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(54) **ROTATIONAL INTRAVASCULAR ULTRASOUND PROBE AND METHOD OF MANUFACTURING THE SAME**

INTRAVASKULÄRE ROTATIONSULTRASCHALLSONDE UND HERSTELLUNGSVERFAHREN DAFÜR

SONDE ULTRASONIQUE INTRAVASCULAIRE ROTATIVE ET SON PROCÉDÉ DE FABRICATION

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Description

BACKGROUND

[0001] Intravascular Ultrasound (IVUS) has become an important interventional diagnostic procedure for imaging atherosclerosis and other vessel diseases and defects. In the procedure, an IVUS catheter is threaded over a guidewire into a blood vessel of interest, and images are acquired of the atherosclerotic plaque and surrounding area using ultrasonic echoes. This information is much more descriptive than the traditional standard of angiography, which only shows an image of the blood flowing through the vessel lumen. Some of the key applications of IVUS include: determining a correct diameter and length of a stent to choose for dilating an arterial stenosis, verifying that a post-stenting diameter and luminal cross-section area are adequate, verifying that a stent is well apposed against a vessel wall to minimize thrombosis and optimize drug delivery (in the case of a drug eluting stent) and identifying an exact location of side-branch vessels. In addition, new techniques such as virtual histology (RF signal-based tissue characterization) show promise of aiding identification of vulnerable plaque (i.e., plaque which is prone to rupture and lead to onset of a heart attack).

[0002] There are generally two standard types of IVUS catheters: mechanical/rotational IVUS catheters and solid state catheters. In a rotational IVUS catheter, a single transducer consisting of a piezoelectric crystal is rotated at approximately 1800 revolutions per minute while the element is excited by a signal. This excitation causes the element to vibrate at a frequency dependant upon its thickness, which depending on the dimensions and characteristics of the transducer this can be from around 9 to 45MHz. The single element transducer of the rotational IVUS catheter can be made very thin and therefore able to vibrate at relatively high frequencies, thus achieving a relatively high resolution, this is of particular value in the near field (close to the outside diameter of the catheter sheath). In addition, this type of catheter configuration facilitates the use of relatively high excitation voltages, increasing the signal to noise ratio.

[0003] In rotational IVUS catheters, the transducer subassembly is situated in a preformed metallic structure called a transducer housing that is attached via adhesive or weld to an end of the drive cable. The metallic transducer housing is often formed with stainless steel. A backing material is formed from a loaded liquid two-part epoxy that is applied to the back side of the transducer subassembly when the transducer subassembly is inserted into the transducer housing. The backing material is then cured to couple the transducer subassembly to the preformed metallic housing.

[0004] The preformed metallic housing can negatively impact image quality because it is constructed of a strongly reflective and resonant material. In addition, the transducer subassembly and transducer housing are usually very small, which makes reliable and consistent manufacture within small tolerances difficult. Secure and precise placement of the transducer subassembly within the preformed transducer housing can also be difficult.

[0005] WO 03/103501 relates to a transducer element having multiple resonant frequencies for use in ultrasonic imaging medical catheters. WO 2008/086613 relates to high resolution imaging using combined high frequency ultrasound (IVUS) and optical imaging methods such as optical coherence tomography (OTC). US 2003/0100834 relates to an ultrasonic probe in which the cost of manufacture is reduced and grippability is improved.

BRIEF SUMMARY

[0006] A rotational intravascular ultrasound probe is disclosed herein for insertion into a body cavity, such as a blood vessel. The probe is defined in claim 12.

[0007] Furthermore, a method of manufacturing a rotational intravascular ultrasound probe is disclosed as defined in claim 1.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008]

Fig. 1 is a fragmentary view of a rotational IVUS probe having a transducer shaft with a molded transducer housing;
Fig. 2 is a fragmentary perspective view of the transducer shaft for the rotational IVUS probe of Fig. 1;
Fig. 3 is an enlarged section view of the transducer shaft taken through line 3-3 of Fig. 2;
Fig. 4 is a perspective view of a mold for forming the molded transducer housing for the transducer shaft of Fig. 2;
Fig. 5 is an exploded perspective view of the mold of Fig. 4;
Fig. 6 is a fragmentary perspective view of the transducer shaft of Fig. 2 disposed within the mold of Fig. 4;
Fig. 7 is another fragmentary perspective view of the transducer shaft of Fig. 2 disposed within the mold of Fig. 4 and showing a drive cable inserted into the mold;
Fig. 8 is another fragmentary perspective view of the transducer shaft of Fig. 2 disposed within the mold of Fig. 4 showing the molded transducer housing after formation in the mold;
Fig. 9 is a fragmentary perspective view of the transducer shaft of Fig. 2 after removal from the mold of Fig. 4; and
Fig. 10 is another fragmentary perspective view of the transducer shaft of Fig. 2 after removal from the mold of Fig. 4 and with a sacrificial layer removed from a transducer subassembly.

DETAILED DESCRIPTION

[0009] Turning to the figures, representative illustrations of the rotational intravascular ultrasound (IVUS) probe having a molded transducer housing and a method of molding the same are shown therein. Referring specifically to Fig. 1, a rotational intravascular ultrasound (IVUS) probe 100 for insertion into a patient for diagnostic imaging is shown. The probe 100 comprises a catheter body 102 and a transducer shaft 104. The catheter body 102 is flexible and has both a proximal end portion 106 and a distal end portion 108. The catheter body 102 is a sheath surrounding the transducer shaft 104. For explanatory purposes, the catheter body 102 in Fig. 1 is illustrated as visually transparent such that the transducer shaft 104 disposed therein can be seen, although it will be appreciated that the catheter body 102 may or may not be visually transparent. The transducer shaft 104 is flushed with a sterile fluid, such as saline, within the catheter body 102. The fluid serves to eliminate the presence of air pockets around the transducer shaft 104 that adversely affect image quality. The fluid can also act as a lubricant. The transducer shaft 104 has a proximal end portion 110 disposed within the proximal end portion 106 of the catheter body 102 and a distal end portion 112 disposed within the distal end portion 108 of the catheter body 102.

[0010] The distal end portion 108 of the catheter body 102 and the distal end portion 112 of the transducer shaft 104 are inserted into a patient during the operation of the probe 100. The usable length of the probe 100 (the portion that can be inserted into a patient) can be any suitable length and can be varied depending upon the application. The distal end portion 112 of the transducer shaft 104 includes a transducer subassembly 114, which is described in further detail below.

[0011] The proximal end portion 106 of the catheter body 102 and the proximal end portion 110 of the transducer shaft 104 are connected to an interface module 116 (sometimes referred to as a patient interface module or PIM). The proximal end portions 106, 110 are fitted with a connector, which is received by a complimentary connector on the interface module 116. The rotation of the transducer shaft 104 within the catheter body 102 is controlled by the interface module 116, which provides a plurality of user interface controls that can be manipulated by a user. The interface module 116 also communicates with the transducer subassembly 114 by sending and receiving electrical signals to and from the transducer subassembly 114 via wires within the transducer shaft 104. The interface module 116 can receive, analyze, and display information received through the transducer shaft 104. It will be appreciated that any suitable functionality, controls, information processing and analysis, and display can be incorporated into the interface module 116.

[0012] Fig. 2 shows the transducer shaft 104 independent from the catheter body 102 for purposes of discussion. The transducer shaft 104 includes a transducer subassembly 114, a transducer housing 118, and a drive cable 120. The transducer subassembly 114 is coupled to the transducer housing 118. The illustrated transducer subassembly 114 is a single transducer subassembly 114 having a single transducer. The transducer housing 118 is attached to the drive cable 120 near a distal end 122 of the drive cable 120. The drive cable 120 is rotated within the catheter body 102 via the interface module 116 to rotate the transducer housing 118 and the transducer subassembly 114.

[0013] The transducer subassembly 114 can be of any suitable type and can include any suitable number of layers. As an example, referring to Fig. 3, the transducer subassembly 114 can include a front matching layer 124, a first electrode layer 126, a transducer layer 128, a second electrode layer 130, and a back matching layer 132. Each layer may be formed from any suitable material. For example, the transducer layer 128 may be formed with any suitable material, including but not limited to a piezoelectric material such as PZT (lead zirconate titanate). As another example, the electrode layers 126, 130 may be formed with any suitable conductive material, including but not limited to gold. The matching layers 124, 132 may be formed with any suitable material, including but not limited to materials having a relatively high acoustic impedance such as loaded plastic or epoxy.

[0014] Referring again to Fig. 2, the transducer housing 118 is integrally molded to the transducer subassembly 114 and drive cable 120. Utilizing a molded transducer housing 118 provides a transducer shaft 104 that can be repeatedly manufactured with precise and accurate placement of the transducer subassembly 114 with respect to the drive cable 120. The scalability of the transducer housing 118 is enhanced because it is easier and more efficient to reliably mold the transducer housing 118 around smaller transducer subassemblies. In addition, the transducer housing 118 offers significant mechanical support and protection to the transducer subassembly 114 during rotation.

[0015] The molded transducer housing 118 may be formed with any suitable material. In certain examples, the molded transducer housing 118 is molded using a material (sometimes referred to as a backing material) that can offer certain advantages to the operation of the probe 100. For example, unlike a metallic housing, which creates a strongly reflective and resonant structure, the transducer housing 118 can be molded using a material having more favorable characteristics. As an example, the material can have a relatively high acoustic impedance and attenuation to contribute to an improvement in image quality. In someexamples, it is desirable for the transducer housing 118 to be rigid such that the transducer subassembly 114 can be securely retained, protected, and consistently directed in the desired circumferential direction as the transducer shaft 104 is rotating. By way of example and not limitation, the material forming the molded transducer housing 118 can include a loaded liquid two-part epoxy such as Master Bond EP30M or

Bondline Silver.

[0016] The transducer housing 118 may comprise one or more materials disposed therein. These materials can act as scatterers and/or absorbers. In certain examples, one or more particles of a metal oxide, such as Cerium Oxide, can be embedded in the transducer housing material to raise both the density and acoustic velocity of the material as well as improve its ability to attenuate ultrasound. In some examples, hollow microspheres can be added to the transducer housing material to scatter errant ultrasound energy. Other structures can be disposed within the transducer housing material. For example, shaped electron-dense features can be molded within the transducer housing 118 to facilitate identification of device orientation on fluoroscopic images. In addition, the density of the transducer housing material can be adjusted to affect the visualization of the transducer housing 118 under fluoroscopy. The greater the electron density, the darker the appearance of the transducer housing 118 when viewed under fluoroscopy.

[0017] In some examples, the transducer housing 118 has channels or receptacles molded therein for the delivery and/or transport of fluids or suspensions. By way of example, the molded transducer housing 118 can be used to deliver drugs, such as anticoagulants, to the patient. The molded transducer housing 118 could also be used to draw fluid disposed near the housing.

[0018] It will be appreciated that any suitable mold may be used to form the molded transducer housing 118. As an example, the molded transducer housing 118 can be formed utilizing a mold such as the injection mold 134 shown in Figs. 4 and 5. The injection mold 134 has a first mold plate 136 and a second mold plate 138. The first mold plate 136 can be disposed below the second mold plate 138. The two mold plates 136, 138 can be brought together and mated to create one or more cavities for receiving portions of the transducer shaft 104 and receiving the material injected into the mold to form the transducer housing 118. The mold can also have injection ports, such as injection port 140, and vent ports, such as vent port 142, as needed for the molding process.

[0019] By way of example and not limitation, the molding of the transducer housing 118 may be accomplished as generally shown in Figs. 6-10. Referring to Fig. 6, a suitable transducer subassembly 114 is provided and disposed within a mold cavity 144 in the first mold plate 136. As illustrated, the transducer subassembly 114 is oversized to facilitate accurate placement of the transducer subassembly 114 within the mold cavity 144. The mold cavity 144 is correspondingly sized to receive the oversized transducer subassembly 114 such that transducer subassemblies can be repeatedly and reliably placed into the first mold plate 136 during mass production. In this way, transducer housings 118 can be consistently molded to maintain a desired distance between the transducer subassembly 114 and the drive cable 120.

[0020] As shown in Figs. 6-9, the transducer subassembly 114 has a removable sacrificial layer 146 disposed over the front of the transducer subassembly 114 to cover the front surface of the transducer subassembly, which is the front matching layer 124 in thisexample. The sacrificial layer 146 protects the transducer subassembly 114 prior to and during the process of molding the transducer housing 118. The sacrificial layer 146 is later removed from the transducer subassembly 114 as described further below.

[0021] Prior to placing the transducer subassembly 114 within the mold cavity 144, as shown in Fig. 6, the transducer subassembly 114 is coupled to a cable 148 including a plurality of electrical wires 150 conductively connected to the transducer subassembly 114 to receive and send signals between the transducer subassembly 114 and the interface module 116. The cable 148 is received within a cable cavity 152 of the mold 134 when the transducer subassembly 114 is inserted into the mold 134.

[0022] Turning to Fig. 7, the drive cable 120 is moved over the cable 148 such that it is positioned near the transducer subassembly 114 in the mold 134. The drive cable 120 surrounds and protects the cable 148 during operation of the probe 100. Once the transducer subassembly 114, the cable 148, and the drive cable 120 are disposed within the mold 134, the first and second mold plates 136, 138 are combined such as shown in Fig. 4, and the material forming the transducer housing 118 is injected into the mold 134 and cured. The first and second mold plates 136, 138 are then separated from one another, thus leaving the transducer shaft 104 in the mold cavity 144 of the first mold plate 136 as shown in Fig. 8. Through this process, the transducer housing 118 is formed in a single molding step.

[0023] The transducer housing 118 is molded over the back matching layer 132, as shown in Fig. 3, and to the drive cable 120, as shown in Fig. 8. The portions of the electrical wires 150 extending between the drive cable 120 and the transducer subassembly 114 are molded within the transducer housing 118. Referring to Figs. 2 and 8, in the illustrated example, the transducer housing 118 is generally cylindrical with a domed end. As shown, the transducer housing 118 is linear in shape to facilitate the rapid rotation of the transducer shaft 104. In addition, the front surface of the transducer subassembly 114 is oriented in a plane that is generally perpendicular to a plane extending radially from the rotational axis of the transducer shaft 104 through the center of the transducer subassembly 114. In some embodiments, the transducer housing 118 can be molded to position the transducer subassembly 114 in other suitable orientations. For example, the transducer housing 118 can be molded such that the front surface of the transducer subassembly 114 can be oriented in a plane that is approximately 30°, 45°, or 60° relative to a plane extending radially from the rotational axis of the transducer shaft 104 through the center of the transducer subassembly 114. It will be appreciated that the transducer housing 118 can have any suitable shape and any suitable size. In addition, the transducer subassembly 114 can be oriented in any suitable manner.

[0024] Turning to Fig. 9, the transducer shaft 104 is removed from the mold with the transducer housing 118 fully formed and the sacrificial layer 146 still attached. At this point, the sacrificial layer 146 has served its purpose of protecting the front surface of the transducer subassembly 114 during the molding process and can be removed as shown in Fig. 10.

[0025] Depending on the size of the oversized transducer subassembly 114, it may require trimming to allow for the transducer shaft 104 to rotate as desired within the catheter body 102. The transducer subassembly 114 may be trimmed, for example, by cutting each side of the transducer subassembly 114 at or near the outer periphery of the transducer housing 118 such as represented by fracture lines 154. The transducer subassembly 114 may be completely cut through the fracture lines 154, or alternatively, the fracture lines 154 may be formed and the transducer subassembly 114 can be broken along the fracture lines 154. In some examples, the transducer subassembly 114 can be ground to reduce its size. The transducer shaft 104 is thus produced, as shown in Fig. 2, such that it can be rotated to obtain a circumferential image of surrounding tissue during operation of the probe 100.

[0026] It is noted that transducer layer 128, as shown in Fig. 3, may be any suitable size. In some examples, the transducer subassembly 114 is very thin and can have a thickness on the order of approximately 50 micro meters. For purposes of explanation, the transducer subassembly 114 and other features of the probe 100 may be shown larger than scale in the figures.

[0027] In some examples, the transducer shaft 104 can have more than one transducer subassembly 114. For example, the molded transducer housing 118 can have two diametrically opposed transducer subassemblies 114. In anotherexample, the molded transducer housing 118 can have three transducer subassemblies 114 circumferentially positioned 120° from one another. Having more than one transducer subassembly 114 permits the probe 100 to operate at multiple frequencies to provide comprehensive information on the target tissue. Generally, lower frequencies can penetrate deeper into tissue, whereas higher frequencies can provide more information on tissue near the probe 100, such as plaque composition. Operating with more than one transducer subassembly 114 can also permit the transducer shaft 104 to be rotated at a lower speed.

[0028] In some examples, in addition to or in place of the transducer subassembly 114, the probe 100 can have a prism and lens configuration for the practice of optical coherence tomography or photo acoustic imaging.

[0029] Besides intravascular ultrasound, other types of ultrasound probes can be made using the teachings provided herein. By way of example and not limitation, other suitable types of probes include non-intravascular intraluminal ultrasound probes, intracardiac echo probes, laparoscopic, and interstitial probes. In addition, the probe 100 maybe used in any suitable anatomy, including, but not limited to, coronary, carotid, neuro, peripheral, or venous. The scalability of the probe 100, accomplished via the molding process described herein, makes the probe 100 particularly useful for small vessel applications.

[0030] Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein.

[0031] Illustrative examples of a mechanical rotational IVUS probe are described herein. Variations of the disclosed examples will be apparent to those of ordinary skill in the art in view of the foregoing illustrative examples. Those skilled in the relevant art will employ such variations as appropriate.

Claims

1. A method of manufacturing a rotational intravascular ultrasound probe for insertion into a vasculature, the method comprising:

   providing an injection mold having a recess and a cable cavity (152);
   providing an intravascular ultrasonic transducer for obtaining an intravascular image through rotation, the transducer including a front surface for transmitting and receiving ultrasonic waves and a sacrificial layer (146) disposed over the front surface, the transducer being coupled to a cable (148);
   disposing the transducer within the recess;
   disposing the cable (148) within the cable cavity (152);
   moving a drive cable (120) over the cable (148) into the mold;
   injecting a material into the recess and the cable cavity to form a transducer housing attached to the transducer and the drive cable; and
   removing the sacrificial layer (146) after the transducer housing is formed.

2. The method of claim 1 wherein the transducer is oversized when disposed within the recess, and further comprising reducing the size of the transducer after the transducer housing is formed.

3. The method of claim 1 wherein the transducer is the only transducer molded to the transducer housing (118).

4. The method of claim 1 wherein the transducer includes a plurality of layers (124, 126, 128, 130).

5. The method of claim 1 wherein the transducer housing (118) is rigid.

6. The method of claim 1 wherein the material is an epoxy.

7. The method of claim 1 wherein the transducer includes a piezoelectric material.

8. The method of claim 1 wherein the transducer, the transducer housing (118), and the drive cable (120) form a transducer shaft (104), and further comprising inserting the transducer shaft into a catheter (102).

9. The method of claim 1 wherein the transducer housing (118) is generally cylindrical.

10. The method of claim 1 wherein the transducer housing (118) has a domed end.

11. The method of claim 1 wherein the transducer housing (118) has a linear shape.

12. A rotational intravascular ultrasound probe (100) for insertion into a vasculature, the probe comprising:

an elongate catheter having a flexible body (102);
an elongate transducer shaft (104) disposed within the flexible body, the transducer shaft having:

a proximal end portion (110) and a distal end portion (112);
a drive cable (120) extending from the proximal end portion to the distal end portion;
an ultrasonic transducer for obtaining an intravascular image through rotation, the transducer disposed near the distal end portion;
wherein the ultrasonic transducer includes a front surface for transmitting and receiving ultrasonic waves and a removable sacrificial layer (146) disposed over the front surface, the transducer being coupled to a cable (148), the drive cable (120) being positioned over the cable (148);
a transducer housing (118) molded to the drive cable (120) and the ultrasonic transducer.

13. The rotational intravascular ultrasound probe (100) of claim 12 wherein the transducer is the only transducer molded to the transducer housing (118).

14. The rotational intravascular ultrasound probe of claim 12 wherein the transducer housing (118) is rigid.

15. The rotational intravascular ultrasound probe (100) of claim 12 wherein the transducer housing (118) is molded with an epoxy.

16. The rotational intravascular ultrasound probe (100) of claim 12 wherein the transducer includes a piezoelectric material.

17. The rotational intravascular ultrasound probe (100) of claim 12 wherein the transducer housing (118) is generally cylindrical.

18. The rotational intravascular ultrasound probe (100) of claim 12 wherein the transducer housing (118) has a linear shape.

Patentansprüche

1. Verfahren zur Herstellung einer intravaskulären Rotationsultraschallsonde zur Einführung in ein Gefäßsystem, wobei das Verfahren umfasst:

Bereitstellen einer Spritzgussform mit einer Aussparung und einem Kabelhohlraum (152);
Bereitstellen eines intravaskulären Ultraschallwandlers zum Erhalten eines intravaskulären Bildes durch Rotation, wobei der Wandler eine vordere Oberfläche zum Übertragen und Empfangen von Ultraschallwellen und eine über der vorderen Oberfläche angeordnete Opferschicht (146) einschließt, wobei der Wandler mit einem Kabel (148) gekoppelt ist;
Anordnen des Wandlers in der Aussparung;
Anordnen des Kabels (148) innerhalb des Kabelhohlraums (152);
Bewegen eines Antriebskabels (120) über das Kabel (148) in die Form;
Einspritzen eines Materials in die Aussparung und den Kabelhohlraum, um ein Wandlergehäuse zu bilden, das an dem Wandler und dem Antriebskabel angebracht ist; und
Entfernen der Opferschicht (146), nachdem das Wandlergehäuse gebildet ist.

2. Verfahren nach Anspruch 1, wobei der Wandler eine Übergröße aufweist, wenn er innerhalb der Aussparung angeordnet ist, und weiter umfassend das Reduzieren der Größe des Wandlers nach dem Bilden des Wandlergehäuses.

3. Verfahren nach Anspruch 1, wobei der Wandler der einzige Wandler ist, der an das Wandlergehäuse (118) geformt ist.

4. Verfahren nach Anspruch 1, wobei der Wandler eine Vielzahl von Schichten (124, 126, 128, 130) einschließt.

5. Verfahren nach Anspruch 1, wobei das Wandlergehäuse (118) steif ist.

6. Verfahren nach Anspruch 1, wobei das Material Epoxy ist.

7. Verfahren nach Anspruch 1, wobei der Wandler ein piezoelektrisches Material einschließt.

8. Verfahren nach Anspruch 1, wobei der Wandler, das Wandlergehäuse (118) und das Antriebskabel (120) einen Wandlerschaft (104) bilden, und weiter umfassend das Einführen des Wandlerschafts in einen Katheter (102).

9. Verfahren nach Anspruch 1, wobei das Wandlergehäuse (118) im Allgemeinen zylindrisch ist.

10. Verfahren nach Anspruch 1, wobei das Wandlergehäuse (118) ein kuppelförmiges Ende aufweist.

11. Verfahren nach Anspruch 1, wobei das Wandlergehäuse (118) eine lineare Form aufweist.

12. Intravaskuläre Rotationsultraschallsonde (100) zur Einführung in ein Gefäßsystem, wobei die Sonde umfasst:

einen länglichen Katheter aufweisend einen flexiblen Körper (102);
einen länglichen Wandlerschaft (104), der in dem flexiblen Körper angeordnet ist, wobei der Wandlerschaft aufweist:

einen proximalen Endabschnitt (110) und einen distalen Endabschnitt (112);
ein Antriebskabel (120), das sich vom proximalen Endabschnitt zum distalen Endabschnitt erstreckt;
einen Ultraschallwandler zum Erhalten eines intravaskulären Bildes durch Rotation, wobei der Wandler nahe dem distalen Endabschnitt angeordnet ist;
wobei der Ultraschallwandler eine vordere Oberfläche zum Übertragen und Empfangen von Ultraschallwellen und eine über der vorderen Oberfläche angeordnete entfernbare Opferschicht (146) einschließt, wobei der Wandler mit einem Kabel (148) gekoppelt ist, wobei das Antriebskabel (120) über dem Kabel (148) positioniert ist;
ein Wandlergehäuse (118), das an das Antriebskabel (120) und den Ultraschallwandler geformt ist.

13. Intravaskuläre Rotationsultraschallsonde (100) nach Anspruch 12, wobei der Wandler der einzige Wandler ist, der an das Wandlergehäuse (118) geformt ist.

14. Intravaskuläre Rotationsultraschallsonde nach Anspruch 12, wobei das Wandlergehäuse (118) steif ist.

15. Intravaskuläre Rotationsultraschallsonde (100) nach Anspruch 12, wobei das Wandlergehäuse (118) mit einem Epoxy geformt ist.

16. Intravaskuläre Rotationsultraschallsonde (100) nach Anspruch 12, wobei der Wandler ein piezoelektrisches Material einschließt.

17. Intravaskuläre Rotationsultraschallsonde (100) nach Anspruch 12, wobei das Wandlergehäuse (118) im Allgemeinen zylindrisch ist.

18. Intravaskuläre Rotationsultraschallsonde (100) nach Anspruch 12, wobei das Wandlergehäuse (118) eine lineare Form aufweist.

Revendications

1. Procédé de fabrication d'une sonde ultrasonique intravasculaire rotative pour insertion dans un système vasculaire, le procédé comprenant :

la fourniture d'un moule à injection ayant un creux et une cavité de câble (152) ;
la fourniture d'un transducteur ultrasonique intravasculaire pour obtenir une image intravasculaire par rotation, le transducteur incluant une surface frontale pour transmettre et recevoir des ondes ultrasoniques et une couche sacrificielle (146) disposée sur la surface frontale, le transducteur étant couplé à un câble (148) ;
la disposition du transducteur dans le creux ;
la dispositif du câble (148) dans la cavité de câble (152) ;
le déplacement d'un câble d'entraînement (120) par-dessus le câble (148) dans le moule ;
l'injection d'un matériau dans le creux et la cavité de câble pour former un boîtier de transducteur fixé au transducteur et au câble d'entraînement ; et
le retrait de la couche sacrificielle (146) une fois que le boîtier de transducteur a été formé.

2. Procédé selon la revendication 1, dans lequel le transducteur est surcalibré lorsqu'il est disposé dans le creux, et comprenant en outre la réduction de la taille du transducteur une fois le boîtier de transducteur formé.

3. Procédé selon la revendication 1, dans lequel le transducteur est le seul transducteur moulé sur le

boîtier de transducteur (118).

4. Procédé selon la revendication 1, dans lequel le transducteur inclut une pluralité de couches (124, 126, 128, 130).

5. Procédé selon la revendication 1, dans lequel le boîtier de transducteur (118) est rigide.

6. Procédé selon la revendication 1, dans lequel le matériau est une résine époxyde.

7. Procédé selon la revendication 1, dans lequel le transducteur inclut un matériau piézoélectrique.

8. Procédé selon la revendication 1, dans lequel le transducteur, le boîtier de transducteur (118) et le câble d'entraînement (120) forment un arbre de transducteur (104), et comprenant en outre l'insertion de l'arbre de transducteur dans un cathéter (102).

9. Procédé selon la revendication 1, dans lequel le boîtier de transducteur (118) est de forme générale cylindrique.

10. Procédé selon la revendication 1, dans lequel le boîtier de transducteur (118) a une extrémité en forme de dôme.

11. Procédé selon la revendication 1, dans lequel le boîtier de transducteur (118) a une forme linéaire.

12. Sonde ultrasonique intravasculaire rotative (100) pour insertion dans un système vasculaire, la sonde comprenant :

un cathéter allongé ayant un corps souple (102) ;
un arbre de transducteur allongé (104) disposé dans le corps souple, l'arbre de transducteur ayant :

une partie d'extrémité proximale (110) et une partie d'extrémité distale (112) ;
un câble d'entraînement (120) s'étendant de la partie d'extrémité proximale à la partie d'extrémité distale ;
un transducteur ultrasonique pour obtenir une image intravasculaire par rotation, le transducteur étant disposé près de la partie d'extrémité distale ;
dans lequel le transducteur ultrasonique inclut un surface frontale pour transmettre et recevoir des ondes ultrasoniques et une couche sacrificielle enlevable (146) disposée par-dessus la surface frontale, le transducteur étant couplé à un câble (148), le câble d'entraînement (120) étant disposé par-dessus le câble (148) ;
un boîtier de transducteur (118) moulé sur le câble d'entraînement (120) et le transducteur ultrasonique.

13. Sonde ultrasonique intravasculaire rotative (100) selon la revendication 12, dans laquelle le transducteur est le seul transducteur moulé sur le boîtier de transducteur (118).

14. Sonde ultrasonique intravasculaire rotative selon la revendication 12, dans laquelle le boîtier de transducteur (118) est rigide.

15. Sonde ultrasonique intravasculaire rotative (100) selon la revendication 12, dans laquelle le boîtier de transducteur (118) est moulé avec une résine époxyde.

16. Sonde ultrasonique intravasculaire rotative (100) selon la revendication 12, dans laquelle le transducteur inclut un matériau piézoélectrique.

17. Sonde ultrasonique intravasculaire rotative (100) selon la revendication 12, dans laquelle le boîtier de transducteur (118) est de forme générale cylindrique.

18. Sonde ultrasonique intravasculaire rotative (100) selon la revendication 12, dans laquelle le boîtier de transducteur (118) a une forme linéaire.

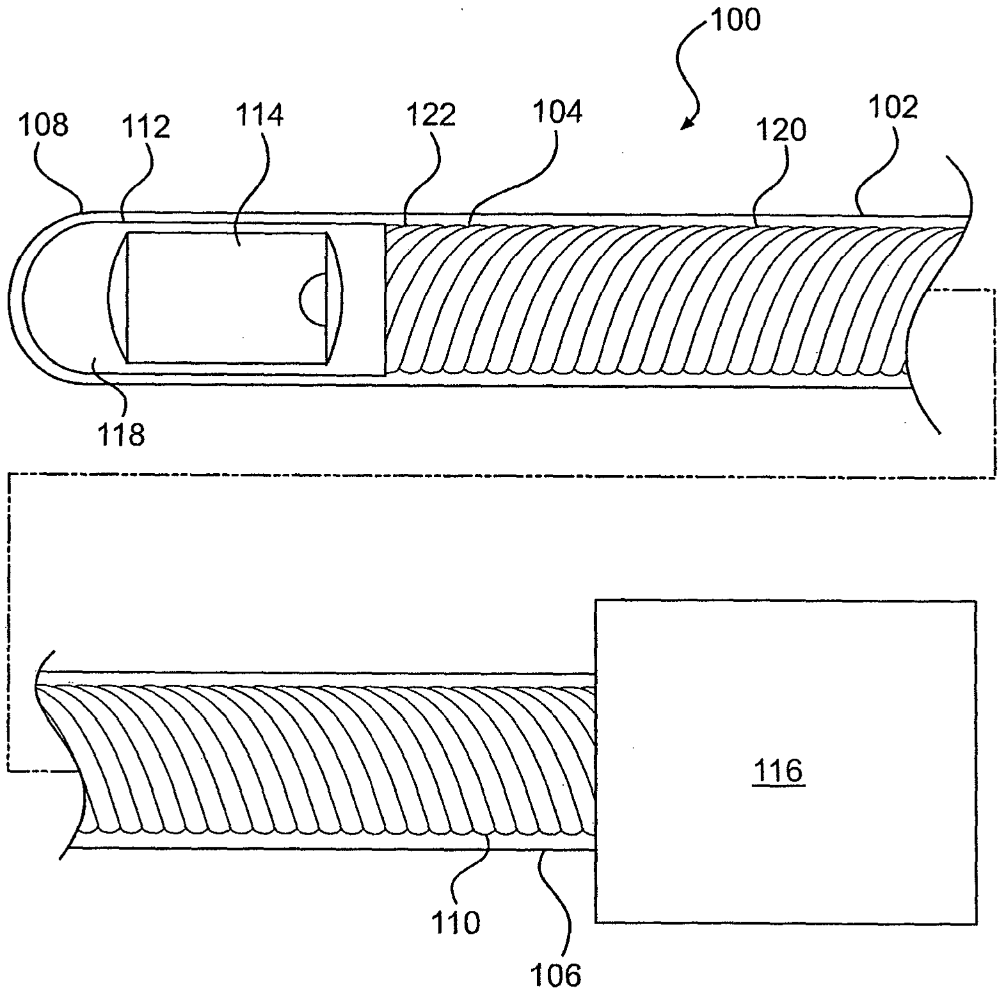

FIG. 1

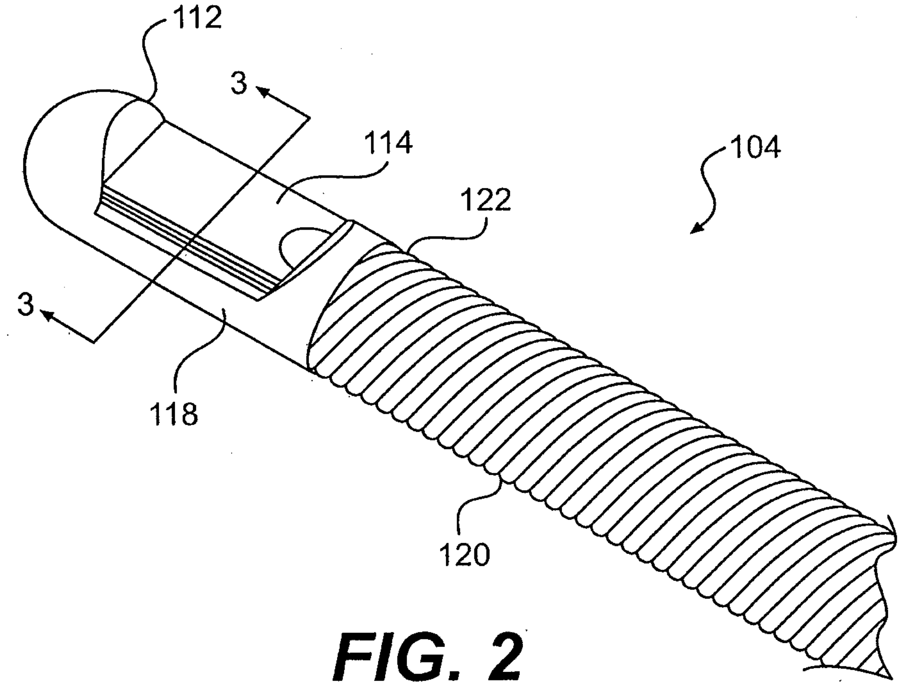

FIG. 2

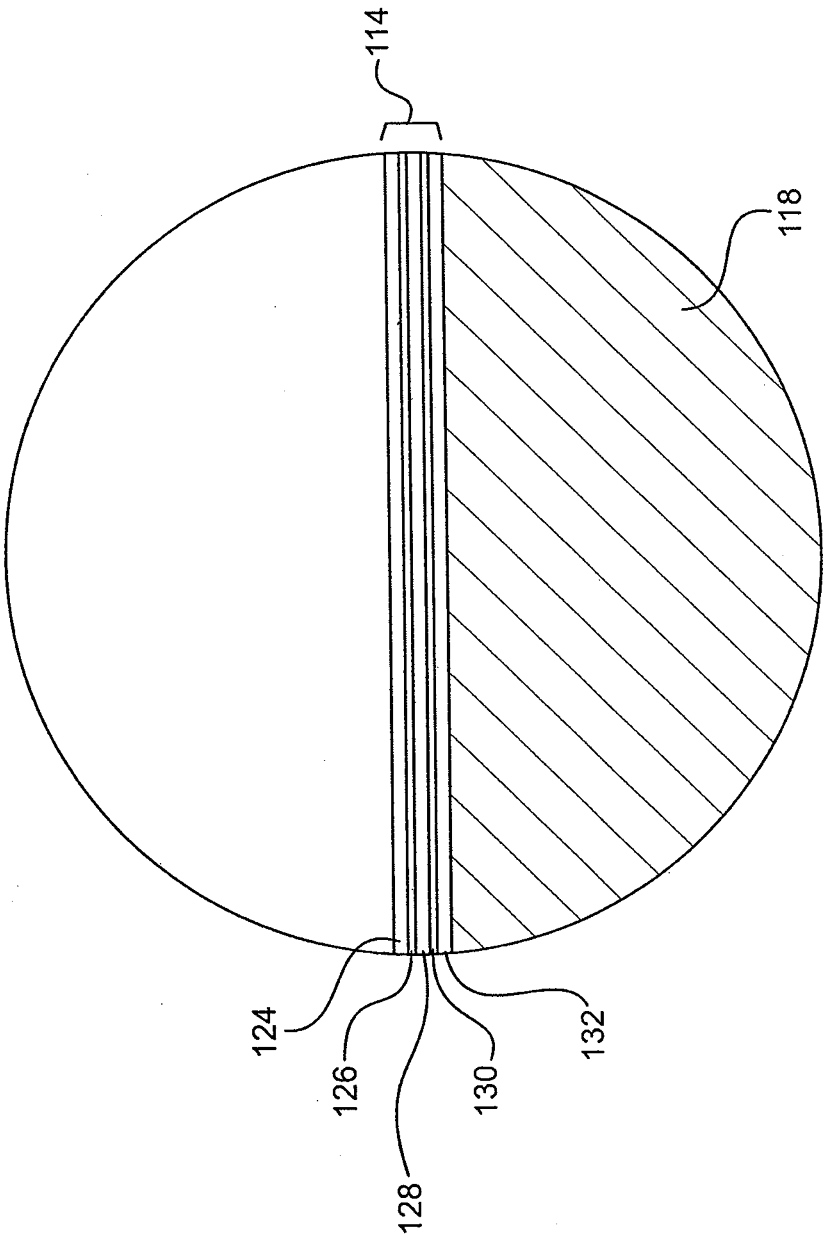

FIG. 3

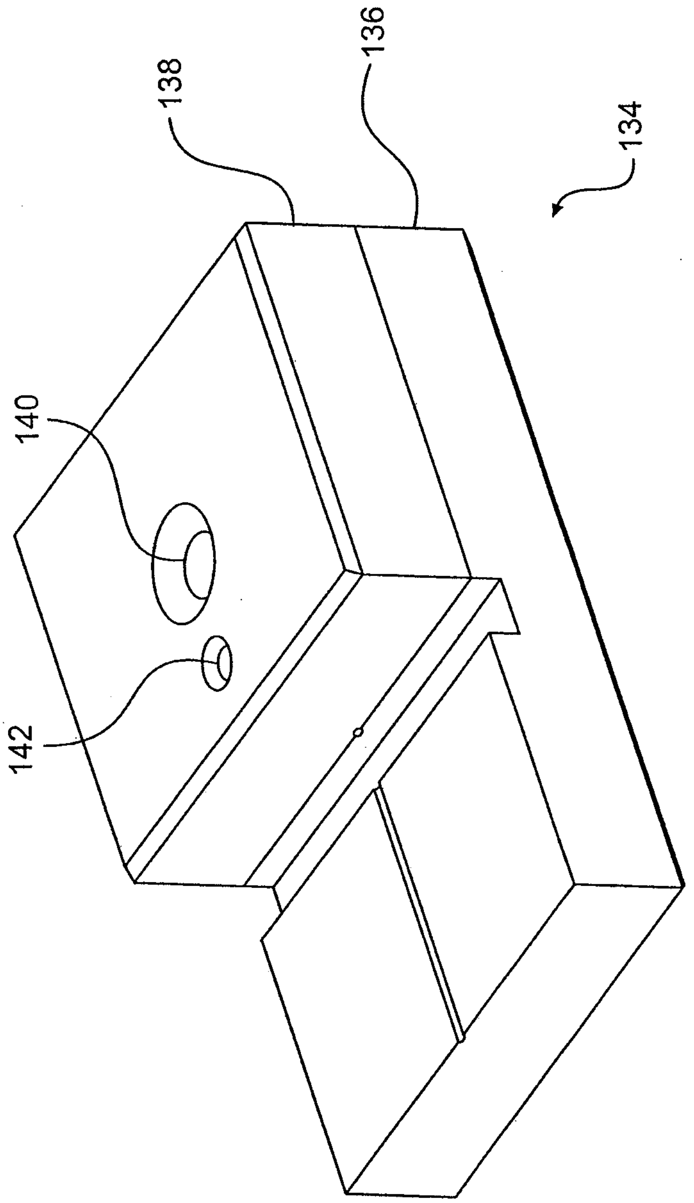

FIG. 4

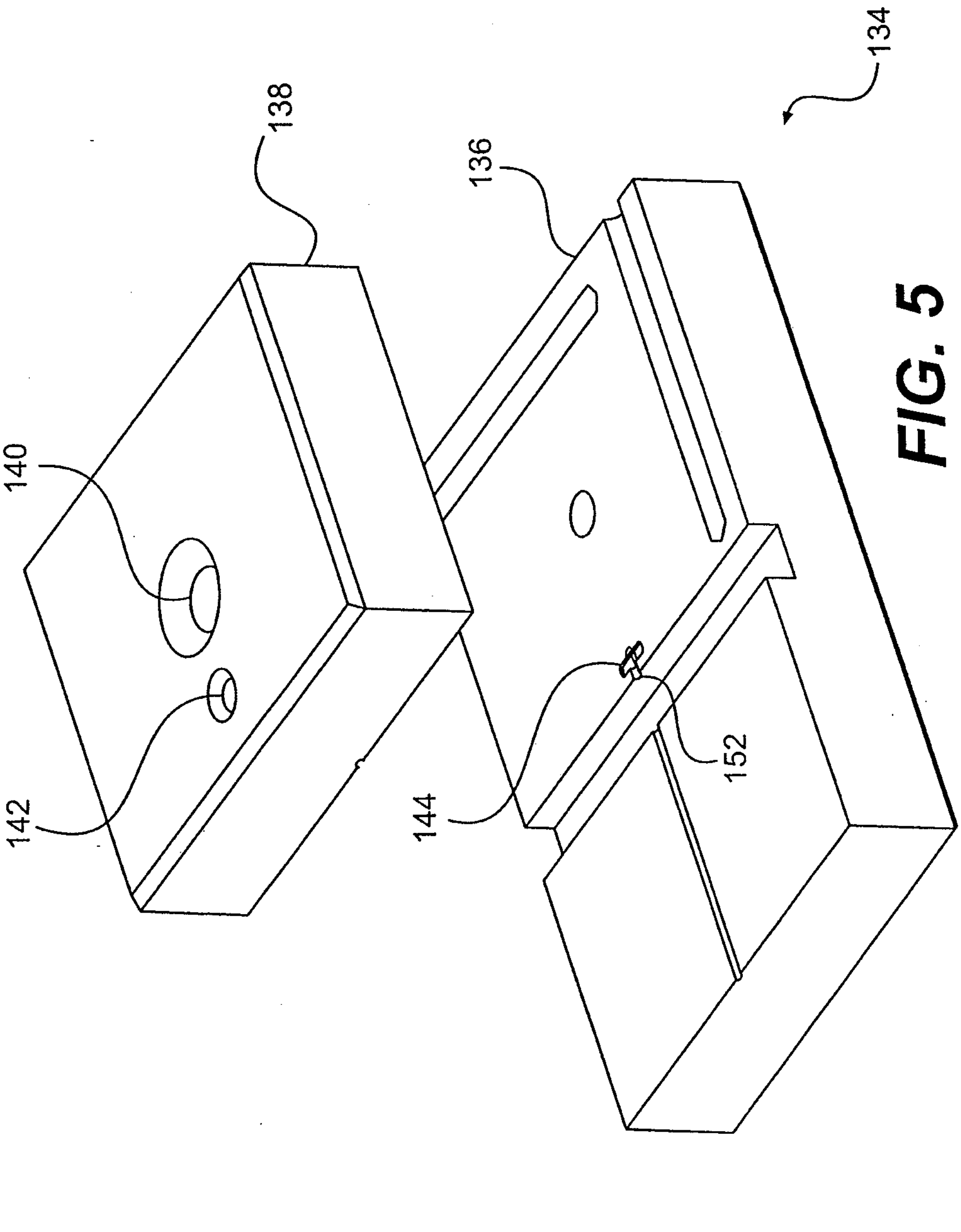

FIG. 5

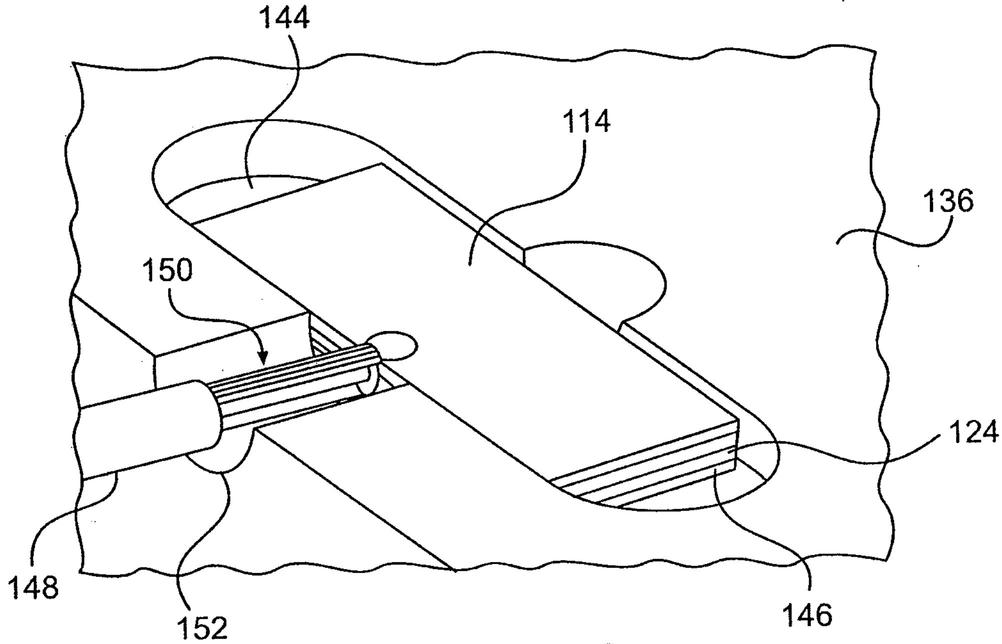

FIG. 6

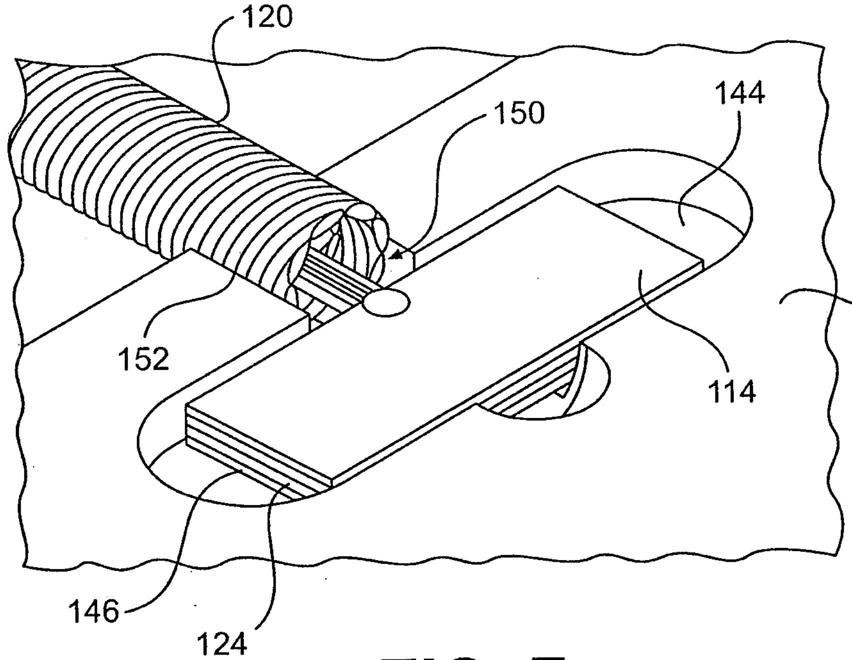

FIG. 7

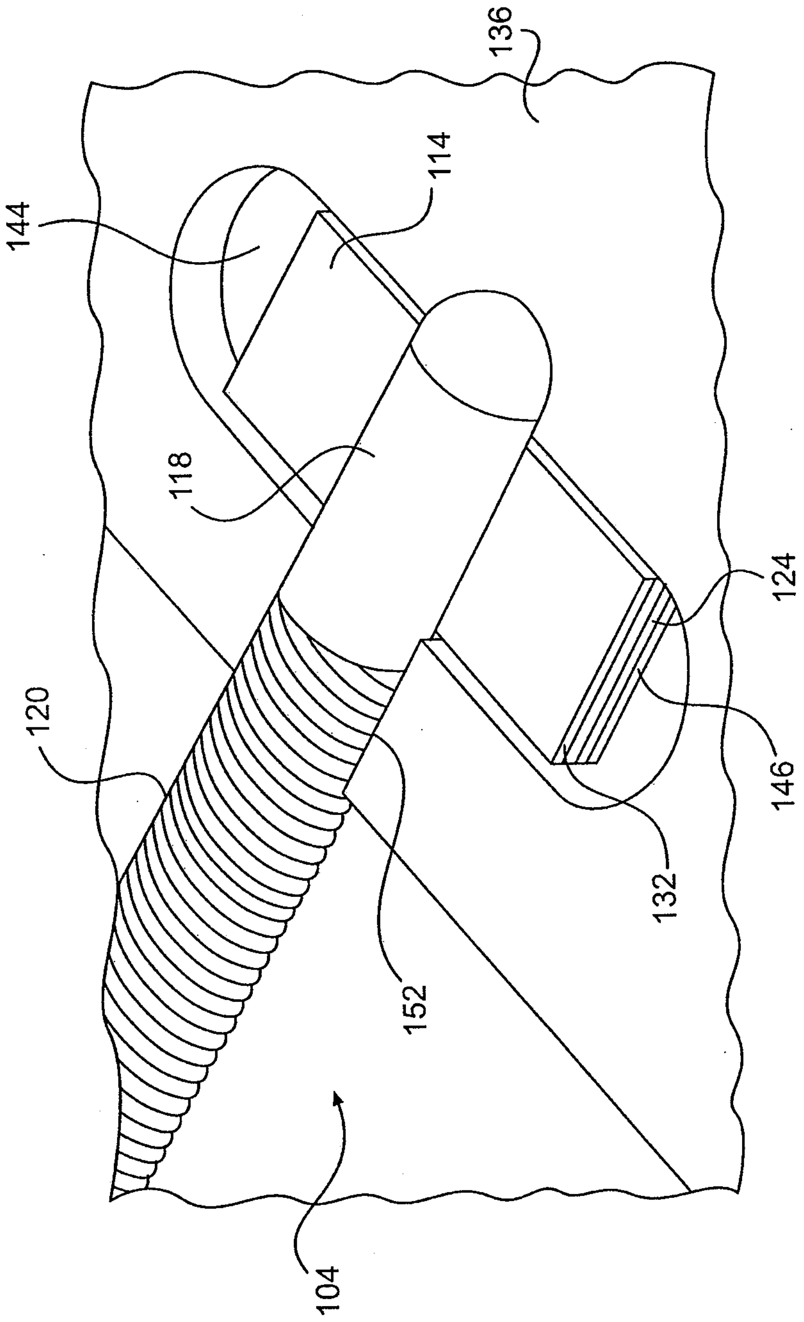

FIG. 8

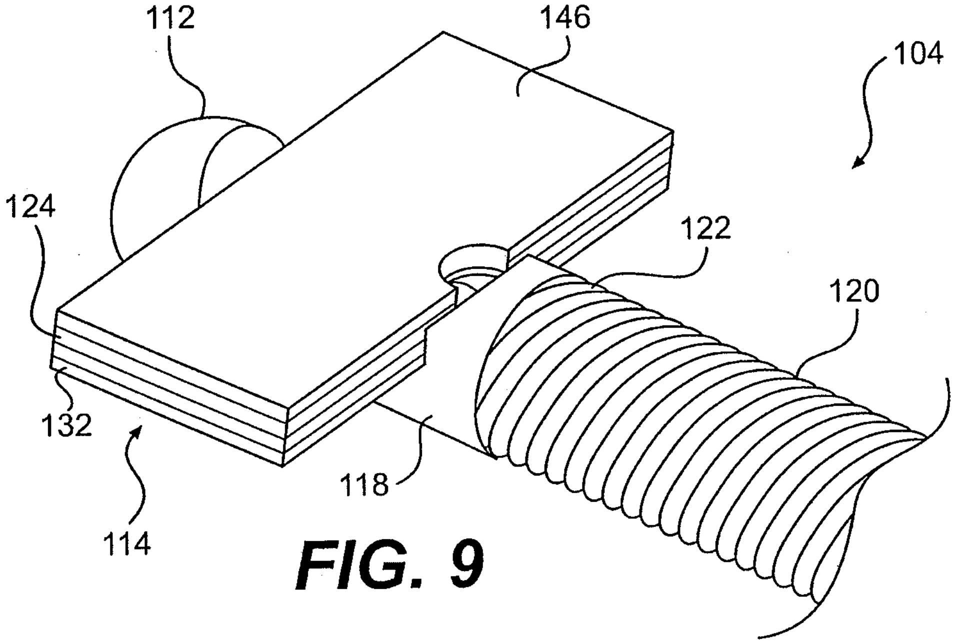
112
146
104
124
122
120
132
118
114

FIG. 9

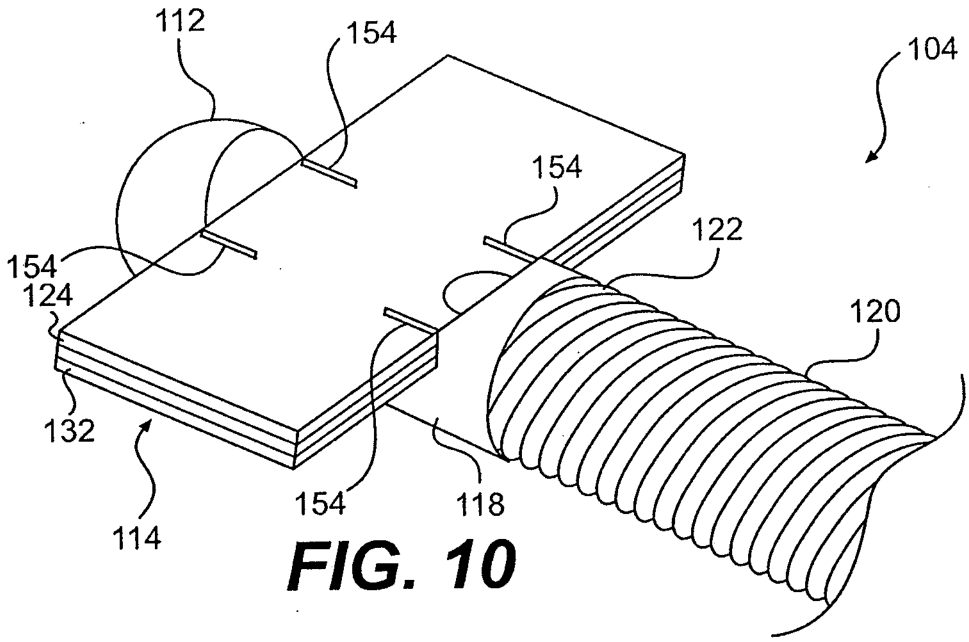
112
154
104
154
154
124
122
120
132
114
154
118

FIG. 10

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- WO 03103501 A **[0005]**
- WO 2008086613 A **[0005]**
- US 20030100834 A **[0005]**

patsnap

专利名称(译)	血管内旋转超声探头及其制作方法		
公开(公告)号	EP2378977B1	公开(公告)日	2020-02-12
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[标]申请(专利权)人(译)	火山公司		
申请(专利权)人(译)	火山CORPORATION		
当前申请(专利权)人(译)	火山CORPORATION		
[标]发明人	DAVIES STEPHEN CHARLES HOSSACK NORMAN SMITH PETER HOWARD		
发明人	DAVIES, STEPHEN, CHARLES HOSSACK, NORMAN SMITH, PETER, HOWARD		
IPC分类号	A61B8/12 G01N29/24 A61B8/08		
CPC分类号	A61B5/0066 A61B5/0084 A61B5/0095 A61B8/0891 A61B8/12 A61B8/445 A61B8/4461 Y10T29/49005 A61B8/08 A61B8/0833 A61B8/085 A61B8/44 A61B8/4444 A61B8/4455 A61B8/4483 A61B8/4494 B29C45/0053 B29C45/14549		
代理机构(译)	德哈恩波尔ERIK		
优先权	12/339477 2008-12-19 US		
其他公开文献	EP2378977A2 EP2378977A4		
外部链接	Espacenet		

摘要(译)

用于插入脉管系统中的旋转血管内超声探头及其制造方法。 旋转血管内超声探头包括具有挠性主体的细长导管和设置在挠性主体内的细长换能器轴。 换能器轴包括近端部分，远端部分，从近端部分延伸至远端部分的驱动轴，设置在远端部分附近以通过旋转获得圆周图像的超声换能器以及换能器壳体 模制到驱动轴和超声换能器。

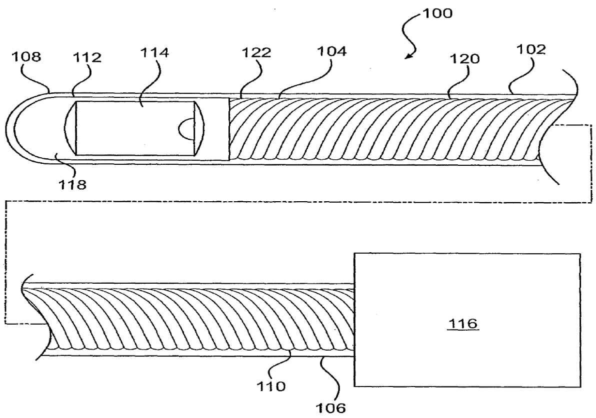

FIG. 1