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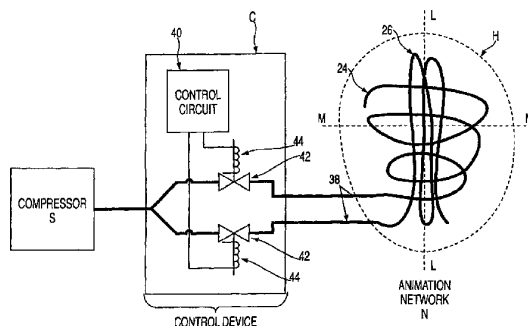
(71) 出願人 502160970
 ザ・チェンバーレイン・グループ
 THE CHAMBERLAIN GROUP
 アメリカ合衆国、マサチューセッツ州、グ
 レイト・バリントン、サウス・メイン・ス
 トリート 934
 934 South Main Stre
 et, Great Barrington,
 MA 01230 U. S. A.
 (74) 代理人 100057874
 弁理士 曾我 道照
 (74) 代理人 100110423
 弁理士 曾我 道治

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(54) 【発明の名称】 心臓手術用トレーナおよびその作製方法

(57) 【要約】

心臓手術用および他の同様な処置用のトレーナは、心臓モデル (H) などの器官モデル、対応する実際の器官と同様の動きを該モデルに与えるよう適合された活動網状組織 (N)、および該活動網状組織の動作を制御するために用いられる制御装置 (C) を備える。上記心臓モデルは、2つのセクション、すなわち、心筋を擬態した内部鑄造物と、心膜を擬態した外殻とから構成される。このモデルは、内部鑄造物を形成すること、該鑄造物を塗装すること、ひいてはこの鑄造物の周囲に外殻を形成することによって製造される。このモデルは、好ましくはシリコンゴム製である。



【特許請求の範囲】

【請求項 1】

心臓手術用トレーナであって、
比較的軟質な材料製の心臓モデルと、
前記心臓モデル内に配設されており、自然に拍動する心臓の二次元の動きを擬態して前記心臓モデルを動かすように構成されている活動網状組織と、
前記活動網状組織に接続され、該活動網状組織を選択的に作動する制御装置とを備える心臓手術用トレーナ。

【請求項 2】

前記活動網状組織は、それぞれの軸に沿って配向された複数の管を備える請求項 1 に記載のトレーナ。 10

【請求項 3】

前記管は、加圧されると寸法が変わるように構成されている請求項 2 に記載のトレーナ。

【請求項 4】

前記管は、加圧されると長さが変わる請求項 3 に記載のトレーナ。

【請求項 5】

前記各管は、両端部を有する可撓性パイプと、該パイプの該両端部に取り付けられたメッシュとを備え、前記パイプおよび前記メッシュは、該パイプが加圧されると半径方向に拡張し、前記メッシュは、前記パイプが加圧されると、該パイプを強制的に長手方向に短くさせる請求項 4 に記載のトレーナ。 20

【請求項 6】

互いに垂直な 2 軸に沿って配設された 2 つの管から構成される請求項 2 に記載のトレーナ。

【請求項 7】

前記心臓モデルが動いている速度を選択するために、ユーザにより作動可能な速度選択装置をさらに備える請求項 1 に記載のトレーナ。

【請求項 8】

擬態医療処置の訓練装置として使用するための筋肉のような動きを有する生体器官用の解剖学的トレーナであって、
生体器官の解剖学的細部を有する器官モデル部と、 30
前記器官モデルに接続される活動網状組織と、
前記活動網状組織に接続されて、前記器官モデルの動きを誘導するように前記活動網状組織を作動させる制御装置とを備える解剖学トレーナ。

【請求項 9】

前記活動網状組織は、前記器官モジュールに埋め込まれた管を備え、前記制御装置は、該管内の圧力を選択的に変更してその寸法を変えるように適合されている請求項 8 に記載のトレーナ。

【請求項 10】

前記活動網状組織は、2 つの管を備え、前記制御装置は、算定された同期方法で前記管内の圧力を変えて、前記器官モデルに多次元の回転運動を与えるように動作可能である請求項 9 に記載のトレーナ。 40

【請求項 11】

前記管は、加圧されると半径方向に拡張することができる可撓性パイプと、該パイプに取り付けられており、該パイプが拡張すると該パイプを短くさせるように構成されているメッシュとを備える請求項 9 に記載のトレーナ。

【請求項 12】

前記活動網状組織は、圧縮ガスにより作動され、該圧縮ガスを供給するように適合されている圧縮機をさらに備える請求項 8 に記載のトレーナ。

【請求項 13】

前記器官モデルは、心臓モデルである請求項 8 に記載のトレーナ。 50

【請求項 14】

胸部モデルをさらに備え、前記心臓モデルは、該胸部モデル内に配設されている請求項 13 に記載のトレーナ。

【請求項 15】

心臓モデルを製造する方法であって、
心筋を擬態した内部鋳造物を形成する工程と、
心外膜を擬態した外殻を前記内部鋳造物上に形成する工程とを備える方法。

【請求項 16】

血管を擬態した外管を前記外殻に適用する工程をさらに備える請求項 15 に記載の方法。

【請求項 17】

前記心臓モデルに三次元の回転運動を与えるよう作動可能な活動網状組織を追加する工程をさらに備える請求項 15 に記載の方法。

【請求項 18】

前記心筋の第 1 の彫刻を作製し、該彫刻を用いて前記内部鋳造物を鋳造する工程をさらに備える請求項 15 に記載の方法。

【請求項 19】

心臓全体に対応する第 2 の彫刻を作製し、該第 2 の彫刻を用いて前記内部鋳造物上に外殻を形成する工程をさらに備える請求項 18 に記載の方法。

【請求項 20】

心筋に類似するように前記内部鋳造物を塗装する工程をさらに備える請求項 19 に記載の方法。

【請求項 21】

前記彫刻を用いて前記内部鋳造物および前記外殻を鋳造する請求項 19 に記載の方法。

【請求項 22】

可撓性材料製の心臓モデルにリアルな動きを与える方法であって、
各直交軸に沿って配向されたコイルとして形成された少なくとも 2 つの管を前記心臓モデル内に埋め込む工程と、
前記管を予め定まったシーケンスで加圧する工程とを備える方法。

【請求項 23】

前記管は、加圧されると拡張する請求項 22 に記載の方法。

【請求項 24】

前記管は、拡張する際に長手方向に収縮する請求項 23 に記載の方法。

【請求項 25】

前記管の一方は、他方よりも先に加圧される請求項 22 に記載の方法。

【発明の詳細な説明】

【0001】

発明の分野

本発明は、解剖学的訓練装置の分野に関する。特に、本発明は、実際的ではあるが擬態された方法で医療処置を実施するために、心臓モデルと、心臓を模造する該モデルにリアルな動きを与える手段とを備える心臓手術用トレーナに関する。

【0002】

従来技術の説明

心血管疾患は、米国、欧州、および日本において主な死因であり、毎年、他の全ての疾病を組み合わせたものよりも多くの命を奪っている。この疾患が広まったことにより、心臓関連の多数の医療処置が実施されてきている。実際に、心臓カテーテル検査、開心術、冠状動脈バイパス手術、心臓移植、および冠動脈形成術を含む心臓病の医療方法の数が、過去十年間で着実に増加し続けてきた。これらの処置は、一般に、心臓病患者の医療状態に有益な効果があるが、いずれの特定の心臓病処置の成功も、手術を行う医師の訓練と経験に結びついている。

【0003】

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現在、心臓外科医にとって、人の心臓に医療処置（たとえば心臓バイパス手術）を行うことで経験を得るための最善の方法は、経験豊富な外科医の監視のもとで生身の患者に実際に処置を行うことによることである。しかしながら、明らかな理由から、このことは、新米の外科医に外科技術を教示するのに最も望ましい方法ではない。死体を使用すれば、本物の心臓で作業する機会が与えられるので、この訓練の代替的な方法が提供される。しかしながら、この方法にも多くの不利な点がある。死体で作業を行うことは、心臓組織が生きた心臓の組織とは同じではなく、心筋の収縮に関連した動きがないことは明らかであるため、非現実的である。さらに、死体は費用がかかり、一般に供給が少ない。さらに、死体は、非常に限られた数の処置にしか使用することができない。最後に、死体を取り扱うことは、政府機関によって規制されていることが多い。

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【0004】

実際の人体での訓練のための他の技術的な代替法が提案されたが、それらはすべて、実際の心臓の外観、質感の動き、およびその組織を十分に擬態していないという点で不十分である。たとえば、Yongに付与された特許である米国特許第6,234,804号は、心臓のレプリカを取り巻いている内部空洞を有する胸部モデルを教示している。この心臓装置は、出血または流血、および心臓を通る加圧された血液循環を擬態するように装備されているが、心臓の心筋層の収縮を擬態するための機構はない。したがって、この装置は、拍動している心臓で行なわれるように意図されている医療処置に対して実際のツールを提供しない。Promに付与された米国特許第6,062,866号、Yunkerに付与された米国特許第5,951,301号、およびMontgomeryに付与された米国特許第5,634,797号は、他の心臓モデルを記載しているが、それらは同様に、心筋の動きを擬態することができるモデルを提供していないという点で不十分である。

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【0005】

Izzatに付与された米国特許第5,947,744号は、「拍動する心臓」訓練の提供を試みている装置を開示している。しかしながら、この装置の、カムおよび可変速度モータを使用したプラットフォームのそのままの実装は、軟質の組織のような材料製の解剖学的に正確な三次元心臓モデル(anatomically correct three-dimensional cardiac model)に組み込むには適切ではない。さらに、心臓モデルの1つの室に対して流体を汲み上げ、また、汲み出す方法、すなわち表面に打ち当たる(striking)カムによって流体を汲み上げ、汲み出す方法は、複雑な心筋の動きのリアルな擬態を行うには不十分である。

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【0006】

本発明の目的および概要

従来技術の不十分性を考慮して、本発明の主要な目的は、医師の訓練、試験、または教育指導に使用することができる解剖学的に正確な心臓モデルを備えた心臓トレーナを設計することにある。

【0007】

心臓の動きを実際に擬態した動きが可能な、解剖学的に正確な心臓モデルを提供することが他の目的である。

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【0008】

正確でリアルな心臓モデルを製造するための、効率的で経済的な方法を提供することがさらに別の目的である。

【0009】

さらなる目的は、本明細書に含まれる本発明の記載から明らかであろう。

【0010】

簡潔には、本発明により構成される心臓手術用トレーナは、2つの部分、すなわち、心筋を擬態した内部鋳造物と、心外膜に対応する外殻とから構成される心臓モデルを備える。この双方の部分は、シリコンゴムなどの可撓性材料からなっており、人の心臓に可能な限り近く見せるために、たとえばシリコンを基材とした塗料を用いて塗装される。

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【0011】

この心臓モデルは、2つの段階プロセスを用いて製造される。最初の段階では、彫刻が心筋の内部表面および外部表面に対応して製造される。この彫刻を用いて、内部鋳造物のための鋳型を製造する。次に、別個の鋳型を心臓全体に対応して製造し、上記内部鋳造物をその別個の鋳型内に導入して、内部鋳造物上に外殻が成形されるようにする。

【0012】

好ましくは、このモデルは、活動網状組織および制御装置を介してそのようにリアルな動きが与えられる。活動網状組織は、心臓モデル内に埋め込まれ、かつ直交軸の周りに巻きつけられた管で構成されている。制御装置は、拍動する心臓に類似した多次元の回転運動を心臓モデルに与えるような制御方法で、管内の圧力を変える。一実施形態では、上記管は、該管が半径方向に拡張すると長手方向に収縮するように製造される。 10

【0013】

一実施形態では、上記心臓を、心膜のウェル (pericardial well) に関して胸部モデル内に組み入れて、胸骨切開によりアクセス可能な該心臓モデルを保持しておくことが可能である。この胸部は、解剖学的に正確な肋骨、肋間間隙、および人工皮膚も備えて製造されて、実物そっくりな操作中枢をもたらす。この胸部は、持ち運びができるスーツケースタイプのホルダー内に合ったサイズであってもよい。

【0014】

この装置の使用により、外科医、外科医学生、および他の医学専門家は、ポンプなしで、無停止の心臓手術のための処置および医療装置の使用における訓練ができる。例として、適用可能な訓練用途には、全開心処置、内視鏡処置、ロボット処置、心臓バイパス、心臓安定化、左内胸動脈 (LIMA) および右内胸動脈 (RIMA) 切開、心膜縫合、内視鏡的ポート選択および配置が挙げられる。この装置は、他の心臓の処置あるいは新たな処置を教示するために使用することもできる。 20

【0015】

本発明の詳細な説明

次に図面、特に図1を参照すると、本発明により構成された心臓トレーナTの主要な構成要素は、長手方向軸L-L、活動網状組織N、制御装置C、および圧縮空気源Sを有する心臓モデルH (輪郭線で示す) を含む。

【0016】

図2、図2A、図2Bに示すように、心臓モデルHは、解剖学的細部において実際の人の心臓と一致するように構成され、配設されている。心臓モデルHは、成人または小児の心臓を擬態するために、異なるサイズ、形状、色などに製造することができる。さらに、心臓モデルHは、必要であれば、健康な心臓または疾患した心臓を擬態することができる。好ましくは、心臓モデルHは中空である。本発明の一実施形態では、心臓モデルHは、空洞10、12を備えて形成され、これらの空洞は、それぞれ、右心房および右心室、左心房および左心室を擬態している。場合に応じて、これらの室房10、12は、心臓弁 (図示せず) を擬態した弁または機能しない要素を含み得る。この実施形態では、心臓モデルHはリアルな動きを与えられない。 30

【0017】

別の実施形態では、心臓モデルHは、改変した形状の空洞で形成されて、活動網状組織Nを保有する。いずれの実施形態においても、心臓モデルHの空洞10、12は、孔14を介してアクセスすることが可能であり、循環静脈および循環動脈への結合を擬態する。下記に詳細に説明するように、優位的には、孔14を用いて活動網状組織Nに圧縮空気を供給し得る。 40

【0018】

図2、図2A、図2Bに示すように、心臓モデルHは、2つの構成要素、すなわち、心筋または心筋層を擬態した内部鋳造物16と、心外膜を擬態した外殻18とから構成される。部材16および18の双方はシリコン製である。内部鋳造物16は通常、厚さ約0.476~0.953cm (=約3/16~3/8インチ) を有し、外殻18は、厚さ約0. 50

159～0.476cm(=約1/16～3/16インチ)を有する。好ましくは、動脈を擬態するために、ある所定の位置で、直径約0.318cm(=約1/8インチ)および長さ3.81cm(=1.5インチ)のシリコン管20が心臓モデルHに取り付けられる。これらの管は、血液を擬態するために赤色の液体で満たされてよい。

【0019】

図3のフローチャートは、本発明による心臓Hを製造するための方法を示している。

【0020】

最初のステップ100において、心筋層に近似のサイズおよび形状を有する一塊りのロウを彫刻して、上記心臓の内部空間を画定する空洞を形成する。ステップ102において、硬質ウレタンなどの鑄造媒体をこの一塊りのロウ中に注ぎ入れて、2つの雄型マスタコア(positive master core)を作製する。 10

【0021】

次に、ステップ104において、上記一塊りのロウの外側を彫刻して、所望の心筋層の最終的な形状およびサイズを確定する。ステップ106において、標準的な鑄造技術を用いてもとの外側の彫刻に対応する第1の雌型マスタ鑄型(negative master mold)を製造する。ロウをその鑄型から取り外した際に残った要素が、心筋(図5を参照)のための雌型マスタ鑄型62、および心臓の空洞10、12を画定する2つの雄型マスタコア(図5のコア60など)である。この2つの雄型マスタコアは、渦巻き状に組まれて定着した形状をしており、整合ソケット(図示せず)によって雌型マスタ鑄型に正しく合わされている。ステップ108において、このコアは、雌型マスタ鑄型から取り外され、心筋層の外側の、立体雄型マスタを形成する。この立体雄型マスタも硬質ウレタン製である。 20

【0022】

ステップ110において、正しく合わされたコアを雌型マスタ内の整合ソケットに戻して、鑄型中に液体シリコンゴムを注入しそれを硬化させることによって複数の内部鑄造物が製造される。

【0023】

ステップ112において、各鑄造物は、心筋層に類似するようにその外表面に塗料を施すことによって塗装される。シリコンを基材とした塗料がこの目的に優れた結果をもたらすことが判明した。いくつかの場合では、へらで鑄造物にシリコンを塗ることによって、さらに他の組織も擬態することができる。鑄造物の塗装後、鑄造物を約4時間乾燥させる。こうして塗装された各鑄造物が、対応する内部鑄造物16を形成する。 30

【0024】

ステップ114において、粘土または他の適切な材料が第1の雄型マスタに加えられ、それによって最終の心臓モデルHの形状およびサイズを実質的に有する第2の雄型マスタを形成する。すなわち、このステップにおいて第1の雄型マスタに加えられた粘土が、外殻18の形状およびサイズを確定する。ステップ116において、第2の雌型マスタが第2の雄型マスタから形成される。

【0025】

ステップ118において、ステップ112からの鑄造物を第2の雌型マスタ中に置いて第2の鑄型を形成する。ステップ120において、略透明または半透明シリコンゴムを第2の鑄型に注ぎ入れて内部鑄造物16の周囲に外殻18を形成する。この外殻が硬化した後、ステップ122において、各鑄造物を鑄型から取り出して切開する。空洞10、12を画定するコアをこの切開により取り除き、次に鑄造物を閉じて、切開部分にシリコンゴムを塗布することにより封鎖する。この結果もたらされる組み立て品を仕上げて心臓モデルHを形成する。この仕上げステップの一部として、シリコンの光沢のあるクリアコートをと、たとえば軽くスプレーすることによって外表面に被着させる。 40

【0026】

この結果もたらされる心臓モデルHは、非常にリアルな輝き、湿った外観、および触感を有する。この心臓モデルは、それ自体で教示的ツールとして使用され得る。血管20が備 50

えられている場合、心臓モジュールは、これらの血管上で実践する手段としても使用され得る。

【0027】

さらにいっそうの実物感を得るために、活動網状組織Nを取り付けることによって心臓モデルHに実物的な動きを与えることができる。活動網状組織Nは、圧力下でガス（典型的には空気）によって作動されると寸法を変えるように構成された複数の気送管から構成される。より具体的には、これらの管は、網状組織Nが作動されるときに、心臓モジュールが所定速度で2つの垂直な軸の周りにねじれるようにして、収縮および拡張を逐次行うように適合されている。その結果、実際の心臓の動きを擬態した三次元ねじれ運動がもたらされる。

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【0028】

図1を参照すると、網状組織Nは2つの管を備えている。第1の管24は、長手方向軸L-Lの周りに配列したループにより螺旋パターンになって配設されている。第2の管26は、心臓モデルHの長手方向軸L-Lに対して垂直な軸M-Mの周りに環状に配設されている。

【0029】

図4は管24の詳細を示しているが、長さ以外は管26も同じ構造を有するものと理解されたい。管24は、薄い可撓性のプラスチックパイプ32と織メッシュ34とから形成される。パイプ32およびメッシュ34は、両方とも容易に拡張可能である。この管の一端は28で示したように封鎖されているが、他端は開いており、下記に説明するように圧力下で空気を提供するように適合された管継ぎ手33を収容するようになっている。重要なことは、管の両端それぞれに隣接して、メッシュ34が、接着剤、つなぎ材、または他の同様な手段によりパイプ32に取り付けられていることである。

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【0030】

この構造では、メッシュ34およびパイプ32は、各管が加圧されるとパイプ32が半径方向に拡張することにより、メッシュ34も同様に半径方向に拡張させるように適合されているが、このパイプとメッシュの間の30で示した連結部により、メッシュはパイプ32を強制的に軸方向に収縮させる。このメッシュは、ナイロンあるいはポリエステル製であってもよい。このパイプは、ラテックス製であってもよく、外径0.318~0.953cm(=1/8~3/8インチ)を有する。

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【0031】

一方、種々の構造を用いて活動網状組織を提供することができ、好適な実施形態を図1に示す。各管24および26の開口端32は、制御装置Cに取り付けるために各拡張部38によって接続される。管は、以下のように心臓モデルHに挿入される。上記のように、心臓モデルHを製造するプロセスのステップの1つは、空洞彫刻を行うこと（図3のステップ102）である。このステップの一部として、図5に示した空洞彫刻60には、溝（図示せず）が設けられており、この溝は、管24、26についての所望の形状を確定する。空洞彫刻またはコアが完成した後、管24、26は、空洞彫刻60の周りに巻きつけられる。次に、コアが第1の雌型マスタ62に配置されると（ステップ110）、管24、26は、内部鋳造物が形成された場合にその内部鋳造物が管24、26を包囲するように、自動的に適正に配向され位置付けられる。図5に示すように、管24、26の実質的な部分がコア60を超えて延びる。その結果、各内部鋳造物がコア60と第1の雌型マスタの間に覆いわたる際に、管24、26が、その鋳造物中、最終的には鋳造物16中にしっかり埋め込まれる。

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【0032】

図1を参照すると、制御装置Cは制御回路40、各ソレノイド44を介して該制御回路40によって作動される2つの自動弁42（各管24、26に対して1つずつ）、および操作者が使用して心臓モデルHの「拍動」速度を選択することができる速度選択装置41を備えている。制御回路40は、圧縮機Sから管24、26への空気流を選択的に制御する手段を提供する。制御回路40は、マイクロプロセッサ（たとえばParallax, I

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ncにより市販されているBasic Stamp II)で構成すればよい。マイクロプロセッサは、管24、26を選択的に加圧するために所定のシーケンスで弁を開閉するようプログラムされる。たとえば、図6に示すように、管24、26は、速度選択装置41に関してユーザが選択した速度に応じて、図示のように定時の間隔でのシーケンスで加圧できる。図6に示すように、管26が先に加圧され、約100～150ミリ秒後に管24が加圧されることが好ましい。この構成により、心臓モジュールHは、生きた拍動する心臓の動きとまさに同じような三次元揺動運動(three-dimensional rocking motion)を与えられることがわかった。当業者には、心臓モジュールHに動きを与える他の手段も同様に使用できるということが理解されるであろう。たとえば、空気のかわりに液体を用いて管24、26を選択的に加圧してもよい。

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【0033】

さらに、図示の実施形態では閉じたシステムが用いられるが、心臓モジュールHを通る血液の流れをも模擬する循環システムも提供され得る。

【0034】

上述したように、心臓モジュールHには、1つまたは複数の血管20を設けられ得る。次に、これらの血管20を製造する方法を図7のフローチャートとともに説明する。ステップ210において、特定の血管の内径に近似した金属ロッドを設け、ナイロンメッシュで被覆する。好ましくは、このナイロンメッシュをロッドの周りに巻く。次にステップ212において、ロッドを、ロッドおよびメッシュよりもわずかに大きい内径を有する管に挿入して、所望の厚さに近似させる。シリコンまたはウレタンのモデリング材料を、ステップ214においてその管中およびロッドの周りに約 $6.89 \times 10^5 \text{ Pa}$ (=約100 psi)で注入する。

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【0035】

こうして得られた血管モデルは、本物の血管の外観と触感を有する。メッシュは、縫合が必要とされる医療処置を擬態するために縫合を保持する補強を提供する。材料の選択および帯域を狭くすることにより、この血管が本物の血管の崩壊を擬態できるようにもする。これらは、他の人体器官(たとえば心臓または胸部)に、ガイドストリングにより端部をふさいで、人体器官の孔を介してそのガイドストリングを通すことによって取り付けることができる。次に、ガイドストリングを用いて器官に血管を引き込んだ後、ガイドストリングを取り外すことができる。

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【0036】

心臓モデルHの「拍動」中に、血管20を用いて冠状動脈吻合を実施することもできる。

【0037】

図8に示すように、完成すると、心臓モデルHは胸部レプリカX内に配設することができ、この胸部は、好ましくは通常サイズの成人男性の胸部であり、首から横隔膜および肩から肩にかけて仰向けになった患者を表すことを意図するものである。この胸部は、テーブルトップ上に置かれるように意図された平台上に載置されている。胸部は、胸骨切開術などの切開術(opening or incisions)を施され、胸骨切開を表すために、軟質鋳造物を部分的または完全に挿入された。追加の切開は、胸郭切除術または内視鏡ポートを含み得る。胸骨切開部分(sternotomy)の縁には心膜のようなウェルがあり、心臓Hに対し三角布(sling)として機能する。このウェルに沿って、軟質で可撓性のある補強された心膜のような材料が並べられている。胸部Xは、胸骨切開部分の縁の下に押し込まれたLIMAおよびRIMA茎も含有し得る。これらの茎は、左内胸動脈および静脈あるいは右内胸動脈および静脈を含んでおり、胸部Xから切り離すことが可能である。胸部Xはまた、その下部において制御装置Cを隠蔽する役割を果たし得る。

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【0038】

胸部Xは、他の構成要素によっても拡大し得る。一代替形態は、完全な人工皮膚を有する。別の胸部Xは、人工肋骨、および肋骨を収縮させる肋間間隙を有する。胸部Xは、持ち運び可能なスーツケース容器に入れることができるような寸法にするために単純化するこ

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とができる。

【0039】

本発明を種々の実施形態を参照しながら説明してきたが、これらの実施形態は、本発明原理の例示的な適用にすぎないことが理解されるであろう。本明細書に説明された本発明の例示的な実施形態のほかに、本発明の精神および範囲から逸脱することなく、多数の変形形態を行ってもよく、かつ他の構成を考案してもよい。たとえば、開示の方法を用いて心臓以外の生体器官を複製することができることは当業者には容易に明らかとなろう。同様に、モデルの被包性層 (encapsulated layer) における動き分散網状組織 (motion distribution network) での筋肉のような動きを生み出す別の手段も明らかとなろう。さらに、制御装置 C も心臓モデルの内側に配設することができ、それによって、全体のサイズ、および当該心臓手術用トレーナの複雑性が低減する。

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【図面の簡単な説明】

【図 1】

本発明により構成され、解剖学的に正確な心臓モデルを備えた心臓手術用トレーナのブロック図である。

【図 2】

図 1 のトレーナの心臓モデルの右側立面図である。

【図 2 A】

線 L-L に沿って取られた、図 2 の心臓モデルの断面図である。

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【図 2 B】

シリコン管を有する心臓モデルの前面図である。

【図 3】

図 2 および図 2 A の心臓モデルを製造するために用いられる方法を示したフローチャートである。

【図 4】

図 1 の活動網状組織に使用される管である。

【図 5】

空洞彫刻および活動網状組織の管を備えた第 1 の雌型の鋳型の立面図である。

【図 6】

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2 つの管の加圧を示したタイミング図である。

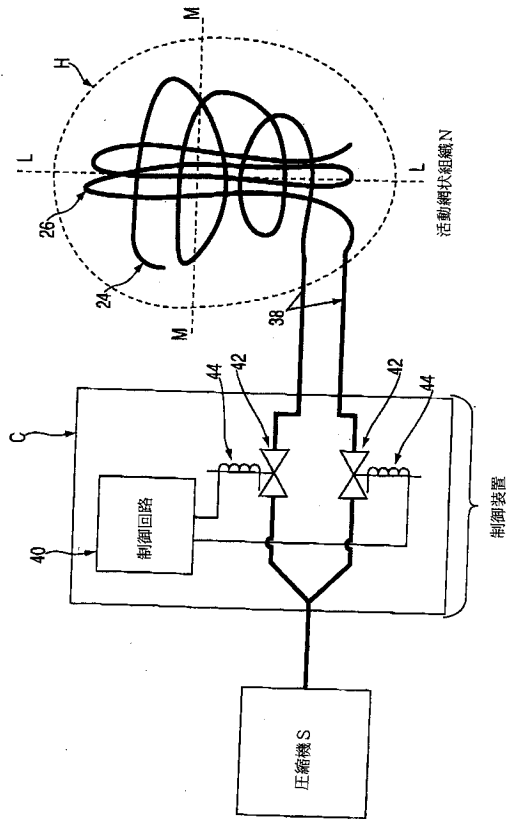
【図 7】

血管を模造した管を製造するためのフローチャートである。

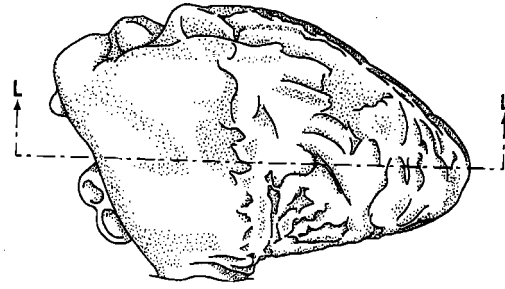
【図 8】

本発明により構成され、人工胸部に配設された心臓モデルである。

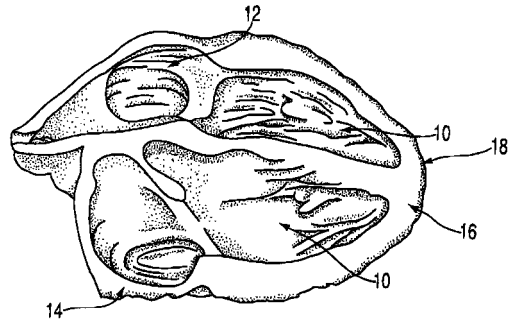
【図 1】



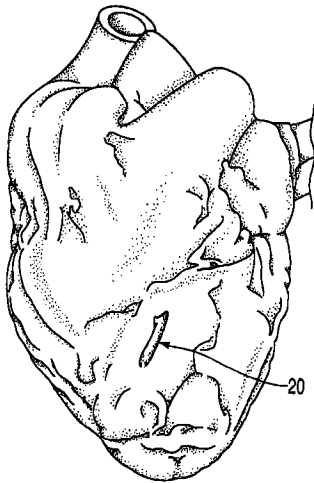
【図 2】



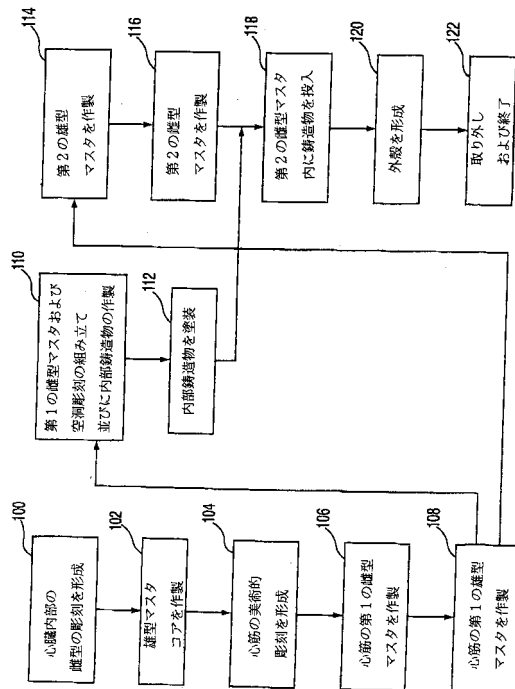
【図 2 A】



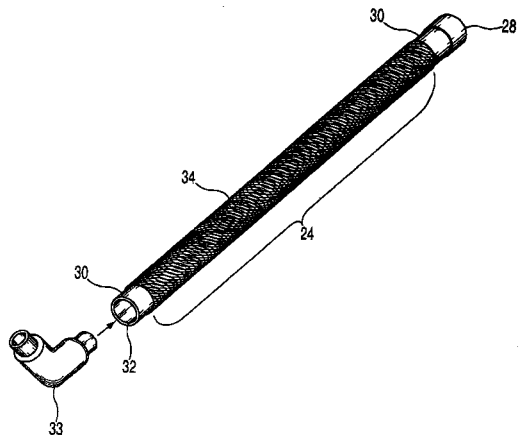
【図 2 B】



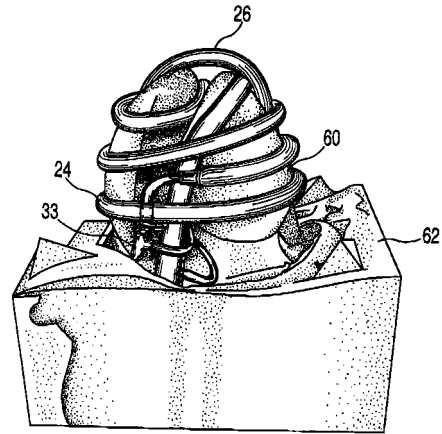
【図 3】



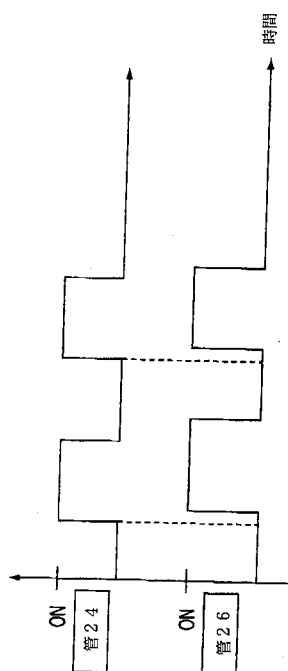
【図 4】



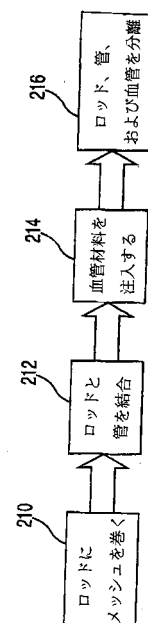
【図 5】



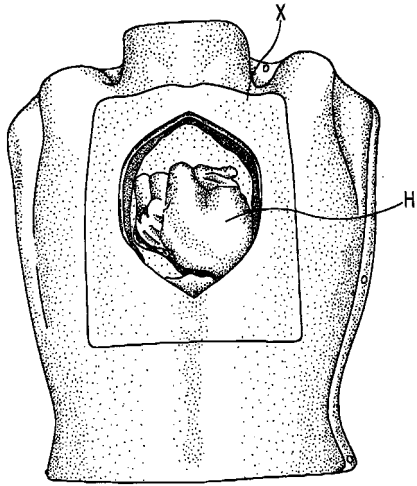
【図 6】



【図 7】



【図 8】



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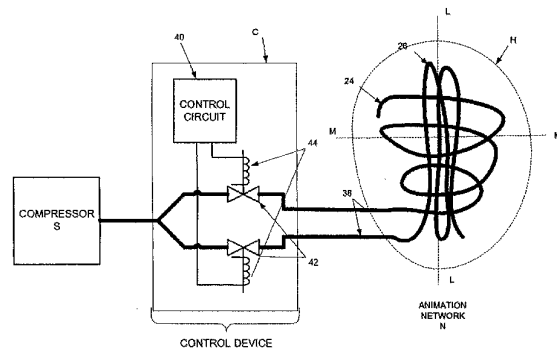
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954 South Main Street, Great Barrington, MA 01230 (US).(72) Inventor: CHAMBERLAIN, Eric, Roger, 19 Church
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(54) Title: A CARDIAC SURGICAL TRAINER AND METHOD FOR MAKING SAME



(57) Abstract: A trainer for cardiac surgery and other similar procedures includes an organ model such as a cardiac model (H), an animation network (N) adapted to impart to the model a motion similar to the corresponding natural organ and a control device (C) used to control the operation of the animation network. The cardiac model is made of two sections, an inner cast simulating the myocardium and an external shell simulating the pericardium. The model is made by forming an inner cast, dressing the cast and then forming the shell around the cast. The model is preferably made of silicon rubber.

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

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A CARDIAC SURGICAL TRAINER AND METHOD FOR MAKING SAME

BACKGROUND OF THE INVENTION

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A. Field of the Invention

The present invention relates to the field of anatomical teaching apparatus. More particularly, it relates to a cardiac surgical trainer including a heart model and means for animating the model for mimicking the heart for practicing medical procedures in a realistic but simulated manner.

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B. Description of the Prior Art

Cardiovascular disease is the leading cause of death in the United States, Europe and Japan claiming more lives each year than all other diseases combined. The prevalence of this disease has resulted in the performance of numerous cardiac related medical procedures. In fact, the number of cardiac procedures including cardiac catheterization, open heart surgery, coronary artery bypass surgery, heart transplants and coronary angioplasty has steadily risen for the past ten years. While these procedures are having a beneficial effect on the medical condition of cardiac patients in general, the success of any particular cardiac procedure is linked to the training and experience of the doctors performing the operation.

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Currently, the best method for a cardiac surgeon to obtain experience in performing medical procedures on the human heart, such as cardiac bypass operations, is by actually performing a procedure on a live patient

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under supervision of an experienced surgeon. However, for obvious reasons this is not the most desirable method for teaching surgical techniques to new surgeons. The use of a cadaver offers an alternative this training method because provides the opportunity to work on a real heart. However this
5 approach also has many disadvantages. Working on a cadaver is unrealistic because the heart tissues are not identical to the tissues of live heart and the movement associated with contractions of the myocardium is obviously missing. Additionally, cadavers are expensive and are generally in short supply. Moreover, a cadaver can be used only for a very limited number of
10 procedures. Finally, the handling of cadavers are often regulated by governmental agencies.

Other technological alternatives for training on real bodies were suggested but they are all deficient in that they do not adequately simulate the look, feel movement of real heart, and its tissues. For example, the patent to
15 Yong, U.S. Patent No. 6,234,804, teaches a model thorax with an internal cavity enclosing a replica of a heart. While the heart device is equipped to simulate bleeding or blood flow and pressurized circulation through the heart, there is no mechanism for simulating the contractions of the myocardial layer of the heart. Thus, the device does not provide a realistic tool for medical
20 procedures intended to be performed on a beating heart. Prom, U.S. Patent No. 6,062,866, Younker, U.S. Patent 5,951,301, and Montgomery, U.S. Patent No. 5,634,797, describe other cardiac models, however they are similarly deficient in that they fail to provide a model capable of simulating myocardial motion.

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The Izzat, U.S. Patent No. 5,947,744 discloses a device which attempts to provide "beating-heart" training. However, the device's crude implementation of a platform using a cam and variable speed motor are not appropriate for incorporation in an anatomically correct three-dimensional cardiac model made of soft tissue-like material. Moreover, the methods of
5 pumping fluid in and out of a single chamber in a model heart or by a cam striking the surface are insufficient to provide for realistic simulation of complex myocardial motion.

10 OBJECTIVES AND SUMMARY OF THE INVENTION

In view of prior art deficiencies, the principal objective of the present invention is to design a cardiac trainer including an anatomically correct heart model that can be used for the training, testing or educational instruction of physicians.

15 It is a further objective to provide an anatomically correct heart model that is capable of movement that simulates realistically the movement of a heart.

It is a still further objective to provide for an efficient and economical method for manufacturing an accurate and realistic heart model.

20 Additional objectives will be apparent from the description of the invention as contained herein.

Briefly, a cardiac surgical trainer constructed in accordance with this invention includes a heart model consisting of two portions: an inner cast simulating the myocardium and an outer shell corresponding to the

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epicardium. Both portions are made of a flexible material such as silicone rubber and are painted to look as close as possible to a human heart, using for example, silicone based paints.

The heart model is made using a two stage process. In a first stage
5 sculptures are made corresponding to the inner and outer surfaces of the myocardium. The sculptures are used to make molds for the inner cast. Next, a separate mold is made corresponding to the whole heart and the inner cast is introduced into the separate mold to allow the shell to be molded thereon.

10 Preferably, the model is animated so through an animation network and a control device. The animation network consists of tubes imbedded in the heart model and coiled around orthogonal axes. The control device changes the pressure within the tubes in a controlled manner so as to impart to the heart model a multi-dimensional rotational motion similar to a beating
15 heart. In one embodiment, the tubes are made so that they contract longitudinally when they expand radially.

In one embodiment, the heart may then be incorporated into a model thorax with a pericardial well to hold the model heart, which is accessible through a sternotomy opening. The thorax may also be made with
20 anatomically correct ribs, intercostal spaces and artificial skin to yield a life-like operating center. The thorax may be sized to fit within a suitcase type holder for portability.

With this device, surgeons, surgical students and other medical professionals may be trained in procedures and the use of medical devices for

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off-pump non-arrested heart surgery. By way of example, possible training applications include full open heart procedures, endoscopic procedure, robotic procedures, heart bypass, heart stabilization, left anterior mammary artery (LIMA) and right anterior mammary artery (RIMA) dissection, pericardial
5 suturing, endoscopic port selection and placement. The device may be used to teach other cardiac procedures or to develop new procedures.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig.1 shows a block diagram of a cardiac surgical trainer constructed
10 in accordance with this invention, including an anatomically correct heart model;

Fig. 2 shows a right elevational view of the heart model for the trainer of Fig. 1;

Fig. 2A shows a cross sectional view of heart model of Fig. 2 taken
15 along lines L-L;

Fig. 2B shows an anterior view of the heart model including a silicone tube;

Fig. 3 shows a flow chart illustrating the method used to make the heart model of Figs. 2 and 2A;

20 Fig. 4 shows a tube used in the animation network of Fig. 1;

Fig. 5 shows an elevational view of the first negative mold with a cavity sculpture and the tubes of the animation network;

Fig. 6 shows a timing diagram illustrating the pressurizing of the two tubes;

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Fig. 7 shows flow chart for making tubes imitating blood vessels;

Fig. 8 shows the heart model constructed in accordance with this invention and disposed in an artificial thorax.

5 DETAILED DESCRIPTION OF THE INVENTION

Referring now to the Figures, and more particularly Fig. 1, the main components of a cardiac trainer T constructed in accordance with this invention include a heart model H (shown in outline) having a longitudinal axis L-L, animating network N, a control device C and a source of compressed air

10 S.

As shown in Figs. 2, 2A, 2B the heart model H, is constructed and arranged to conform in anatomical details to an actual human heart. The heart model H may be made with different sizes, shapes, colors, etc. to simulate an adult or a pediatric heart. Moreover heart model H may also simulate either a healthy or a diseased heart, as required. Preferably, the heart model H is hollow. In one embodiment of the invention, the heart model H is formed with cavities 10, 12 that simulate respectively the right and the left atrium and ventricle. Optionally, these chambers 10, 12 may include valves or non-functioning elements simulating heart valves (not shown). In this embodiment the heart model H is not animated.

In another embodiment, the heart model H is formed with altered-shaped cavities to hold the animation network N. In either embodiment, the cavities 10, 12 of the heart model H are accessible through holes 14 simulating connections to the circulatory veins and arteries. As discussed in

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more detail below, advantageously, the holes 14 may be used to supply compressed air to the animation network N.

As seen in the Figs. 2, 2A, 2B the heart model H consists of two components, an inner cast 16 which simulates the cardiac muscles or myocardium and an outer shell 18 that simulates the epicardium. Both members 16 and 18 are made of silicone. The inner cast 16 typically has a thickness of about 3/16 to 3/8 " and the shell 18 has a thickness of about 1/16 to 3/16 ". Preferably, at certain predetermined locations, silicone tubes 20 having a diameter of about 1/8" and a length of 1.5" are attached to the heart model H to simulate arteries. These tubes may be filled with a red colored liquid to simulate blood.

The flow chart of FIG. 3 depicts a method for fabricating the heart H in accordance with the invention.

In the first step 100 a block of wax having the approximate size and shape of the myocardium is carved to create hollow cavities that define the interior spaces of the heart. In step 102 a casting medium such as a rigid urethane is poured into the block of wax to create two positive master cores.

Next, in step 104 the exterior of the block of wax is sculpted to define the final shape and size of the desired myocardium. In step 106 a first negative master mold is made that corresponds to the original exterior sculpture using standard molding techniques. When the wax is removed from the mold, the elements that remain are the negative master mold 62 for the myocardium (See Fig. 5); and the two positive master cores (such as cores 60, in Fig. 5) that define the cavities 10, 12 of the heart. The two positive

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master cores have convoluted interlocking shapes and are registered by alignment sockets (not shown) to the master negative mold . In step 108 the cores are removed from the negative master mold and a solid positive master of the myocardium layer exterior is created. The solid positive master is also
5 made of a rigid urethane.

In step 110 the registered cores are returned to the alignment sockets in the negative master and a plurality of interior castings are made by pouring liquid silicone rubber into the mold and letting it set.

In step 112 each casting is dressed by applying paint to its outer
10 surface so that it resembles the myocardium. It was found that silicone-based paints provide superior results for this purpose. In some cases, some extra tissues may also be simulated by adding dabs of silicone on the castings with a spatula. After the castings are dressed, they are allowed to dry for about four hours. Each casting thus dressed forms a corresponding inner cast 16.

15 In step 114 clay or other suitable material is added to the first positive master thereby forming a second positive master having substantially the shape and size of the final heart model H. That is, the clay added to the first positive master in this step defines the shape and size of the outer shell 18. In step 116 a second negative master is formed from the second positive
20 master.

In step 118 the castings from step 112 are placed into the second negative master to form a second mold. In step 120 a substantially transparent or translucent silicon rubber is poured into the second mold to form shell 18 around inner cast 16. After the shell is set, in step 122 each

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casting is removed from the mold and cut open. The cores defining cavities 10, 12 are removed through the cuts and the castings are then closed and sealed by applying silicone rubber into the cut. The resulting assembly is finished to form the heart model H. As part of this finishing step, a shiny clear
5 coat of silicone is applied to the outer surface, for example by applying a light spray.

The resulting heart model H has glistening, wet look and feel that is very realistic. This heart model may be used as a teaching tool by itself. If it is provided with the vessels 20, the heart module may be used as a means of
10 practicing on these vessels as well.

In order to provide even more realism, the heart model H can be animated by installing an animation network N. The animation network N is constructed from a plurality of pneumatic tubes arranged so that they change dimension when actuated by a gas (typically, air) under pressure. More
15 specifically, the tubes are arranged so that when the network N is activated, the tubes contract and expand sequentially in a manner so as to cause the heart module to twist about two perpendicular axes at a predetermined rate resulting in a three-dimensional twisting motion that simulates the motion of an actual heart.

20 As shown in Fig. 1, the network N includes two tubes. The first tube 24 is arranged in a spiral pattern with loops arranged around longitudinal axis L-L. The second tube 26 is arranged in loops oriented around axis M-M perpendicular to longitudinal axis L-L of the heart model H.

Fig. 4 shows details of tube 24, it being understood that except for its

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length, tube 26 has the same construction. Tube 24 is formed of a thin flexible plastic pipe 32 and a woven mesh 34. Both the pipe 32 and mesh 34 are radially expandable. One end of the tubes is sealed as at 28 while the other end is open to receive the coupling 33 arranged to provide air under
5 pressure as discussed below. Importantly adjacent to each of the ends of the tube, the mesh 34 is attached to the pipe 32 by an adhesive, by ties or other similar means.

In this configuration, the mesh 34 and pipe 32 are arranged so that when the respective tube is pressurized, the radial expansion of the pipe 32
10 causes the mesh 34 to expand radially as well, however, because of the attachment between the pipe and the mesh at 30, the mesh forces the pipe 32 to contract axially. The meshes may be made of nylon or polyester. The pipes may be made of latex and have a outer diameter of 1/8-3/8".

While various configurations can be used for providing the animation
15 network, the preferred embodiment is shown in Fig. 1. The open end 32 of each tube 24, 26 is connected by a respective extension 38 for attachment to control device C. The tubes are inserted in the heart model H as follows. As mentioned above, one of the steps of the process of making the heart model H is the making of cavity sculptures (step 102, Fig. 3). As part of this step,
20 the cavity sculptures 60 shown in Fig. 5 are provided with grooves (not shown) that define the desired shapes for the tubes 24, 26. After the cavity sculptures or cores are completed, the tubes 24, 26 are wound around the cavity sculpture 60. Then, when the cores are positioned in the first negative master 62 (step 110), the tubes 24, 26 are automatically properly oriented and

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positioned so that when the interior casting is formed, it envelopes the tubes 24, 26. As seen in Fig. 5, a substantial portion of the tubes 24, 26 extends beyond the cores 60. As a result, when each interior casting is over between the cores 60 and the first negative master, the tubes 24, 26 are firmly
5 embedded in the casting and, eventually in the cast 16.

Returning to Fig. 1, the control device C includes a control circuit 40, two automatic valves 42 (one for each tube 24, 26) operated by the control circuit 40 through respective solenoids 44 and a rate selector 41 that can be used by an operator to select a 'beat' rate for the heart model H. The control
10 circuit 40 provides the means for controlling the selectively the air flow into the tubes 24, 26, from compressor S. The control circuit 40 may be a microprocessor, for example a Basic Stamp II by Parallax, Inc. The microprocessor is programmed to open and close the valves in a predetermined sequence to selectively pressurize tubes 24, 26. For example,
15 as shown in Fig. 6, the tubes 24, 26 may be pressurized in a sequence, as shown, at regular intervals, dependent on the rate selected by the user on a rate selector 41. Preferably, the tube 26 is pressurized first, and tube 24 is pressurized about 100-150 msec later, as illustrated in Fig. 6. It was found that with this arrangement the heart module H is imparted a three-dimensional
20 rocking motion very similar to the motion of a live, beating heart. Those skilled in the field will recognize that other means of imparting motion to the heart module H may be used as well. For example, a liquid may be used instead of air to selectively pressurize the tubes 24, 26.

Moreover, while in the embodiment shown a closed system is used, a

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circulatory system may also be provided in which the blood flow through the heart module H is also mimicked.

As mentioned above, the heart module H may be provided with one or more blood vessels 20. A method for making these blood vessels 20 is now
5 described in conjunction with the flow chart of Fig. 7. In step 210, a metal rod that approximates the inside diameter of a particular vessel is provided and covered with a nylon mesh. Preferably the nylon mesh is rolled around the rod. The rod is then inserted into a tube having an inner diameter that is slightly larger than the rod and mesh in step 212 to approximate a desired
10 thickness. Silicone or urethane modeling material is pumped into the tube and around the rod in step 214 at about 100 psi.

The model vessel thus obtained has the look and feel of a real vessel. The mesh provides reinforcement to hold sutures for simulating a medical procedure where suturing is required. The selection of materials and the
15 narrow width also permit the vessel to simulate the collapse of a real vessel. They may be attached to other body organs, such as the heart or a thorax, by tying off an end with a guide string and threading the guide string through a hole in the organ. The guide string may then be removed after using it to pull the vessel into the organ.

20 The vessels 20 may be used to practice coronary artery anastomosis while the heart model H is 'beating.'

As shown in FIG 8, upon completion, the heart model H may be placed within a replica thorax X. The thorax is preferably an typical-sized adult male chest intended to represent a patient lying on his back from the neck to

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diaphragm and shoulder to shoulder. It is mounted to a flat base meant to sit on a tabletop. The thorax may be provided with openings or incisions such as a sternotomy, partial or full, inset with a soft casting to represent the sternotomy opening. Additional openings or incisions, might include

5 thoracotomy opening or endoscopic ports. At the edge of the sternotomy is a pericardial-like well, which serves as a sling for the heart H. The well is lined with a soft, flexible reinforced pericardium-like material. The thorax X may also contain LIMA and RIMA pedicles tucked under the edges of the sternotomy that contain left or right internal mammary arteries and veins that

10 are capable of being dissected from the thorax X. The thorax X may also serve to conceal the control device C in its base.

The thorax X may be augmented with other components as well. One alternative has full artificial skin. Another thorax X has artificial ribs and intercostals spaces which permit rib retraction. The thorax X may be

15 simplified to permit a dimension that allows it to be placed in a portable suitcase container.

Although the invention has been described with reference to various embodiments, it is to be understood that these embodiments are merely illustrative of an application of the principles of the invention. Numerous

20 modifications, in addition to the illustrative embodiments of the invention discussed herein may be made and other arrangements may be devised without departing from the spirit and scope of the invention. For example, it will be readily apparent to one skilled in the art that the disclosed methods may be used to replicate biological organs other than the heart. Similarly,

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alternative means for generating muscle-like motion in a motion distribution network in an encapsulated layer of a model will also be apparent. Moreover, the control device C can be disposed inside the heart model as well thereby reducing the overall size and complexity of the subject cardiac surgical trainer.

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We claim:

1. A cardiac surgical trainer comprising:

a heart model made of a relatively soft material;

an animation network disposed in said heart model and arranged to move said heart model in a manner so as to simulate a two-dimensional motion of a natural beating heart; and

a control device connected to said animation network to selectively activate said animation network.

2. The trainer of claim 1 wherein said animation network includes a plurality of tubes oriented along respective axes.

3. The trainer of claim 2 wherein said tubes are arranged to change a dimension when pressurized.

4. The trainer of claim 3 wherein said tubes change in length when pressurized.

5. The trainer of claim 4 wherein each tube comprises a flexible pipe having two ends and a mesh attached to the ends of the pipe, wherein said pipe and mesh expand radially when said pipe is pressurized, and wherein said mesh forces said pipe to shorten longitudinally when said pipe is pressurized.

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6. The trainer of claim 2 comprising of two tubes arranged along respective perpendicular axes.
7. The trainer of claim 1 further comprising a rate selector operable by a user to select a rate at which said heart model is moving.
8. An anatomical trainer for a biological organ having muscle-like motion for use as a training device in simulated medical procedures comprising:
- an organ model part having anatomical details of a biological organ;
 - an animation network coupled to said organ model; and
 - a control device connected to said animation network to operate said animation network in a manner that induces a movement of said organ model.
9. The trainer of claim 8 wherein said animation network includes a tube imbedded in said organ module and said control device is adapted to selectively change a pressure within said tube to change its dimensions.
10. The trainer of claim 9 wherein said animation network includes two tubes and wherein said control device is operable to change pressures within said tube in a synchronized manner calculated to impart a multi-dimensional

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rotational motion to said organ model.

11. The trainer of claim 9 wherein said tube includes a flexible pipe that can expand radially when pressurized and a mesh attached to the pipe and arranged to shorten the pipe when the pipe is expanded.

12. The trainer of claim 8 wherein said animation network is powered by compressed gas, further comprising a compressor adapted to supply said compressed gas.

13. The trainer of claim 8 wherein said organ model is a heart model.

14. The trainer of claim 13 further comprising a thorax model, said heart model being disposed in said thorax model.

15. A method for making a heart model comprising:
forming an inner cast simulating the myocardium;
forming an outer shell on said inner cast, said outer shell simulating the epicardium.

16. The method of claim 15 further comprising applying external tubes to said outer shell, said tubes simulating blood vessels.

17. The method of claim 15 further comprising adding an animation

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network, said animation network being operative to impart a three-dimensional rotational motion to said heart model.

18. The method of claim 15 further comprising creating a first sculpture of said myocardium and using said sculpture to mold said inner cast.

19. The method of claim 18 further comprising creating a second sculpture corresponding to the total heart and using said second sculpture to form a shell on said inner cast.

20. The method of claim 19 further comprising painting said inner cast to resemble the myocardium.

21. The method of claim 19 wherein said sculptures are used to mold said inner cast and said shell.

22. A method of animating a model heart made of a flexible material comprising:

imbedding in said model heart at least two tubes formed into coils oriented along respective orthogonal axes; and
pressurizing said tubes in a predetermined sequence.

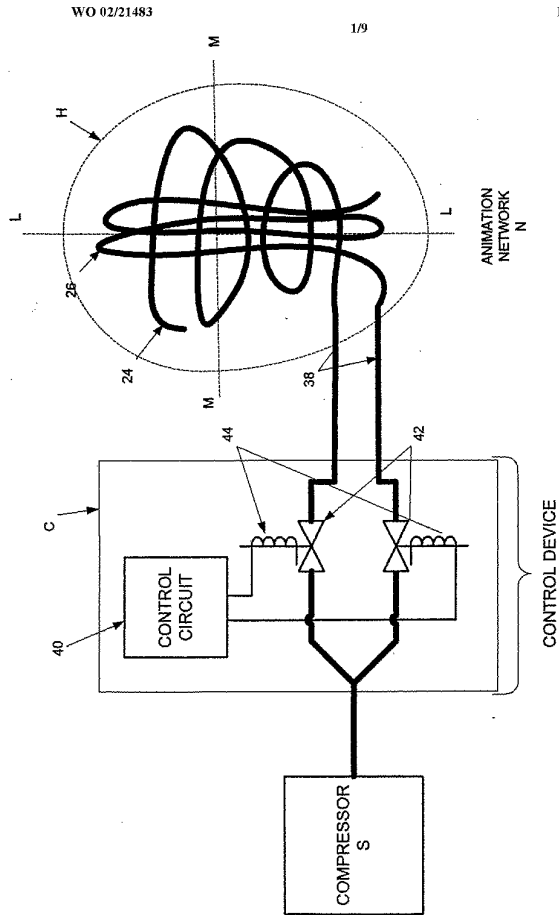
23. The method of claim 22 wherein said tubes expand when pressurized.

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24. The method of claim 23 wherein said tube contract longitudinally as they expand.

25. The method of claim 22 wherein one of said tubes is pressurized prior to the other.



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Fig. 2: HEART FROM RIGHT

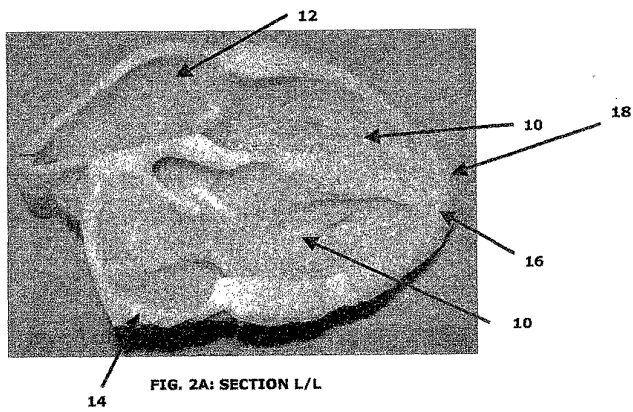


FIG. 2A: SECTION L/L

10F2

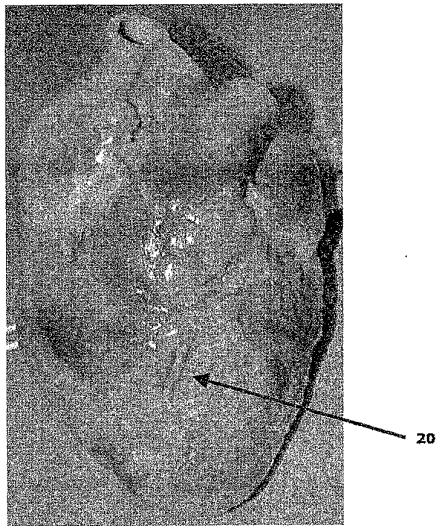


Fig. 2B: HEART ANTERIOR VIEW

20F2

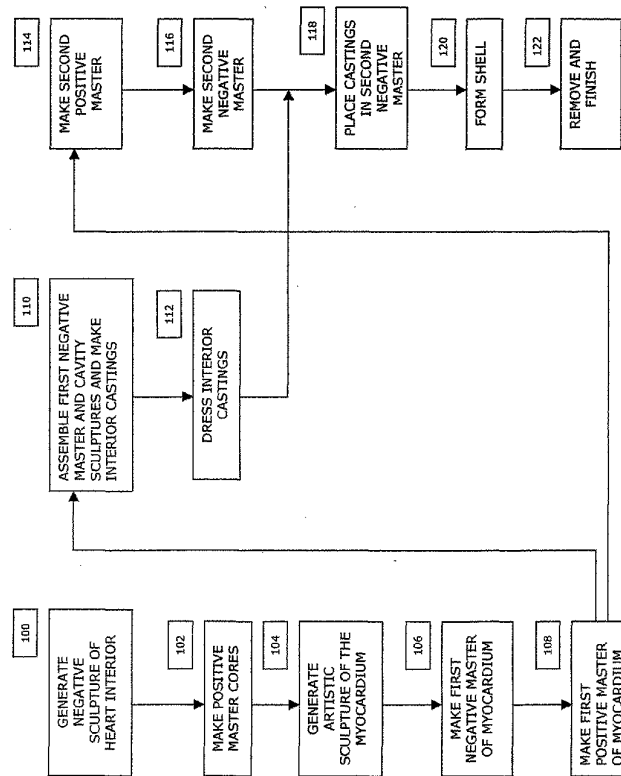
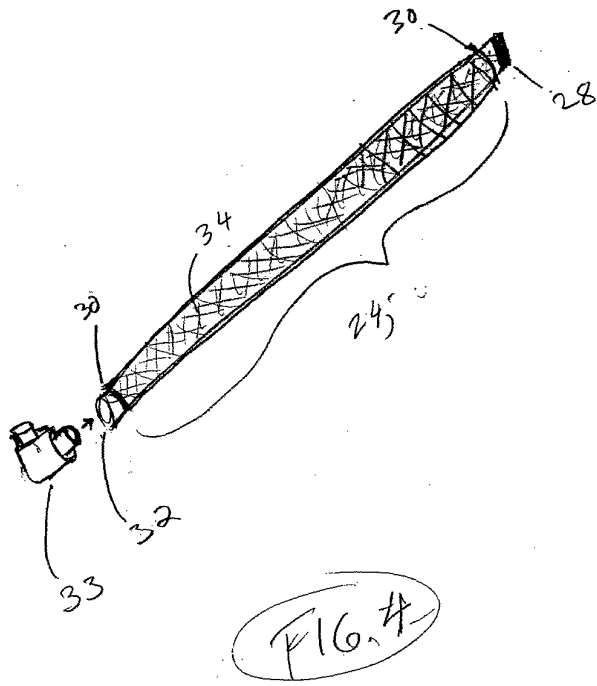


Fig. 3

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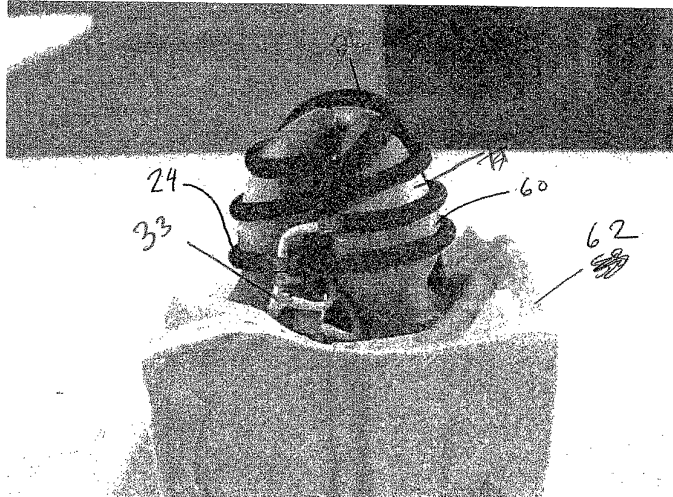


FIG 5

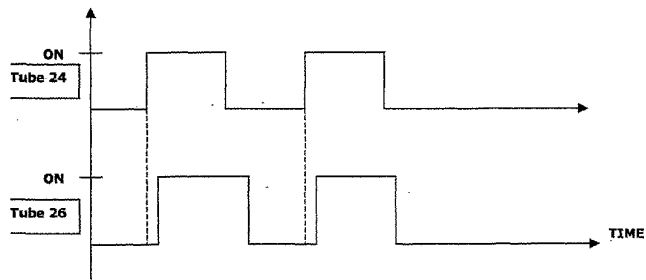


Fig. 6

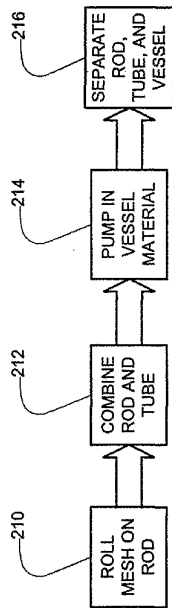


FIG. 7

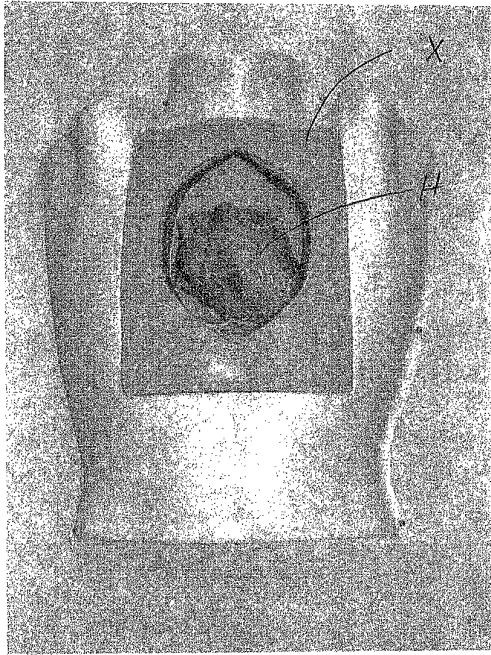


Fig
8

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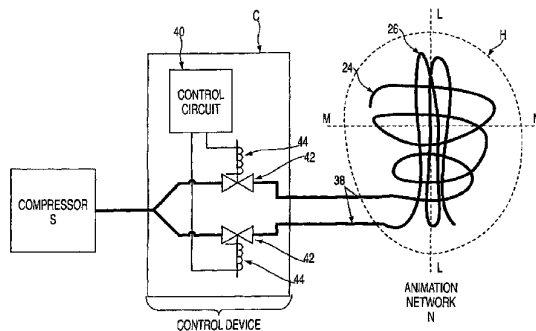
(71) Applicant: THE CHAMBERLAIN GROUP [US/US];
934 South Main Street, Great Barrington, MA 01230 (US).(72) Inventor: CHAMBERLAIN, Eric, Roger; 19 Church
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[Continued on next page]

(54) Title: A CARDIAC SURGICAL TRAINER AND METHOD FOR MAKING SAME



(57) Abstract: A trainer for cardiac surgery and other similar procedures includes an organ model such as a cardiac model (11), an animation network (N) adapted to impart to the model a motion similar to the corresponding natural organ and a control device (C) used to control the operation of the animation network. The cardiac model is made of two sections, an inner cast simulating the myocardium and an external shell simulating the pericardium. The model is made by forming an inner cast, dressing the cast and then forming the shell around the cast. The model is preferably made of silicon rubber.

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A CARDIAC SURGICAL TRAINER AND METHOD FOR MAKING SAME

BACKGROUND OF THE INVENTION

5

A. Field of the Invention

The present invention relates to the field of anatomical teaching apparatus. More particularly, it relates to a cardiac surgical trainer including a heart model and means for animating the model for mimicking the heart for practicing medical procedures in a realistic but simulated manner.

10

B. Description of the Prior Art

Cardiovascular disease is the leading cause of death in the United States, Europe and Japan claiming more lives each year than all other diseases combined. The prevalence of this disease has resulted in the performance of numerous cardiac related medical procedures. In fact, the number of cardiac procedures including cardiac catheterization, open heart surgery, coronary artery bypass surgery, heart transplants and coronary angioplasty has steadily risen for the past ten years. While these procedures are having a beneficial effect on the medical condition of cardiac patients in general, the success of any particular cardiac procedure is linked to the training and experience of the doctors performing the operation.

15

Currently, the best method for a cardiac surgeon to obtain experience in performing medical procedures on the human heart, such as cardiac bypass operations, is by actually performing a procedure on a live patient

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under supervision of an experienced surgeon. However, for obvious reasons this is not the most desirable method for teaching surgical techniques to new surgeons. The use of a cadaver offers an alternative this training method because provides the opportunity to work on a real heart. However this
5 approach also has many disadvantages. Working on a cadaver is unrealistic because the heart tissues are not identical to the tissues of live heart and the movement associated with contractions of the myocardium is obviously missing. Additionally, cadavers are expensive and are generally in short supply. Moreover, a cadaver can be used only for a very limited number of
10 procedures. Finally, the handling of cadavers are often regulated by governmental agencies.

Other technological alternatives for training on real bodies were suggested but they are all deficient in that they do not adequately simulate the look, feel movement of real heart, and its tissues. For example, the patent to
15 Yong, U.S. Patent No. 6,234,804, teaches a model thorax with an internal cavity enclosing a replica of a heart. While the heart device is equipped to simulate bleeding or blood flow and pressurized circulation through the heart, there is no mechanism for simulating the contractions of the myocardial layer of the heart. Thus, the device does not provide a realistic tool for medical
20 procedures intended to be performed on a beating heart. Prom, U.S. Patent No. 6,062,866, Younker, U.S. Patent 5,951,301, and Montgomery, U.S. Patent No. 5,634,797, describe other cardiac models, however they are similarly deficient in that they fail to provide a model capable of simulating myocardial motion.

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The Izzat, U.S. Patent No. 5,947,744 discloses a device which attempts to provide "beating-heart" training. However, the device's crude implementation of a platform using a cam and variable speed motor are not appropriate for incorporation in an anatomically correct three-dimensional cardiac model made of soft tissue-like material. Moreover, the methods of pumping fluid in and out of a single chamber in a model heart or by a cam striking the surface are insufficient to provide for realistic simulation of complex myocardial motion.

OBJECTIVES AND SUMMARY OF THE INVENTION

In view of prior art deficiencies, the principal objective of the present invention is to design a cardiac trainer including an anatomically correct heart model that can be used for the training, testing or educational instruction of physicians.

It is a further objective to provide an anatomically correct heart model that is capable of movement that simulates realistically the movement of a heart.

It is a still further objective to provide for an efficient and economical method for manufacturing an accurate and realistic heart model.

Additional objectives will be apparent from the description of the invention as contained herein.

Briefly, a cardiac surgical trainer constructed in accordance with this invention includes a heart model consisting of two portions: an inner cast simulating the myocardium and an outer shell corresponding to the

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epicardium. Both portions are made of a flexible material such as silicone rubber and are painted to look as close as possible to a human heart, using for example, silicone based paints.

The heart model is made using a two stage process. In a first stage
5 sculptures are made corresponding to the inner and outer surfaces of the myocardium. The sculptures are used to make molds for the inner cast. Next, a separate mold is made corresponding to the whole heart and the inner cast is introduced into the separate mold to allow the shell to be molded thereon.

10 Preferably, the model is animated so through an animation network and a control device. The animation network consists of tubes imbedded in the heart model and coiled around orthogonal axes. The control device changes the pressure within the tubes in a controlled manner so as to impart to the heart model a multi-dimensional rotational motion similar to a beating
15 heart. In one embodiment, the tubes are made so that they contract longitudinally when they expand radially.

In one embodiment, the heart may then be incorporated into a model thorax with a pericardial well to hold the model heart, which is accessible through a sternotomy opening. The thorax may also be made with
20 anatomically correct ribs, intercostal spaces and artificial skin to yield a life-like operating center. The thorax may be sized to fit within a suitcase type holder for portability.

With this device, surgeons, surgical students and other medical professionals may be trained in procedures and the use of medical devices for

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off-pump non-arrested heart surgery. By way of example, possible training applications include full open heart procedures, endoscopic procedure, robotic procedures, heart bypass, heart stabilization, left anterior mammary artery (LIMA) and right anterior mammary artery (RIMA) dissection, pericardial
5 suturing, endoscopic port selection and placement. The device may be used to teach other cardiac procedures or to develop new procedures.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig.1 shows a block diagram of a cardiac surgical trainer constructed
10 in accordance with this invention, including an anatomically correct heart model;

Fig. 2 shows a right elevational view of the heart model for the trainer of Fig. 1;

Fig. 2A shows a cross sectional view of heart model of Fig. 2 taken
15 along lines L-L;

Fig. 2B shows an anterior view of the heart model including a silicone tube;

Fig. 3 shows a flow chart illustrating the method used to make the heart model of Figs. 2 and 2A;

20 Fig. 4 shows a tube used in the animation network of Fig. 1;

Fig. 5 shows an elevational view of the first negative mold with a cavity sculpture and the tubes of the animation network;

Fig. 6 shows a timing diagram illustrating the pressurizing of the two tubes;

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Fig. 7 shows flow chart for making tubes imitating blood vessels;

Fig. 8 shows the heart model constructed in accordance with this invention and disposed in an artificial thorax.

5 DETAILED DESCRIPTION OF THE INVENTION

Referring now to the Figures, and more particularly Fig. 1, the main components of a cardiac trainer T constructed in accordance with this invention include a heart model H (shown in outline) having a longitudinal axis L-L, animating network N, a control device C and a source of compressed air

10 S.

As shown in Figs. 2, 2A, 2B the heart model H, is constructed and arranged to conform in anatomical details to an actual human heart. The heart model H may be made with different sizes, shapes, colors, etc. to simulate an adult or a pediatric heart. Moreover heart model H may also
15 simulate either a healthy or a diseased heart, as required. Preferably, the heart model H is hollow. In one embodiment of the invention, the heart model H is formed with cavities 10, 12 that simulate respectively the right and the left atrium and ventricle. Optionally, these chambers 10, 12 may include valves or non-functioning elements simulating heart valves (not shown). In
20 this embodiment the heart model H is not animated.

In another embodiment, the heart model H is formed with altered-shaped cavities to hold the animation network N. In either embodiment, the cavities 10, 12 of the heart model H are accessible through holes 14 simulating connections to the circulatory veins and arteries. As discussed in

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more detail below, advantageously, the holes 14 may be used to supply compressed air to the animation network N.

As seen in the Figs. 2, 2A, 2B the heart model H consists of two components, an inner cast 16 which simulates the cardiac muscles or myocardium and an outer shell 18 that simulates the epicardium. Both members 16 and 18 are made of silicone. The inner cast 16 typically has a thickness of about 3/16 to 3/8 " and the shell 18 has a thickness of about 1/16 to 3/16 ". Preferably, at certain predetermined locations, silicone tubes 20 having a diameter of about 1/8" and a length of 1.5" are attached to the heart model H to simulate arteries. These tubes may be filled with a red colored liquid to simulate blood.

The flow chart of FIG. 3 depicts a method for fabricating the heart H in accordance with the invention.

In the first step 100 a block of wax having the approximate size and shape of the myocardium is carved to create hollow cavities that define the interior spaces of the heart. In step 102 a casting medium such as a rigid urethane is poured into the block of wax to create two positive master cores.

Next, in step 104 the exterior of the block of wax is sculpted to define the final shape and size of the desired myocardium. In step 106 a first negative master mold is made that corresponds to the original exterior sculpture using standard molding techniques. When the wax is removed from the mold, the elements that remain are the negative master mold 62 for the myocardium (See Fig. 5); and the two positive master cores (such as cores 60, in Fig. 5) that define the cavities 10, 12 of the heart. The two positive

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master cores have convoluted interlocking shapes and are registered by alignment sockets (not shown) to the master negative mold . In step 108 the cores are removed from the negative master mold and a solid positive master of the myocardium layer exterior is created. The solid positive master is also
5 made of a rigid urethane.

In step 110 the registered cores are returned to the alignment sockets in the negative master and a plurality of interior castings are made by pouring liquid silicone rubber into the mold and letting it set.

In step 112 each casting is dressed by applying paint to its outer
10 surface so that it resembles the myocardium. It was found that silicone-based paints provide superior results for this purpose. In some cases, some extra tissues may also be simulated by adding dabs of silicone on the castings with a spatula. After the castings are dressed, they are allowed to dry for about four hours. Each casting thus dressed forms a corresponding inner cast 16.

15 In step 114 clay or other suitable material is added to the first positive master thereby forming a second positive master having substantially the shape and size of the final heart model H. That is, the clay added to the first positive master in this step defines the shape and size of the outer shell 18. In step 116 a second negative master is formed from the second positive
20 master.

In step 118 the castings from step 112 are placed into the second negative master to form a second mold. In step 120 a substantially transparent or translucent silicon rubber is poured into the second mold to form shell 18 around inner cast 16. After the shell is set, in step 122 each

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casting is removed from the mold and cut open. The cores defining cavities 10, 12 are removed through the cuts and the castings are then closed and sealed by applying silicone rubber into the cut. The resulting assembly is finished to form the heart model H. As part of this finishing step, a shiny clear
5 coat of silicone is applied to the outer surface, for example by applying a light spray.

The resulting heart model H has glistening, wet look and feel that is very realistic. This heart model may be used as a teaching tool by itself. If it is provided with the vessels 20, the heart module may be used as a means of
10 practicing on these vessels as well.

In order to provide even more realism, the heart model H can be animated by installing an animation network N. The animation network N is constructed from a plurality of pneumatic tubes arranged so that they change dimension when actuated by a gas (typically, air) under pressure. More
15 specifically, the tubes are arranged so that when the network N is activated, the tubes contract and expand sequentially in a manner so as to cause the heart module to twist about two perpendicular axes at a predetermined rate resulting in a three-dimensional twisting motion that simulates the motion of an actual heart.

20 As shown in Fig. 1, the network N includes two tubes. The first tube 24 is arranged in a spiral pattern with loops arranged around longitudinal axis L-L. The second tube 26 is arranged in loops oriented around axis M-M perpendicular to longitudinal axis L-L of the heart model H.

Fig. 4 shows details of tube 24, it being understood that except for its

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length, tube 26 has the same construction. Tube 24 is formed of a thin flexible plastic pipe 32 and a woven mesh 34. Both the pipe 32 and mesh 34 are radially expandable. One end of the tubes is sealed as at 28 while the other end is open to receive the coupling 33 arranged to provide air under
5 pressure as discussed below. Importantly adjacent to each of the ends of the tube, the mesh 34 is attached to the pipe 32 by an adhesive, by ties or other similar means.

In this configuration, the mesh 34 and pipe 32 are arranged so that when the respective tube is pressurized, the radial expansion of the pipe 32
10 causes the mesh 34 to expand radially as well, however, because of the attachment between the pipe and the mesh at 30, the mesh forces the pipe 32 to contract axially. The meshes may be made of nylon or polyester. The pipes may be made of latex and have a outer diameter of 1/8-3/8".

While various configurations can be used for providing the animation
15 network, the preferred embodiment is shown in Fig. 1. The open end 32 of each tube 24, 26 is connected by a respective extension 38 for attachment to control device C. The tubes are inserted in the heart model H as follows. As mentioned above, one of the steps of the process of making the heart model H is the making of cavity sculptures (step 102, Fig. 3). As part of this step,
20 the cavity sculptures 60 shown in Fig. 5 are provided with grooves (not shown) that define the desired shapes for the tubes 24, 26. After the cavity sculptures or cores are completed, the tubes 24, 26 are wound around the cavity sculpture 60. Then, when the cores are positioned in the first negative master 62 (step 110), the tubes 24, 26 are automatically properly oriented and

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positioned so that when the interior casting is formed, it envelopes the tubes 24, 26. As seen in Fig. 5, a substantial portion of the tubes 24, 26 extends beyond the cores 60. As a result, when each interior casting is over between the cores 60 and the first negative master, the tubes 24, 26 are firmly
5 embedded in the casting and, eventually in the cast 16.

Returning to Fig. 1, the control device C includes a control circuit 40, two automatic valves 42 (one for each tube 24, 26) operated by the control circuit 40 through respective solenoids 44 and a rate selector 41 that can be used by an operator to select a 'beat' rate for the heart model H. The control
10 circuit 40 provides the means for controlling the selectively the air flow into the tubes 24, 26, from compressor S. The control circuit 40 may be a microprocessor, for example a Basic Stamp II by Parallax, Inc. The microprocessor is programmed to open and close the valves in a predetermined sequence to selectively pressurize tubes 24, 26. For example,
15 as shown in Fig. 6, the tubes 24, 26 may be pressurized in a sequence, as shown, at regular intervals, dependent on the rate selected by the user on a rate selector 41. Preferably, the tube 26 is pressurized first, and tube 24 is pressurized about 100-150 msec later, as illustrated in Fig. 6. It was found that with this arrangement the heart module H is imparted a three-dimensional
20 rocking motion very similar to the motion of a live, beating heart. Those skilled in the field will recognize that other means of imparting motion to the heart module H may be used as well. For example, a liquid may be used instead of air to selectively pressurize the tubes 24, 26.

Moreover, while in the embodiment shown a closed system is used, a

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circulatory system may also be provided in which the blood flow through the heart module H is also mimicked.

As mentioned above, the heart module H may be provided with one or more blood vessels 20. A method for making these blood vessels 20 is now
5 described in conjunction with the flow chart of Fig. 7. In step 210, a metal rod that approximates the inside diameter of a particular vessel is provided and covered with a nylon mesh. Preferably the nylon mesh is rolled around the rod. The rod is then inserted into a tube having an inner diameter that is slightly larger than the rod and mesh in step 212 to approximate a desired
10 thickness. Silicone or urethane modeling material is pumped into the tube and around the rod in step 214 at about 100 psi.

The model vessel thus obtained has the look and feel of a real vessel. The mesh provides reinforcement to hold sutures for simulating a medical procedure where suturing is required. The selection of materials and the
15 narrow width also permit the vessel to simulate the collapse of a real vessel. They may be attached to other body organs, such as the heart or a thorax, by tying off an end with a guide string and threading the guide string through a hole in the organ. The guide string may then be removed after using it to pull the vessel into the organ.

20 The vessels 20 may be used to practice coronary artery anastomosis while the heart model H is 'beating.'

As shown in FIG 8, upon completion, the heart model H may be placed within a replica thorax X. The thorax is preferably an typical-sized adult male chest intended to represent a patient lying on his back from the neck to

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diaphragm and shoulder to shoulder. It is mounted to a flat base meant to sit on a tabletop. The thorax may be provided with openings or incisions such as a sternotomy, partial or full, inset with a soft casting to represent the sternotomy opening. Additional openings or incisions, might include

5 thoracotomy opening or endoscopic ports. At the edge of the sternotomy is a pericardial-like well, which serves as a sling for the heart H. The well is lined with a soft, flexible reinforced pericardium-like material. The thorax X may also contain LIMA and RIMA pedicles tucked under the edges of the sternotomy that contain left or right internal mammary arteries and veins that

10 are capable of being dissected from the thorax X. The thorax X may also serve to conceal the control device C in its base.

The thorax X may be augmented with other components as well. One alternative has full artificial skin. Another thorax X has artificial ribs and intercostals spaces which permit rib retraction. The thorax X may be

15 simplified to permit a dimension that allows it to be placed in a portable suitcase container.

Although the invention has been described with reference to various embodiments, it is to be understood that these embodiments are merely illustrative of an application of the principles of the invention. Numerous

20 modifications, in addition to the illustrative embodiments of the invention discussed herein may be made and other arrangements may be devised without departing from the spirit and scope of the invention. For example, it will be readily apparent to one skilled in the art that the disclosed methods may be used to replicate biological organs other than the heart. Similarly,

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alternative means for generating muscle-like motion in a motion distribution network in an encapsulated layer of a model will also be apparent. Moreover, the control device C can be disposed inside the heart model as well thereby reducing the overall size and complexity of the subject cardiac surgical trainer.

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We claim:

1. A cardiac surgical trainer comprising:

a heart model made of a relatively soft material;

an animation network disposed in said heart model and arranged to move said heart model in a manner so as to simulate a two-dimensional motion of a natural beating heart; and

a control device connected to said animation network to selectively activate said animation network.

2. The trainer of claim 1 wherein said animation network includes a plurality of tubes oriented along respective axes.

3. The trainer of claim 2 wherein said tubes are arranged to change a dimension when pressurized.

4. The trainer of claim 3 wherein said tubes change in length when pressurized.

5. The trainer of claim 4 wherein each tube comprises a flexible pipe having two ends and a mesh attached to the ends of the pipe, wherein said pipe and mesh expand radially when said pipe is pressurized, and wherein said mesh forces said pipe to shorten longitudinally when said pipe is pressurized.

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6. The trainer of claim 2 comprising of two tubes arranged along respective perpendicular axes.
7. The trainer of claim 1 further comprising a rate selector operable by a user to select a rate at which said heart model is moving.
8. An anatomical trainer for a biological organ having muscle-like motion for use as a training device in simulated medical procedures comprising:
- an organ model part having anatomical details of a biological organ;
 - an animation network coupled to said organ model; and
 - a control device connected to said animation network to operate said animation network in a manner that induces a movement of said organ model.
9. The trainer of claim 8 wherein said animation network includes a tube imbedded in said organ module and said control device is adapted to selectively change a pressure within said tube to change its dimensions.
10. The trainer of claim 9 wherein said animation network includes two tubes and wherein said control device is operable to change pressures within said tube in a synchronized manner calculated to impart a multi-dimensional

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rotational motion to said organ model.

11. The trainer of claim 9 wherein said tube includes a flexible pipe that can expand radially when pressurized and a mesh attached to the pipe and arranged to shorten the pipe when the pipe is expanded.

12. The trainer of claim 8 wherein said wherein animation network is powered by compressed gas, further comprising a compressor adapted to supply said compressed gas.

13. The trainer of claim 8 wherein said organ model is a heart model.

14. The trainer of claim 13 further comprising a thorax model, said heart model being disposed in said thorax model.

15. A method for making a heart model comprising:
forming an inner cast simulating the myocardium;
forming an outer shell on said inner cast, said outer shell simulating the epicardium.

16. The method of claim 15 further comprising applying external tubes to said outer shell, said tubes simulating blood vessels.

17. The method of claim 15 further comprising adding an animation

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network, said animation network being operative to impart a three-dimensional rotational motion to said heart model.

18. The method of claim 15 further comprising creating a first sculpture of said myocardium and using said sculpture to mold said inner cast.

19. The method of claim 18 further comprising creating a second sculpture corresponding to the total heart and using said second sculpture to form a shell on said inner cast.

20. The method of claim 19 further comprising painting said inner cast to resemble the myocardium.

21. The method of claim 19 wherein said sculptures are used to mold said inner cast and said shell.

22. A method of animating a model heart made of a flexible material comprising:

imbedding in said model heart at least two tubes formed into coils oriented along respective orthogonal axes; and
pressurizing said tubes in a predetermined sequence.

23. The method of claim 22 wherein said tubes expand when pressurized.

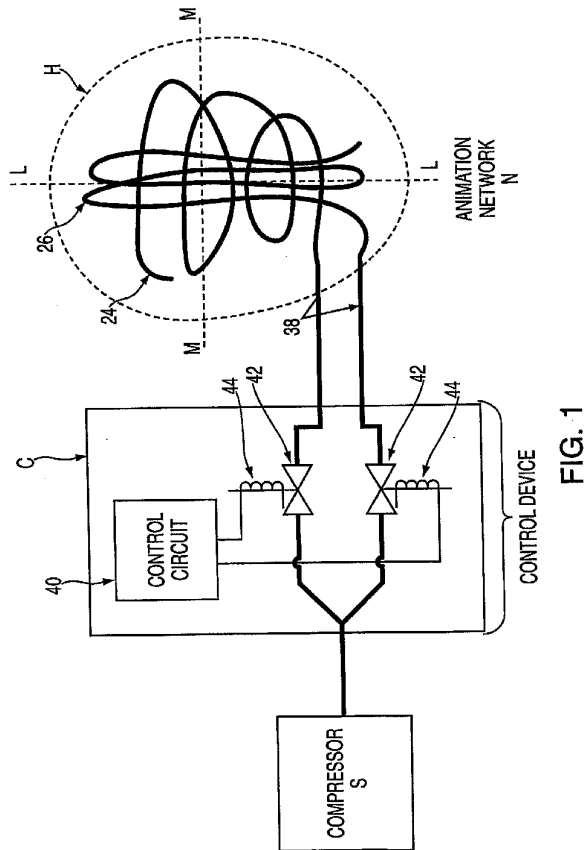
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24. The method of claim 23 wherein said tube contract longitudinally as they expand.

25. The method of claim 22 wherein one of said tubes is pressurized prior to the other.

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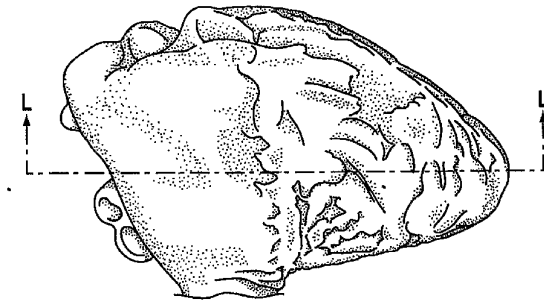


FIG. 2

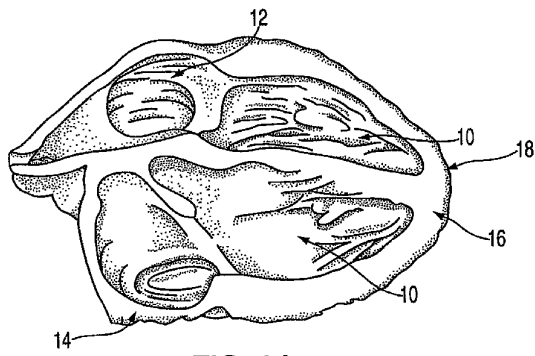


FIG. 2A

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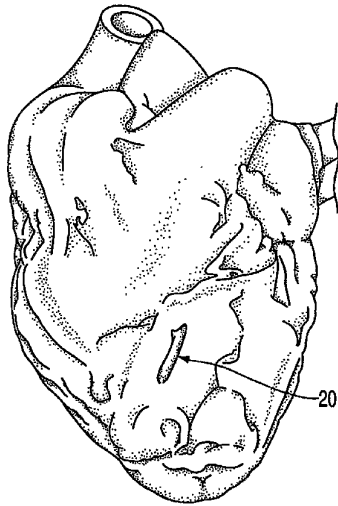


FIG. 2B

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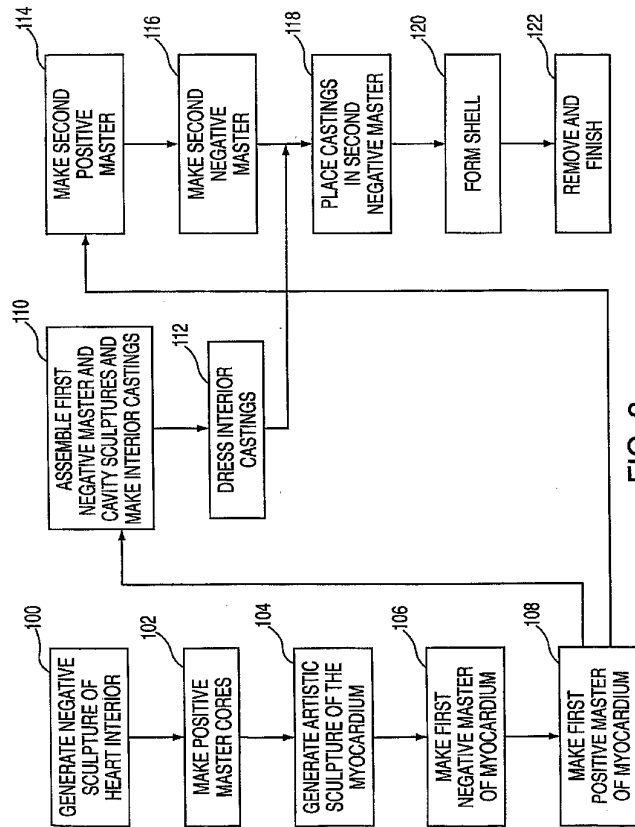


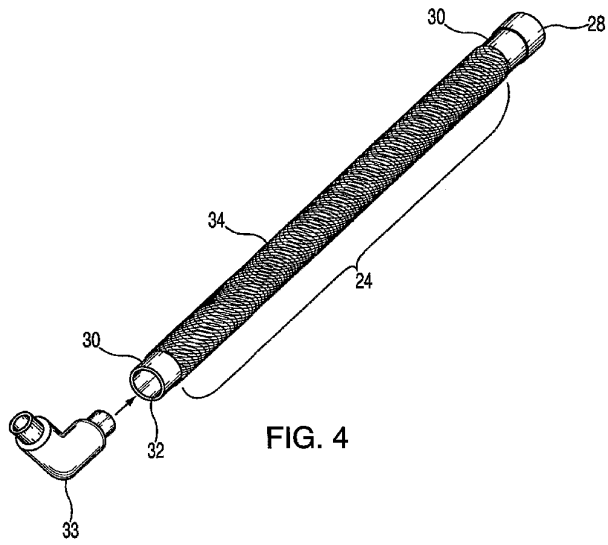
FIG. 3

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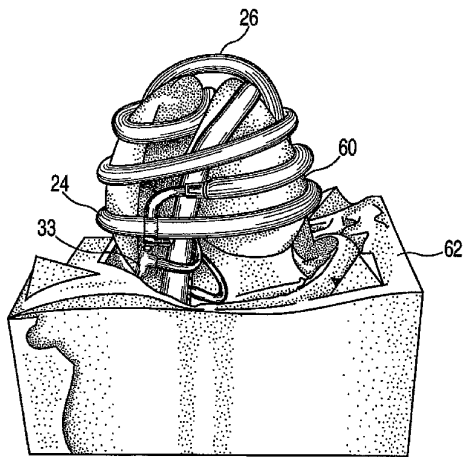


FIG. 5

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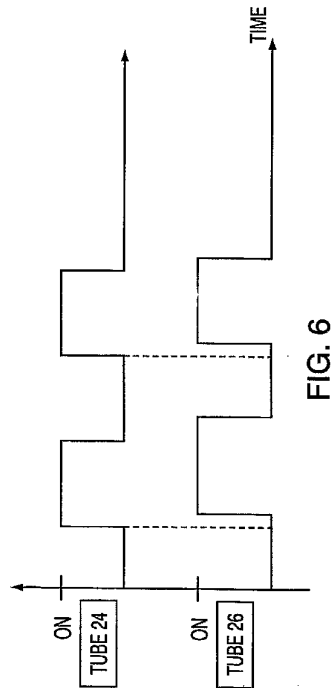


FIG. 6

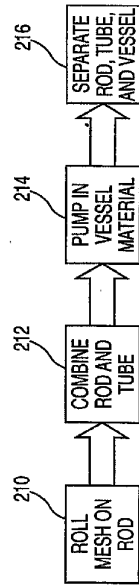


FIG. 7

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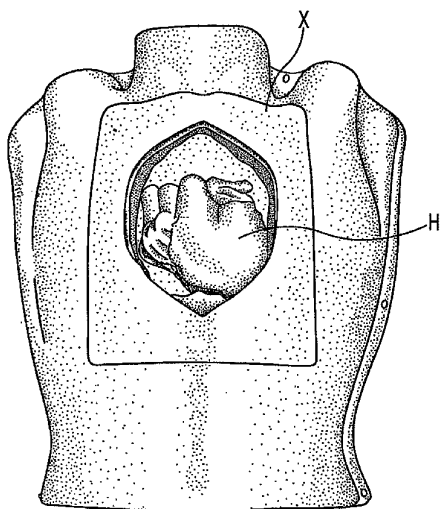


FIG. 8

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【国際調査報告】

INTERNATIONAL SEARCH REPORT		International application No. PCT/US01/42005
A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : G09B 23/28 US CL : 434/272 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) U.S. : 434/272,267,266,262 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) Please See Continuation Sheet		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,947,744 A (IZZAT) 07 September 1999, See entire document.	1,8
A	US 4,639, 223 A (KELLER, JR.) 27 January 1987, See entire document.	
A	US 5,941,710 A (JAMPOTANG et al) 24 August 1999, See entire document.	
A	US 5,722,413 A (PUTCHER et al) 03 March 1998, See entire document.	
A, P	US 6,234,804 B1 (YONG) 22 May 2001, See entire document.	
A	US 6,074,214 (BROWNE-WILKINSON) 13 June 2000, See entire document.	
A	US 5,041,973 A (LEBRON et al) 20 August 1991, See entire document.	
☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "B" earlier application or patent published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 07 November 2001 (07.11.2001) Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230		Date of mailing of the international search report 23 JAN 2002 Authorized officer Valencia Martin-Wallace Telephone No. 703-308-1148 <i>Patricia Venet Juncos</i> <i>Paralegal Specialist</i> <i>Technology Center 3700</i>

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/42005

Continuation of B. FIELDS SEARCHED Item 3:
EAST
search terms: heart model

フロントページの続き

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(74)代理人 100071629

弁理士 池谷 豊

(74)代理人 100084010

弁理士 古川 秀利

(74)代理人 100094695

弁理士 鈴木 憲七

(74)代理人 100111648

弁理士 梶並 順

(74)代理人 100109287

弁理士 白石 泰三

(74)代理人 100116953

弁理士 中村 礼

(72)発明者 チェンバーレイン、エリック・ロジャー

アメリカ合衆国、マサチューセッツ州、ストックブリッジ、チャーチ・ストリート 19

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