

Production Order: 500000164476

Material: SA0254-06 Rev G

Material Type: Production
Version: Plant / Business Unit:

Description: Printed Shaft 144C Prox End Color
B CMDR

Order Type: ZSTD

| Opr No. | Planned Work Center Description | Operation Details | | | | |
|---------|--|---|-------------------|------------------|----------|-----|
| | | Comp. Qty. | Scrap Qty & Desc. | Date Comp. | Initials | |
| 50 | CATASY04 Catheter Assembly 4 Count: Yes  | 500 | 0 | 01 Aug 22 /M/08 | | |
| | Prepare Materials MPI0398 Rev. A Line Clearance MPI0230 Rev. E By: M/28 | | | Date: 28 Jul /22 | | |
| 100 | CATASY04 Catheter | Straighten First Jacket MPI0398 Rev. A | | | N/A | N/A |

Notes: DA 2289, DA 2262

NIA

Notes: DA 2032, DA 2262 N/A N/A

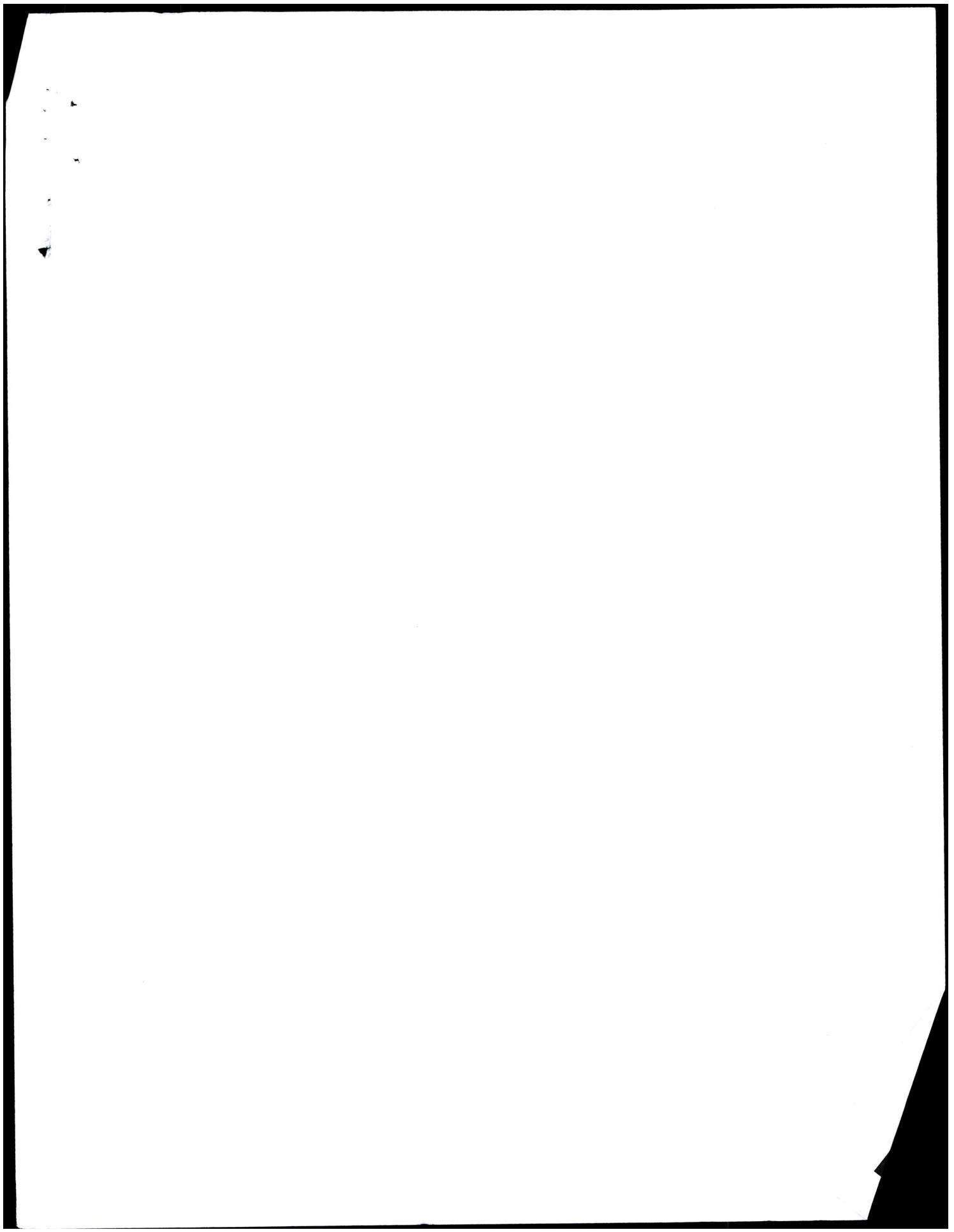
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| Opn No. | Planned WorkCenter Description | Operation Details | | | | | | Comp. Qty. | Scrap Qty & Desc. | Date Comp. | Initials |
|---------|-------------------------------------|---|----------------|-----|----------|------------|-----------------|------------|-------------------|---|----------|
| | | Component Number | Req'd Rev Used | UOM | Qty. | Batch No. | Actual Qty Used | | | | |
| | Assembly 4 | | | | | | | 500 | 0 | 01Aug22 AD42 | |
| | Straighten First Jacket | | | | | | | | | | |
| | Confirmation Rqrd(Milestone) | 1000-1190-01 | A | FT | 2708.350 | 0000152198 | 2708.350 | | | | |
| | | | | | | N/A | N/A | | | | |
| 150 | CATASY04 | Positioning Braid Over First Jacket | | | | | | 500 | 0 | 01Aug22 TX64 | |
| | Catheter Assembly 4 | MPI0398 Rev. A.0 Record Braid Pic Count for 15 parts below: Braid Production Lot No: 0000162197 | | | | | | | | MHID TNC27 S169 V184 V706 AH69 SP63 | |
| | | 1. | 40 | 2. | 40 | 3. | 40 | | | | |
| | | 4. | 40 | 5. | 40 | 6. | 40 | | | | |
| | | 7. | 40 | 8. | 40 | 9. | 40 | | | | |
| | | 10. | 40 | 11. | 40 | 12. | 40 | | | | |
| | | 13. | 40 | 14. | 40 | 15. | 40 | | | | |
| | Positioning Braid Over First Jacket | 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. | | | | | | | | | |
| | Confirmation Rqrd(Milestone) | Braid Production Lot No: 0000160927 | | | | | | | | | |
| | | Notes: | | | | | | | | | |

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| Opn No. | Planned WorkCenter Description | Operation Details | | | | | Comp. Qty. | Scrap Qty. | Date Comp. | Initials |
|---------|---|-------------------|-----------|----------|------|-----------|------------|------------|------------|-------------------|
| | | Component Number | Req'd Rev | UOM | Oty. | Batch No. | | | | |
| | Strain Relief Reflow Confirmation Rqrd(Milestone) | MM0527-01 | B | <u>B</u> | PC | 500 | 0000141884 | 500 | | |
| | | RM0096-01 | F | <u>E</u> | PC | 167 | 52467 | 166 | | |
| | | | | | | | N/A | N/A | | |
| 250 | CATASY04 Position Tubing For Reflow Catheter Assembly 4 | Component Number | Req'd Rev | UOM | Oty. | Batch No. | | | | |
| | | MM0186-00 | D | <u>D</u> | PC | 500 | 0000143316 | 500 | 0 | Aug20 |
| | | MM0523-03 | C | <u>C</u> | PC | 500 | 0000139521 | 500 | | MH10 Cx32 7/26/23 |
| | | | | | | | N/A | N/A | | |
| | | | | | | | N/A | N/A | | |
| | Notes: | | | | | | | | | |
| | | | | | | | | | | |
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| Opn No. | Planned Work Center Description | Operation Details | | | | Comp. Qty. | Scrap Qty & Desc. | Date Comp. | Initials |
|---------------|---------------------------------|-------------------|------------|----|-----|-------------------|-------------------|-------------|------------|
| | MM0524-01 | B | <u>B</u> | PC | 500 | <u>0000148246</u> | <u>500</u> | | <u>N/A</u> |
| | MM0530-01 | B | <u>B</u> | PC | 500 | <u>0000139442</u> | <u>440</u> | <u>60</u> | <u>N/A</u> |
| | RM7586-02 | D | <u>D</u> | PC | 500 | <u>48300</u> | <u>49826</u> | <u>250</u> | |
| | MM0185-01 | I | <u>I</u> | PC | 500 | <u>0000145541</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>Bulk</u> | <u>N/A</u> |
| | MM1540-01 | B | <u>B</u> | PC | 500 | <u>0000158323</u> | <u>500</u> | | |
| Notes: | | | | | | | | | |
| <u>N/A</u> | | | | | | | | | |
| <u>N/A</u> | | | | | | | | | |
| <u>N/A</u> | | | | | | | | | |

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|--------------|---------------------------------|--|-----------------------|-----|--|---------------------------------|--------------------|-------------------------|----------|
| 300 | CATASY04 Catheter Assembly 4 | Reflow MPI0398 Rev. <u>AQ</u> | | | | N/A | N/A | N/A | N/A |
| | | Temp = 415°F (+/- 15°F) Speed = 4.5 in/min (+/- 0.5 in/min) | | | | 500 | 0 | 01Aug22 MS41 EE65 | |
| | Reflow | Component Number | Req'd Rev Rev Used | UOM | Oty. | Batch No. | Actual Oty Used | | |
| 1000-1154-01 | A | <u>A</u> | PC | 500 | <u>52191,53449</u> <u>52525,55036</u> | <u>195,050</u> <u>200,10</u> | | | |
| 350 | CATASY04 Catheter Assembly 4 | Skive Heat Shrink MPI0398 Rev. <u>AQ</u> | | | | | | 01Aug22 MS41 EE65 | |
| | Skive Heat | | | | | | | | |

Notes:

| |
|-----|
| N/A |
| N/A |
| N/A |

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01Aug22 Aug 22

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

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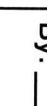
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| Opr No. | Planned WorkCenter Description | Operation Details | | | | Comp Qty. | Scrap Qty & Desc. | Date Comp. | Initials |
|---------|---|---|------------------------|------------------------------------|-----------|-----------|-------------------|------------|--------------|
| 500 | Anneal Shaft  | N/A | N/A | N/A | N/A | 356 | 0 | 01 AUG 22 | NIA |
| 500 | Catheter Assembly 4  | Leak Test/Prox Cut/Ring Gage-Dim 13/21 MPI0398 Rev. <u>A1</u> | FM5104694 FM5104695 | (Rework if needed - Use FM5104983) | | | | | |
| 550 | Leak Test/Prox Cut/Ring Gage-Dim 13/21  | | | | | 356 | 0 | 01 AUG 22 | MPO6 PV62 |
| 550 | CATHASY04 Catheter Assembly 4  | Distal Cut MPI0398 Rev. <u>A1</u> Line Closure MPI0230 Rev. <u>E</u> By: _____ Date: <u>01 Aug 22</u> Distal Cut | | | | 356 | 0 | 01 AUG 22 | MPO6 PV62 |
| 600 | PADPRIN1 Pad Print  | Pad Print Set Up MPI0276 Rev. <u>E</u> | 138 | 0 | 02 AUG 22 | BB49 | | | |

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| Opr No. | Planned WorkCenter Description | Operation Details | Comp. Qty. | Scrap Qty & Desc. | Date Comp. | Initials |
|-----------------|--|--|------------|-------------------|-----------------------|----------|
| Count: Yes | Line Clearance MPI0230 Rev. E | By: <u>TL42</u> Date: <u>02 Aug 22</u> | 218 | 0 | <u>02 Aug 22 GL42</u> | |
| Pad Print Setup | <p><u>N/A</u></p> <p>TMI0503 (circle TMI used) TMI0735</p> <p>Cliché - TL0525 Cliché - TL0567</p> <p>Ink # RM7407-01 Ink - RM7407-01</p> <p>Thinner - RM7408-01 Thinner - RM7408-01</p> <p>Hardener - RM7409-01 Hardener - RM7409-01</p> <p>Customized Measuring Equipment - Caliper</p> <p>Inspection Gauge TMI0843</p> <p>Setup Rod # TL0815</p> <p>Program - #10</p> <p>Ink Viscosity (REF) -5 to 6</p> <p>Pad - TL0545 or equivalent</p> <p>Fence - TL0538</p> <p>Drying Oven - TM10643</p> <p>Drying Racks-TL0531, TL0532</p> | | | | | |

Notes:

N/A
N/A
N/A

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| Opr No. | Planned WorkCenter Description | Operation Details | | | | Comp. Qty. | Scrap Qty & Desc. | Date Comp. | Initials |
|-----------|--------------------------------|--|-----|-------|-----------|------------|-------------------|------------------|-----------------------|
| | | | | | | | | | |
| 650 | PADPRIN1 Pad Print | Verification MPI0276 Rev. E Section 15.0 | | | | 138 | 0 | 02 Aug 22 BY4476 | N/A GL42 02 Aug 22 |
| | Verification | | | | | | | | |
| | Component Number | Req'd Rev Used | UOM | Oty. | Batch No. | | | | |
| RM7407-01 | B | E | L | 0.050 | 55227 | 218 | 0 | 02 Aug 22 GL42 | N/A |
| | | | | | | | | | |
| | Notes: | | | | | | | | |
| | | N/A | | | | | | | |
| | | N/A | | | | | | | |
| | | N/A | | | | | | | |

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| Opr No. | Planned WorkCenter Description | Operation Details | | | | Comp. Qty. | Scrap Qty & Desc. | Date Comp. | Initials |
|---------------|--------------------------------|---|-----|-----|-------|------------|-------------------|-------------------|----------|
| | | R | B | L | 0.005 | 54359 | 0.010 | N/A | |
| 700 | PADPRIN1 | Prepare Surface for Ink MPI0276 Rev. E Section 15.5 Polynit wipes 99% IPA | | | | 138 | 0 | 02 Aug 2021 14:48 | |
| | Pad Print | | | | | 218 | 0 | 02 Aug 2021 14:42 | |
| 750 | PADPRIN1 | Print Parts MPI0276 Rev. E Section 20.0 Inspection gauge TMI0843 | | | | 138 | 0 | 02 Aug 2021 14:48 | |
| | Pad Print | | | | | 218 | 0 | 02 Aug 2021 14:42 | |
| | Print Parts | | | | | | | | |
| Notes: | | N/A | N/A | N/A | | | | | |

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| Opr No. | Planned WorkCenter Description | Operation Details | | Comp. Qty. | Scrap Qty & Desc. | Date Comp. | Initials |
|---------|----------------------------------|--|--|------------|-------------------|-----------------|----------|
| 800 | PADPRIN1 Pad Print | In-Process Inspection and Rework MPI0276 Rev. <u>E</u> Section 30.0 Polynit Wipes 99% IPA Mag Light | | 138 | 0 | 02 Aug 22 14:48 | |
| | In-process Inspection and Rework | | | 218 | 0 | 02 Aug 22 14:42 | |
| 850 | PADPRIN1 Pad Print | Curing Oven MPI0340 Rev. <u>B</u> Section 35.0 | | 138 | 0 | 02 Aug 22 14:49 | |
| | Curing Oven | Curing oven for 120 +30/15 minutes Parts sit for 8 hours minimum after curing oven | | 218 | 0 | 02 Aug 22 14:42 | |
| | Curing Oven | Lot Completion time: <u>3:16 AM</u> By: <u>GL42</u> Date: <u>03 Aug 22</u> | | | | | |
| | Confirmation Reqd(Milestone) | | | | | | |
| 900 | PADPRIN1 Pad Print | Transfer Parts to Production MPI0276 Rev. <u>E</u> Section 40.0 | | N/A | N/A | N/A | N/A |
| | Notes: | <u>N/A</u> <u>N/A</u> <u>N/A</u> | | | | | |

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| Opr No. | Planned WorkCenter Description | Operation Details | Comp. Qty. | Scrap Qty & Desc. | Date Comp. | Initials |
|---------|---|--|------------|-------------------|-------------------|----------|
| | | Transfer Parts to Line Time: <u>12:30pm</u> By: <u>BH48</u> Date: <u>03 Aug 22</u> | | | | |
| 950 | PADPRIN1 Pad Print Count: Yes Confirmation Reqd(Milestone) | Cleaning MPI0276 Rev. <u>E</u> Section 50.0 Line Clearance MPI0230 Rev. <u>E</u> By: <u>BH48</u> Date: <u>03 Aug 22</u> | 356 | 0 | 03 Aug 22 BH48 | |
| 1000 | CATASY04 In-Process Dimensional Inspection Confirmation Reqd(Milestone) | | N/A | N/A | N/A | N/A |
| Notes: | | N/A N/A N/A | | | | |

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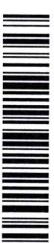
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| Opr No. | Planned WorkCenter Description | Operation Details | | | | Initials |
|---------|---|---|-------------------|------------|----------|----------|
| | | Comp Qty | Scrap Qty & Desc. | Date Comp. | | |
| N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| 1070 | CATHASY04 Catheter Assembly 4 | Rework MPI0398 Rev. _____ | | | | |
| | | Material consumed | | | | |
| | | Material | Batch | Rev | Qty | |
| | | Material | Batch | Rev | Qty | |
| | | Material | Batch | Rev | Qty | |
| | | Material | Batch | Rev | Qty | |
| 1090 | QUALITY1 Quality Inspection & Review | Required Inspection Perform Quality Inspection per QIP Document #3107613 Record Data in SAP Inspection Plan | | | | |
| | | 290 | 0 | 0 | 04KU6Z22 | Lto3 |
| | | 309 | | | | |
| | | 290 | 0 | 04KU6Z22 | Lto3 | |
| | | 309 | | | | |
| | Quality Inspection & Review | | | | | |
| | Notes: | N/A | N/A | N/A | | |

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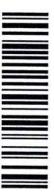
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|------------|--------------------------------------|---|------------|------------------------|---------------|----------|
| N/A | Confirmation Reqd(Milestone) | N/A | N/A | N/A | N/A | N/A |
| 1100 | PACKINT1 Packing assembly | Packaging Instructions SP10087 REV. <u>M</u> | 309 | 0 04NG12 TRUAG10 | 8/17/21 | |

Notes:

N/A
N/A
N/A

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Batch Number: 0000164476

By: BAT1 TRN APIO

Date: 04 AUG 22

Reviewed By:

WJ32

Date:

05 AUG 22

Notes:

N/A

N/A

N/A

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

M106 Aug 22



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Document No: EM5104983

Document

Document Type: Manufacturing Form

Title: SA0254 Cause of Rework Form

PRODUCTION ORDER# 500000164476

Attachment B: Cause of Rework.

OPER 400.0

Attachment B: Cause of Rework

Dim 13 (Go Gauge) **Dim 21 (Go gauge)**

OPER 500.0

Status CURRENT Effective 10/27/2020