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(54) Title: TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY

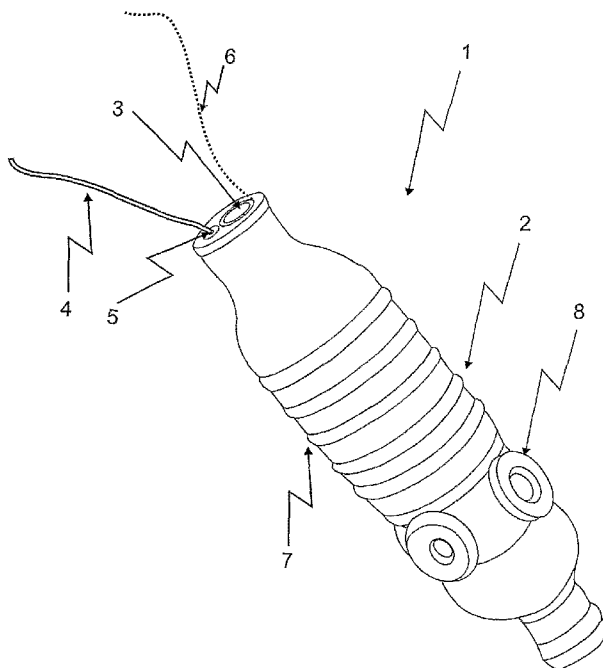


Fig. 1

(57) Abstract: The steps that constitute the "TEMPORARY ESOPHAGEAL NONSURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY" are described as follows: 1st step - anamnesis, medical history, patient's examination and analysis of the patient's clinical; 2nd step - in positive case, multidisciplinary approach of the patient and his or her family and the social relations connected with his or her obesity development background; 3rd step - patient's biometric reading from their body weight in order to determine the dimensions to be used in the manufacture of the specific "Esophageal Flow Controller" for that patient as well as to determine the extension of the wire to be fixed onto one of their upper second permanent molar teeth; 4th step - introduction of the deflated "Esophageal Flow Controller" into the patient's esophagus by means of an ambulatory procedure with simple sedation that is typical in the esophageal endoscopic exam - EDA; 5th step - enough time clinical observation for the patient to get used to the "Esophageal Flow Controller"; 6th step - patient is performing his regular living activities - medical team will be available and will monitor the patient constantly; 7th step - removal of EFC will be carried out under the same ambulatory conditions as its introduction; 8th step - the patient will be forwarded to the multidisciplinary team; 9th step - casual follow-up for medical-scientific research purposes and patient support; 10th step - Eventual plastic surgery of the body shape that was developed during the obesity time.

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## **“TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY”**

### ***Fields of this Patent:***

- Treatment of obesity;
- 5 - Alimentary reeducation;
- Economy and efficiency in Public Health in the obesity treatment.

### ***State of the Art.***

Eating is a part of human behavior that depend on motivation. The amount of food intake is influenced by non-biological factors which include social  
10 circumstances, cultural customs, cost, convenience, and period of the day. Nevertheless, physical and biological factors such as sight, smell, taste and, especially, the basal metabolical rate and the size of its spares of energy also regulate the appetite (KAULING 2007).

However, due to the uncontrollable eating act, an epidemic which is the  
15 pathology called obesity can be noticed in the current society. Obesity has become a serious public health problem, due to its high prevalence, the difficulty in controlling it and the high rate of recurrence (PETRIBU et al. 2006).

Throughout history, food habits have marked important stages in the human  
20 evolution process. In the beginning, men were limited to hunting, fishing and gathering vegetables and other biological materials. Along with their great cultural evolution, men started a process of control over the environment and cultivation techniques and this development has taken them, little by little, to the current situation.

25 Obesity causes are not thoroughly understood and defined in the literature yet. It is known to involve genetic, physiological, metabolic and appetite cerebral regulation factors as well as environmental and psychosocial conditions besides cultural factors (DOHERTY 1999, SUDO et al. 2007, HALPERN et al. 2004).

An individual is regarded as obese when their Body Mass Index (BMI) is above the value considered to be normal or overweight. In order to calculate a person's BMI, one must divide their weight in kilograms by their square height in meters ( $\text{Kg}/\text{m}^2$ ). In general, an index which is lower than twenty-five is regarded to be normal whereas one between twenty-five and thirty is considered to be overweight.

Thus, it can be stated that obesity is one of the major problems in public health and it has been reaching epidemic proportions both in developed countries and in those developing. It is a pathology determined by the association of several factors and it is this multiple cause that makes its treatment even more difficult.

#### **Implications of obesity for health.**

In a 1985 Conference at the National Institute of Health (NIH) in the United States of America, the implications of obesity for health were set in a consensus, especially in the case of morbid obesity which is when the BMI is above  $40 \text{ kg}/\text{m}^2$ . Among these implications, the increased risk of diseases such as high blood pressure, diabetes mellitus, hypertriglyceridemia, low levels of HDL cholesterol, some kinds of cancer, joint diseases, respiratory disorders, venous stasis disorders (varicose veins), hepatic stenosis, gallbladder stones, infertility, menstrual disorders, sleep apnea and hyperventilation were included. (HOJO *et al.* 2007, BERG *et al.* 2001).

Besides the diseases mentioned above, there are other factors that act and interact in food intake and energy storage regulation. The homeostatic imbalance is a very common factor in obese people and it leads to a complete change in the neuronal, endocrinal, adipocytal and intestinal factors. It is also known that the appetite expression, which is codified chemically in the hypothalamus, gets unbalanced due to the homeostatic imbalance (HALPERN *et al.* 2004, LORDELO *et al.* 2007).

Other less accounted problems are also brought about by obesity, such as psychological and social disorders due to physical limitation, low self-esteem

and difficulty in being inserted in the scenery advertised by the media. (JARDIM 2007, SUDO *et al.* 2007, STEVENS *et al.* 1998).

Due to the seriousness of such a disease, there is an international and a national tendency of searching for methods and treatments that are more efficient, as it is shown next.

#### **Treatment methods – advantages and disadvantages.**

There are many ways of trying to treat obesity, such as diet, medication, non-surgical intervention methods and surgical treatment. Regarding the diet and the medication treatment, the effectiveness and success of many of these proposals are known to be not completely satisfactory, as such treatments are not able to offer a definitive loss of weight. This is due to several factors such as the obese people's indiscipline, setting where they live - among other behavioral factors, slow result accomplishment that leads to the client's impatience, besides other factors (DAMIANI *et al.* 2000).

The non-surgical procedures applied in the obesity treatment are the ones that use the Bioenterics Intra-gastric Balloon (BIB). It is silicone prosthesis with a spherical shape and a smooth surface and it has a valve through which it is inflated inside the patient's stomach. It is introduced through the mouth and taken into the stomach, filled with physiological saline solution and methylene blue that acts as an indicator in case the balloon blows. Its application is via endoscope and it is kept in position so as to provide a satiety feeling. (SUGERMAN *et al.* 2000).

Another more recent example is the Heliosphere Bag<sup>®</sup>, which has similar shape and material as the BIB<sup>®</sup> and it is also placed in the stomach; though it is filled with gas (ALMEIDA 2006). In all cases, the use of these balloons can only take place if all the recommended medical measures have already been applied and carried out, like diet and exercises, by the patients and the obtained results have been proven unsatisfactory. (ALMEIDA 2006).

However, its application is inadvisable in the following cases:

1. Patients with esophageal-gastroduodenal lesions history;
2. Hiatal hernia that is bigger than 3cm;

3. Peptic esophagitis that is equal or above the degree C;
4. Gastric or duodenal ulcers;
5. Gastroesophageal varicose veins;
6. Esophageal and/or pharyngeal stenoses;
- 5 7. Previous abdominal or bariatric surgery;
8. Pregnancy and lactation;
9. Drug addiction, alcoholism and chronic medication;
10. Psychiatric disorders.

These restrictions limit the use of this kind of treatment in many cases of  
10 obesity, as many patients present one or more of the items listed above.  
Another fundamental point is that the intragastric balloon is a device for  
temporary use, which is very useful when trying to accomplish a modest  
reduction. However, due to the ephemeral nature of this weight loss, it is  
convenient to have a close connection with surgery (EVANS 2001, DOLDI  
15 2004).

The surgical treatment arises as an efficient method for controlling the weight  
in the long run. The first surgeries used to treat obesity date back in 1954  
and they are based on the reduction of nutrient absorption by the derivation  
of great part of the small bowel. These surgeries resulted in a significant and  
20 permanent reduction of about 40% of the weight. Nevertheless, they brought  
about functional damage due to malabsorption to such an extent and  
frequency that they were given up in the 70's (HOJO *et al.* 2007, GARRIDO  
2000).

Nowadays, the techniques that replace the former derivations focus on the  
25 attainment of a decreased gastric and of part of the intestine capacity, being  
then restricted to the food intake and part of its absorption (MARTINS 2005,  
BROLIN 2002, MARTIN 1995, TONETO 2004, BUCHWALD *et al.* 2004,  
ALMEIDA 2006, MIGUEL *et al.* 1994).

Although this kind of surgery has quite satisfactory results regarding the  
30 weight loss, the reduction of some discomforts, partial recovery of the quality

of life and of the expectations of social and motor life, it brings undesirable serious consequences in some cases.

During the initial postsurgical period, food intolerance with associated vomit (CAPELLA *et al.* 2003), infections, dehiscence, stomach stenosis, marginal  
5 ulcers, various lung problems and deep thrombophlebitis are noticed and they may occur in about 10% of the cases or more. During the late postsurgical period, other problems which may lead to the need of a new surgery may take place. For instance, a distal esophagus and a bag dilatation, persistent vomit (with or without the stomach obstruction),  
10 cholecystitis or weight loss flaw may occur (BERG *et al.* 2001, BROLIN 2002, DELFINO 2007).

In the long run, nutrient deficiencies may occur – especially of vitamin B<sub>12</sub>, folacin and iron – and they are usual after the gastric by-pass and lead to the need of a treatment. Another consequence that may take place is the  
15 dumping syndrome, which is characterized by a quick emptying of the stomach and other symptoms (HOJO *et al.* 2007), making the method ineffective. Some changes related to some of the hormones involved in the food intake and satiety process may also occur, as for example:

- 20 i) Cholecystokinin;
- ii) Polypeptide Y;
- iii) Ghrelin;
- iv) Leptin.

These hormones are released when the food gets in touch with the stomach and intestine, and, in this kind of surgery, there is a reduction of the contact  
25 in both areas. When the food enters the stomach and intestine, countless hormones are released into the blood. These hormones also influence with the functions that promote nutrient digestion by means of actions in motility, secretion and absorption (CAMPOS 2007, CUMMINGS 2007, DEMARIA 2005).

30 The actions of these hormones, which are produced by the digestive system, in cerebral centers that control the proper balance between appetite and

satiety are responsible for the average number of calories that we feel compelled to intake at our daily meals. The smelling and tasting stimuli produced by the food take part in the intake regulation. All these peripheral signals are integrated in the nervous system along with the consequent  
5 release of the neurotransmitters.

The change in digestive tract at any spot will bring about some disorder, and this is the main and serious negative point of the aforesaid surgical procedures.

We can, then, summarize the State of the Art regarding the obesity  
10 treatments, whether surgical or not, with a few words: - low effectiveness, high recurrence percentage, causing iatrogenic harms, application is restricted to few patients and high costs.

#### **Innovations introduced by this Patent over the State of the Art.**

The "TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR  
15 THE TREATMENT OF OBESITY", object of this Patent, is a brand-new method for the obesity treatment which has the following innovations, as described below:

1 – It is minimally invasive as it is not a digestive system surgical intervention, but, yet, an ambulatory procedure that discards general or local  
20 anesthesia (only minor sedation is used like the ones used in the high digestive endoscopy exam – EDA) being, then, of low risk and low cost;

2 – It produces a fast body weight loss without excessive sufferings due to patient's food privation, because he/she feels completely satisfied, fed and he/she does not lose the physiological integrity of the digestion, both in the  
25 sense of the release of endogenous hormones and in the sense of the total absorption of all the elements and oligoelements present in the food;

3 – It produces – with its proper multidisciplinary follow-up after the procedure – a definitive weight loss through a food habit reeducation, here understood as the attainment of the physical and psychological satiety

without the compulsion of having great amounts of food, as it happens with the obese people;

4 – It gives back the regular weight to the patients as well as the pleasure of tasting the foods and eating them moderately without feeling guilty or  
5 anxious, such common feeling among the obese people, and it provides them with all the advantages stemmed from the body weight normality.

The “TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY” makes use of the “ESOPHAGEAL FLOW CONTROLLER”, described by the PCT/BR2009/000346, in which such  
10 device is broadly explained.

In order to pinpoint this Patent, before reporting the “Treatment” and its various stages, the summarized and schematic description will be shown, as follows.

Figure 1 is a front diagonal view of the “Esophageal Flow Controller - EFC”  
15 set (1), cited above, made of a sterilized hypoallergenic latex derived from the plant *Hevea brasilienses*, previously built in compliance with the intervention planning and biometrical measurements of each patient, in which we see the external tube (2) that is flexible and dilatable, with transversal grooves (7) in its exterior part to settle itself with the longitudinally grooved  
20 anatomy of the patient’s esophagus and keeping it in the correct position during all the necessary time, the reduced internal tube (3), which is rigid and that does not change its dimensions and shape when the device is inflated with gas, a scalp (6) and a valve (5) through which a catheter is introduced – not shown here – and it is used for conducting the gas for inflating it in the  
25 moment of its placement and to deflate it in the moment of its removal and the surgical wire (4) that will act not only as an auxiliary measure of the extension of the device introduction inside the patient’s esophagus, which is previously determined during the intervention planning when the device in question will be inserted in the patient’s esophagus during the ambulatory  
30 procedure for its placement, but also to be fixed, by any means, preferably to the upper second permanent molar tooth, in such a way that the



“Esophageal Flow Controller - EFC” set (1) does not move distally during its permanence time. We can also see the suction cups (8) in the lower part.

The steps that constitute the “TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY” are described as follows:

1st step – anamnesis, medical history, patient’s examination and analysis of the patient’s clinical exams in order to decide about whether prescribing – or not – the “TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY”;

2nd step – in positive case, multidisciplinary approach of the patient and his or her family and the social relations connected with his or her obesity development background, which will determine the actions cited in the step called “post-intervention follow-up”, mainly about the weight loss and the maintenance of this loss;

3rd step – patient’s biometric reading from their body weight in order to determine the dimensions to be used in the manufacture of the specific “Esophageal Flow Controller - EFC” for that patient as well as to determine the of the wire to be fixed onto one of their upper second permanent molar teeth, such a wire whose dimension will act as the correct localization measure, along the patient’s esophagus, of the “Esophageal Flow Controller - EFC” and which will allow its removal when its permanence period inside the patient’s esophagus is over;

4th step – introduction of the deflated “Esophageal Flow Controller - EFC” into the patient’s esophagus by means of an ambulatory procedure with simple sedation that is typical in the esophageal endoscopic exam – EDA ; once it is properly positioned, which will be confirmed by an X-ray, its inflation will be carried out by injecting gas accordingly to the related explanations in Figure 1, followed by the removal of the gas conductor catheter and by the fixation of the wire onto the upper second permanent molar tooth on one of the patient’s jaw sides;

5th step – enough time clinical observation for the patient to get used to the “Esophageal Flow Controller - EFC”, first meal intake and assessment of the patient’s general condition regarding comfort, satiety after first meal, vomit events, nauseas, etc.

- 5 6th step – although the patient is performing his regular living activities at this phase, the medical team will be available and will monitor the patient constantly by talking to them, by their reports on their physical and psychological conditions until the intervention planning pre-determined time is fulfilled so that, in case of any disorder, they can take immediate action;
- 10 7th step – when the permanence time specific for each patient is over, according to what was set in the planning, the patient will be evaluated about their body weight loss and the intervention for the “Esophageal Flow Controller - EFC” removal will be carried out under the same ambulatory conditions as its introduction, with light sedation that is typical in the
- 15 ambulatory esophageal endoscopic interventions; in this intervention, the “Esophageal Flow Controller” will be deflated through a catheter that is identical to the one used when inflating it during the introduction of the device, and this will be removed from the inside of the esophagus by being simply pulled out by the cited wire;
- 20 8th step – the patient will be forwarded to the multidisciplinary team that will be part of the psychophysical and social follow-up of the patient, their diet, individual and family psychological follow-up, physical exercises if it is the case, just as it had been previously planned for the needed follow-up work in order to prevent recurrences;
- 25 9th step – casual follow-up for medical-scientific research purposes and patient support;
- 10th step – this step will depend upon the patient’s will and goes beyond the scope of this Patent, as it is about the patient’s submitting – after medical advice at a proper time and according to their own decision – to the plastic
- 30 surgery of the body shape that was developed during the obesity time.

## CLAIMS

1. "TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY", that is minimally invasive as it is not a digestive system surgical intervention and a definitive weight loss through a food habit reeducation giving back the regular weight to the patients as well as the pleasure of tasting the foods and eating them moderately without feeling guilty or anxious, **characterized by** the patient keeps the physiological integrity of the digestion, both in the sense of the release of endogenous hormones and in the sense of the total absorption of all the elements and oligoelements present in the food and by being an ambulatory procedure that discards general or local anesthesia, using only minor sedation, constituted by the follow steps: 1st step – anamnesis, medical history, patient's examination and analysis of the patient's clinical exams; 2nd step – in positive case, multidisciplinary approach of the patient and his or her family and the social relations connected with his or her obesity development background; 3rd step – patient's biometric reading from their body weight in order to determine the dimensions to be used in the manufacture of the specific "Esophageal Flow Controller" for that patient as well as to determine the extension of the wire to be fixed onto one of their upper second permanent molar teeth; 4th step – introduction of the deflated "Esophageal Flow Controller - EFC" into the patient's esophagus by means of an ambulatory procedure with simple sedation that is typical in the esophageal endoscopic exam – EDA; 5th step – enough time clinical observation for the patient to get used to the "Esophageal Flow Controller - EFC"; 6th step – patient is performing his regular living activities - medical team will be available and will monitor the patient constantly; 7th step – removal of EFC will be carried out under the same ambulatory conditions as its introduction; 8th step – the patient will be forwarded to the multidisciplinary team; 9th step – casual follow-up for medical-scientific research purposes and patient support; 10th step – Eventual

plastic surgery of the body shape that was developed during the obesity time.

2. "TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY", according to claim 1, **characterized** by the 2<sup>nd</sup> step will determine the actions in the step called "post-intervention follow-up".
3. "TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY", according to claim 1, **characterized** by the wire length used in the 3<sup>rd</sup> step will act as the correct localization measure, along the patient's esophagus, of the "Esophageal Flow Controller - EFC" and which will allow its removal when its permanence period inside the patient's esophagus is over.
4. "TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY", according to claim 1, **characterized** by the 4<sup>th</sup> step – introduction of "Esophageal Flow Controller-EFC" – once it is properly positioned, which will be confirmed by an X-ray, its inflation will be carried out by injecting gas and followed by the removal of the gas conductor catheter and by the fixation of the wire onto the upper second permanent molar tooth on one of the patient's jaw sides.
5. "TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY", according to claim 1, **characterized** by the 5<sup>th</sup> step – observation of the "Esophageal Flow Controller - EFC", leads the first meal intake and assessment of the patient's general condition regarding comfort, satiety after first meal, vomit events, nauseas, etc.
6. "TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY", according to claim 1, **characterized** by the 6<sup>th</sup> step gives the reports on the physical and psychological conditions of the patient until the intervention planning pre-determined time is fulfilled so that, in case of any disorder, they can take immediate action.

7. "TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY", according to claim 1, **characterized** by the 7<sup>th</sup> step – removal of the "Esophageal Flow Controller - EFC" – which will be deflated through a catheter that is identical to the one used when inflating it during the introduction of the device, and this will be removed from the inside of the esophagus by being simply pulled out by the cited wire.
8. "TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY", according to claim 1, **characterized** by the 8<sup>th</sup> step – the patient is forwarded to the multidisciplinary team that will be part of the psychophysical and social follow-up of the patient, their diet, individual and family psychological follow-up, physical exercises if it is the case, just as it had been previously planned for the needed follow-up work in order to prevent recurrences.
9. "TEMPORARY ESOPHAGEAL NON-SURGICAL PROCEDURE FOR THE TREATMENT OF OBESITY", **characterized by** using the "Esophageal Flow Controller" set (1) made of a sterilized hypoallergenic latex derived from the plant *Hevea brasilienses*, previously built in compliance with the intervention planning and biometrical measurements of each patient, in which we see the external tube (2) that is flexible and dilatable, with transversal grooves (7) in its exterior part to settle itself with the longitudinally grooved anatomy of the patient's esophagus and keeping it in the correct position during all the necessary time, the reduced internal tube (3), which is rigid and that does not change its dimensions and shape when the device is inflated with gas, valve (5) through which a catheter is introduced and it is used for conducting the gas for inflating it in the moment of its placement and to deflate it in the moment of its removal and the surgical wire (4) that will act not only as an auxiliary measure of the extension of the device introduction inside the patient's esophagus, which is previously determined during the intervention planning when the device in question will be inserted in the patient's esophagus during the ambulatory procedure for its placement,

but also to be fixed, by any means, preferably to the upper second permanent molar tooth, in such a way that the "Esophageal Flow Controller" set (1) does not move distally during its permanence time.

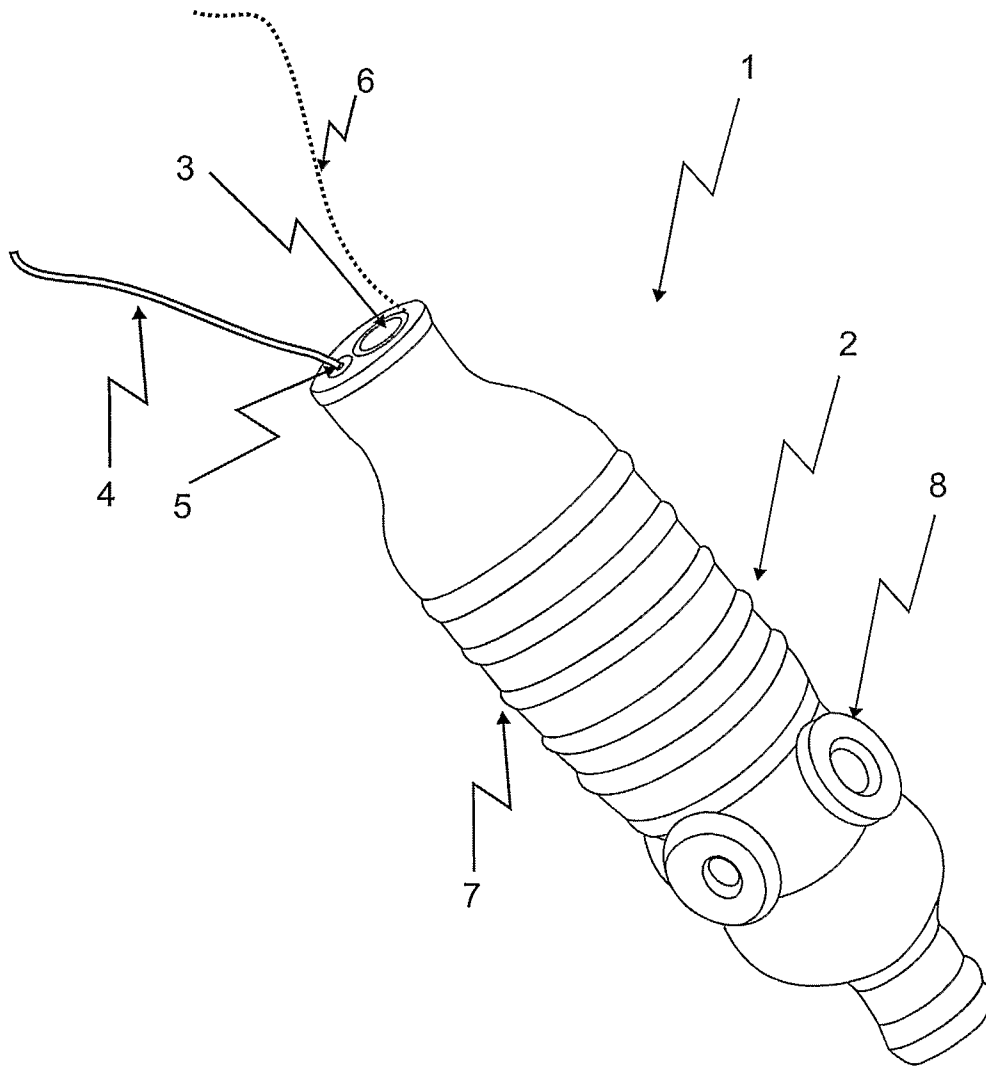


Fig. 1

## INTERNATIONAL SEARCH REPORT

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PCT/BR 2009/000402

A. CLASSIFICATION OF SUBJECT MATTER IPC <sup>8</sup> : <b>A61F 5/00</b> (2006.01) 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) IPC <sup>8</sup> : A61F 5/00		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WPI, EPODOC		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2004/080336 A2 (SYNECOR) 23 September 2004 (23.09.2004) <i>whole document</i>	1, 9
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"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)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"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</p> <p>"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</p> <p>"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</p> <p>"&amp;" document member of the same patent family</p>		
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Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US A1 2005267499	2005-12-01
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