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| **Function** | **Failure Mode** | **Effects** | **Severity** | **Cause(s)** | **Occurrence** | **Current Controls** | **D** | **CRIT** | **RPN** | **Recommended Actions** |
| Hard constraint prevents surface penetration | Motor fails to supply required counter-torque | Gross mistakes in surface cutting | 8 | Underestimate of motor torque requirements and/or defective motor components | 2 | Safety factor of at least 5 on motor torque requirement | 8 | Detection requires setting a lower limit based on each surface input | 128 | Ensure proper setup and adjustment of motor to receive specified performance |
| Hard constraint implementation device (bolt) yields | Free-fall of cutting tool onto surgical work area | 10 | Improper design of implementation device and/or underestimation of required force it must proved | 1 | Real life example (from last year) has been used extensively and shows no deficiency | 8 | Detection requires setting a lower limit based on each surface input | 80 | Set up a periodical check up on the implementation mechanism to maintain its performance |
| Motor loses power supply | Free-fall of cutting tool onto surgical work area | 10 | Improper placement of wiring and miscalculation of required slack in the cords | 3 | Robust and rigid connection cables with excess slack | 5 | Detection requires continuous checkup on the strength and “secure-ness” of the connections | 150 | Come up with a simple and cheap method to hold cables and wiring in place but does not make them overly taught and restrictive to motion |
| Hard constraint position is updated to counteract a dynamic (moving) load | Motor fails to move hard constraint fast enough to the updated position | Gross mistakes in surface cutting | 8 | Underestimate of motor speed requirements and/or defective motor components | 5 | Safety factor of at least 3 on motor speed requirements | 8 | Detection requires measurement of consistent surface penetration as a result of slow speed updating | 320 | Reduce the actuation link (attached to the motor) in order to the reduce the time required for the hard constraint to move to position |
| Motor loses power supply | Gross mistakes in surface cutting | 10 | Improper placement of wiring and miscalculation of required slack in the cords | 3 | Robust and rigid connection cables with excess slack | 5 | Detection requires continuous checkup on the strength and “secure-ness” of the connections | 150 | Come up with a simple and cheap method to hold cables and wiring in place but does not make them overly taught and restrictive to motion |
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| vertical gravity compensation | spring yields | force at given location reduces | 2 | stretching spring past elastic limit | 1 | microcontroller varifies idle position | 1 | detection requires calibration of device for idle position and upper and lower limit | 2 | none |
| spring breaks | no verticle gravity compensation will exist | 5 | fatigue of spring | 3 | none | 10 | N/A | 150 | Ensure spring selection and sizing considers fatigue requirements |
| spring becomes misaligned | force at given location varies | 2 | spring is knocked | 5 | microcontroller varifies idle position | 1 | detection requires calibration of device for idle position and upper and lower limit | 10 | none |
| design extends out of desired range | 1 | radial link prevents undesirable motion | 1 | detection requires calibration of device for idle position and upper and lower limit | 2 | none |
| no verticle gravity compensation will exist | 5 | design extends out of desired range | 1 | user notices misalignment | 8 | difficult to dect, therefore must prevent | 40 | ensure guides are positioned to ensure spring cannot fall off device |
| stop device rotating about joint 1 | device rotates about joint 1 | device rotates undesirably about joint 1 - user must apply addition force during operation | 2 | device is positioned so that torque to resist rotation is less than torque applied by device | 6 | microcontroller varifies tool position is within desired range | 3 | desired tool position must be specified to reduce the input force from user required while still providing the necessary operating envelop | 36 | torque produced by counterweight or motor must be optimized to minimize potential to exceed range |
| device rotates beyond implemented envelop - interaction with patient and objects not considered in design | 8 | device is positioned so that torque to resist rotation is less than torque applied by device | 6 | physical stopper positioned to limit rotation about joint 1 | 1 | all possible orientations of the device at the specified angles must be considered to ensure the tool cannot come into contact with objects outside operating vacinity | 48 | optimize physical stopper position |
| Calculate position of tool, blocker, or gravity compensation | Calculated position different from actual /desired position | Gross mistakes in surface cutting | 8 | Encoder has inadequate resolution, software implementation incorrect, bugs, hardware failure | 7 | Initial device calibration, code review | 5 | Difficult to detect until testing on actual device | 280 | none |
|  | Motors erratic | Gross mistakes in surface cutting | 10 | Software implementation incorrect, bugs, hardware failure | 2 | Progressive development, code review | 10 | Difficult to detect until testing on actual device | 200 | none |