Title: BIODEGRADABLE SELF-INFLATING INTRAGASTRIC IMPLANTS AND METHOD OF CURBING APPETITE BY THE SAME

Abstract: The present invention discloses a biodegradable self-inflating or self opening intragastric implant for curbing appetite, constructed from one or more discrete expandable, stretchable and/or deformable members. The expandable elements are adapted to expand in vivo when in contact with gastric juice for a predetermined period of time and/or heated to about 37°C. At least a portion of the expandable elements are shape memory members and/or orientation memory being in their deflated state ex vivo, and further being in their native inflated state in vivo when in contact with gastric juice for a predetermined period of time or heated to the in vivo body temperature.
BIODEGRADABLE SELF-INFLATING INTRAGASTRIC IMPLANTS AND
METHOD OF CURBING APPETITE BY THE SAME

FIELD OF THE INVENTION

The present invention generally relates to biodegradable self-inflating intragastric implants and to methods of curbing appetite by the same means.

BACKGROUND OF THE INVENTION

Obesity is a major health problem in developed countries. In the United States, the complications of obesity affect nearly one in five individuals at an annual cost of approximately $40 billion. Except for rare pathological conditions, weight gain is directly correlated to overeating.

Intragastric volume-occupying devices provide the patient a feeling of satiety after having eaten only small amounts of food. Thus, the caloric intake is diminished while the subject is satisfied with a feeling of fullness. Currently available volume-occupying devices have many shortcomings. For example, complex gastric procedures are required to insert some devices.

There has been ongoing clinical use of intragastric balloons for several years, and its success in the treatment of certain individuals with morbid obesity is well accepted.

United States Patent Application No. 2004/0186502 to Sampson et al. discloses a self-inflating intragastric volume-occupying balloon including a valve providing fluid communication into the balloon from outside. The '502 application further discloses a method for occupying stomach volume comprising the step of inserting the self-inflating intragastric balloon into the stomach, through the esophagus, while the balloon is deflated, then inflating the balloon by activating liquid influx through the aforesaid self-sealing valve.

United States Patent 4,607,618 to Angelchik discloses semi-rigid skeleton members, collapsible to a shape and dimensions suitable to be endoscopically inserted into the stomach through the esophagus and cardiac opening by means of feeding tube.
United States Patent 5,129,915 to Cantenys discloses a balloon intended to be swallowed and to occupy a given volume of the stomach in the presence of other balloons of the same type. This invention is designed to facilitate weight reduction of an individual and consists of an envelope containing two chemicals which can react with each other and with water at an elevated temperature in order to form a gas effecting the inflation of the balloon.

There remains a long felt need for a biodegradable intragastric implant that can be delivered to the stomach by conventional oral administration and that controllably inflates after an approximate predetermined delay time.

SUMMARY OF THE INVENTION

It is thus an object of the present invention to disclose a novel treatment for curbing appetite and/or treating obesity. This treatment is adapted for providing selective medical care and obesity therapy specifically suited to the ever-changing needs of an individual patient: wherein his eating habits; his daytime and nighttime behavior; his physiological and mental characteristics; his size and age are considered and effectively targeted.

Another object of the present invention is to present a cost effective biodegradable self-inflating intragastric implant for curbing appetite and treating obesity, constructed from one or more discrete expandable and/or deformable members.

BRIEF DESCRIPTION OF THE FIGURES

In order to understand the invention and to see how it may be implemented in practice, a plurality of preferred embodiments will now be described, by way of non-limiting example only, with reference to the accompanying drawing, in which figures 1 to 16 present schematic illustrations of the implant. Figures 17 and 18 presenting a lateral cross-section and a top views, respectfully, of a lock mechanism comprising a connector locking a segment to a joint.
DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The following description is provided, alongside all chapters of the present invention, so as to enable any person skilled in the art to make use of the said invention and sets forth the best modes considered by the inventor for carrying out this invention. Various modifications, however, will remain apparent to those skilled in the art, since the generic principles of the present invention have been defined specifically to provide a biodegradable self-inflating intragastric implant for curbing appetite, constructed from one or more discrete expandable members and a treatment of curbing appetite by the same.

The appetite is curbed by a volume-occupying implant temporarily installed in the stomach of the patent. The installation is provided according to one embodiment of the present invention for a respectively short period of time (e.g., few hours) and/or heated to about 37°C.

This self-inflated implant is deployed in the stomach automatically, e.g., by utilizing shape memory materials, and/or orientation memory materials, shape memory alloys and/or orientation memory alloys or polymers or flexible materials adapted to expand themselves; utilizing biocompatible compositions; providing gas formation inflating the same or any combination thereof. It is acknowledged in this respect that at least a portion of the member is of a shape memory and/or orientation memory nature.

The term 'discrete expandable members' is related hereinafter to structural elements temporary interconnected only by a means of a biodegradable or disassembled tie, such that small debris is produced by the member which is easily evacuated from the stomach after use. Said members may be composed of biodegradable compositions, such as PLA, PGA, polysaccharides pastas, gelatins, nylons, especially nylon 12 etc.

The term "Pasta" refers hereinafter to mixtures of carbohydrates, e.g., flour and fluids, e.g., water, possibly with a predetermined measure of proteins, especially egg-related proteins.

The term "Gelatin" refers hereinafter to a protein product derived through partial hydrolysis of the collagen extracted from skin, bones, cartilage, ligaments, etc.

It is according to one embodiment of the present invention wherein the expandable elements are adapted to expand in vivo when they come into contact with gastric juice for a predetermined period of time and/or heated to about 37°C.
Said period of time may vary widely. For some purposes and in a non-limiting manner, it ranges from about 0.5 hour to 8 hours, preferably about 3 hours from initial contact with the gastric juice and/or at an elevated body temperature. The device is alternatively adapted to expand/form in vivo in a time being less than T2 and more than T1, wherein T1 is less than T2; where T2 is about 2 to 7 minutes; and where T2 is about 20 to 40 minutes.

For some other purposes, further in a non-limiting manner, it ranges from about 8 hours to about 24 hours. For other purposes, still in a non-limiting manner, it ranges from about 24 hours to about 96 hours. It is nevertheless acknowledged that longer periods of time are possible, such as 1 day to 30 days or more. Said predetermined period of time is selected by the specialist and reflects inter alia the size of the stomach (e.g. the age of the patient), food digestive parameters in the stomach and along the digestion tracks, conditions of the stomach and its sphincters, the content of the gastric juice etc, the patient’s general physiological and mental condition etc. Said predetermined period of time may be equal intervals or may vary from time to time, from meal to meal etc.

The device is preferably provided wherein the self inflating device is further composed of at least one element selected from a group comprising a bio-absorbable element; bio-degradable element, disintegrating element or any combination thereof.

It is also according to one embodiment of the present invention wherein the device is self-inflated spontaneously and does not contain any inflating valves or the like, nor external inflating means.

It is also according to one embodiment of the present invention wherein at least a portion of the expandable elements are shape memory and/or orientation memory members being in their deflated state ex vivo, and further being in their native inflated state in vivo upon contact with gastric juice or when heated to the temperature inside the stomach for a predetermined period of time. The composition is selected in a non limiting manner form alloys, polymers, silicon or rubber-like materials etc.

It is also according to one embodiment of the present invention wherein at least a portion of the expandable elements are adapted to disassemble in vivo when in contact with gastric juice for a predetermined period of time.
It is also according to one embodiment of the present invention wherein the discrete expandable elements as defined in any of the above provide *in vivo* a two-dimensional sheet. The term sheet is related hereinafter to any 2D object. Said sheet may be provided in any size, shape or thickness. Hence, for example, oval thin sheets are useful, as well as polygonal double-layered ones. Said sheet may be smooth and/or comprise protruding patterns. The sheet may be provided tightly rolled, collapsed or otherwise forcibly packed inside a digestible capsule.

It is also according to one embodiment of the present invention wherein the device defined above is characterized *inter alia* by both a planar body portion and a frame portion.

It is also according to one embodiment of the present invention wherein the planar body portion is deployed *in vivo* so that a sheet-like plane is provided. The planar body portion can be twisted *in vivo* so that a bent, curved and/or folded object can be provided. Alternatively or additionally, the planar body portion is twisted *in vivo* so as to provide a coiled helix. Hence, the sidewalls of the stomach are in contact with the said flexible implant. The degree of the flexibility of the implant is provided by either the materials used in its construction or the manner said implant is opened or inflated *in vivo*. Moreover, the exact *in vivo* intragastric location of the implant is determined by those two factors of materials and structure when inflated.

It is also according to one embodiment of the present invention wherein the above mentioned planar body portion is selected from a group comprising *inter alia* a continuous membrane portion (e.g., a semi-permeable sheet, preventing solids or liquid from penetrating the implanted membrane), a mesh-like net or screen (e.g., a woven or knitted mesh, silicon materials, netting comprising many interlocking structural elements etc.), at least one aperture or open bore extending within the said planar body portion or any combination thereof.

It is also according to one embodiment of the present invention wherein the frame portion is selected from a group comprising at least one expandable and/or deformable rib being in its deflated state *ex vivo* and in its inflated state *in vivo*; and further wherein at least a portion of said ribs are interconnected by means of a tie such that a multi-dimensional inflated frame is provided. The term 'rib' is related hereinafter to any maneuverable, inflatable or expandable structural element of the
device. Said ribs may be thin or thick, smooth or roughened, simple or shaped members. The ribs are comprised of one or more structural elements, and may be interconnected with one or more other ribs. Some of the ribs may be elastic (e.g., construction spreading ribs), some may include springs or spring-like means, some may be rigid, some may be and/or orientation memory materials, e.g., made of Nitinol, shape-memory polymeric compositions or a combination thereof.

It is also according to one embodiment of the present invention wherein at least a portion of the rib disassembles in vivo. This biodegradable characteristic may be provided by bringing the rib into contact with gastric juice for a predetermined period of time and/or heated to about 37°C. The terms 'disassemble' and/or 'biodegradable' are related hereinafter to a measurable activity of breaking down (pertaining to matter), decomposing under natural conditions characteristic of the stomach, taking apart, dismantling and/or coming apart. Those terms are especially related to activities provided in the stomach, whereat a low pH and a warm environment is provided. Other conditions however, are possible for providing said disassembling and/or biodegrading activities, such as the presence of one or more components of the gastric juice, additive coexistence etc.

It is also according to one embodiment of the present invention wherein the implant comprises a plurality of ribs providing the device's infrastructure. At least one portion of said ribs is interconnected with at least a portion of other ribs by a means of a tie. The term 'tie' is related hereinafter to any joint, connection, link etc adapted to couple two or more structural elements. Said tie may be driven from physical, chemical or biological means.

It is also according to one embodiment of the present invention wherein one or more ties are disassembled in vivo, possibly a biodegradable tie or ties are disassembled by effective contact with gastric juice for a predetermined period of time and/or heated to about 37°C.

It is also according to one embodiment of the present invention wherein the discrete expandable elements form in vivo a three-dimensional object.

It is also according to one embodiment of the present invention wherein said ribs are characterized by proximal and distal ends. Said proximal end comprising a sliding means; wherein at least a portion of the ribs are being connected to at least one shaft
by the said sliding means, such that the inflation of the structure *in vivo* is provided by sliding the said sliders along the said shaft or shafts. The sliding means could be fork-like surrounding at least a portion of the shaft. Said means may alternatively comprise a rotating hinge and/or at least one protruding element slidable in a recess located in the shaft etc.

It is also according to one embodiment of the present invention wherein the distal ends of the ribs comprise anchoring means, such that said ribs are interconnected with at least one end of the shaft by means of the said anchoring means.

It is also according to one embodiment of the present invention wherein the implant is deflated *ex vivo* and inflated *in vivo*. It is characterized by an umbrella-like structure and comprises a so-called umbrella-like assembly. This assembly comprises at least one shank, a plurality of slidable ribs and a canopy attached thereto. One or more ribs are adapted to slide along the main longitudinal axis of the shank while being connected to a pole of said shank. This unique implant's expanding mechanism is thus translating longitudinal 2D movement to a 3D lateral expanding maneuver.

It is thus in the scope of the present invention wherein at least a portion of the planar body defined above is provided as the canopy of the umbrella-like device.

It is also according to one embodiment of the present invention wherein the implant is a self-inflated structure comprising two or more umbrella-like assemblies and/or two or more interconnected umbrellas. Thus for example, the multi-component structure comprising two umbrella- assemblies: a first assembly is adapted to inflate towards one pole of the shank, and said second assembly is adapted to inflate towards the opposite pole of the shank; the assemblies are either separated or interconnected. Hence, a conch-like close or open structure is obtained.

It is also according to one embodiment of the present invention wherein at least a part of the planar body portion is adapted to disassemble *in vivo*. Preferably, yet not exclusively, the planar body portion is adapted to disassemble *in vivo* when in contact with gastric juice for a predetermined period of time and/or heated to about 37°C.

It is also according to one embodiment of the present invention, wherein the discrete expandable elements provided *in vivo* a three-dimensional bladder. The bladder comprises a body portion and infrastructural elements which are deflated *ex vivo* and inflated *in vivo*. The 3D shape of the bladder when inflated *in vivo* is selected from a
group comprising, in a non-limiting manner, balloon, football-like, basketball-like polygonal bag-shaped construction, hose-like, stent-like or ring-like shape, floating pot-like objects, floating on the upper level of the gastric juice, coiled helix or any combination thereof. The terms football and basketball are denoted to approximately round balloon-like implants, wherein the infrastructure or frame provided by the discrete structural elements is provided by obtaining hexagonal/pentagonal elements (so called 'football' structure) or concaved curvatures and arcs (e.g., basketball structure).

It is also according to one embodiment of the present invention, wherein the bladder is constructed by a means of interconnected structural elements. Said elements are at least partially disassembled in vivo. Preferably, the elements are at least partially disassembled in vivo when in contact with gastric juice for a predetermined period of time and/or heated to about 37°C.

It is also according to one embodiment of the present invention, wherein the bladder is constructed by means of structural elements interconnected by mutual joints. The joints are at least partially disassembled in vivo. Preferably, the joints are at least partially disassembled in vivo when in contact with gastric juice for a predetermined period of time and/or heated to about 37°C. Moreover, the bladder is potentially and at least partially disassembled in vivo. Preferably, when in contact with gastric juice for a predetermined period of time and/or heated to about 37°C.

It is also according to one embodiment of the present invention, wherein a swallowable device as defined in any of the above is disclosed. This swallowable is adapted (a) to be administrated orally to the patient in its collapsed configuration, (b) to be transported to the stomach in its deflated state, (c) to expand therein up to a predetermined size, (d) after a predetermined period of time and/or heated to about 37°C to disassemble and (e) to be then totally evacuated from the stomach.

It is still according to another embodiment of the present invention, wherein an implantable device according to any of the above is disclosed. This implantable device is adapted (a) to be implanted via the mouth of the patient in its collapsed configuration, (b) to be transported to the stomach in its deflated state, (c) to expand therein up to a predetermined size, (d) after a predetermined period of time and/or heated to about 37°C to disassemble; and (e) to be totally evacuated from the stomach.
It is also according to one embodiment of the present invention, wherein one or more of the above defined discrete expandable members are made of materials selected from nickel titanium alloys (nitinol); polymeric compositions, such as polyglycolide, poly l-lactic (PLA) poly glycolide acid (PGA) or any PLA-PGA mixture thereof; poly(l-xi.-caprolactone), poly(dioxanone), poly(glycolide-co-trimethylene carbonate), poly(hydroxybutyrate-co-hydroxyvalerate), polyglyconate polyanhydrides or polyorthesters; polydioxanone, organic materials, such as protein based compositions; inorganic materials such as double or triple salt compositions, radiopaque materials or any mixture thereof. Commerically available materials are also useful for providing degradable implants, e.g., Vicryl® by Ethicon. The expandable members are preferably, yet not exclusively coated with at least one layer comprising slow-released therapeutic compositions, biocompatible coating materials, biological glues etc.

It is also according to one embodiment of the present invention, wherein the body of the self-inflated device is made of materials selected in a non-limiting manner from polymeric compositions, such as the PLA-PGA compositions and others defined above, organic or inorganic materials (such as anhydrated carbohydrates known in the art, commercially available polyethylene glycol, pure dried silica gels etc) gels, hydrogels, hydratable fillers, swelling agents, organic compositions, inorganic compositions, dry powders or any mixture thereof.

It is also according to one embodiment of the present invention, wherein the body of the device comprises compositions selected from a group comprising inter alia slow-release therapeutic compositions, medication, pH buffers, anti-acid compositions, anti-inflammatory agents, anti histamines, additives, lubricants, UV contrasting agents, test and small agents, digestive-related therapeutic agents, probiotic bacteria cultures or any combination thereof.

It is also according to one embodiment of the present invention, wherein the implant as defined in any of the above is coated by a digestible capsule or the like, adapted to facilitate an easy introduction of the device into the stomach.

Another mechanism for inflating the implant is provided by gas formation due to chemical or biological reactions. Thus, for example, carbon dioxide formation is provided by admixing an effective measure of sodium bicarbonate and potassium.
bicarbonate with the gastric juice, comprising *inter alia* water soluble acid at a very low pH.

It is also according to one embodiment of the present invention, wherein a method of curbing the appetite is disclosed. This method comprises introducing a biodegradable self-inflating intragastric implant, constructed from one or more discrete expandable members. It is preferably according to another embodiment of the present invention, wherein the method is provided by using the implant as defined in any of the above.

The method preferably comprises the following steps: (a) applying a biodegradable self-inflating intragastric implant in its *ex vivo* deflated state; (b) introducing the deflated implant into the stomach of a patient; e.g., via the esophagus (c) inflating the same *in vivo* to a predetermined size and shape; (d) after a predetermined period of time and/or heated to about 37°C, disassembling the same; (e) evacuating the disassembled debris outside the stomach of the patient.

The method comprising swallowing the intragastric implant in its *ex vivo* deflated state. Alternatively, the method comprising endoscopically implanting the intragastric implant in its *ex vivo* deflated state into the stomach of the patient.

It is also according to one embodiment of the present invention, wherein a novel treatment for curbing appetite is provided. This treatment comprises a periodic oral administration of biodegradable self-inflating intragastric implant constructed from one or more discrete expandable members. The intervals between each administration are determined by an expert and are in correlation with both physiological and mental characteristics of the patient. This treatment is especially useful wherein the deflated implant is swallowed before meals such that the food intake during the meal and afterwards is decreased.

It is lastly according to another embodiment of the present invention, wherein the aforesaid treatment is comprised of administration of swallowable and biodegradable self-inflating implants as defined in any of the above, wherein the implants used in the treatment vary in size and/or shape.

Hence, for example, treatment is initiated by administrating implants that are inflated *in vivo* to small intragastric objects, e.g., balloons of small external diameter, folded 2D planar insertions or sheet-like implants, floating balloons or a combination thereof. In the course of the treatment, said implants are administrated such that their
final *in vivo* volume and size is respectively bigger and/or its shaped so that their rim is leaning or pushing to a predetermined measure the sidewalls of the stomach, e.g., by utilizing bigger balloons, bladders, 3D helix-like insertions etc. After a physiological steady state is obtained, other implants according to the present invention are usable, such as floating pot-like insertions, meshed-wall devices etc. At the end of said acute treatment, maintaining treatment may employ other especially designed implants.

Reference is made now to the figures, illustrating a few possible embodiments of the present invention, wherein figure 1A presents a flexible biodegradable thread comprising shape memory and/or orientation memory characteristics and one or more ingredients located in its inner volume, figure 1B presents a cross section of the same. In figures 1A and 1B the tubes are made of biodegradable material (like pasta tubes), the connection between them is of a biodegradable rubber-like material, such as chewing gum or similar materials. Figure 2 illustrates similar tubes wherein the tube and it’s a cylinder materials and the connection between them is rubber like material. Figure 3 illustrates similar tubes additionally comprising a number of strengthening biodegradable wires attached to the sides of the tube. Figure 4A illustrates similar embodiment wherein the strengthening biodegradable wires are extended from the sides, figure 4B illustrates a cross section of the same. Figure 5A illustrates similar embodiment wherein instead of the rubber defined above, a spring-like member is extended throughout the biodegradable materials, figure 5B illustrates a cross section of the same. Figure 6 illustrates similar embodiment as illustrated in Figure 4A. It is acknowledged in this respect that biodegradable members are selected from the tube-like portions, the reinforcement members or any combination thereof. All members are preferably yet not exclusively constructed in a manner that flexible and non-breaking apart fragments and members are provided.

It is acknowledged in this respect that biodegradable members may be coupled to the tube-like portions, the reinforcement members or any combination thereof. All members are preferably yet not exclusively constructed in a manner that flexible and non-breaking apart fragments and members are provided.

Figure 7A illustrates similar embodiment wherein the implant is one spring-like member made of biodegradable materials. Figure 7B illustrates a cross-section of the same. Figure 8A illustrates a hollow flexible biodegradable tube full of gas. The tube
is filled with a gas. When the tube is accommodated in a warm body it expands to its predetermine shape. Figure 8B illustrates a cross section of the same. Figure 9A illustrates an embodiment wherein the spring and the rubber materials are described. Figures 9 disclose a multiple spring-like members interconnected in its longitudinal axis. Figure 9B illustrates a cross section of the same.

It is in the scope of the present invention wherein the implantable or swallowable device as defined in any of the above further comprises at least one segment having an inner volume, said volume comprises a compressed gas adapted to inflate said device in vivo. The gas may be generated in vivo, e.g., by diluting gas formatting materials (calcium carbonate for example) in the intragastric solution or otherwise. Alternatively or additionally, said gas may be compressed or generated ex vivo before swallowing or implanting the said device. The gas formation may also be provided by reacting two or more compositions in vivo so as to expose at least one gas generation composition to the gastric fluid, such as providing a number of apertures in a membrane (of biodegradable nature for example) enveloping said gas-forming composition.

The present invention also discloses a method of curbing appetite that comprises the steps of applying a biodegradable self-inflating intragastric implant in its ex vivo deflated state; introducing the deflated implant into the stomach of a patient; inflating the same in vivo to a predetermined size and shape by means of pressing a gas inside an inner portion of the implant such that said gas provided said device's in vivo inflating; after a predetermined period of time and/or heated to about 37°C, disassembling the same and evacuating the disassembled debris outside the stomach of the patient.

Figure 10A discloses a snare-like or other shape that is adapted to jump back to its original shape after folding. Figure 10B discloses a cross-section of the same. Figure 11A discloses the same in its expanded configuration. Figure 11B discloses a cross section of the same. Figure 12 presents a cup-like implant in its folded unexpanded configuration. Figure 13A presents the same in the deployed configuration, e.g., wherein the sheet-like member is made of nylon-like materials, and especially pH sensitive materials adapted to pill after being immersed for a predetermined time in the gastric environment. Figure 13B illustrates vertical cross section of the same. Figure 13C illustrates horizontal cross section of the same. Figure 14A presents a
circular implant in its collapsed conformation. Figure 14B illustrates a cross section of the same. Figure 15 presents the same in its rolled structure, adapted to gain only a narrow diameter such that its intragastric application is enabled. The circumference of said implant may comprise of a number of detaching members, as illustrates in Fig. 16A, providing an in vivo disassembling of the implant after a predetermined time. Figure 16B represents a cross section of the same. Said members are made, for example, of PLA coated with edible compositions, such as polysaccharides, pasta, gelatin, nylon 12, nylon 6 or any mixture thereof.

It is in the scope of the present invention wherein at least a portion of the segments are interconnected by means of at least one connector, being either disposable (degradable) or not. Said connectors are of various shapes and sizes, and selected from hooks, mortar and mortar structures, wire or chain-like connections or any other joint known in the art.

Reference is made now to figures 17 and 18 presenting a lateral cross-section and a top views, respectfully, of a contactor according one embodiment of the present invention. Said contactor comprising inter alia a joint 171, here a plastic-made (e.g., PLA-PGA biocompatible and biospendable material) circular member having an axis (172) in which segment 174 is rotating, said segment comprising at least one aperture (173), which fits in size and shape perturbing member (173), such that by rotating the segment to a certain measure (here, about 90 degrees), segment 174 is lock on joint 171. Said segment is preferably yet not exclusively composed of PLA-PGA materials, wherein joint 171 is coated by a silicone containing layer. Said locking mechanism is adapted to reversibly immobilize each of a portion of the segments to a predetermined 3D orientation when placed into the gastric juice, before disassembling.

It is further in the scope of the present invention wherein the self-inflating intragastric implant is assembled and/or disassembled (biodegraded) in a series of following or simultaneous events. Said implant thus may comprise more than one type of biodegradable ingredients. For example, the ingredients may be constructed of segments or layers or coatings of various biodegradability measure such that an in vivo non-linear disassembling is provided.
CLAIMS

1. Biodegradable self-inflating or self opening intragastric implant for curbing appetite, constructed from one or more discrete expandable, stretchable and/or deformable members.

2. The device according to claim 1, wherein the expandable elements are adapted to expand in vivo when in contact with gastric juice for a predetermined period of time and/or heated to about 37°C.

3. The device according to claim 1, wherein at least a portion of the expandable elements are shape memory members and/or orientation memory being in their deflated state ex vivo, and further being in their native inflated state in vivo when in contact with gastric juice for a predetermined period of time or heated to the in vivo body temperature.

4. The device according to claim 1, wherein at least a portion of the expandable elements are adapted to disassemble in vivo when in contact with gastric juice for a predetermined period of time and/or exposed to the in vivo elevated temperature.

5. The device according to claim 1, wherein the discrete expandable elements provided in vivo a two-dimensional sheet.

6. The device according to claim 5 characterized inter alia by both a planar body portion and a frame portion.

7. The device according to claim 6, wherein the planar body portion is deployed in vivo so as a sheet-like plane is provided.

8. The device according to claim 6, wherein the planar body portion is twisted in vivo so that a bent, curved and/or folded object is provided.

9. The device according to claim 6, wherein the planar body portion is twisted in vivo so that a coiled helix is provided.

10. The device as defined in claim 6 or any of its dependent claims, wherein the planar body portion is selected from a group comprising a continuous membrane portion, a mesh-like net or screen, at least one aperture or open bore exceeding therein said planar body portion or any combination thereof.
11. The device as defined in claim 6 or any of its dependent claims, wherein the frame portion is selected from a group comprising at least one expandable and/or deformable rib being in its deflated state *ex vivo* and in its inflated state *in vivo*; and further wherein at least a portion of said ribs are interconnected by means of a tie and/or a shape memory and/or orientation memory connector such that a multi-dimensional inflated frame is provided.

12. The device according to claim 11, wherein at least one portion of the rib disassembles *in vivo*.

13. The device according to claim 12, wherein at least one portion of the rib disassembles *in vivo* on being in contact with gastric juice for a predetermined period of time.

14. The device according to claim 11, comprising a plurality of ribs providing the device's infrastructure; wherein at least one portion of said ribs is interconnected with at least one portion of other ribs by a means of a tie.

15. The device according to claim 14, wherein one or more ties, shape memory and/or orientation memory connectors are disassembled *in vivo*.

16. The device according to claim 14, wherein one or more ties are disassembled *in vivo* when said tie or ties are being contacted with gastric juice for a predetermined period of time and/or heated to about 37°C.

17. The device according to claim 1, adapted to disassemble in a time lower than 72 hours from initially coming into contact with the gastric juice and/or heated to about 37°C.

18. The device according to claim 17, adapted to disassemble in a time ranging from about 1 to 24 hours from initially coming into contact with the gastric juice and/or heated to about 37°C.

19. The device according to claim 17, adapted to disassemble in a time ranging from about 3 hours from initially coming into contact with the gastric juice.

20. The device according to claim 19, said the device is adapted to expand/form *in vivo* in a time being less than T2 and more than T1, wherein T1 is less than T2; where T2 is about 2 to 7 minutes; and where T2 is about 20 to 40 minutes.
21. Biodegradable self-inflating or self opening intragastric implant for curbing appetite, constructed from one or more discrete expandable, stretchable and/or deformable members; wherein the discrete expandable elements provided in vivo a three-dimensional object.

22. The device according to claim 21, wherein the self inflating device is further composed of at least one element selected from a group comprising a bio-absorbable element; bio-degradable element, disintegrating element or any combination thereof.

23. The device according to claim 21, wherein said ribs are characterized by proximal and distal ends; said proximal end including a sliding means wherein at least a portion of the ribs are being connected to at least one shaft by means of said sliding means, such that the inflation of the structure in vivo is provided by sliding said sliders along said shaft or shafts.

24. The device according to claim 23, wherein the distal ends of the ribs comprise anchoring means or locking means, such that said ribs are interconnected with at least one end of the shaft by means of the said anchoring or locking means.

25. The device according to claim 23 being deflated ex vivo and inflated in vivo comprising an umbrella-like assembly comprising at least one shank, a plurality of slidable ribs and a canopy attached thereto, wherein said ribs are adapted to slide along the main longitudinal axis of the shank while being connected to one pole of said shank, thus translating longitudinal 2D movement to a 3D lateral expanding maneuver.

26. The device according to claim 25, wherein at least a portion of the planar body is provided as the canopy of the umbrella-like device.

27. The device according to claim 25, comprising two or more umbrella-like assemblies and/or two or more interconnected umbrellas.

28. The device according to claim 27, comprising a first and second or more umbrella-like assemblies and/or two or more interconnected umbrellas; said first assembly is adapted to inflate towards one pole of the shank, and said second assembly is adapted to inflate towards the opposite pole of the shank; said assemblies are either separated or interconnected.
29. The device according to claim 1, wherein at least a portion of the planar body portion is adapted to disassemble *in vivo*.

30. The device according to claim 29, wherein at least a portion of the planar body portion is adapted to disassemble *in vivo* when in contact with gastric juice for a predetermined period of time and/or when exposed to the *in vivo* body heat.

31. The device according to claim 21, wherein the discrete expandable elements provided *in vivo* a three-dimensional bladder; said bladder comprising a body portion and an infrastructural elements being deflated *ex vivo* and inflated *in vivo*.

32. The device according to claim 21, wherein the bladder shape when inflated *in vivo* is selected from a group comprising balloon, football-like, basketball-like polygonal bag-shaped construction, hose-like, stent-like or ring-like shape, floating pot-like objects coiled helix or any combination thereof.

33. The device according to claim 32, wherein the bladder is constructed by a means of interconnected structural elements; said elements are at least partially disassembled *in vivo*.

34. The device according to claim 32, wherein the bladder is constructed by a means of interconnected structural elements; said elements are at least partially disassembled *in vivo* when it being contacted with gastric juice for a predetermined period of time and/or when exposed to the *in vivo* body heat.

35. The device according to claim 32, wherein the bladder is infrastructured by a means of structural elements interconnected by a means of mutual joints; said joints are at least partially disassembled *in vivo*.

36. The device according to claim 35, wherein the bladder is infrastructured by a means of structural elements interconnected by a means of mutual joints; said joints are at least partially disassembled *in vivo* upon being in contact with gastric juice for a predetermined period of time and/or heated to about 37°C.

37. The device according to claim 32, wherein the bladder is at least partially disassembled *in vivo*. 

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38. The device according to claim 37, wherein the bladder is at least partially disassembled and/or expanded in vivo upon being in contact with gastric juice for a predetermined period of time and/or heated to about 37°C.

39. A swallowable device according to claim 1 or any of its dependent claims, adapted to be administrated orally by the patient in its collapsed configuration, to be transported to the stomach in its deflated state, to expand therein up to a predetermined size, after a predetermined period of time and/or heated to about 37°C to disassemble and then to be totally evacuated the stomach.

40. An implantable device according to claim 1 or any of its dependent claims, adapted to be implanted via the mouth of the patient in its collapsed configuration, to be transported to the stomach in its deflated state, to expand therein up to a predetermined size, after a predetermined period of time and/or heated to about 37°C to disassemble and then to be totally evacuated from the stomach.

41. The device according to claim 1 or any of its dependent claims, wherein the one or more ununited expandable and/or deformable member are made of materials selected from shape-memory materials, nickel titanium alloys, polymeric compositions, organic materials, polysaccharides, rubber-like and silicon–like materials, inorganic materials or any mixture thereof.

42. The device according to claim 1 or any of its dependent claims, wherein one or more discrete expandable members are made of materials selected from nickel titanium alloys, polymeric compositions, organic materials, inorganic materials or any mixture thereof.

43. The device according to claim 42, wherein the expandable member are coated with a layer comprising slow-release therapeutic compositions.

44. The device according to claim 1 or any of its dependent claims, wherein the body of the self-inflated device is made of materials selected from polymeric compositions, especially PLA and/or PGA, liquid adorable materials, gels, hydrogels, hydratable fillers, swelling agents, organic materials, inorganic materials, pasta, gelatin, nylon 12, dry powders or any mixture thereof.

45. The device according to claim 44, wherein the body of the device comprises compositions selected from slow-release therapeutic compositions,
medicaments, pH buffers, anti histamines, additives, lubricants, test and small agents, probiotic bacteria or any combination thereof.

46. The device according to claim 1 or any of its dependent claims being coated in a digestible capsule, adapted to facilitate the introduction of the device into the stomach.

47. The device according to claim 1 or any of its dependent claims comprising at least one segment having an inner volume, said volume comprising a compressed gas adapted to inflate said device in vivo.

48. A method of curbing appetite and/or obesity treating comprising introducing biodegradable self-inflating intragastric implant, infrastructured by one or more discrete expandable and/or deformable members.

49. A method of curbing appetite comprising introducing biodegradable self-inflating intragastric implant as defined in claim 1 or in any of its depended claims.

50. The method according to any of claims 48 or 49, comprising
   a. applying a biodegradable self-inflating intragastric implant in its ex vivo deflated state;
   b. introducing the deflated implant into the stomach of a patient;
   c. inflating the same in vivo to a predetermined size and shape;
   d. after a predetermined period of time and/or heated to about 37°C, disassembling the same;
   e. evacuating the disassembled debris outside the stomach of the patient.

51. The method according to claim 50, comprising swallowing the intragastric implant in its ex vivo deflated state.

52. The method according to claim 50, comprising endoscopically implanting the intragastric implant in its ex vivo deflated state into the stomach of the patient.

53. The method according to claim 50, additionally comprising the step of compressing a gas inside an inner portion of the implant such that said gas provides for said device's in vivo inflation.
54. A treatment for curbing appetite comprising a periodic oral administration of biodegradable self-inflating intragastric implant constructed from one or more discrete expandable members.

55. The treatment according to claim 54, wherein the deflated implant is swallowed before meals such that the food intake during the meal and afterwards is decreased.
Fig. 2

Fig. 3
Fig. 13A

Fig. 13B
Fig. 16A

Fig. 16B
Fig. 17

Fig. 18