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(54) **MECHANICAL GUN-TYPE CIRCUMCISION DEVICE WITH GLANS PROTECTION SYSTEM FOR SAFE CUTTING AND CAUTERIZATION OF THE FORESKIN**

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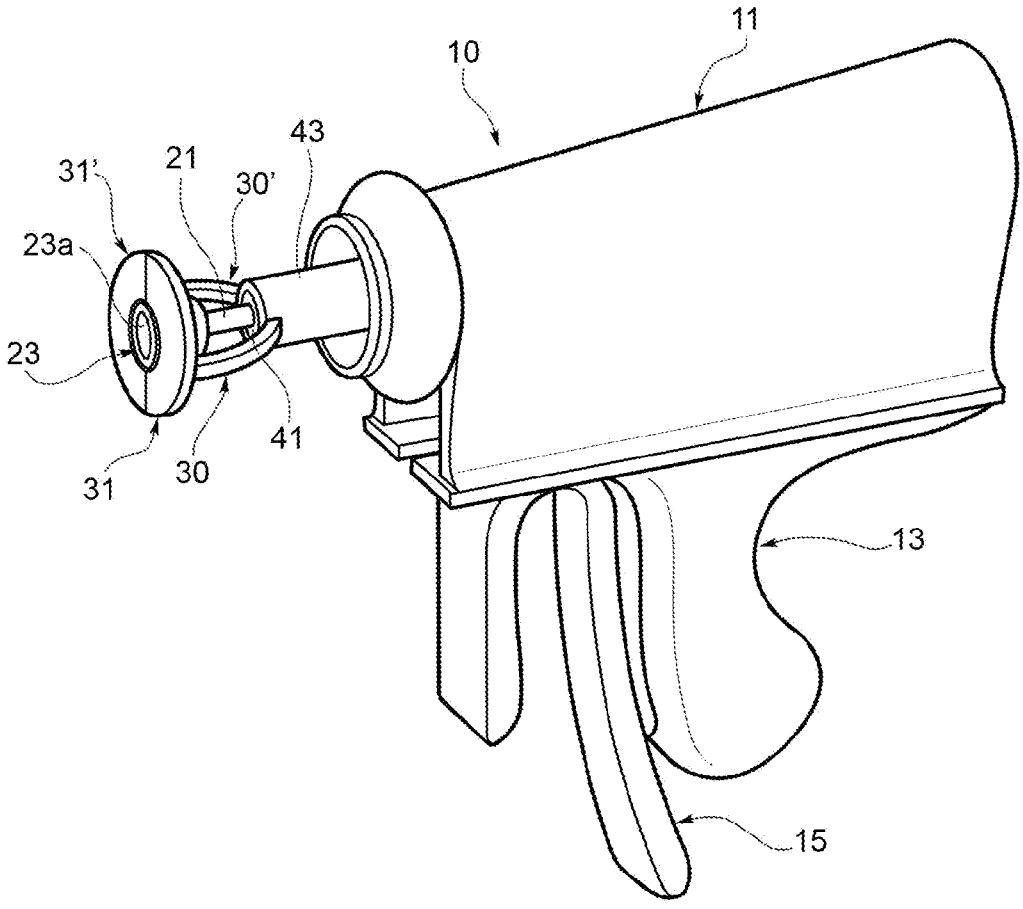
(57) **ABSTRACT**

Circumcision device including a housing (**10**) comprising a handgrip part (**13**) and a control member (**15**), a guide part (**20**) comprising a stem (**21**) and a shearing template (**23**) fixedly arranged on a distal end of the stem (**21**), said shearing template having a concave distal surface (**23***a*) and a side surface (**23***b*) tapered in the proximal direction, a pair of arms (**30**, **30'**), each having a distal end provided with a semi-annular blade (**31**, **31'**), each arm being rotatable about an axis (y, y') perpendicular to the extension direction of the stem (**21**), between an open position and a shearing position in which the semi-annular blades (**31**, **31'**) are closed to form a ring perpendicular to the extension axis of the stem (**21**) and have a cutting edge (**32**, **32'**) which engages the side surface (**23***b*) of the shearing template (**23**), and an actuating mechanism (**40**) for controlling rotation of the arms (**30**, **30'**) in response to an actuation of the control member (**15**).



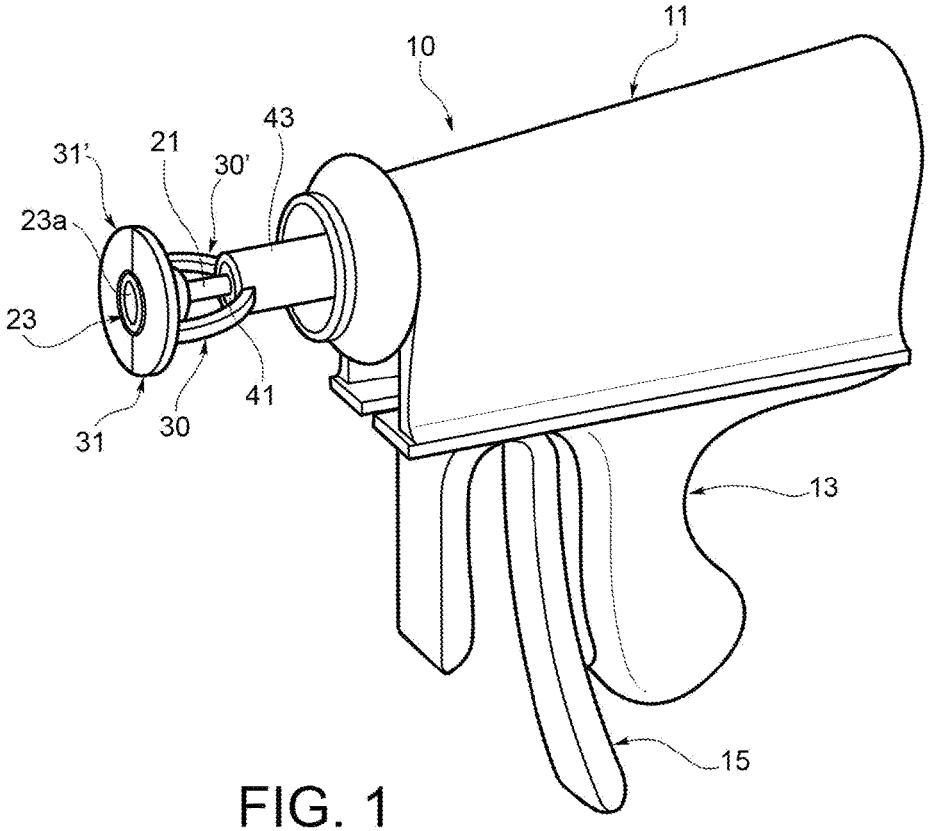


FIG. 1

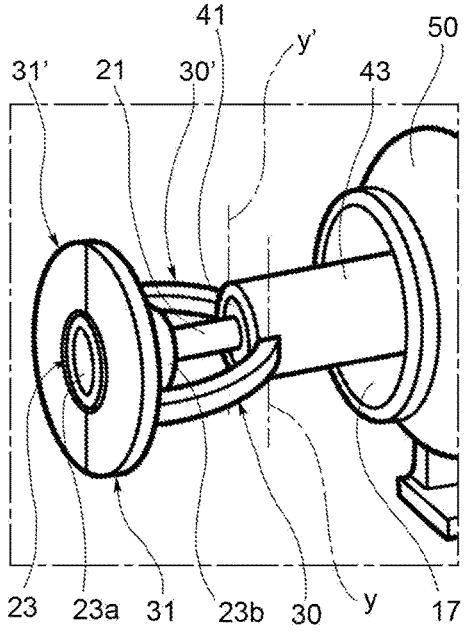


FIG. 2b

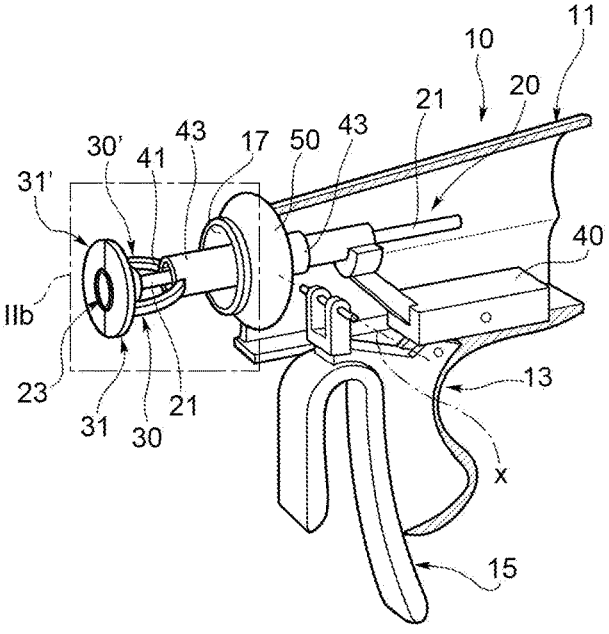


FIG. 2a

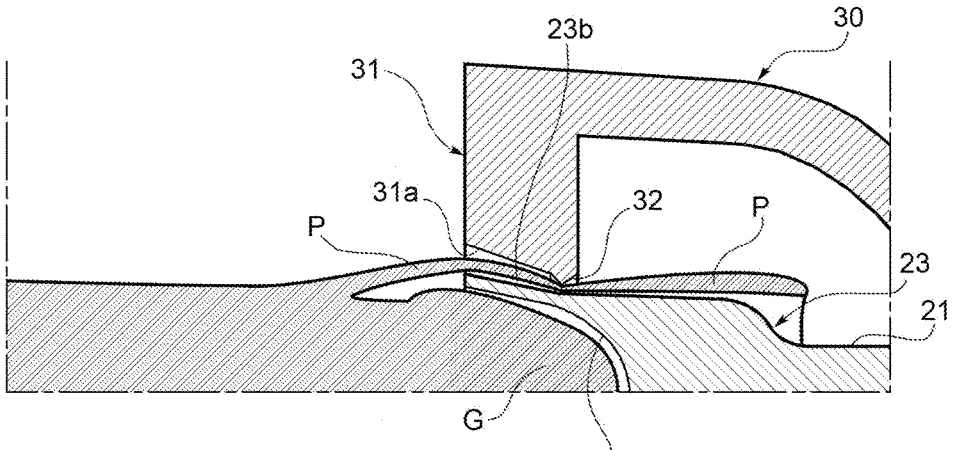


FIG. 7

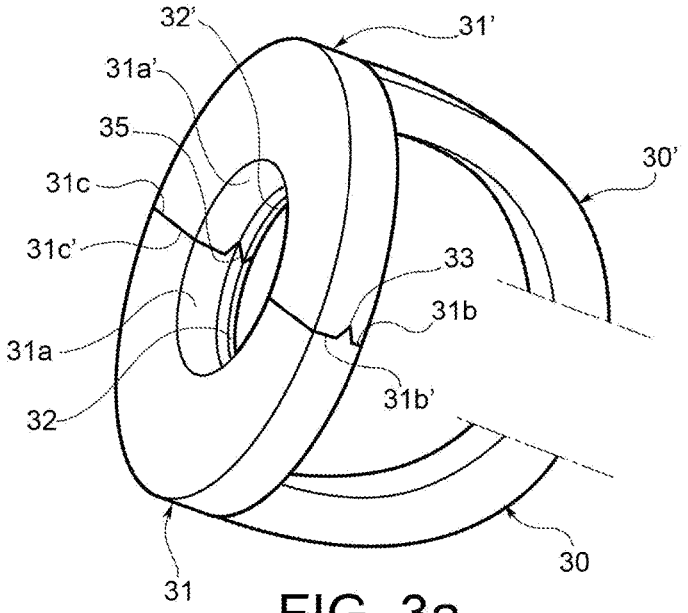


FIG. 3a

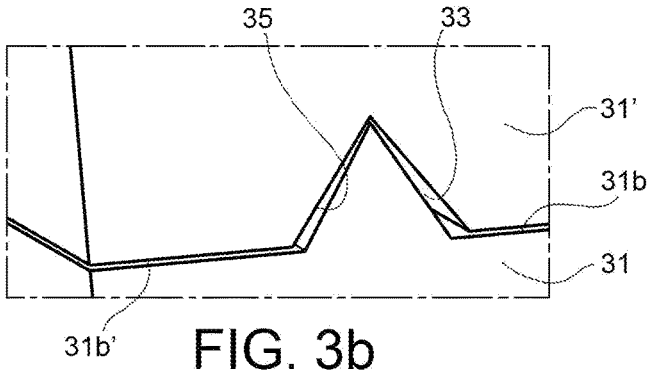


FIG. 3b

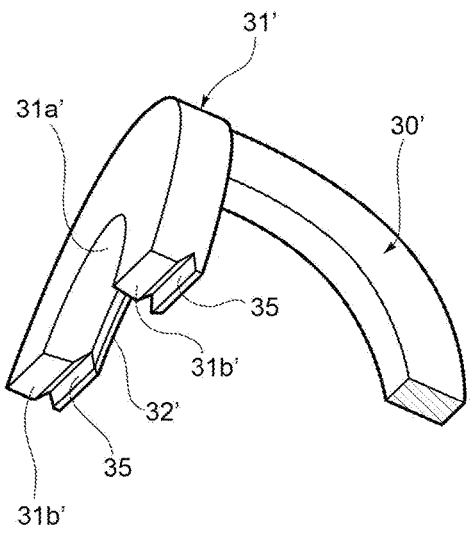


FIG. 3c

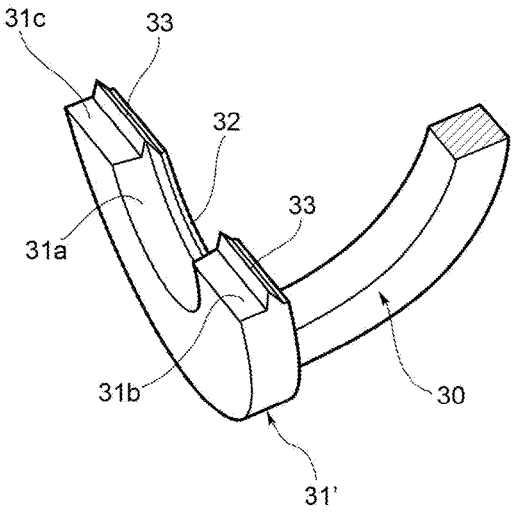


FIG. 3d

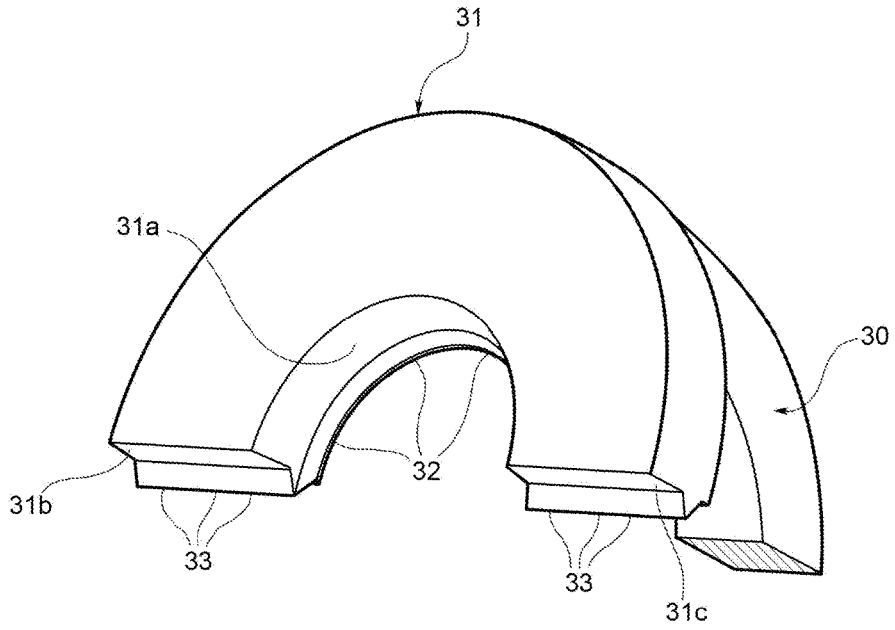
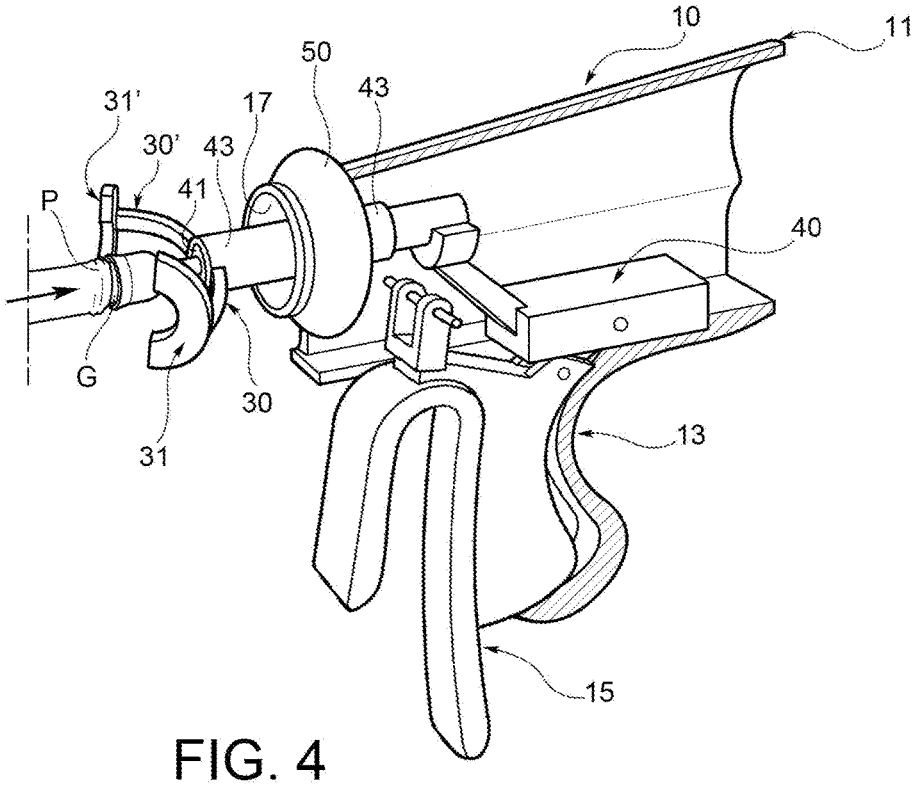


FIG. 3e


10
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43
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17
30'
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41
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40
G
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31
13
15

FIG. 4

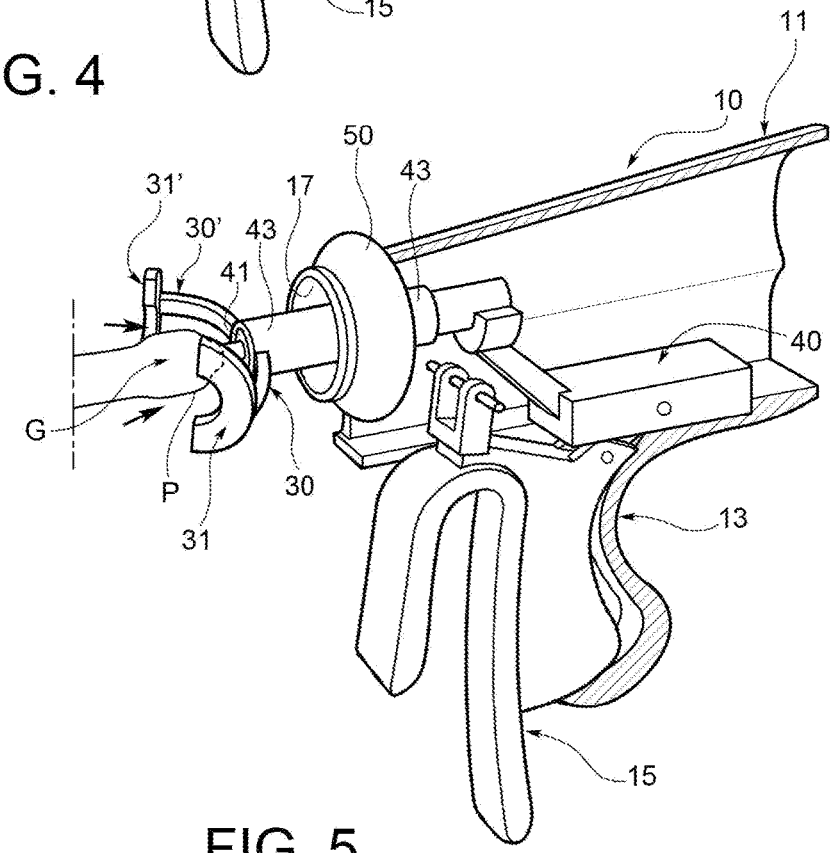
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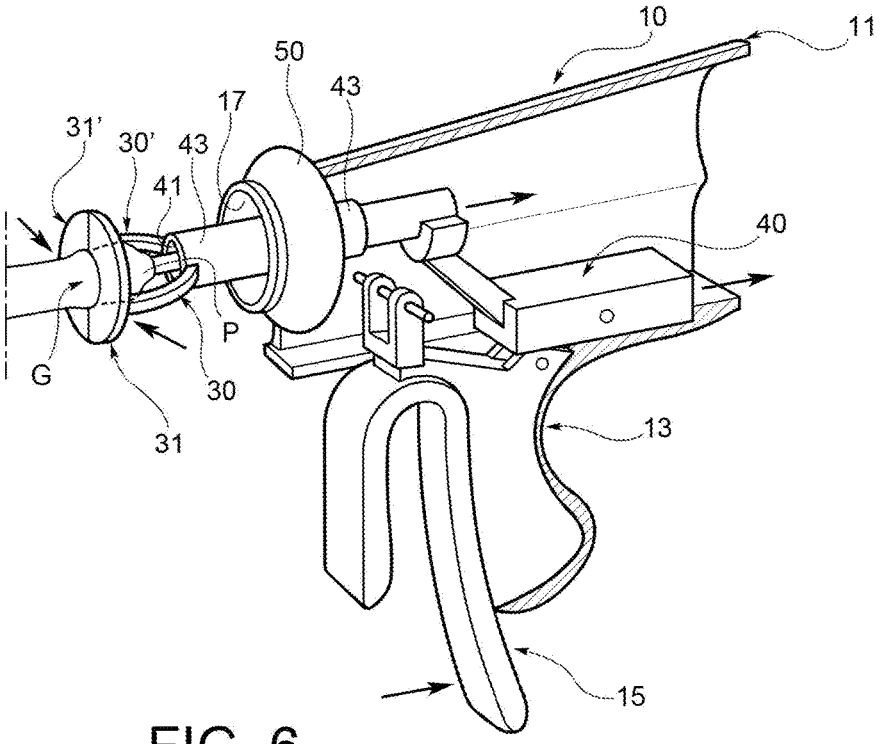
FIG. 5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30'
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FIG. 6

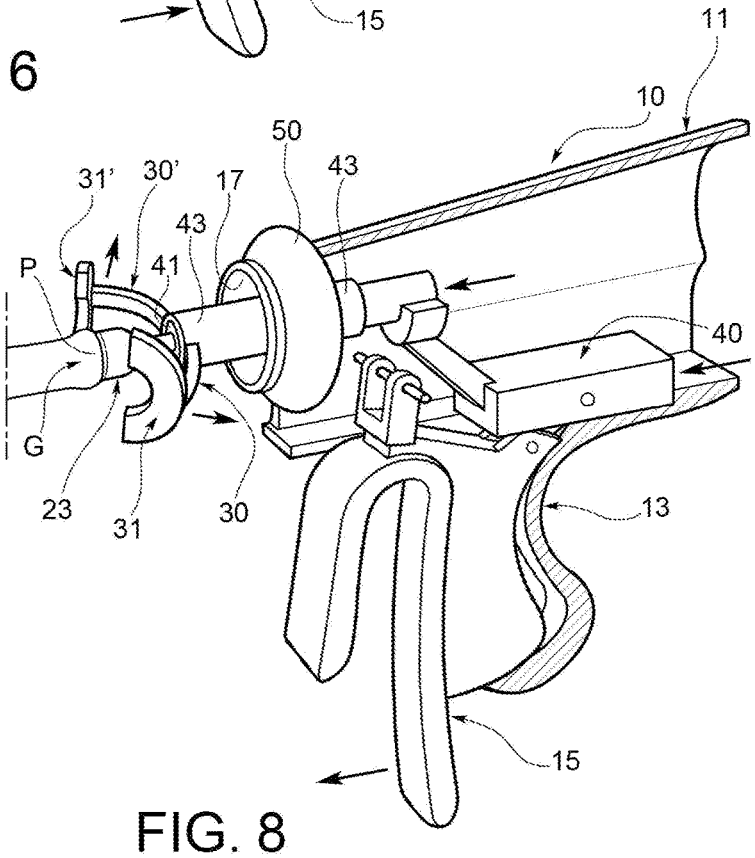
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FIG. 8

MECHANICAL GUN-TYPE CIRCUMCISION DEVICE WITH GLANS PROTECTION SYSTEM FOR SAFE CUTTING AND CAUTERIZATION OF THE FORESKIN

[0001] The present invention relates in general to circumcision techniques.

[0002] Circumcision is a respected religious ritual which is so well-established that, on occasions, it is performed without minimum guarantees as regards safety or protection of the anatomy of the glans. Consequently, the injury resulting from the use of inappropriate procedures is extensive, both for the patient, who is obliged to resort to plastic and reconstructive surgery, and for the national health service, which must assume the costs thereof.

[0003] In some cases circumcision is also required in order to correct certain pathologies of the male genital organ.

[0004] The circumcision operations are usually carried out with the aid of clips which tension the foreskin which to be removed using a scalpel. Also known are circumcision devices, such as that described in the document EP U.S. Pat. No. 2,606,839 A1, which consists of a ring which, on the one hand, performs easy cutting of the phimosis, but on the other hand does not respect the anatomy of the glans. In addition no provision is made for cauterization.

[0005] One object of the present invention is to provide a circumcision device which is both simple and safe to use.

[0006] Another object is to provide a device which may be realized in a particularly low-cost manner so that it may be used in particular as a disposable tool.

[0007] In view of these objects, the invention relates to a circumcision device which includes:

[0008] a housing comprising a handgrip part integral with the housing, wherein at least one control member is arranged on the handgrip,

[0009] a guide part comprising a stem integral with the housing, said stem being arranged partially within the housing and outwardly protruding through an opening of the housing, and a shearing template fixedly arranged on a distal end of the stem, said shearing template having a concave distal surface and a side surface tapered in the proximal direction,

[0010] a pair of arms, each having a distal end provided with a semi-annular blade, each arm being rotatable about an axis perpendicular to the extension direction of the stem, between an open position and a shearing position in which the semi-annular blades are closed to form a ring perpendicular to the extension axis of the stem and have a cutting edge which engages the side surface of the shearing template, and

[0011] an actuating mechanism for controlling rotation of the arms in response to an actuation of the control member.

[0012] The gun-type anatomical device forming the subject of the present invention guides the surgeon so as to perform a perfectly round cut perpendicular to the axis of the penis, since the tip of the glans is inserted inside the distal concavity of the shearing template and the axis of the shearing template and that of the penis coincide. The blades, with closing of the gun, perform a cut perpendicular to the axis of the stem, plus a cut in the two side zones where the two blades touch each other.

[0013] The present apparatus may be designed as a disposable device protected by a container with a sterile atmosphere inside. This device, if used observing the appropriate hygienic requirements and respecting the anatomy of the glans, ensures a correct and optimum procedure.

[0014] Preferred embodiments of the invention are defined in the dependent claims which are to be understood as forming an integral part of the present description.

[0015] Further characteristic features and advantages of the device according to the invention will become clear from the following detailed description of an embodiment of the invention, provided with reference to the accompanying drawings which are provided purely by way of a non-limiting example and in which:

[0016] FIG. **1** is a simplified perspective view of a circumcision device according to the present invention;

[0017] FIGS. **2***a* and **2***b* are, respectively, a cut-away view and a simplified view of the device according to FIG. **1** and a view, on a larger scale, of a detail of FIG. **2***a*;

[0018] FIGS. **3***a*-**3***e* are, respectively, a view of a pair of arms provided with blades of the device according to FIG. **1**, a detail on a larger scale of FIG. **3***b*, a view of each of the arms provided with a blade, and a view of a blade with respective cutting edges; and

[0019] FIGS. **4** to **8** are simplified perspective views illustrating the method for using the device according to FIG. **1**.

[0020] With reference to FIGS. **1**, **2***b*-**2***a*, **3***a*-**3***e*, these figures show a circumcision device including a housing **10** which is made of plastic and which comprises a main housing part **11** and a handgrip part **13** integral with the housing **10**. At lest one control member **15** is arranged on the handgrip part **13**. In the example shown the control member **15** consists of a lever which can be actuated manually and which is hingeably mounted on the housing **10** and is rotatable about a transverse axis x (FIG. **2***a*).

[0021] With reference to FIG. **2***a*, the device also includes a guide part **20** comprising a stem **21** integral with the housing **10** and a shearing template **23** arranged fixed on a distal end of the stem. The stem **21** is arranged partially inside the housing **10** and protrudes outwardly though an opening **17** of the housing **10**. The shearing template **23** has a substantially bell-like form and has a concave distal surface **23***a* and a side surface **23***b* tapered in the proximal direction.

[0022] The device also includes a pair of arms **30**, **30'** each having a distal end which is provided with a semi-annular blade **31**, **31'** made of medical grade metal. Each arm **30**, **30'** is rotatable about an axis y, y' perpendicular to the direction of extension of the stem **21**, between an open position (shown in FIGS. **5** and **8**) and a shearing position in which the semi-annular blades **31**, **31'** are closed to form a ring perpendicular to the extension axis of the stem **21**. In the shearing position the semi-annular blades **31**, **31'** have a cutting edge which engage the side surface **23***b* of the shearing template **23** (see FIG. **7**).

[0023] With particular reference to FIGS. **3***a*-**3***e*, each semi-annular blade **31**, **31'** has a main working surface **31***a*, **31***a'* having a curved profile tapered in the proximal direction and a pair of secondary working surfaces **31***b*, **31***c*; **31***b'*, **31***c'* arranged on diametrically opposite sides of the main working surface **31***a*, **31***a'* of the respective blade **31**, **31'**. A curved cutting edge **32**, **32'** is provided on the main working surface **31***a*, **31***a'*, which cutting edge forms a circular closed curve when the blades are in the shearing position. Furthermore, when the blades in the shearing position, the secondary working surfaces **31***b*, **31***c* of one of the blades engages

the working surfaces **31***b*', **31***c*' of the other blade. The pair of secondary working surfaces **31***b*, **31***c* of one of the blades is provided with a secondary cutting edge **33**; the other pair of secondary working surfaces **31***b*', **31***c*' is provided with a groove **35** designed to receive the respective secondary cutting edge **33** when the blades are in the shearing position (see in particular FIG. **3***b*).

[0024] The device also includes an actuating mechanism **40** for performing rotation of the arms **30**, **30'** in response to an actuation of the control member **15**. In particular, the actuating mechanism comprises an inner barrel **41** and an outer barrel **43** arranged coaxially with the stem **21**. The inner barrel **41** is arranged translationally integral with the stem **21**, while the outer barrel **43** is arranged translatable along it. The actuating mechanism also comprises further components which connect the lever **15** to the outer barrel **43** and have the function of converting the rotary movement of the lever **15** into the translational movement of the outer barrel **43**. This mechanism may comprise for example an articulated quadrilateral.

[0025] Each arm **31**, **31'** has a proximal end hinged together with the inner barrel **41** (along the respective axis y, y') and can be rotationally actuated by a translation of the outer barrel **43**. For this purpose an articulation (not shown), which connects the respective arm **31**, **31'** to the outer barrel **43**, may be provided. The actuating mechanism **40** therefore causes translation of the outer barrel **43** in response to an actuation of the control member **15** and then, by means of the translation of the outer barrel **43**, causes rotation of the arms **30**, **30'**.

[0026] The actuating mechanism **40** may comprise a spring (not shown) or other resilient elements for biasing the arms **30**, **30'** into the open position. Consequently, actuation of the lever **40** which causes closing of the blades **31**, **31'** occurs against the resilient force of the spring.

[0027] The actuating mechanism **40** may comprise a locking member, for example a ratchet (not shown), which has the function of locking automatically the blades **31**, **31'** in the shearing position at the end of the closing movement of the arms **30**, **30'**. In this case a release member, for example a pushbutton (not shown), must be provided, said release member being arranged on the handgrip **13** and being actuatable manually so as to release the blades **31**, **31'** from the shearing position.

[0028] A handling ring **50** rotatable around the stem **21** is arranged on the opening **17** of the housing **10**. The handling ring **50** is rotationally integral with the inner barrel **41** and the outer barrel **43**. This arrangement allows the entire device to be rotated about an axis of rotation defined by the handling ring **50** and the barrels **41**, **43**, therefore keeping stationary the arms **30**, **30'** with the blades **31**, **31'**. For this purpose, therefore, the part of the actuating mechanism **40** which connects the control member **15** to the outer barrel **43** must be configured so as to allow the rotation of the outer barrel **43** about its longitudinal axis.

[0029] The operation starts with a local anaesthetic, performed by means of injection or ointment, or with sedation. Operationally speaking, the surgeon inserts the concave distal surface **23***a* of the shearing template **23** over the tip of the glans G (FIG. **4**) in order to protect it and slides the foreskin P (FIG. **5**) over the outer surface **23***b* thereof, so that the two membranes of the foreskin are facing the two semi-annular blades. Operation of the lever **15** causes these blades to close (FIG. **6**), performing a cut and compressing the end part of the side surface **23***b* of the bell-type shearing template (where the geometry of the side surface **23***b* is tapered and has an abrupt variation in inclination—see the circled area indicated by A in FIG. **7**). Once cutting has been performed, the device remains locked, the surgeon not being required to exert any force on the lever **15**. After a time interval of about two minutes, the surgeon releases the pushbutton, the two blades open again (FIG. **8**) and the excess foreskin part is removed. In this way the foreskin is reshaped.

[0030] As can be understood, the semi-annular blades once closed coincide in a geometrically perfect manner with the outer surface of the shearing template and perform within a section thereof a circular shaped cut with a zone close to the cut which is compressed and consolidated. It is thus possible to perform a safe mini-invasive operation which may be implemented in a quick and easy manner. The procedure lasts no longer than ten minutes. Once the operation has been terminated, differently from the situation with other apparatus, the patient must merely wear a small, circular, fatty gauze dressing for about two days.

[0031] In addition to being used for circumcision, the present device, suitably modified, may also be used to perform circular cuts with dimensions determined by the central shearing template.

1. Circumcision device, characterized by including

a housing (**10**) comprising a handgrip part (**13**) integral with the housing (**10**), wherein at least one control member (**15**) is arranged on the handgrip part (**13**),

a guide part (**20**) comprising a stem (**21**) integral with the housing (**10**), said stem being arranged partially within the housing (**10**) and outwardly protruding through an opening (**17**) of the housing (**10**), and a shearing template (**23**) fixedly arranged on a distal end of the stem (**21**), said shearing template having a concave distal surface (**23***a*) and a side surface (**23***b*) tapered in the proximal direction,

a pair of arms (**30**, **30'**), each having a distal end provided with a semi-annular blade (**31**, **31'**), each arm being rotatable about an axis (y, y') perpendicular to the extension direction of the stem (**21**), between an open position and a shearing position in which the semi-annular blades (**31**, **31'**) are closed to form a ring perpendicular to the extension axis of the stem (**21**) and have a cutting edge (**32**, **32'**) which engages the side surface (**23***b*) of the shearing template (**23**), and

an actuating mechanism (**40**) for controlling rotation of the arms (**30**, **30'**) in response to an actuation of the control member (**15**).

2. Device according to claim **1** wherein, in the shearing position, the cutting edge (**32**, **32'**) of the semi-annular blades (**31**, **31'**) engages the side surface (**23***b*) of the shearing template (**23**) at a point having an abrupt variation in inclination.

3. Device according to claim **1**, wherein the actuating mechanism (**40**) comprises an inner barrel (**41**) and an outer barrel (**43**) arranged coaxially with the stem (**21**), the inner barrel (**41**) being translationally integral with the stem (**21**) and the outer barrel (**43**) being translatable along it,

wherein each arm (**30**, **30'**) has a proximal end hinged together with the inner barrel (**41**) and is rotationally actuatable by a translation of the outer barrel (**43**), and

wherein the actuating mechanism (**40**) is designed to control the translation of the outer barrel (**43**) in response to an actuation of the control member (**15**).

4. Device according to claim **1**, wherein a handling ring (**50**) rotatable around the stem (**21**) is arranged at the opening (**17**) of the housing (**10**), said handling ring being rotationally integral with the inner barrel (**41**) and the outer barrel (**43**).

5. Device according to claim **1**, wherein each semi-annular blade (**31**, **31'**) has a main working surface (**31***a*, **31***a'*) which has a curved profile and is tapered in the proximal direction and on which a curved cutting edge (**32**, **32'**) is arranged, said cutting edge forming a closed curve when the blades (**31**, **31'**) are in the shearing position.

6. Device according to claim **5**, wherein each blade (**31**, **31'**) has a pair of secondary working surfaces (**31***b*, **31***c*; **31***b'*, **31***c'*) arranged on diametrically opposite sides of the main working surface (**31***a*, **31***a'*) of the respective blade (**31**, **31'**), the secondary working surfaces (**31***b*, **31***c*) of one of the blades engaging the secondary working surfaces (**31***b'*, **31***c'*) of the other blade when the blades are in the shearing position.

7. Device according to claim **6**, wherein the pair of secondary working surfaces (**31***b*, **31***c*) of one of the blades is provided with a secondary cutting edge (**33**), the other pair of secondary working surfaces (**31***b'*, **31***c'*) being provided with a groove (**35**) for receiving the respective secondary cutting edge (**33**) when the blades are in the shearing position.

8. Device according to claim **1**, wherein said at least one control member (**15**) comprises a hand-actuatable lever, and the actuating mechanism (**40**) is configured to transform a rotation of the lever into a rotation of the arms (**30**, **30'**) and/or a translation of the outer barrel (**43**).

9. Device according to claim **8**, wherein the actuating mechanism is configured to automatically lock the blades in the shearing position at the end of a closing movement of the arms.

10. Device according to claim **9**, wherein said at least one control member comprises a release member actuatable by hand for unlocking the blades from the shearing position, the actuating mechanism being configured to bias the arms into the open position.

* * * * *