DEPARTMENT OF Biomedical Engineering
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"Rapid Needle Alignment for Localization of Breast Tumors"

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According to Wiley Online Library Cancer statistics, 1 in 8 women are diagnosed with breast cancer in their lifetimes. Tumors that are best seen on mammography undergo a mammographic-image based wire localization procedure in which the lesion is localized using a needle containing a fine wire with a hook, so the surgeons can identify the location of non-palpable lesions during the lumpectomy procedure. The current method for performing the procedure is a manual technique that often requires multiple corrections and x-ray images; this contributes to patient discomfort, pain, and anxiety, and greatly increases procedure time [3]. Our product is specifically designed for standardizing the needle localization procedure, reducing procedure time, improving Breast Center efficiency, and enhancing quality of care.

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. More 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 design criteria and problem statement. For all intents and purposes, our rapid needle alignment device aims to solve an issue that has not yet been adequately addressed.

Our device incorporates a clinically implementable design with a smooth finish and ergonomic features. It utilizes ring holes and a pin hinge for stability on a single-handed design; a tubular chamber and flat flanges to ensure a perpendicular, accurate insertion; and a countersink for maximum insertion depth while retaining needle stability. This is a novel device and patentability has been discussed with WARF. Filing a provisional patent should serve to protect our intellectual property while we evaluate our options. We are currently exploring the most cost-effective and sterile manufacturing method. However, considering the niche market this device serves, we see commercialization potential in pitching our device to localization-related companies like Hologic and GE Healthcare to include as a package with the fenestrated plates and/or the needles. In that case, allowing the companies to select their preferred manufacturing method might be more realistic.

We tested the device through an IRB approved study that includes 9 physicians. The study results show that the guide decreases procedure time by more than half, and it has the potential to improve the accuracy and efficiency of this procedure by ensuring guided, perpendicular puncture on the first try (i.e. lowers the number of corrections). According to Merrill et al., the average time spent on this procedure per patient is 157.7 ± 71.7 minutes, however, the operative time for lumpectomies is only 55.5 ± 16.6 minutes. Thus, this procedure limits the number of lumpectomies performed per day, and thus reducing procedure time will greatly improve efficiency and save cost for Breast Centers.

Overall, the guide streamlines the pre-lumpectomy localization procedure so that it is not as heavily dependent on the skill level of the clinician. Most importantly, our guide 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.