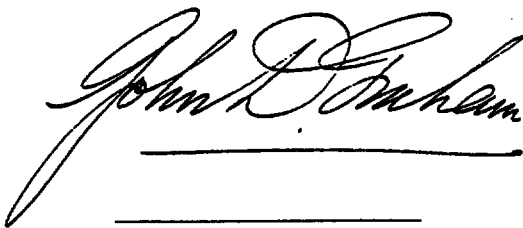


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IN THE MATTER of
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No. 88 908 701.9
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in the name Dr. Norbert
Roewer

I, John Douglas Graham, c/o D.F. Long & Co.
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SE10 8BX, do hereby certify that I am conversant with the English
and German languages and am a competent translator thereof, and
I verify that the attached translation corresponds to the
original text of the German language claims of the specification
of European Patent Application No. 88 908 701.9, Publication
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(Signature)

Signed this 5th day of February 1993

European Patent 0 423 234 B1

Dr. Norbert Roewer

GASTRIC PROBE

The invention concerns a gastric probe with a suction tube adequately suitable for drawing off the stomach contents, a stomach balloon which is held in place at the entrance to the stomach by tension of the tube, and a nasal stopper for fixing the state of tension of the tube in the intended position. A gastric probe of this type is known for example from United States Patent 3,046,988.

It has not yet been possible to eliminate the aspiration of acidic stomach contents into the bronchi as a cause of fatalities among patients under anaesthesia (Anaesthetist 1987, 36, pp. 599-607). The commencing- and ending-phases of the anaesthesia are particularly critical during insertion and removal of the anaesthesia tube, as irritation of the throat is particularly severe in these phases and the tube in the airway is not yet or no longer held by a cuff, which during normal positioning of the tube generally prevents passage of the stomach contents into the bronchi (with the exception of paediatric tubes, which have no cuff). There is an increased risk in non-fasting patients (emergency cases) and in patients with increased pressure on the stomach or intestine (pregnancy, ileus). In these cases the stomach contents are aspirated off with a normal gastric probe before insertion and removal of the anaesthesia tube. However, this does not guarantee safety, as evacuation of the stomach is generally incomplete and intestinal contents can pass back into the stomach. Slow aspiration of stomach contents can also cause inflammation of the lungs in intensive care patients undergoing prolonged assisted respiration.

This disadvantage can be overcome by a probe of the initially mentioned type known from German Patent Application 2412553, which has a stomach balloon, which after positioning of the probe in the stomach is inflated and positioned at the entrance to the stomach in such a way as to prevent reflux of stomach contents. The balloon is fastened in this position so that, after its inflation in its free position in the stomach the apparatus can be drawn back

until a resistance indicates the position of the balloon at the entrance to the stomach. A cuff in the oesophagus is then inflated in order to hold the probe in the intended position by its friction against the wall of the oesophagus and to produce additional resistance to reflux of stomach contents. However, this probe has not been widely accepted. Because of the risk of perforation the oesophageal cuff should be inflated to only a relatively low pressure. As the oesophagus – also by reason of anomalies – can vary greatly in its diameter, the oesophageal cuff must be relatively wide. This means that when it is under low inflation pressure the possibility of contrary, as it were rolling deformation of its ends makes it incapable of being fixed in an axial position. This disadvantage cannot be avoided by the presence of an external control balloon, which indicates only the state of inflation of the cuff.

As already mentioned above (US Application 3,046,988), a probe is known which has a stomach balloon and an oesophageal balloon which compress the surface vessels in the oesophagus and at the entrance to the stomach in order to stop haemorrhages. The tension in the suction tube, which is intended to ensure the correct position of the stomach balloon, is maintained by a nasal stopper. However, despite the inconvenience associated with this it is preferred in practice in these cases to use a weight-loaded line tension (lowered rod tube, obviously used beforehand) in association with the suction tube, as the strength of the tension is easily and reliably determined by this. Nasal stoppers are generally used only in those cases (primarily with endotracheal tubes) in which only low fixing tensions occur which need not be accurately maintained. This is due to the fact that the frictional state of a nasal stopper on the pertinent probe tube can be extremely variable, depending on how much secretion there is on the surface of the tube. In the present state of knowledge a nasal stopper is therefore not suitable for use in cases in which – as with the type of stomach probes required by the invention – a predetermined and high tension is to be applied, especially when maintenance of the predetermined tension is the more important, the greater the tension.

However, the invention recognizes that a nasal stopper is very suitable for maintaining a high suction tube tension predetermined within narrow limits when the method of the invention for inserting the tube is used. The distinctive feature of this method is that the tube is slack and the stomach balloon is inflated in the stomach to a low pressure and then, after tensioning of

the suction tube and the resultant positioning of it at the entrance to the stomach, the balloon is inflated to a higher pressure and the probe is fixed in this position by means of the nasal stopper. The performance of this procedure is made possible with a gastric probe as claimed in the invention because the separate lumen of the tube connected with the stomach balloon is connected to a pressure monitor in the outer region of the probe which is designed to indicate at least two pressures, the lower of which is assigned to the free inflated state of the stomach balloon with an untensioned tube and the higher of which is assigned to the tensioned state of the tube.

Systems are known in which probe balloons are connected to external check balloons (DE-A (German Patent Application) 3509797, DE-C 3303582, DE-A 3412553), though these indicate only the degree of inflation as such, but not the inflation pressure. The use of a check balloon with an indication of pressure for special cases is also known (German Application 3,610,091, United States Application 4,185,638). Such pressure indication has so far not been meaningful with stomach balloons for apparatus of this type, as it stated nothing about the system pressure, which is dependent on the tension of the suction tube and was therefore not obvious. There also exists the following fundamental difference between these and the invention: in the known cases that pressure which is to be attained by compressed air is controlled directly by the external pressure controller, and the compressed air supply is shut off when the indicator on the apparatus shows the desired pressure. In the case of the invention only the lower pressure corresponds to this familiar use. The higher pressure step on the other hand does not serve to check or control the pressure supply or indeed any pressure, but for checking and controlling the tension of the suction tube. A very simple and accurate means of establishing the tension of the suction tube is thus provided, which then makes possible the use of a simple fixing device, namely the nasal stopper.

Whereas the tension of the suction tube during use of a pulling-cord arrangement remains constant independently of any movements of the patient, such movements can affect the tension of the suction tube when a nasal stopper is being used. In order to keep the changes caused by this small, the suction tube possesses appropriate elasticity of elongation.

A preferred embodiment of the invention is illustrated more fully in the following with reference to the drawing, the only Figure of which shows the probe in actual use.

The probe is led in the usual way through the nose 1, the throat 2 and the oesophagus 3 into the stomach 4. It consists of the suction tube 5 with a suction connection 6, a section 7 (oesophageal section) intended to lie in the oesophagus 3 and a section 8 (stomach section) intended to lie in the stomach 4. At the upper end of the stomach section 8 the balloon 9 is arranged like familiar cuffs, the volume of which for an adult is for example at least about 20 ml. It can be inflated through an additional lumen with a connection 10 and non-return valve 21 after the probe has been inserted. A further lumen with a connector 11 can be provided for further purposes, for example for preventing negative pressure in the stomach. The suction tube 5 has in the stomach section 8 apertures 12 for aspiration of the stomach contents. The tube also carries a nasal stopper 13, which according to the enlarged drawing of this component (Figure 1a) consists of a soft foam rubber ring 14 and, in front of this, a holder 15 which is of a harder structure for ensuring that the stopper is held firmly in position.

At least during the critical phases the tension of the tube is selected by appropriate adjustment of the nasal stopper so that the balloon 9 lies sufficiently closely to the entrance to the stomach. This largely prevents passage of the stomach contents into the oesophagus. As that part of the suction tube in the oesophageal section 7 has no apertures, the stomach contents also cannot get into oesophagus by way of the tube. Constant aspiration through the gastric probe is not necessary in view of the closing action of the balloon 9.

Unlike known gastric probes, which are generally removed after aspiration of the stomach contents and before insertion and removal of the anaesthesia tube, it may be useful to leave the probe as claimed in the invention in place during these critical phases and possibly also during operations.

The probe as claimed in the invention can also be used for preventing slow, insidious aspiration in intensive care patients undergoing prolonged assisted respiration.

The connection 10 of the lumen leading to the stomach balloon is provided with a pressure monitor 16. A short tube 17 with wall-apertures 18 is surrounded by a cuff 19, which is expediently protected by a transparent case 20, the interior of which is connected to the outside atmosphere by an aperture (which is not shown). When no pressure difference is acting on the cuff 19, this essentially lies close to the tube 17. The difference between the diameter of the cuff and that of the case 20 permits a sufficiently accurate estimation of the pressure step indicated by the degree of inflation of the cuff 19. The cuff 19 can for example be of such a size that, when it just begins to inflate or when it has reached half the diameter of the case, the stomach balloon shows the pressure required for its initial free inflation in the stomach, whereas the position of the cuff 19 in the case 20 shown in the drawing indicates the pressure step desired for the normal position of the balloon at the entrance to the stomach.

The probe is used in such a way that it is first placed in the cuff of the stomach balloon on the suction tube and then a volume of air which leads to the free inflation of the balloon in the stomach up to the lower pressure indicated by the check balloon 19 is blown in through the connection 10. The stomach balloon is then brought into the illustrated position at the entrance to the stomach by traction on the suction tube. The positioning pressure increases the internal pressure of the stomach balloon, which is indicated by the check balloon 19. The desired position pressure of the stomach balloon is reached when the check balloon shows a certain pressure step and the nasal stopper 13 is pushed against the nose so that this condition is fixed. Continuous monitoring of the desired condition is ensured by the check balloon. Any movements between the stomach and the nose have no substantial effect on the tight fit of the stomach balloon at the entrance to the stomach, as they are compensated by the elasticity of the suction tube over its great length between the stomach and the nose.



Patent Claims

1. Gastric probe comprising a suction tube (5) of adequate size to pass out stomach contents, a stomach balloon (9) held in position against the entrance to the stomach by tensioning the suction tube, and a nasal stopper (13) for fixing the tension state of the suction tube, characterised in that a separate lumen of the suction tube, connected to the stomach balloon (9) is connected to a pressure monitoring device (16) in the external part of the stomach tube, this device being set up to display at least two pressure steps, the free, inflated state of the stomach balloon with the suction tube not under tension being assigned to the lower of these steps, and the state of tension of the suction tube being assigned to the higher step.
2. Gastric probe in accordance with Claim 1, characterised in that the suction tube (5) possesses elasticity of elongation.