



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/AU90/00583 (22) International Filing Date: 7 December 1990 (07.12.90) (30) Priority data: PJ 7792 11 December 1989 (11.12.89) AU (71)(72) Applicant and Inventor: GRIGGS, William, Middleton [AU/AU]; 15 Avenel Gardens Road, Medindie, S.A. 5081 (AU). (74) Agent: COLLISON & CO.; 117 King William Street, Ade- laide, S.A. 5000 (AU). (81) Designated States: AT (European patent), AU, BE (Euro- pean patent), CA, CH, CH (European patent), DE (Eu- ropean patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), US.		Published <i>With international search report.</i>
(54) Title: TRACHEOSTOMY METHOD AND APPARATUS <div style="text-align: center;"> </div>		
(57) Abstract <p>Percutaneous tracheostomy. The trachea is penetrated by a hollow needle and a guide wire (43) is inserted into the trachea through the needle. The needle is removed leaving the wire (43) in the trachea. An instrument specifically adapted for use in tracheostomy operations, having two jaws (8) each with a groove (6) which cooperate when the jaws (8) are closed to form a passage, is inserted into the trachea opening with the guide wire (43) extending through the passage. The instrument is opened after insertion to widen the trachea opening. The instrument jaws (8) are curved so that when they are inserted into the trachea and spread to dilate the opening there is minimal risk of damage other than in the region of dilation. A tracheostomy tube is inserted into the opening via the wire (43) and the wire is withdrawn.</p>		

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TRACHEOSTOMY METHOD AND APPARATUS

This invention relates to the field of tracheostomy and more particularly relates to a method and apparatus whereby a tracheostomy tube may be
5 inserted into the trachea of a patient in a minimum of time and with a minimum risk of secondary injury.

The term patient will be used in this specification in a general sense but may include human or animal subjects.

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The surgical procedure of tracheostomy has often to be carried out in emergency situations and thus the operation ideally should be completed in a minimum amount of time. While emergency airway access can be accomplished by making an incision into the trachea the more permanent
15 tracheostomy requires the incision into the trachea to receive a tracheostomy tube which has an inflatable cuff which is inflated after insertion to seal the tube in the trachea so that inspiration and expiration of air is all accomplished by use of the tracheostomy tube.

20 A number of percutaneous tracheostomy techniques have been described to perform a tracheostomy easily and rapidly for instance at a bedside but many of these have been slow, difficult to perform and/or had a significant likelihood of secondary injury such as injury to the of the trachea at points other than where the incision is made. In general the process requires the
25 forming of a hole in the wall of the trachea by splitting it laterally between the tracheal rings. In the past this has been achieved by the use of a number of dilators of increasing diameter but this process has taken some time and actually on occasion some secondary injury to the trachea because longitudinal as well as lateral forces are applied by such devices.

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This present invention proposes an alternative arrangement which will provide substantially lateral splitting between the tracheal rings while providing a minimum risk of secondary damage to the trachea.

35 In one form therefore the invention is said to reside in a tracheostomy instrument comprising a pair of members pivoted to each other intermediate their ends, one end of each of the members being formed as a jaw to co-operate with the jaw of the other member, the pair of jaws being curved, each of the jaws having on a co-operating face a groove extending from the end of

the jaw along at least part of the length of the jaw and terminating in an opening on the side of the jaw, the grooves on the two jaws co-operating when the jaws are in a closed position to provide a passage such that a wire can be threaded therethrough, the other end of the members each providing
5 a handle and means to engage each other to lock the jaws in the closed position.

In one preferred embodiment of the invention the members are pivoted together such that moving the handle ends together moves the jaw ends
10 together. Alternatively the instrument may be constructed so that the members are pivoted together such that moving the handle ends together moves the jaws ends apart.

The curve of the jaws may be up to 90°.
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Preferably the jaws are tapered towards their ends.

The means to engage the handles may comprise co-operating ratchet parts on each handle.
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The jaws may further have rounded ends so as to provide minimal damage to the interior of the trachea.

In a further form the invention may be said to reside in a method of inserting
25 a tracheostomy tube into the trachea of a patient, the method including the steps of inserting a hollow needle into the trachea, threading a guide wire through the needle and passing the wire into the trachea to extend in the trachea towards the lungs of the patient, removing the needle and leaving the wire in place, threading an instrument over the wire and sliding the
30 instrument along the wire until it extends into the trachea, the instrument having jaws which may be separated once within the trachea to split the trachea and the jaws being curved so that the jaws can extend into the trachea and extend down the trachea, spreading the jaws to split the trachea wall through which the jaws are inserted transversely, removing the
35 instrument while leaving the wire in the trachea, threading a tracheostomy tube along the wire into the trachea and removing the wire.

The dilation instrument may be as described above.

In one preferred embodiment one or more tubular dilators can be threaded over the wire to enlarge the incision before the insertion of the instrument.

- 5 The instrument for ease of description can be described as being similar to a pair of forceps the instrument having curved jaws and on the co-operating faces of each jaw there is provided a groove extending from the end of the jaws back along the jaws and then opening to one side of the jaws. The instrument may be locked by its ratchet or other locking means in the closed position and then the instrument can be threaded over the wire and into the
- 10 incision in the trachea. The handles of the instrument are then operated to unlock the ratchet or other locking mechanism and the jaws are then spread to dilate the incision transversely between tracheal rings while not making significant longitudinal movement.
- 15 This then generally describes the invention but to assist with understanding of the invention reference will now be made to the accompanying drawings which show preferred embodiments of the invention.

In the drawings

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FIG. 1 shows a first embodiment of an instrument according to this invention,

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FIG. 2 shows a second embodiment of an instrument according to this invention, and

FIGS 3 to 8 show the various stages of insertion of a tracheostomy tube into a patient according to this invention.

- 30 Now looking more closely at the drawings and in particular FIG. 1 it will be seen that the instrument comprises members 1 and 2 each of which have a jaw end 3 and a handle end 4. The jaw end 3 has jaws 8 with a co-operating face 5 along which extends a groove 6. The jaw 8 terminates in a rounded tip 7. A pivot 10 is provided intermediate the ends of the members 1 and 2 and extending away from the jaws opposite the pivot are the handle ends 4 terminating in handles 11. The handle ends also include co-operating ratchet parts 12 and 13 which enable the instrument to be locked with the
- 35 jaws in the closed position so that the groove 6 in each jaw part 8 co-operate to form a passage through which a dilation wire may be passed.

The instrument is constructed in this embodiment such that moving the handles together moves the jaws together.

- 5 FIG. 2 shows an alternative embodiment of tracheostomy instrument according to the invention. In this invention the two members 20 and 21 are pivoted at point 22 such that the handle ends 23 and 24 are moved apart the jaw ends 25 and 26 are moved together. The jaw ends 25 and 26 include co-operating faces such as the face 27 on the jaw 25 and a groove 28 in the co-operating face. It may be particularly noted that the jaws 27 and 26 are curved along their length so that when the tracheostomy instrument is inserted into the trachea while the instrument may extend directly out from the trachea the tips of the jaws 29 and 30 extend down the trachea and as the jaws are spread they will do minimum damage to the inside walls of the trachea.

- The locking arrangement of the embodiment shown in FIG. 2 comprises a pair of arms 31 and 32 pivoted at their joining parts at 33 and pivoted at 34 and 35 to the handle ends 24 and 23 respectively and this pivot arrangement may include an over centre locking arrangement so that as the handles are moved apart the jaws are moved closer together and the locking arrangement locks them in this closed position. The advantage of the embodiment shown in FIG. 2 is that spreading the jaws is achieved by moving the handle ends closer together and hence there is a limit to the amount of spreading which can be achieved.

Now looking at FIGS. 3 to 8 one embodiment of a method of performing a percutaneous tracheostomy will be discussed.

- 30 The percutaneous tracheostomy is usually performed while the patient is receiving either general anaesthesia or local anaesthesia. The patient may be positioned with a pillow or sand bag under the shoulders to increase the extension of the neck.
- 35 A first stage is to locate the cricoid cartilage 40. A mid-line traverse percutaneous incision of approximately 1.5 to 2 cm. in length is made immediately below the level of cricoid cartilage. An intravenous needle and cannula with an attached fluid filled syringe is inserted in the mid-line of the incision and directed posteriorly while withdrawing the plunger of the

attached syringe as shown in FIG. 3. The needle is directed to pass between the cricoid and first tracheal ring 41 or between the first tracheal ring 41 and the second tracheal ring 42. As soon as air begins to bubble into the syringe the outer plastic cannula is advanced into the lumina of the trachea and the inner needle is removed. A guide wire 43 preferably with a J-tip 44 is introduced into the trachea through the plastic cannula and then the plastic cannula is removed leaving the guide wire in place as shown in FIG. 4. The use of the plastic cannula avoids the risk of advancing the needle through the back wall of the trachea during wire insertion.

As shown in FIG. 5 the tip 46 of the guide wire is passed into the tip of 47 of the tracheostomy dilation instrument 47 and passed up through the passage formed into the jaws of the instrument. The forceps are then advanced along the wire through the soft tissues of the neck until the tip 47 passes into the trachea and then the instrument 48 is rotated so that the tip 47 is directed down the trachea in substantially the centre of the trachea as shown in FIG. 6. The handles of the instrument 48 are then moved to open the jaws to substantially the same diameter as the skin incision to split the wall of the trachea between two tracheal rings. This can be particularly seen in FIG. 7 which is shown partially in cut away view where the jaws 49 and 50 of the instrument 48 have been spread between tracheal rings 41 and 42 so that a transverse split is made without longitudinal damage to the trachea. The guide wire 43 remains in the trachea.

The forceps 48 are then removed with the guide wire 43 remaining in the trachea and extending down the trachea. A tracheostomy tube 51 is then threaded over the guide wire 43 preferably with a trocar 52 or internal guide so that the tip 53 of the tracheostomy tube 51 passes along the wire and down the trachea. Once the tracheostomy tube is inserted into the trachea down to the hilt 54 then the cuff 55 is inflated by means not shown and the appropriate breathing circuit is connected.

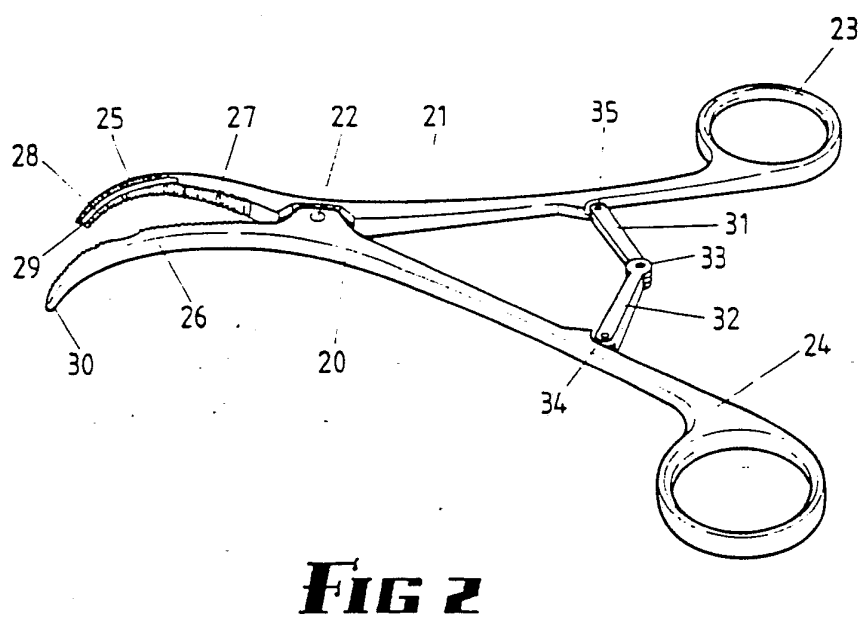
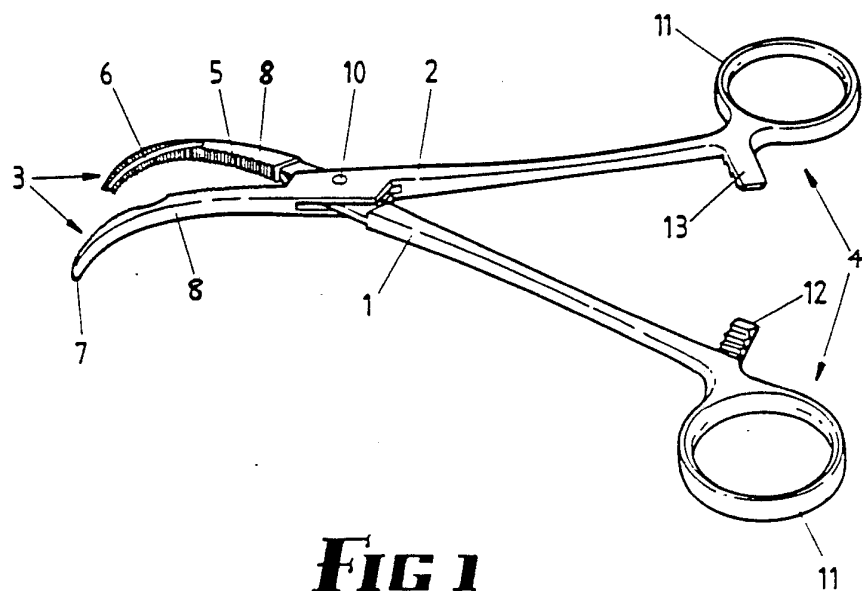
Through this invention the inventions have provided a method and an instrument which simplifies the process of percutaneous tracheostomy and provides less risk of secondary injury particularly owing to the curved nature of the instrument jaws so that during the dilation procedure the ends of the jaws lie in the long axis of the trachea and there is less risk of secondary damage to the lateral or posterior tracheal walls.

1. A tracheostomy instrument comprising a pair of members pivoted to each other intermediate their ends, one end of each of the members being formed as a jaw to co-operate with the jaw of the other member, the pair of jaws being curved, each of the jaws having on a co-operating face a groove
5 extending from the end of the jaw along at least part of the length of the jaw and terminating in an opening on the side of the jaw, the grooves on the two jaws co-operating when the jaws are in the closed position to provide a passage such that a wire can be threaded therethrough, the other end of the members each providing a handle and means to engage each other to lock
10 the jaws in a closed position.
2. An instrument as defined in Claim 1 wherein the members are pivoted together such that moving the handle ends together moves the jaw ends together.
15
3. An instrument as in Claim 1 wherein the members are pivoted together such that moving the handle ends together moves the jaw ends apart.
- 20 4. An instrument as in Claim 1 wherein the curve of the jaws is up to 90°.
5. An instrument as in Claim 1 wherein the jaws are tapered towards their ends.
25
6. An instrument as in Claim 1 wherein the means to engage the handles comprise co-operating ratchet parts on each handle.
7. An instrument as in Claim 1 wherein the jaws have rounded ends
30 so as to provide minimal damage to the interior of the trachea.
8. A tracheostomy instrument comprising a pair of members pivoted to each other intermediate their ends, one end of each of the members being formed as a jaw to co-operate with the jaw of the other member, the jaws
35 being curved, tapered towards their ends and having rounded ends, each of the jaws having on a co-operating face a groove extending from the end of the jaw along at least part of the length of the jaw and terminating in an opening on the side of the jaw, the grooves on the two jaws co-operating when the jaws are in the closed position to provide a passage such that a

wire can be threaded therethrough, the other end of the members each providing a handle and co-operating ratchet parts to engage each other to lock the jaws in a closed position.

- 5 9. A method of inserting a tracheostomy tube into the trachea of a patient, the method including the steps of, inserting a needle into the trachea, threading a guide wire through the needle and passing the wire into the trachea to extend within the trachea towards the lungs of the patient, removing the needle and leaving the wire in place, threading a dilation
10 instrument over the wire and sliding the instrument along the wire until it extends into the trachea, the instrument having jaws which may be separated once within the trachea to dilate the trachea and the jaws being curved so that the jaws can extend into the trachea and extend down the trachea, spreading the jaws to dilate the trachea wall through which the jaws
15 are inserted, removing the instrument while leaving the wire in the trachea, threading a tracheostomy tube along the wire and into the trachea, and removing the wire.
- 10 10. A method as in Claim 8 wherein the instrument is as defined in
20 Claim 1.
11. A method as in Claim 8 further including the step of threading a dilation catheter onto the guide wire before insertion of the dilation instrument.

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SUBSTITUTE SHEET

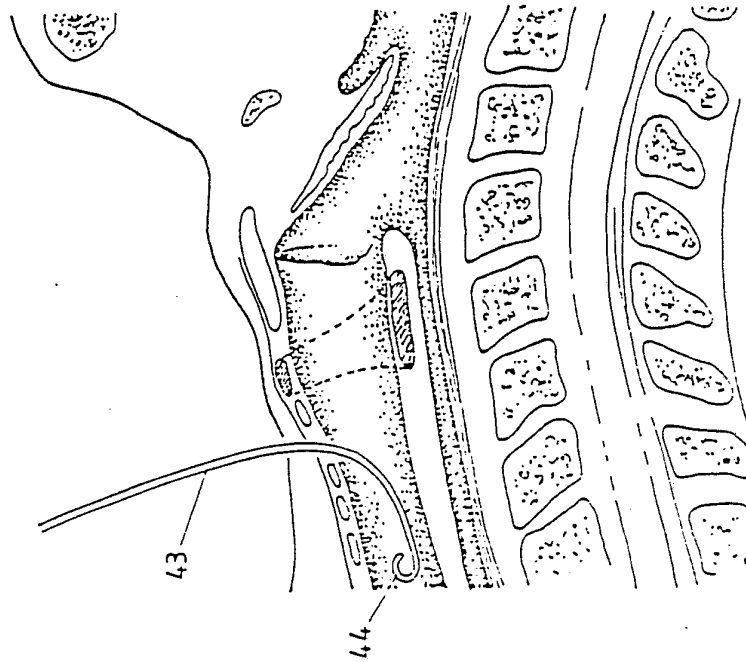


FIG 4

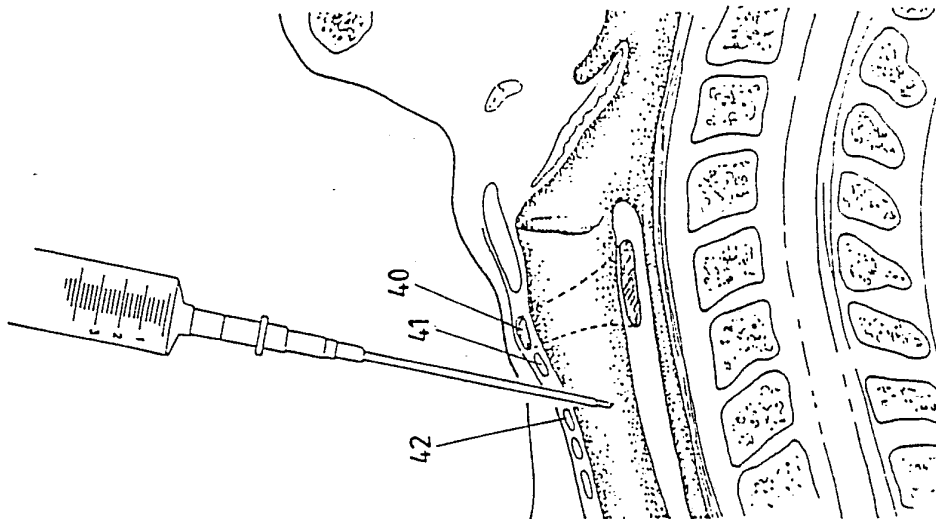
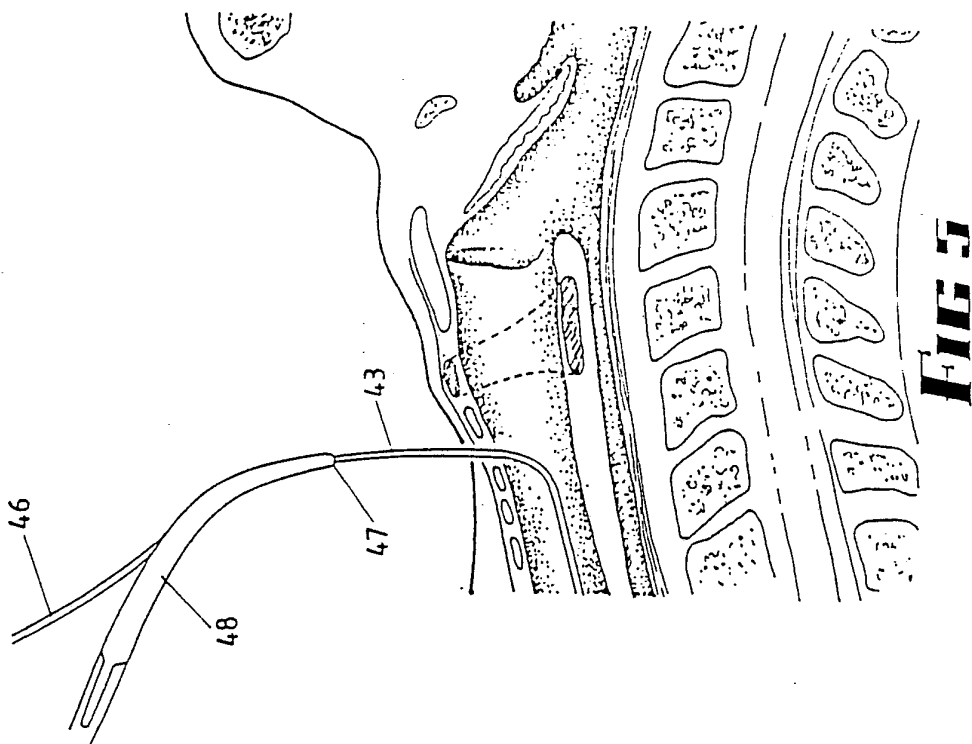
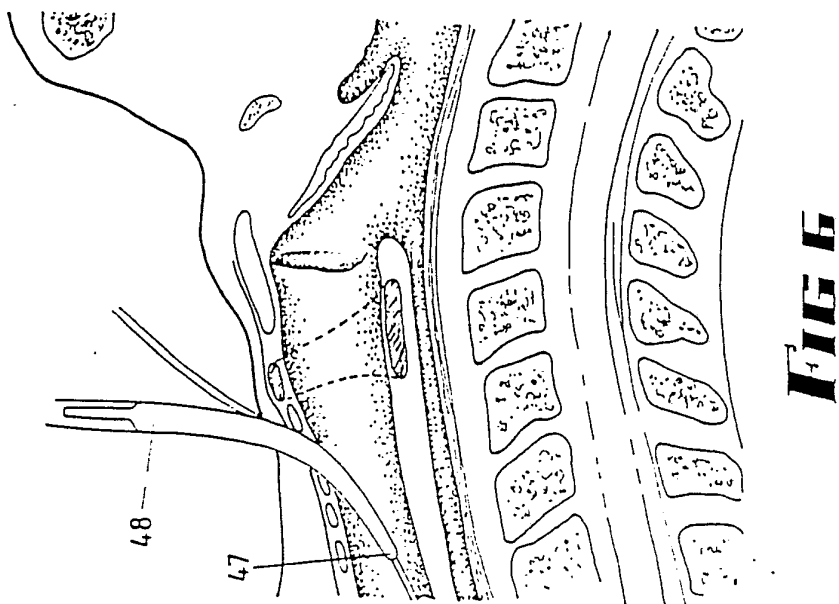


FIG 3

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SUBSTITUTE SHEET

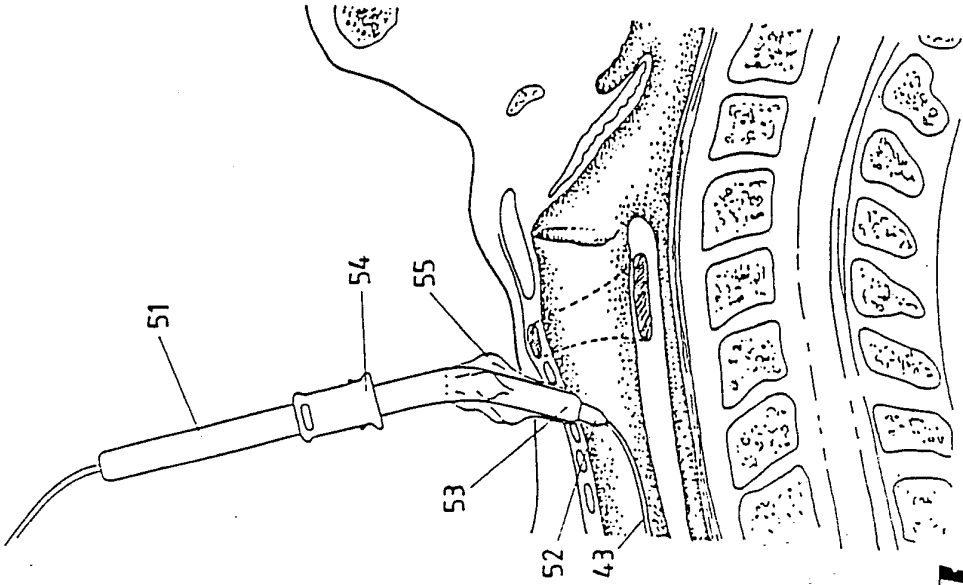


Fig. 6

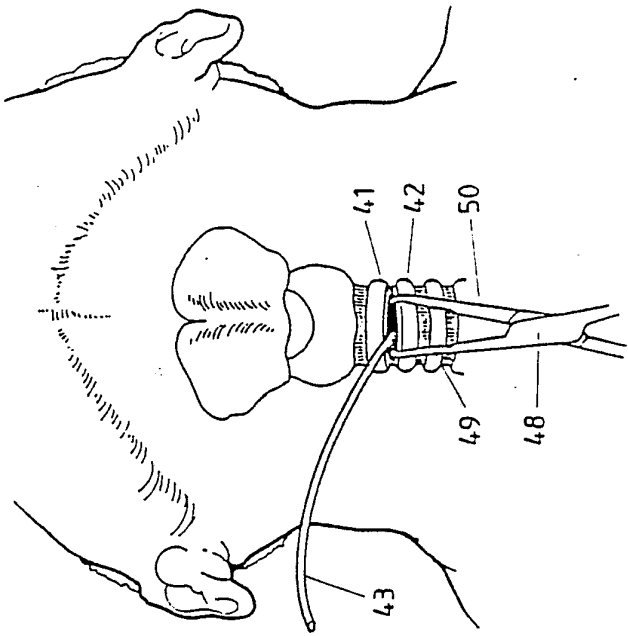
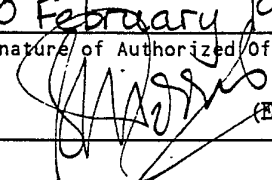


Fig. 7

INTERNATIONAL SEARCH REPORT

International Application No. **PCT/AU 90/00583**

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 6		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int. Cl. ⁵ A61B 17/02, A61M 29/00		
II. FIELDS SEARCHED		
Minimum Documentation Searched 7		
Classification System	Classification Symbols	
IPC	A61B 17/00, 17/02, A61M 29/00	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched 8		
AU : IPC as above		
III. DOCUMENTS CONSIDERED TO BE RELEVANT 9		
Category*	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages 12	Relevant to Claim No 13
X	AU,B, 72866/87 (594461) (WALTAP LIMITED) 8 October 1987 (08.10.87)	(1,3-5,7,9-10)
Y	see page 1 line 26 - page 2 line 6, page 4 line 26 - page 5 line 15, Figure 1 and 2	(2,6,8)
Y	US,A, 4693250 (COONS) 15 September 1987 (15.09.87) see col 4 line 24 - col 5 line 16, Figures 1-4	(1-3,5-8)
Y	FR,A, 2036538 (EDWARD WECK AND CO, INC) 24 December 1970 (24.12.70) see Figure 1	(1-3,5-8)
A	US,A, 3817250 (WEISS et al) 18 June 1974 (18.06.74)	
A	US,A, 4520810 (WEISS) 4 June 1985 (04.06.85)	
A	AU,A, 46581/72 (WEISS) 21 March 1974 (21.03.74)	
(continued)		
<p>* Special categories of cited documents: 10 "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</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"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.</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
11 February 1991 (11.02.91)	20 February 1991	
International Searching Authority	Signature of Authorized Officer	
Australian Patent Office	 (E.N. PERRIS)	

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A	Derwent Abstract Accession no. L2826E/34, Class P31, SU,A, 874041 (ASLANYAN) 25 October 1981 (25.10.81)
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V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE 1

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

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

2. ☐ Claim numbers , 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:

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

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING 2

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 of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ 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 claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
☐ No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 90/00583

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Members			
AU 72866/87	CH 670570	DK 6151/87	ES 2005117		
	FI 875249	FR 2596272	GB 2196535		
	IL 78295	IL 81378	NL 8720178		
	NO 874900	PT 84577	SE 8704755		
	WO 8705792	ZA 8702149	US 4889112		
FR 2036538	BE 730495	DE 1616123	GB 1167697		
	US 3459187				
US 3817250	BR 7308246	FR 2203648	IL 43502		
	IT 997897	JP 49095487			
US 4520810	IL 66852				

END OF ANNEX