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(54) **PEROPERATIVE SENSING HEAD ADAPTED TO BE COUPLED TO AN ABLATION TOOL**

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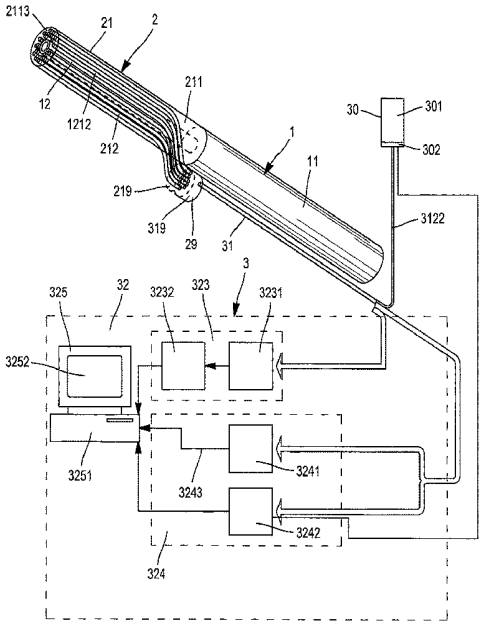
(57) **ABSTRACT**

A peroperative probe for guiding a manual excision tool. The probe includes a detection head, an optical fiber for the reception and guidance of a signal emitted by radioactive tracers and fluorescent molecules in a tissue area, a photo-detector for converting the emitted signal into an electrical signal, a transmitter for transmitting information carried by the electrical signal to an analysis equipment, and a fastener for attaching the probe onto the manual excision tool, so that the excision tool can be used to remove a portion of tissue from the tissue area emitting the signal.

11 Claims, 6 Drawing Sheets



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A61B 1/00	(2006.01)
A61B 17/22	(2006.01)
A61B 17/00	(2006.01)
A61B 17/32	(2006.01)

(52) **U.S. Cl.**

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See application file for complete search history.

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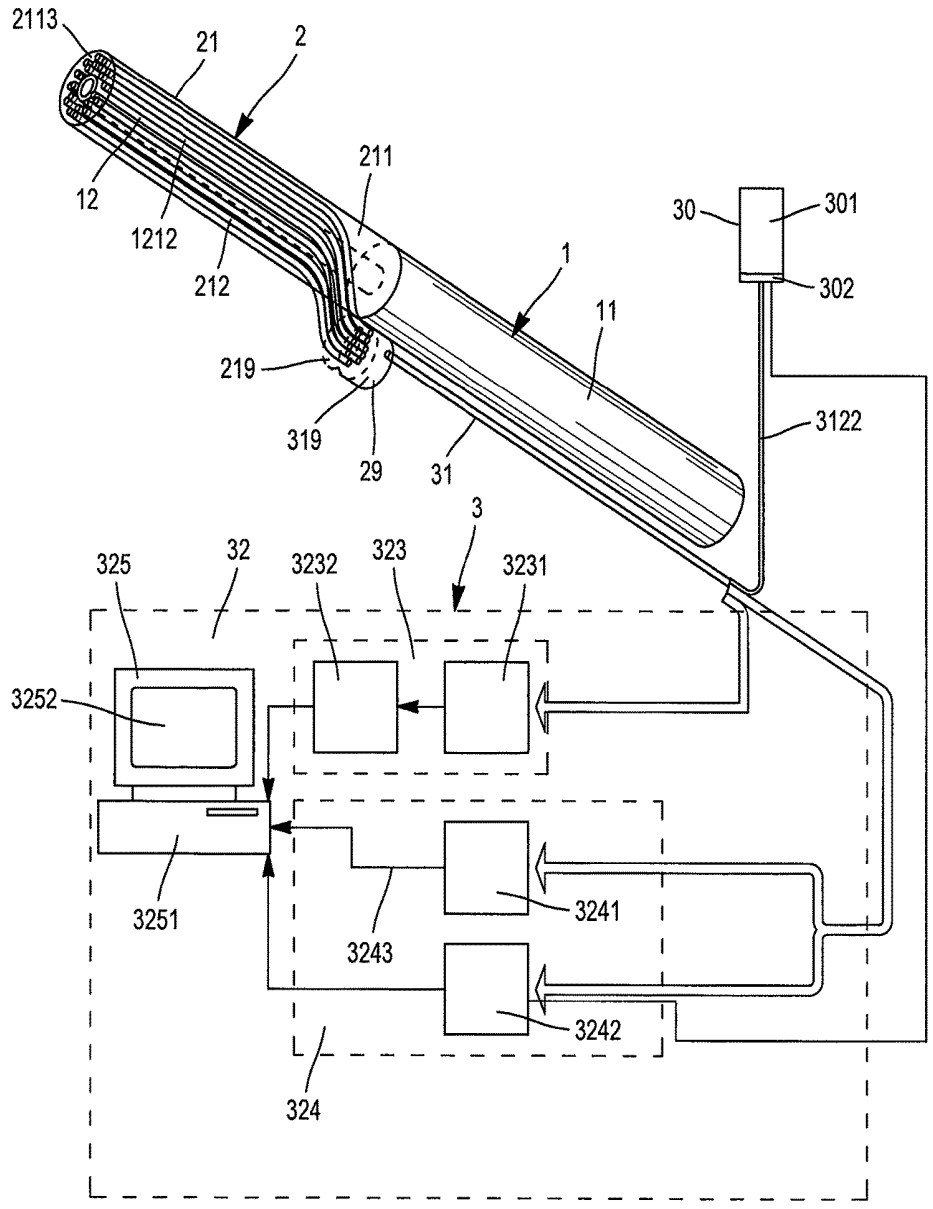
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FIG. 1

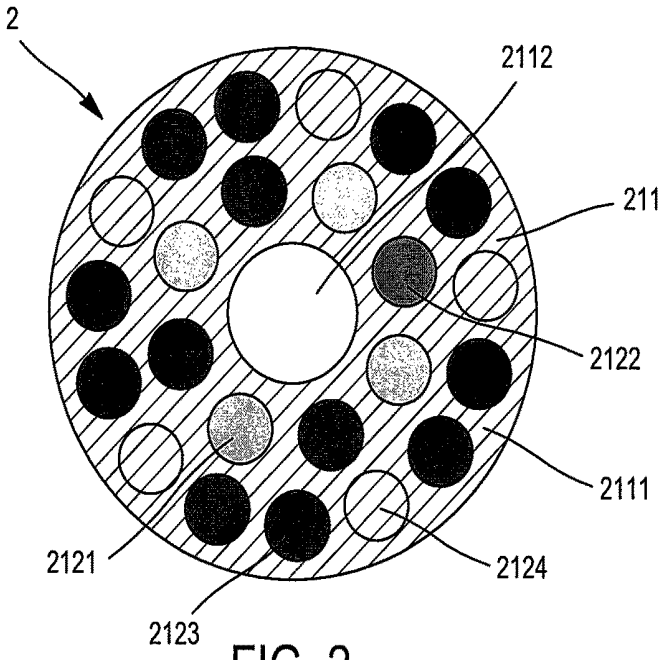

FIG. 2

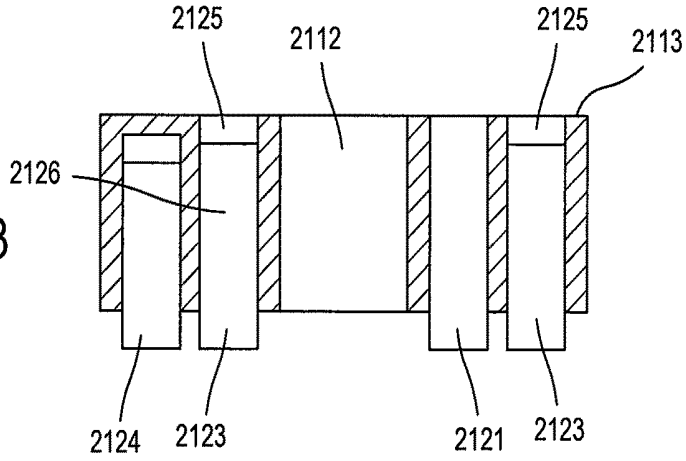

FIG. 3

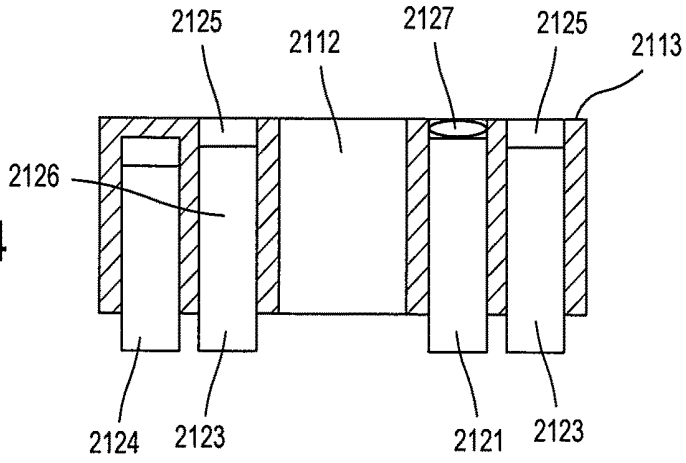

FIG. 4

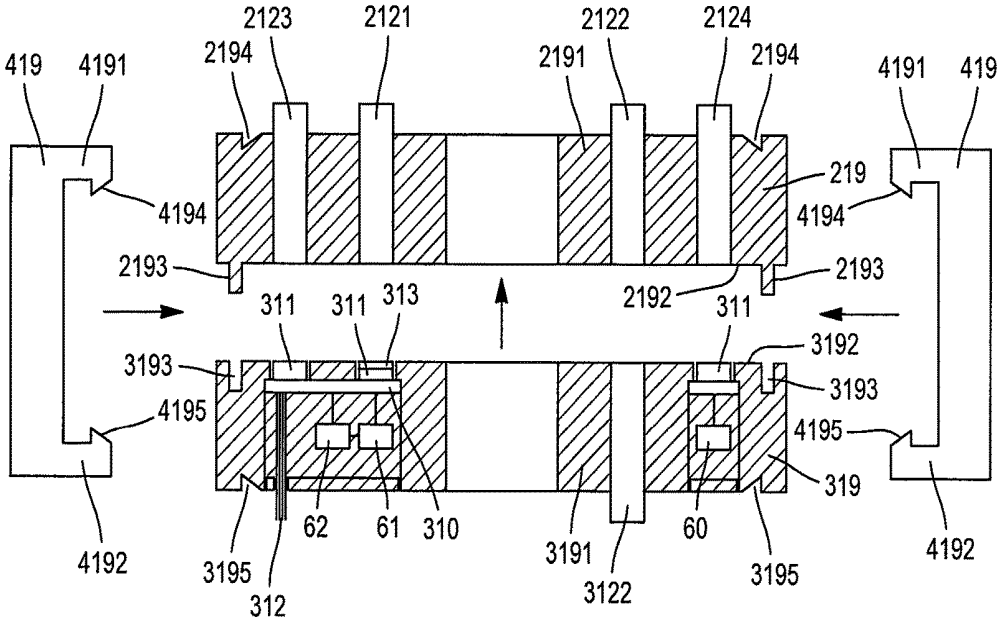
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FIG. 5A

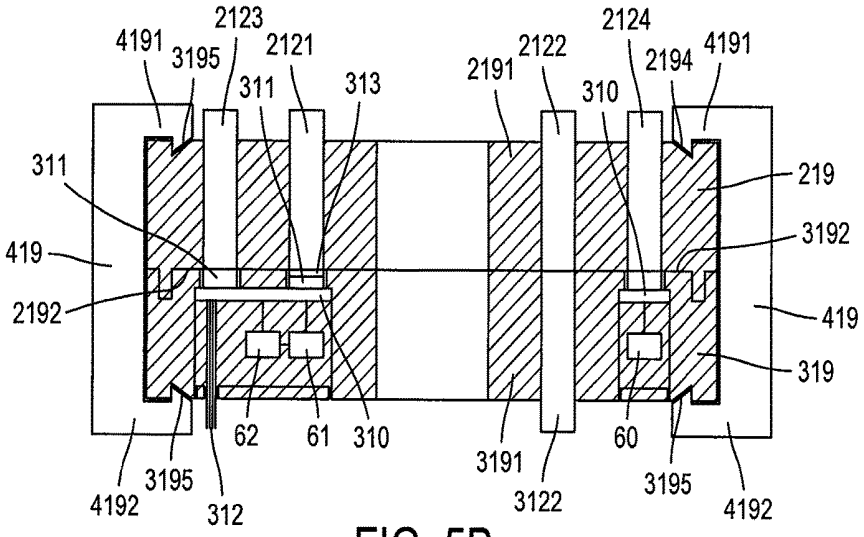
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FIG. 5B

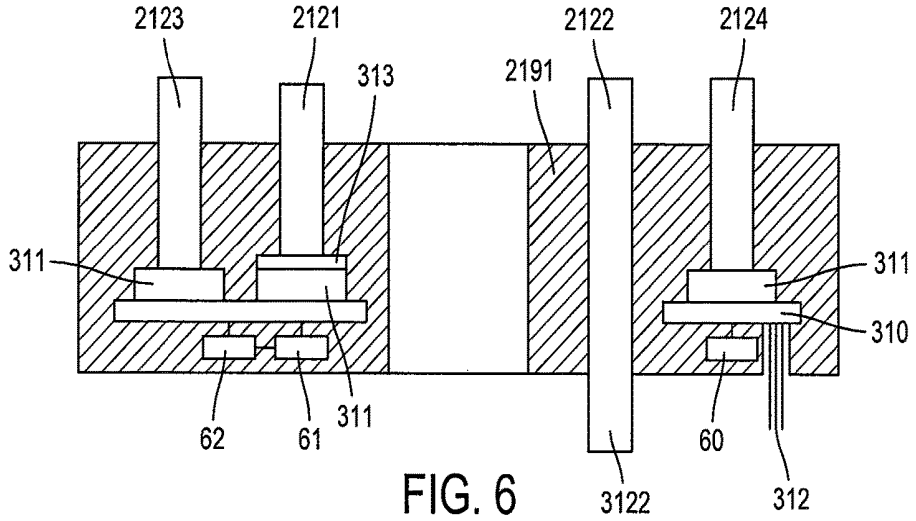

FIG. 6

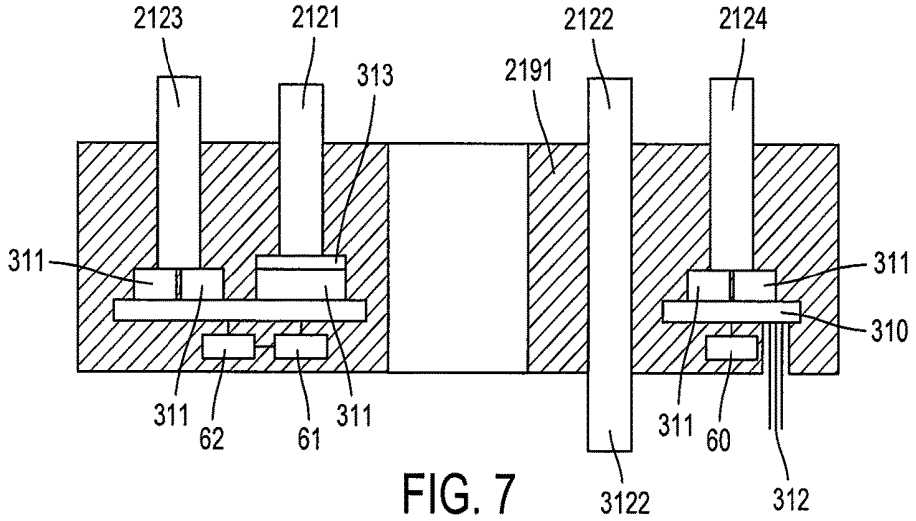

FIG. 7

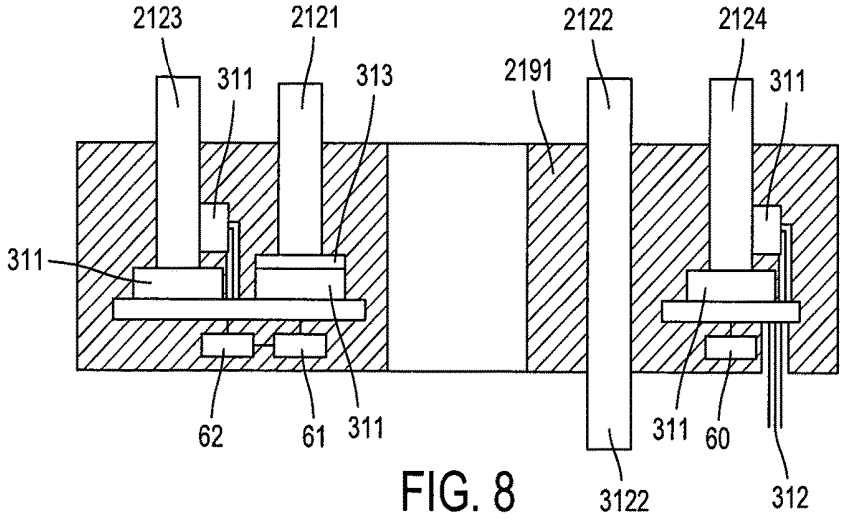

FIG. 8

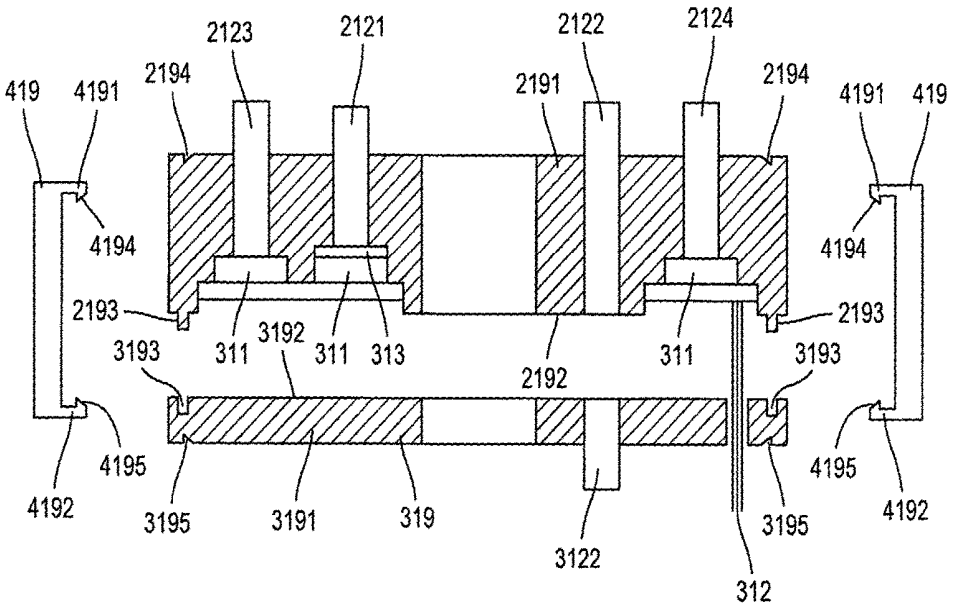
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FIG. 9

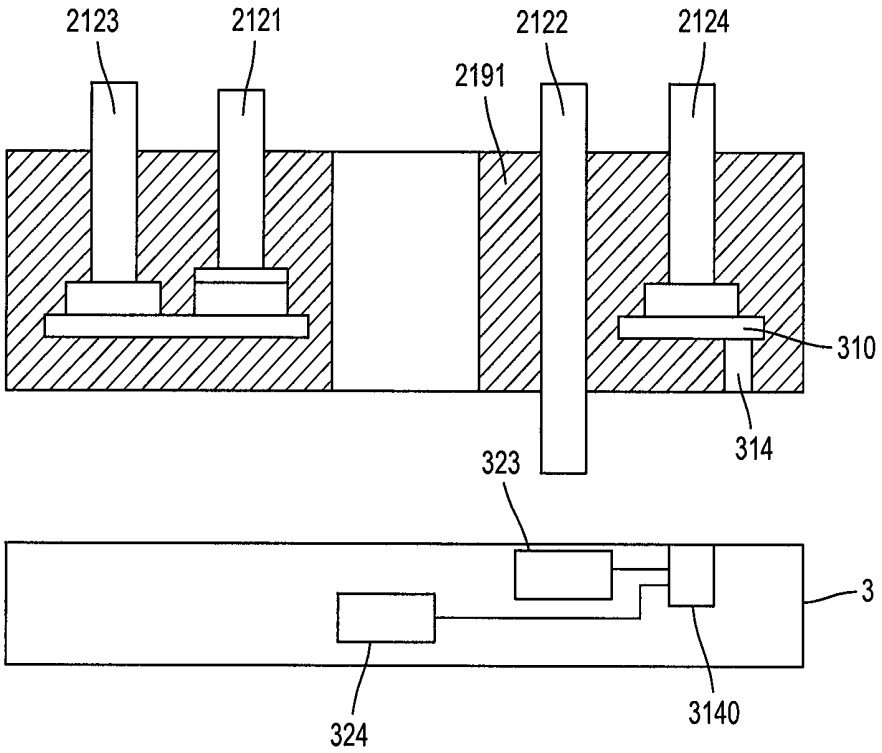

FIG. 10

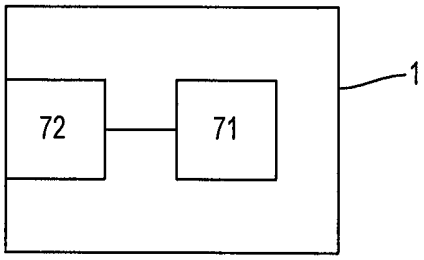

FIG. 11

PEROPERATIVE SENSING HEAD ADAPTED TO BE COUPLED TO AN ABLATION TOOL

FIELD OF THE INVENTION

The invention relates to assistance with the surgical treatment of biological tissue, in particular of cancerous tumours.

BACKGROUND OF THE INVENTION

Assistance with the surgical treatment of cancer is currently based on several techniques.

In a first type of technique called "pre-operative imaging techniques", before the operation the surgeon creates an image of the tissue area to be treated in order to locate, as well as possible, the tissue parts to be excised.

Pre-location of the tumour, by means of x-ray tomography or of IRM is used, for example, to obtain the precise anatomical topography of the tumorous volume and thus to choose the most appropriate surgical approaches. When coupled with mechanical stereotaxic or optical guidance, preoperative location leads to more narrowly defined and therefore less traumatising access paths, especially in the case of deep lesions.

In neurosurgery, this technique can be complemented by the use of a functional isothermal remanent magnetisation (IRM) imaging appliance, which is used, before the surgical procedure, to precisely identify the functional cerebral zoned located close to the tumour. On the basis this information, the surgeon is then able to optimise the extent of the zone to be excised while also minimising the risks of postoperative morbidity.

Preoperative imaging techniques have allowed the introduction of surgical procedures that are more precise and less invasive.

However, these techniques have limits in terms of performance and ergonomic design. In particular, these techniques are ill-suited to operations requiring location of small tumours and their metastatic disseminations if any.

In addition, the displacement of the tissue during the surgical procedure (in particular in the brain) often renders obsolete the location of lesions effected before the operation.

According to a second type of technique, the surgeon takes tissue samples during the operation, and these samples are analysed extemporaneously, so as to ensure the quality of the operating procedure of the surgeon.

These techniques, which rely upon precise anatomopathological diagnosis of the tissue samples have the advantage of being very reliable.

Such techniques are very costly however.

In addition, the time necessary to obtain a diagnosis from the samples may sometimes significantly increase the time of the surgical procedure.

Given the drawbacks associated with the preoperative imaging techniques and the tissue sampling techniques, a third type of technique called "preoperative techniques" has appeared. These techniques employ monitoring tools that are suitable of working in an operating suite, and thus of supplementing the outside imagers by helping the practitioner to determine the margins of a tumorous resection or a biopsy more precisely and in real time.

Two families of preoperative technique are currently under study. The first family of techniques, called "anatomical preoperative techniques", is based upon standard anatomical imaging systems, such as optical endoscopy systems, ultrasound echography, x-ray tomography or isothermal remanent magnetisation (IRM). The second family of techniques, called "functional preoperative techniques", are based upon the detection of signals emitted by the tissue by virtue of miniaturised systems. The signals are particles or radiation emitted by radioactive tracers or fluorescent molecules present in the tissue and specific to the tumorous lesions looked for.

According to the anatomical preoperative techniques, in order to guide his actions, the surgeon uses an anatomical imaging appliance identical in principle to those used in clinical diagnosis departments but whose characteristics, in terms of dimensions and ergonomy, have been adapted for use in operating suites.

As a complement to preoperative examination, low-field IRM and the x-ray tomography are used mainly in the operating suite in order to correct location errors associated with the displacement of the tissue during the procedure and to guide the biopsy procedures. The anatomical imaging systems are in fact used to repeat, in real time, the images created before the procedure and, as a consequence, to monitor the distortion of anatomical structures in real time. Evaluation of the preoperative IRM for surgery of the gliomas has thus shown that these techniques allow one to improve identification of the extent of the tumorous resection in relation to the procedures in which only stereotaxic guidance based on preoperative images was used.

Ultrasound echography is also used in the operating suite to assist with the surgical treatment of tumours. This technique has the advantage of being a lot less expensive and costly to put in place than low-field IRM or x-ray tomography. The principal field of application of preoperative ultrasound echography is the location of non-palpable breast tumours and tumours of the liver. More generally, this technique is particularly adapted for the precise location of deep lesions.

According to the functional preoperative techniques, the surgeon uses a miniaturised detection device that is suitable for detecting radioactive tracers or light radiation specific to the histology or the physiological or metabolic behaviour of the tumorous lesions looked for. Since the function of an organ is often disrupted before its structure, these techniques are therefore theoretically more sensitive and specific than anatomical preoperative techniques in order to distinguish the healthy tissue from the cancerous tissue.

It is thus possible to optimise identification of the extent of the tumorous resection beyond the margins identified by the preoperative examination and without having to wait for the results of extemporaneous examinations of tissue samples.

These techniques can also be used to improve the diagnosis precision of biopsies by guiding the surgeon to relevant regions of tissue to determine the histological nature of the tumour.

In general, miniaturisation of the detection devices used also leads to easier application of the functional preoperative technique in the operating suite, since it only slightly modifies the surgical protocol in relation to the more expensive and restrictive anatomical preoperative techniques.

Various counting or functional preoperative imaging devices have been developed. Some are even currently commercialised. However these devices are notable for several instrumental and methodological limits. Since there currently exists no system for functional preoperative imaging that allows the location and the simultaneous excision of the tumorous tissue. The current protocols combine two different tools which are used sequentially—the detection system (probe, microscope) and the excision tool (ultra-

sound aspiration device or electric lancet). This dissociation leads to correlation errors between the position of the tumour identified on the image and its actual position in the wound, and therefore reduces the precision of the excision procedure, in particular in the absence of anatomical location. The other limit of the functional preoperative devices relates their specific natures (associated with the tracers used) that is not total and therefore results in a non-negligible number of false negatives.

SUMMARY OF THE INVENTION

One aim of the invention is to allow the surgeon to perform an ablation with better precision and greater rapidity than with the devices of the prior art.

This problem is solved in the context of the present invention by using a preoperative probe to guide an excision tool in accordance with claim **1**.

The detection head is adapted to be coupled to an excision tool so that the surgeon can perform detection and tumorous ablation operations in a single procedure, and with a single instrument.

More precise location of the tumorous tissue is thus achieved, because the correlation errors between the position of the tumour obtained from the signal the probe and its actual position in the operative wound are eliminated.

The ability to simultaneously measure the concentration of radioactive tracers and fluorescent molecules also allows one to benefit from the complementarity of the information acquired by these two methods, and therefore to reinforce the specificity of tumour detection.

Advantageously, a probe according to the invention measuring a signal emitted by fluorescent molecules in a tissue area, in response to a light excitation signal, also measures a light signal obtained by reflection of the light excitation signal by the tissue. The specificity is still further increased.

By virtue of the detection head, which records the signals emitted by the tissue, the surgeon can observe the treated tissue area in real time.

Advantageously, it is possible to couple the probe to a neuronavigation system so as to allow the surgeon to view the position of the probe in relation to the tumour and to the various cerebral structures identified during the preoperative IRM.

In addition, the detection head can easily be replaced by a detection head with different characteristics, in order to adapt the probe to the specific constraints of the different surgical protocols, as well as to the different signals emitted by the tissue.

The probe is particularly suitable for the surgical excision of tumours of the central nervous system, including the brain and the spinal marrow. In fact, more than for any other cancer, the precision of the surgical treatment of this pathology determines the vital and functional prognosis of the patient.

The probe can exhibit the characteristics of claims **2** to **20**.

The invention also relates to a manual tool in accordance to claim **21**, comprising an excision tool and a preoperative probe according to claim **1** for guiding the excision tool.

Finally, the invention relates to a system according to claim **22**. This system can exhibit the characteristics of claim **23**.

BRIEF DESCRIPTION OF THE DRAWINGS

Other characteristics and advantages or the invention will emerge from the description that follows, which is purely illustrative and non-limiting and should be read with reference to the appended figures, in which:

FIG. **1** schematically represents a set for the surgical treatment of biological tissue according to one embodiment of the invention,

FIG. **2** schematically represents, in a front view, a detection head of a preoperative probe according to one embodiment of the invention,

FIG. **3** schematically represents, in a side view and in section, a detection head of a preoperative probe according to one embodiment of the invention,

FIG. **4** schematically represents, in a side view and in section, a detection head of a preoperative probe according to a variant of the embodiment of FIG. **3**,

FIGS. **5**A and **5**B schematically represent, in a side view and in section, connection components of a probe according to a first embodiment of the invention,

FIG. **6** schematically represents, in a side view and in section, connection components of a probe according to a second embodiment of the invention,

FIG. **7** schematically represents, in a side view and in section, connection components of a probe according to a third embodiment of the invention,

FIG. **8** schematically represents, in a side view and in section, connection components of a probe according to a fourth embodiment of the invention,

FIG. **9** schematically represents, in a side view and in section, connection components of a probe according to a fifth embodiment of the invention,

FIG. **10** schematically represents, in a side view and in section, connection components of a probe according to a sixth embodiment of the invention,

FIG. **11** schematically represents a probe according to a seventh embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

In FIG. **1**, the set for the surgical treatment of biological tissue represented includes an excision tool **1**, a preoperative probe **2**, and an analysis equipment **3**.

The excision tool **1** includes a gripping part **11** and an excision part **12**. The excision tool **1** is an ultrasound aspiration device for example, in particular used during the surgical treatment of gliomas in order to excise the tumorous tissue. In the case of an ultra-sound aspiration device, the excision part **12** includes a tube **1212** for the emission of ultrasound and for the aspiration of pulverised tissue.

The preoperative probe **2** includes a detection head **21** forming a part for clinical use. The detection head **21** takes the form of an end-section adapted to be fitted tightly onto the excision tool **1**.

The detection head **21** includes a body **211** of generally cylindrical shape, a bundle **212** of detection optical fibres extending inside the body **211**, a connection component **219** and a fastener.

The analysis equipment **3** includes a light source **30**, a reusable transmission element **31** and an analysis instrument **32**.

The light source **30** includes a laser or a lamp **301** and an excitation filter **302**. The laser or the lamp **301** is adapted to emit light in the form of a continuous ray or light pulses of controlled length. The filter **302** is adapted to filter the light generated by the laser or the lamp **301** and to transmit an excitation signal containing photons with wavelengths adapted to excite fluorescent molecules contained in the tissue to be treated. The fluorescent molecules then emit a

fluorescent light signal, whose wavelength is different from the wavelength of the excitation signal. The fluorescence is in fact electromagnetic radiation, usually in the form of visible or infrared light, coming from the emitting fluorescent molecules excited by a light excitation signal of shorter wavelength. The fluorescent radiation ceases suddenly when the excitation stops.

As illustrated in FIGS. **1** to **3**, the detection head **21** includes a body **211** and a bundle **212** of detection optical fibres lying inside the body **211**, in the longitudinal direction of the latter.

The body **211** is generally of tubular shape. The body **211** includes a cylindrical wall **2111** formed in metal, in stainless steel for example, or in any other material that is compatible with a surgical procedure, and a central channel **2112**. The wall **2111** encloses the bundle **212** of detection optical fibres. The optical fibres of the bundle **212** are distributed around the central channel **2112** and lie substantially parallel to the central channel **2112**.

The bundle **212** of optical fibres includes a plurality of fibres **2121** for detecting light radiation, one excitation fibre **2122**, a plurality of radioactive tracer detection fibres **2123**, and a plurality of control fibres **2124**.

The fibres **2121**, **2122** and **2123** lie between an end surface **2113** of the body **211** and the connection component **219**. More precisely, the ends of the fibres **2121**, **2122** and **2123** are flush with the surface **2113**.

The fibres **2121** for detecting light radiation are composed of clear fibres. These fibres **2121** are adapted to receive and guide a light signal emitted by biological tissue.

The excitation fibre **2122** is also composed of a clear fibre. This fibre **2122** is adapted to guide a light excitation signal generated by the source **30** in the direction of the biological tissue, so as to excite fluorescent molecules contained in this tissue.

The radioactive tracers detection fibres **2123** include a scintillating end portion **2125** and a main clear portion **2126**, with the scintillating end portion **2125** being fused to the main clear portion **2126**, by heating for example. The scintillating end portion **2125** is adapted to interact with radioactive β particles (β^+ particles or β^- particles) emitted by the tissue previously marked by radioactive tracers and to convert them into a light signal. The main portion **2126** is adapted to guide the light signal emitted by the end portion **2125**.

The scintillating portion **2125** typically has a length of about 1 mm and the clear portion **2126** typically has a length of about 10 cm. The scintillating **2125** and clear **2126** portions typically have a diameter of the order of 1.5 mm.

The control fibres **2124** are identical to the radioactive tracer detection fibres **2123**, except that the control fibres **2124** are rendered blind to the β particles. More precisely, the control fibres **2124** lie below the end surface **2113** of the body **211**, so that the end of the control fibres **2124** is obstructed by a metal layer with a thickness of about 400 μm.

The radioactive tracers detection fibres **2123** and the control fibres **2124** are sensitive to γ radiation of 511 electron volts (eV) emitted by the tissue after the annihilation of β^+ particles. This γ radiation represents background noise in the detection of β^+ particles. The control fibres **2124** allow one to quantify the γ radiation with a view to subtracting it from the signals measured by the fibres **2123** and to thus to obtain a signal due to the β^+ particles only.

To allow more precise quantification of the γ radiation, the plastic scintillator may be replaced by an inorganic scintillator such as Lutetium Oxyorthosilicate doped with cerium (LSO) for example, which has a higher density and therefore a better detection efficiency for the γ radiation.

The wall **2111** in which the optical fibres **2121**, **2122**, **2123** and **2124** of the detection bundle **212** are buried constitutes a screen for the fibres. This screen isolates the fibres from the ambient light and any parasitic β particles that could arrive at the scintillating portions **2125** from the sides or via the rear of the fibres **2123**.

FIG. **4** illustrates a variant of the detection head **21**. In this variant, the fibres **2121** and **2122** of the detection head does not extend to the end surface **2113** of the body **211**. More precisely, the fibres **2121** and **2122** lie below the surface **2113**. The detection head **21** includes an optical element **2127** associated with each fibre **2121** and **2122**, which focuses the light coming from the tissue to the fibres **2121** and which focuses the light coming from the fibre **2122** to the tissue. Each optical element **2127** includes a microlens for example. Focusing of the incident light allows to increase the local light concentration and, as a consequence, the sensitivity of the treatment set. In addition, the collection of the light coming from the tissue with the aid of a microlens improves the spatial resolution of the treatment set.

The preoperative probe **2** further includes a fastener for attaching the probe onto the manual excision tool.

The preoperative probe **2** further includes a photo-detection unit **29** and a transmitter **31**.

The photo-detection unit **29** comprises a plurality of photo-detectors **311** and comprises a battery **60** for supplying a power signal to each photo-detector **311**. The battery may be located in the detection head. Alternatively the detection head is connected to an external power source which comprises the battery. Alternatively the battery is not comprised in the detection head.

Each photo-detector **311** is coupled with at least one fibre **2121** or **2123** or **2124** of the bundle **212**.

Each photo-detector **311** is adapted to convert a light signal that it receives into an electrical signal representing a single pixel. Therefore, the photo-detection unit **29** produces as many pixels as many photo-detectors **311** comprised in the photo-detection unit **29**.

Each photo-detector **311** may be a silicon photo-multiplier (SiPM), which is a very compact detector.

The transmitter **31** is adapted to receive electrical signals produced by the photo-detection unit **29** and transmit information carried by electrical signals to the analysis instrument.

FIGS. **5**A and **5**B schematically represent a first embodiment for the probe **2**.

In this embodiment, the preoperative probe **2** includes a detachable part which can be connected to the detection head.

The detachable part includes a connection component **319**, the photo-detection unit **29** and the transmitter **31**.

Connection components **219** and **319** are intended to allow connection between the detection optical fibre bundle **212** of the detection head **21** and the photo-detection unit **29** of the detachable part.

In FIG. **5**A, the connection components **219** and **319** are detached from each other.

Connection component **219** includes a body **2191** in which detection fibres **2121**, **2122**, **2123** and **2124** are buried. The body **2191** includes a plane connection surface **2192**. The ends of the fibres **2121**, **2122**, **2123** and **2124** are flush with the connection surface **2192**.

Likewise, connection component **319** includes a body **3191** in which at least one transmission fibre **3122** is buried.

The body **3191** includes a plane connection surface **3192**. The photo-detectors **311** are flush with the connection surface **3192**. Besides, the end of each transmission fibre **3122** is flush with the plane connection surface **3192**.

Body **2191** includes connection studs **2193** projecting from the connection surface **2192**. Body **3191** includes connection orifices **3193** extending back from the connection surface **3192**. The studs **2193** are adapted to be inserted into the orifices **3193** in order to orientate the connection components **219** and **319**. In addition, the studs **2193** and the orifices **3193** are arranged so that when the studs **2193** are inserted into the orifices **3193**, connection surface **2192** comes into contact with connection surface **3192**, and the end of fibre **2121** comes into contact with the end of fibre **3122**, in order to connect the fibres together. The ends of each fibre **2121**, **2122** and **2124** also come into contact with the top surface of each photo-detector **311**.

The probe can also include locking components **419** intended to hold the connection components **219** and **319** in engagement. Each locking components is U-shaped and includes two branches **4191** and **4192**. At each free end, each branch **4191** and **4192** respectively has a projection **4194** and **4195**.

Each of the connection components **219** and **319** respectively includes notches **2194** and **3195**.

The locking components **419** are adapted to hug together the connection components **219** and **319** when they are in mutual engagement. To this end, the components **219** and **319** are inserted between the branches **4191** and **4192** of the locking components **419**. The presence of the projections **4194** and **4195** causes the separation of the branches **4191** and **4192** by elastic deformation. The projections **4194** and **4195** are then adapted to be inserted into the notches **2194** and **3195** by elastic return of the branches **4191** and **4192**.

Each photo-detector **311** of the photo-detection unit **29** is coupled to a single fibre **2121** or **2123** or **2124**. As an example, FIG. **5**A shows a first photo-detector coupled with a fibre **2123**, a second photo-detector coupled with a fibre **2121**, and a third photo-detector coupled with a fibre **2124**.

In this embodiment, the transmitter **31** comprises an integrated circuit **310** and a transmission cable **312**.

The integrated circuit **310** is buried in component **319** between the transmission cable **312** **31** and the photo-detection unit **29**. Although not entirely visible on FIGS. **5**A and **5**B, the integrated circuit **310** is connected to each photo-detector of the photo-detection unit **29**.

The integrated circuit **310** is adapted to receive the electrical signal delivered by each photo-detector of the photo-detection unit **29**. Each received electrical signal is routed by the circuit on a respective conducting wire of the transmission cable **312**. Thus, the transmission cable **312** can carry a plurality of electrical signals representing a plurality of pixels.

The integrated circuit **310** can further comprise (or be coupled to): at least one temperature sensor **61** (for example one temperature sensor per photo-detector) and a power management circuit **62**.

Each temperature sensor **61** is adapted for sensing a temperature of at least one of the photo-detectors **311**.

The power management circuit **62** is connected to the battery **60** and to each temperature sensor **61**. The power management circuit **62** is adapted to adjust the power signal supplied by the battery **60** to a given photo-detector **311**, based on the temperature sensed by the temperature sensor **61** associated with the given photo-detector **311**. For instance, a voltage supplied by the battery **60** to the photo-detectors **311** can be adjusted so as to stabilize the behaviour of the photo-detectors over time.

The transmission cable **312** includes multiple electrical conducting wires. The transmission cable **312** is connected to the analysis instrument **32**. The transmission cable **312** typically has a length of 2 meters, to route the electrical signals coming from the detection head **21** to the analysis equipment **32** located outside the operative field.

In FIG. **5**B, the connection components **219** and **319** are brought into mutual engagement and the locking components **419** hold the connection components **219** and **319** in mutual engagement. Under this configuration of the probe the end of fibre **2123** is in contact with the first photo-detector, the end of fibre **2121** is in contact with the second photo-detector, and the end of fibre **2124** is in contact with the third photo-detector.

As can be seen in FIG. **1**, the single-use detection head **21** is adapted to be attached in a detachable manner to the excision tool **1**. To this end, the excision part **12** of the tool **1** is adapted to be inserted into the detection head **21**. More precisely, the aspiration tool **1212** of the excision tool **1** is adapted to be inserted into the channel **2112** of the detection head **21** so that the aspirating end of the aspiration tool **1212** is flush with the end surface **2113** of the detection head **21**.

Secondly, the connection components **219** and **319** are adapted to be brought into mutual engagement in order to couple the bundle **212** of detection optical fibres optically to the photo-detection unit **29**. The connection components **219** and **319** are detachable connection components. This allows easy manual connection and disconnection.

The single-use detection head **21** can therefore be replaced easily by another head.

When the connection components **219** and **319** are brought into engagement, the excitation fibre **2122** of the detection head is connected to the transmission fibre **3122** of the transmission cable **312**.

The transmission fibre **3122** is connected firstly to the source **30** and secondly to the excitation fibre **2122** so as to guide the excitation radiation, emitted by the source **30**, to the tissue to be treated.

The analysis equipment **32** includes a first acquisition unit **323**, a second acquisition unit **324** and a PC **325**.

The wires of the transmission cable **312** carrying information from the detectors coupled to fibres **2123** and fibres **2124** are connected to the first acquisition unit **323**.

The first acquisition unit **323** includes pre-amplification electronics **3232** and amplification electronics **3233**.

The pre-amplification electronics **3232** and the amplification electronics **3233** are adapted to integrate and then to amplify the electrical signals carried by the transmission cable **312**. The unit **323** then transmits the analogue signals to the PC **325** for their digitisation and their treatment.

The wires of the transmission cable **312** carrying information from the detectors coupled to fibres **2121** are connected to the second acquisition unit **324**.

The second acquisition unit **324** includes a first conversion electronics unit **3241** and a photon counting electronics unit **3242**.

The first conversion electronics unit **3241** is adapted to integrate, amplify and convert the analogue electric signals received from the transmission cable **312** **31** in digital signals, in order to allow direct transfer to the PC **325** via a USB cable **3243**.

The photon counting electronics unit **3242** is suited to count and measuring the time of passage of fluorescence photons based on the electrical pulses carried by the trans-

mission cable **312**. The time of passage is measured with respect to the excitation time of tissue by source **30**.

The photo counting unit **3242**, is connected to the PC **325**, for instance via a USB cable, in order to allow direct transfer of the data counted and measured by the photon counting unit to the PC **325**.

The PC **325** includes a digitising and calculating unit **3251** and a display screen **3252**. The digitising and calculating unit **3251** is adapted to receive and to process the signals generated by units **323** and **324**. The digitising and calculating unit **3251** is also adapted to control the display screen **3252**.

The use and the operation of the surgical treatment set that has just been presented will now are described.

Before an operation, the surgeon chooses a detection head **21** that is suitable for the operative wound and for the type of tumour to be treated.

The surgeon attaches the detection head **21** to the excision tool **1** by inserting the aspiration tool **1212** into the channel **2112** of the detection head **21**.

Then the surgeon connects the fibre bundles **212**, **312** together by means of the connection components **219** and **319**.

During the operation, the surgeon performs the excision of a visible part of the tumour.

Next, the surgeon inserts the end of the probe **2** into the operative wound. More precisely, the surgeon positions the probe **2** so that the end surface **2113** of the detection head **21** is positioned facing a tissue zone to be treated. The surgeon moves over the operative wound by means of the detection head **21** and positions the detection head **21** in a plurality of successive positions. For each position of the head **21**, the surgeon creates a mapping of the signals emitted from the tissue zone facing the end surface **2113**. For each position of the detection head **21**, the acquisition time of the mapping does not exceed a few seconds.

The preoperative probe allows firstly to detect particle-emitting radioactive tumorous tracers.

When a β particle emitted by the tissue area is received by one of the fibres **2123**, the scintillating portion **2125** of the fibre **2123** generates a light signal (a pulse) that is guided by the clear portion **2126** of the detection fibre **2123**.

The light signal is guided to a corresponding photo-detector. The photo-detector generates an electrical signal (electrical pulse), whose amplitude is proportional to the intensity of the light signal and represents a pixel.

The electrical signal is transmitted via the integrated circuit **310** to a corresponding wire of the transmission cable **312 31**, which transmits the electrical signal to the acquisition unit **323**.

The acquisition unit **323** supplies the number associated with the fibre **2123** affected by the β particle or a gamma radiation, and the energy deposited in the scintillating portion **2125**. The acquisition unit **323** amplifies and digitises the electrical signals generated by the photo-detectors **311** coupled to the fibres **2123**, and transmits the amplified signals to the digitising and calculating unit **3251**.

In addition, the control fibres **2124** are sensitive only to the γ radiation generated by the tissue.

A given control fibre **2124** guides a second light signal to another photo-detector. This photo-detector generates a second electrical signal (electrical pulse) that is proportional to the intensity of the second light signal and represents another pixel.

The second electrical signal is also transmitted by a dedicated wire of the transmission cable **312 31** to the acquisition unit **323**.

The γ radiation resulting from annihilation of the β+ particles in the tissue, represents background noise for the process of locating tumorous lesions in the operative wound. These signals can in fact come from regions, specific or non specific to attachment of the β^+ tracer, that are very distant from the tissue zone analysed by the probe.

In order to distinguish the γ signals from the β^+ signals, the surgical treatment set has the following characteristics.

According to a first characteristic, the scintillating portions **2125** of the fibres **2123** are formed from a plastic material, which are not very sensitive to the high-energy γ radiation. In fact the plastic material has a low density (typically 1.05 g/cm3 and is composed of elements with a low atomic number (6 at most for Carbon). The simulated γ efficiency of a scintillating plastic fibre, 2 mm in diameter and 1 mm in length, located to 0.1 mm from a one-off source of ^{18}F, is thus about 300 impacts per second per microCurie (cps/μCi) against a β^+ efficiency of $1.7.10^4$ cps/μCi in the same configuration.

In the case of treatment of a cerebral tumour, this radiation can come from the whole of the brain however. The contribution of the γ background noise to the β+ signal can therefore become very high, despite the intrinsic low sensitivity of the plastic material constituting the scintillating portion.

According to a second characteristic, the digitising and calculating unit **3251** is adapted to select the signals that it receives according to the energy of the particle that has interacted with the scintillating portion. The theoretical study of the energy spectrum of the γ radiation that has interacted with the scintillating portion in fact shows that 40% of the γ detected radiation generates an energy of between 0 and 1000 keV, while the energy distribution of the β+ articles is between 0 and 500 keV.

The digitising and calculating unit **3251** is therefore adapted to select only the signals whose energy is greater than a threshold of between 50 and 100 kiloelectronvolt (keV).

According to a third characteristic, each radioactive tracer detection fibre **2123** is associated with a control fibre **2124**. The control fibres **2124** are sensitive to the γ radiation but are insensitive to the β+ particles. The unit **3251** is adapted to subtract, from the count corresponding to the signals generated by a radioactive tracer detection fibre **2123**, the γ count corresponding to the signals generated by the associated control fibre **2124**, in order to obtain a measurement of the β+ signal only.

It will be noted in this regard that several radioactive tracer detection fibres **2123** can be associated with a single control fibre **2124** so as to optimise the portion of the detection surface **2113** sensitive to the β articles.

The digitising and calculating unit **3251** is adapted to compare the count of the pulses corresponding to the radioactive tracer concentration measures at the fibres **2123** of the detection head **21** with a reference count measured previously in a zone of the operative wound composed of healthy tissue only.

When the difference between the measured count and the reference count is greater than a threshold standard deviation (greater than 3 for example) then the unit **3251** will identify the tissue area as tumorous.

The digitising and calculating unit **3251** commands the screen **3252** so that the latter displays a mapping of the tissue area on which the number of β particles detected by each fibre **2123** is indicated.

The surgeon may thus view an image of the treated tissue zone on the screen **3252** in real time, which indicates the

distribution of the radioactive tracer concentration at the fibres **2123** of the detection head **21**.

The preoperative probe is also used for tumorous tissue detection by fluorescent optical techniques.

Thus, the clear fibres **2121** receive the fluorescent radiation emitted by fluorescent molecules present in the tissue after the molecules have been excited by a light excitation signal conducted by the fibre **2122** to the tissue. The light signal containing the fluorescent light radiation is guided by the clear fibres **2121** to a photodetector **311** of the photo-detecting unit through a filter **313** arranged between the proximal end of the fibre and the photo-detector. The filter **313** selects a specific wavelength or range of wavelengths from the light signal guided by the optical fibre **2121** and produces a filtered fluorescence signal, wherein the photo-detector is arranged to receive the filtered signal.

The photo-detector generates an electrical signal whose amplitude is proportional to the intensity of the filtered fluorescence signal. This electric signal is received firstly by the acquisition unit **324**.

The unit **3241** supplies the intensity of the fluorescence light corresponding and the number associated with the fiber **2121**, which collected the fluorescence light. The conversion electronics unit **3241** digitises the filtered fluorescent signal and transmits the digitised signal to the digitising and calculating unit **3251**. The unit **3242** supplies the number of photons of the filtered fluorescent signal and measure their time of passage; the unit **3242** then transfers counted data and measured times directly to the unit **3251**.

The digitising and calculating unit **3251** is adapted to compare the count of the radiation detected by the fibres **2121** with a reference count, measured previously in a zone of the operative wound composed of healthy tissue only. When the difference between these counts is greater than a predetermined threshold (the count has a standard deviation greater than 3 in relation to the reference count for example), the unit **3251** will identify the tissue area as tumorous.

In addition, the digitising and calculating unit **3251** is adapted to compare the intensity of the fluorescent radiation in a selected and adjustable range of wavelength of the fluorescence spectrum detected by the fibres **2121** with a reference intensity measured previously in a zone of the operative wound composed of healthy tissue only. For example, when the "red" contribution of the spectrum (wavelengths between 600 and 700 nm) is greater by more than 100% in relation to the reference spectrum, the unit **3251** will identify the tissue area as tumorous.

In addition, the digitising and calculating unit **3251** is adapted to calculate the decay time of the fluorescence from the signals of the unit **3242** and to compare these with reference decay times measured previously in a zone of the operative wound composed of healthy tissue only. When at least one of the measured decay times has a standard deviation that is greater by 50% in relation to the reference time, the unit **3251** will identify the tissue area as tumorous.

Finally, the digitising and calculating unit **3251** is adapted to process in combination the various data produced by the devices **3233**, **3241**, **3242** and **3223**. The identification of tumorous tissue is thus based on complementary data and leads to results that are more reliable than with independent use of the different data.

In particular, for several measurements based on different independent parameters from the same tissue area indicating a tumorous zone without however exceeding the thresholds specified for a reference zone, the unit **3251** will identify the zone as tumorous. In the opposite case, in which a meaningful measurement (standard deviation greater than 3) is not confirmed, or if it is contradicted by other measurements, then the unit **3251** will not propose excision of the corresponding tissue.

The processing unit **3251** controls the screen **3252** so that the latter displays several two-dimensional graphs each representing the tissue area. The first graph indicates the count of the β tracers at each fibre **2123**.

The unit **3251** may command the screen **3252** to present a second graph representing the intensity of the fluorescent radiation according to the wavelength of the radiation. Beforehand, the surgeon will have chosen a wavelength window and, in this second graph, the screen **3251** will display only the intensity of the fluorescent radiation at the fibres **2121** whose wavelengths are between the lower limit and the upper limit of the window chosen by the surgeon.

The unit **3251** also controls the screen **3252** so that the screen **3252** displays a third graph representing the decay time of the radiation emitted by the fluorescent molecules detected at the fibres **2121**.

The surgeon may thus view several mappings of spatial distributions of measured intensities and of the parameters specific to the treated tissue zone on the screen **3252**, in real time.

The screen **3252** may simultaneously display several measured mappings and superimposed these on each other.

The screen **3252** may also display a table summarising the results of the measurements taken individually and offer conclusions to the surgeon.

According to the mapping or mappings displayed by the screen **3252**, the surgeon may decide whether to excise the tissue zone by means of the excision tool **1**.

A second embodiment of the probe **2** is depicted on FIG. **6**.

This second embodiment differs from the first embodiment shown on FIGS. **5**A and **5**B in that the photo-detection unit **29**, the filter **313**, the integrated circuit **310** and the transmitter **31** are buried in the detection head, rather than in a detachable part connectable to the detection head.

A third embodiment of the probe **2** is depicted on FIG. **7**.

This third embodiment differs from the second embodiment in that many photo-detectors can be coupled to one same fibre, for instance a fibre **2123** and/or a fibre **2124**.

In the particular example depicted on FIG. **7**, two photo-detectors **311** are arranged in the body of the probe and put in contact with the proximal end of a fibre **2123**, and two other photo-detectors **311** are arranged in the body of the probe and put in contact with the proximal end of a fibre **2124**. Each photo-detector produces a distinct electrical signal representing a pixel.

Such arrangement is advantageous in that most of photo-detectors generate a noise, said "dark noise". Since dark noises generated by two distinct photo-detectors are not correlated, the influence of said dark noises can be removed by detecting in coincidence both electrical signals produced by the two photo-detectors. Thus, the detection threshold may be very low and the beta sensitivity is increased.

Of course, coupling more than one photo-detector with one single fibre can also be included in the first embodiment.

A fourth embodiment of the probe **2** is depicted on FIG. **8**.

As in the third embodiment, a plurality of photo-detectors can be coupled with one same fibre. However, at least one photo-detector of this plurality is arranged to contact with the proximal end of the same fibre, whereas at least one other photo-detector is arranged to contact with a lateral side of the same fibre. This arrangement improves collection of light by the plurality of photo-detectors.

A fifth embodiment of the probe **2** is depicted on FIG. **9**.

This fifth embodiment differs from the first embodiment in that the detection head comprises the photo-detecting unit and the integrated circuit **310**, whereas the detachable part comprises a portion of transmission fibre **3122**.

It can be noted that each fibre **2122** and a corresponding fibre **3122** can be distinct (as shown in the first and fifth embodiment) or parts of a same fibre (as shown in the second, third and fourth embodiments).

In all variants of the treatment set described above, the transmitter **31** comprises a cable connected to the analysis instrument.

In another embodiment illustrated in FIG. **10** referred to as "wireless embodiment", the transmitter comprises a wireless communication module **314** connected to the integrated circuit **310**. The wireless communication module **314** is adapted to convert an electrical signal received from the integrated circuit **310** into a radio signal. In the wireless embodiment, the light source **30** can be included in the detection head. In this embodiment, the light source **30** may comprise at least one LED. The light source **30** may include at least three LED in order to compute a 3D position.

The analysis instrument comprises a wireless communication module **3140** adapted to receive the radio signal and converts it into an electric signal and transmits the electric signal the to the PC **325**.

Both wireless communication modules can support various wireless communication protocols: Wi-Fi, Bluetooth, etc.

Now referring to FIG. **11**, the probe can also comprise a position transmitter **72** for transmitting the 3D position of the probe to an position analysis equipment (for example to the analysis instrument **32**, or to another equipment).

In another embodiment, the position transmitter comprises a luminescent source, such as a LED, and the position analysis equipment comprises a camera for capturing an image showing light emitted by the luminescent source, and a processor for estimating the position of the probe based on the captured image.

In still another embodiment, the luminescent source is replaced by a predetermined marker applied on a surface of the probe and known by the position analysis equipment. Therefore, the processor can detect the pattern of the marker in an image captured by the camera and estimate the position of the probe based on the pattern.

The position sensor **71** may be located in the detection head, or located in a detachable navigation module connectable to the detection head.

The position sensor **71** may be included in any embodiment described upwards.

The 3D localisation of the probe allows correlating more accurately the position of the excision tool and the image of the distribution of the radioactive or fluorescent signals produced by the optical fibres. In practice, because the 3D position in space of the detection optical fibers is measured through the position sensor, the true position of tumor tissue identified from the radioactive and/or fluorescence signals detected by the optical fibers is also determined. Thus, the surgeon can put the tip of the excision tool perfectly on contact with the tumor areas in order to remove them. The 3D localisation also allows to check that the overall surgical wound has been explored by recording the positions in space already traveled by the probe.

It will be noted that the number and arrangement of the optical fibres in the detection head **21** can easily be modified, so as to meet the constraints of the different surgical protocols.

The probe **2** may be rendered more versatile by providing a range of interchangeable detection heads **21** that satisfy the various specifications (compactness, sensitivity, resolution, etc.).

It is thus possible to provide a detection head that included only on clear fibre **2121** and one excitation fibre **2122** for detection of the fluorescent molecules present in the tissue.

It is also possible to provide a detection head that includes only one radioactive β tracer detection fibre **2123** and one control fibre **2124**. This type of detection dead is particularly suitable for surgical procedures that require extreme compactness of the probe, such as excision procedures under endoscopy or biopsies.

At the other extreme, it is possible to provide a detection head that includes several concentric layers of detection fibres **2121** and **2123**, used to perform mapping of the spatial distribution of the radioactive tracers and of the light radiation in a field of view of the order of 2 square centimeters (cm^2). This type of detection head is suitable for surgical procedures that call for rapid exploration of the operative wound, or for operations that are limited by high non-specific fixing of the radioactive tracers.

In contrast to a counting probe, the option to create a mapping of the tissue area to be treated in fact allows one to distinguish the tumorous signals specific to the background noise, and therefore to improve the signal to noise ratio, which can be badly affected by the heterogeneity of the tracer fixing in the tissue surrounding the lesion.

Between these two extreme configurations just presented, detection heads with intermediate arrangements of fibres, in terms of number and positioning, may also be envisaged.

Advantageously, it is possible to combine and sum the data coming from each fibre in a single signal. The sum is then used as a single mono-pixel detector, in such a way that the probe has a better sensitivity for more rapid identification of the zones to be treated.

The treatment set just described allows simultaneous measurement of the concentration of radioactive tracers and the fluorescent molecule distribution. This association is used to increase the complementarity of the histological, metabolic and molecular data supplied by these different measurements, and thus to increase the efficiency of preoperative detection of tumours.

The probe just described is of small dimensions and is easy to manipulate, thus allowing access to narrow regions of operative wounds (cavities of the order of 3 to 5 cm for cerebral tumours for example).

In addition, the probe allows precise and rapid location of the zones of tissue to be excised.

Coupling with the excision tool in fact allows the surgeon to view, in real time, a mapping of the tissue area located close to the excision tool, and therefore to perform a more precise and rapid excision of the tumorous tissue in a single procedure, having first marked it out.

Finally, the probe allows more specific detection of the tumours than with the techniques of the prior art. In fact, combining the detection of several types of tracer allows one to supply more precise and reliable information on the nature of the tissue treated.

A probe according to the invention, measuring a signal emitted by fluorescent molecules in a tissue area, in response to a light excitation signal, advantageously also measures a light signal obtained from the reflection of the light excitation signal by the tissue.

In the foregoing developments, a bundle of micro-optical fibres of very small diameter can naturally replace each optical fibre described.

The invention claimed is:

1. A preoperative probe for use with an analysis equipment for guiding a manual excision tool, comprising:

a single-use detection head comprising a first body having a first optical fiber for the reception and guidance of a signal representative of both beta and gamma particles emitted by radioactive tracers in a tissue area, a second optical fiber for reception and guidance of a signal representative of gamma radiation only, and a first planar connection surface having a connection stud, the first and second optical fibers each having an end disposed flush with the first planar connection surface; and

a reusable detachable part comprising a second body having a second planar connection surface and a connection orifice, a first photo-detector for converting the signal guided by the first optical fiber into a first electrical signal, a second photo-detector for converting the signal guided by the second optical fiber into a second electrical signal, and an integrated circuit coupled to the first and second photo-detectors to output information for processing to the analysis equipment, each of first and second photo-detectors disposed flush with the second planar connection surface;

a transmitter for transmitting the information output by the integrated circuit to the analysis equipment; and

locking component for removably coupling the second body to the first body so that the first and second planar surfaces mate, the first optical fiber is disposed adjacent to the first photo-detector, the second optical fiber is disposed adjacent to the second photo-detector and the connection stud and the connection orifice interengage.

2. The probe according to claim 1, wherein the transmitter comprises a wireless communication module.

3. The probe according to claim 1, wherein the transmitter comprises a transmission cable coupled to the reusable detachable part.

4. The probe according to claim 1, wherein at least one of the first and second photo-detectors comprises a silicon photomultiplier.

5. The probe according to claim 1, wherein the detection head comprises a handpiece configured to be manipulated by a clinician.

6. The probe according to claim 5, wherein handpiece is configured to receive an excision tool.

7. The probe according to claim 1, further comprising a temperature sensor for sensing a temperature of one of the first and second photo-detectors.

8. The probe according to claim 7, further comprising a battery for supplying a power signal to the first and second photo-detectors and the integrated circuit is configured to adjust the power signal based on the temperature sensed by the temperature sensor.

9. The probe according to claim 1, wherein the transmitter is arranged to transmit information carried by the first electrical signal and the second electrical signal to the analysis equipment.

10. The probe according to claim 1, further comprising a third photo-detector, wherein the first photo-detector comprises a surface in contact with an end of the first optical fiber, and the third photo-detector comprises a surface in contact with a side of the first optical fiber or the end of the first optical fiber.

11. The probe according to claim 1, further comprising a third photo-detector, wherein the second photo-detector comprises a surface in contact with an end of the second optical fiber, and the third photo-detector comprises a surface in contact with a side of the second optical fiber or the end of the second optical fiber.

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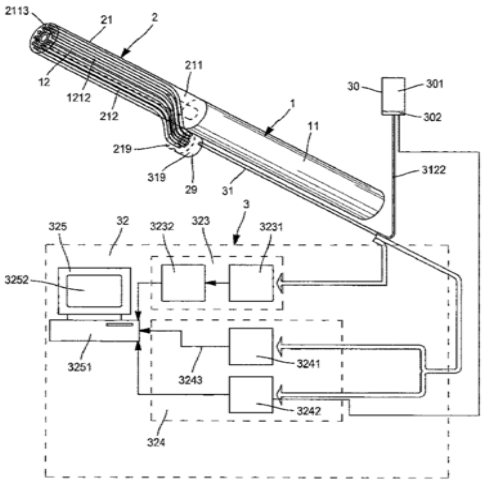
外部链接	Espacenet USPTO		

摘要(译)

用于引导手动切除工具的手术探针。该探头包括检测头，用于接收和引导组织区域中放射性示踪剂和荧光分子发射的信号的光纤，用于将发射的信号转换成电信号的光电检测器，用于发送信息的发送器通过电信号向分析设备和用于将探针附接到手动切除工具上的紧固件，使得切除工具可用于从发出信号的组织区域移除一部分组织。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