



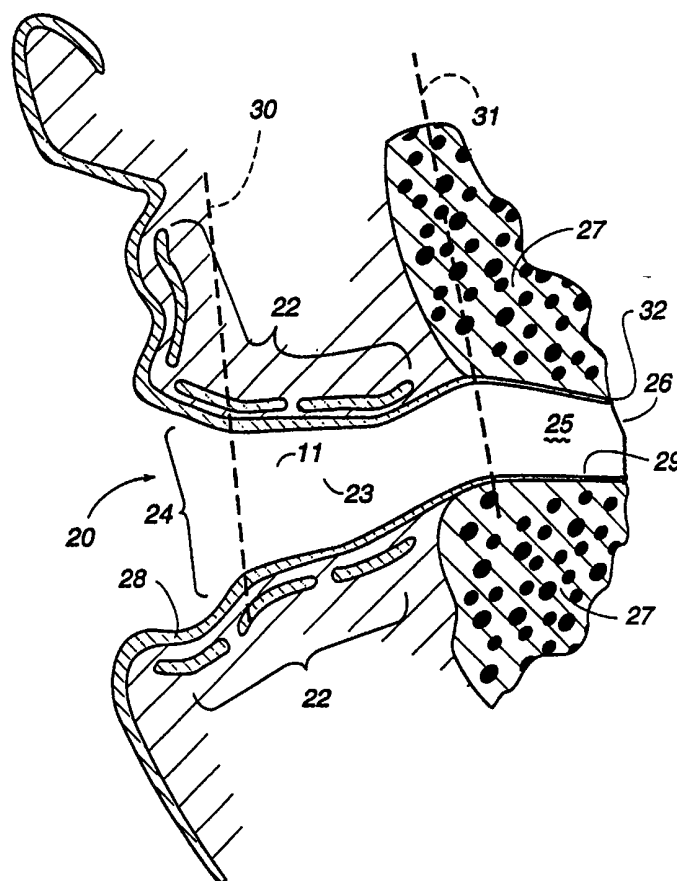
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(54) Title: ACOUSTIC COUPLER

(57) Abstract

An acoustic coupler is detachably secured to a receiver assembly for deep insertion into an individual's ear canal. The acoustic coupler provides a semirigid, thin walled, cylindrical coupling sleeve that is adapted to be attached over a cylindrical receiver assembly. A conforming sealing material is attached diametrically over the coupling sleeve to fit comfortably and to seal the individual's ear canal acoustically. The coupling sleeve is substantially concentric to the receiver assembly for a highly space efficient interface and a user friendly replacement method. Attachment of the acoustic coupler to the receiver assembly is accomplished by applying a minimal axial (push) force to secure the acoustic coupler to the receiver assembly. The coupler remains securely attached thereto, and can withstand considerable axial detachment (pull) forces without being dislodged within or outside the ear canal. Applying a rotational (twist) force with respect to the receiver housing detaches the acoustic coupler from the receiver housing. Because rotational movements are minimal during insertion or removal of the coupler from the individual's ear, accidental detachment is not possible.



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ACOUSTIC COUPLER

BACKGROUND OF THE INVENTION

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TECHNICAL FIELD

The invention relates to earpiece, hearing aid, and audio technology. More particularly, the invention relates to acoustic couplers that seal comfortably and that are adapted to be deeply inserted into an individual's ear canal.

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DESCRIPTION OF THE PRIOR ART

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Coupling sound from a receiver (speaker) into an individual's ear canal presents many design challenges for manufacturers of hearing aids, and audio and communication devices. These challenges include achieving high fidelity sounds, comfortable fit, acoustic sealing, and ease of insertion and removal.

Anatomy and Morphology of the Ear Canal.

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Figures 1 and 2 show a cross section anatomical view of the ear canal in the coronal and transverse planes of the head, respectively. The ear canal, for the purpose of this invention, can be described as having three segments. The first segment represents the medial concha cavity **20** just behind the tragus **21**, which is relatively large and is surrounded by cartilaginous tissue **22**. The second cavity **23**, medial to the aperture **24** of the external acoustic meatus **11**, is generally smaller and is also surrounded by cartilaginous tissue **22**. The third cavity **25** defines the final canal segment near the tympanic membrane **26** and is surrounded by dense bony tissue **27**. The tissue **28** lining the cartilaginous region **23** is relatively thick and has a well developed subcutaneous layer, thus allowing some expansion to occur. In contrast, the tissue **29** lining the bony region **25** is relatively thin and therefore, little or no tolerance for expansion exists in this region. The cartilaginous region **23** is the major area of cerumen (earwax) production and accumulation in the ear canal.

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The shape of a typical external ear canal, unlike that shown in most artistic renderings is rarely cylindrical or conical with a gradual narrowing towards the tympanic membrane. Instead, most ear canals are nonuniform with various levels of tortuous contours. Some canals have severe restrictions in the cartilaginous area. The

ear canal is generally “S” shaped with a first bend **30** occurring approximately at the aperture of the ear canal, and a second bend **31** occurring at the cartilaginous-bony junction.

5 The cross sectional diameter of the ear canal and the orientation of various regions within the canal are known to vary considerably from one individual to another. For example, the length from the aperture **24** to the lateral edge **32** of tympanic membrane **26** ranges from about 20 mm to about 25 mm. The cross section shape is generally oval. The smallest diameter is generally in the bony region **25** in the transverse plane and ranges from about 4 mm to about 7 mm. The largest diameter is in
10 the medial concha region **20** in the coronal plane and ranges from about 10 mm to about 18 mm.

The morphology of the ear canal reveals substantial deformation within the cartilaginous area **23** of the canal as a result of mandibular motion associated with talking, chewing, yawning, and biting. This deformation is generally caused by the
15 asymmetric stresses from the actions of the mandibular condyle **33** on neighboring cartilaginous tissue. These deformations have radial components, *e.g.* constrictions, and axial components, *i.e.* inward and outward motion. These radial and axial deformations can generally be felt when one inserts a finger in the ear canal and moves the jaw. In one study, using magnetic resonance imaging (MRI), the deformation was
20 shown to be as much as 25% in the anterior-posterior direction of the cartilaginous region of the canal (see, for example R. J. Oliveira, B. Hammer, A. Stillman, J. Holm, C. Jons, R.H. Margolis, *A Look at Ear Canal Changes with Jaw Motion*, Ear and Hearing, Vol. 13, No. 6, pp. 464-466 (1992)).

The unique and tortuous nature of individual canals in combination with the
25 dynamic canal deformations due to mandibular motion, present unsolved challenges to users of current hearing aids and other electroacoustic devices for coupling sound into the ear canal.

The Challenges of Acoustic Coupling within the Ear Canal.

30 A canal hearing device (in-the-canal and completely-in-the-canal hearing devices are referred to collectively herein as canal devices) must provide adequate acoustic sealing within the ear canal to prevent sound leakage from the receiver (speaker) outlet of the device into the microphone inlet. Such leakage causes acoustic feedback, which
35 is manifested by an annoying whistling sound. Feedback is a common problem experienced by many hearing aid users. Similarly, in earpieces for use with certain

audio and communication devices, adequate sealing deep within the ear canal is required to provide fidelity and efficient sound production.

Because of the variability of shapes and sizes of ear canals, as discussed above, and because of acoustic seal requirements to prevent feedback, most hearing devices currently on the market require custom fabrication to ensure an exact fit of the earpiece to the canal of the individual. Such custom fabrication requires an impression of the ear canal, typically made by a dispensing professional. Subsequently, a custom device or earmold is fabricated by the manufacturer according to the impression received. The insertion and removal of the impression material within the deep portion of the ear canal is not only uncomfortable, but potential complications due to hematoma or bleeding may occur (see G. Gudmunsen, *Fitting CIC Hearing Aids - Some Practical Pointers*. The Hearing Journal, Vol. 47, No. 7, pp. 46-47).

Unfortunately, even with custom earpieces or canal devices, small gaps between the ear piece and the wall of the ear canal frequently occur. These gaps, which are a significant source of acoustic feedback, occur because ear impressions are unable to mimic the geometry of the ear canal identically. Furthermore, gaps also occur during canal deformations associated with jaw movements.

Providing a tighter fit to minimize gaps and improve sealing is usually accompanied by discomfort, irritation, or even pain, particularly in the bony portion of the canal which is sensitive and more prone to discomfort and irritation.

Feedback is especially problematic for persons who wear canal devices, as compared with persons who wear larger hearing devices, such as behind-the-ear types, because the microphone sound inlet in canal devices is relatively closer to the receiver outlet. The proximity of microphone to receiver in canal devices provides less distance through which acoustic energy can travel, thus increasing the possibility of feedback. For these reasons, canal devices are typically not recommended for persons with significant hearing losses because they require greater amplification and thus are more prone to feedback than with other devices.

Another key challenge in the design of acoustic coupling in canal devices is that of space limitation within an ear canal. For cosmetic reasons, consumers demand the smallest possible devices, as evident by the dramatic increase in the use of canal devices versus larger behind-the-ear alternatives. However, even with recent advances in microminiaturization, it is not practical to include an earmold coupler to canal devices as typically used in behind-the-ear (BTE) hearing devices. Because larger devices do not have to fit entirely within the confined space of an ear canal, such devices may serially incorporate an earmold for coupling sound from a receiver that is external to the canal.

Another disadvantage of this serial coupling is the acoustic effects associated with long and narrow tubing. Transmitting an acoustic signal through narrow bore tubing in lengths exceeding approximately 10 mm, as commonly employed in such BTE devices, produces undesired alterations to the frequency response of the acoustic signal delivered to the tympanic membrane.

Replaceable acoustic couplers that seal and conform to a variety of ear canals are desirable because they eliminate the need for impressions and custom fabrication. However, current attachment mechanisms, including threading or compression fitting of miniature connections, render their application to canal devices impractical due to the dexterity requirements, particularly for the elderly who represent the largest segment of the hearing impaired population.

Several methods have been described for coupling the acoustic output of a receiver into the ear canal. Ward *et al* (U.S. patent nos. 5,031,219 and 5,201,007) disclose an earmold consisting of an acoustic conduction tube having a flexible flanged tip. The flanged tip conforms to the ear canal to provide an acoustic seal. The earmold of the device as shown in Figures 1-6 is designed for coupling with a receiver (speaker) presumably positioned outside the ear canal.

Similarly, Ahlberg *et al* (U.S. patent no. 4,880,076) and Oliveira *et al* (U.S. patent no. 5,002,151) disclose a replaceable compressible polymeric foam sleeve (Figs. 1 and 2 in both patents) having a duct **16** formed with a female screw thread **20** which mates with a male screw thread **12** of an earpiece. The receiver, not shown in any of the figures, is presumably either within the earpiece or external thereto, but coupled serially to the replaceable acoustic coupler.

Hardt (U.S. patent no. 4,607,720) discloses a silicone rubber sealing plug that is detachably connected to the housing of a hearing aid via a miniature coupling element. The sealing plug is coupled via a snap, friction, or threading mechanism.

A significant disadvantage of the prior art is the serial positioning of a foam sleeve with respect to a canal hearing device or an ear piece. This not only adversely affects the characteristics of sound from the receiver, but also consumes considerable space within the ear canal. These limitations render such a replaceable acoustic coupler unsuitable for canal devices.

Another disadvantage of the prior art is the attachment method disclosed, which requires considerable dexterity for the threading or alignment of the miniature connecting parts. This is especially problematic for persons of limited dexterity, *e.g.* elderly or physically handicapped persons, as is the case with many hearing aid users.

Garcia *et al* (PCT patent application no. PCT/IB95/00164) disclose a hearing aid having a sealing collar which is positioned deep within the bony portion of the ear

canal. The collar is attached through a connecting part at the medial (innermost) end of canal device. Although the collar is considerably more space efficient than the prior art device described above, the attachment method also demands considerable dexterity (e.g. see Garcia *et al*, page 7, line 9: "The collar is detachably connected to the housing by its fixing portion, in the present case via a bayonet coupling...[, enabling] the collar to be replaced simply by means of suitable tool.").

Shennib *et al* (U.S. patent application serial no. 08/365,913) disclose an acoustic seal which is attached to a receiver module, as shown in Figures 15-18. The acoustic seal provides little or no addition to the length to the hearing device. However, the disclosed invention does not teach improvements in the placement and manipulation of the acoustic seal.

It would be advantageous to provide an acoustic coupler that seals comfortably and effectively, and that may be deeply inserted into the ear canal of an individual.

15 SUMMARY OF THE INVENTION

The invention provides an intracanal earpiece consisting of a receiver assembly and a replaceable acoustic coupler that provide improved acoustic sealing and user comfort when positioned within an ear canal. The acoustic coupler is detachably secured to a receiver assembly for deep insertion into the ear canal. The acoustic coupler can be easily replaced without any special tools, even by persons of limited dexterity.

The invention provides an earpiece assembly for coupling sound deep into the ear canal without adversely affecting the size of the ear piece or the characteristics of the sound emanating from the receiver.

In the preferred embodiment of the invention, the acoustic coupler provides a semirigid, thin walled, cylindrical coupling sleeve that is adapted to be attached over a cylindrical receiver assembly. A conforming sealing material is attached diametrically over the coupling sleeve to fit comfortably, and to seal the ear canal acoustically. The coupling sleeve of the acoustic coupler is essentially concentric to the receiver assembly for a highly space efficient interface and a user friendly replacement method.

Attachment of the acoustic coupler to the receiver assembly is performed by applying a minimal axial (push) force to secure the acoustic coupler to the receiver assembly. The coupler remains securely attached and can withstand considerable axial detachment (pull) forces without being dislodged within or outside the ear canal. However, by applying a rotational (twist) force with respect to the receiver housing, the acoustic coupler can be easily detached from the receiver housing. Because rotational

movements are minimal during insertion or removal of the coupler from the ear, accidental detachment is not possible. This unique snap on, twist off mechanism eliminates the necessity of precisely aligning and positioning the separate members relative to each other to attach the acoustic coupler onto the receiver housing, a major benefit to the elderly, who may be visually impaired and/or of limited manual dexterity.

The receiver assembly contains a unique thread form along its outer perimeter. This relatively rigid member is threaded with a directionally tapered thread form and mates with a similarly tapered female thread form along the inner perimeter of the coupling sleeve of the acoustic coupler. The male thread exists only in two opposite locations on the perimeter of the receiver assembly, with the remainder of the perimeter being relieved at least to the minor diameter of the male thread. The coupling sleeve is relatively elastic and thin walled, such that the axial pressure developed by pushing the coupling sleeve onto the receiver assembly deforms the coupling sleeve into an elliptical shape. However, the sleeve is sufficiently rigid such that rotational forces do not deform the sleeve. Thus detachment is only possible by unmating the threads of the receiver assembly and the coupling sleeve through rotational motion, thereby providing a safe and convenient attachment method.

The coupling sleeve substantially surrounds the receiver assembly radially, rather than being serially connected. This arrangement minimizes the length of the earpiece assembly. This feature of the invention is especially significant for canal devices, where any added length of rigid material is likely to jeopardize safety, comfort, or cosmetic acceptance of the earpiece.

The invention also offers a user friendly cartridge for the dispensing and attaching of the acoustic coupler. The dispensing cartridge contains removable acoustic couplers whereby the consumer can push the receiver assembly of the earpiece against the coupler within the dispensing cartridge and cause the coupler to snap on. The consumer subsequently removes the coupler from the dispensing cartridge for insertion and use in the ear canal, thus preventing unnecessary contamination of the acoustic seal due to handling, *e.g.* when the consumer touches the coupler during installation.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an anatomical view of an ear canal in coronal plane;

Figure 2 is an anatomical view of an ear in the transverse plane;

Figure 3 is a sectioned view of the earpiece showing a receiver assembly and an acoustic coupler;

Figure 4a is a cross section of a circular receiver housing and a circular coupling sleeve after insertion;

Figure 4b is a cross section of a circular receiver housing and a circular coupling sleeve during insertion;

5 Figure 5 is a sectioned view of the earpiece showing radial deformation of the coupling sleeve in response to axial push forces;

Figure 6a is a cross section of an elliptical receiver housing and an elliptical coupling sleeve before detachment;

10 Figure 6b is a cross section of an elliptical receiver housing and an elliptical coupling sleeve during attachment and detachment;

Figure 7 is a cross section of the earpiece within the ear canal;

Figure 8 is a side view showing venting pathway between the receiver housing and coupling sleeve;

15 Figure 9 is a plot of the acoustic attenuation of an earpiece with venting of one slit versus two slits;

Figures 10-16 show various shapes and forms of conforming acoustic seals;

Figure 17 shows a dispensing cartridge with disposable acoustic seals;

Figure 18 shows the form of acoustic seal within the dispensing cartridge before (top) and during (bottom) the attachment to the receiver housing;

20 Figure 19 is a coronal view of the ear canal showing a canal hearing device with an earpiece; and

Figure 20 is a coronal view of the ear canal with an earpiece for connection to an external audio device.

25 DETAILED DESCRIPTION OF THE INVENTION

The invention described herein is used to couple acoustic signals in an individual's ear canal. An earpiece and acoustic coupler are adapted for use with any hearing device or any audio system to couple sound to the ear canal. The invention is particularly applicable for use in conjunction with the Articulated Hearing Device described by Shennib *et al* (U.S. patent application serial no. 08/365913).

30 The invention provides an intracanal earpiece consisting of an acoustic coupler having a coupling sleeve that mates over a cylindrical receiver assembly. The earpiece can be deeply inserted into an individual's ear canal.

35 Figure 3 is a cross sectional representation of an earpiece **40** showing a receiver assembly **48** and an acoustic coupler **50** according to the presently preferred embodiment of the invention. The earpiece **40** may be part of a canal hearing device

10, as shown in Figure 19, or part of an audio system external to the ear canal but coupled, either electrically via a signal cable 39 or by other means, to the earpiece, as shown in Figure 20. A handle 38 (Figure 20) facilitates insertion and removal of the hearing device, as well as providing strain relief for wires 37 within the signal cable 39. Other means for coupling audio signals into the earpiece may include, for example, a wireless link such as a radio frequency (RF) or infrared link (IR).

The receiver assembly of the canal device or the audio system may be articulated to facilitate handling and deep insertion into the ear canal. Articulation may be achieved by a ball joint 12, as shown in Figure 18.

10 The receiver assembly 48 (Fig. 3) contains a receiver 41 coupled to a receiver housing 42 via a receiver housing coupler 43. A receiver guard 47 is provided to protect the receiver from environmental and physiologic residue, including cerumen (earwax). A receiver sound port 49 provides an outlet for sound emission to a coupler sound port 55, and subsequently to the tympanic membrane 26. A vibration isolator 15 44 is provided to isolate the mechanical vibration of the receiver 41 from the receiver housing 42, and subsequently from the hearing device 10. Relatively rigid and tapered male threads 45 are provided for coupling the receiver housing with an acoustic coupler 50. Figure 4 shows the partial threads 45 which are positioned on opposite sides on the perimeter of the receiver housing 42.

20 The acoustic coupler 50 (Fig. 3) contains a coupling sleeve 52 having coupling threads 53 and a conforming acoustic seal 51 which conforms to the shape of the ear canal when inserted therein. The coupling sleeve 52 is made of an elastically deformable, thin walled material, such as plastic. A venting slit 54 is provided for pressure venting and low frequency acoustic relief.

25 During the attachment process, the receiver assembly 48 is inserted into the acoustic coupler 50, as shown in Figures 3, 4a, 4b, and 5. Attachment is performed by applying axial (push) forces to the acoustic coupler which cause deformation of the coupling sleeve 52 as it is being pushed against the tapered and partial male thread 45 of the receiver assembly 48. As Figures 4a, 4b, and 5 illustrate, the axial forces 80 30 engaging the male threads of the receiver housing create radial forces 81 which deform the essentially elastic coupler into an elliptical shape, thus allowing the coupler thread to slide over the crests of the tapered male thread of the receiver housing. Figures 4a and 4b show the perimeter of the coupler sleeve 52A and 52B during (Fig. 4b) and after (Fig. 4a) the insertion process, respectively. The coupler sleeve deforms to an 35 essentially elliptical shape 52A as defined by the perimeter of the receiver housing with its partial male threads 45 and relieved area 46 of the receiver housing 42.

When the acoustic coupler is fully engaged, the coupling sleeve **52** is fully restored to its original cylindrical form **52B** (Figs. 4a and 4b) and **52** (Fig. 5). The mated receiver and coupling threads, **45** and **53**, respectively, ensure secure attachment of the acoustic coupler **50** to the receiver assembly **48**. The interlocking, tapered design of the mated threads prevents reasonable pull axial forces from detaching the acoustic coupler, allowing mainly rotational (twist) forces to remove the acoustic coupler.

After the acoustic coupler **50** is attached to the receiver assembly **48**, as described above, the coupled parts are then inserted and positioned deeply within an individual's ear canal. Because rotational (twist) forces are minimal during insertion, removal, or while the device is being worn in the ear canal, the acoustic coupler remains securely attached during normal use. Removal of the acoustic coupler from the receiver assembly is simply performed by rotating (twisting) the acoustic coupler **50** with respect to the receiver assembly **48**. Such motion is only possible when the acoustic coupler **50** is external to the ear canal, thus preventing the potential accidental removal of the acoustic coupler **50** from the receiver assembly **48** while the earpiece is in the ear canal.

The material and dimensional designs of the receiver housing **42** and the acoustic coupler **50**, particularly the threads, are selected to minimize axial attachment forces and rotational detachment forces. This results in a simple snap on, twist off mechanism which can be readily understood and operated, even by persons having limited dexterity or poor vision.

In another embodiment of the invention, the receiver housing and the acoustic coupler have an elliptical shape to improve fit and acoustic sealing for ear canals that are generally oval. Figures 6a and 6b show a cross section of an elliptical receiver housing with threads **45** on the larger diameter and a relieved area **46** on the narrow diameter. The elastically deformable coupling sleeve **52** is also elliptical. Similarly, the coupling sleeve deforms **52B** during the attachment process (Fig. 6b) and its partial female threads **53** (Fig. 5) mate with the partial male threads **45** of the receiver housing. The detachment (Fig. 6b) is performed by a force **82** applied inwardly on the minor axis of coupling sleeve which causes the major axis to expand **52B**, thus disengaging the mated threads. A simultaneous pull force removes the acoustic coupler from the receiver assembly. This inward squeeze and pull combination is simple and can be easily performed manually.

The invention is not limited to the specific shape, attachment, and detachment methods disclosed above, and other configurations will become obvious to those skilled in the art.

To facilitate insertion and optimize acoustic sealing deep in the ear canal, the wall thickness of the acoustic coupler sleeve **52** and the receiver housing **42** are substantially less than the thickness of the conforming acoustic seal **51** or the diameter of the receiver **41**. Figure 7 shows a cross section of the earpiece within the ear canal and demonstrates the sealing and space efficiencies of the invention. The receiver **41** is at the center with a vibration isolator **44** between the receiver **41** and the receiver housing **42**. The receiver housing threads **45** mate with the coupler sleeve **52**. The diameter added to the receiver **41** by the surrounding structures is minimal to maximize the diameter of the conforming acoustic seal **51**. This is essential to optimize the ability of the acoustic seal **51** to conform and seal comfortably within typically odd shaped regions in the ear canal, as shown in Figure 7. The unique design of the invention allows for use of conventional miniature hearing aid receivers, such as model nos. ES3126 and SD3183, manufactured by Knowles Electronics of Itasca, Illinois.

The vibration isolator **44** within the receiver assembly **48** is typically made of a viscoelastic material which also protects the receiver from potential damage if the earpiece is dropped onto a hard surface.

The earpiece includes a venting system that equalizes the pressure within the ear canal to that of the outside environment. This is desirable to protect the tympanic membrane **26** from sudden pressure changes during insertion and removal of the earpiece, or during actual pressure changes in the outside environment. Furthermore, such venting alleviates occlusion effects which include undesirable low frequency acoustical energy generated within the external ear canal during walking or jaw movements or due to the user's own voice. These occlusion effects can be substantially reduced via a vent. However, the dimensions and design of the vent must be such that pressure equalization and alleviation of occlusion effects are achieved without producing significant high frequency leakages to prevent the oscillatory feedback typically associated with such high frequency leakages.

An example of a venting system in the earpiece of the invention is shown in Figure 8. Venting is provided via a venting path **71** which consists of the space between the coupling sleeve **52** and the relieved area **46** of the receiver housing **42** and through a venting slit **54** on the coupling sleeve **52**. The shape and dimensions of the spacing and venting slit determine the characteristics of the venting.

A plot of the acoustic attenuation of the earpiece showing the effect of a single venting slit (dashed line) versus two venting slits (solid line) is shown in Figure 9. Each slit has a cross section area of approximately 0.25 mm². Acoustic attenuation is plotted by computing the difference between the sound pressure produced near the coupler sound port **55** (Fig. 3) within a first coupler (*i.e.* a 0.5 cc coupler) and the

leaking sound pressure measured in a second coupler containing a venting slit **54**. Two miniature probe tubes and probe tube amplifiers, *i.e.* model no. ER-7C, manufactured by Etymotic Research, Inc., were used for the measurements of sound pressure level within each coupler. A two channel signal analyzer, model no. SR780, manufactured
5 by Stanford Research System, was used for the analysis and display of the acoustic attenuation across audiometric frequencies up to about 5000 Hz.

Figure 9 shows that the venting system maintains a significant attenuation (exceeding 45 dB) at frequencies above 2000 Hz. However, relatively less attenuation (more leakage) is produced at low frequencies, particularly below about 200 Hz. This is
10 a desirable effect because most individuals require significant attenuation only at high frequencies to minimize high frequency feedback, but require less attenuation at lower frequencies to alleviate occlusion effects.

Venting can be achieved in a variety of ways within the intracanal earpiece and thus is not limited to the pathway within the coupling of the receiver assembly and the coupling sleeve. For example, a vent tube **61** may be included in the conforming
15 acoustic seal **51**, as shown in Figure 10. Venting can also be inherent in the property of the material used for the conforming acoustic seal. For example, certain types of polyurethane foam allow a limited amount of air leakage due to the open cell nature of their structure. Also, venting may be provided by a pathway designed into the receiver
20 housing (not shown).

The acoustic coupler is provided with a debris guard **57** (Fig. 3) for protection of the receiver and collection of environmental and physiologic debris, including cerumen. An acoustic coupling tube **56** is provided closer to the eardrum for coupling
25 sound emanating from the receiver. The acoustic coupling tube **56** is preferably soft and flexible, but of sufficient rigidity to prevent collapse of the walls of the sound port **55** upon insertion of the acoustic coupler **50** into the ear canal, thus preventing occlusion of sounds emanating from the receiver **41**.

Even though the coupling sleeve **52** closely follows the dimensions of the receiver housing because it essentially surrounds the receiver housing, the conforming
30 acoustic seal **51** extends variably radially and axially to accommodate a broad range of human ear canal sizes and shapes.

Figures 10-16 show an assortment of conforming acoustic seals **51** that is representative, but not exhaustive, of acoustic seals that may be used in accordance with the invention. The underlying coupling sleeve **52** and other common elements of the
35 acoustic coupler are not always shown in Figures 10-16 for the sake of brevity and clarity.

Figure 10 shows an acoustic seal having minimal dimensions for small or short ear canals. The shape is slightly tapered to facilitate deep insertion within the ear canal. In this embodiment no acoustic coupling tube **56** is required because the sound port **55** is short and unlikely to be occluded within the ear canal.

5 Figure 11 shows an acoustic seal having a relieved area **58** to facilitate deep insertion and comfort, particularly for ear canals that are highly tortuous. The acoustic coupling tube **56** may be fabricated by attaching a soft tubing, such as silicone tubing, or may be formed by *in situ* molding of compliant material, such as RTV silicone, hot melt adhesive, or epoxy, within the sound port **55**.

10 Figure 12 shows an acoustic coupler having a conforming acoustic seal with flanges **59** that substantially extend beyond the coupling sleeve **52** towards the tympanic area **26**. However, the coupling sleeve **52** substantially surrounds the receiver housing (not shown).

15 Figure 13 shows a conforming acoustic seal having flanges **69** that substantially surround the coupling sleeve **52**.

Figure 14 shows a conforming acoustic seal having flanges that both surround and extend beyond the coupling sleeve **52**.

Figure 15 shows a conforming acoustic seal having a backward fold **67**.

20 The design of the flanges and surface texture of the conforming acoustic seal **51** can be optimized to facilitate the insertion and removal of the earpiece, as well as to assist in the retention of the earpiece while it is in an individual's ear canal.

25 The material of the conforming acoustic seal is preferably soft and compliant to adapt to the variable and irregular shape of the human ear canal. Polymeric foams and elastomers, such as polyurethane or silicone rubber materials, are known for their desirable properties as well as their safe and biocompatible use within the ear canal.

30 To facilitate insertion of the conforming acoustic seal, the material used in one embodiment is a polymer which can be compressed substantially and rapidly outside the ear canal, yet is relatively slow to decompress within the ear canal, thus allowing the user to easily insert it into the ear canal prior to full recovery of its uncompressed shape and size. The compression and slow recovery properties of the material are partially determined by the fabrication process and composition of the material. For example, a partially open cell foam structure allows the air to leak out when compressed and recover with time as air refills the cells. It is desirable for the conforming acoustic seal to recover within approximately 30 seconds to seal the ear canal rapidly, while allowing
35 enough time for the user to fully insert the earpiece into their ear canal, thus minimizing the feedback experience prior to sufficient recovery.

To facilitate the insertion of the earpiece into the ear canal, particularly for persons of limited dexterity, it is desirable to provide a lubricous acoustic seal by applying or treating the surface of the conforming acoustic seal with the appropriate lubricant **62**, as shown in Figure 16. Petroleum jelly and mineral oil were applied to the surfaces of the acoustic seals and were found to be effective lubricants when used in moderate amounts. Lubricous properties may also be in the form of additives within the conforming acoustic seal material. Other lubricous coatings or additives include hydrogel, polyvinyl pyrrolidone (PVP), polyvinyl alcohols (PVA), siliconization, flouropolymers, waxes, and oils.

Coatings and additives for the conforming acoustic seal can also have medicinal properties, including bacterial agents such as Silver/silver oxide, iodine, antibiotics, surfactants, fungicidal agents, and anti-inflammatory agents. These medicinal substances can reduce the affects of ear canal irritation and infections due to inadvertent contamination of acoustic coupler or the ear canal.

Furthermore, coatings, additives, and design features, such as flanges, can be optimized to assist in removal of ear canal debris as disposable acoustic couplers are replaced by the user.

The invention also provides a user friendly cartridge for the dispensing of the acoustic coupler, as shown in Figures 17 and 18. The dispensing cartridge **70** contains cavities **71** that contain removable disposable acoustic couplers **50**. The consumer can push a receiver assembly **48** against the acoustic coupler **50** within the dispensing cartridge **70**, causing the coupler to snap on to the receiver assembly, and then subsequently remove the acoustic coupler **50** from the dispensing cartridge **70** for insertion and use in the ear canal. The shape of the cavity **71** may be tapered, as shown in Figure 18. A tapered area **72** temporarily compresses the acoustic coupler while it is being connected to the receiver assembly **48**. This temporary compression facilitates subsequent insertion and expansion of the acoustic coupler within the ear canal. In another embodiment, the acoustic couplers are precompressed in cavities having smaller diameters. The precompressed acoustic couplers subsequently expand within the ear canal.

EXAMPLE

A prototype of the earpiece consisting of an acoustic coupler and a receiver housing were fabricated. Force measuring instruments, model nos. FGV-5 and FGV-50, manufactured by Shimpo, were used to measure peak axial forces related to attaching and detaching the acoustic coupler from receiver housing, and also to measure

the typical peak force required for removing the earpiece from the ear canal. A torque measuring instrument, model no. MGT10Z, manufactured by Mark 10, was used for measuring rotational torque required for normal detachment of the acoustic coupler.

5 For purposes of the discussion herein, the test parameters are defined as follows:

- Axial Attachment Force (F_{ax-att}), is the peak axial force in Newtons required to attach the acoustic coupler to the receiver housing;
- 10 • Axial Detachment Force (F_{ax-det}) is the peak axial force in Newtons required to detach the acoustic coupler from the receiver housing;
- Rotational Detachment Torque ($T_{rot-det}$) is the peak torque in Newton-centimeters required to detach the acoustic coupler from the receiver housing; and
- 15 • Earpiece Removal Force (F_{ep-rem}) is the peak force (essentially axial) in Newtons required for the removal of the earpiece from the ear canal.

20 The test was repeated on two different acoustic coupler samples representative of the invention.

The results including the average of the two samples are included in Table 1, below:

25

Table 1. Test Results

| Test Parameter | Sample #1 | Sample #2 | Average |
|------------------------------------|------------------|------------------|----------------|
| Axial Attachment Force (Nt) | 5.93 | 5.79 | 5.86 |
| Axial Detachment Force (Nt) | 21.0 | 36.6 | 28.8 |
| Rotational Detachment Torque (Ncm) | 0.71 | 0.93 | 0.82 |
| Earpiece Removal Force (Nt) | 2.06 | 1.61 | 1.84 |

5 The results confirm that the axial detachment forces are considerably greater than the axial attachment forces and the earpiece removal forces, thus minimizing the opportunity for accidental detachment of the acoustic coupler outside and within the ear canal. The results also confirm that because the rotational detachment torque is minimal, rotational detachment represents the preferred method of detaching the acoustic coupler from the receiver housing.

10 Although the invention is described herein with reference to the preferred embodiment, one skilled in the art will readily appreciate that other applications may be substituted for those set forth herein without departing from the spirit and scope of the invention. Accordingly, the invention should only be limited by the Claims included below.

CLAIMS

1. An intracanal acoustic coupler for coupling acoustic signals from an intracanal receiver assembly and delivering said acoustic signals into an individual's ear canal, comprising:
5 a coupling sleeve adapted to be positioned substantially concentric over said receiver assembly;
means associated with said coupling sleeve for attaching said acoustic coupler to said receiver assembly using minimal push axial forces, wherein axial pull forces are significantly higher than said push axial attachment forces; and
10 an acoustic seal provided about said coupling sleeve, said acoustic seal adapted to conform to the shape of said individual's ear canal when inserted therein.
2. The acoustic coupler of Claim 1, wherein said means for attaching comprise a snap on mechanism for attaching said acoustic coupler to said receiver assembly, and a rotational, twist off mechanism for detaching said acoustic coupler from said receiver assembly.
15
3. The acoustic coupler of Claim 1, wherein said means for attaching comprise a snap on mechanism for attaching said acoustic coupler to said receiver assembly, and a squeeze and pull mechanism for detaching said acoustic coupler from said receiver assembly.
20
4. The acoustic coupler of Claim 1, wherein said acoustic coupler is adapted to be readily replaceable.
25
5. The acoustic coupler of Claim 1, wherein said acoustic coupler is disposable.
6. The acoustic coupler of Claim 1, wherein said acoustic coupler is adapted for use with either of a hearing device or an intracanal earpiece.
30
7. The acoustic coupler of Claim 6, wherein said hearing device is a canal device.
8. The acoustic coupler of Claim 1, wherein said acoustic coupler is adapted for use with an intracanal earpiece in conjunction with an external audio system connected thereto via at least one of a cable and a wireless link.
35

9. The acoustic coupler of Claim 6, wherein said hearing device and intracanal earpiece are articulated.
- 5 10. The acoustic coupler of Claim 1, wherein said coupling sleeve is thin walled and elastically deformable.
11. The acoustic coupler of Claim 1, wherein said coupling sleeve has either a circular or an elliptical shape.
- 10 12. The acoustic coupler of Claim 1, wherein said means for attaching further comprise partial locking threads formed on or at said receiver assembly, wherein said threads deform said coupling sleeve during attachment of said acoustic coupler.
- 15 13. The acoustic coupler of Claim 12, wherein said partial locking threads are tapered to deform said coupling sleeve.
14. The acoustic coupler of Claim 1, wherein said acoustic seal is substantially concentric to said coupling sleeve.
- 20 15. The acoustic coupler of Claim 1, wherein said acoustic seal is adapted to extend past said receiver assembly towards an individual's eardrum.
- 25 16. The acoustic coupler of Claim 1, wherein said acoustic seal is both substantially concentric to said coupling sleeve, and extends past said receiver assembly towards an individual's eardrum.
17. The acoustic coupler of Claim 1, wherein said acoustic seal has at least one relieved region to facilitate insertion into an individual's ear canal.
- 30 18. The acoustic coupler of Claim 1, wherein said acoustic seal has at least one flange.
19. The acoustic coupler of Claim 1, wherein said acoustic seal has at least one backward fold.
- 35

20. The acoustic coupler of Claim 1, wherein said acoustic seal has either a lubricous coating or an additive that facilitates insertion or removal of said acoustic coupler within an individual's ear canal.
- 5 21. The acoustic coupler of Claim 6, wherein said acoustic seal is adapted to facilitate retention of either of said canal device or said intracanal earpiece within an individual's ear canal.
- 10 22. The acoustic coupler of Claim 1, further comprising:
a debris guard for the protection of a receiver within said receiver assembly and for the collection of debris within an individual's ear canal.
- 15 23. The acoustic coupler of Claim 1, further comprising:
one or more surface features for extraction of debris within an individual's ear canal.
- 20 24. The acoustic coupler of Claim 1, wherein said acoustic seal comprises either a material or a coating of a medicinal substance including at least one of an antibacterial, antibiotic, anti-inflammatory, and antifungacital agent.
- 25 25. The acoustic coupler of Claim 1, further comprising:
a venting system for pressure relief and to alleviate occlusion effects.
27. The acoustic coupler of Claim 1, wherein said acoustic seal is formed of a material that is compressible and that recovers to a less compressed state within an individual's ear canal after a sufficient time interval to facilitate insertion, sealing, and retention of said acoustic coupler within an individual's ear canal.
- 30 27. The acoustic coupler of Claim 26, wherein said material substantially recovers within about 30 seconds.
- 35 28. An intracanal earpiece, comprising:
a receiver assembly containing a receiver;
an acoustic coupler for coupling acoustic signals from said receiver assembly and delivering said acoustic signals into an individual's ear canal, comprising:
a coupling sleeve adapted to be positioned substantially concentric over said receiver assembly;

means associated with said coupling sleeve for attaching said acoustic coupler to said receiver assembly using minimal push axial forces, wherein axial pull forces are significantly higher than said push axial attachment forces; and

5 an acoustic seal provided about said coupling sleeve, said acoustic seal adapted to conform to the shape of said individual's ear canal when inserted therein.

29. The intracanal earpiece of Claim 28, wherein said means for attaching comprise a snap on mechanism for attaching said acoustic coupler to said receiver assembly, and a rotational, twist off mechanism for detaching said acoustic coupler from said receiver
10 assembly.

30. The intracanal earpiece of Claim 28, wherein said means for attaching comprise a snap on mechanism for attaching said acoustic coupler to said receiver assembly, and a squeeze and pull mechanism for detaching said acoustic coupler from said receiver
15 assembly.

31. The intracanal earpiece of Claim 28, wherein said acoustic coupler is adapted to be readily replaceable.

20 32. The intracanal earpiece of Claim 28, wherein said acoustic coupler is disposable.

33. The intracanal earpiece of Claim 28, wherein said acoustic coupler is adapted for use with either of a hearing device or an intracanal earpiece.
25

34. The intracanal earpiece of Claim 33, wherein said hearing device is a canal device.

35. The intracanal earpiece of Claim 28, wherein said acoustic coupler is adapted for use with an intracanal earpiece in conjunction with an external audio system connected thereto via at least one of a cable and a wireless link.
30

36. The intracanal earpiece of Claim 33, wherein said intracanal hearing device and intracanal earpiece are articulated.
35

37. The intracanal earpiece of Claim 28, wherein said coupling sleeve is thin walled and elastically deformable.

38. The intracanal earpiece of Claim 28, wherein said coupling sleeve has either a circular or an elliptical shape.
- 5 39. The intracanal earpiece of Claim 28, wherein said means for attaching further comprise partial locking threads formed on or at said receiver assembly, wherein said threads deform said coupling sleeve during attachment of said acoustic coupler.
- 10 40. The intracanal earpiece of Claim 39, wherein said partial locking threads are tapered to deform said coupling sleeve.
41. The intracanal earpiece of Claim 28, wherein said acoustic seal is substantially concentric to said coupling sleeve.
- 15 42. The intracanal earpiece of Claim 28, wherein said acoustic seal is adapted to extend past said receiver assembly towards an individual's eardrum.
- 20 43. The intracanal earpiece of Claim 28, wherein said acoustic seal is both substantially concentric to said coupling sleeve, and extends past said receiver assembly towards an individual's eardrum.
44. The intracanal earpiece of Claim 28, wherein said acoustic seal has at least one relieved region to facilitate insertion into an individual's ear canal.
- 25 45. The intracanal earpiece of Claim 28, wherein said acoustic seal has at least one flange.
46. The intracanal earpiece of Claim 28, wherein said acoustic seal has at least one backward fold.
- 30 47. The intracanal earpiece of Claim 28, wherein said acoustic seal has either a lubricous coating or an additive that facilitates insertion or removal of said acoustic coupler within an individual's ear canal.
- 35 48. The intracanal earpiece of Claim 34, wherein said acoustic seal is adapted to facilitate retention of either of said canal device or said intracanal earpiece within an individual's ear canal.

49. The intracanal earpiece of Claim 28, further comprising:
a debris guard for the protection of a receiver within said receiver assembly and
for the collection of debris within an individual's ear canal.
- 5
50. The intracanal earpiece of Claim 28, further comprising:
one or more surface features for extraction of debris within an individual's ear
canal.
- 10
51. The intracanal earpiece of Claim 28, wherein said acoustic seal comprises either
a material or a coating of a medicinal substance including at least one of an antibacterial,
antibiotic, anti-inflammatory, and antifungacital agent.
- 15
52. The intracanal earpiece of Claim 28, further comprising:
a venting system for pressure relief and to alleviate occlusion effects.
- 20
53. The intracanal earpiece of Claim 28, wherein said acoustic seal is formed of a
material that is compressible and that recovers to a less compressed state within an
individual's ear canal after a sufficient time interval to facilitate insertion, sealing, and
retention of said acoustic coupler within an individual's ear canal.
- 25
54. The intracanal earpiece of Claim 53, wherein said material substantially recovers
within about 30 seconds.
- 30
55. A dispenser for dispensing one or more intracanal acoustic couplers, said one or
more acoustic couplers each having an acoustic seal provided about a coupling sleeve,
wherein said acoustic seal is adapted to conform to the shape of an individual's ear
canal when inserted therein, wherein means associated with said acoustic coupler are
adapted to attach said acoustic coupler to a receiver assembly using minimal push axial
forces, wherein axial pull forces are significantly higher than said push axial attachment
forces, the dispenser comprising:
a cartridge comprising one or more cavities formed therein for dispensing one
or more acoustic couplers.
- 35
56. The dispenser of Claim 55, wherein said one or more cavities are tapered for
temporary compression of said acoustic coupler during attachment of said acoustic
coupler to said receiver assembly.

57. The dispenser of Claim 55, wherein said one or more cavities are smaller than said acoustic coupler to precompress said acoustic seal prior to attachment of said acoustic coupler to said receiver assembly.

5

58. The dispenser of Claim 55, wherein said intracanal acoustic coupler is disposable.

10

59. The dispenser of Claim 15, wherein said acoustic seal further comprises an acoustic coupling tube.

60. The dispenser of Claim 42, further comprising:
an acoustic coupling tube.

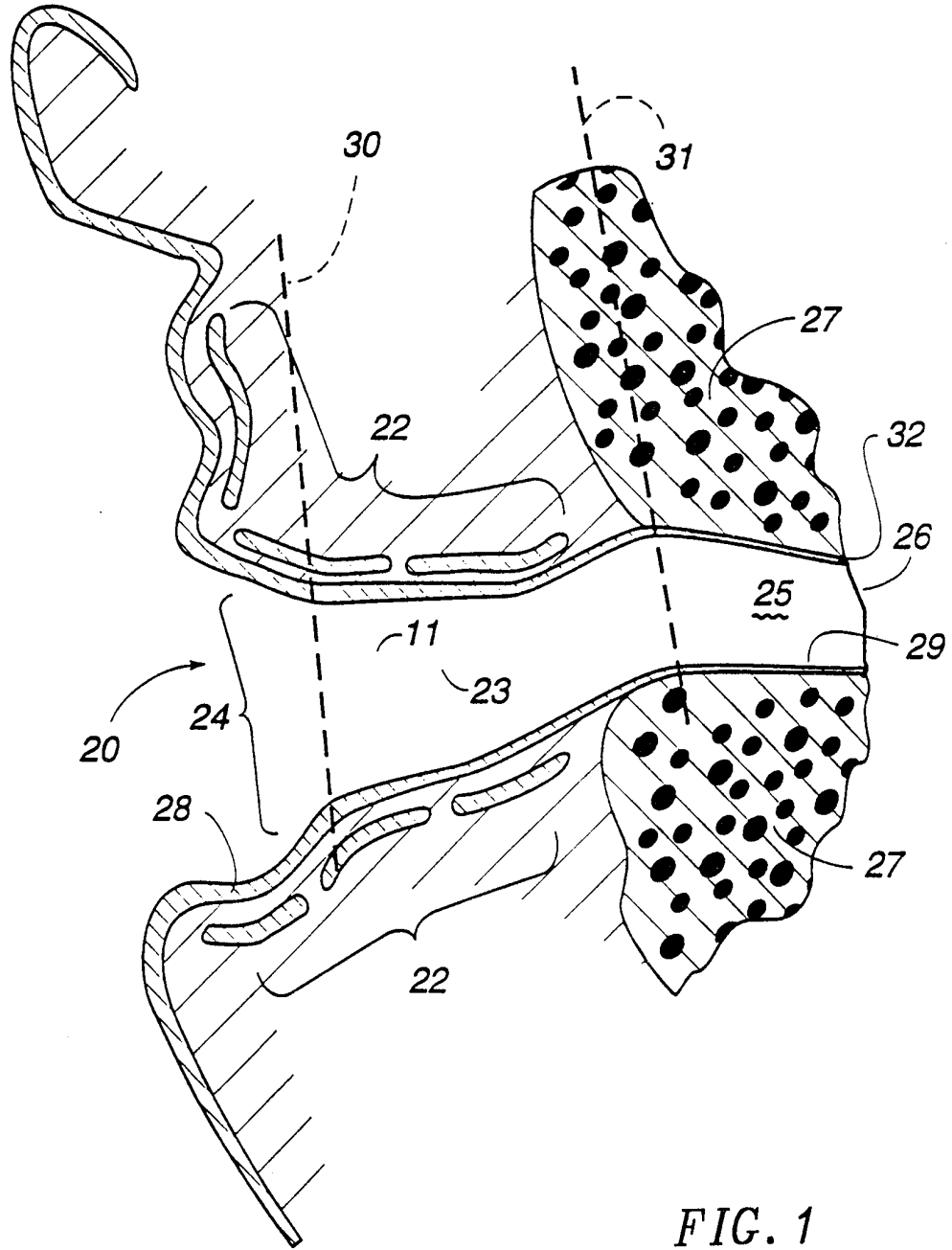


FIG. 1

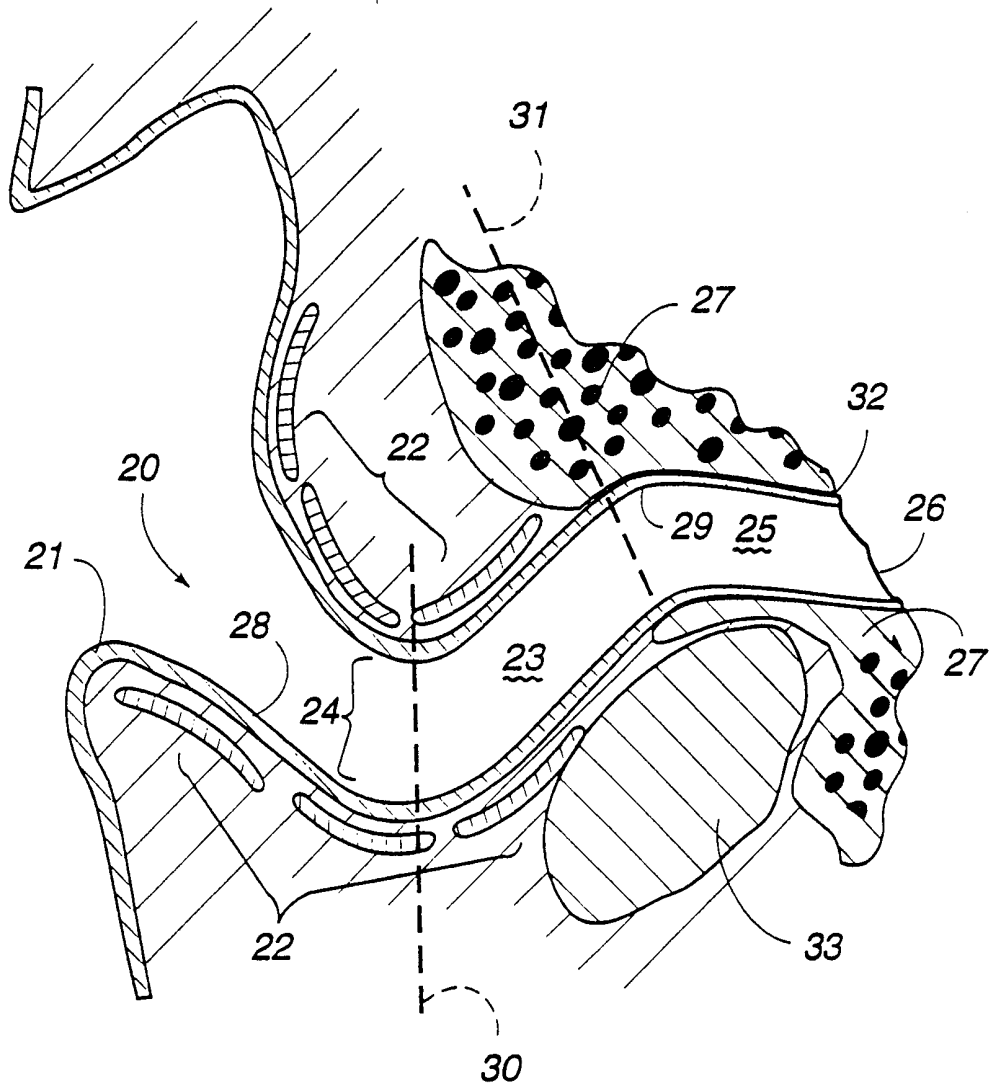


FIG. 2

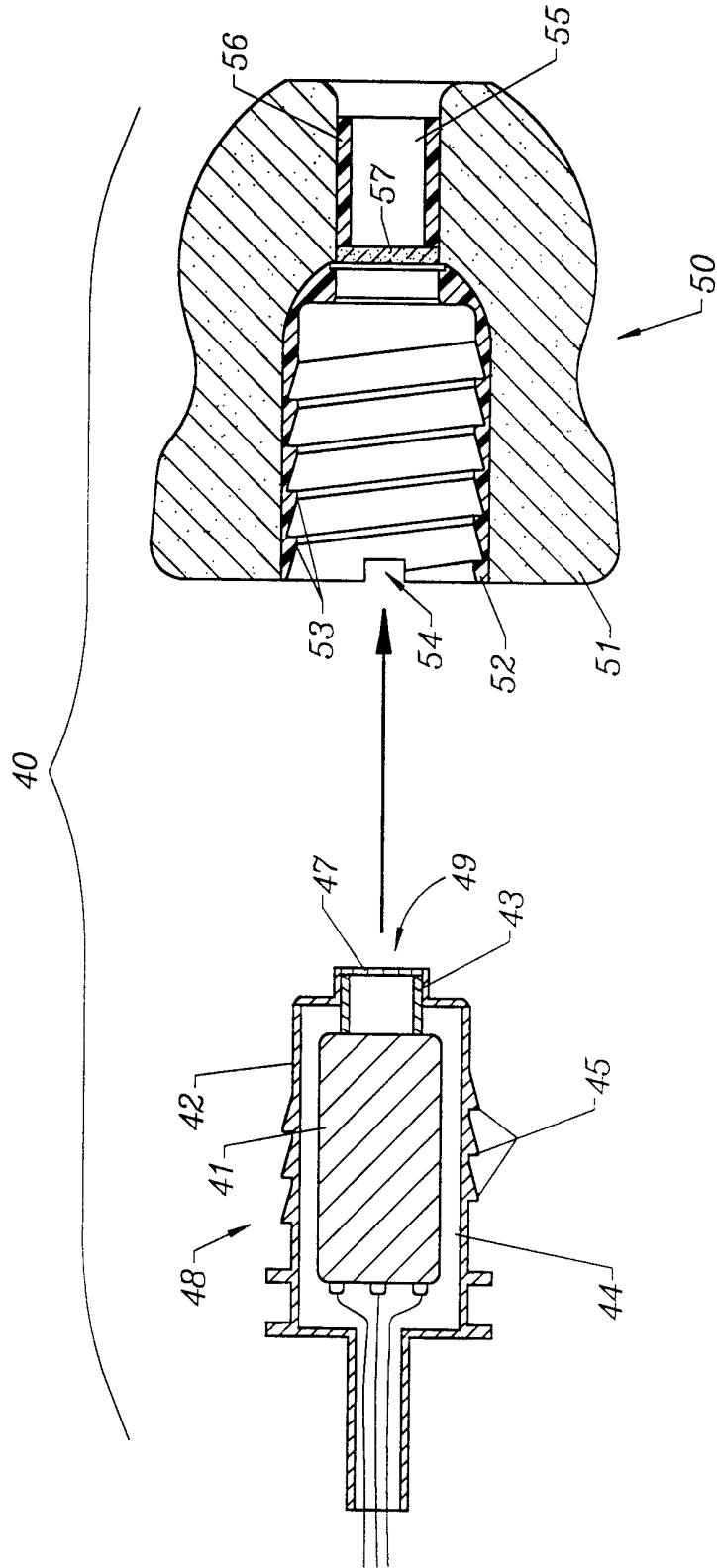


FIG. 3

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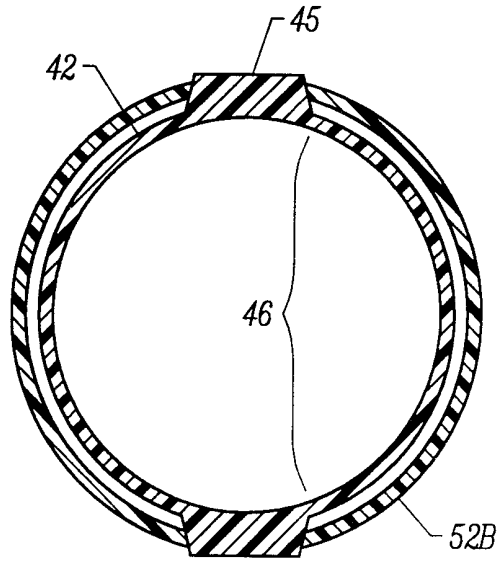


FIG. 4a

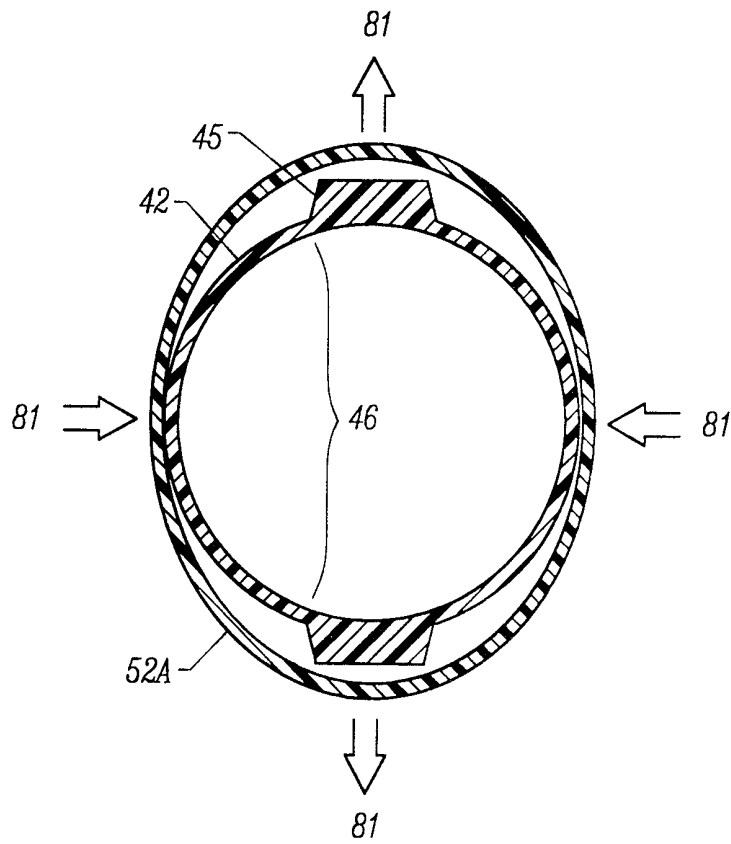


FIG. 4b

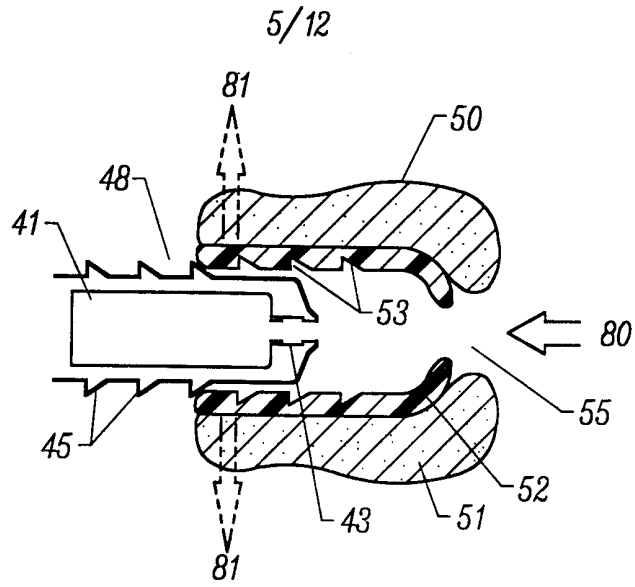


FIG. 5

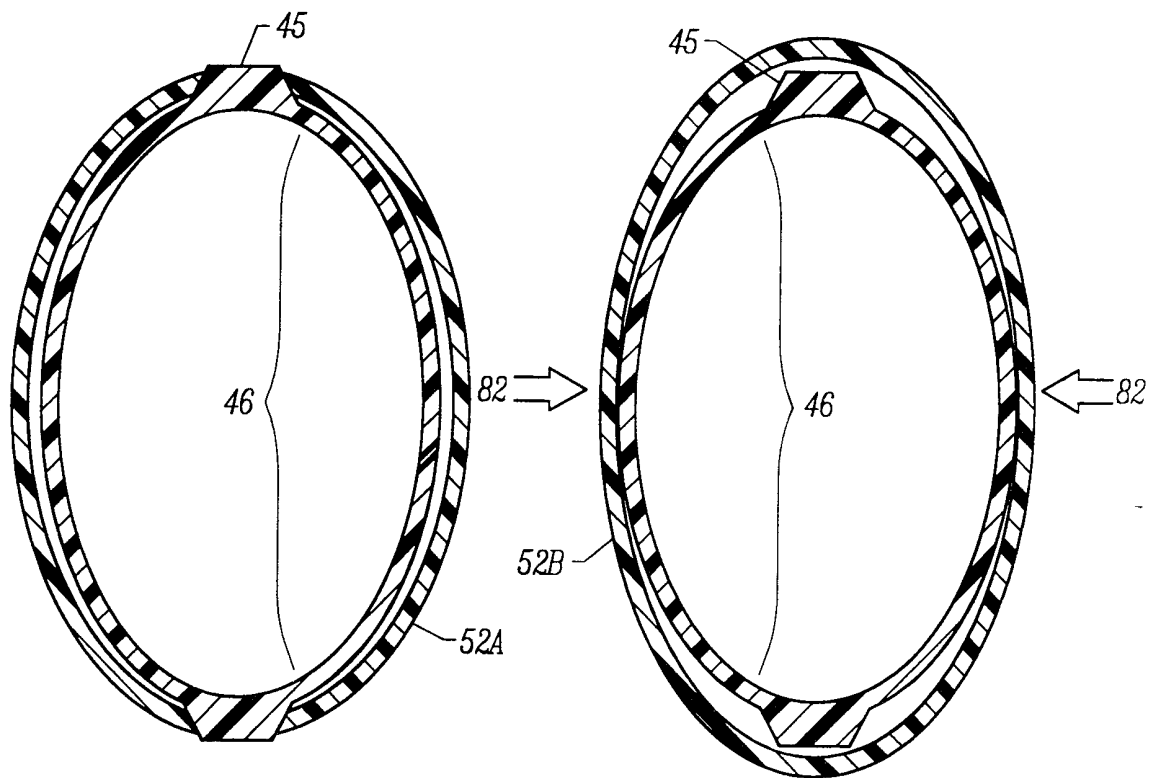


FIG. 6a

FIG. 6b

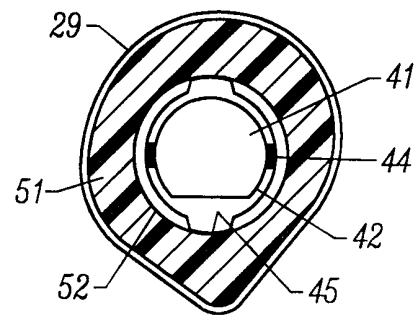


FIG. 7

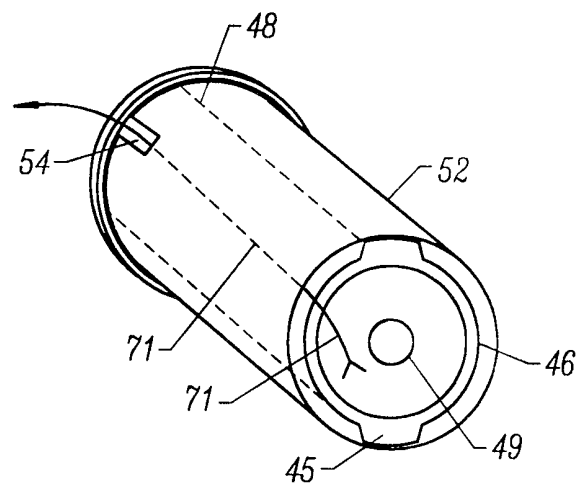


FIG. 8

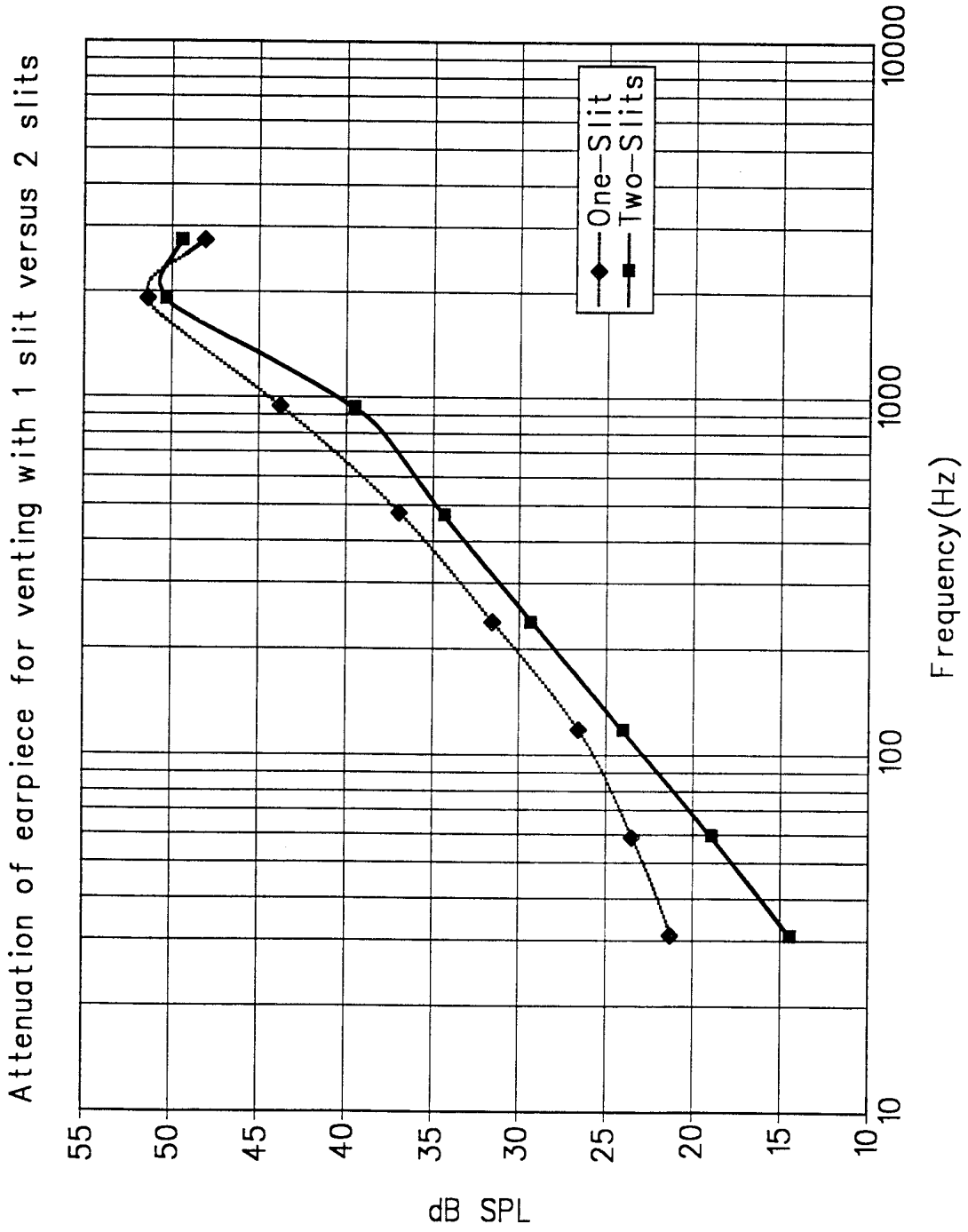


FIG. 9

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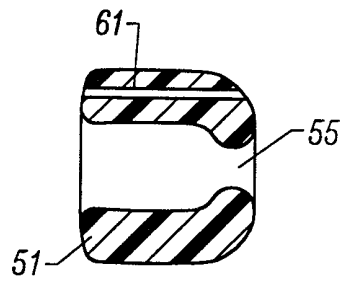


FIG. 10

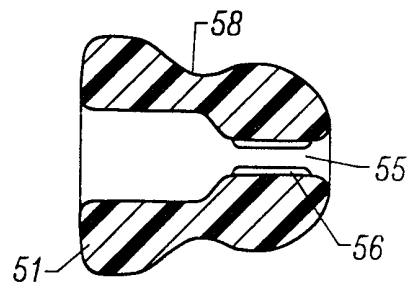


FIG. 11

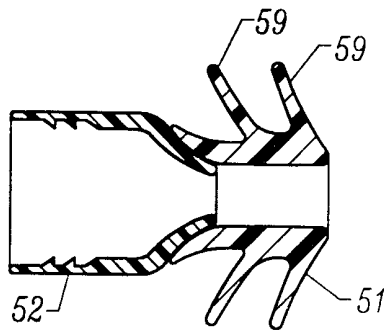


FIG. 12

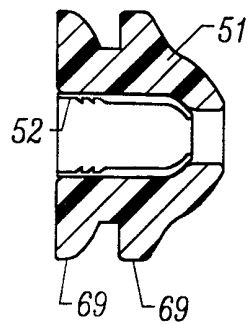


FIG. 13

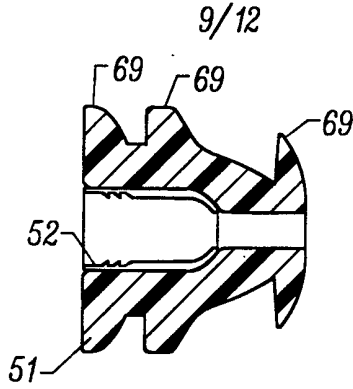


FIG. 14

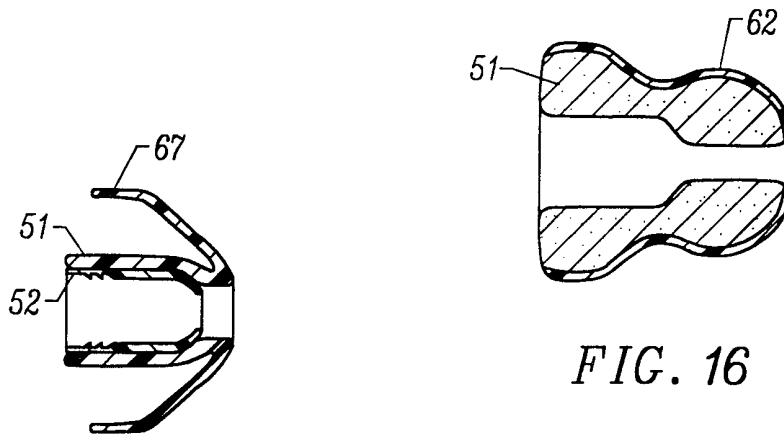


FIG. 16

FIG. 15

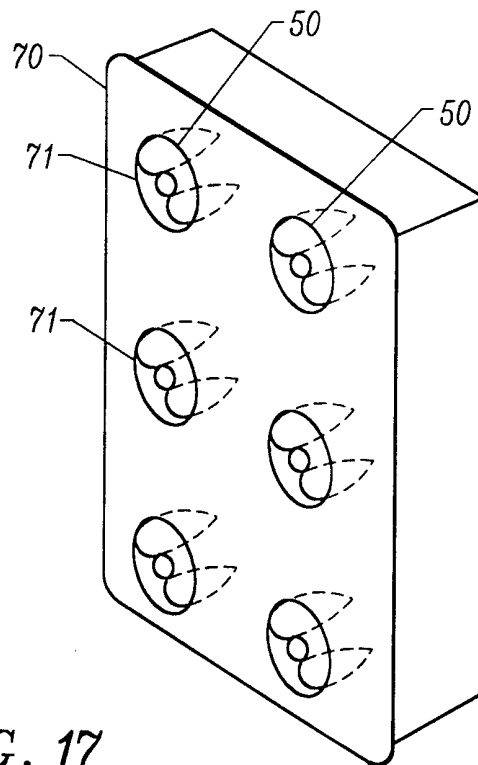


FIG. 17

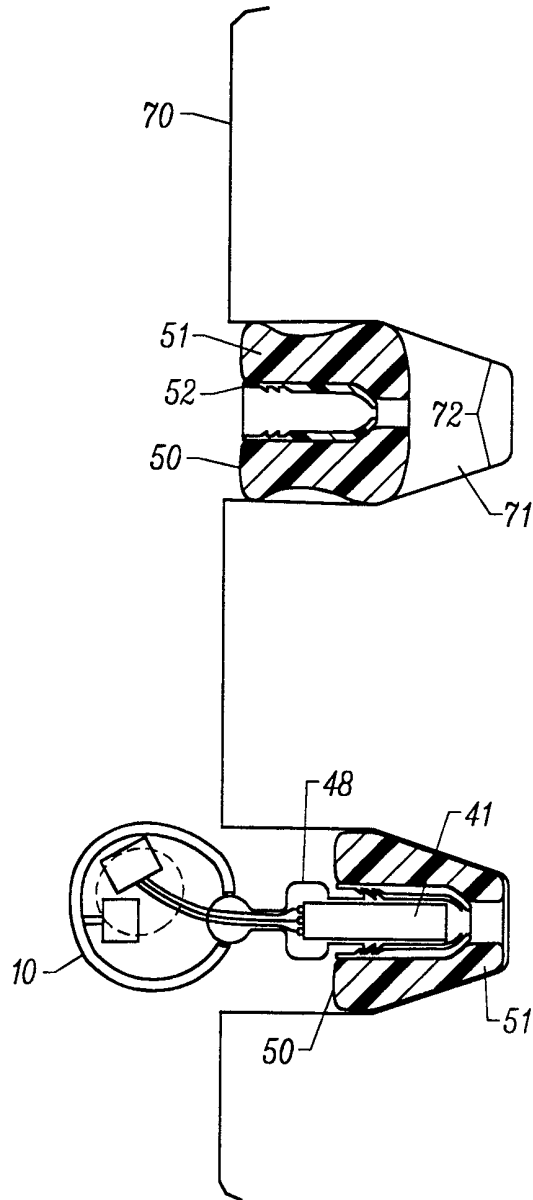


FIG. 18

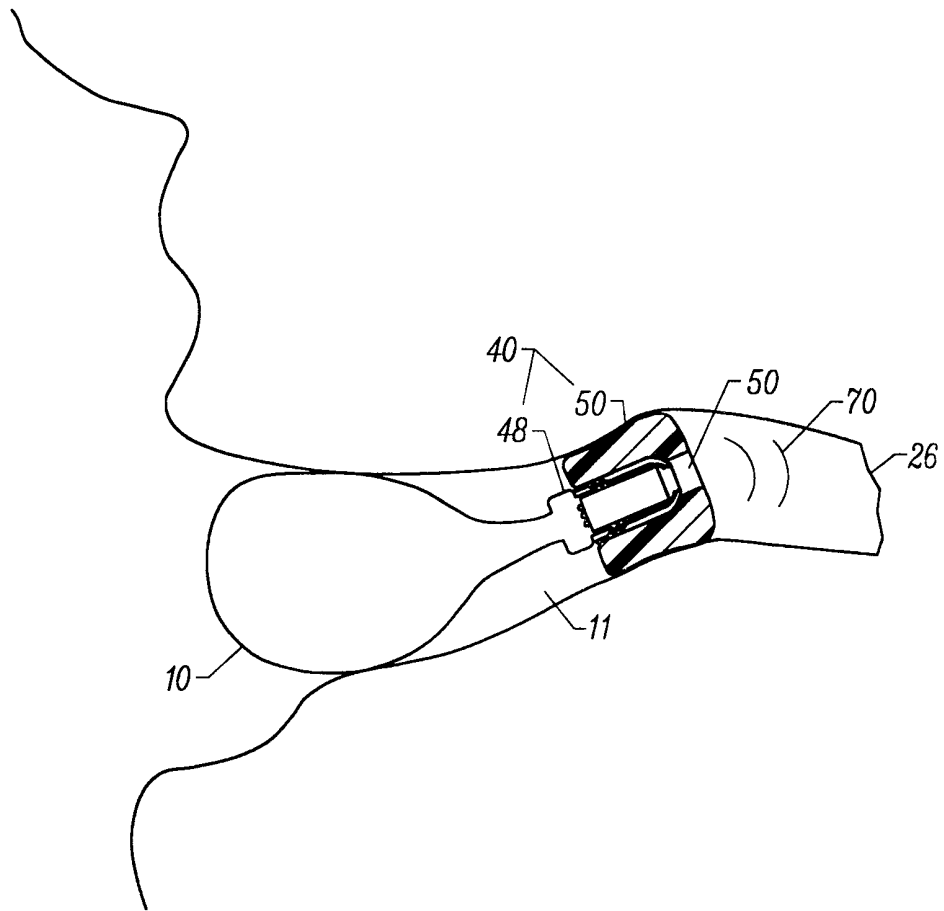


FIG. 19

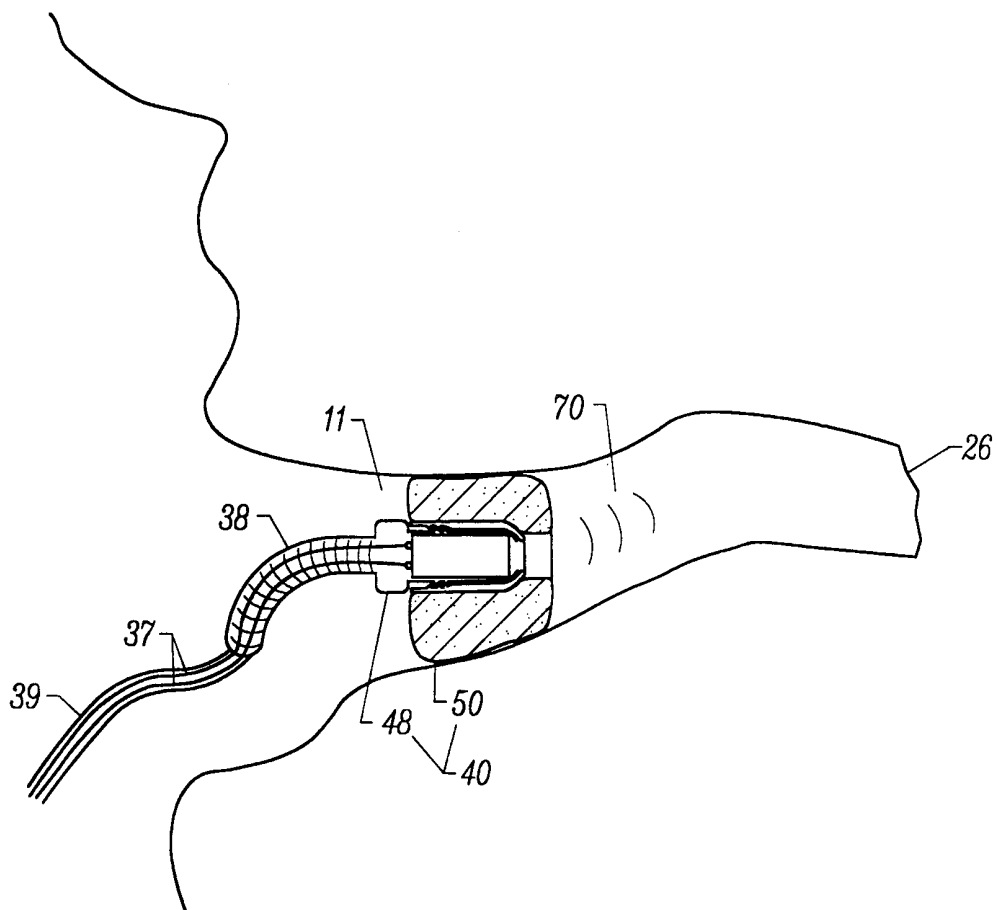


FIG. 20