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1	Provisional Cover Sheet (SB16)	ProvisionalSBCIRC2NEW.pdf	943485 dc0b32323986a62cd79b9d2e5d17de47b450f26d	no	4

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	Document Description		Start	End	
	Specification		1	5	
	Claims		6	6	

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3	Drawings-only black and white line drawings	finaldiagramspapa2.pdf	2551789 9036754e0669674745e4ac6ce2ff6d8132a2156	no	7
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4	Fee Worksheet (PTO-875)	fee-info.pdf	28277 044204f6c368d98748fd30c127ecd87e0be3ed72	no	2
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Code: TR.PROV

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PTO/SB/16 (04-07)

Approved for use through 06/30/2010 OMB 0851-0032

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Provisional Application for Patent Cover Sheet

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)

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All Inventors Must Be Listed – Additional Inventor Information blocks may be generated within this form by selecting the Add button.

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Title of Invention

Circumcision devices and methods

Attorney Docket Number (if applicable)

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Applicant claims small entity status under 37 CFR 1.27

Yes, applicant qualifies for small entity status under 37 CFR 1.27

No

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Signature	/Oren Fuerst/			Date (YYYY-MM-DD)	2009-09-21
First Name	Oren	Last Name	Fuerst	Registration Number (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.

HIV claimed thus far more than 25m lives, with over 2m lives a year. 2/3 of those infected with HIV are in sub-Saharan Africa, 1.5M deaths/year. Attempts to reduce infection rates (e.g. education for safe sex, condom distribution) offer only a partial results

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.”

Studies show that the **Relative risk for HIV infection was 44-71% lower in circumcised men.** However, only 30% of the world's males are circumcised. Current circumcision methods require mini-surgery and are not scalable. Results vary according to training and medical setting

Today's methods of circumcisions:

- Mini-surgeries requiring medical facilities
- Not scalable
- Require sterile environments & trained doctors
- Leave patients with stitches and bandages for a few days

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 require anesthesia 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 inner ring should be 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 the outer ring may be of constant diameter, while the inner ring 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.

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.

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 then 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.

There are medical /physiological features that support the mechanism the device utilizes will lead to spontaneous detachment of the prepuce after 2 to 3 days. The external distendable ring with a width of 3 mm will exert a uniform pressure of 0.2 to 0.3 atm on the prepuce circumferentially. This pressure is 3 to 4 times higher then the arterial pressure in the subcutaneous arteries and will stop the blood flow to

the prepuce. Within approx 6 to 8 hours the prepuce will undergo ischemic necrosis (this is the time that skin and subcutaneous tissue undergo necrosis in case of ischemia). This necrosis induces a mild inflammatory reaction at the demarcation between the necrotic and healthy skin. Such inflammatory reaction is known to causes resorbtion and degradation of the intercellular matrix and collagen fibers and will result in detachment of the necrotic foreskin. The normal erections will impose recurrent axial forces on the demarcation line and will expedite the detachment of the necrotic skin. During this slow process of ischemic necrosis at the parting line between the remaining and the necrotic foreskin the pressure between the two rings will collapse the blood vessels causing hemostasis.

In addition, while the inner ring could be manufactured in a variety of sizes, to fit a variety of ages and sizes, the inner rings could be produced in one unit with the ability to select the appropriate inner ring. This could solve the need to maintain multiple unit sizes at clinics, a problem noted by health agencies worldwide.

Example 1:

An illustrative example of the circumcision device is shown in Figure 4. The introducer 41 is manufactured of a plastic material and has a top part 42 that could be inserted in the back of the inner ring 43. Inner ring 43 is manufactured of the same material and has a softer inside part as well as a groove 44. Outer o-ring 45 is made of silicone and with a diameter to fit snugly in the groove 44 of Inner ring 43.

One method of conducting the circumcision is described in Figure 5. In step 51, the foreskin is separated and inverted to allow for better handling of the circumcision. In step 52 the circumcision device is deployed on the penis and the o-ring is loosely placed on the penis. In Step 53, the foreskin is placed on top of the inner ring and in Step 54, the o-ring is placed on the foreskin that covers the inner ring. In Step 55, the o-ring is snugly in the groove of the inner ring. In Step 56 the introducer is removed.

Example 2:

Figure 6 shows an a possible alternative design whereby multiple sizes of the Inner rings are manufactured on a single unit design device 61. In addition, the diagram shows how the O-ring could be easily deployed using another plastic ring. The design also includes the introducer on the same unit as the inner rings.

In the diagram, multiple steps/widths of the inner ring are available for selection on the plastic design 62. The appropriate size is selected and the other steps could be torn (if the size selected is not the smallest size) by pulling the wrapper/plastic selector 63. The tearing does not affect the functionality of the design as the selection is done by pulling connectors around the device. This is similar to the way by which some drugs or dietary supplement are kept in a tamper proof package. The introducer can also be manufactured and be part of the single unit design.

In addition, the kit will contain different o-ring diameters (item 64) to fit each of the steps of the inner rings. In addition, the kit could include a plastic ring 65 to hold the

O-ring before deployment. This will enable an easier deployment of the O-ring on the inner ring, reducing the likelihood of being tangled by the male pubic hair.

Example 3

Figure 3 illustrates an alternative design for the mechanism of single unit for multiple penis sizes. In this example, the mechanism of selecting the inner ring and separating it and the introducer is via a thinner plastic at the region of interest. Once the ring is selected (before deployment) the other smaller rings are broken from the unit. Similarly, after deployment, the introducer is separated by applying pressure on the thinner area of the plastic, thereby breaking it.

The main advantages of the described method and device over other methods and devices of circumcision are as follow:

Scalable & Simple:

- Fits for mass circumcision campaigns
- No need for anesthesia or sterile environment (just cleaning)
- Can be deployed by almost anyone
- allows for multiple sizes to be used by a single unit

Bloodless & Painless:

- Predictable Foreskin detachment after two days.
- Adjustable for removal of precise amount of desired foreskin
- Inner ring is oversized by 1cm (no pain during erections)
- Inner ring is 2 cm long and coated by soft material causing no inconvenience to the patient.
- Patient only sees the external o-ring of 1 mm width
- Mechanism of Action is Controlled necrosis: two rings fit one over the other and exert constant uniform pressure on each other and on the tissue interposed between them.

Inexpensive:

- Compared to mini-surgery costs

CLAIMS:

1. 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
2. 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.
3. 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
4. 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
5. 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
6. the device according to claim 1 whereby the device include multiple sizes of the inner ring on a single unit
7. the device according to claim 6, whereby the single unit design allows for detachment of the relevant inner ring size
8. the device according to claim 1 whereby a plastic unit (introducer) is assisting in holding the inner ring while deploying the elastic outer ring on the foreskin

Figure 1

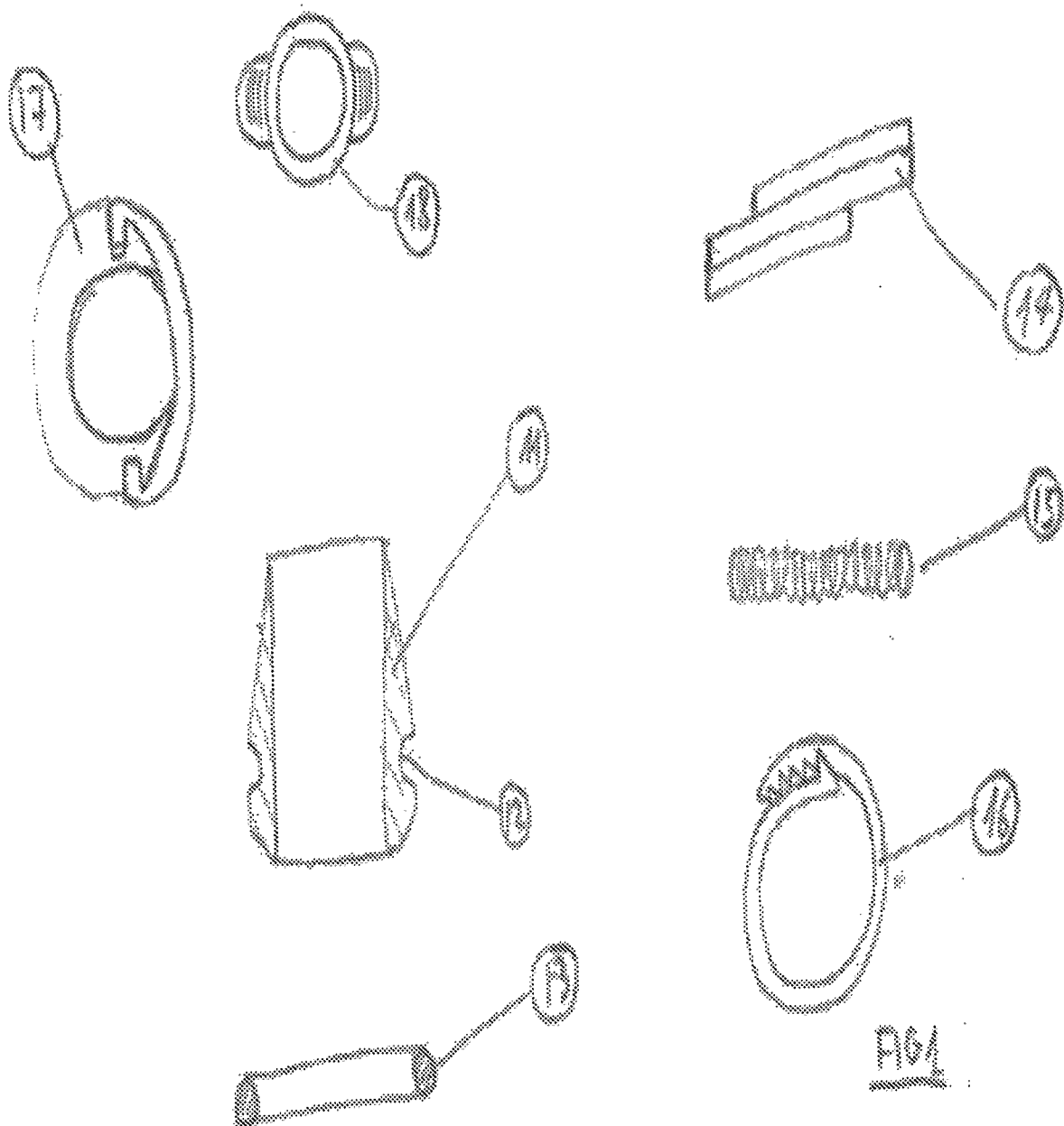


Figure 2

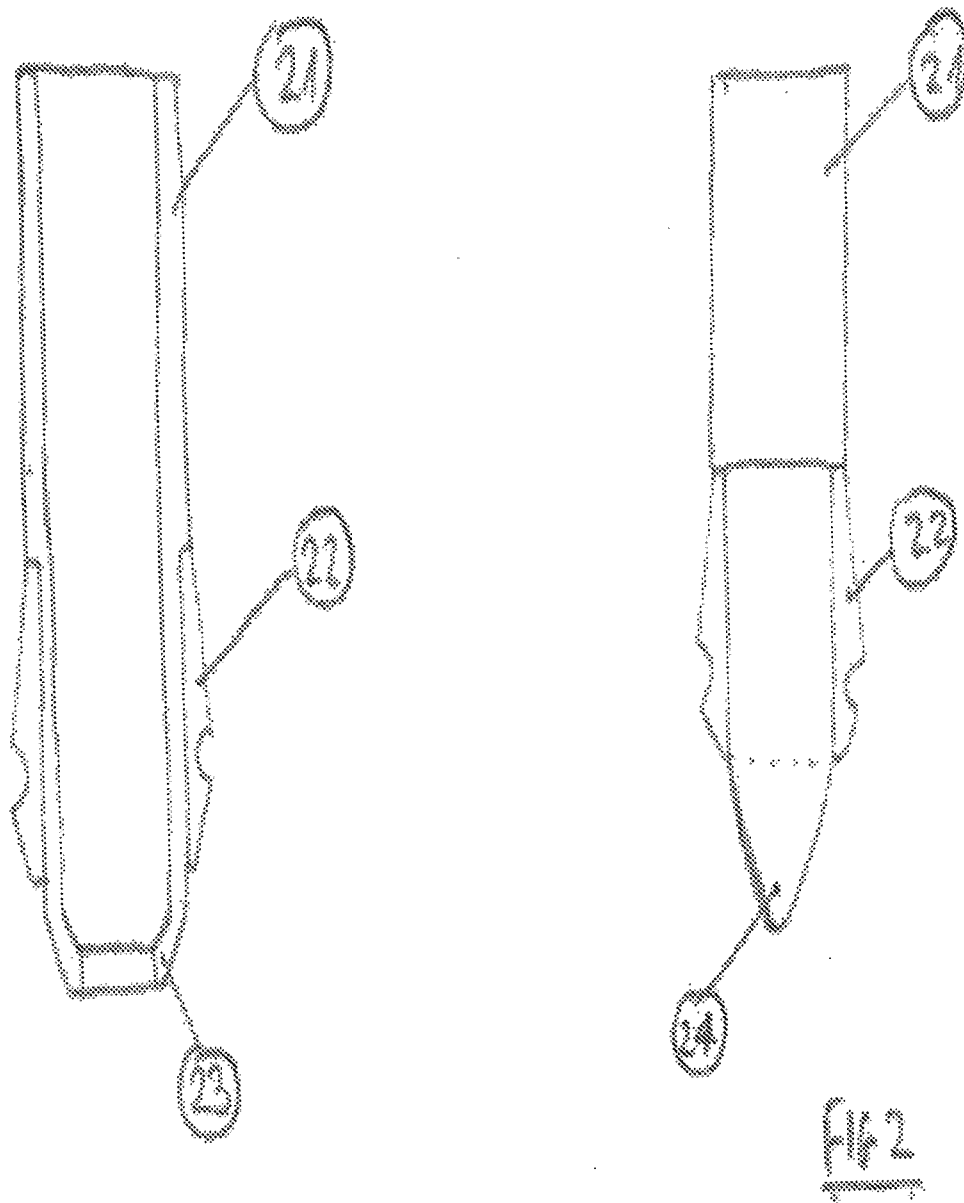


Figure 3

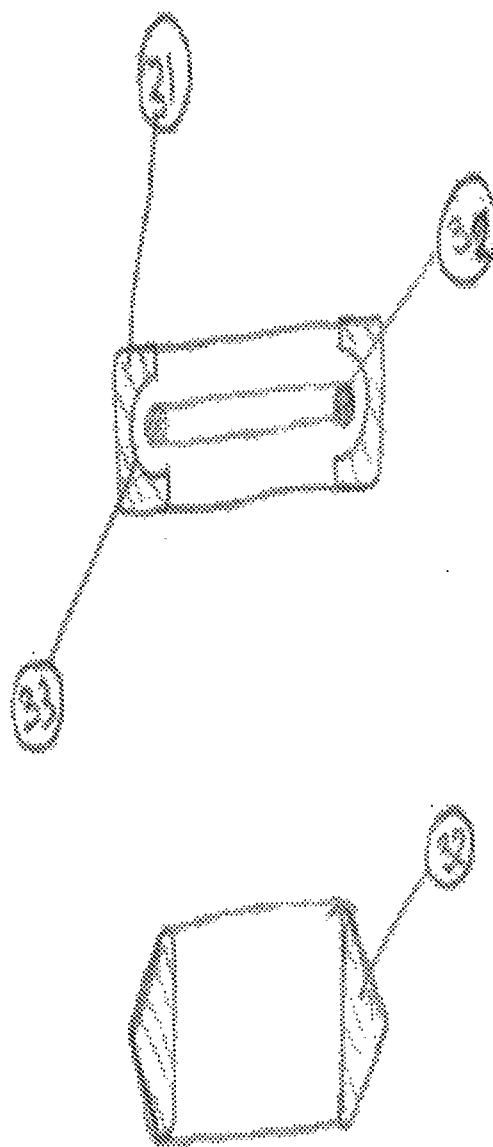
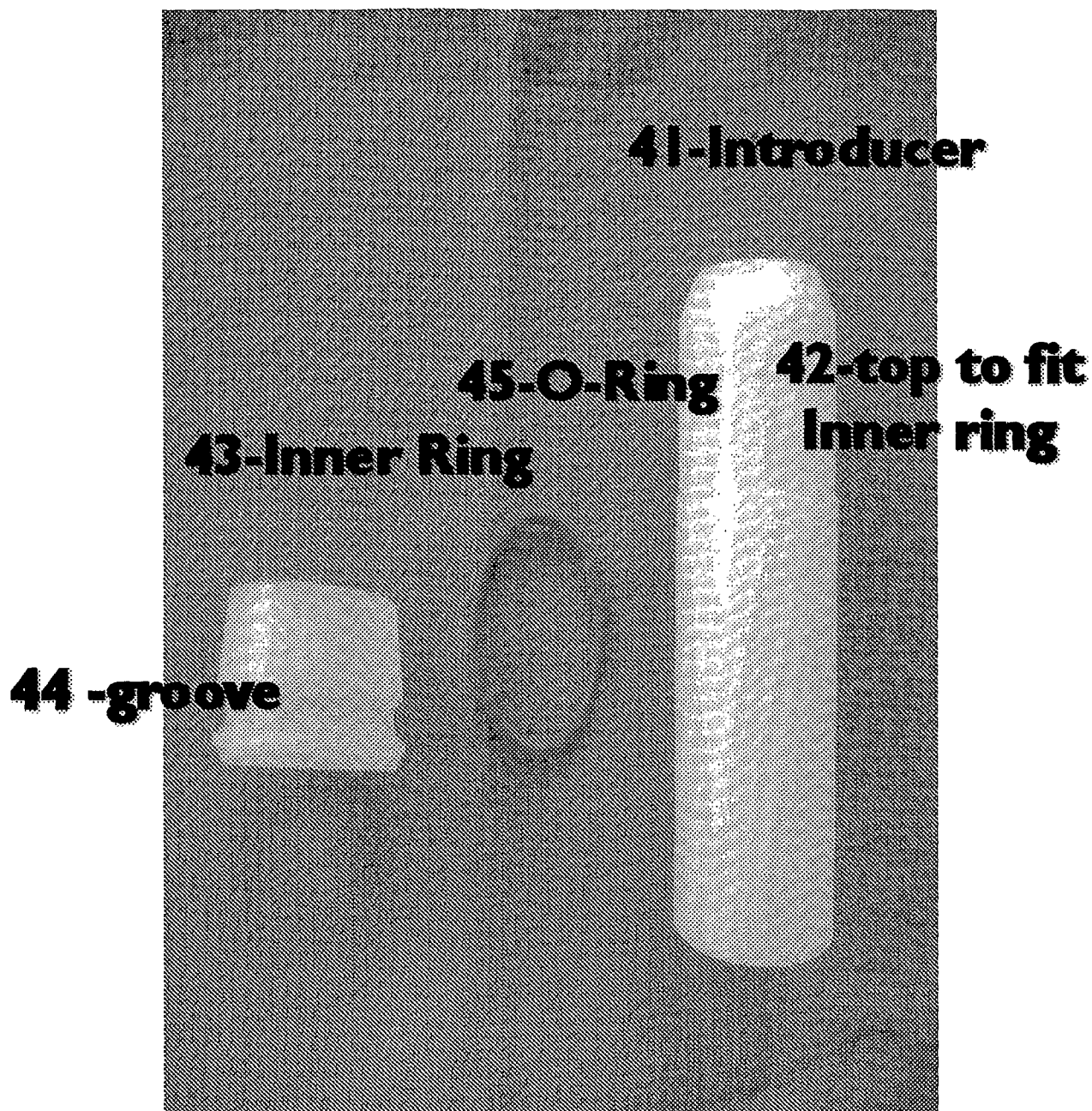
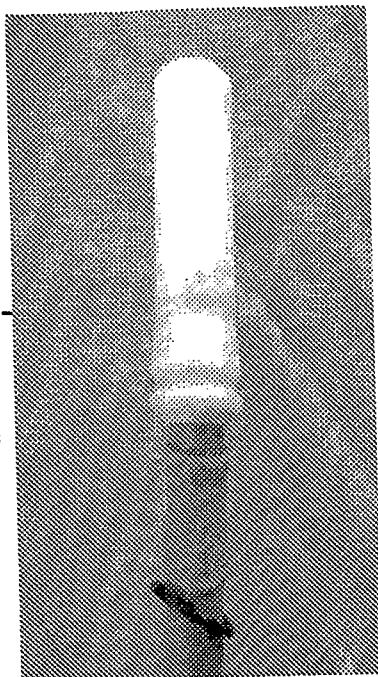


Figure 4- Circ Product Elements





51- Prepare
Foreskin



52-Place Circ



53-Apply Foreskin
Above Inner Ring.



54 Fasten O-Ring ,
initiating Necrosis
Process.



55- Fit the O-Ring
in the groove ,
initiating Necrosis
Process.



56- Remove
Introducer and
Wait 2 Days for
Foreskin to Fall

Diagram 6- Multiple sizes on one device

61- Device for multiple penis sizes (single unit design)

63- plastic selector

62- multiple sizes inner rings

64- multiple sizes o-rings

65- Plastic Ring to hold O-ring during deployment

Figure 7

