Abstract: A circumcision device comprises a support means having a glans penis locating portion locatable thereon, the glans penis locating portion having a first end and a second end, and a base portion being displaceably located on the support means, the base portion providing an opening through which the second end of the glans penis locating portion is locatable, and the base portion being displaceable between an open position and a closed position by an adjustment means; the first end of the glans penis locating portion providing an opening through which a glans penis is locatable, and over which a prepuce of a located glans penis is foldable; a prepuce crushing area of a located glans penis being defined between a prepuce crushing surface at the first end of the glans penis locating portion and a corresponding base portion prepuce crushing surface on the base portion; at least one operating mechanism of the adjustment means being operable to apply a crushing force to the prepuce crushing area, the operating mechanism of the adjustment means being able to be disabled by at least one disabling means; and the disabling means allowing the adjustment means to be disabled with a single application of the circumcision device.
Universal Circumcision Device

Technical field

[0001] The invention relates to a circumcision device. More particularly, the invention relates to a universal circumcision device, which is a single-use device.

Background art

[0002] The reasons for performing the surgical procedure of circumcision are varied, certain of which are for religious reasons and others are for its health benefits. One of the health benefits of circumcision has been the proven reduction of the incidence of HIV infections by 70%. In a country such as South Africa, for example, which currently has the highest prevalence of HIV in the world, it has been estimated that one new HIV infection can be prevented for every 3 to 4 circumcision procedures performed. Apart from reducing the chances of contracting HIV when a male patient has been circumcised, circumcision also includes further public health benefits such as, for example, reducing cervical cancer in women, reducing prostate cancer in the male patient, and reducing the transmission of sexually transmitted diseases (STD's), amongst others.

[0003] The circumcision device of the present invention and prior art circumcision devices, such as the Plastibell, ShangRing, Prepex, AlisKlamp, Gomco clamp and SmartKlamp all achieve circumcision in a similar manner by isolating the prepuce (or foreskin) of the glans penis of a male patient, and applying pressure to the prepuce to form a crush line. The prior art devices, however, do not have, or have only a minimal feature, for adjusting the amount of mucosa and prepuce to be removed adequately.

[0004] The above mentioned prior art circumcision clamps and rings are constructed from either steel, such as in the Gomco clamp, or from plastic. They are designed for the healthcare practitioner to position the prepuce over one component and engage a locking mechanism on a companion component. When the locking mechanism is engaged, the prepuce is crushed between the plastic components, except in the case of the Gomco clamp, where the prepuce is crushed between its steel components. This crushing action causes
ischaemic necrosis of the distal remaining part of the prepuce, ischaemic necrosis being the dying of live tissue by the cutting off of the blood supply to the tissue.

[0005] The overall design of the bell shaped prior art plastic circumcision devices and the steel Gomco clamp is similar. However, there are differences in the application of the circumcision, such as in the case of the plastic devices and the steel Gomco clamp, where the prepuce is pulled over a bell-shaped component. Conversely, in the case of the Plastibell device, crushing is accomplished with a piece of string, and with the PrePex device, crushing is achieved with an elastic band (elastator). In further contrast, the ShangRing uses its companion part for crushing.

[0006] The ShangRing device consists of two parts comprised of an inner and an outer ring, and each of these parts has two halves. The inner ring is placed over the glans penis, at the level of the coronal sulcus. The prepuce is everted (folded back) over the inner ring, and after a releasing incision, the outer ring halves are locked together, crushing the prepuce between the two rings.

[0007] All of the above mentioned prior art devices, except for the Gomco clamp, must remain on the patient for between 5 to 7 days, after which the patient has to return to have the device removed. In the case of the Gomco clamp the device is removed after crushing, and with adults it is also sutured. The Plastibell is only used with children, and the string and ring fall away after approximately 5 days.

[0008] With the plastic Klamp devices and rings, a wide necrotic (dead tissue) band develops at the crushing area, and this wide necrotic band falls off after about 7 to 10 days. In this case, therefore, healing is by secondary intention and takes much longer, for example, from 6 to 8 weeks.

[0009] The present invention provides for a circumcision device and circumcision technique, which results in a narrow crush area on the prepuce and this allows for relatively faster healing that takes place between 3 to 4 weeks. In addition, the healing obtained with the current invention is by primary intention and not by secondary intention, as is the case with the above mentioned prior art devices.
Further, the present invention provides a single use device which prevents the misuse thereof by untrained medical professionals and which prevents the potential spread of disease from uncontrolled or unsupervised multiple use of the device.

Disclosure of the invention

According to a first aspect of the invention there is provided a circumcision device comprising:

- a support means having a glans penis locating portion locatable thereon, the glans penis locating portion having a first end and a second end, and a base portion being displaceably located on the support means, the base portion providing an opening through which the second end of the glans penis locating portion is locatable, and the base portion being displaceable between an open position and a closed position by an adjustment means;

- the first end of the glans penis locating portion providing an opening through which a glans penis is locatable, and over which a prepuce of a located glans penis is foldable;

- a prepuce crushing surface being defined at the first end of the glans penis locating portion, the base portion being in the closed position when it is located in proximity to the prepuce crushing surface at the first end of the glans penis locating portion;

- a base portion prepuce crushing surface being provided on the base portion, the base portion prepuce crushing surface corresponding to the prepuce crushing surface at the first end of the glans penis locating portion, the base portion prepuce crushing surface being located on a surface of the base portion in proximity to the opening in the base portion;

- the prepuce crushing area of a located glans penis having its prepuce foldable over the first end of the glans penis locating portion, being defined between the prepuce crushing surface at the first end of the glans penis locating portion and the corresponding base portion prepuce crushing surface on the base portion;

- at least one operating mechanism of the adjustment means being operable to apply a crushing force to the prepuce crushing area, the
operating mechanism of the adjustment means being able to be disabled by at least one disabling means; and
- the disabling means allowing the adjustment means to be disabled with a single application of the circumcision device.

[0012] Preferably the prepuce crushing area is substantially narrow and the crushing force appliable to the substantially narrow prepuce crushing area enables the prepuce to be removable within a substantially short time after the crushing force is applied.

[0013] It will be understood that the amount of prepuce selected for removal is adjustable and that it is this selected amount of prepuce that is removable. It will further be understood that the removal of the selected prepuce within the substantially short time after crushing allows the patient to be able to heal by primary intention.

[0014] The glans penis locating portion preferably has a tubular shape, and a folded prepuce is locatable over the outer surface of the glans penis locating portion. It is further preferable that a folded prepuce is at least locatable over a bell shaped portion of the outer surface of the glans locating portion.

[0015] In one form of the invention the prepuce crushing surface on the glans penis locating portion is located on the outer surface of the tubular shaped glans penis locating portion in proximity to its first end. Further in this form of the invention, the base portion prepuce crushing surface is preferably located substantially at the rim of the opening in the base portion through which the second end of the glans penis locating portion is locatable and the base portion prepuce crushing surface is at an angle of substantially twenty degrees to the upper surface of the base portion.

[0016] Preferably the base portion is displaceable within a substantially limited range when the operating mechanism of the adjustment means is disabled by the disabling means.

[0017] In the preferred form of the invention the amount of prepuce that is to be selected for removal is adjustable. Preferably, the substantially limited range of displacement of the base portion before the crushing force is applied provides a
user with the ability to make adjustments to the amount of prepuce that is to be selected for removal.

[0018] Further according to the invention, the desired amount of mucosa for removal may be selected. The selection may be made prior to applying the crushing force to the substantially narrow prepuce crushing area.

[0019] It will be understood that the circumcision device provides an adjustment means for adjusting a base portion and for adjusting the crushing force applied to a chosen crushing area on a prepuce of a glans penis of a patient, the adjustment means being capable of being disabled with a single application of the circumcision device, thus causing the circumcision device to be inoperable after a single application.

[0020] In one form of the invention at least a portion of the circumcision device is made of a clear or transparent material, allowing a user to see though it. Preferably the glans locating portion of the circumcision device is made of a transparent material. Even further, the transparent material is preferably lightweight, such as, for example, a plastic material.

[0021] Preferably at least a portion of the base portion of the circumcision device is made of a metal material, such as, for example stainless steel.

[0022] In a further form of the invention there may be two adjustment means. Preferably the two adjustment means are located at opposing ends from one another, each adjustment means including an elongate member which is extendable between at least the base portion and the support means. Further, the adjustment means is preferably adjustable so that the base portion may be displaceable between an open position and a closed position. Preferably the adjustment means includes an operating mechanism which includes a screw type operation. The operating mechanism may further include a disabling means. The disabling means may comprise a terminal retracting position, the terminal retracting position being a position beyond where the operating mechanism of the adjustment means is non-retractable. The operating mechanism of the adjustment means may be further adjustable beyond the terminal retracting position within a substantially limited adjustment range.
Further according to the invention, the second end of the glans penis locating portion may include a non-return portion that may provide that the glans locating portion is securable on the support means. Preferably the non-return portion comprises a flaring section, the flaring section being outwardly extendable on the support means when the glans penis locating portion is located on the support means, and thereby allowing the glans penis locating portion to be securable on the support means. Preferably the glans penis locating portion further includes a stop means, the stop means being insertable into the second end of the glans locating portion. It will be understood that the stop means provides a way in which the glans penis locating portion is prevented from being removed from the support means once the flaring section of the non-return portion is extended outwardly on the support means, by preventing the flaring sections from being retractable.

Even further according to the invention the support means may be substantially flexible and the adjustment means may be substantially flexible. In this form the preferably elongate member of each adjustment means is substantially flexible. This flexibility enables each elongate member of each adjustment means, as well as the support means, to be bendable under the force appliable to the adjustment means. In this form of the invention the elongate member of each adjustment means is bendable and the support means is bendable when the device is displaceable from the open position to the closed position and as a crushing force is appliable to the prepuce crushing area of a located prepuce of a glans penis. The elongate member of each adjustment means and the support means are resiliently able to return to their unbended states once the locating portion with the located circumcised glans penis has been removed from the device. In this form the elongate members of the adjustment means are extendable at a distance substantially further from the support means than before the device was used, due to the adjustment means having reached the terminal retracting position, and the operating mechanism of the adjustment means no longer being retractable. In this way, the locating portion of the device is no longer locatable in the device, as the operating mechanism is no longer retractable. The reason is that the locating portion is no longer extendable
between the base portion and the support means, and is thus no longer locatable on the support means, resulting in the device is thus being unusable after a single use.

[0025] According to a second aspect of the invention there is provided a method of circumcision using a circumcision device according to the first aspect of the invention, the method comprising:

- locating a glans penis into the first end of the glans penis locating portion of the circumcision device;

- folding the prepuce of the located glans penis over the first end of the locating portion, and locating the prepuce over the outer surface of the glans locating portion;

- adjusting the prepuce to the desired position;

- adjusting the base portion located on the support means between an open position and a closed position by an adjustment means, the base portion being in the closed position when it is located in proximity to the first end of the glans penis locating portion;

- disabling the adjustment means so that the operating mechanism of the adjustment means is non-retractable;

- applying the desired crushing force upon the prepuce in the prepuce crushing area by means of the adjustment means and crushing the prepuce along the prepuce crushing area, the prepuce crushing area being defined between the prepuce crushing surface at the first end of the glans penis locating portion and the corresponding base portion prepuce crushing surface on the base portion, the crushing force applied to the prepuce crushing area being adjustable by means of the adjustment means;

- cutting the prepuce of the glans penis along a cutting area, the cutting area being defined in proximity to the prepuce crushing area;

- displacing the glans locating portion with the circumcised glans penis from being secured on the support means; and

- removing the circumcised glans penis from the glans penis locating portion.
[0026] The method according to the invention, may further include locating the glans penis locating portion on the support means and securing the glans penis locating portion with the located glans penis on the support means.

[0027] In one form of the invention the method may further comprise removing the cut portion of the prepuce from the circumcision device. Preferably the prepuce crushing area is substantially narrow and the crushing force appliable to the substantially narrow prepuce crushing area enables the prepuce to be removable within a substantially short time after crushing.

[0028] The amount of prepuce that is to be selected for removal may be adjustable. Preferably, the substantially limited range of displacement of the base portion before the crushing force is appliable allows the amount of prepuce that is to be selected for removal to be adjustable.

[0029] According to the method of invention, the amount of mucosa that may be selected for removal is adjustable. This selection of the amount of mucosa required for removal may be made prior to applying the crushing force to the substantially narrow prepuce crushing area.

[0030] It will be understood that the method of circumcision using a circumcision device according to the first aspect of the invention, allows for selection of the desired crushing area and cutting area by the adjustment of the device when applied to a patient and by adjustment of the located prepuce, and for prevention of tampering by a patient once the desired crushing area and cutting area have been selected. It will further be understood that the circumcision device can only be used by permanently disabling the device and the device is therefore not able to be re-used.

[0031] **Brief description of the drawings**

[0032] The invention will now be described in more detail with reference to the accompanying drawings wherein:

Figure 1 shows an isometric view of a circumcision device in an open position according to an embodiment of the invention;

Figure 2 shows an isometric side view of the circumcision device in an open position as shown in Figure 1;
Figure 3 shows an isometric end view of the circumcision device in an open position as shown in Figure 1;
Figure 4 shows an isometric view of a circumcision device in a closed position according to an embodiment of the invention;
Figure 5 shows a side view of the circumcision device in a closed position as shown in Figure 4;
Figure 6 shows an end view of the circumcision device in a closed position as shown in Figure 4;
Figure 7 shows an isometric view of a support means of the circumcision device according to an embodiment of the invention;
Figure 8 shows a side view of the support means of Figure 7;
Figure 9 shows a side view of the support means along A-A of Figure 8;
Figure 10 shows a top view of a support means of Figure 7;
Figure 11 shows an isometric view of a part of an adjustment means of the circumcision device according to an embodiment of the invention;
Figure 12 shows a side view of the part of the adjustment means of Figure 11;
Figure 13 shows an isometric view of a clip of the adjustment means of the circumcision device according to an embodiment of the invention;
Figure 14 shows a top view of the clip of Figure 13;
Figure 15 shows a side view of the clip of Figure 13;
Figure 16 shows an isometric view of a base portion of the circumcision device according to the invention;
Figure 17 shows a top view of the base portion of Figure 16;
Figure 18 shows a sectioned side view of the base portion along B-B of Figure 17;
Figure 19 shows an expanded sectioned side view of the base portion at C of Figure 18;
Figure 20 shows an isometric view of a glans penis locating portion according to an embodiment of the invention;
Figure 21 shows a top view of the glans penis locating portion of Figure 20;
Figure 22 shows a side view of the glans penis locating portion of Figure 20, from one side;
Figure 23 shows a side view of the glans penis locating portion of Figure 20, from the other side to that of Figure 22; Figure 24 shows an isometric view of a stop means according to an embodiment of the invention; Figure 25 shows a top view of the stop means of Figure 24; Figure 26 shows a side view of the stop means of Figure 24; Figure 27 shows a side view of a portion of a support means in an open position and a portion of an adjustment means according to an embodiment of the invention; Figure 28 shows a sectioned side view along D-D of the portions of Figure 27; Figure 29 shows an expanded sectioned side view at E of Figure 28; Figure 30 shows a side view of a portion of the support means in a closed position and a portion of an adjustment means according to an embodiment of the invention; Figure 31 shows a sectioned side view along F-F of the portions of Figure 30; Figure 32 shows an expanded sectioned side view at G of Figure 31; Figure 33 shows a side view of the circumcision device in a closed position according to a further embodiment of the invention; Figure 34 shows a perspective view of a circumcision device according to an even further embodiment of the invention; Figure 35 shows a schematic side view of the circumcision device of Figure 34 in an open position; and Figure 36 shows a schematic side view of the circumcision device of Figure 34 in a closed crushing position.

**Detailed description of the invention**

[0033] A circumcision device 10 according to an embodiment of the invention is shown in Figures 1 to 6. Circumcision device 10 comprises a support 12 and a base portion in the form of a crushing base plate 14. Support 12 includes a glans penis locating portion in the form of a locating tube 16 located thereon, tube 16 having a first end 18 and a second end 20. Base plate 14 is displaceably located on support 12, and has an opening 22 therein through which the second end 20 of locating tube 16 is locatable. Base plate 14 is displaceable by an
adjustment means 24 between an open position as shown in Figures 1 to 3 and Figures 27 to 29, and a closed position as shown in Figures 4 to 6 and Figures 30 to 33.

[0034] Circumcision device 10 is preferably mostly made of a clear or transparent material, allowing a user to see though it, and in certain circumstances device 10 may be made of a transparent material in order to make it easier for visibility during use of the device. The material used to manufacture circumcision device 10 is also preferably of a light weight, such as, for example a plastic material. In particular, tube 16 is preferably made of a clear see-through or transparent material with a bell shape 44 at its first end 18. An exception to the material preferably being of a clear or transparent is that base plate 14 is preferably made of a metallic material such as, for example, stainless steel, although it may also be made of a light weight material such as, for example, a plastic material.

[0035] The present invention seeks to provide a safer, more cost effective method of circumcision, and the circumcision device of the invention provides an adjustable application for the adequate removal of mucosa and skin of the prepuce (foreskin) of a glans penis, which is important in the prevention of infection by the HIV virus. The present invention also requires the minimum amount of additional instruments to be used, and these include mosquito forceps, if necessary, and a scalpel blade. Being preferably an assembled single unit, other than the removable glans penis locating tube 16, as opposed to other prior art devices, assists in the elimination of errors in application and eases teaching of the use of the device to healthcare professionals. The present device has a glans penis locating tube 16 that may be of clear material, and is preferably completely transparent (see-through), thus allowing for the control and adjustment of the adequate amount of mucosa and prepuce that is to be removed by the healthcare professional during the circumcision surgical procedure. There is a minimal crushing area (less than 2.5 mm) facilitating healing by primary intention (in 3 to 4 weeks), unlike use with other devices that allow for healing by secondary intention (in 6 to 8 weeks) with a thick (4 to
5mm) crushing surface and an increase in the chances of infection during the healing process.

[0036] The circumcision technique that is used with the circumcision device 10 of the present invention is safe, bloodless, and sutureless, and was developed according to the recommendations of the WHO guidelines' framework of male medical circumcision devices. Healing of the wound is by primary intention, which is faster than secondary intention, gives cosmetically superior results, and eliminates the need for patients to have to return approximately one week after the initial procedure is done for removal of the device. In contrast, the patients who have been treated with the Prepex, ShangRing, and other plastic prior art circumcision devices that are currently viable, are required to return approximately one week after the initial procedure is done, for removal of the device.

[0037] In addition to the above features of the circumcision device and method of circumcision of the present invention, the device of the present invention is also well suited for up-scaling circumcisions in resource limited settings, due to its quick and easy application.

[0038] Adjustment means 24 of circumcision device 10 as shown in the accompanying figures comprises two elongate members having elongate adjusting screw sections 26, two clips 28 and two operating handles 27. The arrangement of the support 12, base plate 14, tube 16; and the two elongate adjusting screw sections 26, two clips 28 and two operating handles 27 being located in support 12, when all assembled and used in the circumcision procedure, results in the prepuce (foreskin) of the glans penis of a patient being easily adjustable to the correct position for the desired amount of the prepuce to be removed by circumcision.

[0039] The threads of the screw sections 26 are angled in order to provide gradual compression of prepuce by means of the crushing base plate 14. This also allows for easier adjusting of mucosa, without losing a marked position of outer skin at the level of the corona. Additionally, this allows for the removal of an adequate amount of mucosa during the circumcision surgical procedure.
[0040] A prepuce crushing surface 30 is defined at the first end 18 of tube 16. A base portion prepuce crushing surface 32 is provided on base plate 14 and is preferably at an angle of substantially 20 degrees to the upper facing surface 33 of the base plate 14. The crushing surface 32 corresponds to the crushing surface 30, and as shown in the accompanying figures, crushing surface 32 is located on the upper facing surface 33 of base plate 14 that is in proximity to the opening 22 of base plate 14. The crushing area 34 is defined between crushing surface 30 and the corresponding crushing surface 32, when the base plate 14 is in the closed position, as shown in Figures 4, 5 and 6. Operating handles 27 located at the ends of each of the adjusting screws 26 are operable by a user to apply the required adjustable crushing force to the crushing area 34.

[0041] Crushing surface 30 on tube 16 is perfectly matched to the crushing surface 34 on base plate 14. The result of this is that the application of a crushing force to a portion of a prepuce located in the crushing area 34 enables complete haemostasis by equal circumferential compression of the crushed area of the prepuce. If the circumcision device 10 is left on the patient, and correctly applied and positioned, it will not dislodge spontaneously, and has minimal interference with daily activities due to its design, construction and light weight.

[0042] The relative distance between base plate 14 and support 12 is adjustable by means of the adjustment means 24. In this way support 12 is displaceable between an open position as shown in Figures 1, 2 and 3, and a closed position as shown in Figures 4, 5 and 6, the closed position being the crushing position. The operating mechanism of adjustment means 24 includes an elongate screw section 26, a clip 28 and an operating handle 27 being located on support 12. As shown in the accompanying figures, the two screw sections 26 and two clips 28 of the two adjustment means 24 are each located in one of the side sections 29 of support 12. In Figures 28, 29, 31 and 32, each of the clips 28 can be seen to be located in a narrow section 31 of the elongate screw section 26 of each adjustment means 24.

[0043] A combination of the design features of the narrow section 31 and the grooves on the clips 28 that are located in the narrow section 31 comprises a disabling
means for the operation of each adjustment means 24. This disabling means comprises a terminal retracting position, which is a position beyond where the operating mechanism of the adjustment means is non-retractable. When a user adjusts the adjustment means 24 from the open to the closed position by turning on the operating handles 27, each of the elongate screw sections 26 are caused to move relatively upwardly into its related side section 29 of the support means 12, and towards the direction of the attached base plate 14. This then also moves the narrow section 31, having the clip 28 located thereon, relatively upwardly into the related side section 29 and toward the direction of the attached base plate 14. This movement continues until it reaches a point where a protruding section 35 of the side section 29 is located into a recess 36 of the clip 28, resulting in the adjustment means 24 no longer being able to be retracted, as section 35 cannot then be removed from being located in recess 36. Within this terminal retracting position further adjustment of adjustment means 14 may be possible over a substantially small limited adjustment range, as there is a relatively small space provided for this by there being a small space for movement of section 35 possible while it is located inside recess 36.

[0044] Circumcision device 10 ensures that the glans penis and the penis shaft are completely protected during the application and removal process of the prepuce. It is preferable if device 10 does not need to be left on the patient, as it is preferred that the device is removed within a substantially short time after the crushing force is applied such as, for example, after approximately 5 minutes or slightly longer if required. If, however, it is left on the patient for a much longer period of time such as, for example, 4 days, any pain experienced by the patient on removal is minimal to non-existent. An advantage provided by the use of device 10 is that there is a significantly reduced risk of infection with quicker healing, due to device 10 having a narrow crushing ring design.

[0045] Further stability is provided in device 10 by a non-return portion in the form of two flared sections 38 being located at the second end 20 of tube 16. Once tube 16 has been inserted through opening 22 of base plate 14 and a through opening 40 in support 12, the flared sections 38 secure tube 16 to support 12 by flaring and extending outwardly, thus gripping the underside of support 12 and
preventing removal of tube 16. In addition, a stop 42 comprising a tube having a rimed outer edge may be provided at the second end of tube 16. When inserted at the second end of tube 16, this stop 42 prevents the flared sections 38 from extending back inwardly and thus prevents tube 16 from being pulled out of opening 40 in support 12, while device 10 is being used. This also prevents tube 16 from being removed from support 12 until such time as stop 42 is again removed.

[0046] Removal of device 10 from a patient is simple and requires stop 42 to be removed, flared sections 38 to be pushed inwardly, and tube 16 to be pulled out of support 16 and base plate 14. As the adjustment means 24 is no longer retractable after it has been used, device 10 is not re-usable and has been permanently disabled; unlike in other prior art circumcision devices.

[0047] A further embodiment of device 10, as shown in Figure 33, comprises device 10 having a secondary disabling mechanism. In this embodiment support 12 is substantially flexible and the two elongate members of the adjustment means 24 are also substantially flexible. This flexibility enables each of the elongate members of adjusting means 24, as well as support 12, to be slightly bendable under the force applied to the adjustment means 24, as shown by lines J and K, respectively, in Figure 33. Both the elongate members of the adjustment means 24 and support 12 are slightly bendable in this way when device 10 is used in a circumcision application, and base plate 14 is displaced from the open position to the closed position and a crushing force is applied to the prepuce crushing area 34 of a located prepuce. Once the located prepuce has been crushed and then cut, and tube 16 with the circumcised glans penis located therein has been removed from the device, the elongate member of each adjustment means 24 and support 12 is able to return to its unbended state due to its resilience. The result of this is that the elongate members of the adjustment means 24 are now extended to a further distance from the support 12 than they were before device 10 was used in a circumcision application, due to the adjustment means 24 having reached the terminal retracting position, as described above, and the operating mechanism of the adjustment means 24 thus no longer being retractable. In this way, tube 16 of device 10 is no longer locatable in the device.
as it can no longer extend between the base plate 14 and the support 12, and is also thus not securable to support 12. The result of this being that tube 16 is no longer locatable in support 12 with the flared sections 38 no longer being able to secure tube 16 to support 12. This then further ensures that device 10 is thus further disabled and unusable after one circumcision application of the device.

[0048] The method of circumcision by using a circumcision device 10 in a further embodiment of the invention comprises removing the prepuce (foreskin) of a male penis of various sizes, from infant and child sizes, to various adult sizes. This method is now further described with reference to Figures 1 to 6. The glans penis (the head) of the penis is inserted into the bell shape 44 of tube 16, as indicated by arrow H. The prepuce is folded or pulled over tube 16, and then pulled through the crushing base plate 14 and through opening 22 of support 14, as indicated by arrows i. During application, prepuce is easily adjustable to the correct position around the outer surface of tube 16, with a minimum amount of instruments being needed, at most a curved mosquito/straight artery, if at all. The threads of screw sections 26 of the adjusting means 24 are angled in order to provide gradual compression of the prepuce, allowing for easier adjusting of mucosa, without losing a marked position of the outer skin at the level of the corona. The crushing area 34 defined by the crushing surface 32 on the crushing base plate 14 is narrow, allowing for better healing by primary intention. Primary healing is quicker, creates less necrotic tissue, and leaves less chance for infection. The crushing surface 30 on tube 16 is perfectly matched to the crushing surface on the corresponding crushing surface 32 on base plate 14; hence applying a crushing force to the defined crushing area 34 ensures complete haemostasis by equal circumferential compression. In addition, applying the crushing force by the adjustment means 24 also causes the elongate members of the adjustment means 24 to bend slightly outwards under the pressure, and the support 12 to bend slightly away from base plate 14 under the pressure, as shown by lines J and K, respectively, in Figure 33.

[0049] Once the circumcision device 10 is in the closed position, as shown in Figures 4, 5 and 6, the screw sections 26 of adjustment means 24 have been moved relatively upwardly into the side section 29 of support 12. The narrow section
31, having the clip 28 located thereon, has thus also then been moved relatively upwardly into the side section 29 until it has reached a point where a protruding section 35 of the section 29 fits into a recess 36 of the clip 28. This results in the adjustment means 24 no longer being able to be retracted. When this terminal retracting position has been reached, further adjustment of the adjustment means 24 may be possible over a small adjustment range as there is a relatively small space provided for this. These small adjustments are then used to ensure that the correct pressure is applied on the prepuce skin via the required force being applied to the crushing base plate 14 by the adjustment means 24, as each individual patient's prepuce skin may be different from another's. This in turn allows for the removal of an adequate amount of mucosa, which is crucial in providing protection against HIV and other STD's.

[0050] For additional stability to be provided during the procedure undertaken with the use of device 10, once tube 16 with the inserted glans penis located therein has been inserted through opening 22 of base plate 14 and through opening 40 in support 12, the flared sections 38 on tube 16 secure it to support 12 by flaring and extending outwardly, and thus gripping the underside of support 12. Additionally, a stop 42 comprising a tube having a rimed outer edge is then inserted at the second end of tube 16. This inserted stop 42 prevents the flared sections 38 from extending back inwardly and thus prevents tube 16 from being pulled out of opening 40 in support 12 while the procedure is being undertaken. This also prevents tube 16 from being removed from the support 12 while the procedure is undertaken.

[0051] When all the adjustments required by the medical professional user are completed, the medical professional cuts down firmly on the prepuce and flush with crushing base plate 14 onto the bell shape 44 of the tube 16, making sure to protect the glans and shaft of the penis at all times. The applied cut to the prepuce can take place on a cutting line which is indicated by 46 in Figures 16 and 17. The device 10 has been designed to take into account the thicker prepuce in the African male population. The device thus makes use of the relative space between the location of the adjustment means 24 and the tube 16 in base plate 14 of device 10, making the application of device 10 easier and
allowing for easier cutting of the prepuce, with any size scalpel blade. The glans penis and the penis shaft are completely protected from any injury during the application and the removal process, unlike with the prior art ring devices.

Once device 10 is ready for removal, as in the recommended primary method of use, which is within a substantially short time after the crushing force is applied, such as, for example, within 5 minutes in which circumferential crushing is applied or slightly longer if required, stop 42 is removed from tube 16. The flared sections 38 of tube 16 are then pushed inwardly so that these flared sections 38 are no longer located on the underside of support 12. Tube 16 with the located and now circumcised glans penis is then removed through opening 22 of device 10. The pain on removal is minimal to non-existent, due to the narrow crushing line made by the crushing base plate design and the contour of the bell part of the device. Device 10 is preferably removed after approximately 5 minutes, as recommended, followed by the crushing line-being-covered-by-a-liquid wound dressing being applied which then dissolves over time while the wound heals. Alternatively, device 10 may be left on for 4 days if this is preferred, before removal.

Device 10 is not re-usable after use, due to the terminal retracting position of the adjustment means 24 being reached during use of the device, and further due to the combination of the flexible nature of the elongate members of the adjustment means 24 and the support 12 returning to their unbent shapes after use of the device, and thus causing tube 16 no longer to be locatable on support 12. Device 10 is thus truly a single use circumcision device.

An even further embodiment of the invention as shown in Figures 34, 35 and 36 comprises a circumcision device 50 that is a single unit. Circumcision device 50 is preferably made of a clear or transparent material, allowing a user to see though it and increasing visibility during use of the device. The material used to manufacture circumcision device 50 is preferably of a light weight, such as, for example a plastic material.

Like reference numerals used in the accompanying figures which refer to the various embodiments of device 10 are also used to designate like parts of device 50 in Figures 34, 35 and 36.
The distinguishing features of device 50 are that locating tube 16 is located on, and forms part of, support 12. Further, adjustment means 24 of circumcision device 50 comprises two adjusting screws 52 and 54. The arrangement of the support 12, base plate 14, tube 16 and the adjusting screws 52, 54 when assembled, results in the prepuce (foreskin) of the glans penis of a patient to be easily adjustable to the correct position for the desired amount of the prepuce to be removed by circumcision. The threads of adjusting screws 52, 54 are angled laterally outwards, in order to provide gradual compression of prepuce by means of the crushing base plate 14. This also allows for easier adjusting of mucosa, without losing a marked position of outer skin at the level of corona. Additionally, this allows for removing an adequate amount of mucosa which is selected during the circumcision surgical procedure.

In this further embodiment of the invention it will be noted that the crushing surface 30 of tube 16 follows the anatomical shape of the coronal rim of a typical glans penis, and that this shape includes the typical slanted shape of the coronal rim of a glans penis that is due to the frenulum. In the same way, base portion crushing surface 32 which corresponds to crushing surface 34 is also shaped to follow the anatomical shape of the coronal rim of a typical glans penis, and this shape thus also includes the typical slanted shape of the coronal rim of the glans penis that is due to the frenulum. The resultant crushing line obtained from the application of device 50 and the circumcision technique applied when using it thus leaves the generally more aesthetically pleasing V-shaped scar line on ventral surface of the penis of the patient.

The method of circumcision using circumcision device 50 is similar to that of the embodiment of the invention in device 10, with a few differences dictated by the features which distinguish it from device 10. The glans penis (the head) of the penis is inserted into the bell shape 44 as indicated by arrow L, which, in this further embodiment, is shaped according to the anatomical appearance of the glans shaped portion of the tube 16. The prepuce is folded or pulled over tube 16, and then pulled through the crushing base plate 14, as indicated by arrows M. As with device 10, during application, prepuce is easily adjustable to the correct position around the outer surface of tube 16, with a minimum amount of
instruments being needed, at most a curved mosquito/straight artery, if at all. The threads of adjusting screws 52, 54 are angled laterally outwards, in order to provide gradual compression of the prepuce, allowing for easier adjusting of mucosa, without losing a marked position of the outer skin at the level of the corona. The crushing area 34 defined by the crushing surface 32 on the crushing base plate 14 is narrow, allowing for better healing by primary intention. Primary healing is quicker, creates less necrotic tissue, and leaves less chance for infection. The crushing surface 34 on tube 16 is perfectly matched to the crushing surface on the corresponding crushing surface 32 on base plate 14, hence applying a crushing force to the defined crushing area 34 ensures complete haemostasis by equal circumferential compression.

[0059] Once the circumcision device 50 is in the closed position as shown in Figure 36, the flat parts of the operating mechanisms 56, 58 of the adjusting screws 52, 54 will snap off at position 60. This will happen when the correct pressure is applied on the prepuce skin via the required force being applied to the crushing base plate 14 by the adjustment means 24. This in turn allows for the removal of an adequate amount of mucosa, which is crucial in providing protection against HIV and other STD's. When all the adjustments required by the medical professional user are done, cutting of the prepuce can take place on a cutting line which is indicated by 62 in Figure 36. As with device 10, device 50 has been designed to take into account the thicker prepuce in the African male population. Device 50 thus makes use of the space between the adjusting screws 52, 54 and tube 16, making the application of the device 50 easier and allowing for easier cutting of the prepuce, with any size scalpel blade. The glans penis and the penis shaft are completely protected from any injury during the application and the removal process, unlike with the prior art ring devices. Removal of circumcision device 50 from a patient is simple and requires cutting of the adjusting screws 52, 54 at indicated positions 64, as shown in Figure 36. Further cutting out of sections 66 and 68 of the adjustment screws 52, 54, respectively, ensures that none of the components of the device 50 are re-usable after use. This results in device 50 being permanently disabled, as with device 10, and device 50 truly being a single use circumcision device.
Claims

1. A circumcision device comprising:
   - a support means having a glans penis locating portion locatable thereon, the
     glans penis locating portion having a first end and a second end, and a base
     portion being displaceably located on the support means, the base portion
     providing an opening through which the second end of the glans penis locating
     portion is locatable, and the base portion being displaceable between an open
     position and a closed position by an adjustment means;
   - the first end of the glans penis locating portion providing an opening through
     which a glans penis is locatable, and over which a prepuce of a located glans
     penis is foldable;
   - a prepuce crushing surface being defined at the first end of the glans penis
     locating portion, the base portion prepuce crushing surface in proximity to
     the prepuce crushing surface at the first end of the glans penis locating
     portion;
   - a base portion prepuce crushing surface being provided on the base portion, the
     base portion prepuce crushing surface corresponding to the prepuce crushing
     surface at the first end of the glans penis locating portion, the base portion
     prepuce crushing surface being located on a surface of the base portion in
     proximity to the opening in the base portion;
   - the prepuce crushing area of a located glans penis having its prepuce foldable
     over the first end of the glans penis locating portion, being defined between the
     prepuce crushing surface at the first end of the glans penis locating portion and
     the corresponding base portion prepuce crushing surface on the base portion;
   - at least one operating mechanism of the adjustment means being operable to
     apply a crushing force to the prepuce crushing area, the operating mechanism of
     the adjustment means being able to be disabled by at least one disabling means;
     and
   - the disabling means allowing the adjustment means to be disabled with a single
     application of the circumcision device.
2. A circumcision device as claimed in claim 1, wherein the prepuce crushing area is substantially narrow and the crushing force applicable to the substantially narrow prepuce crushing area enables the prepuce to be removable within a substantially short time after the crushing force is applied.

3. A circumcision device as claimed in claims 1 or 2, wherein the glans penis locating portion has a tubular shape having a bell shaped portion at its first end, and a folded prepuce is locatable over the outer surface of the bell shaped portion of the glans penis locating portion.

4. A circumcision device as claimed in any of claims 1 to 3, wherein the prepuce crushing surface on the glans penis locating portion is located on the outer surface of the tubular shaped glans penis locating portion in proximity to its first end.

5. A circumcision device as claimed in any of claims 1 to 4, wherein the base portion prepuce crushing surface is located substantially at the rim of the opening in the base portion.

6. A circumcision device as claimed in any of claims 1 to 5, wherein the base portion is displaceable within a substantially limited range when the operating mechanism of the adjustment means is disabled by the disabling means.

7. A circumcision device as claimed in any of claims 1 to 6, wherein the amount of prepuce that is to be selected for removal is adjustable.

8. A circumcision device as claimed in claim 7, wherein the substantially limited range of displacement of the base portion before the crushing force is applicable allows the amount of prepuce that is to be selected for removal to be adjustable.

9. A circumcision device as claimed in any of claims 1 to 8, wherein the amount of mucosa that is to be selected for removal is adjustable.

10. A circumcision device as claimed in any of claims 1 to 9, wherein there are two adjustment means located at opposing ends from one another, each adjustment means including an elongate member which is extendable between at least the base portion and the support means, and the adjustment means is adjustable so that the base portion is displaceable between an open position and a closed position.
11. A circumcision device as claimed in any of claims 1 to 10, wherein the adjustment means includes an operating mechanism, the operating mechanism further including a disabling means.

12. A circumcision device as claimed in claim 11, wherein the disabling means comprises a terminal retracting position, the terminal retracting position being a position beyond where the operating mechanism of the adjustment means is non-retractable.

13. A circumcision device as claimed in claim 12, wherein the operating mechanism of the adjustment means is further adjustable beyond the terminal retracting position within a substantially limited adjustment range.

14. A circumcision device as claimed in any of the preceding claims, wherein the second end of the glans penis locating portion includes a non-return portion that provides that the glans locating portion is securable on the support means.

15. A circumcision device as claimed in any of the preceding claims, wherein the support means is substantially flexible and the adjustment means is substantially flexible, and this flexibility enables the adjustment means, as well as the support means, to be bendable under a force appliable to the adjustment means.

16. A circumcision device as claimed in claim 15, wherein the adjustment means is bendable and the support means is bendable when the device is displaceable from the open position to the closed position and as a crushing force is appliable to the prepuce crushing area of a located prepuce of a glans penis.

17. A circumcision device as claimed in claim 16, wherein the adjustment means and the support means are resiliently able to return to their unbended states once the locating portion with the located circumcised glans penis has been removed from the device.

18. A circumcision device as claimed in claim 17, wherein the adjustment means is extendable at a distance substantially further from the support means than before the device was used, due to the adjustment means having reached the terminal retracting position, and the operating mechanism of the adjustment means no longer being retractable.
19. A circumcision device as claimed in claim 18, wherein the locating portion of the device is no longer locatable in the device as the operating mechanism of the adjustment means is no longer retractable.

20. A method of circumcision using a circumcision device according to claim 1, the method comprising:
- locating a glans penis into the first end of the glans penis locating portion of the circumcision device;
- folding the prepuce of the located glans penis over the first end of the locating portion, and locating the prepuce over the outer surface of the glans locating portion;
- adjusting the prepuce to the desired position and adjusting the amount of prepuce for removal;
- adjusting the base portion located on the support means between an open and a closed position by means of the adjustment means, the base portion being in the closed position when it is located in proximity to the first end of the glans penis locating portion;
- disabling the adjustment means so that the operating mechanism of the adjustment means is non-retractable;
- applying the desired crushing force upon the prepuce in the prepuce crushing area by means of the adjustment means and crushing the prepuce along the prepuce crushing area, the prepuce crushing area being defined between the prepuce crushing surface at the first end of the glans penis locating portion and the corresponding base portion prepuce crushing surface on the base portion, the crushing force applied to the prepuce crushing area being adjustable by means of the adjustment means;
- cutting the prepuce of the glans penis along a cutting area, the cutting area being defined in proximity to the prepuce crushing area;
- displacing the glans locating portion with the circumcised glans penis from being secured on the support means; and
- removing the circumcised glans penis from the glans penis locating portion.
21. A method as claimed in claim 20, which further includes locating the glans penis locating portion on the support means and securing the glans penis locating portion with the located glans penis on the support means.

22. A method as claimed in claims 20 or 21, wherein the prepuce crushing area is substantially narrow and the crushing force appliable to the substantially narrow prepuce crushing area enables the prepuce to be removable within a substantially short time after crushing.

23. A method as claimed in any of claims 20 to 22, wherein the amount of mucosa that is to be selected for removal is adjustable.
**INTERNATIONAL SEARCH REPORT**

**A. CLASSIFICATION OF SUBJECT MATTER**

INV. A61B17/326

ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database consulted during the international search (name of database and, where practicable, search terms used)

EPO-Internal, WPI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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**Further documents are listed in the continuation of Box C.**

**X** See patent family annex.

* Special categories of cited documents:

**A** document defining the general state of the art which is not considered to be of particular relevance

**E** earlier application or patent but published on or after the international filing date

**L** later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

**P** document published prior to the international filing date but later than the priority date claimed

**T** document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

**W** document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

**X** document member of the same patent family

Date of the actual completion of the international search

23 April 2014

Date of mailing of the international search report

30/04/2014

Name and mailing address of the ISA:
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016

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Column 1, line 60 - Column 2, line 69;  
Figures 1-3                                      | 1                    |
**INTERNATIONAL SEARCH REPORT**

**Box No. II**  
Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **[x]** Claims Nos.:  20-23  
because they relate to subject matter not required to be searched by this Authority, namely:  
   Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2.  

2.  

3.  

**Box No. III**  
Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  
   - As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2.  
   - As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of additional fees.

3.  
   - As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4.  
   - No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- The additional search fees were accompanied by the applicant’s protest and, where applicable, the payment of a protest fee.
- The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- No protest accompanied the payment of additional search fees.

Form PCT/ISA/21 0 (continuation of first sheet (2)) (April 2005)
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