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EP 2258296 A1

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Other: **Online: WPI, EPODOC**

(54) Title of the Invention: **Non-ablative radio-frequency treatment of skin tissue**
Abstract Title: **Non-Ablative Radio-Frequency Treatment of Skin Tissue**

(57) RF energy for skin conditioning is applied with a non-ablative electrode 18 having a shank end 16 within a handpiece 12. The handpiece incorporates an inline switch to prevent electrical shock to the patient when the energized electrode surface makes or breaks contact with the skin. The switch is formed between a contact surface 28 at the end of the slidable electrode 18 and the facing contact surface 32 of a fixed contact 34 within the handpicce. At least those contact surfaces are coated with a noble metal, preferably of gold, to reduce erosion and pitting due to making and breaking of the inline switch contacts during a skin conditioning procedure using RF energy from the non-ablative electrode.

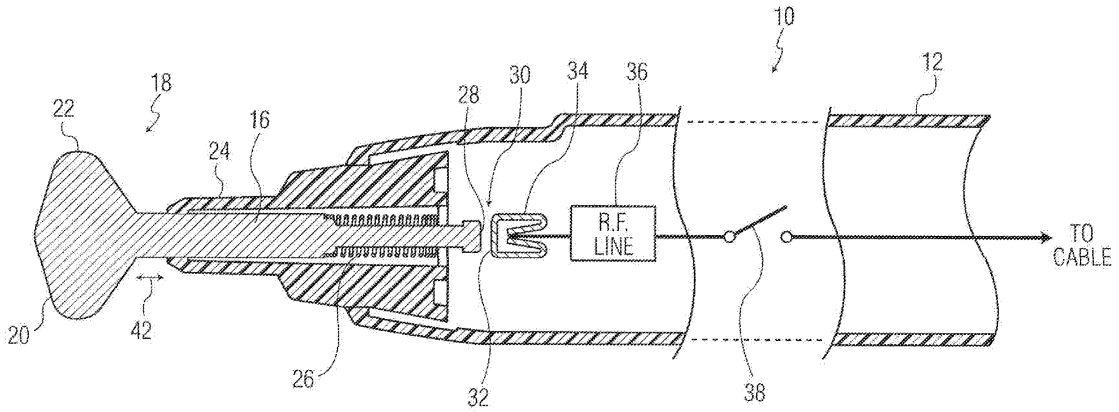

FIG. 2

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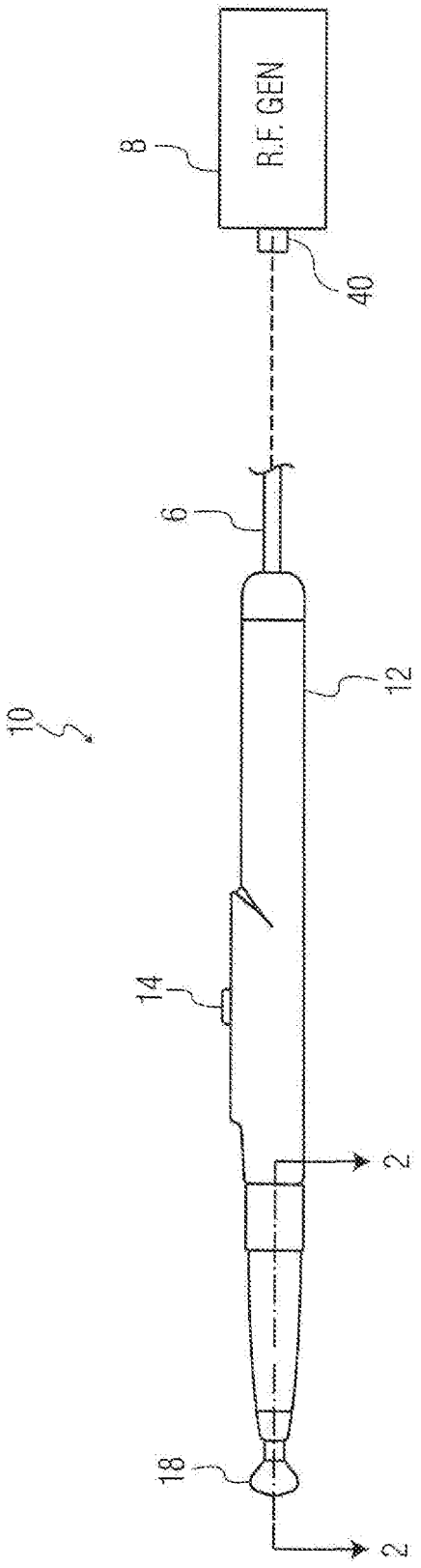

FIG. 1

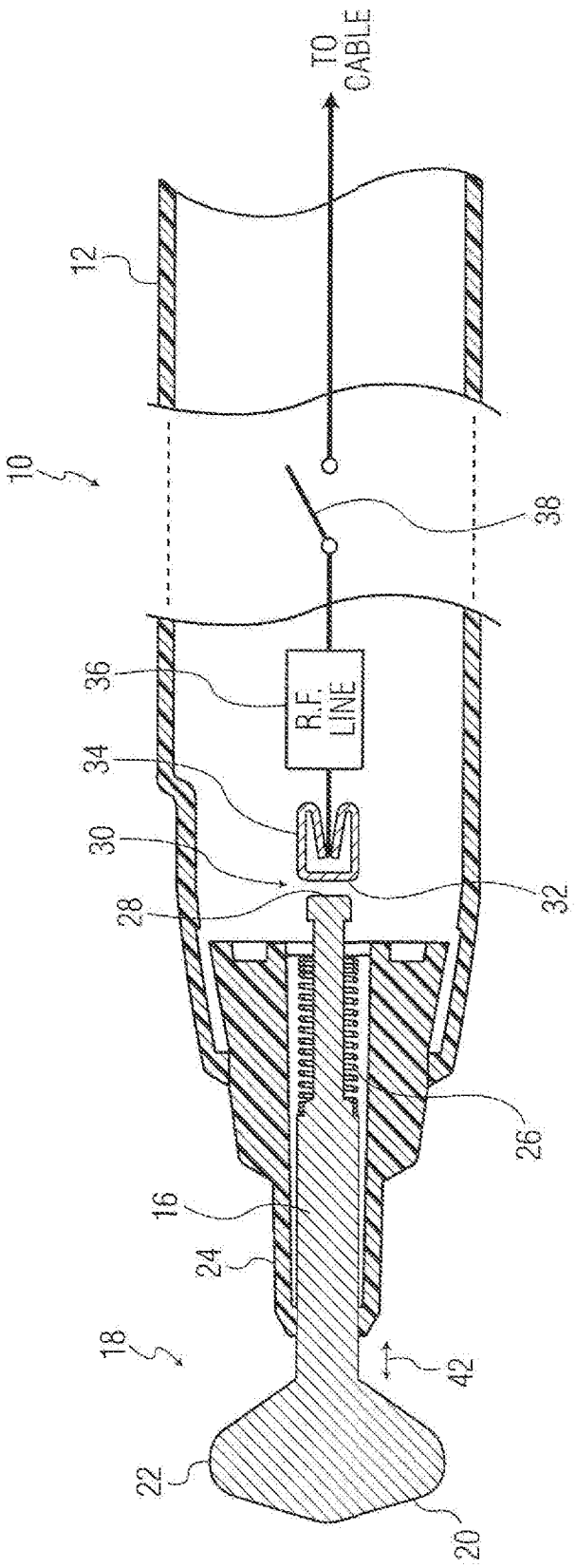

FIG. 2

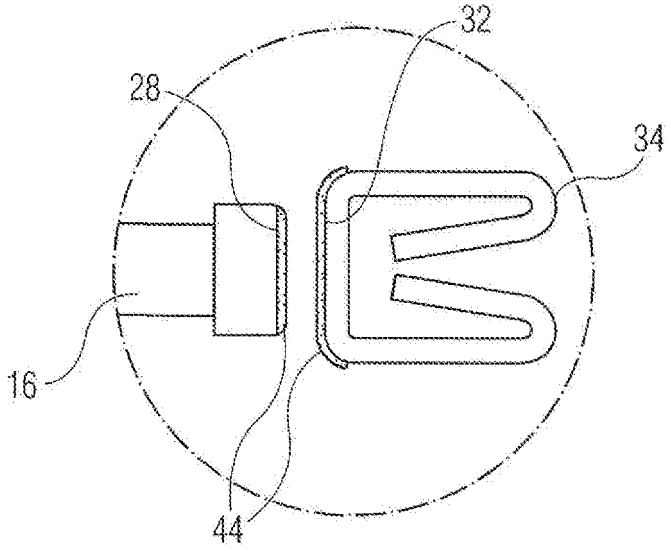

FIG. 3

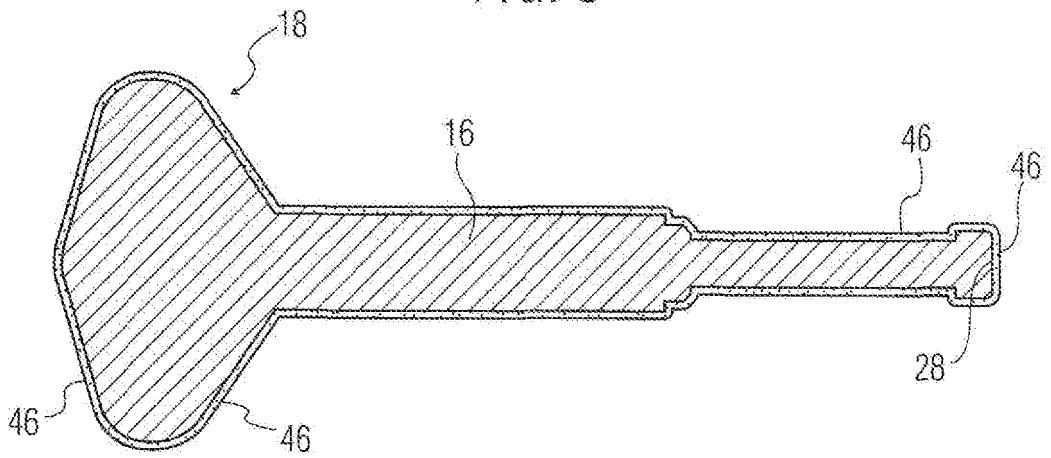

FIG. 4

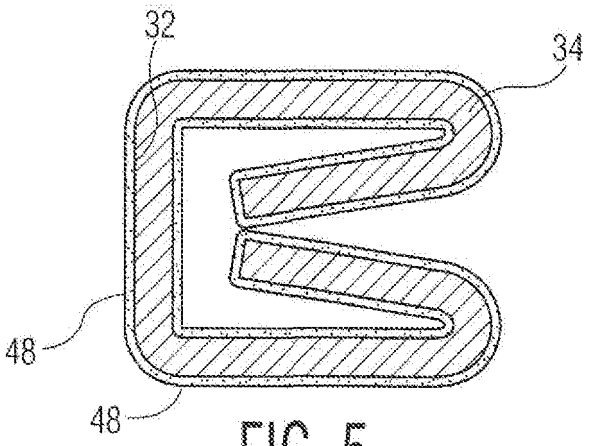

FIG. 5

NON-ABLATIVE RADIO-FREQUENCY TREATMENT OF SKIN TISSUE

This invention relates to apparatus and a procedure for treating skin tissue using non-ablative radio-frequency energy. It also relates to novel handpieces using monopolar or bipolar electrodes for use in such procedures.

A commonly-assigned copending application, Ser. No. 12/455,661, filed 6/5/09, Publ. # 2010-0312233-A1, the contents of which are herein incorporated by reference, describes an electrode configuration and procedure for use for topical application to the tissue surface or skin of a patient for the non-ablative treatment of periorbital rhytides and midface laxity or in general removal of wrinkles or other cosmetic skin tightening procedures to improve the appearance of skin tissue.

In this radio-frequency (RF) non-ablative tissue surface treatment, it is desirable to raise the tissue temperature to about 41-65°C to affect underlying skin collagen to tighten the surface tissue, being careful to avoid overheating the skin tissue possibly causing burns and residual scarring. It does this by applying RF energy via a generally rounded non-ablative electrode to the patient's skin tissue and continuously manually moving the activated electrode while in contact with the skin to avoid overheating the skin. The prior application treats another problem that arises at the RF frequencies and voltages described, namely, the electric shock that may possibly occur while the electrode surface with RF energy present approaches or separates from the skin creating a narrow air-gap that may breakdown causing a spark from the electrode to the skin. In a preferred embodiment, this result is achieved by, essentially, moving the air-gap from the skin to inside the handpiece holding the electrode, by making the electrode, connected to a shank, axially slidable and spring-loading the shank away from a fixed contact inside the handpiece. Thus a dielectric-gap is created inside the handpiece between the shank end contact surface and the contact surface of the fixed electrode, and that dielectric-gap is not closed until the active electrode surface has been pressed up against the skin surface with sufficient pressure to overcome the light spring pressure. The dielectric-gap is preferably an air-gap but a different dielectric gas or liquid may be used to fill this gap. The interior fixed electrode is in turn directly electrically connected to the usual cable connecting the handpiece to an output connector on the RF generator. In operation, the surgeon or other user typically uses the standard footswitch to energize the generator which will provide the desired RF voltage via the cable to the fixed electrode, and that RF voltage will be transferred to the active electrode surface only after and

while the movable electrode shank is moved inward causing its contact surface to engage the contact surface of the fixed electrode, such as when the active electrode surface is in actual contact with the patient's skin.

However, it turns out that some users in carrying out the procedure tend to move the active electrode away from the skin and back in contact more often than other users, and the more frequent opening and closing of the interior dielectric-gap causes arcing that tends to erode or pit the contact surfaces. This action may cause the lifetime of the handpiece to vary in an undesired manner depending on the user habits.

An object of the present invention is to employ RF energy for skin conditioning with non-ablative electrodes in a handpiece incorporating means to prevent electrical shock to the patient when the electrode surface makes or breaks contact with the skin.

A further object of the invention is to increase the lifetime of a shock-free electrosurgical handpiece with a non-ablative generally rounded electrode intended for use in procedures for tightening the skin or reducing wrinkles of a patient.

In accordance with an aspect of the invention, it has been found that simply constituting the contact surfaces forming the interior dielectric-gap of a noble metal greatly reduces the extent of erosion and pitting of the contact surfaces increasing the lifetime of use of a shock-free electrosurgical handpiece intended for skin tightening using RF energy.

Noble metals are generally considered to be those metals that are resistant to corrosion and oxidation in moist air, but for our purposes gold is the preferred noble metal but platinum, rhodium, and palladium will also work. In a preferred embodiment, the outermost gold coating has a minimum brinell hardness of 200 knoop.

In a preferred embodiment, the shock-free handpiece comprises an inline switch formed by a fixed contact inside the handpiece axially aligned with a spring-loaded narrow diameter shank extending rearward from the enlarged active electrode protruding frontward from the handpiece. The area of the fixed electrode facing the shank end forms together with the latter contact areas defining the dielectric-gap which when closed transmits the RF energy to the active electrode, and when opened blocks the RF energy from the active electrode. Improved results are obtained when at least one of those contact areas are constituted of the noble metal, but it is preferred that both of the contact surfaces are constituted of the noble metal. The noble metal contact surfaces can be obtained by making the combined electrode-shank and the fixed electrode entirely of the noble metal, or by attaching as by brazing or threading a noble metal tip to the facing shank and fixed contact areas. But it is preferred in accordance with the invention

merely to coat the contact areas with the noble metal.

When, for example, the electrode, shank, and fixed contact have a core of brass, then it is preferred that plating be used as the coating procedure. It is also preferred when brass is the core to first provide an undercoating of, for example, nickel, preferably of nickel-sulfamate, on the brass and the noble metal on the nickel, to prevent brass constituents from diffusing into the noble metal. Alternatively, an undercoating of copper-cyanide can be substituted. When using gold as the noble metal, which is preferred, it is not much more costly to plate with gold the entire electrode and shank when formed as one-piece of metal such as of brass. Similarly, it is not much more costly to plate with gold the entire fixed electrode.

RF non-ablative skin tightening is preferred as it is believed that the RF technology produces an electric current that generates heat through resistance in the dermis and subcutaneous skin tissue. The thermal effect depends on the conductivity features of the treated tissue. Collagen fibrils, when heated, will denature and contract, which is believed to lead to the observed tissue tightening. Non-ablative RF treatment has a lower risk of complications, shorter recovery time and less disruption of regular activities than other skin tightening procedures.

The various features of novelty which characterize the invention are pointed out with particularity in the claims annexed to and forming a part of this disclosure. For a better understanding of the invention, its operating advantages and specific objects attained by its use, reference should be had to the accompanying drawings and descriptive matter in which there are illustrated and described preferred embodiments of the invention, like reference numerals designating the same or similar elements.

Embodiments of the present invention will now be described by way of further example only and with reference to the accompanying drawings, in which:

Fig. 1 is a schematic view of one form of a shock-free handpiece with a generally rounded electrode according to the invention, shown schematically connected to an RF generator of a known type;

Fig. 2 is partly cross-sectional view along lines 2-2 of the handpiece of Fig. 1 showing the electrode in its RF-disconnected position;

Fig. 3 is an enlarged view of one form of the internal in-line switch in accordance with the invention;

Fig. 4 is a cross-sectional view showing just the electrode-shank portion of a modified embodiment in accordance with the invention;

Fig. 5 is a cross-sectional view showing just the internal fixed contact portion of a

modified embodiment in accordance with the invention.

In the present application, Fig. 1 is a schematic view of one form of RF applying device 10 in accordance with the invention connected by a standard cable 6 to an electrosurgical generator 8. It comprises a handle or handpiece 12 with an operating button or fingerswitch 14 and with a front end adapted to receive and hold for axial movement the electrically-conductive shank end 16 of an electrically-conductive, non-ablative electrode 18 whose active electrode surface 20 is generally rounded or dome-shaped or slightly conical as shown. To be non-ablative, the front surface of the electrode should have at least rounded edges 22 to prevent sharp edge regions where the RF field could concentrate, but it could have an overall shallow conical form which appears generally rounded to the eye as described in commonly-assigned Published Application EP 2298205-A1. The handle 12 is electrically-insulating. The electrode 18 may be screwed onto the elongated electrically-conductive shank 16, and both move together as a single unit axially within the center bore 24 of the handle 12. Alternatively, as shown, the combined electrode 18 and electrically-conductive shank 16 may be manufactured from a single piece of metal, usually of brass. Axially in Figs. 1 and 2 is the longitudinal horizontal axis of the assembly. The electrode 18 is biased outwardly in a first position as shown in the figure by an internal compression spring 26. The proximal end (viewed from the cable 6 end of the handpiece 12) of the shank, that is flat and that will be referred to as the electrode contact surface 28, is spaced by a contact dielectric-gap 30 from a contact surface 32 (referred to as the fixed contact surface) of a fixed electrically-conductive contact 34 mounted in a central part of the handle. The latter is connected via a block 36 labeled "RF Line" and a switch 38 actable directly or indirectly by the button 14 to handpiece terminals (not shown) at the right end of the handpiece for connection to the cable 6. The RF Line 36 electrical circuitry, which is not important to the invention, may be conventional circuitry converting signals created by the handpiece fingerswitch for activating specific operating modes of the RF generator 8 to which the opposite end of the cable 6 is connected, or may include timing circuitry, or may include a relay actuated by the button 14 whose contacts in turn connect the RF to the fixed contact, but for purposes of the present invention fundamentally simply transmits the RF energy supplied by the activated generator 8 to the fixed contact 34 when the fingerswitch 14 is depressed. Fig. 1 shows the handpiece 10 connected by the cable 6 to an output connector 40 on the chassis of a conventional RF electrosurgical generator 8, for example, of a type manufactured by Ellman International, Inc. of Oceanside, NY.

The electrode contact surface 28 and the fixed contact surface 32 define the dielectric-gap 30 referred to herein as the in-line electrical switch between the RF source 8 and the active electrode surface 20. The axial movement of the electrode 18 indicated at 42 is equal to the length of the contact gap 30. When the active electrode surface 20 of the handpiece 10 held by the physician is pressed against the patient's skin directly or via a coupling material such as a gel with the button 14 depressed in carrying out a non-ablative skin procedure, the electrode 18 is displaced from its first position shown in Fig. 1 with the contact gap 30 open to a second position (not shown), compressing the spring 26, and with sufficient pressure applied the contact gap 30 is closed and the electrode shank 16 becomes electrically-connected to the fixed contact 34, and thus RF voltage available at the output connector 40 of the RF generator 8 becomes active on the active electrode surface 20 thus applying RF energy to the skin tissue directly or via the coupling gel. "Skin or tissue contact" should be understood to mean directly or via the coupling material. The first position of the electrode illustrated in Fig. 2 will be referred to as the RF-disconnected position, whereas the second position (not shown here but illustrated in Fig. 3 of Published Application 2010-0312233-A1) will be referred to as the RF-connected position. Note that placing the electrode 20 in contact with the skin does not energize the electrode with RF; the electrode 20 must be displaced a certain distance, the contact gap 30, before the electrode becomes energized. Similarly, withdrawing the handpiece from the patient will first break the electrical contact 30 internally as the spring expands and deenergizes the electrode before it breaks contact with the skin. While the internal contact end 28 of the shank is shown flat, other shapes may be used if desired. The embodiment illustrated in Fig. 2 utilizes axial loading of the electrode to implement the RF-connected position, but it will be evident from the teachings in the referenced related application that other electrode movements, such as sideways, can be substituted. Moreover, while the handpiece shown is a monopolar handpiece, from the disclosure in the referenced related application, it will be evident that the present invention can also be applied to the contact surfaces of a bipolar handpiece.

The present invention is concerned with reducing possible pitting and erosion of the contact surfaces 28, 32 while RF voltage is present at the contacts as they make and break the in-line switch. In accordance with the invention, as shown in Fig. 3, at least one of those contact surfaces and preferably both are constituted 44 of a noble metal that resists corrosion. I have found that gold is particularly well suited for this purpose because it is relatively inexpensive in the form of a thin layer and plates easily onto brass, a popular metal for the electrode, preferably using an undercoat of nickel or similar metal. Platinum, rhodium, and palladium will also prove suitable, though somewhat more expensive. I have found that gold plating 44 both the contact

surfaces 28, 32 of the in-line switch increase the lifetime of the handpiece by at least a factor of two, and lifetime increases of three or more times the lifetime of a handpiece with uncoated contact surfaces have also been achieved.

While the benefits of the invention will be achieved just by providing contact surfaces of the noble metal, it turns out that it is not much more expensive and certainly easier to coat as by plating the entire electrode 18 and connected shank 16 including the contact surface 28 with a noble metal 46, as shown in Fig. 4. Similarly, it is not much more expensive and certainly easier to plate the entire fixed contact 34 including the contact surface 32 with a noble metal 48, as shown in Fig. 5. These modified embodiments are illustrated in Figs. 4 and 5.

The thickness of the coatings 44, 46 and 48 is not critical. I have found that a thickness of at least 10 micro inch, preferably between about 20 and 80 micro inch, with 45 micro inch being preferred is satisfactory.

When brass is used as the core, it is preferred to provide one or more undercoatings of alternative substances between the brass and an outermost coating of gold. The uindercoat can itself be of gold or of copper cyanide or nickel sulfamate. The thickness of the undercoat is not critical. With an outermost gold coating, it is preferred that it have a minimum brinell hardness of 200 knoop.

The spring-loaded electrode end scheme works to prevent shock to the patient essentially by moving the initial "spark" contact gap away from the patient's skin and puts the spark gap within the handpiece itself, and forces the user to make skin contact prior to RF energy being supplied. During release, the contact is opened first within the handle itself and not at the patient's skin.

The RF generator used preferably output RF currents in the range of about 0.2-10 MHz. Continuous wave power can be used.

While the invention has been described in connection with preferred embodiments, it will be understood that modifications thereof within the principles outlined above will be evident to those skilled in the art and thus the invention is not limited to the preferred embodiments but is intended to encompass such modifications.

Claims

1. A device for use in a non-ablative surgical procedure for improving the appearance of skin tissue of a patient by applying RF energy thereto via a contacting non-ablative electrode under conditions such that as the electrode approaches the patient's tissue to make contact a dielectric gap is maintained until such time as firm contact has been established between the patient's tissue and the electrode and such that as the electrode is moved away from the patient tissue to break contact a small dielectric gap is created prior to the separation of the electrode from the surface of the patient's tissue, said dielectric gap assuring that energy does not flow to the patient without the proper contact between the patient tissue and the contacting electrode having been established, the device comprising:

(a) a handpiece having means for receiving RF energy from a generator when activated, the handpiece having a handle and supporting a movable electrode, the movable electrode having at one end an active electrode surface to be brought into contact with the patient's tissue to apply the received RF energy to the tissue when the generator is activated, the electrode further comprising an electrically-conductive portion terminating at a second end in an electrode contact surface,

(b) the handpiece further comprising a fixed contact having a fixed contact surface spaced from the electrode contact surface and connected to the means for receiving RF energy, the spacing between the fixed contact surface and the electrode contact surface defining a dielectric-gap preventing the presence of RF energy on the electrode which but for the dielectric gap inside the handle would allow the active electrode surface to be active in the process of making and breaking electrode contact to the tissue thereby causing an electric shock to the patient both immediately before making electrode contact and/or immediately after breaking electrode contact to the tissue,

(c) the electrode, upon being forcibly applied to the tissue, moving in a direction closing the inside dielectric gap and establishing electrical connection between the fixed contact surface and the electrode contact surface thereby establishing RF energy on the active electrode surface,

(d) at least one of the electrode contact surface and the fixed contact surface being constituted of a noble metal to reduce erosion and pitting at the contact surfaces as they make and break contact during the procedure.

2. A device as claimed in claim 1, wherein both the electrode contact surface and the fixed contact surface are constituted of the noble metal.

3. A device as claimed in claim 1 or claim 2, wherein the electrode is slidably supported on the handpiece to form an in-line switch between the handpiece's RF receiving means and the electrode that selectively disconnects and connects from the handpiece's RF receiving means as the electrode moves from a first RF-disconnected position with the electrode surface separate from the patient's skin to a second RF-connected position when and while the electrode surface is in contact with the patient's skin.

4. A device as claimed in any one of the preceding claims, wherein the handle has a longitudinal axis, and the electrode is supported for axial movement along the axis.

5. A device as claimed in any one of the preceding claims, wherein the noble metal is selected from the group consisting of gold, platinum, rhodium, and palladium, and the electrode has a rounded or slightly conically-shaped active surface.

6. A device as claimed in any one of the preceding claims, wherein the electrode is spring-loaded into its RF-disconnected position.

7. A device as claimed in any one of the preceding claims, wherein the electrode comprises a material other than a noble metal and a noble metal is attached to form the electrode contact surface.

8. A device as claimed in claim 7, wherein the active electrode surface and electrode portion form a one-piece construction of metal, and the entire one-piece metal construction is plated with the noble metal.

9. A device as claimed in any one of the preceding claims, wherein the fixed contact comprises a material other than a noble metal and a noble metal is attached to form the fixed contact surface.

10. A device as claimed in claim 9, wherein the entire fixed electrode is plated with the noble metal.

11. A device as claimed in any one of the preceding claims, wherein the electrode and

fixed contact are constituted of brass with the electrode contact surface and the fixed contact surface coated with gold as the outermost coating.

12. A device as claimed in claim 11, wherein the gold coating has a minimum thickness of 10 micro inch.

13. A device as claimed in claim 11, wherein the gold coating has a thickness between about 20 micro inch and 80 micro inch.

14. A device as claimed in any one of claims 11 to 13, wherein the outermost gold coating has a minimum brinell hardness of 200 knoop.

15. A device as claimed in any one of claims 11 to 14, wherein the gold coating has one or more undercoatings of alternative substances between the outermost gold coating and the brass.

16. A device as claimed in claim 15, wherein the undercoatings is copper cyanide, or nickel sulfamate, or gold.

INTELLECTUAL PROPERTY OFFICE

Application No:	GB1208043.8	**Examiner:**	Paul Jenkins
Claims searched:	1-16	**Date of search:**	30 August 2012

Patents Act 1977: Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
A	-----	EP2258296 A1 (ELLMAN)

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC^{X} :

Worldwide search of patent documents classified in the following areas of the IPC

A61N

The following online and other databases have been used in the preparation of this search report

WPI, EPODOC

International Classification:

Subclass	Subgroup	Valid From
A61N	0001/32	01/01/2006
A61B	0018/14	01/01/2006