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(54) **TYMPANIC THERMOMETER PROBE COVER WITH FILM SUPPORT MECHANISM**

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(73) Assignee: **Tyco Healthcare Group LP**, Mansfield, MA (US)

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Related U.S. Patent Documents

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(64) Patent No.: **7,354,194**
Issued: **Apr. 8, 2008**
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Filed: **Nov. 23, 2005**

(51) **Int. Cl.**
G01K 1/08 (2006.01)

(52) **U.S. Cl.** **374/158**; 374/209; 374/208; 600/184

(58) **Field of Classification Search** 374/120–121, 374/158, 208, 209, 163, 183, 185; 600/549, 600/474; 702/131
See application file for complete search history.

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Primary Examiner — Gail Verbitsky
(74) *Attorney, Agent, or Firm* — Lisa E. Winsor, Esq.

(57) **ABSTRACT**

A probe cover for a tympanic thermometer probe comprises a generally tubular body having an opening for receiving the thermometer probe and an infrared transparent window at a distal end thereof. In one embodiment, a film support extends radially inward from the distal end of the body and supports an infrared transparent film spanning the window. The film support has an inner edge that is substantially free from corners turning in the plane of the window. A plurality of end ribs are spaced apart and disposed about an inner circumference of the distal end of the body to engage a distal end of the thermometer probe and form an insulating gap by preventing contact of the film by the thermometer probe. The insulating gap also extends proximally into spaces between the end ribs, reducing thermal contact between the thermometer probe and a circumferential inner surface of the probe cover.

25 Claims, 24 Drawing Sheets

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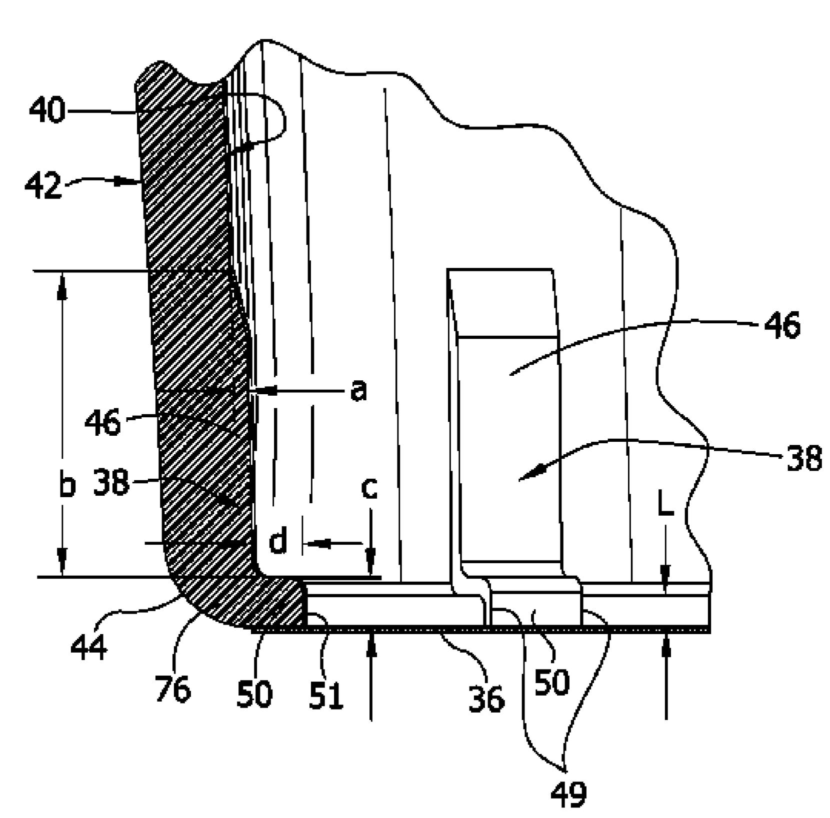

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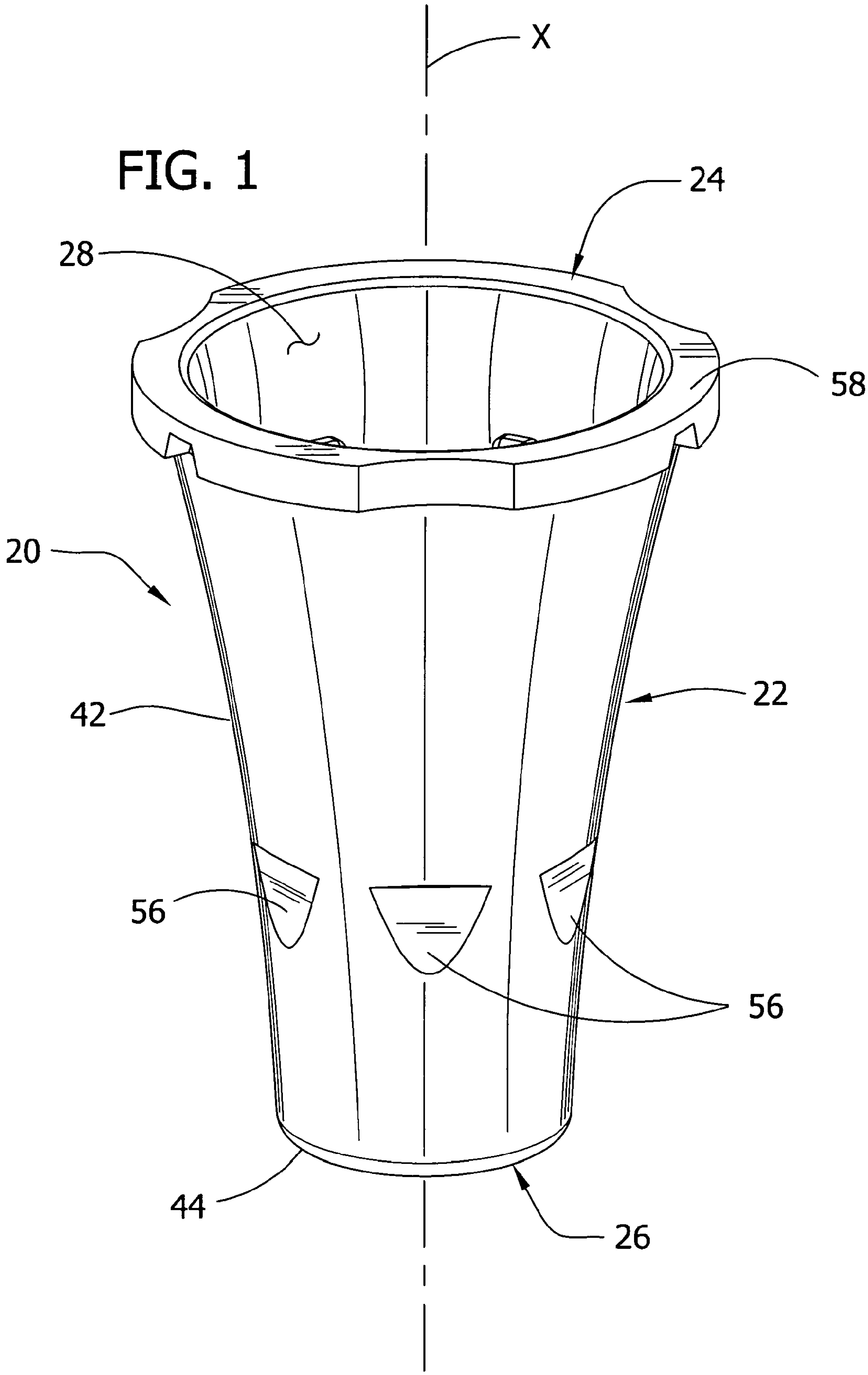


FIG. 1

FIG. 2

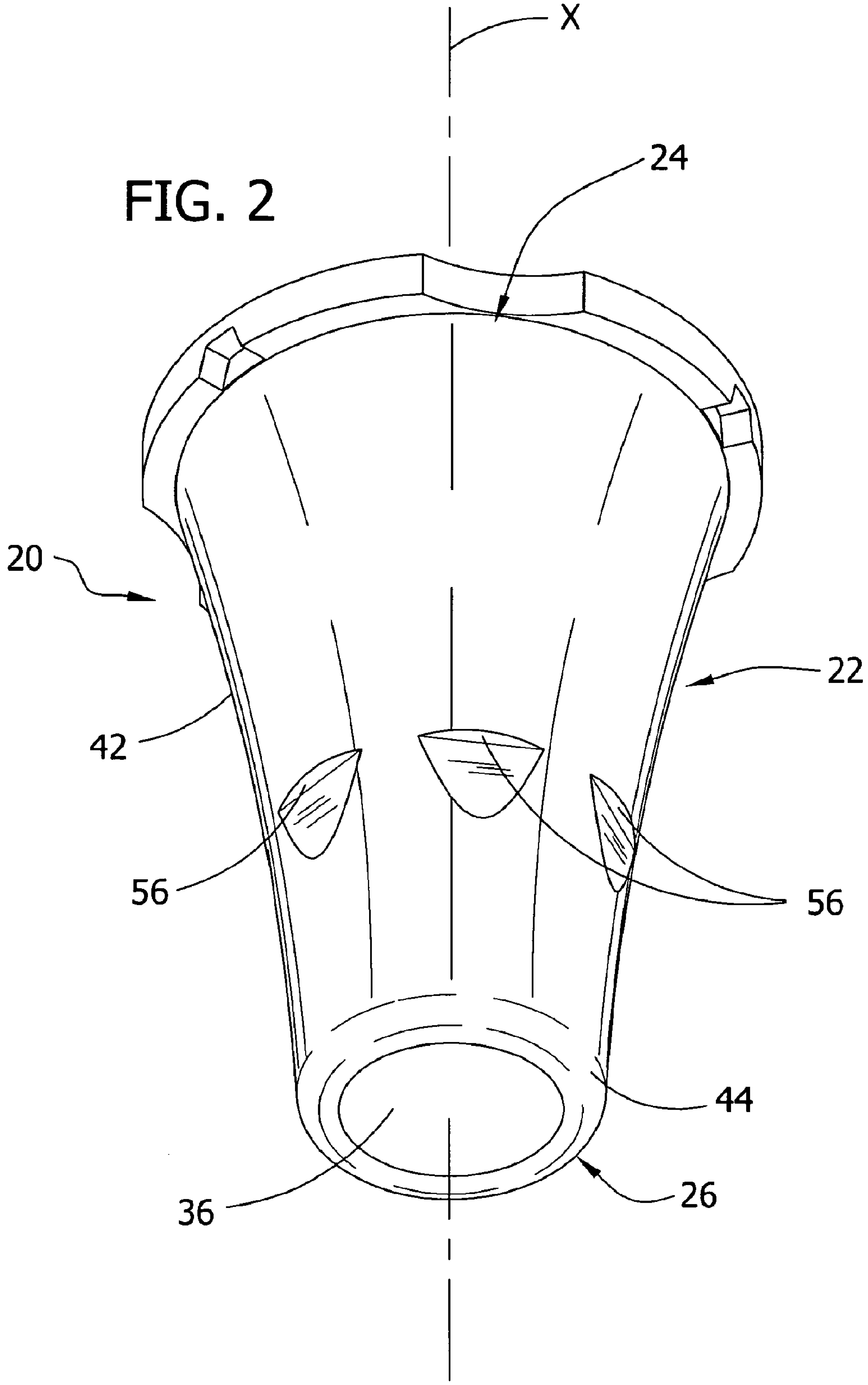
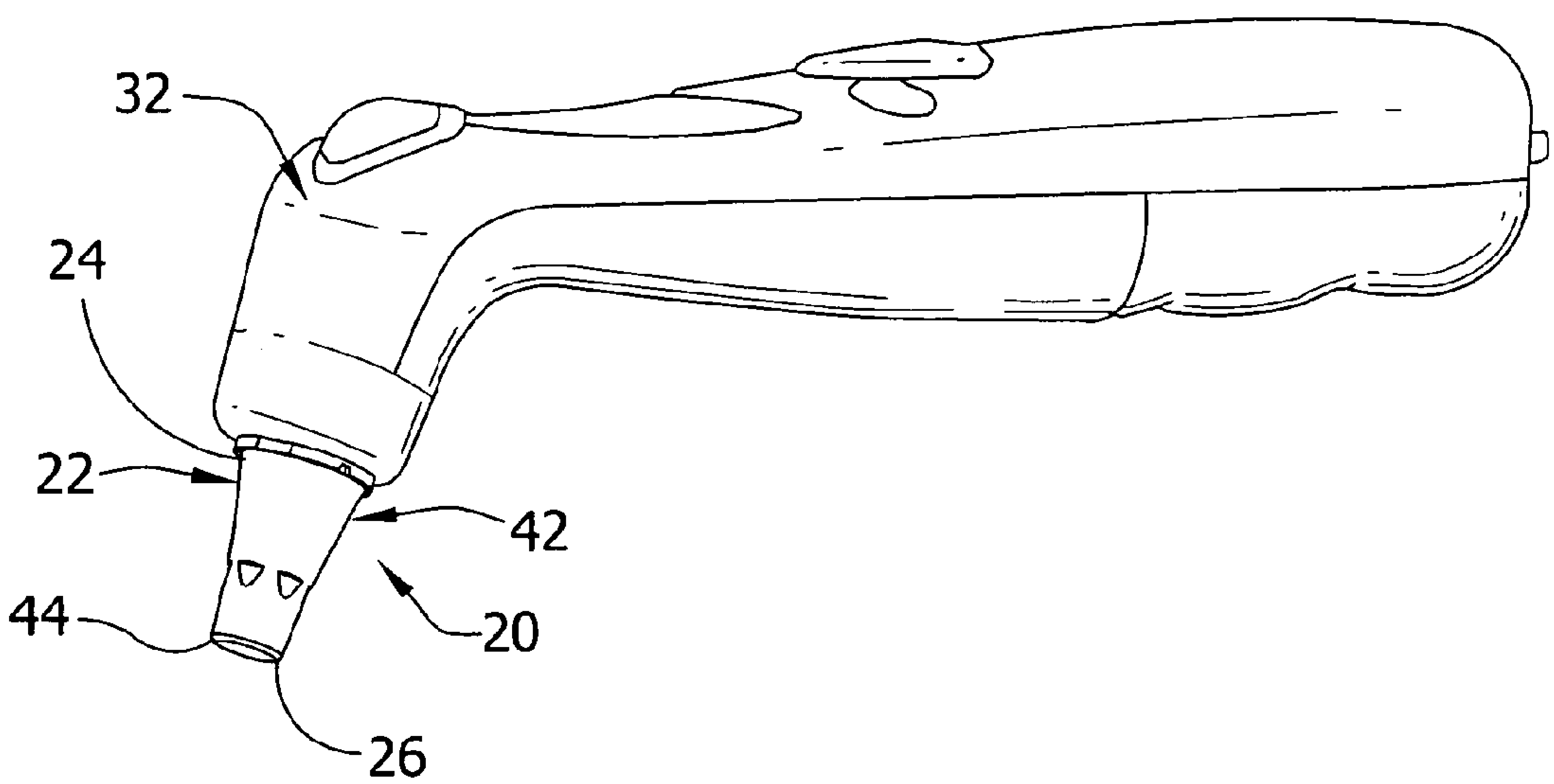


FIG. 3



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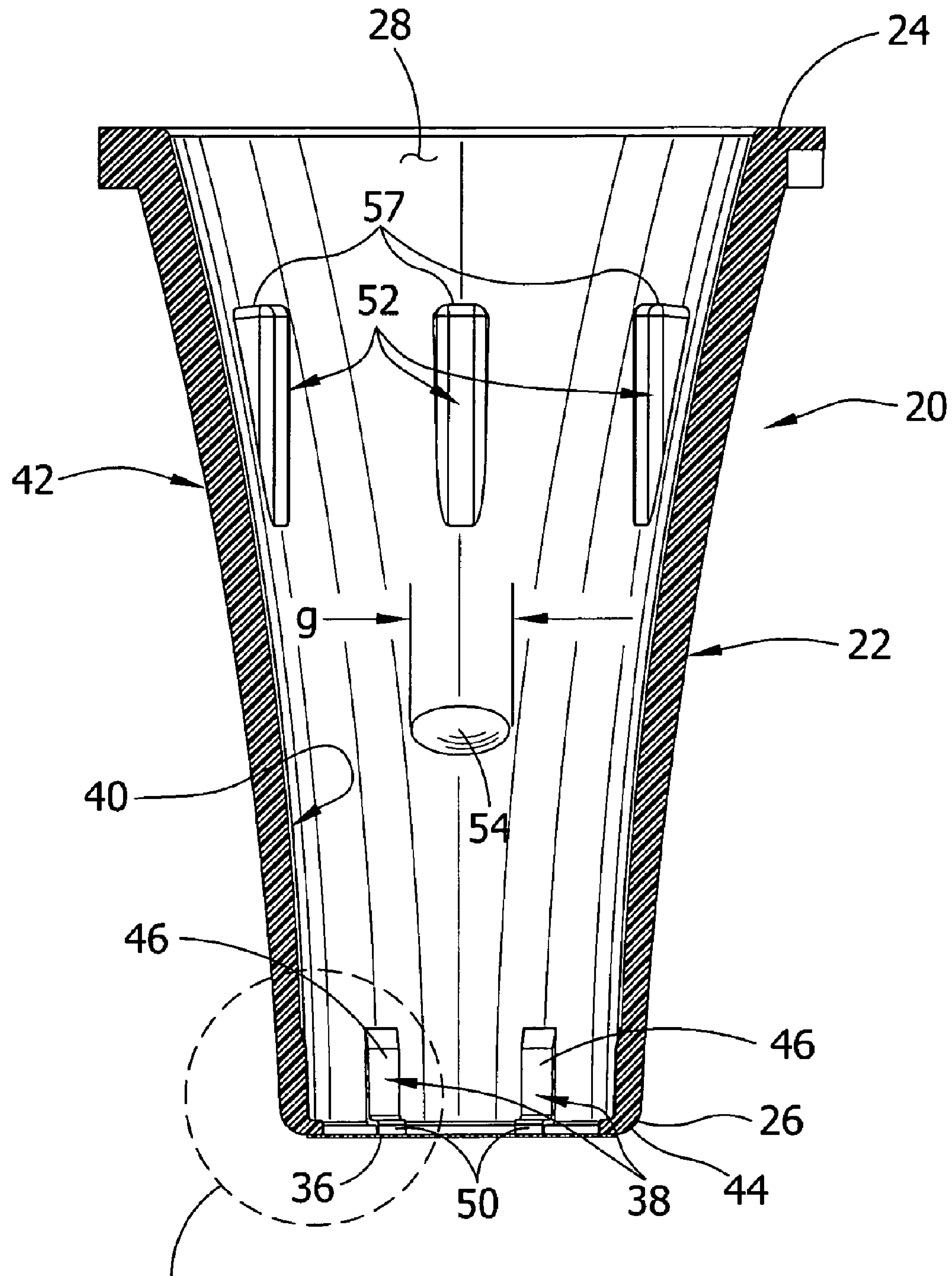

FIG. 5

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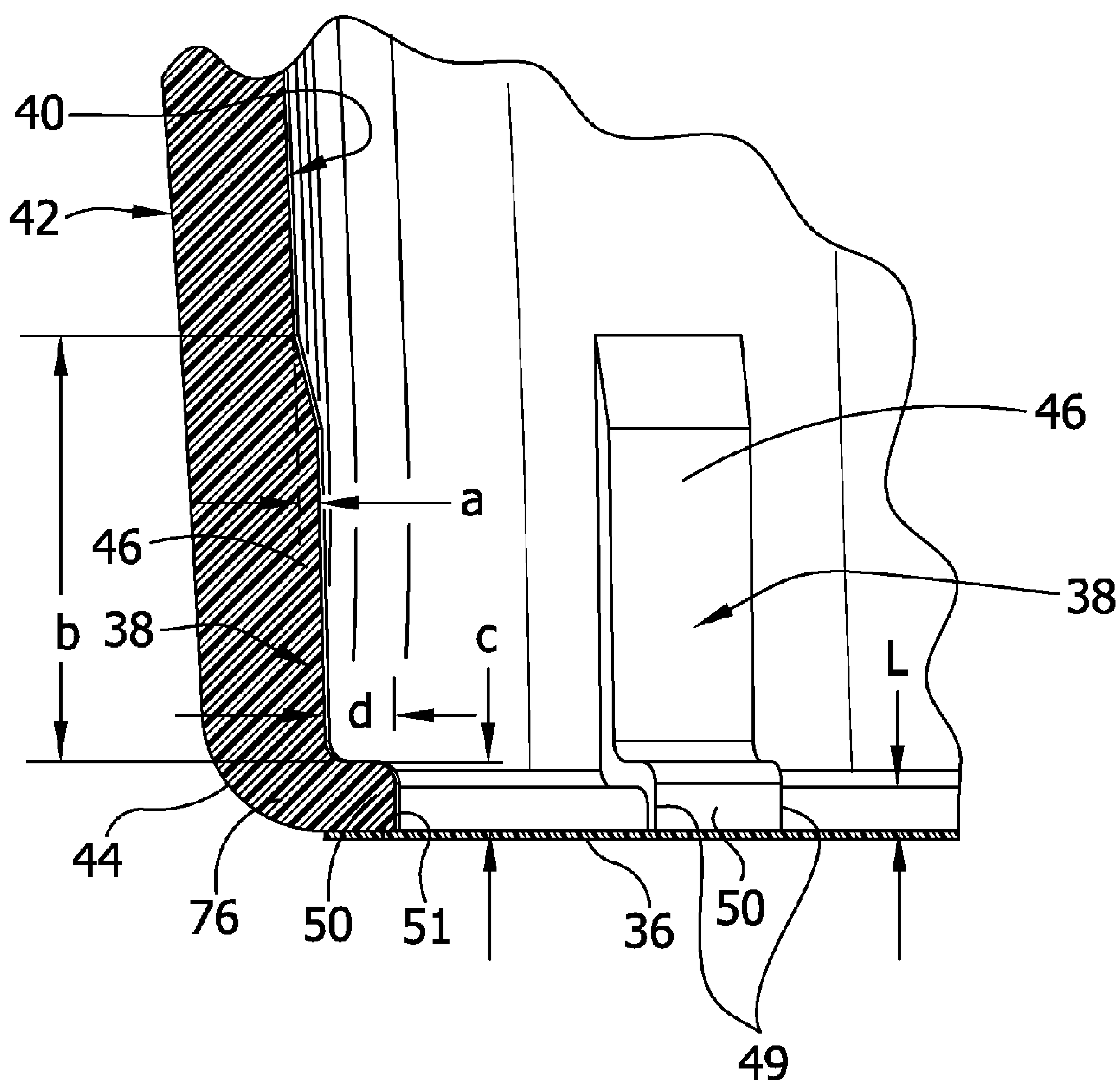
FIG. 5



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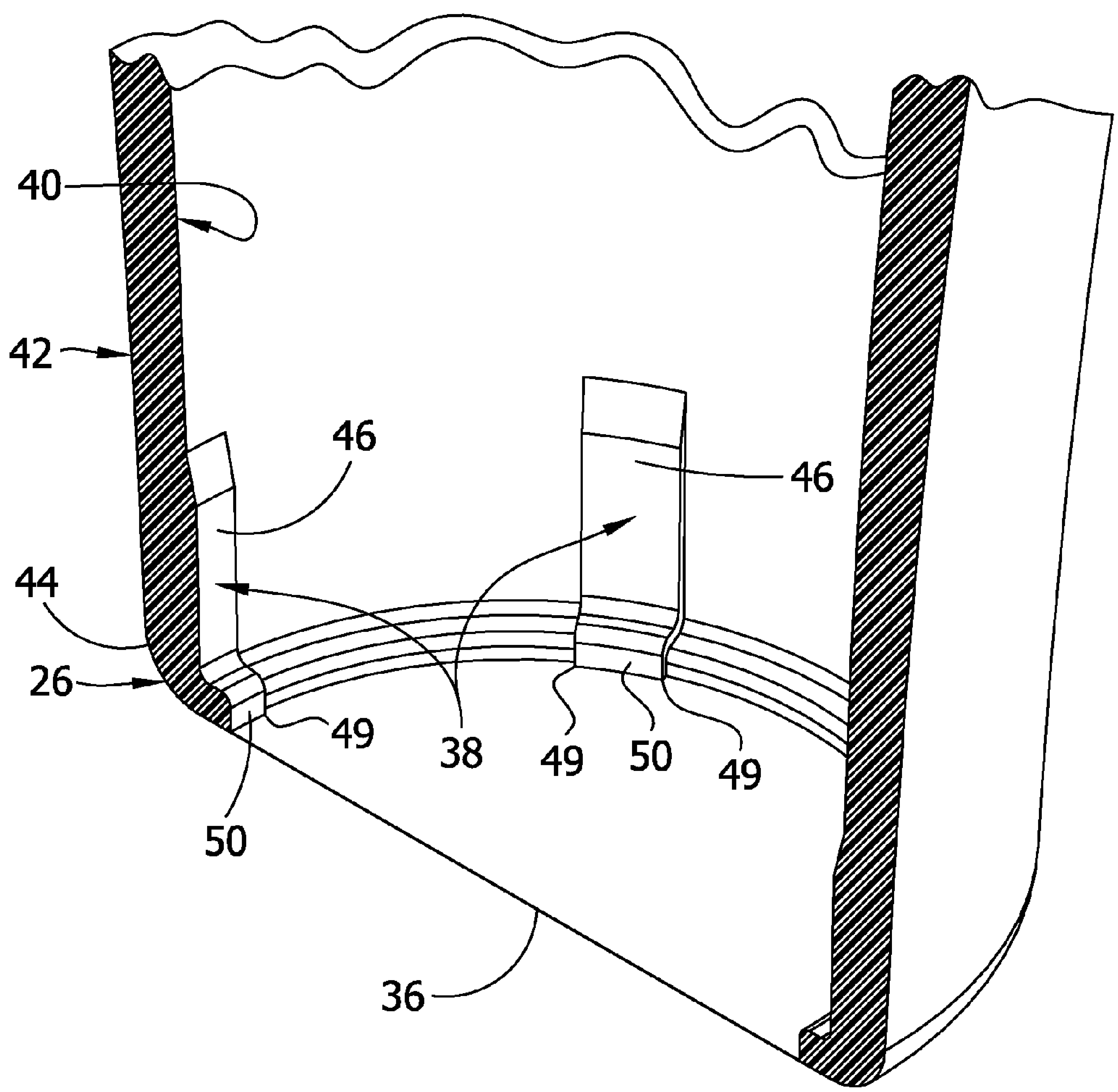

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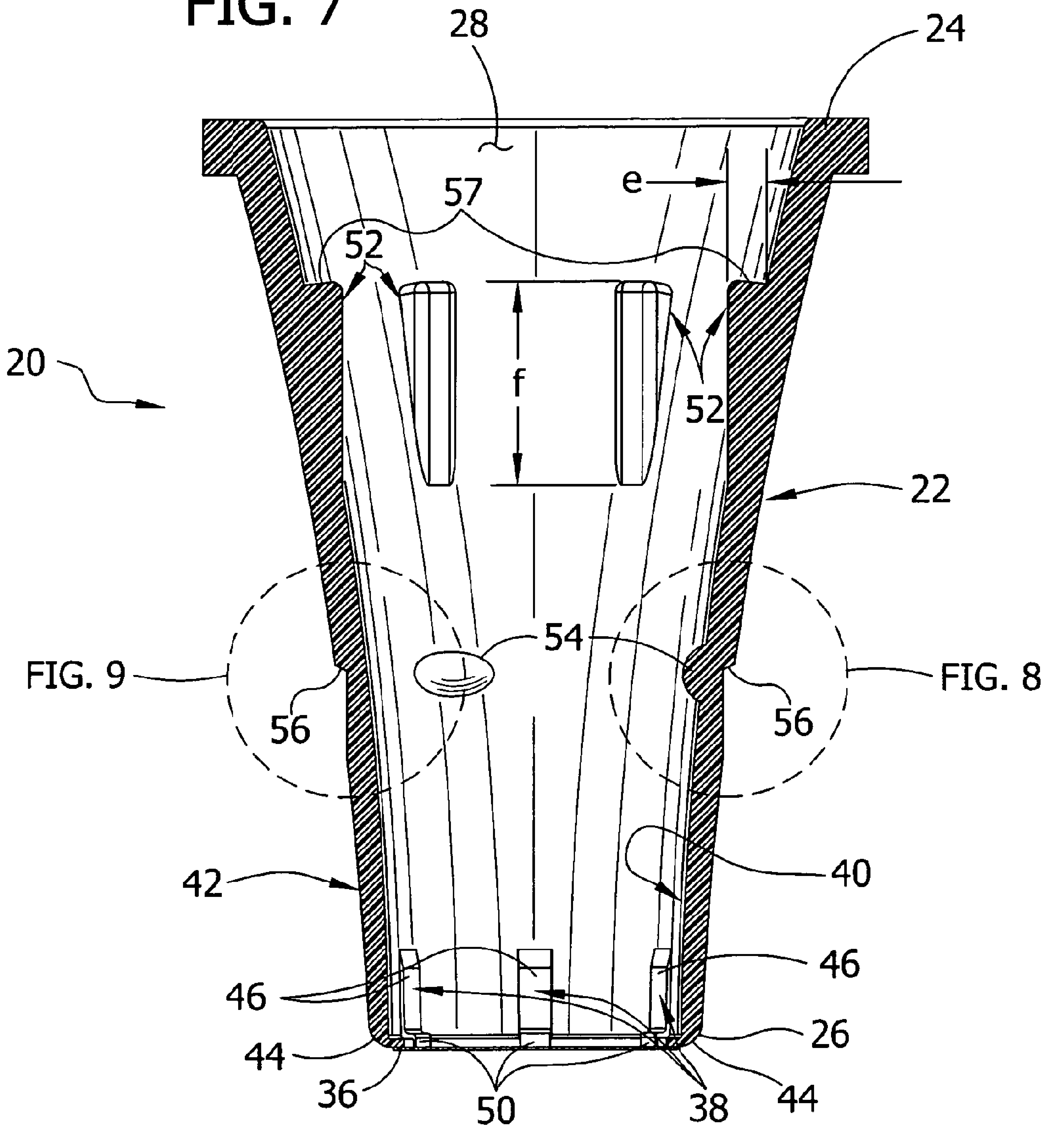

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FIG. 9
FIG. 8
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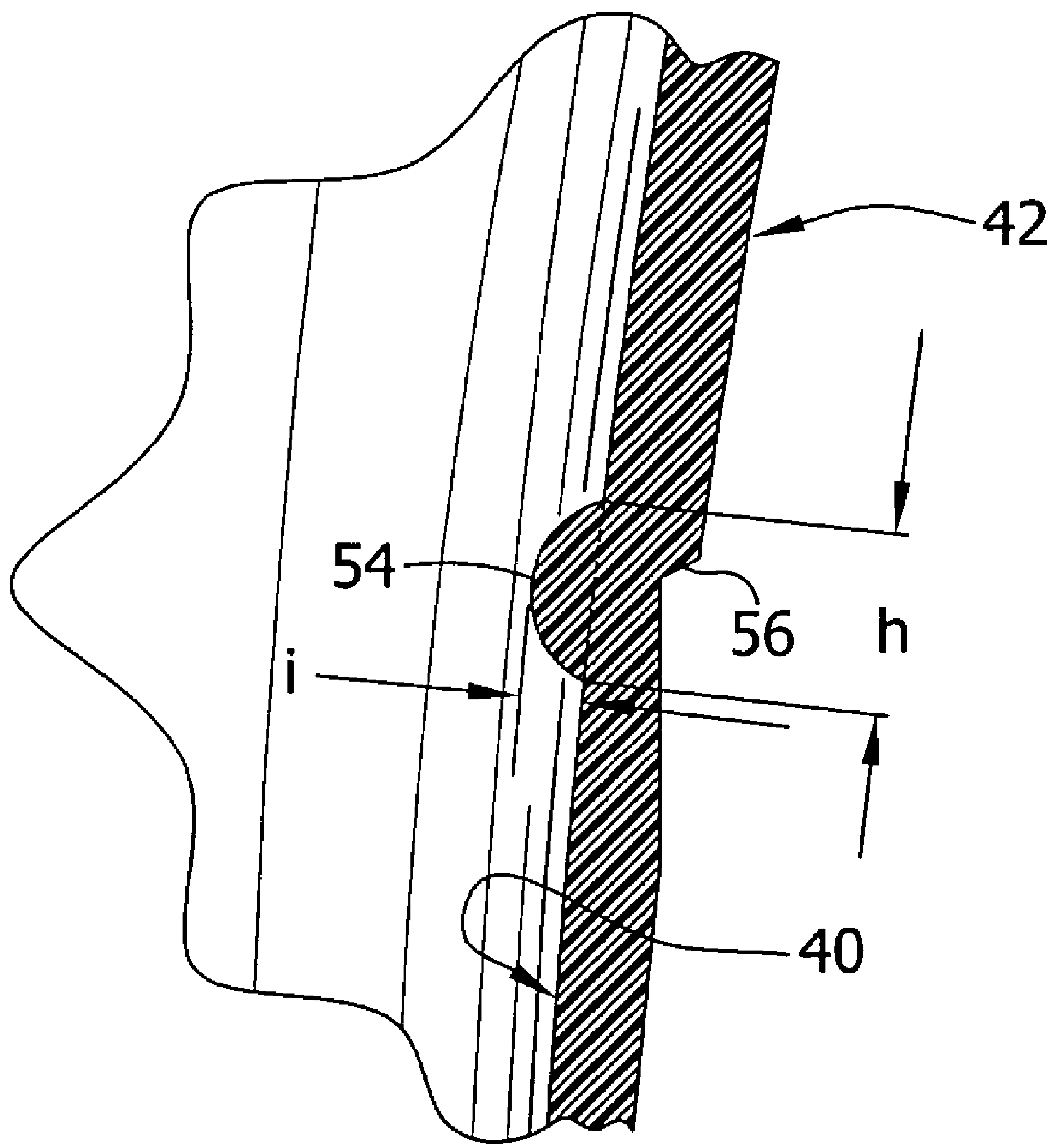
FIG. 8



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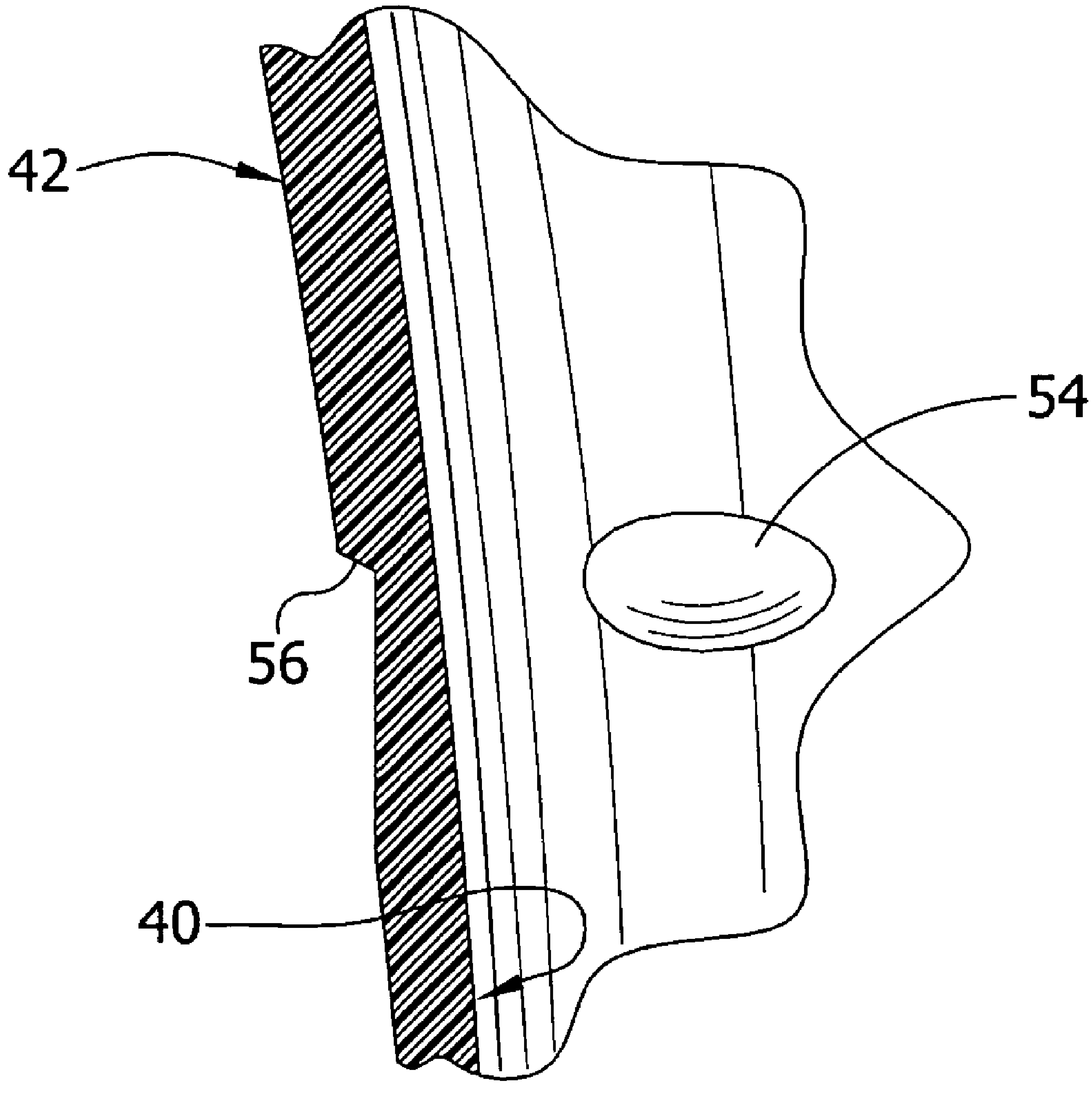

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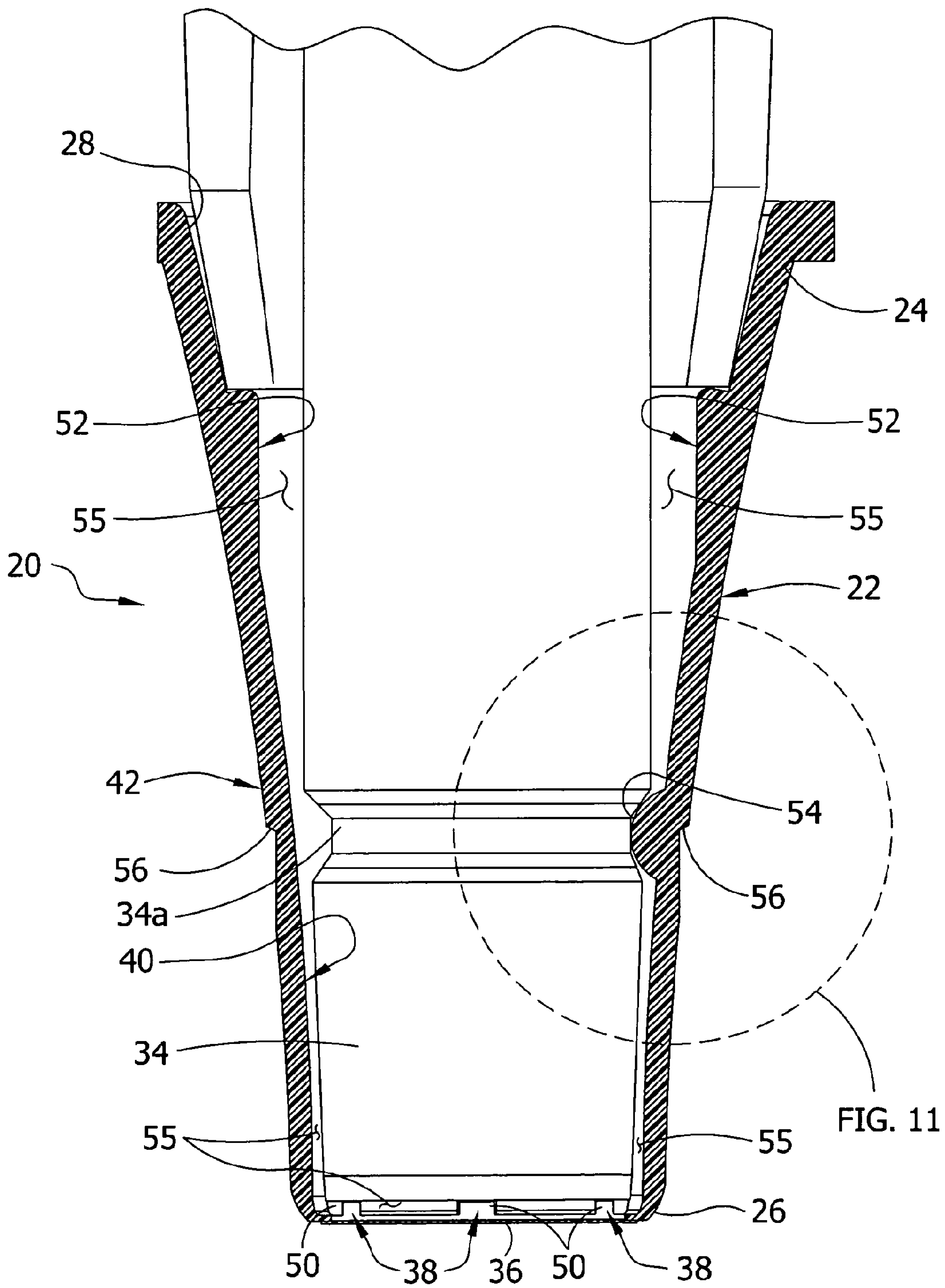
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FIG. 11
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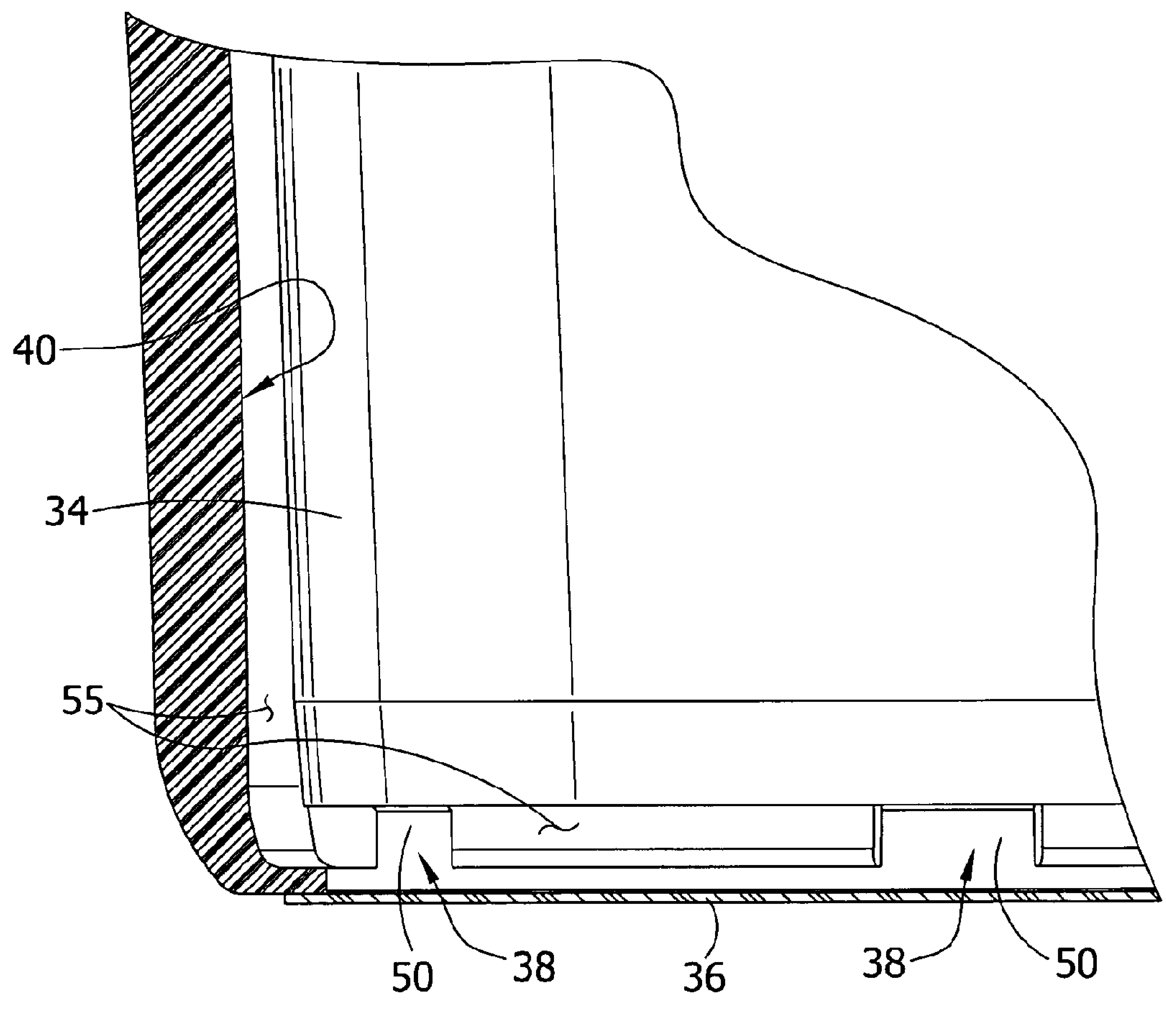
FIG. 10A



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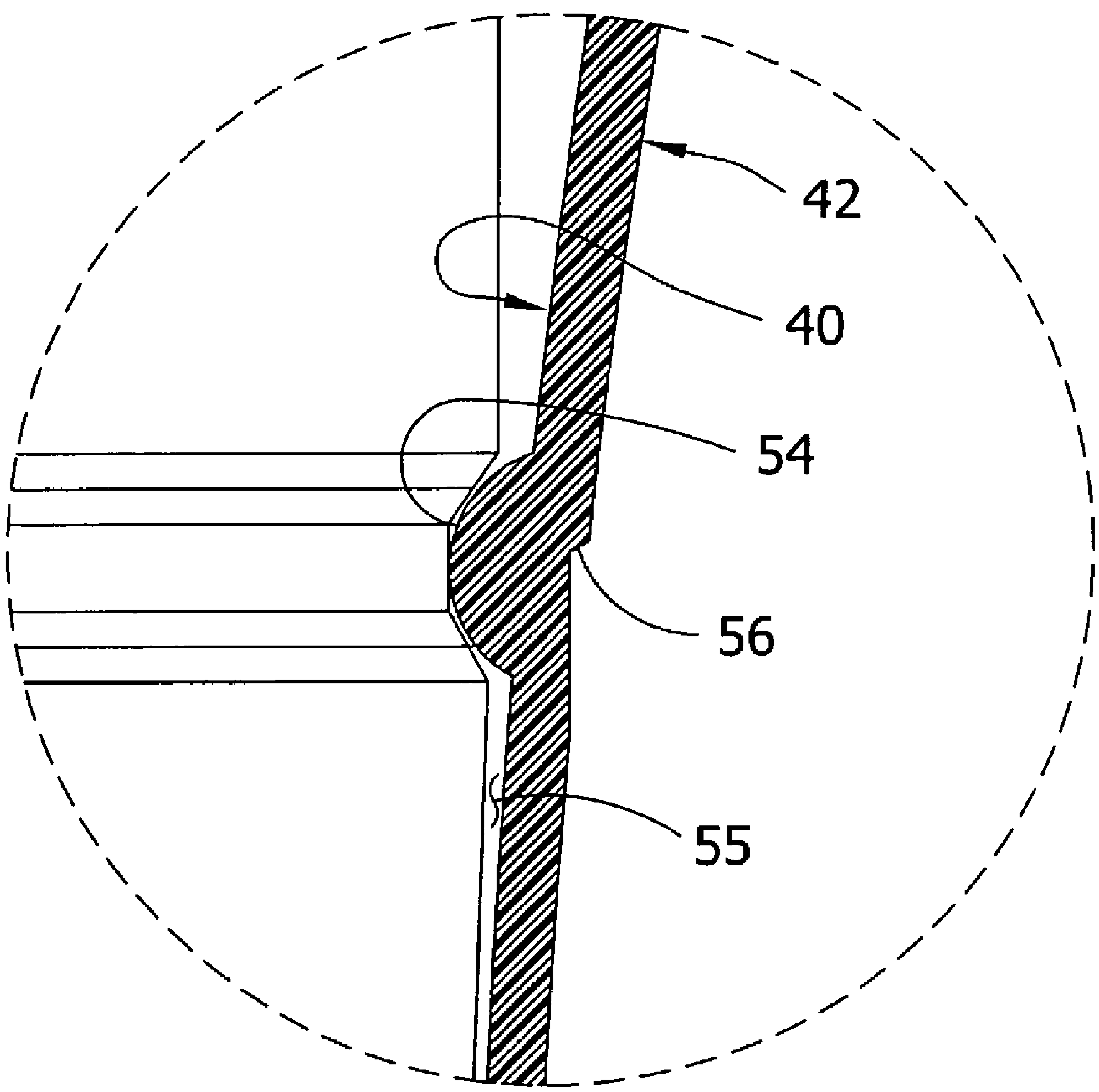

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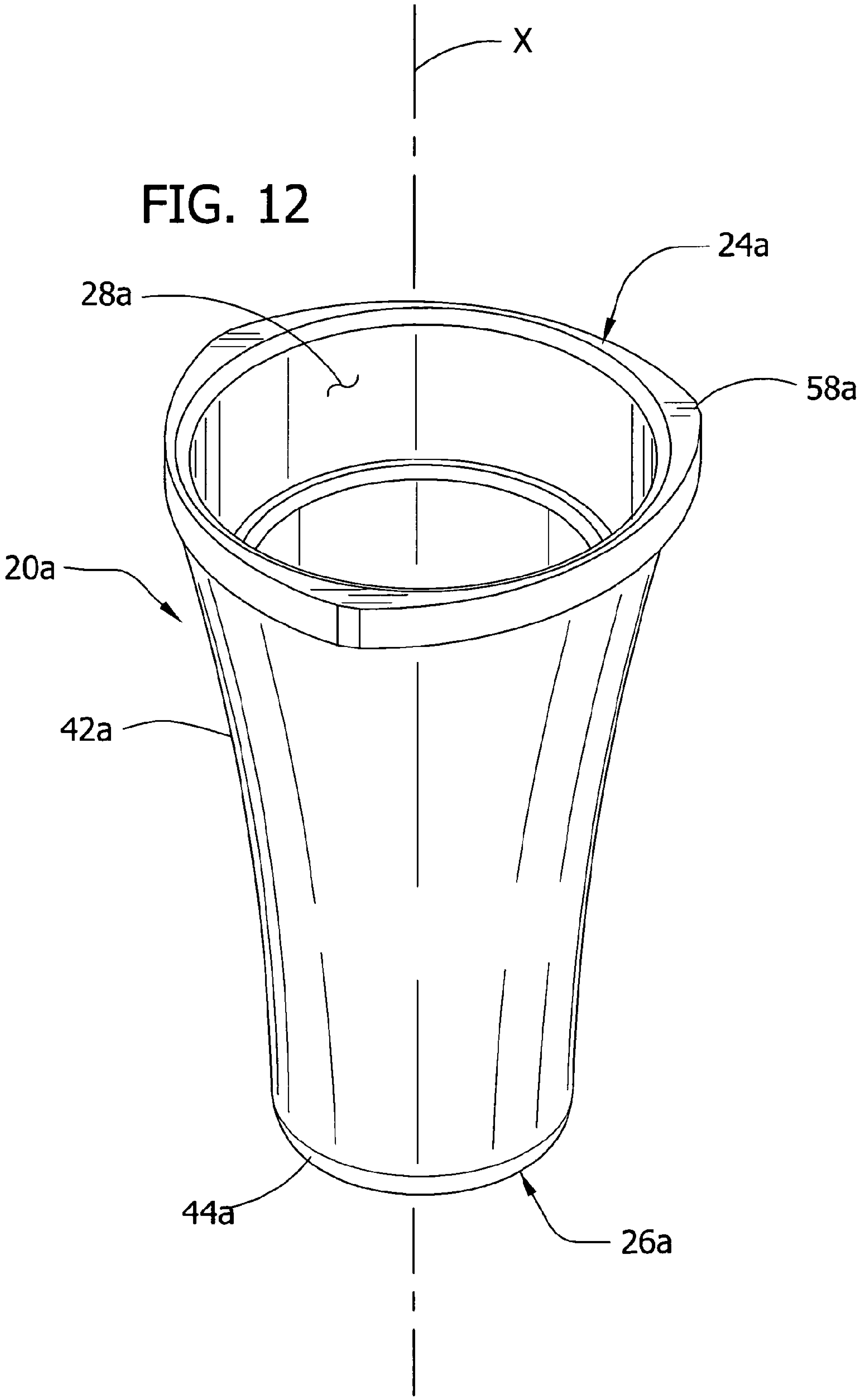

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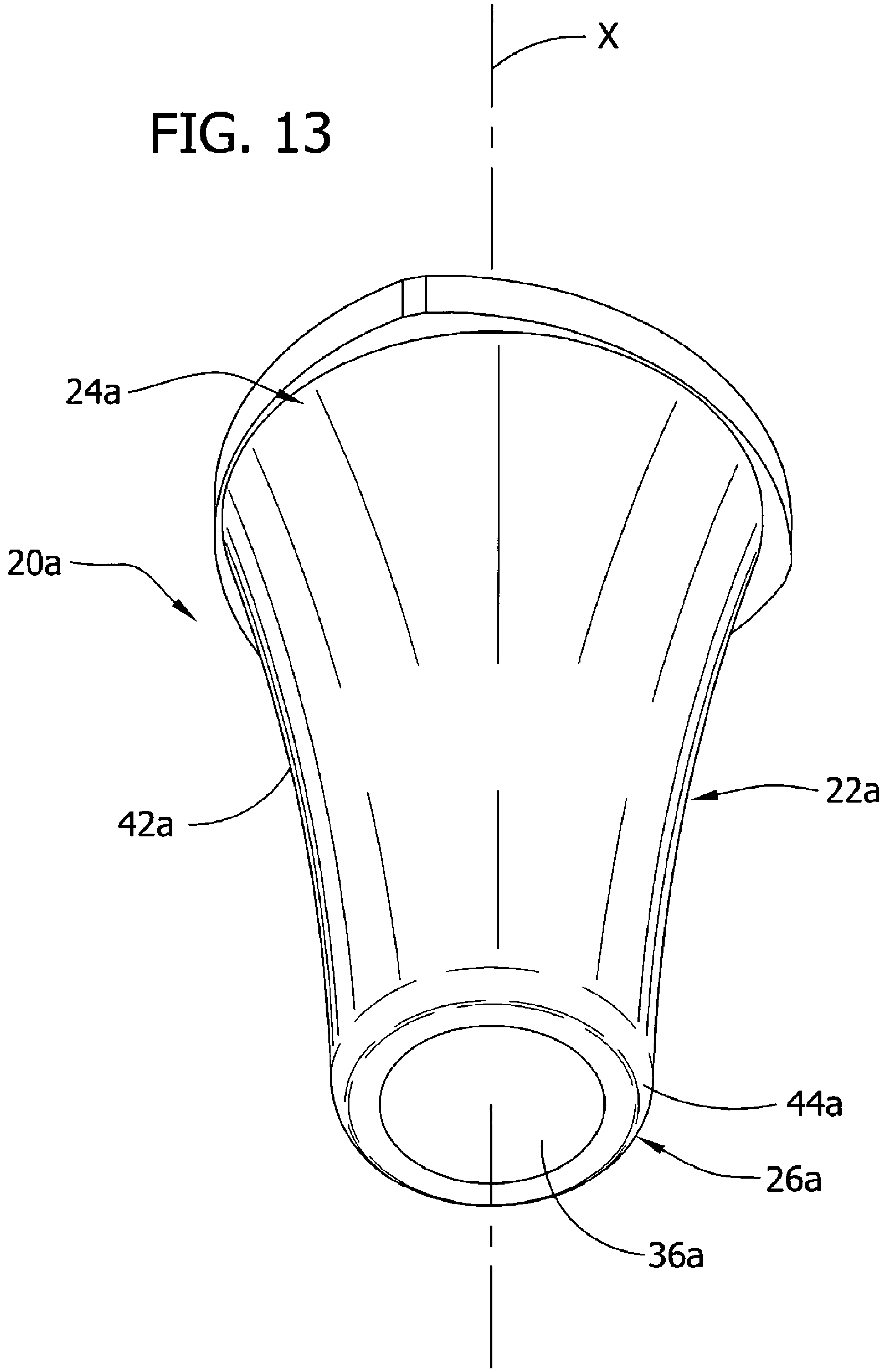

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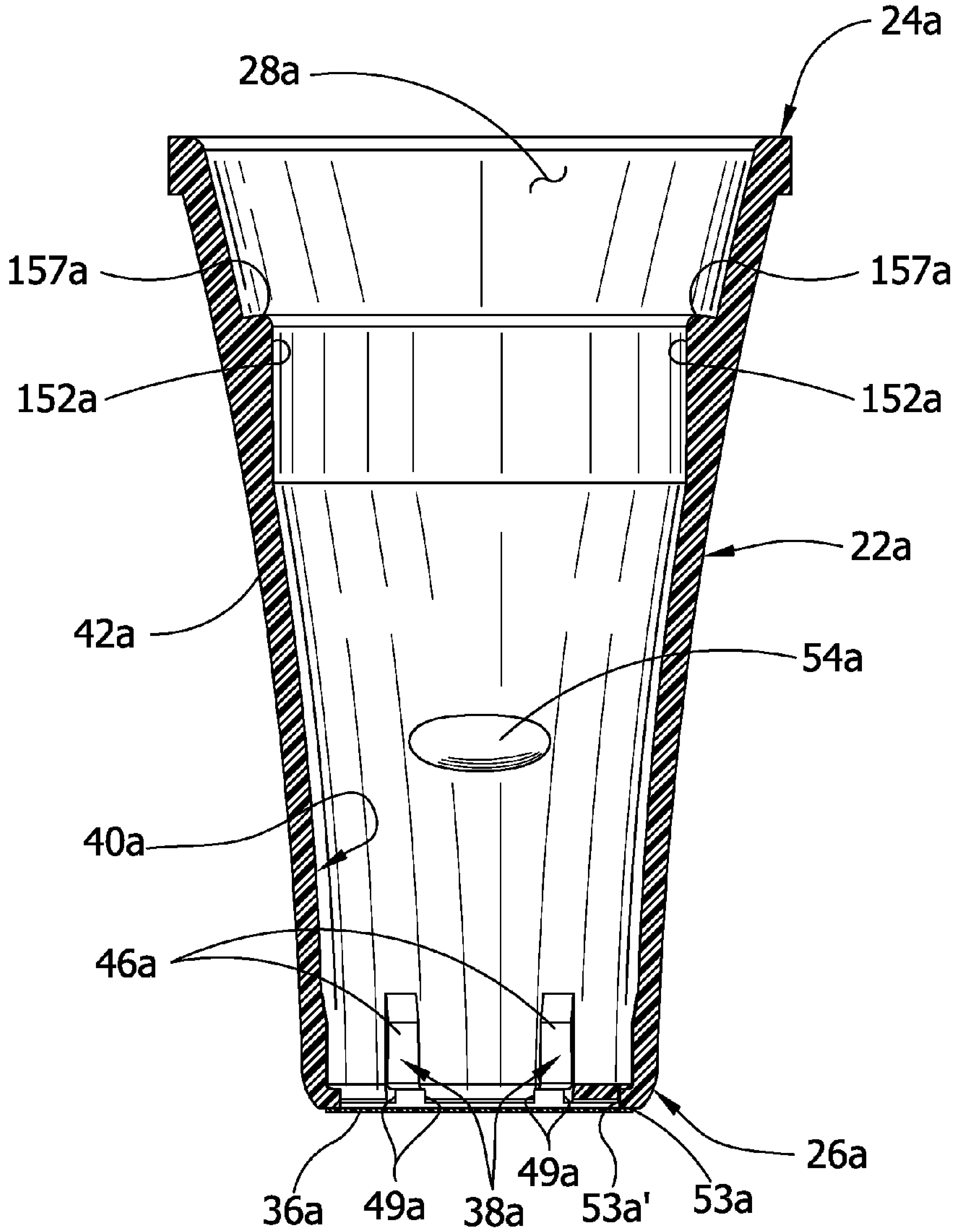

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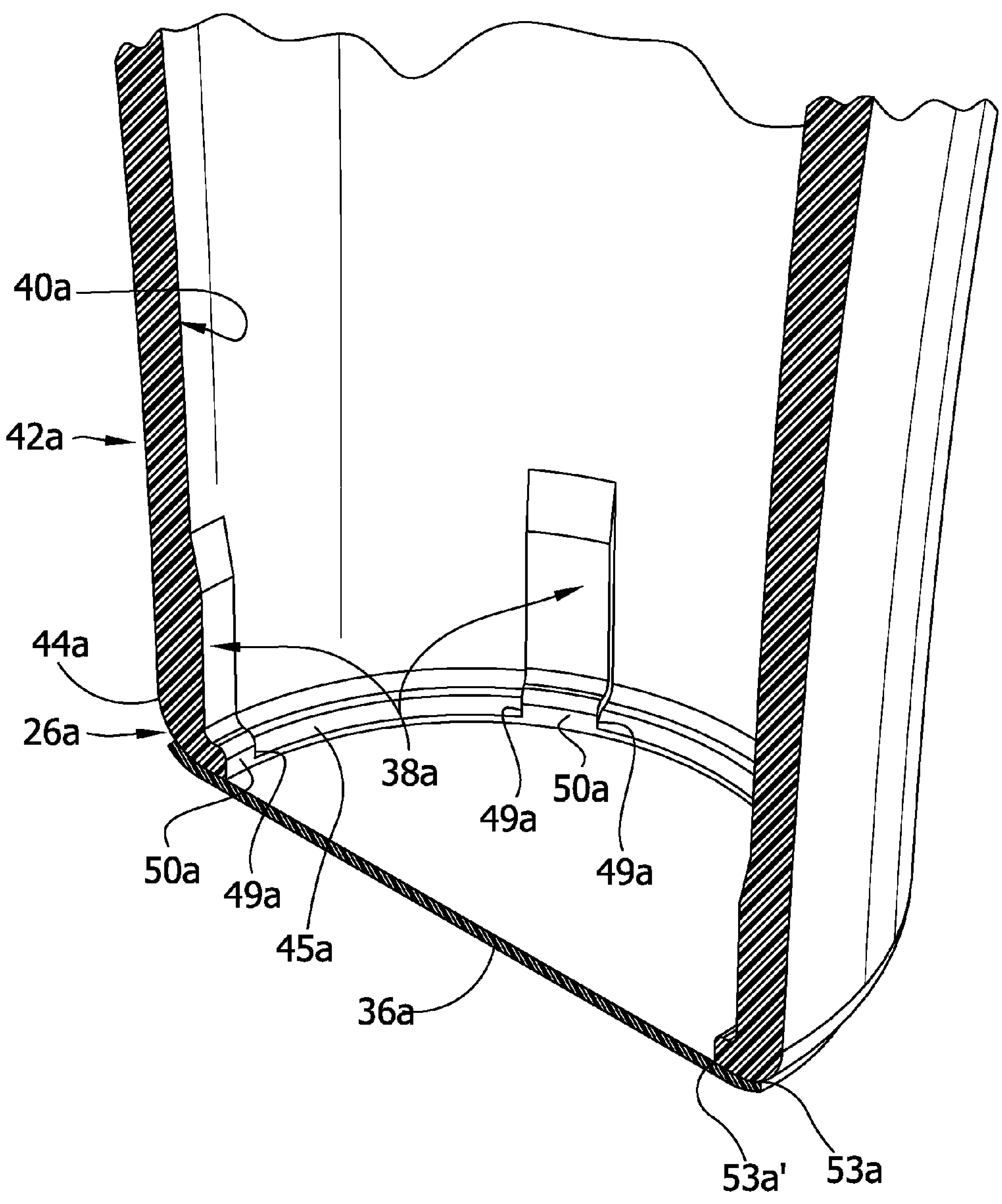
FIG. 15



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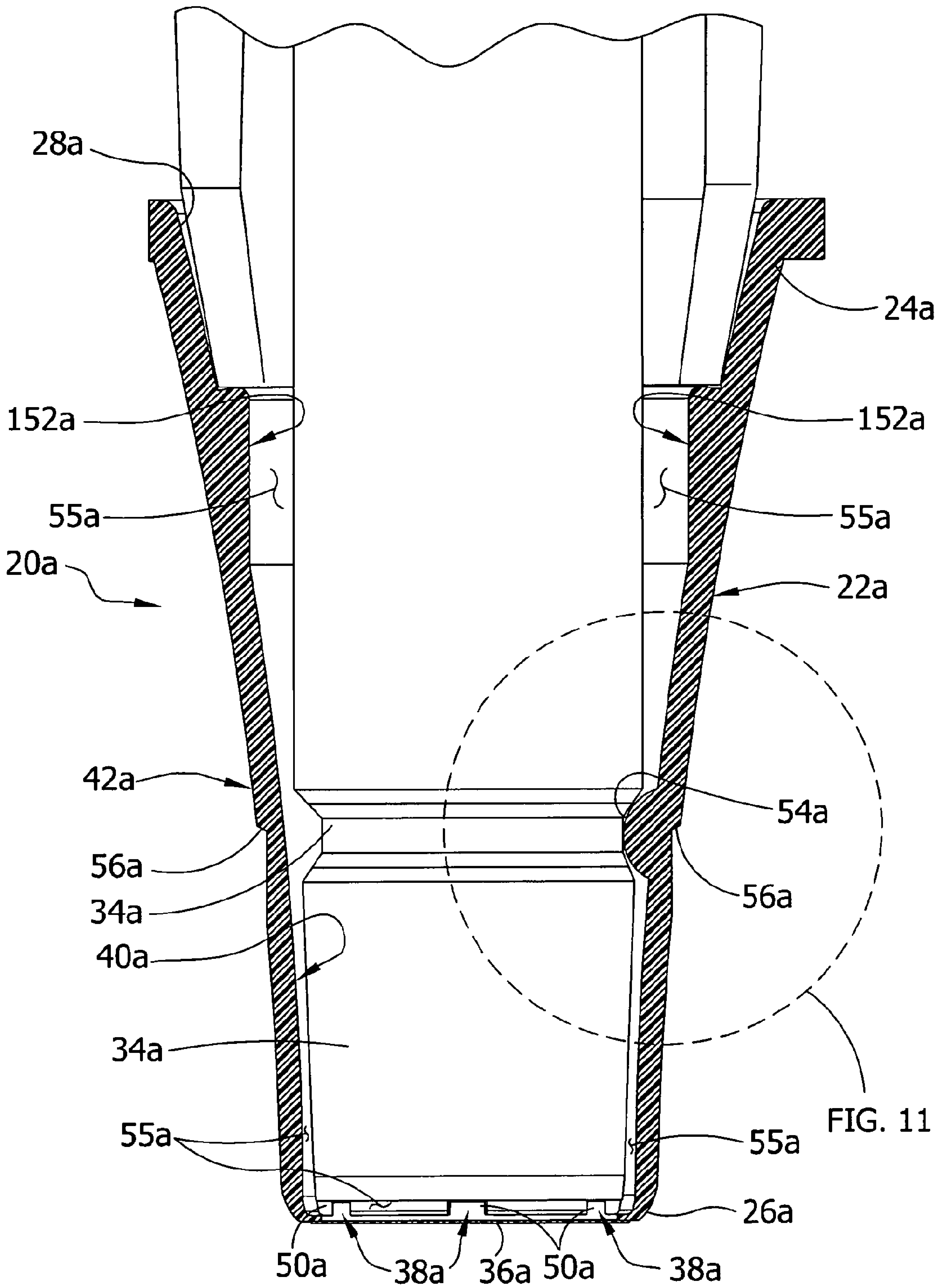
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FIG. 11

FIG. 16A

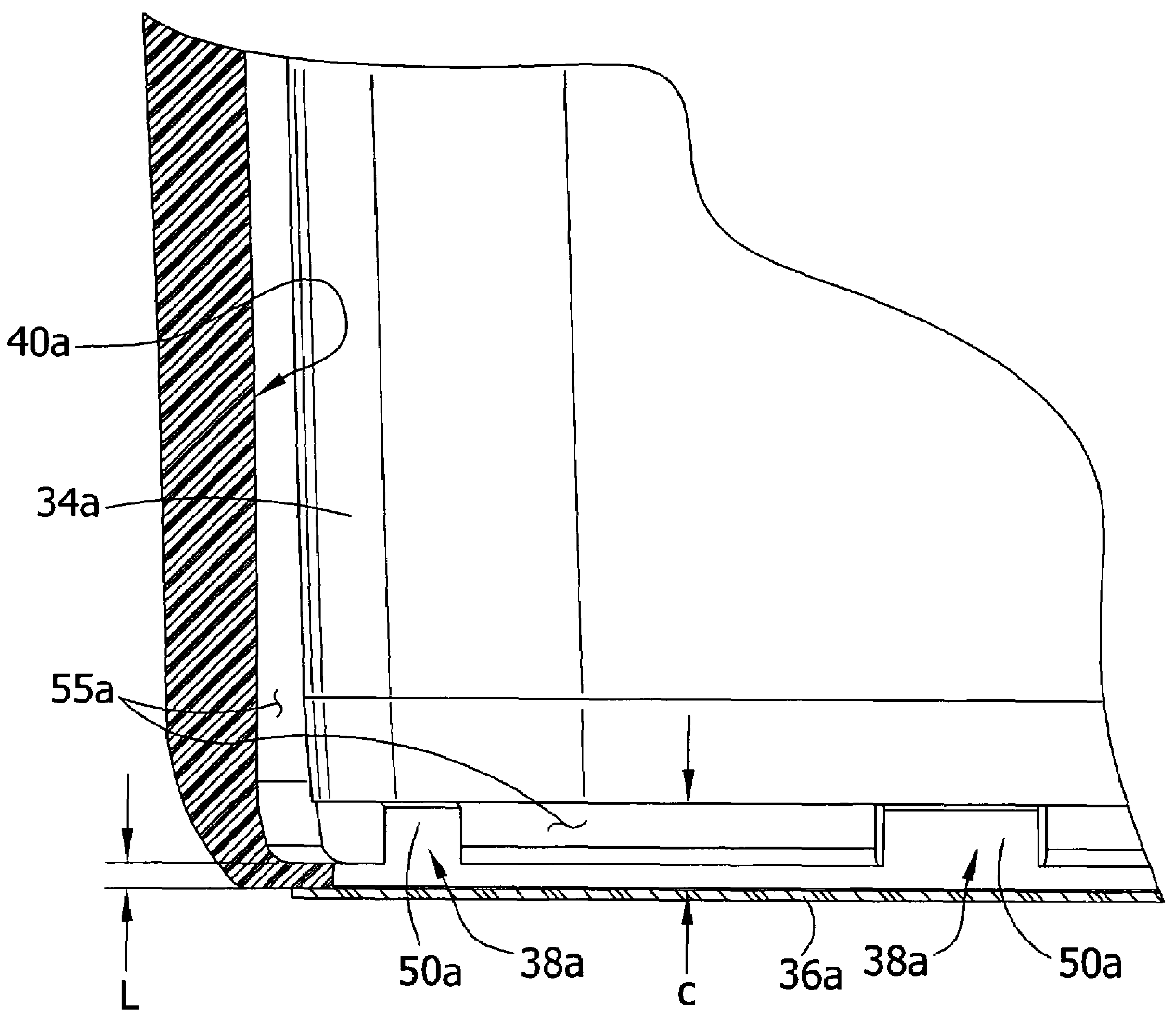


FIG. 17

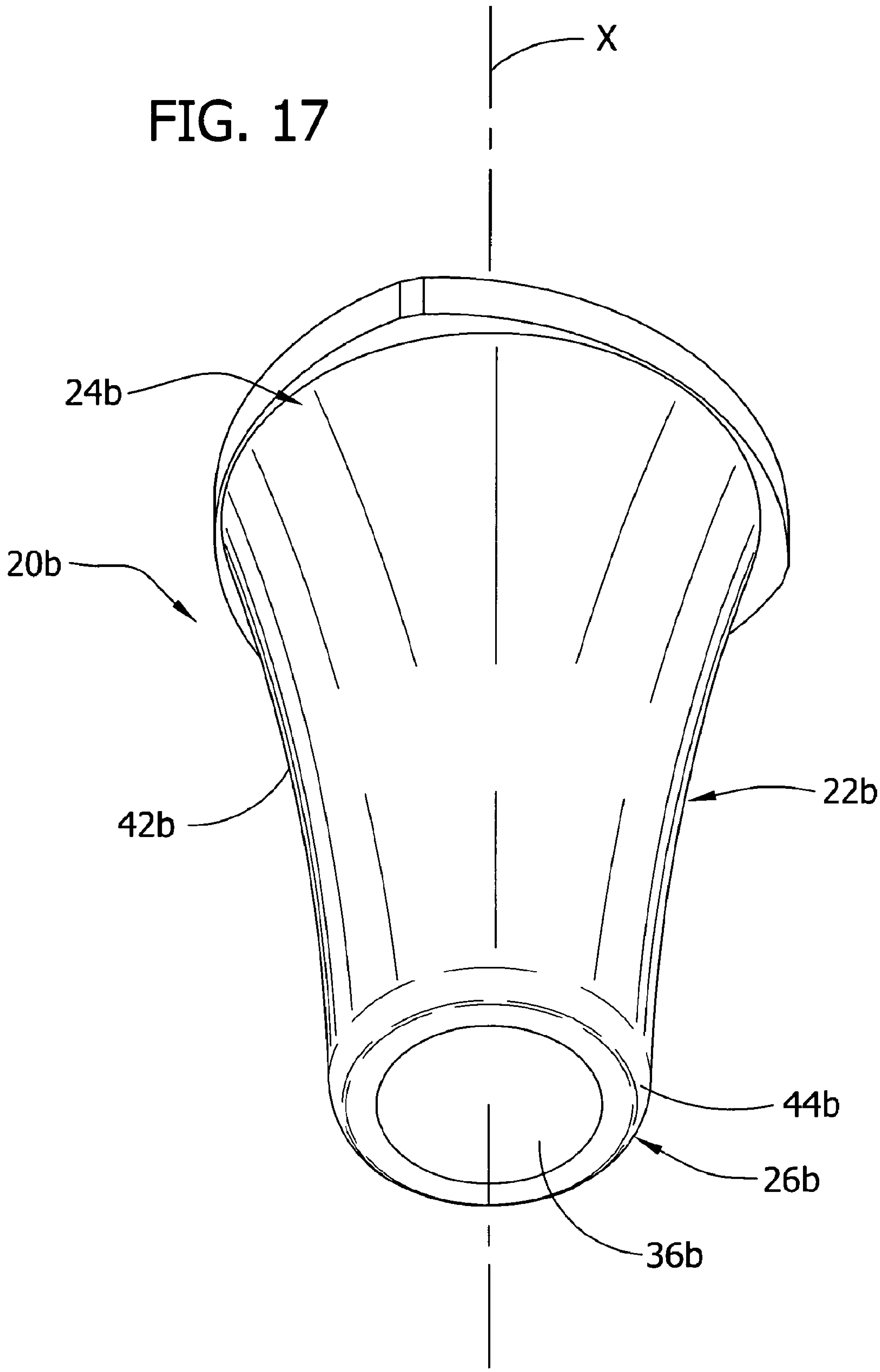


FIG. 18

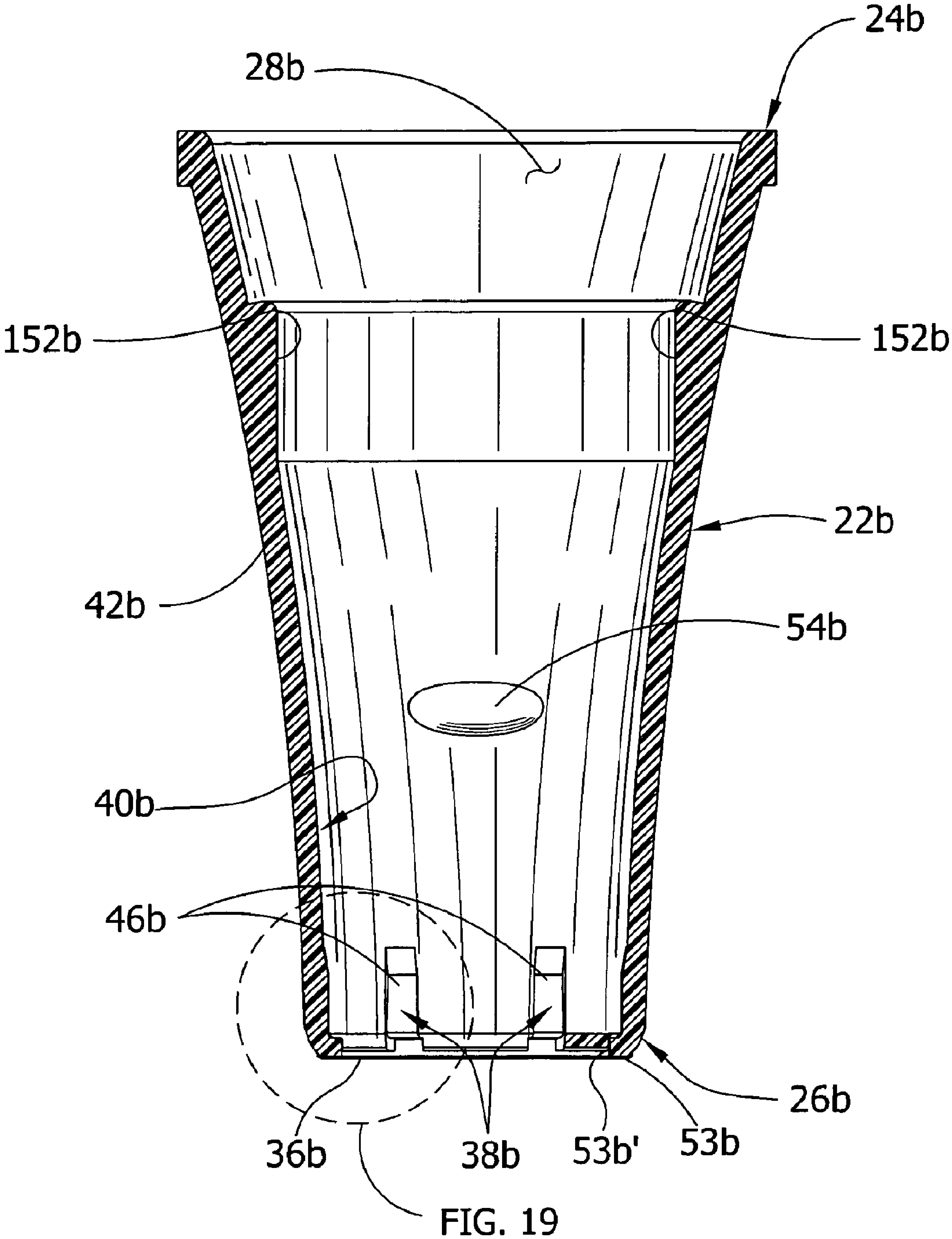


FIG. 19

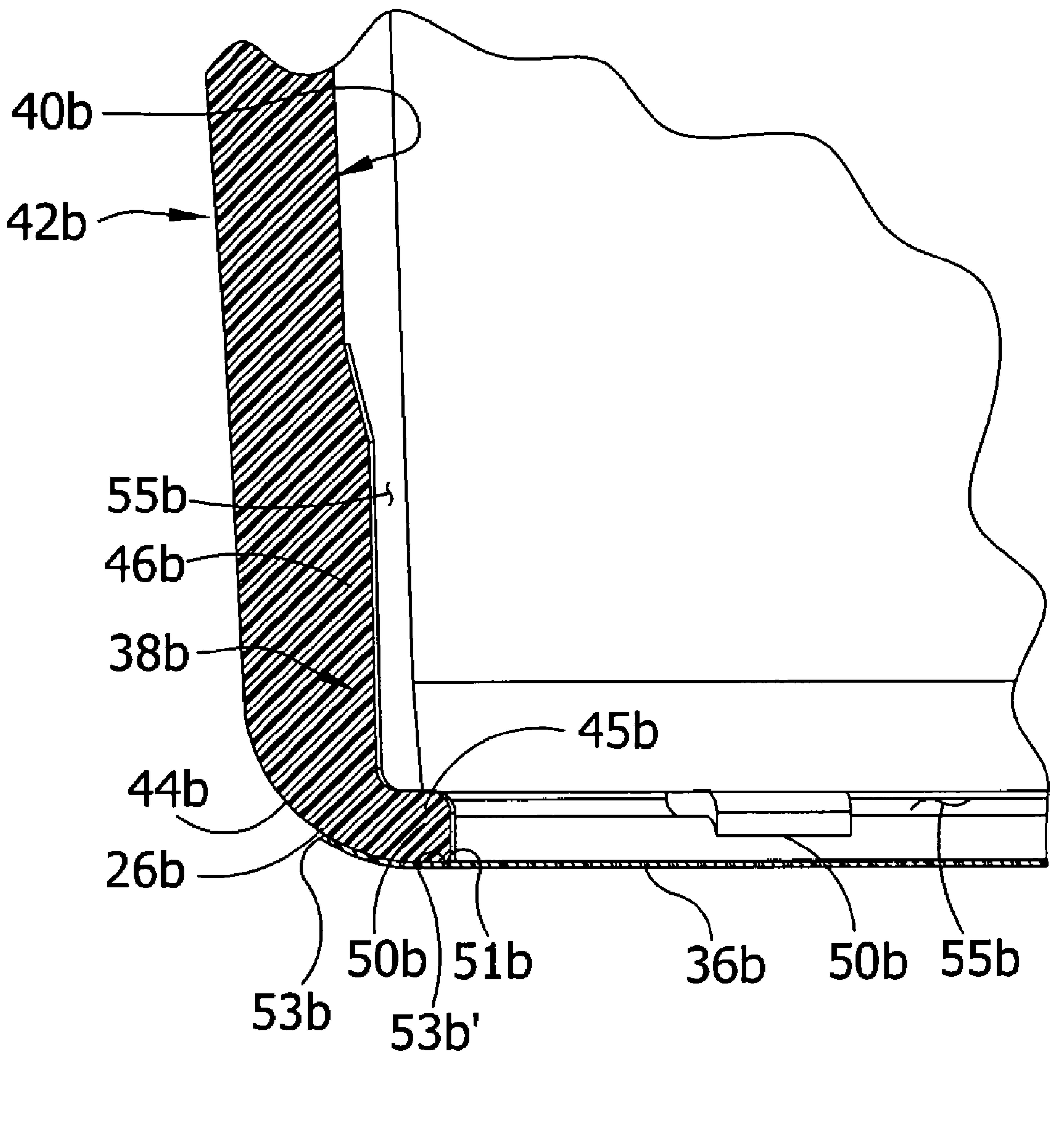


FIG. 20

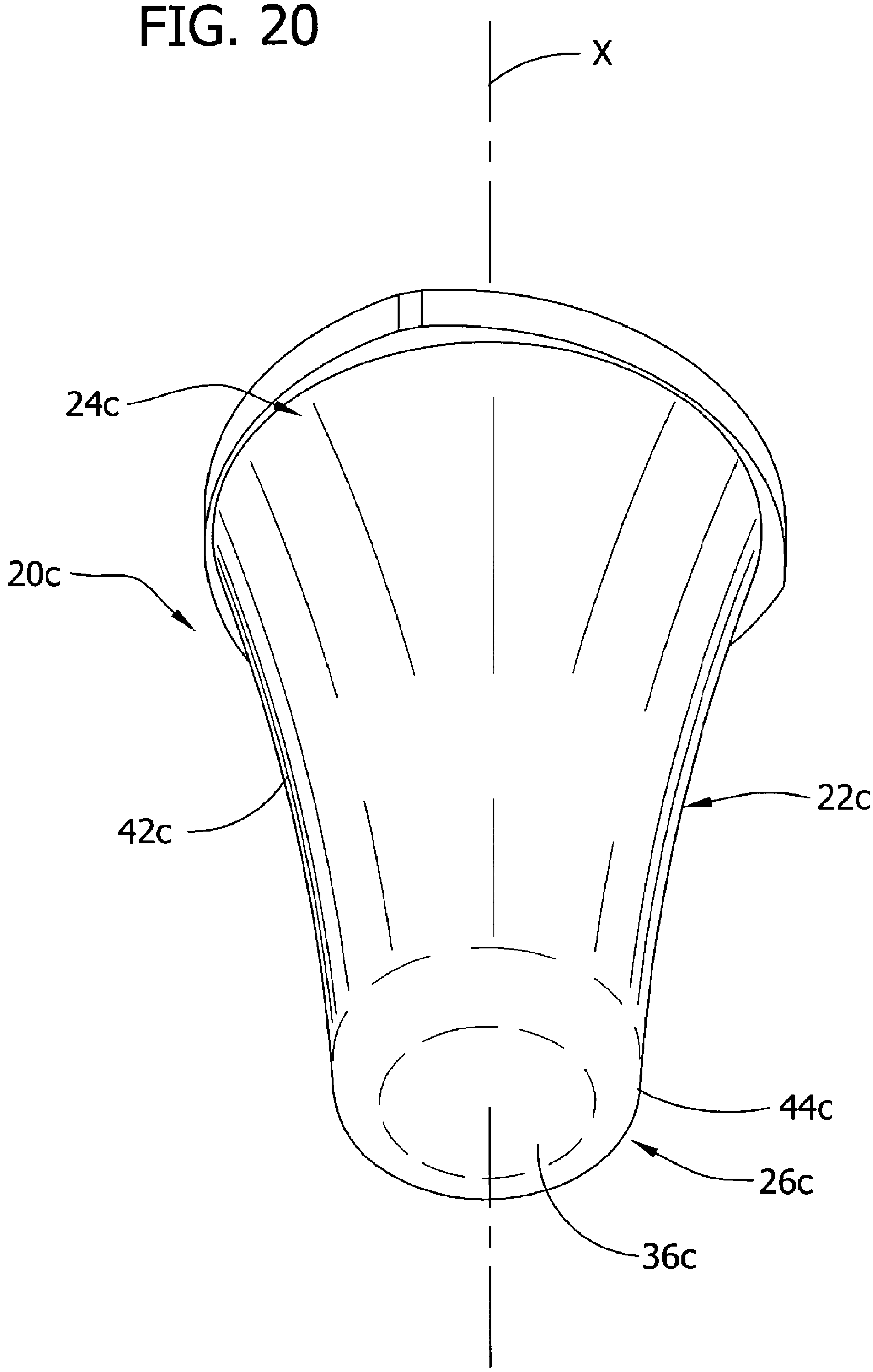
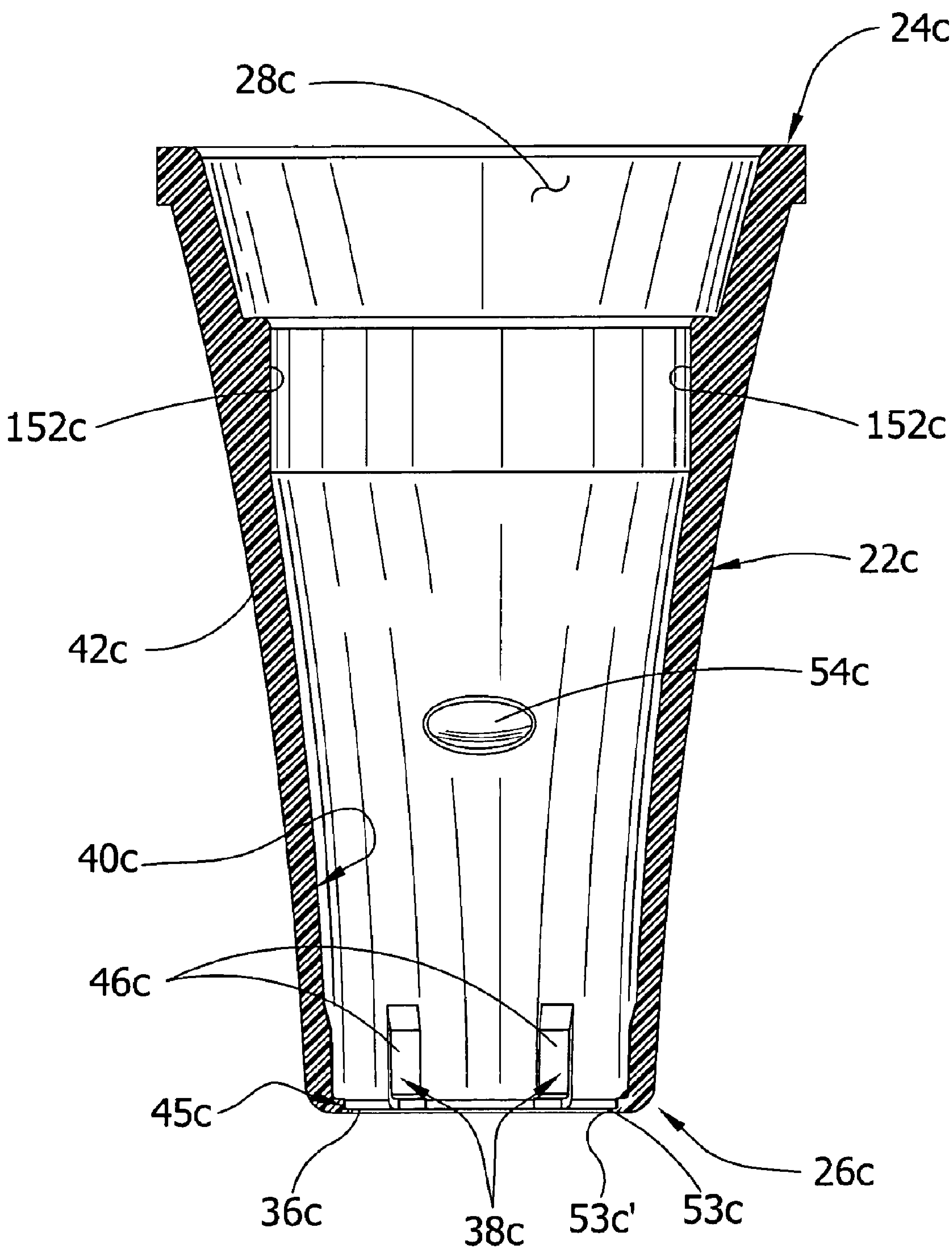
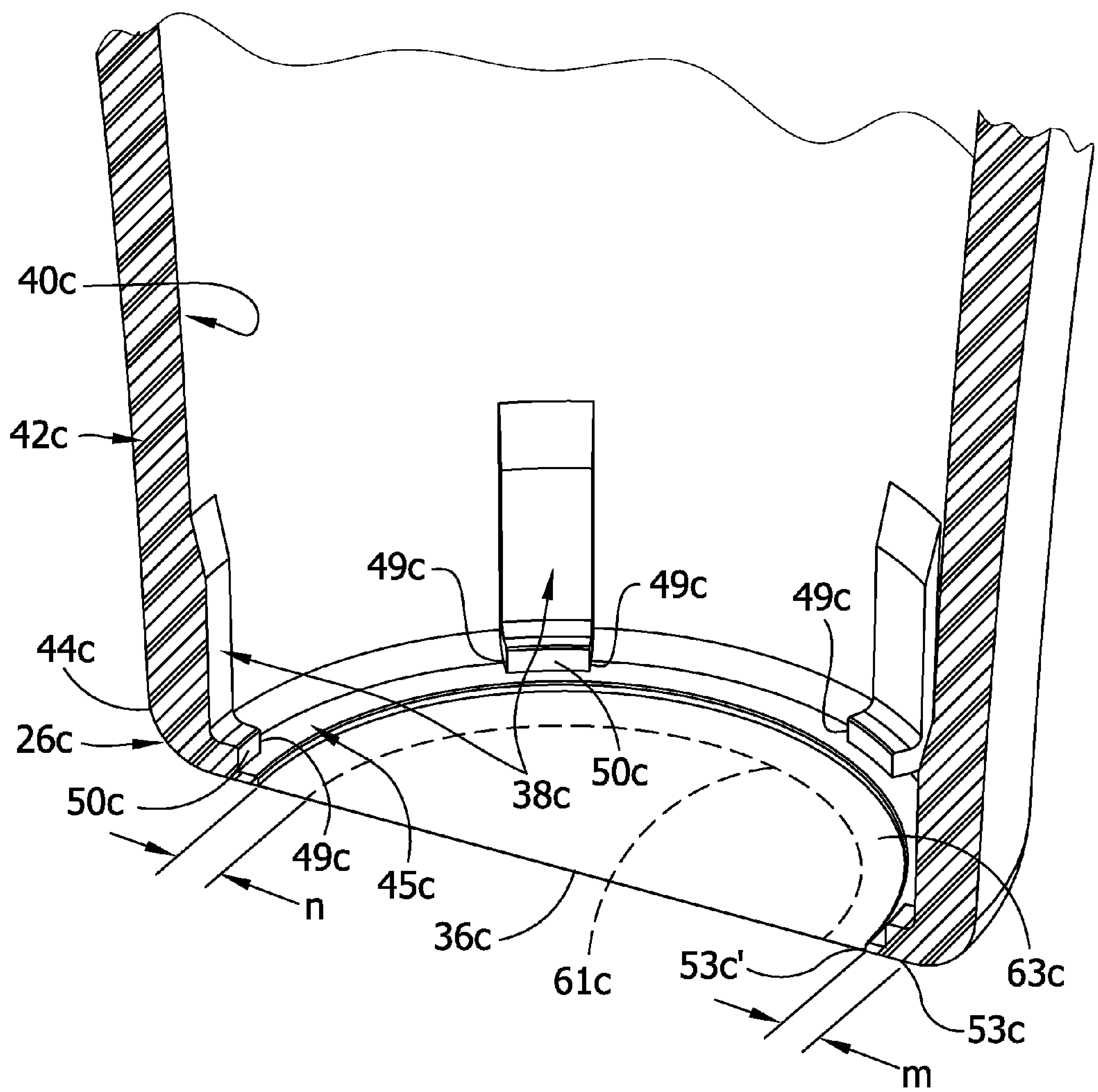


FIG. 21



AMENDED

FIG. 22



TYMPANIC THERMOMETER PROBE COVER WITH FILM SUPPORT MECHANISM

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

FIELD OF THE INVENTION

The present disclosure generally relates to the field of biomedical thermometers, and more particularly, to a probe cover for a tympanic thermometer.

BACKGROUND OF THE INVENTION

Medical thermometers are typically employed to facilitate the prevention, diagnosis and treatment of diseases, body ailments, etc. for humans and other animals, as is known. Doctors, nurses, parents, care providers, etc. use thermometers to measure a subject's body temperature for detecting a fever, monitoring the subject's body temperature, etc. An accurate reading of a subject's body temperature is needed for effective use and should be taken from the internal or core temperature of a subject's body. Several thermometer devices are known for measuring a subject's body temperature, such as, for example, glass, electronic, ear (tympanic).

Glass thermometers, however, are very slow in making measurements, typically taking several minutes to determine body temperature. This can result in discomfort to the subject, and may be very troublesome when taking the temperature of a small child or an invalid. Further, glass thermometers are susceptible to error and are typically accurate only to within a degree.

Electronic thermometers have shorter measurement times and improve accuracy over glass thermometers. Electronic thermometers, however, still typically take about thirty (30) seconds to get an accurate reading. They can also cause discomfort as the thermometer device must be inserted into the subject's mouth, rectum or axilla.

Tympanic thermometers are generally considered by the medical community to be superior for taking a subject's temperature. Tympanic thermometers provide rapid and accurate readings of core temperature, overcoming the disadvantages associated with other types of thermometers. Tympanic thermometers measure temperature by sensing infrared emissions from the tympanic membrane (eardrum) in the external ear canal. The temperature of the tympanic membrane accurately represents the body's core temperature. Further, it only takes a few seconds to measure a subject's temperature in this manner.

In operation, a tympanic thermometer is prepared for use and a probe cover is mounted onto a sensing probe extending from a distal portion of the thermometer. The probe cover provides a sanitary barrier between the subject and the thermometer. A practitioner or other care provider inserts a portion of the probe having the probe cover mounted thereon into a subject's outer ear canal to sense the infrared emissions from the tympanic membrane. The infrared light emitted from the tympanic membrane passes through a window of the probe cover and is directed to the sensing probe by a waveguide. The essential feature of the window is that it is substantially transparent to infrared radiation, thereby allowing infrared radiation from the tympanic membrane to pass through the probe cover to the heat sensing probe of the thermometer. Although an open window would be suitable for taking a temperature measurement, a film (e.g., a plastic film) having a thickness on the order of the wavelength of radiation in the far infrared range typically spans the window to provide a sanitary barrier.

The practitioner presses a button or similar device to cause the thermometer to take a temperature measurement. The microelectronics process electrical signals from the heat sensor to determine eardrum temperature and render a temperature measurement in a few seconds or less. The probe is removed from the ear canal and the probe cover discarded. A new probe cover is used each time the thermometer is used with a new subject.

Known tympanic thermometers typically include a probe containing a heat sensor such as a thermopile, a pyroelectric heat sensor, etc. See, for example, U.S. Pat. Nos. 6,179,785, 6,186,959, and 5,820,264. These types of heat sensors are particularly sensitive to the eardrum's radiant heat energy. The accuracy with which the sensing probe senses the infrared radiation emitted by the eardrum directly corresponds with the overall accuracy, repeatability and usability of the tympanic thermometer. The sensing probe must be sensitive to the low level of infrared energy emitted by an eardrum while providing a high degree of accuracy, repeatability and thermal noise immunity.

Current tympanic thermometers employ probe covers that may adversely affect accuracy of a temperature reading. The probe cover window of the probe cover typically contacts the probe. Consequently, the distal end of the probe can become disadvantageously heated by conductive heat transfer from the window, which is heated by its proximity to the subject. This may cause the sensing probe to detect radiation emitted from the heated distal end of the probe or other undesirable sources causing thermal noise that can lead to inaccurate temperature measurement. Further, current probe cover designs suffer from other drawbacks, such as poor retention characteristics with the probe and subject discomfort when inserted in the ear canal. In addition, the window through which the infrared radiation passes may be distorted during the measurement process. Such distortions may be caused by manufacturing inconsistencies and/or by deformation of the probe cover upon insertion of the probe into the cover or by insertion of the probe into the ear canal.

Therefore, it would be desirable to overcome the disadvantages and drawbacks of the prior art with a probe cover for a tympanic thermometer that improves accuracy and reliability of temperature measurements, for example by reducing conductive heat transfer to the probe and/or reducing error from distortions in the film barrier covering the window. It would also be desirable for such a probe cover to be comfortable for the subject. Further, it would be highly desirable if the probe cover was designed to facilitate stacking (e.g., nesting) of multiple probe covers for convenience in storage.

SUMMARY OF THE INVENTION

One embodiment of a probe cover of the present invention for a probe of a tympanic thermometer has a generally tubular body. The body has an opening at a proximal end for receiving a thermometer probe and a window at a distal end of the body. A film support extends radially inward from the distal end of the body toward a longitudinal axis of the body. The film support has an inner edge extending circumferentially around the longitudinal axis and defining a perimeter of the window. A film is at least partially supported by the film support and spans the window. A plurality of end ribs are spaced apart and disposed about an inner circumference of the distal end of the body. Each of the end ribs is positioned to engage a distal end of the thermometer probe and prevent contact of the film by the thermometer probe. At least some of the end ribs converge with the film support. The probe cover is substantially transparent to infrared radiation through the window. The perimeter of the window is substantially free from corners in a plane of the window.

Another embodiment of a probe cover has a generally tubular body. The body has an opening at a proximal end of the body for receiving a thermometer probe and a window at a distal end of the body. The body defines a circumferential inner surface extending generally from the proximal end to the distal end of the body. A film support extends radially inward from the distal end of the body toward a longitudinal axis thereof. The film support has an inner edge extending circumferentially around the longitudinal axis and defining a perimeter of the window. A film is at least partially supported by the film support and spans the window. The probe cover is configured to maintain a gap between the film and a distal end of the thermometer probe received in the opening. The gap has extensions into areas between the circumferential inner surface of the body and a side of the thermometer probe. The probe cover is substantially transparent to infrared radiation through the window. The perimeter of the window is substantially free from corners in a plane of the window.

Still another embodiment of a probe cover has a generally tubular body. The body has an opening at a proximal end of the body for receiving the thermometer probe and a window at a distal end of the body generally opposite the proximal end. A film support extends radially inward from the distal end of the body toward a longitudinal axis thereof. The film support has an inner edge extending circumferentially around the longitudinal axis and defining a perimeter of the window. The film support defines a substantially flat distally facing surface at the distal end of the body. A film is attached to at least a portion of the flat distally facing surface of the film support and spans the window. The film is substantially transparent to electromagnetic radiation for passing electromagnetic radiation through the window.

Yet another embodiment of a probe cover of the present invention has a generally tubular body. The body has a window at a distal end of the body and an opening at a proximal end of the body for receiving the thermometer probe having an electromagnetic radiation sensor with a general conical field of vision passing through the window when the probe is received in the tubular body. A film support extends radially inward from the distal end of the body toward a longitudinal axis thereof. The film support has an inner edge extending circumferentially around the longitudinal axis and defining a perimeter of the window. A film is supported at least in part by the film support and spans the window. The film is substantially transparent to electromagnetic radiation for passing electromagnetic radiation through the window. The film support is sized and shaped so that when the probe is received in the tubular body, the inner edge of the film support defining the window perimeter lies closely proximate to the field of vision of the electromagnetic radiation sensor.

Other objects and features will be in part apparent and in part pointed out hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. **1** and **2** are perspective views of one embodiment of a probe cover of the present invention from different vantage points;

FIG. **3** is a perspective view of the probe cover mounted on a tympanic thermometer;

FIG. **4** is a cross-section of the probe cover in a plane through each of a pair of opposing end ribs of the probe cover;

FIG. **5** is an enlarged view of a portion of the cross-sectioned probe cover shown in FIG. **4**;

FIG. **6** is an enlarged perspective view of a portion of the cross sectioned probe cover shown in FIG. **4** including the distal end thereof;

FIG. **7** is cross-section of the probe cover in a plane extending through a protuberance on the inside of the probe cover and a pair of indentations on opposite sides of the outside of the probe cover;

FIG. **8** is an enlarged view of a portion of the cross-sectioned probe cover showing the bisected protuberance in the area of detail indicated in FIG. **7**;

FIG. **9** is an enlarged view of a portion of the cross-section probe cover including one of the indentations in the area of detail indicated in FIG. **7**;

FIG. **10** is a cross-section of the probe cover as mounted onto a tympanic thermometer;

FIG. **10**A is an enlarged partial view of a distal end of the cross-sectioned probe cover and thermometer shown in FIG. **10**;

FIG. **11** is an enlarged view of a portion of the cross-sectioned probe cover showing the area of detail indicated in FIG. **10**;

FIGS. **12** and **13** are perspective views of another embodiment of a probe cover of the present invention from two different vantage points;

FIG. **14** is a cross-section of the probe cover shown in FIGS. **12** and **13** in a plane through a pair of opposing end ribs;

FIG. **15** is an enlarged perspective view of the cross-sectioned probe cover shown in FIGS. **12**-**14** showing a distal end thereof;

FIG. **16** is a cross-section of the probe cover shown in FIGS. **12**-**15** mounted on a thermometer probe;

FIG. **16**A is an enlarged partial view of a distal end of the cross-sectioned probe cover and thermometer shown in FIG. **16**;

FIG. **17** is a perspective view of another embodiment of a probe cover of the present invention;

FIG. **18** is a cross-section of the probe cover shown in FIG. **17** in a plane through each of a pair of opposing end ribs;

FIG. **19** is an enlarged view of a portion of the cross-sectioned probe cover shown in FIG. **18** with a thermometer probe received therein showing one of the end ribs and a portion of a film support in the area of detail indicated in FIG. **18**;

FIG. **20** is a perspective view of still another embodiment of a probe cover of the present invention;

FIG. **21** is a cross-section of the probe cover shown in FIG. **20** in a plane through each of a pair of opposing end ribs; and

FIG. **22** in an enlarged perspective view of a portion of the cross-sectioned probe cover shown in FIG. **21** showing a distal end thereof.

Corresponding reference characters indicate corresponding parts throughout the drawings.

DETAILED DESCRIPTION

The exemplary embodiments of the probe cover and methods of use disclosed are discussed in terms of medical thermometers for measuring body temperature, and more particularly, in terms of a probe cover used with a tympanic thermometer that reduces unwanted heat transfer from the probe cover to a probe of the tympanic thermometer. Some embodiments of the invention may limit heat transfer from the probe cover to the probe of a tympanic thermometer; alleviate problems associated with distortion of a film membrane used to provide a sanitary barrier; enhance comfort to a subject during body temperature measurement; guard against spread of bacteria and disease; and/or facilitate health care practices aimed at prevention, diagnosis and/or treatment of diseases, body ailments, and the like. Some embodiments of the invention facilitate reliable and repeatable manufacturing of probe covers, particularly as related to the joining of an infrared transparent film to the end of the probe cover.

In the discussion that follows, the term "proximal" will refer to the portion of a structure that is closer to a practitioner in normal use, while the term "distal" will refer to the portion that is further from the practitioner in normal use. As used herein, the term "subject" refers to a human patient or other animal having its body temperature measured. The term "practitioner" refers to a doctor, nurse, parent or other care provider using a tympanic thermometer to measure a subject's body temperature, and may include support personnel.

The component portions of the probe cover, which is disposable, are fabricated from materials suitable for measuring body temperature via the tympanic membrane with a tympanic thermometer measuring apparatus. These materials may include, for example, plastic materials, such as, for example, polypropylene, polyethylene, etc. The materials used can vary depending on the particular temperature measurement application and/or preference of a practitioner. For example, a body of the probe cover can be fabricated from high density polyethylene (HDPE).

The probe cover has a window portion or film that can be fabricated from a material substantially transparent to infrared radiation and impervious to moisture, ear wax, bacteria, etc. The film, for example, may be fabricated from low density polyethylene (LDPE) and may have a thickness in the range of 0.0005 to 0.001 inches, although other ranges are contemplated. The film may be semi-rigid or flexible, and can be monolithically formed with the remaining portion of the probe cover or integrally connected thereto via, for example, thermal welding, stamping, etc. One skilled in the art, however, will realize that other materials and fabrication methods suitable for assembly and manufacture of probe covers would be appropriate and do not deviate from the scope of the invention.

Some embodiments of the invention, which are illustrated in the accompanying figures, will now be described in greater detail. Referring first to FIGS. **1**-**11**, there is illustrated one embodiment of a probe cover of the present invention, generally designated **20**. The probe cover **20** defines a longitudinal axis X and has a generally tubular body **22**, which extends in a tapered configuration from a proximal end **24** to a distal end **26**. This design enhances comfort to a subject (not shown) during a temperature measurement procedure. The probe cover may be generally cylindrical, frustoconical or otherwise tapered or curved for insertion within the ear of the subject without departing from the scope of the invention. The proximal end **24** defines an opening **28** configured for receipt of a heat sensing probe **34** at a distal end of a tympanic thermometer **32**, as shown in FIGS. **3** and **10**. The heat sensing probe **34** is configured to detect infrared energy emitted by the tympanic membrane of the subject. The tympanic thermometer **32** may include a waveguide to facilitate sensing of the tympanic membrane heat energy.

A film **36** spans a window at the distal end **26** of the body **22**. The film **36** is substantially transparent to infrared radiation and configured to facilitate sensing of infrared emissions by the heat sensing probe **34**. For instance, the film **36** can be substantially perpendicular to the longitudinal axis X of the body **22** to allow for passage of infrared radiation through the probe cover **20** generally in the direction of the longitudinal axis to the heat sensing probe **34**. The film **36** is preferably impervious to ear wax, moisture and bacteria, which may help prevent spread of disease.

As shown in FIGS. **4**-**7**, the distal end **26** includes one or more end ribs **38** (e.g., a plurality of end ribs as shown in the drawings) disposed about an inner circumferential surface **40** of tubular body **22**. The end ribs **38** have a longitudinal portion **46** extending proximally along the inner circumferential surface **40** of the tubular body **22**. The longitudinal portion **46** projects a thickness a (FIG. **5**) and extends a length b along inner surface **40**. The end ribs **38** also have a transverse portion **50** projecting along a transverse surface **51** (i.e., generally perpendicular to longitudinal axis X) of film **36**. The dimensions a, b, c and d are selected to facilitate support and engagement of the end ribs **38** with heat sensing probe **34** and to limit conductive heat transfer from the probe cover to the probe as described herein.

For example, in one embodiment of the invention, the dimension a is between about 0.002 inches and about 0.005 inches (e.g., about 0.003 inches); the dimension b is between about 0.035 inches and about 0.100 inches (e.g., about 0.083 inches); the dimension c is between about 0.010 and about 0.030 inches (e.g., about 0.017 inches); and the dimension d is between about 0.007 inches and about 0.020 inches (e.g., about 0.013 inches). Those skilled in the art will understand that the foregoing dimensions are exemplary and that the dimensions can vary substantially, particularly in view of the fact that probe covers are often designed for use with a particular tympanic thermometer and there is substantial variation in the size and shape of tympanic thermometers. The dimensions of a probe cover designed for use with the same tympanic thermometer can also vary significantly without departing from the scope of the invention. Those skilled in the art will also find guidance for the dimensioning probe covers in the description herein.

The transverse portions **50** of the end ribs **38** engage heat sensing probe **34** as the probe cover is placed thereon to prevent contact of the film **36** by the heat sensing probe **34**. In this regard, the transverse portions **50** of the end ribs **38** are spacers that keep the heat sensing probe **34** spaced apart from film **36**. Dimension c (FIG. **5**) of the transverse portions **50** provides the depth necessary to maintain an air/fluid gap or cavity **55** (FIGS. **10** and **10**A) between the heat sensing probe **34** and the film **36**. In one embodiment, the dimension c is selected so the air gap **55** is between about 0.005 inches and about 0.025 inches thick (e.g., about 0.017 inches thick) at the distal end of the thermometer probe **34**. Similarly, the longitudinal portions **46** of the end ribs **38** engage the heat sensing probe **34** to prevent contact of the inner circumferential surface **40** of the body **22** by the heat sensing probe. Thus, the insulating air gap **55** between the distal end of the heat sensing probe **34** and the probe cover extends proximally along the side of the heat sensing probe between probe and the end ribs **38**. Limiting contact between the distal end of the heat sensing probe **34** and the probe cover **20** in this manner reduces opportunity for unwanted heat transfer between the probe cover and the heat sensing probe, allowing more accurate temperature measurements to be taken.

The probe cover **20** is sized to result in an interference fit with the heat sensing probe **34**. In particular, when the longitudinal portions **46** of the end ribs **38** engage the heat sensing probe **34** as the probe cover is being placed thereon, the heat sensing probe slightly deforms the end ribs **38**, forcing them to spread apart from one another slightly at the distal end of the body **22**. The spreading of the end ribs **38** at the distal end of the body is transmitted to the film **36**, thereby stretching the film and causing it to become radially taught. This stretching reduces distortion (e.g., wrinkling) of the film **36** and allows for improved accuracy of temperature measurement.

The tubular body **22** has an outer circumferential surface **42**, which includes an arcuate surface **44** adjacent the distal end **26**. The arcuate surface **44** curves inward toward the longitudinal axis X, thereby enhancing comfort and facilitating insertion of probe cover **20** into a subject's ear canal. The degree of inward curvature of the arcuate surface **44** may be varied to suit the needs of a particular application or to suit a particular preference. Moreover, a chamfered or tapered shape could be used rather than an arcuate surface without departing from the scope of the invention.

As shown in FIGS. **4** and **7**, the body **22** defines one or more longitudinal ribs **52** (e.g., a plurality of longitudinal ribs as shown in the drawings) projecting from the inner circumferential surface **40** and being proximally spaced from the distal end **26** of the body and the end ribs **38**. The longitudinal ribs **52** project a thickness e (FIG. **7**) from the inner circumferential surface **40** and extend a length f along the inner circumferential surface **40**. For example, the dimension e may be between about 0.015 inches and about 0.040 inches and the dimension f may be between about 0.10 inches and about 0.30 inches. The longitudinal ribs **52** each define a transverse face **57** that is configured to engage a shoulder on the heat sensing probe **34** when the probe cover **20** is placed thereon. The dimensions e and f are selected to configure the longitudinal ribs **52** and the transverse faces **57** thereof to facilitate releasable retention of probe cover **20** on the heat sensing probe **34**. The transverse faces **57** of the longitudinal ribs **52** can be used as thrust surfaces for a probe cover eject mechanism.

As shown in FIG. **7**, the body **22** defines one or more inner protuberances **54** (e.g., a plurality of inner protuberances as shown in the drawings) projecting from the inner circumferential surface **40** of the body **22** and being proximally spaced from the distal end **26** thereof. The inner protuberances **54** shown in the drawings are spaced at intervals and have an elliptical configuration having a width g (FIG. **4**) and a height h (FIG. **8**). The width g is larger than the height h. The inner protuberances **54** have a radial curvature projecting a thickness i (FIG. **8**) from the inner circumferential surface **40** for being received in an annular groove **34**a (FIG. **10**) formed in the probe **34**. When the probe cover **20** is mounted on the thermometer probe **34**, the protuberances **54** lie in the groove **34**a and hold the probe cover **20** against movement in the direction of the longitudinal axis X relative to the probe. Like the end ribs **38** and longitudinal ribs **52**, the inner protuberances **54** help maintain the air gap **55** of separation between heat sensing probe **34** and the tubular body **22**, thereby reducing undesired heating of heat sensing probe **34** from contact with the probe cover **20**. The dimensions g, h, and i can be adjusted as needed to suit the size and shape of the annular groove for any particular thermometer. The body **22** also defines one or more indentations **56** (FIG. **9**) in the outer circumferential surface **42** thereof, which are proximally spaced from the distal end **26** of the body.

The probe cover **20** includes a flange **58** disposed adjacent the proximal end **24** of the body (see, FIG. **1**). The flange **58** extends around the circumference of proximal end **24** of the body **22** providing strength and stability for mounting of the probe cover **20** on the tympanic thermometer **32**.

In use, the probe cover **20** is mounted on the heat sensing probe **34** (as shown in FIGS. **10** and **10**A) and the film **36** is separated from direct engagement with the heat sensing probe via the air gap **55** maintained by the engagement of the end ribs **38** with the heat sensing probe. Likewise the air gap **55** extends along the side of the heat sensing probe **34** in the spaces between the end ribs **38** and is maintained proximally therefrom by engagement of the inner protuberances **54** and the inner circumferential surface **40** proximal of the longitudinal ribs **52** with the side of the heat sensing probe. The limited contact between the probe cover **20** and heat sensing probe **34** and the air gap **55**, which serves as a layer of insulation, reduces undesired conductive heat transfer from the probe cover to the probe **34** and thereby reduces distorted readings and thermal noise interference. Consequently, the probe cover **20** facilitates a more accurate temperature measurement.

To measure a subject's (not shown) body temperature, a practitioner (not shown) pulls the subject's ear back gently to straighten the ear canal so that heat sensing probe **34** can receive infrared emissions directly from the tympanic membrane. The tympanic thermometer **32** is manipulated by the practitioner such that a portion of the probe cover **20**, which is mounted on the heat sensing probe **34**, is easily and comfortably inserted within the subject's outer ear canal. The heat sensing probe **34** is properly positioned to sense infrared emissions from the tympanic membrane that are indicative of the subject's body temperature. Infrared light emitted from the tympanic membrane passes through the film **36** to the heat sensing probe **34**.

The tympanic thermometer **32** is manufactured to be reused, but the probe cover **20** is disposable. Accordingly after one use, the probe cover **20** is discarded and another one of the probe covers may be mounted on the heat sensing probe **34**. Thus, the probe covers **20** provide a sanitary barrier for the heat sensing probe **34** to reduce spread of bacteria and disease. Other methods of use of the tympanic thermometer **32** and the probe cover **20** are envisioned, such as, for example, alternative positioning, orientation, etc. without departing from the scope of the invention.

Another embodiment of the probe cover, generally designated **20**a, is described with reference to FIGS. **12**-**16**. Yet another embodiment of the probe cover, generally designated **20**b, is described with reference to FIGS. **17**-**19**. Still another embodiment of the probe cover, generally designated **20**c, is described with reference to FIGS. **20**-**22**. Although the actual designs of probe covers **20**a, **20**b, and **20**c are different in some respects from the embodiment of the probe cover **20** described above, the materials and manufacturing processes used to make probe covers **20**a, **20**b, and **20**c may be substantially the same as those described for probe cover **20** except where noted. Further, probe covers **20**a, **20**b, and **20**c may operate in substantially the same manner as probe cover **20**, except as noted. Wherever possible, reference numbers used to describe elements of probe covers **20**a, **20**b, and **20**c are based on the reference numbers used to describe similar elements of probe cover **20** with the letters “a”, “b”, and “c”, respectively, appended thereto.

Referring to FIGS. **12**-**16** probe cover **20**a comprises a tubular body **22**a defining a longitudinal axis X and extending in a tapered configuration from a proximal end **24**a to a distal end **26**a. Proximal end **24**a defines an opening **28**a configured to receive a distal end **30** of a tympanic thermometer **32**, such as, for example, a heat sensing probe **34**. The particular tapered configuration shown in the drawings is believed to be comfortable for many subjects when inserted into the ear canal, but the tubular body can have a different tapered configuration, be generally cylindrical, or frustoconical without departing from the scope of the invention. One or more end ribs **38**a (e.g., a plurality of end ribs as shown in the drawings) is disposed about an inner circumferential surface **40**a of the tubular body **22**a at the distal end **26**a thereof.

One difference between the probe cover **20**a shown in FIGS. **12-16** and the probe cover **20** described previously is that a heat shrinkable film **36**a that is substantially transparent to infrared radiation is secured to the tubular body **22** at the distal end **26**a thereof. In contrast to the design of probe cover **20**, the probe cover **20**a is designed to substantially avoid stretching the film **36**a upon receipt of the thermometer probe **34** in the opening **28**a. Instead, the film **36**a is made taught by subjecting the probe cover **20**a to a heat treatment that shrinks the film **36**a after the film is insert molded to the distal end **26**a of the probe **20**a during the formation of the probe. Shrinkage of the film **36**a during the heat treatment takes up slack in the film and results in a film that is substantially free from wrinkles and other distortions that are of concern from the standpoint of thermometer performance.

The end ribs **38**a are configured to engage the heat sensing probe **34** and keep it spaced apart from the film **36**a in substantially the same way that end ribs **38** do for the probe cover **20** described above. Thus, the end ribs **38**a maintain an insulating air gap **55**a between the distal end of the thermometer probe **34** and the film **36**a (FIG. **16**). The air gap **55**a also extends proximally between the longitudinal portions **46**a of the end ribs **38**a. However, in contrast to probe cover **20**, there is enough clearance between the longitudinal portions **46**a of the end ribs **38**a and the thermometer probe **34** so that the end ribs **38**a are not required to spread apart to accommodate the thermometer probe. Although probe cover **20**a is configured so that there is substantially no spreading of the film **36**a, it is understood that it is permissible to configure a probe cover to result in some stretching of a heat shrunk film upon receipt of the probe **34** without departing from the scope of the invention as long as the amount of stretching is within acceptable tolerance levels.

A film support **45**a is disposed at the distal end **26**a of the body **22**a. The purpose of the film support **45**a is to prevent stress concentrations at the boundary between the film **36**a and the contact points of the film with the body **22** at its distal end**[.]** from accumulating in the film **36**a during the heat shrink process. For example, the end ribs **38** of probe cover **20** project into the window (best seen in FIG. **6**) and cause the perimeter of the window to have corners *49* turning in the plane of the window. In other words, it is possible to move around the corners *49* defined by the end ribs **38** while always remaining in the plane of the window. If the film **36** of probe cover **20** **[**were**]** *is* subjected to a heat shrink treatment, the corners *49* of the end ribs **38** undesirably concentrate stresses in the film, which makes the film vulnerable to tearing. The concentration of stresses at the end ribs **38** also introduce distortions (e.g., wrinkles) into the film **36**, interfering with accurate temperature measurement. The film support **45**a of probe cover **20**a has a distally facing film supporting surface **53**a (FIG. **15**). In the embodiment shown in the drawings, the film supporting surface **53**a is generally perpendicular to the longitudinal axis X. The distal ends of the end ribs **38**a can converge and be coplanar with the film supporting surface **53**a, as shown in FIGS. **14** and **15**, in which case the end ribs can be characterized as part of the film supporting surface. On the other hand, a film support can be distinct from end ribs without departing from the scope of the invention. In some embodiments, the film support **45**a is integrally formed as one piece of material with the tubular body **22**a and end ribs **38**a.

The film supporting surface **53**a extends circumferentially around the longitudinal axis X at the distal end **26**a of the body **22**a. The film **36**a is secured to the film supporting surface **53**a (FIG. **16**A). For example, the film **36**a may be secured to the film supporting surface **53**a at a plurality of points (e.g., in a substantially continuous band of attachment points). Significantly, the film supporting surface **53**a, particularly the inner edge **53**a' thereof is substantially free from corners and sharp curvatures turning in a plane of the window. *The corners 49a at the ends of the end ribs 38a do not extend into the plane of the window defined by the inner edge 53a' of the film supporting surface 53a.* The absence of corners and sharp curvatures in the inner edge **53**a' of the film supporting surface **53**a enhances more balanced tensioning of the film **36**a during the heat shrink process. This helps prevent wrinkling and tearing of the film **36**a. In contrast, the film **36** of the probe cover **20** described above is secured to the generally rectangular distal surfaces of the inward projections **50** of the end ribs **38**. The projections **50** have corners *49* that can concentrate stresses in the film **36** and cause wrinkling or tearing of the film, particularly if the film is subjected to heat shrinking.

When manufacturing probe covers in which a separate film is attached to the body of a probe cover, it is desirable to secure the film to the body while the body is still hot (e.g., from an injection molding process) to facilitate bonding of the film to the body. Another advantage of the film support **45** is that helps reduce distortions that can be produced when the film **36**a is attached to the body **22**a while it is still hot. The end ribs **38**a (like the end ribs **38** of the probe cover **20** described above) hold heat longer than other parts of the body **22**a because of their greater relative mass. Consequently, the relatively hotter end ribs **38**a can produce localized shrinkage of the film **36**a upon contact with the film. Although not as hot as the end ribs **38**a, portions of the film supporting surface **53**a extend between the end ribs and are warmer than the atmosphere. During manufacturing of the probe cover **20**a, this reduces temperature gradients experienced by the film **36**a compared to temperature gradients that would be encountered by film **36** in the probe cover **20** described previously, thereby reducing the impact of distortions resulting from local shrinkage of the film. The relatively greater surface area of the film supporting surface **53**a and the corner-free inner edge **53**a' thereof also reduce the impact of any local shrinkage that does occur in the film **36**a by making it easier for the film to form a good seal with the body **22**a and by moving the perimeter of the window inward and away from the parts of the film that are most affected by local shrinkage.

As best seen in FIG. **15**, for example, the film support **45**a of probe cover **20**a is a ring at the distal end **26**a of the body **22**a extending along the inner circumferential surface **40**a of the body **22**a intermediate and coextensive with the distal ends of the end ribs **38**a. It will be understood that the ring can have various shapes other than circular without departing from the scope of the present invention. The film support **45**a extends the same distance inward toward the longitudinal axis X as the end ribs **38**a. Thus, the inner edge **53**a' of the film support **45**a is smooth and continuous. The inner edge **53**a' of the film support **45**a is also substantially free from segments having outward curvature. Further, the inner edge **53**a' of the film support **45**a is substantially free from projections jutting inward (e.g., toward the longitudinal axis X). In the embodiment shown in FIGS. **16** and **16**A, the ring of the film support has an axial thickness L that is less than the depth c of the inward projections of the end ribs **38**a, thereby allowing the insulating air gap **55**a to extend between the inward projections **50**a of the end ribs **38**. Consequently, the probe cover **20**a promotes consistent and accurate temperature measurements. In one embodiment, the dimension L is between about 0.002 inches and about 0.008 inches (e.g., about 0.005 inches). The difference between the dimension L and the dimension c is preferably between about 0.007 inches and about 0.015 inches (e.g., about 0.012 inches).

Another difference between the probe cover **20**a shown in FIGS. **12-16** and the probe cover **20** described previously is that probe cover **20**a has a continuous annular shoulder **152**a instead of the plurality of longitudinal ribs **52** spaced circumferentially around the inner circumferential surface **40** of probe cover **20**. The annular shoulder **152**a has a proximally facing shelf **157**a and tapers distally from the shelf to blend in with the inner circumferential surface **40**a of the body **22**a. The proximally facing shelf **157**a of the annular shoulder **152**a can be used as a thrust surface for a probe cover eject mechanism.

Referring now to FIGS. **17-19** and the embodiment of the probe cover **20**b shown therein, it is noted that the probe cover **20**b is substantially the same as probe cover **20**a, except at its distal end **26**b. The probe cover **20**b comprises an arcuate surface **44**b at the distal end **26**a of the tubular body **20**b; much like the previously described probe covers **20**, **20**a. However, the film support **45**b blends smoothly into the arcuate surface **44**b and there is no edge or other boundary marking the transition from the outer circumferential surface **42**b of the tubular body **22**b and the film supporting surface **53**b of the film support **45**b. Further, the film **36**b, which is a heat shrinkable film substantially similar to film **36**a, is secured to and extends over the arcuate surface **44**b at the distal end of the probe cover **20**b. Extending the film **36**b outward onto the arcuate surface **44**b and securing it thereto provides more surface area for a greater attachment strength between the body **22**b and the film **36**b. It also reduces the potential for rips and tears formed in the perimeter of the film **36**b (e.g., when cutting the film in a manufacturing process) to propagate far enough inward to allow contaminants to enter the probe cover **20**b through the film or otherwise interfere with proper performance of the probe cover.

The wall thickness along the arcuate surface **44**b can gradually decrease as the arcuate surface extends toward the distal end **26**b to transition from a thicker wall proximally of the distal end to a thinner wall for the film support **45**b, as shown in the drawings. This allows the insulating air gap **55**b to extend between the inward projections **50**b of the end ribs **38**b.

In other respects, the film support **45**b is essentially the same as the film support **45**a describe above. In particular, the inner edge **53**b' of the film support **45**b is substantially the same as the inner edge **53**a' of the film support **45**a of probe cover **20**a and reduces stress concentrations when the film **36**b is heat shrunk and the problems associated therewith in substantially the same way.

Referring now to FIGS. **20-22** and the embodiment of the probe cover **20**c shown therein, it is noted that the probe cover **20**c is substantially the same as the probe cover **20**a shown in FIGS. **13-16** except as noted. One difference between probe cover **20**c and the probe cover **20**a is best seen in comparison of FIGS. **22** and **15**. Referring first to FIG. **15**, the inner edge **53**a' of the film support **45**a is flush with the inward faces of the inward projections **50**a of the end ribs **38**a. In contrast, the inner edge **53**c' of the film support **45**c shown in FIG. **22** extends farther inward than the end ribs **38**c. For instance the film support **45**c can be configured to have a distally facing generally planar film supporting surface **53**c having a width m between about 0.007 inches and about 0.020 inches (e.g., about 0.017 inches). This provides greater surface area for attaching the film **36**c to the film support **45**c. For instance, the area of the distally facing film supporting surface **53**c of film support **45**c may be between about 0.01 square inches and about 0.02 square inches. In one embodiment, the area of the distally facing film supporting surface **53**c is at least about 20 percent of the total area of the window defined by the inner edge **53**c' of the film support **45**c. Generally, the larger the distally facing surface is in all of the embodiments, the more bonding area is provided for the film. This feature also decreases the opportunity for quality defects that may occur during molding the probe covers. Particularly during the release of the mold, there is an opportunity for the film to tear at the edge or to develop pin holes. Although these still may occur in manufacturing, the chances of them causing the probe cover to be of compromised quality are reduced because of the increased surface area for bonding provided by the film support. *Moreover, the corners 49c of the end ribs 38c do not extend into the plane of the window defined by the inner edge 53c' of the film support 53c and do not define any portion of the perimeter of the window.*

In contrast, the film support **45**a shown in FIG. **15** does not extend as far toward the longitudinal axis X out of a concern (which is common in the art) that the probe cover **20**a might block some of the generally conical field of view of an IR sensor (not shown) in the thermometer probe **34**. In contrast, in the embodiment shown in FIGS. **20-22**, the inventors have extended the film support **45**c far enough inward so that the inner edge **53**c' of the film support **45**c defining the window perimeter lies closely proximate to the field of vision of the IR sensor (broadly, an electromagnetic radiation sensor).

Referring to FIG. **22**, for example, the intersection of the periphery of the field of view of an IR sensor in the probe **34** (not shown in FIG. **22**) with the film **36**c is indicated by a dashed line **61**c. Because the inner edge **53**c' of the film support **45**c is configured to extend farther inward and encroach on (without entering) the field of view of the IR sensor, there is a relatively smaller annular space (designated **63**c on FIG. **22**) between the inner edge **53**c' of the film support **45**c and the field of vision of the IR sensor at the window. For example, the annular space **63**c preferably has a width n that is less than about 0.050 inches. The annular space **63**c preferably has an area which is less than about 60 percent of an area of the window. In one embodiment, the annular space has an area that is less than about 51 percent of the area of the window, an in one embodiment the area of the annular space is about 9 percent of the area of the window.

The probe cover **20**c operates in substantially the same way as the other probe covers **20**, **20**a, and **20**b described in detail herein. However, any rips, tears, or other damage in the film **36**c caused during cutting of the film during manufacturing are less likely to propagate into the window or otherwise interfere with temperature measurement because of the greater distance they would have to propagate to reach the window from the edge of the film.

Those skilled in the art will recognize that the embodiments described above are examples of the invention and that there is room for substantial variation in the design of the probe cover within the scope of the invention. In particular, the size, shape, and/or configuration of the probe cover can be modified to achieve the advantages of the invention for virtually any available tympanic thermometer. Also, the size, shape, and/or configuration of the body, arcuate surface, window, end ribs, film support, and/or other elements of the probe cover can be modified from the sizes, shapes and configurations described herein and shown in the drawings to accommodate various preferences for style, comfort, and/or other design criteria without departing from the scope of the invention.

Accordingly, it will be understood that various modifications may be made to the embodiments disclosed herein. Therefore, the above description should not be construed as limiting, but merely as exemplification of the various embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the claims appended hereto.

What is claimed is:

1. A probe cover for a probe of a tympanic thermometer, said probe cover comprising:

a generally tubular body having a longitudinal axis, an opening at a proximal end of the body for receiving a thermometer probe, and a film window at a distal end of the body generally opposite said proximal end;

a film support extending radially inward from said distal end of the body toward said longitudinal axis and having an inner edge extending circumferentially around said longitudinal axis and defining a perimeter of said window; and

the film window is secured at a film support surface at a distal end of the film support and extends beyond the inner edge of the film support, the film extends over the film support surface and substantially toward an outer edge of the body,

a plurality of end ribs spaced apart and disposed about an inner circumference of the distal end of the body, each of the end ribs being positioned to engage a distal end of the thermometer probe and prevent contact of the film by the thermometer probe, wherein the inner edge of the film support extends substantially the same distance inward as a transverse portion of each of the plurality of end ribs and further wherein at least some of the end ribs converge with the film support,

the probe cover being substantially transparent to infrared radiation through the window, and the perimeter of the window being substantially free from corners in a plane of the window.

2. A probe cover as recited in claim **1**, wherein the inner edge of the film support is substantially free from segments having an outward curvature.

3. A probe cover as recited in claim **1**, wherein the perimeter of the window is substantially free from segments projecting into the window.

4. A probe cover as recited in claim **3**, wherein the perimeter of the window is generally smooth and continuous.

5. A probe cover as recited in claim **4**, wherein the perimeter of the window is substantially circular.

6. A probe cover as recited in claim **1**, wherein the film support is formed as one piece of material with the body.

7. A probe cover as recited in claim **6**, wherein the end ribs are formed as one piece of material with the body.

8. A probe cover as recited in claim **1**, wherein each of the end ribs comprises a projection extending radially inward toward said longitudinal axis along a surface of the film support.

9. A probe cover as recited in claim **8**, wherein the projections of the end ribs extend toward the longitudinal axis no farther than the inner edge of the film support.

10. A probe cover as recited in claim **8**, wherein the inner edge of the film support extends farther toward the longitudinal axis than the projections.

11. A probe cover as recited in claim **1**, wherein the body has an arcuate surface adjacent the distal end, the film being secured to the arcuate surface.

12. A probe cover as recited in claim **1** wherein the film support defines a substantially flat distally facing surface at the distal end of the body having a generally annular area that is at least about 20 percent of a total area of the window.

13. A probe cover for a probe of a tympanic thermometer, said probe cover comprising:

a generally tubular body having a longitudinal axis, an opening at a proximal end of the body for receiving a thermometer probe, and a window at a distal end of the body generally opposite said proximal end, the body defining a circumferential inner surface extending generally from the proximal end to the distal end;

a film support extending radially inward from said distal end of the body toward said longitudinal axis and having an inner edge extending circumferentially around said longitudinal axis and defining a perimeter of said window;

a plurality of end ribs at the distal end of the body, the end ribs further comprising a transverse portion;

the inner edge and the transverse portion of the end ribs substantially extend the same distance inward toward the centerline of the longitudinal axis of the tubular body; and

the film is secured at a film support surface at a distal end of the film support and beyond the inner edge of the film support, the film extends over the film support surface and substantially toward an outer edge of the body,

the probe cover being configured to maintain a gap between the film and a distal end of the thermometer probe received in the opening, said gap having extensions into areas between said circumferential inner surface of the body and a side of the thermometer probe, the probe cover being substantially transparent to infrared radiation through the window, the perimeter of the window being substantially free from corners in a plane of the window.

14. A probe cover as recited in claim **13** in combination with a thermometer probe received in the opening.

15. A probe cover as recited in claim **14**, wherein said inner edge of the film support is substantially free from segments having an outward curvature.

16. A probe cover as recited in claim **15**, wherein the perimeter of the window is substantially free from segments projecting into the window.

17. A probe cover as recited in claim **16**, wherein the perimeter of the window is generally smooth and continuous.

18. A probe cover as recited in claim **17**, wherein the perimeter of the window is substantially circular.

19. A probe cover as recited in claim **13**, wherein the film support is formed as one piece of material with the body.

20. A probe cover as recited in claim **19** wherein the end ribs are formed as one piece of material with the body.

21. A probe cover as recited in claim **13**, further comprising a plurality of end ribs, each end rib projecting radially inward toward said longitudinal axis along a surface of the film support.

22. A probe cover as recited in claim **21**, wherein the end ribs extend toward the longitudinal axis no farther than the inner edge of the film support.

23. A probe cover as recited in claim **22**, wherein the end ribs each have an inner edge that is flush with the inner edge of the film support.

24. A probe cover as recited in claim **13**, wherein the body comprises an arcuate surface adjacent the distal end, the film being secured to the arcuate surface.

25. A probe cover as recited in claim **13** wherein the film support defines a substantially flat distally facing surface at the distal end of the body having a generally annular area that is at least about 20 percent of a total area of the window.

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