Oct. 29, 1968 E. A. GALLEHER, JR 3,407,817

CATHETER WITH CUFF INFLATER AND INDICATOR

Filed July 26, 1965

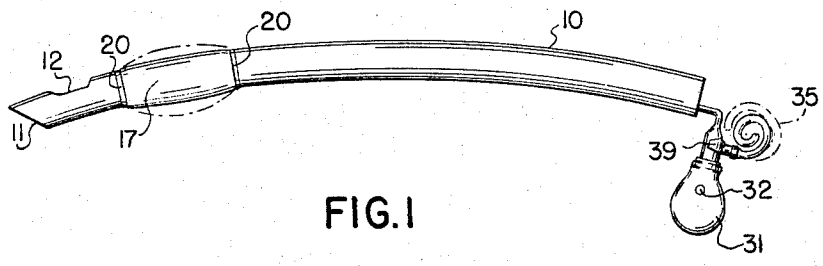

FIG. 1

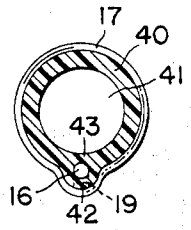

FIG. 6

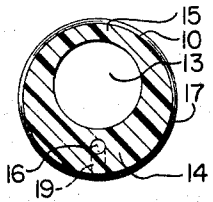

FIG. 2

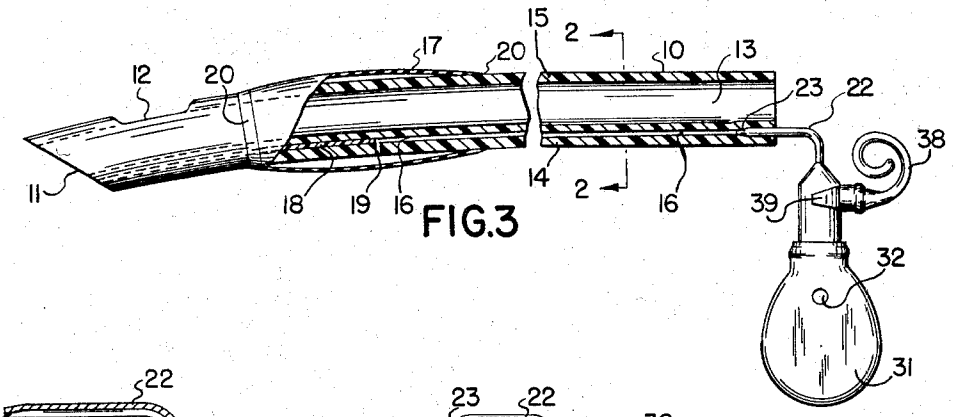

FIG. 3

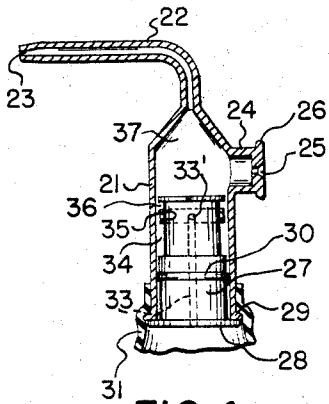

FIG. 4

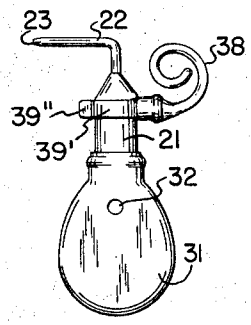

FIG. 5

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United States Patent Office 3,407,817 Patented Oct. 29, 1968

3,407,817

CATHETER WITH CUFF INFLATER AND INDICATOR

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Filed July 26, 1965, Ser. No. 474,807
4 Claims. (Cl. 128—351)

ABSTRACT OF THE DISCLOSURE

A catheter with a manually inflatable cuff, said catheter comprising a tube having a main bore opening through the ends of the tube and a longitudinally extending passage in the wall of the tube, said passage being plugged adjacent one end of said tube and communicating with the cuff through said wall to inflate said cuff, cuff inflating means inserted in said passage at the other end of said tube, said means including a check valve, a hand pressure bulb, and a pressure indicating member, said member indicating the extent to which the cuff is inflated by means of said hand pressure bulb and having means associated therewith for simultaneously deflating the cuff and indicating member.

My invention relates to catheter constructions such as those of the endotracheal type and relates more particularly to a catheter having means associated with, and as a component part of, the construction for manually inflating the catheter cuff and simultaneously visually indicating the degree to which the cuff is being inflated.

Another object of the invention is a catheter having an inflatable cuff of low modulus having high resistance to ozone, oxygen, heat and normal hospital chemicals such as anesthetic agents and ordinary cold sterilants at room temperatures, and which is orally inflatable at low pressures.

Another object is a catheter construction which readily lends itself to economical production, which is substantially of the same outside diameter throughout its length when the cuff is deflated, and which is provided with an internal independent passage or duct formed within the wall of the catheter and communicating with the cuff and a combined inflater and inflation indicator.

A further object is a novel cuff inflater and pressure indicator means for connection with a passage or duct in the catheter tube leading to the cuff and which is readily removably applied to the end of the catheter remote from the cuff.

Still another object is to provide means for inflating the catheter cuff by the application of successive low pressure cumulative impulses up to a desired inflation pressure in the cuff and to visually indicate step by step the accumulated inflated condition of the cuff.

Another object is to prevent overinflation of the cuff and serious damage to membranes when the cuff is hidden from view as in a body cavity when in use.

Another object is to provide means to quickly deflate the cuff and indicator when desired, as in removing the catheter from the body cavity or in the event of emergency.

Other objects and advantages of this invention will become more apparent as the following description of an embodiment thereof progresses, reference being made to the accompanying drawing in which like reference characters are employed to designate like parts throughout the same.

In the drawings:

FIGURE 1 is a side elevation of a catheter of the endotracheal type showing the cuff and inflation indicator in solid lines when deflated and illustrating the same in broken lines when inflated;

FIGURE 2 is a transverse section taken on line 2—2 of FIGURE 3;

FIGURE 3 is a longitudinally distended view of the catheter illustrated in FIGURE 1 and is broken away in part in vertical section to clearly show the passage or duct formed in the catheter tube wall and the manner in which the inflater and inflation indicator device is assembled on the remote end of the catheter tube. In this view the cuff is shown as only slightly inflated;

FIGURE 4 is a vertical enlarged section through the inflater device;

FIGURE 5 is a side elevation of a modified form of the inflater-indicator means; and

FIGURE 6 is a transverse section similar to that taken on line 2—2 of FIGURE 3 but illustrates a modified wall structure surrounding the inflation passage.

Referring now more particulary to the accompanying drawing which illustrates one general form of my invention, the catheter tube is indicated at **10**, and, as illustrated in FIGURE 6, preferably employs a tube of suitable flexible material such as rubber, rubber compounds, or other plastic compositions, the wall defining the tube being of substantially uniform thickness in cross section throughout the length of the tube.

The annular tube wall **40** is of uniform thickness and its bore **41** is concentric with the outer smooth surface **10**. The passage **16** formed longitudinally within the wall **40** is surrounded with a wall thickness not substantially greater than that at **40**, since the thickness of the wall material on diametrically opposed sides of the passage **16**, as at **42** and **43**, and radial with respect to the longitudinal axis of the bore **41** is substantially one-half the thickness of the tube wall at other points around the tube.

A slightly modified form of catheter tube is shown in section in FIGURE 2 in which the wall defining the bore **13** of the tube can be eccentric to the true central axis of the tube. Both tubes terminate at one end in a bevelled round pointed nose portion **11**, there being an opening **12** near the bevelled nose of the tube for reciprocal passage of material from the main bore **13** into the organ or cavity with which it communicates.

The catheter tube formed as in FIGURE 2 provides a thicker tube wall portion **14** adjacent one side of the bore **13** and a relatively narrow portion **15** diametrically opposite **14**. It is through this thicker wall **14** that the passage or duct **16** is formed. Since the passage, when so formed, will extend throughout the length of the tube, and since the purpose of this passage is to conduct fluid pressure to the inflatable cuff **17**, it must be plugged up and sealed, as at **18**, from the nose portion of the catheter tube to a point underlying the cuff. A branch or transverse passage **19** then is formed through the wall **14** and communicates with the interior of the cuff and the passage **16**, as shown in FIGURE 3.

When the catheter tube is first formed an in FIGURES 2 and 6, nosed as at **11**, the opening **12** formed, and the section of the passage **16** plugged up at **18**, but before the cuff is assembled on the tube, the tube is preferably dipped in a film forming solvent solution of a material compatible with the material of the tube, i.e., having the same properties as that of the tube material whereby to coat the inner surface of the bore **13** and the outer surface of the tube. The inflatable cuff, which is preferably a thin walled rubber sleeve of low modulus and having high resistance to ozone, oxygen, heat and normal hospital chemicals such as anesthetic agents and ordinary sterilants at room temperatures, is then snugly telescoped over the tube end and adjusted to overlie at its midpoint, the branch passage **19**. The uninflated sleeve snugly fits the tube and lies smoothly and unwrinkled thereagainst. In

this position, the cuff is then bonded to the catheter tube by brushing or otherwise applying a compatible cement to the tube and the opposite ends of the cuff while turning the tube, as indicated at **20**.

As a material part of this invention as applied to tubes having cross sectional walls of either FIGURE 2 or FIGURE 6, I provide means for insertion into an end of the passage **16** for inflating the cuff and for observing the degree to which the cuff is inflated. Such means preferably consists of thumb and finger actuated pump, a check valve, a pressure indicator and a pressure release for deflating the cuff quickly.

As shown, one form of check valve included in such means may be a body comprising a hollow casing **21** terminating at one end in a passage **22** of considerably reduced diameter and bore and preferably extending laterally of the body. The passage **22** terminates in a tapered open end or nose **23** for easy insertion into the open end of the passage **16** at one end of the catheter tube as shown in FIGURE 3.

The valve body or casing is also formed with a boss **24** having an opening **25** through its end wall and is provided with an external bead **26** about its periphery.

The casing **21** is open at its lower end to receive a check valve unit **27** which is provided at its bottom end with an annular flange **28** overlying the annular external bead **29** of the casing open end, whereby to permit the unit to be inserted to its full length terminating at its upper end below the boss **24**. An O-ring packing **30** is carried in an annular groove in the unit **27** and seals against the internal wall of the casing **21** preventing leakage of pressure below the ring.

A compressible bulb **31** is fitted at its open end over the flange **28**, and bead **29**, and the lower external wall of the casing **21**, as shown in FIGURE 4, and is provided with an air inlet opening **32** to the atmosphere when it is uncovered by the finger of the operator.

In the form shown, the check valve unit is provided with a duct or passage **33** communicating at one end with the bulb **31** and opens laterally at its other end toward the space **34**, as at **33'**. A resilient band **35** of thin rubber encircles the upper portion of the unit and overlies and normally closes the opening **33'**, but when the bulb **31** is depressed with the finger and thumb of the operator closing the opening **32**, air under compression within the bulb will unseat the band and allow the air pressure to enter the space **34** and pass around the upper end **36** of the valve unit **27** and into the upper chamber **37** of the housing, through the tube **22** and into the passage **16**, **19** and thence to the interior of the cuff **17**. At the same time fluid pressure will be delivered through the opening **25** and into a pressure indicator tube **38** having a normally preset coiled or helical form. The indicator is telescoped at its open end over the boss **24** as shown, and responds with the cuff to each pressure pulse upon compression of the bulb **31**, by a progressive unwinding of the coil, as illustrated in broken lines in FIGURE 1. As the pressure builds up in inflating the cuff, it will proportionately uncoil the pressure indicator tube **38**, clearly and visually indicating to the operator the degree of inflation of the cuff which, of course, when inserted into the trachea or other body cavity, is hidden from view.

Thus, when the cuff is inflated to the desired extent, as indicated by the pressure indicator, the accumulated pressure in the cuff and indicator can be released quickly by lifting the tab or skirt **39** upwardly and pulling it outwardly of the boss sufficiently to exhaust the pressure in the entire line to the outside atmosphere through the opening **25** and past the raised tab **39** and the head **26**. With back pressure on the band **35** while the cuff and pressure indicator tube are inflated, the opening **33'** remains closed and consequently there will be no release of pressure through the bulb **31**.

With reference to FIGURE 5, it will be observed that the structure is substantially the same as the corresponding inflating means shown in FIGURE 3 except that the tab **39'** extends around the casing **21** beyond a point corresponding to the terminal end of the tab **39** and terminates in a lip **39''** extending radially from the casing to provide easy access for the user to firmly grip the lip to raise the tab **39'** from the opening **25** to exhaust pressure therethrough from the passage **16** and the cuff **17**.

It is to be understood that while a catheter tube having a cross section such as is illustrated in FIGURE 6, that is, in which the thickness of the material forming tube wall **40** is substantially uniform throughout, whereas that illustrated in section in FIGURE 2 is thicker in the area of the passage **16** and progressively thinner to a diametrically opposed area, it is intended that either form shall be employed in the overall invention as disclosed herein.

In this form (FIGURE 6), the tube wall **40** is of uniform thickness throughout its transverse cross-sections, it being understood that the sum of the thickness of the wall portions **42** and **43** on both sides of the passage **16** in a direction radial to the longitudinal axis of the tube **10** is substantially equal to the thickness of the wall **40** in other radial directions through the tube. Thus the tube bore **41** is concentric to the major area of the outer wall of the tube as distinguished from the eccentric relationship of these corresponding parts as shown in FIGURE 2.

From the above, it will be understood that by my novel invention, the possibility of producing trauma in the patient due to overinflation of the cuff is substantially eliminated and that, in other respects, such as the smooth unobstructed exterior surfaces of the catheter and deflated cuff, the safety factor in its use is materially increased over those catheters of which I am aware are now in general use.

Various changes may be made in the details of construction and arrangement of parts of the invention without departing from the spirit thereof or the scope of the appended claims.

I claim:

1. A catheter comprising a tube of elongated configuration adapted to be inserted in a body passageway and having a main bore opening through the ends of the tube, a through-passage extending longitudinally within the wall of the tube and having plug means inserted therein adjacent one end of said tube to seal said passage, an inflatable cuff encircling the tube at a position near said one end of the tube, said tube passage having communication through the wall of the tube adjacent said plug means with the interior of the inflatable cuff, cuff inflating means inserted in the passage near the opposite end of the tube, said inflating means having a pressure release opening therein, resilient means removably secured over said opening in sealing relation thereto, said resilient means in said sealing relation indicating the extent to which said cuff is inflated in response to fluid pressure from said inflating means, and said resilient means when removed from said sealing relation simultaneously deflating itself and said cuff.

2. A catheter comprising a tube of elongated configuration adapted to be inserted in a body passageway and having a main bore opening through the ends of the tube, a passage formed longitudinally of the tube within the wall of the tube, an inflatable cuff encircling the tube at a position near one open end of the tube, said passage having communication through the wall of the tube with the interior of the inflatable cuff, cuff inflating means inserted in the passage near the opposite end of the tube, said inflating means having a pressure release opening therein, resilient means removably secured over said opening in sealing relation thereto, said resilient means in said sealing relation indicating the extent to which said cuff is inflated in response to fluid pressure from said inflating means, and said resilient means when removed from said sealing relation simultaneously deflating itself and said cuff.

3. A catheter comprising a tubular structure of elon-

gated configuration adapted to be inserted in a body passageway and having a main bore opening through the ends of the tube, a passage formed longitudinally of the tube within the wall of the tube, an inflatable cuff encircling the tube at a position near one open end of the tube, said passage having communication through the wall of the tube with the interior of the inflatable cuff, cuff inflating means inserted in the passage near the opposite end of the tube, resilient means responsive to fluid pressure in the passage and cuff for indicating the state of inflation of the cuff, said cuff inflating means comprising a valve casing, a check valve in the casing, a hand pressure bulb for delivering fluid pressure in successive impulses through the valve in one direction to the cuff and to said indicating means simultaneously for building up the inflation of the cuff and indicating the extent to which the cuff is inflated, and means associated with said resilient means for simultaneously deflating the cuff and resilient means.

4. An endotracheal catheter and pressure indicating structure comprising a catheter tube of elongated configuration for insertion in the trachea, a passage formed within the tube wall and extending from the distal end of the tube to a portion underlying an inflatable catheter cuff, said cuff encircling the tube and having communication with the passage, means inserted in the distal end of the passage for inflating the cuff and indicating the degree of inflation thereof and comprising a hand pressure bulb having an opening communicating with the atmosphere, a check valve within said means, said valve having at least one passageway communicating between said bulb and a point adjacent the distal end of said tube, and an elastic element overlying said passageway in sealing relation thereto said point, said bulb on compression moving

said element to permit flow of fluid from within the bulb to the distal end of said tube into said passage, a boss on said means adjacent said distal end and having a bore therethrough communicating with the interior of said means adjacent said point, a pressure indicating member fitted over said boss, said indicating member being cumulatively responsive to each of a succession of pressure impulses generated each time the bulb is compressed while its said opening is closed, said indicating member including a flexible tube having a preset coiled configuration when dormant, but in which, under the influence of said fluid pressure, the configuration is progressively varied as the applied fluid pressure is increased.

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