



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification⁶ :
A61M 25/09, A61N 1/05

A1

(11) International Publication Number: **WO 98/07465**

(43) International Publication Date: 26 February 1998 (26.02.98)

(21) International Application Number: PCT/SE97/01291

(22) International Filing Date: 16 July 1997 (16.07.97)

(30) Priority Data:
9602998-8 16 August 1996 (16.08.96) SE

(71) Applicant (for all designated States except US): PACESETTER AB [SE/SE]; S-175 84 Järfälla (SE).

(72) Inventor; and

(75) Inventor/Applicant (for US only): BOSTRÖM, Mats [SE/SE]; Sturegatan 21, S-172 31 Sundbyberg (SE).

(74) Agent: KALLING, Sven; Pacesetter AB, Patent Dept., S-175 84 Järfälla (SE).

(81) Designated States: JP, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

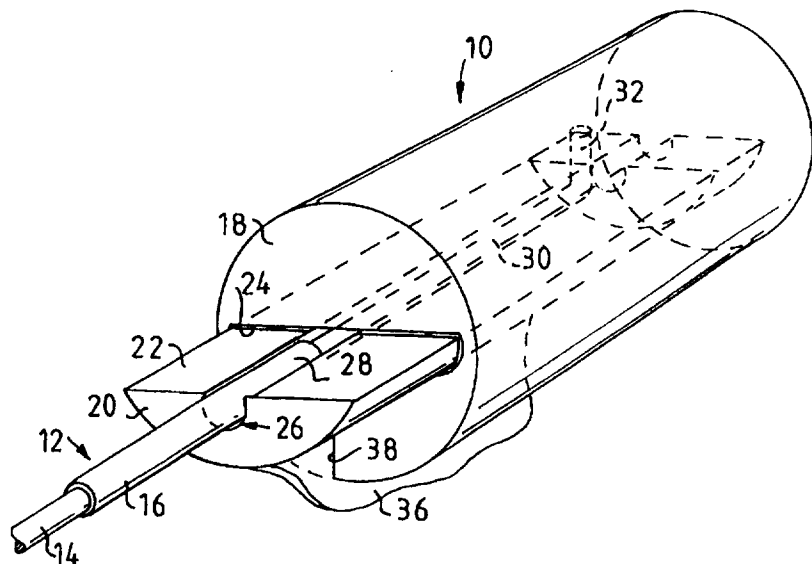
Published

With international search report.

(54) Title: OPERATING DEVICE FOR A STYLET UNIT

(57) Abstract

The invention relates to a device for manipulating a stylet unit (12), comprising a stylet sleeve (16) and a stylet (14), for positioning an electrode cable in a body cavity. The device (10) has a first part and a second part (18, 20), that are able to move in relation to each other. A groove (26) is arranged in the interface area (22) of one part (20), which presses against a flat surface (24) on the other part (18).



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MX	Mexico	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon	KR	Republic of Korea	PL	Poland		
CN	China	KZ	Kazakstan	PT	Portugal		
CU	Cuba	LC	Saint Lucia	RO	Romania		
CZ	Czech Republic	LI	Liechtenstein	RU	Russian Federation		
DE	Germany	LK	Sri Lanka	SD	Sudan		
DK	Denmark	LR	Liberia	SE	Sweden		
EE	Estonia			SG	Singapore		

Operating device for a stylet unit**Field of the invention**

The present invention relates to a device for manipulating a stylet unit,
5 consisting of a stylet sleeve and a stylet located therein, for positioning
an electrode cable in a body cavity, according to the preamble of the
attached main claim.

The prior art

A device for operating a stylet unit of the above kind for achieving a
10 desired stiffening of an electrode cable during its advancement into a body
cavity, e.g. via a vein into the atrium of the heart, and a desired final
position for the distal end of the electrode cable by providing the cable
with a bent L- or J-like shape is previously known through US-A-5 170 787.
Here, the distal end of the stylet is pre-bent and is kept retracted inside
15 the stylet sleeve during the electrode cable's insertion phase, giving the
distal end of the electrode cable an essentially straight shape, the stylet,
in the final positioning of the distal end of the electrode cable, being
exposed outside its tubular sleeve to cause the distal end of the electrode
cable to assume the desired curved shape. In order to achieve the exposure
20 of the pre-bent distal end of the stylet outside its tubular sleeve, the
aforementioned US-A-5 170 787 proposes a device which either moves the
stylet distally in relation to a stationary sleeve or moves the tubular
sleeve proximally in relation to a stationary stylet. In principle, the
latter option is preferable, since it does not entail any movement of the
25 electrode cable in relation to the stylet unit's operating device. The known
operating device comprises two stiff tubes, one telescoping inside the
other, in order to obtain a stiffening that prevents the stylet from
buckling when its free proximal end is slid distally inside the tubular
sleeve respectively when the tubular sleeve is slid proximally over the free
30 proximal end of the stylet in the operating device. This means that the
operating device's total linear elongation is relatively large, since the

total length of the telescoping tubes must be twice the length of the stylet's stroke in relation to the tubular sleeve.

Our previous patent application EP-A-773036 proposed an operating device for
5 a stylet unit of the initially cited kind in which the stiff, telescoping
tubes of the operating device according to the American patent are replaced
by a compressible helical spring which supports the free, proximal end of
the stylet and which, in turn, is guided with a tight fit in an elongate
cavity in a handle housing. In this way the total length of the operating
10 device can be shortened considerably while the number of device parts could
be reduced, resulting in lower manufacturing costs for the operating device.

Summary of the invention

However, the purpose of the present invention is to propose an operating
15 device of the initially mentioned kind which can be even shorter, have even
fewer parts and, accordingly, be made cheaper than previously proposed
devices while retaining the requisite strength and reliability.

For this purpose, the means for stylet support and control in the operating
20 device according to the present invention is characterized by the features
set forth in the characterizing part of the appended main claim. In this
instance, the stiff, telescoping control tubes or the stylet guiding spring
in previously proposed operating devices are not needed and are replaced by
a simple stylet groove at the interface between both main parts of the
25 operating device.

The shortest total length for the operating device is achieved when one of
its parts is devised as a rotatably supported roller body in a handle
section in which the stylet and stylet sleeve are able to traverse a non-
30 linear path when the stylet and stylet sleeve are moved in relation to one
another when the configuration of the distal end of the electrode cable is
to be changed.

Additional features of the operating device according to the invention are set forth in the subsequent dependent claims and will be further described with reference to attached drawings.

5

Description of drawings

FIG. 1 is a schematic, skeleton drawing in perspective of an operating device with linear operation according to a first embodiment of the present invention;

10

FIG. 2 is an end view of the operating device in FIG. 1;

FIG. 3 is a fragmentary, longitudinal sectional view of the operating device in the area of the stylet's attachment to the handle section;

15

FIG. 4 is a schematic, exploded skeleton view in perspective of a second embodiment of an operating device, with non-linear operation, according to the invention;

20 FIG. 5 is a schematic side view of a first, practical embodiment of the operating device, with non-linear operation, according to the invention;

FIG. 6 is a schematic side view of a second, practical embodiment of operating device, with non-linear operation, according to the invention.

25

Preferred embodiments

FIG. 1 shows a schematic view of an embodiment, generally designated 10, of a device according to the invention for manipulating a stylet unit 12 during the introduction and implantation of an electrode cable (not shown) in a body cavity, such as through a vein into the right atrium of the heart, for the purpose of achieving the desired stiffening of the electrode cable

30

during its introduction and achieving the desired positioning and configuration, e.g. a J shape, for the distal end of the electrode cable. The operating device 10 according to the invention is therefore intended for manipulating a stylet unit 12 of the kind comprising an internal stylet 14 enclosed in a tubular sleeve 16, both the sleeve 16 and the stylet 14 being intended for insertion into the central channel of the electrode cable for stiffening the cable during its introduction and for bending the distal end thereof into the desired shape. For this purpose, the distal end section of the internal stylet 12 is pre-bent in the known manner but enclosed inside the tubular sleeve 16 during the electrode cable's advancement in order to keep the distal end of the stylet unit 12 and, accordingly, the electrode cable essentially straight. When the distal end of the electrode cable has been maneuvered into e.g. the right atrium of the heart, the tubular stylet sleeve 16 can be retracted, whereupon the pre-tensioning of the exposed, pre-bent distal end section of the stylet 14 inside the electrode cable causes the distal end section of the electrode cable to bend into the desired shape, e.g. an L shape or a J shape. Alternately, the stylet can be moved out from the stylet sleeve, but this would result in simultaneous retraction of the electrode cable from the operating device. The operating device 10 according to the invention is therefore designed to guide this movement of the stylet sleeve 16 in relation to the stylet 14.

The embodiment of the operating device 10, shown in FIGS. 1-3, according to the invention is of a type with linear operation and comprises, in principle, a first part, for instance a housing 18 devised as a handle, and a second part, devised as a slide, which is supported so as to be linearly movable into and out from the housing 18. The slide 20 has an upper surface 22 which slides with a tight fit against the opposing surface 24 of a cavity in the housing 18. A groove 26, in which a proximal end section 28 of the stylet sleeve 16 is attached, is made on the upper surface 22 of the slide 20. A proximal end section 30 of the stylet 14, which projects from this end section 28, extends to the rear in the groove 26 to an attachment point at

which the end of the stylet 32 is bent up and fastened in a perpendicular blind hole 34 opening onto the groove 26 in the housing 8, as best shown in FIG. 3. The groove 26 and the opposite surface 24 accordingly form a guide channel which encloses the stylet 14 with a relatively tight fit, preventing
5 it from buckling when the slide 20 and stylet sleeve 16 slidably are withdrawn to the rear. The slide 20 has a grip section 36, which extends through a slot 38 into the lower part of the housing 18 to facilitate linear movement of the slide 20 in relation to the housing 18.

10 The operating device according to the embodiment in FIG. 1-3 operates as follows:

Before the electrode cable is introduced into the body cavity, the stylet unit 12 is fully inserted into the electrode cable with the stylet 14
15 enclosed by the stylet sleeve 16, i.e. the operating slide 20 is held in a forward, distal end position in the housing 18. When the tubular sleeve's 16 distal end reaches the distal end of the electrode cable, the latter can be inserted into the body cavity, e.g. the right atrium of the heart. When the cable reaches the atrium, the distal end section of the electrode cable is
20 bent into the desired L shape or J shape by retracting the slide 20, i.e. in a proximal direction, with the fingers, the tubular sleeve 14 accompanying the slide 20 and exposing the pre-bent distal end of the stylet 14 at the distal end of the electrode cable, thus bending the cable into the desired shape depending on how much of the bent, distal end of the stylet is
25 exposed. Here, the primary task of the groove 26 is to enclose or stiffen the proximal, free end section 30 of the stylet 14 with a relatively tight fit, thereby preventing buckling thereof due to friction between the stylet 14 and the sleeve 16 when the latter is retracted along the stylet 14.

30 After the distal end of the electrode cable reaches its final position, it can be actively affixed to the heart wall by manual rotation of a rotation sleeve (not shown), on the proximal end of the slide 20, to which the

electrode cable's proximal contact pin is attached.

Within the scope of the present invention, the relative movement of the housing 8 and slide 20 can alternately be reversed in the embodiment according to FIGS. 1-3, i.e. the proximal end of the stylet 14 can be
5 attached to the slide 20, the stylet housing 16 attached to the housing 18 and the groove 26 devised in the housing, the stylet 14 being insertable into and out of a stationary sleeve 16. However, this means that the distance between the distal end of the electrode cable and the operating
10 device 10 would increase when there is distal displacement of the stylet 14, and the proximal end of the electrode cable therefore must be free to follow this movement.

FIG. 4 shows a skeleton view of an alternative embodiment of the operating
15 device according to the invention, which operates with non-linear relative movement between the stylet and the stylet sleeve. Thus, this embodiment employs a housing 18' in which a roller body 20' is rotatably arranged in a cavity 40 in the housing. The roller body 20' has a peripheral guide groove 26' for the stylet 14, and the housing 18' has a through hole 42 for the
20 proximal end section of the stylet sleeve 16 which is to be fastened to the guide groove 26', The housing 18' further has an attachment point 34', located opposite the stylet groove 26', for the proximal end of the stylet 32. Thus, by rotating the roller body 29' relative to the housing 18', the stylet sleeve 16 can be moved towards the attachment point 34', thereby
25 sliding over the stylet 14, guided so as to prevent stylet buckling in the stylet groove 26', the pre-bent distal end section of the stylet 14 being moved out from the stylet sleeve 16 to the degree required to shape the distal end section of the electrode cable into a suitable J shape. Since non-linear relative motion is achieved between the stylet 14 and the sleeve
30 16, in this instance, the operating device 16 can be devised with a shorter length.

FIGS. 5 and 6 schematically depict two practical embodiments of a control device according to FIG. 4.

In FIG. 5, the housing 18' has been devised as a handle, so rotation of the
5 roller body 20' can be performed with one finger.

In the embodiment according to FIG. 6, the roller body 20" can be rotated in relation to the handle 18" with a lever 44 in the middle of same, so the stylet unit can be manipulated by manually pressing the lever 44 and handle
10 18" towards each other. Here, the lever 44 is preferably pre-tensioned with a spring (not shown) which presses the lever 44 towards an end position away from the housing 18".

In the embodiments according to FIGS. 4-6, the relative movement of the
15 stylet and the stylet sleeve also can be reversed, i.e. the stylet's and sleeve's attachment points and the groove's location in the housing and roller body respectively can change place.

Claims

1. A device for manipulating a stylet unit (12), comprising a stylet sleeve (16) and a stylet (14) located therein, for positioning an electrode cable in a body cavity, said device (10) comprising a first part and a second part (18, 20; 18', 20'; 18'', 20''), which are joined together and movably arranged in relation to each other, one of the said first part and second part being adapted to receive and fixate a proximal end (32, 28) of one of said stylet (14) and stylet sleeve (16), whereas the other of the said first part and second part is adapted to receive and fixate a proximal end (28, 32) of the other stylet (14) and stylet sleeve (16), and a means in the device adapted for supporting and guiding a proximal section (30) of the stylet (14) which projects outside the stylet sleeve (16) when stylet and stylet sleeve move in relation to each other, characterized in that the means adapted for supporting and guiding the stylet (14) consists of a groove, located in one of the mutually moveable parts (8, 20; 18', 20'; 18'', 20''), which is to enclose the stylet (14) and which is devised in the surface of one part in the interface area (22) touching the other part.
2. The device according to claim 1, characterized in that the first part (18; 18'; 18'') is adapted to receive and fixate the proximal end (32) of the stylet (14), whereas the second part (20; 20'; 20'') is adapted to receive the proximal end of (28) of the stylet sleeve (16), said first part (18, 18', 18'') being movably supported relative to said second part (20; 20'; 20'').
3. The device according to claim 2, characterized in that the groove (26; 26') which is to surround the stylet (14) has a depth and width largely corresponding to the diameter of the stylet sleeve (16).

4. The device according to claim 1, **characterized** in that said first part (18; 18'; 18'') is stationary in relation to said second part (20; 20'; 20'') which is movingly supported, said second part being adapted to receive and fixate the proximal end of the stylet (14), whereas said first part is adapted to receive the proximal end of the stylet sleeve (16).
- 5
5. The device according to claim 4, **characterized** in that the groove to enclose the stylet has a depth and width which corresponds at least to the diameter of the stylet (14) but does not essentially exceed the diameter of the stylet sleeve (16).
- 10
6. The device according to any of claims 1-5, **characterized** in that said first part (18) is devised as a handle section, and said second part is devised as a slide (20) capable of linear movement in relation to the handle part.
- 15
7. The device according to any of claims 1-5, **characterized** in that said second part (20) is devised as a handle section, and said first part is devised as a slide (18) capable of linear movement in relation to the handle part.
- 20
8. The device according to any of claims 1-5, **characterized** in that said first part (18'; 18'') is devised as a handle section and said second part as a body (20'; 20'') which is supported so as to be able to rotate in relation to the handle section.
- 25
9. The device according to claim 8, **characterized** in that the rotatable body (20'; 20'') is in the form of a roller body.
- 30
10. The device according to claim 9, **characterized** in that a lever (44), devised to interact with the handle section (18''), is connected to the roller body (20'').

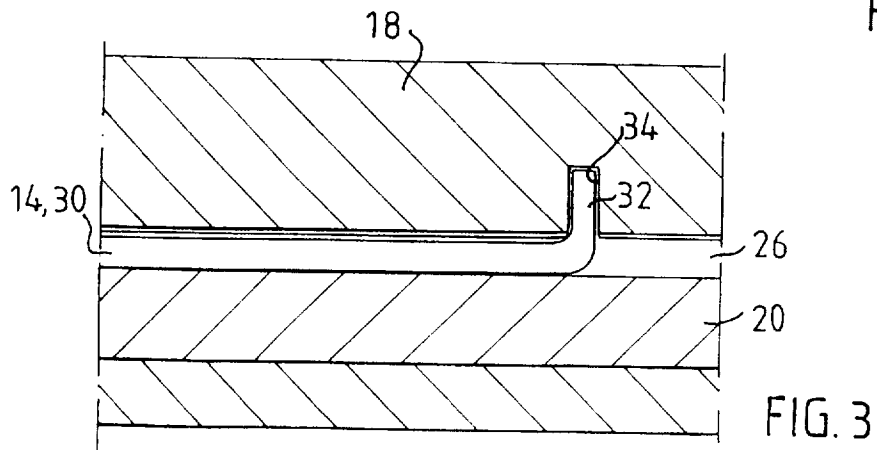
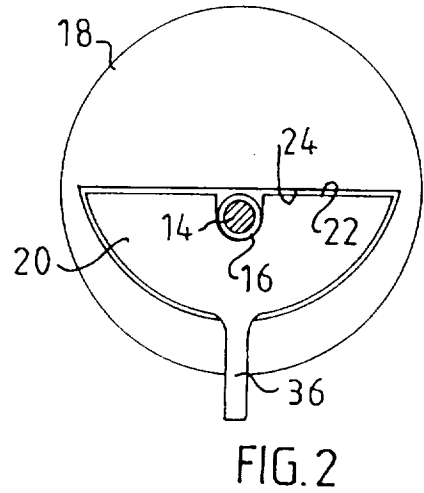
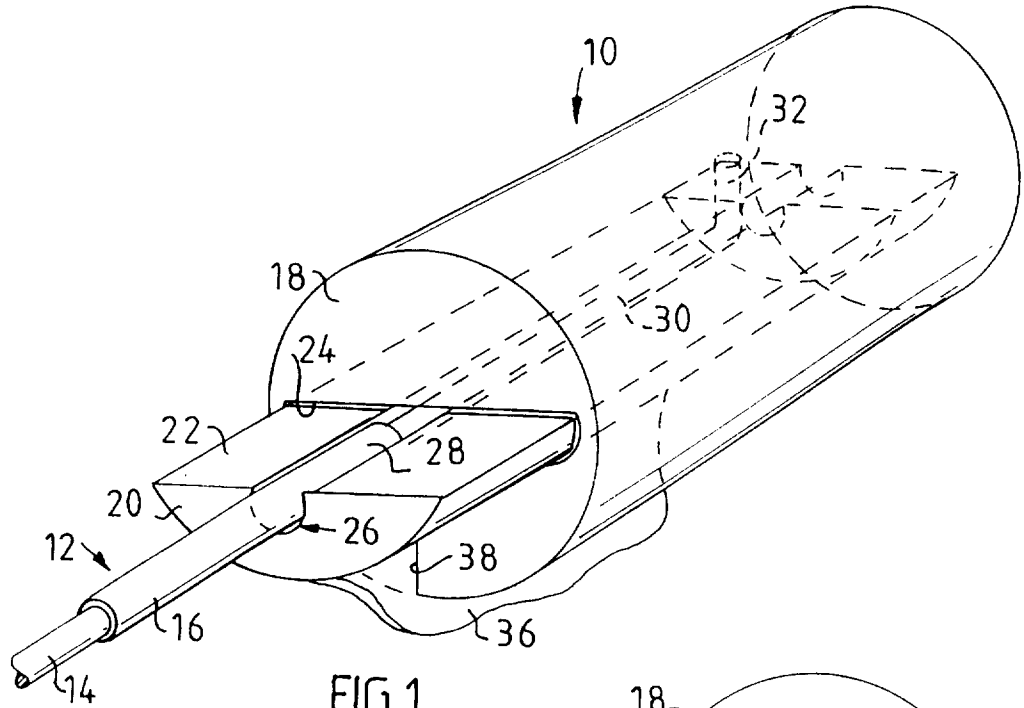
11. The device according to any of claims 1-5, **characterized** in that said second part (20'; 20'') is devised as a handle section and said first part as a body (18'; 18'') which is supported so as to be able to rotate in relation to the handle section.

5

12. The device according to claim 11, **characterized** in that the rotatable body (18'; 18'') is in the form of a roller body.

13. The device according to claim 12, **characterized** in that a lever (44),
10 devised to interact with the handle section (20''), is connected to the roller body (18'').

14. The device according to any of claims 1-13, **characterized** in that the proximal end (32) of the stylet (14) is to be fastened to one of the first
15 and second parts by means of a bend of the end of the stylet which is approx. 90°.



2/2

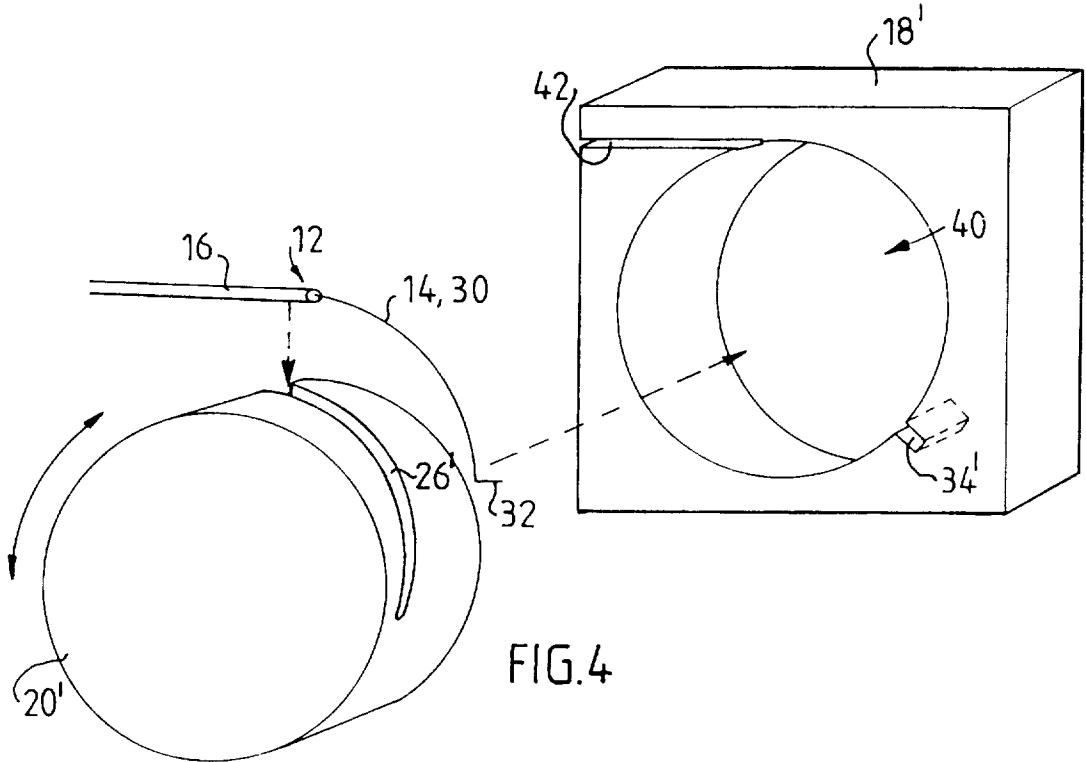


FIG. 4

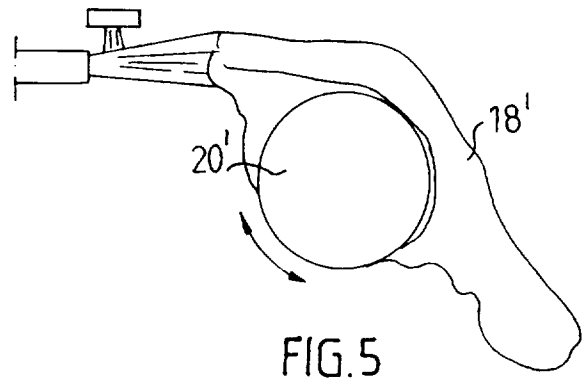


FIG. 5

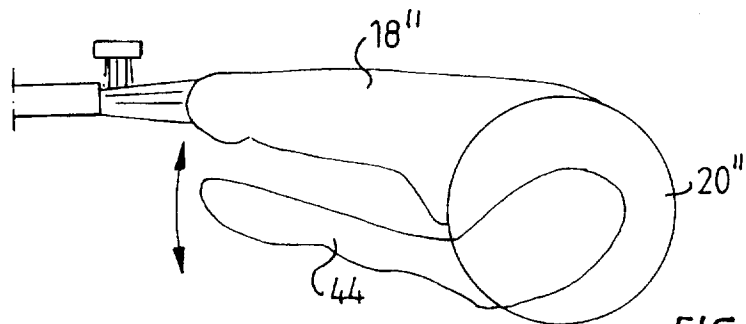


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 97/01291

A. CLASSIFICATION OF SUBJECT MATTER		
IPC6: A61M 25/09, A61N 1/05 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)		
IPC6: A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
SE,DK,FI,NO classes as above		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4858810 A (M.J. INTLEKOFER ET AL.), 22 August 1989 (22.08.89), column 1, line 33 - line 44, figure 1 --	1-14
A	EP 0534747 A1 (COOK INCORPORATED), 31 March 1993 (31.03.93), column 1, line 11 - line 28, figure 1 --	1-14
A	US 5170787 A (U. LINDEGREN), 15 December 1992 (15.12.92), column 1, line 46 - column 2, line 47 --	1-14
A	US 5396902 A (K.R. BRENNEN ET AL.), 14 March 1995 (14.03.95), abstract, the figures --	1-14
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
Date of the actual completion of the international search		Date of mailing of the international search report
16 Sept 1997		24-10-1997
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86		Authorized officer Thomas Skagersten Telephone No. +46 8 782 25 00

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 97/01291

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0050606 A1 (GUSTAVSSON BENGT ET AL.), 28 April 1982 (28.04.82), abstract, the figures --	8-13
A	EP 0368330 A1 (TERUMO KABUSHIKI KAISHA), 16 May 1990 (16.05.90), column 3, line 54 - line 57, figures 1,4 -----	14

INTERNATIONAL SEARCH REPORT
Information on patent family members

01/09/97

International application No.
PCT/SE 97/01291

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4858810 A	22/08/89	NONE	
EP 0534747 A1	31/03/93	AT 148353 T AU 664713 B AU 2527892 A CA 2078925 A DE 69217149 D,T US 5159861 A US 5325746 A JP 6091007 A	15/02/97 30/11/95 01/04/93 28/03/93 28/05/97 03/11/92 05/07/94 05/04/94
US 5170787 A	15/12/92	DE 69019509 D,T EP 0450181 A,B JP 4224769 A SE 9001174 D SE 9002130 D	15/02/96 09/10/91 14/08/92 00/00/00 00/00/00
US 5396902 A	14/03/95	AU 6943494 A CA 2159824 A EP 0702577 A JP 8510666 T WO 9427666 A US 5439006 A	20/12/94 08/12/94 27/03/96 12/11/96 08/12/94 08/08/95
EP 0050606 A1	28/04/82	AT 8578 E,T SE 431062 B,C SE 8007400 A US 4397091 A	15/08/84 16/01/84 23/04/82 09/08/83
EP 0368330 A1	16/05/90	JP 2131776 A	21/05/90