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(54) **Title:** EXTERNALLY INFLATABLE GASTRIC BALLOON DEVICE

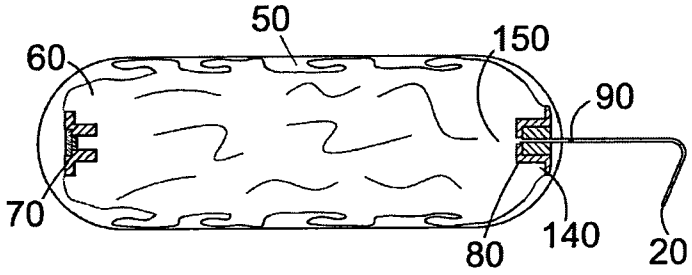

Fig. 2

(57) **Abstract:** The present invention is concerned with new and improved externally inflatable gastric balloons devices, more particularly orally ingested externally inflatable gastric balloon devices.

EXTERNALLY INFLATABLE GASTRIC BALLOON DEVICE

The present invention is concerned with new and improved externally inflatable gastric balloons devices, more particularly orally ingested externally inflatable gastric balloon devices.

Obesity is the primary health problem in the United States today. The complications of obesity cost approximately $60 billion a year. There is a clear need and desire to provide effective, safe and convenient methods and means to treat patients to reduce or prevent obesity.

The most commonly used methods to reduce obesity are diets. It is well known that most diets fail, and that within one year of finishing a diet regimen, most dieters are back to (or even exceed) their original weight. Certain pharmaceuticals are in development to curb hunger or reduce overeating. These are still relatively new and will require additional testing. Surgical intervention is also widely used, but it is very risky and may carry significant side effects.

Another method to reduce overeating is the use of gastric (also called intragastric) balloons. Their use reduces caloric intake by reducing the volume of food that can be accommodated by the stomach of a patient. Food volume, or caloric mass, is the overall reason for weight gain to begin with. When caloric intake exceeds caloric need, weight is gained. The gastric balloon takes up stomach volume (or, increases “dead space”) in the stomach so that the caloric intake is reduced. The balloon simply takes up space that otherwise could be taken up by food.

Development of gastric balloons for weigh reduction was initiated in the late 1970’s and early 1980’s. This began with the "Garren-Edwards Bubble", as demonstrated by US 4899747. This described a method to treat obesity using a balloon that is inserted into the stomach with a catheter fed through the oesophagus. The patient requires sedation

under general anaesthesia for the procedure. Once inside the stomach, the balloon was inflated via the catheter with either air or liquid. Once the desired level of inflation is achieved, the catheter is removed. The balloon remains in the stomach for several months and the patient can achieve some weight loss benefit. However, the invention suffers the significant disadvantage that in order to remove the balloon, the patient must be sedated again under general anaesthesia, a catheter inserted oesophageally having at its end a grasping tool, the balloon punctured to empty its contents, and the deflated balloon retrieved using the grasping tool.

Further problems were encountered with products made according to the '747 patent that resulted in patient complications. These problems included early deflation, intestinal obstruction, and difficulty in removing the device. Such limitations prevented wide scale use of the device.

US 4723547 (Kullas) describes an inflatable balloon designed to be inserted by a device similar to an endoscope. The balloon is then filled externally via the endoscope-like tool, which is connected to the balloon by a pierceable self-sealing plug. Once inserted, the balloon is disconnected from its filling device by withdrawal of the needle from the septum using the endoscope-like device, which retracts the needle into the endoscope-like device end. This balloon is not designed to be swallowed.

More recent products have been introduced designed to minimize some of these problems.

US 6981980 (Sampson) describes a swallowable and self-inflatable intragastric balloon. This invention self-inflates using bicarbonate within the balloon. The chemistry is activated just before swallowing by injecting acid into the interior of the balloon through a self-sealing valve. The carbon dioxide producing chemical inflates the balloon fully. The balloon remains in the stomach for a period of approximately one month. At that time, a biodegradable plug in the balloon wall begins to erode, thereby causing the balloon to deflate.

Notably, there are substantial problems with the deflation, and the devices of US 6981980 are prone to slow deflation. Further, the design of a plug which directly holds back the internal pressure of the balloon like a cork is inherently easier to fail or leak than a device of the present invention (below) which uses a switch means to control deflation.

Other prior art includes US 2006/0058829.

Other gastric balloon devices include the likes of BioEnterics Intragastric Balloon (BIB) produced by Inamed, Inc. (Inamed Health, Santa Barbara, CA, USA), the Heliosphere (Helioscopie SA, France) and the Ullorex Oral Intragastric Balloon (OIB) (Phagia Technology, Inc., Stuart, FL, USA).

The BIB type product is a balloon that is placed in the stomach of a patient with an endoscope and filled with 400-800ml of saline. It is typically left in the stomach for 6-8 months and is then removed endoscopically.

The Heliosphere type product is an air-filled balloon of similar size to the BIB type product, and is inserted and removed endoscopically.

The use of an endoscope to effect insertion and removal of intragastric devices is problematic and dangerous, particularly with the risk of anaesthesia toxicity. It also, of course, increases the cost of procedures and can result in extended hospital in-patient stays.

The OIB type product is a balloon that is encapsulated into a swallowable pill. Immediately prior to a patient swallowing the pill, an activating liquid is injected into it. After a delay of several minutes (during which the patient should swallow the pill), the liquid activates a bicarbonate reaction that releases carbon dioxide gas into the balloon interior. Within 30 minutes, the balloon is fully inflated. The life of the balloon is approximately 30 days before a bioabsorbable plug in the balloon wall dissolves, allowing it to deflate and to pass from the stomach naturally.

Problems with the BIB and Heliosphere type devices include the need for endoscopy and general anaesthesia for insertion/removal.

Problems with the Ullorex type devices include the size of the pill (approximately half the size of an average ring finger, which can be a formidable obstacle to many patients).

Oesophageal inflation is life-threatening, and with the Ullorex type devices, premature inflation or incomplete passage of the pill during swallowing cannot be guaranteed not to happen, meaning that swallowing procedures must take place in an endoscopically-equipped environment, in case emergency removal is required.

With the Ullorex type devices, after successful swallowing by the patient, correct location must be ensured by radiography – dumping syndrome can occur, also known as rapid gastric emptying, in which the stomach contents are transported into the small intestine too rapidly. Patients who have previously undergone surgery to remove or bypass part of the stomach are particularly prone to dumping condition. With the ingestion of a device that will inflate post-swallowing, the device must be located in the stomach when it inflates and not in the small intestine – if the device enters the small intestine then its inflation can be life-threatening. Thus, radiography is required to determine the location of the balloon, and surgical facilities are required in case emergency removal is required.

The automatically-inflating intragastric devices are also dependent upon the devices operating properly and the chemistry working properly. If there is a problem with the chemistry, a leak, or another mechanical failure, the balloon may only partially inflate. However, this would not be known unless radiography is used to determine inflation of the balloon or unless severe pain or further complications occur in the event of the partially-inflated balloon obstructing the pyloric sphincter or intestine.

Furthermore, post-swallowing of the Ullorex type devices requires another radiograph to ensure proper positioning. Other problems such as partial inflation may also lead to obstruction, and radiography is used to determine this.

The BIB and Heliosphere type devices are both deflated by endoscopy. Again, that is a great problem involving many aspects of medical safety and also widespread use. This major obstacle is overcome by a device which is designed to deflate spontaneously and pass naturally.

The Ullorex type device uses a bio-absorbable plug which allows the balloon to deflate spontaneously in 3-4 weeks, and then the balloon is passed naturally. This spontaneous deflation and passage obviates the need for endoscopic removal of the device.

The plug in the balloon wall of the Ullorex type device is composed of a bio-absorbable polymer that degrades in 3-4 weeks under normal physiological conditions. This plug is essentially a tiny "wall" in the balloon's surface that degrades spontaneously. However, this presents a number of problems.

Notably, the plug in the wall of the Ullorex type device degrades in a gradual fashion. This means that a tiny pinhole develops first, followed by another pinhole, etc., until enough seepage occurs to deflate the balloon. This gradual leaking of the gaseous interior causes the balloon to deflate gradually over a period of many minutes to perhaps an hour. However, if deflation is too gradual, or if the patient's stomach is actively trying to push the balloon through the pyloric sphincter at the time of deflation, the balloon may only partially deflate and thus cause obstruction.

According to the present invention, there is provided an externally inflatable gastric balloon device comprising:

(i) a balloon defining a balloon volume;

(ii) fluid inlet valve means; and

(iii) a filling connector comprising a connecting tube connected to said fluid inlet valve means;

wherein said connecting tube is in fluid communication with said balloon volume via said fluid inlet valve means, said connecting tube being in-use separable from said fluid inlet valve means.

The present invention seeks to overcome the prior art disadvantages and provides an improved externally-inflatable gastric balloon device. In particular, the present invention seeks to help ensure that the gastric balloon device is properly locate din the stomach of a patient, allow this to be achieved simply and conveniently, provide for a conveniently ingestible gastric balloon device, provide for simple and convenient recovery of a connecting tube after inflation of the gastric balloon device, and avoid the need for invasive surgical procedures and unnecessary or repeat radiography.

By "separable from said fluid inlet valve means" is meant that the connecting tube is separable from at least part of the fluid inlet valve means such that in-use it can be retrieved from a patient. Thus, where the fluid inlet valve means comprises multiple component parts, one or more of them can be retained with the connecting tube when it becomes separated from the rest of the valve means.

For the present purposes, the term "fluid" means liquids and gases

Preferably, the connecting tube is flexible. Preferable materials include polyurethane and silicone.

Where the connecting tube is made of a material which can undergo significant longitudinal stretching (for example at least 5, 6, 7, 8, 9 or 10%) at the tensions that will be applied to it in-use (for example resulting from the connecting tube being pulled on to separate it from the fluid inlet valve means, an additional material such as a thread may be provided which does not undergo significant longitudinal stretching at those tensions. Suitable materials include nylon and Kevlar (RTM). Thus, preferably the connecting tube is provided with a stretch-resistant material extending along its longitudinal length.

More preferably still, the gastric balloon device is also provided with fluid supply means. Examples of suitable fluid supply means include a syringe, hand pump, motorised pump, compressed gas supply, and compressed gas cylinder, each having a supply of liquid or gas to be passed to the interior of the balloon via the connecting tube. Preferably, the fluid supply means is provided with a supply of fluid.

Preferably, the connecting tube is provided with an in-use non-swallowable collar. More preferably, the collar is engageable with the connecting tube without preventing fluid flow along the connecting tube past the collar. Preferably, the connecting tube is provided with a scale. Thus, by measuring a patient to determine a reference length for their oesophagus, the collar can be engaged with the connecting tube at a suitable position such that the patient can swallow the gastric balloon device up until the collar contacts their mouth and further swallowing of the connecting tube is prevented. At this point, the patient will have swallowed the correct length of connecting tube for the gastric balloon device to be located in their stomach, ready for inflation. Preferably, the collar is engaged with the connecting tube by an adhesive. More preferably, the collar is self-adhesive.

In certain embodiments, the fluid inlet valve is a one-way valve.

Preferably, the fluid inlet valve is a self-sealing valve such as a self-sealing gasket valve. Suitable materials for self-sealing gasket valves include silicone. A wide range of valve means will be readily apparent to one of ordinary skill in the art, and can be readily employed in the devices of the present invention.

Preferably, the fluid inlet valve means (also referred to herein as a "base unit") is located in a housing (also referred to herein as a "base unit housing") defining an opening at one end that is in fluid communication with the balloon volume.

Preferably, the filling connector comprises a cannula, more preferably a rigid cannula. In embodiments where the fluid inlet valve means comprises a self-sealing gasket valve, the cannula passes through the self-sealing gasket valve and is resistant to the pressures exerted by the self-sealing gasket valve such that fluid can flow through the self-sealing gasket valve via the cannula. Preferably, the cannula is retained in the self-sealing gasket valve by a friction fit.

Preferably, the cannula has a needle tip. Preferably, the cannula is provided with needle tip guard means. Preferably, such needle tip guard means are configured such that when

the cannula is removed or separated from the fluid inlet valve means, the needle ip guard means extends over the needle tip, thereby hindering or preventing the needle tip from contacting other bodies, for example preventing the needle tip from contacting oesophageal tissue as it is removed from the patient along the oesophagus. Suitable needle tip guard means are widely known in the art and are readily available to one of ordinary skill in the art.

In embodiments where the fluid inlet valve is a self-sealing gasket valve, it preferably takes the form of an expandable septum, for example made from silicone. In these cases, the septum can be pressure formed in a housing defining an opening at one end that in-use will be in fluid communication with a balloon volume. A rigid cannula which is capable of withstanding the pressures exerted upon it by the septum material is inserted into the septum so that it is in fluid communication with the opening in the base unit housing. The cannula is retained in place and in fluid communication with the opening in the base unit housing and thus with the balloon volume due to the septum material causing a friction fit. In use, the balloon volume is filled via the cannula and connecting tube, and the cannula is removed by pulling on the connecting tube – the inflated balloon is pulled upwards but its movement is restricted as it contacts the walls of the upper stomach, causing the cannula to be pulled from the septum. As this occurs, the septum material expands to fill the gap left by the cannula and thus seal the septum, preventing further fluid flow through the fluid inlet valve means and the opening in the housing.

Preferably, the gastric balloon device or any external component part thereof such as the connecting tube is coated with or comprises a lubricant. Suitable lubricants include polyethylene glycol which can be incorporated into any connecting tube material, and polyethylene oxide which can be used as a lubricant coating. Other lubricants will be readily apparent to one of ordinary skill in the art.

Preferably, the connecting tube is at least partially contained within a wrapper. Preferably, the wrapper is rapidly-dissolving in water or saliva. This makes the gastric balloon device easy to handle and allows a patient to easily position the wrapped

connecting tube with their tongue at the back of their mouth. Preferable wrapper materials include thin sheets of a rapidly dissolving gelatine.

In certain embodiments, the filling connector in-use becomes separable from the fluid inlet valve means in stomach fluids, and otherwise resists separation from the fluid inlet valve means. In particular, it is preferred that the filling connector resists separation from the fluid inlet valve means in a non-liquid environment. This can, for example, be achieved by way of a degradable or biodegradable component (as discussed below) which degrades in a liquid environment such as in stomach fluids.

Preferably, the gastric balloon device is provided in an orally ingestible encapsulated form. Preferably, the encapsulation material is degradable in stomach fluids. More preferably, it is rapidly degradable in stomach fluids, for example within a period of about 1, 2, 3, 4 or 5 minutes. Preferably, the capsule degrades in about one minute. Preferably, the capsule is a gelatine.

Preferably, the balloon is folded up and/or compressed in the capsule.

Preferably, the encapsulation material retains the filling connector or connecting tube.

Preferably, the connecting tube or filling connector is provided with an at least one protrusion. More preferably, the at least one protrusion contacts and is retained by the encapsulation material. In certain embodiments, the at least one protrusion is located extending into the encapsulation material. Preferably, the at least one protrusion is located internal to the gastric balloon device relative to an outer surface of the encapsulation material. Preferably, the at least one protrusion is located inwards of the gastric balloon device relative to an inner surface of the encapsulation material. In-use this causes additional resistance to the separation of the connecting tube from the fluid inlet valve means and can help prevent accidental separation of the connecting tube from the fluid inlet valve means. When the capsule is not degraded, separation of the connecting tube from the fluid inlet valve means is additionally resisted by frictional resistance between the capsule and the at least one protrusion.

In one embodiment (detailed below), the fluid inlet valve means comprises a stainless steel collar surrounding a silicone septum having extending through it a rigid cannula of a filling connector. The connecting tube is then connected to the cannula and has extending from it at a protrusion which contacts and is retained by the encapsulation material. The protrusion is internal to the gastric balloon device relative to an inner (i.e. inwards-facing) surface of the encapsulation material. Thus, to move the connecting tube would require the capsule to move, and thus the connecting tube is retained in position relative to the fluid inlet valve means by the encapsulation material.

In particular, this helps prevent separation of the filling connector from the balloon/fluid inlet valve means during handling and swallowing, after which the capsule dissolves or is degraded.

Thus after swallowing by a patient, the capsule dissolves or is degraded to allow the balloon to be filled and expand.

A wide range of ways of deflating gastric balloon devices are known, and the externally inflatable gastric balloon devices of the present invention can be configured to use any of those means.

Also provided according to the present invention is a self-deflating gastric balloon device comprising:

(i) a balloon defining a balloon volume; and

(ii) valve means comprising:

(a) a valve body having attached to it said balloon and defining a passage having:

(I) a first end located internal to said balloon volume; and

(II) a second end located external to said balloon volume; and

(b) degradable switch means,

said switch means controlling fluid flow through said passage, such that with said switch means in a non-degraded state fluid flow through said passage is prevented, and with said switch means in a degraded state fluid flow through said passage can occur, said balloon remaining attached to said valve body.

Thus, the externally inflatable gastric balloon devices of the present invention can additionally comprise valve means comprising:

(a) a valve body having attached to it said balloon and defining a passage having:

(I) a first end located internal to said balloon volume; and

(II) a second end located external to said balloon volume; and

(b) degradable switch means,

said switch means controlling fluid flow through said passage, such that with said switch means in a non-degraded state fluid flow through said passage is prevented, and with said switch means in a degraded state fluid flow through said passage can occur, said balloon remaining attached to said valve body.

In particular, the present invention provides a degradable switch means as part of valve means, and in contrast to the prior art devices, the degradable switch means does not form a direct path for fluid flow in the deflation process of the balloon. Rather, this element switches the valve means between open and closed states.

Preferably, the switch means comprises a switch body and biodegradable securing means.

The balloon is attached to the valve body using any suitable means, including by use of adhesive, bonding agent, and RF welding.

A wide range of valve arrangements are contemplated in the present invention. In all of the embodiments, the balloon remains attached to the (deflation) valve body. This presents an advantage over prior art devices in that the valve body does not become separated from the balloon and so in the degraded state, fluid (for the present purposes, the term "fluid" means liquids and gases) is free to flow from the balloon through the valve means.

In particular, this means that the valve body will not cause a partially blocked state in which the rate of deflation of the balloon is limited, in contrast to other prior art devices

which use a plug which upon degradation of a component part can move relative to the balloon and partially block any orifice, thus resulting in a slower than intended rate of deflation. Slow deflation can be particularly problematic since a slowly deflating balloon can pass to the small intestine in a partially deflated state, causing blocking of the intestine or pyloric sphincter.

Preferably, the biodegradable securing means comprises a biodegradable layer about at least a part of the periphery of said switch body. In the valve means, in the non-degraded state the switch body plus biodegradable layer acts to block fluid flow through the passage. In the degraded state, the biodegradable layer is degraded and the switch body is able to move relative to the valve body and with a greater fluid pressure existing within the balloon than in the stomach (for example due to the balloon containing a pressurised gas or due to the stomach exerting mechanical pressure upon the balloon) the switch body is caused to exit the passage, thus allowing the flow of fluid from the balloon volume.

Preferably, the biodegradable layer is located on the periphery of the switch body adjacent the inner wall of the passage so as to secure the switch body within the passage and block fluid flow through the passage.

In other embodiments, the biodegradable layer has a toroidal shape. In certain embodiments, this is a ring shape.

Preferably, the biodegradable securing means is non-toxic. More preferably, it is a gelatine, or a degradable polymer selected from the group consisting of: polylactic acid and polyglycolic acid.

Preferably, the switch means is biodegradable. Preferably, the switch means is non-toxic. Preferably, the biodegradable securing means or switch means is biodegradable in stomach fluids (i.e. digestive/gastric fluids in the stomach) in a predetermined period of time. Preferably the biodegradable securing means or switch means is biodegradable in a fluid in-use present in the device. Preferably, it enters a degraded state after a period

of at least 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 or 12 weeks. More preferably, the biodegradable securing means enters a degraded state after a period of 1 or 2 months.

Exact formulations of biodegradable securing means or switch means to give a period during which the biodegradable securing means remains mechanically sound, the switch means being in the non-degraded state and fluid flow through the passage being prevented, will be readily apparent to one of ordinary skill in the art.

There are multiple ways in which the biodegradable securing means or switch means can be provided to degrade in a chosen period of time. For example, the composition of the biodegradable material may be changed or provided in order that it will perform its role for a predetermined period of time. Alternatively, a chosen thickness of biodegradable material can be provided.

Preferably, the biodegradable securing means or switch means or biodegradable part thereof has a surface external to the balloon volume and other components. Thus, in use in the stomach of a patient it is exposed to stomach fluids and degrades.

In certain embodiments, the biodegradable securing means or switch means or biodegradable part thereof does not have a surface exposed to the balloon volume. Depending upon the nature of the biodegradable securing means or switch means or biodegradable part thereof, and upon the nature of the fluid in-use contained in the balloon volume, it can be desirable to prevent fluid from the balloon volume contacting it since it may result in its partial degradation and a partially degraded state in which restricted fluid flow can occur through the passage via the partially degraded biodegradable securing means or switch means or biodegradable part thereof.

In other embodiments, the biodegradable securing means or switch means or biodegradable part thereof has a surface exposed to the balloon volume. Thus, a fluid having a known degradative effect upon the biodegradable securing means or switch means or biodegradable part thereof can be placed in the balloon volume. This allows the biodegradable securing means or switch means or biodegradable part thereof to be degraded at a predetermined rate, in contrast to the variable rate that can occur when

degradation is caused by stomach fluids. In such embodiments, the biodegradable securing means or switch means or biodegradable part thereof is preferably not degradable by stomach fluids.

In certain embodiments, the switch body comprises a head section and a tail anchor section, and the biodegradable securing means comprises a biodegradable layer about at least a part of the periphery of the head section. In the valve means, in the non-degraded state the head section with its biodegradable layer acts to block fluid flow through the passage. In the degraded state, the biodegradable layer is degraded and the switch body is able to move relative to the valve body and in-use is caused to exit the passage, thus allowing the flow of fluid from the balloon volume. However, the tail anchor section ensures that the switch body cannot totally separate from the valve body and balloon.

Preferably, the tail anchor section comprises an elongate body connected at a first end to the head section and having extending from a second end retaining means which in-use engage the balloon or first end of the valve body and prevent the switch body from exiting the passage through the second end but do not prevent fluid flow through the passage.

In alternative embodiments, the tail anchor section comprises a flexible connector that connects the head section to the valve body or balloon. Preferably, the flexible connector is a thread.

In certain embodiments, the switch body is positioned in the passage and dimensioned to block fluid flow through the passage, and the biodegradable securing means is attached to, abuts or engaged with the valve body and prevents the switch body from exiting the passage. Preferably, the biodegradable securing means extends over the valve second end. Preferably, the biodegradable securing means is attached to the switch body.

In certain embodiments, the biodegradable securing means is attached to an external face of the valve body. In other embodiments, the biodegradable securing means is

attached to the inner wall of the passage. In certain embodiments, the biodegradable securing means is attached to the switch body.

More preferably, the biodegradable securing means is at least one of the group consisting of: hook, bar, and strap. In certain embodiments, the biodegradable securing means comprises 2, 3, 4, 5 and 6 hooks.

In other embodiments, the biodegradable securing means comprises a layer extending over a cross-section of the passage and located in the passage between the valve second end and the switch body. In such embodiments, the biodegradable securing means is preferably attached to the inner wall of the passage and to the switch body.

In certain embodiments, the biodegradable securing means comprises a layer located in the passage between the valve second end and the switch body, the layer attached to the inner wall of the passage and extending over a cross-section of the passage.

In certain embodiments, the switch body is positioned in the passage and dimensioned to block fluid flow through the passage, and the valve body additionally comprises at least one arm, rim, recess, or securing means, the biodegradable securing means comprising a layer located in said passage between the valve second end and the switch body, the layer being engaged with or attached to the at least one arm, rim, recess or securing means so as to prevent the switch body from exiting the passage through the valve second end. Preferably, biodegradable securing means extends over a cross-section of the passage. In certain embodiments, the layer takes the form of a plate extending across the passage.

In certain embodiments, the switch body comprises a sprung valve which has open and closed positions and which urges to the open position, and the biodegradable securing means comprises closure means which retain the sprung valve in the closed position. In certain embodiments, the sprung valve is a duckbill valve. In certain embodiments, the closure means comprise a clamp.

In certain embodiments, the switch body comprises a flexible body defining a lumen extending from and in fluid communication with the passage and movable between:

(i) a first closed state in which fluid flow through said flexible body is blocked; and

(ii) a second open state in which fluid flow can occur through said flexible body,

and said biodegradable securing means comprises a body secured on, in or to said valve body, in a non-degraded state said biodegradable securing means causing said flexible body to be in said first closed state, and in a degraded state said biodegradable securing means not causing said flexible body to be in said first closed state.

Preferably, in said first closed state said flexible body is compressed or folded or has a kink in it. Preferably, in said second open state said flexible body is non-compressed or extended.

Thus, in the degraded state, the biodegradable securing means allows the flexible body to be in the second extended state.

In-use fluid pressure from the balloon urges the flexible body to the second extended state. In the non-degraded state, movement from the first compressed state to the second extended state is prevented by the biodegradable securing means. In the degraded state, the biodegradable securing means does not block movement of the flexible body and so it is free to move to the second extended state.

In certain embodiments, the switch body comprises a flexible body defining a lumen extending from and in fluid communication with the passage and movable between:

(i) a first closed state in which fluid flow through said flexible body is blocked; and

(ii) a second open state in which fluid flow can occur through said flexible body,

and the biodegradable securing means comprises a body secured about the flexible body and retaining the flexible body in the first closed state, in a non-degraded state the biodegradable securing means retaining the flexible body in the first closed state, and in

a degraded state the biodegradable securing means not causing the flexible body to be in the first closed state.

Thus, in the degraded state, the biodegradable securing means allows the flexible body to be in the second open state.

In-use fluid pressure from the balloon urges the flexible body to the second open state. In the non-degraded state, movement from the first closed state to the second open state is prevented by the biodegradable securing means. In the degraded state, the biodegradable securing means does not block movement of the flexible body and so it is free to move to the second open state.

Preferably, the flexible body comprises a flexible tube. Preferably, the biodegradable securing means comprises a biodegradable clip, tie or thread.

Preferably, in the non-degraded state, the biodegradable securing means causes the flexible body to be in a folded state, the fold in the flexible body causing it to be closed to fluid flow. In the degraded state, the flexible body is free to move to an unfolded state and the flexible body to be open to fluid flow. Preferably, the flexible body is surrounded by the valve body.

Preferably, in the non-degraded state, the biodegradable securing means compresses the flexible body, causing it to be closed to fluid flow. In the degraded state, the flexible body is not compressed and is open to fluid flow.

As detailed above, a large number of ways are known of placing a gastric balloon device in the stomach of a patient, and any of these may be used with the devices of the present invention. Thus, the gastric balloon device can be inserted surgically, for example with the use of an endoscope type device. Preferably, the gastric balloon device is an orally ingestible gastric balloon device.

More preferably, the gastric balloon device is provided in an orally ingestible encapsulated form. Preferably, the encapsulation material is degradable in stomach

fluids. More preferably, it is rapidly degradable in stomach fluids, for example within a period of about 1, 2, 3, 4 or 5 minutes. Preferably, the capsule degrades in about one minute. Preferably, the capsule is a gelatine.

In certain embodiments, the fluid inlet valve is combined with the (deflation) valve means. In such embodiments, the fluid inlet valve is preferably self-sealing. Preferably, the switch body comprises the fluid inlet valve.

In preferred embodiments where the switch means comprises a switch body and biodegradable securing means, the connecting tube or filling connector is connected to a self-sealing fluid inlet valve which forms the switch body and is secured by the biodegradable securing means. In-use, the balloon volume is filled via the connecting tube, and the connecting tube or filling connector is then separated from the fluid inlet valve which seals to prevent further fluid flow through it. When the biodegradable securing means is degraded and the degradable switch means enters the degraded state, the fluid inlet valve (the switch body) is released and fluid can flow out of the passage.

Also provided according to the present invention is a method of administering a gastric balloon device to a patient, comprising the steps of:

(i) providing said patient with a gastric balloon device according to the present invention;

(ii) said patient orally ingesting the gastric balloon device;

(iii) inflating the balloon with a fluid supplied through the connecting tube;

(iv) separating the connecting tube from the fluid inlet valve means; and

(v) withdrawing the connecting tube from the oesophagus of the patient.

Preferably, such a method additionally comprises the step of determining a reference length of the patient's oesophagus,

the step of providing the patient with a gastric balloon device according to the present invention comprising selecting or adjusting the length or swallowable length of the connecting tube to correspond to the determined reference length of said patient's oesophagus.

Also provided according to the present invention is a method of providing a patient with a gastric balloon device, comprising the steps of:

(i) placing a self-deflating gastric balloon device according to the present invention in the stomach of a patient;

(ii) causing or allowing said gastric balloon device to inflate; and

(iii) allowing said degradable switch means to degrade and said balloon of said self-deflating gastric balloon device to deflate.

In certain embodiments, the method further comprises the step of removing the deflated self-deflating gastric balloon device.

In other embodiments, the method further comprises the step of allowing the patient to excrete the deflated self-deflating gastric balloon device. The balloon deflates with assistance from the natural physiological contractions of the stomach which cause the balloon to be emptied and to collapse and crush the balloon, allowing it to pass through the pyloric sphincter and through the intestine to be excreted.

Preferably, such a method is a method of appetite suppression or weight control.

The invention will be further apparent from the following description with reference to the several figures of the accompanying drawings which show by way of example only forms of externally inflatable gastric balloon devices. Of the Figures:

Figure 1 shows a plan view of an externally inflatable gastric balloon device including connecting tube and filling means;

Figure 2 shows a close-up cross-section along lines I-I, showing the base unit;

Figure 3 shows a close-up perspective cut-away view of the collar, septum and cannula of the externally inflatable gastric balloon device of Figure 17;

Figure 4 shows a perspective view of the externally inflatable gastric balloon device in an inflated state;

Figure 5 shows a fluid inlet with an elastomeric septum used as fluid inlet valve means;

Figure 6 shows the fluid inlet of Figure 5, with the cannula partially removed;

Figure 7 shows the fluid inlet of Figure 5 with the cannula wholly removed and further fluid flow through the elastomeric septum blocked;

Figure 8 shows a cross-section through a first valve means;

Figure 9 shows a perspective view of a second valve means;

Figure 10 shows a cross-section through a third valve means;

Figure 11 shows a cross-section through a fourth valve means;

Figure 12 shows a cross-section through a fifth valve means;

Figure 13 shows a cross-section through a sixth valve means;

Figure 14 shows a cross-section through a seventh valve means;

Figure 15 shows a cross-section through an eighth valve means;

Figure 16 shows a plan view of an externally inflatable gastric balloon device plus connecting tube and filling means, the connecting tube being wrapped in a rapidly dissolving thin gelatine film;

Figure 17 shows the fluid inlet of Figure 17 with a modified connecting tube incorporating a tubing enlargement.

In use, a patient (not shown) who is to be administered gastric balloon device 10 is first measured and comparison made to reference tables to determine a reference distance between their mouth and stomach, and thus the distance that device 10 must to travel to be located in their stomach. This also determines a reference distance between their mouth and the pyloric sphincter, and thus the distance beyond which device 10 must not travel in order to avoid blocking the pyloric sphincter or entering the duodenum.

Device 10 is dimensioned to be conveniently swallowable by a patient. Connecting tube 20 is a thin-walled small-bore polyurethane tube with an outer diameter of about 0.35mm and an internal diameter of about 0.29mm. To prevent longitudinal stretching of connecting tube 20 when mechanical force is exerted upon it, it incorporates a Kevlar (RTM) thread (not shown) extending along its full length. Connecting tube 20 is manufactured incorporating polyethylene glycol to make it hydrophilic and in-use lubricious and swallowable.

As will be appreciated, in methods where the gastric balloon device 10 is provided with a connecting tube 20, a patient can find the appearance or act of being fed an extended length of connecting tube 20 to be unpleasant. Therefore, in certain embodiments (Figure 16), connecting tube 20 is provided wrapped and bundled in a rapidly-dissolving wrapper 25, which is made from a thin sheet of gelatine and which is simple and easy to swallow and which upon contact with saliva dissolves to allow connecting tube 20 to extend and gastric balloon device 10 to pass to the stomach.

Attached to device 10 is connecting tube 20 and filling syringe 30 containing fluid 40. In this embodiment, the gastric balloon device is to be inflated with fluid 40. In other embodiments, a compressed gas cylinder 100 is provided and the gastric balloon device 10 is inflated with gas.

Device 10 comprises a gelatine capsule 50 containing within it folded and compressed balloon 60 having at one end valve means 70 and at another end base unit housing 140 and base unit 80 from which extends cannula 90 which is connected to connecting tube 20. In-use, the saliva of the patient wets gelatine capsule 50, making it easily swallowable.

In one embodiment, device 10 is manufactured with balloon 60, valve means 70, base unit housing 140 and elastomeric septum 430 (base unit 80) assembled and compressed. Cannula 90 has a needle tip and is slid through elastomeric septum 430, in the process defining slit 420. Connecting tube 440 is then placed over cannula 90 such that fluid can flow through connecting tube 440 and cannula 90 into balloon volume 200. Gelatine capsule 50 is provided in two halves, a first half having no openings, and a second half defining an opening through which cannula 90 and connecting tube 440 can fit. The first half is then placed over the valve means 70 end, and the second half is slid along connecting tube 440 over the base unit housing 140 end until it contacts tubing enlargement 450, and the two ends are then joined together.

Filling syringe 30 is in fluid communication with the interior volume of balloon 60 via connecting tube 20, and cannula 90.

As shown in Figures 5-7, elastomeric septum 430 (base unit 80) is formed and cured in base unit housing 140. Elastomeric septum 430 operates as a self-sealing gasket valve. Thus, with cannula 90 extending through septum 430 (Figure 5) it is in fluid communication with balloon volume 200 and is retained by a friction fit with septum 430.

In use, after the patient has been measured and a reference distance from the mouth to the stomach has been determined, a gastric balloon device 10 with a suitable length connecting tube 20 is selected and connected to filling syringe 30. Gastric balloon device 10 is then swallowed by the patient and is passed to the stomach. When the patient has confirmed that they have fully swallowed device 10, it is known to be in the stomach and not to have entered the pyloric sphincter since connecting tube 20 is not of sufficient length to allow that to occurr

In the stomach, gelatine capsule 50 dissolves within 1-2 minutes and balloon 60 can be inflated.

Filling syringe 30 is used to fill balloon 60 with a desired volume of fluid 40, causing it to expand and reduce the stomach volume available to the patient, thus acting as an appetite suppressant. In the inflated state shown in Figure 4, balloon 60 has a diameter of about 100mm.

In order to remove connecting tube 20 and cannula 90, connecting tube 20 is pulled, causing balloon 60 to be pulled and to contact the wall of the upper stomach, preventing its further movement. At that point, the pulling force exerted on connecting tube 20 causes cannula 90 to be pulled out of slit 420 which it previously created in septum 430, which self-seals behind it (Figure 6). When cannula 90 has been wholly pulled from slit 420 in septum 430 (Figure 7), it can continue to be pulled from the patient and is retrieved from the oesophagus of the patient together with connecting tube 20.

Balloon 60 is self-deflating, and this deflation is achieved by valve means 70. Various embodiments of valve are shown in Figures 8-15 and 17, and in each of them valve

means 70 comprises valve body 170 defining passage 180 having a second end 190 located external to balloon volume 200 and a first end 210 internal to balloon volume 200. Valve means 70 is attached to balloon 60 and also comprises degradable switch means 220 which controls fluid flow through passage 180, such that with degradable switch means 220 in a non-degraded state fluid flow through passage 180 is prevented, and with degradable switch means 220 in a degraded state fluid flow through passage 180 can occur.

A first embodiment of valve means 70 is shown in Figure 8 in which switch means 220 comprises a switch body and biodegradable securing means, namely plug 230 and biodegradable hooks 240. Plug 230 is positioned in passage 180 and dimensioned to block fluid flow through passage 180, and biodegradable hooks 240 made of gelatine are attached to external surface 250 of valve body 170 and to plug 230, preventing plug 230 from exiting passage 180.

In use, when located in the stomach of a patient, the biodegradable hooks 240 are absorbed by the stomach fluid over a period of about two months. Whilst the biodegradable hooks 240 remain mechanically sound, movement of plug 230 from passage 180 is prevented and thus fluid flow through passage 180 is cannot occur. When biodegradable hooks 240 lose their mechanical integrity, plug 230 is able to move relative to passage 180 and exits it into the stomach. At this point, fluid 40 is able to flow from balloon volume 200 through passage 180, and is caused to do so either by a fluid pressure created when balloon 60 was filled, or due to a mechanical pressure exerted by the stomach.

Thus, switching occurs between a first non-degraded state and a second degraded state. In the first non-degraded state fluid flow is prevented, whereas in the second degraded state, fluid flow can occur. Importantly, this fluid flow in the second degraded state can be considered to be a free fluid flow, and is distinct from prior art devices which during the degradation process allow a continually increasing amount of fluid flow to occur and do not provide the binary fluid flow states of the present invention.

In a second embodiment of valve means 70 shown in Figure 9, operation is as per Figure 8, except that instead of biodegradable hooks 240, biodegradable strap 260 is provided which is attached to external surface 250 of valve body 170 and abuts plug 230, preventing plug 230 from exiting passage 180.

In use, operation is as per Figure 8. Notably, movement of plug 230 along passage 180 to balloon volume 200 is prevented by pressure exerted upon it by fluid 40 in the balloon volume, either due to fluid 40 being inserted into balloon 60 at an elevated pressure relative to stomach fluids or due to the stomach exerting a mechanical pressure upon balloon 60.

In a third embodiment (not shown), the gastric balloon device 10 of Figure 9 is provided, but biodegradable strap 260 is replaced with a biodegradable bar which is attached to and engaged with a surface feature of valve body 170 and which is attached to plug 230.

In another embodiment (not shown), a gastric balloon device is supplied as per the second embodiment, but with biodegradable strap 260 attached to the inner wall of passage 180.

A fourth embodiment is shown in Figure 10, and in it plug 270 is located in passage 180 and blocks fluid flow through passage 180. In a plane perpendicular to the longitudinal axis of passage 180, plug 270 is recessed at its radial periphery, and a generally ring shaped biodegradable layer 280.

Biodegradable layer 280 is attached to valve body 170 and to plug 270 and has an external surface 290 which in use in the stomach of a patient is exposed to stomach fluids and is degraded.

As for the other embodiments, fluid flow through passage 180 is prevented when degradable switch means 220 is in the non-degraded state, whereas with degradable switch means 220 in the degraded state, fluid flow can occur through passage 180 by fluid pressure causing plug 270 to exit passage 180 into the stomach.

In a fifth embodiment (Figure 11), switch means 220 comprises plug 230 and biodegradable securing means 300. At the second end 190 of passage 180, valve body 170 is recessed to define a rim 310 (also referred to as a "dado"). Biodegradable securing means 300 is located in passage 180 between plug 230 and second end 190 so as to prevent plug 230 from exiting passage 180 through second end 190. Biodegradable securing means 300 is engaged with rim 310 and extends across the cross-section of passage 180.

In other embodiments (not shown) valve body 170 is provided with arms and securing means, and the biodegradable securing means is engaged with them. In other embodiments, it is attached to them. In other embodiments, the biodegradable securing means does not extend over the whole of a cross-section of passage 180, but still prevents plug 230 from exiting passage 180 through second end 190.

In another embodiment (not shown), gastric balloon device 10 is provided as per the fifth embodiment, but valve body is not recessed and instead of biodegradable securing means 300 being engaged with a rim, instead it is attached to the inner wall of passage 180 and extends over a cross section of passage 180.

In a sixth embodiment (Figure 12), switch means 220 comprises head section 320 and tail anchor section 330 comprising elongate body section 340 and anchor 350 which in-use abuts the first end 210 of valve body 170 and prevents switch means 220 from exiting passage 180 through second end 190 but does not prevent fluid flow through passage 180.

At the second end 190 of passage 180, valve body 170 is recessed to define a rim 310. Switch means 220 also comprises biodegradable securing means 300 located in passage 180 between head section 320 and second end 190 so as to prevent head section 320 from exiting passage 180 through second end 190. Biodegradable securing means 300 is attached to rim 310 and extends across a part of the cross-section of passage 180.

In a seventh embodiment (not shown), tail anchor section 330 is replaced with a flexible thread which is attached to the underside of valve body 170 beyond first end 210 and which prevents head section 320 from becoming separated from the rest of gastric balloon device 10.

In an eighth embodiment (Figure 13), switch means 220 comprises duckbill valve 360 and biodegradable clamp 370. Duckbill valve 360 is movable between (i) an open state in which the valve leaves 380 are apart and in which fluid flow can occur through the valve 360, and (ii) a closed state in which the valve leaves 380 are brought together and in which fluid flow cannot occur through the valve 360. Duckbill valve 360 is sprung and urges to the open position. In order to close duckbill valve 360, external force must be exerted to bring together valve leaves 380.

In this embodiment, external force is provided by biodegradable clamp 370 which clamps valve leaves 380 in the closed position.

As for the other embodiments, with the switch means in the non-degraded state, fluid flow through passage 180 (i.e. between first end 210 and second end 190) is prevented. As biodegradable clamp 370 degrades and becomes mechanically unsound, the force exerted by the sprung duckbill valve 360 on its valve leaves 380 causes them to move apart and duckbill valve 360 to go into the open state.

In a ninth and preferred embodiment, switch body 220 comprises (i) flexible tube 390 defining a lumen therein extending within and from and in fluid communication with passage 180, and (ii) biodegradable securing means 400. Valve body 170 is recessed at the second end 190 of passage 180 to define (i) a volume in which flexible tube 390 can fit in a compressed state, particularly in a folded state, and (ii) a rim to which is attached biodegradable securing means 400 which extends across the whole cross-section of passage 180.

When switch body 220 is manufactured in this embodiment, flexible tube 390 is caused to be compressed and folded by biodegradable securing means 400, meaning that fluid flow through flexible tube 390 is blocked.

In use, upon degradation of biodegradable securing means 400 in the stomach of a patient, flexible tube 390 is able to go to (and is caused to go to by fluid pressure exerted by fluid 40 in balloon volume 200) a second unfolded (extended) non-compressed state in which fluid flow can occur through it.

Thus, this embodiment provides an extremely simple and convenient gastric balloon device 10.

In a tenth and most preferred embodiment (Figure 15), similarly to the ninth embodiment, switch body 220 comprises flexible tube 390 defining a lumen therein extending within and from and in fluid communication with passage 180. Switch means 220 also comprises biodegradable tie 410.

Valve body 170 is recessed at the second end 190 of passage 180 to define a volume in which flexible tube 390 can fit in both a folded state and an extended state, thus allowing flexible tube 390 to extend and allow fluid flow through flexible tube 390 when switch means 220 is in a degraded state and not be blocked by flexible tube being pressed against the patient's stomach wall.

When switch body 220 is manufactured in this embodiment, flexible tube 390 is caused to be compressed and folded to place it in a first closed state, and is held in that form by biodegradable tie 410, meaning that fluid flow through flexible tube 390 is blocked.

In use, upon degradation of biodegradable tie in the stomach of a patient, flexible tube 390 is able to go to (and is caused to go to by fluid pressure exerted by fluid 40 in balloon volume 200) a second unfolded open state in which fluid flow can occur through it.

Thus, this embodiment provides an extremely simple and convenient gastric balloon device 10.

In an eleventh embodiment (Figure 17), base unit 460 comprises stainless steel collar 110 which has an axial length of 4mm and having on its external surface an absorbable coating 480 of polylactic co-glycolide (PLGA), and located on its inward surface a silicone elastomeric septum 430 which is a self-sealing gasket valve and which contains rigid cannula 90. Base unit 80 additionally comprises base unit housing 470. Cannula 90 traverses the length of elastomeric septum 430.

Connecting tube 440 has a tubing enlargement 450 contained within gelatine capsule 50 and which helps prevent separation of cannula 90 from elastomeric septum 430. Thus, when capsule 50 is not degraded, separation of cannula 90 from elastomeric septum 430 is resisted in addition to the resistance caused by elastomeric septum 430 itself, and when capsule 50 is degraded, separation of cannula 90 from elastomeric septum 430 is resisted only by elastomeric septum 430.

Stainless steel collar 110, absorbable coating 480 and elastomeric septum 430 are contained within combined base unit housing and valve body 470.

In-use, after degradation of capsule 50 and removal of cannula 90 and connecting tube 440, elastomeric septum 430 self-seals to prevent further fluid flow.

Balloon 60 is discontinuous over the external surface 160 of valve body 170 and in-use allows stomach fluids to come into contact with biodegradable coating 480 (and similar parts 240, 260, 300, 370, 400, 410 above). Over a period of 1-2 months, absorbable PLGA coating 480 is degraded by stomach fluids and finally with absorbable coating 480 mechanically unsound, the switch means enters the degraded state and pressure exerted by fluid contained within balloon volume 200 causes elastomeric septum 430 and stainless steel collar 110 to be ejected from the passage defined by combined base unit housing and valve body 470, allowing fluid flow through the passage and balloon 60 to deflate.

Thus, this embodiment also provides an extremely simple and convenient gastric balloon device.

In each of the above embodiments, gastric balloon device 10 is orally ingestible, and a patient is provided with a gastric balloon device 10 by:

(i) orally ingesting gastric balloon device 10;

(ii) gastric balloon device 10 being inflated with fluid 40 from filling syringe 30; and

(iii) allowing gastric balloon device 10 to degrade and deflate.

Such a method is a method of appetite suppression and weight control.

It will be appreciated that it is not intended to limit the present invention to the above embodiments only, many variations being readily apparent to a person of normal skill in the art without departing from the scope of the appended claims.

Reference signs:

10 – gastric balloon device

20 – connecting tube

25 – rapidly dissolving wrapper

30 – filling syringe

40 – fluid

50 – gelatine capsule

60 – balloon

70 – valve means

80 – base unit

90 – cannula

100 – compressed gas cylinder

110 – stainless steel collar

140 – base unit housing

160 – upper surface

170 – valve body

180 – passage

190 – second end

200 – balloon volume

210 – first end

220 – switch means

230 – plug

240 – biodegradable hook

250 – external surface

260 – biodegradable strap

270 – plug

280 – biodegradable layer

290 – external surface

300 – biodegradable securing means

310 – rim

320 – head section

330 – tail anchor section

340 –body section

350 – anchor

360 – duckbill valve

370 – biodegradable clamp

380 – valve leaves

390 – flexible tube

400 – biodegradable securing means

410 – biodegradable tie

420 – slit

430 – elastomeric septum

440 – connecting tube

450 – tubing enlargement

460 – base unit

470 – combined base unit housing and valve body

480 – absorbable coating

CLAIMS

1. An externally inflatable gastric balloon device comprising:

(i) a balloon defining a balloon volume;

(ii) fluid inlet valve means; and

(iii) a filling connector comprising a connecting tube connected to said fluid inlet valve means;

wherein said connecting tube is in fluid communication with said balloon volume via said fluid inlet valve means, said connecting tube being in-use separable from said fluid inlet valve means.

2. An externally inflatable gastric balloon device according to claim 1, wherein said connecting tube is flexible.

3. An externally inflatable gastric balloon device according to claim 1, wherein said connecting tube additionally comprises a stretch-resistant material extending along its longitudinal length.

4. An externally inflatable gastric balloon device according to claim 1, wherein it additionally comprises fluid supply means.

5. An externally inflatable gastric balloon device according to claim 4, wherein said fluid supply means is selected from the group consisting of: syringe, hand pump, motorised pump, compressed gas supply, and compressed gas cylinder.

6. An externally inflatable gastric balloon device according to claim 1, wherein said connecting tube is provided with an in-use non-swallowable collar.

7. An externally inflatable gastric balloon device according to claim 6, wherein said in-use non-swallowable collar is engageable with said connecting tube without preventing fluid flow along said connecting tube.

8. An externally inflatable gastric balloon device according to claim 6, wherein said in-use non-swallowable collar is self-adhesive.

9. An externally inflatable gastric balloon device according to claim 1, wherein said connecting tube is provided with a scale.

10. An externally inflatable gastric balloon device according to claim 1, wherein said fluid inlet valve is a one-way valve.

11. An externally inflatable gastric balloon device according to claim 1, wherein said fluid inlet valve is a self-sealing gasket valve.

12. An externally inflatable gastric balloon device according to claim 1, wherein said filling connector comprises a cannula.

13. An externally inflatable gastric balloon device according to claim 1, wherein said fluid inlet valve is a self-sealing gasket valve and said filling connector comprises a cannula.

14. An externally inflatable gastric balloon device according to claim 1, wherein said externally inflatable gastric balloon device or an external component part thereof is coated with or incorporates a lubricant.

15. An externally inflatable gastric balloon device according to claim 1, wherein said connecting tube is at least partially contained within a wrapper.

16. An externally inflatable gastric balloon device according to claim 15, wherein said wrapper is rapidly-dissolving in water or saliva.

17. An externally inflatable gastric balloon device according to claim 1, wherein said externally inflatable gastric balloon device is provided in an orally ingestible form encapsulated in an encapsulation material.

18. An externally inflatable gastric balloon device according to claim 17, wherein said encapsulation material is degradable in stomach fluids.

19. An externally inflatable gastric balloon device according to claim 17, wherein said connecting tube comprises at least one protrusion which contacts and is retained by said encapsulation material.

20. A method of administering a gastric balloon device to a patient, comprising the steps of:

(i) providing said patient with a gastric balloon device according to claim 1;

(ii) said patient orally ingesting said gastric balloon device;

(iii) inflating said balloon with a fluid supplied through said connecting tube;

(iv) separating said connecting tube from said fluid inlet valve means; and

(v) withdrawing said connecting tube from the oesophagus of said patient.

21. A method of administering a gastric balloon device to a patient according to claim 20, wherein it additionally comprises the step of determining a reference length of said patient's oesophagus,

the step of providing said patient with a gastric balloon device comprising selecting or adjusting the length or swallowable length of said connecting tube to correspond to the determined reference length of said patient's oesophagus.

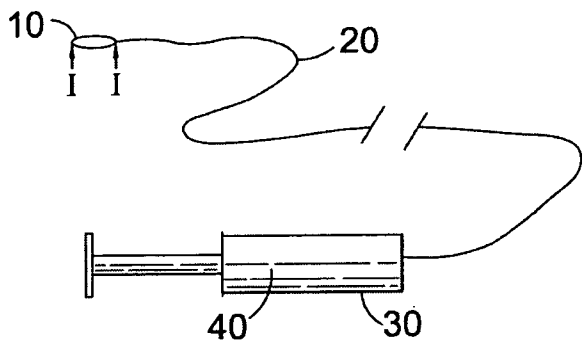

Fig. 1

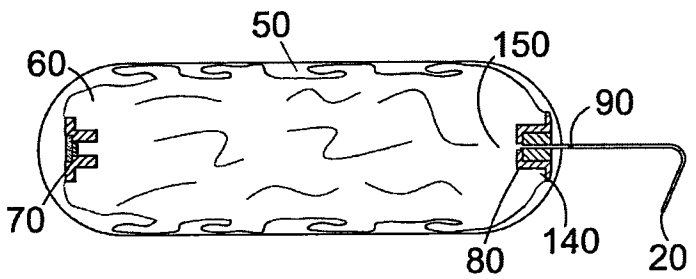

Fig. 2

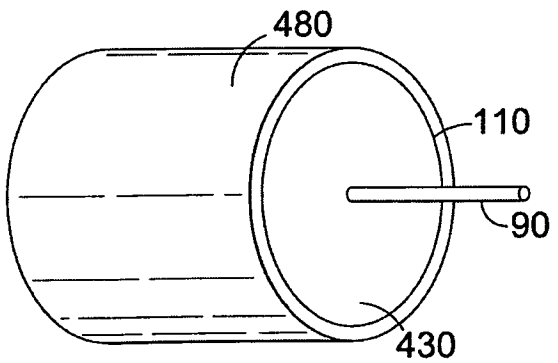

Fig. 3

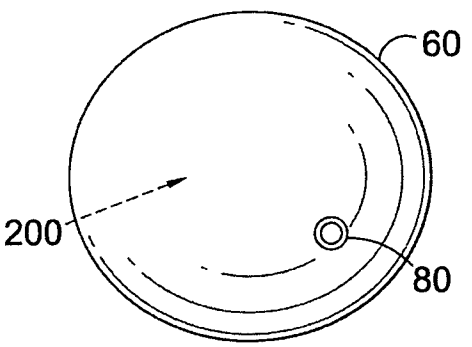

Fig. 4

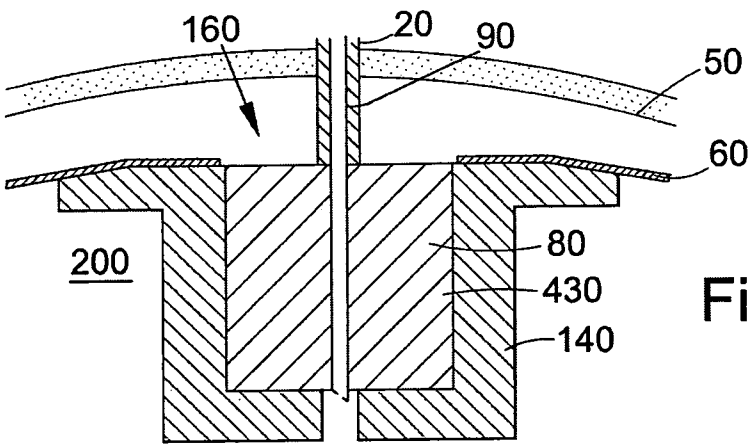

Fig. 5

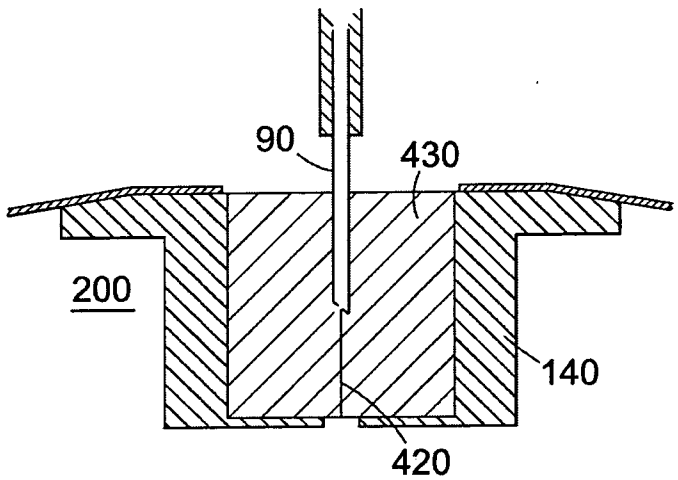

Fig. 6

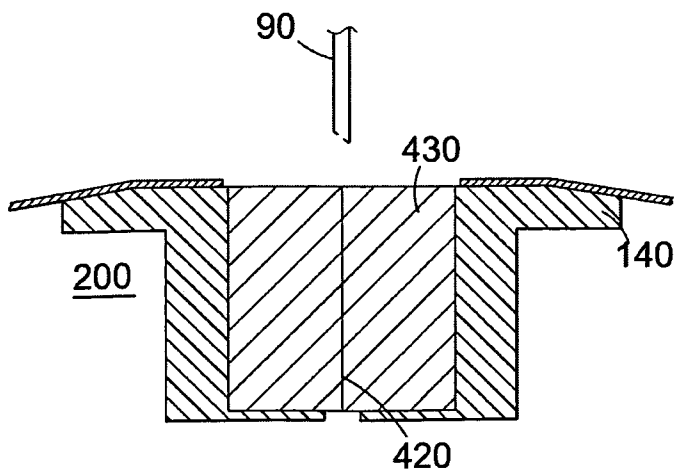

Fig. 7

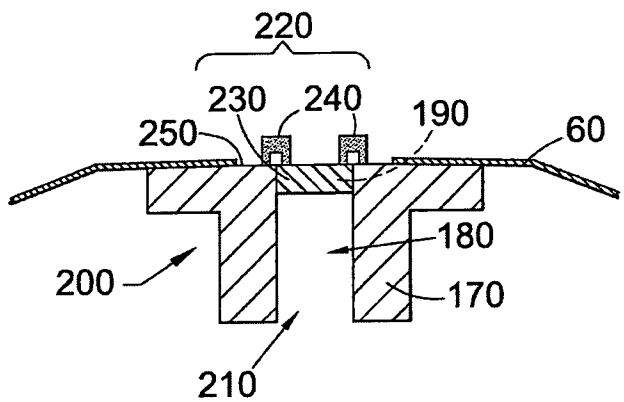

Fig. 8

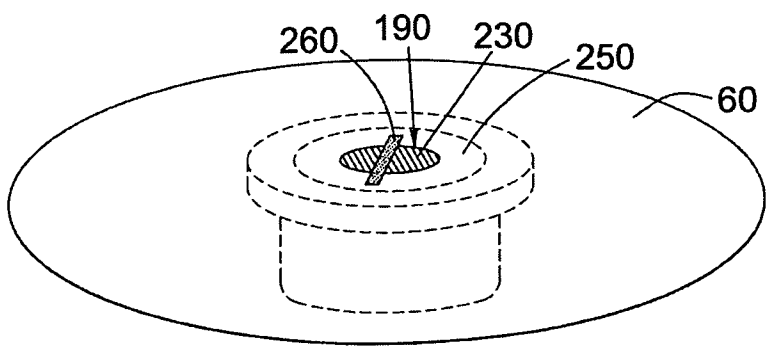

Fig. 9

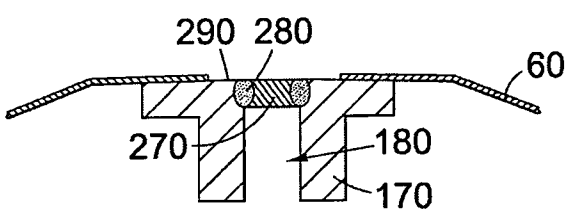

Fig. 10

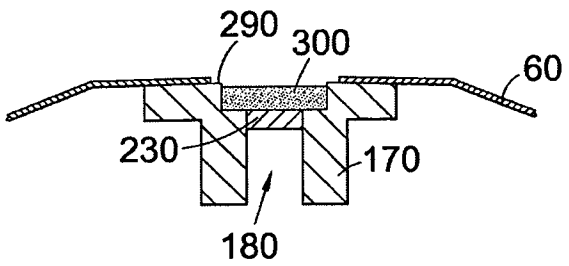

Fig. 11

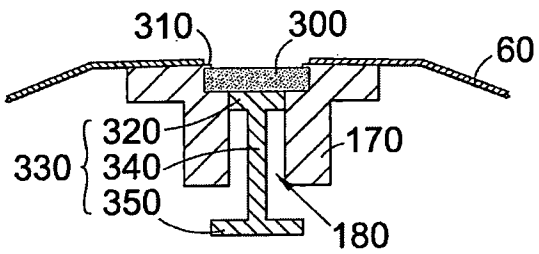

Fig. 12

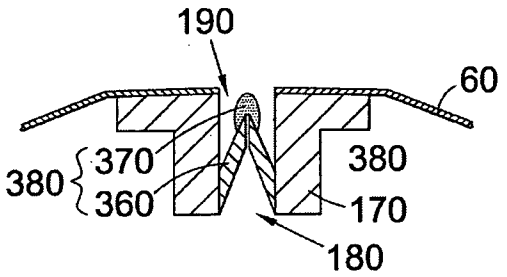

Fig. 13

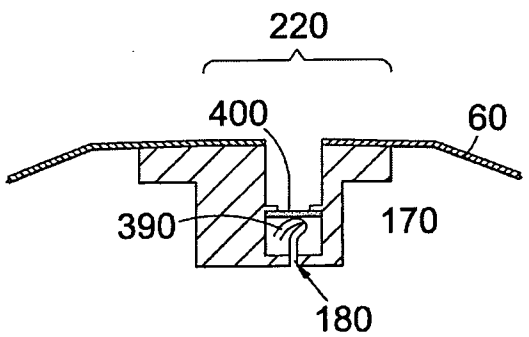

Fig. 14

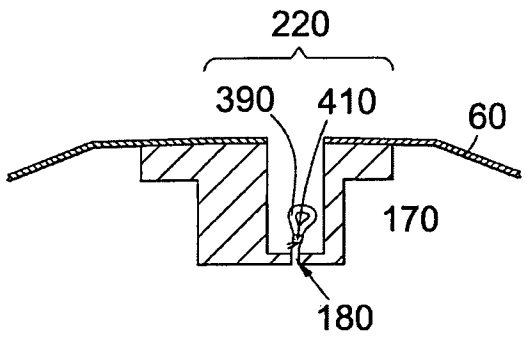

Fig. 15

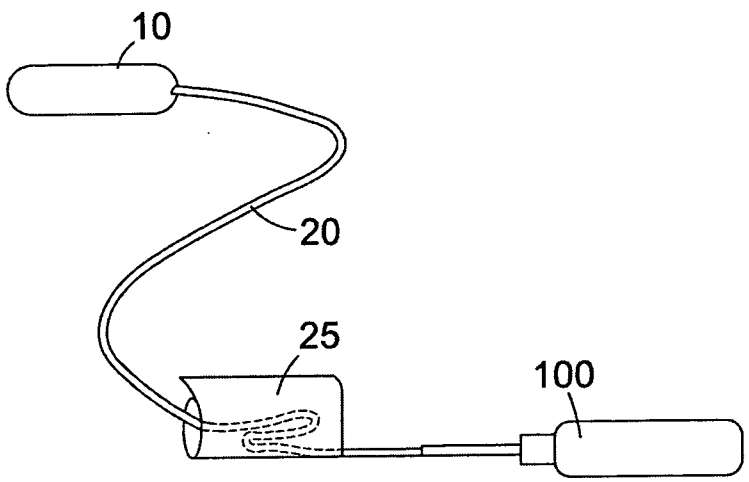
10
20
25
100

Fig. 16

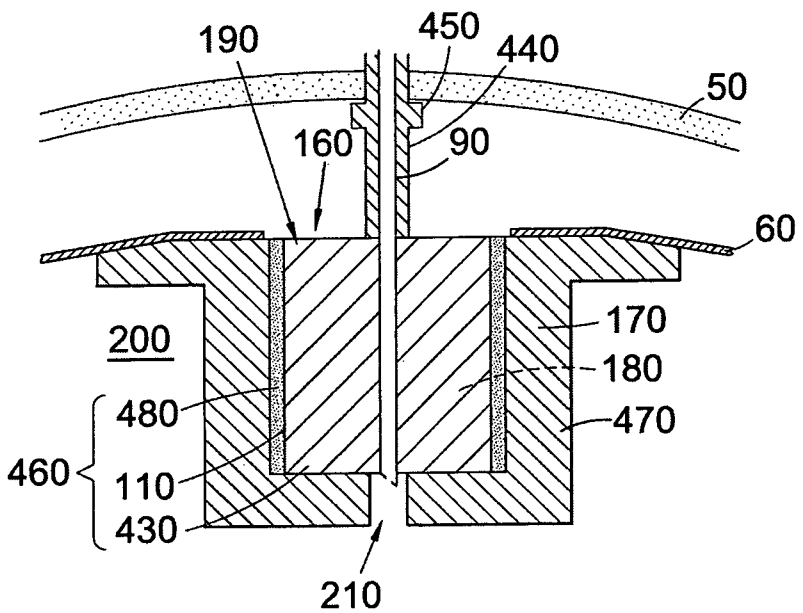
190
450
440
50
160
90
60
200
170
180
480
470
460
110
430
210

Fig. 17

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/009604

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/00

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)
A61F

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 practical, 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.
X Y	WO 86/06611 A (BARD INC C R [US]) 20 November 1986 (1986-11-20)	1-5,9-15 6-8, 17-19
X	US 4 739 758 A (LAI N C JOSEPH [US] ET AL) 26 April 1988 (1988-04-26) the whole document	1-5, 10-13
X	US 2003/171768 A1 (MCGHAN JIM J [US]) 11 September 2003 (2003-09-11) paragraph [0016]	1
Y	GB 331 453 A (MOR KUENSZTLER) 3 July 1930 (1930-07-03) page 1, line 73 - page 2, line 8; claims 1-4; figures	6-8

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"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 when the document is taken alone

"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
6 February 2009	27/02/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Fax: (+31–70) 340–3016	Sánchez y Sánchez, J

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2008/009604

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2006/020929 A (PHAGIA TECHNOLOGY [US]; SAMPSON DOUGLAS C [US]; ZANAKIS MICHAEL [US]) 23 February 2006 (2006-02-23) abstract ----	17-19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2008/009604

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

1. [X] Claims Nos.: 20, 21
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
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. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2008/009604

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 8606611 A	20-11-1986	AU 5907386 A	04-12-1986
		EP 0221993 A1	20-05-1987
		JP 62503012 T	03-12-1987
		US 4723547 A	09-02-1988
US 4739758 A	26-04-1988	NONE	
US 2003171768 A1	11-09-2003	NONE	
GB 331453 A	03-07-1930	NONE	
WO 2006020929 A	23-02-2006	AU 2005272597 A1	23-02-2006
		CA 2577040 A1	23-02-2006
		EP 1814622 A2	08-08-2007