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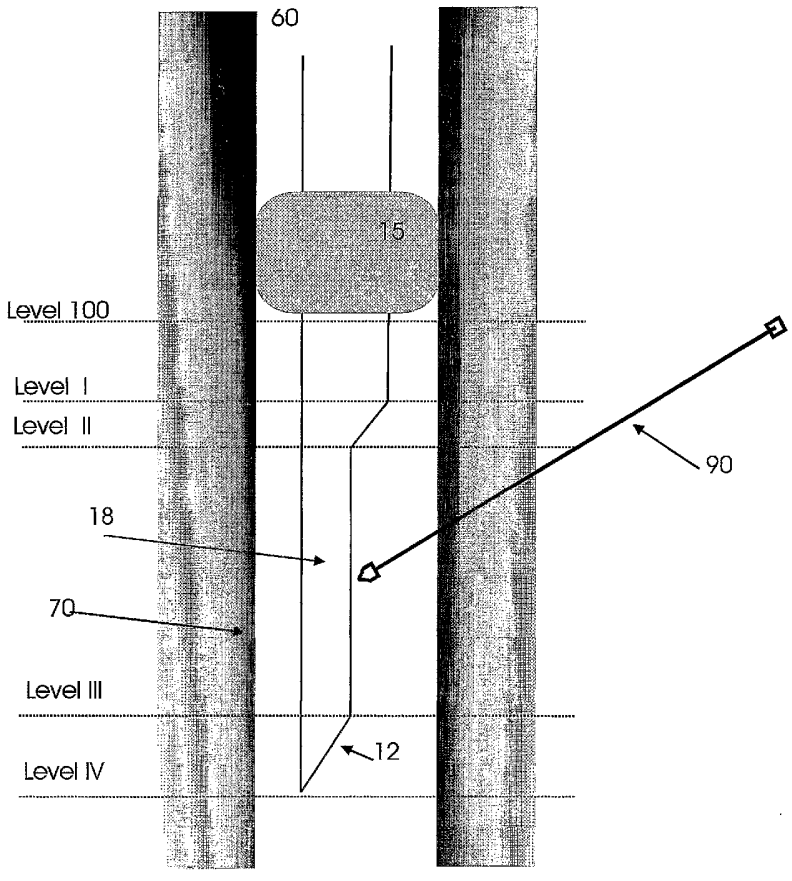
[Continued on next page]

(54) **Title:** ENDOTRACHEAL TUBE WITH TRACHEA PROTECTION



(57) **Abstract:** Trachea-over-protection endotracheal tube, (TOP-tube). TOP-tube is an endotracheal tube (10) characterized in that it has a main part (18) that shields the posterior wall of trachea and protects it from damaging by tracheostomy instruments during any kind of tracheostomy procedure. TOP-tube may have a black line at the concave side (13) as a guide to ensure that the tube is not twisted, can be black colored at a large area to help anyone to use a light-guide instrument (track-light). TOP-tube may have an indicator cuff, it may have a main part with stiff edges that can be expanded after the inflation of an expandable balloon, may have some holes in order to maintain the proper ventilation in cases of tracheal bronchus and it may also have a smooth, round-shaped, patient posterior end, (like a golf club) to protect the trachea during the insertion.

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— *with amended claims*

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.

TITLE OF THE INVENTION

ENDOTRACHEAL TUBE WITH TRACHEA PROTECTION

FIELD OF THE INVENTION

This invention relates to an endotracheal tube and its use during any kind of tracheostomy procedure.

BACKGROUND

A patient may be ventilated and supplied with anaesthetic gas via an airway in the form of an endotracheal tube inserted via the mouth or nose, the patient end being located in the trachea below the vocal chords. In other cases, a laryngeal mask airway may be used for ventilation, the patient end of this device terminating in the region of the pharynx. Alternatively, the patient may be ventilated by means of a tracheostomy tube, the patient end of which is inserted in the trachea via a surgically made opening in the patient's neck. Tracheostomy tubes are preferable for long term use because they do not provide any obstruction in the mouth and are better tolerated by the patient. In some cases, a patient may be ventilated initially using an endotracheal tube and then by a tracheostomy tube, when it becomes apparent that the patient will need prolonged ventilation.The surgical operation needed to introduce the tracheostomy tube involves cutting through the skin and tissue over the trachea in order to make the tracheostomy. One problem with this is that, if the cut is made too deep, it can cause damage to the posterior wall of the trachea. This risk is particularly great where a percutaneous or cricothyroid puncture tracheostomy is made.

OBJECT OF THE INVENTION

The object of the present invention is to provide an improved endotracheal tube, which offers major protection of the posterior wall of the trachea during any kind of tracheostomy procedure.

SUMMARY OF THE INVENTION

According to the aspect of the present invention there is provided an endotracheal tube of the above-specified kind, characterized in that it has a main part that shields the posterior wall of the trachea and protects it from damaging by the tracheostomy instruments during tracheostomy procedure. This main part of the tube lies just above the patient's end of the endotracheal tube, which is located in patient's trachea. Just above this main part there is a middle part of the tube that lies just below the inflated cuff, which is placed (the cuff) just above the vocal cords during the tracheostomy procedure.

The endotracheal tube may have a black line at the concave side as a guide to ensure that the tube is not twisted.

The endotracheal tube may be black colored at an area that can include the inflated cuff, the middle part and the main part in order to help anyone who wants to use a light-guided instrument (a track-light for example), as a guide of the exact location of the main part of the endotracheal tube.

The endotracheal tube may have an indicator cuff at the front side of the main part to ensure that the tracheostomy instrument is at the right position.

The endotracheal tube may have a main part with stiff edges that can be expanded after the inflation of an expandable balloon which can also be used as an indicator cuff.

The endotracheal tube may have at the one or at both sides some holes in order to maintain the proper ventilation in cases of tracheal bronchus.

The endotracheal tube may also have a smooth, round-shaped, patient posterior end, (like a golf-club) in order to protect the posterior wall of the trachea during the insertion of the tube.

DESCRIPTION OF THE DRAWINGS

Figure 1 is a side view of a usual endotracheal tube in use just before tracheostomy.

Figure 2 is a front view of a usual endotracheal tube just before tracheostomy.

Figure 3 is a sectional front view of the patient end of a usual endotracheal tube.

Figure 4 is a sectional side view of a usual endotracheal tube during the tracheostomy procedure

Figure 5 is a side view of the trachea-over-protection endotracheal tube in use just before tracheostomy.

Figure 6 is a front view of the trachea-over-protection endotracheal tube just before tracheostomy.
Figure 7 is a sectional front view of the patient end of the trachea-over-protection endotracheal tube
Figure 8 is a transverse sectional view of the trachea-over-protection endotracheal tube between levels I-II
Figure 9 is a transverse sectional view of the trachea-over-protection endotracheal tube between levels II-III
Figure 10 is a transverse sectional view of the trachea-over-protection endotracheal tube between levels III-IV
Figure 11 is a transverse sectional view of the trachea-over-protection endotracheal tube between levels 100-I
Figure 12 is a sectional side view of a the trachea-over-protection endotracheal tube during the tracheostomy procedure
Figure 13 is a front view of the trachea-over-protection endotracheal tube with the black line16
Figure 14 is a sectional side view of the trachea-over-protection endotracheal tube with indicator-cuff 19 during the tracheostomy procedure
Figure 15 is a transverse sectional view of the trachea-over-protection endotracheal tube with an indicator-cuff 19 during the tracheostomy procedure
Figure 16 is a transverse sectional view of the trachea-over-protection endotracheal tube with the expandable edges 20 (like swing doors) and the expanding cuff 21 during the tracheostomy procedure
Figure 17 is a front view of the trachea-over-protection endotracheal tube which is black colored at an area 17 that can include the inflated cuff 15, the middle part and the main part 18.
Figure 18 is a front view of the trachea-over-protection endotracheal tube which is black colored at an area 17 that can include the inflated cuff 15, the middle part and the main part 18 with the black line16.
Figure 19 is a side view of the trachea-over-protection endotracheal tube in use with some holes 22 at the middle and the main part 18.
Figure 20 shows a sagittal cut (in the middle) of the trachea-over-protection endotracheal tube in use with a smooth, round-shaped, patient posterior end 23. (like golf club)

DETAILED DESCRIPTION OF THE INVENTION

In order to understand better this invention it is described at first a usual endotracheal tube during tracheostomy procedure and after that the trachea-over-protection endotracheal tube during the tracheostomy procedure. With reference at first to figures 1,2,3 and 4 it is shown a usual endotracheal tube oral or nasal 50 with a concave 53 and a convex 54 side, having a machine end 51 with a connector projecting from the patient's mouth or nose and a patient's end 52 located in the patient's trachea 60.An inflated cuff 55 close to the patient's end 52 is inflated to seal the outside of the tube with the inside of the trachea 60.

Normally the cuff 55 is inflated bellow the vocal cords -level 100- and gas is administered to the patient via the tube 50. When it becomes apparent that the patient will require a tracheostomy, such as, for example, if he is thought to need prolonged ventilation, the cuff 55 on the tube 50 is deflated and the tube 50 is pulled out of the patient's mouth by a distance sufficient to bring the cuff and inflate it again above the vocal cords –level 100- this time, to the position shown in figures 1 and 2.

During the percutaneous tracheostomy as shown in fig. 4, an incision is made through the skin and tissue of the neck overlying the trachea 60 with a tracheostomy instrument 90 (like a needle) as a guide. The risk of damaging the posterior wall 70 of the trachea 70 is great, especially under circumstances like tracheomalacia or others.

With reference now to figures 5-12 it is shown the trachea-over-protection endotracheal tube 10 (oral or nasal) with a concave 13 and a convex 14 side, having a machine end 11 with a connector projecting from the patient's mouth or nose and a patient's end 12 located in the patient's trachea 60.
An inflated cuff 15 close to the patient's end 12 is inflated to seal the outside of the tube with the inside of the trachea 60. The cuff 15 is normally inflated bellow the vocal cords (level 100) and gas is administered to the patient via the tube 10. When it becomes apparent that the

patient will require a tracheostomy, such as, for example, if he is thought to need prolonged ventilation, the cuff 15 of the tube 10 is deflated and the tube 10 is pulled out of the patient's mouth by a distance sufficient to bring the cuff and inflate it again above the vocal cords – level 100- this time, to the position shown in figures 5 and 6.

During the percutaneous tracheostomy as shown in fig. 12, an incision is made through the skin and tissue of the neck overlying the trachea 60 with a tracheostomy instrument 90 (needle) as a guide. The main part 18 of this invention lies between levels I-III of the trachea-over-protection endotracheal tube. As shown in fig. 12 during the tracheostomy procedure the main part 18 of the trachea-over-protection endotracheal tube protects the posterior wall 70 of the trachea from any damage the tracheostomy instrument could cause. In fig. 9 a transverse sectional view of the trachea-over-protection endotracheal tube is shown between levels II-III and shows the protection of the posterior wall 70 of the trachea.

The main part 18 of the trachea-over-protection endotracheal tube 10 can be made of the same material –plastic or any other material used nowadays in industry for usual tubes- as the whole trachea-over-protection endotracheal tube,it can be enforced by another material or it can be made from a material totally different.

In order to ensure that the main part of the trachea-over-protection endotracheal tube is not twisted, the trachea-over-protection endotracheal tube has a black line 16 in the concave 13 side to help the man who is rensponsible for the intubation of the patient, as shown in fig. 13.

The trachea-over-protection endotracheal tube can be black colored at an area 17 that can include the inflated cuff 15, the middle part and the main part 18 in order to help anyone who wants to use a light-guide instrument (a track-light for example), as a guide of the exact location of the main part of the endotracheal tube which is the right position of the tracheostomy instrument 90, as shown in figs. 17-18.

As shown in figs. 14-15 the trachea-over-protection endotracheal tube can have an indicator – cuff 19, which is positioned at the front side of the main part 18 of the trachea-over-protection endotracheal tube. During the tracheostomy procedure the tracheostomy instrument passes through the indicator-cuff 19 and the man who makes the tracheostomy is sure about the right progress of the procedure.

In fig. 16 is shown a trachea-over-protection endotracheal tube with a stiff part 20 at both edges of the main part 18 that can expand –like swing door- after inflation of an expandable balloon 21 which can also be used as an indicator cuff.

The trachea-over-protection endotracheal tube as shown in figure 19 (which is a side view) may also have at the one or at both sides of the middle and/or the main part 18 some holes 22 in order to maintain the proper ventilation in cases of tracheal bronchus.

As shown in fig. 20 the trachea-over-protection endotracheal tube may also have a smooth, round-shaped, patient posterior end 23 (like a golf club in a sagittal cut) in order to protect the posterior wall of the trachea during the insertion of the tube.

Because of natural differences between patients (men – women, adults-children, tall-short etc) the length, the exact diameter or even the material of every part of the trachea-over-protection endotracheal tube can vary without departing from the spirit of the invention.

CLAIMS

1. A trachea-over-protection endotracheal tube 10 (oral or nasal) with a concave 13 and a convex 14 side, having a machine end 11 with a connector projecting from the patient's mouth or nose and a patient's end12 located in the patient's trachea 60 characterized in that it has a main part 18 in the right position to shield the posterior wall 70 of the trachea from damaging by tracheostomy instrument 90 during any kind of tracheostomy procedure.

2. A trachea-over-protection endotracheal tube according to claim 1 characterized in that the main part 18 of the trachea-over-protection endotracheal tube 10 can be made of the same material –plastic or any other material used nowadays in industry for usual tubes- as the whole trachea-over-protection endotracheal tube,it can be enforced by another material or it can be made from a material totally different.

3. A trachea-over-protection endotracheal tube according to claims 1 and 2 characterized in that it has a black line 16 on the concave 13 side to ensure the man who makes the tracheostomy that the trachea-over-protection endotracheal tube is not twisted.

4. A trachea-over-protection endotracheal tube according to claims 1 and 2 characterized in that it may be black colored at an area17 that can include the inflated cuff 15, the middle part and the main part 18 in order to help anyone who wants to use a light-guide instrument (a track-light for example), as a guide of the exact location of the main part of the endotracheal tube.

5. A trachea-over-protection endotracheal tube according to claims 1 and 2 characterized in that it has at the one or at both sides of the middle part or/and the main part 18 some holes 22 in order to maintain the proper ventilation in cases of tracheal bronchus.

6. A trachea-over-protection endotracheal tube according to claims 1 and 2 characterized in that it has a smooth, round-shaped, patient posterior end 23. (like a golf club in sagittal cut) in order to protect the posterior wall of the trachea during the insertion of the tube.

7. A trachea-over-protection endotracheal tube according to claims 1 and 2 characterized in that it has an indicator-cuff 19 at the front side of the main part 18 to ensure that the tracheostomy instrument is in the right position.

8. A trachea-over-protection endotracheal tube according to claims 1 and 2 characterized in that there is a stiff part 20 at both edges of the main part 18 that can expand –like swing doors- after inflation of an expandable balloon 21, which can also be used as an indicator cuff.

9. A trachea-over-protection endotracheal tube substantially as herein before described with reference to figs. 5 to 12 of the accompanying drawings.

10. A trachea-over-protection endotracheal tube substantially as herein before described with reference to figs. 5 to12 as modified by any one of figs. 13 to 20 of the accompanying drawings.

11. A trachea-over-protection endotracheal tube substantially as herein before described characterized in that because of natural differences between patients (men – women, adults-children, tall-short etc) the length, the exact diameter or even the material of every part of the trachea-over-protection endotracheal tube can vary without departing from the spirit of the invention.

12. Any novel feature or combination of features as herein before described.

AMENDED CLAIMS

[Received by the International Bureau on 16 July 2004 (16.07.04): original claims 1-12 replaced by amended claims 1-8]

1. A trachea-over-protection endotracheal tube 10 (oral or nasal) with a concave 13 and a convex 14 side, having a machine end 11 with a connector projecting from the patient's mouth or nose and a patient's end12 located in the patient's trachea 60 characterized in that it has a main part 18 in the right position to shield the posterior wall 70 of the trachea from damaging by tracheostomy instrument 90 during any kind of tracheostomy procedure.

2. A trachea-over-protection endotracheal tube according to claim 1 characterized in that the main part 18 of the trachea-over-protection endotracheal tube 10 can be made of the same material –plastic or any other material used nowadays in industry for usual tubes- as the whole trachea-over-protection endotracheal tube,it can be enforced by another material or it can be made from a material totally different.

3. A trachea-over-protection endotracheal tube according to claims 1 and 2 characterized in that it has a black line 16 on the concave 13 side to ensure the man who makes the tracheostomy that the trachea-over-protection endotracheal tube is not twisted.

4. A trachea-over-protection endotracheal tube according to claims 1 and 2 characterized in that it may be black colored at an area17 that can include the inflated cuff 15, the middle part and the main part 18 in order to help anyone who wants to use a light-guide instrument (a track-light for example), as a guide of the exact location of the main part of the endotracheal tube.

5. A trachea-over-protection endotracheal tube according to claims 1 and 2 characterized in that it has at the one or at both sides of the middle part or/and the main part 18 some holes 22 in order to maintain the proper ventilation in cases of tracheal bronchus.

6. A trachea-over-protection endotracheal tube according to claims 1 and 2 characterized in that it has a smooth, round-shaped, patient posterior end 23. (like a golf club in sagittal cut) in order to protect the posterior wall of the trachea during the insertion of the tube.

7. A trachea-over-protection endotracheal tube according to claims 1 and 2 characterized in that it has an indicator-cuff 19 at the front side of the main part 18 to ensure that the tracheostomy instrument is in the right position.

8. A trachea-over-protection endotracheal tube according to claims 1 and 2 characterized in that there is a stiff part 20 at both edges of the main part 18 that can expand –like swing doors- after inflation of an expandable balloon 21, which can also be used as an indicator cuff.

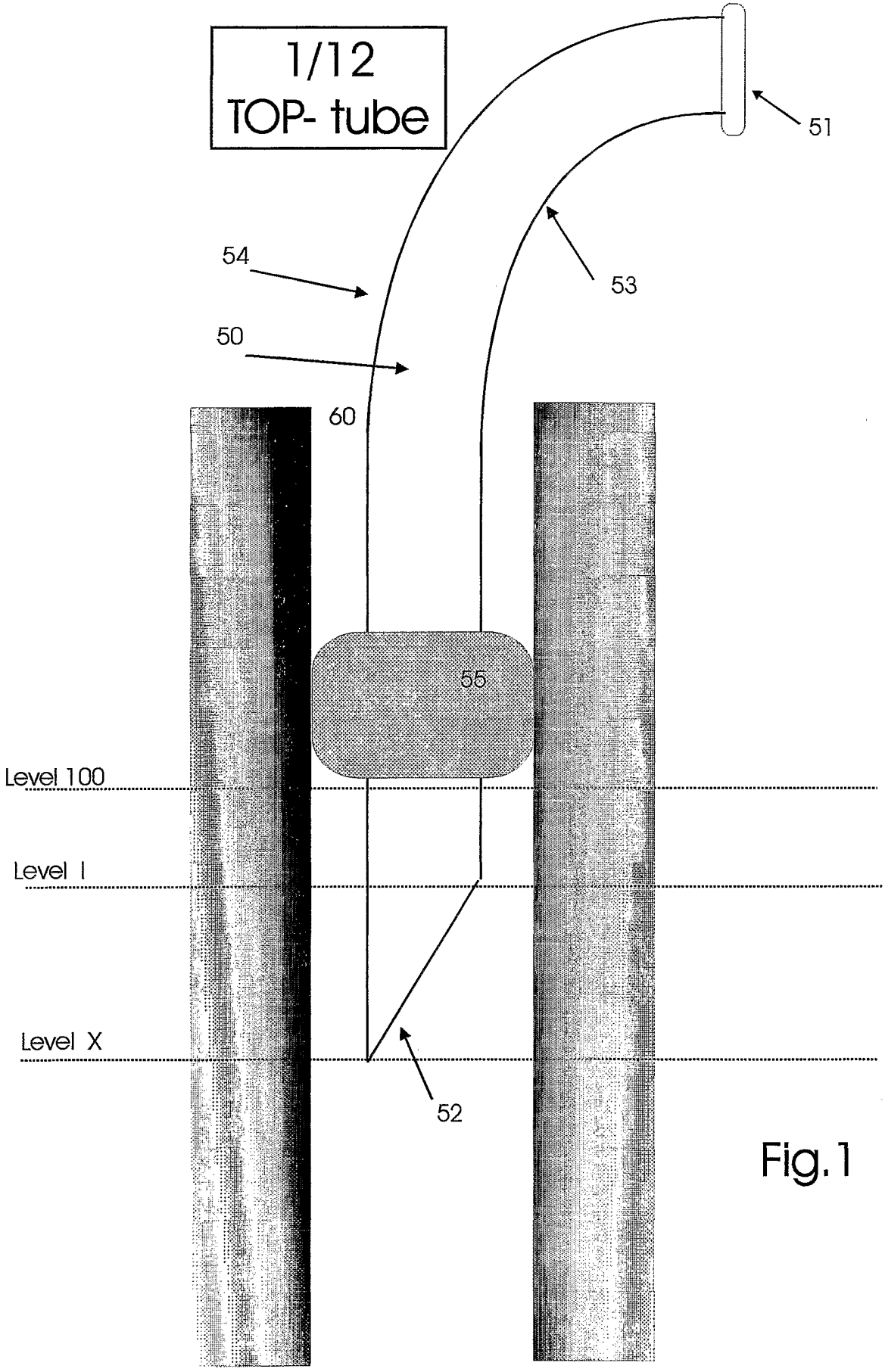


Fig.1

2/12
TOP- tube

Fig. 2

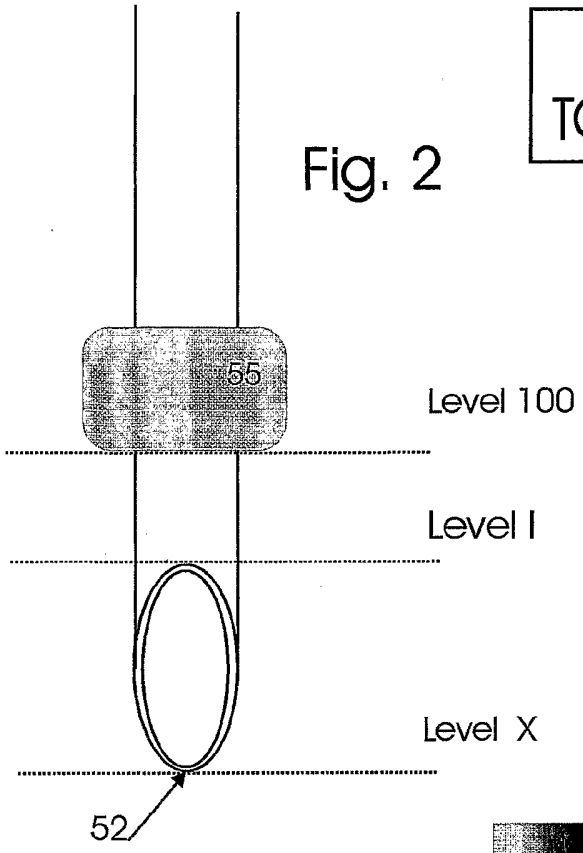
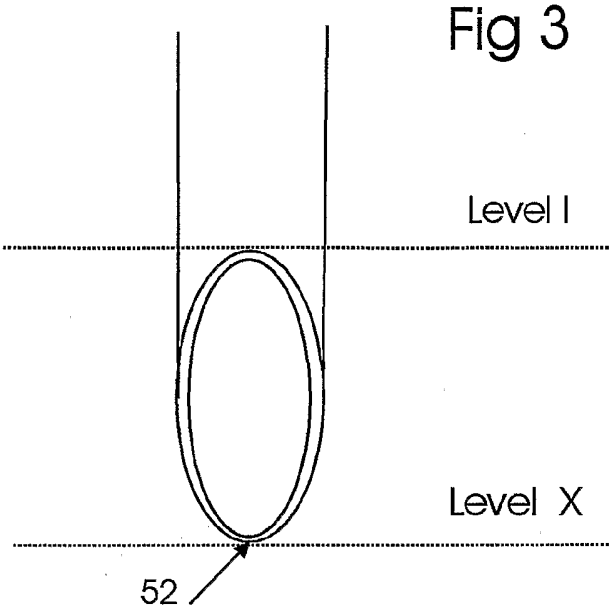


Fig 3



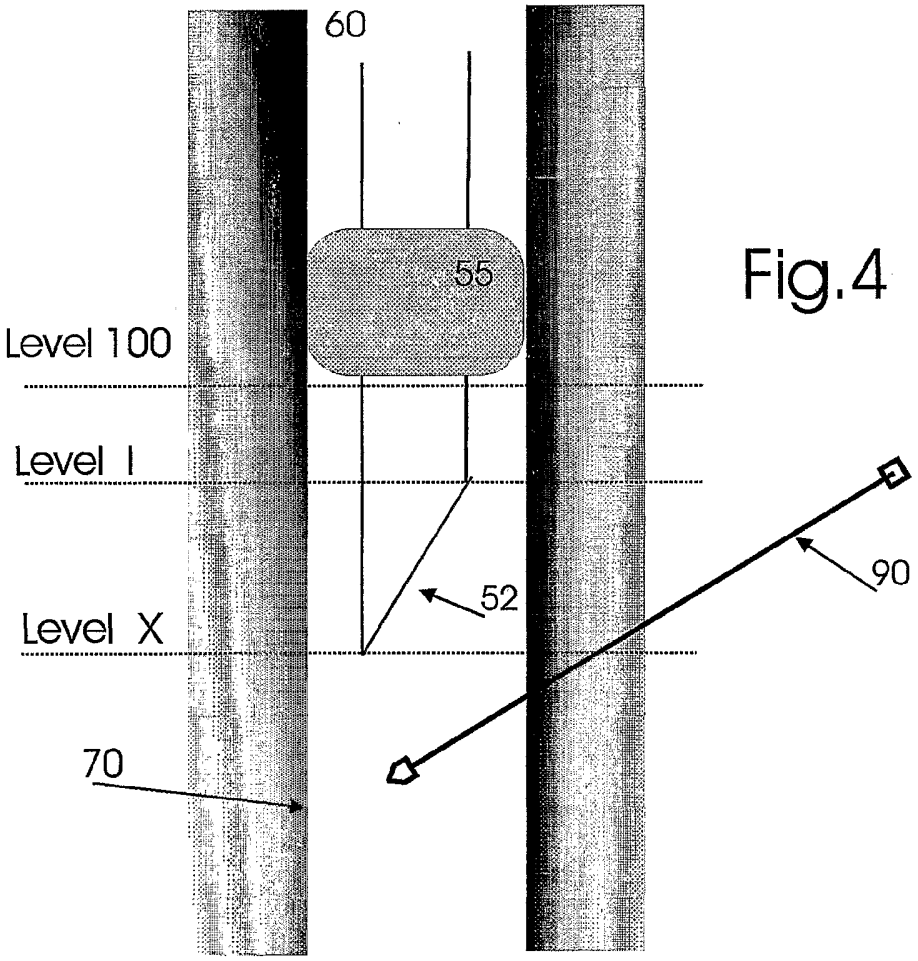


Fig.4

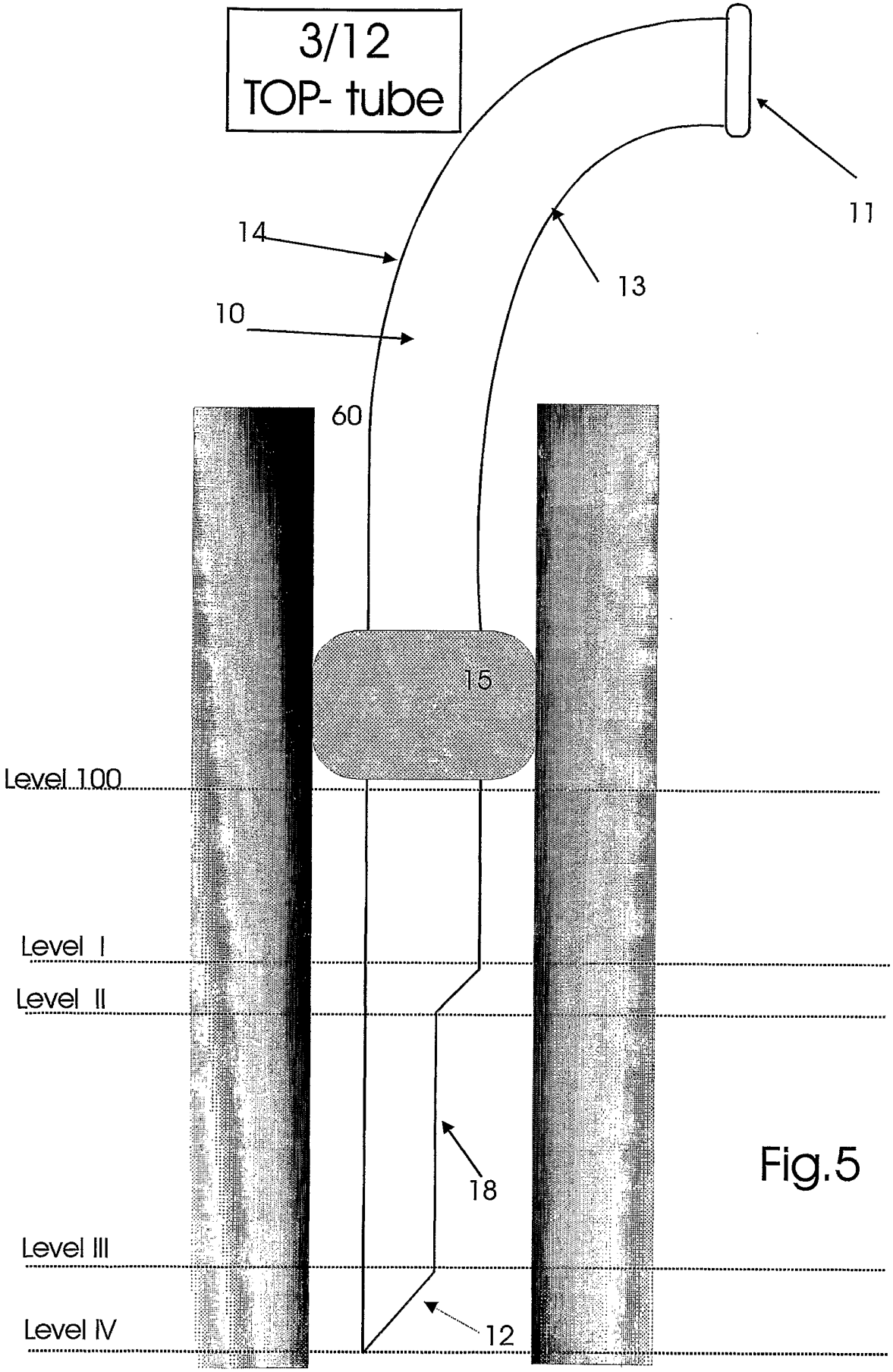

3/12
TOP- tube
11
14
13
10
60
15
Level 100
Level I
Level II
18
Level III
Level IV
12

Fig.5

4/12
TOP- tube

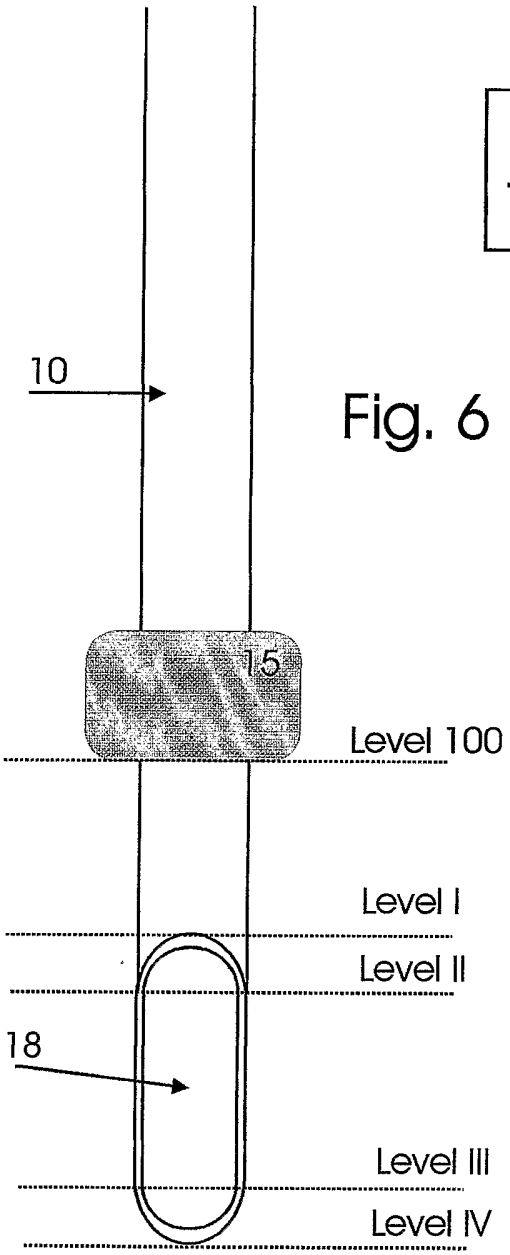
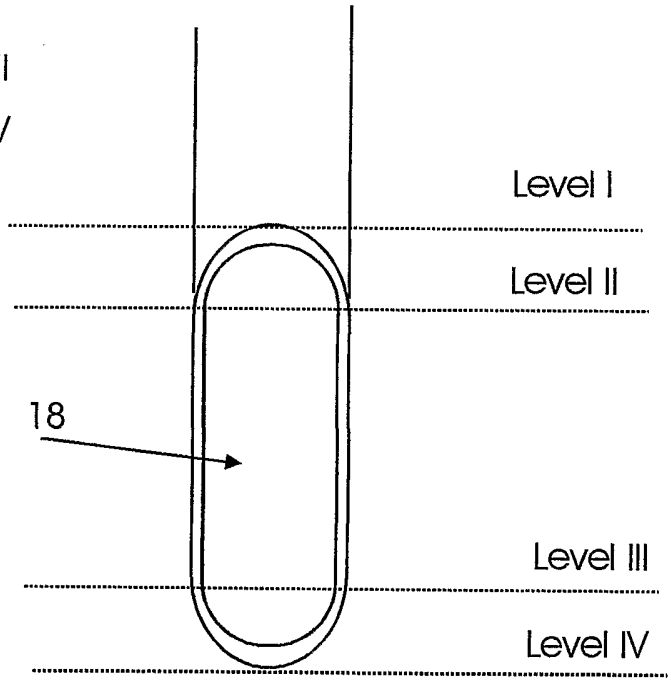


Fig. 6

Fig. 7



5/12
TOP- tube

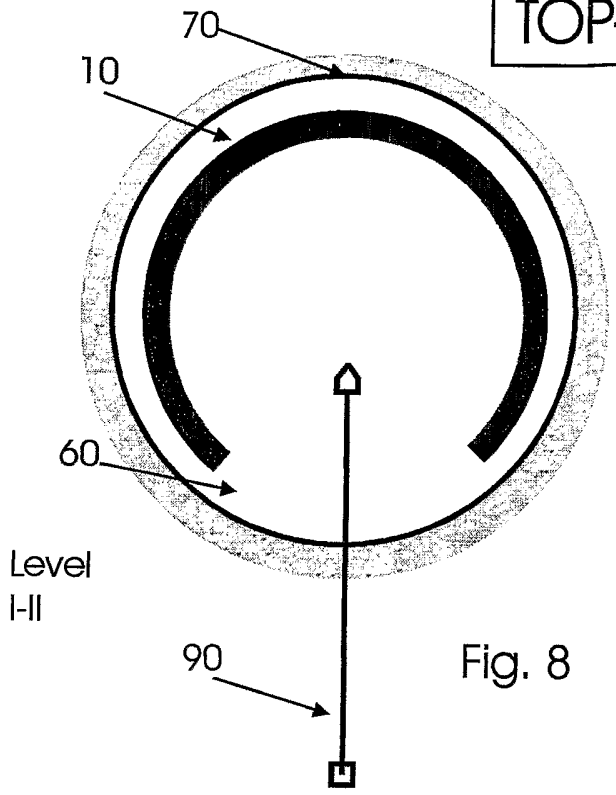


Fig. 8

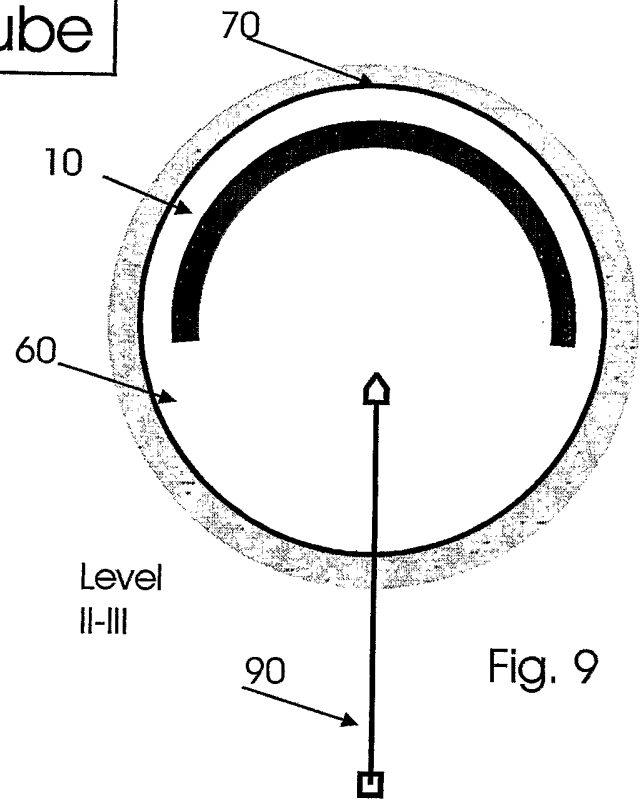


Fig. 9

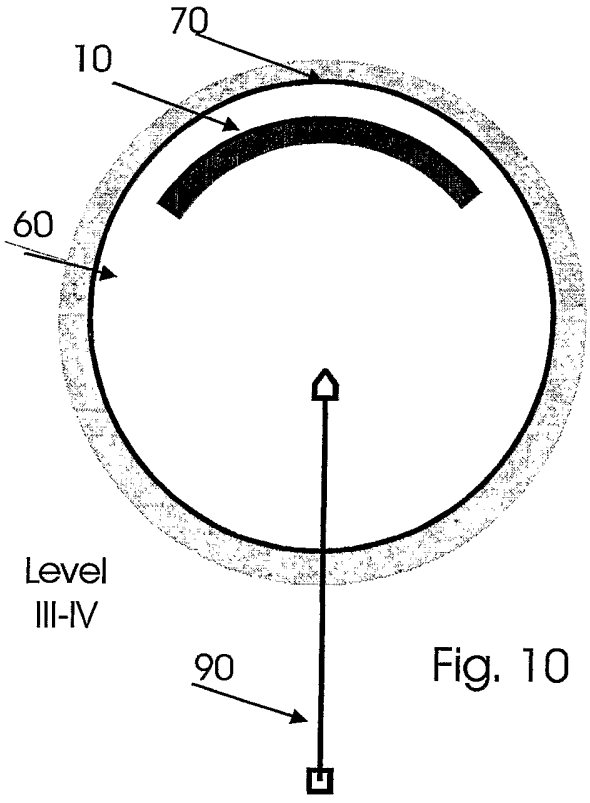


Fig. 10

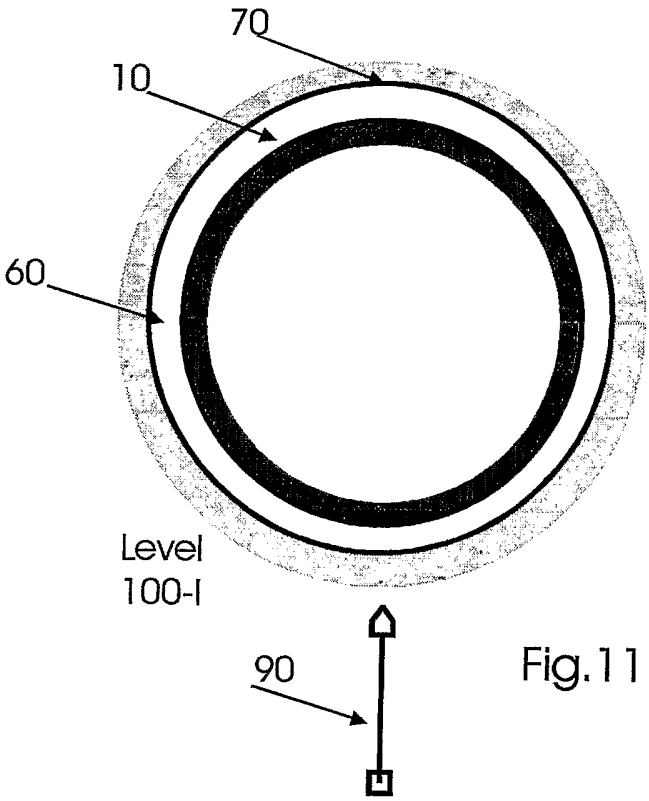


Fig.11

6/12
TOP- tube

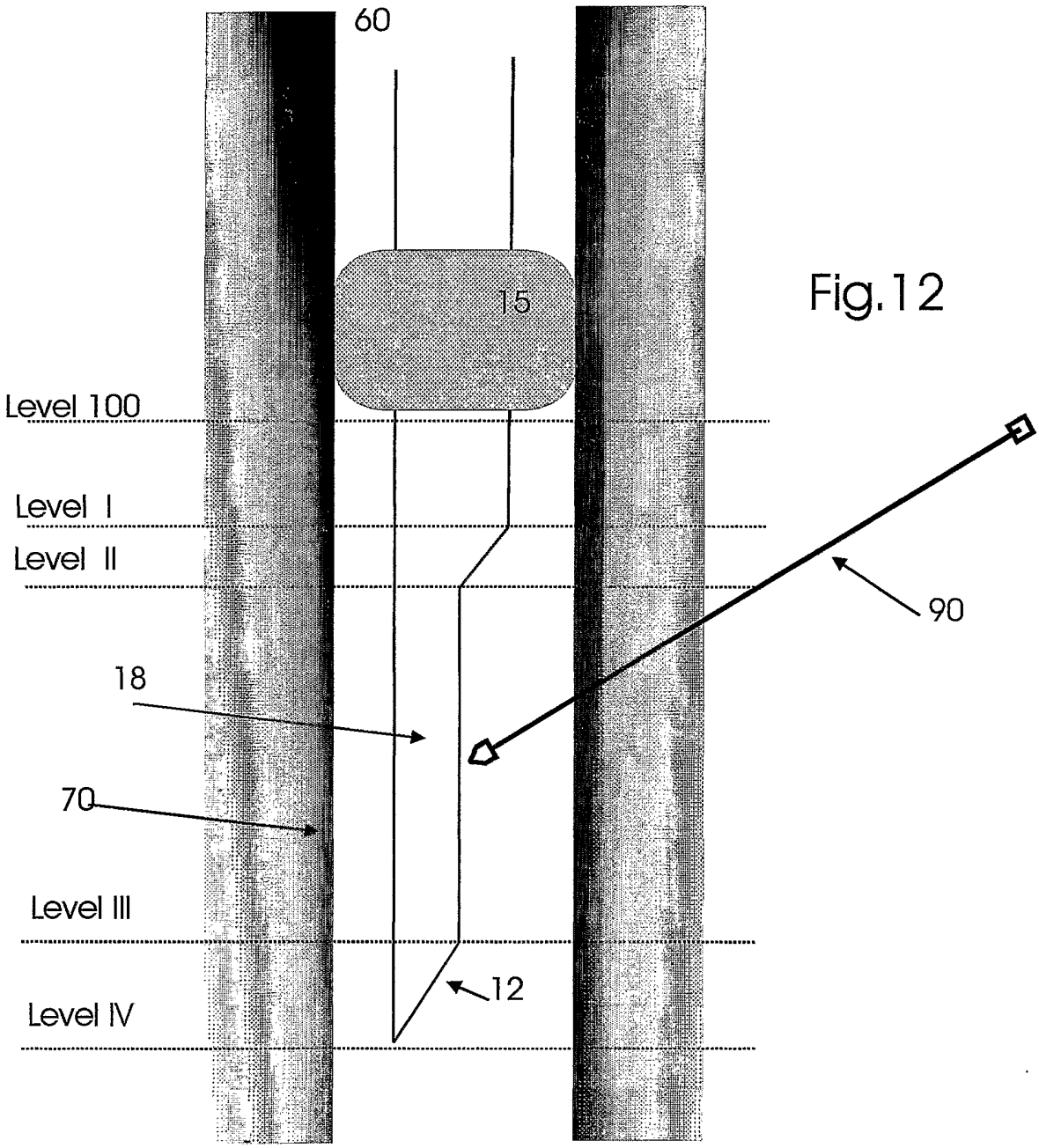


Fig.12

7/12
TOP- tube

Fig. 13

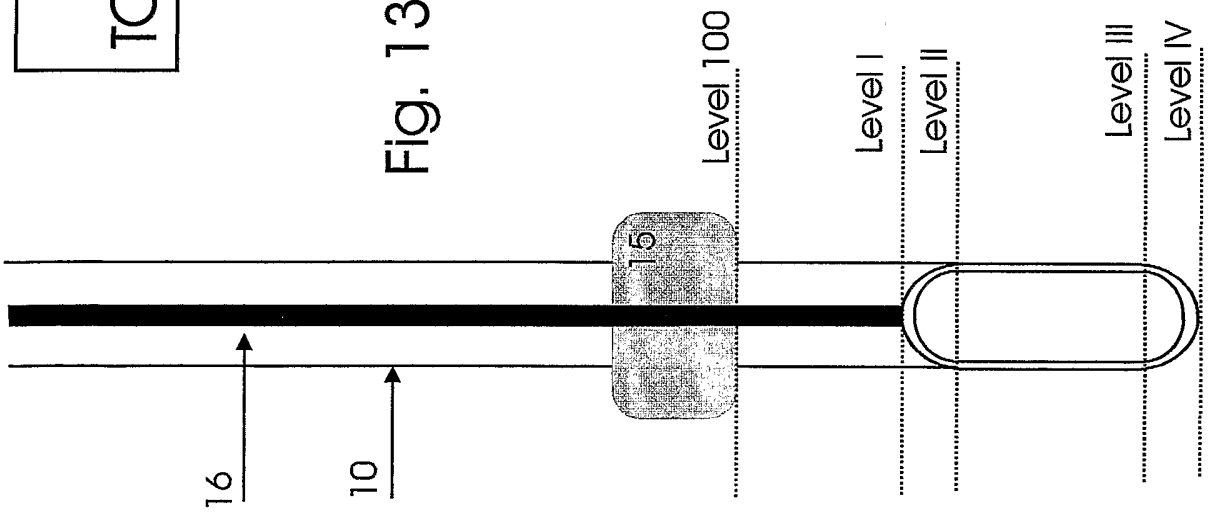
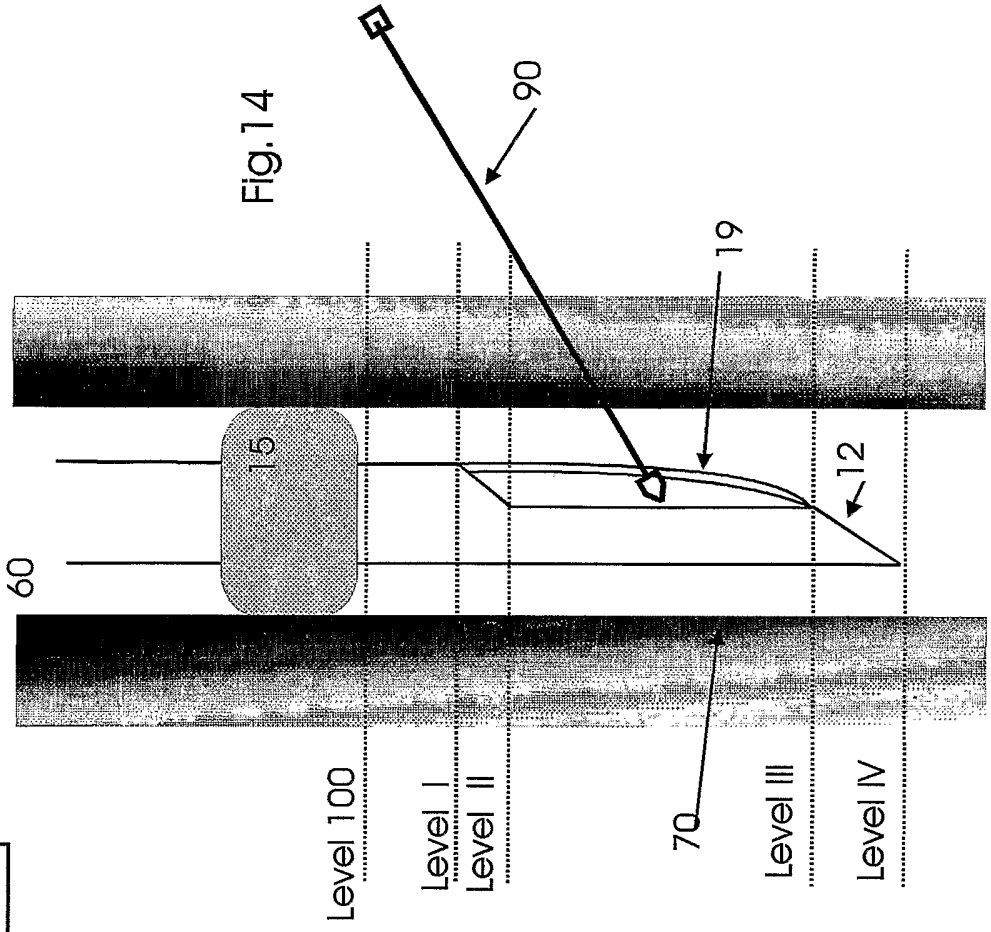


Fig.14



8/12
TOP- tube

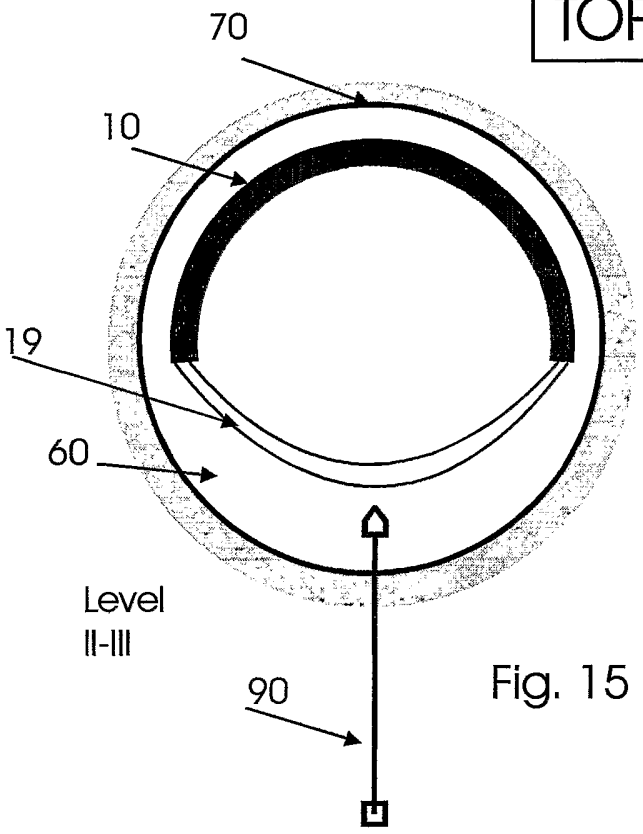


Fig. 15

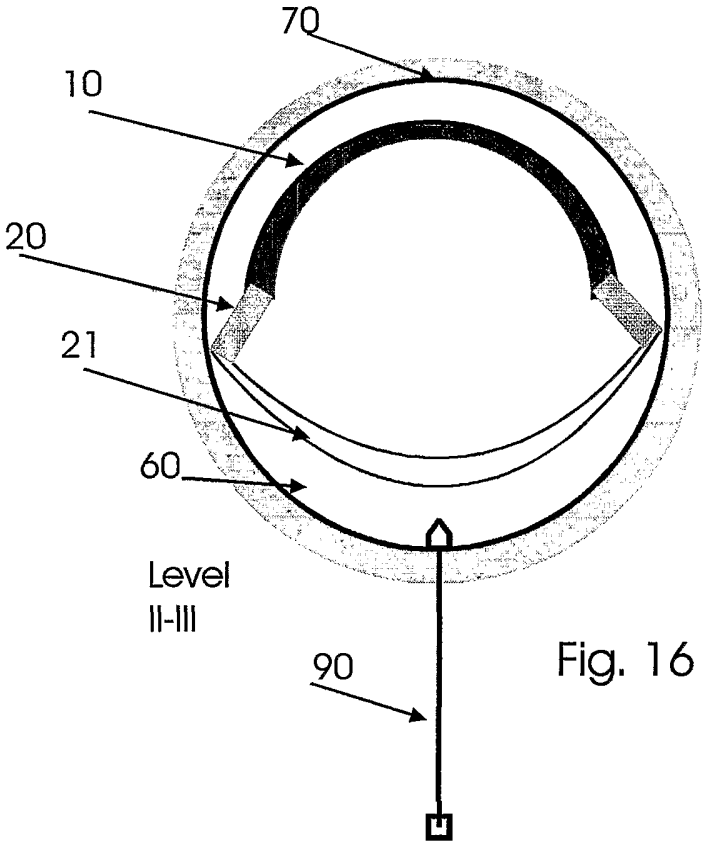


Fig. 16

9/12
TOP- tube

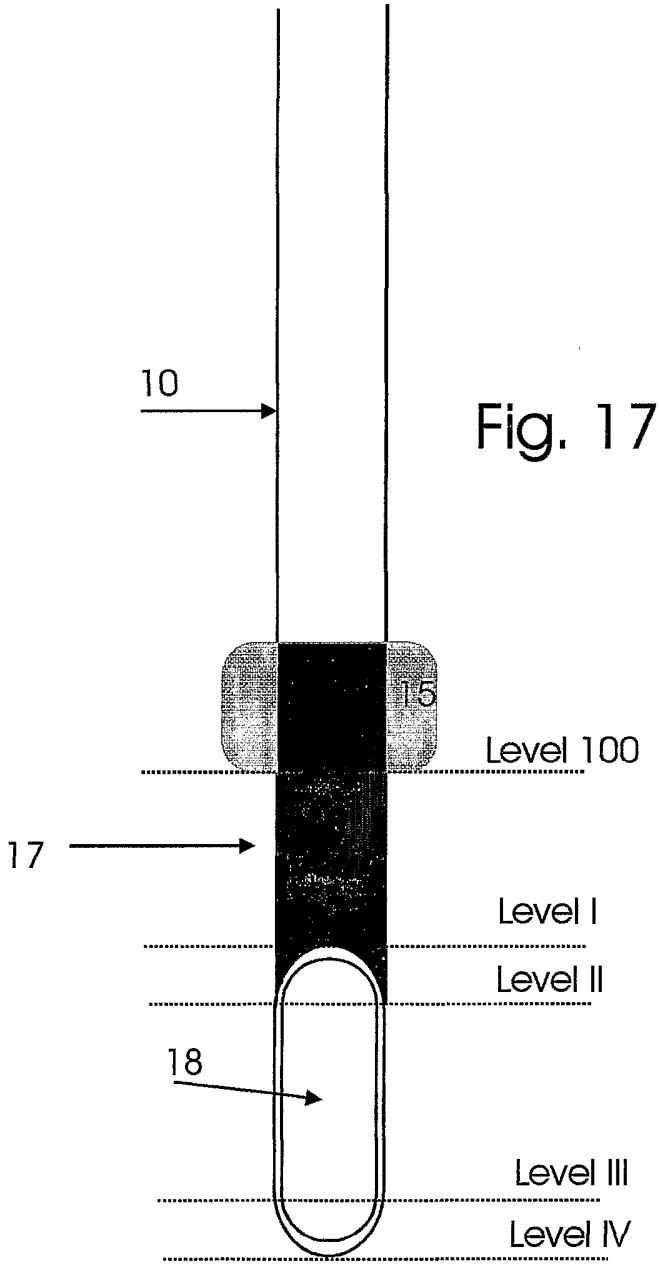


Fig. 17

10/12
TOP- tube

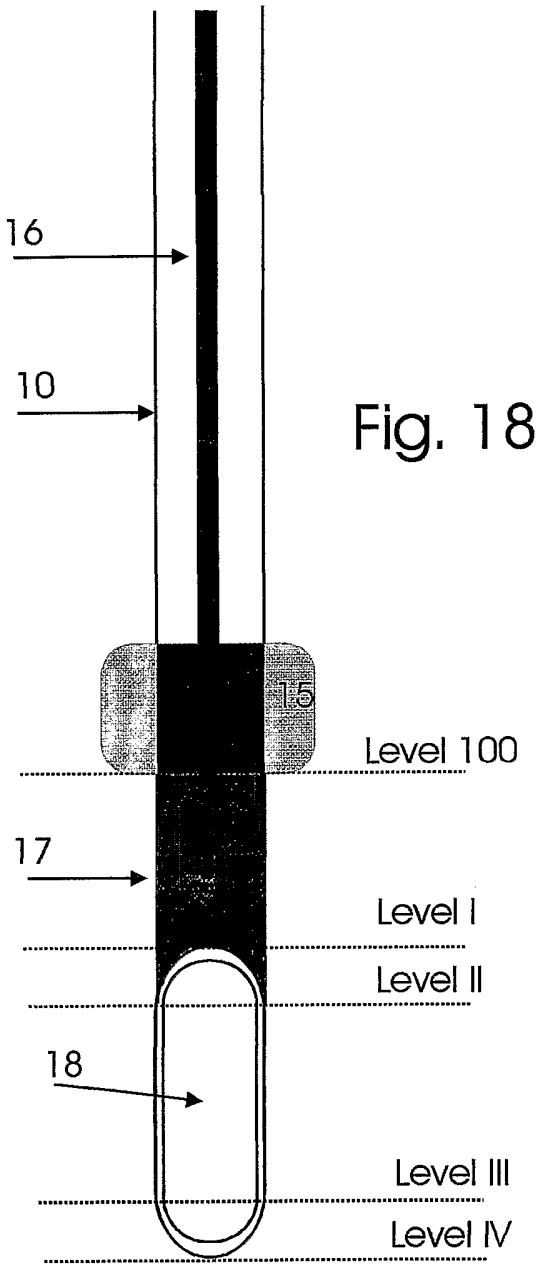


Fig. 18

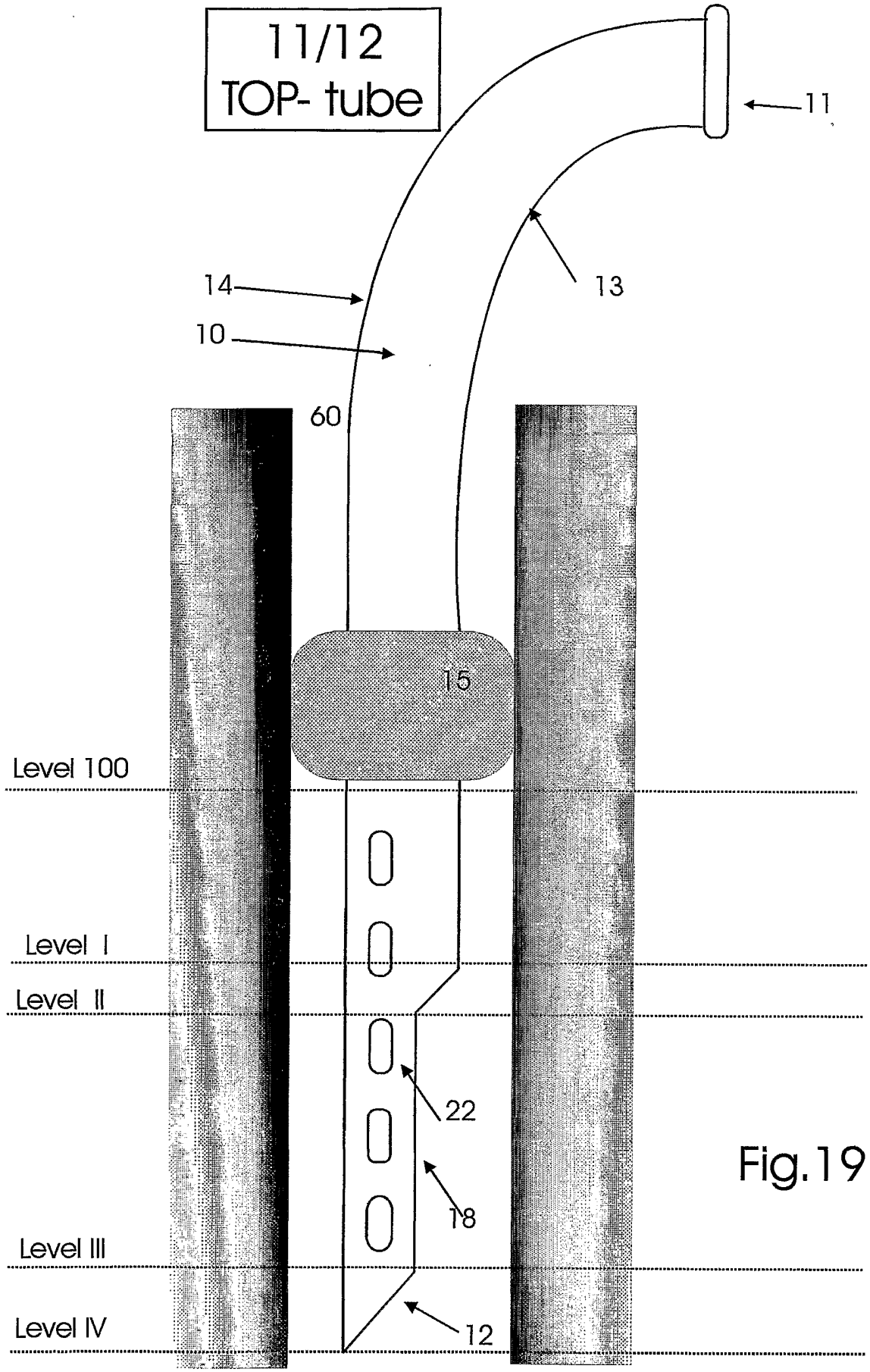

11/12
TOP- tube
11
13
14
10
60
15
Level 100
Level I
Level II
22
18
Level III
Level IV
12

Fig.19

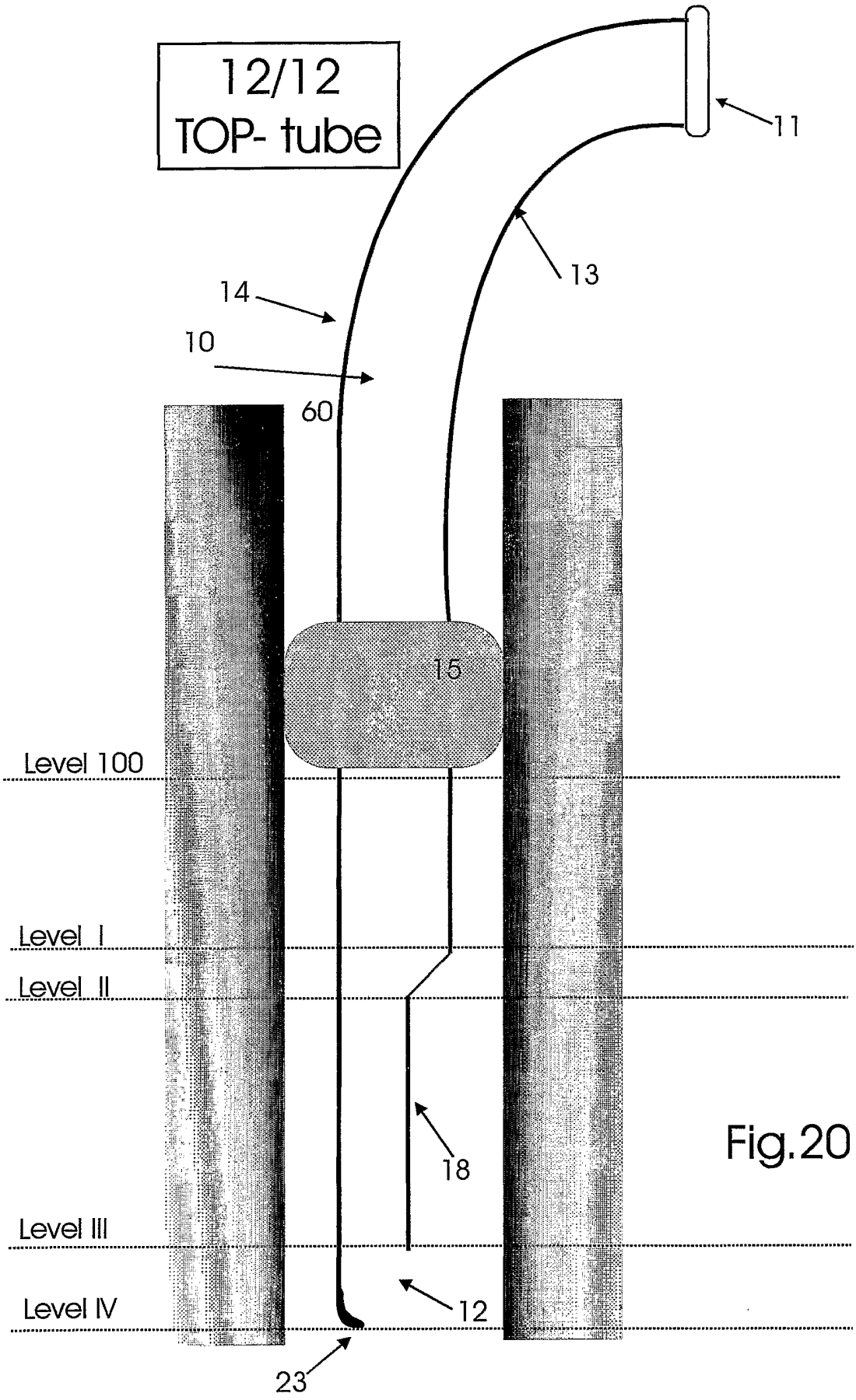

12/12
TOP- tube
11
13
14
10
60
15
Level 100
Level I
Level II
18
Level III
Level IV
12
23

Fig.20

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GR 03/00057

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M16/04

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 A61M

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 836 860 A (SMITHS INDUSTRIES PLC) 22 April 1998 (1998-04-22)	1,2,6
Y	the whole document	5
A		3,4,7,8

X	US 6 575 158 B1 (CHELLY JACQUES ET AL) 10 June 2003 (2003-06-10)	1,2,6
Y	the whole document	5
A		3,4,7,8

Y	US 3 788 326 A (JACOBS H) 29 January 1974 (1974-01-29) figures 5,7,8,10B,12A,13-18	5

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

☒ Patent family members are listed in 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 June 2004	24/06/2004

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	Lager, J

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 9-12

The claims make references to the description and/or drawings, Rule 6.2(a) PCT.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 9-12
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

rmation on patent family members

Inter[redacted]nal Application No
PCT/GR 03/00057

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 3794026 A	26-02-1974