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(54) **TRANSVASCULAR PRESSURE SENSING DEVICE**

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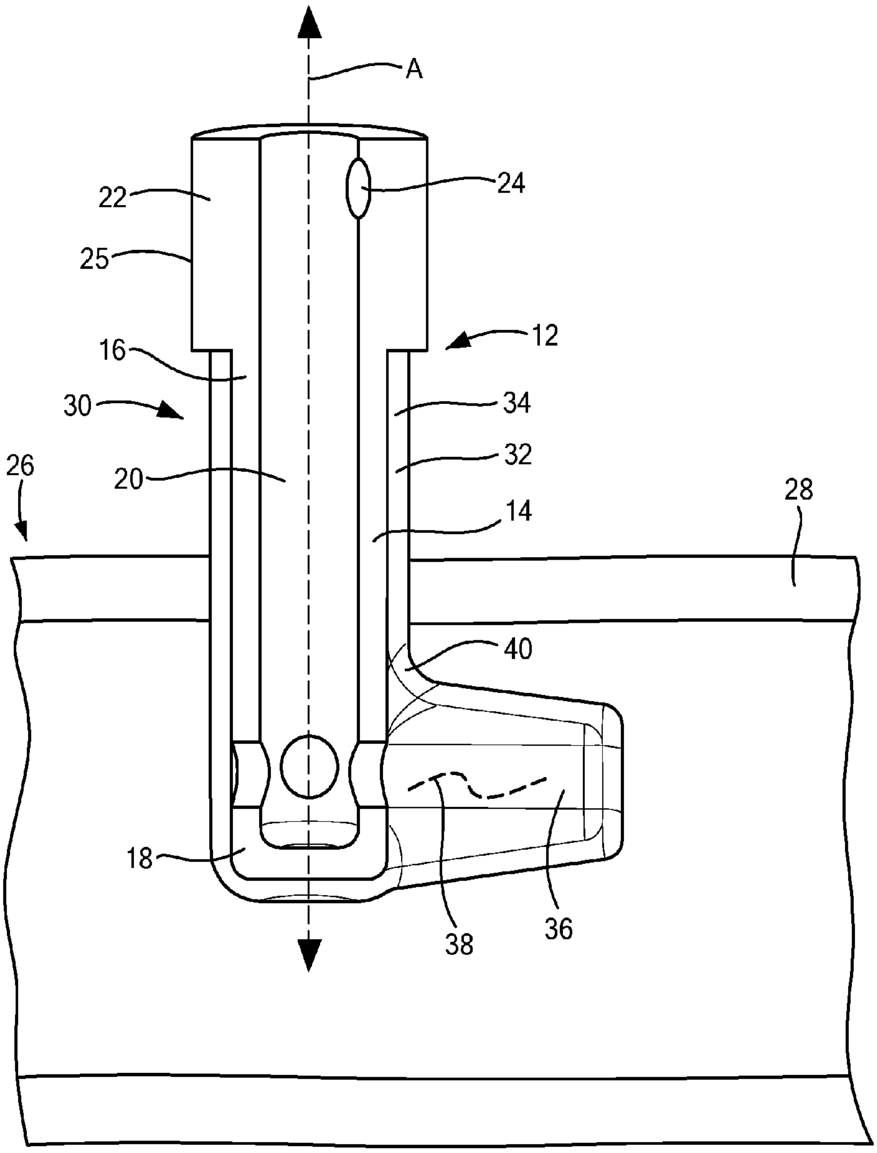
(57) **ABSTRACT**

A transvascular pressure sensing device including a housing having a proximal portion and a distal portion opposite the distal portion, the proximal portion including a blood pressure sensor disposed therein, a compliant balloon surrounding at least a portion of the housing and defining a fluid chamber therebetween, the fluid chamber including a first portion defining a first volume and a second portion defining a second volume greater than the first volume, and a fluid disposed within the fluid chamber and exerting a hydraulic pressure on the balloon, the blood pressure sensor being configured to measure a change in the hydraulic pressure when a force is distributed over the second portion of the balloon.



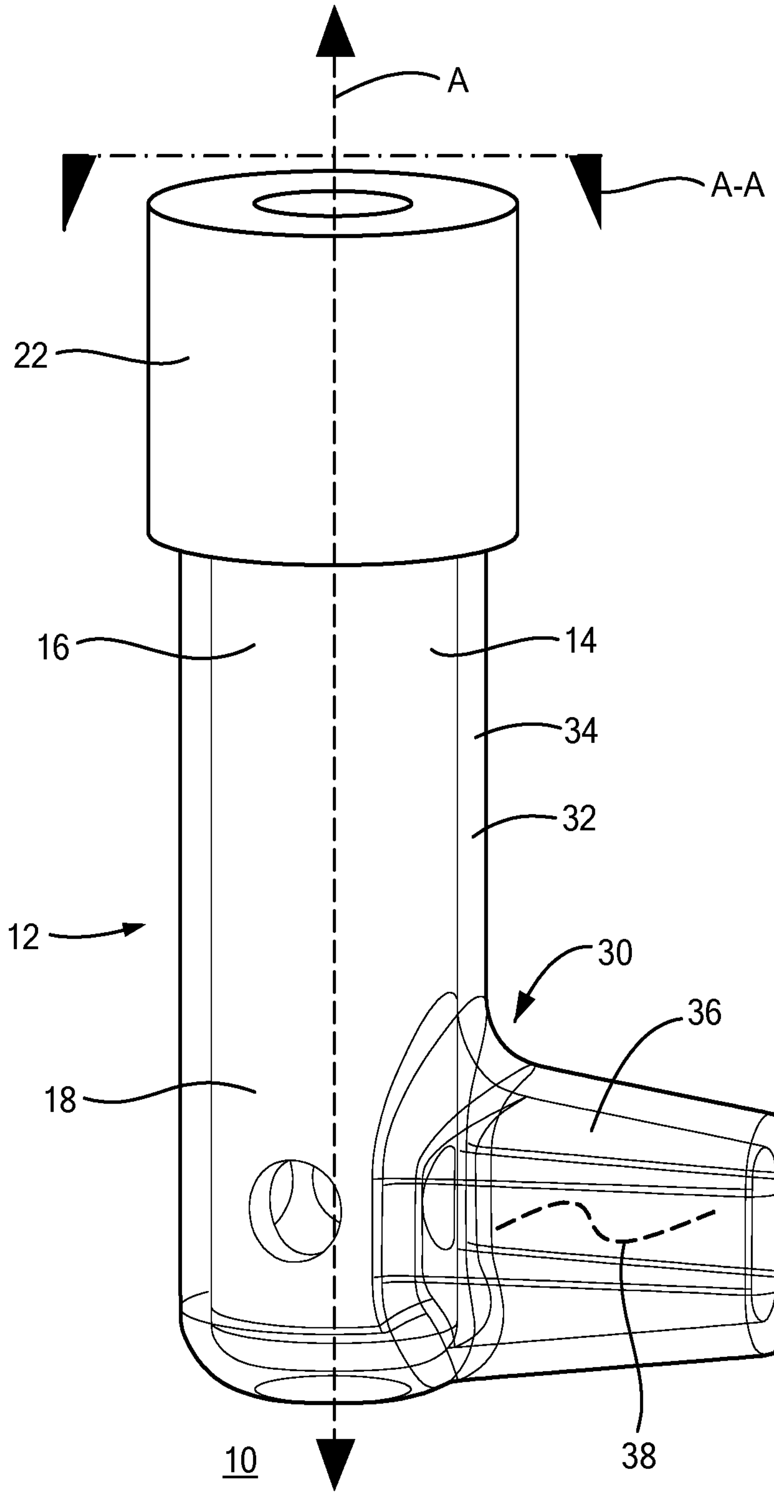


FIG. 1

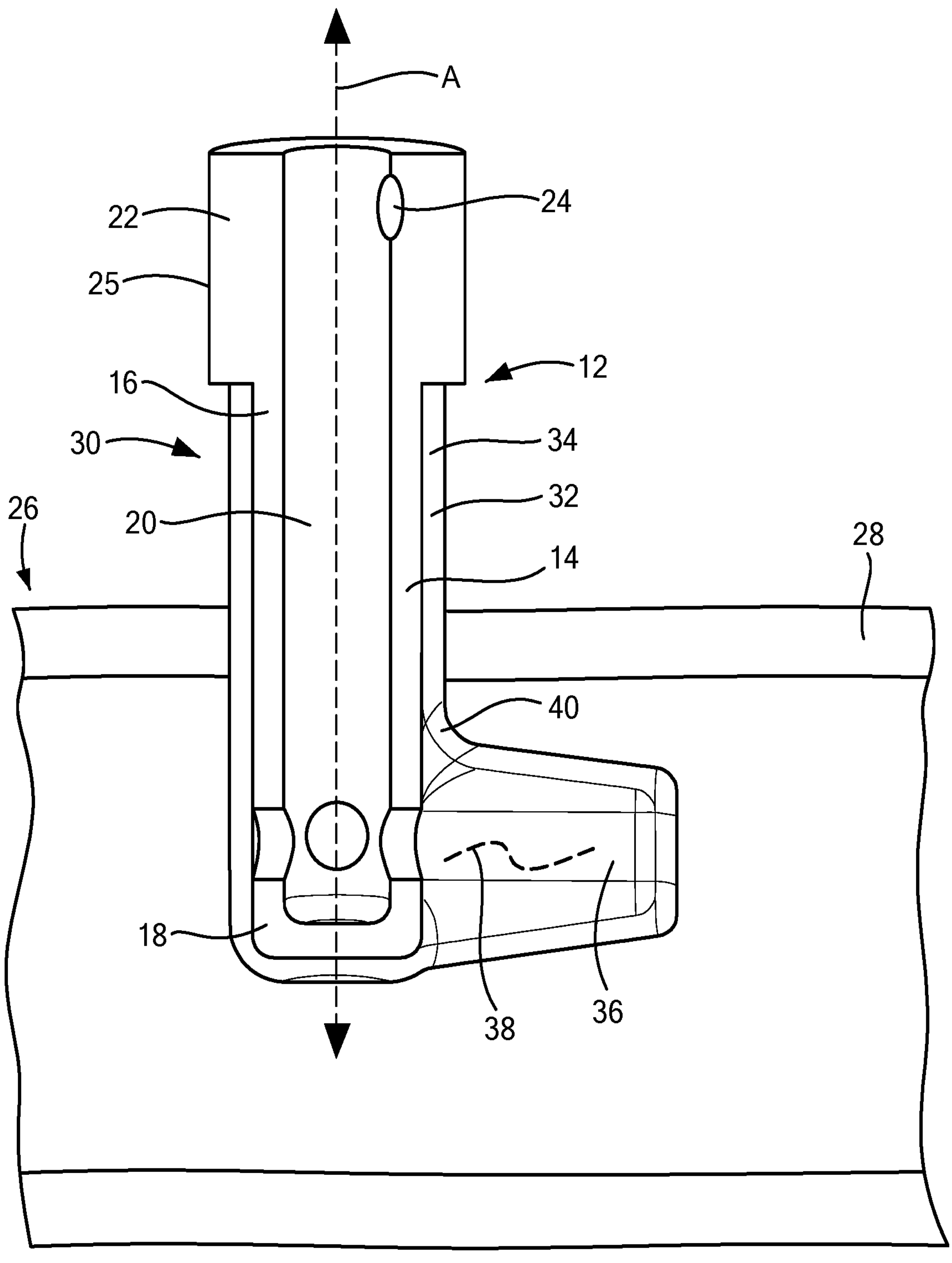


FIG. 2

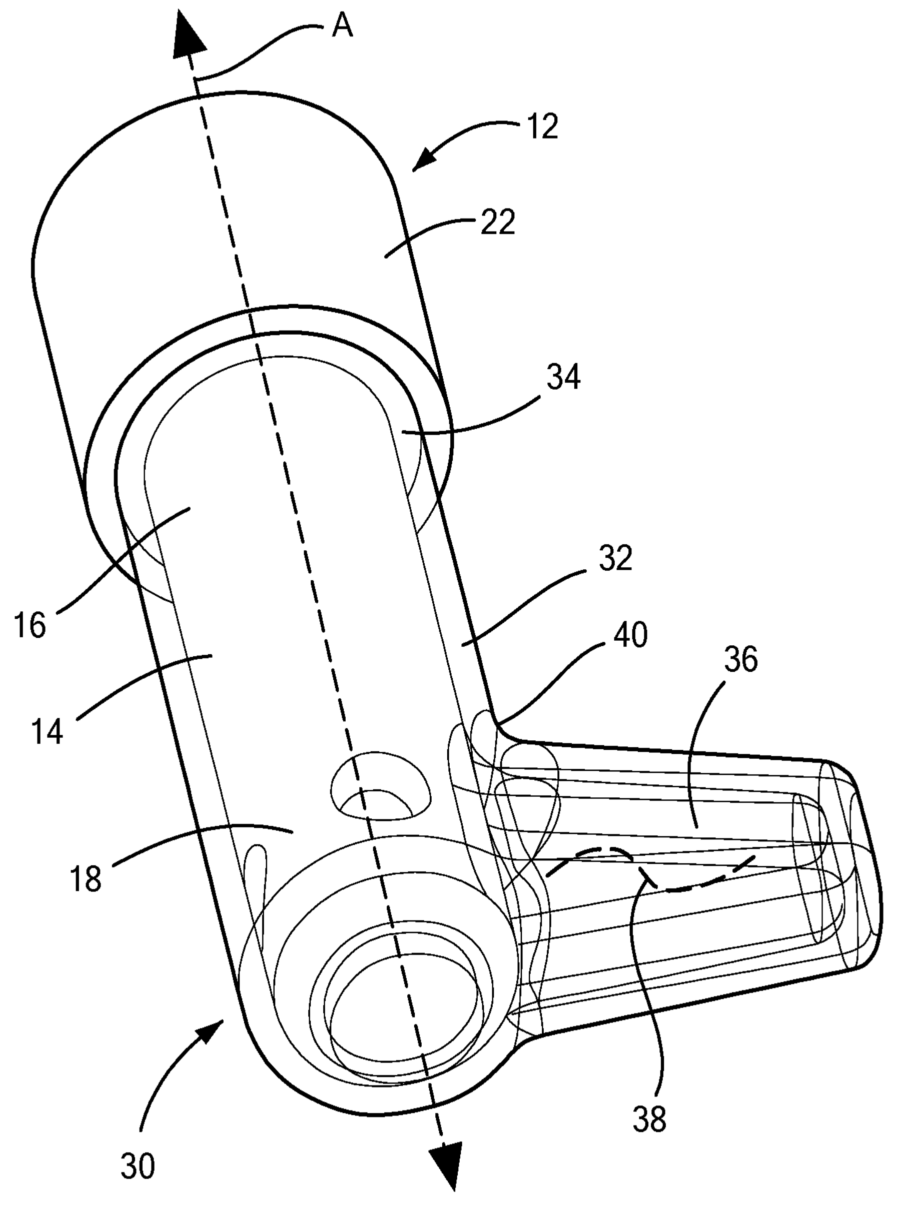


FIG. 3

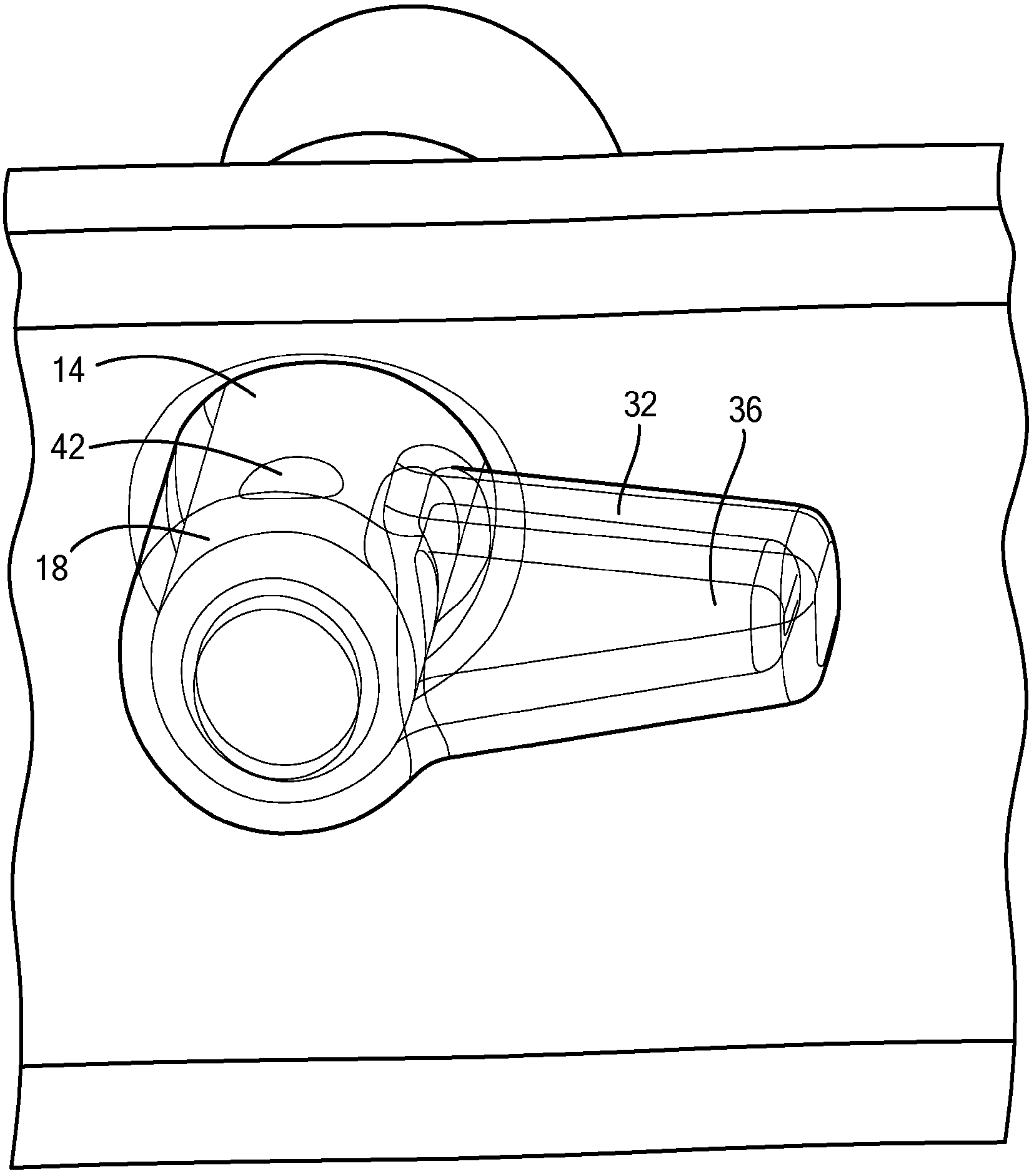


FIG. 4

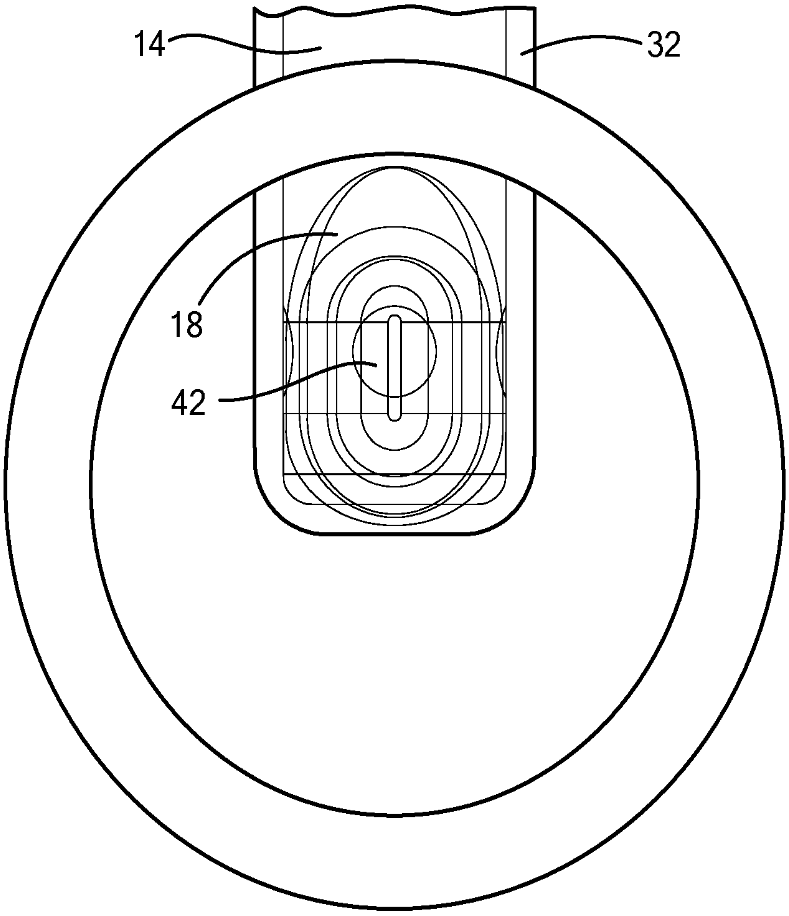


FIG. 5

TRANSVASCULAR PRESSURE SENSING DEVICE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application is related to and claims priority to U.S. Provisional Patent Application Ser. No. 62/678,296, filed May 31, 2018, entitled TRANSVASCULAR PRESSURE SENSING DEVICE, the entirety of which is incorporated herein by reference.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] n/a

FIELD

[0003] The present disclosure relates to a device and method for communicating a hydraulic blood pressure from within a blood vessel to outside of the blood vessel.

BACKGROUND

[0004] A patient's vital signs provide information useful for detecting and/or monitoring medical conditions. Known devices for measuring vital signs include, for example, blood pressure cuffs which attach to a patient's upper arm, pulse oximeters designed to be placed around the patient's fingertip, thermometers for measuring body temperature, stethoscopes for observing biological sounds, tonometers, and pressure transducers including those in the form of transvascular devices having metal diaphragms.

[0005] Known pressure transducers typically include a housing containing a pressure measuring system, a diaphragm, and a substance, such as oil, for transferring a pressure exerted on the diaphragm to the pressure measuring system. The manufacturing of such pressure transducers may be difficult as a deflection of the diaphragm at the diaphragm's center should be no greater than a thickness of the diaphragm for accuracy. Further, metal diaphragms are known to present problems, such as lack of sensitivity in addition to manufacturing limitations. For example, metal diaphragms having a diameter of approximately 1.0 millimeter are too small to compensate for relatively small variations in deflection leading to non-compliance. Moreover, known transvascular devices typically necessitate the presence of significant hardware inside the blood vessel that may be hazardous for the patient including blood flow obstructions and the potential for thrombus formation.

SUMMARY

[0006] The present invention advantageously provides a transvascular pressure sensing device having a housing including a proximal portion and an opposing distal portion, the proximal portion including a blood pressure sensor disposed therein, a compliant balloon surrounding at least a portion of the housing and defining a fluid chamber between the balloon and the portion of the housing, the fluid chamber including a first portion defining a first volume and a second portion defining a second volume greater than the first volume, and a fluid disposed within the fluid chamber and exerting a hydraulic pressure on the balloon, the blood pressure sensor being configured to measure a change in the hydraulic pressure when a force is distributed over the second portion of the balloon.

[0007] In another aspect of the invention, the balloon is made of a flexible polyurethane material having a width between 90 to 110 micrometers.

[0008] In another aspect of the invention, the balloon is configured to provide a uniform hydraulic pressure between the first portion and the second portion of the fluid chamber.

[0009] In another aspect of the invention, the housing is elongated and of a cylindrical shape.

[0010] In another aspect of the invention, the proximal portion and the distal portion of the housing define a housing axis extending therethrough, and the second portion of the fluid chamber is transverse with respect to the housing axis.

[0011] In another aspect of the invention, the balloon defines a partially enclosed internal channel extending from the proximal portion to the distal portion, and the distal portion defines a plurality of apertures extending therearound.

[0012] In another aspect of the invention, the proximal portion of the housing includes a sensor casing in fluid communication with the balloon and having the blood pressure sensor disposed therein.

[0013] In another aspect of the invention, the blood pressure sensor is a pressure sensitive MEMS device.

[0014] In another aspect of the invention, the first portion of the fluid chamber contours the proximal portion of the housing and the second portion of the fluid chamber extends away from the distal portion of the housing.

[0015] In another aspect of the invention, the second portion of the fluid chamber narrows in a direction away from the housing.

[0016] In another aspect of the invention, the fluid chamber is of an L-shape.

[0017] In another configuration, the present invention includes a blood pressure communication device having a blood pressure probe including a housing having a proximal portion, a distal portion opposite and proximal portion, and defining an internal channel extending therebetween, a balloon enclosing the internal channel, the balloon defining a tapered fluid chamber extending away from the distal portion of the housing, a fluid stored within the balloon, the fluid characterized by a hydraulic pressure equal to a pressure applied to the balloon, and a pressure sensor in communication with the housing, the pressure sensor being configured to measure the hydraulic pressure.

[0018] In another aspect of the invention, the balloon is configured to be disposed within a blood vessel and the pressure sensor is configured to be disposed outside of the blood vessel.

[0019] In another aspect of the invention, the fluid is a silicone.

[0020] In another aspect of the invention, the balloon is made of a polyurethane material.

[0021] In another aspect of the invention, the pressure sensor is a pressure sensitive MEMS device.

[0022] In another aspect of the invention, the distal portion of the housing defines an aperture extending therethrough, the aperture being in fluid communication with the internal channel.

[0023] In another aspect of the invention, the balloon is of an L-shape tapering in a direction away from the housing.

[0024] In another aspect of the invention, the balloon defines a circumference between 0.5 to 1.5 millimeters at the proximal portion of the housing.

[0025] In an additional configuration, the present invention includes an implantable blood pressure sensor having an elongated cylindrical housing including a first distal portion having a tip and a proximal portion opposite the distal portion, a flexible diaphragm at least partially surrounding the housing and including an extension member extending away from the housing, the extension member defining a fluid chamber between the flexible diaphragm and the second portion of the housing, a non-compressible fluid disposed within the fluid chamber, the non-compressible fluid including a hydraulic pressure equal to a pressure applied to the diaphragm, and a pressure sensor disposed within the tip of the housing for measuring a change in the hydraulic pressure resulting from the pressure applied to the diaphragm.

BRIEF DESCRIPTION OF THE DRAWINGS

[0026] A more complete understanding of the present application, and the attendant advantages and features thereof, will be more readily understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

[0027] FIG. **1** is a side view of a blood pressure communication device including a blood pressure probe having a housing and a compliant balloon surrounding at least a portion of the housing in accordance with the present invention;

[0028] FIG. **2** is a side cross-sectional view of the blood pressure communication device taken along section A-A of FIG. **1** and being disposed within an exemplary blood vessel in accordance with the present invention;

[0029] FIG. **3** is a perspective bottom view of the blood pressure communication device of FIG. **1** in accordance with the present invention;

[0030] FIG. **4** is a partial perspective bottom view of the blood pressure communication device of FIG. **1** disposed within an exemplary blood vessel in accordance with the present invention; and

[0031] FIG. **5** is a partial side view of the blood pressure communication device of FIG. **1** disposed within an exemplary blood vessel in accordance with the present invention.

DETAILED DESCRIPTION

[0032] Before describing in detail exemplary embodiments, it is noted that the embodiments reside primarily in combinations of device and method steps related to communicating a hydraulic blood pressure from within a blood vessel to outside of the blood vessel. Accordingly, the device and method steps have been represented where appropriate by conventional symbols in the drawings, showing only those specific details that are pertinent to understanding the embodiments of the present disclosure so as not to obscure the disclosure with details that will be readily apparent to those of ordinary skill in the art having the benefit of the description herein.

[0033] As used herein, relational terms, such as "first" and "second," "top" and "bottom," and the like, may be used solely to distinguish one entity or element from another entity or element without necessarily requiring or implying any physical or logical relationship or order between such entities or elements. The terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the concepts described herein. As used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises," "comprising," "includes" and/or "including" when used herein, specify the presence of stated features, integers, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, integers, steps, operations, elements, components, and/or groups thereof.

[0034] Unless otherwise defined, all terms (including technical and scientific terms) used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosure belongs. It will be further understood that terms used herein should be interpreted as having a meaning that is consistent with their meaning in the context of this specification and the relevant art and will not be interpreted in an idealized or overly formal sense unless expressly so defined herein.

[0035] In embodiments described herein, the joining term, "in communication with" and the like, may be used to indicate electrical or data communication, which may be accomplished by physical contact, induction, electromagnetic radiation, radio signaling, infrared signaling or optical signaling, for example. One having ordinary skill in the art will appreciate that multiple components may interoperate and modifications and variations are possible of achieving the electrical and data communication.

[0036] Referring now to the drawings in which like reference designators refer to like elements there is shown in FIGS. **1-2** an exemplary blood pressure communication device generally designated as "**10**." FIG. **1** depicts a side view of the device **10** and FIG. **2** depicts a side cross-sectional view of the device **10** taken along section A-A of FIG. **1**. The blood pressure communication device **10** may be referred to herein as a transvascular pressure sensing device or "the device **10**" and includes a blood pressure probe **12** configured to be at least partially implanted in a blood vessel of a patient, such as a human or animal patient, for communicating a hydraulic pressure within the blood vessel to a pressure sensor outside of the blood vessel.

[0037] The probe **12** may include a housing **14** having a proximal portion **16** and a distal portion **18** opposite the proximal portion **16**. The proximal portion **16** and the distal portion **18** define a housing axis "A" extending therethrough and, as shown in FIG. **2**, an internal channel **20** extending along the housing axis. The housing **14** is made of a biocompatible material, such as and without limitation, a polyurethane material that may be elongated and of a cylindrical shape, although other shapes are within the scope of the present invention.

[0038] The proximal portion **16** of the housing **14** may include a tip **22** or stem made of a rigid polyurethane material for housing a blood pressure sensor **24** therein. The blood pressure sensor **24** may be disposed within a sensor casing **25** in the proximal portion **16** of the housing. The sensor casing **25** may be made from a biocompatible material or other material that is safe to use inside the body for long or short periods of time. As depicted using an exemplary blood vessel **26** of FIG. **2**, the blood pressure sensor **24** may be disposed outside of a wall **28** of the blood vessel **26**, whereas the distal portion **18** may be transvascular, i.e., configured to be disposed through the wall **28** of the blood vessel **26**. Although the pressure sensor **24** is depicted within the tip **22**, in other configurations, the pressure sensor **24** may be disposed in a separate housing (not shown) in communication with the probe **12** or the pressure sensor may be disposed in another location in the device **10**. In one configuration, the pressure sensor **24** is a pressure sensitive MEMS device, however other types of pressure sensors **24** may be used which are configured to measure hydraulic pressure. The term "hydraulic pressure" generally refers to fluid in a confined space, i.e. a closed system, wherein the fluid is a medium to transmit force. This is in accordance with the discovery of Pascal that a pressure applied to any part of a confined fluid transmits to every other part with no loss. The pressure acts with equal force on all equal areas of the confining walls in a direction perpendicular to the wall surfaces. The pressure sensor **24** may be coupled to one or more electronic circuits, a display, and the like (not shown) associated with power and operation of the pressure sensor **24**.

[0039] A compliant balloon **30** surrounds at least a portion of the housing **14** and defines a fluid chamber **32** between the housing **14** and the balloon **30**. In one configuration, the balloon **30** may be a flexible diaphragm that at least partially surrounds the housing **14**. In other words, the housing **14** and the balloon **30** define a space or gap therebetween and the fluid chamber **32** is within the space or gap. In one configuration, the balloon **30** is made of a material such as a flexible polyurethane manufactured and sold under the name Biospan® having a width between 90 to 110 micrometers ("um"). In other configurations the balloon **30** may be made of another flexible material having various widths or thicknesses and may also be characterized as a flexible diaphragm. The sensor casing **25** may be in fluid communication with the balloon **30** and the blood pressure sensor **24** may be disposed within the sensor casing **25**.

[0040] The fluid chamber **32** includes a first portion **34** surrounding some or all of the proximal portion **16** of the housing **14** and a second portion **36** surrounding the distal portion **18** of the housing **14** to at least partially enclose the internal channel **20**. In particular, the first portion **34** of the fluid chamber **32** contours the housing **14**, whereas the second portion **36** of the fluid chamber **32** extends away from the housing **14**. The second portion **36** of the fluid chamber **32** may also be an extension member of the housing **14** that extends away from the housing **14** and the extension member may define a fluid chamber **32** between the balloon **30**/flexible diaphragm and the distal portion **18** of the housing **14**. For example, the first portion **34** of the fluid chamber **32** contours the proximal portion **16** of the housing and the second portion **36** of the fluid chamber **32** extends away from the distal portion **18** of the housing **14**. As such, the first portion **34** defines a first volume and the second portion **36** defines a second volume greater than the first volume for storing a fluid **38** that exerts or exhibits a hydraulic pressure on the balloon **30**. The fluid **38** may be a non-compressible fluid such as, without limitation, a silicone.

[0041] When the distal portion **18** of the probe **12** and the second portion **36** of the fluid chamber **32** are disposed within the blood vessel **26**, the hydraulic pressure of the fluid **38** within the fluid chamber **32** is approximately equal to a force or pressure applied to the balloon **30** by the blood vessel **26**. Such hydraulic pressure, including any changes to the hydraulic pressure as a result of the force from the blood vessel **26**, may be measured by the blood pressure sensor **24** disposed outside of the blood vessel **26**. In other words, the device **10** is configured to provide communication of the hydraulic pressure within the blood vessel **26** to the pressure sensor **24** outside of the blood vessel **26**. The material of the balloon **30** is sufficiently thin and flexible to provide a uniform hydraulic pressure between the first portion **34** and the second portion **36** of the fluid chamber **32**. In other words, the material and flexibility of the balloon **30** is sufficient to prevent a pressure differential between the fluid pressure within the balloon **30** and the blood pressure around the second portion **36** of the fluid chamber **32**. Additionally, any fluid stored within the balloon **30** may have a hydraulic pressure of the fluid **38** that is equal to the pressure which is applied to the balloon **30**. In one configuration, the non-compressible fluid may be characterized by a hydraulic pressure of the fluid **38** that is equal to the pressure applied to the balloon **30**/flexible diaphragm.

[0042] With reference to FIGS. **1-3**, the second portion **36** of the fluid chamber **32** is depicted transverse with respect to the housing axis and including an L-shape that narrows or tapers in a direction away from the distal portion **18** of the housing **14**. The structure of the balloon **30** allows the second portion **36** of the fluid chamber **32** to be isolated from the blood vessel wall **28** while being positioned in a blood flow path through the blood vessel **26**. When the balloon **30** is covering the fluid chamber **32**, the balloon **30** may have an L-shape that narrows or tapers in a direction away from the housing **14**.

[0043] In one exemplary configuration, the balloon **30** defines a circumference between 0.5 to 1.5 millimeters around the housing **14** at a location adjacent a curved transition region **40** where the balloon expands to define the second portion **36** of the fluid chamber **32** having the L-shaped volumetric boundary with the volume greater than that of the first portion **34**. The pressure sensitivity of the device **10** can be maintained despite small changes in mechanical properties of the polymer material of the device **10** and despite small changes in the volume of the fluid **38** as a result of the relatively large diaphragmatic surface of the second portion **36** of the fluid chamber **32** relative to the first portion **34**.

[0044] Referring now to FIGS. **4** and **5**, the distal portion **18** of the housing **14** defines one or more apertures **42** extending therethrough, the apertures **42** being in fluid communication with the internal channel **20** (FIG. **2**) to establish fluid communication between the second portion **36** of the balloon **30** and the pressure sensor **24** (FIG. **2**). The internal channel **20** may be a partially enclosed and/or fully enclosed internal channel **20**. The number of apertures **42** is not limited to a particular number and may include one aperture, 3-4 apertures extending around the circumference of the housing **14**, or another configuration suitable for providing fluid communication along the internal channel **20**. The balloon **30** may enclose the internal channel **20** and the balloon **30** may define a tapered fluid chamber **32** which extends away from the distal portion **18** of the housing **14**.

[0045] It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described herein above. In addition, unless mention was made above to the contrary, it should be noted that all of the accompanying drawings are not to scale. A variety of modifications and variations are possible in light of the above teachings without departing from the scope and spirit of the invention, which is limited only by the following claims.

What is claimed is:

1. A transvascular pressure sensing device comprising:

a housing including a proximal portion and a distal portion opposite the distal portion, the proximal portion including a blood pressure sensor disposed therein;

a compliant balloon surrounding at least a portion of the housing and defining a fluid chamber between the balloon and the portion of the housing, the fluid chamber including a first portion defining a first volume and a second portion defining a second volume greater than the first volume; and

a fluid disposed within the fluid chamber and exerting a hydraulic pressure on the balloon, the blood pressure sensor being configured to measure a change in the hydraulic pressure when a force is distributed over the second portion of the balloon.

2. The pressure sensing device of claim **1**, wherein the balloon is made of a flexible polyurethane material having a width between 90 to 110 micrometers.

3. The pressure sensing device of claim **1**, wherein the balloon is configured to provide a uniform hydraulic pressure between the first portion and the second portion of the fluid chamber.

4. The pressure sensing device of claim **1**, wherein the housing is elongated and of a cylindrical shape.

5. The pressure sensing device of claim **1**, wherein the proximal portion and the distal portion of the housing define a housing axis extending therethrough, and the second portion of the fluid chamber is transverse with respect to the housing axis.

6. The pressure sensing device of claim **1**, wherein the balloon defines a partially enclosed internal channel extending from the proximal portion to the distal portion, and the distal portion defines a plurality of apertures extending therearound.

7. The pressure sensing device of claim **1**, wherein the proximal portion of the housing includes a sensor casing in fluid communication with the balloon and having the blood pressure sensor disposed therein.

8. The pressure sensing device of claim **1**, wherein the blood pressure sensor is a pressure sensitive MEMS device.

9. The pressure sensing device of claim **1**, wherein the first portion of the fluid chamber contours the proximal portion of the housing and the second portion of the fluid chamber extends away from the distal portion of the housing.

10. The pressure sensing device of claim **9**, wherein the second portion of the fluid chamber narrows in a direction away from the housing.

11. The pressure sensing device of claim **1**, wherein the fluid chamber is of an L-shape.

12. A blood pressure communication device comprising:

a blood pressure probe including a housing having a proximal portion, a distal portion opposite the proximal portion, and defining an internal channel extending therebetween;

a balloon enclosing the internal channel, the balloon defining a tapered fluid chamber extending away from the distal portion of the housing;

a fluid stored within the balloon, the fluid characterized by a hydraulic pressure equal to a pressure applied to the balloon; and

a pressure sensor in communication with the housing, the pressure sensor being configured to measure the hydraulic pressure.

13. The blood pressure communication device of claim **12**, wherein the balloon is configured to be disposed within a blood vessel and the pressure sensor is configured to be disposed outside of the blood vessel.

14. The blood pressure communication device of claim **12**, wherein the fluid is a silicone.

15. The blood pressure communication device of claim **12**, wherein the balloon is made of a polyurethane material.

16. The blood pressure communication device of claim **12**, wherein the pressure sensor is a pressure sensitive MEMS device.

17. The blood pressure communication device of claim **12**, wherein the distal portion of the housing defines an aperture extending therethrough, the aperture being in fluid communication with the internal channel.

18. The blood pressure communication device of claim **12**, wherein the balloon is of an L-shape tapering in a direction away from the housing.

19. The blood pressure communication device of claim **12**, wherein the balloon defines a circumference between 0.5 to 1.5 millimeters at the proximal portion of the housing.

20. An implantable blood pressure sensor comprising:

an elongated cylindrical housing including a proximal portion having a tip and a distal portion opposite the proximal portion;

a flexible diaphragm at least partially surrounding the housing and including an extension member extending away from the housing, the extension member defining a fluid chamber between the flexible diaphragm and the distal portion of the housing;

a non-compressible fluid disposed within the fluid chamber, the non-compressible fluid characterized by a hydraulic pressure equal to a pressure applied to the diaphragm; and

a pressure sensor disposed within the tip of the housing for measuring a change in the hydraulic pressure resulting from the pressure applied to the diaphragm.

* * * * *

patsnap

专利名称(译)	经血管压力传感装置		
公开(公告)号	US20190365326A1	公开(公告)日	2019-12-05
申请号	US16/423515	申请日	2019-05-28
[标]发明人	VERKAIK JOSIAH		
发明人	VERKAIK, JOSIAH		
IPC分类号	A61B5/00 A61B5/0235 A61B5/0215		
CPC分类号	A61B5/0215 A61B5/02241 A61B2562/028 A61B5/0235 A61B5/6876 A61B5/6884 A61B5/02141 A61B5/6865 A61B5/6866		
优先权	62/678296 2018-05-31 US		
外部链接	Espacenet USPTO		

摘要(译)

一种跨血管压力感测装置，包括：具有壳体的壳体，该壳体具有近侧部分和与该远侧部分相对的远侧部分，该近侧部分包括设置在其中的血压传感器；顺应性球囊，该顺应性球囊围绕壳体的至少一部分并且在其之间限定流体室， 所述流体腔室包括：第一部分，其限定第一体积；第二部分，其限定大于所述第一体积的第二体积；以及流体，其布置在所述流体室内并向所述球囊施加液压，所述血压传感器配置为测量 当力分布在球囊的第二部分上时液压的变化。