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(54) Title: IMPLANTABLE SONIC WINDOWS FOR IMAGING THE THORACIC CAVITY

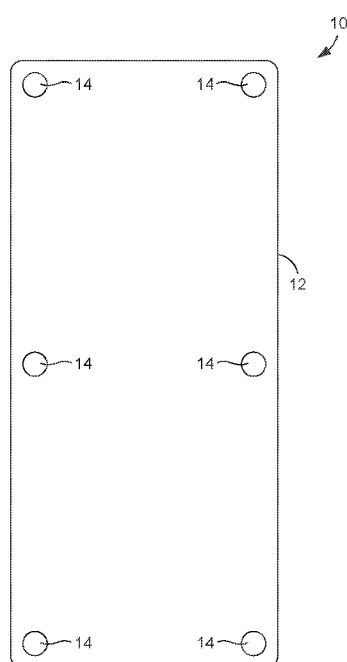


FIG. 1A

(57) Abstract: Implantable sonic window includes a body that is sized and configured to overlies an opening formed through the rib cage, wherein the body is made of a sonically transparent material through which ultrasonic waves can pass. In some embodiments, the polymeric material is polyether ether ketone (PEEK), high molecular weight Polyethylene, Polyoxymethylene (POM), or Polypropylene.

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*
- *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*
- *of inventorship (Rule 4.17(iv))*

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- *with international search report (Art. 21(3))*

IMPLANTABLE SONIC WINDOWS FOR IMAGING THE THORACIC CAVITY

Cross-Reference to Related Application(s)

This application claims priority to co-pending U.S. Provisional Application serial number 62/472,095, filed March 16, 2017, which is hereby incorporated by reference herein in its entirety.

Background

Various techniques are used for cardiac imaging, including computed tomography (CT) imaging and magnetic resonance imaging (MRI). While these techniques are effective, they require large, expensive equipment, which creates challenges to their use. In contrast, ultrasound imaging can be performed using much simpler equipment. For example, ultrasound imaging can be performed in an office setting using a handheld probe connected to a small ultrasound machine.

While ultrasound imaging is advantageous for these reasons, it can be difficult to image the heart and its blood vessels using ultrasound imaging due to the presence of the thoracic cage, or rib cage, which comprises the sternum and the

ribs. Specifically, these bones can block the ultrasonic waves that are emitted by the ultrasound probe to prevent full imaging of the heart and its vessels. It can, therefore, be appreciated that it would be desirable to have a way in which ultrasound cardiac imaging can be performed without interference from the rib cage.

Brief Description of the Drawings

The present disclosure may be better understood with reference to the following figures. Matching reference numerals designate corresponding parts throughout the figures, which are not necessarily drawn to scale.

Fig. 1A is a front view of a first embodiment of an implantable sonic window.

Fig. 1B is a side view of the implantable sonic window of Fig. 1A.

Fig. 2 is an anterior view of the rib cage with the implantable sonic window of Fig. 1 shown attached to the rib cage using wires.

Fig. 3 is an anterior view of the rib cage with the implantable sonic window of Fig. 1 shown attached to the rib cage using fasteners.

Fig. 4 is an anterior view of the rib cage with the implantable sonic window of Fig. 1 shown attached to the rib cage using clamps.

Fig. 5 is an anterior view of the rib cage with a second embodiment of an implantable sonic window shown attached to the rib cage using fasteners.

Fig. 6 is a lateral view of the rib cage illustrating ultrasound imaging of the thoracic cavity through an implantable sonic window that has been attached to the rib cage.

Detailed Description

As described above, it would be desirable to have a way in which ultrasound

cardiac imaging can be performed without interference from the rib cage. Disclosed herein are implantable ultrasonic windows that can be affixed to the rib cage over an opening formed in the rib cage that protects the organs within the thoracic cavity while still enabling ultrasound imaging of the heart and its vessels, as well as any other organs within the cavity. In some embodiments, the opening can be an opening in the sternum that is formed during a cardiac surgical procedure, such as a coronary bypass. In some embodiments, the sonic window is made of a strong but sonically translucent polymeric material.

In the following disclosure, various specific embodiments are described. It is to be understood that those embodiments are example implementations of the disclosed inventions and that alternative embodiments are possible. All such embodiments are intended to fall within the scope of this disclosure.

Figs. 1A and 1B illustrate a first embodiment of a sonic window 10 that can be used to overlie an opening formed in the rib cage, such as through the sternum, for purposes of ultrasound imaging of organs in the thoracic cavity, including the heart and its vessels. As shown in the figures, the window 10 comprises a generally planar body 12 that is unitarily formed from a single piece of material. The material is strong but sonically translucent such that ultrasonic waves can easily pass through it for purposes of imaging the organs. By way of example, the material is a polymeric material, such as polyether ether ketone (PEEK), high molecular weight polyethylene, polyoxymethylene (POM), or polypropylene. While the body 12 has been described as being "planar," it is noted that, in at least some embodiments, the body can be deformed to match the contours of the rib cage to which it is to be applied. Such deformation can be achieved by the user (e.g., surgeon) prior to implantation of the sonic window 10, for example, by first heating it to a temperature

at which its material is malleable.

In the illustrated embodiment, the body 12 is generally rectangular such that it includes four corners and four outer edges 14. In such a case, the body 12 can have length and width dimensions in the range of approximately 2 to 12 inches. Other dimensions are possible, however, and, in general, the dimensions will correspond to the size of the opening that has been formed through the rib cage. While the body 12 is shown as being rectangular in Figs. 1A and 1B, it is noted that the body can have substantially any shape. For example, Fig. 5 illustrates a non-rectilinear configuration for an implantable sonic window. Generally speaking, the body 12 has a thickness that is much smaller than its length and width. In some embodiments, the body can be approximately 1 to 6 millimeters (mm) (e.g., 3 mm) thick.

As shown in Figs. 1A and 1B, mounting holes 14 can be formed through the body 12 to facilitate attachment of the implantable sonic window 10 to the rib cage. In the illustrated embodiment, six holes 14 are formed along the periphery of the body 12, although a greater or smaller number of holes (including none) can be used. The holes 14 are adapted to receive fastening elements that can pass through the body 12 and either around the ribs or into the bone of the sternum or ribs. By way of example, the fastening elements can comprise wires, screws, bone anchors, or clamps. In some embodiments, the holes are approximately 1 mm in diameter.

Fig. 2 illustrates an example application of an implantable sonic window 20 similar to that shown in Fig. 1. More particularly, Fig. 2 illustrates the sonic window 20 secured to a rib cage 22 over an opening 24 formed in the sternum 26. By way of example, the opening 24 can have been formed during a sternoplasty procedure as part of a cardiac surgical procedure. In this example, the sonic window 20 has been secured with wires 28, such as stainless steel wires, that have been wrapped around

individual ribs adjacent the sternum 24.

Fig. 3 illustrates a further application of an implantable sonic window 30. In this example, the sonic window 30 is secured to the rib cage 22 with fasteners 32, such as screws, bolts, or anchors.

Fig. 4 illustrates yet another application of an implantable sonic window 40. In this example, the sonic window 40 is secured to the rib cage 22 with adjustable clamps 42 that clamp onto the sternum 26.

Fig. 5 illustrates another embodiment of an implantable sonic window 50. In this embodiment, the sonic window 50 includes a lateral extension 52 that extends over the left paramedian rib area to enable full visualization of the left cardiac ventricle. As with the embodiment shown in Fig. 3, fasteners 54 are used to secure the sonic window 50 to the rib cage 22. As can be appreciated from the example of Fig. 5, the sonic windows can have substantially any size and shape that would facilitate ultrasound imaging.

As described above, the implantable sonic windows can be used in a diagnostic manner to image the organs of the thoracic cavity. Fig. 6 illustrates an example of this. As shown in that figure, an implantable sonic window 60 has been affixed to the rib cage 22 and an ultrasound probe 62 can be used to transmit ultrasonic radiation through the skin (not shown) and the window, and into the thoracic cavity. In some embodiments, Doppler ultrasound can be performed to observe blood flow through the heart and its blood vessels. Although images obtained from the ultrasound imaging may provide enough information on their own, it is noted that other imaging modalities can be used to supplement that information. For example, if desired, CT scanning and/or MRI imaging can be used in conjunction with the ultrasound imaging to obtain a more complete picture of what is happening

within the patient's thoracic cavity.

CLAIMS

Claimed are:

1. An implantable sonic window comprising:
a body that is sized and configured to overlies an opening formed through the rib cage, wherein the body is made of a sonically transparent material through which ultrasonic waves can pass.
2. The implantable sonic window of claim 1, wherein the sonically transparent material comprises a polymeric material.
3. The implantable sonic window of claim 2, wherein the polymeric material is one of polyether ether ketone (PEEK), high molecular weight polyethylene, polyoxymethylene (POM), or polypropylene.
4. The implantable sonic window of claim 1, wherein the body is approximately 1 to 2 millimeters thick.
5. The implantable sonic window of claim 1, wherein the body comprises mounting holes that facilitate securing of the sonic window to the rib cage.
6. The implantable sonic window of claim 5, further including wires that secure the body to the rib cage.
7. The implantable sonic window of claim 5, further including fasteners that secure the body to the rib cage.

8. The implantable sonic window of claim 1, further comprising clamps that secure the body to the rib cage.

9. A method for imaging the thoracic cavity comprising:
attaching an implantable sonic window to the rib cage in a manner so as to cover an opening formed through the rib cage, the sonic window being made of a sonically translucent material through which ultrasonic waves can pass; and
transmitting ultrasonic waves into the thoracic cavity through the sonic window.

10. The method of claim 9, wherein the implantable sonic window is made of one of polyether ether ketone (PEEK), high molecular weight polyethylene, polyoxymethylene (POM), or polypropylene.

11. The method of claim 9, wherein attaching comprises securing the sonic window to the rib cage using wires.

12. The method of claim 9, wherein attaching comprises securing the sonic window to the rib case using fasteners.

13. The method of claim 9, wherein securing comprises securing the sonic window to the rib case using clamps.

14. The method of claim 9, further comprising imaging organs within the

thoracic cavity using ultrasonic waves reflected from the organs.

15. The method of claim 14, wherein imaging comprises imaging blood flow through the organs using Doppler ultrasound imaging.

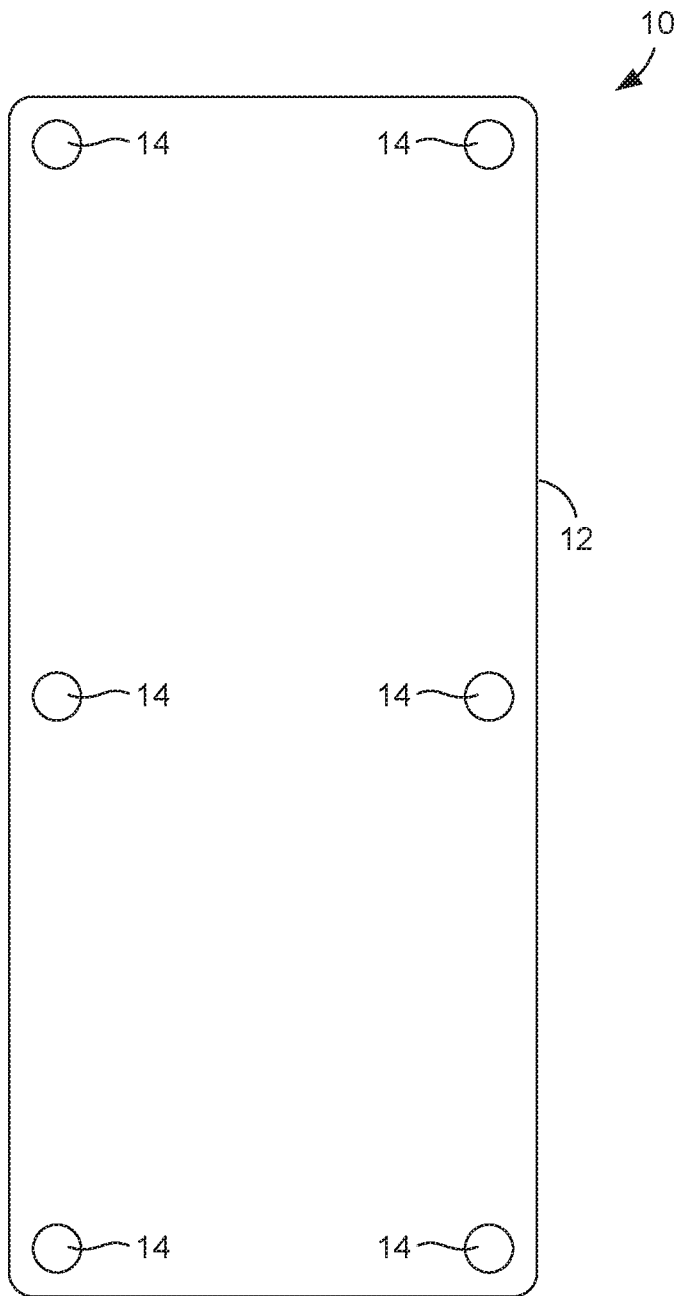


FIG. 1A

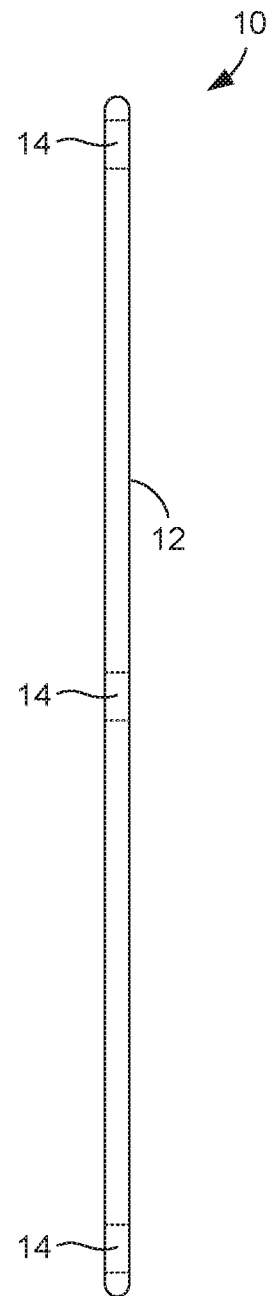
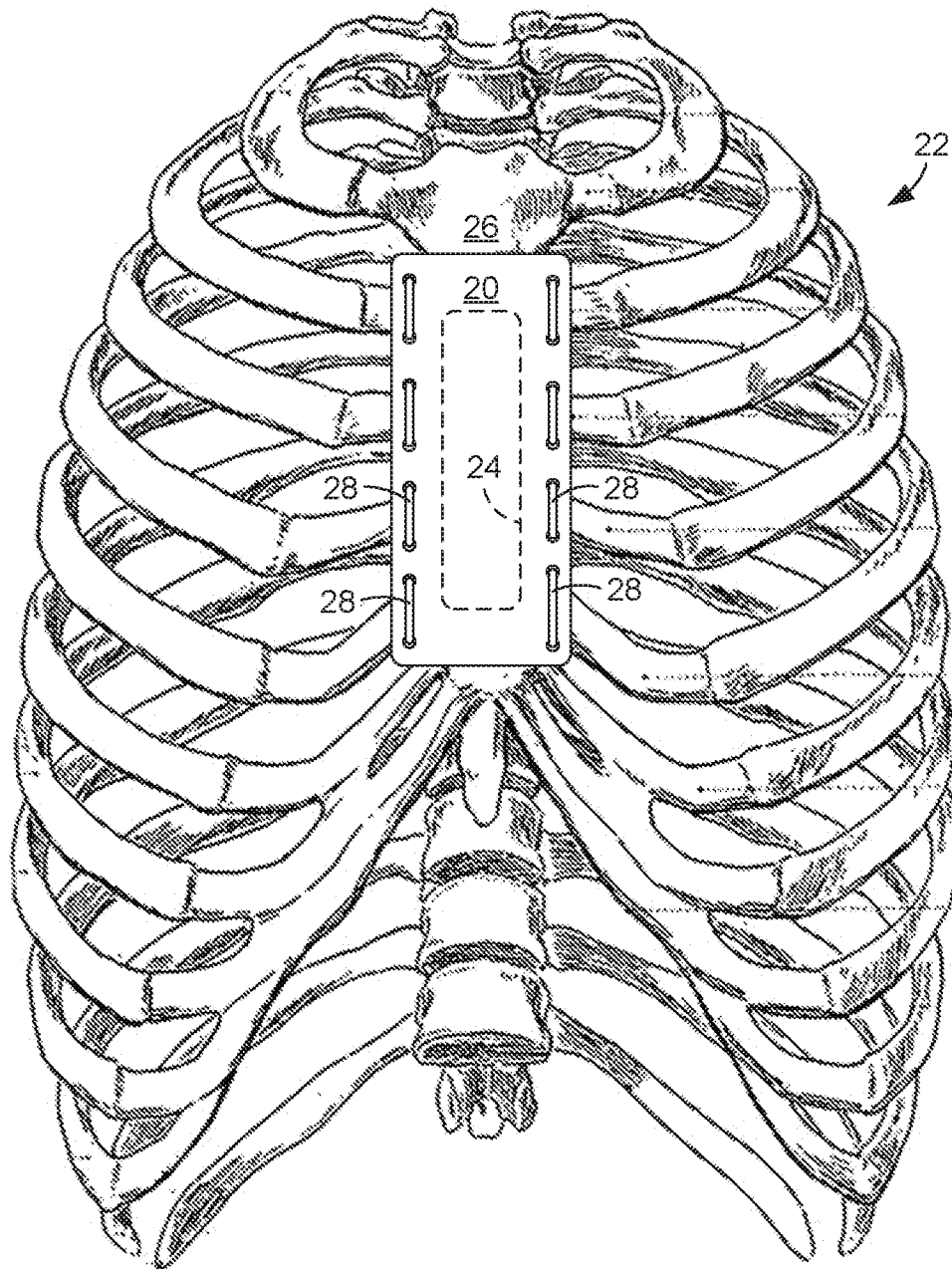
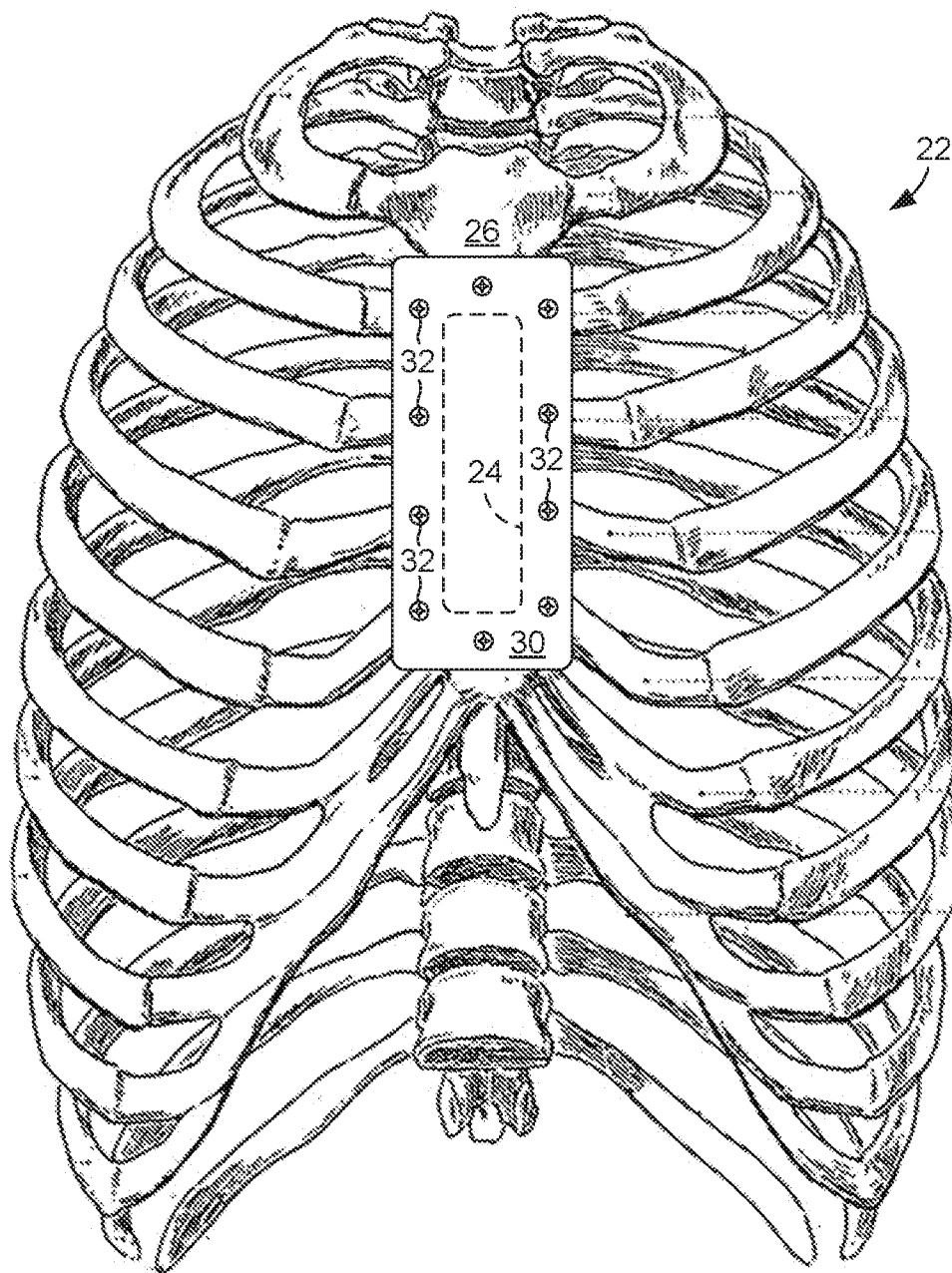
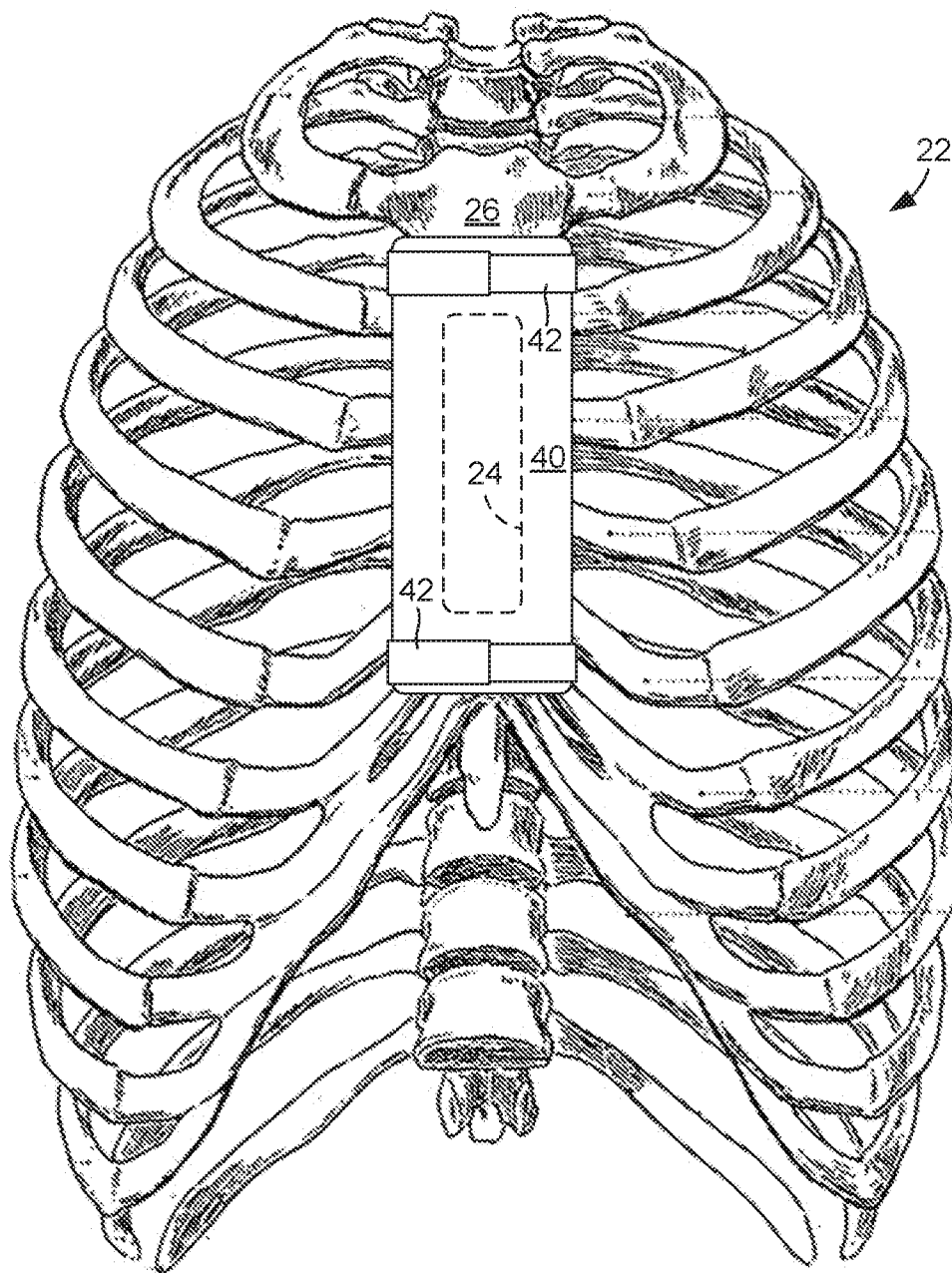
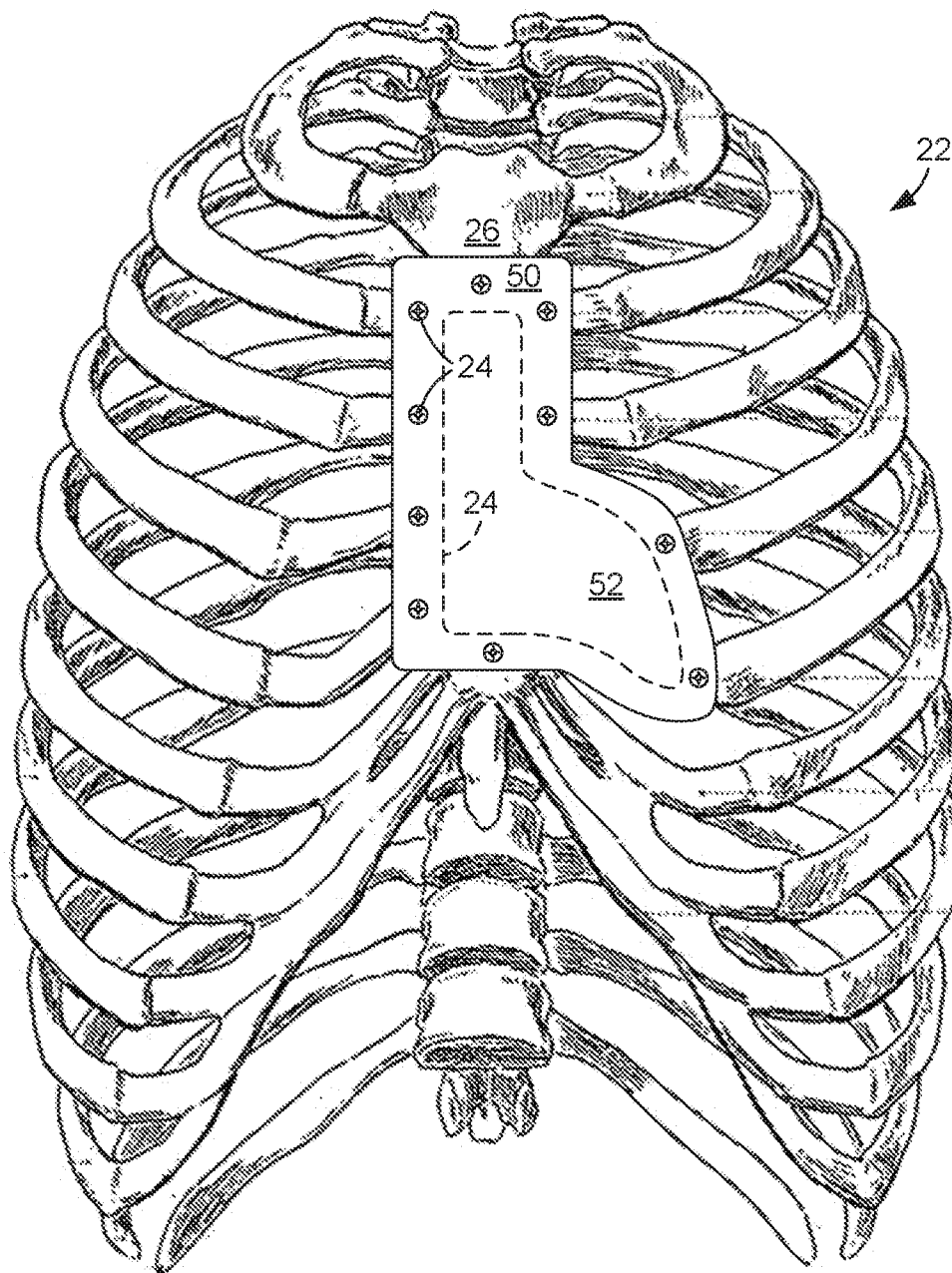


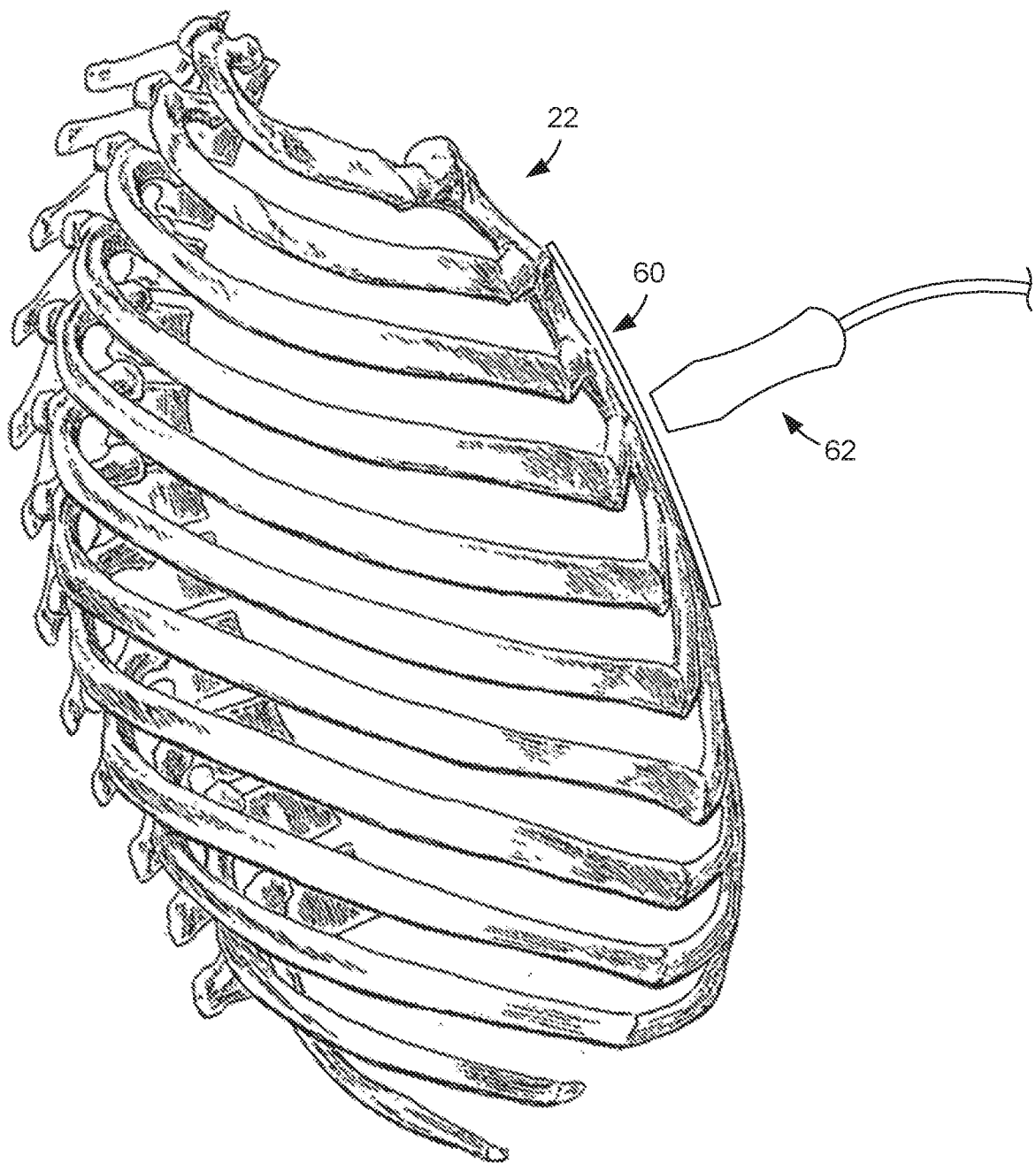
FIG. 1B

**FIG. 2**

**FIG. 3**

**FIG. 4**

**FIG. 5**

**FIG. 6**

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2018/022962

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/00; A61B 17/56; A61B 17/58; A61B 17/68; A61B 17/80; A61B 17/84 (2018.01)

CPC - A61B 17/8076; A61B 17/58; A61B 17/68; A61B 17/683; A61B 17/80; A61B 17/8033; A61B 17/8085; A61B 17/823; A61B 17/842 (2018.02)

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)

See Search History document

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

USPC - 600/437; 600/443; 606/280; 606/286; 606/905 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2015/0230237 A1 (THE CHARLOTTE-MECKLENDURG HOSPITAL AUTHORITY D/B/A CAROLINAS HEALTHCARE SYSTEM) 27 August 2015 (27.08.2015) entire document	1-7 --- 9-15
X --- Y	US 2009/0234357 A1 (MORALES et al) 17 September 2009 (17.09.2009) entire document	1, 8 --- 13
Y	US 2014/0330123 A1 (MANWARING et al) 06 November 2014 (06.11.2014) entire document	9-15
Y	DOSEMECI et al. Utility of Transcranial Doppler Ultrasonography for Confirmatory Diagnosis of Brain Death: Two Sides of the Coin. Transplantation. Vol. 77, 71-75, No. 1. 15 January 2004. entire document	15

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

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Date of the actual completion of the international search

29 April 2018

Date of mailing of the international search report

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