

A Low-Cost Uterine Balloon Tamponade for the Management of Severe Postpartum Hemorrhage



Nancy Muller

Senior Program Officer

Reproductive Health Supplies Coalition

Maternal Health Supplies Caucus Meeting

Brussels, Belgium

March 20, 2018

Filling the gap for a low-cost, safe, and regulated medical device



Effective, but relies on off-the-shelf components and assembly.

\$\$



Effective, innovative, reliable, fills the cost and regulation gap between the condom balloon and the Bakri balloon.

\$\$



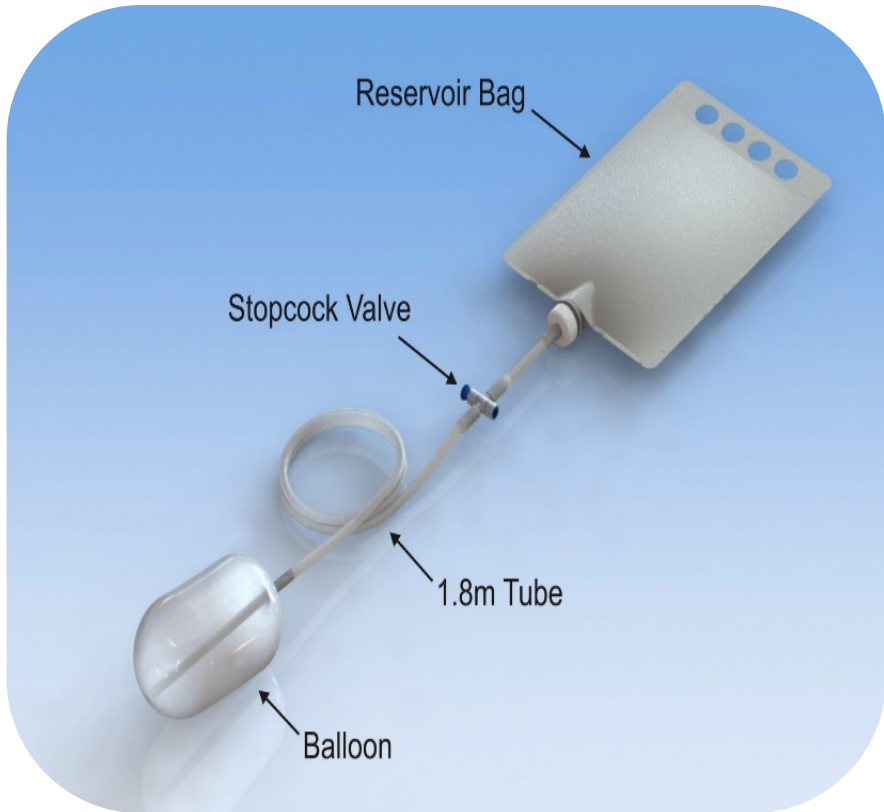
Effective, reliable, but expensive.

\$\$\$\$\$\$
\$\$\$\$\$\$

Key considerations:

- Safety.
- Ease-of-use.
- Acceptability.
- Manufacturability/Availability.
- Potential marketability.
- Cost.
- Regulated/ quality assured.
- Included in procurement and distribution systems.

The Ellavi UBT product characteristics



- Pre-assembled system, ready for use.
- Ellavi is manufactured in South Africa by Sinapi Biomedical that specializes in high quality, low cost medical devices.
- Single unit includes a reservoir bag that can be filled with 750 mL of fluid, a valve that can be closed during transport and a cylindrical balloon designed to conform to the shape of the uterus.
- Gravity filled: frees up provider to care for patient.
- Can be inserted, filled, and begin working in less than a minute.
- Pressure regulated open system allows the uterus to contract and retract to arrest the bleeding.
- Low cost: a fraction of the cost of current devices on the market.
- Latex free: passes biocompatibility tests.
- Comes in a sterile package with a set of illustrated instructions.

Current Status of the Ellavi UBT

- CE mark certification (EU regulatory approval) expected by end of March 2018.
- Registration in countries expected to follow.
- Clinical validation in hospital setting completed in South Africa.
- Medical Research Council of South Africa supporting operational feasibility of use in clinics.
- Ellavi UBT product launched in early 2018.
- Low volume manufacturing plant in place and producing small quantities for pilot programs.
- Large scale manufacturing will be set up by end of 2018. Cost of manufacturing per unit estimated, for high volumes, between US\$5-6.
- Cost-effectiveness analysis documented in Kenya –indicates highly cost effective if between US\$5- \$15.
- Introduction in PPH control strategy and collaboration with partners in the field is being advocated.



Photo: PATH/Patrick McKern

Research / Design

Develop / Validate

Approve /
Recommend

Introduce /
Optimize

Scale up / Apply

Thank you!

The PATH team:

Elizabeth Abu-Haydar

Steve Brooke

Rachel Hammack

Tara Herrick

Peggy King

Crystal Lawrence

Mutsumi Metzler

Mercy Mvundura

Gene Saxon

The UBT has received support from USAID, The Health Innovation Portfolio, private foundations, and individual donors.

PATH has no conflict of interests, we have no financial stake nor will we have any financial gain from this project.

Partners:

