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PTO/SB/18 (01-04)

Approved for use through 07/31/2008. OMB 0651-0032

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|---|------------------------|---|-----------------|-----|-------|
| Given Name (first and middle [if any]) | Family Name or Surname | Residence (City and either State or Foreign Country) | | | |
| Shaul Ido | Shohat Kilemnik | Kfar HaOranim, Israel Herzliya, Israel | | | |
| Additional Inventors are being named on the _____ separately numbered sheets attached hereto | | | | | |
| TITLE OF THE INVENTION (500 characters max) | | | | | |
| Circumcision devices and methods. | | | | | |
| Direct all correspondence to: CORRESPONDENCE ADDRESS | | | | | |
| <input type="checkbox"/> Customer Number: _____ | | | | | |
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| <input checked="" type="checkbox"/> Firm or Individual Name _____ | | | | | |
| Address _____ | | | | | |
| Address _____ | | | | | |
| City | Kfar HaOranim | State | _____ | Zip | 73134 |
| Country | Israel | Telephone | +972 548 423774 | Fax | _____ |
| ENCLOSED APPLICATION PARTS (check all that apply) | | | | | |
| <input checked="" type="checkbox"/> Specification Number of Pages 4 <input type="checkbox"/> CD(s), Number _____ | | | | | |
| <input checked="" type="checkbox"/> Drawing(s) Number of Sheets 3 <input type="checkbox"/> Other (specify) _____ | | | | | |
| <input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76 | | | | | |
| METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT | | | | | |
| <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. | | | | | |
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| The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government. | | | | | |
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[Page 1 of 2]

Respectfully submitted,

SIGNATURE S. SHOHATTYPED or PRINTED NAME SHAUL SHOHATTELEPHONE +972 548 423774Date July, 16, 2009

REGISTRATION NO. _____

(if appropriate)

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Circumcision devices and methods.

Circumcision, which consists of removal of the foreskin of the penis, is performed on a third of human males worldwide from ancient times. This operation is performed for ritual or hygienic reasons immediately after birth, during childhood, during adolescence or even on young adult subjects.

Lately large randomized controlled studies showed that such procedure can decrease significantly the risk of infection with HIV virus. There is a tendency to perform large scale circumcision of adult males in populations of risk worldwide.

For example, the U.S. Center of Disease Control (CDC) summarizes in <http://www.cdc.gov/hiv/resources/factsheets/circumcision.htm> the biologic plausibility of circumcision to reducing the infection rate with HIV:

"Compared with the dry external skin surface, the inner mucosa of the foreskin has less keratinization (deposition of fibrous protein), a higher density of target cells for HIV infection (Langerhans cells), and is more susceptible to HIV infection than other penile tissue in laboratory studies. The foreskin may also have greater susceptibility to traumatic epithelial disruptions (tears) during intercourse, providing a portal of entry for pathogens, including HIV. In addition, the microenvironment in the preputial sac between the unretracted foreskin and the glans penis may be conducive to viral survival. Finally, the higher rates of sexually transmitted genital ulcerative disease, such as syphilis, observed in uncircumcised men may also increase susceptibility to HIV infection."

Circumcision when performed after the neonatal age by surgeons in a setup of operating room, using sterile instruments, is a safe procedure with a low percentage of complication. However when this procedure is performed by less skilled person and/or not in the setting of an operating room the complications may be severe and their rate is high.

There is a need for a minimally invasive, safe, fast, easy to learn and easy to perform procedure, which does not require special sterile instruments and even does not require an operating room setup, does not requires anaesthesia and which is not expensive.

In an embodiment, Fig. 1, the device consists of an inner ring or tube 11, which may be provided on its outer surface with a circular groove 12. An additional outer ring is provided 13, which is sized to fit over the outer surface or over the groove 12 of the inner ring. The outer ring should be elastic and distend-able, or expandable and should fit snugly in the groove of the inner ring, or over its external surface exerting pressure on it. The external ring should have a large and small size configuration. By passing from the large size to the small size configuration, and at any intermediate configuration, the ring exerts uniform compressive forces on the tissue against the backing of the inner ring.

The inner ring should be manufactured of a non, or minimally compressible biocompatible plastic material such as but not limited to poly-carbonate, silicon, polyether, polyethylene, polyurethane, etc, or from a biocompatible metal such as but not limited to stainless steel, or from a combination thereof. The surfaces of such ring touching the tissues should be soft and resilient. Only the groove 12 that is accommodating the outer ring should be rigid and non-resilient.

The outer ring should be manufactured of an elastic or a distensible material such as but not limited to: silicon, polyurethane or stainless steel, or Nitinol, or any combination thereof. The diameter of the outer ring may be increased by exerting radial forces and the ring may be expanded and when such forces are released and the outer ring fits over the outer rigid surface

of the inner ring or over the rigid groove of the inner ring and it should exert on it and on the tissue situated between them constant uniform forces.

Alternatively the outer ring may consist of a spring 14, with one or more coils that may be stretched to a larger diameter and tends to return to a smaller diameter exerting constant pressure when fitting over the inner ring. Alternatively, the outer expandable ring may consist of a spring with small diameter coils such as but not limited to 1 to 3 mm; which is closed into a circular shaped torus like structure 15.

Alternatively as in Fig. 3, the outer ring 31 may be of constant diameter, while the inner ring 32 may be compressed to a smaller diameter until the outer ring is fitted over it and over the interposed foreskin. After fitting the outer ring the compressive forces on the inner ring are released permitting it to exert constant uniform pressure on the interposed foreskin from inside out against the backing of the inner rigid surface or on an inner rigid groove of the outer ring 33.

The outer ring may be a closed ring, or an open ring that may be compressed to a closed configuration and locked to such configuration by some locking means such as a ratchet means or a snapping means 16. Alternatively the outer ring may comprise 2 or more segments that may be locked in a rigid closed ring configuration 17.

The internal ring should have a small and large size configuration. By passing from the small size to the large size configuration, and at any intermediate configuration, the ring exerts uniform compressive forces on the tissue against the backing of the outer ring.

Alternatively, another configuration may consist an outer ring that has a larger and smaller size configuration and an inner ring that has a smaller and larger size configuration. By passing from the large size to the small size configuration, and at any intermediate configuration, the external ring exerts uniform compressive forces on the tissue against the backing of the inner ring. Simultaneously, by passing from the small size to the large size configuration, and at any intermediate configuration, the internal ring exerts uniform compressive forces on the tissue against the backing of the outer ring.

A method for removing the foreskin by controlled ischemic necrosis with such device is described. Initially the penis and foreskin are thoroughly cleaned. The inner ring and outer ring should have diameters that are larger than the glans penis diameter during erection. The outer ring is pushed over the foreskin and glands on the shaft of the penis. The preputium or foreskin is retracted exposing the glans. The inner ring is passed over the glans. The foreskin is advanced over the inner ring and the outer ring is pushed and advanced until fitting snugly in the groove of the inner ring. The outer ring may be provided with one or more grasping means such as leaflets or rings for facilitating its manipulation 18. The outer ring will exert continuous uniform pressure on the foreskin, compressing it against the non-resilient backing of outer surface, or the groove of the inner ring causing pressure necrosis along a circular line, resulting in separation of the foreskin along such circular line and its detachment. This process may take one or more days and should be not painful due to the compression of the subcutaneous nerves between the two rings. The slow progressive process will cause a neat detachment of the distal fore skin, minimal raw surface that will heal fast with a low propensity for infection, and no bleeding. Since the two rings have larger diameter than the size of the glans there is no chance of strangulation of the glans or of injuring the urethra. Also, in case of misplacement or of pain the rings may be easily removed. Therefore, this procedure should be very safe.

A manipulating means 21 may be provided Fig. 2 for advancing the inner ring over the glands. Such means should conform to the inner surface of the inner ring 22. It should have a circular shape consisting of a ring structure and may have a tapered rim 23 or conical end 25, permitting the advancement of the inner ring through the opening of the foreskin. In case of phimosis, or

constricted foreskin, the inner ring may be advanced through the foreskin opening after dilation of this opening by the tapered rim or end of the manipulating means,

Alternatively, the two rings may have a diameter that is smaller than the diameter of the glans penis. In such case the inner ring is pushed within the opening of the folded foreskin that covers the glans, and pushed against the tip of the glans. The foreskin is pulled and distended over it and then the outer ring is pushed over the foreskin fitting snugly over the inner ring or within the groove of the inner ring and compressing circularly the foreskin between the two rings. The opening of the inner ring will permit the passage of urine until detachment of the foreskin.

The rings could be covered by medicated ointment (or even to included the ointment) to further enable faster and smoother healing of the tissue.

Procedures of controlled removed of tissue by ischemic necrosis are well known to proctologists, that use compression band to remove haemorrhoids. In such case a compressive rubber band is placed over the base and vascular supply of the enlarged haemorrhoid causing ischemic necrosis at the haemorrhoid pedicle and its detachment after one or more days. Such procedures are performed for years and proved to be painless, with no or minimal bleeding and a very low infection rate.

The procedure or removal of the foreskin by controlled ischemic necrosis may be performed by personnel after a short training and does not necessitate an operating room, anaesthesia or sterile surgical instruments. This permits the procedure to be performed very fast and in large numbers at any location in a clean environment.

CLAIMS:

A device for removal of the foreskin of the penis by controlled ischemic necrosis consisting of: an inner ring and an outer ring which fits snugly one over the other and wherein one of these rings is expandable or compressible and the other has a rigid surface and these rings exert constant uniform pressure on each other and on the tissue interposed between them

A method for removal of the foreskin of the penis by controlled ischemic necrosis by compressing uniformly the foreskin between two rings that will result in separation of the foreskin along a circular line and its detachment.

A method of reducing the likelihood of infection with HIV via the minimally invasive method of removal of the foreskin of the penis by compressing uniformly the foreskin between an inner ring and an outer ring which fits one over the other and wherein these rings exert constant uniform pressure on each other and on the tissue interposed between them

A device for removal of the foreskin of the penis by necrosis consisting of: an inner ring and an outer ring which fits one over the other and wherein these rings exert constant pressure on each other and on the tissue interposed between them

A device for removal of the foreskin of the penis by necrosis and delivering medicated ointment consisting of: an inner ring and an outer ring which fits one over the other and wherein these rings exert constant pressure on each other and on the tissue interposed between them, and whereas at least one of the rings is covered or embedded with medicated ointment that is slowly released onto the skin

FIG 4

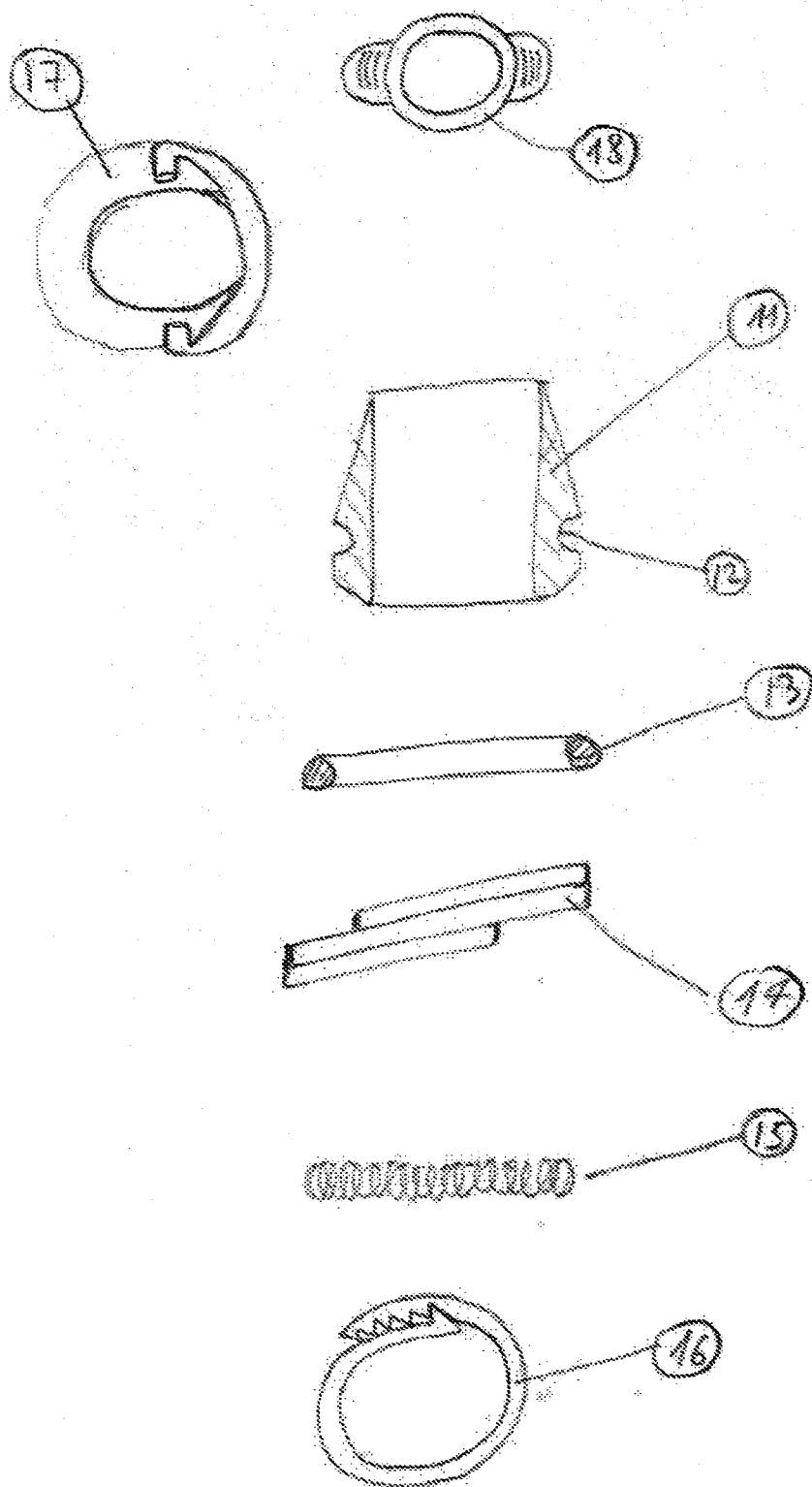


FIG 4

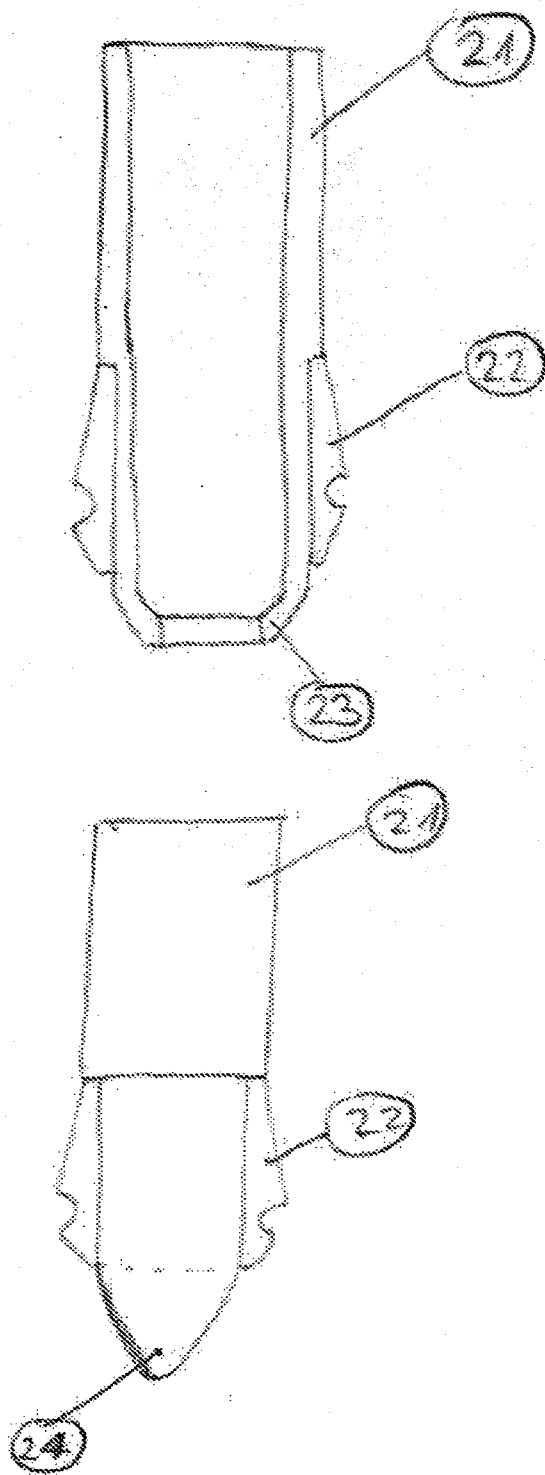


FIG 2

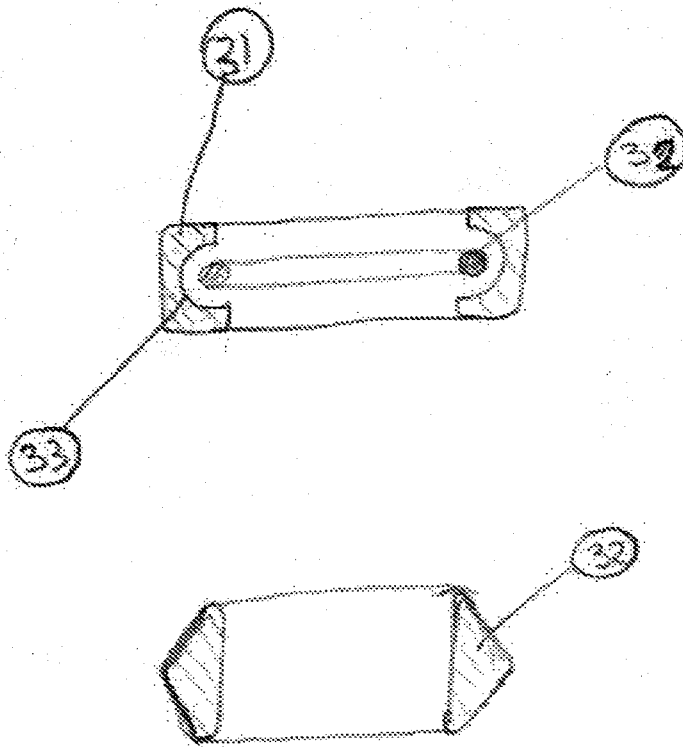


FIG. 3