

Description	
Job Title	Mechanical Developer
Reports to Title	Director Hardware Engineering & QA
General Accountability	<p>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, while making a difference in other people’s lives, here is your chance.</p> <p>The Mechanical Developer is involved in all mechanical design aspects of the TULSA-PRO system from ideation through to manufacturing, as well as future products of the company.</p>
Duties and Responsibilities	<p>Duties and responsibilities will include (but are not limited to):</p> <ol style="list-style-type: none"> 1. Analyze user needs and generate requirements for the company’s products 2. Create aesthetic, functional, and reliable product designs 3. Build models and three-dimensional prototypes of new products 4. Evaluate design ideas for practicality, cost, and market characteristics. 5. Review existing product design, identify weaknesses and propose improvements 6. Analyze mechanical designs 7. Create strategy for the verification of the design, and participate in verification activities as required 8. Produce DHF and DMR documentation for transfer to test/manufacturing 9. Interact with customers, marketing, and sales as required to capture user needs and look for opportunities to improve products 10. Investigate product complaints at clinical/customer sites, perform root cause analysis of failures, and propose remediation in a timely fashion 11. Develop clinical workflow, author content for the user manual, incorporate human factors into designs and train other employees on product use 12. Contribute to risk management content such as hazard analysis 13. Perform project engineering roles as needed. 14. Perform all duties in compliance with the quality management system; actively contribute to the continuous improvement of the QMS
Competencies	
Education	Mechanical Engineering or similar undergraduate degree

Certifications	None
Key Attributes (experience, skills and technical knowledge)	<p>Required:</p> <ul style="list-style-type: none"> ▪ 5 years industrial experience preferably in medical device industry. ▪ Extensive knowledge of SolidWorks ▪ Excellent verbal and written skills. Ability to quickly, clearly, and concisely communicate. ▪ Mechanical aptitude including ability to use common shop tools and measurement equipment ▪ Tenacious problem solver, organized, detail oriented ▪ Knowledge of medical device standards such as IEC-60601-1, ISO 10993 ▪ 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 ▪ Demonstrated ability to troubleshoot problems and perform root cause analysis ▪ Demonstrated ability to communicate with customers. ▪ Knowledge of ASTM standards and testing methods ▪ Competency in mechanical analysis skills such as kinematics, solid and fluid dynamics, heat transfer, material strength <p>Desired:</p> <ul style="list-style-type: none"> ▪ Experience with Agile Product Lifecycle Management ▪ Industrial design experience, design portfolio is an asset ▪ Experience working with MR compatible devices ▪ Experience in design of therapeutic ultrasound devices. ▪ Knowledge of electromechanical design ▪ Familiar with mechatronics components sizing and sourcing ▪ Experience working with adhesives ▪ Experience working with sterilization and disinfection methods ▪ Experience with statistical analysis