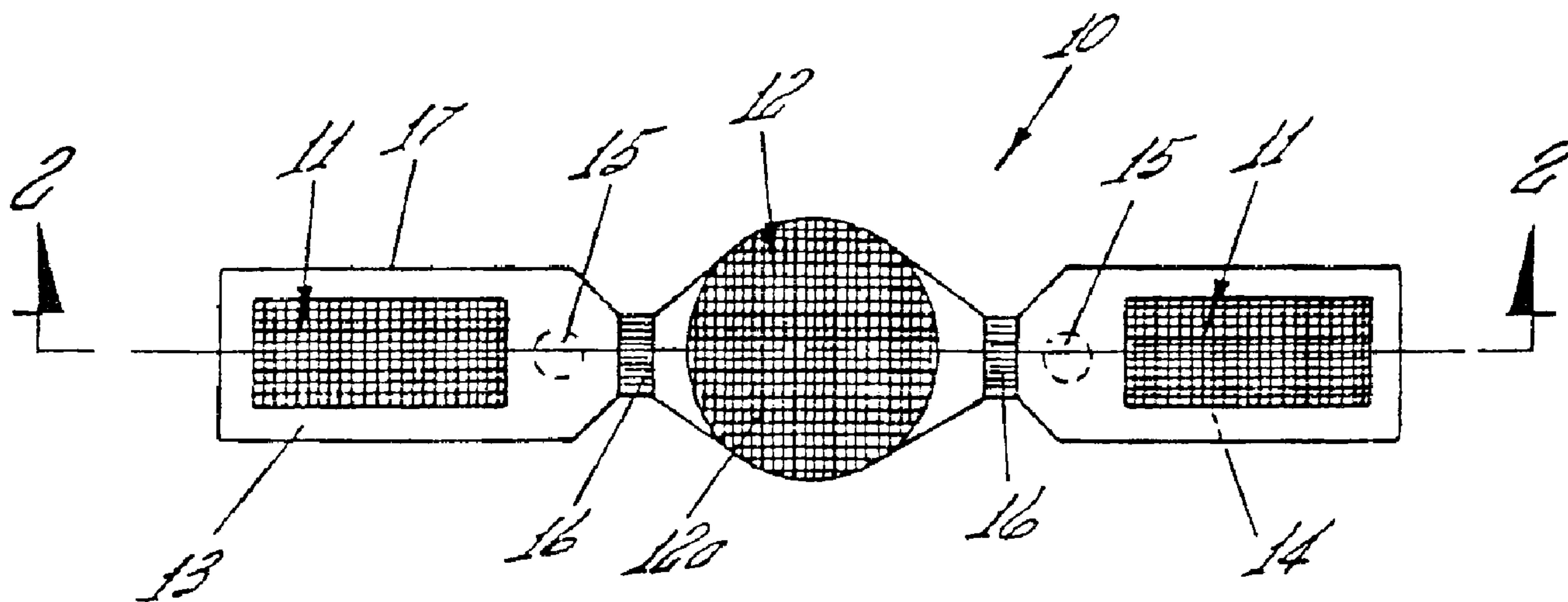




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(54) Titre : ELECTRODES POUR ADMINISTRATION DE MEDICAMENTS PAR IONOPHORESE  
(54) Title: IONTOPHORETIC DRUG DELIVERY ELECTRODES



(57) Abrégé/Abstract:

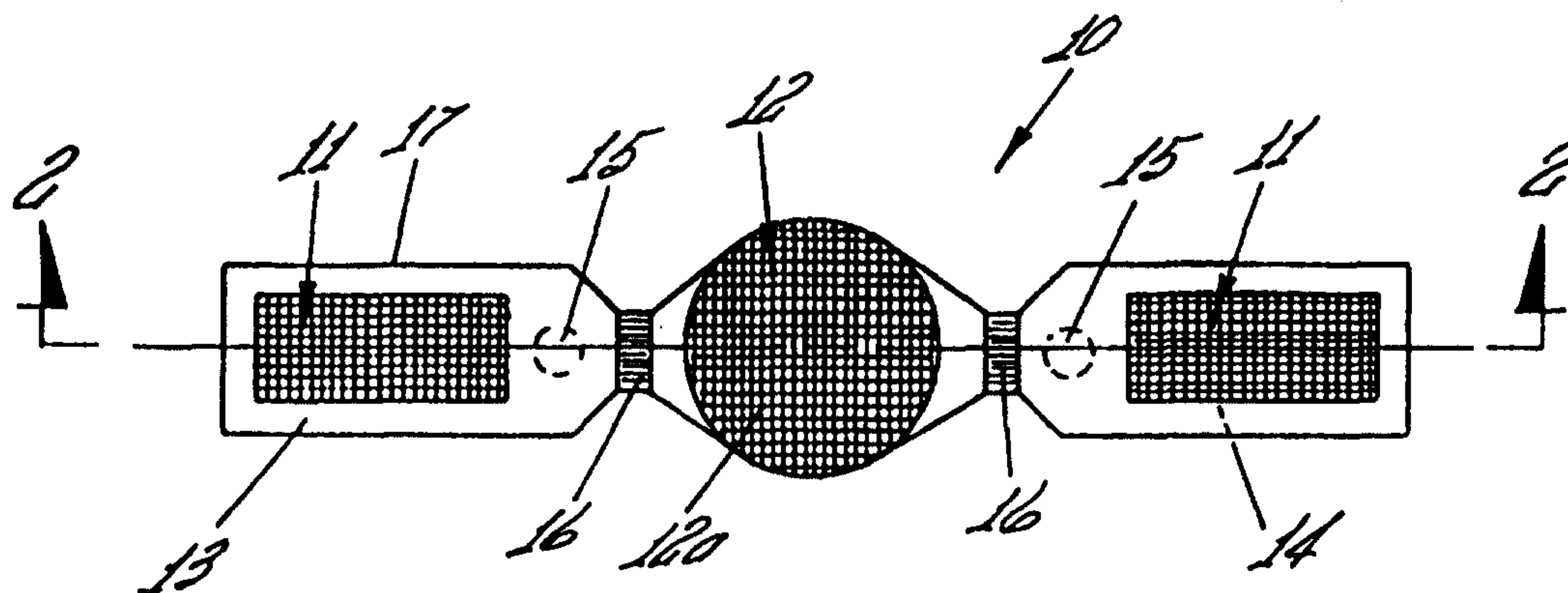
Non-reusable, medicament-dispensing applicator electrodes (10) adapted for use with an iontophoresis device or an ionosonic device for facilitating delivery of medication across the cutaneous membrane into adjacent underlying tissues, and blood vessels. The embodiments of the iontophoresis electrode include an open mesh (12) having cells (12a) in the medicament dispensing portions (11) of the electrode which retain a medicament in the form of liquid, gel or ointment. The cells are adapted to contain, to iontophoretically dispense, and deliver medicament. The medicament-dispensing electrodes (70) are composite or unitary in construction and may be useful in the treatment of acne, and also genital herpes simplex infection. The delivery electrode (71), when used in accordance with the medicated electrode, and method described herein, demonstrated >90 % treatment efficacy in clinical trials for the treatment of genital herpes. The applicator electrode may also be used with an ionosonic handpiece (40).

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(54) Title: IONTOPHORETIC DRUG DELIVERY ELECTRODES



## (57) Abstract

Non-reusable, medicament-dispensing applicator electrodes (10) adapted for use with an iontophoresis device or an ionosonic device for facilitating delivery of medication across the cutaneous membrane into adjacent underlying tissues, and blood vessels. The embodiments of the iontophoresis electrode include an open mesh (12) having cells (12a) in the medicament dispensing portions (11) of the electrode which retain a medicament in the form of liquid, gel or ointment. The cells are adapted to contain, to iontophoretically dispense, and deliver medicament. The medicament-dispensing electrodes (70) are composite or unitary in construction and may be useful in the treatment of acne, and also genital herpes simplex infection. The delivery electrode (71), when used in accordance with the medicated electrode, and method described herein, demonstrated >90 % treatment efficacy in clinical trials for the treatment of genital herpes. The applicator electrode may also be used with an ionosonic handpiece (40).



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1  
2 **TITLE: IONTOPHORETIC DRUG DELIVERY ELECTRODES**

3  
4 **INVENTOR: JULIAN L. HENLEY, M.D.**

5  
6 **SPECIFICATION**

7  
8 **BACKGROUND OF THE INVENTION**

9  
10 1. **Field of the Invention:**

11 This invention relates generally to the transdermal electrokinetic mass transfer  
12 of medication into a diseased tissue, and, more specifically, to a iontophoresis  
13 electrode for the transdermal delivery of medication into diseased tissues and blood  
14 vessels adjacent to the delivery site.

15 2. **Prior Art:**

16 Iontophoresis has been employed for several centuries as a means for applying  
17 medication locally through a patient's skin and for delivering medicaments to the eyes  
18 and ears. The application of an electric field to the skin is known to greatly enhance  
19 the skin's permeability to various ionic agents. This permeability change has been  
20 used, for example, to enhance transcutaneous transport of glucose for monitoring  
21 blood glucose levels. The use of iontophoretic transdermal delivery techniques has  
22 obviated the need for hypodermic injection for many medicaments, thereby eliminating  
23 the concomitant problems of trauma, pain and risk of infection to the patient.

24 Iontophoresis involves the application of an electromotive force to drive  
25 charged ions into the dermal layers comprising or overlying a target tissue.  
26 Particularly suitable target tissue includes tissues adjacent to the delivery site for  
27 localized treatment or tissues remote therefrom in which case the medicament enters  
28 into the circulatory system and is transported to a tissue by the blood. Positively  
29 charged ions are driven into the skin at an anode while negatively charged ions are  
30 driven into the skin at a cathode. Studies have shown increased skin penetration of

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1 drugs at anodic or cathodic electrodes regardless of the predominant molecular ionic  
2 charge on the drug. This effect is mediated by polarization and osmotic effects.

3 Regardless of the charge of the medicament to be administered, a  
4 iontophoretic delivery device employs two electrodes (an anode and a cathode) in  
5 conjunction with the patient's skin to form a closed circuit between one of the  
6 electrodes (referred to herein alternatively as a "working" or "application" or  
7 "applicator" electrode) which is positioned at the site of drug delivery and a passive or  
8 "grounding" electrode affixed to a second site on the skin to enhance the rate of  
9 penetration of the medicament into the skin adjacent to the applicator electrode.  
10 Ultrasonic vibrations may be used in conjunction with iontophoresis to facilitate  
11 iontophoretic deliver of a drug. An apparatus employing both iontophoresis and  
12 ultrasonic vibrations to transdermally deliver medicament is referred to herein as an  
13 ionosonic apparatus.

14 Recent interest in the use of iontophoresis for the transdermal delivery of  
15 drugs to a desired cutaneous or subcutaneous treatment site has stimulated a redesign  
16 of many of such drugs with concomitant increased efficacy of the drugs when  
17 delivered transdermally. As iontophoretic delivery of medicaments become more  
18 widely used, the opportunity for a consumer/patient to iontophoretically self-  
19 administer a transdermal dosage of medicaments simply and safely at non-medical or  
20 non-professional facilities would be desirable and practical. Similarly, when a  
21 consumer/patient travels, it would be desirable to have a personal, easily transportable  
22 apparatus available which is operable for the iontophoretic transdermal delivery of a  
23 medication packaged in a single dosage applicator. A problem which presents an  
24 impediment to potential users is the necessity for reformulating medicaments for  
25 iontophoretic delivery. Such reformulations must be approved by cognizant  
26 regulatory agencies prior to sale. This requires delay and additional expense for the  
27 manufacturer, which additional expense may be passed along to consumers. The  
28 present invention provides a disposable medicament dispensing electrode for use with  
29 a portable iontophoretic medicament delivery apparatus in which the electrode is  
30 adapted for use with the apparatus for self-administering medicament. The



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1 medicament dispensing portion of the electrode can accept, store and dispense  
2 presently approved medicament formulations.

### 4 SUMMARY OF THE INVENTION

5 The present invention discloses a unit dosage medicament applicator electrode  
6 adapted for use with a portable iontophoretic transdermal or transmucosal  
7 medicament delivery apparatus for the self-administration of a unit dose of a  
8 medicament into the skin. While the discussion to follow refers to iontophoretic  
9 devices, it is understood that an ionosonic device is included within the meaning of  
10 iontophoretic devices. The electrode and current supply apparatus is particularly  
11 suited for the localized treatment of herpes infections. The established treatment for  
12 recurrent genital herpetic lesions has been primarily supportive; including local topical  
13 application of anesthesia. Severe cases have been treated with systemic Acyclovir®,  
14 Zovirax® (Glaxo -Wellcome) or Famvir® (SmithKline Beecham). Some cases the  
15 condition is managed with prophylactic long-term dosing administration with a  
16 suitable antiviral agent at great expense. Systemic treatment of acute herpetic flare-  
17 ups may reduce the normal 10-12 day course of cutaneous symptoms into a 6-8 day  
18 episode. Topical treatment of lesions with Acyclovir® has not been as effective as in  
19 vitro studies would suggest. A compound which is not presently available to clinicians  
20 but has demonstrated significant anti herpetic activity is 5-iodo-2 deoxyuridine  
21 (IUDR). Both of those agents have shown limited clinical efficacy when applied  
22 topically to the herpetic lesion. It is the present inventor's contention that the limited  
23 efficacy of topical administration previously observed is, at least in part, due to the  
24 poor skin penetration of these medicaments when applied topically. The present  
25 invention discloses a mesh-like iontophoresis electrode, which contains and dispenses  
26 pre-approved formulations of those medicaments and provides improved transdermal  
27 delivery of these medicaments. The device and associated medicament dispensing  
28 electrodes may be used to treat such diverse conditions as herpes, warts, acne and  
29 psoriasis.

30 Genital herpes (usually herpes simplex II infection) afflicts many people, cause  
31 discomfort, shame, and may contribute to more severe and costly illnesses such as

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1 cervical cancer, prostate cancer, and perinatal blindness from herpetic conjunctivitis.  
2 Certain formulations containing anti-viral and/or anti-microbial drugs have been  
3 approved for topical application by the cognizant regulatory agency. Reformulation  
4 of such compositions for iontophoretic transdermal drug delivery entails significant  
5 delays before such technology is available to the public for general use. The present  
6 invention discloses a medicated iontophoresis electrode for the portable transdermal  
7 delivery of Acyclovir® (9-[(2-hydroxyethoxy)methyl]guanine) or similar anti-viral  
8 agent formulations which have already received (or may in the future receive)  
9 regulatory approval to greatly benefit these afflicted patients. In a second preferred  
10 embodiment of the invention, the medicament delivery electrode is attached to a user-  
11 wearable glove having one or more fingers or merely a finger cot covering at least a  
12 portion of one or more fingers of a user's hand.

13 It is an object of the present invention to provide an iontophoretic medicament  
14 delivery electrode which is adapted to be used with an iontophoresis device operable  
15 for self-administration of medicament into the skin of a person.

16 It is another object of the present invention to provide an improved  
17 iontophoretic transdermal drug delivery apparatus having a medicament-containing  
18 application electrode which dispenses and transdermally delivers a single dosage and  
19 which is disposable and non-reusable.

20 It is a further object of the present invention to provide an iontophoresis  
21 electrode meeting the above objectives which can receive and retain a previously  
22 approved drug formulation for dispensation by ionosonic transdermal delivery.

23 It is still another advantage of the present invention to provide an improved  
24 disposable iontophoretic medicament applicator which meets the above objectives and  
25 which is inexpensive, safe to use and greatly increases the therapeutic efficacy of a  
26 medicament administered thereby.

27 The medicament-containing electrode in accordance with the present  
28 invention, together with an iontophoresis or ionosonic apparatus, provides a means  
29 for transdermally administering medicament dispersed in a variety of previously  
30 approved formulations directly and with high efficiency into a diseased tissue thereby  
31 providing a novel method for treating clinical conditions presenting cutaneous and/or



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mucocutaneous symptoms such as warts, acne, superficial fungus infections, hyperproliferative diseases such as psoriasis, and particularly mucocutaneous Herpes simplex viral eruptions and sequelae associated therewith.

The invention thus provides according to a first aspect for a medicament dispensing iontophoresis applicator electrode comprising a generally thimble-shaped electrically conductive member and an overlying medicament dispensing portion of an electrically non-conducting elastomer having a cell or plurality of cells in at least a portion thereof and wherein the thimble-shaped conductive portion is dimensioned to fit over and conform to the shape of the distal end of a finger.

According to a second aspect, the invention provides for a medicament-dispensing applicator electrode for use with an electrokinetic device to transdermally deliver a medicament to an individual, comprising: a substrate having a first surface and a second surface opposite the first surface, the substrate including a medicament-dispensing portion comprising a cell or a plurality of cells forming an aperture or a plurality of apertures between the first surface and the second surface, the cell or plurality of cells containing the medicament; and a layer of adhesive covering at least a portion of the second surface of the substrate opposite the first surface for releasably attaching the substrate to an electrokinetic device containing an electrical power source for electrokinetically driving the medicament through the first surface and into the individual's skin upon application of an electrical current to effect delivery of the medicament in the cell or plurality of cells to the individual's skin.

According to a third aspect, the invention provides for a medicament-dispensing applicator electrode for use with an electrokinetic device to transdermally deliver a medicament to an individual, comprising: a substrate having a first surface and a second surface opposite the first surface, the substrate including a medicament-dispensing portion comprising a cell or a plurality of cells forming an aperture or a plurality of apertures between the first surface and the second surface, the cells or plurality of cells containing the medicament; and a layer of adhesive covering at least a portion of the first surface of the substrate opposite the second surface for releasably attaching the substrate to an individual's skin, the aperture or plurality of apertures being open along the second surface such that the medicament is electrokinetically driven through the first surface and into the individual's skin upon

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electrically contacting an electrokinetic device containing an electrical power source with the second surface of the medicament-dispensing portion to generate an electrical current to effect delivery of the medicament in the cell or plurality of cells to the individual's skin.

According to a fourth aspect, the invention provides for a medicament-dispensing applicator electrode for use with an electrokinetic device to transdermally deliver a medicament to an individual, comprising: a substrate having a first surface and a second surface opposite the first surface, the substrate including a medicament-dispensing portion between the first surface and the second surface and defining a reservoir for containing the medicament; and a layer of adhesive covering at least a portion of one of the first surface and the second surface of the substrate for releasably attaching the substrate to one of an electrokinetic medicament-delivery device containing an electrical power source or an individual's skin, the second surface of the medicament-dispensing portion being pervious to enable electrical contact through the second surface with the medicament or a carrier therefor such that the medicament is electrokinetically driven from the reservoir through the first surface and into the individual's skin upon transmission of an electrical current through the second surface, the reservoir and the first surface.

According to a fifth aspect, the invention provides for an apparatus for the transdermal delivery of a medicament to an individual, comprising: a medicament-dispensing applicator electrode including a substrate having a first surface and a second surface opposite the first surface, the substrate including a medicament-dispensing portion comprising a cell or a plurality of cells forming an aperture or a plurality of apertures between the first surface and the second surface, the cell or plurality of cells containing the medicament; an electrokinetic device comprising a housing having a portion thereof shaped for grasping within an individual's hand for manual manipulation by the individual, and a first electrode formed of electrically conductive material and in electrical contact with the substrate and with a portion of an individual's skin upon application of the device to the individual's skin with the substrate interposed therebetween; a power source contained within the housing having first and second terminals, the first terminal being in electrical contact with the first electrode; a tactile electrode in electrical contact with the second terminal of the power source and having a surface for electrical contact with another portion of an individual's skin; and the device being operable to electrokinetically drive the medicament from the applicator electrode to



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effect delivery of the medicament in the cell or plurality of cells to the portion of the individual's skin in contact with the substrate on one side thereof in response to completion of an electrical circuit between the first terminal through the first electrode and the substrate via the individual's skin portion and the second terminal via the tactile electrode and the  
5 another portion of the individual's skin.

According to a sixth aspect, the invention provides for an apparatus for the trans-dermal delivery of a medicament to an individual, comprising: a medicament-dispensing applicator electrode; an electrokinetic device; the medicament-dispensing applicator electrode including a substrate having a first surface and a second surface opposite the first  
10 surface, the substrate including a medicament-dispensing portion comprising a cell or a plurality of cells forming an aperture or a plurality of apertures between the first surface and the second surface, the cell or plurality of cells containing the medicament, the substrate having a portion thereof for releasably coupling the substrate to the device; the device comprising a housing having a portion thereof shaped for grasping within an individual's  
15 hand for manual manipulation by the individual, and a first electrode formed of electrically conductive material and exposed for contact with the substrate upon releasable connection to the device; a power source contained within the housing having first and second terminals, the first terminal being in electrical contact with the first electrode; a tactile electrode in electrical contact with the second terminal of the power source and having a surface for  
20 contact with the individual's skin; and the device being operable to electrokinetically drive the medicament from the applicator electrode to effect delivery of the medicament in the cell or plurality of cells to a portion of the individual's skin in contact with the substrate on one side thereof in response to completion of an electrical circuit between the first terminal through the first electrode and the substrate via the individual's skin and the second terminal  
25 via the tactile electrode and another portion of the individual's skin.

According to a seventh aspect, the invention provides for a medicament-dispensing electrokinetic applicator for delivering medicament to a large area of an individual's skin, comprising: a glove-shaped body containing a medicament for application through an outer surface thereof; and a conductive layer formed within the glove-shaped body for connection  
30 with an electrical power source and electrokinetically driving the medicament from the body onto an area of the individual's skin overlaid and in contact with the glove-shaped body upon

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application of an electrical current to effect delivery of the medicament contained in the body to the large area of the individual's skin in contact with the overlying glove-shaped body, wherein the conductive layer comprises a multi-channel electrode.

According to a eighth aspect, the invention provides for an apparatus for the trans-  
5 dermal delivery of medicament to an individual, comprising: a medicament-dispensing electrode; an electrokinetic device; the medicament-dispensing electrode including a substrate having a first surface and a second surface opposite the first surface, the substrate including a medicament-dispensing portion having a cellular structure with one or a plurality of cells dimensioned to retain a medium including the medicament within the confines of the  
10 cellular structure for electrokinetically transporting the medicament from the cell or plurality of cells through the first surface into the individual's skin upon flowing an electrical current between the first surface and the second surface; a tactile conductive portion carried by the substrate having a second cell or a plurality of cells electrically insulated from the medicament-dispensing portion, the second cell or plurality of cells containing an electrically con-  
15 ductive material for electrical connection through the second surface with a conductive portion on the electrokinetic device; and the electrokinetic device including a housing having a portion thereof shaped for manual manipulation by the individual's hand, and a first electrode exposed for contact with the second surface of the substrate upon engagement of the substrate and the device with one another, a power source within the housing and having first  
20 and second terminals, the first terminal being in electrical contact with the first electrode, a tactile electrode in electrical contact with the second terminal of the power source and having a surface for electrical contact with the tactile conductive portion of the applicator electrode, the device being operable to deliver the medicament from the applicator electrode to a portion of the individual's skin in contact with the first surface in response to completion of an  
25 electrical circuit between the first terminal through the first electrode and the substrate via the individual's skin and the second terminal via the tactile electrode, the tactile conductive portion and another portion of the individual's skin.

According to a ninth aspect, the invention provides for a use of a hand-held iontophoretic device comprising an electrode and a medicament dispensing reservoir containing  
30 an antiviral agent, the reservoir being in electrical communication with the electrode, for treating lesions associated with cold sore and genital herpes, wherein the medicament



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dispensing reservoir is in contact with the lesions and a voltage gradient between the electrode and the lesion is present.

According to a tenth aspect, the invention provides for a use of a hand-held ionosonic device comprising an electrode and a medicament dispensing reservoir containing an anti-  
5 viral agent, the reservoir being in electrical communication with the electrode, for treating lesions associated with cold sore and genital herpes, wherein: the medicament dispensing reservoir is in contact with the lesions; ultrasonic vibration in a tissue comprising the lesion is present; and a voltage gradient between the electrode and the lesion is present.

According to a eleventh aspect, the invention provides for a use of a hand-held iono-  
10 sonic device comprising an electrode and a medicament dispensing reservoir containing an ionic compound in electrical communication with the electrode, for treating lesions associated with acne, wherein: the medicament dispensing reservoir comes into contact a the lesion; ultrasonic vibration in a tissue comprising the lesion is present; and a voltage gradient between the electrode and the lesion is present.

15 According to a twelfth aspect, the invention provides for a disposable medicament dispensing applicator electrode for an iontophoretic drug delivery device adapted for the self-administration of a medicament into a person's skin, the device comprising a base assembly having an active terminal adapted to receive and make electrical contact with a detachable medicament dispensing applicator electrode wherein the base assembly comprises: a case  
20 having an elongate, substantially cylindrical outer surface having a size and shape adapted to be comfortably grasped within a person's hand and wherein at least a portion of the outer surface is a tactile electrode formed of an electrically conductive material; and a bipolar electrical power means having a first pole and a second pole; the electrical power means being enclosed within the case and wherein the first pole is in electrical communication with  
25 the tactile electrode; wherein the medicament dispensing applicator electrode comprises: a module containing unit dose of medicament, an electrically conductive working electrode and means thereon adapted for releasably attaching the working electrode to the second pole of the electrical power means wherein the working electrode further comprises an elongate strip constructed of a substantially electrically non-conductive substrate material, the strip  
30 having a central portion containing a medicament in an electrically conductive substrate and laterally symmetric end portions having cutouts therewithin.

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The above objects, features and advantages of the invention are realized by the improved iontophoretic medicament applicator electrode of the present invention. The objects, features and advantages of the invention will become apparent upon consideration of the following detailed disclosure of the invention, especially when it is taken in conjunction with  
5 the accompanying drawings wherein:

### **BRIEF DESCRIPTION OF THE DRAWINGS**

FIG. 1 is a top plan view of a first embodiment of the disposable iontophoretic medicament containing applicator electrode adapted for attachment to an iontophoresis handpiece  
10 wherein the medicament dispensing portion of the electrode is an open mesh.

FIG. 2 is a side elevational view of a preferred embodiment of the disposable non-reusable iontophoretic applicator electrode for use with an iontophoresis handpiece adapted for self-administration.

FIG. 3 is a top plan view of the iontophoresis applicator electrode in accordance with  
15 claim 2.

FIG. 4 is a horizontal cross-sectional plan view of an iontophoresis handpiece adapted for use with the embodiments of the medicament dispensing applicator electrode of the present invention shown in Figures 1 - 3.

FIG. 5 is a perspective view showing the applicator electrode of Figures 1 - 3 releasably affixed to an iontophoresis handpiece in accordance with Figure 4.  
20

FIG. 6 shows a patient preparing to self-administer medicament to a treatment site.

FIG. 7 is a top plan view of an embodiment of a medicament dispensing applicator electrode having unitary construction and an open mesh medicament dispensing portion  
25 similar to the embodiment shown in Figures 1 - 3 and adapted for attachment to the skin of a patient.



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1 FIG. 8 is a horizontal cross-sectional view of the applicator electrode of  
2 Figure 7 taken along section line 8-8.

3 FIG. 9 is a bottom plan view of the applicator electrode of Figure 7.

4 FIG. 10 is a perspective view of an embodiment of an iontophoresis device  
5 and a medicament dispensing applicator electrode adapted to be releasably affixed to a  
6 finger of a patient wherein the medicament dispensing portion of the electrode is an  
7 open mesh.

8 FIG. 11 is a perspective view of the iontophoresis device and applicator  
9 electrode of Figure 10 wherein the thimble-like applicator electrode has been removed  
10 from the patient's finger.

11 FIG. 12 is a partially cut-away view of the iontophoresis applicator electrode  
12 of Figures 10 and 11 showing the relationship between the applicator electrode, an  
13 insulating finger cot and a wrist-worn adaptation of the iontophoresis device shown in  
14 Fig. 4.

15 FIG. 13 is a plan view of a glove embodiment of the applicator electrode in  
16 accordance with the present invention having a large area for medicament delivery.

17 FIG. 14 is a perspective view of a patient using the glove embodiment of FIG.  
18 13 to self-administer a medicament to a relatively large portion of skin underlying the  
19 glove, as in, for example, the treatment of acne.

20 FIG. 15 is a schematic elevational view of a hand-held ionosonic handpiece  
21 having an applicator electrode in accordance with the present invention attached  
22 thereto.

23

#### 24 DESCRIPTION OF THE PREFERRED EMBODIMENT

25 FIG 1 shows, in top plan view, a first preferred embodiment of the hand-held  
26 iontophoretic transdermal medicament delivery apparatus of the present invention.  
27 The first preferred embodiment of the iontophoretic medicament-containing  
28 application electrode is shown at 10. The application electrode 10 is preferably  
29 disposable and non-reusable. The electrode 10 is suitable, for example, for  
30 transdermally delivering anti-viral agents such as Acyclovir® for the treatment of cold  
31 sores or genital herpes. The applicator electrode 10 is adapted for use with an

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1 iontophoresis handpiece such as the handpiece shown in Figures 4 and 5. In use, the  
2 applicator electrode 10 is detachably affixed to a hand-held iontophoresis handpiece  
3 40 which handpiece presents a first electrically conductive surface 41 and a second  
4 electrically conductive surface 42. The handpiece 40 comprises a current driver 45  
5 which receives an electrical voltage from a voltage multiplier 46 which is in electrical  
6 communication with one electrode 47 of an electrical power source 48 such as a  
7 battery. The other electrode 49 of the battery is in electrical communication with a  
8 tactile electrode 42 on the surface of the handpiece 40 which electrode is, in use, in  
9 contact with the skin of one or more fingers of a user. The electrical current from the  
10 current driver 45 is conducted through a wire or conductive strip 44 to the first  
11 electrically conductive surface 41. When the applicator electrode 10 is attached to the  
12 handpiece 40, the current passes through the conductive applicator electrode to the  
13 skin of the user, returning to the second electrically conductive element 42, or "tactile  
14 electrode" to drive the medicament 23 through the mesh-like matrix material 12 and  
15 into the user's skin. The medicament or treatment agent is contained within a viscous  
16 fluid vehicle which, in turn, is contained within a plurality of cellular apertures 12a  
17 comprising the mesh 12.

18 The applicator electrode 10 comprises a substantially flat elongate strip having  
19 lateral ends extending from a central medicament dispensing portion 12. The central  
20 medicament dispensing portion 12 is of mesh-like construction and has vertical cells  
21 dimensioned to accommodate a viscous fluid within the confines of the cellular  
22 structures. The viscous fluid contained within each of the plurality of cells 12a  
23 includes a medicament (not shown) which is in a form suitable for transport under the  
24 influence of an electrical current. The lateral ends of the applicator electrode 10 may  
25 include a mesh-like tactile conductive portion 11 which contains an electrically  
26 conductive gel therewithin. The applicator electrode 10 has a skin-facing surface 13  
27 and a device-facing surface 14. One or a plurality of cells 12a form one or a plurality  
28 of apertures between the upper skin-facing surface 13 and the lower device-facing  
29 surface 14. The device-facing surface 14 may further include an adhesive layer 18  
30 applied thereto suitable for releasably adhering the applicator electrode 10 to the  
31 positive (anode) or negative (cathode) pole of a iontophoresis handpiece. The



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1 positioning of the electrode's tactile conductive portion 11 on the surface of the  
2 handpiece is such that tactile conductive portion 11 makes electrical contact with the  
3 tactile electrode 42 on the handpiece. When the applicator electrode 10 is correctly  
4 positioned on the handpiece, the medicament dispensing reservoir 12 is in electrical  
5 communication with the electrically contacting element 41 on the handpiece. In  
6 addition, one or more small magnets 15 disposed within the applicator electrode 10  
7 may be positioned on the handpiece to activate a switch within said handpiece which  
8 turns the handpiece on and/or off. The relatively narrow, flexible areas 16 on the  
9 electrode 10 enable the applicator electrode 10 to be bent and formed around the  
10 handpiece. Figure 2 shows a cross-sectional view of the applicator electrode 10 of  
11 Figure 1 taken along section lines 2-2. The material 17 forming the structural portion  
12 of the applicator electrode 10 is preferably a non-electrically conducting elastomer. A  
13 bottom view of the applicator electrode 10 of Figures 1 and 2 is shown in Figure 3.

14 Figure 5 is a perspective view of the applicator electrode 10 attached to the  
15 handpiece 40 in position for use. Figure 6 shows a patient preparing to use the  
16 iontophoresis device for administering medicament to herpes lesions on the face. The  
17 patient 60 grasps the tactile electrode 42 with a finger 61 to make electrical  
18 communication therewith. The patient then touches the tip 12 of the applicator  
19 electrode 10 to the lesion 63 thereby completing the electrical circuit and the resulting  
20 current flow driving the medicament into the skin.

21 Turning next to Figure 7, a second preferred embodiment of a medicament  
22 dispensing applicator electrode in accordance with the present invention is shown at  
23 70. The centrally located medicament dispensing portion 71 has cells 72 therewithin  
24 which cells provide an aperture between the upper surface 73 and the lower, skin-  
25 contacting surface 74 of the electrode 70. The applicator electrode 70 is shown in  
26 cross-section along section lines 8-8 in Figure 8. The central medicament dispensing  
27 portion 71 of the electrode 70 is mesh-like in construction. A plurality of vertical cells  
28 72 are molded within the elastomer strip comprising the applicator electrode to form  
29 apertures which communicate between the upper surface 73 and the lower surface 74.  
30 A fluid or semi-fluidic vehicle containing a medicament is placed within the cells 72  
31 which cells are dimensioned to retain the medicament therewithin until an electrical



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1 current is passed therethrough. An adhesive layer 75 is coated upon the lower surface  
2 74 of the applicator electrode. The adhesive is chosen to be hypoallergenic,  
3 biocompatible and to releasably affix the electrode 70 to the skin.

4 A bottom view of the applicator electrode 70 of Figures 7 and 8 is shown in  
5 Figure 9. In use, the embodiment of the applicator electrode 70 shown in Figures 7 -  
6 9 is affixed to the skin via the adhesive surface 75. The iontophoresis handpiece 40 is  
7 grasped between the fingers of the patient such that the tactile electrode (42 in Fig. 5)  
8 is in contact with at least one of the patient's fingers. The handpiece is then advanced  
9 to the medicament dispensing portion 71 of the applicator electrode 70 until it makes  
10 contact therewith. The circuit formed between the fingers grasping the tactile  
11 electrode 42 portion of the handpiece 40 and the lesion is made through the mesh  
12 surface of the medicament dispensing portion of the applicator electrode. Current  
13 flows through the handpiece to the medicament dispensing electrode and into the skin  
14 of the patient to return to the handpiece via the fingers and the tactile electrode to  
15 close the circuit. As the current flows through the medicament dispensing electrode  
16 the current drives the medicament into the skin of the patient.

17 Turning now to Figure 10, a thimble-like medicament dispensing applicator  
18 electrode 100 is shown attached to a finger 105 of a patient. The applicator electrode  
19 100 is in electrical communication with one pole (cathode or anode) of a wrist-worn,  
20 bipolar iontophoresis device 101 by means of a wire 102. The bottom 106 or wrist-  
21 facing, skin-contacting surface of the bipolar iontophoresis device 101 is the other  
22 pole (anode or cathode) comprising a conductive electrode. The iontophoresis device  
23 101 is releasably affixed to the wrist by means of a strap 103. The iontophoresis  
24 device 101 may be constructed similarly to the iontophoresis handpiece 40 except that  
25 the working electrode 41 is attached to the wire 102 and the tactile electrode 42  
26 replaced with a conductive electrode 106 forming the skin-contacting portion of the  
27 device 101 which is in contact with the wrist of the patient. The applicator electrode  
28 100 is electrically isolated from the finger 105 by means of an insulating finger cot  
29 104. Current from the iontophoresis device 101 passes through the conductive wire  
30 102 to an inner electrically conductive thimble 110 (Figure 11) to which the wire is  
31 conductively attached by means of solder. The electrically conductive thimble 110 has



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1 an overlying silicone elastomeric thimble 111. The elastomeric thimble 111 is  
2 homogenous in composition and has an upper surface 112 and a lower surface 113  
3 which comprises a mesh 113a. The mesh 113a has integral therewith a plurality of  
4 retaining cells 114 which cells extend between the electrically conductive thimble 110  
5 and the lower surface 113 and are dimensioned to contain a medicament. In  
6 operation, current from the iontophoresis device 101 passes through the wire 102 to  
7 the electrically conductive thimble 110 of the applicator electrode. The voltage  
8 applied to the surface of the electrically conductive thimble 110 drives medicament  
9 contained within the cells 114 of the mesh 113 into the skin of a user's body. The  
10 current passes through the user's body to the conductive electrode (not shown) which  
11 comprises the wrist-facing portion of the iontophoresis device 101. The iontophoresis  
12 device 101 preferably includes a power source, a voltage multiplier, a driver and an  
13 on/off switch as shown in the handpiece 40, but reconfigured to be worn on the wrist.  
14 An enlarged perspective view of the applicator electrode 100 overlying a finger cot is  
15 shown in structural relationship in Figure 12.

16 The simple design is capable of retaining and dispensing existing medicament  
17 formulations in various viscosities because the size of the retaining cells 72 in the  
18 mesh portion of the electrode may be varied. The structural matrix of the applicator  
19 electrode is a flexible, preferably hypoallergenic, nonelectrically-conductive material.  
20 A suitable material is Silastic®, a silicone elastomer which is biocompatible, non-  
21 conductive, flexible and possessing sufficient structural rigidity to contain  
22 medicaments and a delivery vehicle within the retaining cells 114. Further, Silastic  
23 silicone elastomer is inert so that medicaments will not oxidize or otherwise have their  
24 chemical structures damaged. An electrode constructed from silicone elastomer has a  
25 prolonged shelf-life, is soft and pleasant on contact, is hypoallergenic and sufficiently  
26 flexible to adhere to any anatomical contour such as presented by a thimble. Such  
27 anatomical plasticity is a key advantage to the foregoing design. Other polymers, such  
28 as polyurethane, are suitable as well. A hydrated hydrophilic cotton layer (not shown)  
29 may be interposed between the medicament dispensing portion 71 and the electrically  
30 conductive surface 41 of the handpiece 40 to provide pretreatment hydration of the

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1 medicament dispensing portion or the mesh may be hydrated by the patient  
2 immediately prior to use.

3 With reference to the embodiment of an iontophoresis applicator electrode  
4 shown in Figures 7 - 9, the electrode is easily manufactured using mold technology  
5 wherein uncured silicone elastomer is either poured into a complementary mold or  
6 pressure-mold injected. The lower surface 74 of the non-medicament dispensing  
7 portion of the electrode is coated with skin adhesive. The medicament dispensing  
8 portion 71 functions as a medicament reservoir and is preferably between 1mm and  
9 4mm thick, depending upon the amount of medicament required to be stored in the  
10 cells 72. The medicament-retaining cells 72, which are preferably a hexagonal, honey  
11 comb-like structure, retain the medicament therein through their surface tension.  
12 Hexagonal cells also lessen cross channel conductivity by means of their vertical  
13 orientation. The size and geometry of these cells can vary. The smallest cells, for  
14 instance, would be more suited to retaining liquid medicaments while the larger cells  
15 are better adapted to retain ointment-based medicaments. Medium cells are more  
16 suited to retaining and dispensing gel medicaments and lotions. The silicone walls of  
17 the cells can be chemically modified to change the hydrophobic surface characteristics  
18 thereof and further improve retention of specially formulated liquid medicaments. For  
19 additional cell stability and retention capabilities, the skin-facing surface of the cells  
20 can be covered with non-wicking, fibrous and porous materials commonly used in  
21 electrodes. A composite or unitary construction from a single mold can be used  
22 depending on production cost, it is inexpensive to manufacture and it offers both a  
23 compartment for storage of existing formulations as well as a structural backbone for  
24 the application electrode. The surface treatments of the retaining material bounding  
25 each of the cells to create hydrophilic or hydrophobic surface effects depending on the  
26 formulation to be utilized is well known in the art. An example of such technology is  
27 disclosed, for example, in US patent 5,589,563. For ointments and hydrophobic  
28 materials, silicone is preferred. For water or gel medicaments, surface treatment such  
29 as doping the elastomeric cell surface with hydrophilic molecules can be of additional  
30 benefit, as described herein. The embodiments disclosed herein present the following  
31 advantages:



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1           Inexpensive manufacture;  
2           Use of either injection or pour molding production;  
3           Use of composite sheet cutout assembly;  
4           Anatomically conforming;  
5           Elastomer surface modification for optimum retention of medicament;  
6           Variable retaining cell size;  
7           Variable retaining cell geometry;  
8           Ability to utilize existing medicament formulations;  
9           May use a cotton or (other hydrophilic matrix) layer for rapid pre-treatment  
10          hydration.  
11           May be used with single or multi-channel dispersive iontophoretic drivers; and  
12           May be used with iontophoretic or ionosonic devices.  
13           An embodiment of the present invention adapted for delivering medicament to  
14          a large area of skin is shown in Figure 13. The iontophoresis electrode is contained  
15          within a glove adapted to conform to and be worn upon a patient's hand. The glove  
16          embodiment 130 of the iontophoresis drug delivery electrode comprises an  
17          elastomeric glove 131 having a plurality of holes or open pores 132 in the palmar  
18          surface 133 thereof. Underlying the palmar surface 133 and disposed within the glove  
19          between the skin 134 and glove is an electrically insulating sheet 135 having an inner  
20          surface 136 and an outer surface 137, both of which surfaces are coated with an  
21          electrically conductive layer 138. The inner conductive layer 136 is, in use, in  
22          electrical communication with the skin. The outer conductive layer 137 is in contact  
23          with the interior surface of the glove and the pores 132. A medicament 139 capable  
24          of iontophoretic transdermal delivery is contained within the pores. A bipolar power  
25          source 140 has a working electrode 141 in electrical communication with the outer  
26          conductive layer 137 coating the electrically insulating sheet 135, and a ground  
27          electrode (not shown) which is in electrical communication with the inner conductive  
28          layer coating the electrically insulating sheet. When the power source 140 is  
29          energized, an electrical current flows between the inner conductive layer and the outer  
30          conductive layer, which layers are separated by the electrically insulating sheet, via the  
31          patient's skin. The polarity and amplitude of the current flowing through pores into

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1 the user's skin facilitates entry of the medicament into the skin. The glove  
2 embodiment, shown in use in Figure 14, is particularly useful for transdermally  
3 delivering medicament to large areas of skin.

4 The advantages of a unitary iontophoresis electrode and a glove and finger cot  
5 embodiment of an iontophoresis electrode for drug delivery have been presented. It is  
6 noted that similarly constructed electrodes may be employed for non-invasively  
7 collecting molecular species from the blood. For example, the mesh may be  
8 impregnated with an electrically conductive gel. The polarity of the gel, with respect  
9 to the skin, may be employed to transport blood components through the skin into the  
10 gel where such components may be detected and/or quantitated. Such measurements  
11 are useful for monitoring blood levels of compounds such as glucose or drugs.

12 The hand held iontophoretic device 40 (Figure 4) may be modified to include a  
13 piezoelectric element operable for imparting ultrasonic vibrational motion to the  
14 applicator electrode 12 to further facilitate transdermal delivery of certain  
15 iontophoretically transportable compounds. A schematic view of such a modified  
16 handpiece similar to the handpiece 40 of Figure 4 is shown at 150 in Figure 15. The  
17 applicator electrode 160 includes all embodiments of the applicator electrode  
18 described for the iontophoresis handpiece discussed above. One side of an annular  
19 ultrasonic piezoelectric element 151 is disposed rearwardly to the applicator electrode  
20 160 containing a medicament. Power is supplied to energize the piezoelectric element  
21 151 by means of conductive elements 157 and 152 which are in electrical  
22 communication with an ultrasonic driver 163. An optional current sensitive switching  
23 element (not shown) may be used to energize the piezoelectric element only when  
24 current passes through the applicator electrode circuit. The applicator electrode 160  
25 may include any applicator electrode heretofore described for use with an  
26 iontophoretic handpiece. The applicator electrode 160 may contain an ionic  
27 medicament or a biologically inactive ionic solution which penetrates the skin and  
28 opens clogged pores under the influence of iontophoretically driven transport assisted  
29 by ultrasonic waves in the cutaneous tissue. Stephen et al. have shown in US Patent  
30 4,979,938 that the iontophoretic delivery of hydroxyl ions into the skin can be used to  
31 treat acne. The ionosonic delivery of a similar anion may provide improved opening



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1 of pores in the skin for treating acne. The combination of iontophoretic delivery of a  
2 compound into a tissue, together with inducing ultrasonic vibration in the tissue, may  
3 enable the removal of coloration (such as a blemish, freckle or tattoo) within the skin  
4 by the delivery of a suitable bleaching agent

5 While the invention has been described above with references to specific  
6 embodiments thereof, it is apparent that many changes, modifications and variations in  
7 the materials, arrangements of parts and steps can be made without departing from the  
8 inventive concept disclosed herein. For example, an impregnated conductive gel can  
9 also be used to as medicament containing medium to increase the physical stability and  
10 the tissue adhering characteristics of the electrode. The applicator electrode described  
11 herein, when used with an ionosonic or iontophoretic handpiece can deliver  
12 medicaments for treating diverse medical conditions including, but not limited to acne,  
13 hyperproliferative diseases of the skin, superficial fungal infections, warts, and herpes  
14 type viral infections. Accordingly, the spirit and broad scope of the appended claims  
15 is intended to embrace all such changes, modifications and variations that may occur  
16 to one of skill in the art upon a reading of the disclosure. All patent applications,  
17 patents and other publication cited herein are incorporated by reference in their  
18 entirety.

19

20 What I claim is:

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Claims:

1. A medicament dispensing iontophoresis applicator electrode comprising a generally thimble-shaped electrically conductive member and an overlying medicament dispensing portion of an electrically non-conducting elastomer having a cell or plurality of cells in at least a portion thereof and wherein said thimble-shaped conductive portion is dimensioned to fit over and conform to the shape of the distal end of a finger.
2. The applicator electrode of claim 1 wherein said cell or plurality of cells contain a medicament.
3. The applicator electrode of claim 2 wherein said thimble-shaped electrically conductive member has a first end of an electrically conductive wire affixed thereto.
4. The applicator electrode of claim 3 wherein said electrically conductive wire has a second end in opposition to said first end and includes means for attaching said second end to a pole of a current source.
5. The applicator electrode of claim 2 wherein said medicament dispensing portion further comprises a hydrophilic matrix layer overlying said cell or plurality of cells for pre-treatment hydration by a user immediately prior to use when used with non-ionic medication formulation.
6. The applicator electrode of claim 5 wherein said hydrophilic matrix layer is hydrated.
7. The applicator electrode of claim 2 further comprising an electrically insulating layer underlying said thimble-shaped electrically conductive member.
8. A medicament-dispensing applicator electrode for use with an electrokinetic device to transdermally deliver a medicament to an individual, comprising:



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a substrate having a first surface and a second surface opposite said first surface, said substrate including a medicament-dispensing portion comprising a cell or a plurality of cells forming an aperture or a plurality of apertures between said first surface and said second surface, said cell or plurality of cells containing the medicament; and

a layer of adhesive covering at least a portion of said second surface of said substrate opposite said first surface for releasably attaching said substrate to an electrokinetic device containing an electrical power source for electrokinetically driving said medicament through said first surface and into the individual's skin upon application of an electrical current to effect delivery of said medicament in said cell or plurality of cells to the individual's skin.

9. The applicator electrode of claim 8 further comprising a tactile conductive portion carried by said substrate having a second cell or a plurality of cells electrically insulated from said medicament-dispensing portion, said second cell or plurality of cells containing an electrically conductive fluid for electrical connection through said second surface with a conductive portion on the electrokinetic device.

10. An applicator electrode according to claim 8 wherein said substrate comprises a strip, said medicament-dispensing portion being substantially centrally located along said strip, said layer of adhesive disposed along said second surface on opposite sides of said medicament-dispensing portion for securing the strip to the device.

11. An applicator electrode according to claim 8 wherein said second surface is pervious to enable electrical contact from the electrokinetic device through said second surface with the medicament or a carrier therefor.

12. An applicator electrode according to claim 8 including a switch-actuating member carried by said substrate to enable the electrokinetic device upon attaching said strip to said device.

13. An applicator electrode according to claim 8 in combination with the electrokinetic device wherein said device comprises a housing having a portion thereof shaped for grasping

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within an individual's hand for manual manipulation by the individual, and a first electrode exposed for contact with said second surface of said substrate upon application of said substrate to said device, the power source being contained within said housing and having first and second terminals, said first terminal being in electrical contact with said first electrode, a tactile electrode in electrical contact with said second terminal of said power source and having a surface for electrical contact with the individual's skin;

said device being operable to deliver said medicament from said applicator electrode to a portion of the individual's skin in contact with said first surface in response to completion of an electrical circuit between said first terminal through said first electrode and said substrate via the individual's skin and said second terminal via said tactile electrode and another portion of the individual's skin.

14. A medicament-dispensing applicator electrode for use with an electrokinetic device to transdermally deliver a medicament to an individual, comprising:

a substrate having a first surface and a second surface opposite said first surface, said substrate including a medicament-dispensing portion comprising a cell or a plurality of cells forming an aperture or a plurality of apertures between said first surface and said second surface, said cells or plurality of cells containing the medicament; and

a layer of adhesive covering at least a portion of said first surface of said substrate opposite said second surface for releasably attaching said substrate to an individual's skin, said aperture or plurality of apertures being open along said second surface such that the medicament is electrokinetically driven through said first surface and into the individual's skin upon electrically contacting an electrokinetic device containing an electrical power source with said second surface of said medicament-dispensing portion to generate an electrical current to effect delivery of said medicament in said cell or plurality of cells to the individual's skin.

15. An applicator electrode according to claim 14 wherein said substrate comprises a strip, said medicament-dispensing portion being centrally located along said strip, said layer of adhesive disposed along said first surface on opposite sides of said medicament-dispensing portion for releasably securing the strip to the individual's skin.



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16. An applicator electrode according to claim 14 in combination with the electrokinetic device wherein said device comprises a housing having a portion thereof shaped for grasping within an individual's hand for manual manipulation by the individual, and a first electrode exposed for contact with said second surface of said substrate upon application of said device to the substrate, the power source being contained within said housing and having first and second terminals, said first terminal being in electrical contact with said first electrode, a tactile electrode in electrical contact with said second terminal of said power source and having a surface for electrical contact with the individual's skin;

said device being operable to deliver said medicament from said applicator electrode to a portion of the individual's skin in contact with said first surface in response to completion of an electrical circuit between said first terminal through said first electrode and said substrate via the individual's skin and said second terminal via said tactile electrode and another portion of the individual's skin.

17. An applicator electrode according to claim 14 including a switch-actuating member carried by said substrate to enable the electrokinetic device and thereby generate an electric current to effect delivery of the medicament.

18. A medicament-dispensing applicator electrode for use with an electrokinetic device to transdermally deliver a medicament to an individual, comprising:

a substrate having a first surface and a second surface opposite said first surface, said substrate including a medicament-dispensing portion between said first surface and said second surface and defining a reservoir for containing the medicament; and

a layer of adhesive covering at least a portion of one of said first surface and said second surface of said substrate for releasably attaching said substrate to one of an electrokinetic medicament-delivery device containing an electrical power source or an individual's skin, said second surface of said medicament-dispensing portion being pervious to enable electrical contact through said second surface with the medicament or a carrier therefor such that the medicament is electrokinetically driven from said reservoir through said first surface

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and into the individual's skin upon transmission of an electrical current through said second surface, said reservoir and said first surface.

19. The applicator electrode of claim 18 further comprising a tactile conductive portion carried by said substrate having an electrically conductive fluid electrically insulated from said medicament-dispensing portion for electrical connection through said second surface with a conductive portion on the electrokinetic device.

20. An applicator electrode according to claim 18 wherein said substrate comprises a strip, said medicament-dispensing portion being centrally located along said strip, said layer of adhesive disposed along said second surface on opposite sides of said medicament-dispensing portion for securing the strip to the device.

21. An applicator electrode according to claim 18 in combination with the electrokinetic device wherein said device comprises a housing having a portion thereof shaped for grasping within an individual's hand for manual manipulation by the individual, and a first electrode exposed for contact with said second surface of said substrate upon application of said substrate to said device, the power source being contained within said housing and having first and second terminals, said first terminal being in electrical contact with said first electrode, a tactile electrode in electrical contact with said second terminal of said power source and having a surface for electrical contact with the individual's skin;

said device being operable to electrokinetically deliver said medicament from said applicator electrode to a portion of the individual's skin in contact with said first surface in response to completion of an electrical circuit between said first terminal through said first electrode and said substrate via the individual's skin and said second terminal via said tactile electrode and another portion of the individual's skin.

22. Apparatus for the transdermal delivery of a medicament to an individual, comprising:  
a medicament-dispensing applicator electrode including a substrate having a first surface and a second surface opposite said first surface, said substrate including a medicament-dispensing portion comprising a cell or a plurality of cells forming an aperture or a



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plurality of apertures between said first surface and said second surface, said cell or plurality of cells containing the medicament;

an electrokinetic device comprising a housing having a portion thereof shaped for grasping within an individual's hand for manual manipulation by the individual, and a first electrode formed of electrically conductive material and in electrical contact with said substrate and with a portion of an individual's skin upon application of said device to the individual's skin with said substrate interposed therebetween;

a power source contained within said housing having first and second terminals, said first terminal being in electrical contact with said first electrode;

a tactile electrode in electrical contact with said second terminal of said power source and having a surface for electrical contact with another portion of an individual's skin; and

said device being operable to electrokinetically drive said medicament from said applicator electrode to effect delivery of said medicament in said cell or plurality of cells to the portion of the individual's skin in contact with said substrate on one side thereof in response to completion of an electrical circuit between said first terminal through said first electrode and said substrate via the individual's skin portion and said second terminal via said tactile electrode and the another portion of the individual's skin.

23. Apparatus applicator electrode according to claim 22 including a switch-actuating member carried by said substrate to enable said device and thereby complete the electrical circuit.

24. Apparatus for the transdermal delivery of a medicament to an individual, comprising:

a medicament-dispensing applicator electrode;

an electrokinetic device;

said medicament-dispensing applicator electrode including a substrate having a first surface and a second surface opposite said first surface, said substrate including a medicament-dispensing portion comprising a cell or a plurality of cells forming an aperture or a plurality of apertures between said first surface and said second surface, said cell or plurality of cells containing the medicament, said substrate having a portion thereof for releasably coupling said substrate to said device;

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said device comprising a housing having a portion thereof shaped for grasping within an individual's hand for manual manipulation by the individual, and a first electrode formed of electrically conductive material and exposed for contact with said substrate upon releasable connection to said device;

a power source contained within said housing having first and second terminals, said first terminal being in electrical contact with said first electrode;

a tactile electrode in electrical contact with said second terminal of said power source and having a surface for contact with the individual's skin; and

said device being operable to electrokinetically drive said medicament from said applicator electrode to effect delivery of said medicament in said cell or plurality of cells to a portion of the individual's skin in contact with said substrate on one side thereof in response to completion of an electrical circuit between said first terminal through said first electrode and said substrate via the individual's skin and said second terminal via said tactile electrode and another portion of the individual's skin.

25. A medicament-dispensing electrokinetic applicator for delivering medicament to a large area of an individual's skin, comprising:

a glove-shaped body containing a medicament for application through an outer surface thereof; and

a conductive layer formed within said glove-shaped body for connection with an electrical power source and electrokinetically driving the medicament from the body onto an area of the individual's skin overlaid and in contact with said glove-shaped body upon application of an electrical current to effect delivery of said medicament contained in the body to the large area of the individual's skin in contact with the overlying glove-shaped body, wherein said conductive layer comprises a multi-channel electrode.

26. Apparatus for the transdermal delivery of medicament to an individual, comprising:

a medicament-dispensing electrode;

an electrokinetic device;

said medicament-dispensing electrode including a substrate having a first surface and a second surface opposite said first surface, said substrate including a medicament-



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dispensing portion having a cellular structure with one or a plurality of cells dimensioned to retain a medium including the medicament within the confines of the cellular structure for electrokinetically transporting the medicament from said cell or plurality of cells through said first surface into the individual's skin upon flowing an electrical current between said first surface and said second surface;

a tactile conductive portion carried by said substrate having a second cell or a plurality of cells electrically insulated from said medicament-dispensing portion, said second cell or plurality of cells containing an electrically conductive material for electrical connection through said second surface with a conductive portion on the electrokinetic device; and

said electrokinetic device including a housing having a portion thereof shaped for manual manipulation by the individual's hand, and a first electrode exposed for contact with said second surface of said substrate upon engagement of said substrate and said device with one another, a power source within said housing and having first and second terminals, said first terminal being in electrical contact with said first electrode, a tactile electrode in electrical contact with said second terminal of said power source and having a surface for electrical contact with the tactile conductive portion of the applicator electrode, said device being operable to deliver said medicament from said applicator electrode to a portion of the individual's skin in contact with said first surface in response to completion of an electrical circuit between said first terminal through said first electrode and said substrate via the individual's skin and said second terminal via said tactile electrode, said tactile conductive portion and another portion of the individual's skin.

27. Use of a hand-held iontophoretic device comprising an electrode and a medicament dispensing reservoir containing an antiviral agent, said reservoir being in electrical communication with said electrode, for treating lesions associated with cold sore and genital herpes, wherein the medicament dispensing reservoir is in contact with said lesions and a voltage gradient between the electrode and the lesion is present.

28. Use of claim 27 wherein said medicament comprises (2-amino-1,9-dihydro-9-[(2-hydroxyethoxy)methyl]-6H-purin-6-one) or iontophoretically transportable analogs thereof.

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29. Use of a hand-held ionosonic device comprising an electrode and a medicament dispensing reservoir containing an antiviral agent, said reservoir being in electrical communication with said electrode, for treating lesions associated with cold sore and genital herpes, wherein:

the medicament dispensing reservoir is in contact with said lesions;  
ultrasonic vibration in a tissue comprising the lesion is present; and  
a voltage gradient between the electrode and the lesion is present.

30. Use of claim 29 wherein said medicament comprises (2 amino-1,9-dihydro-9-[(2-hydroxyethoxy) methyl]-6H-purin-6-one) or ionosonically transportable analogs thereof.

31. Use of a hand-held ionosonic device comprising an electrode and a medicament dispensing reservoir containing an ionic compound in electrical communication with said electrode, for treating lesions associated with acne, wherein:

the medicament dispensing reservoir is in contact with a said lesion;  
ultrasonic vibration in a tissue comprising the lesion is present; and  
a voltage gradient between the electrode and the lesion is present.

32. Use of claim 31 wherein said ionic compound is anionic.

33. Use of claim 31 wherein said ionic compound is a hydroxyl ion.

34. Use of claim 31 wherein said ionic compound is cationic.

35. A disposable medicament dispensing applicator electrode for an iontophoretic drug delivery device adapted for the self-administration of a medicament into a person's skin, said device comprising a base assembly having an active terminal adapted to receive and make electrical contact with a detachable medicament dispensing applicator electrode wherein said base assembly comprises: a case having an elongate, substantially cylindrical outer surface having a size and shape adapted to be comfortably grasped within a person's hand and wherein at least a portion of said outer surface is a tactile electrode formed of an electrically



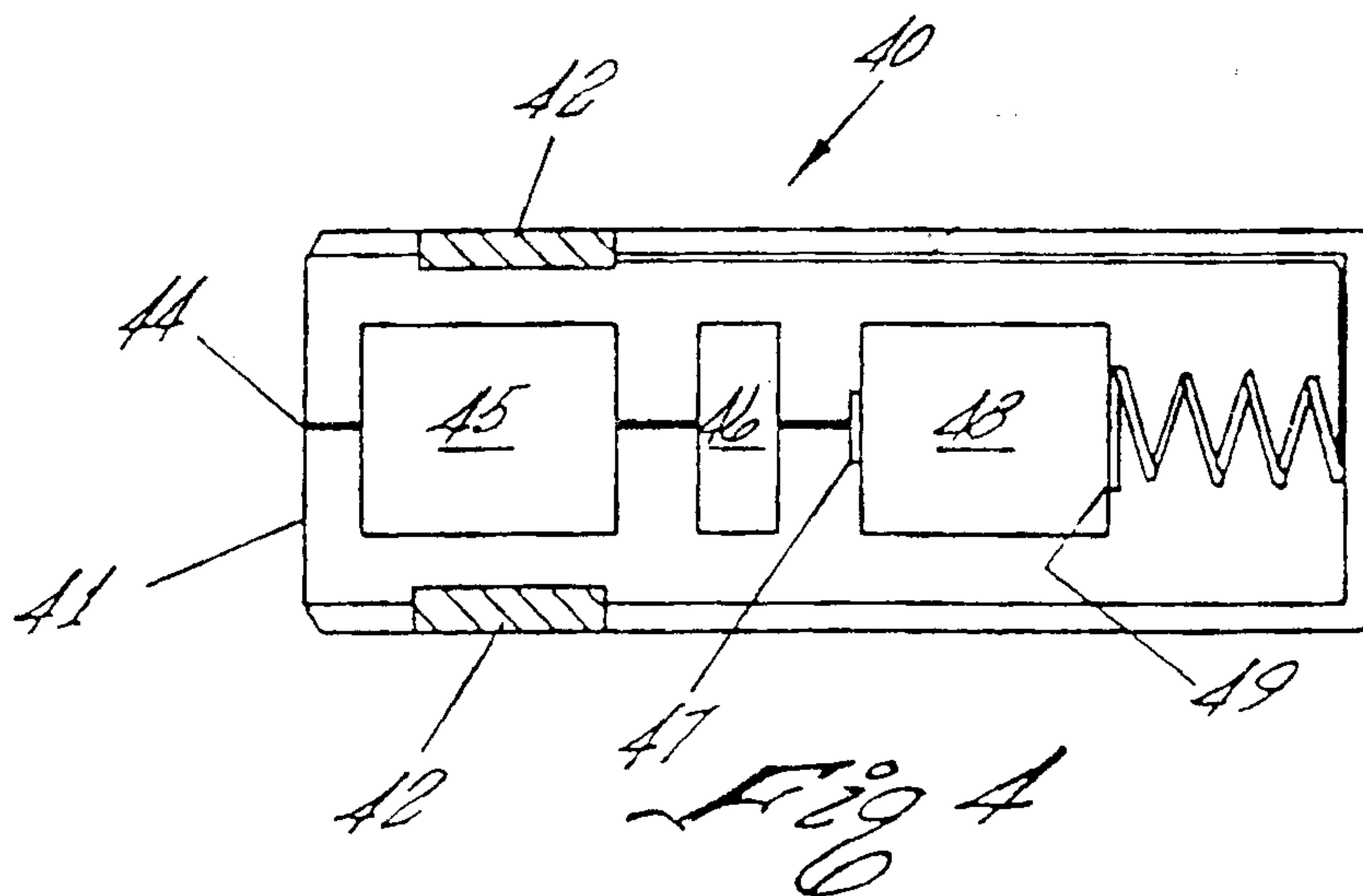
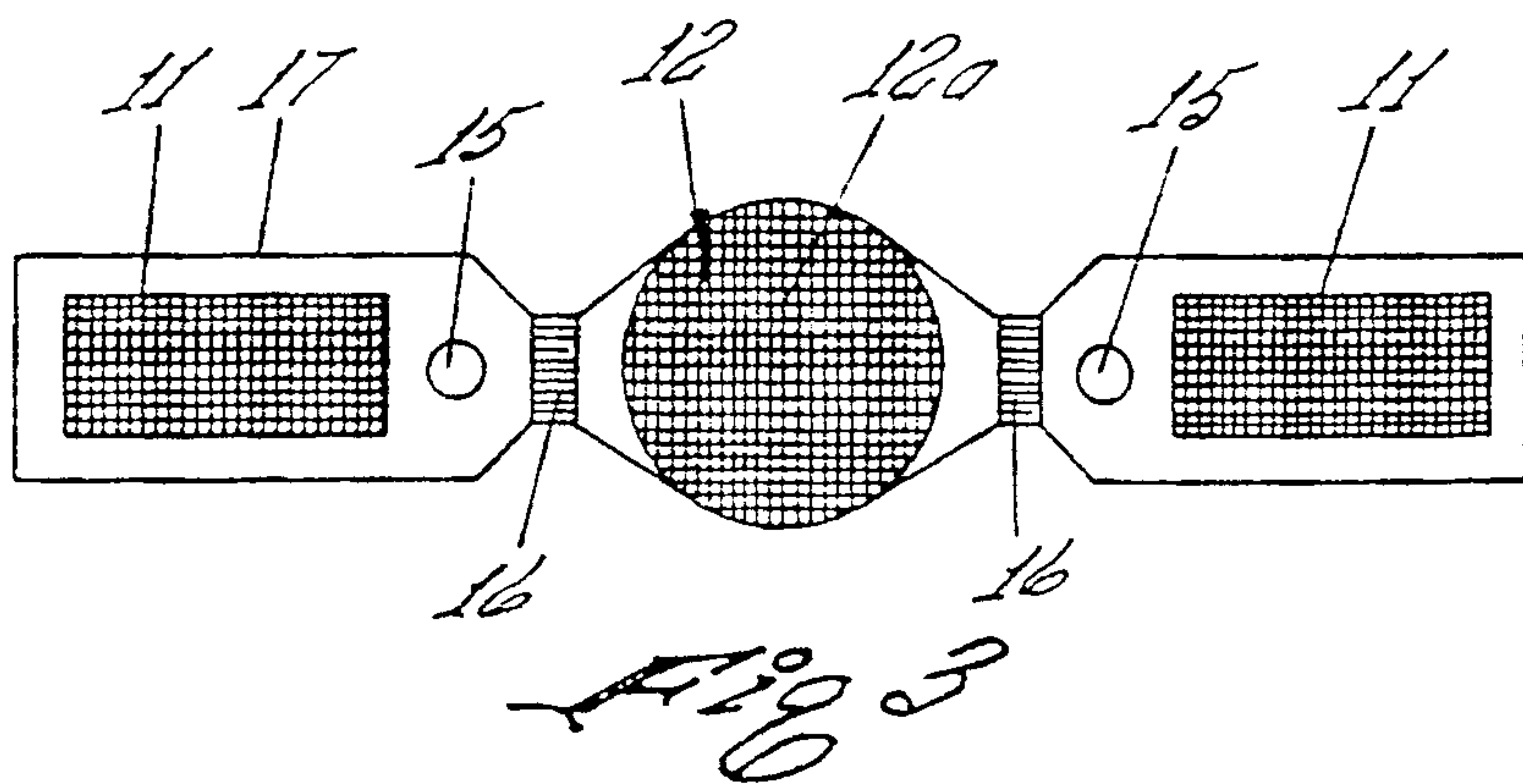
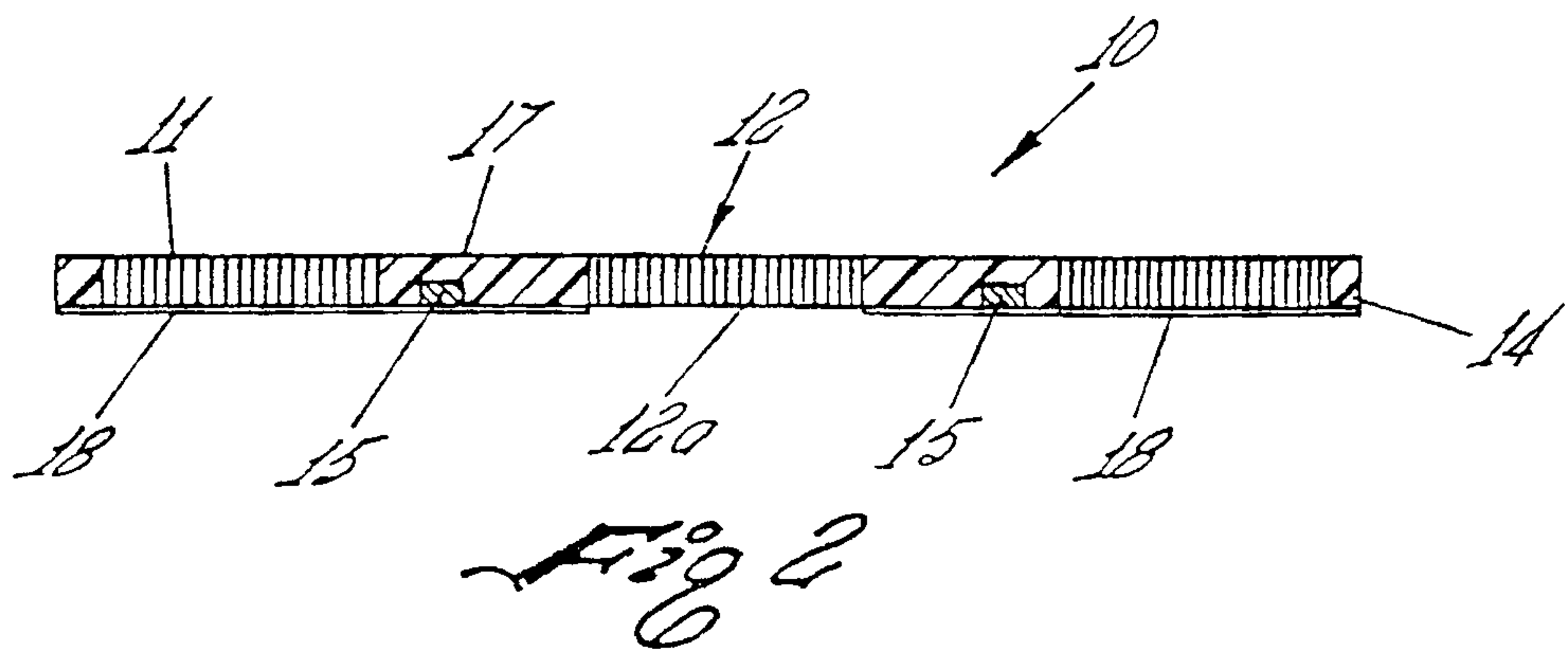
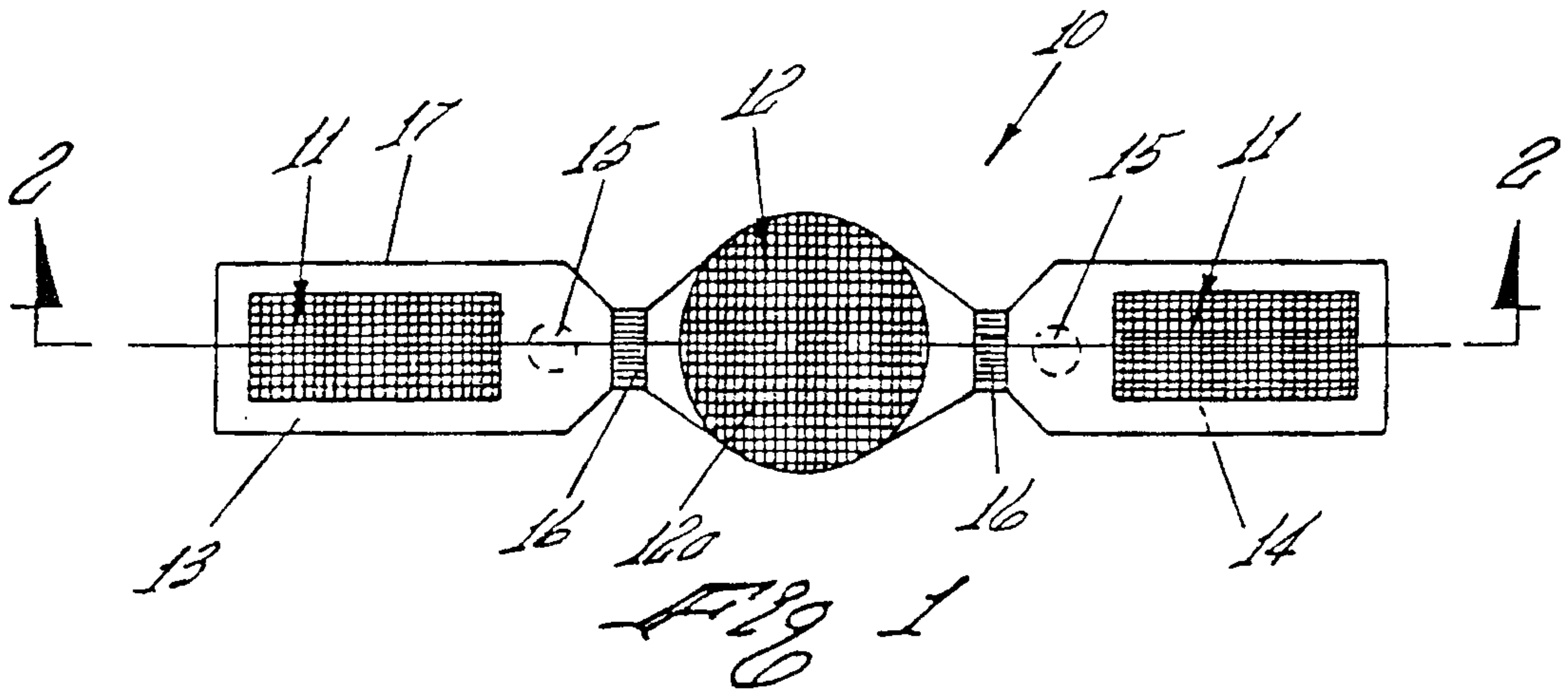
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conductive material; and a bipolar electrical power means having a first pole and a second pole; said electrical power means being enclosed within said case and wherein said first pole is in electrical communication with said tactile electrode; wherein said medicament dispensing applicator electrode comprises: a module containing unit dose of medicament, an electrically conductive working electrode and means thereon adapted for releasably attaching said working electrode to said second pole of said electrical power means wherein said working electrode further comprises an elongate strip constructed of a substantially electrically non-conductive substrate material, said strip having a central portion containing a medicament in an electrically conductive substrate and laterally symmetric end portions having cutouts therewithin.

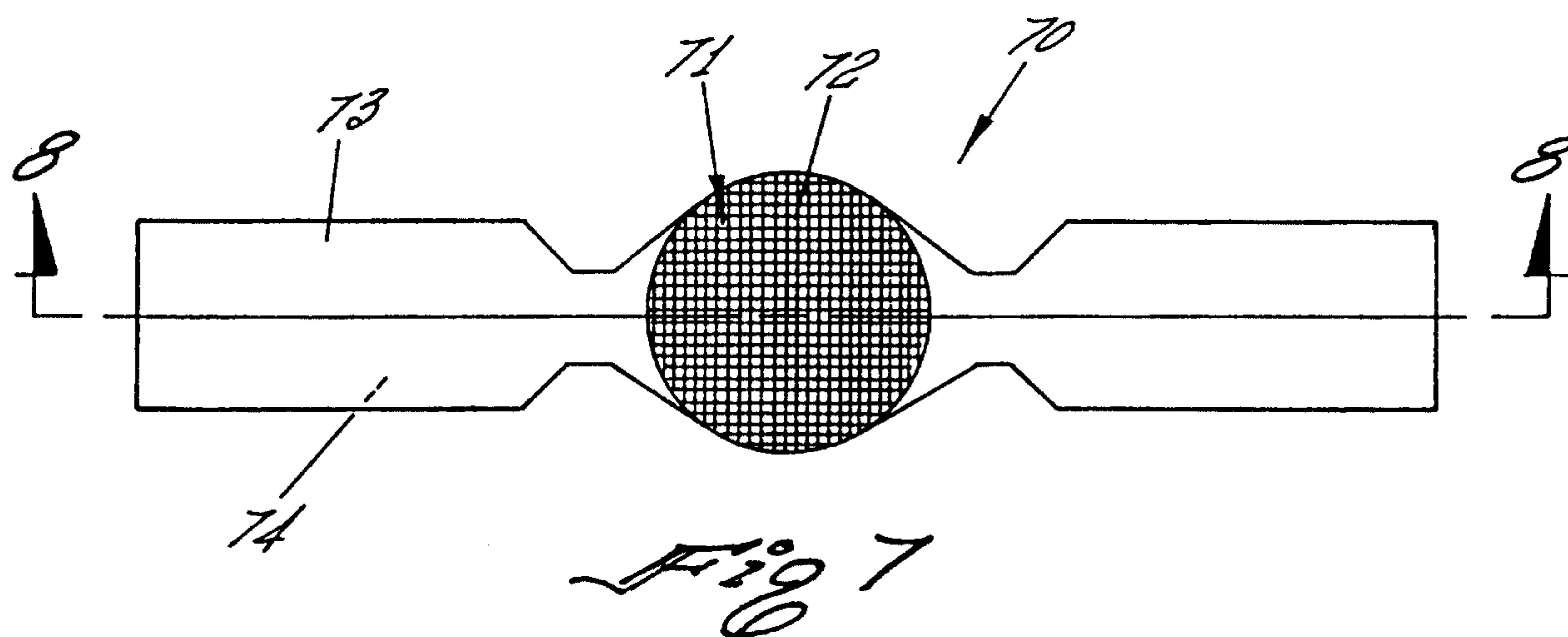
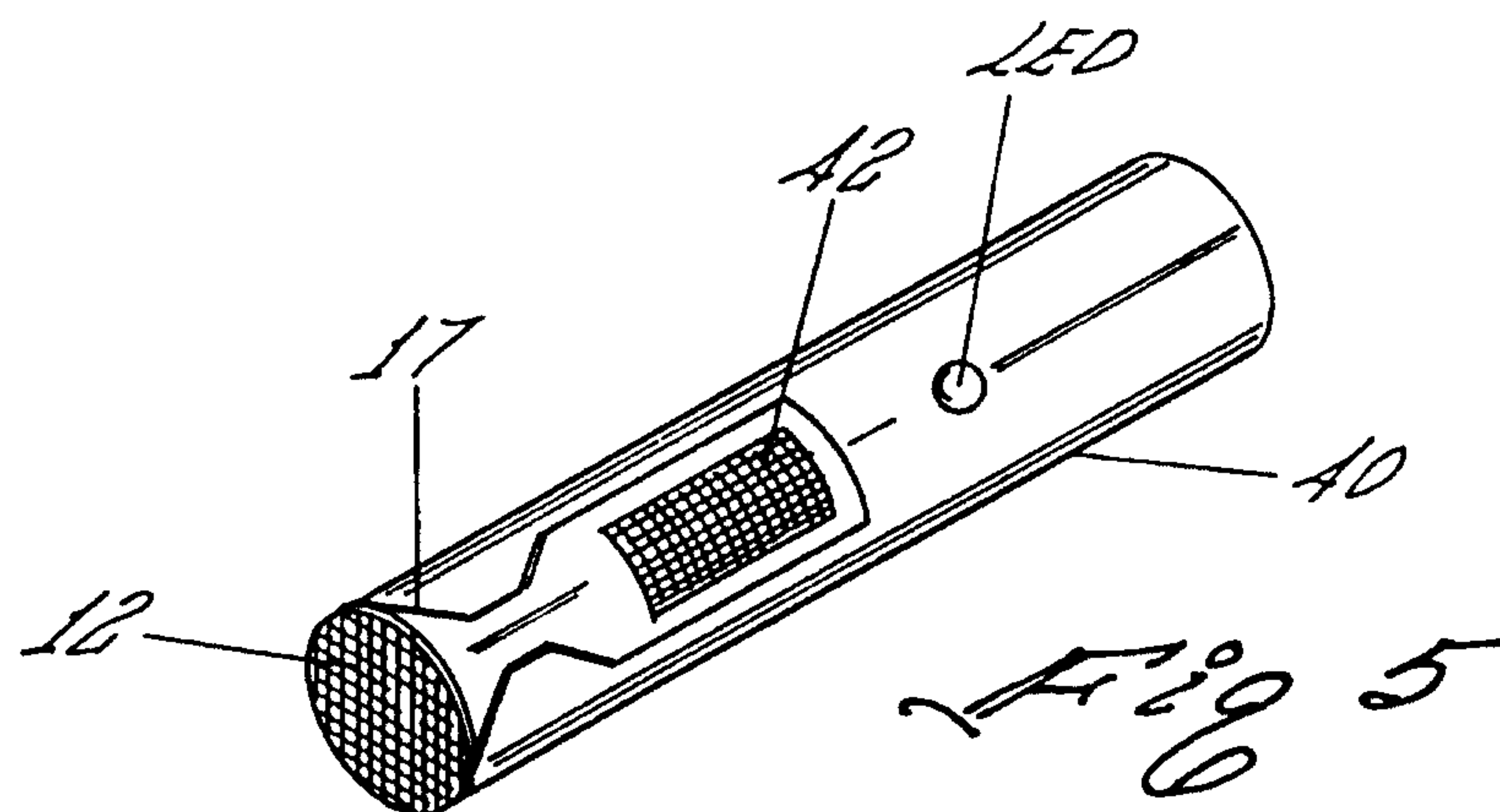
36. The disposable medicament dispensing applicator electrode of claim 35 wherein said cutouts in said laterally symmetric end portions contain an electrically conductive material.

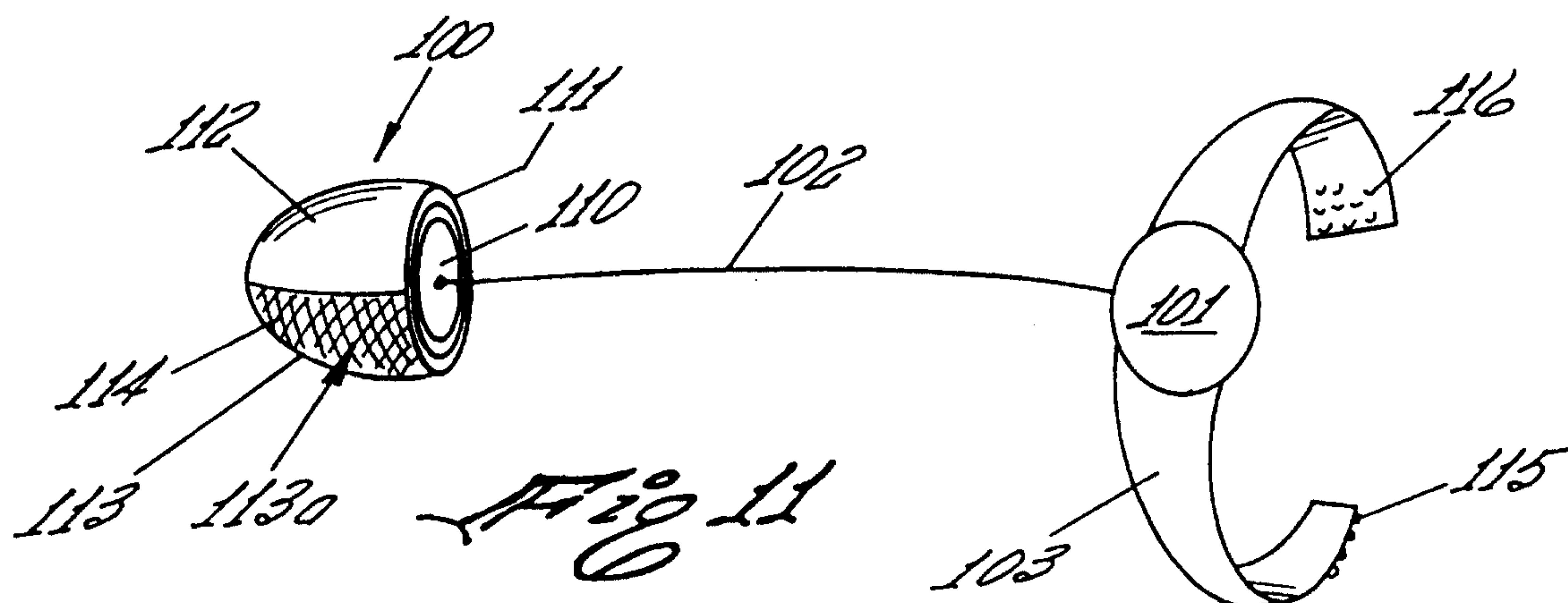
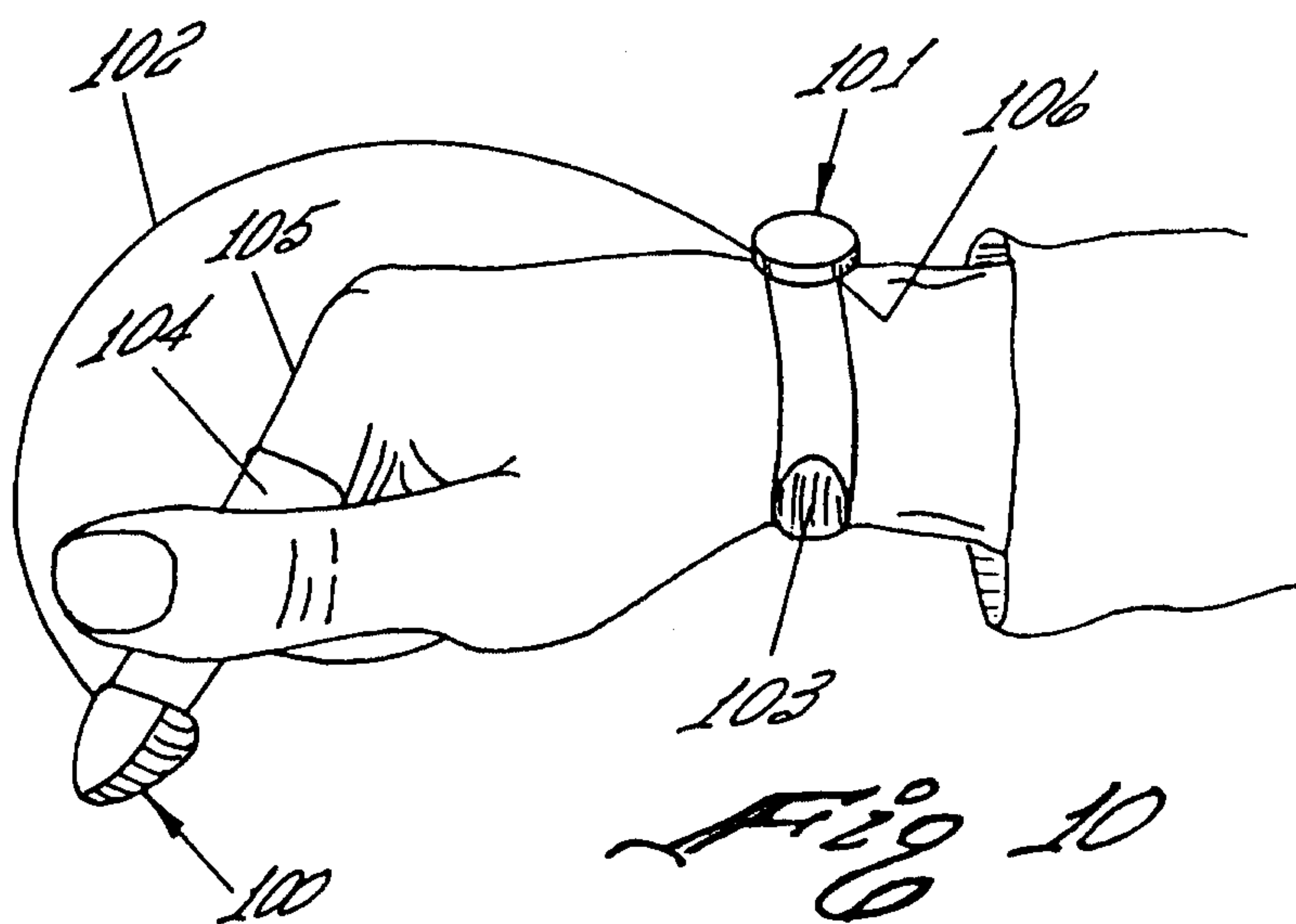
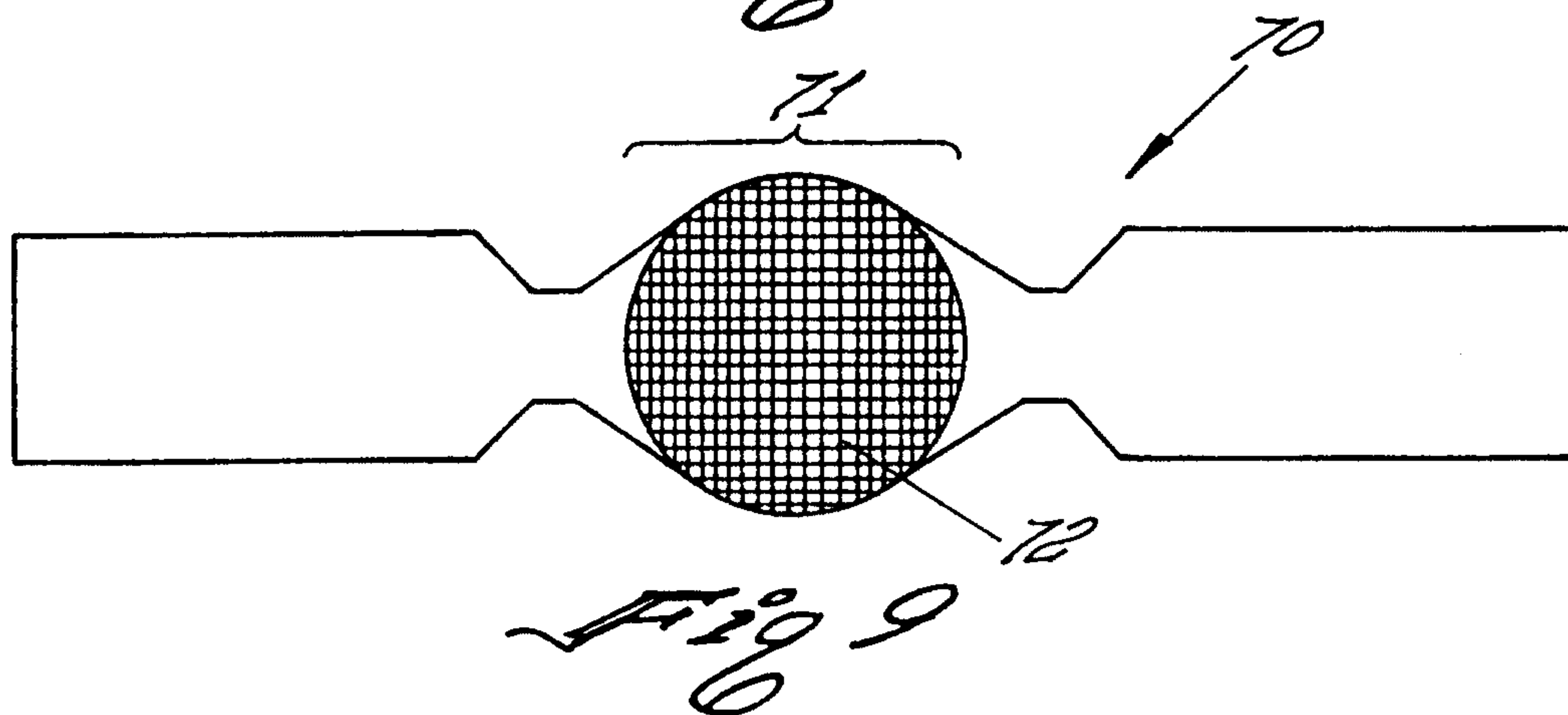
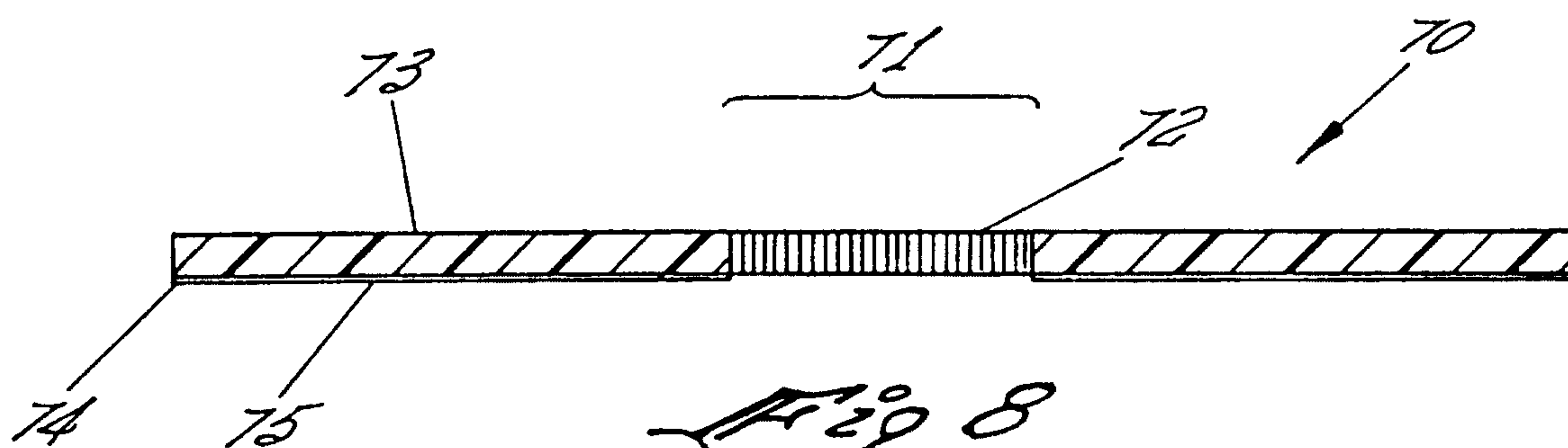
37. The disposable medicament dispensing applicator electrode of claim 36 wherein said electrically conductive material is a gel.

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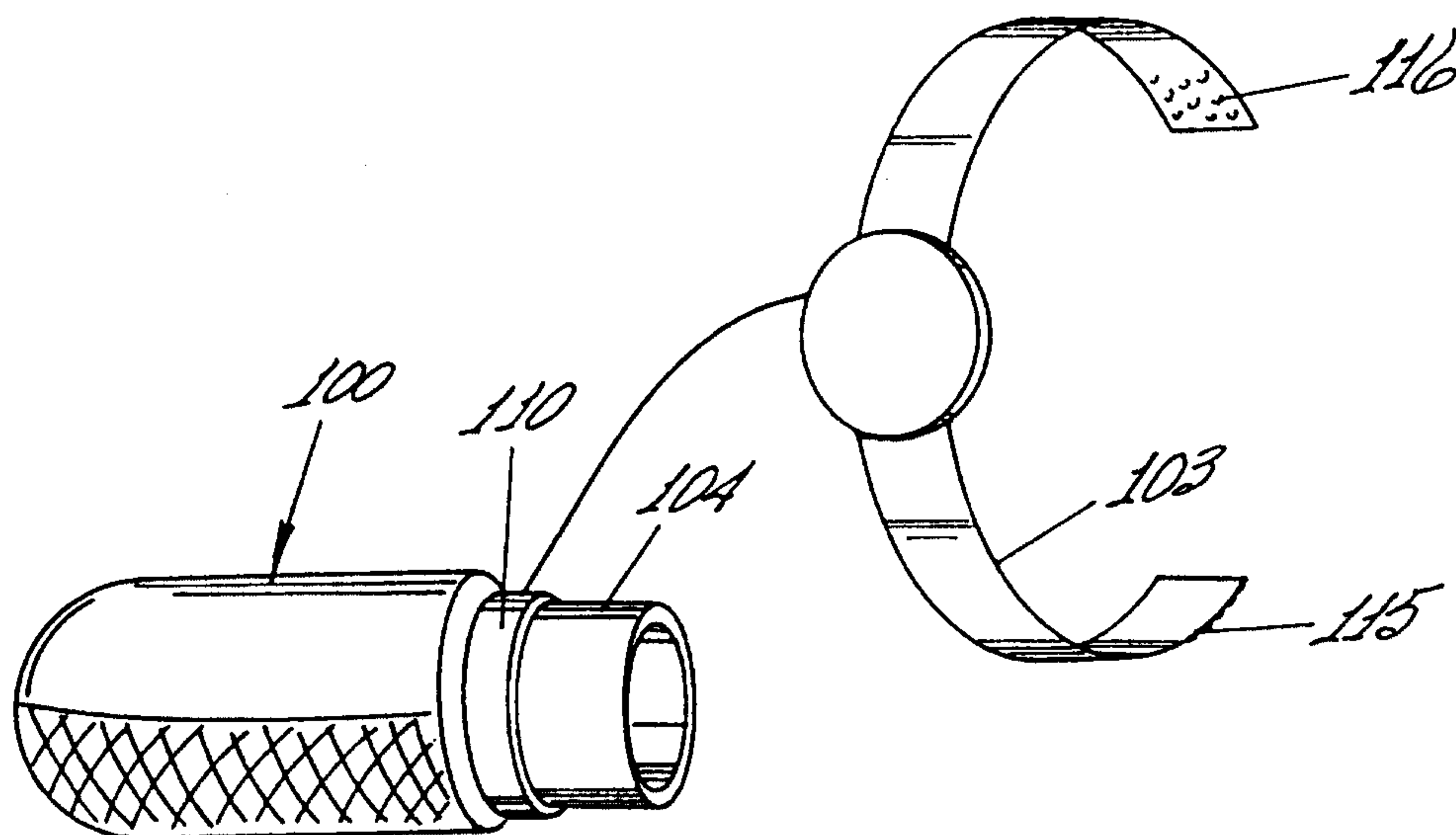


Fig 12

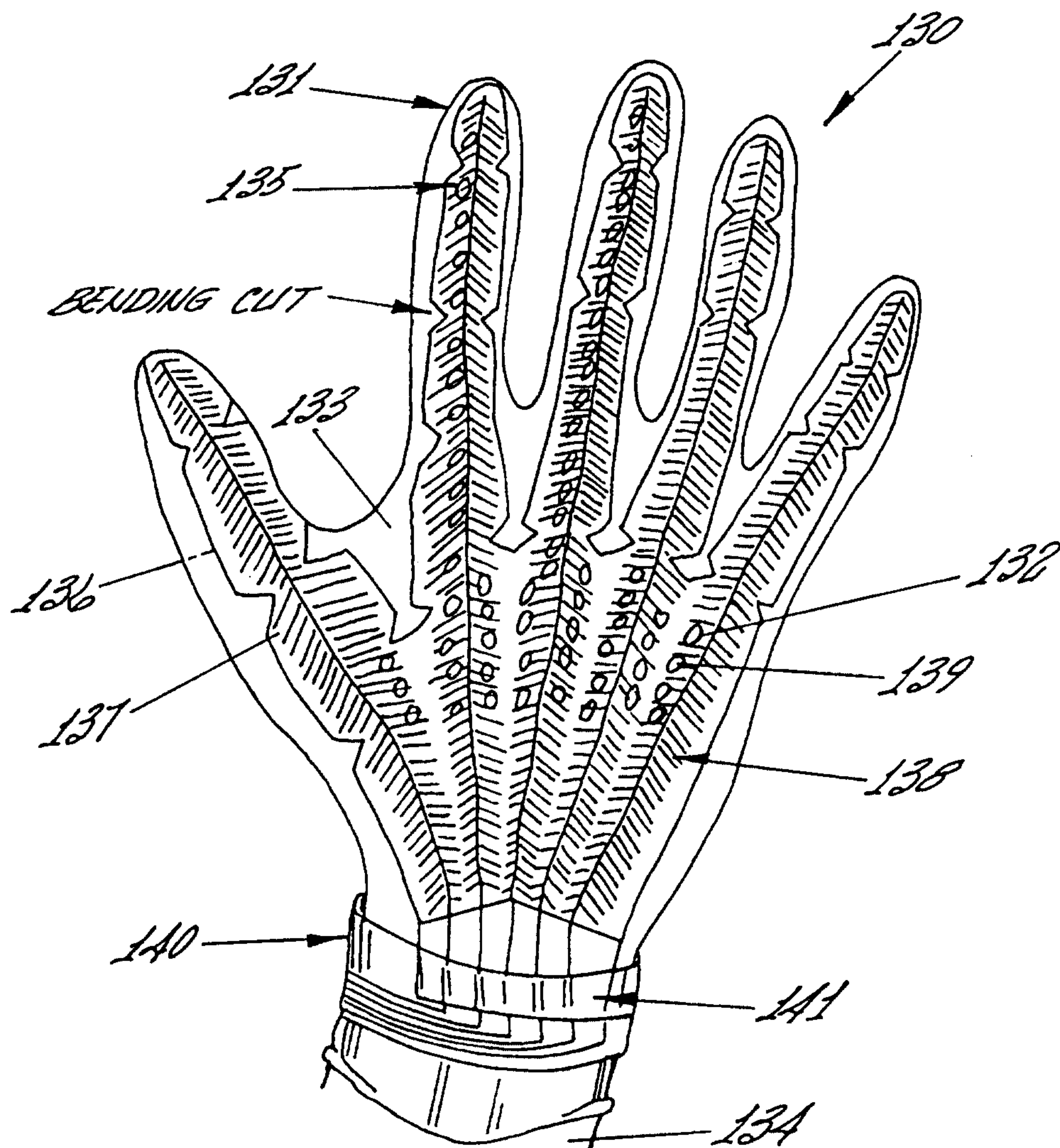
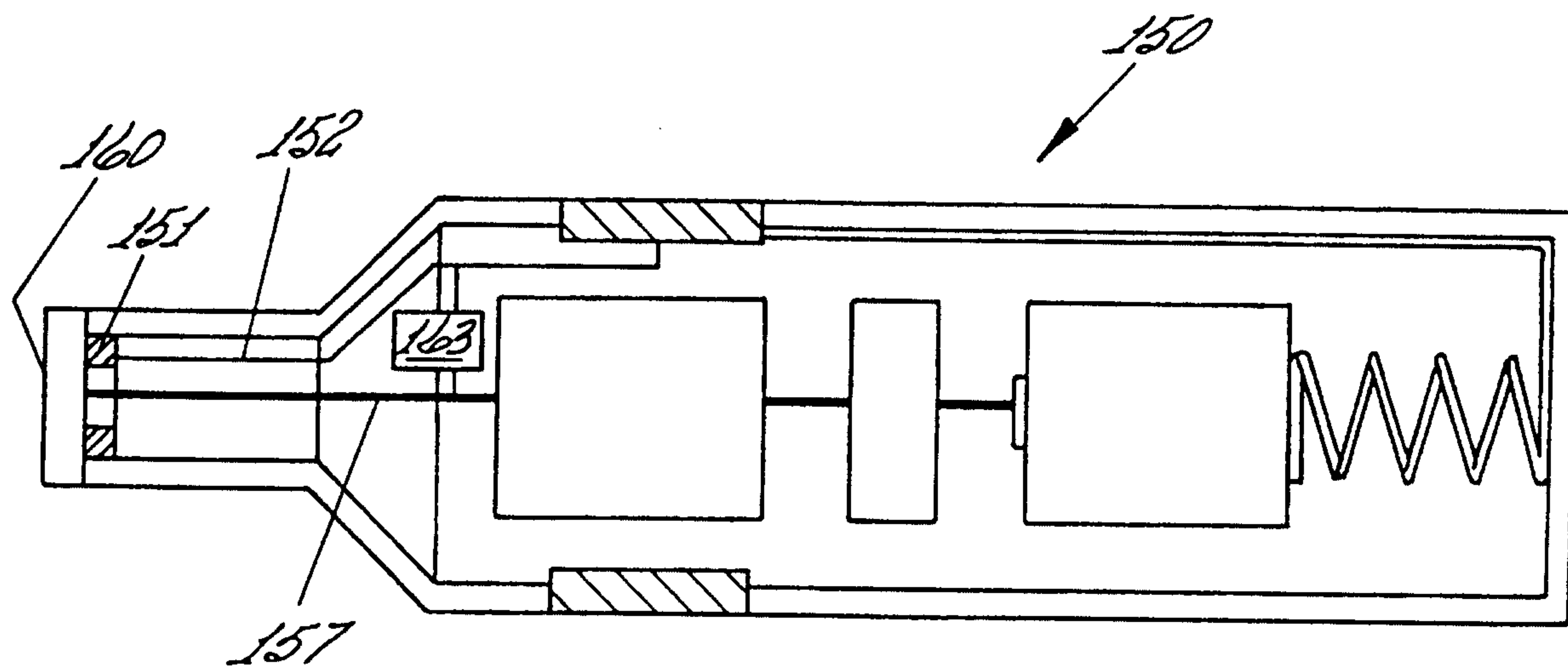


Fig 13

*Fig 14**Fig 15*



