Title: A FORCE FEEDBACK CATHETER ASSEMBLY

Abstract: A force feedback catheter assembly (10) includes a catheter sheath (12). A tip electrode (14) is arranged at a distal end of the catheter sheath (12) to be displaceable axially with respect to the distal end of the catheter sheath (12). A force feedback mechanism (24) has at least a part of which is arranged between the tip electrode (14) and the distal end of the catheter sheath (12). The force feedback mechanism (24) has at least two feedback settings, a first setting to indicate when adequate force is exerted by the tip electrode (14) on tissue at the site to enable a procedure to commence and a second setting to indicate when the force exerted by the tip electrode (14) reaches a level at which undesirable tissue damage could occur.
"A force feedback catheter assembly"

Cross-Reference to Related Applications
The present application claims priority from United States of America Provisional Patent Application No 61/012,150 filed on 7 December 2007, the contents of which are incorporated herein by reference.

Field
This invention relates, generally, to catheters and, more particularly, to a force feedback catheter assembly.

Background
In therapeutic or diagnostic procedures involving placing a catheter in a patient's body, it is often necessary to apply pressure to a distal end of the catheter being used to effect treatment or diagnosis at the site. The pressure to be applied needs to be monitored to ensure that it is not so great that it could cause perforation or other damage to tissue at the site.

However, a balance needs to be struck between the pressure to be applied to obtain effective treatment or diagnosis and the pressure which could cause perforation or other damage to the tissue.

Also, it is often necessary to steer the catheter through a patient's vasculature to reach the site at which the treatment is to be effected. Once again, while steering the catheter, the distal end of the catheter can be brought into contact with walls of the blood vessels and excess force could rupture the walls of the blood vessels with potentially serious consequences.

Summary
According to a first aspect of the invention, there is provided a force feedback catheter assembly which includes
- a catheter sheath;
- a tip electrode arranged at a distal end of the catheter sheath to be displaceable axially with respect to the distal end of the catheter sheath; and
- a force feedback mechanism at least a part of which is arranged between the tip electrode and the distal end of the catheter sheath, the force feedback mechanism having at least two feedback settings, a first setting to indicate when adequate force is exerted by the tip electrode on tissue at the site to enable a procedure to commence and
a second setting to indicate when the force exerted by the tip electrode reaches a level at which undesirable tissue damage could occur.

The procedure may be an ablation procedure in the treatment of heart arrhythmias. In such a procedure tissue damage by ablation is intended. However, excessive force exerted by the tip electrode on the tissue could result in tissue perforation and such tissue damage is undesirable.

The assembly may include an urging element acting on the tip electrode for urging the tip electrode to a rest position relative to the catheter sheath.

The tip electrode may comprise a crown portion and a skirt portion depending from the crown portion, at least the crown portion being conductive. The skirt portion may overly the distal end of the catheter sheath, a sealing arrangement being interposed between the skirt portion and the distal end of the electrode to inhibit the ingress of foreign matter into the catheter sheath.

The catheter sheath may be a tubular element defining a lumen, the force feedback mechanism being contained substantially within the lumen of the catheter sheath.

In an embodiment, the force feedback mechanism may have a conductive member carried by the tip electrode and at least one conductive element arranged in the lumen of the catheter sheath, the arrangement being such that, when the conductive member and the at least one conductive element make electrical and mechanical contact, an indication is given that a predetermined force is being exerted by the tip electrode on the tissue, in use.

More particularly, the force feedback mechanism may include a plurality of conductive elements to provide the at least two force feedback settings, the conductive elements being engageable sequentially by the conductive member of the tip electrode, the arrangement being such that, when a first one of the conductive elements is engaged by the conductive member, a first indication is given that a predetermined force is being exerted by the tip electrode on the tissue and, if a further, following conductive element is engaged by the conductive member, a further indication is given that a higher force is being imparted to the tissue by the tip electrode. When the first indication is given, an electrical circuit may also be completed so that electrical energy, such as radio frequency (RF) energy for ablation purposes, is supplied to the tip electrode. If a greater force is then exerted on the tissue by the tip electrode to cause breaking of electrical contact between the conductive member and the conductive element, the supply of RF energy ceases and, if the following conductive element is
then engaged, an alarm signal may be generated to warn the clinician of the danger of imminent undesirable tissue damage.

One of the conductive member and the conductive element may carry a current carrying contact element to facilitate electrical contact between the conductive member and the conductive element.

In another embodiment, the force feedback mechanism may include a mechanical linkage which is stiff in compression and which extends from the tip electrode, the linkage being connected to a marker in a handle of the catheter assembly.

The handle of the catheter assembly may have markings to indicate to a clinician the force being exerted by the tip electrode on the tissue.

According to a second aspect of the invention, there is provided a force feedback catheter assembly which includes

a catheter sheath;

a tip electrode arranged at a distal end of the catheter sheath to be displaceable axially with respect to the distal end of the catheter sheath, the tip electrode comprising a crown portion and a skirt portion depending from the crown portion, the skirt portion overlying the distal end of the catheter sheath; and

a force feedback mechanism at least a part of which is arranged between the tip electrode and the distal end of the catheter sheath, the force feedback mechanism having at least one feedback setting to provide an indication of the force exerted by the tip electrode on tissue at a site of a patient's body.

The assembly may include a sealing arrangement interposed between the skirt portion and distal end of the electrode to inhibit the ingress of foreign matter into the catheter sheath.

**Brief Description of Drawings**

Fig. 1 shows a side view of a distal part of a first embodiment of a force feedback catheter assembly in a first condition;

Fig. 2 shows a sectional side view of the distal part of the catheter assembly of Fig. 1 in its first condition;

Fig. 2A shows, on an enlarged scale, the part of the catheter assembly encircled by Circle 'A' in Fig. 2;

Fig. 3 shows a side view of the distal part of the force feedback catheter assembly in a second condition;

Fig. 4 shows a sectional side view of the distal part of the catheter assembly of Fig. 3 in its second condition;
Fig. 5 shows a sectional side view of a distal part of a second embodiment of a force feedback catheter assembly in a first condition;

Fig. 6 shows a sectional side view of the distal part of the force feedback catheter assembly in a second condition; and

Fig. 7 shows a three dimensional view of the second embodiment of the catheter assembly.

**Detailed Description of Exemplary Embodiments**

Referring initially to Figs. 1-4 of the drawings, a first embodiment of a distal part of a force feedback catheter assembly is illustrated and is designated generally by the reference numeral 10.

The catheter assembly 10 includes a catheter sheath 12. A tip electrode 14 is displaceably arranged, in an axial direction, at a distal end 16 of the catheter sheath 12.

An urging element in the form of a coil spring 18 (Fig. 2) is arranged between the tip electrode 14 and a shoulder 20 defined slightly inwardly of the distal end 16 of the catheter sheath 12. In this regard, it is to be noted that the catheter sheath 12 is tubular defining a lumen 22. The shoulder 20 projects radially inwardly into the lumen 22.

A force feedback mechanism 24 is arranged between the tip electrode 14 and the distal end 16 of the catheter sheath 12. More particularly, the force feedback mechanism is arranged at a distal end 16 of the catheter sheath 12, distally of the shoulder 20.

The tip electrode 14 has a conductive crown portion 26 with a skirt portion 28 depending from the crown portion 26. The skirt portion 28 can, optionally, be conductive or insulating. The skirt portion 28 overlies the distal end 16 of the catheter sheath 12 as illustrated more clearly in Fig. 2 of the drawings. A plurality of axially spaced, circumferentially extending seals 30 are arranged about the distal end 16 of the catheter sheath 12 for inhibiting ingress of foreign material and bodily fluids into the lumen 22 of the catheter sheath 12.

The coil spring 18 is constrained in a sleeve 32 depending from an interior surface of the crown portion 26 of the tip electrode 14. A free end of the sleeve 32 carries a conductive member in the form of a collar 34. The collar 34, being of a conductive material, forms part of the force feedback mechanism 24.

The force feedback mechanism 24 further includes a plurality of axially spaced conductive elements 36. Each conductive element 36 comprises a channel shaped member defining a channel in which a current carrying conductive element or
conductor 38 is received. The conductor 38 is in the form of a canted coil spring arranged in an annular configuration and received in the channel of its associated conductive element 36. The assembly comprising the conductive member 34, the conductive element 36 and the conductor 38 is, for example, of the type available from Bal Seal Engineering, Inc. of 19650 Pauling, Foothill Ranch, CA, 92610-2610, USA.

The force feedback mechanism 24 comprises three conductive elements 36 arranged in axially spaced relationship at the distal end 16 of the catheter sheath 12 to provide at least two feedback settings. Each conductive element 36 has an electrical lead (not shown) associated with it. The electrical lead of each conductive element 36 can either extend through the lumen 22 of the catheter sheath 12 or, instead, could be embedded in a wall 40 of the catheter sheath 12. In the latter case, the catheter sheath 12 is manufactured in accordance with the manufacturing techniques described in the Applicant’s International Patent Application No. PCT/AU01/01339 dated 19 October 2001 and entitled "An electrical lead".

The conductor 38 received in each conductive element 36 can be of varying mechanical strength so that different forces are required to cause mechanical and electrical engagement of the conductive member 34 with each conductive element 36. Thus, in the position shown in Fig. 2 of the drawings, the conductive member 34 is in mechanical and electrical engagement, or latched, with the distal conductive element 36. This is a rest condition of the tip electrode 14 relative to the catheter sheath 12. As indicated above, the conductive elements 36 are connected via electrical leads to electrical equipment, illustrated schematically at 56 in Fig. 7 of the drawings, associated with the catheter assembly 10. (While Fig. 7 illustrates a second embodiment of the catheter assembly 10, the electrical equipment 56 is applicable also to the catheter assembly 10 of the first embodiment.).

When the tip electrode 14 is in its rest position relative to the catheter sheath 12, the electrical equipment may be quiescent or idling. In other words, no signal emanates from the electrical equipment 56.

When the tip electrode 14 is brought into contact with tissue at a site in a patient’s body and pressure is exerted on the tip electrode 14, it is displaced with relatively little resistance from the distal conductive member 36. For example, a force of less than approximately 10g may be sufficient to displace the tip electrode 14 from the first conductive element 36 of the force feedback mechanism 24. When a greater force is exerted on the tip electrode 14, the conductive member 34 latches to the centre conductive element 36. As indicated above, the force at which this occurs can be selected by appropriate selection of the conductor 38. Typically, a force of about 20g is
required to latch the conductive member to the conductive element 36. When this occurs, a circuit is closed and an enunciator of the electrical equipment 56 is activated. This alerts a clinician to the fact that adequate force is now being brought to bear by the tip electrode on the tissue 14. The clinician then has the option to start the supply of electrical energy, such as radiofrequency (RF) energy for ablation purposes, to be fed to the tip electrode 14. Instead, when the conductive member 34 latches to the centre conductive element 36, the supply of RF energy begins automatically.

If further pressure is brought to bear on the tip electrode 14 so that the conductive member 34 unlatches from the centre conductive element 36, the supply of RF energy automatically ceases. If the conductive member 34 then engages the proximal conductive element 36 and latches to it, a further signal is generated by the electrical equipment 56. This is an alarm signal which alerts the clinician to the fact that tissue perforation or other undesirable tissue damage is imminent. As an example, if a force exceeding 40g is brought to bear on the tip electrode 14, this causes latching of the conductive member 34 with the proximal conductive element 36 and causes generation of the alarm signal. It will be appreciated that the alarm signal could be any suitable enunciator and could be an audible alarm, a visual alarm or both.

Typically, the force required to cause latching of the conductive member 34 with the proximal conductive element 36 is of the order of 40g but this will be dependent on the application of the catheter assembly 10 and by the appropriate selection of the conductors 38.

The alarm condition of the tip electrode 14 is illustrated in Figs. 3 and 4 of the drawings.

Referring now to Figs. 5-7 of the drawings, a second embodiment of a catheter assembly 10 is illustrated. With reference to the previous drawings, like reference numerals refer to like parts, unless other wise specified.

In this embodiment, a support member in the form of an axially extending pin 42 extends proximally from an inner surface of the crown portion 26 of the tip electrode 14. The pin 42 is surrounded by the coil spring 18. A mechanical linkage 44 which is stiff in compression projects from the pin 42 and extends through the lumen 22 of the catheter sheath 12 to be received in a handle 46 (Fig. 7) of the catheter assembly 10.

The linkage 44 is connected to a marker 48 which is displaceably arranged in the handle 46 to be displaceable in the direction of arrows 50. The marker 48 projects through, or is visible in, a window 52 of the handle 46. Gradations or marks 54 are applied to the handle 46 alongside the window 52.
Thus, in use, as the tip electrode 14 exerts pressure on the tissue at the site in the patient's body, the marker 48 is displaced. At a first position, indicated by marker 54.1, this is an indication that the clinician can commence application of RF energy. At a second marker, 54.2, this is an indication that tissue perforation is imminent. It will be appreciated that an electrical connection can also be made so that, when the marker reaches mark 54.1 or 54.2, as the case may be, the RF energy is automatically supplied or an alarm condition is automatically generated, respectively. These electrical connections can be effected by means of components similar to components 34, 36 and 38 described above with reference to the first embodiment. Instead, the electrical connections could be effected by substituting the seals 30 with conductive electrodes and electrically connecting such electrodes to the electrical equipment illustrated schematically at 56 in Fig 7 of the drawings. The spring force of the coils spring 18 is then selected to give the relevant force values.

It is therefore an advantage of the invention that a catheter assembly 10 is provided which provides force feedback to a clinician while the clinician is using the catheter assembly 10. The force feedback can be used to commence the supply of electrical energy to the tip electrode 14 of the assembly 10 automatically and/or generate an alarm when tissue perforation is imminent. This is therefore of benefit, both when the catheter assembly 10 is being steered through the vasculature of the patient's body and when a procedure is being effected at a site in the patient's body at which perforation is a constant danger.

In addition, by enabling a clinician to observe the force being applied, the catheter assembly 10 can be operated remotely. This is beneficial as the clinician can then remove himself/herself from the field of potentially harmfully X-ray radiation during the procedure.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.
CLAIMS:
1. A force feedback catheter assembly which includes
   a catheter sheath;
   a tip electrode arranged at a distal end of the catheter sheath to be displaceable axially with respect to the distal end of the catheter sheath; and
   a force feedback mechanism at least a part of which is arranged between the tip electrode and the distal end of the catheter sheath, the force feedback mechanism having at least two feedback settings, a first setting to indicate when adequate force is exerted by the tip electrode on tissue at the site to enable a procedure to commence and a second setting to indicate when the force exerted by the tip electrode reaches a level at which undesirable tissue damage could occur.

2. The assembly of claim 1 which includes an urging element acting on the tip electrode for urging the tip electrode to a rest position relative to the catheter sheath.

3. The assembly of claim 1 or claim 2 in which the tip electrode comprises a crown portion and a skirt portion depending from the crown portion, at least the crown portion being conductive.

4. The assembly of claim 3 in which the skirt portion overlies the distal end of the catheter sheath, a sealing arrangement being interposed between the skirt portion and distal end of the electrode to inhibit the ingress of foreign matter into the catheter sheath.

5. The assembly of any one of the preceding claims in which the catheter sheath is a tubular element defining a lumen, the force feedback mechanism being contained substantially within the lumen of the catheter sheath.

6. The assembly of claim 5 in which the force feedback mechanism has a conductive member carried by the tip electrode and at least one conductive element arranged in the lumen of the catheter sheath, the arrangement being such that when the conductive member and the at least one conductive element make electrical and mechanical contact, an indication is given that a predetermined force is being exerted by the tip electrode on the tissue, in use.
7. The assembly of claim 6 in which the force feedback mechanism includes a plurality of conductive elements to provide the at least two force feedback settings, the conductive elements being engageable sequentially by the conductive member of the tip electrode, the arrangement being such that, when a first one of the conductive elements is engaged by the conductive member, a first indication is given that a predetermined force is being exerted by the tip electrode on the tissue and, if a further, following conductive element is engaged by the conductive member, a further indication is given that a higher force is being imparted to the tissue by the tip electrode.

8. The assembly of claim 6 or claim 7 in which one of the conductive member and the conductive element carries a current carrying contact element to facilitate electrical contact between the conductive member and the conductive element.

9. The assembly of any one of claims 1 to 5 in which the force feedback mechanism includes a mechanical linkage which is stiff in compression and which extends from the tip electrode, the linkage being connected to a marker in a handle of the catheter assembly.

10. The assembly of claim 9 in which the handle of the catheter assembly has markings to indicate to a clinician the force being exerted by the tip electrode on the tissue.

11. A force feedback catheter assembly which includes
    a catheter sheath;
    a tip electrode arranged at a distal end of the catheter sheath to be displaceable axially with respect to the distal end of the catheter sheath, the tip electrode comprising a crown portion and a skirt portion depending from the crown portion, the skirt portion overlying the distal end of the catheter sheath; and
    a force feedback mechanism at least a part of which is arranged between the tip electrode and the distal end of the catheter sheath, the force feedback mechanism having at least one feedback setting to provide an indication of the force exerted by the tip electrode on tissue at a site of a patient's body.
12. The assembly of claim 11 which includes a sealing arrangement interposed between the skirt portion and distal end of the electrode to inhibit the ingress of foreign matter into the catheter sheath.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
   Int. Cl.
   A61M 25/01 (2006.01)

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)

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 practicable, search terms used)
WPI: USPTO: ESPACE: GOOGLE: IPC (A61M/IC) & KEYWORDS (CATHETER or CANNULA or LUMEN or TUBE or FEEDBACK or FORCE or PRESSURE or SETTING or INDICAT+ or ELECTRODE or DAMAGE or PERFORAT+ or MEASURE or DETECT or SENSE) & SIMILAR TERMS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>See abstract; paragraphs [0052]; [0054]-[0055]; [0071]; figs. 2-3; 104; 126; 128; 425</td>
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<td>WO 2001/070117 A2 (MICROHEART INC.) 27 September 2001</td>
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Date of the actual completion of the international search
04 March 2009

Date of mailing of the international search report
12 MAR 2009

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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.