Reprocessing of Syringe Extension Device for Manual Vacuum Aspiration (MVA) procedures in Low Resource Settings in Sub-Saharan Africa:

Effects on material and manufacturing choices.

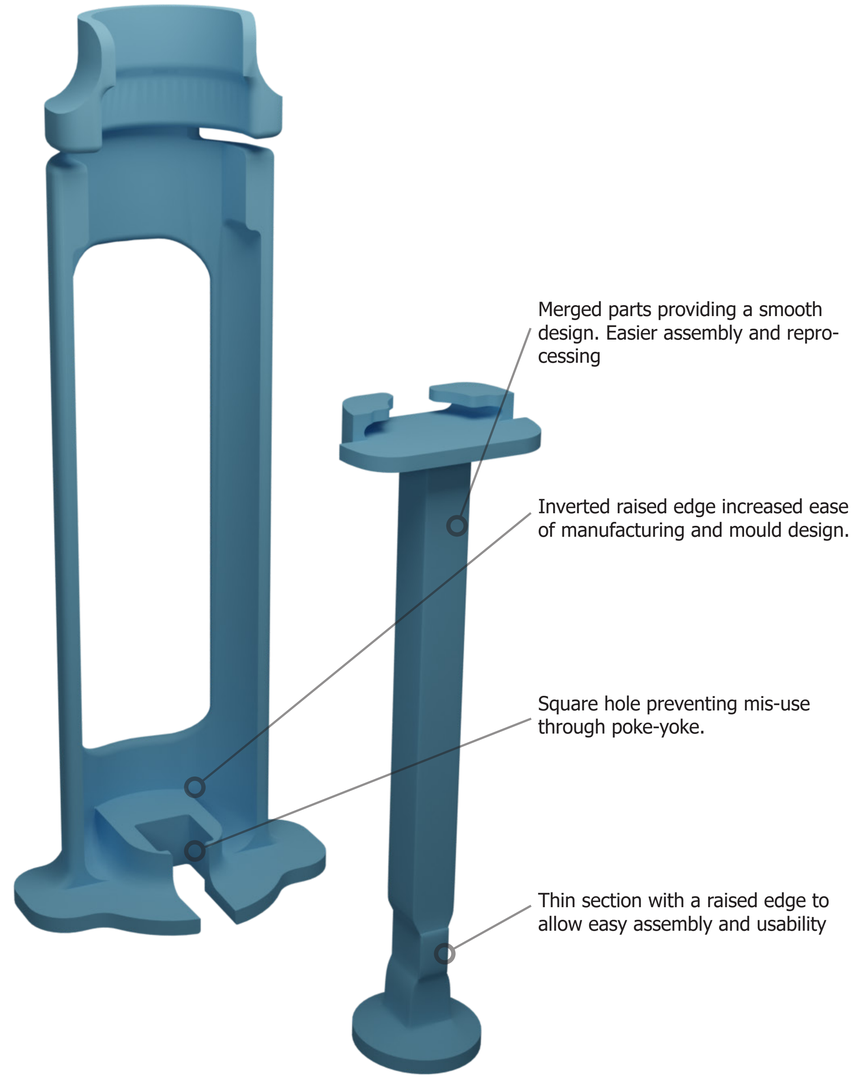
The project focussed on redesigning Chloe SED (Syringe extension Device), a medical device to aid paracervical block application during the process of Manual Vacuum Aspiration (MVA) within the context of East Africa.

The primary objective was to understand how medical-grade Chemical Sterilization and High-Level Disinfection (HLD), and usage of the device in context affect the integrity of the device within its expected lifetime, and to suggest material choice, manufacturing method and recommend design changes for the SED.

A list of design specifications for the project is generated and drivers established. Two materials, PEEK and PP, were selected and an experiment to was developed to understand the impact of reprocessing on the selected materials. Tensile samples were manufactured and tested with 25 cycles of sterilization process as it is done in context.
Based on the test for Chemical sterilization and HLD, PEEK displays 0.36% decrease and a 1.4% increase, whereas PP displays 0.39% increase and a 2.36% decrease in Tensile strength after 25 cycles of sterilization respectively. The elastic range after 25 cycles of use is well within range and the device can safely be used if manufactured using both of the materials, PEEK or PP.

After analyzing the minimum number of devices to be produced, Injection moulding was recommended as the method of manufacturing. PP was selected because it provides sufficient mechanical and chemical characteristics within the lifecycle of the device and because it was cheaper to source and manufacture.

The implications of the results of the research were converted into design directions, the most impactful part was selected, and redesign recommendations were given.This project brings a low-cost necessary medical device one step closer to the market.



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