

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

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VDP Patent, LLC,	:	
	:	Civil Action No.: 06-CV-5821 (GEL)
Plaintiff,	:	(ECF Case)
	:	
- against -	:	
	:	<u>COMPLAINT</u>
Welch Allyn Holdings, Inc., d/b/a Welch Allyn,	:	
Inc., and Harold Ellis Drugs and Surgicals Inc.	:	<u>DEMAND FOR JURY TRIAL</u>
	:	
Defendants.	:	
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Plaintiff VDP Patent, LLC, by and through its undersigned attorneys, for its complaint against Defendants Welch Allyn Holdings, Inc. d/b/a Welch Allyn, Inc. and Harold Ellis Drugs and Surgicals Inc., hereby states as follows:

THE PARTIES

1. Plaintiff VDP Patent, LLC (“VDP”), is a limited liability company organized under the laws of the State of New York, having its principal place of business in this judicial district.

2. Upon information and belief, Defendant Welch Allyn Holdings, Inc. (“Welch Allyn”), d/b/a Welch Allyn, Inc., is a New York corporation, having its principal place of business at 4341 State Street Road, Skaneateles Falls, New York 13153. Upon information and belief, Welch Allyn is a multi-national corporation that sells a variety of medical products and devices directly and through wholesale distributors. Upon information and belief, Welch Allyn is the successor of Welch Allyn, Inc.

3. Upon information and belief, Defendant Harold Ellis Drugs and Surgicals Inc. (“Harold Ellis”) is a corporation incorporated under the laws of the State of New York, with its principal place of business at 440 East 75th Street, New York, New York 10021. Upon information and belief, Harold Ellis is an authorized distributor of Welch Allyn products, including the Welch Allyn Ear Wash System.

JURISDICTION AND VENUE

4. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code.

5. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

6. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b) based upon Defendants’ making, selling, and/or offering for sale in this district products that infringe upon Plaintiff VDP’s patent.

ALLEGATIONS FOR ALL CLAIMS OF RELIEF

7. On August 31, 1999, the United States Patent and Trademark Office duly and lawfully issued United States Patent No. 5,944,711 entitled “Ear-Irrigating Method and Device” (the “’711 Patent”) to Dr. Daniel J. Pender. Plaintiff VDP is the record owner of the ’711 Patent by assignment. The ’711 Patent is a process or method patent, the term of which is current and unexpired. A true and correct copy of the ’711 Patent is attached to this Complaint as Exhibit A.

8. The ’711 Patent is directed, *inter alia*, to an improved method of removing ear wax (known in medical terminology as cerumen) and/or other debris from a patient’s ear ca-

nal by using a medical device that is inserted into the ear to provide leakage-free water irrigation and simultaneous evacuation of cerumen and debris from the patient's ear.

9. Under methods prior to the '711 Patent, water was directed into the patient's ear using a large syringe or other water delivery device. Free run-off of excess water and cerumen debris under such earlier methods required the use of both a drip basin and a protective draping on the patient. An example of the use of a drip basin is illustrated in United States Patent No. 5,685,851. Other cumbersome attempts to address the cerumen leakage problem are illustrated in various patents, including United States Patent Nos. 989,839; 4,036,235; 4,201,212; and 5,395,357. The awkward and unwieldy nature of the methods and devices in these earlier patents illustrates the importance of Plaintiff VDP's sealed system which allows for simultaneous irrigation and evacuation of cerumen through a convenient and continuous process.

10. The invention embodied by the '711 Patent overcame the limitations and inherent drawbacks of prior methods by utilizing a novel method of simultaneously irrigating the patient's ear with body temperature water and evacuating the waste run-off via a watertight seal. The novel method of the '711 Patent thus eliminated the need for the drip basin and protective splatter drape over the patient.

11. The '711 Patent was published in abstract in the Official Gazette of the United States Patent and Trademark Office dated August 31, 1999.

12. Upon information and belief, Defendant Welch Allyn had actual knowledge of the issuance of the '711 Patent at least as early as its issue date of August 31, 1999, and no later than March 1, 2000, the date on which Plaintiff VDP's predecessor-in-interest to the '711 Patent sent Welch Allyn a letter regarding the '711 Patent.

13. Defendants manufacture, sell, and/or distribute an ear wax removal system and associated replacement parts under the trade name “Welch Allyn Ear Wash System” (the “Ear Wash System”). On information and belief, the Ear Wash System was originally introduced by Defendant Welch Allyn in or about June 2001.

14. According to Defendant Welch Allyn’s website, the current price of an Ear Wash System (which includes the Ear Wash System unit, a one snap-aerator, twenty five disposable ear tips, a storage tray, and a set of standard faucet adapters) is \$365.90, and the price of a case of four boxes of replacement ear tips is \$103.50. Upon information and belief, as of November 2004, Defendant Welch Allyn had sold more than 20,000 units of their Ear Wash Systems.

15. According to page 1 of Welch Allyn’s operating manual for the Ear Wash System, the device provides for a “method of irrigation” that “is much cleaner and safer than other irrigation methods currently on the market.” According to page 9 of Welch Allyn’s operating manual, this method involves the insertion of the tip of the Ear Wash System “into the ear to create a seal” that prevents fluid from leaking out of the ear. The delivery handle and detachable tip of the Ear Wash system are connected to a source of running water that provides both irrigation and evacuation of all waste water and debris.

16. Defendants thereafter instruct or provide means which inevitably cause the operator to induce a continuous flow of body temperature water to flush cerumen from the ear and vacuum the excess water and cerumen debris into the tip of the device.

17. Defendant Welch Allyn maintains Internet websites that describe the Welch Allyn Ear Wash System, including <http://www.earwash.welchallyn.com>. That website

claims that the use of Hydrovac Action “simultaneously irrigates the ear while suctioning excess water and discharge away from you and your patient, reducing messy outflow” through the use of a “disposable eartip [that] seals the ear canal; increased pressure flushes cerumen out, an out-flow channel suctions discharge away, and a transparent filter allows you to visualize cerumen collection.” The illustration of the Ear Wash System’s so-called “Hydrovac Action” on the Welch Allyn website for the Ear Wash System is virtually identical to Figure 3 of the ’711 Patent.

18. Upon information and belief, Defendant Welch Allyn has had substantial and continuous contacts with this jurisdiction and this venue, including soliciting and filling orders for Welch Allyn Ear Wash Systems and replacement parts for persons and/or entities in this jurisdiction; maintaining websites that solicit orders from persons and/or entities in this jurisdiction; answering technical questions to persons and/or entities in this jurisdiction; and inducing or causing physicians or other health practitioners to practice the method claimed in the ’711 Patent in this jurisdiction.

19. Upon information and belief, Welch Allyn distributes literature to promote its Ear Wash System, including promotional brochures. At least one of these brochures claims that the Ear Wash System’s “eartip provides a tight seal at the patient’s ear canal” and that the system “features simultaneous irrigation and suction capabilities, which means all discharge is directed away from you and the patient.”

20. Upon information and belief, Welch Allyn distributes at least one demonstration video to promote its Ear Wash System. The video includes a demonstration of how to

use the device to create a watertight seal in the ear canal and then to effect simultaneous irrigation and suction of cerumen through the Ear Wash System.

21. Upon information and belief, Defendant Harold Ellis has had substantial and continuous contacts with this jurisdiction and this venue, including maintaining its principal place of business in the borough of Manhattan; providing in-store pickup for products at its Manhattan location; maintaining a website that is accessible to and targets customers in the New York City area; and providing local New York City area delivery of medical appliances and supplies, including the Welch Allyn Ear Wash System.

22. Upon information and belief, Harold Ellis maintains a website at <http://www.haroldellissurgicals.com> to facilitate its distribution of Welch Allyn products, including the Ear Wash System. Upon information and belief, Harold Ellis solicits online orders through this website for local delivery and in-store pick-up of medical appliances and supplies, including the Welch Allyn Ear Wash System. Upon information and belief, Harold Ellis distributes a wide range of products, including products not listed on its website.

CLAIMS FOR RELIEF

COUNT FOR INFRINGEMENT OF
UNITED STATES PATENT NO. 5,944,711

23. VDP repeats, realleges, and reincorporates by reference the allegations set forth in Paragraphs 1 through 22 of this Complaint.

24. Upon information and belief, Defendants, themselves and/or through their agents, employees, and servants, have infringed and continue to infringe the '711 Patent by mak-

ing, using, offering for sale and/or selling within the United States, and/or importing into the United States, the Welch Allyn Ear Wash System in violation of 35 U.S.C. § 271(a).

25. Upon information and belief, Defendants, themselves and/or through their agents, employees, and servants, have induced and continue to induce others to infringe the '711 Patent in violation of 35 U.S.C. § 271(b).

26. Upon information and belief, Defendants, themselves and/or through their agents, employees, and servants, have contributorily infringed and continue to contributorily infringe the '711 Patent in violation of 35 U.S.C. § 271(b).

27. Defendants have had full notice of the '711 Patent. Upon information and belief, Defendants' infringements have been and continue to be willful and intentional, Defendants having full knowledge of the '711 Patent. This is an exceptional case within the meaning of 35 U.S.C. § 285.

28. Plaintiff VDP is informed and believes and therefore alleges that Defendants' infringements will continue unless enjoined by this Court.

29. Plaintiff VDP is informed and believes and therefore alleges that Defendants have derived and received, and will continue to derive and receive, profits, gains, and other advantages from the foregoing acts of infringement in an amount not presently known to VDP. By reason of such infringing acts, VDP has been damaged and is therefore entitled to monetary relief in an amount to be determined at trial.

30. Plaintiff VDP alleges that the Ear Wash System is different in only minor and insubstantial ways from the device claimed in the '711 Patent, if it differs at all. Both de-

vices work in substantially the same fashion, using a disposable tip inserted in the ear to create a watertight seal and then continuously irrigate the ear canal with warm water to remove cerumen and simultaneously suction away the water run-off. Both devices accomplish substantially the same result, safe irrigation of the ear with reduced splatter of excess water onto the patient and physician.

JURY TRIAL DEMAND

31. Pursuant to Rule 38(b), Federal Rules of Civil Procedure, Plaintiff VDP hereby makes its demand for trial by jury of all issues so triable.

RELIEF REQUESTED

WHEREFORE, Plaintiff VDP prays for judgment in its favor against Defendants for the following relief:

A. An Order declaring that the '711 Patent is valid and has been infringed by Defendants under 35 U.S.C. § 271;

B. A preliminary and permanent injunction, pursuant to 35 U.S.C. § 283, enjoining Defendants, their officers, agents, servants, employees, attorneys, and all other persons in active concert or participation with any of them, from infringing, inducing the infringement of, or contributing to the infringement of the '711 Patent in violation 35 U.S.C. § 271;

C. An award to Plaintiff VDP of damages in an amount not less than a reasonable royalty, adequate to compensate VDP for Defendants' infringement of, inducement to infringe, and contributory infringement of the '711 Patent pursuant to 35 U.S.C. § 284;

D. An Order judging this an exceptional case pursuant to 35 U.S.C. § 285;

E. An Order trebling any and all damages awarded to VDP and/or awarding exemplary damages to VDP because of Defendants' intentional and willful infringements;

F. An award to Plaintiff VDP of its reasonable attorneys fees, pursuant to 35 U.S.C. § 285;

G. An award to Plaintiff VDP of pre-judgment and post-judgment interest and costs of this action against Defendants; and

H. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Dated: August 1, 2006 New York, New York	CAHILL GORDON & REINDEL LLP By <u>/s/ Michael B. Weiss</u> Michael B. Weiss (MW 2063) Jason R. Heller (JH 4247) 80 Pine Street New York, New York 10005 Telephone: 212-701-3000 Facsimile: 212-269-5420 Attorneys for Plaintiff VDP Patent, LLC
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EXHIBIT A



US005944711A

United States Patent [19]

[11] **Patent Number:** **5,944,711**

Pender

[45] **Date of Patent:** **Aug. 31, 1999**

- [54] **EAR-IRRIGATING METHOD AND DEVICE**
- [76] Inventor: **Daniel J. Pender**, P.O. Box 1090, Long Beach, N.Y. 11561
- [21] Appl. No.: **08/994,196**
- [22] Filed: **Dec. 19, 1997**
- [51] Int. Cl.⁶ **A61M 31/00; A61F 9/00**
- [52] U.S. Cl. **604/514; 606/162**
- [58] **Field of Search** 128/864; 606/109, 606/162; 607/137; 600/200, 563, 111, 112; D24/137, 108; 604/35, 36, 38, 39, 41, 49, 54, 73, 93, 104, 187, 257, 290, 291, 313, 346

4,201,212	5/1980	Bradley .	
4,206,754	6/1980	Grossan	604/39
4,282,867	8/1981	Du Toit	604/151
4,995,867	2/1991	Zollinger	604/54
5,312,332	5/1994	Bales et al.	604/49
5,364,343	11/1994	Apolet et al.	604/43
5,395,357	3/1995	Weigel	604/346
5,476,446	12/1995	Arenburg	604/54
5,490,836	2/1996	Desai	601/35
5,662,605	9/1997	Hurwitz	604/54
5,665,094	9/1997	Goldenberg	606/109

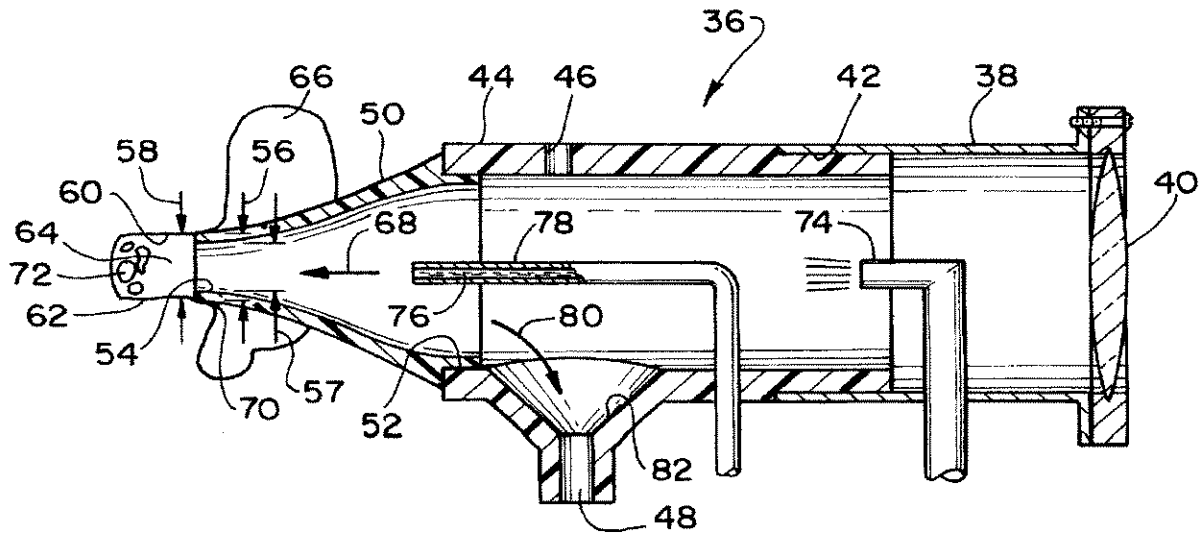
Primary Examiner—Corrine McDermott
Assistant Examiner—Sharon Finkel
Attorney, Agent, or Firm—Myron Amer PC

[57] **ABSTRACT**

Irrigating a patient's ear using an otoscope tip fitted to be seated in the ear canal, similar to the placement of a finger therein to block out noise, through which tip there is a continuous circulation of flushing fluid, wherein the seated position of the tip maintains the patient splatter-free and obviates use of a waterproof apron or the like.

- [56] **References Cited**
- U.S. PATENT DOCUMENTS**
- 989,839 4/1911 Powler .
- 2,039,546 5/1936 McGerry .
- 3,651,808 3/1972 White 604/213
- 4,036,235 7/1977 Hathaway 604/346

1 Claim, 1 Drawing Sheet



U.S. Patent

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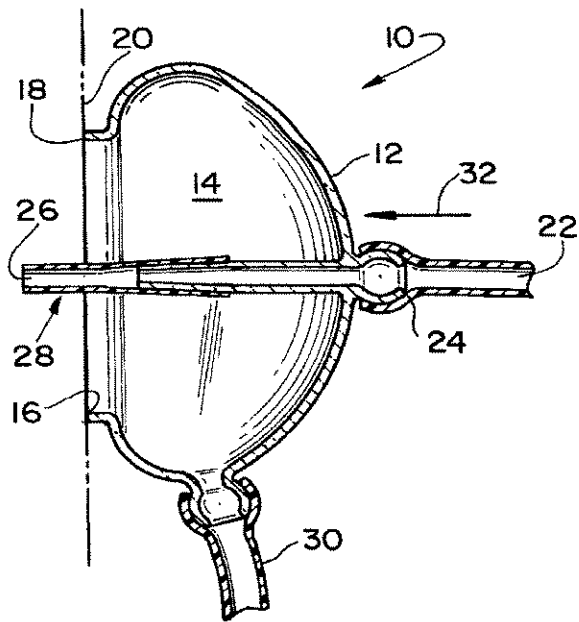


FIG. 1
PRIOR ART

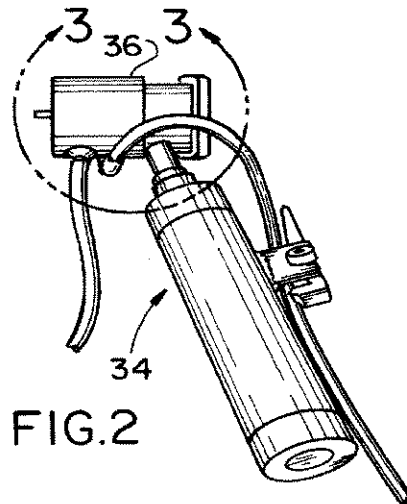


FIG. 2

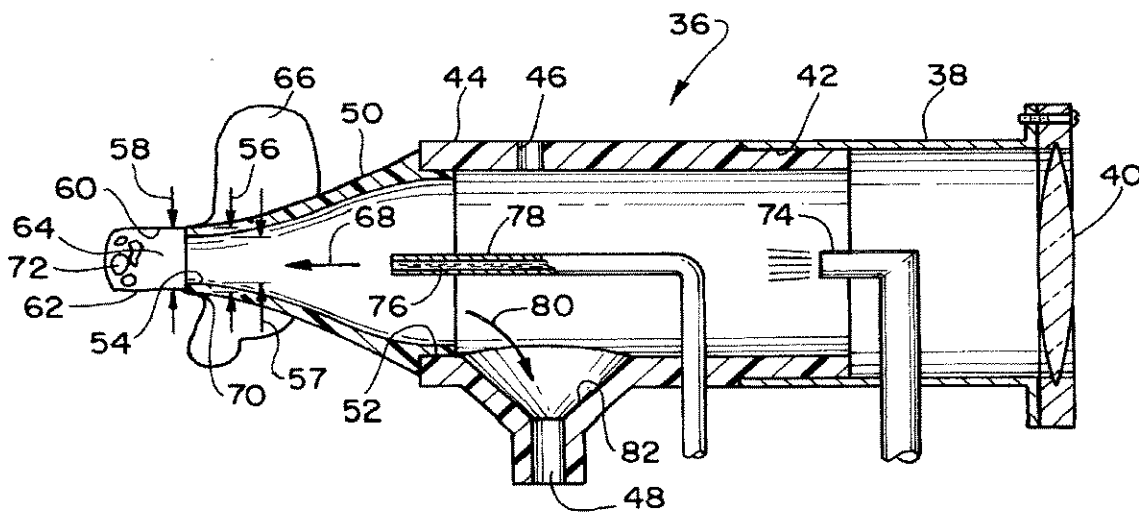


FIG. 3

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EAR-IRRIGATING METHOD AND DEVICE**FIELD OF THE INVENTION**

The present invention generally relates to improvements for an ear irrigation procedure of the type using water to flush cerumen and like debris from a patient's ear canal, the improvements more particularly greatly facilitating this procedure as well as obviating a splattering or other inconvenience to the patient.

BACKGROUND OF THE INVENTION

Removal of ear cerumen is required from time to time and is achieved by syringing body temperature or warm water into the patient's ear canal, as described and illustrated in U.S. Pat. No. 4,201,212 for "Surgical Apparatus For Use In Syringing A Patient's Ear" issued to Margaret E. Bradley on May 6, 1980. In carrying out this procedure, in which a syringe is the water-delivering device of choice, there is an inherent complication. That is, the use of a syringe which has a limited volume and therefore a limited amount of flushing warm water has to be removed from time to time during the ear canal irrigation procedure. Each time that the syringe is removed there is, of course, the loss of any fluid-tight seal and this results in leaking of any exiting flow of the irrigating or flushing warm water, in turn requiring the use of a waterproof apron, and the like, the latter being exemplified by the "Splatter-Free Ear Irrigation Device" of U.S. Pat. No. 5,395,357 issued to Perry L. Weigel on Mar. 7, 1995.

The present invention contemplates eschewing the use of a syringe in carrying out the ear irrigation procedure, which contributes the attendant benefit of more effectively maintaining the patient splatter-free without using a waterproof apron, as is typically the practice, or using other like garments, as well as providing other noteworthy benefits.

SUMMARY OF THE INVENTION

Broadly, it is an object of the present invention to overcome the foregoing and other shortcomings of the prior art.

More particularly, it is an object of the present invention to perform the ear irrigation procedure under a fluid-tight seal which is readily applied, much like, by analogy, inserting a finger in the ear canal to muffle or render inaudible external noise which, of course, is not the object of the within inventive method, but achieves an intended object of providing a fluid-tight seal to prevent splattering of the patient, all as will be better understood as the description proceeds.

BRIEF DESCRIPTION OF THE DRAWING

The description of the invention which follows, together with the accompanying drawings should not be construed as limiting the invention to the example shown and described, because those skilled in the art to which this invention appertains will be able to devise other forms thereof within the ambit of the appended claims.

FIG. 1 is a side elevational view of a prior art device for flushing wax debris or so-called cerumen from an ear canal of a patient;

FIG. 2 is a perspective view of a so-called otoscope typically used for cerumen removal embodying the within inventive structural features and having the within inventive operating mode; and

FIG. 3 is a partial sectional view, on an enlarged scale, of the ear canal-receiving tip of the otoscope.

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Preliminarily it is to be generally understood that the prior art use of a syringe which has a limited volume and therefore a limited amount of flushing warm water has to be removed from time to time during the ear canal irrigation procedure. Each time that the syringe is discharged into the ear canal, it does result in the leaking of irrigating or flushing warm water exiting from the syringe which, in turn, requires the use of a waterproof apron, and the like.

DESCRIPTION OF THE PREFERRED EMBODIMENT

A solution addressing this problem is described and illustrated in U.S. Pat. No. 989,839 for "Ear Irrigating Device" issued to E. P. Fowler on Apr. 18, 1911, a representative pertinent drawing from this patent being identified as FIG. 1. The prior art device **10** includes a glass bulb-like ear-covering component **12** bounding an internal compartment **14** sized to fit over a patient's ear (not shown) having an opening **16** opening into the compartment **14** which is bounded by an edge **18** that during use of the device **10** is held against area **20** surrounding the patient's ear, in an effort to establish a fluid-tight seal at the site of engagement between the area **20** and the edge **18**.

Beneath the glass ear cover **12** and thus under the observation of a qualified physician or the like, body temperature water is fed from a syringe (not shown) through a rear opening **22** of a nozzle **24** and through a front opening **26** of a tip **28** of the nozzle **24** into a patient's ear canal, and exits through a flexible tube **30** or the like with flushed-out cerumen. During repeated use of syringe-supplied flushing water, the fluid-tight seal at the engagement site of area **20** and edge **18** must be maintained to prevent splattering the patient. Even assuming an effort being made to exert an extent of pressure in the direction of arrow **32** contributing to maintaining the fluid-tight seal **18, 20** there is a tendency in the device of the '839 patent and in all known more modern devices to leak because of bony and raised and recessed areas in the surrounding head area **20** resulting in failure to establish total surface-to-surface contact between the head area **20** and the ear-cover front opening edge **18**.

Underlying the present invention is the recognition that an operating mode which contemplates the use of a continuous warm water supply under pressure is one which obviates the removal of the ear-irrigating instrument prior to an observed completion of cerumen removal. This operating mode as just very generally described correspondingly obviates the need for the use of a waterproof apron as is made necessary by an instrument removal and the loss of seal between the ear speculum and the wall bounding the ear canal. That is, in the operating mode of the within inventive otoscope instrument, designated **34** in FIG. 2, the flushing warm water is removed by a vacuum pump to a sump and there is no release of the seal between the otoscope tip and the wall bounding the ear canal until the cerumen removal is completed, all as will now be explained in reference to FIGS. 2 and 3.

The otoscope **34** has, pertinent to the within inventive operating mode, a flushing water delivery and removal head **36** shown in enlarged scale and in longitudinal cross section in FIG. 3. In a preferred embodiment of three cooperating housing components, head **36** has a rear cylindrical housing member **38** with a view port lens **40** telescoped, as at **42**, to a medial housing member **44** with an air vent **46** diametrically opposite a flushing water exit port **48**, and, as its third housing component, a front tip, generally designated **50**, telescoped, as at **52**, to extend forwardly of the medial housing member **44**.

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The front opening 54 of the inside diameter 57 bounds a tip 50 is of a cylindrical shape in cross section and of a selected outside diameter 56, wherein the selected diameter is slightly oversized with respect to a diameter 58 of an anatomical opening 60 bounded by the ear speculum or wall 62 bounding the ear canal 64 of the patient's ear 66. In use, the tip 50 is inserted in the direction 68 towards and into the ear canal 64 until established contact of the differing diameters 56 and 58 is made much like a friction fit, as at 70. This friction fit 70 is analogous to inserting a finger in the ear canal to muffle or render inaudible external noise which, of course, is not the object of the within inventive method, but achieves an intended object of providing a fluid-tight seal at the site 70.

Still referring to FIG. 3, it is noted for completeness' sake that visibility to observe the removal of cerumen 72 is provided by a fiber optic light source 74, that body temperature flushing water 76 is delivered under appropriate pressure from a pump through a nozzle 78 in a direction towards the ear canal 64 from whence it returns with cerumen 72 in an opposite direction 80 into a conical well shape 82 having the noted exit port 48 to a sump in which the exiting water, that is laden with cerumen 72, is appropriately disposed of at the option of the physician, it being important only that the fluid-tight seal or friction fit seal is maintained during the flowing in, and the exiting flow from, the ear until observation through the lens 40 indicates that the removal of cerumen 72 is completed.

While the apparatus for practicing the within inventive method, as well as said method herein shown and disclosed

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in detail is fully capable of attaining the objects and providing the advantages hereinbefore stated, it is to be understood that it is merely illustrative of the presently preferred embodiment of the invention and that no limitations are intended to the detail of construction or design herein shown other than as defined in the appended claims.

What is claimed is:

1. A method of irrigating a patient's ear using an otoscope of a type having an operating mode of flushing cerumen therefrom with body temperature water, said method comprising the steps of configuring a tip of said otoscope in a cylindrical shape in cross section and of a selected outside diameter, selecting a tip outside diameter that is slightly oversized with respect to a diameter of an anatomical opening of said patient's ear canal, inserting said tip into said ear canal, establishing at a site of engagement of said different diameters of said tip and said ear canal opening a friction fit obviating fluid leakage externally of said site, providing a source of body temperature water and a return sump therefore, and continuously flowing said body temperature water from said source into and removing water and cerumen from said ear of said patient for return to said sump through said tip until the removal of cerumen is completed, whereby a maintained said fluid leakage seal during said continuous flowing of said body temperature water obviates a splattering of said patient.

* * * * *