

Non-surgical male circumcision device

Country of origin | Israel

Health problem addressed

Three randomized controlled clinical trials in Africa showed that male circumcision can reduce risk of HIV transmission among heterosexual men by as much as 60%. Public health leaders aim to circumcise 20 million men by 2015 in 14 nations in Sub-Saharan Africa; Africa has reached less than 5% of its goal with existing surgical methods.

Product description

The device consists of an Inner Ring, Elastic Ring and Applicator. The device applies controlled radial elastic pressure to compress the foreskin and cut off circulation. The distal foreskin becomes necrotic and is removed after 5-7 days. The procedure takes less than 5 minutes, is bloodless, requires no injected anesthesia, no sutures, no sterile settings and can be conducted by low cadre nurses, as validated scientifically by the Government of Rwanda.



Product functionality

This simple and scalable device was specifically developed to provide voluntary circumcision to men, ages 15 to 49, living in 14 priority nations in Sub-Saharan Africa where there are high rates of HIV transmission and limited healthcare infrastructure.

Developer's claims of product benefits

Currently, the only WHO recommended method for circumcision is surgery, which entails skills and infrastructure that are hard to attain in resource-scarce settings. Other devices that were not specifically designed for resource-poor settings entail blood (albeit less than surgery), require injected anesthesia, cutting of live tissue and a sterile setting. Compared to surgery, this device is safer, simpler (no sutures, 3 vs 10 days of training, and with low cadre, non-surgically trained nurses, significantly reducing burden to health system), and more scalable (done in less than 5 minutes vs. over 20). It is the only non-surgical device in market --bloodless, no injected anesthesia, no sterile settings--offering a viable solution for resource poor settings.

Operating steps

Clients are measured to select ring size. The circumcision line is marked based on WHO guidelines. The inner ring is inserted. An elastic ring is aligned with the inner ring to compress the foreskin and stop blood flow. Verification thread is then cut. Ischemic necrosis is initiated. Device remains in situ for 5-7 days, and is then removed.

Development stage

The device is FDA cleared (K103695) and certified CE Mark Class IIa and is manufactured using USP Class VI biocompatible elastomeric materials compliant to ISO 13485 Medical Devices (Quality Management systems) and FDA, 21 CFR177. 2600. The device is currently undergoing clinical trials by the government of Zimbabwe and Rwanda. To date the device was studied in 3 independent clinical trials in Rwanda on over 880 subjects.

Future work and challenges

The challenges are scalability, uptake and government commitment. If governments have a viable and sustainable solution with minimal burden to the health system, they are more likely to commit resources, enable task shifting policies, and achieve the national and regional HIV prevention goals.

User and environment

User: Nurse, community health workers

Training: Yes; will be provided by Rwandan Centers of Excellence

Maintenance: None

Environment of use

Settings: Rural, urban, primary (health post, health center), secondary (general hospital)

Requirements: Clean (though nonsterile) setting, trained healthcare provider, bed, biologics disposal box

Product specifications

Dimensions (mm): 22 x 60 x 60

Weight (kg): 0.011

Consumables: Gauze pads, scissors, spatula, forceps, dressing, betadine, anesthetic cream

Life time: 5 years

Shelf life: 2 years

List price (USD): 15-20

Other features: Portable

Contact details Tzameret Fuerst | Email non.surgical.mc@gmail.com | Telephone +972 77 693 5607 | Fax +972 37 621 196

http://www.who.int/medical_devices