



- (51) **International Patent Classification:**
A61M 16/04 (2006.01) *A61M 16/00* (2006.01)
- (21) **International Application Number:**
PCT/US2014/011639
- (22) **International Filing Date:**
15 January 2014 (15.01.2014)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
13/742,146 15 January 2013 (15.01.2013) US
- (71) **Applicant:** COVIDIEN LP [US/US]; 15 Hampshire Street, Mansfield, Massachusetts 02048 (US).
- (72) **Inventor; and**
- (71) **Applicant (for US only):** MORRIS, Sean [IE/IE]; Clooncundra, Ballymurray, Roscommon (IE).
- (74) **Agent:** ANDERSON, Matthew; 6135 Gunbarrel Avenue, Boulder, Colorado 80301 (US).
- (81) **Designated States** (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

- (84) **Designated States** (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) **Title:** TRACHEAL DILATION APPARATUS AND METHOD OF MANUFACTURE

(57) **Abstract:** A tracheal dilator system and method of manufacture are provided, suitable for dilating a passageway into a patient airway. In one embodiment, a medical system having a tracheal dilator is provided. The tracheal dilator includes a first plurality of openings and a guide lumen configured to provide a pathway for the insertion of a guide wire during use of the tracheal dilator. The tracheal dilator further includes a first flow lumen configured to fluidly couple the first plurality of openings to a medical device, wherein the medical device is configured to provide a suctioning force through the first plurality of openings during use of the tracheal dilator.



WO 2014/113448 A1

TRACHEAL DILATION APPARATUS AND METHOD OF MANUFACTURE

BACKGROUND

5

The present disclosure relates to a tracheal dilation techniques, and more particularly to a tracheal dilation via a dilation cannula structure.

10 This section is intended to introduce the reader to various aspects of art that may be related to various aspects of the present disclosure, which are described and/or claimed below. This discussion is believed to be helpful in providing the reader with background information to facilitate a better understanding of the various aspects of the present disclosure. Accordingly, it should be understood that these statements are to be read in this light, and not as admissions of prior art.

15

A wide range of applications exist for artificial ventilation, which may call for the use of tubes that are inserted into a patient. Such tubes may include endotracheal tubes, tracheostomy tubes, and so forth. In the latter case, the tubes are typically inserted into an opening or stoma formed in the neck and trachea of the patient. In both cases, the tubes may be used for artificial ventilation or for assisting patient ventilation. The stoma is typically formed either surgically, through a procedure such as a cricothyroidotomy, tracheostomy, or through a micro-surgical procedure such as percutaneous dilation. Cricothyroidotomy requires the use of a surgical team working in a sterilized environment to create an opening in the cricothyroid membrane, thus providing access to the patient's airway. The procedure typically involves the cauterizing of blood vessels, and typically has the patient undergoing general anesthesia.

25

Percutaneous dilation entails using an instrument, such as a needle or a scalpel, to make a small opening between the tracheal rings on a frontal or anterior region of the patient's neck. The needle or scalpel may then be inserted through the opening in the tracheal rings to allow a passageway into the patient's airway. A dilator may then be

30

pushed inwardly towards the trachea to enlarge the stoma. It would be beneficial to provide for a more efficient dilation apparatus.

SUMMARY

5

The present disclosure provides a novel dilation device that includes one or more lumens with openings fluidly coupled to a pumping device. In a first mode of operation, the pumping device, such as a pump or a ventilator, may be used to provide positive airflow suitable for expelling a gas (e.g., air) through the dilator openings and creating a cushion effect. By “lubricating” the stoma opening, the cushion effect may aid in the insertion of the dilator, thus minimizing tearing of tissue and additionally minimizing the clinician’s insertion effort. In a second mode of operation, the pumping device may provide for a suctioning force suitable for vacuuming fluids (e.g., secretions) and tissue particles during the dilation, thus minimizing bleeding and patient discomfort. Accordingly, any bleeding may be minimized and effluent entering the airway may be eliminated.

The positive airflow may be provided at the beginning of insertion of the dilator, and then the pumping device may switch to providing suctioning once the dilator tip is inserted, or vice versa. In other modes of operation, only positive airflow or only suctioning may be used. In certain embodiments, the dilation device may be a curved and/or cone shape dilator, similar to a horn, with increasing diameter from a distal tip to a proximal base. As the dilator penetrates the stoma, the increasing diameter of the dilator may gradually expand the stoma until a desired size is reached, suitable for the insertion of a tracheostomy tube. By using the multiple lumens connected to openings disposed on the dilator for positive airflow and/or suctioning, the dilation techniques described herein may minimize trauma and provide for a more efficient and faster dilation procedure.

In accordance with one embodiment, a medical system having a tracheal dilator is provided. The tracheal dilator includes a first plurality of openings and a guide lumen configured to provide a pathway for the insertion of a guide wire during use of the tracheal dilator. The tracheal dilator further includes a first flow lumen configured to fluidly couple

the first plurality of openings to a medical device, wherein the medical device is configured to provide a suctioning force through the first plurality of openings during use of the tracheal dilator.

5 In a similar arrangement, a tracheal dilator is provided. The tracheal dilator includes a guide cannula configured to provide a pathway for the insertion of a guide wire during use of the tracheal dilator. The tracheal dilator additionally includes a first flow cannula comprising a first plurality of openings, wherein the first flow cannula is configured to fluidly couple the first plurality of openings to a medical device, and wherein
10 the medical device is configured to provide a positive flow of a gas through the first plurality of openings during use of the tracheal dilator.

Also provided is a method for manufacturing a tracheostomy dilator. The method includes manufacturing a guide cannula configured to provide a pathway for the insertion
15 of a guide wire during use of the tracheostomy dilator. The method additionally includes manufacturing a first flow cannula comprising a first plurality of openings, wherein the first flow cannula is configured to fluidly couple the first plurality of openings to a medical device, and wherein the medical device is configured to provide a positive flow of a gas through the first plurality of openings during use of the tracheal dilator.

20

BRIEF DESCRIPTION OF THE DRAWINGS

Advantages of the disclosed techniques may become apparent upon reading the following detailed description and upon reference to the drawings in which:

25

Fig. 1 is a sectional view of a patient's tracheal region and an insertion of a percutaneous needle;

Fig. 2 is a sectional view of a guide wire and the percutaneous needle inserted
30 into the tracheal region of **Fig. 1**;

Fig. 3 is a sectional view illustrating an embodiment of a multiple lumen dilator disposed in a tracheal region;

Fig. 4 is a sectional view of the of an embodiment of the multiple lumen dilator of **Fig. 3**, illustrating a guide lumen and a flow lumen;

Fig. 5 is a sectional view of a distal tip of an embodiment of the multiple lumen dilator of **Fig. 3**;

Fig. 6 is a side view of an embodiment of the multiple lumen dilator of **Fig. 3** having a curved shape;

Fig. 7 is a perspective view of an embodiment of a manifold of the multiple lumen dilator of **Fig. 6**;

Fig. 8 is a rear view of a of an embodiment of the manifold of the multiple lumen dilator of **Fig. 7**;

Fig. 9 is a view of flow lumen openings having circular shapes;

Fig. 10 is a view of flow lumen openings having teardrop shapes;

Fig. 11 is a view of flow lumen openings having reverse teardrop shapes; and

Fig. 12 is a view of flow lumen openings having slit shapes.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

One or more specific embodiments of the present techniques will be described below. In an effort to provide a concise description of these embodiments, not all features of an actual implementation are described in the specification. It should be appreciated that in the development of any such actual implementation, as in any engineering or design project, numerous implementation-specific decisions must be

made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which may vary from one implementation to another. Moreover, it should be appreciated that such a development effort might be complex and time consuming, but would nevertheless be a routine undertaking of design, fabrication, and manufacture for those of ordinary skill having the benefit of this disclosure.

Fig. 1 is a sectional view illustrating a placement of a percutaneous needle **10** in a trachea **12** of a patient **14**. By inserting the percutaneous needle **10** into the trachea **12**, an initial opening or tracheal passageway **16** into an airway **18** is created, suitable for dilation. As depicted, the patient **14** is disposed in a supine position, with a chin **20** slightly elevated. In certain circumstances, a rostral traction on the trachea **12** may be applied so as to gain neck hyperextension and better access to a frontal neck region **22**. General or local anesthesia may be used to dull or eliminate any discomfort during the dilation procedure. Additionally, the patient **14** may be intubated, such as by using an endotracheal tube **24**. Indeed, the systems and methods disclosed herein enable a dilation procedure with artificial respiration kept *in situ*. It is also to be noted that the systems and methods disclosed herein enable dilation without artificial respiration support (e.g., without the endotracheal tube **24**).

As depicted, a cannula **26** of the percutaneous needle **10** may be inserted in a direction **28**, and enter the trachea **12** between a first **30** and a second **32** tracheal rings. As the percutaneous needle **10** is advanced in the direction **28**, an aspiration of air through the needle **10** may indicate that the needle **26** has reached a desired position inside of the patient airway **18**. Other methods useful in verifying that the cannula **26** is in the desired position may be used, such as a bronchoscopic survey, an ultrasound survey, and the like. It is also to be noted that other instruments may be used in creating the initial passageway **16** through the trachea **12**. For example, a scalpel may also be used to provide a vertical or horizontal slit passageway **16** into the trachea **12**. By using minimally invasive techniques to breach the trachea **12**, scarring and other unsightly neck trauma may be minimized or avoided. Likewise, major bleeding during the dilation procedure may be eliminated. Once a clinician has verified that the needle cannula **26** has reached the desired position inside the airway **18**, a body **34** of the needle

10 may be removed. A guide wire, such as a J-tip guide wire, may then be inserted through the cannula **26** of the needle **10**, as described in more detail below with respect to **Fig. 2**.

5 **Fig. 2** is a sectional view depicting the insertion of a J-tip guide wire **36** into the patient's airway **18**. Because the figure contains like elements found in **Fig. 1**, these like elements are denoted using like reference numbers. As illustrated, the guide wire **36** is disposed inside of the needle cannula **26** and inserted so that a generally curved tip **38** is positioned inside the patient's airway **18**. Using a guide wire, such as the J-tip guide
10 wire **36**, may enable a more efficient insertion of the dilation systems described herein. However, the dilation systems described herein may also be inserted into the trachea **12** without the use of any type of guide wire. When the J-tip guide wire **36** is used, the curved tip **38** may cause less trauma because the curved portion of the tip **38** is less likely to puncture the patient airway **18**. That is, the curved tip **38** may prevent a
15 "poking" or dagger effect. Once the curved tip **38** is inside the airway **18**, the clinician may insert the guide wire **36** into a hollow shaft of a dilator, and then "slide" the dilator over the guide wire **36** to position a dilator partially inside of the patient airway **18**, as depicted in **Fig. 3**.

20 **Fig. 3** is a sectional view illustrating a multi-lumen dilator **40** having a distal portion **42** positioned inside of the tracheal passageway **16**. As mentioned above, the guide wire **36** may be disposed inside a guide lumen **44** of the multi-lumen dilator **40** and used as a guide into the patient airway **18**. One or more flow lumens **46** may also be provided. In one embodiment, the guide lumen **44** may not be used and the single (or
25 multiple) lumens **46** may be used. The flow lumens **46** may be fluidly coupled to a medical device **48**, such as a pump (e.g., vacuum pump and/or positive pressure pump) and/or a ventilator, by using one or more conduits **50**. In a first operating mode, the medical device **48** may provide for positive airflow suitable for providing a gas (e.g., air, medicines) in the direction **52** inwardly into the dilator lumen(s) **46**, thus delivering a
30 positive pressure flow that may exit through a plurality of openings **54**. The aforementioned gas flow may then create a cushion of air, which may surround the dilator **40** and provide for gaseous lubrication during the insertion (or retrieval) of the

dilator **40**. The positive fluid flow pressure may also be controllable, thus providing for the air cushion effect in a wide variety of patient anatomies, including neonatal, pediatric, and adult patients. The medical device may use the ideal gas law, i.e., $P \times V = n \times R \times T$, where P is a fluid flow pressure suitable for inflating a volume V at a
5 temperature T based on the number of moles n of a gas and on the ideal gas constant R . Accordingly, the desired volumetric pressure may be found. For example, the inflation P may be between about 15cm H₂O and 10,000cm H₂O.

In a second operating mode, the medical device **48** may create a vacuum suitable
10 for suctioning secretions, gas, and loose particles through the openings **54** and into the medical device **48** in a direction **56**. The suctioning mode of operations may be particularly useful in certain situations, including emergency response situations such as when the patient is more prone to bleeding. The suctioning force may be varied by the clinician to accommodate various usage scenarios, for example, from heaving fluid
15 flows to light fluid flows. Accordingly, patient secretions entering the airway **18** may be minimized or eliminated. By providing for gas flow and/or the vacuum force, the medical device **48** may enable a more efficient dilation while minimizing trauma. In certain embodiments, the multi-lumen dilator **40** includes an increasing diameter from a distal tip **58** to a proximal base **60**, which may be useful in expanding the passageway **16**
20 as the dilator **40** is moved inwardly towards the airway **18**. To aid in the insertion into the airway **18**, the dilator **40** may include a generally conically-shaped body, as described in more detail with respect to **Fig. 4**.

Turning now to **Fig. 4**, the figure is a cross-sectional view of an embodiment of
25 the multi-lumen dilator **40** having a conically-shaped body **62** and an angled portion **64** having an angle α . In the depicted embodiment, the angled portion **64** may include the openings **54**, while a portion **66** may not include any openings **54**. In another embodiment, the portion **66**, or section of the portion **66**, may also include the openings **54**. In one embodiment, the portion **64** may be between 1/10 to 1/2 of a total length of the
30 dilator **40**. The angle α may enable the use of a levering force useful in providing added leverage when dilating the stoma. For example, the clinician may insert the distal tip **58** into the stoma with only a partial (or complete) section of the portion **64** in the stoma,

and then use the tissues in the passageway **16** as a fulcrum to further dilate and insert the dilator **64** further inwardly into the airway **18**. The angle α may be between 90° to 270° . Indeed, in one embodiment, the angle α may be 180° , thus forming a straight, unbent line between the portions **64** and **66**.

5

Also depicted are the lumens **44** and **46**. As mentioned previously, the lumen **44** may be used as a guide lumen suitable for use of the guide wire **36** as shown in **Fig. 3**. Once the guide wire **36** is disposed inside of the lumen **44**, the dilator **40** may then follow the guide wire **36** inwardly into the airway **18**. The lumen **46** may be fluidly
10 coupled to the medical device **48** and used to provide for gaseous flow outwardly from the openings **54**, and/or used to suction secretions and particulates inwardly into the lumen **46** and the medical device **48**. Accordingly, the multi-lumen dilator **40** may be used to more easily dilate the stoma as well as to minimize or eliminate secretions from entering into the patient airway **18**. The dilator **40** may be manufactured from a material
15 such as a polyvinylchloride, a polyurethane, thermoplastic elastomers, a polycarbonate plastic, silicon, an acrylonitrile butadiene styrene (ABS), or a polyvinyl chloride (PVC). The lumens **44** and **46** may be molded, overmolded, computer numerical control (CNC) machined, milled, or otherwise formed into the desired shape (e.g., tubular shape).

20 In another embodiment, as shown in **Fig. 5**, the flow lumens **46** may be circumferentially disposed around the guide lumen **44**, thus disposing the plurality of openings **54** circumferentially around the guide lumen **44**. More specifically, **Fig. 5** is a front view of the distal tip **58** showing four fluid lumens **46** disposed circumferentially around the guide lumen **44**. In the depicted embodiment, the guide lumen **44** may be
25 included as a conduit formed by a tubular member or inner cannula **70**. The inner cannula **70** may be disposed inside of a tubular member or outer cannula **72**, and attached to the outer cannula **72** by using support members **74**. The support members **74** may include a length equal to the length of the inner and/or outer cannula **70**, **72**. The support members **74** may provide a chamber or lumen **46** by dividing a region between
30 exterior surfaces of the inner cannula **70** and inner surfaces of the outer cannula **70**. More specifically, each lumen **46** may be formed as a chamber by using, for example, neighboring support members **74** as side walls, the inner cannula's **70** outer surface as a

floor, and the outer cannula's 72 inner walls as a roof. The support members 74 may include rectangular members, posts, columns, and other shapes suitable for dividing the region between the exterior surface of the inner cannula 70 and the inner surface of the outer cannula 70 into the lumens 46. The support members 74 may be adhered (glued or thermally bonded) to the cannulae 70 and 72, or may be molded or overmolded to connect the inner cannula 70 to the outer cannula 72. By providing for multiple lumens 46, the openings 54 may be disposed in a variety of locations, including locations circumferentially surrounding the outer cannula 72, as described in more detail below with respect to Fig. 6.

Fig. 6 is a side view of the dilator 40 including a plurality of the openings 54 disposed circumferentially around outer surfaces of the outer cannula 72. Also shown in dashed lines is the inner guide cannula 70 disposed inside of the outer cannula 72. It is to be understood that, while in the depicted embodiment the dilator 40 includes a curved shaped, in other embodiments, the dilator 40 may include a straight shape or an angled shape (e.g., as shown in Fig. 4). As mentioned above, the dilator 40 may increase in diameter from the distal tip 58 to a proximal base 76. For example, the distal tip 58 may include a diameter D1 of between 1.0mm to 10mm, while the proximal base 76 may include a diameter D2 of between 5mm to 15 mm or more. The dilator 40 may also include markings 78 disposed throughout a portion or throughout the entirety of the length of the outer cannula 72. The markings may include measurements in millimeters (mm), inches, or other units useful in visually indicating a depth of penetration of the dilator 40 into the patient's neck.

In embodiments where multiple fluid lumens 46 are used, a manifold 80 may be used to couple the multiple lumens 46 to the conduit 50 shown in Fig. 3. For example, the manifold 80 may include a connection port 82 that may couple with the conduit 50 by being inserted into the conduit 50 (or vice versa). Accordingly, secretions (e.g., blood) may be suctioned from the openings 54 and/or gases (e.g., air, oxygen) and other medicines may be delivered through the openings 54, by using the manifold 80. In one embodiment, the manifold 80 may be provided as a "cap" or circular housing, suitable

for mating with the proximal base **76**, as described in more detail below with respect to **Fig. 7**.

Fig. 7 is a perspective view of an embodiment of the manifold **80** first shown in **Fig. 6**. As mentioned above, the manifold **80** may be used to fluidly couple multiple lumens **56** to a single conduit **50**, which may then be coupled to the medical device **48**. In the depicted embodiment, the manifold **80** includes a hollow cap **84**. An interior diameter (ID) of the hollow cap **84** may be equal to (or slightly less than) D2, thus enabling the insertion of the proximal base **76** of the dilator **40** inside of the hollow cap **84**. In one embodiment, an interference fit (e.g., press fit, friction fit) between the proximal base **76** and the hollow cap **84** may be sufficiently strong to securely hold the components **76** and **84** in place during use. For, cleaning, the manifold **80** may be detached from the proximal base **76**, for example, by using manual force. In another embodiment, a set of threads may be disposed about the proximal base **76** with matching grooves disposed inside of the hollow cap **84**, and used to securely attach and detach the proximal base **76** to the manifold **80**.

Gases (e.g., air, oxygen) and/or medicines may be delivered into an interior **86** of the hollow cap by using, for example, the conduit **50** attached to the connection port **82**. In some embodiments, an flow blocking member **88** may be inserted inside of the inner cannula **70** and used to block flow through the inner cannula and into the hollow cap **84**. The flow blocking member **88** may include a guide passage **90** suitable for inserting the guide wire **36** through the hollow cap **84**, through the inner cannula **70**, and into the patient. In other embodiments, the flow blocking member **88** may not be used, and the suction and/or positive pressure flow may be provided through the inner cannula **70** in addition to the flow lumens **46**. By providing for the manifold **80**, the multiple lumens **46** (and guide lumen **44**) may be more easily connected to the medical device **48**.

Fig. 8 is a rear view of the manifold **80** coupled to the proximal base **76** (shown in dashed lines) of the dilator **40**. More specifically, the figure depicts a distal end of the inner cannula **70**, the outer cannula **72**, and the connecting members **74** used in forming the lumens **46**. Also depicted are the coupling member **82** and the guide passageway **90**.

It is to be noted that, while in the depicted embodiment the proximal base **76** is lodged into the hollow cap **84** by using the interference fit, in other embodiments, other techniques such as threads and grooves may be used to fasten and unfasten the manifold **80** from the proximal base **76**. Once attached to the proximal base **76**, the manifold **80** may be coupled to the medical device **48** through the connector **82** and conduit **50**, and the medical device **48** may then provide a suctioning and/or a positive pressure flow during dilation operations. In certain embodiments, as described in more detail below with respect to **Figs. 9-12**, the dilator suctioning and/or positive pressure flow may enter and/or exit through the openings **54** having various shapes.

10

Fig. 9 is a view of the openings **54** having circular shapes **92** and **94** disposed on the outer cannula. In the depicted embodiment, the circular shapes **92** include a larger diameter as compared to the shapes **94**. The smaller shapes **94** may be disposed closer to the distal tip **58**, while the larger shapes **92** may be disposed further away from the distal tip **58**, or vice versa. The shapes **92** and **94** may also be disposed interspersed with each other. The circular shapes **92** and **94** may be useful in providing a uniform incoming and/or outgoing flow through the openings **54**. Further, because of their circular nature, the shapes **92** and **94** may present the same or similar entry/exit edge when the dilator **40** is being inserted into the trachea **12**. Accordingly, dilation trauma and the entry force may be minimized.

20

Fig. 10 is a view of the openings **54** having teardrop shapes **96** and **98**. In the depicted embodiment, the teardrop shapes **96** are larger when compared to the shapes **98**. The smaller shapes **98** may be disposed closer to the distal tip **58**, while the larger shapes **96** may be disposed further away from the distal tip **58**, or vice versa. The shapes **96** and **98** may also be disposed interspersed with each other. The teardrop shapes **96** and **98** may be useful in further minimizing dilation trauma by providing for a proximal bulb end and a distal tail end. As the outer cannula **72** moves into the trachea **12**, the proximal bulb end may suction (or pressurize) the tissue first while the distal tail end may minimize trauma. If further trauma minimization is desired, the shapes **96** and/or **98** may be reversed so that the tail end enters the trachea before the bulb end during dilation, as depicted in **Fig. 11**.

30

Fig. 11 is a view of the openings **54** having reverse teardrop shapes **100** and **102**. In the depicted embodiment, the reverse teardrop shapes **100** are larger when compared to the shapes **102**. The smaller shapes **102** may be disposed closer to the distal tip **58**, while the larger shapes **100** may be disposed further away from the distal tip **58**, or vice versa. The shapes **100** and **102** may also be disposed interspersed with each other. The reverse teardrop shapes **100** and **102** may be useful in minimizing dilation trauma by providing for a proximal tail end and a distal bulb end. As the outer cannula **72** moves into the trachea **12**, the proximal tail end may aid in gliding through the tissue while the distal bulb end may suction (or pressurize) the tissue. If further trauma minimization is desired, the slit-like shapes may be used, as further described in **Fig. 12**.

Fig. 12 is a view of the openings **54** having slit shapes **104** and **106**. In the depicted embodiment, the slit shapes **104** are larger when compared to the shapes **106**. The smaller shapes **106** may be disposed closer to the distal tip **58**, while the larger shapes **104** may be disposed further away from the distal tip **58**, or vice versa. The shapes **104** and **106** may also be disposed interspersed with each other. The slit shapes **104** and **106** may be useful in minimizing dilation trauma by providing for a proximal tail end and a distal tail end. As the outer cannula **72** moves into the trachea **12**, the proximal tail end may aid in gliding through the tissue. As the outer cannula **72** is removed from the trachea **12**, the distal tail end may also aid in gliding through the tissue, thus minimizing tissue trauma. It is to be noted that additional shapes may be used, including square shapes, triangle shapes, diamond shapes, oval shapes and so on, which may be easier to manufacture. Further, all of the illustrated and mentioned shapes (e.g., circles, teardrops, slits, squares, triangles, diamonds, ovals) may be provided alone or in combination with each other and fluidly coupled to the lumens **46** of the dilator **40**.

CLAIMS

What is claimed is:

1. A medical system comprising:
5 a tracheal dilator comprising:
a first plurality of openings;
a guide lumen configured to provide a pathway for the insertion of a guide
wire during use of the tracheal dilator; and
a first flow lumen configured to fluidly couple the first plurality of openings
10 to a medical device, wherein the medical device is configured to provide a suctioning force
through the first plurality of openings during use of the tracheal dilator.
2. The system of claim 1, comprising the medical device, wherein the medical device
15 is configured to provide a positive pressure flow of a gas during use of the
tracheal dilator.
3. The system of claim 2, wherein the medical device comprises a ventilator, a pump,
or a combination thereof.
- 20 4. The system of claim 1, wherein the tracheal dilator comprises an angled distal
portion and a straight proximal portion, and wherein the angled distal portion comprises an
angle α with the straight proximal portion.
5. The system of claim 4, wherein α comprises an angle between approximately 90°
25 and approximately 180°.
6. The system of claim 1, wherein the tracheal dilator comprises a second plurality
of openings and a second flow lumen, and wherein the second flow lumen is configured
to fluidly couple the second plurality of openings to the medical device.
30
7. The system of claim 6, wherein the tracheal dilator comprises a manifold
configured to couple the first and the second flow lumens to the medical device.

8. The system of claim 1, wherein the tracheal dilator comprises an inner cannula, an outer cannula, and a plurality of connecting members coupling the inner cannula to the outer cannula, and wherein the inner cannula comprises the guide lumen.

5

9. The system of claim 8, wherein a chamber formed by an outer surface of the inner cannula, an inner surface of the outer cannula, a first connecting member of the plurality of connecting members, and a second connecting member of the plurality of connecting members comprises the first flow lumen.

10

10. The system of claim 1, wherein at least one of the first plurality of openings comprises a circular shape, a diamond shape, a square shape, a teardrop shape, a reverse teardrop shape, a dual teardrop shape, or a combination thereof.

15

11. A tracheal dilator comprising:

a guide cannula configured to provide a pathway for the insertion of a guide wire during use of the tracheal dilator; and

a first flow cannula comprising a first plurality of openings, wherein the first flow cannula is configured to fluidly couple the first plurality of openings to a medical device,

20

and wherein the medical device is configured to provide a positive flow of a gas through the first plurality of openings during use of the tracheal dilator.

25

12. The tracheal dilator of claim 11, wherein the medical device is configured to provide a suctioning force through the first plurality of openings during use of the tracheal dilator.

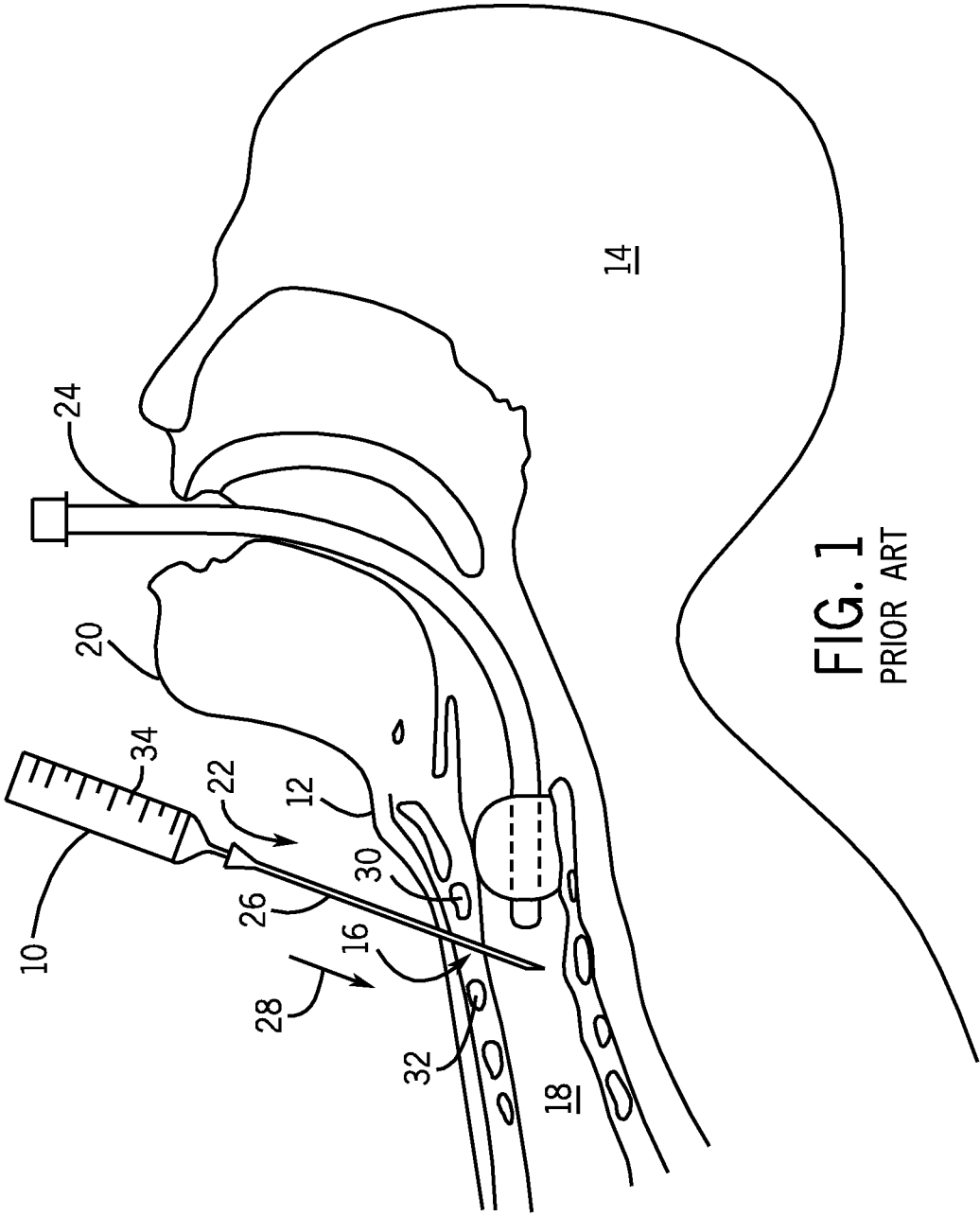
30

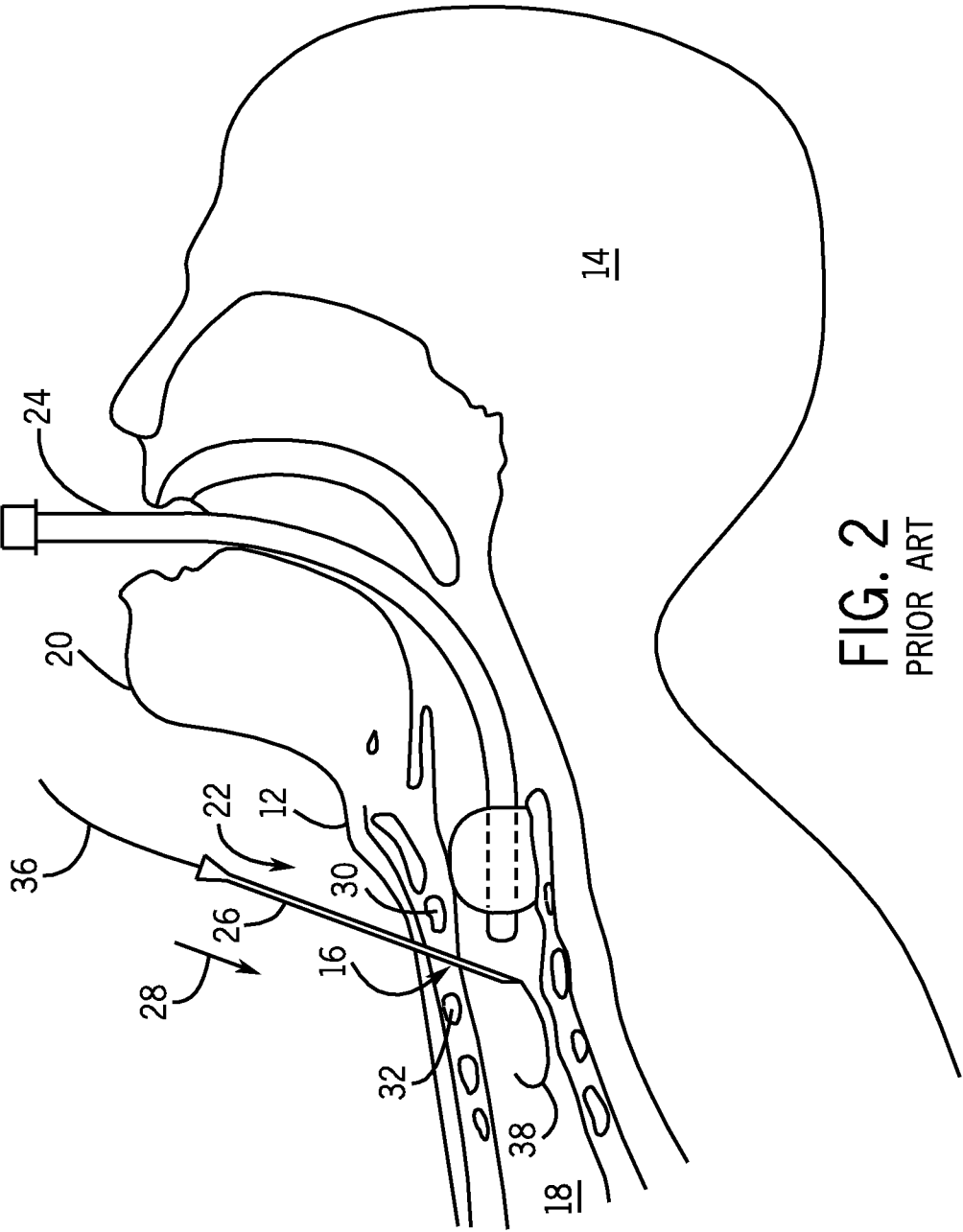
13. The tracheal dilator of claim 11, comprising an angled distal portion and a straight proximal portion, and wherein the angled distal portion comprises an angle α with the straight proximal portion.

14. The tracheal dilator of claim 11, wherein α comprises an angle between approximately 90° and approximately 180°.

15. The tracheal dilator of claim 11, wherein the tracheal dilator comprises a shape increasing in diameter from a distal tip to a proximal base.
- 5 16. The tracheal tube of claim 15, wherein the shape comprises a curved shape, a conical shape, or a combination thereof.
17. The tracheal dilator of claim 11, comprising a second flow cannula comprising a second plurality of openings, wherein the second flow cannula is configured to fluidly
10 couple the second plurality of openings to the medical device.
18. A method for manufacturing a tracheostomy dilator comprising:
manufacturing a guide cannula configured to provide a pathway for the insertion of
a guide wire during use of the tracheostomy dilator; and
15 manufacturing a first flow cannula comprising a first plurality of openings, wherein the first flow cannula is configured to fluidly couple the first plurality of openings to a medical device, and wherein the medical device is configured to provide a positive flow of a gas through the first plurality of openings during use of the tracheal dilator.
- 20 19. The method of claim 18, wherein at least one of the plurality of openings comprises a circular shape, a diamond shape, a square shape, a teardrop shape, a reverse teardrop shape, a dual teardrop shape, or a combination thereof.
20. The method of claim 18, comprising manufacturing a second flow cannula
25 comprising a second plurality of openings, wherein the second flow cannula is configured to fluidly couple the second plurality of openings to the medical device, and wherein the medical device is configured to provide a positive flow of the gas through the first and the second plurality of openings during use of the tracheal dilator.

30





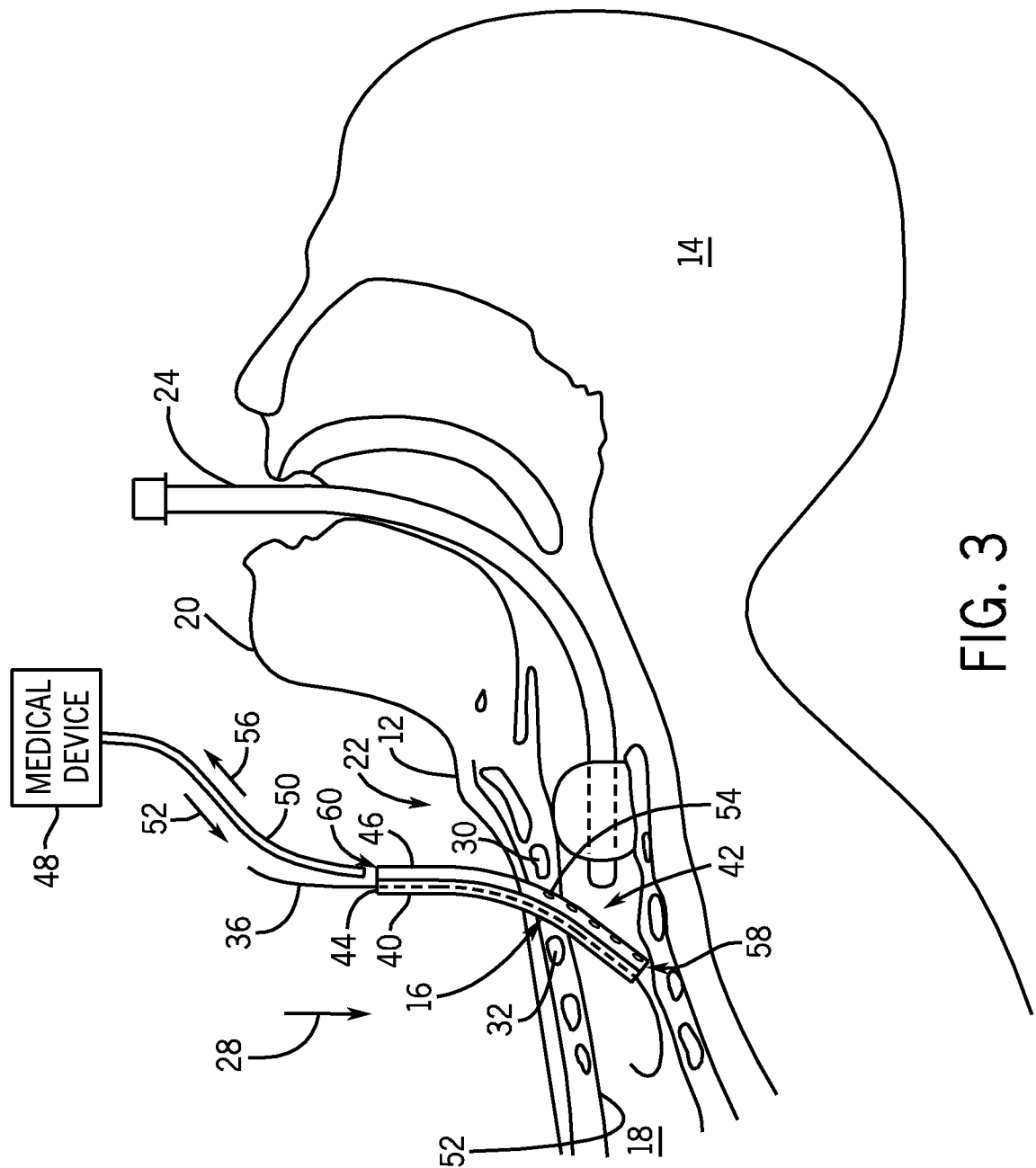


FIG. 3

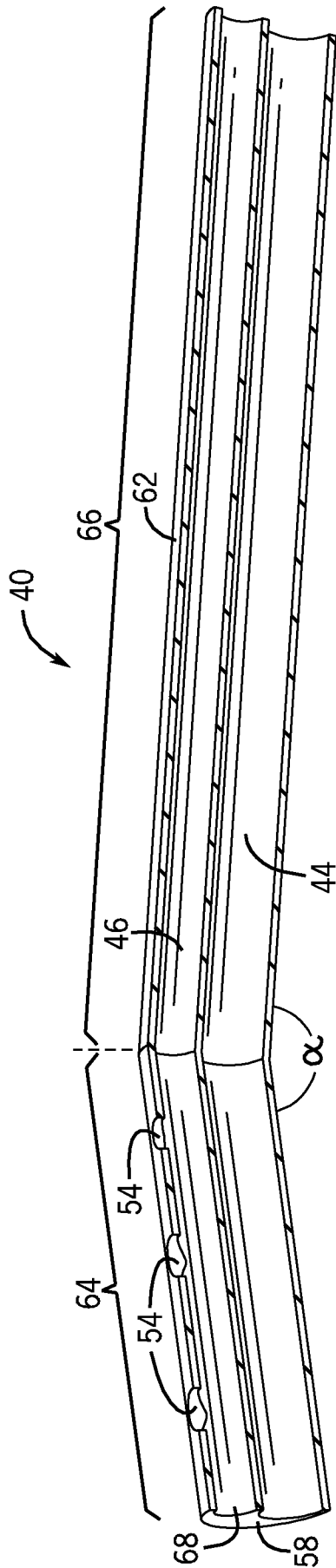


FIG. 4

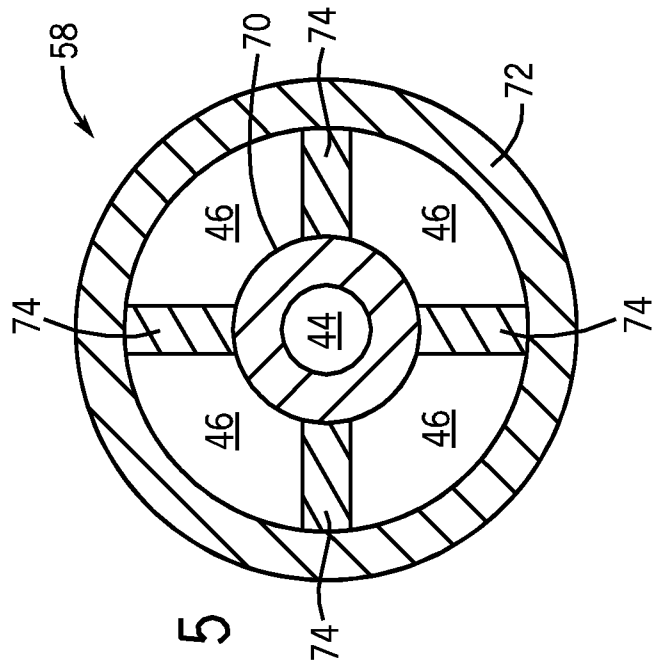
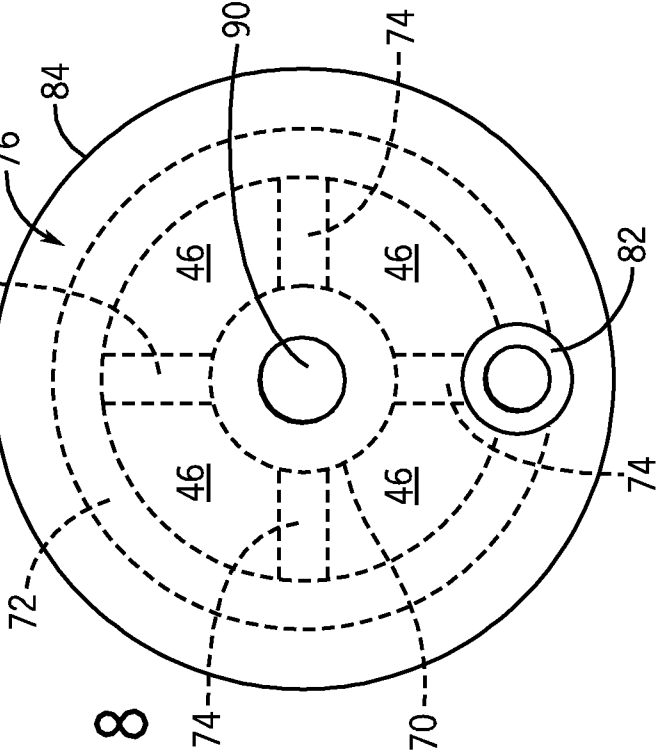
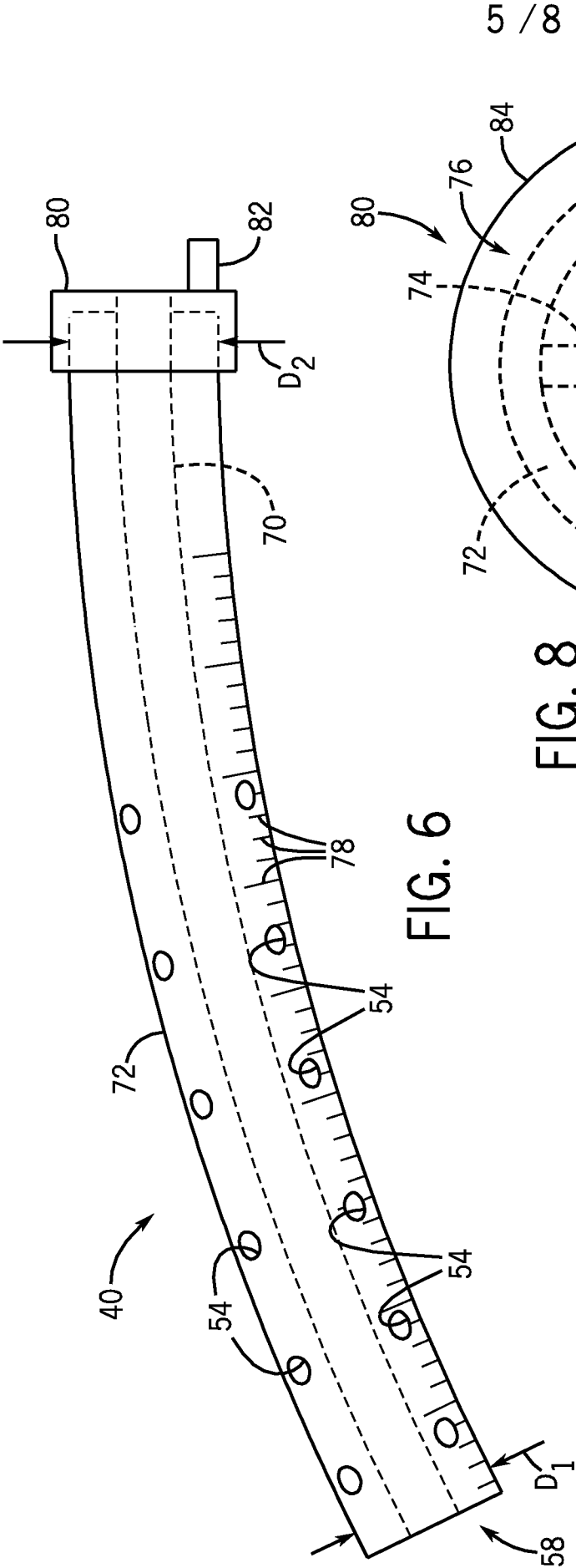


FIG. 5



6 / 8

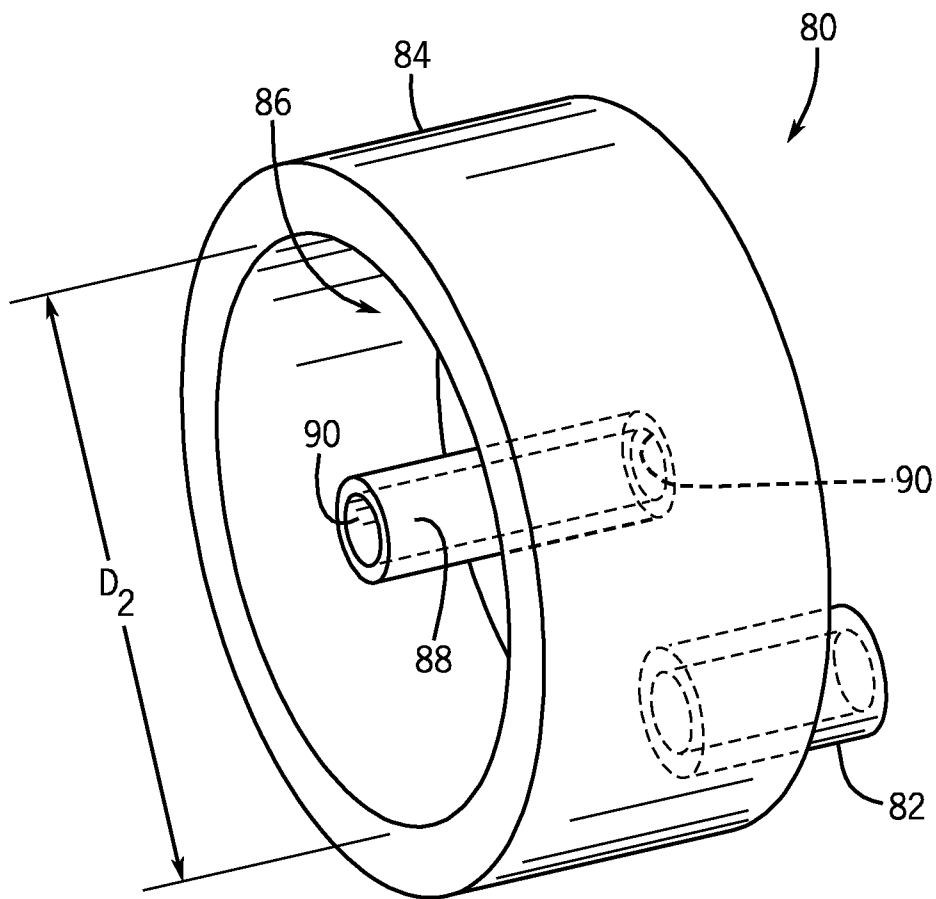


FIG. 7

7 / 8

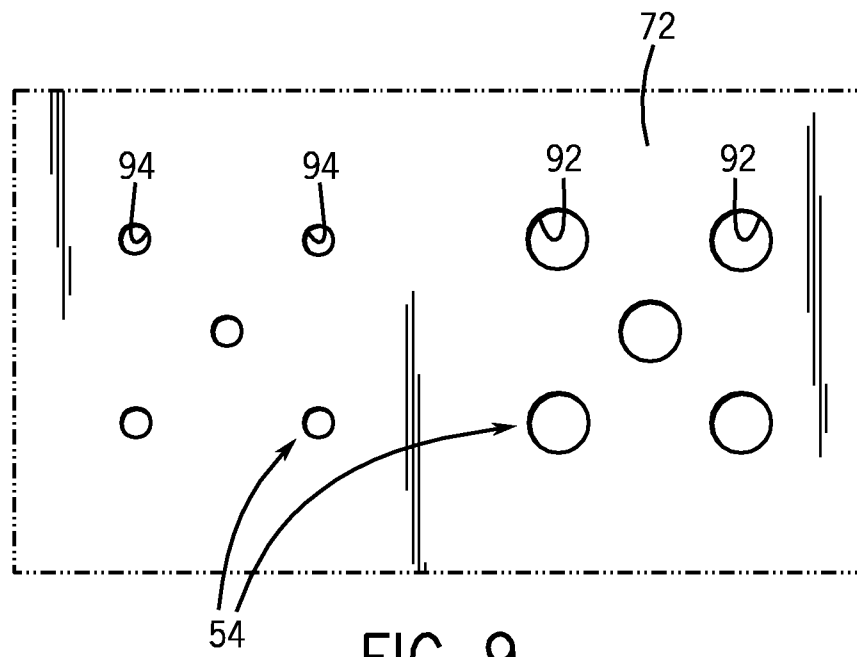


FIG. 9

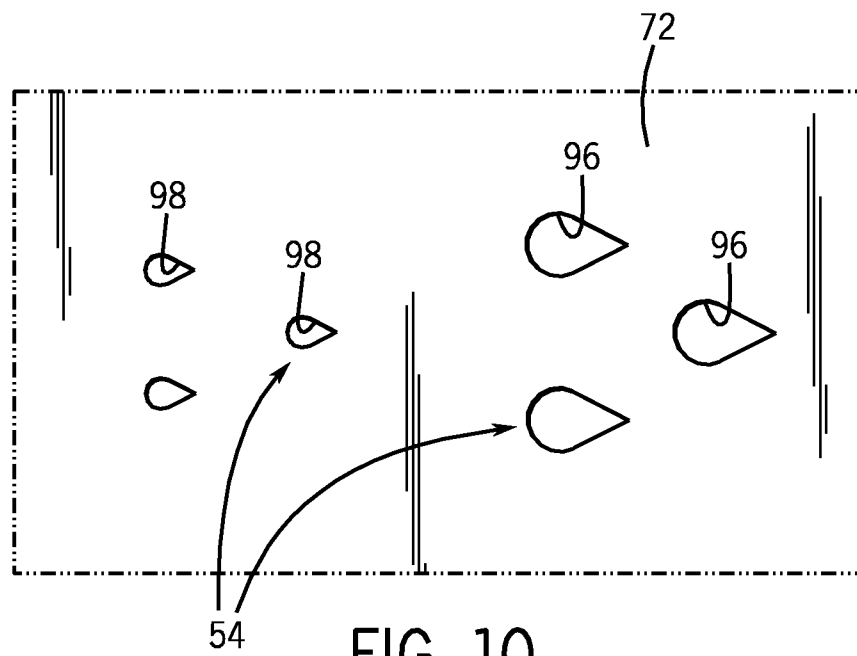


FIG. 10

8 / 8

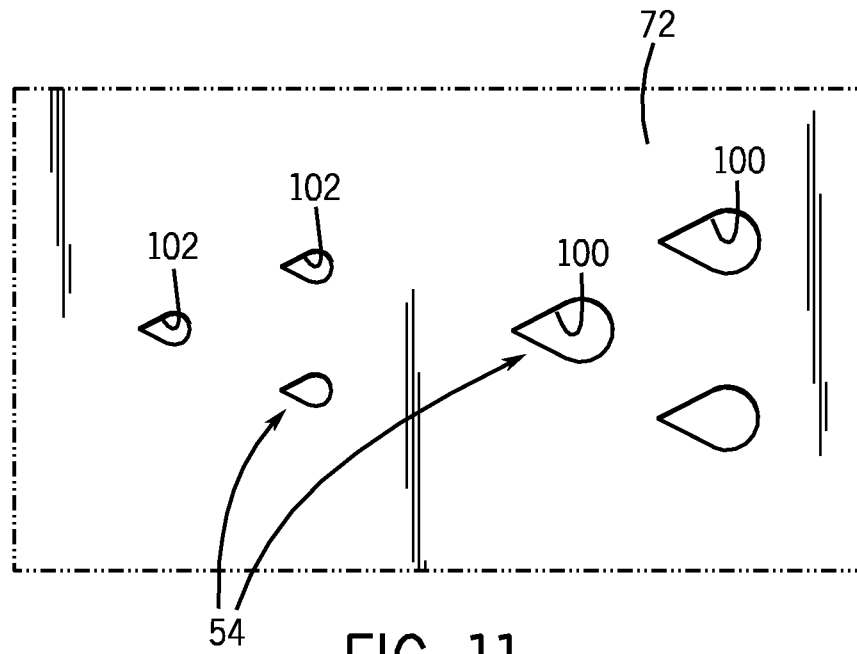


FIG. 11

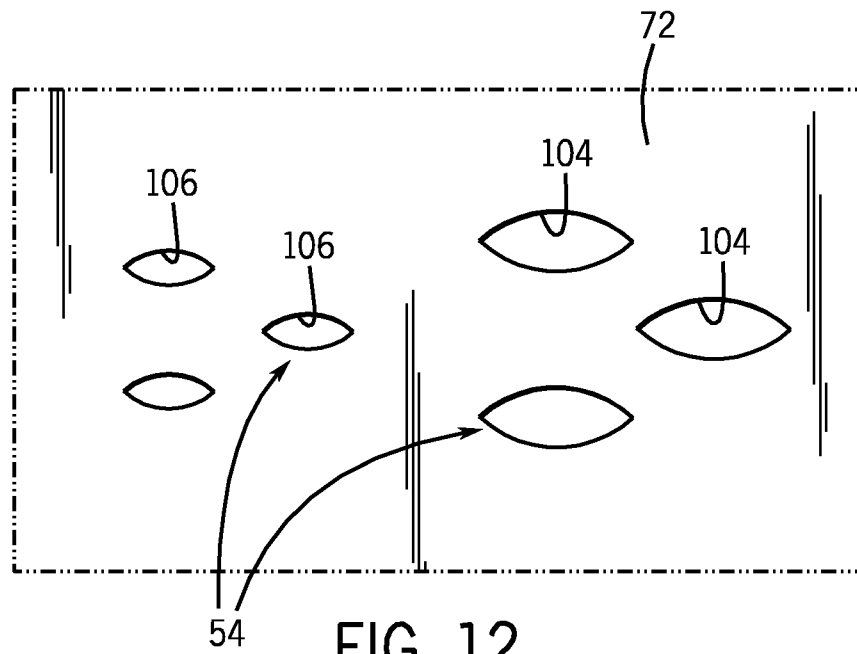


FIG. 12

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 2014/011639

A. CLASSIFICATION OF SUBJECT MATTER		
A61M 16/04 (2006.01) A61M 16/00 (2006.01) According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
A61M 16/00-16/04, 29/00		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
FIPS, EAPATIS, USPTO, Patentscope, Espacenet, PubMed		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2013/0000635 A1 (NELLCOR PURITAN BENNETT LLC) 03.01.2013, paragraphs [0004], [0028]-[0030], [0034], [0041], [0044], [0046], [0048], claim 1, fig. 3	1-20
Y	US 2008/0271741 A1 (PETER KENNETH GRAHAM et al.) 06.11.2008, paragraphs [0006]-[0007], [0030], [0033]	1-20
A	US 4364391 A (FREDERIC J. TOYE) 21.12.1982	1-20
☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.		
* Special categories of cited documents: “A” document defining the general state of the art which is not considered to be of particular relevance “E” earlier document but published on or after the international filing date “L” document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) “O” document referring to an oral disclosure, use, exhibition or other means “P” document published prior to the international filing date but later than the priority date claimed “T” later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention “X” document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone “Y” document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art “&” document member of the same patent family		
Date of the actual completion of the international search		Date of mailing of the international search report
22 April 2014 (22.04.2014)		07 May 2014 (07.05.2014)
Name and mailing address of the ISA/ FIPS Russia, 123995, Moscow, G-59, GSP-5, Berezhkovskaya nab., 30-1		Authorized officer
Facsimile No. +7 (499) 243-33-37		E. Smirnova
		Telephone No. 8(495)531-64-81