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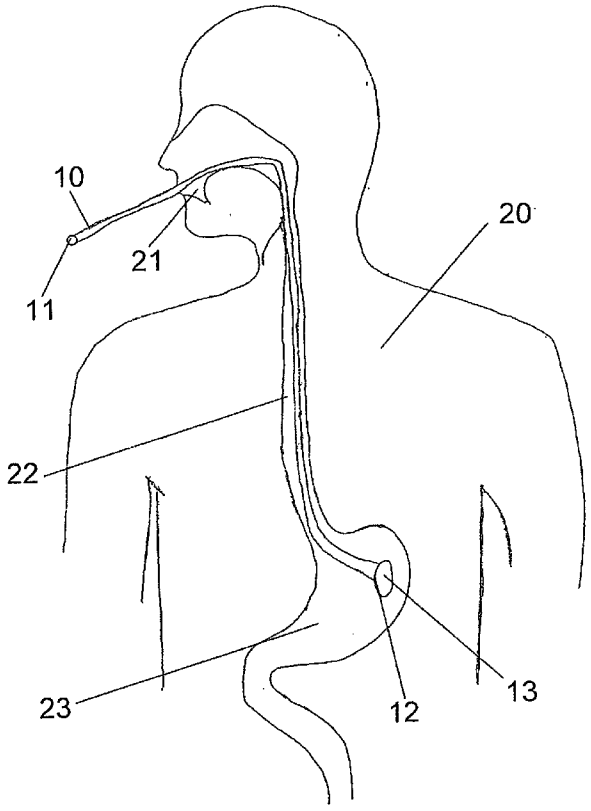
(54) Title: SELF-APPLICABLE GASTRIC TUBE ASSEMBLY



(57) Abstract: The invention relates to a gastric tube assembly comprising a tube with first and second ends and a lump element attached to the second end of the tube, wherein the tube and the lump element are dissolvable, said lump element being configured to be swallowed by a patient, thereby feeding said tube through the patient's oesophagus.

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Self-Applicable Gastric Tube Assembly

FIELD OF THE INVENTION

The invention relates to a gastric tube assembly for introducing a fluid into a patient's stomach.

BACKGROUND OF THE INVENTION

Gastric tubes are commonly used for introducing fluids into the stomach or the small intestine of a patient who is unconscious or otherwise not able to swallow fluids, e.g. due to dysphagia or in case of enteral nutrition. The commonly used gastric tubes are usually inserted by force through the nasal passageways and may abrade tissue in the nostril and nasopharynx and/or may cause discomfort to the patient. In order to facilitate insertion of a gastric tube, US 5,391,158 A suggests to use a weight attached to a guide string, both made of digestible material. The weight is inserted through a nostril and is then swallowed by the patient. Once the weight and the guide string are in place, the free end of the guide string is inserted through an aperture of a naso-gastric tube which is then inserted into the nostril. However, the naso-gastric tube still needs to be pushed forward on the guide string, whereby injuries and perforations may occur. Further, insertion of the tube usually requires the help of medical staff.

In some situations, however, it is desired to insert a gastric tube without the help of medical staff. For example, in preparation of a colonoscopy, the patient is usually required to drink large quantities of fluid containing polyethylene glycol and electrolytes. For many patients, drinking the fluid causes substantial discomfort, such that some may refrain from taking prophylactic colonoscopy examinations at all. It is thus desirable to introduce the fluid into the patient's stomach, bypassing his taste buds and viscosity sensation. This may, e.g. be done via a gastric tube. With the known naso-gastric tubes, however, the patient would need to see the physician a day before the colonoscopy in order to insert the tube and to apply the liquid.

It is therefore an object of the present invention to provide a gastric tube that is easy and safe to insert and may be applied by the patient him- or herself.

SUMMARY OF THE INVENTION

The above problem is solved by a gastric tube assembly according to claim 1 and a kit according to claim 9. Preferred embodiments are defined in the dependent claims.

The present invention provides a gastric tube assembly comprising a tube with first and second ends and a lump element attached to the second end of the tube, wherein the tube and/or the lump element comprise dissolvable material, said lump element being configured to be swallowed by a patient, thereby feeding said tube through the patient's oesophagus.

The assembly of the present invention allows easy application of the tube at home by the patient him- or herself. In particular, the patient may put the lump element into his mouth and swallow it. As the lump element moves down the patient's oesophagus towards the stomach, the tube is dragged along. In other words, the tube is applied by means of traction forces. As compared to commonly used gastric tubes which are pushed forward by force, the risk of abrading tissue is minimized. Unlike common gastric tubes being pushed forward, the tube of the present invention may easily be applied by the patient himself, without requiring the help of medical staff.

When the lump element reaches the stomach, the tube extends through the oesophagus, with the second end being positioned in the stomach and the first end being positioned outside the mouth and accessible for introducing a fluid. The first end of the tube may then be used to insert the fluid through the tube into the patient's stomach.

In some embodiments, the tube is dissolvable and when the desired fluid quantity has been introduced, the patient may swallow the rest of the tube, which is further facilitated by the physiological peristaltic movement of the oesophagus. The tube may then be dissolved within the patient's body, e.g. within the stomach and/or the intestines. Herein, the term "dissolvable" relates more particularly to the capability of being dissolved in a patient's gastrointestinal tract.

In some embodiments, only the lump element is dissolvable, and when the desired fluid quantity has been introduced, the tube/assembly may be retracted from the patient via his/her mouth. But even if the tube is made from a material that is per se dissolvable in the gastrointestinal tract, it may still be retracted rather than being swallowed. More precisely, by the time

that the lump element has dissolved or has at least been separated from the tube, the portion of the tube that is located in the oesophagus will not have dissolved and can be retracted rather than being swallowed. The separation of the tube and the lump element may e.g. be occasioned by the dissolution of a portion at the second end of the tube which is located in the stomach and therefore dissolving. In other words, even if it is intended to retract at least a portion of the tube after the desired fluid quantity has been introduced, using a tube material that dissolves in the gastrointestinal tract can be of advantage because it permits a separation of the lump element from the tube. A further advantage of a dissolvable tube is that there is no harm, if it should be inadvertently swallowed. The separation of the lump element from the tube can also be assisted by the retraction of the tube, where the lump element is stripped off the second end of the tube at the stomach entrance, in particular at the entrance muscle of the stomach. The lump element can thereafter dissolve in the stomach. This is particularly advantageous since the tube need not be kept in the oesophagus for an extended time after the fluid has been successfully introduced, thereby increasing the comfort for the patient.

In some embodiments, the tube and the lump element are comprised of dissolvable materials. With both, the tube and the lump element being dissolvable, they may be completely dissolved within the patient's body. Hence, no undissolved parts of the assembly need to go through the intestines, thereby avoiding any complications. As set forth below, the tube and the lump element may, in particular, be dissolvable in the patient's stomach.

As the assembly is applied by swallowing the lump element, no pushing force is required, thus avoiding the risk of injuries and perforation.

In the present disclosure, the term "dissolvable" refers to the conditions in the human body, e.g. in the stomach and/or the intestines. It may, but does not necessarily imply that the tube and/or the lump element are digestible, i.e. that material is received into the patient's blood by a digestion process. It rather implies that the material of the tube and/or the lump element is configured to dissolve when being subjected to the environment within the stomach or the intestines of the patient, e.g. by comprising food material.

In some embodiments, the tube and/or the lump element substantially consist of dissolvable material. Hence, the risk of complications due to undissolved remainders passing through the patient's gastrointestinal tract is reduced.

The tube may be comprised of a flexible and tear-proof material. The first end of the tube may be open such that it may be connected to an adapter or a syringe. The second end of the tube may be open and/or the tube may comprise one or more holes in the vicinity of the second end. The holes may, in particular, be positioned in different directions, such that fluid leaving the tube is directed towards different regions of the stomach. The tube may have a circular cross section. This is advantageous as trauma is avoided when the tube moves down the oesophagus.

The lump element may comprise a pill-shaped element. In preferred embodiments, the lump element may comprise a pill, a lozenge, a capsula or a tablet, in particular a dragée. The lump element may e.g. comprise a molded compound and/or may be coated, e.g. with a sugar coating. In some embodiments, the lump element may be flavoured in order to make the application of the tube assembly more comfortable for the patient. In some embodiments, the lump element is soft or comprises a soft sheath to avoid injuries and to further facilitate swallowing.

In a preferred embodiment, the lump element is configured to dissolve faster than the tube when inserted into the patient's stomach. Even if, after insertion, the lump element happens to block an opening at the second end of the tube such that fluid is kept form leaving the tube, the blocking may be removed by waiting until the lump element has substantially dissolved. In some embodiments, the lump element is configured to substantially dissolve in less than about 60 min, in particular, in less than about 30 min and, preferably, in less than about 15 min when inserted into the patient's stomach.

In a preferred embodiment, the tube comprises a sheet material, in particular gelatine, preferably leaf gelatine. The use of sheet material allows to easily form a tube. Further, gelatine is easy to process, tear-proof and dissolvable. The tube and/or the lump element may additionally or alternatively comprise a compliant and/or food material. In some embodiments, the tube and the lump element are comprised of a same or of different materials.

In some embodiments, the lump element is attached to the second end of the tube by lodging it into an opening of the tube. In some embodiments, the lump element is attached to the second end of the tube by a suture. In particular, the suture may be comprised of a dissolvable material. In some embodiments, the lump element may be attached to the second end of the tube by a chemical process or by gluing. The suture or glue, respectively, is preferably of compliant material, e.g. of food material.

According to a preferred embodiment, the lump element has a larger diameter than the tube. It is hence ensured that the tube follows the lump element when it is moved down the oesophagus by the peristaltic movement. In some embodiments, the lump element is weighted, e.g. by comprising a liquid-filled cavity. The liquid may, in particular, comprise water.

According to a preferred embodiment, the assembly further comprises a connection element attached to the first end of the tube to allow a fluid-tight connection between said tube and a reservoir containing a fluid to be administered through said gastric tube assembly or between said tube and an intermediate part to be arranged in fluid communication between said tube and said reservoir. In some embodiments, the connection element comprises threads, in particular, external or internal threads. The connection element may, in particular, comprise an adapter, preferably for a three-way stop-cock and/or a Luer Lock adapter. This facilitates introduction of a fluid into the tube. The reservoir may, in particular, comprise means for pressurized application of a fluid, like e.g. a syringe.

According to a preferred embodiment, the tube has an outer diameter of between 2 mm and 8 mm, in particular, of between 2.5 mm and 7 mm and, preferably, of between 3 mm and 6 mm. With such a diameter, the tube easily passes through the patient's oesophagus.

According to a preferred embodiment, the tube has a length of between 45 cm and 100 cm, in particular, of between 50 cm and 80 cm and, preferably of between 55 cm and 70 cm. With this length, the tube extends between the patient's stomach and a position outside the patient's mouth, such that, when inserted, the first end of the tube is easily accessible to introduce a fluid into the tube. When the gastric tube assembly is applied, a first portion of the tube's length remains outside the patient's mouth to facilitate introduction of the fluid, while a second portion of the tube's length extends from the patient's oral cavity to the stomach.

According to a preferred embodiment, before application, the tube is folded, rolled or reeled up along at least a part of its length. In some embodiments, the tube is folded, rolled or reeled up only along the second portion of the tube's length. The tube may be folded, rolled or reeled up at least partially around the lump element. This facilitates packaging and transport of the tube assembly. Further, if the tube is folded e.g. in a concertina like or fanfold fashion, this would ensure that the tube unfolds as it follows the lump element. Thus the tube would not be pulled along its entire length down through the oral cavity and the oesophagus but would rather unfold and the unfolded part would be approximately stationary with respect to at least

parts of the inner wall of the oral cavity and the oesophagus. This would reduce a foreign body sensation and a possible gag reflex during introduction of the tube.

According to a preferred embodiment, the lump element has a maximum dimension of about 2 cm, in particular, of about 1.5 cm and, preferably, of about 1 cm. The maximum dimension may be, e.g. a length or a diameter. In some embodiments, the lump element has an oval shape. In that case, the maximum dimension may be the lump element's length. With such a dimension, the patient may easily swallow the lump element. Yet, this size is still large enough such that the lump element can be efficiently propelled by the oesophagus' peristaltic movement, thereby generating a sufficient dragging force to pull the tube downwards towards the stomach.

In a further aspect, the present invention provides a kit comprising a gastric tube assembly of the aforementioned kind and a reservoir with a fluid for uptake by a patient. The kit may be conveniently handed over to the patient for applying the kit at home by him- or herself. In some embodiments, the kit further comprises an intermediate part to be arranged in fluid communication between the tube of the gastric tube assembly and the reservoir. This facilitates assembling the kit at home.

In a preferred embodiment, the fluid is for uptake by a patient in preparation for a colonoscopy, wherein said fluid preferably contains electrolytes and/or polyethylene glycol.

In still a further aspect, the present invention provides a method for applying a gastric tube assembly of the aforementioned kind. The method comprises giving the patient the lump element to swallow and, subsequently, introducing a fluid via the first end of the tube, especially after the second end of the tube has reached the patient's stomach.

Further, in particular in embodiments in which the tube does not comprise a dissolvable material, the method may further comprise the step of retracting the tube from the patient's body via the patient's mouth, especially after the fluid has been introduced by the tube.

In some embodiments, the method step of introducing a fluid may further comprise introducing the fluid over a time of between 5 min and 45 min, in particular, of between 8 min and 30 min and, preferably, of between 10 min and 20 min.

In some embodiments, the step of introducing the fluid may comprise introducing the fluid at a rate of between 0.5 ml/s and 5 ml/s, in particular, of between 1 ml/s and 4 ml/s and, preferably, of between 2 ml/s and 3 ml/s. The rate may, in particular, be substantially constant over time. In some embodiments, the step of introducing the fluid comprises introducing between 0.3 l and 3 l, in particular, between 1 l and 2.5 l and, preferably, between 1.5 l and 2.2. l of said fluid.

SHORT DESCRIPTION OF DRAWING

The invention is now described with reference to the attached drawing, which shows the gastric tube assembly inserted into a patient's body.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

The Figure shows an embodiment of a gastric tube assembly according to the invention. The assembly comprises an oro-gastric tube 10 with a first open end 11 and a second open end 12. The assembly further comprises a lump element 13 attached to the second end 12 of the tube 10. In this embodiment, the tube 10 has a length of about 60 cm and a diameter of about 4 mm. The cross section of the tube 10 is circular. The walls of the tube 10 are comprised of a thin sheet of food material.

The lump element 13 is comprised of a pill-shaped tablet which may be flavoured. In particular, the lump element 13 may have a peppermint flavour. The length of the lump element is about 1 cm. In particular, the lump element 13 may be a Mentos® dragée.

In order to apply the gastric tube system, the patient 20 takes the lump element 13 into his mouth 21 and swallows it. The lump element 13 then moves down the patient's oesophagus 22. This movement is facilitated by the natural peristaltic movement of the oesophagus 22. Since the lump element 13 is attached to the second end 12 of the tube 10, it pulls the tube 10 down the oesophagus 22. When the lump element 13 reaches the patient's stomach 23, the tube extends between the patient's stomach 23 and a position outside the patient's mouth 21, as shown in the Figure. A first portion of the tube 10 extends outside the patient's mouth 21, the first portion having a length of about 40 cm. A second portion of the tube 10 extends between the patient's mouth 21 and his or her stomach 23. The second portion has a length of about 50 cm, of which about 40 cm extend between the patient's front teeth and his or her

cardia, and another 10 cm extend from the cardia into the stomach. In other words, the first end 11 of the tube is outside the patient's mouth 21, while the second end 12 of the tube is within the stomach 23 of the patient 20. The tube assembly may now be used to introduce fluid into the stomach 23. For this, an adapter (not shown) may be attached to the first end 11 of the tube 10. The adapter, in turn, may be connected to a syringe containing the fluid. By actuating the syringe, the fluid is pressed through the tube 10 into the patient's stomach 23. After having introduced the fluid into the stomach 23, which may take as little as a few minutes, the syringe and the adapter may be removed from the first end 11 of the tube 10.

In some embodiments, the tube 10 is comprised of a dissolvable material. In these embodiments, the patient 20 may easily swallow the tube 10 as a whole after introduction of the fluid, which is assisted by the peristaltic movement of the patient's oesophagus 22. The tube 10 will then be dissolved in the patient's body, e.g. in his stomach or intestines.

In some embodiments, only the lump element 13 is comprised of a dissolvable material. In these embodiments, the tube 10 may easily be retracted from the patient 20 via the patient's mouth 21 after introduction of the fluid. In this case, the first end 11 of the tube 10 may be pulled away from the patient's mouth 21, while the remainder of the tube 10 follows. As the lump element 13 has dissolved, it does not block passage on the tube's way back through the oesophagus 22, thus avoiding any complications.

REFERENCE SIGNS

10	Tube
11	First end
12	Second end
13	Lump element
20	Patient
21	Mouth
22	Oesophagus
23	Stomach

Claims

1. A gastric tube assembly comprising a tube (10) with first (11) and second (12) ends and a lump element (13) attached to the second end (12) of the tube (10), wherein the tube (10) and/or the lump element (13) are dissolvable, said lump element (13) being configured to be swallowed by a patient (20), thereby feeding said tube (10) through the patient's oesophagus (22).

2. The assembly of claim 1, wherein the lump element (13) is configured to dissolve faster than the tube (10) when inserted into a patient's stomach (23).

3. The assembly of any of the preceding claims, wherein the lump element (13) has a larger diameter than the tube (10).

4. The assembly of any of the preceding claims, wherein the lump element (13) comprises a pill, a lozenge, a capsula or a tablet, in particular, a dragée.

5. The assembly of any of the preceding claims, wherein the tube (10) comprises a sheet material, in particular gelatine.

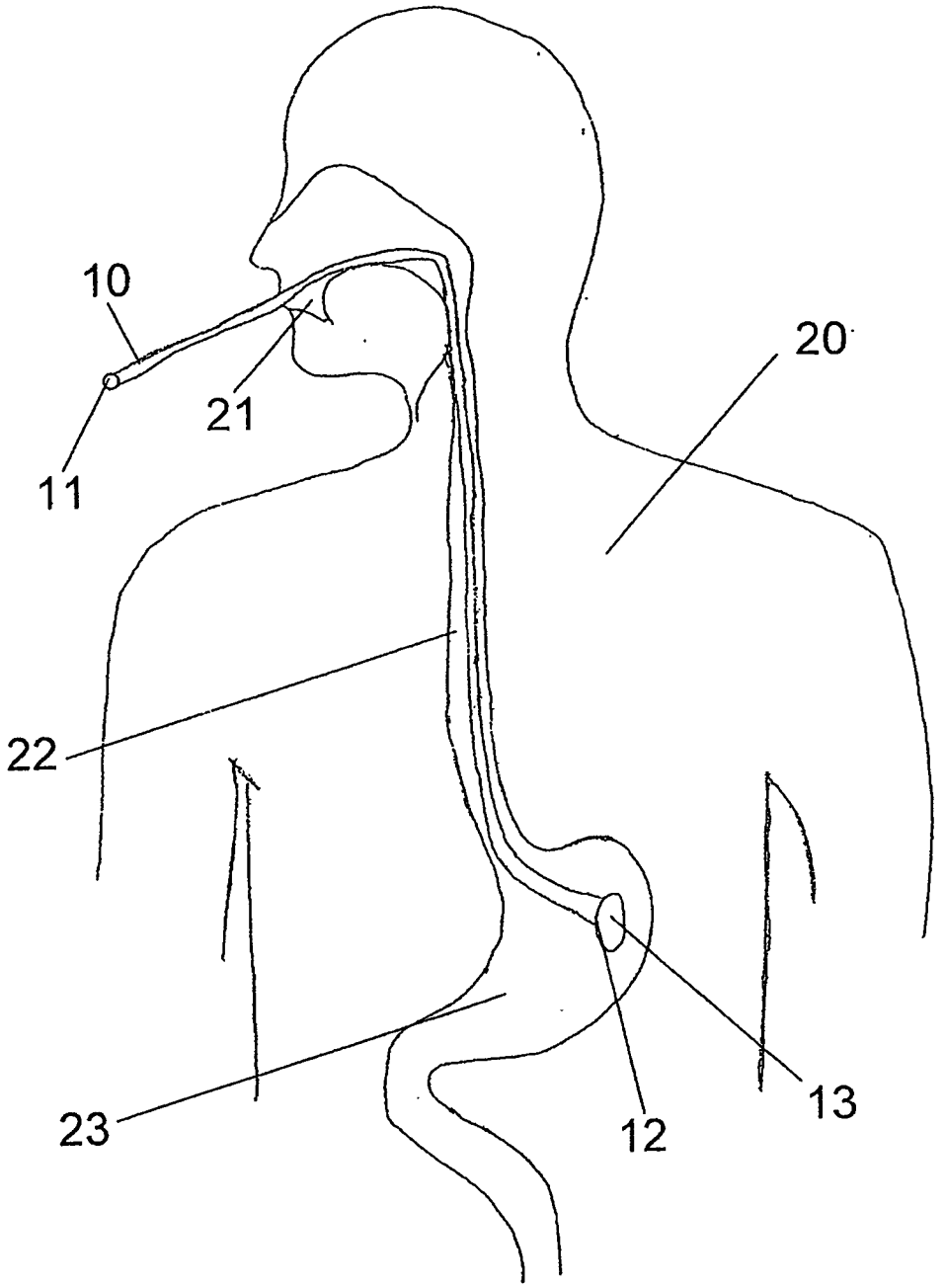
6. The assembly of any of the preceding claims, further comprising a connection element attached to the first end (11) of the tube (10) to allow a fluid-tight connection between said tube (10) and a reservoir containing a fluid to be administered through said gastric tube assembly; or
between said tube (10) and an intermediate part to be arranged in fluid communication between said tube (10) and said reservoir.

7. The assembly of any of the preceding claims, wherein the tube (10) has an outer diameter of between 2 mm and 8 mm, in particular, of between 2.5 mm and 7 mm and, preferably, of between 3 mm and 6 mm.

8. The assembly of any of the preceding claims, wherein the lump element (13) has a maximum dimension of about 2 cm, in particular, of about 1.5 cm and preferably, of about 1 cm.

9. A kit, comprising a gastric tube assembly according to any of the preceding claims and a reservoir with fluid for uptake by a patient (20).

10. The kit of claim 9, wherein the fluid is for uptake by a patient (20) in preparation of a colonoscopy, and wherein said fluid preferably contains electrolytes and/or polyethylene glycol.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INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER
INV. A61J15/00
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61J

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 October 2012	30/10/2012

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INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2012/003844

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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