

[54] **MIDDLE EAR INFLATOR**  
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[21] Appl. No.: **162,562**

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[52] **U.S. Cl.**..... **128/1 R**, 128/184, 128/303 R, 222/215, 239/327, 239/328, 285/374, 285/379

[51] **Int. Cl.** **A61b 17/24**, A61m 13/00, A61m 1/00

[58] **Field of Search**..... 128/1 R, 184, 303 R, 128/68, 76 R, 184; 138/26; 222/206, 215; 239/327, 328; 46/88; 285/374, 379

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[57] **ABSTRACT**

A medical device for gently forcing air through the nostrils and eustachian tubes into the middle ear. The middle ear inflator comprises a hollow body portion having a nozzle for insertion into the patient's nostril at one end and an inflatable balloon attached to the other end. The device provides a steady and gentle stream of air at a pressure sufficient to treat ear disorders without causing injury or unnecessary discomfort to the patient.

**12 Claims, 4 Drawing Figures**

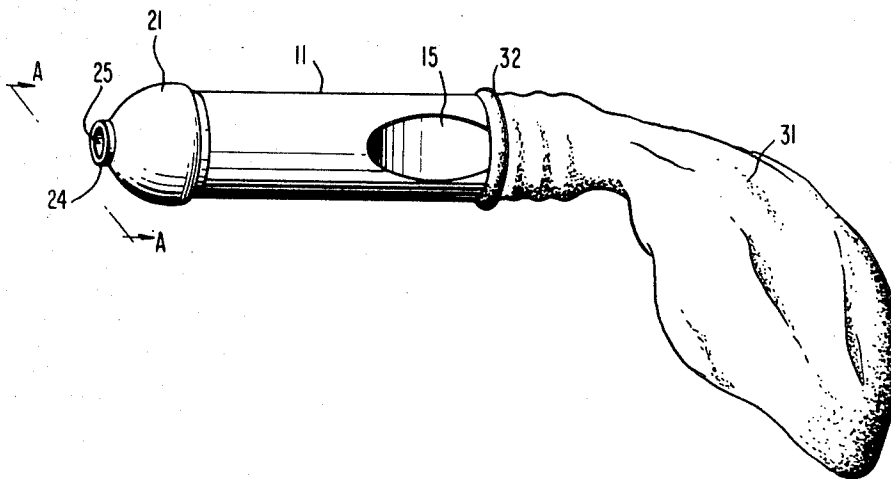


FIG. 1

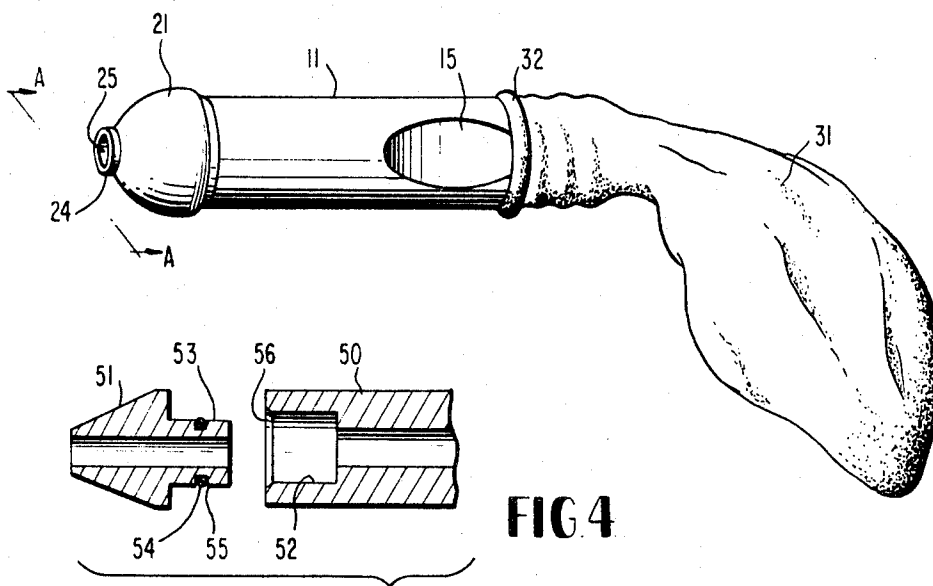


FIG. 4

FIG. 2

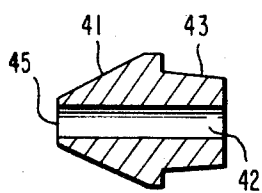
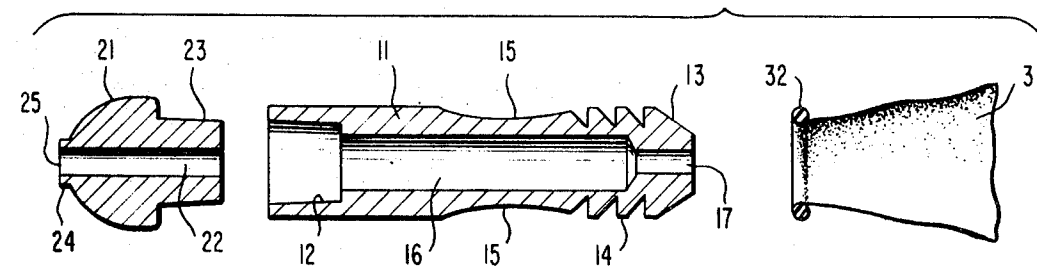


FIG. 3

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## MIDDLE EAR INFLATOR

## BACKGROUND OF THE INVENTION

It is known in the medical arts to treat certain disorders of the ear by forcing air under pressure through the nose and eustachian tube and into the middle ear. Such treatment is useful, for example, when the tympanic membrane (ear drum) is found to be retracted or when the middle ear space is filled with serous otitis fluid. If normal atmospheric pressure can be maintained in the middle ear for a sufficient length of time, the retraction of the ear drum can be alleviated and the serous otitis fluid will either drain out of the eustachian tube or be absorbed by the mucosa of the middle ear. In either of the latter situations the middle ear is relieved of the fluid.

Previous devices used to effect such treatment, such as the device disclosed in U.S. Pat. No. 2,516,762, have not proved completely satisfactory.

A serious disadvantage of these typical prior art devices is that they are also unsuitable as a steady source of gentle air pressure. Intermittent or pulsatory air pressure is provided by the squeezing of a rubber bulb. The amount of pressure to be supplied to the patient must be maintained at a relatively low level to prevent possible injury. The prior devices, such as shown in the aforesaid patent, because of the intermittent and pulsatory pressure, do not provide sufficiently close control of the magnitude of the pressure. It can readily be understood, for example, that the pressure of the air from an apparatus similar to that disclosed in the aforesaid U.S. Pat. No. 2,516,762, depends primarily on the pressure applied to the bulb and the time in which it is applied. A quick, strong squeeze results in a corresponding quick, strong emission of air from the device. This type of system can easily result in excessive pressure, as a result of which, the patient being treated can suffer pain and even serious injury.

In addition, these devices are often bulky and inconvenient to carry in a medical bag or in a pocket. Also, their structures are relatively complicated and expensive to manufacture.

It is an object of this invention to provide an apparatus for forcing air into the middle ear which consistently provides a steady and gentle source of air pressure over a period of several seconds sufficient to treat ear disorders without causing injury or unnecessary discomfort to the patient.

It is an object of this invention to provide an apparatus for forcing air into the middle ear which facilitates close control of the magnitude of the pressure applied to the patient in order to prevent injury to the patient.

It is also an object of this invention to provide an apparatus for forcing air into the middle ear which is simple in structure and inexpensive to manufacture.

It is a further object of this invention to provide an apparatus for forcing air into the middle ear which is small in size and can be conveniently carried in a pocket or a medical bag.

These and other objects of the present invention are achieved by providing apparatus for forcing air into the middle ear comprising a hollow body portion, a nozzle adapted to fit a human nostril and attached at one end of said body portion and a thin-walled, non-porous, elastic balloon attached to the other end of said body portion, said balloon distending to an expanded configuration when exhaled into by a human operator and

gradually expelling air and contracting by its own elasticity when subsequently released. A suitable balloon may be provided by the use of a common toy balloon. Further details of the invention will be explained hereinafter in the description of the preferred embodiment.

## BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a preferred embodiment of the invention;

FIG. 2 is an exploded view of the device shown in FIG. 1 in section along the line A—A;

FIG. 3 shows an alternative configuration for the nozzle of the invention.

FIG. 4 depicts an alternate means for attaching the nozzle of the middle ear inflator to the body portion.

## DESCRIPTION OF THE PREFERRED EMBODIMENT

The middle ear inflator of the present invention comprises three portions: a hollow body portion; a nozzle adapted to fit a human nostril; and a thin walled elastic balloon which expands in size when inflated and which gradually expels air and contracts by its own elasticity when subsequently released.

The body portion 11 of the preferred embodiment of the middle ear inflator is shown in the form of a tube and defines an interior chamber 16. It is understood that the said body portion could suitably take any of a number of forms, for example, it could be a hollow hexagonal or rectangular prism. The female portion 12 of a tapered fitting is formed at one end of the said body portion 11 to facilitate attachment of the nozzle 21. The opposite end of the said body portion is beveled slightly as shown at 13 to facilitate attachment of the thin-walled elastic balloon 31. Gripping means may be formed on the said body portion next to the beveled end 13 to assist in retaining the balloon 31 in attachment to body portion 11. Any suitable gripping means may be used. Circumferential ridges such as shown in the figures, having a diameter greater than the normal diameter of the balloon mouth 32 but within its elastic limit, are preferred due to the ease of forming such ridges on the body portion. If desired, slight depressions 15 may be formed in the sides of the body portion 11 to facilitate holding of the device during use by placing the fingers therein.

The nozzle 21 has the general shape of a hemispheroid with outlet 25 centrally located on the spherical surface thereof. Integral with the base or planar surface of the nozzle is the male portion 23 of the tapered fitting adapted to mate with the female portion 12 on body portion 11 and to thereby attach nozzle 21 to body portion 11. A passage 22 extends through nozzle 21 from the male portion 23 of the tapered fitting to the outlet 25. An axially extending flange 24 may be formed about the outlet 25 of the nozzle 21 to facilitate easy alignment of the outlet with the nostril of a patient.

FIG. 3 shows an alternate configuration for the nozzle of the middle ear inflator. Nozzle 41 has the general shape of a conical frustrum. The outlet 45 of nozzle 41 is centrally located in the top surface of the frustrum. Attached to the base of said nozzle 41 is the male portion 43 of a tapered fitting adapted to mate with female portion 12 on body portion 11 thereby attaching nozzle 41 to body portion 11. A passage 42 extends through

nozzle 41 from the male portion 43 of the tapered fitting to the outlet 45.

FIG. 4 shows another means for attaching the nozzle to the body portion of the middle ear inflator. Body portion 50 is provided with a cylindrical socket 52 instead of a tapered socket. Likewise, on nozzle 51, a cylindrical plug 53 is substituted for the male portion of the tapered fitting. Plug 53 is slightly smaller in diameter than socket 52 and is provided with an annular groove 55 containing a resilient slip ring 54. Ring 54 fits tightly in groove 55 and has an outside diameter slightly larger than the diameter of socket 52. Thus, when plug 53 is inserted into socket 52, slip ring 54 is compressed against the wall of the socket thereby sealing the nozzle to the body portion and frictionally retaining the nozzle in place. The lip of socket 52 may be beveled slightly as shown at 56 to facilitate insertion of the plug 53 with the ring 54.

Numeral 31 designates a narrow-necked, thin-walled, non-porous balloon of flexible elastic material having a mouth 32. If a person exhales strongly, directly into mouth 32 of balloon 31, the balloon will distend or expand in size until the internal pressure caused by blowing is counter-balanced by the ambient external pressure and the elastic forces tending to return the stretched walls of the balloon to their original size. The portion of the balloon next to the mouth 32 will hereinafter be referred to as the neck of the balloon. By pressing the sides of the neck of the balloon together, mouth 32 may be closed off and pressure retained in balloon 31. When the neck of the balloon is subsequently released, the elastic forces of the stretched walls will gradually expel air from the balloon, and the walls of the balloon will contract over a period of several seconds until the internal pressure is equal to the ambient external pressure. Accordingly, the flow of air from the balloon is uninterrupted, i.e., continuous, or steady, over a period of several seconds.

Conventional toy balloons of the type readily available are satisfactory for use with this invention. Commercially available balloons of this type generally produce maximum pressures on the order of 20 m.m. of mercury. However, pressures on the order to 30 m.m. of mercury may be employed with no danger of damaging the delicate parts of the middle ear. Balloons may easily be specially manufactured with the requisite strength and resilience to develop such pressures. It is possible by adjusting the thickness of the walls or the strength of the material forming the walls to construct the balloon of the invention so that if a predetermined internal pressure limit is exceeded, due to inflation of the bag by an operator with exceptionally strong lungs, the bag will rupture thereby preventing any pressure higher than the specified limit from being applied to a patient. The specified rupture limit is of a magnitude which is sufficient to provide sufficient pressure to treat the disorder but insufficient to cause damage or excessive pain to the ear. Thus, a preferred maximum pressure range for balloons utilized with the invention is from about 10 to about 30 m.m. of mercury although pressures somewhat outside of that range normally would be acceptable.

The neck of the balloon is smaller in diameter than the diameter of ridges 14 on body portion 11 so that when the mouth and neck of the balloon are applied over the beveled end 13 of body portion 11, the elasticity of the balloon will cause said balloon 31 and said

body portion 11 to seal tightly together in order to prevent air from escaping therebetween. The diameter of the neck portion of balloon 31 should not, however, be so much smaller than the diameter of ridges 14 that attachment of the balloon 31 to body portion 11 is made difficult or that the elastic limit of balloon 31 will likely be exceeded and the balloon torn in applying the balloon over the beveled end 13 of body portion 11.

The three portions of the middle ear inflator are assembled by mating the male portion 23 of the tapered fitting on the nozzle 21 to the female portion 12 of the tapered fitting on the body portion 11 and by applying the mouth and neck of balloon 31 over the beveled end 13 of body portion 11. When thus assembled, a channel is formed to convey air from the balloon 31 to the outlet 25 comprising balloon 31, opening 17, chamber 16, passage 22 and outlet 25. The nozzle and body portion may be made as a one piece, integral unit, but it is preferred that the nozzle and body portions be formed separately and assembled as a unit for use.

#### USE OF THE MIDDLE EAR INFLATOR

The mouth portion 32 of the balloon 31 is placed over the beveled end 13 of body portion 11 and secured to body portion 11 by engagement of the mouth and neck of the balloon with ridges 14. The open end of body portion 11 is placed to the mouth of the operator who exhales strongly therethrough into the balloon 31. The resulting increased internal pressure in balloon 31 causes said balloon to distend to an expanded configuration until said increased internal pressure is counterbalanced by the ambient external pressure and the elastic forces of the stretched walls of the said balloon. The neck portion of balloon 31 is then closed off by pressing a portion of the balloon wall over opening 17 in the beveled end 13 of body portion 11 with the thumb or finger. Nozzle 21 is attached to the open end of body portion 11 by mating the male portion 23 and the female portion 12 of the tapered joint. The inflated and assembled unit is held in one hand with the thumb or finger over the end 13 retaining the air in balloon 31 and generally with other fingers, such as the index and second fingers in the depressions 15. The outlet 25 of the nozzle is inserted into a nostril of the patient. The other nostril of the patient's nose is compressed and the patient swallows a small amount of water. It is well known that the action of swallowing slightly opens the eustachian tube which leads from the pharynx to the middle ear. As the patient swallows, the thumb or finger is removed from the end 13 of body portion 11 thereby releasing the air held in balloon 31. The elastic walls of balloon 31 gradually contract and air is steadily and gently expelled from the balloon through opening 17, chamber 16, passage 22 and outlet 25 from the device through the nostril, pharynx and eustachian tube into the middle ear of the patient.

The nozzle can be constructed as to fit easily a nostril of any size so that it may be used interchangeably for patients ranging from small infants to adults with unusually large nostril openings. Any suitable material such as plastic, metal or wood may be used to form the nozzle and air tube of the middle ear inflator. If desired, the nozzles may be made disposable and a new nozzle used for each patient. Alternatively, the entire apparatus may be made of inexpensive materials and readily disposed of after use. Any suitable flexible elastic mate-

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rial may be used to form the balloon of the middle ear inflator.

In can now readily be seen that the middle ear inflator provides a gentle, uninterrupted flow of air under pressure of readily controllable magnitude sufficient to treat ear disorders without causing injury or unnecessary discomfort to the patient. Modifications of the apparatus described hereinabove will undoubtedly occur to those skilled in the art, therefore, the scope of this invention is to be limited solely by the scope of the appended claims.

I claim:

1. A method of treating disorders of the ear in a human patient comprising the steps of:

15 providing apparatus comprising a hollow body having a nozzle adapted to fit a human nostril at one end and an inflatable balloon secured to the other end, inflating the balloon with an innocuous gas to distend the balloon to an expanded configuration at a controlled pressure sufficient to treat the ear disorder but insufficient to cause damage or excessive pain to the ear;

20 closing off the inflated balloon to prevent escape of the gas therefrom;

fitting the nozzle into one nostril of the patient's nose;

25 closing off the patient's other nostril whereby the nose is sealed;

releasing the gas from the balloon by permitting the balloon to gradually contract by its own elasticity

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whereby the gas will be steadily and gently expelled therefrom through the hollow body and the nozzle and through the patient's nostril, pharynx and eustachian tube into the middle ear of the patient.

2. The method of claim 1 comprising the additional step of causing the patient to swallow thereby opening the patient's eustachian tube to receive the gas from the balloon.

3. The method of claim 2 wherein the patient is caused to swallow a liquid.

4. The method of claim 1 wherein said inflating is performed orally.

5. The method of claim 2 wherein said inflating is performed orally.

6. The method of claim 3 wherein said inflating is performed orally.

7. The method of claim 1 wherein said controlled pressure is not greater than about 30 m.m. of mercury.

8. The method of claim 2 wherein said controlled pressure is not greater than about 30 m.m. of mercury.

9. The method of claim 3 wherein said controlled pressure is not greater than about 30 m.m. of mercury.

10. The method of claim 4 wherein said controlled pressure is not greater than about 30 m.m. of mercury.

11. The method of claim 5 wherein said controlled pressure is not greater than about 30 m.m. of mercury.

12. The method of claim 6 wherein said controlled pressure is not greater than about 30 m.m. of mercury.

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