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**Laura Hinson, Madeline Lee, Sophia Triantis,
and Valerie Zawicki**
Johns Hopkins University

\$10,000 "Cure it!" Lemelson-MIT Student Prize Undergraduate Team Winner

Ithemba: A reusable, low-cost, contamination-free breast biopsy device

The Problem: Breast cancer is the most common cancer affecting women worldwide. Early diagnosis is critical for a more positive prognosis, given that five-year survival rates for Stage I breast cancer are 90%, Stage II are 65%, Stage III are 33%, and Stage IV are 6%.¹ The gold standard for breast cancer diagnosis is the retrieval of tumor tissue from the breast using a core-needle biopsy (CNB). CNBs are deployed via a driver device that can be disposable or reusable. In the developed world, the driver is typically disposable and costs between \$40 to \$200. In low and middle-income countries (LMICs), the cost of disposable drivers is too high, so a reusable driver is most commonly utilized. While there are existing reusable driver devices on the market, they are very susceptible to contamination. The cleaning process for a reusable driver is expensive and can take up to 24 hours to complete.

Due to the costs and issues surrounding diagnosis with CNB, many LMICs use alternative methods that are not as efficient or safe. For example, in areas where it is not possible to obtain CNB tools or where there is a lack of trained personnel, patients may be referred to hospitals that are hours away, where doctors will surgically remove any tumors in the breast. This is costly, invasive, and much riskier than standard biopsy, so some patients tend to decline this option and therefore remain undiagnosed.

¹ Adisa AO, Lawal OO, Adesunkanmi AR. Paradox of wellness and nonadherence among Nigerian women on breast cancer chemotherapy. *J Cancer Res Ther.* 2008; 4:107–10.

The Solution: Team Ithemba invented a reusable CNB driver device with very low contamination risk that can be used for cost-effective breast biopsies. The novel component of their driver device is a chamber that collects contaminants and separates the needle attachment from the spring mechanism that fires the disposable needle. Because of this, the driver can be easily sterilized with a bleach wipe and reused. This offers hospitals and physicians a significant cost savings, as the device has an expectant lifespan of up to twenty years before it needs to be replaced.

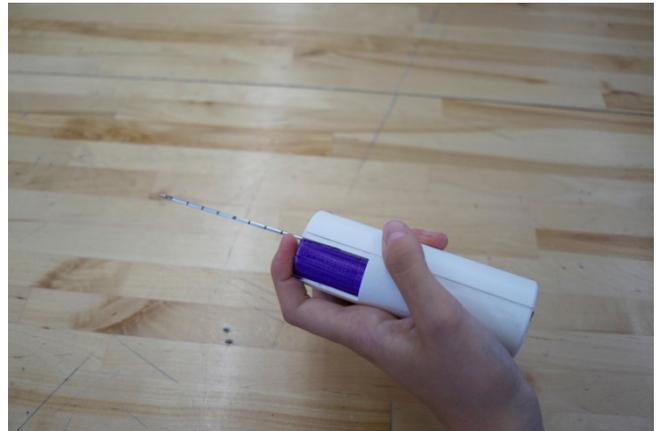


Figure 1: Prototype of Ithemba's breast biopsy device.

In addition, Ithemba's invention is quieter and more ergonomic compared with current drivers, which have gun-like shapes and loud firing noises that often deter patients from having the procedure. The device is also more environmentally sustainable than entirely disposable devices, as only the biopsy needles are thrown away after each procedure.

Commercialization: The current global breast biopsy market was valued at approximately \$976.7 million in 2016 and is projected to grow to \$1,420 million by 2023.² Based on initial conversations with manufacturing experts, Ithemba plans to keep their prices below those leading the market with existing reusable devices priced around \$1800 and needles at \$40. While they are still in the process of solidifying their estimated costs, the team is focusing on considering low cost manufacturing methods so that the cost remains within the affordable range of the target customer.

After the device meets the design requirements based on FDA guidelines for biopsy devices, and completes bench testing for contamination, functionality, and usability, Ithemba will partner with the Hlokomela Clinic in South Africa to perform clinical trials. The team has also incorporated as a Limited Liability Company in order to gain liability protection and tax advantages, and filed for a patent in May of 2018.

² <https://www.alliedmarketresearch.com/breast-biopsy-market>