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FIGURE ①

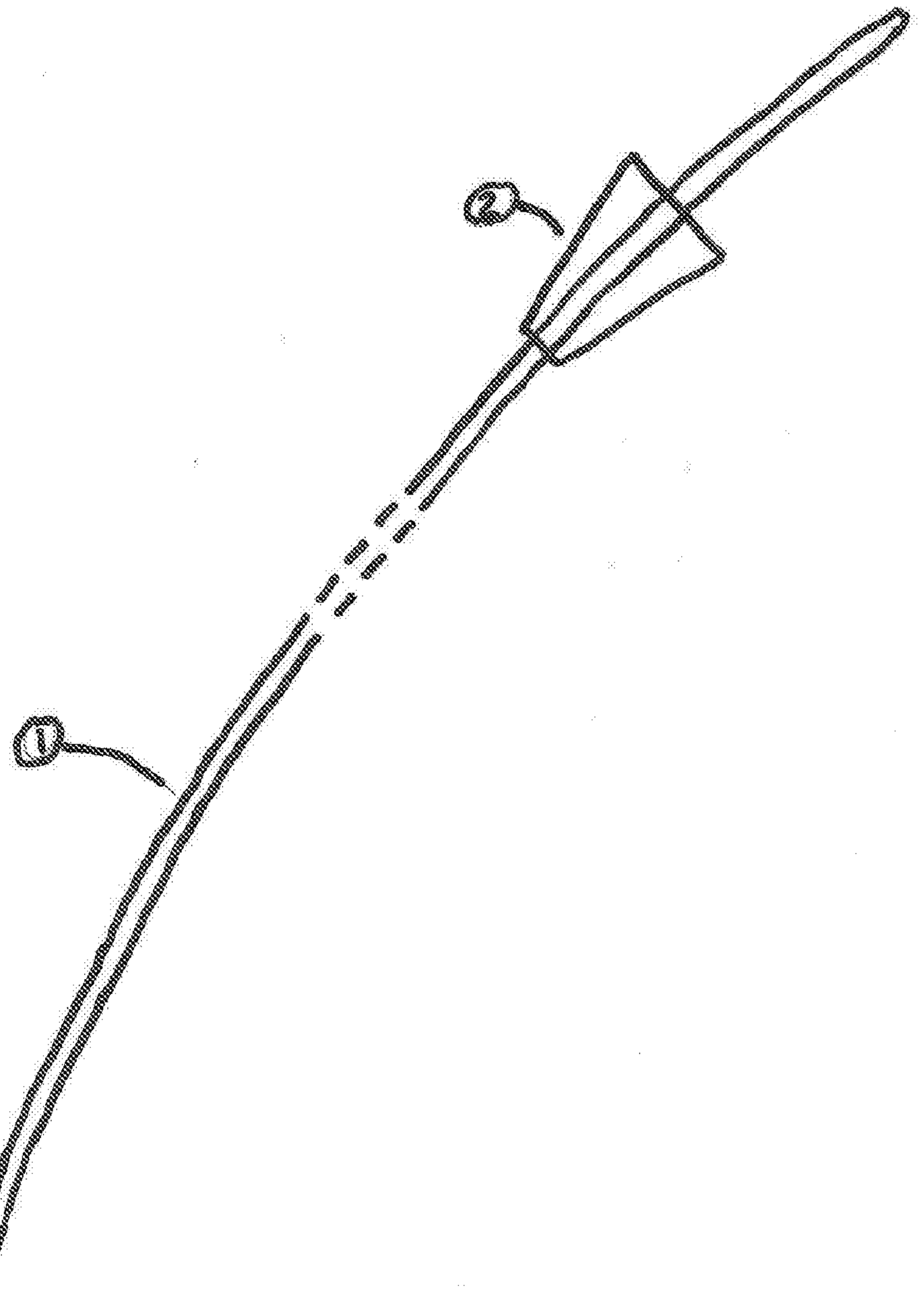


FIGURE 2

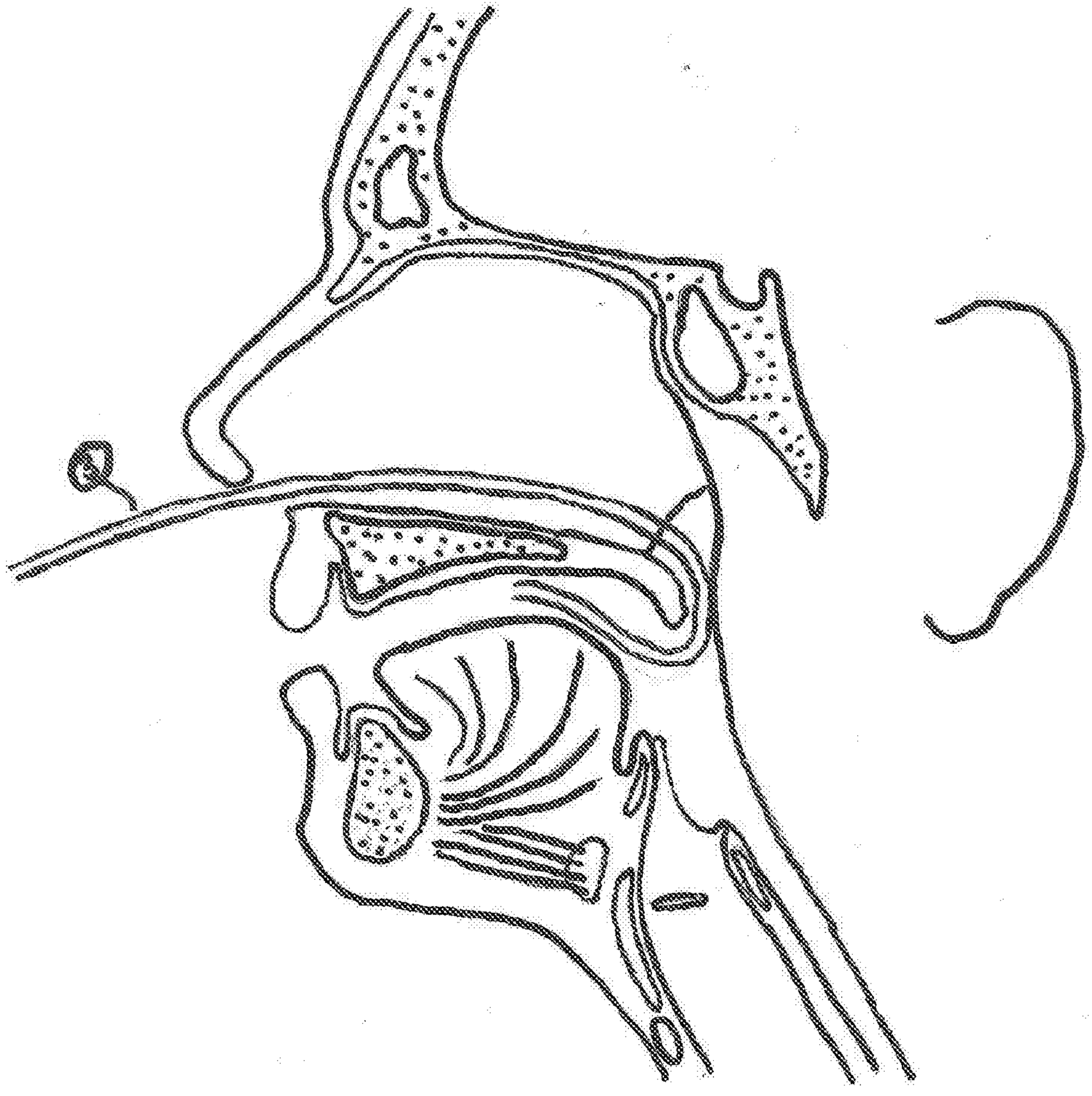


FIGURE 3

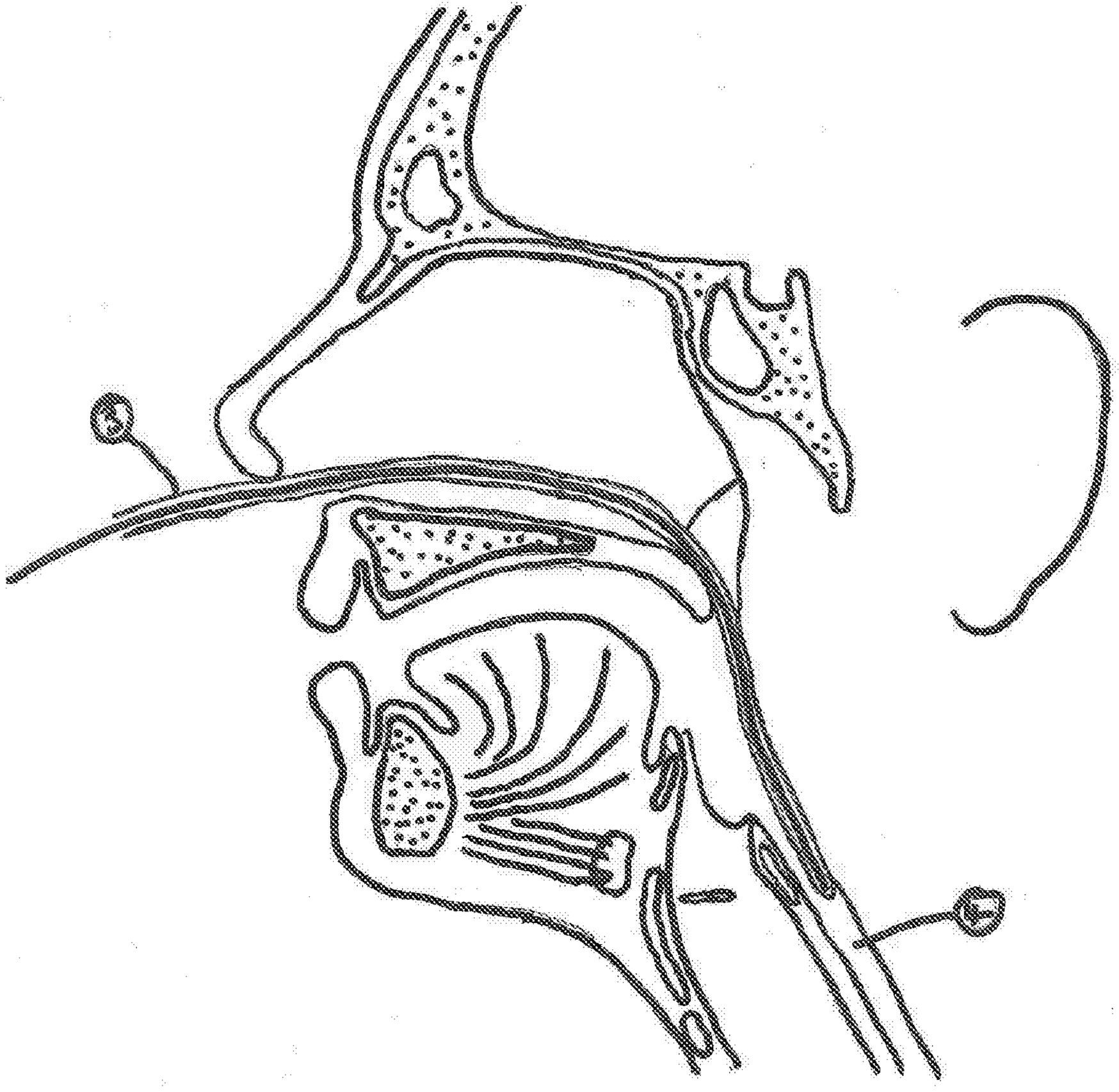


FIGURE 4

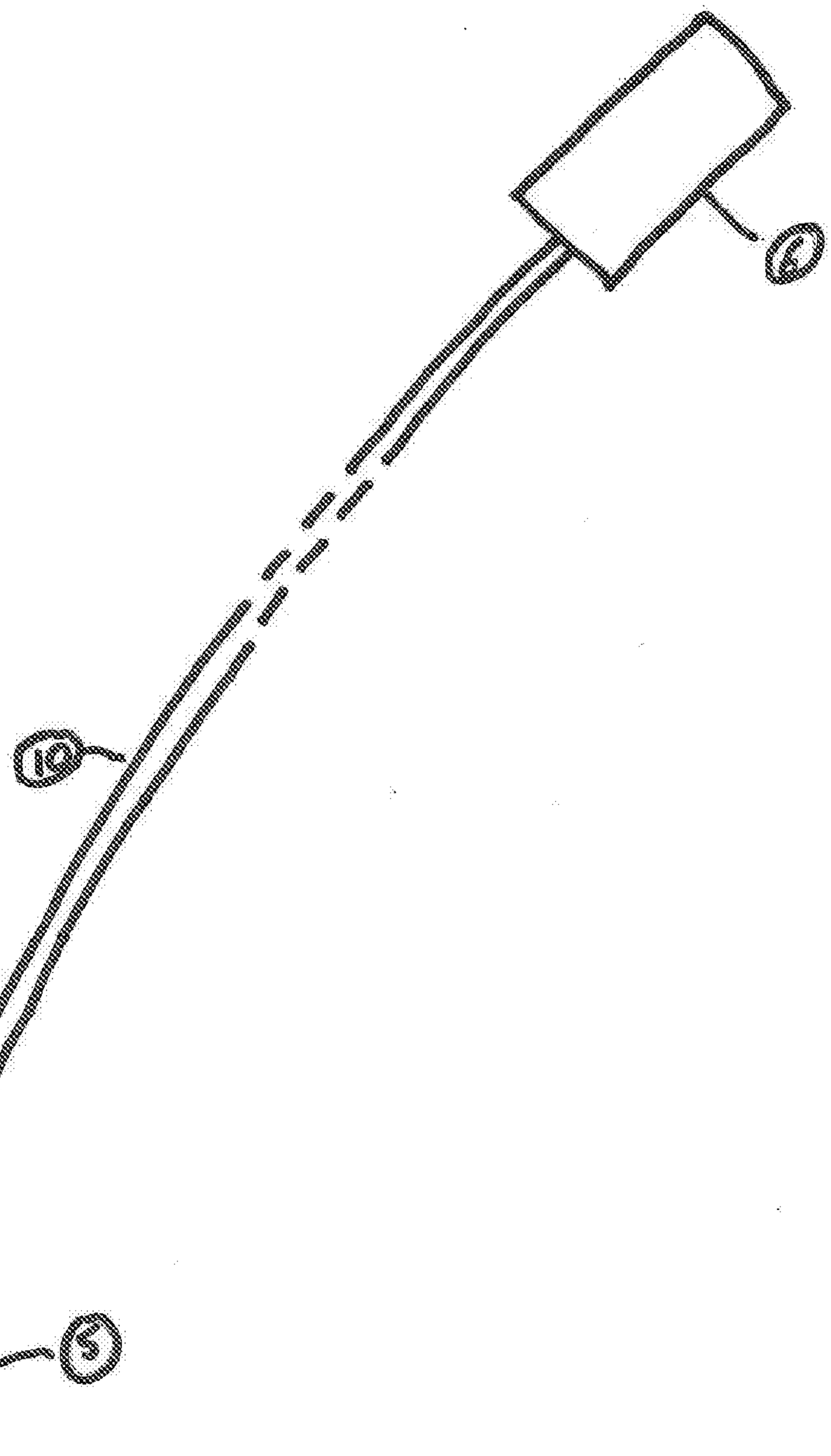


FIGURE 5

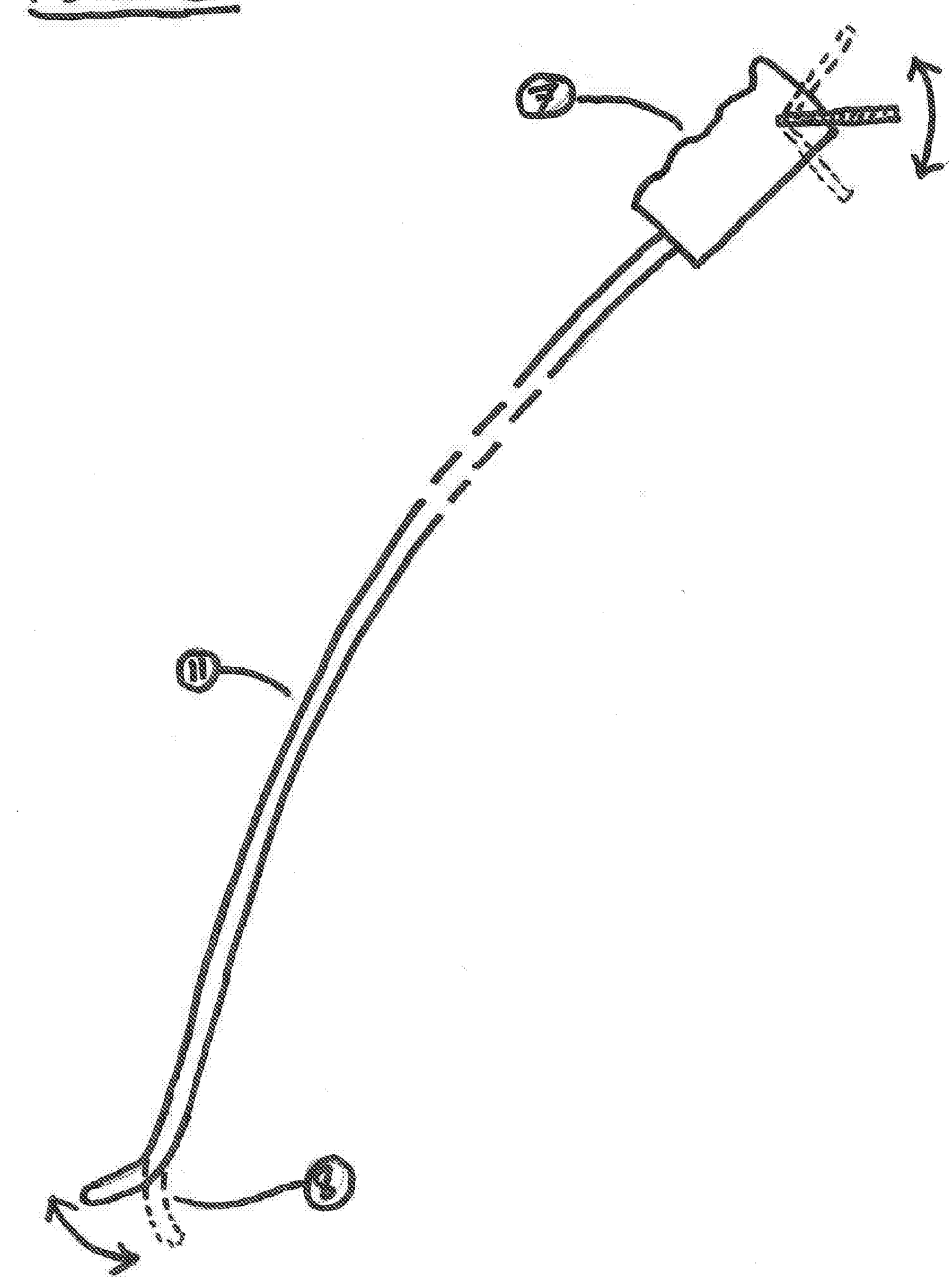


FIGURE 6

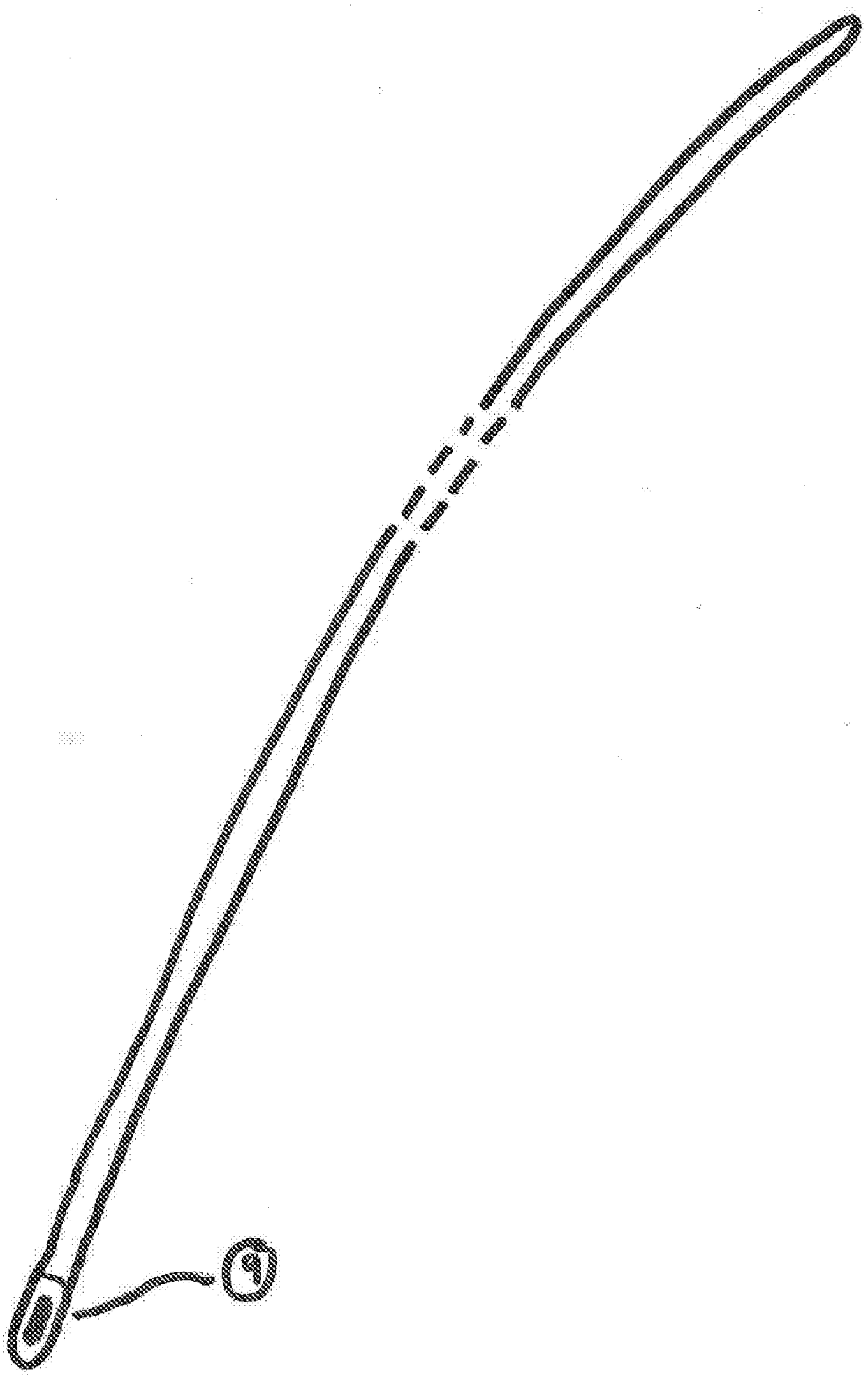
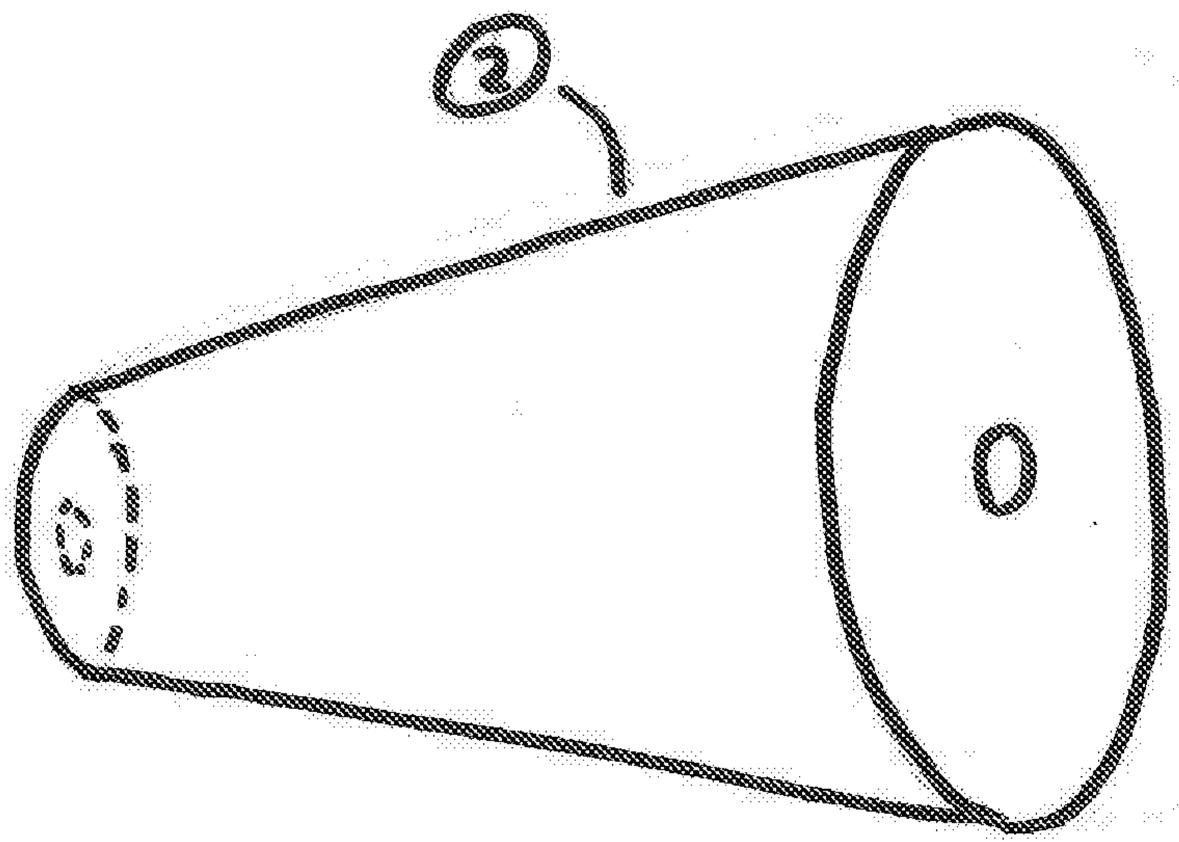


FIGURE 2



Title: Introducer Rod

Description:

This invention relates to a device to facilitate the insertion of a nasogastric tube.

Nasogastric tubes are commonly used in surgical patients to allow the introduction of or evacuation of gases, liquids and solids from the gastrointestinal tract. This includes awake patients as well as anaesthetised patients in theatre. Frequent replacement of these devices is often required in the post-operative setting due to inadvertent removal by the patient.

The procedure is often difficult in the awake patient for a number of reasons. Firstly, it is uncomfortable for the patient and often induces a gag reflex. At the same time, due to the flexibility and curvature of the nasogastric tube, it often coils in the oropharynx and fails to enter the oesophagus. This requires repeat attempts and further distress for the patient.

Trauma associated with the process of attempted insertion is often seen as the nasogastric tube is inserted through the nose via one of the nares through the nasopharynx and oropharynx into the oesophagus and finally into the stomach.

Under general anaesthetic, similar difficulties in the insertion of a nasogastric tube is encountered. In order to achieve successful cannulation of the oesophagus, direct laryngoscopy is frequently required. Under direct vision the tip of the nasogastric tube can be manipulated with use of a magills forceps into the oesophagus. With incremental clamping with the forceps and distal movement, gradual advancement of the nasogastric tube is achieved along the oesophagus and into the stomach. This process is associated with significant morbidity, namely trauma to teeth, gums, nasopharyngeal and oropharyngeal structures including the lingula, which is particularly vulnerable.

Incorrect placement of the nasogastric tube down the trachea may result in damage to the larynx, vocal cords and lungs. Feeding through such a wrongly placed tube might result in pneumonitis and death.

Another complication of the insertion of a nasogastric tube is the coiling either in the oesophagus or in the stomach. This can lead to a knot formation, which only tightens as attempts are made to withdraw the nasogastric tube. This may result to significant risk of morbidity and mortality.

To overcome all of these problems, the present invention proposes a nasogastric tube introducer device to facilitate the passage of a nasogastric tube, which is of appropriate stiffness. A possible range of flexural modulus being 2-800 MPa. The stiffness would vary along its length in a graduated and segmented manner to allow increased flexibility at certain points to promote correct conformation to aid correct placement.

This nasogastric tube introducer device is simply in the form of a biocompatible flexible rod of a stiffness that purports to increased success at insertion of a nasogastric tube. It would also reduce the chance of coiling of the nasogastric tube at any point during its insertion. A possible range of flexural modulus for the device would be in the region of 2 MPa -800 MPa, perhaps tending towards 200 MPa. The flexibility of the introducer rod would vary in segments along it's length to bend at appropriate moments during it's insertion to conform with the anatomy facilitating the correct route through the nasopharynx and oropharynx down into the oesophagus.

The rod or 'introducer' would be used as a guide for existing nasogastric tubes and as a way of increasing stiffness. It would be introduced into the lumen of the nasogastric tube prior to commencing its insertion. It may also have a device, which can slide up and down the introducer with which would be used to help hold the device in place inside the nasogastric tube. This device or 'bung' would be made of rubber, sponge, plastic or some other appropriate material.

The rod will have a diameter small enough to fit down the lumen of existing nasogastric tubes and be of a suitable length in order to protrude by a sufficient amount from the end of existing nasogastric tubes. The introducer rod will be produced in a colour easily distinguishable from other equipment such as yellow or black.

Once the nasogastric tube and introducer have successfully been advanced into the stomach the introducer can then be removed.

The invention will now be described by way of example and with reference to the accompanying drawings in which:

Figure 1 shows the rod or 'introducer' (1), and stabilising 'bung' (2)

Figure 2 shows the problem of coiling within the oropharynx of the nasogastric tube (3) with conventional insertion techniques.

Figure 3 shows how the use of the 'introducer' would facilitate the placement of the nasogastric tube (3) more posterior into the oesophagus (4) and thus down into the stomach.

Figure 4 shows an alternative rod (10) with a light scattering terminal section (5) with the attached removable proximal light source (6).

Figure 5 shows an alternative rod (11) that has a steering mechanism with a detachable, reusable handle (7) which controls an up and down mechanism for movement of the terminal section of the rod (8).

Figure 6 shows an alternative rod which houses a ferromagnetic part within the terminal section (9).

Figure 7 shows the 'bung' device (2) alone revealing its lumen which would allow passage of the introducer. It would taper in order to allow use with varying sized nasogastric tubes which would have varying proximal opening aperture sizes.

In figure 1, an embodiment showing the introducer rod is shown (1). This would be longitudinal and of an appropriate diameter to fit existing nasogastric tubes. The flexibility/stiffness of the rod would vary at different sections of differing length along its length from the tip in a graduated manner to facilitate correct passage into the oesophagus. It would be of a suitable colour to easily identify it from other equipment and it may also have length markings printed on its surface using a suitable recognised grading system.

The 'bung' device (2) is also shown which would be able to slide up and down the length of the rod but with some resistance to afford the stabilising effect of the nasogastric tube. Its proximal end will taper such that it would grip snugly the proximal opening of the nasogastric tube to hold it in place. This gripper or 'bung' would allow a temporary but firm attachment of the two devices, but would easily pull away once the introducer is to be removed.

In figure 2, the commonly found problem of coiling is demonstrated. Nasogastric tubes come in preformed packets in a coiled form. Once inserted into the nose, they quickly become increasingly flexible and tend to coil, thus increasing the chance of coiling in the oropharynx or at any point along its path of insertion.

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In figure 3, demonstrates the effect of the use of the 'introducer'. The nasogastric tube would be guided to the posterior oropharyngeal wall with resultant preferential intubation of the oesophagus (4).

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In figure 4, an alternative embodiment of the device may also contain a disposable main introducer with a central fine fibreoptic core which would enable the transmission of light from a reusable light source attached to the proximal end of the device down the introducer to the tip of the introducer The introducer would have a terminal section of a particular character, colour and material in order to scatter the light. The reusable light source would attach to the proximal part of the introducer through either a screw or clip mechanism or some other such appropriate method to maximise the transmission of light.

This would be a possible method of confirming correct placement of the nasogastric tube and the introducer within its lumen. With the light source on, in a darkened room with correct placement within the stomach the skin surface which correlates to the anatomical region of the stomach would appear to 'glow'. Failure to correctly place the nasogastric tube and introducer within the stomach would lead to the light source being hidden behind the sternum or within the airway.

In figure 5, another alternative embodiment is illustrated whereby a detachable proximal handle is connected to the introducer. This would house a lever attached to a mechanism running through the length of the 'introducer' which would allow upwards and downwards movement of the tip of the introducer within the lumen of the nasogastric tube. This could therefore be used to guide correct placement of the

nasogastric tube during its advancement through the nose, nasopharynx, oropharynx and oesophagus and finally into the stomach.

Figure 6 shows a further alternative embodiment which would have the introducer rod as in figure 1 but its terminal section would house a small piece of ferromagnetic metal. The purpose of this metal would be to allow detection through use of a small hand held metal-detector used externally to approximate distance to the piece of metal and thus be used as a method of detecting successful placement of the introducer and nasogastric tube within the stomach.

Claims:

1. An introducer rod for facilitating passage of a nasogastric tube, where the rod is of appropriate stiffness which varies along its length in a graduated and segmented manner, allowing increased flexibility at certain points to promote correct conformation to aid correct placement, wherein a flexural modulus is in the range of 2-800 MPa.

2. An introducer rod according to claim1, which comprises a plastics or rubber material.

3. An introducer rod according to claims 1 & 2, wherein a plastics material is selected from the group consisting of silicone, polyvinyl chloride, polyurethane, polyethylene, polypropylene, polycarbonate, polyacrylate, polyester, polytetrafluroroethylene, and combinations and or copolymers thereof.

4. An introducer rod according to claim 1, which is of a diameter such that it will pass down the lumen of existing nasogastric tubes.

5. An introducer rod according to claim 1, which is of a length such that it will protrude after insertion through the lumen of existing nasogastric tubes.

6. An introducer rod according to any of the preceding claims in which is of a colour easily distinguishable from other equipment such as yellow or black.

7. An introducer rod according to any of the preceding claims which includes a fibreoptic core and light scattering terminal component.

8. An introducer rod according to claim 7, wherein a proximal part has an attachment for a light source.

9. An introducer rod according to claim 7, with a light source in the form of a housing, battery and bulb which would attach to the proximal end of the introducer as described in claim 7, allowing transmission of light down the fibreoptic core.

10. An introducer rod according to claim 1, modified to include a mechanism for moving a tip up and down through use of a detachable handle and lever mechanism.

11. An introducer rod according to claim 1, that has a piece of ferromagnetic material at the distal part of the introducer rod.

12. An introducer rod according to claim 1, whereby a separate metal detector would be used as part of a single system to detect the ferromagnetic material as described in claim 11.