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(54) **Shape imparting mechanism insertion**

Einführung eines Form verleihenden Mechanismus

Introduction d'un mécanisme conférant une forme

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Description

Field

[0001] This invention relates, generally, to a steerable catheter and, more particularly, to a shape imparting mechanism for a catheter and to a catheter including such a shape imparting mechanism.

Background

[0002] Electrophysiology catheters are medical devices which are used in measuring electrical signals within the heart, most often, in the diagnosis of various arrhythmias. These catheters are also used for treating arrhythmias via ablative techniques.

[0003] To access a region of the heart to be treated, the catheter is inserted through the femoral vein of the patient. The tip of the catheter is steered through the vascular system of the patient to the desired location. The catheter is introduced into the femoral vein of the patient using an introducer. In order to steer the catheter through the vascular system of the patient, it is desirable that the catheter have as small an outside diameter as possible. This can be achieved using a catheter manufactured according to the Applicant's manufacturing techniques as described in its International Patent Application No. PCT/AU01/01339 dated 19 October 2001 and entitled "An electrical lead". In International Patent Application No. PCT/AU01/01339, the wall of the electrical lead is formed by an inner tubular member about which electrical conductors are helically wound. An outer jacket is deposited over the electrical conductors. In so doing, the electrical conductors are embedded in the wall of the electrical lead leaving an unimpeded lumen.

[0004] It is often desired that the distal region of the catheter adopts a certain shape in order to effect ablation at a desired site in the patient's body. The Applicant has filed International Patent Application No. PCT/AU2005/000216 dated 18 February 2005 and entitled "A steerable catheter" which covers a steering shaft for use with its catheter which is received in the lumen of the catheter. A distal end of the steering shaft may be pre-formed in the desired shape to be imparted to the distal region of the electrode sheath of the catheter.

[0005] US 2001/0039413 A1 and US 2003/0199960 A1 disclose catheters having an outer sleeve positioned on the catheter sheath, the outer sleeve being axially displaceable relative to the length of the catheter sheath. EP 1 048 314 A1 discloses a steering mechanism for a catheter.

Summary

[0006] According to the invention, there is provided a shape imparting mechanism for a catheter according to claim 1.

[0007] A tip of the elongate element may be rounded to aid insertion into the lumen of the electrode sheath of the catheter.

[0008] The elongate element may include a withdrawal inhibiting means at its distal end to inhibit withdrawal of the distal end into the sleeve. The withdrawal inhibiting means may be any device which enlarges a diameter of the distal end of the elongate element at least in one dimension. Thus, the withdrawal inhibiting means may be a deposit of an adhesive, a crimped region of the elongate element, an attachable collar, or the like.

[0009] At least the distal part of the elongate element may be of a shape memory material which allows the distal part to adopt its irregularly shaped configuration when the sleeve is in its first, retracted position.

[0010] The elongate element may have a bend-enhancing portion arranged proximally of the irregularly shaped distal part, the sleeve, when in its first position, exposing the bend-enhancing portion to facilitate steering of the irregularly shaped distal part of the elongate element, in use.

[0011] In addition, or instead, a kink may be imparted to a distal part of the elongate element, proximally of the rounded tip of the elongate element.

[0012] When used in conjunction with the irregularly shaped configuration of the distal part of the elongate element, the kink may be arranged distally of the irregularly shaped configuration of the elongate element, the kink defining an angled distal portion which is arranged at a predetermined, acute angle relative to an axis of that part of the elongate element arranged proximally of the kink.

[0013] According to the invention, there is also provided a catheter assembly according to claim 8.

[0014] The control mechanism may comprise a slider arrangement which is axially slidably arranged on the handle to facilitate displacement of the sleeve from its first position to its second position and vice versa.

[0015] The electrode sheath may have a distal end pre-formed into a predetermined shape. The pre-formed distal end of the electrode sheath may have an irregular shape corresponding to, and imparted by, the irregularly shaped configuration of the distal part of the elongate element.

Brief Description of the Drawings

[0016]

Fig. 1 shows a schematic, three dimensional view of a distal part of a shape imparting mechanism, in accordance with an embodiment of the invention, for a catheter with an insertion facilitating arrangement of the mechanism in a first, retracted position;

Fig. 2 shows a schematic, three dimensional view of a distal part of the mechanism with the insertion facilitating arrangement in a second, extended position;

Fig. 3 shows a schematic, three dimensional view of

a distal part of an electrode sheath of a catheter with the shape imparting mechanism of Fig. 1 received in a lumen of the electrode sheath with the insertion facilitating arrangement of the shape imparting mechanism in its extended position;

Fig. 4 shows a schematic, three dimensional view of a distal part of the electrode sheath of the catheter with the shape imparting mechanism therein with the insertion facilitating arrangement in its retracted position;

Fig. 5 shows a schematic, three dimensional view of a catheter handle with a control mechanism for the shape imparting mechanism in a first position;

Fig. 6 shows a schematic, three dimensional view of the handle with the control mechanism in a second position;

Figs. 7A-7D show schematic, side views of distal parts of another embodiment of a shape imparting mechanism for a catheter;

Fig. 8 shows a schematic, sectional side view of the mechanism of Fig. 7D being inserted into an electrode sheath of the catheter;

Fig. 9 shows a schematic, enlarged, sectional side view of the shape imparting mechanism of Fig. 7D received in the electrode sheath of the catheter;

Fig. 10 shows a schematic, three dimensional view of a distal part of further embodiment of a shape imparting mechanism for a catheter;

Fig. 11 shows a schematic, three dimensional view of a distal part of an electrode sheath for use with the shape imparting mechanism of Fig. 10;

Fig. 12 shows the combination of the shape imparting mechanism of Fig. 10 received in the electrode sheath of Fig. 11;

Fig. 13 shows a schematic, three dimensional view of a distal part of an embodiment of an electrode sheath of a catheter;

Fig. 14 shows an initial stage in preparing the electrode sheath of Fig. 13 for insertion into a patient's body; and

Fig. 15 shows the electrode sheath ready for insertion into the patient's body.

Detailed Description of Exemplary Embodiments

[0017] Referring initially to Figs. 1-4 of the drawings, a first embodiment of a shape imparting mechanism for a catheter is illustrated and is designated generally by the reference numeral 10.

[0018] In this embodiment, the shape imparting mechanism 10 includes an elongate element 12. The elongate element 12 is dimensioned to fit within a lumen of an electrode sheath 14 (Fig. 3) of a catheter.

[0019] The elongate element 12 is a tubular member 13 and has an actuator (not shown) arranged within the tubular member 13 as described in the Applicant's co-pending International Patent Application No. PCT/AU2005/000216, referenced above. The actuator is fast with the tubular member 13 at a distal point 16 of the tubular member 13.

[0020] A distal part 18 of the elongate element 12, distally of the point 16 has an irregularly shaped configuration 20, such as a loop-shape as shown in Fig. 1 of the drawings. It will, however, be appreciated that the distal part 18 of the elongate element could have any other desired irregularly shaped configuration 20. The distal part 18 is, for example, implemented as an extension of the actuator received in the tubular member 13 as described in greater detail in PCT/AU2005/000216.

[0021] The shape imparting mechanism 10 includes an insertion facilitating arrangement 22. In this embodiment, the insertion facilitating arrangement 22 is a sleeve 24 displaceably received on the elongate element 12. The sleeve 24 is axially displaceable on the elongate element 12 between a first, retracted position, shown in Fig. 1 of the drawings, in which the loop shape 20 of the distal part 18 of the elongate element 12 is exposed and a second, extended position, as shown in Fig. 2 of the drawings, in which the sleeve 24 overlies the distal part 18 of the elongate element 12 to collapse the elongate element 12 into a substantially rectilinear, or straight, configuration.

[0022] A distal end of the elongate element 12 carries a withdrawal inhibiting means in the form of an enlarged formation such as a deposit of adhesive or a crimped formation to inhibit withdrawal of the extreme distal end of the elongate element 12 into the sleeve 24.

[0023] As described in Applicant's co-pending Application No. PCT/AU2005/000216, referenced above, the steering mechanism described in that specification has a bend-enhancing portion arranged proximally of the distal point 16. When the sleeve 24 is in the second position, as shown in Fig. 2 of the drawings, the bend-enhancing region (not shown) of the tubular member 13 is exposed proximally of the sleeve 24 enabling the distal part 18 of the elongate element 12 to be steered through the patient's body to the desired site. When the sleeve 24 is moved to its first position the bend-enhancing region of the tubular member 13 is exposed distally of the sleeve 24. This allows the irregularly shaped configuration 20 of the elongate element 18 to be steered into position at the desired location at the site to be treated in the patient's body.

[0024] Thus, in use, for insertion of a catheter incorporating a shape imparting mechanism 10 into the vasculature of the patient's body, the sleeve 24 is arranged in its second configuration, as shown in Fig. 2 of the drawings. The shape imparting mechanism 10 is received within a lumen of the electrode sheath 14, as described above, so that, as shown in Fig. 3 of the drawings, a distal part 26 of the electrode sheath carrying the electrodes 28 is, correspondingly, in a straight or rectilinear configuration. This facilitates steering of the distal part 26 of the electrode sheath 14 through the vasculature of the patient to the desired site in the patient's body.

[0025] A catheter incorporating the shape imparting

mechanism 10 of this embodiment is intended particularly for use in treating arrhythmias in the left atrium of the patient's heart. Thus, while the distal part 26 of the electrode sheath is in its straight configuration, the electrode sheath 14 can be steered through the patient's heart into the right atrium, piercing the septum and into the left atrium. When in position in the left atrium, the sleeve 24 is withdrawn to its first position, as shown in Fig. 1 of the drawings, exposing the loop shape 20 of the distal part 18 of the elongate element 12. The distal part 18 of the elongate element 12 is of a shape memory alloy, such as Nitinol, so that, when the sleeve 24 is withdrawn to its first position, the distal part 18 adopts its pre-formed loop shape 20. When this occurs, a corresponding loop shape 30 (Fig. 4) is imparted to the distal part 26 of the electrode sheath 14 of the catheter.

[0026] Referring now to Figs. 5 and 6 of the drawings, a catheter assembly, in accordance with a further embodiment, is illustrated and is designated generally by the reference numeral 32. The catheter assembly 32 comprises the electrode sheath 14 mounted on a carrier 34 at a distal end of a handle 36 of the assembly 32. The handle 32 also carries the shape imparting mechanism 10 which is not shown in Figs. 5 and 6 as it is received within the lumen of the electrode sheath 14.

[0027] The handle 36 comprises an elongate body 38 with the carrier 34 mounted at a distal end of the body 38. A control mechanism in the form of a slide 40 is mounted on the handle 38 and is displaceable axially to control steering of the distal end 26 of the electrode sheath 14 via the shape imparting mechanism 10 which is connected to the slide 40 within the body 38.

[0028] The assembly 32 includes a further control mechanism, also in the form of a slide 42, which is axially displaceable on the body 38 between a first position, as shown in Fig. 5 of the drawings and a second position as shown in Fig. 6 of the drawings. The sleeve 24 of the insertion facilitating arrangement 22 of the shape imparting mechanism 10 is connected to the slide 42 so that, when the slide 42 is in the position shown in Fig. 5 of the drawings, the sleeve 24 is in its first position. Conversely, when the slide 42 is in its second position, as shown in Fig. 6 of the drawings, the sleeve 24 is, correspondingly, in its second position overlying the distal part 18 of the elongate element 12 of the shape imparting mechanism 10.

[0029] Reverting to Fig. 1 of the drawings, it is to be noted that a tip 44 of the distal part 18 of the shape imparting mechanism 10 has a rounded configuration to facilitate insertion into the lumen of the electrode sheath 14 and to inhibit the formation of a discontinuity which can snag on the wall of the lumen of the electrode sheath 14.

[0030] Referring now to Figs. 7A-7D, 8 and 9 of the drawings, another embodiment of the shape imparting mechanism 10 is illustrated. With reference to the previous drawings, like reference numerals refer to like parts, unless otherwise specified.

[0031] In this embodiment, the insertion facilitating arrangement 22 of the shape imparting mechanism 10 comprises a kink 46 imparted to the distal part 18 of the elongate element 12 proximally of the rounded tip 44 of the elongate element 12. Further, the kink 46 is arranged distally of the irregularly shaped configuration 20 of the distal part 18 of the elongate element 12 to facilitate insertion of the irregularly shaped configuration 20 of the elongate element 12 into the lumen of the electrode sheath 14.

[0032] As illustrated more clearly in Figs. 8 and 9 of the drawings, the kink 46 defines an angled distal portion 48 which is arranged at a predetermined, acute angle A (Fig. 9) relative to an axis 50 of a part 52 of the elongate element 12 arranged immediately proximally of the kink 46.

[0033] Typically, a lumen 54 (Fig. 9) of the electrode sheath 14 has an inner diameter of approximately 1 mm to 1.5 mm. The length of the kink 46 and the angle A are governed by the inner diameter of the lumen 54 of the electrode sheath 14. For example, the length of the kink 46 may be of the order of about 2 mm at an angle A of up to 45° to facilitate insertion of the irregularly shaped configuration 20 of the distal part 18 of the elongate element 12 into the lumen 54 of the catheter 14.

[0034] Figs. 7A-7D show variations of the irregularly shaped configurations 20 which could be imparted to the distal part 18 of the elongate element 12 of the shape imparting mechanism 10. It will be understood that this is not an exhaustive illustration of the variations of irregularly shaped configurations 20 in which the distal part 18 could be configured. They are included for illustrative purposes only. It will, however, be noted that, in each case, the kink 46 is arranged distally of the irregularly shaped configuration 20 of the distal part 18 of the elongate element 12.

[0035] In this embodiment, in use, the elongate element 12 is inserted into the lumen 54 of the electrode sheath 14 by inserting the kink 46 into the lumen 54 of the electrode sheath 14. The rounded tip 44 and rounded transition 56 between the kink 14 and the part 52 of the distal part 18 of the elongate element inhibits discontinuities and facilitates sliding movement of the distal part of the elongate element 12 within the lumen 54 of the electrode sheath 14 of the catheter.

[0036] Referring now to Figs. 10-15 of the drawings, another embodiment of a catheter assembly 60 is described. With reference to the previous drawings, like reference numerals refer to like parts unless otherwise specified. In this embodiment, the catheter assembly 60 includes a shape imparting element 10 such as that described above with reference to Figs. 1-4 of the drawings. The assembly 60 also includes an electrode sheath 14.

[0037] The distal part 26 of the electrode sheath 14 is formed into an irregularly shaped configuration 62 corresponding to the irregularly shaped configuration 20 of the distal part 18 of the shape imparting element 10. For example, as illustrated, the distal part 26 of the assembly

60 is formed into a loop shape 62.

[0038] The electrode sheath 14 is manufactured in accordance with the Applicant's manufacturing technique as described in its International Patent Application No. PCT/AU01/01339, referenced above. In an initial step of the manufacturing process, an electrical lead is provided in which the lumen carries a core of a malleable material such as, for example, a copper core. To form the loop shape 62 at the distal part 26 of the electrode sheath 14, the distal part 26 is heat set into the required shape. This is achieved by forming the loop shape 62 with the copper core in the lumen of the electrode sheath 14. The electrode sheath 14 is then placed in an oven at a temperature of about 140 °C to 150 °C for approximately 5 minutes. This allows the distal part 26 of the electrode sheath 14 to set in the desired loop shape 62.

[0039] After heat treatment, the electrode sheath 14 is removed from the oven, is straightened out and the copper core is removed. When released from the straight shape, the plastics forming the lumen of the electrode sheath 14 re-forms into the loop shape 62.

[0040] To use the assembly 60, the electrode sheath 14 is, initially, used with a straight stylet 64 (Fig. 14). The straight stylet 64 is of the type described in the Applicant's co-pending International Patent Application No. PCT/AU2005/000216, referenced above. Thus, the stylet 64 has a bend-enhancing portion 66 at a distal region of the stylet 64.

[0041] The stylet 64 is inserted into the lumen of the electrode sheath 14 and is driven fully home so that the loop shape 62 is straightened out as shown in Fig. 15 of the drawings under the effect of the stylet 64. In other words, the distal part 26 of the electrode sheath 14 adopts a straight configuration.

[0042] In this configuration, the electrode sheath 14 is inserted into the vasculature of the patient's body and is steered to the desired site in the patient's body. At the desired site, the straight stylet 64 is removed from the lumen of the electrode sheath 14. Withdrawing the stylet 64 causes the loop shape 62 to re-form at the distal part 26 of the electrode sheath 14.

[0043] The shape imparting element 10 is then inserted into the lumen of the electrode sheath 14. Prior to insertion, the sleeve 24 of the insertion mechanism 22 is moved to the position shown in Fig. 2 of the drawings so that the loop shape 20 at the distal part 18 of the shape imparting mechanism 10 is straightened out.

[0044] When the tip of the shape imparting mechanism 10 reaches the distal part 26 of the electrode sheath 14 and, prior to being inserted into the loop shape 62 of the electrode sheath 14, the sleeve 24 is withdrawn from the loop shape 20 of the shape imparting mechanism 10. The distal part 18 of the shape imparting mechanism is, however, constrained in the lumen of the electrode sheath 14 which inhibits the loop shape re-forming.

[0045] The distal part 18 of the shape imparting mechanism 10 is then driven fully home so that the distal part 18 of the shape imparting mechanism 10 is coincident with the loop shape 62 of the electrode sheath 14. Because the distal part 18 of the shape imparting mechanism 10 is similar to the loop shape 62 of the electrode sheath 14, when the distal part 18 is received within the loop shape 62 of the electrode sheath 14, the distal part 18 limits distortion of the distal part 62 of the electrode sheath 14 so that it maintains its desired pre-formed shape.

[0046] It will be appreciated that while the embodiment above has been described with reference to the distal parts 18 and 62 being loop-shaped, the distal parts 18 and 62 could be pre-formed into any desired shape necessary.

[0047] It is an advantage of the invention that a shape-imparting mechanism 10 is provided which facilitates insertion into the lumen of an electrode sheath 14 of a catheter. It is a further advantage of the invention that a catheter assembly 60 is provided which has a pre-formed distal shape 62 which is coincident with a pre-firmed distal part 18 of a shape imparting mechanism 10 received therein so that distortion of the distal part 62 of the electrode sheath 14 is limited when the shape imparting mechanism 10 is received within the lumen of the electrode sheath 14.

[0048] 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 shape imparting mechanism (10) for a catheter, the shape imparting mechanism including:

   an elongate element (12) dimensioned to fit within a lumen (54) of an electrode sheath (14) of a catheter, a distal part (18) of the elongate element (12) having a non-rectilinearly shaped part (20);

   a sleeve (24) received on the elongate element (12), the sleeve (24) being axially displaceable relative to the elongate element (12) between a second, extended position in which the non-rectilinearly shaped part (20) of the elongate element (12) is collapsed into a substantially rectilinear configuration by the sleeve (24), and a first, retracted position in which the non-rectilinearly shaped part (20) of the elongate element (12) adopts its non-rectilinear shape;

   characterized in that

   the elongate element (12) has a bend enhancing portion arranged proximally of the non-rectilinearly shaped part (20), wherein the bend enhancing portion is exposed distally of the sleeve

(24) to facilitate steering of the non-rectilinearly shaped part (20) of the elongate element (12) when the sleeve (24) is in its first position.

2. The mechanism of claim 1 in which a tip (44) of the elongate element (12) is rounded to aid insertion into the lumen (54) of the electrode sheath (14) of the catheter.

3. The mechanism of claim 1 in which the elongate element (12) includes a withdrawal inhibiting means at its distal end to inhibit withdrawal of the distal end of the elongate element (12) into the sleeve (24).

4. The mechanism of claim 1 or claim 3 in which at least the distal part (18) of the elongate element (12) is of a shape memory material which allows the distal part (18) to adopt its non-rectilinear shape when the sleeve (24) is in its first position.

5. The mechanism of any one of claims 1 to 4 in which the bend enhancing portion is exposed proximally of the sleeve (24), when the sleeve (24) is in its second position.

6. The mechanism of any one of claims 2 to 5 in which a kink (46) is imparted to a distal part of the elongate element (12), proximally of the tip (44) of the elongate element (12).

7. The mechanism of claim 6 in which the kink (46) is arranged distally of the non-rectilinearly shaped part (20) of the elongate element (12), the kink (46) defining an angled distal portion which is arranged at a predetermined, acute angle relative to an axis of the part of the elongate element (12) arranged proximally of the kink (46).

8. A catheter assembly (32) which includes:

a handle (36) having a proximal end and a distal end;
a shape imparting mechanism (10), as claimed in any of claims 1 to 7 extending from the distal end of the handle (36);
an electrode sheath (14) carried on the distal end of the handle (36) with the shape imparting mechanism (10) being received within a lumen (54) of the electrode sheath (14); and
a control mechanism carried on the handle (36) for effecting control of the axial displacement of the sleeve (24) of the shape imparting mechanism (10).

9. The assembly of claim 8 in which the control mechanism comprises a slider arrangement (42) which is axially slidably arranged on the handle (36) to facilitate displacement of the sleeve (24) from its first position to its second position and vice versa.

10. The assembly of claim 8 or 9 in which the electrode sheath (14) has a distal end pre-formed into a predetermined shape.

11. The assembly of claim 10 in which the pre-formed distal end of the electrode sheath (14) has a shape corresponding to the non-rectilinearly shaped part (20) of the distal part (18) of the elongate element (12).

Patentansprüche

1. Formgebungsmechanismus (10) für einen Katheter, wobei der Formgebungsmechanismus umfasst:

ein längliches Element (12), das bemessen ist, in ein Lumen (54) einer Elektrodenhülse (14) eines Katheters zu passen, wobei ein distaler Teil (18) des länglichen Elements (12) einen nicht-geradlinig geformten Teil (20) hat;
eine auf dem länglichen Element (12) aufgenommene Hülle (24), wobei die Hülle (24) relativ zu dem länglichen Element (12) zwischen einer zweiten, ausgestreckten Position, in welcher der nicht-geradlinig geformte Teil (20) des länglichen Elements (12) durch die Hülle (24) zu einer im Wesentlichen geradlinigen Konfiguration kollabiert wird, und einer ersten, eingezogenen Position, in welcher der nicht-geradlinig geformte Teil (20) des länglichen Elements (12) seine nicht-geradlinige Form annimmt, axialversetzbar ist;
dadurch gekennzeichnet, dass
das längliche Element (12) einen Biegungsunterstützungsabschnitt hat, der proximal zu dem nicht-geradlinig geformten Teil (20) angeordnet ist, wobei der Biegungsunterstützungsabschnitt distal zu der Hülle (24) freiliegt, um ein Lenken des nicht-geradlinig geformten Teils (20) des länglichen Elements (12) zu erleichtern, wenn die Hülle (24) in ihrer ersten Position ist.

2. Mechanismus gemäß Anspruch 1, bei dem eine Spitze (44) des länglichen Elements (12) gerundet ist, um eine Einführung in das Lumen (54) der Elektrodenhülse (14) des Katheters zu unterstützen.

3. Mechanismus gemäß Anspruch 1, bei dem das längliche Element (12) ein Rückzieh-Hemmmittel an seinem distalen Ende umfasst, um ein Rückziehen des distalen Endes des länglichen Elements (12) in die Hülle (24) zu hemmen.

4. MechanismusgemäßAnspruch 1 oderAnspruch 3, bei dem wenigstens der distale Teil (18) des längli-

chen Elements (12) aus einem Formgedächtnismaterial besteht, das ermöglicht, dass der distale Teil (18) seine nicht-geradlinige Form annimmt, wenn die Hülle (24) in ihrer ersten Position ist.

5. Mechanismus gemäß Anspruch 1 bis 4, bei dem der Biegungsunterstützungsabschnitt proximal zu der Hülle (24) freiliegt, wenn die Hülle (24) in ihrer zweiten Position ist.

6. Mechanismus gemäß einem der Ansprüche 2 bis 5, bei dem ein Knick (46) in einen distalen Teil des länglichen Elements (12), proximal zu der Spitze (44) des länglichen Elements (12), eingebracht ist.

7. Mechanismus gemäß Anspruch 6, bei dem der Knick (46) distal zu dem nicht-geradlinig geformten Teil (20) des länglichen Elements (12) angeordnet ist, wobei der Knick (46) einen winkligen distalen Abschnitt bestimmt, der in einem vorbestimmten, spitzen Winkel relativ zu einer Achse des proximal zu dem Knick (46) angeordneten Teils des länglichen Elements (12) angeordnet ist.

8. Katheteranordnung (32), welche umfasst:

einen Griff (36) mit einem proximalen Ende und einem distalen Ende;
einen Formgebungsmechanismus (10) gemäß einem der Ansprüche 1 bis 7, der sich von dem distalen Ende des Griffs (36) erstreckt;
eine Elektrodenhülse (14), die auf dem distalen Ende des Griffs (36) getragen ist, wobei der Formgebungsmechanismus (10) in einem Lumen (54) der Elektrodenhülse (14) aufgenommen ist; und
einen auf dem Griff (36) getragenen Steuermechanismus zum Bewirken einer Steuerung der axialen Versetzung der Hülle (24) des Formgebungsmechanismus (10).

9. Anordnung gemäß Anspruch 8, bei welcher der Steuermechanismus eine Gleitanordnung (42) aufweist, die axial gleitbeweglich an dem Griff (36) angeordnet ist, um eine Versetzung der Hülle (24) aus ihrer ersten Position in ihre zweite Position und umgekehrt zu erleichtern.

10. AnordnunggemäßAnspruch 8 oder 9, bei derdie Elektrodenhülse (14) ein distales Ende hat, das zu einer vorbestimmten Form vorgeformt ist.

11. Anordnung gemäß Anspruch 10, bei der das vorgeformte distale Ende der Elektrodenhülse (14) eine Form hat, die dem nicht-geradlinig geformten Teil (20) des distalen Teils (18) des länglichen Elements (12) entspricht.

Revendications

1. Mécanisme conférant une forme (10) pour un cathéter, le mécanisme conférant une forme comportant :

un élément oblong (12) dimensionné pour passer à l'intérieur d'un lumen (54) d'une gaine d'électrode (14) d'un cathéter, une partie distale (18) de l'élément oblong (12) possédant une partie en forme non-rectiligne (20) ;
un manchon (24) accroché sur l'élément oblong (12), le manchon (24) étant déplaçable axialement par rapport à l'élément oblong (12) entre une seconde position projetée, dans laquelle la partie en forme non-rectiligne (20) de l'élément oblong (12) est affaissée dans une configuration principalement rectiligne par le manchon (24), et une première position rétractée dans laquelle la partie en forme non-rectiligne (20) de l'élément oblong (12) adopte sa forme non-rectiligne ;
caractérisé en ce que
l'élément oblong (12) possède une partie renforçatrice de pliage agencée proximalement de la partie en forme non-rectiligne (20), dans lequel la partie renforçatrice de pliage est exposée distalement du manchon (24) afin de faciliter le guidage de la partie en forme non-rectiligne (20) de l'élément oblong (12) lorsque le manchon (24) est dans sa première position.

2. Mécanisme selon la revendication 1 dans lequel une extrémité (44) de l'élément oblong (12) est arrondie afin d'aider à l'introduction dans le lumen (54) de la gaine d'électrode (14) du cathéter.

3. Mécanisme selon la revendication 1 dans lequel l'élément oblong (12) comprend un moyen d'inhibition du retrait sur son embout distal afin d'inhiber le retrait de l'embout distal de l'élément oblong (12) dans le manchon (24).

4. Mécanisme selon la revendication 1 ou la revendication 3 dans lequel au moins la partie distale (18) de l'élément oblong (12) est en un matériau de mémoire de forme qui permet à la partie distale (18) d'adopter sa forme non-rectiligne lorsque le manchon (24) est dans sa première position.

5. Mécanisme selon une quelconque des revendications 1 à 4 dans lequel la partie renforçatrice de pliage est exposée proximalement du manchon (24), lorsque le manchon (24) est dans sa seconde position.

6. Mécanisme selon une quelconque des revendications 2 à 5 dans lequel une coque (46) est conférée sur une partie distale de l'élément oblong (12), proxi-

malement de l'extrémité (44) de l'élément oblong (12).

7. Mécanisme selon la revendication 6 dans lequel la coque (46) est agencée distalement de la partie en forme non-rectiligne (20) de l'élément oblong (12), la coque (46) définissant une partie distale angulaire qui est disposée sur un angle aigu prédéterminé par rapport à un axe de la partie de l'élément oblong (12) agencée proximalement de la coque (46).

8. Assemblage de cathéter (32) qui comporte :

une poignée (36) possédant un embout proximal et un embout distal ;
un mécanisme conférant une forme (10), tel que revendiqué dans une quelconque des revendications 1 à 7, se projetant à partir de l'embout distal de la poignée (36) ;
une gaine d'électrode (14) supportée sur l'embout distal de la poignée (36) avec le mécanisme conférant une forme (10) étant reçu dans un lumen (54) de la gaine d'électrode (14) ; et
un mécanisme de contrôle supporté sur la poignée (36) en vue d'effectuer la commande du déplacement axial du manchon (24) du mécanisme conférant une forme (10).

9. Assemblage selon la revendication 8 dans lequel le mécanisme de contrôle comprend un agencement coulissant (42) qui est agencé de manière coulissante axialement sur la poignée (36) afin de faciliter le déplacement du manchon (24) de sa première position vers sa seconde position et inversement.

10. Assemblage selon les revendications 8 ou 9 dans lequel la gaine d'électrode (14) possède un embout distal préfaçonné dans une forme prédéterminée.

11. Assemblage selon la revendication 10 dans lequel l'embout distal préfaçonné de la gaine d'électrode (14) possède une forme correspondant à la partie en forme non-rectiligne (20) de la partie distale (18) de l'élément oblong (12).

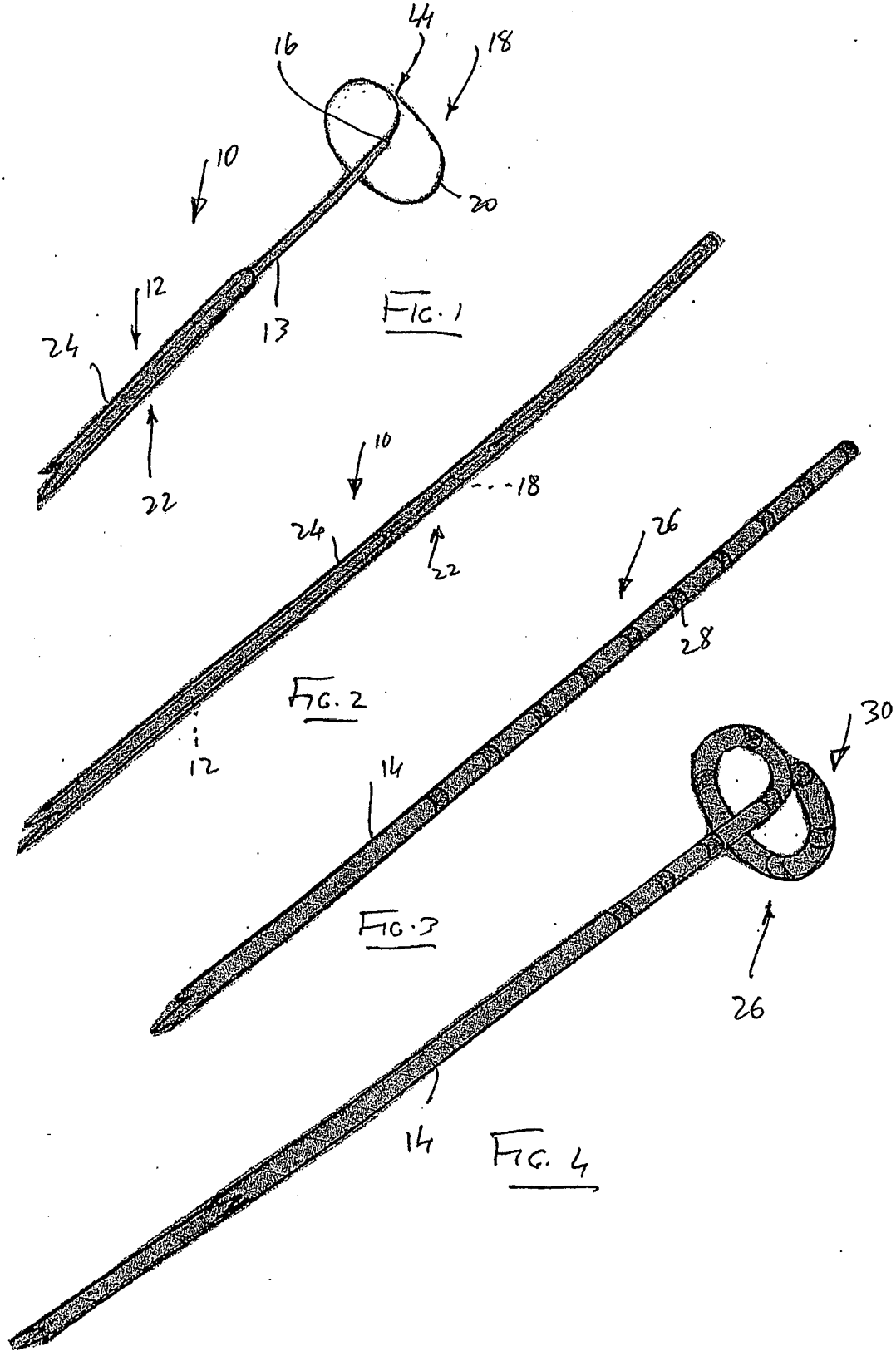

FIG. 1

FIG. 2

FIG. 3

FIG. 4

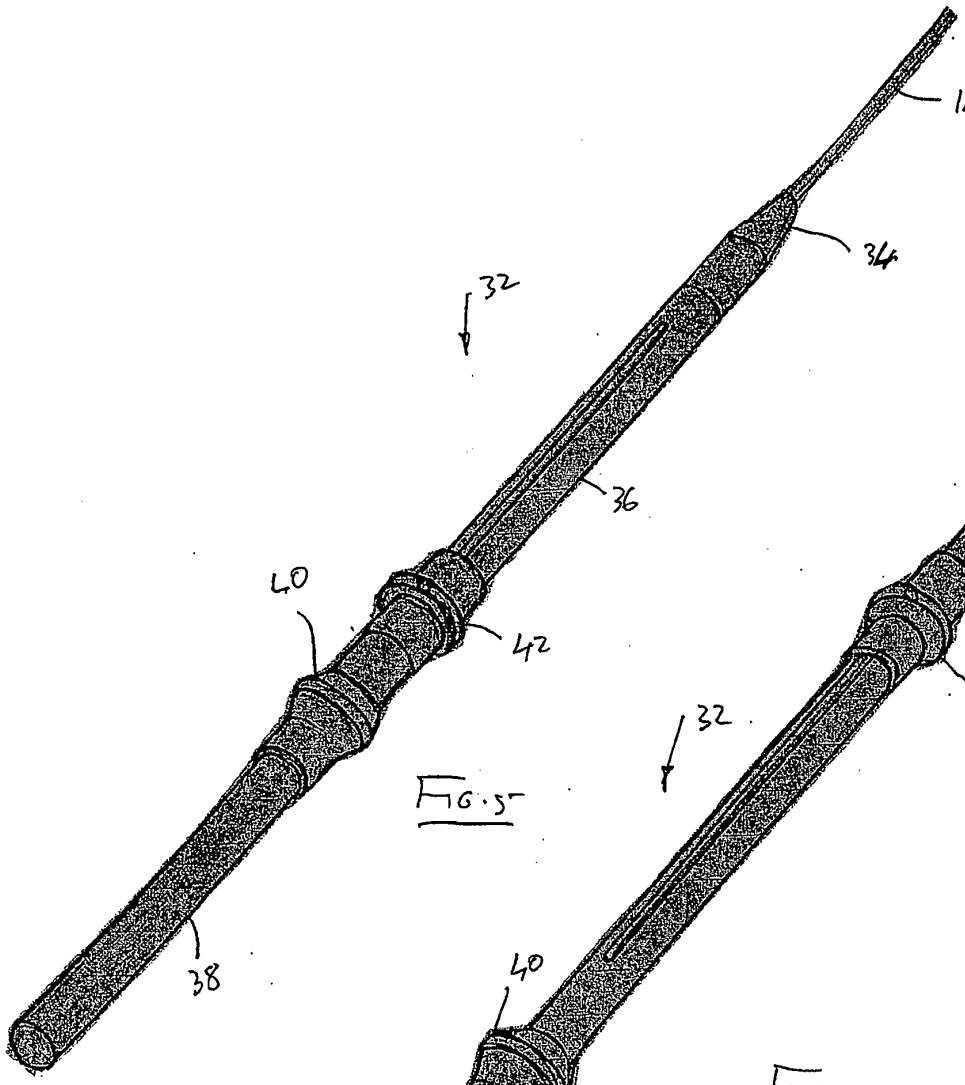

FIG. 5

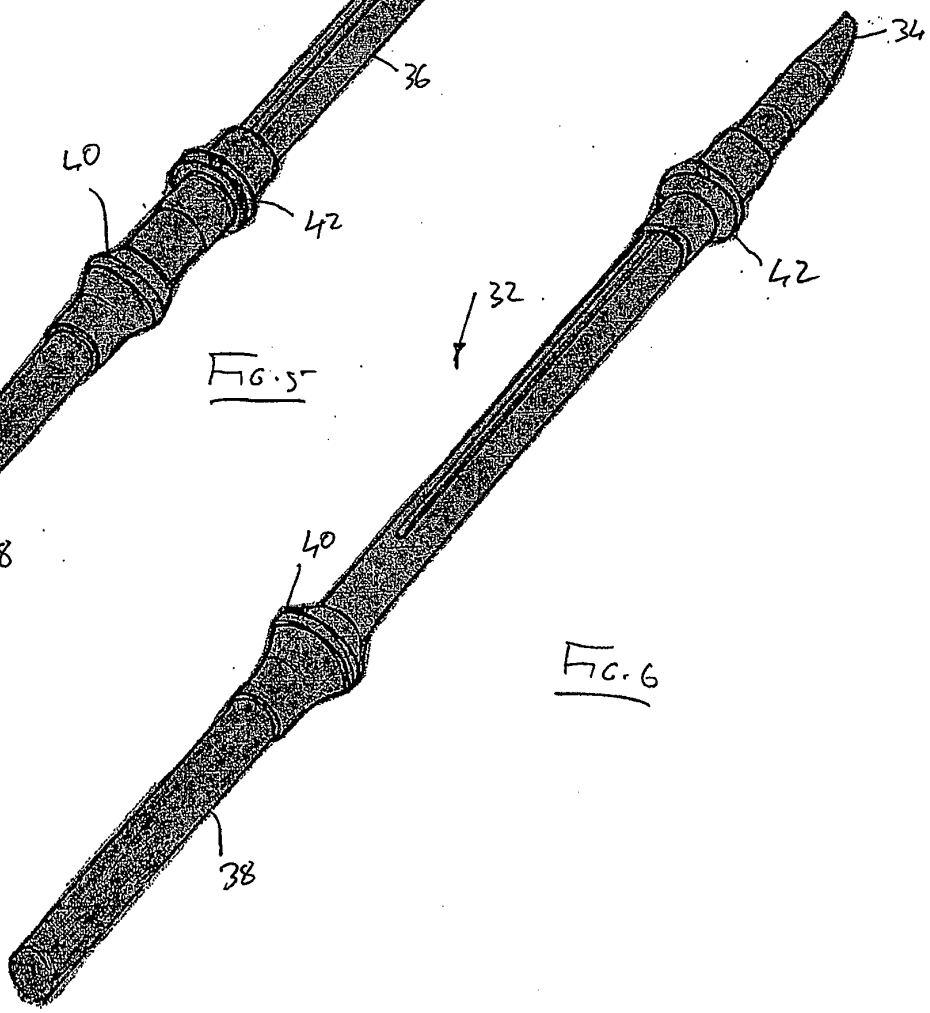

FIG. 6

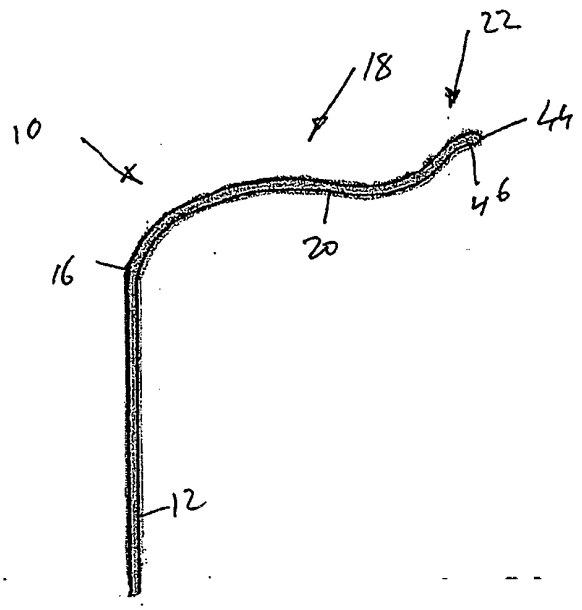

FIG. 7A

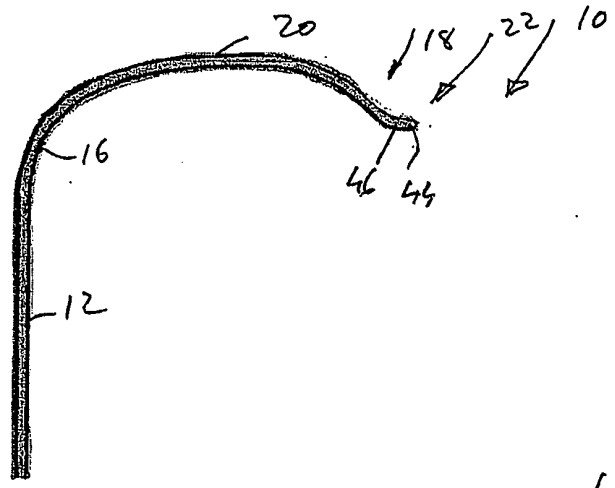

FIG. 7B

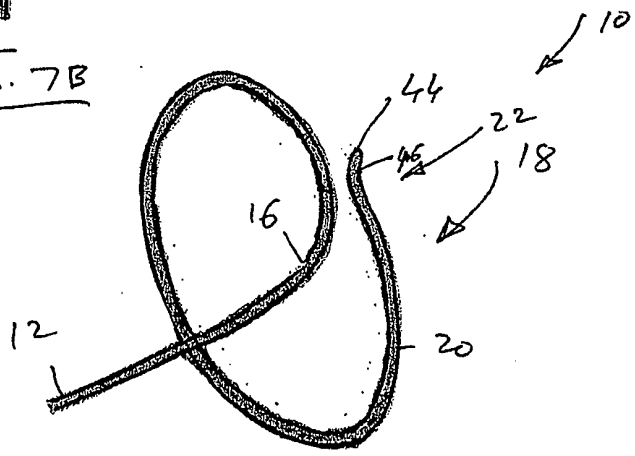

FIG. 7C

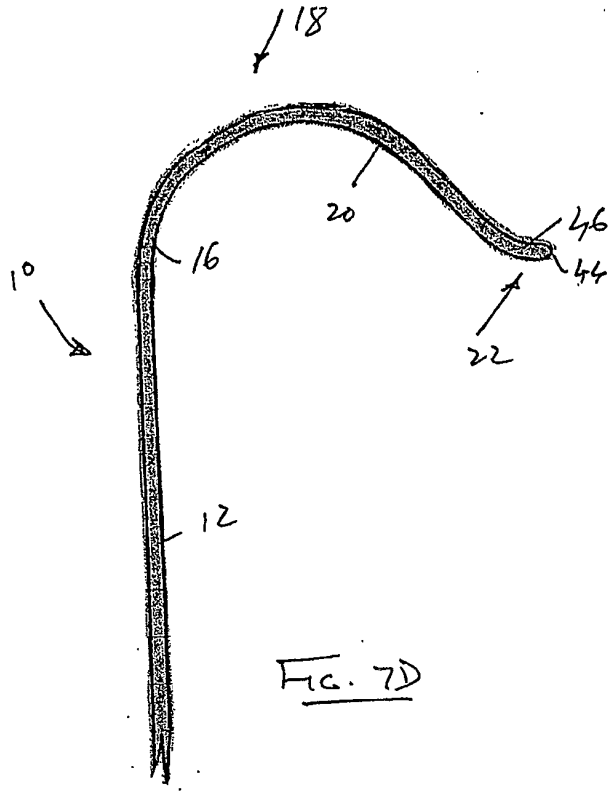

FIG. 7D

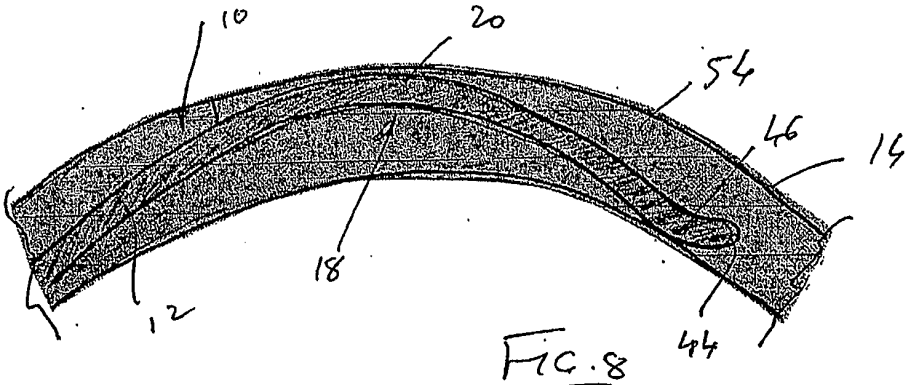

FIG. 8

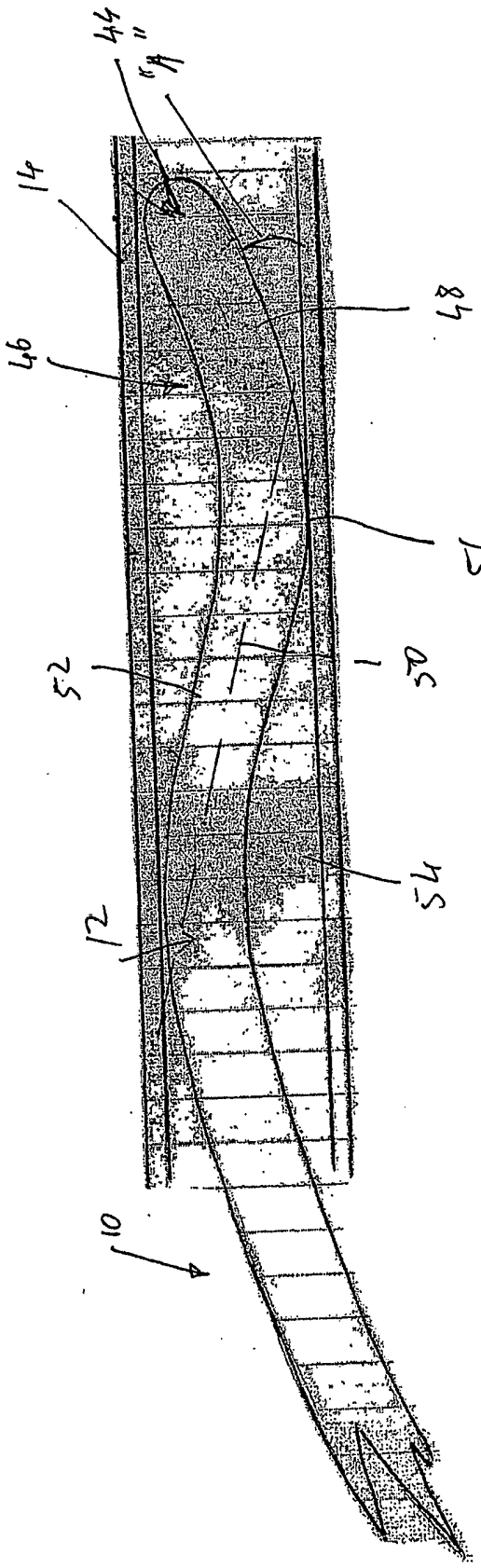

FIG. 9

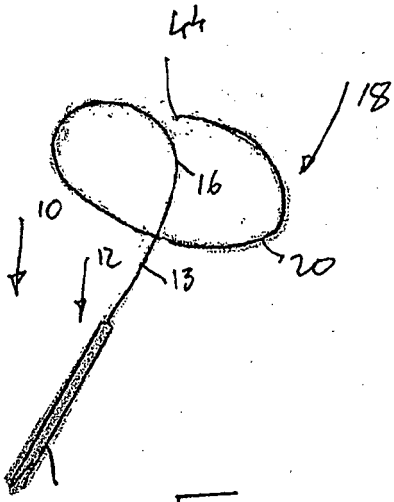

FIG. 10

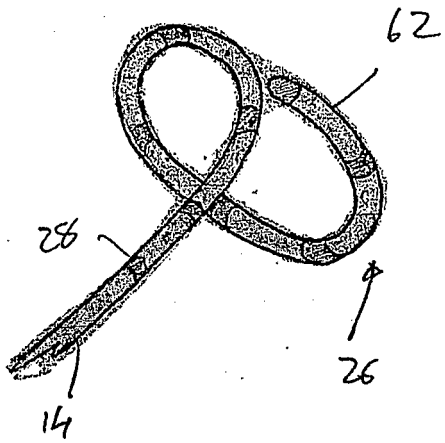

FIG. 11

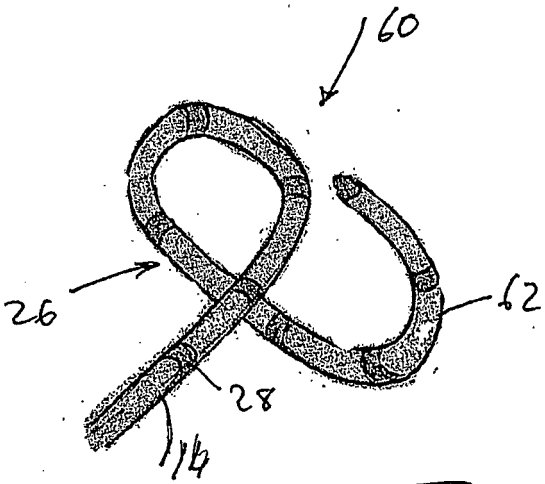

FIG. 12

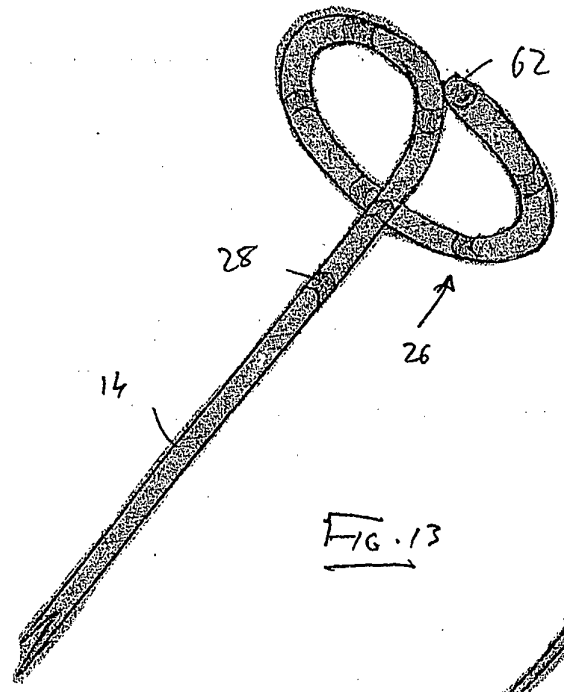

FIG. 13

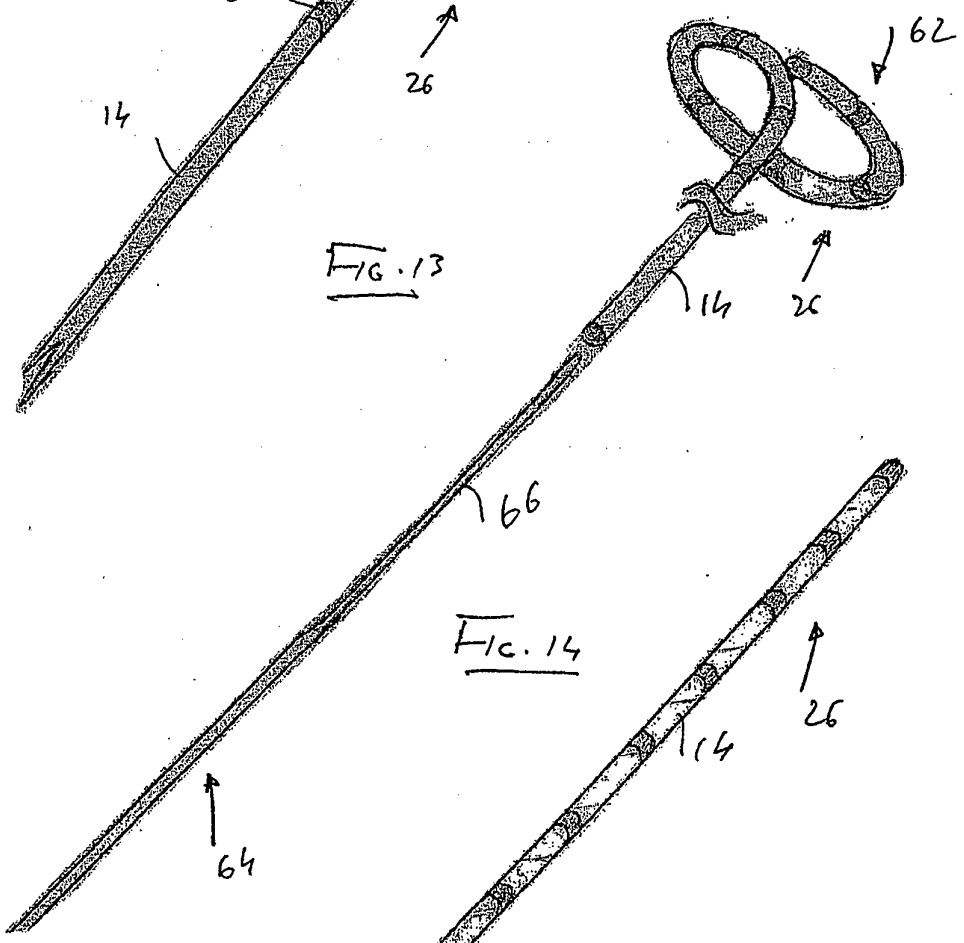

FIG. 14

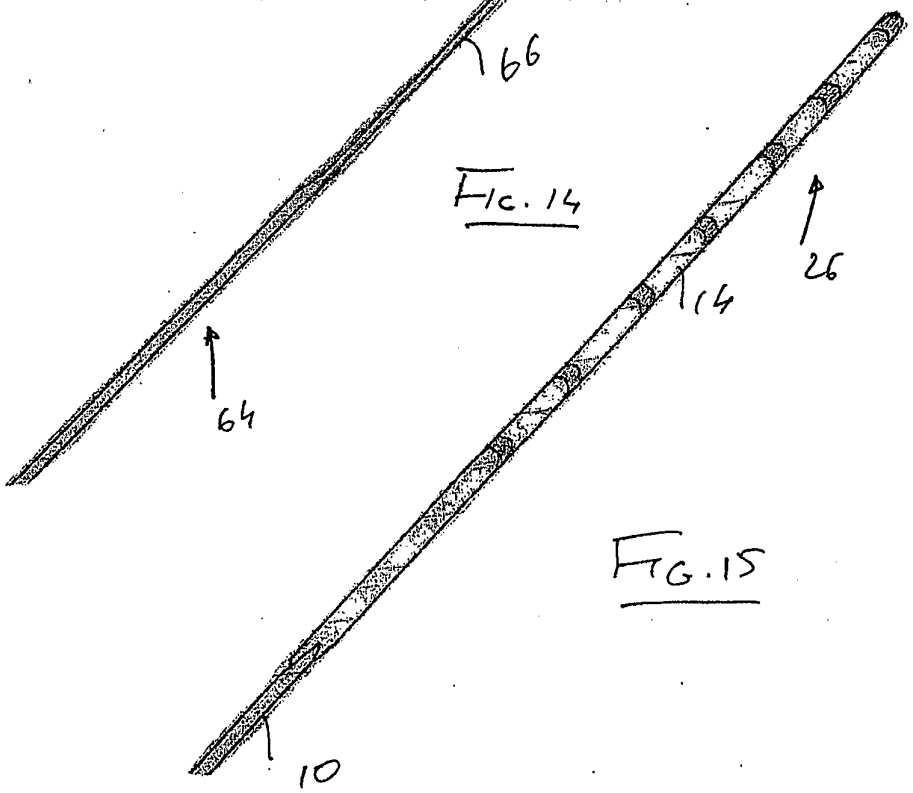

FIG. 15

REFERENCES CITED IN THE DESCRIPTION

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- EP 1048314 A1 **[0005]**

专利名称(译)	形状赋予机构插入		
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申请(专利权)人(译)	CATHRX LTD		
当前申请(专利权)人(译)	CATHRX LTD		
[标]发明人	ANDERSON NEIL LAWRENCE PARTLETT MATTHEW		
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优先权	60/798931 2006-05-08 US		
其他公开文献	EP2015825A1 EP2015825A4		
外部链接	Espacenet		

摘要(译)

用于导管的形状赋予机构（10）包括细长元件（12），其尺寸适于配合在导管的电极护套14的内腔中。插入促进装置（22）承载在细长元件（12）的远端，以便于将细长元件（12）的远端插入导管的电极护套（14）的内腔中。公开了一种制造导管护套的方法。