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(54) **Title:** APPARATUS FOR USE IN METHODS OF COSMETIC SURGERY AND TO SUCH METHODS

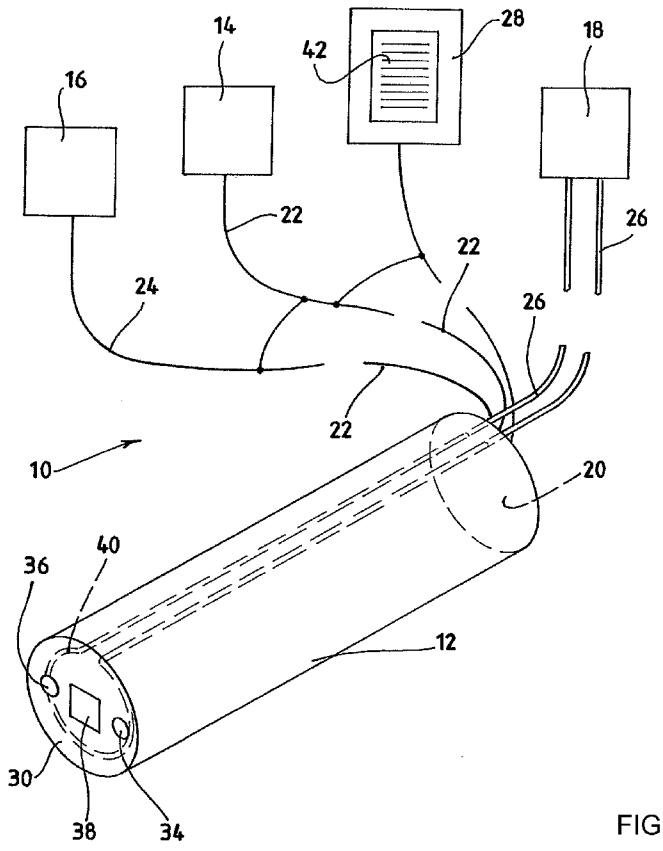


FIG..1

(57) **Abstract:** A method of non-invasive treatment of the human body is described by ablating a muscle or a nerve controlling the muscle. The method comprises stimulating a muscle to emit an electromyographic signal. The electromyographic signal is detected to ascertain the location of the said muscle or alternatively the nerve. The muscle or nerve is heated by means of optical energy while cooling the skin in the vicinity of the said muscle or nerve. Then radio frequency energy is applied to the muscle or nerve to ablate or partially to ablate said muscle or nerve.

WO 2008/116232 A1

APPARATUS FOR USE IN METHODS OF COSMETIC SURGERY AND TO SUCH METHODS

[0001] This invention relates to apparatus for use in methods of cosmetic surgery and to such methods.

[0002] Aging is associated with the development of lines and wrinkles caused by actinic damage, gravitational effect, sleep lines, and muscular action. Skin wrinkles are grooves in the skin. Wrinkles can be on the surface of the skin or can be quite deep. Wrinkles may be categorized as either static (persistent, permanent) or dynamic (expression related). Dynamic facial wrinkles occur due to movement or muscle activity in the affected area, associated with repeated facial movements, such as frowning or even heavy natural use of facial expressions (raising eyebrows, laughing, etc). Dynamic wrinkles (our focus) will improve by reducing the muscle activity in the affected area.

[0003] Many facial muscles of expression insert on to the undersurface of the skin. Following contraction, including baseline muscle tone, a visible line or wrinkle will develop in the skin that will deepen permanently over time. This type of wrinkle cannot be removed by any type or superficial skin treatment, but can only be treated at the source: the muscle itself.

[0004] Facial expression depends on the balance of agonist-antagonist muscle interactions. As an example the brow position is governed by a balance between elevator (frontalis) and depressor (orbicularis; corrugators; procerus) muscles. If the depressor muscles are weakened or paralysed the elevators become dominant and the brow position rises. The same is true for other areas. The corners of the lips are elevated (levator

anguli oris) or depressed (depressor anguli oris) by different muscles, thus to lift the corner of the mouth depressors would be weakened or paralysed. This theory is adapted to many areas of the face.

[0005] Aside from altering the status of muscle balance, individual muscles may be selected for weakening or paralysis to diminish its affect on the skin in that particular area.

[0006] Known techniques for ablation of the nerves causing muscle movement are known. These include the use of toxins such as Botulinum toxin (known commercially as Botox® and Dysport®) which are produced by bacteria called Clostridium botulinum. Botox® acts by blocking acetylcholine, a chemical that is responsible for transmitting electrical impulses that cause muscle contraction. This results in muscle paralysis. The resultant paralysis, however, is temporary, as the new growth of nerves will re-innervate the muscles. This treatment has disadvantages making the process inefficient. Experience has shown that these are inaccurate in the their nerve targeting and unpredictable in their efficiency and the length of time of this effect.

[0007] Direct excision of nerves and electric ablation is very invasive and destructive. It involves side effects of scarring, substantial surrounding tissue damage and necessity for significant anaesthesia. Previous attempts at radio frequency (RF) ablation of the nerve group involved the use of a percutaneous insertion of an insulated bipolar needle vertically through the eyebrow skin to entrap the corrugator nerve plexus. This too is invasive and causes tissue damage as well as being rather inefficient.

[0008] US 7,238,183 (Kreindel) describes a method for treating a skin target being a skin defect such as a vascular lesion, pigmented lesion, acne, unwanted hair or wrinkle. The method includes heating the target by optical means, cooling the skin and then applying radio frequency heating to the target. This will affect the target e.g. by ablating muscle. Although this process is a significant step forward because it is non-invasive, the process suffers from the disadvantage that, especially when working with wrinkles in the face, the location of the target being treated transcutaneously cannot be accurately determined by the surgeon. As there are so many tiny muscles (and nerves) involved in different movements of the face in the event that the target is not correctly determined, it is be easy inadvertently to cause unwanted weakening or paralysis of a facial movement.

[0009] According to one aspect of the invention there is provided a method of non-invasive treatment of the human body by ablating a muscle or a nerve controlling the muscle, the method comprising stimulating a muscle to emit an electromyographic signal, detecting the electromyographic signal to ascertain the location of the said muscle or alternatively the nerve, heating the said muscle or nerve by means of optical energy cooling the skin in the vicinity of the said muscle or nerve, and applying radio frequency energy to the muscle or nerve to ablate or partially to ablate said muscle or nerve.

[0010] According to another aspect of the invention there is provided a surgical appliance for ablating selected muscles or nerves of a patient comprising:- a n implement having a working surface which can be applied to the surface of the body of the patient, the said working surface carrying:- a cathode and an anode with suitable electric powering devices, the cathode being arranged to emit an electric power pulse which will stimulate the targeted muscle; a detecting device which will detect an

electromyographic (EMG) pulse emitted by the targeted muscle and which will emit a signal when it has so detected the said electric pulse so that the location of the target will be determined; a pair of spaced optical energy emitting devices which can heat the targeted muscle or nerve, cooling means arranged to cool the skin through which the optical energy must pass, and a pair of radio frequency electrodes connectable to a source of radio frequency electric current and being located so that when actuated they heat the target to oblate it.

[0011] The radio frequency electrodes are preferably bi-polar electrodes. They may be arranged to be connected selectively to the source of radio frequency electric current and to the electric powering device. The electrodes are located at a distance allowing a suitable depth of penetration conveniently being placed 12 to 16mm apart to allow for a RF depth of penetration of approximately six to eight millimetres.

[0012] The optical energy emitting devices are preferably such as to provide an optical light wavelength long enough to reach the target organ with the energy levels of light are sufficiently great to preheat the organ so that the radio frequency can ablate or significantly impede target nerve or muscle function.

[0013] The optical energy emitting devices may comprise a laser conveniently having a sapphire light emitter.

[0014] An embodiment of the invention will now be described by way of example with reference to the accompanying drawing which shows a unit for use in cosmetic aesthetic treatment of the face.

[0015] Referring now to the drawing there is shown a surgical unit 10 of the invention. The unit 10 comprises a cylindrical operating implement 12 which is of such dimensions as to be able to be easily and accurately manipulated by a surgeon for example being in the shape of a thick pen having dimensions of 25mm diameter and 210 mm long. The unit 10 further comprises two electric power packs 14 and 16 which provide radio frequency power to stimulate a muscle respectively. In addition there is a source 18 of cool gases. The power packs 14 and 16 which are connected to the rear end wall 20 of the implement 12 through suitable cabling 22 and 24. The source of cool gases 18 is connected thereto by a flexible fluid conduit 26. The cabling 22 is also connected to a detector box 28 to be described more fully below.

[0016] The front end of the implement 12 is comprised by a smooth and flat end working surface 30 lying at right angles to the axis 32 of the implement 12 and being connected to the cylindrical wall of the implement 12 by a rounded peripheral corner 32.

[0017] Formed on the end surface 30 are a pair of bi-polar electrodes 34 and 36. The electrodes 34 and 36 are spaced apart (centre to centre) by a distance equal to about twice the depth of the targeted muscle. Conveniently this distance is between 12mm and 16mm. By means of suitable switch means (not shown) the electrodes 34 and 36 can be connected to either power pack 14 and 16. Also formed on the end surface between the electrodes 34 and 36 is a rectangular sapphire light guide 38 forming part of a laser which is capable of emitting light in the range of 570 to 590nm at an optical energy of $10J/cm^2$.

[0018] Within the unit 10 and having an end section running adjacent to the end surface 30 is an internal conduit 40 through which cool gases from the source 18 are directed.

[0019] Also within the implement 12 at the end surface 30 there is a preamplifier pod (not shown). This pod is arranged to carry out the following two actions. First it supplies power to the electrodes 32 and 334. Second it detects any EMG signal (i.e. any signal emitted by the muscle when stimulated) that is received by the electrodes 34 and 36 and transmits such EMG signal to the detector box 28.

[0020] The detector box 28 serves as a nerve monitor. It, the detector box 28, is connected via the cabling 22 to the bi polar electrodes 34 and 36 from which it receives an EMG signal. The detector box 28 has a display 42 for indicating a signal which has been received from a muscle as will be described. The display 42 may comprise an oscilloscope display unit but preferably may be a bar code display. The display preferably includes a control to change the colour of the display when the EMG signal increases to a level which would indicate that the location of the nerve or muscle. The detector box 28 may also incorporate an audible signal means which will provide an audible signal when the EMG signal increases to a level which would indicate that the location of the muscle has been located. Alternatively the audible signal means may merely amplify the EMG signal so that the surgeon will be able to ascertain therefrom the location of the muscle.

[0021] In use, the patient will be anaethtised normally by the surgeon will manipulate the implement to pass the end surface 30 of the implement 12 over the skin of a patient in the general location of the muscle which it is desired to ablate.

[0022] Direct current provided by the power pack 16 is applied to the bipolar electrodes to stimulate the muscles below the skin. The electrodes provide a 200μ pulse at an output range of 0,05mA to 5mA. When the implement is close enough to the muscle and/or the nerve controlling for the muscle to be bridged by the electrodes 34 and 36, the muscle will contract when it is acted upon by the pulse from the electrodes. During such contraction the EMG signals of very small voltage (of the order of a millionth to a few thousandth of a volt) are emitted. These signals are detected by the preamplifier pod which sends an appropriate signal to the detector box 28. The surgeon will now be aware of the location of the muscle that is to be ablated. The surgeon will now alter the setting of the implement so that the following actions take place. First the end surface 30 of the implement 12 is cooled by the coolant gases which pass through the internal conduit 40 to reduce the temperature of the surface 30 to about 10°C which in turn will cool the dermis to about 10°C. The optical energy is now applied by the laser and this will raise the temperature of the targeted muscle relative to the surrounding tissue. The electrodes 34 and 36 are then connected by the pod to the radio frequency power pack 14 so that a radio frequency pulse is applied to the heated targeted muscle to ablate the muscle.

[0023] Because the distance apart of the electrodes 34 and 36 is between twelve and sixteen millimetres this will allow an RF depth penetration of approximately six to eight millimetres.

[00024] The degree of ablation is controlled by the surgeon who controlls the dosage of radio frequency applied. Desirably the ablation is not complete or irreversible. This will mean that the muscle will not cause the skin to appear to be paralysed but will only allow small and aesthetically acceptable movements under

control of the muscle. Furthermore the muscle will in due course recover its strength. The dosage for ablation is preferably arranged so that muscle will regain its strength between three months and two years but preferably in about one year.

[0025] The treatment above described can be used inter alia on the corrugator muscles, procerus, lateral orbicularis levator alaeque nasi muscle, depressor anguli oris and platysma muscles, crows feet, glabella, brow depression, lower lid puffiness turnup tip of the nose, dimpling of the chine, smokers lines around the mouth and neck bands. Due to such ablation the muscles will not form corrugations or wrinkles on the skin with a significant aesthetic improvement of the face. In addition the treatment can be used to ablate the protagonist and antagonist muscles controlling turning down of the corners of the mouth and brow depression.

[0026] It has been found that with partial ablation of the muscle this will result in a softening of expression rather than an unnatural paralysis. After a period of time, depending upon the treatment, as menitoned above, the ablated muscle will regain its strength and further treatment will be required. This is generally regarded as a minor inconvenience when compared to the alternative of having a "paralysed look".

[0027] It will be seen that by having the end surface 30 of the implement 12 on the surface of the skin of the patient, the EMG signal can more easily be detected. Furthermore this will avoid extraneous noise from affecting such detection.

[0028] It will be understood that the patient will normally be anaesthetised during the treatment. This is effected by a local anaesthetic block by blocking the nerve being ablated or that which controls muscle to be ablated. Such block taking place away from

the actual area being treated. Typically when muscles in the upper lip are being ablated, an injection is given into the cheek just below the eye. Thus it can be seen that the patient will be awake during the procedure and the procedure can take place in the surgeon's rooms. Of course if desired or if the patient is having another procedure, the procedure of the invention can take place with the patient being under a general anaesthetic.

[0029] It will further be seen that this technique will provide very satisfactory non-invasive cosmetic and aesthetic treatment with the added advantage that no toxins are introduced into the body of the patient. The techniques provides the ability to act transcutaneously non-invasively (i.e without cutting the skin). All other treatments require cutting open the skin or piercing it with needles before delivering the RF dose. In addition the muscle (or nerve) is accurately targeted so that other tissues of the patient are not damaged during this process. This is an important advantage because there are so many tiny muscles (and nerves) involved in different movements of the face and it would be easy to cause unwanted weakening or paralysis of a facial movement if the target is incorrectly selected. It will also be noted that by stimulating the area before the RF shot, one is mimicking the movement that will be directly affected by the RF so the result becomes more predictable.

[0030] The invention is not limited to the precise details hereinbefore described. For example the surgeon may use the EMG signal to detect the location of the nerve which controls the particular muscle that is causing the unwanted wrinkling etc. By ablation of the nerve the action of the muscle will be reduced. The shape and form of the surgical device may vary as desired. The distance apart of the electrodes may vary in dependence upon the depth of the nerve or muscle which it is desired to locate and

to ablate. As an alternative this may be that the electrodes located a about six to ten millimetres apart so that they can heat tissue between three and five millimetres below the dermis. If desired the electrodes can be mounted in a way which would permit their relative location to be adjusted. The surgeon may detect the position of the muscle to be ablated by seeing the movement of the muscle whifh is transmitted through the skin. Thus the detector box and display may be omitted.

CLAIMS

1 A surgical appliance for ablating selected muscles or nerves of a patient comprising an implement having a working surface which can be applied to the surface of the body of the patient, the said working surface carrying:-

a cathode and an anode with suitable electric powering devices, the cathode being arranged to emit an electric power pulse which will stimulate the targeted muscle;

a detecting device which will detect an electromyographic (EMG) pulse emitted by the targeted muscle and which will emit a signal when it has so detected the said electric pulse so that the location of the target will be determined;

a optical energy emitting devices which can heat the targeted muscle or nerve,

cooling means arranged to cool the skin through which the optical energy must pass, and

a pair of radio frequency electrodes connectable to a source of radio frequency electric current and being located so that when actuated they heat the target to oblate it.

2 An appliance as claimed in claim 1 wherein the radio frequency electrodes are bi-polar electrodes.

3 An appliance as claimed in claim 2 wherein the bi-polar electrodes are arranged to be connected selectively to the source of radio frequency electric current and to the electric powering device so that when connected to the powering means they serve respectively as the said cathode and said anode.

4 An appliance as claimed in claim 1, 2 or 3 wherein the electrodes are located at a distance allowing a suitable depth of penetration.

5 An appliance as claimed in claim 4 wherein the electrodes are placed 12 to 16 mm apart to allow for a RF depth of penetration of approximately six to eight millimetres.

6 An appliance as claimed in any one of the preceding claims wherein the optical energy emitting devices such as to provide an optical light wavelength long enough to reach the target organ with the energy levels of light are sufficiently great to preheat the organ so that the radio frequency can ablate or significantly heat the target tissue.

7 An appliance as claimed in claim 6 wherein the optical energy emitting devices provide light in the range of 570 to 590nm at an optical energy of $10J/cm^2$.

8 An appliance as claimed in any one of the preceding claims wherein the optical energy emitting device comprises a laser.

9 An appliance as claimed in claim 8 wherein the laser has a sapphire light emitter.

10 An appliance as claimed in any one of the preceding claims wherein the detector device incorporates a signalling means to indicate to a surgeon when the electromyographic signal is at a maximum.

11 An appliance as claimed in claim 10 wherein the signalling meas is a visual display.

12 An appliance as claimed in claim 11 wherein the visual display changes colour when the electromyographic signal approaches a maximum.

13 A method of non-invasive treatment of the human body by ablating a muscle or a nerve controlling the muscle, the method comprising

stimulating a muscle to emit an electromyographic signal,

detecting the electromyographic signal to ascertain the location of the said muscle or alternatively the nerve,

heating the said muscle or nerve by means of optical energy

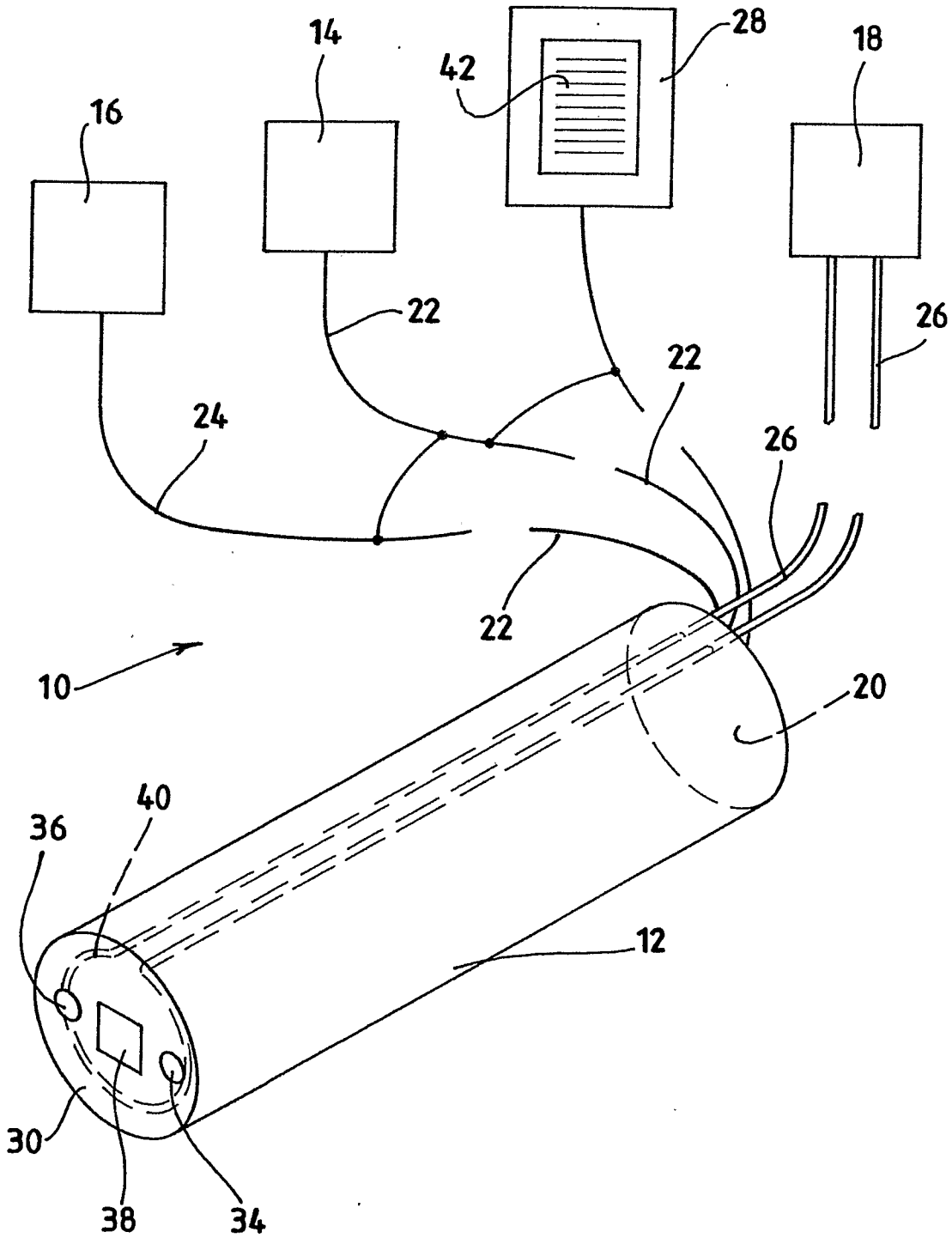
cooling the skin in the vicinity of the said muscle or nerve, and

applying radio frequency energy to the muscle or nerve to ablate or partially to ablate said muscle or nerve.

14 A method as claimed in claim 12 wherein the muscle is stimulated by means of a pulsed electrical stimuli of 2Hz, 200 millisecond duration and 0,5 to 2,9mA.

15 A method of causing muscle or nerve ablation substantially as hereinbefore described in relation to the embodiment.

16 A surgical appliance for ablating selected muscles or nerves of a patient, the appliance having parts arranged and operating substantially as hereinbefore described with reference to and as illustrated in the drawing.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INTERNATIONAL SEARCH REPORT

International application No
PCT/ZA2008/000020

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/14 A61B18/20 A61N1/36 A61B5/0488

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 A61N

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/236487 A1 (KNOWLTON EDWARD W [US]) 25 December 2003 (2003-12-25) paragraphs [0018], [0079], [0100], [0134], [0153], [0178], [0182]	1-12
Y	WO 00/13600 A (VIDA DERM [US]) 16 March 2000 (2000-03-16) page 17, lines 1-13	1-12
A	US 2004/220512 A1 (KREINDEL MICHAEL [IL]) 4 November 2004 (2004-11-04) cited in the application the whole document	1

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

☒ See patent family annex.

* Special categories of cited documents :

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

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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

"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 invention

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 July 2008	08/08/2008

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	Aronsson, Fredrik

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 13-15

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

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Continuation of Box II.2

Claims Nos.: 15-16

No search has been carried out for the subject-matter of claims 15 and 16 (Article 17(2)(b) PCT), because it is impossible to determine the exact scope of said claims (Article 6 PCT). Further, according to Rule 6.2(a) PCT, claims shall not rely on references to the description or drawings (see also the Guidelines, 5.10).

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2)PCT declaration be overcome.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/ZA2008/000020

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

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

1. [X] Claims Nos.: 13-15
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. [X] Claims Nos.: 15-16
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:

see FURTHER INFORMATION sheet PCT/ISA/210

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

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

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

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

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

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

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/ZA2008/000020

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003236487 A1	25-12-2003	NONE	
WO 0013600 A	16-03-2000	AU 5577699 A	27-03-2000
		AU 6139999 A	27-03-2000
		EP 1109501 A1	27-06-2001
		WO 0013599 A1	16-03-2000
		US 6139545 A	31-10-2000
US 2004220512 A1	04-11-2004	WO 03061497 A1	31-07-2003
		US 2003139740 A1	24-07-2003