

(19)



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11)

EP 0 998 321 B9

(12)

CORRECTED EUROPEAN PATENT SPECIFICATION

Note: Bibliography reflects the latest situation

(15) Correction information:

Corrected version no 1 (W1 B1)
Corrections, see page(s) 6,7

(51) Int Cl.:

A61M 25/00 (1968.09) **A61B 5/042** (1990.01)

(48) Corrigendum issued on:

18.01.2006 Bulletin 2006/03

(86) International application number:

PCT/US1997/009051

(45) Date of publication and mention
of the grant of the patent:

20.07.2005 Bulletin 2005/29

(87) International publication number:

WO 1998/005372 (12.02.1998 Gazette 1998/06)

(21) Application number: **97926767.1**

(22) Date of filing: **22.05.1997**

(54) **TRANSNASAL CONDUIT**

ROHRLEITUNG FÜR NAsALE INTUBATION

CONDUIT D'INTUBATION NAsALE

(84) Designated Contracting States:

DE ES FR GB IT

(74) Representative: **Schmitz, Jean-Marie et al**

Denнемeyer & Associates S.A.,
P.O. Box 1502
1015 Luxembourg (LU)

(30) Priority: **01.08.1996 US 695187**

(43) Date of publication of application:

10.05.2000 Bulletin 2000/19

(56) References cited:

WO-A-95/05862	US-A- 4 023 559
US-A- 4 284 076	US-A- 4 593 689
US-A- 4 655 214	US-A- 5 105 807
US-A- 5 458 605	US-A- 5 513 633

(73) Proprietor: **Linder, Gerald S.**

Bel Air, CA 90077 (US)

(72) Inventor: **Linder, Gerald S.**

Bel Air, CA 90077 (US)

EP 0 998 321 B9

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

[0001] The present invention relates to a transnasal conduit according to claim 1.

[0002] The present invention relates generally to nasopharyngeal airways (NPAs) and more particularly to a nasal conduit allowing the atraumatic introduction of probes and diagnostic instruments, particularly transesophageal echocardiography (TEE) sensors.

[0003] Transesophageal echocardiography (TEE) allows physicians to diagnose myocardial function and ischemia during surgery. With TEE surgeons can concurrently assess surgical repairs made during surgical procedures as TEE provides contemporaneous indication of the patient's cardiac and circulatory condition. With TEE, higher initial surgical success rates accompanied by a reduction of complications has been achieved.

[0004] In order to position TEE probes, insertion is often made through the mouth. While this procedure is generally safe, manipulation of the TEE probe can produce dental, pharyngeal, laryngeal, and esophageal injuries. Additionally, orally inserted TEE probes are not well tolerated by conscious patients as the probes tend to move with the patient. With the decreased tolerance by conscious and even ambulatory patients, TEE probes have limited use for dynamic tests such as stress treadmill and exercise echocardiogram tests and the like. However, there is a great interest in achieving use of a TEE probe in ambulatory patients as TEE allows direct diagnosis of a multitude of cardiac abnormalities.

[0005] TEE provides more comprehensive information regarding cardiac performance than electrocardiography (ECG) and pulmonary artery catheters (PAC). Images generated through TEE are also better than transthoracic echocardiography (TTE), which cannot be used when the chest is open. Certain medical advantages arise with TEE in that TEE is not blocked by operating-room monitors, drapes, and/or surgical equipment. However, since epicardial echocardiography (EE) probes require a sterile field and can interfere with surgery, they are also removed when the chest is closed therefore terminating any useful monitoring of the patient. TEE, on the other hand; provides continuous monitoring as well as important patient condition information such as abnormalities in myocardial wall motion and perivalvular leakage without requiring an invasive surgical procedure.

[0006] TEE currently provides means by which a patient's condition can be monitored closely without requiring surgery. However, orally inserted TEE probes are generally used for only relatively short time intervals and mostly in unconscious patients due to the difficulties indicated above. For intensive-care unit (ICU) patients who are conscious, it is highly desirable to have a long-term TEE monitoring the patient continually so that such patients may be diagnosed rapidly and treated appropriately. Additionally, use of TEE probes in conscious patients could be accomplished, thereby allowing dynamic TEE monitoring, if a TEE probe could be placed within a pa-

tient via a nasal instead of an oral route.

[0007] Transnasal insertion of a relatively large-bore TEE probe or the like can inflict trauma upon the nasal mucosa due to the requirements of the TEE probe's electrical signal surface. That surface must generally be wedge-shaped. It is possible to transnasally insert TEE probes through previously inserted nasopharyngeal airways (NPAs).

[0008] The object in using NPAs for probe placement is to avoid bleeding and trauma to the nose during insertion and subsequent probe manipulation. Conventional NPAs, however, are limited as to their usefulness as they may damage the nasal mucosa and nasal structure because of their open, beveled tip. Additionally, NPAs are commonly relatively thick walled, thereby limiting the useful inner diameter for passage of the TEE probe. The relatively small inner diameter of NPAs may deny TEE probe access to a significant segment of the smaller sized adult population which experiences heart and circulatory difficulties to the same degree as other segments of the adult population.

[0009] Use of NPAs with large inner diameters may still pose difficulties when used in conjunction with TEE probes. While such NPAs may be atraumatically inserted into the patient, it remains often difficult to pass TEE probes through them. Additionally, patients can forcefully expel the NPA from their naris occasionally.

[0010] As can be seen, it would be an advancement in the art to provide a transnasal conduit or the like that would allow atraumatic intubation of a TEE probe. Furthermore, such a transnasal conduit should not only resolve the foregoing problems but should also prevent its own migration into the naris as NPAs with small or ill-defined flanges can so migrate. Additionally, such a transnasal conduit should advantageously maintain the probe position relative to the conduit by allowing controlled, temporary securement of the probe to the transnasal conduit.

[0011] WO-A-95/05 862 discloses a catheter (22,28) comprising a hollow lumen having a distal end provided with a tip (23,39) for insertion into a blood vessel, a plurality of peripherally spaced holes (27,38) closely adjacent the tip (23,39), the tip having a terminal aperture (25,40) capable of adopting two configurations, namely an enlarged wire carrying configuration in which it is capable of receiving and passing a wire (24,34), and a restricted configuration in which it is of substantially smaller cross-sectional area than in the enlarged condition, the aperture (25,40) being normally biased into said restricted configuration. The aperture (25,40) may comprise a slit or a plurality of slits (26) or a peripheral restrictor (31,33) in the form of an annulus or a plurality of restrictor members of resilient material such as latex or silicone rubber. The catheter, intended for use in blood vessels, may find uses in coronary work, for example coronary angiography or interventional procedures such as balloon angioplasty of the insertion of stents, as well as for other arterial work.

[0012] US-A-5 105 807 relates to a novel device and novel methods for securing nasal tubing in medical patients. The invention provides, with minimal trauma, discomfort, and distraction to the patient, a means of securing in place nasal tubing inserted through the nasal passage. In addition, the disclosed invention provides a device which can be replaced without removal of a nasal tube already in place.

[0013] US-A-5 517 633 describes an endotracheal tube holder that includes a face plate assembly which is attached to a patient's head by an adjustable headband. The face plate assembly is formed with a face plate adapted to be positioned over the mouth of the patient and is formed with an open end channel terminating with a V-shaped notch over which is superposed a tube holding block that is affixed to the outer surface of the face plate, and also includes a matching v-shaped notch in which an endotracheal tube can be fixedly positioned by a thumb screw, a bite block being integrally secured to the inner surface of the face plate which is also provided with an aligned V-shaped notch. The face plate also includes an opening for ready access to the patient's mouth, as might be required.

[0014] US-A-4 023 559 concerns a sampling catheter comprising an outer tube of resilient material which has an open and a closed end. The closed end is shaped so as to permit unrestricted entry into a body through a channel thereof and has means associated therewith enabling the opening of the closed end and protrusion there-through by an inner tube extending within the outer tube upon said inner tube being pushed against the closed end.

[0015] A sampling sway is provided within the inner tube for extension beyond the end of the inner tube after protrusion thereof through the closed end.

[0016] With the realization of a transnasal conduit allowing the nasal insertion of a TEE probe, conscious ICU, ambulatory, and other patients for whom TEE probes are generally unavailable at the present could now be intubated with a TEE probe transnasally in order to closely monitor contemporaneous cardiac and circulatory function. Better patient diagnosis and earlier detection of cardiac and circulatory symptoms, problems, or anomalies for increased patient care and more efficient allocation of health-care resources could then be provided.

[0017] Currently, no such transnasal conduits are known in the art that resolve the disadvantages of using current NPAs while addressing the shortcomings of current TEE probe insertion procedure.

[0018] The transnasal conduit of the present invention is defined in claim 1.

[0019] The transnasal conduit of the present invention provides a thin walled, large inner diameter conduit for the insertion of a TEE probe into the patient. Such intubation of the TEE probe occurs transnasally, thereby allowing ambulatory use of the TEE probe in conjunction with conscious patients. Current patient cardiac and circulatory status are thereby better monitored and the pa-

tient may be subjected to stress (as with a treadmill or other stress test) while the TEE probe is present. Additionally, ICU patients may be continuously monitored via TEE without suffering the disadvantages with orally inserted TEE probes.

[0020] The transnasal conduit of the present invention has a relatively large inner diameter and relatively thin walls. The relatively large inner diameter provides room for large-bore TEE probes. The thin walls are pliable but protect delicate mucosal tissues adjacent to the walls after intubation.

[0021] The distal end of the transnasal conduit is normally closed or closeable so that a smooth, generally atraumatic conduit surface is initially brought into contact with any surrounding tissue as the transnasal conduit is intubated into the patient. The proximal end of the transnasal conduit is generally flared or has an extended flange shape and is continuous and coterminous with this proximal end to allow the easy introduction of the TEE probe or the like. A pinch clamp means or a collar or the like may be used adjacent the flared end and may have a thumbscrew supported therein for releasably attaching a TEE probe or the like to the transnasal conduit. The screw clamp collar is captively retained between the proximal flared or flanged end and the more distal, larger, eared patient flange (as described below).

[0022] In order to prevent further migration of the transnasal conduit into the patient, a second and more distal flange may be used in conjunction with the collar that allows releasable attachment of the transnasal conduit to the patient's head. The flange may be "eared" as in having lobes with holes or the like through them. An elastic strap, string, or the like may pass through the lobes to provide temporary attachment. Additionally, adhesive means may be used to temporarily attach the transnasal conduit to the patient.

[0023] In use, a well lubricated TEE probe is initially inserted into the conduit until the tip of the probe is within the closed dome or adjacent to the distal conduit tip. Under such circumstances the entire interior lumen of the transnasal conduit is generally accompanied by the presence of at least a portion of the TEE probe. The thumbscrew, pinch clamp means, or other clamping means is tightened to temporarily hold and maintain the TEE probe in relative position with the transnasal conduit. The conduit is then externally lubricated and the conduit-probe assembly is configured by a probe directional mechanism into an NPA curve shape to curvedly conform to the anticipated internal geometry of the patient's transnasal passage.

[0024] The conduit and probe forming the assembly are simultaneously inserted and passed through the naris and into the oropharynx. During this procedure, the enclosed probe acts as the introducer to support the sheathing transnasal conduit. Upon full insertion of the transnasal conduit with its probe into the patient, the pinch clamp is released, freeing the probe from its attachment to the transnasal conduit. The probe is advanced through the

segmented dome or round distal conduit tip to expose the distal end of the probe. The probe is inserted into the esophagus where patient monitoring may occur. The pinch clamp is then re-tightened by turning the thumb-screw to reengage the TEE probe, thereby re-attaching it to the transnasal conduit to hold the TEE probe in place. Removable attachment of the transnasal conduit to the patient is achieved by the patient-contacting eared flange with its elastic strap.

[0025] Alternative embodiments include alternative distal tip configurations. Such alternate distal tip configurations may include a closed diaphragm which opens when a probe is pushed through it as well as a membranous balloon shaped tip which ruptures cleanly when the probe is passed through it. Both of these alternate distal tip configurations allow generally atraumatic insertion of the transnasal conduit with the accompanying probe due to the soft, rounded end of the distal tip configuration.

[0026] In order that the application may be fully understood reference is made to the accompanying drawings:

Figure 1 is a side perspective view of the transnasal conduit of the present invention.

Figure 2 is a side cross sectional view of the transnasal conduit of Figure 1 taken along line 2-2.

Figure 3 is a plan view of the open proximal end of the transnasal conduit of Figure 1.

Figure 4 is a side plan view of the transnasal conduit of Figure 1 showing in partial cutaway section a TEE probe projecting through the distal tip of the transnasal conduit.

[0027] As shown in Figure 1, the transnasal conduit **10** of the present invention has an elongated tube or catheter **12** with a normally closed distal end **14** and an open proximal end **16**. The tube **12** is made of surgically acceptable, pliable plastic or the like that is soft and generally bendable. The material used to construct the tube **12** may maintain a curved shape as shown in Figures 1, 2, and 4, yet may compliantly bend to conform to any number of configurations (especially such configurations as the transnasal conduit **10** can be expected to attain when inserted into the patient).

[0028] The tube **12** may be on the order of 4 to 8 inches long to accommodate the different lengths of nasal passages in adults of different sizes. The tube **12** is generally thinned walled with the thickness of the wall **18** being on the order of a few millimeters (approximately one tenth of an inch). The inner diameter **20** of tube **12** is approximately 7.4 mm to 9.4 mm. This inner diameter may be adjusted according to the size and type of patient in order to accommodate their nasal passages.

[0029] The distal end **14** of the tube **12** is shown in the figures as having three separate lobes **30**. The normally closed, tri-lobed ball end **14** as is shown in the figures is but one embodiment that may be achieved in the present invention. The individual lobes **30** are generally constructed of the same pliable, surgically approved mate-

rials. The distal end **14** of the present invention is generally formed concurrent or contemporaneously with the tube **12**. As shown in Figure 2, each lobe **30** has underlying its outer surface an interior protuberance **32** that conforms with the lobe **30** of the distal tip **14**. The protuberances **32** serve to elastically hold closed the lobes **30** so that the distal end **14** may pass more easily and generally atraumatically through the patient during intubation. Each of the individual lobes **30** is separated from the other lobes **30** by separation lines **34** that generally extend only along the distal tip **14**. The separating lines **34** arise from the separation of each of the individual lobes **30** and show the abutment of each of the lobes **30** against one another.

[0030] The tube **12** may have internal striations providing easier insertion and passage of the probe. Such situations are contemplated as travelling the length of the tube **12** from the open proximal end **16** to the distal end **14**.

[0031] The open proximal end **16** of the tube **12** may be flared or flanged in shape, much like a bell, so as to provide easier introduction of probes and the like. Thus, as shown in Figures 2 and 4, the open proximal end **16** of the conduit **10** is circumscribed by a flange **40** that is continuous and coterminous with the tube **12**. The flange **40** provides an abutting surface by which larger structures such as the collar **42** and/or the flange **50** may prevent migration of the transnasal conduit **10** further into the naris of the patient once full insertion of the transnasal conduit has been achieved. By providing an abutting surface against which other structures circumscribing the perimeter of tube **12** may engage and have their further forward travel prevented, the flange **40** provides a safer, more advantageous, and useful transnasal conduit that maintains its position relative to the patient.

[0032] As shown in Figures 1 through 4, a collar **42** generally circumscribes the tube **12** immediately adjacent the flange **40**. The collar **42** may be made of surgically approved plastic materials or the like and may slide about the exterior of tube **12**. Generally, the collar is positioned adjacent the flange **40** for easy manipulation and full insertion of the transnasal conduit **10** into the patient. The collar is approximately a centimeter in length so that it may fully engage a thumbscrew **44** or the like via the threaded aperture **46**.

[0033] Thumbscrew **44** threadingly engages the collar **42** and travels perpendicularly to the adjacent tube wall **18**. When the thumbscrew **44** is turned so as to travel towards tube **12**, probes or other devices previously inserted into the open proximal end **16** of the transnasal conduit **10** may be pinched, clamped, or otherwise releasably attached to the transnasal conduit **10** by trapping such probes between opposite sides of tube **12**. The pliable walls **18** flex so as to trap the probe between thumbscrew **44** and collar **42**.

[0034] While a thumbscrew threadingly engages the collar **42** is set forth herein, other pinch clamp means may also be advantageously used in conjunction with the

present invention to releasably attach probes or the like relative to the transnasal conduit 10.

[0035] The thumbscrew 44 may also be constructed of surgically approved materials including plastic or the like. The thumbscrew 44 is sufficiently held by the collar 42 so that the thumbscrew 44 may press down upon the pliable materials composing the wall 18 of the tube 12. The pliable nature of the wall 18 allows the thumbscrew to press into the tube 12 to compress any adjacent probe or the like. The pliable nature of wall 18 allows the wall 18 to maintain structural integrity which also provides means by which releasable attachment may be made of probes or the like to the transnasal conduit 10.

[0036] As shown in Figure 1, an additional, more distally located flange may circumscribe the exterior of tube 12. "Eared" patient flange 50 serves as patient attachment means by which the transnasal conduit 10 may be removably attached to the patient in order to better secure the transnasal conduit 10 to the patient and providing for greater patient comfort and securement of the device. The patient flange 50 is generally circular in nature with a central aperture through which the tube 12 may slidably pass until the patient flange 50 engages the collar 42. The patient flange 50 is generally shorter in length than the collar 42 as it need not support any thumbscrew or similar device. The patient flange 50 may be generally the same diameter as the collar 42.

[0037] On opposing sides and extending laterally outward from the perimeter of the patient flange 50 are two lobes or ears 52a, 52b. These flange lobes are each apertured with a single hole so as to provide an aperture through which a preferably elastic string, strap, or other similar device may be used so that the transnasal conduit 10 may be removably attached to the patient. As shown in Figure 1, a strap S is used and is generally doubled back so that the strap S may be encircled about the patient's head. This holds the transnasal conduit 10 in position upon the patient. As with the other elements of the present invention, the patient flange 50 may be constructed of surgically approved materials such as plastic or the like. As with the other elements of the present invention, it is best to avoid latex or latex-based materials in order to reduce the risk of any allergic reaction to such latex materials. As contemplated in the present invention, all materials used are not only approved for surgical use, but are preferably hypoallergenic as well.

[0038] Having described the construction of the present invention, its operation is as follows. Reference may be made to Figure 4 in conjunction with the following description. In order to introduce a transesophageal echocardiography (TEE) probe into a patient for contemporaneous monitoring of cardiac and/or circulatory function or the like, the probe P is initially well lubricated for insertion into the transnasal conduit 10. Such lubrication mainly serves to facilitate the passage of the probe P into the transnasal conduit 10. However, it also serves as means by which injury may be avoided to the patient once the distal end of the probe P emerges from the distal

end 14 of the transnasal conduit 10.

[0039] Upon insertion of the lubricated probe P into the transnasal conduit 10, the distal end of the probe P is inserted into the tube 12 until the distal probe P is generally adjacent, but well within the distal end 14 of the transnasal conduit 10. Thumbscrew 44 or other pinch clamp means is then tightened to secure the probe P relative to the transnasal conduit 10. By tightening the thumbscrew 44, the end of the thumbscrew 44 engages the wall 18 of tube 12. Thumbscrew 44 compresses the wall 18 until it comes into contact with the probe P. The probe P is then secured between the wall 18 adjacent thumbscrew 44 and the wall 18 on the opposite side which is held in place by the portion of collar 42 opposite the thumbscrew 44. The wall 18 is held in place between the collar 42 and the thumbscrew 44. Upon so securing the probe P relative to the transnasal conduit 10, the probe P is then bent into a configuration that allows easier passage while the conduit-probe assembly is slowly inserted into the patient. The disposition of the probe P and the conduit 10 may be such as to anticipate the anatomy of the patient and may achieve its initial configuration with the use of a probe directional mechanism (not shown).

[0040] Once the proper configuration is achieved by the conduit-probe assembly, the exterior of the tube 12, particularly distal end 14, is well lubricated. Intubation of the conduit-probe assembly is initiated by inserting the distal tip end 14 into an open naris of the patient. Intubation then continues until the transnasal conduit 10 is fully inserted into the patient with the patient flange 50 engaging the open naris end and with the patient flange 50 abutting the collar 42 and preferably abutting collar 42 and flange 40. As the probe P is generally stiffer than the soft, pliable tube 12, probe P acts as an introducer for the transnasal conduit 10 during intubation.

[0041] Upon full insertion of the transnasal conduit 10 into the patient, the intubation process is not yet complete. The distal end of the TEE probe P has an electrical signal surface which is used to monitor the patient's condition. Generally, this probe is semi-wedge shaped due to the electrical signal surface area requirements.

[0042] The distal end of the probe P must be brought into the esophagus in order to properly monitor the patient. In order to do so, it must emerge from the distal end 14 of the transnasal conduit. By unthreading thumbscrew 44 or otherwise loosening the pinch clamp, the probe P may be released from its temporary attachment to the transnasal conduit 10 and further inserted into the patient. In so doing, the probe P continues to pass through the transnasal conduit 10 to emerge from the distal conduit end 14. As probe P was previously lubricated prior to insertion into the transnasal conduit 10, such lubrication serves to facilitate passage of the probe P through the tube 12 and also serves to allow easier insertion of the probe P into the patient's esophagus with minimal trauma.

[0043] Once probe P is in place, the thumbscrew 44

or other pinch clamp means are tightened so as to secure the probe **P** with respect to the transnasal conduit **10**. This holds the probe **P** in position with respect to the patient's esophagus and prevents any relative travel between the transnasal conduit **10** and the probe **P**. In order to temporarily hold the conduit-probe assembly to the patient, a strap **S** (Fig. 1) is threaded through the holes **54** in the ears or lobes **52a**, **52b** of the patient flange **50**. In one embodiment, the strap may take the form of an elastic band that is secured to the patient flange **50**. The strap **S** is of such length so as to allow elastic encirclement of the strap **S** about the patient's head, thereby removably attaching the patient flange **50** and the associated transnasal conduit **10** to the patient.

[0044] Upon securing the transnasal conduit **10** with the associated TEE probe **P** to the patient, conscious ICU or ambulatory patients may now be continuously monitored with TEE for diagnostic and monitoring purposes.

[0045] Alternative embodiments of the present invention include alternative distal tip **14** configurations. In one alternative embodiment, a closed diaphragm is used at the closed distal end **14** of the transnasal conduit **10**. The closed diaphragm end opens up when the probe **P** is pushed through it. Additionally, another alternative embodiment exists in use of a membranous balloon-shaped tip which provides and facilitates atraumatic insertion of the conduit-probe assembly into the patient. The membranous, balloon-shaped tip is then ruptured cleanly when the thumbscrew **44** is loosened and the probe **P** is pushed through the membranous, balloon-shaped tip.

[0046] Additionally, a pleated rubber or plastic dome or a thicker unpleated shape may be used at the distal tip **14** of the transnasal conduit **10**. Alternatively, a stiffer unpleated domed shaped tip **14** may prove satisfactory.

[0047] While the present invention has been described with regards to particular embodiments, it is recognized that additional variations of the present invention may be devised without departing from the inventive concept.

[0048] It is an object of the present invention to provide a transnasal conduit for TEE probes and the like.

[0049] It is another object of the invention to provide a transnasal conduit for TEE probes that generally provides atraumatic insertion of the TEE probe.

[0050] It is an additional object of the present invention to provide a transnasal conduit with a closed or normally closable end so that the transnasal conduit may be atraumatically introduced into the patient.

[0051] It is yet another object of the present invention to provide a transnasal conduit which does not migrate with respect to the patient.

[0052] It is another object of the present invention to provide a transnasal conduit that provides easy TEE probe passage.

[0053] It is yet another object of the present invention to provide a transnasal conduit that is releasably attachable to the associated TEE probe.

[0054] It is yet another object of the present invention

to provide a transnasal conduit that is releasably attachable to the patient.

[0055] These and other objects, advantages, and the industrial utility of the present invention will be apparent from a review of the accompanying specification and drawings.

Claims

1. A transnasal conduit (10) for atraumatically guiding a member through delicate mucosal passages of a patient, comprising:

a tube (12), said tube having a relatively thin and pliable wall and a single relatively wide inner diameter with respect to the mucosal passages; said tube (12) having an open proximal end (16) for introduction of a member into said tube; said tube (12) having a plurality of separate lobes (30) formed at a distal end (14) of said tube, said plurality of lobes being contoured to be disposed in abutting relationship for forming a normally closed distal end for promoting atraumatic travel of said tube through the mucosal passages, said plurality of separate lobes being displaceable to open said distal end of said tube responsive to a force applied thereto by advancement of the member through said tube; a flange (40), said flange circumscribing said open proximal end (16) of said tube, said flange providing an abutting surface that helps prevent migration of said tube further into a naris associated with the mucosal passages past said open proximal end; and clamping means (44) for depressing said thin and pliable wall of said tube to temporarily and releasably clamp the member to said tube; whereby said member being temporarily secured to the transnasal conduit by tightening said clamping means to form a conduit-member assembly, said conduit-member assembly is inserted into the mucosal passages until said flange abuts a naris, said clamping means is loosened, and said member passed past said normally closed distal end and opening same so as to expose a distal end of said member, said distal end engaging the patient and allowing monitoring of the patient's condition by said member,

characterized in that said relatively thin and pliable tube wall is striated to allow easier passage of the member through said tube.

2. The transnasal conduit of claim 1, wherein said relatively thin and pliable wall of said tube is approximately one to three millimeters thick.

3. The transnasal conduit of claim 1, wherein said open proximal end is flared for easier introduction of the member into said tube.

4. The transnasal conduit of claim 1, wherein said clamping means further comprises:

a collar, said collar circumscribing said tube, said collar having a threaded aperture formed therethrough in a generally perpendicular orientation with respect to said thin and pliable wall; and
a thumbscrew (44), said thumbscrew threadingly engaging said threaded aperture, said thumbscrew projecting against said thin and pliable wall when increasingly threaded into said threaded aperture to compress said thin and pliable wall and thereby reduce said inner diameter of said tube.

5. The transnasal conduit of claim 1 in which the member is a sensor probe, comprising:

the tube of claim 1, said tube being one to three millimeters thick and one centimeter in diameter, said

relatively thin and pliable wall being striated to allow easier passage of a probe through said tube;

said tube having separate lobes formed on a distal end thereof, said separate lobes being contoured to be disposed in abutting relationship one to another for forming a normally closed distal end of said tube for promoting atraumatic travel of said tube through the mucosal passages, said separate lobes having interior protuberances formed thereon for elastically holding said lobes in said abutting relationship, said separate lobes being displaceable to open said distal end of said tube responsive to a force applied thereto by advancement of the probe through said tube; said tube having a flared open proximal end for easier introduction of the probe into said tube and for providing an abutting surface that helps to prevent migration of said tube further into a naris associated with the mucosal passages past said open proximal end;

pinch clamp-means for pinching said thin and pliable wall of said tube to temporarily and releasably secure the probe within said tube, said pinch clamp means including (1) a collar circumscribing said tube, said collar having a threaded aperture formed therethrough and disposed in a generally perpendicular orientation with respect to said thin and pliable wall, and (2) a thumbscrew threadingly engaging said threaded aperture, said thumbscrew projecting against said thin and pliable wall when increasingly

threaded into said threaded aperture; a patient flange, said patient flange circumscribing said tube and having a pair of ears coupled thereto on opposing sides thereof; and

an elastic strap for coupling said patient flange and said tube to the patient, said elastic strap having a pair of opposing ends respectively coupled to said pair of ears.

6. The transnasal conduit of claim 1, comprising:

a tube, said tube having a relatively thin and pliable wall and a relatively wide inner diameter with respect to the mucosal passages, said tube being striated to allow easier passage of a member through said tube;

said tube having an open proximal end for introduction of the member into said tube;

said tube having a plurality of separate lobes formed at a distal end of said tube, said plurality of lobes being contoured to be disposed in abutting relationship for forming a normally closed distal end for promoting atraumatic travel of said tube through the mucosal passages, said plurality of separate lobes being displaceable to open said distal end of said tube responsive to a force applied thereto by advancement of the member through said tube;

a flange, said flange circumscribing said open proximal end of said tube, said flange providing an abutting surface that helps prevent migration of said tube further into a naris associated with the mucosal passages past said open proximal end; and

clamping means for depressing said thin and pliable wall of said tube to temporarily and releasably clamp the member to said tube.

7. The transnasal conduit of claim 5 for atraumatically introducing a patient monitoring sensor through delicate mucosal passages of a patient, comprising:

a member having a distal end with the sensor coupled thereto; a tube, said tube having a relatively thin and pliable wall and a relatively wide inner diameter with respect to the mucosal passages, said tube having an open proximal end for introduction of said member into said tube, said tube having a plurality of separate lobes formed at a distal end of said tube, said plurality of lobes being disposed in abutting relationship to form said distal end of said tube in a normally closed condition for promoting atraumatic travel of said tube through the mucosal passages, said plurality of separate lobes being displaceable to open said distal end responsive to a force applied thereto by advancement of the member through said tube;

a flange, said flange circumscribing said open proximal end of said tube, said flange providing an abutting surface that helps prevent migration of said tube further into a naris associated with the mucosal passages past said open proximal end; and

clamping means disposed adjacent said flange for depressing said thin and pliable wall of said tube to temporarily clamp said member to said tube for forming an assembly to be inserted into the mucosal passages, said clamping means being releasable to permit advancement of said member past said plurality of lobes to expose said distal end of said member for contact with the patient

8. The transnasal conduit of claim 7, wherein said separate lobes comprise interior protuberances promoting closure of said normally closed distal end.

Patentansprüche

1. Eine transnasale Leitung (10), um atraumatisch ein Element durch empfindliche Schleimhautgänge eines Patienten zu führen, umfassend:

einen Schlauch (12), wobei besagter Schlauch eine relativ dünne und biegsame Wand und einen einzigen, relativ weiten Innendurchmesser in Bezug auf die Schleimhautgänge aufweist; wobei besagter Schlauch (12) ein offenes proximales Ende (16) zur Einführung eines Elements in besagten Schlauch aufweist; wobei besagter Schlauch (12) eine Vielzahl getrennter Lappen (30) aufweist, die an einem distalen Ende (14) besagten Schlauchs gebildet sind, wobei besagte Vielzahl von Lappen eine solche Kontur aufweist, dass sie in Stoßbeziehung angeordnet werden können, um ein normalerweise geschlossenes distales Ende zum Fördern atraumatischer Bewegung besagten Schlauchs durch die Schleimhautgänge zu bilden, wobei besagte Vielzahl getrennter Lappen verschoben werden kann, um besagtes distales Ende besagten Schlauchs als Reaktion auf eine durch Voranbewegen des Elements durch besagten Schlauch darauf ausgeübte Kraft zu öffnen;

einen Flansch (40), wobei besagter Flansch besagtes offenes proximales Ende (16) besagten Schlauchs umgibt, wobei besagter Flansch eine Stoßfläche verschafft, die das Weiterwandern besagten Schlauchs über besagtes offenes proximales Ende in ein zu den Schleimhautgängen gehörendes Nasenloch verhindern hilft; und Klennmittel (44) zum Herunterdrücken besagter dün-

ner und biegsamer Wand besagten Schlauchs, um das Element zeitweilig und lösbar an besagten Schlauch zu klemmen;

wobei

besagtes Element zeitweilig an der transnasalen Leitung befestigt wird, indem besagtes Klemmmittel angespannt wird, um eine Einheit aus Leitung und Element zu bilden, wobei besagte Einheit aus Leitung und Element in die Schleimhautgänge eingeführt wird, bis besagter Flansch an einem Nasenloch anstößt, besagtes Klemmmittel gelockert wird und besagtes Element an besagtem normalerweise geschlossenen distalen Ende vorbei geführt und geöffnet wird, um ein distales Ende besagten Elements freizulegen, wobei besagtes distales Ende an dem Patienten angreift und die Überwachung des Zustandes des Patienten durch besagtes Element gestattet,

dadurch gekennzeichnet, dass besagte relativ dünne und biegsame Schlauchwand gefurcht ist, um ein leichteres Passieren des Elements durch besagten Schlauch zu gestatten.

2. Die transnasale Leitung gemäß Anspruch 1, wobei besagte relativ dünne und biegsame Wand besagten Schlauchs annähernd ein bis drei Millimeter dick ist.

3. Die transnasale Leitung gemäß Anspruch 1, wobei besagtes offenes proximales Ende zum leichteren Einführen des Elements in besagten Schlauch konisch erweitert ist.

4. Die transnasale Leitung gemäß Anspruch 1, wobei besagtes Klemmmittel weiterhin folgendes umfasst:

einen Kragen, wobei besagter Kragen besagten Schlauch umgibt, wobei durch besagten Kragen eine mit Gewinde versehene Öffnung mit einer im allgemeinen senkrechten Orientierung in Bezug auf besagte dünne und biegsame Wand gebildet ist; und

eine Flügelschraube (44), wobei besagte Flügelschraube schraubend an besagter mit Gewinde versehener Öffnung angreift, wobei besagte Flügelschraube gegen besagte dünne und biegsame Wand vorragt, wenn sie zunehmend in besagte mit Gewinde versehene Öffnung geschraubt wird, um besagte dünne und biegsame Wand zusammenzudrücken und **dadurch** besagten Innendurchmesser besagten Schlauchs zu verringern.

5. Die transnasale Leitung gemäß Anspruch 1, worin das Element eine Sensorsonde ist, umfassend:

den Schlauch gemäß Anspruch 1, wobei besag-

ter Schlauch ein bis drei Millimeter dick ist und einen Zentimeter Durchmesser ausweist, wobei beasgte relativ dünne und biegsame Wand gefurcht ist, um ein leichteres Passieren einer Sonde durch besagten Schlauch zu gestatten;

5

wobei besagter Schlauch getrennte Lappen aufweist, die an einem distalen Ende davon geformt sind, wobei besagte getrennte Lappen mit einer solchen Kontur versehen sind, dass sie in Stoßverhältnis zueinander angeordnet werden können, um ein normalerweise geschlossenes distales Ende besagten Schlauchs zu bilden, um eine atraumatische Bewegung besagten Schlauchs durch die Schleimhautgänge zu fördern, wobei an besagten getrennten Lappen innerliche Ausstülpungen geformt sind, um besagte Lappen auf elastische Weise in besagtem Stoßverhältnis zu halten, wobei besagte getrennte Lappen verschiebbar sind, um besagtes distales Ende besagten Schlauchs in Reaktion auf eine durch Voranbewegen der Sonde durch besagten Schlauch darauf ausgeübte Kraft zu öffnen;

10

wobei besagter Schlauch ein konisch erweitertes offenes proximales Ende zum leichteren Einführen der Sonde in besagten Schlauch und zum Verschaffen einer Stoßfläche, die das Weiterwandern besagten Schlauchs in ein zu den Schleimhautgängen gehörendes Nasenloch über besagtes offenes proximales Ende hinaus verhindern hilft, aufweist;

15

Quetsch-Klemmmittel zum Zusammenquetschen besagter dünner und biegsamer Wand besagten Schlauchs, um die Sonde zeitweilig und lösbar innerhalb besagten Schlauchs zu befestigen, wobei besagte Quetsch-Klemmmittel 1. einen besagten Schlauch umgebenden Kragen umfassen, wobei durch besagten Kragen eine mit Gewinde versehene Öffnung geformt ist und er in Bezug auf besagte dünne und biegsame Wand mit einer im allgemeinen senkrechten Orientierung angeordnet ist, und 2. eine Flügelschraube, die schraubbar an besagter mit Gewinde versehener Öffnung angreift, wobei besagte Flügelschraube gegen besagte dünne und biegsame Wand vorragt, wenn sie zunehmend in besagte mit Gewinde versehene Öffnung geschraubt wird;

20

25

30

35

einen Patientenflansch, wobei besagter Patientenflansch besagten Schlauch umgibt und ein Paar Ösen aufweist, die an gegenüberliegenden Seiten davon darangekoppelt sind; und

40

einen Gummigurt, um besagten Patientenflansch und besagten Schlauch an den Patienten zu koppeln, wobei besagter Gummigurt ein jeweils an besagtes Paar Ösen gekoppeltes Paar einander gegenüberliegender Enden aufweist.

45

50

6. Die transnasale Leitung gemäß Anspruch 1, umfassend:

55

einen Schlauch, wobei besagter Schlauch eine relativ dünne und biegsame Wand und einen relativ weiten Innendurchmesser in Bezug auf die Schleimhautgänge aufweist, wobei besagter Schlauch gefurcht ist, um ein leichteres Passieren eines Elements durch besagten Schlauch zu gestatten;

wobei besagter Schlauch ein offenes proximales Ende zum Einführen des Elements in besagten Schlauch aufweist;

wobei besagter Schlauch eine Vielzahl getrennter Lappen aufweist, die an einem distalen Ende davon geformt sind,

wobei besagte Vielzahl getrennter Lappen mit einer solchen Kontur versehen ist, dass sie in verhältnis zueinander angeordnet werden können, um ein normalerweise geschlossenes distales Ende besagten Schlauchs zu bilden, um eine atraumatische Bewegung besagten Schlauchs durch die Schleimhautgänge zu fördern, wobei besagte Vielzahl getrennter Lappen verschiebbar ist, um besagtes distales Ende besagten Schlauchs in Reaktion auf eine durch Voranbewegen der Sonde durch besagten Schlauch darauf ausgeübte Kraft zu öffnen;

einen Flansch, wobei besagter Flansch besagtes offenes proximales Ende besagten Schlauchs umgibt, wobei besagter Flansch eine Stoßfläche verschafft, die das Weiterwandern besagten Schlauchs in ein zu den Schleimhautgängen gehörendes Nasenloch über besagtes offenes proximales Ende hinaus verhindern hilft; und Klemmmittel zum Herunterdrücken besagter dünner und biegsamer Wand besagten Schlauchs, um das Element zeitweilig und lösbar an besagten Schlauch zu klemmen.

7. Die transnasale Leitung gemäß Anspruch 5 zum atraumatischen Einführen eines Patientenüberwachungssensors durch empfindliche Schleimhautgänge eines Patienten, umfassend:

ein Element, das ein distales Ende mit dem daran gekoppelten Sensor aufweist; einen Schlauch, wobei besagter Schlauch eine relativ dünne und biegsame Wand und einen relativ weiten Innendurchmesser in Bezug auf die Schleimhautgänge aufweist, wobei besagter Schlauch ein offenes proximales Ende zum Einführen besagten Elements in besagten Schlauch aufweist, wobei besagter Schlauch eine Vielzahl getrennter Lappen aufweist, die an einem distalen Ende besagten Schlauchs gebildet sind,

wobei besagte Vielzahl von Lappen in einem Stoßverhältnis angeordnet ist, um besagtes distales Ende besagten Schlauchs in einem normalerweise geschlossenen Zustand zu bilden, um eine atrauma-

tische Bewegung besagten Schlauchs durch die Schleimhautgänge zu fördern, wobei besagte Vielzahl besagter getrennter Lappen verschiebbar ist, um besagtes distales Ende in Reaktion auf eine durch Voranbewegen des Elements durch besagten Schlauch darauf ausgeübte Kraft zu öffnen; einen Flansch, wobei besagter Flansch besagtes offenes proximales Ende besagten Schlauchs umgibt, wobei besagter Flansch eine Stoßfläche verschafft, die das Weiterwandern besagten Schlauchs in ein zu den Schleimhautgängen gehörendes Nasenloch über besagtes offenes proximales Ende hinaus verhindern hilft; und Klemmittel, die benachbart zu besagtem Flansch angeordnet sind, um besagte dünne und biegsame Wand herunterzudrücken, um besagtes Element zeitweilig an besagten Schlauch zu klemmen, um eine Einheit zum Einführen in die Schleimhautgänge zu bilden, wobei besagtes Klemmmittel lösbar ist, um das Voranbewegen besagten Elements über besagte Vielzahl von Lappen hinaus zu gestatten, um besagtes distales Ende besagten Elements für den Kontakt mit dem Patienten freizulegen.

8. Die transnasale Leitung gemäß Anspruch 7, wobei besagte getrennte Lappen innerliche Ausstülpungen umfassen, die das Schließen besagten normalerweise geschlossenen distalen Endes fördern.

Revendications

1. Conduit transnasal (10) pour le guidage atraumatique d'un membre à travers des passages muqueux délicats d'un patient, comprenant :

un tube (12), ledit tube possédant une paroi relativement mince et pliable et un diamètre interne unique relativement large par rapport aux passages muqueux :

ledit tube (12) possédant une extrémité proximale ouverte (16) pour l'introduction d'un membre dans ledit tube ;

ledit tube (12) possédant plusieurs lobes séparés (30) formés à l'extrémité distale (14) dudit tube, lesdits plusieurs lobes étant profilés pour venir se disposer en relation de bout à bout pour former une extrémité distale normalement fermée destinée à favoriser le déplacement atraumatique dudit tube à travers les passages muqueux, lesdits plusieurs lobes séparés étant à même de se déplacer pour ouvrir ladite extrémité distale dudit tube en réponse à une force qu'y exerce la progression du membre à travers ledit tube ;

une bride (44), ladite bride entourant ladite extrémité proximale ouverte (16) dudit tube, ladite bride procurant une surface de butée qui favo-

rise le fait d'empêcher la migration ultérieure dudit tube jusque dans une narine associée aux passages muqueux au-delà de ladite extrémité proximale ouverte et

un moyen de serrage (44) pour enfoncer ladite paroi mince et pliable dudit tube dans le but de serrer de manière temporaire et de manière amovible le membre contre ledit tube ; par lequel

ledit membre est fixé de manière temporaire au conduit transnasal en serrant ledit moyen de serrage pour former un assemblage de conduit-membre, ledit assemblage de conduit-membre est inséré dans les passages muqueux jusqu'à ce que la dite bride vienne buter contre une narine, ledit moyen de serrage est relâché, on fait passer ledit membre devant ladite extrémité distale normalement fermée et on l'ouvre de façon à exposer l'extrémité distale dudit membre, ladite extrémité distale entrant en contact avec le patient et permettant la surveillance de l'état du patient à l'aide dudit membre ;

caractérisé en ce que ladite paroi de tube relativement mince et pliable est striée pour faciliter le passage du membre à travers ledit tube.

2. Conduit transnasal selon la revendication 1, dans lequel ladite paroi relativement mince et pliable dudit tube possède une épaisseur approximative de 1 à 3 mm.

3. Conduit transnasal selon la revendication 1, dans lequel ladite extrémité proximale ouverte est évasée pour faciliter l'introduction du membre dans ledit tube.

4. Conduit transnasal selon la revendication 1, dans lequel ledit moyen de serrage comprend en outre :

une bague, ladite bague entourant ledit tube, ladite bague possédant un orifice taraudé qui la traverse dans une orientation généralement perpendiculaire par rapport à ladite paroi mince et pliable ; et

une vis à clé de violon (44), ladite vis à clé de violon entrant en contact par filet de vis avec ledit orifice taraudé ; ladite vis à clé de violon faisant saillie contre ladite paroi mince et pliable lorsque son vissage progresse dans ledit orifice taraudé dans le but de comprimer ladite paroi mince et pliable, et d'ainsi réduire ledit diamètre interne dudit tube.

5. Conduit transnasal selon la revendication 1, dans lequel le membre est une sonde de détection comprenant :

le tube selon la revendication 1, ledit tube pos-

sédant une épaisseur de 1 à 3 mm et un diamètre de 1 cm ;

ladite paroi relativement mince et pliable étant striée pour faciliter le passage de la sonde à travers ledit tube ;

ledit tube possédant des lobes séparés former à son extrémité distale, lesdits lobes séparés étant profilés pour venir se disposer en relation de bout à bout les uns avec les autres pour former une extrémité distale normalement fermée dudit tube dans le but de favoriser la progression atraumatique dudit tube à travers les passages muqueux, lesdits lobes séparés possédant des saillies internes façonnées pour maintenir de manière élastique lesdits lobes dans ladite relation de bout à bout, lesdits lobes séparés étant à même de se déplacer pour ouvrir ladite extrémité distale dudit tube en réponse à une force qu'y exerce la progression de la sonde à travers ledit tube ;

ledit tube possédant une extrémité proximale ouverte évasée pour faciliter l'introduction de la sonde dans ledit tube et pour procurer une surface de butée qui favorise le fait d'empêcher la migration ultérieure dudit tube jusque dans une narine associée aux passages muqueux au-delà de ladite extrémité proximale ouverte ;

un moyen de serrage par pincement pour pincer ladite paroi mince et pliable dudit tube dans le but de fixer de manière temporaire et amovible la sonde à l'intérieur dudit tube, ledit moyen de serrage par pincement englobant (1) une bague entourant ledit tube, ladite bague possédant un orifice taraudé qui la traverse et qui est disposé en orientation généralement perpendiculaire par rapport à ladite paroi mince et pliable, et (2) une vis à clé de violon qui vient s'engrener par filet de vis avec ledit orifice taraudé, ladite vis à clé de violon faisant saillie contre ladite paroi mince et pliable lorsque son vissage progresse dans ledit orifice taraudé ;

une bride pour patient, ladite bride pour patient entourant ledit tube possédant une paire d'oreilles qui sont accouplées sur ses côtés opposés ; et

une bande élastique pour l'accouplement de ladite bride pour patient et dudit tube au patient, ladite bande élastique possédant une paire d'extrémités opposées respectivement accouplées à ladite paire d'oreilles.

6. Conduit transnasal selon la revendication 1, comprenant :

un tube, ledit tube possédant une paroi relativement mince et pliable et un diamètre interne unique relativement large par rapport aux passages muqueux, ledit tube étant strié pour faciliter

le passage d'un membre à travers ledit tube ; ledit tube possédant une extrémité proximale ouverte pour l'introduction du membre dans ledit tube ;

ledit tube possédant plusieurs lobes séparés formés à l'extrémité distale dudit tube, lesdits plusieurs lobes étant profilés pour venir se disposer en relation de bout à bout pour former une extrémité distale normalement fermée destinée à favoriser le déplacement atraumatique dudit tube à travers les passages muqueux, lesdits plusieurs lobes séparés étant à même de se déplacer pour ouvrir ladite extrémité distale dudit tube en réponse à une force qu'y exerce la progression du membre à travers ledit tube ;

une bride, ladite bride entourant ladite extrémité proximale ouverte dudit tube, ladite bride procurant une surface de butée qui favorise le fait d'empêcher la migration ultérieure dudit tube jusque dans une narine associée aux passages muqueux au-delà de ladite extrémité proximale ouverte ; et

un moyen de serrage pour enfoncer ladite paroi mince et pliable dudit tube dans le but de serrer de manière temporaire et de manière amovible le membre contre ledit tube.

7. Conduit transnasal selon la revendication 5, pour l'introduction atraumatique d'un capteur de surveillance d'un patient à travers des passages muqueux délicats d'un patient, comprenant :

un membre possédant une extrémité distale à laquelle est accouplé le capteur ;

un tube, ledit tube possédant une paroi relativement mince et pliable et un diamètre interne unique relativement large par rapport aux passages muqueux, ledit tube possédant une extrémité proximale ouverte pour l'introduction dudit membre dans ledit tube ; ledit tube possédant plusieurs lobes séparés formés à l'extrémité distale dudit tube, lesdits plusieurs lobes étant disposés en relation de bout à bout pour former ladite extrémité distale dudit tube normalement fermée pour favoriser le déplacement atraumatique dudit tube à travers les passages muqueux, lesdits plusieurs lobes séparés étant à même de se déplacer pour ouvrir ladite extrémité distale dudit tube en réponse à une force qu'y exerce la progression du membre à travers ledit tube ;

une bride, ladite bride entourant ladite extrémité proximale ouverte dudit tube, ladite bride procurant une surface de butée qui favorise le fait d'empêcher la migration ultérieure dudit tube jusque dans une narine associée aux passages muqueux au-delà de ladite extrémité proximale ouverte ; et

un moyen de serrage disposé en position adjacente à ladite bride pour enfoncer ladite paroi mince et pliable dudit tube dans le but de serrer de manière temporaire ledit membre contre ledit tube pour former un assemblage qui doit être inséré dans les passages muqueux, ledit moyen de serrage étant amovible pour permettre la progression dudit membre au-delà desdits plusieurs lobes dans le but d'exposer ladite extrémité distale dudit membre à des fins de mise en contact avec le patient.

8. Conduit transnasal selon la revendication 7, dans lequel lesdits lobes séparés comprennent des saillies internes favorisant la fermeture de ladite extrémité distale normalement fermée.

20

25

30

35

40

45

50

55

