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(54) Title: TUBULAR DEVICES FOR INTRODUCTION INTO BODY ORIFICES

![Diagram of tubular device]

(57) Abstract

A tubular device for introduction into a body orifice or duct, the tubular device comprising: an elongate tubular element (5) of flexible material to provide, following its introduction into the body orifice or duct, an inside surface and an outside surface, support means (3) of tubular form connected to one end of the flexible tubular element (5), the flexible element extending into the tubular support means in inside-out condition whereby a major part of said outside surface is disposed radially inwardly of a major part of said inside surface, and means (1) to expel the elongate tubular element longitudinally outwards of the support means in a progressive manner from said one end thereof and such as to present said outside surface to the body orifice or duct and with said inside surface disposed internally of said outside surface.
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TUBULAR DEVICES FOR INTRODUCTION INTO BODY ORIFICES

This invention relates to tubular devices for introduction into body orifices or ducts. The body may be of any physical material, e.g. metal or plastics material, but the present invention is considered to be particularly suited to orifices or ducts in an animal (particularly a human) body. Such animal orifices or ducts may be oral, rectal, penile or other orifices made for surgical purposes, e.g. vascular surgery or surgery on the digestive tracts.

There are several medical conditions and circumstances in which a tubular device is inserted into a body orifice to rest inside a body duct. Examples include exploration of the bladder via a catheter introduced through the urethra, posterior sealing of the nasal fossae by means of an expandable probe, and general surgery (especially vascular and gastric surgery).

In the past, the tubular devices generally employed are rigid-walled structures having sufficient stiffness in their longitudinal direction as to enable them readily to overcome any frictional resistance encountered as they are pushed longitudinally into the body orifices or ducts. In medical applications, this gives rise to a substantial risk of infection since the external portion of a biological duct (e.g. the urethra) is usually contaminated with germs and these germs are drawn down with and by the tubular device into the internal portions of the duct (these internal portions being usually relatively sterile in normally healthy conditions). It is estimated that some 40% of infections arising in hospital are urinary infections of which the major cause is considered to be due to the introduction of catheters.

Furthermore, the introduction of the tubular devices has in the past necessitated frictional engagement of the wall of
the body's duct or orifice and, in medical applications (e.g. with catheters, endoscopes, bronchoscopes, fibroscopes and the like), this has involved the patient in trauma and pain.

For example, the tubular devices currently employed for urinary probing and exploration of the bladder are inserted via the urethra causing a rubbing on the walls of the mucous membrane of the urethra, the consequence of which is a frictional dragging effect giving rise to patient trauma. Germs which are usually found in the distal portion of the urethra are thus dragged or carried towards the proximal portion and inside the bladder. There is thus the possibility of urinary infection, which is an important cause of iatrogenic infections having serious consequences for the patient. Additional precautions therefore need to be taken to avoid these side-effects, making patient treatment more expensive and/or more painful.

It is considered desirable to provide a tubular device for introduction into a body orifice or duct which avoids or at least minimises one or more of the above-described and/or other disadvantages of the prior art.

According to one aspect of the present invention there is provided a tubular device for introduction into a body orifice or duct, comprising an elongate hollow element of flexible material, and means for effecting said introduction by changing at least part of the flexible element from an inside-out condition to an inside-in and outside-out condition.

Preferably said changing is effected progressively.

According to another aspect of this invention there is provided a tubular device for introduction into a body orifice or duct, the tubular device comprising:
an elongate tubular element of flexible material to provide, following its introduction into the body orifice or duct, an inside surface and an outside surface, support means of tubular form connected to one end of the flexible tubular element, the flexible element extending into the tubular support means in inside-out condition whereby a major part of said outside surface is disposed radially inwardly of a major part of said inside surface, and means to expel the elongate tubular element longitudinally outwards of the support means in a progressive manner from said one end thereof and such as to present said outside surface to the body orifice or duct and with said inside surface disposed internally of said outside surface.

According to still another aspect of this invention there is provided a tubular device comprising a relatively rigid sleeve, means for securing to one end of the sleeve a flexible tube (e.g. of section corresponding to that of the tubular duct into which the flexible tube is to be inserted), said flexible tube being in inside-out or reversed disposition within the rigid sleeve so as to present an annular space between the sleeve and the flexible tube within it, and tubular driving means operating from the annular space to drive said flexible tube from inside of the sleeve outwards and across the boundary or edge of said driving means such that the sleeve is introduced into the orifice or duct without rubbing along the said orifice or duct.

As the indispensable condition, in the case of medical applications, is that the material placed in direct contact with the patient's tissues should be sterile, at least part of the tubular device is preferably of inexpensive (e.g. plastics) material so that the device may be used as as a once-only or throw-away item (i.e. a "disposable" item).
Preferably the flexible tube is of a natural or synthetic rubber or rubber-like material, e.g. a latex rubber or the like.

5 Preferably the sleeve is of a rigid plastics material enabling the sleeve to be manually held, i.e. used as a holder or support for said one end of the flexible tube, during said introduction of the device's flexible tube. By way of non-limiting example, embodiments of the present invention will now be described with reference to the accompanying drawings, of which:

Figure 1 is a schematic side view of a first embodiment of the invention,

15 Figure 2a is a schematic side view of a conventional fibroscope,

Figure 2b is a schematic side view of a second embodiment of the present invention incorporating the fibroscope of Fig 2a, and

Figure 3 is a schematic side view of a third embodiment of the present invention.

25 The catheter illustrated schematically in Fig. 1 is intended to be introduced into the tubular duct, for example the urethral duct, of a patient. It comprises a short tube 3 (open at both ends) of relatively rigid plastics material attached to one end of an elongate tubular element 5 of a highly flexible impervious material, e.g. a natural or synthetic rubber or a suitable plastics material, and further comprises an elongate tube 1 of relatively rigid plastics material that is mounted slidably in tube 3. The rigid tube 1 initially contains the flexible tube 5 in inside-out condition with the majority of its intended outer surface initially disposed inwardly of the majority of its
intended inner surface. The rigid tube 1 is employed to expel the flexible tube 5 and cause it to be introduced into the human body orifice or duct so as to engage the duct wall.

This push tube 1 comprises a forward part of hollow cylindrical form and closed rear part 2. The forward cylindrical part is disposed with its open front within the annular space between the inside-out flexible tube 5 and the short tube 3. The closed rear portion 2 is suitably widened or shaped to enable it to be readily pushed by the thumb in the forwards direction. A fastening member 4 is provided at the forward end of the holder or support tube 3 for securing thereto the open rear (or trailing) end of flexible tube 5.

As shown in Fig. 1, the majority of the flexible tube 5 is initially in a "rolled back" form within the push tube 1 so as to be disposed in inside-out condition inwardly of push tube 1. The outer support or guiding tube 3 is disposed over the push tube 1 and has one end 4 secured to the outwardly-folded mouth of the flexible tube 5.

In use, the front end of the assembly is placed in the orifice or mouth of the tubular duct into which it is to be inserted, and held in position by the operator holding the outer support or holding tube 3 with one hand. With the other hand the operator then pushes the push tube 1 in the forwards direction so as to cause unrolling of the flexible tube 5 which is thus introduced progressively into the duct, applying itself (without rubbing) onto the inner wall of said tubular duct. This is achieved solely by the sliding of the flexible tube 5 across the front edge 6 of said push tube. Optionally this edge 6 is provided with means facilitating such sliding, e.g. a thickening of the edge 6 or the provision at this edge of rotatable means which also minimise or abviate frictional sliding across the edge 6.
Optionally, the front part of the guide tube 3 may be provided with a frusto-conical mouth piece 7 (shown by broken lines in Fig. 1) to facilitate the application of the device at the inlet of the tubular duct. As illustrated, the mouth piece 7 has a cylindrical flange 8 at the radially innermost end of its wide part. The fastening member 4 comprises an annular ring encompassing the forward end of the guide tube 3 so as to define therewith a peripheral groove. The flange 8 is arranged to fit into this peripheral groove together with the free end of the flexible tube 5 whereby they are both simultaneously secured by the retaining member 4.

The embodiment of Fig 2b utilises a catheter substantially similar to that of Fig 1 as a covering for a conventional fibroscope (shown schematically in Fig 2a) for visually inspecting, and optionally sampling, an internal body location without contaminating the area with bacteria or germs (other than those already previously present at the selected location). In this case, the push tube 1 has its rear end 9 secured at a suitable location to the outer surface of the fibroscope, the rear head 10 of the latter acting as the push member proper (equivalent to portion 2 in Fig 1). The flexible tube 5 is initially disposed, as in the previous case, in inside-out condition inside said pusher tube 1, and the mouth or free end of the flexible tube 5 is also secured on the front edge of the guide tube 3, which may also have the same shape as in the device of Fig. 1.

Fig. 3 illustrates an embodiment wherein the push tube 1 has been replaced by a piston 11 which slides in seal-tight manner inside the cylindrical guide tube 3, this tube 3 being filled with a suitable liquid or gas. The flexible tube 5 is disposed, as before, in inside-out condition within the tube 3, the mouth or free end of tube 5 being secured in the same manner as previously mentioned to the front end of the guide tube 3. In this case, pushing
forward the piston 11 compresses the liquid or gas contained in the guide tube which, in turn, pushes the flexible tube 5 forward and outwardly of the guide tube so that tube 5 progressively adopts the shape of the body's orifice or duct into which it is being introduced or inserted.

An embodiment similar to that of Fig 3 is considered suitable for use as a probe for sealing the nasal fossae (posterior sealing). In this case the tubular device, by utilising a driving liquid or gas (air) pushed by a piston, facilitates that (when the insertion has been completed) the probe can expand to the extent of the volume of the cavity for an intimate and uniform contact to be achieved between the material introduced and the mucous membrane of the nasal fossae. This ensures the provision of an adequate and even pressure which makes it possible to stop the haemorrhage.

It will be appreciated that each of the above-described embodiments of the invention provides that frictional rubbing (by dragging through of the tubular device) does not occur between the wall of the flexible tube and the wall of the orifice or duct into which the flexible tube is inserted, but rather that any frictional contact occurs inside the device. From an alternative viewpoint, each of the above-described embodiments of the invention provides for insertion of a flexible tube inside a tubular duct by means of a simple progressive contact of the facing surfaces of same, without any frictional rubbing taking place, penetration being substantially without the adherence or friction hindering insertion, particularly where the diameters of said tubes are similar.

It is considered that utilisation of the above-described embodiments of the present invention may possibly eliminate the relative longitudinal displacement of the flexible tube.
and the duct into which it is inserted, and/or (where the duct is the urethra) possibly overcome the narrowing constituted by the vesico-urethral sphincter.

5 It is also considered that each of the above-described embodiments of the present invention can be readily removed, when necessary, from the body orifice or duct by simply pulling tube 3 outwards. Alternatively withdrawal might perhaps be achieved by inserting a narrow bore tubular element right down into tube 5, the element having a small opening at its leading end which is closed off by the flexible tube so that by evacuating the narrow bore of the tubular element and withdrawing the element outwardly, the flexible tube 5 is again rolled back into inside-out condition as it is withdrawn from the orifice or duct with the said element.

It will be appreciated that embodiments of the present invention may be applied not only in medicine (for example probing, fibroscopy, sampling, surgery (e.g. vascular and digestive surgery) and other medical techniques utilising urinary and other catheters, bronchoscopes, fibroscopes, and digestive, pulmonary and other endoscopes), but also has corresponding and/or similar applications in veterinary practice as well as numerous applications in industry.

Although basic or rudimentary embodiments of the invention have been described, it is considered that modifications thereto and other embodiments may be readily devised by those skilled in this art without departing from the scope of the invention as defined in the following claims.
CLAIMS

1. A tubular device for introduction into a body orifice or duct, comprising an elongate hollow element of flexible material, and means for effecting said introduction by changing at least part of the flexible element from an inside-out condition to an inside-in and outside-out condition.

2. A device according to Claim 9 wherein said changing is effected progressively.

3. A tubular device for introduction into a body orifice or duct, the tubular device comprising:
   an elongate tubular element of flexible material to provide, following its introduction into the body orifice or duct, an inside surface and an outside surface,
   support means of tubular form connected to one end of the flexible tubular element, the flexible element extending into the tubular support means in inside-out condition whereby a major part of said outside surface is disposed radially inwardly of a major part of said inside surface, and
   means to expel the elongate tubular element longitudinally outwards of the support means in a progressive manner from said one end thereof and such as to present said outside surface to the body orifice or duct and with said inside surface disposed internally of said outside surface.

4. A tubular device comprising a relatively rigid sleeve, means for securing to one end of the sleeve a flexible tube, said flexible tube being in inside-out or reversed disposition within the rigid sleeve so as to present an annular space between the sleeve and the flexible tube within in it, and tubular driving means operating from the annular space to drive said flexible tube from inside of
the sleeve outwards and across the boundary or edge of said driving means such that the sleeve is introduced into the orifice or duct without rubbing along the said orifice or duct.

5. A device according to Claim 4 wherein the flexible tube is of diametric cross-section corresponding to that of the tubular duct into which the flexible tube is to be inserted.

6. A device according to Claim 4, wherein the tubular driving means comprises a tubular stem in which the flexible tube, in inside-out condition, is disposed, the tubular stem when pushed from the rear, sliding along the outer sleeve to introduce the flexible tube along the tubular duct.

7. A device according to Claim 6, wherein the tubular stem has a forward open end provided with a rounded edge to minimise frictional contact between the flexible tube and said forward open end of the tubular stem during flexible tube introduction.

8. A device according to Claim 6, wherein the tubular stem has a forward open end provided with rolling means which facilitate the sliding of the flexible tube on said edge.

9. A device according to Claim 4, wherein the tubular driving means comprises a piston of outer diameter equal to the inner diameter of the sleeve, fluid contained in the sleeve being in use compressed by the piston and thereby acts on the flexible tube to introduce it without rubbing into the tubular duct.
10. A device according to any one of Claims 4 to 9, wherein a frusto-conical part is provided on the forward end of the sleeve, said part converging as it extends forwards, the open front end of said part permitting the passage therethrough of the flexible tube and the tubular driving means.
I. CLASSIFICATION OF SUBJECT MATTER

According to International Patent Classification (IPC) or to both National Classification and IPC

**IPC**: A 61 M 25/00

II. FIELDS SEARCHED

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched.

III. DOCUMENTS CONSIDERED TO BE RELEVANT

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IV. CERTIFICATION

Date of the Actual Completion of the International Search: 10th June 1987

Date of Mailing of this International Search Report: 14 Jul 1987

International Searching Authority: EUROPEAN PATENT OFFICE

Signature of Authorized Officer: [Signature]
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 European Patent Office EDF file on 24/06/87.

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