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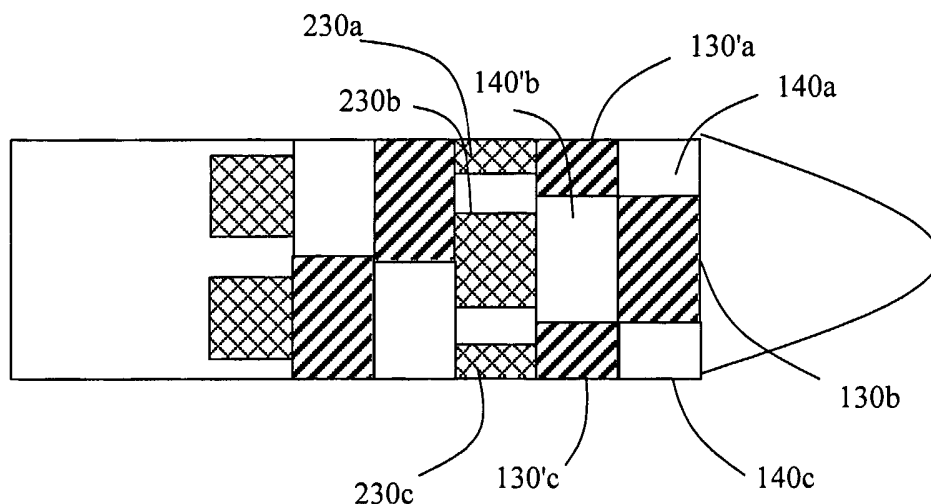
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(54) Title: AN APPARATUS FOR CONTROLLED DIRECTIONAL MONITORING AND DESTRUCTION OF TISSUE



(57) Abstract: A measuring probe for directional measuring of a volume of destroyed tissue, is disclosed comprising: an elongate body with a distal end adapted to be inserted into the tissue to be measured and several independently controllable output means and reception means. The output means are adapted to emit an electromagnetic radiation into the tissue and the reception means for receiving electromagnetic radiation from the output means reflected from the surrounding tissue. Further, an electrode for directional destruction of tissue is disclosed, comprising an elongate body with a distal end adapted to be inserted into the tissue to be destroyed and at least three output areas for emitting a tissue destroying medium, such as a current, into the tissue. The output areas are independently operable, whereby the supply of the tissue-destroying medium to the surrounding tissue becomes directionally controllable. Still further, a combination electrode for both directional measuring and directional destruction is disclosed.

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AN APPARATUS FOR CONTROLLED DIRECTIONAL MONITORING AND
DESTRUCTION OF TISSUE

Technical Field

The present invention relates to a measuring probe for directional measuring of a volume of destroyed tissue, an electrode for directional destruction of tissue, as well as an electrode for combined directional measurement and tissue destruction. The tissue destruction is preferably obtained by generation of a controlled coagulation, so-called lesion, and is advantageously used e.g. in the brain. The invention also relates to systems incorporating such probes and/or electrodes.

Background

When treating certain diseases, the method is used to destroy a predetermined and well-specified area in a tissue. For instance, Parkinson's disease may be treated by controlled coagulation, so-called lesion or ablation, in the brain. This is carried out by an electrode being inserted into the specified area by using a stereotactic frame. Then a main unit which is connected to the electrode is set to supply a required high-frequency current to the specified area, heat being generated at the tip of the electrode and coagulation being provided. The main unit makes it possible to control current intensity, frequency, duration of treatment periods etc. An example of such an ablative surgery device is LEKSELL® NEURO GENERATOR, which is commercially available from Elekta Instrument AB in Sweden.

Conventionally, a problem with this kind of equipment has been that it is difficult to control during treatment how large a volume is being destroyed. During an ablative intervention, the surgeon has virtually no possibility to monitor the growth of the coagulated volume. Parameters such as temperature, power, impedance

and time in automated lesioning systems or temperature, current, impedance and time in semi-manual lesioning systems together with the surgeon's skill and experience are the only lead to get a rough estimation of the lesion growth and final size of the coagulated volume. This implies that the setting of the equipment will be very complicated and require great skill and experience of the user. Thus, there is also a risk of the treatment not being as successful as it could be. This problem is solved by the apparatus disclosed in WO 00/42928 by the same applicant. By means of this apparatus, the destroyed volume of tissue could be measured continuously during the lesion process. However, should the destroyed area be unevenly distributed, the exact shape, volume and location of the destroyed area is still difficult to determine with an adequate precision.

Further, control and shaping of the destroyed volume is still a problem. The destroyed volume is normally formed as a sphere around the tip of the electrode. However, in most cases, the volume of the predetermined tissue to be destroyed may not take the form of a sphere, and in most cases the volume form provided by the electrode does not match the volume form of the tissue to be destroyed. This results in the destruction of an unnecessarily large volume, leading to an increase in unwanted secondary effects.

Further, in known devices, it is necessary to introduce the electrode into the tissue in such a way that the tip becomes located in a exact predetermined position within the volume of tissue to be destroyed. Typically, the tip should be located in the centre of the spherical volume to be destroyed. However, in practice, this may prove difficult to achieve. If the actual tip position is displaced from the intended preferred position, a larger volume of destruction must be used, leading to the destruction of an unnecessarily large volume and an increase of unwanted secondary effects.

Additionally, one drawback with all ablative surgeries are the irrevocably destruction of the tissue, and it is a continuous need for minimizing this destruction.

5 An alternative neurological therapeutic method, used particularly in the brain, is to use so called deep brain simulation (DBS). In this type of therapy, a DBS electrode is introduced into the brain, and a stimulating electric current is delivered through the electrode, and
10 to the volume of the brain surrounding the tip part of the electrode. In order to more precisely stimulate only the desired brain target it has been proposed to use directional stimulation electrodes, in which the stimulation essentially occurs only in a radial section
15 out from the electrode tip part. Such electrodes are e.g. known from WO 02/45795 and WO 02/068042. However, control and shaping of the treated volume is still a problem. It is still difficult to place the electrode in an exact position where the treatment effect is maximized and the
20 side effects are minimized. Further, if the volume of the volume to be treated does not match the sectional volume in which the stimulating electric current is delivered, the electrode need to be physically repositioned, e.g. turned around its axis or reintroduced into the brain in
25 a different position. Such repositioning of the electrode tip part is in practice difficult to achieve with any degree of precision, since the electrode need to be manoeuvred from the proximal part outside the patient, and through the flexible and elastic body of the
30 electrode. Further, repositioning of the electrode in this very sensitive area is hazardous and associated with significant health risks for the patient.

Object of the Invention

35 It is therefore an object of the present invention to provide an improved method and apparatus where the

above-mentioned disadvantages of previously known solutions entirely, or at least partly, are alleviated.

This object is achieved by means of an apparatus according to the appended claims.

5

Summary of the invention

According to a first aspect of the invention, a measuring probe for directional measuring of a volume of destroyed tissue is provided, comprising:

10 an elongate body with a distal end adapted to be inserted into the tissue to be measured;

at least one output means for emitting an electromagnetic radiation into the tissue, said output means being arranged at the distal part of the elongate

15 body;

at least one reception means for receiving electromagnetic radiation from the output means reflected from the surrounding tissue, the reception means being arranged in the vicinity of a corresponding output means

20 on the distal part of the elongate body;

at least one additional output means or reception means, said additional output means or reception means being arranged at different circumferential positions on the distal part of the elongate body from said first

25 output means or reception means, and being independently operable from the same, in order to receive electromagnetic radiation reflected in distinguishable part volumes of the surrounding tissue.

30 The measuring probe could e.g. be used in preparation for, during or after ablative surgery. However, the probe may not only serve as a complement to a therapeutic tool, but also for diagnostic purposes. When the probe is inserted into a specific tissue to be

35 measured, tissue in different parts surrounding the probe may be measured separately, in distinguishable volumes, due to the independent operability of the output and/or

reception means. Since the distinction between different parts is accomplished by means of controlling the output and/or reception means, the measurement of different parts may further be achieved without any repositioning of the probe, such as turning, twisting or reinsertion into the tissue. Accordingly, the probe makes it possible to precisely control how large a volume that is being destroyed during e.g. an ablative intervention, as well as the shape, volume and location of the destroyed volume. Not only does this facilitate the work of the surgeon, but it also significantly reduces the risks involved for the patient. Further, the improved measurement provided by the probe makes it possible to limit the volume destroyed during the intervention, leading to a decrease in unwanted secondary effects. The directional measurement provided by the probe also makes it possible to investigate the tissue characteristics in different directions during introduction of the electrode into the tissue and e.g. detect blood vessels etc. in the lesioning volume.

The measurement being performed by the probe in the different directions may use similar measurements techniques as is disclosed in WO 00/42928 by the same applicant, said document hereby in its entirety being incorporated by reference. Especially it is preferred to use light, white or monochromatic, for the measurement, from which several tissue-specific parameters can be monitored and be used to determine e.g. type of tissue chromophores and blood perfusion. However, the probe may be used for logging a variety of different parameters, which gives the surgeon a tool for tissue determination, a sharper targeting, and makes the intervention safer.

The probe could further be used for measurements in real time during a surgical intervention. Further, the probe may be a part of an automatized lesioning process, in which the lesioning process can be monitored and automatically shut-off when or if a pre-set maximum

lesion size is exceeded. Alternatively or additionally lesioning could be automatically inhibited if other unwanted events or conditions are recognized, such as if a larger vessel or other structure is detected within the
5 volume to be destroyed.

By a suitable arrangement of the output means and/or reception means on the distal part of the probe, and especially around the circumference of the same, the field of view can preferably be arbitrarily chosen
10 360 degrees around the probes axis without rotating the electrode itself. It is preferred that at least four output means are provided at different circumferential positions on the distal part of the elongate body, and preferably at least six, and most preferably eight.
15 Hereby an adequate and reliable circumferential resolution in the measurements could be obtained. To this end, it is also preferred that the output means are arranged symmetrically and equidistantly.

In order to achieve a good axial resolution, at
20 least two output means and/or reception means are preferably arranged at different axial positions on the distal part of the elongate body. In a preferred embodiment, the output means and/or reception means are arranged along at least two axially separated ring-like
25 paths on the elongate body, each path comprising at least two circumferentially separated output means. Hereby, a good resolution in both the circumferential and the axial direction could be accomplished in a relatively easy and inexpensive fashion.

30 In one embodiment, the radiation output of the output means are radially restricted, each output means preferably exposing a radial section being essentially $360^\circ/n$, where n is the number of circumferentially separated output means along a common circumferential
35 path. Hereby, the measurement values corresponding to different output means are easy to relate to the tissue in different sections. Alternatively, or additionally,

the reception means may be adapted to receive reflected input from a limited radial section in the same fashion.

The relation of the measurement signals to certain parts of the surrounding tissue, whether it is in the
5 circumferential/radial direction or in the axial direction, or preferably in both, could basically be achieved in three different ways:

- The output means are adapted to expose different areas of the surrounding tissue. This could be
10 accomplished by the way the output means are positioned on the distal part of the probe, and/or by using output means with a certain output directivity. Consequently, activation of different output means, either alone or in various combinations, leads to a differentiation in the
15 exposure of various parts of the surrounding tissue. Accordingly, such measurements directly provides information relating to the parts of the tissue being exposed. Further, if the exposure areas of some output means are overlapping, combinations of different
20 measurements may be used to compute additional information regarding certain parts.

- The reception means are adapted to receive reflected radiation from different areas of the surrounding tissue. This could be accomplished by way the
25 reception means are positioned on the distal part of the probe, and/or by using reception means with a certain directivity. Consequently, activation of different reception means, either alone or in various combinations, could be used for differentiation between various parts
30 of the surrounding tissue in the same manner as discussed above in relation to the output means.

- A combination of directionally controllable output means and directionally controllable reception means. Hereby, the measurement probe becomes more
35 reliable and with a better resolution and controllability.

In each of the first and third alternative, it is preferred that essentially all of the output means are independently operable. In each of the second and third alternative it is preferred that essentially all of the reception means are independently operable.

The electromagnetic radiation emitted by the output means is preferably but not necessarily within the wavelength range of light, and preferably but not necessarily visible light. However, the wavelength used is preferably dependent on which parameter to be investigated.

According to another aspect of the invention, an electrode for directional destruction of tissue is provided, comprising:

an elongate body with a distal end adapted to be inserted into the tissue to be destroyed;

at least three output areas for emitting a tissue destroying medium, such as a current, into the tissue, said output areas being arranged at different circumferential positions on the distal part of the elongate body;

conductors leading to the output areas through the elongate body from a proximal end, for controlling the supply of a tissue-destroying medium;

wherein the output areas are connected to separate conductors and independently operable, whereby the supply of the tissue-destroying medium to the surrounding tissue becomes directionally controllable.

The conductors preferably supplies the tissue-destroying medium to the output areas from an external source. However, alternatively, it is also possible to use internal sources, whereby the tissue-destroying medium will be generated within the electrode. In the latter alternative, the conductors are used for controlling said internal sources.

This electrode could e.g. be used as a therapeutic tool for ablative surgery. When the electrode is inserted into a specific tissue to be destroyed, tissue in different parts surrounding the probe may be destroyed separately, in distinguishable volumes, due to the independent operability of the output areas. Since the distinction between different parts is accomplished by means of controlling the output areas, the destruction of different parts may further be achieved without any repositioning of the electrode, such as turning, twisting or reinsertion into the tissue. Accordingly, the electrode makes it possible to control how large a volume that is being destroyed during e.g. an ablative intervention, as well as the shape, volume and location of the destroyed volume. Not only does this facilitate the work of the surgeon, but it also significantly reduces the risks involved for the patient. Further, the improved controllability provided by the electrode makes it possible to limit the volume destroyed during the intervention, leading to a decrease in unwanted secondary effects.

By a suitable arrangement of the output areas on the distal part of the electrode, and especially around the circumference of the same, the direction in which the tissue destruction should occur can preferably be arbitrarily chosen 360 degrees around the electrode axis without rotating the electrode itself.

It is preferred that at least four output areas are provided at different circumferential positions on the distal part of the elongate body, and preferably at least six, and most preferably eight. Hereby an adequate and reliable circumferential resolution could be obtained. To this end, it is also preferred that the output areas are arranged symmetrically and equidistantly.

In order to achieve a good axial resolution, at least two output areas are preferably arranged at different axial positions on the distal part of the

elongate body. In a preferred embodiment, the output areas are arranged along at least two axially separated ring-like paths on the elongate body, each path comprising at least two circumferentially separated output areas. Hereby, a good resolution in both the circumferential and the axial direction could be accomplished in a relatively easy and inexpensive fashion.

In order to increase the controllability, it is preferred that essentially all the output areas are independently operable.

The supplied medium could be chosen in dependence on the type of surgical operation. However, in a preferred embodiment the medium is, or is transformed into, heat for controlled coagulation of the tissue. Most preferably, the supplied medium is high-frequency current which is transformed into heat in the tissue, due to the inherent resistance in the tissue.

According to still another aspect of the invention, an electrode for measuring and destroying of tissue is provided, comprising:

an elongate body with a distal end adapted to be inserted into the tissue to be measured and destroyed; measuring means arranged at different circumferential positions on the distal part of the elongate body for directionally measuring destroyed tissue in the surrounding tissue; and destruction means arranged at different circumferential positions on the distal part of the elongate body for performing directionally controllable destruction of tissue in the surrounding tissue.

According to this aspect, the concepts of directional measurement and directional destruction are combined into one electrode, providing a very efficient tool for e.g. ablative surgery. Hereby, a single electrode could be introduced into the tissue, and

thereafter the directional measurement and directional
destruction could be used sequentially or in parallel to
form a very precise intervention without any
repositioning of the electrode. Accordingly, the
5 electrode makes it possible to precisely control how
large a volume that is being destroyed during e.g. an
ablative intervention, as well as the shape, volume and
location of the destroyed volume. At the same time, the
required number of penetrations of the electrode into the
10 organ to be treated is significantly reduced.

Further, since the measurement and destruction
origins from the same spot within the organ to be
operated, the correlation between the measurement and the
destruction is significantly facilitated.

15 The electrode could be used for measurements in real
time during the surgical intervention. Further, the
electrode is well suited for an automatized lesioning
process, in which the lesioning process can be monitored
and automatically shut-off when or if a pre-set maximum
20 lesion size is exceeded. Alternatively or additionally
lesioning could be automatically inhibited if other
unwanted events or conditions are recognized, such as if
a larger vessel or other structure is detected within the
volume to be destroyed.

25 All the characteristics and advantages discussed
above in relation to the first aspects of the invention
may partly or fully be incorporated in the combination
electrode according to the third aspect of the invention.

30 According to still another aspect of the invention,
a system for measuring destruction of tissue is provided,
comprising a control unit and a directional measuring
probe of the above-discussed type.

35 According to still another aspect of the invention,
a system for destruction of tissue is provided,
comprising a control unit and an electrode for

directional destruction of tissue of the above-discussed type.

According to still another aspect of the invention, a system for measuring and destruction of tissue, comprising a control unit and an electrode for directional measurement and destruction of tissue of the above-discussed type.

These and other aspects of the invention will be apparent from and elucidated with reference to the embodiments described hereinafter.

Brief Description of the Drawings

For exemplifying purposes, the invention will be described in closer detail in the following with reference to embodiments thereof illustrated in the attached drawings, wherein:

Fig. 1 is a schematic view of a system including a measurement probe, according to one embodiment of the present invention;

Fig 2 is a detailed cross-section of the distal part of a measuring probe according to an embodiment of the invention;

Fig 3-6 are side views illustrating different arrangements of reception means and output means on a distal end of a measurement probe;

Fig. 7 is a schematic view of a system including a tissue destroying electrode, according to one embodiment of the present invention;

Fig 8 is a side view illustrating an arrangement of output areas on a distal end of an tissue destroying electrode;

Fig 9-11 are elevational cross-sectional views illustrating operation of different combinations of output areas in a tissue destroying electrode;

Fig. 12 is a schematic view of a system including a electrode for combined measurement and tissue

destruction, according to one embodiment of the present invention;

Fig 13 is a side view illustrating an arrangement of output means, reception means and output areas on a distal end of an tissue destroying electrode;

Fig 14 is an example of an interface on which the measurement output may be presented on a display;

Fig 15 is an alternative example of an interface on which the measurement output may be presented on a display;

Fig 16 is a schematic transversal cross-sectional view of a probe/electrode; and

Fig 17 is a schematic transversal cross-sectional view of an alternative embodiment of a probe/electrode.

Description of Preferred Embodiments

The invention will now be described in more detail by way of embodiments and with reference to the accompanying drawings.

Measurement probe

A measurement probe is schematically illustrated in fig 1. The probe comprises an elongate body 100 with a distal end 110 adapted to be inserted into the tissue to be measured and a proximal end 120 not to be inserted. At the distal end, output means 130 are arranged for emitting an electromagnetic radiation into the tissue in a directionally controllable fashion. To this end, the output means are arranged at different circumferential positions on the distal part of the elongate body. Further, reception means 140 are arranged in the vicinity of the output means for receiving electromagnetic radiation from the output means reflected from the surrounding tissue.

The measurement being performed by the probe in the different directions preferably use optical measurements techniques as is disclosed in WO 00/42928 by the same

applicant, said document hereby in its entirety being incorporated by reference. Especially it is preferred to use light, white or monochromatic, for the measurement, from which several tissue-specific parameters can be monitored and be used to determine e.g. type of tissue and blood perfusion. Depending on which parameter that is of interest to observe, the light source can be chosen to optimize the investigation. Tentative *in vitro* and *in vivo* experiment have shown that both the reflectance spectroscopy and the laser Doppler technique may be utilized in order to monitor the lesion growth and final size during an intervention. Hence, either of or a combination of spectroscopy and laser Doppler could be used to:

- 15 • monitor the blood perfusion, which in turn can be used in a general diagnostic sense and/or to monitor a lesioning process and determine the size of a coagulated volume
- 20 • discriminate unlesioned from lesioned tissue (grey or white)
- discriminate white from grey tissue

Said techniques may also be used together with microdialysis and micro recording systems in order to provide additional information about the tissue characteristics, etc. When utilised with micro recording and/or microdialysis, two fibres are preferably introduced along a trajectory parallel to micro recording and/or microdialysis trajectories, whereby the microcirculation can be investigated.

30 The reception means and/or the output means are independently operable in order to measure the reflection from distinguishable different parts of the surrounding tissue. The directional resolution is further improved by a suitable arrangement of the output means and/or reception means on the distal part of the probe, and various alternative embodiments in this respect are discussed more thoroughly in the following.

Control lines 131, 141, as illustrated in fig 2, are further arranged within the elongate body from the proximal end to the output means and reception means at the distal end.

5 The control lines to the output means preferably comprises optical fibers 131 for provision of the electromagnetic radiation to the output means from an external source. Preferably, a separate control line is provided for each output means, whereby independent
10 operation of each output means is easy to achieve. Alternatively, the probe may comprise one or several radiation sources, whereby the control lines may instead be adapted to control said source(s), e.g. by means of electric control signals.

15 The control lines to the reception means preferably also comprises optical fibers 141 for transferring the received reflected radiation to external detection means. Preferably, a separate control line is provided for each reception means, whereby independent operation of each
20 reception means is easy to achieve. Alternatively, the probe may comprise one or several conversion means and/or detection means, whereby the control lines may instead be adapted to control said conversion means and detection means, e.g. by means of electric control signals.

25 As illustrated in fig 2, the optical fibers 131, 141 may be arranged inside the elongate body. At the distal part, the optical fibers preferably end close to a reflecting surface 132, 142 for transmitting the radiation radially towards the surrounding tissue from
30 the axially extending fiber and vice versa. The area between the fiber end, the reflective surface and the surface of the probe is preferably of a material 133, 143 transparent to the electromagnetic radiation used.

35 The optical fibers are preferably arranged inside the elongate body, close to the peripheral wall of the probe, and circumferentially distributed. Such an arrangement is illustrated in fig 16, which illustrates a

transversal cross-section in a position above the output means. In this embodiment the fibers are arranged in four different groups, corresponding to the number of distinct circumferential directions being observed. However, other
5 grouping arrangements are possible as well. Further, the fibers may be equidistantly arranged in the circumferential, as is schematically illustrated in fig 17, which illustrates a transversal cross-section in a position above the output means of an alternative
10 embodiment.

In order to be truly independently operable, the detector unit can comprise one detector and one light source to each sector to be distinguishably measured.

The relation of the measurement signals to certain
15 parts of the surrounding tissue, whether it is in the circumferential/radial direction or in the axial direction, or preferably in both, could basically be achieved in three different ways:

- The output means are adapted to expose
20 different areas of the surrounding tissue. This could be accomplished by the way the output means are positioned on the distal part of the probe, and/or by using output means with a certain output directivity. Consequently, activation of different output means, either alone or in
25 various combinations, leads to a differentiation in the exposure of various parts of the surrounding tissue.

- The reception means are adapted to receive reflected radiation from different areas of the surrounding tissue. This could be accomplished by way the
30 reception means are positioned on the distal part of the probe, and/or by using reception means with a certain directivity. Consequently, activation of different reception means, either alone or in various combinations, could be used for differentiation between various parts
35 of the surrounding tissue in the same manner as discussed above in relation to the output means.

- A combination of directionally controllable output means and directionally controllable reception means.

All these three different types of directional
5 measurements provides information relatable to
distinguishable parts of the tissue being exposed.
Further, if the exposure areas are overlapping,
combinations of different measurements may be used to
compute additional information regarding certain parts.

10 In the following, some examples of arrangements of
the reception means and the output means on the distal
part are described. However, it should be appreciated by
those versed in the art that the disclosed arrangement
patterns for the reception means are equally suitable for
15 arrangement of the output means, and vice versa.

In fig 3, a distal part of the measurement probe is
illustrated where a first circular path comprises an
omnidirectional output means 130, for emitting radiation
to the surrounding tissue in all circumferential
20 directions. Thereabove, in a second path, four reception
means 140a-c are arranged. Each reception means receive
radiation from a distinguishable radial section of the
surrounding tissue, and are independently operable.
Thereabove, in a third path, is arranged another output
25 means 130', in a fourth path four additional reception
means 140'a-c, in a fifth path another output means 130",
etc. The plurality of reception means within each path
enables directional measurement in the circumferential
direction, whereas the plurality of paths enables
30 directional measurement in the axial direction.

In fig 4, an alternative arrangement is illustrated.
In this embodiment, a first circular path comprises an
omnidirectional reception means 140, for receiving
reflected radiation from the surrounding tissue in all
35 circumferential directions. Thereabove, in a second path,
four output means 130a-c are arranged. The output means
are selectably operable, and the reception means receive

radiation from the output means currently in operation. Thereabove, in a third path, is arranged another reception means 140', in a fourth path four additional output means 130'a-c, in a fifth path another reception
5 means 140", etc. Thus, the plurality of output means within each path enables directional measurement in the circumferential direction, whereas the plurality of paths enables directional measurement in the axial direction.

It is also possible to use several reception means
10 and several output means within each path. Such an embodiment is illustrated in fig 5, and enables an even better directional resolution and controllability.

It is further possible to mix the reception means and the output means in each path. Such an embodiment is
15 illustrated in fig 6, and enables an even better directional resolution and controllability. It is also possible to arrange the different paths in different types of staggered relationships.

The measuring probe could e.g. be used in
20 preparation for, during or after ablative surgery. However, the probe may not only serve as a complement to a therapeutic tool, but also for diagnostic purposes.

In one embodiment, the radiation output of the
25 output means are radially restricted, each output means preferably exposing a radial section being essentially $360^\circ/n$, where n is the number of circumferentially separated output means along a common circumferential path. Hereby, the measurement values corresponding to
30 different output means are easy to relate to the tissue in different sections. Alternatively, or additionally, the reception means may be adapted to receive reflected input from a limited radial section in the same fashion.

By transmitting light to a specific sector, the
35 optical properties in that sector can be investigated, leaving the other sectors unaffected.

The probe may also have a key in the shaft to make it unmovable in relation to for instance a stereotactic frame, whereby a reference is provided for the measurement directions.

5 By means of the directional measurement probe discussed above, any inhomogeneity in the tissue (such as tissue type & structure, blood vessels, lesions, abnormalities, etc.) in the proximity of the electrode can be located in relation to the electrodes position for
10 instance in a stereotactic frame. This in turn can be used:

- before and/or after a surgical intervention, such as a thermal coagulation, in order to give a status of a defined tissue volume in the proximity of the
15 electrode.
- before, during and/or after a surgical intervention in order to guide/navigate the medical equipment used towards a defined tissue volume.
- during a surgical intervention, such as a thermal
20 coagulation, in order to monitor the currently performed surgery.
- during a surgical intervention, such as a thermal coagulation, in order to control the currently performed surgery. This can be done either indirect
25 (visually or audibly to the surgeon) or direct (controlling the surgical instrument to perform as decided).

Surgical intervention in this application includes any surgical procedure in the nervous system.

30

Naturally, the number of reception means and/or input means within each path may be higher or lower, and further the number of axially separated paths may be higher or lower. Further, the paths need not be circular,
35 but tilted, oval paths are feasible as well, and also helical paths and the like. Still further, reception means and/or the output means need not be adjacent to

each other, but could be more or less separated on the probe surface.

Electrode for tissue destruction

5 A measurement electrode is schematically illustrated in fig 7. The electrode comprises an elongate body 200 with a distal end 210 adapted to be inserted into the tissue to be measured and a proximal end 220 not to be inserted. At the distal end, output areas 230 are
10 arranged for emitting an tissue destroying medium into the tissue in a directionally controllable fashion. To this end, the output areas are arranged at different circumferential positions on the distal part of the elongate body.

15 The output areas are independently operable in order to supply the tissue destroying medium into distinguishable different parts of the surrounding tissue. The directional controllability is further improved by a suitable arrangement of the output areas on
20 the distal part of the electrode, and various alternative embodiments in this respect are discussed more thoroughly in the following.

 Control lines (not illustrated) are further arranged within the elongate body from the proximal end to the
25 output areas at the distal end.

 The supplied medium could be chosen in dependence on the type of surgical operation. However, in a preferred embodiment the medium is, or is transformed into, heat for controlled coagulation of the tissue. Most
30 preferably, the supplied medium is high-frequency current which is transformed into heat in the tissue, due to the inherent resistance in the tissue. The high-frequency current is preferably generated in an external generator, and transferred to the output areas through the control
35 lines. In the tissue the current is transformed into heat and, thus, causes a lesion round the tip of the electrode. However, other media are also possible, such

as direct transmission of heat in the electrode, electromagnetic radiation such as microwaves, or transmission of laser light. Other destroying techniques are also conceivable, such as transmission of a
5 refrigerating medium, transmission of a destroying chemical or the like.

The medium transmission could be controlled in order to determine how large a tissue volume should be destroyed. If, for instance, high-frequency current is
10 used as a medium, the control may take place with respect to current intensity, frequency, duration of treatment periods etc.

The electrode may, for instance, be a monopolar or bipolar electrode for transmission of current, as is
15 already known within the field of equipment for lesion within neurosurgery. The distributed output areas forms one of the poles.

In the following, some examples of arrangements of the output areas are discussed. In fig 8, a distal part
20 of the tissue destroying electrode is illustrated where a first circular path comprises four output areas 230a-b, for emitting the tissue destroying medium to the surrounding tissue in controllable directional directions. Thereabove, in a second path, four output
25 areas 230'a-c are arranged. Each output area outputs the tissue destroying medium to a distinguishable radial section of the surrounding tissue, and are independently operable. Thereabove, in a third path, is arranged another four output areas 230", etc. The plurality of
30 output areas within each path enables directional tissue destruction in the circumferential direction, whereas the plurality of paths enables directional destruction in the axial direction. The output means in the different paths are preferably arranged in a staggered fashion.

35 The electrode may also have a key in the shaft to make it unmovable in relation to for instance a

stereotactic frame, whereby a reference is provided to be used e.g. in combination with measurement directions.

By the distributed arrangement of the output areas, it is possible, depending on which terminals that are active, to form an arbitrary volumetric coagulation in both shape and size in relation to the electrodes position for instance in a stereotactic frame. As an illustration of this, fig 9-11 illustrates the current distribution as a result of activation of different output areas in an electrode with four circumferentially distributed output areas. Fig 9 illustrates the current distribution when one output areas is active; fig 10 illustrates the current distribution when two adjacent output areas are active; and fig 11 illustrates the current distribution when two diametrically positioned output areas are active.

Naturally, the number of output areas within each path may be higher or lower, and further the number of axially separated paths may be higher or lower. Further, the paths need not be circular, but tilted, oval paths are feasible as well, and also helical paths and the like. Still further, the output areas need not be adjacent to each other, but could be more or less separated on the electrode surface.

25

Electrode for measurement and tissue destruction

The measurement probe and the destruction electrode discussed in the foregoing may be used as separate units. However, it is also possible, and often preferred, to combine said functionalities into one single electrode. This embodiment will now be discussed in more detail.

A measurement electrode is schematically illustrated in fig 12. The electrode comprises an elongate body 300 with a distal end 310 adapted to be inserted into the tissue to be measured and a proximal end 320 not to be inserted. At the distal end, output means and reception

35

means are arranged for directional measurement, as well as output areas 330 for directional tissue destruction.

The arrangement, operation and functionality of the output means and reception means are basically the same as discussed above with reference to the measurement probe.

The arrangement, operation and functionality of the output areas are basically the same as discussed above with reference to the electrode for tissue destruction.

One example of an arrangement of the output means, reception means and output areas is disclosed in fig 13. Fig 13 illustrates a distal part of the electrode for both measurement and tissue destruction, wherein a first circular path in an alternating fashion comprises reception means 140a-b and output means 130b. Thereabove, in a second path, reception means 140'b and output means 130'a-b are likewise arranged, in an alternating fashion and in a staggered relationship towards the first path. The first and second paths are arranged for directional measurement. Thereabove, in a third path, are arranged four output areas 230a-c for directional tissue destruction. The pattern of the first three paths may then be repeated in one or several additional sets of paths, and these additional sets of paths could advantageously be displaced in a staggered fashion from the first set of paths.

By the distributed arrangement of reception means and output means as well as the output areas on the same electrode, it is possible to perform both the directional measurement as discussed in the foregoing and the directional tissue destruction from the same position. This increases the precision, and the of relating the measurements to the position of the electrode during the tissue destruction is significantly facilitated.

Further, the combined electrode need only be introduced into the tissue once, and thereafter the

directional measurement as well as the directional destruction could be used sequentially or in parallel to form a very precise intervention without any repositioning of the electrode.

5 The combined electrode is particularly well suited for measurements in real time during the surgical intervention, and for use in an automatized lesioning process, in which the lesioning process can be monitored and automatically shut-off when or if a pre-set maximum
10 lesion size is exceeded. Alternatively or additionally lesioning could be automatically inhibited if other unwanted events or conditions are recognized, such as if a larger vessel or other structure is detected within the volume to be destroyed.

15

Naturally, the number of output means, reception means and output areas within each path may be higher or lower, and further the number of axially separated paths may be higher or lower. Further, arrangement of output
20 areas, reception means and output areas within the paths may be chosen in many different ways. Further, the paths need not be circular, but tilted, oval paths are feasible as well, and also helical paths and the like. Still further, the output means, reception means and output
25 areas need not be adjacent to each other, but could be more or less separated on the electrode surface.

System

In the foregoing, different embodiments of probes
30 and electrodes for measurement and/or tissue destruction have been discussed. Said probes and electrodes are preferably used as a part in a system for measurement and/or tissue destruction. Such systems will now be discussed more thoroughly.

35

A system for directional measurement could comprise a probe solely for measurement, or an electrode for

combined measurement and tissue destruction, both of which are discussed in detail in the foregoing. Such a system is schematically illustrated in fig 1.

The system comprises a probe/electrode connected to control unit for monitoring the measurement. The control unit receives measurement signals from the probe/electrode and comprises a detector and a signal-processing unit for transformation and evaluation of the received measurement signals. The control unit also outputs control signals to the reception means and/or the output means of the probe/electrode, as discussed in the foregoing, such as electromagnetic radiation from an external source or electric control signals, for controlling the directional measurement. The control signals are preferably also used as an input to the evaluation process, together with e.g. positioning information for the probe/electrode, e.g. referring the position to a stereotactic frame.

The measurement preferably utilize either of the laser Doppler principle and reflectance spectroscopy, or a combination thereof. Optical fibres lead, in the former, monochromatic light, or in the latter white light, to the tissue through the tip of the probe/electrode. The monochromatic light will interact with the tissue and the moving blood cells in the proximity of the tip. The intensity and frequency content of the backscattered light, lead via optical fibres from the tip, are detected in the control unit and are utilised to estimate the volume of the lesioned tissue. The white light will interact with the tissue and during the lesioning process the tissue characteristics will change which can be seen as a change of the spectral pattern. This can be used to e.g. discriminate lesioned from unlesioned tissue.

The evaluation of the reflected radiation in order to correlate them to a certain volume of destroyed tissue in a certain direction, can be performed in different

ways, which would be apparent for those skilled in the art. For instance, direct correlation between the measuring results of the measured characteristic and the volume of tissue can be established for different cases, such as operation of different output areas and combinations of the same, different types of tissue etc. Further, the control can take place on the basis of stored table results. The correlation between measuring results and volume in certain directions can advantageously be measured in advance in a simulation environment. For instance, such measurements can be carried out in such a system as is disclosed in Applicant's Swedish patent application WO 99/00063, where lesions are generated in a solution of protein, such as albumin. When producing such lesions in a test fluid, the directional volume and shape of the lesion can be determined in time, for instance, by being calculated through filming with a video camera at the same time as the corresponding measurement as described above can be carried out. Thus, it is possible to relate measuring results to a predetermined directional volume size.

The control unit provides an measurement output signal, based on the evaluation process. The output signal may be provided to a display or other types of audio or video interfaces towards the user. However, the output signal may additionally or alternatively be used to control a tissue destroying device.

The measurement output may be presented on a display as illustrated in fig 14. Here, the size of the lesion is quantitatively illustrated in four different directions during the surgical intervention, wherein the height of four different staples illustrates the size of the lesion in a corresponding direction. In addition, the graphical illustration of the size of the lesion may be complemented with a quantitative amount of the lesion size, e.g. in mm³. Such an alternative embodiment is illustrated in Fig 15, where the interface incorporates

both the perfusion and the DC, monitored and quantitatively illustrated in four different directions during the surgical intervention. However, many other ways of visualisation of the lesioning process are
5 feasible.

The control unit may be implemented in dedicated hardware, or as software in e.g. a conventional personal computer, or as a combination thereof.

10 A system for directional tissue destruction could comprise a probe solely for tissue destruction, or an electrode for combined measurement and tissue destruction, both of which are discussed in detail in the foregoing. Such a system is schematically illustrated in
15 fig 7.

The system comprises an electrode connected to a control unit for controlling the tissue destruction. The control unit preferably receives measurement signals from a probe/electrode and comprises a processing means for
20 generating control signals for controlling the supply of the tissue destroying medium through the different output areas, as discussed in the foregoing.

The control unit may be implemented in dedicated hardware, or as software in e.g. a conventional personal
25 computer, or as a combination thereof.

A system for directional measurement and tissue destruction could comprise several probes/electrodes. Each probe/electrode may be used solely for measurement or tissue destruction, or electrodes for combined
30 measurement and tissue destruction could be used. However it is also possible to use only one electrode for combined measurement and tissue destruction. Such a system is schematically illustrated in fig 12.

This system is basically a combination of the
35 measurement system and the tissue destroying system discussed above. The system comprises one or several electrodes and one or several control units.

However, with this combined system, the coagulation process can not only be monitored and controlled but also optimised to give a pre-determined size and shape. The lesioning process could continuously visualised on a display or a computer screen during the intervention.

The control unit may be implemented in dedicated hardware, or as software in e.g. a conventional personal computer, or as a combination thereof.

The systems discussed above could be stand-alone units or be integrated in conventional lesioning equipment. The measurement techniques discussed above may also used together with microdialysis and/or microrecording system in order to give additional clinical information about the tissue characteristics.

15

Method of use

In the following, a method of using the system for combined directional measurement and tissue destruction should be destroyed more thoroughly. If only one of the functions measurement and tissue destruction should be used, the method discussed in the following is applicable to the parts corresponding to that function.

In use, patient is initially prepared for stereotactic surgery according to standard procedures.

Before lesioning, the electrode is introduced stereotactically through the brain towards the target. During this procedure the type of tissue in different directions could preferably detected and visualised on a display. Optionally, by holding the electrode still a few seconds during introduction, the blood perfusion or other tissue specific parameters can be monitored and visualised on a display.

At the target site, the blood perfusion and tissue specific parameters are investigated before the lesioning. If e.g. an abnormal blood perfusion is detected in any direction, an alert is given to the

35

surgeon. A maximum volume to be destroyed can then be set to act as a reference to the apparatus during lesioning.

During the intervention, the growth of the lesion could be continuously monitored and visualized, either graphically or as a number on a display. In addition, or as an alternative, the monitoring may also include a sound alert or automatic shut-off when the lesioned tissue volume reaches a pre-set volume.

The lesion in different directions may either be controlled manually by the surgeon, or be controlled automatically based on pre-set parameters decided by the surgeon.

After the intervention, the lesioning parameters could preferably be printed and/or downloaded to a computer memory for record keeping and possible later investigation. Thereafter, the electrode is retracted and the procedure ended. The stereotactic surgery is then closed according to standard procedures.

For planning the lesion, and determine a suitable volume and shape, a surgical planning system, such as the Leksell SurgiPlan, could be used.

Concluding comments

The invention as discussed above is preferably intended for performing measurements and producing lesions in the brain for the treatment of, for instance, Parkinson's disease. However, the invention can also be used to other ends, such as ablation in hearts, in treatments by destroying a defined volume of tissue in the liver, the medulla oblongata, prostate and also in other tissues. One way of destroying the tissue may involve the supply of heat to the medium, either directly or via high-frequency current, microwaves or other types of electromagnetic radiation, laser light or the like. Other media can, however, also be used, for other

destroying techniques, such as cold or deadly chemical agents that acts locally.

Furthermore, the invention is particularly well suited for a continuous, feed-back control. However, it
5 is also possible to carry out measuring at certain occasions only, such as at regular intervals and, then, control lesioning on the basis of these measurements.

Such and other obvious modifications must be considered to be within the scope of the present
10 invention, as it is defined by the appended claims. It should be noted that the above-mentioned embodiments illustrate rather than limit the invention, and that those skilled in the art will be able to design many alternative embodiments without departing from the scope
15 of the appended claims.

CLAIMS

1. An electrode for measuring and destroying of
5 tissue, comprising:
 an elongate body with a distal end adapted to be
 inserted into the tissue to be measured and destroyed;
 measuring means arranged at different
 circumferential positions on the distal part of the
10 elongate body for directionally measuring destroyed
 tissue in the surrounding tissue; and
 destruction means arranged at different
 circumferential positions on the distal part of the
 elongate body for performing directionally controllable
15 destruction of tissue in the surrounding tissue.
2. The electrode of claim 1, wherein the measuring
means comprises:
 at least two output means for emitting an
 electromagnetic radiation into the tissue, said output
20 means being arranged at different circumferential
 positions on the distal part of the elongate body;
 at least two reception means for receiving
 electromagnetic radiation from the output means reflected
 from the surrounding tissue, said reception means being
25 arranged in the vicinity of a corresponding output means
 on the distal part of the elongate body;
 wherein at least some of the output means and
 reception means are independently operable, in order to
 receive electromagnetic radiation reflected in
30 distinguishable part volumes of the surrounding tissue.
3. The electrode of claim 1 or 2, wherein the
destruction means comprises:
 at least three output areas for emitting a tissue
 destroying medium, such as a current, into the tissue,
35 said output areas being arranged at different
 circumferential positions on the distal part of the

elongate body;

conductors leading to the output areas through the elongate body from the proximal end, for supply of a tissue-destroying medium from an external source;

5 wherein the output areas are connected to separate conductors and independently operable, whereby the supply of the tissue-destroying medium to the surrounding tissue becomes directionally controllable.

4. The electrode of any one of the claims 1-3,
10 wherein the measuring means and the destruction means are operable simultaneously, whereby a feed-back control is obtainable.

5. A measuring probe for directional measuring of a volume of destroyed tissue, comprising:

15 an elongate body with a distal end adapted to be inserted into the tissue to be measured;

at least one output means for emitting an electromagnetic radiation into the tissue, said output means being arranged at the distal part of the elongate
20 body;

at least one reception means for receiving electromagnetic radiation from the output means reflected from the surrounding tissue, said reception means being arranged in the vicinity of a corresponding output means
25 on the distal part of the elongate body;

at least one additional output means or reception means, said additional output means or reception means being arranged at different circumferential positions on the distal part of the elongate body from said first
30 output means or reception means, and being independently operable from the same, in order to receive electromagnetic radiation reflected in distinguishable part volumes of the surrounding tissue.

6. The measuring probe of claim 5, wherein at
35 least four output means are provided at different circumferential positions on the distal part of the

elongate body, and preferably at least six, and most preferably eight.

7. The measuring probe of claim 5 or 6, wherein the output means provided at different circumferential positions on the distal part of the elongate body are arranged symmetrically and equidistantly.

8. The measuring probe of any one of the claims 5-7, wherein at least two output means are arranged at different axial positions on the distal part of the elongate body.

9. The measuring probe of claim 8, wherein the output means are arranged along at least two axially separated ring-like paths on the elongate body, each path comprising at least two circumferentially separated output means.

10. The measuring probe of any one of the claims 5-9, wherein the radiation output of the output means are radially restricted, each output means preferably exposing a radial section being essentially $360^\circ/n$, where n is the number of circumferentially separated output means along a common circumferential path.

11. The measuring probe of any one of the claims 5-10, wherein essentially all of the output means are independently operable.

12. The measuring probe of any one of the claims 5-11, wherein essentially all of the reception means are independently operable.

13. The measuring probe of any one of the claims 5-12, wherein the electromagnetic radiation emitted by the output means is within the wavelength range of light, and preferably visible light.

14. The measuring probe of any one of the claims 5-13, further comprising input waveguides leading to the output means through the elongate body from the proximal

end, for supply of the electromagnetic radiation from an external source, and return waveguides for returning reflected radiation to an external measuring unit.

15 15. An electrode for directional destruction of tissue, comprising:

an elongate body with a distal end adapted to be inserted into the tissue to be destroyed;

10 at least three output areas for emitting a tissue destroying medium, such as a current, into the tissue, said output areas being arranged at different circumferential positions on the distal part of the elongate body;

15 conductors leading to the output areas through the elongate body from a proximal end, for controlling the supply of a tissue-destroying medium;

wherein the output areas are connected to separate conductors and independently operable, whereby the supply of the tissue-destroying medium to the surrounding tissue becomes directionally controllable.

20 16. The electrode of claim 15, wherein at least four output areas are provided at different circumferential positions on the distal part of the elongate body, and preferably at least six, and most preferably eight.

25 17. The electrode of claim 15 or 16, wherein the output areas provided at different circumferential positions on the distal part of the elongate body are arranged symmetrically and equidistantly.

30 18. The electrode of any one of the claims 15-17, wherein at least two output areas are arranged at different axial positions on the distal part of the elongate body.

35 19. The electrode of claim 18, wherein the output areas are arranged along at least two axially separated ring-like paths on the elongate body, each path

comprising at least two circumferentially separated output areas.

20. The electrode of any one of the claims 15-19, wherein essentially all the output areas are
5 independently operable.

21. The electrode of any one of the claims 15-20, wherein the supplied medium is, or is transformed into, heat for controlled coagulation of the tissue.

22. The electrode of claim 21, wherein the supplied
10 medium is high-frequency current.

23. A system for measuring and destruction of tissue, comprising a control unit and an electrode according to any one of the claims 1-4 connectable to the control unit.

15 24. A system for measuring destruction of tissue, comprising a control unit and a measuring probe according to any one of the claims 5-14 connectable to the control unit.

20 25. A system for destruction of tissue, comprising a control unit and an electrode according to any one of the claims 15-22 connectable to the control unit.

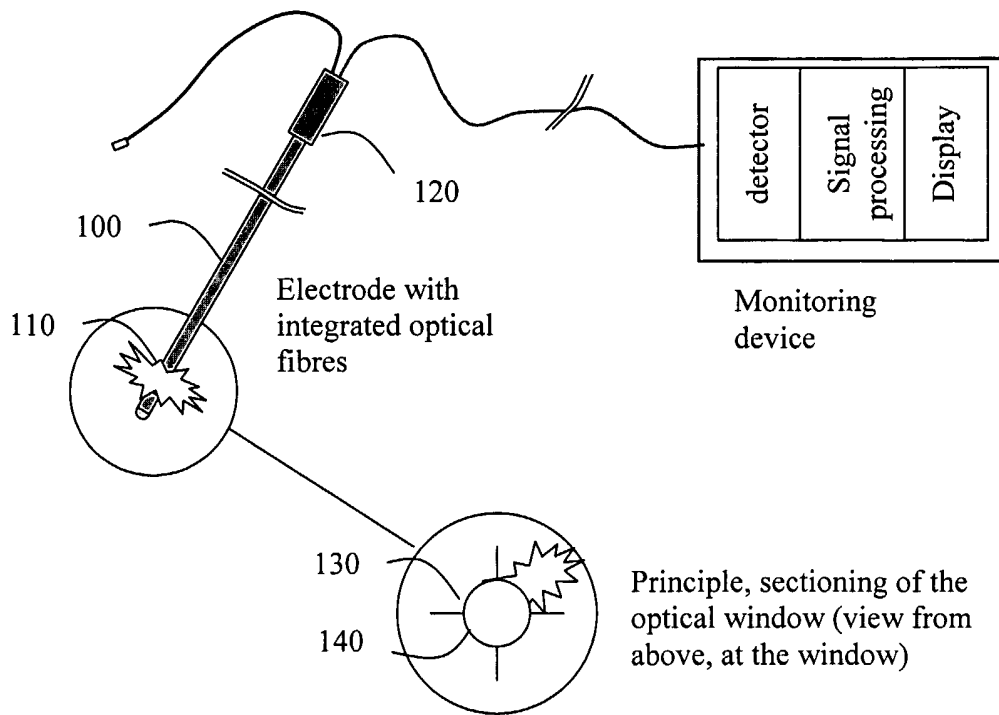


Fig 1

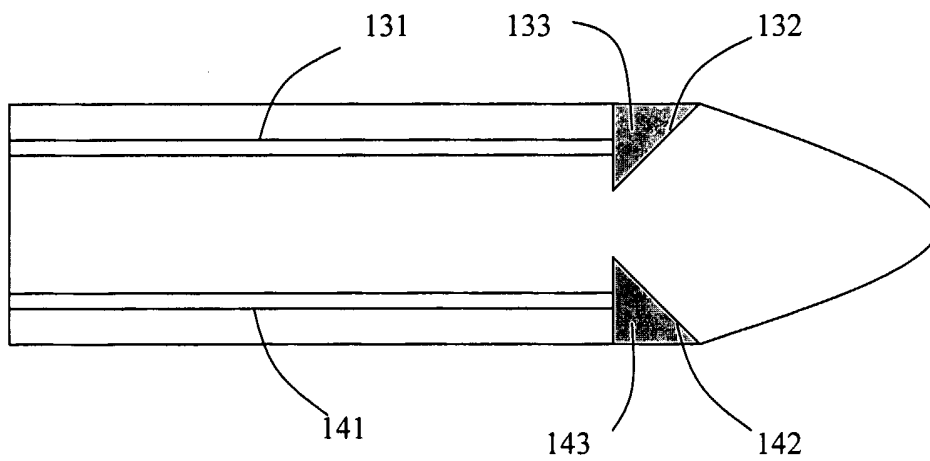


Fig 2

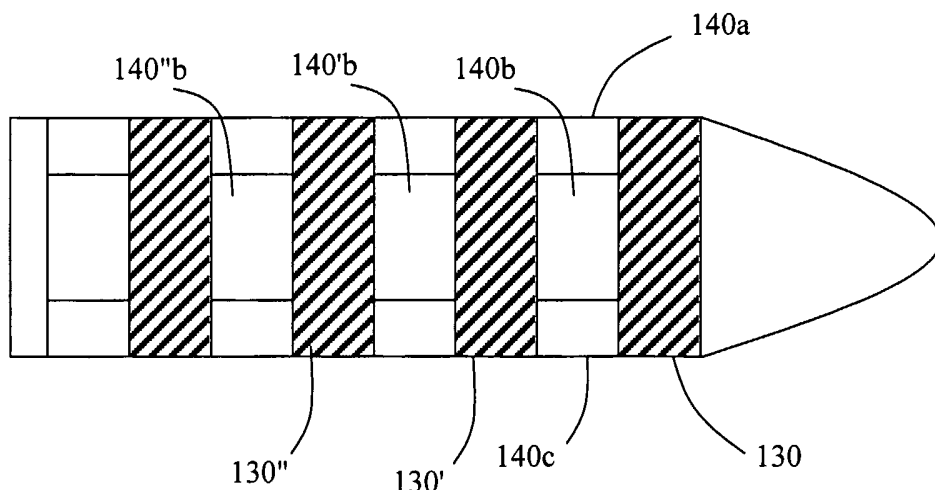


Fig 3

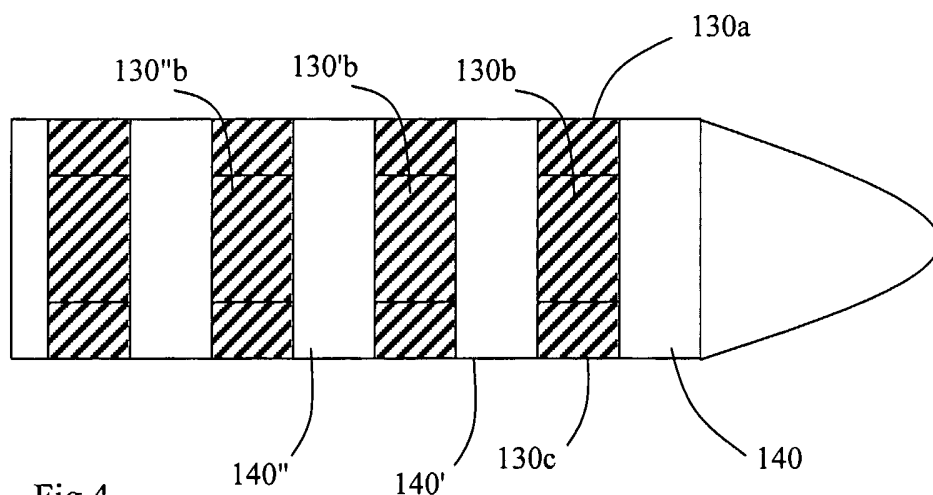


Fig 4

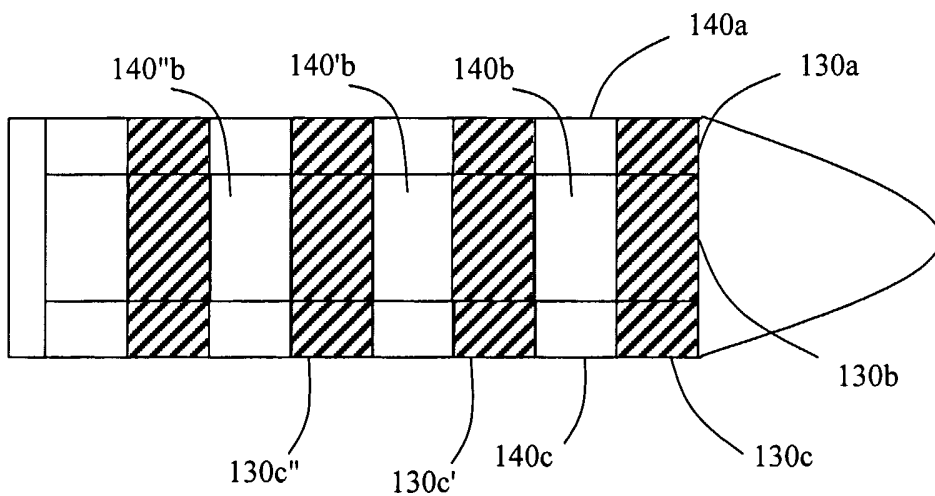


Fig 5

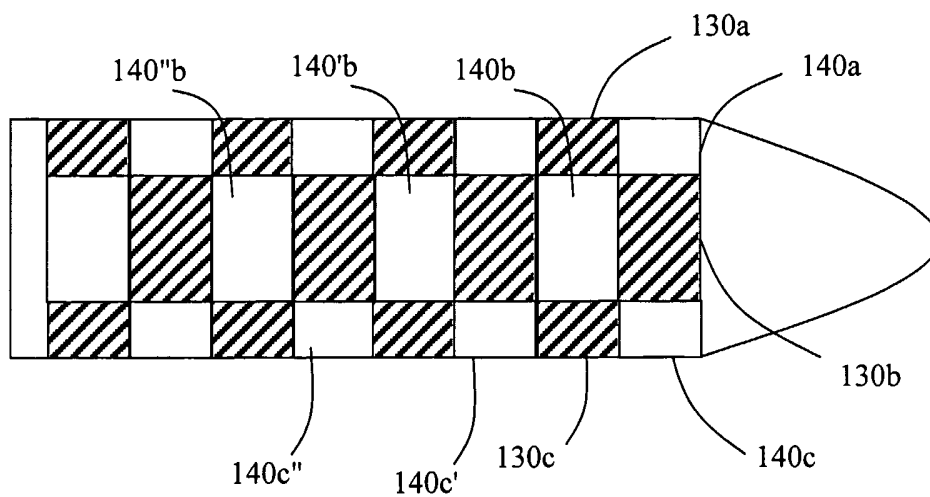


Fig 6

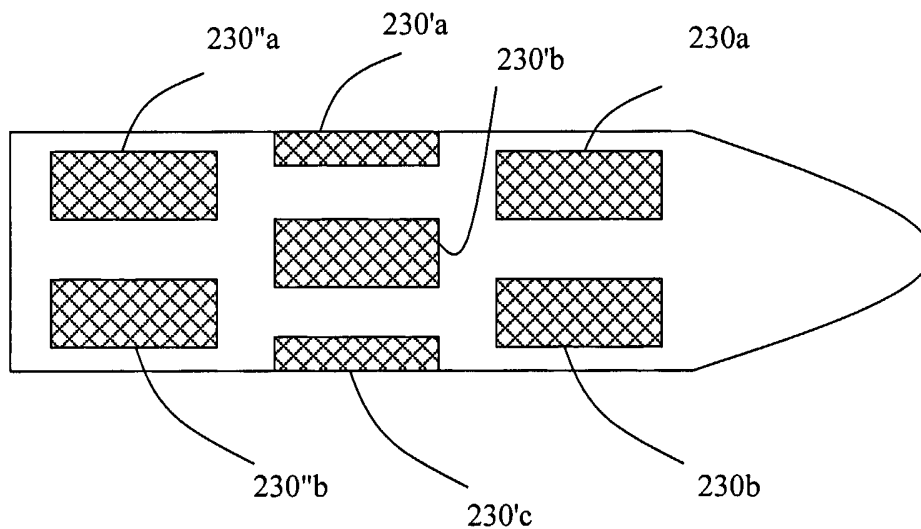


Fig 8

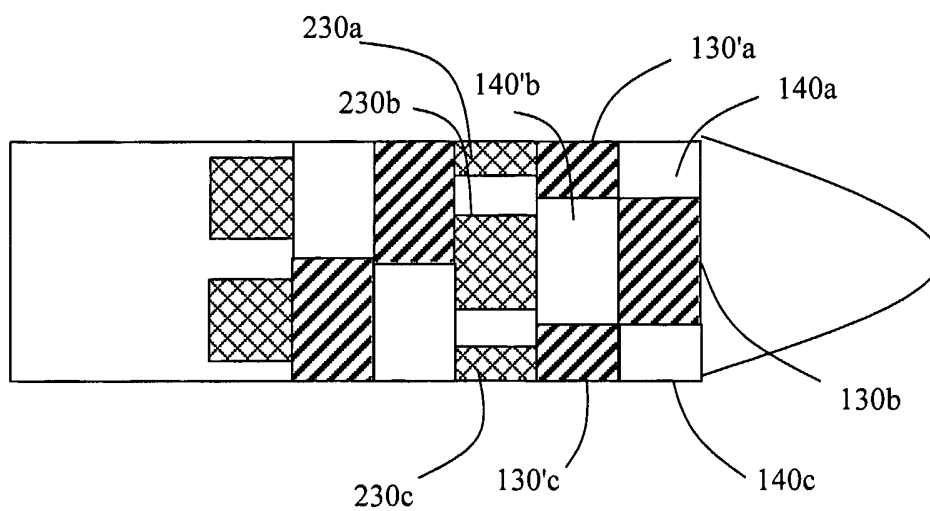


Fig 13

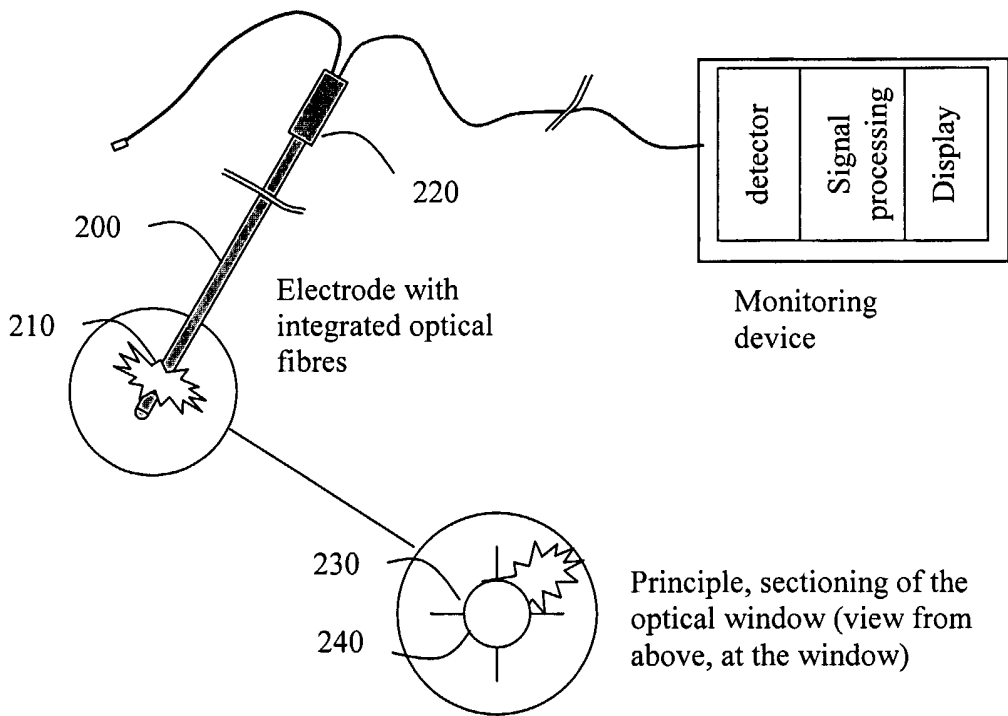


Fig 7

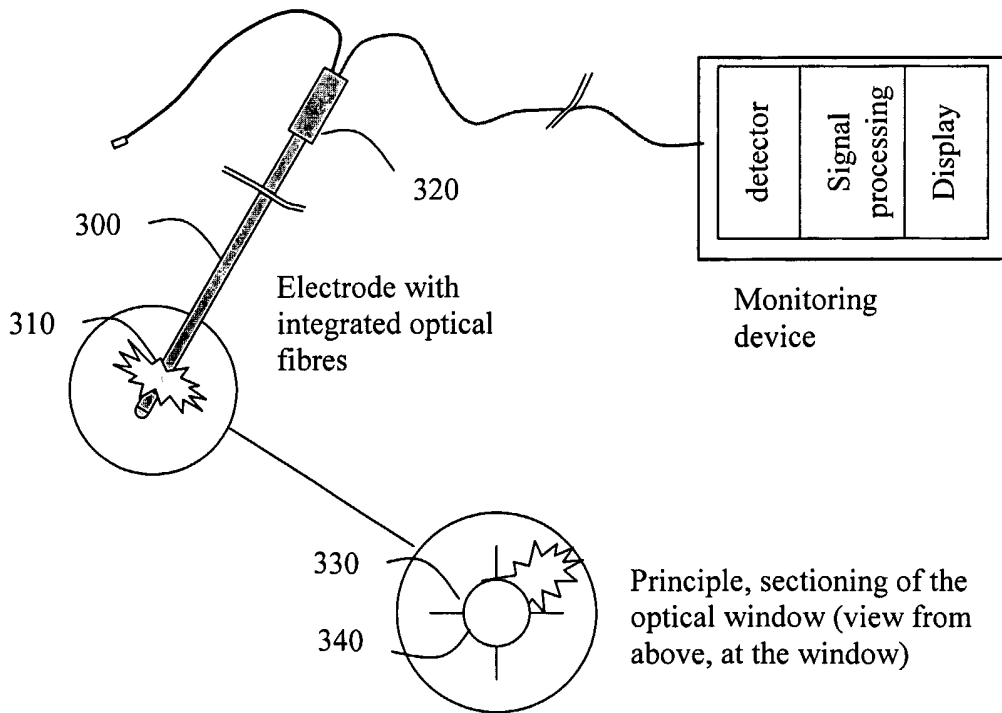


Fig 12

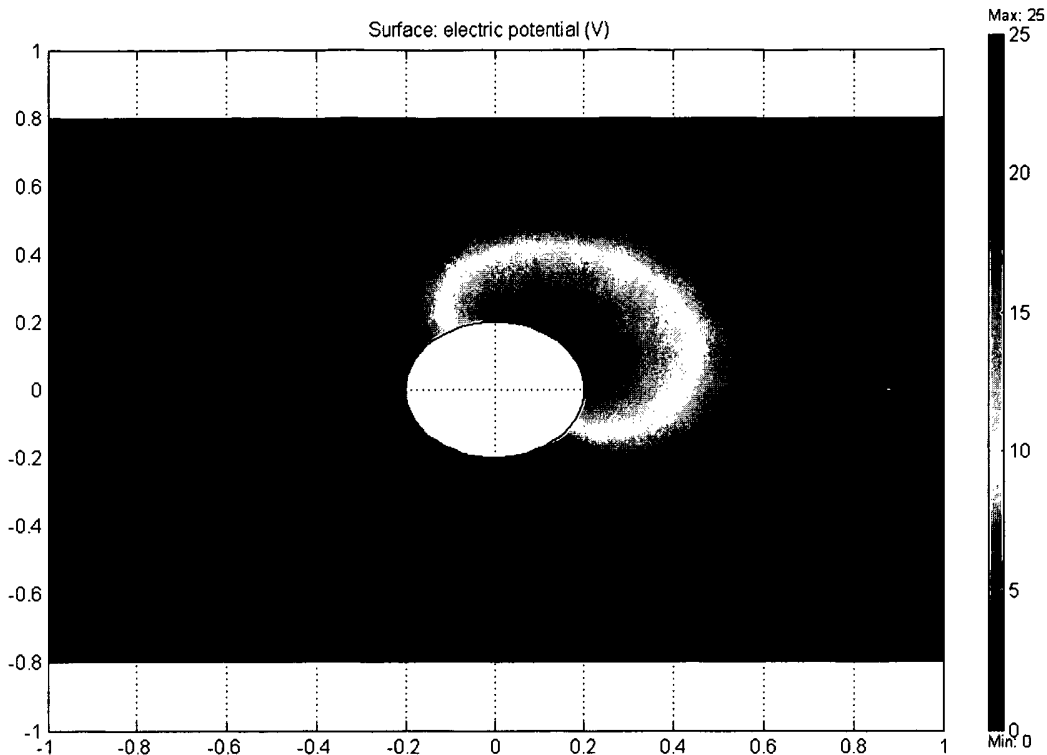


Fig 9

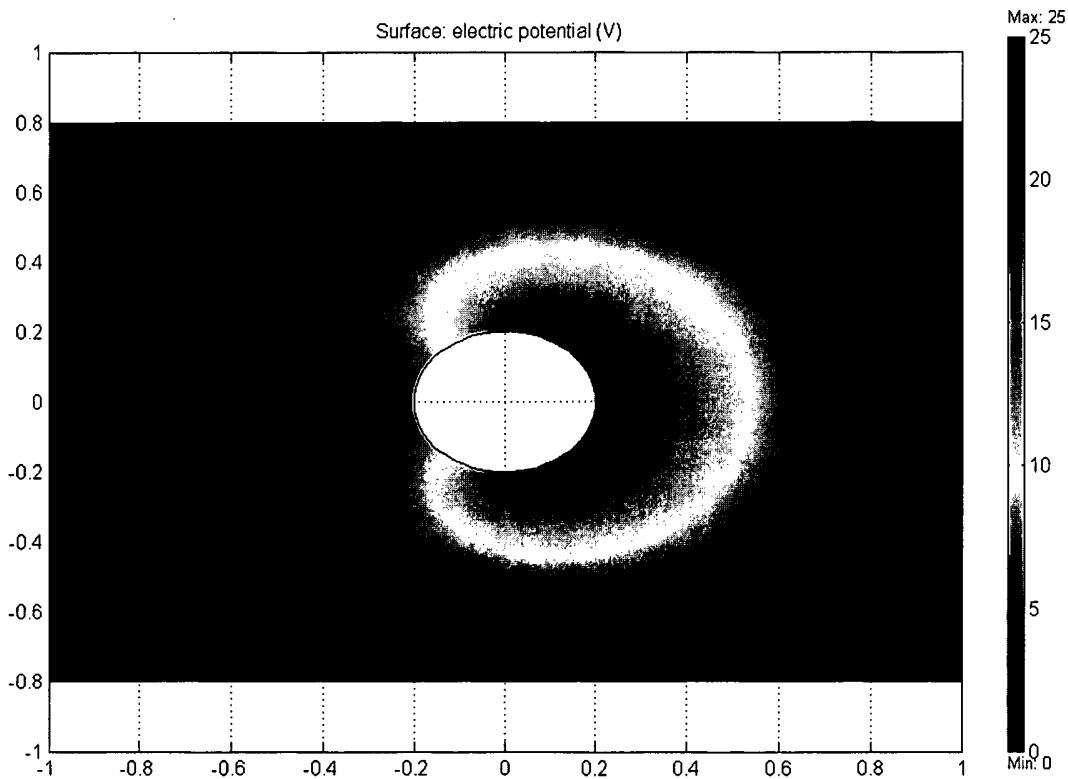
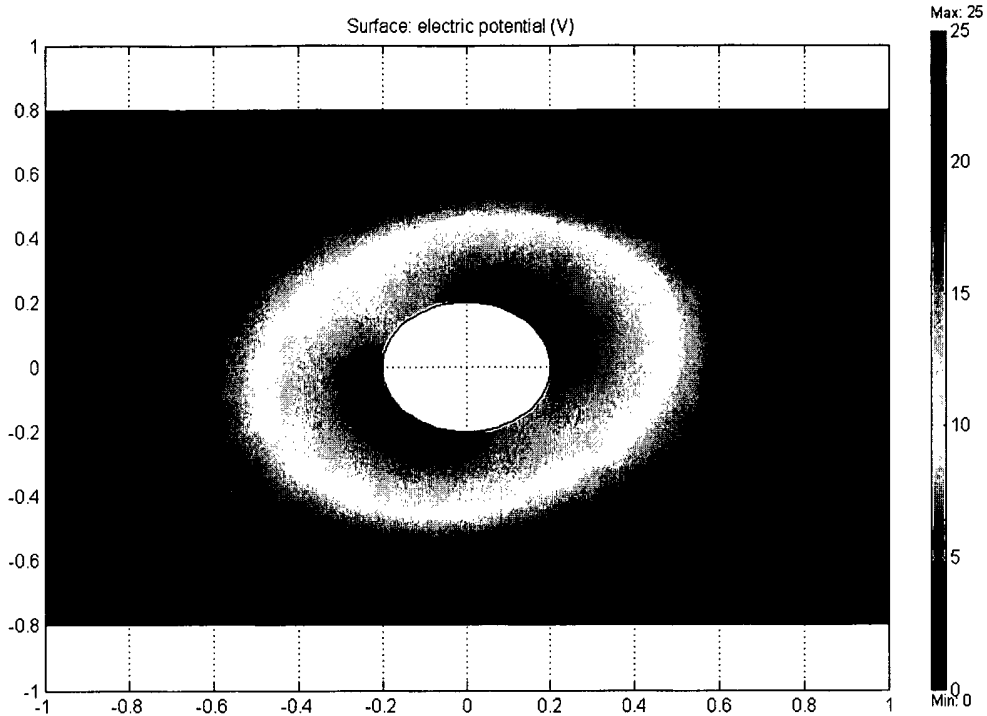


Fig 10



5 Fig 11

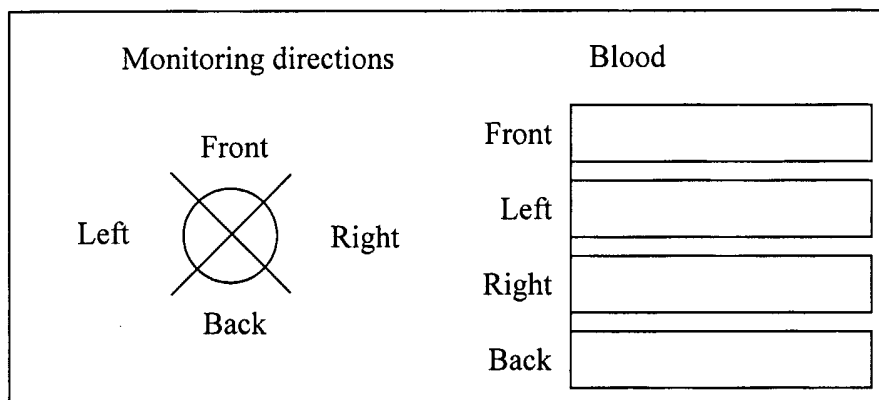


Fig 14

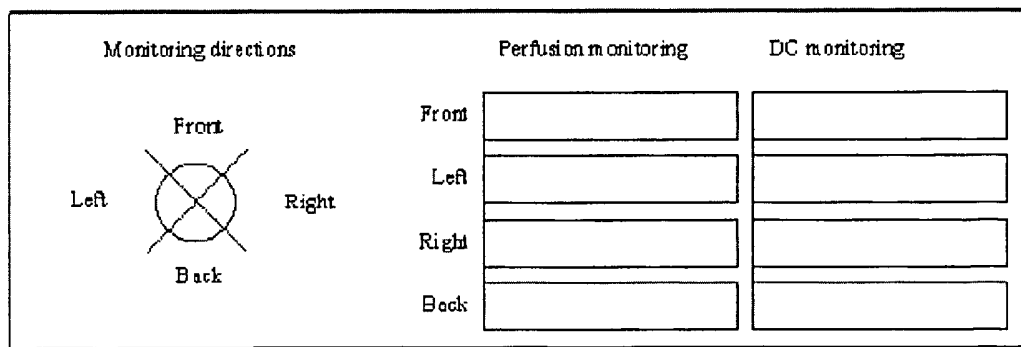


Fig 15

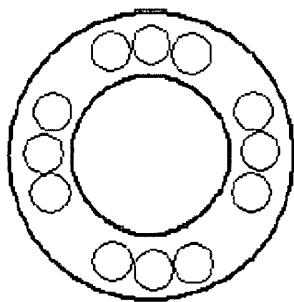


Fig 16

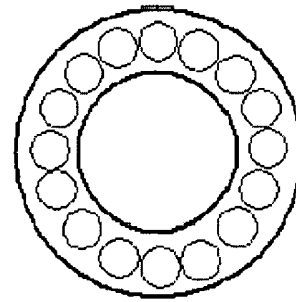


Fig 17

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 2004/001693

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 18/14, A61B 18/18

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)

IPC7: A61B, A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6511478 B1 (R.R.BURNSIDE ET AL), 28 January 2003 (28.01.2003), column 5, line 31 - line 64; column 13, line 42 - column 14, line 8; column 17, line 18 - line 36, col.19, li.4-li.29	1,3,4,15-23, 25
Y	--	2,6-12
X	US 20020026188 A1 (D.J.BALBIERZ ET AL), 28 February 2002 (28.02.2002), abstract, paragraphs 0047-0050,0055-0058, 0089	5,13,14,24
Y	--	2,6-12

 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 application or patent 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

23 February 2005

Date of mailing of the international search report

02-03-2005

Name and mailing address of the ISA/

Swedish Patent Office

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Authorized officer

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Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 2004/001693

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 20020151778 A1 (K.DOWLATSHAHI), 17 October 2002 (17.10.2002), paragraphs 0010-0018 -- -----	1-25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 2004/001693**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. Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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 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:

- I. An electrode for measuring and destroying of tissue.
- II. A measuring probe for directional measuring of a volume of destroyed tissue.
- III. An electrode for directional destruction of tissue.

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.

INTERNATIONAL SEARCH REPORT
Information on patent family members

30/01/2005

International application No.
PCT/SE 2004/001693

US	6511478	B1	28/01/2003	AU	8576901	A	08/01/2002
				CA	2413129	A	03/01/2002
				EP	1299044	A	09/04/2003
				JP	2004500957	T	15/01/2004
				US	20030120271	A	26/06/2003
				WO	0200129	A	03/01/2002

US	20020026188	A1	28/02/2002	AU	4975201	A	15/10/2001
				AU	5113401	A	15/10/2001
				CA	2404923	A	11/10/2001
				EP	1272117	A	08/01/2003
				JP	2003528684	T	30/09/2003
				NZ	522128	A	29/08/2003
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