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(54) Gastrostomy tube device for enteral nutrition

(57) A gastrostomic tube device for enteric nutrition is produced by forming in a single piece a tubular body comprising two ducts, one of which, having larger diameter and being provided with non-return valve means, is used to supply the nutritional material, while the other duct, having smaller diameter and being formed in the thickness of the wall of the duct of larger diameter, is connected to the inside of the cavity of a retaining balloon which is formed by an extension of the tubular body, which extension has a wall of variable, small thickness and which is folded back onto the tubular body itself until it envelops the outlet end of the duct having the smaller diameter.

Also arranged on the tubular body there is a radiopaque marker, which can be detected by X-rays in order to check the position of the balloon inside the gastric cavity, and a radiopaque insert arranged along the small-diameter duct connected to the cavity of the retaining balloon.

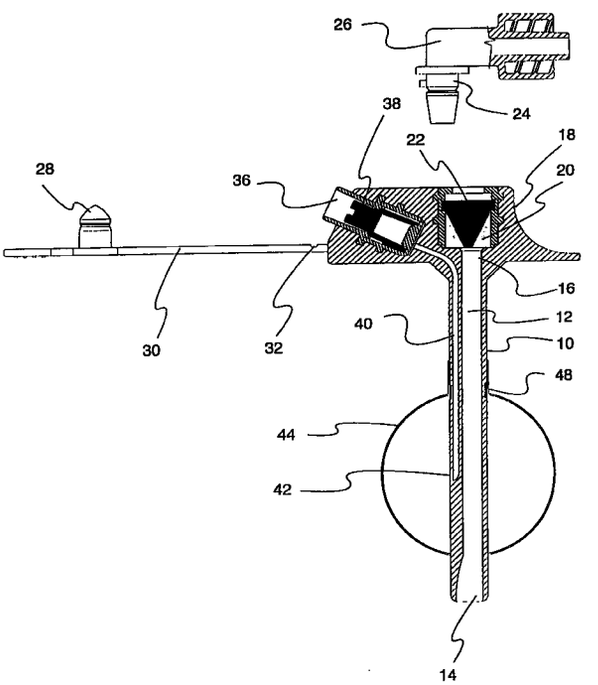

Fig. 1

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Description

The present invention relates in general to gastrostomic devices for medical use, in particular for the long-term enteric nutrition of patients incapable of the natural ingestion of food and/or medicaments.

It is known that it is not possible to feed orally and/or to administer drugs orally to patients who are suffering from specific disorders, such as, for example, patients who are comatose or who have lost consciousness.

In such cases, in addition to the parenteral feeding which is generally adopted for brief periods and normally only for hospitalised patients (a typical example is that of the nutrition and/or pharmacological treatment of patients who are the subject of surgical operations), it is possible to use the so-called enteric route which permits partial use of the digestive system, usually the stomach, excluding the upper portions of the digestive system which cannot be used.

Within the scope of the enteric route, a solution generally adopted is that of introducing nasally one or more tubes extending as far as the inside of the gastric or intestinal cavity (nasogastric probe or nasojejunal probe).

This solution has some disadvantages, including principally the discomfort caused to the patient, (as a result of which the so-called compliance is minimal and the periods of use have to be reduced to a minimum), and, secondly, the fact that the substantial length of the above-mentioned tubes and their necessarily small diameter restrict the type of nutrition solely to liquid substances.

Recent years have seen the proposal and implementation of solutions which may be grouped under the general name of gastrostomic devices which substantially provide for the formation, through the abdominal wall, of a passageway or duct which connects the gastric cavity to the outside, thus permitting the direct introduction of food, also in a form equivalent to the "premasticated" form which normally passes to the stomach during normal nutrition. Of course, although it has considerable limitations, the situation in this case has substantially less serious disadvantages for the patient.

In practice, a technique known as PEG "Percutaneous Endoscopic Gastrostomy" is initially performed, which consists in introducing a catheter through the oral cavity and the oesophagus until it reaches the stomach; from here the end of the catheter is pulled to the outside through a hole formed in the abdominal wall and the catheter is secured in position by means of a holding tab.

At this point it is possible to introduce food directly into the gastric cavity for a given time without damaging the upper oesophageal tract and without the problems and disadvantages associated with the use of nasal probes.

Some time alter positioning the catheter, the formation of a type of tissue passageway takes place and at this point it is possible to replace the catheter by a gastrostomic device or tube which is referred to in jargon as a "button" because it is in the form of a button attached to the patient's epidermis.

The gastrostomic tubes or "buttons" currently in use are principally of two types, namely the "balloon" and "mushroom" types, and they differ from one another principally in the form of the retaining element inside the gastric cavity and in the methods of insertion into the above-mentioned tissue passageway or "stoma" of the patient.

In the case of the mushroom-type gastrostomic tube, the tube is introduced by means of an obturator inserted into the internal hole of the gastrostomic tube and urged in such a manner as to confer on the mushroom-head retaining element an elongate, substantially conical, profile in order to reduce its diameter and thus to facilitate passage through the stoma, releasing it when it has passed completely into the gastric cavity. However, despite this measure, the operation is not only painful for the patient but also entails the risk of damaging the walls of the stoma especially when removing and/or replacing the device.

The introduction of the balloon device is easier because it is carried out with the balloon completely deflated and adhering to the tube walls. When the introduction is complete, the balloon is inflated and it thus maintains the end of the gastrostomic tube inside the stomach. The external end of the gastrostomic tube is for its part provided with a plug or a non-return valve which enables the end to be connected periodically to a supply of nutrient material or the like to be introduced into the stomach (in addition to permitting the expulsion of air or gas present in the gastric cavity).

The length of the gastrostomic tube is of course chosen in accordance with the length of the stoma.

The balloon-type gastrostomic devices or tubes known and constructed hitherto comprise several components assembled at the manufacturing stage, and therefore require substantial labour, but, in particular, the regions of adhesion of the various components are the critical points of the device, compromising its aesthetic and functional quality.

Secondly, a periodic check to establish that the internal end of the gastrostomic tube is correctly positioned inside the stomach means that the design of the device must provide for the possibility of radiographic observation.

Commercially available devices meet this requirement by using for the tubular part a longitudinal strip produced from co-extruded radiopaque material which usually involves the entire thickness of the tube wall.

This solution involves a weakening of that portion of the device and a reduction in the adhesiveness of the material in the regions where the expanding balloon is to be adhesively bonded.

The principal aim of the present invention is to pro-

vide a gastrostomic tube device which is improved both from the structural point of view and from the functional point of view.

More specifically, the aim of the present invention is to provide a gastrostomic tube device of which the structure permits practical industrial manufacture and, at the same time, easy location of the position of the device using radiographic techniques.

This aim is achieved with a device of the type comprising a tubular element which can be inserted through a stoma in the patient's abdominal wall, the tubular element having a first end provided with an inflatable balloon in order to be maintained inside the gastric cavity, and a second end which has a base resting and maintained on the patient's epidermis and which is provided with removable closure means and on-off valve means, characterised in that the tubular element is divided into two ducts, the first duct, having the larger diameter, being used for the passage of the nutritional material and being connected to the removable closure means and to the on-off valve means, and the second duct, having walls produced from radiopaque material, being connected to the inflatable balloon and being provided with a non-return valve arranged at the external end relative to the patient's epidermis, and position-marking means of material opaque to X-rays are provided on the outer surface of the gastrostomic tube.

In the preferred embodiment of the present invention, the second duct is formed, with a small diameter, in the thickness of the wall of the first duct, the balloon, in the non-inflated state, is constituted by a tubular extension, of variable thickness, of the first end of the tubular element, and the tubular extension is folded back onto the outer surface of the first end of the tubular element and is secured in a sealing manner to the outer surface of the tubular element in such a manner as to envelop the lower outlet mouth of the second duct.

In addition, the position-marking means are preferably constituted by a thin silver ring which, during the manufacture of the tubular element, is anchored to the outer surface thereof; and is covered by the tubular extension forming the balloon during the adhesive bonding stage.

The silver ring is used to indicate exactly the position of the proximal point of attachment of the balloon, while a further tube of small thickness produced from radiopaque material is inserted coaxially in the small-diameter duct in order to indicate the position of the tubular portion of the device.

These and other features and advantages of the present invention will become clear from the following description which is given with reference to the appended drawings, in which:

Figure 1 is a view in longitudinal section of the gastrostomic tube device in the operative state;

Figure 2 is a top view of the gastrostomic tube device;

Figure 3 is a view of the device of Figure 1 in the non-operative state;

Figure 4 is a view similar to that of Figure 3 of a variant and

Figure 5 is a sectional view on the section plane V-V of Figure 3 and Figure 4.

Referring to the drawings, the gastrostomic tube device according to the invention which, as shown by the Figures, is produced in a single piece from biocompatible plastics material (for example by means of injection or "transfer") comprises a tubular element or body, generally indicated 10, which comprises a first duct or principal duct 12 having a distal end 14 and a proximal end 16. The proximal end 16 starts from a cylindrical or discoidal body 18 and more precisely from a chamber 20 which accommodates a separate and removable non-return valve 22 which can be connected to a bayonet coupling 24 of an elbow connector 26 which can in turn be connected to a supply of nutrient material. The upper end of the chamber 20 is shaped in such a manner as to permit the releasable connection of a plug 28 formed with a strip 30 which is in a single piece with the discoidal body 18 and which is provided with a notch 32 promoting the bending of the strip.

The discoidal body 18 has a flat base 34, which is to rest on the patient's epidermis in the area of the outer mouth of the stoma or tissue duct of the patient, and, in addition to the chamber 20, comprises a second chamber 36 which accommodates an inflating and non-return valve 38 communicating with the proximal end of a second duct 40 which extends parallel to the duct 12 over a portion of its length and which is formed in the thickness of the wall of the tubular body 10.

The distal end of the duct 40 has a hole 42 which, as shown in Figure 1, communicates with the inside of the balloon 44, which is shown in that Figure in the inflated position and thus in the position in which it maintains the tubular body 10 inside the gastric cavity.

It will be readily appreciated from Figures 3 and 4 that the balloon 44 is formed by a tubular extension 50 or 60 of the tubular body 10. In the case of Figure 3, the upstream or proximal end 51 of the tubular extension 50, which is shown in the state before the balloon is inflated, is fixed firmly to the outer surface of the tubular body 10, while the distal end 53 is secured in position when the device is being finished (for example by adhesive bonding or heat-sealing) in the region of the distal end 14 of the tubular body 10.

As can be seen in Figure 3, the proximal end 51 of the tubular extension 50 envelops the outlet mouth 42 of the second duct 40.

An alternative embodiment of the device is that represented in Figure 4 which shows how the balloon 44 is in this case formed by a tubular jacket 60 of reduced thickness which is concentric with the tubular body 10. In order to form the balloon 44, the tubular jacket 60 is secured permanently to the outer surface of the tubular

body (for example, by heat-sealing or by means of a suitable adhesive) in the area of its distal end 61 once it has been folded back onto the tubular body 10 to the extent that it envelops the mouth 42 of the duct 40. The proximal end 63 of the balloon 60, like the proximal end 51 of the embodiment of Figure 3, is fixed firmly to the outer surface of the tubular body 10.

In the case of both embodiments, before the heat-sealing or adhesive bonding, a ring of material opaque to X-rays, for example a silver ring 48, is positioned on the outer surface of the tubular body at a predetermined distance from the base 34 of the discoidal body 18, and is simultaneously secured by adhesive bonding to the end 61 of the tubular extension 60 in the case of the embodiment of Figure 4. As shown in Figure 1, the ring is adjacent to the limit of the balloon 44 and therefore, using simple radiography, it is possible to establish from the position of the ring 48 whether the balloon 44 and thus the gastrostomic device is positioned correctly in the gastric cavity.

It will be readily appreciated from the above description that the device according to the present invention has numerous advantageous aspects.

Firstly, it can be readily manufactured by unitary moulding from a suitable plastics material and requires only the positioning of the valves 22 and 38, the folding back of the tubular extension 60 onto the body 10 and the adhesive bonding of those two elements only to be ready for use.

Secondly, it is easy to check that the retaining balloon is positioned correctly inside the gastric cavity.

Thirdly, it is possible to minimise the extent to which the discoidal body projects from the patient's epidermis. In this connection, it should be pointed out that the drawings are not to scale but are suitably enlarged so that the invention can be better understood.

The invention has been described in connection with a preferred embodiment but it will be understood that modifications and variants which are equivalent thereto mechanically and in terms of design are possible and can be provided for without departing from the scope of the invention.

Claims

1. Gastrostomic tube device of the type comprising a tubular body (10) which can be inserted through a stoma in the patient's abdominal wall, the tubular body having a first end provided with an inflatable balloon (44) in order to be maintained inside the gastric cavity, and a second end having a base resting and maintained on the patient's epidermis, the second end being provided with removable closure means (28) and on-off valve means (22), characterised in that the tubular body (10) is divided into at least two ducts (12, 40), of which a first duct (12) of larger diameter is suitable for the passage of nutritional material and is connected to the removable closure means (28) and also to the on-off valve means (22), while a second duct (40) is connected to the inflatable balloon (44) and is provided with a non-return valve (38) arranged at the external end relative to the patient's epidermis, the second duct (40) being constituted by a thin-walled tube of material opaque to X-rays, and the device also comprising position-marking means (48) of material opaque to X-rays on the outer surface of the tubular body.

2. Gastrostomic tube device according to Claim 1, characterised in that the second duct (40) is formed, with a small diameter, in the thickness of the wall of the first duct (12) using material opaque to X-rays, and in that the balloon (44), in the non-inflated state, is constituted by a tubular extension (60) of the first end of the tubular body (10), which extension is folded back onto the outer surface of the first end of the tubular body and is secured in a sealing manner to the outer surface of the tubular body in such a manner as to envelop the lower outlet mouth of the second duct.

3. Gastrostomic tube device according to Claim 1 or Claim 2, characterised in that the position-marking means (48) are constituted by a thin silver ring which, during the manufacture of the tubular body (10), is anchored to the outer surface thereof.

4. Gastrostomic tube device according to Claim 3, characterised in that the silver ring is anchored to the outer surface of the tubular body (10) in a position adjacent to that of the tubular extension (60) after the latter has been folded back onto the outer surface of the tubular body (10).

5. Gastrostomic tube device according to any one of Claims 2 to 4, characterised in that the tubular extension (60) which is to form the balloon (44) and which has a reduced and variable thickness is arranged concentrically on the outside of the tubular body (10), to the outer surface of which it is secured permanently.

6. Gastrostomic tube device according to any one of the preceding Claims, in which the second duct (40) is obtained by overmoulding.

7. Gastrostomic tube device according to any one of Claims 2 to 6, wherein the tubular extension (60) is fixed firmly to the outer surface of the tubular body (10), to which surface it is secured by the adhesive bonding of one end (61) only.

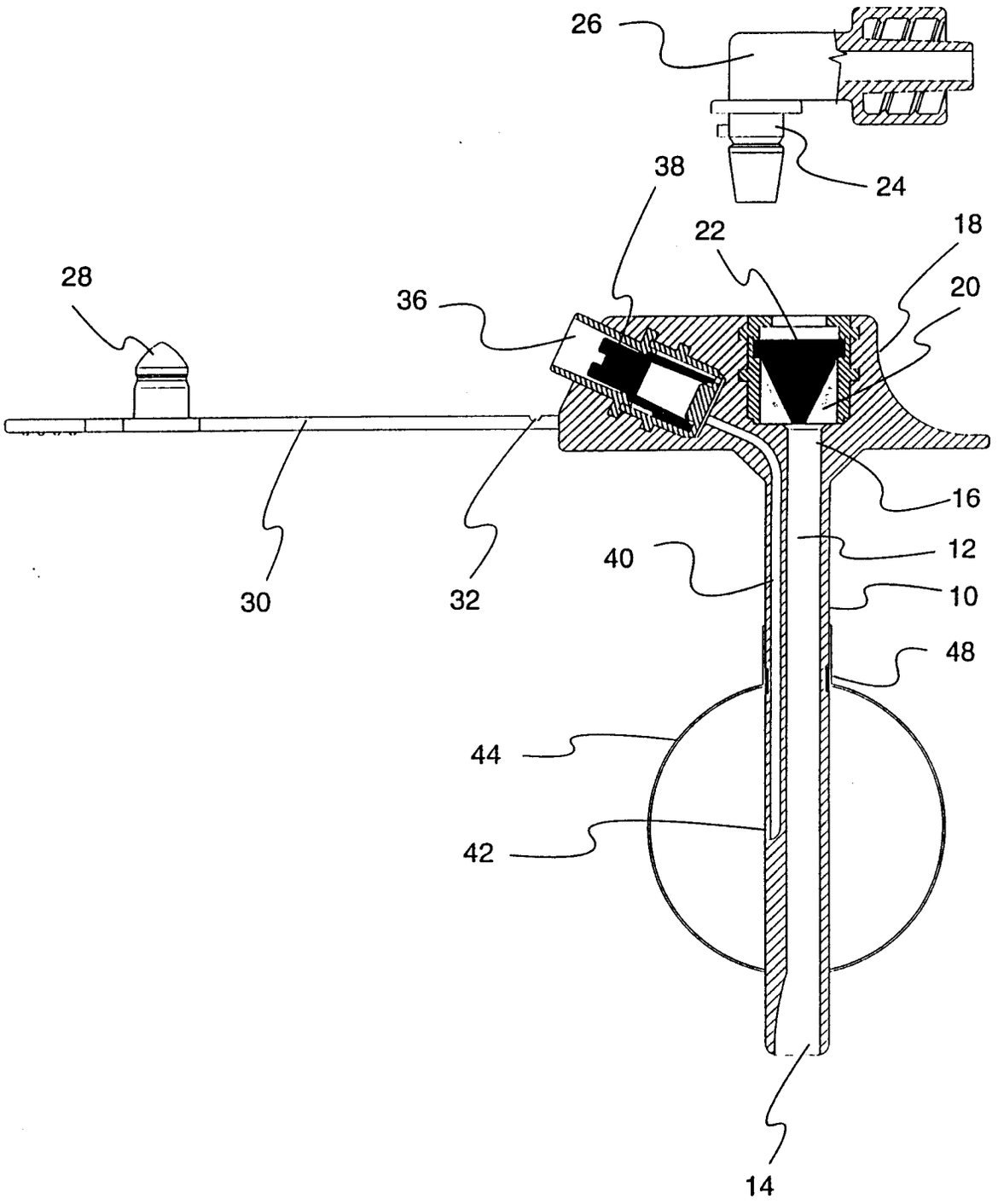

Fig. 1

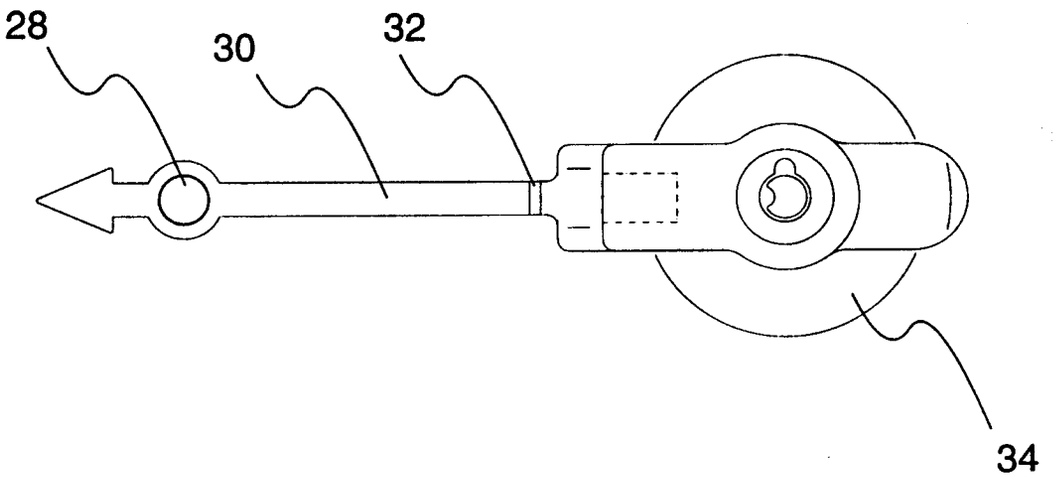

Fig. 2

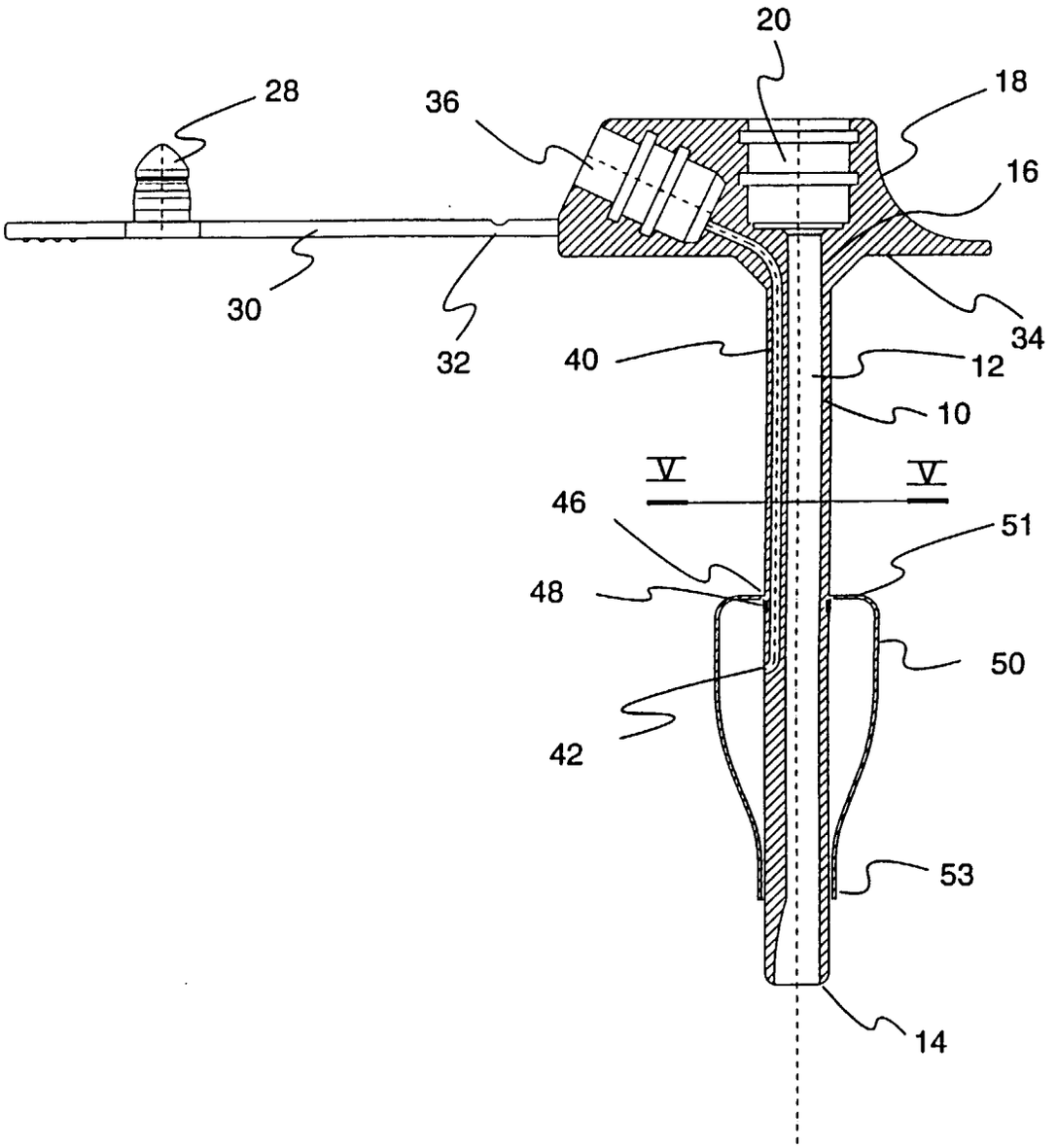

Fig. 3

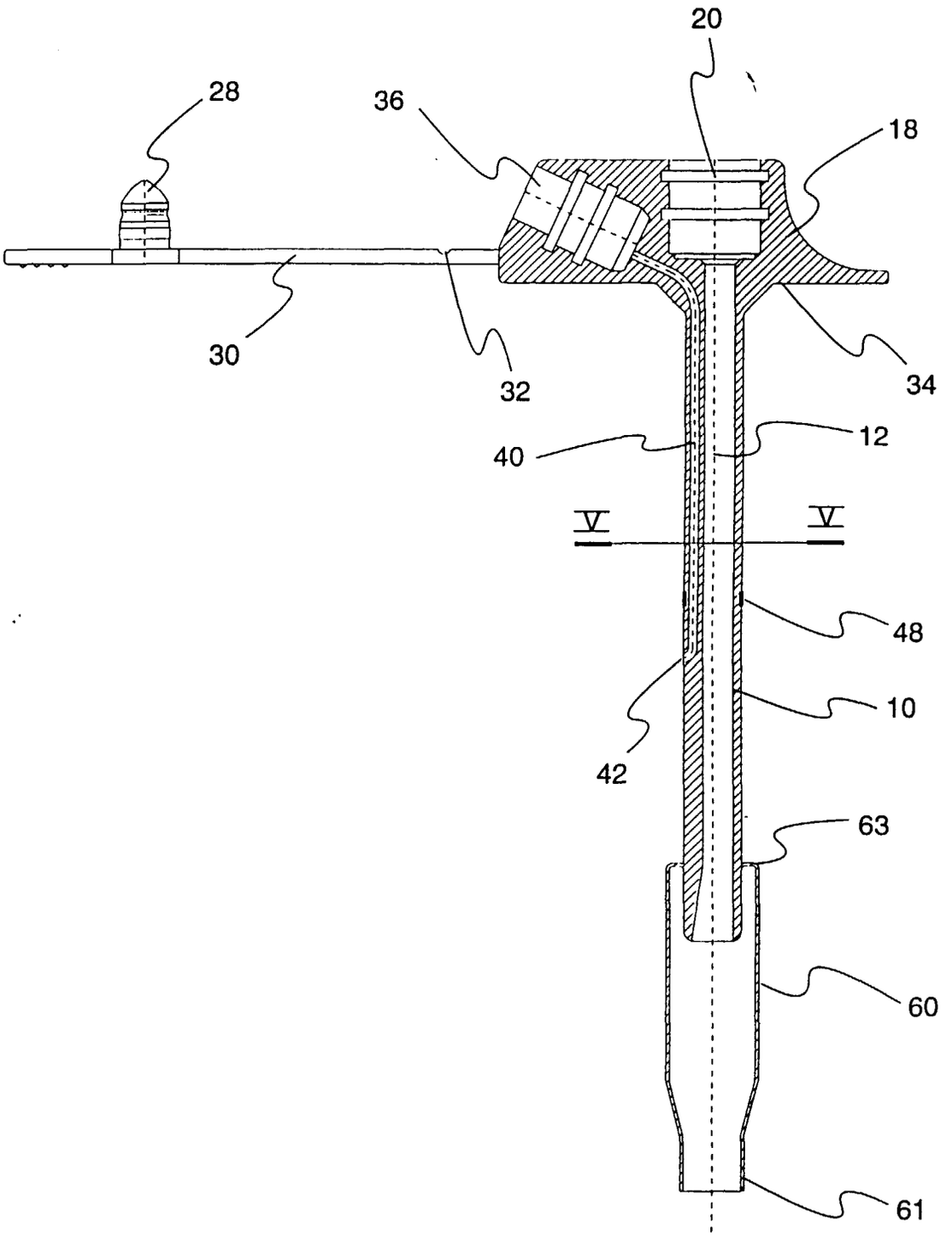

Fig. 4

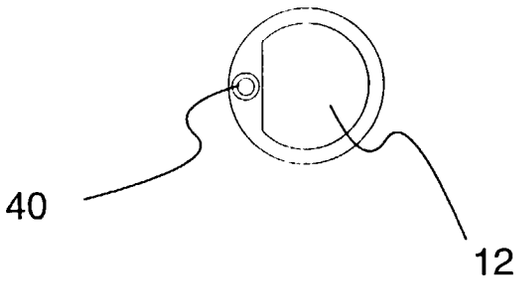

Fig. 5

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 97 20 3914

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Y A	US 5 556 385 A (CORPAK, INC.) * the whole document *	1 2	A61J15/00
Y A	US 5 342 321 A (TELEFLEX, INC.) * the whole document *	1 2	
Y A	US 4 323 071 A (ADVANCED CARDIOVASCULAR SYSTEMS , INC.) * column 11, line 54 - line 66; figure 12 *	1 3	
Y A	US 4 702 252 A (SMITHS INDUSTRIES PUBLIC LIMITED COMPANY) * column 3, line 5 - line 9; figures *	1 3	
A	EP 0 408 198 A (SMITHS INDUSTIES PUBLIC LIMITED COMPANY) * column 3, line 47 - line 54 *	3	
A	EP 0 318 918 A (TERUMO KABUSHIKI KAISHA) * claim 5 *	3	TECHNICAL FIELDS SEARCHED (Int.Cl.6)
A	US 4 225 371 A (THE KENDALL COMPANY) * column 2, line 42 - line 64; figures 3,4 *	4	A61J A61M
A	US 4 863 424 A (BLAKE) * column 5, line 51 - column 6, line 55; figures 8-12 *	5,7	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	18 March 1998	Baert, F

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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