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# Device for support of an organ ex vivo and method using such device

#### Abstract

A device for support of an organ ex vivo comprises a chamber with a first engagement feature. A support structure includes a second engagement feature. The first and second engagement features may be engaged so that the chamber body is carried by the support structure for rotation. The chamber body comprises first and second chamber components. In a first orientation of the chamber body, the first chamber component provides support for a first surface of the organ, and the second chamber component is removable so that a second surface of the organ is exposed to manipulation from outside the chamber body. In a second surface of the organ, and the first chamber component is removable so that the first surface of the organ is exposed to manipulation from outside the chamber body.

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# **Background/Summary**

RELATED APPLICATION (1) This application is a divisional of U.S. patent application Ser. No. 16/131,210, filed Sep. 14, 2018, which claims priority to U.S. Provisional Patent Application Ser. No. 62/559,198, filed Sep. 15, 2017, and to U.S. Provisional Patent Application Ser. No. 62/619,271, filed Jan. 19, 2018, the subject matter of each of which is incorporated herein by reference in its entirety.

#### FIELD OF THE INVENTION

(1) The present invention relates to a device for support of an organ or tissue ex vivo and to a method using such a device and, more particularly, to a device that comprises both a chamber with removable components and structure carrying the chamber for rotation into first and second orientations and to a method that uses such a device.

#### BACKGROUND OF THE INVENTION

(2) In the transplantation of organs, it may be desired to perform a medical procedure on the organ ex vivo before implantation into a patient. A surgeon may, for example, remove excess or damaged tissue from the organ before implantation into the patient. In the case of a liver, the surgeon may divide the liver so that the divided sections of the liver may be implanted into different patients. The more an organ is handled or manipulated ex vivo, however, the greater the likelihood of damage to the organ as a result of such handling. It is desirable, therefore, to reduce the amount of handling of an organ ex vivo, while still permitting the surgeon to perform necessary or desired procedures on the organ prior to implantation.

#### SUMMARY OF THE INVENTION

- (3) The present invention is directed to a device for support of an organ or tissue ex vivo and to a method using such a device and, more particularly, to a device that comprises both a chamber with removable components and structure carrying the chamber for rotation into first and second orientations and to a method that uses such a device.
- (4) In accordance with an embodiment of the present invention, a device for support of an organ or tissue ex vivo comprises a chamber that includes a chamber body configured and dimensioned to extend around the organ or tissue ex vivo. The chamber includes a first engagement feature. The device also comprises a support structure that includes a second engagement feature. The second engagement feature is configured and dimensioned to engage the first engagement feature such that the chamber body is carried by the support structure for rotation about an axis extending through the chamber from a first side of the chamber to an opposite second side of the chamber. The chamber body comprises a first removable chamber component and a second removable chamber component. The chamber body when carried by the support structure is rotatable around the axis from a first orientation to a second orientation. The second orientation is different than the first orientation. The first removable chamber component in the first orientation of the chamber body provides support for a first surface of the organ or tissue ex vivo when disposed in the chamber body. The second removable chamber component in the second orientation of the chamber body provides support for a second surface of the organ or tissue ex vivo when disposed in the chamber body. The second removable chamber component is removable from engagement with the chamber body without disengaging the first and second engagement features from one another when the organ or tissue is disposed in the chamber body and the chamber body is in the first orientation so that the first removable chamber component provides support for the first surface of the organ or tissue while the second surface of the organ or tissue is exposed to manipulation from outside the chamber body. The first removable chamber component is removable from engagement with the chamber body without disengaging the first and second engagement features from one another when the organ or tissue is disposed in the chamber body and the chamber body is in the second orientation so that the second removable chamber component provides support for the second surface of the organ or tissue while the first surface of the organ or tissue is exposed to manipulation from outside the chamber body.

(5) In accordance with another embodiment of the invention, a method for performing a surgical procedure uses a device comprising a chamber including a chamber body configured and dimensioned to extend around an organ or tissue ex vivo. The chamber body includes a first removable chamber component and a second removable chamber component. The chamber also includes a first engagement feature. The device also comprises support structure including a second engagement feature configured and dimensioned to engage the first engagement feature such that the chamber body is carried by the support structure for rotation about an axis extending through the chamber from a first side of the chamber to an opposite second side of the chamber. The method comprising the step of positioning the chamber body including the first removable chamber component such that the support structure carries the chamber body and the chamber body is in a first orientation. The method also comprises the step of disposing an ex vivo organ or tissue in the chamber body so that a first surface of the ex vivo organ or tissue is supported by the first removable chamber component and a second surface of the ex vivo organ or tissue is exposed to manipulation from outside the chamber body. The method further comprises the steps of performing a first surgical procedure on the ex vivo organ or tissue, engaging the second removable chamber component with the chamber body, and rotating the chamber body including the first and second removable chamber components around the axis from the first orientation to a second orientation. Further still, the method comprises the step removing the first removable chamber component from engagement with the chamber body so that the second surface of the ex vivo organ or tissue is supported by the second removable chamber component and the first surface of the ex vivo organ or tissue is exposed to manipulation from outside the chamber body. The method yet still further comprises the step of performing a second surgical procedure on the ex vivo organ or tissue.

# **Description**

#### BRIEF DESCRIPTION OF THE DRAWINGS

- (1) The foregoing and other features and advantages of the present invention will become apparent to one skilled in the art upon consideration of the following description of the invention and the accompanying drawings, in which:
- (2) FIG. **1** is a perspective view of an assembled device for support of an organ or tissue ex vivo in accordance with the present invention;
- (3) FIG. **2** is an side view of the device of FIG. **1**;
- (4) FIG. 3 is a side view of the device of FIG. 1 orthogonal to the view of FIG. 2;
- (5) FIG. **4** is an exploded view of the device of FIG. **1**
- (6) FIG. 5 is an exploded view of certain components of the device of FIG. 1; and
- (7) FIG. **6** is a view of the device of FIG. **1** in use.

## **DETAILED DESCRIPTION**

- (8) FIGS. **1** through **6** illustrate a device **10** for support of an organ or tissue ex vivo, in accordance with an example of the present invention. The device **10** includes a chamber **12**, support structure **14**, and a basin **16**.
- (9) The chamber **12** includes a chamber body **18** and a first engagement feature or chambermounted engagement feature **20** attached directly to or connected directly to the chamber body. The chamber body **18** includes a removable first chamber half or first chamber component **22** and a removable second chamber half or second chamber component **24**. As best seen in FIG. **4**, the first and second chamber components **22** and **24** are substantially identical in configuration and dimensions, including being substantially identical in both size and shape.
- (10) Each of the first and second chamber components **22** and **24** is shaped generally like a frustum of a pyramid. Specifically, the first chamber component **22** includes a rectangular rim **26** with four

orthogonally disposed legs or sides **28***a*, **28***b*, **28***c*, and **28***d*. Two opposed sides **28***b* and **28***d* are longer than the remaining two sides **28***a* and **28***c* so that the rim **26** has a rectangular shape when viewed from above. Extending downward, as viewed in FIGS. **1** and **4**, from a lower edge **30** of the rim **26** along the four sides **28***a*, **28***b*, **28***c*, and **28***d* are four angled side members **32***a*, **32***b*, **32***c*, and **32***d* that are joined together in the shape of a frustum of a hollow pyramid. Along their respective lower edges, the four angled side members **32***a*, **32***b*, **32***c*, and **32***d* are joined to a flat base member **34**.

- (11) In a similar manner, the second chamber component **24** includes a rectangular rim **36** with four orthogonally disposed legs or sides **38***a*, **38***b*, **38***c*, and **38***d*. Two opposed sides **38***b* and **38***d* are longer than the remaining two sides **38***a* and **38***c* so that the rim **36** has a rectangular shape when viewed from above. Extending upward, as viewed in FIGS. **1** and **4**, from an upper edge **40** of the rim **36** along the four sides **38***a*, **38***b*, **38***c*, and **38***d* are four angled side members **42***a*, **42***b*, **42***c*, and **42***d* that are joined together in the shape of a frustum of a hollow pyramid. Along their respective upper edges, the four angled side members **42***a*, **42***b*, **42***c*, and **42***d* are joined to a flat base member **44**.
- (12) As may be apparent from FIG. 1, an upper edge 46 of the rim 26 of the first chamber component 22 and a lower edge 48 of the rim 36 of the second chamber component 24 are configured and dimensioned to mate with one another. Both the upper edge 46 of the rim 26 and the lower edge 48 of the rim 36 may be flat, as shown. Alternatively, the upper edge 46 of the rim 26 and the lower edge 48 of the rim 36 may include inter-engageable mating features, such as laterally offset raised ridges or lips (not shown). The position of such a lip on the upper edge 46 of the rim 26 may be complementary to the position of such a lip on the lower edge 48 of the rim 36 to help keep the first and second chamber components 22 and 24 from sliding or otherwise moving laterally or side-to-side (as viewed in FIGS. 1 and 4) relative to one another. For example, such a lip on the upper edge 46 of the rim 26 may be dimensioned to lie outside of and extend around the complementary lip on the lower edge 48 of the rim 36 when the first and second chamber components 22 and 24 are positioned in engagement with one another.
- (13) The first and second chamber components **22** and **24** may be formed of metal, plastic, or any other relatively rigid material. The rigidity of the material of which the first and second chamber components 22 and 24 is formed may be sufficient to support the weight of an organ or tissue ex vivo without deflection and also sufficient to support or resist without deflection any pressure applied during a medical or surgical procedure on the organ or tissue supported ex vivo on the first and/or second chamber component. Particularly if the first and second chamber components 22 and **24** are formed of plastic, the first and second chamber components may be single use disposable members. Alternatively, and particularly if the first and second chamber components 22 and 24 are formed of metal, the first and second chamber components may be sterilizable re-usable members. (14) As can be seen in FIGS. 1 and 4, the first and second chamber components 22 and 24 include one or more drainage holes, passages, or openings **50** and **52**, respectively, which extend from inside the first and second chamber components to outside the first and second chamber components so as to facilitate drainage of fluids, such as blood and other liquids, from the first and second chamber components. One or more openings **50** and **52** may extend through the base members **34** and **44** from inside the respective first or second chamber component **22** or **24** to outside the respective first or second chamber component. One or more openings **50** and **52** may also or alternatively extend through one or more of the four angled side members **32***a*, **32***b*, **32***c*, and **32***d* of the first chamber component **22** and/or one or more of the four angled side members **42***a*, **42***b*, **42***c*, and **42***d* of the second chamber component **24** from inside the respective first or second chamber component to outside the respective first or second chamber component. To provide the openings **50** and **52**, the base members **34** and **44** and/or the angled side members **32***a*, **32***b*, **32***c*, **32***d* and **42***a*, **42***b*, **42***c*, **42***d* may, for example, be formed of mesh material or of perforated sheet material.

- (15) Attached to or mounted to or on the chamber body **18**, as previously indicated, is the chamber-mounted engagement feature **20**. The chamber-mounted engagement feature **20** comprises a stepped first cylinder, stepped first circular member, or stepped first disc **60**, which is directly attached to or directly connected to a first side of the chamber body **18**, and a stepped second cylinder, stepped second circular member, or stepped second disc **160**, which is directly attached to or directly connected to an opposite second side of the chamber body. The first and second discs **60** and **160** are substantially the same in configuration and size. Accordingly, while only the first disc **60** is described in detail, the second disc **160** includes all of the structure and features that are found in the first disc.
- (16) The first cylinder or first disc **60** is formed as two inter-engageable cylinder or disc halves or portions **62** and **64**. As best seen in FIG. **5**, first disc portion **62** has a smaller diameter semicylindrical outer surface **66** and a larger diameter semi-cylindrical outer surface **68**. Extending between and joining the semi-cylindrical outer surfaces **66** and **68** is a flat semi-annular outer surface **70**. Spaced apart or separated from the flat semi-annular outer surface **70** by the larger diameter semi-cylindrical outer surface 68 is a flat semi-circular end surface 72, which extends parallel to the semi-annular outer surface **70**. Spaced apart or separated from the flat semi-annular outer surface **70** by the smaller diameter semi-cylindrical outer surface **66** is a flat semi-circular end surface **74**, which extends parallel to the semi-annular outer surface **70** and to the end surface **72.** Extending from the end surface **72** to the end surface **74** along a plane that includes diameters of the semi-cylindrical outer surfaces **66** and **68** is a flat T-shaped mating surface **76**. The T-shaped mating surface **76** mates with a corresponding surface of the second disc portion **64**. Also extending from the end surface **72** to the end surface **74** is a concave semi-cylindrical surface **78**, which extends along, but is narrower than, the "vertical" or "upright portion" of the "T" of the mating surface **76**. Adjacent the end surface **72**, two cylindrical openings or recesses **80** are formed in the mating surface **76**, with one recess being positioned on each side of the concave semicylindrical surface **78**.
- (17) Like the first disc portion **62**, second disc portion **64** has a smaller diameter semi-cylindrical outer surface **86** and a larger diameter semi-cylindrical outer surface **88**. Extending between and joining the semi-cylindrical outer surfaces **86** and **88** is a flat semi-annular outer surface **90**. Spaced apart or separated from the flat semi-annular outer surface 90 by the larger diameter semicylindrical outer surface 88 is a flat semi-circular end surface 92, which extends parallel to the semi-annular outer surface 90. Spaced apart or separated from the flat semi-annular outer surface **90** by the smaller diameter semi-cylindrical outer surface **86** is a flat semi-circular end surface **94**, which extends parallel to the semi-annular outer surface **90** and to the end surface **92**. Extending from the end surface 92 to the end surface 94 along a plane that includes diameters of the semicylindrical outer surfaces **86** and **88** is a flat T-shaped mating surface **96**. The T-shaped mating surface **96** mates with the mating surface **76** of the first disc portion **62**, as will be explained in more detail below. Also extending from the end surface 92 to the end surface 94 is a concave semicylindrical surface 98, which extends along, but is narrower than, the "vertical" or "upright portion" of the T-shaped mating surface **96**. Adjacent the end surface **92**, two cylindrical openings or recesses (not shown) are formed in the mating surface **96**, with one recess being positioned on each side of the concave semi-cylindrical surface **98**.
- (18) Each of the first and second disc portions **62** and **64** of the chamber-mounted engagement feature **20** is directly attached to a corresponding first or second chamber component **22** or **24**. More particularly, the first disc portion **62** of the first disc **60** of the chamber-mounted engagement feature **20** is directly attached to or directly connected to a first side **102** of the first chamber component **22**. The second disc portion **64** of the first disc **60** of the chamber-mounted engagement feature **20** is directly attached to or directly connected to a first side **104** of the second chamber component **24**.
- (19) To attach the first disc portion **62** to the first chamber component **22**, four recesses or passages

**106** are formed in the first disc portion. The passages **106** extend from the flat semi-annular outer surface **70** of the first disc portion **62** to the flat end surface **72**. Two of the passages **106** are stepped. The larger diameter portion **107** of each such stepped passage **106** is located adjacent the flat semi-annular outer surface **70** and the smaller diameter portion **108** of each such stepped passage **106** is located adjacent the end surface **72**. Threaded fasteners **109** are inserted into the two stepped passages **106**. An enlarged head **110** of each threaded fastener **109** engages the step formed in the corresponding stepped passage **106**, and a threaded shank **111** of the fastener is screwed into a threaded socket **112** of a nut **113** that engages an inwardly facing or inner surface of the side **28***a* of the rim **26** of the first chamber component **22**. In a similar manner, to attach the second disc portion 64 to the second chamber component 24, four recesses or passages 116 are formed in the second disc portion. The passages **116** extend from the flat semi-annular outer surface **90** of the second disc portion **64** to the flat end surface **92**. Two of the passages **116** are stepped. The larger diameter portion **117** of each passage **116** is located adjacent the flat semi-annular outer surface **90** and the smaller diameter portion 118 of each passage 116 is located adjacent the end surface 92. Threaded fasteners **119** are inserted into the two stepped passages **116**. An enlarged head **120** of each threaded fastener 119 engages the step formed in the corresponding stepped passage 116, and a threaded shank **121** of the fastener is screwed into a threaded socket **122** of a nut **123** that engages an inwardly facing or inner surface of the side **38***a* of the rim **36** of the second chamber component 24.

- (20) The first cylinder or first disc **60** may be formed of metal, plastic, or any other relatively rigid material. Two suitable plastic materials are polytetrafluoroethylene (PTFE), such as a material sold under the brand name Teflon®, and polyoxymethylene, such as a material sold under the brand name Delrin®. The rigidity of the material of which the first disc **60** is formed may be sufficient to support the weight of the chamber **12** and an organ or tissue in the chamber without deflection and also sufficient to support or resist without deflection any pressure applied during a surgical procedure on the organ or tissue in chamber. Depending on the material from which the first disc **60** is made, various alternative mechanisms may be used in lieu of the threaded fasteners for attaching the first disc **60** to the first chamber component **22**. For example, if the first disc **60** is formed from metal, it may be possible to weld the first disc to the first chamber component **22**. Other alternative attachment mechanisms include adhesives.
- (21) To assemble the chamber body 18 and thus the chamber 12, the first and second chamber components **22** and **24** are positioned relative to one another such that the upper edge **46** of the rim **26** of the first chamber component **22** and the lower edge **48** of the rim **36** of the second chamber component **24** mate with one another or are in direct contact or engagement with one another substantially all along their respective perimeters. When the first and second chamber components **22** and **24** are positioned such that the upper edge **46** of the rim **26** of the first chamber component 22 mates with the lower edge 48 of the rim 36 of the second chamber component 24, the flat Tshaped mating surface **76** of the first disc portion **62** and the flat T-shaped mating surface **96** of the second disc portion 64 will be mated with one another or will be positioned in direct contact or engagement with one another throughout substantially all of each surface. To assist in positioning the first and second disc portions **62** and **64** properly with respect to one another and to assist in maintaining the first and second disc portions in proper alignment with one another, dowel pins or indexing pins **124** may be inserted into the recesses **80** formed in the mating surface **76** of the first disc portion **62** and into the recesses (not shown) formed in the mating surface **96** of the second disc portion **64**. The recesses **80** in the mating surface **76** of the first disc portion **62** will be aligned with the recesses (not shown) in the mating surface **96** of the second disc portion **64** when the first and second disc portions are properly positioned with respect to one another. Proper positioning of the first and second disc portions **62** and **64** may also assist in properly positioning the first and second chamber components **22** and **24** with respect to one another.
- (22) When the chamber body 18 and thus the chamber 12 is assembled with the first and second

chamber components 22 and 24 positioned in direct contact or engagement with one another and in alignment with one another, the first and second disc portions 62 and 64 are positioned relative to one such that they form the complete stepped first disc 60, which is a portion of the chamber-mounted engagement feature 20 includes a complete first disc 60, the chamber-mounted engagement feature can facilitate rotation of the chamber body 18 and the chamber 12. In particular, by engaging the chamber-mounted engagement feature 20 with a second engagement feature or support-mounted engagement feature 150 that has a complementary shape and that is incorporated into or mounted to or on the support structure 14, the chamber body 18 and the chamber 12 may be supported or carried by the support structure and also be rotatable about an axis as the chamber-mounted engagement feature is rotated relative to the second engagement feature or support-mounted engagement feature 150. Although such a support-mounted engagement feature 150 and support structure 14 may have numerous different configurations, one particular design of a second engagement feature and support structure is shown generally in FIG. 1 and in detail in FIG. 5.

- (23) As generally shown in FIG. **1**, the support structure **14** comprises an elongated first bracket **130**, which is directly attached to or mounted on a first side of the basin **16**, and an elongated second bracket **170**, which is directly attached to or mounted on an opposite second side of the basin. The first and second brackets **130** and **170** are substantially the same in configuration and size. Accordingly, while only the first bracket **130** is described in detail, the second bracket **170** includes all of the structure and features that are found in the first bracket.
- (24) The first bracket **130** may be formed of metal, plastic, or any other relatively rigid material. The rigidity of the material of which the first bracket **130** is formed may be sufficient to support the weight of the chamber **12** and an organ or tissue in the chamber without deflection and also sufficient to support or resist without deflection any pressure applied during a surgical procedure on the organ or tissue in chamber.
- (25) The first bracket **130** includes a rectangular first body portion **132**. The first body portion **132** of the first bracket **130** has a first major surface **134**, which is substantially rectangular in shape, and an opposite, second major surface **136**, which is also substantially rectangular in shape. At one end 138 of the first body portion 132 and thus the first bracket 130, a rectangularly shaped first bracket support portion **140** extends away from the first body portion **132**. The first bracket support portion **140** is oriented transverse to and, more particularly, substantially perpendicular to the first body portion **132**. The second major surface **136** of the first body portion **132** is presented in substantially the same direction as the first bracket support portion **140** extends. At the opposite end **142** of the first body portion **132** and thus the first bracket **130**, a U-shaped first chamber support portion **144** extends away from the first body portion **132**. The first chamber support portion **144** is oriented transverse to and, more particularly, substantially perpendicular to the first body portion **132**. The first major surface **134** of the first body portion **132** is presented in substantially the same direction as the first chamber support portion **144** extends. The first bracket support portion **140** engages the basin **16** in a manner described in more detail below. The first chamber support portion **144** provides or defines a portion of the support-mounted engagement feature **150**, which is configured and dimensioned to engage the chamber-mounted engagement feature **20** such that the chamber body **18** is carried by the support structure **14** for rotation. (26) As shown in FIG. 5, the first chamber support portion **144** includes two laterally spaced apart projections **146** that form or define the legs of the "U" shape. Extending along the lengths of the two projections **146** and across the first chamber support portion **144** between the two projections is a U-shaped surface **148**. The U-shaped surface **148** includes a curved surface portion extending across the first chamber support portion **144** between the two projections **146** and two straight surface portions extending along the lengths of the two projections. The U-shaped surface, including its curved surface portion, is configured and dimensioned to receive each of the smaller diameter semi-cylindrical outer surfaces 66 and 86 of the first and second disc portions 62 and 64,

respectively, when the first and second disc portions are engaged with one another to form the first disc **60**, when the first disc portion individually or separately engages the U-shaped surface, and when the second disc portion individually or separately engages the U-shaped surface. The first disc **60** is therefore shaped and dimensioned to engage the U-shaped surface **148**, including its curved surface portion, throughout approximately one-half of the smaller circumference of the first disc and is free to rotate relative to the U-shaped surface while being supported on the U-shaped surface. Each of the two projections **146** is long enough to extend upwardly beyond the center of the first disc **60** when the first disc **60** is supported by the U-shaped surface **148**. The two projections **146** thus tend to keep or maintain the first and second disc portions **62** and **64** from separating or sliding relative to one another as the first disc rotates. The support-mounted engagement feature **150** thus comprises the first chamber support portion **144** of the first bracket **130**, including the projections **146** and the U-shaped surface **148**, which U-shaped surface includes the curved surface portion.

(27) To engage the chamber-mounted engagement feature **20** with the support-mounted engagement feature **150**, the chamber body **18** and the directly attached chamber-mounted engagement feature **20** may be moved vertically in a downward direction, as viewed in FIG. **5**, so as to move the first disc **60** between the projections **146** of the first chamber support portion **144** of the first bracket **130** and into contact with the U-shaped surface **148**. As a result of such downward movement, the chamber-mounted engagement feature **20** directly engages the support-mounted engagement feature **150**. Such movement may be easily accomplished, as can the reverse upward movement required to disengage the chamber body 18 and the chamber-mounted engagement feature **20** from the first chamber support portion **144** of the first bracket **130** and the supportmounted engagement feature **150**. Although the U-shape of the first chamber support portion **144** facilitates easy and convenient movement of the chamber-mounted engagement feature **20** into and out of engagement with the support-mounted engagement feature **150**, there are numerous alternative configurations for the support-mounted engagement feature **150**. For example, one of the projections **146** could be shaped to curve around and over the open end of the "U" shape so that the resulting support-mounted engagement feature **150** would be a substantially circular member with a notch or opening in an upper right or upper left quadrant, as viewed in FIG. 5, of the circular shape through which the first disc **60** could be moved into the substantially circular member and into engagement with the support-mounted engagement feature. As another alternative, the first chamber support portion **144** could simply be formed with a circular bore extending through the first chamber support portion into which the first disc **60** could be moved axially to engage the chamber-mounted engagement feature **20** with the support-mounted engagement feature **150**. As a further alternative, the first chamber support portion **144** could include one or more hinged links that could be swung into a position to open a notch or opening through which the first disc **60** could be moved laterally or vertically into engagement with a curved interior support surface 148 of the first chamber support portion.

(28) To this point, the chamber-mounted engagement feature **20** has been described as comprising the stepped first disc **60** directly engaged with or directly attached to the chamber body **18** at a first side **156** of the chamber body and the support-mounted engagement feature **150** has been described as comprising the first chamber support portion **144** of the first bracket **130** located adjacent the stepped first disc **60** and the first side of the chamber body. As previously stated and as shown in FIGS. **1**, **4**, **5**, and **6**, the chamber-mounted engagement feature **20** also includes a stepped second cylinder or stepped second disc **160** at a second side **158** of the chamber body **18** opposite the first side **156**, and the support-mounted engagement feature **150** also comprises a second chamber support portion **176** of a second bracket **170** located adjacent the stepped second disc **160** and the second side **158** of the chamber body. The stepped second disc **160** is in all respects identical to the stepped first disc **60** and includes two inter-engageable disc halves or disc portions **162** and **164**. The first disc portion **162** of the second disc **160** of the chamber-mounted engagement feature **20** is

directly attached to or directly connected to a second side **166** of the first chamber component **22** opposite the first side **102**. The second disc portion **164** of the second disc **160** of the chamber-mounted engagement feature **20** is directly attached to or directly connected to a second side **168** of the second chamber component **24** opposite the first side **104**. Similarly, as previously stated, the second bracket **170** of the support structure **14** is in all respects identical to the first bracket **130** and includes a second body portion **172**, a second bracket support portion **174**, and a second chamber support portion **176**. The support-mounted engagement feature **150** thus also comprises the second chamber support portion **176** of the second bracket **170**, including its projections **175** and U-shaped surface **177**, which U-shaped surface includes a curved surface portion.

- (29) When the first disc **60** is engaged with the first chamber support portion **144** of the first bracket **130** and the second disc **160** is engaged with the second chamber support portion **176** of the second bracket **170**, the chamber body **18** and thus the chamber **12** can be rotated about an axis **180** that extends through the chamber from the first side **156** of the chamber to the opposite second side **158** of the chamber. The axis **180** also extends through the centers of the first and second discs **60** and **160**. As shown, the chamber body **18** and thus the chamber **12** can be rotated manually via direct engagement by a person's hand in either a clockwise direction **178** around the axis **180** or an opposite counter-clockwise direction **179** around the axis. The chamber body **18** and thus the chamber **12** may also be rotated by a manually operated crank (not shown) that may be connected to one or both of the first and second discs **60** and **160** or by a motor (not shown) that may similarly be connected to one or both of the first and second discs **60** and **160**. Such a motor (not shown) may be controlled by a controller (not shown) responsive to inputs from a keyboard (not shown), a touch screen (not shown), and/or one or more sensors (not shown).
- (30) As previously described, the first bracket **130** of the support structure **14** is mounted on the basin **16**. The second bracket **170** of the support structure **14** is similarly mounted on the basin **16**. The basin **16** performs several functions and thus provides several functional features for the device **10**. One function is to provide a mounting structure on which the first and second brackets **130** and **170** of the support structure **14** may be mounted. Another function is to provide a container into which fluids, such as blood and other liquids, from an ex vivo organ or tissue in the chamber **12** may drain and/or into which excess, unwanted, or non-viable material from the organ or tissue in the chamber may be placed by a surgeon or other healthcare provider. A further function is to provide a portable carrier to permit or facilitate movement or relocation of the chamber **12** and the support structure **14**. The foregoing functions may, however, be provided by other structure or another device or by more than one other structure or other device.
- (31) The basin **16** may be formed of metal, plastic, or any other relatively rigid material. The rigidity of the material of which the basin **16** is formed may be sufficient to support the weight of the chamber **12** and an organ or tissue in the chamber without deflection and also sufficient to support or resist without deflection any pressure applied during a surgical procedure on the organ or tissue in chamber. If the basin **16** were not providing a mounting structure on which or to which the first and second brackets **130** and **170** of the support structure **14** are mounted, but were only, for example, providing a container into which fluids from an ex vivo organ or tissue in the chamber **12** may drain and/or into which excess, unwanted, or non-viable material from the organ or tissue in the chamber may be placed by a surgeon or other healthcare provider, the basin may be made from less rigid material
- (32) As can be seen in FIGS. **1-4**, the basin **16** is generally shaped like a frustum of a pyramid and thus is similar in shape to, but with larger dimensions than, the first chamber component **22**. The basin **16** includes a rectangular rim **182** with four orthogonally disposed L-shaped legs or sides **184***a*, **184***b*, **184***c*, and **184***d*. Extending downward, as viewed in FIGS. **2** and **3**, from a lower edge **186** of the rim **182** along the inward ends of the four L-shaped sides **184***a*, **184***b*, **184***c*, and **184***d* are four angled side members **188***a*, **188***b*, **188***c*, and **188***d* that are joined together in the shape of a frustum of a hollow pyramid. Along their respective lower edges, the four angled side members

**188***a*, **188***b*, **188***c*, and **188***d* are joined to a flat base member **190**. Except for certain ports, which will be described hereinafter, all of the rim **182**, the four angled side members **188***a*, **188***b*, **188***c*, and **188***d*, and the flat base member **190** are formed of solid materials free of any openings. The use of solid materials free of openings permits the basin **16** to perform the function of providing a container into which fluids, such as blood and other liquids, from an ex vivo organ or tissue in the chamber **12** may drain and/or into which excess, unwanted, or non-viable material from the organ or tissue in the chamber may be placed by a surgeon or other healthcare provider. The four angled side members **188***a*, **188***b*, **188***c*, and **188***d* help direct fluids to the base member **190** for collection and disposal. The base member **190** also provides a bottom surface that may facilitate placing the device **10** in a stable position on the top of a medical cart, table, or other structure.

- (33) To assist in moving the basin **16** and thus the entire device **10**, an L-shaped handle **192** is fixed to or otherwise connected to or attached to an outwardly presented or exterior surface **194** of the side **184***a* of the rim **182** of the basin **16**. One leg **196** of the handle **192** is secured, for example, by welding, by rivets, or by threaded fasteners, such as screws, to the side **184***a* of the rim **182**. The other leg **198** of the handle **192** projects away from the outwardly presented or exterior surface **194** of the side **184***a* of the rim **182** and may be grasped to help pick up and relocate the basin **16**. A similar L-shaped handle **202** is fixed to or otherwise connected to or attached to an outwardly presented or exterior surface **204** of the side **184***c* of the rim **182** of the basin **16**, which is opposite the side **184***a* to which the handle **192** is fixed or connected or attached. One leg **206** of the handle **202** is secured, for example, by welding, by rivets, or by threaded fasteners, such as screws, to the side **184***c* of the rim **182**. The other leg **208** of the handle **202** projects away from the outwardly presented or exterior surface **204** of the side **184***c* of the rim **182** and may be grasped to help pick up and relocate the basin **16**.
- (34) As best seen in FIGS. 1 and 5, to enable the first bracket 130 of the support structure 14 to be removably mounted on the basin **16**, a guide **210** is fixed, secured, or otherwise attached, for example, by welding, by rivets, or by threaded fasteners **211**, such as screws, to an inwardly presented or interior surface **212** of the side **184***a* of the rim **182** of the basin **16**. The guide **210** includes three linear portions **214**, **216**, and **218** arranged in the shape of a "U." Each of the linear portions **214**, **216**, and **218** is L-shaped in cross-section taken orthogonal to its respective length. The guide **210** is fixed to the side **184***a* of the rim **182** so that a slot is formed between one leg of the L-shape of each linear portion **214**, **216**, and **218** and the interior surface **212** of the side **184***a*. The linear portions **214**, **216**, and **218** of the guide **210** are also fixed or mounted to the side **184***a* such that the slot formed by each of the upright linear portions **214** and **218** opens toward or is presented toward the slot formed by the opposite linear portion. As a result, the first bracket support portion 140 of the first bracket 130 may be slid, in a downward direction as viewed in FIG. 5, into the oppositely facing slots to mount the first bracket **130** on the basin **16**. Movement of the first bracket support portion **140** in a downward direction, as viewed in FIG. **5**, is limited by the laterally extending linear portion **216** of the guide **210**, which rests on a laterally extending leg of the L-shaped side **184***a* of the rim **182** of the basin **16**.
- (35) Similarly, as best seen in FIG. **1**, a guide **220** is fixed, secured, or otherwise attached, for example, by welding, by rivets, or by threaded fasteners, such as screws, to an inwardly presented or interior surface **222** of the side **184***c* of the rim **182** of the basin **16**. The guide **220** includes three linear portions **224**, **226**, and **228** arranged in the shape of a "U." Each of the linear portions **224**, **226**, and **228** is L-shaped in cross-section taken orthogonal to its respective length. The guide **220** is fixed to the side **184***c* of the rim **182** so that a slot is formed between one leg of the L-shaped cross-section of each linear portion **224**, **226**, and **228** and the interior surface **222** of the side **184***c*. The linear portions **224**, **226**, and **228** of the guide **220** are also fixed or mounted to the side **184***c* such that the slot formed by each of the upright linear portions **224** and **228** opens toward or is presented toward the slot formed by the opposite linear portion. As a result, the second bracket support portion **174** of the second bracket **170** may be slid, in a downward direction as viewed in

FIG. **1**, into the oppositely facing slots to mount the second bracket **170** on the basin **16**. Movement of the second bracket support portion **174** in a downward direction, as viewed in FIG. **1**, is limited by the laterally extending linear portion **226** of the guide **220**, which rests on a laterally extending leg of the L-shaped side **184***c* of the rim **182** of the basin **16**.

(36) To facilitate the delivery of fluids and, more particularly, liquids, to an ex vivo organ or tissue in the chamber 12 and/or to facilitate the insertion of electrical wires into the chamber for connection to sensors in, on or adjacent to an ex vivo organ or tissue in the chamber, multiple ports **230** extend through the rim **182** of the basin **16** and through the base member **190**. As shown, two ports **230***a* and **230***b* extend through the vertically extending leg of the L-shaped side **184***a* of the rim **182** from the outwardly presented or exterior surface **194** of the side **184***a* to the inwardly presented or interior surface **212**. Adjacent the exterior surface **194**, each of the ports **230***a* and **230***b* has an exterior fitting **232***a*, *b* to accept and retain a length of plastic tubing. Similarly, adjacent the interior surface **212**, each of the ports **230***a* and **230***b* has an interior fitting **234***a*, *b* to accept and retain a length of plastic tubing. A passage (not shown) extends through each of the ports **230***a* and **230***b* so that fluid can flow from an exterior fitting **232** to an interior fitting **234** (or in the opposite direction) or a wire can extend from an exterior fitting to an interior fitting. Likewise, two ports **230**c and **230**d extend through the vertically extending leg of the L-shaped side **184***c* of the rim **182** from the outwardly presented or exterior surface **204** of the side **184***c* to the inwardly presented or interior surface **222**. Adjacent the exterior surface **204**, each of the ports **230***c* and **230***d* has an exterior fitting **232***c*, *d* to accept and retain a length of plastic tubing. Similarly, adjacent the interior surface **222**, each of the ports **230***c* and **230***d* has an interior fitting **234***c*, *d* to accept and retain a length of plastic tubing. A passage (not shown) extends through each of the ports **230***c* and **230***d* so that fluid can flow from an exterior filling **232***c*, *d* to an interior fitting **234***c*, *d* (or in the opposite direction) or a wire can extend from an exterior fitting to an interior fitting.

(37) A further port **230***e* (FIG. **3**) extends through the laterally extending leg of the L-shaped side **184***a* of the rim **182** from an outwardly presented or exterior surface **236** of the side **184***a* to an opposite inwardly presented or interior surface (not shown). Adjacent the exterior surface 236, the port **230***e* has an exterior fitting **232***e* to accept and retain a length of plastic tubing. Similarly, adjacent the interior surface **238**, the port **230***e* has an interior fitting (not shown) to accept and retain a length of plastic tubing. A passage (not shown) extends through the port **230***e* so that fluid can flow from the exterior fitting **232***e* to the interior fitting (or in the opposite direction) or a wire can extend from one fitting to the other fitting. Likewise, a port **230***f* (FIGS. **1** and **3**) extends through the laterally extending leg of the L-shaped side **184***c* of the rim **182** from an outwardly presented or exterior surface **240** of the side **184***c* to an opposite inwardly presented or interior surface **242**. Adjacent the exterior surface **240**, the port **230** has an exterior fitting **232** f to accept and retain a length of plastic tubing. Similarly, adjacent the interior surface **242**, the port **230** *f* has an interior fitting **234***f* to accept and retain a length of plastic tubing. A passage (not shown) extends through the port **230** f so that fluid can flow from the exterior fitting **232** f to the interior fitting **234***f* (in in the opposite direction) or a wire can extend from one fitting to the other fitting. (38) To assist with drainage of fluids, such as blood and other liquids, from an ex vivo organ or tissue in the chamber **12** and from the basin **16**, two ports **230***g*, *h* (FIGS. **2** and **3**) extend through the base member **190** of the basin **16**. As shown, the two ports **230***g*, *h* extend through the base member **190** from the outwardly presented or exterior surface **244** of the base to the inwardly presented or interior surface (not shown). Adjacent the exterior surface **244**, each of the ports **230***g*, *h* has an exterior fitting **232***g*, *h* to accept and retain a length of plastic tubing. Adjacent the interior surface (not shown), however, each of the ports **230***g*, *h* terminates substantially flush with the interior surface to allow fluids, such as blood and other liquids, directed to the base member **190** to drain into the ports. A passage (not shown) extends through each of the ports **230***g*, *h* so that fluid can flow from an interior end of the port to an exterior fitting **232***g*, *h*.

- (39) The number and locations of the various ports **230** may be varied in accordance with, for example, the intended use of the device **10**, the configuration of the chamber **12**, and/or the configuration of the basin **16**. The device **10** may thus have more or fewer ports **230** than shown and described above, and the ports may be located in different positions, as desired. (40) As an optional feature to provide a portable carrier to permit or facilitate movement or relocation of the chamber **12** and the support structure **14** and/or to help protect the chamber from the environment, the basin **16** may have a lid **250**, as shown in FIG. **4**. The lid **250** is generally shaped like a frustum of a pyramid and is similar in shape to the basin **16**. The lid **250** includes a rectangular rim **252** with four orthogonally disposed legs or sides **254***a*, **254***b*, **254***c*, and **254***d*. Extending upward, as viewed in FIG. 4, from an inner edge 256 of the rim 252 along the inward ends of the four sides **254***a*, **254***b*, **254***c*, and **254***d* are four angled side members **258***a*, **258***b*, **258***c*, and **258***d* that are joined together in the shape of a frustum of a hollow pyramid. Along their respective upper edges, the four angled side members **258***a*, **258***b*, **258***c*, and **258***d* are joined to a flat base member **260**. All of the rim **252**, the four angled side members **258***a*, **258***b*, **258***c*, and **258***d*, and the flat base member **260** are formed of solid materials free of any openings. An outer edge **262** of the rim **252** extends outwardly and downwardly as a lip and may be supported on a corresponding outwardly and downwardly extending upper edge 264 of the rim 182 of the basin 16 so as to enclose the chamber 12.
- (41) In preparation for use, the device **10** may be laid out as shown in FIG. **6**. In particular, the basin **16** may be supported on a suitable surface or support member (not shown), and the first chamber component **22** may be placed in the basin with the first disc portions **62** and **162** of the first and second discs **60** and **160** in contact with and supported by the first and second chamber support portions **144** and **176** of the first and second brackets **130** and **170**. The lid **250** is positioned away from and not in contact with the basin 16 and the second chamber component 24 is similarly portioned away from and not in contact with the first chamber component **22**. An ex vivo organ **270**, such as a liver, may be placed on a first cushion or first compliant member **272**, such as a disposable sponge or foam pad, with a first surface 275 of the organ in contact with the first compliant member. The organ **270** and the first compliant member **272** may then be placed in the first chamber component 22 such that the first compliant member 272 is positioned between the organ and the first chamber component. The first compliant member 272 is sufficiently compliant and shock absorbing to protect the organ 270 from injury from the first chamber component 22 when the chamber is moved. The first compliant member 272 is also sufficiently stiff to permit a medical or surgical procedure to be performed on the organ **270** when supported in the first chamber component **22**. The first compliant member **272** is further formed and shaped to allow fluids, such as blood and other liquids, to drain from the organ **270** through the openings **50** in the first chamber component **22** and thus into the basin **16**. The first compliant member **272** may optionally include one or more features, such as a glue strip, to help attach the compliant member temporarily and releasably to the first chamber component 22.
- (42) To facilitate use of the chamber 12 as intended and as described hereinafter, a second cushion or second compliant member 274 may also be provided. The second compliant member 274 is substantially the same in configuration, dimensions, and construction as the first compliant member 272. The second compliant member 274, when in use, is placed on the organ 270 in contact with a second surface 276 of the organ different than and disposed opposite the first surface 275 of the organ supported by the first compliant member 272. The second chamber component 24 may then be placed on the first chamber component 22 such that the second compliant member 274 is positioned between the organ 270 and the second chamber component. The chamber 12 will then be complete and will surround or be positioned around the organ 270. With the organ 270 disposed between the first and second compliant members 272 and 274 and between the first and second chamber components 22 and 24, the chamber 12 and thus the organ may be rotated about the axis 180 without injury to or significant movement of the organ relative to the chamber.

- (43) In the transplantation of organs, such as the organ **270**, it is typical to perfuse the organ with a suitable perfusion liquid from at least the point in time at which the organ is harvested or removed from the donor, and potentially prior to removal from the donor, until the point in time at which the organ is placed into the body of a recipient and connected to appropriate vessels and ducts in the recipient's body. To permit perfusion liquid to be delivered to the organ **270**, the perfusion liquid must be able to flow from outside the basin **16**, through the basin, and into the chamber **12**. One arrangement for delivering perfusion liquid to an organ, such as the organ **270**, is illustrated in FIG. **6**. In FIG. **6**, one end of a first length of sterilized, medical grade plastic tubing **280** is connected to a source of perfusion liquid (not shown). The other end of the first length of tubing **280** is connected to the exterior fitting **232***a* of the port **230***a*, which extends through the vertically extending leg of the L-shaped side **184***a* of the rim **182** of the basin **16**. One end of a second length of sterilized, medical grade plastic tubing **282** is connected to the interior fitting **234***a* of the port **230***a*. The second length of tubing **282** then passes through the first disc **60** from outside the chamber **12** into the interior of the chamber.
- (44) To pass through the first disc **60**, the second length of tubing **282** extends along the concave semi-cylindrical surface **78** of the first disc portion **62** and/or along the corresponding concave semi-cylindrical surface **98** of the second disc portion **64**. When the first chamber component **22** and the second chamber component **24** are in contact with and aligned with one another, the first and second disc portions **62** and **64** will likewise be in contact with and aligned with one another and the concave semi-cylindrical surfaces **78** and **98** will be presented toward each other to define a passage through the first disc **60** into which the second length of tubing **282** may be inserted to pass through the cylinder. The concave semi-cylindrical surfaces **78** and **98** may have a smooth finish, for example, a surface provided by a low friction coating, to allow the first disc **60** to rotate easily without tending to cause the second length of tubing **282** to rotate and thus twist. As an alternative, a short sleeve (not shown) may be inserted into the passage through the first disc **60** or placed around the second length of tubing **282** to facilitate rotation of the first disc relative to the second length of tubing. The end of the second length of tubing **282** inside the chamber **12** may then be connected to the organ **270**, for example, to a portal vein or hepatic artery of a liver, for delivery of perfusion liquid to the organ.
- (45) For certain organs, such as a liver, it may be desirable or necessary to deliver perfusion liquid to more than one vessel or duct in the organ. If, for example, perfusion liquid is to be delivered at a first pressure and/or flow rate to a first vessel or duct of an organ, such as a portal vein of a liver, and at a second pressure or flow rate to a second vessel or duct or the organ, such a hepatic artery of a liver, it may be desirable or necessary to have a flow of perfusion liquid to the organ separate from the flow through the first and second lengths of tubing **280** and **282**. As illustrated in FIG. **6**, one end of a third length of sterilized, medical grade plastic tubing **284** is connected to a source of perfusion liquid (not shown). The other end of the third length of tubing **284** is connected to the exterior fitting **232***f* of the port **230***f*, which extends through the laterally extending leg of the L-shaped side **184***c* of the rim **182** of the basin **16**. One end of a fourth length of sterilized, medical grade plastic tubing **286** is connected to the interior fitting **234***f* of the port **230***f*. The fourth length of tubing **286** then passes through the second disc **160** from outside the chamber **12** into the interior of the chamber.
- (46) To pass through the second disc **160**, the fourth length of tubing **286** extends along the concave semi-cylindrical surface (not shown) of the first disc portion **162** and/or along the corresponding concave semi-cylindrical surface (not shown) of the second disc portion **164**. When the first chamber component **22** and the second chamber component **24** are in contact with and aligned with one another, the first and second disc portions **162** and **164** will likewise be in contact with and aligned with one another and the concave semi-cylindrical surfaces (not shown) will be presented toward each other to define a passage through the second disc **160** into which the fourth length of tubing **286** may be inserted to pass through the cylinder. The concave semi-cylindrical

surfaces (not shown) may have a smooth finish, for example, a surface provided by a low friction coating, to allow the second disc **160** to rotate easily without tending to cause the fourth length of tubing **286** to rotate and thus twist. As an alternative, a short sleeve (not shown) may be inserted into the passage through the second disc **160** or placed around the fourth length of tubing **286** to facilitate rotation of the second disc relative to the second length of tubing. The end of the fourth length of tubing **286** inside the chamber **12** may then be connected to the organ **270**, for example, to a portal vein or hepatic artery of a liver, for delivery of perfusion liquid to the organ. (47) Because the chamber-mounted and support-mounted engagement features 20 and 150 are configured and dimensioned to facilitate rotation of the chamber body 18 and thus chamber 12 relative to the support structure **14**, it may be necessary to limit, block or prevent such rotation at one or more times during a transplantation surgery to allow a surgeon or other healthcare provider to perform a medical procedure or surgical procedure on the organ **270** in the chamber body. FIG. **5** illustrates one particular mechanism to limit, block or prevent rotation of the chamber body 18 and thus the chamber **12**. As shown in FIG. **5**, a pin **290** has an elongated cylindrical body **292** with a tapered end **294** and a transverse opening **296** adjacent an end **298** opposite the tapered end **294**. A spring-loaded ball **300** is received in a recess adjacent the tapered end **294** and a ring or a cross member **302** is received in the opening **296** adjacent the opposite end **298**. The body **292** of the pin 290 is dimensioned to fit into a passage or hole 304 formed in and extending through one projection **146** of the first chamber support portion **144** of the first bracket **130**. The body **292** is also dimensioned to fit into each of the two passages **106** in the first disc portion **62** that do not receive a threaded fastener **109**.

(48) Advancing the pin **290** through the hole **304** in the first bracket **130** toward the chamber body **18** and the first disc **60** and into a passage **106** in the first disc portion **62** will cause the pin to hold the chamber body and thus the chamber **12** against rotation. The spring-loaded ball **300** will help hold the pin **290** in engagement with the first disc **60**. There are two passages **106** in the first disc portion **62** that do not receive a threaded fastener **109**, and there are two passages **116** in the second disc portion **64** that do not receive a threaded fastener **119**. One such passage **106** in the first disc portion **62** (in the upper right-hand area of the first disc portion **62**) and one such passage **116** in the second disc portion **64** (in the lower left-hand area of the second disc portion **64**) are disposed approximately 180° apart from one another. By advancing the pin 290 into one of these two passages **106**, **116**, the chamber body **18** and thus the chamber **12** may be held or locked in position against rotation in a first orientation and a different second orientation disposed approximately 180° apart from one another. If desired, the pin **290** may be employed to engage the second disc **160** though a hole (not shown) in the second bracket **170** or a second pin (not shown) may be similarly employed to engage the second disc **160** though such a hole in the second bracket **170**. (49) When a surgeon or other healthcare provider is to perform a transplantation procedure, the surgeon or other healthcare provider may employ a device such as the device **10** of FIGS. **1-6** in implementing a process or method for performing a medical or surgical procedure on an organ or tissue ex vivo. For example, if the surgeon or other healthcare provider is performing a transplantation of an organ **270**, such as a liver, the surgeon or other healthcare provider may position the chamber 12 such that the chamber body 18, including the first chamber component 22, is carried by the support structure **14**, in a first orientation, as shown in FIG. **6**. In the first orientation, the first chamber component 22 is oriented to provide support for the first surface 275 of the organ **270**, when disposed in the chamber body **18**. In particular, the upper edge **46** of the rim **26** of the first chamber component **22** is substantially horizontal and the remainder of the first chamber component, including the four angled side members 32a, 32b, 32c, and 32d and the base member **34**, is disposed below the rim **26**.

(50) The organ **270** is disposed in the chamber body **18** so that the first surface **275** of the ex vivo organ **270** is supported by the first chamber component **22** and the second surface **276** of the organ **270** is exposed to manipulation from outside the chamber body. The first chamber component **22** 

may directly support the first surface 275 of the organ 270 by being in direct contact with the first surface of the organ or the first chamber component 22 may indirectly support the first surface of the organ by having the first compliant member 272 disposed between the first chamber component and the organ. Depending on the circumstances, the organ 270, such as a liver, may be disposed in the chamber body 18 prior to positioning the chamber body in the first orientation. The second surface 276 of the ex vivo organ 270 or tissue may be exposed to manipulation from outside the chamber body 18 by either removing the second chamber component 24 from the chamber body, if the organ is already disposed in the chamber body before the surgeon or other healthcare provider initiates this method, or by not placing the second chamber component in contact with the first chamber component 22, if the organ 270 is positioned in the chamber body after the chamber body is placed in its first orientation. The organ 270 may be connected to the second and fourth lengths of tubing 282 and 286 so that perfusion liquid or other liquid is delivered to the organ during the medical or surgical procedure.

- (51) With the chamber body **18** in its first orientation, the surgeon or other healthcare provider may perform a first medical or surgical procedure on the organ **270**. This first medical or surgical procedure, which may, for example, involve removing excess, unwanted, or non-viable tissue from the organ **270** or separating the organ into two viable pieces, if the organ is a liver, for example, is performed by having medical or surgical instruments directed from outside the chamber body **18** manipulate, engage or interact with the organ **270**, particularly the second surface **276** of the organ. The surgeon or other healthcare provider may manipulate, engage or interact with the organ **270** by reaching into or otherwise accessing the volume or space that would otherwise be blocked from such access by the second chamber component **24**. The manipulation may involve use of, for example, a scalpel or a suturing needle. While the surgeon or other healthcare provider is performing the first medical or surgical procedure, the chamber body **18** and thus the chamber **12** may locked or blocked from or held against rotation by the engagement of the pin **290** with the first disc **60** or by another suitable mechanism.
- (52) After performing the first medical or surgical procedure, the surgeon or other healthcare provider may then engage the second chamber component 24 with the first chamber component 22, which in the absence of the second chamber component constitutes, in effect, the chamber body 18. Before the surgeon or other healthcare provider engages the second chamber component 24 with the first chamber component 22, the surgeon or other healthcare provider may place the second compliant member 274 in contact with the second surface 276 of the organ 270 so that the second compliant member 274 is interposed between the second surface of the organ and the second chamber component 24. Thereafter, the surgeon or other healthcare provider may slide the pin 290 out of engagement with the first disc 60 and then rotate the chamber body 18, including the first and second chamber components 22 and 24, around the axis 180 from its first orientation to a second orientation. Rotation of the chamber body 18 may be accomplished by grasping the chamber body and rotating the chamber body by hand or the rotation may be accomplished by operating a motor (not shown) or crank (not shown) coupled to the first or second disc 60 or 160 and thus to the chamber body.
- (53) The second orientation of the chamber body **18** is about 180° around the axis **180** from the first orientation. In the second orientation of the chamber body **18**, the second chamber component **24** is oriented to provide support for the second surface **276** of the organ **270**, when disposed in the chamber body **18**. In particular, the lower edge **48** of the rim **26** of the second chamber component **24** becomes the uppermost surface of the second chamber component and is substantially horizontal. The remainder of the second chamber component **24**, including the four angled side members **42***a*, **42***b*, **42***c*, and **42***d* and the base member **44**, is disposed below the edge **48** of the rim **36**. The organ **270** is disposed in the chamber body **18** so that the second surface **276** of the ex vivo organ **270** is supported by the second chamber component **24** and the first surface **275** of the organ **270** may be exposed to manipulation from outside the chamber body. The second chamber

component **24** may directly support the second surface **276** of the organ **270** by being in direct contact with the second surface of the organ or the second chamber component **24** may indirectly support the second surface of the organ by having the second compliant member **274** disposed between the second chamber component and the organ.

- (54) When the chamber body **18** has been rotated to its second position, the pin **290** may be engaged with the second disc portion **64** of the first disc **60** to block or prevent rotation of the chamber body **18**. The surgeon or other healthcare provider may then remove the first chamber component 22 from engagement with the second chamber component 24, and thus the chamber body 18, and also remove the first compliant member 272 from engagement with the first surface **275** of the organ **270**. As a result, the second surface **276** of the ex vivo organ **270** is supported by the second chamber component **24** and the first surface **275** of the organ **270** is exposed to manipulation from outside the chamber body. With the chamber body **18** in its second orientation, the surgeon or other healthcare provider may perform a second medical or surgical procedure on the organ **270**. This second medical or surgical procedure, which may, for example, involve removing excess, unwanted, or non-viable tissue from the organ 270 or separating the organ into two viable pieces, if the organ is a liver, for example, is performed by having medical or surgical instruments directed from outside the chamber body 18 manipulate, engage or interact with the organ **270**, particularly the first surface **275** of the organ. The surgeon or other healthcare provider may manipulate, engage or interact with the organ **270** by reaching into or otherwise accessing the volume or space that would otherwise be blocked from such access by the first chamber component **22**. The manipulation may involve use of, for example, a scalpel or a suturing needle. (55) If the surgeon or other healthcare provider decides that additional medical or surgical procedures are desirable or necessary and should be performed on the second surface 276 of the organ **270**, the surgeon or other healthcare provider may again place first compliant member **272** on the organ and place the first chamber component **22** in a mating orientation in direct contact with the second chamber component **24** so that the chamber body **18** is again complete and can be rotated into its first orientation, as described above. Thereafter, the pin **290** may be engaged to block or prevent rotation of the chamber body 18, the second chamber component 24 may be removed from direct contact with the first chamber component 22, and the second compliant member 274 may be removed from contact with the second surface 276 of the organ 270. The second surface **276** of the organ **270** will then again be exposed to manipulation from outside the chamber **12**. The foregoing steps of rotating the chamber body **18** and removing either the first chamber component **22** or the second chamber component **24** and the associated first or second compliant member 272 or 274 may be repeated as required until the organ 270 is ready to be transplanted into a recipient patient's body.
- (56) During the performance or implementation of the process or method described above, once the first or chamber-mounted engagement feature 20 is engaged with the second or support-mounted engagement feature 150, at least a portion of the chamber-mounted engagement feature remains engaged with the support-mounted engagement feature even as the first and second chamber components 22 and 24 are individually moved into and out of engagement with one another. Stated differently, the second chamber component 24 can be removed from engagement with the first chamber component 22, and thus the chamber body 18, without disengaging the chamber-mounted and support-mounted engagement features 20 and 150, respectively, from one another when the organ 270 is disposed in the chamber body and the chamber 12 is in the first orientation. Specifically, while the second chamber component 24 is disengaged from the first chamber component 22 and the second disc portions 64 and 164 are disengaged from the first disc portions 62 and 162, the first disc portions 62 and 162 and thus the first and second discs 60 and 160 and the chamber-mounted engagement feature 20 remain engaged with the first and second chamber support portions 144 and 176 of the first and second brackets 130 and 170, respectively, and thus the support-mounted engagement feature 150. Likewise, the first chamber component 22 can be

removed from engagement with the second chamber component 24, and thus the chamber body 18, without disengaging the chamber-mounted and support-mounted engagement features **20** and **150**, respectively, from one another when the organ **270** is disposed in the chamber body and the chamber **12** is in the second orientation. Specifically, while the first chamber component **22** is disengaged from the second chamber component **24** and the first disc portions **62** and **162** are disengaged from the second disc portions **64** and **164**, the second disc portions **64** and **164** and thus the first and second discs **60** and **160** and the chamber-mounted engagement feature **20** remain engaged with the first and second chamber support portions 144 and 176 of the first and second brackets **130** and **170**, respectively, and thus the support-mounted engagement feature **150**. (57) Although each of the first and second chamber components **22** and **24** is described and illustrated as generally resembling a frustum of a pyramid with a rectangular base, which permits the chamber body **18** to fit into and rotate within the basin **16**, the first and second chamber components may have other shapes. Each of the first and second chamber components **22** and **24** may, for example, be shaped generally as a frustum of a pyramid with a square, rather than a rectangular, base. Each of the first and second chamber components 22 and 24 may alternatively be shaped as hemispheres, as halves of an ellipsoid, halves of a cylinder, or any other geometric shape that would permit the first and second chamber components to be readily engaged and disengaged with one another. The shapes used for the first and second chamber components **22** and **24** and the shape of the basin **16** would be selected to permit the chamber body **18** to fit into and rotate within the basin.

- (58) Similarly, while the chamber body **18** is described and illustrated as being comprised of two substantially identical halves or components, other configurations of the chamber body are possible. For example, the rims **26** and **36** of the first and second chamber components **22** and **24** may alternatively be formed as a single member, which may be permanently attached directly to or connected directly to the first and second discs **60** and **160**. The removable first chamber component **22** would then comprise the four angled side members **32***a*, **32***b*, **32***c*, and **32***d* and the base member **34**, and the removable second chamber component **24** would then comprise the four angled side members **42***a*, **42***b*, **42***c*, and **42***d* and the base member **44**. Such an alternative chamber body **18** would then have releasable attachment mechanisms, such as latches, to connect each of the alternative first and second chamber components **22** and **24** to the single member comprised of the two rims **26** and **36**.
- (59) Yet another alternative configuration of the chamber body 18 may be the use of more than two removable chamber components. For example, as described above, the chamber body 18 may comprise a frame, such as a single member formed from the two rims 26 and 36, to which removable chamber components, such as the previously described alternative first and second chamber components 22 and 24, are releasably attached or connected. If the chamber body 18 alternatively comprised three removable chamber components, the frame may alternatively comprise three rims permanently secured to two spaced apart triangular plates to which the first and second discs 60 and 160 may be directly and permanently attached. Any number of removable chamber components may be possible, but as the number of removable chamber components increases, the overall dimensions of the chamber will tend to increase and the amount of working room provided by removing an individual chamber component will tend to decrease. Conversely, the use of two chamber components 22 and 24 that directly engage one another will tend to provide the both the smallest overall dimensions for the chamber 12 and the greatest working room when one of the chamber components is removed.
- (60) The device **10** has been described and illustrated as including one mechanism, which includes the pin **290**, to limit, block or prevent rotation of the chamber body **18** and thus the chamber **12**. As previously indicated, the particular mechanism described and illustrated is just one example of such a mechanism. Other mechanisms may be used, as desired, to facilitate use of the device **10**. For example, in one such alternative mechanism, the larger circumference portion of one or both of the

first and second discs **60** and **160** may include two notches or indentations located about 180° apart. In lieu of the pin **290**, a spring-biased latch member or follower may engage and travel on the larger circumference portion of one or both of the first and second discs **60** and **160**. As the follower reaches each notch or indentation, the spring bias will tend to cause the follower to engage and remain in the notch or indentation. By appropriately locating the notches or indentations, the engagement of the follower with one notch on the first or second disc 60 or 160 would tend to maintain the chamber body **18** in the first orientation, while engagement of the follower with the other notch on the first or second disc would tend to maintain the chamber body 18 in the second orientation. As another alternative mechanism, if rotation of the chamber body **18** is accomplished by operating a motor or crank coupled to the first or second disc **60** or **160** and thus to the chamber body **18**, the gear train from the motor or crank to the first or second disc may be lockable in positions corresponding the first and second orientations of the chamber body. (61) More generally, the device **10** has been described and illustrated as a device for use during the final stage of a transplantation process when an ex vivo organ or tissue is about to be implanted into a recipient patient. The device **10** could, however, be used earlier in the transplantation process, such as when an organ or tissue is being removed from a donor's body and/or during transportation of a donated organ or tissue ex vivo. Such use may involve an external, portable source of perfusion fluid, including a pump and a source of electrical power. Such use may also or alternatively involve a portable electric motor and a releasable drive mechanism to connect the motor to one or both of the first and second discs **60** and **160** to enable the chamber body **18** to be rotated periodically or intermittently during transportation of the organ or tissue ex vivo and thereby assist in reducing trauma or damage to the organ or tissue resulting from resting on single surface of the organ or tissue for an extended period during transportation. For example, such a drive mechanism may include a hollow shaft extending from outside the basin through the rim 182 into engagement with one of the first and second discs **60** and **160**, thereby providing both a mechanism for delivering rotational movement to the chamber 12 and, via the hollow interior of the shaft, a flow conduit for perfusion liquid. Use of the device **10** earlier in the transplantation process may further or alternatively involve sensors placed on, in, or near the organ or tissue ex vivo and a visually perceptible device, such as a display screen of a hand-held or other device, for monitoring data from such sensors and/or wireless transmission devices to transmit data from such sensors to a remote device, such as a hand-held device, for monitoring such data. (62) From the above description of the invention, those skilled in the art will perceive improvements, changes and modifications. Such improvements, changes, and/or modifications within the skill of the art are intended to be covered by the appended claims.

## **Claims**

1. A method for performing a surgical procedure using a device comprising a chamber including a chamber body configured and dimensioned to extend around an organ or tissue ex vivo, the chamber body including a first removable chamber component and a second removable chamber component, the chamber body being carried by a support structure of the device for rotation about an axis extending through the chamber from a first side of the chamber to an opposite second side of the chamber, the method comprising the steps of: (a) positioning the chamber body including the first removable chamber component such that the support structure carries the chamber body and the chamber body is in a first orientation; (b) disposing an ex vivo organ or tissue in the chamber body so that a first surface of the ex vivo organ or tissue is supported by the first removable chamber component and a second surface of the ex vivo organ or tissue is exposed to manipulation from outside the chamber body; (c) performing a first surgical procedure on the ex vivo organ or tissue; (d) engaging the second removable chamber component with the chamber body; (e) rotating the chamber body including the first and second removable chamber components around the axis

from the first orientation to a second orientation; (f) removing the first removable chamber component from engagement with the chamber body so that the second surface of the ex vivo organ or tissue is supported by the second removable chamber component and the first surface of the ex vivo organ or tissue is exposed to manipulation from outside the chamber body; and (g) performing a second surgical procedure on the ex vivo organ or tissue.

- 2. The method of claim 1, wherein the chamber includes a first engagement feature, the support structure including a second engagement feature configured and dimensioned to engage the first engagement feature such that the chamber body is carried by the support structure for rotation about the axis.
- 3. The method of claim 2, wherein the second removable chamber component is removable from engagement with the chamber body without disengaging the first and second engagement features from one another when the organ or tissue is disposed in the chamber body and the chamber body is in the first orientation so that the first removable chamber component provides support for the first surface of the organ or tissue while the second surface of the organ or tissue is exposed to manipulation from outside the chamber body.
- 4. The method of claim 2, wherein the first removable chamber component is removable from engagement with the chamber body without disengaging the first and second engagement features from one another when the organ or tissue is disposed in the chamber body and the chamber body is in the second orientation so that the second removable chamber component provides support for the second surface of the organ or tissue while the first surface of the organ or tissue is exposed to manipulation from outside the chamber body.
- 5. The method of claim 2, wherein the first engagement feature includes a circular member attached to the chamber body, the second engagement feature including a curved surface configured and dimensioned to receive the circular member of the first engagement feature.
- 6. The method of claim 5, wherein the first engagement feature includes (a) a first circular member directly attached to a first side of the chamber body and (b) a second circular member directly attached to a second side of the chamber body opposite and spaced apart from the first side, the second engagement feature including a first curved surface configured and dimensioned to receive the first circular member of the first engagement feature and a second curved surface configured and dimensioned to receive the second circular member of the first engagement feature, the second curved surface being spaced apart from the first curved surface.
- 7. The method of claim 2, wherein the first engagement feature includes a disc separable into a first disc portion and a second disc portion, the first disc portion being directly attached to the first removable chamber component and the second disc portion being directly attached to the second removable chamber component.
- 8. The method of claim 7, wherein the support structure includes a bracket, the second engagement feature including a curved surface portion of the bracket, the curved surface portion being configured and dimensioned to receive the disc of the first engagement feature.
- 9. The method of claim 2, wherein at least one of the first engagement feature and the second engagement feature is configured and dimensioned to provide a passage along the axis through which fluid may pass from outside the chamber body to inside the chamber body.
- 10. The method of claim 1, wherein the first removable chamber component and the second removable chamber component when both engaged with the chamber body are disposed opposite one another, the chamber body when carried by the support structure being rotatable around the axis from the first orientation through about 180° to the second orientation.
- 11. The method of claim 1, wherein the first removable chamber component and the second removable chamber component are configured and dimensioned to engage one another directly to form the chamber body.
- 12. The method of claim 1, wherein the first removable chamber component is a first half of the chamber body and the second removable chamber component is a second half of the chamber body,

the first half of the chamber body being substantially identical in configuration and dimensions to the second half of the chamber body.

- 13. The method of claim 1, wherein the first removable chamber component includes at least one first drainage opening through which fluid can pass from inside the chamber body to outside the chamber body, the second removable chamber component including at least one second drainage opening through which fluid can pass from inside the chamber body to outside the chamber body.
- 14. The method of claim 13, further comprising a basin on which the support structure is removably mountable, the basin being positioned to receive fluid from at least one of the at least one first drainage opening and the at least one second drainage opening.
- 15. The method of claim 14, wherein the chamber includes a first engagement feature, the support structure including a second engagement feature configured and dimensioned to engage the first engagement feature such that the chamber body is carried by the support structure for rotation about the axis, and wherein the support structure includes a bracket removably mounted on the basin, the second engagement feature including a curved surface portion of the bracket, the curved surface portion being configured and dimensioned to receive a disc portion of the first engagement feature.
- 16. The method of claim 14, wherein the basin includes at least one passage through which fluid can pass from inside the basin to outside the basin.
- 17. The method of claim 14, further comprising a cover removably mountable on the basin.
- 18. The method of claim 14, wherein the basin is configured and dimensioned to permit the chamber to be rotated in the basin when the support structure is mounted on the basin and the chamber body is carried by the support structure.
- 19. The method of claim 1, further comprising a first cushion member and a second cushion member, the first cushion member being configured and dimensioned to be positioned on the first removable chamber component between the first removable chamber component and the ex vivo organ or tissue, the second cushion member being configured and dimensioned to be positioned on the second removable chamber component between the second removable chamber component and the ex vivo organ or tissue.
- 20. The method of claim 1, further comprising a mechanism engageable to block rotation of the chamber body about the axis when the chamber body is in one of the first orientation and the second orientation.