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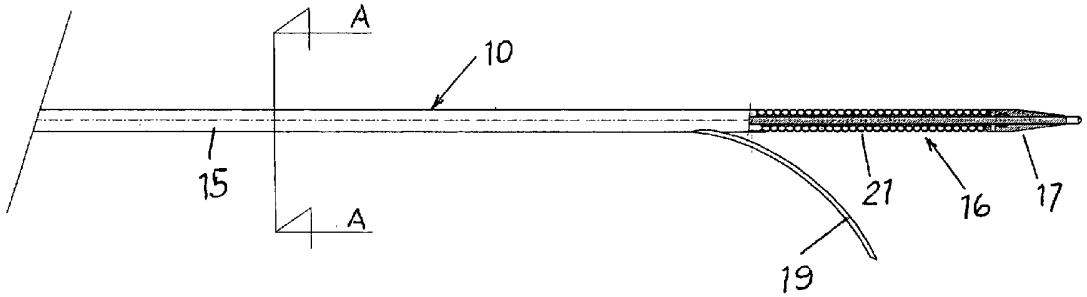
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CATHETER WITH FLEXIBLE COOLED ELECTRODE



(57) Abstract: The invention concerns a catheter for the treatment of tumours and other affections using hyperthermia induced by radio frequency, which comprises a tubular body (10) with or without anchoring balloon at its distal end, an active electrode (16) positioned around said body and connected to a radio frequency generator, and at least one thermistor needle (19) to measure the temperature around said electrode. The active electrode (16) is flexible and connectable to a supply source of a fluid for cooling the electrode. It includes a helical conduit (21, 25) which can be metal, conductive ceramic or graphite.

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"CATHETER WITH FLEXIBLE COOLED ELECTRODE"

Field of the Invention

This invention concerns in general devices for therapeutic and surgical use in the treatment of tumours and other affections using hyperthermia, that is to say thermal ablation, induced by radio frequency, and refers in particular to a catheter with an electrode for this use.

Prior Art

There are already some well known catheters for the purpose mentioned, among which one using a metal plaque as an active electrode, connectable to a radio frequency generator, positioned along a tubular body of the catheter near the distal metal point and/or a possible inflatable anchoring balloon. The plaque can be copper, steel or some other metal, it partially encompasses at least the tubular body of the catheter it is to and, in order to avoid exceeding the treatment temperature induced by the radio frequency which could cause burns, it must be cooled.

For this purpose, the plaque has been designed with a double wall to form a cavity or hollow space in which a cooling fluid is circulated, usually water, supplied by an appropriate source.

An active electrode in the form of a plaque designed in this way forms however a rigid section which has a negative influence on the flexibility of the catheter in the part where it is housed and which above all is not easy to manufacture.

Object and Summary of the Invention

One of the object of this invention is to propose on the contrary a catheter for local treatments using hyperthermia induced by radio frequency equipped with an active electrode having a new configuration and advantageously flexible.

Another object of the invention is to provide a cooled electrode which integrates well with the smoothness and flexibility characteristics of the body of the catheter and which is easier to manufacture and decidedly efficient.

These objects are achieved in a catheter for therapeutic and surgical treatment using radio frequency having a distal part which houses an electrode made up of a helical duct, coaxial with the catheter tube, attached to a metal point and/or a possible anchoring balloon and connectable to a radio frequency generator and also to a supply source of cooling fluid.

The duct containing the electrode can be made in different ways, with different shapes and with various conductive materials and results in being advantageously flexible, facilitating in this way the introduction and use of the catheter in the affected part to be treated as required.

Brief Description of the Drawings

Greater details of the invention will become more evident in the following description made with reference to the indicative and non-limiting drawings enclosed, in which:

Fig. 1 is a view of a portion of the catheter complete with an active electrode;

Fig. 2 is a view of an enlarged cross-section of the catheter in direction of arrows A-A in Fig. 1;

Fig. 3 is an enlarged longitudinal view of the electrode according to a first example;

Fig. 4 is a similar longitudinal section of a second example of the electrode;

Fig. 5 is a view of a cross section in direction of arrows B-B in Fig. 4; and

Fig. 6 is a view, once again a longitudinal section, of another example of a an electrode.

Detailed Description of the Invention

As represented the catheter comprises a body 10 which can be made up of a tubular element with a number of ducts or, as shown, with several tubes 11, 12, 13 and 14 located side by side longitudinally and enclosed in an insulating elastic sheath 15. In its distal part, the body of the catheter houses an active electrode 16, which will be described below, plus a metal point end piece 17 with or without an anchoring balloon, the latter not shown. In a proximal part, not shown, the catheter is equipped with connectors for connection to the control devices of the various functions provided.

Between the ducts or tubes in the body 10 of the catheter, one duct or tube 11 is allocated for receiving a guide wire or spindle 18 which can extend as far as the metal point. The metal point 17 and possible balloon are attached to the free end of the tube 11, and the electrode 16 is positioned directly or indirectly around a portion of the said tube.

Another duct or tube 12 is allocated to receive a so-called thermistor needle 19, which extends until it protrudes, in a retractable form, from one side of the body 10 near the electrode 16. The needle 19 is usual tubular, may have an external coating, and the leads 20 of a thermocouple for measuring the temperature around the electrode, pass through it.

Other ducts or tubes 13 and 14 are envisaged for the delivery and return of a cooling fluid to the electrode 16, leading from a cooling liquid supplier, preferably water.

The active electrode 16, in compliance with this invention, is made up of a helical duct 21. It is placed coaxially to the catheter body, that is around the tube 11, or a tubular element attached to the latter, and connects up to an appropriate radio frequency generator by means of a lead – not shown – passing through the body of the catheter.

Duct 21 can be metal, conductive ceramic, graphite or other suitable material, and the cross section of which can be of any shape, round, oval, rectangular, etc. It can be constructed in several ways. For example it can be single helical, achieved by turning a single tubular initial element helicoidally in an intermediate part so that the portions from opposite parts of the helicoidal zone represent, all or in part, fluid delivery and return tubes 13, 14 which must flow along and cool the electrode 16.

According to another example, the duct 21 housing the electrode 16 can be double helical, achieved by winding parts of the two parallel branches of an initial tubular element, already bent into a U shape, contemporarily and helically, so that two straight sections of said branches

of the initial tubular element enclose, all or in part, fluid delivery and return tubes 13, 14 which cool the electrode.

However, the coils of the electrode in the shape of a helical duct 21 can be linked together, centrally to tube 11 or the tubular element around which they are wound, by a resin or an adhesive. Externally they can be free as shown in Fig. 3, or better enclosed in a sheath 22, as shown in Fig. 4, which can either be a conductive ceramic or graphite, the flexibility however of the electrode remains unharmed.

Furthermore, in particular when electrode 16 is used in a conductive ceramic or graphite covering, the helical duct 21 can be enclosed in two cylindrical, concentric and attached sleeves, one internal 23 and the other external 24 – Fig. 6. In this way, at least in the surface of one sleeve in contact with the other sleeve there is at least one helical duct 25 to form the helical passage required. This helical passage has preferably and advantageously, a rectangular cross section and the delivery and return tubes 13, 14 for the electrode cooling fluid will be connected to it.

"CATHETER WITH FLEXIBLE COOLED ELECTRODE"

* * *

CLAIMS

1. A catheter for the treatment of tumours and other affections using hyperthermia induced by radio frequency, comprising a tubular body (10) equipped with a metal point and/or an anchoring balloon at its distal end, an active electrode (16) placed around said body, attached to the metal point and/or balloon and connected to a radio frequency generator, and at least one thermistor needle (19) to measure the temperature around said electrode, characterised in that the active electrode (16) is flexible and connectable to a cooling fluid supply source for cooling the electrode itself.

2. The catheter according to claim 1, wherein said flexible electrode (16) includes a helical duct (21) coaxial and attached to a section of the tubular body of the catheter.

3. The catheter according to claims 1 and 2, wherein the flexible electrode (16) is in the shape of a single helical tube and connected to a radio frequency generator.

4. The catheter according to claim 3, wherein said flexible electrode (16) is formed of a helically wound tubular element (21), and wherein the two opposite ends of said tubular element are connected to or merge into two tubes (13,14) for delivery and return of the electrode cooling fluid.

5. The catheter according to claims 1 and 2, wherein said flexible electrode (16) is in the shape of a double helical tube and connected to a radio frequency generator.

6. The catheter according to claim 5, wherein said flexible electrode (16) consists of two parallel sections of a helically wound tubular element, said sections being the two branches of a U bent tubular element so as to become joined, and where free ends of each coil are connected to or part of two tubes (13,14) for delivery and return of the electrode cooling fluid.

7. The catheter according to any of the previous claims, wherein the helically wound tubular element (21) to form said flexible electrode (16) is of metal, conductive ceramic, graphite or something similar.

8. The catheter according to any of the previous claims, wherein the coils of the helically shaped flexible electrode (16) are both joined together and attached to the catheter body by a resin seal or adhesive.

9. The catheter according to any of the previous claims, wherein the helically shaped flexible electrode (16) is enclosed externally in a ceramic, graphite or similar sheath or sleeve (22).

10. The catheter according to claim 1, wherein said electrode is formed of two concentric and attached cylindrical sleeves (23,24), one internal and the other external, where at least one surface of a sleeve is helically grooved and forms with the surface in contact with the other sleeve at least one helical passage (25) connectable to two tubes for delivery and return of the electrode cooling fluid, and where said sleeves are made of a material such as conductive ceramic, graphite or something similar.

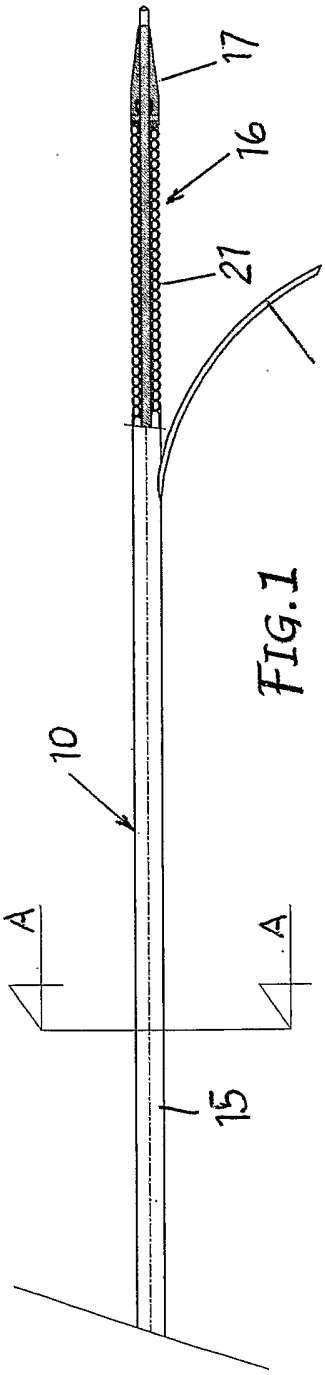

FIG.1

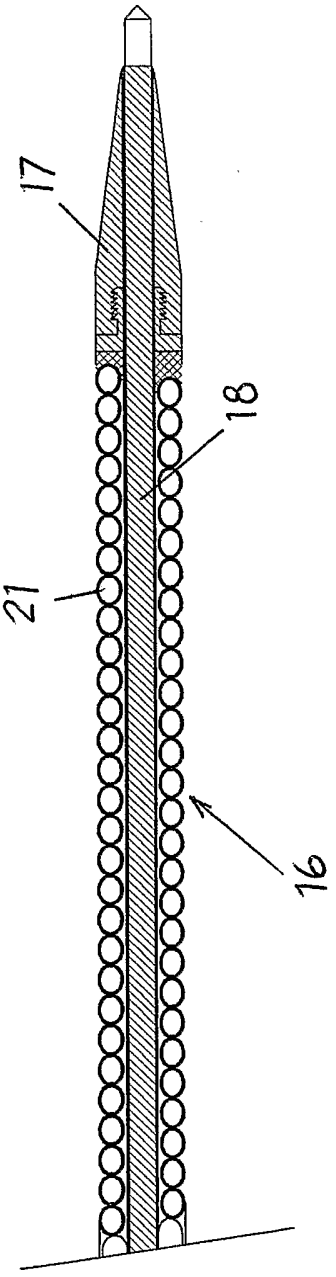

FIG.3

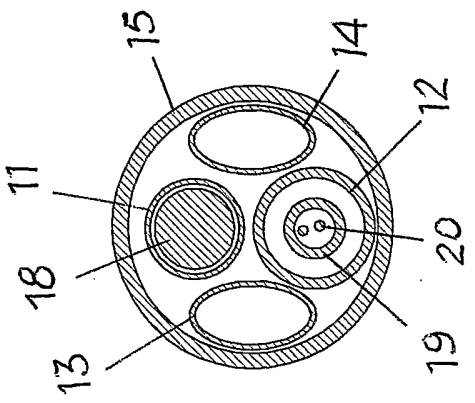

FIG.2

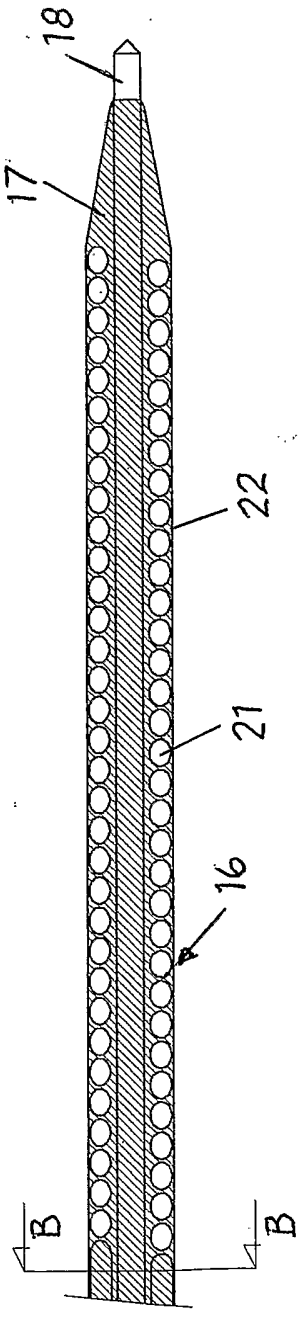

FIG.4

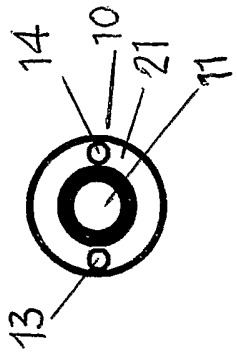

FIG.5

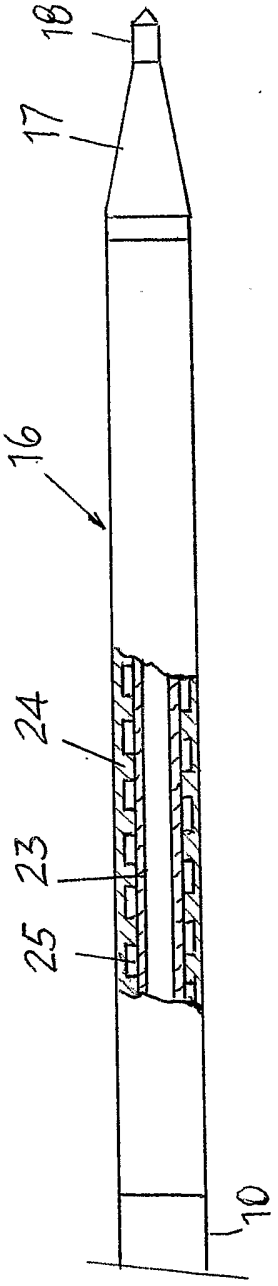

FIG.6

INTERNATIONAL SEARCH REPORT

PCT/IT 03/00027

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/18 A61N1/06

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)
IPC 7 A61B A61N

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

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

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2001/011161 A1 (BAKER JAMES ALLEN ET AL) 2 August 2001 (2001-08-02) page 2, column 2, line 8-35 -page 3, column 2, line 32-36; figures 1,8	1-3 4-10
P,X P,Y	US 6 461 351 B1 (WOODRUFF EILEEN A ET AL) 8 October 2002 (2002-10-08) column 9, line 22 -column 10, line 9; figure 6	1 4-10
A	US 5 603 697 A (WARNER GLEN G ET AL) 18 February 1997 (1997-02-18) claim 1; figure 1	1-10

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

☒ Patent family members are listed in annex.

° Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 May 2003	14/05/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Chopinaud, M

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