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(54) **Improved system with an inflatable member for being arranged in the patient's respiratory tract**

(57) A system with at least one inflatable member configured for being arranged in a part of the patient's respiratory tract, comprising a catheter carrying the at least one inflatable member to be arranged in the respiratory tract, said catheter comprising a fluid line for filling the inflatable member with a fluid; a pressure monitoring and control member to be arranged outside the patient's body, said pressure monitoring member being in fluid communication with the inflatable member and being configured to receive, during operation, fluid from the inflatable member when the pressure increases above a predetermined threshold pressure and to return said received fluid when the pressure decreases below said predetermined threshold pressure; wherein the pressure monitoring and control member is an elastically expandable balloon made from a material which is configured to expand elastically when the pressure in the balloon increases above a predetermined threshold pressure and to contract when the pressure decreases below said predetermined threshold pressure.

Improved system with an inflatable member for being arranged in the patient's respiratory tract

TECHNICAL FIELD

The present invention relates to a system with an inflatable member configured for being arranged in a part of the patient's respiratory tract.

BACKGROUND OF THE INVENTION

Transesophageal echocardiography (TEE) is an ultrasonic imaging method widely used imaging technique for evaluating cardiac structure, function, and valvular anatomy. TEE has also provided a new perspective on the thoracic aorta, and there is growing evidence that the technique contributes valuable and sometimes unique information about aortic structure and pathology.

TEE involves introducing an echo probe into the patient's esophagus and transmitting ultrasound waves across the thorax in the direction of the heart and aorta. However, visualization of the ascending aorta by internal TEE is limited by an air structure, i.e. the trachea and main left and right bronchi. This is due to an important physical limitation of ultrasound: absorption of ultrasound waves. This absorption is dependent of the medium and expressed in terms of the "half power distance": the distance in which half of the ultrasound energy will be absorbed. For water this is 360 cm, bone 0,2 cm and for air 0.06 cm. This means that in practice ultrasound waves will not travel through bone or air. Unfortunately, by the anatomical location of the distal aorta ascendens, the arch and the upper part of the main vascular side branches, it is difficult to view this area by TEE because the view is obstructed by the trachea. The trachea is located between the esophagus and the vascular tree, so all echoes are reflected by the trachea, which is filled with air.

In order to solve this problem, WO 00/53098 in the name of the Applicant proposes the use of an inflatable member that may be arranged in the trachea or in one of the bronchi and that may be filled with an ultrasonic transmission fluid, e.g. water or a saline solution in minor concentrations. Obviously, this can only be done during operative surgery, when the patient is mechanically ventilated or on cardiopulmonary bypass, since in order to be effective the balloon has to completely filled with saline and will block the trachea or bronchus. US 8,936,554 also in the name of the Applicant discloses a further improved method and system for ultrasonic imaging using improved positioning means for positioning the inflatable member at a predetermined location in the tract.

SUMMARY OF THE INVENTION

A problem which arises when performing the TEE assisted by an inflatable member placed in the respiratory tract, is that the indirect contact between the TEE probe and the inflatable member via the esophagus and trachea walls, especially during the movement of the TEE probe in the esophagus, causes a large increase in pressure within the inflatable member. This pressure increase increases the pressure applied to the trachea wall. If the pressure applied to the trachea wall is too much, it causes potential tissue damage to the trachea. Also in other applications where a device is manipulated close to an inflatable member placed in the respiratory tract, a pressure increase within the inflatable member may lead to damage of the trachea.

The object of embodiments of the invention is to provide a system with an inflatable member for positioning in a part of the patient's respiratory tract which allows for an improved pressure control such that damage can be avoided.

According to a first aspect there is provided a system with at least one inflatable member configured for being arranged in a part of the patient's respiratory tract. The system comprises a catheter, and a pressure monitoring and control member. The catheter carries the at least one inflatable member to be arranged in the respiratory tract, and comprises a fluid line for filling the inflatable member with a fluid. The pressure monitoring and control member intends to be arranged outside the patient's body. The pressure monitoring and control member is in fluid communication with the inflatable member and being configured to receive, during operation, fluid from the inflatable member when the pressure increases above a predetermined threshold pressure and to return said received fluid when the pressure decreases below said predetermined threshold pressure. The pressure monitoring and control member is an elastically expandable balloon made from a material which is configured to expand elastically when the pressure in the balloon increases above a predetermined threshold pressure and to contract when the pressure decreases below said predetermined threshold pressure.

Embodiments of the invention are based inter alia on the inventive insight that in case of an increase of pressure inside the inflatable member arranged in the respiratory tract, above a predetermined threshold pressure, the elastically expandable balloon will expand rather than the inflatable member. The balloon is located outside the patient, and the increase in volume thereof will limit the pressure increase within the inflatable member, resulting in no or less damage to the trachea wall.

Preferably, the elastically expandable balloon and the inflatable member are configured such that, when there is exerted a pressure against the inflatable member, when positioned in the respiratory tract and filled with fluid, fluid is displaced from the inflatable member to the expandable balloon. In other words, the expendable balloon should be sufficiently flexible to allow expansion in case of pressure on the internal balloon.

According to an exemplary embodiment, the system further comprises an imaging device, preferably an ultrasonic imaging device, configured to be arranged in or on the patient's body; wherein said fluid is an imaging liquid. The above system enables the transmission of the ultrasound waves through the imaging liquid in the inflatable member without absorption by the air in the respiratory tract, and enables a safe evaluating of an organ in a patient's body by ultrasound.

According to another exemplary embodiment, the volume of the elastically expandable balloon, in the non-expanded state, is at least 10 percent of the volume of the inflatable member. In this way the volume of the elastically expandable balloon may be large enough to absorb the influx of excessive fluid coming from the inflatable member in case of increasing pressure within the respiratory tract.

According to yet another exemplary embodiment, the material of the elastically expandable balloon is a thermoplastic elastomer, preferably a thermoplastic polyurethane elastomer, e.g. Pellethane 2363-80A.

Preferably the tensile modulus of the material of the elastically expandable balloon is as follows, wherein the ASTM D412 test method is used:

- 50% Elongation: between 2 and 6 MPa
- 100% Elongation: between 4 and 9 MPa
- 300% Elongation: between 8 and 16 MPa.

Preferably, the durometer hardness of the material of the elastically expandable balloon, using test method ASTM D2240, is between 75A and 85A Shore.

Preferably the durometer hardness of the material of the elastically expandable balloon, using test method ASTM D2240, is lower than the durometer hardness of the material of the inflatable member, more preferably at least 2A Shore lower, most preferably at least 5A Shore lower.

Preferably the tensile modulus of the material of the elastically expandable balloon, wherein the ASTM D412 test method is used, is lower than the tensile modulus of the material of the inflatable member, more preferably at least 1 MPa lower at 50% elongation, and at least 2 MPa lower at 100% elongation.

According to a further developed embodiment, the predetermined threshold pressure of the system lies in a range between 30 and 70 mm Hg. The elastically expandable balloon will expand when the pressure exceeds the predetermined threshold, thereby buffering the pressure increase in the inflatable member within the respiratory tract, so that damage to the trachea wall can be avoided.

According to a further developed embodiment, the volume of the elastically expandable balloon, in the non-expanded state, is between 2 and 10 ml, preferably between 2,5 and 6 ml, so that volume of the elastically expandable balloon may be large enough to absorb the influx of excessive imaging fluid coming from the inflatable member in case of increasing pressure within the respiratory tract.

According to yet another exemplary embodiment, the expansion of the elastically expandable balloon, when the pressure is above the predetermined threshold pressure is essentially linear with respect to the pressure, so that the pressure within the inflatable member can be monitored by measuring the size of the expandable balloon.

According to yet another exemplary embodiment, the material of the inflatable member is a thermoplastic polyurethane elastomer, e.g. Pellethane 2363-90AE.

Preferably the tensile modulus of the material of the inflatable member is as follows, wherein the ASTM D412 test method is used:

- 50% Elongation: between 5 and 9 MPa
- 100% Elongation: between 7 and 13 MPa
- 300% Elongation: between 15 and 25 MPa.

Preferably, the durometer hardness of the material of the inflatable member, using test method ASTM D2240, is between 85A and 95A shore.

According to yet another exemplary embodiment, wherein the inflatable member, in the non-expanded state, has a volume between 20 ml and 60 ml, preferably between 30 ml and 50 ml, so that it enables the filling of a substantial portion of the respiratory tract.

According to yet another exemplary embodiment, the system further comprises positioning means for positioning the inflatable member at a predetermined location in the respiratory tract, so that the imaging examination can be performed at the right anatomical locations. The positioning means may comprise guide means that are attached to or integrated with the flexible catheter. These guide means allow the inflatable member carried by catheter to be swiftly and easily guided to its predetermined position. Preferably, the guide means comprises a stylet arranged in the catheter and having a distal end at a tip of the catheter, said stylet extending beyond the inflatable member.

According to yet another exemplary embodiment, the elastically expandable balloon of the system has a thickness between 0.01 mm and 0.1 mm, preferably between 0.03 mm and 0.07 mm.

According to yet another exemplary embodiment, the system further comprises a breathing tube having a first end and a second end. The first end of the trachea tube is adapted for connection to a source of respiratory gas, and the second end is adjacent to and surrounded by the inflatable member. In this way during mechanical ventilation of the patient through the breathing tube, the system forms a gas tight seal against the tracheal wall and prevents aspiration of secretion, meanwhile preventing damage to the tracheal wall when the breathing tube is manipulated. Indeed, manipulating the breathing tube may cause a pressure increase in the inflatable member but this pressure increase will cause the elastically expandable balloon located outside the patient's body to expand avoiding that a high pressure is exerted on the wall of the respiratory tract.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and characteristics of the present invention, as well as the methods of operation and functions of the related elements of structures and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended as a definition of the limits of the invention. As used in the specification and the claims, the singular form of "a", "an", and "the" include plural referents unless the context clearly dictates otherwise.

Fig. 1 is a schematic view of an exemplary embodiment of the system of the invention, including an elastically expandable balloon connected to the inflatable member;

Fig. 2 is a detailed view of a first embodiment of the elastically expandable balloon;

Fig. 3 is a detailed view of a second embodiment of the elastically expandable balloon;

Fig. 4 is a schematic view of another exemplary embodiment of the system of the invention, including a full length stylet, showing the elastically expandable balloon connected to the inflatable member filled with fluid;

Fig. 5 is a detailed, enlarged scale view of the encircled area III in Fig. 4;

Fig. 6 is a schematic view of an exemplary embodiment of an ultrasonic imaging system of the invention, including a pull wire;

Fig. 7 is a detailed, enlarged scale view of the encircled area X in Fig. 6;

Fig. 8 is a partial sectional view of a patient's upper body showing the ultrasonic imaging system of the invention during visualization of an organ.

Fig. 9 is a partial sectional view of another exemplary embodiment of a system of the invention including a tracheal breathing tube in place within a trachea and surrounded by an inflatable member connected to a pressure monitoring and control member.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For purposes of the description hereinafter, the terms "upper", "lower", "right", "left", "vertical", "horizontal", "top", "bottom", "lateral", "longitudinal" and derivatives thereof shall relate to the invention as it is oriented in the drawing figures. However, it is to be understood that the invention may assume various alternative variations and step sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the invention. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

It is to be understood that the invention may assume various alternative variations and step sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the invention.

In the first shown exemplary embodiment (Fig. 1), the system comprises at least one inflatable member 7 carried by a flexible catheter 6. For instance in the actual practice of ultrasonic imaging, the flexible catheter 6 carrying the inflatable member 7 will be guided through the patient's trachea into the right position, e.g. patient's left main bronchus. In this embodiment, the guide means include a short stylet 11, which may be arranged between the inflatable member 7 and the distal end of the catheter 6. Positioning of the catheter 6 and the inflatable member 7 is done by manipulating the proximal end of the catheter 6. The presence of the stylet 11 adds stiffness to the distal end of the flexible catheter 6, improving directional control and predictability of the

movement, thereby it allows the inflatable member 7 to be swiftly and accurately positioned in the respiratory tract. Such short stylet has an additional advantage that it does extend across the inflatable member 7, so that it will not interfere with the travel of ultrasonic waves and there is no need to retract it before imaging.

After the inflatable member 7 has been positioned at the right position in the respiratory tract, it is filled with a fluid, e.g. water or a saline solution in minor concentrations, through the flexible catheter 6. The inflatable member 7, in the non-expanded state, has a volume between 30 ml and 70 ml, preferably between 40 ml and 60 ml. The fluid is injected into the catheter 6 by means of a syringe (not shown), which is connected to a fill connector 20 at the proximal end of a fill line 21. The distal end of this fill line 21 in turn is connected to a proximal end of the catheter 6 through a connector 23. The degree of filling of the inflatable member 7 may be visually determined by monitoring an elastically expandable balloon 24, which is arranged at the end of a pilot line 25. This pilot line 25 is also connected to the catheter 6 through the connector 23. In case of an increasing pressure within the inflatable member 7 exceeding the threshold level, e.g. during the movement of echo probe in the oesophagus or the movement breathing tube in the respiratory tract, the pressure may cause a reflux of the fluid from the inflatable member 7 to the elastically expandable balloon 24. Such reflux may lead to an expansion of the elastically expandable balloon 24, thereby limiting the pressure increase within the inflatable member to a safety level. The predetermined threshold pressure of the system lies in a range between 30 and 90 mm Hg, such threshold pressure ensures a safe pressure within the inflatable member leading to no or less damage to the trachea wall.

In a first embodiment the elastically expandable balloon 24 has a main body 105 with a sphere shape (Fig. 2). In an alternative embodiment the elastically expandable balloon 24 has a main body 105 of a cylindrical shape, in between two semi-spherical ends 105a, 105b (Fig. 3). In the embodiments of figures 2 and 3 the elastically expandable balloon 24 has one open tube end 110 connected to on one side of the main body 105 of the balloon 24. The open tube end 110 can be connected to the end of a pilot line 25 such that fluid can flow from the pilot line 25 to the expandable balloon 24. Preferably the tube end 110 is integrally made with the main body 105 of the balloon 24. Optionally the other side of the main body 105 of the balloon 24 also has an open tube end 120. Preferably, the volume of the elastically expandable balloon 24, in the non-expanded state, is at least 10 percent of the volume of the inflatable member 7, preferably between 2 and 10 ml, more preferably between 2.5 and 6 ml. In this way the volume of the elastically expandable balloon 24 may be large enough to absorb the influx of excessive fluid coming from the inflatable member in case of increasing pressure within the respiratory tract. Preferably, the material of the

inflatable member 7 is a thermoplastic elastomer, more preferably a thermoplastic polyurethane elastomer, e.g. Pellethane 2363-90AE. Preferably, the material of the elastically expandable balloon 24 is a thermoplastic elastomer, preferably a thermoplastic polyurethane elastomer, e.g. Pellethane 2363-80A. Preferably, the wall of the expandable balloon 24, in the non-expanded state, has a thickness between 0.01 mm and 0.1 mm, preferably between 0.03 mm and 0.07 mm. The expansion of the elastically expandable balloon 24, when the pressure is above the predetermined threshold pressure, may be essentially linear with respect to the pressure, so that the pressure within the inflatable member 7 can be monitored by measuring the size, e.g. the perimeter, of the expandable balloon 24.

There are various possibilities for guiding the catheter 6 carrying the inflatable member 7 to the predetermined position in e.g. the left bronchus 8.

In another exemplary embodiment the stylet 11 extends over the entire length of the flexible catheter 6 (Fig. 4 and 5). A distal end 12 of the stylet 11 extends beyond the inflatable member 7 to a distal end 13 of the catheter 6. A proximal end 14 of the stylet 11 protrudes from the proximal end of the catheter 6 outside the patient's body and extends through the centre prong of a trident connector 23 (Fig. 5). This centre prong is closed by a cap 15 carrying a valve member 26, the function of which will be described below. This arrangement allows the inflatable member 7 to be swiftly and accurately positioned in the respiratory tract 3, since the presence of the stylet 11 adds stiffness to the flexible catheter 6, thus improving directional control and predictability of the movement. To allow the stylet 11 to be retracted after the inflatable member 7 has been filled with the fluid, without the risk of fluid leaking from the system, the proximal end 14 of the stylet 11 protrudes from the catheter 6 through a valve member 26. In the illustrated embodiment this valve member 26 is a one-way valve that is arranged in the centre prong of the trident connector 23.

In a further embodiment of the invention which is illustrated in figures 6 and 7 the guide means comprise a wire 431 rather than a stylet. A distal end 432 of the wire 431 is eccentrically connected to the flexible catheter 406 and a proximal end 433 of the wire 431 is connected to a pulling member 434 arranged outside the patient's body 1 (Fig. 6). The wire 431, which is very thin, provides excellent guidance of the catheter 406 with minimum obstruction of the image. The inflatable member 407 is positioned in the respiratory tract by manipulating the pulling member 434. By pulling on the wire 431, its effective length within the catheter 406 will decrease. Since the wire 431 is eccentrically attached to the catheter 406, shortening of the wire 431 will lead to the catheter 406 assuming a curved shape, at least in the vicinity of the point where the wire 431 is

attached. In the illustrated embodiment this attachment point is located near the distal end 413 of the catheter 406. This location allows optimum control of the catheter 406.

In this embodiment the inflatable member 407 is again filled by means of a syringe which may be connected to a fill connector 420 at the end of a fill line 421. This fill line 421 is again connected to the catheter 406 through a trident connector 423, in this case through the centre prong thereof. Also connected to the trident connector 423 is a pilot line 425 carrying an elastically expandable balloon 424. Finally, the proximal end of the wire 431 is guided through the third prong of the trident connector 423. In order to prevent fluid leakage, the proximal end 433 of the pull wire 431 protrudes from this third prong through a valve member, in particular a one-way valve 426 (Fig. 7).

In a preferred exemplary embodiment illustrated in figure 8 the system comprises an ultrasonic imaging device, which enables the imaging of an organ in a patient's body 1, in particular the heart or the aorta 2, through a part of the patient's respiratory tract 3. First an ultrasonic imaging device 4, for instance an echo probe, is arranged in or on the patient's body 1. In the shown embodiment, the echo probe 4, which is carried on a flexible catheter 9, is introduced into the patient's oesophagus 5 (Fig. 8). Then another flexible catheter 6 carrying an inflatable member 7 is introduced into the respiratory tract 3. The inflatable member 7 is positioned at a predetermined location in the respiratory tract 3. When the organ to be imaged is the ascending aorta 2, the predetermined position will be in the top part of the left bronchus 8. The flexible catheter 6 carrying the inflatable member 7 will be guided through the patient's trachea 16 by first introducing an endotracheal tube 17 into the trachea 16. This tube 17 is somewhat stiffer than the catheter 6 and therefore easier to control. The catheter 6 is then inserted in the endotracheal tube 17. After leaving the endotracheal tube 17 the distal end 13 of the catheter 6 and the inflatable member 7 are guided into the left bronchus 8.

In another exemplary embodiment illustrated in figure 9 the system comprises a trachea breathing tube 900 which enables mechanical ventilation without aspiration of secretion, for instant, during anaesthesia of the patient. The proximal end of the breathing tube 900 is adapted for connection to a source of respiratory gas. The distal end of the breathing tube 900 which is located within the trachea 910 is surrounded by an inflatable member 907 which is connected via a flexible catheter 906 to a connector 923. The connector 923 provides fluid communication between the catheter 906 and an elastically expandable balloon 924 located externally of the patient’s body. The expandable balloon 924 is connected to the connector 923 via a fluid line 925. The connector 923 is further connected to a fluid source 930, e.g. a syringe, outside the patient’s body, for filling the inflatable member 907 with a fluid. When the breathing tube 900 is in place within the trachea 910, the

inflatable member 907 is inflated to an extent so as to form a seal against the wall of the trachea and prevent aspiration of fluid in either direction along the trachea. An elastically expandable balloon 924 is provided at the one of the outer ends of the catheter 906 as a visual indication of the approximate pressure in the inflatable member 907, as well as a controller for sudden pressure increase in the inflatable member 907. In case of excessive pressure increase exceeding the predetermined threshold pressure within the inflatable member 907, e.g. because of the movement of breathing tube 910 or spontaneous breathing, the elastically expandable balloon 924 may expand to limit the pressure increase within the inflatable member 907 to a safety level, thereby causing no damage to the respiratory tract wall.

Thus, embodiments of the invention provide a system with which an inflatable member that is to be filled with a fluid may be positioned at a predetermined position within the respiratory tract of a patient, which allows for an improved pressure control aimed at avoiding damage to the respiratory tract wall. This in turn allows a safer procedure for e.g. the ultrasonic imaging of certain parts of the circulatory system, in particular the heart or aorta, using an imaging device that is arranged in the patient's oesophagus, as well as for mechanical ventilation using a breathing tube during anaesthesia.

Although the invention has been described in detail for the purpose of illustration based on what is currently considered to be the most practical and preferred embodiments, it is to be understood that such detail is solely for that purpose and that the invention is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements that are within the spirit and scope of the appended claims. For example, it is to be understood that the present invention contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

Conclusies

1. Een systeem met ten minste één opblaasbaar element (7) dat ingericht is om aangebracht te worden in een deel van de luchtpijp van een patiënt, omvattende:

- een katheter (6) die het ten minste één opblaasbaar element (7) dat bedoeld is om aangebracht te worden in de luchtpijp, draagt, waarbij de katheter een fluïdumlijn (8) omvat voor het vullen van het opblaasbaar element met een fluïdum;
- een drukmonitor- en controle-element (24) dat bedoeld is om aangebracht te worden buiten het lichaam van de patiënt, welk drukmonitorelement in fluïdumverbinding is met het opblaasbaar element en ingericht is om, in werking, fluïdum te ontvangen van het opblaasbaar element wanneer de druk boven een voorafbepaalde drempeldruk stijgt, en om het ontvangen fluïdum terug te geven wanneer de druk onder de voorafbepaalde drempeldruk daalt;
- waarbij het drukmonitor- en controle-element een elastisch uitzetbare ballon is die vervaardigd is uit een materiaal dat ingericht is om elastisch uit te zetten wanneer de druk in de ballon boven een voorafbepaalde drempeldruk stijgt, en om te contracteren wanneer de druk onder de voorafbepaalde drempeldruk daalt.

2. Het systeem volgens conclusie 1, verder omvattende een beeldvormingsinrichting, bij voorkeur een ultrasoonbeeldvormingsinrichting, die ingericht is om aangebracht te worden in of op het lichaam van de patiënt; waarbij het fluïdum een beeldvormingsvloeistof is.

3. Het systeem volgens conclusie 3, verder omvattende een tracheabuis met een eerste einde en een tweede einde, waarbij het eerste einde ingericht is voor verbinding met een bron van ademhalingsgas, waarbij het tweede einde zich naast het opblaasbaar element bevindt en omgeven is door het opblaasbaar element.

4. Het systeem volgens één der voorgaande conclusies, waarbij het volume van de elastisch uitzetbare ballon, in de niet geëxpandeerde toestand, ten minste 10 procent van het volume van het opblaasbaar element is.

5. Het systeem volgens één der voorgaande conclusies, waarbij het materiaal van de elastisch uitzetbare ballon een thermoplastisch elastomeer is, bij voorkeur een thermoplastisch polyurethaan elastomeer.

6. Het systeem volgens één der voorgaande conclusies, waarbij de durometerhardheid van het materiaal van de elastisch uitzetbare ballon, gebruikmakend van testmethode ASTM D2240, lager

is dan de durometerhardheid van het materiaal van het opblaasbaar element, meer bij voorkeur ten minste 2A Shore lager, meest bij voorkeur ten minste 5A Shore lager.

7. Het systeem volgens één der voorgaande conclusies, waarbij de elasticiteitsmodulus van het materiaal van de elastisch uitzetbare ballon, waarbij de ASTM D412 testmethode wordt gebruikt, lager is dan de elasticiteitsmodulus van het materiaal van het opblaasbaar element, meer bij voorkeur ten minste 1 MPa lager bij 50% verlenging, en ten minste 2 MPa lager bij 100% verlenging.

8. Het systeem volgens één der voorgaande conclusies, waarbij de voorafbepaalde drempeldruk in een bereik tussen 30 en 70 mm Hg ligt.

9. Het systeem volgens één der voorgaande conclusies, waarbij het volume van de elastisch uitzetbare ballon, in de niet geëxpandeerde toestand, tussen 2 en 10 ml ligt, bij voorkeur tussen 2,5 en 6 ml.

10. Het systeem volgens één der voorgaande conclusies, waarbij de expansie van de uitzetbare ballon, wanneer de druk boven de voorafbepaalde drempeldruk is, in hoofdzaak lineair varieert ten opzichte van de druk.

11. Het systeem volgens één der voorgaande conclusies, waarbij het materiaal van het opblaasbaar element een thermoplastisch elastomeer is, bij voorkeur een thermoplastisch polyurethaan elastomeer.

12. Het systeem volgens één der voorgaande conclusies, waarbij het opblaasbaar element, in de niet geëxpandeerde toestand, een volume heeft tussen 20 ml en 60 ml, bij voorkeur tussen 30 ml en 50 ml.

13. Het systeem volgens één der voorgaande conclusies, verder omvattende positioneringsmiddelen voor het positioneren van het opblaasbaar element op een voorafbepaalde locatie in de luchtpijp.

14. Het systeem volgens de voorgaande conclusie, waarbij de positioneringsmiddelen geleidingsmiddelen omvatten die bevestigd zijn aan of geïntegreerd zijn met de flexibele katheter.

15. Het systeem volgens conclusie 14, waarbij de geleidingsmiddelen een stilet omvatten dat aangebracht is in de katheter en dat een distaal einde heeft bij een tip van de katheter, waarbij het stilet zich tot voorbij het opblaasbaar element uitstrekt.

16. Het systeem volgens één der voorgaande conclusies, waarbij de elastisch uitzetbare ballon een dikte heeft tussen 0,01 mm en 0,1 mm, bij voorkeur tussen 0,03 mm en 0,07 mm.

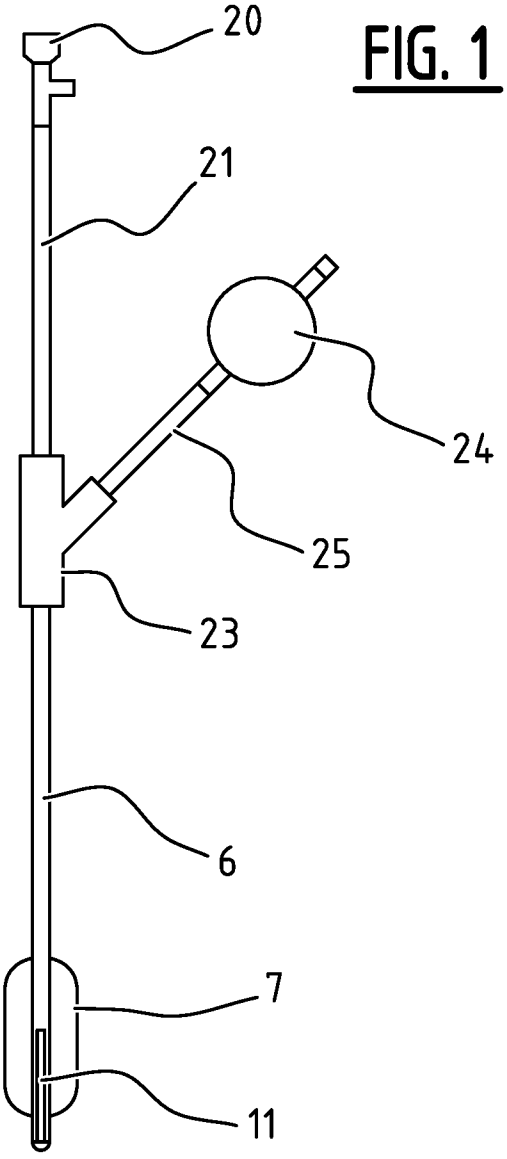

FIG. 1

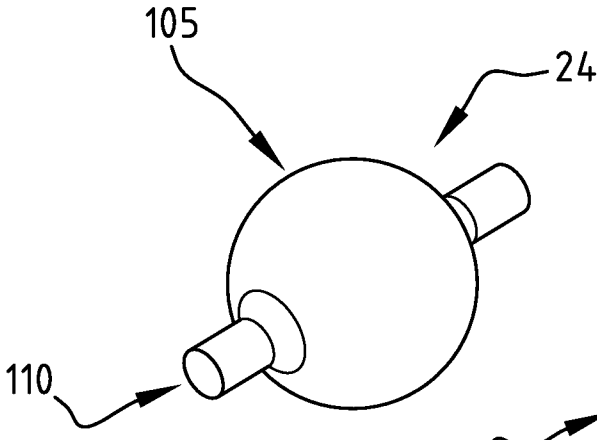

FIG. 2

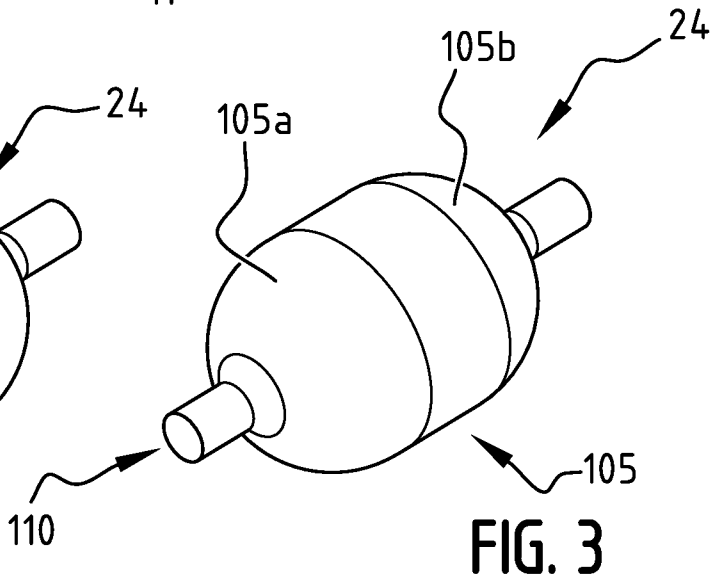

FIG. 3

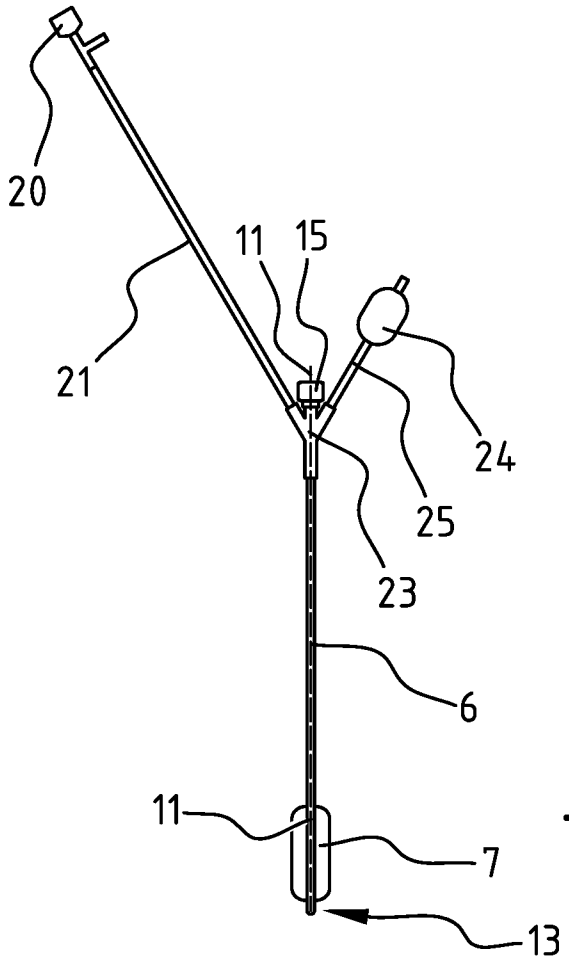

FIG. 4

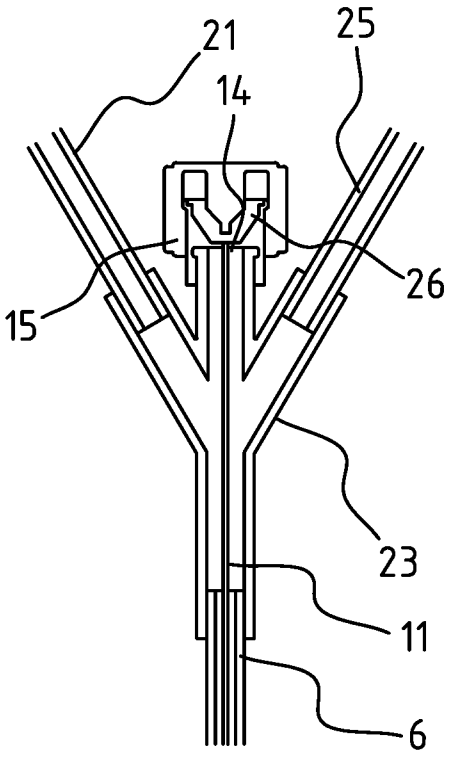

FIG. 5

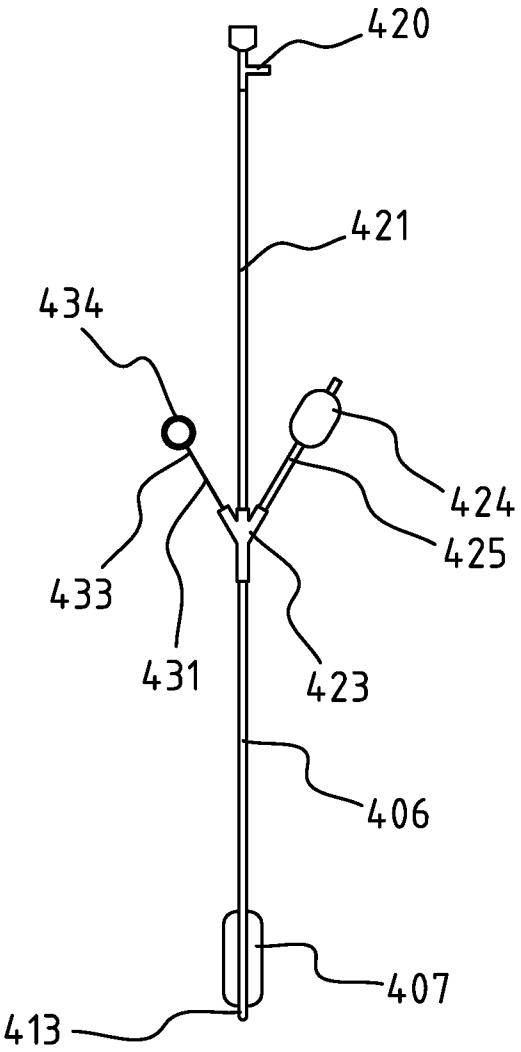
420
421
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FIG. 6

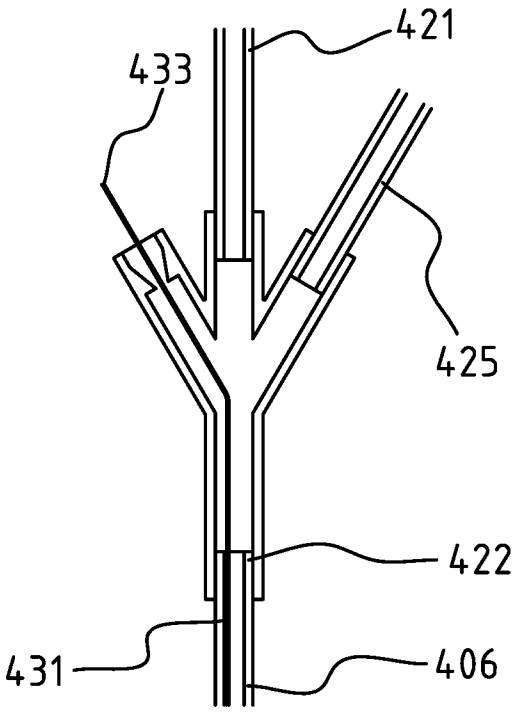
421
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FIG. 7

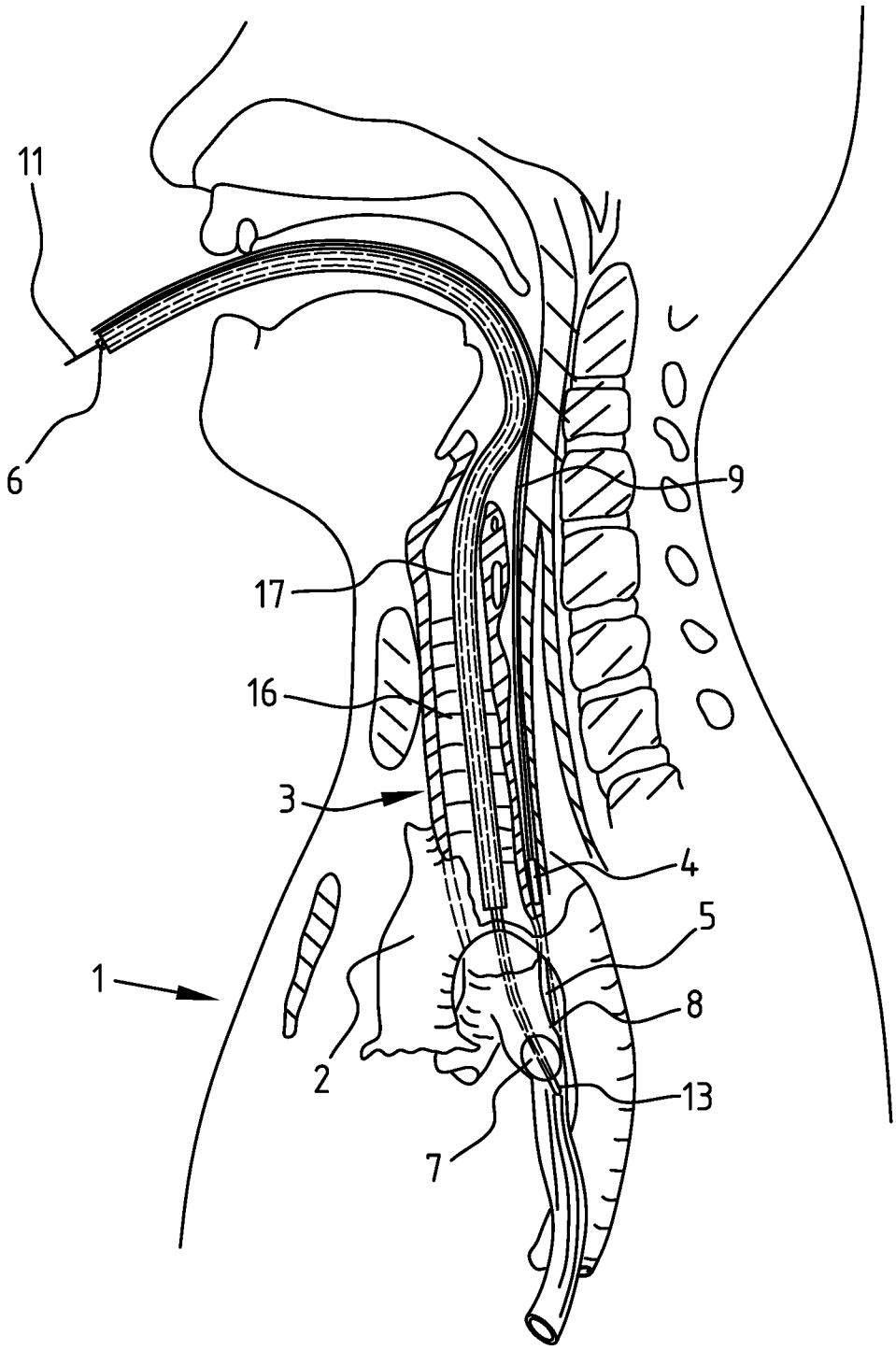

FIG. 8

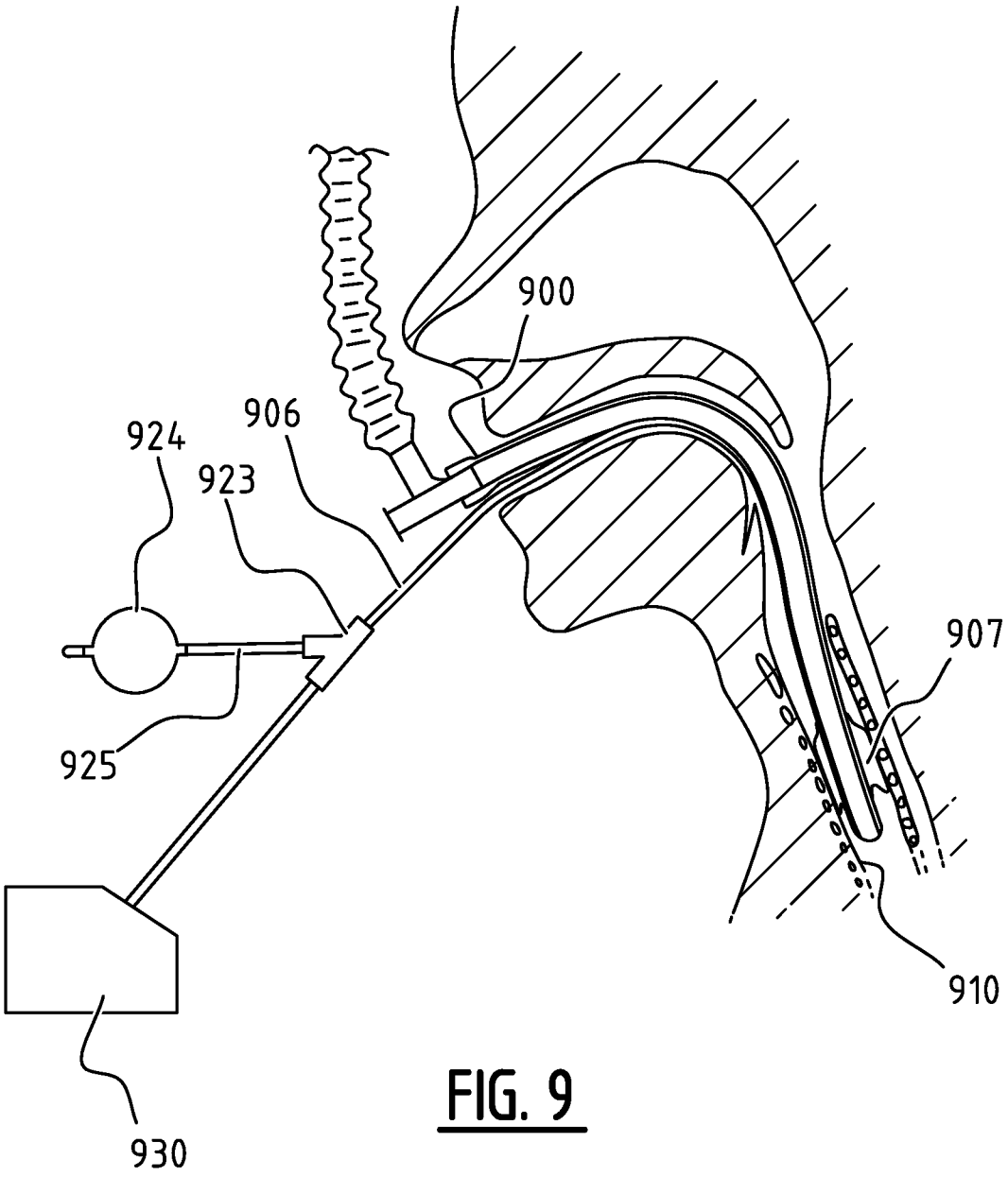

FIG. 9

Abstract

A system with at least one inflatable member configured for being arranged in a part of the patient's respiratory tract, comprising a catheter carrying the at least one inflatable member to be arranged in the respiratory tract, said catheter comprising a fluid line for filling the inflatable member with a fluid; a pressure monitoring and control member to be arranged outside the patient's body, said pressure monitoring member being in fluid communication with the inflatable member and being configured to receive, during operation, fluid from the inflatable member when the pressure increases above a predetermined threshold pressure and to return said received fluid when the pressure decreases below said predetermined threshold pressure; wherein the pressure monitoring and control member is an elastically expandable balloon made from a material which is configured to expand elastically when the pressure in the balloon increases above a predetermined threshold pressure and to contract when the pressure decreases below said predetermined threshold pressure.

SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE
	2H/2TT52/SC/2
Nederlands aanvraag nr. **2017970**	Indieningsdatum **09-12-2016**
	Ingeroepen voorrangsdatum
Aanvrager (Naam) **Stroke2Prevent B.V.**	
Datum van het verzoek voor een onderzoek van internationaal type **04-03-2017**	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr. **SN68503**

I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)

Volgens de internationale classificatie (IPC)

A61B8/08;A61B8/12;A61B18/00

II. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte minimumdocumentatie

Classificatiesysteem	Classificatiesymbolen
IPC	**A61B**

Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

III.	☐ **GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES**	(opmerkingen op aanvullingsblad)
IV.	☐ **GEBREK AAN EENHEID VAN UITVINDING**	(opmerkingen op aanvullingsblad)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2017970

A. CLASSIFICATIE VAN HET ONDERWERP
INV. A61B8/08 A61B8/12 A61B18/00
ADD.

Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.

B. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte minimum documentatie (classificatie gevolgd door classificatiesymbolen)
A61B

Onderzochte andere documentatie dan de minimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)
EPO-Internal, WPI Data

C. VAN BELANG GEACHTE DOCUMENTEN

Categorie *	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
X	US 2016/249859 A1 (BABKIN ALEXEI V [US] ET AL) 1 september 2016 (2016-09-01)	1,2,4,6, 7,9,10, 12-16
Y	* samenvatting * * figuren 1-11 * * alinea [0049] - alinea [0083] *	3,5,11
X	US 2010/268159 A1 (ENGEL REBECCA L [US] ET AL) 21 oktober 2010 (2010-10-21) * samenvatting * * figuren 1-26 * * alinea [0036] - alinea [0062] *	1,8
Y	EP 1 034 743 A1 (NIERICH ARNO [BE]) 13 september 2000 (2000-09-13) * samenvatting * * figuren 1-3 * * alinea [0016] - alinea [0020] *	3

-/--

[X] Verdere documenten worden vermeld in het vervolg van vak C.

[X] Leden van dezelfde octrooifamilie zijn vermeld in een bijlage

* Speciale categorieën van aangehaalde documenten

"A" niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

"D" in de octrooiaanvrage vermeld

"E" eerdere octrooi(aanvrage), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

"L" om andere redenen vermelde literatuur

"O" niet-schriftelijke stand van de techniek

"P" tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur

"T" na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvrage, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

"X" de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

"Y" de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

"&" lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie

Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid	Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type
22 augustus 2017	

Naam en adres van de instantie	De bevoegde ambtenaar
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Moehrs, Sascha

1

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2017970

C.(Vervolg). VAN BELANG GEACHTE DOCUMENTEN

Categorie *	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
Y	WO 99/64099 A1 (CARDEON CORP [US]) 16 december 1999 (1999-12-16) * samenvatting * * figuren 1-19 * * bladzijde 9, regel 26 - bladzijde 9, regel 29 * -----	5,11

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar de stand van de techniek: NL 2017970

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
US 2016249859 A1	01-09-2016	EP 3057511 A1	24-08-2016
		US 2016249859 A1	01-09-2016
		WO 2015057533 A1	23-04-2015
US 2010268159 A1	21-10-2010	GEEN	
EP 1034743 A1	13-09-2000	AT 327714 T	15-06-2006
		AU 772367 B2	22-04-2004
		CA 2402419 A1	14-09-2000
		DE 60028349 T2	29-03-2007
		DK 1161181 T3	02-10-2006
		EP 1034743 A1	13-09-2000
		EP 1161181 A1	12-12-2001
		ES 2263462 T3	16-12-2006
		NZ 514741 A	28-11-2003
		US 2007038109 A1	15-02-2007
		WO 0053098 A1	14-09-2000
WO 9964099 A1	16-12-1999	AU 762236 B2	19-06-2003
		CA 2334978 A1	16-12-1999
		EP 1091782 A1	18-04-2001
		WO 9964099 A1	16-12-1999

WRITTEN OPINION

File No.	Filing date *(day/month/year)*	Priority date *(day/month/year)*	Application No.
SN68503	09.12.2016		NL2017970

International Patent Classification (IPC)
INV. A61B8/08 A61B8/12 A61B18/00

Applicant
Stroke2Prevent B.V.

This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the application
- ☐ Box No. VIII Certain observations on the application

Examiner
Moehrs, Sascha

Application number

WRITTEN OPINION

NL2017970

Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing:

   ☐ contained in the application as filed.

   ☐ filed together with the application in electronic form.

   ☐ furnished subsequently for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes:	Claims	3, 5, 9-12, 16
	No:	Claims	1, 2, 4, 6-8, 13-15
Inventive step	Yes:	Claims	
	No:	Claims	1-16
Industrial applicability	Yes:	Claims	1-16
	No:	Claims	

2. Citations and explanations

see separate sheet

WRITTEN OPINION

Box No. VII Certain defects in the application

see separate sheet

Reference is made to the following documents:

D1	*US 2016/249859 A1 (BABKIN ALEXEI V [US] ET AL) 1 september 2016 (2016-09-01)*
D2	*US 2010/268159 A1 (ENGEL REBECCA L [US] ET AL) 21 oktober 2010 (2010-10-21)*
D3	*EP 1 034 743 A1 (NIERICH ARNO [BE]) 13 september 2000 (2000-09-13)*
D4	*WO 99/64099 A1 (CARDEON CORP [US]) 16 december 1999 (1999-12-16)*

Re Item V

1 The present application does not meet the criteria of patentability, because the subject-matter of independent claim 1 is not new.

1.1 Document *D1* discloses *(the references in parentheses applying to this document)*:

Een systeem *(see the system according to figures 1 - 11)* met ten minste één opblaasbaar element *(figure 5: 230)* dat ingericht is om aangebracht te worden in een deel van de luchtpijp van een patiënt *(description, paragraph 0060)*, omvattende:

- een katheter *(figure 5: 200)* die het ten minste één opblaasbaar element *(230)* dat bedoeld is om aangebracht te worden in de luchtpijp draagt *(see figure 5)*, waarbij de katheter een fluïdumlijn *(the fluid line which is connected to inflation and deflation ports 232, 234)* omvat voor het vullen van het opblaasbaar element met een fluïdum *(see the description, paragraphs 0060 - 0063)*;

- een drukmonitor- en controle-element *(the whole control system according to figure 11)* dat bedoeld is om aangebracht te worden buiten het lichaam van de patiënt *(figure 11: only 610, and 620 is inside the patient)*, welk

drukmonitorelement in fluïdumverbinding is met het opblaasbaar element en ingericht is om, in werking, fluïdum te ontvangen van het opblaasbaar element wanneer de druk boven een voorafbepaalde drempeldruk stijgt, en om het ontvangen fluïdum terug te geven wanneer de druk onder de voorafbepaalde drempeldruk daalt *(see the control according to the description, paragraphs 0080 - 0083)*;

- waarbij het drukmonitor- en controle-element een elastisch uitzetbare ballon is die vervaardigd is uit een materiaal dat ingericht is om elastisch uit te zetten wanneer de druk in de ballon boven een voorafbepaalde drempeldruk stijgt *(see the elastic properties of the balloon according to the description, paragraph 0066)*, en om te contracteren wanneer de druk onder de voorafbepaalde drempeldruk daalt *(the constant value of the pressure according to the description, paragraphs 0080 - 0083 is considered as the threshold)*.

The subject-matter of claim 1 is therefore not new.

Note, also document *D2* discloses the subject-matter of independent apparatus claim 1, see particularly *D2: abstract; figures 1 - 26; description, paragraphs 0036 - 0062.*

2 Dependent claims 2 - 16 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of patentability.

2.1 The subject-matter of dependent claims 2, 4, 6, 7, 8, and 13 - 15 is not new, see particularly

Claim 2
D1: description, paragraphs 0058 - 0062;

Claim 4
D1: see figure 5;

Claims 6, and 7
The subject-matter of claims 6, and 7 are unclear, because they include a reference to a test method. Therefore, the subject-matter is considered to be

included in the prior art as well.

Claim 8
D2: according to the description, paragraph 0040, such a pressure range is common;

Claims 13 - 15
D1: the catheter itself corresponds to the positioning element.

2.2 The subject-matter of dependent claims 3, 5, and 11 is not inventive. Document *D1* is considered as the closest prior art with respect to these claims and the person skilled in the art is aware of the additional features from the following documents:

Claim 3
D3: abstract; figures 1-3; and according to the description, paragraphs 0016 - 0020, it is common to combine TEE with appropriate ventilation;

Claims 5, and 11
D4: abstract; figures 1 - 19; and according to the description, page 9, lines 26 - 29, it is common to use elastomers.

2.3 The subject-matter of dependent claims 9, 10, 12, and 16 is also not inventive. It relates to obvious design options (related to the characteristics, size and behavior of the balloon) which come within the scope of the customary practice followed by persons skilled in the art.

Re Item VII

3 The vague and imprecise statement in the description on page 10 ("... spirit and scope of the appended claims ...") implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in a lack of clarity of the claims when the description is used to interpret the claims. This statement should therefore be deleted to remove this inconsistency.

4 The relevant background art disclosed in *D1 - D4* is not mentioned in the description, nor are these documents identified therein.

5 Claim 3 is not clear, because it appears to depend on the wrong claim.