COMMONWEALTH of AUSTRALIA
Patents Act 1952

APPLICATION FOR A STANDARD PATENT

643977

I/We

Smith & Nephew Richards Inc.

of

1450 Brooks Road, Memphis, Tennessee, 38116, United States of America

hereby apply for the grant of a Standard Patent for an invention entitled:

Permanent middle ear vent tube

which is described in the accompanying complete specification.

Details of basic application(s):-

Number	Convention Country	Date
485642	United States of America	27 February 1990

The address for service is care of DAVIES & COLLISON, Patent Attorneys, of 1 Little Collins Street, Melbourne, in the State of Victoria, Commonwealth of Australia.

DATED this TWENTY SEVENTH day of FEBRUARY 1991

To: THE COMMISSIONER OF PATENTS

.....
a member of the firm of
DAVIES & COLLISON for
and on behalf of the
applicant(s)

Davies & Collison, Melbourne

1257AU

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PATENTS ACT 1952

DECLARATION IN SUPPORT OF CONVENTION OR NON-CONVENTION APPLICATION FOR A PATENT

Insert title of invention.

In support of the Application made for a patent for an invention entitled: Permanent Middle Ear Vent Tube.

Insert full name(s) and address(es) of declarant(s) being the applicant(s) or person(s) authorized to sign on behalf of an applicant company.

~~We~~ I, Howard Roy Berkenstock, Jnr., of
Smith & Nephew Richards Inc
of 1450 Brooks Road,
Memphis,
Tennessee 38116,
United States of America.

do solemnly and sincerely declare as follows :-

Cross out whichever of paragraphs 1(a) or 1(b) does not apply

1(a) relates to application made by individual(s)
1(b) relates to application made by company; insert name of applicant company.

1. (a) ~~I am / We are~~ the person named in the accompanying

or (b) I am authorized by

Smith & Nephew Richards Inc

the applicant ~~s~~ for the patent to make this declaration on ~~its~~ their behalf.

Cross out whichever of paragraphs 2(a) or 2(b) does not apply

2(a) relates to application made by inventor(s)
2(b) relates to application made by company(s) or person(s) who are not inventor(s); insert full name(s) and address(es) of inventors.

2. (a) ~~I am / We are~~ the actual inventor of the invention

or (b)
Anthony F. JAHN
of 20 North Brae Court,
Tenafly,
New Jersey 07670,
United States of America

State manner in which applicant(s) derive title from inventor(s)

~~is / are~~ the actual inventor of the invention and the facts upon which the applicant ~~is / are~~ entitled to make the application are as follows :- by virtue of an assignment between Anthony F. Jahn and Smith & Nephew Richards Inc dated 29th January 1990. Whereby the applicant is the assignee of the aforesaid actual inventor in respect of the invention.

Cross out paragraphs 3 and 4 for non-convention applications. For convention applications, insert basic country(s) followed by date(s) and basic applicant(s).

3. The basic application as defined by Section 141 of the Act ~~was / were~~ made
in USA on the 27th February 1990
by Anthony F. Jahn
in ..... on the .....
by .....
in ..... on the .....
by .....

4. The basic application referred to in paragraph 3 of this Declaration ~~was / were~~ the first application made in a Convention country in respect of the invention the subject of the application.

Insert place and date of signature.

Declared at Memphis Tennessee this 3 day of May 1991

Signature of declarant(s) (no attestation required)

H.R. Berkenstock, Jnr.

Note: Initial all alterations.

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(12) PATENT ABRIDGMENT (11) Document No. AU-B-71937/91
(19) AUSTRALIAN PATENT OFFICE (10) Acceptance No. 643977

(54) Title
PERMANENT MIDDLE EAR VENT TUBE

(51)[5] International Patent Classification(s)
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(21) Application No. : **71937/91** (22) Application Date : **27.02.91**

(30) Priority Data

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485642	**27.02.90**	**US UNITED STATES OF AMERICA**

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(56) Prior Art Documents
US 3982545
US 4744792
US 4094303

(57) Claim

1. A permanent middle ear ventilation tube, comprising an elongated base portion having a longitudinally extending opening therethrough and a flange at one end thereof, the longitudinally extending opening extending through the flange, the base portion and the flange being formed of a non-compressible, biocompatible material, and the flange being circular in shape and extending radially and eccentrically from the elongated base portion.

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COMPLETE SPECIFICATION

NAME & ADDRESS
OF APPLICANT:

Smith & Nephew Richards Inc.
1450 Brooks Road
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United States of America

NAME(S) OF INVENTOR(S):

Anthony F. JAHN

ADDRESS FOR SERVICE:

DAVIES & COLLISON
Patent Attorneys
1 Little Collins Street, Melbourne, 3000.

COMPLETE SPECIFICATION FOR THE INVENTION ENTITLED:

Permanent middle ear vent tube

The following statement is a full description of this invention, including the best method of performing it known to me/us:-

The present invention relates to ~~an apparatus and method for~~ a ventilation tube. permanent ~~ventilation of the~~ middle ear.

Successful treatment of persistent serous otitis media, adhesive otitis media and certain types of chronic suppurative otitis media require some means of permanently aerating the middle ear. There are known procedures for inserting ventilation tubes through the tympanic membrane to equalise pressure and drain fluids from the middle ear.

Insertion of ventilation tubes through the tympanic membrane has disadvantages because tissue growth and other factors cause movement and eventual extrusion of the tube from the tympanic membrane. Extrusion of a ventilation tube enhances the risk of perforation of the tympanic membrane which can require surgery to repair and could result in the formation of scar tissue on the tympanic membrane.

Ventilation tubes have been designed for longer retention in the tympanic membrane. These tubes generally have enlarged flanges and are formed of compressible materials such as silicon rubber. In such tubes, the flanges are compressed for insertion through

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an incision in the tympanic membrane and released in the middle ear cavity. These large flanges operate to anchor the ventilation tube and inhibit easy extrusion. While large-flanged ventilation tubes may be retained for a longer period of time, they suffer from the same extrusion and perforation problems discussed above and generally are extruded within three to four years after insertion.

The compressible materials used such as the silicone rubber are not suitable for permanent implantation. The materials have been described as having a "tacky" surface, which is somewhat porous and causes retention of fluid on the implant, impeding drainage and increasing risk of infection. More suitable biocompatible materials are not useful in these large-flanged implants because of their rigid structure.

US Patent 3982545 describes another type of ventilation tube deemed to be permanent, which is inserted through a specific region of the bony external ear canal. Although this tube is designed to be permanent, it also has problems. As described in United States Patent 3982545, the tube is installed by the relatively complicated surgical procedure of first exposing the middle ear structure by cutting a flap in

the tympanic membrane to determine whether the patient's facial recess and bony overhang are adequate for the procedure. This procedure opens the tympanic membrane and requires drainage of the middle ear during the procedure. This procedure also requires drilling through the facial ridge or alternatively through the mastoid air cells, with the concomitant risk of damage to the facial nerve. The implant described in United States Patent 3982545 is also formed of a compressible material such as silicone to facilitate its insertion and retention in the drilled canal, which has the problems discussed above.

The present invention provides a permanent ventilation tube for the middle ear, which seeks to solve or at least alleviate the problems discussed above.

In accordance with a first aspect of the present invention there is provided a permanent middle ear ventilation tube, comprising an elongated base portion having a longitudinally extending opening therethrough and a flange at one end thereof, the longitudinally extending opening extending through the flange, the base portion and the flange being formed of a non-compressible, biocompatible material, and the flange being circular in shape and extending radially and eccentrically from the elongated base portion.

Preferably, an end of the base portion opposite the flanged end is formed with a bevel extending away from the side of the base portion from which the flange extends.

The tube is preferably installed by separating the fibrous annulus of the tympanic membrane from the bony canal wall and forming a groove in the bone of the external canal. The ventilation tube is then inserted into the drilled canal. The implant is then rotated and pushed to rest the length of the tubular base portion in the groove in the bone of the external canal. In its final position, the flange of the implant rest along the vertical wall of the middle ear chamber while the opposite end of the tubular base portion projects into the outer ear cavity.

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An embodiment of the invention will now be described by way of example only with reference to the accompanying drawings in which:-

Figure 1 is a perspective view of an ear showing in particular in cross section the outer and middle ear cavity separated by a tympanic membrane under which a tube according to an embodiment of the present invention has been implanted;

Figure 2 is a perspective view of the tube;

Figure 3 is a front plan view of the tube of Figure 2;

Figure 4 is an end plan view of the tube of Figure 2;

Figure 5 is a schematic view of the tympanic membrane in which a tube according to an embodiment of the present invention has been implanted; and

Figures 6-9 are sectional views of a tympanic membrane showing a procedure for implanting a tube of an embodiment of the present invention.

Referring in particular to Figure 1, the tube and method of an embodiment of the present invention will be described in detail. Figure 1 illustrates a typical ear 10 which includes an outer ear cavity 12 and middle ear cavity 14 separated by a tympanic membrane 16. Vibrations caused by sound waves impinging on the tympanic membrane 16 are transmitted in the form of vibrations

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through a chain of three movable bones known as ossicles 18 to the internal ear (not shown).

A ventilation tube 20 ~~of the present invention~~ is shown inserted under the tympanic membrane 16 in order to provide communication between the outer and middle ear cavities 12, 14, respectively, for the reasons discussed above. The method of insertion is described in greater below.

The tube 20, shown in detail in Figs. 2-4, includes an elongated tubular base portion 22 with an opening or lumen 24 extending throughout the length of the base portion 22. A flange 26 is formed at the proximal end of the base portion 22. As shown best in Fig. 4, the flange 26 is circular in shape and eccentrically arranged so that it is flush against one side of the tubular member 22.

The flange 26 extends perpendicularly away from the opposite side of the tubular member 22 so that the outer wall of the base portion member 22, see Fig. 4, is tangential to the outer edge of the circular flange 26. This structure of the tube with what is called an eccentric flange allows the tube to be inserted easily into an opening formed in the tympanic membrane through a "buttoning" process as described below. The distal

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end of the tube 22 is preferably beveled at an angle A greater than 20°, preferably about 45°. This beveled surface 28 is at the opposite end of the ~~bod~~ tube 20 to the extended edge of the flange 26 so that as shown in Fig.1, the beveled end faces away from the wall that defines the outer ear canal 12 to allow ventilation between the middle ear cavity 14 and outer ear cavity 12.

The ventilation tube 20 is formed of a non-compressible biocompatible material. The material can be formed with a porous outer surface or one which encourages surface adhesion of surrounding material. An example of suitable known materials with a porous outer surface to encourage tissue ingrowth are porous ultra-high molecular weight polyethylene. Other known biocompatible materials designed to allow for surface adhesion of surrounding tissue are dense hydroxylapatite which encourages osteointegration or surface adhesion of surrounding tissue to the outer surface of the tube 20. Another suitable material is titanium with a matte surface formed by chemical etching which has also been found to provide suitable surface adhesion of surrounding tissue.

As shown in Fig. 5, the tube 20 is implanted at the outer perimeter of the tympanic membrane 16 under a

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fibrous ring 30 which connects the tympanic membrane 16 to surrounding bone 32. An advantage of the described tube and method ~~of the present invention~~ is that the tube 20 can be implanted at any desired point around the periphery of the tympanic membrane 16.

As shown in Figs. 6-9, the method of implanting the tube 20 includes drilling an notch with a suitable microsurgical drill bit 34 into the bony annulus of the tympanic membrane ring 30 preferably forming a small notch in the surrounding bone 32.

As shown in Fig. 7, the beveled or distal end 28 of the tube 20 is grasped by a pair of standard microsurgical forceps 36 so that eccentric flange 26 is inserted through the opening formed in the bony annulus 32. After the flange 26 is inserted in the position shown in Fig. 7, the tube is moved so that it rests in the preformed notch of the body annulus.

When the tube 20 is in the position shown in Fig. 8, the flange 26 is facing toward the tympanic membrane and the beveled distal end 28 is facing the surrounding bone 32, which are opposite the way the tube should be oriented. In order to position the tube 20 properly, the forceps 36 are manipulated to rotate the tube 20 in the direction of an arrow C shown in Fig. 8 to the

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position shown in Fig. 9 where the flange rests adjacent to a ridge 38 located in the middle ear cavity which tends to hold the tube 20 in place and prevents it from extruding out of the tympanic membrane 16. In this position, the distal end is facing upwardly so that free ventilation from the middle ear cavity 14 to the outer ear cavity 12 is no impeded.

By providing the tube of the design described above, a permanent implantation can be made which will remain in place indefinitely. With the tube being formed with an eccentric flange, the tube can easily be button-holed in place as described then rotated so that the flange rests against a naturally occuring ridge to prevent it from being extruded from the ear. This implantation method is desirable because the tube is formed of a non-compressible material. By beveling the distal end of the tube, the cross sectional area is increased for better ventilation and decreased likelihood of clogging.

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THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A permanent middle ear ventilation tube, comprising an elongated base portion having a longitudinally extending opening therethrough and a flange at one end thereof, the longitudinally extending opening extending through the flange, the base portion and the flange being formed of a non-compressible, biocompatible material, and the flange being circular in shape and extending radially and eccentrically from the elongated base portion.

2. A tube according to claim 1, wherein the base portion is tubular in shape.

3. A tube according to any one of the preceding claims, wherein an end of the base portion opposite the flanged end is formed with a bevel extending away from the side of the base portion from which the flange extends.

4. A tube according to claim 3, wherein the angle of the bevel is greater than 20°.

5. A tube according to claim 4, wherein the angle of the bevel is about 45°.

6. A tube according to any one of the preceding claims, wherein at least the outer surface of the base portion and the flange are formed with pores to accommodate tissue ingrowth.

7. A tube according to any one of the preceding claims, wherein at least the outer surface of the base portion and the flange are formed to encourage tissue adherence.

8. A tube according to claim 7, wherein base portion and flange are formed of dense hydroxylapetite.

9. A tube according to claim 7, wherein the base portion and flange are formed

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of titanium with the outer surface chemically treated to form a surface which encourages tissue adherence.

10. An ear ventilation tube substantially as hereinbefore described with reference to the drawings.

DATED this 28th day of September 1993
Smith & Nephew Richards Inc.
By Their Patent Attorneys
DAVIES COLLISON CAVE

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71987/91

FIG. 1.

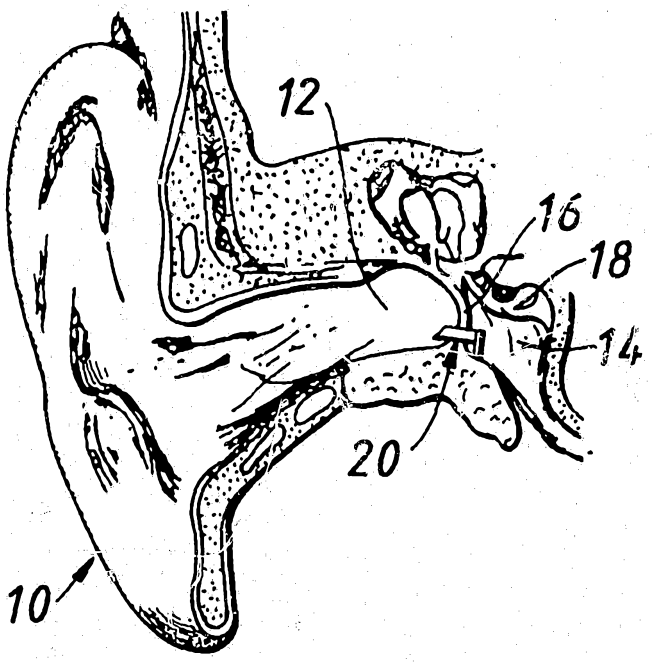

FIG. 2.

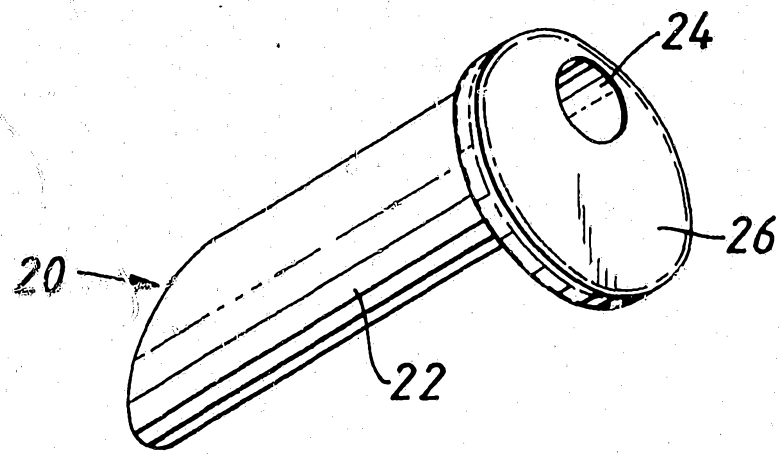

FIG. 3.

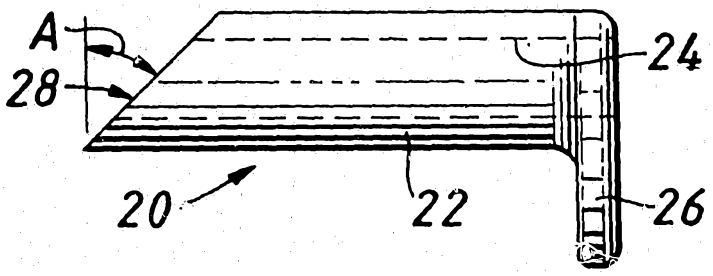

FIG. 4.

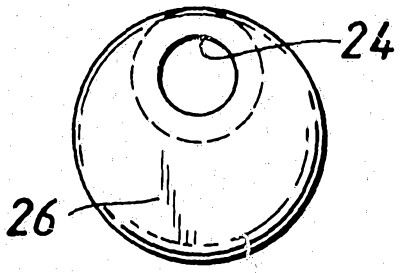

FIG. 5.

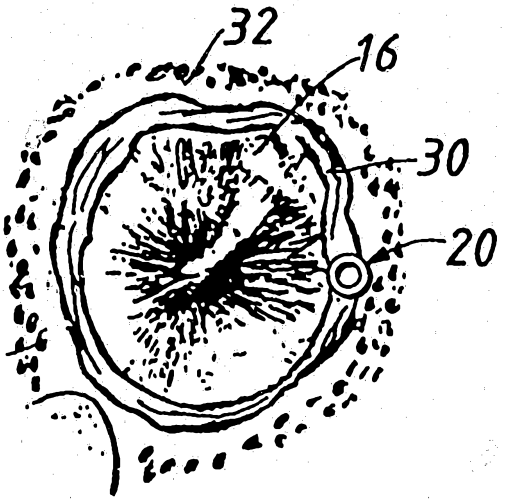

FIG. 6.

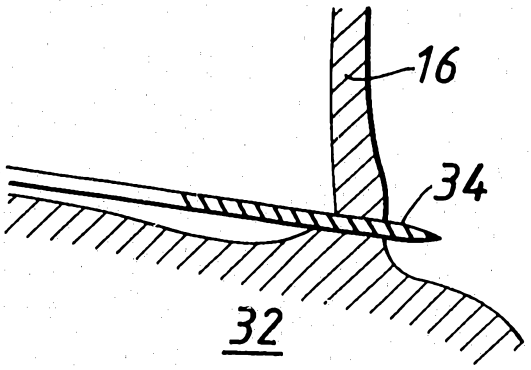

FIG. 7.

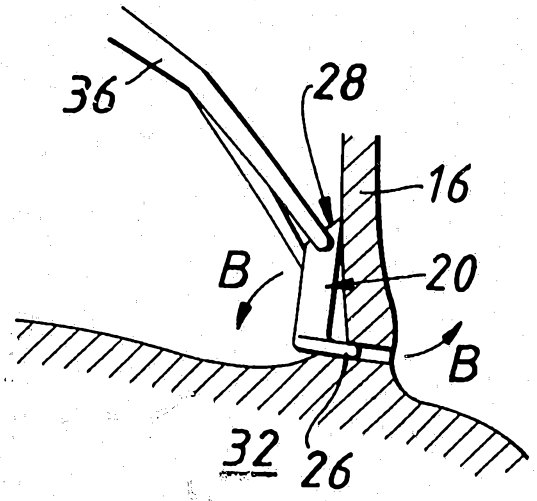

FIG. 8.

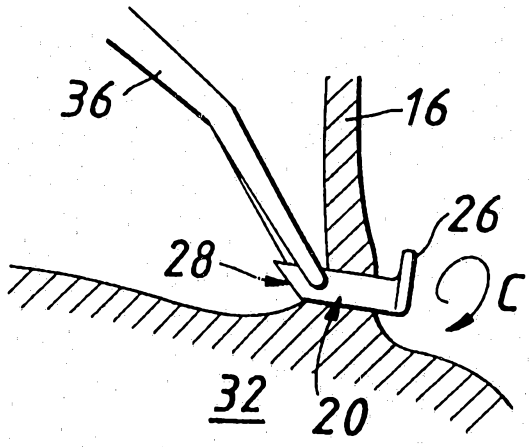

FIG. 9.