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54 **An instrument for the treatment of sinusitis.**

57 An instrument for treating sinusitis enabling the introduction of one end of a plastic tube into a maxillary sinus and anchoring it there for successive irrigations distributed over a period of time. Said end of the plastic tube (4) is provided with an arcuate bend for securing after introduction. Introduction is made by entering the tube into the lumen of a cannula (1), whereby the arcuate bend is elastically straightened. The sharp end (3) of the cannula (1) is introduced into the sinus, and the tube is then slid out with its said end into the sinus and regains its arcuate bend for securing, and the cannula is removed, the plastic tube securely remaining until purposely removed.



The present invention regards an instrument useful for the treatment of sinusitis, and particularly useful for repeated irrigations for treating maxillary sinusitis. More particularly, it regards an instrument for the treatment of sinusitis comprising tube means provided with a sharp end for piercing and making a hole in tissue for entering a cavity, and a plastic tube provided for entering one end thereof into said cavity through said tube means, said one end being provided with anchoring means for removably securing said one end within said cavity, said securing means comprising means for forming said one end into a shape incompatible with said hole.

One of the most important and efficient known methods for treating maxillary sinusitis is the drainage of purulent secretion, by means of introducing a liquid through a catheter or the like, which is introduced into the sinus, whereby the liquid and pus may exit through the existing natural lument (ostium).

It is often necessary to renew this operation, which is unpleasant and painful particularly due to the introduction of a cannula through bone, albeit made under local anesthesia. Therefore, instruments have been constructed where an introduced tube may be left for renewed irrigation through the same hole made in the tissue. Another reason why this is desirable is that it is advantageous to provide ventilation of the sinus when its ostium is obstructed by inflammation of the mucus.

One instrument used for this purpose is the Foley catheter (see Abdel-Salam & Gibb, J. Laryngology and Otology 95(1981) 221-223). A trocar is used for introducing a catheter which at its end is provided with an inflatable balloon for retention. In order to inflate the balloon, the catheter

must be provided with a special lumen used only for this purpose, beside the lumen used for irrigation. Therefore, the catheter and the trocar must have a rather large diameter, making a correspondingly large hole.

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Another known instrument comprises a catheter tube provided at its end with wings which at introduction are folded together but which will fold out, roughly into a T-form after introduction by means of a trocar (see Illum & Jepsen, Acta Otolaryngol. 73 (1972) 506-512). Also this
10 instrument needs a trocar of relatively large diameter, due mainly to the fact that the wings are obtained by cutting the tube, and therefore, the tube cannot be of very small diameter.

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Although the known instruments can be kept in place for subsequent irrigations, (they both have anchoring means which tend to disturb venting mainly due to their size and form) it would be desirable to keep the mucous membrane
20 as mechanically undisturbed as possible during the time when the catheter is left in place, which may be for several days. Further, it would be desirable to have a round, soft form likely not to disturb even used in cavities of different size and form, and which is not likely
25 to blow out when a patient sneezes.

It is therefore a first object of the invention to obtain an instrument permitting the insertion of a securable catheter by means of a piercing instrument having a diameter as small as possible. It is a second object to be
30 able to obtain an anchorable catheter having anchoring means that are less voluminous and less prone to disturb mucous tissue than what has been the case in the prior art. A third object is to obtain an inexpensive but versa-
35 tile instrument.

Those objects and other objects and advantages are obtained, according to the invention, by providing an instrument of the kind mentioned in the introduction, wherein the anchoring means comprise an arcuate bend at one end of the plastic tube when free, which bend is
5 elastically stretched out when kept in the tube used for its introduction. This end, when let free inside the cavity, will reform its arcuate bend, which serves as an anchoring means. When positively drawn out of
10 its hole, it will straighten out and can be pulled out after the end of treatment of the patient.

For easy manufacture, it is suitable to form the arcuate bend as a helix. The plastic tube end may then be wound
15 a couple of turns on to a mandrel and be given a permanent tendency to keep its form by suitable heat treatment.

It is also suitable to form the end of the plastic tube
20 as a spiral bend, e.g. in a plane perpendicular to the general direction of the tube. This will give a particularly gentle distributed anchoring likely to give minimum strain to the mucus inside the cavity.

25 It is preferred to utilize a plastic tube of the kind provided with X-ray absorbent matter, as this gives considerable ease in X-ray explorations.

For maximum irrigation efficiency, it is preferred to provide the arcuate portion of the plastic tube with several
30 openings, from which irrigation liquid may exit. This also tends to improve ventilation between irrigations, as probably not all the openings will be obstructed by pus.

35 The invention will now be further described in relation to non-limiting embodiments thereof. Fig 1 shows a par-

tially sectioned cannula provided with a straightened plastic tube. Fig 2 shows a plastic tube set free, showing an example of an anchoring configuration. Fig. 3 shows another example of an anchoring configuration.

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The partially sectioned view of Fig 1 shows a cannula 1, provided with a standard Luer-Lok^(R) fitting 2 at one end and a sharp cutting edge 3 at the other end. Inside the cannula is a plastic tube 4 having, beside its end hole 5, several side openings 6. Although naturally not visible in Fig 1, where the plastic tube 4 is everywhere straight, its material is internally tensioned so that when brought out of the lumen of the cannula, the form of its end will bend into a form susceptible to its anchoring in a cavity when entered by means of the cannula. Thus, when used, the cannula is pierced through a tissue wall of a cavity, and then, the tube 4 is moved out through the lumen and exits at 3. The cannula may be drawn back and removed, leaving the plastic tube in place. The end of this tube then takes an arcuate bend, exemplified in Figs 2 and 3. Many forms are possible for the arcuate bend.

The bend as of Fig 2 is obtained by rolling the plastic tube over a suitable mandrel and held there during successive heating and cooling cycles, whereby the tensions created by rolling are evened out, such that the arcuate form becomes permanented.

When mounting the tube 4 within the cannula 1, this is best performed by entering the tube 4 from the pointed end 3. In order to facilitate this, the end of the lumen should be deburred at its inner edge, as otherwise, its edge may damage the plastic tube 4, particularly when the arcuate form is drawn in.

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