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Capillary action collection device and container assembly

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ABSTRACT

A container assembly is disclosed including an outer container, a hollow inner member, and a closure. The outer container has a closed bottom, an open top, and a sidewall extending therebetween. The hollow inner member is disposed within the outer container and has an inner surface defining at least one capillary channel. The inner member includes a first end adjacent to the open top of the outer container and has an outer periphery seated against the sidewall of the outer container. The closure has a proximal end and a distal end. The closure proximal end is seated at least partially within the first end of the inner member to seal the outer container and inner member and define a fluid collection chamber. The closure distal end defines a recessed area shaped to direct fluid under capillary action to the at least one capillary channel in the inner member

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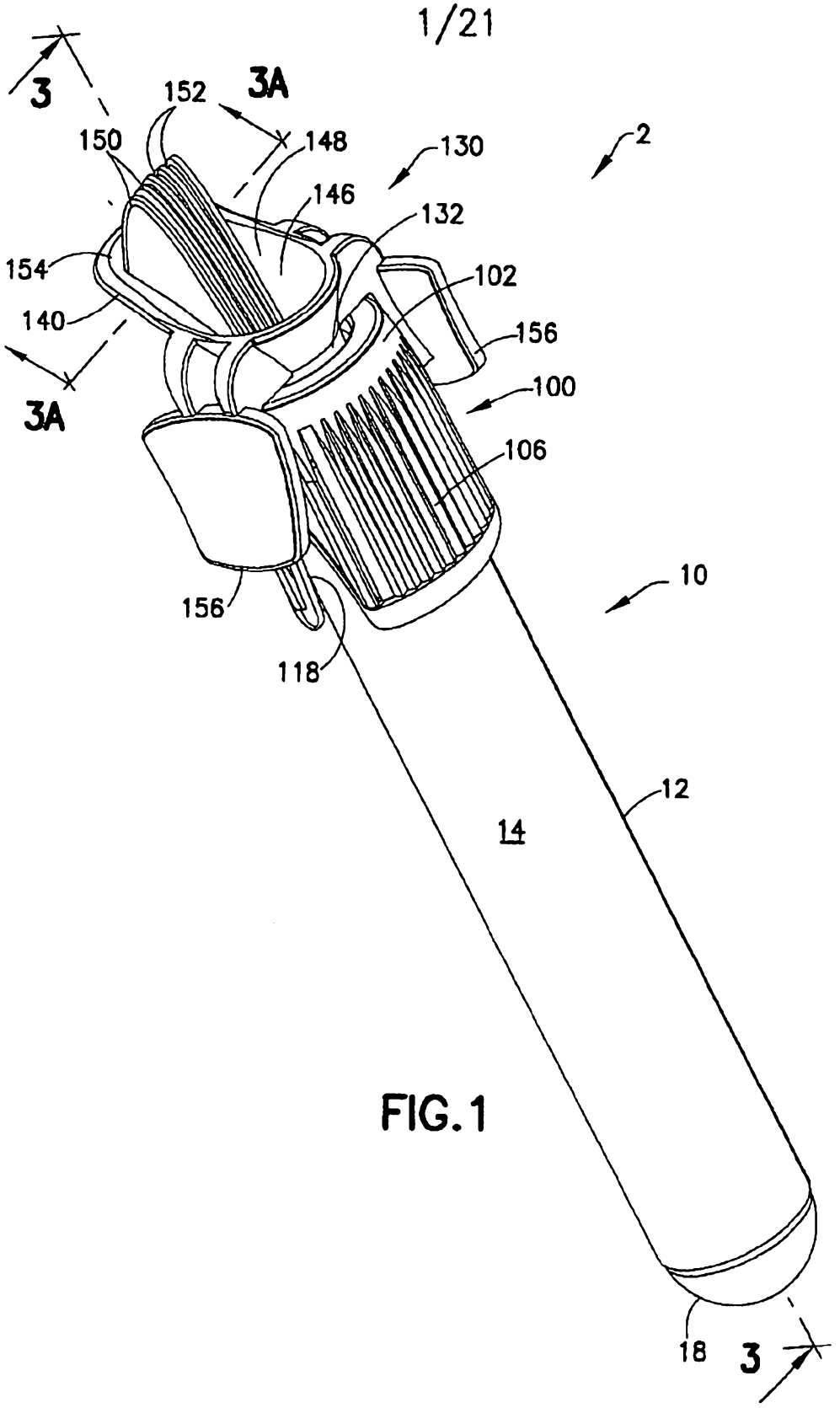

FIG. 1

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COMPLETE SPECIFICATION
STANDARD PATENT

Invention Title:

Capillary action collection device and container assembly

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

CAPILLARY ACTION COLLECTION DEVICE AND CONTAINER ASSEMBLY

CROSS REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to United States Provisional Patent Application No. 61/034,025, filed March 5, 2008, entitled "Capillary Action Collection Device and Container Assembly", the entire disclosure of which is herein incorporated by reference.

BACKGROUND OF THE INVENTION

Field of the Invention

[0002] The present invention relates to a device for the collection, storage, and transfer of a blood or specimen sample obtained from a patient for medical diagnostic testing. More specifically, the present invention relates to a device for collection of blood samples from a patient. The device also includes a cap assembly having a stopper for closing and sealing the device after the blood or specimen sample has been collected. The stopper incorporates space elimination features to funnel the blood or specimen sample to a probe assembly of a testing instrument during transfer from the collection tube.

Description of Related Art

[0003] Conventional capillary collection devices typically provide a microtube or collection container having a raised receiving lip or funnel feature that engages the skin surface of a patient that has been pierced, so as to draw a blood sample from the capillaries located just beneath the skin surface. The internal collection cavities of conventional collection containers are typically straight-walled and do not provide any specimen flow-enhancing features. Conventional containers typically do not promote the flow of drawn blood into the cavity during the collection process, and a typically not structured to allow direct withdrawal of a sample from within the cavity by standard instrumentation. Accordingly, a significant amount of the collected blood or specimen sample is trapped on the sidewall of the cavity due to surface tension during collection and during transfer.

[0004] After collection, conventional collection containers are typically sealed by a cap assembly disposed on the collection container. Conventional cap assemblies typically provide a flat bottom surface in communication with the collection cavity. As a result, a significant dead volume amount of sample is trapped within the collection cavity during transfer of the specimen, since neither the collection container nor the cap assembly adequately funnel or channel the collected blood sample to the aspiration hole of the probe

needle. As can be appreciated, conventional collection assemblies retain a significant amount of wasted sample within the container. This requires that a significantly greater volume of sample must be collected within the collection container than is actually required to perform the necessary diagnostic test. The volume of sample collected is particularly important in capillary applications, in which a very small volume of blood is typically available. The avoidance of waste specimen is therefore a particularly important concern. Also of concern is the exposure of a specimen to medical practitioners during the sampling procedure, and compatibility of the collection container with standard diagnostic and analysis instrumentation.

[0005] Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present disclosure as it existed before the priority date of each claim of this application.

[0005A] Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

SUMMARY OF THE INVENTION

[0006] In one embodiment, a container assembly is disclosed including an outer container, a hollow inner member, and a closure. The outer container has a closed bottom, an open top, and a sidewall extending therebetween. The hollow inner member is disposed within the outer container and has an inner surface defining at least one capillary channel. The inner member includes a first end adjacent to the open top of the outer container and has an outer periphery seated against the sidewall of the outer container. The closure has a proximal end and a distal end. The closure proximal end is seated at least partially within the first end of the inner member to seal the inner member and the outer container and define a fluid sample chamber. The closure distal end defines a recessed area shaped to direct fluid under capillary action to the at least one capillary channel in the inner member.

[0007] The hollow member may extend from the open top to the closed bottom of the outer container and includes a second end supported against the closed bottom. The at least one capillary channel may extend longitudinally along the inner surface of the inner member.

The at least one capillary channel may extend only a portion of the length of the inner surface of the inner member. The at least one capillary channel may include a plurality of capillary channels equally distributed around the inner surface of the inner member. The recessed portion of the closure may be concave or conically-shaped and may define at least one capillary channel therein.

[0008] The first end of the inner member may define a socket portion for receiving the closure proximal end, and the closure proximal end may include a collar portion for sealing against the socket portion. The socket portion may have retaining tabs for retaining the collar portion therein. The peripheral collar portion may include at least two sealing shoulders contacting the socket portion. The at least two sealing shoulders contact the socket at orthogonal locations.

[0009] The closure may have a closure body tapering inward from the closure proximal end to the closure distal end to define an annular space or cavity about the closure body with the inner surface of the inner member. A cap member may be in interlocking engagement with the closure.

[0010] Another aspect disclosed herein is a collector for accessing a container assembly. The collector includes a collector body having a proximal end and a distal end. A penetrating needle cannula may be associated with the distal end of the collector body, which is shaped to pierce an elastomeric closure on a sample collection container. Channel members may be provided on the collector body, which define intervening capillary channels to guide fluid to the penetrating needle cannula.

[0011] The rim portion may define a concave-shaped collection area. The collector body may define a central bore and at least one internal capillary channel may be defined in the central body in the bore for guiding fluid under capillary action to the penetrating needle cannula. The channel members may bulge upward from the rim portion. The penetrating needle cannula may define at least one longitudinally-extending capillary channel. Additionally, the penetrating needle cannula may define at least one longitudinally-extending capillary channel and at least one longitudinally-extending vent channel. The penetrating needle cannula may comprise a generally H-shaped transverse cross-sectional shape. Fingertabs extend outward from the collector body.

[0012] In another embodiment, a container assembly comprises an outer container, an inner member, a closure, and a wall element. The outer container comprises a closed bottom, an open top, and a sidewall extending therebetween. The hollow inner member is disposed

within the outer container and has an inner surface. The inner member comprises a first end adjacent to the open top of the outer container and having an outer periphery seated against the sidewall of the outer container and a second end. The closure is seated at least partially within the first end of the inner member to seal the outer container and define a fluid sample chamber. The wall element is adapted to seal against the inner surface of the inner member and is adapted to move within the inner member under centrifugal force applied to the container assembly. The wall element comprises a generally cylindrical body having a sidewall defining at least one capillary channel therein

[0013] The inner member may define an internal rim at a transition location between a first internal diameter and a second internal diameter and the wall element may be seated in engagement with the internal rim such that, upon application of centrifugal force, the wall element compresses radially inward sufficiently to unseat from the internal rim and move downward in the inner member. The wall element may comprise at least one external flange engaged with the internal rim. The wall element body may comprise an upper portion and a lower portion, with the upper portion having a larger diameter than the lower portion. The generally cylindrical body may comprise a plurality of external flanges engaged with the internal rim. In use, upon application of centrifugal force to the container assembly, the plurality of external flanges desirably flex radially inward sufficiently such that the plurality of external flanges disengage from the internal rim and the wall element moves downward in the inner member.

[0014] In a further aspect, the inner member may define an internal rim at a transition location between a first internal diameter and a second internal diameter and the wall element may comprise a plurality of external flanges engaged with the internal rim. Upon application of centrifugal force to the container assembly, the plurality of external flanges may flex radially inward sufficiently to disengage from the internal rim

[0015] In yet another embodiment, a container assembly includes a collection container having a closed bottom, an open top, and a sidewall extending therebetween having an inner surface defining at least one capillary channel. The container assembly also includes a closure having a proximal end and a distal end. The closure proximal end may be seatable at least partially within the open top of the collection container to seal the collection container and define a fluid sample chamber. The closure distal end may define a recessed area shaped to direct fluid under capillary action to the at least one capillary channel in the collection container.

[0016] In a further embodiment, a container assembly includes a collection container having a closed bottom, an open top, and a sidewall extending therebetween defining an interior. The collection container also includes a closure seatable at least partially within the open top of the collection container. A wall element is disposed within the interior of the collection container, the wall element adapted to compress radially inward under centrifugal force applied to the container assembly to move downward within the interior. The wall element comprises a generally cylindrical body having a sidewall defining at least one capillary channel therein.

[0017] In yet a further embodiment, a container assembly includes a collection container having a bottom, an open top, and a sidewall extending therebetween defining an interior. The container assembly also includes a closure seatable at least partially within the open top of the collection container. The container assembly further includes a wall element disposed within the interior of the collection container and movable from a first position to a second position under the application of a centrifugal force applied to the wall element in a direction away from the open top end towards the bottom. The wall element comprises a generally cylindrical body having a sidewall defining at least one capillary channel therein.

[0018] In one configuration, the wall element has an element height, and travels less distance than the element height when moving from the first position to the second position. The wall element may be frictionally engaged with the collection container in both the first position and the second position, such that a frictional force exists between the wall element and the collection container. The frictional force may be greater in the second position than in the first position. Optionally, the wall element includes a tapered rim. The tapered rim may provide a sealing engagement between the wall element and the collection container in both the first position and the second position.

[0019] Further details and advantages will become clear upon reading the following detailed description in conjunction with the accompanying drawing figures, wherein like parts are designated with like reference numerals throughout.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] **FIG. 1** is a perspective view of a fluid sample collection device pursuant to one embodiment.

[0021] **FIG. 2** is an exploded perspective view of the device shown in **FIG. 1**.

[0022] **FIG. 3** is a cross-sectional view of the device taken along line **3-3** in **FIG. 1**.

[0023] **FIG. 3A** is a partial cross-sectional view of the device taken along line **3A-3A** in **FIG. 1**.

[0024] **FIG. 4** is an exploded cross-sectional view of the device shown in **FIG. 1**.

[0025] **FIG. 5** is a cross-sectional view showing a partially assembled container assembly forming a part of the device shown in **FIG. 1**.

[0026] **FIG. 6** is a perspective view of an inner member associated with the container assembly of **FIG. 5**.

[0027] **FIG. 7** is a longitudinal cross-sectional view of the inner member associated with the container assembly shown in **FIG. 5**.

[0028] **FIG. 8** is a detailed cross-sectional view showing the location of a wall element associated with the container assembly shown in **FIG. 5**.

[0029] **FIG. 9** is a top perspective view of the inner member associated with the container assembly shown in **FIG. 5**.

[0030] **FIG. 10** is a perspective view of the wall element associated with the container assembly shown in **FIG. 5**.

[0031] **FIG. 11** is a longitudinal cross-sectional view of the wall element shown in **FIG. 10**.

[0032] **FIG. 12** is a second longitudinal cross-sectional view of the wall element shown in **FIG. 10**.

[0033] **FIG. 13** is a top perspective view showing a closure and cap member used to seal the container assembly shown in **FIG. 5**.

[0034] **FIG. 14** is a bottom perspective view of the closure and cap member shown in **FIG. 13**.

[0035] **FIG. 15** is a cross-sectional view showing the association of the closure and cap member of **FIGS. 13-14** with the container assembly shown in **FIG. 5** and completing the assembly of the container assembly.

[0036] **FIG. 16** is a longitudinal cross-sectional view of the closure used with the container assembly shown in **FIG. 15**.

[0037] **FIG. 17** is a top perspective view of the collection device shown in **FIG. 1**.

[0038] **FIG. 18** is a front perspective view showing a collector used with the collection device shown in **FIG. 1**.

[0039] **FIG. 19** is a longitudinal cross-sectional view of the collector shown in **FIG. 18**.

[0040] **FIG. 20** is a perspective view of a distal end of the collector shown in **FIG. 18** showing features of a penetrating needle cannula of the collector.

[0041] **FIG. 21** is another perspective view of the distal end of the collector shown in **FIG. 18** showing features of the penetrating needle cannula of the collector.

[0042] **FIG. 22** is a detailed cross-sectional view showing the location of the wall element associated with the container assembly in a pre-centrifuge state of the container assembly.

[0043] **FIG. 23** is a detailed cross-sectional view showing the location of the wall element associated with the container assembly after centrifuging of the container assembly.

[0044] **FIG. 24** is a top perspective view of another embodiment of the collector optionally used with the collection device shown in **FIG. 1**.

[0045] **FIG. 25** is a front perspective view of a third embodiment of the collector optionally used with the collection device shown in **FIG. 1**.

[0046] **FIG. 26** is a side perspective view of the embodiment of the collector shown in **FIG. 25**.

DESCRIPTION OF PREFERRED EMBODIMENTS

[0047] For purposes of the description hereinafter, spatial orientation terms, if used, shall relate to the referenced embodiment, device, component, or feature as it is oriented in the accompanying drawing figures or otherwise described in the following detailed description. However, it is to be understood that the embodiments, devices, components, or features described herein may assume many alternative variations. It is also to be understood that the specific embodiments, devices, components, and features illustrated in the accompanying drawing figures and described herein are simply exemplary and should not be considered as limiting.

[0048] Referring initially to **FIGS. 1-4**, a device **2** for collecting a fluid sample, such as a blood sample, is generally shown. Collection device **2** is an assembly of components, generally comprising a container assembly **10** and a collector **130** adapted to access the container assembly **10** and, further, guide fluid flow under capillary action into container assembly **10** as described herein. Container assembly **10** generally comprises a first or outer container **12**, a second or inner container or member **20** disposed within outer container **12**, an optional internal wall element **50** disposed in inner member **20**, and a stopper or closure **70** for sealing outer container **12** and inner member **20**. Wall element **50** may be associated with inner member **20** but is optional in the construction of container assembly **10** as described

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herein. A cap member **100** is associated with closure **70** to aid in handling of container assembly **10** and further assists closure **70** in sealing outer container **12** and inner member **20**. As described herein, closure **70** and cap member **100** may be separate components or formed together as a combined structure. Outer container **12** may be any container or vessel capable of containing a fluid sample, typically a blood sample, therein, and is desirably in the form of a conventional blood collection tube or vessel. Outer container **12** may be constructed of any known material, such as glass or molded plastic material such as polyethylene terephthalate (PET). Outer container **12** is a generally cylindrical-shaped container having a sidewall **14** defining an open top end **16** and a closed bottom end **18**. The closed bottom end **18** may have a rounded or arcuate shape as in the form of a conventional blood collection tube. Outer container **12** is sealed at the open top end **16** by closure **70**, described herein, which is a pierceable or puncturable component formed of rubber or molded plastic material but may be made of any pierceable elastomeric material.

[0049] Referring further to **FIGS. 5-7**, inner member **20** is a generally cylindrical or tubular body that is received within outer container **12** as illustrated. Inner member **20** is desirably disposed entirely within outer container **12**. Inner member **20** has a first or proximal end **22** adjacent or proximate to the open top end **16** of outer container **12** and a second or distal end **24** adjacent or proximate to the closed bottom end **18** of outer container **12**. Inner member **20** includes external longitudinal ribs or stabilizers **26** that extend substantially a length **L** of the inner member **20**, desirably from a socket portion **28** formed at the first end **22** of inner member **20** to the second end **24** of inner member **20**. Socket portion **28** forms a rim structure or lip at first end **22**. The external ribs or stabilizers **26** are adapted to engage or contact the inner surface of sidewall **14** of outer container **12** and maintain the positioning of inner member **20** within outer container **12**. The external ribs or stabilizers **26** may be segmented or non-continuous along the length **L** of inner member **20** if desired. Additionally, the external ribs or stabilizers **26** may be omitted if the outer periphery of inner member **20** is sized and shaped to be received within outer container **12** with minimal clearance therebetween and thereby generally contact the inner surface of sidewall **14** or outer container **12** around the entire outer periphery or circumference of the inner member **20**. Socket portion **28** comprises a plurality of inward-extending retaining tabs **30** for interfacing with closure **70** as described herein. Socket portion **28** defines a vertical sidewall **32** and a recessed internal rim **34**. As will be apparent from **FIGS. 5-7**, retaining tabs **30** may be provided on an inward projecting collar or rim structure formed on socket sidewall **32**.

Socket internal rim **34** is recessed in socket portion **28** and faces the open top end **16** of outer container **12**. While retaining tabs **30** are desirably individual structures, a single continuous and desirably deflectable or deformable rib structure or shoulder may be provided in place of the illustrated retaining tabs **30**.

[0050] Inner member **20** defines a central bore **36** that may extend completely through the inner member **20,** or may extend partially therein. For example, a lower portion of inner member **20** may be a solid cylinder while the upper portion defines central bore **36**. An inner surface **38** of the inner member **20** and defining bore **36** further includes or defines a plurality of capillary channels **40**. Capillary channels **40** extend generally from socket portion **28** and, more particularly, from socket internal rim **34** downward in the inner surface **38** of inner member **20** to a bore diameter transition location or area described herein. Capillary channels **40** are desirably uniformly spaced around the periphery or circumference of bore **36** and are defined in the inner surface **38** of inner member **20** to extend in a longitudinal direction along the inner surface **38** of inner member **20**. As illustrated, capillary channels **40** desirably extend only a portion of the length **L** of inner member **20** for reasons explained herein and are generally parallel in orientation. Inner member **20** is formed such that bore **36** exhibits differing diameters along the length **L** of inner member **20**. In particular, bore **36** has a first internal diameter **D1** at an upper area or portion **42** of inner member **20** and a second, smaller internal diameter **D2** at a lower area or portion **44** of inner member **20**. Thus, hollow or tubular inner member **20** has a first internal diameter **D1** over an upper portion **42** of the inner member **20** and a second internal diameter **D2** over a lower portion **44** of the inner member **20**. An internal rim **46** is defined at a transition location between the first internal diameter **D1** and second internal diameter **D2** of bore **36**. Internal rim **46** defines a demarcation location between the upper, larger diameter portion **42** and lower, smaller diameter portion **44** of inner member **20**. A substantial portion of the lower portion of inner member **20** may be formed as a solid structure if desired. Capillary channels **40** are formed in the upper portion **42** of inner member **20**. As shown in **FIG. 7**, for example, capillary channels **40** are formed in inner surface **38** of inner member **20** only in upper portion **42** of inner member **20**. Thus, capillary channels **40** extend along only a portion of the inner surface **38** of inner member **20** in the upper portion **42**. In particular, capillary channels **40** terminate a distance above internal rim **46** in bore **36** such that a receiving space or area **48** is defined for accommodating wall element **50**. However, wall element **50**, as alluded to previously, is optional. If desired, it may be omitted entirely or be provided as an integral part of inner

member **20**, for example, formed as a bottom wall extending across the inner member at the location of internal rim **46**.

[0051] Referring additionally to **FIGS. 8-12**, in an initial, "pre-centrifuge" state of container assembly **10**, wall element **50** is disposed or situated in inner member **20** and located in the receiving space or area **48** associated with upper portion **42** of inner member **20**. As described in the foregoing, receiving space or area **48** is an area of the bore **36** in inner member **20** that is located just below the terminus of capillary channels **40**. While the operational use of wall element **50** is described fully herein, briefly, wall element **50** is intended in one embodiment to move downward in inner member **20** when container assembly **10** is exposed to centrifugal force in a conventional centrifuge machine thereby increasing the head space available in a volume defined above the wall element **50**. Wall element **50** is formed in one embodiment as a generally cylindrical shaped body adapted to be received in central bore **36** of inner member **20** but may take other forms as described herein. In the depicted embodiment, wall element **50** has a first or upper end **52** and a second or lower end **54**. As shown in **FIG. 12**, the upper end or portion **52** of wall element **50** has a larger diameter than the lower end or portion **54**. The upper end **52** of wall element **50** defines an outward tapered or tapering rim **56** that is intended to contact the inner surface **38** of inner member **20** in bore **36** and, further, engage or contact the receiving area **48** in the upper portion **42** of bore **36** in inner member **20**. Wall element **50** has a generally H-shaped cross-section along a vertical bisecting plane that is defined by a peripheral or circumferential sidewall **58** and a bisecting connecting wall **60**. Sidewall **58** and bisecting wall **60** define a cup-shaped recess or cavity **62**. A plurality of capillary channels **64** similar to capillary channels **40** in inner surface **38** of inner member **20** are defined by tapered rim **56** and sidewall **58** and extend downward along sidewall **58** to connecting or "bottom" wall **60**. A plurality of external flanges **66** is provided on the outer side or surface of sidewall **58** and extend from outward tapered rim **56** downward to the bottom or second end **54** of wall element **50**. As wall element **50** is intended to compress radially inward so as to "wedge" downward in inner member **20** during centrifuging, it is desirable that the body of the wall element **50** be made of a material sufficiently elastically deformable that radial inward flexing may result under centrifugal force. Desirably, this may also be accomplished by forming external flanges **66** to be sufficiently flexible or "deflectable" to allow the external flanges **66** to flex or compress radially inward toward a central axis **C** of wall element **50** under centrifugal forces typically present in conventional centrifuges used in medical

applications. Accordingly, the external flanges **66** may be formed of a different material from the main body of wall element **50** if desired. Desirably, external flanges **66** each define a notch **68** with a tapered edge **69** that seats on the internal rim **46** defined in bore **36** in inner member **20**. As centrifugal force acts on wall element **50**, external flanges **66** deflect radially inward to unset the tapered edge **69** in each notch area **68** defined by the respective external flanges **66**, allowing the wall element **50** to move or "wedge" downward in inner member **20** under the applied centrifugal force. While the external flanges **66** may alone deflect or compress radially inward, depending on the material comprising wall element **50**, second or lower end **54** of wall element **50** may also exhibit some radial inward compression toward central axis **C**.

[0052] In summary, wall element **50** may be entirely omitted from container assembly **10** or may be provided as part of inner member **20** as described previously (for example, as a bottom wall) or, as described immediately above, may be provided as a separate component disposed in inner member **20**. It is further optional for the wall member **50** to exhibit the wedging movement described immediately above and may be provided to set or define a collection volume in inner member **20** above the wall member **50**. Accordingly, while wall member **50** has been described according to one compressive-type embodiment in the foregoing, it may take other forms such as a simple disc-shaped component, a cup-shaped component, and other forms, such as solid geometrical forms. In these latter forms, the wall member **50** may be spherical or cylindrical in shape as two non-limiting but possible forms for the wall member **50**.

[0053] Referring to **FIGS. 13-16**, closure **70** is used to seal outer container **12** and inner member **20** from the exterior environment. If desired, outer container **12** may be in the form of a conventional blood collection tube or vessel that may be evacuated by conventional means. Thus, closure **70** may be adapted to interface with outer container **12** and, in particular, inner member **20** to maintain a vacuum condition in outer container **12**. Closure **70** comprises a cylindrical closure body **72** having a first or proximal end **74** and a second or distal end **76**. Closure body **72** further comprises an upward extending rim **78** forming first or proximal end **74** and a depending tapered portion **80**. Depending tapered portion **80** generally tapers inward at a gradual angle. The distal end **76** of closure body **72** defines a distal recess or hollow area **82** which may generally be concave-shaped but also may take other configurations. As an example, distal recess **82** may be conical-shaped or take other similar formations as desired. A plurality of capillary channels **84** are formed or defined in

distal recess **82**. As shown in **FIG. 14**, for example, capillary channels **84** that extend outward and downward in distal recess **82** form an apex point in distal recess **82** to a circumferential or peripheral edge **85** formed by distal recess **82** at the distal end **76** of closure body **72**. As further shown in **FIG. 14**, capillary channels **84** generally divide distal recess **82** into approximately 90° quadrants in one exemplary embodiment.

[0054] A collar or rim portion **86** extends radially outward from closure body **72** below upward extending rim **78**. Collar portion **86** of closure body **72** defines upper, and lower, and generally opposed circumferential or peripheral grooves **88**, **90**. Collar portion **86** is formed with two generally orthogonally-orientated sealing shoulders, comprising a first sealing shoulder **92** and a second sealing shoulder **94**. An engagement surface **96** is formed adjacent to first sealing shoulder **92** for interfacing with socket portion **28** of inner member **20**. Moreover, the proximal end **74** of closure body **72** defines a proximal recess **98**. As shown in **FIG. 16**, proximal recess **98** exhibits a generally concave-shape similar to distal recess **82** but may exhibit other shapes such as a generally conical-shape or possibly even a generally cylindrical-shape. Proximal recess **98** provides a location or area for accessing the outer container **12** via use of collector **130** described herein. Briefly, however, collector **130** includes a puncturing or piercing element such as a puncturing needle cannula which is used to puncture closure **70** by inserting the puncturing element through closure body **72** in proximal recess **98**. As noted previously, closure body **72** is made of pierceable rubber or other pierceable elastomeric material.

[0055] In one desirable combination, cap member **100** is generally adapted to interface with closure **70** to form a combined closure structure for sealing outer container **12** and inner member **20** from the exterior environment. Cap member **100** comprises a generally cylindrical body **102** that defines a central bore **104**. Cap member **100** comprises an outer wall **106** that may be textured for facilitating handling by a user of container assembly **10**. An inner wall **108** is spaced inward from outer wall **106** and terminates at a distal end with engagement rim **110**. Engagement rim **110** is adapted to engage in a friction fit manner within upper circumferential groove **88** defined by collar portion **86** extending outward from closure body **72** of closure **70**. Once closure **70** and cap member **100** are joined in the foregoing manner, the joined closure **70** and cap member **100** may be associated with outer container **12** and inner member **20** as described herein. However, it is also possible to first associate closure **70** with inner member **20** and thereafter associate cap member **100** with closure **70** in an alternative assembly process. Moreover, it may be desirable to form closure

70 and cap member 100 together into a single component that is assembled to inner member 20 and outer container 12. This may be accomplished, for example, by forming closure 70 and cap member 100 together in a two-shot molding process.

[0056] Assembled or joined closure 70 and cap member 100 are used to enclose and seal outer container 12 and inner member 20 by forming a sealing engagement between collar portion 86 associated with closure body 72 and socket portion 28 of inner member 20 and between the exterior of socket portion 28 of inner member 20 and the inner surface of the sidewall 14 of outer container 12. This double or dual sealing engagement is formed by inserting the tapered portion 80 of closure body 72 of closure 70 into the bore 36 defined by inner member 20 so that collar portion 86 is received within socket portion 28 of inner member 20. As collar portion 86 is received in socket portion 28, second sealing shoulder 94 is placed in engagement with socket internal rim 34 and first sealing shoulder 92 is placed in engagement with socket sidewall 32. As collar portion 86 is initially inserted into socket portion 28, the first sealing shoulder 92 engages retaining tabs 30 and pressure is applied downward so that the first sealing shoulder 92 slides past the retaining tabs 30 and the sealing engages socket sidewall 32 of socket portion 28. As collar portion 86 is received fully in socket portion 28 with second sealing shoulder 94 in engagement with socket internal rim 34 and first sealing shoulder 92 in engagement with socket sidewall 32, retaining tabs 30 engage the peripheral or circumferential engagement surface 96 on collar portion 86 to secure the engagement thereof in socket portion 28. In an alternative assembly process, closure 70 may be first associated with socket portion 28 of inner member 20 in which case collar portion 86 may deflect somewhat about upper circumferential groove 88 as the collar portion 86 is inserted into socket portion 28 until the first sealing shoulder 92 engages the socket sidewall 32 below retaining tabs 30 and the retaining tabs 30 engage engagement surface 96 on collar portion 86. Thereafter, engagement rim 110 may be inserted into the upper circumferential groove 88 defined by collar portion 86 as described previously.

[0057] Once closure 70 is associated with inner member 20, collar portion 86 exerts an outward force on socket portion 28 such that the exterior surface of socket sidewall 32 presses against the inner surface of sidewall 14 of outer container 12 forming a generally fluid tight seal therebetween. A similar generally fluid tight seal is provided by the engagement of first sealing shoulder 92 on collar portion 86 and the inner surface of socket sidewall 32. The dual engagement of second sealing shoulder 94 against socket internal rim 34 and first sealing shoulder 92 against the inner surface of socket sidewall 32 provides

redundancy in the seal between collar portion **86** and socket portion **28**. Typically, the former engagement of second sealing shoulder **94** against socket internal rim **34** forms the primary fluid seal while the latter engagement of the first sealing shoulder **92** against the inner surface of socket sidewall **32** provides a secondary fluid seal. However, these engagements have additional advantages as well. As described previously, second or bottom circumferential groove **90** is formed opposite from top circumferential groove **88** by collar portion **86**. Once the second sealing shoulder **94** is seated against socket internal rim **34** of socket portion **28**, an annular cavity **112** is defined by bottom circumferential groove **90** and the socket internal rim **34**. This "first" annular cavity **112** is in fluid communication or connection with a second annular cavity **114** defined between the tapered external surface of tapered portion **80** of closure body **72** and the inner surface **38** of inner member **20** in bore **36**. These fluidly-connected cavities **112, 114** may be used to provide a visual indication to a user of collection assembly **10** when a fluid sample, typically blood, has reached a maximum fill volume for the container assembly **10**. As will be appreciated from **FIG. 15**, for example, with closure **70** associated or engaged with inner member **20**, an enclosed fluid sample chamber **116** is defined within container assembly **10**. Fluid sample chamber **116** is generally bound or defined by the inner surface **38** of inner member **20**, bisecting or interconnecting wall **60** of wall element **50**, and collar portion **86** of closure body **72**. This fluid sample chamber **116** is accessible via use of collector **130** as described herein and as illustrated in **FIG. 3**. It will be clear from **FIG. 15**, for example, that capillary channels **84** in distal recess **82** of closure body **72** are located in proximity to capillary channels **40** in the inner surface **38** of inner member **20** but need not directly connect to capillary channels **84** for fluid flow under capillary action to pass from capillary channels **84** to capillary channels **40** as the distal circumferential edge **85** of taper portion or barrel **80** of closure body **72** provides a sufficient access route or edge for a capillary fluid sample to pass outward to the inner surface **38** of inner member **20** and enter capillary channels **40** therein.

[0058] With closure **70** associated or engaged with inner member **20** as described hereinabove, cap member **100** is positioned such that outer wall **106** of cap member **100** extends downward over the exterior of sidewall **14** of outer member **12** and may be grasped by a user of container assembly **10**. Cutouts **118** may be provided in opposing sides of outer wall **106** of cap member **100** so that the visual-indication fill feature provided by interconnecting annular cavities **112, 114**, described previously, is available for external inspection to a user of container assembly **10**. Such visual inspection is made by viewing the

tapered portion **80** of closure body **72** of closure **70** through sidewall **14** of outer container **12**. For such visual fill indication to be apparent to the user, inner member **20** is made of similar material as outer container **12** such as a molded clear plastic material. This visual-indication fill feature is akin to a flash chamber known in the medical field in blood collection applications and is described further herein.

[0059] Referring further to **FIGS. 17-21**, an embodiment of collector **130** used to gain access to fluid sample chamber **116** and, further, direct or collect a bodily fluid sample such as blood under capillary action into fluid sample chamber **116** is shown. In this embodiment, collector **130** comprises a generally tubular-shaped body **132** comprising a first or proximal end **134** and a second or distal end **136** and an annular sidewall **138** extending therebetween. The proximal end **134** comprises a rim portion **140** that generally tapers outward from collector body sidewall **138** at the first or proximal end **134** of collector body **132**. Collector body sidewall **138** defines a central bore **142** extending through the collector body **132**. As shown, for example, in **FIG. 17**, a central wall or divider **144** extends across bore **142** between opposed sides of sidewall **138**. An inner surface of collector body **132** defining bore **142** optionally defines a plurality of longitudinally-extending capillary channels (not shown). If provided, at least two capillary channels are defined in bore **142** defined by sidewall **138** of collector body **132**, typically at least on opposed sides of bore **142**. An inner surface **146** of rim portion **140** has a generally curved or arcuate shape and rim portion **140** generally defines a concave, cup-shaped collector area or recess **148**. Collector area or recess **148** forms an expanded area or volume where, for example, a patient may place his or her fingertip after being pricked with a lancet or other device so that a blood sample may be taken under capillary action. Central divider or wall **144** prevents the patient from inserting his or her fingertip fully into bore **142**. Collector area or recess **148** is also adapted, as described herein, for collecting a capillary sample of fluid and directing the same into central bore **142** defined by collector body **132**.

[0060] A series or plurality of channel members **150** is desirably present on collector body **132** and, in particular, on rim portion **140** and sidewall **138** of collector body **132**. Channel members **150** extend along the inner surface **146** of rim portion **140** and desirably extend downward into and through central bore **142** defined by sidewall **138** to terminate approximately at the distal end **136** of collector body **132**. Channel members **150** are spaced apart to define intervening capillary channels **152** which are approximately parallel to one another. A further feature of rim portion **140** is that the rim portion **140** may comprise an

upward and generally outward extending rear wall or flange **154**. Rear wall or flange **154** tapers outward in a generally similar manner to rim portion **140** but extends further laterally outward as well as upward from rim portion **140**. Rear wall or flange **154** may be used to visually guide a user of collector **130** in placing a patient's fingertip into rim portion **140**. Channel members **150** in the embodiment illustrated generally bulge upward from rim portion **140** and, particularly, upward from rear wall **154**. The bulged form of channel members **150** has several functions but is primarily provided to guide insertion of a patient's fingertip into rim portion **140**. However, the steepness of the capillary channels **152** due to the bulged shape of channel members **150** has advantages in increasing the potential energy available to cause capillary action fluid flow in the capillary channels **152**.

[0061] Channel members **150** and, more particularly, intervening capillary channels **152** form capillary flow channels to guide a fluid sample downward into central bore **142** defined by sidewall **138** of collector body **132** under capillary action. Thus, capillary channels **152** operate generally as fluid guides to guide a desired fluid sample into central bore **142** in collector body **132**. It will be appreciated from **FIG. 3** discussed previously, that an outer diameter of sidewall **138** of collector body **132** is slightly smaller than an inner diameter of the inner wall **108** of cap member **100** so that collector body **132** may be inserted into central bore **104** of the body **102** of cap member **100**. Finger tabs **156** may extend outward and downward from rim portion **140** and extend downward along the outer side or surface of collector body **132** to provide locations for the user of collector **130** to place his or her fingers. Surface texturing may be provided on finger tabs **156** if desired for ergonomic purposes. As shown in **FIG. 18**, an annular area **158** is defined between finger tabs **156** and the outer surface of sidewall **138** which is sized large enough to accommodate the radial thickness of the body **102** of cap member **100** between the outer wall **106** and inner wall **108** thereof.

[0062] Another feature of collector **130** is the provision of an accessing needle cannula **160** at the distal end **136** of collector body **132** used to pierce or puncture closure body **72** to gain access to the interior of container assembly **10** and, particularly, fluid sample collection chamber **116**. Puncturing or penetrating needle cannula **160** comprises a first or proximal end **162** and a second or distal end **164**. The proximal end **162** of penetrating needle cannula **160** is disposed in a receiving recess **166** defined in collector body **132** at distal end **136**. The proximal end **162** of penetrating needle cannula **160** may be secured in receiving recess **166** by conventional means in the medical art such as by medical grade adhesive and like securing

techniques. Penetrating needle cannula **160** may alternatively be formed integral with collector body **132** of collector **130**. Penetrating needle cannula **160** has a generally H-shaped transverse cross section and terminates in a generally flat-faced needle point **168** which is suited to puncturing closure body **72** of closure **70**. Due to the H-shape of the cross-section of penetrating needle cannula **160**, two opposed and longitudinally extending channels **170**, **172** are defined in penetrating needle cannula **160**. Channels **170**, **172** extend the length of penetrating needle cannula **160** and, as shown in **FIG. 19**, for example, terminate at the proximal end **162** of penetrating needle cannula **160**. While not immediately apparent from **FIG. 21**, for example, capillary channels may have different diameters so that one channel may operate as a fluid conduction capillary channel **172** while the second channel may operate as a vent channel or conduit **170** to atmospheric pressure when penetrating needle cannula punctures closure body **72** of closure **70** during use. Central divider or wall **144**, in addition to the previously discussed purpose of limiting finger insertion into bore **142**, is present for the purpose of dividing or separating channels **170**, **172** for the two distinct functions identified in the foregoing. The upper termination point of dedicated capillary channel **172** is located in close proximity to the distal terminus of capillary channels **152** defined by channel members **150** on collector body **132**. In this regard, once a fluid sample has accumulated in capillary channels **152**, a generally seamless capillary action fluid flow path is present through to the distal end **136** of penetrating needle cannula **160**.

[0063] Referring briefly to **FIGS. 24-26**, two additional embodiments of collector **130** are shown. In **FIG. 24**, collector **130a** has the same features of collector **130** described in the foregoing, however, channel members **150a** do not exhibit the "bulged" configuration of channel members **150** described previously. In this configuration, the channel members **150a** do not extend above the level of rim portion **140a** and rear wall **154a**. In the embodiment of collector **130b** depicted in **FIGS. 25-26**, channel members **150b** are omitted entirely and reliance is made on capillary channels **152b** now defined within central bore **142b** in collector body **132b** (and/or in rim **146b**) to conduct a fluid sample flow under capillary action to capillary channel **172b** in penetrating needle cannula **160b**. Alternatively, channels **152b** may be omitted and the interior of collector body **132b**, including bore **142b** and/or rim **146b**, may be treated such that these surfaces are hydrophilic which will conduct fluid along these surfaces to needle cannula **160b**. Such surface treatment may include an applied surfactant applied, for example, by plasma vapor deposition, to channel fluid downward to

needle cannula **160b**. All or portions of bore **142b** and rim **146b** may be treated. Additionally, collector **130b** also illustrates that finger tabs **156b** are optional in each embodiment described hereinabove and collector **130b** may integrated as part of cap member **100** if desired. This configuration may be applied to each of collectors **130**, **130a** discussed previously.

[0064] Referring now additionally to **FIGS. 22-23**, use of collection device **2** comprising container assembly **10** and collector **130** will now be described. In an assembled configuration, container assembly **10** and inner member **20** are disposed in outer container **12**. As noted previously, in an initial "pre-centrifuge" state of container assembly **10**, wall element **50** is disposed or situated in inner member **20** and located in the receiving space or area **48** associated with upper portion **42** of inner member **20**. Moreover, in the assembled configuration, closure **70** and cap member **100** interface with inner member **20** and outer container **12** in the manner described previously. To use collection device **2**, collector **130** is used to gain access to the fluid sample chamber **116** in container assembly **10**. This is accomplished by a user piercing the closure body **72** of closure **70** with the penetrating needle cannula **160** associated with collector **130**. Penetrating needle cannula **160** is inserted into proximal recess **98** in closure body **72** and pierces the container body **72** at this location. Once collector **130** is associated with container assembly **10**, as best shown in **FIG. 3**, a fluid sample may be taken from a patient. Typically, a small puncture wound is made in the patient's fingertip by a lancet or similar device and the patient's fingertip is inserted into the rim portion **140** on collector body **132** of collector **130**. The provision of "bulged" channel members **150** on collector body **132** guides the placement of the patient's fingertip within the collection area **148** of collector body **132**. As the fluid sample, in this example blood, is extracted from the patient's fingertip, the small quantity of blood "drips" garnered as a result of a small puncture wound may not flow easily due to surface tension forces. In order to overcome these forces, the blood "drips" are channeled into capillary channels **152** defined by channel members **150**. As noted previously, these capillary channels **152** connect with capillary channel **172** in penetrating needle cannula **160** which is separated from vent channel **170** by dividing wall **144** as described previously. Any blood "drips" that do not adequately enter capillary channels **152**, for example, by missing the capillary channels **152** are channeled into capillary channels (not shown) in central bore **142** defined by the sidewall **138** of collector body **132**, and these capillary channels likewise lead to the capillary channel **172**. In view of the foregoing, it will be appreciated that interconnecting capillary channels **152**,

172 provide a fluid path for small volume blood samples or "drips" to be directed into the fluid sample chamber **116** of container assembly **10**. As noted previously, one of the channels **170**, **172** in puncturing needle cannula **160** operates to channel the small volumes of blood into the fluid sample chamber **116** of container assembly **10** (*i.e.*, capillary channel **172**) while the second channel operates as a vent channel **170** to atmospheric pressure to enable the venting of air within the fluid sample chamber **116** to the atmosphere as blood fills the fluid sample chamber **116**.

[0065] Once the blood volumes begin to enter fluid sample chamber **116** via puncturing needle cannula **160**, the blood has a tendency due to surface tension to adhere to sidewall elements bounding or defining the fluid sample chamber **116**. To channel blood to the bottom of fluid sample chamber **116**, blood in capillary channel **172** typically migrates outward to enter capillary channels **84** in the distal recess **82** defined at the end of tapered portion **80** of closure body **72**. Blood enters capillary channels **82** and is conducted by these capillary channels **84** outward to inner surface **38** of inner member **20**. As noted previously, distal circumferential edge **85** of tapered portion or barrel **80** of closure body **72** provides a sufficient access route or edge for a capillary fluid sample to pass outward to the inner surface **38** of inner member **20** and enter capillary channels **40** therein. Capillary channels **40** conduct blood volume downward to wall element **50** and the capillary channels **64** therein conduct the blood volume into the cup-shaped recess or cavity **62** defined by wall element **50**. As blood volume builds up above wall element **50**, fluid sample chamber **116** is filled. A visual indication of when fluid sample chamber **116** is filled with fluid is provided by viewing the area around tapered portion **80** of closure body **72** of closure **70** through sidewall **14** of outer container **12**. As noted previously, cutouts **118** are desirably provided in opposing sides of outer wall **106** of cap member **100** so that the visual-indication fill feature provided by interconnecting annular "flash" cavities **112**, **114**, described previously, is available for external inspection to a user of container assembly **10**.

[0066] Once a fluid sample, such as blood, is present in fluid sample chamber **116**, collector **130** may be removed from container assembly **10**. It is often desirable to centrifuge the fluid sample, typically blood, to separate its constituent elements into layers as mentioned previously. Often, after centrifuging is complete, it is desirable to place the container assembly **10**, now containing a separated fluid sample, in one or more diagnostic machines. However, it is also possible to place container assembly **10** directly into such diagnostic machines, such as hematology devices, without centrifuging when it is desired to test a

whole, "un-separated" blood sample. In order for some diagnostic machines to operate properly, a small head space or volume may be necessary above the level of fluid in the container assembly **10**. However, if container assembly **10** is filled substantially to the level of collar portion **86** of closure body **72** of closure **70**, which will be indicated by the visual-indication fill feature provided by the interconnecting annular "flash" cavities **112**, **114**, described previously, some diagnostic machines may not work properly. Wall element **50** is used to optionally provide a small head space or volume during the centrifuging process as mentioned previously. However, this head space is not always necessary in diagnostic machines. In these situations, wall element **50** may be one of the embodiments described previously that does not exhibit a "wedging" movement during centrifuging. In these alternative embodiments, wall element **50** simply defines the lower boundary of fill chamber **116**.

[0067] An initial, "pre-centrifuge" state of wall element **50** is shown in **FIG. 22** wherein the wall element **50** is disposed or situated in inner member **20** and located in the receiving space or area **48** associated with upper portion **42** of inner member **20**. The location or level of the upper end **52** of wall element **50** is denoted by the letter **A** in **FIG. 22**. When container assembly **10** is exposed to centrifugal force in a conventional centrifuge machine as an example, wall element **50** wedges downward by the methods and manner described previously (namely, radial compression of external flanges **66** and/or radial compression of all or portions of the body of wall element **50**), whereby the upper end **52** of wall element **50** is now located further down in inner member **20** as denoted by the letter **B** in **FIG. 23**. In one embodiment, the wall element 50 has an element height **H**, and the distance the wall element **50** travels within the inner member **20** is less than element height **H**. In such a configuration, the element height **H** is less than the distance the wall element **50** travels between the first location **A** and the second location **B**. As wall element **50** moves downward in inner member **20** when container assembly **10** is exposed to centrifugal force in a conventional centrifuge machine, a small head space or volume is made available or defined above the fluid sample level in container assembly **10**. It will be appreciated that while wall element **50** has specific application to container assembly **10** described in this disclosure, it may have general use in any fluid collection and centrifuging application where it is desired to provide a small head space volume above a fluid sample after centrifuging the fluid sample. Typically, the distance from level **A** to level **B** is about one-half to three-quarters of the height or length of the wall element **50**.

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[0068] While several embodiments of a collection device and container assembly adapted to collect a fluid sample under capillary action and associated methods were described in the foregoing detailed description, those skilled in the art may make modifications and alterations to these embodiments without departing from the scope and spirit of the invention. Accordingly, the foregoing description is intended to be illustrative rather than restrictive.

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THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A container assembly comprising:

an outer container comprising a closed bottom, an open top, and a sidewall extending therebetween;

a hollow inner member disposed within the outer container and having an inner surface, the inner member comprising a first end and a second end, wherein the first end is adjacent to the open top of the outer container and has an outer periphery seated against the sidewall of the outer container;

a closure seated at least partially within the first end of the inner member to seal the outer container and define a fluid sample chamber; and

a wall element adapted to seal against the inner surface of the inner member and adapted to move within the inner member under centrifugal force applied to the container assembly, wherein the wall element comprises a generally cylindrical body having a sidewall defining at least one capillary channel therein.

2. The container assembly as claimed in claim 1, wherein the inner member defines an internal rim at a transition location between a first internal diameter and a second internal diameter and the wall element is seated in engagement with the internal rim, and wherein upon application of centrifugal force, the wall element compresses radially inward sufficiently to unseat the wall element from the internal rim.

3. The container assembly as claimed in claim 2, wherein the wall element comprises at least one external flange engaged with the internal rim.

4. The container assembly as claimed in claim 1, 2 or 3, wherein the wall element comprises an upper portion and a lower portion, the upper portion having a larger diameter than the lower portion.

5. The container assembly as claimed in claim 1, wherein the inner member defines an internal rim at a transition location between a first internal diameter and a second internal diameter and the wall element comprises a plurality of external flanges engaged with the internal rim, such that upon application of centrifugal force to the container assembly, the plurality of external flanges flex radially inward sufficiently to disengage the plurality of external flanges from the internal rim.

6. A container assembly comprising:

a collection container having a closed bottom, an open top, and a sidewall extending therebetween defining an interior;

a closure seatable at least partially within the open top of the collection container; and

a wall element disposed within the interior of the collection container and adapted to compress radially inward under centrifugal force applied to the container assembly to move downward within the interior, wherein the wall element comprises a generally cylindrical body having a sidewall defining at least one capillary channel therein.

7. A container assembly, comprising:

a collection container having a bottom, an open top, and a sidewall extending therebetween defining an interior;

a closure seatable at least partially within the open top of the collection container; and

a wall element disposed within the interior of the collection container and movable from a first position to a second position under the application of a centrifugal force applied to the wall element in a direction away from the open top end towards the bottom, wherein the wall element comprises a generally cylindrical body having a sidewall defining at least one capillary channel therein.

8. The container assembly of claim 7, wherein the wall element has an element height, and travels less distance than the element height when moving from the first position to the second position.

9. The container assembly of claim 7 or claim 8, wherein the wall element is frictionally engaged with the collection container in both the first position and the second position, wherein a frictional force exists between the wall element and the collection container, the frictional force being greater in the second position than in the first position.

10. The container assembly of any one of claims 7 to 9, wherein the wall element further comprises a tapered rim, the tapered rim providing sealing engagement between the wall element and the collection container in both the first position and the second position.

11. A container assembly according to any one of the preceding claims and substantially as described herein with reference to the accompanying drawings.

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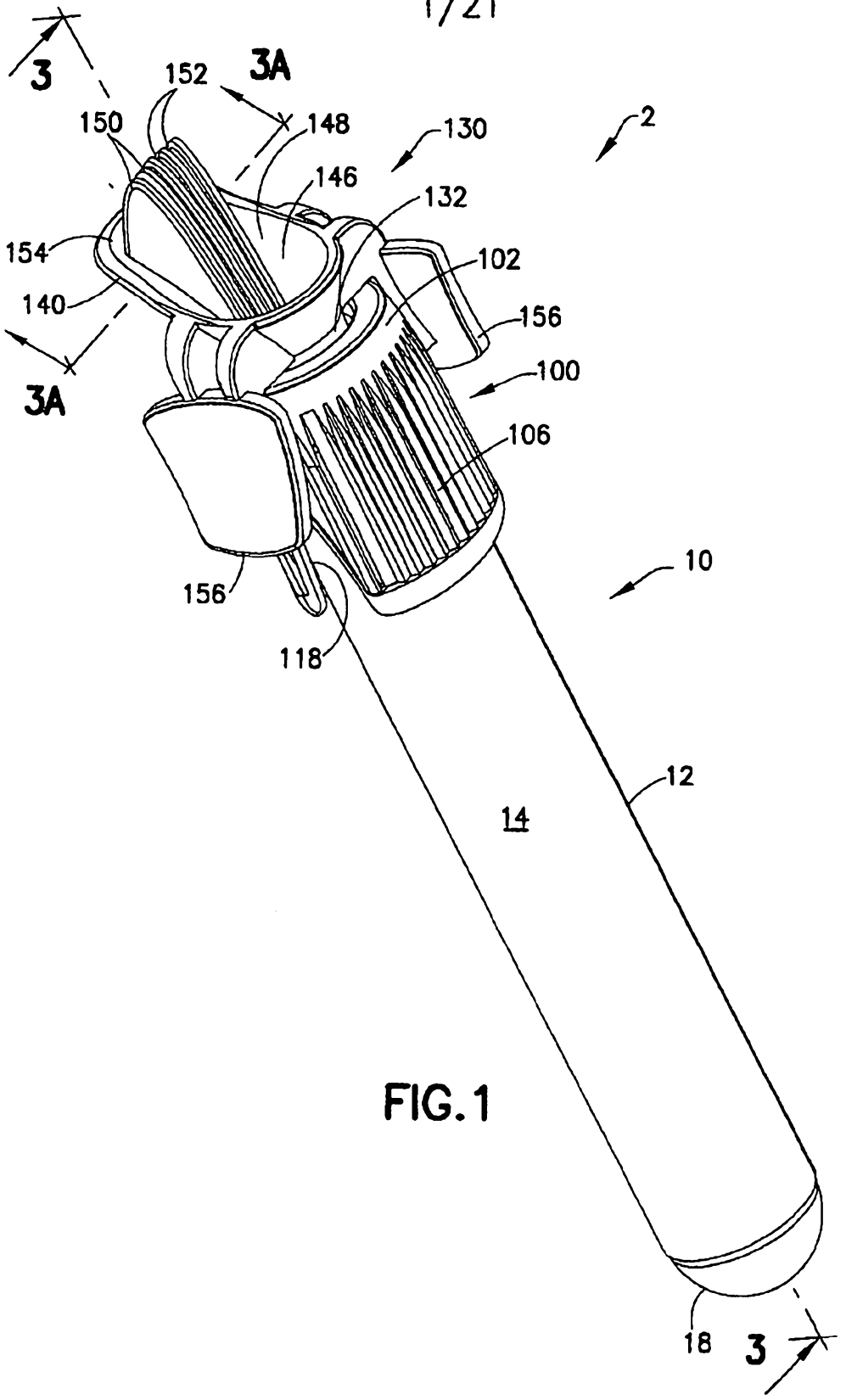

FIG. 1

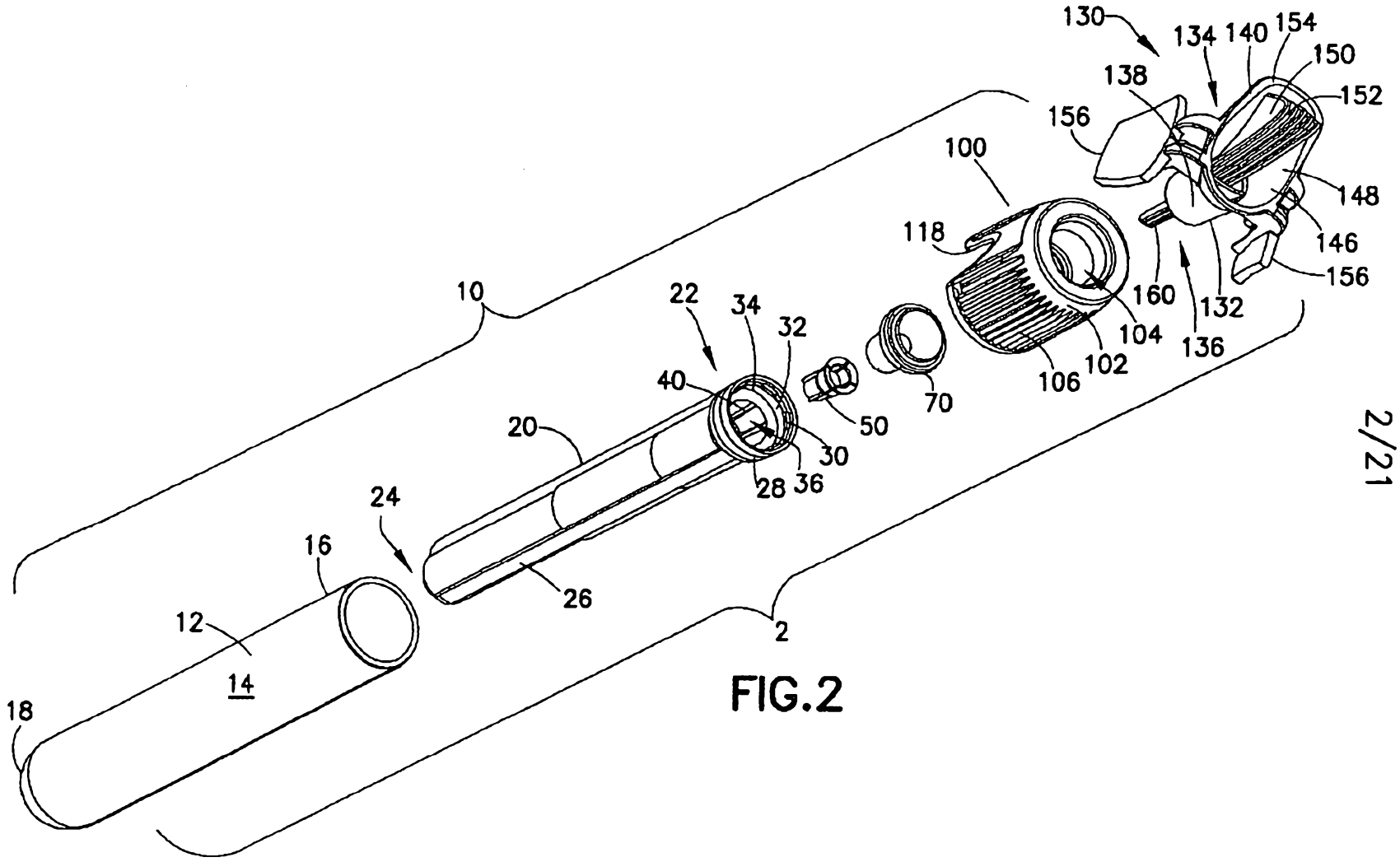
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FIG.2

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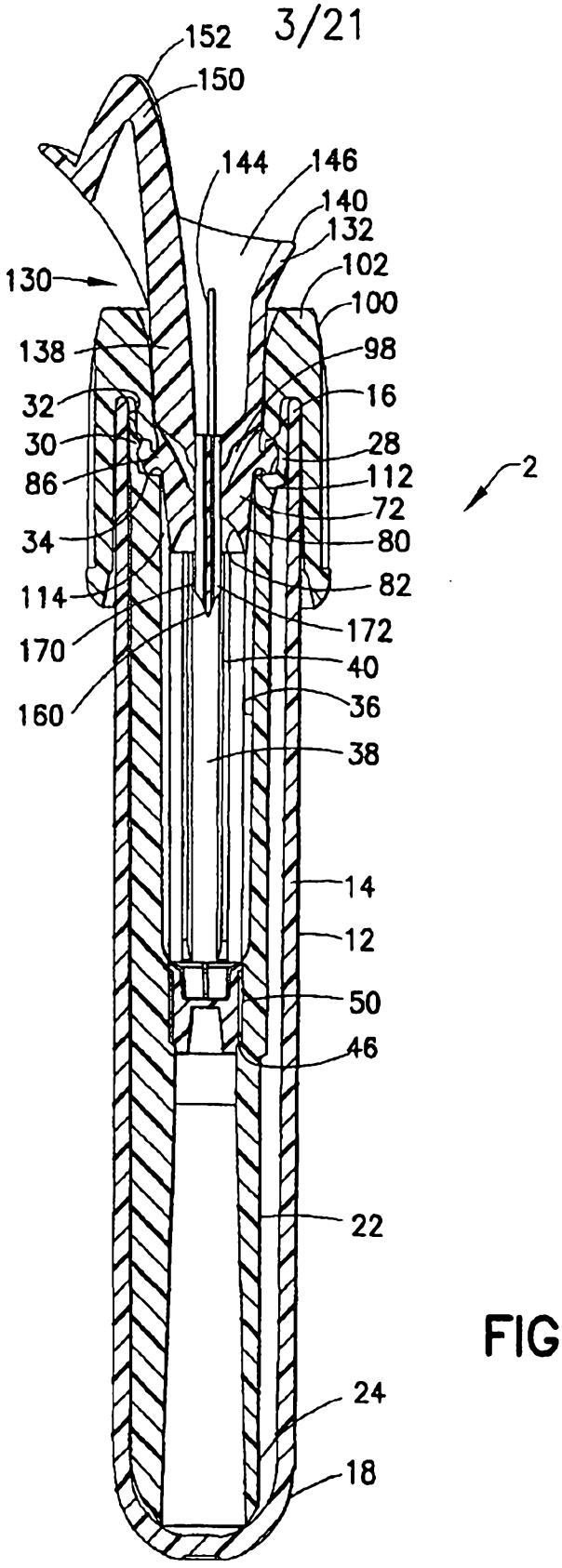

FIG.3

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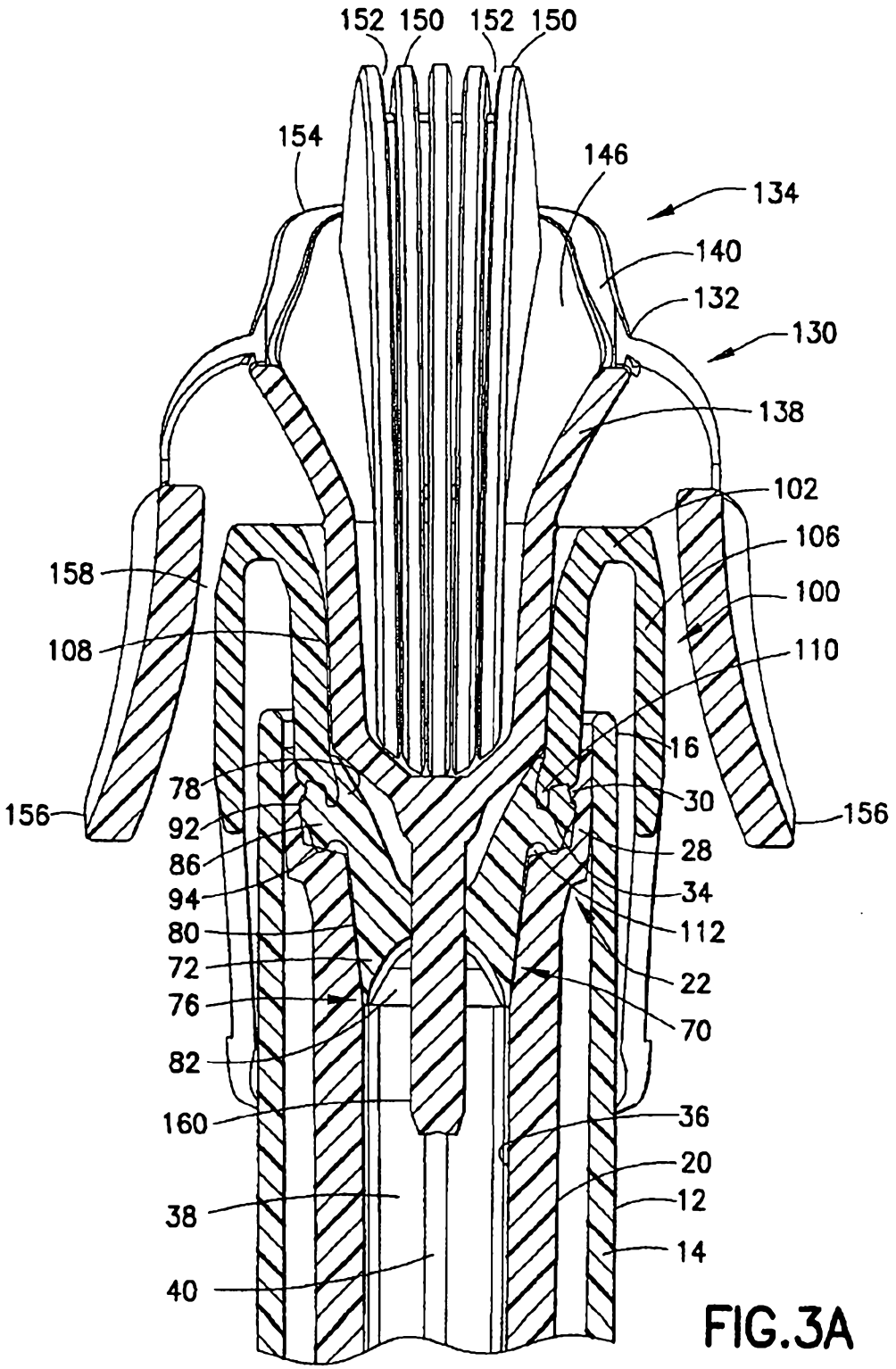

FIG.3A

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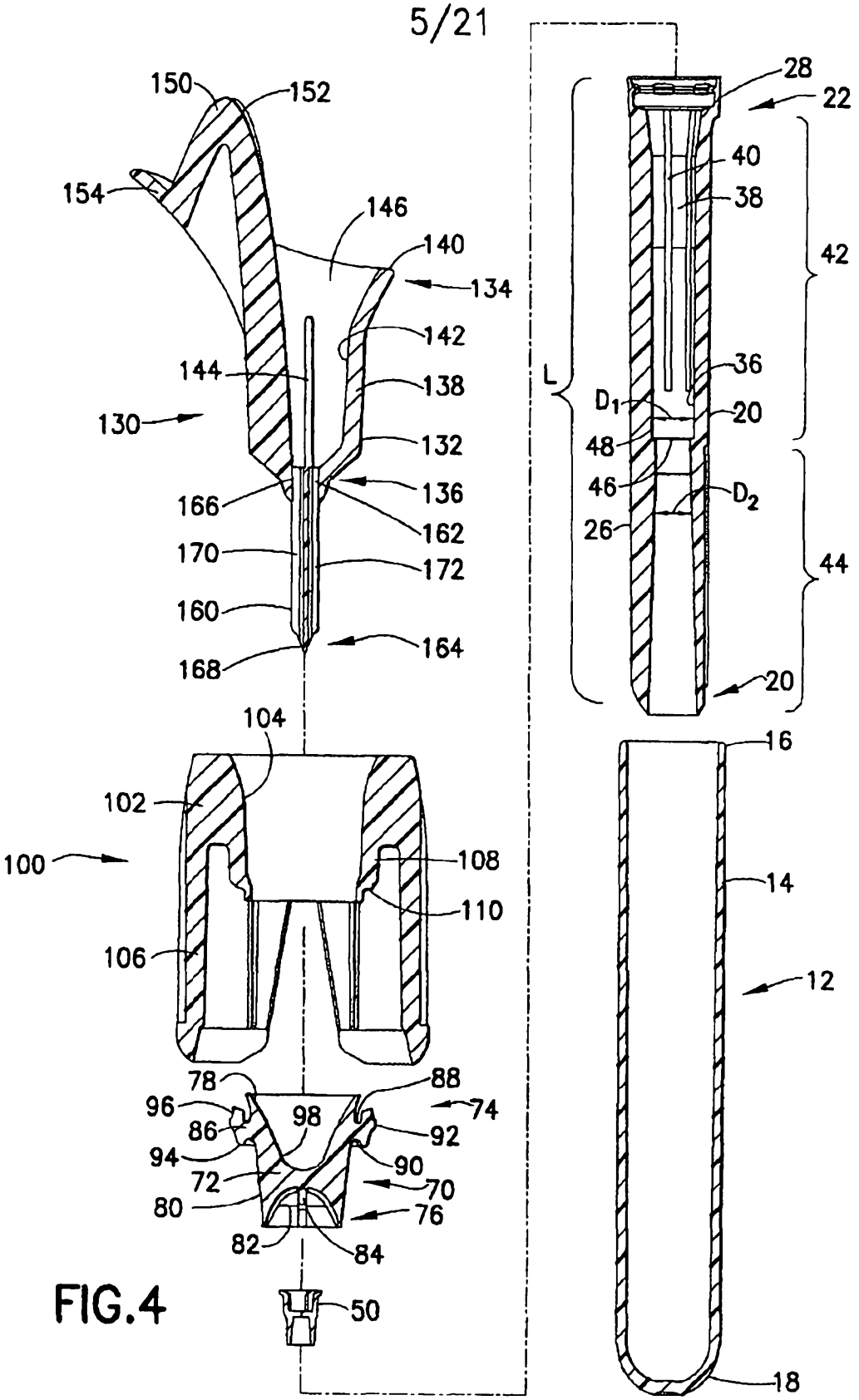

FIG.4

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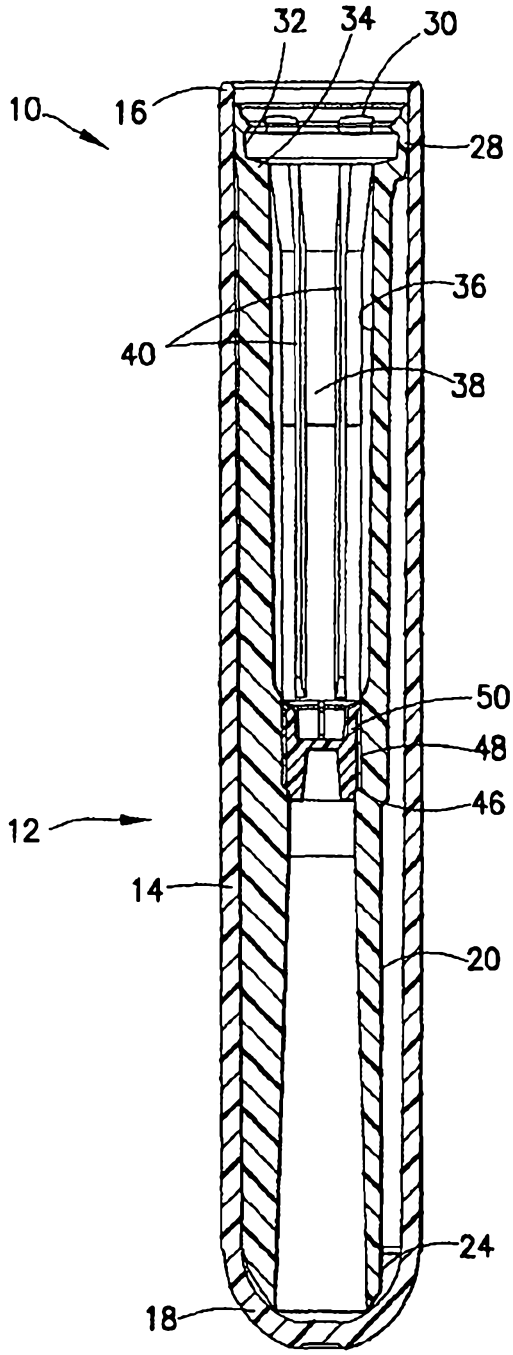

FIG.5

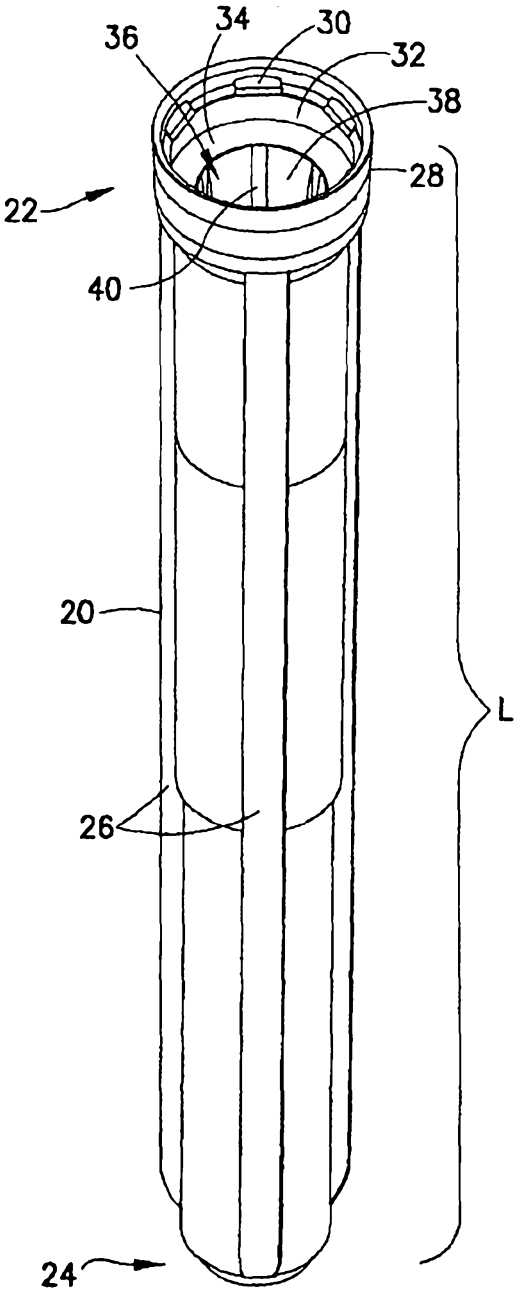

FIG.6

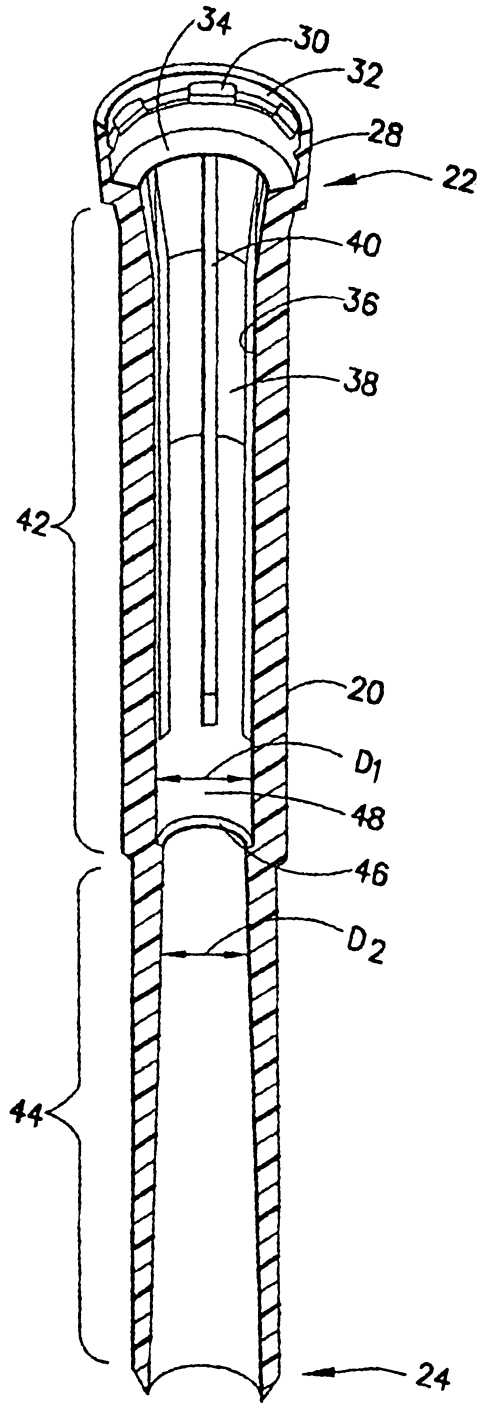

FIG. 7

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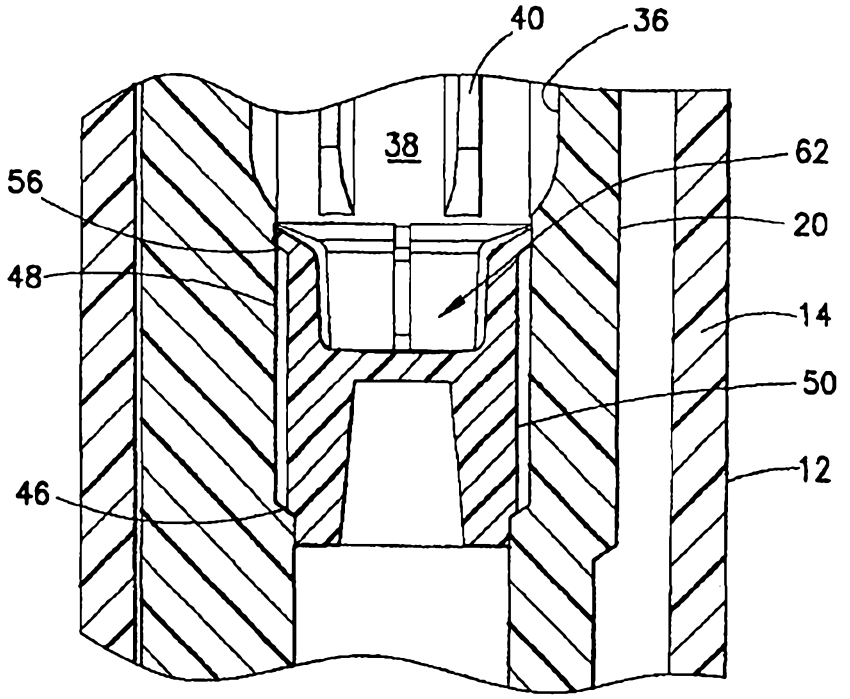

FIG.8

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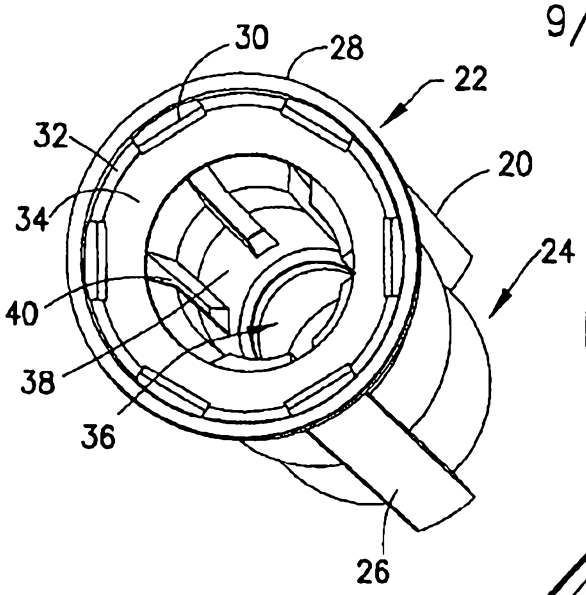

FIG.9

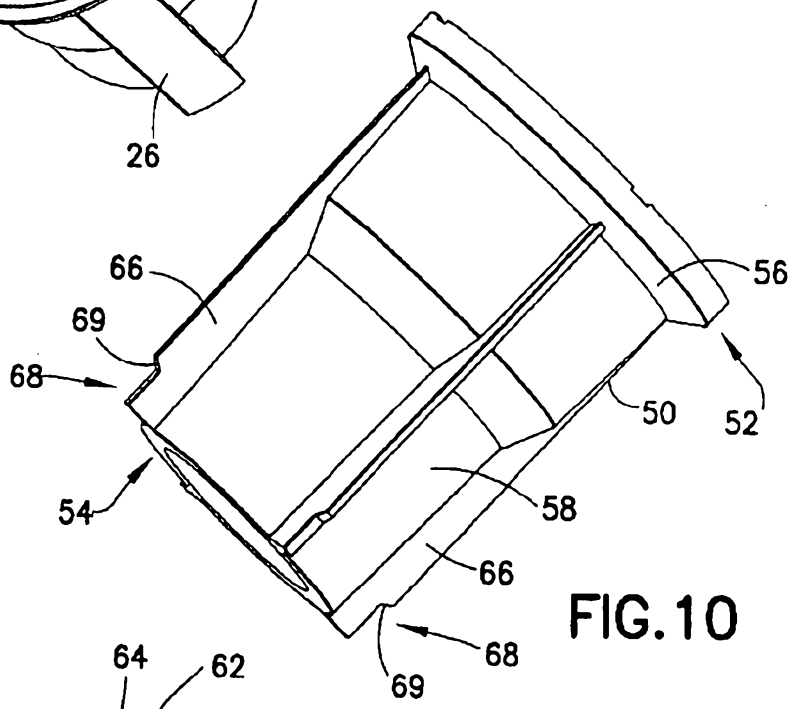

FIG.10

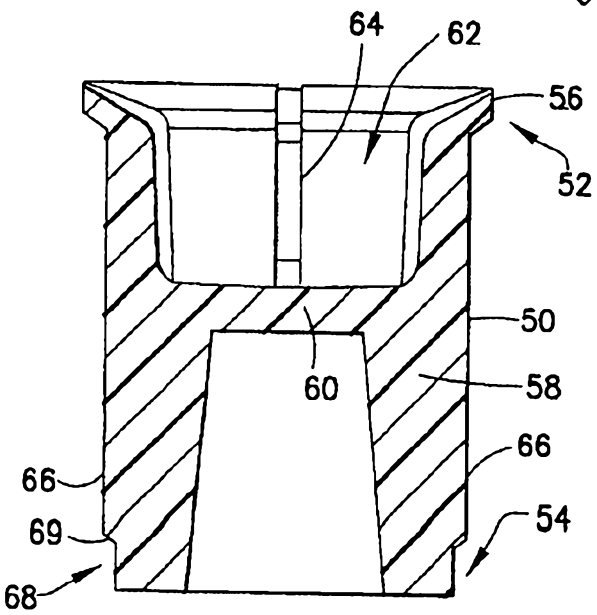

FIG.11

2012203335 06 Jun 2012

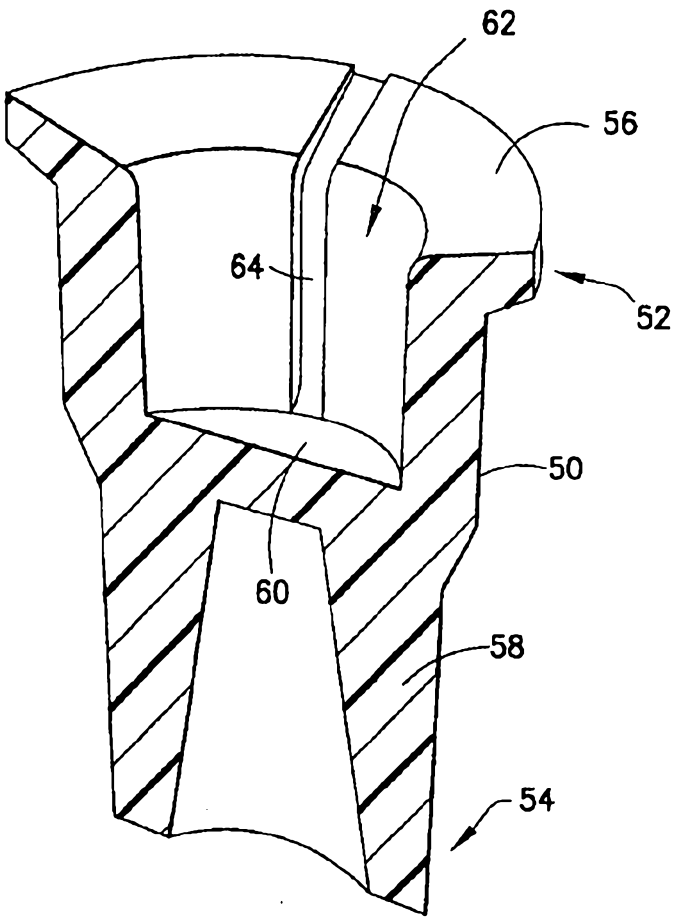

FIG.12

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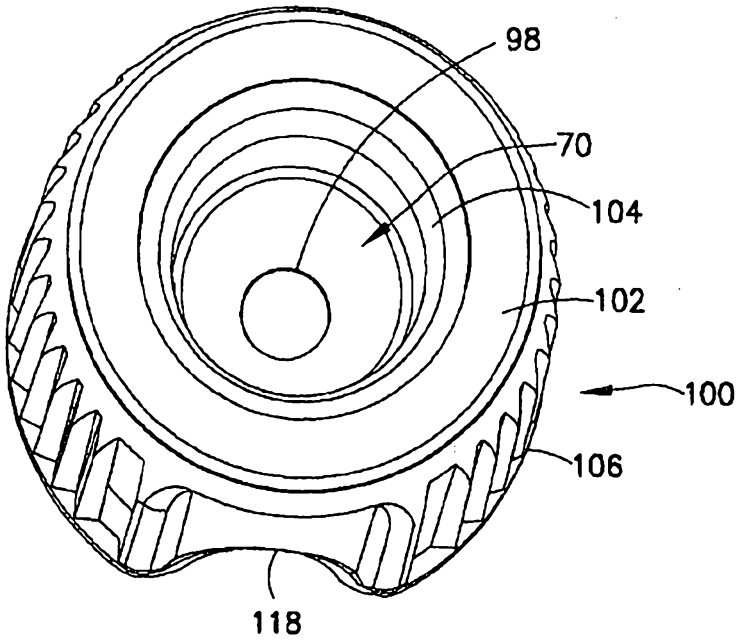

FIG.13

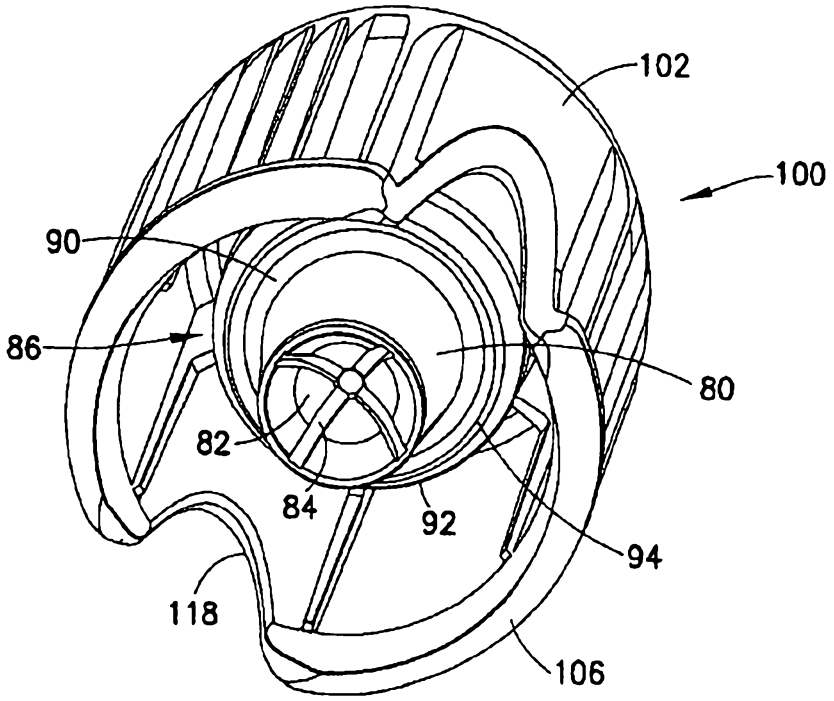

FIG.14

2012203335 06 Jun 2012

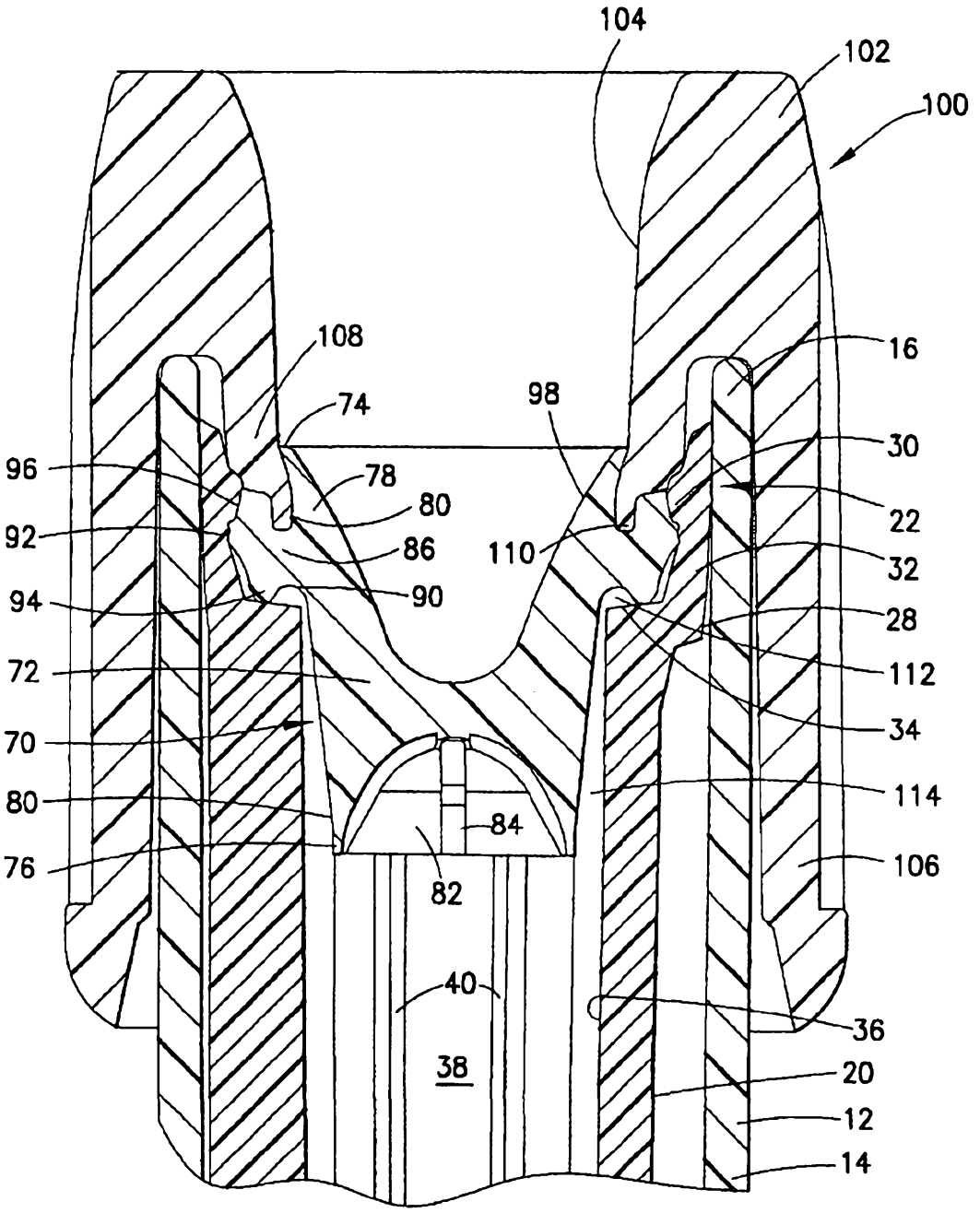

FIG.15

2012203335 06 Jun 2012

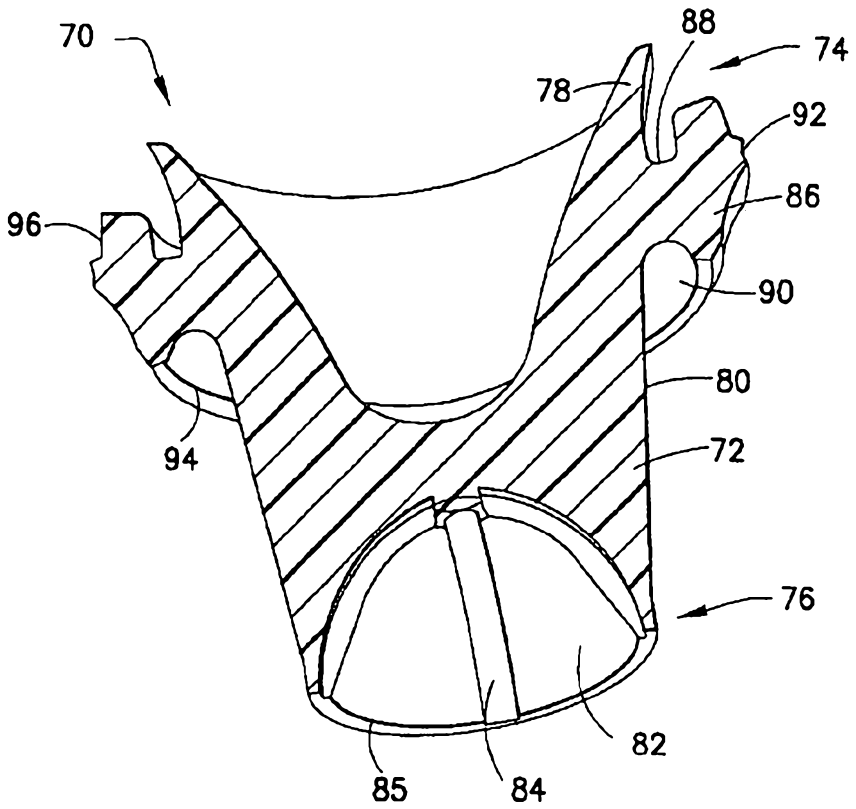

FIG.16

2012203335 06 Jun 2012

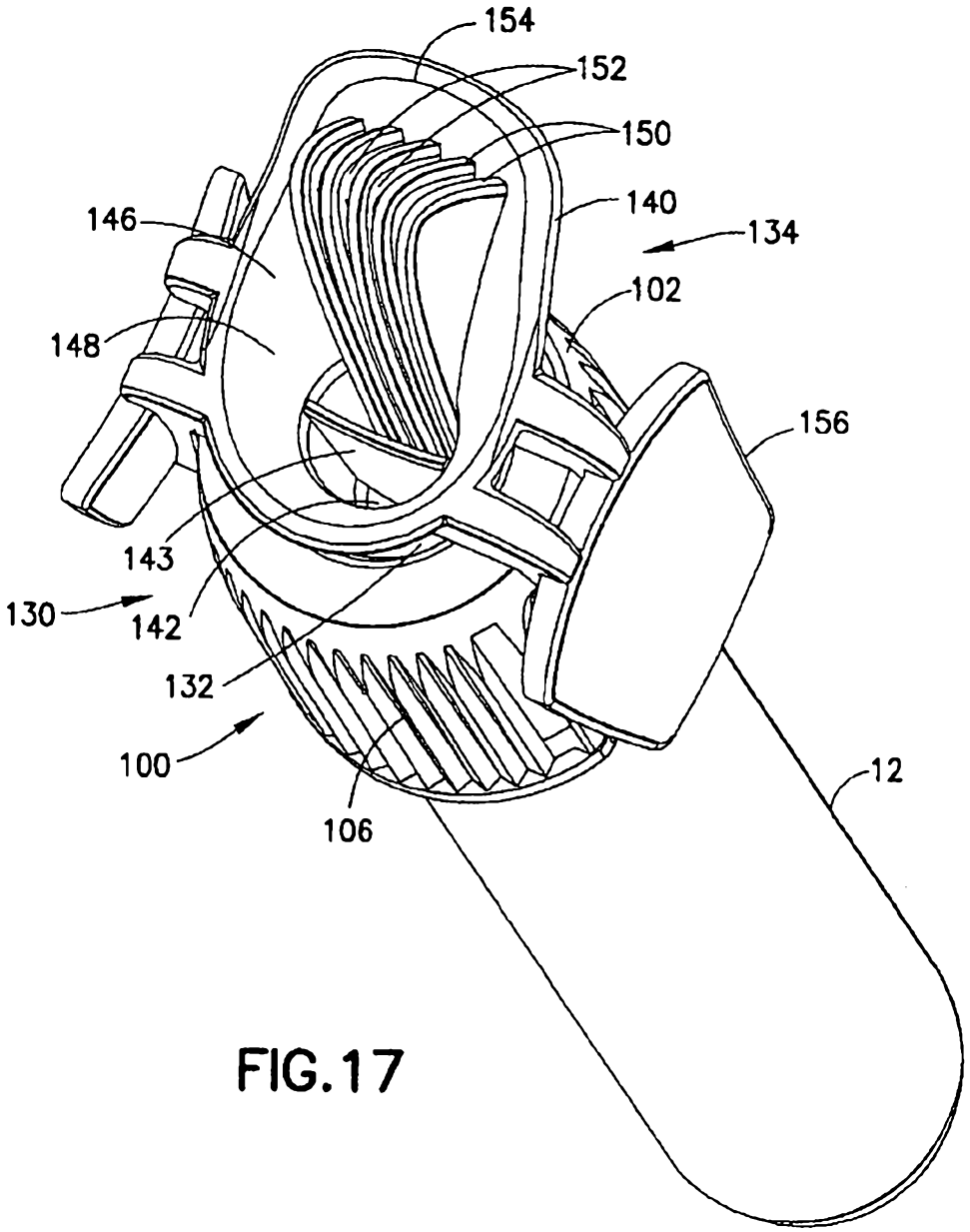

FIG.17

2012203335 06 Jun 2012

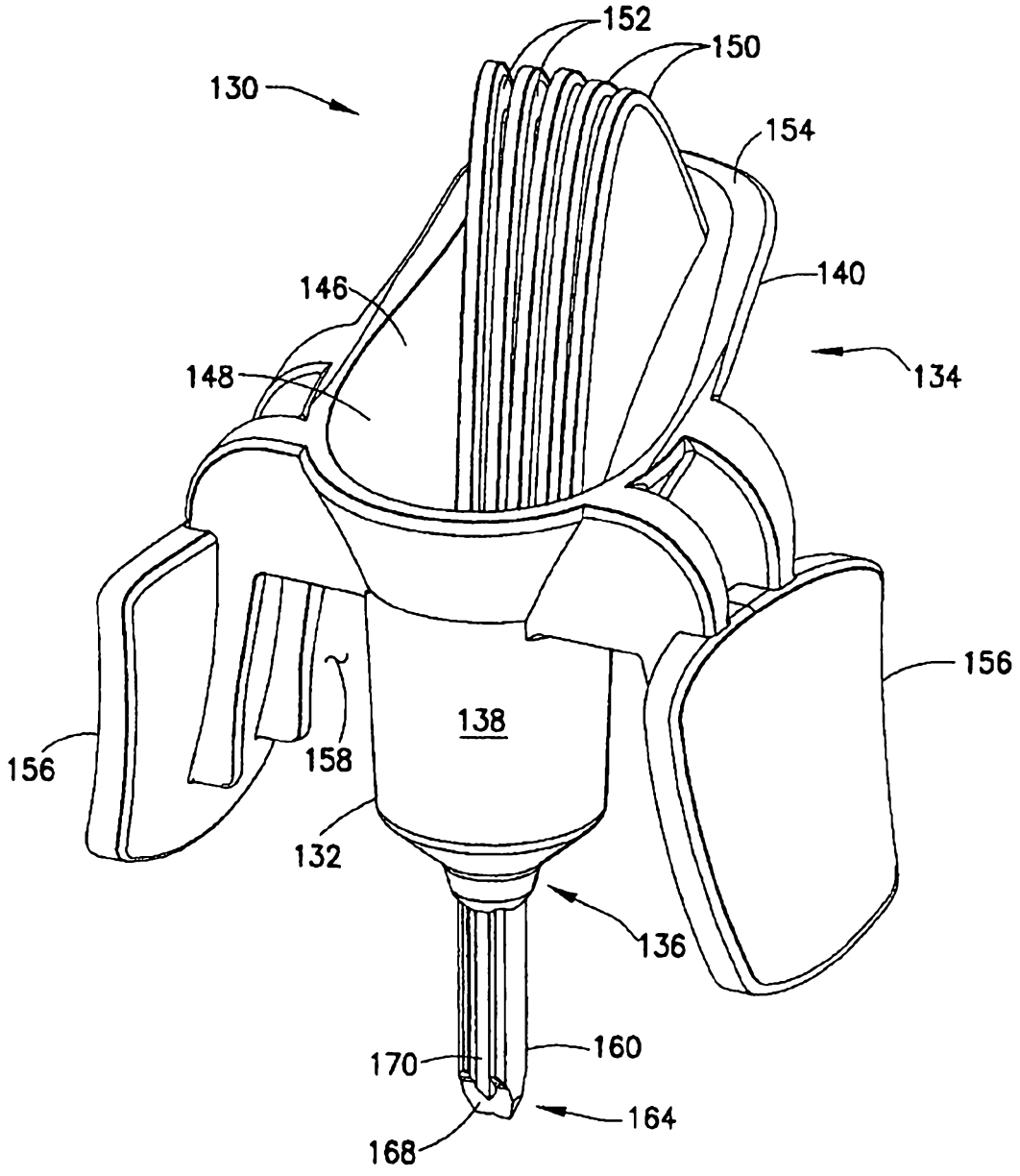

FIG.18

2012203335 06 Jun 2012

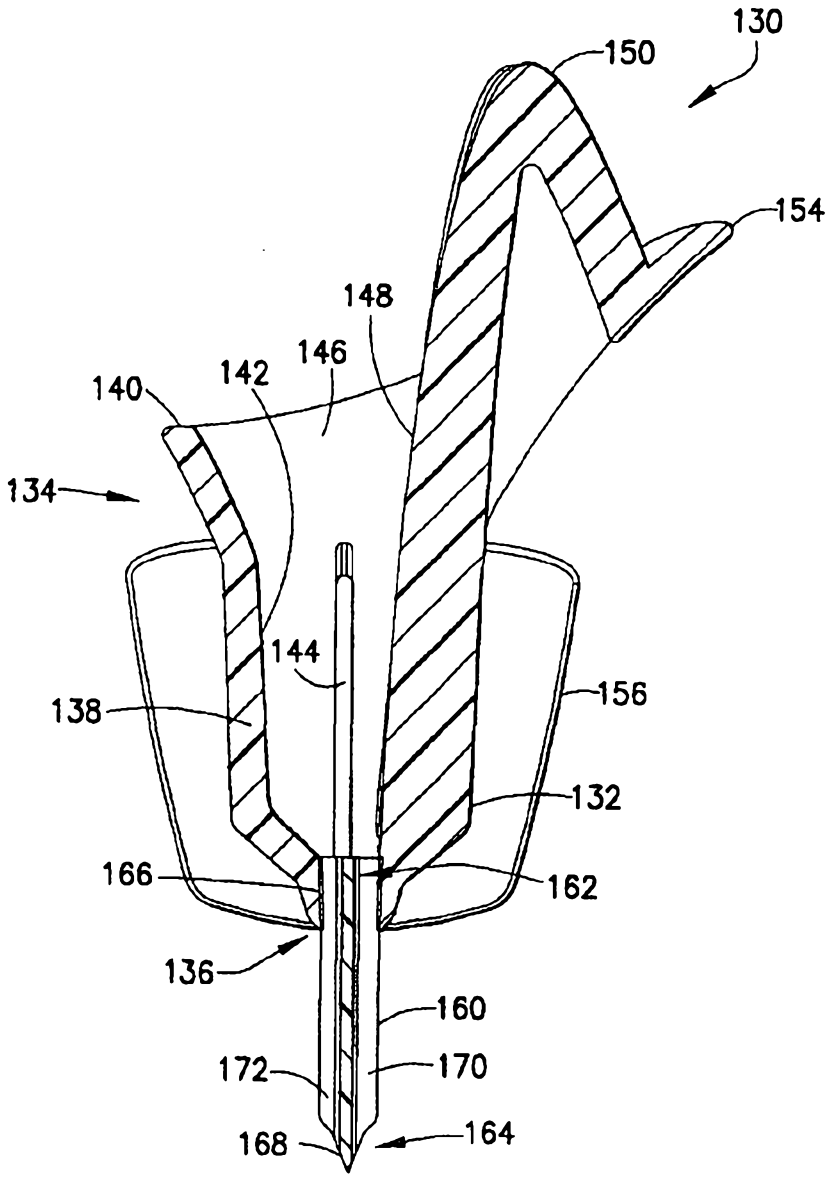

FIG.19

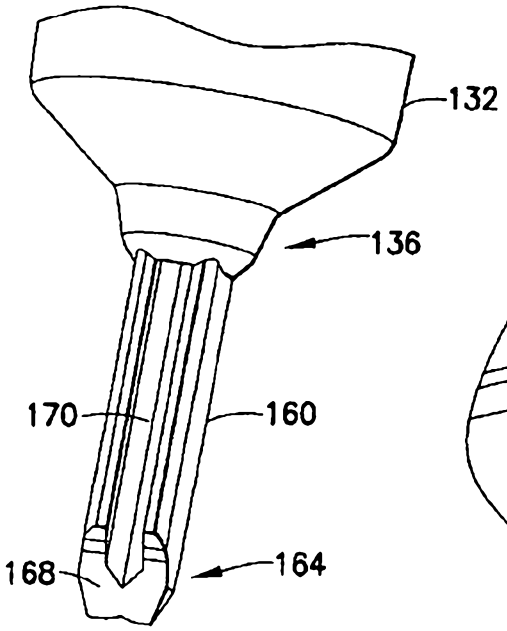

FIG.20

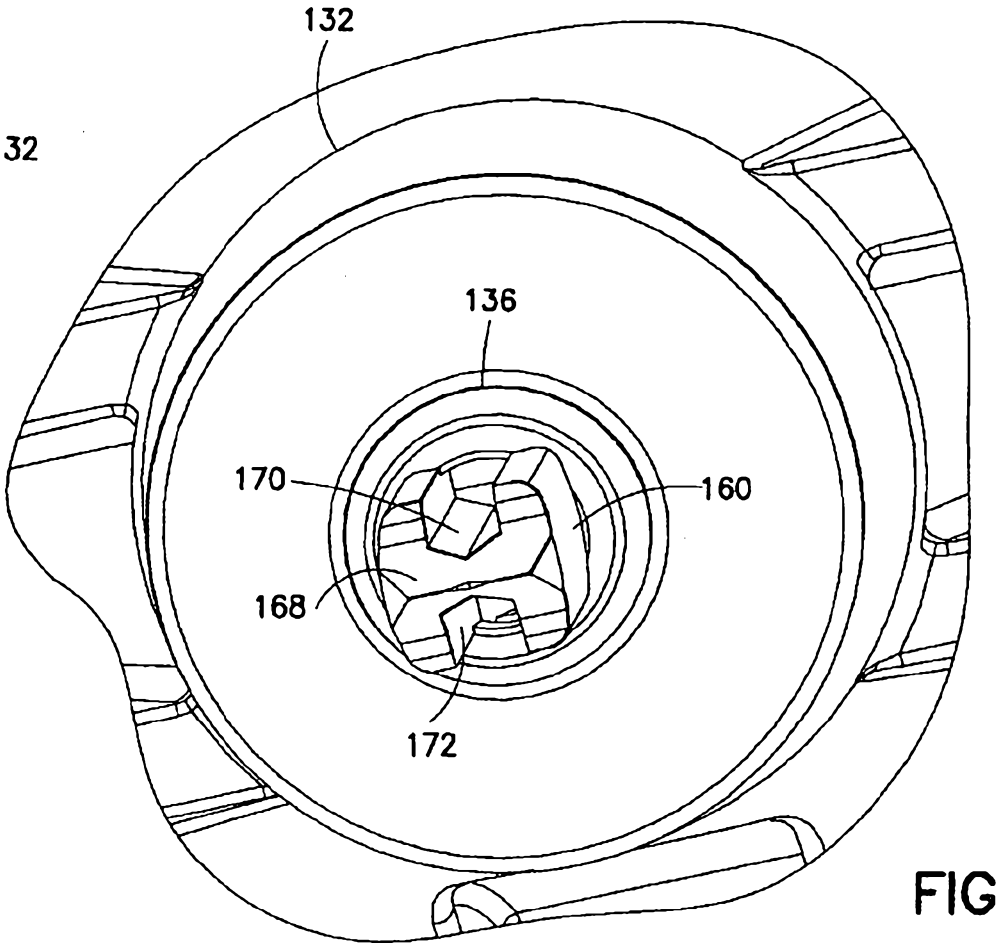

FIG.21

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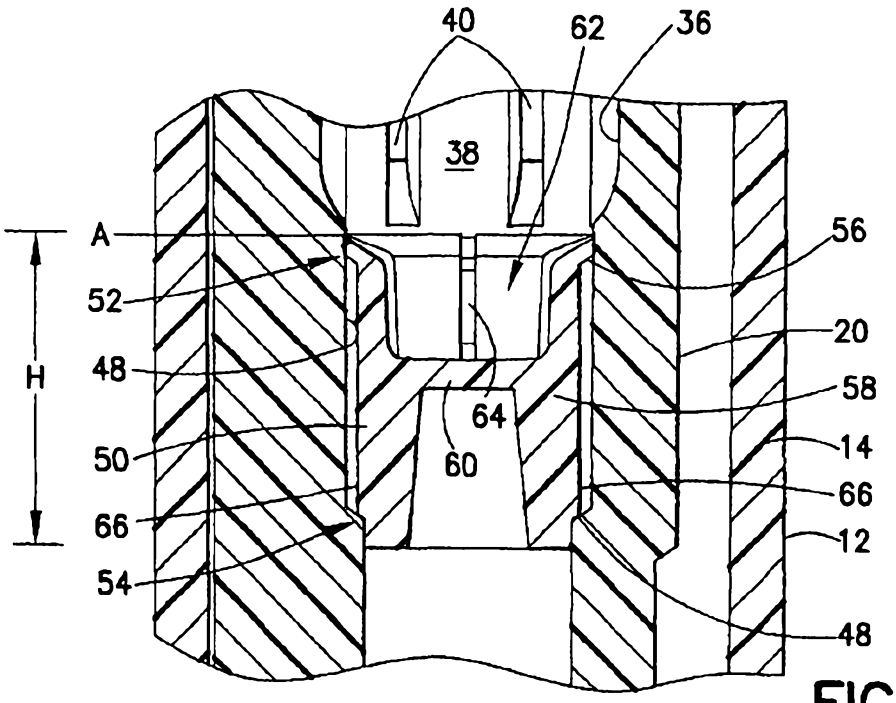

FIG.22

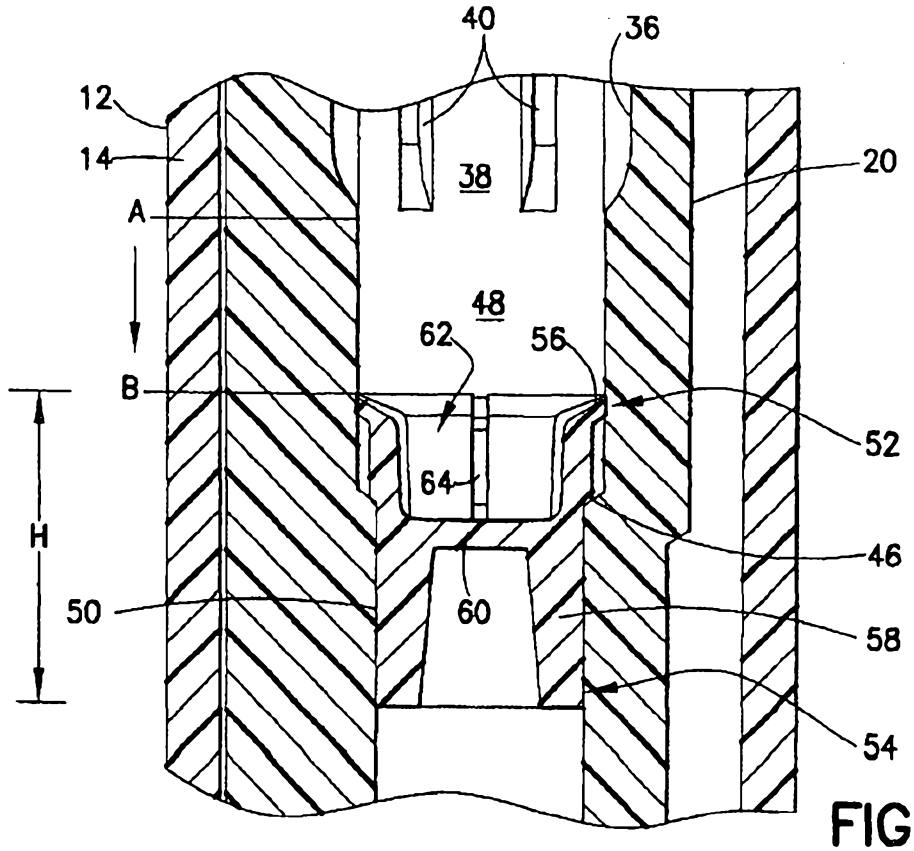

FIG.23

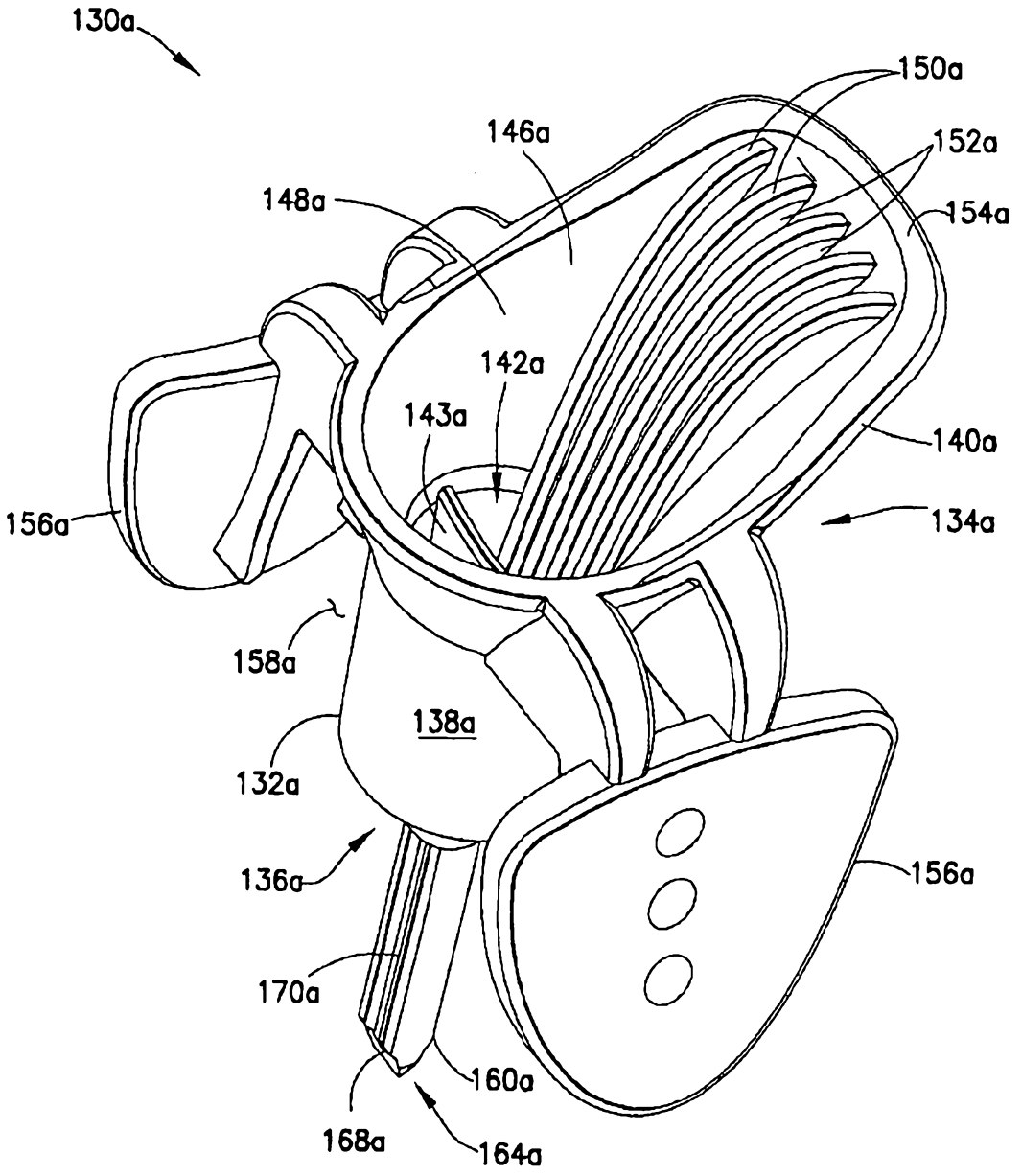
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FIG.24

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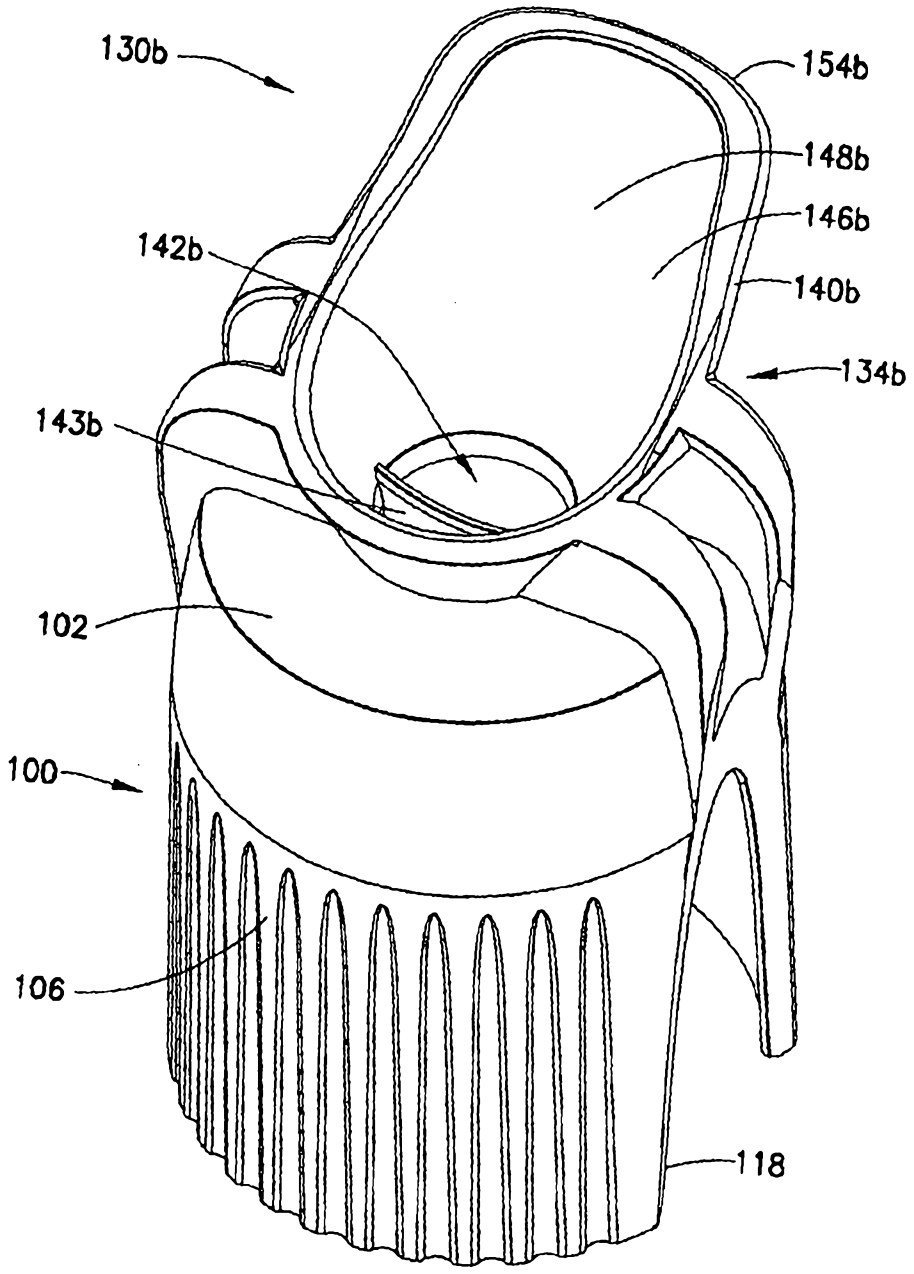

FIG.25

2012203335 06 Jun 2012

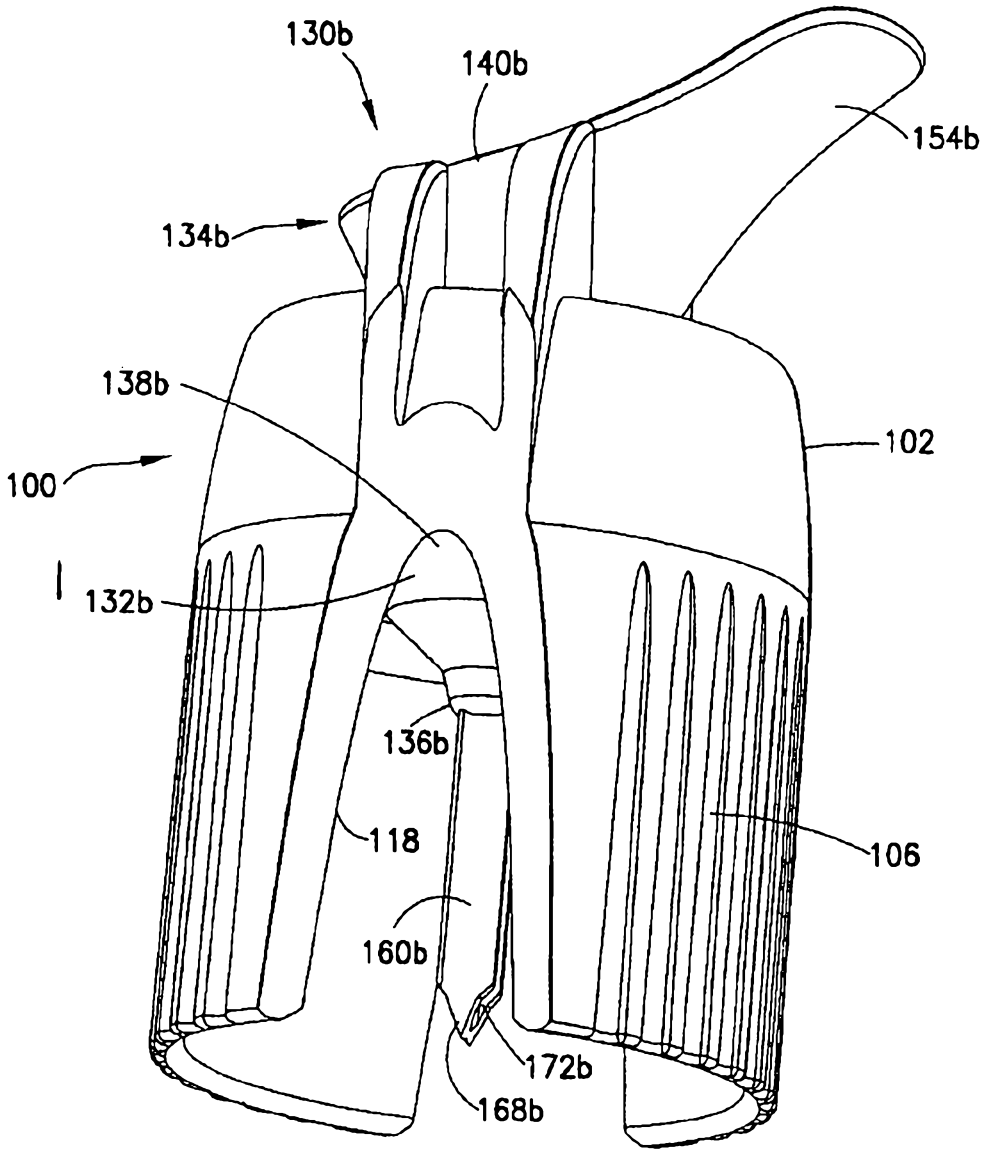

FIG.26