dryfit restraining of isolating features or the shaft (no bonding involved)  
1. As an aid for protecting the exterior surface of features of the shaft from damage, foreign material, etc. (Temporary protective jacket)

These FEP are used for the following processes:

Table 2

Part Number	RM0567	RM0357	Current	Proposed	FEP Supplier	Zeus	Fluorinated Ethylene Propylene	All applications outlined	below except tipping	All applications outlined	below including tipping	Only to be used in tipping	Process used	All applications outlined	below except tipping	All applications outlined	below including tipping	Only to be used in tipping	Recovered ID	.210" min	.240" min	.230" min	.250" min	.131" max	.131" max	.010" ± .002"	Wall thickness (ref.)
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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														
TE Brooklyn Park, MN	TE Brooklyn Park, MN	PTFE 1.168ID x 0.02W 60L	PTFE Liner 0.168 ID x 0.02 Wall x 60	PTFE ESI 1000-2727	PTFE ESI 1000-2726	Zeus Industrial Tubing ESI	Zeus Industrial Tubing ESI	0.030 ID x 0.0015 W	0.030 ID x 0.0015 W	0.0015 W	0.0015 W	TE Brooklyn Park, MN	ZEUS INDUSTRIAL TUBING	ZEUS INDUSTRIAL TUBING
RM7538-02	RM7591-01	PTFE ESI 1000-2726	PTFE ESI 1000-2727	PTFE ESI 1000-2727	PTFE ESI 1000-2726	PTFE Free Wall x 60	PTFE Free Wall x 60	0.168 ID x 0.02 Wall x 60	0.168 ID x 0.02 Wall x 60	0.0015 W	0.0015 W	TE Brooklyn Park, MN		

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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 Limer Ext Sub-Lite-Wall Tech 60L	SA0474-01	Bypassed during matrix compilation	SA0474-01	FEP Limer 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	103-0340 PET Shrink Tube	SA0579-01	The part was previously introduced using DA 2112. Not required anymore.	0.400" MIN.1DX0.250" MAX.0DX20"1	Not part of S040473-01 BOM	0.400" MIN.1DX0.250" MAX.0DX20"1	SA0473-01	FEP HS 64L.270Exp ID .010W 1.6-1	SA0473-01	Not part of S040473-01 BOM	RM8203-01

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

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- \*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.

Table 4

TL1019-01	Main shipping Mandrel	SA0579-01	Bypassed during matrix compilation	SA0579-01	FE P HS .188 Exp ID 1.6-1 Shrink R	SA0579-01	Bypassed during matrix compilation	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	Bypassed during matrix compilation	SA0579-01	FE P Heat Shrink, 0.150" Expanded ID, 1.6:1 Shrink Ratio	SA0579-01	Bypassed during matrix compilation	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	Bypassed during matrix compilation	SA0579-01	0.064", Avg. Wall 0.0010"
TL1021-02	Small shipping Mandrel	SA0579-01	Bypassed during matrix compilation	SA0579-01	FE P HS .400" MIN.IDX0.250"MAX.ODX20" L	SA0613-01	Bypassed during matrix compilation	SA0613-01	BW 304SS .003 Single Lead min.	SA0613-01	300kpsi	SA0613-01	Bypassed during matrix compilation	SA0613-01	FE P Heat Shrink, 0.150" Expanded ID, 1.6:1 Shrink Ratio	SA0579-01	Bypassed during matrix compilation	SA0579-01	0.064", Avg. Wall 0.0010"	SA0579-01	0.064", Avg. Wall 0.0010"	SA0579-01	Bypassed during matrix compilation	SA0579-01	0.064", Avg. Wall 0.0010"
RM4004-02																									
RM0138-01	BW 304SS .003 Single Lead min.	SA0613-01	Bypassed during matrix compilation	SA0613-01	FE P HS .188 Exp ID 1.6-1 Shrink R	SA0579-01	Bypassed during matrix compilation	SA0579-01	FE P Heat Shrink, 0.150" Expanded ID, 1.6:1 Shrink Ratio	SA0579-01	1.6:1 Shrink Ratio	SA0579-01	Bypassed during matrix compilation	SA0579-01	FE P Heat Shrink, 0.150" Expanded ID, 1.6:1 Shrink Ratio	SA0579-01	Bypassed during matrix compilation	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	Bypassed during matrix compilation	SA0579-01	0.064", Avg. Wall 0.0010"
RM0380-02																									
RM0380-03																									
RM8581-02																									
RM8581-03																									

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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.
- All lots manufactured with raw materials that were initially missing as part of DA2245 from table 4 were from the approved suppliers. After reviewing all the affected Edwards part between June 7<sup>th</sup> and June 24<sup>th</sup>2022 (DA 2245 active date). The review was done to ensure LHR's / 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 RM's. Therefore, there is no risk to part of DA 2263 attachment.
- All the above 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
- The raw material-approved supplier matrix (as an attachment to DA 2263) provides 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.

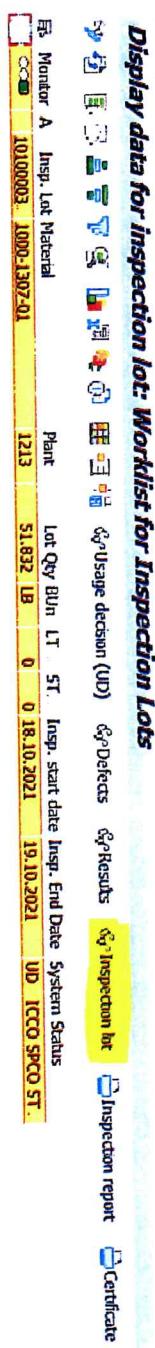
3) How to find Certification(s) in SAP-ERP System:

Login to SAP PRM portal.

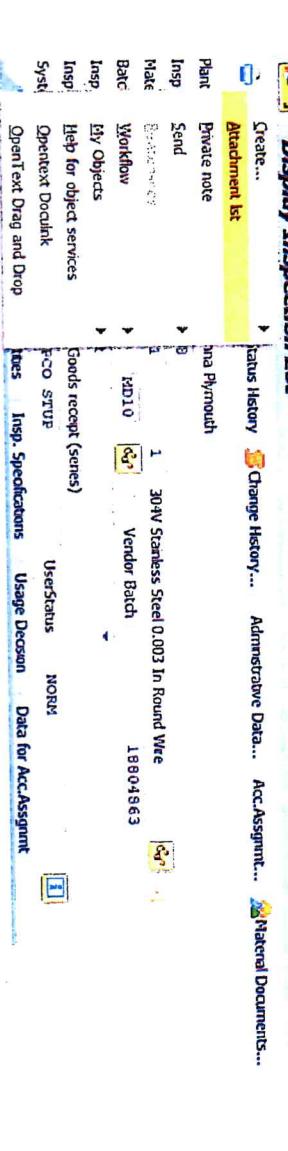
Go to "Inspection Lot Selection" using QA33 Transaction code.

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	

*Cub 6 Aug 22  
05*

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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05 Aug 22

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	

846  
05 Aug 22

## 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	

✓46  
05 Aug 22

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	

05 Aug 2021

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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Cx46  
05 Aug 22

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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05 Aug 22

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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ATTACHED MEMO FOR MORE INFORMATION

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DA(2263) ATTACHMENT

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	

Cx46  
05 Aug 22

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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05 Aug 22

^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:ID 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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Cx46  
06 Aug 22

## 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	

*X46*  
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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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05 Aug 2024

## 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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05 Aug 22

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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	

X46 Aug 2005

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 <sup>st</sup> layer (.002x.012)52" L	Ulbrich specialty wire product LLC	N/A
RM8149-01	Annealed Braid, 2 <sup>nd</sup> layer (.002x.012)30" L	Ulbrich specialty wire product LLC	N/A

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

*✓  
N/A  
CX46 05 Aug 22*

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:

C44-05 Aug 22

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#

05 Aug 22  
Cx46

		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#