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| **Failure Mode** | **Effects** | **Causes (Occurrences)** | **Controls (Detectability)** | **Recommended Action** |
| Leakage in handle | Motor malfunction/potential shock | Improper sealing of all edges and openings, improper manufacturing | Leak test | Leak testing under pressurized liquid |
| Burr/sharp edge on handle | Cut surgeon and potentially patient | Improper 3D print or plastic molding, improper manufacturing | Eye inspection | Lightly de-burr and sand all edges and surfaces |
| Detachment of the wires to spools | Relaxation of the distal tip, loss of actuation ability | Improper manufacturing at attachment site | Cycle testing | Iterate on attachment method and test to find the best solution |
| Detachment of spools to motors | Relaxation of the distal tip, loss of actuation ability | Wearing down of plastic connection | Cycle testing before releasing product to market | Through testing of the resolution of the injection mold or 3D printer, create an interface between the two parts that has the greatest surface contact to decrease contact stress that leads to wear |
| Detachment of wires to marker band | Loss of actuation ability | Less experience in laser welding leads to poor welds | Inspection under microscope in laser welding machine and force testing for each wire | Develop process for specific wires and marker bands used to ensure consistent and reliable welds |
| Detachment of catheter to handle | Loss of actuation function, loss of sterility and waterproof ability | Poor adhesive | Visual inspection | Design the attachment with the chosen adhesive in mind (materials used, surface finish) to ensure solid bond |
| Any sort of electrical failures | Possible shock to patient or surgeon. Loss of movement | Poor electronic connections | Testing the connection points of wires | Print as much of the circuitry on a PCB as possible, minimizing the number of wires and connections |
| Misalignment of wires within the handles | Catheter does not actuate in the appropriate direction | Wire threading through the lumen(s) isn’t aligned during the manufacturing process | Meeting manufacturing inspection criteria | Allow for rework to maintain process yield. Keep wiring loose around spools until correct actuation is ensured in multiple directions |
| Kinking of catheter at change in durometer region or tip | Catheter not steerable properly. Can lead to damage to walls of arteries/veins | Poor reflow in areas connecting different durometers and too much pull force | Force testing to determine maximum force needed to kink the catheter and govern the motors to not be able to generate that amount of force | Increase number of reflows/changes of durometer to decrease sudden changes in stiffness |
| Lost calibration from manufacturer to end user | Obtained results/ data are not accurate | Equipment not inspected on a daily basis | More frequent inspection of equipment | More frequent inspection of equipment |
| Steel braiding being exposed | Damage to walls of arteries/veins. Can cause serious complications to surgery | Poor reflow technique leading to exposed braids when wires are pulled | Visual inspection | Better training of manufacturing workers |
| \*\*\*\*Long time spent on shelf leading to power drainage in batteries | Loss of motor power, failure to reach maximum actuation angles | Extended time between manufacturing and use | Testing of battery life | Set limit on maximum shelf life |

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|  | **Severity** | | **Occurrence** | | **Detectability** | |  | |
| **Failure Mode** | **Effects** | **Rating (S)** | **Causes** | **Rating (O)** | **Controls** | **Rating (D)** | **RPN = SxOxD** | **Recommended Action** |
| Loss of waterproofing ability causing leakage in handle | Motor malfunction and potential shock | 10 | Improper sealing of all edges and openings, improper manufacturing | 3 | Leak test | 3 | 90 | Leak testing under pressurized liquid |
| Burr/sharp edge on handle | Cut surgeon and potentially patient | 10 | Improper 3D print or plastic molding, improper manufacturing | 7 | Eye inspection | 1 | 70 | Lightly de-burr and sand all edges and surfaces |
| Detachment of the wires to spools | Relaxation of the distal tip, loss of actuation ability | 6 | Improper manufacturing at attachment site | 2 | Cycle testing | 3 | 36 | Iterate on attachment method and test to find the best solution |
| Detachment of spools to motors | Relaxation of the distal tip, loss of actuation ability | 7 | Wearing down of plastic connection | 1 | Cycle testing before releasing product to market | 3 | 21 | Through testing of the resolution of the injection mold or 3D printer, create an interface between the two parts that has the greatest surface contact to decrease contact stress that leads to wear |
| Detachment of wires to marker band | Loss of actuation ability | 6 | Less experience in laser welding leads to poor welds | 2 | Inspection under microscope in laser welding machine and force testing for each wire | 6 | 72 | Develop process for specific wires and marker bands used to ensure consistent and reliable welds |
| Electrical failures | Possible shock to patient or surgeon. Loss of movement | 10 | Poor electronic connections | 3 | Testing the connection points of wires | 7 | 210 | Print as much of the circuitry on a PCB as possible, minimizing the number of wires and connections |
| Misalignment of wires within the handle | Catheter does not actuate in the appropriate direction | 7 | Wire threading through the lumen(s) isn’t aligned during the manufacturing process | 3 | Meeting manufacturing inspection criteria | 4 | 84 | Allow for rework to maintain process yield. Keep wiring loose around spools until correct actuation is ensured in multiple directions |
| Kinking of catheter at change in durometer (stiffness) region or tip | Catheter not steerable properly. Can lead to damage to walls of arteries/veins | 10 | Poor reflow in areas connecting different durometers and too much pull force | 6 | Force testing to determine maximum force needed to kink the catheter and govern the motors to not be able to generate that amount of force | 2 | 120 | Increase number of reflows/changes of durometer to decrease sudden changes in stiffness |
| Steel braiding being exposed | Damage to walls of arteries/veins Can cause serious complications to surgery | 10 | Poor reflow technique leading to exposed braids when wires are pulled | 3 | Visual inspection | 2 | 60 | Better training of manufacturing workers |
| Detachment of catheter to handle | Loss of actuation function, loss of sterility and waterproof ability | 10 | Poor adhesive | 1 | Visual inspection | 1 | 10 | Design the attachment with the chosen adhesive in mind (materials used, surface finish) to ensure solid bond |

For a medical device that is used in a clinical setting, prioritizing patient outcomes is of the utmost importance. With that being said, airing on the side of caution is the standpoint our group sided with. If we felt the failure mode specified could harm the patient in any way, shape, or form, a higher severity was granted to alleviate liability issues. Therefore this produced several failure modes with a higher severity resulting in more than half of the failure modes having a severity of ten. The underlying theme from this is that the product can induce great harm to a patient or user. Consequently more precautions are needed to be taken in the design and manufacturing of this product to limit failures. Because of this, actions should be taken for the occurrence and detectability ratings to be decreased in order to minimize the likelihood of severe failures.

One example of a low risk failure with a high severity rating was the detachment of the catheter to the handle. Even with a catastrophic severity rating, it had our lowest RPN due to it being very infrequent and also highly detectable. The failure mode with the highest RPN was an electrical failure. Although it is all encompassing, some of the consequences of the failure could injure the operator or the patient, causing the severity to be a ten. Not only is it potentially damaging to the people involved, it also could be difficult to detect the severity of the damage, leading to a score of seven in the detectability category. Multiplying the three ratings gives a high score of 210 as an RPN.