Reusable Blood Giving Sets for Pothawira Surgical Center

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Design Project Goal

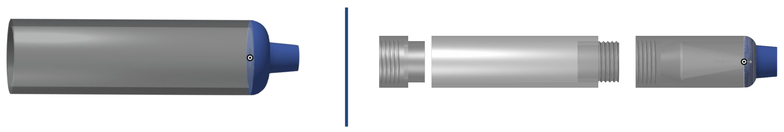
Our project aims to create an affordable, reusable, and sterilizable method for blood-giving sets to address the limited availability of single-use sets for the Pothawira Surgical Center in Salima, Malawi.

Background and Motivation

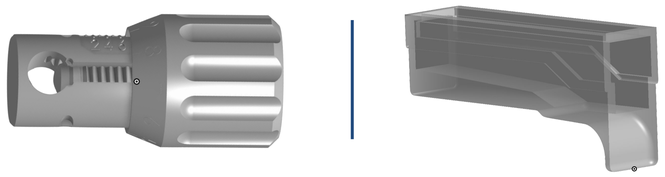
- **High Maternal Mortality Rates:**
  - 25th highest maternal mortality rate in the world[1]
  - Blood loss due to postpartum hemorrhaging (PPH) is the leading cause of maternal mortality[3]
- **Challenges in Blood Supply**:
  - Salima, Malawi, serves a population of 560,000 but only receives 10 units of blood per week from the government[4]
  - Blood has a very short shelf life, often lasting less than 4 hours without proper storage[5]
  - Blood is only donated when a relative is in urgent need[4]
- **Inadequate Healthcare Facilities**:
  - Patients commute 2 hours away to get transfusion sets[4]
  - Many women give birth on the floor of clinics without adequate care or clean environments[4]
- **Current solutions are not sustainable**
  - Disposable solutions are not easy to source or store[4]

Design Choices

Drip chamber: One vs two compartments



Flow Regulator: McMaster Carr vs Roller Clamp



Design Objectives and Testing

Design Objective	Test	Results
Ensure effective bacterial removal from the set after sterilization	Autoclaved components (clamp, mesh, tubing) at 121°C for 40 min; analyzed bacterial growth (*E. coli*) using ImageJ[10]	**PASS** - No bacterial growth observed
Transfusion set is leak-proof during use	Assembled set with Ziploc bags filled with water; simulated use and observed for leakage at connections	**PASS** - No significant leakage in 5 tests; minor leakage in 1 test due to puncture seal
Verify that all materials in the set are biocompatible and met ISO 10993 standards	Reviewed material data sheets and product descriptions for compliance with biocompatibility standards[11]	**FAIL** - Majority of materials passed; Dowsil 734 Sealant failed, requiring replacement
Components can withstand a minimum lateral compressive load of 200 N	Applied lateral force using a vice and measured load at failure with a high-capacity scale	**PASS** - All components passed
Cost-efficient for affordability in resource-limited settings	Conducted cost analysis using BOM; calculated per-set cost based on material quotes	**PASS** - Total cost was $23.71 per set

Final Design Solution

Material	Use	Attributes
Biomed Amber Resin	3D Printed Components	Biocompatible, rigid, semi-transparent[6]
Platinum-Cured Silicone	Tubing	Flexible, biocompatible, sterilizable[7]
304 Stainless-Steel Mesh	Filter	Corrosion-resistant, durable, efficient[8]
DOWSIL Flowable Sealant	Permanent Adhesive	Airtight, easy application, food grade[9]

Blood Bag Spike:

- Standard transfusion set design pierces the blood bag port, allowing blood to flow into the drip chamber.
- 3D printed from Biomed Amber Resin for durability and precision.

Threaded Connections:

- Allow for easy disassembly of the chamber for sterilization.
- Create a leak-proof seal between components to maintain functionality.

Two Component Drip Chamber:

- The deformable top portion generates a pressure differential to draw blood into the chamber.
- The rigid bottom portion provides a secure housing for the blood filter.

Mesh Filter:

- 160 µm stainless steel mesh removes particles while maintaining blood flow.
- Designed with a lip for secure placement in the drip chamber.

Roller Clamp Flow Regulator:

- Allows precise control of blood flow rate during transfusion, ensuring safe and consistent delivery.

Luer Lock Needle Connection:

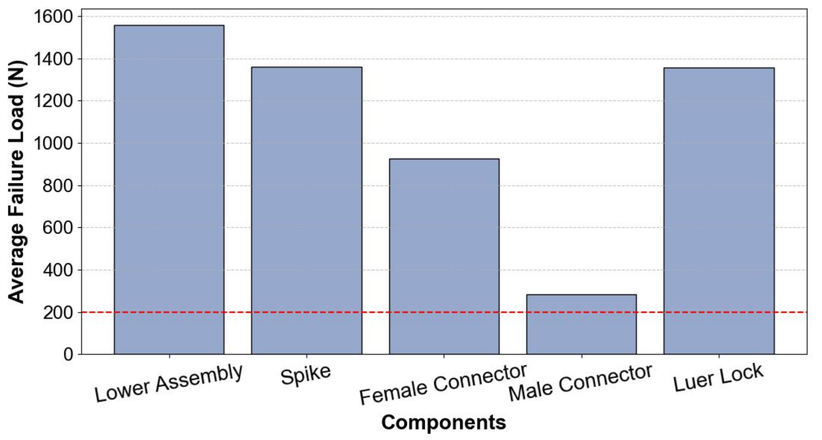
- Provides a secure, standardized connection between the transfusion set and the needle
- Prevents leaks and ensures compatibility with medical equipment

Results

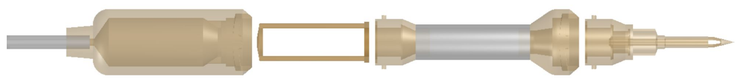
***E. coli* Removal Results:** Device is able to be sterilized without bacterial growth after autoclaving

Resin (Roller clamp)	Metal Mesh (Filter)	Platinum-Cured Silicone Tube	(-) Control (glass beaker)	(+) Control (colonies in tube)

Compressive Failure Test Results: All components of device can withstand compressive force of 200N



Conclusions and Future Work



- **Twist-and-Lock Mechanism**: Replaced screw-in components with a twist-and-lock system for durability, airtight sealing, and ease of use, using a platinum-cured O-ring
- **Redesigned Drip Chamber**: Larger chamber for robust, industry-standard filtration
- **Enhanced Flow Modulator**: Improved modulation control, ridged roller, stronger walls, removable design
- **Sealant Replacement**: Identify a biocompatible alternative to DOWSIL 734 to ensure compliance with ISO 10993 standards

References

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[4] A. Alaniz and J. Mayer Hope, "The Blood Transfusion Set Deficiency In Salima, Malawi," 2024.
[5] Brunskill et al., "What Is the Maximum Time That RBCs Can Be Left Out?," *Transfusion Med. Reviews*, 2012
[6] Formlabs et al., *BioMed Amber Resin Tech. Data Sheet*, 2023.
[7] Avantor Fluid Handling et al., *Cert. Qual. Tubing MFLEX Silicone No. 16*, 2024.
[8] Xu et al., *J. Mater. Res. Technol.*, 2024.
[9] Dow Chemical Company et al., *DOWSIL 734 Flowable Sealant Tech. Data Sheet*, 2020.
[10] CDC et al., *Steam Sterilization* 2024
[11] FDA et al., *Use of ISO 10993-1 Guidance*, 2023.

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