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(71) Applicant *(for all designated States except US)*: **CARBOMEDICS INC.** [US/US]; 1300 East Anderson Lane, Austin, TX 78752 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **SAUTER, Joseph, A.** [US/US]; 5101 Bervely Skyline, Austin, TX 78731 (US).

(74) Agent: **EICH, Raymund, F., Ph., D.**; Williams, Morgan & Amerson, 10333 Richmond, Suite 1100, Houston, TX 77042 (US).

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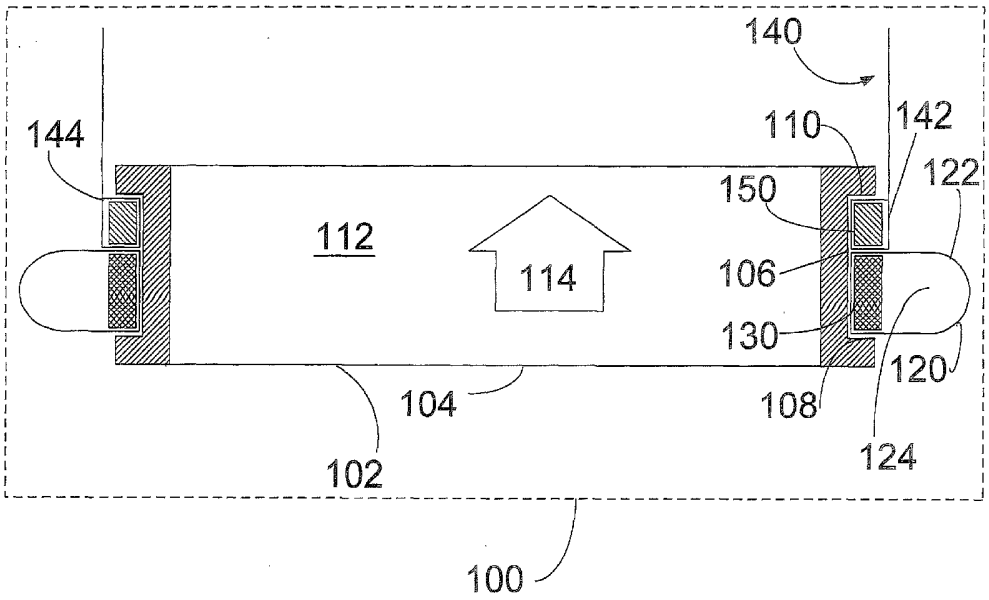
(54) Title: IMPLANTABLE PROSTHETIC HEART VALVE COMPRISING A VALVE BODY AND A TUBULAR VASCULAR GRAFT



(57) Abstract: We disclose an implantable prosthetic heart valve, comprising: a valve body comprising an orifice member, wherein the orifice member comprises an external groove; a sewing cuff; a sewing cuff retaining member seated within the external groove of the orifice member and coupling the sewing cuff to the orifice member; a tubular vascular graft; and a graft retaining member seated within the external groove of the orifice member and coupling the tubular vascular graft to the orifice member.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

IMPLANTABLE PROSTHETIC HEART VALVE COMPRISING A VALVE BODY AND A TUBULAR VASCULAR GRAFT

BACKGROUND OF THE INVENTION

The present invention relates generally to the field of prosthetic heart valves. More particularly, it concerns prosthetic heart valves combined with a tubular vascular graft.

In the mammalian heart, deoxygenated blood flows into the right atrium through the superior vena cava and the inferior vena cava. Upon contraction of the right atrium, the deoxygenated blood flows into the right ventricle. When the right ventricle contracts, the deoxygenated blood is pumped through the pulmonary artery to the lungs. Oxygenated blood returning from the lungs enters the left atrium. From the left atrium, the oxygenated blood flows into the left ventricle, which in turn pumps oxygenated blood to the body via the aorta and lesser arteries branching thereoff.

This pumping action is repeated in a rhythmic cardiac cycle in which the ventricular chambers alternately contract and pump, then relax and fill. As is well known, a series of one-way cardiac valves prevent backflow of the blood as it moves through the heart and the circulatory system. Between the atrial and ventricular chambers in the right and left sides of the heart are the tricuspid valve and the mitral valve, respectively. At the exits of the right and left ventricles are the pulmonic and aortic valves, respectively.

It is well known that various heart diseases may result in disorders of the cardiac valves. For example, diseases such as rheumatic fever can cause the shrinking or pulling apart of the valve orifice, while other diseases may result in endocarditis, an inflammation of the endocardium (membrane lining the heart). Resulting defects in the valves hinder the normal functioning of the atrioventricular orifices and operation of the heart. More specifically, defects such as the narrowing of the valve opening (valvular stenosis) or the defective closing of the valve (valvular insufficiency) result in an accumulation of blood in a heart cavity or regurgitation of blood past the valve. If uncorrected, prolonged valvular stenosis or valvular insufficiency can cause damage to the heart muscle, which may eventually necessitate total valve replacement.

These defects may be associated with any of the cardiac valves, although they occur most commonly in the left side of the heart. For example, if the aortic valve between the left ventricle and the aorta narrows, blood will accumulate in the left ventricle. Similarly, in the case of aortic valve insufficiency, the aortic valve does not close completely, and blood in the aorta flows back past the closed aortic valve and into the left ventricle when the ventricle relaxes.

In many cases, complete valve replacement is required. Mechanical artificial heart valves for humans are frequently fabricated from titanium, pyrolitic carbon, or biologic tissue, including tissue from cattle, swine, or man. Such valves have become widely accepted and used by many surgeons.

Mechanical prosthetic heart valves typically comprise a rigid orifice supporting one, two or three rigid occluders, or leaflets. The occluders pivot between open and shut positions and thereby control the flow of blood through the valve. The orifice and occluders are commonly formed of pyrolytic carbon, which is a particularly hard and wear-resistant form of carbon. To minimize deflection of the orifice and possible interference with the movement of the occluders, the orifice is often surrounded by a stiffening ring, which may be made of titanium, cobalt chromium, or stainless steel. In one valve configuration, the orifice and stiffening ring are captured within a knit fabric sewing or suture cuff. This prosthetic valve is placed into the valve opening and the sewing cuff is sutured to the patient's tissue. Over time, tissue grows into the fabric of the cuff, providing a secure seal for the prosthetic valve.

However, in many patients, once degeneration of a valve has occurred, it may occur that surrounding blood vessels are also diseased. Particularly in the case of the aortic valve, surgeons have found that the portion of the aorta adjacent to the valve is often degenerated to the degree that it must be replaced. Consequently, both the aortic valve and a segment of the ascending aorta may be replaced at the same time. When this technique was being developed, the surgeon would stitch a segment of vascular graft to the sewing ring of the mechanical valve after implanting the mechanical heart valve. However, this required a relatively long duration of surgery, and the quality of stitching could only be tested *in vivo* after implantation, making leaks difficult to detect and potentially deleterious to the well-being of the patient.

Subsequently, a valve having a preattached graft was developed. The graft is typically attached to the sewing ring. A drawback of this configuration is that the valve size has to be reduced in order to accommodate the additional bulk of the graft end. Hence, the valve

implanted with this combination is generally smaller than that which a surgeon would ordinarily implant. This results in a restriction in the available flow area, with associated resistance to flow. Furthermore, the orifice area (pressure drop across the valve) is proportional to the fourth order power of the internal diameter of the valve. Thus, any decrease in the internal diameter of the valve is undesirable, as it reduces the volume of blood that can be pumped with the available heart muscle.

SUMMARY OF THE INVENTION

In one embodiment, the present invention relates to an implantable prosthetic heart valve, comprising a valve body comprising an orifice member, wherein the orifice member comprises at least one external groove; a tubular vascular graft; and a graft retaining member seated within the external groove of the orifice member and coupling the tubular vascular graft to the orifice member.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings form part of the present specification and are included to further demonstrate certain aspects of the present invention. The invention may be better understood by reference to one or more of these drawings in combination with the detailed description of specific embodiments presented herein.

Figure 1 shows a cross-sectional view of an implantable prosthetic heart valve according to one embodiment of the present invention.

Figure 2 shows a cross-sectional view of an implantable prosthetic heart valve according to one embodiment of the present invention.

Figure 3 shows a cross-sectional view of an implantable prosthetic heart valve according to one embodiment of the present invention.

Figure 4 shows a cross-sectional view of an implantable prosthetic heart valve according to one embodiment of the present invention.

Figure 5 shows a cross-sectional view of an implantable prosthetic heart valve according to one embodiment of the present invention.

Figure 6 shows a cross-sectional view of an implantable prosthetic heart valve according to one embodiment of the present invention.

Figure 7 shows a cross-sectional view of an implantable prosthetic heart valve according to one embodiment of the present invention.

Figure 8 shows a cross-sectional view of an implantable prosthetic heart valve according to one embodiment of the present invention.

Figure 9 shows a cross-sectional view of an implantable prosthetic heart valve according to one embodiment of the present invention.

DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

The present invention will now be described with reference to the attached figures. The words and phrases used herein should be understood and interpreted to have a meaning consistent with the understanding of those words and phrases by those skilled in the relevant art. No special definition of a term or phrase, *i.e.*, a definition that is different from the ordinary and customary meaning as understood by those skilled in the art, is intended to be implied by consistent usage of the term or phrase herein. To the extent that a term or phrase is intended to have a special meaning, *i.e.*, a meaning other than that understood by skilled artisans, such a special definition will be expressly set forth in the specification in a definitional manner that directly and unequivocally provides the special definition for the term or phrase.

The present invention relates to an implantable prosthetic heart valve, suitable for replacing a heart valve present in a valve annulus.

One embodiment of an implantable prosthetic heart valve according to the present invention is shown in cross-section in Figure 1. The implantable prosthetic heart valve **100** comprises a means for defining a blood flow path, such as a valve body **102** comprising an orifice member **104**, defining a blood flow annulus **112**, or the like. (The implantable prosthetic heart valve **100** also comprises one or more leaflets, not shown, coupled to the valve body **102** by any coupling means known in the art, capable of reversibly closing the blood flow annulus **112**). The orifice member **104** and the leaflets, not shown, may be made from any appropriate material, such as pyrolitic carbon, a polymer comprising carbon, a polymer comprising silicon, or others known in the art. The orifice member **104** may be toroidal or approximately toroidal in shape. The orifice member **104** comprises at least one external

groove **106**. In one embodiment, the external groove **106** is circumferential, *i.e.*, extends around the entire circumference of the orifice member **104**. In one embodiment, the external groove **106** may have an upstream shoulder **108** and a downstream shoulder **110**. The implantable prosthetic heart valve **100** is designed for blood flow in the direction **114**, i.e., in a direction approximately parallel to a line segment considered between the upstream shoulder **108** and the downstream shoulder **110**.

In an exemplary embodiment, the external groove **106** has a width (*e.g.*, a distance between the upstream shoulder **108** and the downstream shoulder **110**) of from about 2.0 mm to about 8.0 mm, and a depth (*e.g.*, the height of the upstream shoulder **108** or the downstream shoulder **110**) of from about 0.2 mm to about 0.8 mm.

The implantable prosthetic heart valve **100** comprises means for attaching the implantable prosthetic heart valve **100** to the interior wall of a blood vessel. An example of such an attaching means is schematically depicted in Figures 1-9 as a sewing cuff **120** disposed about at least a portion, and possibly the entirety of, orifice member **104**. The sewing cuff **120** may comprise one or more layers or folds of cloth **122** and, optionally, a filler **124**, such as texturized yarn, polytetrafluoroethylene (Teflon®) felt, or molded silicon, among others known in the art. The sewing cuff **120** may comprise a suture lip or other portion suitable for affixing to tissue via suturing. An exemplary sewing cuff is described in U.S. Pat. No. 6,299,638, hereby incorporated herein by reference.

The sewing cuff **120** is coupled to the orifice member **104** by a coupling means, such as a sewing cuff retaining member **130** seated within an external groove **106** of the orifice member **104**. In one illustrative embodiment, the sewing cuff retaining member **130** may be a solid ring, such as a split ring or the like. The sewing cuff retaining member **130** may be fabricated from cobalt-chromium alloy, stainless steel, or other biocompatible material. The sewing cuff retaining member **130** may be fabricated as a component of the sewing cuff **120**, or the sewing cuff **120** can be attached to the sewing cuff retaining member **130**, such as by stitching, after seating the sewing cuff retaining member **130** within an external groove **106**.

In one exemplary embodiment, the sewing cuff retaining member **130** is a stainless steel wire from about 20 AWG to about 40 AWG (about 0.8 mm diameter to about 0.08 mm diameter).

The implantable prosthetic heart valve **100** also comprises a means for substituting for a diseased arterial segment, such as a tubular vascular graft **140**, which may have a proximal

graft end **142**. ("Proximal," in this context, refers to the end nearest the upstream shoulder **108**). The tubular vascular graft **140** may be prepared according to techniques known in the art. In one embodiment, the tubular vascular graft **140** is cloth, such as woven polyethylene terephthalate (PET). In another embodiment, the tubular vascular graft **140** is a sinus valsalva taken from a mammalian donor, such as cattle, swine, or man.

The tubular vascular graft **140** is coupled to the orifice member **104** by coupling means, such as a graft retaining member **150** seated within the external groove **106** of the orifice member **104**. In one illustrative embodiment, the graft retaining member **150** may be a solid ring, such as a split ring or the like. The graft retaining member **150** may be fabricated from cobalt-chromium alloy, stainless steel, or other biocompatible material. The graft retaining member **150** may be fabricated as a component of the tubular vascular graft **140**, or the tubular vascular graft **140** may be attached to the graft retaining member **150**, such as by stitching, after seating the graft retaining member **150** within the external groove **106**. Typically, and in the embodiments shown in Figures 1-9, the tubular vascular graft **140** comprises a cloth layer which is wrapped around the graft retaining member **150**. The cloth layer is typically stitched to itself at point **144** and excess cloth trimmed.

In one exemplary embodiment, the graft retaining member **150** is a stainless steel wire from about 20 AWG to about 40 AWG (about 0.8 mm diameter to about 0.08 mm diameter).

As will be apparent to the skilled artisan, there are two possible arrangements of the sewing cuff retaining member **130** and the graft retaining member **150**. In one embodiment, shown in Figures 1-4, the graft retaining member **150** is seated between the sewing cuff retaining member **130** and the downstream shoulder **110** of the external groove **106**. In another embodiment, shown in Figures 5-8, the graft retaining member **150** is seated between the sewing cuff retaining member **130** and the upstream shoulder **108** of the external groove **106**.

Instead of being a solid member, as shown in Figures 1 and 5, the sewing cuff retaining member **130**, the graft retaining member **150**, or both may be a helical ring, such as a spring. Figures 2 and 6 show an implantable prosthetic heart valve **100**, wherein both the sewing cuff retaining member **130** and the graft retaining member **150** are springs. Figures 3 and 7 show an implantable prosthetic heart valve **100**, wherein the sewing cuff retaining member **130** is a solid ring and the graft retaining member **150** is a spring. Figures 4 and 8 show an implantable prosthetic heart valve **100**, wherein the sewing cuff retaining member **130** is a spring and the graft retaining member **150** is a solid ring.

In the embodiments described above, the valve body **102** has a single external groove **106**, in which both the sewing cuff retaining member **130** and the graft retaining member **150** are seated. An alternative embodiment is shown in Figure 9, in which the valve body **102** has a first external groove **106a** and a second external groove **106b**, wherein the graft retaining member **150** (in Fig. 9, a solid ring) is seated in the first external groove **106a** and the sewing cuff retaining member **130** (in Fig. 9, a solid ring) is seated in the second external groove **106b**. ("First" and "second" are terms of convenience, and do not imply any particular order of the two external grooves in time or space). The skilled artisan will recognize that embodiments in which the valve body **102** has a first external groove **106a** and a second external groove **106b**, wherein the relative seating locations and types of the sewing cuff retaining member **130** and the graft retaining member **150** correspond to those of Figures 2-8, are within the scope of the present invention, though not shown.

A surgeon may use the implantable prosthetic heart valve **100** to replace a defective native, natural, or prosthetic heart valve and an adjacent defective native or natural vascular segment, according to techniques known in the art. In one embodiment, the present invention relates to a method of implanting a prosthetic heart valve comprising a tubular vascular graft into a patient, comprising removing a prior heart valve and adjacent arterial section from the vasculature of the patient; placing the prosthetic heart valve into the position formerly occupied by the removed prior heart valve, wherein the prosthetic heart valve comprises a valve body comprising an orifice member, wherein the orifice member comprises an external groove; a sewing cuff; a sewing cuff retaining member seated within the external groove of the orifice member and coupling the sewing cuff to the orifice member; a tubular vascular graft; and a graft retaining member seated within the external groove of the orifice member and coupling the tubular vascular graft to the orifice member; and attaching the prosthetic heart valve and tubular vascular graft to the vasculature of the patient. The attachment is typically performed between the prosthetic heart valve and tubular vascular graft and a fibrous ring of annular tissue in the vascular system of the patient. In one embodiment, attaching may be effected by stitching between the sewing cuff and the annular tissue of the patient, and by stitching between the tubular vascular graft and the annular tissue of the patient.

In one embodiment, the defective heart valve is the aortic valve, and the defective vascular segment is the sinus valsalva of the aorta.

In another embodiment, the present invention relates to a method of attaching a tubular vascular graft to a valve body comprising an orifice member, wherein the orifice member comprises at least one external groove, the method comprising:

coupling the tubular vascular graft to the orifice member with a graft retaining member seated within the external groove of the orifice member.

Coupling may be effected in a number of ways. In one embodiment, the graft retaining member is a split ring that is seated in the external groove; the split is then substantially closed by mechanical actuation; and the tubular vascular graft is then affixed to the seated graft retaining member by stitching. Alternatively, the graft retaining member can be sufficiently pliant to deflect around non-groove portions of the orifice member and subsequently be seated in the external groove, with subsequent affixture of the tubular vascular graft to the seated graft retaining member by stitching. In other embodiments, the tubular vascular graft is at least partially affixed to the graft retaining member, such as by stitching, and then the graft retaining member is seated in the external groove of the orifice member.

All of the apparatus disclosed and claimed herein may be made and executed without undue experimentation in light of the present disclosure. While the compositions and methods of this invention have been described in terms of preferred embodiments, it will be apparent to those of skill in the art that variations may be applied to the apparatus described herein without departing from the concept, spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An implantable prosthetic heart valve, comprising:

a valve body comprising an orifice member, wherein the orifice member comprises a least one external groove;

a tubular vascular graft; and

a graft retaining member seated within the external groove of the orifice member and coupling the tubular vascular graft to the orifice member.

2. The implantable prosthetic heart valve of claim 1, further comprising a sewing cuff, and a sewing cuff retaining member seated within an external groove of the orifice member and coupling the sewing cuff to the orifice member.

3. The implantable prosthetic heart valve of claim 1, wherein the sewing cuff retaining member is a solid ring.

4. The implantable prosthetic heart valve of claim 1, wherein the sewing cuff retaining member is a spring.

5. The implantable prosthetic heart valve of claim 1, wherein the graft retaining member is a solid ring.

6. The implantable prosthetic heart valve of claim 1, wherein the graft retaining member is a spring.

7. The implantable prosthetic heart valve of claim 1, comprising one external groove, wherein the external groove has an upstream shoulder and a downstream shoulder and the graft retaining member is seated between the sewing cuff retaining member and the upstream shoulder of the external groove.

8. The implantable prosthetic heart valve of claim 1, comprising one external groove, wherein the external groove has an upstream shoulder and a downstream shoulder and the graft

retaining member is seated between the sewing cuff retaining member and the downstream shoulder of the external groove.

9. The implantable prosthetic heart valve of claim 1, comprising two external grooves, wherein graft retaining member is seated in a first external groove and the sewing cuff retaining member is seated in a second external groove.

10. An implantable prosthetic heart valve, comprising:

a means for defining a blood flow path;

a means for substituting for a diseased vascular segment; and

a means for coupling the tubular vascular graft to the means for defining a blood flow path.

11. The implantable prosthetic heart valve of claim 10, further comprising a means for attaching the implantable prosthetic heart valve to the interior wall of a blood vessel, and a means for coupling the attaching means to the means for defining a blood flow path.

12. A method of attaching a tubular vascular graft to a valve body comprising an orifice member, wherein the orifice member comprises at least one external groove, the method comprising:

coupling the tubular vascular graft to the orifice member with a graft retaining member seated within the external groove of the orifice member.

13. A method of implanting a prosthetic heart valve comprising a tubular vascular graft into a patient, comprising:

removing a prior heart valve and adjacent arterial section from the vasculature of the patient;

placing the prosthetic heart valve into the position formerly occupied by the removed prior heart valve, wherein the prosthetic heart valve comprises a valve body comprising an orifice member, wherein the orifice member comprises at least one external groove; a sewing cuff; a sewing cuff retaining member seated within an external groove of the orifice member and coupling the sewing cuff to the orifice member; a tubular vascular graft; and a graft

retaining member seated within an external groove of the orifice member and coupling the tubular vascular graft to the orifice member; and

attaching the prosthetic heart valve and tubular vascular graft to the vasculature of the patient.

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14. The method of claim 13, wherein the position formerly occupied by the removed prior heart valve is the aortic valve position, and the adjacent arterial section is the sinus valsalva.

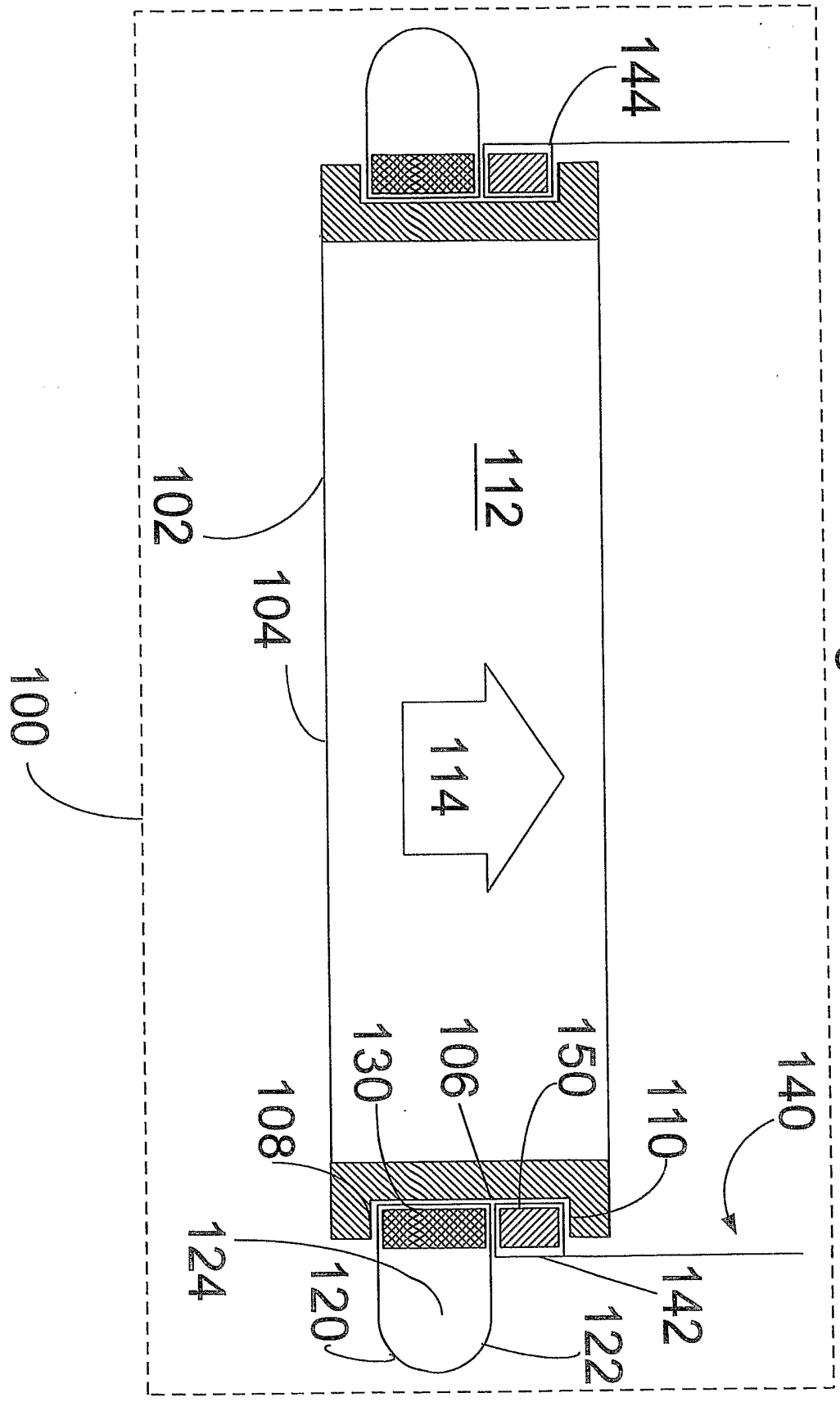

Figure 1

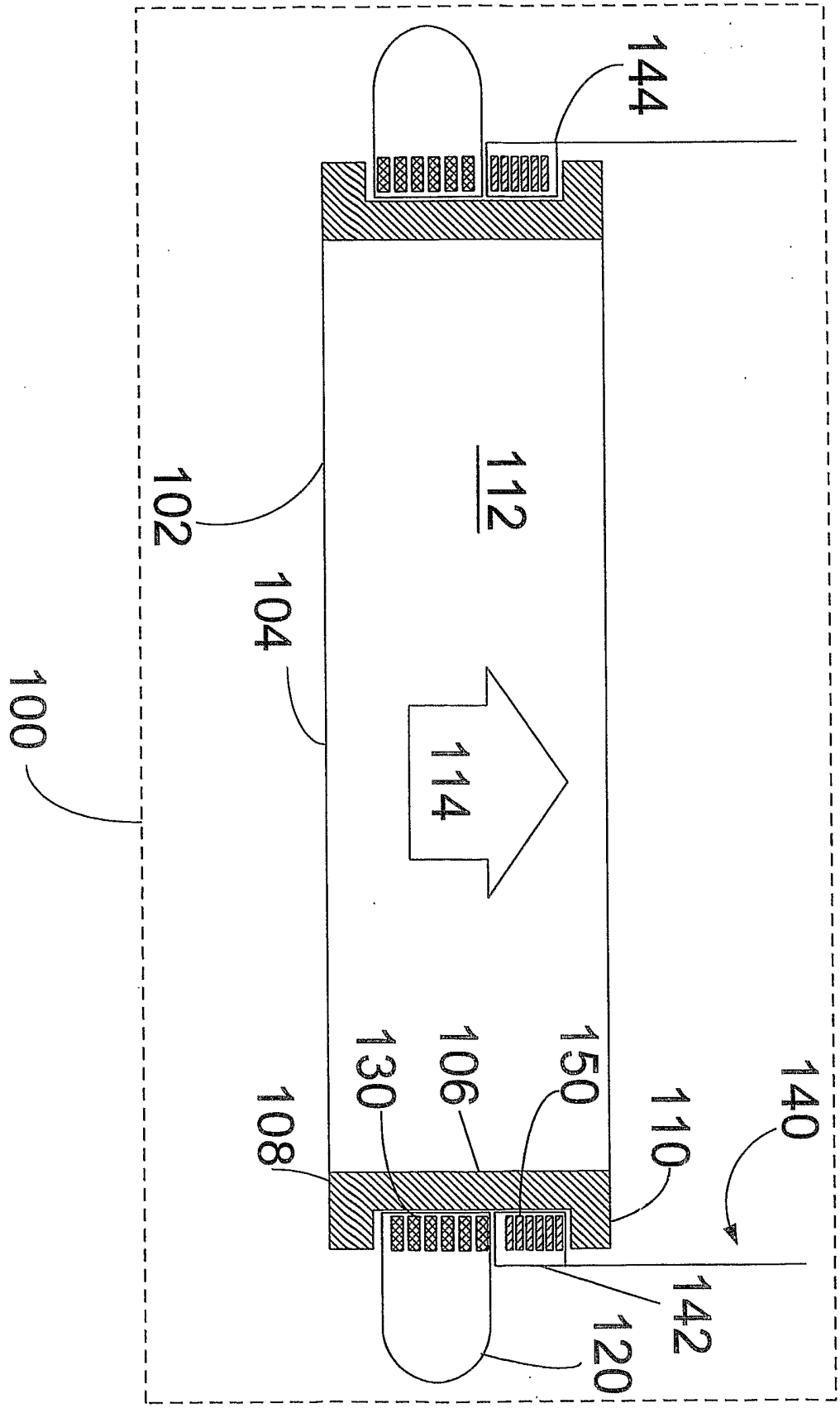

Figure 2

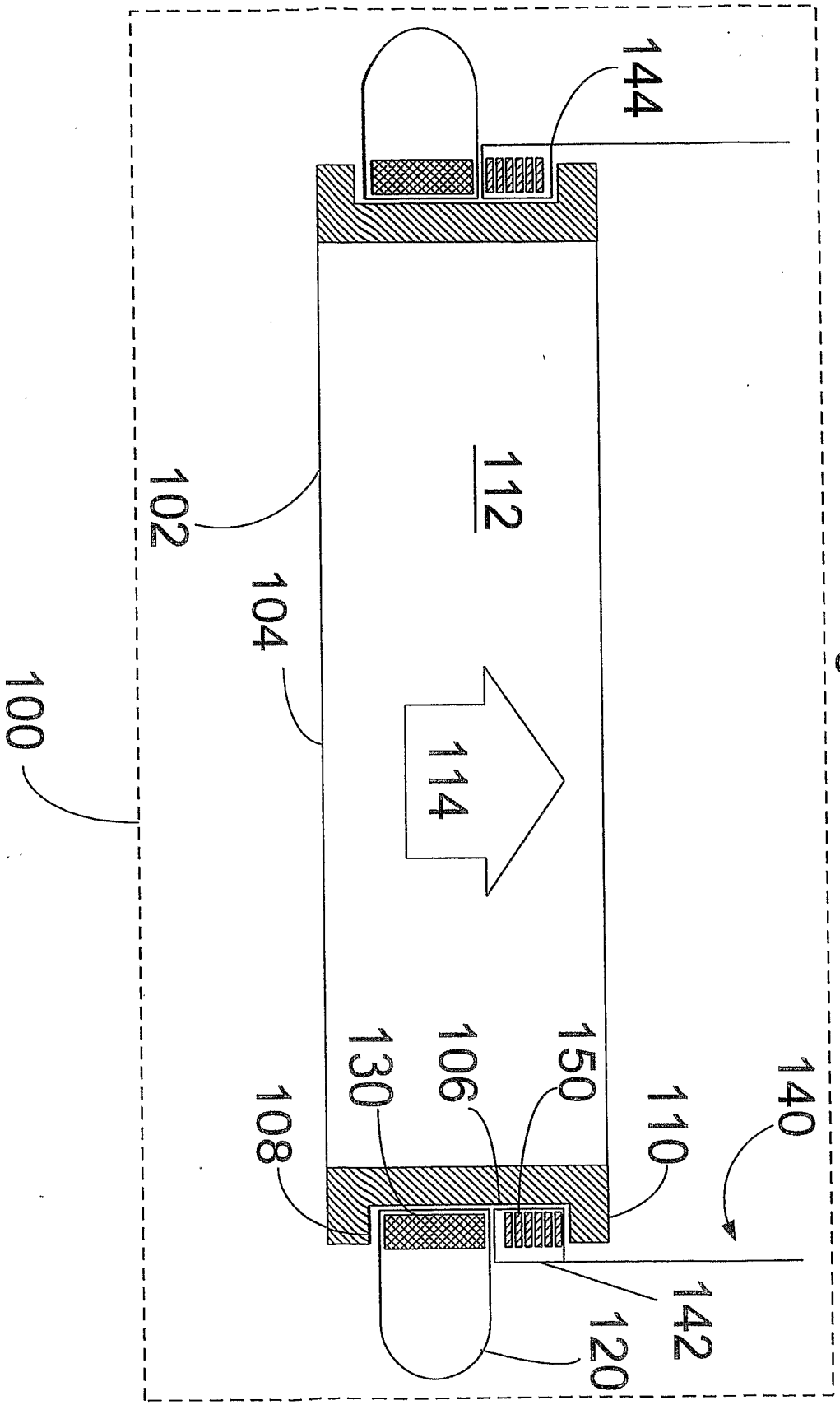

Figure 3

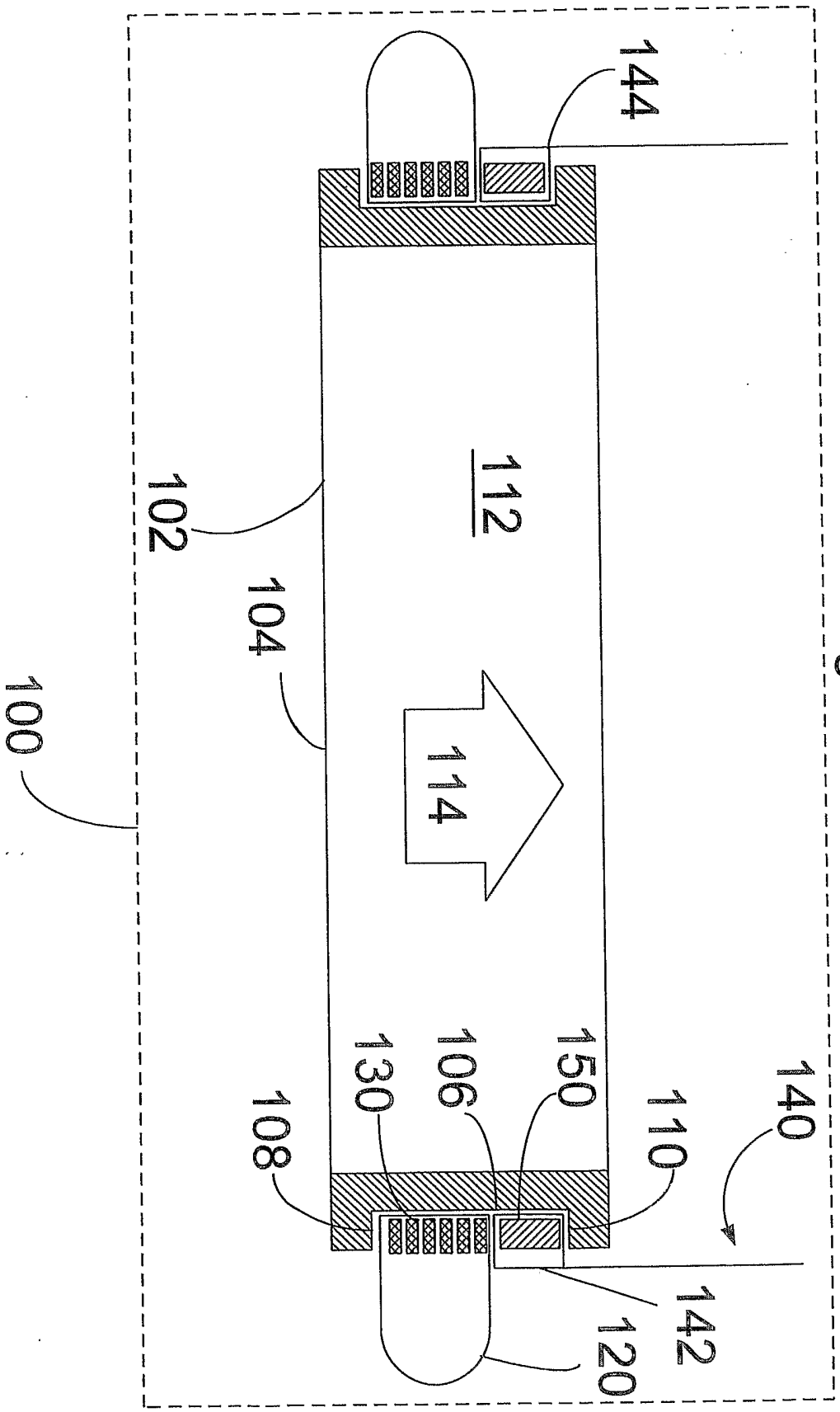

Figure 4

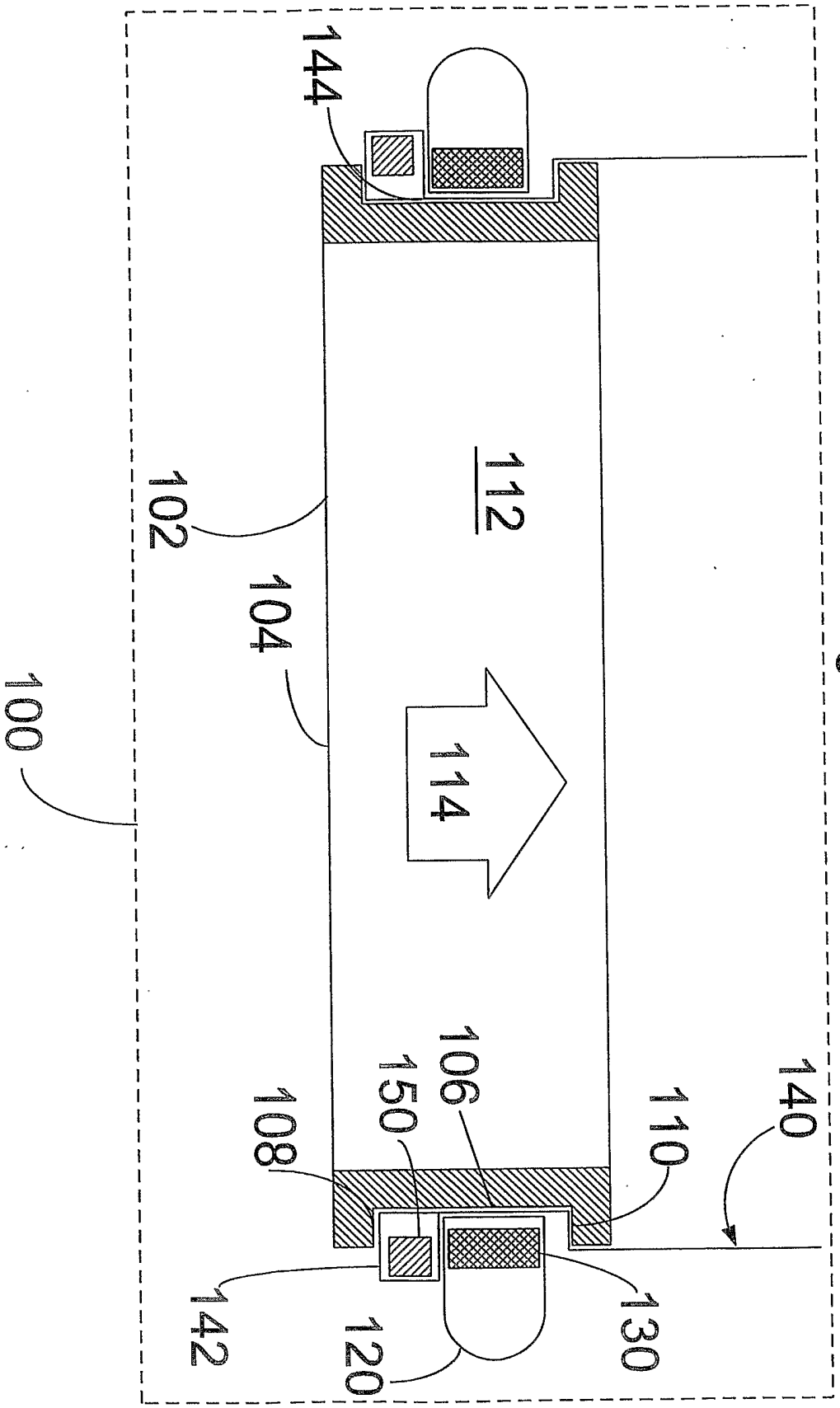

Figure 5

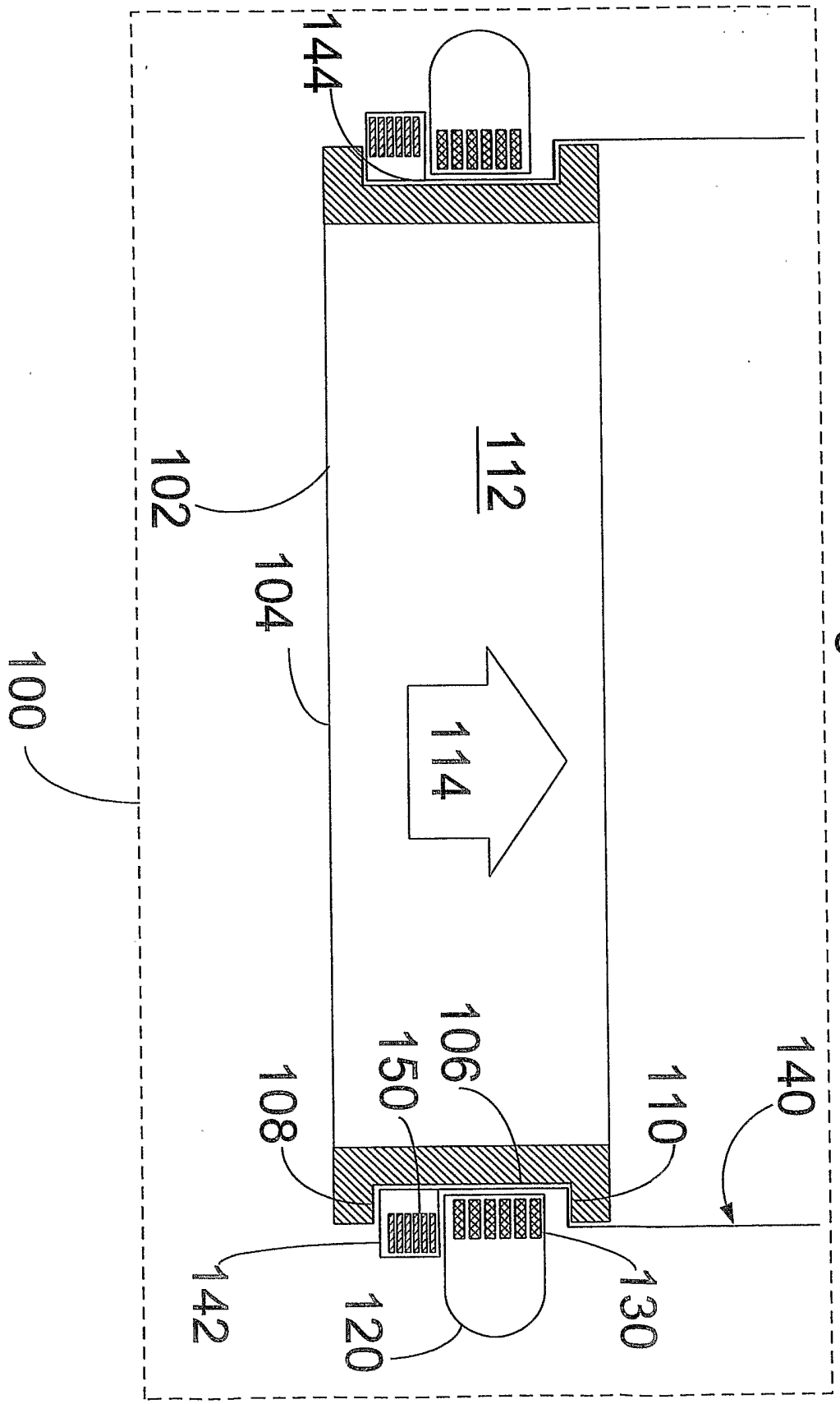

Figure 6

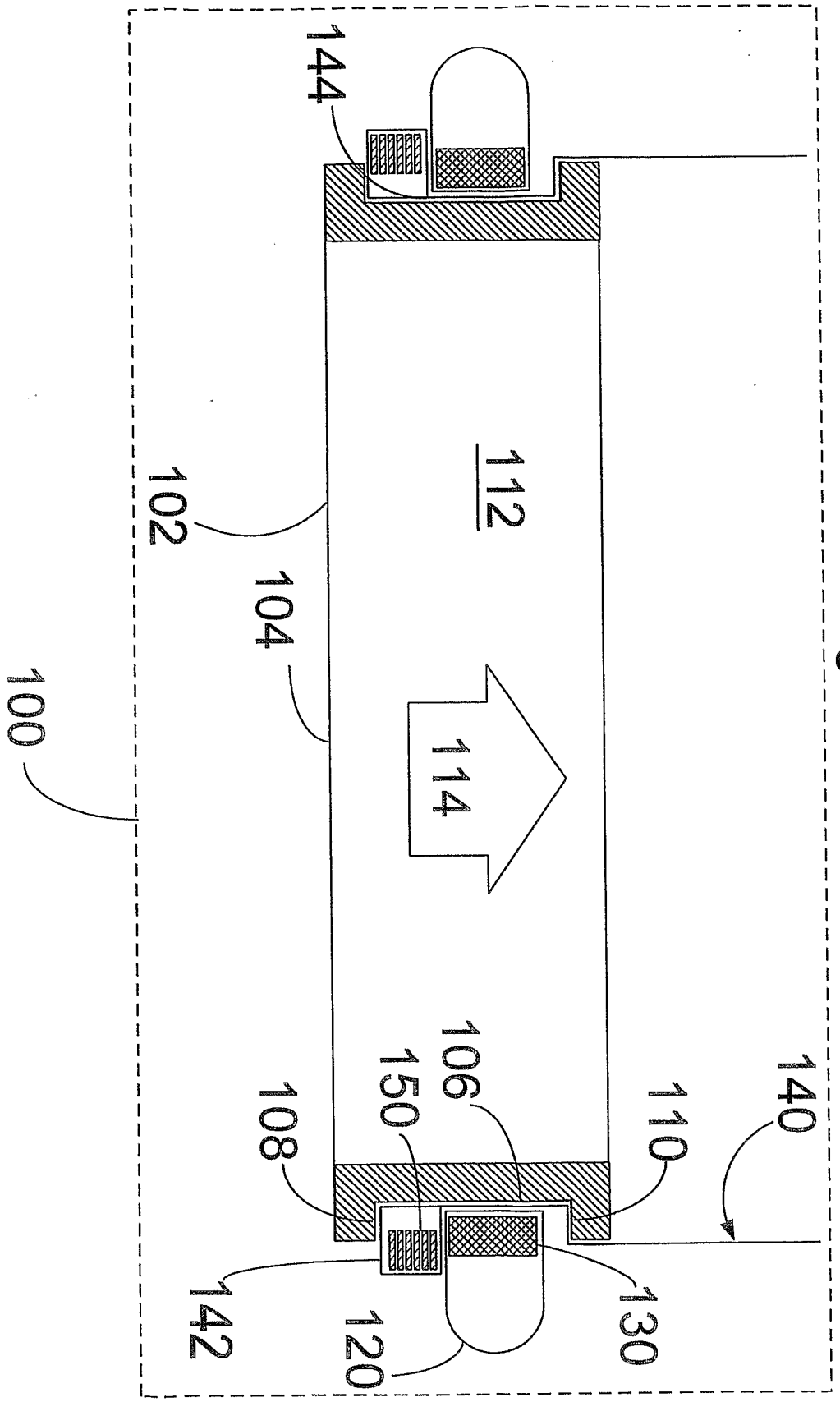

Figure 7

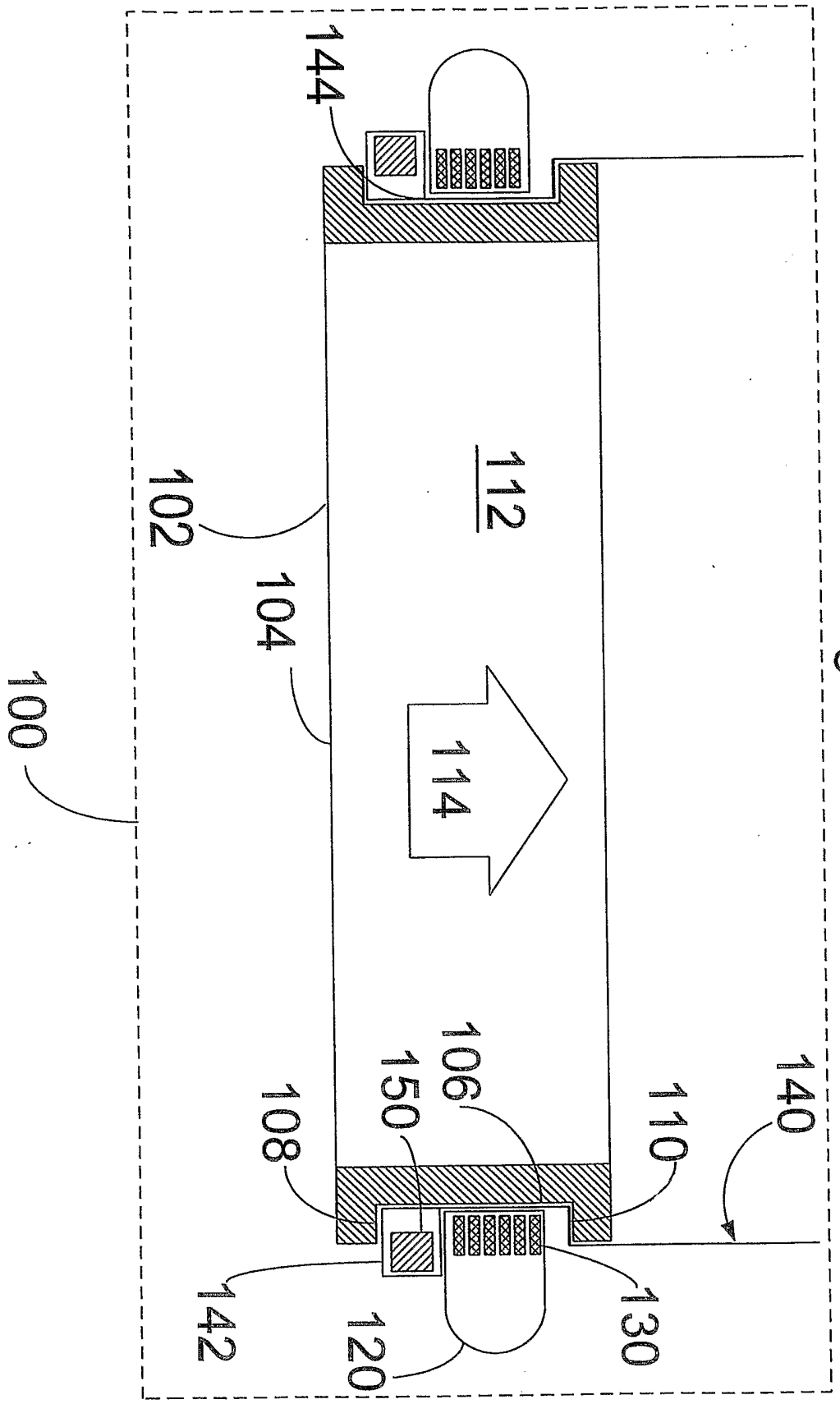

Figure 8

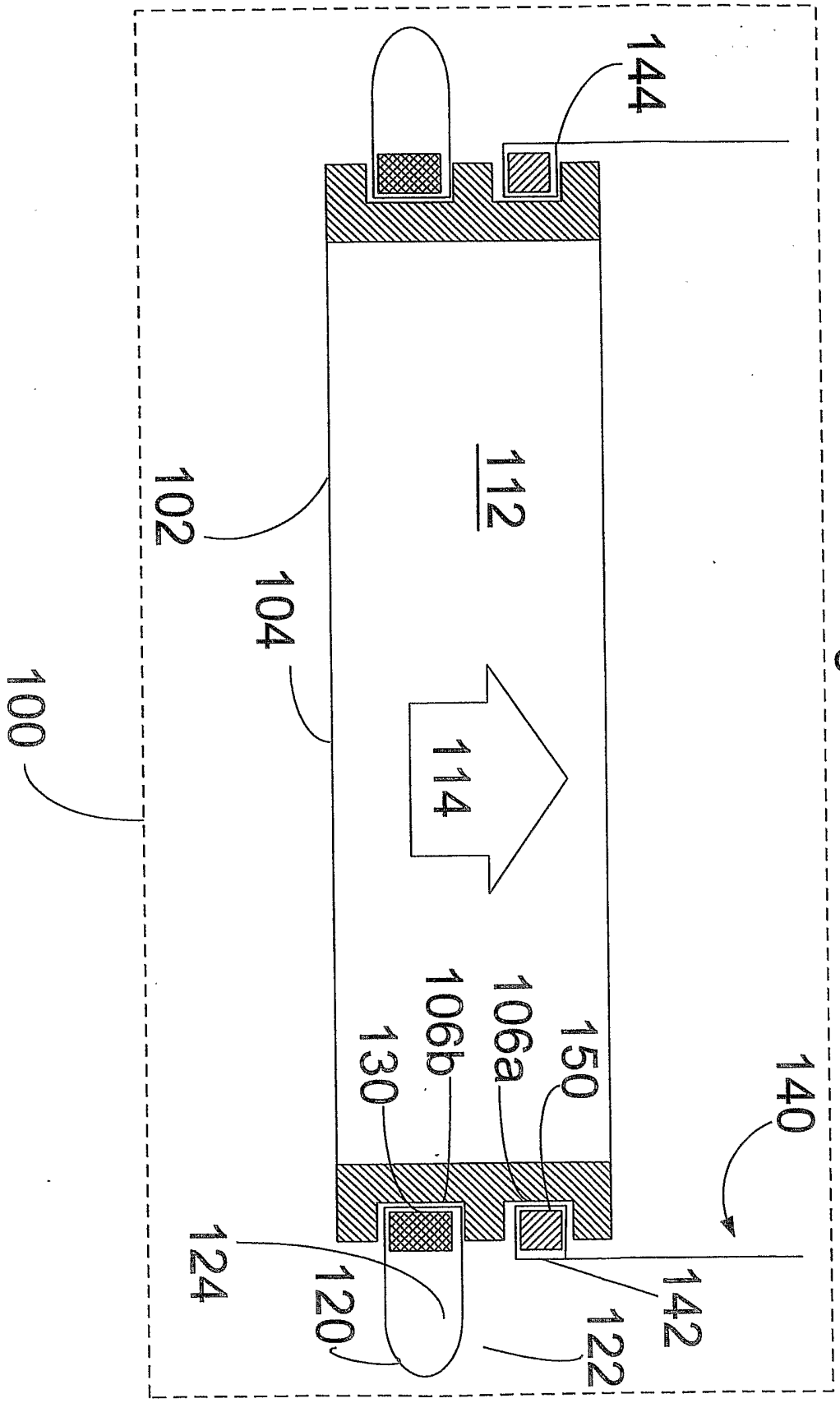

Figure 9

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/011246

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 891 195 A (KLOSTERMAYER ET AL) 6 April 1999 (1999-04-06)	10,11
A	column 4, line 1 - line 17; figure 3	1,12

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 September 2005	28/09/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Smith, C

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/011246

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 13, 14
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US2005/011246

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5891195 A	06-04-1999	NONE	