DEPARTMENT OF
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UNIVERSITY OF WISCONSIN–MADISON

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"Rapid Needle Alignment for Localization of Breast Tumors"

Design Excellence Executive Summary

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1 in 8 women and approximately 2000 men in the United States are diagnosed with breast cancer in their lifetimes[1]. Once diagnosed, patients fight an emotionally and physically draining battle. Common treatment regimens include surgery along with chemotherapy and radiation treatments. These treatments expose patients to sources of secondary malignancies, and the x-ray diagnostic imaging exposes patients to additional risk factors. Our product is specifically designed for assisting with the needle localization procedure performed before lumpectomies, or local tumor removal surgeries. The mammogram-guided procedure is used for inserting a needle with a wire that is left inside the patient for guiding surgeons. The procedure is mostly manual, depending heavily on the radiologist's skill levels to guide the needle and correctly aim for the tumor. Most localizations require numerous corrections and x-ray images to secure the needle in the correct location.

Currently, there is only one comparable needle-assisting device on the market, the percutaneous needle alignment system, however it fails to reduce the amount of corrections required and thus radiation exposure of the patients. Most importantly, it does not fit into the fenestrated plate used in the localization procedure for compressing the breast, and therefore it is not a true competing device given our circumstances. For all intents and purposes, the rapid needle alignment device aims to solve an issue that has not yet been adequately addressed.

The final iteration of the device currently being tested incorporates a clinically accurate design with a smooth finish and ergonomic features to improve ease of use and safety. It utilizes ring holes for stability on a single-handed design. Its tubular chamber, pin hinge, and flat flanges ensure a perpendicular, accurate insertion. Finally, its countersink provides maximum insertion depth while retaining needle stability. The device aims to improve the accuracy, efficiency, and safety of this procedure by ensuring smooth, guided, perpendicular puncture on the first try, decreasing the number of images needed and hence the amount of radiation to which the patients are exposed, and streamlining the procedure so that it is not as heavily dependent on the skill level of the clinician.

This design was approved by IRB for pre-clinical testing and was then used in pre-clinical testing to collect pilot data. After testing, it was discovered that the device has the potential to greatly reduce procedure time and radiation exposure for the patient. Additionally, it could be implemented into any clinical setting that performs these procedures, as there is virtually no competition on the market. If commercialized, these benefits could be received by a multitude of clinicians and patients alike.

[1] R. L. Siegel, K. D. Miller, and A. Jemal, "Cancer Statistics, 2017," Wiley Online Library. [Online]. Available: http://onlinelibrary.wiley.com/doi/10.3322/caac.21387/epdf. [Accessed: 03-Oct-2017].