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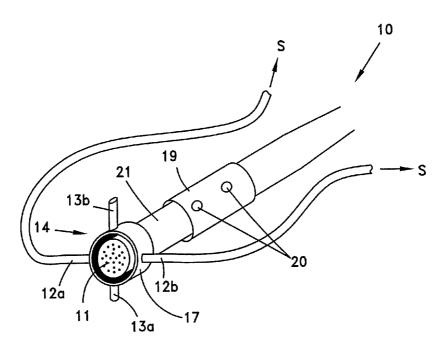
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(54) Title: APPARATUS AND METHOD FOR REMOVING PIGMENTS FROM A PIGMENTED SECTION OF SKIN



(57) Abstract: An apparatus for removing a pigmented section of skin, comprises a) a skin puncturing device; b) an array of one or more needles connected to said device for puncturing the skin at said pigmented section; and c) a mediating member attached to said device and to suction means, for allowing said suction means to collect the mixture of the pigments with the cellular fluids at said punctured section of the skin.



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# A PIGMENTED SECTION OF SKIN

#### Field of the Invention

The present invention relates to the field of pigment removal. More particularly, the invention relates to an apparatus and to a method for removing a pigmented section of skin, particularly a tattoo.

#### **Background of the Invention**

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Tattoos are created by injecting ink into the skin. Today, in most cases, the injection of the ink is done by one or more solid needles which are attached to a device (referred to hereinafter as "skin puncturing device"). Preferably, but not limitatively, the skin puncturing device is a hand-held device. The skin puncturing device moves the needle along the longitudinal axis of the device, similar to the movement of a needle in a sewing machine. Usually the skin puncturing device moves the needle at a rate of several vibrations per minute (e.g., the needles may puncture the skin at the rate of 50 to 3,000 times per minute). Prior to the penetration of the needle into the skin, the needle is dipped in a suitable solution which contains pigment (e.g., ink) and then this solution is sucked up through a suitable tube system of the skin puncturing device. After receiving the solution the skin puncturing device is used to puncture the top layer of the skin and injects insoluble, micrometer-sized particles of ink

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into the dermal layer of skin (i.e., dermis), preferably, about one millimeter deep. As a result, the ink is not located in the epidermis, but it infiltrates the cells in the dermis. Since the cells of the dermis are relatively fixed, the tattoo's ink remains at the dermis, thereby permanently tattooing the skin.

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For a variety of reasons, there are people who wish to remove a tattoo (or other pigment) from their skin. However, because tattoos become an integral part of the cells in the dermis, removing them is not an easy task. In the prior art several methods for removing tattoos have been suggested, which, however are usually invasive; some methods even require surgery and may also be painful. Such known methods are:

- Dermabrasion, wherein skin is "sanded" (i.e., abraded) to remove the surface which contains the tattoo;
- Cryosurgery, wherein the area where the tattoo is located is frozen prior to its removal; and
- Excision, wherein the dermatologic surgeon removes the tattoo with a scalpel and closes the wound with stitches (In some cases involving large tattoos, a skin graft from another part of the body may be necessary).

However, such tattoo-removal methods are painful and may also create scars.

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Other methods for tattoo removal use lasers. Lasers offer a bloodless alternative to the abovementioned methods and may also have fewer side effects. Each removal procedure is done in a single treatment, or in a series of treatments. Patients may or may not require topical or local anesthesia. Lasers remove tattoos by producing short pulses of intense light, which pass through the top layers of the skin and are then selectively absorbed by the tattoo pigment. This laser energy causes the tattoo pigment to be fragmented into smaller particles, which are then removed by the body's immune system. However, there is still a possibility that using a laser may cause scarring. Furthermore, it is difficult with a laser to remove pigments of yellow and green. Such colors selectively absorb laser light and can only be treated by selected lasers based on the pigment color. Moreover, there are side effects of laser procedures which may cause hyper pigmentation, or an abundance of color in the skin at the treatment site, and hypo pigmentation, where the treated area lacks normal skin color.

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In addition, tattoo removal using each of the above methods is long and expensive.

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All the methods described above have not yet provided satisfactory solutions to the problem of removing a pigmented section of skin by simple

means.

5 It is an object of the present invention to provide a method for removing a

pigmented section of skin while overcoming the drawbacks of the prior art.

It is another object of the present invention to provide a method for

removing a pigmented section of skin at a relatively low cost.

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Other objects and advantages of the invention will become apparent as the

description proceeds.

**Summary of the Invention** 

15 The present invention relates to an apparatus for removing a pigmented

section of skin, which comprises: (a) a skin puncturing device; (b) an array

of one or more needles connected to said device for puncturing the skin at

said pigmented section; and (c) a mediating system attached to said device

and to suction means for allowing said suction means to collect the

mixture of the pigments with the cellular fluids at said punctured section

of skin, wherein said member is capable of creating an essentially isolated

area above said punctured section of skin, which is suitable for puncturing

and for suction of the area.

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According to a preferred embodiment of the invention, the mediating system comprises a mediating member having one or more openings through which the suction means collects the mixture of the pigments with the cellular fluids and, optionally, with externally-injected materials.

According to a preferred embodiment of the invention, the mediating member further comprises means for attaching it to a source of a cleaning material, for applying the cleaning material onto the punctured skin, thereby cleaning the punctured area during the removal of the pigments from the pigmented section of the skin. Preferably, the means for attaching the mediating member to the source of a cleaning material are one or more openings through which the source of cleaning material delivers the cleaning material onto the punctured skin.

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Preferably, the mediating system is attached to the skin puncturing device in such a way that the openings of the mediating member are located adjacent to the sharp edge of the array of needles.

According to another preferred embodiment of the present invention, the one or more needles are hollow. The hollow needles are provided with openings suitable to be connected to a source of cleaning material for applying the cleaning material onto the punctured skin, thereby cleaning

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the punctured area during the removal of the pigmented section of skin.

The cleaning material may also consist of, or comprise as an additive, one or more antiseptic and/or disinfecting material.

5 Preferably, the cleaning material is a fluid, air under pressure or a combination of both fluid and air pressure.

Preferably, the mediating member is attached to the puncturing device with one or more screws.

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According to a preferred embodiment of the invention, the skin puncturing device is an electric device for creating tattoos (i.e., a tattooing machine).

The present invention further relates to a method for removing a pigmented section of a skin, which comprises: a) providing a skin puncturing device which includes one or more needles and suction means; b) puncturing the skin at said pigmented section with said needles while said skin puncturing device contains no ink and performing suction (with said suction means), of the mixture of the pigments with the cellular fluids at said punctured section of the skin; c) optionally, providing a pad containing one or more materials capable of absorbing moisture from said mixture; and d) bandaging said punctured skin with said pad, thereby

causing the pigment residue at said section to migrate from their location

towards the outer layer of the skin.

According to a preferred embodiment of the present invention, the method

further comprises applying (e.g., spraying) fluids on the punctured section

of skin for cleaning said section.

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According to another preferred embodiment of the present invention, the

method further comprises bandaging the punctured skin with a pad

containing one or more antiseptic materials for preventing infections.

According to a preferred embodiment of the invention the material applied

to the pigments is saline.

15 Brief Description of the Drawings

The above and other characteristics and advantages of the invention will

be better understood through the following illustrative and non-limitative

detailed description of preferred embodiments thereof, with reference to

the appended drawings, wherein:

- Fig. 1 schematically illustrates an apparatus for removing a

pigmented section of a skin, according to a preferred embodiment of

the present invention;

- Fig. 2 schematically illustrates the components of the apparatus of Fig. 1;
- Fig. 3 schematically illustrates a skin puncturing device provided with the apparatus of Fig. 1;
- 5 Fig. 4 illustrates the actual dimensions of an array of needles;
  - Fig. 5 schematically illustrates a mediating member according to an alternative preferred embodiment of the invention;
  - Fig. 6 illustrates the actual dimensions of the tip of an apparatus, according to a preferred embodiment of the invention;
- Fig. 7 schematically shows an apparatus for removing pigments from a pigmented section of skin, constructed according to another preferred embodiment of the invention;
  - Fig. 8 schematically illustrates the different components of the apparatus of Fig. 7;
- Fig. 9 shows some of the elements of the apparatus of Fig. 7 in perspective view;
  - Fig. 10 schematically shows the apparatus of Fig. 7, in working position when attached to a typical tattooing gun;
  - Fig. 11 schematically shows a boundary element used for limiting the spreading of the mixture of cellular fluids and pigments; and

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- Figs. 12-14 schematically illustrate an apparatus according to yet another preferred embodiment of the invention.

#### <u>Detailed Description of Preferred Embodiments</u>

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As stated above, the present invention relates to an apparatus for removing a pigmented section of a skin by puncturing the skin at the pigmented section of the skin and concurrently performing a suction of the mixture of the pigments with the cellular fluids (with or without externally added fluids) at the punctured section of the skin.

Figs. 1 and 2 schematically illustrate the apparatus 10 for removing a pigmented section of a skin, according to a preferred embodiment of the present invention. Apparatus 10 comprises an array of one or more needles 11 (the tips of which are seen in the figure) for puncturing the skin at the pigmented section, and a mediating system 14.

Apparatus 10 operates when attached to a device which causes needles 11 to vibrate, such as a typical tattooing machine (i.e., skin puncturing device). Needles 11 can be attached to a skin puncturing device by any suitable method well known to a person skilled in the art of tattooing and not described

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herein in detail, for the sake of brevity, for example by rod 15 (Fig. 2)

which has typical connecting means 16 suitable to be connected to the skin puncturing device and which is provided with the array of needles 11 at the other end.

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Mediating system 14 is attached to the skin puncturing device and to suction means. Mediating system 14 comprises tube 21 and a mediating member 17. Member 17 is used for allowing the suction means to collect the mixture of the pigments with the cellular fluids at the punctured section of skin, wherein member 17 is capable of creating and essentially sealed cavity above the punctured section of skin.

Mediating member 17 has one or more openings, such as opening 22, through which the suction means collects the mixture of the pigments with the cellular fluids. Tube 21 of mediating system 14 is used for connecting system 14 to the skin puncturing device 30 (Fig. 3), used to actuate the needles. Tube 21 is provided with one or more openings 18, as shown in Fig. 2(a). Member 17 is attached to tube 21 (e.g., by one or more screws) adjacent to openings 18.

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According to a preferred embodiment of the invention, the array of needles 11 is inserted within tube 21 of system 14 and thus opening 18 of tube 21 and openings 22 of member 14 are located adjacent to the edges of needles 11.

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Preferably, openings 22 of member 17 are suitable to be connected to a tubule 12a and 12b of suction means (not shown) for performing the suction operation. Tube 21 also comprises fastening means for attaching

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system 14 to the skin puncturing device 30 (Fig. 3). Preferably, but not limitatively, the fastening means are screws 20 and a ring 19. Of course, the fastening means can be any suitable means, which are well within the scope of a person skilled in the art.

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According to a preferred embodiment of the invention member 17 is further provided with additional openings 23, suitable to be connected to tubules 13a and 13b, in turn connected to one or more sources of cleaning material(s) (not shown). The cleaning materials are used to clean the punctured area of skin of residues of blood, cellular fluids and pigments, during the removal treatment, by applying (e.g., by spraying) the cleaning material on the punctured skin, thereby cleaning the punctured area during the removal of the pigmented section of skin. For example, the cleaning material can be air under pressure, water or another fluid suitable to be sprayed onto a punctured human body. Of course, the cleaning material can be a combination of two or more materials, such as air pressure and water.

According to another preferred embodiment of the present invention, one
or more of the needles are hollow. Each hollow needle has one or more
openings suitable to be connected to a source of cleaning material for
spraying the cleaning material onto the punctured skin, thereby cleaning
the punctured area during the removal of the pigmented section of skin, or

for injecting it therein. For instance, the cleaning material can be sprayed on the skin through the cavity along each hollow needle.

By employing the apparatus 10 of the present invention, removing a pigmented section of a skin, can be achieved as follows:

- attaching apparatus 10 to a skin puncturing device;

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- puncturing the skin at said pigmented section with needles 11 while the skin puncturing device contains no ink; and
- performing suction, with the suction means, of the mixture of the pigments with the cellular fluids at said punctured section of skin, (and, optionally, of any externally-added fluid) as described hereinabove.

Optionally, after completion of the puncturing of the skin at the pigmented section and completion of the suction operation, the treated section of skin can then be bandaged with a suitable adsorbing pad. The pad must contain one or more materials, such as saline, which will cause the pigment residue, at the punctured section, to migrate and to be absorbed into the outer layer of skin. Preferably, but not limitatively, the pad is an adsorbent pad able to absorb moisture from a mixture of tattoo ink and cellular fluid. Of course, the materials which will cause the pigments at the punctured section to migrate and to be absorbed into the outer layer of skin may be in the form of a solution, a solid material or a combination of both a solution and a solid material.

Preferably, after puncturing the area, a treatment for preventing infections should be provided for the skin in that area. Of course, the adsorbent pad may contain one or more antiseptic materials, such as Benzalkonium Chloride based cream (e.g., Bepanthen), Silver sulfadiazine based cream (e.g., Silverol) etc. Such antiseptic materials may also be applied separately. For example, the absorbent pad or other individual pads may contain pastes and/or creams known in the art, such as Vitamerfen, Bepanthen, Silverol and the like. Alternatively, the antiseptic based cream may be applied directly to the treated area and covered by a pad.

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Preferably – but not limitatively, the skin puncturing device is a typical electric device for creating tattoos provided with the apparatus 10 of the present invention.

According to a preferred embodiment of the present invention, the apparatus 10 includes one or more needles 11, such as the one used for creating tattoos. Preferably, after attaching apparatus 10 to a skin puncturing device, the user may operate this device in the same way as that for creating tattoos, but without using ink. As an option, an aqueous solution or other material that does not contain pigments may be used

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(i.e., injected to the punctured area) instead of the ink, thereby the pigments may be further diluted and may be sucked away more easily.

In typical puncturing devices the penetrating depth of needles 11 into the skin is adjustable. Preferably, but not limitatively, the needles 11 do not penetrate beyond the hypodermic layer of the skin and thus no further damage to the skin is created while using the apparatus 10 of the present invention.

This invention can typically be used with any existing tattooing device, such as those produced by the firm of *Lauro Paolini*, *Italy*. For example, Fig. 3 schematically illustrates a typical tattooing device 30 provided with the apparatus 10 of Fig. 1, for removing pigmented sections of skin. Numeral 118 indicates a connection to suction means (not shown).

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Fig. 4 shows an example of actual dimensions of a rod 15, according to a particular embodiment of the invention. All dimensions are given in millimeters.

Fig. 5 schematically shows a particular arrangement for the treatment of fluids of means 17. SL denotes a port through which cellular fluids can be removed by suctions. If an additional fluid (e.g., warm saline or sterile water) is employed, it is supplied, in this particular embodiment, via port

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FI and then removed, together with debris from the treatment area, via port FO.

Fig. 6 schematically shows a head for mediating element 17, through which needles 11 operate (not shown) via an opening of about 5mm in diameter. The whole length of the head is, in this embodiment, only 25mm. Thus, the small dimensions of a typical apparatus according to the invention can be appreciated through the indicative dimensions provided in the figure.

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Fig. 7 schematically shows an apparatus 100 for removing pigments from a pigmented section of skin, constructed according to another preferred embodiment of the invention. Apparatus 100 comprises an array of one or more needles 101 for puncturing the skin, a rod 106 to which the array of needles 101 is connected, a first drainage 102 for evacuating the mixture of the pigments and cellular fluids, a second drainage 103 for evacuating extra fluids and a mediator 111 for allowing to connect an external device for supplying cleaning materials, such as water or another fluid suitable to be sprayed on a punctured human body.

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Fig. 8 schematically illustrates the different components of apparatus 100, according to one preferred embodiment of the invention. This figure shows the four different components of apparatus 100. Component (a) is the rod

106, which is provided at one end with the array of needles 101 and at the other end with a hook 105 for connecting apparatus 100 to a vibration unit (e.g., the tattooing gun 113 of Fig. 10). Component (b) comprises the second drainage 103 connected to a hollow cylindrical body 113 through which rod 106 is inserted and used to move or vibrate during the removal operation. Component (c) is the mediator 111. Mediator 11 comprises a tube 104 for leading the fluids or cleaning materials into apparatus 100 and fastening means 110 for connecting an external source of cleaning material to apparatus 100. Fig. 9 (c) is a perspective view of mediator 111. Component (d) is a conical element 107, which houses needles 101. Conical element 107 also comprises the first drainage 102. Component (b), (c) and (d) are connected to one another, while component (a) is inserted into components (b) through (d). Fig. 9 (a) show rod 106 in its inserted position within conical element 107.

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- Fig. 9 (b) is a schematic top view of conical element 107. This figure shows channels 114 which are used to lead the cleaning material towards the array of needles 101.
- Fig. 10 schematically shows apparatus 100 attached to a typical tattooing gun 113.

Fig. 11 schematically shows a boundary element 114 used for limiting the spreading of the mixture of cellular fluids and pigments. Element 114 comprises a boundary ring 116 for limiting the spreading area and a tube 115 for evacuating the mixture. Ring 116 is provided with a hole 117, through which the mixture is sucked into tube 115. Tube 115 can be connected to external suction means for evacuating the mixture from the punctured area. Opening 118 is the connection to the suction device.

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Figs. 12-14 schematically illustrate an apparatus according to yet another preferred embodiment of the invention. Fig. 12 shows an array of needles of the type shown in Fig. 4, in which the needles are connected to a piston-like member 120, which operates within a cylinder (not shown), as will be further explained with reference to Fig. 13.

In Fig. 13 element 15 is shown in broken lines, with its piston-like element 120 and needles 11, in its inserted position into a cylinder, 121.

Cylinder 121 is provided with an inlet 122, for clean fluid to be applied to the area on which operation is taking place, and outlet 123 for the debris and dissolved pigments to be removed therefrom. The vacuum generated by piston-like element 120, displaced within cylinder 121, generates a suction action, as will be apparent to the skilled person, which causes the fluids to be pumped out of the cylinder. In the position shown in Fig. 14, piston-like element 120 closes opening 123. At that stage the empty space

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around the needle is filled with clear liquid and, when the piston-like element is displaced upwards, the fluid is sucked away. The group of needles located below the piston-like element can contain different numbers of needles. The piston-like element is responsible both for the creation of a vacuum and for the inflowing of liquid into the treated area.

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The above examples and description have of course been provided only for the purpose of illustration and are not intended to limit the invention in any way. As will be appreciated by the skilled person, the invention can be carried out in a great variety of ways, employing more than one technique from those described above, all without exceeding the scope of the invention. WO 2005/020828

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#### **CLAIMS**

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- 1. An apparatus for removing a pigmented section of skin, comprising:
  - a) a skin puncturing device;
  - b) an array of one or more needles connected to said device for puncturing the skin at said pigmented section;
  - c) a mediating member attached to said device and to suction means, for allowing said suction means to collect the mixture of the pigments with the cellular fluids at said punctured section of the skin.

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2. Apparatus according to claim 1, wherein said mediating member is capable of creating an essentially isolated area above said punctured section of skin, which is suitable for puncturing and for suction of the area.

- 3. Apparatus according to claim 1, wherein the mediating member comprising one or more openings through which the suction means collect the mixture of the pigments with the cellular fluids.
- 4. Apparatus according to claim 1, wherein the mediating member further comprises means for connecting said member to a source of a cleaning material for applying said cleaning material onto the

punctured skin, thereby cleaning the punctured area during the removal of the pigmented section of skin.

5. Apparatus according to claim 3, wherein the means for connecting the mediating member to the source of a cleaning material are one or more openings through which cleaning material can be delivered.

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- 6. Apparatus according to claims 3 or 5, wherein the mediating member is attached to the skin puncturing device in such a way that the openings are located adjacent to the sharp edge of the array of needles.
- 7. Apparatus according to claim 1, wherein one or more needles are hollow, said hollow needles having openings suitable to be connected to a source of cleaning material for applying said cleaning material onto the punctured skin, thereby cleaning the punctured area during the removal of pigments from the pigmented section of skin.
- 8. Apparatus according to claim 4, wherein the cleaning material is a fluid, air under pressure or a combination of both a fluid and air pressure.

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- 9. Apparatus according to claim 1, wherein the mediating member is attached to the puncturing device with one or more screws.
- 10. Apparatus according to claim 1, wherein the skin puncturing deviceis a tattooing machine.
  - 11. A method for removing pigments from a pigmented section of a skin, comprising:
    - a) providing a skin puncturing device which includes an array of one or more needles and a mediating member attached to suction means;

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- b) puncturing the skin at said pigmented section with said needles while said skin puncturing device contains no ink; and
- c) performing a suction, with said suction means, of the mixture of the pigments with the cellular fluids at said punctured section of the skin.
- 12. A method according to claim 11 further comprising delivering a fluid to the treated area.
- 13. A method according to claim 12, wherein the fluid is injected to the area in which the pigments are located.

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14. A method according to claim 11, further comprising:

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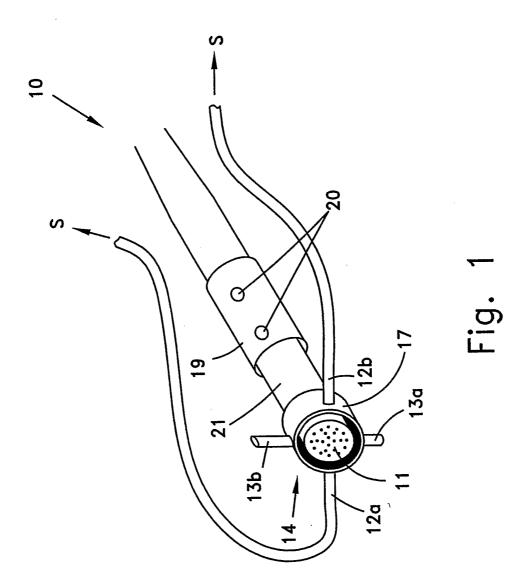
- a) providing a pad containing one or more materials capable of absorbing moisture from said mixture; and
- b) bandaging said punctured skin with said pad, thereby causing the pigment residue at said section to migrate from its location toward the outer layer of the skin.
- 15. A method according to claim 11, further comprising applying fluids onto the punctured section of skin for cleaning said section.

16. A method according to claim 11, further comprising bandaging the punctured skin with a pad containing one or more antiseptic materials for preventing infections.

- 15 17. A method according to claim 11, wherein the skin puncturing device is a tattooing machine.
  - 18. A method according to claim 12, wherein the material delivered to the pigments is saline.
  - 19. Apparatus for removing a pigmented section of a skin, substantially as described and illustrated.

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20. A method for removing a pigmented section of a skin, substantially as described and illustrated.



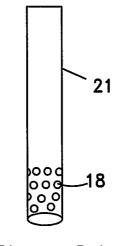


Fig. 2A

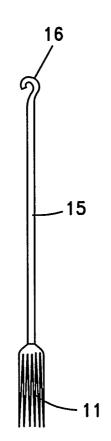


Fig. 2C

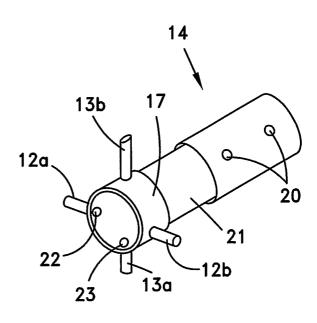
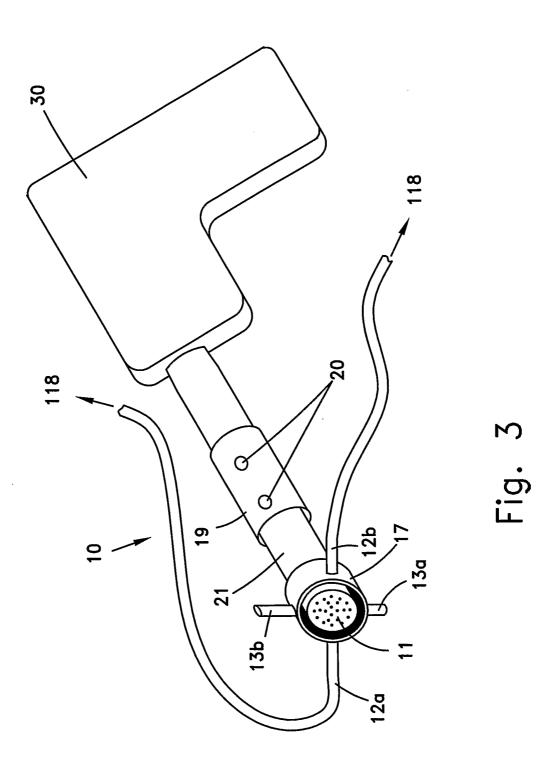


Fig. 2B





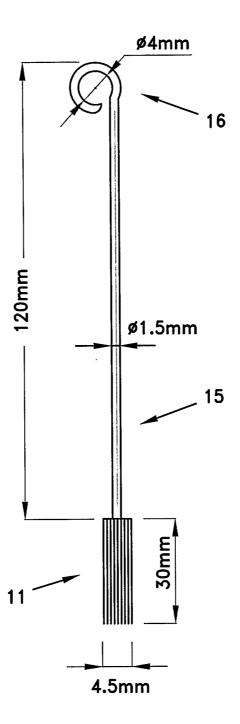


Fig. 4

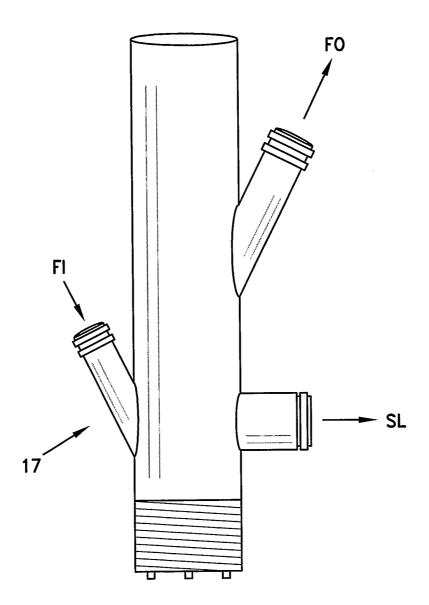


Fig. 5



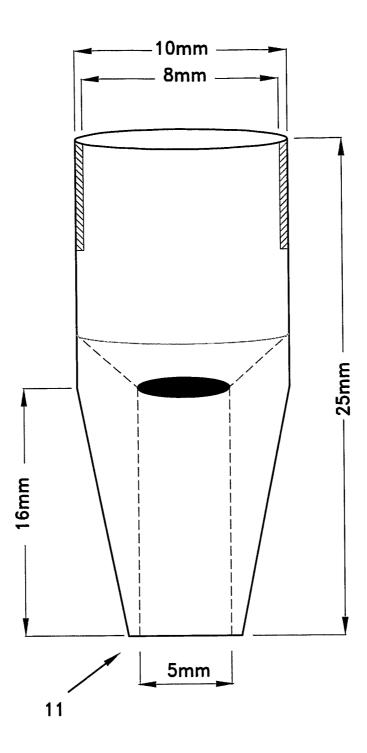
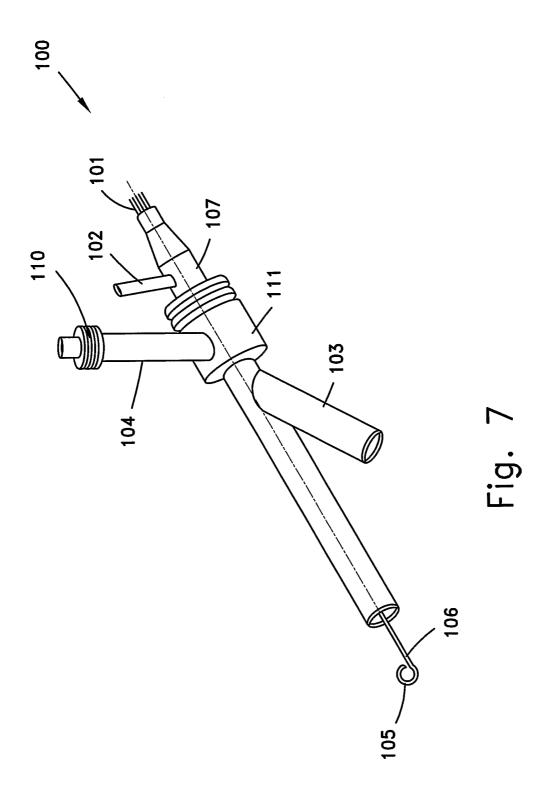
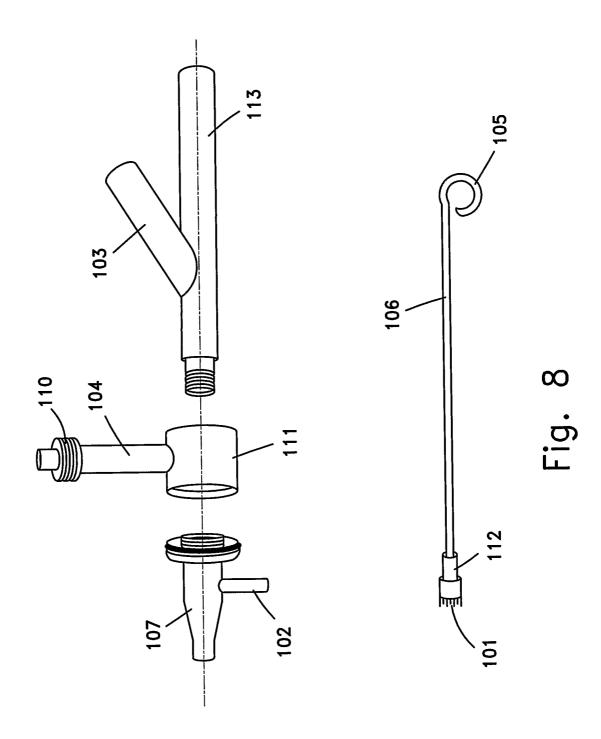
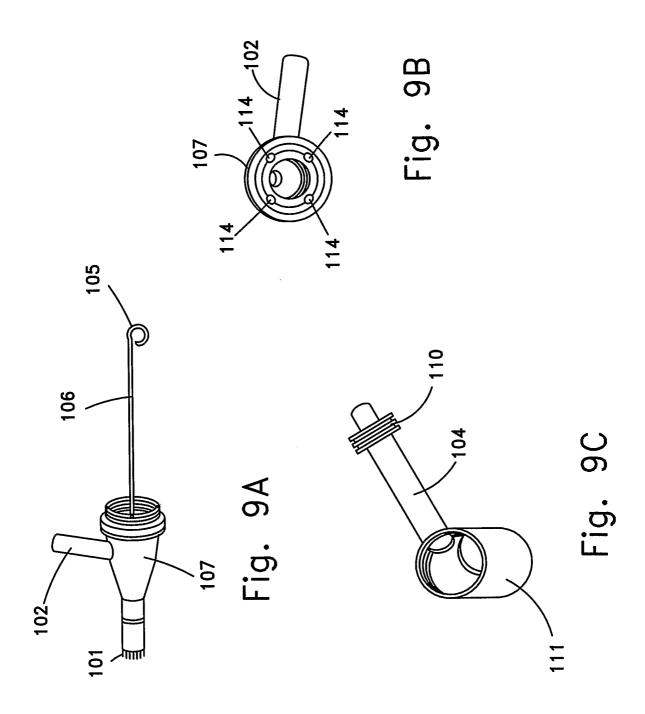


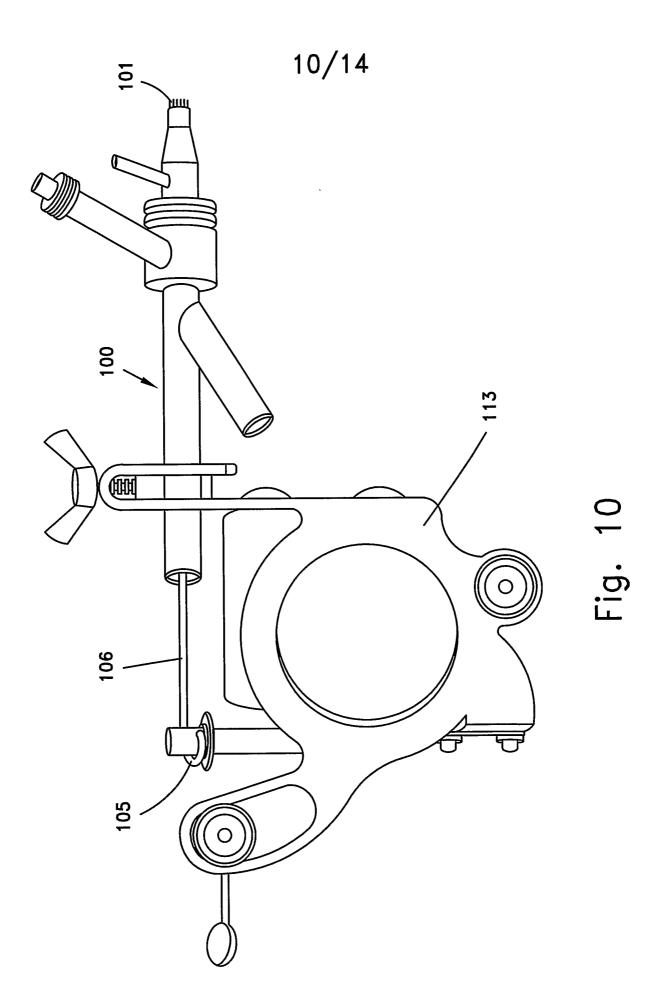
Fig. 6

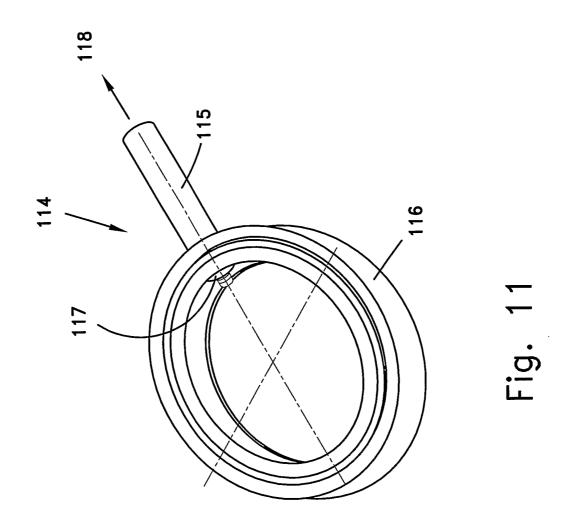


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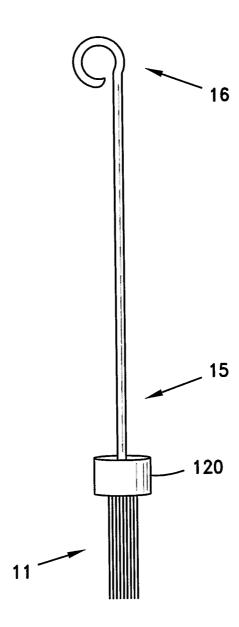


Fig. 12

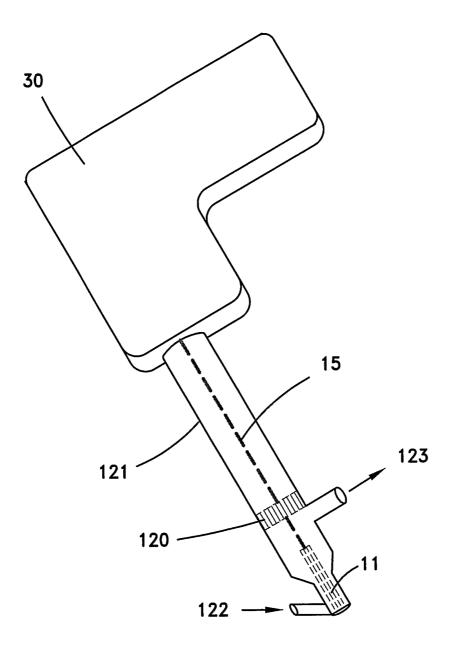


Fig. 13

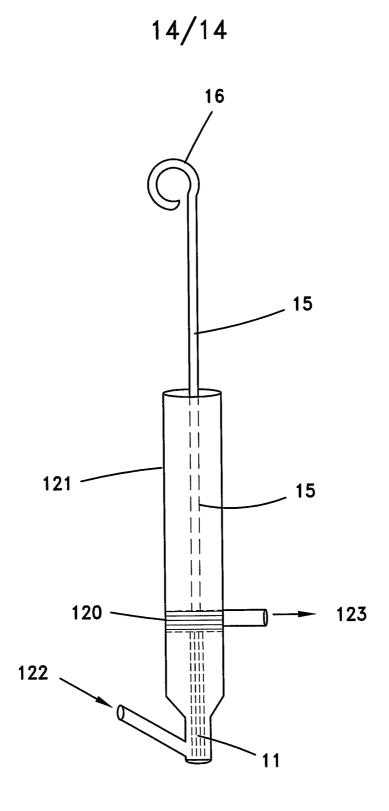


Fig. 14

#### INTERNATIONAL SEARCH REPORT

rnational Application No

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B17/20 A61B A61B17/34 A61M37/00 According to International Patent Classification (IPC) or to both national classification and IPC B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61B IPC 7 A61M Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal C. DOCUMENTS CONSIDERED TO BE RELEVANT Relevant to claim No. Citation of document, with indication, where appropriate, of the relevant passages Category ' 1 - 9, 19US 2002/183688 A1 (LASTOVICH ALEXANDER G X ET AL) 5 December 2002 (2002-12-05) paragraph '0038! - paragraph '0041! paragraph '0052! - paragraph '0053! paragraph '0056! - paragraph '0062!; figures 11,12 1-3,6,7,US 6 607 513 B1 (LASTOVICH ALEXANDER G ET χ 9,19 AL) 19 August 2003 (2003-08-19) claims 1-4; figures 1,2 FR 983 602 A (LUNAUD) 1 - 3χ 26 June 1951 (1951-06-26) figure 2 1 WO 02/36027 A (MALODOBRY W) Α 10 May 2002 (2002-05-10) page 9, paragraph 2 - page 10, paragraph 2 Patent family members are listed in annex. Further documents are listed in the continuation of box C. χ Special categories of cited documents: "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance earlier document but published on or after the international "X" document of particular relevance; the claimed invention filing date cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the citation or other special reason (as specified) document is combined with one or more other such docu-ments, such combination being obvious to a person skilled "O" document referring to an oral disclosure, use, exhibition or other means document published prior to the international filing date but "&" document member of the same patent family later than the priority date claimed Date of mailing of the international search report Date of the actual completion of the international search 13/01/2005 6 January 2005 Name and mailing address of the ISA Authorized officer European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016 Moers, R

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C./Continus	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	FC1/1L2004/000/84		
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A	WO 00/74767 A (EPPSTEIN JONATHAN; PAPP JOSEPH (US); HATCH MICHAEL R (US); ALTEA TECH) 14 December 2000 (2000-12-14) page 33, line 30 - page 34, line 2 page 7, line 22 - line 29		1	

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International application No.
PCT/IL2004/000784

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X Claims Nos.: 11-18, 20 because they relate to subject matter not required to be searched by this Authority, namely:  Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest  The additional search fees were accompanied by the applicant's protest.  No protest accompanied the payment of additional search fees.

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