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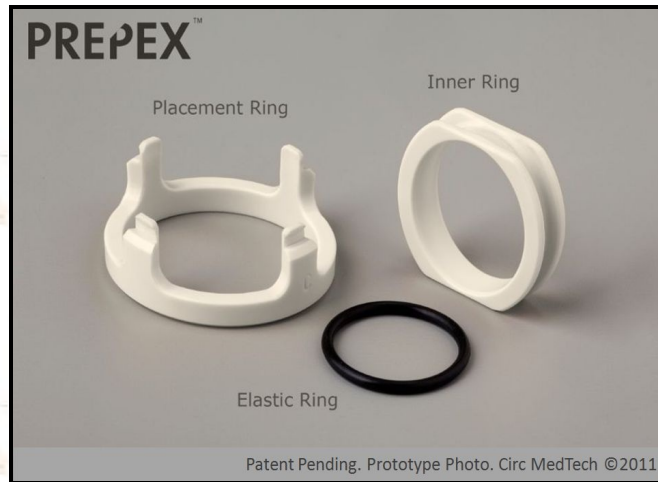
These search terms are highlighted: **safety and efficacy study of the prepex system for male circumcision**

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The PrePex™ device

Developed in 2009/10 by Fuerst, Kilemnick & Shohat and marketed by a company called Circ MedTech Limited, this device is specifically aimed at the sub-Saharan market in Africa and is designed for use in non-sterile environments by minimally trained healthcare professionals. Possibly uniquely for modern clamps, it claims to be suitable for routine use without anaesthesia. In common with many fit-&-wear clamps, it requires no sutures.

Circ MedTech is an ad-hoc private company incorporated in the British Virgin Islands. The CEO is [Tzameret Fuerst](#); prior to the formation of Circ MedTech she was the Director of New Product Development at [Keter Plastic](#) (an Israeli company that is one of the world's largest plastics manufacturers) and was a Strategic Planner at the advertising agency [Geller-Nessis](#).



Procedure: Something akin to an industrial grade 'O'-Ring is used to induce ischemic necrosis. Unsprung from the “placement ring”, the 'O'-Ring engages with a groove in the inner ring that has been pre-positioned under the foreskin. For several days, the wearer walks around with only the 'O'-Ring visible; the applicator has by then been removed. The foreskin dies off and, when it has, the device is removed by flicking the 'O'-Ring out of the groove of the component that is still out of sight, hidden in the sulcus.

Early criticism of the PrePex device suggested that a significant amount of inner foreskin would remain after circumcision, resulting in a failure to remove as many Langerhans cells as other methods. However, confidential images seen by Circlist show that the finalised design can produce a ‘low’ style if the device is correctly used.

Questions and Answers about the PrePex device

Here are some questions raised in "Letters to the Editor" along with the answers given by Circ MedTech’s CEO:

1. **Q:** Why did Circ MedTech use military personnel as test subjects? They are not fully representative of the general population in several respects: Fitness, pain tolerance, diet, hygiene régimes, environmental factors that have infection control implications....

A: Only 5 patients out of 100 in the safety study were soldiers. In the comparison study currently underway (clinicaltrials.gov ID NCT01284088), all patients are civilians. Kanombe is a military *and* district hospital. The promising results of the Rwandan Government study will be public information very soon in prestigious conferences, in medical journals and on the circlist.com website.

2. **Q:** Is it really the case that the foreskin is NOT at first severed in a PrePex circumcision, but left intact for a week to necrotise 'in situ'?

A: Yes, it is true. The device is left in situ for 7 days, until the foreskin is fully necrotized. This is part of what makes the patent pending device and method safe and simple to use, with very little training (you don't even have to be a nurse). This also enables a bloodless procedure (no cutting of live tissue!), a critical factor in rural settings. There is no anesthesia (so no needles!), no blood, no sutures and no sterile settings required, as the device comes in contact only with intact skin. There were no infections or complications throughout the whole study from anyone while the device was in situ, confirming the safety of the technique. From discussions with patients after the study, one of the key benefits raised was that the procedure had no blood.

3. **Q:** Adults only, or child sizes too?

A: For now, only adult sizes are readily available, but we will have child sizes too.

Known use



We are aware of the clamp being used in small numbers within Rwanda but not, so far, elsewhere.

Field trial reports on official websites:

<http://clinicaltrials.gov/ct2/show/NCT01150370>

<http://clinicaltrials.gov/ct2/show/NCT01284088>

A [preliminary report](#) can be seen on the Rwanda Ministry of Health website.

On 15 February 2011, IRIN (a publication of the UN Office for the Coordination of Humanitarian Affairs) published an [article](#) reporting the success of the field trials.

On 28 February 2011 a paper was presented to the 18th Conference on Retroviruses and Opportunistic Infections, Hynes Convention Center, Boston MA, as follows:

Paper # 1007 : Safety and Efficacy Study of the PrePex System for Male Circumcision

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1. Kanombe Hospital, Kigali, Rwanda;
2. Rwanda Central Hospital, Kigali;
3. Dr. Anita Asiimwe, Executive Secretary of CNLS (Commission Nationale de Lutte contre le SIDA, Rwanda National AIDS Control Commission);
4. Dr. Agnes Binagwaho, Permanent Secretary in the Ministry of Health, Kigali, Rwanda.

Background: Our study aims to assess the safety and efficacy of a new medical device that enables bloodless male circumcision while eliminating the need for anesthesia and sutures. The device is explored to be integrated into the Republic of Rwanda's national male circumcision program for HIV prevention.

Methods: From June to September 2010, 40 pre-screened, healthy males aged 18 to 35 years were enrolled in an ongoing, prospective single-center study in the Kanombe Hospital, Kigali, Rwanda. Subjects signed informed consent and met inclusion criteria. The study was approved by the National Ethics Committee. Male circumcision was investigated using a new device, the PrePex System (Circ MedTech), designed to facilitate simple, safe, and scalable male circumcision by minimally trained medical personnel in non-sterile environments. No sutures or anesthesia were used for any step of the procedure. Circumcision site was marked and cleaned; then the appropriate-sized device was deployed on the foreskin, blocking blood flow. Subjects were discharged wearing

the device. After 7 days the necrotic foreskin and device were removed. Standard clinical report forms and photographs were used to gather and analyze data on safety (rates of adverse events, device complications), pain level using a Visual Analogue Scale (VAS), and efficacy (circumcision outcomes, compliance).

Results: From device deployment to device removal, there were no clinical adverse events and no device-related incidents. Following device removal, there was 1 mild adverse event of diffused edema that resolved with minimal intervention. All subjects achieved the endpoint of complete circumcision, glans fully exposed. Daily routines continued, and no absent or sick days were required beyond arriving for deployment and removal. Average healing (complete epithelialization and no drainage) was 16.9 days (± 4) post removal. Minimal pain (VAS score < 2) was reported during deployment and immediately after removal, with brief pain (30 to 40 seconds) during device removal, which required no anesthesia. There were 4 times more volunteers than were needed and all those selected arrived for the procedure, indicating acceptance.

Conclusions: Our findings demonstrate the safety and efficacy of the PrePex System for male circumcision without bleeding, sutures, or anesthesia. The PrePex System has the potential to facilitate rapid scale-up in national programs for HIV prevention, an imminent need in Sub-Saharan Africa.

Acknowledgements

The following resources were used in the preparation of this web page:



[Manufacturer's website](#) and personal correspondence with the CEO.



Record for the multinational patent application [WO2011007358 \(A2\)](#).



Proceedings of the 18th Conference on Retroviruses and Opportunistic Infections [Paper #1007](#).

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