

USF Patents

October 2024

Percutaneous endoscopic gastronomy tube for optimized gastric sumping

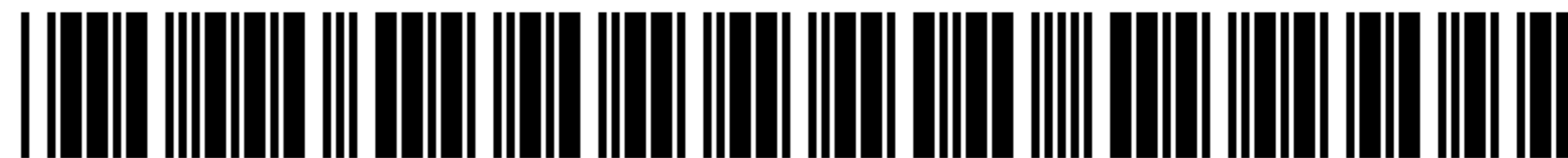
Justin Robert Daggett

Follow this and additional works at: https://digitalcommons.usf.edu/usf_patents

Recommended Citation

Daggett, Justin Robert, "Percutaneous endoscopic gastronomy tube for optimized gastric sumping" (2024). *USF Patents*. 1452.
https://digitalcommons.usf.edu/usf_patents/1452

This Article is brought to you for free and open access by Digital Commons @ University of South Florida. It has been accepted for inclusion in USF Patents by an authorized administrator of Digital Commons @ University of South Florida. For more information, please contact digitalcommons@usf.edu.



US012115301B2

(12) **United States Patent**
Daggett

(10) **Patent No.:** **US 12,115,301 B2**
(45) **Date of Patent:** ***Oct. 15, 2024**

(54) **PERCUTANEOUS ENDOSCOPIC GASTRONOMY TUBE FOR OPTIMIZED GASTRIC SUMPING**

(71) Applicant: **University Of South Florida**, Tampa, FL (US)

(72) Inventor: **Justin Robert Daggett**, Denver, NC (US)

(73) Assignee: **University of South Florida**, Tampa, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1477 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **16/527,113**

(22) Filed: **Jul. 31, 2019**

(65) **Prior Publication Data**

US 2019/0351110 A1 Nov. 21, 2019

Related U.S. Application Data

(63) Continuation of application No. 15/829,329, filed on Dec. 1, 2017, now Pat. No. 10,376,619, which is a continuation of application No. 14/720,307, filed on May 22, 2015, now Pat. No. 9,867,915.

(60) Provisional application No. 62/023,268, filed on Jul. 11, 2014.

(51) **Int. Cl.**
A61M 1/00 (2006.01)

(52) **U.S. Cl.**
CPC **A61M 1/964** (2021.05); **A61M 2210/1053** (2013.01)

(58) **Field of Classification Search**
CPC A61M 1/0088; A61M 2039/0261; A61M 25/04; A61M 2210/1053; A61J 5/0015; A61J 5/003

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,470,665 A	5/1949	Stiehl	
2,492,384 A	12/1949	Kaslow	
3,114,373 A	12/1963	Andersen	
3,421,510 A	1/1969	Kettenbach	
3,915,171 A *	10/1975	Shermeta A61J 15/0065 D24/112
3,999,554 A	12/1976	Kim et al.	
4,356,824 A	11/1982	Vazquez	
4,666,433 A	5/1987	Parks	
5,273,523 A	12/1993	Sozuki et al.	

(Continued)

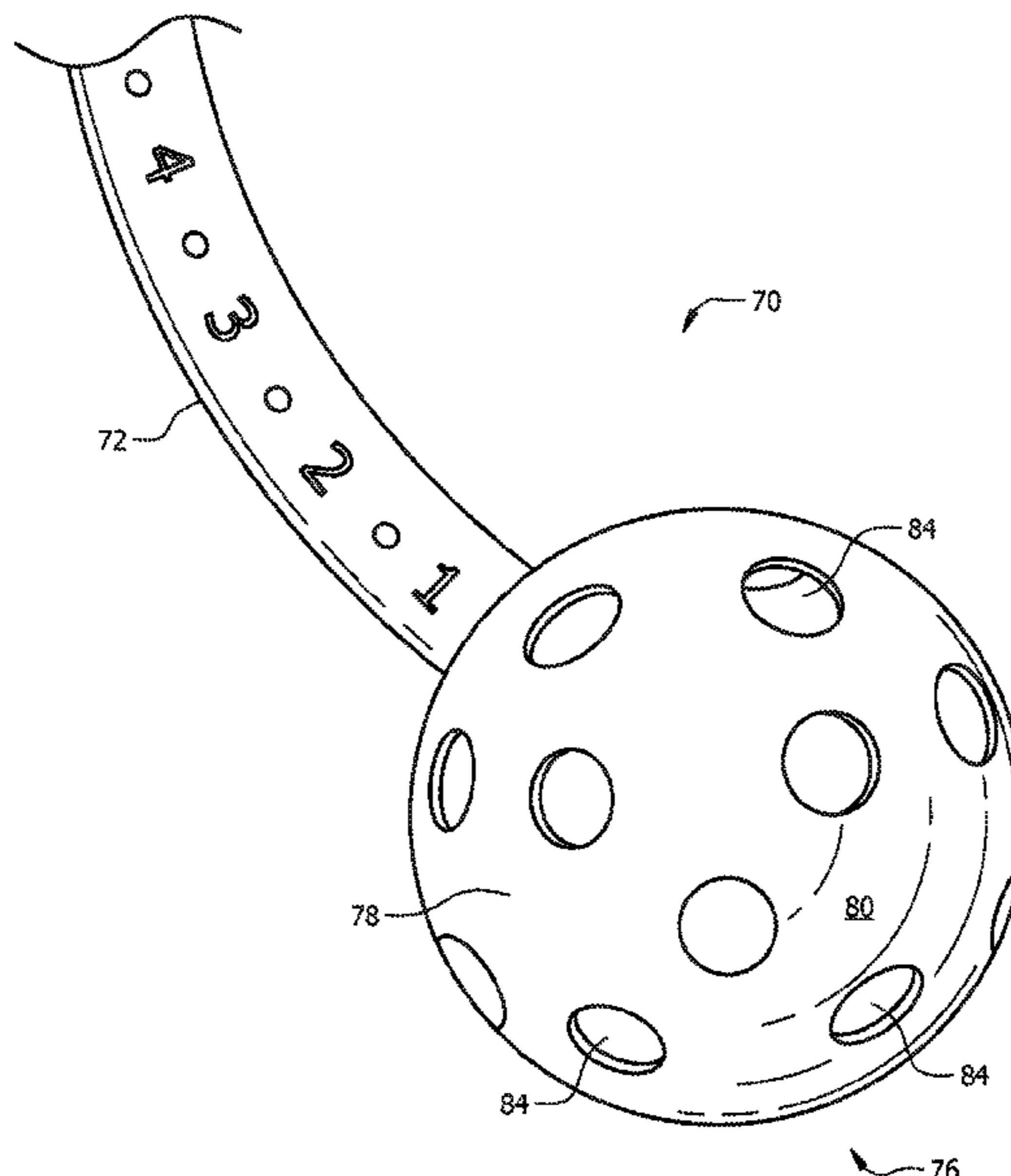
Primary Examiner — Lauren P Farrar

(74) *Attorney, Agent, or Firm* — Nicholas Pfeifer Smith & Hopen, P. A.

(57) **ABSTRACT**

An improved percutaneous endoscopic gastrostomy (PEG) tube that allows continuous suctioning/sumping without occlusion of the tube by the gastric wall. The PEG tube includes a hollow drainage tubing coupled to a ventilated bell cap. The bell cap can be open or closed to the external environment is ventilated via apertures, crenellations and grooves, and hemispherical arches. The PEG tube minimizes, or completely eliminates, the need for a user thereof to frequently flush the tube, thus also curtailing intermittent suctioning and allowing for longer periods of uninterrupted drainage. Furthermore, the PEG tubes of the current invention reduce clogging of the tube by larger gastric matter that is intended to be suctioned out of the patient or subject.

11 Claims, 11 Drawing Sheets



(56)

References Cited

U.S. PATENT DOCUMENTS

5,356,391	A *	10/1994	Stewart	A61J 15/0015 604/174
5,391,159	A	2/1995	Hirsch et al.	
6,030,361	A *	2/2000	Miyashiro	A61M 25/04 604/523
6,322,538	B1	11/2001	Elbert et al.	
7,582,072	B2	9/2009	McMichael	
9,867,951	B2	1/2018	Daggett	
2007/0060823	A1	3/2007	Giroux et al.	
2014/0276502	A1 *	9/2014	Cisco	A61F 5/451 604/355

* cited by examiner

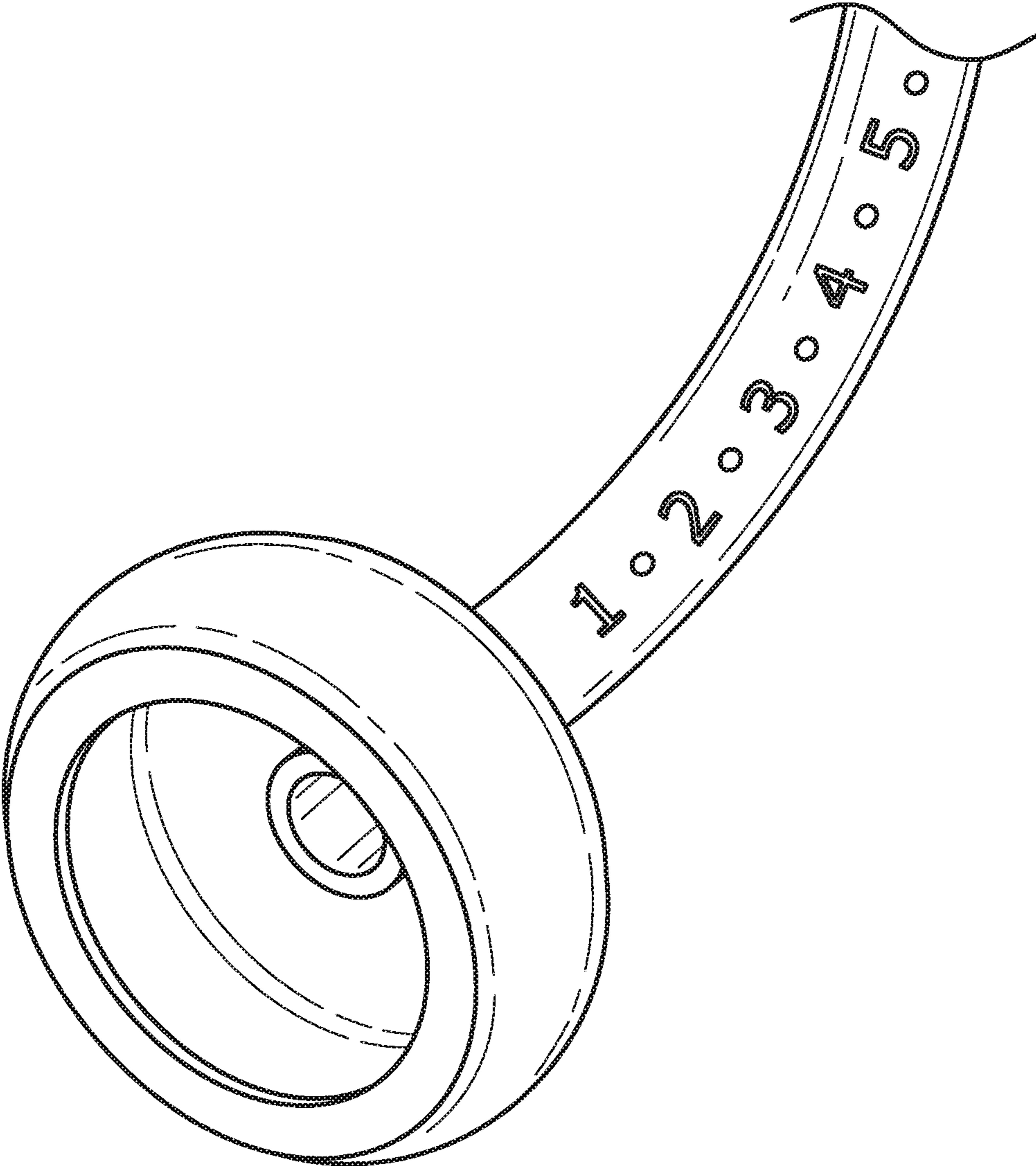


FIG. 1A

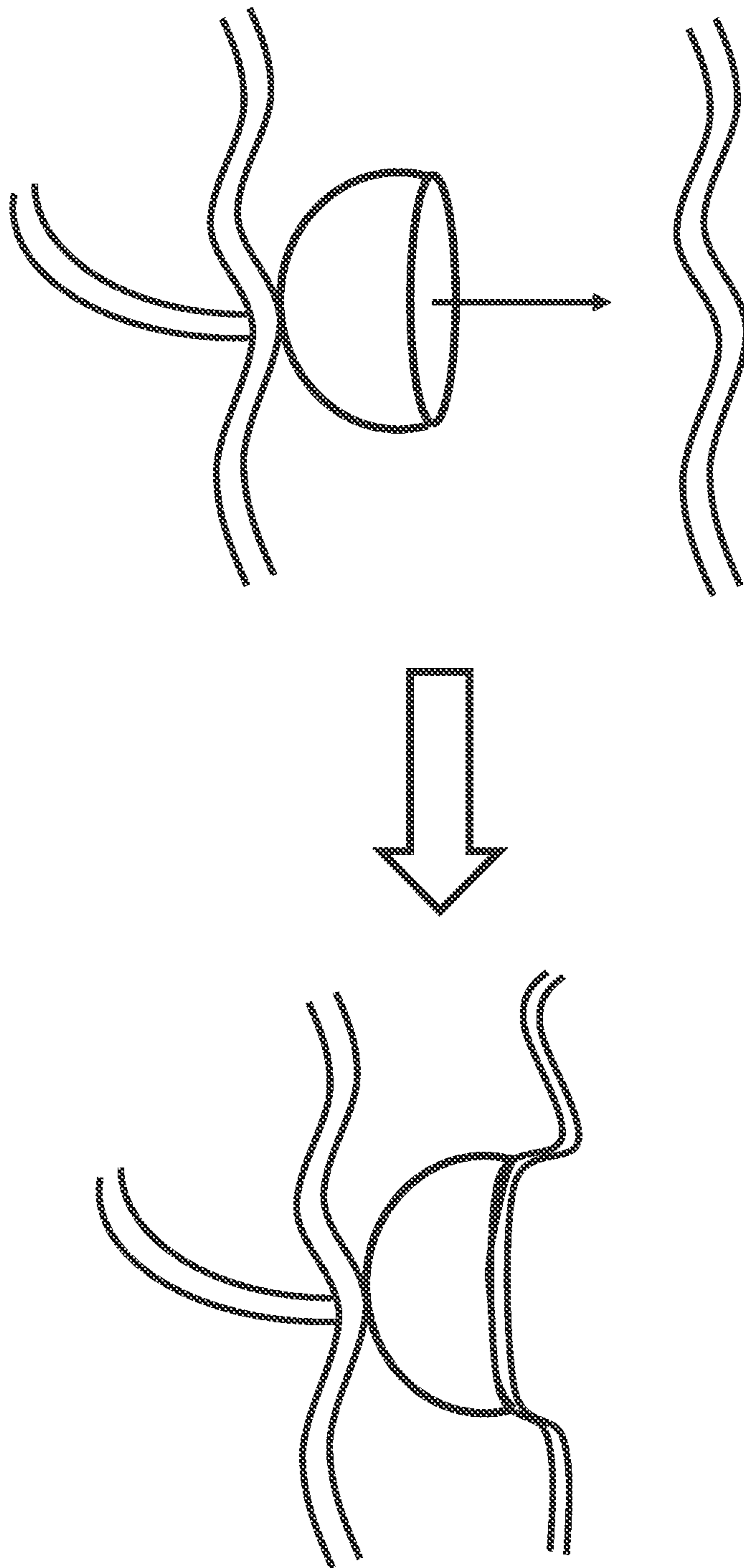


FIG. 1B

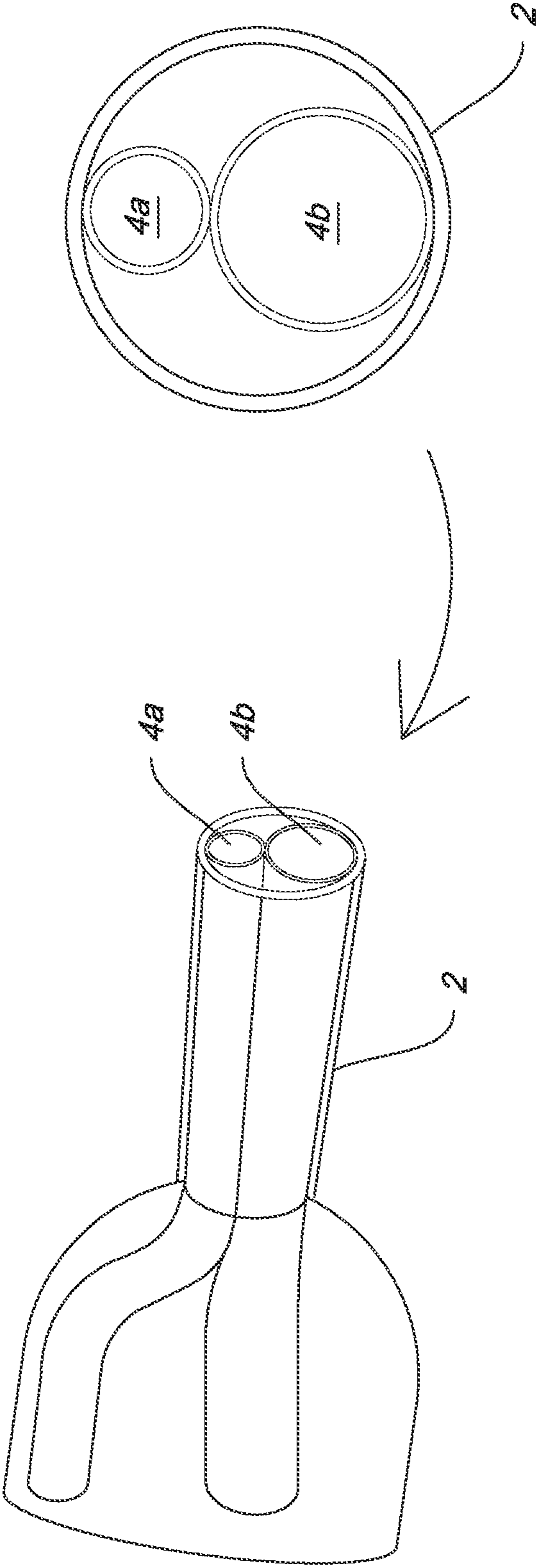


FIG. 2A

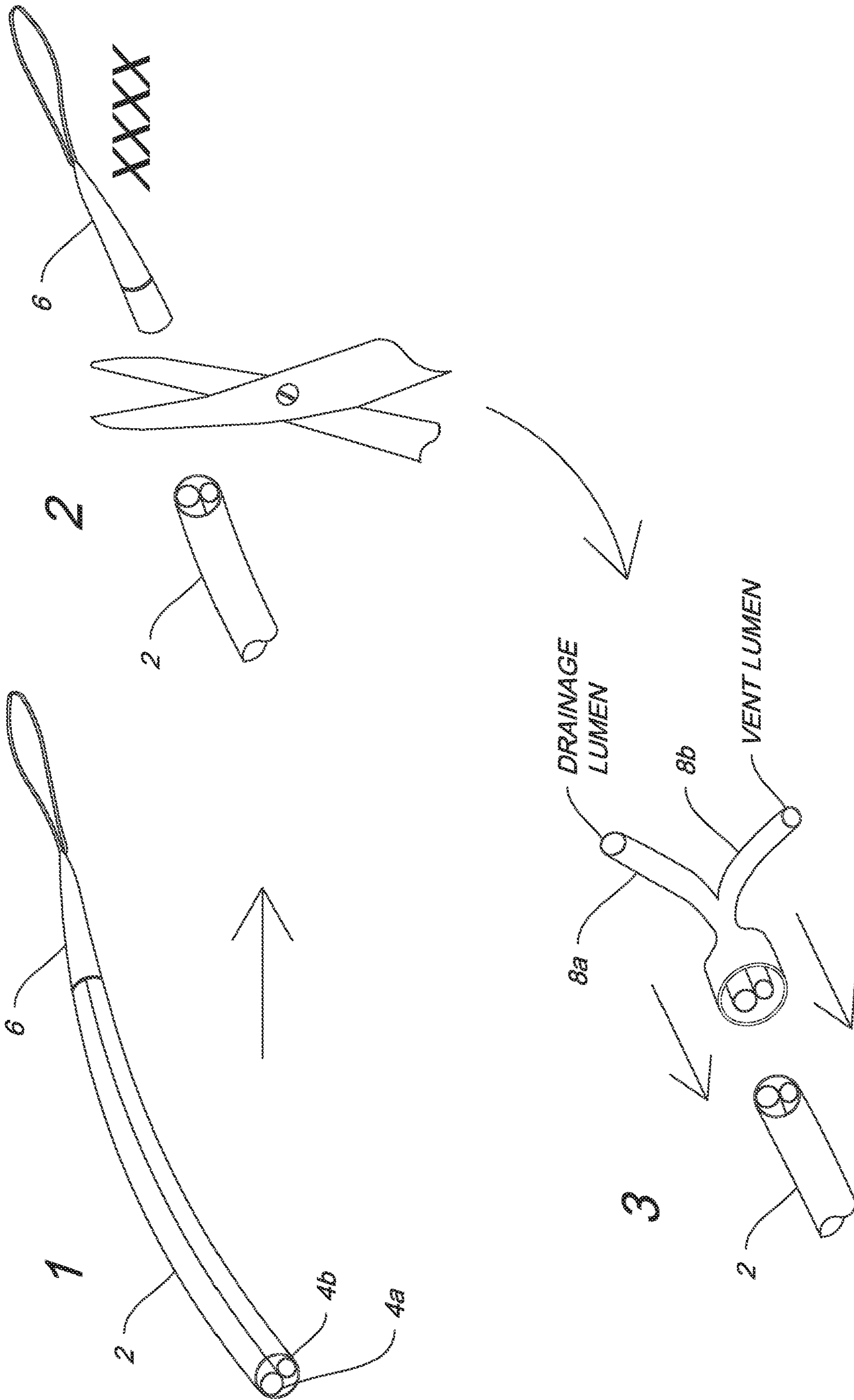


FIG. 2B

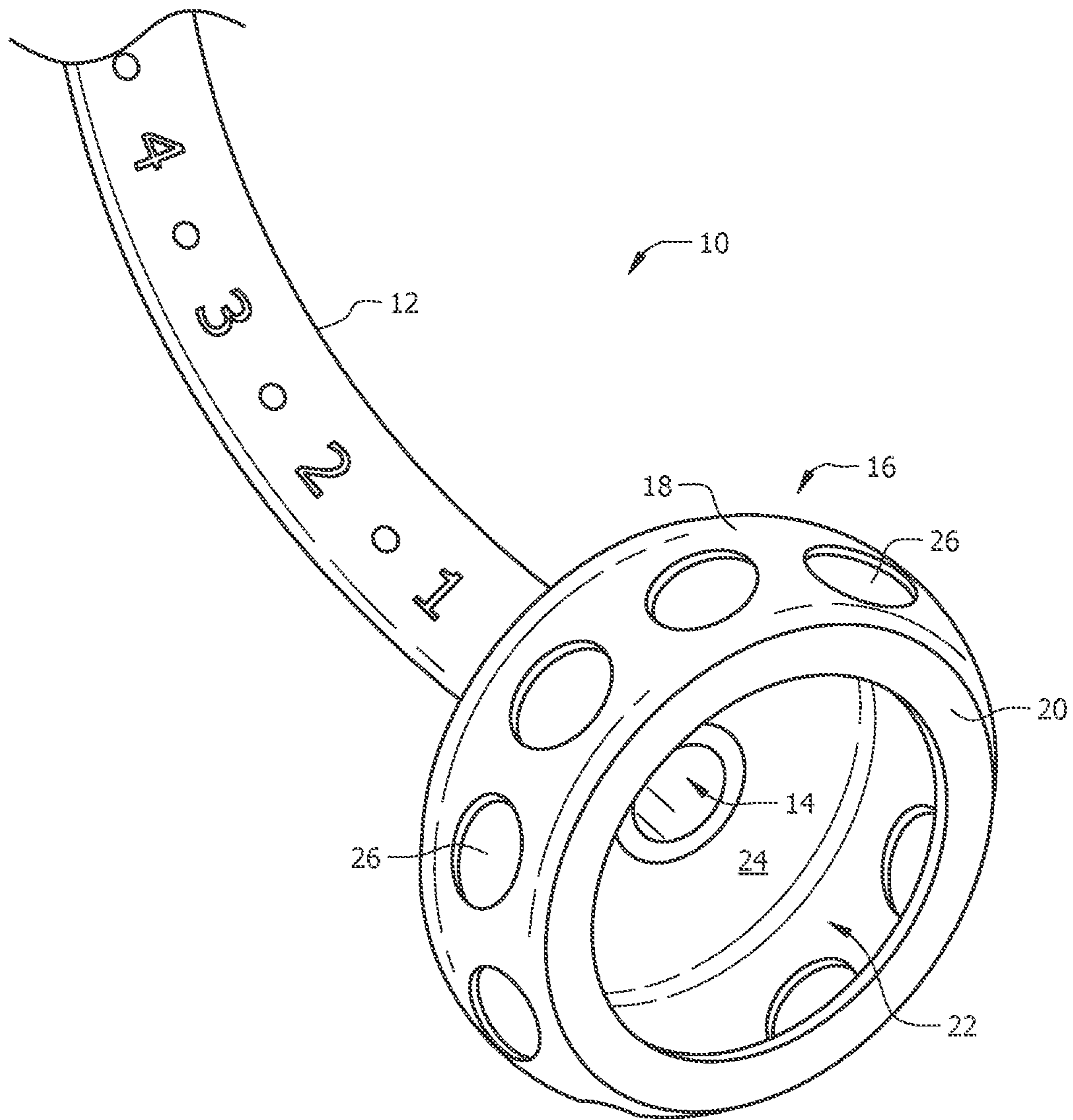


FIG. 3A

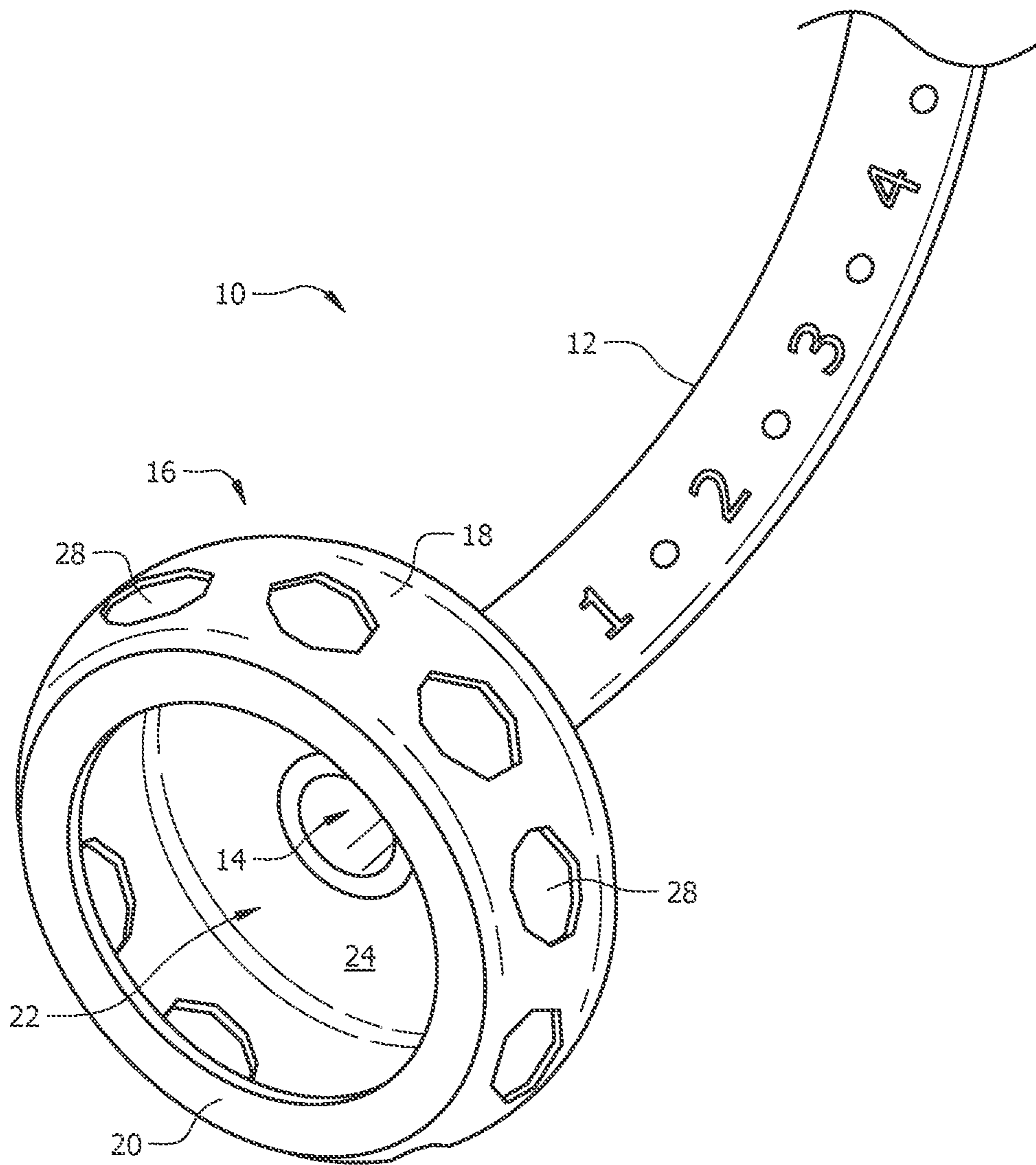


FIG. 3B

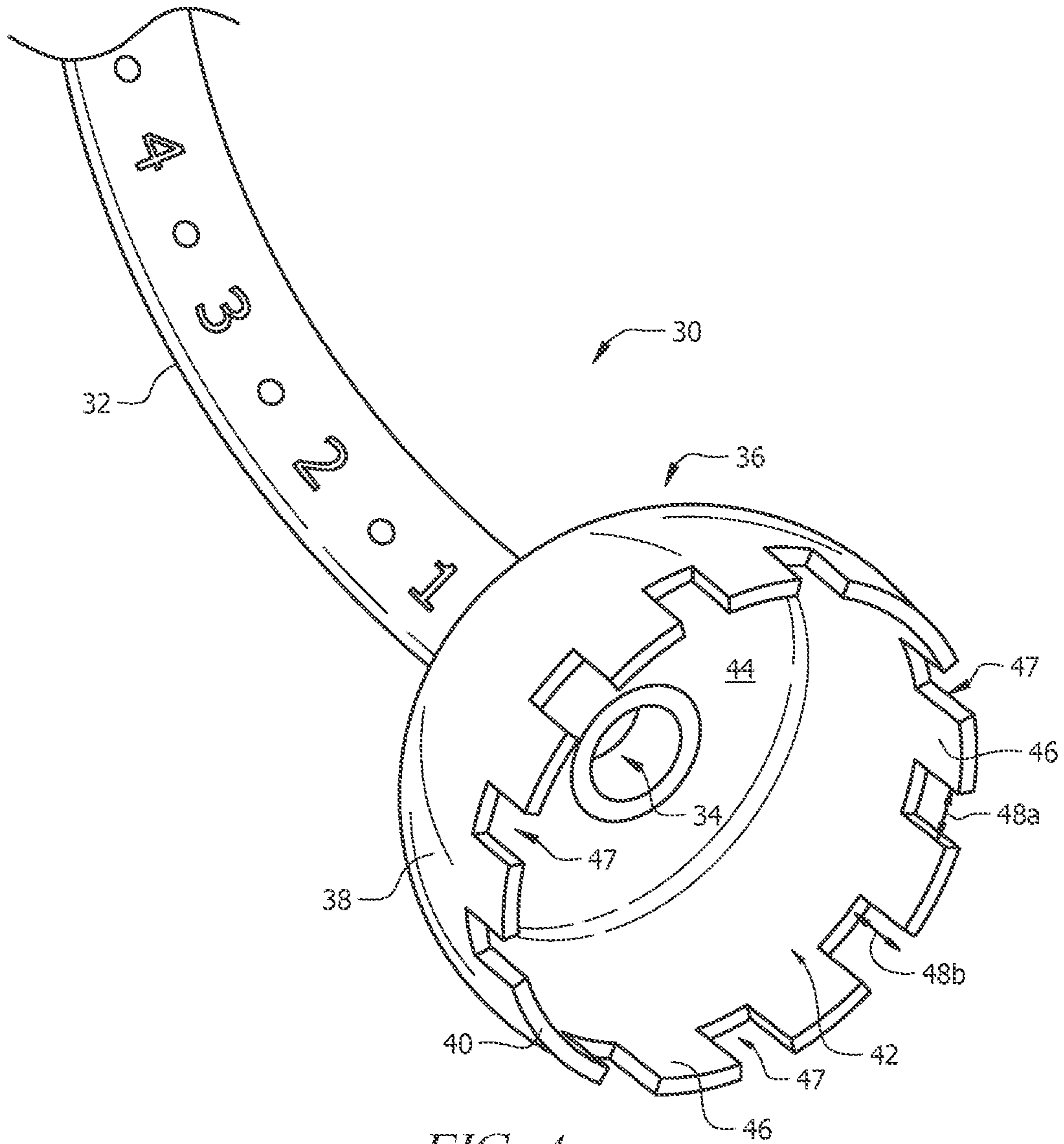


FIG. 4

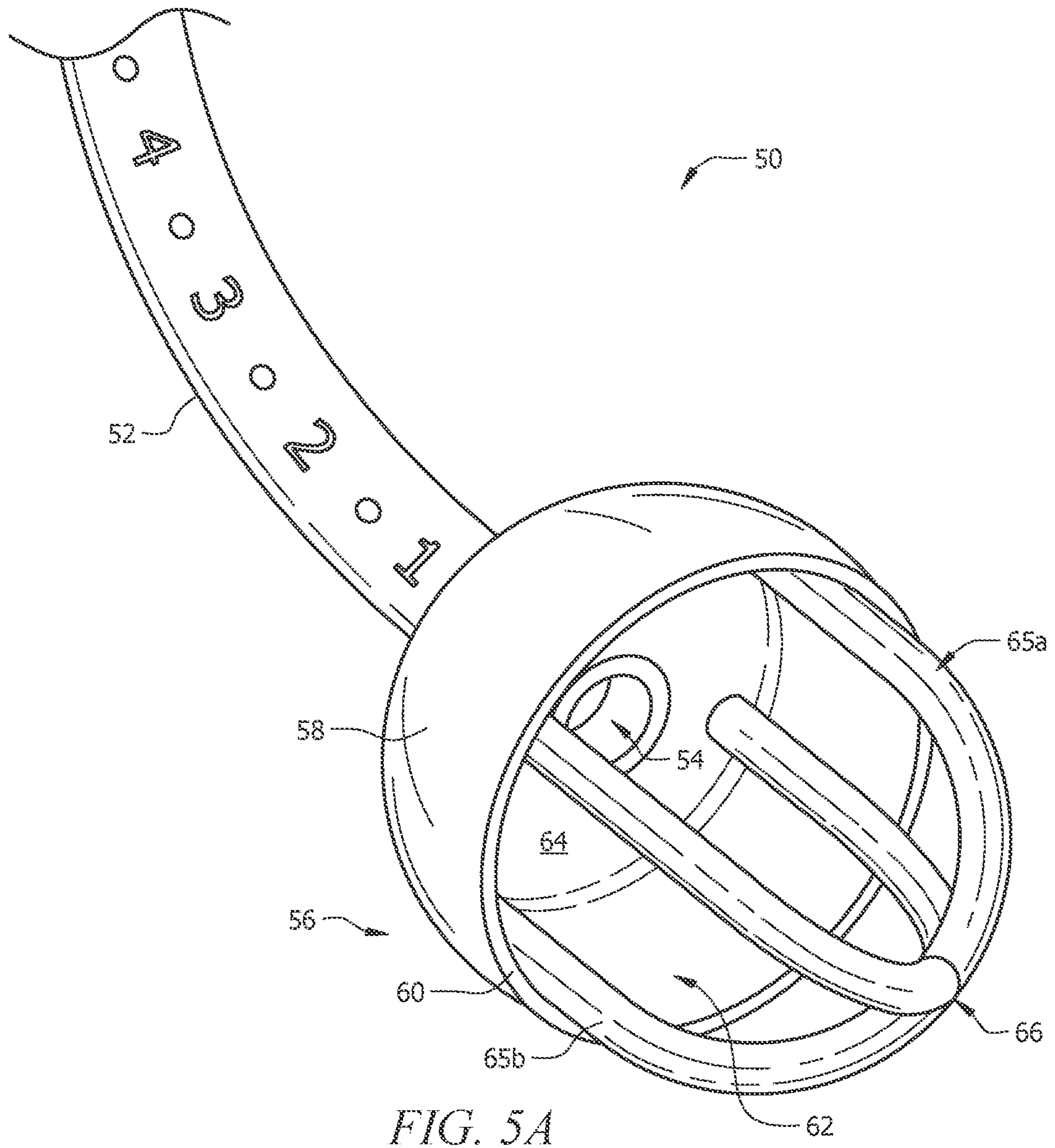
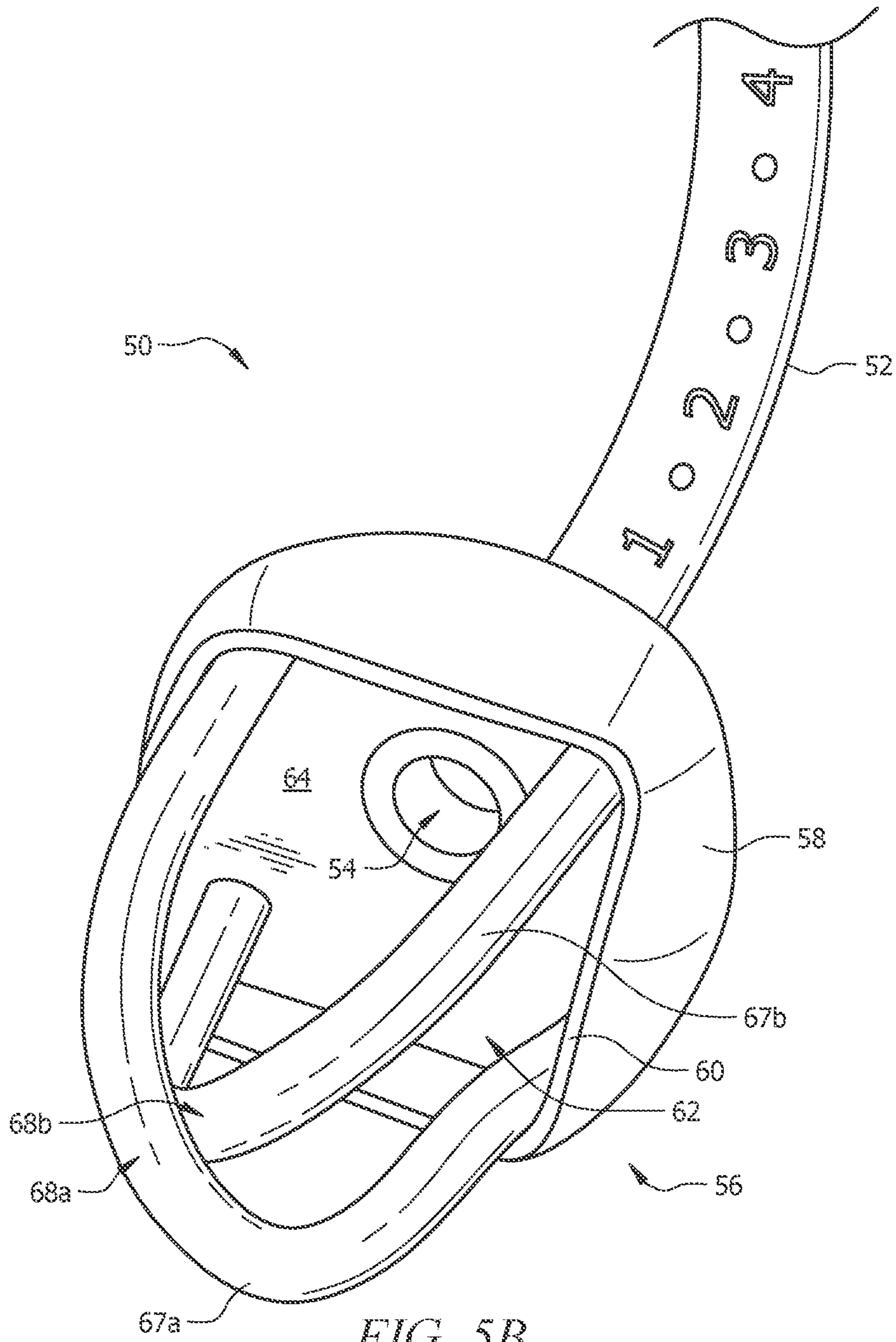


FIG. 5A



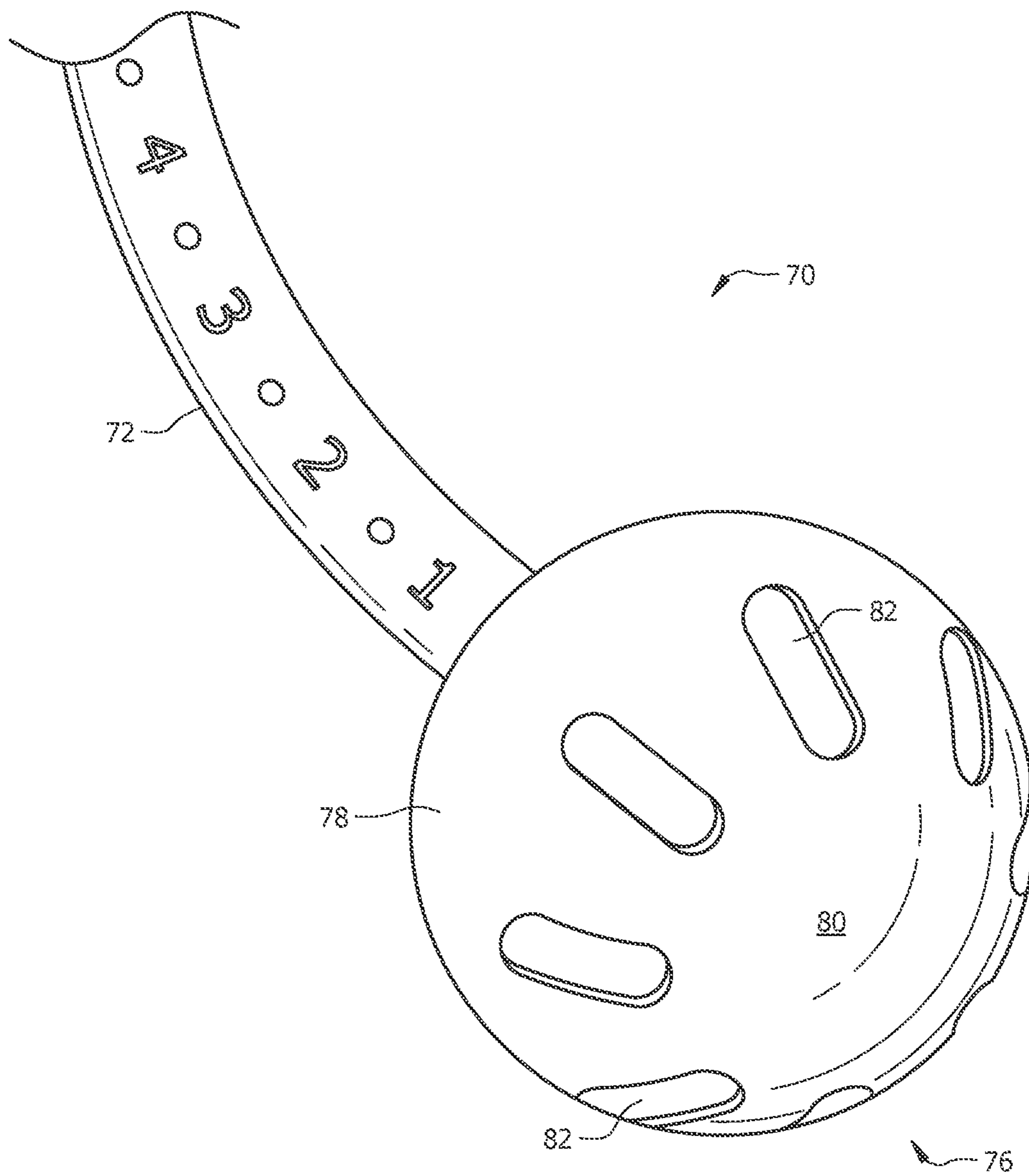


FIG. 6A

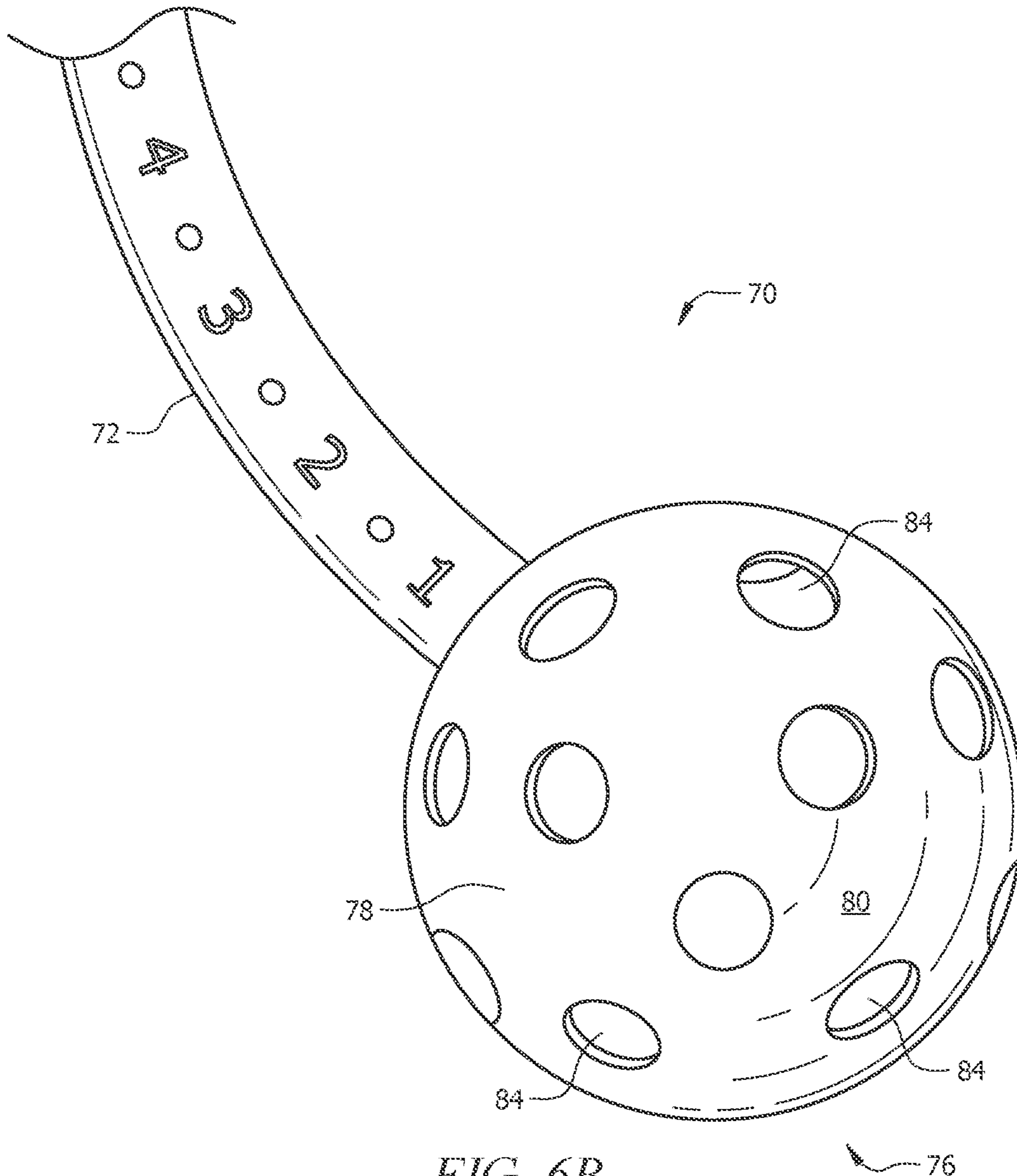


FIG. 6B

**PERCUTANEOUS ENDOSCOPIC
GASTRONOMY TUBE FOR OPTIMIZED
GASTRIC SUMPING**

CROSS-REFERENCE TO RELATED
APPLICATIONS

This nonprovisional application is a continuation of and claims priority to currently pending U.S. Nonprovisional patent application Ser. No. 15/829,329, entitled “Percutaneous Endoscopic Gastronomy Tube for Optimized Gastric Sumping”, filed Dec. 1, 2017, which is a continuation of and claims priority to U.S. Nonprovisional patent application Ser. No. 14/720,307, entitled “Percutaneous Endoscopic Gastronomy Tube for Optimized Gastric Sumping”, filed May 22, 2015 and issued on Jan. 16, 2018 as U.S. Pat. No. 9,867,915, which is a continuation of and claims priority to Provisional Patent Application No. 62/023,268, entitled “Percutaneous Endoscopic Gastronomy Tube for Optimized Gastric Sumping”, filed Jul. 11, 2014 by the same inventor, all of which are incorporated herein in their entireties.

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates, generally, to percutaneous endoscopic gastronomy (“PEG”). More specifically, it relates to an improved PEG tube for optimized gastric sumping.

2. Brief Description of the Prior Art

A standard PEG tube has an intragastric “bell” that resembles the underside of a mushroom cap which holds it in place and prevents it from being pulled free of the abdominal wall (see FIGS. 1A and 1B). When a PEG tube is placed to suction for purposes of gastric drainage this bell frequently contacts the opposite stomach wall creating a seal and preventing further drainage (see FIG. 1B), thus hindering the therapy.

As noted, PEG and nasogastric tubes are known in the art. For example, U.S. Pat. No. 5,356,391 to Stewart discloses a collapsible gastrostomy tube having a collapsible, internal retention flange. The gastrostomy tube is inserted into a patient’s stomach by a percutaneous endoscopic or other suitable technique. However, the internal retention flange comprises a dome shape that would adhere to the contralateral stomach wall when suction is applied, effectively sealing off the tube.

U.S. Pat. No. 5,391,159 to Hirsch et al. discusses a gastrostomy tube is a flexible tube having on one inner end thereof an improved energy absorbent internal retaining member. The energy absorbent internal retaining member has a hollow body portion with two resiliently reversible physical forms or shapes, toroidal-like, and, goblet-like connected to a foreshortened hollow axial stem portion that is attached to or integrally made with the inward end of the flexible tube. The internal retaining member is made in the toroidal-like form. During intentional removal, when under pressure against the stomach mucosa, the internal retaining member snaps into the unrolled, dome-like shape and pulls out through the stoma tract. However, the dome-shaped retaining member still would adhere to the contralateral stomach wall when suction is applied, effectively sealing off the tube.

U.S. Pat. No. 3,421,510 to Kettenbach discloses a design for a temporarily placed surgical drain. These drains are

placed around viscera or in the soft tissue as a temporary treatment after surgery and removed after several days. They cannot, however, be placed into the actual lumens of viscera.

U.S. Pat. No. 5,273,523 to Sozuki et al. discusses a design modification for a nasogastric tube. These tubes are placed through the nose into the stomach and are considered a temporary treatment. While these are well adapted for suctioning/sumping the stomach, they are temporary and cannot be inserted through an abdominal wall.

Similarly, U.S. Patent App. Pub. No. 2007/0060823 to Giroux et al. describes suction venting on a nasogastric tube provided by a sump lumen within the tube and not by a geometric property of the tube itself. These nasogastric tubes are not typically used for long term feeding, as is often done with a PEG tubes due to the long and narrow lumen which is prone to clogging. U.S. Pat. No. 3,999,554 to Kim et al. and U.S. Pat. No. 3,114,373 to Andersen describes a similar nasogastric tube as that seen in U.S. Pat. No. 5,273,523 to Sozuki et al. and U.S. Patent App. Pub. No. 2007/0060823 to Giroux et al. and include the same drawbacks as the described nasogastric publications. Similarly, U.S. Pat. No. 2,492,384 to Kaslow relates to nasogastric tubes as well. While the loop design at the end of this tube could theoretically help prevent occlusion, given the pliability of gastric mucosa, this is unlikely, and again this tube could not be used percutaneously.

U.S. Pat. No. 4,356,824 to Vazquez applies the principles of a nasogastric tube but placed through a gastric tube base. The suction tube utilizes a second interior sump tube to prevent sealing. This design facilitates the prevention of sealing or clogging, but does so by effectively adding several additional tubes and lumens, rather than any geometric alteration of the PEG tube bell itself. Additionally, this tube could not be placed percutaneously via an endoscope as it has multiple tubes and lumens on each end and could not be pulled through a single skin hole and would require a full surgical laparotomy.

U.S. Pat. No. 2,470,665 to Stiehl discloses a suction tip for a tube utilizing an inflatable hood to keep the stomach walls away from the suction tubing to prevent occlusion of the suction ports. However, this apparatus requires inclusion of additional ports on the proximal end of the tube, meaning that it cannot be placed percutaneously like a PEG tube.

Accordingly, what is needed is an improved PEG tube that can more effectively sump or suction out the contents of a body lumen, such as the stomach. However, in view of the art considered as a whole at the time the present invention was made, it was not obvious to those of ordinary skill in the field of this invention how the shortcomings of the prior art could be overcome.

All referenced publications are incorporated herein by reference in their entirety. Furthermore, where a definition or use of a term in a reference, which is incorporated by reference herein, is inconsistent or contrary to the definition of that term provided herein, the definition of that term provided herein applies and the definition of that term in the reference does not apply.

While certain aspects of conventional technologies have been discussed to facilitate disclosure of the invention, Applicants in no way disclaim these technical aspects, and it is contemplated that the claimed invention may encompass one or more of the conventional technical aspects discussed herein.

The present invention may address one or more of the problems and deficiencies of the prior art discussed above. However, it is contemplated that the invention may prove useful in addressing other problems and deficiencies in a

number of technical areas. Therefore, the claimed invention should not necessarily be construed as limited to addressing any of the particular problems or deficiencies discussed herein.

In this specification, where a document, act or item of knowledge is referred to or discussed, this reference or discussion is not an admission that the document, act or item of knowledge or any combination thereof was at the priority date, publicly available, known to the public, part of common general knowledge, or otherwise constitutes prior art under the applicable statutory provisions; or is known to be relevant to an attempt to solve any problem with which this specification is concerned.

BRIEF SUMMARY OF THE INVENTION

The long-standing but heretofore unfulfilled need for a ventilated PEG tube is now met by a new, useful, and nonobvious invention.

In an embodiment, the current invention is a percutaneous endoscopic gastrostomy tube apparatus. The apparatus includes an elongate, substantially hollow drainage tubing that has proximal and distal ends. The drainage tubing is configured to extend through a patient or subject's body with the distal end of the drainage tubing being positioned in a region of interest (e.g., stomach lumen) within the patient or subject's body. A bell cap is coupled to the distal end of the drainage tubing and has a substantially hollow interior in open communication with the interior the drainage tubing. The bell cap has a distal end and also a distal edge at the distal-most portion of the distal end of the bell cap. The apparatus further includes a means of ventilating the bell cap, where the ventilating means is positioned through and along a body of the bell cap and/or through and along the distal edge of the bell cap. This allows the interior of the bell cap to be in open communication with an external environment through the ventilating means.

Optionally, the drainage tubing can include a plurality of channels extending therethrough along a length of the drainage tubing, where one of the channels is a drainage lumen and the other channel is a ventricular lumen.

The distal end of the bell cap may be open or closed to the external environment. When open, the ventilating means may be a plurality of apertures disposed about the circumference of the body of the bell cap. In this case, each aperture can have a diameter that is equal to or less than a diameter of the distal end of the drainage tubing. Alternatively, when the distal end of the bell cap is open to the external environment, the ventilating means can be a plurality of crenellations disposed along the distal edge of the bell cap, such that a groove is formed between each pair of crenellations around the distal edge of the bell cap. In this case, the groove may have a width or length that is equal to or less than a diameter of the distal end of the drainage tubing.

Alternatively, when the distal end of the bell cap is open to the external environment, the ventilating means can be a hemispherical arch attached to the bell cap at two (2) distinct points on the bell cap and extending distally from the bell cap to a distal apex positioned at a spaced distance away from (distal to) the distal edge of the bell cap. These two (2) distinct points of connection between the hemispherical arch and the bell cap may be in diametric opposition to each other. Optionally, the ventilating means may include a second hemispherical arch attached to the bell at another two (2) distinct points on the bell cap and extending distally to a distal apex positioned at a spaced distance away from (distal to) the distal edge of the bell cap. In this case, these

additional two (2) distinct points of connection between the second hemispherical arch and the bell cap may be in diametric opposition to each other. Further, the two hemispherical arches can intersect each other at the distal apexes, such that the spaced distances away from the bell cap are about the same distance away from the bell cap. In other words, the two hemispherical arches would share one apex. Alternatively, the hemispherical arches can intersect, such that one has a further distal apex than the other. In either case, the intersection between the hemispherical arches can form a ninety (90) degree angle between each other.

When the distal end of the bell cap is closed to the external environment, the ventilating means can be an array of apertures formed through and along a surface of the body of the bell cap. Each aperture can have a diameter that is equal to or less than a diameter of the distal end of the drainage tubing. Each aperture may be ovular or elongate in shape. The apertures may have a randomized or ordered arrangement around a circumference of the bell cap.

In another embodiment, the current invention is a percutaneous endoscopic gastrostomy tube apparatus for gastric sumping, comprising any one or more of the foregoing characteristics and features, individually or in combination.

These and other important objects, advantages, and features of the invention will become clear as this disclosure proceeds.

The invention accordingly comprises the features of construction, combination of elements, and arrangement of parts that will be exemplified in the disclosure set forth hereinafter and the scope of the invention will be indicated in the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the invention, reference should be made to the following detailed description, taken in connection with the accompanying drawings, in which:

FIG. 1A depicts a conventional PEG tube.

FIG. 1B depicts a conventional PEG tube contacting or suctioning the opposite abdominal wall, thus hindering further drainage from the stomach lumen.

FIG. 2A depicts an optional multichannel component of the current invention.

FIG. 2B depicts a mechanism and use of the optional multichannel component of the current invention.

FIG. 3A depicts an embodiment of the current invention with apertures disposed around the hemispherical bell cap.

FIG. 3B depicts an alternate embodiment of the current invention, similar to that seen in FIG. 3A but with differently-shaped apertures.

FIG. 4 depicts an embodiment of the current invention with crenellations disposed around the distal edge of the bell cap.

FIG. 5A depicts an embodiment of the current invention with hemispherical arches disposed on the bell cap.

FIG. 5B depicts an alternate embodiment of the current invention, similar to that seen in FIG. 5A but with different apexes of the hemispherical arches.

FIG. 6A depicts an embodiment of the current invention with apertures disposed around the spherical bell cap.

FIG. 6B depicts an alternate embodiment of the current invention, similar to that seen in FIG. 6A but with a randomized arrangement of the apertures.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

In the following detailed description of the preferred embodiments, reference is made to the accompanying draw-

5

ings, which form a part thereof, and within which are shown by way of illustration specific embodiments by which the invention may be practiced. It is to be understood that other embodiments may be utilized and structural changes may be made without departing from the scope of the invention.

As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the content clearly dictates otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the context clearly dictates otherwise.

In certain embodiments, the current invention is a vented percutaneous endoscopic gastrostomy (PEG) tube and/or a method of performing percutaneous endoscopic gastrostomy, substantially as discussed herein.

More particularly, the PEG tube includes an elongate, hollow drainage tubing having a proximal end and a distal end, where the term “proximal” refers to a position closer to the user or physician and “distal” refers to a position closer to the patient or subject in which the PEG tube is inserted. The tubing extends through the patient or subject’s body with the distal end positioned in a region of interest (e.g., stomach lumen) within the patient or subject. A bell cap is coupled to the distal end of the drainage tubing, where the interior of the bell cap and the interior of the tubing are in open communication with each other. The bell cap includes a structural means or mechanism for ventilation that is positioned through and/or along a surface of the bell cap, such that the interior of the bell cap is in open communication with the external environment or gastric environment through the means of ventilation.

The bell cap can have a distal end that is open to the gastric (or visceral) environment. In this case, the means of ventilation may be a plurality of apertures disposed along the circumference of the body or distal end of the bell cap, such that the interior of the bell cap is in open communication with the external environment or gastric environment through the apertures. Each aperture may have a diameter that is equal to or slightly less than the diameter of the hollow drainage tubing. A slightly smaller diameter for each aperture would prevent debris from entering the interior of the bell cap and subsequently plugging or clogging the entrance to the drainage tubing.

Alternatively, the means of ventilation may be a plurality of notches or crenellations formed along an edge or lip of the distal end of the bell cap. Each notch or crenellation may have a width and/or length that is equal to or slightly less than the diameter of the hollow drainage tubing. A slightly smaller width and/or length for each notch or crenellation would prevent debris from entering the interior of the bell cap and subsequently plugging or clogging the entrance to the drainage tubing.

Alternatively, the means of ventilation may be a hemispherical arch attached to the bell cap at two (2) distinct points and extending distally to a distal apex positioned a spaced distance away from and distal to the distal edge of the bell cap. The two (2) distinct points of connection between the arch and bell cap can be positioned in diametric opposition to one another on the bell cap. There may also be a second hemispherical arch attached at another two (2) distinct points of the bell cap at a spaced distance away from and distal to the distal edge of the bell cap. These two (2) distinct points of connection can also be positioned in diametric opposition to one another on the bell cap. In this case, the hemispherical arches can intersect with each other at their distal apexes to form a ninety (90) degree angle between each other. They can intersect such that their distal

6

apexes are the same distance away from and distal to the distal end of the bell cap. In other words, they would share a distal apex, as the apexes would be co-planar with each other. Alternatively, the hemispherical arches can cross each other such that they do not share a common distal apex; rather, one arch has a slightly longer length than the other and has a further distal apex than the other. In this case, they do not necessarily “intersect” each other at all but would be positioned on top of each other to cross each other (i.e., the distal apexes are not co-planar).

Alternatively, the bell cap can have a distal end that is closed to the external environment or gastric environment. In this case, the means of ventilation may be an array of apertures formed through and along the surface of the body and/or closed distal end of the bell cap. Each aperture may have a diameter that is equal to or slightly less than the diameter of the hollow drainage tubing. A slightly smaller diameter for each aperture would prevent debris from entering the interior of the bell cap and subsequently plugging or clogging the entrance to the drainage tubing.

Alternatively, each aperture in the closed bell cap can be ovular or elongate in shape.

Optionally, the hollow drainage tubing may be multichanneled, or in other words include a plurality of channels extending through the length of the drainage tubing. These channels would terminate in a single tapered cone at the tube end to be passed percutaneously. Once passed through the skin this cone would be transected, and a multi-port adapter would be attached to the extraluminal end of the tube.

EXAMPLES

The current invention is an improved PEG tube that allows continuous suctioning/sumping without occlusion of the tube by the gastric wall. The PEG tube minimizes, or completely eliminates, the need for a user thereof to frequently flush the tube, thus also curtailing intermittent suctioning and allowing for longer periods of uninterrupted drainage. Furthermore, the PEG tubes of the current invention reduce clogging of the tube by larger gastric matter that is intended to be suctioned out of the patient or subject. This benefit reduces the time burden on nursing by reducing the need for manual examination and clearing of the tube. Even with the improvements of the PEG tubes of the current invention, the tube still permits standard endoscopic placement and feeding/medication administration by the nurse or physician.

In certain embodiments, the current invention has a form similar to the classic mushroom cap “bell” of a conventional PEG tube but includes several structural and functional modifications and improvements for improved sumping and gastric suctioning, while minimizing the time and frequency of flushing out the PEG tube.

As depicted in FIGS. 2A and 2B, hollow drainage tubing 2 can optionally be multichanneled (e.g., drainage channel 4a and ventricular channel 4b extending through the length of drainage tubing 2), with each channel 4a, 4b having the same or different diameters. Channels 4a, 4b may terminate in tapered cone 6 at the end of drainage tubing 2, to be passed percutaneously.

Drainage channel 4a is associated with the drainage lumen, and ventricular channel 4b is associated with the ventricular lumen. Once cone 6 is passed through the skin, cone 6 can be transected, and a multi-port adapter (formed of ports 8a, 8b) would be coupled to the extraluminal end of drainage tubing 2. Each lumen would respectively lead to

one of ports **8a**, **8b** that split off drainage tubing **2**, as seen in FIG. 2B. A multichannel PEG tube, such as this, performs similar to a nanogastric tube.

Example 1 (FIGS. 3A-3B)

In an embodiment, the current invention is a PEG tube apparatus, generally denoted by the reference numeral **10**, including elongate, hollow drainage tubing **12** and a bell cap, generally denoted by the reference numeral **16**, in the form of a vented hemisphere. Hollow drainage tubing **12** has a proximal end closest to the nurse, physician or other user, and a distal end positioned within the stomach cavity/lumen of the patient or subject. Drainage tubing **12** includes distal tubing opening **14** that terminates in vented hemispherical bell cap **14**.

Bell cap **16** includes body **18** and distal edge **20** formed around distal cap opening **22**, which collectively form the boundaries of its hollow interior **24**. Bell cap **16** is shaped as an inverted mushroom cap or is otherwise cylindrically shaped with its body **18** lined with a plurality of apertures **26**, **28** formed radially around the entire circumference of body **18** of bell cap **14**. Bell cap **16** has a proximal end connected to and in open communication with distal tubing opening **14** of hollow drainage tubing **12**. Bell cap **16** further includes a distal end that is open to the external/gastric environment. Thus, the external/gastric environment is in open communication with hollow interior **24** of bell cap **16** through distal cap opening **22** and through apertures **26**, **28** disposed around body **18** of bell cap **16**.

Apertures **26**, **28** disposed radially around the entire circumference of body **18** of bell cap **16** can have any shape (see circular shape in FIG. 3A and alternate/hexagonal shape in FIG. 3B) or size suitable for the function of PEG tube apparatus **10** or as desired by the user. Typically, though, each aperture **26**, **28** may have a diameter that is about the same as or slightly smaller than the diameter of distal tubing opening **14** of hollow drainage tubing **12**. This is done so that any particulates/matter that are suctioned through apertures **26**, **28** into hollow interior **24** of bell cap **16** and subsequently into hollow drainage tubing **12** through distal opening **14** cannot be so large that they can block or clog drainage tubing **12**, while still also maximizing the amount of particulates/matter that can be suctioned through bell cap **16** and drainage tubing **12** if distal cap opening **22** of bell cap **16** happens to be vacuum suctioned or sealed against an abdominal wall.

Example 2 (FIG. 4)

In an embodiment, the current invention is a PEG tube apparatus, generally denoted by the reference numeral **30**, including elongate, hollow drainage tubing **32** and a bell cap, generally denoted by the reference numeral **36**, in the form of a vented hemisphere. Hollow drainage tubing **32** has a proximal end closest to the nurse, physician or other user, and a distal end positioned within the stomach cavity/lumen of the patient or subject. Drainage tubing **32** includes distal tubing opening **34** that terminates in vented hemispherical bell cap **34**.

Bell cap **36** includes body **38** and distal edge **40** formed around distal cap opening **42**, which collectively form the boundaries of its hollow interior **44**. Bell cap **36** is shaped as an inverted mushroom cap or is otherwise cylindrically shaped with its distal edge **40** lined with a plurality of crenellations or notches **46** formed radially around the entire circumference of the cap with corresponding grooves **47**

formed between crenellations **46**. Bell cap **36** has a proximal end connected to and in open communication with distal tubing opening **34** of hollow drainage tubing **32**. Bell cap **36** further includes a distal end that is open to the external/gastric environment. Thus, the external/gastric environment is in open communication with hollow interior **44** of bell cap **36** through distal cap opening **42** and through grooves **47** disposed around distal edge **40** of bell cap **36**.

Crenellations **46** disposed radially around the entire circumference of distal edge **40** of bell cap **36** can have any size suitable for the function of the PEG tube or as desired by the user. Typically, though, each groove **47** can have width **48a** and/or length **48b** that is about the same as or smaller than the diameter of hollow drainage tube **32** and distal opening **34** thereof. This is done so that any particulates/matter that are suctioned through grooves **47** into hollow interior **44** of bell cap **36** and subsequently into hollow drainage tubing **32** through distal opening **34** cannot be so large that they can block or clog drainage tubing **32**, while still also maximizing the amount of particulates/matter that can be suctioned through bell cap **36** and drainage tubing **32** if distal cap opening **42** of bell cap **36** happens to be vacuum suctioned or sealed against an abdominal wall.

Example 3 (FIGS. 5A-5B)

In an embodiment, the current invention is a PEG tube apparatus, generally denoted by the reference numeral **50**, including elongate, hollow drainage tubing **52** and a bell cap, generally denoted by the reference numeral **56**, in the form of a vented hemisphere or pseudo-sphere. Hollow drainage tubing **52** has a proximal end closest to the nurse, physician or other user, and a distal end positioned within the stomach cavity of the patient or subject. Drainage tubing **52** includes distal tubing opening **54** that terminates in vented hemispherical or pseudo-spherical bell cap **56**.

Bell cap **56** includes body **58** and distal edge **60** formed around distal cap opening **62**, which collectively form the boundaries of its hollow interior **64**. Bell cap **56** is shaped as an inverted mushroom cap or is otherwise cylindrically shaped with one or more hemispherical arches **65a-65b** (FIG. 5A), **67a-67b** (FIG. 5B) attached to its distal edge **60**. Bell cap **56** has a proximal end connected to and in open communication with distal tubing opening **54** of hollow drainage tubing **52**. Bell cap **56** further includes a distal end that is open to the external/gastric environment. Thus, the external/gastric environment is in open communication with hollow interior **64** of bell cap **56** through distal cap opening **62** and through the space between hemispherical arches **65a-65b**, **67a-67b**.

First hemispherical arch **65a**, **67a** has a first end and a second end. The first end of hemispherical arch **65a**, **67a** is attached to a first side of bell cap **56** (e.g., at distal edge **60** of bell cap **56**, at the proximal end of bell cap **56**, along the exterior or interior surface of body **58** of bell cap **56**, etc.). Hemispherical arch **65a**, **67a** follows a path of travel, extending distally from the first side of bell cap **56** until it reaches distal apex **66**, **68a**, (see FIG. 5A for apex **66** and FIG. 5B for apex **68a**). Hemispherical arch **65a**, **67a** continues to follow its path of travel, extending proximally from its distal apex **66**, **68a** until it reaches a second side of the bell cap. As seen in FIGS. 5A-5B, the first and second sides of bell cap **56** typically are in diametric opposition to one another, or in other words are separated from one another by a distance equaling the diameter of the distal end of bell cap **56** if bell cap **56** has a circular distal end (see FIG. 5A). Alternatively, if bell cap **56** has another shape (e.g., rectan-

gular, square, etc.), the arches extend from one side to an opposite side of the bell cap (see FIG. 5B).

In certain embodiments, second hemispherical arch **65b**, **67b** is connected to two (2) sides of bell cap **56** as well and extends distally from bell cap **56**, similar to the connection and disposition of first hemispherical arch **65a**, **67a**. In this case, the arches can intersect with one another at any angle desired.

In an embodiment, however, first and second hemispherical arches **65a-65b**, **67a-67b** would intersect at approximately a ninety (90) degree angle, such that the paths of travel of arches **65a-65b**, **67a-67b** have planes that are perpendicular to each other. Arches **65a-65b** can completely intersect, as in FIG. 5A where arches **65a-65b** share common apex **66**. Alternatively, arches **67a-67b** can tangentially intersect, as in FIG. 5B, where first arch **67a** includes distal apex **68a** that is further distally positioned than second arch **67b**, which includes distal apex **68b** that is further proximally positioned than that of first arch **67a**. Thus, first arch **67a** also has a steeper pitch than second arch **67b**.

Arches **65a-65b**, **67a-67b** are positioned along the distal end of bell cap **56** and form open spaces therebetween that are open distally to the external/gastric environment. Thus, the external/gastric environment is in open communication with hollow interior **64** of bell cap **56** through the space formed between arches **65a-65b**, **67a-67b** and the space between arches **65a-65b**, **67a-67b** and the distal end of bell cap **56**.

The length of arches **65a-65b**, **67a-67b** and the space therebetween and between arches **65a-65b**, **67a-67b** and the distal end of bell cap **56** can have any size suitable for the function of PEG tube **50** or as desired by the user. Arches **65a-65b**, **67a-67b**, which can be circular or rounded in certain embodiments, help prevent distal edge **60** of bell cap **56** from vacuum suctioning or sealing against an abdominal wall, thus allowing continuous suctioning of the particulates/matter desired.

Example 4 (FIGS. 6A-6B)

In an embodiment, the current invention is a PEG tube apparatus, generally denoted by the reference numeral **70**, including elongate, hollow drainage tubing **72** and a bell cap, generally denoted by the reference numeral **76**, in the form of a vented sphere. Hollow drainage tubing **72** has a proximal end closest to the nurse, physician or other user, and a distal end positioned within the stomach cavity of the patient or subject. Drainage tubing **72** includes a distal tubing opening (not shown in these figures but shown in previous figures) that terminates in the vented spherical bell cap.

Bell cap **76** includes body **78** and closed distal edge **80**, which collectively form the boundaries of its hollow interior (not shown in these figures but shown in previous figures). Bell cap **76** is spherically- or otherwise cylindrically-shaped with a plurality of apertures **82**, **84** formed within body **78** of bell cap **76**. Bell cap **76** has a proximal end connected to and in open communication with the distal tubing opening of hollow drainage tubing **72**. Bell cap **76** further includes distal edge **80** that is closed to the external/gastric environment. Apertures **82**, **84** are formed generally along the distal end of bell cap **76** and along the sides of body **78** of bell cap **76** between the distal and proximal ends of bell cap **76**. Apertures **82**, **84** open outwardly to the external/gastric environment. Thus, the external/gastric environment is in

open communication with the hollow interior of bell cap **76** through apertures **82**, **84** disposed around body **78** of bell cap **76**.

Apertures **82**, **84** disposed around the surface or body **78** of bell cap **76** can have any size suitable for the function of the PEG tube or as desired by the user. In an embodiment, though, each aperture **82**, **84** has a diameter or width that is about the same as or slightly smaller than the diameter of hollow drainage tube **72**. This is done so that any particulates/matter that are suctioned through apertures **82**, **84** into hollow drainage tubing **72** cannot be so large that they can block or clog drainage tubing **72**, while still also maximizing the amount of particulates/matter that can be suctioned through bell cap **76** and drainage tubing **72** if certain apertures **82**, **84** in bell cap **76** are vacuum suctioned or sealed against an abdominal wall.

Optionally, each aperture **82**, **84** can be circular (see FIG. 6A) or elongate/ovular (see FIG. 6B). Further, each aperture **82**, **84** can be randomized (see FIG. 6A) or ordered/aligned (see FIG. 6B).

Glossary of Claim Terms

Bell cap: This term is used herein to refer to the distal component or head of a PEG tube, through which matter or particulates from an anatomical region of interest are suctioned or sumped. It is contemplated herein that the bell cap can have any shape or form. Typically, the width or diameter of the bell cap is larger than the diameter of the proximally-positioned elongate, hollow drainage tubing attached thereto.

Closed to the external environment: This term is used herein to refer to a distal end of a bell cap having an edge that is closed or sealed, such as the side of a sphere.

Distal apex: This term is used herein to refer to the point of a hemispherical arch that is furthest away from a user (e.g., nurse, physician, etc.) of the PEG tube.

Distal: This term is used herein to refer to a relative position further from a nurse, physician, user, or other individual installing the PEG tube into a patient or subject

Distinct points: This term is used herein to refer to different connection points on or along a bell cap of a PEG tube according to certain embodiments of the current invention.

External environment: This term is used herein to refer to the surroundings (e.g., gastric environment) of a PEG tube when inserted into a region of interest of a patient or subject.

Less: This term is used herein to refer to a size of an aperture that optimizes the balance between not clogging the drainage tube with excessively large particulates or matter, while still permitting larger size particulates or matter to be removed from the region of interest of the patient or subject.

Means of ventilating: This term is used herein to refer to a structural mechanism that provides additional points of communication between the interior of the bell cap and the external/gastric environment. Examples include, but are not limited to, apertures or slits in the bell cap, notches or crenellations along the distal edge of the bell cap, among other suitable structures that provide open communication between the bell cap interior and external/gastric environment.

Open communication: This term is used herein to refer to a relationship between two (2) structural components of a system, where a fluid would be able to freely travel from the interior of one component to the interior of the other component.

11

Open to the external environment: This term is used herein to refer to a distal end of a bell cap having an edge that is free, such as the wider portion of a hemisphere.

Ordered arrangement: This term is used herein to refer to the positioning of apertures having a clear pattern around a bell cap.

Proximal: This term is used herein to refer to a relative position closer to a nurse, physician, user, or other individual installing the PEG tube into a patient or subject.

Randomized arrangement: This term is used herein to refer to the positioning of apertures having no clear pattern around a bell cap.

Region of interest: This term is used herein to refer to an anatomical area within a patient or subject from which a user (e.g., physician, nurse, etc.) desires to remove particulates or matter or to which the user desires to place a feeding tube or administer medication. An example of a "region of interest" is a stomach lumen of the patient or subject.

Spaced distance: This term is used herein to refer to a predetermined length or distance between a lip on the distal end of a bell cap and the distal apex of a hemispherical arch attached thereto.

The advantages set forth above, and those made apparent from the foregoing description, are efficiently attained. Since certain changes may be made in the above construction without departing from the scope of the invention, it is intended that all matters contained in the foregoing description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described, and all statements of the scope of the invention that, as a matter of language, might be said to fall therebetween.

What is claimed is:

1. A percutaneous endoscopic gastrostomy tube, comprising:

an elongate, hollow drainage tubing having a proximal end and a distal end, said hollow drainage tubing configured to extend through a body of a patient or subject with said distal end of said drainage tubing being positioned in a region of interest within said body of said patient or subject;

a bell cap enclosing said distal end of said hollow drainage tubing, said bell cap having an outer surface establishing a substantially hollow interior that is in open communication with an interior of said hollow drainage tubing and a distal end that is open to an external environment, where in aid outer surface of said bell cap is a sphere when positioned in said region of interest within said body of said patient or subject; and a plurality of apertures disposed through the outer surface of the bell cap, wherein said plurality of apertures provides ventilation between said bell cap and said external environment.

2. A percutaneous endoscopic gastrostomy tube as in claim 1, wherein each aperture in said plurality of apertures

12

has a diameter that is equal to or less than a diameter of said distal end of said drainage tubing.

3. A percutaneous endoscopic gastrostomy tube as in claim 1, wherein each aperture in said plurality of apertures has an opening that is smaller than an opening of said distal end of said drainage tubing.

4. A percutaneous endoscopic gastrostomy tube as in claim 1, wherein each aperture in said plurality of apertures is elongate in shape.

5. A percutaneous endoscopic gastrostomy tube as in claim 1, wherein each aperture in said plurality of apertures is located in a randomized arrangement about said outer surface of said bell cap.

6. A percutaneous endoscopic gastrostomy tube as in claim 1, wherein each aperture in said plurality of apertures is located in an ordered arrangement about said outer surface of said bell cap.

7. A percutaneous endoscopic gastrostomy tube, comprising:

an elongate, hollow drainage tubing having a proximal end and a distal end, said hollow drainage tubing configured to extend through a body of a patient or subject with said distal end of said drainage tubing being positioned in a region of interest within said body of said patient or subject;

a bell cap enclosing said distal end of said hollow drainage tubing, said bell cap having an outer surface establishing a substantially hollow interior that is in open communication with an interior of said hollow drainage tubing, wherein said outer surface of said bell cap is a sphere when positioned in said region of interest within said body of said patient or subject;

a plurality of apertures disposed through the outer surface of the bell cap, wherein said plurality of apertures provides ventilation between said bell cap and an external environment; and

each aperture in said plurality of apertures having an opening that is smaller than an opening of said distal end of said drainage tubing.

8. A percutaneous endoscopic gastrostomy tube as in claim 7, wherein each aperture in said plurality of apertures has a diameter that is less than a diameter of said distal end of said drainage tubing.

9. A percutaneous endoscopic gastrostomy tube as in claim 7, wherein each aperture in said plurality of apertures is elongate in shape.

10. A percutaneous endoscopic gastrostomy tube as in claim 7, wherein each aperture in said plurality of apertures is located in a randomized arrangement about said outer surface of said bell cap.

11. A percutaneous endoscopic gastrostomy tube as in claim 7, wherein each aperture in said plurality of apertures is located in an ordered arrangement about said outer surface of said bell cap.

* * * * *