

JOB DESCRIPTION - RELIABILITY AND SUSTIAINING ENGINEER

| Description | |
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| Job Title | Reliability and Sustaining Engineer |
| Reports to Title | Director Hardware Engineering |
| General Accountability | Our mission is to Profoundly change the standard of care by creating a tomorrow where clinicians can confidently ablate tissue with precision; a tomorrow where patients have access to safe and effective treatment options, so they can quickly return to their daily lives. Changing the standard of care is part of our fabric. We are a group of energetic, problem-solvers focused on innovation, and looking to change the world. If you want to make a Profound impact with your career, here is your chance. The Reliability and Sustaining Engineer is responsible for driving continuous improvement in all mechanical aspects of the TULSA-PRO systems. |
| Duties and Responsibilities | Duties and responsibilities will include (but are not limited to): Investigate product complaints at clinical/customer sites, perform root cause analysis of failures, and propose remediation in a timely fashion Analyze Complaint data and generate prioritized actions to address shortcomings associated with the company's products Review existing product design, identify weaknesses, propose, implement and monitor effectiveness of improvements. Analyze mechanical designs Build early concepts of corrective designs and thoroughly test them Create strategy for the verification of the corrective designs, and participate in verification activities. Produce DHF and DMR documentation for transfer to test/manufacturing Source parts as required, manage vendor issues as needed with Operations team. Interact with customers, marketing, and sales as required to capture user needs and look for opportunities to improve products Contribute to risk management content such as FMEA, PFMEA and hazard analysis Perform all duties in compliance with the quality management system; actively contribute to the continuous improvement of the QMS |

| Competencies | |
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| Education | Mechanical Engineering or similar undergraduate degree |
| Certifications | None |



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Key Attributes (experience, skills and technical knowledge)

Required:

- 1-3 years industrial experience preferably in medical device industry.
- Extensive knowledge of Solidworks
- Demonstrated troubleshooting and root cause analysis skills
- Tenacious problem solver, organized, detail oriented
- In depth knowledge of manufacturing processes such as machining, injection molding, urethane casting, 3D printing and sheet metal
- Demonstrated ability to translate user needs into design specifications
- Knowledge of medical device standards such as IEC-60601-1, ISO 10993
- Knowledge of ASTM standards and testing methods
- Competency in mechanical analysis skills such as kinematics, solid and fluid dynamics, heat transfer, material strength
- Excellent verbal and written skills. Ability to quickly, clearly, and concisely communicate.
- Mechanical aptitude including ability to use common shop tools and measurement equipment

Desired:

- Experience working with MR compatible devices and therapeutic ultrasound devices.
- Knowledge of electromechanical design
- Experience working with cable assemblies and PCBs
- Working knowledge of industrial design
- Experience working with sterilization and disinfection methods
- Experience with statistical analysis