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

Nancy Muller
Senior Program Officer

Reproductive Health Supplies Coalition
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Filling the gap for a low-cost, safe, and regulated medical device

Photos: PATH/Erca Jacoby and Patrick McKern

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.
- Introduction in PPH control strategy and collaboration with partners in the field is being advocated.
Thank you!

The PATH team:
Elizabeth Abu-Haydar
Steve Brooke
Rachel Hammack
Tara Herrick
Peggy King
Crystal Lawrence
Mutsumi Metzler
Mercy Mvundura
Gene Saxon

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