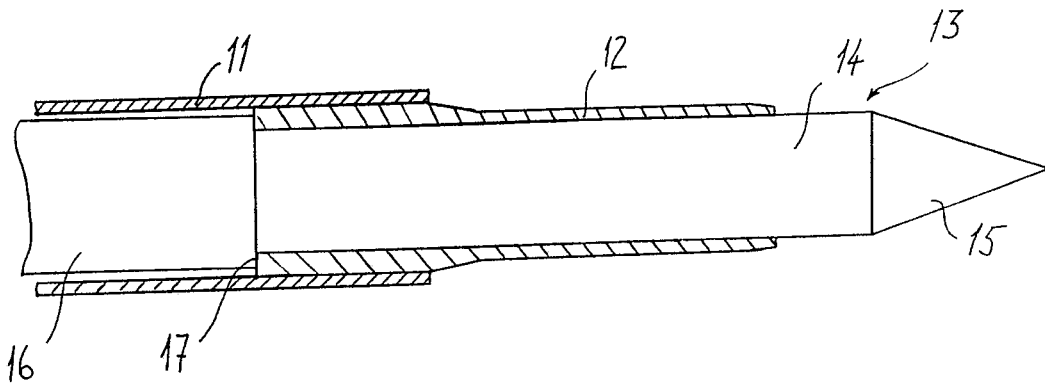


## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification <sup>5</sup> : <b>A61M 27/00</b></p>	<p><b>A1</b></p>	<p>(11) International Publication Number: <b>WO 91/17787</b> (43) International Publication Date: 28 November 1991 (28.11.91)</p>
<p>(21) International Application Number: PCT/SE91/00371 (22) International Filing Date: 23 May 1991 (23.05.91) (30) Priority data: 9001857-3 23 May 1990 (23.05.90) SE (71) Applicant (for all designated States except US): ATOS MEDICAL AB [SE/SE]; Box 309 Lyby, S-242 93 Hörby (SE). (72) Inventors; and (75) Inventors/Applicants (for US only) : PERSSON, Jan-Ove [SE/SE]; Havrevägen 3, S-243 95 Höör (SE). LEJDEBORN, Lars [SE/SE]; Västergöksvägen 70, S-162 24 Vällingby (SE). BERG, Olle [SE/SE]; Elfviksvägen 66, S-181 47 Lidingö (SE).</p>		<p>(74) Agents: STRÖM, Tore, V. et al.; Ström &amp; Gulliksson AB, P.O. Box 4188, S-203 13 Malmö (SE). (81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European 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.  <b>Published</b> <i>With international search report.</i> <i>In English translation (filed in Swedish).</i></p>

(54) Title: DRAIN, DEVICE FOR APPLYING SAID DRAIN AND METHOD FOR APPLYING A SINUS DRAIN



## (57) Abstract

Drain for an antrum, comprising a flexible catheter (11), to be applied with a first end thereof in said antrum and with a second end thereof available externally of said antrum, a device for applying said drain, and a method for applying said drain. One end section of said catheter (11) is connected to a tube (12) made of a material rigid compared to said catheter (11). Said device comprises a needle (13) slideable through said catheter (11) and said tube (12), and a hammer (21) displaceable against said needle (13) for making said needle (13) penetrate a wall defining said antrum. Said needle (13) is inserted into the nose, the needlepoint (15) contacting the bone between the nose and the maxillary sinus. Said tube (12) is adapted over and externally of the front section of said needle (13), said needlepoint (15) extending ahead of a front end of said tube (12), and is brought along a predetermined distance through said bone when said needle is displaced. Said needle (13) is then retracted through said bone, leaving said tube.

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DRAIN, DEVICE FOR APPLYING SAID DRAIN AND METHOD FOR  
APPLYING A SINUS DRAIN

The invention relates to a drain, comprising a flexible catheter to be applied with a first end thereof in an antrum and with a second end thereof available external-  
5 ly of said antrum, a device for applying said drain, and a method for applying said drain.

In the area of both human and veterinary medicine it is normally desirable to get access to an antrum, for instance in inflammatory conditions when pus, blood or  
10 secretion is to be discharged or in other conditions when gases or liquids are to be evacuated. An example in human medicine is infection in the maxillary sinus including pus therein, accumulation of blood or air in the thoracic  
15 cavity after a trauma, urinary retention disabling depletion of the bladder, or conditions including accumulation of blood within or outside of the hard meninx. Also sampling from antrums are customary, for instance bone marrow sampling from medullary cavities.

Infection of maxillary sinus including pus implies specific problems. As a result of swelling of the mucous  
20 membrane in nose and maxillary sinus at an upper respiratory infection the normal outlets of the maxillary sinus are closed. The air normally existing in said maxillary sinus will be resorbed and the partial pressure decreases.  
25 Normally, already at this point the patient experiences a feeling of weight or pressure from the affected maxillary sinus. If the process continues the transport by the cilia is stopped and secretion of the mucous membrane is accumulated. In such an environment the immunological  
30 defence against bacteria is deteriorated, and a bacterial infection with an accumulation of pus could arise. Because of the size and the anatomic structure with an outlet passage in a high position the maxillary sinus is extremely exposed to bacterial infections. There could also be a  
35 spreading of infections to the maxillary sinus from infected teeth of the upper jaw. The treatment comprises a

puncture of the maxillary sinus by inserting a needle into the nasal cavity and engaging the wall of the maxillary sinus. Then the needle is forced through the bone wall into the maxillary sinus. In this way material accumulated in the maxillary sinus can be sucked out for diagnosis, and then the maxillary sinus can be rinsed with a sodium chloride solution. However, it is difficult to puncture the maxillary sinus in this way. A careful anaesthesia is necessary and the doctor in charge has to be experienced.

5

10 In spite of this also experienced otorhinolaryngologists fail when puncturing. A major cause of the problem is that the needle must be pressed through the bone in an oblique angle. A low space anatomy or a thick bone structure to the maxillary sinus in many cases inhibits a puncture. Instead

15 the needle will slide in the mucous membrane and cause a bleeding. Sometimes the maxillary sinus is reached only after applying a very heavy force on the needle and in such a case there is a risk that the needle will move forward through the rear wall of the maxillary sinus or into the

20 eyeball; such complications are well documented. However, as the swelling of the mucous membrane, the closed outlet and a reduced transporting ability of the cilia will remain for a longer period of time (days or weeks), even if the treatment is favourable, it is normally necessary to repeat

25 the treatment several times before a complete healing of the infection is achieved. Each treatment requires a new puncture resulting in further discomfort to the patient and requiring comparatively large costs of treatment of a specialist. In praxis this means that repeated antral

30 washouts are performed only every second or every third day, even though from a medical point of view it would be more appropriate and lead to a faster healing if the antral washouts were made at least on a daily basis. Thus, it is desirable to decrease demands of repeated punctures in each

case but to have a possibility of performing an antral washout as often as possible.

There have been attempts to decrease the number of repeated punctures, for instance by inserting a comparatively rigid catheter in the needle. When pressed into the maxillary sinus in a normal way the needle has been retracted. By a special shape of the catheter, either having the shape of a spiral or being provided with flanges, said catheter has been prevented from falling out of the maxillary sinus and it has been possible to perform antral washouts repeatedly without the necessity of repeated punctures. However, the methods have not become as popular as should have been expected. The reason for this is that none of the methods overcomes the difficulties and risks of forcing the needle into the maxillary sinus, instead a larger force is required to insert the needle and the catheter. Furthermore, the function of the spiral preshaped catheter has been unsafe and the catheter has often come out of the maxillary sinus. Both of said types of catheters have been manufactured by a rigid plastics to make possible the insertion which means that they have been uncomfortable to the patients and caused problems and pain in the opening of the nose.

An object of the present invention is to overcome essentially the drawbacks and the problems mentioned above.

The object has been accomplished by the characterizing features of claim 1 and 4, respectively.

A further object of the invention is to make possible administration of medicins through the device.

The invention will now be described in more detail by means of an embodiment, reference being made to the accompanying drawings, in which,

FIG. 1 is a longitudinal sectional view of a device for draining the maxillary sinus according to the invention,

- FIG. 2 is a longitudinal sectional view of a section of the drain of FIG. 1 in a larger scale and having a needle extending there-through,
- 5 FIG. 3 is a sideview of the needle of FIG. 2,  
FIG. 4 is a longitudinal sectional view of a device for applying the drain according to FIG. 1-3,
- 10 FIG. 5 is a sideview of an alternative embodiment of the drain according to the invention, and  
FIG. 6 are two sideviews from different directions of still another embodiment of the drain according to the invention.

FIG. 1 shows that the drain for maxillary sinus according to the invention comprises a hose or catheter 11 and a tube 12 connected thereto. Said catheter 11 is made of a soft and flexible material so as to extend, after applying said drain, through the nose without any major inconveniences to the patient and to be available from the opening of the nose. A suitable material for said catheter is rubber or thermoplastic elastomer preferably silicone rubber and vinyl chloride plastic. Said tube 11 is made of a rigid and hard material and is provided with thin walls so as to be inserted easily together with a needle through the wall of maxillary sinus. Materials, such as metal, for instance titanium or steel, or rigid plastic can be used in said tube 12. In a preferred embodiment said tube and said catheter are fixidly connected, preferably by gluing, and said catheter surrounds a section of said tube. From the description below it is clear that in the described embodiment the tube will engage a shoulder of a needle.

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FIG. 2 shows a state in which said catheter 11 and said tube 12 have been threaded onto a needle 13, said needle comprising a needle point 15, a point section 14 and a base section 16. Between said point section 14 and said

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base section 16 is provided a stop formed as a radially extending shoulder 17. said tube 12 engages said shoulder 17 when put on the needle 13 from the needlepoint thereof thereby being prevented from a further displacement backwardly. The end of said tube 12 directed towards the needle point is bevelled so as not to act restricting when said needle together with catheter and tube are inserted through the bonewall between the nasal cavity and the maxillary sinus.

FIG. 3 shows the entire needle 13. The end of said needle opposite of the needle point comprises an internally threaded socket 24. Said socket is screwed together with the device described below before the drain is applied. In the preferred embodiment said needle and said socket are made of a material facilitating a reuse after disinfection, for instance steel, but it is also possible to provide needle and socket as expendable products.

To overcome essentially problems during penetration of the bonewall into the maxillary sinus and the insertion of the drain therein a device according to the invention is provided. Said device is shown in FIG. 4 and comprises a cylindrical cover 25 having a head 20 and an end section 28 enclosing several axially arranged hollow spaces. In a first hollow space 19 in said head 20 a needle holder 18 having a threaded front section 26 and a needle 13 detachably connected to said needle holder 18 are arranged axially displaceable. A restriction in displacing the needle holder in the backward direction is provided by a washer 37 and in the forward direction by an impact damper 38 arranged in said first hollow space, said damper being engaged by an exterior flange 38 of said needle holder. A front section 26 of said needle holder is threadedly connected to said socket 24, and a rear section of said needle holder is threadedly connected to one end of a return pin 29, a second end thereof received axially displaceable

within a hammer 21 arranged axially displaceable in said cover.

Said hammer 21 can be moved in a second, elongated and axially extending hollow space 22, the end thereof opposite to said head being closed by an annular damper 36. The end of the return pin received in said hammer comprises an exterior flange engaging an interior shoulder of said hammer when said hammer is moved in the backward direction. Said hammer is by external threads in the end thereof opposite to said head connected to a partly retractable cocking lever 27. Said cocking lever extends through said end section 28 which is screwed into said cylindrical cover 25. Said hammer is provided with an external flange 30. A stop washer 31 is provided engaging said flange 30, and between said stop washer 31 and said end section a coil spring 23 is fixed, said spring being depressed when said cocking lever is moved backwardly from said head. A spacer 32 is provided extending from said hammer towards said head to lock said cocking lever and hammer in a state of tension. Said spacer 32 extends through and is guided in an axial recess in said head and engages an elongated releasing pin 33 that is radially displaceable in a radial recess in said head. Said releasing pin 33 is formed with a first through opening extending in the transverse direction of said releasing pin, the needle holder 18 extending through said recess, and also a smaller recess 34 extending in the same direction through which releaser 33 moves when said releasing pin is disposed in an inner position in said radially extending recess. A spring 35 is provided in the bottom of said radially extending recess, said spring forcing said releasing pin outwardly towards an outer position in which said releasing pin is prevented from a further movement forwardly.

Said hammer is shaped cylindrically and is provided with a thin front section directed towards said head, the



outer diameter of said section being smaller than the inner diameter of said annular damper 36 and said washer 37. Thereby said hammer can be moved through said damper 36 and said washer 37.

5           FIG. 5 and FIG. 6 show two developments of said drain according to the invention. Said tube 12 is provided with elements to hamper an incidental retraction of the drain. Said tube 12 of said drain is according to FIG. 5 provided with barbs 41 in the free end thereof. Such an embodiment  
10 is intended first of all for use for patients having a bad wall to the maxillary sinus, for instance patients previously exposed medical surgery of said wall or patients that have been punctured frequently in a conventional  
15 manner. The barbs are very thin, approximately 0,25 mm, and thereby they are folded during penetration and refolded when retracted.

          In the embodiment according to FIG. 6 said tube 12 of the drain is provided with extending wedge shaped hooks 40, the thinner part thereof disposed in the insertion direc-  
20 tion of said tube.

          The function of the device described above will now be described in more detail. A needle 13 is screwed into said threaded section 26 of said needle holder 18, and then said cocking lever 27 is pulled backwardly against said  
25 spring 23. Said return pin 29 will also move backwardly, thereby bringing also said needle holder. When the spacer 32, while moving together with said hammer 21, has passed through said recess 34 in said releasing pin 33 said spring  
30 34 will bring said releasing pin to an upper position in which said spacer is prevented from a further movement in the forward direction. Now the device is in a ready state shown in FIG. 4. The drain according to the invention is put onto said needle 13, which is inserted into the nose to make the needlepoint engage the bone of the maxillary  
35 sinus. In advance a local anesthetic has been given in the

nose in a suitable way, for instance by an anasthetic spray. Said releasing pin 33 is depressed to allow said spacer 32 pass through said recess 34. Then the hammer 21 is accelerated by the force of said spring 23 and moves  
5 through said damper 36 and said washer 37 and hits the rear section of said needleholder 18, which together with said needle very rapidly is pushed forwardly to make said needle penetrate the bone wall and the front section of the drain pass through said bonewall. During the forward movement of  
10 said hammer said return pin 29 is not directly affected by said hammer. The movement in the forward direction of the needle holder 18 is slowed down when the flange 39 of said needle holder engages said impact damper 38 and when said flange 30 of said needle 21 engages said damper 36. The  
15 length of stroke of said needle is determined by the distance between said washer 37 and said impact damper 38 and said distance is chosen from the anatomic conditions of nose. Then the device including the needle is removed from the nose while leaving said drain. Then repeated washouts  
20 and tests can be made without any further penetrations required because the flexible catheter of the drain is easily available from the opening of the nose.

The very good action of the device is mostly based on the fast pushing, the well determined length of stroke, and  
25 that the needle is slowed down in a controlled way. Other embodiments of the device giving the same function can be provided within the scope of the invention.

The embodiment of said releasing device shown, can be varied in many ways within the scope of the invention, for  
30 instance by using releasing elements from the arms industry. The stop 17 consisting in the shown embodiment of a shoulder can instead in other embodiments comprise one or several radially extending pins or a ring mounted in a groove. Also other embodiments of a stop for restricting

aan axial displacement of the tube and catheter when put on the needle are possible.

5 The drain according to the invention is also to a high degree applicable when administering medicine or other substances to the antrum. To facilitate administration of medicine through the drain in different areas said catheter in one embodiment is provided with a fixed adapter in the free end thereof, said adapter being intended for receiving a cannula or the like. In an alternative embodiment the  
10 free end of said catheter is formed so as to be detachably connected to different types of adapters. The catheter is connected to syringes, dosage aggregates, suction devices or the like.

15 For specific types of medicine or during specific circumstances it is appropriate to administer medicine into the antrum through a hose inserted through the catheter, said hose having a smaller diameter than said catheter. Such a method is appropriate especially when the medicine is intended for a certain part of the antrum.

20 For patients requiring a continuous ventilation of an antrum, for instance the maxillary sinus, the drain according to the invention is provided with a shorted or an excluded catheter.

25 In the last described embodiment the end of the tube opening into said antrum preferably is provided with an exterior flange so as to lower the risk that said tube unintentionally falls out. Also when using the drain according to the first described method it is under certain circumstances appropriate to provide said tube with such a  
30 flange.

## CLAIMS

1. Drain comprising a flexible catheter (11), to be applied with a first end thereof in an antrum and a second end thereof being available exterior of said antrum, c h a -  
5 r a c t e r i s e d in that an end section of said catheter (11) is connected to a tube (12), the material of said tube being rigid compared to the material of said catheter.
- 10 2. Drain according to claim 1, c h a r a c t e r i s e d in that said end section of said catheter (11) surrounds an end section of said tube (12) and that said catheter (11) and said tube (12) are fixidly connected.
- 15 3. Drain according to claim 1 or 2, c h a r a c t e r i s e d in that said tube (12) in the free end thereof is provided with radially extending wedges (40).
- 20 4. Drain according to any of claim 1-3, c h a r a c t e r i s e d in that said tube (12) in the free end thereof is provided with barbs (41) extending therefrom.
- 25 5. Device for applying a drain formed in accordance with claim 1, comprising a catheter (11), a tube (12) connected thereto and an elongated needle (13) arranged within said catheter (11) and said tube (12) for penetrating a wall of an antrum, c h a r a c t e r i s e d in  
that said needle (13) is connected to a needle holder (18) movable between an inner and an outer end position in the longitudinal direction of said needle (13) and in a first hollow space (19) in a head (20), and  
30 that a hammer (21) displaceable in a second hollow space (22) between a rear end and a front end position by means of a force generating means (23), is arranged to engage said needle holder in said inner end position thereof at a predetermined distance from  
35 said front end position of the hammer, said needle holder (18) and thereby said needle (13) being

brought with said hammer (21) when said hammer (21) is displaced to the forward end position thereof.

6. Drain according to claim 5, c h a r a c t e r i s e d in

5 that said needle (13) comprises an point section (14) terminated in a front part by the needlepoint (15) and in the opposite part of said point section (14) a radially extending element (17), and  
that said element (17) extends radially over the inner  
10 radius of said tube (12), said tube (12) engaging said element (17) when said needle (13) has been inserted in said catheter (11) and said tube (12) of the drain.

7. Drain according to claim 6, c h a r a c t e r i s e d in

15 that said extending element (17) is constituted by an annular shoulder extending from said edge section (14).

8. Method for applying a drain into maxillary sinus

20 according to which a needle (13) is inserted in the nose, the needlepoint (15) thereof engaging the bone within the nasal cavity and the maxillary sinus, c h a r a c t e r i s e d  
by mounting a tubular means (12) of said drain over and  
25 externally on a front position of said needle (13), said needlepoint (15) extending over the front end of said tubular means (12),  
by applying kinetic energy to said needle (13) in a  
30 direction towards said bone between the nasal cavity and the maxillary sinus, said energy being sufficient for making said needle penetrate said bone during a forward movement of said needle (13) generated by said kinetic energy,  
by driving said tubular member (12) along with the  
35 movement of the needle,

by stopping said movement of the needle when a  
predetermined distance has been covered, said  
distance being at least large enough to put the  
opening of a front end of said tubular means (12)  
5 into said maxillary sinus, and  
by retracting said needle through said bone between the  
nasal cavity and the maxillary sinus leaving said  
tubular means (12).

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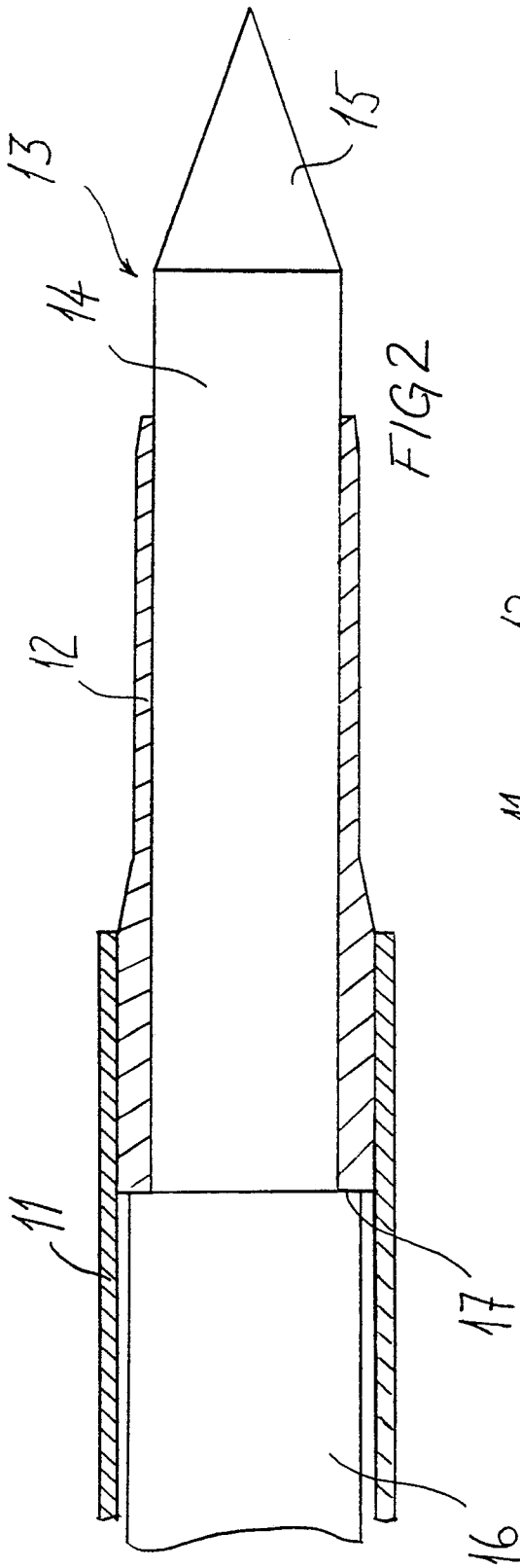


FIG 2

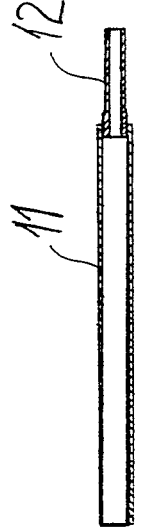


FIG 1

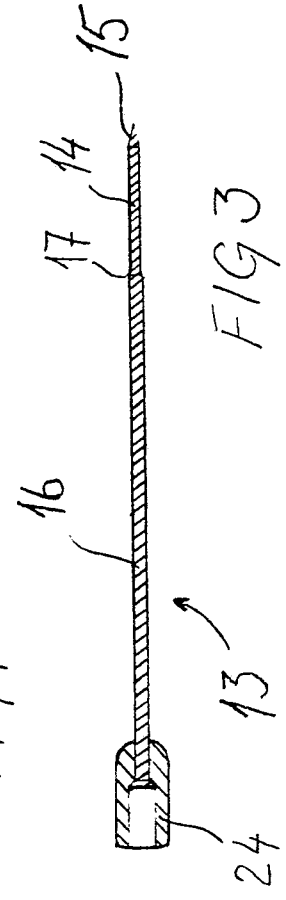
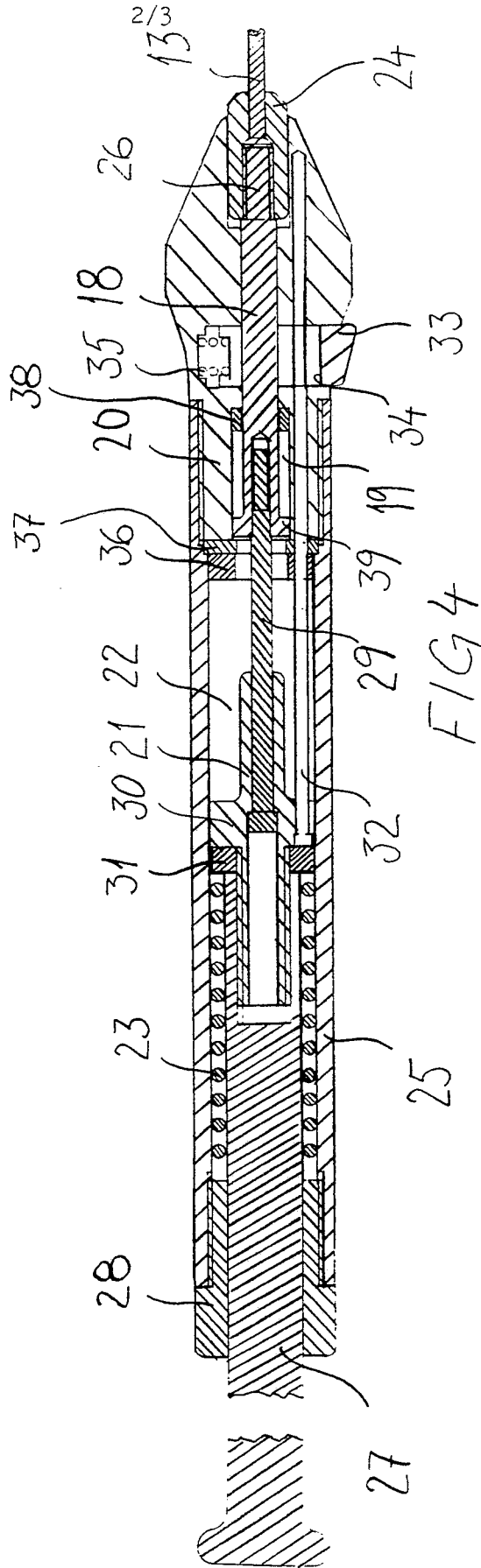
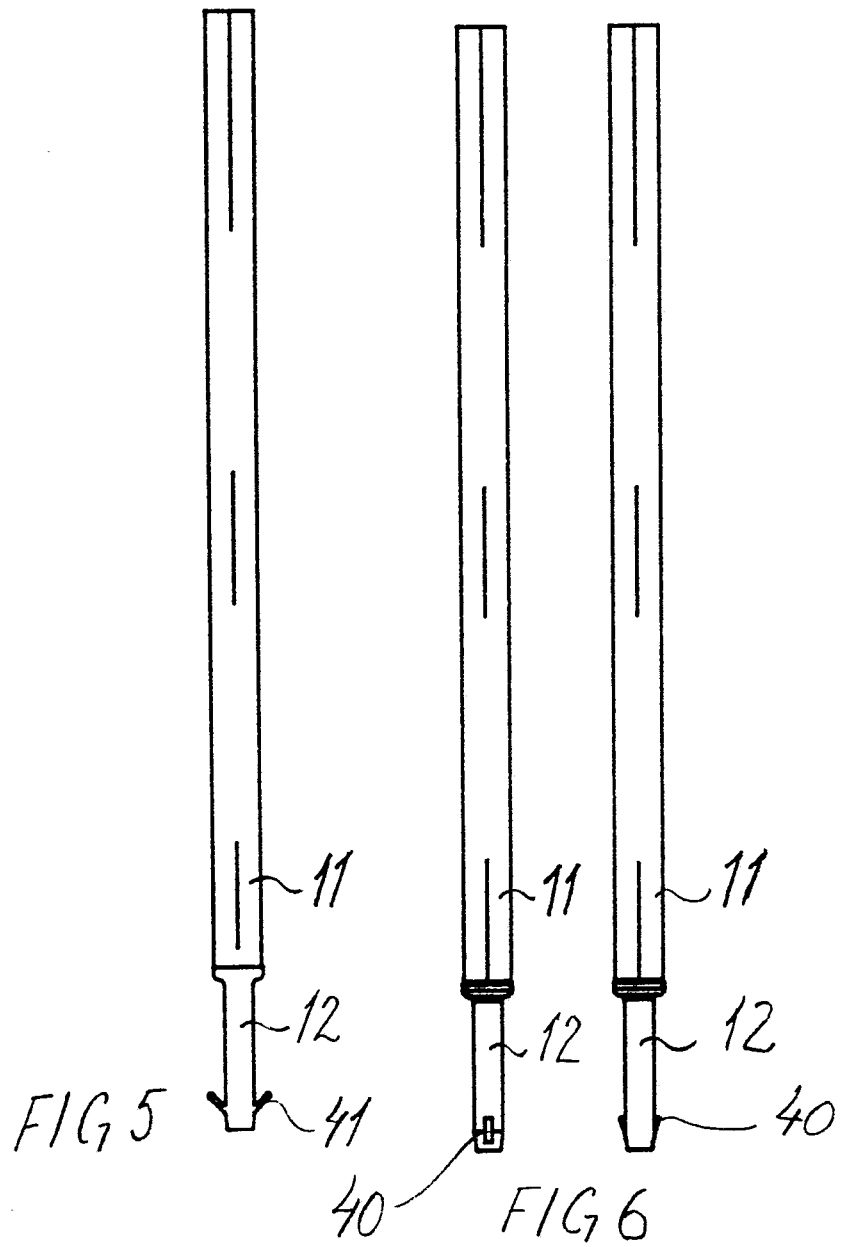


FIG 3

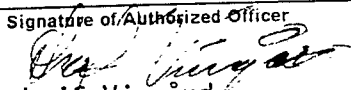






# INTERNATIONAL SEARCH REPORT

International Application No PCT/SE 91/00371

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>6</sup> According to International Patent Classification (IPC) or to both National Classification and IPC IPC5: A 61 M 27/00		
<b>II. FIELDS SEARCHED</b> Minimum Documentation Searched <sup>7</sup>		
Classification System	Classification Symbols	
IPC5	A 61 B; A 61 M	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched <sup>8</sup>		
SE,DK,FI,NO classes as above		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT<sup>9</sup></b>		
Category *	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
A	SE, B, 450996 (OLLE BERG ET AL) 24 August 1987, see the whole document --	1
A	DE, A, 1791178 (VIELBERG) 18 November 1971, see the whole document --	5-7
A	US, A, 3659610 (CIMBER) 2 May 1972, see the whole document -- -----	5
* Special categories of cited documents: <sup>10</sup> "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 "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		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
4th September 1991	1991 -09- 0 9	
International Searching Authority	Signature of Authorized Officer	
SWEDISH PATENT OFFICE	 Leif Vingård	

## FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V.  OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE <sup>1</sup>

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 8, because ~~they~~ <sup>it</sup> ~~relate~~ <sup>-s</sup> to subject matter not required to be searched by this Authority, namely:  
**methods for treatment of the human or animal body by surgery or therapy (Rule 39.1.(iv)).**

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 <sup>2</sup>

This International Searching Authority found multiple inventions in this international application as follows: **The method according to claim 8 is not limited to be performed using the drain according to claims 1-4 or the application device according to claims 5-7.**

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 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 PATENT APPLICATION NO.PCT/SE 91/00371

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.  
The members are as contained in the Swedish Patent Office EDP file on 91-07-31  
The Swedish 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	Publication date	Patent family member(s)	Publication date
SE-B- 450996	87-08-24	NONE	
DE-A- 1791178	71-11-18	NONE	
US-A- 3659610	72-05-02	NONE	