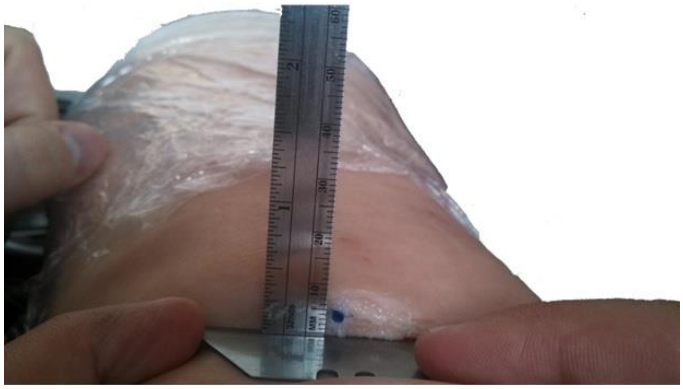
EXECUTIVE SUMMARY

Our project is motivated by a need for the development of a task-shifting device which allows minimally trained health extension workers in rural areas of Ethiopia to insert underarm contraceptive implants. To accomplish this, we defined user requirements and engineering specifications from discussions with our sponsors, examining relevant literature, and benchmarking current products.

Through extensive analysis and down selection, we arrived at the final prototype design to accomplish our user and engineering specifications. Our device removes primary sources of user error that occur when performing the current procedures by controlling the implant insertion depth. Once inserted, the user actuates the applicator-specific plunger mechanism, deploys the implant, retracts the needle, and then removes the device from the patient while leaving the implant behind. Our prototype is functionally equivalent to the production-intent design, with the main differences being materials selected, manufacturing differences, and fastening methods.

Our device validation procedures included: using pork belly as an analogue for the tissue comprising human skin layers, skin height measurements on humans, and ease of use testing for the total device operation. For the pork belly testing, we performed several insertion procedures and measured the average implant depths (2.2 ± 0.65 mm) and horizontal orientations ($0 \pm 1°$). We found that the pork belly closely mimics human skin layer properties, with results differing by less than 10%. Insertion location from medial epicondyle was reliably 9.6 ± 0.3 cm. Finally, the ease of use testing analyzed device operation with users new to the device (80% success, 5 subjects), then these same users with a short training (100% success, 5 subjects).

Figure 1: Implant location in pork belly arm simulator



From testing, we identified engineering and ease of use changes that needed to be made to our design. Some components had to be redesigned and manufactured, while some only required modification. These changes have been completed prior to the delivery of our prototype.

Moving forward, several recommendations for improvements have been identified. Although not a major concern, patient comfort could be increased by the addition of padding to contact areas. The most critical component for moving forward is to perform additional validation testing for FDA 501k approval. Although our prototype is fully functional, we do not recommend the use of our prototype for implantation procedures on humans until FDA clinical trials have been completed.