

# Production Order: 500000066050



Production Order Qty.: 300

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: 8000 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>U</u>  Line Clearance MPI0230 Rev. <u>E</u>  By: <u>CL</u> Date: <u>09 Jan 21</u>		500	0	09Jan21	CL
100	CATASY04  Catheter	Straighten First Jacket MPI0398 Rev. <u>U</u>			N/A	

Notes: DA 1738 DA1787

Date Printed: 09.01.2021 / 07:18:21

Page: 1 of 16



SA0254-06

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000066050



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
		Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used			
	Assembly 4 										
NA	Straighten First Jacket	MM0187-01	E	<u>E</u>	PC	1	<u>0000062288</u>	<u>500</u>	0	09Jan21	PCS
	Confirmation Reqd(Milestone )						<u>N/A</u>	<u>N/A</u>			
150	CATASY04 	Positioning Braid Over First Jacket MPI0398 Rev. <u>u</u>						358	0	09Jan21	SP AW BK SC .47 MTH
	Positioning Braid Over First Jacket	Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used			
	Confirmation Reqd(Milestone )	MM0189-01	D	<u>D</u>	PC	500	<u>0000064797</u>	<u>400</u>	0	09Jan21	
							<u>0000064995</u>	<u>100</u>			

Notes:

N/A

Date Printed: 09.01.2021 / 07:18:21

Page: 2 of 16



SA0254-06

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000066050



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																																			
N/A	N/A	N/A	N/A	N/A	N/A	N/A																																			
200	CATASY04  Catheter Assembly 4  	<p>Strain Relief Reflow MPI0398 Rev. <u>u</u></p> <p>Temp = 420°F 5°F Air Flow = 60 SCFH</p> <table border="1"> <thead> <tr> <th>Component Number</th> <th>Req'd Rev</th> <th>Rev Used</th> <th>UOM</th> <th>Qty.</th> <th>Batch No.</th> <th>Actual Qty Used</th> </tr> </thead> <tbody> <tr> <td>MM0527-01</td> <td>B</td> <td><u>B</u></td> <td>PC</td> <td>500</td> <td>0000058371</td> <td>500</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td>N/A</td> <td>N/A</td> </tr> <tr> <td>RM0096-01</td> <td>F</td> <td><u>F</u></td> <td>PC</td> <td>125</td> <td>27976</td> <td>180</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td>N/A</td> <td>N/A</td> </tr> </tbody> </table>	Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	MM0527-01	B	<u>B</u>	PC	500	0000058371	500						N/A	N/A	RM0096-01	F	<u>F</u>	PC	125	27976	180						N/A	N/A	246  254	0  0	09Jan21  09Jan21	VKA  VX
Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																																			
MM0527-01	B	<u>B</u>	PC	500	0000058371	500																																			
					N/A	N/A																																			
RM0096-01	F	<u>F</u>	PC	125	27976	180																																			
					N/A	N/A																																			
250	CATASY04  Catheter Assembly 4  	<p>Position Tubing For Reflow MPI0398 Rev. <u>u</u></p> <table border="1"> <thead> <tr> <th>Component</th> <th>Req'd</th> <th>Rev</th> <th>UOM</th> <th>Qty.</th> <th>Batch</th> <th>Actual</th> </tr> </thead> </table>	Component	Req'd	Rev	UOM	Qty.	Batch	Actual	188  308	0  4 TOO Tight	09 Jan 21  09Jan21	AN BK SC SP Mei AO																												
Component	Req'd	Rev	UOM	Qty.	Batch	Actual																																			
Notes:  N/A																																									

Date Printed: 09.01.2021 / 07:18:21

Page: 3 of 16



SA0254-06

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000066050



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
<i>NIA</i>	Position Tubing for Reflow	Number	Rev	Used		No.	Qty	Used				
		MM0186-00	D	<u>D</u>	PC	500	<u>P08-061101</u>	<u>500</u>				
		MM0523-03	C	<u>C</u>	PC	500	<u>0000059871</u>	<u>500</u>				
		MM0524-01	B	<u>B</u>	PC	500	<u>0000058676</u>	<u>500</u>				
		MM0530-01	B	<u>B</u>	PC	500	<u>0000057812</u>	<u>500</u>				<i>NIA</i>
		RM7586-02	D	<u>D</u>	PC	500	<u>25632</u>	<u>260</u>				
		RM8745-01	B	<u>B</u>	PC	500	<u>27613</u>	<u>300</u>				
		MM0185-01	I	<u>I</u>	PC	500	<u>0000058372</u>	<u>500</u>				
							<u>NIA</u>	<u>NIA</u>				

Notes:

*NIA*

Date Printed: 09.01.2021 / 07:18:21

Page: 4 of 16



SA0254-06

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000066050



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
		MM1540-01 A <u>A</u> PC 500	<u>0000060069</u>	<u>500</u>								
		MM1539-01 A <u>A</u> PC 500	<u>0000061041</u>	<u>500</u>								
		RM016101-MED <u>N/A</u> F <u>F</u> PC 46	<u>N/A</u>	<u>N/A</u>								
			<u>25704</u>	<u>100</u>								
300	CATASY04 Catheter Assembly 4 	Reflow MPI0398 Rev. <u>u</u>  Temp = 415°F (+/- 15 °F) Speed = 4.5 in/min (+/- 0.5 in/min)						79 417	0 0	09Jan21 VWT		
350	CATASY04 Catheter Assembly 4	Skive Heat Shrink MPI0398 Rev. <u>y</u>						250 246	0 0	09Jan21 MS 11Jan21 YK 11Jan21 Pny		
Notes:												

Date Printed: 09.01.2021 / 07:18:21

Page: 5 of 16



SA0254-06

VWT 09Jan21  
CREGANNA MEDICAL  
is part of





## Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	 <i>N/A</i> Skive Heat Shrink					
400	<b>CATASY04</b> Catheter Assembly 4 Count: Yes  In Process Inspection	In-Process Inspection (Visual Inspection) MPI0398 Rev. <u>u</u>  FM5104693  (Rework if needed. Use FM5104983)	248	2EW	11Jan21	YK
450	<b>CATASY04</b> Catheter Assembly 4  Anneal Shaft	Anneal Shaft MPI0398 Rev. <u>u</u> FM5104692	248 245	0 0	11Jan21 11Jan21	YK Pny

## Notes:



# Production Order: 500000066050



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
500	CATASY04  Catheter Assembly 4    Leak Test/Prox Cut/Ring Gage-Dim 13/21 MPI0398 Rev. <u>U</u>  FM5104694 FM5104695  Leak Test/Prox Cut/Ring Gage-Dim 13/21	Leak Test/Prox Cut/Ring Gage-Dim 13/21 MPI0398 Rev. <u>U</u>  FM5104694 FM5104695  (Rework if needed - Use FM5104983)	81  393	900 Fail  170 scrap 10 ODFail	11 Jan 21	CKU  NYC
550	CATASY04  Catheter Assembly 4    Distal Cut MPI0398 Rev. <u>U</u> Line Closure MPI0230 Rev. <u>E</u> By: <u>ml</u> Date: <u>11 Jan 21</u>	Distal Cut MPI0398 Rev. <u>U</u> Line Closure MPI0230 Rev. <u>E</u> By: <u>ml</u> Date: <u>11 Jan 21</u>	81  393	0  0	11 Jan 21  11 Jan 21	CKY  XX  ml
600	PADPRIN1  Pad Print  Count: Yes    Pad Print Set Up MPI0276 Rev. <u>D</u>  Line Clearance MPI0230 Rev. <u>E</u>	Pad Print Set Up MPI0276 Rev. <u>D</u>  Line Clearance MPI0230 Rev. <u>E</u>	474	0	12 Jan 21	PK

Notes:

N/A

Date Printed: 09.01.2021 / 07:18:21

Page: 7 of 16



SA0254-06

ml 11 Jan 21  
ml 11 Jan 21  
CREGANNA MEDICAL  
is part of



# Production Order: 500000066050



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
N/A	Pad Print Setup	By: <u>PK</u> Date: <u>12 Jan 21</u>  TMI0503 (circle TMI used) Cliché - TL0525 Ink # RM7407-01 Thinner - RM7408-01 Hardener - RM7409-01 Customized Measuring Equipment - Caliper 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 - Caliper 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				N/A

### Notes:

N/A

Date Printed: 09.01.2021 / 07:18:21

Page: 8 of 16



SA0254-06

CREGANNA  
MEDICAL  
is part of



# Production Order: 500000066050



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																				
		<i>U</i> <i>A</i>																								
650	PADPRIN1 Pad Print 	<p>Verification MPI0276 Rev. <u>D</u> Section 15.0</p> <table border="1"> <thead> <tr> <th>Component Number</th> <th>Req'd Rev</th> <th>Rev Used</th> <th>UOM</th> <th>Qty.</th> <th>Batch No.</th> <th>Actual Qty Used</th> </tr> </thead> <tbody> <tr> <td>RM7407-01</td> <td>B</td> <td><u>B</u></td> <td>L</td> <td>0.050</td> <td><u>25383</u></td> <td><u>0.040</u></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td><u>N/A</u></td> <td><u>N/A</u></td> </tr> </tbody> </table>	Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used	RM7407-01	B	<u>B</u>	L	0.050	<u>25383</u>	<u>0.040</u>						<u>N/A</u>	<u>N/A</u>	474	0	12Jan21 PK
Component Number	Req'd Rev	Rev Used	UOM	Qty.	Batch No.	Actual Qty Used																				
RM7407-01	B	<u>B</u>	L	0.050	<u>25383</u>	<u>0.040</u>																				
					<u>N/A</u>	<u>N/A</u>																				

Notes:

*N/A*

Date Printed: 09.01.2021 / 07:18:21

Page: 9 of 16



SA0254-06

CREGANNA  
MEDICAL  
is part of





## Material: SA0254-06 Rev G

Op. No.	Planned WorkCenter Description	Operation Details							Comp. Qty.	Scrap Qty. & Desc.	Date Comp.	Initials
		RM7408-01	B	<u>B</u>	L	0.005	TP53072	0.005		N/A	N/A	
		RM7409-01	B	<u>B</u>	L	0.010	26764	0.010		N/A	N/A	
700	PADPRIN1  Pad Print  	Prepare Surface for Ink MPI0276 Rev. <u>D</u> Section 15.5 Polynit wipes 99% IPA							474	0	12 Jan 21	PK
750	PADPRIN1  Pad Print    Print Parts MPI0276 Rev. <u>D</u> Section 20.0 Inspection gauge TMI0843								474	0	12 Jan 21	PK

Notes:

N/A

Date Printed: 09.01.2021 / 07:18:21

Page: 10 of 16



SA0254-06

CREGANNA  
MEDICAL  
is part of



## Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
800	PADPRIN1 Pad Print  In-process Inspection and Rework	In-Process Inspection and Rework MPI0276 Rev. <u>D</u> Section 30.0 Polynit Wipes 99% IPA Mag Light	474	0	12Jan21	PK
850	PADPRIN1 Pad Print  Curing Oven Confirmation Reqd(Milestone )	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>10:48PM</u> By: <u>KUT</u> Date: <u>12Jan21</u>	474	0	12Jan21	KUT
900	PADPRIN1 Pad Print	Transfer Parts to Production MPI0276 Rev. <u>D</u> Section 40.0	474	0	13Jan21	PK

Notes:

N/A





## Material: SA0254-06 Rev G

Opr No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	 Transfer parts to Production Confirmation Reqd(Milestone )	Transfer Parts to Line Time: <u>7:00 AM</u> By: <u>PK</u> Date: <u>13 Jan 21</u>			N/A	
950	PADPRIN1 Pad Print Count: Yes  Cleaning Confirmation Reqd(Milestone )	Cleaning MPI0276 Rev. <u>D</u> Section 50.0  Line Clearance MPI0230 Rev. <u>E</u> By: <u>PK</u> Date: <u>12 Jan 21</u>	474	0	12 Jan 21	PK
1000	CATASY04	In-Process Dimensional Inspection	N/A	N/A	N/A	N/A

Notes:

N/A

Date Printed: 09.01.2021 / 07:18:21

Page: 12 of 16



SA0254-06

CREGANNA  
MEDICAL  
is part of

## Production Order: 500000066050



**Production Order Document**  
**Production Order Qty: 500**  
**PQ**

Sheet: 1 of 1

**Material: SA0254-06 Rev G**

Opr No.	Planned WorkCenter Description	Operation Details	Comp Qty.	Scrap Qty & Desc.	Date Comp.	Initials
N/A	Catheter Assembly 4   In-Process Dimensional Inspection	MPI0398 Rev. <u>11</u> FM5104662 FM5104696  (No Rework can be done at this OP)  Line Closure MPI0230 Rev. <u>E</u>  By: <u>NT</u> Date: <u>16 Jan 21</u>	90  411 321	24 OD Fail  39 OD FAIL	15 Jan 21  16 Jan 21	NT  NT
1050	QUALITY1  Quality Inspection & Review    Quality Inspection & Review  Confirmation Reqd(Milestone )	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	276	10 - TT 8600 - 05/18 2 - SK over 37 OD - 05 - H16  + PRT - 21 SCR - 7 DS - 3 DISC - 2 5 FM - 1 EW - 1 SKV - 1	18 FEB 21	AP

---

**Notes:**

Date Printed: 09.01.2021 / 07:18:21

Page: 13 of 16



SA0254-06

AP 16 FEB 21  
AP 18 FEB 21  
AP 18 FEB 21

ST 14 Jan 21

**CREGANNA**  
MEDICAL  
is part of





## Material: SA0254-06 Rev G

Opn No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
1070	CATASY04  Catheter Assembly 4  Rework Process  Confirmation Reqd(Milestone )	Rework MPI0398 Rev. <u>u</u>  Material consumed Material <u>N/A</u> Batch <u>N/A</u> Rev <u>N/A</u> Qty <u>N/A</u> Material <u>N/A</u> Batch <u>N/A</u> Rev <u>N/A</u> Qty <u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>
1090	QUALITY1  Quality Inspection & Review  Quality Inspection & Review	Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan	276	0	18FEB21	AP

Notes:

N/A

Date Printed: 09.01.2021 / 07:18:21

Page: 14 of 16



SA0254-06

CREGANNA  
MEDICAL  
is part of

**Production Order: 500000066050**



Production Order Document  
Production Order Qty: 500  
PC

**Material: SA0254-06 Rev G**

Sheet: 1 of 1

Opr. No.	Planned WorkCenter Description	Operation Details	Comp. Qty.	Scrap Qty & Desc.	Date Comp.	Initials
	Confirmation Reqd(Milestone )	N/A		N/A		
1100	PACKINT1 Packing assembly  Packing Instructions Confirmation Reqd(Milestone )	Packaging Instructions SPI0087 REV. H	276	0	18feb21	ES

Notes:

Date Printed: 09.01.2021 / 07:18:21

Page: 15 of 16



SA0254-06

CREGANNA  
MEDICAL  
is part of



**Production Order:** **500000066050**



Production Order Document  
Production Order Qty: 500  
PC

**Material:** **SA0254-06 Rev G**

Sheet: 1 of 1

Batch Number: 0000066050

By: FJ

Date: 18 Feb 21

Reviewed By:

Date: 18 Feb 21

Notes:

Date Printed: 09.01.2021 / 07:18:21

Page: 16 of 16



SA0254-06



CREGANNA  
MEDICAL  
is part of



**CREGANN  
MEDICAL**  
is part of

Document No: FM5104983

Rev: B Document Type: Manufacturing Form  
Title: SA0254 Cause of Rework Form

PRODUCTION ORDER#

66050

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

OPER 400.0

Date	Initial	AB (Prox)	AB (Distal)	DF	DS	EW	FM	Disc	SCR	SKV	VD
11 Jan 21	K	/	/	○	○	2	4	○	9	○	○
11 Jan 21	pny	o	6	o	o	o	2	o	o	o	o

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

OPER 500.0

Date	Initial	Dim 13 (Go Gauge)	Dim 21 (Go gauge)
11 Jan 21	Pass, m/e 1	0	146

66050

PRODUCTION ORDER#

OPER 400.0

### In-Process 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%	2.85x Mag. Light		496	0	PMY 11 Jan 21
Metallic Foreign Material: No embedded metallic and foreign material is allowed along the length of the shaft.	N/A	100%	2.85x Mag. Light		496	0	
All other Foreign Material:							
Particle Size Area: mm <sup>2</sup>	Acceptable Limits per Part	See Table	100%	Tappi Chart and 2.85x Mag. Light	496	0	
< 0.05 mm <sup>2</sup>	No Limit						
0.05 mm <sup>2</sup> ≤ Area < 0.25 mm <sup>2</sup>	3						
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%	2.85x Mag. Light		496	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%	2.85x Mag. Light		496	0	
No flat spots, kinks, delamination, gaps between material transitions and material transitions should not exhibit cracking, no exposed or apparent braid.	N/A	100%	2.85x Mag. Light		493	3	
Verify all ODs along the entire length of shaft are within specification according to print/drawing requirements.	See QA Inspection Requirement	100%	See QA Inspection Equipment		493	0	PMY 11 Jan 21



**CREGANNÀ**  
MEDICAL  
is part of

Document No: FM5104692  
Rev: B  
Document Type: Manufacturing Form  
Title: SA0254 Annealing Oven Log Form

605 D

PRODUCTION ORDER#

OPER 450.0

## Annealing Log Sheet

YK11 5cm<sup>2</sup>

Status CURRENT Effective 10/27/2020



Document No: FM5104694

Rev: B

Document Type: Manufacturing Form

Title: SA0254 Max OD Gauge Check Form

PRODUCTION ORDER# 5000000000

**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	TMI####XX (Ex. TMI0748AC or TMI0747AD)	Initials	Date	Time
Before	Dimension 13	TMI 0748 AN	CL	11 Jan 21	12:10 PM
Before	Dimension 21	TMI 0747 U	CL	11 Jan 21	12:10 PM
After	Dimension 13	TMI 0748 AN	LJ	11 Jan 21	12:25 AM
After	Dimension 21	TMI 0747 U	LJ	11 Jan 21	12:25 AM

PRODUCTION ORDER# 66650

OPER 500.0 Pressure Decay Testing						
Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail
<b>Air Leak Test GN 15</b>	N/A	100%	Issac Pressure Decay Tester	TM10797	493	0
<b>Outer Diameter ▲13 MAX OD at Pad Printed Area</b>	$0.145" +0.002"/-$ $0.004"$ ( $\leq 0.147"$ )	100%	Ring Gauge TM10748 or equivalent	TM10748	474	14
<b>Outer Diameter ▲21 MAX OD</b>	$0.157" \pm 0.003"$ ( $\leq 0.160"$ )	100%	Ring Gauge TM10747 or equivalent	TM10747	474	0



PRODUCTION ORDER# 66050

**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	TMI###XX (Ex. TMI0748AC or TMI0747AD)	Initials	Date	Time
Before	Dimension 13			15 Jan 21	11:10 AM
		TMI 0748 AM	CL	15 Jan 21	12:10 PM
Before	Dimension 21			15 Jan 21	11:10 AM
		TMI 0747 u	CL	15 Jan 21	12:10 PM
After	Dimension 13			16 Jan 21	6:40 AM
		TMI 0748 AM	CL		
After	Dimension 21			16 Jan 21	6:40 AM
		TMI 0747 T	CL		

PRODUCTION ORDER# 66050

OP 1000.0

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
<b>Outer Diameter ▲13 MAX OD at Pad Printed Area</b>	0.145" +0.002"/-0.004" (≤0.147")	100%	Ring Gauge TMI0748 or equivalent	TMI 0748A97	474	0	cky 15 Jan 21
<b>Outer Diameter ▲21 MAX OD</b>	0.157" ± 0.003" (≤0.160")	100%	Ring Gauge TMI0747 or equivalent	TMI 0747U	468	4	cky 15 Jan 21
<b>Outer Diameter ▲2 MAX OD</b>	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0967, or equivalent	TMI 0967J	445	23	cky 15 Jan 21
<b>Outer Diameter ▲2 MIN OD</b>	0.142" ± 0.002" (0.140"-0.144")	100%	Ring Gauges TMI0968, or equivalent	TMI 0968E	445	0	cky 15 Jan 21
<b>Outer Diameter ▲18 MAX OD</b>	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI 50049	415	30	WT 15 Jan 21
<b>Outer Diameter ▲18 MIN OD</b>	0.140" ± 0.002" (0.138"-0.142")	100%	Two Axis Laser Micrometer	TMI 50049	415	0	WT 15 Jan 21

PRODUCTION ORDER# 66050

Document No: FM5104696

Rev: B

Document Type: Manufacturing Form  
Title: SA0254 In-Process Inspection Form

Test/Specification	Dimensions	Sample Plan	Equipment	TMI/TL	# Pass	# Fail	Initial/Date
<b>Outer Diameter ▲3 AVG OD at Pad Printed Area</b>  Measure from distal end of material transition to stop sleeve shoulder  <b>NOTE:</b> Measure AVG OD and record results	0.145 +0.002"/-0.004" (0.141"-0.147")	100%	Two Axis Laser Micrometer 50049	TM2 4/5	0	0	NT 15 Jan 21
<b>Outer Diameter ▲21 AVG OD</b>  Measure from stop sleeve shoulder to 4" distal of stop sleeve shoulder.  <b>NOTE:</b> Measure Avg OD and record results	0.157" ± 0.003" (0.154"-0.160")	100%	Two Axis Laser Micrometer 50049	TM2 4/5	0	0	NT 15 Jan 21
<b>Outer Diameter ▲7 AVG OD</b>  Measure 4" distal the stop sleeve shoulder to the braid termination.  <b>NOTE:</b> Measure and Record results	0.157" ± 0.003" (0.154"-0.160")	100%	Two Axis Laser Micrometer 50049	TM2 4/11	4	4	NT 15 Jan 21
<b>Outer Diameter ▲2 MAX OD</b>  Measure distally from the braid termination to the all the way distal end of the shaft.	0.142" ± 0.002" (0.140"-0.144")	100%	Two Axis Laser Micrometer 50049	TM2 4/11	0	0	NT 15 Jan 21
<b>Outer Diameter ▲2 MIN OD</b>  Measure distally from the braid termination to the all the way distal end of the shaft.	0.142" ± 0.002" (0.140"-0.144")	100%	Two Axis Laser Micrometer 50049	TM2 4/11	0	0	NT 15 Jan 21



**CREGANNA**  
MEDICAL  
is part of

Document No: FM5104983

Rev: B Document Type: Manufacturing Form  
Title: SA0254 Cause of Rework Form

66050

PRODUCTION ORDER#

OPER 1050.0

Record total quantity reworked:

NIA

## Quantity Passed after Rework:

M A

Rework Performed by: NA Date: NA Rework Performed by: NA Date: NA

Re-Inspection Performed by: M.A Date: 1/14/14

Mfg Engineering manager	Renata Holahan	APPROVAL NAME	APPROVAL SIGNATURE	Date
Quality Manager No 9 Dec 20	No 10 Dec 20	Steve-Julie Michn Gpar	Witch-Opatz	19 Dec 20
Operations Manager 41	Operations Manager 41	Operations Manager 41	Operations Manager 41	Operations Manager 41

Training Required:	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	If no, explain: N/A
--------------------	---	---------------------

If no, explain:	Deviation talks about recording the variable data at a operation where we are already checking for the dimension.
Corrective Action Required:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

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

Risk Assessment:	Excluded from QES201 AT affected QES201				
Start Date:	End Date:	Lot Number:	1/9/2020	1/9/2021	N/A
Part Number Affected	Revision	SA0254 - 04/05/06	5	N/A	

Justification:	As per the customer requirement we are starting to record the variable data for dimension 12 and 13 at "inline dimensional inspection operation".
----------------	---

Deviation From:	Currently at "inline dimensional inspection operation" operators record the variable data for Dim 12 and Dim 13. 10 samples from each lot. Variable data record form to be filled by ops just check the dimension using laser mic and ring gauges and do not record any variable data.
Deviation To:	Record the variable data for Dim 12 and Dim 13. 10 samples from each lot. Variable data record form to be filled by ops department ops lead to add to the excel file to monitor variable data behavior.

Document Number Affected	Revision	MP10398	U	N/A
--------------------------	----------	---------	---	-----

Requestor Name:	Govind Sharma
-----------------	---------------

## DEVIATION AUTHORIZATION FORM

DEVIATION AUTHORIZATION NUMBER: DA1738



CREGANNA  
MEDICAL  
Is part of  
Gammatech

Sample	Dim 12 (Max) $0.142'' +/0.002$	Dim 12 min $0.142'' +/-0.002$	N/A	Dim 13 Avg $0.145'' +0.002'' -0.004''$	Dim 13 Max $0.145'' +0.002'' -0.004''$	Test Description: Dim 12 and 13 variable data recording	Tested by: CKy	Lot Number: S00000066050	Part Number: SA0254-xx Q6
1	0.1429	0.1425	0.1450	0.1455	0.1461	0.1429	0.1424	0.1429	0.1424
2	0.1429	0.1424	0.1444	0.1451	0.1451	0.1429	0.1424	0.1429	0.1424
3	0.1421	0.1406	0.1447	0.1452	0.1452	0.1421	0.1406	0.1421	0.1406
4	0.1430	0.1420	0.1420	0.1452	0.1461	0.1430	0.1420	0.1430	0.1420
5	0.1428	0.1424	0.1424	0.1455	0.1461	0.1428	0.1424	0.1428	0.1424
6	0.1436	0.1425	0.1446	0.1455	0.1461	0.1436	0.1425	0.1436	0.1425
7	0.1417	0.1411	0.1455	0.1461	0.1461	0.1417	0.1411	0.1417	0.1411
8	0.1425	0.1418	0.1446	0.1454	0.1461	0.1425	0.1418	0.1425	0.1418
9	0.1426	0.1414	0.1445	0.1451	0.1461	0.1426	0.1414	0.1426	0.1414
10	0.1429	0.1424	0.1446	0.1456	0.1461	0.1429	0.1424	0.1429	0.1424
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									
21									
22									
23									
24									
25									
26									
27									
28									
29									
30									

## TEST DATA SHEET

Requestor Name: Saroenu Chhum			
Document Number Affected: 2100586			
Revision: B			
Deviation From: 100% Inspections at Final Inspection (Do not Require SmartSolve Notification to be issued).			
Deviation To: 100% Inspections at Final Inspection (Do not Require SmartSolve Notification to be issued).			
<p>The following rules apply to these product families: If required for any sum of scraps at final inspection: For products listed below, SmartSolve Notification is not required for any sum of scraps at final inspection: SA0286-01 &amp; -02; SA0254-04, -05 &amp; -06; SA0155-01</p> <p>SmartSolve Notification to be issued).</p> <p>there is a 35% allowance to scrap at final inspection, and this product is an Edwards product at Final Inspection, and this is 100% inspected at Final Inspection, and this product is an Edwards product at Final Inspection, and this is 100% inspected at Final Inspection.</p>			
<p>All lots undergo 100% visual inspection; therefore, there is no risk to the customer for lots released without documentation in the SmartSolve notification.</p> <p><b>Justification:</b></p>			
Part Number Affected	Revision	Start Date:	End Date:
SA0286-01	07	SA0254-04	07
SA0286-02	07	SA0254-05	07
SA0286-04	07	SA0254-06	07
SA0286-05	07	SA0155-01	07
SA0286-06	07	SA0155-02	07
SA0286-07	07	SA0155-03	07
SA0286-08	07	SA0155-04	07
SA0286-09	07	SA0155-05	07
SA0286-10	07	SA0155-06	07
SA0286-11	07	SA0155-07	07
SA0286-12	07	SA0155-08	07
SA0286-13	07	SA0155-09	07
SA0286-14	07	SA0155-10	07
SA0286-15	07	SA0155-11	07
SA0286-16	07	SA0155-12	07
SA0286-17	07	SA0155-13	07
SA0286-18	07	SA0155-14	07
SA0286-19	07	SA0155-15	07
SA0286-20	07	SA0155-16	07
SA0286-21	07	SA0155-17	07
SA0286-22	07	SA0155-18	07
SA0286-23	07	SA0155-19	07
SA0286-24	07	SA0155-20	07
SA0286-25	07	SA0155-21	07
SA0286-26	07	SA0155-22	07
SA0286-27	07	SA0155-23	07
SA0286-28	07	SA0155-24	07
SA0286-29	07	SA0155-25	07
SA0286-30	07	SA0155-26	07
SA0286-31	07	SA0155-27	07
SA0286-32	07	SA0155-28	07
SA0286-33	07	SA0155-29	07
SA0286-34	07	SA0155-30	07
SA0286-35	07	SA0155-31	07
SA0286-36	07	SA0155-32	07
SA0286-37	07	SA0155-33	07
SA0286-38	07	SA0155-34	07
SA0286-39	07	SA0155-35	07
SA0286-40	07	SA0155-36	07
SA0286-41	07	SA0155-37	07
SA0286-42	07	SA0155-38	07
SA0286-43	07	SA0155-39	07
SA0286-44	07	SA0155-40	07
SA0286-45	07	SA0155-41	07
SA0286-46	07	SA0155-42	07
SA0286-47	07	SA0155-43	07
SA0286-48	07	SA0155-44	07
SA0286-49	07	SA0155-45	07
SA0286-50	07	SA0155-46	07
SA0286-51	07	SA0155-47	07
SA0286-52	07	SA0155-48	07
SA0286-53	07	SA0155-49	07
SA0286-54	07	SA0155-50	07
SA0286-55	07	SA0155-51	07
SA0286-56	07	SA0155-52	07
SA0286-57	07	SA0155-53	07
SA0286-58	07	SA0155-54	07
SA0286-59	07	SA0155-55	07
SA0286-60	07	SA0155-56	07
SA0286-61	07	SA0155-57	07
SA0286-62	07	SA0155-58	07
SA0286-63	07	SA0155-59	07
SA0286-64	07	SA0155-60	07
SA0286-65	07	SA0155-61	07
SA0286-66	07	SA0155-62	07
SA0286-67	07	SA0155-63	07
SA0286-68	07	SA0155-64	07
SA0286-69	07	SA0155-65	07
SA0286-70	07	SA0155-66	07
SA0286-71	07	SA0155-67	07
SA0286-72	07	SA0155-68	07
SA0286-73	07	SA0155-69	07
SA0286-74	07	SA0155-70	07
SA0286-75	07	SA0155-71	07
SA0286-76	07	SA0155-72	07
SA0286-77	07	SA0155-73	07
SA0286-78	07	SA0155-74	07
SA0286-79	07	SA0155-75	07
SA0286-80	07	SA0155-76	07
SA0286-81	07	SA0155-77	07
SA0286-82	07	SA0155-78	07
SA0286-83	07	SA0155-79	07
SA0286-84	07	SA0155-80	07
SA0286-85	07	SA0155-81	07
SA0286-86	07	SA0155-82	07
SA0286-87	07	SA0155-83	07
SA0286-88	07	SA0155-84	07
SA0286-89	07	SA0155-85	07
SA0286-90	07	SA0155-86	07
SA0286-91	07	SA0155-87	07
SA0286-92	07	SA0155-88	07
SA0286-93	07	SA0155-89	07
SA0286-94	07	SA0155-90	07
SA0286-95	07	SA0155-91	07
SA0286-96	07	SA0155-92	07
SA0286-97	07	SA0155-93	07
SA0286-98	07	SA0155-94	07
SA0286-99	07	SA0155-95	07
SA0286-100	07	SA0155-96	07
SA0286-101	07	SA0155-97	07
SA0286-102	07	SA0155-98	07
SA0286-103	07	SA0155-99	07
SA0286-104	07	SA0155-100	07
SA0286-105	07	SA0155-101	07
SA0286-106	07	SA0155-102	07
SA0286-107	07	SA0155-103	07
SA0286-108	07	SA0155-104	07
SA0286-109	07	SA0155-105	07
SA0286-110	07	SA0155-106	07
SA0286-111	07	SA0155-107	07
SA0286-112	07	SA0155-108	07
SA0286-113	07	SA0155-109	07
SA0286-114	07	SA0155-110	07
SA0286-115	07	SA0155-111	07
SA0286-116	07	SA0155-112	07
SA0286-117	07	SA0155-113	07
SA0286-118	07	SA0155-114	07
SA0286-119	07	SA0155-115	07
SA0286-120	07	SA0155-116	07
SA0286-121	07	SA0155-117	07
SA0286-122	07	SA0155-118	07
SA0286-123	07	SA0155-119	07
SA0286-124	07	SA0155-120	07
SA0286-125	07	SA0155-121	07
SA0286-126	07	SA0155-122	07
SA0286-127	07	SA0155-123	07
SA0286-128	07	SA0155-124	07
SA0286-129	07	SA0155-125	07
SA0286-130	07	SA0155-126	07
SA0286-131	07	SA0155-127	07
SA0286-132	07	SA0155-128	07
SA0286-133	07	SA0155-129	07
SA0286-134	07	SA0155-130	07
SA0286-135	07	SA0155-131	07
SA0286-136	07	SA0155-132	07
SA0286-137	07	SA0155-133	07
SA0286-138	07	SA0155-134	07
SA0286-139	07	SA0155-135	07
SA0286-140	07	SA0155-136	07
SA0286-141	07	SA0155-137	07
SA0286-142	07	SA0155-138	07
SA0286-143	07	SA0155-139	07
SA0286-144	07	SA0155-140	07
SA0286-145	07	SA0155-141	07
SA0286-146	07	SA0155-142	07
SA0286-147	07	SA0155-143	07
SA0286-148	07	SA0155-144	07
SA0286-149	07	SA0155-145	07
SA0286-150	07	SA0155-146	07
SA0286-151	07	SA0155-147	07
SA0286-152	07	SA0155-148	07
SA0286-153	07	SA0155-149	07
SA0286-154	07	SA0155-150	07
SA0286-155	07	SA0155-151	07
SA0286-156	07	SA0155-152	07
SA0286-157	07	SA0155-153	07
SA0286-158	07	SA0155-154	07
SA0286-159	07	SA0155-155	07
SA0286-160	07	SA0155-156	07
SA0286-161	07	SA0155-157	07
SA0286-162	07	SA0155-158	07
SA0286-163	07	SA0155-159	07
SA0286-164	07	SA0155-160	07
SA0286-165	07	SA0155-161	07
SA0286-166	07	SA0155-162	07
SA0286-167	07	SA0155-163	07
SA0286-168	07	SA0155-164	07
SA0286-169	07	SA0155-165	07
SA0286-170	07	SA0155-166	07
SA0286-171	07	SA0155-167	07
SA0286-172	07	SA0155-168	07
SA0286-173	07	SA0155-169	07
SA0286-174	07	SA0155-170	07
SA0286-175	07	SA0155-171	07
SA0286-176	07	SA0155-172	07
SA0286-177	07	SA0155-173	07
SA0286-178	07	SA0155-174	07
SA0286-179	07	SA0155-175	07
SA0286-180	07	SA0155-176	07
SA0286-181	07	SA0155-177	07
SA0286-182	07	SA0155-178	07
SA0286-183	07	SA0155-179	07
SA0286-184	07	SA0155-180	07
SA0286-185	07	SA0155-181	07
SA0286-186	07	SA0155-182	07
SA0286-187	07	SA0155-183	07
SA0286-188	07	SA0155-184	07
SA0286-189	07	SA0155-185	07
SA0286-190	07	SA0155-186	07
SA0286-191	07	SA0155-187	07
SA0286-192	07	SA0155-188	07
SA0286-193	07	SA0155-189	07
SA0286-194	07	SA0155-190	07
SA0286-195	07	SA0155-191	07
SA0286-196	07	SA0155-192	07
SA0286-197	07	SA0155-193	07
SA0286-198	07	SA0155-194	07
SA0286-199	07	SA0155-195	07
SA0286-200	07	SA0155-196	07
SA0286-201	07	SA0155-197	07
SA0286-202	07	SA0155-198	07
SA0286-203	07	SA0155-199	07
SA0286-204	07	SA0155-200	07
SA0286-205	07	SA0155-201	07
SA0286-206	07	SA0155-202	07
SA0286-207	07	SA0155-203	07
SA0286-208	07	SA0155-204	07
SA0286-209	07	SA0155-205	07
SA0286-210	07	SA0155-206	07
SA0286-211	07	SA0155-207	07
SA0286-212	07	SA0155-208	07
SA0286-213	07	SA0155-209	07
SA0286-214	07	SA0155-210	07
SA0286-215	07	SA0155-211	07
SA0286-216	07	SA0155-212	07
SA0286-217	07	SA0155-213	07
SA0286-218	07	SA0155-214	07
SA0286-219	07	SA0155-215	07
SA0286-220	07	SA0155-216	07
SA0286-221	07	SA0155-217	07
SA0286-222	07	SA0155-218	07
SA0286-223	07	SA0155-219	07
SA0286-224	07	SA0155-220	07
SA0286-225	07	SA0155-221	07
SA0286-226	07	SA0155-222	07
SA0286-227	07	SA0155-223	07
SA0286-228	07	SA0155-224	07
SA0286-229	07	SA0155-225	07
SA0286-230	07	SA0155-226	07
SA0286-231	07	SA0155-227	07
SA0286-232	07	SA0155-228	07
SA0286-233	07	SA0155-229	07
SA0286-234	07	SA0155-230	07
SA0286-235	07	SA0155-231	07
SA0286-236	07		

**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 A	33.46	28.11	27.96	26.12	28.51	28.41	31.64	28	26.41	24.1	28.272	2.6674116	4.378	16.59407248	8.542	PASS
Seg B	21.84	21.56	22.26	22.16	24.68	21.62	22.84	21.74	23.75	25.23	22.768	1.3337316	4.378	16.92892302	8.542	PASS
Seg C	52.22	66.3	68.12	49.44	51.64	55.4	60.59	66.32	68.98	68.82	60.783	7.8973161	4.378	26.20855025	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.

Kochyukov

21 JAN 21